

CO₂ Sensor Kit TG-981T, TG-981T1

Indications for Use

The Nihon Kohden TG-981T and TG-981T1 CO₂ sensor kits are intended for medical purposes to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory status. Along with other methods indicated by the physician for medical diagnosis, these devices are intended as an indicator of patient carbon dioxide concentration during expiration.

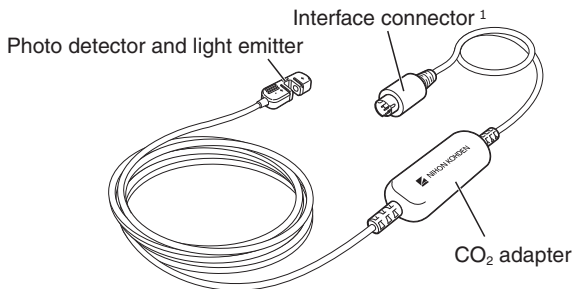
These devices are intended for use by qualified medical personnel.

Caution: United States law restricts these products to sale by or on the order of a physician.

General

The TG-981T and TG-981T1 CO₂ sensor kits measure the expired CO₂ of a patient and send the processed digital data such as end tidal CO₂ and respiration rate to a medical electrical device.

The TG-981T and TG-981T1 CO₂ sensor kits have different serial communication protocols.

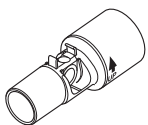


¹ The interface connector for the TG-981T CO₂ sensor kit is gray and the interface connector for the TG-981T1 CO₂ sensor kit is black.

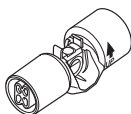
Refer to the operator's manuals of the connected instruments together with this manual.

Optional Items

YG-211TW
airway adapter



YG-213TW¹
neonatal/infant
airway adapter

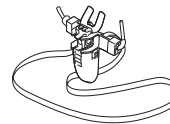


YG-214TW¹
neonatal/infant
airway adapter



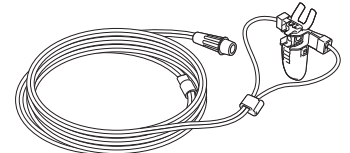
YG-220TW adult cap-ONE nasal adapter, YG-230TW pediatric cap-ONE nasal adapter

Example: YG-220TW

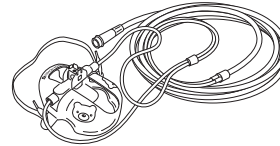


YG-221TW adult cap-ONE nasal adapter, YG-231TW pediatric cap-ONE nasal adapter

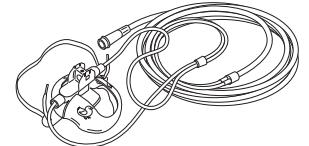
Example: YG-221TW



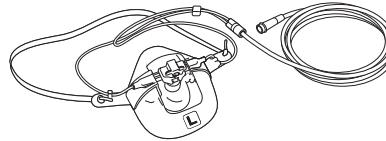
YG-232TW
pediatric cap-ONE mask



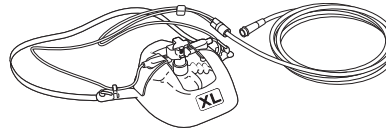
YG-242TW
infant cap-ONE mask



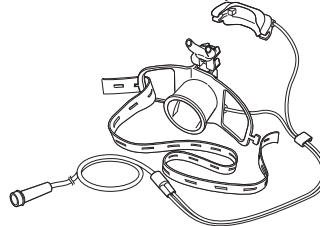
YG-272TW adult cap-ONE mask



YG-282TW adult cap-ONE mask (large)



YG-227TW adult cap-ONE biteblock



Model	Weight	Dead Space	Flow Resistance	Qty	Supply Code
YG-211TW	7 kg or more	4 mL	0.1 kPa (10 mmH ₂ O) or less at 50 L/min	30	R805A
YG-213TW ¹	—	0.5 mL	0.08 kPa (8 mmH ₂ O) or less at 10 L/min	30	R806A
YG-214TW ¹	—	1.8 mL		30	R807A
YG-220TW ²	—	—	—	30	—
YG-221TW ²	—	—	—	30	—
YG-227TW	—	—	—	20	V939B
YG-230TW ²	—	—	—	30	—
YG-231TW ²	—	—	—	30	—

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Printed:

Model	Weight	Dead Space	Flow Resistance	Qty	Supply Code
YG-232TW	20 to 40 kg	3.5 mL	—	10	V933A
YG-242TW	7 to 20 kg	2.5 mL	—	10	V935A
YG-272TW	30 kg or more	7 mL	—	10	V938B
YG-282TW	40 kg or more	10 mL	—	10	V938D

¹ The endotracheal tube size must be 4.0 mm or less.

² Not available in North America.

NOTE • When using any optional item listed above or the YG-225TW or YG-235TW nasal adapter, refer to its operator's manual.

- The patient weight is for reference only. An optional item might not be appropriate for some ventilation or leak conditions.

Symbols

The following symbols are used with this CO₂ sensor kit. The descriptions of each symbol are given in the table below.

Symbol	Description	Symbol	Description
	Caution		Date of manufacture
 Background color: blue	Follow instructions for use		Manufacturer
	European representative		Serial number
	Fragile		Temperature limits
	Keep away from rain		Humidity limits
	This way up		Atmospheric pressure limits
	Stacking limit by number ("n" is the limiting number)		Caution: United States law restricts this product to sale by or on the order of a physician.
IP34	<ul style="list-style-type: none"> • Protected against solid foreign objects of 2.5 mm ø and greater • Protected against splashing water 	IP67	<ul style="list-style-type: none"> • Dust-tight • Protected against the effects of temporary immersion in water
	The CE mark is a protected conformity mark of the European Community. The four digits after the CE mark indicate the identification number of the Notified Body involved in assessing the product's conformity as a medical device.		
	Products marked with this symbol comply with the European WEEE directive 2012/19/EU and require separate waste collection. For Nihon Kohden products marked with this symbol, contact your Nihon Kohden representative for disposal.		

Safety Information

WARNING A warning alerts the user to possible injury or death associated with the use or misuse of the instrument.

CAUTION A caution alerts the user to possible injury or problems with the instrument associated with its use or misuse such as instrument malfunction, instrument failure, damage to the instrument, or damage to other property.

Pay attention to all safety information in this operator's manual.

CO₂ Sensor Kit

WARNING

Never use the CO₂ sensor kit in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.

WARNING

Never use the CO₂ sensor kit in a hyperbaric oxygen chamber. Failure to follow this warning may cause explosion or fire.

WARNING

When performing MRI test, remove CO₂ sensor kit from the patient. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MRI manual.

WARNING

The defibrillation-proof type of the CO₂ sensor kit depends on the instrument to which the CO₂ sensor kit is connected. Refer to the operator's manual of the instrument.

WARNING

Never disassemble or modify the CO₂ sensor kit. If the CO₂ sensor kit is disassembled or modified, the patient and operator may receive electrical shock or skin burn.

WARNING

Do not diagnose a patient based only on data acquired by the connected instrument. Overall judgement must be performed by a physician who understands the features, limitations and characteristics of the connected instrument by reading its operator's manual thoroughly and by reading the biomedical signals acquired by other instruments.

CAUTION

Never autoclave or perform EOG gas sterilization for the CO₂ sensor kit because this damages the airway adapter and the CO₂ sensor kit and safety cannot be guaranteed.

CAUTION

Use the CO₂ sensor kit only with the specified instruments. Use of unspecified instruments may cause skin burn on the patient.

⚠ CAUTION

Do not pull or bend the CO₂ sensor cable, and do not let caster feet run over the cable. Failure to follow these instructions may cause cable discontinuity, short circuit, skin burn on the patient from the sensor temperature increase due to the short circuit of the cable and measurement cannot be performed. If the CO₂ sensor is broken, replace it with a new one.

⚠ CAUTION

- When using an anesthetic instrument with a volatile anesthetic agent, the CO₂ measurement may become inaccurate. Refer to the "Use with Volatile Anesthetic Agents" section.
- Refer to the operator's manual of the connected instrument for the measurement accuracy when using oxygen and N₂O anesthetic gas.

