

- **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.
- **CAUTION:** 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

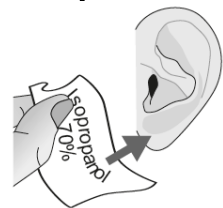
Sentec's Ear Clip EC-MI is intended to attach the Sentec sensors to the earlobe of the patient. It is recommended for patients with mature/intact skin.

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 PCO₂/PO₂ 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).

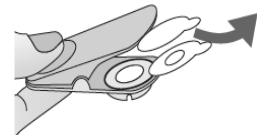
Note: For convenient operation at the bedside, the tCOM+ offers a quick guide on how to apply an Ear Clip. Simply tap on 'Tutorials'.

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

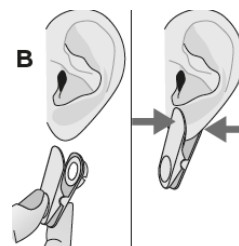
1. Check current tCOM+ Settings/tCOM+ Profile and verify system readiness (message 'Ready for use'). Change tCOM+ Settings/tCOM+ Profile if necessary.
2. Clean the earlobe with a swab moistened with 70% isopropyl alcohol (or according to your institution's skin cleaning/degreasing procedures) and let 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.



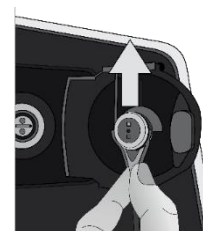
4. Pull the earlobe to stretch its skin and then attach the Ear Clip with its retainer ring on the backside of the earlobe. Verify that the skin under the retainer ring's adhesive is not wrinkled and that the hole in the center of the retainer ring completely covers the skin. Then squeeze gently to ensure that both adhesive tapes stick firmly to the earlobe.



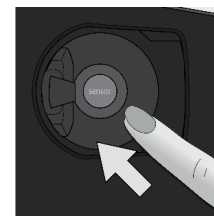
- **CAUTION:** The Sentec Ear Clip (EC-MI) is for single-use only. Neither reattach used clips on the same nor on another patient!

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.

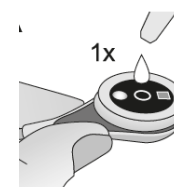


6. Close the Docking Station Door.



7. Check the condition of the sensor membrane and the integrity of the sensor (3.1). Change the membrane if necessary (3.12). 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.

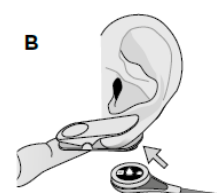


Note: Until the sensor is applied to the earlobe, ensure to hold the sensor such that the Contact Gel does not run off the sensor face. Avoid wetting the adhesive tapes!

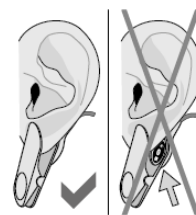
Note: Alternatively, you may apply **1-2 drops** of Contact Gel to the visible skin area in the center of the Ear Clip's retainer ring.

- **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.

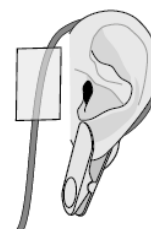


10. Check sensor application! The sensor is applied correctly if its entire dark surface is covered by the earlobe. Ensure that air gaps are eliminated between the skin and the sensor.



- **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.
- **WARNING:** 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.
- **WARNING:** 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 Patient Monitoring

3.7.1 '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 SpO₂/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 PCO₂ 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 SpO₂/PR are enabled, monitor's algorithms typically will flag the PCO₂ and PO₂ readings to be unstable (displayed in grey) and the SpO₂ and PR readings to be invalid (respective values replaced by '---') within 15 seconds and within 30 seconds the low priority alarm 'SpO₂ signal quality' will sound.

Once 'Sensor-On-Patient' is detected, the tCOM+ initiates monitoring, and the enabled parameters stabilize. SpO₂ and PR usually stabilize within a few seconds, whereas PCO₂ typically increases and PO₂ typically decreases to reach a stabilized value within 2 to 10 minutes (see below).

