

## SenTec Digital Monitoring System

- pCO<sub>2</sub>, SpO<sub>2</sub> and pulse
  - noninvasive, continuous, real-time
  - digital V-Sign™ Sensor

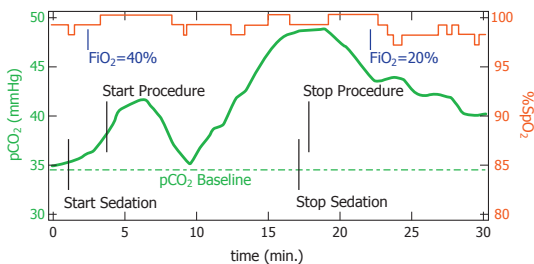


### Features and Benefits

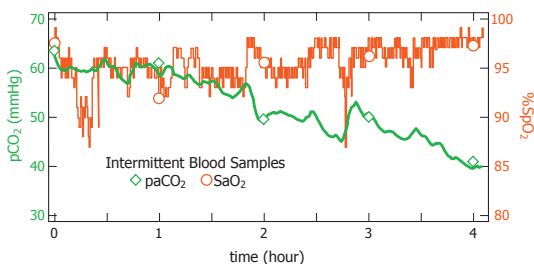
SenTec Digital Monitoring System (SDMS) with V-Sign™ Sensor provides continuous, non-invasive, real-time monitoring of carbon dioxide partial pressure (pCO<sub>2</sub>), oxygen saturation (SpO<sub>2</sub>), and pulse. V-Sign™ Sensor is easily applied to the earlobe or – for pCO<sub>2</sub> monitoring only – to a conventional pCO<sub>2</sub> site. The SDMS responds quickly and accurately to changes in patient's pCO<sub>2</sub>- and/or SpO<sub>2</sub>-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 studies<sup>1</sup> 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 (FIO<sub>2</sub>=40%). The pCO<sub>2</sub> 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 pCO<sub>2</sub> and SpO<sub>2</sub> data therefore are important to reliably detect respiratory problems.



SDMS data during four hours of NPPV in a patient with hypercapnic respiratory failure. Continuous pCO<sub>2</sub> 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 pCO<sub>2</sub>, SpO<sub>2</sub> and pulse. It incorporates the latest opto-electronics and digital signal processing technologies. In combination with local arteria- lization 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 SpO<sub>2</sub> notably earlier than finger pulse oximetry sensors. Applied on sites other than the earlobe V-Sign™ Sensor is currently indicated for pCO<sub>2</sub> monitoring only.

### Measurement principle

Severinghaus-type pCO<sub>2</sub> measurement  
2-wavelength reflectance pulse oximeter

### Digital microtechnology

Opto-electronic components, micro pH-electrode, temperature sensors, and a mixed-signal micro-con- troller 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 (pCO<sub>2</sub>)

Oxygen Saturation (SpO<sub>2</sub>)

Pulse - Plethysmogram and Pulse Rate (PR)

Enabled parameters selectable in "Adult" mode

In "Neonatal" mode SpO<sub>2</sub>/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 cali- brates 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 (pCO<sub>2</sub>)<sup>2</sup>

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 (SpO<sub>2</sub>)

Measurement range: 1 – 100%  
Resolution: 1%  
Accuracy (Arms)<sup>3</sup>: 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 pCO<sub>2</sub>, SpO<sub>2</sub>, 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 Sen- TecLink / Philips VueLink / Spacelabs Flexport / SenTec Datalogger / Serial Printer  
Analog output: 0–1 V (4 channels, selectable para- meter 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)

<sup>1</sup> Clinical study data available on request.

<sup>2</sup> An algorithm proposed by JW. Severinghaus is used to estimate arterial pCO<sub>2</sub> from the measured cutaneous pCO<sub>2</sub>.

<sup>3</sup> SpO<sub>2</sub> accuracy specifications are based on controlled hypoxia studies with healthy, adult volunteers (sensor applied to earlobe) over the specified saturation range.