⚠ CAUTION

This CO₂ sensor kit is calibrated by taking the expired gas to be 37°C temperature and 100% humidity. Measured data varies about -0.4%/°C.

⚠ CAUTION

Keep magnetic objects away from the CO₂ sensor. The magnetic objects may cause an incorrect waveform and measurement value to be displayed.

⚠ CAUTION

Turn off the power of mobile phones, small wireless devices and other devices which produce strong electromagnetic interference around a patient (except for devices allowed by the hospital administrator). Radio waves from devices such as mobile phones or small wireless devices may cause the incorrect data to be displayed.

⚠ CAUTION

When the message requiring the CO₂ sensor replacement is displayed on the connected instrument, check the CO₂ sensor kit and replace with a new one when necessary. CO₂ cannot be monitored while the message is displayed.

⚠ CAUTION

The measured value may be incorrect when the operating temperature changes greatly.

⚠ CAUTION

The CO₂ sensor kit cannot measure the ETCO₂ value and respiration rate during high frequency oscillatory ventilation (HFOV).

Optional Items

⚠ CAUTION

The optional items are non-sterilized and disposable. Use only for a single patient and single use. Failure to follow this instruction causes cross infection and incorrect measurement value.

⚠ CAUTION

Failure to follow the instructions below degrades the anti-fogging ability of the transparent film and results in incorrect measurement.

- Replace an optional item with a new one after using it for the following number of hours.
 - YG-211TW, YG-227TW: 24 hours
 - Others: 72 hours
- Replace an optional item with a new one if blood, sputum or mucus adheres to the transparent film.
- Do not damage the transparent film. Do not let dust or detergent contact the transparent film. Do not touch, wipe or clean the transparent film with fingers or cleaners.
- Do not use an optional item which is past the expiration date.

- NOTE
- Do not let the patient bite cables and sensors.
 - Do not use a damaged or deformed optional item.

Airway Adapter

⚠ WARNING

Do not use the YG-211TW airway adapter on a neonate because the dead space of the airway adapter is about 4 mL.

⚠ WARNING

When using the airway adapter on a patient with low ventilatory volume, check the ventilation taking into consideration the dead space. If the dead space ratio against the ventilatory volume increases, a proper ventilation might not be performed. Also, a correct measured value might not be obtained due to the dead space.

⚠ CAUTION

Only use the specified airway adapter. Otherwise, the maximum performance cannot be guaranteed due to larger dead space, leak or insecure circuit connection, etc.

⚠ CAUTION

Select the airway adapter taking into consideration the patient weight and ventilation volume. If an inappropriate airway adapter is used, the resistance in the respiration circuit may increase and it may cause incorrect measurement value.

⚠ CAUTION

Use the YG-211TW airway adapter with patients over 7 kg.

⚠ CAUTION

Do not connect the YG-214TW airway adapter to a flow sensor or respiration circuit without an inner connector. The measurement is easily affected by the steady flow and the measured value may be inaccurate.

⚠ CAUTION

If a nebulizer is used with the airway adapter, the liquid medicine in the nebulizer may degrade the anti-fogging ability of the transparent film. This may affect the measurement accuracy.

⚠ CAUTION

If a humidifier is used, water droplets may accumulate inside the airway adapter and affect the measurement accuracy. Remove the droplets periodically.

cap-ONE Mask

⚠ WARNING

Use the cap-ONE mask only for supplying oxygen and attaching the CO₂ sensor kit to measure the partial pressure of the expired CO₂.

⚠ WARNING

Never use the cap-ONE mask in a flammable environment, such as close to fire or static electricity. It may cause skin burn to the patient and damage the mask and CO₂ sensor.

⚠ WARNING

Select the cap-ONE mask taking into consideration the patient weight, ventilation volume and mask dimensions. If an inappropriate cap-ONE mask is used, desired oxygen concentration or correct measurement value cannot be obtained.

⚠ WARNING

Before and while using the cap-ONE mask, check that the oxygen connector is not loose or disconnected from the oxygen supply unit and that the oxygen cannula tube is not blocked. Always check the conditions of the patient and oxygen supply circuit.

