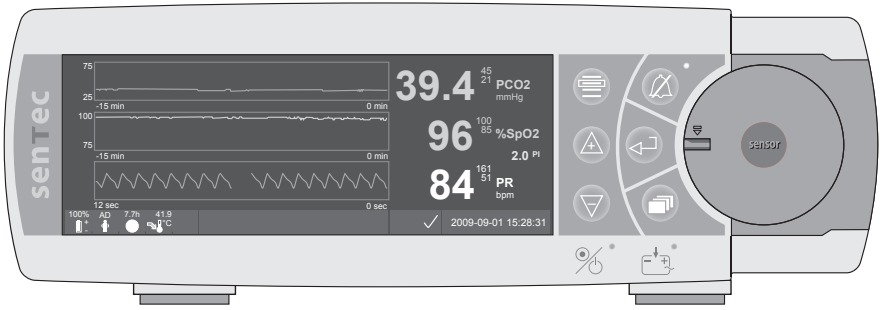
Instruction Manual

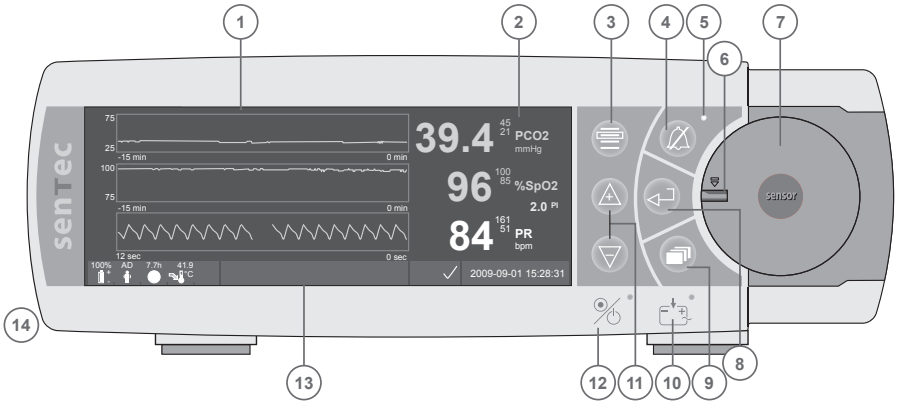
For the **sentec** Digital Monitoring System

(Software version SMB SW-V07.00; MPB SW-V05.00)

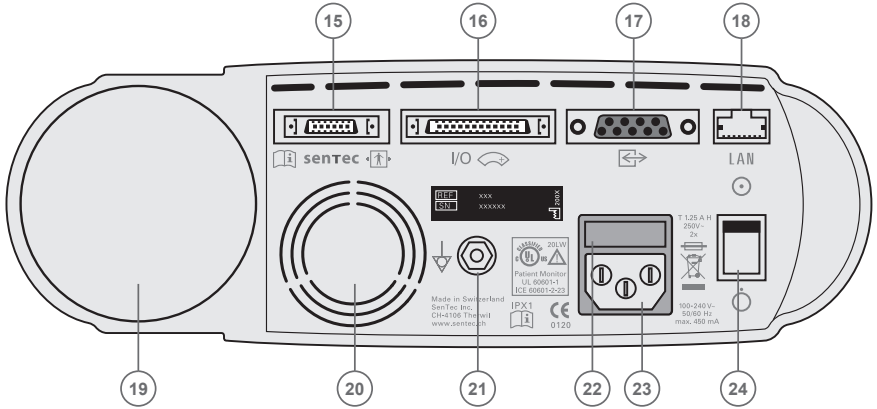
SenTec Digital Monitoring System

Digital Vital Sign Monitoring





1 Trend Display Area
2 Numerical Display Area
3 Menu/Previous Level Button
4 AUDIO PAUSED/OFF Button
5 AUDIO PAUSED/OFF Indicator (yellow LED)
6 Door 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)



15 Sensor Connection Port
16 Multipurpose I/O-Port (Nurse Call & Analog Output)
17 Serial Data Port (RS-232)
18 Network Port (LAN)
19 Gas Bottle Slot
20 Fan
21 Equipotential Terminal Connector (ground)
22 Fuse Holder
23 AC Power Connector
24 ON/OFF Switch

Warranty

The manufacturer warrants to the initial purchaser that each new component of the SenTec Digital Monitoring System (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 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 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

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

CE 0120

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sentec

Contents

Intended Use and Limitations

Intended Use of the SenTec Digital Monitoring System (SDMS)

- The SenTec Digital Monitoring System – consisting of the SenTec Digital Monitor, the sensors and accessories – is indicated for continuous, non-invasive patient monitoring.
- V-Sign™ Sensor VS-A/P, and V-Sign™ Sensor 2 VS-A/P/N, are indicated for use with the SenTec Digital Monitor when continuous, non-invasive monitoring of carbon dioxide tension (pCO_2), oxygen saturation (SpO_2), and pulse rate (PR) are required for adult and pediatric patients. In neonatal patients the use of V-Sign™ Sensor and V-Sign™ Sensor 2 is indicated for carbon dioxide tension monitoring only.
- SenTec's Ear Clip is intended for use with the V-Sign™ Sensor or V-Sign™ Sensor 2 when continuous, non-invasive carbon dioxide tension, oxygen saturation and pulse rate monitoring are required. The Ear Clip is for single-patient use and is indicated to attach the V-Sign™ Sensor or V-Sign™ Sensor 2 to the earlobe of the patient. The use of the Ear Clip is contraindicated for patients whose earlobes are too small to ensure adequate sensor application.
- SenTec's Multi-Site Attachment Rings, MAR-SF and MAR-MI, are intended to attach V-Sign™ Sensor or V-Sign™ Sensor 2 to conventional measurement sites for carbon dioxide tension monitoring when continuous, non-invasive carbon dioxide tension monitoring is required for adult, pediatric, and neonatal patients. They are intended to attach V-Sign™ Sensor 2 to the forehead or cheek when continuous, non-invasive carbon dioxide tension, oxygen saturation, and pulse rate monitoring is required for adult and pediatric patients. The Multi-Site Attachment Rings MAR-SF and MAR-MI, are for single use.
- SenTec's multi-compatible and reusable SpO_2 Soft Sensors, models RSS-L, RSS-M, and RSS-S, are indicated for use with the monitoring devices indicated in the respective sensor directions for use when continuous non-invasive monitoring of oxygen saturation, and pulse rate are required for patients weighing more than 20kg.
- The SenTec Digital Monitoring System is indicated for use in hospitals, hospital-type facilities, intra-hospital transport environments, and – if under clinical supervision – home environments.
- The SenTec Digital Monitoring System is for prescription use only.

