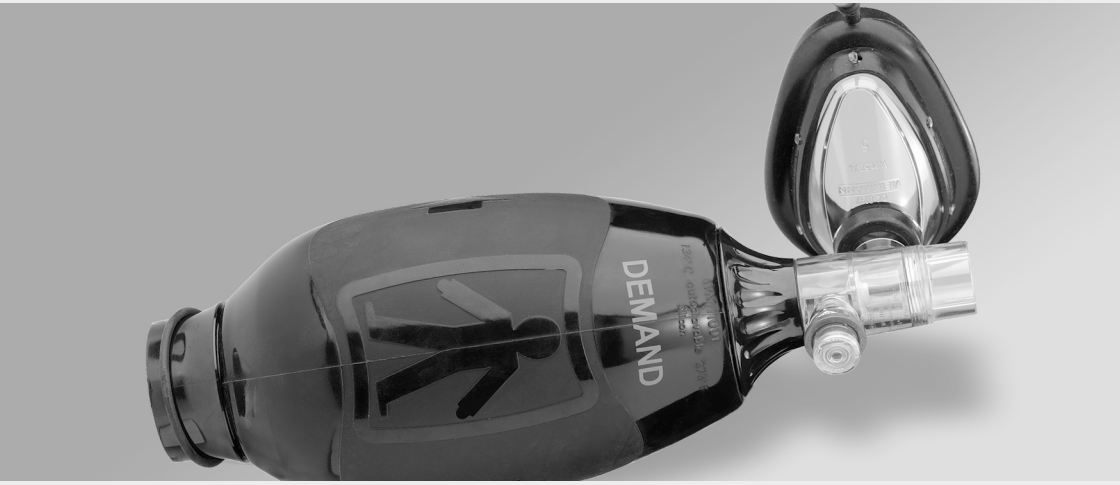
emergency



COMBIBAG

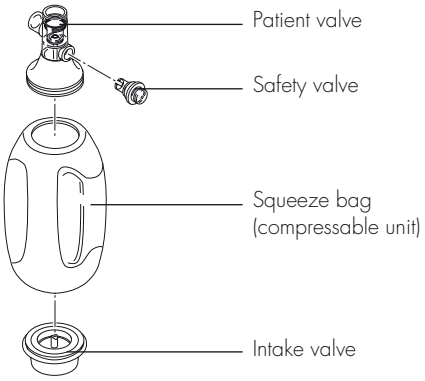
Resuscitator **WM 11000**

Description and Operating Instructions

WEINMANN
medical technology

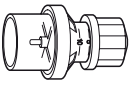
Overview

COMBIBAG

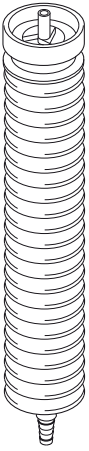


Accessories

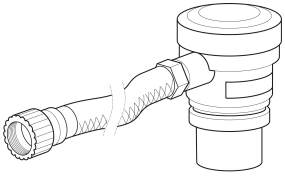
PEEP valve



Oxygen reservoir



DEMAND valve



Contents

1. Basic principle

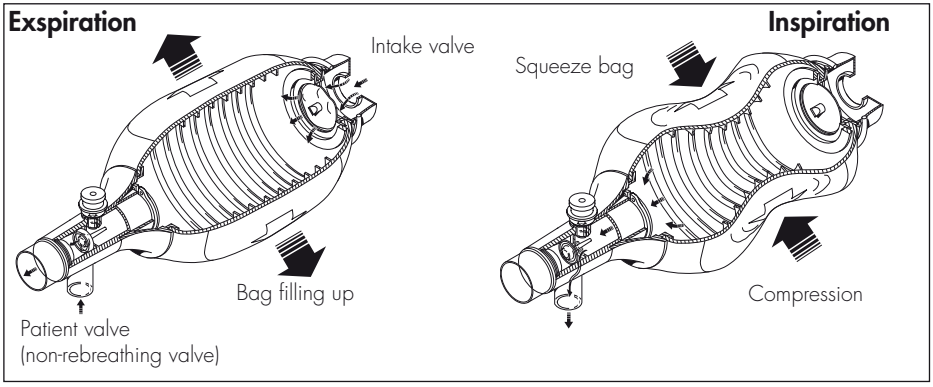
1.1 Purpose

The COMBIBAG is for the manual ventilation of children (from a body weight of 10 kg) and adults via a face mask or endotracheal tube. The respiratory air can be enriched with oxygen.

