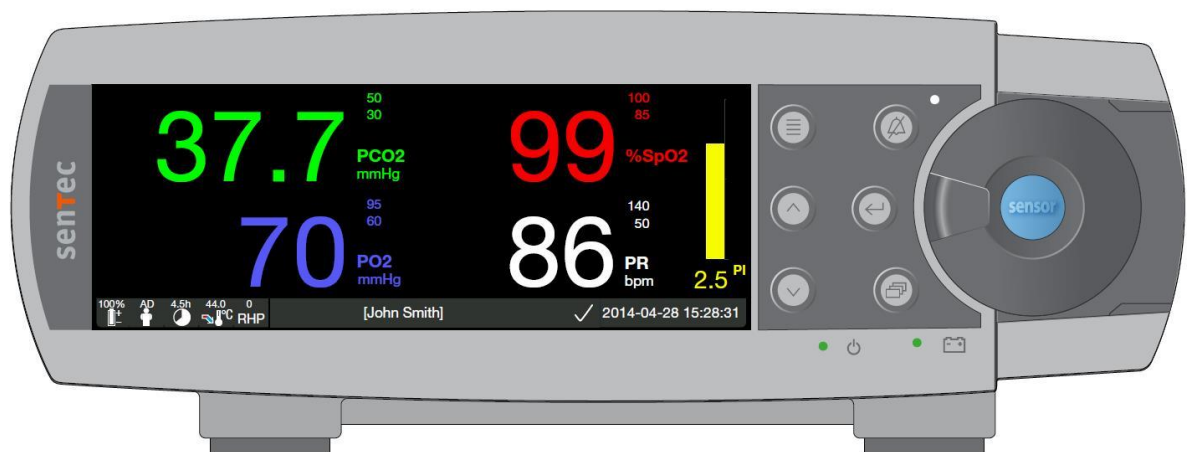# Service Manual

senTec

For the SenTec Digital Monitoring System

(Software Version SMB V08.02; MPB V06.02)

Warranty

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

Warranty Exclusions and System Performance

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

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

Patents/Trademarks/Copyright

International Industrial Design No. DM/054179, Japanese Design No. 1137696, U.S. Design Patent No. D483488.

Canadian Patent No. 2466105, European Patent No. 1335666, German Patent No. 50111822.5-08, Spanish Patent No. 2278818, Hongkong Patent No. HK1059553, U.S. Patent No. 6760610.

Chinese Patent No. ZL02829715.6, European Patent No. 1535055, German Patent No. 50213115.2, Spanish Patent No. 2316584, Indian Patent No. 201300, Japanese Patent No. 4344691, U.S. Patent No. 7862698.

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Patient Monitor

IN ACCORDANCE WITH IEC 60601-1; ANSI/AAMI ES60601-1; CAN/CSA C22.2 No. 60601-1, IEC 60601-1-2, IEC 60601-2-23, ISO 80601-2-61.

CE 0123   SenTec AG, Ringstrasse 39, 4106 Therwil, Switzerland, www.sentec.com

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Abbreviations

AHP	Absolute Heating Power
CO2	Carbon dioxide
DS	Docking Station (calibration unit being integrated in the SDM)
HP	Heating Power
HPM	Heating Power Mode
LED	Light emitting diode
MRI	Magnetic Resonance Imaging
O2	Oxygen
PaCO2	Arterial carbon dioxide partial pressure
PaO2	Arterial oxygen partial pressure
PcCO2	Cutaneous carbon dioxide partial pressure (i.e. the CO2 partial pressure at the skin surface)
PCO2	Used to display/label tcPCO2 on the SDM and – unless explicitly stated otherwise – throughout this manual
PcO2	Cutaneous oxygen partial pressure (i.e. the O2 partial pressure at the skin surface)

PI	Pulsation Index
PO2	Used to display/label tcPO2 on the SDM and – unless explicitly stated otherwise - throughout this manual
POST	Power-On Self-Test
RO	Responsible Organization
PR	Pulse rate
RHP	Relative Heating Power
RMI	Remote monitoring interrupted
SaO2	Arterial oxygen saturation
SDM	SenTec Digital Monitor
SDMS	SenTec Digital Monitoring System
SpO2	Functional oxygen saturation of arterial hemoglobin as measured with a pulse oximeter
TC	Transcutaneous
tcPCO2	Transcutaneous carbon dioxide partial pressure, i.e. an estimate of PaCO2 calculated from the measured PcCO2 and displayed/labeled on the SDM and - unless explicitly stated otherwise - throughout this manual as 'PCO2'
tcPO2	Transcutaneous oxygen partial pressure, i.e. an estimate of PaO2 calculated from the measured PcO2 and displayed/labeled on the SDM and - unless explicitly stated otherwise - throughout this manual as 'PO2'
VOM	V-CareNeT™ Only Mode

1 Introduction

This Manual provides information on

- **maintenance and safety and functionality tests** for the SenTec Digital Monitoring System (SDMS) intended for **qualified personnel only** (*see section 3*);

- **troubleshooting** for the SDMS (*see section 4*). The troubleshooting list covers three levels of recommended troubleshooting procedures a) for the **operator**, b) for **qualified personnel**, and c) for **SenTec authorized technicians** only;

- **repair** procedures that do not require opening the cover of the SDM intended for **qualified personnel only** (*see section 5*).

Note: Repairs that require opening the SDM cover are described within SenTec`s *Repair Manual for the SDMS* (which is distributed to SenTec authorized service personnel only). Within this manual, activities described as "for SenTec authorized service technicians only" refer to activities described in detail within the *Repair Manual for the SDMS* (HB-005755).

This manual must be read carefully prior performing service or repairs. *Section 1.2, "Safety Information"* must be read and understood.

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1.1 Related Documents

To perform service or repairs you must know how to operate the SDMS. The SDMS consists of the SenTec Digital Monitor (SDM), sensors and accessories.

Refer to the following Manuals and Directions for Use:

Table 1 Related Documents

System component	Manual	Content
SDMS	Manual CD	With the exception of the *Repair Manual for the SDMS* all documents listed in this Table are available on the Manual CD.
SDMS	Quick Reference Guide for the SDMS	Routine Use: The *Quick Reference Guide for the SDMS* summarizes the key essentials on just 2 pages.
SDMS	Instruction Manual for the SDMS	Getting started / Using the SDMS: The *Instruction Manual for the SDM*S highlights the essential points when using the SDMS. To ensure proper operation of the SDMS, precisely follow the instructions provided in the *Instruction Manual for the SDMS* step by step. Contains routine checks and maintenance procedures that can be performed by the operator.
SDM	Technical Manual for the SDM HB-005752	The *Technical Manual for the SDM* provides detailed information on the SenTec Digital Monitor (SDM).
SDMS	Service Manual for the SDMS (present manual)	Provides information on maintenance, safety and functionality tests, troubleshooting and repair procedures that **do not require opening the cover** of the SDM as well as on service/maintenance procedures for sensors.
SDMS	Repair Manual for the SDMS HB-005755	The *Repair Manual for the SDMS* covers **repair procedures on the opened SDM**. The *Repair Manual for the SDMS* is **distributed to SenTec authorized service personnel only.**
Sensors / Disposables	Respective Directions for Use	Additional information on SenTec TC Sensors, the Membrane Changer and Membrane Changer Insert, the Ear Clip, the Multi-Site Attachment Rings, and SenTec's Staysite™ Adhesive is provided in the respective Directions for Use.
V-STATS™	Installation Manual for V-STATS™	This manual describes the procedures to install V-STATS™ on a PC.
V-STATS™	Instruction Manual for V-STATS™	The Instruction Manual for V-STATS™ provides detailed information on V-STATS™.

Note: Related forms (as referenced within this manual) are listed in *section 8 "Appendix".*

Note: The *Quick Reference Guide for the SDMS* and the *Instruction Manual for the SDMS* in all available languages can also be downloaded from SenTec's Webpage (https://www.sentec.com/education/customer-portal).

Information / Instructions about the Digital Sensor Adapter Cable, the Contact Gel and the Service Gas are provided in the *Instruction Manual for the SDMS* and the *Technical Manual for the SDM*.

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

1.2   Safety Information

Warnings

This symbol identifies a **WARNING** statement. Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.

Cautions

This symbol identifies a **CAUTION** statement. Cautions alert users to exercise appropriate care for safe and effective use of the product and the care necessary to avoid damage to the product that may occur as a result of use or misuse.

Carefully read all safety information in this Manual and in the *Technical Manual for the SDM (HB-005752)* before operating the device or performing service/repairs.

1.2.1 General Safety Information

WARNING: The SenTec Digital Monitoring System (SDMS) is to be operated by qualified personnel only. Read this manual, accessory Directions for Use, all precautionary information, and specifications before use.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

WARNING: Certain types of mobile telecommunication equipment could potentially interfere with SDM operation. Mobile telecommunication equipment should not be used within five meters (16.4 feet) of the SDM. Otherwise, degradation of the device performance could result.

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

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

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

WARNING: The mains power supply of the SenTec Digital Monitor (SDM) is separated by two Means of Patient Protection (MOPPs) between the sensor port (for the applied part, the sensor) and the interface connectors. The three interface connectors - serial data port, Multipurpose I/O port (analog outputs, nurse call), LAN port - of the SDM are not separated from each other. If at a time accessory equipment is connected to only one of the three interface connectors no additional safety measures are necessary to comply with the requirements of IEC 60601-1. If however accessory equipment is simultaneously connected to two or three of the SDM's interface connectors

additional safety measures may be required to be compliant with the requirements of IEC 60601-1. In case of doubt consult qualified technicians.

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

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

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

CAUTION: To maintain monitor readiness in-between monitoring if using a SenTec TC Sensor:

1. **ALWAYS** clean the sensor before putting it into the Docking Station!

2. **ALWAYS** store the clean sensor in the Docking Station!

3. **ALWAYS** keep the monitor switched on!

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

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

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

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

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

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

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

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

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

1.2.2   Safety Information regarding Repair and Service Operations

WARNING: Maintenance and repair requiring removal of the case or covers must be performed by SenTec authorized service personnel.

WARNING: Before attempting to open or disassemble the SDM, disconnect the device from the AC power outlet.

WARNING: Before replacing fuses of the SDM, disconnect the device from the AC power outlet.

WARNING: Use only accessories and spare parts supplied or recommended by SenTec AG. Do not perform other service and repair activities than specified and described by SenTec AG. Failure to comply may result in physical injury, inaccurate measurements, and/or damage to the device.

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

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

CAUTION: Follow ESD (Electrostatic discharge) precautions when working with the SDM, especially when disassembling and reassembling the SDM and when handling any of the components. Use an ESD protective wrist-strap and table-mat connected to Earth while working with the electronics.

CAUTION: When reassembling the SDM tighten the screws to a torque of 5 Nm. Over-tightening could strip out the screw holes, rendering the part unusable.

2 The SenTec Digital Monitoring System (SDMS)

2.1   Components

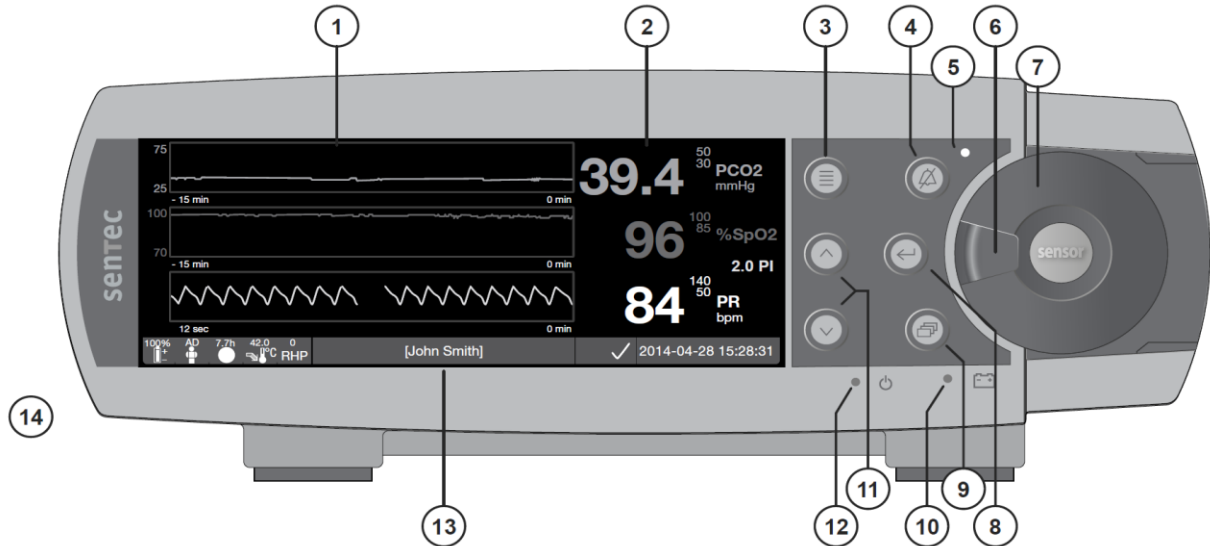The SenTec Digital Monitoring System (SDMS) comprises the following main components:

Table 2   Components of the SDMS

REF	Product
SDM	SenTec Digital Monitor (including mains power cord) SDMs with firmware version SMB SW-V08.00/ MPB SW-V06.00 are available with/without factory preconfigured PO2-option.
VS-A/P/N	V-Sign™ Sensor 2 (for PCO2, SpO2/PR monitoring)
OV-A/P/N	OxiVenT™ Sensor (for PCO2, PO2, SpO2/PR monitoring)
AC-YYY	Digital Sensor Adapter Cable (to connect VS-A/P/N or OV-A/P/N to SDM; YYY=150, 250, 750 cm)
EC-MI	Ear Clip (to apply SenTec TC Sensors at earlobe of patients with mature/ intact skin)
MAR-MI	Multi-Site Attachment Ring MAR-MI (to apply SenTec TC Sensors to patients with mature/ intact skin)
MAR-SF	Multi-Site Attachment Ring MAR-SF (to apply SenTec TC Sensors to patients with sensitive/ fragile skin)
SA-MAR	Staysite™ Adhesive for the Multi-Site Attachment Rings (attaches complementary the MAR-SF/MI to the skin with an additional adhesive film)
GEL-04	Contact Gel (contact liquid to apply SenTec TC Sensors to the patient)
MC-R	Membrane Changer (to change the membrane of SenTec TC Sensors)
MC-I	Membrane Changer Insert (separately bagged, single-use Inserts for the MC-R)
GAS-0812	Service Gas (needed to calibrate SenTec TC Sensors)
V-STATS_CD	V-STATS™ (PC based Trend Data Download/ Analysis, Remote Monitoring, and Configuration Software for SenTec Digital Monitors)

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

## 2.2   The SenTec Digital Monitor (SDM)

2.2.1   Front Panel

1 Trend Display Area

2 Numerical Display Area

3 Menu/ Previous Level Button

4 AUDIO PAUSED/OFF Button

5 AUDIO PAUSED/OFF Indicator (yellow LED)

6 Door Handle

7 Docking Station Door
(colored dot in center of door indicates the SDM's PO2 activation status: **blue** if activated, **orange** otherwise)

8 Enter Button

9 Display Button

10 AC Power/Battery Indicator (green/yellow LED)

11 UP/DOWN Buttons

12 ON/OFF Indicator (green LED)

13 Status Bar

14 Speaker (on the side)

Figure 1   Front Panel of the SDM

Note: SDMs with firmware version SMB SW-V08.00/ MPB SW-V06.00 are available with and without activated PO2-option. If the PO2-option is activated the colored dot in the Docking Station Door of the respective SDM will be **blue**, otherwise **orange**.

2.2.2   Rear Panel
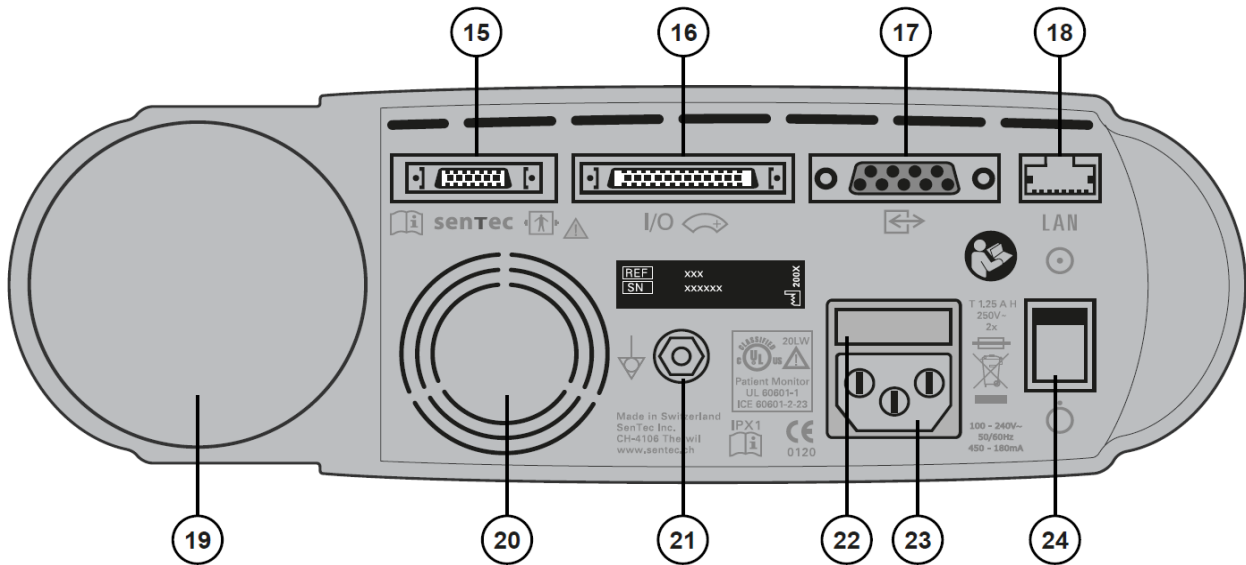
15 Sensor Connection Port

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

17 Serial Data Port (RS-232)

18 Network Port (LAN)

19 Gas Bottle Slot

20 Fan

21 Equipotential Terminal Connector
(ground)

22 Fuse Holder

23 AC Power Connector

24 ON/OFF Switch

Figure 2   Rear Panel of the SDM

WARNING: Refer to *section 1.2.1* for warnings related to connecting/mounting the SDM to accessory equipment.

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

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

3 Maintenance/Safety & Functionality Tests

At normal use there is no internal adjustment or new calibration of the SDM required. However, to guarantee continuous performance, reliability and safety of the SDMS routine checks and maintenance procedures (including cleaning/disinfection) as well as safety checks should be performed regularly.

Routine checks and maintenance procedures that can be performed by the **operator** are provided in the *Instruction Manual for the SDMS*. Instructions for cleaning and/or disinfecting the SenTec Digital Monitor (SDM) and the 'Digital Sensor Adapter Cable', are provided in the *Technical Manual for the SDM*. Please refer to the respective Directions for Use for instructions for cleaning and/or disinfection of SenTec TC Sensors. For a better overview and documentation of periodic routine checks and maintenance to be performed by the operator the SenTec form **HB-007601 "SDMS Maintenance Checklist"** (*see section 8.7*) is available (refer to the Manual CD).

It is recommended that **qualified service personnel** performs the maintenance and a complete safety and functionality test as specified in this Manual at regular intervals (recommended every 12 month but at least every 24 months). Use the **HB-005638 "Protocol for Safety & Functionality Test"** (*see section 8.1 "Protocol for Safety & Functionality Test")* to guide you through the complete "Safety & Functionality Test" and to document your test results. **To perform a complete "Safety & Functionality Test" all tests described in this chapter MUST be performed.**

Note: Prior to maintenance, service or repairs all components of the SDMS must be cleaned and disinfected. If equipment is send to service personnel, a local SenTec representative or to SenTec AG a completed *"Certificate for Disinfection"* (*see section 8.7*) must be attached.

> **WARNING:** If any of the tests specified below fails, the respective problem must be fixed before the equipment is returned to the user.

3.1 SenTec TC Sensors

Verify that the sensor has been cleaned / disinfected as described in the Directions for Use of the sensor. If necessary remove dried up gel / electrolyte reminders with a soft brush while immersing the (membraned) sensor into clean tap water.

3.1.1 Cleaning and Disinfection

For cleaning and disinfection procedures for the SenTec TC Sensors please refer to the respective Directions for Use.

3.1.2 Visual Inspection

Visually inspect the sensor body, cable and membrane for damage. Check the cable plug and its connectors for damages.

If any of the components of the sensor is irreversibly damaged, replace the sensor with a new SenTec TC Sensor.

3.1.3 Labeling

Check presence/legibility of the serial number (label on the plug of the sensor cable).

If the serial number label is not present / legible then connect the sensor to a SDM, switch the monitor on, read the sensor's serial number in the menu "System information", and write it on the plug of the sensor cable.

3.1.4 Sensor LEDs

Connect the sensor to the SDM and switch on the monitor. Verify that the sensor emits red light and is recognized by the SDM. When using an OxiVenT™ Sensor additionally verify that the sensor also emits green light.

Note: In order to be able to verify the function of the green LED, pO2 must be enabled (software option) and the pO2 parameter must be enabled (under `enabled parameters´).

Then insert the sensor into the Docking Station. Verify that the calibration screen activates.

If the above described functions do not operate properly refer to *section 4.2.1 "Troubleshooting PCO2 / PO2 monitoring"* to further evaluate the problem.

3.1.5 Sensor Temperature Display

Check that the measured sensor temperature (as displayed by the temperature indicator located in the Status Bar of the SDM`s display) is within ±0.3 °C of the currently selected 'Sensor SET Temperature' (e.g. as displayed in the upper right corner of the `Ready for use´ or calibration screen:).

3.1.6   Sensor Temperature Surveillance

Note: The 'Sensor Temperature' Icon in the Status Bar indicates the measured sensor temperature (in °C).

Connect the sensor to the SDM and switch on the monitor. Verify that the sensor temperature reaches the SET temperature within 2 to 3 minutes. Then immerse the sensor into clean tap water of 45°C - 50°C and verify that the measured sensor temperature increases (i.e. by observing the temperature indicator located in the Status Bar of the SDM`s display). Verify that the red sensor LED switches off, a low priority alarm starts to sound and that the message "Temp. limiter active" (or 'Sensor problem 38', 'Sensor problem 42') displays.

If the message "Sensor Fault xx" was triggered you must restart the SDM to reset the message. Do not use the sensor if the message "Sensor Fault xx" is not reset by power cycling the SDM. Instead contact qualified service personnel or your local SenTec representative.

Do not use the sensor if the test fails!

> **CAUTION:** Ensure that the temperature of the water bath is < 50°C. Temperatures above 50°C may damage the sensor.

3.1.7   Cleaning / Inspecting without Membrane

1. Remove the sensor membrane using the membrane remover located at the bottom of the Membrane Changer as shown in the figure below (note that the Membrane Changer is shown upside down). Step ❶: Slide the SenTec TC Sensor into the membrane remover with its membrane facing the bottom of the Membrane Changer. Step ❷: Lift the SenTec TC Sensor up to remove the membrane from the sensor body.
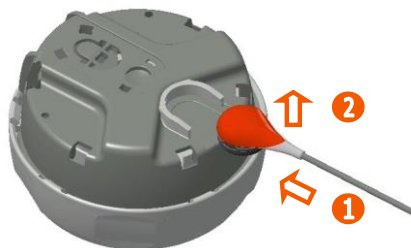
Figure 3   Removal of the Membrane from the TC Sensor

> **CAUTION:** Do not touch any of the measuring units in the center of the sensor surface after removing the sensor membrane. Do not rub the sensor surface.

> **CAUTION:** Do not leave the sensor without membrane in air. Perform the following steps uninterrupted.

2. Immerse the sensor into clean, room temperature tap water for 3 minutes.

3. Use a soft brush to completely remove dried up gel / electrolyte residues from the grooves on the sensor circumference.

4. Softly rinse the sensor with clean tap water.

5. Tap the sensor dry using a clean lint-free towel. Pay attention not to touch the ring and the pH-glass in the center of the sensor surface. Do not rub the sensor surface!

6. Inspect the ring around the pH-glass for damages and brownish color (*see Figure 4 Top view of the V-Sign™ Sensor*). Note that the same criteria apply for the OxiVenT™ Sensor.

If the ring around the pH-glass is broken, parts of it are missing, the brown color is lost, or the ring has a metallic luster, then replace the sensor with a new SenTec TC Sensor.
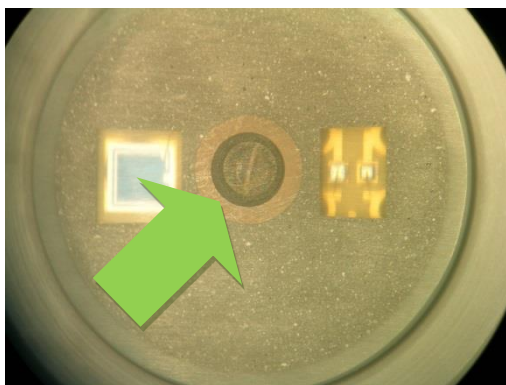
The sensor has an intact brown ring around the pH-glass.
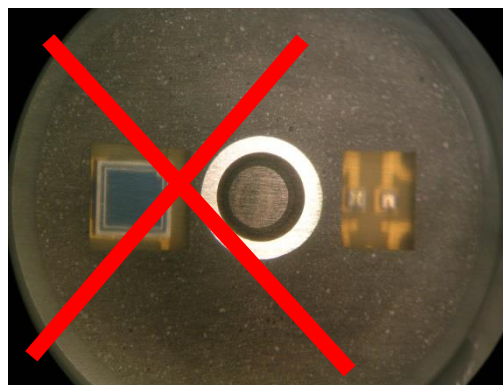
The ring around the pH-glass is intact but has a metallic luster, this sensor needs to be replaced

Figure 4   Top view of the V-Sign™ Sensor

7. Inspect the sensor to ensure that the grooves on the sensor circumference are clean and intact. **If the grooves on the sensor circumference are damaged replace the sensor with a new SenTec TC Sensor.**

8. OxiVenT™ Sensor only: Verify that the white oxygen sensing spot (i.e. off-centered, white, circular spot) is present and intact.

9. If the visual inspections (steps 6 to 8) passed remembrane the sensor using the Membrane Changer (for instructions please refer to the Directions for Use of the Membrane Changer).

10. After placing a new membrane, verify that

    a) the membrane ring is intact and securely seated on the sensor.

    b) there are no air bubbles between membrane and sensor surface.

In case of loose fit, damage or trapped air you must repeat the membrane change. Otherwise confirm the membrane change in the menu of the monitor and calibrate sensor.
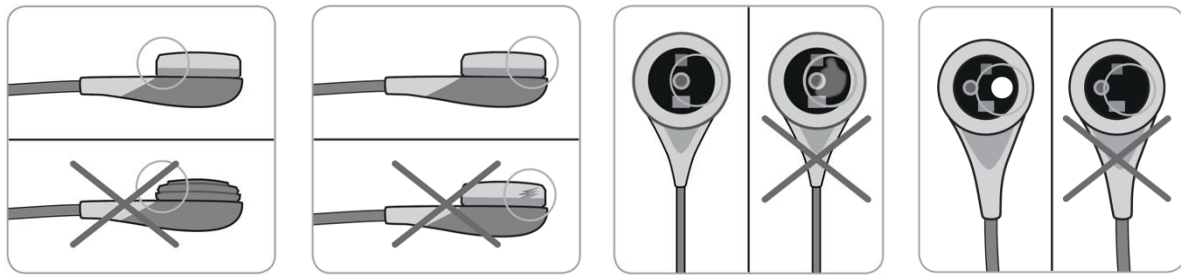
Figure 5   Inspection after remembraning the sensor

3.1.8   PCO2 / PO2 Sensitivity & Calibration Duration

> **WARNING:** A wrong barometer reading or a gas leak can lead to a false positive/negative test result. Prior to performing a 'Sensitivity Test' verify Docking Station integrity/cleanliness (*see section 3.3 "Docking Station"*) and barometer function (*see section 3.2.11 "Barometric Pressure"*).

Note: If the procedure below is not strictly followed the 'Sensitivity Test' will abort. Strictly observe the indicated times. 'Sensor problem 12' (PCO2 sensitivity) or 'Sensor problem 72' (PO2 sensitivity) will only reset, if the test was successful.

Note: If a V-Sign™ Sensor is connected to the SDM the function 'Sensitivity Test' will test the sensor`s PCO2 sensitivity. If an OxiVenT™ Sensor is connected to the SDM the function 'Sensitivity Test' will test the sensor`s PCO2 and PO2 sensitivity in parallel.

Test the PCO2/PO2 sensitivity as follows:

1. Verify that the sensor SET temperature is 42°C (in case of a V-Sign™ Sensor) or 43°C (in case of an OxiVenT™ Sensor) and that the local atmospheric pressure is at least 600 mmHg (80 kPa) (see respective icon).

    Note: You may optionally activate the display of the calibration curve by using "V-STATS™" (PC-Software for the SDM).

2. Insert the sensor into the Docking Station.

3. Use the menu-function 'Measurement Settings / PCO2 Settings / Sensitivity Test' OR the menu-function 'Measurement Settings / PO2 Settings / Sensitivity Test' to activate the test (both menu-functions will initiate the same test). The Status

Message 'Open DS door' displays (accompanied by a high pitched two beep signal tone).

4. Open the Docking Station door within 1 minute to expose the sensor to ambient air. As soon as the door is open the Status Message changes back to 'Sensitivity Test'.

5. After 2 minutes the Status Message 'Insert sensor into DS' and the 'Insert in DS' - pictures appears, insert the sensor into the Docking Station within 10 minutes.

6. Once the sensor is placed in the Docking Station, the sensor will automatically calibrate. In the Status Bar the Status Message 'Sensitivity Test' is displayed, while 'Calibration in progress' is displayed on the screen.

7. In order to determine the calibration duration note down the time interval between message 'Calibration in progress' is displayed on the screen until 'Leak test in progress' (see step 8) is displayed on the screen.

8. After sensor calibration, a leak test of the Docking Station is automatically performed. In the Status Bar the Status Message 'Sensitivity Test' is displayed, while 'Leak test in progress' is displayed on the screen.

If the 'Sensitivity Test' for PCO2 <u>failed</u>, 'Sensor problem 12' will display when the sensor is in the Docking Station and PCO2 subsequently will be flagged as invalid.

If the 'Sensitivity Test' for PO2 <u>failed</u>, 'Sensor problem 72' will display when the sensor is in the Docking Station and PO2 subsequently will be flagged as invalid.

Please refer to **troubleshooting P0305** *(see section 4.2.1 "Troubleshooting PCO2 / PO2 monitoring")* before you repeat the test.

If the 'Sensitivity Test' <u>passed</u>, the Status Message 'Ready for use' appears.

<u>Calibration Duration</u>: The calibration duration should be shorter than 14 minutes. If the calibration duration is longer than 14 minutes `PCO2 slow´ or 'Sensor problem 11' or 'Sensor problem 71' is displayed. Refer to troubleshooting P0304.

3.1.9   PCO2 / PO2 Slope Test

Tools: • Sensor Tester Unit (alternatively an SDM can be used)

• V-STATS Software (optional, to enable calibration curve on SDM)

• interface online log software, e.g. "Hterm" freeware available in the internet (optional, for easier on-line logging of calibration values)

Note: For a V-Sign™ Sensor only the PCO2 Slope Test must be performed. For an OxiVenT™ Sensor both, PCO2 and PO2 Slope Test, must be performed.

Note: The Slope Test can also be performed using a second SDM instead of a Sensor Tester Unit. Also, a single SDM can be used (requiring changing gas bottles after each step). **If you use one single SDM, make sure that the correct gas bottle with the correct gas concentration (with 8% CO2, 12% O2) remains in the SDM at the end of the test.**

Note: Prior performing the Slope Test please ensure that the sensor is properly stabilized, i.e. stored for at least 4 hours in the Docking Station with the monitor switched on. For an overview about the Slope Test please refer to *Figure 6   Examples: PCO2 and PO2 Slope Test*.

Note: After the test ensure to reset all parameters and settings to the ones originally selected by your customer

1.   You may optionally activate the display of the calibration curve by using "V-STATS" (PC-Software for the SDM).

2.   Verify proper function of the SenTec Sensor Tester (ST-DSU). In particular verify the integrity of the Docking Station. Verify the expiration date of the test gas bottles.

3.   Power-cycle the SDM before starting the Slope Test (i.e. turn the SDM off and on again to ensure that the next calibration is a so-called `Initial Calibration´, which calibrates both, the PCO2 and PO2 channel).

4.   Verify that the sensor SET temperature is 42°C or else set the sensor temperature to 42°C (for V-Sign™ Sensor and OxiVenT™ Sensor), the 'Severinghaus Correction Mode' is set to AUTO and that the local atmospheric pressure is at least 600 mmHg (80 kPa) (see respective icon). Note down the atmospheric pressure value. If you are using an OxiVenT™ Sensor ensure that the PO2-parameter is enabled (e.g. select Neo-mode and enable PCO2/PO2 parameters and set sensor SET-temperature to 42°C).

5.   Insert the sensor into the Docking Station of the SDM. Sensor calibration starts automatically. If not: Use the menu-function 'Measurement Settings / PCO2 Settings / Calibrate sensor' to manually activate the sensor calibration (**note:** In case of an OxiVenT™ Sensor this function will initiate a PCO2 and PO2 calibration). After the calibration (with 8% CO2, 12% O2) is finished please wait 6 minutes (this is to ensure that no gas leak is present in the Docking Station of the SDM).

