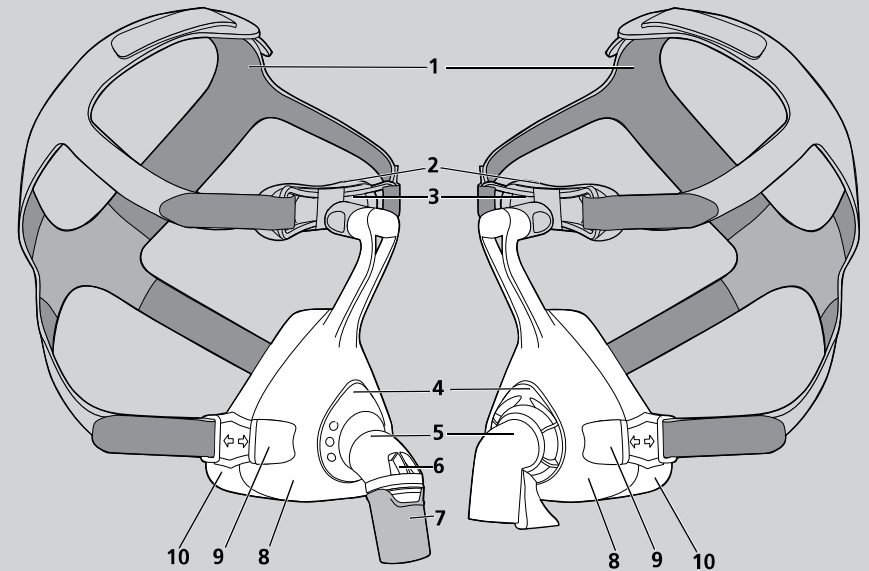


EN Instructions for Use PT Instruções de uso RU Инструкция по пользованию
PL Instrukcja obsługi HR Uputa za uporabu EL Οδηγίες χρήσης CS Návod k použití
SK Návod na použitie DA Brugsanvisning NO Bruksanvisning SV Bruksanvisning
FI Käyttöohje SR Uputstvo za upotrebu MK Патство за употреба

