CO_2 Sensor

Safety and Performance Information

mindray

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Intended Use

⚠Warning

- According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Thus, no residual risk associated with using the medical device should be disclosed due to the risk management report.

Safety Information

⚠Warning

- This product is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on it.
- Do not use this product in the presence of flammable anesthetic gases.
- Check if the accessories and their packages are intact. Do not use them if any damage or contamination is detected.
- Use the accessories before the expiry date if their expiry date is indicated.
- Pay attention to protection during use. This product is not intended to be in direct contact with the human body.
- During use or storage, avoid cable entanglement to reduce pulling force on the cables, preventing patients from being entangled or choked.
- A disposable adapter is intended for one patient use and shall not be reused by other patients to prevent cross-infection.
- During use, replace the airway adapter when it is found dirty and check the airway adapter when the CO_2 waveform is obviously abnormal.
- Ensure that the CO_2 sensor is clean and dry before use. The window of the airway adapter is free of dirt or water stains.
- The measured $EtCO_2$ value may be inaccurate when the patient is treated with aerosol therapy. You are not advised to use the CO_2 sensor in this case.
- Remove the airway adapter from the breathing circuit during aerosol therapy, or the adherent aerosol drug may contaminate the adapter window.
- Do not make any changes to the product.
- Use the CO_2 sensor only with the airway adapters listed in this manual.

- If the baseline of the CO_2 waveform is raised, check the sensor or patient.

NOTE

- Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.
- The $EtCO_2$ value measured by the CO_2 sensor may differ from the CO_2 partial pressure measured by blood gas analysis.
- The CO_2 module generates physiological alarms only after respiratory waves are detected. When using the CO_2 module to monitor a patient, make sure that the module is correctly connected to the patient.
- Disposed of the device in compliance with the local or hospital's guidelines regulating the disposal of such products.

Applying the Sensor

Connecting the Sensor to Mindray Monitor or Ventilator

NOTE

- The warmup duration varies with the ambient temperature of the CO_2 sensor. At the temperature of 25±1ºC, the typical value of the warmup duration is less than 2 minutes.

Zeroing the Sensor

NOTE

- Before zeroing the sensor, remove the airway adapter from the breathing circuit and make sure that the window of the airway adapter is free of dirt.
- Do not rely on the measurement results of the sensor during zeroing.
- For better zeroing effect, you are advised to perform zeroing 2 minutes after connecting the CO_2 sensor to the airway adapter.

Connecting the Airway Adapter to the Patient Breathing Circuit

NOTE

- Before using the CO_2 sensor, set correct barometric pressure values on the monitor or ventilator. Incorrect setting of the value will result in incorrect CO_2 reading.
- Make sure that the sensor is always positioned above the airway adapter, preventing the liquid in the breathing circut from accumulating on the window of the airway adapter and affecting the normal measurement of the CO_2 sensor.

- Elevated levels of oxygen, nitrous oxide, helium and halogenated anesthetics may affect CO_2 measurement.
- To avoid the impact of dead space on CO_2 measurement, place the airway adapter as close to the patient as possible.

Cleaning, Disinfection, and Sterilization

NOTE

- Disconnect the CO_2 sensor from the monitor or ventilator before cleaning and disinfection.
- Do not disinfect or sterilize a disposable adapter.
- Use only cleansers, disinfectants and methods specified in this chapter. Using unapproved substances or methods may damage the device and void the warranty.
- Do not immerse the CO_2 sensor in water or disinfectant. Boiling disinfection is not allowed.
- Avoid the connector pins of the CO_2 sensor cable during cleaning and disinfection.
- Within the service life, a reusable adapter can tolerate 100 cycles of sterilization.
- It is recommended that the product be disinfected as required by the hospital. Do not disinfect the product too frequently to avoid affecting its service life.

Sterilizing the Reusable Airway Adapter

⚠Warning

- Only reusable airway adapters can be sterilized. The CO_2 sensor and disposable airway adapters cannot be sterilized, preventing damage to the sensor and accessories.

Specifications

General

Working environment	Temperature: 0 - 40°C Relative Humidity: 10 - 95%, non-condensing Barometric: 53.3 - 107.4 kPa
Storage and transportation environment	Temperature: -20 - 60°C Relative Humidity: 10 - 95%, non-condensing Barometric: 53.3 - 107.4 kPa

Weight	Sensor: ≤ 20g Sensor and cable: ≤ 85 g
Size (sensor, width x height x depth)	≤ 30 mm x 20 mm x 42 mm
Cable length	2.6 ± 0.1 m (cable and connector included)
Protection against harmful ingress of solid and water	IPX4 (Sensor only)
Protection against dropping	Withstand falling from 2m height for up to 100 times
Input voltage	5 VDC ± 3.5% (provided by Mindray monitor or ventilator)

Measurement Specifications

CO_2 measurement range	0 to 150 mmHg
CO_2 accuracy	0 mmHg to 40 mmHg: ±2 mmHg 41 mmHg to 70 mmHg: ±5% of reading 71 mmHg to 100mmHg: ±8% of reading 101 mmHg to 150mmHg: ±10% of reading
CO_2 resolution	0.1 mmHg
Rise time	< 60ms
awRR specification	Measurement range: 0-150 RPM Accuracy: ±1 RPM Resolution: 1 RPM
Initiation time	In 15 seconds after the sensor is connected to a monitoring device, the $EtCO_2$, $FiCO_2$ and awRR readings shall be displayed. The warm-up time at 25 ºC±1 ºC is <2 min (typical), after which the stated accuracy is met.
Response time	<2 s
Accuracy drift	Meet the requirement for measurement accuracy for at least 6 hours

Effect of interference gases on CO_2 measurements	With the presence of O_2, N_2O, AG or He gases in the mixed gases and under the condition that all compensation settings are correctly set, extra errors in worst cases are as follows: 0 mmHg to 40 mmHg: ±1 mmHg 41 mmHg to 70 mmHg: ±2.5% of the concentration 71 mmHg to 100 mmHg: ±4% of the concentration 101 mmHg to 150 mmHg: ±5% of the concentration In the presence of the following interfering gases, extra errors should be added as follows: Xenon (Concentration ≤ 100%): ±1 mmHg Ethanol (Concentration < 0.1%): 0 mmHg Acetone (Concentration < 1%): ±1 mmHg
Data sample rate	100 Hz

EMC Specification

The CO_2 sensor complies with the EMC standard IEC 60601-1-2:2020.

Note

- Use of the CO_2 sensor adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the CO_2 sensor and the other equipment should be observed to verify that they are operating normally.
- Always position the CO_2 sensor with the adapter in an upright position to avoid collection of fluids in the windows of the adapter. Large concentrations of fluids at this point will obstruct gas analysis.
- Use of portable or mobile communications devices can degrade the performance of the CO_2 sensor.
- If the CO_2 sensor is operated within the electromagnetic environment, it will remain safe and will provide the essential performances as CO_2 accuracy.
- To avoid dead space, place the CO_2 sensor as close to the patient as possible.

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