SENTEC DIGITAL MONITORING SYSTEM with OxiVenT™ Sensor

$tcPCO_2$ | $tcPO_2$ | SpO_2 | PR | HP
Continuous or V-Check™ Mode
Neonates, Pediatrics & Adults
Noninvasive & Easy to Use
Accurate & Fast
Gentle & Safe

Overall System Performance

Transcutaneous Carbon Dioxide Partial Pressure ($tcPCO_2$)[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 < 80 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.

Oxygen Saturation (SpO_2)
Measurement range: 1 – 100%
Resolution: 1%
Accuracy: ±2.25% (A_{rms} over 70% to 100%)[3]
Averaging mode: 2, 4, 6, 8, 12, 16, and 32 sec
Approved sites for SpO_2/PR monitoring: Earlobe, low on forehead, cheek, upper arm, on scapula (shoulder blade)

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

Transcutaneous Oxygen Partial Pressure ($tcPO_2$)[4]
Measurement range: 0 – 800 mmHg (0 – 106.7 kPa)
Resolution: 1 mmHg (0.1 kPa)
Drift[2]: Typically < 0.1%/hour
Response time (T90)[2]: Typically < 150 sec
Linearity[2]: Typically < 1 mmHg (0.13 kPa)
Interferences by anesthetic gases[2]: Negligible
Stabilization/ artifact detection: After sensor application or occurrence of a $tcPO_2$ artifact, $tcPO_2$ is displayed in grey until it (re)stabilizes.

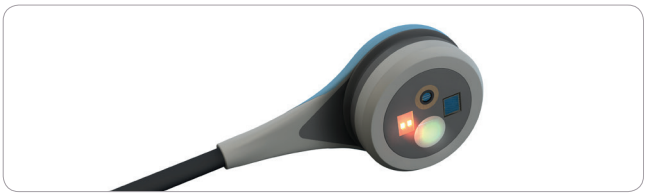
Pulse Rate (PR)
Measurement range: 30–250 bpm
Resolution: 1 bpm
Accuracy: ± 3 bpm

Pulsation Index (PI)
Measurement range: 0.1–10.0%
Resolution: 0.1%

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

[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 SDM 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 43 °C.
[3] SpO_2 accuracy specification is based on controlled hypoxia studies on healthy, adult volunteers over the specified saturation range by applying a SenTec TC Sensor to each of the specified measurement sites.
[4] $tcPO_2$ corresponds to the measured cutaneous PO_2 and provides an estimate of arterial PO_2 (PaO_2). In newborns, $tcPO_2$ correlates with arterial PO_2 (PaO_2) almost in a one to one relationship at a sensor temperature of 43 to 44 °C, whereby the accuracy of $tcPO_2$ compared to PaO_2 is best up to PaO_2 = 80 mmHg (10.7 kPa), above which it increasingly tends to read lower than PaO_2 (especially in adults). Refer to J. W. Severinghaus, The Current Status of Transcutaneous Blood Gas Analysis and Monitoring, Blood Gas News 1998, 7(2):4-9 and references contained therein.

OxiVenT™ Sensor (OV-A/P/N) (Digital, combined $tcPCO_2$/ $tcPO_2$/ SpO_2/ PR sensor)



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

Measurement Principle
Severinghaus-type PCO_2 sensor combined with reflectance 2-wavelength pulse oximetry and an optical fluorescence quenching PO_2 sensor.

Digital Microtechnology
Highly integrated opto-electronic sensor head comprising micro pH-electrode, optical oximetry unit, temperature sensors, heating unit, optical fluorescence excitation/ sensing 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 SenTec Digital Monitor (SDM).

Sensor Memory
Sensor-specific data are stored in the sensor's memory after manufacturing (serial number, factory PCO_2 sensitivity/ calibration, factory PO_2 sensitivity, calibration etc.) and during operation (sensor calibration, membrane change, etc.).

Sensor Membrane Change
Up to 6 weeks (default 4 weeks). Patented '4 Press-and-Turn steps' membrane tool for simple and 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 $tcPCO_2$/ $tcPO_2$ are marked as 'invalid' ($tcPCO_2$/ $tcPO_2$ values replaced by '---'). $TcPO_2$ is calibrated during each mandatory calibration and subsequently approximately once every 24 hours during one of the anyways ongoing PCO_2 calibrations.

SMART CALMEM
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 CALMEM significantly reduces the number of required calibrations and the calibration gas consumption.

Sensor Internal Temperature Control
Sensor Temperature is reliably supervised/ controlled by two independent circuits. In case of errors the sensor's power consuming parts are switched-off.