⚠ WARNING

If arterial oxygen partial pressure does not increase, immediately stop using the cap-ONE mask and select another way to supply oxygen.

⚠ CAUTION

The cap-ONE mask is for adults, infants and children. Do not use the cap-ONE mask for neonates.

⚠ CAUTION

Do not use a damaged or deformed cap-ONE mask. It causes incorrect measurement or insufficient oxygen supply.

⚠ CAUTION

When using the cap-ONE mask on a patient with bleeding disorder, poor general medical condition or malnutrition, observe the patient condition all the time. The cap-ONE mask touches the nose and mouth and may cause pressure sores.

⚠ CAUTION

When using a humidifier unit with the oxygen supply unit, check their compatibility and safety thoroughly.

⚠ CAUTION

Use the cap-ONE mask with 2 L/min or more of oxygen flow rate to reduce rebreathing. Otherwise the patient may rebreathe the expiratory gas in the mask.

⚠ CAUTION

- Follow the physician's instruction when controlling the oxygen flow rate.
- Periodically check the oxygen concentration of the patient with a pulse oximeter or arterial blood gas analyzer.

⚠ CAUTION

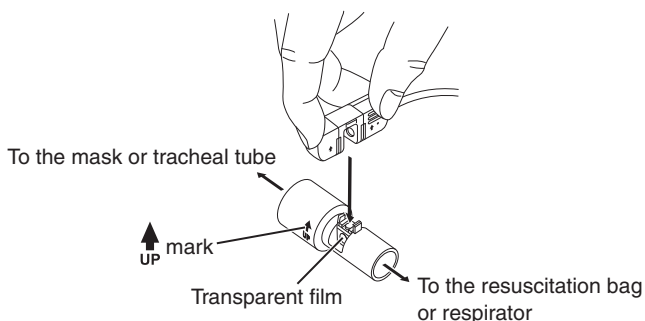
If the patient's respiratory volume is low and the oxygen flow rate is high, CO₂ data becomes inaccurate due to the cap-ONE mask's dead space.

Using the CO₂ Sensor Kit with the Optional Items

- NOTE
- Perform calibration when:
 - an optional item is replaced with a new one.
 - a different type of optional item is used.
 - the operating temperature changes.
 - the measurement room is changed.
 - whenever necessary.
 - Open the optional item package just before using the product.
 - Do not dispose of the optional item package until all the products in the package are used because the model and manufacturer are listed only on the package.

Use with an Airway Adapter

1. Connect the interface connector to the input socket of the instrument.
2. Hold the CO₂ sensor as shown and attach the sensor to the airway adapter until it clicks. You can attach the sensor in either direction.



NOTE: When connecting the airway adapter to the CO₂ sensor, avoid touching the transparent film of the airway adapter with your fingers or any hard object, and avoid the transparent film from dust or chemical solutions. Otherwise measurement may be inaccurate.

3. Perform zero calibration.
For details about zero calibration, refer to the operator's manual of the connected instrument.

There are two ways to do zero calibration.

Calibrating with air:

Expose the CO₂ sensor kit to the air and calibrate it with the connected airway adapter. Adjust zero assuming the CO₂ in the air is about 0.5 mmHg.

Calibrating with N₂ gas:

Connect the airway adapter to the CO₂ sensor and N₂ gas cylinder and flow N₂ gas. Then adjust zero.

NOTE: For disposal of an N₂ gas cylinder, follow the distributor's instruction.

4. Connect the airway adapter to the respiration circuit of the respirator.

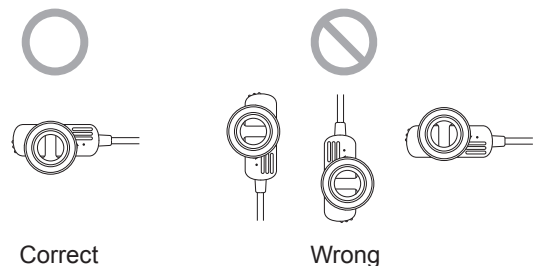
Connect the larger end of the airway adapter to the mask or tracheal tube of the patient, and the smaller end to the resuscitation bag or respirator.

⚠ CAUTION

When using the YG-213TW or YG-214TW airway adapter, fix an endotracheal tube to the respiration circuit so as not to bend the tube.

⚠ CAUTION

Secure the CO₂ sensor to the respiration circuit so that the arrow of the UP mark on the airway adapter is pointing upward. Otherwise, water droplets may accumulate inside the airway adapter and affect the measurement accuracy.



5. Check that there is no leak in the respiration circuit.
6. Attach the CO₂ sensor to a support arm so that the weight of the CO₂ sensor does not affect the patient. Secure it properly.
7. Check that the CO₂ is measured correctly on the connected instrument. For details, refer to the operator's manual of the instrument.

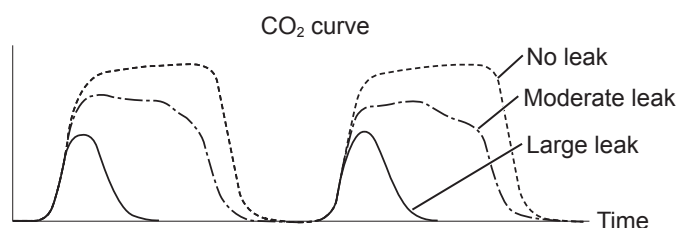
Use with a cap-ONE Mask, cap-ONE Biteblock or cap-ONE Nasal Adapter

Refer to the operator's manual of the cap-ONE mask, cap-ONE biteblock or cap-ONE nasal adapter for details.

Checking the CO₂ Data on the Instrument

Check that the CO₂ data is measured correctly on the instrument. For details, refer to the operator's manual of the instrument.

- NOTE
- Periodically check that water is not accumulating in the respiration circuit. If the water has accumulated, remove it.
 - Especially when a non-cuffed tracheal tube is used, the CO₂ curve may be inaccurate due to leak around the tracheal tube.
 - When using the airway adapter with a steady flow type of respirator, the CO₂ curve may be unstable at the end-expiration due to the low respiratory flow depending on the settings of the respirator.

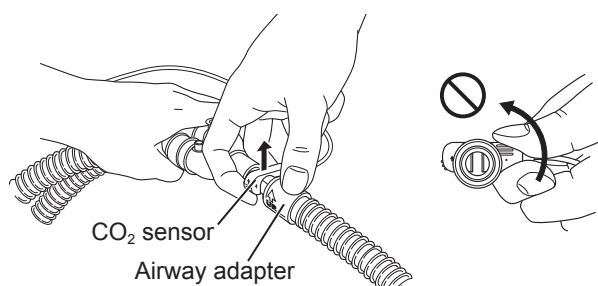


Removing the CO₂ Sensor Kit

NOTE: When removing the CO₂ sensor, do not hold the cable or one side of the sensor. The cable may break or excessive force may damage the CO₂ sensor.

When removing the CO₂ sensor from the airway adapter

Hold the respiration circuit firmly with one hand and hold the CO₂ sensor with the other hand as shown and pull the CO₂ sensor straight up with the index finger and middle finger.



When removing the airway adapter from the respiration circuit

Hold the airway adapter firmly and remove it from the respiration circuit so that excessive force is not applied to the CO₂ sensor.

When removing the CO₂ sensor from the cap-ONE mask, cap-ONE biteblock or cap-ONE nasal adapter

Hold the CO₂ sensor attachment of the cap-ONE mask, cap-ONE biteblock or cap-ONE nasal adapter firmly with one hand and hold the CO₂ sensor with the other hand. Pull the CO₂ sensor straight up to remove the sensor from the mask, biteblock or nasal adapter.

Check Before and After Use

To use the CO₂ sensor kit safely and properly, check the following items.

- No scratches, damage or dirt on the CO₂ sensor kit and cables.
- No fluid or blood on the CO₂ sensor kit and cables.
- No dirt on the photo detector and light emitter on the CO₂ sensor and transparent film on the airway adapter.
- Airway adapter is not damaged or deformed.

Troubleshooting

Problem	Possible Causes	Action
Measurement is not performed.	Bad electromagnetic environment	Turn off the devices which produce strong electromagnetic interference.
The measured value is inaccurate.	Simultaneous use with anesthetic gas	Refer to "Use with Volatile Anesthetic Agents" (p. 8).
	Rapid temperature change. Measurement may be incorrect when there is a rapid temperature change and much condensation.	Wait until the temperature becomes stable and perform the zero calibration.
	High or low temperature environment. Measured data varies about $-0.4\%/^{\circ}\text{C}$.	Measure the value considering the effect of temperature.
	Water is accumulated in an optional item.	Remove the water in the optional item.
Calibration cannot be performed.	An optional item is not connected to the CO ₂ sensor kit.	Connect the optional item correctly.

Cleaning and Disinfection

⚠ CAUTION

- Do not use corrosive solutions or solutions with polishing agents.
- Do not clean the CO₂ sensor with steel wool or sharp objects because it scratches the sensor and causes incorrect measurement.
- Do not use volatile liquids such as thinner, benzene or industrial alcohol because these damage the sensor surface.

After using the CO₂ sensor, clean the CO₂ sensor with a cotton swab moistened with any of the following liquids and leave it to dry. Clean and disinfect the other parts of the CO₂ sensor with any of the following liquids.

- Ethanol (15°C (59°F), 76.9 to 81.4% by vol)
- Diluted mild detergent

The optional items are disposable. You cannot clean, disinfect or sterilize them. Immediately replace them with new ones when they become dirty.

NOTE: When using flammable solvent such as ethanol for cleaning and disinfecting, ventilate the room adequately.

Maintenance

When the CO₂ is not monitored accurately, check the measurement accuracy using CO₂ calibration gas. For stable measurement accuracy, check the measurement accuracy every half year. For details, refer to the operator's manual of the instrument that is connected to the CO₂ sensor kit.

Disposal

For detailed information about disposal, contact your Nihon Kohden representative.

⚠ CAUTION

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

Specifications

Measuring method: Mainstream

Measuring range: 0 to 20 kPa (0 to 150 mmHg)

Measuring accuracy¹: ±0.27 kPa (0 ≤ CO₂ ≤ 5.33 kPa)
 (±2 mmHg (0 ≤ CO₂ ≤ 40 mmHg))
 ±5% of gas level
 (5.33 < CO₂ ≤ 9.33 kPa (40 < CO₂ ≤ 70 mmHg))
 ±7% of gas level
 (9.33 < CO₂ ≤ 13.3 kPa (70 < CO₂ ≤ 100 mmHg))
 ±10% of gas level
 (13.3 < CO₂ ≤ 20 kPa (100 < CO₂ ≤ 150 mmHg))
 (noncondensing)

¹ Essential performance in EMC standard

Accuracy stability: Measurement accuracy is guaranteed for 6 hours after power on.

Total system response time:
 ≤ 0.5 seconds

Power source
 TG-981T: DC 3.3V ±5% to 5V ±5%
 TG-981T1: 5V ±5%

Detectable respiration rate:
 0 to 150 breaths/min ±1 breath/min
 (with I/E ratio of 1:1 and 5% CO₂)

Rise time: < 60 ms for 10 to 90%

Effect on ETCO₂ value caused by RR and I/E ratio:
 (ETCO₂ = 5.1 kPa (38 mmHg))

Respiration rate	I/E ratio			
	1:3	1:2	1:1	2:1
3 bpm	0	0	0	0
30 bpm	0	0	0	0
60 bpm	0	0	0	0
100 bpm	0	0	-0.1 kPa (-1 mmHg)	-0.3 kPa (-2 mmHg)
150 bpm	0	-0.1 kPa (-1 mmHg)	-0.3 kPa (-2 mmHg)	-1.2 kPa (-9 mmHg)

Shaded area indicates respiration rate and I/E ratio combination that results in inspired or expired time period outside the specified measuring accuracy.

ETCO₂ calculation: Calculated from the maximum CO₂ in expiration

Data sampling rate: 40 Hz

Warm-up time: about 10 seconds

O₂, N₂O anesthetic gas effect:
 Depends on the instrument to which the CO₂ sensor kit is connected. Refer to the instrument manual.

Degree of protection provided by enclosures:

Sensor part: IP67 (Dust-tight/Protected against the effects of temporary immersion in water)¹
¹ Not protected during use.

Adapter part: IP34 (Protected against solid foreign objects of 2.5 mm ø and greater/
 Protected against splashing water)

Interface connector:
 Depends on the instrument to which the CO₂ sensor kit is connected.

Degree of protection against shock:
 MIL STD 810G: 2008 516.6 4.6.5
 (except interface connector)
 Shock resistance: 100 drops from 2 m
 (except interface connector)

Degree of protection against electrical shock:
 Defibrillator-proof type BF applied part
 or defibrillator-proof type CF applied
 part ¹
¹ Depends on the instrument to which
 the CO₂ sensor kit is connected.
 Refer to the instrument manual.

Degree of safety of application in the presence of
 FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR
 WITH OXYGEN OR NITROUS OXIDE:
 Equipment not suitable for use in
 the presence of FLAMMABLE
 ANAESTHETIC MIXTURE WITH
 AIR, OR WITH OXYGEN OR
 NITROUS OXIDE

Mode of operation: CONTINUOUS OPERATION

Applicable patients (weight):
 Refer to “Optional Items” (p. 1).

Operating environment
 Temperature: 0 to 40°C (32 to 104°F)
 Humidity: 15 to 95% RH (noncondensing)
 Atmospheric pressure:
 70 to 106 kPa

Transport and Storage environment
 Temperature: -25 to +65°C (-13 to +149°F)
 Humidity: 10 to 95% RH (noncondensing)
 Atmospheric pressure:
 70 to 106 kPa
 It may take up to 1 hour for the CO₂ sensor kit to reach
 full performance when the CO₂ sensor kit is stored at
 -25°C (-13°F) or 65°C (149°F) and then moved to a place
 at 20°C (68°F).

Atmospheric compensation:
 Automatic

Lifetime of the optional items:
 The optional items are disposable.
 Their lifetime is 36 months from the
 month of manufacture.

Safety standard: IEC 60601-1:2005+Amendment 1:2012
 IEC 60601-1-2:2007
 IEC 60601-1-2:2014 ¹
 IEC 60601-1-12:2014 ¹
 ISO 80601-2-55:2011
¹ Only when the connected instrument
 complies with the standard

Electromagnetic Compatibility:
 IEC 60601-1-2:2007
 or IEC 60601-1-2:2014 ¹
¹ Depends on the instrument to which
 the CO₂ sensor kit is connected.

For details on “EMC Related Caution”,
 “Electromagnetic Emissions”,
 “Electromagnetic Immunity” and
 “System Composition for EMC Test”,
 refer to the instrument manual.

Measurement Principle

The mainstream CO₂ measurement principle is based on the
 fact that CO₂ absorbs 4.3 μm wavelength infrared light well.
 Infrared light is emitted from the emitter on the CO₂ sensor,
 passes through the CO₂ sensor cell where some is absorbed
 by CO₂ in the cell, then the unabsorbed light is detected
 by the detector. The CO₂ concentration in the respiration is
 calculated from the ratio of unabsorbed infrared light that
 passed through the CO₂ sensor cell and reference infrared
 light that does not go through the CO₂ sensor cell (single
 wave spectroscopic method).

Use with Volatile Anesthetic Agents

When using volatile anesthetic agents, the displayed value is
 off by the following amount (at 1 atmospheric pressure and
 gas mixtures of 5% CO₂ (5.1 kPa (38 mmHg)) and balance
 N₂, dry gas).

Anesthetic Gas	Concentration	Difference
Halothane	4%	+0.04 kPa (+0.3 mmHg)
Enflurane	5%	+0.12 kPa (+0.9 mmHg)
Isoflurane	5%	+0.22 kPa (+1.7 mmHg)
Sevoflurane	6%	+0.28 kPa (+2.1 mmHg)
Desflurane	15%	+0.39 kPa (+2.9 mmHg)

Note for users in the territory of the EEA and Switzerland:
 Any serious incident that has occurred in relation to the device should be
 reported to the European Representative designated by the manufacturer
 and the Competent Authority of the Member State of the EEA and
 Switzerland in which the user and/or patient is established.

Copyright Notice

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