LMT 67376d 10/2022 EN, PT(BR), RU, PL, HR, EL, CS, SK, DA, NO, SV, FI, SR, MK



CE 0197



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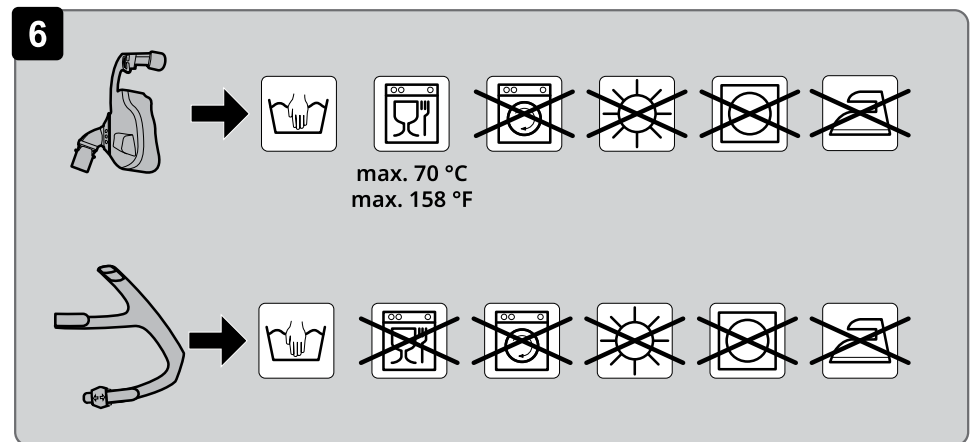
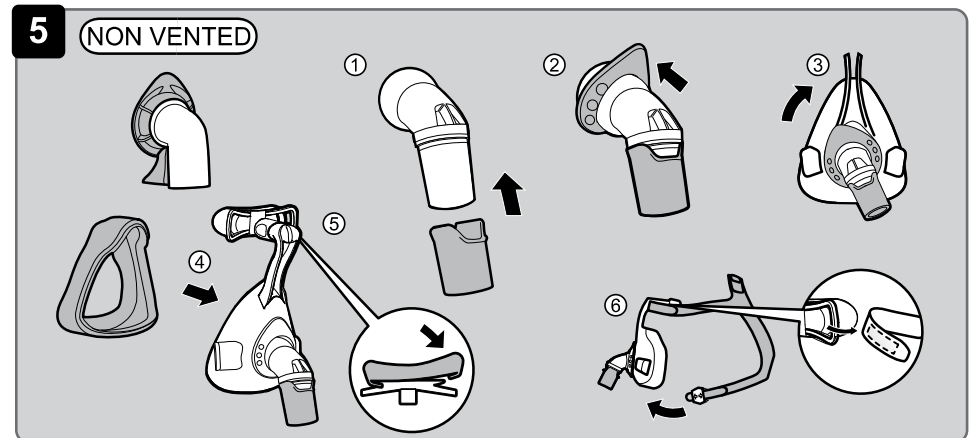
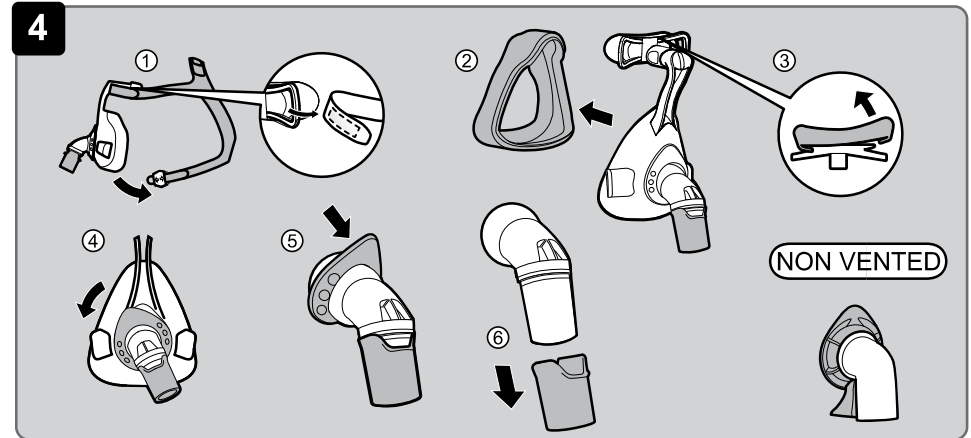
