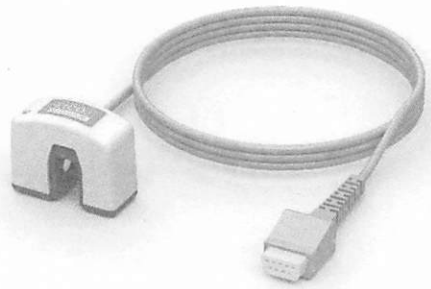
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: E=Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

Contact information

Mainstream EtCO2 Sensor

USER'S GUIDE

ENGLISH



Guidance and manufacturer's declaration - electromagnetic Immunity.									
	The CMZ EtCO2 Sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the EtCO2 Sensor should assure that it is used in such an environment.	IMMUNITY TEST LEVEL (V/m)	27	28	9	28	28	28	9
		Distance (m)	0,3	0,3	0,3	0,3	0,3	0,3	0,3
		Modulation b) (W)	1,8	2	0,2	2	2	2	0,2
		Modulation b)	Pulse modulation b) 18 Hz	FM c) ± 5 kHz deviation 1 kHz sine	Pulse modulation b) 217 Hz	Pulse modulation b) 18 Hz	Pulse modulation b) 217 Hz	Pulse modulation b) 217 Hz	Pulse modulation b) 217 Hz
		Service a)	TETRA 400	GMRS 460, FRS 460	LTE Band 13,17	GSM 800/900,TETRA 800, iDEN 820, CDMA 850,LTE Band 5	GSM 1800;CDMA 1900;GSM 1900; DECT;LTE Band 1, 3,4,25; UMTS	Bluetooth, WLAN, 802.11 b/g/n,RFID 2450,LTE Band 7	WLAN 802.11 a/n
		Band a) (MHz)	380 –390	380 –390	704 – 787	800 – 960	1700 –1990	2400 – 2570	5100 – 5800
		Test Frequency (MHz)	385	450	710/ 745/ 780	810/ 870/ 930	1720/ 1845/ 1970	2450	5240/ 5240/ 5785
		Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment).							

Radiated RF IEC61000-4-3	3 V/m 80MHz – 2.7GHz	3 V/m 80MHz – 2.7 GHz
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [Code SI] is used exceeds the applicable RF compliance level above, the [Code SI] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [Code SI]. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.		

Contents

Notice

About This Edition

Edition:

Document Number:

Publication Date:

This information is subject to change without prior notice.

The information in this document is applicable to the use of the EtCO2 Sensor model CMZ10/20/30/40/50.

Our company shall in no event be liable for any direct, indirect, special or consequential damages including without limitation damages for loss of business profits, loss of income, business interruption, loss of business information, loss of use or other related exposures, however caused, arising from the faulty or incorrect use of the product.

Liability

Our company guarantees that the product delivered has been thoroughly tested to ensure that it meets its published specifications.

Warranty

Please contact us for details regarding warranty and product returns.

Use of the product for other than its intended use, or if it has been repaired by anyone except us or our authorized service center, or altered or modified or used without following the instructions provided with the product, voids the warranty.

Note: Any serious incident that has occurred in relation to this device should be reported to Manufacturer. and the competent authority of the member state in which the user and/or patient is established.

Copyright

8.4 Precautions Regarding

The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below:

Guidance and manufacturer's declaration – electromagnetic emissions.	
The CMZ series EtCO2 Sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the EtCO2 Sensor should assure that it is used in such an environment.	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

Guidance and manufacturer's declaration – electromagnetic immunity.		
The CMZ series EtCO2 Sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the EtCO2 Sensor should assure that it is used in such an environment.		
IMMUNITY test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Not Applicable	/
Surge IEC 61000-4-5	Not Applicable	/
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable	/
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz

Guidance and manufacturer's declaration - electromagnetic Immunity.		
The CMZ series EtCO2 Sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the EtCO2 Sensor should assure that it is used in such an environment.		
Immunity Test	IEC 60601 Test level	Compliance level
Conduced RF IEC61000-4-6	Not applicable	Not applicable

7. Host Communication Specifications

It is the responsibility of the host system to monitor connectivity to the EtCO2 Sensor and provide status information and messages to the user. The Sensor will provide status information to the host via the communication protocol. It is the host's responsibility to provide any visual or audible indications of alert conditions to the end user.

