

Ambu



Ambu A/S

Baltorpbakken 13
2750 Ballerup
Denmark
T +45 72 25 20 00
ambu.com

Ambu® is a registered trademark of Ambu A/S, Denmark
Ambu A/S is certified according to ISO 13485

INSTRUCTIONS FOR USE

Ambu® King Mask

Disposable anesthesia face mask

Ambu



1. Important information – Read before use

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

en

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 King Mask.

Before initial use of the Ambu King 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 King Mask.

1.1. Intended use

Ambu King Masks are intended to direct anesthesia or medical gases into the patient's upper airway without introducing any apparatus into the trachea.

1.2. Indications for use

The Ambu King Mask is used for respiratory care and support, and also intended for use during procedures where anesthetic and medical gases are being supplied.

1.3. Intended patient population

The Ambu King Mask is intended to be used on patients of all ages and comes in 7 sizes to ensure that the inner shape of the dome is spacious enough for the mouth and nose.

- Ambu King Mask #1
- Ambu King Mask #2
- Ambu King Mask #3
- Ambu King Mask #4
- Ambu King Mask #5
- Ambu King Mask #6
- Ambu King Mask #7RD

1.4. Intended user

The Ambu King Mask is for use by medical professionals trained in airway management, such as anesthesiologists, nurses, rescue personnel and emergency personnel.

1.5. Intended use environment

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

1.6. Contra indications

Do not use the scented masks on patients, nor as a user, with known allergies to perfumes as this may cause allergic reactions.

1.7. Clinical benefits

The Ambu King Mask will allow the passage of medical and anesthetic gases to the patient while allowing visualization of the patient mouth and nose through the dome.

1.8. 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. 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.
4. Always ensure to remove all packaging material from the Ambu King Mask prior to use as the pouch could block the patient's airway and prevent ventilation.
5. Always visually inspect the product after unpacking and prior to use as defects and foreign matter can lead to no or reduced ventilation of the patient or reduced delivery of anesthetic and/or medical gases.
6. Do not use the product if inspection fails, as this can lead to no or reduced ventilation or reduced delivery of anesthetic and/or medical gases.
7. Always ensure correct positioning of the 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 or reduced delivery of anesthetic and/or medical gases.
8. Always inspect the proper inflation of the Ambu King Mask cushion before use, as poor sealing might lead to insufficient ventilation of the patient or reduced delivery of anesthetic and/or medical gases.
9. Always visually inspect the inflation and sealing properties of the face mask cushion while in use on the patient, as improper sealing might lead to leakage and reduced or no ventilation of the patient or reduced delivery of anesthetic and/or medical gases.
10. Always ensure correct positioning and sealing of the Ambu King Mask, as improper sealing can lead to spreading of airborne infectious diseases to the user.
11. Do not apply excessive force on the Ambu King Mask when keeping it in position, as it might lead to pressure marks on the patient's face.
12. Do not use the Ambu King Mask for more than 4 accumulated hours over a maximum time span of 1 week, in order to avoid the risk of infection.
13. Do not reuse the Ambu King Mask if visible residues are left inside the device in order to avoid the risk of infection or malfunction.
14. When using supplemental oxygen, do not allow smoking or use of 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. 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. Only use compatible connections or adapters, as forcing non-compatible connections or adapters into the connector of the Ambu King Mask could damage the device, rendering it unusable.
2. Never store the Ambu King Mask in a deformed state, otherwise permanent distortion of the mask could occur, which may reduce the ventilation efficiency or delivery of anesthetic and/or medical gases.
3. 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.
4. Do not clean the Ambu King Mask any other way than described in this IFU. Other procedures may cause deformation or damage to the device.
5. US federal law restricts this device to sale by or on the order of a licensed health care practitioner.

1.9. Potential adverse events

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

1.10. 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 King Mask is a non-sterile, non-conductive, single patient multiple use face mask designed to be handled with either hand. It functions as a means to connect the breathing equipment or anesthetic circuit to the patient's upper airway and allows for direction of anesthetic or medical gases to the patient.

The Ambu King Mask is available in 7 sizes (#1, #2, #3, #4, #5, #6, #7RD). The mask cushion and cushion base is colored according to whether it is unscented (blue), fresh scented (green), bubble gum scented (purple), strawberry scented (pink) or cherry scented (red). The mask includes a check valve to either add or remove air in the cushion.

3. Explanation of symbols used

Symbol indications	Description	Symbol indications	Description
	Single Patient Multiple Use		MR Safe

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

4. Product use

4.1. Inspection and preparation

1. Remove the Ambu King Mask from its packaging and inspect the device. In case of damage, dirt or deformation discard the mask.
2. Check the cushion's inflation for appropriate fit and seal to the patient's face.
3. The hook ring, if present, may be removed if not needed.
4. To adjust the cushion inflation, use a syringe into the check valve to inflate/remove air to achieve the desired cushion pressure.

4.2. Operation

1. Connect the mask to the breathing equipment or anesthetic circuit by pressing the conical connectors together.
2. Apply the mask firmly to the patient's face to achieve a tight seal.
3. Hold the mask tightly against the patients face while securing an open airway through a CE grip or alike.
4. If deemed necessary, the surface of the product can be manually cleaned with water and a mild detergent. Rinse thoroughly with clean water. Allow to dry and check that the Ambu King Mask is fully operational before reuse on the same patient. If not fully operational, the mask shall be discarded.

4.3. After use

Used products must be disposed of according to local procedures.

5. Technical product specifications

5.1. Specifications

Ambu King Mask sizes	#1, #2, #3, #4, #5, #6, #7RD.
Connector size	15 mm OD connector for #1 and #2 according to EN ISO 5356-1. 22 mm ID connector for #3, #4, #5, #6 and #7RD according to EN ISO 5356-1.
Check valve	Compatible with Luer slip syringe.
Operation temperature limits	-20 °C to +50 °C (-4 °F to +122 °F) according to EN 1789.
Storage temperature limits	-40 °C to +70 °C (-40 °F to +158 °F) according to EN 1789 and EN ISO 10651-4.
Recommended long term storage in closed packaging at room temperature, away from sunlight.	

5.2. MRI Safety information

The Ambu King Mask is MR Safe.