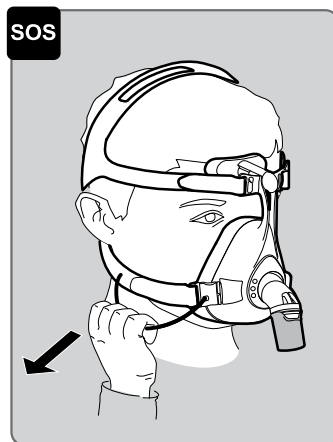
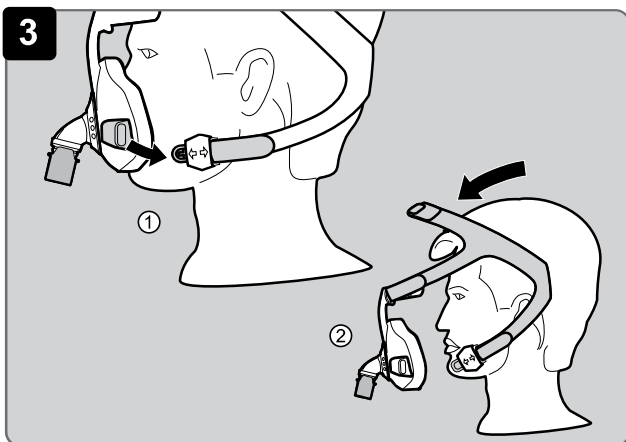
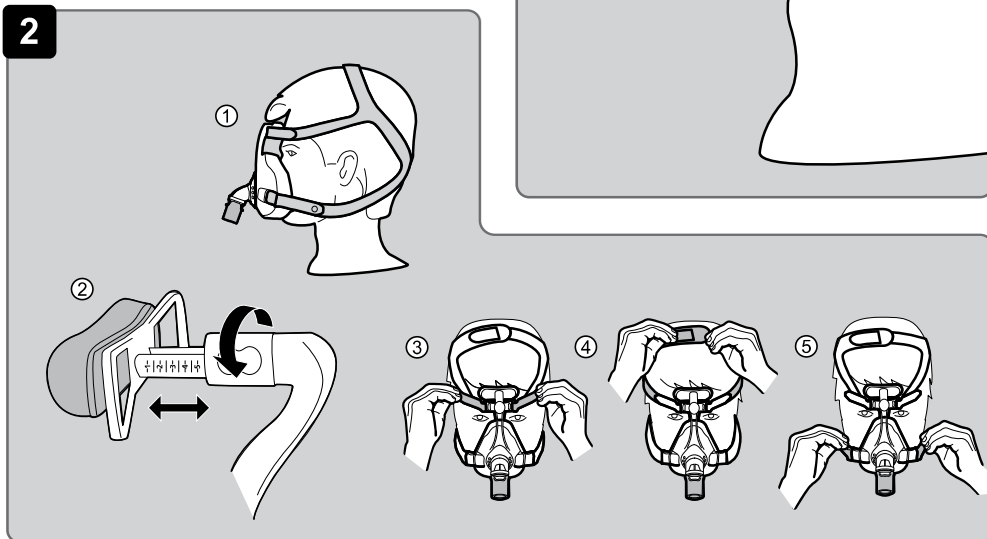
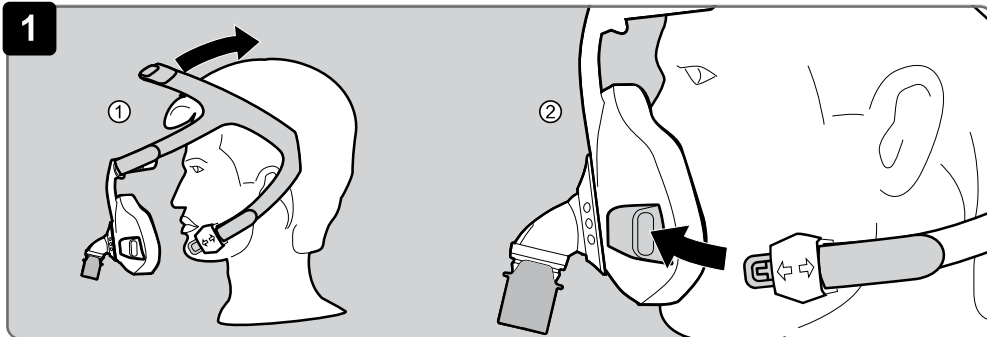
JOYCEeasy Full Face
JOYCEeasy next Full Face
JOYCEeasy next Full Face NV
Full Face Mask
vented, non vented