Serial Communication Format	RS-232, bi-directional, 19200 baud, standard N-8-1.
Data Output	Real time CO2 waveform, gas and barometric pressure compensated, End-tidal CO2 Inspired CO2, Respiratory Rate. Status information.
Serial Communications Protocol	The Mainstream CO2 Sensor system shall use a proprietary protocol as the standard data communication protocol to the Host system. The signal levels shall conform to the RS-232 standard and be a in a bi-directional binary format.

8. EMC Statement

8.1 Description

CMZ EtCO2 Sensor only suitable for professional healthcare environment.

8.2 Precautions in Use

CMZ EtCO2 Sensor should be used with the monitor together.Use of non-specified acessories,Sensors and cable may result in increased electromagnetic emission or decreased electromagnetic immunity of the patient monitoring equipment.

The device or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device or its components should be observed to verify normal operation in the configuration in which it will be used.

When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.

8.3 Matching Accessories

Our company recommends the use of airway adapters produced by Respironics Novametrix, LLC. For the use method and precautions of airway adapter, refer to the Operating Manual of Responics Airway Adapter.

Warning: *Single Patient Use Airway Adapter cannot be reused or disinfected, which will reduce the performance of the system; After use, the airway adapter should be disposed of in accordance with local medical waste regulations.*

1. Intended Use

The EtCO2 Sensor is intended to provide carbon dioxide and respiratory rate monitoring to a host monitoring system (including a monitor or ventilator) during anesthesia/ recovery, in the intensive care unit(ICU), and in Emergency medicine/Transport or Respiratory care.

1.1 Intended Use and Prospective User

The EtCO2 Sensor is intended to provide carbon dioxide and respiratory rate monitoring to a host monitoring system (including a monitor or ventilator) during anesthesia/ recovery, in the intensive care unit(ICU), and in Emergency medicine/Transport or Respiratory care. The EtCO2 Sensor intended for adult, pediatric and infant patients.

EtCO2 Sensor is used only by trained and authorized medical professionals.

1.2 Intended Patients

Adult, Pediatric and infant patients.

1.3 Indications

The EtCO2 Sensor is indicated for the continuous noninvasive monitoring of end tidal carbon dioxide (EtCO2) and respiration rate in patients requiring ventilator support, transport, or anesthesia.

1.4 Contraindications

The EtCO2 Sensor has no absolute contraindications, healthcare professionals make decisions based on the patient's clinical condition.

2. Safety

2.1 Warnings

⚠ *Indicates a potentially harmful condition that can lead to personal injury.*

WARNING! Explosion Hazard: DO NOT use in the presence of flammable anesthetics or other flammable gasses. Use of the Sensor in such environment may present an explosion hazard.

WARNING! Electrical Shock Hazard: Always disconnect the Sensor before cleaning. DO NOT use if it appears to have been damaged. Refer servicing to qualified service personnel.

WARNING! Electrical Shock Hazard: No user serviceable parts inside.

WARNING! No modification of this equipment is allowed.

WARNING! Device is to be used by licensed practitioner, or other qualified medical personnel properly trained in its use.

WARNING! Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.

WARNING! Failure of Operation: If the Sensor fails to respond as described in this user guide; DO NOT use it until approved for use by qualified personnel.

WARNING! DO NOT position the Sensor cables or tubing in any manner that may cause entanglement or strangulation.

WARNING! Reuse, disassembly, cleaning, disinfecting or sterilizing the single patient use on-airway adapters may compromise functionality and system performance leading to a user or patient hazard. Performance is not guaranteed if an item labeled as single patient use is reused.

