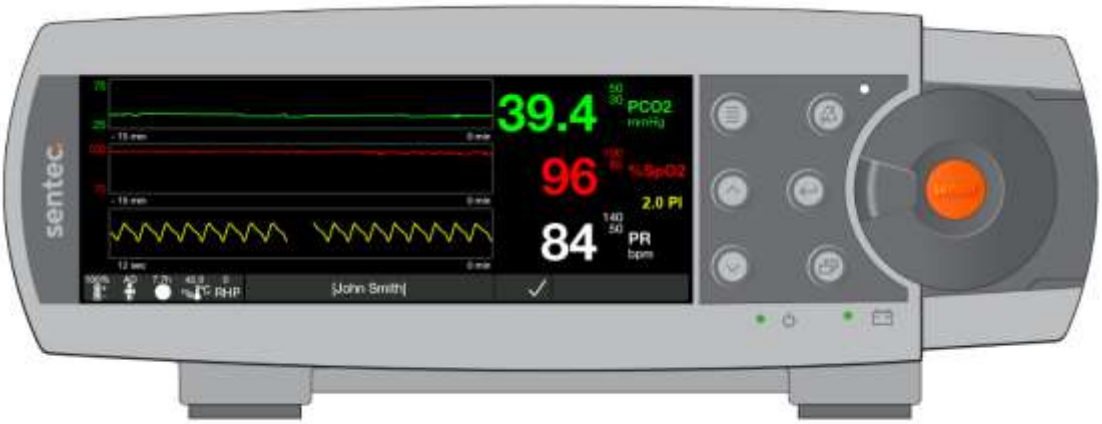
sentec

Technical Manual



For the Sentec Digital Monitor

(Software version SMB SW-V08.03 and higher)

Care with Confidence

HB-005752-w

Warranty

The manufacturer warrants to the initial purchaser that each new Sentec Digital Monitor will be free from defects in workmanship and materials. The manufacturer's sole obligation under this warranty is to at its own choice repair or replace any monitor – for which the manufacturer acknowledges the warranty cover – with a replacement monitor.

Warranty Exclusions and System Performance

Sentec AG can neither guarantee or verify instrument performance characteristics nor accept warranty claims or product liability claims if the recommended procedures are not carried out, if the product has been subject to misuse, neglect or accident, if the product has been damaged by extraneous causes, if accessories other than those recommended by Sentec AG are used, if the warranty seal on the lower side of the monitor is broken, or if instrument repairs are not carried out by Sentec authorized service personnel.

CAUTION: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

Patents/Trademarks/Copyright

International Industrial Design No. DM/054179, Japanese Design No. 1137696, U.S. Design Patent No. D483488.
Canadian Patent No. 2466105, European Patent No. 1335666, German Patent No. 50111822.5-08, Spanish Patent No. 2278818, Hongkong Patent No. HK1059553, U.S. Patent No. 6760610.
Chinese Patent No. ZL02829715.6, European Patent No. 1535055, German Patent No. 50213115.2, Spanish Patent No. 2316584, Indian Patent No. 201300, Japanese Patent No. 4344691, U.S. Patent No. 7862698.

MEDICAL – PATIENT-MONITORING EQUIPMENT

WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH IEC 60601-1:2012 (ed 3.1); ANSI/AAMI ES60601-1:2005/(R)2012; CAN/CSA-C22.2 No. 60601-1:2014, IEC 60601-1-6:2010 (ed. 3)+ A1:2013, IEC 60601-1-8:2006 (ed. 2) + Am. 1: 2012, IEC 60601-2-23: 2011 (ed. 3), ISO 80601-2-61:2011 (ed. 1), 60601-1-11:2015 (ed. 2)

Sentec AG, Ringstrasse 39, 4106 Therwil, Switzerland, www.sentec.com

CE
0123

Contents

Abbreviations

AHP	Absolute Heating Power
CO2	Carbon dioxide
DS	Docking Station (calibration unit integrated in the SDM)
HP	Heating Power
HPM	Heating Power Mode
LED	Light emitting diode
MRI	Magnetic Resonance Imaging
O2	Oxygen
PaCO2	Arterial carbon dioxide partial pressure
PaO2	Arterial oxygen partial pressure
PcCO2	Cutaneous carbon dioxide partial pressure (i.e. the CO2 partial pressure at the skin surface)
PCO2	Used to display/label tcPCO2 on the SDM and – unless explicitely stated otherwise - throughout this manual
PcO2	Cutaneous oxygen partial pressure (i.e. the O2 partial pressure at the skin surface)
PI	Pulsation Index
PO2	Used to display/label tcPO2 on the SDM and – unless explicitely stated otherwise - throughout this manual
POST	Power-On Self-Test
RO	Responsible Organization
PR	Pulse rate
RHP	Relative Heating Power
RMI	Remote monitoring interrupted
SaO2	Arterial oxygen saturation
SDM	Sentec Digital Monitor
SDMS	Sentec Digital Monitoring System
SpO2	Functional oxygen saturation of arterial hemoglobin as measured with a pulse oximeter
TC	Transcutaneous
tcPCO2	Transcutaneous carbon dioxide partial pressure (2.4.1), i.e. an estimate of PaCO2 calculated from the measured PcCO2 and displayed/labeled on the SDM and - unless explicitly stated otherwise - throughout this manual as 'PCO2'
tcPO2	Transcutaneous oxygen partial pressure (2.4.1), i.e. an estimate of PaO2 calculated from the measured PcO2 and displayed/labeled on the SDM and - unless explicitly stated otherwise - throughout this manual as 'PO2'
VOM	V-CareNeT™ Only Mode

1 Safety Information

This section contains safety information requiring users to exercise appropriate caution while using the Sentec Digital Monitoring System.

1.1 Safety Symbols

Symbol	Definition
	**WARNING** Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.
	**CAUTION** Cautions alert users to exercise appropriate care for safe and effective use of the product and the care necessary to avoid damage to the product that may occur as a result of use or misuse.
	**Note** Notes provide additional guidelines or information.

Table 1 Safety Symbol Definitions

1.2 Warnings


WARNING: The Sentec Digital Monitoring System (SDMS) is to be operated by qualified personnel only. Personnel operating the SDMS must be trained for the operations they perform. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.


WARNING: The Sentec Digital Monitor (SDM) is not intended for diagnosis, it is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. The SDM is a cutaneous blood gas monitor and not a blood gas analyzer.


WARNING: Do not use SDMs, sensors, cables, or connectors that appear damaged.


WARNING: Use only equipment, accessories, disposables or parts supplied or recommended by Sentec AG. Use of other parts may result in injury, inaccurate measurements and/or damage to the device.


WARNING: Carefully route and fix cables to reduce the possibility of patient entanglement or strangulation.


WARNING: To ensure patient safety, do not place the SDM in any position that might cause it to fall on the patient.


WARNING: Do not lift the SDM by the sensor cable or the AC power cord because they could disconnect from the SDM, causing the SDM to fall on the patient.


WARNING: Do not pour any liquid on the SDM, its accessories, connectors, switches, or openings in the chassis. If the SDM has been wetted accidentally, it must be removed from AC power, wiped dry externally, allowed to dry thoroughly, and inspected by qualified service personnel before further use.


WARNING: Keep the SDM (as well as any discarded parts) out of reach of children under the age of 5 years. Some parts of the SDM are small enough to be swallowed and may block the trachea.


WARNING: Chemicals from a broken LCD display panel are toxic when ingested. Use caution when handling a SDM with a broken display panel. Electronic components may content toxic chemicals. Do not ingest chemicals from a broken electronic component.


WARNING: Dispose of battery in accordance with local requirements and regulations.


WARNING: Explosion and flammability hazards. Do not use the SDM in the presence of flammable anesthetics/gases or other flammable substances in any environment, which has increased oxygen content.


WARNING: The SDMS only can be used in patients undergoing hyperbaric therapy if the SDM (monitor) remains outside the hyperbaric environment.

WARNING: The SDM is protected against electrostatic/defibrillator discharge. Parameter display may be temporarily affected during discharge/defibrillation, but will rapidly recover. Precisely follow the instructions given in the defibrillator manual.

WARNING: This device has been tested and found to comply with the requirements for medical devices according to the IEC 60601-1-2, and the Medical Device Directive 93/42/EEC. These requirements are designed to provide reasonable protection against harmful interference in a typical medical installation.

WARNING: During electro-surgery the SDM, sensor and cables are to be physically separated from the electro-surgical equipment. The sensor must not be placed between cutting and counter electrode. The display may be temporarily affected during electro-surgery, but will rapidly recover.

WARNING: To ensure protection of patient, operator and equipment from the effects of defibrillation and diathermy/electro-surgery, cables manufactured by Sentec AG must be used.

WARNING: Patient safety and SDMS performance when connected to patients undergoing magnetic resonance diagnostic procedures (e.g. MRI) are unknown and may vary between different setups. The MRI image, for example, potentially could be affected by the SDMS, the MRI unit potentially could lead to inaccurate measurements of the SDMS, or currents induced in the sensor cables potentially could cause burns. Furthermore, objects containing metal (e.g. the Ear Clip, model EC-MI) can become dangerous projectiles when subjected to the strong magnetic fields created by MRI equipment. Before clinical use of the SDMS during such procedures consult a qualified technician/MRI expert and verify proper operation of the SDMS and the MRI equipment. Ensure to remove all objects containing metal from the patient. In case of doubt remove sensors and cables connected to the SDM from the patient during such procedures.

WARNING: During normal operation (except transport), it is recommended that the monitor is always connected to the AC power outlet.

WARNING: Do not connect the SDM to an electrical outlet controlled by a wall switch, because the SDM may be accidentally turned off once the battery is depleted.

WARNING: To avoid risk of electric shock, this equipment must be connected to a supply mains with protective earth. Ensure that power and protective ground lines are connected correctly. If case of doubt (e.g. as this may be the case during home use of the SDM) disconnect the SDM from the outlet and use the battery power during patient monitoring.

WARNING: Do not use the protective earth terminal for any other purpose than protective earthing or functional earthing.

WARNING: For US, respectively Japan: Grounding reliability can only be achieved when the SDM is connected to an equivalent receptacle marked HG (Hospital Grade), respectively HGJ (Hospital Grade Japan).

WARNING: The SDM should not be used adjacent to or stacked with other equipment as these can cause electromagnetic interference and thereby result in incorrect measurements. If adjacent or stacked use is necessary, the SDM should be observed to verify normal operation in the configuration it is to be used.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SDM, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: The use of accessories, sensors, and cables other than those specified may result in increased emission and/or decreased immunity and inaccurate readings of the SDM.

WARNING: When connecting/mounting the SDM to accessory equipment (e.g. PCs, PSG-Systems, (wireless) networks, roll stands, mounting plates, incubators, etc.)), verify proper operation before clinical use of the SDM and accessory equipment. In certain cases it may be required that the SDM and the accessory equipment must be connected to a grounded AC outlet. In case of doubt consult qualified technicians.

WARNING: Accessory equipment (e.g. a PC) connected to the SDM's data ports must be certified according to the IEC 60950 standard. All resulting combinations of equipment must be in compliance with the IEC standard 60601-1 systems requirements. Anyone who connects accessory equipment to the SDM configures a medical system and is, therefore, responsible for ensuring that the resulting system complies with the requirements of standard IEC 60601-1 and the electromagnetic compatibility standard IEC 60601-1-2. Connection of accessory equipment to the SDM`s data ports is to be performed by qualified personnel.

WARNING: The mains power supply of the Sentec Digital Monitor (SDM) is separated by two Means of Patient Protection (MOPPs) between the sensor port (for the applied part, the sensor)

and the interface connectors. The three interface connectors – serial data port, Multipurpose I/O port (analog outputs, nurse call), LAN port – of the SDM are not separated from each other. If at a time accessory equipment is connected to only one of the three interface connectors no additional safety measures are necessary to comply with the requirements of IEC 60601-1. If however accessory equipment is simultaneously connected to two or three of the SDM's interface connectors additional safety measures may be required to be compliant with the requirements of IEC 60601-1. In case of doubt consult qualified technicians.

WARNING: The Roll Stand, model RS_SDM, is intended for use with the SDM only or in combination with the Cable Cleat, model CC_SDM, and the SDM. The mounting plates are intended for use with the Sentec Digital Monitor (SDM) only. Do not use the accessories for devices from other manufacturers than Sentec together with Sentec Digital Monitoring System (SDMS).

WARNING: Do not attach the basket of the Roll Stand, model RS_SDM, in any position that might cause the Roll Stand to tip over and possibly fall on the patient. Ensure that the Roll Stand does not tip over with and without the SDM being mounted to it.

WARNING: This warning applies to all SDMs with serial numbers less than or equal to 302968 provided that the open thread has not been replaced by a blind thread already or is not sealed with slotted setscrew and thread locking adhesive. A screw entering 17 mm (0.67 inches) into one of the SDM's screw holes may touch the primary part of the SDM's power supply. If this screw is electrically conducting the resulting short circuit may cause an electrical isolation failure and, consequently, if the SDM is connected to AC power an electrical shock may occur to a person touching this screw or any other electrically conducting material being in contact with this screw.

WARNING: Sentec TC Sensors can be operated at temperatures above 41 °C. To minimize the risk of erythema (skin reddening) or burns carefully read section 4.8.1 and the warnings therein.

WARNING: Application of any pressure to the measurement site (e.g. by using a pressure bandage) may cause pressure ischemia at the measurement site and, consequently, inaccurate measurements, necrosis or – in combination with heated sensors – burns.

WARNING: When applying a Multisite-Attachment Ring, model MAR-MI, MARe-MI; MAR-SF or MARe-SF, to a patient, make sure to place it so that the patient does not lie on top of it, as this may cause the ring to leave bruises on the patient.

WARNING: It is not recommended to use sensor attachment accessories in patients who exhibit allergic reactions to adhesive tapes. It is not recommended to use the Contact Gel in patients who exhibit allergic reactions.

WARNING: The readings of a SDM can be affected by certain environmental conditions, sensor application errors, and certain patient conditions. On patients in a compromised hemodynamic state PCO2/PO2 measurements, for example, may be inaccurate. See the appropriate sections of this manual for specific information.

WARNING: Always select the measuring site carefully to avoid selecting a site with low perfusion or low signal quality, which can cause incorrect measurements.

WARNING: Verify the movement of the blip bar or plethysmographic waveform and ensure for adequate signal strength before accepting any displayed SpO2/PR/PI data as a current measurement.

WARNING: Do not use a NIBP cuff or other constricting devices on the same appendage as the sensor. A NIBP cuff will interrupt the patient's circulatory blood flow and result in no pulse found or loss of pulse.

WARNING: Failure to cover the sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.

WARNING: Do not use any other cables to extend the length of the sensor cable than the Digital Sensor Adapter Cables provided by Sentec. Increasing the length of the sensor cable with other cables may degrade signal quality and may lead to inaccurate measurements.

1.3 Cautions

CAUTION: To maintain monitor readiness in-between monitoring if using a Sentec TC Sensor:
ALWAYS clean the sensor before putting it into the Docking Station!
ALWAYS store the clean sensor in the Docking Station!
ALWAYS keep the monitor switched on!

CAUTION: Failure to cover the sensor site with a heat shield if operated under a radiant warmer may result in a situation where the sensor temperature exceeds the selected 'Sensor Temperature' and, as a safety precaution, would cause the SDM to switch off the Sentec TC Sensor.

CAUTION: Do not immerse the SDM nor the connectors of any connecting cables in liquid solution. Plugs and connectors meticulously have to be kept clean and dry at all times.

CAUTION: To ensure accurate performance and prevent device failure, do not subject the SDM to heavy moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure. If the SDM becomes wet accidentally, it should be removed from AC power, wiped dry externally, allowed to dry thoroughly, and inspected by qualified service personnel before further use.

CAUTION: Do not sterilize any parts of the SDMS by irradiation, steam, ethylene oxide, or H2O2 plasma.

CAUTION: Ensure that the SDM is properly grounded when operating on AC power. If you are uncertain whether the AC outlet is properly grounded, disconnect the SDM from the outlet and use the battery power. Contact a qualified electrician to examine the outlet for ground connections.

CAUTION: When installing/setting up the SDM, ensure that the SDM can easily be disconnected from the AC power source at any given time.

CAUTION: If the SDMS has been stored below 10 °C / 50 °F, it must be acclimatized for two hours at room temperature before it can be connected to the mains or switched on. The SDMS may not be installed and operated in moist rooms (e.g. bathroom).

CAUTION: Use only hospital-grade power cords provided by Sentec.

CAUTION: Ensure to always use the correct type and rating of live and neutral fuses. Otherwise you risk damage or malfunction of the SDM.

CAUTION: If the monitor is operated on an AC power source with a depleted battery and the AC power is subsequently lost, the monitor will shut down immediately.

CAUTION: Ensure that the fan of the SDM is clear of any obstructions and that the SDM is located in a well-ventilated dust-free atmosphere. Failure to do so could cause damage or malfunction of the SDM.

2 Introduction

2.1 The Sentec Digital Monitoring System (SDMS)

The Sentec Digital Monitoring System (SDMS) – consisting of the Sentec Digital Monitor (SDM), sensors, disposables and accessories (2.3) – is designed for continuous and noninvasive monitoring of transcutaneous CO2 partial pressure (PCO2), transcutaneous O2 partial pressure (PO2), functional oxygen saturation (SpO2), pulse rate (PR), pulsation index (PI) and heating power (HP) in **adult** and **pediatric** patients as well as for PCO2, PO2 and HP monitoring in **neonatal** patients (4.8.2).
The Sentec Digital Monitor (SDM), the core of the SDMS, is a portable, stand-alone patient monitor providing PCO2, SpO2, PR, PI, and HP if used with the digital **V-Sign™ Sensor 2** (model VS-A/P/N) or PCO2, PO2, SpO2, PR, PI and HP if used with the digital **OxiVenT™ Sensor** (model OV-A/P/N). The V-Sign™ Sensor 2 and OxiVenT™ Sensor must be connected to the SDM using Sentec's Digital Sensor Adapter Cable (models AC-150, AC-250, AC-750).

Note: SDM software versions SMB SW-V08.00and later discontinue support of i) V-Sign™ Sensor (model VS-A/P), the predecessor of V-Sign™ Sensor 2 (model VS-A/P/N) and ii) the SpO2 Adapter Cable (model SC-150) and, hence, the SpO2 Soft Sensor (model RSS-M). If a V-Sign™ Sensor (model VS-A/P) or a SpO2 Adapter Cable (with or without SpO2 Soft Sensor), is connected to a SDM with software version SMB SW-V08.00 or later, the message 'Incompatible sensor' (4.3.5) will display.

Note: Throughout this manual, the notion '**Sentec TC Sensor**' refers to Sentec sensors providing **trans**cutaneous blood gas measurements, i.e. to the V-Sign™ Sensor 2 and the OxiVenT™ Sensor.

SDMs with software versions SMB SW-V08.00 up to SW-V08.03 are available in a software-configuration **without activated PO2-option** and in a configuration **with activated PO2-option**. If the PO2-option of a SDM is activated the 'SDM-Options' Indicator in the lower left corner of the 'Power-On Self-Test' (POST) Screen (4.2.2, Figure 3, 4.6) and on the second page of the menu 'System Information' (Table 58) display '**PO2**', otherwise '**nPO2**'.

SDMs brought to market as of July 2020 include the activated PO2-option by default.

Note: Field-activation of the PO2-option and/or field-deactivation of the VOM-option are possible. Please contact your local Sentec representative for upgrade information if your monitors PO2-option is not activated and/or its VOM-option is activated.

Note: An OxiVenT™ Sensor that is connected to an SDM without activated PO2-option has an equivalent performance as a V-Sign™ Sensor 2.

Note: For optimum versatility, it is possible to enable/disable the parameters to be monitored in the menu of the SDM (Table 38). Available selections depend on the SDM's PO2-option activation status, the type of the connected sensor and the selected patient mode. For an OxiVenT™ Sensor being connected to a SDM with activated PO2-option, for example, 'PCO2 PO2 SpO2 PR', 'PCO2 PO2', 'PCO2 SpO2 PR', 'PCO2', and 'SpO2 PR' are selectable in Adult mode, whereas in Neonatal mode only 'PCO2 PO2' and 'PCO2' are supported. Note that if only 'SpO2 PR' is enabled Sentec TC Sensors correspond to heated pulse oximeter sensors.

Note: SDMs with SMB SW-V08.00 (and later) are optionally also available in a special software-configuration called 'V-CareNeT™ Only Mode' (4.13.3). SDMs being configured in 'V-CareNeT™ Only Mode' (VOM) are only operational if included in/connected to V-CareNeT™, Sentec's PC based remote monitoring and secondary alarm surveillance software for SDMs. If the VOM-option is activated, the 'SDM-Options' Indicator in the lower left corner of the 'Power-On Self-Test' (POST) Screen (4.2.2, Figure 3, 4.6) and on the second page of the menu 'System Information' (Table 58) display '**VOM nPO2**' if the SDM's PO2-option is not activated, and otherwise '**VOM PO2**'.

Note: After upgrading the software from SMB SW-V07.0x or older to SMB SW-V08.00 (and later) the SDM's PO2-option will not automatically be activated.

Note: Software versions SMB SW-V08.00 and later discontinue the support of SDM's with volatile memory (RAM). Consequently, upgrading the software from SMB SW-V07.0x/MPB SW-V05.0x or older to SMB SW-V08.00 (and later) is only possible for SDMs with non-volatile flash memory for measurement data storage.

Sentec TC Sensors provide superior performance, are robust, reliable and require comparatively low maintenance. They combine within a patented digital sensor design the optical components needed for 2-wavelength reflectance pulse oximetry (2.4.4) with the components needed to measure cutaneous PCO2 (PcCO2) and – when using an OxiVenT™ Sensor – cutaneous PO2 (PcO2) (2.4.1). The OxiVenT™ Sensor measures PO2 with dynamic fluorescence quenching, an oxygen sensing technology measuring the oxygen molecules present in the vicinity of a fluorescent dye being immobilized in a thin carrying layer within the sensor surface. The PCO2 measurement of Sentec TC Sensors is based on a Stow-Severinghaus type PCO2 sensor, i.e. a thin electrolyte layer is confined to the sensor surface with a hydrophobic, CO2 and O2 permeable membrane. The membrane and the electrolyte must be exchanged typically every 28 to 42 days (4.10). With Sentec's patented Membrane Changer the membrane and electrolyte can be changed with the ease of 4 identical Press-and-Turn steps in a highly reproducible manner. Typically, the PCO2 segment of Sentec TC Sensors must be recalibrated every 6 to 12 hours (4.9). The PO2 measurement of the OxiVenT™ Sensor is virtually drift free and, hence, calibration free. Nevertheless, the SDM, as a precaution, calibrates PO2 during each mandatory calibration (Table 65) and subsequently approximately once every 24 hours during one of the anyways ongoing PCO2 calibrations.

As the PCO2 segment and – significantly less frequent – the PO2 segment of Sentec TC Sensors require calibration (4.9), the SDM is equipped with an integrated calibration unit (throughout this manual referred to as Docking Station, Figure 1). Sentec's Service Gas (model GAS-0812) serves as CO2 and O2 calibration reference (8% CO2, 12% O2). Sensor calibration is quick, fully automatic, barometric pressure compensated and sensors can be inserted and removed from the 'Docking Station' with one hand. If used with a Sentec TC Sensor the SDM should be kept switched on in-between monitoring, and the sensor should be stored in the Docking Station. The Sentec TC Sensor will then automatically be recalibrated periodically. This ensure that the connected Sentec TC Sensor is permanently 'Ready for use'.

To achieve local arterialization of the skin tissue at the measurement site, Sentec TC Sensors are operated at a constant 'Sensor Temperature' of typically 41 °C for neonatal and 42 °C for adult/pediatric patients if PO2 is disabled and – if PO2 is enabled – of typically 43 °C for neonatal and 44 °C for adult/pediatric patients, respectively (Table 59). Controls of sensor temperature and application duration are designed to meet all applicable safety standards. To guarantee safe operation Sentec TC Sensors reliably control the sensor temperature with two independent circuits. Additionally, the SDM software redundantly controls the temperature of the connected sensor.

Note: The total electrical power needed to heat a sensor applied to the skin to a constant temperature depends to a small fraction on the local skin blood flow beneath the sensor site (2.4.7, 4.8.6). Once the sensor is stabilized on the skin, fluctuations of the heating power at constant ambient temperature, consequently, may indicate changes in local skin blood flow. To help clinicians to assess at a glance whether a change of PCO2 and/or PO2 reflects a corresponding change of arterial blood gases or is caused/influenced by a significant change of the local skin blood flow beneath the sensor site, Online Trends of 'Relative Heating Power' (RHP) are provided /on certain measurement screens (4.2.3, 4.8.6 and Figure 10).

Sentec TC Sensors can either be applied to the patient's earlobe using Sentec's Ear Clip (model EC-MI) or to various other sites like for example the forehead, the check or the thorax using Sentec's Multi-Site Attachment Rings. There are four Multi-Site Attachment Ring models: the use of models MAR-SF and MARe-SF is recommended for use on patients with sensitive/fragile skin with an increased risk of skin damage when peeling off the Multi-Site Attachment Ring after use (e.g. preterm babies or adult patients undergoing cortisone therapy). Models MAR-MI and MARe-MI as well as the Ear Clip are recommended for use on patients with mature/intact skin. If more secure sensor attachment is required, e.g. if a Sentec TC Sensor is used in high humidity environments, for patients who perspire profusely and/or in challenging patient motion conditions, Sentec's Staysite™ Adhesive pad (model SA-MAR) can be used complementary with the Multi-Site Attachment Rings. Furthermore, to ensure an adequate, hermetically sealed contact between the sensor and the skin a thin layer of a Contact Gel is required when applying Sentec TC Sensors.

The SDM is highly configurable and versatile. **Within a password protected area of V-**STATS™ the Responsible Organization can pre-configure SDMs via serial connection. It is possible (**A**) to configure all safety relevant parameters (4.7.4.1) as well as all menu parameters (4.7.4.2) of the connected SDM on an individual basis and (**B**) to select the 'Profile Mode' of the connected SDM, either 'Basic' (4.7.2) or

'Institutional' (4.7.3). In 'Institutional Mode' the Responsible Organization, furthermore, can store up to 4 'SDM Profiles' on the connected SDM and select one of these profiles as 'Standard Profile'.

Note: Safety relevant parameters cannot be changed in the menu of the SDM. Several of these parameters permit to disable or restrict operator access to certain menu parameters (4.7.2.1, 4.7.3.1). Examples include the restriction of the 'Selectable Sensor Temperature Range' or enabling/disabling the possibility to switch-off the 'AUDIO OFF Reminder' in the menu of the SDM (4.7.4.1).

Note: An 'SDM Profile' is a file which contains a specific setting for almost all SDM parameters. 'SDM Profiles' therefore are helpful to ensure that all SDMs within your institution work the way you want them to. Upon installation of or upgrade to V-STATS™ 4.10, the following write-protected SDM Profiles preconfigured by Sentec and tailored to optimally fit the specific needs of varying clinical settings are stored in V-STATS' internal 'SDM Profiles Database': CRITICAL CARE, GEN. CARE FLOOR, HOME, NICU, OPERATING ROOM, PACU, SLEEP, SMB621 STYLE, V-CHECK (enabling Ventilation Spot Check), and NICU_PO2. Please refer to 'RF-006679 Preconfigured SDM Profiles' or use V-STATS™ to view/print all parameters included in a 'SDM Profile' and their settings in the Sentec-preconfigured 'SDM Profiles'.

Note: The Responsible Organization can customize/manage 'SDM Profiles' within V-STATS™. It is possible a) to import 'SDM Profiles' to V-STATS' 'SDM Profiles Database' (either from the SDM or from the PC), b) to export 'SDM Profiles' from the database to the PC (e.g. to exchange them with other users) as well as c) to rename, print or delete 'SDM Profiles' currently available in the database. Refer also to the Instruction Manual for V-STATS (HB-006042) for details.

Even after initial installation and monitor set-up the operator can at the bed-side individually configure all menu parameters (4.7.4.2) **in the menu of the SDM**. Operator access to certain menu parameters can be disabled or restricted by the Responsible Organization (4.7.4.1) or, depending on the specific context, by the SDM itself. If the SDM is used in 'Institutional Mode' (4.7.3) the operator can at any time restore the selected 'Standard Profile' or select/activate one of the other profiles stored in the SDM in the sub-menu 'Profiles' (Figure 9, Table 50), which is easily accessible via a short-cut in the Quick Access Menu (4.2.5.3, Figure 7) if the sensor is in the Docking Station. Furthermore, if at power-up of the SDM the settings from previous use are different from those of the 'Standard Profile', the sub-menu 'Profiles' automatically activates, thereby offering the option to restore the 'Standard Profile', to select another 'Profile', or to keep the modified profile.

The Online Trends and numeric values displayed by the Sentec Digital Monitor (4.2.3) provide truly continuous monitoring of the enabled parameters and, hence, help clinicians to assess at a glance whether or not the therapeutic procedure/change in therapy (e.g. titration of mechanical ventilation, supplemental oxygen, and/or drugs such as sedatives or opioids) has no, the intended or an unintended effect on the patient's ventilation and oxygenation status. Various measurement screens, furthermore, provide online trends with Δx-values, baseline values and baselines for PCO2, PO2, SpO2 and/or RHP (4.2.3, 4.2.3.9, Figure 4). If a baseline is set, each parameter's corresponding baseline is subsequently displayed graphically (vertical and horizontal white lines) and numerically along with its ΔB-value, i.e. the difference between its current reading and its reading at the instant the baseline was set. Similarly, a parameter's 'Δx-value' corresponds to the difference between its current reading and its reading x minutes ago.

Note: A significant change of a parameter's reading within a certain time 'Δx' may indicate a gradual worsening of the patient's status (e.g. a 'Δ10-value for PCO2' of '+ 7 mmHg' or more). Furthermore, it is recommended to set a baseline before changing therapeutic procedures that potentially could impact patient's ventilation and oxygenation.

Alternatively, the SDM can be operated in V-Check™ Mode (4.13.2), a special operating mode providing Ventilation Spot Checks providing a statistical result screen at the end of the V-Check™ Measurement. A V-Check™ Measurement consists of the V-Check™ Stabilization Phase (default duration 8 minutes) and the V-Check™ Analysis Phase (default duration 2 minutes). If the V-Check™ Measurement is finished the V-Check™ Results Screen (Figure 15) activates, displaying for each of the enabled parameters mean, minimum, maximum, median and standard deviation for the V-Check™ Analysis Phase.

Note: If the protocol 'Serial Printer' is selected and a printer is connected to the SDM, print-out of the trend curves (including the statistical results) is automatically activated upon completion of a V-Check™ Measurement.

During patient monitoring, the measured data are continuously stored in a build-in non-volatile memory providing between 35.2 and 229.9 hours of monitoring data, depending on the current data recording interval being institution-selectable between 1 and 8 seconds, respectively (4.12). Automatic determination of the measurement start- and end-times enables convenient selection of measurement(s) for subsequent on-screen viewing and printing of graphical trends and statistical summary or data download with V-STATS™. Furthermore, various data-links (5) enable easy adoption of the SDM to electronic medical record systems or medical devices such as ventilators, poly(somno)graphs, or (central) patient monitoring systems.

The SDM is a portable, lightweight monitor (2.3 kg/5.1 lbs.) which can operate from AC power up to 13 hours from its internal battery (4.5). Its operating altitude is up to 4000 m (13120 ft.) if operated on AC power and up to 6000 m (19600 ft.) if operated on battery. Its flip feet can serve as carrying handle or to adjust the angle for improved table-top viewing. It is mountable on roll/infusion stands, wall mounts/railings, transport incubators or on top of other medical devices. A sturdy carry bag is available for the SDMS, which easily accommodates the Sentec Digital Monitor, sensors, a power cable, the Quick Reference Guide and Instruction Manual as well as frequently used disposables.

V-STATS™ (model V-STATS_CD), is a PC-based software that offers the following three main features:

- Download of SDM Trend Data stored in the internal memory of SDMs (4.12) via their serial or their LAN interface for subsequent data display, data analysis, and generation of a printable report.
- Configuration of the SDM connected to V-STATS™ via its serial interface (4.7).
- Remote monitoring and secondary alarm surveillance of multiple SDMs connected to the same network as the PC using V-CareNeT™. 'Operator Events', 'Baselines' for PCO2, PO2, SpO2 and RHP (if enabled), and certain SDM settings can be set/controlled remotely on the included SDMs. With V-CareNeT™ simultaneous download of SDM Trend Data from multiple SDMs is possible.

Please refer to the Instruction Manual of V-STATS (HB-006042) for additional information on V-STATS™ and V-CareNeT™.

2.2 Intended use/intended purpose of the SDMS

The Sentec Digital Monitoring System – consisting of monitors, sensors, cables, accessories and disposables for sensor application/maintenance and PC-based software – is indicated for noninvasive patient monitoring of oxygenation and ventilation.

The Sentec Digital Monitoring System is for prescription use only. Devices are non-sterile and non-invasive.

The monitor is not in direct contact with the patient during monitoring. The V-Sign™ Sensor 2, the OxiVenT™ Sensor, the Ear Clip, the Multi-Site Attachment Rings, the Staysite™ Adhesive and the Contact Gel are in contact with the intact skin of the patient during monitoring.

Intended patient population: $tcPCO_2$ and $tcPO_2$ monitoring is indicated in adult/pediatric (older than term birth plus 12 months) and neonatal (younger than term birth plus 12 months) patients. Pulse oximetry monitoring is indicated in adult/pediatric patients only.

The target user population of the Sentec Digital Monitoring System (SDMS) is professional medical personnel, e.g. nurses, physicians, and – if under clinical supervision – lay operators. The correct and safe application of $tcPCO_2$ and $tcPO_2$ measuring equipment requires training of the user (e.g. physiological restrictions, technical aspects such as membrane change, meaning of drift, calibration). Home care providers also require specific training to be allowed to install the SDMS in home environments and to instruct lay persons how to apply the sensors correctly. The lay operator cannot modify the SDM's configuration by using the SDM's menu.

Training: Professional medical personnel and instructed home care personnel are trained by Sentec or a qualified and authorized distributor. The instructed home care personnel provides the lay user with

the lay user manual and explains attachment and detachment of the sensor. The instructed home care personnel also defines the application site for the attachment of the sensor.

Environment of use: In clinical and non-clinical settings such as hospitals, hospital-type facilities, intra-hospital transport environments, clinics, physician offices, ambulatory surgery centers and – if under clinical supervision – home environments. Hospital use typically covers areas such as general care floors, operating rooms, special procedure areas, intensive and critical care areas. Hospital type facilities typically cover facilities such as surgical centers, special nursing facilities and sleep labs outside of the hospital. Intra-hospital transport includes transport of a patient within the hospital or hospital-type facilities.

The SDMS fulfils the requirements of a non-transit operable and portable device to be used in home environments.

WARNING: Use only equipment, accessories, disposables or parts supplied or recommended by Sentec. Use of other parts may result in injury, inaccurate measurements and/or damage to the device.

2.3 List of components

The Sentec Digital Monitoring System comprises the following components:

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental /Storage conditions
SDM	Sentec Digital Monitor	Stand-alone patient monitor.	The Sentec Digital Monitor, model SDM, is a portable stand-alone patient monitor intended for continuous, noninvasive patient monitoring of carbon dioxide partial pressure (PCO_2), oxygen partial pressure (PO_2), functional oxygen saturation (SpO_2) and pulse rate (PR), using either • a single, digital sensor (V-Sign™ Sensor 2) for PCO_2, SpO_2 and PR measurement, OR • a single, digital sensor (OxiVenT™ Sensor) for PCO_2, PO_2, SpO_2 and PR measurement PO_2 measurement with SDM is only possible when used in combination with an OxiVenT™ Sensor.	n/a	7 years	Yes	Transport/storage temperature: 0 – 50 °C Transport/storage humidity: 10 – 95% non-condensing Operating temperature: 10 – 40 °C Operating humidity: 15 – 95% non-condensing Operating altitude: -400 – 4000 m (-1300 – 13120 ft) above sea level if connected to mains; -400 – 6000 m (-1300 – 19600 ft) above sea level if operated on battery.

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental /Storage conditions
VS-A/P/N	V-Sign™ Sensor 2	Digital carbon dioxide tension and oximetry sensor.	The V-Sign™ Sensor 2, model VS-A/P/N, is intended for use with the SDM when continuous, noninvasive monitoring of $tcPCO_2$, SpO_2, and PR are required for adult and pediatric patients. In neonatal patients, the use of V-Sign™ Sensor 2 is indicated for $tcPCO_2$ monitoring only.	n/a	up to 36 months	Yes	Transport temperature: 0 – 50 °C Long term storage temperature: 15 – 26 °C Transport/ store sensor with membrane and protected from light/ radiation.
OV-A/P/N	OxiVenT™ Sensor	Digital carbon dioxide tension, oxygen tension and oximetry sensor	The OxiVenT™ Sensor, model OV-A/P/N, is intended for use with the SDM when continuous, noninvasive monitoring of $tcPCO_2$, and $tcPO_2$, as well as SpO_2, and PR monitoring are required for adult and pediatric patients. In neonatal patients, the use of OxiVenT™ Sensor is indicated for $tcPCO_2$ and $tcPO_2$ monitoring only. $tcPO_2$ monitoring is contraindicated for patients under gas anesthesia.	n/a	12 months	Yes	Transport temperature: 0 – 50 °C Long term storage temperature: 15 – 26 °C Transport/ store sensor with membrane and protected from light/ radiation.
AC-XXX	Digital Sensor Adapter Cable	Adapter cable required to connect digital Sentec sensors to the Sentec Digital Monitor. It transfers the power needed to run the micro-/optoelectronic components (LEDs) and to heat the sensor. It furthermore transmits digitized data between the digital sensor and the SDM.	AC-XXX is intended to connect digital Sentec sensors (V-Sign™ Sensor 2, OxiVenT™ Sensor) to the Sentec Digital Monitor.	AC-150: length 150 cm AC-250: length 250 cm AC-750: length 750 cm	7 years	Yes	Transport/storage temperature: 0 – 50 °C Transport/storage humidity: 10 – 95%

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental /Storage conditions
PSG Cable A to PSG Cable X	PSG Adapter Cable	Adapter Cable to interface the SDM to Polygraphs (PG) or Polysomnographs (PSG). A PSG Cable transfers analogue data from the SMD to the PG or PSG system.	PSG Cables are intended to interface the Sentec Digital Monitor to Polygraphs (PG) or Polysomnographs (PSG).	PSG Cable A PSG Cable B PSG Cable C PSG Cable D PSG Cable E PSG Cable F PSG Cable G PSG Cable H PSG Cable J PSG Cable K PSG Cable L PSG Cable M PSG Cable N PSG Cable P PSG Cable Q PSG Cable X	7 years	Yes	Transport/storage temperature: 0 – 50 °C Transport/storage humidity: 10 – 95%
RFT100VA-XX	Isolation Transformer	Isolates the SDM from mains for use in home use environments.	Isolation Transformers are intended ensure a galvanic separation of the Sentec Digital Monitor from supply voltage in home care installation settings.	RFT100VA-V1: 100-120V AC RFT100VA-V2: 230V±10 % AC	7 years	Yes	Temperature: -10 – 50°C Humidity: not specified Operating altitude: < 2000 m above sea level
V-STATS_CD	V-STATS™	V-STATS™: PC based download, data analysis, remote monitoring, and monitor management software.	V-STATS™ is an optional PC-based software, which is intended for use with the monitor SDM when remote monitoring and/ or trend reporting and statistical analysis of data measured by the monitor is required. V-STATS™ is not intended to provide diagnosis; it is intended to supplement and not to replace any part of the monitoring procedures.	n/a	Not specified	n/a	Not specified

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental /Storage conditions
SDM_ WPC	SDM Water protection cover	This cover provides an IPX2 protection for the SDM against the ingress of water.	SDM_WPC is intended to protect the Sentec Digital Monitor from water ingress to meet the IPX2 requirements.	n/a	7 years	Yes	Not specified

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Shelf life	Reusable	Environmental/ Storage
EC-MI	Ear Clip	Single use sensor application Ear Clip, recommended for patients with mature/intact skin	Sentec's Ear Clip, model EC-MI, is intended to attach the Sentec sensors to the earlobe of the patient, recommended for patients with mature/intact skin. The use of the Ear Clip is contraindicated for patients whose earlobes are too small to ensure adequate sensor application (e.g. neonates).	n/a	2 years	No. Reusing the Ear Clip may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 30 °C Humidity: 25%-60%
MAR-MI	Multi-Site Attachment Ring for mature/ intact skin	Single use sensor application ring, recommended for adult, pediatric and neonatal patients with mature/intact skin	Sentec's Multi-Site Attachment Rings, models MAR-MI and MARe-MI, are intended to attach the Sentec sensors to conventional measurement sites, recommended for adult, pediatric and neonatal patients with mature/intact skin.	n/a	2 years	No. Reusing a MAR-MI may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 30 °C Humidity: 25%-60%
MARe-MI	Multi-Site Attachment Ring Easy for mature/intact skin	Single use sensor application ring, recommended for adult, pediatric and neonatal patients with mature/intact skin		n/a	2 years	No. Reusing a MAR-e-MI may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 30 °C Humidity: 25%-60%

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Shelf life	Reusable	Environmental/ Storage
MAR-SF	Multi-Site Attachment Ring for sensitive/fragile skin	Single-use sensor application ring, recommended for adult, pediatric and neonatal patients with sensitive/fragile skin	Sentec's Multi-Site Attachment Rings, models MAR-SF and MARe-SF, are intended to attach the Sentec Sensors to conventional measurement sites, recommended for adult, pediatric and neonatal patients with sensitive/fragile skin.	n/a	1.5 years	No. Reusing a MAR-SF may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 27 °C Humidity: 40%-60%
MARe-SF	Multi-Site Attachment Ring Easy for sensitive/fragile skin	Single-use sensor application ring, recommended for adult, pediatric and neonatal patients with sensitive/fragile skin		n/a	1.5 years	No. Reusing a MARe-SF may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 27 °C Humidity: 40%-60%
SA-MAR	Staysite™ Adhesive	Single-use adhesive for Multi-Site Attachment Rings (attaches complementary the MAR-SF / MARe-SF / MAR-MI / MARe-MI to the skin with an additional adhesive film)	Sentec's Staysite™ Adhesive, model SA-MAR, is an optional, single-use adhesive which is intended for use with Multi-Site Attachment Rings, models MAR-MI, MARe-MI, MAR-SF, and MARe-SF, if a more secure attachment is required.	n/a	1.5 years	No. Reusing the SA-MAR may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 27 °C Humidity: 40%-60%
MC	Membrane Changer	Membrane change tool, single-use	The Membrane Changer single-use, the Membrane Changer reloadable and the Membrane Changer Insert, MC, MC-R and MC-I, serve as tools to change the electrolyte and membrane of the V-Sign™ Sensor 2 and the OxiVenT™	n/a	2 years	No. The MC single-use is not intended to be reloaded with the MC-I.	Temperature: 10 – 30 °C Humidity: 10%-95%
MC-R	Membrane Changer	Membrane change tool, reloadable		n/a	2 years	Yes, max. 10 times reloadable with MC-I.	Temperature: 10 – 30 °C Humidity: 10%-95%

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Shelf life	Reusable	Environmental/ Storage
MC-I	Membrane Changer Insert	Separately bagged, single-use inserts required to reload a Membrane Changer prior to reuse.	Sensor. The Membrane Changer reloadable (MC-R) can be reused by replacing its insert (MC-I). MC, MC-R and MC-I are not intended for sterilization (e.g. by irradiation, steam, ethylene oxide or plasma method).	n/a	2 years	No. Reusing the MC-I may cause: - loss of functionality of the sensor and incorrect measurements	Temperature: 10 – 30 °C Humidity: 10%-95%
GAS-0812	Service Gas for SDM	Calibration gas for docking station, cylinder of 0.56 l at 9.5 bar. Mixture of 8-vol % CO_2, 12-vol% O_2 and 80-vol% N_2	The Service Gas, model GAS-0812, serves as calibration gas for the Sentec's sensors that monitor tcPCO_2 and/or tcPO_2 (V-Sign™ Sensor 2 and OxiVenT™ Sensor). The Service Gas, model GAS-0812, is intended for use only with the docking station integrated in Sentec's Digital Monitor.	n/a	2 years	Yes, for about one month, depending on use scenarios and sensor condition. Do not use Service Gas if it is expired, this may result in incorrect measurements.	Temperature: 0 – 50 °C Humidity: not specified
GEL-04	Contact Gel	Contact gel for Sentec transcutaneous sensors, bottle of 5 mL	The Contact Gel, GEL-04 and GEL-SD, serves as contact gel to achieve proper gas conduction and heat transfer between the patient's skin and Sentec's sensors.	n/a	2 years	Yes. Do not use Contact Gel if it is expired, to avoid infections or potential allergic reactions.	Temperature: 10 – 30 °C Humidity: 10%-95%
GEL-SD	Single Dose Contact Gel	Contact gel for Sentec transcutaneous sensors, single-dose vials of 0.3 g each		n/a	2 years	No. Do not use Contact Gel if it is expired, to avoid infections or potential allergic reactions. Reusing the GEL-SD may cause: - Contamination (non-resealable)	Temperature: 10 – 30 °C Humidity: 10%-95%

Table 2 List of components

Note: The components listed above do not necessarily correspond to the scope of delivery. Please refer to Sentec's Webpage (www.sentec.com) for additional information and other available accessories.

2.4 Principles of Operation and Limitations

2.4.1 Transcutaneous PCO2 and PO2

Carbon dioxide (CO2) and Oxygen (O2) are gases that readily diffuse through body and skin tissue and, therefore, can be measured by an adequate noninvasive sensor being applied at the skin surface. At a specific site, the cutaneous PCO2 (PcCO2) and cutaneous PO2 (PcO2) measured by such a sensor depend – aside from the corresponding arterial blood gases – on factors such as

- the local skin blood flow beneath the sensor site (supplying O2 and removing CO2),
- the metabolism in the skin tissue beneath the sensor site (consuming O2 and producing CO2),
- the skin structure beneath the sensor site, and
- the gas diffusion properties of the skin tissue beneath the sensor site.

When attempting to assess PaCO2 and PaO2 the dependence of PcCO2 and PcO2 from the aforementioned factors can be minimized and the reproducibility of CO2/O2 measurements at the skin surface can be improved by the two following measures:

1) By warming up the skin tissue beneath the sensor site to a constant temperature which is higher than the normal body surface temperature
   - the capillary blood flow in the skin tissue beneath the sensor site increases, i.e. the supply of arterial blood to the dermal capillary bed beneath the sensor site increases (local arterialization,/hyperemia,/vasodilatation),
   - the metabolism (the O2 consumption rate and the CO2 production rate) in the area beneath the sensor site stabilizes, and
   - the gas diffusion through the skin tissue improves.
2) By selecting an appropriate measurement site, i.e. skin areas with
   - a high density of capillaries,
   - an ample capillary blood flow,
   - a thin epidermis, and
   - little or no deposition of fat.

Note: For neonatal patients, suitable measurement sites for transcutaneous blood gas monitoring include the thorax (under the clavicle, on rib cage), the abdomen, the back, the area low on the forehead, and the inner or anterior aspect of the thigh.

Note: For adult/pediatric patients, suitable measurement sites for transcutaneous blood gas monitoring include the earlobe, the area low on the forehead, the cheek, the upper arm, the area above/on the shoulder blade (scapula), the thorax (under the clavicle), the area behind the ear (on mastoid process), and the area on the lower arm. The first five sites are particularly suitable as they can also be used for SpO2/PR monitoring.

TcPO2 designates an estimate of PaO2 and corresponds to the measured PcO2. In newborns, PO2 measured at the skin surface (PcO2) correlates with arterial PO2 (PaO2) almost in a one-to-one relationship at a sensor temperature of 43 to 44 °C. The accuracy of PcO2 compared to PaO2 is best up to a PaO2 of 80 mmHg (10.67 kPa), above which it increasingly tends to read lower than PaO2. As target PaO2 levels in newborns are usually below 90 mmHg (12 kPa), a correction of PcO2 values measured at a sensor temperature of 43 to 44 °C is normally not necessary. In adults, local variations in skin physiology can affect the correlation between PcO2 and PaO2, which can result in lower readings even at a target PaO2 below 80 mmHg (10.67 kPa).

Note: On the SDM (4.2.3) and throughout this manual (unless explicitly stated otherwise), 'tcPO2' is displayed/labeled as 'PO2'.

PcCO2 values (i.e. PCO2 measured at the skin surface) are usually consistently higher than PaCO2 values in patients of all ages. It is therefore possible to estimate PaCO2 from the measured PcCO2 using an adequate algorithm. tcPCO2 representsan estimate of PaCO2 calculated from the measured PcCO2 with an algorithm developed by J.W. Severinghaus:

$$tcPCO_2(37°C) = \frac{PcCO_2(T)}{10\text{^}((T - 37°C) \times A)} - M$$

The 'Severinghaus Equation' first corrects PcCO2 measured at the sensor temperature (T) to 37 °C by using an anaerobic temperature factor (A) and then subtracts an estimate of the local 'Metabolic Offset' (M).

Note: On the SDM (4.2.3) and throughout this manual (unless explicitly stated otherwise), 'tcPCO2' is displayed/labeled as 'PCO2'.

Note: The PCO2 values displayed by the SDM are corrected/normalized to 37 °C and provide an estimate of PaCO2 at 37 °C.

Note: The denominator in the first term of the 'Severinghaus Equation' is called 'Temperature Correction Factor' (C).

Note: In default settings, the SDM's menu-parameter 'Severinghaus Correction Mode' (Table 40) is set to 'Auto' (4.13.1). In this case, the SDM uses 'Sentec-recommended' settings for the 'Temperature Correction Factor' (C) and 'Metabolic Offset' (M) and automatically adjusts these settings as a function of the selected patient type and sensor temperature. Subject to the institution's permission, the parameter 'Severinghaus Correction Mode' can be set to 'Fixed' to use fixed C and M settings customized by the institution (4.13.1).

Note: Subject to the institution's permission, 'In-Vivo Correction' (IC) of PCO2 values is possible at the bedside (4.11, Table 41). The 'PCO2 In-Vivo Correction' allows adjusting the SDM's PCO2 readings based on the result of an arterial blood gas analysis. The 'PCO2 In-Vivo Correction' adjusts the 'Metabolic Offset' (M) used in the 'Severinghaus Equation' such that the difference between the PCO2 value displayed by the SDM when taking the blood sample and the PaCO2 value as determined by the blood gas analysis cancels out. The 'PCO2 In-Vivo Correction' should only be used when a systematic difference between the SDM's PCO2 readings and PaCO2 is clearly established by several arterial blood gas measurements.

For additional information on transcutaneous blood gas analysis and its limitations (2.4.2), please refer to:

- Severinghaus JW. Transcutaneous blood gas analysis. Respir Care 1982; 27(2):152-159.
- Monaco F et al. Calibration of a Heated Transcutaneous CO2 Electrode to Reflect Arterial CO2. Am. Rev. Resp. Dis. 1983; 127:322.
- Palmisano BW. and Severinghaus JW. Transcutaneous PCO2 and PO2: a multicenter study of accuracy. J Clin Monit 1990;6:189-195
- International Federation of Clinical Chemistry (IFCC), Scientific Division, Committee on pH, Blood Gases and Electrolytes: Guidelines for cutaneous PO2 and PCO2 measurement. Ann Biol Clin 1990;48:39-53
- Severinghaus JW. The Current Status of Transcutaneous Blood Gas Analysis and Monitoring. Blood gas news 1998, 7(2):4-9
- AARC Clinical Practice Guideline: Transcutaneous Blood Gas Monitoring for Neonatal & Pediatric Patients – 2004 Revision & Update. Respir Care 2004;49(9):1069-72.
- Rüdiger M. et al., A survey of transcutaneous blood gas monitoring among European neonatal intensive care units BMC Pediatrics 2005, 5:30

2.4.2 Limitations of Transcutaneous PCO2 and PO2

The following clinical situations or factors may limit the correlation between transcutaneous and arterial blood gas tensions:

- Hypo-perfused skin tissue beneath the sensor site due to low cardiac index, circulatory centralization (shock), hypothermia (e.g. during surgery), use of vasoactive drugs, arterial occlusive diseases, mechanical pressure exercised on measurement site, or inadequate (too low) sensor temperature.
- Arterio-venous shunts, e.g. ductus arteriosus (PO2 specific).
- Hyperoxemia (PaO2 > 100 mmHg (13.3 kPa)) (PO2 specific).
- Inadequate measurement site (placement over large superficial veins, on areas with skin edema (e.g. oedema neonatorum), skin breakdown, and other skin anomalies).
- Improper sensor application resulting in an inadequate, not hermetically sealed contact between the sensor surface and the patient's skin causing the CO2 and O2 gases diffusing out of the skin to intermix with ambient air (2.4.3).
- Exposure of the sensor to high ambient light levels (PO2 specific).

- strong electromagnetic interferences

Note: Some patients may need special attention due to their comorbidities, medication or other reasons, resulting in a potentially impaired skin perfusion. For such patients, Sentec recommends reducing the sensor temperature by 1°C and/or reducing the site time and changing the measurement site more frequently.

Note: Compared to the corresponding arterial blood gases, transcutaneous PCO2 readings are typically too high and PO2 reading too low if the measurement site is hypo-perfused.

Note: The SDMS is not a blood gas device. Keep the above-mentioned limitations in mind when interpreting PCO2 and PO2 values displayed by the SDM.

Note: When comparing PCO2/PO2 values displayed by the SDM with PaCO2/PaO2 values obtained from arterial blood gas (ABG) analysis, pay attention to the following points:

- Carefully draw and handle blood samples.
- Blood sampling should be performed in steady state conditions.
- The PaCO2/PaO2 value obtained from ABG analysis should be compared to the SDM's PCO2/PO2 reading at the time of blood sampling.
- In patients with functional shunts, the sensor application site and the arterial sampling site should be on the same side of the shunt.
- If the menu parameter 'Severinghaus Correction Mode' is set to 'Auto' (4.13.1, Table 40), the PCO2 values displayed by the SDM are automatically corrected to 37 °C (regardless of the patient's core temperature). When performing the ABG analysis, be sure to properly enter the patient's core temperature into the blood gas analyzer. Use the blood gas analyzer's '37 °C-PaCO2' value to compare with the SDM's PCO2 value.
- Verify proper operation of the blood gas analyzer. Periodically compare the blood gas analyzer's barometric pressure against a known calibrated reference barometer.

2.4.3 TC-Stabilization and TC-Artifact Detection Algorithm

A good, hermetically sealed contact between the TC-Sensor and the skin provided, PCO2 typically increases and PO2 typically decrease to a stabilized value after sensor application. Stabilization usually occurs within 2 to 10 minutes, i.e. the time required to warm up and complete local arterialization of the measurement site as well as to achieve equilibrium between the gas concentrations in the skin tissue and the gas concentrations on the sensor surface.

Note: Longer stabilization time may indicate an incorrect sensor application or a poorly selected measurement site.

Referring to 2.4.1, it is herewith emphasized that PCO2 and PO2 only reflect patient's PaCO2 and PaO2 after stabilization. Furthermore, note that once stabilized, so-called 'TC-Artifacts' can (intermittently) disturb PCO2/PO2 readings. Ambient air (intermittently) penetrating between the sensor surface and the skin and typically resulting in fast PCO2 and/or PO2 changes is the most frequent cause for 'TC-Artifacts'. Other causes for 'TC-Artifacts' include defibrillator discharge, electro-surgery, strong electromagnetic interferences, instabilities of the sensor temperature, and – for PO2 – high ambient light levels.

The software of the SDM uses Sentec proprietary technology which is able a) to detect most 'TC-Artifacts' as well as b) to determine when PCO2 and/or PO2 reach their stabilized value after sensor application or after occurrence of a 'TC-Artifact'. The SDM displays the message 'PCO2/PO2 stabilizing' if both transcutaneous parameters are stabilizing or 'PCO2 stabilizing' or 'PO2 stabilizing', respectively, if only one transcutaneous parameter is stabilizing (4.3.5). While stabilizing PCO2 and/or PO2 readings are marked as unstable (value(s) displayed in grey, 4.2.3.8), indicating that PCO2 and/or PO2 readings during stabilization do not accurately reflect the patient's PCO2 and/or PO2 level. Furthermore, if stabilization for one or both TC parameters cannot be achieved within 10 minutes after sensor application or in the event of a 'TC-Artifact' the low priority alarm 'Check sensor application' (4.3.5) is triggered to indicate that adequacy of sensor application must be verified.

Note: In order to reduce the occurrence of 'TC-Artifacts', a good, hermetically sealed contact between the sensor surface and the patient's skin is essential. The contact quality between the skin and the sensor surface can be significantly improved by using a contact liquid. Use only approved Sentec Contact Gel. Furthermore, ensure to verify good contact between the sensor

and the skin after sensor application, to properly secure the sensor cable (strain relief) as well as to routinely inspect adequacy of sensor application during monitoring.

Note: Excessive motion may cause 'TC-Artifacts'. In such cases, try to keep the patient still or change the sensor site to one with less motion.

2.4.4 Pulse Oximetry: SpO2, PR

The SDMS uses pulse oximetry to measure functional oxygen saturation (SpO2) and pulse rate (PR). Pulse oximetry is based on two principles: firstly, oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry) and secondly, the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography).

Pulse oximeter sensors pass red and infrared light into a pulsating arteriolar vascular bed and measure changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) serve as light sources and a photodiode serves as photodetector. The software of a pulsoximeter uses the ratio of red to infrared light absorbed to calculate SpO2.

Pulse oximeters use the pulsatile nature of arterial blood flow to differentiate the oxygen saturation of hemoglobin in arterial blood from the one in venous blood or tissue. During systole, a new pulse of arterial blood enters the vascular bed: blood volume and light absorption increase. During diastole, blood volume and light absorption decrease. By focusing on the pulsatile light signals, effects of nonpulsatile absorbers such as tissue, bone and venous blood are eliminated.

Note: The SDMS measures and displays functional oxygen saturation: the amount of oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. The SDMS does not measure fractional saturation: oxygenated hemoglobin expressed as a percentage of all hemoglobin, including dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin.

Note: Oxygen saturation measurement techniques – including pulse oximetry – are not able to detect hyperoxemia.

Note: Due to the S-shape of the oxyhemoglobin dissociation curve (ODC), SpO2 alone cannot reliably detect hypoventilation in patients being administered with supplemental oxygen.

2.4.5 Limitations of Pulse Oximetry

The following clinical situations or factors may limit the correlation between functional oxygen saturation (SpO2) and arterial oxygen saturation (SaO2) and may cause the loss of the pulse signal:

- dysfunctional hemoglobins (COHb, MetHb)
- anemia
- intravascular dyes, such as indocyanine green or methylene blue
- low perfusion at the measurement site (e.g. caused by inflated blood pressure cuff, severe hypotension, vasoconstriction in response to hypothermia, medication, or a spell of Rynaud's syndrome)
- venous pulsations (e.g. due to use of the forehead, cheek or earlobe as a measurement site on a patient in steep Trendelenburg position)
- some cardiovascular pathologies
- skin pigmentation
- externally applied coloring agents (dye, pigmented cream)
- prolonged and/or excessive patient movement
- exposure of the sensor to high ambient light levels
- strong electromagnetic interferences
- defibrillation

Note: If the quality of the signals measured by the connected sensor's photodiode is temporarily degraded SpO2, PR, and PI are marked as questionable (4.2.3.8). If the quality of these signals continuous to be degraded the message 'SpO2 Signal Quality' (4.3.5) will display and SpO2, PR, and PI will be marked as invalid (i.e. values replaced by '---', 4.2.3.8) within 15 seconds. Additionally, a low priority auditory alarm signal will sound within 30 seconds from the beginning of the degraded signal.

Note: The message 'SpO2 low signal' (4.3.5) is displayed whenever the SDM detects a weak pulsatile signal independently from its severity or impact on the SpO2, PR or PI values. This may be caused by low perfusion at the measurement site. SpO2, PR, and PI are marked as questionable (4.2.3.8) during episodes with a weak pulsatile signal. Verify the sensor application and the appropriateness of the current monitoring site and/or of the sensor application for pulse oximetry and/or TC-monitoring. If necessary, readjust or consider changing the measurement site.

The pulse rate displayed by a pulse oximeter may differ slightly from the heart rate displayed on an ECG monitor due to the differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to physiological changes in the patient or one of the instruments or application of the sensor. The pulsation from intra-aortic balloon support can be additive to the pulse rate displayed by a pulse oximeter.

For additional information on pulse oximetry and its limitations refer to:

- AARC Clinical Practice Guideline: Pulse Oximetry. Respir Care 1991;36:1406-9.
- Clinical and Laboratory Standards Institute (CLSI). Pulse Oximetry; Approved Guideline. CLSI document HS3-A (ISBN 1-56238-562-3) January 2005.

2.4.6 Pulsation Index

The Pulsation Index (PI), as calculated by the SDMS, is defined as the ratio of the amplitudes of the pulsatile and the non-pulsatile infrared signals, expressed in percent. A low PI value indicates weak pulse strength and a high PI value strong pulse strength. The SDM displays the message 'SpO2 low signal' (4.3.5) if there are very low amplitude arterial pulsations.

Note: The PI is relative to a particular monitoring site as physiological conditions vary between monitoring sites and individual patients.

The quality of pulse oximetry as well as of TC-monitoring both rely on a good perfusion of the skin tissue beneath the measurement site (refer to sections 2.4.1, 2.4.2, 2.4.4, and 2.4.5). The Pulsation Index therefore can be useful for quickly evaluating the appropriateness of a monitoring site and/or the sensor application for pulse oximetry and/or TC-monitoring.

At a specific measurement site, changes in PI also occur as a result of local vasoconstriction (decrease in PI) or vasodilatation (increase in PI) in the skin tissue beneath the sensor site. The interpretation of PI changes depends on the clinical context to which it is applied. Factors such as administration of vasoactive drug or changes in patient's hemodynamic status must be taken into consideration.

Note: In a patient attached to a heart-lung machine, perfusion of the skin tissue beneath the sensor site can be good but the pulsatile part of the signal is nearly zero because of the absence of a pulse.

2.4.7 Heating Power

The total electrical power needed to heat a sensor applied to the skin to a constant temperature depends to a small fraction on the local skin blood flow beneath the sensor site. Because the sensor temperature is (usually) above the blood temperature, blood flowing past the sensor site has a cooling effect. As blood flow (and its associated cooling effect) increases the sensor requires more power to maintain the selected sensor temperature and, therefore, the heating power increases. Conversely, as blood flow decreases, the sensor heating power decreases. Once the sensor is stabilized on the skin, fluctuations of the heating power at constant ambient temperature, consequently, may indicate changes in local skin blood flow.

On the SDM, the operator can select between the display of 'Absolute Heating Power' (AHP), 'Relative Heating Power' (RHP), or disable the display of the heating power (4.8.6, Table 39). In **AHP-Mode**, the total power needed to heat the connected sensor to the selected 'Sensor Temperature' is displayed whenever the sensor is outside the 'Docking Station'. In **RHP-Mode**, deviations of the current heating power from a stored RHP-reference value are displayed as plus or minus RHP values once the sensor is

stabilized on the skin (plus if the current heating power is larger than the RHP-reference value, minus if lower, and 0 if identical). AHP and RHP values are displayed in Millwatts (mW).

As explored in sections 2.4.1 and 2.4.2, the correlation between transcutaneous and arterial blood gases tends to decrease with decreasing local skin blood flow beneath the sensor site. Transcutaneous blood gases, therefore, may not accurately reflect the trend of arterial blood gases when the local skin blood flow changes significantly. Consequently, an abrupt change of transcutaneous blood gases coupled with a significant change of RHP readings may indicate a change in local skin blood flow, while abrupt changes of transcutaneous blood gases unaccompanied by a significant change of RHP readings may indicate consistent blood flow but a change in arterial blood gases. To help clinicians to assess at a glance whether a change of PCO2 and/or PO2 reflects a corresponding change of arterial blood gases or is caused or influenced by a significant change of the local skin blood flow beneath the sensor site, RHP Online Trends are provided on certain measurement screens (4.2.3, 4.8.6).

IMPORTANT NOTE: The heating power needed to maintain a constant sensor temperature is also influenced by body temperature changes and ambient temperature changes. Body temperature changes occurring during the time the sensor is applied on the patient typically are small and, hence, only produce minor changes in AHP/RHP values. Ambient temperature changes from air-conditioners, patient warmers, radiant heaters, opening the window etc. can have a fast/significant impact on AHP/RHP values.

IMPORTANT NOTE: When monitoring AHP/RHP values with the goal to assess changes in the local skin blood flow beneath the sensor site, it is essential to select a sensor temperature at least 3 to 4 °C above the blood temperature, to use the sensor in an environment with constant (or only slowly changing ambient temperature) as well as to insulate the sensor from ambient temperature changes with a light covering such as a bed-sheet, or with a material designed to reflect radiant heat energy.

WARNING: Account for potential changes in body temperature, ambient temperature or other environmental conditions when interpreting heating power data.

3 General Information

3.1 How to use this manual

The Technical Manual for the SDM is intended to provide the necessary information for proper operation of the SDM. General knowledge of TC-monitoring and pulse oximetry as well as an understanding of the features and functions of the SDM are a prerequisite for proper use. All users should read this manual thoroughly. More experienced users of the SDM will be able to go directly to the specific topics for the information they may require.

3.2 Related documents

WARNING: The instructions provided in the Quick Reference Guide for the SDMS, the Instruction Manual for the SDMS and the Technical Manual for the SDM must be followed in order to ensure proper instrument performance and to avoid electrical hazards.

The complete documentation for the Sentec Digital Monitoring System (SDMS) comprises:

System component	Manual	Content
SDMS	Quick Reference Guide for the SDMS	Routine Use: The 'Quick Reference Guide for the SDMS' summarizes the key essentials on just 2 pages.
SDMS	Instruction Manual for the SDMS	Getting started/using the SDMS: The 'Instruction Manual for the SDMS' highlights the essential points when using the SDMS.
SDM	Technical Manual for the SDM (present manual)	The 'Technical Manual for the SDM' provides detailed information on the Sentec Digital Monitor (SDM).
SDMS	Service Manual for the SDMS	Provides information on maintenance, safety and functionality tests, troubleshooting and repair procedures that do not require opening the cover of the SDM as well as on service/maintenance procedures for sensors.
SDMS	Repair Manual for the SDMS	The 'Repair Manual for the SDMS' covers repair procedures on the opened SDM. The 'Repair Manual for the SDMS' is distributed to Sentec authorized service personnel only.
Sensors/ Disposables	Respective Directions for Use	Additional information on Sentec TC Sensors, the Membrane Changer, the Ear Clips, the Multi-Site Attachment Rings and the Staysite™ Adhesive pad is provided in the respective Directions for Use.
V-STATS™	Installation Manual for V-STATS™	This manual describes the procedures to install V-STATS™ on a PC.
V-STATS™	Instruction Manual for V-STATS™	The Instruction Manual for V-STATS™ provides detailed information on V-STATS™.

