

Sentec Digital Monitoring System

Instruction Manual

Software version SW-V08.03 and higher

sentec.

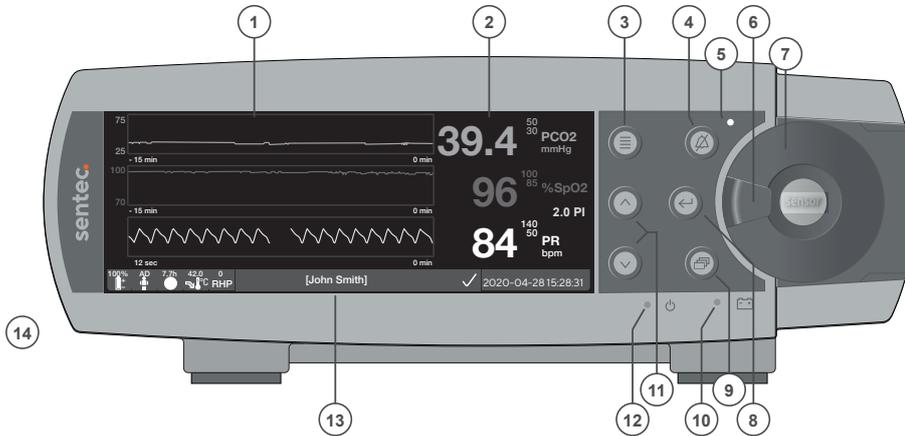


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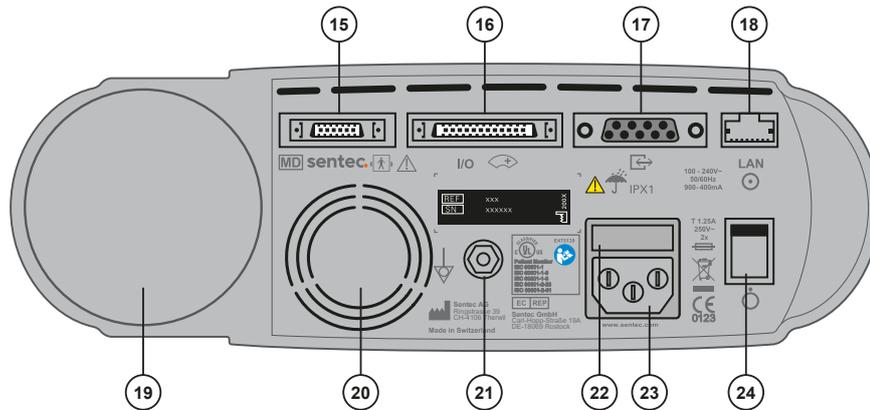
Sentec Digital Monitoring System

Noninvasive Ventilation and Oxygenation Monitoring





- 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)
- 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



Warranty

The manufacturer warrants to the initial purchaser that each new component of the Sentec Digital Monitoring System 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 component – for which the manufacturer acknowledges the warranty cover – with a replacement component.

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.

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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)

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The Sentec Digital Monitoring System (SDMS)

Intended Use / Intended Purpose

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: tcPCO₂ and tcPO₂ 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 tcPCO₂ and tcPO₂ 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.

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental/Storage conditions
SDM	Sentec Digital Monitor	Stand-alone patient monitor.	<p>The Sentec Digital Monitor, model SDM, is a portable stand-alone patient monitor intended for continuous, noninvasive patient monitoring of carbon dioxide partial pressure (PCO₂), oxygen partial pressure (PO₂), functional oxygen saturation (SpO₂) and pulse rate (PR), using either</p> <ul style="list-style-type: none"> • a single, digital sensor (V-Sign™ Sensor 2) for PCO₂, SpO₂ and PR measurement, OR • a single, digital sensor (OxiVenT™ Sensor) for PCO₂, PO₂, SpO₂ and PR measurement <p>PO₂ measurement with SDM is only possible when used in combination with an OxiVenT™ Sensor.</p>	n/a	7 years	Yes	<p>Transport/storage temperature: 0 – 50 °C</p> <p>Transport/storage humidity: 10 – 95% non-condensing</p> <p>Operating temperature: 10 – 40 °C</p> <p>Operating humidity: 15 – 95% non-condensing</p> <p>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.</p>
VS-A/P/N	V-Sign™ Sensor 2	Digital carbon dioxide tension and oximetry sensor.	<p>The V-Sign™ Sensor 2, model VS-A/P/N, is intended for use with the SDM when continuous, noninvasive monitoring of tcPCO₂, SpO₂, and PR are required for adult and pediatric patients.</p> <p>In neonatal patients, the use of V-Sign™ Sensor 2 is indicated for tcPCO₂ monitoring only.</p>	n/a	up to 36 months	Yes	<p>Transport temperature: 0 – 50 °C</p> <p>Long term storage temperature: 15 – 26 °C</p> <p>Transport/ store sensor with membrane and protected from light/ radiation.</p>

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental/Storage conditions
OV-A/P/N	OxiVen™ Sensor	Digital carbon dioxide tension, oxygen tension and oximetry sensor	<p>The OxiVen™ Sensor, model OV-A/P/N, is intended for use with the SDM when continuous, noninvasive monitoring of tcPCO₂, and tcPO₂, as well as SpO₂, and PR monitoring are required for adult and pediatric patients.</p> <p>In neonatal patients, the use of OxiVen™ Sensor is indicated for tcPCO₂ and tcPO₂ monitoring only.</p> <p>tcPO₂ monitoring is contraindicated for patients under gas anesthesia.</p>	n/a	12 months	Yes	<p>Transport temperature: 0 - 50 °C</p> <p>Long term storage temperature: 15 - 26 °C</p> <p>Transport/ store sensor with membrane and protected from light/ radiation.</p>
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, OxiVen™ Sensor) to the Sentec Digital Monitor.	<p>AC-150: length 150 cm</p> <p>AC-250: length 250 cm</p> <p>AC-750: length 750 cm</p>	7 years	Yes	<p>Transport/storage temperature: 0 - 50 °C</p> <p>Transport/storage humidity: 10 - 95%</p>

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 SDM 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 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 AC ±10%	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 dripping water when the monitor is tilted up to 15° (IPX2).	n/a	7 years	Yes	Not specified

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Shelf Life	Reusable	Environmental/Storage conditions
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%

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Shelf Life	Reusable	Environmental/Storage conditions
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				No. Reusing a MARE-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 conditions
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 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				No. Reusing a MAR may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 - 27 °C Humidity: 40%-60%

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Shelf Life	Reusable	Environmental/Storage conditions
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 indicated for use with Multi-Site Attachment Rings, models MAR-MI, MARE-MI, MAR-SF, and MARE-SF, if 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 (MC), the Membrane Changer reloadable (MC-R) and the Membrane Changer Insert (MC-I), serve as tools to change the electrolyte and membrane of the V-Sign™ Sensor 2 and the OxiVen™ Sensor. The Membrane Changer reloadable (MC-R) can be reused by replacing its insert (MC-I).	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	Yes, max. 10 times reloadable with MC-I.				
MC-I	Membrane Changer Insert	Separately bagged, single-use inserts required to reload a Membrane Changer prior to reuse.	No. Reusing the MC-I may cause: - loss of functionality of the sensor and incorrect measurements				

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Shelf Life	Reusable	Environmental/Storage conditions
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 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 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				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	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	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%

Note: Throughout this manual, the term ‘Sentec TC Sensor’ refers to Sentec sensors providing transcutaneous blood gas measurements (i.e. V-Sign™ Sensor 2 and OxiVenT™ Sensor).

Note: The components listed above do not necessarily correspond to the scope of delivery. Please contact us for a list of available disposables and accessories:

www.sentec.com/contact.

Transcutaneous PCO₂ and PO₂

Principles of Operations of tcPCO₂ and tcPO₂

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. If the skin tissue beneath the sensor site is warmed up to a constant temperature local capillary blood flow increases, metabolism stabilizes, gas diffusion improves and, hence, reproducibility and accuracy of CO₂/O₂ measurements at the skin surface improves.

CO₂ tensions measured at the skin surface (PcCO₂) are usually consistently higher than arterial PCO₂ values (PaCO₂) in patients of all ages. It is therefore possible to estimate PaCO₂ from the measured PcCO₂ using an adequate algorithm. TcPCO₂ designates an estimate of PaCO₂ calculated from the measured PcCO₂ with an algorithm developed by J.W. Severinghaus. 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: Hence, the tcPCO₂ values displayed by the SDM are corrected/normalized to 37 °C and provide an estimate of PaCO₂ at 37 °C. On the SDM and throughout this manual (unless explicitly stated otherwise) 'tcPCO₂' is displayed/labeled as 'PCO₂'.

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).

The recommended (and default) 'Sensor Temperature' and 'Site Time' for Sentec TC Sensors depends on the selected patient type and the enabled parameters, as summarized in the following table:

Patient Type	PO ₂ enabled	Recommended Sensor Temperature [°C]	Recommended Site Time [hrs]
Neonatal (if younger than term birth + 12 months)	No	41.0	8.0
	Yes	43.0	2.0
Adult/ Pediatric	No	42.0	8.0
	Yes	44.0	2.0

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



Good to know!

Warming the skin tissue beneath the sensor to a constant temperature improves accuracy as it a) increases capillary blood flow/induces local arterialization, b) stabilizes metabolism, and c) improves gas diffusion through skin tissue. With increasing sensor temperature the application duration ('Site Time') must be evaluated carefully and adjusted accordingly to reduce the risk of burns. Special attention must be given to patients with sensitive skin at the sensor site (p. 32).

Please refer to Technical Manual for the SDM (HB-005752) and the references cited therein for additional information on transcutaneous blood gas monitoring.

Limitations of $tcPCO_2$ and $tcPO_2$

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 (PO_2 specific).
- Hyperoxemia ($PaO_2 > 100$ mmHg (13.3 kPa)) (PO_2 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 CO_2 and O_2 gases diffusing out of the skin to intermix with ambient air.
- Exposure of the sensor to high ambient light levels (PO_2 specific).



CAUTION: Compared to the corresponding arterial blood gases PCO_2 readings are typically too high and PO_2 readings typically too low if the measurement site is hypo-perfused.



CAUTION: The SDMS is not a blood gas device. Keep the above mentioned limitations in mind when interpreting PCO_2 and PO_2 values displayed by the SDM.

When comparing PCO_2/PO_2 values displayed by the SDM with $PaCO_2/PaO_2$ 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 $PaCO_2/PaO_2$ value obtained from ABG analysis should be compared to the SDM's PCO_2/PO_2 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', the PCO_2 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.

Pulse Oximetry

Principles of Operations of Pulse Oximetry

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 pulse oximeter uses the ratio of absorbed red to infrared light 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.



Good to know!

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

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

Limitations of Pulse Oximetry

The following clinical situations or factors may limit the correlation between functional oxygen saturation (SpO_2) and arterial oxygen saturation (SaO_2) 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)
- certain cardiovascular pathologies
- skin pigmentation or tattoos
- externally applied coloring agents (e.g. nail polish, dye, pigmented cream)
- prolonged and/or excessive patient movement
- exposure of the sensor to high ambient light levels
- defibrillation

Sentec TC Sensors

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 with the components needed to measure PCO_2 and – in case of the OxiVenT™ Sensor only – PO_2 .

PO_2 (OxiVenT™ Sensor) is measured 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 incorporated within the sensor surface.

The PCO_2 measurement of Sentec TC Sensors (V-Sign™ Sensor 2, OxiVenT™ Sensor) is based on a Stow-Severinghaus type PCO_2 sensor, i.e. a thin electrolyte layer is confined to the sensor surface with a hydrophobic, CO_2 and O_2 permeable membrane. Membrane and electrolyte must be exchanged

approximately every 28 days. Additionally, the sensor membrane must be changed if it is damaged, not properly seated, or if there is trapped air or dry electrolyte under the membrane. 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 (p. 28).

Calibration of the PCO_2 segment of Sentec TC Sensors is recommended every 6 to 12 hours and mandatory every 12 to 16 hours (p. 27). The PO_2 measurement of the OxiVenT™ Sensor is virtually drift free and, hence, calibration free. Nevertheless, the SDM, as a precaution, calibrates PO_2 during each mandatory calibration and subsequently approximately once every 24 hours during one of the anyways ongoing PCO_2 calibrations.