WARNING! Inspect the on-airway adapters for damage prior to use.

WARNING! DO NOT use the side stream on-airway adapters, if they appear to be damaged or broken.

WARNING! Replace the side stream on-airway adapters, if excessive secretions are observed.

WARNING! Monitor the CO2 waveform (CMZ). If you see changes or abnormal appearance check the patient and the sampling line and water filter. Replace line or water filter if needed.

WARNING! DO NOT operate the EtCO2 Sensor when it is wet or has exterior condensation.

WARNING! DO NOT apply excessive tension to any cable.

WARNING! DO NOT use device on patients with a respiration rate greater than or equal to 150 breaths per minute.

WARNING! DO NOT connect the exhaust tube to the ventilator circuit.

WARNING! DO NOT use it for patients who cannot tolerate an increased airway dead space or who cannot tolerate a 50 ml/min ± 10 ml airflow from the airway.

WARNING! Before use, carefully read these operating instructions.

WARNINGS FOR OEM!

- The host system shall provide any required electrical isolation.
- The Mainstream EtCO2 Sensor is not patient isolated. Use of the Sensor does not require direct patient contact. If isolation is desired or required, it is the responsibility of the Host system to provide the necessary isolation.

WARNING! Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

WARNING! Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING! Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING! When using this product, please provide the operator with matching gloves.

WARNING! Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the model CMZ(CMZ10, CMZ20, CMZ30, CMZ40, CMZ50) series, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

6.3 Host Interface and Physical Characteristics

Voltage Requirements	5VDC ± 5%. Ripple not to exceed 100.0 mV.
Power Rating	<1.2W Typical. <2.0W Warm-up.
Sensor Weight	<85g.
Sensor Size	D*W*H: 48mm * 24.3mm * 35.5mm.
Cable Length	2.4m.

6.4 Environmental

Temperature	Operating: 0 to 40 °C. Storage and Transport: -40 to 70 °C.
Humidity	Operating: 10 to 90% RH, non-condensing. Storage and Transport: 10 to 90% RH, non-condensing.
Atmospheric Pressure	Operating: 55kPa-105kPa. Storage and Transport: 55kPa-105kPa.
Category AP/APG	AP - This device is not suitable for use in the presence of a flammable anesthetic mixture with air or nitrous oxide.
Water Resistance	IPX4 - Splash-proof - Sensor only.
Mode of Operation	Sensor is rated for continuous use. No marking is required.
Protection Against Electric Shock	The Sensor does not provide electrical isolation for enclosure leakage current, patient risk circuit, or patient auxiliary current. It is the responsibility of the Host System to ensure that the power supply conforms to applicable standards - Recommend IEC 60601-1 Type BF.
Shock Impact	IEC TR 60721-4-7 Class 7M3 (designed to withstand environments subject to significant vibrations or high shock levels). EN60068-2-27 Shock. EN60068-2-64 Random Vibration.
Radiated Emissions	Host system dependent, designed to meet the requirements of EN55011- CISPR 11 Class B 30 MHz to 1000 MHz.
Electrostatic Discharge Immunity	Host system dependent, designed to meet the requirements of IEC 61000-4-2 (2001-04) 6 kV conducted 8 kV air discharge.
Radiated Immunity	Host system dependent, designed to meet the requirements of IEC 61000-4-3 (2002-03) 80 MHz to 2.5 GHz, 20 V/m.
Immunity to Conducted Disturbances Induced by RF Fields	Host system dependent, designed to meet the requirements of IEC61000-4-6 (2001-04).

Inspired CO2 Measurement	Range: 3 to 50 mmHg. Method: Lowest reading of the CO2 waveform in the previous 20 seconds. Selection: 20 seconds (not user-selectable).
Gas Compensation	Automatic atmospheric pressure compensation by default.
Main Functions	a) The atmospheric pressure of the detection environment can be monitored, and the monitoring range is 400 to 800 mmHg. b) can monitor the temperature of the detection environment. c) can automatically monitor the airway blockage. d) can automatically monitor whether the gas sampling tube connection is complete. e) can automatically compensate for the detection error caused by atmospheric pressure. f) It can report three units of mmHg, %, kPa.

