

# Infant Ventilation Accessories

## INSTRUCTION FOR USE

### Statement

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This manual provides the instructions necessary to operate the product in accordance with its function and intended use. Observance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety.

Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

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- this product is not damaged by human factors. Human factors refer to unintentional falling, intentional damaging, etc.

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### Product Introduction

This manual contains the instructions for the generator (Infant Jet™).

Intended Use

#### Intended Purpose Statement

The generator is intended for connecting with ventilator that supports non-invasive ventilation for generating continuous or variable positive pressure gas for patients.

#### Indication for Use

The generator is indicated for patients who need non-invasive ventilation.

#### Intended User

The generator must be used by trained clinical professionals.

#### Intended Patient Population

The generator can be used in neonate (including premature babies) and children weighing less than 30kg.

#### Intended Medical Conditions

The generator is expected to be used in medical institutions.

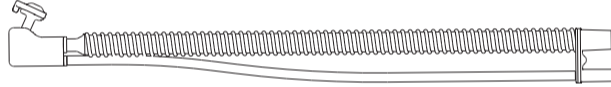
#### Contra-indications

Not identified yet.

#### Side Effects

N/A.

Generator



Model	Product Name
RA15103	Generator

### Usage

Install nasal prong:

Install nasal mask:



Fix generator with the bonnet:

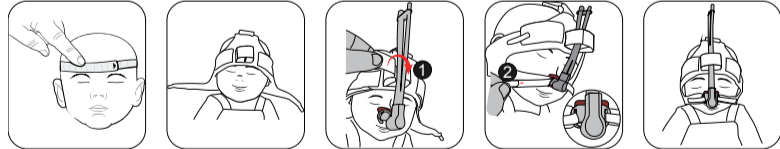


1. Fasten the generator tube with a hook-and-loop tape at the forehead.

2. Put the end of the strap with the hook-and-loop tape through the hook of the generator, and then fasten it firmly.

3. Attach the vertical strap to the hook-and-loop tape on the side of the bonnet.

Fix generator with the headgear:



1. Insert the generator pipeline into the sponge block and fasten it with the hook-and-loop tape.

2. Put the end of the strap with the hook-and-loop tape through the hook of the generator, and then fasten it firmly.

### Notification of Adverse Events

As a health care provider, you may report the occurrence of certain events to SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD., and possibly to the competent authority of the Member state in which the user and / or patient is established. These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

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### Residual Risk Evaluation

According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Thus, no residual risk associated with using the medical device should be disclosed.

### WARNING

- Products covered in this manual are for single use only and must not be used repeatedly. Repeated use may cause unacceptable risks, such as product performance degradation or cross contamination. Do not soak or disinfect this product.
- This product is intended to be used for a maximum of 14 days.
- Use this product only as directed in the product manual to reduce the risk of nasal irritation, septal distortion, and pressure necrosis.
- The product shall be used by properly-trained and authorized medical personnel.
- Properly adjust the straps of infant headgear and bonnet to ensure gentle contact with the patient's skins.
- To prevent high leakage which may cause insufficient ventilation, please check the nasal prong and nasal mask regularly for any displacement or detachment. Do not over tighten the fixation straps.
- If nasal prong and nasal mask are used alternatively, do not always fix them to the same region of the skin.
- Check the package before use. Do not use if the package is damaged.
- Disposal of products shall be in accordance with the local laws and regulations.
- This product is intended to be used with NB300/NB350/NB380 ventilator.

### NOTE

- Select the appropriate size of nasal prong; if between sizes, select the larger one.
- Select the appropriate size of nasal mask to minimize leakage and dead space.
- Choose the appropriate size of headgear or bonnet according to the patient's conditions. If a patient has a severe deformation in its head, using a headgear may lead to insecure fixation.
- Ensure the patient's ears are not folded when headgear/bonnet is used.
- Before fixing the generator, ensure the nasal prong/nasal mask is correctly inserted into the generator.
- Adjust the straps to stabilize the generator and maintain a seal at the nose using the least tension possible.
- Before connecting the breathing circuit, fix the generator and nasal prong/nasal mask first to prevent any injury to the patient from location adjustment.
- Perform regular checks to ensure the generator is stable and that the nasal prong/nasal mask is not over-tight on the patient's nose.
- Observe the leakage of the entire accessory system regularly to ensure the patient is receiving treatment at the preset pressure level.
- Clear any nose secretions of the patient regularly to prevent obstruction.
- It is recommended that the nasal prong and nasal mask are alternated for use once every three to four hours for patient receiving long-term treatment to reduce the pressure on the nose, as the patient's conditions allow.
- Humidifier is recommended to be used together.

Perform a system check after the installation, and perform regular checks at least once every three to four hours to:

- Ensure the generator is stable and secure, and is not pulled upward on the nose.
- Check for any distortion or inflammation in the nose and surrounding tissues.
- Ensure the patient's septum remains clearly visible when the nasal prong is in use.
- Ensure the patient's eyes remain clearly visible and that nares are not blocked when the nasal mask is in use.
- Check whether the fixtures and straps are appropriately tightened, and adjust them as needed to maintain comfort.
- Monitor the patient for gastric insufflation and abdominal distension.
- Monitor for excessive condensation in circuit and generator.

### Customer Service Department

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