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 in neonatal and 42°C in adult/pediatric patients if PO₂ is disabled and – if PO₂ is enabled – of typically 43°C in neonatal and 44°C in adult/ pediatric patients, respectively. Controls of sensor temperature and application duration are designed to meet all applicable standards. To guarantee safe operation, Sentec TC Sensors reliably supervise the sensor temperature with two independent circuits. Additionally, the SDM software redundantly controls the temperature of the connected sensor.

 **WARNING:** Do not alter or modify the sensor. 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.

Additional information on Sentec TC Sensors, the Ear Clip, the Multi-Site Attachment Rings, the Staysite™ Adhesive, the Membrane Changer, and the Membrane Changer Inserts is provided in the respective Directions for Use. Detailed information on the Sentec Digital Monitor is provided in the Technical Manual for the SDM (HB-005752). Information on maintenance, service and repair procedures that do not require opening the cover of the SDM as well as on maintenance and service procedures for Sentec TC Sensors are provided in the SDMS Service Manual (HB-005615).

To ensure proper operation of the SDMS, precisely follow the instructions provided in this Instruction Manual step by step.

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

 **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.

Note: Statements in this manual are only applicable for SDMs with the software version indicated on the cover page.

Note: The SDMS Quick Reference Guide, the SDMS Instruction Manual and various other manuals are available for online viewing at www.sentec.com/ifu.



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



Minimum Requirements

Minimum requirements concerning hardware, IT networks characteristics and IT security measures

In order to protect patient data against cyber threats, it is necessary to implement – and continuously maintain – a holistic, state-of-the-art security concept. Hospitals and other health care providers are responsible for preventing unauthorized access to the facility and to home site systems, devices and networks when installing the SDMS. SDMS should only be connected to a network when appropriate security measures (e.g. firewalls and/or network segmentation) are in place. In case of doubt or any security issues, please consult your IT manager.



WARNING: When connecting/mounting the SDM to accessory equipment (e.g. PCs, poly or polysomnographic systems, multi-parameter bedside monitors, ventilators, Ethernet networks, etc.), verify proper operation before clinical use of the SDM and accessory equipment.



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.

V-STATS™ and V-CareNeT™

Minimum system requirements for V-STATS™ and V-CareNeT™ are described in the V-STATS™ Instruction Manual. A network connection is only required when using V-STATS™ with V-CareNeT™ activated.



WARNING: Do not use an unstable network and make sure that devices connected to the network are not sending too many broadcast packets into the network. It should be implemented and tested by a WiFi-Specialist being familiar with the particular requirements for wireless networks in hospital environments. Ensure that the WiFi-Specialist by taking account for the structural surroundings (construction, shielding, interfering devices, etc.) evaluates how many access points are needed and where they have to be located to guarantee full, interference-free coverage. Proper function of the network that is used is not the responsibility of Sentec.

Sentec recommends that V-STATS™ software updates are applied as soon as they are available and that the latest versions are used. Use of versions that are no longer supported, and failure to apply the latest updates may increase your exposure to cyber threats.

V-STATS™ 4.10 and higher versions offer measures, which allow the user a GDPR-conform handling of patient data (for details see V-STATS™ Instruction Manual).

The current software version of V-STATS™ can be downloaded from Sentec's webpage (<http://www.sentec.com/V-STATS/>).

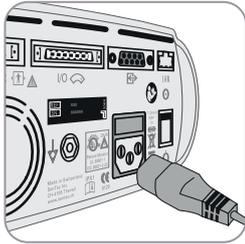


V-STATS™ Instruction Manual and various other manuals are available for online viewing at <https://www.sentec.com/ifu/>.



Setting up the SDMS

Connect SDM to AC Power



Plug the female connector of the power cord into the AC power connector on the rear of the monitor

(23).

Plug the male connector of the power cord into a properly grounded AC power outlet.

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

Verify that the AC power/battery indicator (10) is lit. If the AC power/battery indicator is not lit, check the power cord, fuses, and the AC power outlet.

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).

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.

Battery Operation of the SDM

The SDM is equipped with a rechargeable internal Li-Ion battery that can be used to power the monitor during transport or when AC power is not available. The Status Icon 'Battery' (p. 61) indicates the remaining battery charge (%).

Good to know!

When using an SDM with a 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. It takes approximately 7 hours to fully charge a drained battery.

The AC Power/Battery Indicator (10) provides information on the charging status of the battery:

Green: SDM connected to AC power, battery fully charged

Yellow: SDM connected to AC power, battery charging

LED OFF: SDM not connected to AC power (i.e. powered by internal battery)

⚠ WARNING: Use the device only at the following altitudes (and typical corresponding atmospheric pressures):

If connected to mains: -400 – 4000 m (106 – 62 kPa)

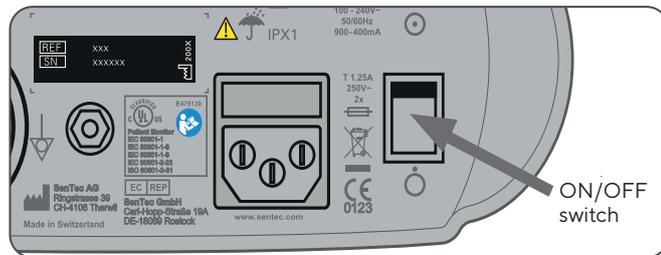
If operating on battery: -400 – 6000 m (106 – 47 kPa)

Otherwise, incorrect measurements can result.

Turning on the SDM

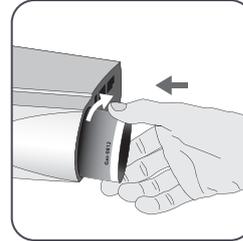
Turn on the SDM by pushing the ON/OFF Switch on the rear panel (24). The SDM will automatically perform a 'Power On Self Test' (POST). Check the date/time settings of the SDM and adjust if necessary.

Note: If the POST fails, discontinue use of the SDM and contact qualified service personnel or your local Sentec representative. Refer to the Technical Manual for the SDM (HB-005752) for a detailed description of the POST.



Installation of the Gas Bottle (Service Gas-0812)

The gas bottle slot is located on the rear of the SDM (19). Remove the old gas bottle by turning it counter-clockwise.



Insert the new gas bottle by turning it clockwise approx. 4.5 turns and thoroughly tighten it (without applying undue force).

⚠ CAUTION: Failure to properly insert the gas bottle may result in incorrect sensor calibrations and may cause increased gas consumption.

The Status Icon 'Gas' (p. 62) indicates the remaining capacity of the gas bottle in %. It is only displayed if a Sentec TC Sensor is connected to the SDM and is in the Docking Station.

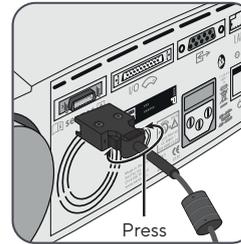
⚠ WARNING: The Service Gas bottle is a pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50 °C (122 °F). Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material.

⚠ 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.

For disposal of empty gas bottles, see chapter **Waste Disposal** (p. 65).

⚠ 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.

Connection/Disconnection of Digital Sensor Adapter Cable



Connect the Digital Sensor Adapter Cable to the SDM. The connection is properly established when both clamps of the plug snap into place in the sensor connection port (15).

Disconnect the cable from the SDM by pressing the two latches on the black plug to release the clamps (see picture) and pull to remove the cable.

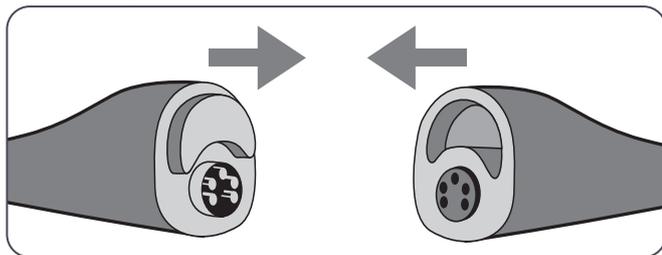
Connection of a Sentec TC Sensor

Take a Sentec TC Sensor (V-Sign™ Sensor 2 or OxiVen™ Sensor).

Important: For PO₂ monitoring you must use an OxiVen™ Sensor and an SDM with activated PO₂-option.

Check the condition of the sensor membrane and the integrity of the sensor (p. 26). Change the membrane if necessary (p. 28). Do not use the sensor if any problems are noted.

Once sensor check/inspection of its membrane are completed successfully, connect the Sentec TC Sensor to the Digital Sensor Adapter Cable.



Thereafter, the SDM usually will display the message 'Calibrate sensor' (for exceptions see description of the feature SMART CALMEM, p. 28).

Insert the sensor into the Docking Station for sensor calibration (p. 27).

If the sensor's 'Membrane Change Interval' has elapsed (this usually applies to new sensors), the SDM will trigger the message 'Change sensor membrane' upon insertion of the

sensor into the Docking Station. In this case, you must change the sensor membrane (p. 28) before the SDM starts calibrating the sensor.

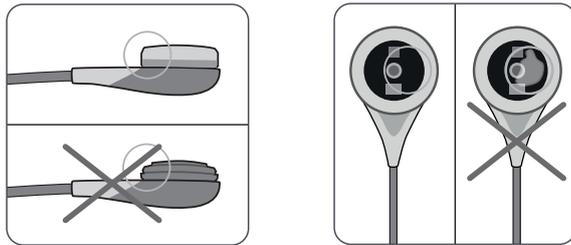
Note: If you have changed the sensor membrane just before connecting the sensor to the SDM, it won't be necessary to change it once again. In this case, simply confirm the membrane change on the monitor (menu 'Membrane Change' - only accessible if the sensor is outside the Docking Station).

Sensor Check, Sensor Calibration/Storage and Membrane Change

Checking a Sentec TC Sensor

Check the condition of the sensor membrane and the integrity of the sensor before and after each use and after changing the membrane (p. 28)!

Ensure that the sensor is clean before visually checking it. If necessary, carefully wipe off any residue from the sensor's surface (including membrane, housing and cable) with 70% isopropanol or another approved cleaning agent (refer to HB-010143 Cleaning and Disinfection Agents on www.sentec.com/ifu).

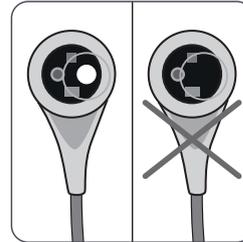


a) Change the sensor membrane if it is damaged or missing, has a loose fit, or if there is trapped air or dry electrolyte under the membrane.

! CAUTION: Do not touch the delicate optical/glass components embedded in the sensor's surface should the membrane be missing.

! CAUTION: Do not use a dry gauze or wipe, as this may damage the sensor membrane or sensor cable.

b) **Do not use** the sensor if there is any visible damage to the sensor housing or cable, if the color of the ring around the glass electrode has a metallic luster (should be brown), or if the sensor's red LED does not light when the sensor is connected to the SDM. Instead, contact qualified service personnel or your local Sentec representative regarding continued use or replacement of the sensor.



c) When operating with an OxiVen™ Sensor, **do not use** the sensor if the off-centered, white, round spot on the sensor surface is missing or is not illuminated in green-cyan color when the OxiVen™ Sensor is connected to the SDM with enabled PO₂ measurement function.

Sensor Calibration and Storage

If a sensor calibration is **mandatory**, the SDM displays the message 'Calibrate sensor', a low priority alarm sounds and PCO_2 and PO_2 are marked as 'invalid' (values replaced by '----').

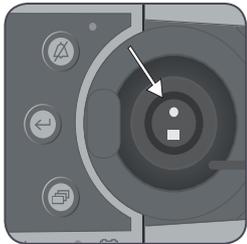


Good to know!

'Calibration Intervals' for Sentec TC Sensors can last up to 12 hours. Once the 'Calibration Interval' has elapsed, sensor calibration is **recommended** (message 'Sensor calibration recommended') and monitoring is possible for another 4 to 6 hours with PCO_2 marked as 'questionable' (p. 43). Thereafter, sensor calibration is **mandatory**. The SDM, as a precaution, calibrates PO_2 during each mandatory calibration and subsequently approximately once every 24 hours during one of the default PCO_2 calibrations.

