4.4. After use
Used products must be disposed of according to local procedures.

5. Technical product specifications

5.1. Specifications

Dimensions (approx.)	Length 55 mm (2.2") Diameter 22 mm (0.9")
Weight (approx.)	6.9 g
Connector port dimensions	Inner diameter 4.0 mm (0.16") Maximum allowed dilated diameter 4.3 mm (0.17")
Pressure measuring limits	5 – 60 cmH_2O (hPa)
Pressure measuring accuracy	± 2 cmH_2O (hPa) at 5, 10, 15, 20 and 30 cmH_2O (hPa) ± 3 cmH_2O (hPa) at 40 cmH_2O (hPa) ± 5 cmH_2O (hPa) at 60 cmH_2O (hPa)
Operation temperature limits	-18 °C to +50 °C (-0.4 °F to +122 °F) according to EN ISO 10651-4
Storage temperature limits	-40 °C to +60 °C (-40 °F to +140 °F) according to EN ISO 10651-4
Recommended long term storage in closed packaging at room temperature, away from sunlight	

5.2. MRI Safety information

The Ambu Disposable Pressure Manometer is tested to be MR Conditional and therefore may be safely used in the MR environment (not inside the MR bore) under the following conditions.

- Static magnetic field of 7 Tesla and less, with
- Maximum spatial field gradient of 20,000 G/cm (200 T/m)
- Maximum force product of 902,000,000 G^2/cm (902 T^2/m)

Use inside the MR bore may influence MR image quality.

RF-induced heating and MR image artifacts have not been tested. Any metallic parts are fully encapsulated and do not have any contact with the human body.

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INSTRUCTIONS FOR USE

Ambu® Disposable Pressure Manometer

Ambu

1. Important information – Read before use

Read these safety instructions carefully before using the Ambu® Disposable Pressure Manometer. The instructions for use may be updated without further notice. Copies of the current version are available upon request. Please be aware that these instructions do not explain or discuss clinical procedures. They describe only the basic operation and precautions related to the operation of the manometer. Before initial use of the Ambu Disposable Pressure Manometer, it is essential for operators to have received sufficient training in resuscitation techniques and to be familiar with the intended use, warnings, cautions, and indications mentioned in these instructions.

There is no warranty on the Ambu Disposable Pressure Manometer.

1.1. Intended use

The Ambu Disposable Pressure Manometer is intended to be used for monitoring the patient's airway pressure.

1.2. Indications for use

The Ambu Disposable Pressure Manometer is indicated in situations where monitoring of the patient airway pressure during ventilation is needed.

1.3. Intended patient population

Patients of all ages including adults, pediatric and infants requiring monitoring of the airway pressure during ventilation.

1.4. Intended user

Medical professionals trained in airway management such as anesthesiologists, nurses, rescue personnel and emergency personnel.

1.5. Contraindications

None known.

1.6. Clinical benefits

Use of the Ambu Disposable Pressure Manometer together with resuscitators, hyper-inflation bags, CPAP masks or circuits allows for monitoring of the patient's airway pressure.

1.7. Warnings and cautions

WARNINGS ⚠

1. For single patient use only. Use on other patients can cause cross infection.
2. Only to be used by intended users who are familiar with the content of this manual, as incorrect use may harm the patient.
3. Always visually inspect the Ambu Disposable Pressure Manometer and perform a functionality test after unpacking, assembly and prior to use, as defects and foreign matter can lead to wrong pressure readouts.
4. Do not use the product if test for functionality fails as this can lead to incorrect pressure readouts.
5. Do not use the Ambu Disposable Pressure Manometer if contaminated by external sources, as this can cause infection.
6. Do not use the Ambu Disposable Pressure Manometer for more than 4 accumulated hours over a maximum timespan of 1 week, in order to avoid the risk of infection.
7. Do not reuse the Ambu Disposable Pressure Manometer if visible moisture or residues are left inside the device in order to avoid the risk of infection or malfunction.
8. When using supplemental oxygen, do not allow smoking or use of device near open flame, oil, grease, other flammable chemicals or equipment and tools, which cause sparks, due to the risk of fire and/or explosion.

CAUTIONS

1. Do not soak, rinse, disinfect or sterilize this device as these procedures may leave harmful residues or cause malfunction of the device. The design and material used are not compatible with conventional cleaning and sterilization procedures.
2. Please see packaging for more specific information about the expiration date, as the use of an expired device might lead to decreased performance or malfunction of the product.
3. US federal law restricts this device to sale by or on the order of a licensed health care practitioner.

1.8. General notes

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

2. Device description

The Ambu Disposable Pressure Manometer is non-sterile and for single patient, multiple use. It is intended to be used for monitoring the patient's airway pressure in the range from 5 – 60 cmH_2O.

The Ambu Disposable Pressure Manometer is suitable for use with Ambu resuscitators or other resuscitators, hyperinflation bags, CPAP masks or circuits, as described in section 4.2 and 4.3.

3. Explanation of symbols used

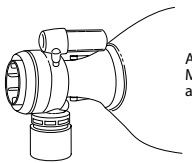
Symbol indication	Description
MR	MR Conditional

A full list of symbol explanations can be found on ambu.com/symbol-explanation.

4. Product use

4.1. Inspection and preparation

1. Visually inspect the Ambu Disposable Pressure Manometer to verify it is intact.
2. Attach the Ambu Disposable Pressure Manometer with its flexible connector port by removing the cap from the manometer port of the breathing device and pressing the two products together to secure the connection.
3. Perform functional testing:
   - Occlude the patient connection port of the attached breathing device while operating it and confirm that the manometer piston moves to its maximum position.
   - Release the pressure and check that the piston returns smoothly back below the "5" cmH_2O reading.



Ambu Disposable Pressure Manometer connected to a resuscitator.

4.2. Operating the Ambu Disposable Pressure Manometer

- Following inspection, attachment and functional testing (section 4.1, step 3) the Ambu Disposable Pressure Manometer is ready for use.
- The patient airway pressure can be read from the position of the black piston ring relative to the value scale on the manometer housing.
- If removing the Ambu Disposable Pressure Manometer during ventilation, remember to replace the cap on the manometer port on the breathing device.

4.3. Compatibility requirements when connecting Ambu Disposable Pressure Manometer to third party breathing devices:

Manometer connector dimensions for fit with third party breathing devices:

- Hole dimension of manometer connector port: diameter Ø 4.0 mm.
- Allowable deformation of the flexible manometer connector port applied by third party breathing device connector: up to Ø 4.3 mm.

Pre-test of compatibility with third party breathing devices:

- Manometer shall not separate from third party breathing device when performing functional testing as described in section 4.1 (step 3).