INSTRUCTION MANUAL

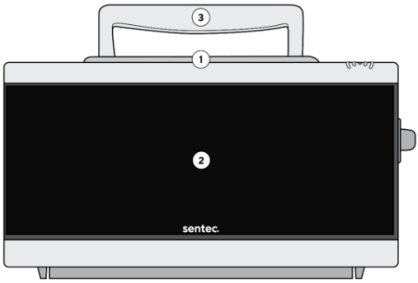
tCOM+ Transcutaneous Monitor & Sensors

SW-Version 01.05 and higher

sentec.

The tCOM+

Front panel



1. LED Bar
2. Touchscreen
3. Handle

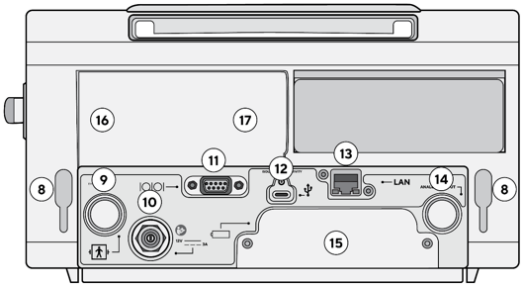
Side panel – left

4. Gas Bottle
5. DATA/SERVICE USB Port (USB C)
6. ON/OFF Button

Side panel – right

7. Docking Station

Back panel



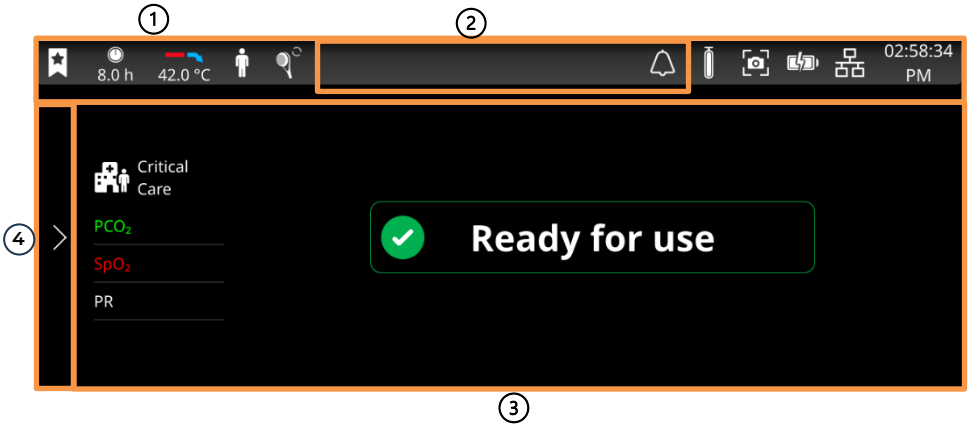
8. Cable Holder Slots
9. Sensor Connection Port
10. DC Power Connector
11. Serial Data Port (RS-232)
12. Isolated Connectivity Port (USB C)
13. Network Port (LAN)
14. Analog Output Port
15. Battery Cover
16. Fan
17. Speaker

Touchscreen

The tCOM+ touchscreen allows user interaction via fingertip/thumb movement, such as tapping icons, words, and symbols, e.g., to bring up or exit screens and to select or toggle options. Swiping gestures can be used for moving screens or setting parameters. Furthermore, a pop-up keyboard allows for entering customized information.

The touchscreen comprises the following sections:

1. Status Bar
2. Alarm Bar
3. Main Screen displaying Main Menu and/or Measurement Screen
4. Arrow to open the Main Menu



All icons used on the tCOM+ touchscreen, except those depicted in the Status Bar, bear a name and/or description.

Note: Refer to 13.6 for a full list of user interface icons.

Warranty

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

Warranty Exclusions and System Performance

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

Unauthorized modifications to Sentec products could void your warranty and alter the regulatory status of the devices. Any resulting service required is not covered under our service agreements. Such modifications can affect the performance or safety of your device in unpredictable ways, and Sentec is not responsible for equipment that has been modified.

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

Patents/Trademarks/Copyright

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

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

MEDICAL – GENERAL MEDICAL EQUIPMENT

AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY

IN ACCORDANCE WITH:

- ANSI/AAMI ES60601-1:2005/A2:2021
- CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14
- CAN/CSA-C22.2 No. 60601-1-6:11 (IEC 60601-1-6:2010+A1:2013+A2:2020, MOD)
- IEC 60601-1-6:2010+AMD1:2013+AMD2:2020
- CAN/CSA-C22.2 No. 60601-1-8:08, (IEC 60601-1-8:2006+A1:2012+A2:2020, MOD)
- IEC 60601-1-8:2006+AMD1:2012+AMD2:2020
- ANSI/AAMI HA60601-1-11:2015 &A1:2021
- CAN/CSA-C22.2 No. 60601-1-11:15, (IEC 60601-1-11:2015+A1:2020, MOD)
- IEC 60601-2-23:2011
- CSA CAN/CSA-C22.2 NO. 60601-2-23:12
- ISO 80601-2-61:2017

Contents

1 The Sentec Digital Monitoring System (SDMS/System)

1.1 Indications for Use / Intended Purpose

Note: This manual uses the term **"system"** to refer to any combination of the tCOM+ and sensors, cables, accessories, disposables, and software.

1.1.1 Indications for Use

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

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

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

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

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

Training: Professional medical personnel and instructed home care personnel are trained by Sentec or a qualified and authorized distributor. The instructed home care personnel provide the lay user with the lay user manual and explains attachment and detachment of the sensor. The instructed home care personnel also define the application site for the attachment of the sensor.

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

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

1.1.2 Intended Purpose of the tCOM+

The tCOM+ is a portable stand-alone patient monitor indicated for continuous, non-invasive patient monitoring of carbon dioxide partial pressure (PCO_2), oxygen partial pressure (PO_2), functional oxygen saturation (SpO_2) and pulse rate (PR), using either

- a single, digital sensor (V-Sign™ Sensor 2) for PCO_2, SpO_2 and PR measurement, OR
- a single, digital sensor (OxiVenT™ Sensor) for PCO_2, PO_2, SpO_2 and PR measurement

PO_2 measurement with tCOM+ is only possible when used in combination with an OxiVenT™ Sensor.

Description tCOM+:
Patient monitor
REF:
103164

Note: For a list of components including their specific intended purpose, contraindications, useful/shelf life, environmental and storage conditions, please refer to Appendix 13.2

1.2 Clinical Benefits

Transcutaneous blood gas monitoring can support improved clinical management of patients:

- Compared to intermittent arterial blood gas analysis, transcutaneous blood gas monitoring can be performed continuously, helping clinicians to identify trends and assess patient status.
- Non-invasive patient monitoring can help reduce the frequency of blood draws, thereby supporting reduction of the associated risks such as iatrogenic blood loss, infection, and pain.
- Performance of transcutaneous monitoring of PCO_2 and PO_2 monitoring is independent of ventilation strategy and lung compromise.
- Transcutaneous PCO_2 monitoring is possible in inpatient, outpatient, or home care settings.

1.3 Transcutaneous PCO_2 and PO_2

1.3.1 Principles of Operations of $tcPCO_2$ and $tcPO_2$

Carbon dioxide (CO_2) and Oxygen (O_2) are gases that readily diffuse through body and skin tissue and, therefore, can be measured by an appropriate non-invasive sensor being applied at the skin surface. If the skin tissue beneath the sensor site is warmed up to a constant temperature, local capillary blood flow increases, metabolism stabilizes, gas diffusion improves and, hence, reproducibility and accuracy of CO_2/O_2 measurements at the skin surface improves.

CO_2 tensions measured at the skin surface ($PcCO_2$) are usually consistently higher than arterial PCO_2 values ($PaCO_2$) in patients of all ages. It is therefore possible to estimate $PaCO_2$ from the measured $PcCO_2$. $TcPCO_2$ designates an estimate of $PaCO_2$ calculated from the measured $PcCO_2$ with an algorithm developed by J.W. Severinghaus. The 'Severinghaus Equation' first corrects $PcCO_2$ measured at the sensor temperature (T) to 37 °C by using an anaerobic temperature factor (A) and then subtracts an estimate of the local 'Metabolic Offset' (M).

Note: The $tcPCO_2$ values displayed by the tCOM+ are corrected/normalized to 37 °C and provide an estimate of $PaCO_2$ at 37 °C. On the tCOM+ and throughout this manual (unless explicitly stated otherwise) '$tcPCO_2$' is displayed/labelled as 'PCO_2'.

In newborns, PO_2 measured at the skin surface (PcO_2) correlates with arterial PO_2 (PaO_2) almost in a one-to-one relationship at a sensor temperature of 43 to 44 °C. The accuracy of PcO_2 compared to PaO_2 is best up to a PaO_2 of 80 mmHg (10.67 kPa), above which it increasingly tends to read lower than PaO_2 (especially in adults). As target PaO_2 levels in newborns are usually below 90 mmHg (12 kPa), a correction of PcO_2 values measured at a sensor temperature of 43 to 44 °C is normally not necessary.

Note: $TcPO_2$ designates an estimate of PaO_2 and corresponds to the measured PcO_2. On the tCOM+ and throughout this manual (unless explicitly stated otherwise), '$tcPO_2$' is displayed/labeled as 'PO_2'.

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

PATIENT TYPE	PO2 ENABLED	RECOMMENDED SENSOR TEMPERATURE [°C]	RECOMMENDED SITE TIME [H]
Neonate (if younger than term birth + 12 months)	No	41.0	8.0
	Yes	43.0	2.0
Adult/ Pediatric	No	42.0	8.0
	Yes	44.0	2.0

Good to know!
Warming the skin tissue beneath the sensor to a constant temperature improves accuracy because it, a) increases capillary blood flow/induces local arterialization, b) stabilizes metabolism, and c) improves gas diffusion through skin tissue. With increasing sensor temperature, the application duration ('Site Time') must be evaluated carefully and adjusted accordingly to reduce the risk of burns. Special attention must be given to patients with sensitive skin at the sensor site (3.2).

1.3.2 Limitations of $tcPCO_2$ and $tcPO_2$

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

- Hypo-perfused skin tissue beneath the sensor site due to low cardiac index, circulatory centralization (shock), hypothermia (e.g., during surgery), use of vasoactive drugs, arterial occlusive diseases, mechanical pressure exercised on measurement site, or inadequate (too low) sensor temperature.
- Arterio-venous shunts, e.g., ductus arteriosus (PO_2 only).
- Hyperoxemia (PaO_2 > 100 mmHg (13.3 kPa)) (PO_2 only).
- Inadequate measurement site (placement over large superficial veins, on areas with skin edema (e.g., oedema neonatorum), skin breakdown, and other skin anomalies).
- Improper sensor application resulting in an inadequate, not hermetically sealed contact between the sensor surface and the patient's skin causing the CO_2 and O_2 gases diffusing out of the skin to intermix with ambient air.
- Exposure of the sensor to high ambient light levels (PO_2 only).

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

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

When comparing PCO_2/PO_2 values displayed by the tCOM+ with $PaCO_2/PaO_2$ values obtained from arterial blood gas (ABG) analysis, pay attention to the following points:

- Carefully draw and handle blood samples.
- Blood sampling should be performed in steady state conditions.
- The $PaCO_2/PaO_2$ value obtained from ABG analysis should be compared to the monitor's PCO_2/PO_2 reading at the time of blood sampling.
- In patients with functional shunts, the sensor application site and the arterial sampling site should be on the same side of the shunt.
- If the menu-parameter 'Severinghaus Correction Mode' is set to 'Auto', the PCO_2 values displayed by the tCOM+ are automatically corrected to 37 °C (regardless of the patient's core temperature). When performing the ABG analysis, be sure to properly enter the patient's core temperature into the blood gas analyzer. Use the blood gas analyzer's '37 °C-$PaCO_2$' value to compare with the monitor's PCO_2 value.
- Verify proper operation of the blood gas analyzer. Periodically compare the blood gas analyzer's barometric pressure against a known calibrated reference barometer.

WARNING: On patients in a compromised hemodynamic state, PCO_2/PO_2 measurements may be inaccurate.

CAUTION: To avoid inaccurate calibration, knowledge of the correct barometric pressure is important. Monthly check the barometer reading of the monitor against a known calibrated reference barometer, or another Sentec monitor (tCOM+, SDM) (4.1).

Note: The Sentec Digital Monitoring System (SDMS) is to be operated by qualified personnel only. Read this manual, accessory Directions for Use, all precautionary information, and specifications before use.
Note: The Sentec Monitors are not intended for diagnosis; they are intended only as an adjunct in patient assessment. They must be used in conjunction with clinical signs and symptoms. The Sentec monitors are transcutaneous blood gas monitors and not blood gas analyzers.

WARNING: Do not use tCOM+ monitors, sensors, cables, or connectors that appear damaged.

Note: The SDMS can only be used in patients undergoing hyperbaric therapy if the monitor remains outside the hyperbaric environment.

1.4 Pulse Oximetry

1.4.1 Principles of Operations of Pulse Oximetry

The SDMS uses pulse oximetry to measure functional oxygen saturation (SpO_2) and pulse rate (PR). Pulse oximetry is based on two principles: firstly, oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry) and secondly, the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography).

Pulse oximeter sensors pass red and infrared light into a pulsating arteriolar vascular bed and measure changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) serve as light sources and a photodiode serves as photodetector. The software of a pulse oximeter uses the ratio of absorbed red to infrared light to calculate SpO_2.

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

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

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

1.4.2 Limitations of Pulse Oximetry

The following clinical situations or factors may limit the correlation between functional oxygen saturation (SpO_2) and arterial oxygen saturation (SaO_2) or may cause the loss of the pulse signal:

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

1.5 Sentec Transcutaneous Sensors

Sentec Transcutaneous (TC) Sensors (V-Sign™ Sensor 2, OxiVenT™ Sensor) provide superior performance, are robust, reliable and require comparatively low maintenance. They combine within a patented digital sensor design the optical components needed for 2-wavelength, reflectance pulse oximetry with the components needed to measure PCO_2 and – when using OxiVenT™ Sensors – PO_2.

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

PO_2 (OxiVenT™ Sensor) is measured with dynamic fluorescence quenching, an oxygen sensing technology measuring the oxygen molecules present in the vicinity of a fluorescent dye being immobilized in a thin carrying layer incorporated within the sensor surface.

The PCO_2 measurement of Sentec TC Sensors is based on a Stow-Severinghaus type PCO_2 sensor, i.e., a thin electrolyte layer is confined to the sensor surface with a hydrophobic, CO_2 and O_2 permeable membrane. Membrane and electrolyte must be exchanged approximately every 28 days. Additionally, the sensor membrane must be changed if it is damaged, not properly seated, or if there is trapped air or dry electrolyte under the membrane. With Sentec's patented Membrane Changer, the membrane and electrolyte can be changed with the ease of 4 identical Press-and-Turn steps in a highly reproducible manner (3.13).

Typically, the PCO_2 segment of Sentec TC Sensors requires calibration every 6 to 12 hours and is mandatory every 12 to 16 hours. The PO_2 measurement of the OxiVenT™ Sensor is virtually drift free and, hence, calibration free. Nevertheless, the tCOM+, as a precaution, calibrates PO_2 during each mandatory calibration and subsequently approximately once every 24 hours during one of the ongoing PCO_2 calibrations.

To achieve local arterialization of the skin tissue at the measurement site, Sentec TC Sensors are operated at a constant recommended sensor temperature of 41 °C in neonatal and 42 °C in adult/pediatric patients if PO_2 is disabled and 43 °C in neonatal and 44 °C in adult/ pediatric patients if PO_2 is enabled. Controls of sensor temperature and application duration are designed to meet all applicable standards. To guarantee safe operation, Sentec TC Sensors reliably supervise the sensor temperature with two independent circuits. Additionally, the tCOM+ software redundantly controls the temperature of the connected sensor.

⚠ **WARNING:** Do not alter or modify the sensor. Use only equipment, accessories, disposables, or parts supplied or recommended by Sentec AG. Use of other parts may result in injury, inaccurate measurements and/or damage to the device.

2 Setting up the Sentec Digital Monitoring System

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

❗ **CAUTION:** The instructions given in the Instruction Manual for the tCOM+ must be followed to ensure proper instrument performance and to avoid electrical hazards.

Note: Statements in this manual are only applicable for tCOM+ with the software version indicated on the cover page.
Note: SDMS related tutorials, the Instruction Manual and various other manuals are available for online viewing on www.sentec.com/ifu.

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

❗ **CAUTION:** Do not lift the monitor by the sensor cable or the AC power cord because they could disconnect from the monitor causing the monitor to fall on the patient.

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

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

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

WARNING: Do not attach accessories of the Roll Stand in any position that might cause it to tip over and possibly fall on the patient. Ensure that the Roll Stand does not tip over with and without the monitor being mounted on it. Refer to the Directions for Use included with the roll stand/wall railing regarding the maximum weight that can be attached to the stand post or wall railing.

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

CAUTION: Bleach can corrode metal. Therefore, use bleach cleaners on outer surface only and do not bring in contact with metallic parts. Always perform a final wipe using 70% Isopropanol.

Note: During normal operation, it is recommended that the monitor is always connected to the AC power outlet.

2.1 Connect tCOM+ to AC Power

Plug the power supply DC connector into the DC Power Connector on the rear of the monitor ⑩ and fix it with the attached nut. Plug the power supply AC connector into the AC power outlet.

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

Note: The AC inlet of the power supply may be exchanged by the correct country-specific adapter (US, UK, AUS, EU) or the country-specific mains cable.
Note: The external power supply of the tCOM+ will automatically adapt to the applicable local voltage: 100 - 240V~ (50/60Hz).
Verify that the connection has been established properly by checking the indication (charging or fully charged) of the battery symbol on the display.
If there is no connection, check the power supply, the power supply adapter, the DC connector, and the AC connector.

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

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

WARNING: Use only power unit provided by Sentec.

WARNING: Interference is possible when a sensitive device (ECG, EEG) is connected to the patient at the same time in home healthcare environments (due to class II power supply without functional earth).

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

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

CAUTION: Use the device only at an altitude of -400 m – 5000 m (-1300 – 16404 ft), (and typical corresponding atmospheric pressures). Otherwise, incorrect measurements can result.

2.2 Battery Operation of the tCOM+

The tCOM+ is equipped with a rechargeable internal Li-Ion battery that can be used to power the monitor during transport or when AC power is not available. The Status Icon 'Battery' (see 13.6) indicates the remaining battery charge (%).

Good to know!

When using the tCOM+, a new, fully charged battery will provide up to 4 hours of monitoring time if the display is permanently on, and up to 7 hours of monitoring time if the display is turned off in sleep mode. It takes approximately 4 hours to fully charge a drained battery.

When tCOM+ is switched on, the status of the battery and of the power connection is displayed in the 'Battery' icon (see Appendix 13.6).

The service life of the battery highly depends on the usage of the battery, the number of recharge cycles and the needs of the specific use. A typical service life of 2-4 years can be expected.

2.3 Turning on the tCOM+

Turn on the tCOM+ by pushing the ON/OFF button (6) on the left side panel. The tCOM+ will automatically perform a 'Power On Self Test' (POST) and show the booting progress. Check the date/time settings of the tCOM+ and adjust, if necessary, by tapping on the time in the Status Bar (note that this adjustment requires a password, see chapter 8). Please observe the tCOM+ startup behavior including warnings/cautions as described in the following passage.

Startup behavior

1. After power on the tCOM+ activates the LED bar and indicates the startup process by a sequential light.

2. A few seconds later, the display is activated and shows the startup process including the result of the POST.

> **CAUTION:** Do not use the monitor if the LED bar or the display of the monitor is not activated. Instead, contact Sentec service personnel or your local Sentec representative.

3. During the POST, the tCOM+ activates the buzzer (one short beep) and the speaker (three short tones).

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

4. At the end of the POST sequence, the result (succeeded of failed) is displayed on the screen. If passed, the monitor offers a profile selection (see 3.4.1).

> **CAUTION:** Do not use the monitor if an internal problem was detected during the POST (display of the message 'failed' with corresponding error code on POST screen). Instead, contact Sentec service personnel or your local Sentec representative.

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

The startup procedure of the monitor takes approximately 60 seconds.

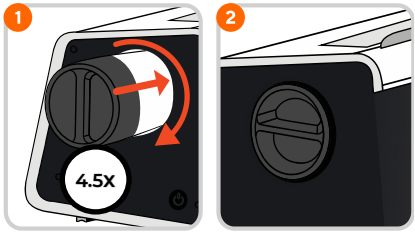
Note: Contact service if the touchscreen is not responsive.

2.4 Installation of the Calibration Gas Bottle

The Status Icon 'Gas' on the top right of the screen (Status Bar) indicates the current gas bottle content.

The gas bottle slot is located on the left side of the tCOM+. Remove the old gas bottle by turning it counterclockwise.

Remove the cap from the new gas bottle. Insert the gas bottle in the slot, turn it approximately four and a half times clockwise and thoroughly tighten it (without applying undue force). After a few seconds, the Status Icon 'Gas' indicates that the gas bottle is properly inserted.



Note: Use Calibration Gas within two months after opening, i.e., inserting bottle into the tCOM+.

Note: Integrity and cleanliness of the Docking Station is important for an accurate calibration. To prevent gas leaks in the Docking Station, always clean the sensor before

inserting it into the Docking Station and do not pull on the cable to open the Docking Station door. Regularly inspect integrity and cleanliness of the Docking Station. Ensure that the gas bottle is fully inserted by turning it clockwise approx. 4.5 turns and thoroughly tighten it. Failure to properly insert the gas bottle may result in incorrect sensor calibrations and subsequently result in inaccurate PCO_2 and/or PO_2 data.

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

WARNING: The Calibration 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.

CAUTION: Do not use expired gas bottles or gas bottles from manufacturers other than Sentec. The use of non-Sentec gas bottles may damage the Docking Station. Improper calibration gas mixtures will result in incorrect sensor calibrations and subsequently result in inaccurate PCO_2 and/or PO_2 data. Dispose of empty gas bottles according to local waste disposal regulations.

WARNING: To avoid risk of an unintended leakage current through the patient, do not touch the brass block of the calibration unit (calibration gas connection) or an interface connector and the patient at the same time.

2.5 Connection/Disconnection of Sensor Adapter Cable

The Sensor Adapter Cable can be connected to the tCOM+ by simply pushing the connector into the Sensor Connection Port (9) at the back of the monitor. The mechanical coding ensures that only correct cables are used, and that their positioning is correct. A clicking sound confirms the proper connection.

The Sensor Adapter Cable can be disconnected by pulling on the connector housing. It will not work by pulling on the cable (push-pull mechanism).

CAUTION: To avoid electrical shock, only use Sentec cables and accessories. Do not use any other cables to extent the length of the sensor cable than the adapter cables provided by Sentec. Increasing the length of the sensor cable with other cables may degrade signal quality and may lead to inaccurate measurements.

2.6 Connection of a Sentec Transcutaneous Sensor

Prior to using a sensor, check the condition of its membrane and the integrity of the sensor (3.1). Change the membrane if necessary (3.13). Do not use the sensor if any problems are noted. Once sensor check/inspection of its membrane are completed successfully, connect the Sentec TC Sensor to the Sensor Adapter Cable.

Thereafter, the tCOM+ will usually display the message 'Calibrate sensor' (for exceptions, see description of the feature ´Smart Cal-Mem´, 3.12).

Insert the sensor into the Docking Station for sensor calibration (3.12).

Note: Even if sensor calibration is not yet mandatory or recommended by the tCOM+, you preferably/additionally should calibrate the sensor in-between monitoring uses, whether between two different patients or, for example, before reattaching the sensor

to the same patient if the sensor was removed from the patient for site inspection or site change.

If the sensor's 'Membrane Change Interval' has elapsed, the tCOM+ will trigger the message 'Change sensor membrane' upon insertion of the sensor into the Docking Station. In this case, you must change the sensor membrane and confirm the membrane change on the monitor screen (3.13) before the tCOM+ starts calibrating the sensor.

CAUTION: Before using a brand-new sensor, the sensor membrane must always be changed, see chapter 3.13. Otherwise, incorrect measurements may occur.

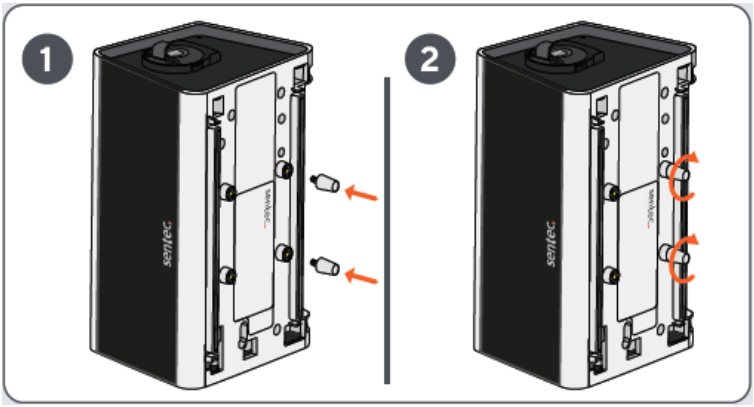
Note: If you have changed the sensor membrane just before connecting the sensor to the tCOM+, it won't be necessary to change it once again. In this case, simply tap on 'Membrane changed' in the Membrane Change menu.

Note: An on-screen tutorial provides step by step guidance on the membrane change procedure (menu icon ´Tutorials´).

2.7 Affixing Tilting Feet and adjusting the Display Angle

In certain settings, e.g., when the monitor is placed on a high shelf, it may be useful to tilt the angle of the tCOM+ display for better visibility. To do so, simply screw in the Tilting Feet as follows:

1. Carefully place the monitor on its left side panel, i.e., where the gas bottle is located.
2. Screw in both Tilting Feet in the slots near the back panel as depicted.
3. Place monitor back in its normal position.



2.8 Turning off the tCOM+

Turn off the tCOM+ by pushing the ON/OFF button on the left side panel and tap on the power off button on the Shut Down Menu Screen.

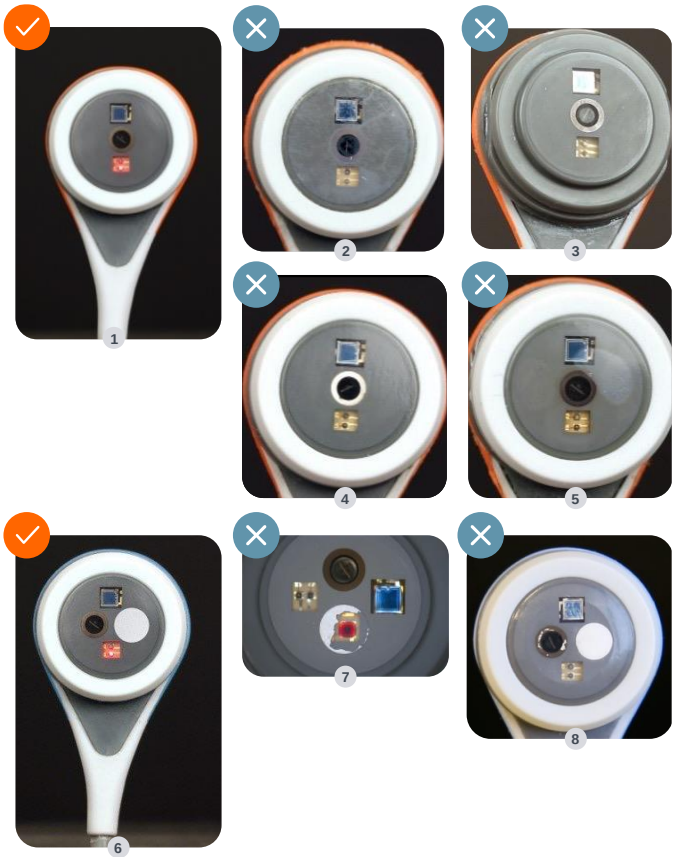
Note: In case of any problem that prevents the monitor from being switched off, the tCOM+ can also be forced to switch off by pressing the ON/OFF button for more than 6 seconds.

3 Patient Monitoring with the tCOM+

3.1 Checking a Sentec Transcutaneous Sensor

Check the condition of the sensor membrane and the integrity of the sensor before and after each use and after changing the membrane (3.13).

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



Checking a V-Sign™ Sensor (see image 1 above): Look for a smooth, clear membrane without scratches or air bubbles. The center ring should be a shade of brown to black and the red LED light should be on when connected to the monitor.

Do not use the sensor if:

- the measurement electrolyte is dried out (image 2). Change the sensor membrane and calibrate before patient monitoring.

- the membrane is damaged, missing (image 3), or has a loose fit. Apply a new membrane and calibrate the sensor before patient monitoring.
- the central ring has a silver luster (image 4), indicating that the sensor has reached the end of its useful life. Replace the sensor.
- there are any air bubbles beneath the membrane (image 5). Change the sensor membrane and calibrate before patient monitoring.
- there is any visible damage to the sensor housing or cable. Replace the sensor.

Checking an OxiVenT™ Sensor (see image 6): ensure the white O_2 spot is white and intact.