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6. Insert the test bottle with 5% CO2 and 6% O2 into the Sensor Tester. Use the menu-function 'PCO2 Settings / Calibrate Sensor' or press the ENTER Button twice to start a calibration. Record PCO2 (5%) and PO2 (6%), i.e. the PCO2/PO2 values just before termination of the calibration. After the calibration is finished please wait 6 minutes (this is to ensure that no gas leak is present in the Docking Station of the SenTec Sensor Tester).

    Note: If you are using an SDM for the Slope Test and in case of an OxiVenT™ Sensor the message `Sensor Problem 73´ appears on the SDM at this stage. This is an expected behavior of the sensor.

7. Compare the measured PCO2 (5%) and PO2 (6%) with the values expected for the respective local atmospheric pressure (see Slope Test Control Table). PCO2 (5%) should be within 5_min and 5_max. PO2 (6%) should be within 6_min and 6_max.

8. Remove the sensor from the Docking Station of the Sensor Tester, insert the sensor into the Docking Station of the SDM and use the menu-'PCO2 Settings / Calibrate Sensor' to start a calibration (with 8% CO2, 12% O2).

    Note: In case of an OxiVenT™ Sensor the message `Sensor Problem 73´ will disappear from the SDM`s display at this stage.

9. Insert the test bottle with 30% CO2 and 21% O2 into the Sensor Tester. Use the menu-function 'PCO2 Settings / Calibrate Sensor' or press the ENTER Button twice to start a calibration. Wait until calibration is finished and record PCO2 (30%) and PO2 (21%), i.e. the PCO2 value just before termination of the calibration.

    Note: If you are using an SDM for the Slope Test and in case of an OxiVenT™ Sensor the message `Sensor Problem 73´ appears on the SDM at this stage. This is an expected behavior of the sensor.

10. Compare the measured PCO2 (30%) and PO2 (21%) with the values expected for the respective local atmospheric pressure (see Slope Test Control Table). PCO2 (30%) should be within 30_min and 30_max. PO2 (21%) should be within 21_min and 21_max.

11. In case of an OxiVenT™ Sensor: In order to clear the message `Sensor Problem 73´ you must do either of the following: a) power-cycle the SDM; b) connect the OxiVenT™ Sensor to a different SDM; or c) perform a calibration with the standard gas concentration (i.e. with 8% CO2, 12% O2).

12. If you have used one single SDM for the Slope Test, always perform a calibration with the standard gas concentration (i.e. with 8% CO2, 12% O2) at the end of the Slope Test.

If the readings are outside the respective limits replace the sensor and report to SenTec the sensor behavior/replacement.
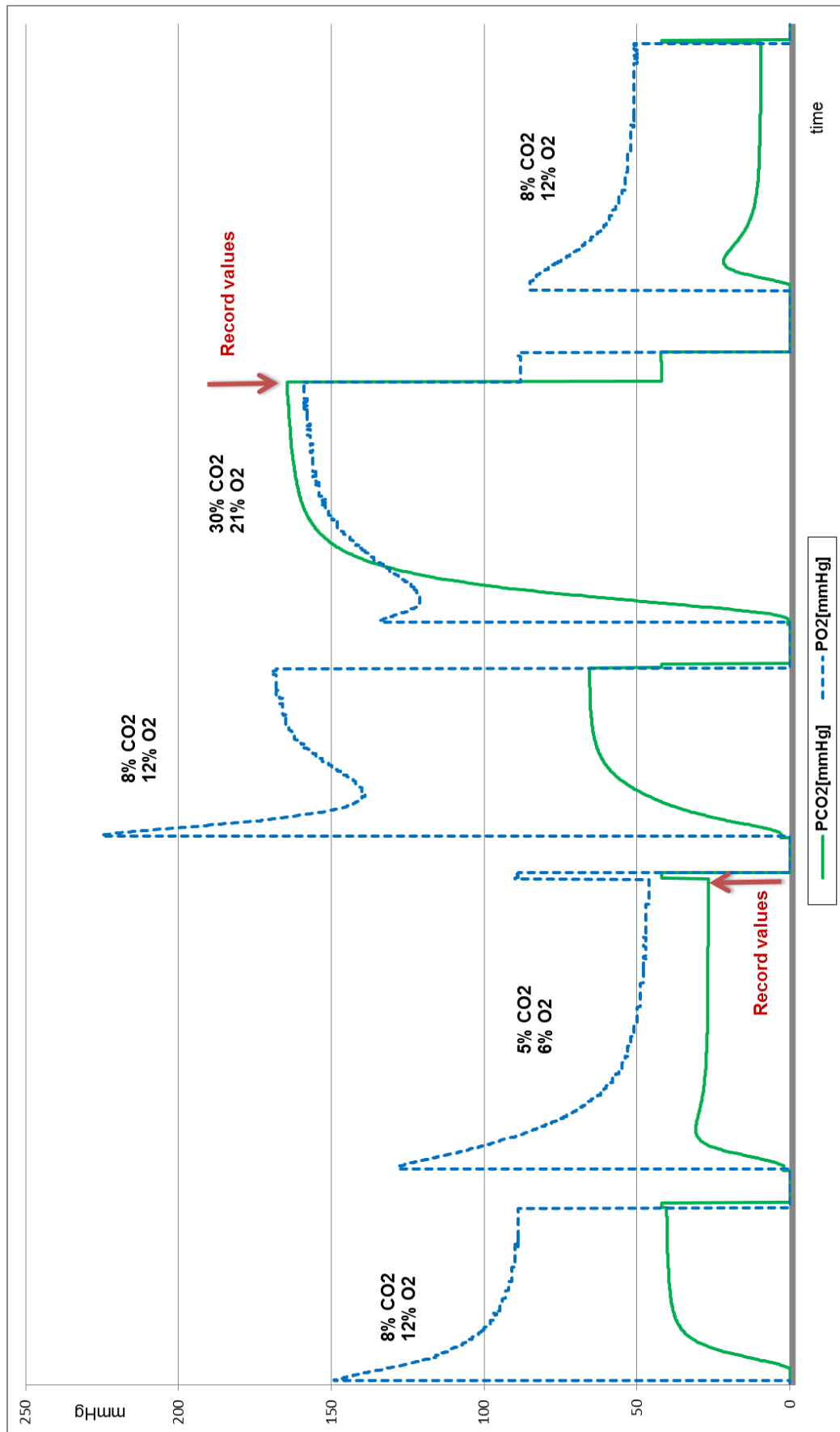
Figure 6   Examples: PCO2 and PO2 Slope Test

Slope Test Control Table CO2 – in mmHg (after 5% and 30% CO2 calibration)

Pcal = value after calibration with 8%CO2.

Table is only valid for sensor temp. of 42°C.

P_{atm}	Pcal	5_min	5_ideal	5_max	30_min	30_ideal	30_max
600	33.5	19.0	19.8	21.1	123	134	144
605	33.8	19.2	20.0	21.3	124	135	145
610	34.1	19.4	20.2	21.5	125	136	146
615	34.4	19.6	20.4	21.7	127	137	148
620	34.7	19.8	20.6	21.9	128	138	149
625	35.0	19.9	20.8	22.1	129	139	150
630	35.3	20.1	21.0	22.3	130	140	151
635	35.6	20.3	21.1	22.5	131	142	152
640	35.9	20.5	21.3	22.7	132	143	154
645	36.2	20.7	21.5	22.9	133	144	155
650	36.5	20.9	21.7	23.1	134	145	156
655	36.8	21.0	21.9	23.3	135	146	157
660	37.1	21.2	22.1	23.5	136	147	159
665	37.4	21.4	22.3	23.7	137	148	160
670	37.7	21.6	22.5	23.9	138	150	161
675	38.0	21.8	22.7	24.1	139	151	162
680	38.3	21.9	22.9	24.3	140	152	163
685	38.6	22.1	23.0	24.5	141	153	165
690	38.9	22.3	23.2	24.7	142	154	166
695	39.2	22.5	23.4	24.9	143	155	167
700	39.5	22.7	23.6	25.1	144	156	168
705	39.8	22.9	23.8	25.3	145	157	170
710	40.1	23.0	24.0	25.5	147	159	171
715	40.5	23.2	24.2	25.7	148	160	172
720	40.8	23.4	24.4	25.9	149	161	173
725	41.1	23.6	24.6	26.1	150	162	174
730	41.4	23.8	24.7	26.3	151	163	176
735	41.7	24.0	24.9	26.5	152	164	177
740	42.0	24.1	25.1	26.7	153	165	178
745	42.3	24.3	25.3	26.9	154	167	179
750	42.6	24.5	25.5	27.1	155	168	181
755	42.9	24.7	25.7	27.3	156	169	182
760	43.2	24.9	25.9	27.5	157	170	183
765	43.5	25.1	26.1	27.7	158	171	184
770	43.8	25.2	26.3	27.9	159	172	185

Slope Test Control Table CO2 – in kPa (after 5% and 30% CO2 calibration)

Pcal = value after calibration with 8% CO_2.

Table is only valid for sensor temp. of 42°C.

P_{atm}	Pcal	5_min	5_ideal	5_max	30_min	30_ideal	30_max
80.0	4.46	2.54	2.64	2.81	16.4	17.8	19.2
80.7	4.50	2.56	2.67	2.84	16.6	18.0	19.3
81.3	4.54	2.58	2.69	2.86	16.7	18.1	19.5
82.0	4.58	2.61	2.72	2.89	16.9	18.3	19.7
82.7	4.62	2.63	2.74	2.92	17.0	18.4	19.8
83.3	4.66	2.66	2.77	2.94	17.1	18.6	20.0
84.0	4.71	2.68	2.79	2.97	17.3	18.7	20.2
84.7	4.75	2.71	2.82	3.00	17.4	18.9	20.3
85.3	4.79	2.73	2.84	3.02	17.6	19.0	20.5
86.0	4.83	2.76	2.87	3.05	17.7	19.2	20.6
86.7	4.87	2.78	2.89	3.08	17.9	19.3	20.8
87.3	4.91	2.80	2.92	3.10	18.0	19.5	21.0
88.0	4.95	2.83	2.95	3.13	18.1	19.6	21.1
88.7	4.99	2.85	2.97	3.16	18.3	19.8	21.3
89.3	5.03	2.88	3.00	3.18	18.4	19.9	21.5
90.0	5.07	2.90	3.02	3.21	18.6	20.1	21.6
90.7	5.11	2.93	3.05	3.24	18.7	20.2	21.8
91.3	5.15	2.95	3.07	3.26	18.8	20.4	22.0
92.0	5.19	2.98	3.10	3.29	19.0	20.5	22.1
92.7	5.23	3.00	3.12	3.32	19.1	20.7	22.3
93.3	5.27	3.02	3.15	3.34	19.3	20.8	22.4
94.0	5.31	3.05	3.17	3.37	19.4	21.0	22.6
94.7	5.35	3.07	3.20	3.40	19.5	21.1	22.8
95.3	5.39	3.10	3.22	3.42	19.7	21.3	22.9
96.0	5.43	3.12	3.25	3.45	19.8	21.5	23.1
96.7	5.47	3.15	3.27	3.48	20.0	21.6	23.3
97.3	5.51	3.17	3.30	3.50	20.1	21.8	23.4
98.0	5.55	3.19	3.32	3.53	20.2	21.9	23.6
98.7	5.60	3.22	3.35	3.56	20.4	22.1	23.7
99.3	5.64	3.24	3.38	3.58	20.5	22.2	23.9
100.0	5.68	3.27	3.40	3.61	20.7	22.4	24.1
100.7	5.72	3.29	3.43	3.64	20.8	22.5	24.2
101.3	5.76	3.32	3.45	3.66	20.9	22.7	24.4
102.0	5.80	3.34	3.48	3.69	21.1	22.8	24.6
102.7	5.84	3.37	3.50	3.72	21.2	23.0	24.7

Slope Test Control Table PO2 – in mmHg (after 6% and 21% O2 calibration)

Pcal = value after calibration with 12% O2

Table is only valid for sensor temp. of 42°C.

P_atm	Pcal	6_min	6_ideal	6_max	21_min	21_ideal	21_max
600	72.0	34	36	38	118	126	134
605	72.6	34	36	38	119	127	135
610	73.2	35	37	38	120	128	136
615	73.8	35	37	39	121	129	137
620	74.4	35	37	39	122	130	138
625	75.0	36	38	39	123	131	139
630	75.6	36	38	40	124	132	140
635	76.2	36	38	40	125	133	141
640	76.8	36	38	40	126	134	142
645	77.4	37	39	41	127	135	144
650	78.0	37	39	41	128	137	145
655	78.6	37	39	41	129	138	146
660	79.2	38	40	42	130	139	147
665	79.8	38	40	42	131	140	148
670	80.4	38	40	42	132	141	149
675	81.0	38	41	43	133	142	150
680	81.6	39	41	43	134	143	151
685	82.2	39	41	43	135	144	152
690	82.8	39	41	43	136	145	154
695	83.4	40	42	44	137	146	155
700	84.0	40	42	44	138	147	156
705	84.6	40	42	44	139	148	157
710	85.2	40	43	45	140	149	158
715	85.8	41	43	45	141	150	159
720	86.4	41	43	45	142	151	160
725	87.0	41	44	46	143	152	161
730	87.6	42	44	46	144	153	162
735	88.2	42	44	46	145	154	164
740	88.8	42	44	47	146	155	165
745	89.4	42	45	47	147	156	166
750	90.0	43	45	47	148	158	167
755	90.6	43	45	48	149	159	168
760	91.2	43	46	48	150	160	169
765	91.8	44	46	48	151	161	170
770	92.4	44	46	49	152	162	171

Slope Test Control Table PO2 – in kPa (after 6% and 21% O2 calibration)

Pcal = value after calibration with 12% O2

Table is only valid for sensor temp. of 42°C.

P_{atm}	Pcal	6_min	6_ideal	6_max	21_min	21_ideal	21_max
80.0	9.6	4.6	4.8	5.0	15.8	16.8	17.8
80.7	9.7	4.6	4.8	5.1	15.9	16.9	18.0
81.3	9.8	4.6	4.9	5.1	16.0	17.1	18.1
82.0	9.8	4.7	4.9	5.2	16.2	17.2	18.3
82.7	9.9	4.7	5.0	5.2	16.3	17.4	18.4
83.3	10.0	4.7	5.0	5.2	16.4	17.5	18.5
84.0	10.1	4.8	5.0	5.3	16.6	17.6	18.7
84.7	10.2	4.8	5.1	5.3	16.7	17.8	18.9
85.3	10.2	4.9	5.1	5.4	16.8	17.9	19.0
86.0	10.3	4.9	5.2	5.4	17.0	18.1	19.1
86.7	10.4	4.9	5.2	5.5	17.1	18.2	19.3
87.3	10.5	5.0	5.2	5.5	17.2	18.3	19.4
88.0	10.6	5.0	5.3	5.5	17.4	18.5	19.6
88.7	10.6	5.1	5.3	5.6	17.5	18.6	19.7
89.3	10.7	5.1	5.4	5.6	17.6	18.8	19.9
90.0	10.8	5.1	5.4	5.7	17.8	18.9	20.0
90.7	10.9	5.2	5.4	5.7	17.9	19.0	20.2
91.3	11.0	5.2	5.5	5.8	18.0	19.2	20.3
92.0	11.0	5.2	5.5	5.8	18.2	19.3	20.5
92.7	11.1	5.3	5.6	5.8	18.3	19.5	20.6
93.3	11.2	5.3	5.6	5.9	18.4	19.6	20.8
94.0	11.3	5.4	5.6	5.9	18.6	19.7	20.9
94.7	11.4	5.4	5.7	6.0	18.7	19.9	21.1
95.3	11.4	5.4	5.7	6.0	18.8	20.0	21.2
96.0	11.5	5.5	5.8	6.0	19.0	20.2	21.4
96.7	11.6	5.5	5.8	6.1	19.1	20.3	21.5
97.3	11.7	5.5	5.8	6.1	19.2	20.4	21.7
98.0	11.8	5.6	5.9	6.2	19.3	20.6	21.8
98.7	11.8	5.6	5.9	6.2	19.5	20.7	22.0
99.3	11.9	5.7	6.0	6.3	19.6	20.9	22.1
100.0	12.0	5.7	6.0	6.3	19.7	21.0	22.3
100.7	12.1	5.7	6.0	6.3	19.9	21.1	22.4
101.3	12.2	5.8	6.1	6.4	20.0	21.3	22.5
102.0	12.2	5.8	6.1	6.4	20.1	21.4	22.7
102.7	12.3	5.9	6.2	6.5	20.3	21.6	22.9

3.1.10   Sensor Characteristics

Pressing the 'ENTER' Button on the SDM, while the sub-menu 'System Information' is open activates a second system information screen, which displays the sensor characteristics (for PCO2 and PO2).

