INSTRUCTIONS FOR USE

Ambu® Mark IV
Reusable resuscitator

Ambu

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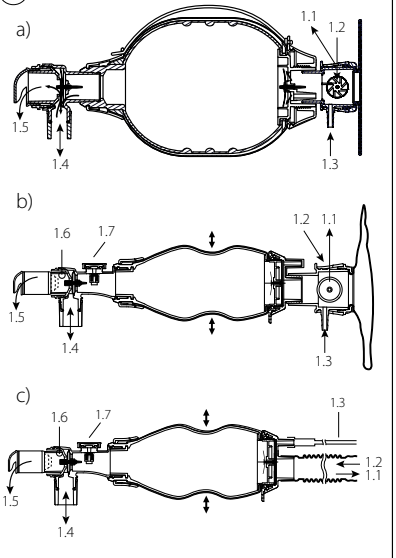

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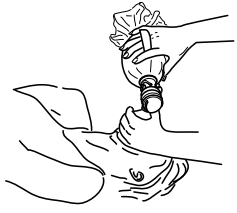

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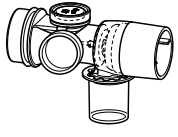
3.1



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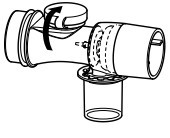

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4.1

ADULT ≥ 15 kg	V_T (ml) x f (breath per min.), I:E ratio = 1:2			
O_2 (l/min.)	250 x 12	600 x 12	750 x 12	900 x 12
2	74	43	39	36
5	100	76	65	58
10	100	100	100	94
15	100	100	100	100

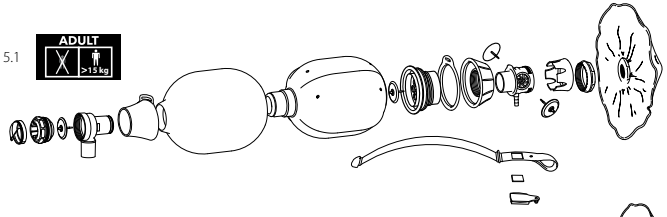
4.2

BABY ≤ 20 kg	V_T (ml) x f (breath per min.), I:E ratio = 1:2							
O_2 (l/min.)	40 x 40		100 x 20		200 x 20		400 x 15	
	Bag	Tube	Bag	Tube	Bag	Tube	Bag	Tube
2	100	100	100	100	61	61	47	49
4	100	100	100	100	100	91	74	74
6	100	100	100	100	100	100	100	84
8	100	100	100	100	100	100	100	91
15	100	100	100	100	100	100	100	97