To calibrate the sensor:

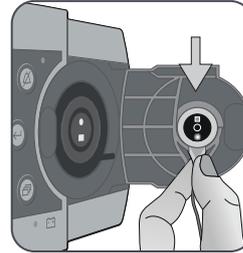
1. Open the Docking Station Door (7) by pulling the door handle.



2. Check the gasket (arrow) in the Docking Station. If necessary, clean the Docking Station and gasket by using a cotton swab moistened with 70% isopropanol (for other approved cleaning agents refer to www.sentec.com/ifu).



CAUTION: Always clean the sensor before placing it in the Docking Station.



3. Hang the sensor into the holder in the inside of the door. Ensure that the sensor's red light is visible.



CAUTION:

Incorrect orientation of the sensor in the Docking Station may cause damage to the sensor, the Docking Station, or parts thereof when closing the Docking Station door.

4. Close the Docking Station Door. The SDM will check the sensor and – if necessary – start the sensor calibration (message 'Calibration in progress'). The message 'Ready for use' will display once calibration is finished.



WARNING: Correct calibration requires the sensor to be properly positioned in the Docking Station Door and the Docking Station Door to be closed.

Note: If the sensor is stored in the Docking Station, additional sensor calibrations can be activated via a 'Quick Access Menu' (p. 55). If enabled, PO_2 is also calibrated during calibrations that are activated with the menu-function 'Calibrate sensor'.



WARNING: 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. Do not expose the sensor to strong ambient light such as direct sunlight, surgical lamps, infrared warming lamps, and phototherapy lights during clinical use. This may cause inaccurate measurements. In such cases, cover the sensor with an opaque material.

Note: After switching on the SDM or after a membrane change, it is recommended to store the sensor in the Docking Station at least for the duration indicated by the yellow information message 'Recommended Sensor Stabilization [min]:' on the 'Ready for use' screen and on the 'Calibration' screen.

Note: To maintain monitor readiness in-between monitoring, always keep the monitor switched on and always store the sensor in the Docking Station.



Good to know!

SMART CALMEM is a feature of Sentec TC Sensors permitting disconnection of the sensor from the SDM for up to 30 minutes without losing the calibration status. Thus, monitoring can temporarily be interrupted without the need to remove the sensor from the patient, e.g. to untangle cables, to turn or move the patient, or if the patient needs to go to the restroom. Furthermore, SMART CALMEM reduces the number of required calibrations and, hence, the consumption of calibration gas.

Changing the Sensor Membrane

The membrane of a Sentec TC Sensor must be changed if the 'Membrane Change Interval' has elapsed. In this case, the SDM displays the message 'Change sensor membrane', triggers a low priority alarm, marks PCO_2/PO_2 as invalid and activates the menu 'Membrane Change' - provided the sensor is in the Docking Station. Additionally, the sensor membrane must be changed if it is damaged, not properly seated, or if there is trapped air or dry electrolyte under the membrane.



Good to know!

The 'Membrane Change Interval' is set to 28 days by default (recommended). Depending on the specific requirements of various clinical settings, the interval can be customized.



CAUTION: Without being requested by the SDM, the sensor membrane must additionally be changed if any of the conditions described in the section 'Checking a Sentec TC Sensor' (p. 26) apply.

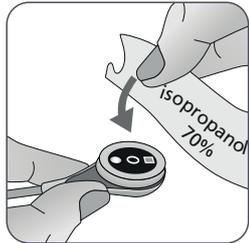


CAUTION: The Contact Gel is **not** needed in any of the membrane change steps. The Contact Gel is only used for sensor application.

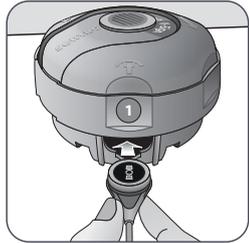
Note: A Membrane Change Tutorial is available for online viewing at www.sentec.com/tv/v0.



Inserting Sensor into Membrane Changer



1. Verify that the sensor is clean before changing its membrane. If necessary, carefully wipe off any residue from the sensor's surface (including membrane, housing, groove and cable) with 70% isopropanol (for other approved cleaning agents refer to www.sentec.com/ifu).



2. Remove protective film from the bottom (MC only) and firmly place the Membrane Changer on a horizontal, dry surface with the colored dot facing up.

3. Insert the sensor into the Membrane Changer with the sensor side facing up. The insert receiver **1** is designed so that improper alignment of the sensor is difficult if not impossible.

Note: Neither touch nor hold the sensor cable while the sensor is inside in the Membrane Changer nor pick up the Membrane Changer as this may lead to dislodging the sensor from the Membrane Changer.

Four Press-and-Turn Steps to Change the Membrane

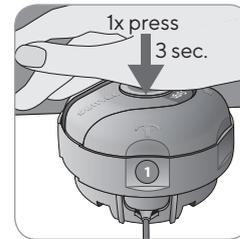
The membrane change procedure consists of four identical press-and-turn steps. To provide better guidance, these steps are marked with the corresponding numbers on the Membrane Changer.

Step 1 removes the old sensor membrane: Press down slowly but firmly with palm of hand and hold for 3 seconds. Release the top. Carry out a visual check to ensure that the membrane is removed. Turn the top portion one click clockwise to the next step. Keep the Membrane Changer horizontal.

Step 2 cleans the sensor surface from old electrolyte: As in step 1, press the membrane changer slowly but firmly, release the top and turn clockwise to the next step.

Step 3 applies new electrolyte on the sensor surface: Press the membrane changer slowly but firmly for 3 seconds, release the top and turn clockwise to the next step.

Step 4 places a new membrane on the sensor: Press the membrane changer top down slowly but firmly for 3 seconds, release the top and turn clockwise to the **✓** symbol. Keep the Membrane Changer **horizontal** while executing the following Press-and-Turn step **4 times**:



a. Press down slowly but firmly with palm of the hand and **hold for 3 seconds**.



b. Turn the top portion one click clockwise to the next stop. Keep the Membrane Changer horizontal! Hold the changer's bottom half in place while turning the top half.

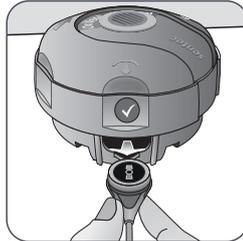


Note: Do not press down on the top while turning!

Note: The membrane timer only resets if you confirm the membrane change on the monitor.

Note: The menu 'Membrane Change' is only accessible if the Docking Station Door is open.

Removing Sensor from Membrane Changer



Press one last time or lift the sensor and remove it from the Membrane Changer. The (✓) symbol indicates that the membrane change is completed.

Inspecting Sensor Membrane

Check the condition of the sensor membrane and the integrity of the sensor (p. 26). Repeat the membrane change if necessary. Do not use the sensor if any problems are noted.

Confirming Membrane Change on SDM

Once the inspection of the sensor membrane is completed successfully, confirm the membrane change on the monitor (menu 'Membrane Change').

Patient Monitoring with the SDMS

Patients with potentially impaired skin perfusion

Some patients may have an increased risk of sustaining skin irritations or even burn injuries. Special attention is recommended when treating patients with one or more of the following conditions:

Patients

- who are very young (prematurely born) or very old
- with congenital heart diseases (esp. neonates, babies)
- after cardiac, cardio-thoracic, major vascular or abdominal surgery
- with significantly reduced cardiac output
- with hypertension and/or hypovolemia, e.g. due to dehydration, blood loss etc.
- in shock, e.g. septic shock, hypovolemic shock
- treated according to a cooling protocol
- with or recovering from burns
- with sensitive skin or skin diseases
- with obesity, especially with concurrent Diabetes Mellitus

Characteristics requiring special attention

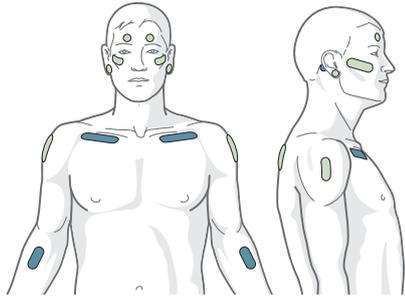
Some patients might be in fair or good conditions, but still require special attention when using a heated sensor. Patients with the following characteristics might have an impaired local skin perfusion:

- application of vasoactive drugs, e.g. epinephrine, norepinephrine, phenylephrine, especially when administered continuously using syringe or infusion pumps
- mechanical pressure, e.g. from positioning, blankets
- external heat sources like warming lamps
- hypothermia/cold stress
- edema
- dehydration
- hypotension
- prolonged capillary refill time
- application of disinfectants and other agents at the measurement site, which might influence skin condition and local perfusion

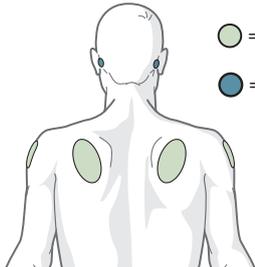
Selection of Patient Type, Measurement Site, and Sensor Attachment Accessory

Refer to the pictures below to select the patient type on the SDM, the measurement site and the sensor attachment accessory. Refer to the following page for additional (important) information.

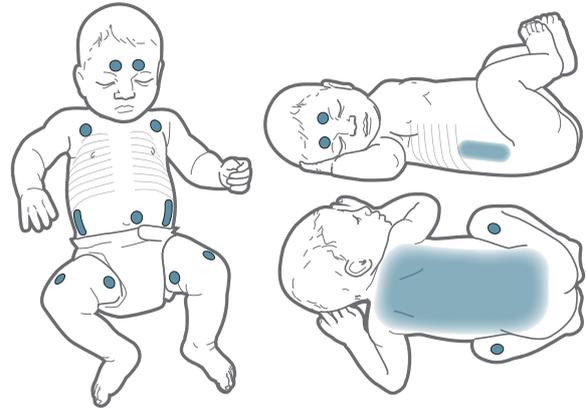
'Adult' if Older than Term Birth + 12 Months



● = PCO₂/SpO₂/PR
● = PCO₂



'Neonatal' if Younger than Term Birth + 12 Months



● ● PCO₂/PO₂
application areas



MAR/e-SF for sensitive, fragile skin, or **MAR/e-MI** for mature, intact skin.

Selection of Sensor Attachment Accessory

Earlobe: Use Ear Clip for mature, intact skin.

All other sites: Use MAR/e-MI for mature, intact skin or MAR/e-SF for sensitive, fragile skin.

Note: Sentec recommends using the Neonatal Mode for patients aged up to term birth plus 12 months. Oxygen saturation can be measured in patients aged term birth plus one month and older using the Adult/Pediatric Mode. In this case, Sentec strongly recommends reducing the temperature and site time to the values of the Neonatal Mode (p. 16).

Note: For PO₂ monitoring, an OxiVenT™ Sensor and an SDM with activated PO₂-option is needed. The respective configuration is indicated on the SDM's 'Power On Self Test' Screen and on the second page of the menu 'System Information'.

 **CAUTION:** Choose a flat, well-perfused area of intact skin (centrally located sites are preferable) for sensor attachment. Avoid placement over large superficial veins or areas of skin breakdown or edema.

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

Note: If more secure sensor attachment is required, e.g. in high humidity environments, for patients who perspire profusely and/or in challenging patient motion conditions, the Staysite™ Adhesive (model SA-MAR) can be used complementary with the Multi-Site Attachment Rings. Please refer to the Directions for Use for the Staysite™ Adhesive.

 **WARNING:** The measurement of SpO₂ and PR with Sentec TC Sensors is only defined on sites specified in the pictures (p. 32). In order to avoid erroneous readings and false alarms of SpO₂ and PR, ensure that the appropriate patient type (Adult) is selected. Ensure to disable the parameters SpO₂/PR for sensor application on other measurement sites.

 **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.

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

⚠ 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 could potentially be affected by the SDMS. The MRI unit 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) 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. 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.

Check SDM Settings and System Readiness

Before initiating patient monitoring, ensure the current SDM Settings/SDM Profile are appropriate for the patient, for the selected measurement site (p. 32), 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'.

Note: If the connected sensor is in the Docking Station, the 'Ready for use' or 'Calibration' screen (summarizing important system information (see below)) displays.

'Ready for use'/'Calibration' screen

If the connected sensor is in the Docking Station 'Ready for use' or 'Calibration in progress' displays in yellow big font in the center of the 'Ready for use'/'Calibration' screen.

