

# INSTRUCTIONS FOR USE

Ambu® Disposable PEEP 20  
Valve for single patient use

Ambu



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## **1. Important information – Read before use**

Read these safety instructions carefully before using the Ambu® Disposable PEEP (Positive End Expiratory Pressure) 20 Valve. 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 PEEP 20 Valve. Before initial use of the Ambu Disposable PEEP 20 Valve, it is essential for operators to have received sufficient training and be familiar with the intended use, warnings, cautions and indications mentioned in these instructions. There is no warranty on the Ambu Disposable PEEP 20 Valve.

### **1.1. Intended use**

The Ambu Disposable PEEP 20 Valve is suitable for use with resuscitators, portable ventilators, and CPAP systems which have airtight connections and can operate with a positive pressure in the patient connector throughout the entire expiratory phase.

#### **1.1.1. Intended patient population**

The Ambu Disposable PEEP 20 Valve is to be used on all age groups from premature infants to elderly.

#### **1.1.2. Intended use environment**

The Ambu Disposable PEEP 20 Valve is intended to be used in several use environments where the need for PEEP might arise. This includes both pre-hospital and hospital environments including MR system rooms (except inside the MR bore during ongoing MRI procedure).

### **1.2. Indications for use**

Use of the Ambu Disposable PEEP 20 Valve is indicated when achievement of a pressure above ambient in the patient's lungs is needed in order to improve oxygenation of the blood, and to treat different respiratory diseases and symptoms.

### **1.3. Intended user**

Medical professionals trained in airway management and use of the PEEP valve function such as anesthesiologists, nurses, rescue personnel and emergency personnel.

## 1.4. Contra indications

None known.

## 1.5. Clinical benefits

Improved oxygenation by means of alveolar stabilization, compliance, increased surface area for gas exchange and residual lung capacity.

## 1.6. Warnings and cautions

Failure to observe these precautions may result in inefficient PEEP and oxygenation of the patient or damage to the equipment.

### WARNINGS

1. Do not use the Ambu Disposable PEEP 20 Valve for more than 72 accumulated hours over a maximum time span of 1 week in order to avoid the risk of infection.
2. Always visually inspect the product after unpacking, assembly and prior to use as defects and foreign matter can lead to no or reduced PEEP during ventilation of the patient.
3. For single patient use only. Use on other patients can cause cross infection.
4. Only to be used by intended users who are familiar with the content of this manual, as incorrect use might harm the patient.
5. Do not reuse the Ambu Disposable PEEP 20 Valve if visible moisture or residues are left inside the device in order to avoid the risk of infection and malfunction.
6. Do not use the product if contaminated by external sources as this can cause infection.
7. Always use the Ambu Disposable PEEP 20 Valve with a manometer as the manometer ensures correct adjustment of PEEP during ventilation. Too high or low PEEP during ventilation may cause barotrauma and hypoxia, respectively.
8. Do not use the product in patients with unilateral (one-sided) lung disease, bronchopleural fistulae or similar conditions unless a medical assessment indicates the necessity, as this can lead to hyperinflation of the lung tissue reducing healing of injured site.

9. Do not use the product in patients with obstructive lung disease, unless a medical assessment indicates the necessity, as increased airway pressure can increase airway irritation and inflammatory response.
10. Do not use the product in patients with a medical condition causing elevated peak and mean airway pressures, unless a medical assessment indicates the necessity, as increased PEEP can lead to barotrauma.
11. Do not use the product in patients suffering from conditions such as cardiogenic shock, myocardial infarction, left heart failure, hypovolaemia or a combination of these conditions resulting in haemodynamic instability unless a medical assessment indicates the necessity, as high PEEP can lead to reduced cardiac output and systemic perfusion.
12. Do not use a product with decreased performance unless a medical assessment indicates the necessity as decreased performance can lead to hypoxia.
13. 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

- 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.
- Do not soak, rinse, chemical disinfect or steam sterilize the device as these procedures may leave harmful residues or cause malfunction of the device.
- Be careful not to unscrew the adjustment cap as it can detach. If this happens the cap can be reattached again.
- 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 the use of the Ambu Disposable PEEP 20 Valve (not exhaustive): Hypoxia, barotrauma including pneumothorax, volutrauma, reduced cardiac output and systemic perfusion.

## 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 PEEP 20 Valve is a positive end-expiratory pressure valve with an Ø 30 mm connector and is compatible with breathing equipment conforming with EN ISO 5356-1. The Ambu Disposable PEEP 20 Valve is for single patient use. The product can be supplied with an adaptor for Ø 22 mm connectors.

## 3. Product use

### 3.1. Operating the PEEP valve

#### Operating instruction

1. Inspect the Ambu Disposable PEEP 20 Valve to make sure it is free of obstructions.
2. Firmly attach the inlet connector of the Ambu Disposable PEEP 20 Valve to the resuscitator, portable ventilator, or CPAP system in accordance with the Manufacturer's Instructions for Use.
3. Rotate the adjustment cap to the desired PEEP setting from 1.5 – 20 cmH<sub>2</sub>O (0.15 – 2.0 kPa).
4. For correct adjustment of the PEEP, a pressure gauge should be connected to the breathing device for monitoring of the PEEP.
5. Used products must be disposed of according to local procedures.

## 4. Technical product specifications

### 4.1. Specifications

Connector size	ID 30 mm (EN ISO 5356-1).
Adapter size	OD 22 mm and OD 30 mm (EN ISO 5356-1).

Adjustment range	1.5 – 20 cmH <sub>2</sub> O (0.15 – 2.0 kPa).
Dimensions	Length 65 – 76 mm (depending on adjustment), diameter 45 mm.
Weight	approx. 35 g.
Operating temperature limits	-18 °C to +50 °C (-0.4 °F to +122 °F), tested according to EN ISO 10651-4.
Storage temperature limits	-40 °C to +60 °C (-40 °F to +140 °F), tested according to EN ISO 10651-4.
Recommended long term storage in closed packaging at room temperature, away from sunlight.	

## 4.2. MRI Safety information

The Ambu Disposable PEEP 20 Valve 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 16,000 G/cm (160 T/m)
- Maximum force product of 721,000,000 G<sup>2</sup>/cm (721 T<sup>2</sup>/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.

## 5. Explanation of symbols used

Symbol indication	Description
	MR Conditional
	Single Patient Multiple Use

A full list of symbol explanations can be found on [ambu.com/symbol-explanation](http://ambu.com/symbol-explanation).

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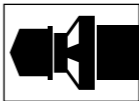
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