

SenTec Digital Monitoring System

- pCO₂, SpO₂ and pulse
 - noninvasive, continuous, real-time
 - digital V-Sign™ Sensor

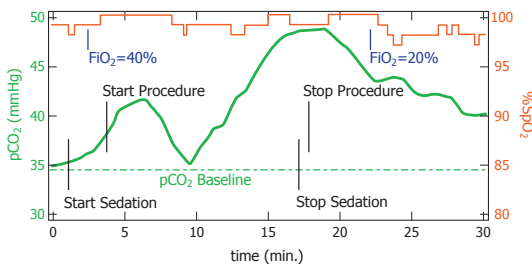


Features and Benefits

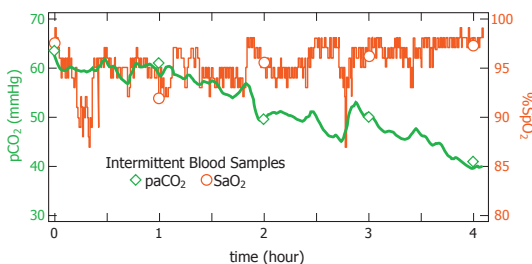
SenTec Digital Monitoring System (SDMS) with V-Sign™ Sensor provides continuous, non-invasive, real-time monitoring of carbon dioxide partial pressure (pCO₂), oxygen saturation (SpO₂), and pulse. V-Sign™ Sensor is easily applied to the earlobe or – for pCO₂ monitoring only – to a conventional pCO₂ site. The SDMS responds quickly and accurately to changes in patient's pCO₂- and/or SpO₂-levels.

Improve patient management by obtaining continuous information on your patient's ventilation and oxygenation. Increase comfort and safety of both your patient and your medical staff. Clinical studies¹ document the accuracy and reliability of the SenTec Digital Monitoring System.

Noninvasive and continuous real-time monitoring of patient ventilation and oxygenation



SDMS data during procedural sedation in a spontaneously breathing patient (FIO₂=40%). The pCO₂ data unambiguously reveal sedation caused hypoventilation. Pulse oximetry reliably detects abnormalities in respiratory function only if patients breath room air. In patients inspiring supplemental oxygen continuous pCO₂ and SpO₂ data therefore are important to reliably detect respiratory problems.



SDMS data during four hours of NPPV in a patient with hypercapnic respiratory failure. Continuous pCO₂ data provide a sensitive method for monitoring alveolar ventilation in patients receiving NPPV.

senTec



V-Sign™ Sensor

The digital V-Sign™ Sensor enables simultaneous monitoring of pCO₂, SpO₂ and pulse. It incorporates the latest opto-electronics and digital signal processing technologies. In combination with local arterialization of the warmed measurement site, V-Sign™ Sensor achieves excellent measuring performance. Applied to the earlobe – a site physiologically close to the central circulation of the cranium – V-Sign™ Sensor detects changes in SpO₂ notably earlier than finger pulse oximetry sensors. Applied on sites other than the earlobe V-Sign™ Sensor is currently indicated for pCO₂ monitoring only.

Measurement principle

Severinghaus-type pCO₂ measurement
2-wavelength reflectance pulse oximeter

Digital microtechnology

Opto-electronic components, micro pH-electrode, temperature sensors, and a mixed-signal micro-controller reside on a digital sensor print. Sensor specific data are stored in a digital memory chip.

Sensor temperature

Set to 42°C (107.6°F) in "Adult" mode
Set to 41°C (105.8°F) in "Neonatal" mode
Preset site time: 8 hours
Supervised by two independent circuits

Sensor membrane change

Every 4 weeks under normal use

Characteristics of the sensor head

Diameter: 14 mm (0.55")
Height: 9 mm (0.35")
Weight: < 3 g (0.1 oz)
Waterproof

Cable

Highly flexible, shielded, polyurethane coated

Transport/Storage (in factory package)

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



For Adult, pediatric, and neonatal use

Non-invasive monitoring with just one sensor:

Carbon Dioxide Partial Pressure (pCO₂)

Oxygen Saturation (SpO₂)

Pulse - Plethysmogram and Pulse Rate (PR)

Enabled parameters selectable in "Adult" mode

In "Neonatal" mode SpO₂/PR are automatically disabled

Accurate and fast measurement

Convenient and safe sensor application

Lightweight sensor head (< 3 g)

Maximum patient comfort

Application areas/Indications

(Neonatal) Intensive Care, Recovery Room, Respiratory Medicine, Sleep Labs, Procedural Settings, Intra-Hospital Transport

(Noninvasive) Ventilation, High Frequency Oscillation Ventilation, (Post) Extubation, Pain Management (Conscious sedation, PCA, titration of opioids), Sleep Diagnostics/Therapy, Titration of oxygen (COPD)



TFT Color Display

Selectable Parameter Color

Various preconfigured Measurement Screens

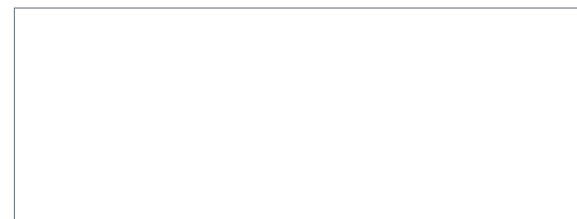
Ready for use

Integrated docking station stores and automatically calibrates the V-Sign™ Sensor

Cost-effective

Reduces the number of blood samples required to assess patients' ventilation and oxygenation

Your local distributor:



SenTec Digital Monitoring System – overall performance

Carbon Dioxide Partial Pressure (pCO₂)²

Measurement range: 0 – 200 mmHg (0 – 26.67 kPa)
Resolution: 0.1 mmHg (0.1 kPa)

In Vitro Performance

Drift: typically < 1%/h
Response time (T90): typically < 80 s

Oxygen Saturation (SpO₂)

Measurement range: 1 – 100%
Resolution: 1%
Accuracy (Arms)³: 70 – 100%: ± 2%

Pulse

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

SenTec Digital Monitor (SDM) – technical specifications

Weight

2.5 kg (5.5 lbs)

Size (HxWxD)

10.2 cm x 27.0 cm x 23.0 cm (4.00" x 10.63" x 9.06")

Compliance

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

Alarms/Indicators

Audible and visual indicators for high/low pCO₂, SpO₂, PR alarms and technical alarms. Audible and/or visual indicators (LEDs) for "Audible alarms muted permanently/temporarily", "SDM on/off", "AC power/battery".

Display/Indicators

640 x 240 pixel TFT Color Display. Trend graphs and numeric values of the measurement parameters. Plethysmographic waveform or blip bar presentation of the pulse. Status messages such as "Sensor off Patient", "Site time elapsed", "Battery low" or "Gas bottle empty" etc. Status icons for "Site Timer", "Battery", "Sensor Temperature", "Barometric Pressure", "Gas".

Interfaces

Digital output: RS / EIA 232; supported protocols SenTecLink / Philips VueLink / Spacelabs Flexport / SenTec Datalogger / Serial Printer
Analog output: 0–1 V (4 channels, selectable parameter ranges)
Nurse-call capability

Patient Data Management

Internal memory: up to 12 days, non-volatile
"V-STATS" (PC-Software) to download, analyze, print data
"SenTec Datalogger" (optional) to record data on MMC-card
Compatible with "Download 2001" (PC-Software)

ENVIRONMENTAL CONDITIONS

Transport/Storage

Temperature: 0–50°C (32–122°F) in shipping carton
Humidity: 10–95% non-condensing
Ambient pressure: 375–800 mmHg (500–1060 hPa)

Operation

Temperature: 10–40°C (50–104°F)
Humidity: 15–95 % non-condensing
Altitude: -390–3685 m (-1280–12000 ft)
Ambient pressure: 525–800 mmHg (700–1060 hPa)

ELECTRICAL

Instrument

Instrument AC Power: 100–240 V (50/60 Hz)
Electrical Safety (IEC 60601-1): Class I, Type BF
Applied Part – Defibrillation Proof, IPX1

Internal Battery

Type: sealed LiIon battery
Battery capacity: 6 hours (new fully-charged battery)

¹ Clinical study data available on request.

² An algorithm proposed by JW. Severinghaus is used to estimate arterial pCO₂ from the measured cutaneous pCO₂.

³ SpO₂ accuracy specifications are based on controlled hypoxia studies with healthy, adult volunteers (sensor applied to earlobe) over the specified saturation range.