tCOM+ with V-Sign™ Sensor 2

The tCOM+ Transcutaneous Monitor features an intuitive interface that displays parameters as values, trends, and deltas with the ability to set preferred alarm limits with onboard tutorials that support smooth caregiver workflows.

The digital V-Sign™ sensor enables continuous and noninvasive monitoring of $tcPCO_2$, SpO_2, PR (pulse rate), and RHP (relative heating power).

Suitable for Adults, Pediatrics & Neonates. SpO_2 and PR available for patients aged term birth plus 12 months.

Overall System Performance

Transcutaneous Carbon Dioxide Partial Pressure (tcPCO₂)[1]
Measurement range: 0–200 mmHg (0–26.7 kPa)
Resolution: 0.1 mmHg (0.01 kPa) below 100 mmHg (10 kPa)/1 mmHg (0.1 kPa) above 100 mmHg (10 kPa)
Drift[2]: Typically < 0.5%/hour
Response time (T90)[2]: Typically < 75 sec
Linearity[2]: Typically < 1 mmHg (0.13 kPa)
Interferences by anesthetic gases: Negligible
Stabilization/artifact detection: After sensor application or occurrence of a $tcPCO_2$ artifact, $tcPCO_2$ is displayed in grey until it (re)stabilizes.
Approved sites for tcPCO₂ monitoring: Monitoring in neonates include the thorax (under the clavicle, on rib cage), abdomen, back, low forehead, and the inner or anterior aspect of the thigh. Approved sites for PCO_2 monitoring in adult and pediatric patients include the earlobe, low forehead, cheek, upper arm, scapula (shoulder blade), thorax (under the clavicle), mastoid process, and lower arm.

Pulse Rate (PR)
Available for patients older than term birth + 12 months.
Measurement range: 30–250 bpm
Resolution: 1 bpm
Accuracy: ± 3 bpm

Pulsation Index (PI)
Available for patients older than term birth + 12 months.
Measurement range: 0.1–10.0%
Resolution: 0.1%

Oxygen Saturation (SpO₂)
Available for patients older than term birth + 12 months.
Measurement range: 1 – 100%
Resolution: 1%
Accuracy: ±2% (A_{rms} over 70% to 100%)[3]
Averaging mode: 2, 3, 4, 6, 8, 12, 16, and 32 sec
Approved sites for SpO2/ PR monitoring: Earlobe, low forehead, cheek, upper arm, and scapula (shoulder blade)

Sensor Heating Power (HP)
Measurement range:
Absolute Heating Power (AHP): 0–999 mW
Relative Heating Power (RHP): -999–999 mW
Resolution: 1 mW

Sensor Temperature
Measurement range: 0.0 – 70.0°C
Resolution: 0.1°C
Accuracy: ± 0.2°C (over 37.0 to 45.0°C)

[1] An algorithm developed by J.W. Severinghaus is used to calculate $tcPCO_2$ from the measured cutaneous PCO_2. This algorithm accounts for temperature and metabolic correction factors. The $tcPCO_2$ values displayed by the tCOM+ are corrected / normalized to 37°C and provide an estimate of arterial PCO_2 ($PaCO_2$) at 37°C. Correction factors can be customized by institution. Additionally, and subject to institution's permission, In-vivo Correction (IC) of $tcPCO_2$ values is possible at the bedside.

[2] Respective specifications based on in vitro tests performed as per IEC 60601-2-23:2011 at a sensor temperature of 42°C.

[3] SpO_2 accuracy specification is based on controlled hypoxia studies on healthy, adult volunteers over the specified saturation range by applying a V-Sign™ Sensor 2 to each of the specified measurement sites.

V-Sign™ Sensor 2 (Digital, combined tcPCO₂/ SpO₂/ PR sensor)

General Characteristics
Suitable for adult, pediatric, and neonatal patients
Reusable, waterproof

Measurement Principle
Electrochemical Severinghaus-type $tcPCO_2$ sensor combined with reflectance 2-wavelength pulse oximetry.

Digital Microtechnology
Highly integrated opto-electronic sensor head comprising micro pH-electrode, optical oximetry unit, temperature sensors, heating unit, all combined in a fully digital design. High definition digitizer and pre-processing in the sensor head provides robust and low noise signals that are digitally transmitted to the tCOM+.

Sensor Memory
Sensor-specific data are stored in the sensor's memory after manufacturing (serial number, factory PCO_2 sensitivity / calibration, etc.) and during operation (sensor calibration, membrane change, etc.).

Sensor Membrane Change
The default membrane change interval is 28 days but may be customized depending on the specific requirements of various clinical settings. The membrane changer tool simplifies the process for a highly reproducible membrane change.

Sensor Calibration
Calibration duration: Typically 3 minutes (ex. factory)
Calibration interval: Up to 12 hours. Once the calibration interval has elapsed, sensor calibration is **recommended**, monitoring is possible for another 4 to 6 hours with $tcPCO_2$ marked as 'questionable'. Thereafter, sensor calibration is **mandatory** and $tcPCO_2$ is marked as 'invalid' ($tcPCO_2$ value replaced by '---').

Smart Cal-Mem
Supports the disconnection of the sensor for up to 30 minutes without losing the calibration status. Furthermore, the sensor can be removed from the Docking Station for up to 10 minutes without initiating a calibration upon reinsertion of the sensor into the Docking Station. Overall, Smart Cal-Mem significantly reduces the number of required calibrations and the calibration gas consumption.

Sensor Internal Temperature Control
To ensure safe operation, the sensor reliably supervises the sensor temperature with two independent circuits. Additionally, the tCOM+ software redundantly controls the temperature of the connected sensor for an extra level of protection.

Sensor Dimensions / Sensor Cable
Diameter x height of sensor head: 14 mm x 9 mm (0.55'' x 0.35'')
Weight of sensor head: < 2.9 g (0.1 oz)
Length of sensor cable: Approximately 80 cm (31''), plus Sensor Adapter Cable available in lengths of Regular (150 cm (59'')), Long (250 cm (98'')), or Extra-Long (750 cm (295'')).
Sensor cable: Highly flexible, shielded cable with coating withstanding cleaning agents and irradiation commonly used in busy hospital environments.

Transport / Storage of Sensor
Transport temperature: 0 – 50°C (32 – 122°F)
Long term storage temperature: 15 – 26°C (59 – 78 °F)
Transport and store sensor with membrane applied; protect sensor from light and radiation.

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tCOM+ Monitor

Physical Characteristics
Weight: 2.5 kg (5.5 lbs)
Size: 15.3 cm (height) x 27.8 cm (width) x 16.2 cm (depth) (6.02'' x 10.95'' x 6.38'')
Transport: Foldable handle located on top of the monitor for monitor transport on the unit.
Mounting: Compatible with 75x75 VESA mounts for roll/infusion stands, wall / railing mounts, transport incubators, etc.
Cable storage: Included cable holder may be attached to the back right or left of the monitor to stow the cable during transport or storage.
Tilting: Option to add feet to the VESA holes to adjust angle for improved table-top viewing.

Sensor Calibration
Built-in sensor calibration chamber for 1-point calibration. Automatic calibration ensures that system is 'Ready for use' if sensor is stored in calibration chamber. Comprehensive controls ensure reliable calibrations.

Sensor Temperature
Selectable range: Configurable by institution between 37.0 and 44°C (Neonate) and 37.0 and 44.5°C (Adult/Pediatric). Safety controls of the monitor may restrict the selectable range depending on the type of the connected sensor, the selected patient mode, or the enabled parameters.
Default sensor temperature: 42.0°C in Adult Mode and 41.0°C in Neonatal Mode.

Site Time
Selectable 'Site Time': Configurable by the institution between 0.5 and 12.0 hours maximum (in steps of 0.5 hours). Depending on the selected patient mode and with increasing sensor temperature, safety controls of the monitor may enforce a shorter site time.
Default 'Site Time': 8.0 hours in Adult Mode at 42.0°C or in Neonatal Mode at 41.0°C (or as restricted by institution and / or safety controls of the monitor).

Site Timer
Timer indicating remaining 'Site Time' during monitoring. An alarm is triggered once 'Site Time' has elapsed.

Site Protection
Safety feature which prevents excessively long exposure of the skin to temperatures exceeding 41°C in adult mode or 40°C in neonatal mode. When Site Protection is active and 'Site Time' has elapsed, the sensor temperature will be reduced to 39°C for Neonatal and Adult Mode (41°C if SpO2 enabled in Adult Mode).

Initial Heating
Temporarily increases sensor temperature after sensor application for faster perfusion and results (in Adult Mode only; +2°C max. 44.5°C; can only be switched on if enabled by institution).

Redundant Sensor Temperature Control on tCOM+
Should the sensor's temperature control fail, the monitor firmware also controls the temperature of the connected sensor. In the event of an error, the sensor will restart or switch off.

Alarm System
Alarm signals: Visual/ auditory alarm signals for high / low tcPCO2, SpO2, PR, and technical alarms.
Alarm inhibition: Auditory alarm signals can be PAUSED (1 or 2 minutes) or switched off permanently (if enabled by institution).
Alarm system status indicators: The on-screen Alarm Bar and LED Bar indicate the active alarm with the highest priority. The highest priority alarm is always displayed in the Alarm Bar. Auditory alarms can be paused for 1 or 2 minutes, or permanently switched off with the AUDIO OFF Reminder (unless disabled by the institution). Visual and auditory alarms may be turned off if option is enabled by the institution.