Note: Hospital use typically covers areas such as general care floors, operating rooms, special procedure areas, intensive and critical care areas. Hospital-type facilities typically cover facilities such as surgical centers, special nursing facilities, and sleep labs outside of the hospital. Intra-hospital transport includes transport of a patient within the hospital or hospital-type facilities.

Limitations of Cutaneous Blood Gas Measurements

The SDMS monitors cutaneous pCO_2. The following clinical situations or factors may affect the correlation between cutaneous and arterial pCO_2 values:

- hypoperfused measurement site due to low cardiac index, shock, circulatory centralization, hypothermia, vasoactive drugs, or mechanical pressure on measurement site (pCO_2 readings are typically too high if the measurement site is hypoperfused)
- inadequate measurement site and/or condition of patient's skin and subcutaneous tissue (placement over large superficial veins or areas of skin breakdown or edema)
- inadequate contact between sensor and patient's skin causing the CO_2 diffusing out of the skin to be intermixed with ambient air
- arterio-venous shunts

Note: The SDMS is not a blood gas device. Keep the above mentioned limitations in mind when interpreting cutaneous pCO_2 values.

Note: When comparing pCO_2 values displayed by the SDM against pCO_2 values obtained from arterial blood gas (ABG) analysis, pay attention to the following points:

- Carefully draw and handle blood samples.
- Blood sampling should be performed in steady state conditions.
- The pCO_2 value obtained from ABG analysis has to be compared to the SDM's pCO_2 at the time of blood sampling.
- The pCO_2 values displayed by the SDM are automatically corrected to 37 °C (regardless of the patient's core temperature). When performing the ABG analysis, make sure to properly enter the patient's core temperature into the blood gas analyzer. Use the blood gas analyzer's "37 °C-pCO_2" value to compare with the SDM's pCO_2 values.
- Verify proper operation of the blood gas analyzer. Periodically compare the blood gas analyzer's barometric pressure against a known calibrated reference barometer.

Limitations of Pulse Oximetry

The SDMS monitors functional oxygen saturation (SpO_2). The following clinical situations or factors may limit the correlation between SpO_2 and arterial oxygen saturation (SaO_2) values:

- dysfunctional hemoglobins (COHb, MetHb)
- intravascular dyes
- low perfusion at the measuring site
- skin pigmentation
- venous pulsations (e.g. due to use of the forehead, cheek, or earlobe as a measurement site on a patient in steep Trendelenburg position)
- anemia
- exposure of the sensor to high ambient light levels

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

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

The SenTec Digital Monitoring System (SDMS)

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

- **SenTec Digital Monitor** (SDM) including power cord (connector depending on country of sale)
- **SDMS Instruction Manual** (language depending on country of sale)
- **SDMS Manual CD** (providing detailed information on all system components, e.g. SDM Technical Manual in English, Directions for Use for V-Sign-Sensors and Disposables, ...)
- **V-Sign™ Sensor** (VS-A/P) and/or **V-Sign™ Sensor 2** (VS-A/P/N) (PCO_2 / oximetry sensors)
- **Digital Sensor Adapter Cable** (to connect V-Sign™ Sensor or V-Sign™ Sensor 2)
- **SpO_2 Soft Sensor** (reusable oximetry sensor)
- **SpO_2 Adapter Cable** (to connect SpO_2 Soft Sensor)
- **V-Sign™ Membrane Changer** (to change membrane and electrolyte of V-Sign™ Sensors)
- **Ear Clip** and **Multi-Site Attachment Rings** (for V-Sign™ Sensor application)
- **Contact Gel** (contact liquid for V-Sign™ Sensors)
- **Service Gas** (Calibration gas for V-Sign™ Sensor calibration)
- **V-STATS™ Installation CD**

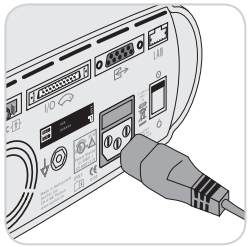
Additional instructions for the SenTec Digital Monitor, the V-Sign™ Sensors, the SpO_2 Soft Sensor, the V-Sign™ Membrane Changer, the Ear Clip and the Multi-Site Attachment Rings are provided in the respective directions for use. To ensure proper operation of the SDMS, precisely follow the instructions provided in this Instruction Manual step by step.

Note: The components listed above do not necessarily correspond to the scope of delivery. A complete list of available products including disposables and accessories is provided on the SenTec Website (www.sentec.ch).

Note: Unless one of the two V-Sign™ Sensor models is explicitly stated the notion "V-Sign™ Sensor" in the following refers to both V-Sign™ Sensor models.

Setting up the SenTec Digital Monitor (SDM)

Connect SDM to AC Power



Plug the female connector of the power cord into the AC power connector on the rear of the monitor (23).

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

The SDM will automatically adapt to the applicable local voltage: 100 - 240V~ (50/60Hz).
Verify that the AC power/battery indicator (10) is lit. If the AC power/battery indicator is not lit, check the power cord, accessible fuses, and the AC power outlet.

Battery Operation of the SDM

The SDM is equipped with a rechargeable internal LiIon battery that can be used to power the monitor during transport or when AC power is not available. A new, fully charged battery will provide 6 hours of monitoring time. The battery icon (75%) indicates the remaining battery charge (%).

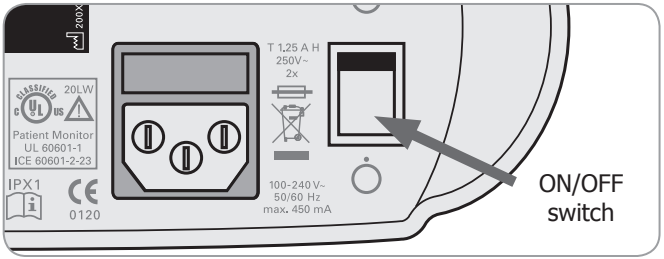
The AC Power/Battery Indicator (10) informs about the charging status of the battery:

green: SDM connected to AC power, battery fully charged
yellow: SDM connected to AC power, battery charging
LED off: SDM not connected to AC power (i.e. powered by internal battery)

It takes approximately 7 hours to fully charge an empty battery.

