

Service Manual

sentec



for the SenTec Digital Monitoring System
(Software Version SMB V06.20; MPB V04.04)

Warranty

The manufacturer warrants to the initial purchaser that each new component of the SenTec Digital Monitoring System (see list of components) will be free from defects in workmanship and materials. The manufacturer's sole obligation under this warranty is to replace any component – for which the manufacturer acknowledges the warranty cover - with a replacement component.

Warranty Exclusions

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, or if instrument repairs are not carried out by SenTec authorized service personnel.

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

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Patient Monitor

WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 60601-1/CAN/CSA C22.2 No. 601.1,
IEC 60601-1-4, IEC 60601-2-23
20LW



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Abbreviations

CO ₂	Carbon dioxide
DS	Docking Station
O ₂	Oxygen
PaCO ₂	Arterial carbon dioxide partial pressure
PCB	Printed circuit board
PcCO ₂	Cutaneous carbon dioxide partial pressure
PCO ₂	PaCO ₂ calculated from the measured PcCO ₂ (cutaneous blood gas measurement)
POST	Power-On Self-Test
PR	Pulse rate
SaO ₂	Arterial oxygen saturation
SDM	SenTec Digital Monitor
SDMS	SenTec Digital Monitoring System
SpO ₂	Functional oxygen saturation of arterial hemoglobin (pulse oximeter measurement)

1 Introduction

This Manual is intended to provide information on the service and repair of the SenTec Digital Monitoring System (SDMS). The SenTec Digital Monitoring System consists of the Sentec Digital Monitor (SDM), the V-Sign™ Sensor and accessories. This Manual is to be used by qualified service personnel only. The service personnel should read this Manual carefully before performing any service or repairs. In particular the *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. Refer to the following Manuals and Directions for Use:

System component	Manual	Content
SenTec Digital Monitoring System	Instruction Manual for the SDMS	Getting started / Using the SDMS
Sentec Digital Monitor	Technical Manual for the SDM	Detailed information on the SDM
Sentec Digital Monitoring System	Service Manual for the SDMS	Provides information on repair and service procedures that do not require to open the cover of the SDMS
Sentec Digital Monitoring System	Repair and Service Manual for the SDMS	Provides information on repair and service procedures of the SDMS

Table 1 Related Documents

1.2 Safety Information

Warnings

This symbol identifies a **WARNING** statement. Warning statements refer to conditions that may lead to risk or injury to the patient or user.



Cautions

This symbol identifies a **CAUTION** statement. Caution statements refer to conditions that may lead to damage or malfunction of the equipment.



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

1.2.1 General Safety Information

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



WARNING: The SDM must be connected to a grounded (3-wire) AC power outlet. Ensure that power and protective ground lines are connected correctly.



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: 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: Equipment is protected against electrostatic discharge. The display may be temporarily affected during discharge to chassis ground, but will rapidly recover.



WARNING: This device has been tested and found to comply with the requirements for medical devices according to the IEC 60601-1-2 (second edition), 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: 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.



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: Do not spray, pour, or spill any liquid on the SDM, its accessories, connectors, switches, or openings in the chassis.



WARNING: If the SDM has been wetted accidentally it must be wiped dry externally, allowed to dry thoroughly, and be inspected by qualified service personnel before further use.



WARNING: If connecting the SDM to any other equipment, verify proper operation before clinical use. Both the SDM and the equipment connected to it must be connected to a properly grounded AC power outlet. Combinations of equipments must be in compliance with IEC/UL 60601-1 systems requirements. Anyone who configures a medical system by connecting additional equipment to the SDM is responsible for ensuring that the resulting system complies with the requirements of IEC 60601-1-1 and IEC 60601-1-2.



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



WARNING:

To maintain monitor readiness:

1. **ALWAYS** clean the sensor before putting it into the Docking Station!
2. **ALWAYS** store the clean sensor in the Docking Station after monitoring!
3. **ALWAYS** keep the monitor switched on!



CAUTION: Do not immerse the SDMS or the connectors of any connecting cables in liquid solution.



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



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. Use of other parts may result in injury, inaccurate measurements and/or damage to the device.



WARNING: Electronic components may contain toxic chemicals. Do not ingest chemicals from a broken electronic component.



CAUTION: Follow ESD (Electrostatic discharge) precautions when working with the SDM, especially when disassembling and reassembling the SDM and when handling any of its components.



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)

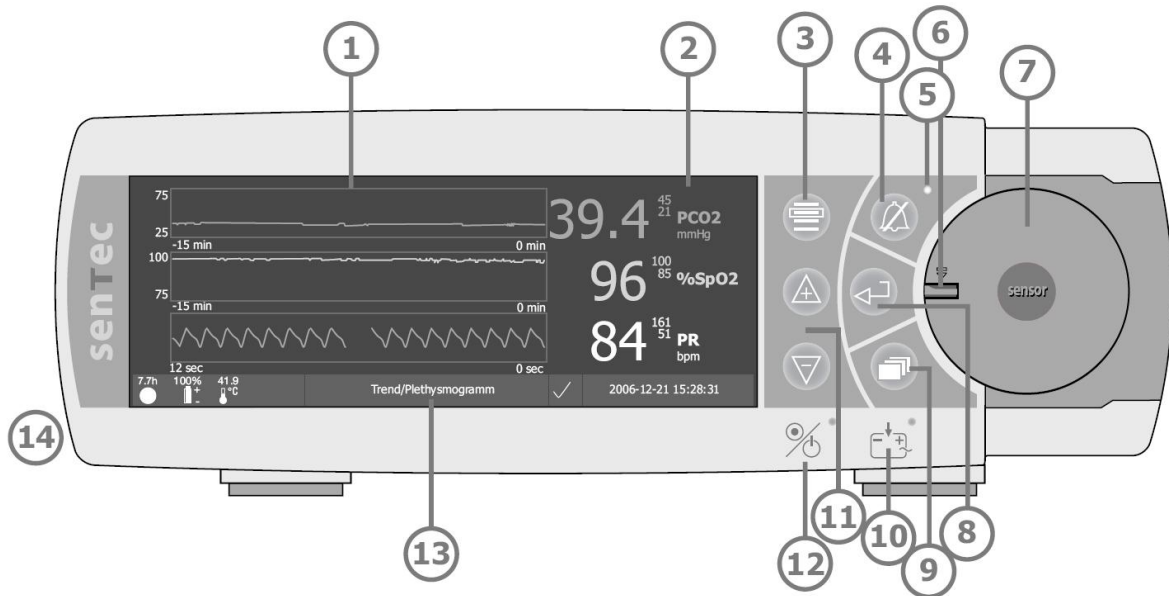
2.1 Components

The SDMS consists of the following components, accessories and disposables:

SenTec Digital Monitor	(REF: SDM)
V-Sign™ Sensor	(REF: VS-A/P)
V-Sign™ Disposable Set	(REF: VS-DSET)
Ear Clip	(REF: EC-A/P)
Multi-Site Attachment Rings for Adults, Pediatrics, Neonates	(REF: MAR-A/P/N)
Multi-Site Attachment Rings for Adults, Pediatrics	(REF: MAR-A/P)
Digital Monitor Extension Cable	(REF: AC-150)
Sensor Gel	(REF: Gel-04)
Service Gas	(REF: Gas-0812)
Mains Power Cord	
V-STATS installation CD	(REF: V-STATS)
Instruction Manual for SDMS	(REF: IM-xx)
User Manual CD	(REF: UMCD)
Quick Reference Guide	(REF: QRG-xx)

