SENTEC DIGITAL MONITORING SYSTEM

SPECIFICATIONS

$TcPCO_2$ | SPO_2 | PR
NONINVASIVE
CONTINUOUS
REAL-TIME

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 (13 kPa)
- 1 mmHg (0.1 kPa) above 100 mmHg (13 kPa)

Drift (in vitro, at 42 °C):
- V-Sign™ Sensor 2: typically < 0.5%/hours

Response time (T90, in vitro, at 42 °C):
- V-Sign™ Sensor 2: typically < 75 sec

Interferences by anesthetic gases (in vitro): negligible.
After sensor application or detection of a $tcPCO_2$ artifact, $tcPCO_2$ values are marked as unstable (displayed in grey) until $tcPCO_2$ (re)stabilizes.

Oxygen Saturation (SpO_2)
Approved sites for SpO_2/PR monitoring:
- V-Sign™ Sensor 2: ear lobe, forehead, cheek
- SpO_2 Soft Sensor: fingertip, toe

Measurement range: 1–100%
Resolution: 1%
Accuracy (A_{rms} over 70% to 100%)[2]: ±2%
Averaging mode: 2, 3, 4, 6, 8, 12, 16, and 32 sec

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

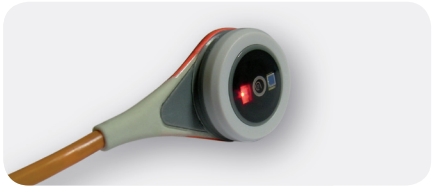
Resolution: 1 mW

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

Pulsation Index (PI)
Measurement range: 0.1–22.0%
Resolution: 0.1%

[1] An algorithm developed by J.W. Severinghaus is used to calculate $tcPCO_2$ from the measured cutaneous PCO_2 ($PcCO_2$). 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 within a password protected area of V-STATS™. Additionally, and subject to institution's permission (password protected), In-vivo Correction (IC) of $tcPCO_2$ values is possible at the bedside.
[2] SpO_2 accuracy specification is based on controlled hypoxia studies on healthy, adult volunteers over the specified saturation range by applying a sensor of the specified sensor type to each of the specified measurement sites.

V-SIGN™ SENSOR 2 (VS-A/P/N)



Physical Characteristics
Reusable, waterproof
Sensor head:
- Size (diameter x height): 14 x 9 mm (0.55 x 0.35")
- Weight: < 2.9 g (0.1 oz)

Sensor cable:
- Highly flexible, shielded, polyurethane coated
- Length: 80 cm (31") (length of Digital Sensor Adapter Cable: 150 cm (59"), 250 cm (98"), 750 cm (295") [on request up to 920 cm (362")])

Patients
Suitable for adult, pediatric, and neonatal patients.

Measurement Principle
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 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 ($tcPCO_2$ sensitivity, serial number, etc.) and during operation (e.g. sensor calibration, membrane change, etc.).

Temperature Control
Supervised and controlled by two independent circuits. Triggers alarm message.
Measurement range: 38–45 °C
Resolution: 0.1 °C
Accuracy: ±0.2 °C

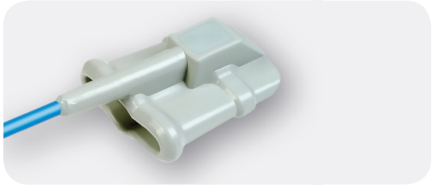
Sensor Membrane Change
Up to 6 weeks

Sensor Calibration
Calibration duration:
- Typically 3 minutes (ex factory)

Calibration interval:
- Up to 12 hours

Transport/Storage
Transport temperature: 0–50 °C (32–122 °F)
Long term storage temperature: 15–26 °C (59–78 °F)
Store sensor with membrane

SpO_2 SOFT SENSOR



Physical Characteristics
Reusable, sensor head consisting of single molded, sheath-like rubber tube, resilient to immersion.
Sensor cable:
- Shielded silicone cable
- Length: 90 cm (35") (length of SpO_2 Adapter Cable: 150 cm (59"), 250 cm (98"), 750 cm (295") [on request up to 920 cm (362")])

Storage temperature:
- -20 °C–+70 °C (-4 °F–158 °F)

Patients
Suitable for patients weighting in excess of 20 kg / 44 lbs.

Measurement Principle
Transmissive 2-wavelength pulse oximetry

Plug-in compatible with Nellcor™ non-OxiMax™ oximetry (Nellcor and OxiMax are registered trademarks of Covidien).

SENTEC DIGITAL MONITOR (SDM) (Software version SMB SW-V07.01; MPB SW-V05.01)

Physical Characteristics
Weight: 2.5 kg (5.5 lbs) – including gas cylinder
Size: 10.2 x 27.0 x 23.0 cm (4.00 x 10.63 x 9.06'')
- Flip feet serving as carrying handle or to adjust angle for improved table-top viewing
- Mountable on roll/infusion stands, wall mounts/ railings, transport incubators, etc.

Preset Site Time
Maximal Selectable Preset Site Time (MS-PST):
- Institution-selectable (password protected) from 0.5 – 12.0 hours (in increments of 0.5 hours; factory default = 12.0 hours at 42 °C)
- Decreases with increasing Sensor SET Temperature
- Operator-selectable: 0.5 hours to MS-PST (in 0.5 hour increments)

Default Preset Site Time (after changing patient mode):
- 8.0 hours (or MS-PST if MS-PST <8 hours) in Adult Mode at 42.0 °C or in Neonatal Mode at 41.0 °C
- Decreases with increasing Sensor SET Temperature

Site Timer
- Indicates remaining monitoring time
- Triggers an alarm once time has elapsed

Sensor SET Temperature
Maximal Selectable Sensor SET Temperature (MS-SST):
- Institution-selectable (password protected) from 39.0 – 43.5 °C (in increments of 0.5 °C; factory default = 42.0 °C)
- In Neonatal Mode restricted to 43.0 °C
- Operator selectable: 39.0 °C – MS-SST (in 0.5 °C increments)

Default Sensor SET Temperature (after changing patient mode):
- In Adult Mode: 42.0 °C or MS-SST (if MS-SST <42.0 °C)
- In Neonatal Mode: 41.0 °C or MS-SST (if MS-SST <41.0 °C)

Initial Heating
Feature which temporarily increases sensor temperature after sensor application (default setting: OFF; operator access requires institution's permission [password protected])

Site Protection
Safety feature which reduces sensor temperature once Preset Site Time and certain delay has elapsed (default setting: ON; operator access requires institution's permission [password protected])

Temperature Control
- SDM software redundantly controls temperature of connected sensor
- Restarts or switches sensor OFF in case of faults

Sensor Calibration
- Built-in sensor calibration chamber for 1-point calibration
- Automatic calibration ensures that system is «Ready for use» if V-Sign™ Sensor is stored in calibration chamber
- Unmatched calibration reability as a result of comprehensive control of sensor calibration

Smart CalMem
The Smart CalMem feature significantly reduces calibration gas consumption as well as the number of calibrations required. It allows the clinician to disconnect the sensor from the extension cable for up to 30 minutes without affecting calibration status. In addition this feature allows room air exposure of sensor for up to 10 minutes.

Alarm System
- Visual and auditory alarm signals for high/low $tcPCO_2$, SpO_2, PR and technical alarms per IEC 60601-1-8. Institution-selectable «Alarm Melodies» (password protected)
- Auditory alarm signals can be PAUSED (1 or 2 minutes) or switched off permanently (if enabled by institution [password protected])
- Alarm system status indicators: Alarm Status Icon, AUDIO Status Icon, AUDIO PAUSED / OFF Indicator (LED indicator); AUDIO OFF Reminder (can be switched off if enabled by institution [password protected])

Display/Indicators
- 16 cm (6.3") diagonal TFT Color Display (LED backlight)
- «Calibration» and «Ready for use» screens displaying important system information (patient mode, sensor temperature and site time related settings, name of profile, patient data during remote monitoring with V-CareNeT™, etc.)
- Various preconfigured, user-selectable measurement screens displaying values, alarm limits and online trends for $tcPCO_2$, SpO_2, PR, baselines for $tcPCO_2$ / SpO_2, delta baseline (B) and delta 10 min (10) values for $tcPCO_2$ / SpO_2, values for pulsation index, and heating power, wiper bar Pleth Wave or blip bar reflecting relative pulse amplitude, monitoring time, status icons, status messages, visual alarm signals, patient data during remote monitoring with V-CareNeT™
- Quick Access Menu with Baseline and Operator Event Markers and other functions