Do not use the sensor if:
- the O_2 spot is damaged (image 7) or is not illuminated in cyan (blueish green) color when the sensor is connected to the tCOM+ with enabled PO_2 measurement function. Replace the sensor.
- the central ring has deteriorated (image 8). Replace the sensor.
- the sensor membrane is damaged, missing, or has a loose fit. Apply a new membrane and calibrate the sensor before patient monitoring.
- if there is trapped air or dry electrolyte under the membrane. Change the sensor membrane and calibrate before patient monitoring.
- there is any visible damage to the sensor housing or cable. Replace the sensor.

If in doubt, contact qualified service personnel or your local Sentec representative regarding continued use or replacement of the sensor.

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

WARNING: Do not use the system if cables or connectors appear to be damaged.

CAUTION: To avoid electrical shock, only use Sentec cables and accessories.

CAUTION: Do not use bleach cleaners on sensors without a membrane or with a defective membrane. This may damage the PCO_2 unit.

CAUTION: Do not change the membrane of Sentec V-Sign™ Sensors or OxiVenT™ Sensors by other means than the Sentec Membrane Changer. Otherwise, the sensor may be damaged, or an inappropriate membrane application may reduce the accuracy of the measurement.

CAUTION: Perform sensor membrane changes under clean working conditions only. Do not touch the sensor membrane with any sharp-edged objects, including your fingernails. Damage of the sensor membrane results in reduced accuracy of the sensor readings.

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

3.2 Patients with potentially impaired skin perfusion or characteristics requiring special attention

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

Patients

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

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

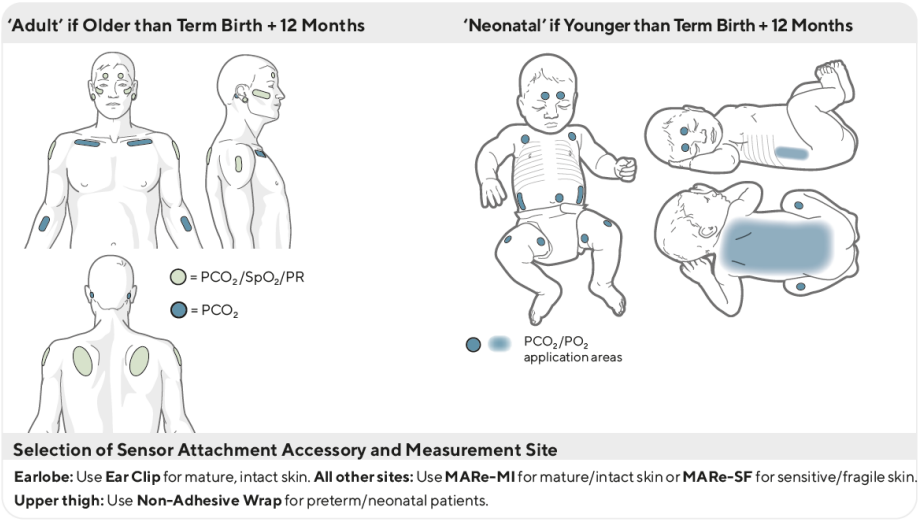
- application of vasoactive drugs, e.g., epinephrine, norepinephrine, phenylephrine, especially when administered continuously using syringe or infusion pumps
- application of mechanical pressure, e.g., from positioning, blankets
- under treatment by external heat sources like warming lamps
- hypothermia/cold stress
- edema
- dehydration
- hypotension
- prolonged capillary refill time

application of disinfectants and other agents at the measurement site, which might influence skin condition and local perfusion

Reduce the sensor temperature and/or site time to avoid thermal injuries to the skin. When using an OxiVenT™ sensor, temperatures above 42 °C are typically required for good PO_2 correlation – if only PCO_2 measurement is required, consider reducing the sensor temperature.

3.3 Patient Type and Selection of Measurement Site / Sensor Attachment Accessory

Before selecting a measurement profile on the tCOM+, determine the patient type. There are various measurement sites and sensor attachment accessories, depending on patient and parameter type. Refer to the image below and the following page for additional (important) information.



Selection of Sensor Attachment Accessory and Measurement Site

Earlobe: Use **Ear Clip** for mature, intact skin. **All other sites:** Use **MARe-MI** for mature/intact skin or **MARe-SF** for sensitive/fragile skin.
Upper thigh: Use **Non-Adhesive Wrap** for preterm/neonatal patients.

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

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

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

WARNING: The measurement of SpO_2 and PR with Sentec TC Sensors is only defined on sites specified in the images (3.3). Choose a profile where the parameters SpO_2/PR are disabled on other measurement sites.

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

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

WARNING: The clinical use of the SDMS is prohibited during magnetic resonance diagnostic procedures (e.g., MRI). Patient safety and system performance, when connected to patients undergoing magnetic resonance diagnostic procedures, are unknown and may vary between different setups. The MRI image could potentially be affected by the SDMS. The MRI unit could lead to inaccurate measurements of the SDMS, or currents induced in the sensor cables potentially could cause burns. Furthermore, objects containing metal (e.g., the Ear Clip) can become dangerous projectiles when subjected to the strong magnetic fields created by MRI equipment.

WARNING: Compatibility issues when using non-Sentec consumables / accessories. Use only equipment, accessories, disposables, or parts supplied or recommended by Sentec AG. Failure to comply may result in physical injury, inaccurate measurements, and/or damage to the device.

CAUTION: Potential low correlation to arterial values when a lower range temperature is selected for the sensor. With decreasing sensor temperature, the correlation between $tcPCO_2$ and $PaCO_2$ gradually decreases. At sensor temperatures below approx. 40 °C, the measured $tcPCO_2$ values do not reliably reflect $PaCO_2$. Sentec therefore recommends that you establish and use Severinghaus correction factors that are adapted to your specific target patient population if attempting to assess PaCO2 when using sensor temperatures below 40 °C.

WARNING: For sensor temperatures below 39 °C, SpO_2/PR readings intermittently might be switched off to maintain sensor temperature.

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

CAUTION: If the 'Enforced Sensor-On-Patient Mode' is active, the monitor's 'Sensor-Off-Patient' detection is disabled, i.e., in this case no 'Sensor off patient' alarm will be triggered. Instead, a 'Check Application' Alarm is triggered within two minutes if the sensor is dislodged or intentionally removed from the patient. If pulse oximetry is enabled, the monitor's algorithms typically will flag the PCO_2 and PO_2 readings as unstable (displayed in grey) and the SpO_2 and PR readings as invalid (respective values replaced by '---') within 15 seconds and within 30 seconds the low priority alarm 'Low SpO_2 signal quality' will sound.

WARNING: Auditory alarm signal sound pressure levels that are less than ambient levels can impede operator recognition of alarm conditions.

WARNING: To avoid erroneous readings and false alarms of SpO_2 and PR, select a neonatal profile if a V-Sign™ Sensor 2 (VS A/P/N) or OxiVenT™ Sensor (OV A/P/N) is applied to neonatal patients. Ensure that for adult/pediatric patients a profile is selected where SpO_2 and PR are disabled if one of these sensors is applied to a site for which the measurement of SpO_2 and PR is not defined.

CAUTION: Avoid applying the Staysite™ Adhesive film in a full circumference around a limb.

3.4 Checking and adjusting tCOM+ Settings

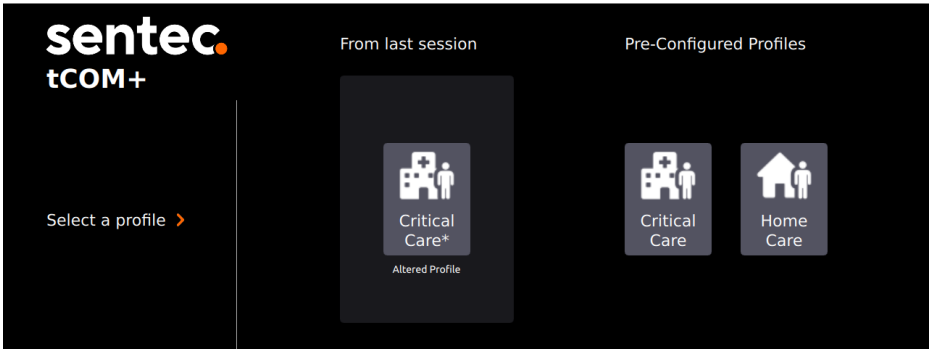
Before initiating patient monitoring, ensure the current tCOM+ Settings/tCOM+ Profile are appropriate for the patient, for the selected measurement site, for the skin condition/skin tissue perfusion at the selected measurement site and for the specific clinical setting. At minimum, confirm the patient type and the enabled parameters as well as the sensor temperature, 'Site Time' and alarm settings. Change the tCOM+ Settings/tCOM+ Profile if necessary (3.4). Furthermore, verify system readiness (message 'Ready for use') and check the 'Available Monitoring Time'.

3.4.1 'Ready for use'/ 'Calibration' screen

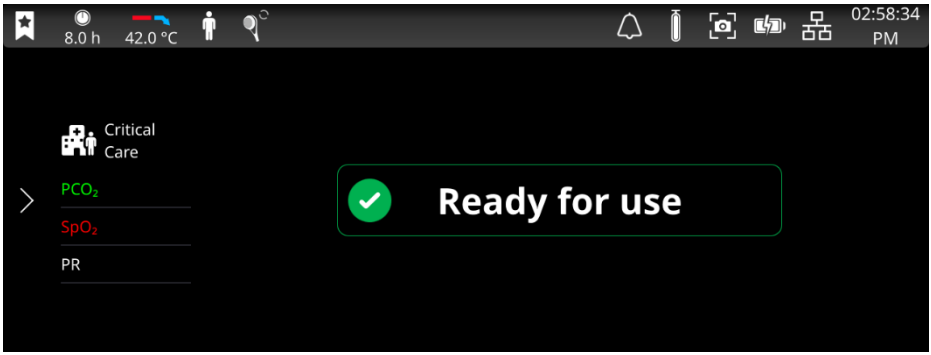
Upon startup, the tCOM+ will display the Profile Selection. From this screen it is possible to select either:

- The last active configuration.
- A pre-configured profile.

Note: This screen is not displayed if there is only one profile, and the last active configuration matches the pre-configured profile. For profile creation, refer to Chapter 3.4.4.



To be able to continue, users must choose one of the profiles depicted. If the connected sensor is in the Docking Station, 'Calibration in progress' or 'Ready for use' is displayed in the center of the screen.



Once sensor calibration is completed, the tCOM+ will display 'Ready for use'.

Good to know!
Profiles can be configured by the responsible organization in the password-protected 'Advanced Settings' to optimally fit the specific needs of varying clinical settings.

Note: A list of icons used in the tCOM+ Status Bar can be found in the Appendix 13.6.

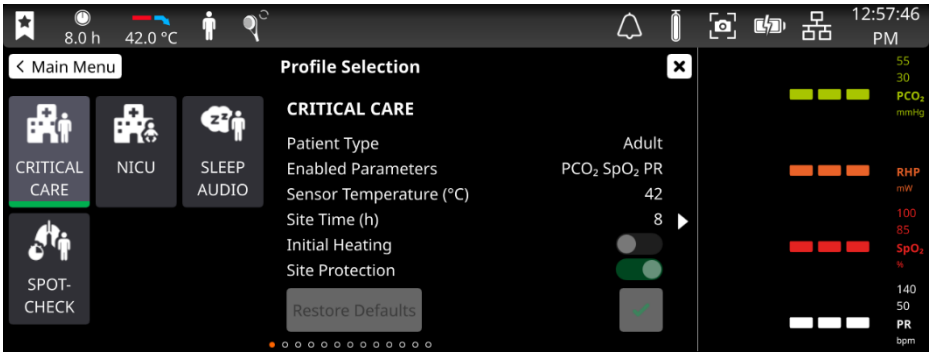
Note: If the tCOM+ is in Sleep Mode, the display is inactive (black). Tap on the display to activate it.

3.4.2 Menu Overview

MENU	MENU ICON	DESCRIPTION
Advanced Settings		Create profiles, configure interface and cybersecurity settings, adjust system settings, e.g., language, date and time Perform software update Note: Settings are password-protected.
Alarms		Adjust alarm settings for enabled parameters
Audio		Adjust audio alarm volume
Baselines		To set baselines for enabled parameters
Display		To adjust display setting and enable various sleep modes
Events		To log and view events, e.g., manipulation or medication
Measurement Settings		Adjust site time and temperature, as well as settings for enabled parameters, and start monitoring ("Enforced Sensor-On-Patient mode")
Profile Selection		To select preconfigured measurement profiles
Review & Export		View screenshots and export screenshots and measurement data
Sensor Maintenance		To calibrate the sensor, confirm membrane change, or perform a sensitivity test
System Information		Lists system-related information
Trend Settings		Adjust trend ranges and time scale for enabled parameters
Tutorials		Step-by-step guides for the most common application and maintenance procedures

3.4.3 Profile Selection

Tapping on the Patient Type icon in the Status Bar or on ´Profile Selection´ in the menu will open the Profile Selection screen, providing a condensed profile preview and the respective profile settings, which are summarized on several consecutive screens. The currently active profile is underlined in green.



It is possible to choose from the list of profiles preconfigured by the Responsible Organization, tailored to meet the specific needs of varying clinical settings. Tap on a profile name to preview its most relevant parameter settings (the patient type, parameters to be measured, site temperature and site time) in the center of the monitor screen. The green line indicates the selected profile for the parameter preview. Swipe right or tap the arrows to view all parameter settings of the selected profile on consecutive screens. To activate the selected profile, simply tap on the green checkbox (grey if profile is already active, or patient measurement is running). Tapping on ´Restore Defaults´ will reset all parameters to the initially preconfigured profile settings.

In the rare event that a profile name appears in red (i.e., invalid), the profile cannot be selected due to inconsistencies in the setup. In this case, it is recommended to open the profile in the 'Edit Profiles' menu, check/correct its settings or delete it and create a new profile (see 3.4.4).

⚠ **WARNING:** Select a profile that is suited for the patient's age and the intended measurement site (see 3.3) prior to use on each patient.

⚠ **WARNING:** Hazards may exist if different profiles or alarm presets are used for the same or similar equipment in any single area, such as intensive care units.

3.4.4 Profile Creation and Profile Import

Profiles can be configured by the responsible organization in the password-protected 'Advanced Settings' – 'Edit Profiles' menu to optimally fit the specific needs of varying clinical settings.

When creating a new profile, the tCOM+ Profile Configuration Assistant guides the user through different screens allowing a selection for the different profile parameter settings.

This overview highlights the most relevant default settings which can be configured in the 'Edit Profiles' menu:

tCOM+ PROFILE PARAMETER SETTINGS		
Care Setting	**Hospital**	**Sleep / Home / Spot Check**
Patient Type	Adult / Neonate	Adult / Neonate
Selectable Parameters	Adult: PCO_2, PO_2, SpO_2/PR Neonate: PCO_2, PO_2	Adult: PCO_2, PO_2, SpO_2/PR Neonate: PCO_2, PO_2
Alarm Settings		
PCO_2 High Limit (mmHg/kPa)	55/7.3	200/26.7
PCO_2 Low Limit (mmHg/kPa)	30/4	0/0
SpO_2 High Limit (%)	100	100
SpO_2 Low Limit (%)	85	85
PR High Limit (bpm)	140	250
PR Low Limit (bpm)	50	30
PO_2 High Limit (mmHg/kPa)	95/12.7	95/12.7
PO2 Low Limit (mmHg/kPa)	60/8.0	60/8.0
Audio Settings		
'Audio OFF' Option	OFF	ON
Alarm Volume	4	4
Audio PAUSED Duration (min)	2	Sleep: 2 Home / Spot-Check: 1
Audio OFF Reminder Option	OFF	ON
Audio OFF Reminder	ON	ON
Time Range for Online Trends	2 h	Sleep: 12 h Home: 8h Spot-Check: 15 min
Temperature Settings		
Max. Sensor Temperature (°C)	Adult: 43.5 Neonate: 43 / 44 (if PO_2 enabled)	42 (exception Spot Check Adult: 43.5)
Min. Sensor Temperature (°C)	40	40

Sensor Temperature (°C)	Adult: 42 Neonate: 41 / 43 (if PO_2 enabled)	Adult Home / Sleep: 42 Adult Spot Check: 43.5 Neonate: 41
Max. Site Time (h)	Adult: 12 Neonate: 8 / 6 (if PO_2 enabled)	Sleep / Home: 12 Spot Check: 0.5
Site Time (h)	Adult: 8 Neonate: 8 / 2 (if PO_2 enabled)	Sleep / Home: 12 Spot Check: 0.5
Site Protection Option	ON	ON
Site Protection	Adult: ON Neonate: ON	Sleep / Home: ON Spot Check: ON
Initial Heating Option	Adult: ON Neonate: OFF	OFF
Initial Heating	OFF	OFF
Heating Power Mode	RHP	Sleep / Home: OFF Spot Check: AHP
Advanced Settings		
Membrane Change Interval (days)	Adult: 28 Neonate: 28 / 14 (if PO_2 enabled)	28
Sleep Mode	Display ON	Sleep / Home: Display OFF - Wake on Touch Spot Check: Display ON

The 'Import' and 'Export' functions allow export of the selected tCOM+ Profile(s) to a USB C stick for import to another tCOM+. This may be particularly helpful if several tCOM+ monitors need to be set up with the same profile(s).

To add an existing profile to the tCOM+, insert the USB C stick to the monitor, tap on ´Import´, and select the profile(s), which appear in a pop-up window. Click ´Finish´ and the selected profile will become available in the Profile Selection (3.4.3). To delete or copy an existing profile, press and hold the profile name.

3.4.5 Temperature and Site Time

To achieve local arterialization of the skin tissue at the measurement site, Sentec TC Sensors are operated at a sensor temperature higher than the body temperature. Warming the skin tissue beneath the sensor to a constant temperature improves accuracy by a) increasing capillary blood flow/induces local arterialization, b) stabilizing metabolism, and c) improving gas diffusion through skin tissue. With increasing sensor temperature, the application duration ('Site Time') must be evaluated carefully and adjusted accordingly to reduce the risk of burns. Special attention must be given to patients with sensitive skin at the sensor site.

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

PATIENT TYPE	PO2 ENABLED	RECOMMENDED SENSOR TEMPERATURE [°C]	RECOMMENDED SITE TIME [H]
Neonate (≤ 12 months)	No	41.0	8.0
	Yes	43.0	2.0
Adult (> 12 months)	No	42.0	8.0
	Yes	44.0	2.0

The following table shows the selectable options for the 'Sensor Temperature' and 'Site Time'. To change either one of these settings, simply tap on the 'Sensor Temperature' or ´Site Time´ icon in the Status Bar.

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

Note: The password-protected 'Advanced Settings' enable the Responsible Organization to configure parameter profiles to restrict the selectable 'Sensor Temperature Range' or the maximum 'Selectable Site Time'. Refer to 3.4.4 for more details on how to set up a profile.

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

PATIENT TYPE	SELECTABLE SENSOR TEMPERATURE	SELECTED SENSOR TEMPERATURE [°C]	DEFAULT SITE TIME [H]	SELECTABLE SITE TIME [H]
Neonate	**37 – 44 °C** -Temperatures above 41.5 °C can only be selected if PCO_2 is enabled -Temperatures above 43.0 °C can only be selected if PO_2 is enabled -Temperatures below 41.0 °C: PO_2 values NOT available	37.0 ≤ T ≤ 40.5	12.0	0.5 – 12.0
		41.0 ≤ T ≤ 41.5	8.0	0.5 – 12.0
		42.0 ≤ T ≤ 42.5	4.0	0.5 – 6.0
		T = 43.0	2.0	0.5 – 4.0
		43.5 ≤ T ≤ 44.0	1.0	0.5 – 2.0
Adult/ Pediatric	**37 – 44.5 °C** -Temperatures above 42.0 °C only if PCO_2 enabled	37.0 ≤ T ≤ 41.5	12.0	0.5 – 12.0
		42.0 ≤ T ≤ 42.5	8.0	0.5 – 12.0

PATIENT TYPE	SELECTABLE SENSOR TEMPERATURE	SELECTED SENSOR TEMPERATURE [°C]	DEFAULT SITE TIME [H]	SELECTABLE SITE TIME [H]
	- Temperatures above 43.5 °C can only be selected if PO_2 is enabled. - Temperatures below 41.0 °C: PO_2 values NOT available	43.0 ≤ T ≤ 43.5	4.0	0.5 – 8.0
		T = 44.0	2.0	0.5 – 4.0
		T = 44.5	1.0	0.5 – 2.0

'Initial Heating' (only available for adult profiles) increases the sensor temperature for about 13 minutes after sensor application, facilitating faster perfusion and measurement values (+2 °C with a maximum of 44.5 °C). If enabled, it can be set to ON/OFF by tapping on the ´Sensor Temperature´ icon in the Status Bar.

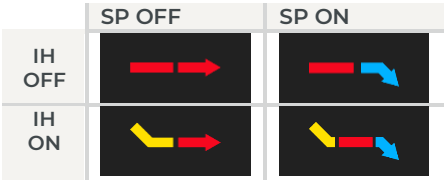
Note: The 'Initial Heating Option' must be enabled by the Responsible Organization within the respective profile.
Note: 'Initial Heating' is deactivated in profiles for patient type Neonate.

'Site Protection' is a safety feature, which prevents excessively long exposure of the skin to temperatures exceeding 41 °C (Adult) or 40 °C (Neonate).
If 'Site Protection' is set to ON, the tCOM+ will reduce the sensor temperature to safe values as summarized in the table below once the sensor application duration exceeds the selected 'Site Time' by more than 10% or 30 minutes. If enabled, 'Site Protection' can be set to ON/OFF by tapping on the ´Sensor Temperature´ icon in the Status Bar.

Note: The 'Site Protection Option' must be enabled by the Responsible Organization within the respective profile.

PATIENT TYPE	'SENSOR TEMPERATURE'	REDUCED TEMPERATURE
Neonate	> 40 °C	39 °C
Adult/ Pediatric	> 41 °C	39 °C (if SpO_2 disabled) 41 °C (if SpO_2 enabled)

The current 'Initial Heating' (IH, left part of arrow) and 'Site Protection' (SP, right part of arrow) states are depicted as follows:



'Site Protection' is only enabled (and depicted with a downward blue arrow) for sensor temperatures above 41 °C in adult profiles and 40 °C in neonatal profiles.
'Initial Heating' is only enabled (and depicted with a yellow downward line) for sensor temperatures below 44.5 °C.

⚠ **WARNING:** The use of temperatures higher than 41 °C requires special attention to patients with susceptible skin, e.g., neonates, geriatric patients, burn victims, patients with skin diseases. Carefully balance benefit (more accurate measurements) versus risk (skin burns) when selecting the sensor temperature and related 'Site Time', consider using Site Protection and - if a short 'Site Time' is impractical - 'Initial Heating' in combination with a suitably low 'Sensor temperature'.

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

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

3.4.6 Alarm Settings & Behavior

The tCOM+ uses visual and auditory alarm signals to alert the user when a physiological measurement parameter (PCO_2, PO_2, SpO_2, PR) violates its alarm limits and to inform the user about technical conditions of the equipment that require operator response or awareness. By degree of urgency and potential hazard, the monitor's alarm conditions are assigned to the following priorities: high priority (SpO_2 limit violation), medium priority (PCO_2, PO_2 or PR limit violation, 'Battery Critical' (if tCOM+ not connected to AC power)), low priority (various technical alarm conditions). All alarm signals of the tCOM+ automatically cease when the associated triggering event has terminated.
Note: The response of transcutaneous PCO_2/PO_2 and SpO_2 measurements to respiratory events such as hyper-/hypoventilation or apnea depend on the blood circulation time from the pulmonary alveoli to a specific measurement site, i.e., on the distance between the pulmonary alveoli to a specific measurement site and the blood flow/velocity. In patients with poor peripheral perfusion, the blood perfusion time between the pulmonary alveoli and the finger or toe is one to two minutes longer than between the pulmonary alveoli and central sites such as the forehead, cheek, or earlobe.

ALARM CONDITION	PRIORITY	AUDIBLE ALARM SIGNALS	VISUAL ALARM SIGNALS	DESCRIPTION
SpO_2 high / low	High	High priority sound 'Oxygen'	LED bar flashing red with approx. 1.4 Hz	SpO_2 limit violation
PR high / low	Medium	Medium priority sound 'Cardiac'	LED bar flashing yellow with approx. 0.7 Hz	PR limit violation
PCO_2 high / low	Medium	Medium priority sound 'Ventilation'	LED bar flashing yellow with approx. 0.7 Hz	PCO_2 limit violation
PO_2 high / low	Medium	Medium priority sound 'Oxygen'	LED bar flashing yellow with approx. 0.7 Hz	PO_2 limit violation
Battery critical	Medium	Medium priority sound 'Battery critical'	LED bar flashing yellow with 0.7 Hz	≤10 minutes before internal battery depleted
Various technical alarms	Low	Low priority sound	LED bar constant cyan	See chapter 4.3 for further details
Various information messages	Info	None	None	See chapter 4.3 for further details
Supervisor alarm	High (Backup alarm)	Supervisor beep	LED bar flashing red with 1 Hz (if possible, depending on the failure mode)	Supervisor watches the main processor of tCOM+. A supervisor alarm is initiated if the main processor does not react.

The tCOM+ ranks the priority of high and medium auditory alarm signals according to the following order: SpO_2 low, SpO_2 high, Battery critical, PR low, PR high, PCO_2 low, PO_2 low, PCO_2 high, PO_2 high. The device ensures that auditory signals do not superpose and only outputs the highest priority acoustic signal.

In addition to the audible alarm signals mentioned above, the tCOM+ provides the following auditory signals:

- The ‘AUDIO OFF Reminder’ (short signal tone) sounds every 60 seconds if the auditory alarm signals are permanently switched off. Switching off this reminder signal may only be done by the responsible organization within the ´Edit Profiles´ menu; its volume is not adjustable.
- The ‘Auditory Power On Self Test Signal’ (three short tones) sounds during the ‘Power On Self Test’; its volume is not adjustable.
- The ‘Pulse Beep’ (short tone) sounds once for each pulse. Its automatic pitch modulation reflects changing SpO_2 levels; use the parameter ‘Pulse Beep’ to switch off/adjust the volume of this signal within the profile.
- The ‘Volume Settings Beep’ emits a sample sound for every volume adjustment.

Tap on the ´Alarms´ icon to set/adjust the ´Alarm Audio Settings´ and the vital alarm limits of the enabled parameters. The default values depicted in the bars can easily be adjusted by moving the slider up and down.

⚠ **WARNING:** Setting alarm limits for physiological measurement parameters to extreme values may render the tCOM+’s alarm system useless for the respective parameter.

⚠ **WARNING:** Ensure to select the upper alarm limit for PO_2 and SpO_2 carefully and according to accepted clinical standards. High oxygen levels may predispose a premature infant to develop retinopathy.

Note: Alarm surveillance for physiological measurement parameters (PCO_2, PO_2, SpO_2, PR) is only active if the respective parameter is valid or questionable. Otherwise, generation of alarm signals for the respective parameter is automatically suspended.

Supervisor Alarm

The correct execution of the tCOM+ software is continuously monitored by an autonomous system (Supervisor). If an anomality in the runtime behavior is detected, e.g., an unexpected power-off or a software malfunction of the tCOM+, an auditory alarm (high pitch sound every 0.5 seconds) is emitted for at least 2 minutes through the internal buzzer. Furthermore, the LED bar flashes red with a frequency of 1 Hz (unless the tCOM+ is powered off and running only on battery power).

The acoustic output of the Supervisor Alarm can be deactivated by pressing the ´ON/OFF Button´.

On next power up the monitor will perform the regular Power-On Self-Test. If this test is performed successfully all internal systems are working as intended and the device can be used for patient monitoring.

Nevertheless, a Supervisor Alarm is an unusual event that indicates that the behavior of the monitor was not as intended. Please inform qualified service personnel or your local Sentec representative in case of such an event for further investigation.

To prevent disturbing stable patients during overnight measurements, such as those taken in a sleep laboratory or home environment, the supervisor alarm is deactivated when the monitor volume is set to 0. This allows the monitor to be used as a data recorder without an alarm function.

⚠ **WARNING:** Verify that the alarm volume is adjusted such that the alarm signals are clearly audible for the operator in the intended environment. Do not disable the audible alarm function or decrease the audible alarm volume if the patient's safety could be compromised.

3.4.6.1 Visual Alarm Signals

The ´Alarm Bar´ and the ´LED bar´ indicate the highest currently active alarm priority. If a physiological parameter violates its alarm limits, the respective parameter, the 'Alarm Bar' and the 'LED bar' flash (with approx. 1.4 Hz for SpO2 and approx. 0.7 Hz for PCO2, PO2, PR). 'Status Messages' (highest priority alarm always visible; a list of all messages is opened when clicking on the Alarm Bar) and/or various 'Status Icons' visualize technical alarm conditions and general information on the system. The monitor's visual alarm signals cannot be deactivated if the alarm is enabled.

⚠ **WARNING:** If the display as well as the notification via Alarm Bar of the tCOM+ is inactive when the parameter 'Sleep Mode' is set to ´Wake on touch´, the display will not reactivate if an alarm condition occurs. In this case, visual alarm signals are **not** visible.

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

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

3.4.6.2 Auditory Alarm Signals

The monitor's auditory alarm signals are priority encoded. A high priority alarm condition is indicated by a high-pitched fast pulsing tone (two bursts of five short pulses repeated every 10 seconds), a medium priority alarm condition by a medium-pitched pulsing tone (one burst of three pulses repeated every 12 seconds), and a low priority alarm condition by a low-pitched slow pulsing tone (one burst of two pulses repeated every 15 seconds).
The volume of auditory alarm signals can be adjusted (levels OFF, 1 to 6). OFF is only selectable if enabled by the institution. If OFF is selected, auditory alarm signals are permanently switched off.
Auditory alarm signals can be paused for 1 or 2 minutes (depending on selected 'Audio Pause Duration' in 'Audio' menu).

❗ **CAUTION:** Using the 'Alarm' icon, auditory alarm signals can be paused.

Note: If auditory alarm signals are permanently switched off, the 'AUDIO OFF Reminder' sounds every 60 seconds (unless disabled by the Responsible Organization).
Note: The operating status of the monitor's auditory alarm signals is visually indicated by the 'Alarm' icon, and acoustically indicated by the 'AUDIO OFF Reminder' (refer to 13.6 for an overview of the icons used in the Status Bar).

⚠ **WARNING:** If an alarm condition occurs while the auditory alarm signals are paused or permanently switched off, the only alarm indication will be visual (if Sleep Mode is not active), but **no** alarm tone will sound.

WARNING: Verify that the alarm volume is adjusted such that the alarm signals are clearly audible for the operator in the intended environment. Do not disable the audible alarm function or decrease the audible alarm volume if the patient's safety could be compromised.

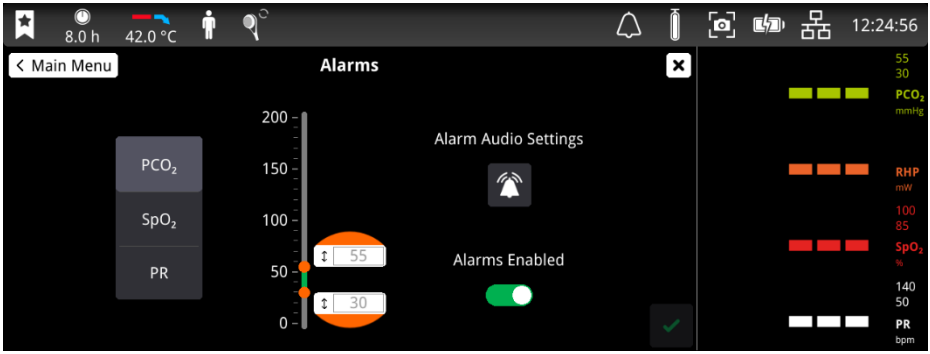
WARNING: Ensure that the speaker is clear of any obstructions. Failure to do so could result in an inaudible alarm signal.

3.4.6.3 Adjusting alarm limits

Tap on the ´Alarms´ icon to enable/disable alarms independently for each parameter.

Sliders may be moved to adjust the alarm limits of the currently selected parameter(s), which are marked orange. By tapping on the values within the slider, each value can be entered directly.

The high and low alarm of a specific vital sign alarm may be enabled and disabled by the ´Alarms Enabled´ toggle switch. If disabled, both the visual and the acoustic alarms are deactivated; the alarm limits shown next to the vital sign value are replaced by a symbol to indicate that the visual and acoustic alarms for this vital sign parameter are disabled.



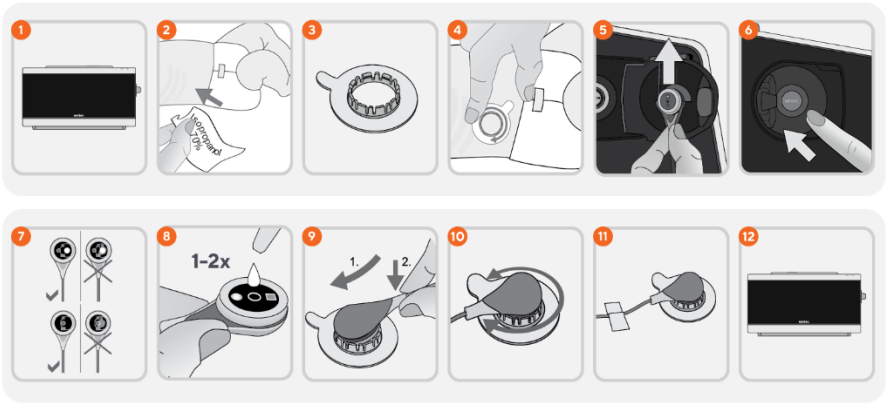
WARNING: If alarms are disabled for a specific parameter, any change of this parameter will not trigger an alarm, neither visually nor acoustically. Ensure that the patient is monitored appropriately by other means.

3.5 Sensor Application using a Multi-Site Attachment Ring

Sentec offers multiple adhesion options to accommodate a wide range of patients and scenarios supporting patient comfort and clinical utility. Use the Multi-Site-Attachment Ring MARe-MI for sensor application on mature skin and the Multi-Site-Attachment Ring MARe-SF for application on sensitive skin.

Note: For convenient operation at the bedside, the tCOM+ offers videos and guides on how to apply a Multi-Site Attachment Ring (Adult and Neonates), available on sentec.com/product-support/tcm/.

CAUTION: Before using a brand-new sensor, the sensor membrane must always be changed, see chapter 3.13. Otherwise, incorrect measurements may occur.



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

> **CAUTION:** The Multi-Site Attachment Rings (models MARe-MI and MARe-SF) are for single-use only. Do not reattach used rings whether used on the same or on another patient!

4. Attach the ring to the measurement site. Verify that the skin under the adhesive is not wrinkled. Then press gently on the retainer ring and move your finger around the ring circumference to ensure a good adhesion of the ring's adhesive to the skin.
5. Open the Docking Station Door and remove the sensor. Always grab the sensor at its neck to avoid strain on the sensor cable.
6. Close the Docking Station Door.
7. Check the condition of the sensor membrane and the integrity of the sensor (3.1). Change the membrane if necessary (3.12). Do not use the sensor if any problems are noted.

Apply 1-2 drops of Contact Gel to the center of the sensor surface. Flip over the sensor just before inserting it into the ring.

Note: Until the sensor is applied to the patient, ensure to hold the sensor such that the Contact Gel does not run off the sensor face.

Note: Only use the approved Sentec Contact Gel.

Note: Alternatively, you can apply 1-2 drops of Contact Gel to the skin area in the center of the attachment ring. As long the sensor is not yet applied to the patient, try to keep the measurement site as horizontal as possible so that the Contact Gel does not run off the measurement site.

Note: Avoid wetting the adhesive tapes!

> **WARNING:** Do not swallow Contact Gel. Keep away from children. Avoid contact with eyes and injured skin. Do not use on patients who exhibit allergic reactions to one of the components. Use only approved Sentec Contact Gel.

8. Holding the sensor at its neck, approach MARe from any side and first insert the nose of the sensor into the retainer ring.

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

9. Then, apply slight downward pressure on its neck. The spring tension of the retainer ring will pull the sensor into place with little to no pressure on the skin.
10. Rotate the sensor in the ring and press the sensor gently against the skin to spread the Contact Gel.

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

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

> **CAUTION:** A good, hermetically sealed contact between the sensor and the skin is essential for TC monitoring!
>
> **WARNING:** Ensure the sensor is applied correctly. Incorrect application of the sensor can cause incorrect measurements.

12. Twist the sensor into the best position. For forehead/cheek placement, wrap the sensor cable once around the ear and tape the cable to the cheek or another applicable site. For other application sites, tape the cable to the skin at a suitable distance. Route the sensor cable properly to avoid entanglement or strangulation and secure it with a Clothing Clip to an appropriate site of the patient's clothing or bed linen. Ensure that the sensor cable is loose enough for not to be stretched during monitoring. Gently press on the sensor as a final application check.
13. Verify that the tCOM+ detects that the sensor was placed on the patient, initiates monitoring and that the enabled parameters stabilize (see 3.7.1). If necessary, readjust sensor application or reposition the sensor.

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

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

> **WARNING:** Application of any pressure to the measurement site (e.g., by using a pressure bandage) may cause pressure ischemia at the measurement site and, consequently, inaccurate measurements, necrosis or – in combination with heated sensors – burns.
>
> **WARNING:** To avoid entanglement or strangulation, secure the sensor cable with a Clothing Clip to an appropriate site of the patient's clothing or bed linen.
>
> **WARNING:** When applying a Multi-Site Attachment Ring, model MARe-MI or MARe-SF, to a patient, make sure to place it so that the patient does not lie on top of it, as this may cause the ring to leave bruises on the patient.
>
> **WARNING:** Always select the measuring site carefully to avoid selecting a site with low perfusion or low signal quality, which can cause incorrect measurements.

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

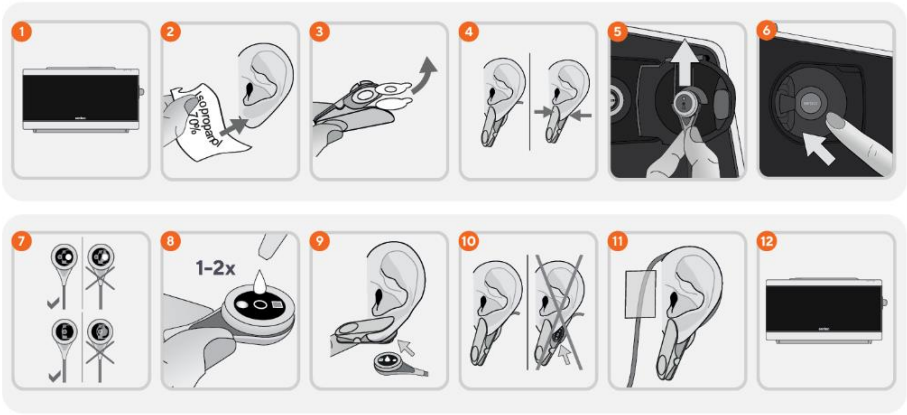
3.6 Sensor Application using an Ear Clip

Sentec's Ear Clip EC-MI is intended to attach the Sentec sensors to the earlobe of the patient. It is recommended for patients with mature/intact skin.

Note: To attach a Sentec TC Sensor with the Ear Clip, the earlobe should be large enough to cover the entire sensor membrane (dark surface of the sensor). Furthermore, application of a Sentec TC Sensor on pierced earlobes may result in incorrect PCO_2/PO_2 measurements. If the earlobe is too small or has multiple piercings, consider using a Multi-Site Attachment Ring (model MARe-MI or MARe-SF) to attach the sensor to an alternate site (see 3.5).

Note: For convenient operation at the bedside, the tCOM+ offers a quick guide on how to apply an Ear Clip. Simply tap on ´Tutorials´.

CAUTION: Before using a brand-new sensor, the sensor membrane must always be changed, see chapter 3.13. Otherwise, incorrect measurements may occur.



1. Check current tCOM+ Settings/tCOM+ Profile and verify system readiness (message 'Ready for use'). Change tCOM+ Settings/tCOM+ Profile if necessary.
2. Clean the earlobe with a swab moistened with 70% isopropanol (or according to your institution's skin cleaning/degreasing procedures) and let it dry. If necessary, remove hair.
3. Take an Ear Clip out of the package, open the clip jaws, and pull off both liners protecting the adhesive tapes of the clip.
4. Pull the earlobe to stretch its skin and then attach the Ear Clip with its retainer ring on the backside of the earlobe. Verify that the skin under the retainer ring's adhesive is not wrinkled and that the hole in the center of the retainer ring completely covers the skin. Then squeeze gently to ensure that both adhesive tapes stick firmly to the earlobe.

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

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

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

6. Close the Docking Station Door.
7. Check the condition of the sensor membrane and the integrity of the sensor (3.1). Change the membrane if necessary (3.13). Do not use the sensor if any problems are noted.
8. Take the sensor and apply **1-2 drops** of Contact Gel to the middle of the sensor surface.

Note: Until the sensor is applied to the earlobe, ensure to hold the sensor such that the Contact Gel does not run off the sensor face. Avoid wetting the adhesive tapes!
Note: Alternatively, you may apply **1-2 drops** of Contact Gel to the visible skin area in the center of the Ear Clip's retainer ring after performing step **9**. As long the sensor is not yet applied to the patient, try to keep the measurement site as horizontal as possible so that the Contact Gel does not run off the measurement site.

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

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

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

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

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

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

CAUTION: Injury of earlobe due to entangled cables. Carefully route and fix cables to reduce the possibility of patient entanglement or strangulation.

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

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

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

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

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

⚠ **WARNING:** Pierced earlobes may result in incorrect $tcPCO_2$ and/or $tcPO_2$ measurements.

❗ **CAUTION:** Do not use the Ear Clip for sensor attachment on any other site than the earlobe. This may cause incorrect measurements.

⚠ **WARNING:** Do not excessively rotate the sensor within the Ear Clip after sensor attachment. This may cause incorrect measurements.

❗ **CAUTION:** Discard the Ear Clip in case of defects or loss of spring tension sufficient to allow slippage or movement of the sensor from its proper position on the earlobe.

3.7 Sensor Application using a Non-Adhesive Wrap

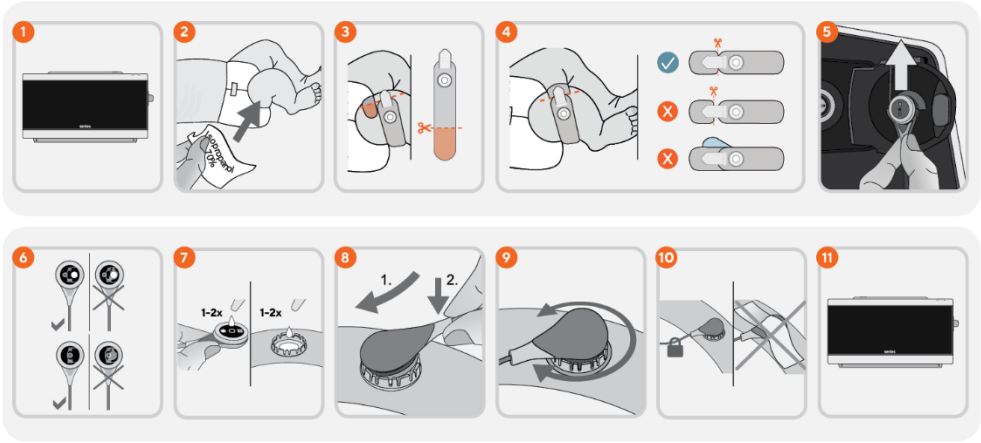
Sentec's Non-Adhesive Wrap is intended to be wrapped around the thigh of neonatal/preterm patients with very sensitive/ fragile skin.

❗ **CAUTION:** Before using a brand-new sensor, the sensor membrane must always be changed, see chapter 3.13. Otherwise, incorrect measurements may occur.

❗ **CAUTION:** Choose a flat, well-perfused area of intact skin on the baby´s anterior or interior upper thigh. Avoid placement over large superficial veins or areas of skin breakdown or edema.

⚠ **WARNING:** Do not use the Non-Adhesive Wrap on injured skin.

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



1. Check current tCOM+ Settings/tCOM+ Profile and verify system readiness (message 'Ready for use'). Change Settings/Profile if necessary.
2. Clean the site on the upper thigh with a swab wetted with 70% isopropanol (or according to your institution's skin cleaning/degreasing procedures) and let it dry. If necessary, remove hair. Take a Non-Adhesive Wrap out of the package.
3. A) Measure the wrap around the upper thigh.
   B) Cut the wrap to avoid overlap of the two ends.

Note: Make sure the closure tab will not contact the patient's skin once the wrap is cut.

4. Apply the wrap and fasten with the closure tab. Ensure that the wrap is securely fixed around the thigh. Verify that the skin under the retainer ring is not wrinkled.

> ⚠ **WARNING:** Make sure the Non-Adhesive Wrap is correctly adjusted to the patient´s thigh to prevent any loosening or overtightening. Avoid overlapping of the two ends or skin contact with the closure tabs.

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

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

6. Check the condition of the sensor membrane and the integrity of the sensor (3.1). Change the membrane if necessary (3.13). Do not use the sensor if any problems are noted.
7. Apply 1-2 drops of Contact Gel to the center of the sensor surface (A). Ensure to keep the sensor horizontal (membrane pointing upwards) so that the liquid does not run off the membrane. Flip over the sensor just before inserting it into the retainer ring.

Note: Alternatively, you can apply 1-2 drops of Contact Gel to the skin area in the center of the retainer ring (B). As long the sensor is not yet applied to the patient, try to keep the measurement site as horizontal as possible so that the contact liquid does not run off the measurement site.

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

8. Holding the sensor at its neck, insert the nose of the sensor into the retainer ring. Then apply slight downward pressure on its neck. The spring tension of the retainer ring will pull the sensor into place with little to no pressure on the skin.
9. Rotate the sensor in the ring and press the sensor gently against the skin to spread the contact liquid.

Note: Check that the sensor can be easily rotated to ensure it is snapped in correctly. Do not affix any tape on the sensor head. Check sensor application! The sensor face must have full contact with the skin for an accurate measurement. Ensure that air gaps are eliminated between the skin and the sensor.

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

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

10. Twist the sensor into the best position. Route the sensor cable properly to avoid entanglement or strangulation and secure it with a Clothing Clip to an appropriate site of the patient's clothing or bed linen. Ensure that the sensor cable is loose enough for not to be stretched during monitoring. Gently press on the sensor as a final application check.
11. Verify that the tCOM+ detects that the sensor was placed on the patient, initiates monitoring and that the enabled parameters stabilize. If necessary, readjust sensor application or reposition the sensor.

Note: PCO2 typically increases and PO2 (if enabled) decreases to reach a stabilized value within 2 to 10 minutes.

> ❗ **CAUTION:** The Non-Adhesive Wrap is intended for single patient use for up to 24 hours. During this period, the user may alternate between measurement sites on the thighs. Change the measurement site within the recommended site time (for details, refer to the table in chapter 3.4.5). Do not re-attach the sensor to the same measurement site if any skin irritations are noted.

3.8 Patient Monitoring

3.8.1 'Sensor-On-Patient' Detection

Once the sensor is correctly applied to the patient, the tCOM+ usually detects that the sensor was put on the patient and initiates monitoring for the enabled parameters. If the sensor is applied on a site approved for SpO_2/PR monitoring, 'Sensor-On-Patient' is typically detected within a few seconds, otherwise within less than 2 minutes.

When obtaining an adequate patient signal is difficult, it may be possible that the tCOM+ is unable to automatically detect 'Sensor-On-Patient'. If in this case PCO_2 is enabled, you may use the 'Start Monitoring' function in the 'Measurement Settings' menu to activate the 'Enforced Sensor-On-Patient Mode' bypassing normal 'Sensor-On-Patient' detection. To reset the tCOM+ to 'Normal Sensor-On-Patient Mode', simply insert the sensor into the Docking Station.

Note: If the 'Enforced Sensor-On-Patient Mode' is active, the monitor's 'Sensor-Off-Patient' detection is disabled, i.e., in this case no 'Sensor off patient' alarm is triggered. There will be a 'Check Application' alarm instead, triggered within two minutes, if the sensor is dislodged or intentionally removed from the patient. If SpO_2/PR are enabled, monitor's algorithms typically will flag the PCO_2 and PO_2 readings to be unstable (displayed in grey) and the SpO_2 and PR readings to be invalid (respective values

replaced by '---') within 15 seconds and within 30 seconds the low priority alarm 'Low SpO_2 signal quality' will sound.

Note: If SpO_2 is enabled, verify the movement of the blip bar or plethysmographic waveform and ensure for adequate signal strength before accepting any displayed SpO_2/PR/PI data as a current measurement.

Once 'Sensor-On-Patient' is detected, the tCOM+ initiates monitoring, and the enabled parameters stabilize. SpO_2 and PR usually stabilize within a few seconds, whereas PCO_2 typically increases and PO_2 typically decreases to reach a stabilized value within 2 to 10 minutes (see below).

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

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

Good to know!
If Initial Heating is ON (only available in adult profiles), the sensor temperature is increased for about 13 minutes after sensor application, facilitating faster perfusion and results (+2 °C with a maximum of 44.5 °C). For further details, refer to 3.4.5.

Once stabilized, TC-readings can be disturbed by so-called 'TC-Artifacts'. Ambient air penetrating between the sensor surface and the skin – the most frequent reason for 'TC-Artifacts' – typically will cause PCO_2 to fall and PO_2 to rise very fast.
If the penetration of ambient air is of short duration only, TC-readings will typically restabilize within a few minutes.
After sensor application or occurrence of a 'TC-Artifact', the tCOM+ displays the message 'PCO_2/PO_2 stabilizing' if both TC-parameters are stabilizing or 'PCO_2 stabilizing' or 'PO_2 stabilizing', respectively, if only one TC parameter is stabilizing. To indicate that TC readings do not reflect the patient's real PCO_2 and/or PO_2 levels during stabilization, the tCOM+ displays PCO_2 and/or PO_2 readings in grey and inhibits alarms related to PCO_2 and/or PO_2 limit violations during stabilization. Furthermore, if stabilization for one or both TC parameters cannot be achieved within 10 minutes, the tCOM+ will trigger the low priority alarm 'Check sensor application' to indicate that correct sensor application should be verified.

Good to know!
To reduce the number of 'TC-Artifacts', a good, hermetically sealed contact between the sensor and the skin is essential. Ensure to use **1-2 drops** of Contact Gel when applying the sensor. Furthermore, verify good contact between the sensor and the skin after sensor application, properly secure the sensor cable, and routinely inspect correct sensor application during monitoring.

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

3.8.3 'Available Monitoring Time'/'Site Time Elapsed' Alarm

During monitoring, the 'Available Monitoring Time' Icon (13.6) continuously indicates the time in the Status Bar (in h) until either the selected 'Site Time' or – if PCO_2 is enabled – the 'Calibration Interval' elapses (whichever occurs first).

When the 'Calibration Interval' elapses before the selected 'Site Time', the 'Available Monitoring Time' Icon turns yellow, the message 'Sensor calibration recommended' is

displayed and monitoring is possible for another 4 to 6 hours with PCO_2 marked as 'questionable'. Thereafter, sensor calibration is mandatory and PCO_2 and PO_2 are marked as 'invalid' (values replaced by '---'). When the 'Site Time' elapses, the icon remains yellow, its background turns to cyan, and the low priority alarm 'Site time elapsed' is triggered. In this case, the sensor must be removed from the patient for site inspection.

Note: To terminate the 'Site time elapsed' alarm, remove the sensor from the patient and confirm the alarm in the Status Bar while the message 'Sensor off patient' is displayed or insert the sensor into the Docking Station.

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

3.8.4 Quality Indicators for Measurement Parameters

The tCOM+ continuously evaluates the quality of the measured parameters and the Δx-values (refer to 3.8.5.1) and baseline values (refer to 3.8.5.2) derived thereof by assessing the severity of conditions presented to the tCOM+. The results of this evaluation are used to display status messages and/or quality indicators for the different parameters. While a parameter is marked as:

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

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

Unstable (grey): Alarm surveillance for the respective parameter is not active and the tCOM+ displays the parameter in grey. PCO_2, for example, is displayed in grey when stabilizing after sensor application or occurrence of a 'PCO_2 artifact'.

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

Good to know!
The change of a parameter's reading within a certain time ('Delta-Time') may indicate a gradual worsening of the patient's status. A 'Δ10-value for PCO_2' of '+ 7 mmHg' or more in a patient receiving opioid analgesics and sedatives, for example, indicates opioid induced hypoventilation and, therefore, may help to earlier recognize a developing respiratory depression, especially in patients receiving supplemental oxygen.

During patient monitoring, a baseline can be set by using the respective icon in the Main Menu. The point of time, at which the baseline was set, and the baseline itself are subsequently flagged as an ´Event´. For more details, refer to 3.8.5.2.

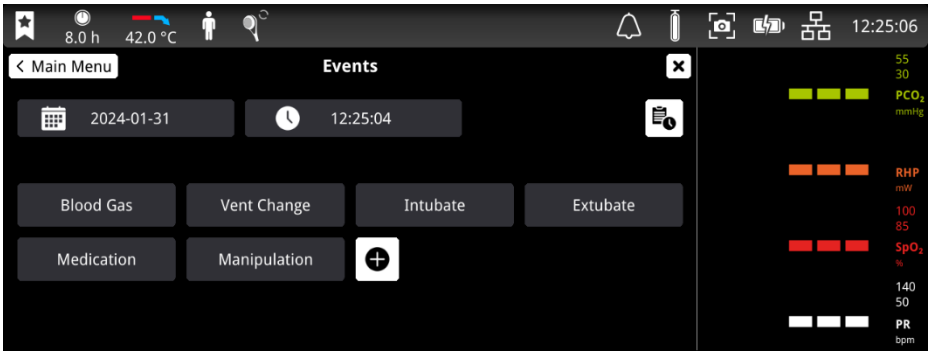
Example: Baseline values for PCO_2 of 33.3 + 10.1 mmHg indicate that the current PCO_2 reading is 10.1 mmHg higher than the baseline of 33.3 mmHg.

Good to know!
To assess the possible impact of a change in patient treatment (e.g., changing ventilator settings, administration of drugs such as sedatives or opioids, changing supply of supplemental oxygen etc.) on the patient's ventilation and/or oxygenation, it is recommended to set a baseline just before changing the treatment. For more details, refer to 3.8.5.2.

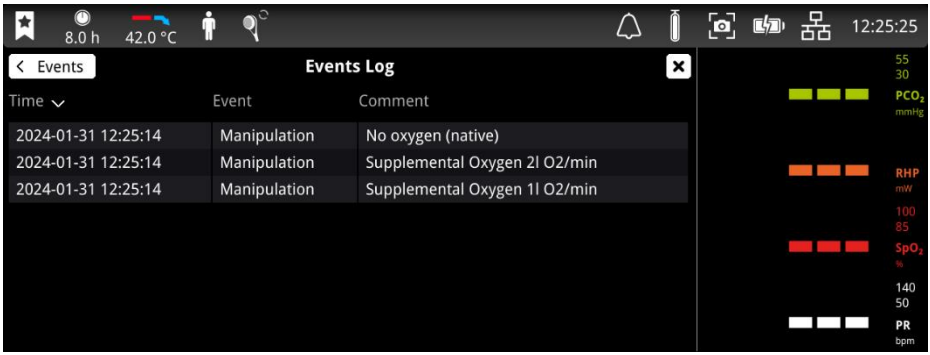
3.8.5 Advanced Measurement Options

3.8.5.1 Events

Tapping on the ´Events´ icon within the Main Menu opens a screen with the option to register an event, e.g., a medication given at a certain date and time, a manipulation or an event created by the user. In addition to several default events, new events can be added and/or customized by touching the ´+´ button (the total number of events is limited to 12).



It is possible to store several events in the tCOM+ for subsequent display on the measurement screen or in the Events Log. Some events, such as a Membrane Change, or a change in the date/time settings, are logged by default.



3.8.5.2 Baselines

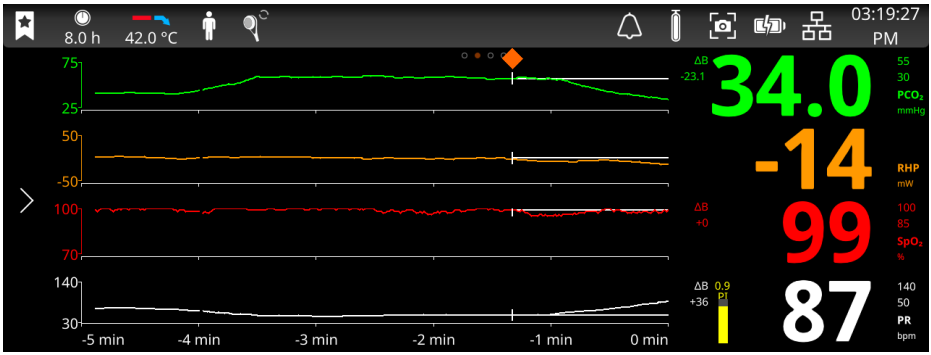
Δx-Values and Baseline Values

Certain preconfigured measurement screens provide online trends with Δx-values, baseline values and baselines for PCO_2, PO_2, SpO_2 and/or RHP.

A parameter's Δx-value is displayed to the right of its online trend and corresponds to the difference between its current reading and its reading x minutes ago. x is called 'Delta-Time' and is adjustable between 1 and 120 minutes. The default value for 'Delta-Time' is 10 minutes.

Example: A Δ10-value for PCO_2 of '+ 8.8 mmHg indicates that the current PCO_2 reading is 8.8 mmHg higher than the PCO_2 reading ten minutes ago.

To access ´Baselines´, tap on the corresponding icon in the Main Menu. Tapping on ´Set´ will set a new baseline. Upon returning to the measurement screen, the baseline is marked with an orange diamond and a line, as depicted in the following image. The baseline can be turned off or reset by touching the respective icon within the ´Baselines´.



3.8.5.3 Heating Power Settings

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

If Heating Power is enabled in the profile, the operator can select between the display of the 'Absolute Heating Power' (AHP) or the 'Relative Heating Power' (RHP) in the menu 'Heating Power Settings´, located in the ´Measurement Settings´. AHP and RHP values are both displayed in Milliwatts (mW).

In 'RHP-Mode', deviations of the current heating power from a stored RHP-reference value are displayed as plus or minus RHP values once the sensor is stabilized on the skin ('plus' if the current heating power is higher than the RHP-reference value, 'minus' if lower, and '0' if identical).

Keep in mind the possible influence of local skin blood flow fluctuations on transcutaneous blood gases. An abrupt change of transcutaneous blood gases coupled with a significant change of RHP readings may indicate a change in local skin blood flow, while abrupt changes of transcutaneous blood gases unaccompanied by a significant change of RHP readings may indicate consistent blood flow but a change in arterial blood gases. Providing RHP online trends underneath PCO_2 online trends or PO_2 online trends, consequently, permits the clinicians to assess whether a change of PCO_2 and/or PO_2 reflects a corresponding change of the respective arterial blood gases or is caused or influenced by a significant change of the local skin blood flow beneath the sensor site.

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

If the sensor is stabilized on the skin, the RHP-reference value can be reset by touching the ´ Heating Power Settings ´ icon within the 'Measurement Settings´ in the Baselines menu.

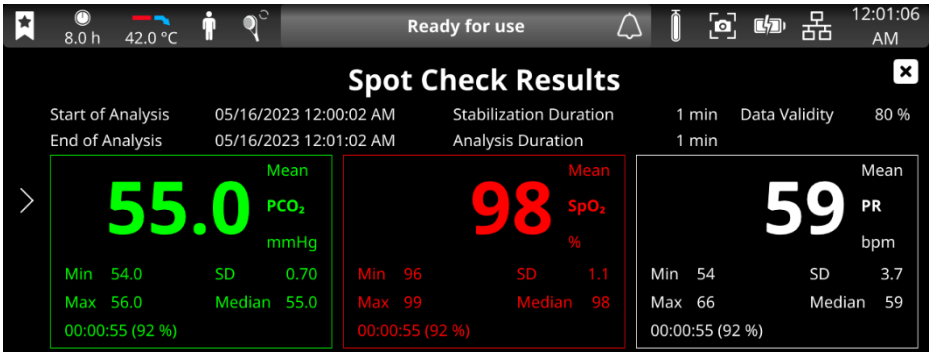
To clear/reset the RHP-reference value, remove the sensor from the patient and insert it into the Docking Station.

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

3.8.5.4 Spot Check

In standard configuration, the tCOM+ numeric values and online trends provide continuous monitoring of the enabled parameters. By choosing the ´Spot Check´ Profile (which can be set up by the Responsible Organization, see 3.4.4), the tCOM+ provides a blood gas Spot Check with a statistical result screen displaying mean, minimum, maximum, median, and standard deviation for the enabled parameters.

A Spot Check Measurement consists of the stabilization phase (default duration 8 minutes) and the measurement phase (default duration 2 minutes). There is a visible countdown in the center of the measurement screen. Once the Spot Check measurement is finished, the ´Spot Check Results´ screen displays the above-mentioned statistical results for the data assessed during the measurement phase. This screen remains on display until pressing the ´x´ button. To access the results at a later stage, simply take a screenshot. Via ´Review and Export´ in the main menu, these screenshots can be viewed and/or exported to a USB stick.



3.8.5.5 PCO_2 In-Vivo Correction

If enabled in the profile, 'In-Vivo Correction' of PCO_2 values is possible at the bedside. The 'PCO_2 In-Vivo Correction' allows for adjusting the PCO_2 readings of the tCOM+ based on the result of an arterial blood gas analysis. The 'PCO_2 In-Vivo Correction' adjusts the displayed PCO_2 value by the offset resulting from the blood gas analysis. The 'PCO_2 In-Vivo Correction' should only be used when a systematic difference between the monitor's PCO_2 readings and $PaCO_2$ is clearly established by several arterial blood gas measurements.

CAUTION: A 'PCO_2 In-Vivo Correction' should only be enabled by personnel understanding the principles and limitations of transcutaneous PCO_2 monitoring. If a 'PCO_2 In-Vivo Correction' is made, it must be checked periodically and adapted in case of changes

CAUTION: The tCOM+ is not a blood gas device. If in-vivo correction is performed, the PCO_2 values displayed by the monitor only remain an estimate of $PaCO_2$.

3.8.5.6 Severinghaus Correction Mode

The tCOM+ uses an algorithm developed by J.W. Severinghaus to calculate PCO_2 from the measured $PcCO_2$. The 'Severinghaus Algorithm' first corrects $PcCO_2$ measured at the sensor temperature (T) to 37 °C by using a 'Temperature Correction Factor' (C) (the denominator in the first term of the 'Severinghaus Equation') and then subtracts an estimate of the local 'Metabolic Offset' (M). If enabled in the profile, the menu 'Severinghaus Correction' in the 'Measurement Settings' permits selecting the mode that is used for the 'Temperature Correction Factor' (C) and the 'Metabolic Offset' (M).

If the menu-parameter 'Severinghaus Correction Mode' is set to 'Auto', the PCO_2 values displayed by the tCOM+ are automatically corrected to 37 °C (regardless of the patient's core temperature). When performing the blood gas analysis, be sure to properly enter the patient's core temperature into the blood gas analyzer. Use the blood gas analyzer's '37 °C-$PaCO_2$' value to compare with the monitor's PCO_2 value.

In Fixed Mode, the tCOM+ uses fixed C and M settings customized by the responsible organization. In fixed mode these values are not adjusted as a function of the selected patient type and sensor temperature.

CAUTION: Users selecting 'Severinghaus Correction Mode' 'Fix' take on responsibility for the performance characteristics of the tCOM+. Selection of 'Temperature Correction' and 'Metabolic Offset' must be based on sound scientific and clinical evidence.

CAUTION: 'Severinghaus Correction Mode' 'Fix' should only be used by personnel understanding the principles and limitations of transcutaneous PCO2 monitoring.

3.9 Sensor Removal with Multi-Site Attachment Ring/Non-Adhesive Wrap

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

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

Sensor Removal for Subsequent Reattachment to Same Site

1. Remove the adhesive tape securing the sensor cable, if applicable.
2. Place a finger on each side of the retainer ring and rotate the sensor towards the index finger. The index finger will act as a wedge and will disengage the sensor from the ring.

3. Clean sensor and cable with a swab wetted with 70% isopropanol to remove any Contact Gel residues or dirt (for other approved cleaning agents refer to sentec.com/ifu).
4. Check the condition of the sensor membrane and the integrity of the sensor (3.1). Change the membrane if necessary (3.13). Do not use the sensor if any problems are noted.

Important: Before reapplying the sensor to the same site, we recommend calibrating the sensor even if calibration is not yet mandatory or recommended by the tCOM+. If you skip the calibration, at least reset the Site Timer by confirming the message 'Sensor off patient' in the Status Bar and continue with step 6.

5. To calibrate the sensor, open the Docking Station Door and hang the sensor in the holder inside the Docking Station Door (the red light will appear). Close the Docking Station Door.
   Note: Sensor calibration – if necessary – will start (message 'Calibration in progress'). The message 'Ready for use' will be displayed once calibration is finished.
6. Clean the skin in the center of the ring with a dry swab or, if necessary, a swab moistened with 70% isopropanol (or according to your institution's skin cleaning/ degreasing procedures) to remove any Contact Gel residues or dirt and let it dry.
7. Carefully inspect the measurement site.

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

8. To reapply the sensor to the same site, continue at step 5 in chapter 'Sensor Application using a Multi-Site Attachment Ring' (3.5) or step 8 in chapter 'Sensor Application using a Non-Adhesive Wrap'(3.7). Make sure to reapply 1-2 drops of Contact Gel to the site before reinserting the sensor into the retainer ring.

Sensor Removal without Reattachment to Same Site

1. Remove the sensor together with the Multi-Site Attachment Ring by carefully lifting the ring's little tab or by gently opening the closure tab and removing the Non-Adhesive Wrap.
2. Clean the skin with a dry swab or, if necessary, a swab with 70% isopropanol (or according to your institution's skin cleaning/degreasing procedures) to remove any Contact Gel residues or dirt and then carefully inspect the site to note any potential skin irritations.
3. Remove the sensor from the retainer ring, discard the ring or wrap and then follow steps 3 to 5 described before to clean the sensor, to check the condition of its membrane and its integrity as well as to insert it in the Docking Station for calibration and/or storage.

Note: To maintain monitor readiness and minimize PCO_2 drift potential, always keep the tCOM+ switched on and connected to power with the sensor in the Docking Station in between monitoring sessions.

3.10 Sensor Removal with Ear Clip

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

Note: For site inspection and/or calibration, the Ear Clip can remain on the same earlobe for up to 24 hours and may be reused for another sensor application. It is recommended

to remove and to discard the Ear Clip after 24 hours and to keep the earlobe free of adhesive for 8 to 12 hours.

Sensor Removal for Subsequent Reattachment to Earlobe

1. Remove the adhesive tape securing the sensor cable.
2. Grab the sensor at its neck with one hand and detach it from the Ear Clip while holding the clip in place with the other hand.
3. Clean the sensor with a swab moistened with 70% isopropanol to remove any Contact Gel residues or dirt (for other approved cleaning agents refer to sentec.com/ifu).
4. Check the condition of the sensor membrane and the integrity of the sensor (3.1). Change the membrane if necessary (3.13). Do not use the sensor if any problems are noted.
   Important: Before reapplying the sensor to the same earlobe, we recommend calibrating the sensor even if calibration is not yet mandatory or recommended by the tCOM+. If you skip the calibration, at least reset the Site Timer by confirming the message 'Sensor off patient' in the Status Bar and then continue with step 6.
5. To calibrate the sensor, open the Docking Station Door and hang the sensor in the holder inside the Docking Station Door (the red light will appear). Close the Docking Station Door.
   Note: Sensor calibration – if necessary – will start (message 'Calibration in progress'). The message 'Ready for use' will display once calibration is finished.
6. Clean the skin in the center of the Ear Clip's retainer ring with a dry swab or, if necessary, a swab moistened with 70% isopropanol (or according to your institution's skin cleaning/degreasing procedures) to remove any Contact Gel residues or dirt and let it dry.
7. Carefully inspect the earlobe.

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

To reapply the sensor to the same earlobe, continue at step 5 in chapter 'Sensor Application using an Ear Clip' (0). Make sure to reapply 1-2 drops of Contact Gel to the sensor's center before reinserting it into the Ear Clip.

Sensor Removal without Reattachment to Same Earlobe

1. Open the clip's jaws and remove it from the earlobe together with the sensor by turning it sideways.
2. Clean the earlobe with a dry swab or, if necessary, a swab moistened with 70% isopropanol (or according to your institution's skin cleaning/ degreasing procedures) to remove any Contact Gel residues or dirt and then carefully inspect the earlobe to note any potential skin irritations.
3. Remove the sensor from the Ear Clip, discard the clip and then follow steps 3 to 5 above to clean the sensor, to check the condition of its membrane and its integrity as well as to insert it in the Docking Station for calibration and/or storage.

Note: To maintain monitor readiness and minimize PCO_2 drift potential, always keep the tCOM+ switched on and store the sensor in the Docking Station in between monitoring.

3.11 Patient Data Management

The tCOM+ automatically stores PCO_2, PO_2, SpO_2, PR, HP and PI data as well as system status information in its internal memory for subsequent data export. The memory provides up to one year of monitoring data. It is possible to review up to 48 hours of data directly on the screen by scrolling back.

Patient Data Management using V-STATS
Patient data acquired by the tCOM+ can be downloaded following these steps:

1. Connect a USB C stick[1] to the DATA/SERVICE USB port located at the left side of the monitor.
2. Click on the 'Review and Export' icon in the main menu and select 'Patient Data'.
3. Select one or several patient measurement files for download to the USB stick. These can be combined by activating the option "Combine to one file".
4. Tap on the download symbol  to save the files to the USB stick.

Note: Only patient measurement files with a "Minimal Measurement Duration" (default 5 minutes, configurable in the tCOM+ Profile) are displayed. The name of the exported .sdl file contains the monitor serial number as well as the date and start time of measurement,. File name: tCOM+_XXXXXX_Measurement_YYYYMMDD_HHMMSS.sdl
For combined measurements, the exported file will contain the start date of the earliest selected measurement. File name:
tCOM+_XXXXXX_Measurement_YYYYMMDD_HHMMSS_XXXX.sdl (the four X at the end contain characters/numbers to distinguish combined measurements).

5. Remove the USB stick from the USB port

Sentec's V-STATS software may be used for tCOM+ data analysis and reporting. V-STATS is available for download on sentec.com/download-v-stats/.

Import the tCOM+ measurement files into V-STATS following the instructions below:
1. Select the V-STATS menu 'File' – 'Import Trend Data'.
2. Select a minimum measurement duration (default 5 min) and click 'Import'.
3. Select the measurement file for analysis.
4. Choose the measurement and enter the respective patient information. Click 'Convert' to import the measurement into the V-STATS database.

Refer to the V-STATS Instruction Manual for more information on data analysis and reporting: sentec.com/manuals/#v-stats-and-v-carenet.

Patient Data Management through external devices
Additionally, the patient data acquired by the tCOM+ can be output through the Analog Output, the serial data port (RS-232), the LAN port or the Wi-Fi connection. The physical ports are located on the rear of the tCOM+ and can be connected to external devices such as multi-parameter bedside monitors, PCs, poly(somno)graphs, ventilators, chart recorders or data loggers.

Note: No component shall be connected to the Connectivity USB port on the back of the monitor. Currently, it does not provide any functionality.

[1] USB C stick format: FAT, exFAT, and NTFS

Note: Accessory equipment (e.g., a PC) connected to the monitor's data ports must comply to IEC 60950-1 or IEC 62368-1. All resulting combinations of equipment must be in compliance with the IEC standard 60601-1 systems requirements. Anyone who connects accessory equipment to the monitor configures a medical system and is, therefore, responsible for ensuring that the resulting system complies with the requirements of standard IEC 60601-1 and the electromagnetic compatibility standard IEC 60601-1-2.

CAUTION: Ensure to properly calibrate the instrument (PG-/PSG-System) attached to the tCOM+ analog output at initial setup and, thereafter, at least monthly.

CAUTION: When connecting/mounting the monitor to the accessory equipment (e.g., PCs, poly or polysomnographic systems, multi-parameter bedside monitors, ventilators, (wireless) networks, roll stands, mounting plates, incubators, etc.), verify proper operation before clinical use of the monitor and accessory equipment. In certain cases, it may be required that the accessory equipment must be connected to a grounded AC outlet. In case of doubt, consult qualified technicians.

CAUTION: Verify proper function of the analog output signals before each application.

CAUTION: The analog output signals do not contain any alarm or system status related information.

3.12 Sensor Calibration and Storage

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

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

To calibrate the sensor:

1. Open the Docking Station Door by pulling the door.
2. Check the gasket in the Docking Station. If necessary, clean the Docking Station and gasket by using a cotton swab moistened with 70% isopropanol.
   CAUTION: Always clean the sensor before placing it in the Docking Station.
3. Hang the sensor into the holder in the inside the door. Ensure that the sensor's red light is visible.
   CAUTION: Incorrect orientation of the sensor in the Docking Station may cause damage to the sensor, the Docking Station, or parts thereof when closing the Docking Station door.

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

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

Note: If the sensor is stored in the Docking Station, enforced sensor calibrations can be activated via the 'Sensor Maintenance' screen. If enabled, PO_2 is also calibrated during calibrations that are activated with the menu function 'Calibrate sensor'.

WARNING: Transport/store Sentec TC Sensors with membrane and protected from light/radiation. If Sentec TC Sensors are stored without membrane, damage of the sensor may occur. Do not expose the sensor to strong ambient light such as direct sunlight, surgical lamps, infrared warming lamps, and phototherapy lights during clinical use. This may cause inaccurate measurements. In such cases, cover the sensor with an opaque material.

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

Note: To maintain monitor readiness in-between monitoring, to reduce the consumption of Calibration Gas, and to keep the Membrane Change Interval at an optimum (3.13), always keep the monitor switched on and always store the sensor in the Docking Station. When switching the tCOM+ off, it will keep the sensor calibration valid for a period of 30 minutes for a possible reboot, provided the same profile (or a profile which does not enforce a new sensor calibration, e.g. due to a different sensor temperature) is selected when re-starting the tCOM+.

When the tCOM+ and the connected sensor are not in use, Sentec recommends wrapping the sensor cable around the detachable cable holders located at the back of the monitor, thus avoiding entanglement or cable damage.

To ensure continuous reliability of the calibration of Sentec TC Sensors, the tCOM+ automatically tests the status of the Docking Station and of the sensor and, if necessary, inhibits the start of a calibration or aborts a running calibration.

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

CAUTION: Accurate sensor calibration is important. Improper sensor calibration subsequently will result in inaccurate PCO_2 and/or PO_2 readings.

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

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

3.13 Changing the Sensor Membrane

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

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

CAUTION: Without being requested by the tCOM+, the sensor membrane must additionally be changed if any of the conditions described in 'Checking a Sentec Transcutaneous Sensor' (3.1) are noted.

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

Note: The tCOM+ provides an on-screen tutorial, which will guide you through the membrane change process step by step.

Note: A full Membrane Change video tutorial is available for online viewing at https://www.sentec.com/product-support/tcm/ .

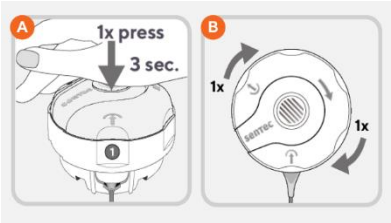
Inserting Sensor into Membrane Changer

1. Verify that the sensor is clean before changing its membrane. If necessary, carefully wipe off any residue from the sensor's surface (including membrane, housing, groove and cable) with 70% isopropanol (for other approved cleaning agents refer to sentec.com/ifu).
2. Remove protective film from the bottom (Membrane Changer model single-use only) and firmly place the Membrane Changer on a horizontal, dry surface with the colored dot facing up.
3. Insert the sensor into the Membrane Changer with the sensor side facing up. The insert receiver ① is designed so that improper alignment of the sensor is difficult if not impossible.

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

Four Press-and-Turn Steps to Change the Membrane

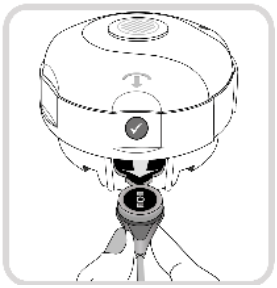
The membrane change procedure consists of four identical press-and-turn steps. To provide better guidance, these steps are marked with the corresponding numbers on the Membrane Changer. Keep the Membrane Changer horizontal while executing the Press-and-Turn step 4 times.



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

Step 1 removes the old sensor membrane: Press down slowly but firmly with palm of hand and hold for 3 seconds. Release the top. Carry out a visual check to ensure that the membrane is removed. Turn the top portion one click clockwise to the next step. Keep the Membrane Changer horizontal.
Step 2 cleans the sensor surface from old electrolyte: As in step 1, press the membrane changer slowly but firmly, release the top and turn clockwise to the next step.
Step 3 applies new electrolyte on the sensor surface: Press the membrane changer slowly but firmly for 3 seconds, release the top and turn clockwise to the next step.
Step 4 places a new membrane on the sensor: Press the membrane changer top down slowly but firmly for 3 seconds, release the top and turn clockwise to the √ symbol.

Removing Sensor from Membrane Changer



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

Inspecting the Sensor Membrane

Check the condition of the sensor membrane and the integrity of the sensor (3.1). Repeat the membrane change if necessary. Do not use the sensor if any problems are noted.

Confirming Membrane Change on tCOM+

Once the inspection of the sensor membrane is completed successfully, confirm the membrane change on the monitor (menu 'Sensor Maintenance'.
Note: The membrane timer only resets if you confirm the membrane change on the monitor.

4 Troubleshooting/Preventive Maintenance

4.1 Routine checks, service, and maintenance procedures

During normal use, the tCOM+ does not require any internal adjustments or additional calibrations. It is recommended that a complete safety and functionality check is performed at regular intervals or in accordance with institutional, local, and governmental regulations.

CAUTION: The cover must only be removed by Sentec service personnel. There are no user-serviceable parts inside the tCOM+.

To guarantee continuous performance, reliability, and safety of the system, the following routine checks and maintenance procedures (including cleaning/disinfection) as well as safety and functionality checks should be performed regularly.

For cleaning and/or disinfection, use 70% Isopropanol or an approved cleaning agent listed in HBQ-122-Cleaning and Disinfection.

	tCOM+	Sentec TC Sensors
Before and After Use	None	**Before and After Use: Visually Inspect** the Sentec TC Sensors **After Use: Clean and disinfect** the Sentec TC Sensor.
Weekly	**Clean and disinfect** the tCOM+ including accessories, Docking Station, and gasket	**Clean and disinfect** the 'Sensor Adapter Cable'
Monthly	**Visual Inspection** of the monitor, Docking Station (incl. Docking Station gasket) and power cord/power supply for functional/mechanical damage **POST** (Power-On-Self-Test) **Barometer Check** **If connected to other devices:** Test functions of the connectivity (if applicable incl. correct data transfer and alarming).	**Visual Inspection** of sensor head, cable, and membrane functional/ mechanical damage **Sensitivity Test** for PCO_2/PO_2 **Sensor Temperature Display**
	Check disposables monthly and **replace any expired products.**	
Quarterly	None	**Clean and soak** the Sentec TC Sensor **without** membrane, see 4.1.2

Recommended annually, but at least biannually	**Qualified service personnel*** shall perform a complete **Safety & Functionality Test** and document the results. To perform a complete Safety & Functionality Test and for service or repair, contact qualified service personnel or your local Sentec representative. Please note that repair and service procedures which require opening the tCOM+ must be performed by Sentec service personnel, only.

***Qualified service personnel should have obtained a relevant technical education/degree, e.g., medical or maintenance technicians.**
Refer to chapter 4.4 for additional/complete check lists and detailed maintenance procedures.

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

4.1.1 Cleaning/disinfection

Due to the nature and seriousness of infectious diseases such as AIDS and Hepatitis B, it is important that equipment and accessories which can come into contact with human or animal tissues or fluids (particularly blood) should always be regarded as contaminated and potentially hazardous.

Contaminated equipment and accessories must be decontaminated. Decontamination must be carried out by a properly trained person. The directions for cleaning and disinfection vary from hospital to hospital. If you are in any doubt regarding contamination or decontamination, consult your local infection control authority/hygiene department.

Recommended cleaning/disinfection procedures for Sentec TC Sensors

For cleaning and/or disinfection of Sentec TC Sensors, use 70% Isopropanol or an approved cleaning agent listed in HBQ-122-Cleaning and Disinfection.

Recommended cleaning/disinfection procedures for the tCOM+

Sentec recommends cleaning the monitor weekly using a wipe moistened with 70% Isopropanol or an approved cleaning agent listed in HBQ-122-Cleaning and Disinfection. However, other cleaning / disinfection procedures may be applied (refer to instructions given below) as often as required per institutional ordinances.

To prevent unintended changes to monitor settings during cleaning of the touch screen, follow these steps:

1. Briefly press the 'ON/OFF Button' on the left side of the panel while the device is running.
2. Next, tap on the 'Lock Screen for Cleaning' icon. This action will deactivate the screen for 20 seconds, with a visible countdown, ensuring monitor settings remain unchanged.

For effective cleaning of the touch screen:

- Utilize a soft, lint-free cloth that is either dry or slightly dampened.
- Gently wipe the screen to remove fingerprints and dirt.

Recommended cleaning/disinfection of the Docking Station:

To clean the gasket of the Docking Station, use a cotton swab (which does not lose any fibers or threads) with 70% Isopropanol or an approved cleaning agent listed in HBQ-122-Cleaning and Disinfection.

Make sure that the Docking Station gasket is completely dry and is well embedded in its notch after disinfection and before using the tCOM+ again.

Dispose of swabs/pads in the receptacle for biological waste immediately after use.

CAUTION: Any particles on the gasket or sensor might prevent a tight fit between the gasket and the sensor and, hence, cause a gas leak. Make sure not to damage the gasket. Allow the gasket to dry before use.

Please refer to **HBQ-122-Cleaning and Disinfection** for an overview of tested and recommended products (see sentec.com/ifu - Further Directions for Use - Care and Maintenance).

Note: As the number of available cleaning and disinfection agents varies from country to country and from hospital to hospital, it is not possible to provide a complete list of all suitable cleaning and disinfection agents. The listed name brand products may be substituted by other name brand products of equivalent composition. Refer to the instructions for use of the respective manufacturer for preparation, application, and disposal of the cleaning agents.

CAUTION: Ensure that no liquid enters the device. Ingress of liquids can cause device damage, electric shock, or device malfunction.

CAUTION: Plugs and connectors meticulously must always be kept clean and dry. Do not expose the tCOM+ to heavy moisture and do not allow any fluids to enter the tCOM+. If the tCOM+ becomes wet accidentally, it should be removed from AC power, wiped dry externally, allowed to dry thoroughly, and inspected by qualified service personnel before further use.

CAUTION: Do not submerge Monitor in water and not to use tCOM+ monitor in splashing water conditions. Apply precautions when cleaning tCOM+ monitor hereby warning not to use other re or procedures other than those recommended by Sentec.

CAUTION: Using other cleaning and disinfection agents than recommended may cause damage and/or deterioration of the device's materials and device failure can result.

CAUTION: Applying mechanical force on the device during cleaning may damage the device's materials and device failure can result.

CAUTION: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the monitor. These substances attack the device's materials and device failure may result.

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

CAUTION: Do not touch, press, or rub the surfaces of the tCOM+ with abrasive cleaning compounds, instruments, brushes, rough surface materials, or bring them into contact with any that could scratch the tCOM+'s surfaces.

4.1.2 Sensor Clean and Soak

To guarantee continuous performance of Sentec TC Sensors, a clean and soak procedure should be performed once every quarter:

1. Remove the sensor membrane using the membrane remover located at the bottom of the Membrane Changer as follows: Slide the Sentec TC Sensor into the membrane remover with its membrane facing the bottom of the Membrane Changer. Then, lift the sensor up to remove the membrane from the sensor body.

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

   CAUTION: Do not leave the sensor without a membrane open to air for a prolonged period of time. Perform the following steps uninterrupted.

2. Immerse the sensor into clean, room temperature water for 3 minutes.
3. Use a soft brush to completely remove dried up gel / electrolyte residues from the grooves on the sensor circumference.
4. Softly rinse the sensor with clean water.
5. Dab the sensor dry using a clean lint-free towel. Pay attention not to touch the ring and the pH-glass in the center of the sensor surface. Do not rub the sensor surface!
6. Inspect the ring around the pH-glass for damage and brownish color. Note that the same criteria apply for the OxiVenT™ Sensor (3.1).
7. If the ring around the pH-glass is broken, parts of it are missing, the brown color is lost, or the ring has a metallic luster, then replace the sensor with a new Sentec TC Sensor (3.1, 3.13).
8. Inspect the sensor to ensure that the grooves on the sensor circumference are clean and intact. If the grooves on the sensor circumference are damaged, replace the sensor with a new Sentec TC Sensor. Do not use the sensor if there is any visible damage to/trapped air underneath the membrane or if the red LED does not light when the sensor is connected to the tCOM+.
9. OxiVenT™ Sensor only: Verify that the white oxygen sensing spot (i.e., off-centered, white, circular spot) is present and intact.
10. If the visual inspections (steps 6 to 8) passed, re-membrane the sensor using the Membrane Changer (see 3.13).

4.2 Troubleshooting during Patient Monitoring

A complete troubleshooting overview is provided in the 'Service Manual for the tCOM+' (HBQ-197). It describes problems, possible causes and the recommended corrective action(s) the operator, or qualified service personnel may perform to resolve the problem. Furthermore, the website offers guidance on frequently asked questions relating to troubleshooting.

4.3 Alerts and Error Messages

4.3.1 Monitor and Sensor problems/faults

The tCOM+ distinguishes between sensor faults (SFxx), monitor faults (MFxx), sensor problems (SPxx) and monitor problems (MPxx). "xx" indicates the respective fault or problem number. Sensor faults relate to situations where – as a safety precaution – the tCOM+ switches the sensor off. In the event of a sensor or monitor fault, the operator must restart the tCOM+ to reset the fault condition. Sensor problems, in contrast, relate to situations where the tCOM+ switches off the sensor temporarily and/or resumes operation (in certain cases with reduced functionality). Monitor problems relate to situations where the tCOM+ requires operator intervention prior to resuming operation.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
Sensor Problem 10: Calibration Failed	SP10	Low priority alarm	The tCOM+ detects that the potential measured by the sensor's pH electrode at the end of the sensor calibration is outside a predefined range / low voltage potential is detected. This alarm ceases when removing the sensor from the Docking Station. Until successful termination of the next sensor calibration, PCO_2 values are marked as invalid, and the alarm is reactivated if the sensor is placed in the Docking Station. **Note:** This message is only generated if PCO_2 is enabled, and the sensor is in the Docking Station.
Sensor Problem 11: Calibration Failed	SP11	Low priority alarm	The tCOM+ detects that the sensor's PCO_2 readings are stable but too slow, as the calibration could not be terminated within 14 minutes. This alarm ceases when removing the sensor from the Docking Station. Until successful termination of the next sensor calibration (within ≤14 minutes), PCO_2 values are marked as invalid, and the alarm is reactivated if the sensor is placed in the Docking Station. **Note:** This message is only generated if PCO_2 is enabled, and the sensor is in the Docking Station.
Sensor Problem 12: Calibration Failed	SP12	Low priority alarm	The tCOM+ detects that the sensor's PCO_2 sensitivity is deteriorated, or an operator initiated 'PCO_2 sensitivity test' has failed. This alarm ceases when removing the sensor from the Docking Station. Until an operator initiated 'PCO_2 sensitivity test' has successfully been terminated, PCO_2 values are marked as invalid, and the alarm is reactivated if the sensor is in the DS. **Note:** This message is only generated if PCO_2 is enabled, and the sensor is in the Docking Station. **Note:** If 'Sensor Problem 12: Calibration Failed' reoccurs after successful termination of an operator initiated 'PCO_2 sensitivity test', it could be possible that the Docking Station is defective.
Sensor Problem 14: Calibration Failed	SP14	Low priority alarm	The tCOM+ detects that the sensor's PCO_2 readings are unstable and/or too slow as an 'Extended Calibration' could not be terminated within 14 minutes. This alarm ceases when removing the sensor from the Docking Station. Until successful termination of the next sensor calibration, PCO_2 values are marked as invalid, and the alarm is reactivated if the sensor is in the Docking Station. **Note:** This message is only generated if PCO_2 is enabled, and the sensor is in the Docking Station. **Note:** An 'Extended Calibration' is initiated if a regular sensor calibration could not be finished successfully within 14 minutes due to an unstable sensor. **Note:** Refer to the Status Messages 'Extended Calibration', 'PCO_2 slow' and 'Sensor Problem 11: Calibration Failed'.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
Sensor Problem 15: Calibration Failed	SP15	Low priority alarm	The tCOM+ detects that the potential measured by the sensor's pH electrode at the end of the sensor calibration is outside a predefined range / high voltage potential is detected. This alarm ceases when removing the sensor from the Docking Station. Until successful termination of the next sensor calibration, PCO_2 values are marked as invalid, and the alarm is reactivated if the sensor is placed in the Docking Station. **Note:** This message is only generated if PCO_2 is enabled, and the sensor is in the Docking Station.
Sensor Problem 20: LED failure	SP20	Low priority alarm	The tCOM+ detects that the sensor's red LED is defective. SpO_2/PR are marked as invalid irrespective of sensor position. The sensor still can be used for PCO_2 (and PO_2) monitoring. PI is also available. **Note:** This message is only generated if SpO_2/PR is enabled, and a Sentec TC Sensor is in the Docking Station. **Note:** 'SP20: LED Failure' resets upon restarting of the tCOM+ or if the problem does not reoccur when inserting the sensor into the Docking Station.
Sensor Fault 21: Contact Service	SF21	Low priority alarm	The tCOM+ detects that the sensor's IR LED is defective. The tCOM+ switches off the sensor. To reset 'SF21: Contact Service' and to restart the sensor, the tCOM+ must be switched off and restarted. Contact qualified service personnel or your local Sentec sales representative if restarting the tCOM+ does not reset the message. **Note:** A defective Docking Station may also trigger SF21.
Sensor fault 31	SF31	Low priority alarm	The tCOM+ detected repeatedly that the difference between the sensor's two redundant temperature measurements has been too large for 80 seconds. The tCOM+ switches the sensor off. To reset 'Sensor fault 31' and to restart the sensor, the tCOM+ must be switched off and restarted. Do not use the sensor if this message cannot be reset by restarting the tCOM+. Instead, contact qualified service personnel or your local Sentec representative.
Sensor fault 33	SF33	Low priority alarm	The tCOM+ has repeatedly not received temperature data from the sensor for 10 seconds. The tCOM+ switches the sensor off. To reset 'Sensor fault 33' and to restart the sensor, the tCOM+ must be switched off and restarted.
Sensor fault 35	SF35	Low priority alarm	The tCOM+ detects repeatedly that temperature readings are frozen for 80 seconds. The tCOM+ switches the sensor off. To reset 'Sensor fault 35' and to restart the sensor, the tCOM+ must be switched off and restarted. Do not use the sensor if this message cannot be reset by restarting the tCOM+. Instead, contact qualified service personnel or your local Sentec representative.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
Sensor Problem 38: High sensor temperature	SP38	Low priority alarm	The message 'Sensor Problem 38: High sensor temperature', caused by condition 'r2' (refer to message 'Sensor exceeds temperature limits' in chapter 4.3.2) persists for 5 minutes. The tCOM+ switches the sensor off and restarts it after 60 seconds. **Note:** Also, refer to messages 'Sensor problem 42: High sensor temperature', 'Sensor fault 39: High sensor temperature', and 'Sensor fault 43: High sensor temperature'. **Note:** No power will be provided to the sensor port for 60 seconds.
Sensor Fault 39: High sensor temperature	SF39	Low priority alarm	The tCOM+ detects that the sensor temperature exceeds 'SET temperature + 0.6 °C' while the sensor did not detect condition 'r1' (refer to message 'High Sensor Temperature' in chapter 4.3.2). The tCOM+ switches the sensor off. To reset 'Sensor fault 39' and to restart the sensor, the tCOM+ must be switched off and restarted. Do not use the sensor if this message cannot be reset by restarting the tCOM+. Instead, contact qualified service personnel or your local Sentec representative. **Note:** Also, refer to messages 'Sensor problem 38: High sensor temperature', 'Sensor problem 42: High sensor temperature', and 'Sensor fault 43 High sensor temperature'.
Sensor Problem 42: High sensor temperature	SP42	Low priority alarm	The message 'Sensor Problem 42: High Sensor Temperature', caused by condition 'a2' (refer to message 'High Sensor Temperature' in chapter 4.3.2) persists for 5 minutes. The tCOM+ switches the sensor off and restarts it after 60 seconds. **Note:** Also refer to messages 'Sensor problem 38: High sensor temperature', 'Sensor fault 39: High sensor temperature', and 'Sensor fault 43: High sensor temperature' **Note:** No power will be provided to the sensor port for 60 seconds.
Sensor Fault 43: High sensor temperature	SF43	Low priority alarm	The tCOM+ detects that the sensor temperature exceeds 45.0 °C while the sensor did not detect condition 'a1' (refer to message 'Sensor exceeds temperature limits' in chapter 4.3.2). The tCOM+ switches the sensor off. To reset 'Sensor fault 43: High sensor temperature' and to restart the sensor, the tCOM+ must be switched off and restarted. Do not use the sensor if this message cannot be reset by restarting the tCOM+. Instead, contact qualified service personnel or your local Sentec representative. **Note:** Also, refer to messages 'Sensor problem 38: High sensor temperature', 'Sensor problem 42: High sensor temperature', and 'Sensor fault 39: High sensor temperature'.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
Sensor fault 51	SF51	Low priority alarm	The tCOM+ repeatedly detected an EEPROM CRC mismatch of the connected sensor and switched the connected sensor off. Do not use the sensor. Contact qualified service personnel or your local Sentec representative.
Sensor fault 53	SF53	Low priority alarm	The tCOM+ repeatedly detected a stack overflow warning of the connected sensor and switched the connected sensor off. To reset 'Sensor fault 53' and to restart the sensor, the tCOM+ must be switched off and restarted. Do not use the sensor if this message cannot be reset by restarting the tCOM+. Instead, contact qualified service personnel or your local Sentec representative.
Sensor fault 61	SF61	Low priority alarm	The tCOM+ detects that a connected sensor draws a current but will not communicate. The tCOM+ therefore interrupts all power to the sensor. Do not use this sensor. Contact qualified service personnel or your local Sentec representative.
Sensor problem 70	SP70	Low priority alarm	The tCOM+ detects that the LED of the connected OxiVenT™ Sensor's PO_2 module is defective. PO_2 is marked as invalid, irrespective of sensor position. The sensor can still be used for monitoring of the other parameters. **Note:** This message is only generated if PO_2 is enabled, and the sensor is in the Docking Station.
Sensor problem 71	SP71	Low priority alarm	The tCOM+ detects that the photodiode of the connected OxiVenT™ Sensor's PO_2 module is defective. PO_2 is marked as invalid, irrespective of sensor position. The sensor can still be used for monitoring of the other parameters. **Note:** This message is only generated if PO_2 is enabled, and the sensor is in the Docking Station.
Sensor Problem 72: PO_2 Calibration Failed	SP72	Low priority alarm	The tCOM+ detects that the sensor's PO_2 sensitivity is deteriorated, or an operator initiated 'PO_2 sensitivity test' has failed. This alarm resets when removing the sensor from the Docking Station. Until an operator initiated 'PO_2 sensitivity test' is successfully terminated, PO_2 values are marked as invalid, and the alarm is reactivated when the sensor is in the DS. **Note:** This message is only generated if PO_2 is enabled, and the sensor is in the Docking Station. **Note:** If 'Sensor problem 72' reoccurs after successful termination of an operator initiated 'PO_2 sensitivity test', it could be possible that the Docking Station is defective.
Sensor Problem 73: PO_2 Calibration Failed	SP73	Low priority alarm	The tCOM+ detects a PO_2 module error for the connected OxiVenT™ Sensor. PO_2 is marked as invalid, irrespective of sensor position. The sensor can still be used for monitoring of the other parameters. Replace the sensor to continue monitoring PO_2.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
			Note: This message is only generated if PO_2 is enabled, and the sensor is in the Docking Station.
Sensor Problem 74: PO_2 Calibration Failed	SP74	Low priority alarm	The tCOM+ detects that the sensor's PO_2 readings are too slow or too unstable as the PO_2 calibration could not be terminated within 14 minutes. This alarm resets when removing the sensor from the Docking Station. Until successful termination of the next PO_2 calibration (within ≤14 minutes), PO_2 values are marked as invalid, and the alarm is reactivated if the sensor is placed in the Docking Station. **Note:** This message is only generated if PO_2 is enabled, and the sensor is in the Docking Station.
Monitor fault xx	MFxx	Low priority alarm	The monitor surveillance has detected monitor fault xx, where xx specifies the fault number. **Note:** Monitor faults xx (MFxx) relate to situations where – as a safety precaution – it is required to restart the tCOM+ to try to reset the fault condition. Do not use the tCOM+ if restarting does not reset the message. Instead, contact qualified service personnel or your local Sentec representative. **Note:** Prior to sending the tCOM+ to repair, it is possible to export trend data.
Monitor problem xx	MPxx	Low priority alarm or information	The monitor surveillance has detected monitor problem xx, where xx specifies the problem number. Switch off and restart the monitor. Do not use the tCOM+ if the message still appears. Instead, contact qualified service personnel or your local Sentec representative. **Note:** Prior to sending the tCOM+ to repair, it is possible to export trend data.

Note: The color and pattern of display Status Bar and LED bar is identical for all alarms listed above.

4.3.2 Technical status messages and status codes

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

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
Atm. P. unstable	AU	Information	During an ongoing sensor calibration, the tCOM+ detects that the atmospheric pressure is unstable and aborts the ongoing sensor calibration. As soon as the atmospheric pressure is restabilized, this alarm ceases and sensor calibration starts automatically. This message also ceases if the sensor is removed from the Docking Station. **Note:** This message only appears if PCO_2 is enabled, and the sensor is in the Docking Station.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
Barometer fault	BF	Low priority alarm	The tCOM+ detects a barometer fault (pressure readings fluctuating implausibly fast or pressure readings out of range). Sensor calibration will not be initiated or a calibration in progress will be aborted. The alarm ceases if the sensor is removed from the Docking Station. **Note:** This message only appears if PCO_2 is enabled, and the sensor is in the Docking Station.
Barometer fault (technical)	BFt	Low priority alarm	The tCOM+ detects a technical barometer fault (chip readout failed). Sensor calibration will not be initiated or a calibration in progress will be aborted. To reset the fault condition, the operator must switch the tCOM+ off and restart it. If the fault reappears after restarting, please contact qualified service personnel. **Note:** This message only appears if PCO_2 is enabled, and the sensor is in the Docking Station.
Battery critical (**not** connected to AC power)	BC	Medium priority alarm	The remaining battery capacity is below a critical value of less than 10%, and the monitor is **not** connected to AC power. If the tCOM+ is not re-connected to AC power and the battery capacity drops to less than 2%, the tCOM+ shuts down. **Note:** The 'Battery Icon' is highlighted yellow if the remaining battery capacity is critical.
Battery critical (connected to AC power)	BCc	Information	The remaining battery capacity is below a critical value and the monitor is connected to AC power. If the tCOM+ is disconnected from AC power, the tCOM+ will soon shut down. **Note:** The 'Battery Icon' is highlighted yellow if the remaining battery capacity is critical.
Battery low	LB	Low priority alarm	The remaining battery capacity is below 15% and the tCOM+ is **not** connected to AC power. **Note:** The 'Battery Icon' is highlighted yellow over a cyan background if the remaining battery capacity is below 15%, irrespective of whether the tCOM+ is connected to AC power or not.
Calibration in progress	SC	Information	Sensor calibration in progress. **Note:** This message only appears if PCO_2 is enabled, and the sensor is in the Docking Station. **Note:** If the 'Calibration Interval' has elapsed prior to (or during) the ongoing calibration, the 'Remaining Monitoring Time Icon' remains highlighted yellow until successful termination of the ongoing calibration.
Calibrate sensor	CSi	Low priority alarm	An event triggering a so-called 'Initial Calibration' occurred and sensor calibration therefore is **mandatory**. Insert the sensor into the Docking Station. Calibration will start automatically.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
			Note: This message only appears if PCO_2 is enabled, and the sensor is outside the Docking Station. **Note:** After an event that triggers a so-called 'Initial Calibration', PCO_2 and – if enabled – PO_2 are marked as invalid. **Note:** Unless the 'Site Time' has expired, the 'Remaining Monitoring Time' icon is highlighted yellow if a calibration is requested. **Note:** If the Status Code 'CSi' is output while the sensor is in the Docking Station, the sensor is not (yet) calibrated.
Calibrate sensor	CSo	Low priority alarm	This message may appear if the PO_2 channel has not been in use for a prolonged time while the PCO_2 channel was active. The PO2 channel therefore requires mandatory calibration. Insert the sensor into the Docking Station. Calibration will start automatically. **Note:** This message only appears if PO_2 is enabled, and the sensor is outside the Docking Station. **Note:** PO2 is marked as invalid. **Note:** Unless the 'Site Time' has expired, the 'Remaining Monitoring Time' icon is highlighted yellow if a calibration is requested. **Note:** If the Status Code 'CSo' is output while the sensor is in the Docking Station, the sensor is not (yet) calibrated.
Change sensor membrane	RS	Low priority alarm	Change of the sensor membrane is required. Change the sensor membrane. **Note:** This message only appears if PCO_2 is enabled. **Note:** PCO_2 is marked as invalid if a change of the sensor membrane is required. **Note:** The alarm condition ceases if you confirm the membrane change on the monitor.
Check sensor application	CA	Low priority alarm	This message is displayed if PCO_2 and/or PO_2 readings do not stabilize within 10 minutes after sensor application or after detection of a 'TC-Artifact'. The adequacy of the sensor application must be verified. Adjust the sensor application if necessary. This alarm ceases as soon PCO_2 and/or PO_2 readings stabilize. **Note:** This message only appears if PCO_2 or PO_2 is enabled, and the 'Sensor-On-Patient' is detected. **Note:** PCO_2 and/or PO_2 are marked as unstable in this situation. **Note:** This message will also appear if the sensor temperature deviates by more than 2 °C from the Sensor Temperature for more than 10 minutes. **Note:** This message will also appear if the 'Enforced Sensor-On-Patient Mode' is active and PCO2 is below

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
			24mmHg cutaneous after a stable reading was detected.
Check sensor placement	CP	Low priority alarm	The tCOM+ detects that the sensor is not properly positioned in the Docking Station and thus not properly recognized. To clear this message, open the Docking Station door, properly insert the sensor, and close the Docking Station door.
Connect sensor	CoS	Low priority alarm	No sensor connected to the tCOM+, the cable of the connected sensor or of the adapter cable used to connect the sensor is defective, or the connected sensor is not compatible with the tCOM+. **Note:** Also see message 'Incompatible sensor'.
Docking Station Error	DFxx	Low priority alarm	The monitor surveillance has detected a Docking Station error. **Note:** This message only appears if PCO_2 is enabled, and the sensor is in the Docking Station. 'xx', the number of the specific Docking Station error, is only indicated in the Status Code but not in the Status Message. **Note:** Sensor calibration will not be initiated or a calibration in progress will be aborted. As soon as the problem is resolved, this alarm ceases and a sensor calibration will start automatically. The alarm also ceases if the sensor is removed from the Docking Station.
Extended Calibration	EC	Information	An extended sensor calibration is in progress after the regular sensor calibration was not successful within 14 minutes due to fluctuating PCO_2 readings during the calibration (this can be the case if the sensor was not used for a longer period). **Note:** This message is only displayed if PCO_2 is enabled, and the sensor is in the Docking Station. **Note:** After successful completion of an 'Extended Calibration', the message 'Ready for use' is displayed. 'PCO_2 slow' is displayed if the duration of the 'Extended Calibration' lasted 14 minutes and 'SP14: Calibration Failed' if the 'Extended calibration' could not be terminated successfully within 14 minutes.
Gas bottle empty	GE	Low priority alarm	Indicates that the gas bottle is empty, or no gas bottle is in place. In the 'Gas Bottle Empty' status a calibration cannot be initiated. **Note:** This message only appears if PCO_2 is enabled, and the sensor is in the Docking Station. **Note:** The 'Gas Icon' appears over a cyan background if the gas bottle is empty and yellow if the remaining capacity is < 10%.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
Gas bottle loose, please tighten	BL	Low priority alarm	The tCOM+ detects that the gas bottle is not inserted properly. This message can be cleared by pressing 'Confirm', which will trigger another check. **Note:** This check is performed under the following conditions: 1. Insertion of a gas bottle detected 2. At the beginning of a normal calibration. Please screw in the gas bottle by additional ¼ - ½ turn to ensure that the gas bottle is inserted properly. If the problem persists, please use another gas bottle.
Docking Station Leak: Check gasket	GL	Low priority alarm	The tCOM+ has detected a Docking Station gas leak. An 'Initial Calibration' is requested when the sensor is removed from the Docking Station and PCO_2/PO_2 values will be marked as invalid until successful termination of the next sensor calibration/mandatory leak test. **Note:** This message only appears if PCO_2 is enabled, and the sensor is in the Docking Station. **Note:** If a gas leak was detected, the next sensor calibration will be followed by a mandatory leak test (see message 'Leak test in progress').
Heating reduced	HR	Low priority alarm	As a safety precaution, the sensor temperature has been reduced by Site Protection as the sensor application duration has overrun the selected 'Site Time' by more than 10% or 30 minutes. To reactivate normal sensor heating, remove the sensor from the patient and confirm the message 'Sensor off patient' in the Status Bar or insert the sensor into the Docking Station. This will also reset the Site Timer. **Note:** The 'Temperature Icon' is highlighted blue if heating is reduced. **Note:** This message only appears if the sensor is on the patient. **Note:** PCO_2/PO_2 is marked as invalid if heating is reduced.
High ambient light	HA	Information	This message is displayed whenever the monitor's oximetry channel detects a high ambient light level independently from its severity or the impact on the SpO_2, PR, or PI values. Shield the sensor from ambient light if this message appears. This message ceases as soon as the ambient light level is within a predefined range. **Note:** This message only appears if SpO_2/PR are enabled, and 'Sensor-On-Patient' is detected. **Note:** SpO_2, PR, and PI are marked as questionable when high ambient light levels are detected.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
High ambient light	SA	Information / Low priority alarm	This message is displayed whenever the monitor's PO_2 channel detects a high ambient light level independently from its severity or the impact on the PO_2 values. Shield the sensor from ambient light if this message appears. This message ceases as soon as the ambient light level is within a predefined range. **Note:** This message only appears if PO_2 is enabled, and 'Sensor-On-Patient' is detected. **Note:** PO_2 is marked as questionable when high ambient light levels are detected. If the ambient light level is too high, PO_2 is marked invalid accompanied by a low priority alarm.
Incompatible sensor	IS	Low priority alarm	The connected sensor is not compatible with the tCOM+ or the Sentec Identification Code stored in its memory is not readable or corrupt. **Note:** To clear this message, a restart of the tCOM+ is required.
Insert sensor into DS	IDs	Information	This message appears during an operator-initiated PCO_2 and/or PO_2 sensitivity test at an intermediate step, when the operator is requested to place the sensor into the DS again. Insert the sensor into the Docking Station within 10 minutes to expose the sensor to the calibration gas (otherwise, the sensitivity test will be aborted).
Leak test in progress	LT	Information	A mandatory leak test is in progress to ensure that the leak, which was detected after the previous calibration, is successfully fixed. The SDMS will be 'Ready for use' only after successful termination of the ongoing leak test.
Monitoring time < 15 min	TL	Information	Indicates that within 15 minutes either the 'Site Time' will expire or – if PCO_2 is enabled – sensor calibration is recommended (whichever will occur first).
PCO_2 slow	PS	Information	This message is displayed if the duration of the last sensor calibration (normal or extended) was 14 minutes. When removing the sensor from the Docking Station, this message ceases. PCO_2 values are marked as questionable until successful termination of the next sensor calibration within 14 minutes. **Note:** This message only appears if PCO_2 is enabled, and the sensor is in the Docking Station. If the sensor is outside the Docking Station/during monitoring only the Status Code 'PS' is output. **Note:** The sensor may still be used for PCO_2 monitoring but the operator must be aware that for a slow sensor, 'PCO_2 stabilization' will take longer, the sensor's response to changes in patient's $PaCO_2$ levels will be slower and the PCO_2 alarm condition delay will be longer than for a fast sensor.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
			Note: Refer to Status Message 'Sensor Problem 11: Calibration Failed' and 'Sensor Problem 14: Calibration Failed',
PCO_2 stabilizing	CE	Information	PCO_2 readings are stabilizing after sensor application or occurrence of a 'PCO_2 artifact'. This message ceases as soon PCO_2 is (re)stabilized. **Note:** This message only appears if PCO_2 is enabled, and 'Sensor-On-Patient' is detected. **Note:** PCO_2 is marked as unstable during PCO_2 stabilization. **Note:** This message will also appear if the actual sensor temperature deviates by more than 2 °C from the set Sensor Temperature. **Note:** If PCO_2 readings do not stabilize within 10 minutes after sensor application or after detection of a 'PCO_2 artifact', the low priority alarm 'Check sensor application' is triggered. **Note:** Ambient air (intermittently) penetrating between the sensor surface and the skin, typically resulting in fast PCO_2 changes, is the most frequent cause for 'PCO_2 Artifacts'. In order to reduce the occurrence of 'PCO_2 Artifacts', a good, hermetically sealed contact between the sensor surface and the patient's skin is essential.
PCO_2/PO_2 stabilizing	TS	Information	This message appears if both transcutaneous parameters are stabilizing after sensor application or after occurrence of a 'TC-Artifact'. Also, see messages 'PCO_2 stabilizing' and 'PO_2 stabilizing'. **Note:** PCO_2 and PO_2 are marked as unstable during stabilization. **Note:** This message only appears if PCO_2 and PO_2 are enabled, and 'Sensor-On-Patient' is detected.
PO_2 stabilizing	OE	Information	PO_2 readings are stabilizing after sensor application or occurrence of a 'PO_2 artifact'. This message ceases as soon PO_2 is (re)stabilized. **Note:** This message only appears if PO_2 is enabled, and 'Sensor-On-Patient' is detected. **Note:** PO_2 is marked as unstable during PO_2 stabilization. **Note:** This message will also appear if the actual sensor temperature deviates by more than 2 °C from the set Sensor Temperature. **Note:** If PO_2 readings do not stabilize within 10 minutes after sensor application or after detection of a 'PO_2 artifact', the low priority alarm 'Check sensor application' is triggered. **Note:** Ambient air (intermittently) penetrating between the sensor surface and the skin, typically resulting in fast PO_2 changes, is the most frequent

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
			cause for 'PO_2 Artifacts'. In order to reduce the occurrence of 'PO_2 Artifacts', a good, hermetically sealed contact between the sensor surface and the patient's skin is essential.
Open Docking Station door	OD	Information	This message appears after activation of an operator-initiated PCO_2 and/or PO_2 sensitivity test. Open the Docking Station within 1 minute to expose the sensor to ambient air (otherwise, the sensitivity test will be aborted). **Note:** This message only appears if PCO_2 is enabled, and the sensor is in the Docking Station.
Ready for use	RU	Information	The tCOM+ and the connected sensor are 'Ready for use'. **Note:** This message only appears if the connected sensor is not 'ON Patient'.
Sensitivity test	ST	Information	This message appears during an operator-initiated PCO_2 and/or PO_2 sensitivity test or after confirming a membrane change upon display of the message 'SP12: Calibration Failed'. At the beginning of the test, it is temporarily replaced by the message 'Open Docking Station door'. It appears again when the DS door is opened. About 2 minutes later, the message 'Close Docking Station door' appears. Once the sensor is placed into the DS, the Status Message 'Sensitivity test' is displayed again. At the end of the test and if the test finished successfully, the Status Message 'Ready for use' appears. 'SP12: Calibration Failed' is displayed if the PCO_2 sensitivity test failed and 'Sensor problem 72' appears if the PO_2 sensitivity test failed.
Sensor calibration recommen-ded	CS	Information	The 'Calibration Interval' has elapsed, and sensor calibration is recommended (but not yet mandatory). Insert the sensor into the Docking Station. Calibration will start automatically. **Note:** This message only appears if PCO_2 is enabled, and the sensor is outside the Docking Station. **Note:** Calibration is recommended if the 'Calibration Interval' has elapsed and the sensor was removed from the Docking Station less than 12 hours ago *(if 'Calibration Interval' ≤ 8 hours)*, less than 13 hours ago *(if 'Calibration Interval' = 9 hours)*, or less than 16 hours ago *(if 'Calibration Interval' = 12 hours)*. **Note:** PCO_2 is marked as questionable if a sensor calibration is recommended. **Note:** Unless the 'Site Time' has expired, the 'Remaining Monitoring Time Icon' is highlighted yellow inside if calibration is recommended. **Note:** If the Status Code 'CS' is output while the sensor is in the Docking Station, the sensor is not (yet) calibrated.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
Sensor Lifetime < yy days *(also see message Sensor usage time < xx h)*	LL	Information	The remaining 'Lifetime' in days or 'Usage Time' in hours (whichever is shorter) of the connected OxiVenT™ Sensor is indicated. **Note:** This message only appears if the connected OxiVenT™ Sensors' is stored in the Docking Station when its remaining 'Lifetime' is less than 30 days or its 'Usage Time' is less than 300 hours. **Note:** Countdown of 'Lifetime' and 'Usage time' starts from first ex-factory use of an OxiVenT™ Sensor. **Note:** The 'Usage time' is only used if PO_2 is enabled and a) while the sensor is outside the Docking Station, i.e., if the OxiVenT™ Sensor is used for PO_2 monitoring or b) during PO_2 calibration. **Note:** The remaining and used 'Lifetime' and 'Usage Time' are indicated on the second page of the menu 'System Information'. **Note:** If the sensor's 'Lifetime' has expired, the tCOM+ triggers the low priority alarm 'Replace sensor' when/as soon as the sensor is in the Docking Station. If the sensor's 'Usage Time' has expired, the OxiVenT™ Sensor functions as a V-Sign™ Sensor only (i.e., no PO_2 monitoring is possible anymore) when/as soon as the sensor is in the Docking Station (tCOM+ triggers `PO_2 Usage Time elapsed´).
Sensor usage time < xx h	LL	Information	Refer to the description of the message 'Sensor Lifetime < yy days' above.
PO_2 Usage Time elapsed	UE	Information	The sensor's 'Usage Time' has expired (OxiVenT™ Sensor only). The OxiVenT™ Sensor functions as a V-Sign™ Sensor only (i.e., no PO_2 monitoring is possible anymore) when/as soon as the sensor is in the Docking Station.
Replace sensor	LE	Low priority alarm	The 'Lifetime' of the connected OxiVenT™ Sensor has expired. Monitoring with this sensor is no longer possible. Replace the sensor. **Note:** This message applies only to OxiVenT™ Sensors. **Note:** To ensure that patient monitoring is not interrupted if the 'Lifetime' expires during monitoring, this low priority alarm condition is only triggered as soon as/when the sensor is in the Docking Station.
Sensor off patient	SO	Low priority alarm	The sensor was dislodged or intentionally removed from the patient. **Note:** Pressing 'Confirm' while this message is displayed will terminate the 'Sensor off patient' alarm condition, reset the Site Timer to the selected 'Site Time', and - if reduced by Site Protection - reactivate sensor heating. The measurement screen will remain active.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
			Note: Inserting the sensor into the Docking Station will also terminate the 'Sensor off patient' alarm condition.
Site time elapsed	TE	Low priority alarm	Indicates that the 'Site Time' has expired. **Note:** The 'Remaining Monitoring Time Icon' is highlighted yellow over a cyan background if the 'Site Time' has expired. **Note:** To terminate the 'Site time elapsed' alarm, remove the sensor from the patient and confirm the message 'Sensor off patient' in the Status Bar or insert the Sentec TC Sensor into the Docking Station.
SpO_2 low signal	LS	Information	This message is displayed whenever the tCOM+ detects a weak pulsatile signal independently from its severity or the impact on SpO_2, PR or PI values. This may be caused by low perfusion at the measurement site. Verify the sensor application and the appropriateness of the monitoring site if this message appears. **Note:** This message only appears if SpO_2/PR are enabled, and 'Sensor-On-Patient' is detected. **Note:** SpO_2, PR, and PI are marked as questionable during episodes with a weak pulsatile signal.
Low SpO_2 signal quality	MA	Low priority alarm or information	If the quality of the signals measured by the connected sensor's photodiode is temporarily degraded, SpO_2, PR, and PI are marked as questionable. If the quality of these signals continues to be degraded, the message 'Low SpO_2 Signal Quality' will display and SpO_2, PR and PI will be marked as invalid (i.e., values replaced by '---') within 15 seconds. Additionally, a low priority auditory alarm signal will sound within 30 seconds from the beginning of the degraded signal. **Note:** This message only appears if SpO_2/PR are enabled, and 'Sensor-On-Patient' is detected. **Note:** A degradation of the signals measured by the connected sensor's photodiode may be caused by patient motion, by certain environmental conditions and/or by low perfusion.
Sensor exceeds temperature limits	OT	Low priority alarm	If the sensor detects that the sensor temperature exceeds predefined limits (relative limit (r1): 'Sensor Temperature' + 0.35 °C; absolute limit (a1): 44.9 °C, the sensor immediately switches off its power-consuming parts and triggers the message 'High Sensor Temperature' with a delay of 10 seconds and the 'Temperature Icon' is highlighted red. The sensor resumes normal operation if the sensor temperature remains within the predefined limits. If despite of this safety precaution the sensor temperature continues to increase and exceeds a second set of predefined limits (relative limit (r2): 'Sensor Temperature' + 0.6 °C; absolute limit (a2): 45.0 °C), the tCOM+ switches off the

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
			sensor after 5 seconds and restarts the sensor after another 15 seconds. **Note:** This message only appears when SpO_2/PR are enabled (compare with HT status code). **Note:** The sensor temperature is supervised and controlled primarily by the sensor and – for redundancy – by the tCOM+. **Note:** Failure to cover the sensor site with a heat shield if operated under an external heat source (e.g., a radiant warmer) may cause the sensor temperature to exceed the above-mentioned predefined limits, thereby triggering the alarm & safety functions. Too high ambient temperature at the sensor site (e.g., in an incubator) may also cause the display of this message. The difference between the 'Sensor Temperature' and the ambient temperature at the sensor site must be at least 4 °C for V-Sign™ Sensors 2 and OxiVenT™ Sensors. **Note:** Also refer to Status Messages 'Sensor problem 38: High sensor temperature', 'Sensor problem 42: High sensor temperature', 'Sensor fault 39: High sensor temperature', 'Sensor fault 43: High sensor temperature'.
Clock battery low	LW	Low priority alarm or information	At power up, the tCOM+ detected that the clock battery is low and the date/time setting of the tCOM+ therefore may be wrong. After the POST screen, a low priority alarm is triggered and a yellow information text appears, instructing the operator to contact a Sentec service technician to change the clock battery as soon as possible and that meanwhile the tCOM+ may be used, provided the monitor's date/time is set to the correct value. **Note:** If the date/time has not been set in the menu of the tCOM+, normal operation of the tCOM+ will not be activated. Once the operator has set the date/time, the low priority alarm ceases and the tCOM+ starts normal operation. The message is continuously displayed to remind the operator that the clock battery must be replaced as soon as possible. **Note:** Also, see message 'Set Date/Time'.
Set Date/Time	DT	Low priority alarm	At power up, the tCOM+ detected that the date/time setting of the tCOM+ is wrong (this is the case if the clock battery was low or removed while the tCOM+ was switched off). After the POST screen, a low priority alarm is triggered, and the sub-menu 'Date/Time' is activated. **Note:** As long as the date/time has not been set in the menu of the tCOM+, normal operation of the tCOM+ will not be activated. Once the date/time has been set, the alarm ceases and the tCOM+ starts normal operation.

STATUS MESSAGE	STATUS CODE	TYPE	DESCRIPTION & POSSIBLE SOLUTION
			Note: Under normal circumstances, this message should only occur after replacement of the clock battery (see message 'Clock battery low').
Remote monitoring interrupted	RL	Low priority alarm	While the tCOM+/patient was remotely monitored the connection between the tCOM+ and the Central Station interrupted. **Note:** The 'Remote monitoring interrupted' alarm condition automatically ceases as soon as the connection between the tCOM+ and the Central Station is restored or a connection with another Central Station is established. Pressing 'Confirm' while this message is displayed will also terminate this alarm condition. **Note:** If the 'Remote monitoring interrupted' alarm condition is triggered while the monitor's alarm system is in the AUDIO OFF state, the tCOM+ will terminate the AUDIO OFF state. **Note:** The 'Remote monitoring interrupted' alarm may be indicative of a system or equipment problem (network, tCOM+, or Central Station PC), causing interruption of the connection between the Central Station and the respective tCOM+.

4.4 Service

To perform a safety check and for service or repair, contact qualified service personnel or your local Sentec representative.
Note: Repair and service procedures which require opening the cover (except battery compartment) of the tCOM+ must be performed by Sentec authorized service personnel trained by Sentec AG or accredited partners.

The following parts are serviceable items that may be replaced by qualified service personnel of the responsible organization with a relevant technical education/degree, e.g., medical technicians:

- Docking Station Gasket
- Docking Station Door
- Silicon Foot
- Battery

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

Contact your local Sentec representative or Sentec service personnel if you need assistance to perform these steps.

4.4.1 Prior to replacing parts

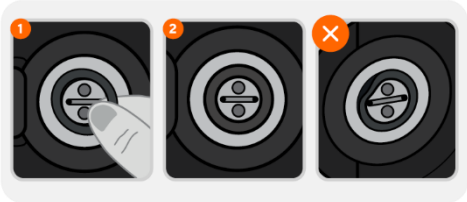
Prior to replacing the parts described in the following chapters perform the following steps:

1. Switch the monitor off.

2. Disconnect all connections on the rear panel of the device.
3. If necessary, clean and disinfect the device.

4.4.2 Replacing the Docking Station Gasket

In the event of a Docking Station leak or a possible damage, qualified service personnel, e.g., medical technicians, should replace the Docking Station Gasket.



1. Clean or disinfect hands. Open Docking Station. Remove the rubber ring (Gasket) as depicted. Alternatively, it is possible to use a pair of plastic tweezers.
2. Place a new Gasket onto the groove of the Docking Station, gently press around the circumference of the Gasket to push it into the groove, using thumb or finger. Note that the calibration chamber (in the center of the Docking Station) has a suspension mechanism and may therefore be pushed inwards without any risk to the monitor.

Make sure the Gasket sits tightly and evenly in the Docking Station groove and does not bulge outwards. Dispose of the used Gasket.

4.4.3 Replacing the Docking Station Door

In the event of a damage on the Docking Station Door, qualified service personnel, e.g., medical technicians, can exchange the door by performing the following steps:

1. Open the Docking Station Door to an angle of approximately 120°.
2. Lift the mounting link of the hinge and remove the Docking Station Door by pulling it out and pressing it down at the same time.
3. Insert the new Docking Station Door with an aperture angle of the door of 45°. 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.

4.4.4 Replacing the Silicon Foot

If the Silicon Foot got lost or extremely contaminated, perform the following steps to replace the Silicon Foot:

1. Remove the old silicon foot.
2. Clean the groove for the silicon foot with a cotton swap soaked with 70% isopropanol.
3. Insert the new silicon foot into the groove by pressing it firmly.

4.4.5 Replacing the Battery

Only use the same type of battery as replacement (RRC power solutions, type RRC2057, 7.2 V / 49.7 Wh).

The performance and degradation of the battery highly depends on the usage scenario of the battery. Do not let the battery discharge fully. Recharge it at least every 6 months.

Perform the following steps to replace the battery:

1. Open the battery cover on the back side of the monitor by means of a torque screwdriver.
2. Remove the old battery.

3. Insert the new battery.
4. Close the battery cover.

4.5 Software Update

The software of the tCOM+ and its connected sensor can be upgraded via the DATA/SERVICE USB Port. This procedure is to be carried out by qualified service personnel with a relevant technical education/degree, e.g., medical technicians: Connect a USB type-C flash drive with the corresponding software to the port and choose 'Software Update' in the ´Advanced Settings´. This will automatically start the upgrade of the relevant components. Ensure to check the software version for accuracy in the System Information menu once the software update is completed.

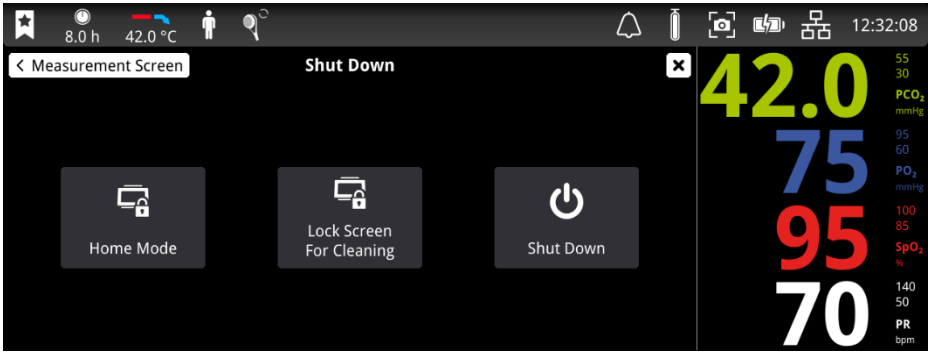
Note: Software updates must be reported to Sentec by using the Repair and Reporting Form, available on sentec.com/ifu, to ensure traceability.

5 Further Applications of the tCOM+

5.1 Home use

The tCOM+ may be used to monitor patients on home ventilation or for other applications outside of hospitals and clinics. After installation and configuration by the home care provider, the patient is the intended operator of the system, albeit, with very limited access to the menu of the tCOM+. This is ensured via the ´Home´ setting/mode. This mode is available once a respective profile has been configured (for details, refer to 3.4).

To set up ´Home´ mode, briefly press the ´ON/OFF Button´ on the left side of the panel. This will bring up the screen depicted as follows. Tap on the ´Home´ icon and enter the 'Activation Pin' configured in the profile for home use. This will deactivate menu access to avoid patients changing monitor settings.



The instructed person from the homecare provider is responsible:

- For choosing an appropriate location for the tCOM+ and setting up the system at the patient's home/site.
- For switching on the monitor in time to allow sensor to stabilize with a sufficient available monitoring time.

- For checking the state of, and, if necessary, changing the gas bottle and sensor membrane.
- For configuring and selecting a patient-specific tCOM+ Profile with the following settings (see 3.4):
- Patient's individual measurement parameters
- Audible alarms permanently deactivated
- Display Sleep Mode set to 'Display OFF – Wake on Touch'
- 'Home Mode' activation PIN code for deactivation of menu access to avoid patients changing monitor settings accidentally or on purpose. **Note:** Press the 'ON/OFF button to activate 'Home Mode' using the configured 'Home Mode' activation pin.
- For selecting appropriate measurement site(s), instructing the patient or caregiver how to use the system, how to perform basic navigation on the monitor and to access the on-screen tutorials on sensor application, and providing the "Directions for Lay Users", HBQ-176, to the patient (see sentec.com/ifu – Home Care)
- To instruct the lay operator regarding the following:
  - In the event of unforeseen incidents, error messages or unexplained changes in the performance of the device, patients shall contact their home care provider's instructed person.
  - To use the tCOM+ only in-house and under the environmental conditions specified in the "Directions for Lay Users", HBQ-176.
  - To carefully route and fix cables to reduce the possibility of entanglement or strangulation.
  - To make no changes to the device setup.
- For switching off and uninstalling the tCOM+ after successful termination of calibration
- For cleaning and disinfecting the tCOM+, the TC Sensors and the Sensor Adapter Cable between uses on different patients.
- For ensuring maintenance (4.1).

Note: The patient or lay operator cannot modify the tCOM+ configuration by using its menu when configured as above.

Note: Display Sleep Mode set to 'Display OFF – Wake on Touch' in combination with audible alarms permanently deactivated results in a monitor state where users are not notified in case of vital sign or technical alarms.

5.1.1 Qualifications / training requirements for home use

Some users of the monitor in the home environment will be caregivers trained on use of the monitor, but not medical professionals. Setting up the system and configuring the tCOM+ shall only be performed by an instructed person from a homecare provider. This instructed person must have received the appropriate training by a Sentec representative or Sentec authorized person.

6 Data Communication

6.1 Wired Communication

WARNING: Only connect devices that comply with IEC 60601-1, IEC 62368-1, or IEC 60950-1 (SELV) to the tCOM+.

CAUTION: To avoid electrical shock, only connect approved devices to the tCOM+.

6.1.1 Serial Data Port (RS-232)

The serial data port (RS-232) of the tCOM+ is used to communicate with external data collection systems such as personal computers or multi-parameter bedside monitors. The interface allows remote monitoring. The serial data port (RS-232) is located on the rear panel of the tCOM+.

Characteristics: default 115'200 baud.

Configuration: Protocol and baud rate is configurable in menu ´Advanced Settings´ - ´Interfaces´ - ´Serial´.

6.1.2 Network Port (LAN)

The Network Port of the tCOM+ is used to communicate with external computer-based data collection systems. The interface allows remote monitoring and download of historical trend data. The Network Port is located on the rear panel of the tCOM+. The Network Port is a standard RJ45 Ethernet connector.

Characteristics: TCP/IP, ports 68 and an additional communication port (default 62768) required.

Configuration: DHCP / static IP address, DNS server and port is configurable in menu ´Advanced Settings´ - ´Interfaces´ - ´LAN´.

6.1.3 Interface Options

The menu ´Advanced Settings´ - ´Interfaces´- 'Interface Options' allows activation of the 'SDM Compatibility Mode' and an associated Compatibility Version. This mode ensures compatibility with legacy connectivity integrations (e.g., with Patient Monitoring Systems, Patient Data Management Systems, PG/PSG Systems or Ventilators) that were developed for the tCOM+ predecessor device, the Sentec Digital Monitor.

Please refer to https://www.sentec.com/transcutaneous-connectivity-overview/ for more information on Interface Options for the tCOM+.

6.1.4 Analog Output

The Analog Output of the tCOM+ provides up to four analog voltage outputs for PCO_2, PO_2, SpO_2, PR, and the Pleth Waveform. The Analog Output is located on the rear panel of the tCOM+.

Characteristics: 0 – 1 V.

Configuration: Channel assignment is configurable in menu ´Advanced Settings´ - ´Interfaces´ - ´Analog / PSG´.

6.1.4.1 Interfacing the tCOM+ with a polygraphic or polysomnographic system

Various ready-made adapter cables are available to interface the tCOM+ with the most common polygraphic (PG) and polysomnographic (PSG) systems: see the PSG Adapter

cables Product Information on https://www.sentec.com/transcutaneous-connectivity-overview/ [2].

To interface the tCOM+ with a polygraphic or polysomnographic system, select the appropriate cable from the connectivity overview on Sentec´s webpage and then perform the following steps:

1. Connect the PSG Adapter Cable to the tCOM+ Analog Output Port
2. Connect the free end(s) of the PSG Adapter Cable to the PG-/PSG-System.
3. On the tCOM+, select the desired parameter(s) and parameter ranges that are assigned to the 0 to 1 Volt output range in the password-protected menu ´Advanced Settings´ - ´Interfaces´ - ´Analog / PSG´ - 'Channel Assignment'. If necessary, adjust the ranges.

Note: The voltage differential varies proportionally from 0 to 1 volt as the pin´s parameter varies over the selected parameter range. The output voltage for a parameter is 0 Volt if its current reading is lower than the lower end of the selected parameter range and 1 Volt if it is larger than the upper end of the selected parameter range, respectively. Ensure that the selected range will comprise all values expected for each parameter.

Examples:

a) PCO_2 Range = 0 - 100 mmHg (default): 0.3 Volt will be output for a reading of 30 mmHg, 0.7 Volt for a reading of 70 mmHg, and 1 Volt for all readings equal or greater than 100 mmHg.

b) SpO_2 Range = 50-100 mmHg (default). 0 Volt will be output for all readings smaller or equal to 50%, 0.5 Volt for a reading of 75%, and 1 Volt for a reading of 100%.

4. Verify that on the PG-/PSG-System the same parameter ranges are selected as on the tCOM+. If necessary, adjust the ranges on the PG-/PSG-System.

5. Calibrate the PG-/PSG-System attached to the analog output of the tCOM+ by using the menu-function ´Calibrate Channels´ within ´Advanced Settings´ - ´Interfaces´ - ´Analog / PSG´.

Note: The menu function ´Calibrate Channels´ will cause the output of 1 Volt for all parameters for 60 seconds, followed by the output of 0 Volt for another 60 seconds. When the calibration sequence is running, the current output voltage is indicated on the display.

Note: By pressing 'Confirm Voltage' it is possible to change from 1 Volt to 0 Volt (if output of 1 Volt is active) or to stop the calibration sequence (if output of 0 Volt is active).

6. Test the Analog Output function. Ensure that the readings displayed on the tCOM+ are properly duplicated on the attached PG-/PSG-System.

Note: Due to the limited resolution of digital-to-analog conversion of the tCOM+'s analog output, the readings duplicated on the attached instrument and those displayed on the tCOM+ may not be identical. The smaller the parameter range that is assigned to the 0–1-Volt output range, the better the resolution and, hence, the better the readings duplicated on the attached instrument match the readings displayed on the tCOM+ (and vice versa).

[2] Not available in all markets.

⚠ **WARNING:** Ensure to properly calibrate the instrument (PG-/PSG-System) attached to the tCOM+'s analog output at initial setup and, thereafter, at least monthly.

⚠ **WARNING:** Verify proper function of the analog output signals before each application.

⚠ **WARNING:** The analog output signals do not contain any alarm or system status related information.

6.1.5 DATA/SERVICE USB Port

The DATA/SERVICE USB Port of the tCOM+ is used for SW upgrades or data downloads through connecting a USB type-C flash drive. The DATA/SERVICE USB Port is located on the left side of the tCOM+.

❗ **CAUTION:** Only connect USB sticks to the DATA/SERVICE USB port. Do not connect any consumer products (e.g., charging units) to this port.

6.1.6 Isolated Connectivity Port

The Isolated Connectivity Port of the tCOM+ may be used to connect other devices in the future. It is currently not in use. The Isolated Connectivity Port is located on the rear panel of the tCOM+.

⚠ **WARNING:** Do not connect any consumer products (e.g., charging units) to this port.

6.2 Wireless Communication

❗ **CAUTION:** This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

6.2.1 Wi-Fi

The tCOM+ provides a Wi-Fi interface to connect to external networks and is used to communicate with external computer-based data collection systems. Stored data and configuration parameters can be read out. Wi-Fi can be configured within a password-protected area upon tapping on the ´Interfaces´ icon.
The Wi-Fi interface provides an 802.11 a/b/g/n/ac Wi-Fi with data rates up to 433.3 Mbps.
The Wi-Fi interface can connect to 2.4 GHz and 5 GHz networks with standard encryption methods WEP/WPA/TKIP/WPA2 AES-CCMP.
Characteristics: TCP/IP, ports 68 and 62768 required.

Recommendations for setting up a Wi-Fi network

The tCOM+ has been tested in simulated environments to ensure that the wireless communication interface works as required in the intended use environment. Nevertheless, as wireless communication environments highly depend on the amount and characteristics of other intended and unintended radiators in the same vicinity (e.g., cellular telephones, pager, NFC or other transmitters), the real performance of the wireless interface in the specific environment may vary. If a reliable communication is required prefer a wired connection to a wireless connection.
The following settings are recommended when the tCOM+ is included in a wireless network:

- Use dedicated Wi-Fi channel, ensure enough separation of adjacent channels
- Avoid disturbers in the same or adjacent Wi-Fi channel

- Use state-of-the-art Wi-Fi encryption
- Always consult your hospital's IT officer before integrating any device in the network

In case of communication problems, please consult your hospital's IT officer.

U.S.A.: FCC

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: Changes or modifications made to this equipment not expressly approved by Sentec may void the FCC authorization to operate this equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Radiation Exposure Statement

The product complies with the US mobile RF exposure limit set forth for an uncontrolled environment and is safe for intended operation as described in this manual. The further RF exposure reduction can be achieved if the product can be kept as far as possible from the user body or set the device to lower output power if such function is available.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

Canada: Innovation, Science and Economic Development Canada (ISED)

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:
(1) This device may not cause interference
(2) This device must accept any interference, including interference that may cause undesired operation of the device.

Canada: Radiation Exposure Statement

This equipment complies with Canada radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 centimeters between the radiator & your body.

Japan: Radio Law
This device is granted approval pursuant to the Japanese Radio Law. This device should not be modified (otherwise the granted designation number will become invalid).

European Union
This device is a 2.4 GHz wideband transmission system (transceiver), intended for use in all EU member states and EFTA countries, except in France and Italy where restrictive use applies.

In Italy, the end-user should apply for a license at the national spectrum authorities to obtain authorization to use the device for setting up outdoor radio links and/or for supplying public access to telecommunications and/or network services.
This device may not be used for setting up outdoor radio links in France and in some areas the RF output power may be limited to 10 mW EIRP in the frequency range of 2454 – 2483.5 MHz. For detailed information, the end-user should contact the national spectrum authority in France.

6.3 Cybersecurity

Network connections potentially expose medical devices to threats from many sources – not just through a local router or server in a hospital or medical office, but from any computer, tablet or smart phone connected to the Internet anywhere in the world. As a result, cybersecurity is deemed to be a shared responsibility.

Sentec is committed to a holistic risk sharing approach and conducts extensive cybersecurity risk management.

Sentec secures the tCOM+ with state-of-the-art cybersecurity measures such as a firewall, VPN, and encrypted communication.

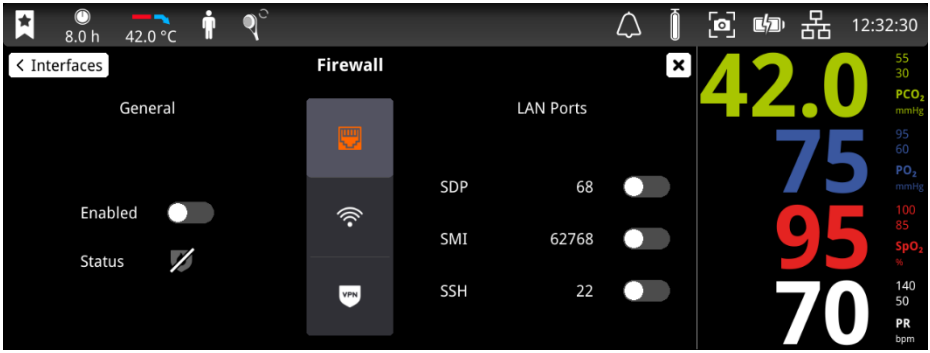
In addition, security related incidents are displayed to the user by the tCOM+ monitor as technical alarms and are logged.

In case that there is a concern that an external party is trying to connect to or interfere with the monitor, stop using the tCOM+ and contact the local Sentec representative immediately.

6.3.1.1 Firewall

Per factory default, all network interfaces of the tCOM+ are protected by a firewall and no service is accessible. A connection through LAN, Wi-Fi or VPN is only possible after configuration of the Firewall settings.

The Firewall settings can be configured in the password-protected menu via the ´Advanced Settings´ - ´Interfaces´ - ´Firewall´.



Within the Firewall menu, the Firewall can be entirely disabled to allow all traffic for LAN and Wi-Fi (e.g., for legacy connectivity applications). Furthermore, single ports in the firewall can be opened individually for LAN, Wi-Fi, and VPN to give access to the available services of the tCOM+, such as Sentec Discovery Protocol (SDP), Sentec Monitor Interface (SMI) or SSH (only available for Sentec-Service).

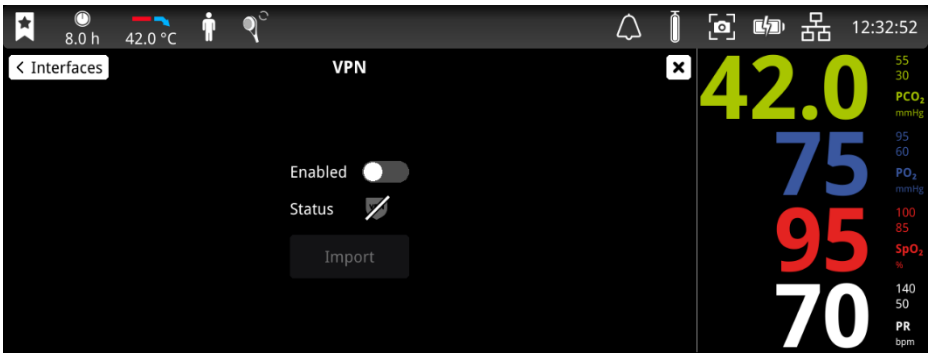
6.3.1.2 VPN

A VPN creates a secure encrypted connection between the tCOM+ and a single computer or a network.

The VPN security model provides:

- confidentiality by encrypting data to ensure that even if the network traffic is sniffed at the packet level, an attacker cannot access raw data
- sender authentication to prevent unauthorized users from accessing the VPN
- message integrity to detect and reject any instances of tampering with transmitted messages

The VPN settings can be configured in a password-protected area, which is accessible via: ´Advanced Settings´- ´Interfaces´ - ´VPN´.



In this menu, a VPN configuration (OpenVPN config file) can be imported to the tCOM+ by clicking the “Import” function and selecting a configuration file on the attached flash drive. After the successful import, a VPN connection can be established from the device by activating the “Enabled“ toggle. Refer to https://openvpn.net/ for more information, documentation, and examples.

Note: The tCOM+ can only act as a VPN client.

6.3.1.3 Encrypted communication

To secure interfaces where no VPN technology is applicable, such as the Serial Data Port (RS-232), and to offer more flexibility for connectivity solutions, Sentec also supports the encryption of the Sentec Monitor Interface (SMI) directly with the authenticated encryption and hashing algorithms “ASCON”.

Encrypted communication can be configured in the via the ´Advanced Settings´ - ´Interface´ - ´Encryption´.

In the Encryption menu, encryption for UDP and Serial can be enabled or disabled individually. Per default, encryption is enabled.

Furthermore, an Encryption Key and a Nonce can be configured. These settings must be configured with the same settings within the connected medical device to allow decryption of messages sent and received.

6.4 Connections to IT networks

Connecting the tCOM+ to a network that incorporates other devices or making subsequent changes to that network can lead to new risks for patients, users, and third parties. Prior to connecting the monitor to the network or the network is changed, these risks must be identified, analyzed, and evaluated by the hospital's IT officer according to the standard IEC 80001-1, “Risk management for IT networks with medical devices”. Based on the results, appropriate measures must be taken.

Examples of subsequent changes to the network include but are not limited to: changing the network configuration, adding new devices to the network, removing devices from the network, or performing upgrades or updates on devices that are connected to the network.

7 Minimum hardware and software requirements

The tCOM+ is a standalone device and there are no hardware or software requirements for operation of the monitor.

8 System access

The tCOM+ provides two levels of access: Operator and Responsible Organization (RO). The RO (usually, the IT officer) must set a secure password (containing 4-16 characters) during the initial guided setup of the tCOM+ and store it securely. Within the 'Advanced Settings', the RO can edit passwords as well as various settings (date and time, pressure unit, LED brightness, interfaces). Furthermore, the RO can configure and edit profiles. Profiles allow configuration of safety relevant options such as the possibility to deactivate alarms. Within a profile, the maximum 'Sensor Temperature' or the maximum 'Site Time' selectable at the bedside, for example, can be adapted to settings, which are safe for the organization´s typical patients.

Operators will only have the possibility to access the monitor settings specified by the Responsible Organization.

