sentec

SenTec Digital Monitoring System

PCO2 | SpO2 | PR

Continuous | Noninvasive | Easy to use | Reliable | Accurate

Overcoming limitations of arterial blood gases, etCO2 and SpO2 monitoring

Arterial blood gas analysis is invasive and only provides snap-shot information on the patient's condition. It is vital to provide continuous monitoring of critically ill patients, whose condition may change rapidly. Furthermore, frequent arterial blood gas analysis is associated with blood loss.[1]*

End-tidal CO2 (etCO2) monitoring has its limits for patients with chronic respiratory failure due to ventilation-perfusion (V/Q) mismatch. The monitoring of etCO2 also depends on the gas sampling quality (leak-free masks and tubing) and requires regular/full breathing cycles to reflect alveolar CO2.

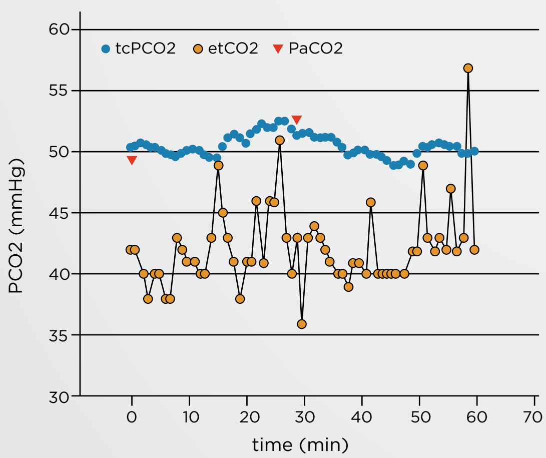


Fig. 1 etCO2 and tcPCO2 data from a COPD patient with invasive ventilation during weaning[2]

*Please refer to the last page for full scientific references.

Measurement of etCO2 is mostly suitable for patients with healthy lungs who have good lung perfusion and ventilation. This is, however, not true in cases such as patients suffering from COPD or ARDS, or patients undergoing one-lung ventilation. Capnography is sometimes inefficient to screen patients for nocturnal alveolar hypoventilation and hypercapnia. Furthermore, etCO2 measurements are often inaccurate in patients receiving noninvasive ventilation (NIV) or in patients who are breathing spontaneously.

Measuring SpO2 alone is not sufficient to detect hyperventilation or hypoventilation.
Due to the S-shape of the oxygen dissociation curve, hypoventilation with a decrease in the PaO2 may not be noticed over a period of time. Especially with the administration of supplemental oxygen, patients can show adequate arterial saturation during hypoventilation.[3]
Changes of arterial CO2 levels can never be detected by SpO2 monitoring alone.

Pulse oximetry doesn't give information about hypoventilation and hyperventilation.

Even the combination of SpO2 and daytime arterial blood gas are not reliable tools for detecting nocturnal hypoventilation, which can occur during long-term NIV and in patients with suspected ventilatory failure.[4]

Noninvasive, continuous monitoring

Combined tcPCO2 and SpO2 measurement is an easy and reliable way to assess patients' ventilation and oxygenation status.

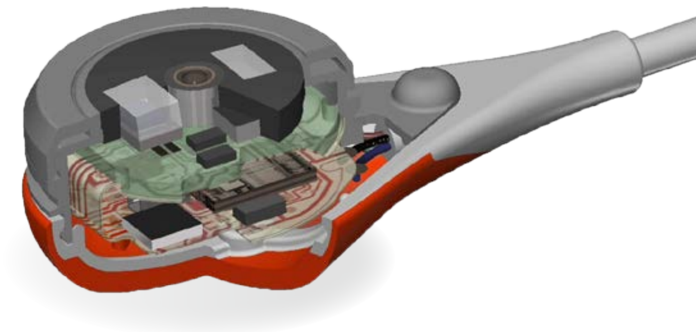
Advantages of digital tcPCO2 and SpO2 monitoring

The Digital SenTec **V-Sign™ Sensor 2** is a Stow-Severinghaus-type PCO2 Sensor combined with reflectance 2-wavelength pulse oximetry.

The highly integrated **digital sensor head** comprises a micro pH-electrode and an optical oximetry unit. The sensor temperature is regulated by two independent temperature sensors. All data is digitized in the sensor head, allowing the transmission of robust, low-noise signals to the monitor.

Sensor sensitivity and calibration data is stored in the sensor head during manufacturing and regularly updated during use.

Automatic sensor calibration ensures that the system is "**Ready for use**" when needed and allows for a long measuring time of up to 12 hours.



Triple parameters – the V-Sign™ Sensor 2 provides continuous, noninvasive measurement of tcPCO2, SpO2 and pulse rate (PR). Information about the pulsation index and Heating Power are also available.

Accurate and reliable

Excellent accuracy

SenTec's sophisticated algorithms ensure high accuracy and minimal technical drift.[5] Additionally, the V-STATS™ software provides a retrospective residual drift correction.

In a 2012 study, Prashant N. Chhajed et al. demonstrated that the SenTec Digital Monitoring System provided accurate results compared to conventional blood gas analysis.

Reliability

SenTec's unique transcutaneous artifact detection algorithm provides reliable data when conventional tcPCO2 monitors tend to fail.

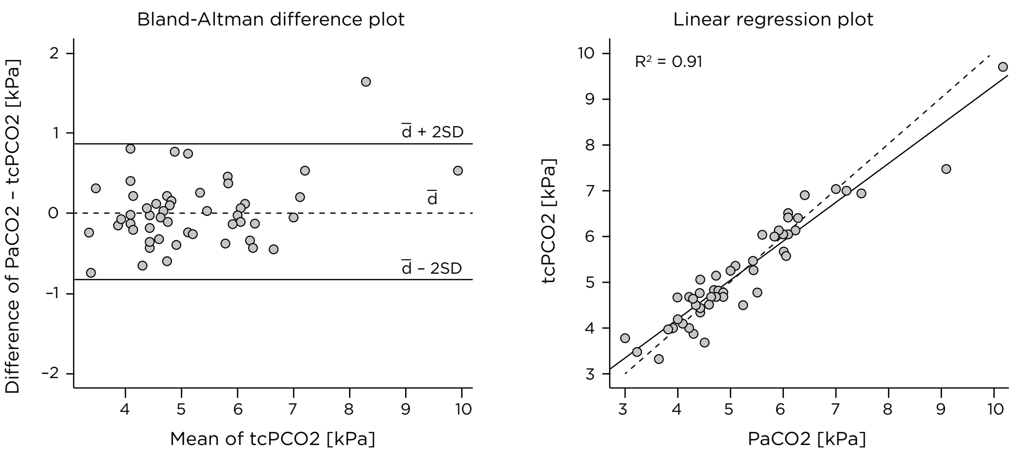


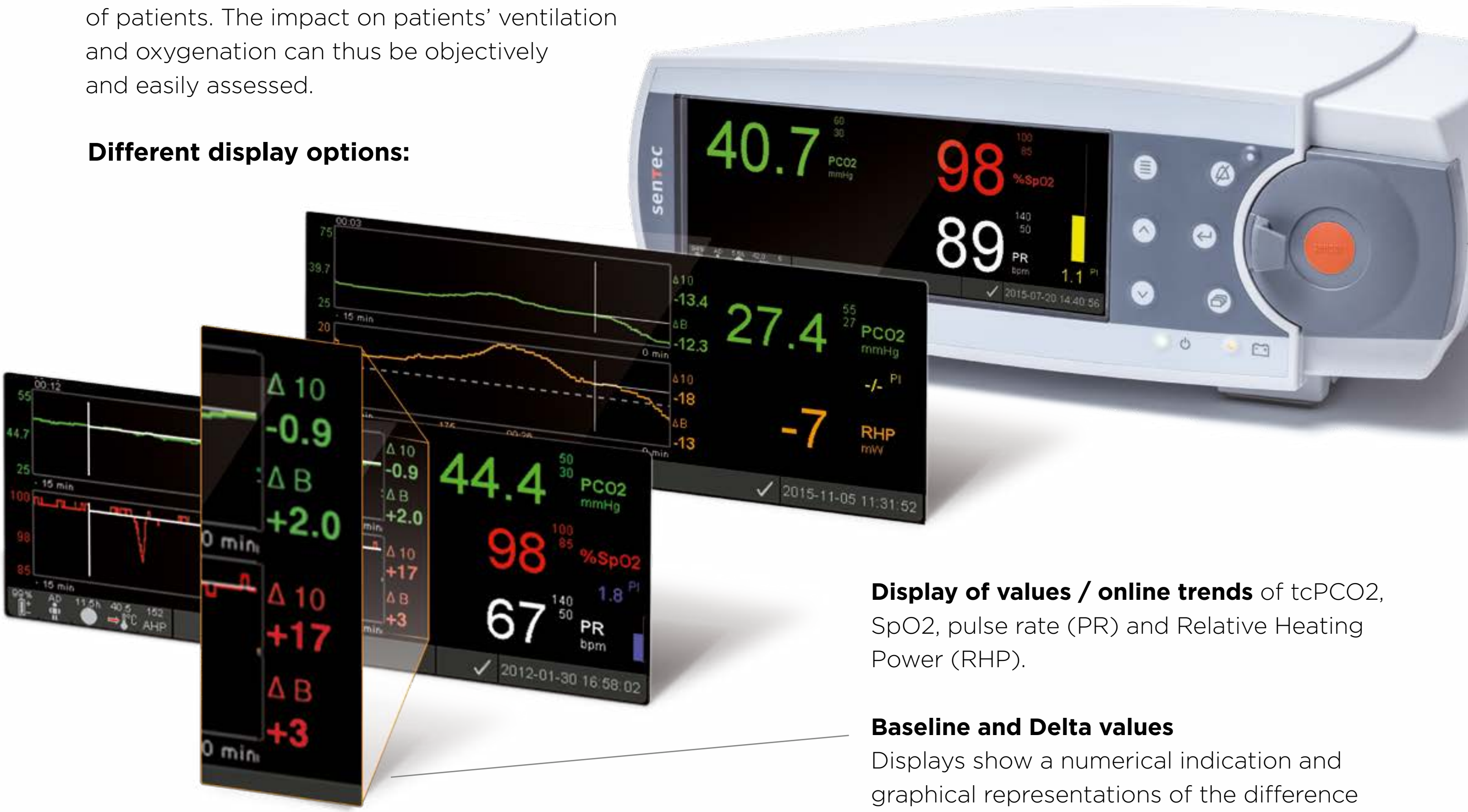
Fig. 2 40 patients were included in the study, tcPCO2 and PaCO2 data from 50 samples were available, tcPCO2 was measured at the infraclavicular site

Fig. 2 above shows a *comparison of tcPCO2 and PaCO2. Measurements were compared using both a Bland-Altman plot (left panel) and linear regression analysis. The Bland-Altman plot displays the mean bias and limit of agreement (solid lines). The linear regression plot displays the line of best fit (solid line) and the identity line (dashed line).*[6]

SenTec's Digital Monitoring System offers intuitive controls and easy-to-read displays.

Tracking changes in therapy
The monitor allows for setting a **baseline** and **markers** just before changing the treatment of patients. The impact on patients' ventilation and oxygenation can thus be objectively and easily assessed.

Different display options:



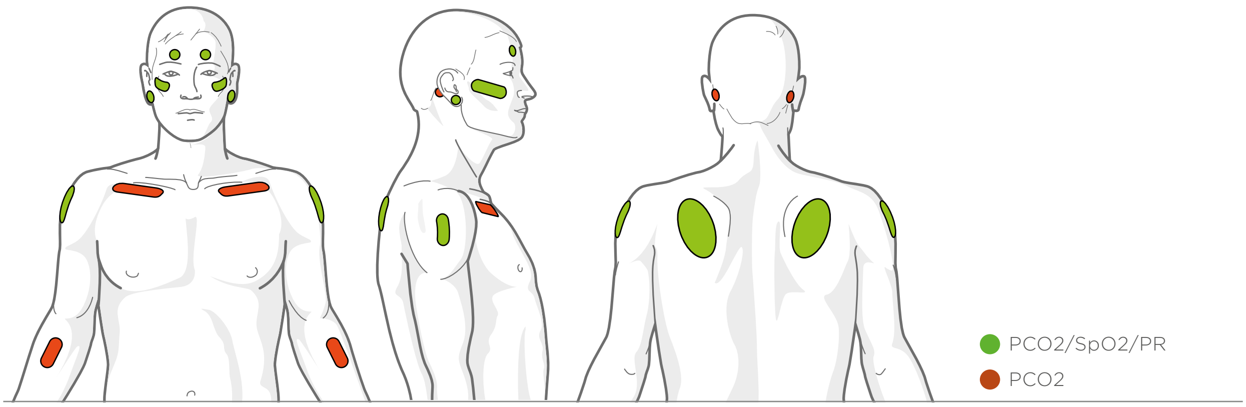
Display of values / online trends of tcPCO2, SpO2, pulse rate (PR) and Relative Heating Power (RHP).

Baseline and Delta values
Displays show a numerical indication and graphical representations of the difference between the current reading and the previously set baseline.

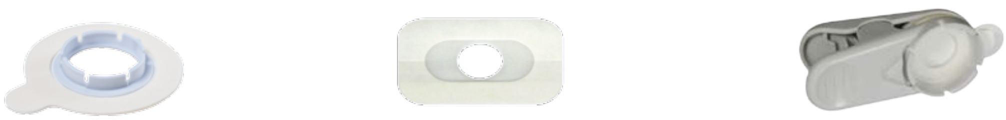
Easy to use

The SenTec Digital Monitoring System has a number of practical and time-saving features.

Choose from multiple validated measurement sites



Safe and gentle sensor application



Multi Site Attachment Ring
Single-use ring for the attachment of SenTec transcutaneous sensors to various measurement sites.

Staysite™ Adhesive
Additional adhesive film to improve fixation of Multi Site Attachment Ring in challenging settings.

Ear Clip
A great solution for overnight monitoring in sleep labs as well as long-term use. Attached to the ear lobe, the sensor doesn't disturb sleep and is suitable for patients wearing masks.

Freely rotatable sensor
Once the sensor is inserted into the Multi Site Attachment Ring, it is rotatable. This gives the caregivers more flexibility to adjust sensor cable positioning during sensor attachment and monitoring.

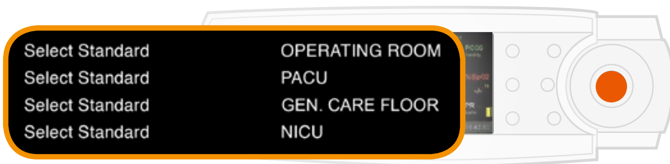
Low maintenance
Recalibration intervals range up to 12 h.

Membrane change interval is normally 28 days and can be extended up to 42 days.

Portability and transportability
Lightweight monitor, mountable on rollstands or infusion stands, and battery life of up to 10 hours allows continuous patient monitoring during intra-hospital transport or in situations when no AC power is available.

The Smart Calmem
As the calibration data is stored in the sensor head, it can be disconnected for up to 30 minutes without the need for recalibration.

Quick system setup
Up to four preset or customizable profiles can be stored and selected on the SenTec Digital Monitor.



Central monitoring
V-CareNeT™ System enables remote monitoring and alarm surveillance for up to 40 SenTec Digital Monitors. This provides an increased level of safety to patients, disturbance free monitoring (e.g. in sleep lab settings) and improved workflow for caregivers.

Wide range of medical applications

Clinical studies underscore the growing acceptance of transcutaneous CO_2 monitoring in many application areas.
For clinical studies, go to www.sentec.ch/application-areas/clinical-studies/

Pulmonology & sleep medicine
Continuous, overnight monitoring of $tcPCO_2$ has become essential for assessing nocturnal hypoventilation, screening for hypercapnia and titration of noninvasive ventilation (NIV). SenTec monitors are connectable to most polygraphic and polysomnography systems.

Homecare
Used under clinical supervision, the SenTec monitoring system allows detection of nocturnal hypercapnia in the patient's home. Data can be downloaded and sent to the referring physician for further analysis and therapy decisions.

Critical care for adults
Continuous transcutaneous monitoring is a promising tool to detect early changes of arterial PCO_2 for patients in critical care. This is particularly valuable in guiding mechanical ventilation or monitoring patients undergoing weaning from ventilator support.

General practitioners
The SenTec Digital Monitor can be used by physicians in their offices in **V-Check™** Mode[7] for ventilation spot checks on patients. A statistical summary of key values ($tcPCO_2$, SpO_2, PR) facilitates analysis.

Neonatal intensive care unit (NICU)
Noninvasive, continuous transcutaneous monitoring supports therapy guidance for neonatals and may lessen the need for blood gas sampling, reducing the chance of infections. Please refer to the SenTec neonatal brochure for more information.

General anesthesia/procedural sedation/surgery
For patients on high frequency or jet ventilation, the use of continuous tcPCO2 monitoring is indicated, as no reliable CO2 values can be gained from etCO2 monitoring. Sedated patients undergoing diagnostic interventions or minimally invasive surgeries are exposed to respiratory depressant drugs. The use of continuous tcPCO2 measurement, therefore, increases the safety of the patients as the ventilation status can be continuously assessed, especially in spontaneously breathing patients.

Post anesthesia care unit (PACU)
Hypoventilation and related hypercapnia is a risk for patients after general anesthesia.[8] Residual amounts of respiratory depressant drugs and opioids from patient controlled analgesia (PCA) systems can critically affect ventilatory drive. The Anesthesia Patient Safety Foundation (APSF) recommends to routinely monitor ventilation in such patients for increased safety.[9] Transcutaneous PCO2 is most suitable for that task, especially in view of the aforementioned limitations of etCO2.

Emergency room
The reliability of transcutaneous CO2 measurement in the emergency room has been proved in clinical studies. *It can be used as real-time guidance for treatment.*[10]

General care floor
In situations where nurse-to-patient ratios preclude direct surveillance, combined tcPCO2/SpO2 patient monitoring can be crucial.

Valuable insights

Making treatment decisions based on data analysis.

V-STATS™ software enables users to download trend data from the internal memory of the monitor and display it on the PC screen for further analysis, reporting, and generation of a printable report. Data download is possible via serial or LAN interface.

Parameters and safety relevant settings such as alarm system management, site time and temperature management are easily configured and saved/stored as user profiles within the V-STATS™ software. All departments can have their specific profiles to support their transcutaneous monitoring requirements – all within the same SenTec device. Profile settings and reports may be easily generated, duplicated, printed and emailed.

The V-STATS™ software streamlines processes and enhances workflow efficiency in multiple clinical settings such as respiratory care and sleep studies.

The V-CareNeT™ System enables remote monitoring and alarm surveillance for multiple SenTec Digital Monitors (SDMs). The central station is the PC running V-STATS™ with **activated V-CareNeT™ Package**.

Broad connectivity

Patient data from the SenTec Digital Monitor can be transferred to bedside monitors, PCs, nurse call systems, chart recorders or data loggers.

Polygraphic (PG) and polysomnography (PSG) systems
Various ready-made adapter cables and interfaces are available to connect the SenTec Digital Monitor to the most common PG or PSG systems, including innovative wireless solutions with Nox Medical.

Connectivity to patient monitoring systems and electronic medical record systems (EMR)
Monitored data from SenTec Digital Monitor can be transferred to selected

- patient monitoring systems (Philips, Dräger, Mindray and Spacelabs) or
- electronic medical record systems (e.g. via Capsule).

For more information, please refer to the following link: www.sentec.ch/fileadmin/PSG/ProductInfoPSGAdapterCables.pdf

A current list of connectable patient monitoring systems is on our website: www.sentec.ch/support-services/device-connectivity/

Clinically validated

Over 100 clinical studies have been conducted with the SenTec Digital Monitoring System.
www.sentec.ch/application-areas/clinical-studies/

Pneumology
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Sleep, pediatrics, NIV
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Heinzelmann I, Gloeckl R, Seeberg S, Damisch T, Stegemann A, Plagmann M, Jerrentrup A, Kenn K Changes in pCO2 levels during 6-minute walking test in patients with very severe COPD, *European Respiratory Society, Annual Meeting 2014, (Vol. P 4495)*

SenTec is an ISO 13485 certified company and its Digital Monitoring System has been approved by regulatory authorities in the United States, Europe, Canada, Japan, South Korea, Taiwan, Australia and other countries.

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