- **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.
- **WARNING:** Do not use expired gas bottles or gas bottles from manufacturers other than Sentec. The use of non-Sentec gas bottles may damage the Docking Station. Improper calibration gas mixtures will result in incorrect sensor calibrations and subsequently result in inaccurate PCO_2 and/or PO_2 data.
  Dispose of empty gas bottles according to local waste disposal regulations.
- **WARNING:** Explosion and flammability hazards. Do not use the tCOM+ in the presence of flammable anesthetics/gases or other flammable substances in any environment which has increased oxygen content.
- **WARNING:** 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.
- **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) 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 (10) 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).

- **WARNING:** 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 (3.12). 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 Calmem', 3.11).
Insert the sensor into the Docking Station for sensor calibration (3.11).

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 (3.12) before the tCOM+ starts calibrating the sensor.

WARNING: Before using a brand-new sensor, the sensor membrane should always be changed.

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 Turning off the tCOM+

Turn off the tCOM+ by pushing the ON/OFF button on the left side panel (6) and tap on the power off button on the display.

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 (3.12).

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 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.
- **WARNING:** 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

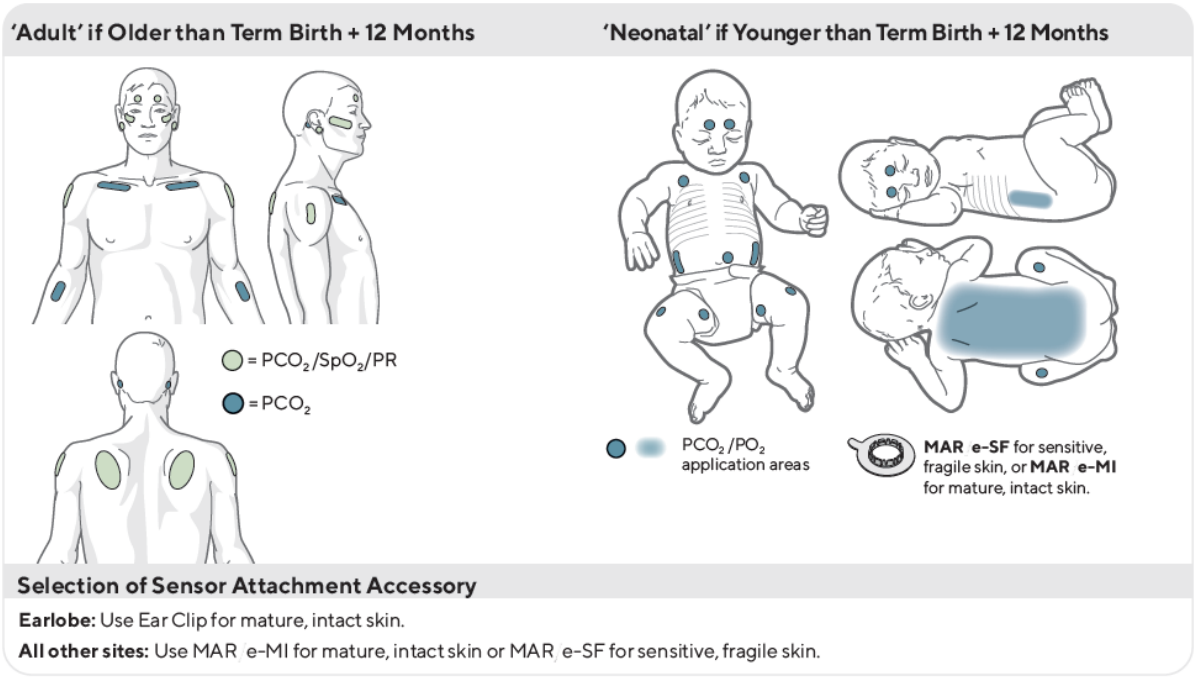
Some patients might be in fair or good physiological condition, but still require special attention when using a heated sensor. Patients with the following characteristics might have an impaired local skin perfusion:

- 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.



- **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:** Patient safety and system performance, when connected to patients undergoing magnetic resonance diagnostic procedures (e.g., MRI), are unknown

and may vary between different setups. The MRI image could potentially be affected by the SDMS. The MRI unit could lead to inaccurate measurements of the SDMS, or currents induced in the sensor cables potentially could cause burns. Furthermore, objects containing metal (e.g., the Ear Clip) can become dangerous projectiles when subjected to the strong magnetic fields created by MRI equipment. Before clinical use of the SDMS during such procedures, consult a qualified technician/MRI expert and verify proper operation of the SDMS and the MRI equipment. Remove all objects containing metal from the patient. In case of doubt, remove sensors and cables connected to the tCOM+ from the patient during such procedures.