Table 3 Related Documents

Note: The 'Quick Reference Guide for the SDMS', the 'Instruction Manual for the SDMS' and various other manuals are available for online viewing at https://www.sentec.com/ifu). Information/Instructions about the 'Digital Sensor Adapter Cable' are only provided in the 'Instruction Manual for the SDMS' and the 'Technical Manual for the SDM'.

Note: Statements in this manual are only applicable for SDMs with the software version indicated on the cover page. If your SDM has another software version than the one indicated on the cover page of this manual, please refer to the corresponding version of this manual.

Note: SDMS related tutorials are available for online viewing at www.sentec.com/tv/

3.3 Using the SDMS

3.3.1 Setting up the SDMS

The SDM should be located close enough to the patient so that the sensor cable is not unduly stretched by movements of the patient. The alarms produced by the monitor should be clearly audible from the operator's position. Lighting on and around the monitor should be such that the displays and indicator lamps are clearly legible and visible.

Please refer to the Instruction Manual for the SDMS for detailed setup instructions. The following topics are covered in the Instruction Manual:

- Connecting the SDM to AC power (also see 4.5.1)
- Battery operation of the SDM (also see 4.5.2)
- Turning on the SDM (also see 4.6)
- Installation of the Gas Bottle (Service Gas-0812)
- Connection/Disconnection of a Digital Sensor Adapter Cable
- Connection of a Sentec TC Sensor
- Checking a Sentec TC Sensor
- Sensor calibration and storage (also see 4.9)
- Changing the sensor membrane (also see 4.10)

When using the monitor in a potentially wet environment, Sentec recommends using the Water Protection Cover (SDM_WPC). This will increase the water protection of the Sentec Digital Monitor from IPX1 to IPX2. The device is thus protected from dripping water when tilted up to 15°. For this purpose, place the protective cover over the monitor and secure it with the two Velcro fasteners on the bottom of the device. This will ensure the exact positioning of the cover and prevent slipping.

WARNING: Do not pour any liquid on the SDM, its accessories, connectors, switches, or openings in the chassis. If the SDM has been wetted accidentally, it must be removed from AC power, wiped dry externally, allowed to dry thoroughly, and inspected by qualified service personnel before further use.

Note: In rooms classified as 'cardiac protected' electrical areas, connect the equipotential ground of the monitor to the equipotential grounding system.

CAUTION: Use only hospital-grade power cords provided by Sentec.

3.3.2 Patient monitoring with the SDMS

Please refer to the Instruction Manual for the SDMS for instructions related to patient monitoring with the SDMS. The following topics are covered in the Instruction Manual:

- Selection of Patient Type, Measurement Site, and Sensor Attachment Accessory
- Checking SDM Settings and System Readiness
- Sensor Application using a Multi-Site Attachment Ring or an Ear-Clip
- Patient Monitoring
- Sensor Removal for subsequent reattachment to same site/without reattachment to same site

WARNING: Before initiating patient monitoring, ensure the current SDM Settings/SDM Profile are appropriate for the patient, for the selected measurement site, for the skin condition/skin tissue perfusion at the selected measurement site, and for the specific clinical setting. At least check the patient type and the enabled parameters as well as Sensor Temperature, Site Time, and alarm specific settings. Change SDM Settings/SDM Profile if necessary. Furthermore, verify 'System Readiness' (message 'Ready for use') and check the 'Available Monitoring Time'.

WARNING: Ensure the sensor is applied correctly. Incorrect application of the sensor can cause incorrect measurements.

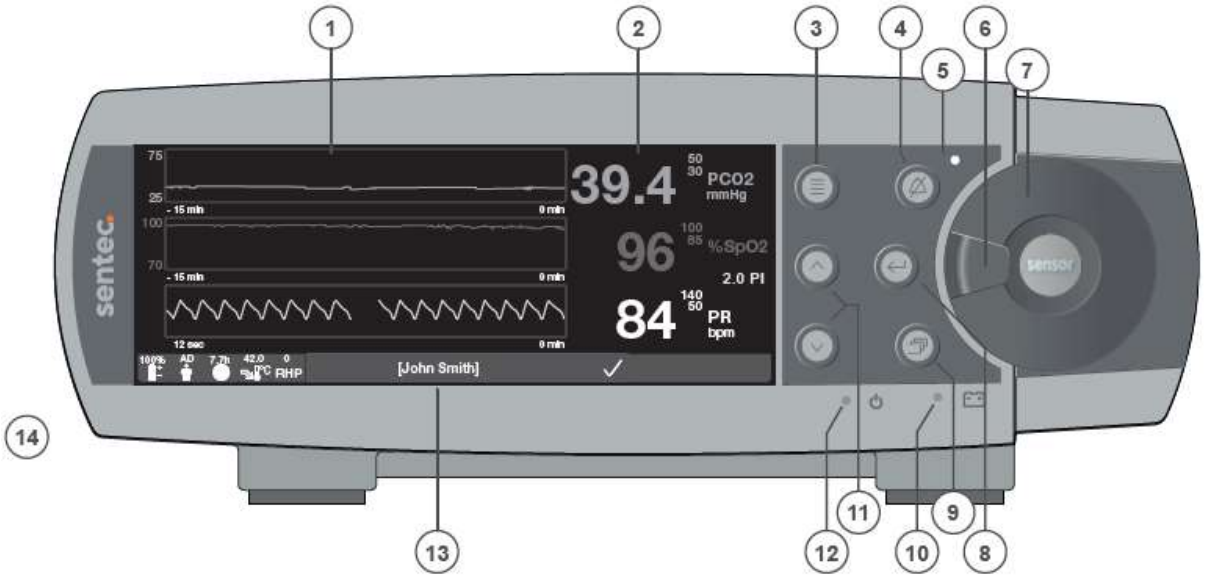
WARNING: It is not recommended to use sensor attachment accessories on patients who exhibit allergic reactions to adhesive tapes. It is not recommended to use the Contact Gel on patients who exhibit allergic reactions.

Note: A good, hermetically sealed contact between the sensor and the skin is essential for TC monitoring!

4 The Sentec Digital Monitor (SDM)

4.1 Controls, Indicators and Symbols

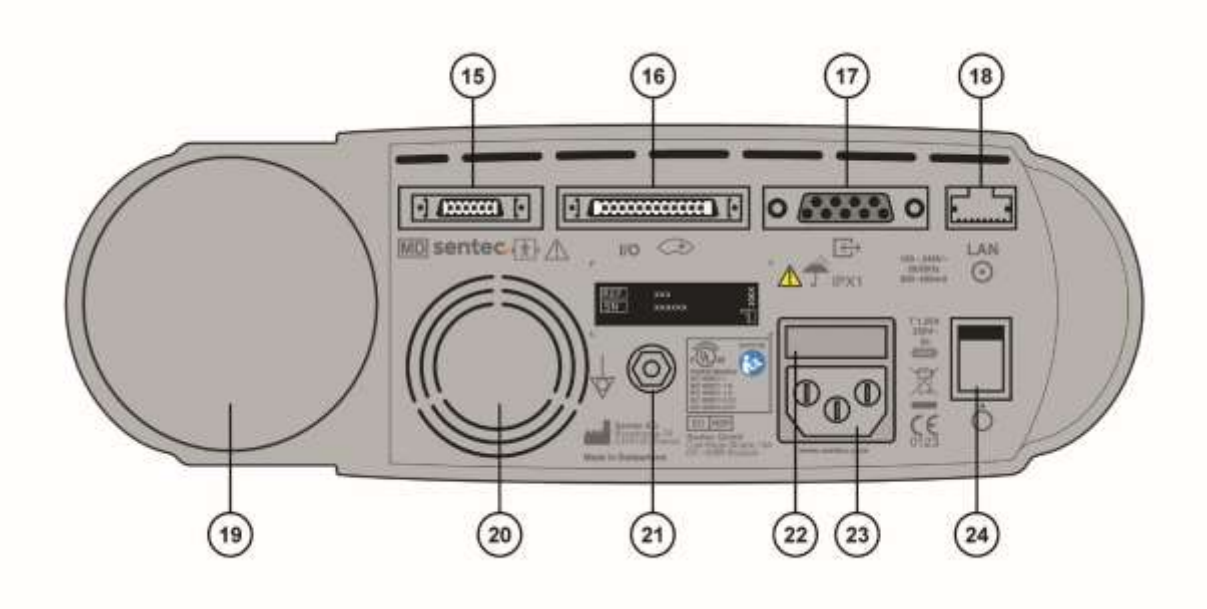
4.1.1 Description of the Front Panel



1 Trend Display Area
2 Numerical Display Area
3 Menu/Previous Level Button
4 AUDIO PAUSED/OFF Button
5 AUDIO PAUSED/OFF Indicator (yellow LED)
6 Door Handle
7 'Docking Station' Door
8 ENTER Button
9 Display Button
10 AC Power/Battery Indicator (green/yellow LED)
11 UP/DOWN Buttons
12 ON/OFF Indicator (green LED)
13 Status Bar
14 Speaker (on the side)

Figure 1 Front Panel of the SDM

4.1.2 Description of the Rear Panel



15 Sensor Connection Port

16 Multipurpose I/O-Port (Nurse call, analog output)

17 Serial Data Port (RS-232)

18 Network Port (LAN)

19 Gas Bottle Slot

20 Fan

21 Equipotential Terminal Connector (ground)

22 Fuse Holder

23 AC Power Connector

24 ON/OFF Switch

Figure 2 Rear Panel of the SDM

WARNING: Refer to sections 1.2 and 5.1 for warnings related to connecting/mounting the SDM to accessory equipment.

CAUTION: Ensure to always use the correct type and rating of live and neutral fuses. Otherwise, you risk damage or malfunction of the SDM.

CAUTION: Ensure that the fan of the SDM is clear of any obstructions and that the SDM is located in a well-ventilated dust-free atmosphere. Failure to do so could cause damage or malfunction of the SDM.

4.1.3 SDM Symbols

The following symbols are located on the rear panel of the SDM (4.1.2):

Symbol	Name	Description
	Mandatory action: refer to instruction manual	Indicates that the instruction manual must be read
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	General warning sign	Indicates a general warning
	Reference Number	Followed by the reference number of the equipment
	Serial Number	Followed by the serial number of the equipment
	Date of Manufacture	Followed by the date of manufacture of the equipment
	Equipotentiality	Equipotential Terminal (ground)
	ON	Monitor ON
	OFF	Monitor OFF
I/O	Multipurpose Port	Nurse Call (5.4.2)+ Analog Output (5.4.1)
	Nurse Call	Nurse Call (integrated into Multipurpose Port)
	RS-232	Serial Data Port (RS-232) (5.2)
LAN	LAN	Local Area Network Port (5.3)
	Defibrillation Proof Type BF	Degree of protection against electrical shock: Defibrillation-proof, Type BF applied part
	Fuse	Indicates fuse type
IPX1	Type IPX1	Degree of protection against harmful ingress of water: Drip-proof equipment
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	CE Label	Indicates that the product complies with the requirements of the Medical Device Directive 93/42/EEC June 1993 or Medical Device Regulation MDR EU 2017/745. If applicable, the 4-digit Notified Body number is added near or below the CE symbol.
	Caution	Refer to accompanying documents for for warnings and precautions
	UL Label	Certifies that representative samples of the products have been investigated by UL in accordance with the referenced Standards. The products have been found to comply with the requirements covering the category.
	WEEE Disposal	European consumers are obliged by law to dispose Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive 2012/19/EU. For details, refer to chapter "Waste Disposal" in the Instruction Manual for the SDMS, HB-005771.

Table 4 SDM Symbols

4.1.4 Controls (Buttons)

The following controls (buttons) are located on the front panel of the SDM (4.1.1):

Button	Name	Function
	Menu/Previous Level Button	to activate the menu to return to the menu on the next higher level (only if 'editing mode' is inactive, exits the menu if pressed while at top level) to de-activate 'editing mode' for the selected menu-parameter* **Note:** Menu access can be disabled by the institution (4.7.4.1), e.g. for home use.
	UP Button	to select a menu item by scrolling the blue menu bar upwards through the menu (only if 'editing mode' is inactive) to increase the value of the menu parameter for which 'editing mode' is active* to increase the brightness (Table 48) of the display (only if a measurement screen is active – see 4.2.3)
	DOWN Button	to select a menu item by scrolling the blue menu bar downwards through the menu (only if 'editing mode' is inactive) to decrease the value of the menu parameter for which 'editing mode' is active* to decrease the brightness (Table 48) of the display (only if a measurement screen is active – see sub-section 4.2.3)
	AUDIO PAUSED/AUDIO OFF Button	to pause auditory alarm signals for 1 or 2 minutes (depending on respective menu setting) to switch OFF auditory alarm signals permanently (by pressing > 3 seconds). **Note**: switching off auditory alarm signals is only possible if enabled by institution (4.7.4.1). **Note**: This button is inactive if the menu parameter 'Alarm Settings/Alarm Volume' is set to OFF.
	ENTER Button	to activate the selected sub-menu or function to activate/de-activate 'editing mode' for the selected menu parameter* to activate Quick Access Menus (only if menu is not open, 4.2.5.2, 4.2.5.3) to terminate the 'Sensor off patient (↲)'**and 'Remote monitoring interrupted (↲)' alarm conditions (4.3.5) to activate the second 'System Information' page (Table 58, only if first 'System Information' page (Table 57) is open)
	Display Button	to cycle between the available measurement screens to de-activate 'editing mode' for the selected menu-parameter* to exit the menu from any menu level (only if 'editing mode' is inactive)

Table 5 Controls (Buttons)

* Changes made (by using the 'UP/DOWN Buttons') to those parameters that are highlighted with a **blue** menu bar in 'editing mode' (Table 20), become immediately effective (i.e. no confirmation is required). For parameters that are highlighted with a **yellow** menu bar in 'editing mode', changes must be confirmed by pressing the 'ENTER Button' before they become effective. To cancel changes/deactivate 'editing mode', use the 'Menu/Previous Level Button' or the 'Display Button'.
**will also reset the 'Site Timer' (4.8.4) and - if reduced by SITE PROTECTION (4.8.5) - reactivate sensor heating.

WARNING: Current values of monitored parameters and visual alarm signals may become illegible if the display brightness (Table 48) is reduced to a too low level.

WARNING: If an alarm condition occurs while the auditory alarm is paused or permanently switched off, the only alarm indication will be visual, and no alarm tone will sound.

WARNING: Do not disable the audible alarm function or decrease the audible alarm volume if the patient's safety could be compromised.

Note: The SDM's ON/OFF switch is located on the rear of the SDM (4.1.2).

Note: The nurse call function (5.4.2) is not active if the auditory alarm signals (4.4.3) of the SDM are paused or permanently switched off.

4.1.5 Visual LED Indicators

The following visual LED indicators are located on the front panel of the SDM (4.1.1):

LED	Color	Meaning
AUDIO PAUSED/AUDIO OFF Indicator 	yellow: flashes yellow: LED off:	Auditory alarm signals (4.4.3) paused for 1 or 2 minutes (Table 49) Auditory alarm signals permanently switched off (activated by pressing 'AUDIO PAUSED/AUDIO OFF Button' > 3 seconds) Auditory alarm signals either active or permanently switched off by setting menu parameter 'Alarm Volume' (Table 37, Table 49) to OFF.
ON/OFF Indicator 	green: LED off:	SDM turned ON SDM turned OFF
AC Power/Battery Indicator 	green: yellow: LED off:	Connected to AC power, battery fully charged Connected to AC power, battery charging Not connected to AC power (i.e. powered by internal battery) **Note**: The AC Power/Battery Indicator functions irrespective of the SDM being switched ON or OFF.

Table 6 Visual LED Indicators

Note: Additional visual indicators are provided in the Status Bar (Figure 8) as 'Status Icons' and 'Status Messages'.

4.1.6 Auditory Indicators/Signals

The following auditory indicators/signals are available on the SDM:

Function	Description
High Priority Alarm (4.4.1)	Alarm Melodies OFF: A high-pitched fast pulsing tone indicating a SpO2 limit violation (two bursts of five short pulses (1 triad and 1 dyad) repeated every 10 seconds). Alarm Melodies ON: Same time sequence as if Alarm Melodies disabled. For each of the two bursts - 'cba-gf' (major scale downwards) sounds for a SpO2 limit violation **Note:** The Responsible Organization can switch 'Alarm Melodies' ON or OFF (4.7.4.1). Use the menu parameter 'Alarm Volume' to adjust the volume of this signal (Table 37, Table 49).

Function	Description
Medium Priority Alarm (4.4.1)	Alarm Melodies OFF: A medium-pitched pulsing tone indicating 'Battery Critical' (only if SDM not connected to AC) or a PCO2, PO2, or PR limit violation (one burst of three pulses (1 triad) repeated every 10 seconds). Alarm Melodies ON: Same time sequence as if Alarm Melodies disabled. - 'Caf' (inverted major chord) sounds for a PCO2 limit violation - 'cba' (top of major scale downwards) sounds for a PO2 limit violation - 'Ceg' (major chord) sound for a PR limit violation - 'cCC' (octave downwards) sound for a Battery Critical Alarm (only if SDM not connected to AC power) **Note:** The Responsible Organization can switch 'Alarm Melodies' ON or OFF (4.7.4.1). Use the menu parameter 'Alarm Volume' to adjust the volume of this signal (Table 37, Table 49).
Low Priority Alarm (4.4.1)	Alarm Melodies OFF: A low-pitched slow pulsing tone indicating a system status that requires operator awareness (one burst of two pulses (1 dyad) repeated every 15 seconds). Alarm Melodies ON: Same time sequence as if Alarm Melodies disabled. For each of the two bursts. 'eC' (major third downwards) sounds for any cause. **Note:** The Responsible Organization can switch 'Alarm Melodies' ON or OFF (4.7.4.1). Use the menu parameter 'Alarm Volume' to adjust the volume of this signal (Table 37, Table 49).
AUDIO OFF Reminder	Signal tone (0.5 seconds) that sounds every 60 seconds if the auditory alarm signals have been switched OFF permanently (4.4.3). The volume of the 'AUDIO OFF Reminder' is not adjustable (either ON or OFF). **Note**: The AUDIO OFF Reminder is ON if the parameter 'AUDIO OFF Reminder selectable' is disabled (4.7.4.1).
Auditory Power-On Self-Test Signal	Auditory signal (three signal tones of 0.2 seconds) to test the SDM's loudspeaker during the Power-On Self-Test (4.6.2). Contact Sentec authorized service personnel or your local Sentec representative if this signal is not activated when switching-on the SDM. The volume of the 'Auditory Power-On Self-Test Signal' is not adjustable.
Ready for use Beep	Low-pitched signal tone (1 second) which sounds at the end of a successful calibration (4.9) of a Sentec TC Sensor. **Note:** The Responsible Organization can switch the 'Ready for use Beep' ON or OFF (4.7.4.1). Use the menu parameter 'Alarm Volume' to adjust the volume of this signal (Table 37, Table 49).
Key Click	A short signal tone (0.2 seconds) indicating that a button has been properly pressed. Use the menu parameter 'Key Click' to switch off/adjust the volume of this signal (Table 49).
Pulse Beep	Short signal tone (0.2 seconds) that sounds once for each pulse. Its automatic pitch modulation reflects changing SpO2 levels.

Function	Description
	Use the menu parameter 'Pulse Beep' to switch off/adjust the volume of this signal (Table 42, Table 49).
Button Disabled Beep	A long, low-pitched signal tone that sounds if a Control Button (4.1.4) is pressed that is currently disabled. This applies to - the menu button if 'Menu Access' has been disabled by the Responsible Organization (4.7.4.1) - all buttons except for the AUDIO PAUSED/AUDIO OFF Button if the 'V-CareNeT required' screen is displayed (4.13.3). The volume of the 'Button Disabled Beep' is not adjustable.
Sensitivity Test Signal	A high pitched two beep signal tone that sounds together with the 'Open DS door' or the 'Insert sensor into DS' message (4.3.5) during a PCO2 and/or PO2 sensitivity test (Table 40, Table 43). Use the menu parameter 'Alarm Volume' to adjust the volume of this signal (Table 37, Table 49). **Note:** This signal will sound even if auditory alarm signals are paused or permanently switched off.
V-Check Completed Beep	A high pitched two beep signal tone that sounds upon successful termination of a V-Check™ Measurement (4.13.2) and activation of the 'V-Check Results Screen' (Figure 15). Use the menu parameter 'Alarm Volume' to adjust the volume of this signal (Table 37, Table 49). **Note:** This signal will sound even if auditory alarm signals are paused or permanently switched off.
Volume Settings	Low-pitched signal tone (1 second) that indicates the selected volume while changing the 'Alarm Volume', 'Key Click Volume', or 'Pulse Beep Volume'.

Table 7 Auditory Indicators/Signals

Note: The SDM does not superpose auditory signals, i.e. it outputs only one acoustic signal at a time. The SDM ranks the output priority for auditory signals as follows (in decreasing order):

- High Priority Alarm
- Medium Priority Alarm
- Low Priority Alarm
- Information Signals: AUDIO OFF Reminder, Auditory Power-On Self-Test Signal, Ready for use Beep, 'Button Disabled Beep', 'Sensitivity Test Signal' and 'V-Check Completed Beep'
- Pulse Beep
- Key Click

An acoustic signal of higher priority is never interrupted by an acoustic signal of lower priority.

Unless inactivated by the operator, Medium Priority and Low Priority auditory alarm signals will complete at least one burst, and High Priority auditory alarm signals will complete at least half of one burst.

Unless inactivated by the operator, the auditory alarm signal corresponding to the currently displayed Alarm Status Icon (4.3.4) will sound.

4.2 Display screens

4.2.1 Types of Display Screens

Besides the 'Power-On Self-Test Screen' (4.2.2, 4.6) and 'Menu screens' (4.2.5), the SDM provides various preconfigured 'Measurement Screens' (4.2.3) as well as a 'Ready for use' and a 'Calibration' screen (4.2.4).

The following table summarizes which display type is active in which situation.

Sensor connected	'Measurement' screens active if ...	'Ready for use' screen active if ...	'Calibration' screen **active** if ...
Yes	'Sensor-On-Patient' or 'Sensor-Off-Patient' (not in 'Docking Station')	Sensor in 'Docking Station' and **Ready for use***	Sensor in 'Docking Station' and **sensor calibration in progress**
No	Always	Not Applicable	Not Applicable

Table 8 Types of Display Screens

*If the 'Ready for use' screen is active, the 'Status Bar' (Figure 8) activates in the bottom of the screen when the operator presses a Control Button (4.1.4) or an alarm condition occurs. If the alarm condition ceases or else 15 seconds after the operator pressed a button, the Status Bar deactivates.

4.2.2 Power-On Self-Test Screen

The 'Power-On Self-Test' screen appearsafter switching on the SDM.

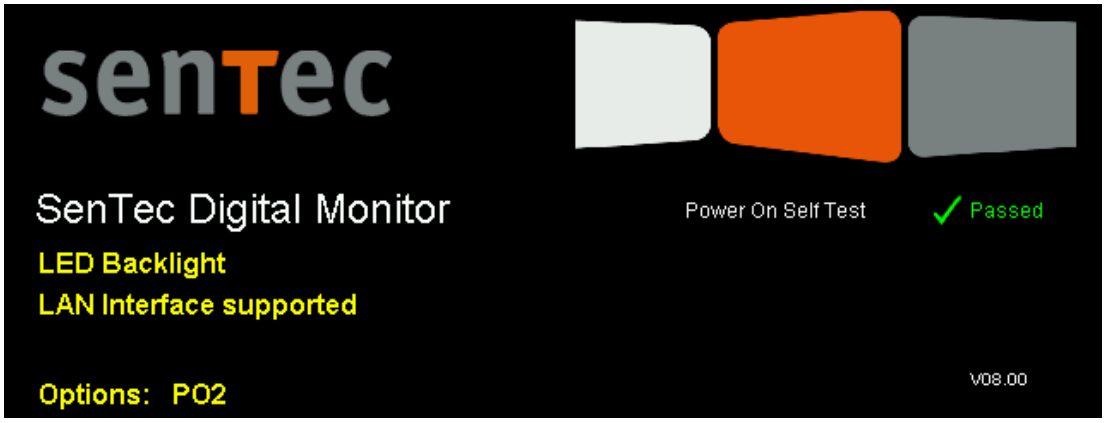


Figure 3 'Power-On Self-Test Screen'

The 'Power-On Self-Test' screen indicates the result ('Passed'/'Failed') of the 'Power-On Self-Test' (POST) (if 'failed', the corresponding error code is displayed (4.3.7, 4.6)). The SMB software version is indicated in the lower right.

Please contact your local Sentec representative for upgrade information if your monitor does not support the LAN Interface or if the display of your monitor does not use an LED Backlight.

If the SDM is operated on internal battery, the operating/monitoring time is significantly affected by the type of the SDM's display backlight (refer to 4.5.2).

The 'SDM-Options' indicator in the lower left indicates the SDM's software-configuration options. For an SDM with SMB-SW-V08.xx, the following four options are possible:

- 'nPO2' indicates that the PO2-option is not activated;
- 'PO2' indicates that the PO2-option is activated;
- 'VOM nPO2' indicates that 'V-CareNeT™ Only Mode' (VOM-option) (4.13.3) is activated and the PO2-option is not activated;

- 'VOM PO2' indicates that the VOM-option and the PO2-option are both activated.

Please contact your local Sentec representative for upgrade information if the PO2-option of your monitor is not activated and/or its VOM-option is activated.

4.2.3 Measurement Screens

4.2.3.1 Overview of all Preconfigured Measurement Screens

Depending on the type of the connected sensor (V-Sign™ Sensor 2 or OxiVenT™ Sensor), the selected patient type and the enabled parameters, different preconfigured measurement screens are available.

Connected Sensor Type	Selected Patient Type	Enabled Parameters	Available Measurement Screens
OxiVenT™ Sensor	'Adult'	PCO2 PO2 SpO2 PR *(only selectable if PO2-option is activated)*	Numerical (PCO2, PO2, SpO2, PR)
	'Adult' or 'Neonatal'	PCO2 PO2 *(only selectable if PO2-option is activated)* *2 Screens with RHP Trend only accessible if Heating Power Mode is set to 'relative'*	PCO2, PO2 Trends *(only in 'Adult Mode')* PCO2, PO2, RHP Trends Numerical (PCO2, PO2) PCO2, PO2 Trends with Δx-/baseline values PCO2, RHP Trends with Δx-/baseline values
OxiVenT™ Sensor or V-Sign™ Sensor 2	'Adult'	PCO2 SpO2 PR	PCO2, SpO2 Trends/Plethysmogram PCO2, SpO2, PR Trends Numerical (PCO2, SpO2, PR) PCO2, SpO2 Trends with Δx-/baseline values PCO2 Trend with Δx-/baseline values
	'Adult' or 'Neonatal'	PCO2 *Screen with RHP Trend only accessible if Heating Power Mode is set to 'relative'*	PCO2 Trend PCO2, RHP Trends PCO2 Trend with Δx-/baseline values PCO2, RHP Trends with Δx-/baseline values
	'Adult'	SpO2 PR	SpO2, PR Trends/Plethysmogram Numerical (SpO2, PR)

Table 9 Overview of available Measurement Screens

WARNING: In order to avoid erroneous readings and false alarms of SpO2 and PR, ensure that the neonatal mode is selected if a V-Sign™ Sensor 2 (VS-A/P/N) or OxiVenT™ Sensor (OV-A/P/N) is applied to neonatal patients. Ensure that for adult/pediatric patients SpO2 and PR are disabled if one of these sensors is applied to a site for which the measurement of SpO2 and PR is not defined (2.2, also refer to the SDMS Instruction Manual).

Note: Values of measured parameters are updated once per second. If a measurement parameter violates an alarm limit, the respective parameter flashes (with 1.4 Hz for SpO2, with 0.7 Hz for PCO2, PO2 and PR).

Note: If PCO2 values are in-vivo corrected, the 'PCO2 In-Vivo Correction' indicator ('IC-indicator') is displayed adjacent to the PCO2 label (IC=xx.x (if 'mmHg'); IC=x.xx (if 'kPa'), where xx.x/x.xx is the current offset, respectively; if additionally a fixed 'Severinghaus Correction' is used, the 'PCO2 In-vivo correction' offset is marked with an asterisk: e.g. 'IC=x.xx*'.).

Note: Blank spaces in the Online Trend indicate those time intervals during which values of a parameter were not available or were marked as unstable or invalid (4.2.3.8).

4.2.3.2 Preconfigured Measurement Screens for 'PCO2 PO2 SpO2 PR'

For the configuration summarized below in Table 10, one preconfigured measurement screen is available.

Note: Press the 'ENTER Button' to open a 'Quick Access Menu' (4.2.5.2) permitting to set a baseline, to set a RHP reference, to mark 'Operator Events' or to perform a 'PCO2 In-Vivo Correction'.

Note: If the display of the SDM is in Sleep Mode (4.2.6), the display is inactive (black). Press any of the Control Buttons (4.1.4) to activate the display.

Sensor type = OxiVenT™ Sensor / Selected Patient Type = Adult
Enabled Parameters = PCO2 PO2 SpO2 PR *(only selectable if SDM's PO2-option is activated)*

Measurement Screen	Description
Numerical (PCO2, PO2, SpO2, PR) 	Current values/alarm limits for PCO2, PO2, SpO2 and PR. Current value for PI. Blip bar reflecting relative pulse amplitude. Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, Heating Power (not displayed if 'Heating Power Mode' = OFF), AUDIO, Alarm.

Table 10 Measurement Screens for PCO2 PO2 SpO2 PR

4.2.3.3 Preconfigured Measurement Screens for 'PCO2 PO2'

For the configuration summarized below in Table 11, 5 preconfigured measurement screens are available. One screen is only available in 'Adult Mode' and two screens are only available if 'Heating Power Mode' is set to 'relative'.

Note: Use the Display Button (4.1.4) to cycle through the measurement screens. Press the 'ENTER Button' to open a 'Quick Access Menu' (4.2.5.2) permitting to set a baseline, to set a RHP reference, to mark 'Operator Events' or to perform a 'PCO2 In-Vivo Correction'.

Note: If the display of the SDM is in Sleep Mode (4.2.6), the display is inactive (black). Press any of the Control Buttons (4.1.4) to activate the display.

Sensor Type = OxiVenT™ Sensor / Selected Patient type = Adult or Neonatal
Enabled Parameters = PCO2 PO2 *(only selectable if SDM's PO2-option is activated)*

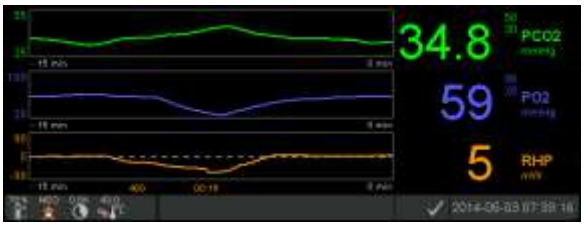
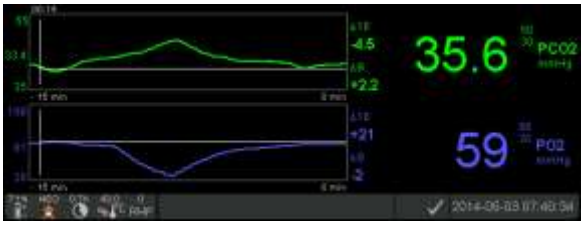
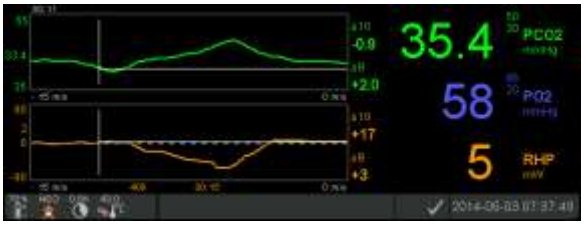
Measurement Screens	Description
PCO2, PO2 Trends 	Current values/alarm limits for PCO2, PO2. Current value for PI. Online Trends for PCO2 and PO2. Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, Heating Power (not displayed if 'Heating Power Mode' = OFF), AUDIO, Alarm. **Note:** Screen only available in Adulte mode.
PCO2, PO2, RHP Trends 	Current values/online trends for PCO2, PO2, RHP. Alarm limits for PCO2, PO2. Current value for PI (in Adult mode only). Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, AUDIO, Alarm. **Note**: Screen only available if 'Heating Power Mode' is set to 'relative'.
Numerical (PCO2, PO2) 	Current values/alarm limits for PCO2, PO2. Current value for PI (in Adult mode only). Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, Heating Power (not displayed if 'Heating Power Mode' = OFF), AUDIO, Alarm.
PCO2, PO2 Trends with Δx-/baseline values 	Current values/alarm limits for PCO2, PO2. Current value for PI (in Adult mode only). Online Trends with Δx-/baseline values (4.2.3.9) for PCO2 and PO2 Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, Heating Power (not displayed if 'Heating Power Mode' = OFF), AUDIO, Alarm.
PCO2, RHP Trends with Δx-/baseline values 	Current values for PCO2, PO2, RHP, PI (PI in Adult mode only). Alarm limits for PCO2, PO2. Online Trends with Δx-/baseline values (4.2.3.9) for PCO2 and RHP Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, AUDIO, Alarm. **Note**: Screen only available if 'Heating Power Mode' is set to 'relative'.

Table 11 Measurement Screens for PCO2 PO2

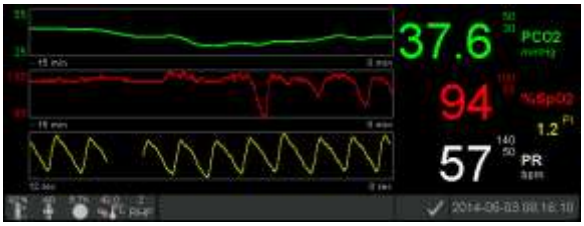
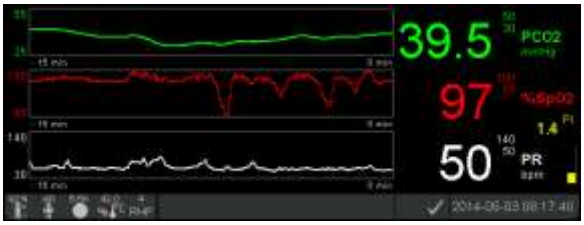
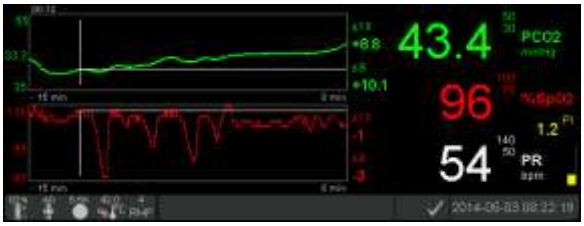
4.2.3.4 Preconfigured Measurement Screens for 'PCO2 SpO2 PR'

For the configuration summarized below in Table 12, five preconfigured measurement screens are available.

Note: Use the Display Button (4.1.4) to cycle through the measurement screens. Press the 'ENTER Button' to open a 'Quick Access Menu' (4.2.5.2), permitting to set a baseline, to set an RHP reference, to mark 'Operator Events' or to perform a 'PCO2 In-Vivo Correction'.

Note: If the display of the SDM is in Sleep Mode (4.2.6), the display is inactive (black). Press any of the Control Buttons (4.1.4) to activate the display.

Sensor type = V-Sign™ Sensor 2 or OxiVenT™ Sensor / Selected Patient type = Adult
Enabled Parameters = PCO2 SpO2 PR

Measurement Screens	Description
PCO2, SpO2 Trends/Plethysmogram 	Current values/alarm limits for PCO2, SpO2, PR. Current value for PI. Online Trends for PCO2, SpO2. 'Wiper bar' plethysmographic waveform reflecting relative pulse amplitude. Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, Heating Power (not displayed if 'Heating Power Mode' = OFF), AUDIO, Alarm.
PCO2, SpO2, PR Trends 	Current values/alarm limits for PCO2, SpO2, PR. Current value for PI. Online Trends for PCO2, SpO2, PR. Blip bar reflecting relative pulse amplitude. Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, Heating Power (not displayed if 'Heating Power Mode' = OFF), AUDIO, Alarm.
Numerical (PCO2, SpO2, PR) 	Current values/alarm limits for PCO2, SpO2, PR. Current value for PI. Blip bar reflecting relative pulse amplitude. Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, Heating Power (not displayed if 'Heating Power Mode' = OFF), AUDIO, Alarm.
PCO2, SpO2 Trends with Δx-/baseline values 	Current values/alarm limits for PCO2, SpO2, PR. Current value for PI. Blip bar reflecting relative pulse amplitude. Online Trends with Δx-/baseline values (4.2.3.9) for PCO2 and SpO2. Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, Heating Power (not displayed if 'Heating Power Mode' = OFF), AUDIO, Alarm.

Measurement Screens	Description
PCO2 Trend with Δx-/baseline values 	Current values/alarm limits for PCO2, SpO2, PR. Current value for PI. Blip bar reflecting relative pulse amplitude. Online Trend with Δx-/baseline values (4.2.3.9) for PCO2 Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, Heating Power (not displayed if 'Heating Power Mode' = OFF), AUDIO, Alarm.

Table 12 Measurement Screens for PCO2 SpO2 PR

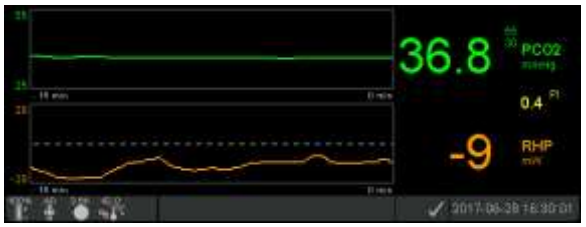
4.2.3.5 Preconfigured Measurement Screens for 'PCO2'

For the configuration summarized below in Table 13 3 preconfigured measurement screens are available. One screen is only available if 'Heating Power Mode' is set to 'relative'.

Note: Use the Display Button (4.1.4) to cycle through the measurement screens. Press the 'ENTER Button' to open a 'Quick Access Menu' (4.2.5.2), permitting to set a baseline, to set an RHP reference, to mark 'Operator Events' or to perform a 'PCO2 In-Vivo Correction'.

Note: If the display of the SDM is in Sleep Mode (4.2.6), the display is inactive (black). Press any of the Control Buttons (4.1.4) to activate the display.

Sensor type = V-Sign™ Sensor 2 or OxiVenT™ Sensor / Selected Patient type = Adult or Neonatal
Enabled Parameters = PCO2

Measurement Screens	Description
PCO2 Trend 	Current value/alarm limits for PCO2. Current value for PI (in Adult mode only). Online Trend for PCO2. Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, Heating Power (not displayed if 'Heating Power Mode' = OFF), AUDIO, Alarm.
PCO2, RHP Trends 	Current values for PCO2, RHP. Alarm limits for PCO2. Current value for PI (in Adult mode only). Online Trends for PCO2 and RHP. Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, AUDIO, Alarm. **Note**: Screen only available if 'Heating Power Mode' is set to 'relative'.

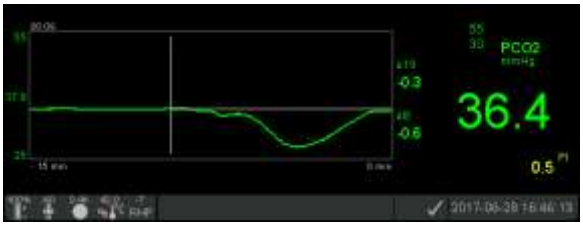
PCO2 Trend with Δx-/baseline values 	Current value/alarm limits for PCO2. Current value for PI (in Adult mode only). Online Trend with Δx-/baseline values (4.2.3.9) for PCO2 Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, Heating Power (not displayed if 'Heating Power Mode' = OFF), AUDIO, Alarm.
PCO2, RHP Trends with Δx-/baseline values 	Current values for PCO2, RHP. Alarm limits for PCO2. Current value for PI (in Adult mode only). Online Trends with Δx-/baseline values (4.2.3.9) for PCO2 and RHP. Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, AUDIO, Alarm. **Note**: Screen only available if 'Heating Power Mode' is set to 'relative'.

Table 13 Measurement Screens for PCO2

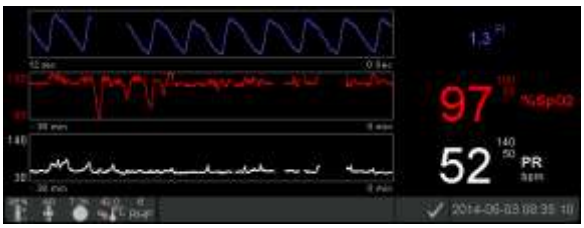
4.2.3.6 Preconfigured Measurement Screens for 'SpO2 PR'

For the configuration summarized below in Table 14, two preconfigured measurement screens are available.

Note: Use the Display Button (4.1.4) to switch between the measurement screens. Press the 'ENTER Button' to open a 'Quick Access Menu' (4.2.5.2), permitting to set a baseline, to set an RHP reference, to mark 'Operator Events' or to perform a 'PCO2 In-Vivo Correction'.

Note: If the display of the SDM is in Sleep Mode (4.2.6), the display is inactive (black). Press any of the Control Buttons (4.1.4) to activate the display.

Sensor type= V-Sign™ Sensor 2 or OxiVenT™ Sensor / Patient type = Adult
Enabled Parameters = SpO2 PR

Measurement Screens	Description
SpO2, PR Trends/Plethysmogramm 	Current values/alarm limits for SpO2, PR. Current value for PI. Online Trends for SpO2, PR. 'Wiper bar' plethysmographic waveform reflecting relative pulse amplitude. Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature*, Heating Power*, AUDIO, Alarm (*Icon not displayed if 'Heating Power Mode' = OFF)

Numerical (SpO2, PR) 	Current values/alarm limits for SpO2, PR. Current value for PI. Blip bar reflecting relative pulse amplitude. Status Bar (Figure 8) with Status Message and Status Icons for Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature*, Heating Power*, AUDIO, Alarm (*Icon not displayed if 'Heating Power Mode' = OFF)

Table 14 Measurement Screens for SpO2 PR

4.2.3.7 Adjustable Display Settings

The following display settings (4.7.4.1, 4.7.4.2) can be adjusted:

Element/Property	Description
Color for PCO2, PO2, SpO2, PR, PI, RHP	The colors for PCO2, PO2, SpO2, PR, PI, and RHP are operator-selectable (Table 48). Choose between red, green, white, blue, orange, yellow, fuchsia and cyan. **Note**: The 'Wiper bar' plethysmogram and the Blip bar reflecting relative pulse amplitude are displayed in the same color as the pulsation index (PI). **Note**: The IC-Indicator (4.11, 4.13.1) is displayed in the same color as PCO2. **Note**: If a parameter is flagged to be unstable (e.g. PCO2 during 'PCO2 stabilization'), the respective parameter is displayed in grey (4.2.3.8).
PCO2/PO2 Units	Units are selectable ('mmHg' or 'kPa') (Table 40, Table 43).
Online Trends – trend-range (y-axis)	The displayed trend-ranges (y-axis) for PCO2, PO2, SpO2, PR, and RHP are individually adjustable (Table 40, Table 43, Table 42, Table 39).
Online Trends – Time Range	The time range of the online trends is adjustable from 15 minutes to 48 hours (Table 38).
Plethysmogram – Time Range	The time range of the plethysmogram is selectable between 3 and 60 seconds (Table 42).
Delta-Time	The Delta-Time can be adjusted (4.2.3.9, 4.7.4.1).

Table 15 Adjustable elements/properties of Measurement Screens

4.2.3.8 Quality Indicators for measurement parameters

The software of the SDM continuously evaluates the quality of the measured data by assessing the severity of conditions presented to the SDMS. The results of this evaluation are used to display Status Messages (below) and/or quality indicators for the different parameters:

Quality	Indicator	Description
Valid	Parameter displayed in selected color.	The respective data are valid. While a parameter is marked as valid • respective online trend curve - if displayed - is updated • alarm surveillance for respective parameter is active
Question-able	Parameter displayed in selected color and '?' adjacent to parameter label.	The respective data are questionable, but still can be used for patient monitoring. While a parameter is marked as questionable • respective online trend curve - if displayed - is updated • alarm surveillance for respective parameter is active

Quality	Indicator	Description
Unstable	Parameter displayed in grey.	The respective data are unstable and likely do not reflect patient data. While a parameter is marked as unstable • respective online trend curve - if displayed - is updated with blank spaces • alarm surveillance for respective parameter is not active **Note**: As the course of the data of a parameter that is marked as unstable may provide helpful information the respective numerical value is displayed in grey (e.g. the course of PCO2 and/or PO2 values during 'TC-Stabilization' (2.4.3) provide helpful feedback on whether or not the sensor is properly applied).
Invalid	'---' replaces parameter. '---' is displayed in grey if 'Sensor-On-Patient' and in the color selected for respective parameter otherwise.	The respective data are invalid and do not reflect patient data. While a parameter is marked as invalid • respective online trend curve - if displayed – is updated with blank spaces • alarm surveillance for respective parameter is not active
'Disabled' or 'Not Available'	Parameter/Object removed from display or – if not removed – replaced by '-/-' in color selected for respective parameter.	If a parameter is 'Disabled' or 'Not Available' (e.g. PO2 is not available if a V-Sign™ Sensor 2 is connected to the SDM) the respective display elements (numeric value, online trend curve, icons) are removed from the measurement screens. If a parameter is not removed it is replaced by '-/-'.

Table 16 Quality Indicators for measurement parameters

4.2.3.9 Δx-values and baseline values

Certain preconfigured measurement screens provide online trends with Δx-values, baseline values and baselines for PCO2, PO2, SpO2 and/or RHP.

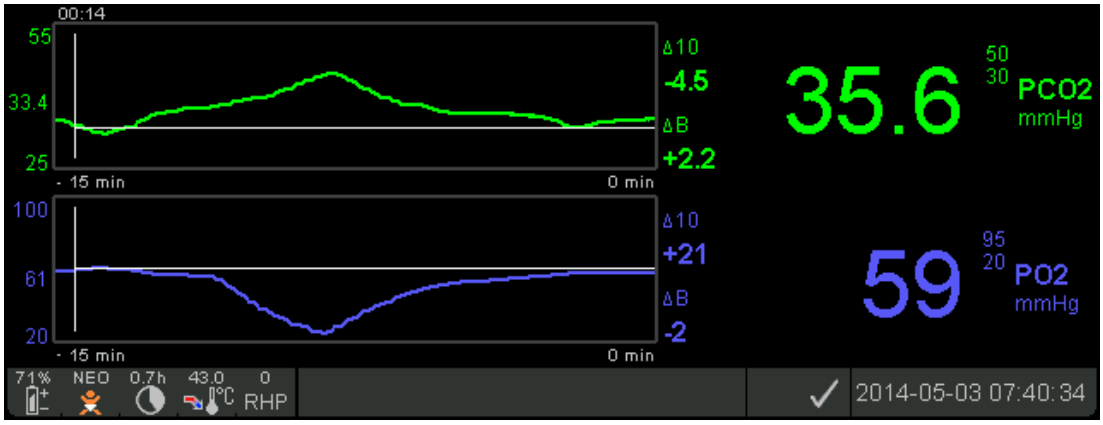


Figure 4 Example of a Measurement Screen with Δx-/baseline values

A parameter's 'Δx-value' is displayed to the right of its online trend and corresponds to the difference between its current reading and its reading x minutes ago. 'x' is called 'Delta-Time' and is adjustable in 1-minute steps between 1 and 120 minutes within a password-protected area of V-STATS™ (4.7.4.1) or remotely with V-CareNeT™. The default value for 'Delta-Time' is 10 minutes.

Example: A 'Δ10-value for PO2' of '+ 21 mmHg' indicates that the current PO2 reading is 21 mmHg higher than the PCO2 reading 10 minutes ago.

Important Note: The change of a parameter reading within a certain time ('Delta-Time') may indicate a gradual worsening of the patient's status. A 'Δ10-value for PCO2' of '+ 7 mmHg' or more in a patient receiving opioid analgesics and sedatives, for example, indicates opioid induced hypoventilation and, therefore, may allow early detection of a developing respiratory depression, especially in patients receiving supplemental oxygen.

During patient monitoring, a baseline can be set by using the respective function in the Quick Access Menu (4.2.5.2). The instant the baseline was set and the baseline itself are subsequently displayed graphically (vertical and horizontal white lines). A timer in the top left of the screen numerically indicates the elapsed time (hh:mm) since the baseline was set. A parameter's baseline is numerically indicated on the left and its ΔB-value, i.e. the difference between its current reading and its reading at the instant the baseline was set, on the right of its online trend.

Example: 'Baseline values for PCO2' of '33.4 + 2.2 mmHg (00:14)' indicate that the current PCO2 reading is 2.2 mmHg higher than the baseline of 33.4 mmHg which was set 14 minutes ago.

Important Note: To assess the possible impact of a change in patient treatment (e.g. changing ventilator settings, administration of drugs such as sedatives or opioids, changing supply of supplemental oxygen etc.) on the patient's ventilation and/or oxygenation, it is recommended to set a baseline just before changing the treatment.

Note: The quality of a parameter's Δx and/or ΔB values depends on the quality of the respective parameter's involved measurement values (4.2.3.8). No alarms are provided for Δx and ΔB values.

4.2.4 'Calibration' screen and 'Ready for use' screen

The 'Ready for use' or 'Calibration' screen appears if a Sentec TC Sensor is connected to the SDM and stored in the 'Docking Station'.

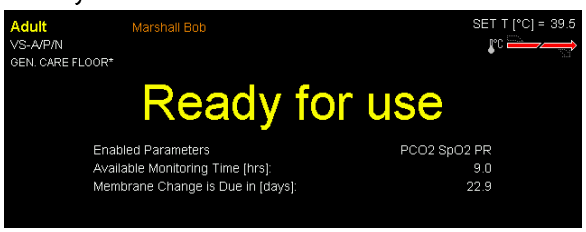
Screen	Description
'Ready for use' screen 	'Ready for use' is displayed in big yellow font in the center of the screen. **Important system information** (see below for description): 'Enabled Parameters', 'Available Monitoring Time', Membrane Change is Due in, 'Recommended Sensor Stabilization', Patient Type, Sensor Type, 'Current SDM Profile', 'Patient Info' (if remotely monitored with V-CareNeT™), Sensor Temperature, Special Temperature Settings, 'V-Check™ Mode Indicator' (Figure 5). **Note**: The 'Status Bar' (Figure 8) additionally appears if the operator presses any of the Control Buttons or if an alarm condition occurs (refer to 'Calibration' screen).
Note: The Responsible Organization has the possibility to enable the display of the 'PCO2 Calibration Curve' within a password protected area of V-STATS™ (4.7.4.1).	
'Calibration' screen (calibration curve disabled) 	'Calibration in progress', 'Leak test in progress', or 'Ready for use' displayed in yellow font in the center of the screen. **Important system information** (refer to 'Ready for use' screen and see below). Status Bar (Figure 8) with Status Message and Status Icons for Battery, Barometer*, Available Monitoring Time, Sensor Temperature, Gas*, AUDIO, Alarm. (*not displayed if PCO2 disabled or not available)
'Calibration' screen (calibration curve enabled) 	Current values for PCO2 and PO2 (the latter only for calibration of an OxiVenT™ Sensor) (**Note**: as the sensor is in the 'Docking Station' these are purely technical values, which do not represent patient data. The PCO2/PO2 values therefore are displayed in grey). 15-min PCO2/PO2 online trend ('Calibration Curve'). 'Patient Info' (if remotely monitored with V-CareNeT™). Status Bar (Figure 8) with Status Message and Status Icons for Battery, Barometer, Available Monitoring Time, Sensor Temperature, Gas, AUDIO, Alarm.

Table 17 'Ready for use' and 'Calibration' screen

Note: Press the 'ENTER Button' to open a 'Quick Access Menu' (4.2.5.3), permitting to activate additional calibrations, to access the sub-menu 'Profiles' or to (de)activate V-Check™ Mode.

Note: If the display of the SDM is in Sleep Mode (4.2.6), the display is inactive (black). Press any of the Control Buttons (4.1.4) to activate the display.

Important system information

In addition to the respective Status Message displayed in big yellow font, various indicators provide Important System Information on the 'Ready for use' screen and – if the calibration curve is disabled – the 'Calibration' screen.

The following information is displayed in the center of the screen:

Enabled Parameters: Indicates the currently enabled parameters. Ensure to select an option that is approved for the patient's age and the intended measurement site.

Note: Use the menu parameter 'Measurement Settings/Enabled Parameters' to change the enabled parameters (Table 38). The selectable options depend on the sensor type, the SDM's PO2 activation status and the selected patient type.

Available Monitoring Time [hrs]: Indicates the time available for patient monitoring, i.e. the time interval after removing the sensor from the 'Docking Station' or applying the sensor to the patient until the selected 'Site Time' (4.8.2) or – if PCO2 is enabled – the 'Calibration Interval' (4.9.4) will elapse (whichever will occur first).

Membrane Change is Due in [days]: Indicates the number of days left before next membrane change (4.10) is mandatory (only if PCO2 enabled).

Note: This information is duplicated in the sub-menu 'Membrane Change' (Table 45).

Recommended Sensor Stabilization [mins]: Indicates the recommended sensor stabilization duration in minutes. Only displayed if sensor stabilization is recommended and if the display of this message is enabled). For details, refer to sub-section 4.9.5.

Note: The Responsible Organization has the possibility to disable the display of this message within a password protected area of V-STATS™ (4.7.4.1).

The following information is displayed in the upper left of the screen:

Patient Type Indicator (yellow): Displays the current patient type ('Neonatal' or 'Adult'). We recommend selecting patient type 'Neonatal' for neonates and babies up to an age of 12 months after term birth. For adult and pediatric patients aged over 12 months, Sentec recommends patient type 'Adult'. (Also referred to as 'Neonatal Mode' or 'Adult Mode', respectively.)

'Patient Info' (orange): During remote monitoring with and if enabled within V-CareNeT™, the 'Patient Info' (the patient name, the patient number or a comment) displayed in the corresponding station's 'Remote Monitoring Window' is duplicated on the SDM.

Note: The 'Patient Info' is also duplicated in the SDM's main menu (Table 36) and - if no Status Message has to be displayed - in the SDM's status bar (Figure 8) enclosed in "["and"]".

Sensor Type Indicator: Displays the model/type of the currently connected sensor.

'Current SDM Profile' Indicator: Indicates the name of the currently selected 'Standard Profile', e.g. 'Sleep' (4.7.3). An asterisk ('*') appears behind the profile name (e.g. 'SLEEP*') if at least one setting of the selected 'Standard Profile' is modified (an example is shown in Figure 9). This indicator is only displayed in 'Institutional Mode' (4.7.3).

The following information is displayed in the upper right of the screen:

'Sensor Temperature' Indicator: Displays the currently selected 'Sensor Temperature' (Table 39). This indicator is only displayed if the connected sensor is heated.

WARNING: Sentec TC Sensors can be operated at temperatures above 41 °C. To minimize the risk of erythema (skin reddening) or burns, carefully read section 4.8.1 and the warnings therein.

'Special Temperature Settings' Indicator: Split-arrow indicating the current configuration of INITIAL HEATING (left part of arrow, 4.8.3, Table 39 – available in Adult Mode only) and SITE PROTECTION (right part of arrow, 4.8.5, Table 39 – available in Neonatal and Adult Mode). Note that this indicator is only displayed if the connected sensor is heated. The following table summarizes the possible configurations (T refers to the 'Sensor Temperature').

	SITE PROTECTION OFF (or ON and T ≤ 41.0 °C in Adult Mode/T ≤ 40.0 °C in Neonatal Mode)	SITE PROTECTION ON (if T > 41.0 °C in Adult Mode/T > 40.0 °C in Neonatal Mode)
INITIAL HEATING OFF (or ON and T=44.5 °C in Adult Mode)		
INITIAL HEATING ON (if T < 44.5 °C in Adult Mode)		

Table 18 **'Special Temperature Settings'** Indicator

V-Check Mode Indicator: If the V-Check™ Mode (4.13.2) is ON the 'V-Check™ Mode Indicator' (Figure 5) is displayed on the left of the 'Sensor Temperature Indicator' and of the 'Special Temperature Settings Indicator'.

Figure 5 **Ready for use screen with V-Check™ Mode Indicator**

4.2.5 Menu screens

The SDM's 'Main Menu' can be opened by pressing the 'Menu' button (4.1.4). It provides access to all sub-menus and all operator accessible menu parameters/functions (4.7.4.2). An example of a 'Menu screen' is provided in Table 19. Pressing the 'ENTER Button' (4.1.4) when the menu is not already open, furthermore, opens one of the two available 'Quick Access Menus' (Figure 6, Figure 7).

Note: Menu access can be disabled by the Responsible Organization within a password-protected area of V-STATS™ (4.7.4.1), e.g. for home use. If menu access is disabled, access to the 'Quick Access Menus' is still possible.

4.2.5.1 Example of a 'Menu screen'

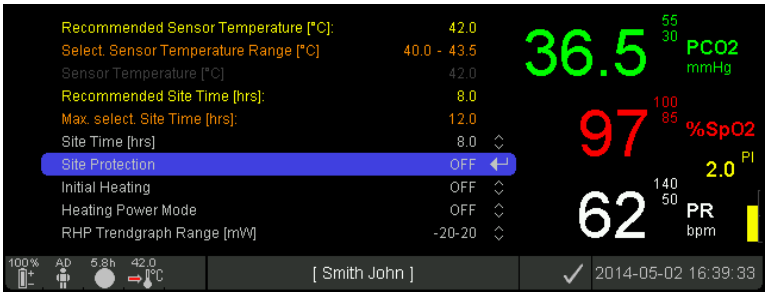
Screen	Description
Example of a Menu screen 	A blue (or yellow), underlying bar highlights the selected sub-menu, menu parameter or function. Current value/alarm limits of monitored parameters (except for PO2) are displayed on the right and the 'Status Bar' (Figure 8) with Status Message and Status Icons is located in the bottom.

Table 19 Example of a Menu screen

The navigation symbols to the right of each menu item are characterized as follows:

Symbol	Description
	Symbolizes 'Functions' or 'Sub-menu Accesses', which are currently not selected.
	Symbolizes 'Parameters', which are currently not selected.
 or 	Symbolize menu items ('Parameters', 'Functions', 'Sub-menu Accesses'), which are currently selected (highlighted by blue menu bar). Pressing the 'ENTER Button' will - activate 'editing mode' for the selected parameter - activate execution of the selected function - access the selected sub-menu
 or 	Symbolize 'Parameters' for which 'editing mode' is activated and, consequently, whose values can be changed with the 'UP/DOWN Buttons'. Changes made (by using the 'UP/DOWN Buttons') to those parameters that are highlighted with a **blue** menu bar in 'editing mode' become immediately effective (i.e. no confirmation is required). In this case, use the 'ENTER Button', the 'Menu/ Previous Level Button' or the 'Display Button' to deactivate 'editing mode'. For parameters which are highlighted with a yellow menu bar in 'editing mode', changes only become effective upon confirmation by pressing the 'ENTER Button'. In this case, use the 'Menu/Previous Level Button' or the 'Display Button' to cancel changes/ deactivate the 'editing mode'.

Table 20 Menu Navigation Symbols

Note: Operator-changeable parameters/functions (4.7.4.2) that are currently changeable/ accessible, are displayed in 'white', otherwise dimmed in 'grey'. Menu items shown in 'Orange' correspond to (safety relevant) parameters that are only changeable by the Responsible Organization (4.7.4.1). General information (e.g. recommendations) is displayed in 'Yellow'.

Note: Current PO2 values and, hence, related visual alarm signals (flashing parameter in the event of a PO2 limit violation) are not displayed on menu screens.

Note: Current values of all monitored parameters and, hence, related visual alarm signals (flashing parameter in the event of a limit violation) are not displayed in the sub-menu 'Review/Print Trend Data' (4.12.4, Table 56), the 'Review Trend Data Screen' (Figure 11), the 'Trend Data Statistics Screen' (Figure 12), and the 'V-Check Results Screen' (Figure 15).

Note: The Status Bar (Figure 8) and the visual alarm signals provided therein are not displayed on the 'Review Trend Data Screen' (Figure 11), the 'Trend Data Statistics Screen' (Figure 12), the 'V-Check Results Screen' (Figure 15) and the 'Ready for use' screen (4.2.4).

Note: If a menu screen or the 'Review Trend Data Screen' (Figure 11) is open during patient monitoring, the SDM will automatically return to the last active 'Measurement screen' if no button is pressed for two minutes. The 'Trend Data Statistics Screen' (Figure 12) and the 'V-Check Results Screen' (Figure 15), in contrast, will remain active in this situation.

Note: If the 'Ready for use' screen (4.2.4) is active, the 'Calibration' screen is activated when the operator presses any of the Control Buttons or if an alarm condition occurs.

4.2.5.2 'Quick Access Menu' when activated from a Measurement Screen

Pressing the 'ENTER Button' when a 'Measurement' screen is active opens the 'Quick Access Menu' shown in Figure 6, offering the possibility to set a baseline, to set an RHP reference, to mark 'Operator Events' or to perform a 'PCO2 In-Vivo Correction'.

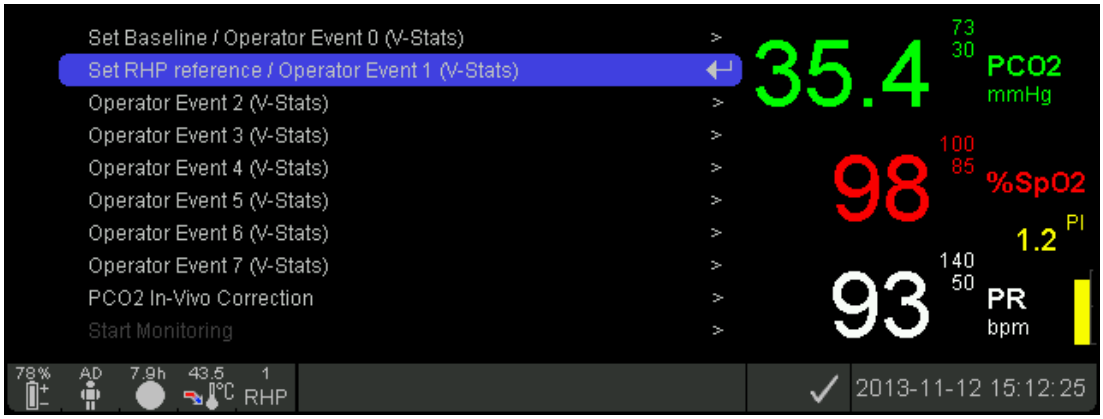


Figure 6 Quick Access Menu accessed from 'Measurement' screen

Menu Item **'Set Baseline/Operator Event 0 (V-STATS)'**: Pressing the ''ENTER Button' while this menu item is selected with the blue, underlying bar, stores an Operator Event 0 (status code E0) in the internal memory of the SDM and returns to the previously active measurement screen. Furthermore, this function sets a new baseline for PCO2, PO2, SpO2, and RHP (if enabled). The instant the baseline was set and the baseline itself are subsequently displayed graphically (vertical and horizontal white lines) on certain measurement screens (4.2.3.1, 4.2.3.2, 4.2.3.9, Figure 4).

Note: Operator Events are currently not visualized on the SDM. After downloading trend data with V-STATS™, they are visualized within V-STATS™ as colored triangles in the respective measurement curves.

Important Note: To assess the possible impact of a change in patient treatment (e.g. changing ventilator settings, administration of drugs such as sedatives or opioids, changing supply of supplemental oxygen etc.) on the patient's ventilation and/or oxygenation, it is recommended to set a baseline just before changing the treatment.

Note: The baseline is reset if the sensor is back in 'Docking Station' for more than 30 minutes, the SDM is turned off, the sensor is changed or the patient type is changed.

Note: If only 'SpO2 PR' are enabled, this function only stores an Operator Event 0 (status code E0) in the internal memory of the SDM.

Menu Item 'Set RHP reference**/Operator Event 1 (V-STATS)**': Pressing the 'ENTER Button' while this menu item is selected with the blue, underlying bar, stores an Operator Event 1 (status code E1) in the

internal memory of the SDM and returns to the previously active measurement screen. If the menu parameter 'Heating Power Mode' (Table 39) is set to 'relative' and the sensor is stabilized on the skin, this function will additionally set a new RHP-reference value (4.8.6).

Note: Operator Events are currently not visualized on the SDM. After downloading trend data with V-STATS™, they are visualized within V-STATS™ as colored triangles in the respective measurement curves.

Note: It is recommended to determine a new RHP-reference value after each sensor application and in particular when applying the sensor to a different measurement site.

Menu Items 'Operator Event x (V-STATS)': Pressing the 'ENTER Button' while one of these menu items is selected with the blue, underlying bar, stores the instant and type of the selected Operator Event x (status code Ex, x: 2-7) in the internal memory of the SDM and then returns to the previously active measurement screen.

Note: Operator Events are currently not visualized on the SDM. After downloading trend data with V-STATS™, they are visualized within V-STATS™ as colored triangles in the respective measurement curves.

Menu item 'PCO2 In-Vivo Correction': Pressing the 'ENTER Button' while this menu item is selected with the blue, underlying bar opens the sub-menu 'PCO2 In-Vivo Correction' (Table 41).

Note: The menu item 'PCO2 In-Vivo Correction' is not accessible (dimmed grey) if the use of 'PCO2 In-vivo Correction' (4.11) is disabled by the Responsible Organization, if PCO2 is disabled or if menu access is disabled.

Note: Access to the sub-menu 'PCO2 In-Vivo Correction' is also possible from the sub-menu 'PCO2 Settings' (Table 40).

Menu item 'Start Monitoring': Pressing the 'ENTER Button' while this menu item is selected with the blue, underlying bar activates the 'Enforced Sensor-On-Patient Mode' and starts 'Monitoring' (regardless whether or not the sensor is attached to the patient).

Note: To reset the SDM to 'Normal Sensor-On-Patient Mode', the sensor must be inserted into the 'Docking Station'.

Note: Correct sensor application provided, the SDM usually detects that the sensor was put on the patient and initiates monitoring for the enabled parameters. If the sensor is applied on a site approved for SpO2/PR monitoring (2.2), 'Sensor-On-Patient' is typically detected within a few seconds, otherwise within less than 2 minutes. When obtaining an adequate patient signal is difficult, it may be possible that the SDM is unable to automatically detect 'Sensor-On-Patient'. If in this case PCO2 is enabled, you may use the 'Start Monitoring' function to activate the 'Enforced Sensor-On-Patient Mode', bypassing standard 'Sensor-On-Patient' detection.

Note: The menu item 'Start Monitoring' is not accessible (dimmed grey) if PCO2 is disabled, if menu access is disabled or if monitoring is already in progress, i.e. 'Sensor-On-Patient'.

WARNING: If the 'Enforced Sensor-On-Patient Mode' is active, the SDM's 'Sensor-Off-Patient' detection is disabled, i.e. in this case no 'Sensor off patient (↲)' alarm (4.3.5) will be triggered. Instead, a 'Check Application' Alarm is triggered within two minutes if the sensor is dislodged or intentionally removed from the patient. If POX is enabled, SDM's algorithms typically will flag the PCO2 and PO2 readings as unstable (displayed in grey) and the SpO2 and PR readings as invalid (respective values replaced by '---', 4.2.3.8) within 15 seconds and within 30 seconds, the low priority alarm 'SpO2 signal quality' will sound (4.2.3.8, 4.3.5).

4.2.5.3 'Quick Access Menu' when activated from 'Ready for use' or 'Calibration' Screen

Pressing the 'ENTER Button' when a Sentec TC Sensor is in the 'Docking Station' and the 'Ready for use' or 'Calibration' Screen is active, opens the 'Quick Access Menu' shown in Figure 7, offering the possibility to activate additional calibrations, to access the sub-menu 'Profiles' (Figure 9, Table 50) or to (de)activate V-Check™ Mode (4.2.5.3).

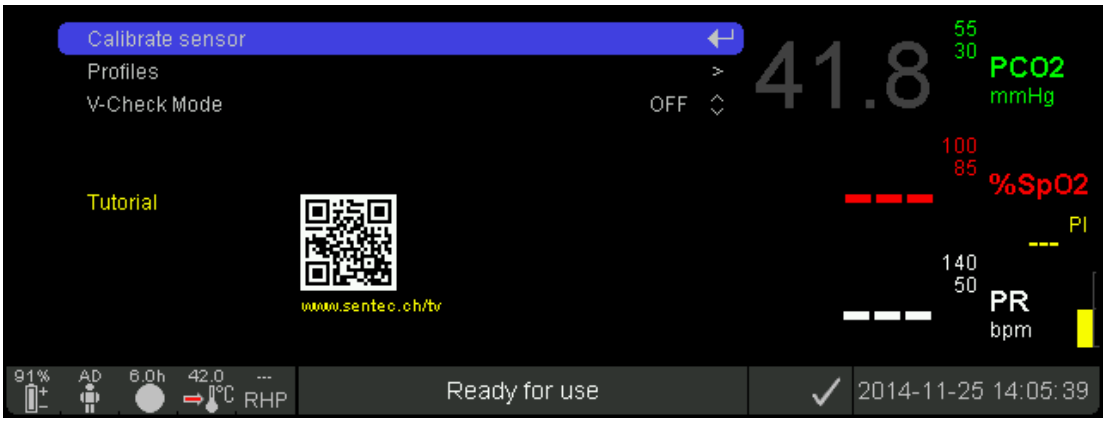


Figure 7 Quick Access Menu accessed from 'Ready for use' screen

Note: The QR-Code provided in the Quick Access Menu above and shown on the right links to SDMS related tutorials that are available for online viewing at www.sentec.com/tv/.

Menu item 'Calibrate Sensor': Pressing the 'ENTER Button' while this menu item is selected with the blue, underlying bar activates a sensor calibration (4.9).

Note: This menu item is dimmed grey (not accessible) if a calibration is in progress or currently not possible.

Note: The function 'Calibrate Sensor' is duplicated in the sub-menu 'PCO2 Settings' (Table 40).

Note: If enabled, PO2 is also calibrated during calibrations that are activated with the menu item 'Calibrate Sensor'.

Menu item 'Profiles': Pressing the 'ENTER Button' while this menu item is selected with the blue, underlying bar opens the sub-menu 'Profiles' (Figure 9, Table 50) where it is possible to restore the selected 'Standard Profile' (if modified) or select a different 'Standard Profile' (4.7).

Note: This menu item is only operable in 'Institutional Mode' (4.7.3).

Note: Access to the sub-menu 'Profiles' is also possible from the sub-menu 'System Settings' (Table 46).

Menu item 'V-Check Mode': This menu item permits to switch ON or OFF the V-Check™ Mode, the SDM Ventilation Spot Check Mode (4.13.2).

Note: This menu item is only accessible if use of V-Check™ Mode is enabled by the Responsible Organization (4.7.4.1). This menu item is not accessible if menu access is disabled.

Note: This parameter is duplicated in the sub-menu 'V-Check Settings' (Table 44).

4.2.6 Display in Sleep Mode

Light emitted by a display may disturb certain patients (e.g. during a sleep study) or - when interfacing the SDM with a patient monitoring system - duplication of the SDM's readings on the display of the patient monitoring system may be confusing for the clinician. The SDM therefore offers the possibility to deactivate the display (display black, back light switched off).

If the menu parameter 'System Settings/Display in Sleep Mode' (Table 46) is set to AUTO or ON, the display inactivates (display black, back light switched off) in the following situations, provided no alarm condition is present:

a) If the sensor is attached to a patient: 30 seconds after (both) TC-parameters have stabilized (2.4.3) or 30 seconds after 'Sensor-On-Patient' detection (if both TC-parameters are disabled or not available).

b) If the sensor is not attached to a patient: 15 seconds after the 'Ready for use' screen was activated.

In ON mode, the display reactivates only when the system detects an operator action (e.g. operator presses a Control Button or opens the 'Docking Station' door) or when the battery level is < 10% and the SDM is not connetcted to AC power. In AUTO mode, the display additionally and automatically reactivates when other alarm situations occur. The display will become inactivate once the above described inactivation conditions are present.

WARNING: If the display of the SDM is inactive when the parameter 'Display in Sleep Mode' is set to ON, the display will not reactivate if an alarm condition occurs. In this case, visual alarm signals are not visible.

Note: If the display of the SDM is inactive/blackened and the ON/OFF indicator lights green (4.1.1, 4.1.5), the display of the SDM is in Sleep Mode.

Note: A new, fully charged battery provides at least 6 hours (if Sleep Mode=OFF or Auto) and up to 13 hours (if Sleep Mode=ON) of operating/monitoring time, depending on the SDM's display type. As an example, for an SDM with an LED Backlight display, a new, fully charged battery will provide up to 10 hours of monitoring time if Sleep Mode=OFF or Auto, and up to 12 hours of monitoring time if Sleep Mode=ON.

Note: The display type of the respective SDM is displayed on the POST screen (Figure 3) and in the sub-menu 'System Settings/Display Settings' (Table 48).

Note: If AC power is not available for a prolonged or unknown period of time, we suggest operating the display of the SDM in Sleep Mode.

Note: If the 'Demo Mode' (4.13.4) is activated, the menu item 'Display in Sleep Mode' is set to OFF (i.e. the Sleep Mode deactivates (if active) and is not accessible (dimmed gray)). After deactivation of the 'Demo Mode', the previous setting of the menu item 'Display in Sleep Mode' is restored.

4.3 Status Bar

4.3.1 Status Bar Overview

The Status Bar (Figure 8) is located at the bottom of all 'Measurement' screens (4.2.3), of all 'Menu' screens (4.2.5) and of the 'Calibration' screen (4.2.4).

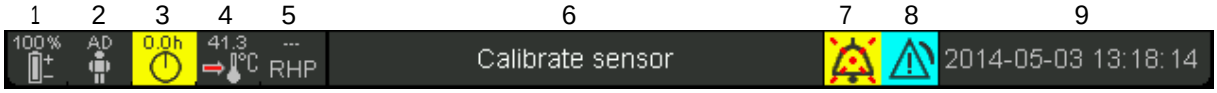


Figure 8 The Status Bar

On the left, it displays up to 5 Status Icons (1 to 5) (4.3.2), the Status Text Field (6) in the middle displays Status Messages (alarm/information messages, 4.3.5). If there is no current Status Message , the name of the currently active menu is displayed in the Status Text Field of menu screens and - during remote monitoring with and if enabled within V-CareNeT™ - the `Patient Info' is displayed in the Status Text Field of measurement screens. Otherwise, the Status Text Field is empty. The Status Text Field is followed by the AUDIO Status Icon (7, 4.3.3) and the Alarm Status Icon (8, 4.3.4). On the very right (9), the Status Bar usually indicates the monitor's date/time in the "yyyy-mm-dd hh:mm:ss" format. On measurement screens (4.2.3), the date/time indication is replaced by the V-Check™ Down-Counter (format hh:mm:ss) in V-Check™ Mode (4.13.2). This down-counter indicates the duration of the 'V-Check™ Measurement' if the V-Check™ Measurement has not yet been started, the remaining time to finish the V-Check™ Measurement during an ongoing V-Check™ Measurement, and 00:00:00 once the V-Check™ Measurement is finished. If the SDMS is not ready for use, it indicates --:--:--.

Note: The Status Bar and, hence, the visual alarm signals provided therein, is not displayed on the 'Review Trend Data Screen' (Figure 11), the 'Trend Data Statistics Screen' (Figure 12), the 'V-Check Results Screen' (Figure 15) and the 'Ready for use' screen (4.2.4).

Note: If the 'Review Trend Data Screen' (Figure 11) is open during patient monitoring, the SDM will automatically return to the last active 'Measurement screen' if no button is pressed for 2

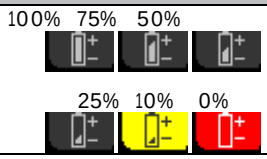
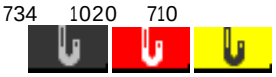
minutes. The 'Trend Data Statistics Screen' (Figure 12) and the 'V-Check Results Screen' (Figure 15), in contrast, will remain active in this situation.

Note: If the 'Ready for use' (4.2.4) screen is active, the 'Calibration' screen appears if the operator presses any of the Control Buttons or if an alarm condition occurs.

Note: During remote monitoring with and if enabled within V-CareNeT™, the 'Patient Info' (the patient name, patient number or a comment) displayed in the corresponding station's 'Remote Monitoring Window' is duplicated on the 'Ready for use/Calibration' screen (4.2.4), in the SDM main menu (Table 36) or in the status bar of measurement screens (4.2.3).

4.3.2 Status Icons

On the left side of the Status Bar (Figure 8), the following five Status Icons are displayed:

Description	**Status Icons** (from left to right)
1) Battery: Icon indicates the remaining battery capacity (%). The icon is highlighted yellow when battery capacity is below 10% and red if the remaining battery capacity is critical. (Format: xxx%)	
On measurement and menu screens (4.2.3, 4.2.5) 2a) Patient Type: Indicates the current patient type. The icon is displayed 'AD' for adult/pediatric patients and 'NEO' for neonatal patients. On 'Calibration screen' (4.2.4) 2b) Barometric Pressure: Indicates the measured ambient barometric pressure ('mmHg' or 'kPa', depending on the menu parameter 'PCO2 unit'). The icon is highlighted red if a barometer fault is detected and yellow if the barometric pressure is unstable during sensor calibration. (Format: xxx if 'mmHg'; xx.x if 'kPa') **Note:** Check the barometer of the SDM system against a calibrated barometer monthly.	 
3) Remaining Monitoring Time: Indicates the remaining monitoring time in hours until the 'Site Time' (4.8.2) will elapse or – if PCO2 is enabled – until a calibration is recommended (whichever occurs first) on measurement and menus screens. The pie chart – which is updated in steps of 20% - indicates the remaining monitoring time in percentage. (Format: xx.xh) When the 'Calibration Interval' elapses while the Remaining Site Time is > 0, the icon is highlighted yellow. The message 'Sensor calibration recommended' or 'Calibrate sensor' together with a low priority alarm is initiated depending on measurement duration or other factors (4.9.2, 4.9.4). When the 'Site Time' has elapsed, the icon is highlighted red, a low priority alarm is triggered ('Site time elapsed') and the sensor must be removed from the patient for site inspection. **Note**: To terminate the 'Site time elapsed' alarm, remove the sensor from the patient and press the 'ENTER Button' when the message 'Sensor off patient (↲)' is displayed or insert the sensor into the 'Docking Station'. Do not reapply the sensor to the same application site without prior inspection of the site. **Note**: On the 'Calibration Screen', the same icon indicates the 'Available Monitoring Time'.	 

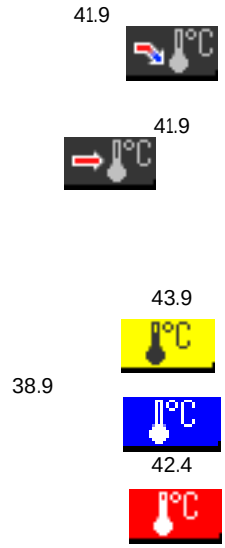
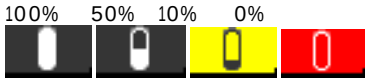
Description	Status Icons (from left to right)
4) Sensor Temperature: Indicates the measured sensor temperature (°C) and the current setting of SITE PROTECTION. (Format: xx.x °C) If SITE PROTECTION (4.8.5) is - **ON** a 'red-blue rightward arrow with tip down' appears to indicate that the sensor temperature will be reduced once the sensor application duration has overrun the selected 'Site Time' by more than 10% or 30 minutes. - **OFF** a 'red rightward arrow' appears to indicate that the sensor temperature will be maintained once the site time has elapsed. The icon is highlighted - yellow if the sensor temperature is temporarily increased after sensor application when INITIAL HEATING (4.8.3) is active - blue if the sensor temperature is reduced once the sensor application duration has overrun the selected 'Site Time' by more than 10% or 30 minutes when SITE PROTECTION (4.8.5) is active. - red if the temperature surveillance of the SDMS detects a sensor temperature-related problem.	
On measurement and menu screens (4.2.3, 4.2.5) **5a) Heating Power:** Indicates the measured electrical power in mW needed to heat a sensor to a constant temperature (2.4.7 , 4.8.6). Depending on the selected 'Heating Power Mode' (Table 39), the absolute heating power (AHP) or the relative heating power (RHP) is displayed (Format: xxx if AHP; ±xxx if RHP; '-/-' is displayed for RHP if no reference value is available. '---' is displayed for RHP if SITE PROTECTION reduces the sensor temperature or if the sensor is OFF Patient). **Note**: The 'Heating Power Icon' appears only if the menu parameter 'Heating Power Mode' is set to 'AHP' or 'RHP' and if the Sentec TC Sensor is outside the 'Docking Station'. On measurement screens with 'RHP Online Trends' (Figure 10), the 'Heating Power Icon' is not displayed. On 'Calibration screen' (4.2.4) **5b) Gas:** Indicates the remaining capacity of the Service Gas Bottle (%). The 'Gas Icon' is highlighted yellow if the remaining capacity is < 10% and red if the gas bottle is empty. (Format: xxx%)	 

Table 21 Description and states of the Status Icons

4.3.3 AUDIO Status Icon

In the Status Bar (Figure 7), the AUDIO Status Icon is located to the right of the 'Status Message'. It indicates the status of auditory alarm signals (4.1.6, 4.4.3).

Description	AUDIO Status Icon
Auditory alarm signals ON: If the auditory alarm signals are ON, the icon is not displayed.	

Description	AUDIO Status Icon
Auditory alarm signals PAUSED: The symbol 'Bell cancel' (with a negation cross of broken lines) appears if auditory alarm signals are paused for 1 or 2 minutes (**Note**: in this situation, the AUDIO PAUSED/AUDIO OFF Indicator lights yellow).	
Auditory alarm signals permanently OFF: The symbol 'Bell cancel' (with a negation cross of solid lines) is displayed if auditory alarm signals are permanently switched off. **Note**: If the auditory alarm signals have been switched off by pressing the AUDIO PAUSED/AUDIO OFF Button > 3 seconds, the 'AUDIO PAUSED/AUDIO OFF Indicator' additionally flashes yellow (4.1.1, 4.1.5).	

Table 22 Description and states of the AUDIO Status Icon

4.3.4 Alarm Status Icon

The 'Alarm Status Icon' in the Status Bar (Figure 8) meets the requirements of IEC 60601-1-8 (Table 2) and indicates the priority of the highest priority alarm condition. If two or more alarm conditions occur at the same time, it indicates the highest currently active alarm priority.

Description	Alarm Status Icon
High Priority Alarm Condition: White triangle with curved line and exclamation mark on red background (flashing with 1.4 Hz).	
Medium Priority Alarm Condition: Black triangle with curved line and exclamation mark on yellow background (flashing with 0.7 Hz).	
Low Priority Alarm Condition: Black triangle with curved line and exclamation mark on cyan background (constantly on).	
No Alarm Condition present: Light grey check mark symbol on dark-grey background (constantly on).	

Table 23 Description and states of the Alarm Status Icon

Note: Unless inactivated by the operator, the auditory alarm signal (4.1.6) corresponding to the currently displayed Alarm Status Icon will sound.

4.3.5 Status Messages/Status Codes

The Status Text Field in the middle of the Status Bar (Figure 6) displays Status Messages (alarm/information messages). If no current Status Message is displayed, the name of the currently active menu is displayed in the Status Text Field of menu screens and - during remote monitoring with and if enabled within V-CareNeT™ - the `Patient Info' is displayed in the Status Text Field of measurement screens. Otherwise, the Status Text Field is empty. Only one Status Message can be displayed at a time. In case two or more alarm conditions/system information of equal priority occur concurrently, the SDM internally ranks the display priority of the possible Status Messages and displays the Status Message corresponding to the alarm condition/system information with the highest internal rank. The Status Codes, which are output in the Status Column of SentecLink's Online data output (5.2.2), make use of the same internal ranking.

Note: In some cases, a Status Code is output without a corresponding Status Message.

Note: If a measurement parameter violates an alarm limit, neither a Status Message nor a Status Code is output. Instead, the respective parameter flashes with 1.4 Hz for SpO2 and with 0.7 Hz for PCO2 or PR, respectively. A plus sign ('+')/minus sign ('-') behind a measured value in SentecLink's Online data output indicates that the high/low alarm limit of the respective parameter has been violated.

Note: Status Codes, alarm limit violations, important settings (e.g. settings for 'Sensor Temperature', 'SpO2 averaging', 'PCO2 In-Vivo Correction' Offset (4.11)) as well as monitor and sensor specific information (serial numbers, software versions) are stored in the internal memory of the SDM together with the measured parameters (PCO2, PO2, SpO2, PR, HP, PI) and are available when downloading Trend Data with V-STATS™ (4.4, 4.12).

The following Table lists all Status Messages in alphabetical order along with the corresponding Status codes. Status Codes without a corresponding Status Messages are provided at the end of the table.

Status Message	Status Code	Type	Description
Atm. P. unstable	AU	Information	During an ongoing sensor calibration the SDM detects that the atmospheric pressure is unstable and aborts the ongoing sensor calibration (4.9.7). As soon as the atmospheric pressure is restabilized, this alarm ceases and sensor calibration starts automatically. This message also ceases if the sensor is removed from the 'Docking Station'. **Note**: This message only appears if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note**: The 'Barometer Icon' (4.3.2) is highlighted yellow if the atmospheric pressure is unstable. **Note**: Refer to troubleshooting P0408 (see Service Manual for the SDMS).
Barometer fault	BF	Low Priority Alarm	The SDM detects a barometer fault (pressure readings fluctuating implausibly fast or pressure readings out of range). Sensor calibration will not be initiated or a calibration in progress will be aborted (4.9.7). The alarm ceases if the sensor is removed from the 'Docking Station'. **Note**: This message only appears if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note:** The 'Barometer Icon' (4.3.2) is highlighted red in this case. **Note**: Refer to troubleshooting P0408 (see Service Manual for the SDMS).
Barometer fault (technical)	BFt	Low Priority Alarm	The SDM detects a technical barometer fault (chip readout failed). Sensor calibration will not be initiated or a calibration in progress will be aborted (4.9.7). To reset the fault condition, the operator must power cycle the SDM, i.e. switch the SDM off and then restart it. If the fault reappears after power cycle then please contact qualified service personnel. **Note**: This message only appears if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note:** The 'Barometer Icon' (4.3.2) is not highlighted in this case. **Note**: Refer to troubleshooting P0408 (see Service Manual for the SDMS).
Battery critical (**not** connected to AC power)	BC	Medium Priority Alarm	The remaining battery capacity is below a critical value and the monitor is **not** connected to AC power. If the SDM is not re-connected to AC power, 3 or less minutes remain until the SDM shuts down (4.5.2).

Status Message	Status Code	Type	Description
			Note: The 'Battery Icon' (4.3.2) is highlighted red if the remaining battery capacity is critical.
Battery critical (connected to AC power)	BCc	Information	The remaining battery capacity is below a critical value and the monitor is connected to AC power. If the SDM is disconnected from AC power, 3 or less minutes will remain until the SDM shuts down (4.5.2). **Note:** The 'Battery Icon' (4.3.2) is highlighted red if the remaining battery capacity is critical.
Battery low	LB	Low Priority Alarm	The remaining battery capacity is below 10% and the SDM is **not** connected to AC power (4.5.2). **Note:** The 'Battery Icon' (4.3.2) is highlighted yellow if the remaining battery capacity is below 10% irrespective of whether the SDM is connected to AC power or not.
Calibration in progress	SC	Information	Sensor calibration in progress (4.9.3). **Note**: This message only appears if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note:** If the 'Calibration Interval' has elapsed prior to (or during) the ongoing calibration, the 'Remaining Monitoring Time Icon' (4.3.2) remains highlighted yellow until successful termination of the ongoing calibration.
Calibrate sensor	CSi	Low Priority Alarm	An event triggering a so-called 'Initial Calibration' (Table 65) occurred and sensor calibration (4.9) therefore is **mandatory**. Insert the sensor into the 'Docking Station'. Calibration will start automatically. **Note**: This message only appears if PCO2 is enabled and the sensor is outside the 'Docking Station'. **Note:** After an event that triggers a so-called 'Initial Calibration', PCO2 and – if enabled – PO2 are marked as invalid (4.2.3.8). **Note:** Unless the 'Site Time' (4.8.4) has expired, the 'Remaining Monitoring Time' icon (4.3.2) is highlighted yellow if a calibration is requested. **Note:** If the Status Code 'CSi' is output while the sensor is in the 'Docking Station', the sensor is not (yet) calibrated.
Calibrate sensor	CSo	Low Priority Alarm	This message may appear if the PO2 channel has not been in use for a prolonged time while the PCO2 channel was active. The PO2 channel therefore requires **mandatory** calibration (4.9). Insert the sensor into the 'Docking Station'. Calibration will start automatically. **Note**: This message only appears if PO2 is enabled and the sensor is outside the 'Docking Station'. **Note:** PO2 is marked as invalid (4.2.3.8). **Note:** Unless the 'Site Time' (4.8.4) has expired, the 'Remaining Monitoring Time' icon (4.3.2) is highlighted yellow if a calibration is requested. **Note:** If the Status Code 'CSo' is output while the sensor is in the 'Docking Station', the sensor is not (yet) calibrated.

Status Message	Status Code	Type	Description
Change sensor membrane	RS	Low Priority Alarm	Change of the sensor membrane is required (4.10.2). Change the sensor membrane. **Note**: This message only appears if PCO2 is enabled. **Note:** PCO2 is marked as invalid (4.2.3.8) if a change of the sensor membrane is required. **Note:** The alarm condition ceases if you confirm the membrane change on the monitor (4.10.3).
Check sensor application	CA	Low Priority Alarm	This message is displayed if PCO2 and/or PO2 readings do not stabilize within 10 minutes after sensor application or after detection of a 'TC-Artifact' (2.4.3). The adequacy of the sensor application must be verified. Adjust the sensor application if necessary. This alarm ceases as soon PCO2 and/or PO2 readings stabilize. **Note**: This message only appears if PCO2 or PO2 is enabled and the 'Sensor-On-Patient' is detected. **Note:** PCO2 and/or PO2 are marked as unstable (4.2.3.8) in this situation. **Note:** This message will also appear if the sensor temperature deviates by more than 2 °C from the Sensor Temperature for more than 10 minutes. **Note:** This message will also appear if the 'Enforced Sensor-On-Patient Mode' is active and PCO2 is below 24mmHg cutaneous after a stable reading was detected. **Note**: Refer to troubleshooting P0100, P0103 (see Service Manual for the SDMS).
Connect sensor	CoS	Low Priority Alarm	No sensor connected to the SDM, the cable of the connected sensor or of the adapter cable used to connect the sensor is defective, or the connected sensor is not compatible with the SDM. **Note**: Also see message 'Incompatible sensor'. **Note**: Refer to troubleshooting P0300, P0301 (see Service Manual for the SDMS).
'DEMO MODE'	DM	Information	The SDM is operated in the 'Demo Mode' (4.13.4).
'Docking Station' fault	DFxx	Low Priority Alarm	The monitor surveillance has detected a 'Docking Station' fault. **Note**: This message only appears if PCO2 is enabled and the sensor is in the 'Docking Station'. 'xx', the number of the specific 'Docking Station' fault (4.3.8), is only indicated in the Status Code but not in the Status Message. **Note**: Sensor calibration will not be initiated or a calibration in progress will be aborted (4.9.7). As soon as the problem is resolved, this alarm ceases and a sensor calibration will start automatically. The alarm also ceases if the sensor is removed from the 'Docking Station'. **Note**: Refer to troubleshooting P0501 (see Service Manual for the SDMS).
Extended Calibration	EC	Information	An extended sensor calibration is in progress after the regular sensor calibration (4.9) was not successful within 14 minutes due to fluctuating PCO2 readings during the calibration (this can be the case if the sensor was not used for a longer period).

Status Message	Status Code	Type	Description
			Note: This message is only displayed if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note**: After successful completion of an 'Extended Calibration', the message 'Ready for use' is displayed. 'PCO2 slow' is displayed if the duration of the 'Extended Calibration' lasted 14 minutes and 'Sensor problem 14' (4.3.6) if the 'Extended calibration' could not be terminated successfully within 14 minutes.
Gas bottle empty	GE	Low Priority Alarm	Indicates that the gas bottle is empty or no gas bottle is in place. In the 'Gas Bottle Empty' status a calibration cannot be initiated (4.9.7). **Note**: This message only appears f PCO2 is enabled and the sensor is in the 'Docking Station'. **Note:** The 'Gas Icon' (4.3.2) is highlighted red if the gas bottle is empty and yellow if the remaining capacity is < 10%.
Gas leak in DS	GL	Low Priority Alarm	The SDM has detected a 'Docking Station' gas leak. An 'Initial Calibration' (Table 65) is requested when the sensor is removed from the 'Docking Station' and PCO2/PO2 values will be marked as invalid (4.2.3.8) until successful termination of the next sensor calibration/mandatory leak test. **Note**: This message only appears if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note**: If a gas leak was detected, the next sensor calibration will be followed by a mandatory leak test (see message 'Leak test in progress'). **Note**: Refer to troubleshooting P0502 (see Service Manual for the SDMS).
Heating reduced	HR	Low Priority Alarm	As a safety precaution, the sensor temperature has been reduced by SITE PROTECTION as the sensor application duration has overrun the selected 'Site Time' by more than 10% or 30 minutes (4.8.5). To reactivate normal sensor heating, remove the sensor from the patient and press the 'ENTER Button' when the message 'Sensor off patient (↲)' appears or insert the sensor into the 'Docking Station'. This will also reset the Site Timer (4.8.4). **Note:** The 'Temperature Icon' (4.3.2) is highlighted blue if heating is reduced. **Note**: This message only appears if the sensor is on the patient. **Note:** PCO2/PO2 is marked as invalid (4.2.3.8) if heating is reduced.
High ambient light	HA	Information	This message is displayed whenever the SDM's oximetry channel detects a high ambient light level independently from its severity or the impact on the SpO2, PR, or PI values (2.4.5). Shield the sensor from ambient light if this message appears. This message ceases as soon as the ambient light level is within a predefined range. **Note**: This message only appears if SpO2/PR are enabled and 'Sensor-On-Patient' is detected. **Note:** SpO2, PR, and PI are marked as questionable (4.2.3.8) when high ambient light levels are detected.

Status Message	Status Code	Type	Description
High ambient light	SA	Information / Low Priority Alarm	This message is displayed whenever the SDM's PO2 channel detects a high ambient light level independently from its severity or the impact on the PO2 values (2.4.2). Shield the sensor from ambient light if this message appears. This message ceases as soon as the ambient light level is within a predefined range. **Note**: This message only appears if PO2 is enabled and 'Sensor-On-Patient' is detected. **Note:** PO2 is marked as questionable (4.2.3.8) when high ambient light levels are detected. If the ambient light level is too high, PO2 is marked invalid (4.2.3.8) accompanied by a low priority alarm.
Incompatible sensor	IS	Low Priority Alarm	The connected sensor is not compatible with the SDM, its software version is not compatible with the SDM's MPB software version, or the Sentec Identification Code stored in its memory is not readable or corrupt. **Note**: SDM software versions SMB SW-V08.00 and later discontinue support of i) V-Sign™ Sensor (model VS-A/P), the predecessor of V-Sign™ Sensor 2 (model VS-A/P/N) and ii) the SpO2 Adapter Cable (model SC-150) and, hence, the SpO2 Soft Sensor (model RSS-M). If a V-Sign™ Sensor (model VS-A/P) or a SpO2 Adapter Cable (with or without SpO2 Soft Sensor) is connected to an SDM with software version SMB SW-V08.00 or later, the message 'Incompatible sensor' is displayed. **Note**: To clear this message, a power cycle of the SDM is required.
Insert sensor into DS	IDs	Information	This message appears during an operator-initiated PCO2 and/or PO2 sensitivity test (4.9.7, Table 40, Table 43) at an intermediate step, when the operator is requested to place the sensor into the DS again. The message is accompanied by a high pitched two beep signal tone. Insert the sensor into the 'Docking Station' within 10 minutes to expose the sensor to the calibration gas (otherwise, the sensitivity test will be aborted).
Leak test in progress	LT	Information	A mandatory leak test is in progress to ensure that the leak, which was detected after the previous calibration, is successfully fixed. The SDMS will be 'Ready for use' only after successful termination of the ongoing leak test (see message 'Gas leak in DS' and 4.9.7). **Note**: This message only appears if PCO2 is enabled and the sensor is in the 'Docking Station'.
Monitoring time < 15 min	TL	Information	Indicates that within 15 minutes either the 'Site Time' (4.8.2) will expire or – if PCO2 is enabled – sensor calibration (4.9.4) is recommended (whichever will occur first).
PCO2 slow	PS	Information	This message is displayed if the duration of the last sensor calibration (normal or extended) was 14 minutes (4.9.3, 4.9.7). When removing the sensor from the 'Docking Station', this message ceases. PCO2 values are marked as questionable (4.2.3.8) until successful termination of the next sensor calibration within 14 minutes. **Note**: This message only appears if PCO2 is enabled and the sensor is in the 'Docking Station'. If the sensor is outside the

Status Message	Status Code	Type	Description
			'Docking Station'/during monitoring only the Status Code 'PS' is output. **Note**: The sensor may still be used for PCO2 monitoring but the operator must be aware that for a slow sensor, 'PCO2 stabilization' (2.4.3) will take longer, the sensor's response to changes in patient's PaCO2 levels will be slower and the PCO2 alarm condition delay (4.4.4) will be longer than for a fast sensor. **Note**: Refer to Status Message 'Sensor problem 11', 'Sensor problem 14', and to troubleshooting P0100, P0104, and P0304 (see Service Manual for the SDMS)
PCO2 stabilizing	CE	Information	PCO2 readings are stabilizing after sensor application or occurrence of a 'PCO2 artifact' (2.4.3). This message ceases as soon PCO2 is (re)stabilized. **Note**: This message only appears if PCO2 is enabled and 'Sensor-On-Patient' is detected. **Note**: PCO2 is marked as unstable (4.2.3.8) during PCO2 stabilization. **Note**: This message will also appear if the actual sensor temperature deviates by more than 2 °C from the set Sensor Temperature. **Note**: If PCO2 readings do not stabilize within 10 minutes after sensor application or after detection of a 'PCO2 artifact', the low priority alarm 'Check sensor application' is triggered. **Note**: Ambient air (intermittently) penetrating between the sensor surface and the skin, typically resulting in fast PCO2 changes, is the most frequent cause for 'PCO2-Artifacts'. In order to reduce the occurrence of 'PCO2-Artifacts', a good, hermetically sealed contact between the sensor surface and the patient's skin is essential. **Note**: Refer to troubleshooting P0100, P0103 (see Service Manual for the SDMS)
PCO2/PO2 stabilizing	TS	Information	This message appears if both transcutaneous parameters are stabilizing after sensor application or after occurrence of a 'TC-Artifact' (2.4.3). Also, see messages 'PCO2 stabilizing' and 'PO2 stabilizing'. **Note**: PCO2 and PO2 are marked as unstable (4.2.3.8) during stabilization. **Note**: This message only appears if PCO2 and PO2 are enabled and 'Sensor-On-Patient' is detected. **Note**: Refer to troubleshooting P0100, P0103 (see Service Manual for the SDMS)
PO2 stabilizing	OE	Information	PO2 readings are stabilizing after sensor application or occurrence of a 'PO2 artifact' (2.4.3). This message ceases as soon PO2 is (re)stabilized. **Note**: This message only appears if PO2 is enabled and 'Sensor-On-Patient' is detected. **Note**: PO2 is marked as unstable (4.2.3.8) during PO2 stabilization. **Note**: This message will also appear if the actual sensor temperature deviates by more than 2 °C from the set Sensor Temperature.

Status Message	Status Code	Type	Description
			Note: If PO2 readings do not stabilize within 10 minutes after sensor application or after detection of a 'PO2 artifact', the low priority alarm 'Check sensor application' is triggered. **Note**: Ambient air (intermittently) penetrating between the sensor surface and the skin, typically resulting in fast PO2 changes, is the most frequent cause for 'PO2-Artifacts'. In order to reduce the occurrence of 'PO2-Artifacts', a good, hermetically sealed contact between the sensor surface and the patient's skin is essential. **Note**: Refer to troubleshooting P0100, P0103 (see Service Manual for the SDMS)
Open DS door	OD	Information	This message appears after activation of an operator-initiated PCO2 and/or PO2 sensitivity test (4.9.7, Table 40, Table 43). The message is accompanied by a high pitched two beep signal tone. Open the 'Docking Station' within 1 minute to expose the sensor to ambient air (otherwise, the sensitivity test will be aborted). **Note**: This message only appears if PCO2 is enabled and the sensor is in the 'Docking Station'.
Ready for use	RU	Information	The SDM and the connected sensor are 'Ready for use'. **Note**: This message only appears if the connected sensor is not 'ON Patient'.
Sensitivity test	ST	Information	This message appears during an operator-initiated PCO2 and/or PO2 sensitivity test (4.9.7, Table 40, Table 43). At the beginning of the test, it is temporarily replaced by the message 'Open DS door', accompanied by a high-pitched two-beep signal tone. It appears again when the DS door is opened. About 2 minutes later, the message 'Insert sensor into DS', also accompanied by the same high-pitched two-beep signal tone appears. Once the sensor is placed into the DS, the Status Message 'Sensitivity test' is displayed again. At the end of the test and if the test finished successfully, the Status Message 'Ready for use' appears. 'Sensor problem 12' is displayed if the PCO2 sensitivity test failed and 'Sensor problem 72' appears if the PO2 sensitivity test failed (4.3.6). **Note**: Refer to troubleshooting P0305 (see Service Manual for the SDMS).
Sensor calibration recommended	CS	Information	The 'Calibration Interval' (Table 66) has elapsed and sensor calibration (4.9) is **recommended** (but not yet mandatory). Insert the sensor into the 'Docking Station'. Calibration will start automatically. **Note**: This message only appears if PCO2 is enabled and the sensor is outside the 'Docking Station'. **Note**: Calibration is recommended if the 'Calibration Interval' has elapsed and the sensor was removed from the 'Docking Station' less than 12 hours ago *(if 'Calibration Interval' ≤ 8 hours)*, less than 13 hours ago *(if 'Calibration Interval' = 9 hours)*, or less than 16 hours ago *(if 'Calibration Interval' = 12 hours)*. For details, see Table 66. **Note:** PCO2 is marked as questionable (4.2.3.8) if a sensor calibration is recommended.

Status Message	Status Code	Type	Description
			Note: Unless the 'Site Time' (4.8.4) has expired, the 'Remaining Monitoring Time Icon' (4.3.2) is highlighted yellow if calibration is recommended. **Note:** If the Status Code 'CS' is output while the sensor is in the 'Docking Station', the sensor is not (yet) calibrated.
Sensor life time < yy days *(also see message Sensor usage time < xx hrs)*	LL	Information	The remaining 'Life Time' in days or 'Usage Time' in hours (whichever is shorter) of the connected OxiVenT™ Sensor (8.4.3) is indicated. **Note**: This message only appears if the connected OxiVenT™ Sensors' is stored in the 'Docking Station' when its remaining 'Life Time' is less than 30 days or its 'Usage Time' is less than 300 hours. **Note**: Countdown of 'Life time' and 'Usage time' starts from first ex-factory use of an OxiVenT™ Sensor. **Note**: The 'Usage time' is only used up if PO2 is enabled and while the sensor is outside the 'Docking Station', i.e. if the OxiVenT™ Sensor is used for PO2 monitoring, and during PO2 calibration (4.9). **Note**: The remaining and used 'Life Time' and 'Usage Time' are indicated on the second page of the menu 'System Information' (Table 58). **Note**: If the sensor's 'Life Time' has expired, the SDM triggers the low priority alarm 'Replace sensor' when/as soon as the sensor is in the 'Docking Station'. If the sensor's 'Usage Time' has expired, the OxiVenT™ Sensor functions as a V-Sign™ Sensor only (i.e. no PO2 monitoring is possible anymore) when/as soon as the sensor is in the 'Docking Station' (SDM triggers `Usage Time elapsed').
Sensor usage time < xx hrs	LL	Information	Refer to the description of the message 'Sensor life time < yy days' above.
Usage Time elapsed	UE	Information	The sensor's 'Usage Time' has expired (OxiVenT™ Sensor only). The OxiVenT™ Sensor functions as a V-Sign™ Sensor only (i.e. no PO2 monitoring is possible anymore) when/as soon as the sensor is in the 'Docking Station'.
Replace sensor	LE	Low Priority Alarm	The 'Life Time' of the connected OxiVenT™ Sensor (8.4.3) has expired. Monitoring with this sensor is no longer possible. Replace the sensor. **Note**: This message applies only to OxiVenT™ Sensors. **Note**: To ensure that patient monitoring is not interrupted if the 'Life Time' expires during monitoring, this low priority alarm condition is only triggered as soon as/when the sensor is in the 'Docking Station'.
Sensor off patient (↲)	SO	Low Priority Alarm	The sensor was dislodged or intentionally removed from the patient. **Note**: Pressing the 'ENTER Button' (4.1.4) while this message is displayed will terminate The 'Sensor off patient (↲)' alarm condition, reset the Site Timer (4.8.4) to the selected 'Site Time', and - if reduced by SITE PROTECTION (4.8.5) - reactivate sensor heating. The measurement screen will remain active.

Status Message	Status Code	Type	Description
			Note: Inserting the sensor into the 'Docking Station' will also terminate the 'Sensor off patient (↲)' alarm condition.
Site time elapsed	TE	Low Priority Alarm	Indicates that the 'Site Time' has expired (4.8.1, 4.8.2, 4.8.5). **Note**: The 'Remaining Monitoring Time Icon' (4.3.2) is highlighted red if the 'Site Time' has expired. **Note**: To terminate the 'Site time elapsed' alarm, remove the sensor from the patient and press the 'ENTER Button' when the message 'Sensor off patient (↲)' appears or insert the Sentec TC Sensor into the 'Docking Station'.
SpO2 low signal	LS	Information	This message is displayed whenever the SDM detects a weak pulsatile signal independently from its severity or the impact on SpO2, PR or PI values. This may be caused by low perfusion at the measurement site (2.4.5). Verify the sensor application and the appropriateness of the monitoring site if this message appears. **Note**: This message only appears if SpO2/PR are enabled and 'Sensor-On-Patient' is detected. **Note**: SpO2, PR, and PI are marked as questionable (4.2.3.8) during episodes with a weak pulsatile signal. **Note**: Refer to troubleshooting P0200 (see Service Manual for the SDMS)
SpO2 signal quality	MA	Low Priority Alarm or Information	If the quality of the signals measured by the connected sensor's photodiode is temporarily degraded, SpO2, PR, and PI are marked as questionable (4.2.3.8). If the quality of these signals continues to be degraded, the message 'SpO2 Signal Quality' will display and SpO2, PR and PI will be marked as invalid (i.e. values replaced by '---', 4.2.3.8) within 15 seconds. Additionally, a low priority auditory alarm signal will sound within 30 seconds from the beginning of the degraded signal. **Note**: This message only appears if SpO2/PR are enabled and 'Sensor-On-Patient' is detected. **Note**: A degradation of the signals measured by the connected sensor's photodiode may be caused by patient motion, by certain environmental conditions and/or by low perfusion (2.4.5). **Note**: Refer to troubleshooting P0200 (see Service Manual for the SDMS)
Temp. limiter active	OT	Low Priority Alarm	If the sensor detects that the sensor temperature exceeds predefined limits (relative limit (r1): 'Sensor Temperature' + 0.35 °C (VS-A/P/N, OV-A/P/N); absolute limit (a1): 44.9 °C (VS-A/P/N, OV-A/P/N), the sensor immediately switches off its power-consuming parts and triggers the message 'Temp. limiter active' with a delay of 10 seconds and the 'Temperature Icon' (4.3.2) is highlighted red. The sensor resumes normal operation if the sensor temperature remains within the predefined limits. If despite of this safety precaution the sensor temperature continues to increase and exceeds a second set of predefined limits (relative limit (r2): 'Sensor Temperature' + 0.6 °C; absolute limit (a2): 45.0 °C), the SDM switches off the sensor after 5 seconds and restarts the sensor after another 15 seconds.

Status Message	Status Code	Type	Description
			Note: This message only appears when SpO2/PR are enabled (compare with HT status code). **Note**: The sensor temperature is supervised and controlled primarily by the sensor and – for redundancy – by the SDM. **Note**: Failure to cover the sensor site with a heat shield if operated under an external heat source (e.g. a radiant warmer) may cause the sensor temperature to exceed the above-mentioned predefined limits, thereby triggering the alarm & safety functions. Too high ambient temperature at the sensor site (e.g. in an incubator) may also cause the display of this message. The difference between the 'Sensor Temperature' and the ambient temperature at the sensor site must be at least 4 °C for V-Sign™ Sensors 2 and OxiVenT™ Sensors. **Note**: Also refer to Status Messages 'Sensor problem 38', 'Sensor problem 42', 'Sensor fault 39', 'Sensor fault 43' (4.3.6).
(no message)	HT	Information	If the sensor detects that the sensor temperature exceeds a predefined limit (relative limit (r1): 'Sensor Temperature' + 0.35 °C (VS-A/P/N, OV-A/P/N), the sensor immediately switches off its power-consuming parts and triggers the status code 'HT' with a delay of 10 seconds and the 'Temperature Icon' (4.3.2) is highlighted red. The sensor continues its normal operation for PCO2 and/or PO2 measurement. However, if despite of this safety precaution the sensor temperature continues to increase conditions as described for the message, 'Temp. limiter active' (with status code 'OT') will become active. **Note**: This message only appears when SpO2/PR are NOT enabled (compare with OT status code). **Note**: The sensor temperature is supervised and controlled primarily by the sensor and – for redundancy – by the SDM. **Note**: Failure to cover the sensor site with a heat shield if operated under an external heat source (e.g. a radiant warmer) may cause the sensor temperature to exceed the above-mentioned predefined limit, thereby triggering the status code and the 'Temperature Icon' (4.3.2) is highlighted red. Too high ambient temperature at the sensor site (e.g. in an incubator) may also cause the display of this status code. The difference between the 'Sensor Temperature' and the ambient temperature at the sensor site must be at least 4 °C for V-Sign™ Sensors 2 and OxiVenT™ Sensors. **Note**: Also, refer to Status Messages 'Temp. limiter active' above and 'Sensor problem 38', 'Sensor problem 42', 'Sensor fault 39', 'Sensor fault 43' in sub-section 4.3.6.
Watch battery low	LW	Low Priority Alarm or Information	At power up, the SDM detected that the watch battery is low and the date/time setting of the SDM therefore may be wrong. After the POST screen, a low priority alarm is triggered and a yellow information text appears, instructing the operator to contact a Sentec authorized service technician to change the Watch Battery as soon as possible and that meanwhile the SDM may be used, provided the SDM's date/time is set to the correct value (4.6.4). **Note**: As long as the date/time has not been set in the menu of the SDM or when using V-STATS™, normal operation of the SDM will not be activated. Once the operator has set the

Status Message	Status Code	Type	Description
			date/time, the low priority alarm ceases and the SDM starts normal operation. The message is continuously displayed to remind the operator that the watch battery must be replaced as soon as possible. **Note**: Also, see message 'Set Date/Time'. **Note**: Refer to troubleshooting P0407 (see Service Manual for the SDMS).
(no message)	AO	Information	This status code indicates that auditory alarm signals are permanently switched off ('AUDIO OFF') (4.4.3). **Note**: If auditory alarm signals are permanently switched off, the AUDIO Status Icon (4.3.3) displays the 'Bell cancel' symbol (with a negation cross of solid lines). If the auditory alarm signals were switched off by pressing the AUDIO PAUSED/AUDIO OFF Button > 3 seconds, then the 'AUDIO PAUSED/AUDIO OFF Indicator' (4.1.5) additionally flashes yellow.
(no message)	AP	Information	This status code indicates that auditory alarm signals are PAUSED for 1 or 2 minutes (4.4.3). **Note**: If auditory alarm signals are PAUSED for 1 or 2 minutes, the AUDIO Status Icon (4.3.3) displays the 'Bell cancel' symbol (with a negation cross of broken lines) and the AUDIO PAUSED/AUDIO OFF Indicator (4.1.5) is highlighted yellow.
(no message)	DPxx	Information	The monitor surveillance has detected 'Docking Station' problem xx, where xx specifies the problem number (4.3.8). **Note**: These status codes are only generated if PCO2 is enabled and the sensor is in the 'Docking Station'.
(no message)	DS	Information	This status code indicates that the connected Sentec TC Sensor is in the 'Docking Station'.
Set Date/Time	DT	Low Priority Alarm	At power up, the SDM detected that the date/time setting of the SDM is wrong (this is the case if the watch battery was low or removed while the SDM was switched off). After the POST screen, a low priority alarm is triggered and the sub-menu 'Date/Time' (Table 47) is activated. **Note**: As long as the date/time has not been set in the menu of the SDM when by using V-STATS™, normal operation of the SDM will not be activated. Once the date/time has been set, the alarm ceases and the SDM starts normal operation. **Note**: Under normal circumstances, this message should only occur after replacement of the watch battery (see message 'Watch battery low' and 4.6.4).
(no message)	E0 – E7	Information	These status codes represent Operator Events marked during patient monitoring in the Quick Access Menu (4.2.5.2).
(no message)	E9	Information	This status code marks the beginning and end of a V-Check™ Analysis Phase (4.13.2). **Note**: These markers are automatically generated during a V-Check™ Measurement.
(no message)	GB	Information	Sentec internal use only (blast). **Note**: Only if PCO2 is enabled and the sensor is in the 'Docking Station'.

Status Message	Status Code	Type	Description
(no message)	IC	Information	This status code indicates that PCO2 values are in-vivo corrected (4.11). **Note**: This message only appears if PCO2 is enabled and 'Sensor-On-Patient' is detected. **Note**: If PCO2 values are in-vivo corrected and the sensor is outside the 'Docking Station', the 'PCO2 In-Vivo Correction' indicator is displayed on the measurement screens (4.2.3).
(no message)	ID	Information	The connected Sentec TC Sensor has neither been stored in the 'Docking Station' nor applied to the patient for more than 2 minutes.
(no message)	IH	Information	This Status Code indicates that INITIAL HEATING (4.8.3) is active. **Note**: Only if sensor is outside the 'Docking Station'. **Note**: The 'Temperature Icon' (4.3.2) is highlighted yellow if INITIAL HEATING is active.
Remote monitoring interrupted (↵)	RL	Low Priority Alarm	While the SDM/patient was remotely monitored with V-CareNeT™ the connection between the SDM and the V-CareNeT™ Central Station interrupted. **Note**: The 'Remote monitoring interrupted' alarm condition automatically ceases as soon as the connection between the SDM and the V-CareNeT™ Central Station is restored or a connection with another V-CareNeT™ Central Station is established. Pressing the 'ENTER Button' (4.1.4) while this message is displayed will also terminate this alarm condition. **Note**: If the 'Remote monitoring interrupted' alarm condition is triggered while the SDM's alarm system is in the AUDIO OFF state (Table 30), the SDM will terminate the AUDIO OFF state. **Note**: The 'Remote monitoring interrupted' alarm condition is also triggered at the V-CareNeT™ Central Station. For details, refer to the Instruction Manual for V-STATS™. **Note:** The 'Remote monitoring interrupted' alarm may be indicative of a system or equipment problem (network, SDM, or Central Station PC), causing interruption of the connection between V-CareNeT™ and the respective SDM.
(no message)	RI	Information	Sentec internal use only. While the SDM/patient is remotely monitored with V-CareNeT™, the 'Patient Info' (the patient's name, a comment or the patient number) displayed in the V-CareNeT™ Central Station in the corresponding station's remote monitoring window is duplicated on the SDM on the 'Ready for use/Calibration' screen (4.2.4), in the SDM's main menu (Table 36), and - if no Status Message has to be displayed - in the SDM's status bar (Figure 8) enclosed in "["and"]".
(no message)	SR	Information	This status code indicates that sensor stabilization is recommended (4.9.5). **Note**: Only if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note**: If this status code is output, the remaining 'Recommended sensor stabilization duration' is displayed on the 'Ready for use' screen (4.2.4).

Status Message	Status Code	Type	Description
(no message)	VR	Information	SDM configured in 'V-CareNeT™ Only Mode' (4.13.3) and the 'V-CareNeT™ required' screen (Figure 16) appears to indicate that the connection to V-CareNeT™ is required.
Sensor problem xx *(in some cases no message)*	SPxx	Low Priority Alarm or Information	The sensor surveillance has detected sensor problem xx, where xx specifies the problem number (4.3.6). **Note**: As a safety precaution and depending on the specific problem, the SDM may temporarily switch off the sensor and/or continue operation with reduced functionality (e.g. marking PCO2 to be invalid (4.2.3.8) after 'Sensor problem 10').
Sensor fault xx	SFxx	Low Priority Alarm	The sensor surveillance has detected sensor fault xx, where xx specifies the fault number (4.3.6). **Note**: As a safety precaution, the SDM switches off the sensor if a sensor fault is detected. The operator must power cycle the SDM to reset the fault condition.
Monitor fault xx	MFxx	Low Priority Alarm	The monitor surveillance has detected monitor fault xx, where xx specifies the fault number (4.3.7). **Note**: Monitor faults xx (MFxx) relate to situations where – as a safety precaution - you must power cycle the SDM to try to reset the fault condition. Do not use the SDM if power-cycling does not reset the message. Instead, contact qualified service personnel or your local Sentec representative.
Monitor problem xx *(in some cases no message)*	MPxx	Low Priority Alarm or Information	The monitor surveillance has detected monitor problem xx, where xx specifies the problem number (4.3.7). **Note**: Monitor problems xx (MPxx) relate to situations where the SDM, as a safety precaution, requires operator intervention or reboots the SMB or signal analysis board prior to resuming operation.

Table 24 Status Messages and Status Codes

4.3.6 Sensor faults and Sensor problems

The SDM distinguishes between sensor faults and sensor problems. Sensor faults xx (SFxx) relate to situations where – as a safety precaution – the SDM switches off the sensor and the operator must power cycle the SDM to reset the fault condition. Sensor problems xx (SPxx), in contrast, relate to situations where the SDM switches off the sensor temporarily and/or resumes operation (in certain cases with reduced functionality). xx indicates the respective fault or problem number.

Status Message	Status Code	Type	Description
Sensor problem 10	SP10	Low priority alarm	The SDM detects that the potential measured by the sensor's pH electrode at the end of the sensor calibration is outside a predefined range (4.9.7). This alarm ceases when removing the sensor from the 'Docking Station'. Until successful termination of the next sensor calibration, PCO2 values are marked as invalid (4.2.3.8) and the alarm is reactivated if the sensor is placed in the 'Docking Station'. **Note**: This message is only generated if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note**: Refer to troubleshooting P0303 (see Service Manual for the SDMS)

Status Message	Status Code	Type	Description
Sensor problem 11	SP11	Low priority alarm	The SDM detects that the sensor's PCO2 readings are stable but too slow, as the calibration could not be terminated within 14 minutes (4.9.7). This alarm ceases when removing the sensor from the 'Docking Station'. Until successful termination of the next sensor calibration (within ≤14 minutes), PCO2 values are marked as invalid (4.2.3.8) and the alarm is reactivated if the sensor is placed in the 'Docking Station'. **Note**: This message is only generated if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note**: Refer to troubleshooting P0304 (see Service Manual for the SDMS).
Sensor problem 12	SP12	Low priority alarm	The SDM detects that the sensor's PCO2 sensitivity is deteriorated (4.9.7) or an operator initiated 'PCO2 sensitivity test' (Table 40) has failed. This alarm ceases when removing the sensor from the 'Docking Station'. Until an operator initiated 'PCO2 sensitivity test' has successfully been terminated, PCO2 values are marked as invalid (4.2.3.8) and the alarm is reactivated if the sensor is in the DS. **Note**: This message is only generated if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note**: Refer to troubleshooting P0305 (see Service Manual for the SDMS) **Note**: If 'Sensor problem 12' reoccurs after successful termination of an operator initiated 'PCO2 sensitivity test', it could be possible that the 'Docking Station' is defective.
(no message)	SP13	Information	The SDM detects an unexpected temperature dependence of the potential measured by the sensor's pH-electrode. INITIAL HEATING (4.8.3) will be disabled. **Note**: This status code is only generated if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note**: To reset SP13, leave the sensor in the 'Docking Station' for a few hours. The SDM then will check temperature dependence of the sensor potential and reset SP13 if normal behavior is observed.
Sensor problem 14	SP14	Low priority alarm	The SDM detects that the sensor's PCO2 readings are unstable and/or too slow as an 'Extended Calibration' could not be terminated within 14 minutes (4.9.7). This alarm ceases when removing the sensor from the 'Docking Station'. Until successful termination of the next sensor calibration, PCO2 values are marked as invalid (4.2.3.8) and the alarm is reactivated if the sensor is in the 'Docking Station'. **Note**: This message is only generated if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note**: An 'Extended Calibration' is initiated if a regular sensor calibration could not be finished successfully within 14 minutes due to an unstable sensor. **Note**: Refer to troubleshooting P0304 (see Service Manual for the SDMS) and the Status Messages 'Extended Calibration', 'PCO2 slow' and 'Sensor problem 11'.
Sensor problem 20	SP20	Low priority alarm	The SDM detects that the sensor's red LED is defective. SpO2/PR are marked as invalid (4.2.3.8) irrespective of sensor

Status Message	Status Code	Type	Description
			position. The sensor still can be used for PCO2 (and PO2) monitoring. PI also is available. **Note**: This message is only generated if SpO2/PR is enabled and a Sentec TC Sensor is in the 'Docking Station'. **Note**: 'Sensor problem 20' resets upon power cycle of the SDM or if the problem does not reoccur when inserting the sensor into the 'Docking Station'. **Note**: Refer to troubleshooting P0302 (see Service Manual for the SDMS)
Sensor fault 21	SF21	Low priority alarm	The SDM detects that the sensor's IR LED is defective. The SDM switches off the sensor. To reset 'Sensor fault 21' and to restart the sensor, the SDM must be switched off and on again. Contact a Sentec authorized service technician or your local sales representative if power cycling the SDM does not reset the message. **Note:** A defective 'Docking Station' may also trigger SF21.
(no message)	SP30	Information	This status code indicates that the SDM detected that the difference between the sensor's two redundant temperature measurements has been too large for 80 seconds. The SDM restarts the sensor. Also see SF31.
Sensor fault 31	SF31	Low Priority Alarm	The SDM detected that SP30 occurred twice within 1 hour. The SDM switches off the sensor. To reset 'Sensor fault 31' and to restart the sensor, the SDM must be switched off and on again. Do not use the sensor if this message cannot be reset by power cycling the SDM. Instead, contact qualified service personnel or your local Sentec representative.
(no message)	SP32	Information	The SDM has not received temperature data from the sensor for 10 seconds. The SDM restarts the sensor. Also see SF33.
Sensor fault 33	SF33	Low Priority Alarm	The SDM detects that SP32 occurred twice within 1 hour. The SDM switches off the sensor. To reset 'Sensor fault 33' and to restart the sensor, the SDM must be switched off and on again. Do not use the sensor if this message cannot be reset by power cycling the SDM. Instead, contact qualified service personnel or your local Sentec representative.
(no message)	SP34	Information	The SDM detects that temperature readings are frozen for 80 seconds. The SDM restarts the sensor. Also see SF35.
Sensor fault 35	SF35	Low Priority Alarm	The SDM detects that SP34 occurred twice within 1 hour. The SDM switches off the sensor. To reset 'Sensor fault 35' and to restart the sensor, the SDM must be switched off and on again. Do not use the sensor if this message cannot be reset by power cycling the SDM. Instead, contact qualified service personnel or your local Sentec representative.
Sensor problem 38	SP38	Low Priority Alarm	The message 'Temp. limiter active', caused by condition r2' (message 'Temp. limiter active' in 4.3.5) persists for 5 minutes. The SDM switches off the sensor and restarts it after 60 seconds. **Note**: Also, refer to messages 'Sensor problem 42', 'Sensor fault 39', and 'Sensor fault 43'.

Status Message	Status Code	Type	Description
			Note: No power will be provided to the sensor port for 60 seconds. **Note**: Refer to troubleshooting P0306 (see Service Manual for the SDMS)
Sensor fault 39	SF39	Low Priority Alarm	The SDM detects that the sensor temperature exceeds 'SET temperature + 0.6 °C' while the sensor did not detect condition 'r1' (message 'Temp. limiter active' in 4.3.5). The SDM switches off the sensor. To reset 'Sensor fault 39' and to restart the sensor, the SDM must be switched off and on again. Do not use the sensor if this message cannot be reset by power cycling the SDM. Instead, contact qualified service personnel or your local Sentec representative. **Note**: Also, refer to messages 'Sensor problem 38', 'Sensor problem 42', and 'Sensor fault 43'. **Note**: Refer to troubleshooting P0306 (see Service Manual for the SDMS)
Sensor problem 42	SP42	Low Priority Alarm	The message 'Temp. limiter active', caused by condition 'a2' (message 'Temp. limiter active' in 4.3.5) persists for 5 minutes. The SDM switches off the sensor and restarts it after 60 seconds. **Note**: Also refer to messages 'Sensor problem 38', 'Sensor fault 39', and 'Sensor fault 43' **Note**: No power will be provided to the sensor port for 60 seconds. **Note**: Refer to troubleshooting P0306 (see Service Manual for the SDMS)
Sensor fault 43	SF43	Low Priority Alarm	The SDM detects that the sensor temperature exceeds 45.0 °C while the sensor did not detect condition 'a1' (message 'Temp. limiter active' in 4.3.5). The SDM switches off the sensor. To reset 'Sensor fault 43' and to restart the sensor, the SDM must be switched off and on again. Do not use the sensor if this message cannot be reset by power cycling the SDM. Instead, contact qualified service personnel or your local Sentec representative. **Note**: Also, refer to messages 'Sensor problem 38', 'Sensor problem 42', and 'Sensor fault 39'.
(no message)	SP50	Information	The SDM detected an EEPROM CRC mismatch of the connected sensor and restarted the connected sensor. Also, see SF51.
Sensor fault 51	SF51	Low Priority Alarm	The SDM detects that SP50 occurred twice within 10 seconds. Do not use the sensor. Contact qualified service personnel or your local Sentec representative.
(no message)	SP52	Information	The SDM detected a stack overflow warning of the connected sensor and restarted the connected sensor. Also, see SF53.
Sensor fault 53	SF53	Low Priority Alarm	The SDM detects that SP52 occurred twice within 1 hour. The SDM switches off the sensor. To reset 'Sensor fault 53' and to restart the sensor, the SDM must be switched off and on again. Do not use the sensor if this message cannot be reset by power cycling the SDM. Instead, contact qualified service personnel or your local Sentec representative.

Status Message	Status Code	Type	Description
(no message)	SP54	Information	The SDM detects transmission problems between the connected sensor and restarts the connected sensor.
Sensor fault 61	SF61	Low Priority Alarm	The SDM detects that a connected sensor draws a current but will not communicate. The SDM therefore interrupts all power to the sensor and issues this sensor fault. Do not use this sensor. Contact qualified service personnel or your local Sentec representative.
Sensor problem 70	SP70	Low Priority Alarm	The SDM detects that the LED of the connected OxiVenT™ Sensor's PO2 module is defective. PO2 is marked as invalid (4.2.3.8), irrespective of sensor position. The sensor can still be used for monitoring of the other parameters. **Note**: This message is only generated if PO2 is enabled and the sensor is in the 'Docking Station'. **Note**: Refer to troubleshooting P0309 (see Service Manual for the SDMS).
Sensor problem 71	SP71	Low Priority Alarm	The SDM detects that the photodiode of the connected OxiVenT™ Sensor's PO2 module is defective. PO2 is marked as invalid (4.2.3.8), irrespective of sensor position. The sensor can still be used for monitoring of the other parameters. **Note**: This message is only generated if PO2 is enabled and the sensor is in the 'Docking Station'. **Note**: Refer to troubleshooting P0309 (see Service Manual for the SDMS).
Sensor problem 72	SP72	Low Priority Alarm	The SDM detects that the sensor's PO2 sensitivity is deteriorated (4.9.7) or an operator initiated 'PO2 sensitivity test' (Table 43) has failed. This alarm resets when removing the sensor from the 'Docking Station'. Until an operator initiated 'PO2 sensitivity test' is successfully terminated, PO2 values are marked as invalid (4.2.3.8) and the alarm is reactivated when the sensor is in the DS. **Note**: This message is only generated if PO2 is enabled and the sensor is in the 'Docking Station'. **Note**: Refer to troubleshooting P0305 (see Service Manual for the SDMS). **Note**: If 'Sensor problem 72' reoccurs after successful termination of an operator initiated 'PO2 sensitivity test', it could be possible that the 'Docking Station' is defective.
Sensor problem 73	SP73	Low Priority Alarm	The SDM detects a PO2 module error for the connected OxiVenT™ Sensor. PO2 is marked as invalid (irrespective of sensor position, 4.2.3.8). The sensor still can be used for monitoring the other parameters. Replace the sensor to continue monitoring PO2. **Note**: This message is only generated if PO2 is enabled and the sensor is in the 'Docking Station'. **Note**: Refer to troubleshooting P0309 (see Service Manual for the SDMS).
Sensor problem 74	SP74	Low priority alarm	The SDM detects that the sensor's PO2 readings are too slow or too unstable as the PO2 calibration could not be terminated within 14 minutes (4.9.7). This alarm resets when removing the sensor from the 'Docking Station'. Until successful termination of the next PO2 calibration (within ≤14 minutes), PO2 values are marked as invalid (4.2.3.8) and the

Status Message	Status Code	Type	Description
			alarm is reactivated if the sensor is placed in the 'Docking Station'. **Note**: This message is only generated if PO2 is enabled and the sensor is in the 'Docking Station'. **Note:** Refer to troubleshooting P0304 (see Service Manual for the SDMS).

Table 25 Sensor problems and Sensor faults

4.3.7 Monitor faults and Monitor problems

The SDM distinguishes between Monitor faults and Monitor problems. Monitor faults xx (MFxx) relate to situations where – as a safety precaution – you must power cycle the SDM to try to reset the fault condition. Monitor problems xx (MPxx), in contrast, relate to situations where the SDM requires operator intervention or reboots the SMB or signal analysis board prior to resuming operation. xx specifies the respective fault or problem number.