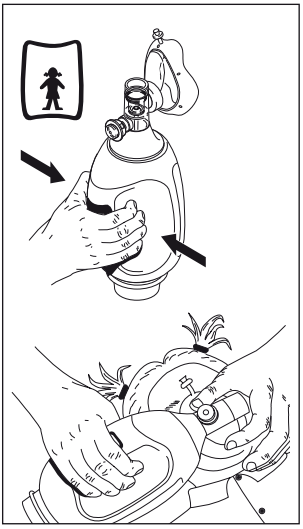
1.2 Function

On squeezing the bag, a volume of gas (air, air enriched with oxygen or pure oxygen) is forced through the resuscitation valve into the patient's lungs.

As soon as the elastic bag is released, it fills up again via the inlet valve, resuming its former shape. At the same time, the diaphragm in the patient valve closes the connection to the bag and opens the expiration passage. The patient then exhales into the atmosphere and expired air cannot flow back into the bag. In case of spontaneous breathing, the patient can breathe independantly in and out via the expiration passage.



1.3 Special Features of the COMBIBAG



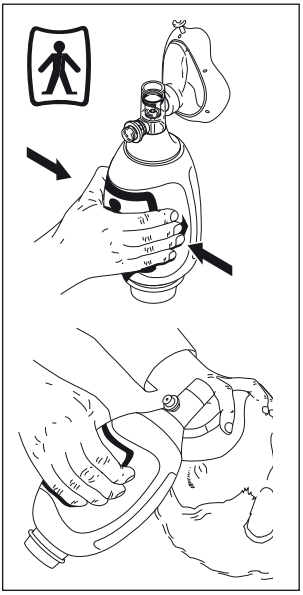
COMBIBAG, the first manual resuscitator with segmental division for adults and children.

Hitherto, at least 2 resuscitation bags were required to ventilate patients of all age groups, a child resuscitation bag and a large adult resuscitation bag.

Now the special design featuring the COMBIBAG covers both functions. The bag is divided into two segments (one large and one small) by two longitudinal troughs, marked with appropriate symbols. The tidal volume required can be obtained by squeezing the adult or child segment:

- up to 500 ml in child ventilation
- 500 - 1200 ml in adult ventilation.

The usual, separate child bag becomes unnecessary. The principle of "two bags in one" is extremely economical and saves space in each emergency kit.



COMBIBAG, the first manual resuscitator with a 2-stage safety valve.

By now, pressure relief as a function of the variable risks present in ventilation via face mask or endotracheal tube remained unsolved.

The majority of manual resuscitators only have a pressure limit at 50 - 60 mbar (50 - 60 cm H2O), a reasonable limit adapted to healthy lung conditions.

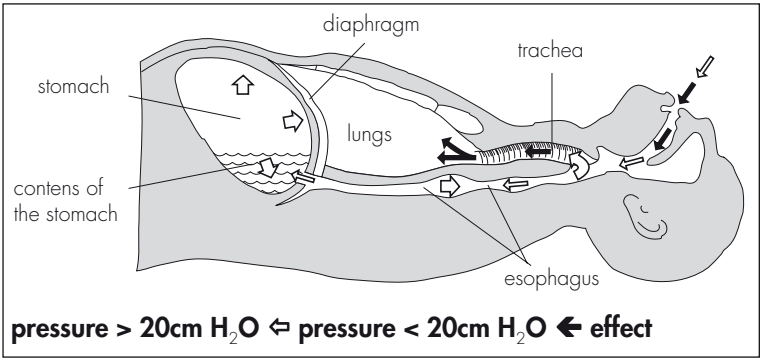
With use of manual resuscitators and face mask ventilation in inexperienced hands, however, there is always the risk that anxiety of the administrator and the eager trial to produce very effective ventilation may lead to an inflation of the stomach at pressures above

20 mbar resulting in regurgitation with following aspiration. Moreover, there is the risk with ventilation of children independant from face mask or endotracheal tube that high ventilation pressures may hurt the lungs.