- **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.
- **WARNING:** 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 Serveringhaus 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.
- **WARNING:** 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 '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.

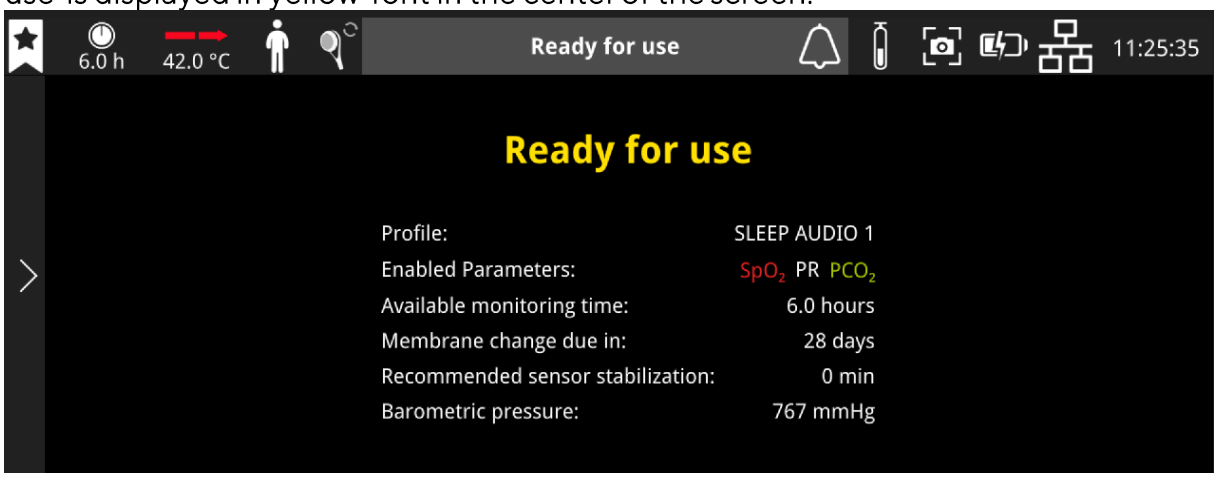
3.4 Checking and adjusting tCOM+ Settings

Before initiating patient monitoring, ensure the current tCOM+ Settings/tCOM+ Profile are appropriate for the patient, for the selected measurement site, for the skin con-

dition/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

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



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

Tapping on the Patient Type icon in the Status Bar will open the Profile Selection screen, where it is possible to view the current profile, preview other profiles, restore profiles and switch to a different profile.

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.

The Status Bar at the top of the screen displays information on the remaining monitoring time, temperature settings, patient type, sensor maintenance, gas bottle, battery, and Wi-Fi state as well as the current time. It also indicates technical messages and alarms. By touching various icons, it is possible to switch to the corresponding screens, to obtain further information, e.g., on the gas bottle state, to take a screenshot, or to jump to 'Favorites'.

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.