2.2 The SenTec Digital Monitor (SDM)

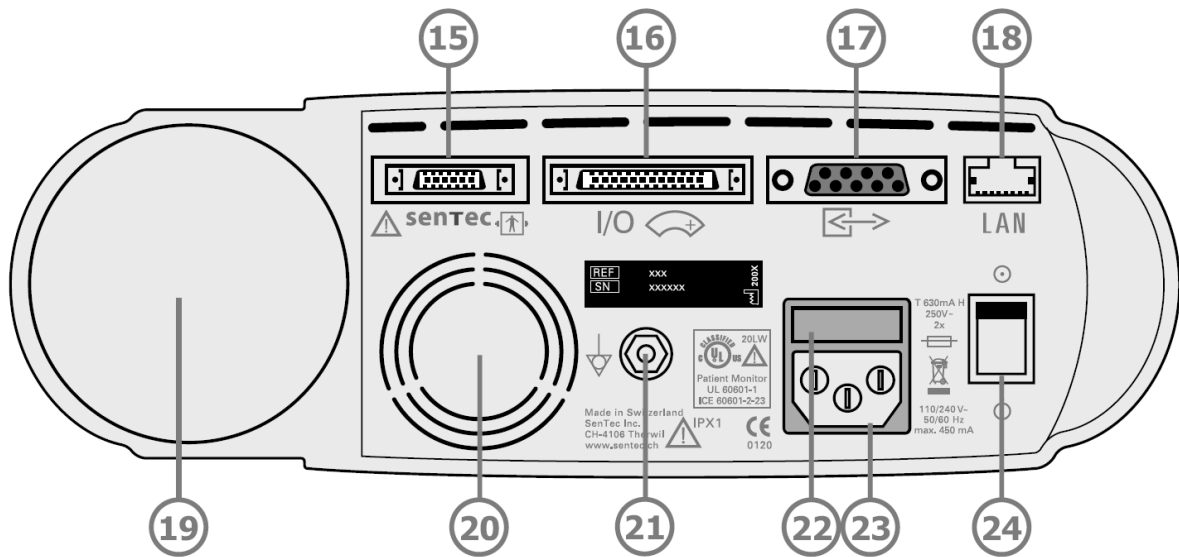
2.2.1 Front Panel



- 1** Trend Display Area
- 2** Numerical Display Area
- 3** Select Button
- 4** Alarm Mute Button
- 5** Alarm Mute Indicator (yellow LED)
- 6** Door Lock
- 7** Docking Station Door
- 8** Enter Button
- 9** Display Button
- 10** AC Power/Battery Indicator (green/yellow LED)
- 11** UP/DOWN Buttons
- 12** ON/OFF Indicator (green LED)
- 13** Status Bar
- 14** Speaker (on the side panel)

Figure 1 Front Panel of the SDM

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

* feature not currently available

Figure 2 Rear Panel of the SDM

3 Maintenance/Safety & Functionality Tests

To guarantee continuous performance, safety, and reliability of the equipment maintenance procedures and checks have to be performed regularly. The maintenance of the SDMS is subdivided into "Cleaning and Disinfection", "Routine Checks" and "Safety & Functionality Tests".

Note: Prior to maintenance, service or repairs all components of the SDMS must be cleaned and disinfected. If equipment is sent to service personnel, a local SenTec representative or to SenTec AG a completed "*Certificate of Disinfection*" (see page 55) must be attached.

"Cleaning and disinfection" procedures are described in the "Technical Manual for the SDM" and in the "Directions for use of the V-Sign™ Sensor".

"Routine Checks" that can be performed by the user are described in the "Instruction Manual for the SDMS" and in the "Technical Manual for the SDM".

The "Safety and functionality tests" specified in the present paragraph must be performed annually by qualified service personnel. If any of the tests specified below fails, the respective problem must be fixed before the equipment is returned to the user.

Note: To perform a complete "Safety & functionality test" all tests described in this chapter MUST be performed.

Note: Use the Protocol "Safety Related Test" (see 7.4 "*Protocol for Safety Related Test*", page 49) to guide you through the complete "Safety & Functionality test" and to document your test results. The system MUST pass all tests mentioned in this protocol.

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

3.1 V-Sign™ Sensor

3.1.1 Visual Inspection

Visually inspect the membrane of the sensor. If you suspect a damage of the membrane, exchange the membrane of the sensor. Visually inspect the sensor body for damages. Check the sensor cable for breaks or damages of the isolation. Check the sensor cable plug and its connectors for damages.

If any of the components of the sensor is irreversibly damaged, replace the sensor with a new V-Sign™ Sensor.

3.1.2 Labeling

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

If the serial number can not be found or read, read the serial number of the V-Sign™ Sensor out of the SDM (sub-menu "System Information") and write it on the plug of the sensor cable.

3.1.3 Sensor LEDs

Switch on the sensor and verify that the sensor emits red light. Then insert the sensor into the Docking Station and verify that the calibration display activates.

If these requirements are not fulfilled refer to *section 4.2.3 "Sensor specific troubleshooting", page 26* to further evaluate the problem.

3.1.4 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 $\pm 3\%$ SpO₂ and ± 3 bpm, respectively.

If these requirements are not fulfilled refer to section 4.2.3 "Sensor specific troubleshooting", page 26 to further evaluate the problem.

3.1.5 Function Test: PCO₂

Calibrate the sensor and apply it to the ear of a healthy person: Verify, that the PCO₂ readings equilibrate (stabilize) within 3 to 10 minutes and are within 33 to 47 mmHg after stabilization.

If this requirement is not fulfilled refer to section 4.2.1 "Troubleshooting PCO₂ Monitoring", page 24 to further evaluate the problem.

For testing the PCO₂ functionality sensor test equipment is available for SenTec authorized service personnel.

3.1.6 PCO₂ Sensitivity Test

Test the PCO₂ sensitivity as follows:

1. Following a calibration, expose the sensor for approximately 3 minutes to ambient air.
2. Reinsert the sensor into the Docking Station. The first displayed PCO₂ value should be at least 30 mmHg (4.0 kPa) lower than after calibration.
3. If this difference is not reached, exchange the membrane of the sensor and repeat the test.
4. If there is no improvement, clean the sensor following the instructions provided in section 5.2 "Cleaning the sensor without membrane", page 35 and repeat the test.

After a renewed missing of this difference, send the V-Sign™ Sensor to your local SenTec representative (refer to section 5.10 "Instructions for Shipment", page 41).

3.1.7 Sensor Temperature Surveillance

Connect the sensor to the SDM and switch the monitor on. Immerse the sensor into water of 45°C – 50°C. Verify that the red sensor LED switches off, a low priority alarm starts to sound and that the message "Sensor fault" or "Temp. limiter active" displays.

If the test fails, send the V-Sign™ Sensor to your local SenTec representative (see section 5.10 "Instructions for Shipment", page 41).

3.2 SenTec Digital Monitor

3.2.1 Visual Inspection


Visually check the entire SDMS for possible damages.

If you detect a damage, the SDM needs to be repaired according to *section 5 "Repairs", page 33.*

3.2.2 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, page 6*).

Rear panel: Labels of all ports, connectors and switches; label with SN, REF and , CE label, UL label and WEEE Disposable label (see *Figure 2, page 7*).

If the requirements for the front or rear panel are not fulfilled contact your local SenTec representative or send back the monitor according to *section 5.10 "Instructions for Shipment", page 41.*









3.2.3 POST

After switching on, the SDM initiates a Power-On Self-Test (POST): Some components of the SDM are checked. The display, as well as the visual and audible indicators (i.e. LED's and speaker) are shortly activated. The result of the POST is indicated by a ✓ (passed) or ✗ (failed) symbol.

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.

If the POST fails, an error message shows up at the bottom of the POST screen, see *section 4 "Troubleshooting", page 22.* The SDM needs to be repaired according to *section 5 "Repairs", page 33.*

3.2.4 Keyboard

5. Activate the Main Menu by pressing  once.
6. Select the menu "System Settings" by pressing  three times.
7. Activate the selection by pressing  once.
8. Select the item "Key Click" by pressing  six times.
9. Switch ON and OFF the Key Click by using the UP  and DOWN  Button. When the Key Click is ON you hear a beep when pushing a button.
10. Push the Display Button  to exit the menus.
11. If you push the Alarm Mute Button  the Alarm Mute Indicator (yellow LED) should lit.

If the requirements for the Keyboard are not fulfilled then contact your local SenTec representative or send back the monitor according to *section 5.10 "Instructions for Shipment", page 41.*

3.2.5 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 wrong refer to *section 4.2.5 "SDM", page 28* to further evaluate the problem.

3.2.6 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, first the Alarm Mute Indicator (yellow LED) and then 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, page 6* for location of the indicator LED's.
2. Control the display for inactive pixels during the POST.

If the requirements for the display and/or LED's are not fulfilled then contact your local SenTec representative or send back the monitor according to *section 5.10 "Instructions for Shipment", page 41.*

3.2.7 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 4.2.5 "SDM", page 28* to further evaluate the problem.

3.2.8 Fan

The fan is active if the battery is charging (AC Power/Battery Indicator lits yellow). The fan has to be able to rotate freely and without causing unusual noises. If you blow into the fan slits on the rear panel of the SDM when the fan is off, the fan has to rotate.

If the requirements for the fan are not fulfilled then refer to *section 4.2.5 "SDM", page 28* to further evaluate the problem.

3.2.9 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 PCO₂ 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 bigger than ± 5 mmHg (0.7 kPa) the SDM has to be repaired. Refer to *section 4.2.5 "SDM", page 28* to further evaluate the problem.

3.2.10 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, page 7*).

Measure the Analog Output voltages for the Pleth Waveform (Pin 1+2), for PR (pin 3+4), for SpO₂ (Pin 5 + 6), and for PCO₂ (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 5 "Repairs", page 33*) 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 PCO₂, SpO₂, 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 specifications are not met, the SDM needs to be repaired. Refer to *section 4.2.5 "SDM", page 28* to further evaluate the problem.

3.2.11 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, page 7*).

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*). Check that data transmission works properly.

If the above specifications are not met, the SDM needs to be repaired. Refer to section 4.2.5 "SDM", page 28 to further evaluate the problem.

3.2.12 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, page 6*) lits green).
2. Adjust the brightness in the menu "General Systems 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. 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.

Alternatively the capacity of the rechargeable battery can be tested using the following procedure:

1. See step 1 and 2 above.
2. Disconnect the SDM from AC power and write down the time.
3. Once the battery capacity is below 10% check the SDM every 5 minutes. Record the time, when the SDM was switched off by the battery management.

The capacity of a new, fully charged battery is about 6 hours of monitoring time. The quality of the Rechargeable Lithium Battery is still acceptable, when the SDM runs for at least 4 hours before the battery management switches off the monitor automatically.

If the specification above is not met, the SDM needs to be repaired. Refer to section 4.2.5 "SDM", page 28 to further evaluate this problem.

3.2.13 Display, Alarm

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

If the above specification is not met, the SDM needs to be repaired. Refer to section 4.2.5 "SDM", page 28 to further evaluate the problem.


3.2.14 Speaker, Alarm

Initiate a low priority alarm (e.g. by disconnecting the V-Sign™ Sensor from the SDM). Verify that the audible component of a low priority alarm is audible (1 single pulse of low pitch, repeated every 10 seconds).

If the specification above is not met, the SDM needs to be repaired. Refer to section 4.2.5 "SDM", page 28 to further evaluate the problem.

3.2.15 Nurse Call, Alarm

Initiate a low priority alarm (e.g. by disconnecting the V-Sign™ Sensor from the SDM). The Nurse Call feature is relay-based and can be tested with the SenTec Test Connector Multipurpose I/O, see section 5.11.1 "Accessories and Spare Parts List", page 42.

Note: If the audible alarm signals of the SDM are silenced , the nurse call function is not active.

If the specifications above are not met, the SDM needs to be repaired. Refer to section 4.2.5 "SDM", page 28 to further evaluate the problem.

3.2.16 Electrical Safety Check

The SenTec Digital Monitoring System (SDMS) has been developed to comply with the standards IEC/UL 60601-1 and CAN/CSA-C22.2 No.601.1-M90. To ensure electrical safety reasons of the equipment the electrical safety check MUST be performed annually.

The electrical safety tests for the SDMS have to be performed in accordance with the standards IEC/UL 60601-1 and CAN/CSA-C22.2 No.601.1-M90 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.

3.2.16.1 Safety test according to IEC/UL 60601-1

Tools

- Safety analyzer for tests according to IEC/UL 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/UL 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, page 7*), 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 M Ω
- Patient Insulation Resistance: Sensor Connection Port (Ground) – housing (equipotential terminal). The resistance must be more than 2 M Ω
- Earth Leakage Current: The current must be below 500 μ A
- Enclosure Leakage Current: The current must be below 100 μ A
- 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 μ A

If the requirements are not met, refer to *section 4.2.5 "SDM", page 28* to further evaluate the problem.

Check the AC power cord for breaks or 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 5.11.1 "Accessories and Spare Parts List", page 42*.

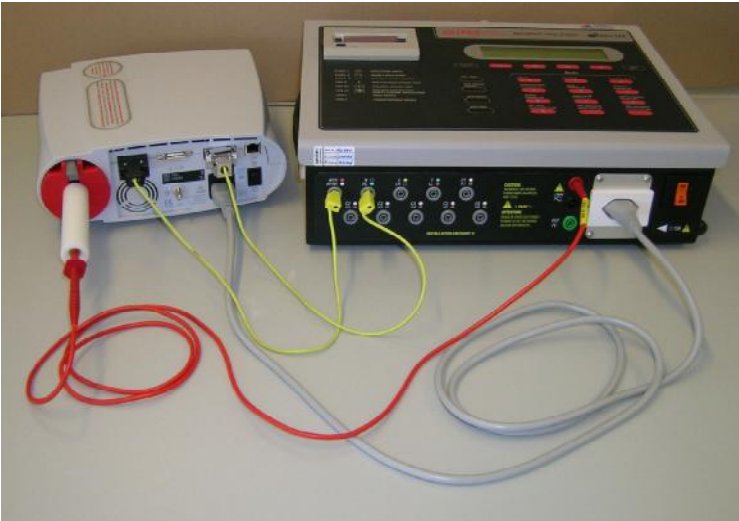


Figure 3 Connections for the Safety Test
Setup with 601PRO_{xL} International Safety Analyzer from BIO-TEK

3.2.16.2 High potential test according to IEC/UL 60601-1

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

WARNING: Before performing the safety test read the operating instructions of the 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 high potential test for accessible parts is performed with a voltage of 1500 VAC during 60 seconds between the following connections of the SDM:

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

Table 2 Connections for the High Potential Test, AP



Figure 4 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:

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

Table 3 Connections for the High Potential Test, PC

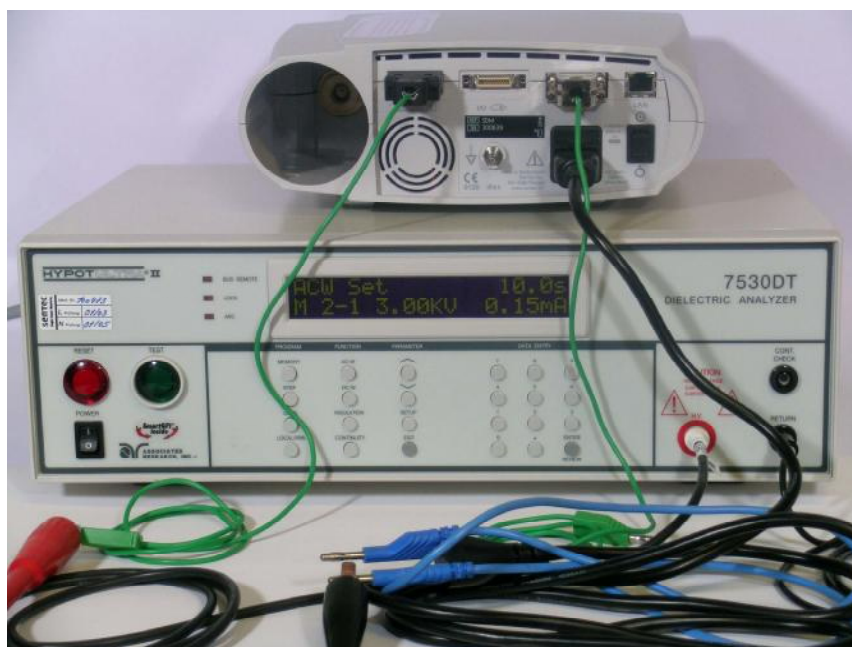


Figure 5 Connections for the High Potential Test, PC

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

If a disruptive discharge occurs section 4.2.5 "SDM", page 28 will help you to evaluate the problem.

3.3 Docking Station

3.3.1 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", page 33.

3.3.2 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 4.2.5 "SDM", page 28 to further evaluate the problem.

3.4 Digital Monitor Extension Cable

3.4.1 Visual Inspection

Check the Digital Monitor Extension Cable for breaks or damages of the isolation. Check the Digital Monitor Extension Cable connectors for damages.

If you detect a damage, the Digital Monitor Extension Cable needs to be replaced by a new Digital Monitor Extension Cable, see section 5.11.1 "Accessories and Spare Parts List", page 42.

4 Troubleshooting

This section describes problems, possible causes and recommended corrective actions. Together with the troubleshooting list located in the *Technical Manual for the SDM* it helps to pinpoint errors from the symptoms they cause. Repairs are described in *section 5 "Repairs", page 33*.

4.1 How to use the troubleshooting list

The troubleshooting list in the *Technical Manual for the SDM* describes problems that are primarily caused by handling errors. The troubleshooting list in this Manual complements the troubleshooting list of the *Technical Manual for the SDM*. It describes possible defects of the device. The problems are numbered unambiguously throughout all documents.

The example in *Table 4* explains how to work with the troubleshooting list.

- a. Along with the defective part service personnel should receive the SenTec repair form from the customer/sender. On the repair form the problem and its possible cause should be described and referenced with the PXXXX number.
- b. Look up the PXXXX number in the troubleshooting list of this Manual. The possible cause and the last action implemented by the user are shaded in dark grey [a].
- c. If the problem cannot be solved continue with lines [b] (troubleshooting at service level). If the problem persist forward the equipment to a SenTec authorized service technician. Take into account that the user might not have performed the corrective actions recommended at user-level, might not have identified the problem correctly, and, therefore, check other possible causes and problems.

Note: Areas shaded in dark grey correspond to that part of the troubleshooting list, which is also provided in the *Technical manual for the SDM*.

Note: The troubleshooting list in the *Technical Manual for the SDM* provides additional recommended corrective actions that can be carried out by the user and, therefore, have no reference to this Manual.

Problem	Possible cause	Recommended action(s)	
P0101 PCO ₂ 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		
	b	SDM defective	If the problem persists contact SenTec authorized service personnel.
	a	PCO ₂ sensitivity of the sensor too low	Test the PCO ₂ sensitivity as follows: <ul style="list-style-type: none"> - Activate the display of the PCO₂ calibration curve. - Following a calibration, expose the sensor for approximately three minutes to ambient air. - Reinsert the sensor into the Docking Station. The first displayed PCO₂ value should be at least 30 mmHg (4.0 kPa) lower than after calibration - If this difference is not reached, remembrane the sensor and repeat the test. After a renewed missing of this difference, consult qualified service personnel.
	b		Clean the sensor as described in <i>section 5.2 "Cleaning the sensor without membrane", page 35</i> and perform the sensitivity test as described in <i>section 3.1.6 "PCO₂ Sensitivity Test", page 10</i> . If problem persists contact SenTec authorized service personnel.

Table 4 Example of a Troubleshooting Procedure

4.2 Troubleshooting List

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

4.2.1 Troubleshooting PCO₂ Monitoring

Problem	Possible cause	Recommended action(s)
P0100 PCO ₂ values increase very slowly / not stable 20 minutes after sensor application	Sensor too slow	Refer to P0304
P0101 PCO ₂ 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.
	SDM defective	If the problem persists contact SenTec authorized service personnel.
	PCO ₂ sensitivity of the sensor too low	Test the PCO ₂ sensitivity as follows: <ul style="list-style-type: none"> - Activate the display of the PCO₂ calibration curve. - Following a calibration, expose the sensor for approximately three minutes to ambient air. - Reinsert the sensor into the Docking Station The first displayed PCO₂ value should be at least 30 mmHg (4.0 kPa) lower than after calibration - If this difference is not reached, remembrance the sensor and repeat the test. After a renewed missing of this difference, consult qualified service personnel.
		Clean the sensor as described in <i>section 5.2 "Cleaning the sensor without membrane", page 35</i> and perform the sensitivity test as described in <i>section 3.1.6 "PCO₂ Sensitivity Test", page 10</i> . If the problem persists contact SenTec authorized service personnel.
	Significant PCO ₂ 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 change (activate the menu "Membrane Change"). After having changed the membrane calibrate the sensor and allow the PCO ₂ part of the sensor to stabilize for 4 hours. If no change of the sensor membrane is needed allow the sensor to stabilize for an additional 2 – 3 hours. If the problem persists contact qualified service personnel.

Problem	Possible cause	Recommended action(s)
	V-Sign™ Sensor defective	If the problem persists, end the V-Sign™ Sensor back to your local SenTec representative according to <i>section 5.10 "Instructions for Shipment", page 41.</i>
P0102 PCO ₂ too high	Docking Station gas leak	Insert the sensor into the Docking Station and observe the system during 20 minutes. When the sensor is in the Docking Station, the SDM evaluates the integrity of the Docking Station system. If a failure occurs, a low priority alarm sounds and the message "Clean DS" is displayed. In this case carefully inspect the door and gasket. Clean the Docking Station gasket and sensor with a cotton swab. Remove any residual threads and fibers then reinsert the sensor to calibrate it. Observe the system during 20 minutes to detect any reoccurrence. If the problem persists contact qualified service personnel.
	Docking Station door mechanically defective	Replace Docking Station door according to <i>section 5.6 "Replacement, Docking Station Door", page 37.</i>
	Gasket defective	Replace gasket according to <i>section 5.7 "Replacement, Docking Station Gasket", page 38.</i>
	SDM defective	Contact SenTec authorized service personnel.
	Wrong/instable barometric pressure during calibration	Refer to P0101
	PCO ₂ sensitivity of the sensor too low	Refer to P0101
	Significant PCO ₂ drift	Refer to P0101
P0103 PCO ₂ suddenly changes		This problem has no reference to this manual.

Table 5 Troubleshooting PCO₂ Monitoring

4.2.2 Troubleshooting SpO₂ and PR Monitoring

Problem	Possible cause	Recommended action(s)
P0200 SpO ₂ and/or pulse rate too low or too high		This problem has no reference to this manual.

Table 6 Troubleshooting SpO₂ and PR Monitoring

4.2.3 Sensor specific troubleshooting

Problem	Possible cause	Recommended action(s)
P0300 Sensor Fault is displayed	Sensor temperature too high (e.g. caused by heat sources such as warming lamps/blankets)	Shield V-Sign™ Sensor from heat source. Switch the SDM off and on again. If problem persists contact qualified service personnel.
		Verify that the temperature of the V-Sign™ Sensor deviates less than 0.2 °C from the SET temperature.
		Repeat the test with the same sensor connected to another SDM.
	V-Sign™ Sensor defective	If the problem persists, send the V-Sign™ Sensor back to your local SenTec representative according to <i>section 5.10 "Instructions for Shipment", page 41</i> .
	SDM defective	If problem does not persist, refer to <i>section 4.2.5 "SDM", page 28</i> to further evaluate the problem.
P0301 Sensor LEDs not luminated	V-Sign™ Sensor or SDM defective	Switch the SDM off and on again. If problem persists contact a qualified service personnel.
	Digital Monitor Extension Cable defective	Replace the Digital Monitor Extension Cable.
		If problem persists, test the same sensor connected to another SDM.
	V-Sign™ Sensor defective	If problem persists, send the V-Sign™ Sensor back to your local SenTec representative according to <i>section 5.10 "Instructions for Shipment", page 41</i> .
	SDM defective	If problem does not persist, refer to <i>section 4.2.5 "SDM", page 28</i> to further evaluate the problem.
P0302 White spots on the membrane		This problem has no reference to this manual.
P0303 After each calibration the SDM requests to exchange the membrane	- No membrane - Defective membrane (holes or scratches) - Old membrane	Change the sensor membrane and confirm as requested by the SDM. After having changed the membrane calibrate the sensor. If the problem persists contact qualified service personnel.
		Clean the sensor as described in <i>section 5.2 "Cleaning the sensor without membrane", page 35</i> . Then calibrate the sensor. If the problem persists, test the same sensor connected to another SDM.
	V-Sign™ Sensor defective	If the problem persists, send the V-Sign™ Sensor back to your local SenTec representative according to <i>section 5.10 "Instructions for Shipment", page 41</i> .
	SDM defective	If the problem does not persist, refer to <i>section 4.2.5 "SDM", page 28</i> to further evaluate the problem.
	Docking Station door is not closed properly	Close Docking Station door properly. If the problem persists contact qualified service personnel.

Problem	Possible cause	Recommended action(s)
	Docking Station door mechanically defective	Replace Docking Station door according to <i>section 5.6 "Replacement, Docking Station Door", page 37.</i>
	Gasket defective	Replace gasket according to <i>section 5.7 "Replacement, Docking Station Gasket", page 38.</i>
	SDM defective	Contact SenTec authorized service personnel.
P0304 Calibration takes very long or is aborted after 14 min	V-Sign™ Sensor too slow	Change the sensor membrane and confirm as requested by the SDM. After having changed the membrane calibrate the sensor. If the problem persists contact qualified service personnel.
		Clean the sensor as described in <i>section 5.2 "Cleaning the sensor without membrane", page 35.</i>
	V-Sign™ Sensor defective	If the problem persists, send the V-Sign™ Sensor back to your local SenTec representative according to <i>section 5.10 "Instructions for Shipment", page 41.</i>
	SDM defective	If the problem does not persist, refer to <i>section 4.2.5 "SDM", page 28</i> to further evaluate the problem.
P0305 V-Sign™ Sensor calibration does not start	V-Sign™ Sensor temperature is too low	Wait until the sensor temperature is less than 0.5 °C below the SET temperature. If the problem persists contact qualified service personnel.
		If the problem persists, test the same sensor connected to another SDM using another extension cable.
	V-Sign™ Sensor defective	If the problem persists, send the V-Sign™ Sensor back to your local SenTec representative according to <i>section 5.10 "Instructions for Shipment", page 41.</i>
	SDM defective	If the problem does not persist, refer to <i>section 4.2.6 "Docking Station", page 31</i> to further evaluate the problem.
P0306 Temp. limiter active is displayed	V-Sign™ Sensor temperature is enhanced because of warming lamps or electric blankets	Shield V-Sign™ Sensor from heat. If the problem persists contact qualified service personnel.
		If the problem persists, test the same sensor connected to another SDM in a room within the specified operating temperatures (10 – 40 °C).
	V-Sign™ Sensor defective	If the problem persists, send the V-Sign™ Sensor back to your local SenTec representative according to <i>section 5.10 "Instructions for Shipment", page 41.</i>
	SDM defective	If the problem does not persist, refer to <i>section 4.2.5 "SDM", page 28</i> to further evaluate the problem.
P0307 Sensor is blocked in the Membrane change tool	Membrane change tool is blocked	Open the Membrane Change Tool as described in <i>section 5.8 "Breaking up the V-Sign™ Disposable Set, page 1.</i> If the problem persists contact qualified service personnel.

Table 7 Sensor specific troubleshooting

4.2.4 Sensor Application specific troubleshooting

Problem	Possible cause	Recommended action(s)
P0400 V-Sign™ Sensor cannot be applied correctly at the inside of the earlobe.		This problem has no reference to this manual.
P0401 Adhesive tape of Ear Clip or Multi-Site Attachment Ring does not attach properly		This problem has no reference to this manual.

Table 8 Sensor Application specific troubleshooting

4.2.5 SDM specific troubleshooting

Problem	Possible cause	Recommended action(s)
P0500 SDM not operational, SDM LEDs not illuminated	SDM defective	Switch the SDM off and on again. If problem persists contact qualified service personnel.
	Main fuses defective	Replace main fuses according to <i>section 5.5 "Replacement, main fuses", page 37.</i>
	SDM defective	Contact SenTec authorized service personnel.
P0501 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.
P0502 100% charged Battery is discharged after less than 3 h	Battery defective	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.

Problem	Possible cause	Recommended action(s)
P0503 Display is dark, ON/OFF indicator is illuminated	SDM in Sleep mode	Press any button. If the problem persists switch the SDM off and on again. If the problem persists contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
P0504 Display is not readable (dark)	Brightness not adjusted correctly.	Switch the monitor off and on again. Readjust the brightness as described in the corresponding section of the <i>Technical Manual for the SDM</i> .
	SDM defective	Switch the SDM off and on again. If the problem persists contact qualified service personnel.
P0505 POST screen does not disappear	POST, i.e. Power On Self Test failed ("failed" is displayed)	Write down the Error code, switch the SDM off and on again. If the problem persists contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
P0506 SDM does not react if any button is pressed	SDM is blocked	Switch the monitor off and on again. If problem persists contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
P0507 Clock shows wrong time and date after each restart.	Low internal battery	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
P0508 Barometric pressure is to low/high	Barometer chip defective	Verify the SDM's barometric pressure with a known calibrated reference barometer. The difference should be within 5 mmHg (0.7 kPa). If the problem persists contact qualified service personnel.
		Verify the SDM's barometric pressure with a known calibrated reference barometer. The difference should be within 5 mmHg (0.7 kPa).
	SDM defective	Contact SenTec authorized service personnel.
P0509 Fan is noisy	Fan defective or polluted	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
P0510 Fan is blocked	Fan defective or polluted	The fan has to be able to rotate freely. If you blow into the fan slits on the rear panel of the SDM, the fan has to rotate. If the problem persists contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.

Problem	Possible cause	Recommended action(s)
P0511 No sound	Volume is on minimum	Regulate the volume in the menu "Alarm Settings" to a higher level. If the problem persists contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
P0512 It is not possible to connect the AC power cord in the SDM AC power connector	Power Entry Module defective	Contact qualified service personnel.
	Fuse Holder not mounted correctly	Mount Fuse Holder correctly according to <i>section 5.5 "Replacement, main fuses", page 37.</i>
	SDM defective	Contact SenTec authorized service personnel.
P0513 Disruptive discharges during the high tension test	SDM defective	Contact SenTec authorized service personnel.
P0514 Wrong or no analog output	SDM defective	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
P0515 No communication over RS-232	SDM defective	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
P0516 No alarm on speaker, nurse call	SDM defective	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
P0517 Safety test does not comply	SDM defective	Contact SenTec authorized service personnel.
P0518 Gas Level Indicator shows wrong indication	SDM defective	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.

Table 9 SDM specific troubleshooting

4.2.6 Docking Station specific troubleshooting

Problem	Possible cause	Recommended action(s)
P0600 Docking Station door does not close properly	Mechanical defect of the Docking Station door	Contact qualified service personnel.
	Gasket not placed correctly	Place gasket correctly in the chamber in the Docking Station according to <i>section 5.7 "Replacement, Docking Station Gasket", page 38.</i>
	Docking Station door mechanically defective	Replace Docking Station door according to <i>section 5.6 "Replacement, Docking Station Door", page 37.</i>
P0601 Docking Station Fault is displayed	Contaminations (e.g. gel residues) disturb the gas flow	Clean Docking Station and V-Sign™ Sensor as described in the corresponding section of the <i>Technical Manual for the SDM.</i> If the problem persists contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
	Docking Station defective	Contact SenTec authorized service personnel.
P0602 Gas leak in DS is displayed	Docking station and/or sensor contaminated with gel residues (causing a leak)	Clean Docking Station and V-Sign™ Sensor as described in the corresponding section of the <i>Technical Manual for the SDM.</i> If the problem persists contact qualified service personnel.
	Docking Station door mechanically defective	Replace Docking Station door according to <i>section 5.6 "Replacement, Docking Station Door", page 37.</i>
	Gasket defective	Replace gasket according to <i>section 5.7 "Replacement, Docking Station Gasket", page 38.</i>
	SDM defective	Contact SenTec authorized service personnel.
P0603 Service Gas bottle cannot be installed properly	SDM is defective	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.
P0604 Consumption of the Service Gas is higher than normally Gas leak in DS is not displayed	High pressure part of the Docking Station Module is leaky	Contact qualified service personnel.
	SDM defective	Contact SenTec authorized service personnel.

P0605 V-Sign™ Sensor calibration does not start, V-Sign™ Sensor LED is illuminated	V-Sign™ Sensor temperature is too low	Wait until the sensor temperature is less than 0.5 °C below the SET temperature. If the problem persists contact qualified service personnel.
	No communication between the Docking Station Module and the Monitor	Hold the V-Sign™ Sensor with the sensor membrane face in front of the Docking Station Calibration Module. A red LED in the upper Window will flicker.
		If the problem persists, repeat the test with the same sensor, but using the Docking Station of another SDM (switched on).
	V-Sign™ Sensor defective	If the problem persists, send back V-Sign™ Sensor to your local distributor according to <i>section 5.10 "Instructions for Shipment", page 41.</i>
	SDM defective	If the problem doesn't persist, contact SenTec authorized service personnel.

Table 10 Docking Station specific troubleshooting

5 Repairs

Repairs shall be carried out by qualified service personnel only. Repairs which require the opening of the case shall only be carried out by SenTec authorized service personnel, trained by SenTec AG or accredited partners.

If you need to return devices for service or repair follow the shipment instructions in *section 5.10 "Instructions for Shipment", page 41.*

Send defective parts together with the completed *"Repair form"* to your local SenTec representative. The *"Repair Form"* may be copied from *section 7.6 "Repair Form", page 53 .*

For orders please use the *"Order Form for Service Technician"*. Record the serial- and LOT number and the hard- and software specific information of the SDMS you order parts for. The *"Order Form for Service Technician"* may be copied from *section 7.5 "Order Form for Service Technician", page 52.*

To ensure traceability – a regulatory requirement – SenTec needs to know the serial and LOT numbers as well as software versions of all components of the SDMS. If you replace a part in the SDM out of your stock, then you have to feedback the serial number of the SDM and the serial and LOT number of the replaced parts with the *"Repair Reporting Form"* on *page 54* to your local distributor.

You can find the spare parts and test tools with their corresponding order number in *section 5.11.1 "Accessories and Spare Parts List", page 42.*

- Test Tools**
- Multimeter
 - SenTec Test connector Multipurpose I/O
 - Screwdriver large slotted 3
 - 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. Use of other than supplied or recommended parts may result in physical injury, inaccurate measurements, and/or damage to the device.



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



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



CAUTION: Observe the 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 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".
2. If necessary, clean and disinfect the device as described in the corresponding section of the *Technical Manual for the SDM*.
4. Set the ON/OFF Switch of the SDM to OFF.
5. Disconnect all connections on the rear panel of the device.

5.2 Cleaning the sensor without membrane

Under certain circumstances (sensor too slow, bad sensitivity), the sensor should be manually cleaned before applying a new membrane.