LMT 67376d

LÖWENSTEIN
medical

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Mask part	Material
Mask cushion, forehead cushion	SI (Silicone)
Retaining ring (hard component)	PP (polypropylene)
Retaining ring (soft component)	TPE (thermoplastic elastomer)
Headgear clip	PA (polyamide), POM (polyoxymethylene)
Forehead support, rotating sleeve, mask body, elbow	PA (polyamide)
Headgear	EL (elastane), PES (polyester), PU (polyurethane), UBL loop, CO (cotton), PA (polyamide)
Anti-asphyxia valve, valve safety device	SI (Silicone), PP (polypropylene)
Quick-release cord	POM (polyoxymethylene), PES (polyester), PA (polyamide)

No parts of the mask contain latex, PVC (polyvinyl chloride) or DEHP (diethylhexyl phthalate).

11 Markings and symbols

The following symbols may be applied to the device, the device label, accessories or packaging.

Symbol	Description
	Unique device identifier (uniform product code for medical devices)
	Permitted temperature range for transport and storage
	Use by date
	Keep out of sunlight
	Order number
	Indicates the product is a medical device
	Lot number
	Manufacturer and, if necessary, date of manufacture
	Follow the instructions for use

Symbol	Description
	CE symbol (confirms that the product conforms to the applicable European directives/regulations)

12 Warranty

Löwenstein Medical Technology gives the customer a limited manufacturer warranty on new original Löwenstein Medical Technology products and any replacement part fitted by Löwenstein Medical Technology in accordance with the warranty conditions applicable to the product in question and in accordance with the warranty periods from date of purchase as listed below. The warranty conditions are available on the website of the manufacturer. We will also send you the warranty conditions on request.

Please bear in mind that any claim to warranty and liability shall be void if neither the accessories recommended in the instructions for use nor genuine replacement parts are used.

In the event of a claim under warranty, contact your specialist dealer.

Product	Warranty periods
Masks including accessories	6 months






13 Declaration of conformity

The manufacturer Löwenstein Medical Technology GmbH + Co. KG (Kronsaalweg 40, 22525 Hamburg, Germany) hereby declares that the product complies with the relevant regulations of the Medical Device Regulations (EU) 2017/745. The unabridged text of the Declaration of Conformity can be found on the manufacturer's website.

In the EU: As a user and/or patient, you must report any serious incidents occurring in conjunction with the product to the manufacturer and to the responsible authority.

1 Operation

The following figures show you how to adjust, apply, remove, dismantle and assemble the mask:

-  Putting on the mask
-  Adjusting the mask
-  Removing the mask
-  Dismantling the mask
-  Assembling the mask

2 Introduction

2.1 Intended use

The JOYCEasy Full Face / JOYCEasy next Full Face mask is used for treating sleep apnea and for non-invasive and non-life-sustaining ventilation of patients with respiratory insufficiency. It serves as a connecting element between the patient and the therapy device. Use non-vented full face masks only in combinations with therapy devices that have an active exhalation valve.

2.2 Contraindications

The mask may not be used in the following situations: Immediate intubation required; loss of consciousness, acute vomiting.

The mask may be used in the following situations only with particular caution: Pressure points and acute injuries to the skin of the face; skin allergies involving the face; deformities of the face or nasopharynx; acute pain affecting the face; cough reflex restricted or absent; claustrophobia; acute nausea. If you are not certain whether one of these situations applies to you, please consult your attending physician or medical advisor. Please also observe the contraindications in the instructions for use of your therapy device.

2.3 Side effects

The following side effects may occur with use of the mask: nasal congestion, dry nose, dry mouth in the morning, feeling of pressure in the sinuses, irritated conjunctiva, skin rashes, pressure marks on the face, irritating noises when breathing. Should such side effects occur, please contact your attending physician or medical advisor.

3 Safety

Risk of injury from mask parts breaking off!

Deteriorated mask parts or those under severe strain may come off and put the patient at risk.

- ⇒ Note useful life.
- ⇒ Check mask parts regularly and replace prematurely if necessary.

Risk of injury from excessive leaking!

Excessive leaking may lead to under-supply to the patient.

⇒ Activate low pressure/leak alarms on the therapy device.

⇒ Use the correct mask size and check that it is securely in position.

Risk of injury from the supply of oxygen!

Oxygen can become deposited in clothing, bedlinen and hair. In conjunction with smoking, naked flames or electrical equipment, it can cause fires and explosions.

- ⇒ Do not smoke.
- ⇒ Avoid naked flames.

