sentec

Digital Transcutaneous
Blood Gas Monitoring

18 MONTHS COMPLETE WARRANTY

SenTec Digital Monitoring System

Effective peri-operative noninvasive PCO2 monitoring

PCO2 | SpO2 | PR

Continuous | Noninvasive | Accurate | Safe | Easy to Use

Overcome the limitations of etCO2 and traditional SpO2

Enhanced monitoring of ventilation and oxygenation

Respiratory depression is one of the most common serious adverse effects associated with sedative drug administration.[1]

Multiple associations recommend or require Ventilation Monitoring[2] in the perioperative field such as:

- MAC procedures
  - Bronchoscopy
  - Upper GI
  - Colonoscopy
- Procedures with High Frequency or Jet Ventilation
- Post-operative period in patients at risk for Opioid Induced Respiratory Depression (OIRD)
- Patients receiving epidural or spinal opioids
- PCA (Patient controlled analgesia) pain management
- Patients on High Flow Nasal Cannula, CPAP or BiLevel ventilation impeding etCO2 accuracy

Measuring SpO2 alone is not sufficient to detect hypoventilation

Hypoventilation is a known risk for patients after general anesthesia[3] and in sedated patients. Especially with the administration of supplemental oxygen, patients can show adequate arterial saturation during hypoventilation.[4]

Overcome the limitations of etCO2

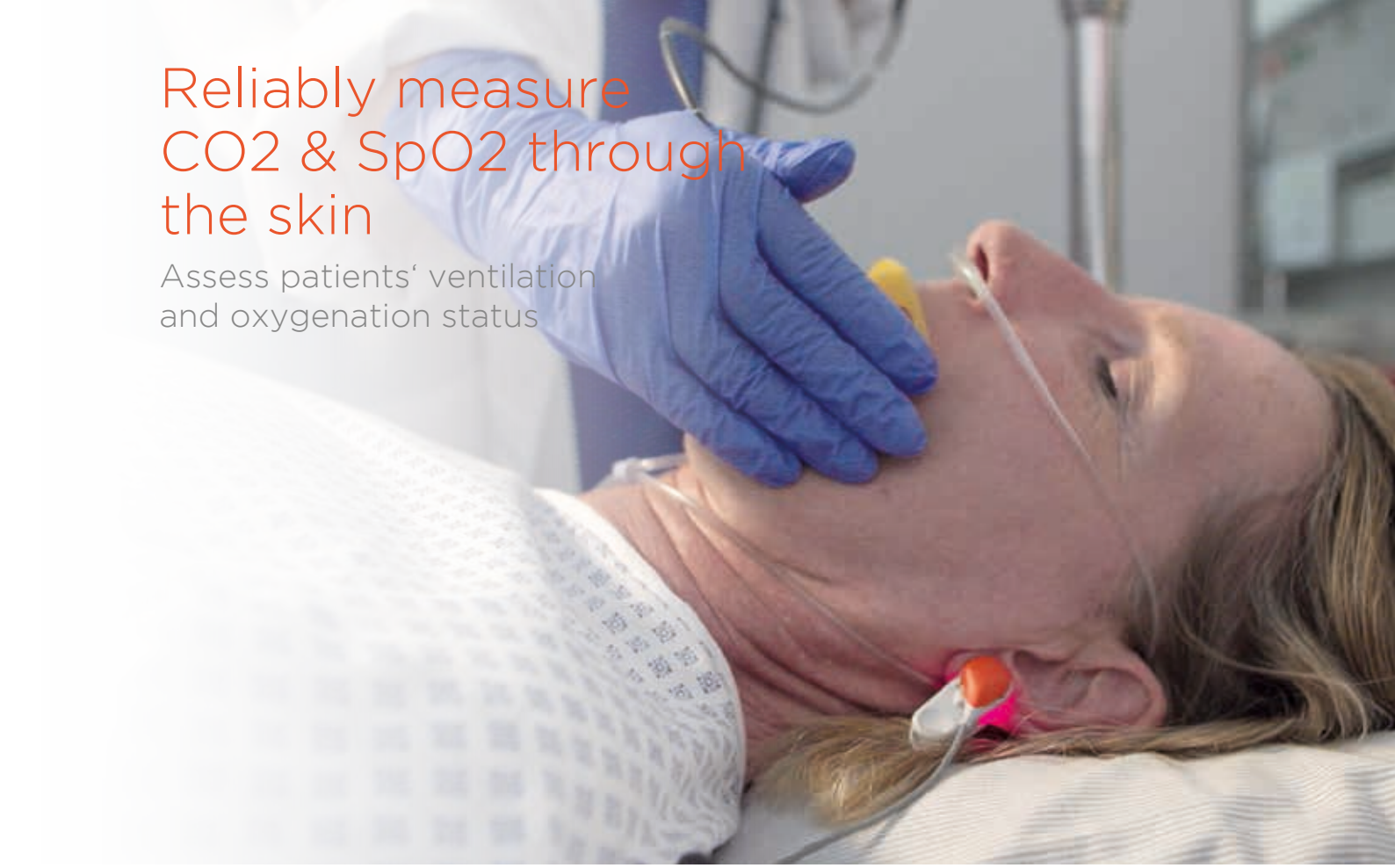
In patients with chronic respiratory failure or ventilator induced impairment, etCO2 has its limits due to ventilation-perfusion (V/Q) mismatch. The monitoring of etCO2 also depends on the gas sampling quality (leak-free masks and tubing) and requires regular/full breathing cycles to reflect alveolar CO2. For patients on High Frequency or Jet Ventilation, the use of continuous tcPCO2 monitoring is indicated, as reliable CO2 values may not be attainable from etCO2 monitoring.

Respiratory rate may not reflect adequate ventilation

The respiratory rate alone does not provide enough information about the tidal volume and hence the efficacy of ventilation.

Reliably measure CO2 & SpO2 through the skin

Assess patients‘ ventilation and oxygenation status



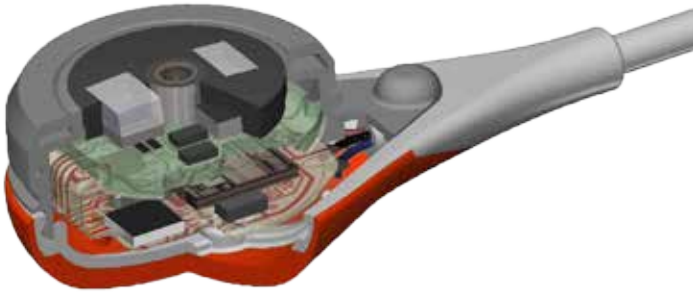
tcPCO2 monitoring reveals hypercapnia even in presence of normal respiratory rates and SpO2 values[5]
Unlike etCO2, tcPCO2 does not require a full breath waveform to accurately reflect arterial CO2 levels.

Better detection of hypercapnia for patients under MAC
In a comparison with end-tidal side-stream capnography for patients under MAC with deep sedation, transcutaneous monitoring correlated better with measured arterial CO2 and was better at detecting states of hypercarbia.[6]

Good correlation with PaCO2 values[7,8,9] independent from
- Ventilation mode (High Frequency, Jet, High Flow, Noninvasive, Invasive Ventilation and Spontaneous Breathing)
- V/Q mismatch
- Airway accessibility (e.g. scope)
- Patient type (adult, pediatric, newborn)

tcPCO2 may help to enhance patient safety and comfort
- During Bronchoscopy and Medical Thoracoscopy[10]
- Significantly reduces incidence, degree and duration of hypercapnia in shoulder surgery patients with MAC.[11]
- tcPCO2 provides higher comfort level for spontaneously breathing patients compared to etCO2 (no mask or cannula)

High accuracy of SpO2, PR and tcPCO2
The heated V-Sign™ Sensor 2 provides continuous, noninvasive measurement of tcPCO2, SpO2 and pulse rate (PR). The heat-induced increase in capillary blood flow in the skin tissue improves the accuracy of tcPCO2 and augments the pulse strength of the pulsating blood, improving the ability to reliably measure SpO2/PR.



Accurate and reliable

Excellent accuracy
SenTec's sophisticated algorithms ensure high accuracy and minimal technical drift.[12]
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.

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

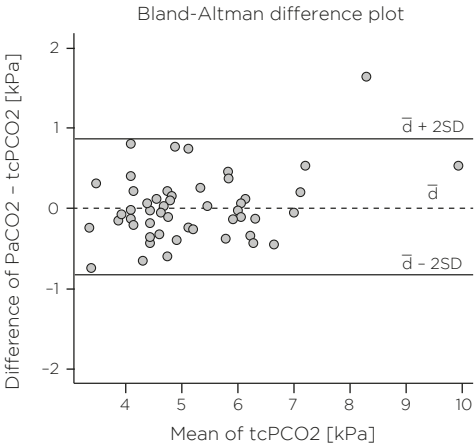


Fig. 1: shows a comparison of tcPCO2 and PaCO2. Measurements were compared using both a Bland-Altman plot (left panel) and linear regression analysis. The Bland-Altman plot displays the mean bias and limit of agreement (solid lines). The linear regression plot displays the line of best fit (solid line) and the identity line (dashed line).[13]

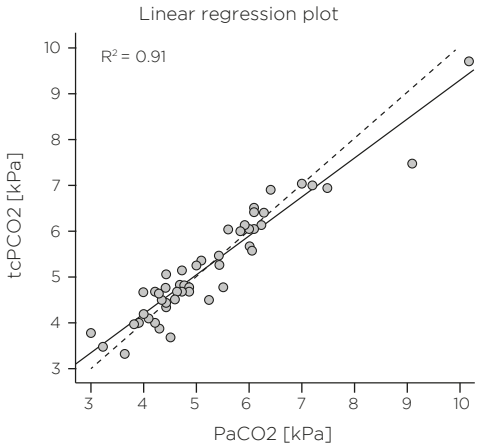
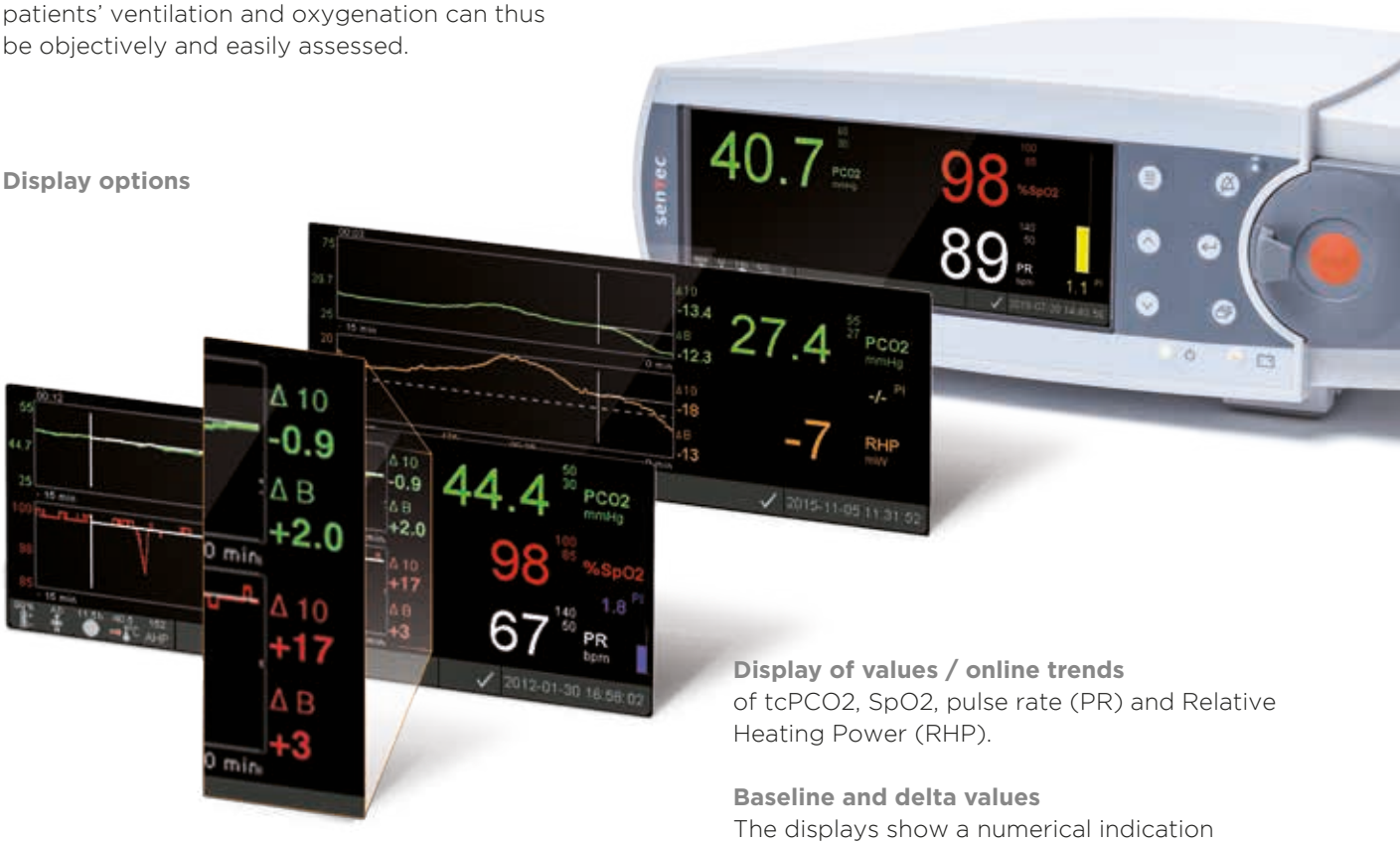


Fig. 2: 40 patients were included in the study. tcPCO2 and PaCO2 data from 50 samples were available. tcPCO2 was measured at the infraclavicular site.

Track changes objectively
Set 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.

Display options

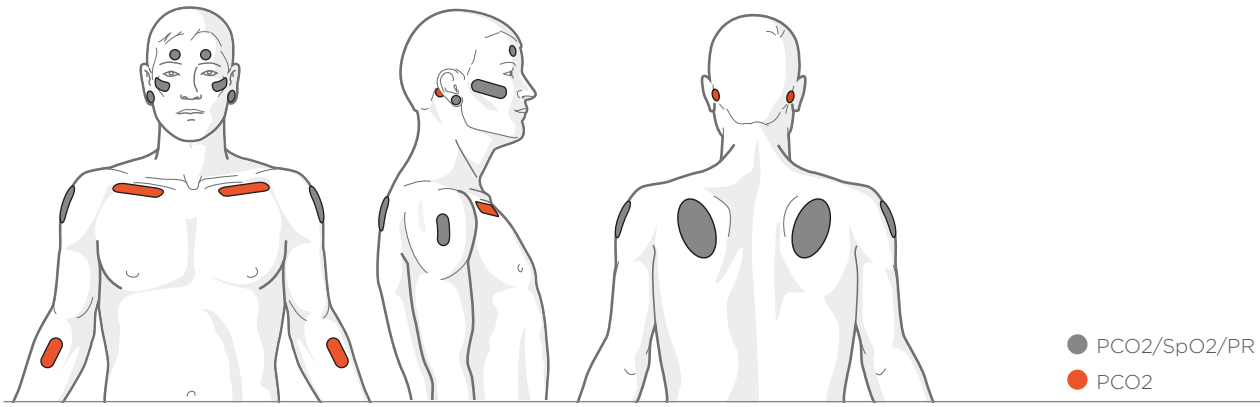


Display of values / online trends
of tcPCO2, SpO2, pulse rate (PR) and Relative Heating Power (RHP).

Baseline and delta values
The displays show a numerical indication and graphical representations of the difference between the current reading and the previously set baseline.

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.

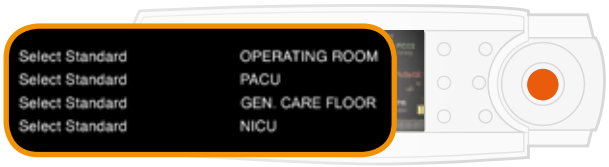
Ear Clip
A great solution for overnight monitoring in sleep labs as well as long-term use. Attached to the ear lobe, the sensor doesn't disturb sleep and is suitable for patients wearing masks.

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

Central monitoring
The 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 an improved workflow for caregivers.

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

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



Portability and transportability
The lightweight monitor can be mounted on rollstands or infusion stands and has a battery life of up to ten hours, which allows continuous patient monitoring during intra-hospital transport or in situations when no AC power is available.

Low maintenance
Recalibration intervals range up to 12 h.

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

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

Noninvasive CO2 Monitoring in the perioperative environment

The SenTec Digital Monitoring System (SDMS) supports caregivers in various clinical situations

Pre-OP

- Identify elevated CO2 levels which potentially indicate comorbidities and require closer monitoring of a patient during peri-anesthesia
- Identify patient's individual CO2 baseline
- May be used in addition to STOP BANG scores

MAC/sedation

Sedated patients may progress to levels of deeper sedation with an increased risk of respiratory compromise, making respiratory monitoring a critical aspect in assuring quality care of the sedated patient. Many MAC cases utilize a scope during the procedure (i.e. bronchoscopy, Upper GI) that impedes upon the reading and accuracy of etCO2, whereas tcPCO2 remains unaffected.

Cardiac ablation using Jet Ventilation

Jet Ventilation (JV) is used during mapping and ablation, decreasing the procedure duration. etCO2 is not available during Jet Ventilation, ABG only intermittent. Case times often run 2.5–4 hours. Without monitoring the patient's lung ventilation status, pulse oximetry alone does not provide sufficient information to assure optimal outcomes.

General anesthesia

In certain procedures involving non-traditional mechanical ventilation techniques tcPCO2 provides a better estimate of PaCO2 and may help to guide ventilation:

- High Frequency Jet (HFJV)
- High Frequency Oscillation (HFOV)
- One-Lung ventilation
- Prolonged apneic phases e.g. with High Flow Nasal Cannula (HFNC)

Post-OP

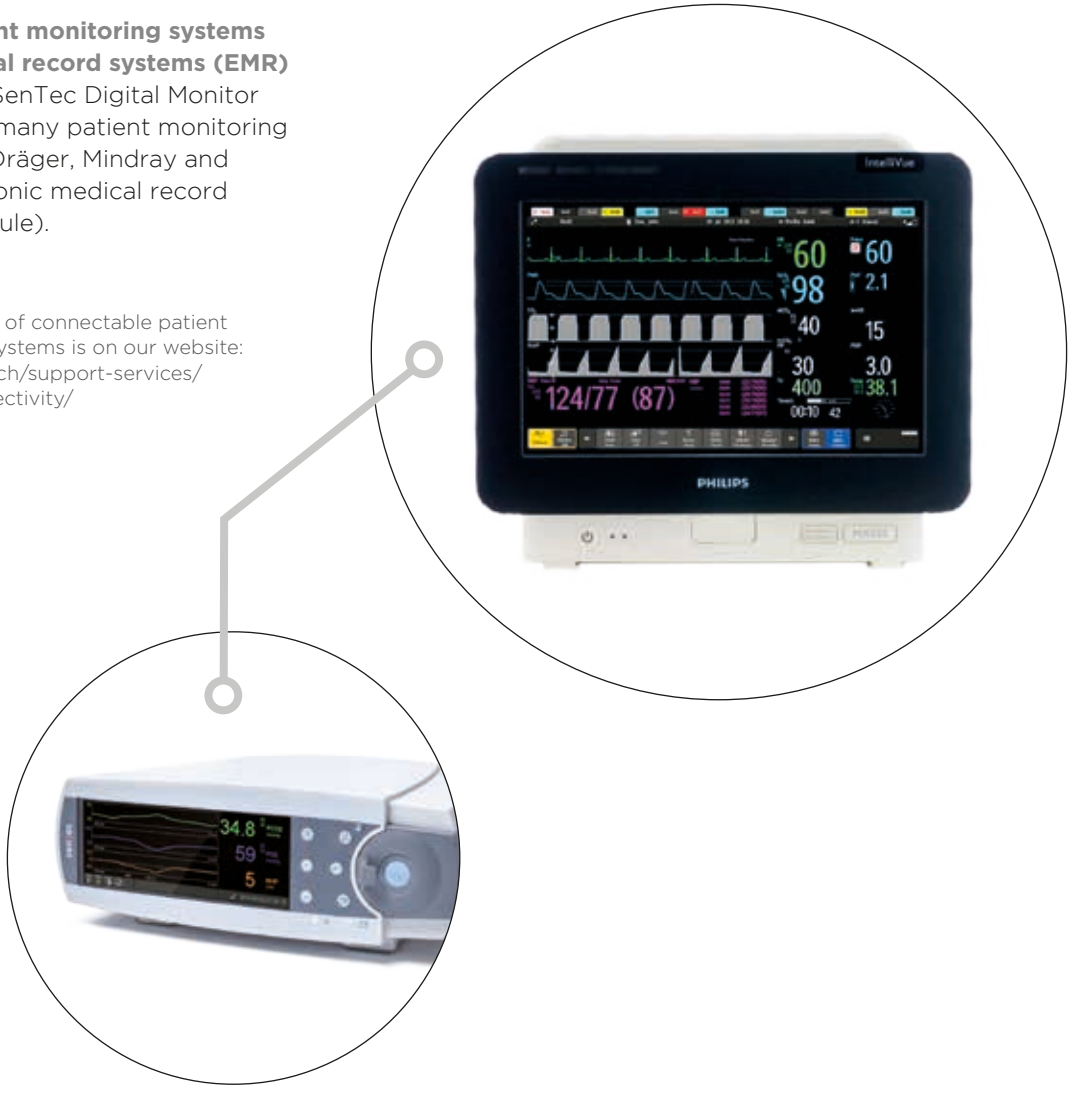
Monitoring respiratory depression as recommended in the practice guidelines[2]:

- High risk patients (e.g. high STOP BANG score, Obesity Hypoventilation Syndrome)
- Patients on PCA pump
- COPD patients
- May help to determine patient is back at his/her PCO2 baseline for safe transfer to lower level care unit
- Epidural pain management

Broad connectivity

Connectivity to patient monitoring systems and electronic medical record systems (EMR)
Monitored data from SenTec Digital Monitor can be transferred to many patient monitoring systems (Philips, GE, Dräger, Mindray and Spacelabs) and electronic medical record systems (e.g. via Capsule).

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



Standards and Guidelines

Recommended ventilation monitoring in peri-anesthesia settings

The Joint Commission Sentinel Event Alert (Issue 49, August 8, 2012)
Screen patients for respiratory depression risk factors. Staff should be educated not to rely on pulse oximetry alone because pulse oximetry can suggest adequate oxygen saturation in patients who are actively experiencing respiratory depression, especially when supplemental oxygen is being used – thus the value of using capnography to monitor ventilation.

ASA Standards for Basic Anesthetic Monitoring
Capnometry for moderate and deep sedation is required unless precluded or invalidated by the nature of the patient, procedure, or equipment.

ASA Taskforce
ASA Taskforce Guidelines for the Prevention, Detection, and Management of Respiratory Depression Associated with Neuraxial Opioid Administration:
(1) all patients receiving neuraxial opioids should be monitored for adequacy of ventilation, oxygenation, and level of consciousness and (2) increased monitoring may be warranted in patients at increased risk of respiratory depression.

American Society of Gastrointestinal Endoscopy
The American Society of Gastrointestinal Endoscopy suggest in their guidelines that external monitoring with capnography should be considered for patients in conscious and deep sedation.

Centers for Medicare and Medicaid Services (CMS)
March 14, 2014; 1-32.
At a minimum, hospitals are expected to address monitoring for over-sedation and respiratory depression related to IV opioids for post-operative patients.

APSF 2011, Essential Monitoring Strategies to Detect Clinically Significant Drug- Induced Respiratory Depression in the Postoperative Period: Conclusions and Recommendations
Recommend Capnography or other monitoring modalities that measure the adequacy of ventilation and airflow is needed.

Hospital Quality Institute – Guidelines of Care Tool Kit for Reducing Harm from Respiratory Depression in Non-ICU Patients Through Risk Mitigation and Respiratory Monitoring
For moderate to high risk patients, continuous ventilation monitoring and oxygenation monitoring is strongly recommended.

Clinically validated

Over 100 clinical studies have been conducted with the SenTec Digital Monitoring System

https://www.sentec.com/ful/application-areas/clinical-studies/

Selected Literature in Anesthesia

1 **Jarzyna, Donna et al.**
American Society for Pain Management Nursing Guidelines on Monitoring for Opioid-Induced Sedation and Respiratory Depression; Pain Management Nursing, Volume 12, Issue 3 , 118-145.e10

2 For a selection of standards and guidelines in ventilation monitoring in peri-anesthesia see previous page

3 **Soto R., Davis M., Faulkner M.**
A comparison of the incidence of hypercapnea in non-obese and morbidly obese perioperative patients using the SenTec transcutaneous pCO2 monitor, Journal of Clinical Monitoring and Computing, 2014, 28:293–298

4 **Mehta A., Chhajed P.**
Cutaneous Capnography, in Jindal SK, Textbook of Pulmonary and Critical Care Medicine, Vol. 2, 2011, p. 1841–1850;

5 **Kopka A., Wallace E., Reilly G. and Binning A.**
Observational study of perioperative PtcCO2 and SpO2 in nonventilated patients receiving epidural infusion or patient-controlled analgesia using a single earlobe monitor (TOSCA). Br J Anaesth. 2007;99(4):567-71

6 **DeOliveira GS., Ahmad S., Fitzgerald PC., McCarthy RJ.**
Detection of hypoventilation during deep sedation in patients undergoing ambulatory gynaecological hysteroscopy: a comparison between transcutaneous and nasal end-tidal carbon dioxide measurements, Br J Anaesth, 2010, vol. 104 (pg. 774-8)

7 **Roediger R. et. Al**
The revised digital transcutaneous PCO2/SpO2 ear sensor is a reliable noninvasive monitoring tool in patients after cardiac surgery. Journal of Cardiothoracic and Vascular Anesthesia. 2011:25. 243-249.

8 **Xue Q., Wu X., Jin J., Yu B., Zheng M.**
Transcutaneous carbon dioxide monitoring accurately predicts arterial carbon dioxide partial pressure in patients undergoing prolonged laparoscopic surgery, 2010, Anesth Analg, 111(2), 417-420

9 **Jacob, Z. C., Fan, R., Reinsel, R. A., Patel, N., & Chandrakantan, A.**
Preliminary Validation of Transcutaneous CO2 Monitoring in Patients Undergoing Cardiac Ablation Using Jet Ventilation. Open Journal of Anesthesiology, 2017, 7(9), 315-327

10 **Chhajed P. N., Rajasekaran R., Kaegi B. & Tamm M.**
Cutaneous Carbon Dioxide Tension Monitoring Might Enhance Patient Safety During Bronchoscopy and Medical Thoracoscopy. CHEST Journal, 2005, Volume 127, Issue 2, 585-588

11 **Baulig W., Keselj M., Baulig B., Guzzella S., Borgeat A. & Aguirre J.**
Transcutaneous continuous carbon dioxide tension monitoring reduced incidence, degree and duration of hypercapnia during combined regional anaesthesia and monitored anaesthesia care in shoulder surgery patients. 2015, Journal of Clinical Monitoring and Computing, 29(4):499-507

12 **Storre JH., Magnet FS., Dreher M., Windisch W.**
Transcutaneous monitoring as a replacement for arterial PCO2 monitoring during nocturnal noninvasive ventilation, Respiratory Medicine 2011, 105(1), 143–150

13 **Chhajed PN., Chaudhari P., Tulasigeri C., Kate A., Kesarwani R., Miedinger D., et al.**
Infraclavicular sensor site: a new promising site for transcutaneous capnography, Scand J Clin Lab Invest, 2012, 72(4), 340-342

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