With the COMBIBAG 2-stage safety valve it is now possible to set a pressure limit:

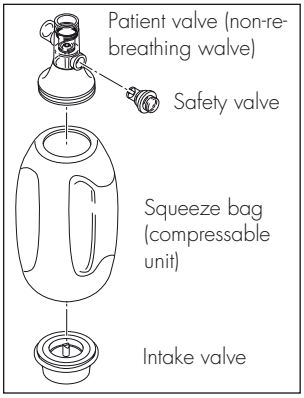
- of 20 mbar (20 cm H_2O) for mask resuscitation child ventilation and
- one of 60 mbar (60 cm H_2O) for resuscitation via an endotracheal tube with adults.

Hazards in ventilating non intubated patients



2. Description of the resuscitator

2.1 COMBIBAG components



The COMBIBAG resuscitator for adults and children consists of 4 working parts:

Patient valve

The patient valve consists of:

- the valve body with bag adapter,
- inspiration cone for connection of the mask or endotracheal tube connector(diameter 22/15 mm)
- valve diaphragm for separating inspiration and expiration
- safety valve (pressure-relief valve).

Safety valve

The safety valve (pressure-relief valve) consists of:

- the valve body with valve fittings and
- white pressure marks (20 and 60 mbar/cm H_2O) and the red valve ring with white arrows and the figures 20 and 60.

Because the safety valve can be accurately adjusted only by the manufacturer WEINMANN, replacement is possible only with delivery of a complete unit. Removal of the safety valve is not permitted.

Squeeze bag

The squeeze bag (compressable unit) is divided into segments by two asymmetrical troughs, marked with pictograms (symbol of a child and of an adult), and creates the gas volume required on squeezing the corresponding segment.

Intake valve

The intake valve consists of:

- valve intake port inner part with connecting socket for oxygen enrichment
- intake port cover
- valve plate to allow the inlet of fresh gas and forming a seal when the bag is squeezed
- silicone ring for hanging up the COMBIBAG.

3. Safety instructions

For your own safety, the safety of your patients, and to comply with the requirements of EU Directive 93/42 EEC, please observe the following points:

- Carefully observe the operating instructions, which is part of the instrument and must be available all the time.
- The detailed knowledge and attention of this operating instructions are the basis for proper use of the COMBIBAG. The instrument is just determined for the field of use stated.
- Malfunctions and a lack of biocompatibility may result if third-party articles are used. Please bear in mind that in these cases any warranty entitlement and liability shall lapse where the accessories recommended in the instructions for use or original spare parts are not utilised.
- To prevent infection or bacterial contamination, please observe section "5. Hygienic preparation" on page 15.
- **Warning:** The unit takes in ambient air so it may not be used in a toxic atmosphere.
- The unit is only allowed to be used by experienced personell trained in resuscitation and well acquainted with the instrument.
- In operation with oxygen it is imperative that smoking and open fire around the oxygen fittings is strictly prohibited.
- Oil and grease should not be used in conjunction with the resuscitation unit.
- Not for infants and children with a body weight below 10 kg.
- More copies of this operating instructions are available from the manufacturer WEINMANN.

4. Operating instructions

4.1 Introductory remarks

Although it is commonly assumed that resuscitation should be carried out only after respiratory failure has been confirmed, it must be emphasized that it should be commenced as soon as symptoms such as:

- cyanosis and/or
- visibly reduced respiratory movements and/or
- very low respiratory frequency and/or
- diminished respiratory murmur and/or
- diminished air flow

indicate dangerous suppression or restriction of spontaneous breathing. This ensures that all forms of hypoventilation, such as dead space breathing and breath "rattling" are covered.

