SLEEP

TRANSCUTANEOUS MONITORING

tCOM+ Competency Checklist

This form is a self-assessment tool. Each user should be able to discuss the rationale for each of the actions and demonstrate competency in the practical applications of the skills applicable to their role.

Full Name:	**Date:**
Department:	
Medical Device: tCOM+ with V-Sign Sensor	

Competencies Required:

- Bedside Experts ☐
- V-STATS™ and Connectivity Experts ☐
- Maintenance and Troubleshooting Experts ☐

Bedside Experts

These users understand how to apply the sensor and attachment rings, choose the appropriate site time and sensor temperature, and manage the sensor after the overnight study.

		Achieved
1.	Identify the clinical indications for using transcutaneous monitoring	☐
2.	Demonstrate or describe how to turn on the monitor	☐
3.	Describe the function of the following sub-menus:	☐
4.	Name the icons relevant to patient monitoring that can be seen in the Status Bar	☐
5.	Define the recommended site time and sensor temperature for overnight monitoring	☐
6.	Name the approved measurement sites for patient monitoring	☐
7.	Describe how the sensor should appear before patient application as well as what problems to identify during visual inspection	☐
8.	Explain how to verify that the monitor is ready to use for patient monitoring	☐
9.	Explain how to reach the maximum monitoring time available for an overnight study	☐
10.	Explain the specific sleep-related monitor settings available in the Sleep Profile	☐
11.	Demonstrate or describe the process for sensor application	☐
12.	Explain how to determine if the transcutaneous value has stabilized after application	☐
13.	Explain some of the main factors that can affect the accuracy of the $tcPCO_2$ reading	☐
14.	Explain or demonstrate how to use Smart Cal-Mem™ and how long the sensor can be disconnected before returning to patient monitoring	☐
15.	Explain the steps to clean and calibrate the sensor after site time elapses	☐

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Connectivity and V-STATS™ Experts

In addition to the Bedside Expert Competencies, these users understand how to integrate the device into their PG/PSG systems, as well as download and create a report from the overnight data.

Achieved

16. Demonstrate how to connect the Sentec monitor to the PG/PSG system ☐
17. Demonstrate how to calibrate the PG/PSG system to the monitor ☐
18. Explain how to test the analog output function by duplicating the readings on the monitor on the attached system ☐

The following competencies apply to institutions using V-STATS™ to download overnight data and create reports.

19. Explain how to create an event on the monitor and list scenarios where it may be helpful to set an event ☐
20. Explain how to select the correct patient monitoring session and create a report in V-STATS ☐
21. Demonstrate how to modify the report header and settings to institution preferences ☐

Maintenance and Troubleshooting Experts

These users are responsible for keeping the Sentec Digital Monitoring System running smoothly, including cleaning procedures, membrane changes, and troubleshooting simple error messages.

Achieved

22. Explain or demonstrate how to change the Gas Bottle ☐
23. Explain how to store the monitor and sensor between studies so they are ready to use for the next patient ☐
24. Explain how often the sensor membrane should be changed and where on the monitor the membrane lifetime is shown ☐
25. Demonstrate or describe how to replace the sensor's membrane ☐

26. Explain the following low-priority alarms or issues and how to fix them:
    - Connect sensor ☐
    - Sensor off patient ☐
    - Values not stabilizing after sensor application ☐

27. Explain how to troubleshoot these error messages and where to find troubleshooting resources:
    - Sensor Problem 11 ☐
    - Sensor Problem 12 ☐
    - Gas Leak in Docking Station ☐

28. Identify the recommended cleaning product to use after every patient monitoring session ☐
29. Describe when and how to complete a sensitivity test ☐
30. Describe when and how to complete a clean and soak of the Sentec sensor ☐

Practitioner Signature _____ **Date** _____

Trainer Signature _____ **Date** _____

TRANSCUTANEOUS MONITORING

tCOM+ Competency Checklist Key

Bedside Experts

1. Clinical Indications

Transcutaneous CO_2 monitoring is indicated for any patient on respiratory support requiring ventilation monitoring in the Sleep Lab.

2. Power On

The ON/OFF button is located on the left side of the monitor beneath the gas cannister.

3. Main Menu

Tap the arrow on the left side of the display to enter the Main Menu.

Alarm Settings: Set and adjust parameter alarm limits

Measurement Settings: Adjust site time and temperature, settings for enabled parameters, and start monitoring.

Trend Settings: Adjust trend ranges and time scale for enabled parameters.

Events: Log and view events, e.g. ventilator changes, blood gases, medication administration, etc.

Tutorials: Access step-by-step guides for application, maintenance, and troubleshooting procedures.

Sensor Maintenance: Calibrate the sensor, confirm a membrane change, view the membrane change interval, and perform a sensitivity test.

Profile Selection: Select a preconfigured measurement profile.

4. Status Bar

Favorites: Build a library of frequently used workflows by saving them to the Favorites menu.

Monitoring Time: indicates the remaining measurement time. Yellow indicates that calibration is recommended; yellow with a cyan background indicates that monitoring time has elapsed.

Heating Mode: indicates whether these settings are on or off and displays sensor temperature.

Patient Type: indicates if the monitor is in Adult or Neonatal Mode.

Sensor Maintenance: opens a menu showing calibration status, membrane change interval, and when the last sensitivity test was performed. Yellow indicates the membrane change is due in < 3 days; yellow with a cyan background indicates that a membrane change is mandatory.

Alarm Bar: displays Status Message about alarms or monitor/sensor information.

Alarm: indicates the status of the auditory alarm signals (ON, Paused, OFF).

Gas Level: indicates the remaining content of the gas bottle. Tapping on the icon will prompt a pop-up message indicating the fill state in %.

Screenshot: takes a screenshot of the current tCOM+ screen. Screenshots can be viewed and exported by going to the **Main Menu** > **Review & Export** > **Screenshots**.

Battery: indicates the battery status and remaining battery capacity in %. The icon is highlighted yellow when the battery is low and yellow with a cyan background when critically low.

5. Measurement Sites

Adult/Pediatric:
PCO_2/SpO_2/Pulse Rate (PR): forehead, cheek, earlobe, upper arm, shoulder blade

PCO_2 only: beneath the clavicle, lower arm

Neonatal (PCO_2 only): forehead, upper chest, abdomen and flanks, upper thighs, and back

6. Site Time and Temperature

Adult/Pediatric patients (older than term birth + 12 months): 42°C for 8 hours (up to 12 hours maximum).

Neonatal patients (younger than term birth + 12 months): 41°C for 8 hours.

Note: Extending the site time from the recommended 8 hours to 12 hours may increase the risk of erythema or other thermal injuries. Pay special attention to patients with fragile or sensitive skin at the sensor site.

7. Sensor Inspection

A good quality sensor has a smooth membrane surface, functioning red LED, and an intact sensor cable. Do not use the sensor if the membrane has a dried-out appearance, air bubbles under the membrane, or if the center ring appears silver instead of brown.

8. Ready for Use

Before initiating patient monitoring, ensure the current tCOM+ Settings and Profile are appropriate for the patient, the selected measurement site, skin condition and perfusion at the selected measurement site, and specific clinical setting. At a minimum, check the patient type, enabled parameters, sensor temperature, site time, and alarm specific settings.

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9. Available Monitoring Time

To ensure the monitor has enough monitoring time available for the overnight study (12 hours maximum), turn on the monitor at least 4 hours before the study. After powering on, allow the sensor to calibrate and stabilize, then keep the monitor on and plugged in to power until the sleep study begins. The available monitoring time is displayed in the Status Bar. For best results, turn on the monitor the morning of the study or keep monitors connected to power and powered on at all times.

10. Sleep Profile

In the Sleep profile, the display is in sleep mode and will only activate when a button is pushed on the monitor. In Sleep Mode, the maximum monitoring time is set at 12 hours. Depending on institutional preferences, the alarms may be turned off.

11. Sensor Application

1. Verify the system displays "Ready for Use."

2. Clean measurement site and allow to dry. Apply the Multi-site Attachment Ring to the measurement site, gently pressing around the ring to ensure good adhesion to the skin. Verify that the skin under the adhesive is not wrinkled.

3. Remove the sensor from the Docking Station and close the door.

4. Apply 1-2 drops of Contact Gel to the skin in the center of the ring or onto the sensor face.

5. Holding the sensor by the neck, (1) insert the sensor nose-first into the ring and (2) press gently downward on the neck until it clicks into place. Rotate the sensor within the ring to distribute the Contact Gel.

6. Tape the sensor cable or use the clothing clip to keep the sensor in place, if desired, and ensure that there will be no tension on the cable during monitoring. Do not tape over the sensor.

12. Stabilization

Transcutaneous readings typically stabilize within 2-10 minutes after sensor application. Once stabilized, the CO_2 reading will turn from gray to green (default color).

13. Troubleshooting $tcPCO_2$ Values

If the $tcPCO_2$ reading is higher than expected, check the measurement site. External pressure on the sensor from the patient's position, bedding, dressings, or other medical devices can decrease blood flow at the measurement site and cause higher $tcPCO_2$ values.