Adult 1 Smith John 2 V-Check 7 SET T [°C] = 42.0 5
VS-A/P/N 3
SLEEP 4

Ready for use

Enabled Parameters PCO2 SpO2 PR
Available Monitoring Time [hrs]: 12.0
Membrane Change is Due in [days]: 28.0

Note: Pressing the Enter Button (p. 55) while the 'Ready for use' screen displays activates a 'Quick Access Menu' with the possibility to activate additional calibrations (p. 27), to access the sub-menu 'Profiles', or to activate the V-Check™ Mode (p. 46).

The following information is displayed in the upper area of the 'Ready for use'/'Calibration' screen:

- ① **Patient Type Indicator (yellow):** Displays the current patient type (Neonatal or Adult).
- ② **Patient Info (orange):** During remote monitoring using V-CareNeT™ (if enabled), the 'Patient Info' (patient name, 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 and – if no status message has to be displayed – in the SDM's status bar enclosed in '[]'.

- ③ **Sensor Type Indicator:** Displays the model/type of the currently connected sensor.
- ④ **Current SDM Profile indicator:** Indicates the name of the currently selected 'Standard Profile' (e.g. 'SLEEP'). An asterisk (*) next to the profile name (e.g. 'SLEEP*') indicates that at least one setting of the selected 'Standard Profile' is modified (only displayed when SDM is in 'Institutional Mode').

Note: In 'Institutional Mode' it is possible – by using V-STATS™ – to store up to 4 SDM Profiles on the SDM and select one of these profiles as 'Standard Profile'. During subsequent use, the operator can restore the selected 'Standard Profile' (if modified) or select a different 'Standard Profile' in the menu 'Profiles'. Furthermore, if at power-up of the SDM the LAST

settings differ from those of the selected 'Standard Profile', this menu activates and offers the option to keep the modified settings, to restore the selected 'Standard Profile' or to select another 'Standard Profile'.



Good to know!

Various profiles preconfigured by Sentec and tailored to optimally fit the specific needs of varying clinical settings are available within V-STATS™.

- ⑤ **Sensor Temperature:** Displays the currently selected sensor temperature (this indicator is only displayed if the connected sensor is heated).



WARNING: The use of temperatures higher than 41 °C requires special attention to patients with susceptible skin, e.g. neonates, geriatric patients, burn victims, patients with skin diseases.

- ⑥ **Special Temperature Settings:** Split-arrow indicating the current configuration of INITIAL HEATING (IH, left part of arrow) and SITE PROTECTION (SP, right part of arrow).

	SP OFF (or ON and $T \leq 41.0$ °C in adults/ $T \leq 40.0$ °C in neonates)	SP ON (if $T > 41.0$ °C in adults/ $T > 40.0$ °C in neonates)
IH OFF (or *)		
IH ON (if **)		

* ON and $T = 44.5$ °C in adults ** $T < 44.5$ °C in adults

Note: Initial Heating is deactivated in Neonatal Mode.

⑦ **V-Check™ Mode Indicator:** If the V-Check™ Mode (p. 46) is ON the 'V-Check™ Mode Indicator' displays on the left of the 'Sensor Temperature Indicator' ⑤ and the 'Special Temperature Settings Indicator' ⑥.

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

Enabled Parameters: Indicates the parameters that are currently enabled. Ensure to select an option that is approved for the patient's age and the intended measurement site (p. 32, 33).

Note: 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' or - if PCO₂ is enabled

- the 'Calibration Interval' (p. 27) will elapse (whichever occurs first).

Membrane Change is due in [days]: Indicates the number of days left until the next membrane change (p. 28) is mandatory (only if PCO₂ is enabled).

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.

Status Bar: If the 'Ready for use' screen displays, temporary display of the 'Status Bar' (p. 61) can be activated by pressing any of the control-buttons (p. 55). The 'Status Bar' also displays during an ongoing sensor calibration or if an alarm condition occurs.

Note: If the SDM is in Sleep Mode, the display is inactive (black). Press any of the control buttons (p. 55) to activate the display.

Sensor Application Using a Multi-Site Attachment Ring



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

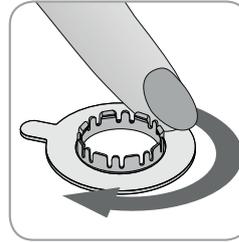
According to the procedure described point by point below, a Multi-Site Attachment Ring (MAR) or Multi-Site Attachment Ring Easy (MARE) is first attached to the measurement site,

1-2 drops of Contact Gel are then applied to the center of the sensor and finally the sensor is snapped into the ring. Alternatively, you can apply 1-2 drops of Contact Gel to the skin area in the center of the attachment ring.

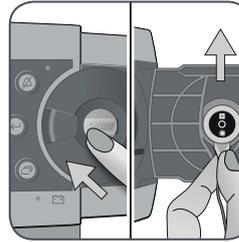
! WARNING: Application of any pressure to the measurement site (e.g. by using a pressure bandage) may cause pressure ischemia at the measurement site and, consequently, inaccurate measurements, necrosis or – in combination with heated sensors – burns.

1. Check current SDM Settings/SDM Profile and verify system readiness (message 'Ready for use', p. 34). Change SDM Settings/SDM Profile if necessary.
2. Clean the site with a swab wetted with 70% isopropanol (or according to your institution's skin cleaning/degreasing procedures) and let it dry. If necessary, remove hair.
3. Take a Multi-Site Attachment Ring out of the package and pull off the liner protecting the adhesive tape of the ring.

! CAUTION: The Multi-Site Attachment Rings (models MAR-MI, MAR-SF, MARE-MI and MARE-SF) are for single-use. Neither reattach used rings on the same nor on another patient!



4. Attach the ring to the measurement site. Verify that the skin under the adhesive is not wrinkled. Then press gently on the retainer ring and move your finger around the ring circumference to ensure a good adhesion of the ring's adhesive to the skin.

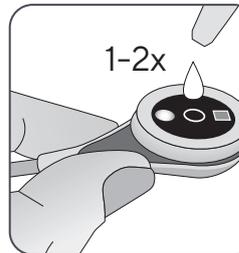


5. Open the Docking Station Door and remove the sensor.

Note: Always grab the sensor at its neck to avoid pulling and tearing the sensor cable.

6. Close the Docking Station Door.

7. Check the condition of the sensor membrane and the integrity of the sensor (p. 26). Change the membrane if necessary (p. 28). Do not use the sensor if any problems are noted.



8. Apply 1-2 drops of Contact Gel to the center of the sensor surface. Ensure to keep the sensor horizontal (membrane pointing upwards) so that the contact liquid does not run off the membrane. Flip over the sensor just before inserting it into the ring.

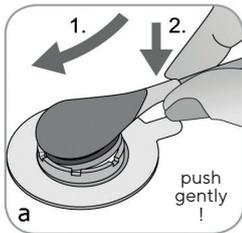
Note: As contact liquid, Sentec recommends using Sentec's Contact Gel.

Note: Alternatively, you can apply **1-2** drops of Contact Gel to the skin area in the center of the attachment ring.

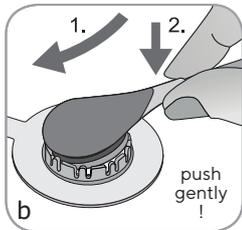
Note: Avoid wetting the adhesive tape!

Note: As long as the sensor is not yet applied to the patient, try to keep the measurement site as horizontal as possible so that the contact liquid does not run off the measurement site.

! 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.



9. Holding the sensor at its neck, approach the MAR from the flap side (a) or the MARE from any side (b) and first insert the nose of the sensor into the retainer ring. Then apply slight downward pressure on its neck. The spring tension of the retainer ring will pull the sensor into place with little to no pressure on the skin. Rotate the sensor in the ring and press the sensor gently against the skin to spread the contact liquid.



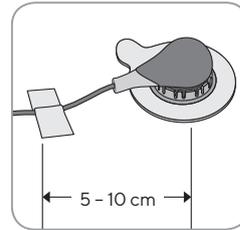
Note: Check that the sensor can be easily rotated to ensure it is snapped in correctly.

10. Check sensor application! Ensure that air gaps are eliminated between the skin and the sensor.

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

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

11. Twist the sensor into the best position. For forehead/cheek placement wrap the sensor cable once around the ear and tape the cable to the cheek or another applicable site. For other application sites, tape the cable to the skin at a distance of 5 to 10 cm from the sensor head, avoiding strain on the sensor itself or on the sensor cable.



Route the sensor cable properly to avoid entanglement or strangulation and secure it with a Clothing Clip to an appropriate site of the patient's clothing or bed linen. Ensure that the sensor cable is loose enough for not to be stretched during monitoring. Gently press on the sensor as a final application check.

12. Verify that the SDM detects that the sensor was placed on the patient, initiates monitoring and that the enabled parameters stabilize. If necessary, readjust sensor application or reposition the sensor.

Note: Typically, PCO_2 increases and PO_2 (if enabled) decreases to reach a stabilized value within 2 to 10 minutes (p. 42). SpO_2 and PR usually stabilize within a few seconds.

Note: If more secure sensor attachment is required, e.g. in high humidity environments, for patients who perspire profusely and/or in challenging patient motion conditions, the Staysite™ Adhesive (model SA-MAR) can complementary be used in addition to the Multi-Site Attachment Rings. Please refer to the Directions for Use for the Staysite™ Adhesive.

Sensor Application Using an Ear Clip

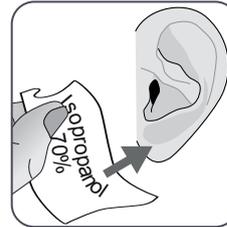
According to the procedure described point by point below, the Ear Clip is first attached to the earlobe, then **1-2** drops of Contact Gel are applied to the sensor surface, and, finally, the sensor is snapped into the Ear Clip attached to the earlobe.

Note: To attach a Sentec TC Sensor with the Ear Clip, the earlobe should 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 PCO_2/PO_2 measurements. If the earlobe is too small or has multiple piercings, consider using a Multi-Site Attachment Ring (model MAR/e-MI or model MAR/e-SF) to attach the sensor to an alternate site (p. 36).

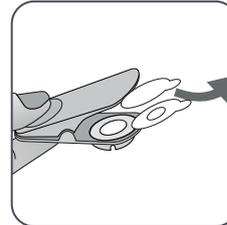
! WARNING: It is not recommended to use sensor attachment accessories on patients who exhibit allergic reactions to adhesive tapes.

! 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.

1. Check current SDM Settings/SDM Profile and verify system readiness (message ‘Ready for use’, p. 34). Change SDM Settings/SDM Profile if necessary.

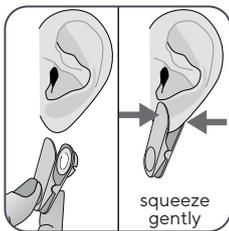


2. Clean the earlobe with a swab wetted with 70% isopropanol (or according to your institution’s skin cleaning/degreasing procedures) and let it dry. If necessary remove hair.



3. Take an Ear Clip out of the package, open the clip jaws and pull off both liners protecting the adhesive tapes of the clip.

! CAUTION: The Sentec Ear Clip (model EC-MI) is for single-use. Neither reattach used clips on the same nor on another patient!

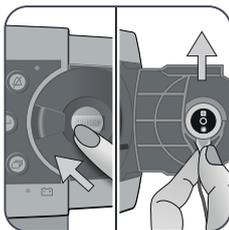


4. Pull the earlobe to stretch its skin and then attach the Ear Clip with its retainer ring on the backside of the earlobe. Verify that the skin under the retainer ring's adhesive is not wrinkled and that the hole in the center of the retainer ring completely covers the skin.

Then squeeze gently to ensure that both adhesive tapes stick firmly to the earlobe.

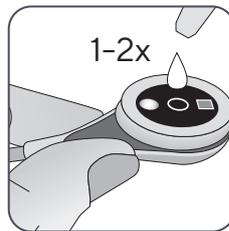
5. Open the Docking Station Door and remove the sensor.

Note: Always grab the sensor at its neck to avoid pulling and tearing the sensor cable.



6. Close the Docking Station Door.

7. Check the condition of the sensor membrane and the integrity of the sensor (p.26). Change the membrane if necessary (p.28). Do not use the sensor if any problems are noted.



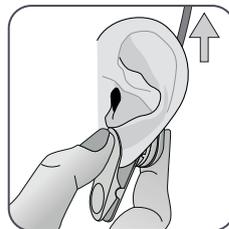
8. Take the sensor and apply **1-2** drops of Contact Gel to the middle of the sensor surface.

Note: Until the sensor is applied to the earlobe, ensure to hold the sensor such that the contact liquid does not run off the sensor face. Avoid wetting the adhesive tapes!

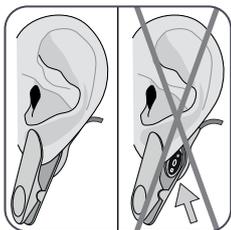
! WARNING: Do not swallow Contact Gel. Keep away from children. Avoid contact with eyes and injured skin. Do not use on patients who exhibit allergic reactions. Use only approved Sentec Contact Gel.



9. Pull the earlobe with the Ear Clip in horizontal position. Move the sensor horizontally into place with the cable preferably pointing to the crown of the head. Insert the sensor into the clip's retainer ring by gently pressing it until it snaps into the clip.



Note: Check that the sensor can be easily rotated to ensure it is snapped in correctly.



10. Check sensor application! The sensor is applied correctly if its entire dark surface is covered by the earlobe. Ensure that air gaps are eliminated between the skin and the sensor.

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

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



11. Wrap the sensor cable around the ear once and tape the cable to the cheek as shown in the picture. Route the sensor cable properly to avoid entanglement or strangulation and secure it with a Clothing Clip to an appropriate site of the patient's clothing or bed linen. Ensure that the sensor cable is loose enough for not to be stretched during monitoring. Gently squeeze the sensor and Ear Clip as a final application check.

12. Verify that the SDM detects that the sensor was placed on the patient, initiates monitoring and that the enabled parameters stabilize. If necessary, readjust sensor application or reposition the sensor.

Note: Typically, PCO₂ increases and PO₂ (if enabled) decreases to reach a stabilized value within 2 to 10 minutes (p. 42). SpO₂ and PR usually stabilize within a few seconds.

Patient Monitoring

'Sensor-On-Patient' Detection

Once the sensor is correctly applied to the patient (see previous sections), 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 (p.32), '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 in the 'Quick Access Menu' (p.55) to activate the 'Enforced Sensor-On-Patient Mode' bypassing normal 'Sensor-On-Patient' detection. To reset the SDM to 'Normal Sensor-On-Patient Mode' simply insert the sensor into the Docking Station.

Note: 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 (8)' alarm will be triggered. There will be a 'Check Application' Alarm instead, triggered within two minutes, if the sensor is dislodged or intentionally removed from the patient. If SpO₂/PR are enabled, SDM's algorithms typically will flag the PCO₂ and PO₂ readings to be unstable (displayed in grey) and the SpO₂ and PR readings to be invalid (respective values replaced by '---') within 15 seconds and within 30 seconds the low priority alarm 'SpO₂ signal quality' will sound.

Once 'Sensor-On-Patient' is detected, the SDM initiates monitoring and the enabled parameters stabilize. SpO₂ and PR usually stabilize within a few seconds, whereas PCO₂ typically increases and PO₂ typically decreases to reach a stabilized value within 2 to 10 minutes (see below).

TC-Stabilization after Sensor Application or 'TC-Artifacts'

A good, hermetically sealed contact between the TC Sensor and the skin provided, TC-readings typically stabilize within 2 to 10 minutes after sensor application, i.e. the time required to warm up the measurement site and to achieve equilibrium between the gas concentrations in the skin tissue and the gas concentrations on the sensor surface.



Good to know!

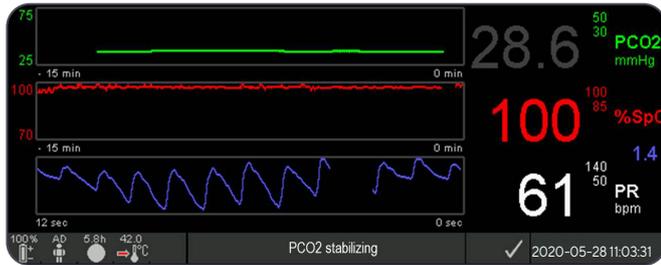
If INITIAL HEATING is ON (only available in Adult Mode), the sensor temperature is increased for about 13 minutes after sensor application, facilitating faster perfusion and results (+2 °C with a maximum of 44.5 °C).

Note: The use of INITIAL HEATING is subject to institution's permission.

Once stabilized, TC-readings can be disturbed by so-called 'TC-Artifacts'. Ambient air penetrating between the sensor surface and the skin – the most frequent reason for 'TC-Artifacts' – typically will cause PCO₂ to fall and PO₂ to rise very fast.

If the penetration of ambient air is of short duration only, TC-readings will typically restabilize within a few minutes.

After sensor application or occurrence of a 'TC-Artifact', the SDM displays the message 'PCO₂/PO₂ stabilizing' if both TC-parameters are stabilizing or 'PCO₂ stabilizing' or 'PO₂ stabilizing', respectively, if only one TC parameter is stabilizing. To indicate that TC readings during stabilization do not reflect the patient's real PCO₂ and/or PO₂ levels, the SDM displays PCO₂ and/or PO₂ readings in grey and inhibits alarms related to PCO₂ and/or PO₂ limit violations during stabilization. Furthermore, if stabilization for one or both TC parameters cannot be achieved within 10 minutes, the SDM will trigger the low priority alarm 'Check sensor application' to indicate that correct sensor application should be verified.



Good to know!

In order to reduce the number of 'TC-Artifacts', a good, hermetically sealed contact between the sensor and the skin is essential. Make sure to use **1-2** drops of Contact Gel when applying the sensor. Always check that there is a good contact between the sensor and the skin after sensor application. Properly secure the sensor cable and routinely check the sensor application during monitoring.

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

Preconfigured Measurement Screens

The SDM's numeric values and online trends provide continuous monitoring of the enabled parameters. Depending on the sensor type, the selected patient type and the enabled parameters, different sets of preconfigured measurement screens are available (numerical, numerical with online trends, numerical with online trend and Δx -/baseline values (p. 44), if SpO₂/PR are enabled all with either a wiper bar Pleth Wave or blip bar reflecting relative pulse amplitude). Use the Display Button (p. 55) to toggle between the available measurement displays.



Quality Indicators for Measurement Parameters

The SDM continuously evaluates the quality of the measured parameters and the Δx -values and baseline values derived thereof by assessing the severity of conditions presented

to the SDM. The results of this evaluation are used to display status messages and/or quality indicators for the different parameters. While a parameter is marked as:

Valid: Alarm surveillance for the respective parameter (if applicable) is active and the SDM displays the parameter in the selected color.

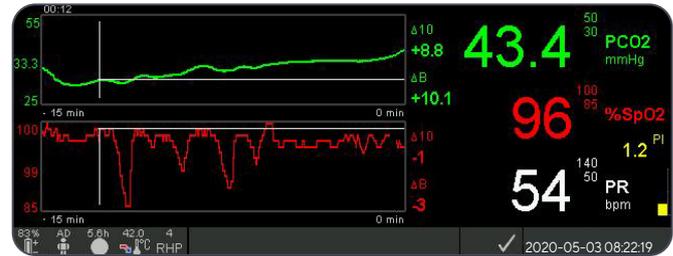
Questionable ('?'): Alarm surveillance for the respective parameter (if applicable) is active and the SDM displays the parameter in the selected color and a '?' adjacent to the parameter;

Unstable (grey): Alarm surveillance for the respective parameter is not active and the SDM displays the parameter in grey. PCO₂, for example, is displayed in grey when stabilizing after sensor application or occurrence of a 'PCO₂ artifact' (p. 42).

Invalid ('---'): Alarm surveillance for the respective parameter is not active and the SDM replaces the parameter with '---'.

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.



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 between 1 and 120 minutes within a password-protected area of V-STATS™. The default value for 'Delta-Time' is 10 minutes.

Example: A 'Δ10-value for PCO₂' of '+ 8.8 mmHg' indicates that the current PCO₂ reading is 8.8 mmHg higher than the PCO₂ reading ten minutes ago.



Good to know!

The change of a parameter's 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 help to earlier recognize 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'. The point of

time, at which 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 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 point the baseline was set, on the right of its online trend.

Example: 'Baseline values for PCO_2 ' of '33.3 + 10.1 mmHg (00:12)' indicate that the current PCO_2 reading is 10.1 mmHg higher than the baseline of 33.3 mmHg which was set 12 minutes ago.



Good to know!

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.

Operator Events

By using the 'Quick Access Menu' it is possible to store up to eight different types of Operator Events in the internal memory of the SDM for subsequent display in V-STATS™ after downloading trend data. Within V-STATS™, operator events are visualized as colored triangles and, among other, can be used to split a measurement into multiple 'Analysis Periods' (e.g. to analyze the different phases of a split night).

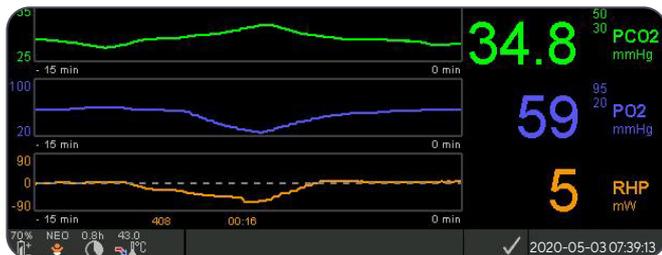
Note: Operator Events are not visualized on the SDM.

RHP Online Trends/Setting RHP Reference

Once a Sentec TC Sensor is stabilized on the skin in an environment with constant ambient temperature, the heating power required to maintain the sensor temperature depends to a small fraction on the local skin blood flow beneath the sensor site and, hence, heating power fluctuations may indicate changes in local skin blood flow.

By using the menu-parameter 'Heating Power Mode' 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. AHP and RHP values are both displayed in Milliwatts (mW).

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 higher than the RHP-reference value, 'minus' if lower, and '0' if identical). On most measurement screens, RHP readings are – as the AHP readings – displayed in the 'Heating Power Icon' (p. 61). On certain measurement screens, however, the RHP-value is displayed underneath the PCO_2 or PO_2 value and the RHP online trend is depicted underneath the PCO_2 or PO_2 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 in the RHP online trend corresponds to a RHP of 0 mW and reflects the RHP-reference value. RHP values below/above the center-line correspond 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.

Keeping in mind the possible influence of local skin blood flow fluctuations on transcutaneous blood gases (p. 16), it is 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, permits 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.

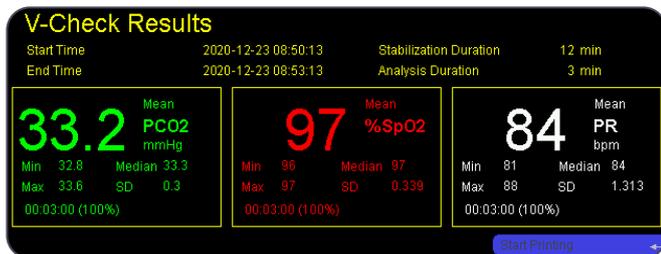
If in RHP-mode the sensor is applied to the patient when no RHP-reference value is yet available, the SDM automatically determines the RHP-reference value once the sensor is stabilized on the skin (which is typically the case 5 to 10 minutes after sensor application).

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 pressing the Enter Button when a measurement screen is active or b) by changing the menu-parameter 'Heating Power Mode' from 'Relative' to 'Absolute' or 'OFF' and back to 'Relative'.

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'.

'V-Check™ Mode'

In standard configuration, the SDM's numeric values and online trends provide continuous monitoring of the enabled parameters. If the menu-parameter 'V-Check™ Mode' is set to ON (only selectable if enabled by the institution), the SDM provides a Ventilation Spot **Check** with a statistical result screen displaying mean, minimum, maximum, median and standard deviation for the enabled parameters.



A V-Check™ Measurement consists of the V-Check™ Stabilization Phase (default duration 8 minutes) and the V-Check™ Measurement Phase (default duration 2 minutes). If the V-Check™ Measurement is finished two short signal tones sound and the V-Check™ Results Screen activates, displaying the above mentioned statistical results for the data assessed during the V-Check™ Measurement Phase. The V-Check™ Results Screen remains displayed until the Menu or Display Button are pressed or another V-Check™ Measurement is started.

Note: The ‘V-Check™ Mode Indicator’ appears on the ‘Ready for use’ and ‘Calibration’ screen (p. 34) if the V-Check™ Mode is ON. On measurement screens (p. 43), the V-Check™ Down-Counter (format hh:mm:ss) is displayed on the very right of the Status Bar (p. 61). 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: Print-out of the trend curves (including the statistical results) is automatically activated upon completion the V-Check™ Measurement if the protocol ‘Serial Printer’ is selected and a printer is connected to the SDM.

Note: The SDM automatically stores V-Check™ Events in its internal memory at the start and at the end of each V-Check™ Measurement Phase. After trend data download to V-STATS™ the start and end of a V-Check™ Measurement Phase are visualized by two colored triangles and it is possible to generate a report which includes the same information as is provided on the SDM’s V-Check™ Results Screen.



Good to know!

To use V-Check™, select the Sentec-preconfigured SDM Profile V-CHECK as standard ‘SDM Profile’. 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.

PCO₂ In-Vivo Correction

Subject to institution’s permission, ‘In-Vivo Correction’ (IC) of PCO₂ values is possible at the bedside. The ‘PCO₂ In-Vivo Correction’ allows for 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’ (p. 15) 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.

Note: The Quick Access Menu' provides a short-cut to the sub-menu 'PCO₂ In-Vivo Correction', which is only accessible if enabled by the institution.

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*').



WARNING: A 'PCO₂ In-Vivo Correction' should only be enabled by personnel understanding the principles and limitations of transcutaneous PCO₂ monitoring (p. 16). If a 'PCO₂ In-Vivo Correction' is made it must be checked periodically and adapted in case of changes.

Patient Data Management

The SDM automatically stores PCO₂, PO₂, SpO₂, PR, RHP and PI data as well as system status information in its internal memory for subsequent on-screen viewing or printing of graphical trends and statistical summary/histograms. The Data Recording Interval is institution-selectable between 1 and 8 seconds and provides between 35.2 and 229.9 hours of monitoring data, respectively. V-STATS™ provides fast data download to the PC with V-STATS™ (approx. 3 min. for 8 hours data at 4-seconds resolution) for subsequent display, analysis and reporting within V-STATS™.

Patient data acquired by the SDM can be output through the multipurpose I/O-port (analog output; nurse call), the serial data port (RS-232) or the LAN port, all located on the rear panel of the SDM. These ports can be connected to external devices such as multiparameter bedside monitors, PCs, poly(somno) graphs, nurse call systems, chart recorders or data loggers.

By using V-CareNet™, for example, remote monitoring and secondary alarm surveillance of multiple SDMs connected to the same network as the PC is possible. 'Operator Events', 'Baselines', and certain SDM settings can be set/controlled remotely on the included SDMs. Furthermore, download of SDM Trend Data is simultaneously possible for multiple SDMs.

'Remaining Monitoring Time'/'Site Time Elapsed' Alarm

During monitoring, the 'Remaining Monitoring Time' Icon (p.61) continuously indicates the 'Remaining Monitoring Time', i.e. the time until either the selected 'Site Time' or – if PCO₂ is enabled – the 'Calibration Interval' elapse (whichever will occur first).

When the 'Calibration Interval' elapses before the selected 'Site Time', the 'Remaining Monitoring Time' Icon is highlighted yellow, the message 'Sensor calibration recommended' is displayed and monitoring is possible another 4 to 6 hours with PCO₂ marked as 'questionable'. Thereafter, sensor calibration is mandatory and PCO₂ and PO₂ are marked as 'invalid' (values replaced by '---'). When the 'Site Time' elapses, the icon is highlighted in red and the low priority alarm 'Site time elapsed' is triggered. In this case, 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 either press the Enter Button while the message 'Sensor off patient (←)' displays or insert the sensor into the Docking Station.



CAUTION: Do not reattach the sensor to the same site if any skin irritations are noted during site inspection.



Good to know!

If the safety feature SITE PROTECTION is ON, the SDM will reduce the sensor temperature to safe values once the sensor application duration overruns the selected 'Site Time' by more than 10% or 30 minutes. PCO_2/PO_2 are marked as 'invalid' thereafter (values replaced by '---').

During monitoring, the current setting for SITE PROTECTION is indicated in the 'Sensor Temperature' icon (p. 61). A 'red-blue rightward arrow with tip down' displays if SITE PROTECTION is ON, a 'red rightward arrow' if it is OFF.

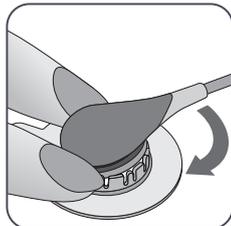
Sensor Removal with Multi-Site Attachment Ring

Remove the sensor from the patient when monitoring is completed or monitoring time has elapsed (message 'Site time elapsed' or 'Calibrate sensor').

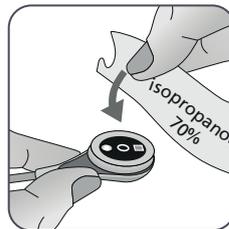
! CAUTION: For site inspection and/or calibration, the Multi-Site Attachment Ring/Easy can remain on the same site for up to 24 hours and may be reused for another sensor application. It is recommended to remove and to discard the Multi-Site Attachment Ring/Easy after 24 hours and to keep the measurement site free of adhesive for 8 to 12 hours.

Sensor Removal for Subsequent Reattachment to Same Site

1. Remove the adhesive tape securing the sensor cable.



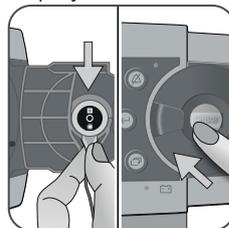
2. Place a finger on each side of the ring and rotate the sensor towards the index finger. The index finger will act as a wedge and will disengage the sensor from the ring.



3. Clean the sensor with a swab wetted with 70% isopropanol to remove any contact liquid residues or dirt (for other approved cleaning agents refer to sentec.com/ifu).

4. Check the condition of the sensor membrane and the integrity of the sensor (p. 26). Change the membrane if necessary (p. 28). Do not use the sensor if any problems are noted.

Important: Before reapplying the sensor to the same site, we recommend calibrating the sensor even if calibration is not yet mandatory or recommended by the SDM. If you skip the calibration, remember to reset the Site Timer by pressing the Enter Button when the message 'Sensor off patient (←)' displays and then continue at step 6.



5. To calibrate the sensor, open the Docking Station Door and hang the sensor in the holder inside the Docking Station Door (the red light will appear). Close the Docking Station Door.

Note: Sensor calibration – if necessary – will start (message 'Calibration in progress'). The message 'Ready for use' will display once calibration is finished.

6. Clean the skin in the center of the ring with a dry swab or, if necessary, a swab wetted with 70% isopropanol (or according to your institution's skin cleaning/degreasing procedures) to remove any contact liquid residues or dirt and let it dry.

7. Carefully inspect the measurement site.

! **CAUTION:** Do not reattach the sensor to the same site if any skin irritations are noted during site inspection.

8. To reapply the sensor to the same site, continue at step 5 in section 'Sensor Application using a Multi-Site Attachment Ring' (p. 36). Make sure to clean the measurement site from any gel residue and to reapply **1-2** drops of Contact Gel to the site before reinserting the sensor into the MAR/e.

Sensor Removal without Reattachment to Same Site

1. Remove the sensor together with the Multi-Site Attachment Ring by carefully lifting the ring's little tab

2. Clean the skin with a dry swab or, if necessary, a swab with 70% isopropanol (or according to your institution's skin cleaning/degreasing procedures) to remove any contact liquid residues or dirt and then carefully inspect the site to note any potential skin irritations.

3. Remove the sensor from the MAR/e, discard the ring and then follow steps 3 to 5 above to clean the sensor, to check the condition of its membrane and its integrity as well as to insert it in the Docking Station for calibration and/or storage.

! **CAUTION:** 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.

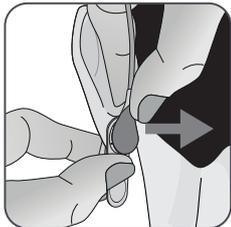
Sensor Removal with Ear Clip

Remove the sensor from the patient when monitoring is completed or monitoring time has elapsed (message 'Site time elapsed' or 'Calibrate sensor').

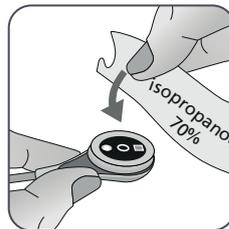
! CAUTION: For site inspection and/or calibration, the Ear Clip can remain on the same earlobe for up to 24 hours and may be reused for another sensor application. It is recommended to remove and to discard the Ear Clip after 24 hours and to keep the earlobe free of adhesive for 8 to 12 hours.

Sensor Removal for Subsequent Reattachment to Earlobe

1. Remove the adhesive tape securing the sensor cable.



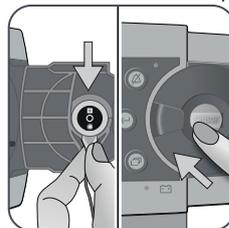
2. Grab the sensor at its neck with one hand and detach it from the Ear Clip while holding the clip in place with the other hand.



3. Clean the sensor with a swab wetted with 70% isopropanol to remove any contact liquid residues or dirt (for other approved cleaning agents refer to sentec.com/ifu).

4. Check the condition of the sensor membrane and the integrity of the sensor (p. 26). Change the membrane if necessary (p. 28). Do not use the sensor if any problems are noted.

Important: Before reapplying the sensor to the same earlobe, we recommend calibrating the sensor even if calibration is not yet mandatory or recommended by the SDM. If you skip the calibration, at least reset the Site Timer by pressing the Enter Button when the message 'Sensor off patient (←)' displays and then continue at step 6.



5. To calibrate the sensor, open the Docking Station Door and hang the sensor in the holder inside the Docking Station Door (the red light will appear). Close the Docking Station Door.

Note: Sensor calibration – if necessary – will start (message 'Calibration in progress'). The message 'Ready for use' will display once calibration is finished.

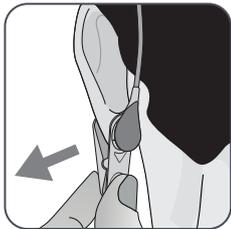
6. Clean the skin in the center of the Ear Clip's retainer ring with a dry swab or, if necessary, a swab wetted with 70% isopropanol (or according to your institution's skin cleaning/degreasing procedures) to remove any contact liquid residues or dirt and let it dry.

7. Carefully inspect the earlobe.

! CAUTION: Do not reattach the sensor to the same earlobe if any skin irritations are noted during site inspection.

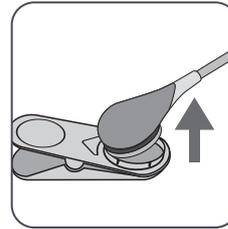
8. To reapply the sensor to the same earlobe, continue at step 5 in section 'Sensor Application using an Ear Clip' (p. 39). Make sure to clean the measurement site from any gel residue and to reapply 1-2 drops of Contact Gel to the sensor's center before reinserting it into the Ear Clip.

Sensor Removal without Reattachment to Same Earlobe



1. Open the clip's jaws and remove it from the earlobe together with the sensor by turning it sideways.

2. Clean the earlobe with a dry swab or, if necessary, a swab wetted with 70% isopropanol (or according to your institution's skin cleaning/ degreasing procedures) to remove any contact liquid residues or dirt and then carefully inspect the earlobe to note any potential skin irritations.



3. Remove the sensor from the Ear Clip, discard the clip and then follow steps 3 to 5 above to clean the sensor, to check the condition of its membrane and its integrity as well as to insert it in the Docking Station for calibration and/or storage.

! CAUTION: 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.

Additional Warnings

Electromagnetic interferences

 **WARNING:** Electrostatic discharge and transient bursts from mains may temporarily interfere with the measurement. This can lead to wrong measurements.

 **WARNING:** Equipment emits electromagnetic fields. This can, for example, disturb other medical devices or Radio Services.

 **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.

Interference from interventional devices

 **WARNING:** The SDM is protected against electrostatic/defibrillator discharge. Parameter display may be temporarily affected during electrostatic discharge/defibrillation, but will rapidly recover. Nevertheless, 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.

Radio equipment

 **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. Wireless mobile devices must be held away from the SDMS by at least 1 m (39.4 inches). Otherwise, degradation of the performance of this equipment and at worst, incorrect measurements could result.

Controls, Indicators and Alarms

Controls (Buttons)

The ON/OFF switch is located on the rear panel of the SDM ⁽²⁴⁾. The following controls (buttons) are located on the front panel of the SDM:

 Menu/ Previous Level Button	<ul style="list-style-type: none"> • 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 deactivate 'editing mode' for the selected menu-parameter* <p>Note: Menu access can be disabled by the institution (e.g. for home use)</p>
 UP Button	<ul style="list-style-type: none"> • 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 of the display (only if a measurement screen is active)
 DOWN Button	<ul style="list-style-type: none"> • 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 of the display (only if a measurement screen is active)

 AUDIO PAUSED /AUDIO OFF Button	<ul style="list-style-type: none"> • 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) <p>Note: Switching off auditory alarm signals is only possible if enabled by the institution.</p> <p>Note: This button is inactive if the menu parameter 'Alarm Settings/Alarm Volume' is set to OFF.</p>
 Enter Button	<ul style="list-style-type: none"> • to activate the selected sub-menu or function • to activate/deactivate 'editing mode' for the selected menu parameter* • to confirm temperature and site time settings exceeding recommended values • to activate 'Quick Access Menus' (only if menu is not open) • to terminate the 'Sensor off patient (→)**' and 'Remote Monitoring Interrupted (→)' alarms • to activate the second 'System Information' page (only if first 'System Information' page is open)
 Display Button	<ul style="list-style-type: none"> • to toggle between the available measurement screens • to deactivate 'editing mode' for the selected menu-parameter* • to exit the menu from any menu level (only if 'editing mode' is inactive)

*For parameters that are highlighted with a **blue** menu bar in 'editing mode', changes become effective immediately without confirmation (see example 1 below). For parameters that are highlighted with a **yellow** menu bar in 'editing mode', changes must be confirmed by pressing the Enter Button to become effective (see example 2 below). To cancel changes/deactivate

'editing mode', use the Menu/Previous Level Button or the Display Button.

** will also reset the Site Timer

Example 1: 'SpO₂ Low Limit'

The parameter 'SpO₂ Low Limit' is included in the menu 'Alarm Settings'. It is an example of a parameter for which changes made with the UP/Down Buttons become **immediately effective without confirmation**. To change the parameter 'SpO₂ Low Limit', proceed as follows:

- Press  to access the menu.
- Press  to open/activate the menu 'Alarm Settings'.
- Press  3 times to scroll down the blue menu bar to the parameter 'SpO₂ Low Limit'.
- Press  to activate 'editing mode' for the parameter 'SpO₂ Low Limit'. Note that the 'Enter' symbol at the end of the line is replaced by up/down arrows and that the color of the menu bar remains blue.
- Press  or  as many times as required to select the desired SpO₂ low limit. Note that changes become effective **immediately**.
- Press ,  or  to deactivate 'editing mode' for the parameter 'SpO₂ Low Limit'. Note that the 'Enter' symbol reappears at the end of the line and that the color of the menu bar remains blue.
- Press  to return to the main menu or  to exit the menu.

Note: Changes made with the UP/Down Buttons immediately become effective without confirmation for all parameters except 'Patient', 'Enabled Parameters' and 'Language' (see example 2).

Example 2: 'Language selection'

The parameter 'Language' is included in the menu 'System Settings'. It is an example of a parameter for which changes **must be confirmed** by pressing the Enter Button before they become effective. To change the parameter 'Language', proceed as follows:

- Press  to access the menu.
- Press  3 times to scroll down the blue menu bar to the menu 'System Settings'.
- Press  to open/activate the menu 'System Settings'.
- Press  3 times to scroll down the blue menu bar to the parameter 'Language'.
- Press  to activate 'editing mode' for the parameter 'Language'. Note that the 'Enter' symbol at the end of the line is replaced by up/down arrows followed by an 'Enter' symbol and that the color of the menu bar changes from blue to yellow.
- Press  or  as many times as required to select the desired language. Note that changes do **not** become effective.
- Press  to confirm the selected language and to deactivate 'editing mode'. To cancel changes and deactivate 'editing

mode' press  or . Note that upon deactivation of the 'editing mode' the 'Enter' symbol reappears at the end of the line and the color of the menu bar changes from yellow to blue.

Note: After language confirmation, the SDM automatically exits the menu.

Note: Operator access to the parameter 'Language' can be disabled by the institution by using V-STATS™ within a password protected area.

Example 3: 'Confirmation of Membrane Change'

To reset the membrane timer after a successful membrane change, the membrane change must be confirmed on the SDM by using the function 'Membrane Change Done' in the menu 'Membrane Change'. To confirm a membrane change, proceed as follows:

- Press  to access the menu.
- Press  twice to scroll down the blue menu bar to the menu 'Membrane Change'.
- Press  to open/activate the menu 'Membrane Change'.

Note: The SDM automatically activates the menu 'Membrane Change' if a sensor with an expired membrane is inside the Docking Station.

- Press  once to scroll down the blue menu bar to the function 'Membrane Change Done'.
- Press  to confirm the membrane change.

Note: The menu 'Membrane Change' and the function 'Membrane Change Done' are dimmed grey (not accessible) if the sensor is attached to the patient or inside the Docking Station. In this case, remove the sensor from the patient or the Docking Station to confirm the membrane change.

LED Indicators

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

 <p>AUDIO PAUSED/ AUDIO OFF Indicator</p>	<ul style="list-style-type: none"> • Yellow LED: Auditory alarm signals paused for 1 or 2 minutes • Yellow LED flashes: Auditory alarm signals permanently switched off (activated by pressing AUDIO PAUSED/AUDIO OFF Button > 3 seconds) • LED OFF: Auditory signals either active or permanently switched off by setting menu parameter 'Alarm Settings/Alarm Volume' to OFF.
 <p>ON/OFF Indicator</p>	<ul style="list-style-type: none"> • Green: SDM turned on • LED OFF: SDM turned off
 <p>AC Power/ Battery Indicator</p>	<ul style="list-style-type: none"> • Green LED: Connected to AC power, battery fully charged • Yellow LED: Connected to AC power, battery charging • LED OFF: Not connected to AC power (i.e. powered by internal battery) <p>Note: The AC Power/Battery Indicator works irrespective of whether the SDM is switched on or off.</p>

Auditory Indicators/Signals

The SDM provides the following auditory signals:

- Auditory alarm signals for high, medium and low priority alarm conditions (p. 48); use the parameter 'Alarm Volume' to adjust the volume of these signals.
- The 'AUDIO OFF Reminder' (short signal tone) sounds every 60 seconds if the auditory alarm signals are permanently switched off. Operator access to switch off this reminder signal is subject to institution's permission; its volume is not adjustable.
- Auditory signal (three signal tones of 0.2 seconds) to test the SDM's loudspeaker during the Power-On Self-Test. Contact Sentec authorized service personnel or your local Sentec representative if this signal is not activated when switching on the SDM.
- The 'Ready for use' Beep (short tone) sounds at the end of a successful calibration of a Sentec TC Sensor. This signal can only be switched ON/OFF by the institution; its volume is not adjustable.
- The Key Click (short tone) indicates that a button has been properly pressed; use the parameter Key Click to switch off/adjust the volume of this signal.
- The 'Pulse Beep' (short tone) sounds once for each pulse. Its automatic pitch modulation reflects changing SpO₂ levels; use the parameter 'Pulse Beep' to switch off/adjust the volume of this signal.

- The 'Button Disabled Beep' (long tone) sounds if a currently disabled button is pressed (e.g. the Menu Button if 'Menu Access' has been disabled by the institution); its volume is not adjustable.
- The 'Button Disabled Beep' (low pitched tone) sounds if a Control Button is pressed that is currently disabled (e.g. if the Menu/Previous Level Button is pressed when 'Menu Access' is disabled by institution).
- The 'V-Check™ Completed Beep' (high pitched two beep tone) sounds upon termination of a V-Check™ Measurement; use the parameter 'Alarm Volume' to adjust the volume of this signal.

Note: The SDM ranks the priority of auditory alarm signals and, to ensure that auditory signals do not superpose, only outputs the highest priority acoustic signal.

Alarms

The SDM uses visual and auditory alarm signals to alert the user when a physiological measurement parameter (PCO₂, PO₂, SpO₂, PR) violates its alarm limits and to inform the user about technical conditions of the equipment that require operator response or awareness. By degree of urgency, the SDM's alarm conditions are assigned to the following priorities: **High priority** (SpO₂ limit violation), **medium priority** (PCO₂, PO₂ or PR limit violation, 'Battery Critical' (if SDM not connected to AC power)), **low priority** (various technical alarm conditions). All alarm signals of the SDM automatically cease when the associated triggering event has terminated.



WARNING: Setting alarm limits for physiological measurement parameters to extreme values may render the SDM's alarm system useless for the respective parameter.



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

Note: Alarm surveillance for physiological measurement parameters (PCO₂, PO₂, SpO₂, PR) is only active if the respective parameter is valid or questionable (p. 43). Otherwise, generation of alarm signals for the respective parameter is automatically suspended.

Visual Alarm Signals

The 'Alarm Status Icon' (p. 61) indicates the highest currently active alarm priority. If a physiological parameter violates its alarm limits, the respective parameter and the 'Alarm Status Icon' flash (with 0.7 Hz for SpO₂ and 1.4 Hz for PCO₂, PO₂, PR). 'Status Messages' (only one at a time) and/or various 'Status Icons' visualize technical alarm conditions and general information on the system status. The SDM's visual alarm signals cannot be deactivated.



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.



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

Auditory Alarm Signals

The SDM's auditory alarm signals are priority encoded. A high priority alarm condition is indicated by a high-pitched fast pulsing tone (two bursts of five short pulses repeated every 10 seconds), a medium priority alarm condition by a medium-pitched pulsing tone (one burst of three pulses repeated every 10 seconds), and a low priority alarm condition by a low-pitched slow pulsing tone (one burst of two pulses repeated every 15 seconds). Alarm melodies can be enabled/disabled by the institution.

The volume of auditory alarm signals can be adjusted (levels OFF, 1 to 6, Rising). OFF is only selectable if enabled by the institution. If 'Rising' is selected, the volume of auditory alarm signals – starting at level 2 – increases at each burst by one level. If OFF is selected, auditory alarm signals are permanently switched off.



CAUTION: Using the AUDIO PAUSED/OFF Button, auditory alarm signals can be paused or permanently switched off (p. 55).

Note: If auditory alarm signals are permanently switched off, the 'AUDIO OFF Reminder' sounds every 60 seconds (unless disabled by the institution).

Note: The operating status of the SDM's auditory alarm signals is visually indicated by the 'AUDIO STATUS Icon' (p. 62), the 'AUDIO PAUSED/AUDIO OFF Indicator' (p. 58), and acoustically indicated by the 'AUDIO OFF Reminder'.

WARNING: If an alarm condition occurs while the auditory alarm signals are paused or permanently switched off, the only alarm indication will be visual, but **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. Do not disable the audible alarm function or decrease the audible alarm volume if the patient's safety could be compromised.

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

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

Note: When the alarm system of an SDM that is remotely monitored via V-CareNeT™ is in the AUDIO OFF state, the SDM will terminate the AUDIO OFF state if the connection between the SDM and the V-CareNeT™ Central Station is interrupted. For details, refer to the Technical Manual for the SDM (HB-005752).

Status Bar with Status Icons and Status Messages

The Status Bar is located in the bottom of nearly all screens.



On the left, it displays up to 5 Status Icons (1 to 5).

The 'Battery' Icon **1** indicates the remaining battery capacity in %. The icon highlights yellow when battery capacity is below 10% and red if the remaining battery capacity is critical.

On measurement/menu screens, position **2** displays the 'Patient Type' Icon ('AD' in 'Adult' mode or 'NEO' in 'Neonatal' mode). On the 'Calibration Screen', however, the 'Barometric Pressure' Icon is displayed in position **2**. The 'Barometric Pressure' Icon indicates the measured ambient barometric pressure in 'mmHg' or 'kPa'. The icon highlights red if a barometer fault is detected and yellow if the barometric pressure is unstable during sensor calibration.