Display/ Indicators
LED Bar: Multiple colors to indicate high, medium, and low priority alarms
Display: 8.8" wide-angle, high color (16.7M) IPS display
Data update rate: 1 sec for tcPCO2, SpO2, PR, RHP
Data validity: Clear representation of data validity / quality for tcPCO2, SpO2, PR, PI, RHP (valid, questionable, unstable, invalid)
Measurement screens: Various preconfigured, user-selectable measurement screens displaying values and real time trends for tcPCO2, SpO2, PR, RHP; alarm limits for tcPCO2, SpO2, PR; Baseline, Baseline values and Delta-x values for tcPCO2, SpO2, RHP; values for pulsation index, AHP; Pleth Wave or blip bar reflecting relative pulse amplitude; visual alarm signals; status icons (e.g., remaining monitoring time) and status messages.
'Calibration' / 'Ready for use' screens: Display important system information about patient mode, profile, and calibration status and/or progress.
Tutorials: Tutorials provide step-by-step instructions for common workflows, including monitoring-specific tutorials like sensor application and sensor cleaning and maintenance-related tutorials like membrane change, sensor clean and soak, and sensitivity test. Certain troubleshooting workflows have interactive guidance available to help users resolve errors in real-time.

Favorites
Favorites: Users may add different monitor menus to their Favorites tab to allow easy access to the most frequently used monitor menus.
Events: Users have the option to register events, i.e., medication administration, manipulation, or another user-created event. Several events can be stored in the tCOM+ for subsequent display on the measurement screen or in the Events log.
Languages: Catalan, Danish, Dutch, English, Finnish, French, German, Italian, Norwegian, Polish, Portuguese, Spanish, Swedish
Highly configurable: Patient Mode, Enabled Parameters, Severinghaus Correction Mode, Heating Power Mode, Spot Check Mode, Parameter Display Color, PCO2/PO2 Unit (mmHg or kPa), time ranges for online trends, sweep speed of Pleth wave, Sleep Mode, Brightness, Audio Settings, Menu Access, etc.

tCOM+ Profiles
Profiles help to ensure standardization of settings on all the monitors in a unit. Profiles can be configured in the password protected Advanced Settings menu to fit the specific needs of the clinical setting.

Special (safety-relevant) tCOM+ Parameters
Within a password-protected area of the monitor, the institution can configure all menu accessible parameters and special parameters to disable or restrict operator access to menu accessible parameters. For example, the maximal Sensor Temperature or Site Time can be adapted and restricted to safe settings for the patient population.

Patient Data Management
The tCOM+ automatically stores PCO2, SpO2, PR, RHP, and PI data in the internal memory for on-screen viewing of trends (up to 48 hours) and data export via the DATA/SERVICE USB port. The Data Recording Interval is 1 second; non-volatile memory provides storage of up to one year.

Data Communication
Wired
- Serial Data Port (RS-232): For communication with external data collection systems such as personal computers or multi-parameter bedside monitors.
- LAN port: for communication with external computer-based data collection systems.
- Analog output (0–1V): provides voltage outputs for tcPCO2, SpO2, PR, and the Pleth waveform (selectable ranges).
- DATA/SERVICE USB Port: for SW upgrades or data download via USB-C.
- Universal Connectivity Port: standard USB-C port for future connectivity options.

Wireless
- Wi-Fi: for connection to external networks and communication with external computer-based data collection systems.

Electrical
Monitor: 12 VDC Power, max. 3 A, by external power supply; Type BF, Applied Part, Defibrillation Proof.
Power supply for hospital use: Class II FE (with functional earth), Electrical Safety (IEC 60601-1)
Power supply for home use: Class II (without functional earth), Electrical Safety (IEC 60601-1)
Internal battery type: rechargeable, sealed Li Ion Battery
Battery Capacity (new, fully-charged): Normal Operation: up to 4 hours; Sleep Mode: up to 7 hours
Charging Time: approximately 4 hours

Environmental
Transport / storage temperature: 0 – 50°C (32 – 122°F)
Transport / storage humidity: 10 – 90% non-condensing
Operating temperature: 5 – 40°C (41 – 104°F)
Operating humidity: 15 – 90% non-condensing
Operating altitude: -400 – 5000 m (-1300 – 16404 ft)
Accuracy: ± 3 mmHg (0.4 kPa)
Built-in barometer: Range: 350 – 820 mmHg (47 – 109 kPa); Accuracy: ± 3 mmHg (0.4 kPa)

Compliance
IEC 60601-1, ANSI/AAMI ES60601-1, CAN/CSA-C22.2 No. 60601-1, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-2-23, ISO 80601-2-61, 60601-1-11, 60601-1-2

Regulatory Approval
The tCOM+ monitor is FDA-cleared and fulfills the General Safety and Performance Requirements stipulated by the EU Medical Device Regulation (EU) 2017/745.