Status Message	Status Code	Type	Description
Monitor fault 04	MF04	Low priority alarm	After switching on the SDM, the SDM detects that the speaker is not properly powered. The messages 'failed' and 'Monitor fault 04' are displayed on the POST screen (4.6 , Figure 3) and the POST screen remains active. Switch the monitor off and on again to try to reset this message. Do not use the SDM if the message cannot be reset. Instead, contact qualified service personnel or your local Sentec representative. **Note:** Prior to sending the SDM to repair, it is possible to download trend data using V STATS™ (2.1, 2.3).
Monitor fault 10	MF10	Low priority alarm	After switching on the SDM, the SDM detects that the fan is not properly powered or a monitor overtemperature. The messages 'failed' and 'Monitor fault 10' are displayed on the POST screen (4.6 , Figure 3) and the POST screen remains active. Switch the monitor off and on again to try to reset this message. Do not use the SDM if the message cannot be reset. Instead, contact qualified service personnel or your local Sentec representative. **Note**: Prior to sending the SDM to repair, it is possible to download trend data using V-STATS™ (2.1, 2.3).
Monitor problem 10	MP10	Information	During runtime of the SDM, the SDM detects that the fan is not properly powered. The message 'Monitor problem 10' is displayed on the SDM screen. Contact qualified service personnel or your local Sentec representative.
Monitor fault 11	MF11	Low priority alarm	After switching on the SDM, the SDM detects a failure of the battery chip. The messages 'failed' and 'Monitor fault 11' are displayed on the POST screen (4.6 , Figure 3) and the POST screen remains active. Switch the monitor off and on again to try to reset this message. Do not use the SDM if the message cannot be reset. Instead, contact qualified service personnel or your local Sentec representative. **Note**: Prior to sending the SDM to repair, it is possible to download trend data using V-STATS™ (2.1, 2.3).
Monitor fault 60	MF60	Low priority alarm	After switching on the SDM, the SDM detects a) that its controller board does not contain a flash memory or b) a failure

Status Message	Status Code	Type	Description
			of its non-volatile flash memory. Switch the monitor off and on again to try to reset this message. Do not use the SDM if the message cannot be reset. Instead, contact qualified service personnel or your local Sentec representative. **Note**: Prior to sending the SDM to repair, it is possible to download trend data using V-STATS™ (2.1, 2.3).
Monitor fault 80	MF80	Low priority alarm	After booting the signal analysis board, the SMB could not establish communication with the signal analysis board within 30 seconds. Switch the monitor off and on again to try to reset this message. Do not use the SDM if the message cannot be reset. Instead, contact qualified service personnel or your local Sentec representative. **Note**: Prior to sending the SDM to repair, it is possible to download trend data using V-STATS™ (2.1, 2.3).
Monitor fault 88	MF88	Low priority alarm	After booting the signal analysis board, the SMB detects that the MPB/MPL software version is not compatible with the SMB software version. Switch the monitor off and on again to try to reset this message. Do not use the SDM if the message cannot be reset. Instead, contact qualified service personnel or your local Sentec representative. **Note**: Prior to sending the SDM to repair, it is possible to download trend data using V-STATS™ (2.1, 2.3).
Monitor problem 42	MP42	Low priority alarm	If the SDM detects that profile data is inconsistent when switching on the SDM, the SDM will shortly display the POST screen (4.6) and then displays the following yellow information text (only in English): *Some of the SDM's Parameter Settings were found to be inconsistent and therefore were reset to factory defaults. Verify the settings and adjust the parameters prior to use if necessary.* *To continue and access the menu please press the 'ENTER Button'.* Once the user has accessed the menu, the SDM starts full operation and the message 'Monitor problem 42' resets. **Note**: 'Monitor problem 42' may also be triggered when a new software version is installed that includes a different parameter setting structure.
(no message)	MP50 to MP59	Information	Appearance of one of these Status Codes indicates that the SDM was reset by the respective watchdog timer due to a software error. **Note:** If the 'Profile Mode' is 'Institutional' (4.7.3) and if the SDM was reset by one of its watchdog timers, the SDM will – after rebooting – maintain the profile from previous use.
(no message)	MP80	Information	This Status Code indicates that the SMB did reboot the signal analysis board as communication between the SMB and the signal analysis board was interrupted for more than 1 second.
Monitor problem 90, 91, 92 etc. (respective number)	MP90 MF91 MP92 MP93 MP94 MF95 MF96	Information	Appearance of one of these Status Codes indicates SDM internal hardware problems. Contact qualified service personnel or your local Sentec representative.

Table 26 Monitor problems and Monitor faults

4.3.8 'Docking Station' faults and 'Docking Station' problems

The SDM distinguishes between 'Docking Station' faults and 'Docking Station' problems. 'Docking Station' faults (DFxx) relate to situations where you must either a) remove the sensor from the 'Docking Station' and then reinsert the sensor into the 'Docking Station' or b) power cycle the SDM to try to reset the fault condition. 'Docking Station' problem-related status codes (DPxx) provide additional information for qualified service personnel when troubleshooting 'Docking Station'-related problems (see Service Manual for the SDMS).

Status Message	Status Code	Type	Description
(no message)	DP01	Information	SDM detects a high residual gas flow when the gas valve is closed. Contact qualified service personnel or your local Sentec representative. **Note**: This status code is only generated if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note**: Refer to troubleshooting P0501, P0504 (see Service Manual for the SDMS).
(no message)	DP02	Information	Sentec internal use only (gas tightness threshold during leak test) **Note**: This status code is only generated if PCO2 is enabled and the sensor is in the 'Docking Station'. **Note**: Refer to troubleshooting P0502 (see Service Manual for the SDMS).
Docking Station fault	DFxx	Low priority alarm	The monitor surveillance has detected 'Docking Station' fault xx, where xx specifies the fault number. • DF02: Gas flow too low during calibration • DF03: Gas flow too high during calibration • DF04 – DF07: DS Supply Voltage related faults • DF08: Gas bottle pressure related fault • DF09: CRC mismatch **Note**: This message is only generated if PCO2 is enabled and the sensor is in the 'Docking Station'. 'xx' is only indicated in the Status Code but not in the Status Message. **Note**: Refer to troubleshooting P0501 (see Service Manual for the SDMS).

Table 27 'Docking Station' **problems and** 'Docking Station' **faults**

4.4 The SDM's Alarm System

4.4.1 Introduction

The SDM's alarm system is designed to meet the requirements of the applicable international standards. It uses visual and auditory alarm signals to alert the operator when a physiological parameter (PCO2, PO2, SpO2, PR) violates its alarm limits (Table 37) during patient monitoring or to indicate technical conditions of the equipment that require operator response or operator awareness. By degree of urgency, the SDM's alarm conditions are assigned to the following priorities:

Priority	Explanation	SDM's Alarm Condition(s)
High	Immediate operator response required	SpO2 violates its upper/lower alarm limit

Priority	Explanation	SDM's Alarm Condition(s)
Medium	Prompt operator response required	PCO2 violates its upper/lower alarm limit PO2 violates its upper/lower alarm limit PR violates its upper/lower alarm limit Charge level of battery critical (monitor not connected to AC power, 4.3.5, 4.5.2)
Low	Operator awareness required	Various technical conditions (4.3.5, 4.3.6)
Information	General system/status information	No alarm

Table 28 Alarm condition priorities

WARNING: Setting alarm limits for PCO2, PO2, SpO2, or PR (Table 37) to extreme values may render the SDM's alarm system for the respective parameter useless.

WARNING: Ensure to select the upper alarm limit for PO2 and SpO2 carefully and in accord with accepted clinical standards. High oxygen levels may predispose a premature infant to develop retinopathy.

Note: Alarm surveillance for physiological parameters (PCO2, PO2, SpO2, PR) is only active if the respective parameter is valid or questionable (4.2.3.8). Otherwise, generation of alarm signals for the respective parameter is automatically suspended.

All alarm signals of the SDM automatically stop being generated when the associated triggering event no longer exists.

Log of occurrence of all alarm conditions and alarm inactivation states

Together with the measured parameters and important settings the SDM stores in its internal memory (4.12.1) a log of the occurrence of

- all alarm conditions: time, alarm condition (status codes for technical alarm conditions (4.3.5);'+' or '-' behind value for limit violation (5.2.2))
- the auditory alarm signal inactivation states (4.4.3)

These data (including the log of the occurrence of alarm conditions/alarm inactivation states) are available when downloading Trend Data with V-STATS™ (2.1, 2.3, 5.2.1).

Note: If the internal memory of your SDM is volatile, the log of alarm conditions will be lost if the SDM shuts down or is switched off. An SDM with a volatile memory must be kept turned on to keep the memory active.

4.4.2 Visual alarm signals

As summarized in the following table, the SDM provides various visual alarm signals:

Alarm Type	Flashing Parameter	Status Message	Status Icon	Alarm Status Icon
Physiological alarm condition (PCO2, PO2, SpO2, PR violating lower/upper alarm limit (Table 37))	SpO2: 1.4 Hz PCO2, PO2, PR: 0.7 Hz (4.2.3)	NO	Not applicable	YES (4.3.4)

Alarm Type	Flashing Parameter	Status Message	Status Icon	Alarm Status Icon
Technical alarm condition (various reasons)	Not applicable	YES (4.3.5, 4.3.6, 4.3.7, 4.3.8)	Only if alarm condition occurs due to one of the variables displayed in the Status Icons (4.3.2)	

Table 29 Visual Alarm Signals

Note: As measurement parameters independently flash on screen, multiple physiological alarm conditions can be visualized simultaneously.

Note: The SDM displays only one Status Message (4.3.5, 4.3.6, 4.3.7, 4.3.8) at a time. If two or more alarm conditions (or system information) of equal priority exist concurrently, the SDM internally ranks the display priority of the possible Status Messages and displays the Status Message with the highest internal rank, corresponding to the alarm condition/system information.

Note: The 'Alarm Status Icon' (4.3.4) meets the requirements of IEC 60601-1-8 and indicates the priority of the highest priority alarm condition. If two or more alarm conditions occur at the same time, it indicates the highest currently active alarm priority

The SDM's visual alarm signals **cannot** be inactivated. With the exception of the following situations, the visible alarm signals therefore are always active/displayed:

1) Current PO2 values and, hence, related visual alarm signals (flashing PO2 in the event of a PO2 limit violation) are not displayed on the menu screens (4.2.5).
2) Current values of all monitored parameters and, hence, related visual alarm signals (flashing parameter in the event of a limit violation) are not displayed in the sub-menu 'Review/Print Trend Data' (4.12.4, Table 56), the 'Review Trend Data Screen' (Figure 11), the 'Trend Data Statistics Screen' (Figure 12), and the 'V-Check Results Screen' (Figure 15).
3) The Status Bar (Figure 8) and the visual alarm signals provided therein are not displayed on the 'Review Trend Data Screen' (Figure 11), the 'Trend Data Statistics Screen' (Figure 12), the 'V-Check Results Screen' (Figure 15) and the 'Ready for use' screen (4.2.4).

Note: If a menu screen or the 'Review Trend Data Screen' (Figure 11) are open during patient monitoring, the SDM will automatically return to the last active 'Measurement screen' if no button is pressed for 2 minutes. The 'Trend Data Statistics Screen' (Figure 12) and the 'V-Check Results Screen' (Figure 15), in contrast, will remain active in this situation.

Note: If the 'Ready for use' (4.2.4) screen is active, the 'Calibration' screen activates if the operator presses any of the Control Buttons or if an alarm condition occurs.

Note: If the menu parameter 'System Settings/Display in Sleep Mode' is set to AUTO or ON the display becomes inactivate in certain situations (4.2.6). In `ON´ mode, the display is only reactivated once the system detects an operator action (e.g. operator presses a control button or opens the 'Docking Station' door with the sensor) or when the battery level is < 10% and the SDM is not conntected to AC power. In `AUTO´ mode, the display is additionally and automatically reactivated when other alarm situations occur.

WARNING: If the display of the SDM is inactive when the parameter 'Display in Sleep Mode' (4.2.6, Table 48) is set to `ON´, the display will not be reactivated if an alarm condition occurs. In this case, visual alarm signals will not be visible.

WARNING: Current values of monitored parameters and visual alarm signals may become illegible if the display brightness (Table 48) is dimmed too much.

WARNING: Do not inactivate or dim the brightness of the monitor's display if the patient's safety could be compromised.

4.4.3 Auditory alarm signals/Inactivation of auditory alarm signals

The SDM's auditory alarm signals (4.1.6) are priority encoded and meet the requirements of IEC 60601-1-8. Within a password protected area of V-STATS™, the Responsible Organization can furthermore switch 'Alarm Melodies' ON or OFF as specified in Annex F of IEC 60601-1-8.

The volume of auditory alarm signals can be adjusted by using the menu parameter 'Alarm Volume' (Table 37, Table 49). If the menu parameter 'Alarm Volume' is set to 'Rising', the volume of auditory alarm signals – starting at level 2 – increases at each burst by one level.

Depending on the setting of the menu parameter 'AUDIO PAUSED Duration' (Table 49), auditory alarm signals can be PAUSED for 1 or 2 minutes by pressing the 'AUDIO PAUSED/OFF Button' (4.1.4). Within a password protected area of V-STATS™, the Responsible Organization can furthermore enable the option for the operator to permanently switch off auditory alarm signals by either pressing the AUDIO PAUSED/OFF Button > 3 sec or by setting the menu parameter 'Alarm Volume' to OFF (Table 37, Table 49). As summarized in the following table, the operating status of the SDM's auditory alarm signals is visually indicated by the 'AUDIO STATUS Icon', the 'AUDIO PAUSED/AUDIO OFF Indicator', and acoustically indicated by the 'AUDIO OFF Reminder'.

Auditory alarm signals	**AUDIO Status Icon** (4.3.3)	**AUDIO PAUSED/OFF Indicator** (4.1.5)	**AUDIO OFF Reminder** (4.1.6)
ON		OFF	OFF
PAUSED for 1 or 2 minutes (activated by briefly pressing 'AUDIO PAUSED/OFF Button')		Constant ON	OFF
OFF (if activated by pressing 'AUDIO PAUSED/OFF Button' > 3 seconds)		Flashing	ON*
OFF (if activated by setting menu parameter 'Alarm Volume' to OFF)		OFF	ON*

Table 30 Operating Status of auditory alarm signals

***Note:** The menu parameter 'AUDIO OFF Reminder' (Table 49) can be set to OFF only if the Responsible Organization enabled operator access to this menu parameter within a password protected area of V-STATS™.

WARNING: If an alarm condition occurs while the auditory alarm is paused or permanently switched off, the only alarm indication will only be visual and no alarm tone will sound.

WARNING: Verify that the alarm volume is adjusted such that the alarm signals are clearly audible for the operator in the intended environment.

WARNING: Do not disable the audible alarm function or decrease the audible alarm volume if the patient's safety could be compromised.

WARNING: The nurse call feature (5.4.2) is inactive whenever the auditory alarm signals are PAUSED or OFF.

Note: If the 'Remote monitoring interrupted' alarm condition (4.3.5) is triggered while the SDM's alarm system is in the AUDIO OFF state, the SDM will terminate the AUDIO OFF state. If the AUDIO OFF state was activated by pressing the AUDIO PAUSED/OFF Button > 3 seconds, the SDM simply terminates the AUDIO OFF state. In this case, the auditory alarm signals will remain active when the 'Remote monitoring interrupted' alarm condition ceases or is terminated by the operator by pressing the 'ENTER Button'.
If the AUDIO OFF state was activated by setting the menu parameter 'Alarm Volume' to OFF this parameter will be set to the setting of the parameter 'RMI AUDIO OFF Disable Volume' (4.7.4.1) as long as the 'Remote monitoring interrupted' alarm condition is active and set to OFF again upon cessation or operator termination of this alarm condition.

WARNING: If the parameter 'RMI AUDIO OFF Disable Volume' (only adjustable within a password protected area of V-STATS™, 4.7.4.1) and the menu parameter 'Alarm Volume' (Table 37, Table 49) are both set to OFF, the AUDIO OFF state of the SDM will not be terminated when the 'Remote monitoring interrupted' alarm condition is triggered. In this case no audible alarm signal may be available for the corresponding SDM/patient (e.g. if the V-CareNeT™ Central Station is switched off, defective or in the AUDIO OFF state).

4.4.4 Alarm Condition Delays and Alarm Signal Generation Delay

IEC 60601-1-8 defines 'Alarm Condition Delay' as the time from the occurrence of a triggering event either in a) the patient, for physiological alarm conditions, or b) in the equipment, for technical alarm conditions, until the alarm system detects an alarm condition. It furthermore defines 'Alarm Signal Generation Delay' as the time from the onset of an alarm condition to the generation of the associated alarm signal(s).

Alarm Signal Generation Delay
Within the SDM, the 'Alarm Signal Generation Delay' is < 2 s applies to all alarm conditions, i.e. once the SDM has detected an alarm condition, the corresponding alarm signal is generated instantly. The alarm signals available at the nurse call (5.4.2) and the SDM's communication interfaces (serial, LAN) are activated during an alarm condition with a delay of max. 2 seconds. For delays until the alarm signal is activated on an external (remote) instrument that is connected to the SDM, please refer to the respective instrument's manual/instructions for use.

Alarm Condition Delays for physiological alarm conditions
Whenever one of the SDM's physiological parameters (PCO2, PO2, SpO2, PR) violates its upper/lower alarm limit, the SDM detects an alarm condition for the respective parameter. As summarized in the following table, delays for physiological alarm conditions therefore depend on the respective parameter's response time:

Physiological Alarm Condition	Factors influencing corresponding parameter's response time at a specific measurement site	Typical Alarm Condition Delay
PCO2 low/high alarm	The response to changes in the carbon dioxide pressure in the skin at a specific measurement site depends on the selected sensor temperature and on the sensor's in-vitro PCO2 response. The slower the sensor's in-vitro PCO2 response, the longer the PCO2 alarm condition delay. **Note**: The indicated alarm condition delay corresponds to the time required to display a 10% to 90% response to a step change in either direction between a test gas containing 5% and 10% CO2. **Note**: If the SDM detects that the sensor's in-vitro PCO2 response is slow, the Status Message 'PCO2 slow' is displayed (4.3.5) and PCO2 values are subsequently marked as questionable (4.2.3.8). **Note**: If 'Sensor problem 11' (PCO2 too slow, 4.3.6) occurs, a low priority alarm sounds, the Status Message 'Sensor problem 11' appears and sensor calibration is inhibited/aborted. PCO2 values are subsequently marked as invalid (4.2.3.8).	< 75 sec (V-Sign™ Sensor 2) < 80 sec (OxiVenT™ Sensor) < 120 sec (if Status Message 'PCO2 slow' is displayed)
PO2 low/high alarm	The response to changes in the oxygen pressure in the skin at a specific measurement site depends on the selected sensor temperature and on the sensor's in-vitro PO2 response. The slower the sensor's in-vitro PO2 response, the longer the PO2 alarm condition delay. **Note**: The indicated alarm condition delay corresponds to the time required to display a 10% to 90% response to a step change in either direction between a test gas containing 6% and 12% O2. **Note**: If 'Sensor problem 74' (PO2 too slow, 4.3.6) occurs, a low priority alarm sounds, the Status Message 'Sensor problem 74' is displayed and sensor calibration is inhibited/aborted. PO2 values are subsequently marked as invalid (4.2.3.8).	< 150 sec (OxiVenT™ Sensor)

Physiological Alarm Condition	Factors influencing corresponding parameter's response time at a specific measurement site	Typical Alarm Condition Delay
SpO2 low/high alarm	The response to changes in oxygen saturation of the arterial blood present at a specific measurement site depends on the menu item 'SpO2 Averaging' (Table 42). The longer the averaging time, the slower the SDM's response to changes in saturation and, hence, the longer the SpO2 alarm condition delay, e.g. to detect desaturations.	Typically 5 sec, but < 10 sec (if 'SpO2 Averaging' = 2 sec) Typically 32 sec, but < 40 sec (if 'SpO2 Averaging' = 32 sec)
PR low/high alarm	The response to changes in the pulse rate at a specific measurement site is determined by the PR averaging time, which is set to 10 seconds.	Typically 10 sec, but < 20 sec

Table 31 Alarm Condition Delays for physiological alarm conditions

Note: The response of transcutaneous PCO2/PO2 and SpO2 measurements to respiratory events such as hyper-/ hypoventilation or apnea depend on the blood circulation time from the pulmonary alveoli to a specific measurement site, i.e. on the distance between the pulmonary alveoli to a specific measurement site and the blood flow/velocity. In patients with poor peripheral perfusion, the blood perfusion time between the pulmonary alveoli and the finger or toe is one to two minutes longer than between the pulmonary alveoli and central sites such as the forehead, cheek or earlobe.

Note: The SDM's data update period for physiological parameters (PCO2, PO2, SpO2, PR) is 1 sec and cannot be changed by the operator. The response time of physiological parameters and, hence, the alarm condition delay of physiological alarm conditions does not depend on the data update period.

Alarm Condition Delays for technical alarm conditions

With the exception of the following alarm conditions, alarm condition delays of all technical alarm conditions are < 5 seconds:

Technical Alarm Condition	Typical Alarm Condition Delay
Sensor off patient (↲)	V-Sign™ Sensor, OxiVenT™ Sensor: < 10 sec

Table 32 Alarm Condition Delays > 5 sec for technical alarm conditions

4.5 Power Supply

4.5.1 Operation on AC Power

If the SDM is connected to AC power, the AC power/battery indicator (4.1.1, 4.1.5) is lit and provides color coded information about the charging status of the battery:

green: Connected to AC power, battery not charging (either because battery is fully charged or charging is paused because of high temperature)

yellow: Connected to AC power, battery charging

LED off: Not connected to AC power (i.e. powered by internal battery)

Note: If the AC power/battery indicator is not lit while the SDM is connected to AC power, check the power cord, accessible fuses and the AC power outlet.

Note: The SDM automatically adapts to the applicable local voltage (100 –240V~ (50/60 Hz)).

Note: Whenever the SDM is connected to AC power, its internal battery is being charged. Therefore, it is recommended that the SDM remains connected to AC power when not in use. This will ensure a fully charged battery whenever it is needed

4.5.2 Operation on Internal Battery

WARNING: Dispose of battery in accordance with local requirements and regulations.

The SDM has an internal Li-Ion battery that can be used to power the SDM during transport or when AC power is not available. When the SDM is running on battery, the AC power/battery indicator is OFF (4.1.1, 4.1.5). The 'Battery' Icon (4.3.2) in the Status Bar informs about the approximate remaining battery capacity (%).

Note: A new, fully charged battery provides at least 6 hours (if Sleep Mode=OFF or Auto) and up to 13 hours (if Sleep Mode=ON) of operating/monitoring time, depending on the SDM's display type. For example, for an SDM with an LED Backlight display a new, fully charged battery will provide up to 10 hours of monitoring time if Sleep Mode=OFF or Auto, and up to 12 hours of monitoring time if Sleep Mode=ON.

Note: The display type of the respective SDM is indicated on the POST screen (4.2.2, 4.6) and in the sub-menu 'System Settings/Display Settings'.

If the SDM is **not** connected to AC power and the battery level is < 10% (i.e. if 30 or fewer minutes of operating/monitoring time is available on the existing battery charge), the 'Battery Icon' (4.3.2) is highlighted yellow, the message 'Battery low' is displayed in the status bar (Figure 8) and a low priority alarm signal begins to sound. Plugging the monitor into AC power will silence the auditory alarm and the message 'Battery low', but the 'Battery Icon' will stay highlighted yellow as long as the battery level is < 10%.

When the battery level is critical (irrespective of whether the SDM is connected to AC power or not) the 'Battery Icon' (4.3.2) is highlighted red and the message 'Battery critical' is displayed in the Status Bar (Figure 8). If the monitor is **not** connected to AC power, a medium priority alarm signal additionally sounds and 3 or fewer minutes remain until the SDM shuts down. Plugging the monitor into AC power will silence the auditory alarm, the message 'Battery critical' is still displayed as long the battery level is critical.

The SDM cannot operate with a fully discharged battery. Before turning on an SDM whose battery charge has been completely depleted, it is recommended to first plug the SDM into an AC outlet to allow the battery to charge for a few minutes. The monitor may then be powered on. To charge a low or dead battery, connect the monitor to AC power. Recharging the battery takes approximately 7 hours. 80% of the battery capacity is available after approximately 5 hours of charging.

Note: It is recommended that Sentec authorized service personnel checks and – if needed – replaces the internal battery every 24 months. Replaced batteries should be disposed of in accordance with local ordinances.

Note: As the battery is used and recharged over a period of time, the amount of time between the onset of the 'Battery critical' alarm and the instrument shut-off may become shorter.

4.6 Power-on Self-Test (POST)

After activation, the SDM performs a power-on self-test (POST), which tests the SDM's circuitry and functions (internal test). Furthermore, various SDM indicators and the display are activated in the following sequence:

4.6.1 Test of visual LED Indicators

During the POST, the SDM activates the visual LED indicators (4.1.5) on its front panel (4.1.1) as described in the following table.

Note: The AC Power/Battery Indicator is not activated during the POST if the SDM is **not** connected to AC power when turning on the SDM.

SDM connected to AC Power (assuming fully charged battery)	**SDM not connected to AC Power**
1. AC Power/Battery Indicator changes from green to orange 2. ON/OFF Indicator is briefly activated (flashing) and then deactivated again 3. ON/OFF Indicator and AUDIO PAUSED/OFF Indicator are activated 4. AUDIO PAUSED/OFF Indicator is deactivated 5. AC Power/Battery Indicator changes from orange to green	1. ON/OFF Indicator is briefly activated (flashing) and then deactivated again 2. ON/OFF Indicator and AUDIO PAUSED/OFF Indicator are activated 3. AUDIO PAUSED/OFF Indicator is deactivated

Table 33 POST – Test of visual LED Indicators

WARNING: Do not use the SDM if the visual LED indicators are not activated during the POST as described above. Instead, contact qualified service personnel or your local Sentec representative

4.6.2 Loudspeaker Test

The loudspeaker test consists of three auditory signal tones of 0.2 seconds (to test the SDM's speaker, 4.1.6) and takes place at the beginning of the POST. Verify the sound.

Note: The volume of the auditory POST signal is not adjustable and corresponds to the volume of auditory alarm signals if set to "4".

WARNING: The auditory POST signal functions as an auditory confirmation that the SDM's speaker is performing properly. Do not use the SDM if the speaker does not function, as in this case auditory alarm signals cannot be heard. Instead, contact qualified service personnel or your local Sentec representative.

WARNING: Verify that the alarm volume is adjusted such that the alarm signals are clearly audible for the operator in the intended environment.

WARNING: Ensure that the speaker is clear of any obstructions. Failure to do so could result in an inaudible alarm signal.

4.6.3 Display Test

The display of the SDM starts and the POST screen (Figure 3) is displayed. Control the display for inactive pixels during the POST (the display background should be uniformly grey to dark grey).

Note: The SMB software version is displayed in the lower right of the POST screen. Software version numbers are usually needed when calling qualified service personnel or your local Sentec representative. Write down the software version number and have it available prior to requesting technical assistance (Table 58).

Note: If the SDM is operated on internal battery, the operating/monitoring time is significantly affected by the type of the SDM's display backlight (4.5.2).

If the SDM did detect an internal problem, the message 'failed' and a corresponding error code (4.3.7) are displayed on the POST screen (Figure 3).

WARNING: Do not use the SDM if the display of the SDM was not activated or if an internal problem was detected during the POST (display of the message 'failed' with corresponding error code (4.3.7) on POST screen (Figure 3)). Instead, contact Sentec authorized service personnel or your local Sentec representative.

If no problems are detected during the POST, the message 'passed' is displayed and after about 5 to 10 seconds the SDM switches

- to one of the currently available measurement screens (4.2.3) if the SDM is configured in 'Basic' Mode (4.7.2) or if the settings from LAST use and those of the selected 'Standard Profile' are identical when the SDM is configured in 'Institutional Mode' (4.7.3).
- to the sub menu 'Profiles' (Figure 9) if the settings from LAST use and those of the selected 'Standard Profile' are different when the SDM is configured in 'Institutional Mode' (4.7.3).

After the POST, check the date/time settings of the SDM and – if necessary – adjust them in the menu of the SDM or by using V-STATS™.

WARNING: Sentec TC Sensors extrapolate from the date and time provided by the SDM when a membrane change is mandatory. It is the user's responsibility to set the date/time of the SDM to the correct values. and it is recommended that the user does so before a Sentec TC Sensor is connected and that the date/time settings are not changed while the sensor remains connected. Since a Sentec TC Sensor can be transported from one SDM to another, having discrepancies in the date/time settings between monitors may cause unexpected membrane change requests. To eliminate this possible problem, all monitors within an institution should be set to the same date/time.

4.6.4 Detection of 'Low watch battery' events

If the voltage of the SDM's internal watch battery falls below a critical level while the SDM is switched off, the SDM's real-time clock will lose its date/time setting. When subsequently switching on an SDM, the date/time of the SDM will be set to 2000-01-01 00:00:00.

If the watch battery is still low when switching on the SDM, the SDM will shortly display the Power-On Self-Test (POST) screen, followed by this information text in yellow (only in English):

> *The Watch Battery is low and the date/time setting of the SDM therefore may be wrong. Contact a Sentec authorized service technician or your local sales representative to change the Watch Battery as soon as possible. Meanwhile you may continue to use the SDM provided that you set the date/time to the correct value. Press ENTER to access the date/time menu.*
>
> *Note: Changing date/time will delete the trend data stored in the internal memory. Prior to changing date/time it is possible to download trend data using V-STATS™ (PC based software of the SDM).*

This text informs the user that the Watch Battery is low and therefore should be replaced as soon as possible. The user may, however, continue to use the SDM if it is ensured that date/time are set to the correct values. Once the user has set the date/time of the SDM in the menu or via V-STATS™, the SDM starts full operation (serial online protocols are enabled). Unless hidden by higher ranked messages, the information message 'Watch Battery Low' will be continuously displayed in the Status Bar to remind the user that the watch battery must be replaced as soon as possible.

If the watch battery is again above the critical level when switching on the SDM (e.g. after having replaced the watch battery), the SDM will shortly display the Power-On Self-Test (POST) screen and then activate the date/time menu and display the low priority alarm message 'Set Date/Time'.

Note: As long as the user has not yet set date/time, the online outputs of all supported protocols (Philips Vuelink/Intellibridge I+II, Spacelabs Flexport, TCB, SentecLink Online) are deactivated. Access to trend data, however, is possible, i.e. trend data can be printed or downloaded with V-STATS™.

Note: The trend data stored in the internal memory of the SDM **are cleared** when the date/time of the SDM are changed.

Note: It is also possible to set the date/time by using V-STATS™. If you want to download the trend data with V-STATS™, first download the data and then set the date/time.

4.7 SDM Configuration - Profiles & Parameters

4.7.1 Introduction

The SDM is highly configurable and versatile (2.1). SDMs with software version SMB SW-V08.xx. support two different sensor types (**Fehler! Verweisquelle konnte nicht gefunden werden.**), are available with/without 'VOM'-option (4.13.3)), and either provide continuous monitoring or Ventilation Spot Checks if operated in V-Check™ Mode (4.13.2). Furthermore, numerous adjustable parameters (4.7.4) permit to optimally adapt the SDM to the specific needs of varying clinical settings.

Within a password-protected area of V-STATS™, the Responsible Organization can pre-configure SDMs via serial connection. It is possible (**A**) to configure all safety relevant parameters (4.7.4.1) as well as all menu parameters (4.7.4.2) of the connected SDM on an individual basis and (**B**) to select the '**Profile Mode**' of the connected SDM, either 'Basic' (4.7.2) or 'Institutional' (4.7.3). In 'Institutional Mode', the Responsible Organization furthermore, can store up to 4 'SDM Profiles' on the connected SDM and select one of these profiles as a 'Standard Profile'.

Note: V-STATS™ displays parameters that are only accessible within V-STATS™ in bold font. **Bold black** font is used for parameters that are part of profiles, **blue bold** font for parameters that are not part of profiles. Parameters that are accessible in the menu of the SDM and within V-STATS™ are displayed within V-STATS™ in plain font. Black plain font is used for parameters that are part of profiles, blue plain font for parameters that are not part of profiles.

In the menu of the SDM, the operator during subsequent use can configure all menu parameters (4.7.4.2) on an individual basis at the bed-side. Thereby, operator access to certain menu parameters can be disabled or restricted by the Responsible Organization (4.7.4.1) or, depending on the specific context, by the SDM itself. If the SDM is used in 'Institutional Mode' (4.7.3), the operator can restore the selected 'Standard Profile' or select/activate one of the other profiles stored in the SDM in the sub menu 'Profiles' (Figure 9, Table 50) at any time. This sub-menu is easily accessible via a shortcut in the Quick Access Menu (4.2.5.3, Figure 7) if the sensor is in the Docking Station. Furthermore, if at power-up of the SDM the settings from previous use are different from those of the 'Standard Profile', the sub-menu 'Profiles' is automatically activated, thereby offering the option to restore the 'Standard Profile', to select another 'Profile', or to keep the modified profile.

Note: After manufacturing, all adjustable parameters of the SDM are preset to factory defaults, i.e. the SDM's factory configuration is active.

Note: Within a password protected area of V-STATS™, the Responsible Organization can restore the 'Default SDM Profile' (i.e. reset all parameters that are included in 'SDM Profiles' to factory defaults) or the SDM's factory configuration at any time (i.e. reset all parameters of the SDM to factory defaults).

4.7.2 Profile Mode: 'Basic Mode'

4.7.2.1 Preconfiguring SDMs in 'Basic Mode'

Within a password protected area of V-STATS™ the Responsible Organization in 'Basic Mode' can, **via serial connection**, pre-configure all safety relevant parameters (4.7.4.1) as well as all menu parameters (4.7.4.2) of the connected SDM on an individual basis.

Note: Safety relevant parameters cannot be changed in the menu of the SDM. Several of these parameters permit to disable or restrict operator access to certain menu parameters. Examples include the restriction of the 'Selectable Sensor Temperature Range', or enabling/disabling the possibility to switch-off the 'AUDIO OFF Reminder' in the menu of the SDM (4.7.4.1).

Note: To pre-configure a SDM in Basic Mode it is recommended to first select the 'SDM Profile' available in V-STATS' internal 'SDM Profiles Database' which best fits the specific needs of the intended clinical setting, to set the current settings of the SDM to the settings of this profile, and then to adjust individual settings as needed.

Note: In 'Basic Mode' no 'SDM Profiles' can be stored on the SDM. In 'Basic Mode' the sub-menu 'Profiles' (Figure 9, Table 50), consequently, is not accessible and no profile name will display on the 'Ready for use/Calibration' screens (4.2.4) and in the main menu (Table 36).

4.7.2.2 Using SDMs at the bed side in 'Basic Mode'

In 'Basic Mode' the operator can modify all currently accessible menu parameters (4.7.4.2) on an individual basis at the bed side. At power-up, the SDM simply maintains the parameter settings from previous use.

Note: Operator access to certain menu parameters or functions may be disabled or restricted by the Responsible Organization (4.7.2.1). The 'AUDIO OFF Reminder', for example, cannot be switched off, if operator access to this parameter is not granted (4.7.4.1). Depending on the specific context operator access to certain menu parameters can also be disabled or restricted by the SDM itself.

Note: In 'Basic Mode' the 'SpO2 Low Limit' (Table 37) will be set to 85% at power-up of the SDM if the 'SpO2 Low Limit' was below 85% when switching off the SDM.

4.7.3 Profile Mode: 'Institutional Mode'

4.7.3.1 Preconfiguring SDMs in 'Institutional Mode'

Within a password protected area of V-STATS™ the Responsible Organization in 'Institutional Mode' can, **via serial connection**,

(**A**) pre-configure all safety relevant parameters (4.7.4.1) as well as all menu parameters (4.7.4.2) of the connected SDM on an individual basis; and

Note: Safety relevant parameters cannot be changed in the menu of the SDM. Several of these parameters permit to disable or restrict operator access to certain menu parameters. Examples include the restriction of the 'Selectable Sensor Temperature Range', or enabling/disabling the possibility to switch-off the 'AUDIO OFF Reminder' in the menu of the SDM (4.7.4.1).

(**B**) store up to 4 'SDM Profiles' on the connected SDM and select one of these profiles as 'Standard Profile'.

Note: An 'SDM Profile' is a file which contains a specific setting for all parameters of the SDM such as the parameters 'Language', 'Profile Mode', 'Demo Mode', 'Patient ID' as well as all parameters related to the Serial Interface and the LAN Interface. 'SDM Profiles' therefore are helpful to ensure that all SDMs within the institution operate in the same setting.

Note: Upon installation of or upgrade to V-STATS 4.10, the following write-protected 'SDM Profiles' preconfigured by Sentec and tailored to optimally fit the specific needs of varying clinical settings are stored in V-STATS' internal 'SDM Profiles Database': CRITICAL CARE, GEN. CARE FLOOR, HOME, NICU, OPERATING ROOM, PACU, SLEEP, SMB621 STYLE, V-CHECK (enabling Ventilation Spot Check), and NICU_PO2. Please refer to the document 'RF-006679 Preconfigured SDM Profiles' or use V-STATS™ to view/print all parameters included in a 'SDM Profile' and their settings in the Sentec-preconfigured 'SDM Profiles'.

Note: The Responsible Organization can customize/manage 'SDM Profiles' within V-STATS™. It is possible a) to import 'SDM Profiles' to V-STATS' 'SDM Profiles Database' (either from the SDM or from the PC), b) to export 'SDM Profiles' from the database to the PC (e.g. to exchange them with other users) as well as c) to rename, print or delete 'SDM Profiles' currently available in the database.

Note: Selecting/activating a 'Standard Profile' will set the current settings of the SDM to the settings of the selected 'SDM Profile'. To pre-configure a SDM in Institutional Mode it is therefore recommended to first select the 'SDM Profile' available in V-STATS' internal 'SDM Profiles Database' which best fits the specific needs of the intended clinical setting, to store at least this profile on the SDM and to select this profile as 'Standard Profile'. During subsequent use the operator can adjust individual settings as needed in the menu of the SDM.

4.7.3.2 Using SDMs at the bed side in 'Institutional Mode'

In 'Institutional Mode', the operator can modify all currently accessible menu parameters (4.7.4.2) on an individual basis at the bed side.

Note: Operator access to certain menu parameters or functions may be restricted by the Responsible Organization (4.7.3.1). The 'AUDIO OFF Reminder', for example, cannot be switched off, if operator access to this parameter is not granted (4.7.4.1). Depending on the specific context, operator access to certain menu parameters can also be disabled or restricted by the SDM itself.

In the sub-menu 'Profiles' (Figure 9, Table 50) – which is easily accessible via a short-cut in the Quick Access Menu if the sensor is in the 'Docking Station' (4.2.5.3, Figure 7) - the operator can at any time restore the 'Standard Profile' or select/activate therein one of the other 'SDM Profiles' stored on the SDM as 'Standard Profile'.

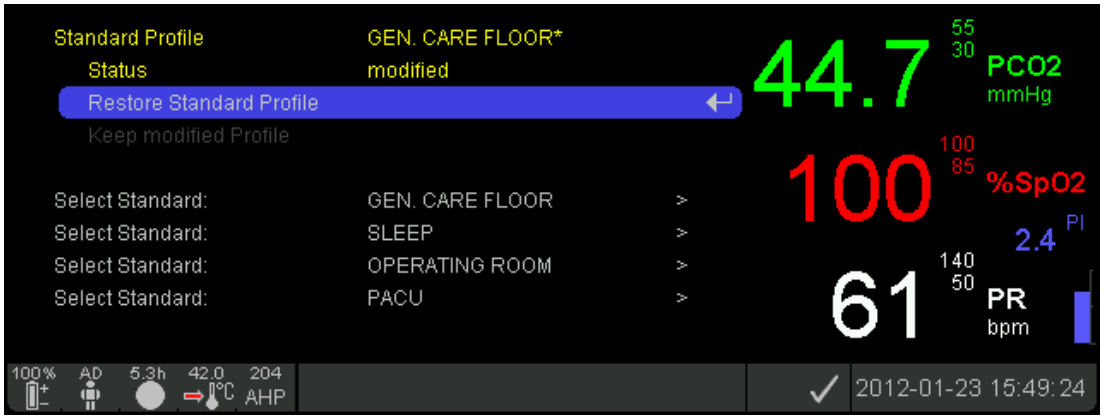


Figure 9 **Sub-menu 'Profiles'**

If at **power-up of the SDM** the settings from previous use are different from the settings of the 'Standard Profile', the sub-menu 'Profiles' automatically activates and offers the option to restore the 'Standard Profile', to keep the modified profile, or to select another 'Profile'. Please refer to Table 50 for a detailed description of the menu items contained in the sub-menu 'Profiles'.

Note: The function 'Restore Standard Profile' is only operable, if at least one current setting differs from its setting in the selected 'Standard Profile'. Otherwise, it is dimmed grey.

Note: Whenever the 'Data Recording Interval' (DRI) is changed, the trend data stored in the internal memory of the SDM are deleted. When attempting to activate a 'SDM Profile' whose DRI differs from the current DRI the message 'Confirm Clearing Trend Data' appears, requesting the operator to confirm clearing of 'Trend Data' before activating the selected 'Standard Profile' as new 'Standard Profile'.

Note: On the SDM, the name of the selected 'Standard Profile' is displayed on the 'Ready for use/Calibration' screen (4.2.4), in the main menu (Table 36), and in the sub-menu 'Profiles' (Figure 9, Table 50). An asterisk appearsbehind the profile name if at least one of the SDM's current settings differs from its setting in the selected 'Standard Profile' (an example is shown in Figure 9).

Note: In certain cases the SDM will automatically overrule the settings of certain parameters to enforce safer values or due to the capabilities of the currently selected sensor type. As a result the current settings of those parameters will differ from their settings in the selected 'Standard Profile' and, hence, an asterisk will display behind the profile name.

Note: If after power-up the SDM automatically activates the sub-menu 'Profiles', the operator cannot exit this sub-menu before he either restores the 'Standard Profile', confirms to keep the modified profile, or selects another 'Profile'.

Note: In 'Institutional Mode', the 'SpO2 Low Limit' (Table 37) will automatically be reset to 85% even if at power-up of the SDM 'Keep modified Profile' is selected and the 'SpO2 Low Limit' was below 85% in the modified profile.

Note: If the sub-menu 'Profiles' is accessed from the menu ('System Settings'/'Profiles') the menu item 'Keep modified Profile' is disabled/dimmed gray.

Note: If the SDM was reset by one of its watchdog timers, the SDM will – after rebooting – maintain the Profile from previous use.

Note: If the current settings differ from those of the selected 'Standard Profile' when disconnecting a sensor from the SDM, the SDM will automatically activate the sub-menu 'Profiles' if the **same** sensor (same type and serial number) is reconnected to the SDM after more than 30 minutes, offering the option to restore the 'Standard Profile', to keep the modified profile, or to select another 'Profile'. In this case the sub-menu 'Profiles' cannot be exited before one of the three options is selected.

Note: If a **different** sensor (different serial number or different type) is connected to the SDM, the 'Standard Profile' will be activated automatically. The setting will be matched as closely to the capabilities of the sensor as possible. If there is a remaining setting mismatch, the name of 'Current SDM Profile' will be marked with an asterisk '*' on the 'Ready for use' and 'Calibration' screens ('Current SDM Profile' - Indicator).

4.7.4 Parameters

4.7.4.1 Parameters selectable by Responsible Organization only

The following table lists the factory default setting and the ranges available for all (safety relevant) parameters, which can only be changed by the Responsible Organization within a password-protected area of V-STATS™ (4.7.2.1, 4.7.3.1).

Note: V-STATS™ displays parameters that are only accessible within V-STATS™ in bold font. **Bold black** font is used for parameters that are part of profiles, **blue bold** font for parameters that are not part of profiles.

Parameter	**Range** (Factory Default in Bold)**/Description**
AUDIO OFF selectable	Range: Enabled, **Disabled** If this parameter is disabled the operator can neither set the menu parameter 'Alarm Volume' (Table 37, Table 49) to OFF nor can he switch off auditory alarm signals by pressing the 'AUDIO PAUSED/AUDIO OFF Button' > 3 seconds (4.1.4). **Note**: If the 'Alarm Volume' is set to OFF, disabling this parameter will set the 'Alarm Volume' to its default value.
AUDIO OFF Reminder selectable	Range: Enabled, **Disabled** If this parameter is disabled the menu parameter 'AUDIO OFF Reminder' (Table 49) is set to ON and is not accessible to the operator.
Alarm Melodies	Range: **ON**, OFF Allows switching Alarm Melodies ON/OFF.
Ready for use Beep	Range: ON, **OFF** Allows switching the Ready for use Beep ON/OFF.
RMI AUDIO OFF Disable Volume	Range: OFF, 1, 2, 3, **4**, 5, 6, Rising If the 'Remote monitoring interrupted' alarm condition (4.3.5) is triggered when the menu parameter 'Alarm Volume' (Table 37, Table 49) is set to OFF, the SDM will set the menu parameter 'Alarm Volume' to the setting of the parameter 'RMI AUDIO OFF Disable Volume' as long as the 'Remote monitoring interrupted' alarm condition is active and set to OFF again upon cessation or operator termination of this alarm condition. **Warning**: If the parameter 'RMI AUDIO OFF Disable Volume' and the menu parameter 'Alarm Volume' (Table 37, Table 49) are both set to OFF, the AUDIO OFF state (Table 30) of the SDM will not be terminated when the 'Remote monitoring interrupted' alarm condition is triggered. In this case, no audible alarm signal may be available for the corresponding SDM/patient (e.g. if the V-CareNeT™ Central Station is switched off, defective or in the AUDIO OFF state).
Delta-Time (mins.)	Range: 1 – 120 minutes in steps of 1 minute (**10 minutes**)

Parameter	Range (Factory Default in Bold)/Description
	Allows adjusting the Delta-Time, which is used to calculate a parameter's 'Δx-value' (4.2.3.9), i.e. the difference between a parameter's current reading and its reading x minutes ago, where x=delta-time.
V-Check Mode selectable	Range: Enabled, **Disabled** If this parameter is disabled, the operator cannot access the sub-menu 'V-Check Settings' (Table 44) and the menu parameter 'V-Check Mode' (4.2.5.3, Table 44), is set to OFF, i.e. the V-Check™ Mode (4.13.2) cannot be switched ON at the bedside.
Max. select. Sensor Temperature (°C)	Range: 'Min. select. Sensor Temperature' – 44.5 °C in steps of 0.5 °C (**44 °C**) The operator is allowed to select the maximum 'Sensor Temperature' for Sentec TC Sensors in the menu of the SDM (4.8.2), i.e. by using this parameter it is possible to restrict the upper end of the operator-selectable 'Sensor Temperature' range. **Note**: The currently operator-selectable Sensor Temperature range is indicated with a corresponding, orange-colored information text in the sub-menu 'Temperature Settings' (Table 39). Unless further restricted by safety controls of the SDM, the upper end of the indicated range corresponds to the setting of the parameter 'Max. select. Sensor Temperature'. **Note**: The maximum Sensor Temperature supported by the SDM is: • for V-Sign™ Sensor 2: 43 °C in Neonatal Mode; 43.5 °C in Adult mode • for OxiVenT™ Sensor: 44 °C in Neonatal Mode; 44.5 °C in Adult mode **Important Note**: The 'maximum sensor-skin interface temperature' is approximately 1 °C lower than the 'sensor core temperature'. **WARNING:** To minimize the risk of erythema (skin reddening) or burns carefully read section 4.8.1 and the warnings therein.
Min. select. Sensor Temperature (°C)	Range: 37.0 – 41.5 °C (or, if smaller, Max. select. Sensor Temperature) in steps of 0.5 °C (**40 °C**) Minimal 'Sensor Temperature' the operator is allowed to select for Sentec TC Sensors in the menu of the SDM (4.8.2), i.e. with this parameter it is possible to restrict the lower end of the operator selectable Sensor Temperature Range. **Note**: The currently 'Selectable Sensor Temperature Range' is indicated with a corresponding, orange-colored information text in the sub-menu 'Temperature Settings' (Table 39). Unless modified by safety controls of the SDM, the lower end of the indicated range corresponds to the setting of the parameter 'Min. select. Sensor Temperature'. **Note**: The minimal Sensor Temperature supported by the SDM is 37 °C for the V-Sign™ Sensor 2 and for the OxiVenT™ Sensor. **Important Note**: The 'maximum sensor-skin interface temperature' is approximately 1 °C lower than the 'sensor core temperature'. **Note**: The difference between the 'Sensor Temperature' and the ambient temperature at the sensor site (e.g. in an incubator) must be at least 4 °C for V-Sign™ Sensors 2 and OxiVenT™ Sensors. **Note**: At sensor temperatures below approx. 40 °C the measured PCO2 and/or PO2 values do not reliably reflect arterial blood gases. Sentec therefore recommends that you establish and use Severinghaus correction factors (4.13.1) that are adapted to your specific target patient population if attempting to assess PaCO2 values when using sensor temperatures below 40 °C. **Note**: At sensor temperatures below 39 °C SpO2/PR readings intermittently might be switched off to maintain sensor temperature.

Parameter	Range (Factory Default in Bold)/Description
Max. select. Site Time (hrs)	Range: 0.5 – 12.0 hrs in steps of 0.5 hrs (**12 hrs**) Maximum 'Site Time' the operator is allowed to select (4.8.2). On the SDM the current setting of this parameter is indicated in the sub-menu 'Temperature Settings' (Table 39). **WARNING:** To minimize the risk of erythema (skin reddening) or burns carefully read section 4.8.1 and the warnings therein.
Site Protection selectable	Range: Enabled, **Disabled** If this parameter is disabled the menu parameter 'Site Protection' (Table 39, 4.8.5) is set to ON and is not accessible to the operator.
Initial Heating selectable	Range: Enabled, **Disabled** If this parameter is disabled the menu parameter 'Initial Heating' (Table 39, 4.8.3) is set to OFF and is not accessible to the operator.
SpO2 Averaging selectable	Range: Enabled, **Disabled** If this parameter is disabled the operator cannot change the setting of the menu parameter 'SpO2 Averaging' (Table 42).
'PCO2 In-Vivo Correction' selectable	Range: Enabled, **Disabled** If this parameter is set to OFF the sub-menu 'PCO2 In-Vivo Correction' (Table 41, 4.11) is not accessible to the operator.
'Severinghaus Correction Mode' selectable	Range: Enabled, **Disabled** If this parameter is disabled the menu parameter 'Severinghaus Correction Mode' (Table 40, 4.13.1) is set to 'AUTO' and is not accessible to the operator.
Severinghaus Temperature Correction	Range: 1.00 ... 2.00 in steps of 0.01 Allows adjusting the 'Temperature Correction Factor' (C) which is used in the Severinghaus equation (2.4.1). **Note**: Only changeable if the parameter 'Severinghaus Correction Mode' (Table 40) is set to 'Fixed'. **Note:** In 'Fixed' mode factory settings for the correction factors are M=0.00 mmHg and C=1.00. If these correction factors are used, the SDM displays uncorrected cutaneous PCO2 (PcCO2) values (2.4.1). **Note:** In 'Fixed' mode the setting of the 'Temperature Correction Factor' is displayed in the sub-menu 'PCO2 Settings' (Table 40).
Severinghaus 'Metabolic Offset'	Range (if 'mmHg'): 0.00 ... 15.00 mmHg in steps of 0.01 mmHg Range (if 'kPa'): 0.000 ... 2.000 kPa in steps of 0.001 kPa Allows adjusting the 'Metabolic Offset' (M) which is used in the Severinghaus equation (2.4.1). **Note**: Only changeable if the parameter 'Severinghaus Correction Mode' (Table 40) is set to 'Fixed'. **Note:** In 'Fixed' mode factory settings for the correction factors are M=0.00 mmHg and C=1.00. If these correction factors are used, the SDM displays uncorrected cutaneous PCO2 (PcCO2) values (2.4.1). **Note:** In 'Fixed' mode the setting of the 'Metabolic Offset' is displayed in the sub-menu 'PCO2 Settings' (Table 40).
Max. permitted Calibration Interval	Range: 1.0 – 12.0 hrs in steps of 0.5 hrs (**12 hrs**) Allows restricting the maximum 'Calibration Interval' (4.9.4). On the SDM the current setting of this parameter is indicated in the sub-menu 'PCO2 Settings' (Table 40).
Message 'Recommended Sensor Stabilization'	Range: **ON**, OFF Allows switching ON/OFF the message 'Recommended Sensor Stabilization' (4.9.5) which (if enabled) is displayed on the 'Ready for use/Calibration' screen (4.2.4) when sensor stabilization is recommended.

Parameter	Range (Factory Default in Bold)/Description
'PCO2 Calibration Curve'	Range: ON, **OFF** Allows to switch ON/OFF the display of the 'PCO2 Calibration Curve' on the 'Calibration' screen (4.2.4).
Membrane Change Interval	Range: 1 – 42 days in steps of 1 day (**28 days**) Allows to adjust the 'Membrane Change Interval' (4.10.4). On the SDM the current setting of this parameter is indicated in the sub-menu 'PCO2 Settings' (Table 40). **Note**: In default settings the 'Membrane Change Interval' is 28 days. Depending on the specific requirements of various clinical settings, it can be customized by the institution between 1 and 42 days. **Note:** Without being requested by the SDM, the sensor membrane additionally must be changed if it is damaged or missing, has a loose fit, or if there is trapped air or dry electrolyte under the membrane. Furthermore, the membrane must be changed after 'High Level Cleaning and Disinfection' of the sensor (4.10.2).
Menu Access	Range: **Enabled**, Disabled If this parameter is disabled the menu of the SDM cannot be accessed at the bed side, i.e. its configuration cannot be modified by using its menu, and, its use drastically simplifies. Disabling menu-access, therefore, can be important/helpful if you want to ensure that neither the medical personnel, the relatives of the patient, nor the patient itself (inadvertently) modify the SDM's configuration (for example if the SDM is used in home care settings or in settings with high personnel turnover). **Note:** If menu access is disabled, a long, low-pitched signal tone sounds if the button 'Menu/Previous Level' is pressed (4.1.4, 4.1.6). **Note:** Access to the 'Quick Access Menus' (4.2.5.2, 4.2.5.3) is possible even if menu-access is disabled. **Note**: Activation of the Sentec-preconfigured profile HOME will disable menu-access.
Language selectable	Range: **Enabled**, Disabled If this parameter is disabled the menu item 'Language' (Table 46) is not accessible for the operator.
Demo Mode selectable	Range: Enabled, **Disabled** If this parameter is disabled the menu item 'Demo Mode' (Table 46) is set to OFF and is not accessible for the operator.
Profile Mode	Range: **Basic**, Institutional To select the Profile Mode (4.7.1, 4.7.2, 4.7.3). **Note**: Not included in profiles
LAN selectable	Range: **Enabled**, Disabled If this parameter is disabled the menu parameter LAN (Table 53) is set to OFF and the sub-menu 'LAN Interface' (Table 53) is not accessible, i.e. communication via LAN cannot be activated by the operator. **Note**: Not included in profiles **Note**: Will be forced to 'Enabled' if the 'VOM'-option (4.13.3) is activated.
Device/Host Name	Range: Alphanumeric string of length 16 (**Sentec-SDM<SN>**) Allows adjusting the Device/Host Name of the SDM. On the SDM the current setting of this parameter is displayed in the sub-menu 'LAN Interface' (Table 53). **Note**: The Device/Hostname is the network name of the SDM, which is visible within the network (router, switches, etc.) **Note**: Not included in profiles

Parameter	Range (Factory Default in Bold)/Description
DHCP Mode	Range: **ON**, OFF Allows selecting the DHCP Mode. If DHCP Mode is set to OFF a static IP Address is used, if set to ON a dynamic IP Address is used. On the SDM the current setting of this parameter is displayed in the sub-menu 'LAN Interface' (Table 53). **Note**: Not included in profiles
IP Address	Range: nnn.nnn.nnn.nnn (e.g. **192.168.1.99**) Allows to enter the IP Address manually if DHCP Mode = OFF. The current setting of this parameter is displayed in the sub-menu 'LAN Interface' (Table 53). **Note**: Not selectable when DHCP Mode = ON **Note**: Not included in profiles
IP Port	Range: 1 ... 65535 in steps of 1 (**62768**) Allows selecting the TCP/UDP Port over which the communication will run. On the SDM the current setting of this parameter is displayed in the sub-menu 'LAN Interface' (Table 53). **Note**: Ensure that no firewall is blocking this port. **Note**: Not included in profiles
Ethernet Mode (10 Mbit/s)	Range: **Auto**, Half duplex, Full duplex The SDM supports an Ethernet network speed of 10 Mbit/s and can run in half or full duplex mode. The negotiation between the SDM and the network is usually done automatically. For certain network environments it might be required to force the SDM into a specific mode (consult your IT manager). It is therefore possible to adjust the SDM into three different modes: auto-negotiation (default and recommended setting), 10 Mbit/s half duplex and 10 Mbit/s full duplex. On the SDM the current setting of this parameter is displayed in the sub-menu 'LAN Interface' (Table 53). **Warning:** Do not change this setting if uncertain what it does, consult your IT manager first as it might have undesired effects on your network. **Note**: Not included in profiles
DNS Mode	Range: **ON**, OFF To activate/deactivate DNS Mode. In ON-mode SDM request the DNS from the DHCP-server by using the 'Fully Qualified Domain Name' (FQDN) option. In OFF-mode, the SDM uses DHCP option 12 (host name option). **Warning:** Do not change this setting if uncertain what it does, consult your IT manager first as it might have undesired effects on your network. **Note**: Not included in profiles **Note**: This parameter is not displayed on the SDM, use V-STATS™ to view its setting.
'Data Recording Interval'	Range: 1 – 8 sec in steps of 1 sec (**4 sec**) Allows adjusting the 'Data Recording Interval' (DRI), i.e. the time interval at which data are stored in the internal memory of the SDM. On the SDM the current setting of this parameter is displayed in the sub-menu Trend Data (Table 55). **Note**: The data stored in the internal memory of the SDM are deleted if the DRI is changed. **Note**: The memory capacity expressed in hours of monitoring time increases if the DRI is increased (4.12.1). **Note**: If the 'Data Recording Interval' is > 1 sec, the data are not additionally filtered prior down sampling.

Parameter	Range (Factory Default in Bold)/Description
Minimal Measurement Duration	Range: 0 – 20 min in steps of 1 min (**5 min**) Allows adjusting the Minimal Measurement Duration. The Minimal Measurement Duration defines how long a measurement must last to be accepted as a valid measurement period (4.12.3). On the SDM the current setting of this parameter is displayed in the sub-menu Trend Data (Table 55).
Patient ID	Range: -1, 0 – 254 in steps of 1 (**-1**) Allows adjusting the 'Patient ID'. The 'Patient ID' that is active on the SDM at the beginning of a new measurement period, will be assigned to this measurement period. During a running patient measurement the 'Patient ID' cannot be changed. On the SDM the current setting of this parameter is displayed in the sub-menu Trend Data (Table 55). **Note**: Not included in profiles
Ranges for PCO2 Histogram	Range (if 'mmHg'): At least 2 values (1 range) and at most 8 values (7 ranges) within 0.1 – 200 mmHg (**200, 100, 85, 70, 55, 40, 25, 0.1 mmHg**) Range (if 'kPa'): At least 2 values (1 range) and at most 8 values (7 ranges) within 0.01 – 26.67 kPa (**26.67, 13.33, 11.33, 9.33, 7.33, 5.33, 3.33, 0.01 kPa**) Allows adjusting the ranges for the PCO2 Histogram. The histogram represents the percental duration the PCO2 readings were within the specified ranges. The PCO2 Histogram is visualized on the Trend Data Statistics Screen (Figure 12) as well as on the Print outs (4.12.5, 4.12.5.3). **Note**: All values but the last represent the upper value of a histogram range.
Ranges for SpO2 Histogram	Range: At least 2 values (1 range) and at most 8 values (7 ranges) within 1 – 100 % (**100, 96, 92, 88, 84, 80, 76, 1%**) Allows adjusting the ranges for the SpO2 Histogram. The histogram represents the percental duration the SpO2 readings were within the specified ranges. The SpO2 Histogram is visualized on the Trend Data Statistics Screen (Figure 12) as well as on the Print outs (4.12.5, 4.12.5.3). **Note:** All values but the last represent the upper value of a histogram range.
Ranges for PR Histogram	Range: At least 2 values (1 range) and at most 8 values (7 ranges) within 30 – 250 bpm (**250, 210, 180, 150, 120, 90, 60, 30 bpm**) Allows adjusting the ranges for the PR Histogram. The histogram represents the percental duration the PR readings were within the specified ranges. The PR Histogram is visualized on the Trend Data Statistics Screen (Figure 12) as well as on the Print outs (4.12.5, 4.12.5.3). **Note:** All values but the last represent the upper value of a histogram range.

Table 34 Parameters selectable by Responsible Organization only

4.7.4.2 Operator selectable parameters/Description of all menu items

The SDM's 'Main Menu' can be opened by pressing the 'Menu' button (4.1.4) and provides access to all sub-menus and all operator accessible menu parameters/functions therein. Pressing the 'ENTER Button' when the menu is not open, furthermore, opens one of the two available 'Quick Access Menus' (different context driven menus when sensor is inside or outside of 'Docking Station', 4.2.5.2, 4.2.5.3).

Note: Menu access can be disabled by the Responsible Organization within a password-protected area of V-STATS™ (4.7.4.1), e.g. for use in home healthcare environments. If menu access is disabled access to the 'Quick Access Menus' is still possible.

Note: If a menu screen or the 'Review Trend Data Screen' (Figure 11) is open during patient monitoring the SDM will automatically return to the last active 'Measurement screen' if no button is pressed during 2 minutes. The 'Trend Data Statistics Screen' (Figure 12) and the 'V-Check Results Screen' (Figure 15), in contrast, will remain active in this situation.

Navigation in the menu

A blue, underlying bar highlights the currently selected menu item (Table 19, Table 20). Use the Control Buttons to navigate in the menu (4.1.4). Use the 'Up/Down Arrow' to move the blue bar, i.e. to select a different menu item. Press the 'ENTER Button' to activate the selected menu item, i.e. to activate 'editing mode' for the selected parameter, to activate execution of the selected function, or to access the selected sub-menu. Press the 'ENTER Button', the 'Menu/Previous Level Button' or the 'Display Button' to deactivate 'editing mode' for the selected menu-parameter. Press the 'Menu/Previous Level Button' to go to the next higher menu level. Press the 'Display Button' to directly exit the menu from any menu level.

Note: Changes made (by using the 'UP/DOWN Buttons') to parameters that are highlighted with a **blue** menu bar in 'editing mode' (Table 20) become immediately effective (i.e. no confirmation is required). Those parameters that are highlighted with a **yellow** menu bar in 'editing mode', changes must be confirmed by pressing the 'ENTER Button' before they become effective. To cancel changes/deactivate 'editing mode', use the 'Menu/Previous Level Button' or the 'Display Button'.

Note: A general description of the 'Menu screen' and an example of a 'Menu screen' is provided in section 4.2.5.1. The navigation symbols on the right of each menu item are explained in Table 20.

Menu hierarchy (Main-Menu and sub-menu, without Quick Access Menus)

The SDM's menu hierarchy is outlined in Table 35 below.

Note: Table 35 only lists the main menu and the various sub-menus. Individual menu items such as parameters or functions are not listed in Table 35. The individual menu items are listed in Table 36 to Table 58.

1st menu level	2nd menu level	3rd menu level	4th menu level
Main Menu	Alarm Settings	--	--
	Measurement Settings	Temperature Settings	--
		PCO2 Settings	'PCO2 In-Vivo Correction'--
		SpO2/PR Settings	--
		PO2 Settings	--
		V-Check Settings	
	Membrane Change	--	--
	System Settings	Date/Time	--
		Display Settings	--
		Audio Settings	
		Profiles	--
	Interfaces	Serial Interface	--
		LAN Interface	--
		Analog Outputs	--
	Trend Data	Review/Print Trend Data	'Review Trend Data Screen' and 'Trend Data Statistics Screen' OR 'V-Check Results Screen'
	System Information	2nd System Information Page	--

Table 35 Menu hierarchy (Main menu and sub-menus)

The following tables list all menu items contained in the 'Main Menu' (Table 36) and the various sub-menus (Table 37 to Table 58). The type of each menu item (access to sub-menu, function, parameter, or information) is identified and for each operator adjustable parameter its factory default setting and selectable range are indicated.

Note: Refer to 4.2.5.2 and 4.2.5.3 for a description of the menu items contained in the two Quick Access Menus.

Note: With the exception of the parameter 'Demo Mode' all operator selectable parameters maintain their setting from previous use upon power-cycle in 'Basic Mode' (4.7.2) and are storable in the institution's 'Standard Profile' (4.7.3).

Note: Operator-changeable parameters/functions (4.7.4.2) that are currently changeable/accessible are displayed in 'white', otherwise dimmed in 'grey'. Menu items shown in 'Orange' correspond to (safety relevant) parameters that are only changeable by the Responsible Organization (4.7.4.1). General information (e.g. recommendations) is displayed in 'Yellow'.

Note: V-STATS™ displaysis displayedparameters that are accessible in the menu of the SDM and within V-STATS™ in plain font. Black plain font is used for parameters that are part of profiles, blue plain font for parameters that are not part of profiles.

Main Menu (1st menu level)

Menu Item	**Type/Range** (Factory Default in Bold)/**Description**
Alarm Settings	Type: Access to respective sub-menu (Table 37)
Measurement Settings	Type: Access to respective sub-menu (Table 38)
Membrane Change	Type: Access to respective sub-menu (Table 45) Not accessible (dimmed gray) if the sensor is 'On Patient', in the 'Docking Station', if the parameter PCO2 is disabled, or if no sensor is connected.
System Settings	Type: Access to respective sub-menu (Table 46)
Interfaces	Type: Access to respective sub-menu (Table 51)
Trend Data	Type: Access to respective sub-menu (Table 55)
System Information	Type: Access to respective sub-menu (Table 57)
Standard Profile	Type: Yellow Information Text In Institutional Mode this indicator displays the name of the currently selected 'Standard Profile', e.g. 'Sleep' (4.7.3). An asterisk ('*') is displayed behind the profile name (e.g. 'SLEEP*') if at least one of the SDM's current settings differs from its setting in the selected 'Standard Profile' (an example is shown in Figure 9).
Patient Info	Type: Orange Information Text During remote monitoring with and if enabled within V-CareNeT™ the 'Patient Info' (the patient's name, a comment or the patient number) being displayed in the corresponding station's remote monitoring window is duplicated in the SDM's main menu. **Note**. The 'Patient Info' is also duplicated on the 'Ready for use/Calibration' screen (4.2.4) and - if no Status Message has to be displayed - in the SDM's status bar (Figure 8) enclosed in "[" and "]".

Table 36 Main Menu (1st menu level)

Sub-menu Alarm Settings (2nd menu level)

Menu Item	Type/Range (Factory Default in Bold)/Description
PCO2 High Limit	Type: Parameter Range (if 'mmHg'): (PCO2 Low Limit+5)...200 mmHg in steps of 1 mmHg (**50 mmHg**) Range (if 'kPa'): PCO2 Low Limit+0.6)...26.7 kPa in steps of 0.1 kPa (**6.7 kPa**) A medium priority alarm (4.4.1) is triggered if PCO2 exceeds this limit.
PCO2 Low Limit	Type: Parameter Range (if 'mmHg'): 0...(PCO2 High Limit-5) mmHg in steps of 1 mmHg (**30 mmHg**) Range (if 'kPa'): 0.0...(PCO2 High Limit-0.6) kPa in steps of 0.1 kPa (**4.0 kPa**) A medium priority alarm (4.4.1) is triggered if PCO2 is beyond this limit.
SpO2 High Limit	Type: Parameter. Range: (SpO2 Low Limit+5)...100% in steps of 1% (**100%**) A high priority alarm (4.4.1) is triggered if SpO2 exceeds this limit.
SpO2 Low Limit	Type: Parameter Range: 0...(SpO2 High Limit-5)% in steps of 1% (**85%**) A high priority alarm (4.4.1) is triggered if SpO2 is below this limit. **Note**: In 'Basic Mode' (4.7.2) the 'SpO2 Low Limit' will be set to 85% at power-up of the SDM if the 'SpO2 Low Limit' was below 85% when switching off the SDM. **Note**: In 'Institutional Mode' (4.7.3) the 'SpO2 Low Limit' will be set to 85% if at power-up of the SDM 'Keep modified Profile' is selected if the 'SpO2 Low Limit' was below 85% when switching off the SDM.
PR High Limit	Type: Parameter Range: (PR Low Limit+10)...250 bpm in steps of 1 bpm (**140 bpm**) A medium priority (4.4.1) alarm is triggered if PR exceeds this limit.
PR Low Limit	Type: Parameter. Range: 30...(PR High Limit -10) bpm in steps of 1 bpm (**50 bpm**) A medium priority alarm (4.4.1) is triggered if PR is beyond this limit.
PO2 High Limit	Type: Parameter Range (if 'mmHg'): (PO2 Low Limit+5)...800 mmHg in steps of 1 mmHg (**95 mmHg**) Range (if 'kPa'): PO2 Low Limit+0.6)...106 kPa in steps of 0.1 kPa (**12.7 kPa**) A medium priority alarm (4.4.1) is triggered if PO2 exceeds this limit.
PO2 Low Limit	Type: Parameter Range (if 'mmHg'): 0...(PO2 High Limit-5) mmHg in steps of 1 mmHg (**60 mmHg**) Range (if 'kPa'): 0.0...(PO2 High Limit-0.6) kPa in steps of 0.1 kPa (**8 kPa**) A medium priority alarm (4.4.1) is triggered if PO2 is beyond this limit.