6.2 Interfering Gas and Vapor Effects

Gas or Vapor	Gas Level	Quantitative Effects
Nitrous Oxide	60	N/A
Halothane	4	N/A
Enflurane	5	N/A
Isoflurane	5	N/A
Sevoflurane	5	N/A
Xenon	80	Negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38 mmHg
Helium	50	No Additional Effect
Metered dose inhaler propellants	Unspecified	Unspecified
Desflurane	15	Concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38 mmHg.
Ethanol	0.1%	N/A
Isopropanol	0.1%	N/A
Acetone	0.1%	N/A
Methane	1%	N/A

(ISO 21647, Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors, Table 105.)

2.2 Cautions

⚠ *Indicates a condition that may lead to equipment damage or malfunction.*

CAUTION! Electrical Shock Hazard; the EtCO2 Sensor is not user serviceable. Refer servicing to qualified personnel.

CAUTION! Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.

CAUTION! Use only approved accessories.

CAUTION! DO NOT use the EtCO2 Sensor if it fails to operate properly, appears to have been damaged, is wet or has exterior condensation.

CAUTION! DO NOT sterilize or immerse the EtCO2 Sensor in liquids.

CAUTION! DO NOT clean the EtCO2 Sensor and accessories except as directed in this guide.

CAUTION! DO NOT apply excessive tension to the EtCO2 Sensor cable.

CAUTION! DO NOT store the EtCO2 Sensor at temperatures less than -40 °C or greater than 70 °C.

CAUTION! DO NOT operate the EtCO2 Sensor at temperatures less than 0 °C or greater than 40 °C.

CAUTION! Remove the sampling kit from the receptacle when not in use.

CAUTION! DO NOT stick appendage into sample receptacle.

CAUTIONS FOR OEM!

- The host system shall monitor for EtCO2 Sensor connectivity and report the status and messages as required.
- In the presence of electromagnetic devices (i.e., electro cautery), patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 20 V/m will not adversely affect Sensor performance.
- Precautionary statement to use only approved accessories.

2.3 Notes

⚠ *A point of particular interest or emphasis intended to provide more effective or convenient.*

NOTE! Recommended operating temperature is 0 °C to 40 °C.

NOTE! The Mainstream EtCO2 Sensor contains no user serviceable parts. Refer service to qualified service personnel.

NOTE! This product and its accessories are latex free.

NOTE! After the life cycle of the EtCO2 Sensor and its accessories have been met, disposal should be accomplished following national and/or local requirements.

NOTE! Nitrous oxide, elevated levels of oxygen, helium, xenon, halogenated hydrocarbons, and barometric pressure can influence the EtCO2 measurement. Levels to be supplied by host monitor.

NOTE! The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

2.4 Product Life

This product should be used and stored under specified conditions. and its validity period is 6 years.

2.5 Symbols and Labels

Symbol	Title
	Gas input.
	Gas output.
	Country of manufacture.
	Use-by date.
	Manufacturer.
	Serial number.
	Batch code.
	Catalog number.
	Authorized representative in the European Community.
	Follow instruction for use.
	Caution (U.S.): Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Do not re-use.
	For EU only: Waste Electrical and Electronic Equipment (WEEE).

6. Specifications

The Mainstream EtCO2 Sensor specifications are subject to change without prior notice. Unless otherwise stated, all CO2 measurements are taken after zeroing , using 5% CO2 gas, balance N2 at 25 degrees Celsius, and Pb.=760 mmHg with2 liters per minute flow. The stabilization time for full specification testing of the EtCO2 Sensor over the entire temperature range is 20 minutes.

6.1 General Specifications

Mode of Sampling	Mainstream.
Principle of Operation	Non-dispersive infrared, dual wavelength, no moving parts.
Initialization Time	Mainstream EtCO2 Sensor displayed in less than 4 seconds, At an ambient temperature of 25 °C, full specifications within 2 minutes.
Reportable Unit	mmHg, %, kPa (three units can choose).
CO2 Measurement Range	0 - 152 mmHg. 0 - 20 %. 0 - 20.3 kPa.
CO2 Response Time	1.6s.
CO2 Resolution	0.1 mmHg @ 0 - 69 mmHg. 0.25 mmHg @ 70 - 152 mmHg.
CO2 Accuracy*	CO2 measurement accuracy: [0, 30]mmHg:±2mmHg; [30, 70]mmHg:±5%; [70, 152]mmHg:±8%. ***Note:*** *Gas temperature at 25 °C.*
CO2 Stability	Short Term Drift: Drift over four hours shall not exceed 0.8 mmHg maximum. Long Term Drift: Accuracy specification will be maintained over a 120 hour period.
CO2 Noise	RMS noise of the Sensor shall be less than or equal to 0.5 mmHg at 5% CO2.
Calibration	No routine user calibration required.
Respiration Rate Range	0 to 150 breaths per minute.
Respiration Rate Accuracy	±1 breath.
Breath Detect Method	adaptive threshold.
Sampling Rate	100 Hz.
EtCO2 Calculation	Method: Peak of the expired CO2 waveform. Selections: 1 breath, 10 second, 20 second. ***Note:*** *the minimum reported differential value between the baseline and the CO2 value shall be 5 mmHg.*

5. Maintenance

5.1 CO2 Accuracy Check

The following procedure should be performed to check the EtCO2 accuracy of the EtCO2 Sensor. It is recommended that this procedure be performed every 12 months.

- Connect the EtCO2 Sensor to the Host monitor. Connect CO2 airway adapter to the EtCO2 Sensor.
- Turn on the Host monitor.
- On the Host monitor, switch to the CO2 Accuracy Mode. This mode requires the CO2 waveform value to be displayed as a digital instantaneous value.
- Wait for the EtCO2 Sensor to warm up to its operating temperature.
- Set the CO2 Units of EtCO2 Sensor to percentage.
- Set the gas compensation of the EtCO2 Sensor to the verification gas mixture.
- Make zeroing.
- Connect a regulated flowing gas mixture of 5% CO2, balance N2 to the airway adapter. Set the flow rate of the gas to 2 liters per minute.
- Allow the gas mixture to stabilize for 30 seconds and observe the CO2 value. The expected value is 5% ± 0.26%.
- If a waveform is present, verify that it appears as a straight line at approximately 5 percent.
- The accuracy check is completed. Remember to restore the EtCO2 Sensor settings for units and gas composition to their previous settings.

5.2 Cleaning

Cleaning the EtCO2 Sensor case, Cable and Connector:

- Before cleaning the Sensor, the power of the host must be turned off.
- It is recommended that users soak a clean dry gauze with 70% to 80% (volume ratio) ethanol disinfectant, and then wipe the surface of the Sensor with the gauze.
- Air dry or wipe off any residual disinfectant with a clean dry cloth.

Note: *Do not immerse or sterilize the Sensor.*

Note: *The Side stream on-airway adapters and side stream sampling kits are single patient use. Treat in accordance with hospital protocols for handling single patient use devices.*

5.3 Airway Adapter

- EtCO2 Sensor is only used with the airway adapters of Part 4.1.2 "Selecting the Accessories" in this manual.
- The airway adapters are intended for single patient use. They are disposable and shall not be re-used. Reuse of single patient use adapters can cause cross infection.
- The airway adapters shall be disposed of in accordance with local regulations for bio-hazardous waste.

Note: *The manufacturer can provide schematics, component lists, legends, calibration details, or other information that helps maintenance personnel repair equipment parts that can be serviced by maintenance personnel authorized by manufacturer.*

	Non sterilization.
	Symbol for temperature limitation/temperature range.
	Symbol for humidity limitation/humidity range.
	Symbol for atmospheric pressure limitation/ atmospheric pressure range.
	Indicates a carrier that contains unique device identifier information.
	Indicates the item is a medical device.
	Indicates the entity importing the medical device.
	CE certification mark.

3. Device Description

3.1 Overview

The EtCO2 Sensor is indicated for the continuous noninvasive monitoring of end tidal carbon dioxide (EtCO2) and respiration rate in patients requiring ventilator support, transport, or anesthesia.

3.2 Principles of Operation

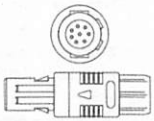
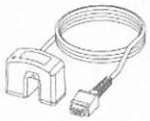
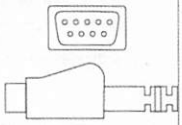
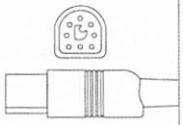
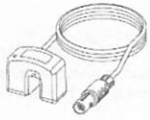
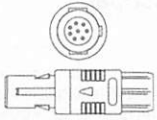
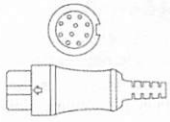
The Mainstream EtCO2 Sensor is used for the continuous measurement of CO2 (carbon dioxide) and respiratory rate(RR).

The Mainstream EtCO2 Sensor is a non-dispersive infrared analyzer. In Sensor, infrared light is generated by the Sensor and beamed through the sample cell to a detector on the opposite side. CO2 from the patient that is aspirated into the sample cell absorbs some of this infrared energy. The Sensor determines CO2 concentration in the breathing gases by measuring the amount of light absorbed by these gases. The Sensor contains a reference channel, used to compensate for optical changes, so that the system is in a state of calibration. EtCO2 is displayed as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO2 waveform (capnogram) may be displayed which is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal tube (ETT) placement. Respiration rate is calculated by measuring the time interval between detected breaths.

3.3 Product Models

This manual is applicable to the Mainstream EtCO2 Sensor produced by Manufacturer.

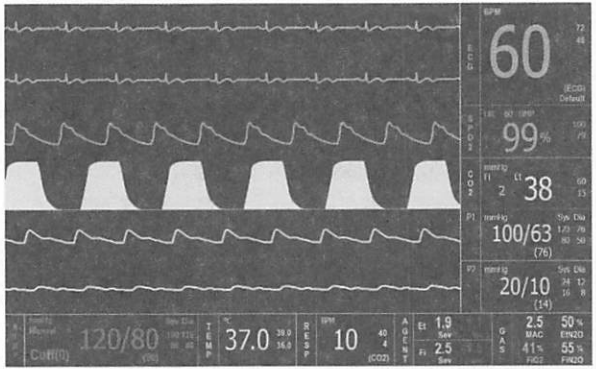
The list of applicable models:

Model NO.	Mode of Sampling	Connector	Compatible with
CMZ10			Respironics OEM
CMZ20			Phasein
CMZ30			Philips
CMZ40			Zoll
CMZ50			Mindray

Note: *Data Interface: RS-232, bi-directional, 19200 baud (Phasein: 9600 baud), standard N-8-1.*

4.4 Capnograph Display

Parameters and measurements display on the screen of the host device that EtCO2 Sensor is connected to. Refer to the host device operator's manual or user. Taking "Expression Model MR400 MRI Patient Monitoring System"as an example, the parameters (including: CO2 real-time waveform, EtCO2 value, FiCO2 value and respiratory rate) are displayed as follows:



4.5 Alerts Informations

Status LED on the Mainstream EtCO2 Sensor:

Indication	Status
Steady blue light	System OK
Steady yellow light	Sensor error
Blinking yellow light	Airway adapter error

4.6 Precautions

- Any degradation in MEASUREMENT ACCURACY of the end-tidal GAS READING as a function of respiratory rate and I:E ratio (inspiratory/expiratory time ratio) over their RATED ranges.
- Known adverse effects on stated performance due to the following:
  - — quantitative effects of gas sample humidity or condensate.
  - — leaks or internal venting of sampled gas.
  - — cyclical pressure of up to 10 kPa (100 cmH2O).
  - — other sources of interference.

4. Check the status of the EtCO2 Sensor and confirm that whether the status bit "EtCO2 Sensor not ready to zero"is set.
5. Start the Zeroing. The maximum time of zeroing is 40 seconds. The typical time for a zeroing is 15-20 seconds.

Note: For best results, wait 5 minutes to allow the EtCO2 Sensor to warm up before performing the Zero procedure.

4.3.2 Zeroing Calibration

Zero calibration should be performed after each replacement of the adapter.

1. Explanation

Zero calibration should be performed after each replacement of the adapter. Zero calibration can eliminate the measurement error caused by the difference of the adapter. Zero calibration must be performed after each replacement. Under the following conditions, the system will prevent zero calibration to avoid wrong calibration.

- After the sampling system is fully connected, it cannot be inserted into the patient's breathing channel.
- When the ambient temperature of the Sensor self-test is unstable.

2. Zero calibration steps.

- Connect the gas path of the Sensor completely.
- The data cable is connected to the dedicated socket of the supporting monitor, ventilator and anesthesia machine.
- After the module is fully warmed up, zero calibration is started.
- One end of the sampling tube has been inserted into the Sensor, and the other end must be exposed to fresh air, away from all CO2 sources, including the breath of the ventilator, patient and user.
- Set the host to the zero calibration function, check the zero status bit, and confirm whether zero calibration can be performed.
- Start zero-point calibration. Zero-point calibration takes 15-20 seconds, and the longest is no more than 40 seconds.

Note: Allow the module to fully warm up before performing a zero calibration to achieve the best performance.

- If the module detects respiration (change in CO2 concentration) during the zero calibration, the zero calibration may fail and display "ZERO FAILED".
- Do not perform zero calibration in the patient's airway.
- After the airway adapter is removed from the patient's airway, do not perform zero calibration within 20s, because CO2 gas remains in the adapter at this time, and it takes about 20S to dissipate.

4. Operating

This section provides information how to setup the EtCO2 Sensor. Mainstream EtCO2 Sensor is a Sensor with rugged, solid-state. It is calibrated in factory and does not require further calibration.

4.1 Selecting Device and Accessories

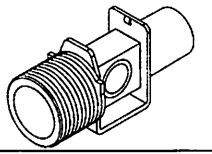
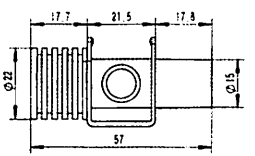
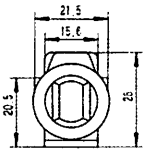
4.1.1 Selecting the Device

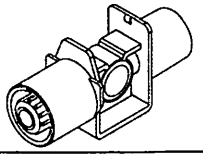
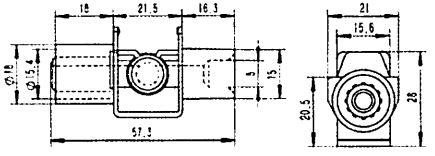
Select the appropriate EtCO2 Sensor according to the device brand and interface type. Regarding the interface types and parameters of EtCO2 Sensor, see the relevant contents in Section 3.3 "Product Models". The device brand and models that can be used with our Sensors after verification are shown in the following table:

EtCO2 Sensor Modle	Device Brand	Series	Model
CMZ10	MEK(Korea)	Patient Monitor	MP800C
CMZ20	eVent Medical	Ventilator	Inspiration® 7i Ventilator
CMZ30	PHILIPS	Patient Monitor	MP50
CMZ40	Zoll	Patient Monitor	R Series® Monitor
CMZ50	MINDRAY	Patient Monitor	BeneView T5

4.1.2 Selecting the Accessories

Choose appropriate airway adapter based on the patient's monitoring situation. Airway adapter taper meets to ISO 5356-1. Other parameters of adapter are shown in the following table:

Type	Pediatric/Adult Disposable Airway Adapter	Pediatric/Adult Reusable Airway Adapter
Specifications	• For intubated patients with endotracheal tube diameters greater than 4 mm; • Adds 5 cc of deadspace; • Pressure drop: 0.50 cmH2O @ 60 LPM 	
Dimension description		

Type	Infant/Pediatric Disposable Airway Adapter	Infant/Pediatric Reusable Airway Adapter
Specifications	• For intubated patients with endotracheal tube diameters greater than 4 mm; • Adds 1 cc of deadspace; • Pressure drop: 0.80 cmH2O @ 10 LPM 	
Dimension description		

Note: All components are Latex free.
Note: All dimensions are in millimeters.
Note: The adapters can be connected to anesthesia, ventilator, or BIPAP/CPAP masks for non-intubated patients.

Note: The company does not provide airway adapter, which needs to be purchased by the user. In addition to the above technical parameters, the purchased adapter shall also meet to the requirements of EU MDR regulations for this product.

Note: The EtCO2 Sensor can be used with the airway adapter produced by Respironics Novametrix, LLC.

Warning: Single Patient Use Airway Adapter cannot be reused or disinfected, which will affect the performance of the system;The airway adapter should be disposed of in accordance with local medical waste regulations.

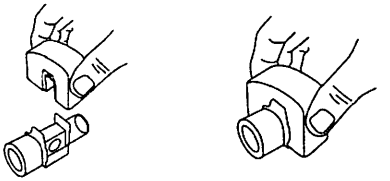
4.2 Setting Up

1. Connect the Sensor to the host monitor.
2. Install the airway adapter. Zero the Sensor if a message indicating you should calibrate the Sensor. Refer to the monitor operator's manual for calibration information.
3. Confirm that the monitor's barometric pressure setting is correct. Refer to the appropriate service manual for information on how to set the barometric pressure.
4. Place the adapter and Sensor in the patient breathing circuit as close to the patient as possible. A location between the endotracheal tube and the ventilator circuit is common.

***Note:** Always position the Sensor with the adapter in an upright position to avoid collection of fluids on the windows of the adapter. Large concentrations of fluids at this point will obstruct gas analysis.*

4.2.1 Combine with the Airway Adapter

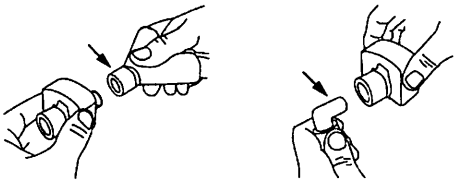
1. Verify the adapter is intact.
2. Make sure the adapter window is dry and clean.
3. Press the Mainstream EtCO2 Sensor onto the airway adapter. it will "click" when properly seated.



4. Make sure the Sensor is properly connected to the adapter, and the adapter window is dry and clean.

4.2.2 Connecting to a Tube

The Mainstream EtCO2 Sensor can be connected to a patient using an endotracheal tube. The following pictures show two methods of connection.



Tube with id15mm according to ISO 5356-1

Tube with De 15mm according to ISO 5356-1

- The cord of the Sensor should be facing away from the patient.
- For optimal results, do not place the adapter between the ET tube and the elbow.

4.3 Zeroing the Sensor

The zeroing allows the EtCO2 Sensor to adjust to the optical characteristics of Airway adapter which can reduce the measurement error. Zeroing is necessary only when requested. The following conditions which system can prevent zero to avoid error correction.

- Breath is detected in last 20 seconds.
- If the temperature is not stable.

4.3.1 Make Zeroing

1. Connect the EtCO2 Sensor and wait until the warm-up message is cleared.
2. Connect the airway adapter to the EtCO2 Sensor, and make sure that the airway adapter away from all sources of CO2 gas, including the ventilator, the patient's breath and your own.
3. Set the device to operate the zeroing.