

SENTEC DIGITAL MONITORING SYSTEM with V-Sign™ Sensor



tcPCO₂ | SpO₂ | PR | HP

Continuous or V-Check™ Mode

Adults, Pediatrics & Neonates

Noninvasive & Easy to Use

Accurate & Fast

Gentle & Safe

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)

Drift²: Typically < 0.5%/hour

Response time (T90)²: Typically < 75 sec

Linearity²: Typically < 1 mmHg (0.13 kPa)

Interferences by anesthetic gases: Negligible

Stabilization/ artifact detection: After sensor application or occurrence of a tcPCO₂ artifact, tcPCO₂ 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%

Oxygen Saturation (SpO₂)

Measurement range: 1 – 100%

Resolution: 1%

Accuracy: ±2% (A_{rms} over 70% to 100%)³

Averaging mode: 2, 4, 6, 8, 12, 16, and 32 sec

Approved sites for SpO₂/ PR monitoring: Earlobe, low on forehead, cheek, upper arm, on 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 tcPCO₂ from the measured cutaneous PCO₂. This algorithm accounts for temperature and metabolic correction factors. The tcPCO₂ values displayed by the SDM are corrected/ normalized to 37 °C and provide an estimate of arterial PCO₂ (PaCO₂) at 37 °C. Correction factors can be customized by institution. Additionally, and subject to institution's permission, In-vivo Correction (IC) of tcPCO₂ 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 SpO₂ 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 (VS-A/P/N) (Digital, combined tcPCO₂/ SpO₂/ PR sensor)



XI.1

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.

XII.1

Sensor Calibration

Calibration duration: Typically 3 minutes (ex. factory)

XII.2

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 tcPCO₂ marked as 'questionable'. Thereafter, sensor calibration is **mandatory** and tcPCO₂ is marked as 'invalid' (tcPCO₂ value replaced by '---').

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) **XVI.1**

Long term storage temperature: 15 – 26 °C (59 – 78 °F) **XVI.2**

Transport/ store sensor with membrane and protected from light/ radiation.

VII.1

General Characteristics

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

VIII.1

Measurement Principle

Severinghaus-type PCO₂ sensor combined with reflectance 2-wavelength pulse oximetry.

IX.1

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 SenTec Digital Monitor (SDM).

X.1

Sensor Memory

Sensor-specific data are stored in the sensor's memory after manufacturing (serial number, factory PCO₂ sensitivity/ calibration, etc.) and during operation (sensor calibration, membrane change, etc.).

SenTec Digital Monitor (SDM) (Software version SMB SW-V08.00; MPB SW-V06.00; without activated PO₂ Channel)

XVII.1 Physical Characteristics

Weight: 2.3 kg (5.1 lbs) – including gas cylinder

XVII.2 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

XVIII.1 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

XIX.1 **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:** 37.0–43.5 °C (or as restricted by institution and/ or safety controls of the SDM). In steps of 0.5 °C.

XIX.2 **Default sensor temperature:** 42.0 °C in Adult Mode and 41.0 °C in Neonatal Mode (or closest setting of selectable range if default Sensor Temperature is outside selectable range).

Initial Heating

XX.1 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

XXI.1 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

XXII.1 **Maximal selectable 'Site Time':** Configurable by institution between 0.5 and 12.0 hours (in steps of 0.5 hours; max. 12.0 hours in Adult Mode at 42 °C and in Neonatal Mode at 41 °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.

XXII.2 **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 SDM).

Site Timer

XXIII.1 Timer indicating remaining 'Site Time' during monitoring. Triggers an alarm once 'Site Time' has elapsed.

Site Protection

XXIV.1 Safety feature which reduces sensor temperature (to 39 °C if SpO₂ disabled and to 41 °C if SpO₂ enabled) once 'Site Time' has elapsed (can only be switched off if enabled by institution).

Alarm System

XXV.1 **Alarm signals:** Visual/ auditory alarm signals for high/ low tcPCO₂, SpO₂, PR, and technical alarms. 'Alarm Melodies' are institution-selectable.

XXV.2 **Alarm inhibition:** Auditory alarm signals can be PAUSED (1 or 2 minutes) or switched off permanently (if enabled by institution).

XXV.3 **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

XXVI.2 **LED indicators:** ON/ OFF; AUDIO PAUSED/ OFF; AC Power/ Battery; Battery Charging

XXVI.1 **Display size:** 16 cm (6.3") diagonal TFT Color Display (LED backlight)

XXVI.3 **Data update rate:** 1 sec for tcPCO₂, SpO₂, PR, RHP; between 1.5 and 30 mm/sec for Pleth Wave

XXVI.4 **Data validity:** Clear representation of data validity/ quality for tcPCO₂, SpO₂, PR, PI, RHP (valid, questionable, unstable, invalid)

XXVI.5 **Measurement screens:** Various preconfigured, user-selectable measurement screens displaying values/ online 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, 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, portuguese, русский (russian), svenska, suomi, türkçe

Highly configurable: Patient Mode, Enabled Parameters, Severinghaus Correction Mode, Heating Power Mode, V-Check™ Mode, Parameter Display Color, PCO₂/PO₂ 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): tcPCO₂, SpO₂, 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 LiIon 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

XXVIII.1

XXVIII.2

XXIX.1

XXIX.2

XXIX.3

XXIX.4

XXIX.5

XXIX.6

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Specifications are subject to change without notice

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