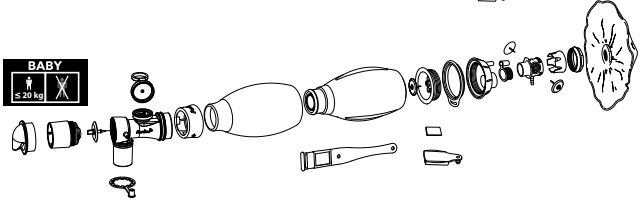
Calculated delivered O_2 %*

5

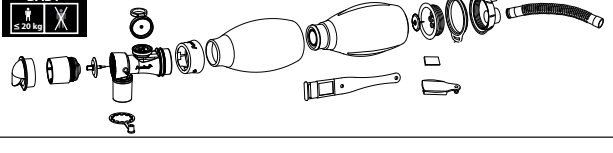
5.1 ADULT >15 kg



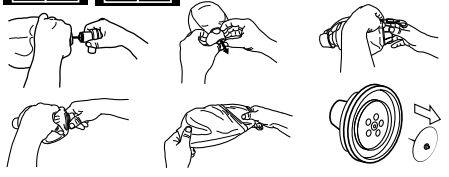
5.2 BABY ≤ 20 kg



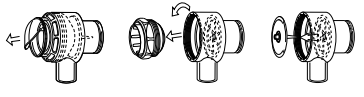
5.3 BABY ≤ 20 kg



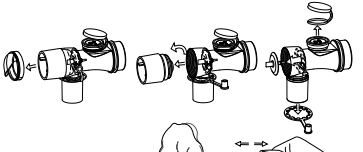
5.4 ADULT >15 kg BABY ≤ 20 kg



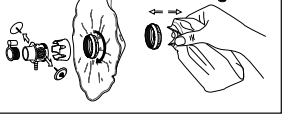
5.5 ADULT >15 kg

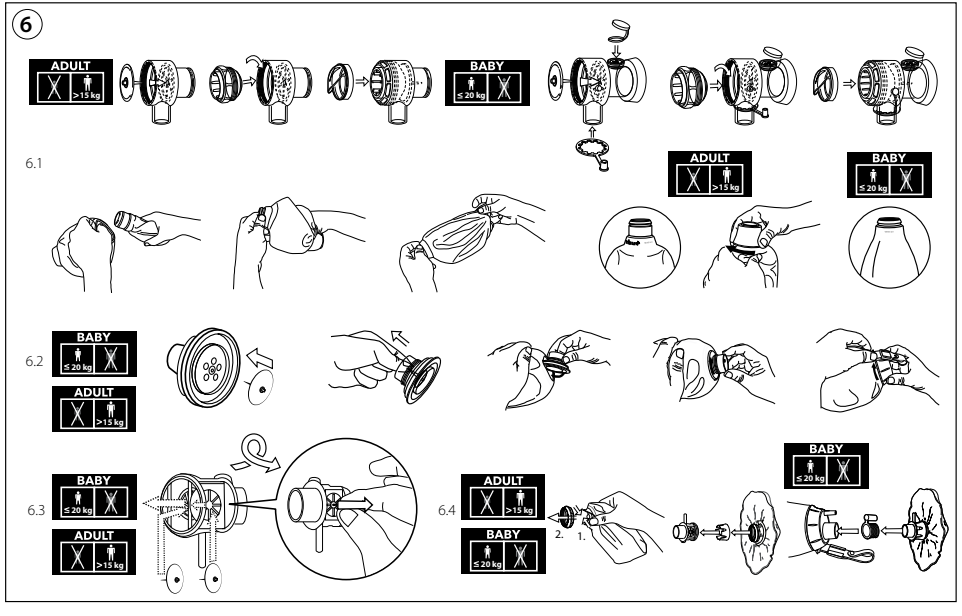


BABY ≤ 20 kg



5.6 ADULT >15 kg BABY ≤ 20 kg

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ADULT
>15 kg
BABY
≤ 20 kg
6.1
ADULT
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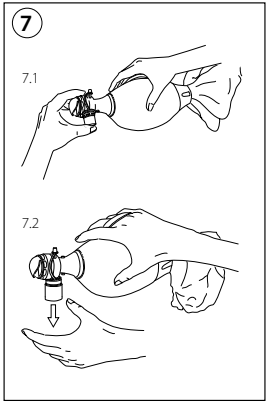
BABY
≤ 20 kg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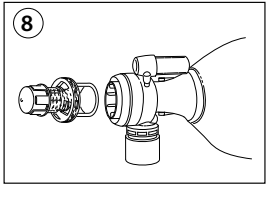
7.1
7.2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4*

EN	Calculated delivered O_2 %, V_T: Ventilation volume, f: Frequency	**LT**	Apskaičiuotas O_2 % tiekimas, V_T: ventiliavimo tūris, f: dažnis
BG	Изчислен доставян O_2 %, V_T: вентилационен обем, f: честота	**LV**	Aprēķinātais piegādātais O_2 %, V_T: elpināšanas tilpums, f: frekvence
CS	Vypočtený dodávaný O_2 %, V_T: Ventilační objem, f: Frekvence	**NL**	Berekend geleverd O_2 %, V_T: Beademingsvolume, f: Frequentie
DA	Beregnet afgivet O_2 %, V_T: Ventilationsvolumen, f: Frekvens	**NO**	Beregnet levert O_2 %, V_T: Ventileringsvolum, f: Frekvens
DE	Berechnetes abgegebenes O_2 %, V_T Beatmungsvolumen, f: Frequenz	**PL**	Obliczone stężenie procentowe dostarczonego O_2, V_T: Objętość wentylacji, f: Częstotliwość
EL	Υπολογισμένο παρεχόμενο O_2 %, V_T: Όγκος αερισμού, f: Συχνότητα	**PT**	Fornecimento calculado O_2 %, V_T: Volume de ventilação, f: Frequência
ES	% de O_2 suministrado calculado, V_T: volumen de ventilación, f: Frecuencia	**RO**	% O_2 furnizat calculat, V_T: volum de ventilare, f: frecvență
ET	Arvutatud edastatav O_2 %, V_T: ventileerimismaht, f: Sagedus	**RU**	Расчетная концентрация O_2 на выходе %, V_T: объем вентиляции, f: частота
FI	Laskennallinen toimitettu O_2 %, V_T: Ventilointitilavuus, f: Taajuus	**SK**	Vypočítaný dodávaný objem O_2 %, V_T: ventilačný objem, f: Frekvencia
FR	% d'O_2 administré calculé, V_T : volume de ventilation, f : Fréquence	**SL**	Izračunan dovedeni O_2 %, V_T: volumen predihavanja, f: Frekvenca
HR	Izračunani isporučeni O_2 %, V_T: ventilacijski volumen, f: Frekvencija	**SV**	Beräknad levererad O_2 %, V_T: Ventilationsvolym, f: Frekvens
HU	Számított leadott O_2 %, V_T: lélegeztetési térfogat, f: frekvencia	**TR**	Hesaplanan verilen O_2 %, V_T: Havalandırma hacmi, f: Frekans
IT	O_2 % erogato calcolato, V_T: volume di ventilazione; f: Frequenza	**ZH**	计算得出可获得的氧气浓度 %, V_T: 通气量, f: 频率
JA	供給酸素濃度計算値 O_2 %, V_T: 換気量、f: 換気回数		

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1. Important information – Read before use

Read these safety instructions carefully before using the Ambu® Mark IV Resuscitator (for adult and children > 15 kg, referred to as Ambu Mark IV Adult) and Ambu® Mark IV Baby Resuscitator (for neonates, infants and children up to 20 kg, referred to as Ambu Mark IV Baby), collectively referred to as Ambu Mark IV. 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 resuscitator. Before initial use of the resuscitator, 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 Ambu Mark IV.

1.1. Intended use

The Ambu Mark IV is a reusable resuscitator intended for pulmonary resuscitation.

1.2. Indications for use

The Ambu Mark IV is indicated in situations where a manual cardio-pulmonary resuscitator is needed for assisted ventilation of patients.

The Ambu Mark IV is indicated for ventilation and oxygenation of patients until a more definitive airway can be established or the patient is recovered.

1.3. Intended patient population

The range of application for each size is:

- Size Adult: Adults and children with a body weight more than 15 kg (33lb).
- Size Baby: Neonates, infants and children with a body weight up to 20 kg (44 lb).

1.4. Intended user

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

1.5. Contra indications

None known.

1.6. Clinical benefits

The basic airway management technique using a manual resuscitator allows for ventilation and oxygenation of patients until a more definitive airway can be established or the patient has recovered.

1.7. Warnings and cautions

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

WARNING ⚠

1. Always reprocess the Ambu Mark IV after each use in order to avoid the risk of infection.
2. Avoid the use of the resuscitator in toxic or hazardous environments to avoid the risk of tissue damage.
3. When using supplemental oxygen, do not allow smoking or use of the 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.
4. Always visually inspect the product and perform a functionality test 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 the functionality test fails, as this can lead to no or reduced ventilation.
6. Only to be used by intended users who are familiar with the content of this manual, as incorrect use might harm the patient.
7. Professionals performing the procedure should assess the choice of resuscitator size and accessories (e.g. face mask, PEEP valve, etc.) in accordance with the patient's specific condition(s), as incorrect use may harm the patient.
8. Do not use the product if contaminated by external sources, as this can cause infection.

9. Ensure that either the splash guard or an Ambu PEEP Valve is attached to the expiratory port. An open expiratory port can be accidentally blocked and result in excessive air volume in the lungs, which could lead to tissue trauma.
10. The manometer cap must always be put on the Manometer port when pressure is not being monitored to avoid leakage, which may lead to reduced O_2 delivery to the patient.
11. Always reprocess the Ambu Mark IV if visible residues or moisture are left inside the device, in order to avoid the risk of infection and malfunction.
12. Do not override the pressure-limiting valve unless a medical assessment indicates the necessity. High ventilation pressures may cause barotrauma.
13. Always ensure that the oxygen reservoir tube is not blocked, as blocking the tube can prevent the compression bag from reinflating, which can result in no possible ventilation.
14. Adding accessories may increase inspiratory and/or expiratory resistance. Do not attach accessories if increased breathing resistance would be detrimental to the patient.
15. Do not reuse the resuscitator on another patient without reprocessing due to the risk of cross-infection.
16. Do not use the product with attached face mask when ventilating infants with congenital diaphragmatic hernia due to the risk of insufflation. Switch to an alternative to using a face mask for directing air to the patient, if available.
17. Be aware of signs of complete/partial upper airway obstruction when using the resuscitator attached to a face mask, as this will lead to no or limited oxygen delivery. Always switch to an alternative to using a face mask for directing air to the patient, if available.
18. Do not use the Ambu Mark IV after reprocessing a maximum of 30 times (15 times for the oxygen reservoir bag) in order to avoid the risk of infection or malfunction of the device.
19. Do not use the Ambu Mark IV when delivery of free-flow oxygen is needed due to possible insufficient administration of oxygen, which can lead to hypoxia.
20. When using the resuscitator with attached face mask, ensure correct positioning and sealing of the face mask, as improper sealing can lead to spreading of airborne infectious disease to the user.

CAUTIONS

1. Do not use substances containing phenols to clean the product. Phenols will cause premature wearing and degradation of the materials resulting in reduced product life span.
2. After cleaning, promptly remove all residues of detergent from the resuscitator, as residues may cause premature wear or reduce product lifetime.
3. Never store the resuscitator in a deformed state, otherwise permanent distortion of the bag could occur, which may reduce the ventilation efficiency.
4. Always watch the movement of the chest and listen for the expiratory flow from the patient valve, in order to check the ventilation. Switch immediately to mouth-to-mouth ventilation if ventilation with the resuscitator cannot be achieved.
5. Do not attempt to disconnect the patient connector from the patient valve as these are permanently attached, and disassembly might lead to device damage and malfunction.
6. Do not attempt to disassemble the resuscitator further than described in these instructions due to the risk of device damage and malfunction.
7. If applicable, please see accessory packaging for more specific information about the individual accessory as incorrect handling may lead to malfunction of the entire product.
8. The use of third-party products and oxygen delivery devices (e.g., filters and demand valves) with the Ambu Mark IV may influence product performance. Please consult the manufacturer of the third-party device to verify compatibility with Ambu Mark IV and obtain information on the possible performance changes.
9. Always keep components from same device together during reprocessing to avoid reassembly of components with different durability leading to the risk of product failure.
10. U.S federal law restricts this device to sale by or on the order of a *licensed health care practitioner.*

1.8. Potential adverse events

Potential adverse events related to resuscitation (not exhaustive): barotrauma, volutrauma, hypoxia, hypercarbia and aspiration pneumonia.

1.9. 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 Mark IV can be connected to the Ambu® Disposable Pressure Manometer, the Ambu PEEP valves and the Ambu face masks, as well as other breathing accessories complying with EN ISO 5356-1 and EN ISO 13544-2.

3. Explanation of symbols used

Symbol indication	Description
	**Adult** Intended ideal body mass greater than 15 kg.
	**Baby** Intended ideal body mass up to 20 kg.
	Global Trade Item Number (GTIN™).

Symbol indication	Description
Rx Only	Prescription use only.
	Lot Number.
	Country of Manufacturer.
	Medical Device.
	MR Conditional.

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

4. Product use

4.1. Principle of operation

The illustration on page 2 (1) shows the ventilation gas flow into the bag and to and from the patient during manual operation of the resuscitator. (a) Mark IV Adult, (b) Mark IV Baby with oxygen reservoir bag, (c) Mark IV Baby with oxygen reservoir tube.

The gas flow is similar when the patient is breathing spontaneously through the device.

The oxygen reservoir 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) (1.2)

1.1 Excess oxygen release, 1.2 Air inlet, 1.3 Oxygen inlet, 1.4 Patient connector, 1.5 Expiration, 1.6 Manometer port, 1.7 Pressure-limiting valve.

4.2. Inspection and preparation

The resuscitator must be unpacked and prepared (including performing a functionality test) for immediate use in emergency situations.

4.2.1. Preparation

- Prepare the resuscitator according to the assembly guide and place all items in the carrying bag supplied with the resuscitator.
- If a face mask is supplied with the resuscitator, ensure to remove the protective pouch (if any) before use.
- Before use on the patient make a brief functionality test as described in section 4.2.2.

4.2.2. Test of function

Resuscitator

Close the pressure-limiting valve with the override cap (this only applies to Ambu Mark IV Baby) and close the patient connector with the thumb 3.2 7.1. Briskly squeeze the bag. The resuscitator shall be resisting the squeeze.

Open the pressure-limiting valve by opening the override cap 3.1 and repeating the procedure. The pressure-limiting valve should now be activated, and it should be possible to hear the exhaust air flow from the valve.

Remove the finger from the patient connector and 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: A slight sound may appear from the moving valve disks during operation. This does not compromise the functionality of the resuscitator.

Oxygen reservoir bag

Supply a gas flow of 10 l/min at the oxygen inlet connector. Facilitate the unfolding of the oxygen reservoir bag. Check that the oxygen reservoir bag fills. If not, check the integrity of the two valve shutters 6.3 or for a torn in the oxygen reservoir bag. Subsequently, adjust the supplied gas flow according to medical indication.

Oxygen reservoir tube

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

Subsequently, adjust the supplied gas flow according to medical indication.

4.3. Operating the resuscitator

- Use recommended techniques to clear the patient's mouth and airway and to position the patient correctly, to secure an open airway.
- Hold the face mask firmly against the patient's face. 2
- Slide your hand (Ambu Mark IV Adult) under the handle (The Ambu Mark IV Baby does not have a support handle).

  Ventilation of the patient: During insufflation observe for chest rise. Release the hand holding the compressible bag abruptly and listen for the expiratory flow from the patient valve and as well for the visual lowering of the chest.
- If continued resistance to insufflation is encountered, check the airway for obstruction and re-position the patient, to ensure an open airway.
- If the patient vomits during ventilation; immediately remove the resuscitator to clear the patient's airway and expel the vomit from the resuscitator by shaking and compressing it forcefully and fast several times before resuming ventilation.

  In the case of excessive amount of vomitus obstructing the air flow, the patient valve may be disassembled and cleaned. For details on dis- and reassembly of the patient valve refer to illustrations 5.5 and 6.1.
- If connecting external devices to the resuscitator, make sure to test for functionality and consult the *Instructions for use* accompanying these external devices.

Manometer port (Only applicable for Ambu Mark IV Baby)

The Ambu Disposable Pressure Manometer or a third-party pressure gauge can be attached to the manometer port, situated on the top of the patient valve. Remove the cap and attach the manometer/pressure gauge 8.

Pressure-limiting valve (Only applicable for Ambu Mark IV Baby)

The pressure-limiting valve is set to open at 40 cmH_2O (4.0 kPa).

If medical and professional assessment indicates that a pressure above 40 cmH_2O is required, the pressure-limiting valve can be overridden by pressing the override cap onto the valve 3.2.

Alternatively, the pressure-limiting valve can be overridden by placing the index finger on the blue button while squeezing the bag.

Oxygen administration

Administer oxygen according to medical indication.

The figure 4 shows calculated delivered oxygen percentages which can be obtained with different ventilation volumes and frequencies at different gas flow rates referring to Mark IV Adult 4.1 and Mark IV Baby 4.2, respectively.

4.4. Reprocessing: cleaning, disinfection, sterilization

Follow these reprocessing instructions after each use to reduce the risk of cross-contamination.

Disassembly

Before reprocessing manually, disassemble the resuscitator into individual components to the level shown in 5.1 (Mark IV Adult), 5.2 (Mark IV Baby with oxygen reservoir bag), 5.3 (Mark IV Baby with oxygen reservoir tube) to make surfaces accessible to cleaning. Follow the method shown in 5.4 5.5 and 5.6.

Keep components from the same device together during reprocessing to avoid reassembly of components with different durability.

Recommended reprocessing procedures

For a complete reprocessing of the Ambu Mark IV, use one of the procedures listed in Table 1.

Product/Component	Recommended reprocessing procedures (select one)
Mark IV Adult and Mark IV Baby (except oxygen reservoir tube)	• Manual cleaning followed by chemical disinfection. • Manual cleaning followed by sterilization. • Automated cleaning, including a thermal disinfection stage, followed by sterilization. • Automated cleaning, including a thermal disinfection stage, followed by chemical disinfection.
Oxygen reservoir tube for Mark IV Baby	• Manual cleaning followed by chemical disinfection.

Table 1: Recommended reprocessing procedures.

Product testing has shown that the Ambu Mark IV resuscitator is fully functional after 30 full reprocessing cycles, as listed in Table 1, with the exception of the oxygen reservoir bag, which can be sterilized maximum 15 times or chemically disinfected maximum 30 times.

It is the user's responsibility to qualify any deviations from the recommended cycles and methods of processing, and to monitor that the recommended number of reprocessing cycles is not exceeded.

Always perform a test of functionality prior to each use (see section 4.2.2.)

Procedures for reprocessing

MANUAL CLEANING

1. Rinse the components under running cold utility (tap) water to remove gross soil.
2. Prepare a detergent bath using a cleaning detergent solution, e.g. Neodisher® MediClean Forte or equivalent, for the removal of residues of dried and denatured blood and proteins, using the detergent manufacturer's recommended concentration.
3. Fully immerse the components to keep them submerged in the solution according to the detergent instruction label. During the soak time thoroughly clean the components with a soft brush and flush the bags and lumens until all visible soil is removed.
4. Thoroughly rinse the articles by fully immersing them in tap water, agitating and allowing them to set for a minimum of 3 minutes.
5. Repeat the previous step two more times for a total of three rinses using a fresh batch of tap water each time.
6. Dry the components with a clean lint-free cloth and compressed air.

AUTOMATED CLEANING AND THERMAL DISINFECTION (NOT APPLICABLE FOR OXYGEN RESERVOIR TUBE)

1. Rinse the components under running cold utility (tap) water to remove gross soil.
2. Place the components onto a manifold rack or in a wire basket contained inside the washer.
3. Select the cycle as listed below:

Stage	Recirculation time (minutes)	Temperature	Detergent type and concentration
Pre-wash	02:00	Cold tap water	N/A
Wash	01:00	43 °C (110 °F) tap water	Neodisher® MediClean Forte or an equivalent detergent using manufacturer's recommended concentration
Rinse	05:00	43 °C (110 °F) tap water	N/A
Thermal disinfection	05:00	91 °C (196 °F)	N/A
Dry Time	07:00	90 °C (192 °F)	N/A

Table 2: Automated cleaning procedure for Mark IV resuscitator.

CHEMICAL DISINFECTION

1. Equilibrate the bath of Cidex OPA, or an equivalent OPA (ortho-phthalaldehyde), disinfectant at the temperature specified in the OPA disinfectant manufacturer's instructions.
2. Ensure the minimum effective concentration (MEC) of the OPA disinfectant using the OPA test strips specified in the OPA disinfectant manufacturer's instructions.
3. Fully immerse the device in the OPA and ensure that all air bubbles are removed from the device surface by agitating the device.
4. Allow the device to soak for the time specified by the OPA disinfectant manufacturer's instructions.
5. Thoroughly rinse the device by fully immersing it in purified water, agitating and allowing it to set for a minimum of 1 minute. During the rinse, flush the bag with the purified water.
6. Repeat step 5 two more times for a total of 3 rinses using a fresh batch of purified water each time.
7. Dry the device using a sterile lint-free cloth.

STERILIZATION (NOT APPLICABLE FOR OXYGEN RESERVOIR TUBE)

Sterilize the product using a gravity steam autoclave running a full cycle at 134 – 135 ˚C (274 – 275 ˚F) with an exposure time of 10 minutes and a dry time of 45 minutes. Leave the components to dry and/or cool completely before reassembling the resuscitator.

Inspection of components

After reprocessing, carefully inspect all components for damage and residuals or excessive wear and replace if necessary. Some methods may cause discoloration of rubber components without impact on their lifetime. In case of material deterioration, e.g. cracking, the components should be discarded and replaced with a new component.

In case of sterilization, the oxygen reservoir bag can look slightly wrinkled. This has no impact on its lifetime or function.

Reassembly

Manually reassemble the components of the resuscitator as shown in **6**.

- When inserting the valve housing of the inlet valve, make sure that the bag opening seats smoothly against the flange.
- When inserting the valve discs, make sure the butt of the stem is pushed through the hole in the middle of the valve seating, as shown in figures **6.3**.
- When mounting the splash guard: Note that the opening of the splash guard should face downwards **6.1**.
- For mounting the oxygen reservoir bag on to Ambu Mark IV Baby, attach the adaptor to the resuscitator inlet valve by mounting the adaptor corrugated connector onto the inlet connector, and additionally covering the oxygen inlet connector with the adaptor cap. Subsequently the oxygen reservoir bag can be connected to the adaptor corrugated connector.

Perform a functionality test after reassembly and before it is prepared for immediate use in emergency situations.

Service

The resuscitator requires no scheduled maintenance other than regular reprocessing, inspection and testing.

4.5. Disposal

Used products must be disposed of according to local procedures.

5. Technical product specifications

5.1. Standards applied

The Ambu Mark IV is conforming with the product specific standard EN ISO 10651-4.

5.2. Specifications

	Mark IV Baby	Mark IV Adult
Resuscitator volume****	420 ml	1450 ml
Delivered volume one hand*, ****	300 ml	600 ml
Delivered volume two hands*, ****	-	900 ml
Dimensions (length x diameter)****	265 x 80 mm	270 x 130 mm
Weight without Reservoir and mask****	190 g	415 g
Pressure-limiting valve**	40 cmH_2O	-
Dead space	≤ 5 ml + 10 % of the delivered volume	≤ 5 ml + 10 % of the delivered volume
Oxygen reservoir bag volume****	1500 ml (bag) 100 ml (tube)	1500 ml

	Mark IV Baby	Mark IV Adult
Inspiratory resistance ***, *****	w. oxygen reservoir tube: 0.6 cmH_2O at 5 l/min 4.0 cmH_2O at 50 l/min w. oxygen reservoir bag: 0.8 cmH_2O at 5 l/min 4.9 cmH_2O at 50 l/min	3,7 cmH_2O at 50 l/min
Expiratory resistance ***, *****	1.3 cmH_2O at 5 l/min 4.4 cmH_2O at 50 l/min	2,2 cmH_2O at 50 l/min
PEEP generated by resuscitator in normal use with added supply gas flow***, *****	w. oxygen reservoir tube: < 2 cmH_2O at 5, 10, and 15 l/min w. oxygen reservoir bag: 2.5 cmH_2O at 5 l/min 3.7 cmH_2O at 10 l/min 4.5 cmH_2O at 15 l/min (V_T 20 ml, f 60)	< 2 cmH_2O at 5, 10, and 15 l/min (V_T 225 ml and 600 ml, f 20)
Patient connector	Outside 22 mm male (EN ISO 5356-1) Inside 15 mm female (EN ISO 5356-1)	
Expiration connector (for PEEP valve attachment)	30 mm male (EN ISO 5356-1)	
Manometer port connector	Ø 4.2 +/- 0.1 mm	
Bag refill valve connector*	-	Inside 32 mm female
Forward and backward leakage	Not measurable	
O_2 inlet connector	According to EN ISO 13544-2	

	Mark IV Baby	Mark IV Adult
Operation temperature limits*	-18 °C to +50 °C (-0.4 °F to +122 °F)	
Storage temperature limits*	-40 °C to +60 °C (-40 °F to +140 °F)	
Recommended long term storage in closed packaging at room temperature, away from sunlight.		

Notes:

– 10 cmH_2O = 1.0 kPa

– V_T: Ventilation volume, f: Frequency (breath per minute).

* Tested according to EN ISO 10651-4.

** Higher airway pressure can be obtained by overriding the pressure-limiting valve.

*** At general test conditions according to EN ISO 10651-4:2009.

**** Values are approximate.

***** Maximum values

5.3. MRI Safety Information

The Ambu Mark IV is 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 – 10,000 G/cm (100 T/m)
- Maximum force product of – 450,000,000 G^2/cm (450 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.

Ambu

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

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