Data update rate:
- $tcPCO_2$, SpO_2, PR: 1 sec
- Pleth Wave: between 1.5 and 30 mm/sec

Clear representation of data validity (valid, questionable, unstable, invalid)
Configurable: patient mode, enabled parameters, parameter color, $tcPCO_2$ unit, time ranges for online trends, sweep speed of pleth wave, sleep mode, brightness, Severinghaus correction mode, V-Check mode, etc.
Languages: català, čeština, dansk, deutsch, english, español, français, italiano, japanese – katakana, polski, nederlands, norsk, português, svenska, suomi, türkçe.
LED indicators: AC Power / Battery; Battery Charging; AUDIO PAUSED / OFF; ON/OFF

Interfaces (isolated from sensor port)
Serial output (RS-/EIA-232): supported protocols: SenTecLink, Philips VueLink/IntelliBridge, TCB Protocol, Spacelabs Flexport, Serial Printer
LAN port (Ethernet 10 Base-T): required for remote monitoring with V-CareNeT™
Analog output (0–1 V): $tcPCO_2$, SpO_2, PR, pleth wave (selectable ranges)
Nurse-call capability: open and close type relays

Patient Data Management
- Non-volatile internal memory
- Data recording interval institution-selectable between 1 and 8 seconds
- Memory capacity (monitoring data): Typically 34 hours at 1-second resolution, Typically 227 hours (9.5 days) at 8-seconds resolution
- Automatic determination of measurement start/end enabling convenient selection of measurement(s) for subsequent on-screen viewing, printing, or downloading to PC
- On-screen viewing and printing of graphical trends and statistical summary for selected measurement(s)
- V-STATS™ features fast download of selected measurement(s) to PC for subsequent analysis, reporting, printing (typically <1 min for 8 hours measurement and data interval of 4 sec) and simultaneous download from multiple SDMs possible with V-CareNeT™

Parameters Settings Management
- Safety-relevant parameters are only changeable/ accessible by using V-STATS™ within a password protected area, all other parameters are operator selectable
- Institution-selectable Parameters Settings Mode: «Basic» or «Institutional» (supporting up to four different profiles)
- Profiles can be stored on SDM by using V-STATS™
- Profiles are managed in a menu. At power-up of SDM settings from previous use can be maintained
- Various preconfigured SDM Parameter Settings are available within a password protected area of V-STATS™ (SLEEP, NICU, ICU, HOME, V-CHECK, General Care Floor (GCF), PACU etc.)
- Menu-Access can be disabled/blocked (e.g. for home use)

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 Li-Ion Battery
- Capacity (new fully charged battery): Up to 11 hours (if Sleep Mode=OFF, AUTO) and up to 16 hours (if Sleep Mode=ON)
- Charging Time: ~7 hours

Environmental
Transport/storage temperature:
0–50 °C (32–155 °F)
Transport/storage humidity:
10–95% non-condensing
Operating temperature: 10–40 °C (50–104 °F)
Operating humidity: 15–95% non-condensing
Operating altitude (connected to mains):
-400–4000 m (-1300–13120 ft)
Operating altitude (operating on battery):
-400–6000 m (-1300–19600 ft)
Built-in barometer:
- Range: 350–820 mmHg (46.7–109.3 kPa)
- Accuracy: ± 3 mmHg (0.4 kPa)

Compliance
IEC 60601-1, UL-60601-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-1-8, IEC 60601-2-23, ISO 9919, ISO 10993, ISO 14971

SenTec AG
Ringstrasse 39 | CH-4106 Therwil
Phone: +41 61 726 97 60
Fax: +41 61 726 97 61
info@sentec.ch
www.sentec.ch

CE 0120

RF-005856-j
Specifications are subject to change without notice

Your local distributor: