MANAGING THE RISKS OF PROCEDURAL SEDATION

Medtronic
Further, Together
Procedural sedation: What are the risks?

While procedural sedation is beneficial to the patient and also helps clinicians effectively perform procedures, there are significant risks involved. Patients are at risk of respiratory depression, which can lead to significant injury or even death. Patients may have apneas or airway obstruction due to sedation depth. And oversedation can lead to slower recovery time and increased hospital length of stay.

Multiple factors contribute to an increased risk of adverse events during procedural sedation, including:
- Patient’s overall health and comorbidities
- Experience and comfort level of anesthesia provider

Procedural sedation is used during most minimally invasive procedures that do not require general anesthesia, including:
- Gastrointestinal (GI) procedures or endoscopy
- Cardiac catheterization lab procedures
- Interventional radiology procedures
- Procedures in the emergency department
<table>
<thead>
<tr>
<th>Sedation is a continuum and patient response is unpredictable</th>
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<tbody>
<tr>
<td><strong>Responsiveness</strong></td>
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<tr>
<td>Normal response to verbal stimulation</td>
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<tr>
<td>Airway</td>
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<td>Spontaneous ventilation</td>
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<td>Cardiovascular function</td>
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A 55-year-old woman, in good health, entered a medical facility for an elective endoscopic retrograde cholangiopancreatography (ERCP) with transduodenal papillotomy. She was monitored continuously with pulse oximetry (SpO₂), ECG and NIBP. The patient received 4 liters per minute of supplemental O₂ through nasal cannula and was given midazolam 2+1 mg ev, propofol 30 mg iv followed by a continuous infusion of propofol 2 mg/kg/h for sedation.

After 20 minutes, the NIBP monitoring indicated low blood pressure; progressively within a few seconds, the SpO₂ decreased from 96% to 65%; the HR, which had been stable at 125 bpm, rose to 135 bpm.

After further evaluation, the patient was intubated and transferred to ICU.

The following day, a cerebral CT scan evidenced a severe anoxic-ischemic damage.

Within 3 days of the event, death was assessed.

What happened is easily explained by an arrest of spontaneous ventilation resulting from accumulation of sedative drugs, or an obstruction of the upper airway resulting in lack of O₂ inhalation/absorption even though provided by the supplemental nasal cannula, or even the summation of the two mechanisms.

In all likelihood, during the procedure the patient experienced hypoventilation due to the summation of several factors, and the enrichment of the inhaled air prevented the onset of hypoxia that accompanies physiological states of hypercapnia and hypoventilation in ambient air.

Clinical studies show that capnography, a noninvasive measurement of exhaled carbon dioxide and the earliest indicator of ventilatory status, reduces the number and duration of hypoxic events in patients undergoing procedures with sedation.⁹⁻¹⁰
What capnography provides

Capnography is a noninvasive, continuous measurement of carbon dioxide during the respiratory cycle as a function of time. It provides critical patient information:

- The earliest indicator of hypoventilation, airway obstruction, no breathing
- Monitors potential risk of oversedation more effectively than pulse oximetry alone
- Validates breathing and airway integrity (waveform shape)
- Accurately monitors respiration rate

Apneic Waveform

CLINICALLY PROVEN

Numerous clinical studies have evaluated the utility of capnographic monitoring in reducing the incidence of respiratory depression and hypoxemia during procedural sedation for endoscopic procedures.

Compelling Clinical Evidence

<table>
<thead>
<tr>
<th>Evidence</th>
<th>PubMed Link</th>
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CAPNOGRAPHY IS RECOMMENDED

Over the last four years, 29 statements worldwide have identified capnography as a tool for managing the risk of respiratory compromise. The European Board of Anaesthesiology (EBA) recently released the latest additions to a growing list of society guidelines identifying capnography as a way to improve patient safety.

<table>
<thead>
<tr>
<th>Society</th>
<th>Recommendation</th>
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<tr>
<td>Academy of Royal Medical Colleges¹</td>
<td>“Where not already in use, as a fundamental standard, capnography for patients receiving sedation should be considered a Developmental Standard.”</td>
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<tr>
<td>American Society for Gastrointestinal Endoscopy²</td>
<td>“Extended monitoring with capnography should be considered as it may decrease the risks during deep sedation.”</td>
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<tr>
<td>American Society of Anesthesiologists³</td>
<td>“During moderate or deep sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.”</td>
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<tr>
<td>Association of Anesthetists of Great Britain and Ireland⁴</td>
<td>“It is also recommended that continuous capnography should be considered during sedation for all patients receiving deep sedation and for all patients receiving moderate sedation whose ventilation cannot be directly observed.”</td>
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<tr>
<td>British Royal College of Anaesthetists/ British Society of Gastroenterology⁵</td>
<td>“Monitoring of respiration with continuous waveform capnography is also recommended for all sedated patients and is essential for those whose ventilation cannot be directly observed. Such monitoring devices are now widely available and should be used for patients receiving propofol sedation for ERCP.”</td>
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<td>Canadian Anesthesiologist Society⁶</td>
<td>“Recommend[s] that capnography monitoring be utilized in all patients undergoing general anesthesia and deeper levels of sedation.”</td>
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<tr>
<td>European Board of Anaesthesiology⁷</td>
<td>“All patients undergoing moderate or deep sedation should be monitored with continuous capnography.”</td>
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<tr>
<td>The Spanish Society of Gastrointestinal Endoscopy⁸</td>
<td>“Capnography may be useful in seriously ill patients with multiple conditions who will undergo long-term sedation for prolonged or complex endoscopy procedures (ERCP, prosthesis placement, etc.). This monitorization measures ventilatory activity, and predicts potential respiratory depression before the pulse oximeter may detect desaturation.”</td>
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Why Microstream™ capnography from Medtronic?

For decades, clinicians have relied on Microstream™ technology to monitor patients’ CO₂ waveforms and end-tidal CO₂ (etCO₂) and alert them to early indications of evolving respiratory compromise.

Microstream™ waveform capnography provides an accurate, reliable and easy-to-use assessment of a patient’s ventilatory status. Available in a wide range of patient monitors and devices, Microstream™ capnography delivers the following clinical benefits:

- **Revolutionary Detection Technology**: Unique CO₂-specific molecular correlation spectroscopy (MSC) measurement technology is unaffected by the presence of other gases such as, O₂, N₂O, He or inhaled anesthetics.

- **Smart Capnography™ algorithms**: A suite of decision support algorithms proven to simplify the use of capnography monitoring, including:
  - **Smart Breath Detection™ algorithm (SBD)**: Reduces low amplitude “non-breath” CO₂ waveform excursions like talking, crying or snoring to provide a more accurate respiratory rate.
  - **Smart Alarm for Respiratory Analysis™ algorithm (SARA)**: Functioning in combination with the SBD algorithm, the SARA algorithm is proven to reduce clinically insignificant respiratory rate alarms.
  - **Integrated Pulmonary Index (IPI)**: Provides the only integrated measure of a patient’s adequacy of ventilation and oxygenation. This algorithm utilizes real-time measures and interactions of four parameters; etCO₂, RR, pulse rate and SpO₂, into a single 1–10 index.
  - **Apnea-Sat Alert (ASA)**: Apnea-Sat Alert provides an automated method of tracking recurring apnea and oxygen desaturation events anytime the patient is being monitored over one hour.

Capnostream™ 20p bedside monitor

The Capnostream™ 20p bedside monitor is built on a legacy of proven performance. Clinicians rely on Microstream™ technology for an accurate, continuous view of ventilation adequacy on intubated and nonintubated patients, from neonate to adult. The new Capnostream™ 20p bedside monitor reveals a more complete picture of your patient’s respiratory status.

Microstream™ capnography is integration capable

Microstream™ capnography can also be integrated into a host of multiparameter monitors. Please see our latest brochure for more details on compatibility with OEM partners.
QUALITY SAMPLING

Quality sampling lines from Medtronic

A key to obtaining an accurate etCO₂ measurement and quality CO₂ waveforms with any capnograph is the sampling line. Measurement technology can only report what is being delivered, so if the sampling line is not providing a representative CO₂ sample, the accuracy of the measurement is impacted.

Medtronic offers a range of sampling lines for various patient populations and procedures. The Smart CapnoLine™ sampling line is ideal for procedural sedation as it was engineered to obtain a quality sample whether the patient is breathing from one or both nares, orally or switching back and forth between nasal and oral breathing. It also delivers oxygen through production of an “oxygen cloud” through the nasal cannula.

![Figure 1: Mouth Breathing etCO₂ Measurement](image1)

![Figure 2: FiO₂ Consistency During O₂ Delivery at 2.5 lpm](image2)

Oxygen delivery

The Smart CapnoLine™ sampling line is designed to deliver oxygen through the production of an “oxygen cloud” in front of the nose and mouth. This is achieved with a series of small holes at the base of the nasal prongs and oral scoop that deliver oxygen. This design is also intended to minimize attenuation of the CO₂ sample by oxygen dilution.
SMART CAPNOLINE™ PLUS O₂ SAMPLING LINE

The Smart CapnoLine™ plus O₂ sampling line monitors patients’ CO₂ for immediate notification of respiratory complications including: airway obstruction, hypoventilation or shallow breathing. Used for lower gastrointestinal procedures, electrophysiology labs, cardiac cath labs and interventional radiology sedation, the system also provides O₂ delivery during the procedures.

The system offers a 4 m CO₂ line which is often needed in sedation areas. It conveniently can be sold with O₂ connector or O₂ tubing attached.

**Smart CapnoLine™ plus O₂ sampling lines are recommended for lower gastrointestinal procedures, electrophysiology labs, cardiac cath labs and interventional radiology sedation.**

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**0.2 micron Filter**
Sterilizing grade filter designed to reduce risk of biohazard contamination of the monitor

**Uni-junction™ Technology**
Enables etCO₂ sampling from either the nares or the mouth

**Oral Scoop**
Provides accurate sampling for mouth breathers
The Smart CapnoLine™ O₂ sampling line with Guardian bite block is designed to capture CO₂ samples and deliver supplemental oxygen during upper endoscopy procedures or any procedure when a bite block is required. The system enhances patient safety during sedation with oral and nasal CO₂ ventilation monitoring, during and after the procedure. The combined CO₂ sampling and O₂ delivery line fits into the bite block to protect delicate endoscopy devices from damage.

**Smart CapnoLine™ sampling lines are recommended for upper endoscopy procedures or any procedure when a bite block is required.**
### Product recommendations for Microstream™ capnography during procedural sedation

#### Upper procedures
- EGD (Esophagastroduodenoscopy)
- EUS (Endoscopic ultrasound)
- ERCP (Endoscopic retrograde cholangiopancreatography)
- Bronchoscopy

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<td>Smart CapnoLine™ O₂, sampling line with Guardian bite block</td>
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<td><strong>If oral approach use:</strong></td>
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<tr>
<td><strong>If nasal approach use:</strong></td>
<td><strong>Smart CapnoLine™ Plus O₂, sampling line</strong></td>
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#### Lower procedures
- Colonoscopy
- Flexible Sigmoidoscopy (no sedation)

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#### Other
- Bronchoscopy

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#### Procedural sedation outside GI lab
- Cardiac Cath Lab
- EP (Electrophysiology lab)
- ED (Emergency Department)
- Interventional Radiology
- TEE (Transesophageal echocardiogram)
- Bronchoscopy

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REFERENCES


