Instructions for use

# Ambu® **SPUR® II**

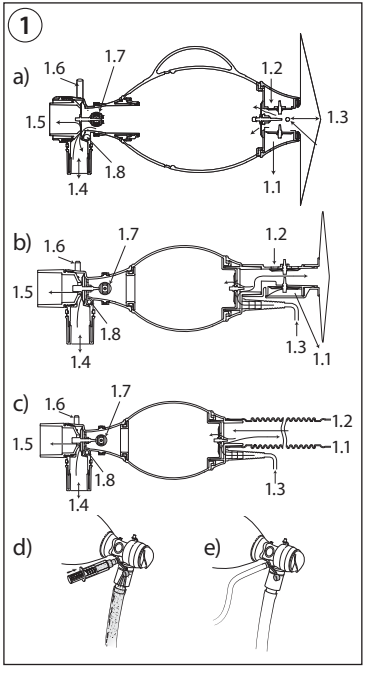
| Symbol Indication |   |   |   |   |   |
|---|---|---|---|---|---|
| **EN** | Adult | Pediatric | Infant | This product is not made with natural rubber latex nor phthalates | Magnetic Resonance Conditional. Static magnetic field of 3-Tesla or less. Spatial gradient magnetic field of 720-Gauss/cm or less. |
| **BG** | За възрастни пациенти | За педиатрични пациенти | За бебета | Този продукт не е произведен с естествен каучуков латекс или фталати | Безопасно за ядрено-магнитен резонанс при определени условия. Статично магнитно поле от 3 тесла или по-малко. Пространствен градиент на магнитното поле от 720 гаус/см или по-малко. |
| **CS** | Dospělí | Děti | Kojenec | Tento výrobek není vyroben z přírodního latexu nebo ftalátů. | Podmíněně použitelné při magnetické rezonanci Statické magnetické pole 3 Tesla nebo méně. Prostorový gradient magnetického pole 720 Gauss/cm nebo méně. |
| **DA** | Voksne | Børn | Spædbarn | Dette produkt er hverken fremstillet med naturgummilatex eller ftalater | Betinget egnet til magnetisk resonans. Et statisk magnetfelt på 3 tesla eller derunder. Rumligt magnetisk gradientfelt på 720 Gauss/cm eller derunder. |
| **DE** | Erwachsene | Kinder | Säuglinge | Dieses Produkt enthält weder natürliches Gummilatex noch Phthalate | Bedingt MR-sicher Statisches Magnetfeld: 3 Tesla oder weniger. Räumlicher Gradient: 720-Gauss/cm oder weniger. |
| **EL** | Ενήλικες | Παιδιατρική | Βρέφη | Αυτό το προϊόν δεν έχει κατασκευαστεί με φυσικό ελαστικό λάτεξ ή φθαλικές ενώσεις | Συνθήκη μαγνητικής τομογραφίας. Στατικό μαγνητικό πεδίο 3-Tesla ή λιγότερο ισχυρό. Χωρική διαβάθμιση μαγνητικού πεδίου 720-Gauss/cm ή χαμηλότερη. |
| **ES** | Adultos | Niños | Bebés | Este producto no está fabricado con látex ni ftalatos | Compatible con resonancia magnética. Campo magnético estático de 3 teslas o menos. Campo magnético de gradiente espacial de 720 gauss/cm o menos. |
| **ET** | Täiskasvanute versioon | Pediaatriline versioon | Imikute versioon | Toode on valmistatud ilma loodusliku kummilateksi ja ftalaatideta | MRT tingimustele vastav. Staatiline magnetväli 3 teslat või vähem. Ruumiline gradientne magnetväli 720 Gs/cm või vähem. |
| **FI** | Aikuinen | Lapsi | Vauva | Tämä tuote ei sisällä luonnonkumilateksia eikä ftalaatteja | Ehdollisesti MK-turvallinen. Staattinen magneettikenttä enintään 3 teslaa. Tilagradienttimagneettikenttä enintään 720 gaussia/cm. |
| **FR** | Adulte | Enfant | Nourrisson | Ce produit n'a été fabriqué ni avec du latex de caoutchouc naturel ni avec des phtalates | Compatible avec l'imagerie par résonance magnétique. Champ magnétique statique de 3 Tesla ou moins. Champ magnétique à gradient spatial de 720 Gauss/cm ou moins. |
| **HR** | Za odrasle | Za pedijatrijsku primjenu | Za dojenčad | Ovaj proizvod nije napravljen s lateksom od prirodne gume niti ftalatima | Uvjeti za magnetsku rezonancu. Statično magnetsko polje jačine 3 tesla ili manje. Prostorni gradijent magnetskog polja od 720 gausa/cm ili manje. |
| **HU** | Felnőtt | Gyermek | Csecsemő | Ez a termék nem természetes latexgumiból, nem ftalátokból készült | MR-környezet. A statikus mágneses sugárzás legfeljebb 3 tesla lehet. A mágneses tér gradiense legfeljebb 720 gauss/cm lehet. |
| **IT** | Adulti | Pazienti pediatrici | Neonati | Il prodotto non è realizzato con lattice di gomma naturale né con ftalati | Compatibilità condizionata con la risonanza magnetica. Campo magnetico statico pari a 3 Tesla o inferiore. Gradiente spaziale del campo magnetico pari a 720 Gauss/cm o inferiore. |
| | | | | | |

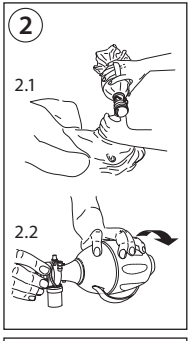
| Symbol Indication |  |  |  |  |  |
|---|---|---|---|---|---|
| **JA** | 成人 | 子供 | 幼児 | 本製品に天然ゴムラテックスあるいはフタル酸エステルは使用されていない | 磁気共鳴条件 3テスタ以下の静磁界。720 ガウス/cm以下の空間傾斜磁場。 |
| **LT** | Suaugusiųjų | Vaikų | Kūdikių | Gaminio sudėtyje nėra nei natūralaus latekso, nei ftalatų | Magnetinio rezonanso sąlygos. Statinis magnetinis laukas – iki 3 tesla vienetų. Magnetinio lauko erdvinis gradientas – iki 720 gausų/cm. |
| **LV** | Pieaugušajiem | Bērniem | Zīdaiņiem | Šis izstrādājums nav veidots no dabīgās gumijas lateksa un ftalātiem | Magnētiskās rezonanses nosacījumi. Statiskais magnētiskais lauks 3 teslas vai mazāks. Telpiskais magnētiskā lauka gradients 720 gausi/cm vai mazāks. |
| **NL** | Volwassene | Kind | Peuter | Dit product is niet vervaardigd met natuurlijke rubberlatex of ftalaten | Voorwaarde magnetische resonantie. Statisch magnetisch veld van 3 tesla of minder. Spatieel magnetisch gradiëntveld van 720 Gauss/cm of minder. |
| **NO** | Voksen | Barn | Spedbarn | Dette produktet er ikke fremstilt av naturlig gummilateks eller ftalater | Magnetisk resonansbetingelse. Statisk magnetfelt på 3 Tesla eller lavere. Magnetfelt med høyeste romgradient på 720 Gauss/cm eller lavere. |
| **PL** | Wersja dla dorosłych | Wersja pediatryczna | Wersja dla niemowląt | Ten produkt nie został wykonany z lateksu z kauczuku naturalnego ani z ftalanów | Warunkowo dopuszczone do stosowania w środowisku rezonansu magnetycznego. Statyczne pole magnetyczne o natężeniu 3 tesli lub mniejszym. Gradient przestrzenny pola magnetycznego równy 720 Gs/cm lub mniej. |
| **PT** | Adulto | Crianças | Infantil | Este produto não é fabricado com borracha de látex natural nem ftalatos | Condicional para Ressonância Magnética. Campo magnético estático igual ou inferior a 3 Tesla. Campo magnético de gradiente espacial igual ou inferior a 720-Gauss/cm. |
| **RO** | Adulți | Copii | Sugari | Acest produs nu este fabricat din latex din cauciuc natural sau din flatați | Condiționat de rezonanța magnetică. Câmp magnetic static de 3 tesla sau mai puțin. Câmp magnetic cu gradient spațial de 720 gauși/cm sau mai puțin. |
| **RU** | Взрослые | Дети | Младенцы | В производстве данного продукта не используются фталаты и латекс из природного каучука | МР-совместимый. Статическое магнитное поле 3 тесла или менее. Пространственный градиент магнитного поля 720 гаусс/см или менее. |
| **SK** | Verzia pre dospelých | Pediatrická verzia | Verzia pre dojčatá | Tento výrobok nie je vyrobený z prírodného gumeného latexu ani ftalátov | Podmienečne bezpečné v prostredí magnetickej rezonancie. Statické magnetické pole s intenzitou max. 3 Tesla. Priestorový gradient magnetického poľa max. 720 Gaussov/cm. |
| **SL** | Za odrasle | Za otroke | Za dojenčke | Ta izdelek ni narejen iz lateksa naravnega kavčuka ali ftalatov | Pogojna uporaba pri magnetni resonanci. Statično magnetno polje z gostoto največ 3 T. Prostorski gradient magnetnega polja 720 G/cm ali manj. |
| **SV** | Vuxna | Barn | Spädbarn | Produkten innehåller inte naturgummilatex eller ftalater | MR-villkorlig. Statiskt magnetfält på högst 3 tesla. Spatialt magnetgradientfält på 720 gauss/cm eller lägre. |
| **TR** | Yetişkin | Pediyatrik | Bebek | Bu ürün doğal kauçuk lateks veya ftalat kullanılarak imal edilmemiştir | Manyetik Rezonans Durumu. 3-Tesla veya daha düşük statik manyetik alan. 720-Gauss/cm veya daha düşük boyutsal gradyan manyetik alan. |
| **ZH** | 成人 | 小童 | 嬰儿 | 本产品不含天然乳胶和邻苯二甲酸盐 | 磁共振条件。不超过 3 特拉斯的静磁场。不超过 720 高斯/厘米的空间梯度磁场。 |

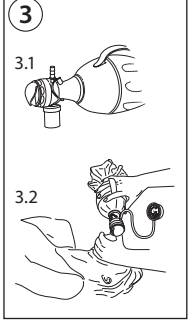
CE 0086

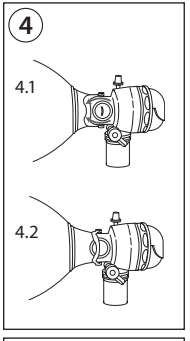
CE mark. The product complies with the EU Council directive concerning Medical Devices 93/42/EEC

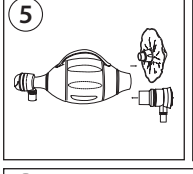

Ambu is certified according to ISO 13485.

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6.1

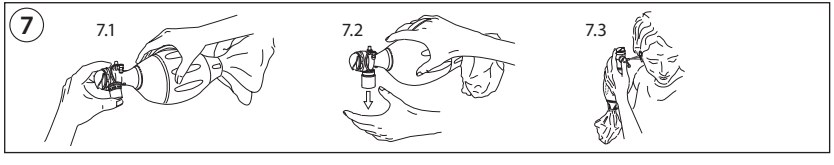
| $O_2$ (l/min) | VT (ml) x f (pr. min.), I:E ratio = 1:2 | | | |
|---|---|---|---|---|
| | 250 x 12 | 600 x 12 | 750 x 12 | 1000 x 12 |
| 2 | 74 | 43 | 38 | 34 |
| 5 | 100 | 76 | 65 | 54 |
| 10 | 100 | 100 | 100 | 87 |
| 15 | 100 | 100 | 100 | 100 |

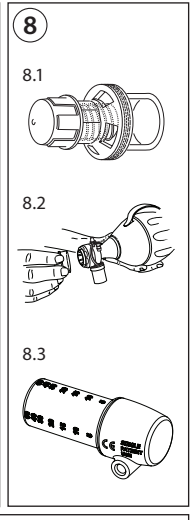
6.2

| $O_2$ (l/min) | VT (ml) x f (pr. min.), I:E ratio = 1:2 | | | |
|---|---|---|---|---|
| | 40 x 40 | 100 x 20 | 200 x 20 | 400 x 15 |
| 1 | 70 | 60 | 40 | 34 |
| 2 | 100 | 100 | 60 | 47 |
| 4 | 100 | 100 | 100 | 73 |
| 6 | 100 | 100 | 100 | 100 |

6.3

| $O_2$ (l/min) | VT (ml) x f (pr. min.), I:E ratio = 1:1 | | | | | |
|---|---|---|---|---|---|---|
| | 40 x 40 | | 100 x 20 | | 150 x 20 | |
| | Reservoir Bag | 10" Tube | Reservoir Bag | 10" Tube | Reservoir Bag | 10" Tube |
| 1 | 70 | 70 | 60 | 60 | 47 | 47 |
| 2 | 100 | 100 | 100 | 100 | 73 | 73 |
| 4 | 100 | 100 | 100 | 100 | 100 | 100 |
| 6 | 100 | 100 | 100 | 100 | 100 | 100 |



## 1. Intended use

The Ambu® SPUR® II resuscitator is a single patient use resuscitator intended for pulmonary resuscitation.
The range of application for each version is:
- Adult: Adults and children with a body weight more than 30 kg (66 lbs).
- Paediatric: Infants and Children with a body weights up to 30 kg (66 lbs).
- Infant: Neonates and infant with a body weight up to 10kg (22 lbs).

## 2. Warning and caution statements

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

**WARNING** ⚠

Oil or grease should not be used in close proximity to oxygen equipment. Do not smoke or use open flame when oxygen is in use – fire may result.
Never override the pressure-limiting valve (if available) unless medical and professional assessment indicates the necessity. High ventilation pressures may cause lung rupture to certain patients. If the pressure-limiting valve is overridden in patients with a bodyweight less than 10 kg (22 lbs.), a manometer must be used to monitor the ventilation pressure to avoid the possibility of a lung rupture.
By adding accessories, it may increase inspiratory and/or expiratory resistance. Do not attach accessories if increased breathing resistance would be detrimental for the patient.

**CAUTION** ⚠

US federal law restricts this device to sale by or on the order of a physician (USA and Canada only)
For use by trained personnel only. The proper application of a facemask to obtain tight seal should be trained in particular. Make sure that the personnel are made familiar with the content of this manual.
Always inspect the resuscitator and perform a functional test after unpacking, cleaning, assembly and prior to use.
Always watch the movement of the chest and listen for the expiratory flow from the valve in order to check the ventilation efficiency. Switch immediately to mouth-to-mouth ventilation if efficient ventilation cannot be obtained.
Insufficient, reduced, or no airflow may result in brain damage to the patient being ventilated.
Do not use the resuscitator in toxic or hazardous atmosphere.
For single patient use only. Use on other patients can cause cross infection. Do not soak, rinse, 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.
Never store the resuscitator in a deformed state other than as folded when delivered by the manufacturer, otherwise permanent distortion of the bag will occur which may reduce the ventilation efficiency. The folding zone is clearly visible on the bag (only Adult and Paediatric versions may be folded).

## 3. Specifications

The Ambu SPUR II resuscitator is in conformity with the product specific standard EN ISO 10651-4. The Ambu SPUR II is in conformity with Council Directive 93/42/EEC concerning Medical Devices.

| | Infant | Paediatric | Adult |
|---|---|---|---|
| Stroke volume one hand | 150 ml | 450 ml | 600 ml |
| Stroke volume two hands | | | 1000 ml |
| Dimensions (length x diameter) | 168 x 71 mm | 234 x 99 mm | 295 x 127 mm |
| Weight, incl. Reservoir and mask: | 140 g | 215 g | 314 g |
| Pressure-limiting valve* | 4.0 kPa (40 cm $H_2O$) | 4.0 kPa (40 cm $H_2O$) | 4.0 kPa (40 cm $H_2O$) |
| Dead space | < 6 ml | < 6 ml | < 6 ml |
| Inspiratory resistance*** | max. 0.10 kPa (1.0 cm $H_2O$) at 50 l/min | max. 0.50 kPa (5.0 cm $H_2O$) at 50 l/min | max. 0.50 kPa (5.0 cm $H_2O$) at 50 l/min |
| Expiratory resistance | 0.2 kPa (2.0 cm $H_2O$) at 50 l/min | 0.27 kPa (2.7 cm $H_2O$) at 50 l/min | 0.27 kPa (2.7 cm $H_2O$) at 50 l/min |
| Reservoir volume | 300 ml (bag) 100 ml (tube) | 2600 ml** | 2600 ml** |
| Patient connector | Outside 22 mm male (ISO 5356-1) Inside 15 mm female (ISO 5356-1) | | |
| Expiration connector (for PEEP valve attachment) | 30 mm male (ISO 5356-1) | | |
| Manometer Port connector | Ø 4,2 +/- 0,1 mm | | |
| Demand Valve Connector | Inside 32 mm female (ISO 10651-4) | | |
| Forward and backward leakage | Not measurable | | |
| M-Port | Standard Luer LS 6 | | |
| $O_2$ inlet connector | according to EN 13544-2 | | |
| Operation temperature | -18°C to +50°C | | |
| Storage temperature | Tested at -40°C and +60°C according to EN ISO 10651-4 | | |
| Long term storage | For long term storage the resuscitator should be kept in closed packaging in a cool place away from sunlight. | | |

* Higher delivery pressure can be obtained by overriding the pressure-limiting valve.
** Also available with pressure limiting valve and manometer port.
*** The SPUR II can be delivered with inspiratory or expiratory filters by Ambu that have been tested to perform within the requirements of the ISO standard. The use of PEEP valves naturally increases the expiratory resistance above the limit in the ISO standard.

## 4. Principle in operation ①

The illustration (1) shows the ventilation gas flow mixtures into the bag and to and from the patient during manual operation of the resuscitator. (a) Adult and paediatric resuscitator, (b) infant resuscitator with closed reservoir, (c) infant resuscitator with open reservoir. The gas flow is similar when the patient is breathing spontaneously through the device. The $O_2$ reservoir assembly is fitted with two valves, one allowing ambient air to be drawn in when the reservoir is empty and one spilling out surplus oxygen when the reservoir bag is full.
1.1 Excess oxygen, 1.2 Air, 1.3 Oxygen inlet, 1.4 Patient, 1.5 Expiration, 1.6 Manometer port, 1.7 Pressure limiting valve, 1.8 M-Port
The M-Port provides access to the inspiratory and expiratory gas flow allowing to connect a syringe for drug delivery (d) or to connect a gas sampling line for measuring sidestream $EtCO_2$ (e).

## 5. Instructions for use

### 5.1 Resuscitator ②

**CAUTION** ⚠

The $O_2$ reservoir bag on the Adult and Paediatric resuscitators are permanently attached to the inlet valve assembly. Do not attempt to disassemble. Do not pull as tearing may occur. For the infant resuscitator, do not attempt to disassemble the reservoir bag attachment by pulling the bag as tearing may occur.

### Preperation

- If the resuscitator is packed in a compressed state, unfold by pulling on the patient valve and the inlet valve.
- If the facemask supplied with the resuscitator is wrapped in a protective pouch, the pouch should be remove before use.
- Fit the facemask and place all items in the plastic bag supplied with the resuscitator.
- The integrity of the kits issued for storage ready for use should be inspected at the interval established in the local protocol.
- Before use on the patient make a brief functional test as described in section 7.

### Patient use

- Clear the patient's mouth and airway using recommended techniques. Use recommended techniques to position the patient correctly to open the airway and to hold the mask firmly against the face. (2.1)
- Slide you hand (Adult Version) or ring and middle finger (Paediatric version) under the support strap. The infant version does not have a support strap. Ventilation without using the support strap can be achieved by turning the bag. (2.2)
- Ventilate the patient. During insufflation observe the rise of the patient's chest. Release the bag abruptly and listen for the expiratory flow from the patient valve and observe lowering of the chest.
- If continued resistance to insufflation is encountered, check the airway for obstruction or correct the backward tilt of the head.
- If the patient vomits during mask ventilation, immediately clear the patient's airway and then freely compress the bag a few times before resuming ventilation. If necessary wipe off the product with a swab containing alcohol and clean the splash guard with tap water.

### 5.2 Manometer port ③

**WARNING** ⚠
Use only for monitoring pressure. The cap must always be put on the connector when pressure is not being monitored.

A pressure gauge can be connected to the manometer port on the top of the patient valve. (This only applies to the version with manometer port).
Remove the cap (3.1) and connect pressure manometer or the tube for the pressure gauge (3.2).

### 5.3 Pressure limitation system ④

**WARNING** ⚠
Never override the pressure-limiting valve (if available) unless medical and professional assessment indicates the necessity. High ventilation pressures may cause lung rupture to certain patients. If the pressure-limiting valve is overridden in patients with a bodyweight less than 10 kg (22 lbs.), a manometer must be used to monitor the ventilation pressure to avoid the possibility of a lung rupture.

If the resuscitator is equipped with a pressure limiting valve, the valve is set to open at 40 cm $H_2O$ (4.0kPa) (4.1).
If medical and professional assessment indicates a pressure above 40 cm $H_2O$ is required pressure limiting valve can be overwritten by pressing the override clip onto the valve (4.2). Alternatively the pressure limiting valve can be overwritten by placing the index finger on the red button while squeezing the bag.

### 5.4 M-Port

The SPUR II comes either with or without M-Port.

**WARNING** ⚠

Use the M-Port only for one of the two; $EtCO_2$ measuring or drug administration, as one can negatively impact the other.
The M-Port should not be used for side-stream $EtCO_2$ monitoring of patients, ventilated with less than 400 ml Tidal Volume.
When the M-port is not in use for either drug administration or connected to an $EtCO_2$- measuring device the M-port must be closed by the cap to avoid excessive leakage from the patient housing.
Do not attach oxygen supply tubing to the M-port.
To ensure proper delivery of the entire dosage, the M-port must be flushed after each use.
If application of M-Port is required, do not use filter, $CO_2$ detector or any other accessories between the patient inspiratory port and the mask or ET tube unless you use the optional adapter with syringe port to bypass filter/$CO_2$ detector/accessories to deliver medication.

#### Measuring $EtCO_2$

For measuring of side stream $EtCO_2$; connect the gas-sampling line for the $EtCO_2$ measuring device to the M-Port of SPUR II. Lock the gas sampling line connector by turning it 1/4 turn clockwise.

#### Applying medication

Carefully observe patient response to the administered medication.
Administration of volumes of 1 ml fluid or above through the M-Port is comparable with administration directly into an endotracheal tube.
The M-Port has been tested with epinephrine, lidocaine and atropine.

**CAUTION** ⚠

An increase in the variation of the dosage of medication actually delivered must be expected when administering volumes below 1 ml fluid and without subsequent flushing with appropriate fluid.
Consult your medical director for proper dosing guidelines.
Change to injection directly in the tube if unusually high flow resistance is felt through the M-Port.

#### Syringe with Luer cone

Remove the M-Port cap. Mount the syringe in the M-Port and lock it by turning it ¼ turn clockwise. Inject drug into the M-Port. Ventilate 5-10 times quickly in succession. Remove the empty syringe, and replace the M-Port cap.

#### Syringe with needle

Insert the needle into the middle of the M-Port cap. Inject drug into the M-Port. Ventilate 5-10 times quickly in succession. Remove the empty syringe.

### 5.5 Demand valve connector ⑤

The Adult and Paediatric resuscitator are available as demand valve versions equipped with an inlet valve that connects to a demand valve. In order to attach the demand valve pull the oxygen reservoir out of the inlet valve. The demand valve can afterwards be inserted into the inlet valve.

## 6. Oxygen administration

Administer oxygen according to medical indication.
Examples of $O_2$ percentages which can be obtained with different volumes and frequencies have been calculated. The $O_2$ percentages can be seen in ⑥ Adult (6.1), Pediatric (6.2), Infant (6.3).
VT: Ventilation volume, f: Frequency

Note: If high ventilation pressures are used, higher $O_2$ flow settings are needed because part of the stroke volume is vented from the pressure-limiting valve.
For infant version, use of supplementary oxygen without reservoir attached will limit the oxygen concentration to 60-80% at 15 liters of $O_2$/min.

## 7. Test of function ⑦

### Resuscitator

Close the pressure-limiting valve with the overwrite cap (This only applies to the version with pressure limiting valve) and close the patient connector with the thumb (7.1). Briskly squeeze the bag. The resuscitator shall offer resistance to the squeeze.

Open the pressure-limiting valve by opening the override cap or by removing the finger and repeating the procedure. The pressure limiting valve should now be activated and it should be possible to hear the expiratory flow from the valve.

Squeeze and release the resuscitator a few times to ensure that air is moving through the valve system and out of the patient valve. (7.2)

Note: As the valve plates are moving during functional test or during ventilation a slight sound may appear. This does not compromise the functionality of the resuscitator.

### Oxygen reservoir bag

Supply a gas flow of 5 l/min to the oxygen bag. Check that the reservoir fills.
If not, check the integrity of the two valve shutters or for a torn reservoir.

### Oxygen reservoir tube

Supply a gas flow of 10 l/min to the oxygen tube. Check that the oxygen flows out at the end of the reservoir tube. If not, check for a blocked oxygen tube.

### M-Port

Remove the M-Port cap and block the patient connector. Squeeze the bag and listen for the sound of air being pressed out through the M-Port. (7.3)

## 8. Accessories ⑧

### Ambu disposable PEEP valve item no. 199102001

For further information please refer to the directions for use of the Ambu PEEP valve. (8.1)

To fit the Ambu PEEP valve (if required) to the resuscitator remove the outlet cap. (8.2)

### Ambu Disposable Pressure Manometer (8.3) item no. 322003000

For further information please refer to the directions for use of the Ambu Disposable Pressure Manometer.

**CAUTION** ⚠
If applicable, please see accessory packaging for more specific information about the individual accessory e.g. expiration date, and MR Conditional.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