Turning on the SDM

Turn on the SDM by pushing the ON/OFF switch at the rear of the SDM (24). The SDM performs a power-on self-test. Check the date/time settings of the SDM and adjust if necessary.



Setting up the SDMS with a V-Sign Sensor

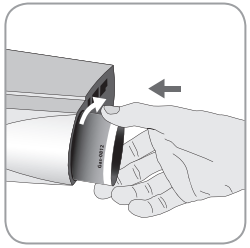
Installation of the Service Gas Bottle

Note: The calibration gas is only required for pCO_2 monitoring with V-Sign™ Sensors.

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

⚠ **WARNING:** Do not use gas bottles from manufacturers other than SenTec. The use of non-SenTec gas bottles may damage the Docking Station. Wrong calibration gas mixtures will result in wrong sensor calibrations, and subsequently result in wrong pCO_2 data.

The gas bottle slot is located on the rear of the SDM (19).



Remove the gas bottle by turning it in counter-clockwise direction.

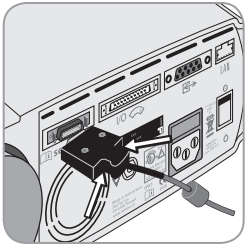
Insert the gas bottle by turning it in clockwise direction and tighten it without applying undue force.

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

Note: The status icon "Gas" (100%) is displayed only if the sensor is in the Docking Station and if the parameter "PCO_2" is enabled. The "Gas" icon highlights yellow if the remaining capacity is below 10% and red if the gas bottle is empty. Replace the gas bottle if the message 'Gas bottle empty' (0%) is displayed in the status bar.

Note: Dispose of empty gas bottles according to local waste regulations for aluminium containers.

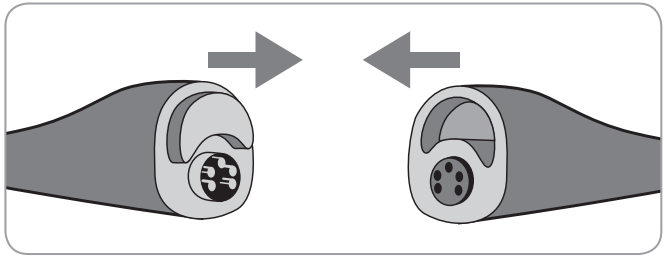
Connection/Disconnection of Digital Sensor Adapter Cable



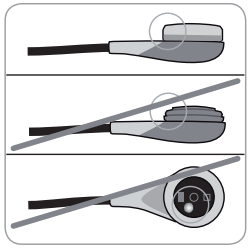
Connect the Digital Sensor Adapter Cable to the SDM. The connection is properly established when both clamps of the plug snap in (15).
Disconnect the cable from the SDM by pressing the two latches on the black plug to release the clamps (see picture) and pull to remove the cable.

Connect V-Sign™ Sensor

Connect the V-Sign™ Sensor to the Digital Sensor Adapter Cable.



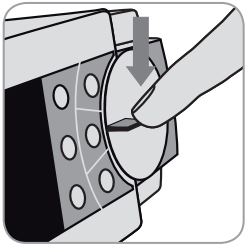
Check the V-Sign™ Sensor



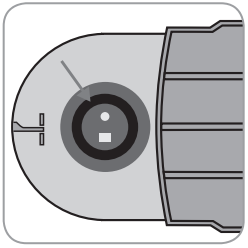
Make sure the sensor membrane is securely fastened, no air bubbles are present under the membrane and that the membrane is hydrated (no white appearance under the membrane). If needed, change the membrane. In case of any residue on the sensor membrane, clean it with 70% isopropanol by carefully wiping the sensor surface. In case of any visible damage of the sensor housing or cable, contact SenTec authorized service personnel or your local SenTec representative. Store the sensor in the Docking Station until it is applied on the patient.

V-Sign™ Sensor Calibration and Storage

If a calibration of the sensor is needed, the SDM will automatically prompt the message 'Calibrate sensor' in the status bar.

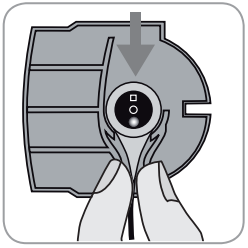


1. Open the Docking Station door (7) on the front side of the monitor by pressing on the front of the door latch (6) from above without applying excessive force.



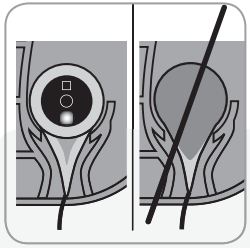
2. Check the gasket in the Docking Station. If necessary, clean Docking Station and gasket by using a cotton swab (Q-Tip) with 70% isopropanol.

⚠ **WARNING:** Always clean the sensor before putting it into the Docking Station.



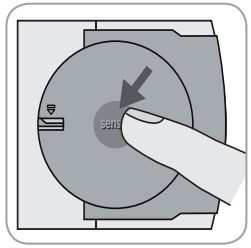
3. Hang the sensor into the holder at the inside of the door (red light visible).

ⓘ **CAUTION:** Wrong orientation of the sensor in the Docking Station might cause damage to the sensor, the Docking Station, or parts of them.



4. The sensor has to be placed properly into the holder to ensure that the Docking Station door can be closed without force.

⚠ **WARNING:** For a correct calibration it is necessary that the sensor is always positioned correctly in the Docking Station door and that the Docking Station door is properly closed.



5. Close the Docking Station door. The SDM now checks the sensor and will automatically start to calibrate the sensor if necessary. If the sensor is ready for use, then this will be displayed accordingly. If a sensor membrane change is required, follow the instructions provided on the following pages and confirm the membrane change as requested by the monitor.

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

⚠ **WARNING:** To maintain monitor readiness, always keep the monitor switched on and always store the sensor in the Docking Station.

The SDM provides a SMART CALMEM function that permits to disconnect and reconnect a calibrated V-Sign™ Sensor without the need to recalibrate the sensor, provided that the disconnection duration is less than 30 minutes and that the "Calibration Interval" does not elapse while the sensor is disconnected.

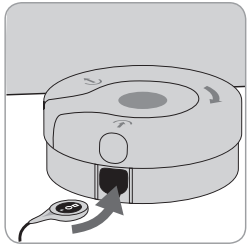
Note: No calibration will be initiated if a calibrated sensor is removed from the Docking Station and re-inserted into the Docking Station after less than 10 minutes.

V-Sign™ Sensor Membrane Change

In factory default settings the "Membrane Change Interval" is 42 days, i.e. under normal use conditions, it is recommended to change the membrane of the V-Sign™ Sensor every 42 days. If the "Membrane Change Interval" has elapsed, the SDM displays the message 'Change sensor membrane', triggers a low priority alarm, activates the menu 'Membrane Change' and marks PCO_2 as unstable. Additionally the membrane of the sensor must be changed if air bubbles are visible underneath the membrane or if the membrane is damaged.

The membrane of the V-Sign™ Sensor is changed with the V-Sign™ Membrane Changer.

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



Insert sensor into membrane changer

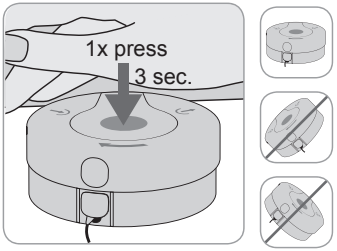
1. Place the V-Sign™ Membrane Changer on a solid flat surface (e.g. table top).

2. Hold the sensor head horizontally (membrane up) and insert it into the V-Sign™ Membrane Changer.

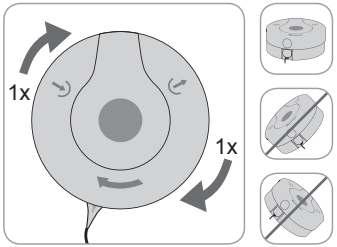
Change sensor membrane in 4 steps

The membrane change procedure consists of the following 4 steps: step 1 removes old sensor membrane, step 2 cleans sensor surface, step 3 applies new electrolyte on sensor surface and step 4 sets new membrane on sensor.

Repeat the following "Press and Turn" procedure **4 times**:



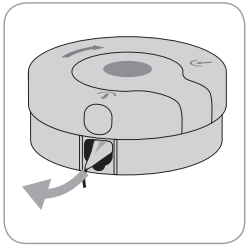
1. Press down slowly but firmly with palm of hand and **hold** for 3 seconds.



2. Keep V-Sign™ Membrane Changer **horizontally**. Grab base of membrane changer with one hand, turn top clockwise with other hand to next stop.
Do not hold the sensor cable while turning, as the sensor may become dislodged from the membrane changer.

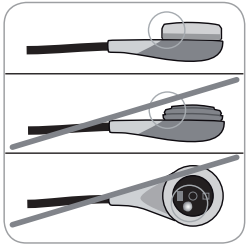
Important: Pay attention to repeat the Press and Turn procedure **4 times!**

Remove sensor from membrane changer



Press once again or lift the sensor to release it and remove the sensor from the V-Sign™ Membrane Changer.

Inspect sensor membrane



1. Verify that the membrane ring is securely seated on the sensor.

2. Verify that there are no air bubbles between membrane and sensor surface.

In case of loose fit or trapped air, you must repeat the membrane change procedure as described above.

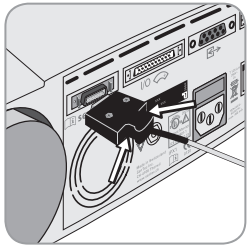
To reset the membrane timer if an unrequested membrane change was performed (e.g. because membrane was damaged), activate the menu item 'Membrane Change' and confirm the membrane change.

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

Important: The Contact Gel (Sensor Gel) is not needed in any step of the remembraning process. The Contact Gel is only used for sensor application.

Setting up the SDMS with the SpO_2 Soft Sensor

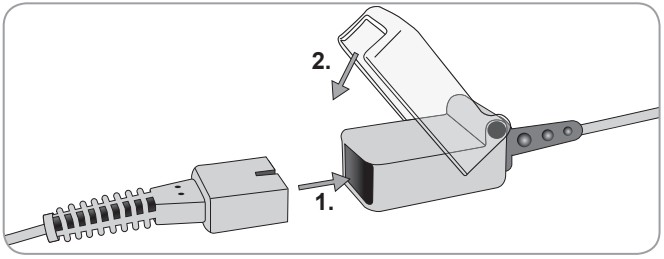
Connection/Disconnection of SpO_2 Adapter Cable



Connect the SpO_2 Sensor Adapter Cable to the SDM. The connection is properly established when both clamps of the plug snap in (15).
Disconnect the cable from the SDM by pressing the two latches on the black plug to release the clamps (see picture) and pull to remove the cable.

Connect SpO_2 Soft Sensor

Open the plastic latch at the opposite end of the SpO_2 Sensor Adapter Cable and plug the sensor and the Adapter Cable together. Snap the plastic latch down over the connectors.



Measurement Sites and Means of Sensor Application

The choice of the sensor and the type of sensor application depends on the parameters to be measured, the skin condition, and the patient´s age.

Adult/Pediatric Patients (> 1 month of age)

Sensor: V-Sign™ Sensor 2 (VS-A/P/N)

Parameters	Measurement site	Skin condition	Sensor application
$pCO_2$and SpO_2/PR	earlobe	intact	Ear Clip
	Low on forehead, cheek	intact	MAR-MI
		sensitive, fragile	MAR-SF
pCO_2	earlobe	intact	Ear Clip
	Low on forehead, cheek, thorax under clavicle, upper arm, area behind earlobe (on mastoid process)	intact	MAR-MI
		sensitive, fragile	MAR-SF

Parameters	Measurement site	Skin condition	Sensor application
SpO_2/PR	earlobe	intact	Ear Clip
	Low on forehead, cheek	intact	MAR-MI
		sensitive, fragile	MAR-SF

Note: To attach the V-Sign™ Sensor 2 (VS-A/P/N) with the Ear Clip, the earlobe needs to be big enough to cover the whole sensor membrane. If the earlobe is too small, you should use a Multi-Site Attachment Ring (model MAR-MI or MAR-SF) to attach the sensor to an alternate site.

⚠ **Warning:** The measurement of SpO_2 and PR with V-Sign™ Sensor 2 (VS-A/P/N) is not defined on sites other than the earlobe, forehead and cheek. In order to avoid erroneous readings and false alarms of SpO_2 and PR, ensure that the appropriate patient mode (Adult) is selected. For sensor application on sites other than the earlobe, forehead, and cheek in adult/pediatric patients furthermore disable the parameters SpO_2/PR in the menu of the SDM.

Sensor: V-Sign™ Sensor (VS-A/P)

Parameters	Measurement site	Skin condition	Sensor application
$pCO_2$and SpO_2/PR	earlobe	intact	Ear Clip
pCO_2	earlobe	intact	Ear Clip
	Low on forehead, cheek, thorax under clavicle, upper arm, area behind earlobe (on mastoid process)	intact	MAR-MI
		sensitive, fragile	MAR-SF
SpO_2/PR	earlobe	intact	Ear Clip

Note: To attach the V-Sign™ Sensor (VS-A/P) with the Ear Clip, the earlobe needs to be big enough to cover the whole sensor membrane. If the earlobe is too small, you should use a Multi-Site Attachment Ring (model MAR-MI or MAR-SF) to attach the sensor on an alternate site.

⚠ **Warning:** The measurement of SpO_2 and PR with V-Sign™ Sensor (VS-A/P) is not defined on sites other than the earlobe. In order to avoid erroneous readings and false alarms of SpO_2 and PR, ensure that the appropriate patient mode (Adult) is selected. For sensor application on sites other than the earlobe in adult/pediatric patients furthermore disable the parameters SpO_2/PR in the menu of the SDM.

Sensor: SpO_2 Soft Sensor (RSS-M)

For patients weighing > 20 kg

Parameters	Measurement site	Skin condition	Sensor application
SpO_2/PR	finger or toe	intact	integrated in sensor

Neonates (i.e. up to 1 month of age)

Sensor: V-Sign™ Sensors (VS-A/P or VS-A/P/N)

Parameters	Measurement site	Skin condition	Sensor application
pCO_2	thorax under clavicle, abdomen, back, low on forehead, inner or anterior aspect of the thigh	mature and intact	MAR-MI
		sensitive, fragile	MAR-SF

Monitoring with the SDMS

Measurement Settings

If the SDMS is ready for use, 'Ready for use' is displayed in big yellow font in the center of the screen. Before you start monitoring, verify the SDM's alarm system (alarm limits, AUDIO OFF Reminder, Alarm Volume) and at least the current settings of the SDM, that are displayed on the "Ready for use" screen, and adjust them if necessary.

The "Ready for use" screen

Information displayed in the upper left corner:
Patient type indicator: Displays the current patient type (Neonatal or Adult).
Sensor type indicator: Displays the model/type of the currently connected sensor.

Information displayed in the upper right corner:
Sensor set temperature: Displays the currently selected SET temperature (this indicator only displays if the connected sensor is heated).

⚠ **Warning:** A sensor SET temperature of 41.5 °C or higher is not recommended to be used on neonates / infants (up to one year of age).

Special heating settings: Displays the current configuration of INITIAL HEATING and SITE PROTECTION. For detailed information on the heating settings, please refer to the SDM Technical Manual.

Information displayed in the center:
Enabled Parameters: Indicates the parameters (pCO_2, SpO_2, PR) which are currently activated. The parameters that can be monitored with the SDMS depend on the sensor type, the patient type and the measurement site. Please refer to page 15 for an overview. Adjust the parameters if necessary.
Available monitoring time [hrs]: Indicates the time available for patient monitoring, i.e. the time interval after removing the sensor from the Docking Station or applying the sensor to the patient until the "Preset Site Time" or – if PCO_2 is enabled – until the "Calibration Interval" elapses (whichever occurs first).

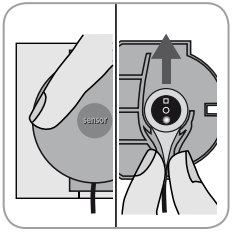
Membrane Change is due in [days]: Indicates the number of days left until the next membrane change is mandatory (only if PCO_2 is enabled).
Recommended sensor stabilization [mins]: Indicates the recommended sensor stabilization duration in minutes if PCO_2 is enabled (only displays if sensor stabilization is recommended and message is enabled).
Current parameter settings: Indicates which of the available parameters settings (standard, operator) is active (only displays in institutional mode). For detailed information on the parameters settings, please refer to the SDM Technical Manual.

Note: If the SDM is in sleep mode, the display is inactive (black). Press any of the control-buttons of the SDM to activate the display.

V-Sign™ Sensor Attachment with the Ear Clip

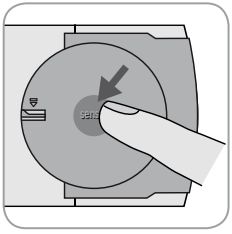
1. Verify that the SDM is "Ready for use" and verify the settings displayed on the "Ready for use" screen.

2. Clean the earlobe with a swab wetted with 70% isopropanol (or according to procedures applying to your institution) and let it dry.

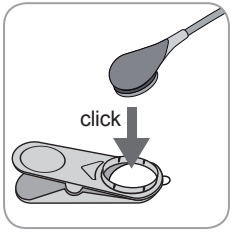


3. Open the Docking Station door (7) on the front side of the monitor by pressing on the front of the door latch (6) from above without applying excessive force and take out the sensor.

Note: Always hold the sensor at the sensor head, do not pull at the sensor cable.

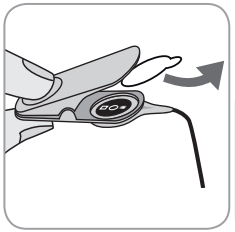


4. Close the Docking Station door by pushing in the middle of the Docking Station door until the door latch snaps in.



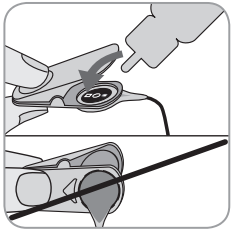
5. Press the sensor into the Ear Clip until it snaps in. **Use a new Ear Clip for each new patient!**

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



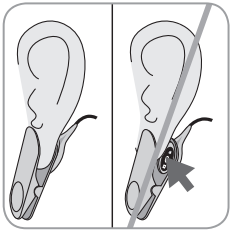
6. Pull off the liner protecting the adhesive tape of the Ear Clip.

⚠ **WARNING:** Do not swallow Contact Gel. Keep away from children. Avoid contact with eyes and injured skin. Use only approved SenTec Contact Gel.

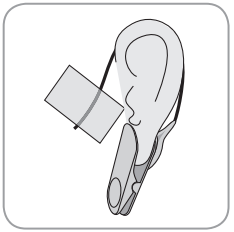


7. Place one **small** drop of contact liquid in the middle of the membrane surface. Make sure to keep the Ear Clip open and to handle the sensor such as the contact liquid does not run off the membrane. Avoid wetting the adhesive pad of the Ear Clip!

Note: As contact liquid you may use SenTec Contact Gel, clean tap water, sterile water, or sterile saline solution.



8. Pull the earlobe in a horizontal position, move in the sensor from the side and attach the sensor from below to the back side of the earlobe. Close the clip from above, then guide the earlobe back in vertical position. The sensor is applied correctly if the whole dark surface is covered by the earlobe. Make sure that the sensor has good contact to the skin (no air gaps between membrane and earlobe).



9. Wrap the sensor cable around the ear once, tape the cable to the cheek as shown in the picture, and secure the cable with the Clothing Clip on the shirt or bed linen. Due to the slightly increased sensor temperature, the maximal site time is automatically controlled by the SDM. Remove the sensor when the remaining monitoring time has elapsed (0.0h) either because the site time has elapsed (status message 'Site time elapsed') or because a calibration of the sensor is required (status message 'Calibrate sensor').

V-Sign™ Sensor attachment with Multi-Site Attachment Rings

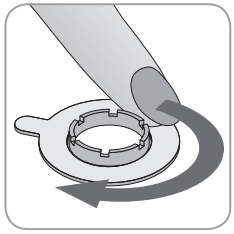
1. Select the appropriate attachment ring (MAR-MI or MAR-SF) and measurement site (see overview on page 15f).

Note: Avoid placement over large superficial veins or areas of skin breakdown.

2. Remove hair from the measurement site if necessary.

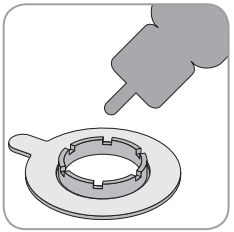
3. Clean the skin at the measuring site with a swab wetted with 70% isopropanol (or according to procedures applying to your institution) and let it dry.

4. Pull off the liner protecting the adhesive tape of the attachment ring.



5. Attach the ring to the measurement site, press gently on the snap ring. Move your finger around the ring circumference to ensure a good seal, i.e. good adhesion of the entire adhesive to the skin.

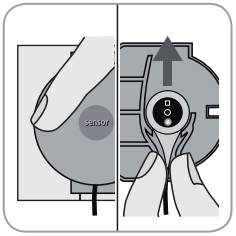
⚠ **Warning:** Do not swallow Contact Gel. Keep away from children. Avoid contact with eyes and injured skin. Use only approved SenTec Contact Gel.



6. Apply one **small** drop of contact liquid to the skin area in the center of the attachment ring. Alternatively you can use a cotton swab (Q-Tip) to apply the contact liquid. Ensure that the contact liquid does not wet the adhesive.

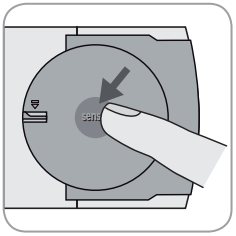
Note: As contact liquid you may use SenTec Contact Gel, clean tap water, sterile water, or sterile saline solution.

7. Verify that the SDM is "Ready for use" and verify the settings displayed on the "Ready for use" screen.

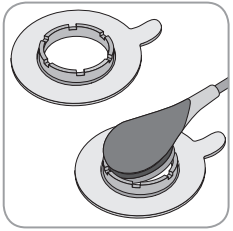


8. Open the Docking Station door (7) on the front side of the monitor by pressing on the front of the door latch (6) from above without applying excessive force and take out the sensor.

Note: Always hold the sensor at the sensor head, do not pull at the sensor cable.

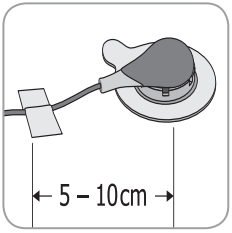


9. Close the Docking Station door by pushing in the middle of the Docking Station door until the door latch snaps in.



10. Holding the sensor at the cable strain relief, approach the MAR from the flap side and first insert the nose of the sensor into the ring. Then apply a slight downward pressure on the cable strain relief. The spring tension of the application device will pull the sensor into place with little to no pressure on the skin. Slightly twist the sensor in the ring and press the sensor gently to ensure distribution of the contact liquid and contact with the skin.

Note: Care must be taken to ensure that air gaps and bubbles are eliminated when placing the sensor onto the skin.

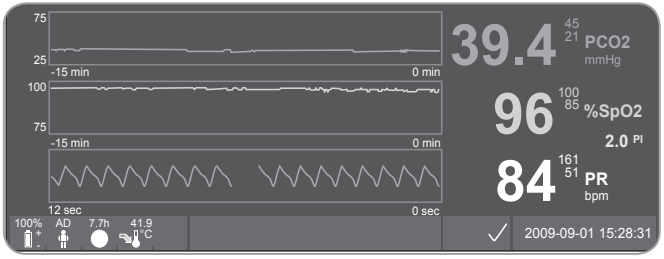


11. Twist the sensor into the best position. For forehead/cheek placement wrap the sensor cable once around the ear and tape the cable to the cheek. For other application sites, tape the cable at a distance of 5 to 10 cm from the sensor head to the skin. Secure it with a Clothing Clip on shirt or bed linen.

Note: Alternatively you may first take out the sensor from the Docking Station, apply one small drop of contact liquid to the center of the sensor membrane surface, and finally insert the sensor into the attachment ring (make sure to handle the sensor such as the contact liquid does not run off the membrane).

