

OPERATOR'S MANUAL

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Printed:

Pediatric/Infant cap-ONE Mask

YG-232T/YG-242T

Symbol	Description
	Attention, consult operator's manual
	Date of manufacture
	Do not reuse
	Expiration date
	Lot number
	The CE mark is a protected conformity mark of the European Community. Products marked with this symbol comply with the requirements of the Medical Device Directive 93/42/EEC.

General

The YG-232T pediatric cap-ONE mask and YG-242T infant cap-ONE mask are for supplying air or oxygen to the patient.

The cap-ONE mask is used with the TG-970P CO₂ sensor kit to measure the partial pressure of the expired CO₂. Refer to the operator's manual of the CO₂ sensor kit together with this operator's manual.

Model	YG-232T	YG-242T
Applicable Patients	For children 20 to 40 kg	For infants 7 to 20 kg
Dead Space	3.5 mL	2.5 mL
Qty	10	10
Supply Code	V933	V935

NOTE

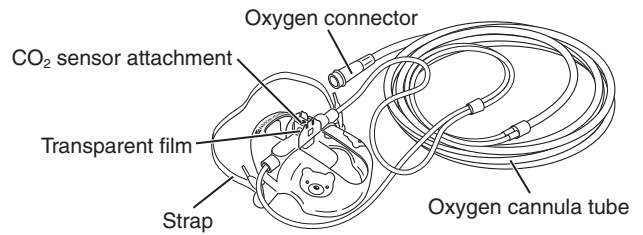
The applicable patient weight is for reference only. The cap-ONE mask might not be appropriate for some ventilation conditions.

Components

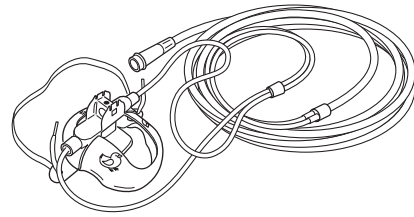
Mask: PVC

Oxygen cannula tube: PVC

YG-232T Pediatric cap-ONE Mask



YG-242T Infant cap-ONE Mask



Safety Information

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 and ventilation volume. 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

This cap-ONE mask is for infants and children. Do not use this 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

Do not use a cap-ONE mask which is past the expiration date.

CAUTION

The cap-ONE mask is non-sterilized and disposable. Use only for a single patient and single use. Failure to follow this instruction causes cross infection.

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

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

- Replace the cap-ONE mask with a new one every 72 hours.
- Replace the cap-ONE mask 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 reuse the cap-ONE mask. It is disposable.

CAUTION

United States law restricts this product to sale by or on the order of a physician.

NOTE

- When using the cap-ONE mask, follow the physician's instruction.
- Only transport and store the cap-ONE mask in the environment conditions which are described on the package. Do not leave the cap-ONE mask in a place with high temperature such as on a dashboard of a car. This may deform the mask and cause inaccurate measurement.

Attaching the cap-ONE Mask

1. Open the package of the cap-ONE mask just before using it to avoid dust gets on the transparent film of the mask.
2. Firmly connect the oxygen connector of the cap-ONE mask to a socket of the oxygen supply unit.

CAUTION

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

NOTE

- Connect the cap-ONE mask only to a socket of an oxygen supply unit which can be firmly connected with the oxygen connector of the cap-ONE mask.
 - Check the socket connection of the oxygen supply unit and oxygen connector occasionally. If the socket connection is loose, replace the cap-ONE mask with a new one.
3. Check that the oxygen cannula tube is not blocked. If block or leakage is found on the cap-ONE mask, replace it with a new one.

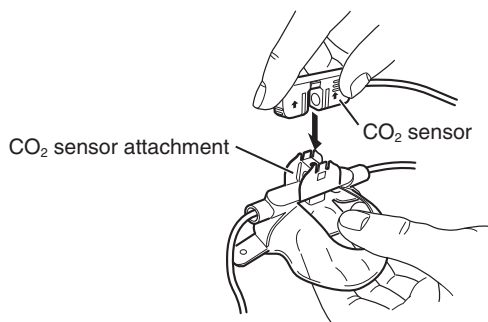
Make sure that oxygen comes out from the mask.

NOTE

Do not bend or twist the cap-ONE mask. This may cause damage or block on the cap-ONE mask.

