

IFU
Cuff Pressure Indicator

DESCRIPTION

Cuff Pressure Indicator is an airway management device, it is used for indicating the cuff pressure. AC0100B is for all Endotracheal, Endobronchial or Tracheostomy Tubes used on adult patients that are ventilated or spontaneously breathing and that require an inflation pressure of between 20-29cmH₂O. AC0100R is for all versions of Laryngeal Masks that require an inflation pressure of between 40-60cmH₂O. AC0100P is for all Endotracheal or Tracheostomy Tubes used on pediatric patients that are ventilated or spontaneously breathing and that require an inflation pressure of between 10-20cmH₂O.

CATEGORIES AND SIZE

Product code	Categories	Models	Sizes
AC0100P	Luer Lock	Cuff Pressure Indicator, with Luer Lock, Pink, Paediatric, Tracheal	10-20cmH ₂ O
AC0100B		Cuff Pressure Indicator, with Luer Lock, Blue, Tracheal	20-29cmH ₂ O
AC0100R		Cuff Pressure Indicator, with Luer Lock, Red, Laryngeal	40-60cmH ₂ O

INTENDED USE

It is used for indicating the intracuff pressure for cuffed devices, such as Endotracheal Tubes, Tracheostomy tubes and Endobronchial tubes.

PATIENT GROUPS

Neonates, children, adults.

INTENDED USERS

Professionally trained doctors and clinical nurses.

INDICATIONS

Use to monitor the intracuff pressure of the cuffed intubation devices.

CONTRAINDICATIONS

Size 20-29cmH₂O: Not suitable for use with Laryngeal Mask.

Size 40-60cmH₂O: Not suitable for use with Tracheal Airway.

COMBINATIONS

This device is used in combination with cuffed devices such as Endotracheal tubes, Tracheostomy tubes and Endobronchial tubes;

Size 10-20cmH₂O: For use with paediatric Tracheal(2.5-5.0#)Airway Devices only;

Size 20-29cmH₂O: For use with Tracheal Airway Devices only;

Size 40-60cmH₂O: For use with Laryngeal Mask Devices only.

WARNING/PRECAUTIONS

- a. Sterile product. Sterilized by Ethylene Oxide.
- b. Do not re-sterilize or re-use.
- c. Please immediately contact the doctor if any allergies happen.
- d. Do not use if the package is damaged. After use, the product should be completely scrapped, and put into the disposable product waste designated by the hospital, which will be treated by the hospital in accordance with local laws and regulations.
- e. Syringes, 3-way stopcocks or other luer tip devices should not be left inserted in the Cuff Pressure Indicator or check valve for extended periods of time for the resulting stress could crack the valve housing and the leakage of cuff.

PRE-USE CHECKS:

- a. Do not use this product unless these checks are fully satisfactory.
- b. Check the expiration date. Products exceeding expiration date, packaging damage or packaging containing foreign matter are strictly prohibited to use.
- c. In the unlikely event of pre-use check failure, do not use but return to supplier for inspection.

DIRECTION FOR USE

These directions are general guidelines intended for use by qualified medical personnel. Any instructions, indications and contraindications given are not exhaustive and it is the clinicians' responsibility to ensure the safe, correct use of this product.

- a. It should be operated and used by the professionally trained doctors and clinical nurses.

- b. Select the Cuff Pressure Indicator according to the requirements of intracuff pressure of combinative devices.
- c. Before use, a doctor or nurse should inspect the package for damage, then open the package and take out the Cuff Pressure Indicator. Do not use if the package or product has been damaged.
- d. Connect Cuff Pressure Indicator with combinative devices.
- e. Inflate the cuff with a syringe and observe the Cuff Pressure Indicator. When the black line is located within the green area, the intracuff pressure is safe.
- f. After use, deflate the cuff which means the black line of Cuff Pressure Indicator is located at the white line.

SHELF LIFE

5 years

DURATION

Less than 30 days

STORAGE CONDITIONS




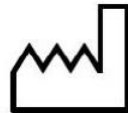



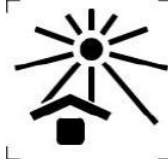








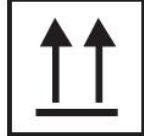

Store product inside containers or outer boxes in a clean, dry area.




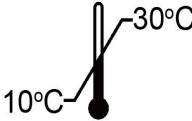



Storage should be within a temperature range of 10–30°C.

Do not expose to direct sunlight or UV light.

Made in China

MEANING OF SYMBOLS ON PACKAGE

	Do not re-use		Manufacturer
	Use-by date		Date of manufacture
	Batch code		Authorized representative in the European Community
	Sterilized using ethylene oxide		Keep away from sunlight
	Do not use if package is damaged		Keep dry
	Consult instructions for use		Catalogue number
	Caution		Doesn't contain DEHP
	CE marking of conformity		Latex free
	This way up		Fragile, Handle with care

	MR Safe		MR unsafe
	MR Conditional		Temperature Limitation
	Medical device		
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