SAFETY AND PERFORMANCE INFORMATION NIHON KOHDEN



Nasal Adapter, Pediatric Nasal Adapter **YG-225TW, YG-235TW**

General

The YG-225TW nasal adapter and YG-235TW pediatric nasal adapter attach over the patient's face to capture nasal and oral expired air.

Safety Information

 ★ WARNING A warning alerts the user to the 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.

⚠ WARNING

The YG-225TW and YG-235TW nasal adapters are for diagnostic purpose only. If the nasal adapter is used as an apnea monitor or in life support or life sustaining situations, the performance of the nasal adapter cannot be guaranteed and it may lead to incorrect diagnosis.

⚠ 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. The CO₂ may mix in the inspiration due to the nasal adapter's dead space, resulting in inaccurate measured value.

⚠ CAUTION

Only use the specified nasal adapter. Otherwise. the maximum performance cannot be guaranteed due to larger dead space volume.

⚠ 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 24 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

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 inaccurate measurement.

⚠ CAUTION

When using the YG-225TW or YG-235TW nasal adapter on a patient with bleeding disorder, poor general medical condition or malnutrition, observe the patient condition all the time. The mouth guide touches the mouth and may cause pressure sores.

⚠ CAUTION

Do not let the patient bite or swallow the CO₂ sensor or nasal adapter.

⚠ CAUTION

Do not use a nasal adapter which is past the expiration date.

⚠ CAUTION

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

⚠ 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.

> 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 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, Germany Phone +49 6003-827-0 Fax +49 6003-827-599

 ϵ 1st Edition: 02 Apr 2019