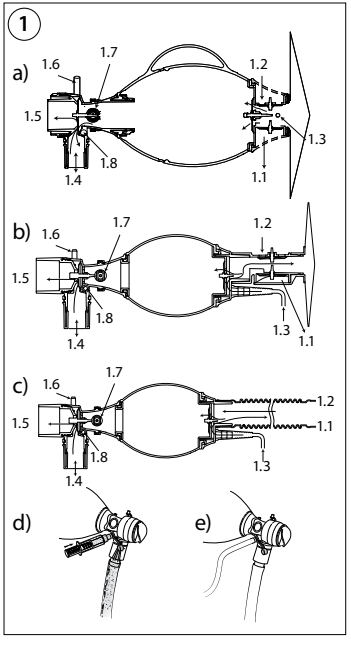
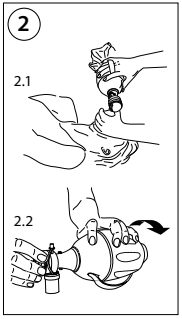
INSTRUCTIONS FOR USE

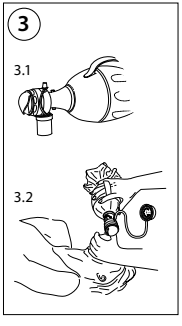
Ambu® SPUR® II
Disposable

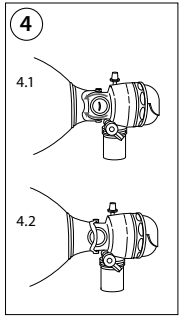
Ambu

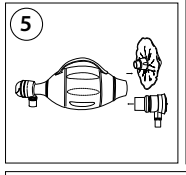
US: Rx only











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6.1

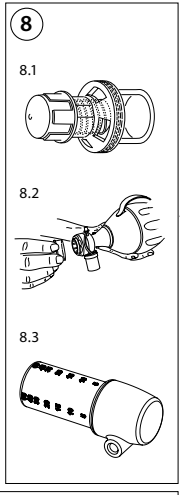
	V_T (ml) x f (p r. min.), I:E ratio = 1:2			
O_2 (l/min)	250 x 12	600 x 12	750 x 12	1000 x 12
2	74	43	38	34
5	100	76	65	54
10	100	100	100	87
15	100	100	100	100

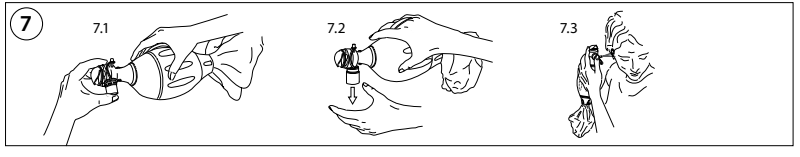
6.2

	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





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).

– **Pediatric:** Infants and children with a body weight up to 30 kg (66 lbs).

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

1.1. Contraindications

No contraindications identified for Ambu SPUR II resuscitators.

2. Warning and caution statements

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

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.

Professionals performing the procedure should assess the choice of resuscitator size and accessories (e.g. face mask, PEEP valve, filters etc.) in accordance with the patient's specific condition(s), as incorrect use may harm the patient.

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.

Adding accessories (e.g. face mask, filters, etc.) in the inspiratory pathway will increase deadspace, which may lead to re-breathing and accumulation of CO_2 (hypercarbia) and/or reduced O_2 delivery to the patient (hypoxia).

Do not use the product if test for functionality fails as this can lead to no or reduced ventilation of the patient.

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.

CAUTION ⚠

For use by trained personnel only. The proper application of a face mask 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 accessories (e.g. face mask, PEEP valve, filters, etc.) 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 Pediatric versions may be folded).

2.1. Potential adverse events related to resuscitation (not exhaustive)

Barotrauma, volutrauma, hypoxia, hypercarbia and aspiration pneumonia.

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	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 (ISO 10651-4)		
Forward and backward leakage	Not measurable		
M-Port	Standard Luer LS6 according to EN 20594-1		
O_2 inlet connector	According to EN 13544-2		
Operation temperature	-18 °C to +50 °C (-0.4 °F to +122 °F)		
Storage temperature	Tested at - 40 °C (-40 °F) and + 60 °C (+140 °F) 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.		

* Tested according to EN ISO 10651-4.

** 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. For further information about the products and specification consult the IFU of the filters. The use of PEEP valves naturally increases the expiratory resistance above the limit in the ISO standard.

4. Principle of 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 pediatric 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 Pediatric 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.

Preparation

- If the resuscitator is packed in a compressed state, unfold by pulling on the patient valve and the inlet valve.
- If the face mask supplied with the resuscitator is wrapped in a protective pouch, the pouch should be remove before use.
- Attach the face mask and other accessories as needed, and place all items in the plastic bag supplied with the resuscitator until ready for use.
- 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.
- If connecting external devices to the resuscitator, make sure to test for functionality and consult the instructions for use accompanying the external device.

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 (Pediatric 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.
- Used products must be disposed of according to local procedures.

5.2. Manometer port (3)

WARNING ⚠

Use only for measuring pressure.

Do not attach any oxygen source to the manometer port, as it will not provide any oxygen to the patient.

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

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 cmH_2O (4.0 kPa) (4.1).

If medical and professional assessment indicates a pressure above 40 cmH_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 ¼ 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 Pediatric 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).

V_T: 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

Ambu disposable PEEP valve item no. 199002020.

For further information please refer to the instruction 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. 322004000.

For further information please refer to the instruction 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. intended patient population, warnings, cautions, expiration date and MR Conditional).

Symbols	Explanation
MR	Conditions for Ambu SPUR II Resuscitator with pop-off valve: Magnetic Resonance Conditional according to ASTM F 2503 and IEC 62570. Following conditions apply: Static magnetic field of 7 Tesla or less. Maximum spatial gradient magnetic field of 10.000 Gauss/cm (100 T/m) and maximum force product of 450 T^2/m. The device shall not be used inside the MR bore.
US: Rx only	Caution: Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

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

Ambu

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

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