9 Specifications

9.1 tCOM+

Physical Characteristics

- Weight: 2.5 kg (5.5 lbs)
- Battery: 230 g (0.5 lbs)
- Gas bottle: 57 g (0.1 lbs)

Size (height x width x depth): 15.3 cm x 27.8 cm x 16.2 cm (6.02" x 10.95" x 6.38")
Ingress Protection: IPx2 (protection against dripping water when tilted at 15°)
Carrying: Foldable handle to carry the monitor
Mounting: Mountable on 75x75 VESA compatible roll/ infusion stands, wall mounts/ railings, transport incubators, etc.
Tilting: Optional feet to add on the VESA mounting points to adjust angle for improved table-top viewing (screen perpendicular to the standing surface)
Cable storage: Optional cable holder can be attached on the right or left rear side of the monitor to stow cable during transport or storage.

Electrical

Monitor: 12 VDC Power, max. 3 A, by external power supply
Power supply for hospital use: Class II FE (with functional earth), Electrical Safety (IEC 60601-1)
Power supply for home use: Class II (without functional earth), Electrical Safety (IEC 60601-1)
Type BF, Applied Part, Defibrillation Proof.
Internal battery type: rechargeable, sealed Li Ion Battery /
Capacity (new fully charged battery): up to 4 hours (if Sleep Mode=OFF)
Charging Time: approx. 4 hours

Environmental

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

Transport/ storage humidity: 10 to 90% non-condensing
Operating temperature: +5 to +40 °C (41 to 104 °F)
Operating humidity: 15 to 90% non-condensing
Operating altitude: -400 to 5000 m (-1300 – 16404 ft)
Built-in barometer: Range: 350-820 mmHg (47-109 kPa) /
Accuracy: ± 3 mmHg (0.4 kPa)

9.2 $tcPCO_2$

Measurement range	0 – 200 mmHg (0 – 26.7 kPa)
Resolution	0.1 mmHg (0.01 kPa) below 100 mmHg (10 kPa) / 1 mmHg (0.1 kPa) above 100 mmHg (10 kPa)
Drift	Typically < 0.5%/hour
Response time (T90)	Typically < 75 sec
Linearity	Typically < 1 mmHg (0.13 kPa)
Interferences by anesthetic gases	Negligible
Stabilization/ artifact detection	After sensor application or occurrence of a $tcPCO_2$ artifact, $tcPCO_2$ is displayed in grey until it (re)stabilizes.
Non-linearity/ hysteresis	+/- 5 mmHg in the range of 0 mmHg – 60 mmHg*

*Essential Performance according to IEC 60601-1

9.3 $tcPO_2$

Measurement range	0 – 800 mmHg (0 – 106.7 kPa)
Resolution	1 mmHg (0.1 kPa)
Drift	Typically < 0.1%/hour
Response time (T90)	Typically < 150 sec
Linearity	Typically < 1 mmHg (0.13 kPa)
Interferences by anesthetic gases	Negligible
Stabilization/ artifact detection	After sensor application or occurrence of a $tcPO_2$ artifact, $tcPO_2$ is displayed in grey until it (re)stabilizes.
Non-linearity/ hysteresis	+/- 5 mmHg in the range of 0 mmHg – 160 mmHg*
$tcPO_2$ LED characteristics	Wavelengths: green-cyan colored Energy: < 5 mW **Note:** This information may be especially useful to clinicians.

*Essential Performance according to IEC 60601-1

9.4 Pulse Oximetry

9.4.1 Oxygen Saturation (SpO_2)

Approved sites for SpO_2/PR monitoring with Sentec TC sensors	Earlobe, low on forehead, cheek, upper arm, scapula (shoulder blade)
Measurement range	1 – 100%
Resolution	1%

Accuracy
(A_{RMS} over 70 to 100% range; all above specified sites)

V-Sign™ Sensor 2	2%*
OxiVenT™ Sensor	2.25%*
SpO2 LED characteristics	Wavelengths: 660 nm, 870-900 nm Energy: < 15 mW **Note:** This information may be especially useful to clinicians.

*Essential Performance according to IEC 60601-1

Note: The SDMS measures functional oxygen saturation.
Note: The plethysmography waveform is normalized in amplitude.
Note: SpO_2 accuracy specification is based on controlled hypoxia studies on healthy, adult volunteers over the specified saturation range by applying a defined sensor type to the specified measurement sites. Pulse oximeter SpO_2 readings were compared to SaO_2 values of blood samples measured by hemoximetry. SpO_2 accuracy is expressed as Arms (root-mean-square). The indicated variation equals plus or minus one standard deviation (1SD), which encompasses 68% of the population.
Note: A functional tester cannot be used to assess the SpO_2 accuracy.

9.4.2 Pulse Rate (PR)

Measurement range	30 – 250 bpm (beats per minute)
Resolution	1 bpm
Accuracy	± 3 bpm

Note: PR accuracy was determined using a Pulse Oximeter Simulator (optical simulator for bench tests).

9.4.3 Function Test SpO_2 + PR

Apply the sensor to the earlobe of a healthy person: Compare SpO_2 and PR readings against the readings of a reference pulse oximeter (e.g., N595 with Durasensor 100 from Nellcor). The SpO_2 and PR reading should be within ± 3% SpO_2 and ± 3 bpm, respectively.

9.4.4 A_{RMS} values using Sentec TC Sensors

The following table shows A_{RMS} values measured using the V-Sign™ Sensor 2 with the tCOM+, whereas SpO_2 accuracy is expressed as A_{RMS} (root-mean-square):

A_{RMS} in SpO_2 Ranges	70 – 100%	70 – 80%	80 – 90%	90 – 100%
Earlobe	1.87	2.20	1.86	1.57
Forehead	1.82	1.95	1.62	1.90
Cheek	1.92	2.42	1.88	1.32
Upper arm	1.38	1.84	1.03	1.03
Shoulder blade	1.91	1.57	1.33	1.11
Average over all sites	**1.83**	2.29	1.60	1.49

The table below shows A_{RMS} values measured using the OxiVenT™ Sensor with the tCOM+, whereas SpO_2 accuracy is expressed as A_{RMS} (root-mean-square):

A_{RMS} in SpO_2 Ranges	70 – 100%	70 – 80%	80 – 90%	90 – 100%
Earlobe	2.44	2.99	2.23	1.76
Forehead	1.35	1.54	1.32	1.22
Cheek	1.29	1.43	1.38	1.11
Upper arm	2.41	2.85	2.34	2.05
Shoulder blade	2.13	2.73	2.04	1.19
Average over all sites	**1.95**	2.35	1.88	1.48

9.5 Power Supply

CAUTION: tCOM+ may only be used with the authorized external power supply, as indicated in the table below:

	Type	Electrical appliance	Environment
Power supply	GlobTek GTM96300-3614.5-2.5-R3A Output Rating: $12V_{DC}$ / 36W	Class II with functional earth connection	Hospital Use
Adapter Europe	GlobTek R-EU-3(R)		
Adapter North America	GlobTek R-NA-3(R)		
Adapter UK	GlobTek R-UK-3(R)		
Adapter Australia/NZ	GlobTek R-SAA-3(R)		

	Type	Electrical appliance	Environment
Power supply	GlobTek GTM96300-3614.5-2.5-R2 Output Rating: $12V_{DC}$ / 36W	Class II without functional earth connection	Home Use
Adapter Europe	GlobTek R-EU-2(R)		
Adapter North America	GlobTek R-NA-2(R)		
Adapter UK	GlobTek R-UK-2(R)		
Adapter Australia/NZ	GlobTek R-SAA-2(R)		

A label on the power supply indicates the intended use environment by the marking "Hospital Use Only" / "Home Use Only".

9.6 Alarm System

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

Alarm Signal Generation Delay

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

Alarm Condition Delays for physiological alarm conditions

Whenever one of the monitor's physiological parameters (PCO_2, PO_2, SpO_2, PR) violates its upper/lower alarm limit, the tCOM+ detects an alarm condition for the respective parameter. As summarized in the following table, delays for physiological alarm conditions therefore depend on the respective parameter's response time:

Alarm Condition Delays for physiological alarm conditions

Physiological Alarm Condition	Factors influencing corresponding parameter's response time at a specific measurement site	Typical Alarm Condition Delay
PCO_2 low/high alarm	The response to changes in the carbon dioxide pressure in the skin at a specific measurement site depends on the selected sensor temperature and on the sensor's in-vitro PCO_2 response. The slower the sensor's in-vitro PCO_2 response, the longer the PCO_2 alarm condition delay. **Note:** The indicated alarm condition delay corresponds to the time required to display a 10% to 90% response to a step change in either direction between a test gas containing 5% and 10% CO_2. **Note:** If the tCOM+ detects that the sensor's in-vitro PCO_2 response is slow, the Status Message 'PCO_2 slow' is displayed and PCO_2 values are subsequently marked as questionable. **Note:** If 'SP11: Calibration Failed (PCO_2 too slow) occurs, a low priority alarm sounds, the Status Message 'Sensor Problem 11: Calibration Failed' appears and sensor calibration is inhibited/aborted. PCO_2 values are subsequently marked as invalid.	< 75 sec (V-Sign™ Sensor 2) < 80 sec (OxiVenT™ Sensor) 120 sec (if Status Message 'PCO_2 slow' is displayed) 120 sec (if Status Message 'Check Application' is displayed in Enforce-Sensor-On-Patient Mode)
PO_2 low/high alarm	The response to changes in the oxygen pressure in the skin at a specific measurement site depends on the selected sensor temperature and on the sensor's in-vitro PO_2 response. The slower the sensor's in-vitro PO_2 response, the longer the PO_2 alarm condition delay. **Note:** The indicated alarm condition delay corresponds to the time required to display a 10% to 90% response to a step change in either direction between a test gas containing 6% and 12% O_2. **Note:** If 'Sensor problem 74' (PO_2 too slow) occurs, a low priority alarm sounds, the Status Message 'Sensor problem 74: PO_2 Calibration Failed' is	< 150 sec (OxiVenT™ Sensor)

Physiological Alarm Condition	Factors influencing corresponding parameter's response time at a specific measurement site	Typical Alarm Condition Delay
	displayed and sensor calibration is inhibited/aborted. PO_2 values are subsequently marked as invalid.	
SpO_2 low/high alarm	The response to changes in oxygen saturation of the arterial blood present at a specific measurement site depends on the menu item 'SpO_2 Averaging' (profile setting adjusted by responsible organization in the password-protected area). The longer the averaging time, the slower the monitor's response to changes in saturation and, hence, the longer the SpO_2 alarm condition delay, e.g., to detect desaturations.	Typically 5 sec, but < 10 sec (if 'SpO_2 Averaging' = 2 sec) Typically 32 sec, but < 40 sec (if 'SpO_2 Averaging' = 32 sec) < 30 sec (if Status Message 'Low SpO_2 signal quality' is displayed in Enforce-Sensor-On-Patient Mode)
PR low/high alarm	The response to changes in the pulse rate at a specific measurement site is determined by the PR averaging time, which is set to 10 seconds.	Typically 10 sec, but < 20 sec

Note: The response of transcutaneous PCO_2/PO_2 and SpO_2 measurements to respiratory events such as hyper-/ hypoventilation or apnea depend on the blood circulation time from the pulmonary alveoli to a specific measurement site, i.e., on the distance between the pulmonary alveoli to a specific measurement site and the blood flow/velocity. In patients with poor peripheral perfusion, the blood perfusion time between the pulmonary alveoli and the finger or toe is one to two minutes longer than between the pulmonary alveoli and central sites such as the forehead, cheek or earlobe.

Note: If PCO_2 and PO_2 is activated in the selected profile the connected V-Sign™ Sensor or OxiVenT™ Sensor needs to be calibrated after startup to measure PCO_2 and/or PO_2. The low priority alarm message 'Calibrate sensor' is displayed as long as the sensor in not calibrated successfully and associated physiological alarms (PCO_2 high/low, PO_2 high low) are inactive.

Note: The monitor's data update period for physiological parameters (PCO_2, PO_2, SpO_2, PR) is 1 sec and cannot be changed by the operator. The response time of physiological parameters and, hence, the alarm condition delay of physiological alarm conditions does not depend on the data update period.

Alarm Condition Delays for technical alarm conditions

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

Alarm Condition Delays > 5 sec for technical alarm conditions

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

Position of user relative to alarm system

The alarm system is designed so that a user can recognize physiological and technical alarm states from a distance of 4 m (color/behavior of LED bar and display) and determine a specific alarm message from a distance of 1 m.

The specified values for the alarm volume apply to a distance of 1 m.

Sound levels
Typical sound levels of acoustic alarm signals are:

	'Alarm Volume'=6 (high)	'Alarm Volume'=1 (low)
High Priority Alarm [dBA]	69.9	45.5
Medium Priority Alarm [dBA]	67.5	43.5
Low Priority Alarm [dBA]	62.5	38.6

9.7 Sensors

Safety
Sensor LED light output falls within Class 1 level, according EN 60825-1:2001. No special safety precautions are required.

Electrical safety
Degree of protection against harmful ingress of water is IPX7, i.e., protection against harmful ingress of water after temporary immersion.

Surface temperature
The temperature of the sensor as well as the maximum sensor temperature is measured according to IEC 60601-2-23, section Foam Block Test.

10 Packaging & packaging damage

Do not use the device if:

- the packaging or sealing label on the monitor are damaged or appear to have been tampered with,
- the packaging has been exposed to environmental conditions outside of those specified for the monitor.

In such a case, return the tCOM+ to Sentec.

Items must be shipped in the original packaging or in other packaging providing the same degree of protection.

11 Waste disposal

The SDMS is manufactured with material compliant with the Restriction of certain Hazardous Substances (RoHS). It contains electronic printed circuit boards, a display, cables, and lithium batteries.

Do not incinerate equipment or gas bottles.

Note: 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 of 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.

tCOM+
Return the tCOM+ to your local Sentec representative or dispose of it according to local regulations. Use original packaging or other packaging providing the same degree of protection for shipping.

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

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

Sentec Transcutaneous Sensors
Return the Sentec Transcutaneous Sensors to your local distributor.

Calibration Gas Bottle
Dispose empty gas bottles according to local waste disposal regulations. Make sure to only dispose empty bottles.

Gas may be discharged from the container as follows:

Ensure that the container is securely positioned. Then, open the container valve **slowly** to permit gas discharge at an appropriate rate.

CAUTION: Environmental contamination due to waste products and/or medical device disposal. Dispose of Calibration Gas bottle according to local regulations.

WARNING: Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material.

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

Consumables
All material used is considered “non-critical”. The consumables may be disposed of in the regular garbage.

12 Incident Reporting

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

12.1 Cybersecurity Vulnerability and Incident Reporting

If a cybersecurity incident has occurred or you have detected a cybersecurity vulnerability in our product(s), please report it to us using the dedicated link on Sentec's website: https://www.sentec.com/quality/. The presented "Link to Vulnerability Reporting" will direct you to the MedISAO (Information Sharing and Analysis Organization) portal, which collects vulnerability data of Sentec products. You may also report cybersecurity incidents or cybersecurity vulnerabilities directly to Sentec using the e-mail address:

regulatory@sentec.com

13 Appendix

13.1 Abbreviations

AHP	Absolute Heating Power
CO_2	Carbon dioxide
DS	Docking Station (calibration unit integrated in the tCOM+)
HP	Heating Power
LED	Light emitting diode
MRI	Magnetic Resonance Imaging
O_2	Oxygen
$PaCO_2$	Arterial carbon dioxide partial pressure
PaO_2	Arterial oxygen partial pressure
$PcCO_2$	Cutaneous carbon dioxide partial pressure (i.e., the CO_2 partial pressure at the skin surface)
PCO_2	Used to display/label $tcPCO_2$ on the tCOM+ and – unless explicitely stated otherwise – throughout this manual
PcO_2	Cutaneous oxygen partial pressure (i.e., the O_2 partial pressure at the skin surface)
PI	Pulsation Index
PO_2	Used to display/label $tcPO_2$ on the tCOM+ and – unless explicitely stated otherwise - throughout this manual
POST	Power-On Self-Test
RO	Responsible Organization
PR	Pulse rate
RHP	Relative Heating Power
RMI	Remote monitoring interrupted
SaO_2	Arterial oxygen saturation
tCOM+	Sentec Patient Monitor
SDMS	Sentec Digital Monitoring System
SpO_2	Functional oxygen saturation of arterial hemoglobin as measured with a pulse oximeter
TC	Transcutaneous
tCOM+	Transcutaneous carbon dioxide and oxygen monitor
$tcPCO_2$	Transcutaneous carbon dioxide partial pressure, i.e., an estimate of $PaCO_2$ calculated from the measured $PcCO_2$ and displayed/labeled on the tCOM+ and - unless explicitly stated otherwise - throughout this manual as 'PCO_2'
$tcPO_2$	Transcutaneous oxygen partial pressure, i.e., an estimate of PaO_2 calculated from the measured PcO_2 and displayed/labeled on the tCOM+ and - unless explicitly stated otherwise - throughout this manual as 'PO_2'

13.2 List of Components

The Sentec Digital Monitoring System comprises the following components:

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental/ Storage conditions
103164	tCOM+	Stand-alone patient monitor.	The Sentec patient monitor, model tCOM+, is a portable stand-alone patient monitor indicated for continuous, non-invasive patient monitoring of carbon dioxide partial pressure (PCO_2), oxygen partial pressure (PO_2), functional oxygen saturation (SpO_2) and pulse rate (PR), using either: · a single, digital sensor (V-Sign™ Sensor 2) for PCO_2, SpO2 and PR measurement, OR · a single, digital sensor (OxiVenT™ Sensor) for PCO_2, PO_2, SpO_2 and PR measurement PO_2 measurement with tCOM+ is only possible when used in combination with an OxiVenT™ Sensor.	n/a	7 years	Yes	Transport/storage temperature: 0 – 50 °C Transport/storage humidity: 10 – 90% non-condensing Operating temperature: 5 – 40 °C Operating humidity: 15 – 90% non-condensing Operating altitude: -400 – 5000 m (-1300 – 16404 ft).

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental/ Storage conditions
VS-A/P/N	V-Sign™ Sensor 2	Digital carbon dioxide tension and oximetry sensor	The V-Sign™ Sensor 2, model VS-A/P/N, is indicated for use with the tCOM+ when continuous, non-invasive monitoring of $tcPCO_2$, SpO_2, and PR are required for adult and pediatric patients. In neonatal patients, the use of V-Sign™ Sensor 2 is indicated for $tcPCO_2$ monitoring only.	n/a	up to 36 months	Yes	Transport temperature: 0 – 50°C Long term storage temperature: 15 – 26°C Transport/ store sensor with membrane and protected from light/ radiation.
OV-A/P/N	OxiVenT™ Sensor	Digital carbon dioxide tension, oxygen tension and oximetry sensor	The OxiVenT™ Sensor, model OV-A/P/N, is indicated for use with the tCOM+ when continuous, non-invasive monitoring of $tcPCO_2$, and $tcPO_2$, as well as SpO_2, and PR monitoring are required for adult and pediatric patients. In neonatal patients, the use of OxiVenT™ Sensor is indicated for $tcPCO_2$ and $tcPO_2$ monitoring only. $tcPO_2$ monitoring is contraindicated for patients under gas anesthesia.	n/a	12 months	Yes	Transport temperature: 0 – 50°C Long term storage temperature: 15 – 26°C Transport/ store sensor with membrane and protected from light/ radiation.

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental/ Storage conditions
103420 103421 103422	Sensor Adapter Cable	Adapter cable required to connect digital Sentec sensors to the tCOM+. It transfers the power needed to run the micro-/optoelectronic components (LEDs) and to heat the sensor. It furthermore transmits digitized data between the digital sensor and the tCOM+.	The Sensor Adapter Cable is required to connect digital Sentec sensors (V-Sign™ Sensor 2, OxiVenT™ Sensor) to the Sentec tCOM+.	Regular: 150 cm Long: 250 cm Extra Long: 750 cm	7 years	Yes	Transport/storage temperature: 0 – 50 °C Transport/storage humidity: 10 – 95%
V-STATS _CD	V-STATS	V-STATS: PC based download, data analysis, remote monitoring, and monitor management software.	V-STATS is an optional PC-based software, which is indicated for use with the monitor TCOM+ when remote monitoring and/ or trend reporting, and statistical analysis of data measured by the monitor is required. V-STATS is not intended to provide diagnosis; it is intended to supplement and not to replace any part of the monitoring procedures.	n/a	Not specified	Yes	Not specified

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental/ Storage conditions
EC-MI	Ear Clip	Single use sensor application Ear Clip, recommended for adult and pediatric patients with mature/intact skin	Sentec's Ear Clip, model EC-MI, is intended to attach the Sentec sensors to the earlobe of the patient, recommended for patients with mature/intact skin. The use of the Ear Clip is contraindicated for patients whose earlobes are too small to ensure adequate sensor application (e.g., neonates).	n/a	2 years	No. Reusing the Ear Clip may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 30 °C Humidity: 25% – 80%
MARe-MI	Multi-Site Attachment Ring Easy for mature/ intact skin	Single use sensor application ring, recommended for adult, pediatric and neonatal patients with mature/intact skin	Sentec's Multi-Site Attachment Rings, model MARe-MI, are intended to attach the Sentec sensors to conventional measurement sites, recommended for adult, pediatric and neonatal patients with mature/intact skin.	n/a	2 years	No. Reusing a MARe may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 30 °C Humidity: 25% – 80%

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental/ Storage conditions
MARe-SF	Multi-Site Attachment Ring Easy for sensitive /fragile skin	Single use sensor application ring, re-commended for adult, pediatric and neonatal patients with sensitive/ fragile skin	Sentec's Multi-Site Attachment Rings, model MARe-SF, are intended to attach the Sentec Sensors to conventional measurement sites, recommended for adult, pediatric and neonatal patients with sensitive/fragile skin.	n/a	1.5 years	No. Reusing a MARe may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 27 °C Humidity: 30% – 80%
103520	Non-Adhe-sive Wrap	Non-adhesive application ring, single-patient use up to 24 hours, recommended for preterm/neona tal patients.	Sentec's Non-Adhesive Wrap is intended to be wrapped around the thigh of neonatal patients with very sensitive/ - fragile skin for subsequent attachment of Sentec Sensors.	n/a	3 years	No Single-patient use up to 24 hours Reusing a Non-Adhesive Wrap may cause: Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10-30 °C Humidity: 30% – 80%

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental/ Storage conditions
SA-MAR	Staysite ™ Adhe-sive for Multi-Site Attach-ment Rings	Single-use adhesive for Multi-Site Attachment Rings (attaches complemen-tary the MARe-SF/ MARe-MI to the skin with an additional adhesive film)	Sentec's Staysite™ Adhesive for MAR, model SA-MAR, is an optional, single-use adhesive which is indicated for use with Multi-Site Attachment Rings, models MARe-MI, and MARe-SF, if more secure attachment is required. The use of the SA-MAR is **contraindicated** in case of: - injured or sensitive/fragile skin or on patients who exhibit allergic reactions to SA-MAR.	n/a	1.5 years	No. Reusing the SA-MAR may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 27 °C Humidity: 40% – 60%
MC	Mem-brane Changer	Membrane change tool, single-use	The Membrane Changer single-use (MC), the Membrane Changer reloadable (MC-R) and the Membrane Changer Insert (MC-I), serve as tools to change the elec-trolyte and membrane of the V-Sign™ Sensor 2 and the OxiVenT™ Sensor. The Membrane Changer reloadable (MC-R) can be reused by replacing its insert (MC-I).	n/a	2 years		Temperature: 10 – 30 °C Humidity: 10% – 95%
MC-R	Mem-brane Changer	Membrane change tool, reloadable				Yes, max. 10 times reloadable with MC-I.	

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental/ Storage conditions
MC-I	Membrane Changer Insert	Separately bagged, single-use inserts required to reload a Membrane Changer prior reuse.	MC, MC-R and MC-I are not intended for sterilization (e.g., by irradiation, steam, ethylene oxide or plasma method).			No. Reusing the MC-I may cause: - loss of functionality of the sensor and incorrect measurements	
103149	Calibration Gas	Calibration gas for Docking Station, cylinder of 0.2 l at 9.5 bar. Mixture of 8–vol % CO_2, 12-vol% O_2 and 80-vol% N_2	The Calibration Gas serves as calibration gas for the Sentec transcutaneous sensors that monitor $tcPCO_2$ and/or $tcPO_2$ (V-Sign™ Sensor 2 and OxiVenT™ Sensor). The Calibration Gas is for use only with the Docking Station integrated in the tCOM+.	n/a	15 months	Yes, for about two months after opening, depending on use scenarios and sensor condition. Do not use Calibration Gas if it is expired.	Temperature: 0 – 50 °C Humidity: not specified

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental/ Storage conditions
GEL-04	Contact Gel	Contact gel for Sentec transcutaneous sensors, bottle 5 mL	The Contact Gel, GEL-04 and GEL-SD, serves as contact gel to achieve proper gas conduction and heat transfer between the patient's skin and the Sentec transcutaneous sensors. Contact Gel makes direct patient contact (intact skin, prolonged exposure <30 days). Avoid contact with injured skin. Do not use on patients who exhibit allergic reactions.	5 mL	3 years	Yes. Do not use Contact Gel if it is expired, to avoid infections or potential allergic reactions.	Temperature: 10 – 30 °C Humidity: 10% – 95%
GEL-SD	Single Dose Contact Gel	Contact gel for Sentec transcutaneous sensors, single-dose vials of 0.3 g each		n/a	3 years	No. Do not use Contact Gel if it is expired, to avoid infections or potential allergic reactions. Reusing the GEL-SD may cause: - Re- and/or cross-infection	Temperature: 10 – 30 °C Humidity: 10% – 95%

Note: The components listed above do not necessarily correspond to the scope of delivery.

13.3 Interferences with other devices

13.3.1 Electromagnetic interferences

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

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

⚠ **WARNING:** Interference is possible when a sensitive device (ECG, EEG) is connected to the patient at the same time in home healthcare environments (due to class II power supply without functional earth).

Note: This device has been tested and found to comply with the requirements for medical devices according to IEC 60601-1-2, and the Medical Device Regulation (EU) 2017/745. These requirements are designed to provide reasonable protection against harmful interference in a typical medical installation.

Interference from interventional devices

The tCOM+ is protected against electrostatic/defibrillator discharge. Parameter display may be temporarily affected during discharge/defibrillation but will rapidly recover. Recovery time after electrostatic/defibrillator discharge: 30 sec (for SPO_2/PR); 60 sec (for TC values).

Note: Certain events may cause the monitor to prompt a calibration request. Precisely follow the instructions given in the defibrillator manual.

During electro-surgery the tCOM+, sensor and cables are to be physically separated from the electro-surgical equipment. The sensor must not be placed between the cutting and counter electrodes.

Radio equipment

❗ **CAUTION:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the tCOM+, including cables specified by the manufacturer. Wireless mobile devices must be held away from the system by at least 1 m (39.4 inches). Otherwise, degradation of the performance of this equipment and at worst, incorrect measurements could result.

⚠ **WARNING:** Avoid exposure to known sources of EMI (Electromagnetic Interference) such as Diathermy, Lithotripsy, Electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment, if possible, to maximize distances.

13.4 Means of Isolation (mains)

The electrical isolation of the tCOM+ is designed and tested during manufacturing process in accordance with IEC 60601-1. The following table provides an overview of the isolation barriers:

Isolation barrier	Isolation
External Power Supply	2 MOPP
Sensor interface	2 MOPP
Isolated Connectivity port	2 MOPP
Analog Output port	2 MOOP
Serial Data Port (RS-232)	2 MOOP
Ethernet port	1 MOOP

The sensor including cable and Sensor Adapter Cable is an applied part according to IEC 60601-1.

13.5 Glossary of Symbols

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

SYMBOL	NAME	DESCRIPTION OF SYMBOL
	Manufacturer	Indicates the medical device manufacturer.
	Date of Manufacture	Indicates the date when the medical device was manufactured.
	European Authorized Representative	Indicates name and address of authorized representative within the European Union
	UK Representative	Indicates name and address of authorized representative within the UK
	Importer	Indicates the entity importing the medical device into the locale.
	Use-by date	Indicates the date after which the medical device is not to be used.
	Period after opening	Identifies the useful lifetime of a product after its package has been opened for the first time (M=months).

SYMBOL	NAME	DESCRIPTION OF SYMBOL
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Keep away from sunlight	Indicates a medical device that needs to be protected from sunlight.
	Temperature limit "Storage" / "Transport"	Indicates the temperature limits to which the medical device can be safely stored or transported (upper and lower limits of temperature are indicated adjacent to the upper and lower horizontal lines).
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed (humidity limitation indicated adjacent to the upper and lower horizontal lines).
	Do not re-use (Single- use)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Single patient multiple use	Indicates that the medical device may be used multiple times (multiple procedures) on a single patient.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Mandatory action: Refer to instruction manual	Indicates that the instruction manual must be read in order to ensure safety.
	General warning sign	Read all warnings and precautions in instructions for use.
	WARNING	Indicates a WARNING in the accompanying documentation.

