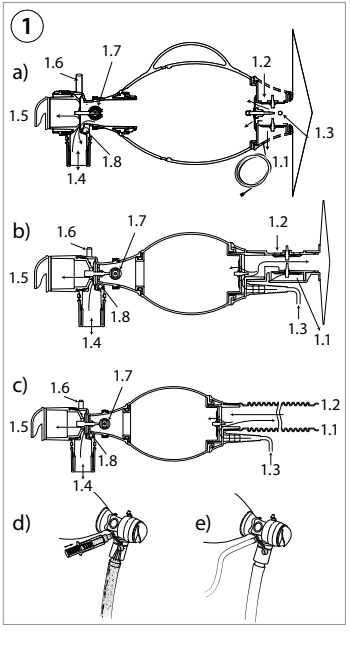
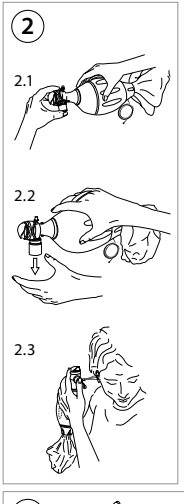
INSTRUCTIONS FOR USE

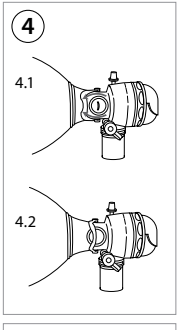
Ambu® SPUR® II
Disposable

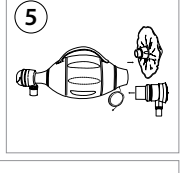
Abridged version
ENG only

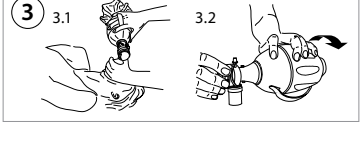
Ambu











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6.1

	V_T (ml) x f (p r. min.), I:E ratio = 1:2			
O_2 (l/min)	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

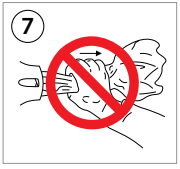
6.2

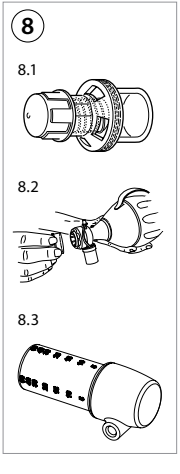
	V_T (ml) x f (p r. min.), I:E ratio = 1:2			
O_2 (l/min)	40 x 40	100 x 20	200 x 20	400 x 15
1	70	60	40	34
2	100	100	60	47
4	100	100	100	73
6	100	100	100	100

6.3

	V_T (ml) x f (p r. min.), I:E ratio = 1:1					
O_2 (l/min)	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

Calculated delivered O_2 %*





6*

EN	Calculated delivered O_2 % , V_i: Ventilation volume, f: Frequency

CE 2797

English

1. Important information – Read before use

Read these safety instructions carefully before using the Ambu® SPUR® II Resuscitator. 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 the Ambu SPUR II Resuscitator.

1.1. Intended use

The Ambu SPUR II Resuscitator is a single patient use resuscitator intended for pulmonary resuscitation.

1.2. Indications for use

The Ambu SPUR II Resuscitator is intended to be used in situations where a manual cardio-pulmonary resuscitator is needed for assisted ventilation.

The Ambu SPUR II Resuscitator is indicated for ventilation and oxygenation of patients until a more definitive airway can be established or the patient has recovered.

1.3. Intended patient population

The size range of applications for each version is:

– **Adult:** Adults and children with a body weight more than 30 kg (66 lb).

– **Pediatric:** Infants and Children with a body weight from 6 kg to 30 kg (13 – 66 lb).

– **Infant:** Neonates and infant with a body weight up to 10 kg (22 lb).

Please note that not all Ambu SPUR II Resuscitator configurations are available for all three patient ranges.

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 and oxygenation of the patient or damage to the equipment.

WARNINGS ⚠

1. Do not use the resuscitator for more than 4 accumulated hours over a maximum time span of 1 week, in order to avoid the risk of infection.
2. Do not reuse the resuscitator if visible moisture or residues are left inside the device, in order to avoid the risk of infection and malfunction.
3. Ensure that either the Splash Guard or 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 can lead to tissue trauma.
4. Avoid the use of the resuscitator in toxic or hazardous environments, to avoid the risk of tissue damage.

5. 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.
6. Do not use the product if contaminated by external sources, as this can cause infection.
7. Always visually inspect the product and perform a functionality test after unpacking, assembly and prior to use, as defects and foreign matters can lead to no or reduced ventilation of the patient.
8. Do not use the product if functionality test fails, as this can lead to no or reduced ventilation.
9. Do not override the pressure-limiting valve unless a medical assessment indicates the necessity. High ventilation pressures may cause barotrauma.
10. For single patient use only. Use on other patients can cause cross infection.
11. Medication cannot be delivered through the M-port if accessories (e.g. filter, CO_2 detector) are connected between the resuscitator and the face mask.
12. Do not leave M-port open after use, in order to avoid leakage, which may lead to reduced O_2 delivery to the patient.
13. The M-Port should not be used for side-stream $EtCO_2$ monitoring of patients ventilated with less than 400 ml Tidal Volume, to avoid inaccurate $EtCO_2$ measurements.
14. When administering medication with a volume below 1 ml, it is required to flush the M-Port to ensure accurate medication dosage delivered.
15. Do not attach oxygen supply tubing to the M-port, as the intended O_2 concentration will not be delivered to the patient.
16. Adding accessories may increase inspiratory and/or expiratory resistance. Do not attach accessories if increased breathing resistance would be detrimental to the patient.
17. Only to be used by intended users who are familiar with the content of this manual, as incorrect use might harm the patient.
18. 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.
19. Do not attempt to attach any demand valve to the infant version, as this can cause high oxygen concentrations, which might be harmful to neonates.
20. Be aware of complete/partial upper airway obstruction signs 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.
21. Do not use 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.
22. 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.
23. Do not use the Ambu SPUR II when delivery of free-flow oxygen is needed due to possible insufficient administration of oxygen, which can lead to hypoxia.
24. 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.
25. Always pre-attach the oxygen tube to the oxygen supply at temperatures above 0 °C, as mounting can become difficult at temperatures below 0 °C, thereby leading to reduce oxygen delivery to the patient.
26. 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. Never store the resuscitator in a deformed state other than as folded when delivered by the manufacturer, otherwise permanent distortion of the bag could occur, which may reduce the ventilation efficiency. The folding zone is clearly visible on the bag (only Adult and Pediatric versions may be folded).
2. 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.
3. 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.
4. Use the M-Port only for one of the two; $EtCO_2$ measuring or drug administration, as this can modify the measured values.
5. 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.
6. The use of third-party products and oxygen delivery devices (e.g. filters and demand valves) with the Ambu SPUR II Resuscitator may influence product performance. Please consult the manufacturer of the third-party device to verify compatibility with Ambu SPUR II Resuscitator and obtain information on the possible performance changes.
7. The oxygen reservoir bag is permanently attached to the inlet valve on adult and pediatric resuscitators, except on demand valve versions. Do not attempt to disassemble. Do not pull the oxygen reservoir bag, as it may result in malfunction of the device.

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 SPUR II Resuscitator can be connected to the Ambu® Disposable Pressure Manometer, the Ambu® PEEP Valves and the Ambu® Face masks, as described in section 4.3 Operating the Resuscitator.

3. Explanation of symbols used

Symbol indication	Description
	**Adult** Intended ideal body mass greater than 30 kg
	**Pediatric** Intended ideal body mass from 6 to 30 kg
	**Infant** Intended ideal body mass up to 10 kg
	MR conditional
	Country of Manufacturer

Symbol indication	Description
	Medical Device
	Single Patient Multiple Use
	Do not pull the oxygen reservoir bag by force

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 1 shows the ventilation gas flow mixtures into the bag and to and from the patient during manual operation of the resuscitator. 1a Adult and pediatric resuscitator, 1b infant resuscitator with closed oxygen reservoir bag (bag reservoir), 1c infant resuscitator with open oxygen reservoir tube (tube reservoir).

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 oxygen reservoir bag is full.

The M-Port provides access to the inspiratory and expiratory gas flow allowing to connect a syringe for drug delivery 1d or to connect a gas sampling line for measuring side stream $EtCO_2$ 1e.

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, 1.8 M-port.

NOTE: attachment to 1.5 can be either a splash guard or a PEEP valve.

4.2. Inspection and Preparation

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

4.2.1. Preparation

– If the resuscitator is packed in a compressed state, unfold by pulling on the patient valve and the inlet valve.
– Prepare the resuscitator and place all items in the carrying bag supplied with the resuscitator.
– If the face mask supplied with the resuscitator is wrapped in a protective pouch, the pouch should be removed before use.

Refer to section 4.2.2. (Oxygen tube) for preparation of the device before use at below 0 °C.

4.2.2. Test of function 2

Resuscitator

Close the pressure-limiting valve with the override clip and close the patient connector with the thumb 2.1. Briskly squeeze the compressible bag. The resuscitator shall resist the squeeze.

Open the pressure-limiting valve by sliding away the override clip and repeating the procedure. The pressure-limiting valve should now be activated, and it should be possible to hear the flow from the valve during brisk compression of the compressible bag.

Squeeze and release the resuscitator a few times to ensure that air is moving through the valve system and out of the patient valve. 2.2

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

Oxygen tube

Mounting of the oxygen tube and test of function for the oxygen reservoir bag and the oxygen reservoir tube should be performed at temperatures above 0 °C. For use of the resuscitator at temperatures below 0 °C, leave the oxygen tube connected to the oxygen supply following the test of function.

Oxygen reservoir bag

Supply a gas flow of 10 l/min at the oxygen inlet connector. Eventually, support unfolding of the bag by hand. Check that the oxygen reservoir bag fills. If not, check the integrity of the two valve shutters or for a torn oxygen reservoir.

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

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. **2.3**

4.3. Operating the resuscitator

– Use recommended techniques to clear the patient's mouth and airway and to position the patient correctly, to open the airway.
– Hold the face mask firmly against the patient's face. **3.1**
– Slide your hand (Adult Version) or ring and middle finger (Pediatric version) under the handle. The infant version does not have a support handle.
  Ventilation without using the support handle can be achieved by turning the bag. **3.2**
  Ventilation of the patient: During insufflation observe for chest rise. Release the hand holding the 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 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.
  If necessary, wipe off the product with a cloth containing alcohol and clean the splash guard with water.

Manometer port

The Ambu disposable pressure manometer as well as 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

Pressure-limiting system **4**

The pressure-limiting valve is set to open at 40 cmH_2O (4.0kPa). **4.1**

If medical and professional assessment indicates a pressure above 40 cmH_2O is required, the pressure-limiting valve can be overridden by moving the override clip onto the valve. **4.2**

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

M-Port

The Ambu SPUR II Resuscitator comes either with or without an M-Port. The M-Port provides access to the inspiratory and expiratory gas flow and can be used for applying medication, where connected to a syringe, and as well used to measure side stream CO_2 ($EtCO_2$). When not in use, remember to close the M-port with the red M-port cap.

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 Ambu SPUR II Resuscitator. Connect the gas sampling line connector by mounting and rotating 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.

Ambu SPUR II Resuscitator demand valve version 5

Ambu SPUR II Resuscitator demand valve version is available in adult and pediatric sizes and can be used either with or without a demand valve and comes with an attachable oxygen reservoir bag.

The inlet valve of the Ambu SPUR II Resuscitator connects to the demand valve via an adapter.

Attachment of the demand valve:

– Remove the oxygen reservoir unit from the Ambu SPUR II Resuscitator inlet valve, if attached.

– Attach the adapter to the demand valve system.

– Insert the demand valve adaptor in the Ambu SPUR II Resuscitator inlet valve.

NOTE: Use only part labeled "compression unit" with adapter and Demand valve. The part labeled "Oxygen Reservoir Bag" is regarded as back-up if the demand valve fails.

Oxygen administration

Administer oxygen according to medical indication.

The figure 6 shows Calculated delivered oxygen percentages which can be obtained with different ventilation volumes and frequencies at different gas flow rates. The oxygen percentages can be seen in 6 Adult 6.1, Pediatric 6.2, Infant 6.3.

Oxygen reservoir bag 7

The thin oxygen reservoir bag plastic foil cannot be detached from its point of fixation to the resuscitator at any time.

Accessories 8

The Ambu SPUR II Resuscitator connectors follows ISO 5356-1 and EN 13544-2 making it compliant to other hospital equipment. When applying external devices, make sure to test for functionality and consult the instructions for use accompanying the external device.

Ambu products compatible with Ambu SPUR II Resuscitator are stated below:

Ambu® Disposable Face Mask

For further information please refer to the instruction for use of the Ambu Disposable Face Mask.

Ambu® Disposable PEEP 20 valve 8.1 8.2

For further information please refer to the instruction for use of the Ambu Disposable PEEP 20 valve or refer to illustration 8.1 in this instruction for use. To fit the Ambu Disposable PEEP 20 valve (if required) to the resuscitator, remove the splash guard. 8.2

Ambu® Disposable Pressure Manometer 8.3

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

4.4. After use

Used products must be disposed of according to local procedures.

5. Technical product specifications

5.1. Standards applied

The Ambu SPUR II resuscitator is conforming with the product specific standard EN ISO 10651-4.

5.2. Specifications

	Infant	Pediatric	Adult
Resuscitator volume	approx. 215 ml	approx. 664 ml	approx. 1547 ml
Delivered volume one hand*	150 ml	450 ml	600 ml
Delivered volume two hands*	-	-	1000 ml
Dimensions (length x diameter) w/o reservoir and accessory	approx. 190 x 71 mm	approx. 223 x 99 mm	approx. 284 x 127 mm
Weight w/o reservoir and accessory	approx. 70 g	approx. 145 g	approx. 220 g
Pressure-limiting valve**	4.0 kPa (40 cmH_2O)	4.0 kPa (40 cmH_2O)	4.0 kPa (40 cmH_2O)
Dead space	≤ 5 ml + 10 % of the delivered volume	≤ 5 ml + 10 % of the delivered volume	≤ 5 ml + 10 % of the delivered volume
Inspiratory resistance***	max 0.1 kPa (1.0 cmH_2O) at 5 l/min	max 0.5 kPa (5.0 cmH_2O) at 50 l/min	max 0.5 kPa (5.0 cmH_2O) at 50 l/min
Expiratory resistance***	max 0.2 kPa (2.0 cmH_2O) at 5 l/min	max 0.27 kPa (2.7 cmH_2O) at 50 l/min	max 0.27 kPa (2.7 cmH_2O) at 50 l/min
Reservoir volume	approx. 300 ml (bag) approx. 100 ml (tube)	approx. 2600 ml (bag)	approx. 2600 ml (bag)
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 (EN ISO 10651-4)	
Forward and backward leakage	Not measurable		
M-Port	Connector compatible with EN ISO 80369-7		
O_2 inlet connector	According to EN 13544-2		
Operation 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.			

* Tested according to EN ISO 10651-4.

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

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

5.3. MRI Safety Information

The Ambu SPUR II Resuscitator[1], and Ambu SPUR II Resuscitator with attached Ambu Disposable PEEP 20 Valve[2], and Ambu SPUR II Resuscitator with attached Ambu Disposable PEEP 20 Valve and Ambu Disposable Pressure Manometer[2] are 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)[1]
  - 16,000 G/cm (160 T/m)[2]
- Maximum force product of
  - 450,000,000 G^2/cm (450 T^2/m)[1]
  - 721,000,000 G^2/cm (721 T^2/m)[2]

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.

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