3.7.2 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 PCO₂ to fall and PO₂ 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 'PCO₂/PO₂ stabilizing' if both TC-parameters are stabilizing or 'PCO₂ stabilizing'

or 'PO₂ stabilizing', respectively, if only one TC parameter is stabilizing. To indicate that TC readings do not reflect the patient's real PCO₂ and/or PO₂ levels during stabilization, the tCOM+ displays PCO₂ and/or PO₂ readings in grey and inhibits alarms related to PCO₂ and/or PO₂ 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.

3.7.3 '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 PCO₂ is enabled – the 'Calibration Interval' elapses (whichever occurs first).

When the 'Calibration Interval' elapses before the selected 'Site Time', the 'Available Monitoring Time' Icon is highlighted yellow, the message 'Sensor calibration recommended' is displayed and monitoring is possible for another 4 to 6 hours with PCO₂ marked as 'questionable'. Thereafter, sensor calibration is mandatory and PCO₂ and PO₂ are marked as 'invalid' (values replaced by '---'). When the 'Site Time' elapses, the icon is highlighted in red 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.

3.7.4 Quality Indicators for Measurement Parameters

The tCOM+ continuously evaluates the quality of the measured parameters and the Δx -values (refer to 3.7.5.1) and baseline values (refer to 3.7.5.2) 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. PCO₂, for example, is displayed in grey when stabilizing after sensor application or occurrence of a 'PCO₂ 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 ' Δ 10-value for PCO₂' 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 3.7.5.2.

Example: Baseline values for PCO₂ of 33.3 + 10.1 mmHg indicate that the current PCO₂ reading is 10.1 mmHg higher than the baseline of 33.3 mmHg.



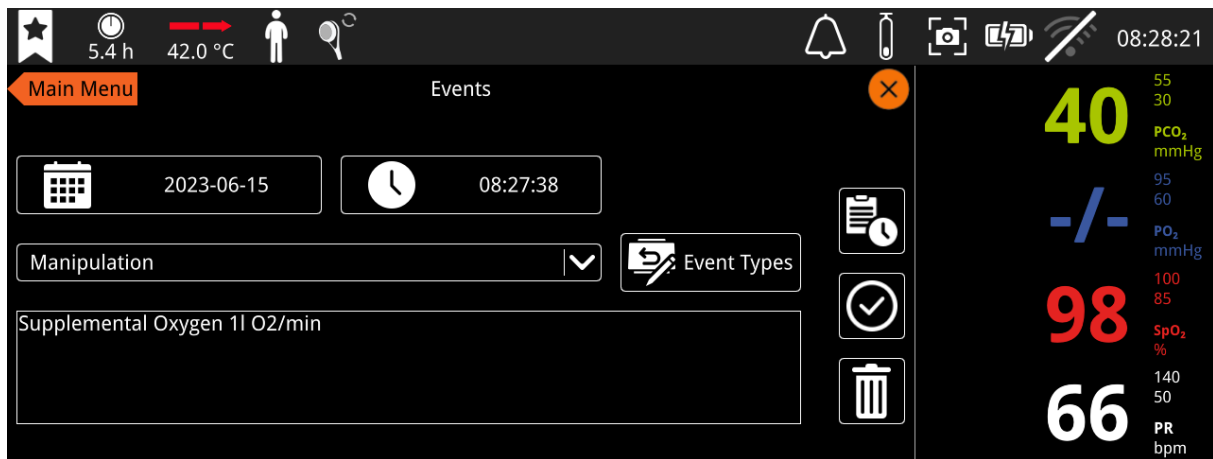
Good to know!

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 3.7.5.2.

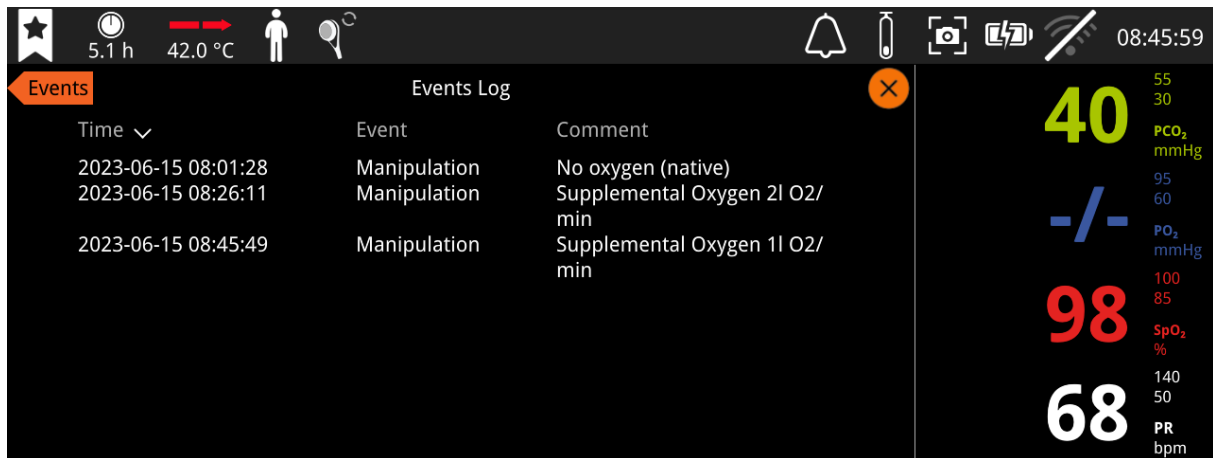
3.7.5 Advanced Measurement Options

3.7.5.1 Events

Tapping on the 'Events' icon within the Main Menu opens a screen with the option to register an event, i.e., a medication given at a certain date and time, a manipulation or an event created by the user.



It is possible to store several events in the tCOM+ for subsequent display on the measurement screen or in the Events Log.



3.7.5.2 Baselines

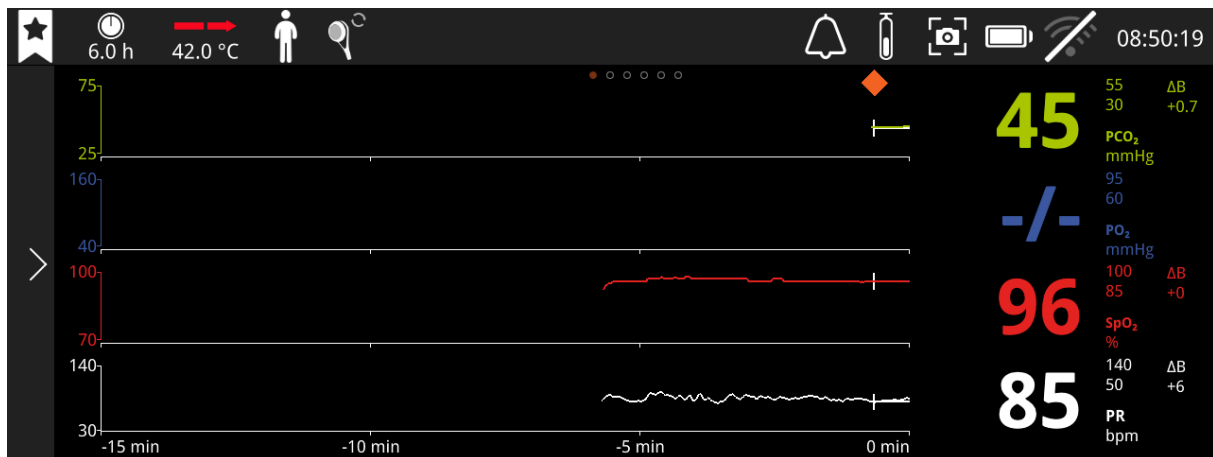
Δx -Values and Baseline Values

Certain preconfigured measurement screens provide online trends with Δx -values, baseline values and baselines for PCO₂, PO₂, SpO₂ 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 $\Delta 10$ -value for PCO₂ of '+ 8.8 mmHg' indicates that the current PCO₂ reading is 8.8 mmHg higher than the PCO₂ 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'.



3.7.5.3 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 PCO₂ online trends or PO₂ online trends, consequently, permits the clinicians to assess whether a change of PCO₂ and/or PO₂ 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.

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

3.7.5.4 PCO₂ In-Vivo Correction

If enabled in the profile, 'In-Vivo Correction' of PCO₂ values is possible at the bedside. The 'PCO₂ In-Vivo Correction' allows for adjusting the PCO₂ readings of the tCOM+ based on the result of an arterial blood gas analysis. The 'PCO₂ In-Vivo Correction' adjusts the displayed PCO₂ value by the offset resulting from the blood gas analysis. The 'PCO₂ In-Vivo Correction' should only be used when a systematic difference between the monitor's PCO₂ readings and PaCO₂ is clearly established by several arterial blood gas measurements.

- **WARNING:** A 'PCO₂ In-Vivo Correction' should only be enabled by personnel understanding the principles and limitations of transcutaneous PCO₂ monitoring. If a 'PCO₂ In-Vivo Correction' is made, it must be checked periodically and adapted in case of changes.
- **WARNING:** The tCOM+ is not a blood gas device. Also, if in-vivo correction is performed, the PCO₂ values displayed by the monitor only remain an estimate of PaCO₂.

3.7.5.5 Severinghaus Correction Mode

The tCOM+ uses an algorithm developed by J.W. Severinghaus to calculate PCO₂ from the measured PcCO₂. The 'Severinghaus Algorithm' first corrects PcCO₂ 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 PCO₂ 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-PaCO₂' value to compare with the monitor's PCO₂ 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.

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

3.8 Sensor Removal with Multi-Site Attachment Ring

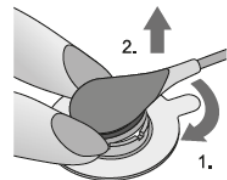
Remove the sensor from the patient when monitoring is completed or monitoring time has elapsed (message 'Site time elapsed' or 'Calibrate sensor').

- **CAUTION:** 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.

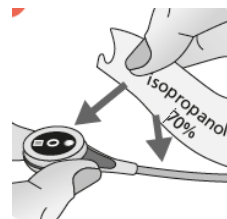
Sensor Removal for Subsequent Reattachment to Same Site

1. Remove the adhesive tape securing the sensor cable, if applicable.

2. Place a finger on each side of the 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).

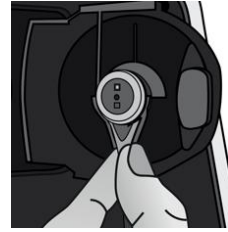


4. Check the condition of the sensor membrane and the integrity of the sensor (3.1). Change the membrane if necessary (3.12). Do not use the sensor if any problems are noted.

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). Make sure to reapply 1-2 drops of Contact Gel to the site before reinserting the sensor into the MARE.

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

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 MARE, discard the ring 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.

CAUTION: To maintain monitor readiness and minimize PCO₂ drift potential, always keep the tCOM+ switched on and connected to power with the sensor in the Docking Station in between monitoring sessions.

3.9 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').

- **CAUTION:** 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 (3.12). 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.

8. To reapply the sensor to the same earlobe, continue at step 5 in chapter 'Sensor Application using an Ear Clip' (3.6). 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.

- **CAUTION:** To maintain monitor readiness and minimize PCO₂ drift potential, always keep the tCOM+ switched on and store the sensor in the Docking Station in between monitoring.

3.10 Patient Data Management

The tCOM+ automatically stores PCO₂, PO₂, SpO₂, PR, RHP 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 acquired by the tCOM+ can be downloaded through the DATA/SERVICE USB port located at the left side of the monitor. Additionally, the data 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, chart recorders or data loggers.

- **WARNING:** No component shall be connected to the Connectivity USB port on the back of the monitor. It does not provide any functionality at the moment.
- **WARNING:** When connecting/mounting the monitor to accessory equipment (e.g., PCs, poly or polysomnographic systems, multi-parameter bedside monitors, ventilators, Ethernet networks, etc.), verify proper operation before clinical use of the monitor and accessory equipment. In certain cases, it may be required that the monitor and the accessory equipment must be connected to a grounded AC outlet. In case of doubt, consult qualified technicians.
- **WARNING:** Accessory equipment (e.g., a PC) connected to the 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.
- **WARNING:** Verify the movement of the blip bar or plethysmographic waveform and ensure for adequate signal strength before accepting any displayed SpO₂/PR/PI data as a current measurement.
- **WARNING:** Ensure to properly calibrate the instrument (PG-/PSG-System) attached to the tCOM+ analog output at initial setup and, thereafter, at least monthly.
- **WARNING:** When connecting/mounting the monitor to the accessory equipment (e.g., PCs, PSG-Systems, (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.