Menu Item	Type/Range (Factory Default in Bold)/Description
Alarm Volume	Type: Parameter Range: OFF, 1, 2, 3, **4**, 5, 6, Rising To adjust the volume of auditory alarm signals, the Ready for use Beep, the PCO2/PO2 Sensitivity Test Signal, and the V-Check Completed Beep (4.1.6). **Note**: 'Rising': Starting at level 2 the Alarm Volume increases at each burst by one level. **Note**: OFF is only selectable if the Responsible Organization did enable the parameter 'AUDIO OFF selectable' (4.7.4.1). **Note**: If 'Alarm Volume'=OFF disabling the parameter 'AUDIO OFF selectable' sets the 'Alarm Volume' to its default value. **Note**: If 'Alarm Volume'=OFF when the 'Remote monitoring interrupted' alarm condition (4.3.5) is triggered the SDM will set the 'Alarm Volume' to the setting of the parameter 'RMI AUDIO OFF Disable Volume' (4.7.4.1) as long as the 'Remote monitoring interrupted' alarm condition is active and set to OFF again upon cessation or operator termination of this alarm condition. **Note**: This parameter is duplicated in the sub-menu 'Audio Settings' (Table 49).

Table 37 Sub-menu Alarm Settings (2nd menu level)

Sub-menu Measurement Settings (2nd menu level)

Menu Item	Type/Range (Factory Default in Bold)/Description
Time Range for Trends	Type: Parameter Range: 15, **30**, 60, 120 [min] 4, 8, 12, 24, 36, 48 [h] Time Range for Online Trends (4.2.3, 4.2.3.7). **Note:** The maximum selectable range is 36 hours for a 'Data Recording Interval' (4.7.4.1) of 1 sec.
Patient	Type: Parameter Range (if OxiVenT™ Sensor): Adult, **Neonatal** Range (if V-Sign™ Sensor 2): **Adult**, Neonatal Allows changing the patient type. **Note**: In 'editing mode' (Table 20) the parameter 'Patient' is highlighted with a yellow menu bar indicating that changes must be confirmed by pressing the 'ENTER Button' before they become effective. To cancel changes/deactivate 'editing mode' use the 'Menu/Previous Level Button' or the 'Display Button'. **Note**: Not accessible (dimmed gray) during patient monitoring or if the connected sensor supports only one patient type or if no sensor is connected to the SDM. **Note**: When changing the sensor type the SDM will maintain the patient type. **Note**: In 'Basic Mode' (4.7.2) changing the patient type sets the 'Sensor Temperature' and the 'Site Time' automatically to the respective default values (4.8.2). In 'Institutional Mode' (4.7.3) when changing the patient type the 'Sensor Temperature' and the 'Site Time' have to be adjusted manually by the Responsible Organization (4.8.2) as the value in the profile takes priority.

Menu Item	Type/Range (Factory Default in Bold)/Description
Enabled Parameters	Type: Parameter Range (if OxiVenT™ Sensor *in Adult Mode): '**PCO2 PO2 SpO2 PR**'; 'PCO2 PO2', 'PCO2 SpO2 PR', 'PCO2', ' SpO2 PR' Range (if OxiVenT™ Sensor *in Neonatel Mode): '**PCO2 PO2**', 'PCO2' **if used on SDM with activated PO2-option* Range (if V-Sign™ Sensor 2 **in Adult Mode): '**PCO2 SpO2 PR**', 'PCO2', 'SpO2 PR' Range (if V-Sign™ Sensor 2 **in Neonatel Mode): '**PCO2**' ***or if OxiVenT™ Sensor is used on SDM without activated PO2-option* Allows selecting the parameters to be monitored. **Note**: In 'editing mode' (Table 20) the parameter 'Enabled Parameters' is highlighted with a yellow menu bar indicating that changes must be confirmed by pressing the 'ENTER Button' before they become effective. To cancel changes/deactivate 'editing mode' use the 'Menu/Previous Level Button' or the 'Display Button'. **Note**: Available options depend on connected sensor type, the SDM's PO2-activation status, and the selected patient type. **Note**: Not accessible (dimmed gray) if for the current configuration only one selection is supported or if no sensor is connected to the SDM. **Note**: When changing the sensor type the SDM will set the parameter 'Enabled Parameters' to the default value of the respective sensor and patient type.
Temperature Settings	Type: Access to respective sub-menu (Table 39)
PCO2 Settings	Type: Access to respective sub-menu (Table 40) **Note**: Not accessible (dimmed gray) if PCO2 disabled or not available
SpO2/PR Settings	Type: Access to respective sub-menu (Table 42) **Note**: Not accessible (dimmed gray) if SpO2-PR disabled or not available
PO2 Settings	Type: Access to respective sub-menu (Table 43) **Note**: Not accessible (dimmed gray) if PO2 disabled or not available
V-Check Settings	Type: Access to respective sub-menu (Table 44) **Note**: Not accessible (dimmed gray) if 'V-Check Mode selectable' (4.7.4.1) is disabled.
Temperature Settings Info	Type: Yellow Information Text The following message appears: *'Verify Temperature Settings after changing patient type'*

Table 38 Sub-menu Measurement Settings (2nd menu level)

Sub-menu Temperature Settings (3rd menu level)

Note: For details, please refer to sub-section 4.8.2.

Menu Item	Type/Range (Factory Default in Bold)/Description
Recommended Sensor Temperature [°C]:	Type: Yellow Information Text Indicates the 'Sensor Temperature' recommended by Sentec for the selected patient type when using a Sentec TC Sensor. **Note**: Displays '-/-' if no sensor is connected.

Menu Item	Type/Range (Factory Default in Bold)/Description
Select. Sensor Temperature Range [°C]:	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Indicates the currently selectable Sensor Temperature range. **Note**: Not accessible (dimmed gray) during patient monitoring or if no sensor is connected. Displays '-/-' - '-/-' if no sensor is connected.
Sensor Temperature [°C]	Type: Parameter Range: Depends on the connected sensor type and the SDM's PO2-activation status (2.1), the selected Patient Type (Table 38), and the maximum and minimal selectable 'Sensor Temperature' set by the Responsible Organization (4.7.4.1). The currently selectable range is indicated in the Orange Information Text one line higher. Also see 4.8.2. Allows selecting the 'Sensor Temperature'. Selectable in steps of 0.5 °C. **Note**: When increasing the 'Sensor Temperature' a reduction of the 'Site Time' may become necessary (4.8.2). **Important Note**: The 'maximum sensor-skin interface temperature' is approximately 1 °C lower than the 'sensor core temperature'. **Note**: Not accessible (dimmed gray) during patient monitoring or if no sensor is connected. Displays '-/-' if no sensor is connected. **Note**: The difference between the 'Sensor Temperature' and the ambient temperature at the sensor site (e.g. in an incubator) must be at least 4 °C for V-Sign™ Sensors 2 and OxiVenT™ Sensors. **Note**: At sensor temperatures below approx. 40 °C the measured PCO2 and/or PO2 values do not reliably reflect arterial blood gases. Sentec therefore recommends that you establish and use Severinghaus correction factors (4.13.1) that are adapted to your specific target patient population if attempting to assess PaCO2 values when using sensor temperatures below 40 °C. **Note**: At sensor temperatures below 39 °C SpO2/PR readings intermittently might be switched off to maintain sensor temperature. **WARNING:** To minimize the risk of erythema (skin reddening) or burns carefully read section 4.8.1 and the warnings therein.
Recommended Site Time [hrs]:	Type: Yellow Information Text Indicates the 'Site Time' recommended by Sentec for the selected patient type and 'Sensor Temperature'. - Adult Mode: **12h** (T ≤ 41.5 °C); **8h** (42 °C ≤ T ≤ 42.5 °C); **4h** (43 °C ≤ T ≤ 43.5 °C); **2h** (44 °C ≤ T ≤ 44.5 °C) - Neonatal Mode: **12h** (T ≤ 40.5 °C); **8h** (41 °C ≤ T ≤ 41.5 °C); **4h** (42 °C ≤ T ≤ 42.5 °C); **2h** (T = 43 °C); **1h** (43.5 °C ≤ T ≤ 44 °C) **Note**: Displays '-/-' if no sensor is connected.
Max. select. Site Time [hrs]:	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Indicates the maximum currently selectable 'Site Time'.

Menu Item	Type/Range (Factory Default in Bold)/Description
Site Time [hrs]	Type: Parameter Range: Depends on the selected Patient Type (Table 38), and Sensor Temperature as well as the 'Maximal Selectable Site Time' set by the Responsible Organization (4.7.4.1). Allows selecting the 'Site Time'. Selectable in steps of 0.5 hrs. **Note**: When increasing the 'Site Time' a reduction of the 'Sensor Temperature' may become necessary (4.8.2). **Note**: Not accessible (dimmed gray) if 'Site Time' has elapsed for more than 30 minutes or if no sensor is connected. Displays '-/-' if no sensor is connected. **WARNING:** To minimize the risk of erythema (skin reddening) or burns carefully read section 4.8.1 and the warnings therein.
Site Protection	Type: Parameter Range: **ON**, OFF Safety feature which in ON mode reduces sensor temperature (if > 41 °C for adults or > 40 °C for neonates) once the 'Site Time' has elapsed for more than a predefined time (4.8.5). **Note**: Not accessible (dimmed gray) and set to ON if Responsible Organization did disable parameter 'Site Protection selectable' (4.7.4.1).
Initial Heating	Type: Parameter Range: ON, **OFF** Feature which in ON mode temporarily increases the sensor temperature in the beginning of the monitoring period for faster site perfusion and faster results (4.8.3). **Note**: Not accessible (dimmed gray) and set to OFF if Responsible Organization did disable parameter 'Initial Heating selectable' (4.7.4.1).
Heating Power Mode	Type: Parameter Range: Absolute, **Relative**, OFF To select the Heating Power Mode (4.8.6).
RHP Trendgraph Range [mW]	Type: Parameter Range: -10 – 10; **-20 – 20**; -50 – 50; -90 – 90; To select the range (y-axis) for the RHP Online Trend (4.2.3, 4.2.3.7).

Table 39 Sub-menu Temperature Settings (3rd menu level)

Sub-menu PCO2 Settings (3rd menu level)

Note: The sub-menu PCO2 Settings is not accessible if PCO2 is disabled.

Menu Item	Type/Range (Factory Default in Bold)/Description
PCO2 Trendgraph Range	Type: Parameter Range (if 'mmHg'): 10-50, 25-55, **25-75**, 35-100, 60-140, 75-200, 120-200, 0-75, 0-100, 0-200 mmHg Range (if 'kPa'): 1.5-7.0, 3.5-7.5, **3.5-10.0**, 4.5-15.0, 8-18.0, 10.0-27.0, 16.0-27.0, 0-10.0, 0-15.0, 0-27.0 kPa To select the range (y-axis) for the PCO2 Online Trend (4.2.3, 4.2.3.7).

Menu Item	Type/Range (Factory Default in Bold)/Description
PCO2 In-Vivo Correction	Type: Access to respective sub-menu (Table 41) **Note**: Not accessible (dimmed gray) if Responsible Organization did disable the parameter 'PCO2 In-Vivo Correction selectable' (4.7.4.1). **Note**: This sub-menu-access is duplicated in one of the two Quick Access Menus (4.2.5.2, Figure 6).
Calibrate Sensor	Type: Function To activate a sensor calibration manually (4.9.3). **Note**: This function is dimmed gray (not accessible) if a calibration is not possible (sensor is outside the 'Docking Station' or due to technical reasons). **Note**: This function is duplicated in one of the two Quick Access Menus (4.2.5.3, Figure 7). **Note**: If enabled, PO2 is also calibrated during calibrations that are activated with the menu-function 'Calibrate Sensor'.
Sensitivity Test	Type: Function To activate a 'PCO2 sensitivity test' manually (4.9.7). **Note**: This function is dimmed gray (not accessible) if a 'PCO2 sensitivity test' is not possible (sensor is outside the 'Docking Station' or due to technical reasons). **Note**: If PO2 is enabled a 'PO2 Sensitivity Test' (Table 43) is made concurrently.
Severinghaus Correction Mode	Type: Function Range: **'Auto'**, 'Fixed' To select the mode that is used for 'Temperature Correction Factor' (C) and the 'Metabolic Offset' (M) being used in the Severinghaus equation (2.4.1). In 'Auto Mode' the SDM uses 'Sentec-recommended' settings for C and M and automatically adjusts these settings as a function of the selected patient type and sensor temperature. In 'Fixed Mode' the SDM uses fixed C and M settings customized by the institution in a password protected area of V-STATS™, i.e. in fixed mode these values are not adjusted as a function of the selected patient type and sensor temperature (4.13.1). **Note**: Not accessible (dimmed gray) and set to 'Auto' if the Responsible Organization did disable the parameter 'Severinghaus Correction Mode selectable' (4.7.4.1).
PCO2/PO2 Unit	Type: Parameter Range: **mmHg**, kPa To select the unit for PCO2, PO2 and the barometric pressure. **Note**: This parameter is duplicated in the sub-menu 'PO2 Settings' (Table 43).
Max. permitted Calibration Interval [hrs]:	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Indicates the maximal currently permitted 'Calibration Interval' (4.7.4.1, 4.9.4).
Calibration is Due in [hrs]:	Type: Yellow Information Text. Indicates the time remaining until the 'Calibration Interval' elapses (4.9.4).
Severinghaus correction: Temp. Correction	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) If the 'Severinghaus Correction Mode' is set to 'Fixed', the current setting of the 'Temperature Correction Factor' (4.7.4.1) is displayed.
Severinghaus correction: 'Metabolic Offset'	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) If the 'Severinghaus Correction Mode' is set to 'Fixed', the current setting of the 'Metabolic Offset' (4.7.4.1) is displayed

Table 40 Sub-menu PCO2 Settings (3rd menu level)

Sub-menu 'PCO2 In-Vivo Correction' (4th menu level)

Note: The sub-menu 'PCO2 In-Vivo Correction' is not accessible if the use of 'PCO2 In-Vivo Correction' (4.11) is disabled by the Responsible Organization (4.7.4.1).

Menu Item	Type/Range (Factory Default in Bold)/Description
Current PCO2 In-Vivo Correction	Type: Yellow Information Text. For details refer to section 4.11.2.
- Date/Time	Type: Yellow Information Text. For details refer to section 4.11.2.
- Offset	Type: Yellow Information Text. For details refer to section 4.11.2.
- Reset	Type: Function. For details refer to section 4.11.2.
Press ENTER when taking ABG Sample	Type: Function. For details refer to section 4.11.2.
- Date/Time	Type: Yellow Information Text. For details refer to section 4.11.2.
- PCO2 (SDMS)	Type: Adjustable Value. For details refer to section 4.11.2.
- PCO2 of ABG Sample	Type: Adjustable Value. For details refer to section 4.11.2.
- Confirm	Type: Function. For details refer to section 4.11.2.
- Cancel	Type: Function. For details refer to section 4.11.2.

Table 41 Sub-menu 'PCO2 In-Vivo Correction' (4th menu level)

Sub-menu SpO2/PR Settings (3rd menu level)

Note: The sub-menu SpO2/PR Settings is not accessible if SpO2-PR are disabled.

Menu Item	Type/Range (Factory Default in Bold)/Description
SpO2 Trendgraph Range	Type: Parameter Range: 0-100, 50-100, **70-100**, 85-100% Range (y-axis) for the SpO2 Online Trend (4.2.3, 4.2.3.7).
PR Trendgraph Range	Type: Parameter Range: 30-80, 30-110, **30-140**, 60-140, 60-170, 90-170, 90-200,120-200,140-250,30-250 bpm Range (y-axis) for the PR Online Trend (4.2.3, 4.2.3.7).
Pulse Beep	Type: Parameter Range: **OFF**, 1, 2, 3, 4, 5, 6 Volume of Pulse Beep (4.1.6). **Note**: This parameter is duplicated in the sub-menu 'Audio Settings' (Table 49).
Pleth Speed	Type: Parameter Range: 30, 15, 10, **7.5**, 6.0, 4.5, 3.0, 1.5 mm/sec (corresponding to a time-span of 3, 6, 9, **12**, 15, 20, 30, 60 sec, respectively) Speed (time-span) of the 'Wiper bar' plethysmographic waveform (4.2.3, 4.2.3.7).

Menu Item	Type/Range (Factory Default in Bold)/Description
SpO2 Averaging	Type: Parameter Range: 2, 3, 4, **6**, 8, 12, 16, 32 secs Averaging time for SpO2 and PR. **Note**: Not accessible/changeable (dimmed gray) if Responsible Organization did disable the parameter 'SpO2 Averaging selectable' (4.7.4.1). **Note**: The longer the averaging time, the more stable the SpO2 readings tend to become. This is due to a dampened response as the signal is averaged over a longer period of time than if shorter average times are used. However, lower average times delay the response of the SDM and reduce the measured variation of SpO2. For the influence of the SpO2 averaging time on the SpO2 alarm condition delay refer to 4.4.4. **Note**: For sleep studies, it is recommended to set SpO2 Averaging to 2 or 3 seconds.

Table 42 Sub-menu SpO2/PR Settings (3rd menu level)

Sub-menu PO2 Settings (3rd menu level)

Note: The sub-menu PO2 Settings is not accessible if PO2 is disabled.

Menu Item	Type/Range (Factory Default in Bold)/Description
PO2 Trendgraph Range	Type: Parameter Range (if 'mmHg'): 0-60, 0-160, 0-800, 20-100, **40-160**, 60-100, 100-300, 160-800 [mmHg] Range (if 'kPa'): 0.0-8.0, 0-21.5, 0.0-107.0, 3.0-13.5, **5.5-21.5**, 8.0-13.5, 13.5-40.0, 21.5-107.0 [kPa] To select the range (y-axis) for the PO2 Online Trend (4.2.3, 4.2.3.7).
Sensitivity Test	Type: Function To activate a 'PO2 sensitivity test' manually (4.9.7, Table 43). **Note**: This function is dimmed gray (not accessible) if a 'PO2 sensitivity test' is not possible (sensor is outside the 'Docking Station' or due to technical reasons). **Note**: If PCO2 is enabled a 'PCO2 Sensitivity Test' (Table 40) is made concurrently.
PCO2/PO2 Unit	This parameter is duplicated in the sub-menu 'PO2 Settings'. Refer to Table 40 for its description.

Table 43 Sub-menu PO2 Settings (3rd menu level)

Sub-menu V-Check Settings (3rd menu level)

Note: The sub-menu 'V-Check Settings' is not accessible if 'V-Check Mode selectable' (4.7.4.1) is disabled by the Responsible Organization.

Menu Item	Type/Range (Factory Default in Bold)/Description
V-Check Mode	Range: ON, **OFF** To switch V-Check™ Mode ON/OFF (4.13.2). **Note**: This parameter is duplicated in one of the two Quick Access Menus (4.2.5.3, Figure 7).
Stabilization Duration	Range: 1 – 60 min in steps of 1 min. (**8 min**) To adjust the duration of the 'V-Check™ Stabilization Phase', i.e. the time span from 'Sensor-On-Patient' detection to the 'Start of the V-Check™ Analysis Phase' (4.13.2).
Analysis Duration	Range: 1 – 120 min in steps of 1 min. (**2 min**) To adjust the duration of the 'V-Check™ Analysis Phase', i.e. the time span from end of V-Check™ Stabilization Phase to End of V-Check™ Measurement (4.13.2). The data measured during this period are used to calculate the V-Check™ Results.
Data Validity	Range: 50-100% in steps of 1%. (**80%**) For each parameter V-Check™ Results are only calculated if the percentage of its valid data recorded during the V-Check™ Measurement exceeds the percentage specified by 'Data Validity'.

Table 44 Sub-menu V-Check™ Settings (3rd menu level)

Sub-menu Membrane Change (2nd menu level)

Note: The sub-menu Membrane Change is not accessible (dimmed gray) if the sensor is 'ON Patient', in the 'Docking Station', or if the parameter PCO2 is disabled (4.10).

Menu Item	Type/Range (Factory Default in Bold)/Description
Membrane Change Interval [days]:	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Indicates the currently selected 'Membrane Change Interval' (4.7.4.1).
Membrane Change is Due in [days]:	Type: Yellow Information Text Indicates the numbers of days left until the 'Membrane Change Interval' elapses, i.e. a change of the sensor membrane will be requested by the SDM. **Note**. This information is duplicated on the 'Ready for use/Calibration' screen (4.2.4).
Cancel	Type: Function To "Cancel" the confirmation of the membrane change/exits Membrane Change menu.
Membrane Change Done	Type: Function To confirm the change of the sensor membrane/returns to the measurement display that was last active. **Note**: This function is not accessible (dimmed gray) if the sensor is 'On Patient', in the 'Docking Station', or if the parameter PCO2 is disabled.

Menu Item	Type/Range (Factory Default in Bold)/Description
Membrane Instruction Info	Type: Yellow Information Text The following message is displayed: *'Exchange of the Sensor Membrane: see Instruction Manual'*
Link to Membrane Change Tutorial	Type: Yellow Information Text The QR-Code provided in this sub-menu and shown on the right links to a Membrane Change Tutorial that is available for online viewing at www.sentec.com/tv/v0/.

Table 45 Sub-menu Membrane Change (2nd menu level)

Sub-menu System Settings (2nd menu level)

Note: With the exception of the parameter 'Demo Mode', all operator-selectable parameters maintain their setting from previous use upon power-cycle in 'Basic Mode' (4.7.2) and are storable in the institution's 'Standard Profile' (4.7.3).

Menu Item	Type/Range (Factory Default in Bold)/Description
Date/Time	Type: Access to respective sub-menu (Table 47) **Note**: Not accessible (dimmed gray) during patient monitoring.
Display Settings	Type: Access to respective sub-menu (Table 48)
Display in Sleep Mode	Type: Parameter Range: **OFF**, Auto, ON To activate/deactivate the Sleep Mode (4.2.6) **Note**: Not accessible (dimmed gray) and set to OFF if 'Demo Mode' is activated.
Language	Type: Parameter Range: català, 中文 (chinese), čeština, dansk, deutsch, **english**, español, français, italiano, ニホンゴ (japanese – Katakana), nederlands, norsk, polski, português, русский (russian), svenska, suomi, türkçe. To select the display language. **Note**: In 'editing mode' (Table 20) the parameter 'Language' is highlighted with a yellow menu bar indicating that changes must be confirmed by pressing the 'ENTER Button' before they become effective. To cancel changes/deactivate 'editing mode' use the 'Menu/Previous Level Button' or the 'Display Button'. **Note**: Pressing the 'ENTER Button' when the parameter 'Language' is in 'editing mode' not only activates the selected language but additionally exits the menu. **Note**: Not accessible (dimmed gray) if Responsible Organization disabled the parameter 'Language selectable' (4.7.4.1). **Note**: Not included in profiles
Audio Settings	Type: Access to respective sub-menu (Table 49)

Menu Item	Type/Range (Factory Default in Bold)/Description
Demo Mode	Type : Parameter Range: **OFF**, ON To activate/deactivate the 'Demo Mode' (4.13.4) **Note**: Not accessible (dimmed gray) and automatically set to OFF if sensor is applied to patient or if Responsible Organization disabled the parameter 'Demo Mode selectable' (4.7.4.1). **Note**: Not included in profiles
Profiles	Type: Access to respective sub-menu (Table 50) **Note**: This menu item is only operable in 'Institutional Mode' (4.7.3). **Note**: This menu item is duplicated in one of the two Quick Access Menus (4.2.5.3, Figure 7).

Table 46 Sub-menu System Settings (2nd menu level)

Sub-menu Date/Time (3rd menu level)

Note: By using V-STATS™ it is possible to set the SDM's date/time to the current date/time of the PC with V-STATS™ (i.e. to synchronize the date/time setting of the SDM and the PC).

Menu Item	Type/Range (Factory Default in Bold)/Description
Day	Type: Parameter. Range : 1 – 31 in steps of 1 (Format : DD)
Month	Type: Parameter Range: 1 – 12 in steps of 1 (Format: MM)
Year	Type: Range: 2000 – 2038 in steps of 1 (Format: YYYY)
Hour	Type: Parameter Range: 0 – 23 in steps of 1 (Format: hh)
Minute	Type: Parameter Range: 0 – 59 in steps of 1 (Format: mm)
Second	Type: Parameter Range: 0 – 59 in steps of 1 (Format: ss)
Set (Clears Trend Data)	Type: Function To activate the new 'Date/Time' setting. **Note**: The 'Trend Data' stored in the internal memory are deleted when setting the 'Date/Time'.

Table 47 Sub-menu Date/Time (3rd menu level)

Sub-menu Display Settings (3rd menu level)

WARNING: Current values of monitored parameters and visual alarm signals may become illegible if the display brightness is dimmed too much.

Menu Item	Type/Range (Factory Default in Bold)/Description
Brightness	Type: Parameter Range: 0 – 100 in steps of 1 (**100**) **Note**: If a measurement screen (4.2.3) is active, the brightness of the display can also be changed during patient monitoring by using the UP/DOWN Buttons (4.1.4).
PCO2 Color	Type: Parameter Range: Red, **Green**, White, Blue, Orange, Yellow, Fuchsia, Cyan
SpO2 Color	Type: Parameter Range: **Red**, Green, White, Blue, Orange, Yellow, Fuchsia, Cyan
PR Color	Type: Parameter Range: Red, Green, **White**, Blue, Orange, Yellow, Fuchsia, Cyan
PI Color	Type: Parameter Range: Red, Green, White, Blue, Orange, **Yellow**, Fuchsia, Cyan
PO2 Color	Type: Parameter Range: Red, Green, White, **Blue**, Orange, Yellow, Fuchsia, Cyan
RHP Color	Type: Parameter Range: Red, Green, White, Blue, **Orange**, Yellow, Fuchsia, Cyan
Display Backlight Type	Type: Yellow Information Text Indicates the backlight type of the SDM's display (either *'LED Backlight'* or *'blank' if a 'CCFL Backlight' is used*). **Note**: If the SDM is operated on internal battery, the operating time is significantly affected by the type of the SDM's display backlight (4.5.2). **Note:** Please contact your local Sentec representative for upgrade information if the display of your monitor does not use a LED Backlight.

Table 48 Sub-menu Display Settings (3rd menu level)

Sub-menu Audio Settings (3rd menu level)

Menu Item	Type/Range (Factory Default in Bold)/Description
Alarm Volume	This parameter is duplicated in the sub-menu 'Alarm Settings'. Refer to Table 37 for its description.
AUDIO PAUSED Duration	Type: Parameter Range: **1**, 2 min Duration auditory alarm signals will be paused after pressing the AUDIO PAUSED/AUDIO OFF Button (4.1.4)
AUDIO OFF Reminder	Type: Parameter Range: **ON**, OFF To switch the AUDIO OFF Reminder (4.1.6) OFF or ON. **Note**: Not accessible (dimmed gray) and set to ON if Responsible Organization did disable the parameter 'AUDIO OFF Reminder selectable' (4.7.4.1).

Menu Item	Type/Range (Factory Default in Bold)/Description
Pulse Beep	This parameter is duplicated in the sub-menu 'SpO2/PR Settings'. Refer to Table 42 for its description.
Key Click	Type: Parameter Range: **OFF**, 1, 2, 3, 4, 5, 6 Volume of the Key Click (4.1.6).

Table 49 Sub-menu Audio Settings (3rd menu level)

Sub-menu Profiles (3rd menu level)

Note: The sub-menu 'Profiles' is only accessible in Institutional Mode (4.7.3).

Menu Item	Type/Range (Factory Default in Bold)/Description
Standard Profile	Type: Yellow Information Text Indicates the name of the currently selected 'Standard Profile', e.g. 'Sleep' (4.7.3). **Note**: An asterisk ('*') is displayed behind the profile name (e.g. 'SLEEP*') if at least one of the SDM's current settings differs from its setting in the selected 'Standard Profile' (see example shown in Figure 9).
Status	Type: Yellow Information Text This indicator displays • 'unchanged' if the current settings and those of the selected 'Standard Profile' are identical • 'modified' if at least the current setting of one parameter differs from its setting in the 'Standard Profile' • 'Verify Alarm Limits!' after selecting/activating a different 'Standard Profile'
Restore Standard Profile	Type: Function This function restores the selected 'Standard Profile'. **Note**: This menu item is dimmed grey (not accessible) if the current settings and those of the selected 'Standard Profile' are identical.
Keep modified Profile	Type: Function If at power-up of the SDM the settings from previous use are different from the settings of the 'Standard Profile', the sub-menu 'Profiles' automatically activates. Use this function to keep the modified profile, i.e. to keep the previous settings. **Note**: This menu item is only operable in the situation described above; otherwise (i.e. during normal use) it is dimmed grey (not accessible).

Menu Item	Type/Range (Factory Default in Bold)/Description
(Select Profile) Select Standard: <profile name> Select Standard: <profile name> Select Standard: <profile name> Select Standard: <profile name>	Type: Function In 'Institutional Mode' the Responsible Organization can store up to 4 'SDM Profiles' on the SDM. Each of the four lines 'Select Standard' indicates the profile name of the 'SDM Profiles' stored in the corresponding profile slot (Figure 9). To select/activate a different 'Standard Profile' use the UP/DOWN Buttons to move the blue, underlying bar to the slot containing the desired 'SDM Profile' and confirm the selection by pressing the 'ENTER Button''ENTER Button'. **Note**: If no 'SDM profile' is stored in a profile slot 'Select Standard' is displayed in grey and no profile name is indicated. **Note:** Whenever the 'Data Recording Interval' (DRI) is changed, the trend data stored in the internal memory of the SDM are deleted. When attempting to activate a 'SDM Profile' whose DRI differs from the current DRI the text 'Select Standard: <profile name>' therefore is replaced with 'Confirm Clearing Trend Data' requesting the operator to confirm clearing of 'Trend Data' before activating the selected 'Standard Profile' as new 'Standard Profile'. Pressing of the 'ENTER Button' while the text 'Confirm Clearing Trend Data' is displayed will activate clearing of trend data and the menu text changes to 'Clearing Trend Data in Progress'. Once clearing of the trend data is completed, the menu text changes back to 'Select Standard: <profile name>'. Note that if you do not confirm that you want to clear the trend data within 10 seconds after the menu text changed from 'Select Standard: <profile name>' to 'Confirm Clearing Trend Data' the menu text changes back to 'Select Standard: <profile name>'.

Table 50 Sub-menu Profile (3rd menu level)

Sub-menu Interfaces (2nd menu level)

Menu Item	Type/Range (Factory Default in Bold)/Description
Serial Interface	Type: Access to respective sub-menu (Table 52) Refer to sub-section 5.2.
LAN Interface	Type: Access to respective sub-menu (Table 53) Refer to sub-section 5.3. **Note**: Not accessible (dimmed gray) if the hardware of the SDM does not support the LAN Interface or if the Responsible Organization set the parameter 'LAN selectable' (4.7.4.1) to OFF.
Analog Outputs	Type: Access to respective sub-menu (Table 54) Refer to sub-section 5.4.1.
Nurse Call	Type: Parameter Refer to sub-section 5.4.2. Range: ON, **OFF**
LAN Interface supported/not supported	Type: Yellow Information Text Indicates whether or not the hardware of the SDM supports the LAN Interface.

Table 51 Sub-menu Interfaces (2nd menu level)

Sub-menu Serial Interface (3rd menu level)

For details, please refer to sub-section 5.2.

Menu Item	Type/Range (Factory Default in Bold)/Description
Protocol	Type: Parameter Range: OFF, **SentecLink**, Philips VueLink/Intellibridge, Philips VueLink/Intellibridge 2, Spacelabs Flexport, Serial Printer, TCB Protocol (Transcutaneous Basic Protocol) To select the Serial Protocol. **Note**: Not included in profiles. **Note**: This parameter is only changeable in the menu of the SDM. It cannot be changed by using V-STATS™.
Baud Rate (SentecLink)	Type: Parameter Range: 19'200, 38'400, 57'600, **115'200** To select the Baud Rate (only if the Protocol 'SentecLink' is selected). **Note**: Not included in profiles **Note**: This parameter is only changeable in the menu of the SDM. It cannot be changed by using V-STATS™.
Printer Info	Type: Yellow Information Text If the protocol 'Serial Printer' is selected, the following information appears: *'Recommended printer: Seiko DPU-414 THERMAL PRINTER. See menu Trend Data to print trend data Baud Rate: 2400 bps'*

Table 52 Sub-menu Serial Interface (3rd menu level)

Sub-menu LAN Interface (3rd menu level)

For additional information please refer to sub-section 5.3.

Note: The sub-Menu LAN Interface is not accessible if the hardware of the monitor does not support the LAN Interface or if the Responsible Organization has set the parameter 'LAN selectable' (4.7.4.1) to OFF. Refer to the V-STATS™ Instruction Manual for changing the corresponding parameter or contact your local Sentec representative for upgrade information.

Menu Item	Type/Range (Factory Default in Bold)/Description
LAN	Type: Parameter Range: **ON**, OFF To switch LAN ON or OFF **Note**: Set to OFF if Responsible Organization has set the parameter 'LAN selectable' (4.7.4.1) to OFF. **Note**: Not included in profiles **Note**: Will be forced to ON if SDM is factory configured in 'V-CareNeT™ Only Mode' (4.13.3)
Device/Host Name	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Indicates the Device/Host Name of the SDM published over DHCP, i.e. the network name of the SDM, which is visible within the network (router, switches, etc.) **Note**: V-CareNeT™ uses the 'Device/Host Name' to identify the different SDMs that are connected to the same network as the PC with V-CareNeT™. During 'Remote Monitoring' or when downloading trend data via LAN the 'Device/Host Name' is indicated in the respective dialog windows of V-CareNeT™.

Menu Item	Type/Range (Factory Default in Bold)/Description
DHCP Mode	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Range: **ON**, OFF Indicates the DHCP mode.
IP Address	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Indicates the current IP Address. **Note**: Automatic IP address assignment via DHCP if DHCP Mode = ON. If DHCP Mode = OFF the IP Address only can be changed by the Responsible Organization.
IP Port	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Indicates the current IP Port (TCP/UDP Port) over which the communication will run. **Note**: Ensure that no firewall is blocking this port.
MAC	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Indicates the unique MAC Address of the SDM
Ethernet Mode	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Range: **auto**, half, full duplex Indicates the configured network mode. **Note**: Using V-STATS the Responsible Organization can set this parameter to auto (recommended), half or full duplex.

Table 53 Sub-menu LAN Interface (3rd menu level)

Sub-menu Analog Outputs (3rd menu level)

For details please refer to sub-section 5.4.1.

Menu Item	Type/Range (Factory Default in Bold)/Description
Output Voltage	Type: Yellow Information Text. Indicates the voltage range (0-1 Volt).
PCO2 Range	Type: Parameter Range (if 'mmHg'): 10-50, 25-55, 25-75, 35-100, 60-140, 75-200, 120-200, 0-75, **0-100**, 0-200 [mmHg] Range (if 'kPa'): 1.5-7.0, 3.5-7.5, 3.5-10.0, 4.5-15.0, 8-18.0, 10.0-27.0, 16.0-27.0, 0-10.0, **0-15.0**, 0-27.0 [kPa] PCO2 range that will be assigned to the 0-1 volt output range.
SpO2 Range	Type: Parameter Range: 0-100, **50-100**, 70-100, 85-100 [%] SpO2 range that will be assigned to the 0-1 volt output range.
PR Range	Type : Parameter Range: 30-80, 30-110, **30-140**, 60-140, 60-170, 90-170, 90-200, 120-200, 140-250, 30-250 bpm PR range that will be assigned to the 0-1 volt output range.
Pleth Range	Type: Information Text (the range for the plethysmogram is not selectable)
Calibration Sequence	Type: Function Activates the calibration sequence for the analog output.

Menu Item	Type/Range (Factory Default in Bold)/Description
Calibration Sequence Info	Type: Yellow/Red Information Text When the calibration sequence is in progress - *'Output Voltage: 1 VOLT (60 sec.). Press ENTER for 0 Volt'* is displayed in yellow while 1 Volt is output - *'Output Voltage: 0 VOLT (60 sec.). Press ENTER to stop sequence'* is displayed in red while 0 Volt is output
'Channel-to-Parameter' Assignment Info for PSG Adapter Cables	Type: Yellow Information Text Various ready-made adapter cables are available to interface the SDM with the most common polygraphic (PG) and polysomnographic (PSG) systems. Channel 0 (CH0) of these cables connects to pin 1 + 2 (Pleth) of the multipurpose I/O port (Table 80), channel 1 (CH1) to pin 3 + 4 (PR), channel 2 (CH2) to pin 5 + 6 (SpO2), and channel 3 (CH3) to pin 7 + 8 (PCO2).

Table 54 Sub-menu Analog Outputs (3rd menu level)

Sub-menu Trend Data (2nd menu level)

For details, please refer to sub-section 4.12.

Menu Item	Type/Range (Factory Default in Bold)/Description
Review/Print Trend Data	Type: Access to respective sub-menu (Table 56)
Clear Trend Data	Type: Function Activating the menu function 'Clear Trend Data' by pressing the 'ENTER Button' changes the text displayed in the menu to 'Confirm Clearing Trend Data' (displayed in yellow). Renewed pressing of the 'ENTER Button' while the text 'Confirm Clearing Trend Data' is displayed will activate clearing of trend data and the menu text changes to 'Clearing Trend Data in Progress' (displayed in yellow). Once clearing of the trend data is completed the menu text changes back to 'Clear Trend Data' (4.12.2). **Note**: Deleting the entire memory takes approximately 20 seconds.
Data Recording Interval [sec.]:	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Indicates at which time interval data currently are stored in the internal memory of the SDM (4.12.1).
Memory Capacity [hrs]:	Type: Yellow Information Text The first number indicates the free memory capacity in hours, whereas the second number in brackets indicates the total memory capacity in hours. The total memory capacity depends on the selected data recording interval (4.12.1).
Minimal Measurement Duration [mins] :	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Indicates the 'Minimal Measurement Duration' (4.12.3).
Patient ID:	Type: Orange Information Text (changeable by Responsible Organization only (4.7.4.1)) Indicates the Patient ID.

Table 55 Sub-menu Trend Data (2nd menu level)

Sub-menu Review/Print Trend Data (3rd menu level)

Note: When the sub-menu 'Review/Print Trend Data' is open, measurement parameters and related visual alarm signals are not visible.

Menu Item	Type/Range (Factory Default in Bold)/Description
From Start of Measurement	Type: Parameter. For details, refer to sub-section 4.12.4. **Note:** If the selected measurement period is a V-Check™ Measurement (4.13.2) the note 'V-Check' appears in orange color to the right of the period number.
To End of Measurement	Type: Parameter. For details, refer to sub-section 4.12.4.
Start Time	Type: Parameter. For details, refer to sub-section 4.12.4.
End Time	Type: Parameter. For details, refer to sub-section 4.12.4.
Review Trend Data	Type: Opens the 'Review Trend Data Screen' (Figure 11) if a regular measurement is selected or the V-Check Results Screen (Figure 15) if a V-Check™ Measurement is selected.
Start Printing	Type: Function. Activates the print-out of the graphical trends/statistical summary of the data comprised within the selected time range (Figure 13). For details refer to sub-section 4.12.4. **Note**: Changes to 'Stop Printing' while printing.
PCO2 Range	Type: Parameter Range (if 'mmHg'): 10-50, 25-55, **25-75**, 35-100, 60-140, 75-200, 120-200, 0-75, 0-100, 0-200[mmHg] Range (if 'kPa'): 1.0-7.0, 3.0-7.0, **3.0-10.0**, 4.0-15.0, 8-18.0, 10.0-27.0, 16.0-27.0, 0-10.0, 0-15.0, 0-27.0 [kPa], Auto Range (y-axis) for the PCO2 Trend plots in the menu 'Trend Data Review' as well as in the graphic printout (refer to sub-sections 4.12.4, 4.12.5, 4.12.5.3).
SpO2 Range	Type: Parameter Range: 0-100, 50-100, **70-100**, 85-100 % Range (y-axis) for the SpO2 Trend plots in the menu 'Trend Data Review' as well as in the graphic printout (refer to sub-sections 4.12.4, 4.12.5, 4.12.5.3)..
PR Range	Type : Parameter Range: 30-80, 30-110, **30 – 140**, 60-140, 60 – 170, 90 – 170, 90 – 200, 120 – 200, 140 –250, 30-250 bpm Range (y-axis) for the PR Trend plots in the menu 'Trend Data Review' as well as in the graphic printout (refer to sub-sections 4.12.4, 4.12.5, 4.12.5.3)..

Table 56 Sub-menu Review/Print Trend Data (3rd menu level)

Sub-menu System Information (2nd menu level)

Note: Pressing the 'ENTER Button' while the sub-menu 'System Information' is open activates the '2nd system information page' (Table 58).

Menu Item		Description
SDM:	Serial Number	Serial number of Sentec Digital Monitor (SDM)
	SMB Hardware Version	Hardware version of SDM's controller board
	SMB Software Version	Software version of SDM's controller board
	MPB Hardware Version/ MPL Hardware Version	Hardware version of SDM's signal analysis board
	MPB Software Version/ MPL Software Version	Software version of SDM's signal analysis board
Sensor:	Type	Type (model) of the connected sensor
	Serial Number	Serial number of connected sensor.
	Hardware Version	Hardware version of connected sensor.
	Software Version	Software version of Sentec TC Sensor
	DOM/op. hours	Date of manufacturing (DOM) and operating hours of sensor.

Table 57 Sub-menu System Information (2nd menu level)

Sub-menu '2nd System Information **Page**' (3nd menu level)

Note: Pressing the 'ENTER Button' while the sub-menu 'System Information' (Table 57) is open activates the second system information page.

Menu Item		Description
DS:	Serial Number	Serial number of the 'Docking Station' (DS). **Note:** Depends on DS-Hardware version. No DS information is displayed, if connected Sentec TC Sensor is not in DS.
	HW/SW Version	Hardware and Software version of DS PCB **Note:** Depends on DS-Hardware version. No DS information is displayed, if connected Sentec TC Sensor is not in DS.
Other:	SMBM Hardware Version	Hardware version of SDM's mother board
Options:	<Active SDM-Options>	The 'SDM-Options' indicator indicates the SDM's software-configuration. For a SDM with SMB-SW-V08.00 the following four options are possible: nPO2: VOM-option (4.13.3) and PO2-option both not activated. PO2: VOM-option not activated, PO2-option activated VOM nPO2: VOM-option activated without activated PO2-option; VOM PO2: VOM-option and PO2-option both activated. **Note**: The 'SDM-Options' indicator is also displayed on the Power-On Self-Test (POST) screen (Figure 3)
Sensor:	PCO2	Sensor characteristic data used for troubleshooting, only for Sentec TC Sensors.
Sensor:	PO2	Sensor characteristic data used for troubleshooting, only for OxiVenT™ Sensor.

Menu Item	Description
Life time (remaining/used)	Remaining and used sensor Life Time in days, only for OxiVenT™ Sensor (8.4.3).
Usage time (remaining/used)	Remaining and used sensor Usage Time in hours, only for OxiVenT™ Sensor (8.4.3).

Table 58 Sub-menu 2nd Page - System Information (3nd menu level)

4.8 Sensor Temperature & Site Timer

4.8.1 Introduction

Warming up the skin tissue beneath the sensor site to a constant temperature above the normal body surface temperature improves the reproducibility and accuracy of transcutaneous PCO2/PO2 measurements (2.4.1, 2.4.2). The heat-induced increase in capillary blood flow in the skin tissue beneath the sensor site (hyperemia) also augments the pulse strength of the pulsating blood and, consequently, improves the SDMS' ability to reliability measure SpO2/PR (2.4.4, 2.4.5).

Attaching a sensor to a patient's skin that is heated to a constant temperature above the normal body surface temperature unfortunately involves a certain risk of erythema (redness of the skin caused by hyperemia of superficial capillaries) or even burns, whereby this risk gradually increases with increasing sensor temperature and - at a given sensor temperature - with increasing exposure time. At sensor temperatures above 43 °C **the formation of an erythema will normally occur**. The skin reddening will disappear in general without side effects or scars within a few days. The occurrence of a burn with formation of a blister must be avoided. It is therefore recommended that **for patients at increased risk for burns** (i.e. patients with sensitive skin at the sensor site (e.g. preterm babies or geriatric patients, burn victims, patients with skin diseases) and/or very low skin tissue perfusion beneath the sensor site (e.g. hypothermic patients, patients with vasoconstrictions, low blood pressure, or circulatory centralization (shock)), a short test measurement is performed initially at the selected sensor temperature. After examination of the site where the sensor was applied, it should be decided on an individual basis how long the sensor may be left in the same position at the selected sensor temperature.

'Sensor Temperatures' and related sensor application durations (the so-called 'Site Time') that are recommended for Sentec TC Sensors (Table 59) were carefully selected to provide in most patients a close correlation between transcutaneous and arterial blood gas values with no to minimal risk of skin burns. Different 'Sensor Temperatures' and 'Site Times' than recommended can be selected by the operator in the sub-menu 'Temperature Settings' (Table 39). In order to account for the specific skin burn risks of the respective patient population and clinical setting, the Responsible Organization can adapt/restrict the operator-selectable 'Sensor Temperature' and 'Site Time' ranges within a password protected area of V-STATS™ (4.7.4.1, Table 62). Furthermore, to avoid unjustifiable risks (e.g. unintended use of a 'Sensor Temperature' of 44.5 °C during 12 hours in a neonatal patient) safety controls of the SDM may – depending on the selected patient type, the enabled parameters and with increasing 'Sensor Temperature' – enforce safer settings for the operator-selectable 'Sensor Temperature' and 'Site Time' ranges than those selected by the Responsible Organization. In 'Neonatal Mode', for example safety controls of the SDM enforce a maximal operator-selectable 'Sensor Temperature' of 43°C for 4.0 hours if PO2 is disabled or – in 'Adult Mode' – a maximal operator-selectable 'Site Time' of 2.0 hours if a 'Sensor Temperature' of 44.5 °C is selected (also see Table 60, Table 61, and Table 62).

Use of INITIAL HEATING (4.8.3), a feature that – for faster site perfusion and results - temporarily increases the sensor temperature above the selected sensor temperature after sensor application. It is only available in Adult Mode and recommended for patients with low skin tissue perfusion beneath the sensor site if a short 'Site Time' is impractical and, therefore, a suitably low 'Sensor Temperature' must be selected. In order to prevent excessively long exposure of the sensor to the skin, finally, the SDM features a 'Site Timer' (4.8.4) which monitors the time the sensor is applied to the patient and triggers the low priority alarm 'Site time elapsed' (4.3.5) if the 'Site Time' has elapsed. If the safety feature SITE PROTECTION (4.8.5) is ON the SDM furthermore will reduce the Sensor Temperature to safe values once the sensor application duration overruns the 'Site Time' by more than 10% or 30 minutes. In patients at increased risk for burns the use of SITE PROTECTION is recommended.

WARNING: Long-term hyperthermia may burn the skin. When producing local hyperemia by means of hyperthermia, a certain risk of applying temperatures harmful to the skin is always present, although the risk is limited due to the SDMS' comprehensive controls.

WARNING: Sensor Temperatures greater than 41 °C require special attention in patients at increased risk for burns. Carefully balance benefit (more accurate measurements) versus risk (skin burns) when selecting the Sensor Temperature and related 'Site Time', consider to use SITE PROTECTION (4.8.5) and – if a short 'Site Time' is impractical - INITIAL HEATING (4.8.3) in combination with a suitably low 'Sensor Temperature'.

WARNING: When selecting 'Sensor Temperature' and/or 'Site Time' remember that the sensitivity of the skin to heat may not only be different from patient to patient, but may also vary in an individual patient while the sensor is applied to it. In particular, any clinical situation resulting in reduced skin blood flow will increase the sensitivity to heat and the risk of skin burn. Also excessive mechanical pressure on the sensor will provoke such condition.

WARNING: Inspect the sensor site when the selected 'Site Time' has elapsed. Do not reattach the sensor to the same site if any skin integrity changes are noted during site inspection.

WARNING: To prevent skin burns, change the sensor site at least every 2 hours for sensor temperatures at or higher than 43 °C in neonates or every 4 hours for sensor temperatures at or higher than 44 °C in adult/pediatric patients.

4.8.2 'Sensor Temperature' & 'Site Time'

WARNING: To minimize the risk of erythema (skin reddening) or burns, carefully read section 4.8.1 and the warnings therein.

The recommended (and default) 'Sensor Temperature' and 'Site Time' for Sentec TC Sensors depend on the selected patient type and the enabled parameters and are summarized in Table 59. We advise selecting patient type 'Neonatal' for neonates and babies up to an age of 12 months after term birth. For adult and pediatric patients aged over 12 months, Sentec recommends patient type 'Adult'.

Patient Type	PO2 enabled	Recommended Sensor Temperature [°C]	Recommended Site Time [hrs]
Neonatal	No	41.0	8.0
	Yes	43.0	2.0
Adult	No	42.0	8.0
	Yes	44.0	2.0

Table 59 Recommended SET Temperatures and Site Times

In the SDM's **factory configuration** the operator can adjust the 'Sensor Temperature' and the 'Site Time' as summarized in Table 60. Note that in factory configuration the 'Selectable Sensor Temperature Range' is restricted to the 40.0 - 44.0 °C range and the 'Maximal Selectable Site Time' to 12.0 hours (maximal possible value).

Note: Depending on the enabled parameters and along with increasing sensor temperature the selectable ranges may be restricted by safety controls of the SDM.

Selected Patient Type	Selectable Temperature [°C]	Selected Temperature [°C]	Default Site Time [hrs.]	Selectable Site Time [hrs.]
Neonates	**40 – 44**	40.0 ≤ T ≤ 40.5	12.0	0.5 – 12.0

(< 12 months)	T > 41.5 only if PCO2 enabled T > 43.0 only if PO2 enabled default = 41 (with PO2 = 43)	41.0 ≤ T ≤ 41.5	8.0	0.5 – 12.0
		42.0 ≤ T ≤ 42.5	4.0	0.5 – 6.0
		T = 43.0	2.0	0.5 – 4.0
		43.5 ≤ T ≤ 44.0	1.0	0.5 – 2.0
Adults/Pediatrics (> 12 months)	**40 – 44** T > 42.0 only if PCO2 enabled T > 43.5 only if PO2 enabled default = 42 (with PO2 = 44)	40.0 ≤ T ≤ 41.5	12.0	0.5 – 12.0
		42.0 ≤ T ≤ 42.5	8.0	0.5 – 12.0
		43.0 ≤ T ≤ 43.5	4.0	0.5 – 8.0
		T = 44.0	2.0	0.5 – 4.0

Table 60 SET Temperature & 'Site Time' (factory setting)

Note: In 'Basic Mode' (4.7.2), changing the patient type sets the 'Sensor Temperature' and the 'Site Time' to the respective default values (Table 59); changing the 'Sensor Temperature' sets the 'Site Time' to the respective default 'Site Time'. In 'Institutional Mode' (4.7.3) the 'Sensor Temperature' and 'Site Time' settings stored in the selected 'Standard Profile' take priority when changing the patient type and/or sensor temperature.

Note: On the SDM the 'Selectable Sensor Temperature Range', the 'Recommended Sensor Temperature', the 'Maximal Selectable Site Time', and the 'Recommended Site Time' are displayed in the sub-menu 'Temperature Settings' (Table 39).

Note: The selected 'Sensor Temperature' and the available monitoring time are displayed on the SDM's 'Ready for use' screen and 'Calibration' screen (4.2.4). The measured sensor temperature is displayed in the 'Temperature Icon' (4.3.2).

Important Note: The 'maximum sensor-skin interface temperature' is approximately 1 °C lower than the 'sensor core temperature'.

Adjusting the 'Selectable Sensor Temperature Range'/'Maximal Selectable Site Time'

Within a password protected area of V-STATS™ the Responsible Organization has the possibility to adjust the 'Selectable Sensor Temperature Range' within the 37 to 44.5 °C range and the 'Maximal Selectable Site Time' within the 0.5 to 12 hours range 4.7.4.1).

WARNING: With decreasing sensor temperature, the correlation between tcPCO2 and PaCO2 gradually decreases. At sensor temperatures below approx. 40 °C, the measured tcPCO2 values do not reliably reflect PaCO2. Sentec therefore recommends that you establish and use Serveringhaus correction factors (4.13.1) that are adapted to your specific target patient population if attempting to assess PaCO2 when using sensor temperatures below 40 °C.

WARNING: For sensor temperatures below 39 °C, SpO2/PR readings intermittently might be switched off to maintain sensor temperature.

Note: If the 'Maximal Selectable Sensor Temperature' and the 'Minimal Selectable Sensor Temperature' are equal, a fixed temperature setting is enforced.

Example 1: Maximum possible range for 'Sensor Temperature' and 'Site Time'

Table 61 shows the selectable options for the 'Sensor Temperature' and 'Site Time' when the Responsible Organization has set the 'Selectable Sensor Temperature Range' to the 37.0 - 44.5 °C range (maximal possible range) and the 'Maximal Selectable Site Time' to 12.0 hours (maximal possible value).

Note: Depending on the enabled parameters and along with increasing sensor temperature the selectable ranges may be restricted by safety controls of the SDM.

Selected Patient Type	Selectable SET Temperature [°C]	Selected SET Temperature [°C]	Default Site Time [hrs.]	Selectable Site Time [hrs.]
Neonates (< 12 months)	**37 – 44** T > 41.5 only if PCO2 enabled T > 43.0 only if PO2 enabled T< 41.0 °C: PO2 values NOT available	37.0 ≤ T ≤ 40.5	12.0	0.5 – 12.0
		41.0 ≤ T ≤ 41.5	8.0	0.5 – 12.0
		42.0 ≤ T ≤ 42.5	4.0	0.5 – 6.0
		T = 43.0	2.0	0.5 – 4.0
		43.5 ≤ T ≤ 44.0	1.0	0.5 – 2.0
Adults/Pediatrics (> 12 months)	**37 – 44.5** T > 42.0 only if PCO2 enabled T > 43.5 only if PO2 enabled T< 41.0 °C: PO2 values NOT available	37.0 ≤ T ≤ 41.5	12.0	0.5 – 12.0
		42.0 ≤ T ≤ 42.5	8.0	0.5 – 12.0
		43.0 ≤ T ≤ 43.5	4.0	0.5 – 8.0
		T = 44.0	2.0	0.5 – 4.0
		T = 44.5	1.0	0.5 – 2.0

Table 61 'Sensor Temperature'/'Site Time' (maximum range)

Example 2: Restricted Range for 'Sensor Temperature' and 'Site Time'

Table 62 shows the selectable options for the 'Sensor Temperature' and 'Site Time' when the Responsible Organization has restricted the 'Selectable Sensor Temperature Range' to the 39.0 – 41.0 °C range and the 'Maximal Selectable Site Time' to 8.0 hours.

Note: Depending on the enabled parameters and along with increasing sensor temperature, the selectable ranges may be restricted by safety controls of the SDM.

Selected Patient Type	Selectable SET Temperature [°C]	Selected SET Temperature [°C]	Default Site Time [hrs.]	Selectable Site Time [hrs.]
Neonates	**39 – 41** T< 41.0 °C: PO2 values NOT available	39.0 ≤ T ≤ 41.0	8.0	0.5 – 8.0
Adults/Pediatrics	**39 – 41** T< 41.0 °C: PO2 values NOT available	39.0 ≤ T ≤ 41.0	8.0	0.5 – 8.0

Table 62 **'Sensor Temperature'** & **'Site Time'** (restricted **range)**

4.8.3 INITIAL HEATING

WARNING: To minimize the risk of erythema (skin reddening) or burns, carefully read section 4.8.1 and the warnings therein.

For most patients, the recommended 'Sensor Temperatures' (Table 59) are sufficient to rapidly enhance and maintain arterialization of the local capillary blood flow beneath the sensor site at a level sufficient to obtain a close correlation between arterial and transcutaneous blood gas values (2.4.1, 2.4.4). If at the recommended sensor temperature arterialization is not sufficient to obtain a close correlation, the correlation may be improved by increasing the sensor temperature.

Increasing the sensor temperature, unfortunately, also increases the risk of skin burns, especially in patients with sensitive skin at the sensor site (e.g. preterm babies or geriatric patients, burn victims, patients with skin diseases) and/or very low skin tissue perfusion beneath the sensor site (e.g. hypothermic patients, patients with vasoconstrictions, low blood pressure, or circulatory centralization (shock)). Consider to use INITIAL HEATING (4.8.3), which is available in Adult Mode only, in combination with a suitably low 'Sensor Temperature' if the use of a short 'Site Time' for such a patient is impractical.

In ON-mode INITIAL HEATING – for faster site perfusion and results – adds +2 °C (with a maximum of 44.5 °C) in adult/pediatric patients to the current 'Sensor Temperature' when removing the Sentec TC Sensor from the 'Docking Station' and during approximately the first 13 minutes after sensor application. Thereafter it reduces the sensor temperature back to the current 'Sensor Temperature'.

WARNING: `INITIAL HEATING´ will re-start each time the sensor has been inserted into the 'Docking Station'. This can potentially lead to multiple sessions of increased temperature when the sensor is repeatedly removed from the patient, placed into the 'Docking Station' and re-applied onto the same measuring site. It is within the responsibility of the clinician to consider potential risk of skin burns for patients with sensitive skin conditions.

Note: INITIAL HEATING initiates and executes the procedure described above only when the sensor is removed from the 'Docking Station'.

Note: If the Sentec TC Sensor is not applied to the patient within 5 minutes after removing it from the 'Docking Station' INITIAL HEATING aborts, i.e. the sensor temperature is reduced to the current 'Sensor Temperature'. INITIAL HEATING also aborts if the sensor is inserted into the 'Docking Station' or is disconnected from the SDM.

Note: The 'Temperature Icon' (4.3.2) turns yellow while INITIAL HEATING temporarily increases the sensor temperature above the selected 'Sensor Temperature'.

In the SDM's factory default setting, INITIAL HEATING is OFF and the menu item 'Initial Heating' (Table 39) is not accessible to the operator (dimmed in gray). The Responsible Organization can enable operator access to the menu item 'Initial Heating' within a password-protected area of V-STATS™ (4.7.4.1). Once enabled by the Responsible Organization the operator has the possibility to set the menu item 'Initial Heating' to ON or OFF. It is not possible to activate INITIAL HEATING in Neonatal Mode.

Note: The 'Special Temperature Settings' Indicator on the 'Ready for use' screen and on the 'Calibration' screen (4.2.4) indicates the current configuration of INITIAL HEATING.

4.8.4 Site Timer

WARNING: To minimize the risk of erythema (skin reddening) or burns, carefully read section 4.8.1 and the warnings therein.

The 'Site Timer' of the SDM is designed to meet the requirements of IEC 60601-2-23 and controls the duration of the sensor application to the patient. Once the SDM detects that the sensor is applied to the patient the 'Site Timer' begins to count down from the selected 'Site Time' (4.8.2, Table 39) to zero. A low priority alarm sounds, the message 'Site time elapsed' (4.3.5) is displayed in the 'Status Bar' (Figure 8) and the 'Remaining Monitoring Time Icon' (4.3.2) turns red when the 'Site Time' has elapsed. If the 'Site Time' has elapsed the sensor must be removed from the patient and the measurement site must be inspected.

Note: If PCO2 is disabled, the 'Remaining Monitoring Time Icon' (4.3.2) indicates the 'Remaining Site Time'. If PCO2 is enabled the 'Remaining Monitoring Time Icon' reflects the 'Remaining Site Time' only if the selected 'Site Time' elapses prior to the 'Calibration Interval'.

Note: When removing the sensor from the patient or if the sensor falls off the patient, the 'Site Timer' interrupts the countdown (if active) and resumes the countdown as soon as the sensor is on the patient again.

Note: When disconnecting the sensor from the SDM, the 'Site Timer' interrupts the count-down (if active) and resumes the countdown when the sensor is reconnected to the SDM. The 'Calibration Timer' (4.9.4), in contrast, continues its countdown when the Sentec TC Sensor is disconnected from the SDM.

Resetting the Site Timer

Table 63 summarizes how to reset the 'Site Timer' to the selected 'Site Time' and – if active – to terminate the 'Site time elapsed' alarm.

Reset condition(s)	Comment(s)
Removing sensor from patient and then a) pressing 'ENTER' when message 'Sensor off patient (↲)' is displayed or b) inserting sensor into 'Docking Station'	Also reactivates sensor heating if reduced by SITE PROTECTION (4.8.5). If PCO2 is enabled and the 'Calibration Interval' has elapsed the remaining monitoring time remains zero and the 'Remaining Monitoring Time Icon' (4.3.2) is highlighted yellow until successful termination of sensor calibration.

Table 63 Resetting the Site Timer

4.8.5 SITE PROTECTION

WARNING: To minimize the risk of erythema (skin reddening) or burns, carefully read section 4.8.1 and the warnings therein.

As described in the sub-section 4.8.4 (Site Timer), the sensor must be removed from the patient and the measurement site must be inspected once the 'Site Time' (4.8.2, Table 39) has elapsed. Despite the low priority alarm, which is triggered when the 'Site Time' has elapsed, it is obviously possible that the operator does not (immediately) remove the sensor from the patient and excessively long exposure of the sensor to the skin may result. Not removing the sensor from the patient after the 'Site Time' has elapsed may increase the risk of skin burns.

SITE PROTECTION is a safety feature, which prevents excessively long exposure of the skin to temperatures exceeding 41 °C in adult mode or 40 °C in neonatal mode.

Note: The use of SITE PROTECTION is particularly recommended for patients with sensitive skin at the sensor site (e.g. preterm babies or geriatric patients, burn victims, patients with skin diseases) and/or very low skin tissue perfusion beneath the sensor site (e.g. hypothermic patients, patients with vasoconstrictions, low blood pressure, or circulatory centralization (shock)).

If SITE PROTECTION is in ON mode and in case of 'Sensor Temperatures' exceeding 41 °C for adults or 40 °C for neonates, SITE PROTECTION automatically reduces the sensor temperature as summarized in Table 64 once the 'Site Time' has elapsed for more than 10 % of the selected 'Site Time' or for more than 30 minutes.

Patient type	'Sensor Temperature'	'Site Time' elapsed since	Reduced temperature [°C]
Neonates	> 40 °C	> 10 % of 'Site Time' (but maximal 30 minutes)	39
Adults/Pediatrics	> 41 °C	> 10 % of 'Site Time' (but maximal 30 minutes)	39 (if SpO2 disabled)
			41 (if SpO2 enabled)

Table 64 SITE PROTECTION – Temperature reduction

Note: A low priority alarm sounds, the Status Message 'Heating reduced' (4.3.5) is displayed, the 'Temperature Icon' (4.3.2) turns blue and – if enabled – PCO2/PO2 are marked as invalid (4.2.3.8) when the sensor temperature is reduced by SITE PROTECTION.

Note: Warming the measurement site augments the pulse oximetric signal strength. SITE PROTECTION therefore reduces the sensor temperature only to 41 °C if SpO2 is enabled.

Note: To reactivate normal heating, remove the sensor from the patient and press ENTER when the message 'Sensor off patient (↲)' is displayed or inserted the sensor into the 'Docking Station'.

In the SDM's factory default setting, SITE PROTECTION is in ON mode and the menu item 'Site Protection' (Table 39) is not accessible to the operator (dimmed in gray). The Responsible Organization can enable operator access to the menu item 'Site Protection' within a password protected area of V-STATS™ (4.7.4.1). Once enabled by the Responsible Organization the operator has the possibility to set the menu item 'Site Protection' to ON or OFF.

Note: The 'Special Temperature Settings' Indicator on the 'Ready for use' screen and on the 'Calibration' screen (4.2.4) as well as the 'Temperature Icon' (4.3.2) indicate the current configuration of SITE PROTECTION.

4.8.6 Heating Power

The total electrical power needed to heat a sensor applied to the skin at a constant temperature depends to a small fraction on the local skin blood flow beneath the sensor site (2.4.7). Because the sensor temperature is (usually) above the blood temperature, blood flowing past the sensor site provides a cooling action. As blood flow (and its associated cooling action) increases, the sensor requires more power to maintain the selected sensor temperature and, therefore, the heating power increases. Conversely, as blood flow decreases, the sensor heating power decreases. Once the sensor is stabilized on the skin, fluctuations of the heating power at constant ambient temperature, consequently, may indicate changes in local skin blood flow.

WARNING: Account for potential changes in body temperature, ambient temperature or other environmental conditions when interpreting heating power data.

On the SDM, the operator can select between the display of the 'Absolute Heating Power' (AHP), the 'Relative Heating Power' (RHP), or disable the display of the heating power by using the menu parameter 'Heating Power Mode' (Table 39). AHP and RHP values are both displayed in Millwatts (mW).

In **AHP-Mode**, the total power needed to heat the connected sensor to the selected 'Sensor Temperature' is displayed in the 'Heating Power Icon' (4.3.2) whenever the sensor is outside the 'Docking Station'.

In **RHP-Mode**, deviations of the current heating power from a stored RHP-reference value are displayed as plus or minus RHP values once the sensor is stabilized on the skin ('plus' if the current heating power is bigger than the RHP-reference value, 'minus' if smaller, and '0' if identical). On most Measurement Screens RHP-readings are – as the AHP-readings – displayed in the 'Heating Power Icon' (4.3.2). On certain Measurement Screens, however, the RHP-value is displayed underneath the PCO2 or PO2 value and the RHP Online Trend is provided underneath the PCO2 Online Trend or PO2 Online Trend. An example of a Measurement Screen with RHP Online Trend is shown in Figure 10.

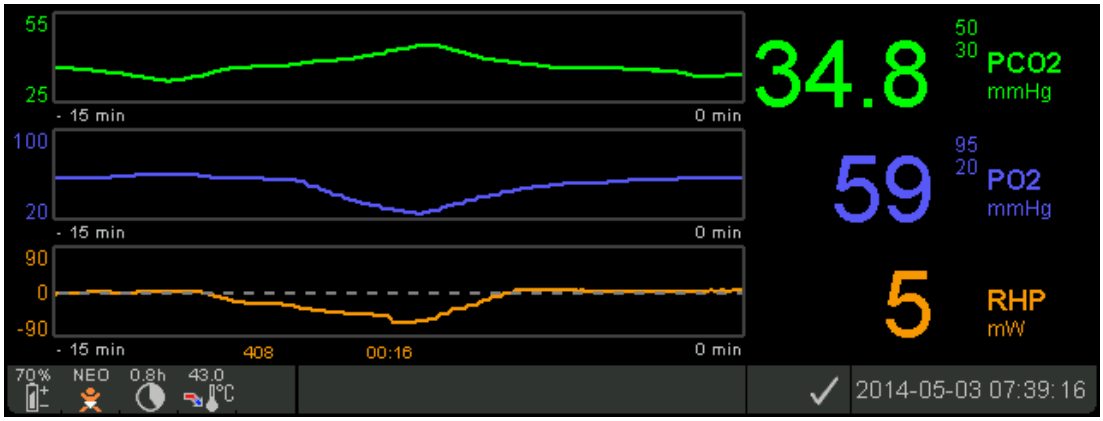


Figure 10 Example of a Measurement Screen with RHP Online Trend

The RHP-reference value ('408' in this example) and the time that has elapsed since it has been determined/set ('00:16' in this example) are displayed underneath the RHP Online Trend. The dashed horizontal center-line corresponds to a RHP of 0 mW and reflects the RHP-reference value. RHP values below/above the center-line corresponds to episodes during which the sensor required less/more power to maintain the sensor temperature than the AHP-reference value. At constant ambient temperature, consequently, RHP values below/above the center-line may indicate episodes with a decreased/increased local skin blood flow beneath the sensor site.

Note: If a new RHP-reference value is set, the RHP plot and – if a baseline is set – the baseline will be redrawn to reflect the new RHP-reference value. In this case, the RHP-reference value and the baseline value will be updated as well.

Note: If a baseline is set, the baseline value is displayed above/below the center-line, if the baseline value is positive/negative.

Keeping in mind the possible influence of local skin blood flow fluctuations on transcutaneous blood gases (2.4.1 and 2.4.2), it becomes understandable that an abrupt change of transcutaneous blood gases coupled with a significant change of RHP readings may indicate a change in local skin blood flow, while abrupt changes of transcutaneous blood gases unaccompanied by a significant change of RHP readings may indicate consistent blood flow but a change in arterial blood gases. Providing RHP Online Trends underneath PCO2 Online Trends or PO2 Online Trends, consequently, permit the clinicians to assess at a glance whether a change of PCO2 and/or PO2 reflects a corresponding change of the respective arterial blood gases or is caused or influenced by a significant change of the local skin blood flow beneath the sensor site.

IMPORTANT NOTE: The heating power needed to maintain a constant sensor temperature is also influenced by body temperature changes and ambient temperature changes. Body temperature changes occurring during the time the sensor is applied on the patient typically are small and, hence, only produce minor changes in AHP/RHP values. Ambient temperature changes from air-conditioners, patient warmers, radiant heaters, opening the window etc. can have a fast/significant impact on AHP/RHP values.

IMPORTANT NOTE: When monitoring AHP/RHP values with the goal to assess changes in the local skin blood flow beneath the sensor site, it is essential to select a sensor temperature at least 3 to 4 °C above the blood temperature, to use the sensor in an environment with constant (or only slowly changing ambient temperature) as well as to insulate the sensor from ambient temperature changes with a light covering such as a bed-sheet, or with a material designed to reflect radiant heat energy.

Automatic determination of the RHP-reference value

If in RHP-mode the sensor is applied to the patient when no RHP-reference value is yet available, the SDM automatically determines the RHP-reference value once the sensor is stabilized on the skin (which is typically the case 5 to 10 minutes after sensor application).

Manually setting a new RHP-reference value

If the sensor is stabilized on the skin the RHP-reference value can be set either a) by using the respective function in the 'Quick Access Menu' that activates after the 'ENTER Button' when a measurement screen is active (4.2.5.2) or b) by cycling the menu-parameter 'Heating Power Mode' from 'Relative' to 'Absolute' or 'OFF' and back to 'Relative'.

Note: It is recommended to determine a new RHP-reference value after each sensor application and in particular when applying the sensor to a different measurement site.

Note: RHP-values are replaced by '---' as long as no RHP-reference value is determined or – if a RHP-reference value is available – if the sensor is off patient or – if the sensor is on patient – the sensor temperature has been reduced by SITE PROTECTION (4.8.5).

Clearing/Resetting the RHP-reference value

To clear/reset the RHP-reference value, either remove the sensor from the patient and insert it into the 'Docking Station' or set the menu-parameter 'Relative Heating Mode' to 'OFF'.

4.9 Calibration of Sentec TC Sensors

4.9.1 Why is a calibration of Sentec TC Sensors needed?

As last manufacturing step, the factory PCO2 and PO2 calibration as well as the factory PCO2 and PO2 sensitivity of each Sentec TC Sensor is individually determined by exposing each sensor to various gas mixtures of known CO2/O2 concentration and then stored in its memory. During subsequent use of a Sentec TC Sensor, the SDM reads the sensor-specific calibration and sensitivity data stored in the sensor's memory and uses them to calculate PCO2 and PO2.

Unfortunately, the PCO2 segment of Sentec TC Sensors is not drift free. It is, therefore, required to periodically re-calibrate the PCO2 segment of Sentec TC Sensors against a gas mixture of known CO2 partial pressure (a so-called one-point calibration). The PO2 segment of the OxiVenT™ Sensor, in contrast, is virtually drift free and, hence, calibration free. Nevertheless, the SDM, as a precaution, calibrates PO2 during each mandatory calibration (Table 65) and subsequently approximately once every 24 hours during one of the anyways ongoing PCO2 calibrations.

Note: The 'PCO2 Sensitivity' and/or 'PO2 Sensitivity' of a Sentec TC Sensor gradually may deteriorate over time or may even be lost abruptly. As using a Sentec TC Sensor with deteriorated 'PCO2 Sensitivity' and/or 'PO2 Sensitivity' would result in incorrect PCO2 and/or PO2 readings, respectively, the software of the SDM continuously monitors the plausibility of the sensor's current 'PCO2 Sensitivity' and 'PO2 Sensitivity' (4.9.7). If the software suspects that a sensor's sensitivity has deteriorated the message 'Sensor problem 12' (for low 'PCO2 Sensitivity') or 'Sensor problem 72' (for low 'PO2 Sensitivity') is displayed and the respective values are marked as invalid (4.2.3.8). Furthermore note, that it is recommended to monthly perform a 'PCO2/PO2 sensitivity test' (Table 40, Table 43).

4.9.2 When to calibrate a Sentec TC Sensor?

If calibration of the connected Sentec TC Sensor is **mandatory** (Table 65), the SDM displays the message '**Calibrate sensor**', a low priority alarm sounds and PCO2/PO2 are marked as 'invalid' (values replaced by '---', 4.2.3.8). If the message '**Sensor calibration recommended**' is displayed, sensor calibration is **recommended** (Table 66) and monitoring is possible with PCO2 marked as 'questionable' (4.2.3.8).

Note: Even if sensor calibration is not yet mandatory or recommended by the SDM, you preferably/additionally should calibrate the sensor in-between monitoring, be it between two different patients or be it, for example, before reattaching the sensor to the same patient if the sensor was removed from the patient for site inspection or site change.

WARNING: To maintain monitor readiness and minimize PCO2 drift potential, always keep the SDM switched on and store the sensor in the 'Docking Station' in-between monitoring!

Events causing a mandatory, so-called 'Initial Calibration'
Switching on the monitor with a sensor being connected to the monitor
Connecting a Sentec TC Sensor to the monitor while the monitor is ON: if no sensor was connected to the SDM since the monitor was switched on if previously a **different** sensor was connected to the SDM if the **same** sensor was disconnected from the monitor for > 30 minutes (4.9.6)
Sentec TC Sensor exposed to ambient air for more than 30 minutes
Sentec TC Sensor removed from 'Docking Station' (for subsequent patient monitoring) more than: 12 hours ago if the 'Calibration Interval' was ≤ 8 hours (Table 66) 13 hours ago if the 'Calibration Interval' was equal to 9 hours (Table 66) 16 hours ago if the 'Calibration Interval' was equal to 12 hours (Table 66)

Membrane change requested by SDM or membrane change confirmed on SDM (4.10)
Changing the 'Sensor Temperature' (Changing the patient type may also cause a change of the 'Sensor Temperature')
Gas leak in 'Docking Station' detected (4.9.7)
Occurrence of 'Sensor problem 10', 'Sensor problem 11', 'Sensor problem 12', or 'Sensor problem 14' (4.9.7)

Table 65 Events causing request of a mandatory 'Initial Calibration'

4.9.3 How to calibrate Sentec TC Sensors?

The SDM is equipped with an integrated calibration and storage chamber, herein referred to as 'Docking Station' (Figure 1). The 'Docking Station' is designed to flush Sentec TC Sensors with Sentec's Service Gas during sensor calibration. The Service Gas is provided from a gas bottle which is fitted to the 'Docking Station' (Figure 2). The Service Gas contains 8 % CO2 and 12% O2 and with the knowledge of the local barometric pressure (4.3.2), which is measured by a built-in barometer, it is possible to calculate the CO2 and O2 partial pressures of the calibration gas. The PCO2 and/or PO2 readings at the calibration end point, i.e. after equilibration/stabilization, are cross-referenced against the CO2 and/or O2 partial pressure of the calibration gas.

To calibrate a Sentec TC Sensor, insert the sensor into the 'Docking Station'. The display switches from the currently active measurement screen (4.2.3) to the 'Calibration' screen (4.2.4), the SDM checks the 'Docking Station' and sensor and – if no errors/problems were recognized (4.9.7) – a sensor calibration automatically starts, i.e. gas containing a known CO2 and O2 concentration streams into the 'Docking Station' chamber. During sensor calibration the message 'Calibration in progress' is displayed. Depending on sensor performance, the calibration duration varies between 2 and 14 minutes. As soon as the PCO2 and/or PO2 readings stabilize the calibration end-point is reached. Based on the sensor's calibration history the SDM updates the 'Calibration Interval' (4.9.4), stores the calibration data in the memory of the sensor, resets the Calibration Timer to the 'Calibration Interval' and displays the message 'Ready for use'. Shortly thereafter the 'Ready for use' screen (4.2.4) is activated.

Note: If a Sentec TC Sensor is stored in the 'Docking Station' and if the monitor is kept switched on, the SDM automatically calibrates the sensor as needed. These features ensure that the Sentec TC Sensor is continuously 'Ready for use'.

WARNING: To maintain monitor readiness and minimize PCO2 drift potential, always keep the SDM switched on and store the sensor in the 'Docking Station' in-between monitoring!

Note: If the sensor is stored in the 'Docking Station', additional sensor calibrations can be activated with the menu-function 'Calibrate Sensor' in a 'Quick Access Menu' (Figure 7) or in the sub-menu 'PCO2 Settings' (Table 40). If enabled, PO2 is also calibrated during calibrations that are activated with the menu-function 'Calibrate Sensor'.

Note: SMART CALMEM (4.9.6) ensures that no calibration is activated if a calibrated sensor is removed from and reinserted into the 'Docking Station' within 10 minutes.

Note: The Responsible Organization has the possibility to enable/disable the display of the 'PCO2 Calibration Curve' (4.7.4.1) within a password protected area of V-STATS™.

4.9.4 'Calibration Interval' & 'Calibration Timer'

Based on the sensor's CO2 exposure time since successful termination of the last mandatory 'Initial Calibration' (Table 65), the SDM updates – as summarized in Table 66 - at the end of each successful sensor calibration

- the 'Calibration Interval', i.e. the time until calibration is recommended after removing a calibrated sensor from the 'Docking Station',
- the time during which sensor calibration is recommended and monitoring is possible with PCO2 marked as 'questionable' (4.2.3.8), and
- the total time during which monitoring is possible before sensor calibration is mandatory.

The Calibration Timer, furthermore, is reset to the updated 'Calibration Interval' at the end of each successful sensor calibration.

Note: The sensor is exposed to CO2 if it is either stored in the 'Docking Station' or attached to a patient.

CO2 exposure time since last 'Initial Calibration'	'Calibration Interval' **(hours)**	**Time with Calibration** recommended' (hours)	**Total time until calibration becomes mandatory (hours)**
< 4 hours	6	6	12
4 to 8 hours	9	4	13
> 8 hours	12	4	16
Any time if internal sensor stability criteria fulfilled.	9 to 12	4	13 to 16

Table 66 'Calibration Interval' **of Sentec TC Sensors**

Note: In factory default settings, the maximal 'Calibration Interval' is 12 hours. Within a password protected area of V-STATS™, the Responsible Organization has the possibility to restrict the 'Maximal 'Calibration Interval" within the 1 to 12 hours range (4.7.4.1). The yellow information text *'Max. permitted Calibration Interval [hrs]'* in the sub-menu 'PCO2 Settings' (Table 40) indicates the maximum, currently permitted 'Calibration Interval'.

Note: The yellow information text 'Calibration is Due in [hrs]' in the sub-menu 'PCO2 Settings' (Table 40) indicates the time remaining until the 'Calibration Interval' elapses. If the sensor is in the 'Docking Station', this time value (after termination of the calibration) represents/corresponds to the current 'Calibration Interval'.

Note: The information text 'Available Monitoring Time [hrs]' on the 'Ready for use' screen and on the 'Calibration' screen indicates the time available for patient monitoring, i.e. the time interval after removing the sensor from the 'Docking Station' or applying the sensor to the patient until the selected 'Site Time' (4.8.2) or - if PCO2 is enabled - the 'Calibration Interval' elapses (whichever will occur first).

The Calibration Timer begins counting down from the current 'Calibration Interval' to zero

- if the sensor is removed from the 'Docking Station' (for more than 10 minutes)
- if the sensor is disconnected from the SDM (for more than 10 minutes)
- if the sensor is in the 'Docking Station' and sensor calibration (once due) is inhibited due to technical reasons (4.9.7).

If the sensor is outside the 'Docking Station' when the 'Calibration Interval' has elapsed, the 'Remaining Monitoring Time Icon' (4.3.2) is highlighted yellow, sensor calibration is **recommended** (message 'Sensor calibration recommended', Table 66)) and monitoring is possible for another 4 to 6 hours with PCO2 marked as 'questionable' (4.2.3.8). Thereafter, sensor calibration is mandatory and PCO2/PO2 are marked as 'invalid' (values replaced by '---', 4.2.3.8).

Note: If the sensor is inserted into the 'Docking Station' while the Calibration Timer is already counting down, the Calibration Timer continues counting down until successful termination of the sensor calibration. If in this case the 'Calibration Interval' is elapsed, the 'Remaining Monitoring Time Icon' (4.3.2) remains highlighted yellow until successful termination of the sensor calibration.

Note: If the sensor is disconnected from the SDM while the Calibration Timer is already counting down, the Calibration Timer continues counting down while the sensor is disconnected. If the sensor is reconnected within less than 30 minutes, the Calibration Timer continues to count down (4.9.6). Reconnecting the sensor after more than 30 minutes causes the request of an 'Initial Calibration' (Table 65).

Note: If during monitoring the 'Calibration Interval' and the 'Site Time' both have elapsed the message 'Site time elapsed' is displayed and the 'Remaining Monitoring Time Icon' (4.3.2) is highlighted red.

4.9.5 Sensor Stabilization

The PCO2 drift of Sentec TC Sensors is typically most prominent after changing the sensor membrane and to a lesser degree after prolonged ambient air exposure of the sensor (approx. > 30 minutes). In these situations, we recommend to store the sensor – with the monitor switched on – in the 'Docking Station', if possible for four hours but at least for the duration indicated by the yellow information message 'Recommended Sensor Stabilization [mins]:' on the 'Ready for use' screen and on the 'Calibration' screen (4.2.4). This time is recommended to stabilize the PCO2 part of the sensor, i.e. to minimize its PCO2 drift potential. The 'Recommended Sensor Stabilization Interval' is updated as summarized in Table 67:

Situation	'Recommended Sensor Stabilization Interval'
After membrane change	90 minutes
After prolonged ambient air exposure of the sensor (> 30 minutes).	45 minutes

Table 67 'Recommended Sensor Stabilization Interval'

After successful calibration, the 'Stabilization Timer' immediately begins counting down from the current 'Recommended Sensor Stabilization Interval' (if > 0) to zero. Once the Stabilization Timer reaches zero, the yellow information message 'Recommended Sensor Stabilization [mins]:' – which is displayed on the 'Ready for use' or 'Calibration' screen (4.2.4) during the countdown – is removed.

Note: Within a password protected area of V-STATS™, the Responsible Organization has the possibility to disable the display of the yellow information message 'Recommended Sensor Stabilization [mins]:' which is displayed on the 'Ready for use'/'Calibration' screen (4.7.4.1).

4.9.6 SMART CALMEM

SMART CALMEM is a software feature of Sentec TC Sensors, which permits to disconnect a **calibrated** Sentec TC Sensor from the SDM for up to 30 minutes without losing the calibration status, provided that the sensor is reconnected within 30 minutes and that the 'Calibration Interval' (4.9.4) does not elapse while the sensor is disconnected. Consequently, monitoring can temporarily be interrupted without the need to remove the sensor from the patient, be it to untangle cables, if the patient must be turned or moved, or if the patient needs to go to the restroom.

SMART CALMEM furthermore ensures that no unnecessary calibration is initiated if a) a calibrated sensor is removed from the 'Docking Station' and reinserted into the 'Docking Station' after less than approx. 10 minutes or b) a calibrated sensor – while in the 'Docking Station' – is disconnected from the SDM and reconnected after less than approx. 10 minutes to the same SDM.

Overall, SMART CALMEM reduces the number of required calibrations and, hence, the calibration gas consumption.

4.9.7 Ensuring calibration reliability

WARNING: Accurate sensor calibration is important. Improper sensor calibration subsequently will result in inaccurate PCO2 and/or PO2 readings.

WARNING: Knowledge of the correct barometric pressure is important for an accurate calibration. Monthly check the barometer reading of the SDM against a known calibrated reference barometer.

WARNING: Integrity and cleanliness of the 'Docking Station' is important for an accurate calibration. A gas leak in the 'Docking Station' potentially might modify the effective calibration gas concentrations of the gas surrounding the sensor during calibration and hence, result in incorrect sensor calibrations. To prevent gas leaks in the 'Docking Station' always clean the sensor before inserting it into the 'Docking Station' and do not pull on the cable to open the 'Docking Station' door. Regularly inspect integrity and cleanliness of the 'Docking Station'.

WARNING: Do not use expired gas bottles or gas bottles from manufacturers other than Sentec. The use of non-Sentec gas bottles may damage the Docking Station. Improper calibration gas mixtures will result in incorrect sensor calibrations and subsequently result in inaccurate PCO2 and/or PO2 data.

WARNING: Ensure that the gas bottle is fully inserted by turning it clockwise approx. 4.5 turns and thoroughly tighten it (without applying undue force). Failure to properly insert the gas bottle may result in incorrect sensor calibrations and may cause increased gas consumption.

WARNING: To ensure continuous reliability of the calibration of Sentec TC Sensors, the SDM automatically tests the status of the 'Docking Station' and of the sensor (4.3.6) and, if necessary, inhibits the start of a calibration or aborts a running calibration.

Calibration reliability test	Description
Calibration gas level	If a Sentec TC Sensor is in the 'Docking Station', the SDM measures the filling level of the calibration gas bottle. The remaining capacity is displayed in the 'Gas Icon' (4.3.2). If the SDM detects that the gas bottle is empty, a low priority alarm sounds, the message 'Gas bottle empty' is displayed and sensor calibration is inhibited. **Note**: The 'Gas Icon' (4.3.2) is highlighted yellow if the remaining capacity is < 10 % and red if the gas bottle is empty.
Gas pressure and gas flow test	If the SDM detects an irregularity in the gas pressure or gas flow during sensor calibration, a low priority alarm sounds, the Status Message 'Docking Station Fault' (4.3.8) appears and sensor calibration is aborted. As soon as the gas pressure or gas flow is stable, this alarm is reset and sensor calibration – if necessary – will be started automatically. **Note**: Refer to troubleshooting P0501 (see Service Manual for the SDMS).
'Docking Station' gas leak test	When the sensor is in the 'Docking Station', the SDM evaluates the gas tightness of the 'Docking Station'. If a gas leak is detected, a low priority alarm sounds, and the Status Message 'Gas leak in DS' is displayed. When removing the sensor from the 'Docking Station', an 'Initial Calibration' (Table 65) will be requested and PCO2 and - if enabled - PO2 values will be marked as invalid (4.2.3.8) until successful termination of the next sensor calibration/mandatory leak test. **Note**: If a gas leak was detected, the next sensor calibration is followed by a mandatory leak test (Status Message 'Leak test in progress'). Once the leak has been repaired successfully the Status Message 'Gas leak in DS' disappears and the Status Message 'Ready for use' is displayed. **Note**: Refer to troubleshooting P0502 (see Service Manual for the SDMS).
Stability of atmospheric pressure	During sensor calibration the SDM monitors the atmospheric pressure measured by its built-in barometer. If the atmospheric pressure changes by more than a predefined amount during the calibration, the SDM aborts the calibration and issues the Status Message'Atm. P. unstable'. As soon the SDM detects that the atmospheric pressure has been stable for more than 30 seconds, the Status Message 'Atm. P. unstable' disappears and the calibration automatically restarts. **Note**: The 'Barometric Pressure Icon' (4.3.2) turns yellow if the barometric pressure is unstable during sensor calibration. **Note:** Refer to troubleshooting P0408 (see Service Manual for the SDMS).
Barometer test	If the Sentec TC Sensor is in the 'Docking Station', the SDM evaluates the plausibility of the barometer readings. If a technical barometer fault is detected or if during sensor calibration the barometer readings change implausibly fast or are outside a predefined range, a low priority alarm sounds, the message 'Barometer fault' is displayed and sensor calibration is inhibited/aborted. If the 'Barometer fault' alarm was triggered by - implausibly fast changing readings or readings that were out of range, the 'Barometric Pressure Icon' (4.3.2) highlights red (status code 'BF'). In this case the Barometer fault' alarm ceases if the sensor is removed from the

Calibration reliability test	Description
	'Docking Station'. Plausibility of barometer readings will be re-evaluated when reinserting the sensor into 'Docking Station'. - a technical fault (chip readout failed), the 'Barometric Pressure Icon' (4.3.2) is not highlighted (status code 'BFt'). In this case the Barometer fault' alarm resets if the SDM is power cycled. If the fault reappears after power cycle then please contact qualified service personnel. **Note:** Refer to troubleshooting P0408 (see Service Manual for the SDMS).
Sensor temperature stability	If the sensor temperature deviates more than a predefined value from the 'Sensor Temperature' sensor calibration is inhibited/aborted. As soon as the sensor temperature is again within the correct range from the 'Sensor Temperature' a sensor calibration – if necessary – will be started automatically. **Note:** The measured sensor temperature is displayed in the 'Temperature Icon' (4.3.2).
Sensor performance	If a Sentec TC Sensor is in the 'Docking Station' the SDM monitors the course of its PCO2 and/or PO2 readings. If the SDM detects that the PCO2 measurement is slow, the Status Message'PCO2 slow' (4.3.5) appears and PCO2 values subsequently are marked as questionable (4.2.3.8). If 'Sensor problem 10' (PCO2 calibration potential outside predefined range), 'Sensor problem 11' (PCO2 too slow), 'Sensor problem 12' (PCO2 sensitivity deteriorated), 'Sensor problem 14' (sensor unstable), 'Sensor problem 72' (low PO2 sensitivity) and/or 'Sensor problem 74' (PO2 too slow) occur a low priority alarm sounds, the Status Message 'Sensor problem xx' is displayed and sensor calibration is inhibited/aborted. PCO2 and/or PO2 values subsequently will be marked as invalid (4.2.3.8, 4.3.6). **Note:** Refer to troubleshooting P0100, P0104, P0303, P0304, and P0305 (see Service Manual for the SDMS).
Membrane change	If a membrane change of the sensor membrane is mandatory, the SDM inhibits/aborts sensor calibration.

Table 68 Calibration reliability tests

4.10 Changing the membrane of Sentec TC Sensors

4.10.1 Why is a change of the membrane of Sentec TC Sensors needed?

The PCO2 measurement principle of Sentec TC Sensors is based on a Stow-Severinghaus type PCO2 sensor: a thin electrolyte layer is confined to the sensor surface under a hydrophobic, CO2 permeable membrane. Although this membrane is nearly impermeable to water, the electrolyte slowly dries out over time and therefore needs to be replaced periodically.

4.10.2 When is a change of the membrane of Sentec TC Sensors needed?

The membrane of a Sentec TC Sensor must be changed if the 'Membrane Change Interval' (4.10.4) has elapsed. If in this case, the sensor is inside or is inserted into the 'Docking Station', the SDM displays the message 'Change sensor membrane', triggers a low priority alarm, marks PCO2/PO2 as invalid (4.2.3.8) and activates the menu 'Membrane Change' (Table 45).

Note: The SDM triggers the request to change the membrane only if the 'Membrane Change Interval' has elapsed and the sensor is in the 'Docking Station'.

Without being requested by the SDM, the sensor membrane **additionally must** be changed if the sensor membrane is damaged or missing, has a loose fit, or if there is trapped air or dry electrolyte under the membrane. Furthermore, the membrane must be changed after 'High Level Cleaning and Disinfection' of the sensor (refer to www.sentec.com/ifu).

4.10.3 How to change the membrane of Sentec TC Sensors?

To change the membrane of Sentec TC Sensors (V-Sign™/OxiVenT™ Sensors), the Membrane Changer (MC or MC-R) must be used. With the ease of 4 identical Press-and-Turn steps the old membrane is removed, the old electrolyte will be wiped off, new electrolyte will be applied and a new membrane will be affixed (for directions, refer to the Instruction Manual for the SDMS, the Directions for use for the Membrane Changer, or the tutorial video on the use of the Membrane Changer (www.sentec.com/tv/v0/).

The SDM is not able to automatically detect if the user changed the sensor membrane. The user therefore **must confirm** the membrane change in the menu of the SDM in order to reset the Membrane Timer to the 'Membrane Change Interval'.

To confirm a membrane change on the SDM:

- remove the Sentec TC Sensor from the 'Docking Station'
- open the sub-menu 'Membrane Change' (Table 45)
- confirm the membrane change by using the menu-function 'Membrane Change Done'. This will reset the membrane timer to the currently selected 'Membrane Change Interval'.

After confirming the membrane change, sensor calibration is mandatory (Table 65). For optimal PCO2 results following a membrane change, it is furthermore recommended to allow the PCO2 part of the sensor to stabilize (4.9.5).

4.10.4 'Membrane Change Interval' & Membrane Timer

Upon confirmation of the membrane change in the menu of the SDM (4.10.3), the Membrane Timer resets to the current 'Membrane Change Interval' and starts counting down.

In factory default settings, the 'Membrane Change Interval' is 28 days. However, the membrane of Sentec TC Sensors may be used up to 42 days. Factors influencing the membrane life include:

- Sensor cleaning procedures (inadequate cleaning agents, rough rubbing of sensor membrane)
- Inappropriate handling of the sensor (maintenance, misuse, disregarding of directions for use)
- Frequency of use
- Aging of the sensor
- Environmental conditions (e.g. dry environments)

Note: The remaining time until the next membrane change is required is indicated by the yellow information message 'Membrane Change is Due in [days]' on the 'Ready for use' and 'Calibration' screen (4.2.4) as well as in the menu 'Membrane Change' (Table 45).

Note: Within a password protected area of V-STATS™, the Responsible Organization has the possibility to select the 'Membrane Change Interval' within a range of 1 to 42 days (4.7.4.1). The yellow information text 'Membrane Change Interval' in the menu 'Membrane Change' (Table 45) indicates the current 'Membrane Change Interval'.

4.11 'PCO2 In-Vivo Correction'

4.11.1 Introduction

The 'PCO2 In-Vivo Correction' allows adjusting the SDM's PCO2 readings based on the result of an arterial blood gas analysis. The 'PCO2 In-Vivo Correction' adjusts the 'Metabolic Offset' (M) used in the 'Severinghaus Equation' (2.4.1) such that the difference between the PCO2 value displayed by the SDM when taking the blood sample and the PaCO2 value as determined by the blood gas analysis cancels out. The 'PCO2 In-Vivo Correction' should only be used when a systematic difference between the SDM's PCO2 readings and PaCO2 is clearly established by several arterial blood gas measurements.

4.11.2 Performing a 'PCO2 In-Vivo Correction'

WARNING: A 'PCO2 In-Vivo Correction' should only be made by personnel who understands the principles and limitations of transcutaneous PCO2 monitoring (2.4.1, 2.4.2). If a 'PCO2 In-Vivo Correction' is made it must be checked periodically and adapted in case of changes.

WARNING: The SDM is not a blood gas device. Also if in-vivo correction is done, the PCO2 values displayed by the SDM remain an estimate of PaCO2.

Note: In the SDM's factory default setting operator access to the sub-menu 'PCO2 In-Vivo Correction' is disabled. The Responsible Organization can enable operator access to the sub-menu 'PCO2 In-Vivo Correction' within a password protected area of V-STATS™ (4.7.4.1).

Note: 'PCO2 In-Vivo Corrections' should not be performed on hemodynamically unstable patients, because the arterial blood gas values and the transcutaneous values may fluctuate considerably.

Note: 'PCO2 In-Vivo Corrections' will bring PCO2 values closer to PaCO2 values, the correlation between PCO2 values and PaCO2 values, however, will remain unchanged.

Note: 'PCO2 In-Vivo Corrections' will not eliminate the blood flow dependence of PCO2 values or any of the other limitations of transcutaneous blood gas measurements (2.4.2). If perfusion of the measurement site changes after the 'PCO2 In-Vivo Correction' has been made the 'PCO2 In-Vivo Correction' may become obsolete/wrong.

Performing a 'PCO2 In-Vivo Correction' involves the following steps:

1) Prior to performing a 'PCO2 In-Vivo Correction' verify that the SDM is monitoring and that the PCO2 readings are stable and the patient is in steady state.

2) Access the sub-menu 'PCO2 In-Vivo Correction' either via the sub-menu 'PCO2 Settings' in the 'Measurement Settings' menu or via the 'Quick Access Menu' (4.2.5.2).

Note: Operator access to the sub-menu 'PCO2 In-Vivo Correction' is only possible if enabled by the Responsible Organization within a password protected area of V-STATS™ (4.7.4.1).

3) When drawing the blood sample press the menu item 'Press ENTER when taking ABG sample'. The SDM will store the corresponding data/time and the current PCO2 reading.

Note: The menu item 'Press ENTER when taking ABG sample' is disabled (dimmed gray) while the measurement site is warming up after sensor application or if PCO2 values are marked as questionable, unstable, or invalid (4.2.3.8).

4) Take the blood sample and perform a blood gas analysis.

5) Re-access the sub-menu 'PCO2 In-Vivo Correction', enter the PaCO2 value by using the menu item 'PCO2 of ABG Sample', and confirm the entered value by pressing 'Confirm'.

Note: Prior to pressing 'Confirm' you may also change the value for the SDM's PCO2 reading at the time the 'PCO2 In-Vivo Correction' Procedure was activated by accessing the menu item 'PCO2 (SDMS)'.

Note: If PCO2 values are in-vivo corrected the 'PCO2 In-Vivo Correction' indicator is displayed adjacent to the PCO2 label, indicating that the displayed values are in-vivo corrected and do no longer show the 'original' values.

Note: The 'PCO2 In-Vivo Correction' procedure can be repeated during the monitoring period if you wish to alter the values again according to the results of new blood samples.

To reset the 'PCO2 In-Vivo Correction' during monitoring use the menu item 'Reset' in the sub-menu 'PCO2 In-Vivo Correction'.

Note: The 'PCO2 In-Vivo Correction' is automatically reset a) when the patient type or sensor temperature is changed, b) when the sensor is inserted into the 'Docking Station', or c) when the sensor is disconnected from the SDM and reconnected to the same SDM after more than 30 minutes.

Each menu item of the sub-menu 'PCO2 In-Vivo Correction' is explained below.

Current 'PCO2 In-Vivo Correction'

Date/Time
This yellow information text indicates when the currently active 'PCO2 In-Vivo Correction' was performed. If 'PCO2' values are not in-vivo corrected, it displays '---'.

Offset
This yellow information text indicates the correction offset used. If 'PCO2' values are not in-vivo corrected, it displays '0'.

Reset
Activating this menu function resets the correction offset to '0'.

Press ENTER when taking ABG sample
This menu item must be used when drawing the blood sample to activate the 'PCO2 In-Vivo Correction' procedure.

Date/Time
If a 'PCO2 In-Vivo Correction' procedure is currently being performed this yellow information text indicates the date/time corresponding to the activation of the 'PCO2 In-Vivo Correction' procedure (dimmed gray if no 'PCO2 In-Vivo Correction' procedure is being applied).

PCO2 (SDMS)
If a 'PCO2 In-Vivo Correction' procedure is currently being performed you may – if necessary – adjust the SDM's PCO2 reading shown at the instant when the 'PCO2 In-Vivo Correction' procedure was activated. It is adjustable in steps of 0.5 mmHg (0.1 kPa) (dimmed gray if no 'PCO2 In-Vivo Correction' procedure is currently being performed).

Note: The value is displayed in orange when the value is edited and different from the SDM's PCO2 reading at the

PCO2 of ABG Sample
If a 'PCO2 In-Vivo Correction' procedure is currently being performed the arterial PCO2 value obtained from the blood gas analysis can be entered here. The initial value of this parameter is set to the SDM's PCO2 reading at the time the 'PCO2 In-Vivo Correction' Procedure was activated. It is changeable in steps of 0.5 mmHg (0.1 kPa) (dimmed gray if no 'PCO2 In-Vivo Correction' Procedure is currently being performed).

Confirm
This menu item must be selected to confirm the PaCO2 value entered in the menu item 'PCO2 of ABG Sample'. When activated, the SDM updates the in-vivo correction offset and returns to the measurement displays. When no 'PCO2 In-Vivo Correction' procedure is currently being performed, this menu item is dimmed gray.

Cancel
This menu item deactivates/aborts any ongoing 'PCO2 In-Vivo Correction' procedure. Consequently, the menu items 'Date & Time', 'PCO2 (SDMS)', 'PCO2 of ABG Sample', and 'Confirm' become disabled (dimmed gray) until renewed activation of a 'PCO2 In-Vivo Correction' procedure.

4.12 Reviewing and printing Trend data

4.12.1 Introduction

The SDM automatically stores PCO2, PO2, SpO2, PR, RHP and PI data as well as alarm limit violations for these parameters in its internal memory. Furthermore it stores status information (4.3.5), important settings (e.g. alarm related settings, sensor temperature related settings), as well as sensor and monitor specific information (serial numbers, software versions). Any time data are available in the internal memory of the SDM it is possible to select the desired measurement range in the sub-menu 'Review/Print Trend Data' (Table 56, 4.12.4) for subsequent on-screen viewing and/or printing of graphical trends and statistical summary (Figure 11, Figure 12, Figure 13). By using V-STATS™ it is furthermore possible to download trend data stored in the internal memory via the SDM's serial or LAN interface (5.2, 5.3) for subsequent data display, data analysis, and generation of a printable report (refer to the V-STATS™ Instruction Manual).

Note: On-screen viewing and/or printing of graphical trends and statistical summary is currently only supported for PCO2, SpO2, PR. Use V-STATS™ to view/print PO2, PI, and HP data.

Note: The SDM stores data according to the FIFO (First In, First Out) principle. Once the memory is full, newly collected data overwrite the oldest data. Ensure to download/print data before the memory fills up and old data is overwritten.

The memory capacity of the SDM depends on the current 'Data Recording Interval':

'Data Recording Interval' [seconds]	Memory Capacity (monitoring time)
1	35 hours (1.4 days)
2	68 hours (2.8 days)
3	99 hours (4.1 days)
4	128 hours (5.3 days)
5	156 hours (6.4 days)
6	182 hours (7.5 days)
7	206 hours (8.5 days)
8	227 hours (9.4 days)

Table 69 Trend Data – Memory Capacity

Note: The 'Data Recording Interval' (DRI) can only be changed by the Responsible Organization within a password protected area of V-STATS™ (4.7.4.1). The data stored in the internal memory of the SDM are deleted when changing the DRI. On the SDM the current DRI setting and the resulting memory capacity are displayed in the sub-menu 'Trend Data' (Table 55).

Note: If the 'Data Recording Interval' is > 1 sec, the data are not additionally filtered before down sampling.

Note: Depending on the frequency of occurrence of 'System Status Changes' (being documented in the internal memory by a changing set of Status Codes (4.3.5)) the memory capacities indicated in the table above will slightly vary. Very frequent 'System Status Changes', consequently, will reduce the memory capacity.

Note: When monitoring a patient (i.e. if the sensor is applied to the patient) data are stored line by line at the selected 'Data Recording Interval'. If, in contrast, the sensor is NOT applied to the patient, data are stored in the internal memory only if technical status information changes. Memory capacity, therefore, mainly is used up while monitoring a patient. The indicated memory capacities, consequently, virtually correspond to pure patient monitoring time and not operating time of the monitor. To retain patient data it is therefore NOT necessary to turn off the SDM when you are not monitoring a patient.

4.12.2 Deleting Trend Data

Trend Data either can be deleted by activating the menu function 'Clear Trend Data' which is available in the sub-menu 'Trend Data' (Table 55) or by using V-STATS™.

Activating the function 'Clear Trend Data' in the sub-menu 'Trend Data' (Table 55) by pressing the 'ENTER Button' changes the text displayed in the menu to 'Confirm Clearing Trend Data' (displayed in yellow). Renewed pressing of the 'ENTER Button' while the text 'Confirm Clearing Trend Data' is displayed will activate clearing of trend data and the menu text changes to 'Clearing Trend Data in Progress' (displayed in yellow). Once clearing of the trend data is completed the menu text changes back to 'Clear Trend Data'.

Note: It is recommend clearing trend data after printing or downloading them.

Note: If you do not confirm that you want to clear the trend data within 10 seconds after the menu text changed from 'Clear Trend Data' to 'Confirm Clearing Trend Data' the menu text changes back to 'Clear Trend Data'.

Note: The trend data stored in the internal memory of the SDM are cleared when the 'Data Recording Interval' or when the Date/time of the SDM is changed.

4.12.3 Determining the Start and End of (a) measurement(s)

The SDM determines the start and end of a measurement using the following criteria.

	Criteria
Start of Measurement	The start of a new measurement is detected upon one of the following status transitions: • 'Sensor-Off-Patient' to 'Sensor-On-Patient' (provided a measurement is not already running)
End of Measurement	The end of a currently running measurement is detected upon one of the following status transitions: • 'Sensor-On-Patient' to 'Sensor-Off-Patient' 2 minutes ago • 'Sensor being inserted into Docking Station' • Occurrence of an event that makes continuation of measurement impossible (fault, sensor being disconnected from SDM, or SDM being switched off)

Table 70 Determining the Start and End of (a) measurement(s)

The SDM stores a list of all measurements with the date/time of the corresponding start-points and end-points in its internal memory. By means of these start times and end times it will subsequently be possible to attribute the measurements to the respective patients when reviewing, printing, or downloading the data. In order to avoid overwhelming the operator with many very short, possibly meaningless measurements, those measurements that are shorter than the 'Minimal Measurement Duration' (default setting = 5 sec) are not available to be reviewed/printed/downloaded.

Note: The Responsible Organization can adjust the 'Minimal Measurement Duration' within a password protected area of V-STATS™ (4.7.4.1). The currently active 'Minimal Measurement Duration' is displayed in the menu 'Trend Data' (Table 55).

Note: Prior using V-Check™ Mode (4.13.2), ensure that the 'Minimal Measurement Duration' is shorter than the overall duration of the 'V-Check Stabilization Duration' and 'V-Check Analysis Duration' (Table 44). Otherwise, V-Check™ Measurements will not be accessible in the sub-menu 'Review/Print Trend Data' (Table 56) for subsequent review/printing.

Note: Referring to Table 70,it becomes understandable that an overnight measurement, for example, may be split up in different measurements on the SDM, e.g. if the sensor has unintentionally fallen off the patient for more than 2 minutes or if the sensor was disconnected from the SDM (e.g. when the patient needed to go to the bathroom).

Note: It is possible to select multiple, successive measurements to be reviewed/printed/downloaded (not applicable for V-Check™ Measurements). Selection of two or more measurements will merge the measurements with 'zero values' added to fill the gaps.

Note: Ensure that the SDM's date/time (4.3.1, Table 47) is synchronized with the date/time of your institution as otherwise the date/times indicated by the SDM for the start and end of the measurements may differ from those noted in your records.

4.12.4 Selecting the time range to be reviewed/printed

The sub-menu 'Review/Print Trend Data' (Table 56) offers the possibility a) to select the time range to be reviewed on screen/printed and b) to adjust for each parameter the range (y-axis) to be used for graphical trends.

Note: The graphical trends and statistical summary corresponding to the data comprised within the selected time range can either be printed directly (Figure 13) or first be displayed on the SDM (Figure 11, Figure 12).

The concept to select the time range for which trend data shall be reviewed/printed is based on the selection of one (or multiple, successive) measurement(s). The SDM assigns to each measurement that is longer than the 'Minimal Measurement Duration' (4.7.4.1) a number. Measurement number '1' is assigned to the oldest measurement currently stored in the internal memory, whereas the most recent (or currently running) measurement has the highest number. As subsequently explained these measurement numbers are used by the menu parameters 'From Start of Measurement' and 'To End of Measurement' to select one (or multiple, successive) measurement(s). Each menu item of the sub-menu 'Review/Print Trend Data' (Table 56) is explained below.

Menu parameter 'From Start of Measurement'
The start-point of the time range to be reviewed/printed is set to the start of the selected measurement. The date/time corresponding to the start of the selected measurement is indicated by the menu parameter 'Start Time' (two lines further down in the menu).

Menu parameter 'To End of Measurement'
The end-point of the time range to be reviewed/printed is set to the end of the selected measurement. The date/time corresponding to the end of the selected measurement is indicated by the menu parameter 'End Time' (two lines further down in the menu).

Note: As a currently running measurement has not yet an end-point, the menu parameter 'To End of Measurement' displays '---' if the selected measurement corresponds to a currently running measurement. In this case, the menu parameter 'End Time' (two lines further down in the menu) displays the current time and is updated once per second.

Note: If you want to review only one measurement, you must select the same measurement number in the menu parameter 'From Start of Measurement' as in the menu parameter 'To End of Measurement'.

Note: When selecting two or more measurements, the measurement number selected in the menu parameter 'From Start of Measurement' must be smaller than or equal to the measurement number selected in the menu parameter 'To End of Measurement'.

Note: Refer to sub-section 4.13.2.3 for the particularities that are applicable when the selected measurement is a 'V-Check™ Measurement'.

Menu parameter 'Start Time'
The date/time of the start-point to be reviewed/printed is set to the selected date/time.

Menu parameter 'End Time'
The date/time of the end-point to be reviewed/printed is set to the selected date/time.

Note: If the selected measurement number in the menu parameter 'From Start of Measurement' or in the menu parameter 'To End of Measurements' is changed, the 'Start Time' or 'End Time' is set to the date/time of the corresponding measurement start or measurement end, respectively.

Note: If the 'Start Time' or 'End Time' is different from the date/time corresponding to the measurement start or measurement end of the selected measurement number, the menu parameter 'Start Time' or 'End Time' is displayed in orange, respectively.

Note: If the 'Start Time' is more than 5 minutes in the past the minimal Time Span is 5 minutes and the selection of 'Start Time' and 'End Time' is restricted accordingly.

Note: The increments used by the software when changing the menu parameters 'Start Time' or 'End Time' depend on the initial time span (i.e. the time span prior to changing 'Start Time' or 'End Time' with the UP/DOWN Buttons) as follows:

Initial Time Span [hours]	Increment [minutes]
≤ 0.5	5
≤ 2	15
≤ 8	30
> 8	60

Table 71 Time Span Increments for Trend Data Review

Note: If accessing the sub-menu 'Review/Print Trend Data' (Table 56) from the menu 'Trend Data' (i.e. the menu on the next higher level, Table 55) the different menu parameters that allow to select the time range to be reviewed/printed are set to the most recent (or currently running) measurement.

Note: If returning to the sub-menu 'Review/Print Trend Data' (Table 56) from the 'Review Trend Data Screen' (Figure 11) by using the Menu/Previous Level Button (4.1.4) the settings of the four parameters that allow to select the time range to be reviewed/printed are maintained. As a result the time range to be reviewed/printed can easily be adjusted (e.g. to zoom in/out) without having to enter the selections again.

Menu item 'Review Trend Data'

Opens the 'Review Trend Data Screen' (Figure 11), which graphically displays trend data according to the user's selections/settings if a regular measurement is selected or the 'V-Check Results Screen' (Figure 15) if a V-Check Measurement is selected.

Menu item 'Start Printing'
Activates the print-out of the graphical trends/statistical summary of the data comprised within the selected time range by using the current ranges (y-axis) (Figure 13). The menu text changes to 'Stop Printing' (displayed in yellow) during printing and changes back to 'Start Printing' once printing has finished.

Note: Pressing of the 'ENTER Button' again while the message 'Stop Printing' is displayed will abort printing and causes the text to change back to 'Start Printing'.

Note: Refer to sub-section 4.12.5.4 for instructions on how to setup/configure the SDM and the printer (Seiko DPU-414 THERMAL PRINTER).

Note: If the menu parameter 'Serial Protocol' is not set to 'Serial Printer' the menu item 'Start Printing' is disabled/dimmed gray.

Note: When activating printing the software sets the Print Mode, the Time Grid Interval and the Time Tick Interval as a function of the Time Span (4.12.5).

Menu parameters 'PCO2 Range', 'SpO2 Range', and 'PR Range'
These three menu parameters allow selecting for each parameter the range (y-axis) that will be used for the Trend Data plots in the 'Review Trend Data Screen' (Figure 11) as well as in the graphic printout (Figure 13). Factory Defaults and possible selections are provided in Table 56.

4.12.5 Reviewing/Printing Trend Data for the selected time range

4.12.5.1 Review Trend Data Screen

If a time range is selected in the sub-menu 'Review/Print Trend Data' (4.12.4, Table 56) that contains a regular measurement the menu item 'Review Trend Data' in the sub-menu 'Review/Print Trend Data' activates the 'Review Trend Data Screen':

Note: If the selected time range contains a V-Check™ Measurement the menu item 'Review Trend Data' activates the 'V-Check Results Screen' (Figure 15).

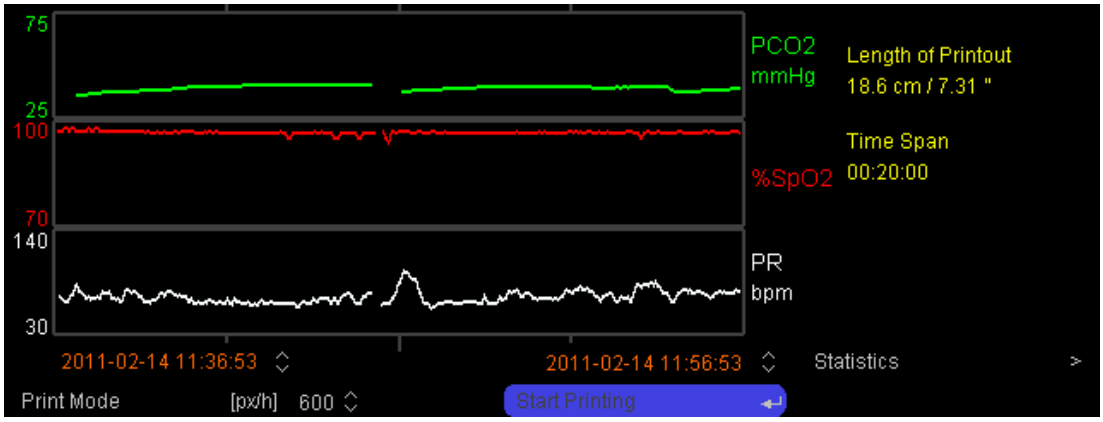


Figure 11 Review Trend Data Screen

Note: When the 'Review Trend Data Screen' is active neither measurement parameters nor the Status Bar (Figure 8) are displayed. Consequently, no visual alarm signals are available if this screen is active.

Note: The 'Review Trend Data Screen' shows an approximate view of the data stored in the memory. **Not all data is shown** on the screen (maximal values, for example, may not be shown). Use V-STATS™ to be sure to see all data.

The 'Review Trend Data Screen' graphically displays trend data according to the selections/settings made in the sub-menu 'Review/Print Trend Data' (Table 56). Each channel is labeled on the right and the displayed range (y-axis) is indicated on the left of the graph. The left and ride border of the graphs corresponds to the start and end time of the selected time range, respectively. Blank spaces represent

episodes during which measurement values were out of range, not available or were marked as unstable or invalid (4.2.3.8).

Note: Use the 'Menu/Previous Level Button' (4.1.4) to return the sub-menu 'Review/Print Trend Data' (i.e. the menu on the next higher level) or the 'Display Button' to exit the menu.

Note: If in one channel no data are displayed, it might be the case that no data are available for this parameter within the selected time range or the data for this parameter fall outside the display range selected for this parameter. In the second case return to the sub-menu 'Review/Print Trend Data' (4.12.4, Table 56) by pressing the 'Menu/Previous Level Button' to adjust the range of the respective parameter.

Note: Please note the difference between 'Online Trends' and 'Trend Data Plots'. In case of an 'Online Trend' the right side of the graph corresponds to the current time and the graph is automatically updated, where the update interval depends on the Time Range selected for Online Trends (Table 38). The SDM provides 'Online Trends' on various of its Measurement Screens (4.2.3). In case of 'Trend Data Plots' (Figure 11) the right side of the graph corresponds to the end time of the selected time range, whereby the end time can be any date/time in the past. Please note furthermore, that 'Trend Data' plots are not updated. The time range must be adjusted and updated in the menu.

As described in detail below, it is possible to refine the displayed time range (i.e. to scroll and/or zoom) by adjusting the start time and end time, respectively. Furthermore, it is possible to activate a further screen providing a statistical summary (Figure 12) or the print-out of the graphical trends/statistical summary (Figure 13).

In addition to the 'Trend Data Plots', the 'Review Trend Data Screen' provides the following functions/information:

'Start Time' (time label on the bottom left of the graphs)
Allows to adjust the date/time of the start-point to be reviewed/printed. Please note that the graph will be updated only after activating the menu function 'Start Printing'/'Update' (see below).

'End Time' (time label on the bottom right of the graphs)
Allows to adjust the date/time of the end-point to be reviewed/printed. Please note that the graph will be updated only after activating the menu function 'Start Printing'/'Update' (see below).

Note: When changing 'Start Time' or 'End Time' the text of the menu function 'Start Printing' (see below) changes from 'Start Printing' to 'Update'. Pressing the 'ENTER Button' while the text 'Update' is displayed will update the trend graph according to the currently displayed 'Start Time' and 'End Time' and the menu text changes back to 'Start Printing'.

Note: If the 'Start Time' or 'End Time' is different from the date/time corresponding to the measurement start or measurement end of the selected measurement number, the menu parameter 'Start Time' or 'End Time' is displayed in orange, respectively.

Note: On the 'Review Trend Data Screen' the 'End Time' is not updated if a currently running measurement is selected. In the sub-menu 'Review/Print Trend Data' (i.e. the menu on the next higher level), the menu parameter 'End Time' displays the current time and is updated every ~4 seconds if a currently running measurement is selected.

Function 'Statistics'
This function activates the 'Trend Data Statistics Screen' (4.12.5.2, Figure 12), providing a statistical summary of the data contained in the time range displayed on the 'Trend Data Review Screen'.

'Print Mode'
The parameter 'Print Mode' allows changing the number of pixels that are used to print a time range of one hour. When activating the 'Review Trend Data Screen', the software sets the 'Print Mode' as a function of the Time Span (Table 72). Subsequently it is possible to modify the 'Print Mode'. Decreasing the 'Print Mode'-value decreases the length of the printout. Changing the 'Print Mode' also changes the interval for the Time Grid and the Time Ticks used in the printout (below).

Print Mode [px/h]	Set if Time Span	Printout length per hour of data		Time Grid Interval for printout	Time Tick Interval for printout
20	>16 hours	0.56 cm/h	0.22 inch/h	04:00:00	01:00:00

40	≤ 16 hours	1.11 cm/h	0.44 inch/h	02:00:00	00:30:00
80	≤ 8 hours	2.23 cm/h	0.88 inch/h	01:00:00	00:15:00
150	≤ 4 hours	4.17 cm/h	1.64 inch/h	01:00:00	00:10:00
300	≤ 2 hours	8.34 cm/h	3.28 inch/h	00:30:00	00:10:00
600	≤ 1 hours	16.7 cm/h	6.56 inch/h	00:15:00	00:05:00

Table 72 Print Mode – Number of pixels per hour of data

Function 'Start Printing'/'Update'
This function has a dual function. 'Start Printing' is displayed if the displayed trend data correspond to the indicated 'Start Time' and 'End Time'. This is always the case when accessing the 'Review Trend Data Screen' from the sub-menu 'Review/Print Trend Data' (i.e. the menu on the next higher level). When changing 'Start Time' or 'End Time', however, the trend data plots are not updated and the menu text therefore changes from 'Start Printing' to 'Update'. Pressing the 'ENTER Button' while the text 'Update' is displayed will update the trend graph according to the currently displayed 'Start Time' and 'End Time' and the menu text changes back to 'Start Printing'.

Pressing the 'ENTER Button' while the text 'Start Printing' is displayed starts printing the trend data in graphic form as currently displayed, i.e. using the current time range and current ranges (y-axis) for the different parameters. The menu text changes to 'Stop Printing' (displayed in yellow) and changes back to 'Start Printing' once printing is finished.

Note: Renewed pressing of the 'ENTER Button' while the message 'Stop Printing' is displayed will abort printing and causes the text to change back to 'Start Printing'.

Note: Refer to sub-section 4.12.5.4 for instructions on how to setup/configure the SDM and the printer (Seiko DPU-414 THERMAL PRINTER).

Note: If the menu parameter 'Serial Protocol' is not set to 'Serial Printer' the menu item 'Start Printing' is disabled/dimmed gray.

Yellow Information 'Length of Printout'
Indicates the length of the printout (curve plus header/footer) in units of cm and inch (") if the currently displayed trend data are printed with the Seiko DPU-414 THERMAL PRINTER. For a given time span the length of the printout can be changed by adjusting the menu parameter 'Print Mode'.

Yellow Information 'Time Span'
The Time Span is equal to the difference in time between the displayed start and end times and is indicated in the HH:MM:SS format.

Note: The increments used by the software when changing the menu parameters 'Start Time' or 'End Time' depend on the initial time span (i.e. the time span prior to changing 'Start Time' or 'End Time' with the UP/DOWN Buttons) as follows:

Initial Time Span [hours]	Increment [minutes]
≤ 0.5	5
≤ 2	15
≤ 8	30
> 8	60

4.12.5.2 Trend Data Statistics Screen

The function 'Statistics' in the 'Trend Data Review Screen' (Figure 11) activates the 'Trend Data Statistics Screen':

Note: When the 'Trend Data Statistics Screen' is open, neither measurement parameters nor the Status Bar (Figure 8) are displayed. Consequently, no visual alarm signals are displayed if this sub-menu is active.

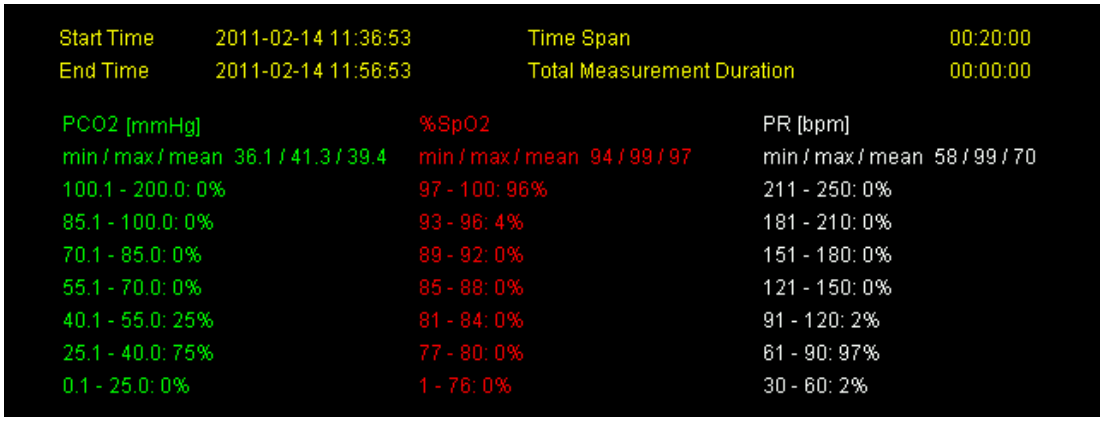


Figure 12 Trend Data Statistics Screen

Note: From the 'Trend Data Statistics Screen' is not possible to directly return to the 'Review Trend Data Screen'. Pressing the 'Menu/Previous Level' Button (4.1.4) when the 'Trend Data Statistics Screen' is displayed re-activates the sub-menu 'Review/Print Trend Data'.

The 'Trend Data Statistics Screen' provides the following information:

Start Time	Indicates the date/time at the beginning of the selected time range. **Note**: Corresponds to the 'Start Time' that was selected in the 'Review Trend Data Screen' when activating the 'Trend Data Statistics Screen'.
End Time	Indicates the date/time at the end of the selected time range. **Note**: Corresponds to the 'End Time' that was selected in the 'Review Trend Data Screen' when activating the 'Trend Data Statistics Screen'.
Time Span	The Time Span is equal to the difference between the Start Time and the End Time. Indicated in hh:mm:ss format.
Total Measurement Duration	Corresponds to the total time during which measurement data are available within the analyzed time range. The Total Measurement Duration is always smaller or equal to the Time Span. Indicated in 'hh:mm:ss' format. **Note:** If, for example, two measurements were selected of 30 minutes each, which are separated from each other by 30 minutes, the Total Measurement Duration will indicate 01:00:00 and the Time Span 01:30:00.
Duration of episodes with data of at least questionable quality	For each parameter, the duration of episodes with at least questionable quality (4.2.3.8) within the selected time range is indicated on the right of the parameter label in the 'hh:mm:ss' format and – in parenthesis – in percentage of the total measurement time.
min/max/mean	For each parameter, the minimum (min), maximum (max), and the mean are provided in the respective parameter's color for the selected time range
Histogram	For each parameter, the histogram is provided in the respective parameter's color for the analyzed time range. The histogram represents the percental duration the readings of the respective parameter were within the specified ranges. **Note**: The Responsible Organization has the possibility to change the ranges (2 to 7 ranges are supported) (4.7.4.1).

4.12.5.3 Description of the Print-Out

The function 'Start Printing' in the sub-menu 'Review/Print Trend Data' (4.12.4, Table 56) and in the 'Review Trend Data Screen' (4.12.5.1, Figure 11) activates the print-out of graphical trends followed by a statistical summary for the currently selected time range.

Note: If the menu parameter 'Serial Protocol' is not set to 'Serial Printer', the menu item 'Start Printing' is disabled/dimmed gray.

An example of a typical printout is schematically shown in Figure 13.

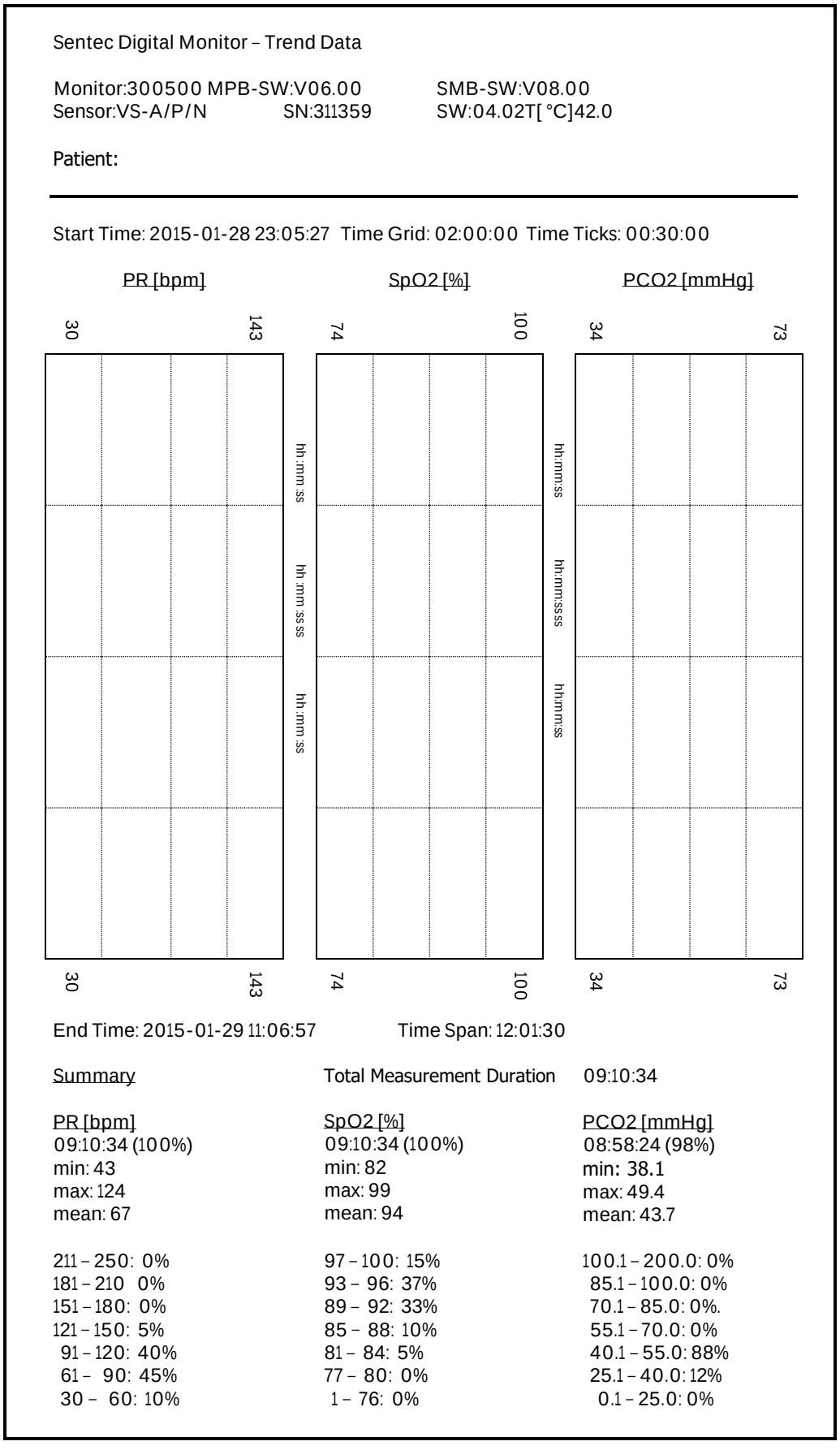


Figure 13 Example of Trend Data Print-Out

The printout includes the following information in the order listed below:

Title line	Displaying 'Sentec Digital Monitor – Trend Data'
Monitor specific information	Serial Number of the SDM and its SMB and MPB or MPL software version
Sensor specific information	Type, Serial Number, software version and Sensor Temperature (if applicable) of the sensor connected to the SDM during the last part of the selected measurement period(s)
Patient data	to be filled in manually
Start Time	Indicates the date/time at the beginning of the selected time range. **Note**: Corresponds to the 'Start Time' that was selected in the sub-menu 'Review/Print Trend Data' or 'Review Trend Data Screen', respectively, when activating the 'Trend Data Statistics Screen'.
Time Grids	Indicates at which interval time grids will be printed on the graphical trends. **Note**: Time labels are printed along with each Time Grid
Time Ticks	Indicates at which interval time ticks will be printed on the graphical trends
Parameter labels/units	For each channel the parameter label and unit is indicated.
Trend Data Plots	For each channel the graphical trends are printed. The displayed range (y-axis) is indicated for each channel.
Trend Data Plots	For each channel the graphical trends are printed. The displayed range (y-axis) is indicated for each channel.
End Time	Indicates the date/time at the end of the selected time range. Note: Corresponds to the 'End Time' that was selected in the sub-menu 'Review/Print Trend Data' or 'Review Trend Data Screen', respectively, when activating the 'Trend Data Statistics Screen'.
Time Span	The Time Span equals to the difference between the Start Time and the End Time. Indicated in hh:mm:ss format.
Total Measurement Duration	Corresponds to the total time during which measurement data are available within the analyzed time range. The Total Measurement Duration is always smaller or equal to the Time Span. Indicated in 'hh:mm:ss' format. Note: If, for example, two measurements were selected of 30 minutes each, which are separated from each other by 30 minutes, the Total Measurement Duration will indicate 01:00:00 and the Time Span 01:30:00.
Duration of episodes with data of at least questionable quality	For each parameter, the duration of episodes with at least questionable quality (4.2.3.8) is indicated underneath the parameter label in the 'hh:mm:ss' format and – in parenthesis – in percentage of the total measurement time.
min/max/mean	For each parameter the minimum (min), maximum (max), and the mean are provided in the respective parameter's color for the selected time range

4.12.5.4 Setting up for printing

For printing trend data stored in the internal memory of the SDM, only use the Seiko DPU-414 THERMAL PRINTER. For further information regarding the use of the Seiko DPU-414 THERMAL PRINTER, refer to its Operation Manual.

WARNING: When using the printer with main line power, it is recommended to use a medical grade power supply complying with the following standards: IEC 60601-1, ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1. If the power supply is not medical grade, the printer must be placed at least 1.5 meters from the patient environment complying with standard IEC 60601-1-2.

WARNING: Refer to sections 1.2 and 5.1 for warnings related to connecting/mounting the SDM to accessory equipment.

The SDM and the Seiko DPU-414 THERMAL PRINTER must be configured properly before printing will be successful.

Printer Configuration

The Seiko DPU-414 THERMAL PRINTER can be configured by DIP switches (DIP SW). There are three DIP SWs and each has 8 parameters to set. Refer to the printer's Operation Manual for directions to set the DIP SW.

The following table provides the parameters setting for DIP SW-1, DIP SW-2, and DIP SW-3 you must select if you want to use the Seiko DPU-414 THERMAL PRINTER with the SDM.

DIP SW	Parameter	Setting	Feedback
1	1	(OFF)	Input = Serial
	2	(ON)	Printing Speed = High
	3	(ON)	Auto Loading = ON
	4	(OFF)	Auto LF = OFF
	5	(ON)	Setting Command = Enable
	6	(OFF)	Printing
	7	(ON)	Density
	8	(ON)	= 100%
2	1	(ON)	Printing Columns = 40
	2	(ON)	User Font Back-up = ON
	3	(ON)	Character Selected = Normal
	4	(ON)	Zero = Normal
	5	(ON)	International
	6	(ON)	Character
	7	(ON)	Set
	8	(OFF)	= U.S.A.
3	1	(ON)	Data Length = 8 bits
	2	(ON)	Parity Setting = No
	3	(ON)	Parity Condition = Odd
	4	(OFF)	Busy Control = XON/XOFF
	5	(ON)	Baud
	6	(OFF)	Rate
	7	(OFF)	Select
	8	(ON)	= 2400 bps

Table 73 Printer Setup – DIP Switch settings

SDM Setup (Protocol selection)

In the menu 'Interfaces/Serial Interface' of the SDM, set the menu parameter 'Protocol' to 'Serial Printer'.

Note: If the menu parameter 'Protocol' is set to 'Serial Printer', the following information text appears in yellow in the menu 'Interfaces/Serial Interface':
Recommended printer: Seiko DPU-414 THERMAL PRINTER
See menu Trend Data to print trend data.
Baud Rate: 2400 bps

Connecting the Seiko DPU-414 THERMAL PRINTER to the SDM

Take the printer cable for the SDM. Connect it to the Serial Data Port (RS-232) of the SDM and to the Serial Data Port (RS-232) of the Seiko DPU-414 THERMAL PRINTER.

Printing

1. Check that all cables are properly connected.
2. Turn the printer ON and ensure the printer's ON LINE green light is on before printing.
3. Start and Stop printing as described in the sub-sections above.

Printing Troubleshooting

The following table lists potential problems that can occur when printing data and suggestions for resolving them.

Problem	Suggested solution
Printer does not print	Check printer cable. Make sure that it is plugged in correctly and that the correct cable is being used. Ensure the printer is turned on. Ensure the printer is 'on-line' (the printer's ON LINE green light must be on). Check DIP switch settings on the printer (in particular check baud rate, data bit, parity, and busy control). Turn off the printer and then turn it on again. There may have been a data overflow event. Make sure that a paper roll is loaded.
Garbled characters are printed	Ensure that the menu parameter 'Interfaces/Serial Interface/Protocol' is set to 'Serial Printer'. Ensure that you use the printer (Seiko DPU-414 THERMAL PRINTER). Check DIP switch settings on the printer (in particular check baud rate, data bit, parity, and busy control).
Printing is interrupted	Ensure that you do not press the 'Stop Printing' function accidentally. Ensure that the cable is not disconnected during printing. Do not change the serial protocol during printing.
Wrong line spacing	The printer was switched on after pressing start printing. To stop printing press 'Stop Printing'. To restart printing make sure the printer is on and press 'Start Printing'.

Table 74 Troubleshooting Printing

Additional Information related to the Seiko DPU-414 THERMAL PRINTER

Ordering: To order the Seiko DPU-414 THERMAL PRINTER contact your local Sentec representative.

Technical Support: For technical support for the Seiko DPU-414 THERMAL PRINTER, refer to the Seiko printer's Operation Manual.

4.13 Special Operating Modes

4.13.1 Severinghaus Correction Mode

Note: This section is only applicable if PCO2 is available/enabled.

WARNING: Anyone who uses Fixed Mode is responsible for the performance characteristics of the SDMS. Selection of C and M must be based on sound scientific and clinical evidence.

WARNING: 'Fixed Mode' should only be used by personal understanding the principles and limitations of transcutaneous PCO2 monitoring (2.4.1, 2.4.2).

The SDM uses an algorithm developed by J.W. Severinghaus to calculate PCO2 from the measured PcCO2 (section 2.4.1). The 'Severinghaus Algorithm' first corrects PcCO2 measured at the sensor temperature (T) to 37 °C by using a 'Temperature Correction Factor' (C) (the denominator in the first term of the 'Severinghaus Equation') and then subtracts an estimate of the local 'Metabolic Offset' (M). The menu-parameter 'Severinghaus Correction Mode' in the sub-menu 'PCO2 Settings' permits to select the mode that is used for the 'Temperature Correction Factor' (C) and the 'Metabolic Offset' (M).

Note: The menu-parameter 'Severinghaus Correction Mode' is not accessible (dimmed gray) and set to 'Auto' if the Responsible Organization has disabled operator access to this parameter.

In **Auto Mode,** the SDM uses 'Sentec-recommended' settings for C and M and **automatically** adjusts these settings as a function of the selected patient type and sensor temperature. In this case, the current settings of C and M are not displayed in the sub-menu 'PCO2 Settings'.

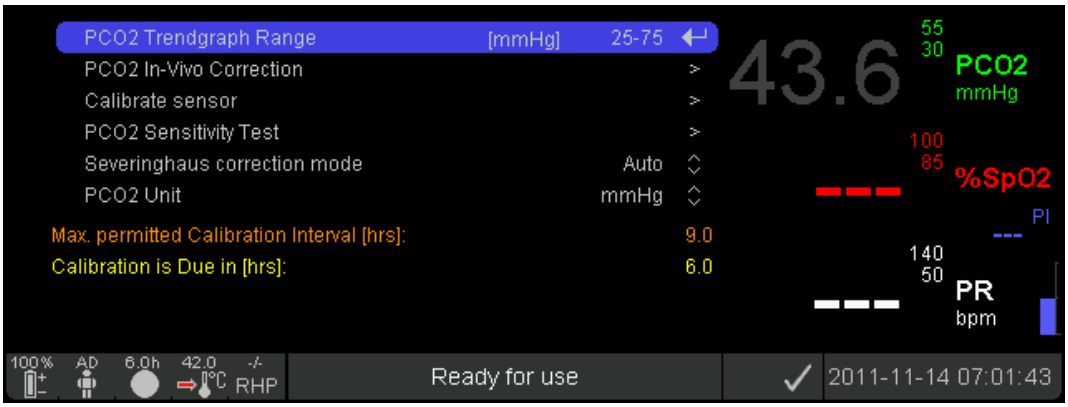


Figure 6 Severinghaus Correction Mode set to 'Auto'

In **Fixed Mode,** the SDM uses **fixed** C and M settings customized by the institution in a password protected area of V-STATS™, i.e. in fixed mode these values are not adjusted as a function of the selected patient type and sensor temperature. In this case, the current settings of C and M are not displayed in the bottom area of the sub-menu 'PCO2 Settings'.

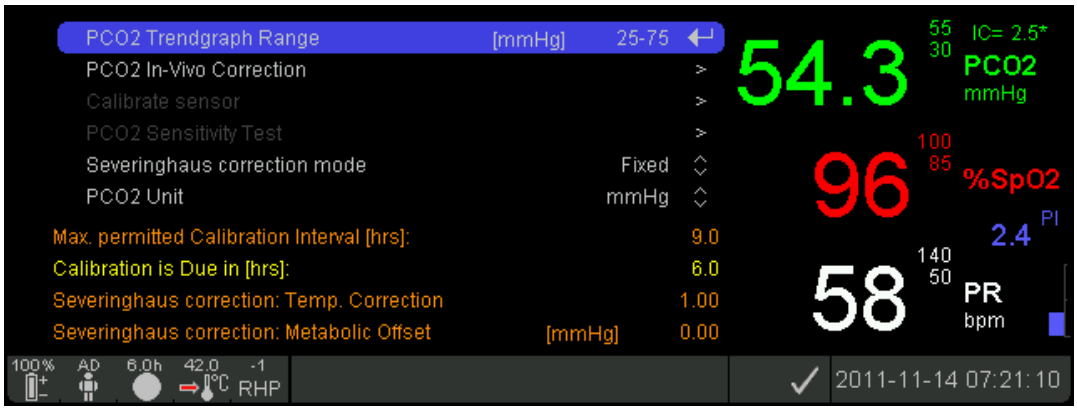


Figure 6 **Severi**nghaus Correction Mode set to 'fixed'

Note: The correction factors M and C can only be changed within a password protected area of V-STATS™.

Note: In 'Fixed' mode, factory settings for the correction factors are M=0.00 mmHg and C=1.00. If these correction factors are used, the SDM displays uncorrected cutaneous PcCO2 values.

Note: In 'Fixed Mode', the IC-Indicator displays 'IC= * (fix)' (if PCO2 is not in-vivo corrected) and 'IC=2.5*' (if PCO2 is in-vivo corrected (4.11) (in this example by 2.5 mmHg)).

4.13.2 V-Check™ Mode

4.13.2.1 Introduction

In standard configuration, the SDM's numeric values and online trends provide continuous monitoring of the enabled parameters. If operated in V-Check™ Mode, in contrast, the SDM provides Ventilation Spot Checks with statistical result screen at the end of V-Check™ Measurements. A V-Check™ Measurement consists of the V-Check™ Stabilization Phase (default duration 8 minutes) and the 'V-Check™ Analysis Phase' (default duration 2 minutes). If the V-Check™ Measurement is finished the 'V-Check™ Results Screen' (Figure 15) activates, displaying for each of the enabled parameters the mean, the minimum, the maximum, the median and the standard deviation within the V-Check™ Analysis Phase.

Note: If the protocol "Serial Printer" is selected and a printer is connected to the SDM, print-out of the trend curves (including the statistical results) is automatically activated upon completion of a V-Check™ Measurement.

Note: V-Check™ Mode is currently only supported for PCO2, SpO2, PR.

Note: In the SDM's factory default setting, operator access to the sub-menu 'V-Check Settings' (Table 44) is disabled and the parameter 'V-Check' is set to OFF and cannot be activated by the operator. Within a password protected area of V-STATS™ the Responsible Organization can enable the use of V-Check™ Mode. Once enabled the operator can access the sub-menu 'V-Check Settings' to adjust V-Check™ related parameters or to activate/deactivate V-Check™ Mode.

Note: If use of V-Check™ is enabled, V-Check™ can also be switched ON or OFF in the Quick Access Menu that activates if pressing the 'ENTER Button' when the Ready for use or Calibration screen is active (4.2.5.3).

Note: On the 'Ready for use' and 'Calibration' screen (4.2.4, Figure 5), the 'V-Check™ Mode Indicator' is displayed on the left of the 'Sensor Temperature Indicator' and of the 'Special Temperature Settings Indicator' if 'V-Check Mode' is ON.

4.13.2.2 V-Check™ Measurement and V-Check™ Results

When the sensor is applied to a patient in V-Check™ Mode, the SDM initiates a 'V-Check™ Measurement' upon 'Sensor-On-Patient' detection. A 'V-Check™ Measurement' consists of the 'V-Check™ Stabilization Phase' (default duration 8 minutes) and the 'V-Check™ Analysis Phase' (default duration 2 minutes).

Note: The duration of the 'V-Check™ Stabilization Phase' and the 'V-Check™ Analysis Phase' can be adjusted in the menu 'V-Check Settings' (Table 44). Ensure that the 'Minimal Measurement Duration' (4.7.4.1) is shorter than the overall duration of the 'V-Check Stabilization Duration' and 'V-Check Analysis Duration' (Table 44). Otherwise V-Check™ Measurement will not be accessible in the sub-menu 'Review/Print Trend Data' (Table 56) for subsequent review/printing of V-Check™ Measurements stored in the SDM's memory (4.13.2.3).

Note: When using V-Check™ Mode, consider to select the Sentec-preconfigured SDM Profile V-CHECK as 'Standard Profile' (4.7.1, 4.7.3). This will set the Sensor Temperature to 43.5 °C, the Site Time to 0.5 hours, SITE PROTECTION to ON, the 'Calibration Interval' to 1 hour, and the 'Time Range for Trends' to 15 minutes.

On measurement screens (4.2.3), the date/time that is normally displayed on the right of the Status Bar (Figure 8) is replaced by the V-Check™ Down-Counter (format hh:mm:ss) in V-Check™ Mode. This down-counter indicates the duration of the 'V-Check™ Measurement' if the V-Check™ Measurement has not yet been started, the remaining time to finish the V-Check™ Measurement during an ongoing V-Check™ Measurement, and 00:00:00 once the V-Check™ Measurement is finished. If the SDMS is not ready for use, it indicates --:--:--. Other than that, the measurement screens in V-Check™ Mode are identical as the measurement screens in regular mode (4.2.3).

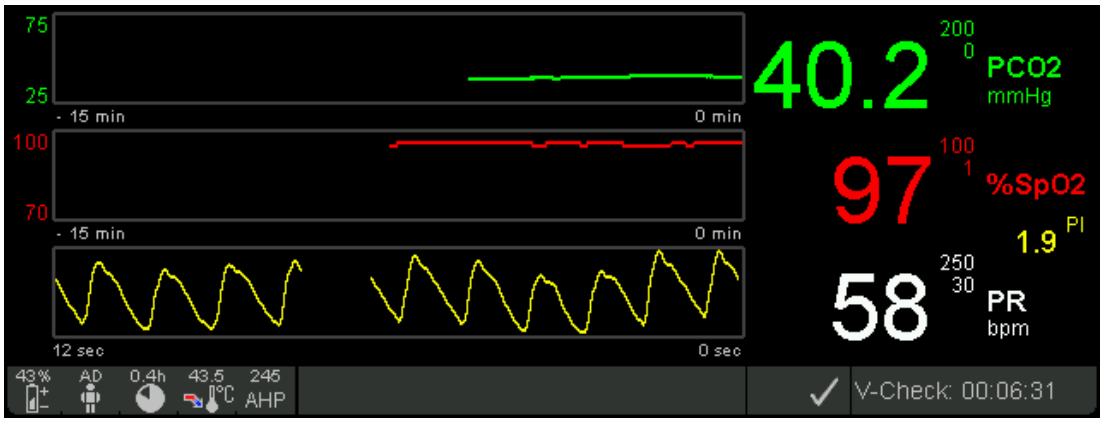


Figure 14 V-Check™ Measurement Screen

If the 'V-Check™ Measurement' is finished, the 'V-Check Completed Beep' (two short signal tones, 4.1.6) sounds and the 'V-Check™ Results' Screen (Figure 15) is activated.

Note: If the protocol "Serial Printer" is selected and a printer is connected to the SDM, print-out of the graphical trends and statistical summary (min, max, mean) is automatically activated upon completion of a V-Check™ Measurement.

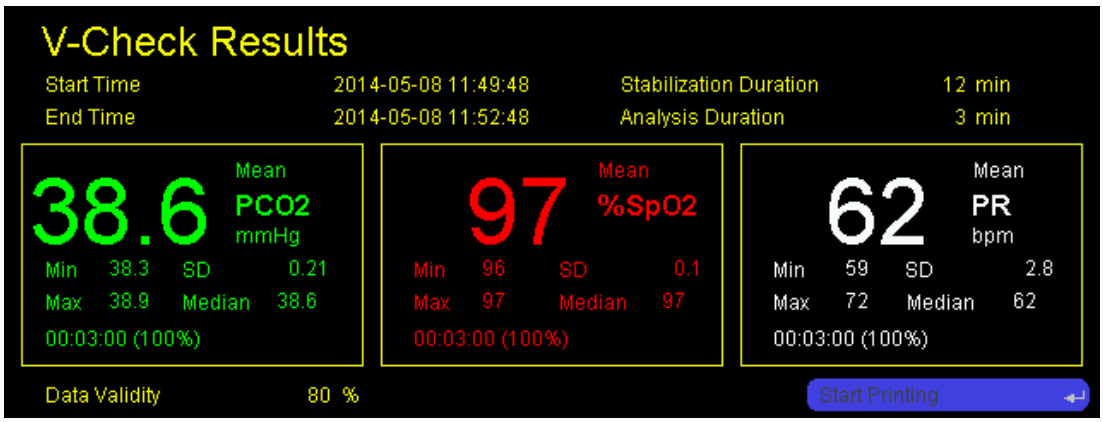


Figure 15 V-Check™ Results Screen

Note: Current values of the monitored parameters, the status bar (Figure 8) and visual alarm signals are not displayed/visible in the 'V-Check Results Screen'.

Note: The V-Check™ Results Screen remains displayed until the operator presses the 'Menu/Previous Level' button or the 'Display' button (4.1.4) or another V-Check™ Measurement is started.

The 'V-Check Results Screen' provides the following information/results:

Start Time	Indicates the date/time at the beginning of the V-Check™ Analysis Phase. **Note**: At the corresponding date/time the status code 'E9' is stored in the SDM's internal memory for subsequent analysis of V-Check™ Measurements with V-STATS™.

End Time	Indicates the date/time at the end of the V-Check™ Analysis Phase/V-Check™ Measurement. **Note**: At the corresponding date/time, the status code 'E9' is stored in the SDM's internal memory for subsequent analysis of V-Check™ Measurements with V-STATS™.
Stabilization Duration	Indicates the duration of the 'V-Check Stabilization Phase', i.e. the time span from 'Sensor-On-Patient' detection to the 'Start of the V-Check Analysis Phase'. Indicated in hh:mm:ss format. **Note**: For future V-Check™ Measurement, the 'Stabilization Duration' can be adjusted in the sub-menu 'V-Check Settings' (Table 44).
Analysis Duration	Indicates the duration of the 'V-Check Analysis Phase', i.e. the time span from the beginning to the end of the 'V-Check Analysis Phase'. **Note**: Only data measured during the 'V-Check Analysis Phase' are used to calculate the 'V-Check Results'. **Note**: For future V-Check™ Measurement, the 'Analysis Duration' can be adjusted in the sub-menu 'V-Check Settings' (Table 44).
Mean, Min, Max, SD, Median	For each enabled parameter, the mean, the minimum (min), the maximum (max), the standard deviation (SD) and the median of its readings within the 'V-Check Analysis Phase' are indicated. **Note**: If for a parameter the percentage of its data with 'valid' quality (4.2.3.8) is smaller than the percentage specified by the parameter 'Data Validity' (see below), results will not be displayed for this parameter but '---' will display instead.
Duration of episodes with data of at least questionable quality	For each parameter, the duration of episodes with at least questionable quality (4.2.3.8) within the 'V-Check Analysis Phase' is indicated underneath 'Max' and 'Median' in the 'hh:mm:ss' format and – in parenthesis – in percentage of the Analysis Duration.
Data Validity	V-Check Results are only calculated for a parameter if the percentage of its valid data (4.2.3.8) within the 'V-Check Analysis Phase' exceeds the percentage specified by the parameter 'Data Validity'. **Note**: The parameter 'Data Validity' can be adjusted in the sub-menu 'V-Check Settings' (Table 44).

4.13.2.3 Reviewing/(Re)printing V-Check™ Measurements

For all 'V-Check™ Measurements' stored in the internal memory of the SDM, it is possible to re-activate the 'V-Check™ Results Screen' (Figure 15) and, if necessary, to reprint the related graphical trends and statistical summary (min, max, mean).

Select the 'V-Check™ Measurements' to be reviewed/(re)printed by using the menu item 'From Start of Measurement' in the sub-menu 'Print/Review Trend Data' (Table 56).

Note: If the number selected in the menu item 'From Start of Measurement' corresponds to the measurement number of a 'V-Check™ Measurement', the menu item 'To End of Measurement' will be forced to display the same number as the menu item 'From Start of Measurement' (and vice versa). If the selected measurement corresponds to a 'V-Check™ Measurement' the orange colored label 'V-Check' is displayed on the right of the menu item 'From Start of Measurement' to indicate that the selected measurement is a 'V-Check™ Measurement'. In this case, the date/time displayed in the menu items 'Start Time' and 'End Time', respectively, are automatically adjusted by the SDM to the beginning and end of the corresponding V-Check™ Analysis Phase, are, consequently, displayed in orange and are not changeable by the operator.

Once the desired 'V-Check™ Measurements' is selected, the corresponding 'V-Check™ Results Screen' (Figure 15) can be reactivated with the function 'Review Trend Data'. To (re)print the related graphical

trends and statistical summary (min, max, mean), ensure that the protocol "Serial Printer" is selected, a printer is connected and then use the function 'Start Printing' in the bottom left of the 'V-Check™ Results Screen' to activate printing.

Note: If a 'V-Check™ Measurement' is on-going, it is not possible to re-activate the 'V-Check™ Results Screen' for other 'V-Check™ Measurements' that are available in the SDM's internal memory.

Note: The length of the print-out increases, depending on the 'V-Check™ Analysis Duration' (Table 44).

'V-Check™ Measurements' can be downloaded and analyzed with V-STATS™. Within V-STATS™, two colored operator event triangles and two vertical grey lines at the position of these Operator Events, indicating the start and end of the 'V-Check™ Analysis Phase', will display in default configuration. By setting the 'Analysis Interval' to the 'V-Check™ Analysis Phase' and by using the report profile 'V-CHECK Report' when printing/storing the report with V-STATS™, will generate a report with the same information as the 'V-Check™ Results Screen' on the SDM.

Note: The only data that are measured when 'V-Check™ Mode' is active, and which are available for subsequent on-screen review/printing, are the data measured during the 'V-Check™ Analysis Phase'. When downloading data to V-STATS™ that were recorded in 'V-Check™ Mode', the start/end times of the measurements that are displayed in the dialog 'Assign measurement period(s) to patients' corresponds to the time range from 'Sensor-On-Patient' detection to 'Sensor-Off-Patient' detection and, hence, the data measured during the 'V-Check™ Stabilization Phase' and after completion of the 'V-Check™ Measurement' are also available.

4.13.3 V-CareNeT™ Only Mode

In this special SDMS configuration, the SDM is factory-preconfigured in 'V-CareNeT™ Only Mode'. After starting-up the SDM and the Power-On Self-Test (POST) (4.6), the 'V-CareNeT™ required' screen appears (Figure 16).

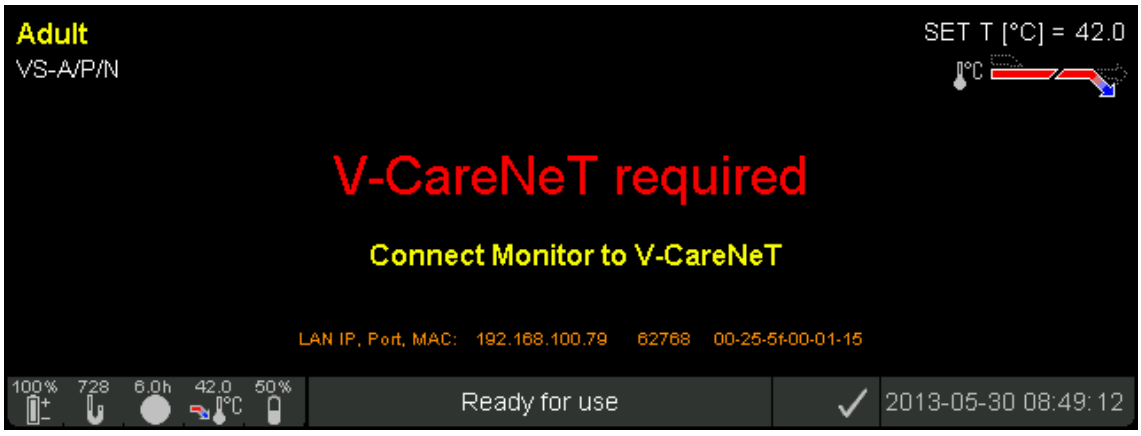


Figure 16 'V-CareNeT™ required' screen

In 'V-CareNeT™ Only Mode', the SDM is not operational/locked (i.e. no measurement data is displayed and no menu functions can be accessed) unless the SDM is connected to V-CareNeT™ (V-STATS™ 3.01.1 or higher and fully activated V-CareNeT™ required).

Note: For network configuration, the LAN IP address, the port number and the MAC address are shown on the 'V-CareNeT™ required' screen, the Status Bar (Figure 8) is displayed in the bottom of the screen.

Note: Resetting the SDM to factory defaults does not deactivate the 'V-CareNeT™ Only Mode'.

If the connection to V-CareNeT™ is interrupted for a time period exceeding 4 hours, the SDM will lock again once the V-Sign™ Sensor 2 is inserted into the 'Docking Station'. The 'V-CareNeT™ required' screen re-appears until the connection to V-CareNeT™ is re-instated.

Note: On-going patient monitoring will not be interrupted if the communication to V-CareNeT™ is lost. All measuring and alarming functions will continue as normal.

Note: A sensor may be calibrated even if the SDM is locked (i.e. if the 'V-CareNeT™ required' screen is displayed).

Note: A measurement may be started even if the SDM is locked (i.e. if the 'V-CareNeT™ required' screen is displayed). However, connection to V-CareNeT™ is required to display the data and to store them into internal memory.

Note: As long as the 'V-CareNeT™ required' screen is displayed, no vital data are shown on the online outputs of all supported protocols (Philips Vuelink/Intellibridge I+II, Spacelabs Flexport, TCB, SentecLink Online).

Note: As long as the 'V-CareNeT™ required' screen is displayed, pressing any button except for the AUDIO PAUSE/OFF button will cause the low pitched 'Button Disabled Beep' to sound.

Note: For devices configured in 'V-CareNeT™ Only Mode', the parameters 'LAN selectable' and 'LAN interface' are both forced to ON and cannot be set to OFF (5.3).

4.13.4 'Demo Mode'

For demonstration and training purposes, the SDM offers a 'Demo Mode', which can be activated by setting the menu parameter 'System Settings/'Demo Mode' to ON (4.7.4.2).

Note The 'Demo Mode' can be activated only if the use of the 'Demo Mode' has been enabled by the Responsible Organization within a password protected area of V-STATS™ (4.7.4.1).

Note The 'Demo Mode' can be activated with or without a sensor connected to the SDM. If a sensor is connected to the SDM, the 'Demo Mode' cannot be activated if the sensor is applied to the patient. If the 'Demo Mode' is already active when applying the sensor to the patient, the 'Demo Mode' automatically deactivates as soon as the system recognizes that the sensor has been applied to the patient.

To clearly identify the 'Demo Mode', the status text field is displayed in yellow and displays the label 'Demo Mode'. In the 'Ready for use' screen (where the status text field is not available), a respective indicator is displayed above the 'Ready for use' label. Otherwise the display elements of the various preconfigured measurement screens are unchanged.

Note With the exception of the messages which are displayed in big yellow font on the 'Calibration' screen ('Calibration in progress', 'Leak test in progress', 'Ready for use') or on the 'Ready for use' screen ('Ready for use') no Status Messages other than 'Demo Mode' are displayed if the 'Demo Mode' is active.

If a Sentec TC Sensor is connected to the SDM and is in the 'Docking Station', the system behaves as usual, i.e. either the 'Calibration' screen or the 'Ready for use' screen is displayed. In order to activate the display of simulated data on one of the available measurement screens the Sentec TC Sensor must neither be in the 'Docking Station' nor applied to the patient.

Note Depending on the type of TC sensor connected to the SDM, only those parameters supported by the respective TC sensor will be demonstrated.

Note PO2 data cannot be demonstrated in monitors where PO2 is not activated.

Note RHP data can only be demonstrated if the parameter 'Heating Power Mode' is set to 'relative'.

If no sensor is connected to the SDM, the 'Demo Mode' does not support the 'Ready for use' or 'Calibration' screen, i.e. in this case the 'Demo Mode' displays simulated data on one of the available measurement screens in all situations.

The 'Demo Mode' runs through a sequence of simulated data for the enabled parameters PCO2, PO2 (only if PO2 is enabled), SpO2, PR and HP which is repeated every 30 minutes and which illustrates the typical behavior of the readings during apnea, hyperventilation and hypoventilation episodes followed by a sequence simulating supply of supplemental Oxygen in a COPD patient (PCO2 increasing due to reduced hypoxic drive). It furthermore illustrates the impact of decreasing local blood flow beneath the sensor site on the relative heating power (increasingly negative values) and the PCO2 (increased values due to reduced CO2 washout from tissue) and PO2 (decreased values due to reduced O2 supply to tissue) readings.

Note that the simulated, purely artificial plethysmographic waveform does not correspond with the current PR value. A constant value of 2% is displayed for PI. Whenever possible the status icons (4.3.2) display measured values or current settings, otherwise the information displayed in the status icons is simulated as well. In the 'Demo Mode' alarm surveillance of physiological parameters is active, i.e. if one of the simulated parameters violates its alarm limits the respective alarm is triggered. Technical alarms (e.g. gas empty) in contrast are not monitored.

Note The simulated data displayed when the 'Demo Mode' is active are not stored in the internal memory of the SDM.

The simulated data are displayed as Online Trends in the respective measurement screen and are output through the various interfaces (serial port (5.2), analog outputs (5.4.1), LAN port (5.3)) for display on external instruments. Where technically possible the simulated data are marked as Demo data and alarm limit violations are communicated, whereas other status information is not output in 'Demo Mode'.

Note The voltage output through the analog outputs (5.4.1) in 'Demo Mode' represents the simulated data for PCO2, SpO2, PR, and the plethysmogram. When interfacing the SDM with a poly- or polysomnographic system the 'Demo Mode' is very useful to verify proper configuration by comparing the simulated data displayed on the SDM with the corresponding readings displayed by the poly- or polysomnographic system.

Note The Nurse Call function (5.4.2) is not supported in 'Demo Mode'.

5 Data Communication

5.1 Overview

Patient data acquired by the Sentec Digital Monitor can be output through its multipurpose I/O-port (analog output (5.4.1); nurse call (5.4.2)), its serial data port (RS-232) (5.2) or its LAN port (5.3), all located on its rear panel (4.1.2). These ports can be connected to external instruments such as multi-parameter bedside monitors, ventilators, personal computers (PC), poly(somno)graphs, nurse call systems, chart recorders, or data loggers. Connection of accessory equipment to the SDM`s data ports is to be performed by qualified personnel.

WARNING: When connecting/mounting the SDM to accessory equipment (e.g. PCs, poly or polysomnographic systems, multi-parameter bedside monitors, ventilators, (wireless) Ethernet networks, nurse call systems, roll stands, mounting plates, incubators, etc.)), verify proper operation before clinical use of the SDM and accessory equipment. In certain cases it may be required that the SDM and the accessory equipment must be connected to a grounded AC outlet. In case of doubt consult qualified technicians.

WARNING: Accessory equipment (e.g. a PC) connected to the SDM's data ports must be certified according to the IEC 60950 standard. All resulting combinations of equipment must be in compliance with the IEC standard 60601-1 systems requirements. Anyone who connects accessory equipment to the SDM configures a medical system and is, therefore, responsible for ensuring that the resulting system complies with the requirements of standard IEC 60601-1 and the electromagnetic compatibility standard IEC 60601-1-2.

WARNING: The mains power supply of the Sentec Digital Monitor (SDM) is separated by two Means of Patient Protection (MOPPs) between the sensor port (for the applied part, the sensor) and the interface connectors. The three interface connectors – serial data port, Multipurpose I/O port (analog outputs, nurse call), LAN port – of the SDM are not separated from each other. If at a time accessory equipment is connected to only one of the three interface connectors no additional safety measures are necessary to comply with the requirements of IEC 60601-1. If, however, accessory equipment is simultaneously connected to two or three of the SDM's interface connectors, additional safety measures may be required to be compliant with the requirements of IEC 60601-1. In case of doubt, consult qualified technicians.

5.2 Serial data port (RS-232)

The serial data port (RS-232) of the SDM is used to communicate with external data collection systems such as personal computers or multi-parameter bedside monitors. The serial data port (RS-232) is located on the rear panel of the SDM (4.1.2). The pin layout of the serial data port (RS-232) is illustrated in Figure 17 (as seen from the backside of the SDM):

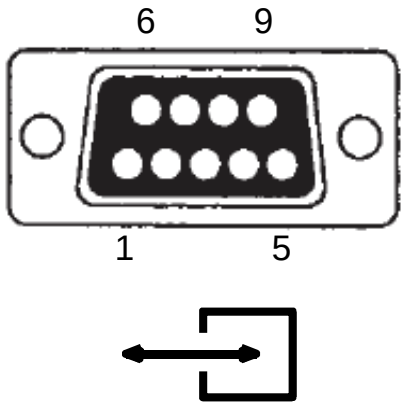


Figure 17 Serial Data Port (RS-232)

The following table shows the pin assignment of the serial data port (RS-232):

Pin	Description
1	Reserved
2	Transmitted data (Tx)
3	Received data (Rx)
4	Reserved
5	Signal ground
6-9	Reserved

Table 75 Pin assignment of the serial data port (RS-232)

Note: Trend data download via the serial interface cannot be activated during an ongoing trend data download via the LAN interface. Other serial data access works normally.

Note: Maximum permitted/possible voltage and current on the SDM's interfaces are specified in 8.4.4 (sub-section 'INTERFACES').

5.2.1 Communication protocols

The menu-parameter 'Interfaces/Serial Interface/Protocol' (Table 52) permits to select the serial communication protocol. Each of the available options is briefly described below:

OFF
If the menu-parameter 'Protocol' is set to OFF data communication via the serial interface is inactive.

SentecLink
SentecLink is Sentec's proprietary communication protocol enabling bidirectional communication and data transfer between the SDM and other devices or PC based applications.

Note: An example of an external PC based application is V-STATS™, Sentec's PC based Remote Monitoring, Trend Data Download/Analysis and Configuration Software for Sentec Digital Monitors. For details, please refer to the Instruction Manual for V-STATS™.

When using SentecLink, the following communication protocol parameters should be set at the receiving device:

Parameter	Setting
Bits per second	User-selectable: 115'200, 57'600, 38'400, 19'200 (SDM's menu parameter 'Interfaces/Serial Interface/Baud Rate (SentecLink)'
Data bits	8
Parity	None
Stop bits	1
Flow control	None

Table 76 Serial port settings for SentecLink

In its default configuration SentecLink

a) continuously outputs on-line (real-time) data of the SDM (5.2.2).
b) constantly checks for an incoming command sent by a host. Once the SDM recognizes an incoming command it sends the corresponding command response. In particular, it is possible to activate the download of the data stored in the internal memory of the SDM (4.12.1) by sending an appropriate command.

Serial Printer
Select this protocol to print trend data stored in the internal memory of the SDM (4.12) using the Seiko DPU-414 THERMAL PRINTER (4.12.5.4).

Philips VueLink/Intellibridge and Philips VueLink/Intellibridge 2
Select one of these protocols to enable data transfer from the SDM to Philips Patient Monitoring Systems via the 'Philips VueLink Open Interface' or 'Philips Intellibridge Open Interface'. For details please refer to the 'VueLink/Intellibridge Installation Manual'.

Spacelabs Flexport
Select this protocol to enable data transfer from the SDM to Spacelabs Healthcare monitors via the 'Flexport System Interface'. For details please refer to the 'Flexport Interface Manual'.

Note: Output of PO2 data with the Spacelabs Flexport protocol is currently not supported.

TCB – TransCutaneous Basic Protocol
Select this protocol to enable data transfer from the SDM in a basic transcutaneous data mode protocol. Use this protocol to connect e.g. to Dräger Monitoring (via MIB Converter). For details please refer to the 'Dräger Installation Manual'.

5.2.2 SentecLink – Online Data Output

Data Flow

Output of Data lines	One data line per second
Output of heading lines	1) Immediately after activation of the protocol 'SentecLink' 2) Every 50 data lines 3) Immediately after one of the heading line elements changes (e.g. when changing the PCO2/PO2 unit from 'mmHg' to 'kPa' or vice versa).

Table 77 SentecLink (Online) – Data Flow

Heading and Data lines content
SentecLink's on-line data output exports the data in an ASCII TSV (tab-separated values) format.

Main heading line		***SENTEC DIGITAL MONITOR ON-LINE DATA***
Monitor info heading line	Column 1	Monitor:<value> *serial number of monitor*
	Column 2	MPB-SW:<value> *software version of signal analysis board*
	Column 3	SMB-SW:<value> *software version of SMB*
	Column 4	DS: < value >.< value > *hardware.software version of Docking Station*
	Column 5	Patm[mmHg]<value> **or** Patm[kPa]<value> *measured barometric pressure (4.3.2)* *(value only if sensor is in docking station, otherwise '---' is output)*
	Column 6	SpO2-Avg[s]<value> *'SpO2 Averaging' (Table 42)*
	Column 7	IVC[mmHg]<value> **or** IVC[kPa]<value> *current 'PCO2 In-Vivo Correction' offset (4.11). In case Serveringhaus Correction Mode (4.13.1) is set to fixed an asterix (*) is added to the value.*
Sensor info heading line	Column 1	Sensor:<value> *sensor type (model)*
	Column 2	SN:<value> *serial number of sensor*
	Column 3	SW:<value> *software version of sensor*
	Column 4	T[°C]:<value> *'Sensor Temperature' (Table 39)*
	Column 5	PID: <value> *patient ID (4.7.4.1)*
	Column 6	<value> *patient type (Table 38) (adult or neonate)*
Data column heading lines	Column 1	Date&Time[yyyy-mm-dd hh:mm:ss]
	Column 2	SpO2[%]<low limit>:<high limit>[a)]
	Column 3	PCO2[mmHg]<low limit>:<high limit>[a)] **or** PCO2[kPa]<low limit>:<high limit>[a)]
	Column 4	PR[bpm]<low limit>:<high limit>[a)]
	Column 5	PO2[mmHg]<low limit>:<high limit>[a)] **or** PO2[kPa]<low limit>:<high limit>[a)]

Main heading line		***SENTEC DIGITAL MONITOR ON-LINE DATA***
	Column 6 Column 7 Column 8	PI[%] HP[mW]<value> if AHP: value=0; else if RHP: value=reference value (--- if not determined) else if HP mode = off value = '-/-' Status
Data lines	Column 1 Column 2 Column 3 Column 4 Column 5 Column 6 Column 7 Column 8	<date><time> <SpO2 value><Limit violation>[b]<questionable>[c] <PCO2 value><Limit violation>[b]<questionable>[c] <PR value><Limit violation>[b]<questionable>[c] <PO2 value><Limit violation>[b]<questionable>[c] <PI value> <HP value> <code>[d]

Table 78 SentecLink (Online) – Heading/Data lines content

[a]) Low and high alarm limits of the respective parameters (Table 37).

[b]) A plus sign ('+') behind a measured value indicates that the high alarm limit of the respective parameter has been violated. A minus sign ('-') behind a measured value indicates that the low alarm limit of the respective parameter has been violated (Table 37).

[c]) A question mark ('?') behind a measured value indicates that the respective parameter is marked as questionable (4.2.3.8).

Note: If a parameter is marked as questionable (4.2.3.8) alarm surveillance for the respective parameter is active. Behind a measured value the following combinations therefore can be added: '+', '-', '?', '+?', and '-?'.

[d]) Output of status codes (4.3.5). It is possible that no (e.g. if during monitoring everything is "OK") or multiple status codes are output. If multiple status codes are output, they are separated from each other by a space.

Depending on the position of the connected sensor, the quality of the respective parameter and/or the operation mode/status the SDM provides the following outputs.

	Sensor Position (Quality of parameter (4.2.3.8))	PCO2	SpO2	PR	PI	HP	PO2
Normal Mode	'ON Patient', respective parameter valid	**Value**	**Value**	**Value**	**Value**	**Value**	**Value**
	'ON Patient', respective parameter questionable	**Value?**	**Value?**	**Value?**	**Value?**	**Value?**	**Value?**
	'ON Patient', respective parameter unstable	u	u	u	u	u	u
	'ON Patient', respective parameter invalid	i	i	i	i	i	i
	'ON Patient', respective parameter not available	-/-	-/-	-/-	-/-	-/-	-/-
	Off Patient, respective parameter enabled	---	---	---	---	**Value** (if AHP-Mode), "-/-" (if RHP Mode)	---
	Off Patient, respective parameter not available	-/-	-/-	-/-	-/-	-/-	-/-

	Sensor Position (Quality of parameter (4.2.3.8))	PCO2	SpO2	PR	PI	HP	PO2
	In 'Docking Station', respective parameter enabled	**Value**	---	---	---	"---" for AHP, "-/-" for RHP	--- (**value** during PO2 calib. only)
	In 'Docking Station', respective parameter not enabled	-/-	-/-	-/-	-/-	-/-	-/-
	No sensor connected	-/-	-/-	-/-	-/-	-/-	-/-
'Demo Mode' (4.13.4)	'ON Patient' (not applicable in 'Demo Mode'. Note: 'Demo Mode' automatically deactivates if the sensor is applied to the patient)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
	OFF Patient ('Demo Mode')	**Value**	**Value**	**Value**	**Value**	**Value**	**Value**
	In 'Docking Station' (Sentec TC Sensors only)	**Value**	---	---	---	---	--- (**value** during PO2 calib. only)
	No sensor connected ('Demo Mode')	**Value**	**Value**	**Value**	**Value**	**Value**	**Value**

Table 79 SentecLink (Online) – Data Output

Note: Measurement parameters can be enabled/disabled in the menu 'Measurement Settings' (Table 38). Available selections depend on the connected sensor type and the selected patient type.

Note: In 'Neonatal Mode', PI is always disabled, in 'Adult Mode' it is always enabled (even if SpO2/PR is disabled).

5.3 LAN port

The LAN port of the SDM is used to communicate with external computer based data collection systems. The LAN port is located on the rear panel of the SDM (4.1.2). The LAN port is a standard 10Base-T Ethernet connector. Use shielded Category 5 (use at least Cat5) Ethernet cables to connect the monitor to a network socket, hub or switch. You may also use a shielded Category 5 (use at least Cat5) cross-over Ethernet cable for direct connection of the monitor to a computer without a hub or switch.

Note: Trend data download via the serial interface cannot be activated during an ongoing trend data download via the LAN interface. Other serial data access works normally.

Note: A locking mechanism prevents multiple V-CareNeT™ instances from remotely monitoring the same SDM simultaneously.

Note: Maximum permitted/possible voltage and current on the SDM's interfaces are specified in 8.4.4 (sub-section`INTERFACES´).

5.3.1 IP address and port assignment

The SDM can be configured for automatic IP address assignment via DHCP (Dynamic Host Configuration Protocol). If the network does not have a DHCP server the IP address can also be configured manually. Network settings can be configured via V-STATS™ within a password protected area (4.7.4.1). The port used for the communication with the monitor is preconfigured to 62768. The communication of the SDM is via UDP (User Datagram Protocol) according to RFC 768 as part of the

internet protocol suite. One of three different Ethernet network modes can be selected: Auto, half, and full duplex. Auto is the default and recommended setting.

Note: Please contact a responsible IT person for correct network configuration of the monitor in your organization. A wrong setting might disrupt the network integrity and cause data communication errors.

Note: When using shielded Category 5 (use at least Cat5) cross-over Ethernet cables make sure to assign an IP address manually as there is no DHCP service available in a direct connection setting. It might also be necessary that you set the IP address of the interfacing computer manually.

5.3.2 Configuration of the SDM's network settings by using V-STATS™

Within a password protected area of V-STATS™ the Responsible Organization can define the SDM's network settings (4.7.4.1). The following parameters can be configured: 'LAN selectable', 'Device Name/Host name', 'DHCP Mode', 'IP Address', 'IP Port', 'Ethernet Mode', 'DNS Mode'.

Note: The settings of the parameters 'Device Name/Host name', 'DHCP Mode', 'IP Address', 'IP Port', 'MAC Address' and 'Ethernet Mode' are displayed in the sub-menu 'Interfaces/LAN Interface' (Table 53). Use V-STATS™ to see the setting of the parameter 'DNS Mode'.

Note: If the SDM is factory-preconfigured in 'V-CareNeT™ Only Mode' (4.13.3) the LAN configuration is forced to ON and cannot be switched off.

Note: The respective SDM and V-STATS should be in the same subnet.

5.3.3 Communication with V-STATS™/V-CareNeT™

V-STATS™/V-CareNeT™ uses a DHCP broadcast command for device discovery in the network (BOOTP). All SDMs within the broadcast range will respond to the broadcast with their IP address and subsequent communication is then possible. V-STATS™/V-CareNeT™ also provide a DNS mode to optionally request an update of DNS records from the DHCP server (DHCP option 81).

Note: The broadcast range is usually within the same subnet, but can also be across subnets depending on the router configuration or firewall.

Note: If V-STATS™/V-CareNeT™ need to communicate across subnets the router (and/or the firewall) has to be configured to forward DHCP broadcast packets. Usually this is already the case in a network setting where one DHCP server serves several subnets. Usually device discovery will work within a DHCP domain. Please contact a responsible IT person for correct network configuration of the monitor in your organization. A wrong setting might disrupt the network integrity and cause data communication errors.

After device discovery V-STATS™/V-CareNeT™ will provide a list of SDMs found in the network and subsequently remote monitoring can be activated with one or more SDMs.

Note: Firewall settings of the PC and network have to allow the sending/receiving of DHCP discovery frames for automatic device discovery to work.

5.4 Multipurpose I/O port

The multipurpose I/O-port is located on the rear panel of the SDM. The pin layout of the multipurpose I/O-port is illustrated below (as seen from the backside of the SDM):

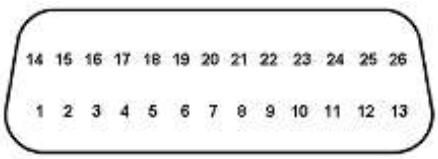


Figure 18 Multipurpose I/O Port

The multipurpose I/O-port provides 'analog output' (Pins 1 – 8) and 'nurse call' (Pins 24 – 26). The following table shows the pin assignment of the multipurpose I/O-port:

	Pin	Signal	Description
Analog Outputs (5.4.1)	1 + 2 (CH0)	Pleth (**signal** + ground)	Output voltage: 0 – 1.05 Volt Assignable parameter ranges: See Table 54.
	3 + 4 (CH1)	PR (**signal** + ground)	Output voltage: 0 – 1.05 Volt Assignable parameter ranges: See Table 54.
	5 + 6 (CH2)	SpO2 (**signal** + ground)	Output voltage: 0 – 1.05 Volt Assignable parameter ranges: See Table 54.
	7 + 8 (CH3)	PCO2 (**signal** + ground)	Output voltage: 0 – 1.05 Volt Assignable parameter ranges: See Table 54.
	9 – 23	Reserved	--
Nurse Call (5.4.2)	24	Common lead for Nurse Call relays 1 + 2	--
	25 (NC)	Nurse call relay 1	active closed **closes** when alarm sounds (only if 'nurse call' is enabled)
	26 (NO)	Nurse call relay 2	active open **opens** when alarm sounds (only if 'nurse call' is enabled)

Table 80 Pin assignment multipurpose I/O port

Note: Various ready-made adapter cables are available to interface the SDM with the most common polygraphic (PG) and polysomnographic (PSG) systems. Channel 0 (CH0) of these cables connects to pin 1 + 2 (Pleth) of the multipurpose I/O port, channel 1 (CH1) to pin 3 + 4 (PR), channel 2 (CH2) to pin 5 + 6 (SpO2), and channel 3 (CH3) to pin 7 + 8 (PCO2). PIN 2, PIN 4, PIN 6 and PIN 8 have a common Ground (GND).

Note: Maximum permitted/possible voltage and current on the SDM's interfaces are specified in 8.4.4 (sub-section`INTERFACES').

Note: Output of PO2, PI and HP data via the Analog Output is currently not supported.

5.4.1 Analog Output

The SDM provides analog voltage outputs for PCO2, SpO2, PR, and the Pleth Waveform on pins 1 – 8 of the multipurpose I/O-port (Table 80). The output voltage represents a specific measured parameter's current value. Depending on the position of the connected sensor and/or the operation mode/status of the SDM the analog output is active or inactive (i.e. set to 0 Volt).

	Sensor Position (Quality of parameter (4.2.3.8))	PCO2	SpO2	PR	Pleth
Normal Mode	'ON Patient', respective parameter valid or questionable	**Signal**	**Signal**	**Signal**	**Signal**
	'ON Patient', respective parameter unstable, invalid, or not enabled/available	0 Volt	0 Volt	0 Volt	Signal/ 0.5 Volt
	'Off Patient'	0 Volt	0 Volt	0 Volt	0.5 Volt
	In 'Docking Station' (only for Sentec TC Sensors)	0 Volt	0 Volt	0 Volt	0 Volt

	Sensor Position (Quality of parameter (4.2.3.8))	PCO2	SpO2	PR	Pleth
	No sensor connected	0 Volt	0 Volt	0 Volt	0 Volt
'Demo Mode' (4.13.4)	**'ON Patient'** (not applicable, the 'Demo Mode' automatically deactivates if the sensor is applied to the patient)	n.a.	n.a.	n.a.	n.a.
	'Off Patient' ('Demo Mode')	**Signal**	**Signal**	**Signal**	**Signal**
	In 'Docking Station' (only for Sentec TC Sensors)	0 Volt	0 Volt	0 Volt	0 Volt
	No sensor connected ('Demo Mode')	**Signal**	**Signal**	**Signal**	**Signal**

Table 81 Analog output signals

Note: Output of PO2, PI and HP data via the Analog Output is currently not supported.

5.4.1.1 Interfacing the SDM with a polygraphic or polysomnographic system

Various ready-made adapter cables are available to interface the SDM with the most common polygraphic (PG) and polysomnographic (PSG) systems: see the PSG Adapter cables Product Information on

https://www.sentec.com/products/sentec-device-connectivity/

(or try https://www.sentec.com – Knowledge Center – Customer Portal - Connectivity and select `PSG Adapter Cables Product Information´)

To interface the SDM with a polygraphic or polysomnographic system select the appropriate cable from the `PSG Adapter Cables Product Information´ on Sentec`s webpage and then perform the following steps:

1. Connect the PSG Adapter Cable to the SDM's Multipurpose I/O-Port (Figure 2).
2. Connect the free end(s) of the PSG Adapter Cable to the PG-/PSG-System. Channel 0 (CH0) of Sentec's PSG Adapter Cables connects to pin 1 + 2 (Pleth) of the multipurpose I/O port (Table 80), channel 1 (CH1) to pin 3 + 4 (PR), channel 2 (CH2) to pin 5 + 6 (SpO2), and channel 3 (CH3) to pin 7 + 8 (PCO2)

Note: The 'Channel-to-Parameters' assignment is displayed as yellow information text in the menu 'Interfaces/Analog Outputs' (Table 54).

Note: If you do not want to interface all parameters with the PG-/PSG-System, only connect the plug(s) of the desired parameter(s) and close the unused plugs with blind plugs.

3. On the SDM, verify the parameter ranges that are assigned to the 0 to 1 Volt output range in the menu 'Interfaces/Analog Outputs' (Table 54). If necessary adjust the ranges.

Note: The voltage differential varies proportionally from 0 to 1 volt as the pin's parameter varies over the selected parameter range. The output voltage for a parameter is 0 Volt if its current reading is lower than the lower end of the selected parameter range and 1 Volt if it is larger than the upper end of the selected parameter range, respectively. Ensure for each parameter that the selected range will comprise all values expected for this parameter.

Examples:
a) PCO2 Range = 0 - 100 mmHg (default): 0.3 Volt will be output for a reading of 30 mmHg, 0.7 Volt for a reading of 70 mmHg, and 1 Volt for all readings equal or greater than 100 mmHg.

b) SpO2 Range = 50-100 mmHg (default). 0 Volt will be output for all readings smaller or equal to 50%, 0.5 Volt for a reading of 75%, and 1 Volt for a reading of 100%.

4. Verify that on the PG-/PSG-System the same parameter ranges are selected as on the SDM. If necessary adjust the ranges on the PG-/PSG-System.
5. Calibrate the PG-/PSG-System attached to the analog output of the SDM by using the menu-function 'Calibration Sequence' in the menu 'Interfaces/Analog Outputs' (Table 54).

Note: The menu function 'Calibration Sequence' will cause for all parameters the output of 1 Volt during 60 seconds, followed by the output of 0 Volt during another 60 seconds. When the calibration sequence is running the current output voltage is indicated on the display.

Note: By pressing ENTER it is possible
to change from 1 Volt to 0 Volt (if output of 1 Volt is active)
to stop the calibration sequence (if output of 0 Volt is active)

6. Test the Analog Output function. Ensure that the readings displayed on the SDM are properly duplicated on the attached PG-/PSG-System.

Note: The voltage output through the analog outputs in `Demo Mode' (4.13.4) represents the simulated data for PCO2, SpO2, PR, and the plethysmogram. When interfacing the SDM with a PG-/PSG-System the `Demo Mode' is very useful to verify proper configuration by comparing the simulated data displayed on the SDM with the corresponding readings displayed by the poly- or polysomnographic system.

Note: Due to the limited resolution of digital-to-analog conversion of the SDM's analogoutput the readings duplicated on the attached instrument and those displayed on the SDM are not exactly identical. The smaller the parameter range that is assigned to the 0-1 volt output range is (Table 54), the better is the resolution and, hence, the better the readings duplicated on the attached instrument match the readings displayed on the SDM (and vice versa).

WARNING: Ensure to properly calibrate the instrument (PG-/PSG-System) attached to the SDM's analog output at initial setup and, thereafter, at least monthly.

WARNING: Verify proper function of the analog output signals before each application.

WARNING: The analog output signals do not contain any alarm or system status related information.

WARNING: Refer to sections 1.2 and 5.1 for additional warnings related to connecting/mounting the SDM to accessory equipment.

5.4.2 Nurse Call

WARNING: The nurse call feature is inactive whenever the auditory alarm signals are PAUSED or OFF.

WARNING: The nurse call feature should not be used as the primary source of alarm notification. The auditory and visual alarms of the SDM, used in conjunction with clinical signs and symptoms, are the primary sources for notifying medical personnel that an alarm condition exists.

Note: For further specifications regarding maximum voltage and current on the SDM interfaces, refer to 8.4.4 (sub-section `INTERFACES').

The nurse call feature of the SDM works in conjunction with the nurse call system of your institution when the monitor activates an auditory alarm signal (4.4.3). It duplicates auditory alarm signals to the nurse call system of your institution, i.e. whenever an auditory alarm signal of the SDM sounds, your institution's nurse call system is activated. The nurse call feature is accessed through the data port pins 24, 25 and 26 of the multipurpose I/O-port.

The nurse call interface of the SDM is relay-based and is available when the SDM is operating either on AC power or on battery power. The remote location is signaled anytime there is an auditory alarm signal. If the auditory alarm signal has been PAUSED or switched OFF, the nurse call function is also inactive. The nurse call function can be switched on or off in the menu 'Interfaces'.

Pins 24 and 25 provide a relay that closes when an alarm is sounding on the monitor. Pins 24 and 26 provide a relay that opens when an alarm is sounding. Pin 24 is a common lead for both relays.

WARNING: Verify proper function of the Nurse Call before each application.

Testing the Nurse Call function

The nurse call feature should be tested whenever setting up the SDM in a location that uses the SDM's nurse call. One way to test the nurse call function is to create an alarm condition (e.g. sensor disconnected) and verify that your facility's nurse call system is activated.

WARNING: Refer to sections 1.2 and 5.1 for additional warnings related to connecting/mounting the SDM to accessory equipment.

6 Maintenance

6.1 Maintenance overview

With normal use, the SDM does not require any internal adjustments or additional calibrations. However, to guarantee continuous performance, reliability and safety of the SDMS, routine checks and preventive maintenance procedures (including cleaning/disinfection) as well as safety checks should be performed regularly.

Instructions for **cleaning and/or disinfection** of the Sentec Digital Monitor (SDM) and the 'Digital Sensor Adapter Cable' are provided in sub-section 6.2. Please refer to www.sentec.com/ifu for instructions for cleaning and/or disinfection of Sentec TC Sensors.

The most important **routine checks and maintenance procedures** that should be performed by the operator (be it daily, weekly or monthly) are provided in the 'Instruction Manual for the SDMS'. Additional routine checks and preventive maintenance procedures (e.g. cleaning of Sentec TC Sensors without membrane) as well as the complete safety check for the SDMS (SDM, Sentec TC Sensors (including the 'Digital Sensor Adapter Cable') are provided in the 'Service Manual for the SDMS'. Safety checks should be performed by qualified service personnel at regular intervals (at least every 24 months) or in accordance with local and governmental regulations. On www.sentec.com/ifu, you may download the form `SDMS Maintenance Checklist´, which provides an overview of required maintenance activities. It also serves to document maintenance activities performed.

The 'Service Manual for the SDMS' also provides information on **repair and service procedures** which do not require opening the cover of the SDM. To perform a safety check and for service or repair, contact qualified service personnel or your local Sentec representative. Please note that repair and service procedures which require opening the cover of the SDM must be performed by Sentec authorized service personnel only.

Note: 'Instructions for Shipments' when equipment or accessories are to be returned for a safety check and/or for service/repair, finally, are provided in sub-section 6.3.

WARNING: The cover of the SDM should be removed only by Sentec authorized service personnel. There are no user-serviceable parts inside the SDM.

6.2 Cleaning and Disinfection

Due to the nature and seriousness of infectious diseases such as AIDS and Hepatitis B, it is important that equipment and accessories which can come into contact with human or animal tissues or fluids (particularly blood) should always be regarded as contaminated and potentially hazardous.

Contaminated equipment and accessories must be decontaminated. Decontamination must be carried out by a properly trained person. The directions for cleaning and disinfection vary from hospital to hospital. If you are in any doubt regarding contamination or decontamination, consult your local infection control authority/hygiene department.

When equipment or accessories are to be returned to the supplier or factory for service/repair, the clinical user is required to ensure that the device has been properly decontaminated. A 'Certificate of Disinfection' has to be completed by the person responsible for the device, and this certificate must accompany the device on its return for service or repair. Where equipment is to be serviced on site, a 'Certificate of Disinfection' may also be required by the service engineer.

Note: A PDF of the 'Certificate of Disinfection' is available on www.sentec.com/ifu.

WARNING: Before cleaning the monitor, always switch it off and disconnect it from AC power.

CAUTION: Plugs and connectors meticulously have to be kept clean and dry at all times. Do not expose the SDM to heavy moisture and do not allow any fluids to enter the SDM. If the SDM becomes wet accidentally, it should be removed from AC power, wiped dry externally, allowed to dry thoroughly, and inspected by qualified service personnel before further use.

CAUTION: Using other cleaning and disinfection agents than recommended may cause damage and/or deterioration of the device's materials and device failure can result.

CAUTION: Applying mechanical force on the device during cleaning may damage the device's materials and device failure can result.

CAUTION: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the monitor. These substances attack the device's materials and device failure may result.

CAUTION: Do not sterilize any parts of the equipment by irradiation, steam or ethylene oxide. Do not autoclave or pressure sterilize.

CAUTION: Do not touch, press or rub the surfaces of the SDM with abrasive cleaning compounds, instruments, brushes, rough surface materials, or bring them into contact with any that could scratch the SDM's surfaces.

Recommended cleaning/disinfection procedures for Sentec TC Sensors

For cleaning and/or disinfection of Sentec TC Sensors, use 70% Isopropanol or an approved cleaning agent listed on www.sentec.com/ifu.

Recommended cleaning/disinfection procedures for the Sentec Digital Monitor

Sentec recommends cleaning the SDM weekly using a wipe soaked in 70% Isopropanol. However, other cleaning / disinfection procedures may be applied (refer to instructions given below) as often as required per institutional ordinances.

As the number of available cleaning and disinfection agents varies from country to country and from hospital to hospital, it is not possible to provide a complete list of all suitable cleaning and disinfection agents. The below listed name brand products may be substituted by other name brand products of equivalent composition. Refer to the instructions for use of the respective manufacturer for preparation, application and disposal of the cleaning agents.

Surface cleaning & low level disinfection:

Name brand / manufacturer	Composition	Recommended procedure
WEBCOL Alcohol Prep Pads (Cardinal Health™/Covidien™)	70% Isopropanol	Carefully wipe the outer surfaces with alcohol wipes and allow to dry.
Mikrozid (Schülke Mayr) pre-soaked wipes	25% Ethanol, 35% Isopropanol	

Low level disinfection:

Name brand / manufacturer	Composition	Recommended procedure
Kodan® forte (Schülke&Mayr)	45,0 g 2-Propanol, 10,0 g 1-Propanol, 0,20 g Biphenyl-2-ol, 30% H_2O_2	Carefully wipe the outer surfaces. Wait 5 min. Perform a final wipe using 70% Isopropanol. Allow to dry.
Gigasept® AF (Schülke&Mayr)	15 g Didecyldimethylammoniumchloride, 10 g Phenoxypropanole, 6,9 g Aminoalkylglycine; 15 – 30% non-ionic tensides.	Prepare a 4% solution (e.g. 960 ml deionized water plus 40 ml Gigasept AF). Note that the 4% dilution has a shelf-life of 7 days. Carefully wipe the outer surfaces. Wait 15 min. Perform a final wipe using 70% Isopropanol. Allow to dry.
Terralin Protect (Schülke&Mayr)	22 g Quaternary ammonium compounds, Benzyl-C12-16-alkyldimethyl, Chloride, 17 g 2-Phenoxyethanol, 0,9 g Aminoalkylglycine, 5 – 15% non-ionic tensides.	Prepare a 2% solution (e.g. 980 ml deionized water plus 20 ml Terralin Protect). Carefully wipe the outer surfaces. Wait 15 min. Perform a final wipe using 70% Isopropanol. Allow to dry.

Name brand / manufacturer	Composition	Recommended procedure
Sanoclean AR (Sanosil)	1.5% Hydrogen peroxide (0.003% silver)	Carefully wipe the outer surfaces. Wait 15 minutes. Perform a final wipe using 70% Isopropanol. Allow to dry.
Dismozon plus (Bode Chemie)	Magnesium monoperoxyphthalate 958 mg/g	Prepare a 3.6% solution (e.g. 36g of Dismozon granulate per liter of deionized water). Note: The diluted solution has a shelf-life of 8h. Carefully wipe the outer surfaces. Wait 15 minutes. Perform a final wipe using 70% Isopropanol. Allow to dry.
Microbac Forte (Bode Chemie)	20% Benzyl-C12-18-alkyldimethylammonium-chloride; 5% N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	Prepare a 2% solution (e.g. 980 ml deionized water plus 20 ml Microbac Forte). Carefully wipe the outer surfaces. Wait 15 minutes. Perform a final wipe using 70% Isopropanol. Allow to dry.
Prevantics™ Device Swab (PDI)	3.15% Chlorhexidine Gluconate (w/v) and 70% Isopropyl Alcohol (v/v)	Carefully wipe all Sentec TC Sensor surfaces and the cable with the pre-soaked PDI wipe for 5 seconds. Let dry for 5 seconds. Remove all PDI residues using 70% Isopropanol. Allow to dry.
Super Sani Cloth (PDI)	0.25% n-alkyl dimethyl ethylbenzyl ammonium chlorides 0.25% n-alkyl dimethyl benzyl ammonium chlorides	Carefully wipe the outer surfaces. Wait 2 minutes. Perform a final wipe using 70% Isopropanol. Allow to dry.
CaviCide or CaviWipe (METREX® RESEARCH CORPORATION)	0.28% Diisobutyl-phenoxyethoxyethyl dimethyl benzyl ammonium chloride; Isopropanol	Spray CaviCide or CaviWipe directly onto the outer surface. Allow surface to remain visibly wet for 3 minutes. Perform a final wipe using 70% Isopropanol. Allow to dry.

High level disinfection:

Name brand / manufacturer	Composition	Recommended procedure
Cidex OPA (J&J) Note: Requires pre-cleaning using an enzymatic cleaner: ENZOL (J&J) or Prolystica (Steris)	0.55% ortho-Phthalaldehyde Subtilisin	First, remove debris using an enzymatic detergent: Wipe the outer surfaces with a wipe soaked in enzymatic solution and wait for 5 minutes. Remove enzymatic cleaner by wiping all surfaces with towel soaked in water. Second, perform high level disinfection: Wipe the outer surfaces with a wipe soaked in Cidex OPA and wait for 12 minutes. Remove Cidex OPA solution by wiping all surfaces 3x with towel soaked in water. Use a fresh wipe each time. Third, final wipe: Perform a final wipe using 70% Isopropanol. Allow to dry.
Sani Cloth Bleach (PDI) Or Clorox Healthcare Bleach Germicidal Wipes	Sodium Hypochloride: Approx. 6000 ppm / 5500 ppm available free chlorine	Carefully wipe the outer surfaces. Wait 4 minutes. Perform a final wipe using 70% Isopropanol. Allow to dry.
CAUTION: Bleach can corrode metal. Therefore, use bleach cleaners on outer surface only and do not bring in contact with metallic parts. Always perform a final wipe using 70% Isopropanol.		
Mikrozid® PAA wipes (Schülke & Mayr)	0.07% Per-Acetic acid; Hydrogen Peroxide, Acetic acid	Carefully wipe the outer surfaces. Wait 15 minutes. Perform a final wipe using 70% Isopropanol. Allow to dry.

Dispose of swabs/pads in the receptacle for biological waste immediately after use.

Recommended cleaning/disinfection of the `Docking Station':

To clean the gasket of the SDM 'Docking Station' use a cotton swab (which does not lose any fibers or threads) with 70% isopropanol.

Make sure that the gasket of the SDM 'Docking Station' is completely dry and is well embedded in its notch after disinfection and before using the SDM again.

Dispose of swabs/pads in the receptacle for biological waste immediately after use.

CAUTION: Any particles on the gasket or sensor might prevent a tight fit between the gasket and the sensor and, hence, cause a gas leak. Make sure not to damage the gasket. Allow the gasket to dry before use.

6.3 Instructions for shipment of the SDM

Please contact your local Sentec representative prior to returning any material to the supplier or factory for a safety check and/or service/repair.

Unless otherwise expressly agreed, shipment costs and costs for repair and service work will be billed to the sender.

The following instructions apply to all shipments of the SDMS or any part of it (e.g. for service or repair) to qualified / Sentec authorized service personnel, your local Sentec representative or Sentec AG:

1. Unless otherwise instructed please return only the SDM and / or Sentec TC Sensor with Extension Cable, but without any disposables such as the Membrane Changer, Sensor Gel, Ear Clips, Manuals or the Service Gas.

Note: Do NOT ship Service Gas bottles together with the SDM. Gas bottles have to be declared as "dangerous goods", a special IATA form is required and special packing instructions apply.

Note: It's recommended to ship SDM with a fully charged battery. If possible charge battery before SDM shipment.

2. Devices must be properly disinfected. For disinfection instructions, please refer to www.sentec.com/ifu and the sub-section 6.2 in the Technical Manual for the SDM. The "Certificate of Disinfection" and, if applicable, the "Repair or Investigation Request Form" are to be completed by the responsible person and have to be shipped together with the SDMS.
3. If you send back electronic parts, make sure to follow applicable ESD precautions.
4. Items must be shipped in the original packaging or in other packing providing the same degree of protection. Use sanitized packing material only. Use a box size 40x40x18 cm (16x16x7 inches) if you ship one monitor. If you ship two monitors, pack them in two boxes of the same size and then fit them in a larger box of 40x40x40 cm (16x16x16 inches). If you use boxes of other dimensions than mentioned above, ensure that boxes are not too large and that the monitor is well padded.
5. The completed forms "Certificate of Disinfection" and, if applicable, the "Repair or Investigation Request Form" must accompany the shipment (to be sent inside the package).

Note: PDF-copies of the 'Certificate of Disinfection' and the 'Repair or Investigation Request Form' are available on www.sentec.com/ifu.

Important note: Any shipment to qualified / Sentec authorized service personnel, local representative or Sentec AG lacking this documentation or shipments sent without authorization in writing (e.g. by e-mail) by Sentec staff will be returned immediately and unopened at the sender's expense.

7 Troubleshooting

7.1 Troubleshooting overview

Troubleshooting is provided in the 'Service Manual for the SDMS'. It describes problems (e.g. "Too high PCO2"), possible causes and the recommended corrective action(s) the operator, qualified or Sentec authorized service personnel may perform to resolve the problem. To each problem a number (PXXXX) is assigned.

In the Troubleshooting section of the 'Service Manual for the SDMS', the problems are categorized as follows:

- Troubleshooting PCO2/PO2 monitoring
- Troubleshooting SpO2/PR monitoring
- Sensor specific troubleshooting
- SDM specific troubleshooting
- 'Docking Station' specific troubleshooting

When equipment is forwarded to qualified/Sentec authorized service personnel for further analysis and/or repair, the PXXXX number should be indicated in the 'Repair or Investigation Request Form'. Indicating PXXXX number(s) will help the service engineer to pinpoint the problem and, hence, to repair the equipment faster.

Note: A PDF of the 'Repair or Investigation Request Form' is available on www.sentec.com/ifu.

Note: Sentec offers a variety of video tutorials related to SDMS handling and troubleshooting on www.sentec.com/ifu.

8 Annex

8.1 Electromagnetic Compliance Declaration

WARNING: The use of accessories, sensors, and cables other than those specified by Sentec AG may result in increased emission and/or decreased immunity of the SDMS.

8.1.1 Electromagnetic emissions

The SDMS is intended for use in the electromagnetic environment specified below. The customer or the user of the SDMS should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The SDMS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The SDMS is suitable in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

8.1.2 Electromagnetic immunity

The SDMS is intended for use in the electromagnetic environment specified below. The customer or the user of the SDMS should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient (Bursts) IEC 61000-4-4	± 2 kV power supply lines ± 1 kV input/output lines	± 2 kV power supply lines ± 1 kV input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 0,5 kV, ± 1 kV line-to-line ± 0,5 kV, ± 1 kV, ± 2 kV line to ground	± 0,5 kV, ± 1 kV line-to-line ± 0,5 kV, ± 1 kV, ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle *at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°* 0 % UT; 1 cycle and 70 % UT; 25/30 cycles *at 0°*	0 % UT; 0,5 cycle *at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°* 0 % UT; 1 cycle and 70 % UT; 25/30 cycles *at 0°*	Mains power quality should be that of a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Power frequency (50/60) Hz magnetic fields IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Portable and mobile RF communications equipment should be used no closer to any part of the SDMS, including cables, than the recommended separation distance d calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000-4-6	V = 3 Vrms 150 kHz to 80 MHz 6 V [c] in ISM bands between 0,15 MHz and 80 MHz	V = 3 Vrms 150 kHz to 80 MHz 6 V [c] in ISM bands between 0,15 MHz and 80 MHz	d = 1.17 √P
Radiated RF IEC 61000-4-3	E = 3 V/m 80 MHz to 2,5 GHz Immunity to proximity fields [d]	E = 3 V/m 80 MHz to 2,5 GHz Immunity to proximity fields [d]	d = 1,17 √P 80 MHz to 800 MHz d = 2,33 √P 800 MHz to 2,5 GHz
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol[b]: 			
Note: At 80 MHz and 800 MHz, the higher frequency range applies. **Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SDMS is used exceeds the applicable RF compliance level above, the SDMS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SDMS.			
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			
[c] The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.			
[d] Immunity to proximity fields from RF wireless communication equipment			

Table: Test specification RF wireless communication equipment

Test Frequency [MHz]	Band [MHz]	Service	Modulation	Maximum Power [W]	Distance [m]	Immunity Test Level [V/m]
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ±5kHz deviation 1kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Bans 5	Pulse modulation 18Hz	2	0.3	28

1720 1845 1970	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,	Pulse modulation 217Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9

8.1.3 Recommended separation distances

For Services listed in the Table under 8.1.2, a minimum separation distance of 0.3m should be respected. For other Frequencys, please use the following table to calculate the minimum separation distance:

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz – 80 MHz $d = 1{,}17\sqrt{P}$	80 MHz – 800 MHz $d = 1{,}17\sqrt{P}$	800 MHz – 2,5 GHz $d = 2{,}33\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,70	3,70	7,37
100	11,7	11,7	23,3
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note: At 80 MHz and 800 MHz, the higher frequency range applies.			
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

8.1.4 Cables

Cables (used together with the SDMS) comply with
- RF emissions, CISPR 11, Class B/Group 1
- Harmonic emissions, IEC 61000-3-2
- Voltage fluctuations/flicker emissions, ICE 61000-3-3
- Electrostatic discharge (ESD), IEC 61000-4-2
- Electric fast transient/burst, IEC 61000-4-4
- Surge, IEC 61000-4-5
- Voltage dips, short interruptions and voltage variations on power supply input lines, IEC 61000-4-11
- Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8
- Conducted RF IEC 61000-4-6
- Radiated RF, IEC 61000-4-3

Sensors/Cables	Maximum Length
Sentec TC Sensors	0.8 m
Digital Sensor Adapter Cable	7.5 m

8.2 Compliance with various European Directives

The SDMS (monitor, sensors, related disposables and accessories (2.1, 2.3)) complies with the requirements of the Medical Device Directive 93/42/EC, Medical Device Regulation EU 2017/745and the directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment, otherwise known as RoHS II. Furthermore, Sentec AG has taken the necessary steps to comply with the directive 2012/19/EU on waste electrical and electronic equipment (otherwise known as WEEE, Table 4).

8.3 Compliance to standards

The SDMS complies with IEC 60601-1:2012 (ed 3.1); ANSI/AAMI ES60601-1:2005/(R)2012; CAN/CSA-C22.2 No. 60601-1:14, IEC 60601-1-6:2010 (ed. 3)+ A1:2013, IEC 60601-1-8:2006 (ed. 2) + Am. 1: 2012, IEC 60601-2-23: 2011 (ed. 3), ISO 80601-2-61:2017 (ed. 2), 60601-1-11:2015 (ed. 2), 60601-1-2:2014 (ed. 4).

8.4 Technical specifications

8.4.1 Environmental Transport/Storage Conditions

TRANSPORT/STORAGE CONDITIONS

The following conditions apply for short-term storage of all items of the Sentec Digital Monitoring System (2.1, 2.3) if transported/stored in the original shipping carton:

Temperature	0 - 50 °C (32 – 122 °F)
Humidity	10 – 95% (non-condensing)

For the products indicated below, we recommend the following long term storage conditions:

	Temperature	Humidity
Service Gas	Max. 50 °C (122°F)	Not specified
Ear Clip	10 – 30 °C (50 – 86°F)	25 – 60%
Multi-Site Attachment Rings (MAR/e-MI)	10 – 30 °C (50 – 86°F)	25 – 60%
Multi-Site Attachment Rings (MAR/e-SF)	10 – 27 °C (50 – 80°F)	40 – 60%
Membrane Changer, Contact Gel	10 – 30 °C (50 – 86°F)	Not specified
Staysite™ Adhesive	10 – 27 °C (50 – 80°F)	40 – 60%
Sentec TC Sensors	15 – 26 °C (59 – 78 °F)	Not specified
Isolation Transformers (RFT100VA-V1/-V2)	-10 – 50 °C (14 – 122 °F)	Not specified

Note: Always store the SDM with a fully charged battery.

CAUTION: Transport/store Sentec TC Sensors with membrane and protected from light/radiation. If Sentec TC Sensors are stored without membrane, damage of the sensor may occur.

OPERATING CONDITIONS

Humidity	15 – 95% (non-condensing)	
Temperature	10 – 40 °C (50 – 104 °F)	(instrument)
	connected to mains	operating on battery
Altitude (and typical corresponding atm. pressure)	-400–4000 m (-1300–13100 ft.) 795–465 mmHg (106–62 kPa)	-400–6000 m (-1300–19600 ft.) 795–353 mmHg (106–47 kPa)
Built-in barometer	Range	350–820 mmHg (47–109 kPa)
Built-in barometer	Accuracy	± 3 mmHg (0.4 kPa)

Note: When connected to mains, the altitude specification of SDM models with serial number **less than 303381** is **2000 m (6500 ft.) above sea level**. Please verify your SDM's capabilities with your local Sentec representative or the manufacturer before connecting the SDM to mains above 2000 m (6500 ft.) above sea level.

Note: If the barometer reading is outside the specified range the message 'Barometer fault' (4.3.5) is displayed and a low priority alarm sounds.

8.4.2 Overall System performance

Note: In vitro specifications are based on tests performed per IEC 60601-2-23:2011 at 42 °C for the V-Sign™ Sensor 2 and at 43 °C for the OxiVenT™ Sensor, respectively.

Note: For a list of factors which may interfere with the accuracy or may lead to signal lost situations, see 2.4.2 and 2.4.5.

CARBON DIOXIDE PARTIAL PRESSURE (PCO2) (2.4.1)

An algorithm developed by J.W. Severinghaus is used to calculate PCO2 from the measured PcCO2. This algorithm accounts for temperature and metabolic correction factors. The PCO2 values displayed by the SDM are corrected/normalized to 37 °C and provide an estimate of PaCO2 at 37 °C.

Measurement range	0 – 200 mmHg (0 – 26.7 kPa)
Resolution	0.1 mmHg (0.01 kPa) below 100 mmHg (10 kPa) 1 mmHg (0.1 kPa) above 100 mmHg (10 kPa)
Drift (in vitro)	typically < 0.5%/h
Response time (T90, in vitro)	
V-Sign™ Sensor 2	typically < 75 s
OxiVenT™ Sensor	typically < 80 s
Linearity (in vitro)	typically < 1.0 mmHg (0.13 kPa)
Interference with anesthetic gases	Negligible
Stabilization/Artifact Detection Algorithm	After sensor application or occurrence of a PCO2 artifact, PCO2 is displayed in grey (4.2.3.8) until it (re)stabilizes (2.4.3).
PCO2 In-Vivo Correction	Subject to institution's permission In-Vivo Correction (IC) of PCO2 values is possible at the bedside (4.11).
Adjustable Severinghaus Correction	Correction factors can be customized by institution (4.13.1).

OXYGEN PARTIAL PRESSURE (PO2) (2.4.1)

TcPO2 designates an estimate of PaO2 and corresponds to the measured PcO2. In newborns, PO2 measured at the skin surface (PcO2) correlates with arterial PO2 (PaO2) almost in a one-to-one relationship at a sensor temperature of 43 to 44 °C. The accuracy of PcO2 compared to PaO2 is best up to a PaO2 of 80 mmHg (10.67 kPa), above which it increasingly tends to read lower than PaO2. As target PaO2 levels in newborns are usually below 90 mmHg (12 kPa), a correction of PcO2 values measured at a sensor temperature of 43 to 44 °C is normally not necessary. In adults, local variations in skin physiology can affect the correlation between PcO2 and PaO2, which can result in lower readings even at a target PaO2 below 80 mmHg (10.67 kPa).

Measurement range	0 – 800 mmHg (0 – 106.7 kPa)
Resolution	1 mmHg (0.1 kPa)
Drift (in vitro)	typically < 0.1%/h
Response time (T90, in vitro)	typically < 150 s
Linearity (in vitro)	typically < 1 mmHg (0.13 kPa)
Interference with anesthetic gases	Negligible
Stabilization/Artifact Detection Algorithm	After sensor application or occurrence of a PO2 artifact, PO2 is displayed in grey (4.2.3.8) until it (re)stabilizes (2.4.3).

OXYGEN SATURATION (SpO2) (2.4.4)

Approved sites for SpO2/PR monitoring with Sentec TC Sensors	Earlobe, low on forehead, cheek, upper arm, on scapula (shoulder blade)	
Measurement range	1 – 100%	
Resolution	1%	
Accuracy (Arms over 70 to 100% range)	Measurement Site(s)	Accuracy
V-Sign™ Sensor 2	All above specified sites	± 2%
OxiVenT™ Sensor	All above specified sites	± 2.25%
Signal Averaging	2, 3, 4, 6, 8, 12, 16, and 32 sec (only selectable if enabled by Responsible Organization)	

Note: The SDMS measures functional oxygen saturation.

Note: SpO2 accuracy specification is based on controlled hypoxia studies on healthy, adult volunteers over the specified saturation range by applying a sensor of the specified sensor type to the specified measurement sites. Pulse oximeter SpO2 readings were compared to SaO2 values of blood samples measured by hemoximetry. SpO2 accuracy is expressed as Arms (root-mean-square). The indicated variation equals plus or minus one standard deviation (1SD), which encompasses 68% of the population.

Note: A functional tester cannot be used to assess the SpO2 accuracy.

V-Sign™ Sensor 2:
The table below shows A_{RMS} values measured using the V-Sign™ Sensor 2 with the Sentec Digital Monitor (SDM). Refer to 8.5.1 for detailed SpO2 accuracy plots:

A_{RMS} in SpO2 Ranges	70 – 100%	70 – 80%	80 – 90%	90 – 100%
Earlobe	1.87	2.20	1.86	1.57
Forehead	1.82	1.95	1.62	1.90
Cheek	1.92	2.42	1.88	1.32
Upper arm	1.38	1.84	1.03	1.03
Shoulder blade	1.91	1.57	1.33	1.11
Average over all sites	**1.83**	2.29	1.60	1.49

OxiVenT™ Sensor:
The table below shows A_{RMS} values measured using the OxiVenT™ Sensor with the Sentec Digital Monitor (SDM). Refer to 8.5.2 for detailed SpO2 accuracy plots:

A_{RMS} in SpO2 Ranges	70 – 100%	70 – 80%	80 – 90%	90 – 100%
Earlobe	2.44	2.99	2.23	1.76
Forehead	1.35	1.54	1.32	1.22
Cheek	1.29	1.43	1.38	1.11
Upper arm	2.41	2.85	2.34	2.05
Shoulder blade	2.13	2.73	2.04	1.19
Average over all sites	**1.95**	2.35	1.88	1.48

PULSE RATE (PR) (2.4.4)

Measurement range	30 – 250 bpm (beats per minute)
Resolution	1 bpm
Accuracy	± 3 bpm

Note: PR accuracy was determined using a Pulse Oximeter Simulator (optical simulator for bench tests).

Note: A functional tester cannot be used to assess the PR accuracy.

PULSATION INDEX (PI) (2.4.6)

Measurement range	0.1 – 10%
Low signal threshold	0.2%
Resolution	0.1%

SENSOR HEATING POWER (HP) (2.4.7, 4.8.6)

Measurement range	Absolute Heating Power (AHP): 0 – 999 mW
	Relative Heating Power (RHP): - 999 – 999 mW
Resolution	1 mW

SENSOR TEMPERATURE

Measurement range	0.0 – 70.0 °C
Resolution	0.1 °C
Accuracy	± 0.2 °C (over 37.0 to 45.0 °C)

8.4.3 Sentec TC Sensors (V-Sign™ Sensor 2 and OxiVenT™ Sensor)

PATIENTS

Suitable for neonates, pediatrics, and adults.

APPROVED MEASUREMENT SITES

	Skin Type	Patient	Measurement Sites	Approved Parameters
Ear Clip	Mature intact	Adults/Pediatrics	Earlobe (provided big enough for proper sensor application and no multi-piercings)	PCO2 PO2 SpO2 PR
MAR/e-MI	Mature intact	Adults/Pediatrics	Low on forehead Cheek Area on upper arm Area above/on shoulder blade (scapula)	PCO2 PO2 SpO2 PR
			Other conventional PCO2, PO2 sites (On thorax (area under clavicle, on rib cage), area behind ear (on mastoid process), area on lower arm)	PCO2 PO2
		Neonates	On thorax (area under clavicle, on rib cage) Abdomen Back Low on forehead Inner or anterior aspect of the thigh	PCO2 PO2
MAR/e-SF	Sensitive fragile	same as for MAR/e-MI		

Note: A flat, well-perfused area is needed (centrally located sites are preferable). Avoid placement over large superficial veins or areas of skin breakdown or edema.

Note: To attach a Sentec TC sensor with the Ear Clip, the earlobe should to be large enough to cover the entire sensor membrane (dark surface of the sensor). Furthermore, application of a Sentec TC Sensor on pierced earlobes may result in incorrect PCO2/PO2 measurements. If the earlobe is too small or has multiple piercings consider using a Multi-Site Attachment Ring (model MAR-MI or model MAR-SF) to attach the sensor to an alternate site.

MEASUREMENT PRINCIPLE

Severinghaus-type PCO2 sensor combined with reflectance 2-wavelength pulse oximetery and – when using an OxiVenT™ Sensor – an optical measurement based on O2 fluorescence quenching.

DIGITAL MICROTECHNOLOGY

Highly integrated opto-electronic sensor head comprising micro pH-electrode, optical oximetry unit, temperature sensors, heating unit, and – when using an OxiVenT™ Sensor - an optical fluorescence excitation and sensing unit, all combined in a digital design. High definition digitizer and pre-processing in the sensor head provides robust and low noise signals that are digitally transmitted to the Sentec Digital Monitor (SDM).

SENSOR MEMORY

Sensor-specific data are stored in the sensor's memory after manufacturing (serial number, factory PCO2 sensitivity/calibration, factory PO2 sensitivity/calibration (for OxiVenT™ Sensor only), etc.) and during operation (sensor calibration, membrane change, etc.).

SENSOR INTERNAL TEMPERATURE SURVEILLANCE

To reliably assure patient safety the sensor temperature is controlled by two built-in temperature sensors. With a delay of 10 seconds the sensor switches-off its power-consuming parts, triggers the low priority alarm 'Temp. limiter active', outputs/stores the status code OT (4.3.5), and highlights the

'Temperature Icon' (4.3.2) red if the current sensor temperature exceeds a) the SET temperature by more than 0.35 °C (relative limit: r1) or b) 44.9 °C (absolute limit: a1). The sensor resumes normal operation once the sensor temperature is again within the predefined limits.

Note: If condition (r1) is violated while SpO2/PR is disabled and the sensor is on the patient the 'Temperature Icon' (4.3.2) highlights red, the message 'Temp. limiter active', however, will not display and instead of the status code OT the status code HT is output/stored in the internal memory of the SDM.

Note: Second level redundant temperature control is implemented in the Sentec Digital Monitor (see below for details).

Note: Also refer to Status Messages 'Sensor problem 38', 'Sensor problem 42', 'Sensor fault 39', 'Sensor fault 43' (4.3.6).

SENSOR CALIBRATION (4.9)

'Calibration Interval' (Table 66)	typically 12 hours	
	6 hours	After successful termination of an 'Initial Calibration' (Table 65)
	9 hours	At least 4 hours CO2 exposure after successful termination of 'Initial Calibration' (Table 65)
	12 hours	At least 8 hours CO2 exposure after successful termination of 'Initial Calibration' (Table 65)

Note: By using V-STATS™ the Responsible Organization has the possibility to select/restrict the 'Calibration Interval' within the 1 to 12 hours range (4.7.4.1).

Note: Once the 'Calibration Interval' has elapsed, calibration is **recommended** (message 'Sensor calibration recommended', Table 66) and monitoring is possible for another 4 to 6 hours with PCO2 marked as 'questionable' (4.2.3.8). Thereafter (or after any event causing the request of an 'Initial Calibration') sensor calibration is mandatory and PCO2/PO2 are marked as 'invalid' (values replaced by '---', 4.2.3.8).

Note: As a precaution, the SDM calibrates PO2 (for OxiVenT™ Sensor only) during each mandatory calibration (Table 65) and subsequently approximately once every 24 hours during one of the anyways ongoing PCO2 calibrations.

Calibration duration (ex factory)	typically 3 minutes if only PCO2 is calibrated. If PO2 is also calibrated the calibration duration is typically longer.
SMART CALMEM (4.9.6)	Supports the disconnection of the sensor for up to 30 minutes without losing the calibration status. Furthermore, the sensor can be removed from the 'Docking Station' for up to 10 minutes without initiating a calibration upon reinsertion of the sensor into the Docking Station. Overall, SMART CALMEM significantly reduces the number of required calibrations and, hence, the calibration gas consumption.

SENSOR MEMBRANE CHANGE (4.10)

Up to 6 weeks. In factory default settings the 'Membrane Change Interval' is 28 days (4.10.4). Patented '4 Press-and-Turn steps' membrane tool for simple and highly reproducible membrane change.

SENSOR LED CHARACTERISTICS

PO2 measurement	Wavelengths: green-cyan colored Energy: < 5 mW
SpO2 measurement	Wavelengths: 660 nm, 880-890 nm Energy: < 15 mW

Note: This information may be especially useful to clinicians.

SAFETY

Sensor LED light output falls within Class 1 level, according EN 60825-1:2001. No special safety precautions are required. Electrical safety: Degree of protection against harmful ingress of water is IPX7, i.e. protection against harmful ingress of water after temporary immersion.

BIOCOMPATIBILITY

Biocompatibility testing has been conducted on Sentec TC Sensors in compliance with ISO 10993-1. The evaluations include cell cytotoxicity, skin irritation and sensitization potential.

PHYSICAL SPECIFICATIONS

General		waterproof, reusable
Sensor Head	Size (diameter x height) Weight (sensor head)	14 mm x 9 mm (0.55 in x 0.35 in) < 2.9 g (0.1 oz.)
Sensor Cable	Description	highly flexible, shielded cable with coating withstanding commonly used cleaning agents and irradiation
	Length	approx. 80 cm
	Color	Grey (for V-Sign™ Sensors 2 with serial numbers SN315004 or lower the cable color is orange).
Digital Sensor Adapter Cable	Length	AC-150 : 150 cm AC-250 : 250 cm AC-750 : 750 cm

Note: For additional information, refer to the Directions for Use on www.sentec.com/ifu.

Usage Time/Life Time

Under normal wear and tear the expected Life Time for V-Sign™ Sensor 2 is 18 month, provided the recommended procedures are carried out and the sensor is not subject to misuse, neglect or accident.

The 'Usage Time' and 'Life Time' of the OxiVenT™ Sensor are limited. If an OxiVenT™ Sensor is connected to the SDM, the remaining and used 'Life Time' (in days) and 'Usage Time' (in hours) are indicated on the second page of the menu 'System Information' (Table 58). If the sensor's remaining 'Usage Time' is less than 300 monitoring hours OR its remaining 'Life Time' is less than 30 days the SDM displays the message 'Sensor usage time < xx hours' OR 'Sensor life time < yy days' if the sensor is in the 'Docking Station' (4.3.5). Here, xx specifies the remaining 'Sensor usage time' in hours and yy the remaining 'Sensor life time' in days.

If the sensor's 'Life Time' has expired the SDM triggers the low priority alarm 'Replace sensor' when/as soon as the sensor is in the 'Docking Station'. Thereafter, monitoring with the connected OxiVenT™ Sensor is not any longer possible.

If the sensor's 'Usage Time' has expired, the SDM triggers the message `Usage Time elapsed´and no PO2 monitoring is possible anymore (but PCO2, SpO2, PR monitoring is still possible) when/as soon as the sensor is in the 'Docking Station'.

Note: The 'Usage Time' and 'Life Time' of the OxiVenT™ Sensor were evaluated under the assumption of normal wear and tear and that the recommended procedures will be carried out and that the sensor will not be subject to misuse, neglect or accident.

Note: Countdown of the 'Life Time' and 'Usage Time' of OxiVenT™ Sensors start from first ex-factory use. The 'Usage time' is only used up if PO2 is enabled and while the sensor is outside the 'Docking Station', i.e. if the OxiVenT™ Sensor is used for PO2 monitoring, and during PO2 calibration (4.9).

Note: Since countdown of the 'Life Time' of OxiVenT™ Sensors starts from first ex-factory use ensure that the SDM`s date and time settings are correct (Table 47) the OxiVenT™ Sensor is

connected to during first ex-factory use! Otherwise the 'Life Time' of the OxiVenT™ Sensor may be used up too quickly.

8.4.4 Sentec Digital Monitor (SDM)

PHYSICAL CHARACTERISTICS

Weight	2.3 kg (5.1 lbs)
	Note: Weight of gas cylinder is below 100 g (0.22 lbs)
Size (height x width x depth)	10.2 cm x 27.0 cm x 23.0 cm (4.00 in x 10.63 in x 9.06 in)
Flip feet	Serves as carrying handle or to adjust the angle for improved table-top viewing

Mountable on roll/infusion stands, wall mounts/railings, transport incubators, etc.

WARNING: Refer to sections 1.2 and 5.1 for warnings related to connecting/mounting the SDM to accessory equipment.

ALARM SYSTEM (4.4)

Visual and auditory alarm signals for physiological (high/low PCO2, PO2, SpO2, or PR) and technical alarms are provided. An 'Alarm Status Icon' (4.3.4) indicates the priority of the highest currently active alarm condition. The SDM's auditory alarm signals are priority encoded. By using V-STATS™ the Responsible Organization can switch ON or OFF 'Alarm Melodies' (4.7.4.1).

The SDM's visual alarm signals cannot be inactivated (4.4.2). Auditory alarm signals can be PAUSED for 1 or 2 minutes (4.4.3). In factory default configuration it is not possible to permanently switch off auditory alarm signals. By using V-STATS™ the Responsible Organization can enable the possibility that the operator can permanently switch off auditory alarm signals (4.7.4.1). The 'AUDIO STATUS Icon' (4.3.3) and the 'AUDIO PAUSED/OFF Indicator' (4.1.5) visually indicate the status of the auditory alarm signals.

If the auditory alarm signals are permanently switched-off the 'AUDIO OFF Reminder' sounds every 60 seconds (4.4.3). In factory default it is not possible to switch off the 'AUDIO OFF Reminder'. By using V-STATS™ the Responsible Organization can enable the option that the operator can switch off the 'AUDIO OFF Reminder' (4.7.4.1).

Note: When the alarm system of a SDM that is remotely monitored with V-CareNeT™ is in the AUDIO OFF state (Table 30), the SDM will terminate the AUDIO OFF state if the connection between the SDM and the V-CareNeT™ Central Station interrupts (4.4.3).

The SDM stores in its internal memory the auditory alarm inactivation states and a log of all alarm conditions (4.4.1).

Typical sound levels of acoustic alarm signals are:

	'Alarm Volume'=6 (high)		'Alarm Volume'=2 (low)	
	Melodies ON	Melodies OFF	Melodies ON	Melodies OFF
High Priority Alarm [dBA]	66.3	66.9	42.1	42.4
Medium Priority Alarm [dBA]	66.0	62.8	41.3	39.1
Low Priority Alarm [dBA]	63.2	57.7	36.1	33.7

AUDITORY INDICATORS (4.1.6)

Auditory indicators for:

- High, Medium, and Low Priority Alarm Signals (can only be switched off permanently if enabled by Responsible Organization)
- AUDIO OFF Reminder (can only be switched off if enabled by Responsible Organization)
- Auditory Power-On Self-Test Signal
- Ready for use Beep (only if enabled by Responsible Organization)
- 'Button Disabled Beep' (sounds if any button is pressed when the Menu Access is disabled (4.7.4.1) or if any button – with the exception of the AUDIO PAUSED/AUDIO OFF Button – is pressed when the 'V-CareNeT™ required' screen is displayed (4.13.3))

- Key Click (can be switched ON or OFF in the menu)
- Pulse Beep (variable pitch beep tone enables clinicians to hear point-by-point changes in SpO2)
- Volume Settings (to indicate selected volume while changing 'Alarm Volume', 'Key Click Volume', or 'Pulse Beep Volume')
- 'V-Check™ Completed Beep' (two short signal tones indicating the completion of a V-Check™ measurement (4.13.2))
- PCO2/PO2 Sensitivity Test Signal (high pitched two beep signal tone that sounds when during the 'PCO2 sensitivity test' and/or 'PO2 sensitivity test' the Status Messages 'Open DS door' or 'Insert Sensor into DS' are displayed)

VISUAL LED INDICATORS (4.1.5)

SDM ON/OFF; AUDIO PAUSED/OFF'; AC Power/Battery; Battery Charging

DISPLAY

Display type	16cm (6.3") diagonal TFT Color Display (640x240 pixels)
Display backlight type	LED Backlight (The message 'LED Backlight' is displayed on the POST screen (Figure 3) and in the sub-menu 'System Settings/Display Settings' (Table 48) if the display of your SDM uses a LED Backlight)
Data update period	Numerical values of PCO2, PO2, SpO2, PR: 1 sec Online Trend curves: depends on selected 'Time Range for Trends' Plethysmographic waveform: selectable between 1.5 and 30 mm/sec
Validity of parameters (4.2.3.8)	Valid (numerical value displayed in selected color); Questionable (numerical value displayed in selected color and '?' displayed adjacent to parameter label); Unstable (numerical value displayed in grey); Invalid (numerical value replaced by '---').
Highly configurable	Patient mode selectable (Table 38) Enabled parameters selectable (Table 38) Parameter color selectable (Table 48) PCO2/PO2 unit selectable (Table 40) Alarm limits selectable (Table 37) AUDIO Settings adjustable (Table 49) Time Range for Online Trends (x-axis) selectable (Table 38) Ranges for Online Trends (y-axis) selectable (Table 40, Table 42, Table 43) Time Range/sweep speed for plethysmographic waveform selectable (Table 42) Language selectable (català, 中文 (chinese),čeština, dansk, deutsch, english, español, français, italiano, ニホンゴ (japanese - katakana), polski, nederlands, norsk, português, русский (russian), svenska, suomi, türkçe) (Table 46) Display in Sleep Mode selectable (4.2.6) Brightness adjustable (Table 48). One-touch brightness adjustment if a measurement screen is active (4.1.4) Profile Mode ('Basic' or 'Institutional') selectable (4.7.4.1) Menu-access selectable (4.7.4.1) Severinghaus Correction mode (4.13.1) V-Check™ Mode (4.13.2) Heating Power Mode (4.8.6) V-CareNeT™ Only Mode (4.13.3)
Display options	Various user-selectable measurement screens (4.2.3) providing: - Alarm limits for PCO2/PO2/SpO2/PR - Current values/online trends for PCO2/PO2/SpO2/PR/RHP - Current value for PI, AHP, and IC indicator (if applicable) - Baseline and Baseline values (baseline, Δt, time elapsed since setting baseline) for PCO2/PO2/SpO2/RHP (4.2.3.9)

- Delta-x values ('Δx-values') for PCO2/PO2/SpO2/RHP (range for x is 1-120 mins.; default=10 mins.) (4.2.3.9)
- Status Bar (Figure 8) with status icons, Status Messages and date/time
- 'Patient Info' during remote monitoring with V-CareNeT™
- 'Quick Access Menu' (4.2.5.2) to set a new Baseline, a new RHP reference value, Operator Events or to access the menu 'PCO2 In-Vivo Correction' during monitoring; to enforce monitoring/'Sensor-On-Patient' status when the sensor is outside the 'Docking Station'.
- 'Quick Access Menu' (4.2.5.3) to initiate a sensor calibration, to access the menu 'Profiles' or to activate/deactivate the V-Check™ Mode if the sensor is in the 'Docking Station'.
- 'Wiper bar' plethysmographic waveform or blip bar reflecting relative pulse amplitude (not displayed if SpO2 PR are disabled).
- Status Icons (4.3.2) for Battery, Patient Type/Barometric Pressure, Remaining Monitoring Time, Sensor Temperature*, Heating Power*/Gas, AUDIO, Alarm. (*Icon not displayed if connected sensor is not heated, if 'Heating Power Mode' = OFF, or on screens with RHP online trends)

Screens related to Trend Data Review (Figure 11) and Trend Data Statistics (Figure 12) for PCO2/SpO2/PR

'Calibration' and 'Ready for use' screen providing important system information (4.2.4)

Power-On Self-Test screen (Figure 3) and menu screens (Table 19)

SENSOR TEMPERATURE & SITE TIME MANAGEMENT (4.8.2)

Sensor Temperature	Default / Recommended	Selectable (Restrictable)
Adult Mode	42.0 °C *(44.0 °C with PO2)*	37.0 – 44.5 °C, steps of 0.5 °C *> 42.0 °C only if PCO2 enabled* *> 43.5 °C only if PO2 enabled* *< 41.0 °C: PO2 values NOT available*
Neonatal Mode	41.0 °C *(43.0 °C with PO2)*	37.0 – 44.0 °C, steps of 0.5 °C *> 41.5 °C only if PCO2 enabled* *> 43.0 °C only if PO2 enabled* *< 41.0 °C: PO2 values NOT available*

Note: The difference between the 'Sensor Temperature' and the ambient temperature at the sensor site (e.g. in an incubator) must be at least 4 °C for V-Sign™ Sensors 2 and OxiVenT™ Sensors.

Note: In factory default the 'Maximal Selectable Sensor Temperature' (MS-SST) is 44.0 °C and the 'Minimal Selectable Sensor Temperature' is 40.0 °C, whereby temperatures > 43.5 ° are only supported for OxiVenT™ Sensor. By using V-STATS™ the Responsible Organization has the possibility to adjust the setting of these two parameters, thereby defining the 'Select. Sensor Temperature Range'.

Note: In certain situations safety controls of the SDM will overrule the 'Selectable Sensor Temperature Range' configured by the Responsible Organization. If, for example, the Responsible Organization configured a 'Selectable Sensor Temperature Range' of 38.0 to 44.0 °C, this range will be restricted to 41.0 to 43.0 °C if an OxiVenT™ Sensor is used in neonatal mode with PO2 disabled.

Note: The 'maximum sensor-skin interface temperature' is approximately 1 °C lower than the 'sensor core temperature'.

INITIAL HEATING (4.8.3)

INITIAL HEATING is a feature that – for faster site perfusion and results – adds +2 °C (with a maximum of 44.5 °C) in Adult Mode to the current 'Sensor Temperature' when removing the sensor from the 'Docking Station' and during approximately the first 13 minutes after sensor application. Thereafter it reduces the sensor temperature back to the current 'Sensor Temperature'.

Note: In factory default INITIAL HEATING is OFF and the menu item 'Initial Heating' is not accessible to the operator (dimmed in grey). By using V-STATS™ the Responsible Organization can enable operator access to the menu item 'Initial Heating'. Once operator access is enabled the operator has the possibility to set the menu item 'Initial Heating' to ON or OFF.

Site Time (4.8.2) — Selectable between 0.5 and 12 hours (or as restricted by institution and/or safety controls of the SDM). In steps of 0.5 hours

Note: In factory default the 'Maximal Selectable Site Time' is 12 hours. By using V-STATS™ the Responsible Organization has the possibility to restrict this parameter in the 0.5 to 12 hours range.

Note: Depending on the selected patient mode and with increasing Sensor Temperature safety controls of the SDM will enforce a safer setting by restricting the 'Maximal Selectable Site Time' (e.g. to 4 hours if Sensor Temperature = 43.0 °C in Neonatal Mode).

Site Timer (4.8.4) — The Site Timer controls the duration of sensor application to the patient. It is counting down from the selected Site Time to zero during monitoring. The Site Timer will trigger a low priority alarm when the Site Time has elapsed.

SITE PROTECTION (4.8.5) — SITE PROTECTION is a safety feature that in ON mode reduces the sensor temperature to 39.0 °C (if SpO2 PR disabled) or to 41.0 °C (if SpO2 PR enabled) if the 'Sensor Temperature' is > 41.0 °C for adults or > 40.0 °C for neonates and once the sensor application duration has overrun the selected 'Site Time' by more than 10% or 30 minutes.

Note: In factory default, SITE PROTECTION is ON and the menu item 'Site Protection' is not accessible to the operator (dimmed in grey). By using V-STATS™ the Responsible Organization can enable operator access to the menu item 'Site Protection'. Once operator access is enabled the operator has the possibility to set the menu item 'Site Protection' to ON or OFF.

REDUNDANT SENSOR TEMPERATURE SURVEILLANCE ON SDM

To guarantee safe operation should the sensor's temperature control (8.4.3) fail, the SDM software redundantly controls the temperature of the connected sensor by applying the following criteria:

SDM detects that	Additional Condition	Message/Action
the difference between the sensor's two redundant temperature measurements is bigger than a predefined value.	for 80 seconds	Status Code SP30/SDM restarts sensor
	SP30 occurred twice within 1 hour	'Sensor fault 31'/SDM switches off sensor
no temperature data received from sensor.	for 10 seconds	Status Code SP32/SDM restarts sensor
	SP32 occurred twice within 1 hour	'Sensor fault 33'/SDM switches off sensor
temperature readings are frozen.	for 80 seconds	Status Code SP34/SDM restarts sensor
	SP34 occurred twice within 1 hour	'Sensor fault 35'/SDM switches off sensor
current temperature > 'SET temperature + 0.6 °C'	none	'Temp. limiter active'/SDM restarts sensor
	for 5 minutes	'Sensor problem 38'/SDM switches off sensor and restarts it after 60 seconds
	sensor's temperature supervision did not detect 'r1' (relative limit)	'Sensor fault 39'/SDM switches off sensor
current temperature > 45 °C	none	'Temp. limiter active'/SDM restarts sensor
	for 5 minutes	'Sensor problem 42'/SDM switches off sensor and restarts it after 60 seconds

SDM detects that	Additional Condition	Message/Action
	sensor's temperature supervision did not detect 'a1' (absolute limit)	'Sensor fault 43'/SDM switches off sensor

INTERFACES (5)

Serial Interface (RS-/EIA-232)	Supported protocols: Philips VueLink/Intellibridge, Spacelabs Flexport, SentecLink (baud rate selectable), Serial Printer, TCB – basic transcutaneous data protocol
LAN Port (Ethernet 10 BaseT)	Supported protocols: SentecLink (for Remote Monitoring with V-CareNeT™)
Analog output	0 – 1 V for PCO2, SpO2, PR, Pleth Waveform (parameter ranges selectable)
Nurse-call capability	Yes (open and close type relays)
Max. current (Nurse-call)	100 mA (Nurse-call is protected with a F125 mA (fast) fuse type)
Max. voltage (to be applied over all interface ports)	25 VAC/36 VDC

Note: By Using V-STATS™ the Responsible Organization can enable/disable the LAN Port, change the 'Device/Host Name', select the 'DHCP Mode', the 'IP Address' (if 'DHCP Mode'=OFF), the 'IP Port' (TCP/UDP Port) the 'Ethernet Mode', and the 'DNS Mode'.

WARNING: Refer to sections 1.2 and 5.1 for warnings related to connecting/mounting the SDM to accessory equipment.

PATIENT DATA MANAGEMENT (4.12)

Automatic storage of measured patient data in internal non-volatile memory according to the FIFO (First In First Out) principle. The memory capacity (Table 69) depends on the selected data recording interval which is institution-selectable between 1 and 8 seconds (between 35 and 227 hours monitoring data).

Note: Depending on the occurrence of status code changes the memory capacities will slightly vary. Very frequent status code changes will reduce the memory capacity.

Note: The data recording interval can only be changed by using V-STATS™, i.e. it can NOT be changed in the menu of the SDM. The currently active data recording interval, the free and total memory capacity are displayed in the menu 'Trend Data'.

Note: If the 'Data Recording Interval' is > 1 sec, the data are not additionally filtered before down sampling.

Note: The data stored in the internal memory of the SDM are deleted if the data recording interval is changed.

The SDM determines the start and the end of measurements using predefined criteria (4.12.3) and stores a list of all measurements with the date/time of the corresponding start-points and end-points. By means of these start times and end times identification/selection of the measurement to be reviewed, printed or downloaded easily is possible (4.12.4). For the selected measurement range on-screen viewing and printing of graphical trends and statistical summary is possible for PCO2, SpO2, and PR (4.12.5). V-STATS™ provides fast data download of PCO2, PO2, SpO2, PR, PI and HP to PC (approx. 3 min. for 8 hours data at 4-seconds resolution) for subsequent display, analysis, and reporting within V-STATS™. With V-CareNeT™ simultaneous download is possible from multiple SDMs.

ELECTRICAL

Internal Battery	Type	Rechargeable, sealed LiIon battery

	Capacity (operation time with new, fully charged battery at a sensor temperature of 42 °C)	at least 6h (Sleep Mode=OFF or Auto), up to 13h (Sleep Mode=ON), depending on display type of the SDM.
	Charging time	~7 h
Instrument	Instrument AC Power	100 - 240V~ (50/60 Hz)
	Current	900 – 400 mA
	Mode of operation	suitable for continuous operation
Electrical Safety	Type of protection against electrical shock	Class I (if AC powered) Class II (with internal reserve power source, i.e. if battery powered)
	Degree of protection against electrical shock	Type BF, APPLIED PART – DEFIBRILLATION PROOF
	Recovery time after electrostatic/defibrillator discharge	30 sec (for SpO2/PR); 60 sec (for TC values) Note: Certain events may cause the SDM to promt a calibration request.
	Degree of protection against harmful ingress of water	IPX1
	Degree of safety in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Not suitable

Note: The correct type and rating of live and neutral fuses must always be used.

SDM Configuration – Profiles & Parameters

Operator changeable parameters	Most parameters can be changed by the operator on an individual basis in the menu of the SDM (4.7.4.2).
Safety relevant parameters	Within a password-protected area of V-STATS™ the Responsible Organization can configure all menu accessible parameters as well as special parameters not being accessible in the menu of the SDM (4.7.4.1). Several of these special parameters permit to disable or to restrict operator access to menu accessible parameters. The maximal 'Sensor Temperature' or the maximal 'Site Time' selectable at the bedside, for example, can be adapted to settings being safe for your typical patients.
SDM Profiles	A 'SDM Profile' is a file which contains a specific setting for almost all SDM parameters. 'SDM Profiles' therefore are helpful to ensure that all SDMs within your institution can be configured the way you want them to. Various preconfigured 'SDM Profiles' tailor-made to meet the specific needs of varying clinical settings (ICU, NICU, Sleep Lab, etc.) are available within V-STATS™. Furthermore, the Responsible Organization can customize/manage 'SDM Profiles' within V-STATS™. It is possible a) to import 'SDM Profiles' to V-STATS' 'SDM Profiles Database' (either from the SDM or from the PC), b) to export 'SDM Profiles' from the database to the PC (e.g. to exchange them with other users) as well as c) to rename, print or delete 'SDM Profiles' currently available in the database.
Selectable Profile Mode	In 'Basic Mode' (4.7.2) the SDM at power-up maintains the settings from previous use. By using V-STATS™ it is possible to set the SDM's current settings to those of a 'SDM Profile' available within V-STATS™, in 'Basic Mode' it is, however, not possible to store 'SDM Profiles' on the SDM. In 'Institutional Mode' (4.7.3) up to 4 'SDM Profiles' can be stored on the SDM. During use of the SDM, the operator can at any time restore the

	'Standard Profile' (if modified) or select a different 'SDM Profile' in the menu 'Profiles' (Figure 9, Table 50). If at power-up the settings differ from those of the 'Standard Profile' the modified settings can be maintained, the 'Standard Profile' can be restored, or a different 'SDM Profile' can be selected.

SENSOR CALIBRATION (4.9)

Calibration chamber	Integrated calibration chamber ('Docking Station') (Figure 1, Figure 2)
Barometric pressure	Measured automatically by a built-in barometer.
Calibration mode	Fully automatic 1-point calibration. If needed, calibration automatically starts if sensor is inside 'Docking Station'. To ensure that the sensor is continuously 'Ready for use' the sensor is periodically recalibrated if stored in the 'Docking Station'. Manual activation of a calibration is additionally possible by using the menu function 'Calibrate Sensor' in the 'Quick Access Menu' (Figure 7) or in the menu 'Measurement Settings/PCO2 Settings' (Table 40). If enabled, PO2 is also calibrated during calibrations that are activated with the menu-function 'Calibrate Sensor'.
Sensor stabilization indicator	The message 'Recommended Sensor Stabilization [mins]:' is displayed on the 'Ready for use' and on the 'Calibration' screen (4.2.4) to indicate when and if, how long, the sensor should be stored in the 'Docking Station' prior to start monitoring (4.9.5).

ENSURING SYSTEM RELIABILITY

The SDM performs various tests to ensure system reliability:

Power-On Self-Test (4.6)	After turning on the SDM performs a power-on self-test (POST), which tests the SDM's circuitry and functions (internal test). Furthermore the SDM's various indicators and display activate.
Watch-dog Timers	The software of the SDM features watchdog timers that will reset the SDM in case of software errors.
Various tests ensuring calibration reliability (4.9.7)	To ensure continuous reliability of sensor calibration, the SDM automatically tests the status of the 'Docking Station' and of the sensor and, if necessary, inhibits the start of a calibration or aborts a running calibration.
Testing functionality of connected sensor (4.3.6)	Various tests to diagnose potential problems or faults of the connected sensor.
Testing functionality of SDM (4.3.7, 4.3.8)	Various tests to diagnose potential problems or faults of the SDM.

8.4.5 Service Gas

WARNING: Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50 °C (122 °F). Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material.

WARNING: Do not use expired gas bottles or gas bottles from manufacturers other than Sentec. The use of non-Sentec gas bottles may damage the Docking Station. Improper calibration gas mixtures will result in incorrect sensor calibrations and subsequently result in inaccurate PCO2 and/or PO2 data.

Volume	0.56 l 9.5 bar (138 PSI)
Contents	approx. 5.7 l at atmospheric pressure at sea level 1 bar (14.5 PSI) at 21 °C (70 °F)

Net weight	7 g
Components	8.00 ± 0.075% CO2 (carbon dioxide) 12.00 ± 0.05% O2 (oxygen) balance N2 (nitrogen)
Service Gas cylinder	TRG 300; 75/324/EWG; 94/1/EG; D.O.T.-2Q; Aerosols UN 1950 Non-flammable gas max. operating pressure: 12 bar (174 PSI) deformation pressure: >18 bar (261 PSI) burst pressure: >21.6 bar (313 PSI)

Note: Dispose empty gas bottles according to local waste regulations for aluminum containers.

For additional information on the Service Gas, refer to the Instruction Manual for the SDMS and the respective Directions for Use.

8.4.6 Contact Gel

WARNING: Do not swallow Contact Gel. Keep away from children. Avoid contact with eyes and injured skin. Do not use on patients who exhibit allergic reactions. Use only approved Sentec Contact Gel.

Contents	
GEL-04	5 ml
GEL-SD	0.3 g

Biocompatibility testing has been conducted on the Contact Gel in compliance with ISO 10993-1. The evaluations include cell cytotoxicity, skin irritation and sensitization potential. A Material Safety Data Sheet is available upon request for the Contact Gel.

For additional information on the Contact Gel, refer to the Instruction Manual for the SDMS and the respective Directions for Use.

8.4.7 Ear Clip

WARNING: It is not recommended to use sensor attachment accessories on patients who exhibit allergic reactions to adhesive tapes.

Biocompatibility testing has been conducted on the Sentec Ear Clip in compliance with ISO 10993-1. The evaluations include cell cytotoxicity, skin irritation and sensitization potential.

The Ear Clip is recommended for adult and pediatric patients with mature, intact skin. It is contraindicated for patients whose earlobes are too small to ensure adequate sensor application (e.g. neonates).

Note: The Ear Clip features a carefully selected low-pressure/low-torque spring to avoid pressure ischemia and pressure induced low perfusion. A too strong spring could cause pressure ischemia at the ear lobe and, consequently, inaccurate measurements, necrosis or – in combination with the heated Sentec TC Sensors – burns.

Note: Due to the snap ring, the sensor can be rotated in the Ear Clip, allowing optimal positioning.

For additional information on the Sentec Ear Clip refer to the Instruction Manual for the SDMS and the respective Directions for Use.

8.4.8 Multi-Site Attachment Ring / Multi-Site Attachment Ring Easy

WARNING: It is not recommended to use sensor attachment accessories on patients who exhibit allergic reactions to adhesive tapes.

Biocompatibility testing has been conducted on the Multi-Site Attachment Ring, models MAR-MI, MARe-MI, MAR-SF and MARe-SF, in compliance with ISO 10993-1. The evaluations include cell cytotoxicity, skin irritation and sensitization potential.

The MAR-MI/ MARe-MI is recommended for adult, pediatric and neonatal patients with mature, intact skin. The MAR-SF/ MARe-SF is recommended for adult, pediatric and neonatal patients with sensitive, fragile skin.

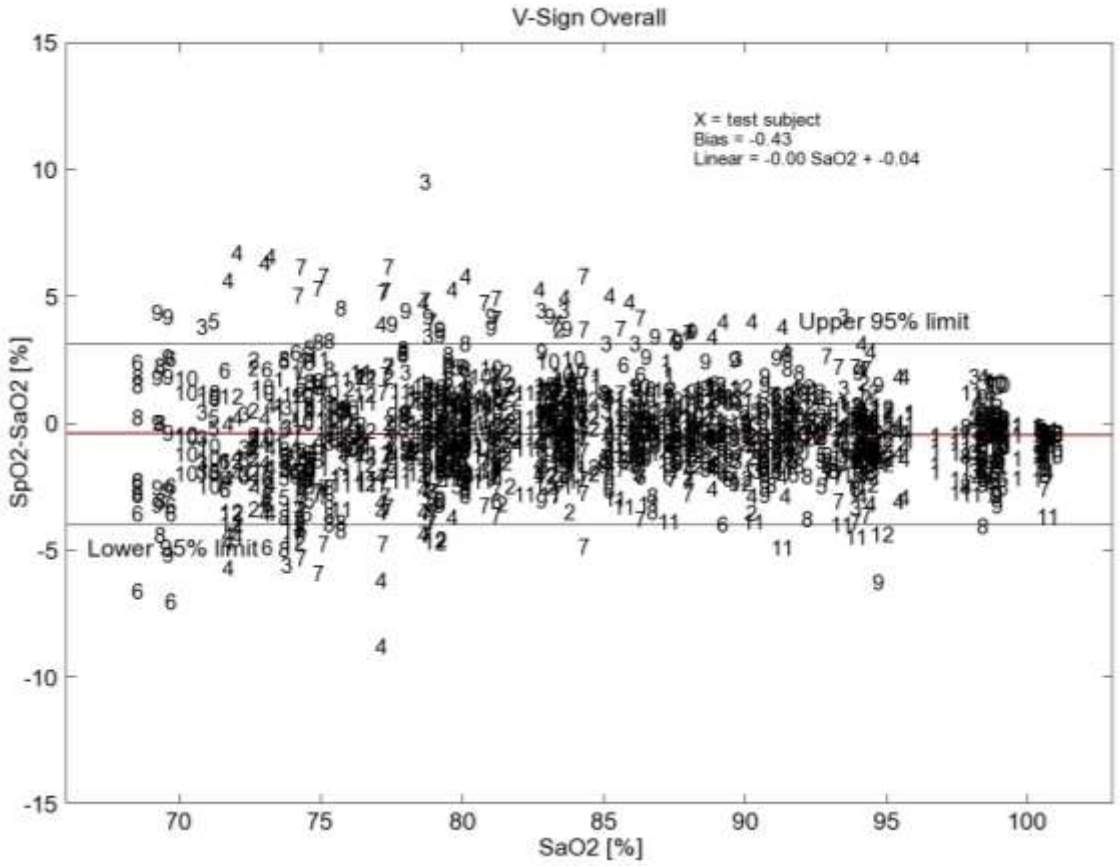
Note: The snap rings of the MAR-MI and MAR-SF are identical, as well as those of the MARe-MI and MARe-SF. The snap ring is optimized to ensure easy insertion/removal of the sensor into/from the ring. For use in neonates, easy sensor insertion into the ring is important. Easy sensor removal from the ring (without removing MAR/e-MI or MAR/e-SF) from the patient) permits to use the same MAR/e-MI or MAR/e-SF after site inspection and/or calibration.

Note: Due to the snap ring, the sensor can be rotated in the MAR/e-MI or MAR/e-SF, allowing optimal positioning and routing of the sensor cable.

For additional information on the Multi-Site Attachment Rings, refer to the Instruction Manual for the SDMS and the respective Directions for Use.

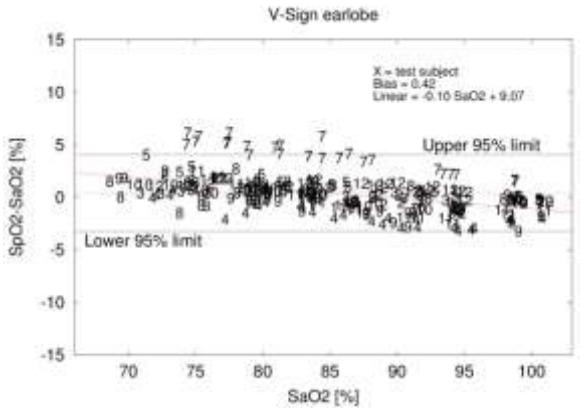
8.5 Detailed SpO2 Accuracy Plots

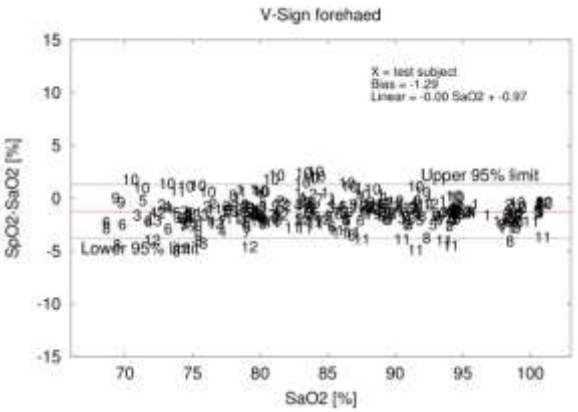
8.5.1 V-Sign™ Sensor 2

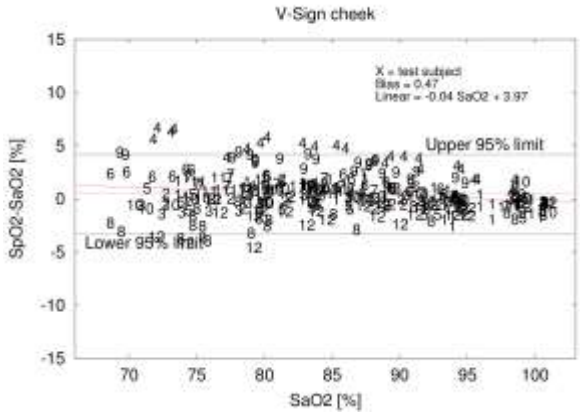


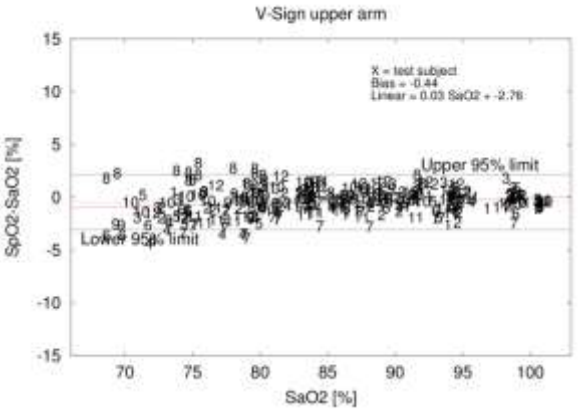
SpO2 accuracy analysis for V-Sign™ Sensor 2: Data points are identified with the ID of each individual test subject. Data from 12 healthy volunteers (7 males/5 females) of different skin pigmentation (3 light, 4 light-medium, 2 medium, 3 dark) were included in the analysis. The subjects were between 23 and 29 years old.

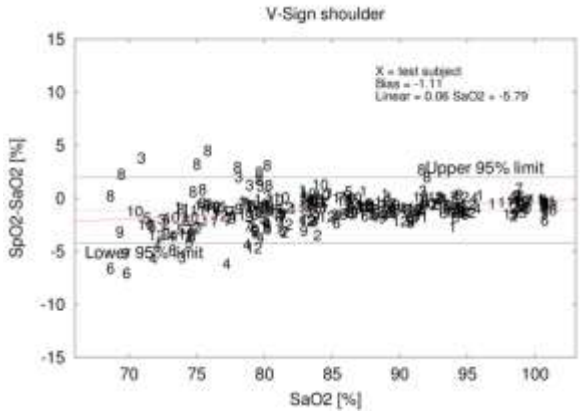
Detailed plots for SpO2 accuracy of the V-Sign™ Sensor 2 per individual measuring site are given below:


V-Sign earlobe
X = test subject
Bias = 0.42
Linear = -0.10 SaO2 + 9.07
Upper 95% limit
Lower 95% limit
SpO2-SaO2 [%]
SaO2 [%]

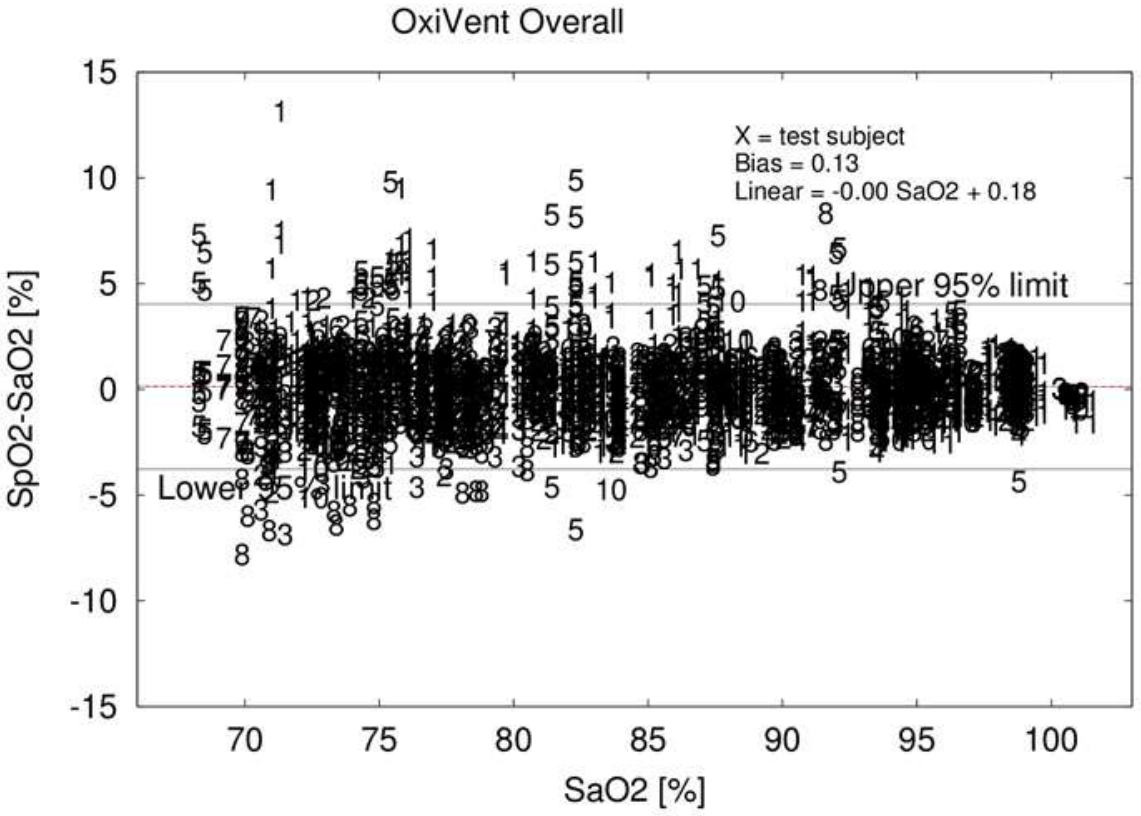

V-Sign forehaed
X = test subject
Bias = -1.29
Linear = -0.00 SaO2 + -0.97
Upper 95% limit
Lower 95% limit
SpO2-SaO2 [%]
SaO2 [%]


V-Sign cheek
X = test subject
Bias = 0.47
Linear = -0.04 SaO2 + 3.97
Upper 95% limit
Lower 95% limit
SpO2-SaO2 [%]
SaO2 [%]


V-Sign upper arm
X = test subject
Bias = -0.44
Linear = 0.03 SaO2 + -2.76
Upper 95% limit
Lower 95% limit
SpO2-SaO2 [%]
SaO2 [%]

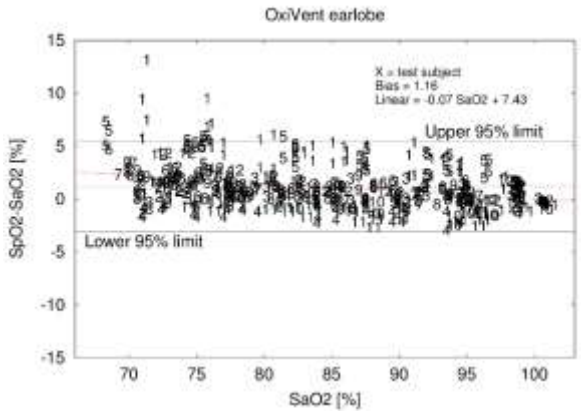

V-Sign shoulder
X = test subject
Bias = -1.11
Linear = 0.06 SaO2 + -5.79
Upper 95% limit
Lower 95% limit
SpO2-SaO2 [%]
SaO2 [%]

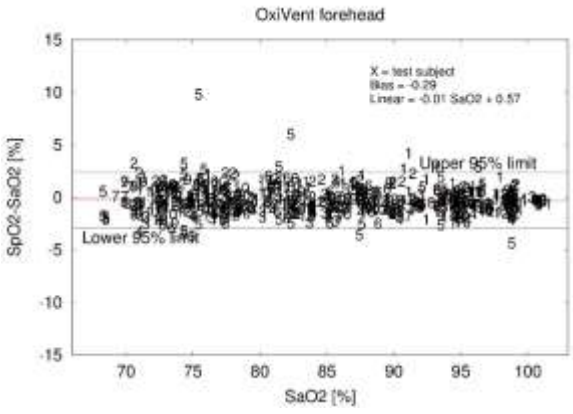
8.5.2 OxiVenT™ Sensor

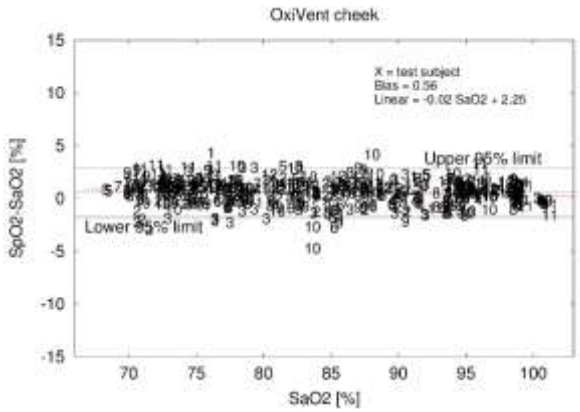


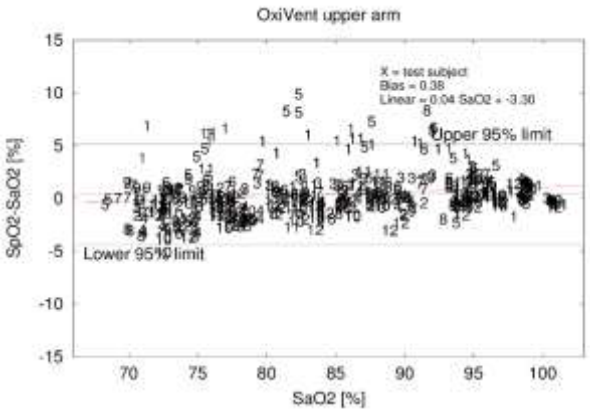
SpO2 accuracy analysis for OxiVenT™ Sensor: Data points are identified with the ID of each individual test subject. Data from 12 healthy volunteers (7 males/5 females) of different skin pigmentation (5 light, 5 medium, 2 dark) were included in the analysis. The subjects were between 23 and 34 years old.

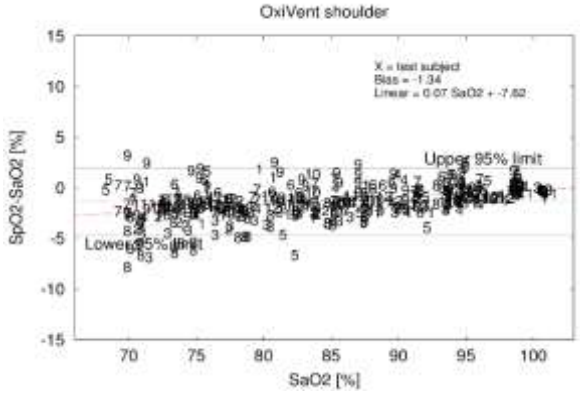
Detailed plots for SpO2 accuracy of the OxiVenT™ Sensor per individual measuring site are given below:






OxiVent cheek
X = test subject
Bias = 0.56
Linear = -0.02 SaO2 + 2.25
Upper 95% limit
Lower 95% limit
SpO2-SaO2 [%]
SaO2 [%]


OxiVent upper arm
X = test subject
Bias = 0.38
Upper 95% limit
Lower 95% limit
SpO2-SaO2 [%]
SaO2 [%]


OxiVent shoulder
X = test subject
Bias = -1.34
Upper 95% limit
SpO2-SaO2 [%]
SaO2 [%]

Figures

Tables

Sentec AG, Ringstrasse 39, 4106 Therwil, Switzerland, www.sentec.com

Date of issue: 05/2021