Risk of injury from re-inhaling CO₂!

If the mask is used incorrectly, CO₂ may be re-inhaled.

- ⇒ Do not close off the exhalation system of the mask.
- ⇒ Only put on the mask for an extended period if the therapy device is running.

⇒ Only use the mask within the quoted therapy pressure range.

⇒ Do not use the mask on patients who are unable to take it off themselves.

Risk of injury if the mask slips!

If the mask slips or falls off, the therapy is ineffective.

- ⇒ Monitor patients with restricted spontaneous respiration.
- ⇒ Activate low pressure/leakage alarms on the therapy device.

Risk of injury from anesthetic gases!

Anesthetic gas may escape through the exhalation valve and put third parties at risk.

⇒ Never use the mask during anesthesia.

Risk of injury from lack of cleaning!

The mask may show contamination, which can possibly put the patient at risk.

- ⇒ Clean the mask before using for the first time (see section entitled "Cleaning and hygiene treatment").
- ⇒ Clean the mask regularly.

4 Product description

4.1 Overview

A diagram of the individual parts can be found on the title page.

1. Headgear
2. Forehead cushion
3. Forehead support
4. Retaining ring
5. Elbow
6. Anti-asphyxia valve (only vented)
7. Rotating sleeve (only vented)
8. Mask body
9. Headgear clip
10. Mask cushion

4.2 Compatible devices

With many combinations of device, actual pressure in the mask will not correspond to prescribed therapy pressure, even if the therapy device is displaying the correct pressure. Have the combination of devices adjusted by a physician or specialist dealer so that actual pressure in the mask corresponds to therapy pressure. The therapy pressure required may vary between different mask types, so prescription of a suitable therapy pressure should in each case involve adjusting/adapting therapy to suit the mask type which is also going to be used during therapy itself.

4.3 Exhalation system

vented variants

Vented variants (transparent elbow and rotating sleeve) have an integrated exhalation system. The retaining ring and mask body are shaped so that there is a gap between these parts. The exhaled air can escape through this gap.

Non-vented variants

Non-vented variants (blue retaining ring and elbow) do not have an exhalation system. Only use non-vented full-face masks in combination with therapy devices which have an active exhalation valve and have alarms and safety systems for any device failure. If you are using the non-vented variant with an external exhalation valve, please see the associated instructions for use.

4.4 Anti-asphyxia valve

⚠ WARNING

Risk of asphyxia if anti-asphyxia valve not working properly!

Residues may cause the valve to stick and lead to CO₂ being re-inhaled.

⇒ Check before every use that the openings of the anti-asphyxia valve are clear.

If the therapy device fails, the anti-asphyxia valve opens so that the patient can breathe ambient air.

5 Cleaning and hygiene treatment

⚠ WARNING

Risk of injury from inadequate cleaning!

Residues may congest the mask, impair the integrated exhalation system and jeopardize therapy success.

⇒ For patients with a compromised immune system or particular background of illness, disinfect mask components daily following consultation with the physician.

5.1 Clean mask

1. Wash your hands before cleaning.
2. Dismantle mask (see Figure 4).
3. Clean mask in accordance with the table below:

Action	Daily	Weekly
Wash mask parts by hand in hot water (approx. 30 °C) and with mild detergent (1 ml detergent to 1 l water) for 15 minutes.	X	
Clean mask parts thoroughly with a cloth or a soft brush for at least 3 minutes when washing. Or: Put mask parts in the top basket of the dishwasher. Select a washing program with a max. temperature of 70 °C and a max. time of 90 minutes. Use a mild dishwasher detergent (1 ml dishwasher detergent to 1 l water). Only wash mask parts in a dishwasher separately, do not mix with dirty crockery.		X
Wash the headgear by hand in hot water (approx. 30 °C) and with mild detergent (1 ml detergent to 1 l water) for 15 minutes.		X

4. Rinse all parts with clear water.
5. Allow all parts to air-dry.
6. Perform a visual inspection.
7. If necessary: replace damaged parts.
8. Re-assemble mask (see Figure 5).



Discolorations of mask components do not impair the functionality of the mask.

5.2 Hygiene treatment (clinical sphere)

On change of patient, inadequate hygiene treatment may lead to a risk of infection for the patient. In the event of a change of patient, subject the mask to a hygiene treatment in line with the "Information on hygiene treatment" brochure. The brochure can be found on the manufacturer's website. We will send you this brochure on request.

6 Disposal

You can dispose of all parts in domestic waste.

7 Troubleshooting

Fault	Cause	Remedy
Pain from pressure on the face.	Mask too tight.	Loosen headgear slightly.
Draft in the eye.	Mask too loose.	Tighten headgear slightly.
	Mask does not fit.	Contact your specialist dealer.
Therapy pressure is not reached.	Mask not correctly adjusted.	Re-adjust mask (see Figure 2).
	Mask cushion amaged.	Replace mask cushion.
	Patient circuit leaking.	Check connectors, check tubes properly located.
	Anti-asphyxia valve defective (only vented).	Replace anti-asphyxia valve.

8 Technical specifications

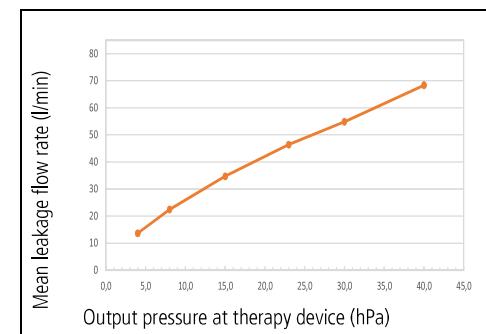
Product class to MDR (EU) 2017/745	IIa
Dimensions (W x H x D)	
Size S	90 mm x 145 mm x 101 mm
Size M	90 mm x 155 mm x 101 mm
Size L	96 mm x 170 mm x 105 mm
Weight	
Size S	120 g
Size M	126 g
Size L	134 g
Death space volume	
Size S	180 ml
Size M	210 ml
Size L	270 ml
Therapy pressure range	
JOYCEasy Full Face	4 hPa - 30 hPa
JOYCEasy next Full Face	4 hPa - 40 hPa
Tube connection: tapered connection to EN ISO 5356-1	
vented	Ø 22 mm (male)
non vented	Ø 22 mm (female)
Temperature range:	
Operation	+5 °C to +40 °C
Transport and storage	-20 °C to +70 °C

Flow resistance, vented at 50 l/min	0.3 hPa ± 0.1 hPa
at 100 l/min	0.7 hPa ± 0.1 hPa
Flow resistance, non-vented at 50 l/min	0.03 hPa ± 0.1 hPa
at 100 l/min	0.1 hPa ± 0.1 hPa
Flow resistance, anti-asphyxia valve (only vented)	
Inspiration at 50 l/min:	0.6 hPa ± 0.1 hPa
Exhalation at 50 l/min:	0.8 hPa ± 0.1 hPa
Switching pressure	
Anti-asphyxia valve (only vented)	
• Open:	≤ 0.5 hPa
• Close:	≤ 0.8 Pa
Quoted two-figure noise emission value to ISO 4871:	
- Sound pressure level	13 dB(A)
- Sound power level	21 dB(A)
- Uncertainty factor	3 dB(A)
Service life	5 years
Useful life	up to 12 months ¹
Standards applied	EN ISO 17510:2020

¹ The mask materials deteriorate if exposed to e.g. aggressive detergents. In individual cases it may be necessary to replace mask parts sooner.

9 Pressure/flow curve

The characteristic pressure/flow curve shows the leakage flow as a function of therapy pressure.



10 Materials

Only use the mask after consulting your physician if you are allergic to any of the following substances: