

INSTRUCTIONS FOR USE

Ambu® Disposable Face Mask

Ambu



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1. Important information – Read before use

Read these safety instructions carefully before using the Ambu® Disposable Face Mask.

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 Ambu Disposable Face Mask.

Before initial use of the Ambu Disposable Face Mask, it is essential for operators to have received sufficient training in using the product and to be familiar with the intended use, warnings, cautions, and indications mentioned in these instructions.

There is no warranty on the Ambu Disposable Face Mask.

1.1. Intended use

The Ambu Disposable Face Mask is a disposable face mask intended for oxygenating and ventilating the airways.

The device is for use in hospital and pre-hospital (EMS) environments.

For use by CPR trained personnel only.

1.1.1. Intended patient population

The Ambu Disposable Face Mask product is intended to be used on patients of all ages and comes in 6 sizes to ensure that the inner shape of the dome is spacious enough for the mouth and nose.

- Ambu Disposable Face Mask, Large Adult
- Ambu Disposable Face Mask, Medium Adult
- Ambu Disposable Face Mask, Small Adult
- Ambu Disposable Face Mask, Toddler
- Ambu Disposable Face Mask, Infant
- Ambu Disposable Face Mask, Neonate

1.1.2. Intended use environment

The Ambu Disposable Face Mask is intended to be used in pre-hospital (EMS) and hospital environments including MR system rooms.

1.2. Indications for use

The Ambu Disposable Face Mask is used for respiratory care and support.

1.3. Intended user

The Ambu Disposable Face Mask is for use by medical professionals, rescue and emergency personnel trained in airway management.

1.4. Contra indications

None known.

1.5. Clinical benefits

The Ambu Disposable Face Mask will allow for passage of air to the patient and visualization through the dome.

1.6. Warnings and cautions



Failure to observe these precautions may result in inefficient ventilation of the patient, cross-infection or damage to the equipment.

WARNINGS

1. For single patient multiple 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 ensure to remove all packaging material from the Ambu Disposable Face Mask prior to use as the pouch could block the patient's airways and prevent ventilation.
4. Always visually inspect the product after unpacking, assembly and prior to use as defects and foreign matter can lead to no or reduced ventilation of the patient.
5. Do not use the product if inspection fails, as this can lead to no or reduced ventilation.
6. Do not use the product if contaminated by external sources, as this can cause infection.
7. Always inspect the proper inflation of the Ambu Disposable Face Mask cushion before use, as poor sealing might lead to insufficient ventilation of the patient.
8. Always ensure correct positioning and sealing of the Ambu Disposable Face Mask, as improper sealing can lead to spreading of airborne infectious disease to the user.

9. Do not use the Ambu Disposable Face Mask for more than 4 accumulated hours over a maximum time span of 1 week, in order to avoid the risk of infection.
10. Do not reuse the Ambu Disposable Face Mask if visible residues are left inside the device in order to avoid the risk of infection or malfunction.
11. Always ensure correct positioning of the Ambu Disposable Face Mask on the patient by performing, with either hand, an appropriate jaw thrust through relevant hand grip strategy, or by head straps connected to the hook rings. Reposition if applicable, as improper sealing of the face mask could lead to insufficient ventilation of the patient.
12. Do not apply excessive force on the face mask when keeping it in position, as it might lead to pressure marks on the patient's face.
13. Always visually inspect the inflation and sealing properties of the disposable face mask cushion while in use on the patient, as improper sealing might lead to leakage and reduced or no ventilation of the patient.
14. When using supplemental oxygen, do not allow smoking or use the device near an open flame, oil, grease, other flammable chemicals or equipment and tools, which cause sparks, due to the risk of fire and/or explosion.
15. Professionals performing the procedure should assess the choice of face mask size and compatible devices (e.g. resuscitator, etc.) in accordance with the patient's specific condition(s), as incorrect use may harm the patient.
16. Do not use the product when ventilating patients with severe facial trauma and/or eye injury due to the risk of improper sealing and aggravation of injury unless a medical assessment indicates the necessity. Switch to an alternative method for directing air to the patient, if available.

CAUTIONS

1. Never store the Ambu Disposable Face Mask in a deformed state, otherwise permanent distortion of the mask could occur, which may reduce the ventilation efficiency.
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. Do not clean the Ambu Disposable Face Mask any other way than described in this IFU. Other procedures may cause deformation or damage to the device.
4. Only use compatible connections or adapters, as forcing non-compatible connections or adapters into the connector of the Ambu Disposable Face Mask could damage the device, rendering it unusable.
5. US Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

1.7. Potential adverse events

Potential adverse events related to use of face masks (not exhaustive): Pressure wounds, hypoxia and aggravation of already existing facial and eye injuries.

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 Face Mask is a non-sterile, non-conductive, single patient multiple use face mask, designed for use with manual and automatic resuscitators and ventilators. The Ambu Disposable Face Mask is available with or without a check valve and with or without a hook ring.

3. Product use

3.1. Inspection and preparation

1. Remove the Ambu Disposable Face Mask from its packaging and inspect for proper inflation of the cushion.
2. Inspect the cushion for any damage or leakage.
3. Remove and discard the four-prong hook ring if not required.
4. If needed, use a syringe to inflate/remove air to achieve the desired cushion pressure (mask with check valve only).

3.2. Operation

1. Apply the mask firmly to the patient's face to achieve a tight seal.
2. Hold the mask tight against the face while securing an open airway through a jaw thrust.
3. If deemed necessary, the surface of the product can be manually cleaned for same patient use with water and a mild detergent. Rinse thoroughly with clean water. Allow to dry, and check that the Ambu Disposable Face mask

is fully operational before reuse on the same patient. If not fully operational, the Ambu Disposable Face Mask shall be discarded.

3.3. After use

Used products must be disposed of according to local procedures.

4. Technical product specifications


4.1. Specifications

Ambu Disposable Face Mask sizes	Neonate, Infant, Toddler, Small/Medium/Large Adult
Connector size	15 mm OD connector for Neonate and Infant according to ISO 5356-1. 22 mm ID connector for Toddler, Small/Medium/Large Adult according to ISO 5356-1.
Check valve	Compatible with Luer slip syringe (Mask with check valve only).
Operation temperature limits	-20 °C to +50 °C (-4 °F to +122 °F) according to EN 1789 and ISO 10651-4.
Storage temperature limits	-40 °C to +70 °C (-40 °F to +158 °F) according to EN 1789 and ISO 10651-4.
Recommended long term storage in closed packaging at room temperature, away from sunlight.	

4.2. MRI Safety information

The Ambu Disposable Face Mask is MR Safe.

5. Explanation of symbols used

Symbol indication	Description
	MR Safe

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

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Ambu A/S
Baltorpbakken 13
2750 Ballerup
Denmark
T +45 72 25 20 00
ambu.com

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