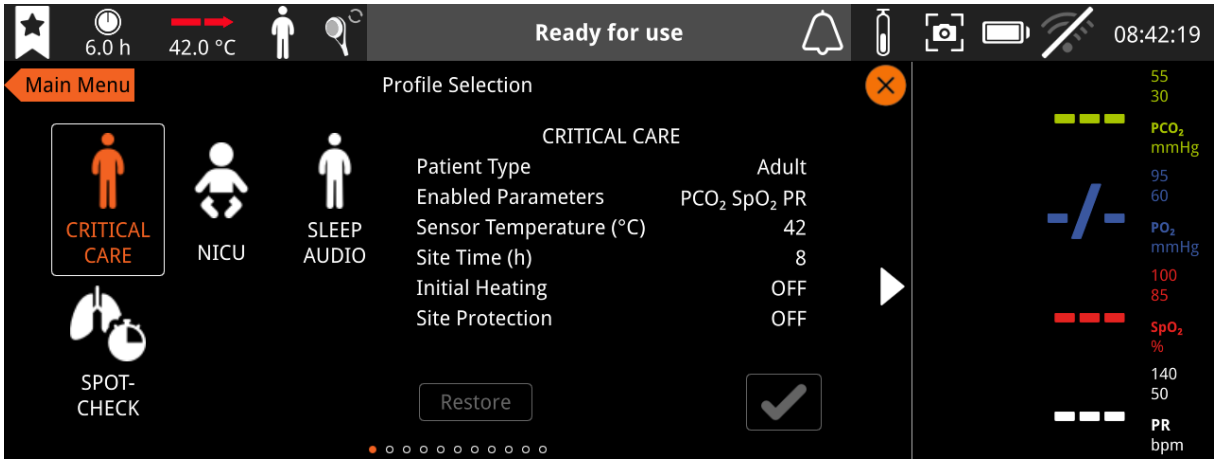
3.4.2 Menu Overview

Menu	Menu icon	Description
Advanced Settings		Edit profiles, configure interface and cybersecurity settings, adjust system settings, e.g., language, date and time Enable demo mode 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		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

Click on the ´Profile Selection´ icon to view the currently active profile, which is highlighted in orange. Here, the active profile and its temperature and site time as well as

parameter settings/modifications (highlighted in yellow) are summarized on several consecutive screens.



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 white frame 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). Tapping on 'Restore' will reset all parameters to the initially preconfigured profile settings.

- **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 Configuration

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

When creating a new profile, the tCOM+ Profile Wizard 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 'Profile Edit' 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
PO_2 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: OFF Neonate: ON	Sleep / Home: OFF 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

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	**PO_2 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.

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	r	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

Patient Type	Selectable Sensor Temperature	Selected Sensor Temperature [°C]	Default Site Time [h]	Selectable Site Time [h]
	-Temperatures below 41.0 °C: PO_2 values NOT available			
Adult/Pediatric	37 – 44.5 °C -Temperatures above 42.0 °C only if PCO_2 enabled - Temperatures above 43.5 °C can only be selected if PO_2 is enabled. - Temperatures below 41.0 °C: PO_2 values NOT available	37.0 ≤ T ≤ 41.5	12.0	0.5 – 12.0
		42.0 ≤ T ≤ 42.5	8.0	0.5 – 12.0
		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.

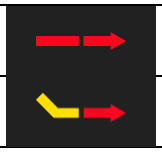
Note: The 'Initial Heating Option' must be enabled by the Responsible Organization within the respective profile.
Note: 'Initial Heating' is deactivated in profiles for patient type Neonate.

'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:

	SP OFF	SP ON
IH OFF		
IH ON		

'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'. 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	5 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 'Profile Edit' 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 second) is issued 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.

3.4.6.1 Visual Alarm Signals

The 'Alarm Bar' as well as 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 SpO_2 and approx. 0.7 Hz for PCO_2, PO_2, 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 status. The monitor's visual alarm signals cannot be deactivated as long as 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.
- **WARNING:** Current values of monitored parameters and visual alarm signals may become illegible if the display brightness is dimmed too much.
- **WARNING:** Do not inactivate or dim the brightness of the monitor's display if the patient's safety could be compromised.

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).

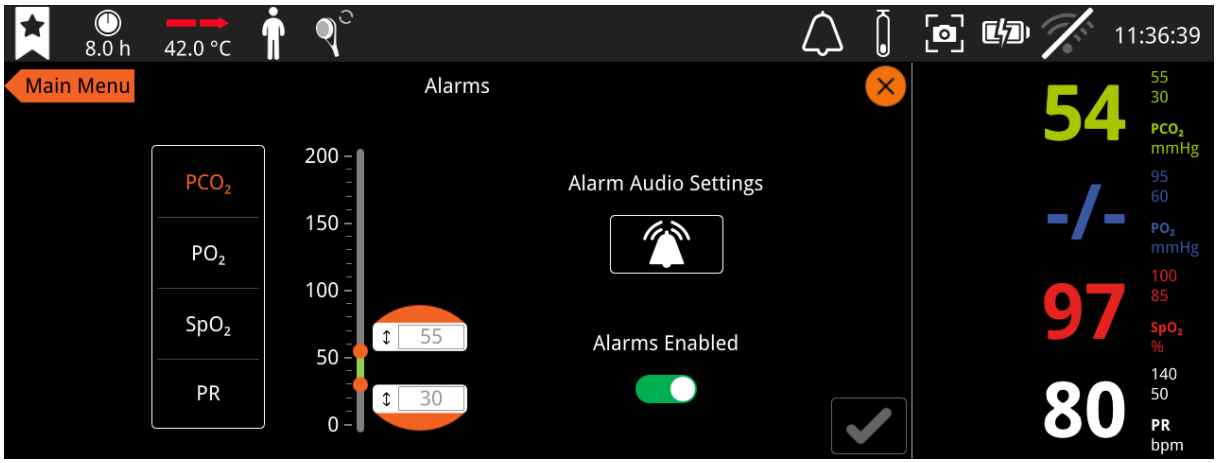
- **WARNING:** If an alarm condition occurs while the auditory alarm signals are paused or permanently switched off, the only alarm indication will be visual, but no alarm tone will sound.
- **WARNING:** Verify that the alarm volume is adjusted such that the alarm signals are clearly audible for the 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.

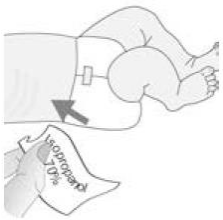
3.5 Sensor Application using a Multi-Site Attachment Ring

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/.

WARNING: Before using a brand-new sensor, it is imperative to perform a membrane change, see chapter 3.12. Otherwise, incorrect measurements may occur.

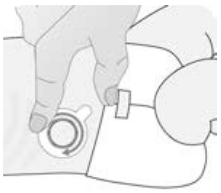
1. Check current tCOM+ Settings/tCOM+ Profile and verify system readiness (message 'Ready for use'). Change tCOM+ Settings/tCOM+ Profile if necessary.
2. Clean the site with a swab moistened with 70% isopropanol (or according to your institution's skin cleaning/degreasing procedures) and let it dry. If necessary, remove hair.



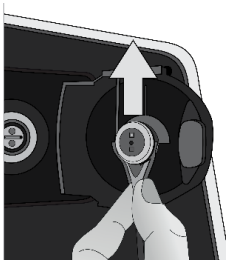
3. Take a Multi-Site Attachment Ring out of the package and pull off the liner protecting the adhesive tape of the ring.

- **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!

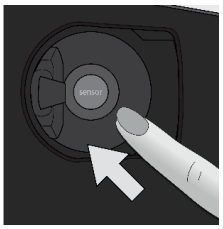
4. Attach the ring to the measurement site. Verify that the skin under the adhesive is not wrinkled. Then press gently on the retainer ring and move your finger around the ring circumference to ensure a good adhesion of the ring's adhesive to the skin.



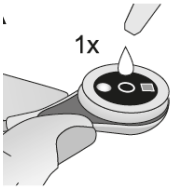
5. Open the Docking Station Door and remove the sensor.
Note: Always grab the sensor at its neck to avoid strain on the sensor cable.



6. Close the Docking Station Door.



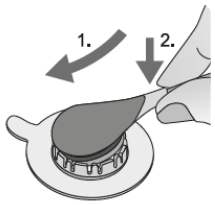
7. Check the condition of the sensor membrane and the integrity of the sensor (3.1). Change the membrane if necessary (3.12). Do not use the sensor if any problems are noted.
8. Apply **1-2 drops** of Contact Gel to the center of the sensor surface. Ensure to keep the sensor horizontal (membrane pointing upwards) so that the Contact Gel does not run off the membrane. Flip over the sensor just before inserting it into the ring.



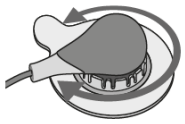
Note: Only use the approved Sentec Contact Gel.
Note: Alternatively, you can apply **1-2 drops** of Contact Gel to the skin area in the center of the attachment ring.
Note: Avoid wetting the adhesive tape!
Note: As long the sensor is not yet applied to the patient, try to keep the measurement site as 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.
- **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.

9. Holding the sensor at its neck, approach the MARe from any side and first insert the nose of the sensor into the retainer ring. Then apply slight downward pressure on its neck. The spring tension of the retainer ring will pull the sensor into place with little to no pressure on the skin.



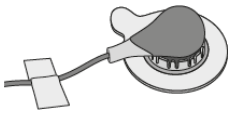
Rotate the sensor in the ring and press the sensor gently against the skin to spread the Contact Gel.



Note: Check that the sensor can be easily rotated to ensure it is snapped in correctly.
10. Check sensor application! Ensure that air gaps are eliminated between the skin and the sensor.
Note: A good, hermetically sealed contact between the sensor and the skin is essential for TC monitoring!

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

11. Twist the sensor into the best position. For forehead/cheek placement, wrap the sensor cable once around the ear and tape the cable to the cheek or another applicable site. For other application sites, tape the cable to the skin at a 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.



12. 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.