The 'Remaining Monitoring Time' Icon **3** indicates the 'Remaining Monitoring Time' (Format: xx.xh) on measurement/menu screens, whereas on the 'Calibration Screen' the same icon indicates the 'Available Monitoring Time'. The pie chart – which is updated in steps of 20% – indicates the remaining monitoring time in percentage. The icon highlights yellow if only the 'Calibration Interval' has elapsed and it highlights red whenever the 'Site Time' has elapsed.

The 'Sensor Temperature' Icon **4** indicates the measured sensor temperature (°C) and the current setting of SITE

PROTECTION. A 'red-blue rightward arrow with tip down' appears if SITE PROTECTION is ON, a 'red rightward arrow' if it is OFF. The 'Sensor Temperature' Icon is marked yellow during INITIAL HEATING, blue if SITE PROTECTION has reduced the sensor temperature and red if the SDMS' temperature surveillance detected a sensor temperature-related problem.

On measurement/menu screens, position (5) either displays the 'Absolute Heating Power' (AHP), the 'Relative Heating Power' (RHP), both in mW, or no icon if Heating Power Mode is OFF, whereas position (5) displays the 'Gas Icon' on the 'Calibration Screen'. The 'Gas Icon' indicates the remaining capacity of the Service Gas Bottle in %. It is marked yellow if the remaining capacity is below 10% and red if the gas bottle is empty (format: xxx%).

Note: On measurement/menu screens with RHP online trends, no icon is displayed at position (5).

The Status Text Field (6) in the middle displays Status Messages (alarm/information messages). If there is no current Status Message, the name of the presently active menu is displayed in the status text field of menu screens and - during remote monitoring via V-CareNeT™ - the 'Patient Info' is displayed in the status text field of measurement screens.

The AUDIO Status Icon (7) on the right of the status text field indicates the status of the SDM's auditory alarm signals (ON, PAUSED, OFF).

The Alarm Status Icon (8) indicates the ranking of the highest priority alarm condition (flashing white triangle with curved line and exclamation mark on red background in a **high priority alarm** condition; flashing black triangle with curved line and exclamation mark on yellow background in a **medium**

priority alarm condition; black triangle with curved line and exclamation mark on cyan background in a **low priority alarm** condition; light grey check mark symbol on dark-grey background if no alarm condition).

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 (p. 43), the date/time indication is replaced by the V-Check™ Down-Counter (format hh:mm:ss) in V-Check™ Mode (p. 46). 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 --:--:--.



Good to know!

The date/time of the SDM can be adjusted in the menu; or, by using V-STATS™, it is possible to set the SDM's date/time to the current date/time of the PC (i.e. to synchronize the date/ time setting of the SDM and the PC).

Maintenance of the SDMS

During 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 maintenance procedures (including cleaning/disinfection) as well as safety and functionality checks should be performed regularly.

The Technical Manual for the Sentec Digital Monitor (SDM) provides instructions for cleaning and/or disinfecting the SDM and the Digital Sensor Adapter Cable. Please refer to sentec.com/ifu.

Routine Checks

The following checks should be performed regularly:

- Before and after every use check the Sentec TC Sensors (p. 26).
- Weekly clean and disinfect Sentec TC Sensors and the Digital Sensor Adapter Cable.
- ‘Power On Self Test’ (POST): Every time the SDM is switched on (p. 23), the POST is performed automatically. If your SDM is permanently switched on, switch it off and on again once a month to perform a POST.
- Weekly clean the Docking Station gasket using a cotton swab moistened with 70% isopropanol (for other approved cleaning agents refer to sentec.com/ifu).

- Monthly inspect the Docking Station Door and gasket for mechanical and functional damages.
- Monthly check the SDM, sensors, sensor adapter cables and power cord for mechanical or functional damages. Defective parts must be replaced by original replacement parts.
- Monthly perform a ‘Sensitivity Test’ PCO_2/PO_2 (can be activated in the menus ‘ PCO_2 Settings’ or ‘ PO_2 Settings’).
- Monthly check the sensor temperature by comparing the displayed sensor temperature to the sensor SET Temperature.
- Monthly check the barometer reading of the SDM against a calibrated barometer.
- Monthly check the alarm function of the SDM and correct functioning of its interfaces (if used).

Refer to the Service Manual for the SDMS and sentec.com/ifu for additional/complete check lists and detailed maintenance procedures.

Note: Check the disposables monthly and replace any expired products.

Service

It is recommended that a complete safety and functionality check is performed at regular intervals (recommended every 12 months but at least once every 24 months) or in accordance with institutional, local and governmental regulations (refer to the Service Manual for the SDMS for details). 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.



WARNING: The cover should only be removed by Sentec authorized service personnel. There are no user-serviceable parts inside the SDM.

Waste Disposal

The SDMS is manufactured with environment-friendly material. It contains electronic printed circuit boards, a display, cables and lithium batteries.

Do not incinerate equipment or gas bottles.

WEEE Disposal: European consumers are obliged by law to dispose Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive:

1. All electrical and electronic waste, must be stored, collected, treated, recycled and disposed of separately from other waste
2. Consumers are obliged by law to return electrical and electronic devices at the end of their service lives to the public collection points set up for this purpose or point of sale. Details to this are defined by the national law of the respective country.

Note: By recycling materials or other forms of utilizing old devices, you are making an important contribution to protecting our environment.

Sentec Digital Monitor

Return the SDM to your local Sentec representative or dispose it according to local regulations.



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

Cables

Dispose the cables according to local regulations. The copper contained can be recycled.

Sentec TC Sensors

Return the Sentec TC Sensors to your local distributor.

Service Gas Bottle

Dispose empty gas bottles according to local waste disposal regulations for aluminum containers. Make sure that only empty gas bottles are disposed.

Gas may be discharged from the container by **carefully** opening the container valve.

Ensure that the container is positively supported.

Open the container valve **slowly** to permit gas discharge at an appropriate rate.



CAUTION: Ensure that the operation is carried out in a well ventilated area and vented gases may disperse. Noise level should be controlled to meet local regulations.



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.

Consumables

All material used is considered "non critical". The consumables may be disposed with the regular garbage collection.

Specifications

SDM

Physical Characteristics

Weight: 2.3 kg (5.1 lbs) – including gas cylinder

Size: 10.2 cm x 27.0 cm x 23.0 cm (4.00" x 10.63" x 9.06")

Flip feet: Flip feet serving as carrying handle or to adjust angle for improved table-top viewing.

Mountable: Mountable on roll/ infusion stands, wall mounts/ railings, transport incubators, etc.

Electrical

Instrument: AC Power: 100 – 240 V (50/60 Hz), max. 900 mA/ Electrical Safety (IEC 60601-1): Class I, Type BF, Applied Part – Defibrillation Proof, IPX1.

Internal battery: Type: rechargeable, sealed Lilon Battery/

Capacity (new fully charged battery): up to 10 hours (if Sleep Mode=OFF, AUTO) and up to 12 hours (if Sleep Mode=ON)/ Charging Time: approx. 7 hours

Environmental

Transport/ storage temperature: 0 – 50 °C (32 – 122 °F)

Transport/ storage humidity: 10 – 95% non-condensing

Operating temperature: 10 – 40 °C (50 – 104 °F)

Operating humidity: 15 – 95% non-condensing

Operating altitude: -400 – 4000 m (-1300 – 13120 ft) if connected to mains; -400 – 6000 m (-1300 – 19600 ft) if operated on battery.

Built-in barometer: Range: 350 – 820 mmHg (47 – 109 kPa)/ Accuracy: ± 3 mmHg (0.4 kPa)

tcPCO₂ and tcPO₂

tcPCO₂

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	Typically < 0.5%/hour
Response time (T90)	<ul style="list-style-type: none">• V-Sign™ Sensor 2 < 75 sec.• OxiVenT™ Sensor < 80 sec.
Linearity	Typically < 1 mmHg (0.13 kPa)
Interferences by anesthetic gases	Negligible
Stabilization/artifact detection	After sensor application or occurrence of a tcPCO ₂ artifact, tcPCO ₂ is displayed in grey until it (re)stabilizes.

tcPO₂

Measurement range	0 – 800 mmHg (0 – 106.7 kPa)
Resolution	1 mmHg (0.1 kPa)
Drift	Typically < 0.1%/hour
Response time (T90)	Typically < 150 sec.
Linearity	Typically < 1 mmHg (0.13 kPa)
Interferences by anesthetic gases	Negligible
Stabilization/artifact detection	After sensor application or occurrence of a tcPO ₂ artifact, tcPO ₂ is displayed in grey until it (re)stabilizes.

Pulse Oximetry

Oxygen Saturation (SpO₂)

Approved sites for SpO₂/PR monitoring with Sentec TC sensors

Earlobe, low on forehead, cheek, upper arm, scapula (shoulder blade)

Measurement range 1 – 100%

Resolution 1%

Accuracy
(Arms over 70 to 100% range; all above specified sites)

• V-Sign™ Sensor 2 ± 2%

• OxiVenT™ Sensor ± 2.25%

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 defined 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.

Pulse Rate (PR)

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.

Incident Reporting

Any serious incident that has occurred in relation to the Sentec Digital Monitoring System has to be reported to Sentec (service@sentec.com) and/or to the competent authority of the country, where the incident occurred. If you are not sure, whether an incident is a reportable event, you can contact Sentec first.

Glossary of Symbols

The table below summarizes symbols used on the SDMS (including all its related parts), on the packaging and in the associated documentation. These symbols indicate information essential for proper use; the order of their appearance is not prioritized.

Symbol	Name	Description of Symbol
	Manufacturer	Indicates the medical device manufacturer.
	Date of Manufacturer	Indicates the date when the medical device was manufactured.
	Use-by date	Indicates the date after which the medical device is not to be used.
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	European Authorized Representative	Designated point of contact to represent a non European Union (EU) manufacturer within the EU.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Medical Device	Indicates that the device is a medical device.

Symbol	Name	Description of Symbol
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed (upper and lower limits of temperature are indicated adjacent to the upper and lower horizontal lines).
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed (humidity limitation indicated adjacent to the upper and lower horizontal lines).
	Atmospheric pressure limitation	Indicates the atmospheric pressure limits to which the medical device can be safely exposed.

Symbol	Name	Description of Symbol
	Do not re-use (Single use)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Mandatory action: refer to instruction manual	Indicates that the instruction manual must be read
	General warning sign	Indicates a general warning
	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.
	Prescription only	Caution: Federal Law (U.S.) restricts these devices to sale by or on the order of a physician.
	Caution	Refer to accompanying documents for warnings and precautions

Symbol	Name	Description of Symbol
	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.
	Keep out of reach of children	Keep out of reach of children
	Do not swallow	Do not swallow Contact Gel.
	Avoid contact with eyes	Avoid contact with eyes
	Keep away from sunlight	To indicate the transport package which shall not be exposed to sunlight.
	WEEE Disposal	European consumers are obliged by law to dispose Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive 2012/19/EU.
	Equipotentiality	Equipotential Terminal (ground)
	ON (SDM rear button)	Monitor ON

Symbol	Name	Description of Symbol
	OFF (SDM rear button)	Monitor OFF
I/O	Multipurpose Port	Nurse Call + Analog Output
	Nurse Call	Nurse Call (integrated into Multipurpose Port)
	RS-232	Serial Data Port (RS-232)
LAN	LAN	Local Area Network Port
	Defibrillation Proof Type BF	Degree of protection against electrical shock: Defibrillation-proof, Type BF applied part
	Fuse	Indicates fuse type
IP	IP Code	Classification of degree of ingress protection provided by enclosures for electrical equipment according to IEC/EN 60529.
	Transformer	Indicates that the product is a non-short-circuit proof isolating transformer.
Pri: 	Circuit Breaker	Circuit breakers for transformer protection on the primary side against overloads and short-circuits.

Symbol	Name	Description of Symbol
	Gases under pressure - Compressed gas	Warning: H280 - Contains gas under pressure; may explode if heated.
	Non-flammable, non-toxic gases	Indicates gases, which are neither flammable nor poisonous.

sentec.



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