4. Connect the CO₂ adapter connector of the TG-970P CO₂ sensor kit to the input socket of the monitor. Wait for about 10 seconds until the CO₂ sensor kit warms up.

- Attach the CO₂ sensor to the CO₂ sensor attachment of the cap-ONE mask until it clicks. The CO₂ sensor can be attached in either direction.



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

Calibrating with air:

Expose the CO₂ sensor kit to the air and calibrate it with the connected cap-ONE mask. Adjust it assuming the partial pressure of CO₂ in the air is about 0.5 mmHg.

NOTE

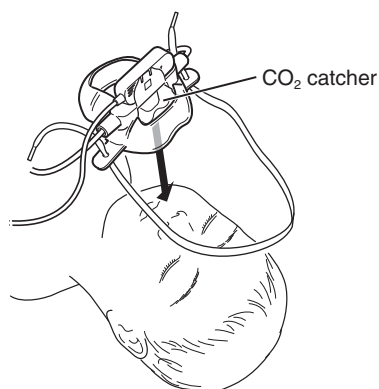
Perform calibration when:

- the cap-ONE mask is replaced with a new one.
- the operating temperature changes.
- the measurement room is changed.

- Position the CO₂ catcher (the small cup inside the mask) under the patient's nose and check that the waveform of the expired CO₂ appears on the monitor. Adjust the position as necessary.

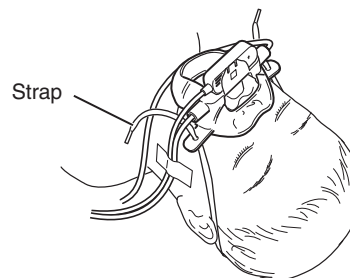
NOTE

Keep the distance between the CO₂ catcher and the top of the mouth and nose within 1 cm. CO₂ cannot be measured correctly if the CO₂ catcher is far from the nose and mouth.

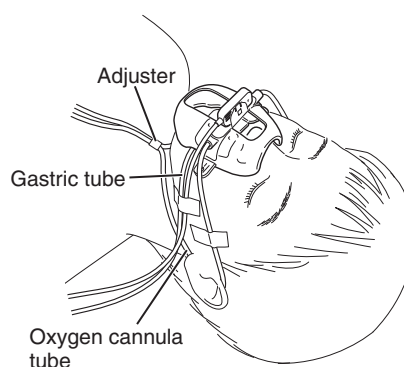


- Attach the cap-ONE mask firmly to the patient using one of the following three ways. The gastric tube can be inserted through the cutout on the sides of the mask.

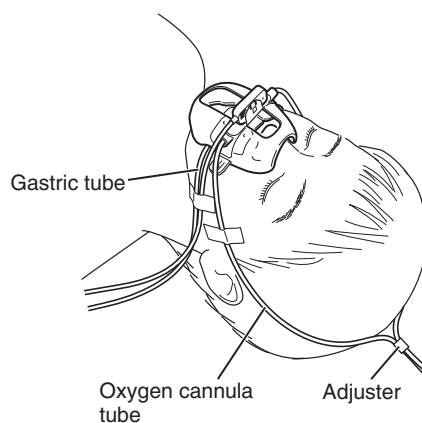
- Fasten the cap-ONE mask to the patient's head with the strap. Pull the ends of the strap to adjust the strap length.



- Hook the oxygen cannula tubes around the patient's ears and adjust the tightness with the adjuster.



- Tighten the oxygen cannula tubes on the patient's head and adjust the tightness with the adjuster at the top of the head.



NOTE

- Do not tighten the strap or oxygen cannula tubes too tight. It may cause blood congestion. Observe the patient condition periodically.
- Oral care is possible when the mask is attached. However pay attention not to get the CO₂ sensor attachment dirty.

- Tape the tubes and CO₂ sensor cable on the cheek with surgical tape.

10. Supply the oxygen to the patient. Oxygen concentration changes depending on the respiratory volume of the patient. Adjust the oxygen flow rate to obtain the desired oxygen concentration. Refer to the following table as a guide for the oxygen concentration.

Oxygen Flow Rate	Oxygen Concentration	
	YG-232T (Children)	YG-242T (Infants)
2 L/min	40%	60%
4 L/min	50%	70%
6 L/min	60%	80%

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

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

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.

