# SAFETY AND PERFORMANCE INFORMATION NIHON KOHDEN



# YG-220T, YG-221T Adult cap-ONE Nasal Adapter YG-230T, YG-231T Pediatric cap-ONE Nasal Adapter

## General

The YG-220T or YG-221T adult cap-ONE nasal adapter or YG-230T or YG-231T pediatric cap-ONE nasal adapter is used with a TG-970P, TG-971T4, TG-980P or TG-981T4 CO<sub>2</sub> sensor kit to measure the partial pressure of the expired CO<sub>2</sub> of the patient. The YG-221T and YG-231T can also deliver oxygen or medical air, using the built-in oxygen cannula tubes.

This nasal adapter can be used with a Nihon Kohden specified instrument that measures the partial pressure of the expired  $CO_2$ .

# **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 the Operator's Manual or Installation Guide.

# For YG-220T, YG-221T, YG-230T or YG-231T

#### **⚠ WARNING**

Do not use the nasal adapter where it may catch fire, such as near fire or where static electricity is generated. Doing so may cause the nasal adapter to catch fire and cause skin burn to the patient or operator.

#### ⚠ WARNING

When using the nasal adapter on a patient with low ventilatory volume, check the ventilation taking into consideration the 1.1 mL dead space of the nasal adapter. If that dead space is too much for this patient, appropriate ventilation might be impossible. The CO<sub>2</sub> may mix in the inspiration due to the nasal adapter's dead space, resulting in the measurement being incorrect or difficulty in detecting no breath.

#### **⚠** CAUTION

Do not use the nasal adapter for a neonate because the dead space volume of the nasal adapter is about 1.1 mL.

#### **⚠** CAUTION

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

- · Replace the nasal adapter with a new one every 72 hours.
- · Replace the nasal adapter with a new one if blood, sputum or mucus adhere 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.

#### **↑** CAUTION

When using the nasal adapter to monitor the CO<sub>2</sub> partial pressure of a patient with an oxygen mask, have an additional method of monitoring the patient condition, such as monitoring the SpO<sub>2</sub> or PaCO<sub>2</sub> level by a specialized monitoring device, such as a pulse oximeter or arterial blood gas monitoring device, because the oxygen flow delivered from the oxygen mask may affect the CO<sub>2</sub> measurement, resulting in the measurement being incorrect.

#### ⚠ CAUTION

Check the nasal adapter exterior every before use. Do not use it if it is damaged or deformed.

#### **⚠** CAUTION

Do not let the patient bite or swallow the nasal adapter.

#### **⚠** CAUTION

When using the nasal adapter on the patient, periodically check that the mouth guide does not touch the patient's nose or mouth, as it may cause pressure sores.

#### **↑** CAUTION

When using the nasal adapter for a patient with a nasotracheal intubation equipment, fix the nasal adapter firmly so it does not press the equipment or the nasal tube is not disconnected. Failure to follow this caution may cause incorrect measurement data to be displayed or prevent the equipment to serve its purpose, resulting in the patient to receive inadequate medical treatment.

#### **⚠** CAUTION

The nasal adapter is non-sterilized and disposable. Use only for a single patient and single use. Failure to follow this instruction may cause cross infection or incorrect measurement.

#### **⚠** 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.

#### For YG-221T or YG-231T

#### **⚠ WARNING**

If arterial oxygen partial pressure does not increase when using the YG-221T or YG-231T nasal adapter to deliver oxygen to the patient, immediately stop using the nasal adapter and select another way to deliver oxygen. Failure to do so may cause insufficient oxygen delivery to the patient.

#### **⚠ WARNING**

Before and during use, check that the oxygen cannula tube is firmly connected to the oxygen supply unit and that the oxygen tube is not bent, broken, or blocked. Failure to do so may cause insufficient oxygen delivery to the patient.

#### **↑** CAUTION

Before using the YG-221T or YG-231T nasal adapter together with a humidifier, check the following conditions are met. If any of these conditions are not met, do not use the humidifier together with the nasal adapter. Otherwise, it may cause insufficient oxygen delivery.

- The oxygen cannula tube connector of the nasal adapter can be securely connected to the humidifier.
- The oxygen cannula tubes are not clogged when oxygen is supplyed to the nasal adapter through the humidifier.

#### 

When using the YG-221T or YG-231T nasal adapter to supply oxygen to the patient, follow the physician's instructions to control the oxygen flow

#### **⚠** CAUTION

When using the YG-221T or YG-231T nasal adapter to supply oxygen to the patient, periodically check the patient's oxygen saturation (SpO<sub>2</sub>) level or partial pressure of carbon dioxide in arterial blood (PaCO<sub>2</sub>) using a specialized monitoring device, such as a pulse oximeter or arterial blood gas monitoring device. Failure to do so may cause insufficient oxygen delivery to the patient.

## **⚠** CAUTION

When using the YG-221T or YG-231T nasal adapter to supply oxygen to the patient, set the oxygen supply to 5 L/min or lower. Otherwise, CO<sub>2</sub> cannot be correctly measured because the oxygen flow affects the expired gas flow.

This Safety and Performance Information is an extract from the general and safety information sections of the most recent edition of Operator's Manual or Installation Guide. Therefore, the contents of your Operator's Manual or Installation Guide may differ from those of this Safety and Performance Information. For detailed operating procedures, follow the instructions of your Operator's Manual or Installation Guide.



Manufacturer

NIHON KOHDEN CORPORATION 1-31-4 Nishiochiai, Shinjuku-ku,

Tokyo 161-8560, Japan Phone +81 3-5996-8041 https://www.nihonkohden.com/

EC REP European Representative

NIHON KOHDEN EUROPE GmbH Raiffeisenstrasse 10, D-61191 Rosbach, German Phone +49 6003-827-0 Fax +49 6003-827-599

1st Edition: 25 Jun 2019