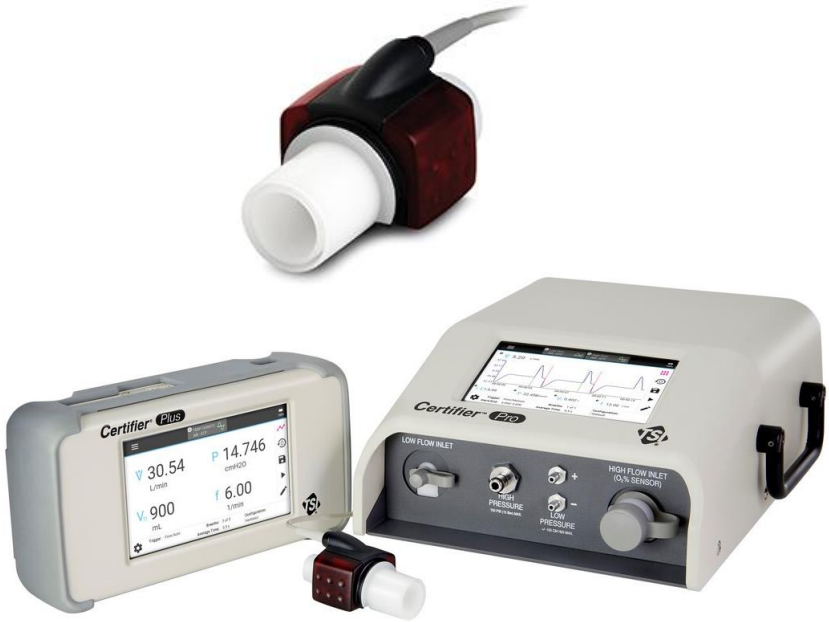
Certifier™ Anesthesia Sensor Kit

Model 4093

User Manual

P/N 6017331, Revision B
February 2024



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Warnings, Cautions, and Notes

Operation

WARNING

When operated in conjunction with TSI® Certifier™ flow analyzers, the anesthesia sensor is used for testing purposes only and should not be used for human measurements.

CAUTION

Read the user manual, accessories directions for use, all precautionary information, and specifications before use.

Safety

WARNINGS

- Anesthesia sensor should only be used for the purpose and in the manner described in this manual.
- **DO NOT** adjust, repair, open, disassemble, or modify the sensor. Damage to the device may result in degraded performance.
- The anesthesia sensor not intended to be in patient contact.
- The anesthesia sensor is not designed for MRI environments.

NOTICES

- Disconnect the device from power by removing the device cable connection from the Certifier™ flow analyzer.
- Use and store the sensor in accordance with specifications.

Performance

WARNINGS

- Use only airway adapters manufactured by Masimo®.
- No modification of the probe or airway adapters is allowed.
- Light transmission can be affected by and moisture pooling on the airway adapter XTP™ windows. When using heated humidifiers special care should be paid to position the airway adapter in a vertical position and to change airway adapter if necessary.
- Use of this equipment adjacent to or stacked with other equipment should be avoided as 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 properly.
- Make sure the anesthesia sensor is used in the electromagnetic environment specified in this manual.
- Use of high-frequency electrosurgical equipment in the vicinity of the sensor may produce interference and cause incorrect measurements.
- 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 sensor including cable. Otherwise, degradation of the performance of the sensor could result.
- Incorrect zeroing of the anesthesia sensor will result in false gas readings.
- Use of accessories and cables other than those specified or provided could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Replace the airway adapter if rainout/condensation occurs inside the airway adapter.

CAUTION

DO NOT operate the anesthesia sensor outside of the specified operating environment.

Cleaning and Service

WARNING

To avoid electric shock, always physically disconnect the anesthesia sensor and any electrical connections before cleaning.

CAUTIONS

- **NEVER** submerge the sensor in water or any other liquid solution this may cause permanent damage to the sensor.
- **DO NOT** apply excessive pressure on the IR-windows.
- **NEVER** saturate the anesthesia sensor completely with any disinfection solution.
- Only perform maintenance procedures specifically described in the manual; otherwise, return the sensor for servicing. Improper maintenance may result in damage to the internal parts. Damage to internal parts may result in no or inaccurate readings.
- **DO NOT** clean the sensor with any chemical other than those specified in this manual. These substances may affect the device's materials and damage internal parts.
- The anesthesia sensor and airway adapters are non-sterile devices. **DO NOT** submerge the sensor or airway adapters in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.
- **DO NOT** use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended in this manual. Permanent damage to sensor may occur if other unspecified solutions are used.

NOTICE

The presence of ambient air (0% CO_2) in the airway adapter is of crucial importance for a successful Zeroing. Special care should be taken to avoid breathing near the airway adapter before or during the Zeroing procedure.

Compliance

WARNING

Any changes or modifications not expressly approved by Masimo® shall void the warranty for this equipment and could void the user's authority to operate the equipment.

CAUTIONS

- **Disposal of Product**: Comply with local laws in the disposal of the device and/or its accessories.
- Airway adapters shall be disposed of in accordance with local regulations for bio hazardous waste.
- For FCC compliance information, refer to Masimo's operator's manual.

NOTICE

Use the anesthesia sensor in accordance with the environmental specifications stated in this operator's manual.

List of Components

Anesthesia Sensor Kit (Model 4093)

Material Description	Part Number	Image
Anesthesia Sensor Cell (with DB9 connector cable)	130386	
Convertor, DB9 Serial to USB-A	130402	
Anesthesia Airway Adapter, Adult/Pediatric	130403	

Optional Accessory

Description	Part Number	Image
Anesthesia Airway Adapter, Infant	130404	

Multi-Gas Anesthetic Analyzer

The anesthesia sensor is a mainstream gas analyzer that works in conjunction with the TSI® Certifier™ Plus or Certifier™ Pro test systems to measure real-time gas concentrations of CO_2, N_2O, and anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane, and Desflurane.

Principle of Operation

The measurement of CO_2, N_2O, and anesthetic agents in gas mixtures is based on the fact that different gas components absorb infrared light at specific wavelengths. A beam of infrared light is directed through the gas flow in the anesthesia sensor adapter. As the beam passes through the adapter, some of the light is absorbed by the gas mixture.

The amount of absorbed light is measured by a miniaturized spectrometer which incorporates multiple light filters and an infrared detector that converts the light beam to an electrical signal and then a digital value. The ratio of light measured through the filters is used to calculate the gas concentration.

Available Measurements

Symbol	Description
AA_1	Anesthetic agent as a percentage of concentration (if detected, that specific agent will be displayed).
CO_2	Concentration of carbon dioxide as a percentage.
N_2O	Concentration of nitrous oxide as a percentage.
P_{ATM}	Atmospheric pressure displayed in units cmH_2O, kPa, Pa, hPa, mbar, mmHg, inH_2O, or psi.

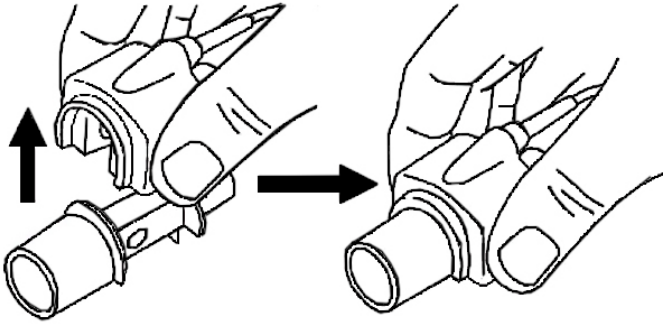
Connecting the Anesthesia Sensor

The anesthesia sensor is connected to the USB-A port of the Certifier™ flow analyzer which provides power and user control from its instrument display.

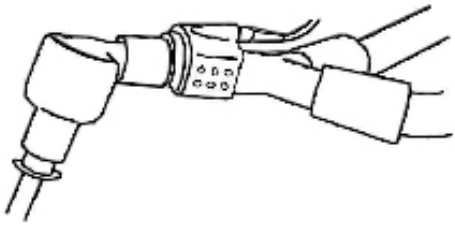
An airway adapter is inserted into the sensor module which can then connect to the test circuit. There are two types of airway adapters that can be used with the anesthesia sensor: adult/pediatric and infant.

Follow the steps below to setup the anesthesia sensor:

1. Attach an airway adapter to the anesthesia sensor. The adapter will click when properly seated.



2. Connect the anesthesia sensor cable to either USB-A port on the Certifier™ flow analyzer using the supplied DB-9 serial to USB converter.
3. Power on the Certifier™ instrument and configure the anesthesia sensor measurements.
4. Wait a minimum of 30 seconds then perform the zeroing procedure.
5. The green status LED on the anesthesia sensor illuminates when the sensor is ready for use.
6. Connect the attached airway adapter to the anesthesia test circuit.
7. Position the anesthesia sensor with the status LED pointing upwards.

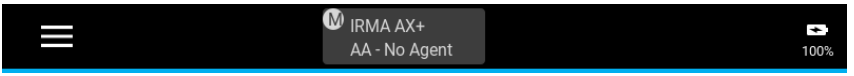


CAUTIONS

- **DO NOT** run anesthetic agents through Certifier™ flow modules/channels.
- Use of the anesthesia sensor with Certifier™ Flow Analyzers is for testing purposes only and should not be used for human measurements.

Touchscreen Operation

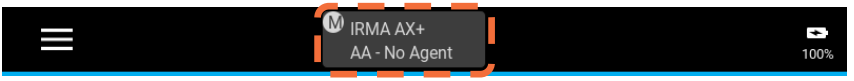
Once the anesthesia sensor is connected to the Certifier™ flow analyzer, a module card will be generated at the top of the dashboard for the connected sensor.



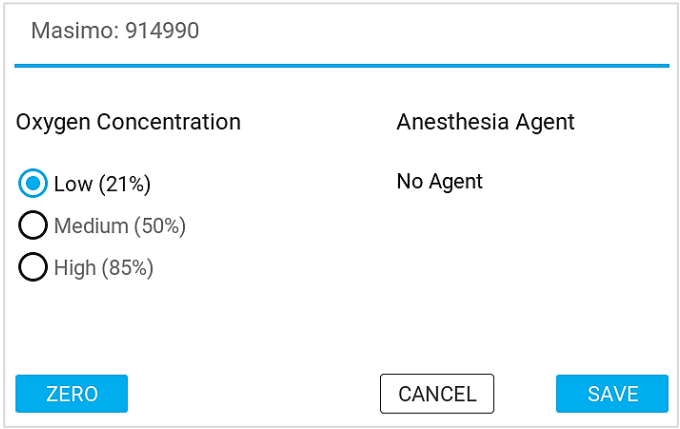
Module Card

The module card will display the model number of the connected sensor (IRMA AX+) and the anesthetic agent detected by the anesthesia sensor. If no anesthetic agent is detected, the module card will display “No Agent.”

Press the IRMA AX+ module card to view and edit settings for the anesthesia sensor.



The manufacturer (Masimo®) and serial number (ex. 914990) of the anesthesia sensor are displayed in the heading of the module card dialog screen.



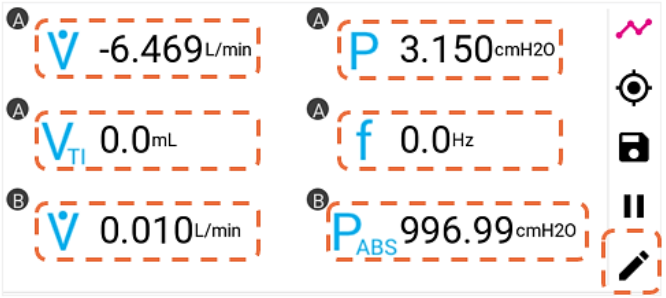
Three different levels of oxygen concentration can be selected based on the oxygen percentage present in the gas flowing through the anesthesia sensor.

If an anesthetic agent is detected, it will be displayed in this dialog screen. “No Agent” will be displayed if the sensor does not detect an anesthetic agent.

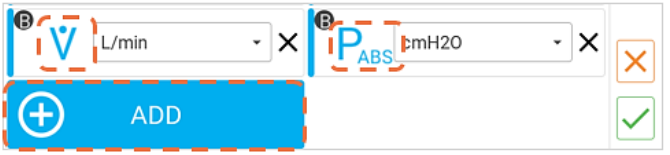
NOTICE
Anesthetic agents cannot be selected by the user but instead are automatically detected by the anesthesia sensor.

Selecting Measurements

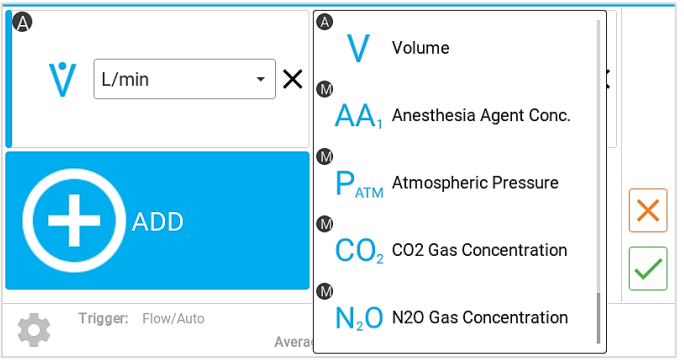
From the Parameter screen, access the measurement selection screen by pressing on any of the currently displayed measurement symbols, readings, or units of measurement, or by pressing the pencil icon in the right navigation bar.



Press the **(+) ADD** tile to select an additional measurement, or press the measurement symbol of a currently selected measurement to change that measurement parameter.

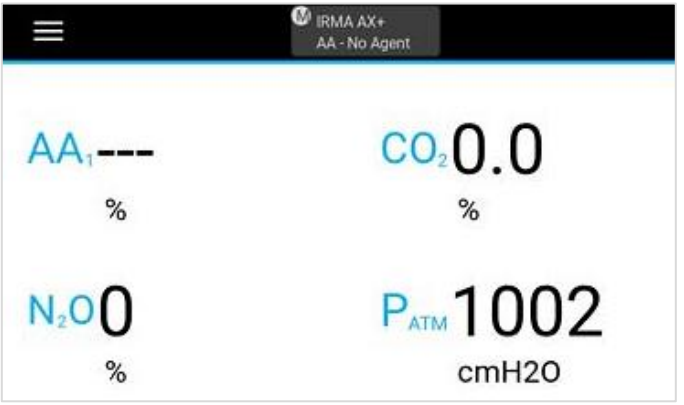


Once pressed, a list of available measurements will be displayed in alphabetical order. If more than one module is connected, a letter (ex. M, A, B) will indicate which module the measurement is coming from. The letter “M” is used to indicate measurements coming from the Masimo® anesthesia sensor module. Swipe up and down to scroll through the list options then tap to select.



Press the orange **X** button in the right navigation bar at any time to disregard all changes and return to the **Parameter** screen.

Press the green ✓ checkmark button in the right navigation bar to save changes and returns you to the **Parameter** screen.



Zeroing the Anesthesia Sensor

Zeroing should be performed every time the airway adapter is replaced, or whenever an offset in gas values or an unspecified gas accuracy message is displayed.

Before proceeding with the zeroing procedure, allow 30 seconds for warm up after powering on the anesthesia sensor or after changing the adapter. The green LED on the sensor will be blinking for approximately 5 seconds while zeroing is in process.

Zeroing Procedure

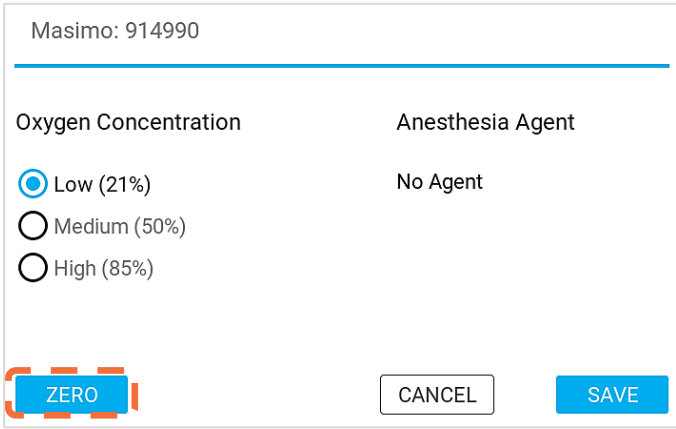
Zeroing is performed by snapping a new airway adapter on the anesthesia sensor without connecting to the test circuit and then using the Certifier™ flow analyzer to transmit a zero reference command to the anesthesia sensor.

NOTICE

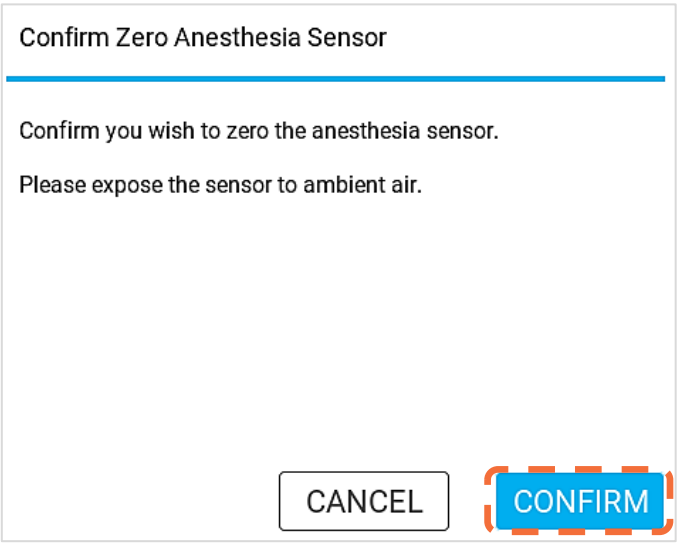
The presence of ambient air (0% CO_2) in the airway adapter is of crucial importance for a successful zeroing. No span zeroing is required.

Press the flow module card for the anesthesia sensor.

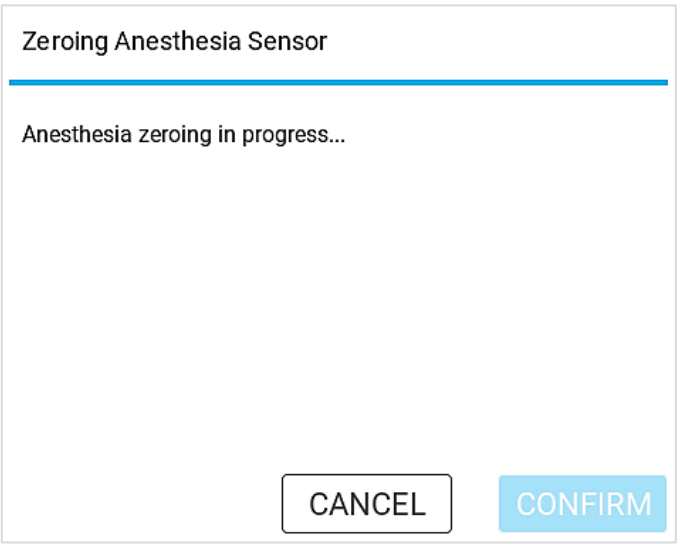
On the anesthesia sensor module card, select the **ZERO** button.



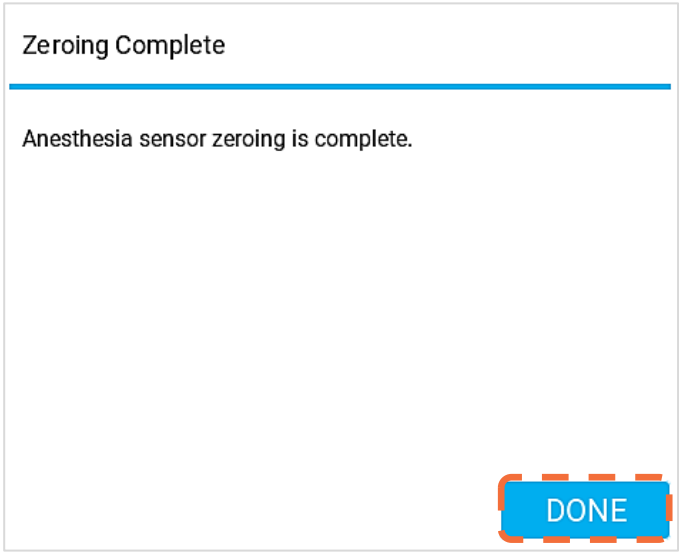
Expose the anesthesia sensor to ambient air and press **CONFIRM**.



A dialog screen will appear while the anesthesia sensor goes through the zeroing process. It takes approximately 5–10 seconds to zero the anesthesia sensor.



A message will be displayed once the zeroing process has completed. Press **DONE** to return to the previous screen.



Status LED

The status LED provides visual indication of the anesthesia sensor status and illuminates in different colors depending on the state of the device.

NOTICE
Without an airway adapter connected, the status LED will not illuminate.

The status LED is located above the airway adapter inlet on the front of the anesthesia sensor device.

LED	Status
Steady green light	Anesthesia sensor OK
Blinking green light	Zeroing in progress
Steady blue light	Anesthesia agent present
Steady red light	Anesthesia sensor error
Blinking red light	Check airway adapter

Messages and Errors

Descriptions of active messages or errors from the anesthesia sensor can be viewed in the Active Warnings and Errors screen on the Certifier™ display. The following table lists the common anesthesia sensor related messages, their possible cause, and the next steps.

Message	Possible Cause	Next Steps
No adapter (check adapter)	An airway adapter is not installed.	Connect an airway adapter to the sensor.
Replace adapter (check adapter)	The airway adapter should be replaced.	Replace the airway adapter.
Ambient pressure out of range (unspecified accuracy)	Ambient pressure measurement is outside of operating range.	Verify operating conditions according to the specifications. If normal, replace the sensor.
Temperature out of range (unspecified accuracy)	The internal temperature is outside of the operating range.	Verify operating conditions according to the specifications. If normal, replace the sensor.
Software error (gas sensor error)	Sensor software error.	If persistent, replace the sensor.
Hardware error (gas sensor error)	Sensor hardware error.	If persistent, replace the sensor.
Factory calibration lost/missing (gas sensor error)	The sensor's factory calibration is lost or missing.	If persistent, replace the sensor.
Motor speed out of bounds	Sensor is exposed to excessive movement or vibrations.	Ensure sensor is used in a controlled environment where it is not subject to excessive movement/vibration.

Message	Possible Cause	Next Steps
Agent identifications and concentrations are unreliable	The sensor has detected something that is not necessarily one of the agents we are measuring.	e.g., Isopropanol vapors can be incorrectly identified as Halothane which will result in this alarm.
N_2O outside specified range	Measured N_2O concentration < 0 vol% or > 100 vol% most likely caused by poor zeroing.	Perform zeroing.
CO_2 outside specified range	CO_2 level above 15 vol% Specified range: 0–15 vol% ±(0.2 vol% +2% of reading)	Check that supplied CO_2 gas concentration is within our specified range.
At least on agent outside specified accuracy range	One of the supplied agents is outside our specified accuracy range.	Check that supplied AA gas concentration is within our specified range.
Zero reference calibration required	Inaccurate zero reference.	Perform zeroing.

Troubleshooting

The table below lists the symptoms, possible causes, and recommended corrective actions for problems that may be encountered while operating the anesthesia sensor.

If the symptom is not listed or if none of the recommended corrective actions solve the problem, contact technical support at technical.services@tsi.com or customer support at 800-680-1220 or 651-490-2860 for assistance.

Symptom	Possible Cause	Corrective Action
Measurement values are not displaying.	Anesthesia sensor requires a power cycle.	Disconnect and reconnect the sensor to the Certifier™ flow analyzer.
Status LED is dark (indicator is off).	Sensor is not plugged into Certifier™ flow analyzer or there is an internal error.	Verify the sensor is connected to the Certifier™ flow analyzer.
Status LED is steady red.	Sensor requires a power cycle or has an internal error.	Disconnect and reconnect the sensor to the Certifier™ flow analyzer.
Gas readings from the sensor are questionable.	Sensor is not connected correctly to the test circuit or the test circuit is leaking.	Disconnect and reconnect sensor to test circuit and check the test circuit for leaks.
Gas readings from the sensor are questionable.	Sensor may need to be zeroed.	Zero the anesthesia sensor.

Maintenance

Once a year it is recommended to perform a gas span check on the anesthesia sensor with a reference instrument or with calibration gas.

To do an operational check on the anesthesia sensor:

1. Connect an airway adapter to the anesthesia sensor.
2. Connect the anesthesia sensor to the Certifier™ flow analyzer and power on the instrument.
3. Verify that the anesthesia sensor status LED displays a steady great light.
4. Breathe briefly into the anesthesia sensor airway adapter and verify that a CO_2 values are displayed on the Certifier™ flow analyzer.

Cleaning

To clean the anesthesia sensor:

1. Remove the airway adapter.
2. Wipe each of the sensor's outer surfaces, paying attention to crevices and hard to reach areas, until the surfaces are free of any visible residue using one of the following solutions:
   a. A cloth moistened with 70% isopropyl alcohol
   b. A quaternary ammonium chloride solution wipe
   c. A soft bristled brush as needed.
3. Repeat the above cleaning step using a fresh cloth or wipe.
4. Allow the sensor to thoroughly dry before using again.

The surfaces of the anesthesia sensor have been tested to be chemically resistant to the following disinfections/solutions:

- 70% Isopropyl alcohol
- 70% Ethyl alcohol
- Quaternary ammonium chloride solution wipes
- Cidex® Plus (3.4% glutaraldehyde)
- 0.5% sodium hypochlorite (1:10 bleach to water solution)
- Accelerated hydrogen peroxide

NOTICE
The airway adapters are not intended to be cleaned.

CAUTIONS

- **DO NOT** immerse the anesthesia sensor in any liquid and never saturate the sensor completely with any disinfection solution.
- **DO NOT** apply excessive pressure on the IR-windows.

Specifications

Measurements

Standard Conditions

The following measurement specifications are valid with no drift for dry single gases at 22 ±5˚C and 1013 ±40 hPa.

Gas	Range*	Accuracy
CO_2	0 to 15 vol% 15 to 25 vol%	±(0.2 vol% +2% of reading) Unspecified
N_2O	0 to 100 vol%	±(2 vol% +2% of reading)
HAL, ISO, ENF	0 to 8 vol% 8 to 25 vol%	±(0.15 vol% +5% of reading) Unspecified
SEV	0 to 10 vol% 10 to 25 vol%	±(0.15 vol% +5% of reading) Unspecified
DES	0 to 22 vol% 22 to 25 vol%	±(0.15 vol% +5% of reading) Unspecified

*****All gas concentrations are reporting in units of volume percent and may be translated into mmHg or kPa by using the reported atmospheric pressure.

All Conditions

The following measurement specifications are valid with no drift for all specified environmental conditions except for interference specified in the sections Interfering Gas Vapor Effect and Effects from Water Vapor Partial Pressure on Gas Readings.

Gas	Accuracy
CO_2	±(0.3 kPa +4% of reading)
N_2O	±(2 kPa +5% of reading)
Agents**	±(0.2 kPa +10% of reading)

**The accuracy specification for the anesthesia sensor is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set.

Gas Concentration Conversion

Gas concentration is reported in units of volume percent. The concentration is defined as: %gas = (partial pressure of gas component)/(total pressure of gas component)*100.

Note that the total pressure of the gas mixture is estimated by measuring the actual atmospheric pressure (range 525 to 1200 hPa) in the sensor probe.

Electrical and Environmental

Item	Specification
Power Supply	4.5 to 5.5 VDC ≤ 1.4 W (normal operation @ 5V) < 2.0 W (power surge @ 5V can last up to 300 ms when entering measurement mode from sleep mode or during start-up)
Operating Temperature	10 °C to 40 °C (50 °F to 104 °F)
Storage/Transport Temperature	-40 °C to 70 °C (-40 °F to 158 °F)
Operating Humidity	< 50 hPa H_2O (non-condensing) (68% RH at 40 °C)
Storage/Transport Humidity	10% to 95% RH (non-condensing) (95% RH at 40°C)
Operating Atmospheric Pressure	525 to 1200 hPa (525 hPa corresponding to an altitude of 5211m/17,100 feet)
Storage/Transport Atmospheric Pressure	500 to 1200 hPa (500 hPa corresponding to an altitude of 5572m/18,280 feet)
Compliance	EN ISO 80601-2-55:2018, EN 60601-1-2:2015, EN ISO 5356-1:2015, MDD 92/42/EEC

Physical Characteristics

Item	Specification
Dimensions*	38 x 37 x 34 mm (1.49 x 1.45 x 1.34 in.)
Weight*	< 25 g (< 0.05 lbs.)
Cable Length	2.5 m ±0.1 m (98 in. ±4 in.)
Expected Service Life	5 years

*Excluding cable.

General

Item	Specification
Data update frequency	20 Hz
Compensation	Automatic pressure, temperature and full spectral interference correction.
Calibration	Zeroing recommended when changing airway adapter, no span calibration is required.
Warm-up time	< 20 seconds (agent identification enabled and full accuracy)
Rise time* (@ 10 l/min)	CO_2 ≤ 90 ms N_2O ≤ 300 ms HAL, ISO, ENF, SEV, DES ≤ 300 ms
Primary agent threshold	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol% as long as apnea is not detected.
Agent identification time	< 20 seconds (typically < 10 seconds)
Automatic agent detection	Primary agent
Analyzer system response time**	< 1 second
Recovery time after defibrillator test	Unaffected
Drift of measurement accuracy	No drift
Surface temperature at ambient temperature of 23 °C (73.4 °F)	Maximum 46 °C (115 °F)
Compliance	EN ISO 80601-2-55:2018, EN 60601-1-2:2015, EN ISO 5356-1:2015

*Measured at 10 l/min with gas concentration steps corresponding to 30% of total measuring range for each gas.

**Measured according to EN ISO 80601-2-55.

Airway Adapters

Item	Specification
Disposable adult/pediatric	Adds less than 6 ml dead space. Pressure drop less than 0.3 cm H_2O @ 30 L/min.
Disposable infant	Adds less than 1 ml dead space. Pressure drop less than 1.3 cm H_2O @ 10 L/min.

Effects from Water Vapor Partial Pressure on Gas Readings

The effects of water vapor are illustrated by the examples in the following table. The two columns on the right show the relative error in displayed concentrations when adding or removing water vapor from the gas mixture, and referencing the measurement to dry gas conditions at actual temperature and pressure (ATPD) or saturated conditions at body temperature (BTPS).

The table illustrates that the gas concentrations at body temperature saturated (BTPS), are 6.2% lower than the corresponding concentrations in the same gas mixture after removal of all water vapor (ATPD).

Temp (ºC)	RH (%)	P (hPa)	H_2O part. Press. (hPa)	Err rel (%)	Err rel ATPD (%)	Err rel (%) BPTS
10	20	1013	2	0	-0.2	6.0
20	20	1013	5	0	-0.5	5.7
25	0	1013	0 (ATPD)	0	0	6.2
25	23	1013	7.3	0	-0.7	5.5
25	50	1013	16	0	-1.6	4.6
30	80	1013	42	0	-4.1	2.0
37	100	1013	63 (BTPS)	0	-6.2	0
37	100	700	63	0	-9.0	-2.8

Interfering Gas Vapor Effect

Gas or Vapor	Gas Level	CO_2	Agent	N_2O
N_2O[4]	60 vol%	- [1 2]	- [1]	- [1]
HAL[4]	4 vol%	- [1]	- [1]	- [1]
ENF, ISO, SEV[4]	5 vol%	- [1]	- [1]	- [1]
DES[4]	15 vol%	- [1]	- [1]	- [1]
Xe (Xenon)[4]	80 vol%	-10% of reading[3]	- [1]	- [1]
He (Helium)[4]	50 vol%	-6% of reading[3]	- [1]	- [1]
Metered dose inhaler propellants[4]	Not for use with metered dose inhaler propellants			
C_2H_5OH (Ethanol)[4]	0.3 vol%	- [1]	- [1]	- [1]
C_3H_7OH (Isopropanol)[4]	0.5 vol%	- [1]	- [1]	- [1]
CH_3COCH_3 (Acetone)[4]	1 vol%	- [1]	- [1]	- [1]
CH4 (Methane)[4]	3 vol%	- [1]	- [1]	- [1]
CO Carbon monoxide[5]	1 vol%	- [1]	- [1]	- [1]
NO Nitrogen monoxide[5]	0.02 vol%	- [1]	- [1]	- [1]
O_2 Oxygen[5]	100 vol%	- [1 2]	- [1]	- [1]

Note 1: Negligible interface, effect included in the measurement specifications “Accuracy, all conditions” above.

Note 2: For probes not measuring N_2O or O_2 the concentrations shall be set from the host. The anesthesia sensor does not measure O_2.

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol% Helium, the actual measured CO_2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO_2.

Note 4: According to EN ISO 80601-2-55 standard.

Note 5: In addition to the EN ISO 80601-2-55 standard.

Knowledge Beyond Measure.

TSI Incorporated – Visit our website **www.tsi.com** for more information.

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