3.1.11   Function Test: PCO2 / PO2

Calibrate the TC Sensor and apply it to the ear of a healthy person: Verify, that the $PCO2_2$ readings equilibrate (stabilize) within 2 to 10 minutes and are within 33 to 47 mmHg after stabilization.

In case of an OxiVenT™ Sensor additionally test PO2 function:

Power-cycle the SDM (i.e. switch it off and on again). Then calibrate the OxiVenT™ Sensor. After successful calibration the PO2 function test can be performed as follows: Open the Docking Station Door in order to expose the sensor to ambient air. Then enable the 'Enforced Sensor On Patient Mode' in order to start measuring PO2 (i.e. by entering the Quick Access Menus and selecting 'Start Monitoring'). Wait until PO2 readings equilibrate (stabilize), usually within 2 to 10 minutes. Check the atmospheric pressure (Patm) and verify that PO2 readings are within the range shown in the tables below. Note that PO2 ranges in the tables below are only valid for ambient temperatures between 18°C and 28°C and relative humidity between 30% r.H. and 60% r.H.!

If these requirements are not met refer to *section 4.2.1 "Troubleshooting PCO2 / PO2 monitoring"* to further evaluate the problem.

> **Note:** In case of an OxiVenT™ Sensor it is recommended to check the remaining 'Usage Time' / 'Life Time'. This can be done on the SDM`s `Sub-menu System Information´ (refer to the *Technical Manual for the SDM* for further information).

PO2 Function Test Control Table PO2 – in mmHg and kPa

PO2 ranges are valid for ambient temperatures between 18°C and 28°C and relative humidity between 30% r.H. and 60% r.H!

Patm [mmHg]	ambient_ min	ambient PO2	ambient_ max	Patm [kPa]	ambient_ min	ambient PO2	ambient_ max
600	116	123	130	80.0	15.4	16.4	17.4
605	117	124	131	80.7	15.6	16.6	17.5
610	118	125	133	81.3	15.7	16.7	17.7
615	119	126	134	82.0	15.9	16.9	17.8
620	120	128	135	82.7	16.0	17.0	17.9
625	121	129	136	83.3	16.1	17.1	18.1
630	122	130	137	84.0	16.3	17.3	18.2
635	123	131	138	84.7	16.4	17.4	18.4
640	124	132	139	85.3	16.6	17.6	18.5
645	125	133	140	86.0	16.7	17.7	18.6
650	126	134	141	86.7	16.8	17.8	18.8
655	127	135	142	87.3	17.0	18.0	18.9
660	128	136	143	88.0	17.1	18.1	19.1
665	129	137	144	88.7	17.3	18.3	19.2
670	130	138	145	89.3	17.4	18.4	19.3
675	132	139	146	90.0	17.5	18.5	19.5
680	133	140	147	90.7	17.7	18.7	19.6
685	134	141	148	91.3	17.8	18.8	19.8
690	135	142	149	92.0	18.0	19.0	19.9
695	136	143	150	92.7	18.1	19.1	20.0
700	137	144	151	93.3	18.2	19.2	20.2
705	138	145	152	94.0	18.4	19.4	20.3
710	139	146	153	94.7	18.5	19.5	20.5
715	140	147	154	95.3	18.6	19.6	20.6
720	141	148	156	96.0	18.8	19.8	20.7
725	142	149	157	96.7	18.9	19.9	20.9
730	143	151	158	97.3	19.1	20.1	21.0
735	144	152	159	98.0	19.2	20.2	21.2
740	145	153	160	98.7	19.3	20.3	21.3
745	146	154	161	99.3	19.5	20.5	21.4
750	147	155	162	100.0	19.6	20.6	21.6
755	148	156	163	100.7	19.8	20.8	21.7
760	149	157	164	101.3	19.9	20.9	21.8
765	150	158	165	102.0	20.0	21.0	22.0
770	151	159	166	102.7	20.2	21.2	22.1

3.1.12 Function Test: SpO2 + PR

Apply the sensor to the earlobe of a healthy person: Compare SpO2 and PR readings against the readings of a reference pulse oximeter (e.g. N595 with Durasensor 100 from Nellcor). The SpO2 and PR reading should be within ± 3% SpO2 and ± 3 bpm, respectively.

If this requirement is not met refer to *section 4.2.1 "Troubleshooting SpO2 / PR monitoring"* to further evaluate the problem.

3.2 SenTec Digital Monitor

3.2.1 Cleaning and Disinfection

Clean or disinfect the SDM (including AC power cord) as often as required per institutional ordinances (recommended weekly). For cleaning and disinfection instructions refer to the *Technical Manual for the SDM* (HB-005752).

3.2.2 Visual Inspection

Visually check the entire SDM for possible damages.

If you detect a damage, the SDM needs to be repaired according to *section 5 "Repairs".*

3.2.3 Labeling

Check the SDM for presence and legibility of the following labels and symbols:

Front panel: Symbols for buttons and LED's (*see Figure 1 Front Panel of the SDM*).

Rear panel: Labels of all ports, connectors and switches; label with SN, REF and � label, CE label, UL label and WEEE Disposable label (*see Figure 2   Rear Panel of the SDM*).

If the above requirements are not met contact your local SenTec representative or send back the monitor according to *section 8.6 "Instructions for Shipment".*

> ⚠ **For SenTec authorized service technicians only:** If the above requirements for the front panel are not fulfilled then replace the SDM Case, upper part according to the *Repair Manual for the SDMS* (HB-005755).

3.2.4 Electrical Safety Check

The SenTec Digital Monitoring System (SDMS) has been designed to comply with the standards IEC 60601-1, ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No.60601-1 (UL and cUL). To ensure electrical safety of the equipment it is recommended that **qualified service personnel** performs the electrical safety check once a year (but every two years the latest) and after repair.

The electrical safety tests for the SDMS have to be performed in accordance with the standards IEC 60601-1, ANSI/AAMI ES60601-1 (USA) or CAN/CSA-C22.2 No.60601-1 (Canada) for instruments classified as Class 1 and Type BF (defibrillation proof). Technicians must be familiar with these standards applicable to the institution and the country. Test equipment and its application must comply with the applicable standard.

3.2.4.1 High potential test according to IEC 60601-1

Note: If the cover of the SDM has not been opened, this test is not required.

Tools
- AC High potential tester (e.g. Model 7530DT HypoULTRA®II from Associated Research, Inc.)

> **WARNING:** Before performing the high potential test read the operating instructions of the AC High potential tester.

> **WARNING:** Never touch the equipment under test or anything connected to it while high voltage is applied during the high potential test. High voltage can lead to injury or death.

The sensor is an applied part of Type BF. The interface ports of the SDM meet the same requirements as the sensor port and are tested in an analogous manner.

The high potential test for accessible parts is performed with a voltage of 1500 VAC during 60 seconds between the following connections of the SDM:

Table 3   Connections for the High Potential Test, AP

High Potential Test, Accessible Parts (AP)		
	Connection 1	**Connection 2**
1. Measurement	Phase connected to neutral of the AC power cord	Equipotential Terminal

Figure 7   Connections for the High Potential Test, AP

Setup with Model 7530DT HypoULTRA®II from Associated Research, Inc.

The high potential test for patient circuits is performed with a voltage of 3000 VAC during at least 1 second between the following connections of the SDM:

Table 4   Connections for the High Potential Test, PC

High Potential Test, Patient Circuits (PC)		
	Connection 1	**Connection 2**
2. Measurement	Phase connected to neutral of the AC power cord	Ground of the sensor connection port
3. Measurement	Phase connected to neutral of the AC power cord	Ground of the Serial Data Port
4. Measurement	Ground of the Sensor connection port	Ground of the Serial Data Port
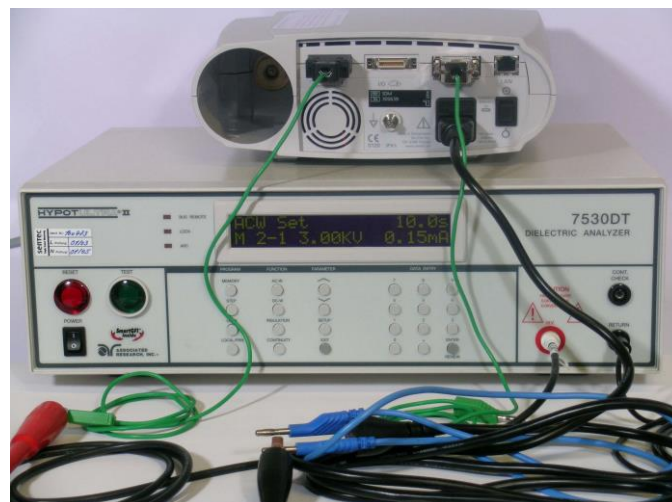
Figure 8   Connections for the High Potential Test, PC

Setup with Model 7530DT HypoULTRA®II from Associated Research, Inc.

If a disruptive discharge occurs refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

3.2.4.2 Safety test according to IEC 60601-1

Tools
- Safety analyzer for tests according to IEC 60601-1 (e.g. 601PROXL International Safety Analyzer from BIO-TEK)

If the required equipment is not available, send the SDM to your local SenTec representative for testing.

> **WARNING:** Before performing the safety test read the operating instructions of your safety analyzer.

> **WARNING:** Never touch the equipment under test or anything connected to it while high voltage is applied during the high potential test. High voltage can lead to injury or death.

The sensor is an applied part of Type BF. The interface ports of the SDM meet the same requirements as the sensor port and are tested in an analogous manner.

The safety test is performed according to IEC 60601-1. The following connections must be tested (while the SDM is switched on):

- Protective Earth Resistance Test: Earth wire of the AC power cord, equipotential terminal (ground, *see Figure 2   Rear Panel of the SDM*), gas bottle (Caution: the container might be insulated from the thread by the color). The resistance between two of these must be less than 0.2 Ω. Minimum current: USA = 1 A, Europe = 5 A

- Insulation Resistance Test: AC Power Connector – housing (equipotential terminal). The resistance must be more than 2 MΩ

- Patient Insulation Resistance: Sensor Connection Port (Ground) – housing (equipotential terminal). The resistance must be more than 2 MΩ

- Earth Leakage Current: The current must be below 500 µA

- Enclosure Leakage Current: The current must be below 100 µA

- Patient Leakage Current Test: Sensor Connection Port (Ground) and interface (Ground of the Serial Data Port) – all other connectors. The current must be below 100 µA

If the above described functions do not operate properly, the SDM needs to be repaired. Refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

Check the AC power cord for damages of the isolation. Check the connectors for damages.

The AC power cord must be tested when connected to the AC power outlet. Thereby the cable must be swayed to detect potential cable breaks or loose contacts. The AC power cord must be tested together with the Ground Integrity.

If the above specifications are not met, then the AC power cord needs to be replaced by a new AC power cord from SenTec AG, see *section 8.2 "Testing Accessories and Spare Parts"*.
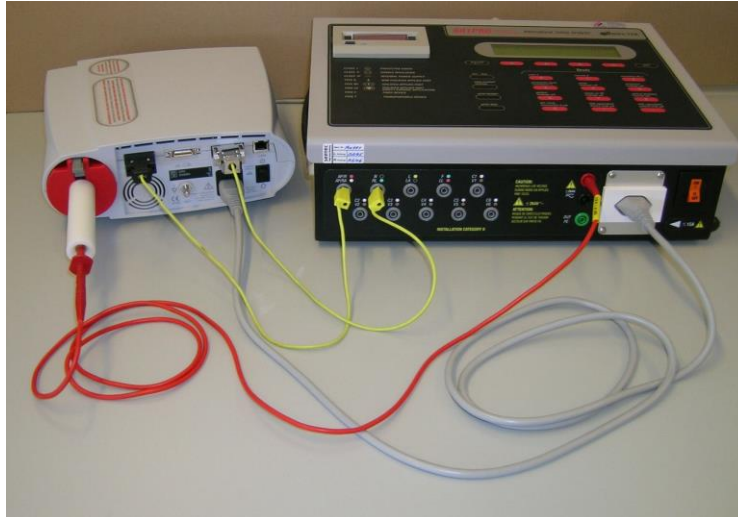
Figure 9   Connections for the Safety Test

Setup with 601PRO_{XL} International Safety Analyzer from BIO-TEK

3.2.5   POST

After turning on the SDM performs a power-on self-test (POST), which tests the SDM's circuitry and functions (internal test). The display, as well as the visual and audible indicators (i.e. LED's and speaker) are activated. The result of the POST is indicated by a ✓ (passed) or ✗ (failed) symbol. If no problems are detected during the POST the message 'passed' (✓) is displayed; else the message 'failed' (✗) is displayed.

Note: The message "FLASH Memory Inside" is displayed on the POST screen, if the hardware version of your monitor supports a non-volatile FLASH memory.

Note: The message "LAN Interface supported" is displayed on the POST screen, if the hardware version of the SDM supports the LAN interface.

Note: The message "LED Backlight" is displayed on the POST screen, if the backlight is a LED type.

If the POST fails, an error message shows up at the bottom of the POST screen, refer to P0405 *(see section 4.2.4 "SDM specific troubleshooting").* The SDM needs to be repaired according to *section 5 "Repairs".*

⚠ **For SenTec authorized service technicians only:** Replace the defective parts according to the *Repair Manual for the SDMS* (HB-005755).

3.2.6   Keyboard

1.   Activate the Main Menu by pressing ⬚

2.   Select the menu "System Settings" by going down in the menu using ⬚

3.   Activate the selection by pressing ⬚

4.   Select the item "Key Click" by navigating through the menu using ⬚ or ⬚

5.   Activate the selection by pressing ⬚ once.

6.   Adjust the volume of the Key Click by using the UP ⬚ and DOWN ⬚ Button. When the Key Click is ON you hear a beep when pushing a button.

7.   Push the Display Button ⬚ twice to exit the menus.

8.   If you push the AUDIO PAUSED / OFF Button ⬚ the AUDIO PAUSED / OFF Button Indicator (yellow LED) should light up (note: if the parameter "Alarm Volume" is set to OFF pressing the AUDIO PAUSED / OFF Button has no function).

If the above described functions do not operate properly contact your local SenTec representative or return the monitor according to *section 8.6* "Instructions for Shipment".

> ⚠ **For SenTec authorized service technicians only:** If the above requirements for the Keyboard are not fulfilled then replace the SDM Case, upper part according to the *Repair Manual for the SDMS* (HB-005755).

3.2.7   Clock Settings

Verify that the clock settings are correct. If necessary, adjust the clock in the SDM Menu "System Settings → Date / Time".

Power cycle the SDM and control the clock settings.

If the clock settings are not correct refer to *section 4.2.4* "SDM specific troubleshooting" to further evaluate the problem.

> ⚠ **For SenTec authorized service technicians only:** Replace the defective parts according to the *Repair Manual for the SDMS* (HB-005755).

3.2.8   Display/LED's

Check indicator LED's and the display for defects:

1. Connect the SDM to AC power. Switch the SDM OFF and ON again: During the POST, the Alarm Mute Indicator (yellow LED) and the ON/OFF Indicator (green LED) are activated. The AC Power/Battery Indicator LED is lit yellow (battery charging) or green (battery full). Refer to *Figure 1   Front Panel of the SDM* for location of the indicator LED's.

2. Control the readability of the following critical areas: graph window, numerical displays, status bar may be accepted.

If the above described functions do not operate properly contact your local SenTec representative or send back the monitor according to *section 8.6* "Instructions for Shipment".

⚠ **For SenTec authorized service technicians only:** If the above requirements for the LEDs are not fulfilled then replace the SDM Case, upper part according to the *Repair Manual for the SDMS* (HB-005755).

If the above requirements for the display are not fulfilled then replace the display according the *Repair Manual for the SDMS* (HB-005755).

3.2.9   Speaker (POST)

Switch ON the SDM and verify three signal tones of 0.2 seconds each during the POST.

If the speaker does not sound during the POST refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

3.2.10   Fan

The fan should briefly activate during POST. The fan should rotate freely and without causing unusual noises. The fan should rotate without obstruction when you blow into the fan slits on the rear panel of the SDM (note that the fan needs to be off during this test).

If the above described functions do not operate properly refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

3.2.11   Barometric Pressure

Tools   • Reference Barometer

Compare the barometric pressure measured by the SDM against a calibrated reference barometer. The barometric pressure measured by the SDM is displayed in the status bar if PCO_2 is enabled and if the sensor is in the docking station. The unit (mmHg or kPa) depends on the setting of the menu parameter "Pressure Unit".

If the difference between the two barometric pressure readings is larger than ± 3 mmHg (0.4 kPa) the SDM has to be repaired. Refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

3.2.12   Analog Output

Tools   • Multimeter

            • SenTec Test Connector Multipurpose I/O

For a detailed description of the analog output refer to the *Technical Manual for the SDM*. The analog output is part of the Multipurpose I/O Port *(see Figure 2   Rear Panel of the SDM)*.