1. The V-Sign™ Sensor must be disinfected. Check that the completed "Disinfection protocol" is enclosed. If necessary, clean and disinfect the V-Sign™ Sensor as described in the V-Sign™ Sensor Directions for Use.
6. Remove the sensor membrane using the membrane remover located at the bottom of the V-Sign™ Disposable Set as shown in *Figure 6*. Step ❶: Slide the V-Sign™ Sensor into the membrane remover with its membrane facing the bottom of the V-Sign™ Disposable Set. Step ❷: Lift up the V-Sign™ Sensor to remove the membrane from the sensor body.
7. Clean the V-Sign™ Sensor by immersing it for 5 minutes in clean water. Then rinse it with running water. Use demineralized or distilled water.
8. Dry the V-Sign™ Sensor using a clean lint-free towel. Carefully pat it without rubbing. Pay attention not to damage the glass membrane in the middle of the sensor surface.
9. To change the sensor membrane, activate the menu item "Membrane Change" and confirm the membrane change as requested by the monitor. Refer to the *Directions for Use of the V-Sign™ Disposable Set*.



Figure 6 Removal of the Membrane from the Sensor

5.3 Replacement, Tip-up Foot

1. Follow the procedure described in *section 5.1 "Prior to Repair", page 35*.
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 5.11.1 "Accessories and Spare Parts List", page 42*) 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.

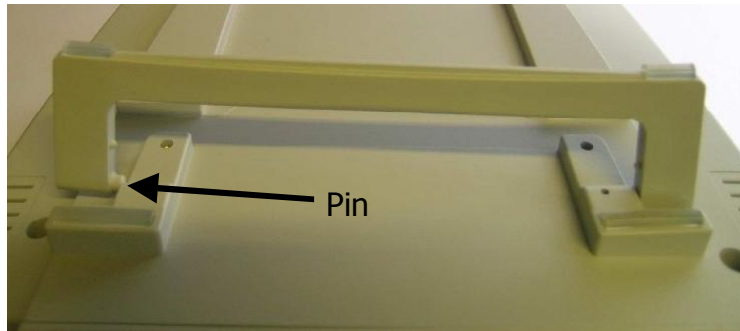


Figure 7 Replacement, Tip-up Foot

5.4 Replacement, Silicon Foot

1. Follow the procedure described in *section 5.1 "Prior to Repair", page 35*.
2. Clean the groove for the silicon foot with a cotton soaked with 70% isopropanol.
3. Put one drop of silicon glue (see *section 5.11.1 "Accessories and Spare Parts List", page 42*) in the groove.
4. Insert the new silicon foot into the groove by pressing firmly.
5. Allow the glue to dry.



Figure 8 Replacement, Silicon Foot

5.5 Replacement, main fuses

1. Follow the procedure described in *section 5.1 "Prior to Repair", page 35*.
10. 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 9*.
11. Replace the defective fuses with time delay, high breaking capacity fuses, T 630mA H, 250V~ (see *section 5.11.1 "Accessories and Spare Parts List", page 42*).
12. Reinsert the holder into the AC Power Connector.



Figure 9 Replacement, Main Fuses

5.6 Replacement, Docking Station Door

1. Follow the procedure described in *section 5.1 "Prior to Repair", page 35*.
13. Open the Docking Station Door (to an angle of approximately 120° (see *Figure 10*)).
14. 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.
15. Insert the new Docking Station Door (parallel to the case) with an aperture angle of the door of 45° (see *section 5.11.1 "Accessories and Spare Parts List", page 42*). 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.
16. Switch on the monitor and check if POST is passed without an error. After maximum one minute the measuring display will appear.
17. Put the sensor into the Docking Station, a calibration will start after maximum two minutes. Ten minutes after calibration no message "Docking Station Fault" or "Clean Docking Station" should appear.
If the sensor membrane needs to be changed, follow the instructions in the *Instruction Manual of the SDM*.

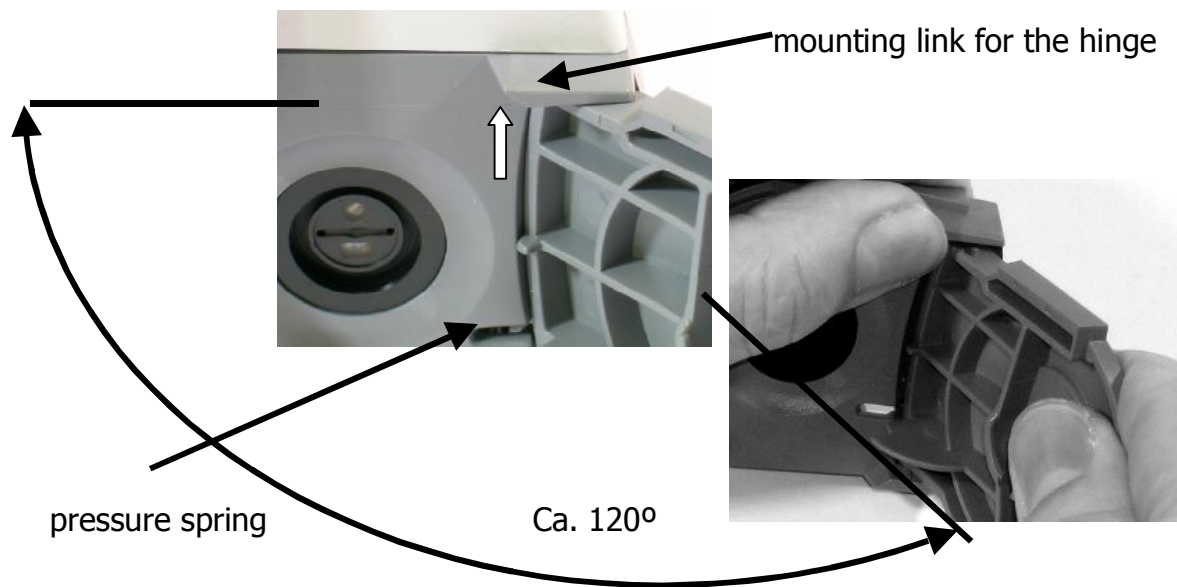


Figure 10 Docking Station Door removal

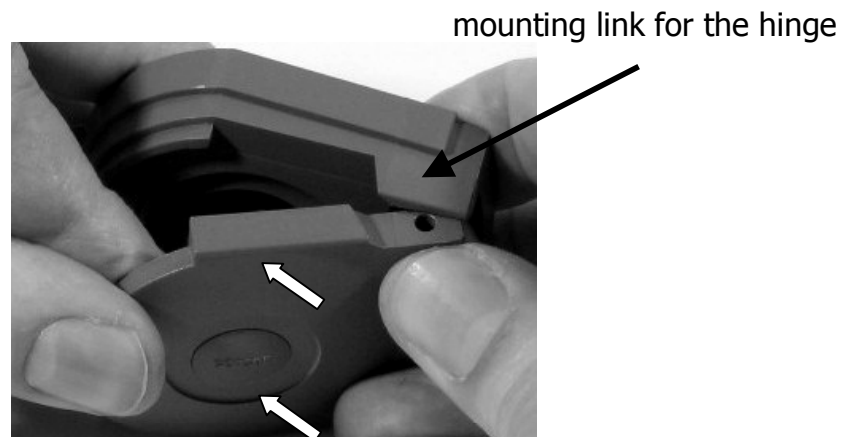


Figure 10 Docking Station Door Insertion

5.7 Replacement, Docking Station Gasket

1. Follow the procedure described in *section 5.1 "Prior to Repair", page 35*.
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 soaked with 70% isopropanol, allow to dry.
5. Insert the new gasket (see *Figure 11*) by pressing it with a cotton swab soaked with 70% isopropanol into the lining groove. Make sure that no cotton wool remains on the gasket as it may cause leak problems. Place the **asymmetric** gasket as shown in *Figure 12*.
6. Allow to dry.

7. Switch on the monitor and check if POST is passed without any error. After one minute max. the measuring display will appear.
8. Put the sensor into the Docking Station, a calibration will start after maximum two minutes max. Ten minutes after calibration no message "Docking Station Fault" or "Clean Docking Station" should appear.
If the sensor membrane needs to be changed, follow the instructions in the *Instruction Manual of the SDM*.

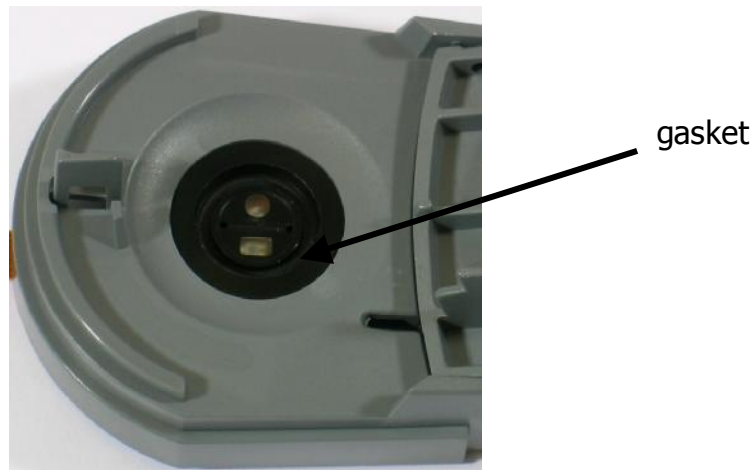


Figure 11 Replacement, Docking Station Gasket

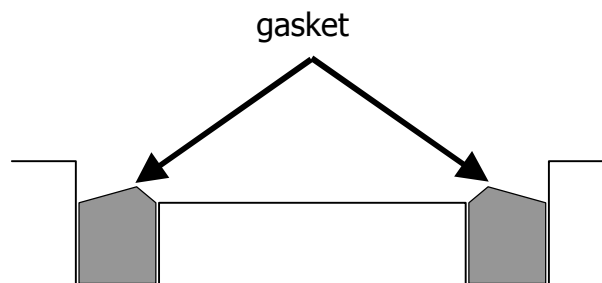


Figure 12 Positioning of the Docking Station Gasket

5.8 Breaking up the V-Sign™ Disposable Set

If the sensor is blocked at any position of the V-Sign™ Disposable Set (Tool), then the Tool can be opened as follows:

Break off the 6 latches indicated in *Figure 13* (holding together top and bottom part of Tool by inserting a screwdriver).

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



Note: This procedure will irreversibly destroy the V-Sign™ Disposable Set, but not harm the sensor if executed with care.

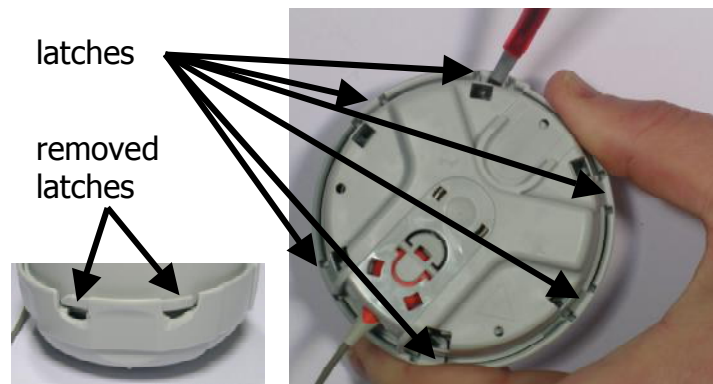


Figure 13 Breaking up the V-Sign™ Disposable Set

5.9 Firmware Updates

The firmware of the SDMS consists of four items:

1. SMBC – Controllerboard software (User Interface)
2. MPB – Multiparameterboard software (Measuring Algorithm)
3. Docking Station software (Calibration Control)
4. Sensor software (Measuring Algorithm)

Each software item can be updated independently. Whereas the SMBC, MPB and Docking Station software can be updated by flashing a new version in the flash memory of the existing boards, the update of the sensor software requires the replacement of the sensor.

WARNING: Firmware update of the SDM should be carried out only by SenTec authorized service personnel.



5.10 Instructions for Shipment

Please contact SenTec AG before returning any material.

Unless otherwise expressly agreed, shipment costs and costs for repair and service work will be billed to the sender.

The following instructions apply to all shipments of SDMS or any part of it (e.g. for service or repair) to qualified/SenTec authorized service personnel or your local SenTec representative:

1. Please return only the SDM and/or V-Sign™ Sensor with Extension Cable, but without power cord and without any disposables such as the V-Sign™ Disposable Set, the Sensor Gel, the Ear Clip, or the Service Gas. **Important: do not ship Service Gas** bottles together with the SDM. Gas bottles have to be declared as "dangerous goods", a special IATA form is required and special packing instructions apply.
2. Devices must be properly disinfected. For disinfection instructions please refer to the directions for use of the V-Sign™ Sensor and the sub-section "Cleaning and Disinfection" in the SDM's *Technical Manual*. The "Certificate of Disinfection" and, if applicable, the "Repair Form" are to be completed by the responsible person and have to be shipped together with the SDMS.
3. If you send back electronic parts, make sure to follow applicable ESD precautions.
4. Items must be shipped in the original packaging or in other packing providing the same degree of protection. Use sanitized packing material only.
5. Pack the components as shown in *Figure 14*.



Figure 14 Packing in the Original Box

6. The completely filled in forms "Certificate of disinfection" and, if applicable, "Repair form" must accompany the shipment and be accessible without opening up the packaging. Insert them into the transparent envelope that holds the transportation documents and pack list or use a separate transparent envelope.

Important: Any shipment to SenTec AG lacking this documentation or showing improperly filled in documentation will be returned immediately and unopened at the sender's expense.

5.11 Accessories and Spare Parts

WARNING: Use only 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.



You will receive original SenTec spare parts from your local SenTec representative.

5.11.1 Accessories and Spare Parts List

Accessories and Spare Parts List				
Order no.	Part designation	Comments	LOT/SN	PU
SDM	SenTec Digital Monitor			1
VS-A/P	V-Sign™ Sensor			1
VS-DSET	V-Sign™ Disposable Set			9
EC-A/P	Ear Clip			24
MAR-A/P/N	Multi-Site Attachment Ring (Adults/Pediatrics/Neonates)			24
MAR-A/P	Multi-Site Attachment Ring (Adults/Pediatrics)			50
AC-XXX	Digital Monitor Extension Cable	150cm, 250cm, 750cm or customized length		1
Gel-04	Sensor Gel			1
Gas-0812	Service Gas	5,7l (9,5 bar)		6
VS-TSET	Training Set			1
MP-WR	Mounting Plate, wall rails			1
MP-RSH	Mounting Plate, roll stands heads			1
MP-IW	Mounting Plate, infusion stands & wall rails			1
IM-xx	Instruction Manual for SDMS			1
E100967	VueLink Adapter			1
UMCD	User Manual CD			1

Accessories and Spare Parts List				
Order no.	Part designation	Comments	LOT/SN	PU
E100857	AC Power Connector			1
E100858	Fuse Holder for AC Power Connector			1
E100838	Fuse, 250VAC, T630mA H	time delay, high breaking capacity		10
E100414	Mains Connecting Cable			1
E100145	Docking Station Door			1
E100380	Docking Station Gasket			5
E100454	Silicon Feet Set	6 feet		1
E100884	Silicone Glue	omniVISC1050		1
E100171	Tip-up Foot	excl. silicone feet		1
E100463	Serrated lock washer	M6		10
E100451	AC Power Cord, Europe			1
E100452	AC Power Cord, Switzerland			1
E100693	AC Power Cord, Italy			1
E100694	AC Power Cord, Australia			1
E100695	AC Power Cord, United Kingdom			1
E100747	AC Power Cord, Japan HGJ			1
E100748	AC Power Cord, USA, Canada, HGC			1
E100795	AC Power Cord, Denmark			1
E100796	AC Power Cord, China			1
E100797	AC Power Cord, Israel			1
E100798	AC Power Cord, Korea			1
E100701	SenTec Test Connector Multipurpose I/O			1
ST-DSU	Equipment for testing V-Sign sensors	Uses gas with 5% and 30% CO ₂		1
S100005	Test gas for ST-DSU 5% CO ₂			6
S100005	Test gas for ST-DSU 30% CO ₂			6

PU: Packaging Unit

Table 11 Accessories and Spare Parts List

6 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.

6.1 SenTec Digital Monitor

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

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.

6.2 Cables

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

6.3 V-Sign™ Sensor

Return the V-Sign™ Sensor to your local distributor.

6.4 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.