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: Approx. 80 cm (31'') [plus Digital Sensor Adapter Cable of 150 cm (59''), 250 cm (98''), or 750 cm (295'') length]
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/ store sensor with membrane and protected from light/ radiation.

Sensor Life Time
The sensor is granted in the sense of a license to the customer and its use is only granted and permitted during the life time (license period). With expiration of the life time its operation automatically terminates. The life time (license period) is 12 months after first ex-factory use. For the avoidance of doubt, the license is granted for the life time only and is not renewed or prolonged in case the sensor is repaired or replaced by SenTec due to defect.

SenTec Digital Monitor (SDM) (Software version SMB SW-V08.00; MPB SW-V06.00; **with** activated PO_2 Channel)

Physical Characteristics
Weight: 2.3 kg (5.1 lbs) – including gas cylinder
Size: 10.2 cm x 27.0 cm x 23.0 cm (4.00'' x 10.63'' x 9.06'')
Flip feet: Flip feet serving as carrying handle or to adjust angle for improved table-top viewing.
Mountable: Mountable on roll/ infusion stands, wall mounts/ railings, transport incubators, etc.

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 guarantee reliable calibrations.

Sensor Temperature
Selectable sensor temperature range: Configurable by institution between 37.0 and 44.5 °C (in steps of 0.5 °C; default range=40.0-44.0 °C). Safety controls of the SDM may restrict the selectable range depending on the type of the connected sensor, the selected patient mode, or the enabled parameters.
Selectable range: 37.0–44.5 °C with OxiVenT™ Sensor and 37.0–43.5 °C with V-Sign™ Sensor 2 (or as restricted by institution and/ or safety controls of the SDM). In steps of 0.5 °C. PO_2 only available with 41 °C or higher.
Default sensor temperature: If $tcPO_2$ is enabled 43.0 °C in Neonatal Mode and 44.0 °C in Adult Mode. Otherwise, 41.0 °C in Neonatal Mode and 42.0 °C in Adult Mode (or closest setting of selectable range if default Sensor Temperature is outside selectable range).

Initial Heating
Temporarily increases sensor temperature after sensor application for faster perfusion and results (Neo + 1.5 °C max. 43.5 °C/ Adult +2 °C max. 44.5 °C; can only be switched on if enabled by institution).

Redundant Sensor Temperature Control on SDM
To guarantee safe operation should the sensor's temperature control fail, the SDM firmware redundantly controls the temperature of the connected sensor. Restarts or switches off sensor in case of errors.

Site Time
Maximal selectable 'Site Time': Configurable by institution between 0.5 and 12.0 hours (in steps of 0.5 hours; max. 6.0 hours in Neonatal Mode at 43 °C or in Adult Mode at 44 °C). Depending on the selected patient mode and with increasing sensor temperature safety controls of the SDM may enforce a safer setting.
Selectable range: 0.5-12.0 hours (or as restricted by institution and/ or safety controls of the SDM). In steps of 0.5 hours.
Default 'Site Time': 2.0 hours in Neonatal Mode at 43.0 °C or in Adult Mode at 44.0 °C (or as restricted by institution and/ or safety controls of the SDM).

Site Timer
Timer indicating remaining 'Site Time' during monitoring. Triggers an alarm once 'Site Time' has elapsed.

Site Protection
Safety feature which reduces sensor temperature (to 39 °C if SpO_2 disabled and to 41 °C if SpO_2 enabled) once 'Site Time' has elapsed (can only be switched off if enabled by institution).

Alarm System
Alarm signals: Visual/auditory alarm signals for high/low $tcPCO_2$, $tcPO_2$, SpO_2, PR, technical alarms. 'Alarm Melodies' are institution-selectable.
Alarm inhibition: Auditory alarm signals can be PAUSED (1 or 2 minutes) or switched off permanently (if enabled by institution).
Alarm system status indicators: Alarm Status Icon, AUDIO Status Icon, AUDIO PAUSED/ OFF Indicator (LED indicator), AUDIO OFF Reminder (can only be switched off if enabled by institution).

Display/Indicators
LED indicators: ON/OFF; AUDIO PAUSED/OFF; AC Power/Battery; Battery Charging
Display size: 16 cm (6.3'') diagonal TFT Color Display (LED backlight)
Data update rate: 1 sec for $tcPCO_2$, $tcPO_2$, SpO_2, PR, RHP; between 1.5 and 30 mm/sec for Pleth Wave
Data validity: Clear representation of data validity/quality for $tcPCO_2$, $tcPO_2$, SpO_2, PR, PI, RHP (valid, questionable, unstable, invalid)
Measurement screens: Various preconfigured, user-selectable measurement screens displaying values/ online trends for $tcPCO_2$, $tcPO_2$, SpO_2, PR, RHP; alarm limits for $tcPCO_2$, $tcPO_2$, SpO_2, PR; Baseline, Baseline values and Delta-x values for $tcPCO_2$, $tcPO_2$, SpO_2, RHP; values for pulsation index, AHP, IC indicator; wiper bar Pleth Wave or blip bar reflecting relative pulse amplitude; visual alarm signals; status icons (e.g. remaining monitoring time) and status messages; 'Patient info' during remote monitoring with V-CareNeT™
'Calibration'/ 'Ready for use' screens: 'Calibration' and 'Ready for use' screens displaying important system information (patient mode, sensor temperature and 'Site Time' related settings, name of profile, 'Patient info' during remote monitoring with V-CareNeT™, etc.)
'Quick Access Menus': To set new Baseline, new RHP reference, or 'Operator Events' during monitoring (and other functions).
Languages: Català, čeština, dansk, deutsch, english, español, français, italiano, japanese (katakana), polski, nederlands, norsk, português, русский (russian), svenska, suomi, türkçe
Highly configurable: Patient Mode, Enabled Parameters, Severinghaus Correction Mode, Heating Power Mode, V-Check™ Mode, Parameter Display Color, PCO_2/PO_2 Unit, (time) ranges for online trends, sweep speed of Pleth wave, Sleep Mode, Brightness, Audio Settings, Menu Access, Profile Mode ('Basic' or 'Institutional')

SDM Profiles
'SDM Profiles' help to ensure that all your SDMs can be configured the way you want them to. Within V-STATS™ preconfigured 'SDM Profiles' tailor-made to meet the specific needs of varying clinical settings are available. With V-STATS™, 'SDM Profiles' can be customized and up to 4 'SDM Profiles' can be stored on the SDM. During use of the SDM, the operator at any time can restore the active 'SDM Profile' (if modified) or select a different profile in the menu of the SDM. If at power-up the settings differ from those of the active 'SDM Profile' the modified settings can be maintained, the active 'SDM Profile' can be restored, or a different 'SDM Profile' can be selected.

Special (safety-relevant) SDM Parameters
Within a password-protected area of V-STATS™ the institution can configure all menu accessible parameters as well as special parameters not being accessible in the menu of the SDM. Several of these special parameters permit to disable or to restrict operator-access to menu accessible parameters. The maximal 'Sensor Temperature' or the maximal 'Site Time' selectable at the bedside, for example, can be adapted to settings being safe for your typical patients.

Patient Data Management
Data Recording Interval institution-selectable between 1 and 8 seconds; non-volatile memory providing between 35/ 227 hours monitoring data (at 1-/8-seconds resolution); automatic determination of measurement start/ end enables convenient selection of measurement(s) for on-screen viewing/ printing of graphical trends and statistical summary. V-STATS™ provides fast data download to PC (approx. 3 min. for 8 hours data at 4-seconds resolution) for subsequent display, analysis, and reporting within V-STATS™. With V-CareNeT™ simultaneous download is possible from multiple SDMs.

Interfaces (isolated from sensor port)
Serial output (RS-/EIA-232): Supported protocols: SenTecLink, Philips VueLink/IntelliBridge, Spacelabs Flexport, Serial Printer, TCB
LAN port (Ethernet 10 BaseT): For Remote Monitoring with V-CareNeT™
Analog output (0–1V): $tcPCO_2$, SpO_2, PR, pleth wave (selectable ranges)
Nurse-call: Open and close type relays

Electrical
Instrument: AC Power: 100 – 240 V (50/60 Hz), max. 450 mA/ Electrical Safety (IEC 60601-1): Class I, Type BF, Applied Part – Defibrillation Proof, IPX1.
Internal battery: Type: rechargeable, sealed Lilon Battery/ Capacity (new fully charged battery): up to 10 hours (if Sleep Mode=OFF, AUTO) and up to 12 hours (if Sleep Mode=ON)/ Charging Time: approx. 7 hours

Environmental
Transport/storage temperature: 0 – 50 °C (32 – 122 °F)
Transport/storage humidity: 10 – 95% non-condensing
Operating temperature: 10 – 40 °C (50 – 104 °F)
Operating humidity: 15 – 95% non-condensing
Operating altitude: -400 – 4000 m (-1300 – 13120 ft) if connected to mains; -400 – 6000 m (-1300 – 19600 ft) if operated on battery.
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 60601-1-2, IEC 60601-1-8, IEC 60601-2-23, ISO 80601-2-61, ISO 10993, ISO 14971

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Specifications are subject to change without notice

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