Monitoring with the V-Sign™ Sensor

Depending on the selected patient type (menu-parameter 'Measurement Settings/Patient'), and the selected parameters (menu-parameter 'Measurement Settings/Enabled Parameters') different preconfigured measurement screens are available.



The SDM displays the current values, trend graphs, and plethysmographic waveform for SpO_2, pCO_2 und PR. Furthermore it displays high and low alarm limits, Pulsation Index, alarms, alarm/status messages and status icons (Battery, Patient Type, Remaining Monitoring Time, Sensor Temperature, Heating Power (if enabled), AUDIO, Alarm). Additionally, the pulse can be monitored by a mutable audio-signal. Its automatic pitch modulation reflects changing SpO_2 levels. For detailed information on the measurement screens, please refer to the SDM Technical Manual.

Before you start monitoring, check the following settings:
- Alarm limits for the selected parameters
- Trendgraph Ranges for the selected parameters
- Time Range for Trends

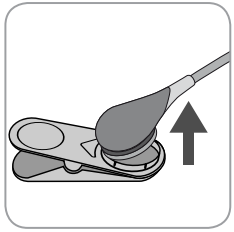
After sensor application, cutaneous pCO_2 readings typically stabilize within 2 to 10 minutes, i.e. the time required to warm up/induce local arterialization of the measurement site as well as to achieve equilibrium between the CO_2 concentration in the skin tissue and the CO_2 concentration in the sensor's electrolyte. During pCO_2 stabilization pCO_2 values increase and the message 'PCO_2 stabilizing' displays and pCO_2 readings are marked as unstable (value displayed in grey), thereby indicating that pCO_2 readings during pCO_2 stabilization do not reflect patient's pCO_2 level.

If the measured values do not stabilize, check the correct application of the sensor. In order to reduce the occurrence of air gaps/leaks between the sensor and the skin, a good contact between the sensor and the patient's skin is essential. Make sure that the sensor cable is fixed on the skin to get a good strain relief.

During pCO_2 stabilization both visual and auditory alarms are inhibited.

Detachment of the sensor

Ear Clip



1. Remove the adhesive tape and the Ear Clip carefully from the patient's earlobe. Detach the sensor carefully from the Ear Clip.
Note: You may also remove the sensor from the Ear Clip and leave the Ear Clip attached to the earlobe for further measurements.

Important: Always inspect skin before further use of the same measurement site.

Multi-Site Attachment Ring

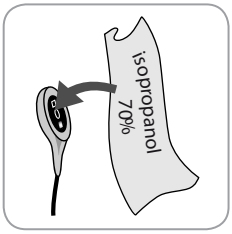
Note: For inspection of the measurement site or calibration of the sensor it is not required to remove the Attachment Ring from the skin.

1. Hold the ring with one finger on every side of the sensor.

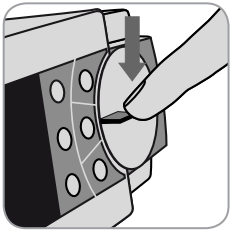
2. Without squeezing the flange, rotate the sensor /cable connection over your finger to release the sensor.

3. Remove the Attachment Ring from the skin by carefully pulling at the little tab.

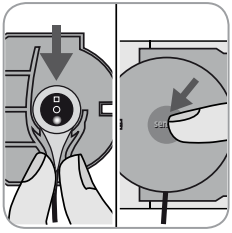
Note: Careful removal of the adhesive tape from the skin is important.



4. After use and before inserting the sensor into the Docking Station, remove any gel residues or dirt from the sensor and the patient´s skin with a swab wetted with 70% isopropanol.



5. Open the Docking Station door (7) on the front side of the monitor by pressing on the front of the door latch (6) from above without applying excessive force.



6. Hang the sensor (red light visible) into the holder at the inside of the Docking Station door. Close the Docking Station door. If necessary, sensor calibration starts automatically. Note the messages displayed by the SDM.

Note: The display of the SDM will indicate readiness with the "Ready for use" screen.

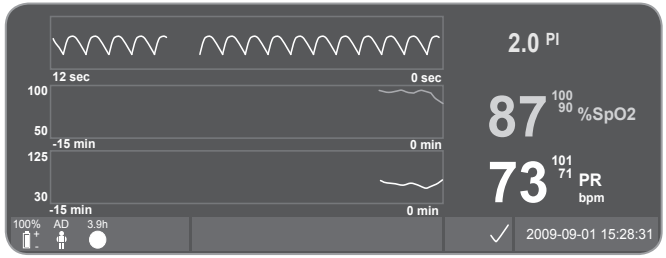
Attachment of the SpO_2 Soft Sensor

Select a suitable site for the SpO_2 Soft sensor. The patient's first finger is the preferred location. Alternative sites recommended are the thumb, large toe, or little finger.

Fit the sensor as illustrated in the SpO_2 Soft Sensor Directions for Use. The patient's finger must be inserted right to the end of the sensor. Direct the cable along the patient's finger and parallel to the arm. Affix with adhesive tape if required.

Monitoring with the SpO_2 Soft Sensor

Two preconfigured measurement screens are available.



The SDM displays the current values, trend graphs, and plethysmographic waveform for SpO_2 and PR. Furthermore it displays the Pulsation Index, high and low alarm limits, alarms, alarm/status messages and status icons (Battery, Patient Type, Remaining Monitoring Time, AUDIO, Alarm). Additionally the pulse can be monitored by a mutable audio-signal. Its automatic pitch modulation reflects changing SpO_2 levels. For detailed information on the measurement screens, please refer to the SDM Technical Manual.

After sensor application, SpO_2 and PR readings typically stabilize within the first minute. During SpO_2 and PR stabilization SpO_2 and PR readings are marked as unstable (value displayed in grey).

If the measured values do not stabilize, check the correct application of the sensor. Make sure that the sensor cable is fixed on the skin to get a good strain relief.

During SpO_2 and PR stabilization both visual and auditory alarms are inhibited.