- **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.
- **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.

3.11 Sensor Calibration and Storage

If a sensor calibration is **mandatory**, the tCOM+ displays the message 'Calibrate sensor', a low priority alarm sounds and PCO₂ and PO₂ 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 PCO₂ marked as 'questionable'. Thereafter, sensor calibration is **mandatory**.

The tCOM+, as a precaution, calibrates PO₂ during each mandatory calibration and subsequently approximately once every 24 hours during one of the default PCO₂ calibrations.

To calibrate the sensor:

1. Open the Docking Station Door by pulling the door.
2. Check the gasket (arrow) 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.

- **WARNING:** 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, PO₂ 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 (3.12), always keep the monitor switched on and always store the sensor in the Docking Station.

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.

- **WARNING:** 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.
- **WARNING:** Accurate sensor calibration is important. Improper sensor calibration subsequently will result in inaccurate PCO₂ and/or PO₂ readings.
- **CAUTION:** 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 CALMEM 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 CALMEM reduces the number of required calibrations and, hence, the consumption of calibration gas.

3.12 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 PCO₂/PO₂ as invalid and activates the menu 'Membrane Change' – provided the sensor is in the Docking Station. 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 for up to 31 days.

- **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 www.sentec.com/ifu.

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 (MC 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  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.

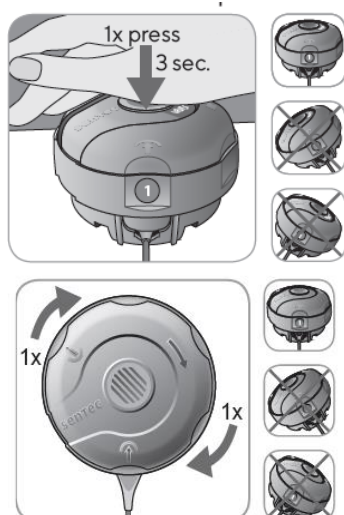
Step 1 removes the old sensor membrane: Press down slowly but firmly with palm of hand and hold for 3 seconds. Release the top. Carry out a visual check to ensure that the membrane is removed. Turn the top portion one click clockwise to the next step. Keep the Membrane Changer horizontal.

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.

Keep the Membrane Changer horizontal while executing the following Press-and-Turn step 4 times:

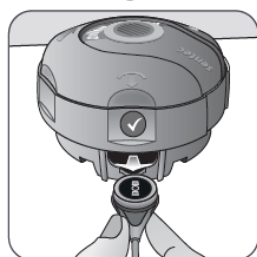


a. Press down slowly but firmly with palm of the hand and hold for 3 seconds.

b. Turn the top portion one click clockwise to the next stop. Keep the Membrane Changer horizontal! Hold the changer's bottom half in place while turning the top half.

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

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') or via the 'Membrane Changed' button in the on-screen tutorial.

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.

- **WARNING:** The cover must only be removed by Sentec authorized 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.

	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+, 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 chapter “Clean and soak sensor”

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.
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Refer to the Service Manual for the tCOM+ (HB-013767, available on sentec.com/ifu) for additional/complete check lists and detailed maintenance procedures.

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

4.1.1.1 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 HB-010143-Cleaning and Disinfection Agents.

Recommended cleaning/disinfection procedures for the tCOM+

Sentec recommends cleaning the monitor weekly using a moist 70% Isopropanol wipe. However, other cleaning / disinfection procedures may be applied (refer to instructions given below) as often as required per institutional ordinances.

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.

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 **HB-010143-Cleaning –and –Disinfection Agents** for an overview of tested and recommended products (see [sentec.com/ifu](https://www.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.

- **WARNING:** Before cleaning the monitor, always switch it off and disconnect it from AC power.
- **CAUTION:** Plugs and connectors meticulously must be kept clean and dry at all times. 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:** 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.

4.1.1.2 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.