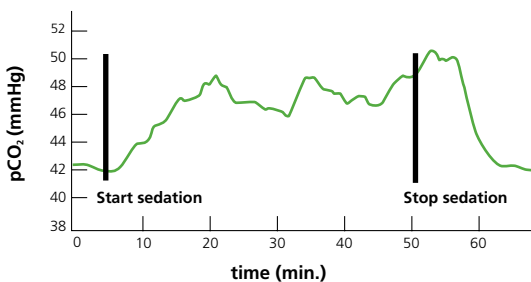


SenTec Digital Monitoring System

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

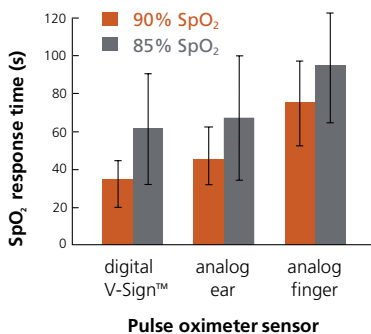


V-Sign™ Sensor pCO₂ data in a Propofol-sedated patient undergoing gastrointestinal endoscopy. The pCO₂ data reflect the course of sedation.

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 and responds quickly and accurately to changes in patients' pCO₂- and 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.



SpO₂ response times of V-Sign™ Sensor and two analog pulse oximeter sensors to changes in FiO₂ in healthy adult volunteers (error bars ± 1 SD). When applied to the earlobe, the digital V-Sign™ Sensor reaches the 90%-alarm limit on average 15 to 42 seconds earlier than analog ear or finger sensors.

Non-invasive Monitoring of Ventilation

senTec
Single Sensor Monitoring

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 preferred central circulation of the cranium – V-Sign™ Sensor detects changes in SpO₂ notably earlier than analog ear and finger pulse oximetry sensors.

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)
Supervised by two independent circuits

Sensor membrane exchange:

Every 2 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



Non-invasive monitoring with a single digital sensor Carbon Dioxide Partial Pressure (pCO₂)

Oxygen Saturation (SpO₂)

Pulse - Plethysmogram and Pulse Rate (PR)

Highly accurate and fast measurement

Digital signal processing

Convenient and safe sensor application

Lightweight sensor head (< 3 g)

Maximum patient comfort

For adult and pediatric use

Wide range of applications

Intensive Care, Post Extubation, Respiratory Medicine, Titration of Ventilation, Conscious Sedation, PCA, Sleep Lab, Palliative Units, Titration of opioids and tranquilizers, COPD, Titration of oxygen, Intra-hospital Transport, Research Use etc.

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

640x240 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", "SDM Status", "Date and Time".

Interfaces

Digital output: RS/EIA 232; supported protocols SenTecLink / Philips Vuelink / Spacelabs Flexport / SenTec Datalogger
Analog output: 0 – 1 V from multipurpose I/O-port
Nurse-call capability

Patient Data Management

48-hours internal memory
"SenTec Datalogger" with 240-hours external memory (optional)
"V-STATS" (PC-software) to download, view, analyze and print patient data (optional)

ENVIRONMENTAL CONDITIONS

Transport/Storage

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

Operation

Temperature: 10 to 40 °C (50 to 104 °F)
Humidity: 15 to 95 % non-condensing
Altitude: -390 to 3658 m (-1280 to 12000 ft)
Ambient pressure: 525 to 800 mmHg (700 to 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 Lilon battery
Battery capacity: 6 – 7 hours (new fully-charged battery)



TFT Color Display

Selectable Parameter Color

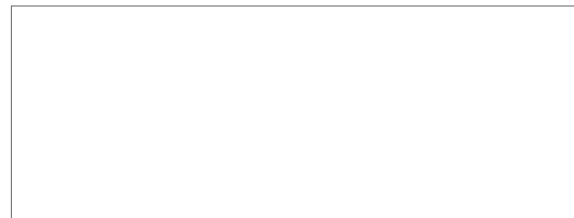
Ready for use

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

Single Sensor Monitoring

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Specifications are subject to change without notice



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 over the specified saturation range.