Measure the Analog Output voltages for the Pleth Waveform (Pin 1+2), for PR (pin 3+4), for SpO_2 (Pin 5 + 6), and for PCO_2 (Pin 7 + 8) using a voltmeter. To facilitate the connection of the lead of the voltmeter to the pins, it is recommended to use the SenTec Test Connector Multipurpose I/O (*see section 8.2 "Testing Accessories and Spare Parts"*) or a 26 pin Mini Delta Ribbon connector (e.g. 3M part no. 10126-3000VE).

In the menu "Interfaces / Analog Outputs" the parameter range that is attributed to the 0 to 1 Volt output range can be changed for PCO_2, SpO_2, and PR. During measurements on the patient the voltage differential varies proportionally from 0 to 1 Volt as the pin's parameter varies over the selected parameter range.

Activating the menu function "Calibration Sequence" in the menu "Interfaces / Analog Outputs" causes for all parameters the output of 1 Volt during 60 seconds, followed by the output of 0 Volt during another 60 seconds. When the calibration sequence is running the current output voltage is indicated on the display.

Note: By pressing ENTER it is possible
       a) to change from 1 Volt to 0 Volt (if output of 1 Volt is active)
       b) to stop the calibration sequence (if output of 0 Volt is active)

If the above described functions do not operate properly, the SDM needs to be repaired. Refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

3.2.13 Serial Data Port (RS-232)

For a detailed description of the Serial Data Port (RS-232) refer to the corresponding section of the *Technical Manual for the SDM*. The Serial Data Port is located on the rear panel of the SDM (*see Figure 2   Rear Panel of the SDM*).

To verify the data transmission to an external device (e.g. PC) activate the protocol "SenTecLink" (proceed as described in the *Technical Manual for the SDM)*.

Connect one end of a serial cable to the serial data port (RS-232) of the SDM and connect the other end of the cable to a serial port of your PC. If your computer has no serial port but USB-ports an USB232 Converter Cable can be used.

Start V-STATS software on your PC. Select the appropriate COM-port in the Sub-menu "Communication / Settings … "). Start the sub-menu "Communication / with SDM (via Serial Interface) …", this opens dialog "Communication with SDM (via Serial Interface)" with the "Connection Status" indicator showing the status of the communication between V-STATS™ and the SDM (for detail description see *V-STATS Instruction Manual*).

Verify that data transmission between V-STATS™ and the SDM works properly. The "Connection Status" indicator lights green if the connection is established and the communication is successful between V-STATS™ and SDM.

If the above described functions do not operate properly, the SDM needs to be repaired. Refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

3.2.14 LAN Test

In order to test correct LAN communication the following steps need to be performed:

- You will need a network environment to plug in your PC running a registered V-STATS™ and the SDM. Alternatively you may use a crossover LAN cable and connect the PC and SDM. Attach PC and SDM to the network. Note: Please consult the online help of V-STATS™ for further information.

- Configure the SDM and connect the SDM to the PC via serial cable .

- Run V-STATS™ (latest version) and open the dialog-window "Communication with SDM (via Serial Interface)…" by clicking on the respective big button in the center main window or on the icon in the upper menu-bar of the graphic window or by using the menu "Communication / with SDM (via Serial Interface) …"

- Activate/check LAN link: Click on the control 'Profiles / SDM settings' and select 'Interfaces' tab of Current SDM Profile. Verify that 'LAN selectable' is checked and that 'LAN' is set to 'On'. Also select appropriate setting for 'DHCP mode', depending on your network configuration (set to 'Off' in case of direct connection with crossover cable). Enter IP address when DHCP mode was set to 'Off'. Normally the other settings can be left at their defaults.

- Close 'Profiles / SDM settings' window.

- On the SDM: navigate to menu Interfaces → LAN interface. If in DHCP mode you should now see the IP address assigned by the DHCP server.

- With V-STATS™: Using the trial mode of V-CareNeT™ start a remote monitoring session with the SMD.

- Note: consult online help if you need specific help on how to start the communication.

- Verify that a green icon is shown in the V-CareNeT™ Control Window for the connection status of the SDM (**LAN test 1**).

- After admitting a patient: The Remote Monitoring Window is shown, click in the black data field and open the Additional Data window.

- Verify that the time displayed in the status bar of the window corresponds to the time of the SDM (lagging no more than 5 seconds) and that the serial number in the Monitor Configuration / Status Information field corresponds to the serial number of the device under test (**LAN test 2**).

3.2.15 Capacity of Rechargeable Lithium Battery

Tools   • A PC with a terminal emulation software

Test using a PC:

1. Connect the SDM to AC power and wait until the battery is completely charged. (AC Power/Battery Indicator on the front panel of the SDM (*see Figure 1*) lits green).

2. Adjust the brightness in the menu "Systems Settings / Display Settings" to 100%.

3. Activate the communication protocol "SenTecLink" in the menu "Interfaces / Serial Interfaces".

4. Connect the Serial Data Port (RS-232) of the SDM to an external PC and record the on-line data using a terminal program.

5. Activate data recording using a terminal program and disconnect the SDM from AC power.

6. When the battery capacity is below 10% the status message "Battery Low" displays and the status code "LB" is recorded. Once the remaining battery is critical the message "Battery critical" displays and the status code "BC" is output. The time stamp of the last data set recorded on the PC corresponds to the time when the battery was empty and the SDM switched off automatically. With the first and last time stamps of the recorded data set you can calculate the running time.

In case of a SDM with a display with 'CCFL Backlight' a new, fully charged battery provides approximately 6 hours of monitoring time (if SLEEP MODE = OFF) and approximately 13 hours (if SLEEP MODE = ON).

In case of a SDM with a display with 'LED Backlight' a new, fully charged battery provides approximately 11 hours of monitoring time (if SLEEP MODE = OFF) and approximately 16 hours (if SLEEP MODE = ON).

Note: The message 'LED Backlight' displays on the POST screen (*see section 3.2.5* POST) and in the sub-menu "System Settings / Display Settings" if the display of your SDM uses an 'LED Backlight'.

If the above described functions do not operate properly, the SDM needs to be repaired. Refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

3.2.16 Display, Alarm

Initiate a low priority alarm (e.g. by disconnecting the SenTec TC Sensor from the SDM). Verify that the corresponding status message is displayed in the status bar.

If the above described functions do not operate properly, the SDM needs to be repaired. Refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

3.2.17 Speaker, Alarm

Initiate a low priority alarm (e.g. by disconnecting the SenTec TC Sensor from the SDM). Verify that the audible component of a low priority alarm is audible (one burst of two pulses (1 dyad) repeated every 15 seconds).

If the above described functions do not operate properly, the SDM needs to be repaired. Refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

3.2.18 Nurse Call, Alarm

Tools   • SenTec Test Connector Multipurpose I/O

Verify that the menu parameter 'Interfaces / Nurse Call' is set to ON. Then initiate a low priority alarm (e.g. by disconnecting the SenTec TC Sensor from the SDM during a monitoring session). The Nurse Call feature is relay-based and can be tested with the SenTec Test Connector Multipurpose I/O, *see section 8.2 "Testing Accessories and Spare Parts".*

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

If the above described functions do not operate properly, the SDM needs to be repaired. Refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

3.3 Docking Station

3.3.1 Cleaning and Disinfection

Clean or disinfect the Docking Station (including the Docking Station gasket) as often as required per institutional ordinances (recommended weekly) using a cotton swab moistened with 70% isopropanol.

3.3.2 Visual Inspection

Inspect the Docking Station door and the gasket for mechanical damages. The closing mechanism must lock properly.

If you detect a possible damage, replace the defective part according to *section 5 "Repairs"*.

Note: We recommend changing the gasket of the Docking Station annually.
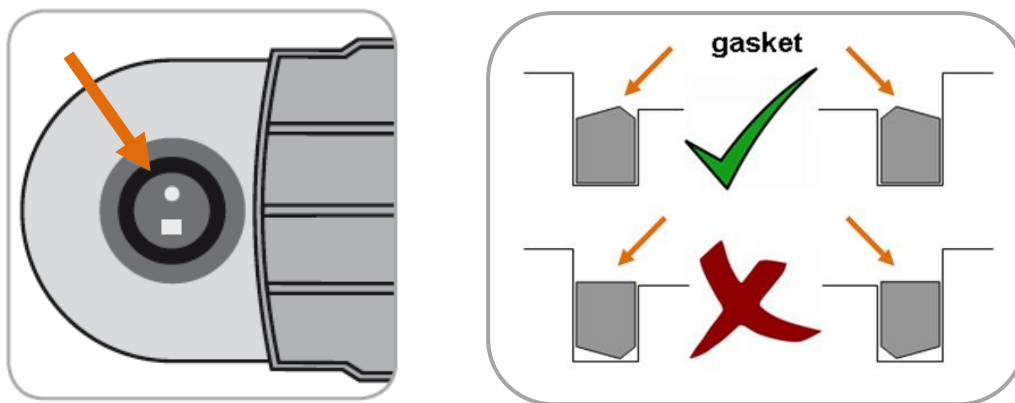
Figure 10   Correct orientation of the Docking Station Gasket

3.3.3 Gas Level Indicator

Tools   • Full *Service Gas* bottle

Check the functionality of the gas level indicator using a new gas bottle.

1. Screw in a new gas bottle and switch the SDM ON.

2. Insert the sensor in the Docking Station and verify that the "100% gas icon" displays in the status bar.

3. Remove the gas bottle from the SDM and verify that the yellow "0% gas icon" displays in the status bar.

If the expected result is not observed, refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

3.4 Digital Sensor Adapter Cable

3.4.1 Cleaning and Disinfection

Clean or disinfect the `Digital Adapter Cable´ as often as required per institutional ordinances (recommended weekly). For cleaning and disinfection instructions refer to the *Technical Manual for the SDM* (HB-005752).

3.4.2 Visual Inspection

Check the Digital Sensor Adapter Cable for damages of the isolation. Check the Digital Sensor Adapter Cable connectors for damages.

If you detect damages, the Digital Sensor Adapter Cable needs to be replaced by a new Digital Sensor Adapter Cable.

3.5   Opening the Membrane Changer

If the sensor is blocked within the Membrane Changer at any position, it can be opened as follows:

Identify the 6 latches holding together top and bottom part of the Membrane Changer together (see Figure 11   Opening the Membrane Changer). Insert a screwdriver behind the latches and use it as leverage to break out the 6 latches.

WARNING: Wear protective goggles while breaking out the 6 latches.

CAUTION: This procedure will irreversibly destroy the Membrane Changer, but not harm the sensor if executed with care.
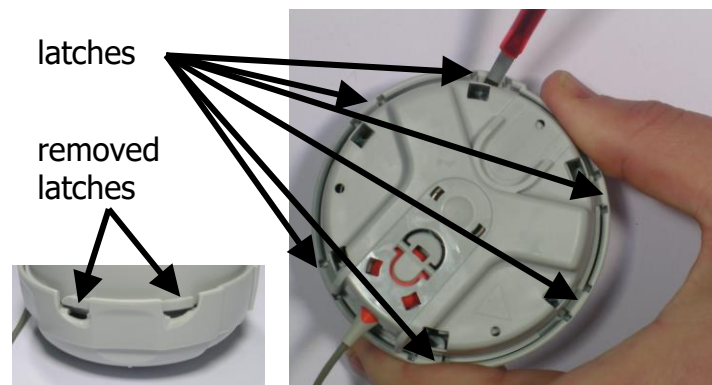
Figure 11   Opening the Membrane Changer

4 Troubleshooting

This section describes problems, possible causes and recommended corrective actions. Repairs (without having to open the SDM cover) are described in *section 5 "Repairs"*. Repairs that require opening the cover of the SDM are to be performed by SenTec authorized service technicians only and are described in detail within the *Repair Manual*.

Prior to maintenance, service or repairs all components of the SDMS must be cleaned and disinfected. If equipment is send to service personnel, a local SenTec representative or to SenTec AG a completed *"Certificate for Disinfection"* (*see section 8.7*) must be attached.

If you need to return devices for service or repair follow the shipment instructions in *section 8.6 "Instructions for Shipment".*

Send defective parts together with the completed *"Repair or Investigation Request Form"* to your local SenTec representative. The *"Repair or Investigation Request Form"* may be copied from *section 8.3 "Repair or Investigation Request Form".*

4.1   How to use the troubleshooting list

The troubleshooting list describes possible defects of the device. The problems are numbered (PXXXX) unambiguously. Please reference the respective PXXXX code whenever applicable.

The trouble shooting list comprises up to three levels of recommended actions to be performed

> **[1]** by the **operator** (shaded in dark grey) and, if the problem persists,
>
> **[2]** by a **qualified technician** (shaded in light grey), i.e. troubleshooting at service level (according to this manual) and, if the problem persists,
>
> **[3]** by **SenTec authorized service technicians** only (no shading), i.e. troubleshooting at repair level (according to the *Repair Manual*).

> **Note:** Take into account that the operator might not have performed the corrective actions recommended at operator-level and/or might not have identified the problem correctly. Therefore, check other possible causes and problems.

The example in *Table 5   Example of a Troubleshooting Procedure* explains how to work with the troubleshooting list.

Table 5   Example of a Troubleshooting Procedure

Problem	Possible cause	Recommended action(s)	Trouble shooting level
P0XXX **PCO2** too low	Wrong/instable barometric pressure during calibration	Verify that the barometric pressure reading of the SDM is stable during calibration and does not deviate from a known calibrated reference barometer by more than 5 mmHg (0.7 kPa). Otherwise contact qualified service personnel.	**a** (operator)
	SDM defective	If problem persists contact SenTec authorized service personnel.	**b** (qualified technician)
	MPB (Multiparameterboard, SM1A) defective	Replace MPB according to section 5.16. ⚠ **To be performed by SenTec authorized service technicians only.**	**c** (SenTec authorized technician)
	PCO2 sensitivity of the sensor too low	Test the PCO2 sensitivity (see section 3.1.8 PCO2 / PO2 Sensitivity & Calibration Duration). If the test is not passed, remembrane the sensor and repeat the test. After a renewed missing of this difference, consult qualified service personnel.	**a** (operator)
		Clean the sensor as described in section 3.1.7 Cleaning / Inspecting without Membrane and perform the `Sensitivity Test´ as described in section 3.1.8. If problem persists contact SenTec authorized service personnel.	**b** (qualified technician)
	SenTec TC **Sensor defective**	If problem persists the sensor is defective. Replace it by original replacement parts. ⚠ **To be performed by SenTec authorized service technicians only.**	**c** (SenTec authorized technician)

4.2 Troubleshooting List

This section describes problems, possible causes and recommended actions for troubleshooting.

Note: Shadings in the troubleshooting table reflect different levels of recommended actions, i.e. for the operator (dark grey), qualified service personnel (light grey) and SenTec authorized service technicians (no shading), *see section 4.1 "How to use the troubleshooting list"* for details.

4.2.1 Troubleshooting PCO2 / PO2 monitoring

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

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

Note: This section only is applicable for SenTec TC Sensors with PCO2 and/ or PO2 enabled.

Table 6   Troubleshooting PCO2/ PO2 Monitoring

Problem	Possible Cause(s)	Recommended corrective action(s)
P0100 After sensor application or a 'TC artifact' PCO2 values increase slowly or PO2 values decrease slowly or do not stabilize within 10 minutes	Sensor loosely attached to patient (air between sensor and skin; no contact liquid)	Verify that the sensor is securely attached and ensure that air gaps are eliminated between the skin and the sensor. If needed, reapply the sensor (on same or an alternate site). For instructions refer to the *Quick Reference Guide for the SDMS* or the *Instruction Manual for the SDMS*. Consider to use the Staysite™ Adhesive (model SA-MAR) to complementary attach Multi-Site Attachment Rings 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. **Note**: Typically PaCO2 is > 25 mmHg in humans and PCO2 of ambient air < 0.5 mmHg. If the contact between the sensor and skin is not hermetically sealed PCO2 readings, consequently, may <u>increase slowly</u> after sensor application or a 'TC artifact' and be <u>too low</u> thereafter. **Note**: Typically PaO2 is < 100 mmHg in humans and PO2 of ambient air > 130 mmHg. If the contact between the sensor and skin is not hermetically sealed PO2 readings, consequently, may <u>decrease slowly</u> after sensor application or a 'TC artifact' and be <u>too high</u> thereafter. **Note**: Also refer to Status Messages 'Check sensor application', 'PCO2 stabilizing', 'PO2 stabilizing', or 'PCO2/ PO2 stabilizing' (refer to the *Technical Manual for the SDM*).
	Sensor applied to a measurement site that is inadequate / not recommended for PCO2/ PO2 monitoring	Apply sensor to a recommended measurement site with an appropriate Sensor Attachment Accessory. For instructions refer to the *Quick Reference Guide for the SDMS* or the *Instruction Manual for the SDMS*.
	Excessive use of contact liquid	Remove sensor. Clean sensor and measurement site with an alcohol pad. Reapply the sensor using only one drop of contact liquid.

Problem	Possible Cause(s)	Recommended corrective action(s)
	PCO2 and/ or PO2 part of the sensor is slow	Refer to P0304
P0101 PCO2 too low OR PO2 too high	Sensor loosely attached to patient (air between sensor and skin; no contact liquid)	Refer to identical 'Possible Cause' in P0100 for recommended corrective action(s)
	Sensor applied to a measurement site that is inadequate/ not recommended for PCO2/ PO2 monitoring	Refer to identical 'Possible Cause' in P0100 for recommended corrective action(s)
	Arterio-venous shunts, e.g. ductus arteriosus.	Ensure that the sensor site and thee arterial sampling site are on the same side of the shunt
	PCO2 part of the sensor unstable (causing drift)	Allow the sensor to stabilize for an additional 1 – 2 hours, i.e. store the sensor in the Docking Station with the monitor being switched on (refer to the *Technical Manual for the SDM* for additional sensor stabilization related information). **Note**: After switching-on the monitor or after membrane change, it is recommended to store the sensor in the Docking Station with the monitor being switched on for the duration indicated by the yellow information message 'Recommended Sensor Stabilization [min]: on' the "Ready for use" screen and on the "Calibration" screen (see *Technical Manual for the SDM*).
	Wrong / expired calibration gas was used during last calibration	Verify that SenTec Service Gas is used. If expired replace with a new gas bottle!
	Wrong / unstable barometric pressure during last calibration	Refer to P0408
	PCO2 and or PO2 sensitivity of the sensor low/ deterioriated	Refer to P0305

Problem	Possible Cause(s)	Recommended corrective action(s)
	PO2 Measurement is influenced by high ambient light levels	Shield SenTec TC Sensor from strong ambient light. **Note**: Refer to Status Message 'High ambient light' (with Status Code 'SA').
		Clean/Inspect the sensor as described in *section 3.1.7* "*Cleaning / Inspecting without Membrane"* and perform the 'Sensitivity Test' as described in *section 3.1.8* "*PCO2 / PO2 Sensitivity & Calibration Duration*". If problem persists contact SenTec authorized service personnel.
	Significant PCO2 drift	Verify that the sensor is not affected by loose fit of the membrane, trapped air under the membrane. If needed perform an unrequested membrane exchange (activate the menu "Membrane Change"). After membrane exchange calibrate the sensor and allow the PCO2 part of the sensor to stabilize for 4 hours. If no remembraning is needed allow the sensor to stabilize for an additional 2 – 3 hours.
	SDM defective	Contact SenTec authorized service personnel or our local SenTec sales representative.
	MPB (Multiparameter-board, SM1A) defective	Replace MPB according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SenTec TC Sensor defective	Perform the PCO2 Slope Test according to *section 3.1.9* "*PCO2 / PO2 Sensitivity & Calibration Duration".* If the PCO2 slope test fails replace sensor. ⚠ **To be performed by SenTec authorized service technicians only.**

Problem	Possible Cause(s)	Recommended corrective action(s)
P0102 PCO2 too high OR PO2 too low	Low perfusion at the (hypoperfused) measurement site	Limitation of the method**. Evaluate the patient status**. Shock, low cardiac index,hypothermia and inadequate local vasodilatation are physiological limitations of the method. Avoid any mechanical pressure / stress on the measurement site. Verify that the **sensor temperature** is appropriately selected for the specific patient/ skin condition at the measurement site and the enabled parameters. When selecting/ increasing sensor temperature carefully balance benefit (more accurate measurements) versus risk (potential skin burns). Carefully read the section "Sensor Temperature & Site Timer" in the *Technical Manual for the SDM*.
		Remember: In most patients PO2 monitoring requires higher temperatures than PCO2 monitoring. In newborns, PO2 correlates with PaO2 almost in a one to one relationship at a sensor temperature of 43 to 44 °C, whereby the accuracy of PO2 compared to PaO2 is best up to PaO2 = 80 mmHg (10.67 kPa), above which it increasingly tends to read lower than PaO2 (especially in adults).
	Sensor applied to a measurement site that is inadequate / not recommended for PCO2 monitoring.	Refer to identical 'Possible Cause' in P0100 for recommended corrective action(s)
	Arterio-venous shunts, e.g. ductus arteriosus.	Ensure that the sensor site and thee arterial sampling site are on the same side of the shunt
	Presence of hyperoxemia (PaO2 > 100 mmHg)	**Remember**: In newborns, PO2 correlates with PaO2 almost in a one to one relationship at a sensor temperature of 43 to 44 °C, whereby the accuracy of PO2 compared to PaO2 is best up to PaO2 = 80 mmHg (10.67 kPa), above which it increasingly tends to read lower than PaO2 (especially in adults).
	PCO2 part of the sensor unstable (causing drift)	Refer to identical 'Possible Cause' in P0101 for recommended corrective action(s)

Problem	Possible Cause(s)	Recommended corrective action(s)
	Wrong / expired calibration gas was used during last calibration	Refer to identical 'Possible Cause' in P0101 for recommended corrective action(s)
	Wrong / unstable barometric pressure during last calibration	Refer to P0408
	Undetected gas leak in Docking Station.	Refer to P0502
	PCO2 and or PO2 sensitivity of the sensor low/ deteriorated	Refer to P0305
	PO2 Measurement is influenced by high ambient light levels	Shield SenTec TC Sensor from strong ambient light. **Note**: Refer to Status Message 'High ambient light' (with Status Code 'SA') (see *Technical Manual for the SDM*).
		Clean/Inspect the sensor as described in *section 3.1.7 "Cleaning / Inspecting without Membrane"* and perform the 'Sensitivity Test' as described in *section 3.1.8 "PCO2 / PO2 Sensitivity & Calibration Duration"*. If problem persists contact SenTec authorized service personnel.
	Docking Station door mechanically defective	Replace Docking Station door according to *section 5.5 "Replacement, Docking Station Door"*.
	Gasket defective	Replace gasket according to *section 5.6 "Replacement, Docking Station Gasket"*.
	SDM defective	Contact SenTec authorized service personnel or our local SenTec sales representative.
	Calibration Module defective	Replace Calibration Module according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	Docking Station Module defective	Replace Calibration Module according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**

Problem	Possible Cause(s)	Recommended corrective action(s)
P0103 PCO2 and/ or PO2 suddenly change / change very fast ('TC artifact')	Sensor loosely attached to patient (air between sensor and skin; no contact liquid)	Refer to identical 'Possible Cause' in P0100 for recommended corrective action(s)
	Adhesive pad of Ear Clip / Multi-Site Attachment Ring does not stick any more	Reapply the sensor with a new Ear Clip / Multi-Site Attachment Ring. Pay attention not to wet the adhesive. For instructions refer to the *Quick Reference Guide for the SDMS* or the *Instruction Manual for the SDMS*. Consider to use the Staysite™ Adhesive (model SA-MAR) to complementary attach Multi-Site Attachment Rings 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.
	Electrocautery, HF surgery, defibrillation (mainly PCO2 specific)	The values will come back to normal after electrocautery, HF surgery or defibrillation.
P0104 PCO2 and/ or PO2 changes very slowly	Sensor applied to a measurement site that is inadequate / not recommended for PCO2 monitoring.	Refer to identical 'Possible Cause' in P0100 for recommended corrective action(s)
	Excessive use of contact liquid	Refer to identical 'Possible Cause' in P0100 for recommended corrective action(s)
	PCO2 and/ or PO2 part of the sensor is slow	Refer to P0304.

4.2.2   Troubleshooting SpO2 / PR monitoring

Note: This section is applicable for SenTec TC Sensors (if SpO2 / PR are enabled) and for SenTec's oximetry sensors.

Table 7   Troubleshooting SpO2/ PR Monitoring

Problem	Possible Cause(s)	Recommended action(s)
P0200 SpO2 and / or PR too low or too high	Venous pooling (e.g. Trendelenburg position)	Limitation of the method. For placement of the sensor on the earlobe, forehead or cheek: avoid conditions where the head is positioned lower than the heart.
	Some cardiovascular pathologies (e.g. causing cardiac arrhythmias)	Limitation of the method.
	Inadequate local blood flow at the measurement site	Evaluate the patient status. Shock, low cardiac index, inadequate local vasodilatation are physiological limitations of the method. Verify the sensor application and the appropriateness of the monitoring site. Avoid any mechanical pressure / stress on the sensor or measurement site. Secure the sensor cable with adhesive tape and a clothing clip **Note**: Refer to the Status Message 'SpO2 low signal' (see *Technical Manual for the SDM*).
	Electrocautery, HF surgery, defibrillation	The values will come back to normal after electro-cautery, HF surgery or defibrillation.
	Sensor applied to a measurement site that is inadequate / not recommended for SpO2 monitoring.	Apply sensor to a measurement site recommended/ approved for SpO2/ PR monitoring with an appropriate Sensor Attachment Accessory. For instructions refer to the *Quick Reference Guide for the SDMS* or the *Instruction Manual for the SDMS*.
	Artifacts due to patient movements	Verify the sensor application and the appropriateness of the monitoring site. Secure the sensor cable with adhesive tape and a clothing clip. **Note**: Refer to the Status Message 'SpO2 signal quality' (see *Technical Manual for the SDM*).

Problem	Possible Cause(s)	Recommended action(s)
	SpO2/ PR Measurement is influenced by high ambient light levels	Shield SenTec TC Sensor from strong ambient light (e.g. lamps). **Note**: Refer to Status Message 'High ambient light' (with Status Code 'HA') (see *Technical Manual for the SDM*).
	Dysfunctional hemoglobin	Physiological limitation of the method. In patients with high carboxyhemoglobin levels (e.g. smokers) functional saturation measured with a pulse oximeter will overestimate functional saturation determined with a CO-oximeter.
	Excessive use of contact liquid causing light shunting	Remove the SenTec TC Sensor. Clean sensor and measurement site with an alcohol pad. Reapply the sensor using only one drop of contact liquid.
	Intravascular dyes	Limitation of the method. Dyes used as tracer, contrast medium, etc. may absorb light at the same wavelength as the one used for pulse oximetry measurements.

4.2.3 Sensor specific troubleshooting

Table 8   Sensor specific troubleshooting

Problem	Possible Cause(s)	Recommended action(s)
P0300 Despite a SenTec TC Sensor is connected to the SDM the message 'Connect sensor' displays	Bad contact (cables not properly connected)	Verify connections (disconnect and reconnect all cables) and – if necessary – power cycle the SDM.
	SenTec TC Sensor and / or 'Digital Sensor Adapter Cable' defective	To identify the defective part, exchange the 'Digital Sensor Adapter Cable' or the SenTec TC Sensor and try again (if necessary permute and try on a different SDM). In case of damage of the SenTec TC Sensor replace it by original replacement parts. In case of damage of the 'Digital Sensor Adapter Cable' replace it by original replacement parts.
	SDM defective	If problem persists contact qualified service personnel.
	SDM defective	Refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

Problem	Possible Cause(s)	Recommended action(s)
P0301 Despite oximetry sensor is connected to the SDM the message 'Connect sensor' displays	Bad contact (cables not properly connected)	Verify connections (disconnect and reconnect all cables) and – if necessary – power cycle the SDM.
	Oximetry sensor and / or 'SpO2 Adapter Cable' defective	To identify the defective part, exchange the 'SpO2 Adapter Cable' or the oximetry sensor and try again (if necessary permute and try on a different SDM). In case of damage of the oximetry sensor replace it by original replacement parts. In case of damage of the 'SpO2 Adapter Cable' replace it by original replacement parts.
	SDM defective	If problem persists contact qualified service personnel.
	SDM defective	Refer to *section 4.2.4* "*SDM specific troubleshooting*" to further evaluate the problem.
P0302 Sensor's red LED does not light (message 'Connect sensor' <u>not</u> displayed)	As a safety precaution sensor or SDM did switch off all power consuming parts	Refer to Status Messages 'Temp. limiter active', 'Sensor problem 38', 'Sensor problem 42', 'Sensor fault 39', 'Sensor fault 43' (see *Technical Manual for the SDM*).
	Red LED defective	Refer to messages 'Sensor problem 20', 'Sensor fault 20' and 'Sensor fault 21' (see *Technical Manual for the SDM*).
P0303 Message 'Sensor problem 10'	Membrane related (no or defective membrane)	Membrane the sensor if membrane is missing. Change the membrane if it is damaged, has a loose fit, or if there is trapped air or dry electrolyte under the membrane.
	Wrong / expired calibration gas was used during last calibration	Verify that SenTec Service Gas is used. If expired replace with a new gas bottle!
	Substantial gas leak in Docking Station	Refer to P0502 **Note**: In this situation the message 'Gas leak in DS' would not display as 'Sensor problem 10' has a higher internal rank.
	PCO2 electrode contaminated	If after having changed the sensor membrane the problem persists contact qualified service personnel.

Problem	Possible Cause(s)	Recommended action(s)
		Clean the sensor as described in *section 3.1.7* *"Cleaning / Inspecting without Membrane"*. Then calibrate the sensor.
	SenTec TC Sensor defective	If the problem persists the SenTec TC Sensor is defect. Replace it with a new one.
	Calibration Module defective	Replace the Calibration Module according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SDM defective	Refer to *section 4.2.4* *"SDM specific troubleshooting"* to further evaluate the problem.
P0304 PCO2 slow (too slow) / Message 'Sensor problem 11, 14' OR PO2 slow (too slow) / Message 'Sensor problem 74'	Membrane related (defective or dried up electrolyte)	Change the membrane : - if it is damaged or missing, has a loose fit, or if there is trapped air or dry electrolyte under the membrane - sensor calibration takes almost 14 minutes or cannot be completed within 14 minutes **Note**: If the PCO2 calibration takes 14 minutes the message 'PCO2 slow' displays and PCO2 subsequently will be flagged as questionable. **Note**: If the PCO2 calibration cannot be finished within 14 minutes the message 'Sensor problem 11' displays and PCO2 subsequently will be flagged as invalid. **Note**: If the calibration cannot be finished within approx. 30 minutes – due to failed extended calibration – the message 'Sensor problem 14' displays and PCO2 subsequently will be flagged as invalid. **Note**: If the PO2 calibration cannot be finished within 14 minutes the message 'Sensor problem 74' displays and PO2 subsequently will be flagged as invalid.
	PCO2 electrode and/ or white PO2 sensing spot contaminated	If after having changed the sensor membrane the calibration still takes almost 14 minutes or cannot be completed within 14 minutes contact qualified service personnel to clean the sensor without membrane.
		Clean the sensor as described in *section 3.1.7* *"Cleaning / Inspecting without Membrane"*. Then calibrate the sensor.

Problem	Possible Cause(s)	Recommended action(s)
	SenTec TC Sensor defective	If the problem persists the SenTec TC Sensor is defect. Replace it with a new one.
P0305 PCO2 sensitivity of the sensor low / Message 'Sensor problem 12' OR PO2 sensitivity of the PO2 sensor low / Message 'Sensor problem 72'	Membrane related (defective or dried up electrolyte)	Change the membrane: - if it is damaged or missing, has a loose fit, or if there is trapped air or dry electrolyte under the membrane - if the 'Sensitivity Test' fails. **Note**: If the 'Sensitivity Test' fails the message 'Sensor problem 12' displays and PCO2 subsequently will be flagged as invalid **Note**: If the 'Sensitivity Test' fails the message 'Sensor problem 72' displays and PO2 subsequently will be flagged as invalid
	PCO2 electrode and/ or white PO2 sensing spot contaminated	If after having changed the sensor membrane the 'Sensitivity Test' still fails contact qualified service personnel to clean the sensor without membrane.
		Clean/Inspect the sensor as described in *section 3.1.7 "Cleaning / Inspecting without Membrane"* and perform the 'Sensitivity Test' as described in *section 3.1.8 "PCO2 / PO2 Sensitivity & Calibration Duration"*. If problem persists contact SenTec authorized service personnel.
	SenTec TC Sensor defective	If the problem persists the SenTec TC Sensor is defect. Replace it with a new one.
	Docking Station Solenoid Valve defective **Note:** Only for SMB 7.00 or lower.	If problem persists the Docking Station Solenoid Valve is defective. Replace it by original replacement parts according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0306 Status Message 'Temp. limiter active' / Message 'Sensor problem 38-42'	Temperature of the SenTec TC Sensor is increased, e.g. because of warming lamps or electric blankets	Shield sensor from heat.
	SenTec TC Sensor defective	If the problem persists the SenTec TC Sensor is defect. Replace it with a new one.
	SDM defective	Refer to *section 4.2.4 "SDM specific troubleshooting"* to further evaluate the problem.

Problem	Possible Cause(s)	Recommended action(s)
P0307 Sensor is blocked in Membrane Changer tool	Membrane change tool is blocked	Open the Membrane Change Tool as described in *section 3.5 "Opening the Membrane Changer"*.
P0308 SenTec TC Sensor calibration does not start	Sensor temperature is too low	Wait until the sensor temperature is less than 0.5 °C below the SET temperature.
		If problem persists, test the same sensor connected to another SDM using another extension cable.
	SenTec TC Sensor defective	If the problem persists the SenTec TC Sensor is defect. Replace it with a new one.
	SDM defective	If problem (i.e. testing the sensor connected to another SDM) does not persist, then the problem is related to the SDM, refer to *section 4.2.4 "SDM specific troubleshooting"*, to further evaluate the problem.
P0309 OxiVenT™ Sensor connected to SDM, but PO2 measurement flagged to be invalid or not available	PO2 option of the SDM not activated or – if activated - PO2 not enabled in the menu of the SDM	Ensure that PO2 option of the SDM is activated and PO2 is enabled in the menu of the SDM. After doing so, verify that the off-centered white spot is illuminated in green cyan color.
	LED of the PO2-module defective	The sensor can still be used for monitoring of the other parameters but PO2. Replace OxiVenT™ Sensor if you wish to continue monitoring PO2. **Note**: In this case the SDM should display the message 'Sensor problem 70' (see *Technical Manual for the SDM*).
	Photodiode of the PO2-module defective	The sensor can still be used for monitoring of the other parameters but PO2. Replace OxiVenT™ Sensor if you wish to continue monitoring PO2. **Note**: In this case the SDM should display the message 'Sensor problem 71' (see *Technical Manual for the SDM*).

Problem	Possible Cause(s)	Recommended action(s)
	PO2-module error detected	General PO2-module error detected (e.g. off-centered white spot missing).
		The sensor can still be used for monitoring of the other parameters but PO2. Replace OxiVenT™ Sensor if you wish to continue monitoring PO2.
		Note: In this case the SDM should display the message 'Sensor problem 73' (see *Technical Manual for the SDM*).

4.2.4   SDM specific troubleshooting

Table 9   SDM specific troubleshooting

Problem	Possible Cause(s)	Recommended action(s)
P0400 SDM not operational, SDM LEDs not illuminated	SDM switched off	Switch on SDM.
	SDM not connected to mains and battery depleted	Connect the SDM to the mains. Allow battery to charge.
	Mains power supply defective	Choose another mains power supply for connecting the SDM.
	SDM defective	Switch the SDM off and on again.
		If problem persists contact qualified service personnel.
	Main fuses defective	Replace main fuses according to section 5.4 Replacement, main fuses.
	SDM defective	Contact SenTec authorized service personnel.
	AC/DC Power Supply not connected	Connect AC/DC Power Supply according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	AC/DC Power Supply defective	Replace AC/DC Power Supply according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**

Problem	Possible Cause(s)	Recommended action(s)
	SMBM (Motherboard) defective	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0401 Display is dark, AC Power / Battery indicator (green / yellow LED) illuminated ON / OFF indicator (green LED) dark	SDM switched off	Switch on SDM. If problem persists contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	Power ON/OFF Switch not connected	Connect Power ON/OFF Switch according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	Power ON/OFF Switch defective	Replace Power ON/OFF Switch according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBC (Controller Board) defective	Replace SMBC according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBM (Motherboard) defective	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0402 fully charged Battery is discharged after less than 4 h	Battery defective	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	Insufficient capacity of the rechargeable Lithium Battery	Replace Rechargeable Lithium Battery according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	Rechargeable Lithium Battery defective	Replace Rechargeable Lithium Battery according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**

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Problem	Possible Cause(s)	Recommended action(s)
	MPB (Multiparameterboard, SM1A) defective	Replace MPB according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBC (Controller Board) defective	Replace SMBC (Controller Board) according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	Docking Station Module defective	Replace Docking Station Module according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBM (Motherboard) defective	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	Display Module defective	Replace Display Module according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0403/P0504 Display is dark, ON / OFF indicator is illuminated OR Display is not readable (dark)	SDM in Sleep Mode	Press any button. If the problem persists switch the SDM off and on again. If problem persists contact qualified service personnel.
	Brightness not adjusted correctly.	Switch the monitor off and on again. Then readjust the brightness ('UP/DOWN Buttons').
	SDM defective	Switch the SDM off and on again. If problem persists contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	Display Module not connected	Connect Display Module according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	Display Module defective	Replace Display Module according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**

Problem	Possible Cause(s)	Recommended action(s)
	SMBC (Controller Board) defective	Replace SMBC according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBM (Motherboard) defective	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0405 POST screen does not disappear	POST failed	Write down the Error code, switch the SDM off and on again. If problem persists contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	SMBC (Controller Board) defective	Replace SMBC according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBM (Motherboard) defective	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0406 SDM does not react if any button is pressed	Menu-Access disabled	Refer to P0420
	SDM firmware is not responding (firmware has crashed)	Switch the monitor off and on again. If problem persists contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	Keyboard not connected	Connect Keyboard according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	Keyboard defective	Replace Keyboard according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**

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Problem	Possible Cause(s)	Recommended action(s)
	SMBC (Controller Board) defective	Replace SMBC according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBM (Motherboard) defective	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0407 'Watch battery low' displays	Internal watch / clock battery is low	Must be replaced, contact qualified service personnel. **Note**: Refer to the sub-section 'POST' in the *Technical Manual for the SDM* and to Status Messages 'Watch battery low' and 'Set Date / Time'.
	SDM defective	Contact SenTec authorized service personnel.
	Internal battery on SMBC (Controller Board) low	Replace internal battery on SMBC according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBC (Controller Board) defective	Replace SMBC according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0408 Wrong / unstable barometric pressure	Barometer chip defective	Verify that the barometric pressure reading of the SDM is stable during calibration and does not deviate from a known calibrated reference barometer by more than 3 mmHg (0.4 kPa). Otherwise contact qualified service personnel. **Note**: The 'Barometer Icon' only displays if PCO2 is enabled and the SenTec TC Sensor is connected to the SDM and inside the Docking Station. **Note**: Also refer to Status Messages 'Atm. P. unstable' and 'Barometer fault'.
	SDM defective	Contact SenTec authorized service personnel.
	MPB (Multiparameter-board, SM1A) defective	Replace MPB according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**

Problem	Possible Cause(s)	Recommended action(s)
P0409 Fan is noisy	Fan defective or polluted	Remove mains connection and – if active – wait until fan operation stops, then clean ventilation slots. Contact qualified service personnel if problem persists.
	SDM defective	Contact SenTec authorized service personnel.
	Fan polluted	Clean case and Fan according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	Fan defective	Replace Fan according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0410 Fan is blocked	Fan defective or polluted	The fan has to be able to rotate freely. Check ventilation slots if something is blocking the fan. If problem persists contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	Fan not connected	Connect Fan according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	Fan polluted	Clean case and Fan according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	Fan defective	Replace Fan according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBC (Controller Board) defective	Replace SMBC according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**

Problem	Possible Cause(s)	Recommended action(s)
	SMBM (Motherboard) defective	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0411 No sound	Auditory alarm signals are PAUSED or OFF	Reactivate auditory alarm signals (if necessary)
	Volume is on minimum	Adjust the volume in the menu "Alarm Settings".
	Speaker is defective	Verify that 3 beeps are audible during POST. If problem persists contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	Speaker not connected	Connect Speaker according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	Speaker defective	Replace Speaker according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBC (Controller Board) defective	Replace SMBC according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBM (Motherboard) defective	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0412	AC Power Cord is defective	Replace the AC Power Cord.
	Power Entry Module defective	Contact qualified service personnel.
	Fuse Holder not mounted correctly	Mount Fuse Holder correctly according to *section 5.4 "Replacement, main fuses"*.
	SDM defective	Contact SenTec authorized service personnel.

Problem	Possible Cause(s)	Recommended action(s)
It is not possible to connect the AC power cord in the SDM AC power connector	AC Power Connector defective	Replace AC Power Connector according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0413 Disruptive discharges during the high tension test	SDM defective	Contact SenTec authorized service personnel.
	SMBM (Motherboard) defective	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0414 Wrong or no analog output	SDM defective or wrong / defective cable	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	SMBC (Controller Board) defective	Replace SMBC according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBM (Motherboard) defective	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0415 No communication over RS-232	Wrong serial communication protocol	Make sure to select appropriate serial protocol
	SDM defective or wrong / defective cable	Contact qualified service personnel.
	SDM defective	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	SMBC (Controller Board) defective	Replace SMBC according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**

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Problem	Possible Cause(s)	Recommended action(s)
	SMBM (Motherboard) defective	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0416 No alarm on speaker, nurse call	Auditory alarm is muted	Auditory alarm signals can be muted for 1 minute, 2 minutes or permanently with the Alarm Mute Button. Push the Alarm Mute Button. Refer to P0411.
	SDM defective	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	SMBC (Controller Board) defective	Replace SMBC according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	SMBM (Motherboard) defective	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0417 Safety test does not comply	SDM defective	Contact SenTec authorized service personnel.
	Protective Earth Resistance is more than 0.2 Ω	Control the Protective Earth wiring between the AC Power Connector, the Equipotential Terminal and the Gas bottle. ⚠ **To be performed by SenTec authorized service technicians only.**
	Protective Earth wiring defective	If problem persists, replace Protective Earth according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
	Leakage current too high	Replace SMBM according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**

Problem	Possible Cause(s)	Recommended action(s)
P0418 Gas Level Indicator shows wrong indication	Gas level indicator shows wrong results	Repeat the test with the same sensor connected to the same SDM using the Docking Station of another SDM (Both SDMs need to be switched on). Make sure the sensor is in the Docking Station and the door is closed correctly, wait 5 seconds. Contact qualified service personnel if the problem persists.
	SDM defective	Contact SenTec authorized service personnel.
	DS Module defective	Replace DS Module according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only.**
P0419 Despite a SenTec TC Sensor is connected to the SDM the message 'Connect sensor' displays	Refer to P0300	
P0420 SDM Menu cannot be accessed	Menu cannot be activated when pressing menu button, a long low tone is audible instead	Blocked menu access: Menu access has been deactivated by the Responsible Organization.

4.2.5   Docking Station specific troubleshooting

Table 10   Docking Station specific troubleshooting

Problem	Possible Cause(s)	Recommended action(s)
P0500 Docking Station door does not close properly	Sensor cable jammed in the door	Adjust cable and close the Docking Station door properly.
	Sensor not inserted properly in the Docking Station door.	Insert the sensor properly and close the door.
	Mechanical defect of the Docking Station door	Contact qualified service personnel.
	Mechanical defect of the Docking Station door	Replace Docking Station door according to *section 5.5* *"Replacement, Docking Station Door"*.
	Gasket not placed correctly	Place gasket correctly in the chamber in the Docking Station according to *section 5.6* *"Replacement, Docking Station Gasket"*.
	Docking Station door mechanically defective	Replace Support for Docking Station Door according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only**.
P0501 Message 'Docking Station Fault' is displayed	Contaminations (e.g. gel residues) disturb the gas flow	Clean Docking Station and SenTec TC Sensor and then insert the sensor into the Docking Station. If problem persists contact qualified service personnel. Note: Refer to the *Instruction Manual for the SDMS*.
	Docking Station defective	Contact SenTec authorized service personnel.
	Docking Station Module defective	Replace Docking Station Module according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only**.
P0502 Message 'Gas leak in DS' is displayed or a gas leak is	Sensor not properly positioned in Docking Station during last calibration.	Verify that the sensor is clean and is properly placed into the holder at the inside of the Docking Station door and that the door properly closes (refer to the *Instruction Manual for the SDMS*).

Problem	Possible Cause(s)	Recommended action(s)
suspected (see Status Code DP02 in memory dump)	Gasket of Docking Station contaminated	Clean the Docking Station gasket with a cotton swab with 70% isopropanol. Remove any residual threads and fibers and allow to dry. **Note**: Always clean the sensor before inserting it into the Docking Station.
	Gasket of Docking Station defective or missing	Carefully inspect the gasket and verify that it is present and well embedded in its notch. If damaged contact qualified service personnel.
	Docking Station door and / or closing mechanism defective	Carefully inspect the door and the closing mechanism for mechanical or functional damage. The closing mechanism must properly lock in place. If damaged contact qualified service personnel.
	Docking Station door mechanically defective	Replace Docking Station door according to *section 5.5 "Replacement, Docking Station Door"*.
	Gasket defective / missing	Place gasket correctly in the chamber in the Docking Station according to *section 5.6 "Replacement, Docking Station Gasket"*.
	SDM defective	Contact SenTec authorized service personnel.
	Calibration Module defective	Replace Calibration Module according to the *Repair Manual for the SDMS*. ⚠️ **To be performed by SenTec authorized service technicians only**.
	Docking Station Module defective	Replace Docking Station Module according to the *Repair Manual for the SDMS*. ⚠️ **To be performed by SenTec authorized service technicians only**.
	Note: Also refer to messages 'Gas leak in DS', 'Leak test in progress' described in the *Technical Manual for the SDM*.	
P0503 Service Gas bottle cannot be installed properly	Plastic lid of the new Service Gas bottle not removed	Remove the plastic lid and install the Service Gas bottle.
	Foreign body in the slot for the Service Gas bottle	Switch off the SDM, disconnect it from the mains supply and remove the foreign body from the slot on the rear panel of the SDM.

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Problem	Possible Cause(s)	Recommended action(s)
	Thread of the Service Gas bottle is damaged	Use a new Service Gas bottle and install it as described in *Instruction Manual for the SDMS*.
	SDM is defective	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	Docking Station Module defective	Replace Docking Station Module according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only**.
P0504 Consumption of the *Service Gas* is higher than usual (message 'Gas leak in DS' does not display)	Low pressure side residual gas flow too high	Verify whether DP01 status code is flagged. Contact qualified service personnel.
	High pressure part of the Docking Station Module is leaky	Contact qualified service personnel.
	Unstable sensor requiring too many calibrations	Remembrane sensor and observe gas consumption. If problem persists, contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	Gasket in the Docking Station Module thread for the Service Gas is polluted or damaged	Clean gasket in the Docking Station Module thread according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only**.
	Docking Station Solenoid Valve defective	If problem persists the Docking Station Solenoid Valve is defect. Replace it by original replacement parts according to the *Repair Manual for the SDMS*. ⚠ **To be performed by SenTec authorized service technicians only**.

Problem	Possible Cause(s)	Recommended action(s)
P0505 Sensor calibration does not start, Sensor LED is illuminated	Refer to P0308	
P0506 Gas Level Indicator shows wrong indication	Refer to P0418	

5 Repairs of the SDM

Repairs described in this chapter do not require opening the SDM`s cover and shall be carried out by qualified service personnel only.

Repairs that require opening the cover of the SDM are to be performed by SenTec authorized service technicians only (i.e. trained by SenTec AG or accredited partners) and are described in detail within the *Repair Manual*.

Prior to maintenance, service or repairs all components of the SDMS must be cleaned and disinfected. If equipment is send to service personnel, a local SenTec representative or to SenTec AG a completed *"Certificate for Disinfection"* (*see section 8.7*) must be attached.

If you need to return devices for service or repair follow the shipment instructions in *section 8.6 "Instructions for Shipment"*.

Send defective parts together with the completed *"Repair or Investigation Request Form"* to your local SenTec representative. The *"Repair or Investigation Request Form"* may be copied from *section 8.3 "Repair or Investigation Request Form"*.

To ensure traceability – a regulatory requirement – SenTec AG needs to know the serial and LOT numbers as well as software versions of all components of the SDMS. **This means, if you replace parts of the SDM of if you perform a software update you must report the serial number of the respective SDM and the serial and LOT numbers of the replaced parts using the *"Repair Reporting Form"* see *section 8.4* to your local distributor.**

For spare parts and test tools refer to in *section 8.2 "Testing Accessories and Spare Parts"*.

Tools	• Screwdriver large slotted 3 mm
	• A pair of pointed tweezers
	• A pair of normal tweezers

> **WARNING:** Maintenance and repairs requiring removal of the case or covers may only be carried out by SenTec authorized service personnel trained by SenTec AG or accredited partners.

> **WARNING:** Use only accessories and spare parts supplied or recommended by SenTec AG. Do not perform other service and repair activities than specified and described by SenTec AG. Failure to comply may result in physical injury, inaccurate measurements, and/or damage to the device.

> **WARNING:** Before replacing fuses of the SDM, disconnect the device from the AC power.

> **CAUTION:** Follow ESD (Electrostatic discharge) precautions when working with the SDM, especially when disassembling and reassembling the SDM and when handling any of the components. Use an ESD protective wrist-strap and table-mat connected to Earth while working with the electronics.
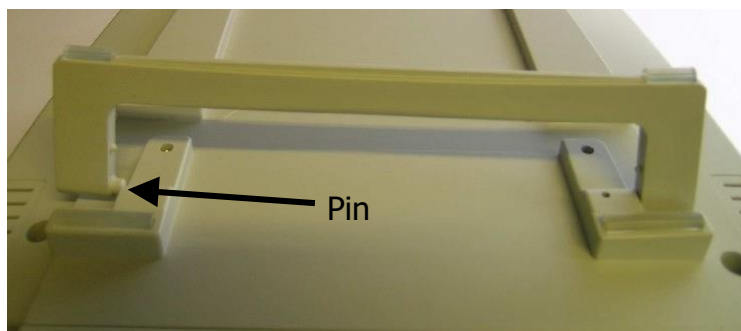
5.1 Prior to Repair

1. Prior to repair all components of the SDMS must be cleaned and disinfected as described in the corresponding section of the *Technical Manual for the SDM*. Check that the sender completed and enclosed the *"Disinfection Certificate"* (*see section 8.7*).

2. If necessary, clean and disinfect the device as described in the corresponding section of the *Technical Manual for the SDM*.

3. Set the ON/OFF Switch of the SDM to OFF.

4. Disconnect all connections on the rear panel of the device.

5.2 Replacement, Tip-up Foot

1. Follow the procedure described in section 5.1 "Prior to Repair".

2. Fold out the tip-up foot. Expand it on one side to release the first pin from the positioning hole. Then remove the whole Tip-up foot.

3. Fix the new tip-up foot (see *section 8.2 "Testing Accessories and Spare Parts"*) by inserting one pin into the positioning hole on one side. Enlarge the tip-up foot and engage the second pin on the other side.

Figure 12   Replacement, Tip-up Foot

5.3   Replacement, Silicon Foot

1.   Follow the procedure described in *section 5.1 "Prior to Repair"*.

2.   Clean the groove for the silicon foot with a cotton swap soaked with 70% isopropanol.

3.   Put one drop of silicon glue (see *section 8.2 "Testing Accessories and Spare Parts"*) in the groove.

4.   Insert the new silicon foot into the groove by pressing firmly.

5.   Allow the glue to dry.

Figure 13   Replacement, Silicon Foot

## 5.4   Replacement, main fuses

1.   Follow the procedure described in *section 5.1 "Prior to Repair"*.

2.   Remove the fuse holder from the AC Power Connector by compressing the two tabs on both sides of the lid and pulling out the fuse holder according to *Figure 14 Replacement, Main Fuses*.

3.   Replace the defective fuses with time delay, high breaking capacity fuses, by fuses with rated current as specified on the SDM rear panel (see section 8.2 "Testing Accessories and Spare Parts")

4.   Reinsert the holder into the AC Power Connector.
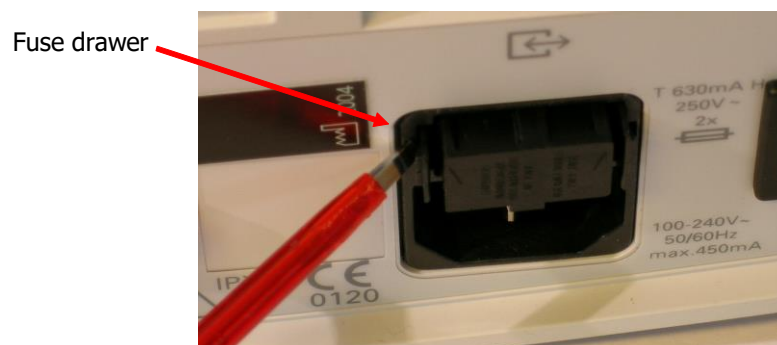
Figure 14   Replacement, Main Fuses

5.5 Replacement, Docking Station Door

1. Follow the procedure described in *section 5.1 "Prior to Repair"*.

2. Open the Docking Station Door (to an angle of approximately 120° (*see Figure 15 Docking Station Door Insertion*).

3. Lift the mounting link for the hinge and remove the Docking Station Door by pulling it out and pressing it down at the same time.

4. Insert the new Docking Station Door (parallel to the case) with an aperture angle of the door of 45° (see *section 8.2 "Testing Accessories and Spare Parts"*). The door must not be closed further, as this could damage the pressure spring. First press on the bottom, then on the top of the door to insert the hinge into the mounting link.

5. Switch on the monitor.

6. Put the sensor into the Docking Station to calibration the sensor. After calibration wait 6 minutes to verify that the message `Gas leak in DS´ does not display.

mounting link for the hinge

pressure spring   approx. 120º
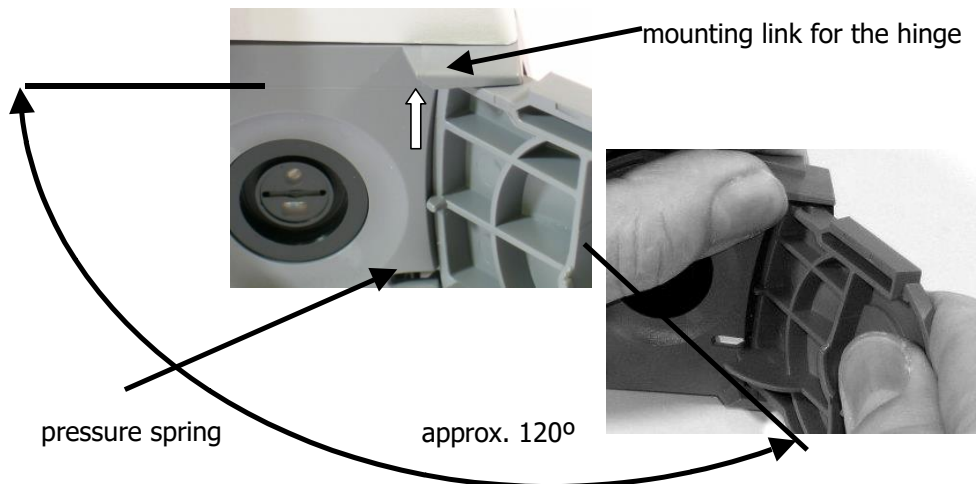
Figure 10   Docking Station Door removal


mounting link for the hinge
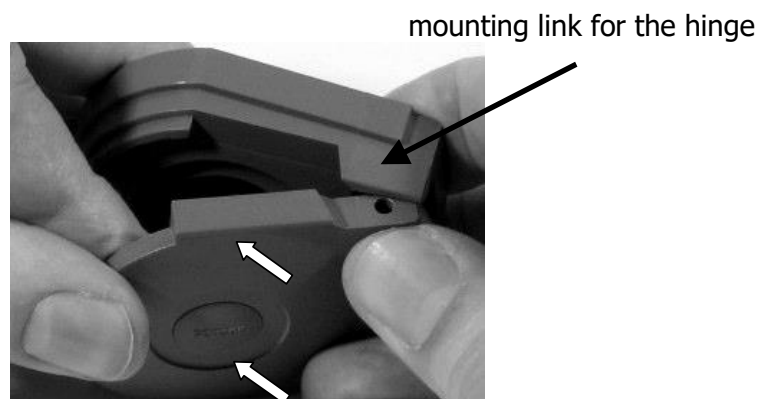
Figure 15   Docking Station Door Insertion

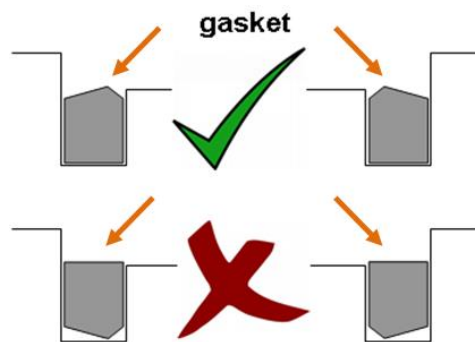# 5.6   Replacement, Docking Station Gasket

1. Follow the procedure described in *section 5.1 "Prior to Repair"*.

2. Open the Docking Station door.

3. Remove the defective gasket using tweezers. Take care not to damage the lining groove.

4. Clean the lining groove using a cotton swap soaked with 70% isopropanol, allow to dry.

Note: Do not use grease or talcum powder for pre-treatment of gasket before inserting it. Clean especial carefully the lining groove, as described above, if grease or talcum powder has been used before.

5. Insert a new (**asymmetric**) gasket (see *Figure 16   Replacement, Docking Station Gasket and Figure 17   Positioning of the Docking Station Gasket*) by pressing it with a cotton swab soaked with 70% isopropanol into the lining groove. Make sure that no cotton fibers remain on the gasket as this might cause leak problems.

6. Allow to dry.

7. Switch on the monitor.

8. Put the sensor into the Docking Station to calibration the sensor. After calibration wait 6 minutes to verify that the message "Gas leak in DS" does not display.
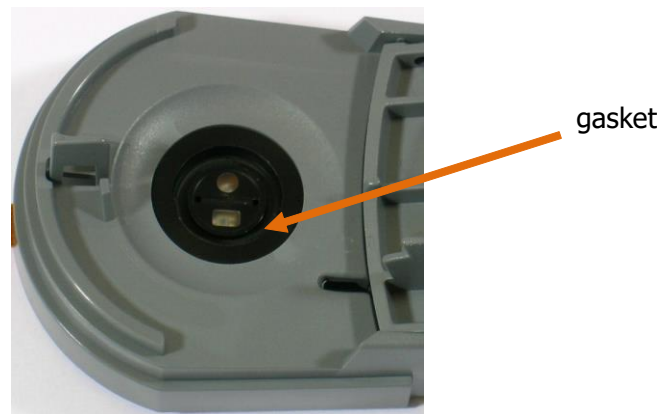
gasket

Figure 16   Replacement, Docking Station Gasket

Figure 17   Positioning of the Docking Station Gasket

6 Software Updates

The field-upgradable software of the SDM consists of two items:

1. SMBC – Controller Board software (User Interface, Memory and Interface management)

2. MPB – Multiparameterboard software (Signal Analysis Algorithm)

The SMBC and MPB software can be updated by trained and authorized personnel by flashing a new version in the flash memory of the existing boards (note: detailed instructions are included in separate documents).

> **WARNING:** Software updates of the SDM must be carried out by trained and authorized personnel. Software updates must be reported to SenTec by using the Repair Reporting Form, *see section 8 "Appendix"*, to ensure traceability.

7 Disposal

The SDMS is constructed 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.

7.1   SenTec Digital Monitor

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

7.2   Cables

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

7.3   SenTec TC Sensors

Return the SenTec TC Sensors to your local distributor.

7.4   Service Gas Bottle

Dispose the gas bottles according to local regulations. Make sure that only empty gas bottles are disposed.

> **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.

7.5   Consumables

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

8 Appendix

8.1 Protocol for Safety & Functionality Test

This protocol is intended to be used by qualified service personnel.

Please refer to the document:

HB-005638

8.2 Testing Accessories and Spare Parts

> **WARNING:** Use only testing accessories and spare parts supplied or recommended by SenTec AG. Use of other than supplied or recommended parts may result in physical injury, inaccurate measurement and/or damage to the device.

Contact SenTec authorized service personnel.

8.3 Repair or Investigation Request Form

Please refer to the document:

HB-005643

8.4 Repair Reporting Form

Please refer to the document:

HB-005729

8.5 Customer Feedback Form

Please refer to the document:

HB-006872

8.6 Instructions for Shipment

Please refer to the document:

HB-005891

8.7 Certificate for Disinfection

Please refer to the document:

HB-005637

8.8 SDMS Maintenance Checklist

This checklist is intended to be used by the operator.

Please refer to the document:

HB-007601

8.9 Interfaces - Pin Assignement

> **WARNING:** The mains power supply of the SenTec Digital Monitor (SDM) is separated by two Means of Patient Protection (MOPPs) between the sensor port (for the applied part, the sensor) and the interface connectors. The three interface connectors - serial data port, Multipurpose I/O port (analog outputs, nurse call), LAN port - of the SDM are not separated from each other. If at a time accessory equipment is connected to only one of the three interface connectors no additional safety measures are necessary to comply with the requirements of IEC 60601-1. If however accessory equipment is simultaneously connected to two or three of the SDM's interface connectors additional safety measures may be required to be compliant with the requirements of IEC 60601-1. In case of doubt consult qualified technicians.

8.9.1   Sensor Connection Port
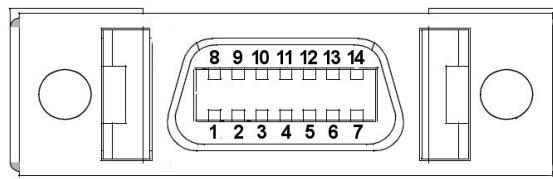
Figure 18   Sensor Connection Port

Table 11   Pin Assignment, Sensor Connection Port

Pin(s)	Signal
1 - 3	(reserved)
4	Signal Ground
5	Received Data (RX, from Sensor)
6	Transmitted Data (TX, to Sensor)
7 - 9	(reserved)
10	5 V, for sensor supply only
11	Supply Ground
12	3.3 V, for sensor supply only
13 - 14	(reserved)

8.9.2 The Serial Data Port (RS-232)
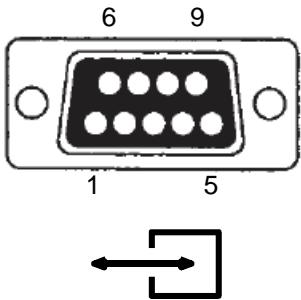
Figure 19   Serial Data Port (RS-232)

Table 12   Pin Assignment, Serial Data Port (RS-232)

Pin(s)	Signal
1	(reserved)
2	Transmitted Data (TX, from SDM)
3	Received Data (RX, to SDM)
4	(reserved)
5	Signal Ground
6 − 9	(reserved)

8.9.3 Multipurpose I/O Port
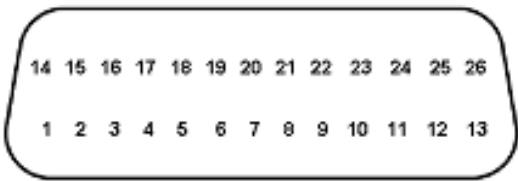
Figure 20   Multipurpose I/O Port

Table 13   Pin Assignment, Multipurpose I/O Port

	Pin(s)	Signal	Signal Range	Voltage
Analog Output	**1**	Pleth Signal	Voltage: 0 – 1.05 V Parameter Range: min – max (not selectable)	
	2	Pleth Ground		
	3	PR Signal	Voltage: 0 – 1.05 V Parameter Range: 30–80, 30–125, 50–120, 100–250, 30–250 (bpm)	
	4	PR Ground		
	5	SpO$_2$ Signal	Voltage: 0 – 1.05 V Parameter Range: 0-100, 50-100, 70-100, 85-100 (%)	
	6	SpO$_2$ Ground		
	7	PCO$_2$ Signal	Voltage: 0 – 1.05 V Parameter Range: 10-50, 25-55, 25-75, 35-100, 60-140, 75-200, 120-200, 0-75, 0-100, 0-200 [mmHg] / 1.5-7, 3.5-7.5, 3.5-10.0, 4.5-15.0, 8-18.0, 10.0-27.0, 16.0-27.0, 0-10.0, 0-15.0, 0-27.0 [kPA]	
	8	PCO$_2$ Ground		
	9 – 13	(reserved)		
	14	Ground		
	15 - 16	(reserved)		
	17	Ground		
	18 - 19	(reserved)		
	20 - 21	Ground		
	22	3.3 V, max. 15 mA		
	23	Ground		
Nurse Call	**24**	Common lead for Nurse Call relays 1 + 2	-	-
	(24 + 25)	Nurse Call relay 1	open, close	<u>closes</u> upon SDM audible alarm
	(24 + 26)	Nurse Call relay 2	close, open	<u>opens</u> upon SDM audible alarm

Note: Output of PO2, PI and HP data via the Analog Output is currently not supported.

8.9.4 Network Port (LAN)

The LAN port of the SDM is used to communicate with external computer based data collection systems. The LAN port is located on the rear panel of the SDM. The LAN port is a standard 10Base-T Ethernet connector. Use Category 3 (Cat3) or preferably Category 5 (Cat5) Ethernet cables for connection of the monitor to a network hub or switch. You may also use a cross-over Ethernet cable for direct connection of the monitor to a computer without a hub or switch.

Note: While trend data are downloaded via the LAN interface the serial interface of the SDM is inactivated. Once data download via the LAN interface is completed the serial interface is reactivated.

8.10 Technical Specifications

See the corresponding section of the *Technical Manual for the SDM*.

8.11 Contact

Phone: +41 61 726 97 60

Monday to Friday, 08:30 - 12.00 und 14.00 - 17:00 (GMT +01:00)

e-Mail: service@sentec.com

HB-005615-j
Date of release: 02/2019

SenTec Digital Monitoring System