Controls and Alarms of the SDM

Buttons

The SDM can be controlled with six buttons:

Menu/Previous Level Button	• to access the menu • to return to the menu on the next higher level (only if 'editing mode' is inactive) • to de-activate the 'editing mode' for the selected menu-parameter
and **UP & DOWN Button**	• to navigate the grey menu bar up- and downwards (only if 'editing mode' is inactive) • to increase or decrease the value of the menu parameter for which the 'editing mode' is active **Note:** most changes immediately become effective without confirmation • to increase or decrease brightness of the display (only during patient monitoring)
AUDIO PAUSED/ AUDIO OFF Button	• to pause auditory alarm signals for 1 or 2 minutes (depending on menu setting) • to switch OFF auditory alarm signals permanently (by pressing > 3 seconds) **Note:** switching off auditory alarm signals is only possible if enabled by Responsible Organization (for details refer to the SDM Technical Manual) **Note:** This button is inactive if the menu parameter 'Alarm Settings / Alarm Volume' is set to OFF by the responsible organization.
Enter Button	• to activate the selected sub-menu or function • to activate/deactivate 'editing mode' for the selected menu parameter • to confirm latched alarms (for details refer to the SDM Technical Manual)
Display Button	• to switch between the available measurement displays • to deactivate 'editing mode' for the selected menu-parameter • to return to the measurement display from any menu level (only if 'editing mode' is inactive)

Note: The ON/OFF switch is located on the rear of the SDM (24).

Example 1: "Language"

Note: This parameter may be disabled by the responsible organization.

Operate the menu of the SDM as follows:

- Press to access the menu.
- Scroll down to 'System Settings' with (press 3 times).
- Press to acces the menu 'System Settings'.
- Scroll down to 'Language' with (press 3 times).
- Press to activate the 'editing mode' for the menu parameter 'Language'. The 'Enter' symbol at the end of the line will change to the 'editing mode' symbol (up and down arrows).
- Press or to select a language.
- Press to deactivate the 'editing mode'. The 'editing mode' symbol at the end of the line will change to the 'Enter' symbol.
- Press to move down to the next menu line 'Confirm Language/Main View' and press to confirm. The SDM automatically returns to the Main Screen.

Example 2: "Membrane Change"

Operate the menu of the SDM as follows:

Note: The menu 'Membrane Change' can only be accessed if the sensor is neither in the Docking Station nor on patient.

- Press to access the menu.
- Scroll down to 'Membrane Change' with (press 2 times).
- Press to acces the menue 'Membrane Change'.
- Scroll down to 'Membrane Change Done' with (press once).
- Press to confirm that you have changed the sensor membrane.

Important: The membrane timer only resets, if you confirm the membrane change.

LED Indicators

The SDM uses three LEDs for visual indication of alarms, on/off status and power status:

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

Alarms

The SDM uses auditory (this section) and visual alarm signals (refer to the previous and the following section), to alert the user when a measurement value violates its alarm limits or to indicate technical conditions of the equipment that require operator response or awareness.

Note: For a detailed description of alarm melodies, which can be switched on by the responsible organization, please refer to the SDM Technical Manual.

The following auditory alarms can be distinguished:

High priority alarm:
A high-pitched fast pulsing tone indicating a SpO_2 limit violation (two bursts of five short pulses repeated every 10 seconds).

Medium priority alarm:
A medium-pitched pulsing tone indicating a pCO_2 or PR limit violation (one burst of three pulses) repeated every 10 seconds) or a Battery Critical Alarm (only if SDM not connected to AC).

Low priority alarm:
A low-pitched slow pulsing tone indicating a system status that requires operator awareness (one burst of two pulses repeated every 15 seconds).

Note: If a parameter is unstable or invalid, the alarm surveillance for the respective parameter is not active. For details, please refer to the SDM Technical Manual.

By pressing the AUDIO PAUSED/AUDIO OFF button, auditory alarm signals can be muted for 1 or 2 minutes (depending on menu setting) or permanently (if pressing > 3 seconds).

⚠ **WARNING:** The function "Nurse Call" is inactive when alarms are muted.

Status Bar

The status bar appears on most of the display screens.

- At the left, it displays up to 5 status icons.
- In the status text field in the middle, it displays Status Messages (alarm/information messages).
- The status text field is followed by the AUDIO status icon indicating the status of auditory alarm signals (ON, PAUSED, or OFF)
- The Alarm Status Icon indicates the priority of the highest priority alarm condition (flashing white triangle with curved line and exclamation mark on red background in a high priority alarm condition; flashing black triangle with curved line and exclamation mark on yellow background in a medium priority alarm condition; black triangle with curved line and exclamation mark on cyan background in a low priority alarm condition; light grey check mark symbol on dark-grey background if no alarm condition)
- On the right, date and time are indicated in the "yyyy-mm-dd hh:mm:ss" format.

For a detailed description of the status bar, please refer to the SDM Technical Manual.

Maintenance of the SDM

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.

Instructions for cleaning and/or disinfection of the SenTec Digital Monitor (SDM), the Digital Sensor Adapter Cable, and the SpO2 Adapter Cable are provided in the SDM Technical Manual. Please refer to the respective Directions for Use for instructions for cleaning and/or disinfection of the V-Sign™ Sensor and the SpO_2 Soft Sensor.

Routine Checks

The following checks should be performed regularly:

- Power on self test (POST): Every time the SDM is switched on, the POST is performed automatically. If you keep the SDM always switched on, monthly switch it off and on again to start the POST.
- Monthly check the SDM for mechanical and functional damages.
- Monthly inspect the sensors for mechanical and functional damages.
- Monthly check the power cord and the Digital Sensor Adapter Cable for mechanical or functional damages. Defective cables must be replaced by original replacement parts.
- Monthly check the barometer ( ) of the SDM against a known calibrated barometer.
- Monthly check the alarm function of the SDM.
- Weekly clean the Docking Station gasket using a cotton swab (Q-Tip) with 70% isopropanol.
- Monthly inspect the Docking Station door and gasket for mechanical damages.

Refer to the SDM Technical Manual and the Directions for Use of the sensors for additional/complete check lists and detailed maintenance procedures.

Note: Please check the disposables monthly. Replace expired products!

Service

It is recommended to perform a safety check at regular intervals (at least every 24 months) or in accordance with local and governmental regulations (refer to the Service Manual for the SDMS for details). To perform a safety check and for service or repair, contact qualified service personnel or your local SenTec representative. Please note that repair and service procedures which do require to open the cover of the SDM must be performed by SenTec authorized service personnel.

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

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