SYMBOL	NAME	DESCRIPTION OF SYMBOL
	Medical Device	Indicates that the product is a medical device according to the Medical Device Regulation MDR EU 2017/745.
	Prescription only	**CAUTION:** Federal Law (U.S.) restricts these devices to sale by or on the order of a physician.
	CAUTION	Indicates a CAUTION in the accompanying documentation.
	UL Label	Certifies that representative samples of the products have been investigated by UL in accordance with the referenced standards. The products have been found to comply with the requirements covering the category.
	Keep out of reach of children	Keep out of reach of children
	Do not swallow	Do not swallow Contact Gel.
	Avoid contact with eyes	Avoid contact with eyes
	WEEE Disposal	European consumers are obliged by law to dispose Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive 2002/96/EC: 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 of this are defined by the national law of the respective country.
	Defibrillation Proof Type BF	Degree of protection against electrical shock: Defibrillation-proof, Type BF applied part
IP	Ingress Protection	Degree of protection against harmful ingress of water
	Bluetooth	Device is equipped with Bluetooth functionality.
	RFID tag, general	To indicate the presence of the RFID tag incorporated within the packaging, container, or

SYMBOL	NAME	DESCRIPTION OF SYMBOL
		equipment without identifying the specific air interface or data structure employed.
	Non-flammable, non-toxic gases	Indicates gases which are neither flammable nor poisonous.
	Compressed gas GHS04	This GHS04 Compressed Gas Symbol Sign helps in the identification of containers and alert users of the chemical hazards to which they may be exposed.
	No open flame	To prohibit smoking and all forms of open flame.
	Atmospheric pressure limitation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Temperature limit	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported, or used.
	Battery	Indicates the presence of a battery
	Stand-by	Indicates the switch by means of which part of the equipment is switched on to bring it into the stand-by condition.
	Serial interface	To identify a connector for a serial data connection.
	Universal Serial Bus (USB)	Indicates a port or plug that meets the generic requirements of the Universal Serial Bus (USB).
	Power input	Indicates input voltage and current.
	Non-ionizing electromagnetic radiation	Indicates equipment that includes RF transmitters.
	RFID	Indicates the location of an RFID transmitter.
	CE Marking	Indicates that the product complies with the requirements of the relevant EU Directives and Regulations as outlined in the EU Declaration of Conformity. If applicable, the 4-digit Notified Body number is added near or below the CE symbol.

SYMBOL	NAME	DESCRIPTION OF SYMBOL
UK CA	UK Conformity Assessed	UK Conformity Assessed (UKCA) marking is a conformity mark that indicates conformity with the applicable requirements for products sold within Great Britain.
FCC ID XZZYYNNNNN	FCC (U.S.A.)	Indicates that the equipment has been FCC certified.
IC: XXXXXX-YYYYYYYYYY	ISED Label (Canada)	Indicates wireless certification in Canada.
R YYY-XXXXX	MIC certification (Japan)	Indicates market authorization for radio products in Japan.
R-NZ	ACMA (Australia) and MBIE (New Zealand) certification	Indicates certification by the Australian Communications and Media Authority (ACMA) as well as the New Zealand Ministry of Business, Innovation and Employment (MBIE). It equates to Australian and New Zealand market approval for manufacturers of wireless technology products.

13.6 User Interface icons

The following table provides an overview of the Status Bar icons, some of which are displayed by default, some may vary depending on status/connection. Tapping on these icons either opens a relevant menu or pop-up message (e.g., the sensor symbol opens the ´Sensor Maintenance´ screen, the battery symbol prompts a message containing power source and status information).

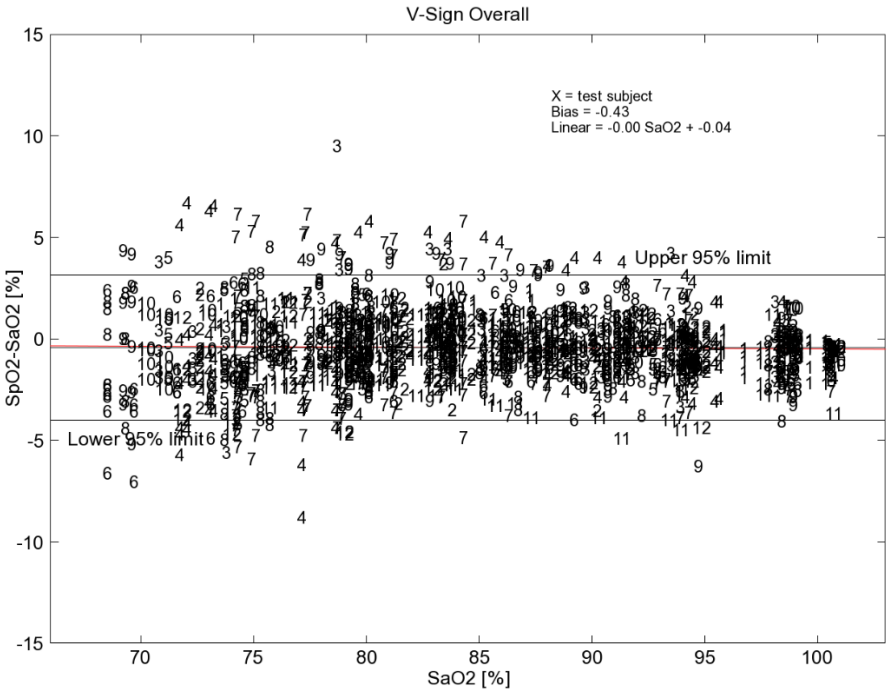
Icon	Icon Description
	Favorites
	Monitoring time - indicates the remaining measuring time (in h) Yellow inner part: sensor calibration is recommended or mandatory Yellow with cyan background: available monitoring time has elapsed
	Heating mode / Sensor Temperature – indicates the measured sensor temperature (°C) and the current setting of 'Initial Heating' and 'Site Protection'. 'Initial Heating' is marked with an initial yellow downward line. A red-blue downward arrow appears if 'Site Protection' is enabled, a red rightward arrow if it is disabled. The sensor temperature is marked blue if 'Site Protection' has reduced the sensor temperature and red if the temperature surveillance detected a sensor temperature-related problem.
	'Initial Heating' - on 'Site Protection' - off

	‘Initial Heating’ - off ‘Site Protection’ - off
	‘Initial Heating’ - off ‘Site Protection’ - on
	‘Initial Heating’ - on ‘Site Protection’ - on
	Patient type – Adult – tap for quick access to ‘Profile Selection’ menu
	Patient type – Neonate – tap for quick access to ‘Profile Selection’ menu
	Sensor maintenance – Membrane change Grey: membrane can be used for more than 3 days Yellow: membrane change is due in three days or less Yellow with cyan background: Membrane change required
	Sensor maintenance This menu allows the initiation of a sensor calibration, confirmation of a membrane change as well as performing a sensitivity test.
	Alarm – active and combined with associated error message
	Alarm – temporarily muted
	Alarm – permanently muted
	Gas level - indicates the remaining content of the gas bottle Tapping on the icon will prompt a pop-up message indicating the filling state in %. Yellow inner part: filling state 10% or less Cyan background: gas bottle empty
	Screenshot
	Battery – view battery status and capacity Cyan background: battery status low Yellow background: battery status critical

	connected to AC power, charging
	not connected, charged < 75 %
 	LAN connected /disconnected
 	Bluetooth connected/disconnected
	Wi-Fi connected/disconnected

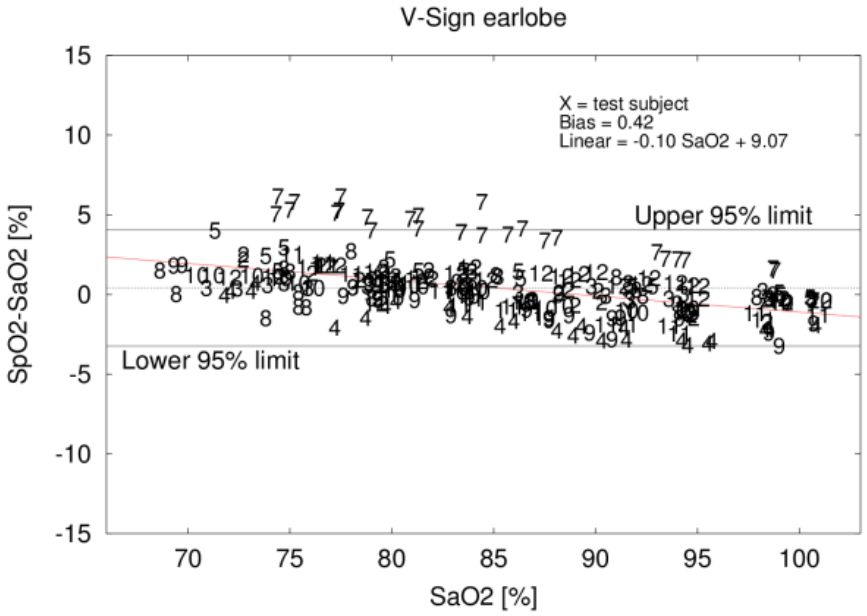
13.7 Detailed SpO_2 Accuracy Plots

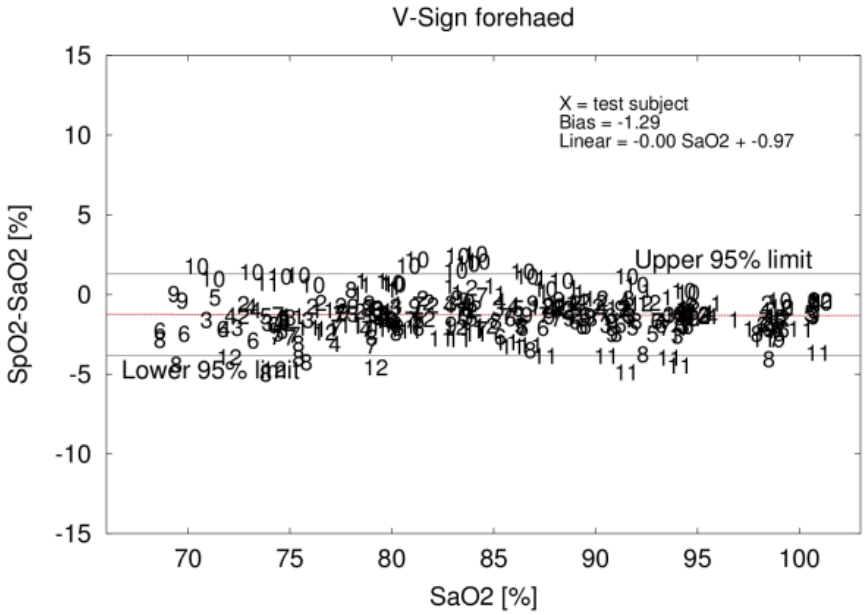
13.7.1 V-Sign™ Sensor 2

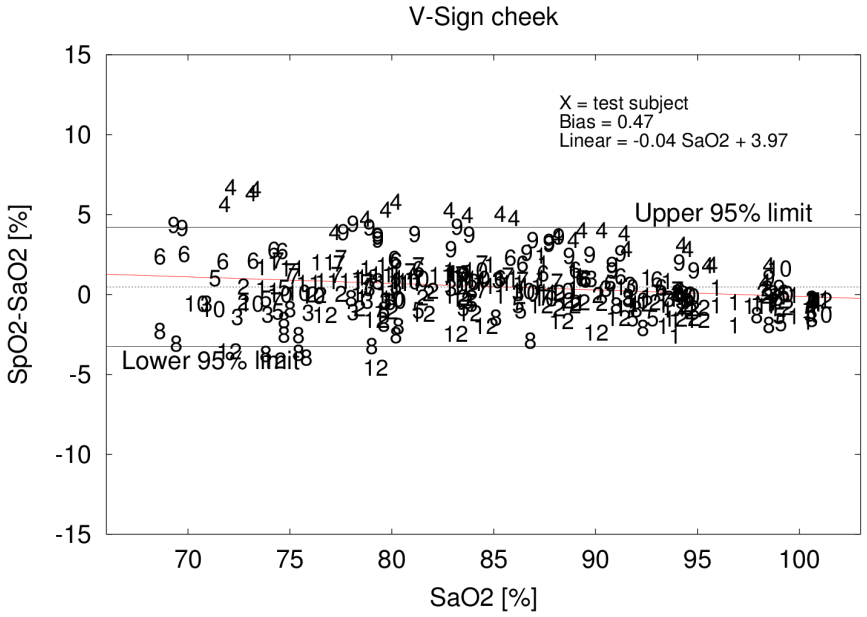


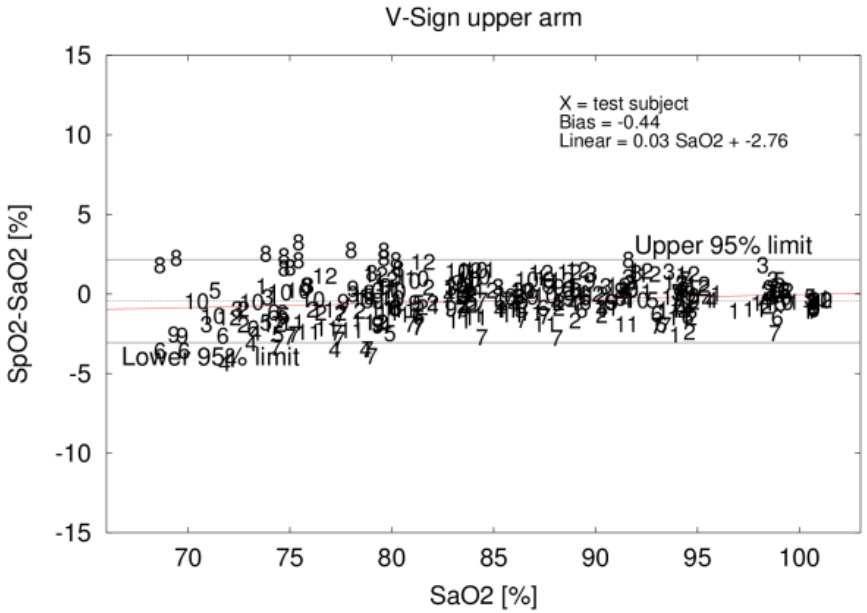
SpO_2 accuracy analysis for V-Sign™ Sensor 2: Data points are identified with the ID of each individual test subject. Data from 12 healthy volunteers (7 males/5 females) of different skin pigmentation (3 light, 4 light-medium, 2 medium, 3 dark) were included in the analysis. The subjects were between 23 and 29 years old.

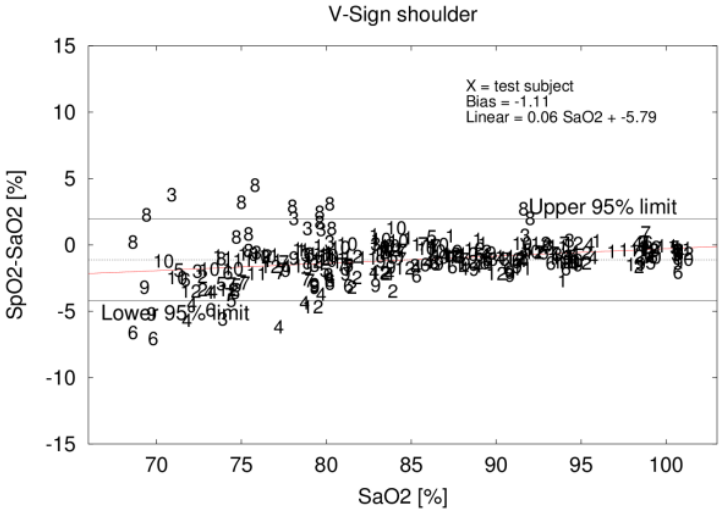
Detailed plots for SpO_2 accuracy of the V-Sign™ Sensor 2 per individual measuring site are given as follows:


V-Sign earlobe
X = test subject
Bias = 0.42
Linear = -0.10 SaO2 + 9.07
Upper 95% limit
Lower 95% limit
SpO2-SaO2 [%]
SaO2 [%]
15
10
5
0
-5
-10
-15
70
75
80
85
90
95
100

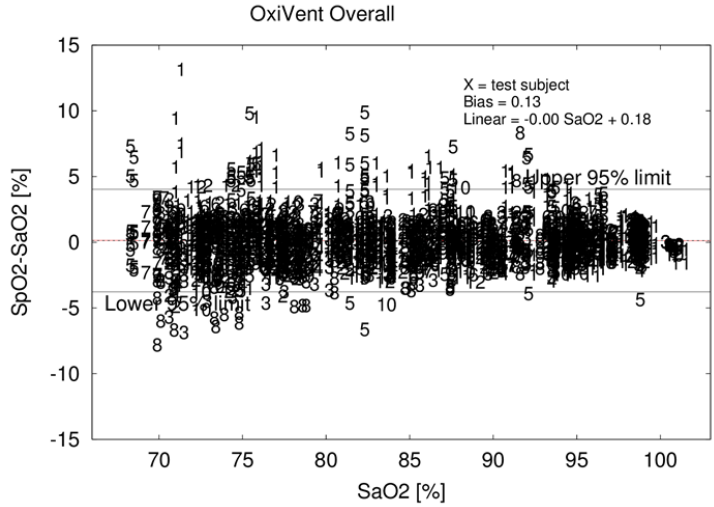

V-Sign forehaed
X = test subject
Bias = -1.29
Linear = -0.00 SaO2 + -0.97
Upper 95% limit
Lower 95% limit
SpO2-SaO2 [%]
SaO2 [%]
15
10
5
0
-5
-10
-15
70
75
80
85
90
95
100


V-Sign cheek
X = test subject
Bias = 0.47
Linear = -0.04 SaO2 + 3.97
Upper 95% limit
Lower 95% limit
SpO2-SaO2 [%]
SaO2 [%]
15
10
5
0
-5
-10
-15
70
75
80
85
90
95
100


V-Sign upper arm
X = test subject
Bias = -0.44
Linear = 0.03 SaO2 + -2.76
Upper 95% limit
Lower 95% limit
SpO2-SaO2 [%]
SaO2 [%]
15
10
5
0
-5
-10
-15
70
75
80
85
90
95
100

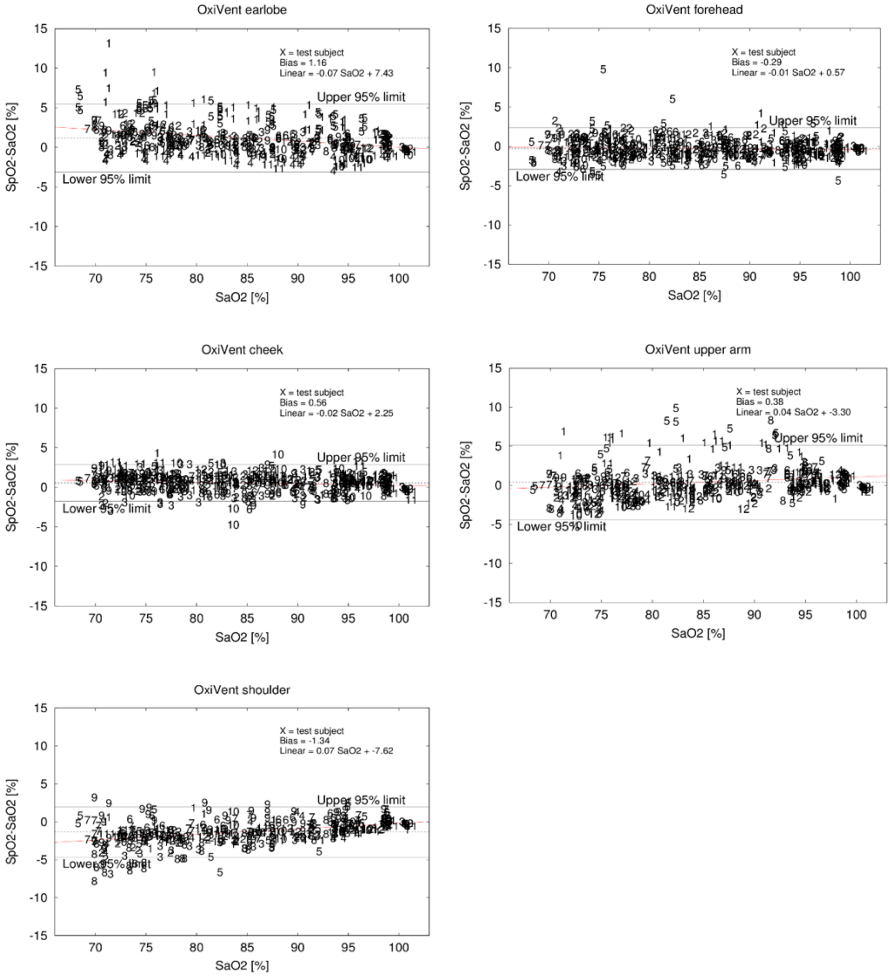


13.7.2 OxiVenT™ Sensor



SpO_2 accuracy analysis for OxiVenT™ Sensor: Data points are identified with the ID of each individual test subject. Data from 12 healthy volunteers (7 males/5 females) of different skin pigmentation (5 light, 5 medium, 2 dark) were included in the analysis. The subjects were between 23 and 34 years old.

Detailed plots for SpO_2 accuracy of the OxiVenT™ Sensor per individual measuring site are given below:



13.7.3 Pigmentation dependence of SpO_2

Sentec is aware that the current pulse oximeter technique based on two measuring wavelengths is affected by skin pigmentation within the absorption path. To review such potential effects in Sentec's own pulse oximeter devices, data from controlled desaturation studies were pooled and analyzed for racial bias. The data was split into three groups of volunteers: highly pigmented skin, low pigmented skin, and all skin types containing data of all subjects as reference group. From the Bland Altman plots, the bias, standard deviation was extracted, and root mean square error (Arms) was calculated for each group and application site. Across all approved application sites, a difference between low and high pigmentation of 0.7% was noted. On earlobe and upper arm, a larger difference of 2.29% and 1.23% were observed, respectively, while on three other sites almost no significant bias was present. Therefore, this bias cannot solely be explained by pigmentation only.

In conclusion, a small racial bias in pulse oximetry for certain application sites could be observed within this data set. Most of the deviations are within Sentec's claims of accuracy, however, and all deviations are within FDA's limits of accuracy.

13.8 Electromagnetic Compliance Declaration

⚠ **WARNING:** The use of accessories, sensors, and cables other than those specified by Sentec may result in increased emission and/or decreased immunity of the SDMS.

⚠ **WARNING:** Transient bursts from mains or data cables may temporarily interfere with the measurement.

13.8.1 Electromagnetic emissions

The SDMS is intended for use in the electromagnetic environment specified below. The customer or the user of the SDMS should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The SDMS uses RF energy intentionally for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A (in combination with Hospital Use Power Supply)	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. **Note:** The Home Use Power Supply provides appropriate emissions characteristics, please use such a power supply in residential environments.
RF emissions CISPR 11	Class B (in combination with Home Use Power Supply)	The tCOM+, in combination with the Home Use Power Supply, is suitable in all establishments, residential environments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	The tCOM+ is in both configurations suitable for all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

RF transmission frequencies and characteristics

Frequency band	Type / Characteristics	Effective Radiated Power
2.4 GHz Wi-Fi	IEEE 802.11 a/b/g/n/ac EU: 2.4 GHz to 2.483 GHz FCC/ISED: 2.4 GHz to 2.473 GHz MIC: 2.4 GHz to 2.495 GHz RCM: 2.4 GHz to 2.483 GHz	79.4 mW
5 GHz Wi-Fi	IEEE 802.11 a/b/g/n/ac EU: 5.15 GHz to 5.35 GHz (Ch 36/40/44/48/52/56/60/64) 5.47 GHz to 5.725 GHz (Ch 100/104/108/112/116/120/124/128/132/136/140) 5.725 GHz to 5.85 GHz (Ch 149/153/157/161/165) FCC: 5.15 GHz to 5.35 GHz (Ch 36/40/44/48/52/56/60/64) 5.47 GHz to 5.725 GHz (Ch 100/104/108/112/116/120/124/128/132/136/140/144) 5.725 GHz to 5.85 GHz (Ch 149/153/157/161/165) ISED: 5.15 GHz to 5.35 GHz (Ch 36/40/44/48/52/56/60/64) 5.47 GHz to 5.725 GHz (Ch 100/104/108/112/116/132/136/140/144) 5.725 GHz to 5.85 GHz (Ch 149/153/157/161/165) MIC: 5.15 GHz to 5.35 GHz (Ch 36/40/44/48/52/56/60/64) 5.47 GHz to 5.725 GHz (Ch 100/104/108/112/116/120/124/128/132/136/140) RCM: 5.15 GHz to 5.35 GHz (Ch 36/40/44/48/52/56/60/64) 5.47 GHz to 5.725 GHz (Ch 100/104/108/112/116/132/136/140) 5.725 GHz to 5.85 GHz (Ch 149/153/157/161/165)	200 mW
2.4 GHz Bluetooth	Bluetooth 5.2 2.4 GHz – 2.4835 GHz	7.9 mW
13.56 MHz NFC	ISO/IEC 15693	100 mW

13.8.2 Electromagnetic immunity

The SDMS is intended for use in the electromagnetic environments of hospital and home healthcare.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient (Bursts) IEC 61000-4-4	± 2 kV power supply lines ± 1 kV input/output lines	± 2 kV power supply lines ± 1 kV input/output lines	Mains power quality should be that of a typical hospital or home environment.
Surges IEC 61000-4-5	± 0.5 kV, ± 1 kV line-to-line ± 0.5 kV, ± 1 kV, ± 2 kV line to ground	± 0.5 kV, ± 1 kV line-to-line ± 0.5 kV, ± 1 kV, ± 2 kV line to ground	Mains power quality should be that of a typical hospital or home environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles at 0°	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles at 0°	Mains power quality should be that of a typical hospital or home environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Proximity magnetic fields IEC 61000-4-39	134.2 kHz, 65 A/m 13.56 MHz, 7.5 A/m Home Use only: 30 kHz, 8 A/m Time per step: 3 sec	134.2 kHz, 65 A/m 13.56 MHz, 7.5 A/m Home Use only: 30 kHz, 8 A/m Time per step: 3 sec	Mains power quality should be that of a typical hospital or home environment.
Power frequency (50/60) Hz magnetic fields IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment.
Portable and mobile RF communications equipment should be used no closer to any part of the SDMS, including cables, than the recommended separation distance d calculated from the equation applicable to the frequency of the transmitter.			

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	V = 3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur bands between 0.15 MHz and 80 MHz	V = 3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur bands between 0.15 MHz and 80 MHz	d = 1.17 √P The tCOM+ is suitable for the electromagnetic environment of typical homes, commercial or hospital settings.
Radiated RF IEC 61000-4-3	E = 3 V/m (hospital) E = 10 V/m (home) 80 MHz to 2.7 GHz Immunity to proximity fields from RF wireless communication equipment	E = 3 V/m E = 10 V/m (home) 80 MHz to 2.7 GHz Immunity to proximity fields from RF wireless communication equipment	d = 1.17 √P 80 MHz to 800 MHz d = 2.33 √P 800 MHz to 2.7 GHz The tCOM+ is suitable for the electromagnetic environment of typical homes, commercial or hospital settings.

Test specification RF wireless communication equipment

Test Frequency [MHz]	Band [MHz]	Service	Modulation	Maximum Power [W]	Distance [m]	Immunity Test Level [V/m]
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5kHz deviation 1kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Bans 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,	Pulse modulation 217Hz	2	0.3	28
1845						
1970						

2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

13.8.3 Cables

Cables (used together with the SDMS) comply with

- RF emissions, CISPR 11, Class B/Group 1
- Harmonic emissions, IEC 61000-3-2
- Voltage fluctuations/flicker emissions, ICE 61000-3-3
- Electrostatic discharge (ESD), IEC 61000-4-2
- Electric fast transient/burst, IEC 61000-4-4
- Surge, IEC 61000-4-5
- Voltage dips, short interruptions, and voltage variations on power supply input lines, IEC 61000-4-11
- Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8
- Conducted RF IEC 61000-4-6
- Radiated RF, IEC 61000-4-3

Sensors/Cables	Maximum Length
Sentec TC Sensors	0.8 m
Digital Sensor Adapter Cable	7.5 m

13.8.4 Compliance

The tCOM+ monitor complies with the following standards: IEC 60601-1 (general safety), IEC 60601-1-2 (EMC), IEC 60601-1-6 (usability), IEC 60601-1-8 (alarms), IEC 60601-1-11 (home healthcare), IEC 60601-2-23 (transcutaneous monitors), ISO 80601-2-61 (pulse oximeters), ISO 14971 (risk management), IEC 62366 (usability engineering), IEC 62304 (software in medical devices), ISO 10993-1 (biocompatibility), ISO 20417 (information supplied by manufacturers), ISO 15223-1 and -2 (symbols).

This product complies with the requirements of the Medical Device Regulation (EU) 2017/745.

Care with Confidence

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

EC REP

Sentec GmbH
Carl-Hopp-Str. 19A
18069 Rostock
Germany

UK REP

Sentec Medical Ltd
71-75 Shelton Street
Covent Garden
London, WC2H 9JQ
United Kingdom

CE
0123

Date of release: 2024-12
HBQ-179-V9