6.5 Consumables

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

7 Appendix

7.1 Pin Assignment

7.1.1 Sensor Connection Port

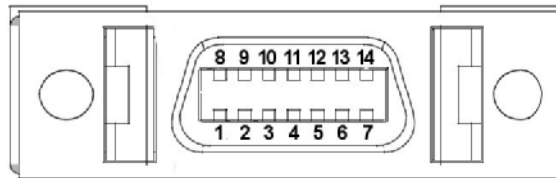


Figure 15 Sensor Connection Port

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)

Table 12 Pin Assignment, Sensor Connection Port

7.1.2 The Serial Data Port (RS-232)

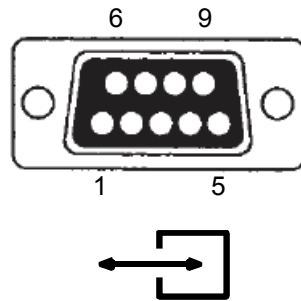


Figure 16 Serial Data Port (RS-232)

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)

Table 13 Pin Assignment, Serial Data Port (RS-232)

7.1.3 Multipurpose I/O Port

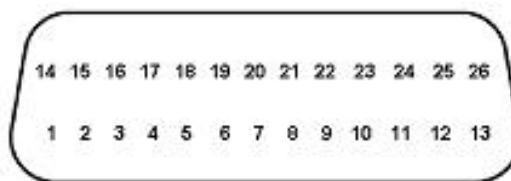


Figure 17 Multipurpose I/O Port

	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, 0-15.0, 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

Table 14 Pin Assignment, Multipurpose I/O Port

7.2 Technical Specifications

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

7.3 Contact

phone: +41 61 726 97 60

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

[eMail: hotline@sentec.ch](mailto:hotline@sentec.ch)

7.4 Protocol for Safety Related Test

The SenTec Digital Monitoring System (SDMS) has been designed to comply with the standards IEC/UL 60601-1 and CAN/CSA-C22.2 No.601.1-M90. For safety reasons it is strongly recommended that the SDMS undergoes a technical safety check at least once a year and after repair.

Please fill in this form (one form per monitor). This document must be filed until at least the next safety related test is performed.

Record the serial number and the hard- and software specific information of the tested items. You will find this information in the SDM menu "System information".

SenTec Digital Monitor, serial no.:

SMB hardware version:

SMB software version:

MPB hardware version:

MPB software version:

V-Sign™ Sensor, serial no.:

Sensor hardware version:

Sensor software version:

SenTec Digital Monitoring System	Not passed	Passed
Safety related test	<input type="checkbox"/>	<input type="checkbox"/>

Date of the next safety related test

Organization:

Location:

Service technician (name):

Place, date:

Signature:

This document must be filed until at least the next safety related test is performed.

Test tools

Multimeter:

AC High potential tester:

Safety analyzer:

Reference barometer:

Fill in the tables below to confirm that the tests have been performed successfully (see manual for details).

V-Sign™ Sensor		
Test	Results	Passed
Visual inspection		<input type="checkbox"/>
Labeling		<input type="checkbox"/>
Sensor LED		<input type="checkbox"/>
Function test: SpO ₂ + PR	Value: %,bpm Reference: %,bpm	<input type="checkbox"/>
Function test: PCO ₂	Value: mmHg (kPa)	<input type="checkbox"/>
PCO ₂ Sensitivity Test		<input type="checkbox"/>
Sensor Temperature Surveillance		<input type="checkbox"/>

SenTec Digital Monitor		
Test	Results	Passed
Visual inspection		<input type="checkbox"/>
Labeling		<input type="checkbox"/>
POST		<input type="checkbox"/>
Keyboard		<input type="checkbox"/>
Clock settings		<input type="checkbox"/>
Display/LED's		<input type="checkbox"/>
Speaker (POST)		<input type="checkbox"/>
Fan		<input type="checkbox"/>
Barometric pressure		<input type="checkbox"/>
Analog output		<input type="checkbox"/>
Serial data port (RS-232)		<input type="checkbox"/>
Rechargeable Lithium Battery capacity	Runtime until shut down h min.	<input type="checkbox"/>

SenTec Digital Monitor		
Test	Results	Passed
Display, alarm		<input type="checkbox"/>
Speaker, alarm		<input type="checkbox"/>
Nurse Call, alarm		<input type="checkbox"/>
Safety test IEC/UL 60601-1		<input type="checkbox"/>
Ground integrity, inclusive power cord, max. 0.2Ω	Value: Ω	<input type="checkbox"/>
Isolation resistance, min. 2MΩ	Value: MΩ	<input type="checkbox"/>
Patient isolation resistance, min 2MΩ	Value: MΩ	<input type="checkbox"/>
Earth leakage current, max. 500μA	Value: μA	<input type="checkbox"/>
Enclosure leakage current, max. 100μA	Value: μA	<input type="checkbox"/>
Patient leakage current, max. 100μA	Value: μA	<input type="checkbox"/>
AC power cord, visual and safety test		<input type="checkbox"/>
High tension test IEC/UL 60601-1, accessible parts, 1500VAC, 1 minute	<input type="checkbox"/> No disruptive discharge 1. measurement: μA	<input type="checkbox"/>
High tension test IEC/UL 60601-1, patient circuits, 3000VAC, min. 1 second	<input type="checkbox"/> No disruptive discharge 2. measurement: μA 3. measurement: μA 4. measurement: μA	<input type="checkbox"/>

SDM Docking Station		
Test	Results	Passed
Visual inspection		<input type="checkbox"/>
Gas indicator		<input type="checkbox"/>

Digital Monitor Extension Cable		
Test	Results	Passed
Visual inspection		<input type="checkbox"/>

7.5 Order Form for Service Technician

Please use this form to order original SenTec spare parts (one form per monitor). Send this document to your local distributor.

Record the serial number and the hard- and software specific information of all components of the SDMS to be repaired, even if you order only one component of the system. You will find this information in the SDM menu "System information".

SenTec Digital Monitor, serial no.:

SMB hardware version:

SMB software version:

MPB hardware version:

MPB software version:

V-Sign™ Sensor, serial no.:

Sensor hardware version:

Sensor software version:

Pos.	Order no.	Part designation	Quantity
1			
2			
3			
4			
5			
6			
7			
8			
9			

Organization:

Location (delivery address):

.....

Ordered by (name):

Place, date:

Signature:

7.6 Repair Form

Send this document together with any defective part. Describe the problem and possible causes you found during your tests. Use the troubleshooting list provided in the manuals to identify the problem (PXXXX number) and the possible cause.

Fill in the serial number and the hard- and software specific information of the complete SDMS (Monitor and Sensor) to be repaired, even if you send back only one component of the system. You will find this information in the SDM menu "System information".

SenTec Digital Monitor, serial no.:

SMB hardware version:

SMB software version:

MPB hardware version:

MPB software version:

V-Sign™ Sensor, serial no.:

Sensor hardware version:

Sensor software version:

Pos	Part designation	Comment: problem (PXXXX)/possible cause	Installation date *
1			
2			
3			
4			

* Date of installation or acceptance into service

Organization:

Location:

.....

Name:

Place, date:

Signature:

7.7 Repair Reporting Form

To ensure traceability, you must send back the following information to the authorized service center, if any of the following items is repaired, replaced or updated.

Record the new serial number, the new LOT number and the new hard- and software specific information of the repaired or updated SDMS (one form per monitor). You will find this information in the menu "System information", on the labels of the printed circuit boards or on the packing.

SenTec Digital Monitor, serial no.:

SMBC, serial no.:

SMBC, LOT no.: PA

SMB software version:

MPB, serial no.:

MPB, LOT no.: PA

MPB software version:

SMBM, serial no.:

SMBM, LOT no.: PA

Docking Station Module

SC2A, serial no.:

SC2A, LOT no.: PA

Rechargeable Li-Battery, Lot No.:

AC/DC Power Supply, Lot No.:

Display Module, Lot No.:

SDM Case, upper part, Lot No.:

V-Sign™ Sensor, serial no.:

Sensor hardware version:

Sensor software version:

Organization:

Location:

Service technician (name):

Place, date:

Signature:

7.8 Certificate of Disinfection

All items must be disinfected before shipment. This certificate serves as proof of disinfection. Any items arriving at qualified/SenTec authorized service personnel or your local SenTec representative lacking this certificate or being accompanied by an improperly issued certificate will be disinfected at the sender's expense without prior notice. The sender will be held liable for any harm attributed to improper disinfection.

For disinfection instructions please refer to the directions for use of the V-Sign™ Sensor and the sub-section "Cleaning and Disinfection" in the SDM's technical manual.

Items in shipment

SenTec Digital Monitor, serial no.:
(label on rear panel)

V-Sign™ Sensor, serial no.:
(label on connector)

Complete this table to identify the items that have been disinfected.

Item	In shipment	Disinfected
SenTec Digital Monitor	<input type="checkbox"/>	<input type="checkbox"/>
SDM Docking Station (incl. gasket)	<input type="checkbox"/>	<input type="checkbox"/>
V-Sign™ Sensor (incl. cable)	<input type="checkbox"/>	<input type="checkbox"/>
Digital Monitor Extension Cable	<input type="checkbox"/>	<input type="checkbox"/>
AC power cord	<input type="checkbox"/>	<input type="checkbox"/>
.....	<input type="checkbox"/>	<input type="checkbox"/>
.....	<input type="checkbox"/>	<input type="checkbox"/>

Sender:

Organization:

Location:

.....

Disinfected by (name):

Place, date:

Signature:

Important: This document has to remain with the disinfected items until returned to the sender.