CAPNOSTAT® 5 Design Guide

File Approval

Responsible Engineer: RICHARD DANIELS 12.14.06

Printed Name Signature Date

Revision	C.O.	Date	Author	Description
56	N3292	4-Dec-06	R. Daniels	Update

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Respironics Novametrix, LLC.
5 Technology Drive
Wallingford, Connecticut, U.S.A. 06492
Tel. (203) 697-6450

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Patents

4,859,858 4,859,859 4,914,720 5,146,092 5,153,436 5,369,277 5,616,923 5,793,044. Other foreign and US patent pending.

Revision History

10-Jun-04	Rev. 50, CO_N1167
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04-Dec-06	Rev. 56, CO_N3292

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Contents

Section 1 *Overview*

The CAPNOSTAT 5 CO_2 Sensor is designed specifically for mainstream measurement of CO_2 using sophisticated infrared absorption spectroscopy. With mainstream, measurements are taken at the patient's airway at a sampling frequency of 100 Hz, so response is faster and there is less chance of erroneous, artifact data. The analyzer portion of the sensor cannot be contaminated with patient secretions, and there are no pumping or pneumatic components to replace. So, maintenance requirements and overall cost-of-ownership are minimized. The exclusive Respironics Novametrix family of airway adapters are easy to use and durable enough even for long-term ventilator patients. Yet, they are inexpensive and disposable.

The CAPNOSTAT 5 CO_2 Sensor can be integrated with other components, software packages and accessories, making it easy for you to configure your patient monitoring systems with state-of-the-art respiratory management and analysis technology.

The CAPNOSTAT 5 CO_2 Sensor measures CO_2 in the patient airway at 100 Hz. This sensor uses the same interface to the patient monitoring system as the Quo™ Mainstream O_2/CO_2 Sensor and the LoFlo Sidestream CO_2 Module making it easy to configure a patient monitoring system with state-of-the-art O_2 and CO_2 monitoring technology that is affordable and easy to use.

Indication for Use

- The CAPNOSTAT 5 CO_2 Sensor is to be used as prescribed by a physician or licensed medical practitioner trained in the use of the equipment.
- The use of the CAPNOSTAT 5 CO_2 Sensor is contraindicated in patients where the physician or licensed medical practitioner deems it invalidated by the nature of the patient, procedure or equipment.

Medical use of the product

- The CAPNOSTAT 5 CO_2 Sensor is used to continuously monitor carbon dioxide and report $ETCO_2$, inspired CO_2 and respiratory rate of the intubated and non-intubated adult, pediatric, infant and neonatal patient.
- The CAPNOSTAT 5 CO_2 Sensor is indicated for use in care areas such as, but not limited to critical care, intensive care, anesthesia, medical/surgical units, LTAC units, emergency department, sleep labs and during intra-hospital transport and inter-hospital transport.
- For use in monitoring patients in respiratory distress, respiratory arrest or that have asthma, COPD or other disorders where the patient's $ETCO_2$ and capnogram will benefit the caregiver in the treatment of the patient.
- For use in monitoring patients pre- and post-intubation.
- To assist in the setup, management and weaning of the patient that is connected to a "conventional" mechanical ventilator.

Regulatory Clearance

- The CAPNOSTAT 5 CO_2 Sensor has received FDA 510K clearance (K042601).
- The CAPNOSTAT 5 CO_2 Sensor complies with the Medical Device Directive (93/42/EEC) and is CE marked (CE 0086).

Principles of Operation

The CAPNOSTAT 5 CO_2 Sensor is used for the continous measurement of CO_2 and respiratory rate. The sensor measures CO_2 by using the infrared absorption technique. The principle is based on the fact that CO_2 molecules absorb infrared (IR) light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR beam is passed through a gas sample containing CO_2, the electronic signal from the photodetector (which measures the remaining light energy) is measured. This signal is then compared to the energy of the IR source and adjusted to accurately reflect CO_2 concentration in the sample. The CAPNOSTAT 5 CO_2 Sensor's response to a known concentration of CO_2 is stored at the factory in the sensor's memory. A reference channel accounts for optical changes in the sensor, allowing the system to remain in calibration without user intervention.

Section 2 *Safety*

Warnings

WARNING

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

- **Explosion Hazard:** DO NOT use in the presence of flammable anesthetics. Use of the CAPNOSTAT 5 CO_2 Sensor in such environment may present an explosion hazard.
- **Electrical Shock Hazard:** Always disconnect the CAPNOSTAT 5 CO_2 Sensor before cleaning. Do NOT use if it appears to have been damaged. Refer servicing to qualified service personnel.
- Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
- **Failure of Operation:** If the CAPNOSTAT 5 CO_2 Sensor fails to respond as described in this user guide; DO NOT use it until approved for use by qualified personnel.
- DO NOT position the sensor cables or tubing in any manner that may cause entanglement or strangulation. Support the CAPNOSTAT 5 airway adapter to prevent stress on the ET tube.
- Reuse, disassembly, cleaning, disinfecting or sterilizing the single patient use CO_2 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.
- Inspect the CO_2 airway adapters for damage prior to use. DO NOT use the CO_2 airway adapters if they appear to be damaged or broken.
- Replace the CO_2 airway adapters if excessive secretions are observed.
- If the CO_2 waveform (Capnogram) appears abnormal, inspect the CO_2 airway adapters and replace if needed.
- Monitor the CO_2 waveform (Capnogram) for elevated baseline. Elevated baseline can be caused by sensor or patient problems.
- Periodically check the CO_2/Flow sensor and tubing for excessive moisture or secretion buildup.
- While using the CO_2/Flow sensor, a system leak, such as that caused by an uncuffed endotracheal tube or a damaged CO_2/Flow sensor may significantly effect flow-related readings. These include flow, volume, pressure and other respiratory parameters.
- Do not operate the CAPNOSTAT 5 CO_2 Sensor when it is wet or has exterior condensation.
- **Warnings for the OEM:**
  - The Host system shall provide any required electrical isolation.
  - The CAPNOSTAT 5 CO_2 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.
  - It is the responsibility of the Host system to provide appropriate current limiting on the CAPNOSTAT 5 power supply rails.

Cautions

CAUTION

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

- **Electrical Shock Hazard**; the CAPNOSTAT 5 CO_2 Sensor is not user serviceable.
- Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
- Caution: Federal (U.S.A.) law restricts the CAPNOSTAT 5 CO_2 Sensor to sale, distribution, or use by or on the order of a licensed medical practitioner.
- Use only Respironics Novametrix approved accessories
- DO NOT use the CAPNOSTAT 5 CO_2 Sensor if it is wet or has exterior condensation.
- DO NOT use the CAPNOSTAT 5 CO_2 Sensor if it appears to have been damaged. Refer servicing to qualified personnel.
- DO NOT use the CAPNOSTAT 5 CO_2 Sensor if it fails to operate properly.
- DO NOT sterilize or immerse the CAPNOSTAT 5 CO_2 Sensor in liquids.
- DO NOT clean the CAPNOSTAT 5 CO_2 Sensor except as directed in this guide.
- Avoid possible damage to the CAPNOSTAT 5 CO_2 Sensor by following the cleaning and disinfection instructions in this guide.
- Do not apply excessive tension to the CAPNOSTAT 5 CO_2 Sensor cable.
- Do not apply excessive tension to any sensor cable or pneumatic tubing.
- Excessive moisture in the CO_2/Flow sensor may affect the accuracy of the flow measurement.
- To avoid the affects of excessive moisture in the measurement circuit, insert the CO_2/Flow sensor in the ventiator circuit with the tubes upright.
- It is recommended that the CO_2/Flow sensor be removed from the circuit whenever an aerosolized medication is delivered. This is due to the increased viscosity of the medications which may contaminate the sensor windows, causing the sensor to fail prematurely.
- Do not store the CAPNOSTAT 5 CO_2 Sensor at temperatures less than -40º F (-40º C) or greater than 158º F (70º C).
- Do not operate the CAPNOSTAT 5 CO_2 Sensor at temperatures less than 32º F (0º C) or greater than 113º F (45º C).
- **Cautions for the OEM:**
  - The Host system shall monitor for CAPNOSTAT 5 CO_2 Sensor connectivity and report the status and messages as required.
  - In the presence of electromagnetic devices (i.e., electrocautery), patient monitoring may be interrupted due to electromagnetic interference. Electromagnetic fields up to 20 V/m will not adversely affect system performance.

Notes

NOTE

A point of particular interest or emphasis intended to provide more effective or convenient operation

- The CAPNOSTAT 5 CO_2 Sensor contains no user serviceable parts. Refer service to qualified service personnel.
- Components of this product and its associated accessories which have patient contact are free of latex.
- Disposal of the CAPNOSTAT 5 CO_2 Sensor and its accessories should comply with national and/or local requirements.
- Nitrous oxide, elevated levels of oxygen, helium and halogenated hydrocarbons can influence the CO_2 measurement.
- Barometric pressure compensation is required to meet the stated accuracy of the CAPNOSTAT 5 CO_2 Sensor.
- As with all flow measuring devices, adverse conditions may affect the accuracy of the flow measurement.
- DO NOT place the combined CO_2/Flow sensor between the ET tube and the elbow (pediatric/adult circuit), as this may allow patient secretions to block the adapter windows.
- The white-striped tubing of the flow sensor should always be proximal to the patient.
- Position the combined CO_2/Flow sensor with its windows in a vertical and NOT a horizontal position: this helps keep patient secretions from “pooling” on the windows.
- To prevent “rain-out” and moisture from draining into the tubing of the flow sensor or combined CO_2/Flow sensor, keep the tubing in an upright position.
- Periodically check the flow sensor and tubing for excessive moisture or secretion buildup.

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Section 3 *Sensor Specifications*

CAPNOSTAT 5 CO_2 Sensor specifications are subject to change without notice. All information supplied is company confidential. Unless otherwise stated, all CO_2 measurements are made following an airway adapter zero, with 5% CO_2 gas, balance N_2 at 25 degrees C, and Pb = 760 mmHg with 2 liters per minute flow.

The stabilization time for full specification testing of the CAPNOSTAT 5 CO_2 Sensor over the entire temperature range is 20 minutes.

CAPNOSTAT 5 CO_2 SENSOR - SPECIFICATIONS	
Carbon Dioxide Monitoring:	
Transducer Type	Mainstream
Principle of Operation	Non-dispersive infrared (NDIR) single beam optics, dual wavelength, no moving parts.
Initialization Time	Capnogram displayed in less than 15 seconds, at an ambient temperature of 25° C, full specifications within 2 minutes,
CO_2 Measurement Range	0 to 150 mmHg 0 to 19.7% 0 to 20 kPa (Barometric Pressure supplied by Host)
CO_2 Calculation Method	BTPS (Body Temperature Pressure Saturated)
CO_2 Rise Time (10 - 90% of step change of final CO_2 value)	Less than 60 ms - Adult reusable or single patient use Less than 60 ms - Infant reusable or single patient use
CO_2 Resolution	0.1 mmHg 0 to 69 mmHg 0.25 mmHg 70 to 150 mmHg
CO_2 Accuracy *	0 - 40 mmHg ± 2 mmHg 41 - 70 mmHg ± 5% of reading 71 - 100 mmHg ± 8% of reading 101 - 150 mmHg ± 10% of reading * NOTE: Temperature at 35° C.
CO_2 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.

CAPNOSTAT 5 CO_2 SENSOR - SPECIFICATIONS	
CO_2 Noise	RMS noise of the sensor shall be less than or equal to 0.25 mmHg at 7.5% CO_2
Sampling Rate	100 Hz
Respiration Rate Range	0 to 150 breaths per minute (BPM)
Respiration Rate Accuracy	± 1 breath
Calibration	No routine user calibration required. An airway adapter zero is required when changing to a different style of airway adapter. Safety lock-outs: • System does not allow adapter zero for 20 seconds after the last breath is detected. • System does not allow adapter zero if temperature is not stable.
$ETCO_2$ Calculation	Method: Peak of the expired CO_2 waveform Selections: 1 breath, 10 second, 20 second **Note**: the minimum reported differential value between the baseline and the CO_2 value shall be 5 mmHg.
Inspired CO_2 Measurement	Range: 3 to 50 mmHg Method: Lowest reading of the CO_2 waveform in the previous 20 seconds Selection: 20 seconds (not user-selectable)
Compensations (Host Controlled)	Compensations for: Expired O_2, balance gas (N_2, N_2O, He) and anesthetic agents Uses gas compensation information and barometric pressure to correct the raw carbon dioxide value
O_2 Compensation	Range: 0 to 100% Resolution: 1% Default: 16%
N_2O Compensation	Range: 0 (off) or 1 (on) Default: Off Note: If ON, the balance of the mixture is O_2
He Compensation	Range: 0 (off) or 1 (on) Default: Off Note: If ON, the balance of the mixture is O_2
Total Pressure	Range: 400-850 mmHg. Total pressure = Barometric plus Airway pressure. Barometric pressure provided by host. Recomended accuracy of pressure transducer: ± 1% FS

CAPNOSTAT 5 CO_2 SENSOR - SPECIFICATIONS		
Anesthetic Agent Effects (MAC levels)	Anesthetic Agent Sensitivity (uncompensated)	Accuracy specification will be maintained for halogenated anesthetic agents present at accepted MAC (Minimum Alveolar Concentration) clinical levels. (Refer to Table A)
	Anesthetic Agent Sensitivity (compensated)	Testing at Agent levels defined by accepted regulatory standards (i.e. ASTM F1456, ISO 21647). (Refer to Table B)
Cross-sensitivity Compensation Error*	0-40 mmHg: ± 1 mmHg additional error 41-70 mmHg: ± 2.5% additional error 71-100 mmHg: ± 4% additional error 101-150 mmHg: ± 5% additional error * Additional worst case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.	

Additional notes regarding cross-sensitivity compensation errors:

Xenon: The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by an additional 5 mmHg at 38 mmHg.

Desflurane: The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38 mmHg.

Ethanol, Isopropanol, Acetone, Methane: CO_2 accuracy will not be affected by the presence of 0.1% ethanol, 0.1% isopropanol, 0.1% acetone or 1% methane.

Quantitative effects of humidity and condensation: Full accuracy specifications will not be maintained for all non-condensing humidity levels.

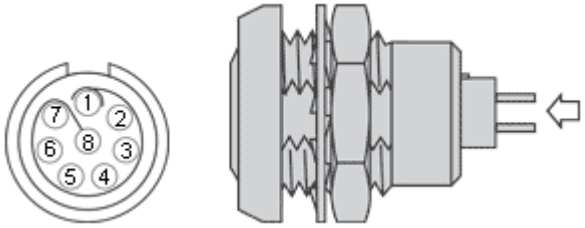
Table A

Gas or Vapor	Halothane	Enflurane	Isoflurane	Desflurane
MAC Level % (v/v)	0.74	1.68	2.00	6.30

(From Olivier C. Wenker: *Review of Currently Used Inhalation Anesthetics: Part I*. The Internet Journal of Anesthesiology, 1999, Volume 3 Number.)

Table B	
Gas or Vapor	**Gas Level**
Nitrous oxide	60
Halothane	4
Enflurane	5
Isoflurane	5
Sevoflurane	5
Xenon	80
Helium	50
Metered dose inhaler propellants	Unspecified
Desflurane	15
Ethanol	Unspecified
Isopropanol	Unspecified
Acetone	Unspecified
Methane	Unspecified

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

CAPNOSTAT 5 SENSOR - SPECIFICATIONS (Cont.)	
Physical Characteristics and Host Interface:	
Physical characteristics	Weight: 25 grams – CAPNOSTAT 5 CO_2 Sensor only; 78 grams CAPNOSTAT 5 CO_2 Sensor with cable and standard LEMO connector Size: 33 mm high x 43 mm wide x 23 mm deep 3 meter cable standard
Interconnection	Standard - Lemo Redel 8-pin plastic Sensor Plug: PAB.M0.8GL.AC39GZ Bend Relief: GMA.1B.030.DJ Host Receptacle: PKB.M0.8GL.LJ Pinout: 1 VA 5.0V 2 SHIELD SHIELD return 3 DGND Digital return 4 VSRC 5.0V 5 TxD Serial data from CAPNOSTAT 6 RxD Serial data from Host 7 AGND Analog return 8 SYNC Waveform synchronization* *NOTE: If unused, terminate the SYNC signal with a 2K ohm resistor to digital ground. 
Compatibility and Interoperability	The CAPNOSTAT 5 CO_2 Sensor is not interchangeable with previous versions of the CAPNOSTAT. The CAPNOSTAT 5 CO_2 Sensor is compatible with current Respironics Novametrix CO_2 airway adapters.

CAPNOSTAT 5 SENSOR - SPECIFICATIONS (Cont.)	
CAPNOSTAT 5 Mainstream CO_2 Sensor Voltage requirements	The Host System shall supply the required voltages and provide appropriate current limiting. VA: +5.00 VDC ± 5.0% @ 125 mA (620 mW) typical; 225 mA (1.125 W) maximum Ripple not to exceed 50.0 mV VSRC: DC Output Voltage: +5 V Output Current: 0.370 A peak. Peak rating is for a period of 10 mS and an ON time of 5 mS. Total Regulation: ± 5 % Ripple/Noise: 0.5% rms, 1% pk-pk, 20 MHz Bandwidth, differential mode. Transient Response: 1000 µs typical response time for return to within 0.5% of final value. Maximum voltage deviation is 3%.
CAPNOSTAT 5 CO_2 Sensor Power rating	Rated input: 1.1 Watts typical, Steady-state, Up to 1.5W maximum on power-up (Warm-up).
Power Supply Requirements (Future Capabilities)	VA: +5.00 VDC ± 5.0% @ 225 mA (1.125 mW) typical (Steady-state); 425 mA (2.125 W) maximum (Warm-up). Ripple not to exceed 50.0 mV Total System Power: Warm-up: 2.4 W maximum Steady-state 1.4 W typical
Environmental:	
Temperature and Humidity	Operating: 0 to 45°C, 10 to 90% RH, non-condensing Storage: -40 to 70°C, <90% RH, non-condensing
Atmospheric Pressure	Storage: 375-795 mmHg
Protection against electric shock	The sensor does not provide electrical isolation. It is the responsibility of the Host System to ensure that the power supply conforms to applicable standards - Recommend IEC Type BF.
Mode of operation	CAPNOSTAT 5 CO_2 Sensor is rated for continuous use. No marking is required.
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 head only)
Shock Impact	EN60068-2-6 Sinusoidal Vibration EN60068-2-27 Shock EN60068-2-64 Random Vibration Able to withstand repeated six-foot drops onto tiled floor while operating
Radiated emissions	Host system dependent, designed to meet the requirements of EN55011 - CISPR 11 Class B 30 MHz to 1000 MHz

CAPNOSTAT 5 SENSOR - SPECIFICATIONS (Cont.)	
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 IEC 61000-4-6 (2001-04)
Data Interference	RS-232, bi-directional, 19200 baud, standard N-8-1
Mechanical:	
Mechanical strength (Standard CAPNOSTAT 5 connector) (Testing based on Respironics Novametrix standard CAPNOSTAT 5 CO_2 Sensor configuration)	Cable Strain Relief, resistance to pull-out: Cable strain (bend) relief system for the sensor enclosure shall withstand a pull of 30 pounds without failure to either the cable or the enclosure. Cable Strain Relief, flexibility: The connector strain relief system shall be capable of withstanding an excess of 10,000 bend cycles. Connector Retention Force: The average retention force of the standard connector when pulling on the cable shall be 90 Newtons (20 pounds).
Regulatory:	
Regulatory	Designed to meet the following: • IEC 60601-1-2 • EN55011 • CISPR 11 Class B (Radiated and Conductive Emissions) • IEC 61000-4-2 Electrostatic Discharge Immunity • IEC 61000-4-3 Radiated Immunity Designed to comply with the following: • 93/42/EEC (MDD CE Marking) • FDA standards • ASTM F1456-01 Minimum Performance and Safety Requirements for Capnometers • ISO 21647:2004(E) Medical Electrical Equipment, particular requirements for the basic safety and essential performance of respiratory gas monitors

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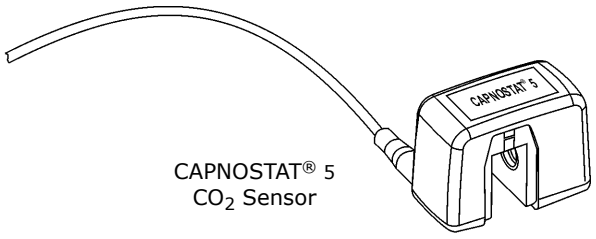
Section 4 Using the CAPNOSTAT® 5

This section provides information regarding the CAPNOSTAT 5 CO_2 Sensor and its use with CO_2 airway adapters. The CAPNOSTAT 5 CO_2 Sensor is a rugged, solid-state, mainstream sensor. It is factory calibrated and does not require further calibration.

Sensor Connections



Connecting the CAPNOSTAT® 5 CO_2 Sensor to the Host System

1. Insert the CAPNOSTAT 5 CO_2 Sensor connector into the receptacle of the host monitor as shown in Figure 1.
2. Make sure the arrows on the connector are at the top of the connector and line up the two keys of the connector with the receptacle and insert.
3. To remove the connector, grasp the body portion of the connector back and remove.

   Note: Do not remove by pulling cable.

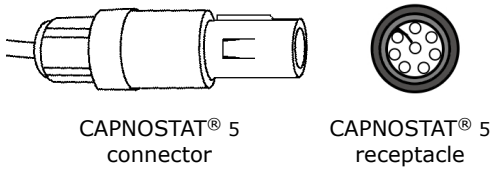
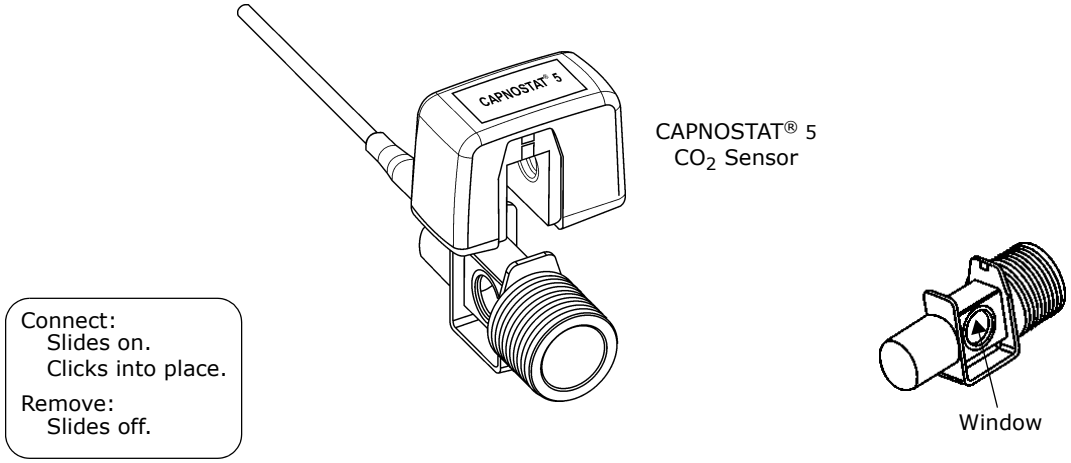
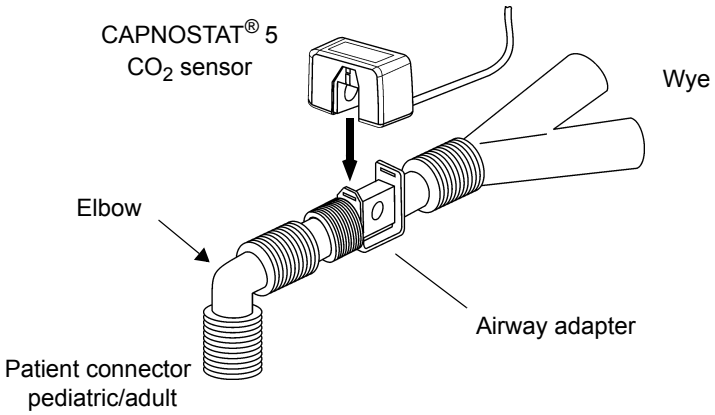


Figure 1

Shown below is the CAPNOSTAT 5 CO_2 Sensor connection to a Respironics Novametrix CO_2 adapter



Shown below is the CAPNOSTAT 5 CO_2 Sensor with a patient circuit:



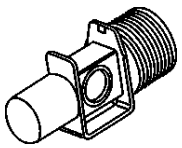
CO_2 Adapters

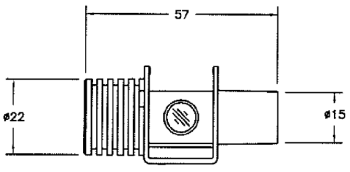
For monitoring CO_2, select an airway adapter based on the patient and monitoring situation. Airway adapter taper meets ISO 5356-1.

Attach the CAPNOSTAT CO_2 sensor to the monitor and adapter as described above.

Pediatric/Adult Single Patient Use Airway Adapter

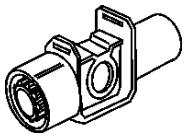
- Catalog No. 6063
- For intubated patients with endotracheal tube diameters greater than 4 mm
- Adds 5 cc of deadspace
- Weight: 7.7 grams
- Pressure drop: 0.40 cmH_2O @ 60 LPM
- Color: Clear

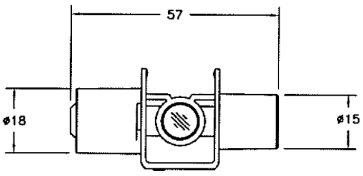




Infant/Pediatric Single Patient Use Airway Adapter

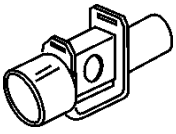
- Catalog No. 6312
- For intubated patients with endotracheal tube diameters less than or equal to 4 mm
- Adds less than 1 cc of deadspace
- Weight: 9.1 grams
- Pressure drop: 0.74 cmH_2O @ 10 LPM
- Color: Purple

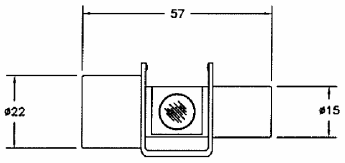




Pediatric/Adult Reusable Airway Adapter

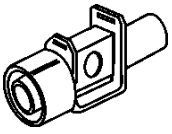
- Catalog No. 7007
- For intubated patients with endotracheal tube diameters greater than 4 mm
- Adds 5 cc of deadspace
- Weight: 12.0 grams
- Pressure drop: 0.38 cmH_2O @ 60 LPM
- Color: Black

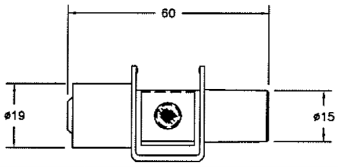




Infant/Pediatric Reusable Airway Adapter (

- Catalog No. 7053
- For intubated patients with endotracheal tube diameters less than or equal to 4 mm
- Adds less than 1 cc of deadspace
- Weight: 14.9 grams
- Pressure drop: 0.68 cmH_2O @ 10 LPM
- Color: Red

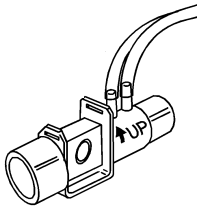
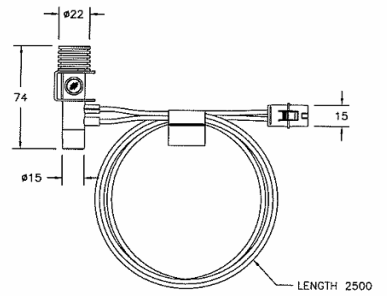
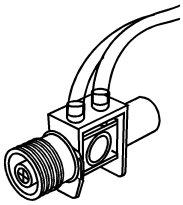
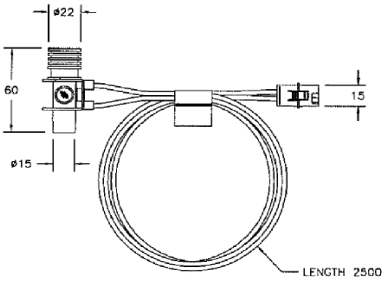
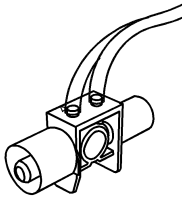
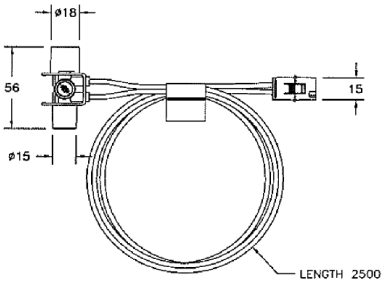




Note: All components are Latex free.
Note: All dimensions are in millimeters.
Note: Color pigment does not alter the specifications of the material.
Note: The adapters can be connected to anesthesia, ventilator, or BIPAP/CPAP masks for non-intubated patients.

Patient Connections

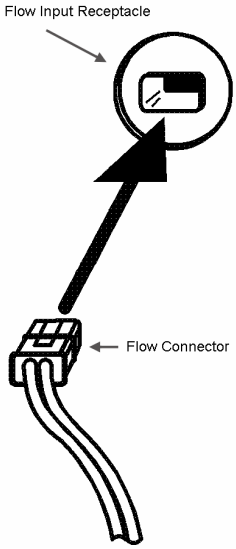
1. Selecting a Sensor:

Combined CO_2/Flow Sensor Identification Table	
Pediatric/Adult Combined CO_2/Flow Sensor • Catalog No. 6719 • For intubated patients with endotracheal tube diameters greater than 5.5 mm • Adds 8 cc of deadspace • Weight: 9.8 grams • Pressure Drop: 2.1 cmH_2O at 60 LPM • Color: Clear 	
Pediatric Combined CO_2/Flow Sensor • Catalog No. 6716 • For intubated patients with endotracheal tube diameters of 3.5-6.0 mm • Adds less than 4 cc of deadspace • Weight: 10.5 grams • Pressure Drop: 2.1 cmH_2O at 30 LPM • Color: Green 	
Neonatal Combined CO_2/Flow Sensor • Catalog No. 6720 • For intubated patients with endotracheal tube diameters of 2.5-4.0 mm • Adds less than 1 cc of deadspace • Weight: 9.6 grams • Pressure Drop: 3.1 cmH_2O at 10 LPM • Color: Purple 	
Material: Sensor Body - Polycarbonate, Tubing - PVC, Connector - ABS Plastic	
Note: All components are Latex free. **Note**: All dimensions are in millimeters. **Note**: The weight is for the sensor only. Does not include the tubing or connector. **Note**: Color pigment does not alter the specifications of the material. **Note**: The adapters can be connected to anesthesia, ventilator, or BIPAP/CPAP masks for non-intubated patients.	

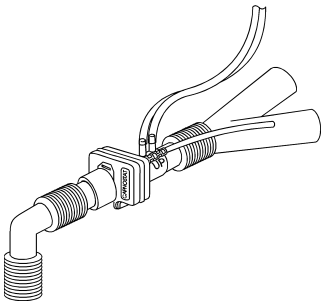
Combined CO_2/Flow Patient Sensor Selection Table				
RANGE				
Sensor	**ETT (mm)**	**Volume (ml)**	**Flow**	**Deadspace**
Neonatal	2.5 - 4.0	1 - 100	0.25 - 25 LPM 3 - 417 ml/sec	Less than 1 cc
Pediatric	3.5 - 6.0	30 - 400	0.5 - 120 LPM 8 - 2000 ml/sec	Less than 4 cc
Pediatric/Adult	> 5.5	200 - 300	2.0 - 180 LPM 33 - 3000 ml/sec	8 cc

2. Connect the Combined CO_2/Flow sensor to the host flow input receptacle.

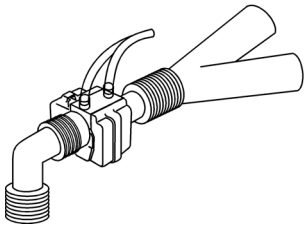
   Note: Always insert the connector into the receptacle before inserting the Combined CO_2/Flow sensor into the circuit.



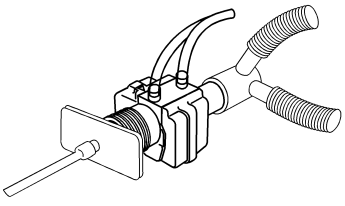
3. Connect the combined CO_2/Flow sensor to the patient breathing circuit.



Adult/Pediatric Combined CO_2/Flow sensor



Pediatric Combined CO_2/Flow sensor



Neonatal Combined CO_2/Flow sensor

CAPNOSTAT® 5 CO_2 Sensor Adapter Zero

The CAPNOSTAT 5 is compatible only with Respironics Novametrix mainstream CO_2 airway adapters. Each airway adapter has a unique set of optical characteristics. The adapter zero allows the CAPNOSTAT to adjust to the optical characteristics of each of the different adapter types.

An "Adapter Zero" is a quick process that allows the Host system to adjust to the special characteristics of a particular CAPNOSTAT 5 CO_2 Sensor; it is necessary only when requested. Such a request may occur the first time a particular CAPNOSTAT CO_2 Sensor is connected to a particular Host, or if a change is detected in the CAPNOSTAT 5 CO_2 Sensor.

Adapter Zero

To perform an Adapter Zero:

1. Set the Host to the zeroing function.
2. Connect the CAPNOSTAT 5 CO_2 Sensor and, if necessary, wait for the sensor warm-up message to clear.
3. Query the status of the CAPNOSTAT 5 CO_2 Sensor to check that the status bit "CO_2 Sensor not ready to zero," is not set.
4. Place the CAPNOSTAT 5 CO_2 Sensor onto a clean and dry CO_2 adapter that is exposed to room air and away from all sources of CO_2, including the ventilator, the patient's breath and your own.
5. Start the adapter zero. The maximum time for a CAPNOSTAT zero is 40 seconds. The typical time for a zero is 15-20 seconds.

NOTE

For best results, connect the CAPNOSTAT 5 CO_2 Sensor to an adapter and wait 2 minutes before performing the Adapter Zero procedure.

Section 5 Maintenance

CAPNOSTAT 5 CO_2 Sensor

Cleaning and Disinfecting

Cleaning the outside of the CAPNOSTAT 5 CO_2 Sensor:

- Use a cloth dampened with isopropyl alcohol 70%, a 10% aqueous solution of sodium hypochlorite (bleach), disinfectant spray cleaner such as Steris Coverage® Spray HB, ammonia, or mild soap.
- Wipe down with a clean water-dampened cloth to rinse and dry before use. Make certain that the sensor windows are clean and dry before reuse.

Airway Adapters

Cleaning

Reusable adapters:

- Clean by rinsing in a warm soapy solution followed by soaking in a liquid disinfectant such as isopropyl alcohol 70%, a 10% aqueous solution of sodium hypochlorite (bleach), a gluteraldehyde 2.4% solution such as Cidex®, Steris System 1® or ammonia. It should then be rinsed out with sterile water and dried.
- May be disinfected using the methods listed below:
  - Steam Autoclave - adult adapters only
  - Immerse and soak in Cidex® or equivalent 2.4 glutaraldehyde solution for a 10 hour soak.
  - Immerse and soak in Perasafe® or equivalent peracetic acid .26% solution for a 10 minute soak.
  - Cidex® OPA - follow the manufacturer's instructions for use.
- Before reusing the adapter, ensure the windows are dry and residue free and that the adapter has not been damaged during handling or the cleaning/disinfecting process.

Disposable adapters:

- Treat all single patient use airway adapters in accordance with institutional protocol for single patient use items.
- DO NOT insert any object, such as a brush, into the CAPNOSTAT 5 CO_2 airway adapter. Irreparable damage may occur to the CO_2 windows.

Cleaning Test Criteria

The adapter testing criteria for cleaning included testing of the physical and dimensional integrity, optical performance and gas leaks. The adapters were not tested for sterility after the testing. Respironics Novametrix makes no claims of sterility of these adapters when cleaned by the methods tested.

Methods tested

The test adapters were cycled 100 times for each method tested.

- Warm water rinse, cold disinfecting with Cidex or Steris Systems, pasteurization and autoclave
- Autoclave at 121 degrees C (250 degrees F), 20 minutes, unwrapped

NOTE: Methods listed are to be used as guidelines for cleaning only. Respironics Novametrix is not responsible for product sterility.

Test Results

There was no significant difference between the baseline data and the data recorded after 100 cycles. Therefore, the methods described in this design guide and applicable user manuals are the only recommended cleaning and disinfecting methods for the Respironics Novametrix Reusable CO_2 Airway Adapters.

Airway Adapter Material

Part Number	Airway Adapter Type	Body	Heat sink	Window	O-Ring	Mouthpiece
7007-01	Adult - Reusable	Polyetherimide	Aluminum, black oxide finish	Al_2O_3 - Sapphire	N/A	N/A
7053-01	Infant - Reusable	Polyetherimide	Aluminum, black oxide finish	Al_2O_3 - Sapphire	N/A	N/A
6063-01	Adult - Single Patient Use	Polycarbonate	N/A	Polypropylene	Nickel Plated Brass	N/A
6312-01	Infant – Single Patient Use	Polycarbonate	N/A	Polypropylene	Nickel Plated Brass	N/A
6421-01	Adult – Single Patient Use with Mouthpiece	Polycarbonate	N/A	Polypropylene	Nickel Plated Brass	Polypropylene

Maintenance Schedule

The CAPNOSTAT 5 CO_2 Sensor should be compared against calibration gas every 12 months.
NOTE: Accuracy is affected by temperature and barometric pressure.

CO_2 Accuracy Check

The following procedure should be performed to check the CO_2 accuracy of the CAPNOSTAT 5 Sensor. It is recommended that this procedure be included as part of a periodic maintenance schedule.

1. Attach the CAPNOSTAT 5 CO_2 Sensor to the Host monitor. Attach a Respironics Novametrix CO_2 airway adapter to the CAPNOSTAT 5 CO_2 Sensor. Make sure the CAPNOSTAT 5 Sensor is disconnected from the patient circuit.
2. Turn on the Host monitor.
3. On the Host monitor, change to the CO_2 Accuracy Mode. This mode can be either a separate accuracy check/diagnostic screen or a CO_2 averaging mode. This mode will need to display the CO_2 waveform value as a numeric instantaneous value.
4. Using the sensor status provided in the CAPNOSTAT 5 Serial protocol, wait for the CAPNOSTAT 5 Sensor to warm up to its operating temperature. (Look for the CAPNOSTAT temperature status to be set to “Stable Operating Temperature” in the Serial protocol).
5. Set the CO_2 Units setting of the CAPNOSTAT 5 to percent.
6. Set the Barometric Pressure setting of the CAPNOSTAT 5 to the ambient barometric pressure.
7. Set the gas temperature setting of the CAPNOSTAT 5 to the temperature of the flowing gas (typically room temperature).
8. Zero the CAPNOSTAT 5 on the airway adapter being used in this test.
9. Attach a regulated flowing gas mixture of 5% (± 0.03%) CO_2, balance N_2 to the airway adapter. Set the flow rate of the gas to 2 - 5 liters per minute.
10. Set the gas compensation settings of the CAPNOSTAT 5 to the calibration gas mixture.
11. Allow 10 seconds for the gas mixture to stabilize and observe the CO_2 value. The expected value is 5% ± 0.26%.
12. If a waveform is present, verify that it appears as a straight line at approximately 5 percent.
13. The accuracy check is now complete. Remember to set the CAPNOSTAT settings for gas temperature, units and gas composition back to their previous settings.
14. This accuracy check can be completed in just a few minutes.

Note: The calibration gas mixture and regulator are available from Respironics Novametrix.

- Gas Regulator: PN 6081-00
- Calibration Gas (carton of 4): PN 8964-00

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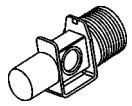
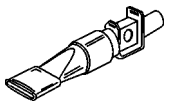
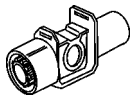
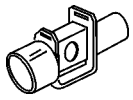
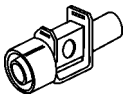
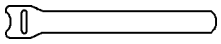
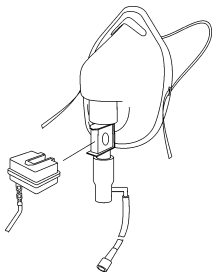
Section 6 *Accessories*

Accessories		
Airway Adapters	6063-00	Single-Patient Use Adult Airway Adapter 
	6421-00	Single-Patient Use Adult Airway Adapter with Mouthpiece 
	6312-00	Single-Patient Use Infant Airway Adapter 
	7007-00	Reusable Adult / Pediatric Airway Adapter 
	7053-00	Reusable Infant Airway Adapter 
Cable Management	6934-00 Cable Management Straps  8751-00 CO_2 Sensor Holding Clips 	
CO_2 Mainstream Monitoring Mask	9960PED-00 CAPNO$_2$*mask* - pediatric 9960STD-00 CAPNO$_2$*mask* - adult standard 9960LGE-00 CAPNO$_2$*mask* - adult large 	

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Section 7 *Device Classification*

Device Classification	
IEC/EN 60601-1:	
IEC 60601-1 § 5.1 Type of protection against electrical shock	Class I and II externally powered equipment
IEC 60601-1 § 5.2 Type of protection against electrical shock	Recommended: Type BF equipment
IEC 60601-1 § 5.3 Type of protection against harmful ingress of water	IPX 4 – Splash proof Equipment (sensor head only)
IEC 60601-1 § 5.4 Methods of sterilization	(See Maintenance on page 21.)
IEC 60601-1 § 5.5 Degree of safety of application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.	Type AP equipment: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or nitrous oxide.
IEC 60601-1 § 5.6 Mode of operation	Continuous operation

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Section 8 *Host Communication*

Specifications

Host Communication Specifications	
Serial Communications protocol	The CAPNOSTAT 5 CO_2 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.
Serial communication rate	Nominal data rate between the sensor and the Host system will be 19200 Baud, standard N-8-1
Data Output	Real time CO_2 waveform, gas and barometric pressure compensated, End-tidal CO_2, Inspired CO_2, Respiratory Rate.
	The CAPNOSTAT 5 CO_2 Sensor provides the Host System with status information through the communications protocol.
Sensor recognition	The CAPNOSTAT 5 CO_2 Sensor shall provide the Host system with sensor recognition capabilities and firmware revision through the communications protocol.

Host Communication Protocol

See controlled document number 1015115DS1, “Communication Interface to the CAPNOSTAT 5,” included with this Design Guide.

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