4.2 Checking the function

The function of the COMBIBAG resuscitation bag should be proven before each use and can be checked in a few seconds as follows:

- Squeeze the bag with the right hand and cover the patient valve with the left hand: regardless of the relief valve setting, air can be felt and heard to flow into the left hand.
- Release the bag: it expands rapidly and air can be heard to flow through the inlet valve.

- Relief valve setting 20 mbar (20 cm H_2O): on closing the inhalation passage with the ball of the left thumb and squeezing the bag with the right hand, air flows through the relief valve openings.
- Relief valve setting 60 mbar (60 cm H_2O): on closing the inhalation passage with the ball of the left thumb, the bag can only be squeezed under considerable pressure and air escapes more slowly and quietly than at the 20 mbar pressure setting.

4.3 Guide values for ventilation

When carrying out artificial ventilation with resuscitators without adjustable frequency and tidal volume (unless additional measuring instruments such as pressure gauges or volumeters are employed), success of the procedure can only be judged from indirect signs, such as clearly visible thorax movements, disappearance of cyanosis, reduction in pallor, etc. Because of this, certain guide values should be noted after commencing resuscitation, in which, as a rule, some degree of hyperventi-lation is desirable. This is important since, with prolonged resuscitation, inadequate ventilation (hypoventilation) leads to considerable damage and ventilation with too high frequency and excessive tidal volume (hyperventilation) also has serious drawbacks.

	Cycles per min.	**Tidal volume in ml**
– Children (from a body weight of 10 kg)	40 - 60	20 - 35
– Childgen, 5 years old	20 - 35	150 - 200
– Childgen, 10 years old	18 - 25	300 - 400
– Juveniles	16 - 20	300 - 500
– Adults	12 - 16	500 - 1000

Ventilation must be carried out if spontaneous breathing cannot be established once the airways are

cleared and the patients spontaneous breathing must be assisted or controlled if it is inadequate.

4.4 Mask ventilation

Proceed as follows:

- lay the patient on his back
- extend the head and neck
- pull the red ring on the COMBIBAG relief valve upwards (pressure limit 20 mbar/cm H_2O)
- C-grip: left hand lifts the lower jaw back and seals the mask over the mouth and nose
- rhythmically squeeze and release the appropriate segment (adult and infant) at the recommended frequency
- if necessary, insert a Wendl-airway through the nose or use a Guedel-airway to improve access to the nasopharyngeal cavity
- the mask must seal tightly
- the red ring on the relief valve should be pushed down (pressure limit 60 mbar/cm H_2O) in exceptional cases only, where adequate ventilation still cannot be achieved. However, inflation of the stomach is not then excluded and must be considered!

4.5 Ventilation via an endotracheal tube

To prevent additional complications (overinflation of the stomach with consequent aspiration), ventilation via a correctly placed endotracheal tube is to be aimed at wherever possible:

- Intubation
- Press the red ring on the COMBIBAG relief valve downwards (pressure limit 60 mbar/cm H_2O)
- Even with ventilation via an endotrachel tube, one should aim for a pressure limit of 20 mbar/cm H_2O in order to limit the drop in the heart circulation time caused by increase in resistance in the pulmonary circulation.

4.6 Increasing the oxygen concentration

In emergency situations, oxygen concentrations above that in the ambient air (21 vol. %), or even 100% oxygen may be indicated, since oxygen deficiency often has to be reckoned with at the first supply phase. Any oxygen concentration can be administered with the COMBIBAG resuscitator. Oxygen concentrations up to 48% can be administered directly via the oxygen socket on the intake connection. If a higher concentration of oxygen is to be administered, an oxygen reservoir or a demand valve can be used.

Connect corrugated hose

- Fit the oxygen reservoir into the cone on the intake socket and
- push the oxygen connecting tube onto the connector at the end of the corrugated hose.

Connect demand valve

- Attach demand valve with appropriate adapter WM 22169.
- Follow the instructions for use for the demand valve.

4.7 PEEP ventilation

Many disturbances in lung function (disturbances in distribution, exudation, atelectasis, etc.) can be prevented, or their effects reduced, by application of a Positive-End-Expiratory-Pressure (PEEP).

A PEEP valve can be fitted directly to the exhalation passage of the patient valve.

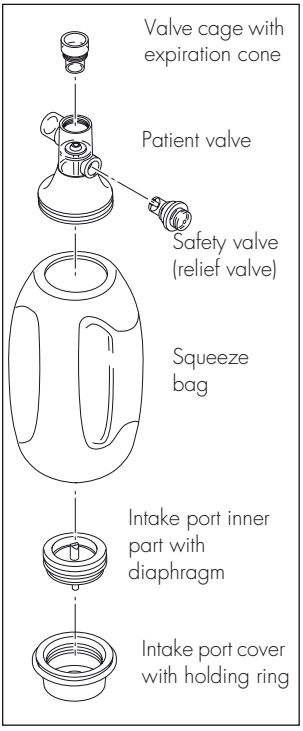
4.8 Volume measurement

To prevent hypo- or hyperventilation in the case of prolonged manual resuscitation with the COMBIBAG, a volumeter for measuring the expired gas volume can be connected to the expiration branch of the patient valve.

4.9 Use of HME-Filters

For hygienical reasons and for climatizing the breathing air, the inspiratory branch of the patient valve can be fitted with commercial 15/22 mm standard cone HME-filters (heat and moisture exchanger). This insignificantly increases the inspiratory as well as the expiratory resistance. The extend of the death space volume has to be considered particularly with children. Observe the operating instructions of the manufacturer and chapter "3. Safety instructions" on page 9.

5. Hygienic preparation



COMBIBAG should undergo hygienic purification after every use.

Upon completion of the purification process, carry out a functional test.

Individual parts of the COMBIBAG resuscitator are made of silicon or polysufone.

Use soapy water to **clean** COMBIBAG and rinse under running water. For cleaning purposes, take apart the bag, separating the pieces into components as described.

Warning: When assembling or disassembling

COMBIBAG, do not use any sharp-edged objects.

The patient valve does not have to be dismantled in order to be cleaned!

Should you choose to dismantle the valve anyway, **do not unscrew the cap of the valve** since that could change the pressure setting of the valve.

To **disinfect** the equipment, use a disinfectant that is suitable for rubber and polysulfone. Be sure to observe the instructions for the disinfectant. We recommend GIGASEPT FF.

Sterilization with steam, hot air or gas should be carried out according to standard practices after careful cleaning of the individual parts.

The oxygen reservoir **cannot be sterilized**. It should be cleaned and disinfected.

5.1 Cleaning during use

Should the valve become blocked as a result of regurgitation, clean it as follows:

- Unscrew the valve cage.
- Clean the valve element and valve body with the finger or by gentle tapping.
- Rapidly squeeze the bag several times to blow out any foreign particles.
- Screw in the valve cage, check the function and continue ventilation.

Note: Always check the function of the resuscitator after cleaning and re-assembly!

- Partially cover the patient connection.
- Squeeze the bag and check the valve element for correct function and leak-tightness (see "4.2 Checking the function" on page 10).

5.2 Maintenance and service

With proper use and maintenance of the COMBIBAG no additional service is required. Just the intake diaphragm should be examined once a year. The diaphragm is ready for proper use if no cracking spots are visible.

Wavy, distorted or sticked items have to be replaced.

A frequent functional check is recommended to be carried out according to Pt. "4.2 Checking the function".

6. Spare parts

6.1 Standard scope of supply

Item no.*	Description of component	Order no.
	COMBIBAG resuscitation bag for adults and children, without face masks	WM 11090
22	COMBIBAG resuscitation bag for adults and children with 1 face mask, consisting of: – COMBIBAG resuscitation bag – ventilation mask with inflatable silicone cushion for adults, Size 5 – COMBIBAG operating instructions	WM 11020 WM 11000 WM 5074 WM 16009
22 **23**	COMBIBAG resuscitation bag for adults and children with 2 masks, consisting of: – COMBIBAG resuscitation bag – ventilation mask with inflatable silicone cushion for adults, Size 5 – ventilation mask with inflatable silicone cushion for children and young people, Size 3 – COMBIBAG operating instructions	WM 11025 WM 11000 WM 5074 WM 5082 WM 16009
	COMBIBAG resuscitation bag for adults and children with 2 face masks, consisting of: – COMBIBAG resuscitation bag – silicone ventilation mask for adults, Size 5 – silicone ventilation mask for young people, Size 3 – COMBIBAG operating instructions	WM 11026 WM 11000 WM 5084 WM 5083 WM 16009

Item no.*	Description of component	Order no.
	COMBIBAG resuscitation bag for adults and children with 3 face masks, consisting of:	WM 11050
	– COMBIBAG resuscitation bag	WM 11000
22	– ventilation mask with inflatable silicone cushion for adults, Size 5	WM 5074
23	– ventilation mask with inflatable silicone cushion for children and young people, Size 3	WM 5082
24	– ventilation mask with inflatable silicone cushion for babies, Size 1	WM 5086
	– COMBIBAG operating instructions	WM 16009

*See illustration on page 21.

6.2 Accessories

Item no.*	Description of component	Order no.
	PEEP valve with tapered connector, infinitely adjustable from 0 - 10 mbar (22 mm external diameter)	WM 3215
14 – 17	Oxygen reservoir for COMBIBAG	WM 11052

*See illustration on page 21.

The following combination units with adapter are available for WEINMANN COMBIBAG DEMAND resuscitation bags:

Item no.*	Description of component	Order no.
	Spiracle demand valve with pressure tube 1,500 mm, G 3/8" connection	WM 22127
	Spiracle demand valve with pressure tube 1,500 mm, sealing nipple, Walther type	WM 22128
	Spiracle demand valve with pressure tube 1,500 mm, DIN 13260 connector	WM 22129
	Ventilation mask, transparent, with inflatable silicone cushion:	
22	– Adult size 5	WM 5074
23	– Children and young people, Size 3	WM 5082
24	– Babies and small children, Size 1	WM 5086

Item no.*	Description of component	Order no.
	Ventilation mask, all-in-one, silicone – Size 5 – Size 4 – Size 3 – Size 2 – Size 1 – Size 0	 WM 5084 WM 5085 WM 5083 WM 5092 WM 5091 WM 5090
 21 **20** **19** **18**	Rendell-Baker ventilation mask, silicone: – Children, Size 3 – Children, Size 2 – Small children, Size 1 – Babies, Size 0	 WM 5063 WM 5062 WM 5061 WM 5060
 21 **20** **19** **18**	Set of Rendell-Baker ventilation masks, silicone, consisting of 1 ventilation mask each – for children from 3-12 years (WM 5063), – for children from 1-3 years (WM 5062), – for small children up to one year old (WM 5061), – for infants (WM 5060)	 WM 15482
	Set of oropharyngeal tubes (Guedel type) consisting of 1 tube each – for adults, Size 3, – for young people, Size 2, – for children, Size 1, – for small children, Size 0, – for infants, Size 000	 WM 15483

*See illustration on page 21.

6.3 Spare parts

For COMBIBAG

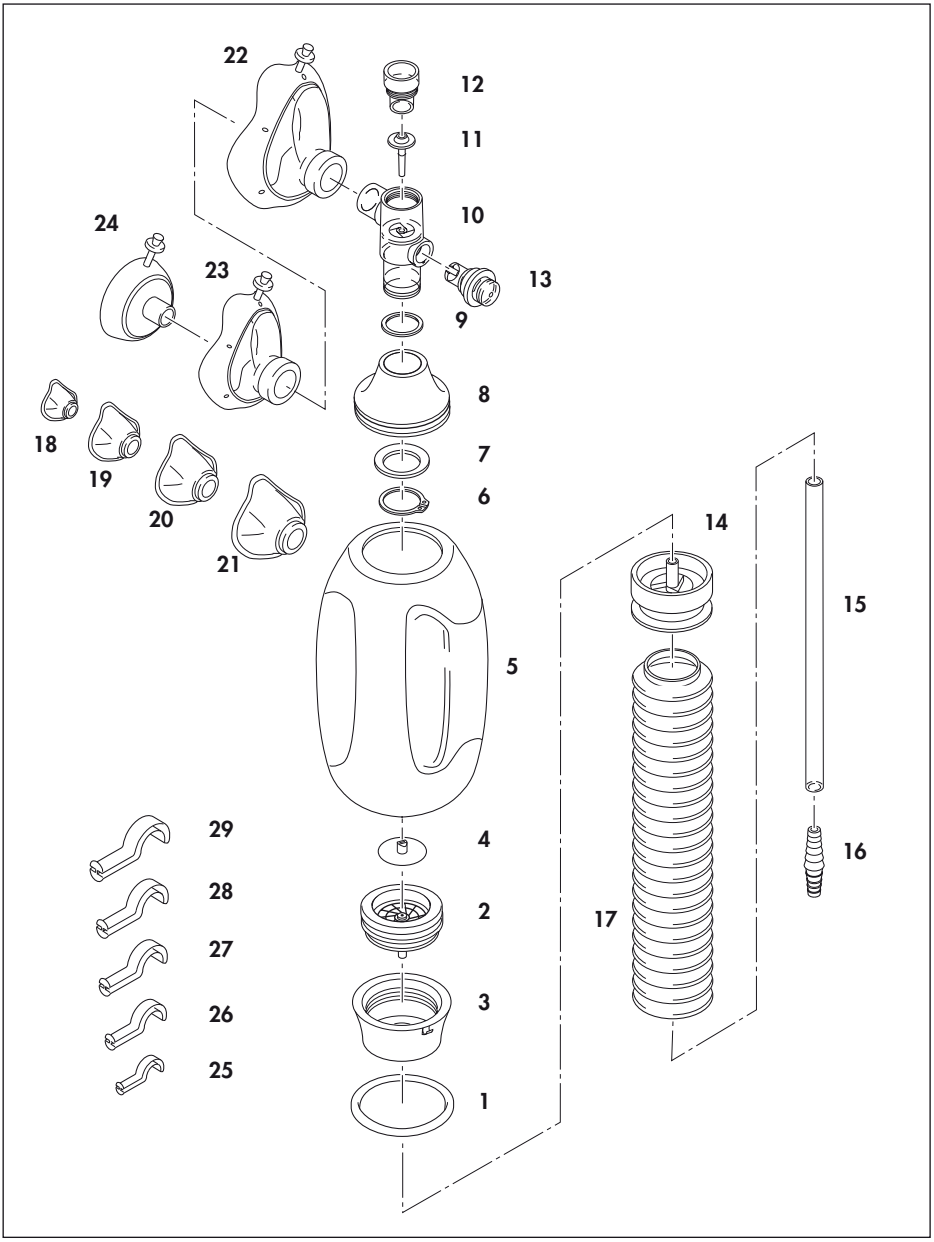
Item no.*	Description of component	Order no.
	COMBIBAG resuscitation bag for adults and children	WM 11000
	Cord ring, Ø 42 mm (old suspension ring)	WM 1145/43
1	Suspension ring, new, Ø 60 mm	WM 1145/49

Item no.*	Description of component	Order no.
	Seal 30/35 x 0.5 mm	WM 1145/82
5	Bellows	WM 11001
	Valve housing	WM 11002
6 – 12	Ventilation valve, without safety valve	WM 11003
	Guide stub	WM 11004
	Valve element	WM 11006
	Valve insert	WM 11007
4	Inlet membrane	WM 11008
2	Intake stub, inner part	WM 11021
3	Intake stub, outer part	WM 11022
13	2-stage safety valve	WM 11030
6 – 13	Ventilation valve, complete	WM 11035
	Disk spring	WM 11043
	Intake stub with inlet membrane	WM 11051
	Adapter for OXYMAND demand valve, 17 mm internal diameter, 24 mm external diameter	WM 22169
	Lockring 30 x 1.5 mm	WM 50455

*See illustration on page 21.

For ventilation masks

Description of component	Order no.
Mask binding ring (for WM 5074 and WM 5082)	WM 11073
Sealing plug (for WM 5074, WM 5082, WM 5086)	WM 11074
Inflatable silicone mask cushion (for WM 5074)	WM 11086
Inflatable silicone mask cushion (for WM 5082)	WM 11087
Inflatable silicone mask cushion (for WM 5086)	WM 11088
Mask body (for WM 5074)	WM 11097
Mask body (for WM 5082)	WM 11098
Mask body (for WM 5086)	WM 11099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7. Technical and performance data

	COMBIBAG
Classification acc. to EC directive 93/42/EEC	IIa
Dimensions (L x D)	340 mm x 130 mm (inflated)
Weight	390 g
Scope of use: – Child grip – adult grip	 10 – 16 kg body weight >16 kg body weight
Pressure relief	optionally 20 mbar and 60 mbar
Resistance of inspiration	2.17 mbar at 50 l/min
Resistance of expiration	2.23 mbar at 50 l/min
Patient access	15 mm tapered connecting socket and 22 mm tapered plug according to ISO 5356
Expiration branch	30 mm tapered plug according to ISO 5356
Junction for oxygen intake	nozzle Ø 6 mm
Dead space	5 ml
Forward leak	0.05 l
Temperature range – Storage – Operation	 –40 °C to +70 °C –18 °C to +50 °C
Materials – Valves – Squeeze bag (compressable unit), valve diaphragms	 polysulphone silicone

Tidal volumes and respiratory frequencies (cycles per minute)

The follwing frequencies and tidal volumes are obtained during ventilation with COMBIBAG:

	Cycles per min.	Tidal volume in ml
Child grip 2 fingers 3 fingers 4 fingers hand	> 60	 150 150 - 200 200 - 300 300 - 500
Adult grip 1 hand 2 hands	> 25	500 - 950 1200

Inspiratory Oxygen concentration

The oxygen concentration achievable during ventilation depends on the oxygen flow set, the minute volume and the respiratory frequency. The follwing oxygen concentrations are achieved, depending upon the type of oxygen supply (direct supply or oxygen supply with reservoir):

Flow	Adults		Children			
			ganze Hand		3 Finger	
	without reservoir	with reservoir	without reservoir	with reservoir	without reservoir	with reservoir
l/min	%	%	%	%	%	%
2	28	35	31	37	35	46
4	36	48	36	52	43	70
6	39	59	40	65	47	83
9	43	73	46	79	53	95
12	46	83	49	90	58	100
15	48	87	53	96	59	100

CE 0197

Frequency:

adults:	12/min
children, hand:	20/min
children, 3 fingers:	25/min

8. Warranty

- WEINMANN offers a warranty that the product, when used in accordance with requirements, will remain free from defects for a period of two years from date of purchase. For products whose durability is clearly indicated as less than two years, the warranty expires on the expiration date indicated on the packaging or in the user's manual.
- Claims against the warranty can be made only when accompanied by the sales receipt, which must show salesperson and date of purchase.
- We offer no warranty in the case of:
  - Disregard of usage instructions
  - Operating errors
  - Improper use or handling
  - Third-party intervention by non-authorized persons for the purpose of device repair
  - Acts of God, e.g., lightning strikes, etc.
  - Transport damage as a result of improper packaging of returned items
  - Lack of maintenance
  - Operational and normal wear and tear, which includes, for example, the following components.
    - Filter
    - Batteries and recheargable batteries
    - Articles for one-time usage, etc.
  - failure to use original spare parts.
- WEINMANN is not liable for consequential harm caused by a defect if it is not based on intention or gross negligence. WEINMANN is also not liable for minor physical injury to life or limb resulting from negligence.
- WEINMANN reserves the right to decide whether to eliminate defects, to deliver a defect-free item or to reduce the purchase price by a reasonable amount.
- If WEINMANN rejects a claim against the warranty, it assumes no expense for transport between customer and manufacturer.
- Implied warranty claims remain unaffected by these changes.

9. Declaration of conformity

WEINMANN Geräte für Medizin GmbH + Co. KG declares herewith that the product complies fully with the respective regulations of the Medical Device Directive 93/42/EEC. The unabridged text of the Declaration of Conformity can be found on our website at www.weinmann.de

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