NOTE

Do not pull the oxygen cannula tube excessively while supplying the oxygen to the patient. The tube may disconnect from the cap-ONE mask and oxygen may not be supplied to the patient.

11. Check that the partial pressure of the expired CO₂ is measured correctly on the monitor. Refer to the operator's manuals of the monitor and CO₂ sensor kit for details.

If the measured partial pressure of the inspired CO₂ is high, do the following.

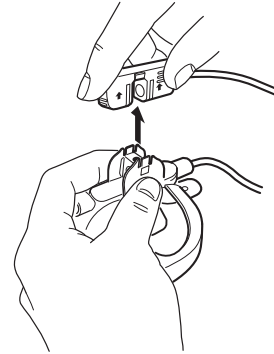
- Remove the CO₂ sensor from the cap-ONE mask.
- Reattach it to the mask.
- Perform calibration again. Refer to step 6.

NOTE

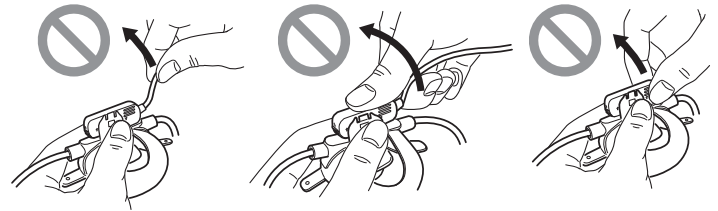
- Do not let the patient bite the mask, tubes or CO₂ sensor cable.
- Arrange the tubes and CO₂ sensor cable so they do not coil around the patient.

Removing the cap-ONE Mask

1. Remove the surgical tape, then the cap-ONE mask from the patient.
2. Hold the CO₂ sensor attachment firmly with one hand and the CO₂ sensor with the other hand as shown. Pull the CO₂ sensor straight up with three fingers to remove the sensor from the mask.



Bad examples



NOTE

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

3. Disconnect the oxygen connector from the oxygen supply unit. Hold the oxygen connector, not the oxygen cannula tube.

Check Before Use

To use the cap-ONE mask properly and safely, check the following items before attaching the cap-ONE mask to the patient.

- No loose or disconnection on the oxygen connector.
- No block on the oxygen cannula tube.
- No damage, deformation or dirt on the cap-ONE mask.

Cleaning, Disinfection and Sterilization

The cap-ONE mask is disposable. You cannot clean, disinfect or sterilize it. Immediately replace it with a new one when it becomes dirty.

Expiration Date

The cap-ONE mask is disposable. The expiration date is 36 months including the month of manufacture.

Disposing

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

Mechanical Strength

Resistance to shock: MIL STD 810F 516.5 4.5.5:2000 (when the product is in the package)

Resistance to kinking: EN 13544-2:2002 5.1.5
EN 13544-2 Amendment 1:2009 5.1.5
(except for the thinner oxygen cannula tubes)

Airtightness: EN 13544-2:2002 5.1.4
EN 13544-2 Amendment 1:2009 5.1.4

Strength of connection:

Oxygen cannula tube and oxygen connector:
EN 13544-2:2002 5.1.3
EN 13544-2 Amendment 1:2009 5.1.3

Oxygen connector and oxygen supply unit:
EN 13544-2:2002 5.1.4
EN 13544-2 Amendment 1:2009 5.1.4

Environment

Store the cap-ONE mask away from direct sunlight, high temperature and humidity.

Operating environment

Temperature: 10 to 40°C (50 to 104°F)
Humidity: 30 to 85% (noncondensing)
Atmospheric pressure: 700 to 1060 hPa

Transport and storage environment

Temperature: -20 to +65°C (-4 to +149°F)
Humidity: 10 to 95%
Atmospheric pressure: 700 to 1060 hPa

Safety Standard

Safety standard: IEC 60601-1:1988
IEC 60601-1 Amendment 1:1991
IEC 60601-1 Amendment 2:1995
ISO 10993-1:2009

Options

Refer to the operator's manual of the TG-970P CO₂ sensor kit for details.

Description	Model	Qty	Supply Code
CO ₂ sensor kit	TG-970P	1	P909
CO ₂ sensor	TG-221T	1	P924
CO ₂ adapter	JG-970P	1	K987
Surgical tape	#1527	1	Y242

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