If the $tcPCO_2$ reading is lower than expected, check the sensor application. Air between the sensor and the skin caused by a loose sensor attachment, loose application ring, or lack of Contact Gel can cause lower $tcPCO_2$ values.

14. Smart Cal-Mem™

The sensor can be disconnected from the sensor adapter cable for up to 30 minutes without needing to remove the sensor from the skin and recalibrate. To use Smart Cal-Mem, simply unplug the sensor, allow the patient to get out of bed or perform other necessary tasks, and reconnect within 30 minutes. The $tcPCO_2$ values will begin to stabilize once the sensor is reconnected.

15. Sensor Cleaning and Calibration

Once the site time elapses, remove the sensor and inspect the skin. Gently clean the sensor face and outer rim with 70% isopropanol. Do not scrub or apply force when cleaning the sensor surface. Hang the sensor in the Docking Station door with the red light facing out and close the door. The monitor 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 complete.

V-STATS™ and Connectivity Experts

16. PG/PSG Connectivity

Connect the PSG Cable to the tCOM+ Analog Output Port on the back of the monitor. Connect the free ends of the adapter cable to the PG-/PSG-system. Verify the channel assignment and parameter ranges in the **Advanced Settings** > **Interfaces** > **Analog/PSG** > **Channel Assignment** menu and check that they match the PG-/PSG-system.

17. PG/PSG System Calibration

To calibrate the PG-/PSG-system and the tCOM+, follow the following steps:

1. Go to the **Advanced Settings** > **Interfaces** > **Analog/PSG** menu and choose **Calibrate Channels**.

2. The sequence will run automatically, causing all parameters to output 1 Volt for 60 seconds, followed by an output of 0 Volt for another 60 seconds.

3. By pressing **Confirm Voltage**, it is possible to change from 1 Volt to 0 Volt and to stop the calibration sequence.

18. Testing Analog Output

Test the Analog Output function by briefly monitoring on a participant. Ensure that the readings displayed on the tCOM+ are correctly displayed on the connected PG-/PSG-System.

19. Adding an Event

During patient monitoring, events may be added to track and assess the impact of various interventions, such as a blood gas, ventilation setting change, intubation, extubation, medication administration, or manipulation.

Press and hold at the time of the event to open the **Events** menu or open the **Main Menu** and choose **Events**. Adjust the date and time as needed, then choose from the preconfigured events or create a custom event. Press **Confirm** to set the event, which will be visually represented by an orange diamond at the top of the trend graph.

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20. Overnight Reports

1. Connect a USB-C stick to the DATA/SERVICE USB port located at the left side of the monitor.

2. Click on the **Review & Export** icon in the Main Menu and select **Patient Data**.

3. Select the patient measurement file(s) for download to the USB stick.

4. Tap on the export symbol to save the files to the USB stick.

5. Connect the USB to your PC and open V-STATS software.

6. In V-STATS, select **File** > **Import Trend Data**.

7. Select a minimum measurement duration (default 5 min) and select **Import**.

8. Select the measurement file(s) for analysis.

9. Select **Convert** to import the measurement into the V-STATS database.

21. Report Personalization

In the main V-STATS menu, navigate to **Settings** > **V-STATS Settings**. Enter your "Admin Password." A new window will open with various report settings, including Report Heading, PCO_2/PO_2 Unit to change from mmHg to kPa, and Channel Settings.

Maintenance and Troubleshooting Experts

22. Changing the Gas Bottle

Remove the old gas bottle by turning it counterclockwise. Remove the cap from the new gas bottle. Insert the gas bottle into the slot and turn it clockwise, approximately 4.5 turns. Do not overtighten the gas bottle. After a few seconds, the **Gas Level** icon will update to show the status of the new bottle.

23. Monitor and Sensor Storage

During periods of frequent use, the sensor should be stored in the Docking Station with the monitor turned on and connected to power. When not in use, the sensor should remain stored in the Docking Station with the cable carefully and loosely wrapped.

24. Membrane Change Interval

The membrane of a Sentec transcutaneous sensor must be changed every 28 days —sooner if the membrane is damaged or missing, has a loose fit, or if there is trapped air or dry electrolyte beneath the membrane. The **Sensor Maintenance** menu, which can be accessed by tapping the **Sensor Maintenance** icon in the Status Bar, indicates the remaining time until the next membrane change.

When the Sensor Maintenance icon turns yellow, the membrane change is due in 3 days or less. When the icon turns yellow with a cyan background, the membrane change is required.

25. Changing the Sensor Membrane

Keep the Membrane Changer horizontal while executing the four pressing and turning steps.

1. Remove the old sensor membrane: Press down slowly but firmly with palm of hand and hold for 3 seconds, then release. Turn the top portion of the membrane changer one click clockwise to move to the next step. Leave the Membrane Changer in the horizontal position, do not pick it up.

2. Clean the old electrolyte off the sensor surface: As in step 1, press the Membrane Changer slowly but firmly, then release the top and turn clockwise to the next step without moving or tipping the Membrane Changer.

3. Apply 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.

4. Place 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. Press one last time or lift the sensor and remove it from the Membrane Changer. Check the condition of the sensor membrane and the integrity of the sensor.

To confirm the membrane change and reset the membrane change interval, enter the **Sensor Maintenance** menu, and select **Membrane Changed**. This will initiate an automatic calibration.

Note: View illustrated instructions for the membrane change by opening the **Main Menu** and choosing **Tutorials**.

26. Low Priority Alarms

Connect Sensor: Check to make sure the sensor adapter cable is plugged into the back of the monitor and the adapter cable is connected to the sensor. To identify the defective part, exchange the sensor adapter cable or the Sentec sensor and try again.

Sensor off patient: Check the sensor application. The sensor may be loosely attached to the patient, Contact Gel may not have been used during sensor application, or the monitoring site may have poor perfusion.

Values not stabilizing: The sensor may be loosely attached to the patient with air between the sensor and the skin or insufficient Contact Gel. Verify that the sensor is securely attached and reapply the sensor on the same site if needed. Ensure that the sensor is applied to a recommended monitoring site.

27. Troubleshooting Common Error Messages

Sensor Problem 11: Check the sensor's center ring. If the ring is brown and intact (not white or silver), remove the membrane and perform a clean and soak. After gently drying the sensor, apply a new membrane. Confirm the membrane change on the monitor and allow the sensor to calibrate. If the SP11 Error persists, contact qualified service personnel.

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Sensor Problem 12: Check the sensor's center ring. If the ring is brown and intact (not white or silver), remove the membrane and perform a clean and soak. After gently drying the sensor, apply a new membrane. Place the sensor in the Docking Station and confirm the Membrane Change in the **Sensor Maintenance** menu. A Sensitivity Test will start automatically after confirming the membrane change for sensors with an SP12 error. The sensor must pass the Sensitivity Test to clear the SP12 Error. If the SP12 Error persists, contact qualified service personnel.

Gas Leak in DS: Verify that the sensor is clean and properly placed into the holder at the inside of the Docking Station (DS) door. If the Gas Leak continues after calibration, check the gasket of the DS. Clean the DS gasket with 70% isopropanol. If the gasket is missing or defective, replace the gasket and calibrate the sensor. If the Gas Leak persists, contact qualified service personnel.

Note: View illustrated troubleshooting instructions by opening the **Main Menu** and choosing **Tutorials**.

28. Sensor Cleaning

The sensor face, housing, and cable should be cleaned after each monitoring session with 70% isopropanol or other approved cleaning agent. The sensor should always be stored in the Docking Station. The monitor should be cleaned weekly with a wipe soaked with 70% isopropanol. Only use the approved cleaning agents to clean and disinfect the monitor and sensor. For a full overview of the recommended low- and high-level cleaning agents, refer to HBQ-122 Cleaning and Disinfection Agents.

29. Sensitivity Test

The sensitivity test should be completed monthly. To perform a sensitivity test:

1. Insert the sensor into the Docking Station.

2. Press the **Sensor Maintenance** icon and select **Sensitivity Test**.

3. Follow the on-screen prompts which will instruct the user to open the Docking Station door for two minutes. Once the door is closed, the monitor will automatically perform a leak test, sensor calibration, and a sensitivity test.

If the Sensitivity Test passed, the Status Message 'Ready for use' appears.

Note: View illustrated instructions for the Sensitivity Test by opening the **Main Menu** and choosing **Tutorials**.

30. Clean and Soak

The clean and soak should be completed quarterly (every three months).

1. Remove the sensor membrane using the membrane re-mover on the bottom of the Membrane Changer.

2. Immerse the sensor into clean, room temperature water for 3 minutes.

3. After 3 minutes, gently rinse the sensor with clean water.

4. Lightly dab the sensor dry using lint-free gauze. Do not touch the ring and pH-glass in the center of the sensor. Do not rub the sensor surface.

5. Inspect the ring around the pH glass to ensure it is brown and intact.

6. Inspect the sensor to ensure that the grooves on the sensor circumference are clean and intact.

7. Once the visual inspections are passed, re-membrane the sensor using the Membrane Changer.

Note: View illustrated instructions for the Clean and Soak by opening the **Main Menu** and choosing **Tutorials**.