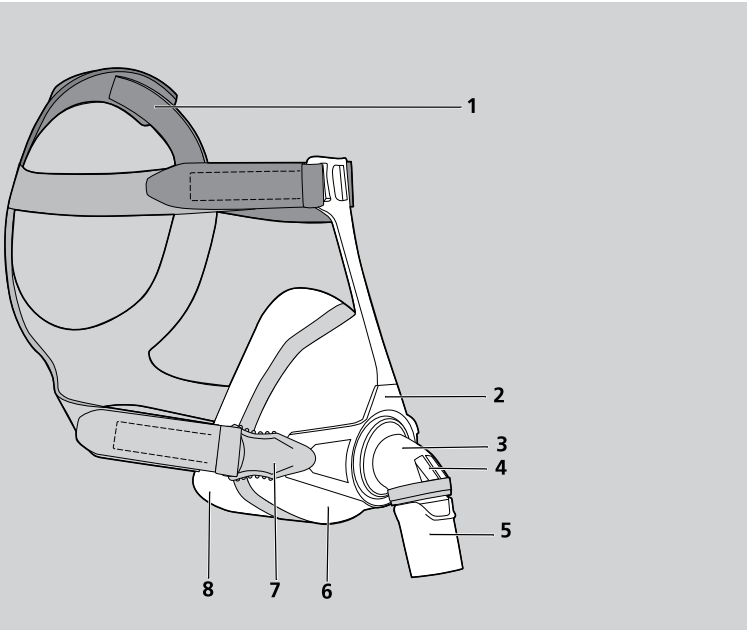
DE Gebrauchsanweisung **EN** Instructions for Use **FR** Mode d'emploi
NL Gebruiksaanwijzing **IT** Istruzioni d'uso **TR** Kullanma Kılavuzu
ES Manual de instrucciones

WM 68290g 06/2021 DE, EN, FR, NL, IT, TR, ES_MX



CARA Full Face

Full Face Mask

CE 0197

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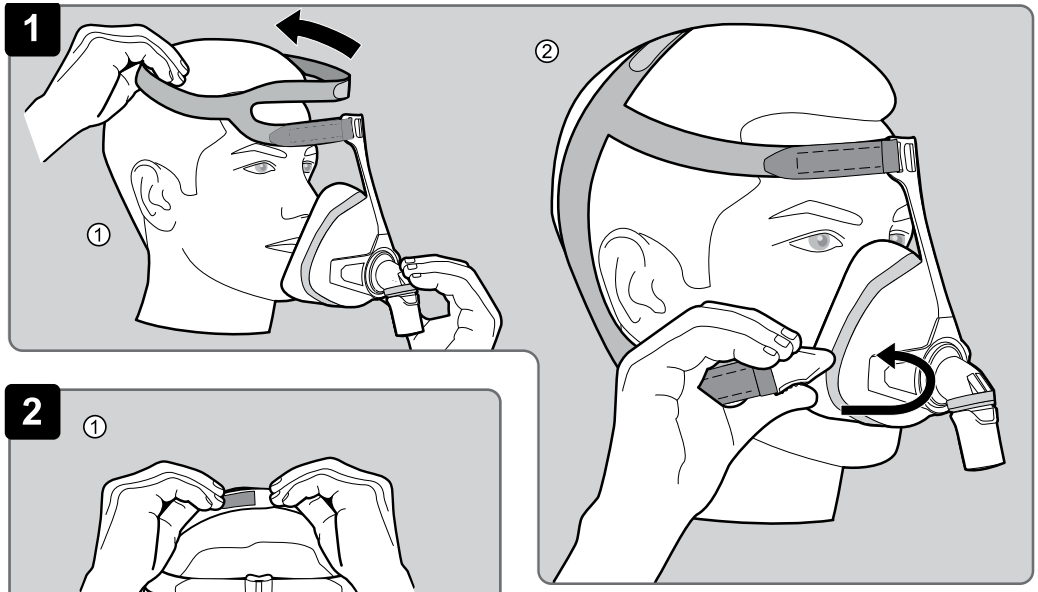
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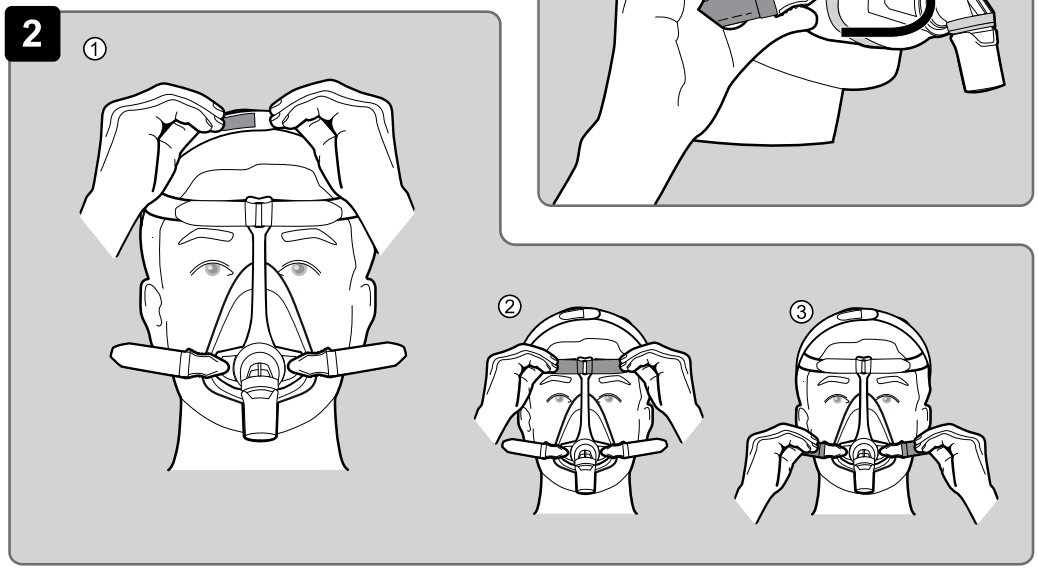
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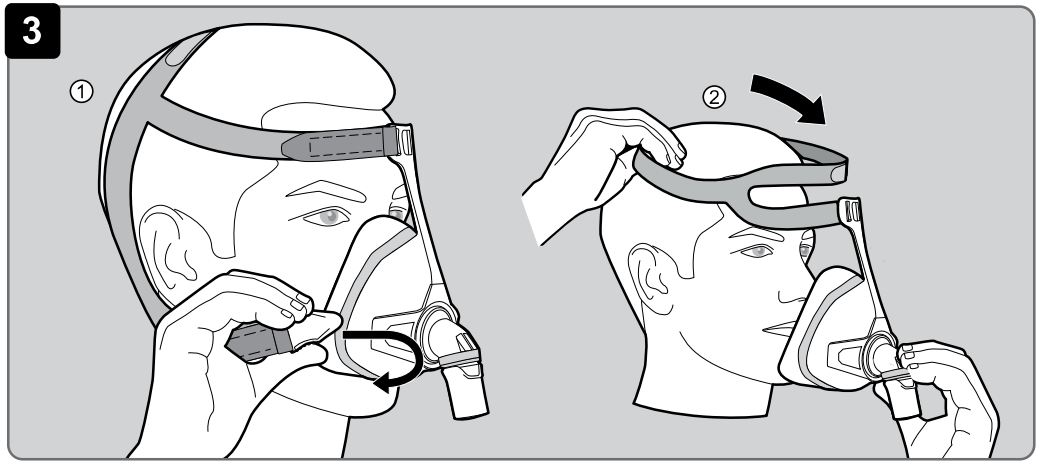
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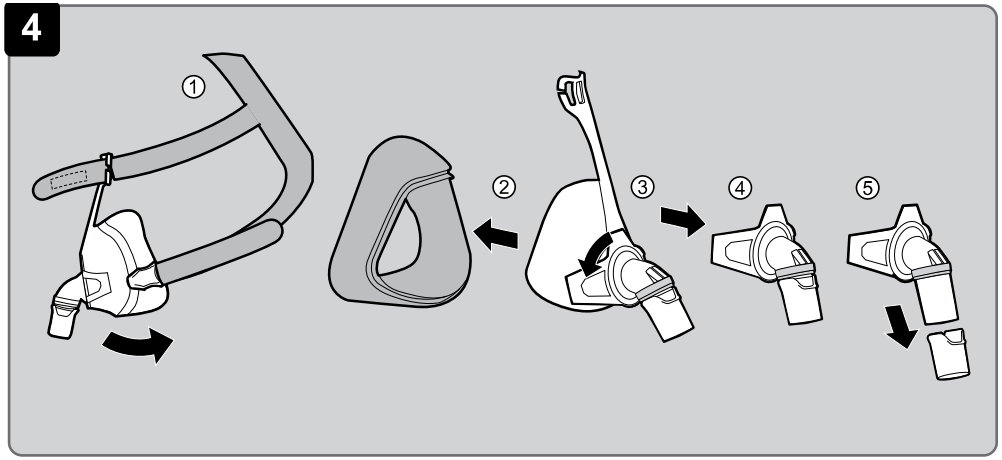
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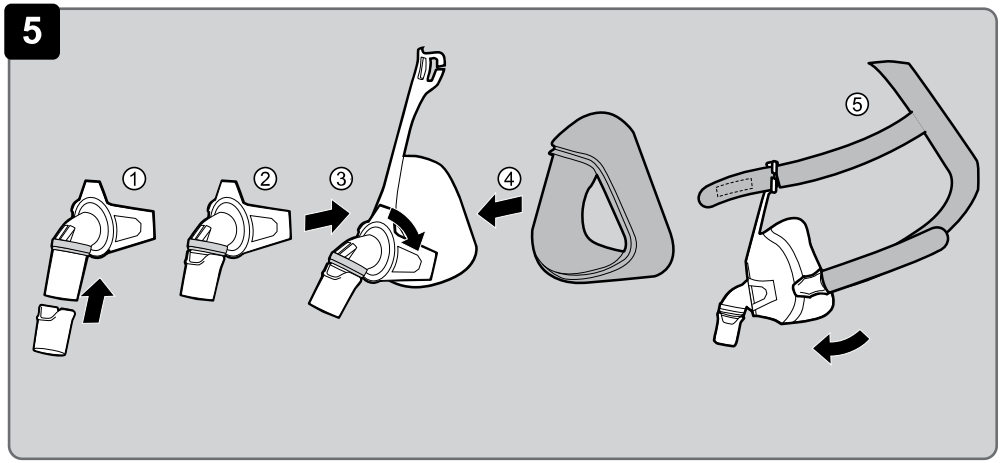
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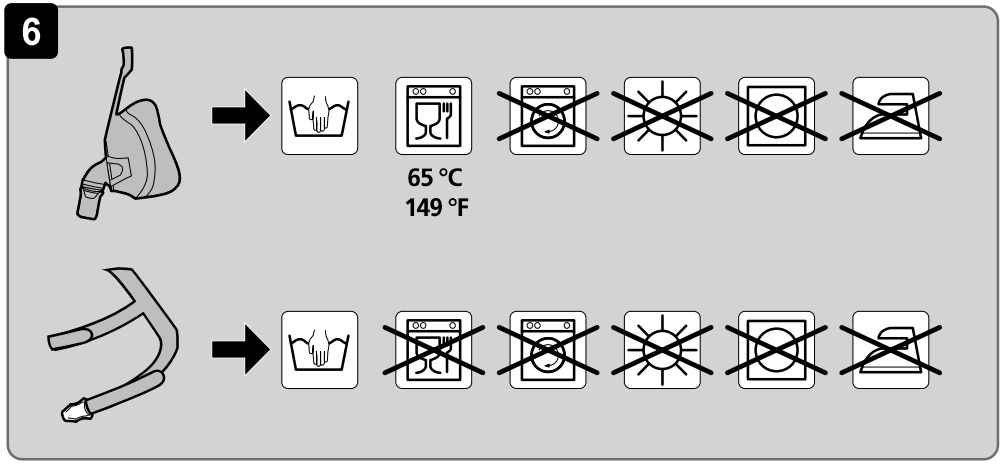
6
65 °C
149 °F

Mask part	Material
Mask cushion	SI (silicone)
Link	PA (polyamide)
Headgear clip	PA (polyamide)
Rotating sleeve, mask body, elbow	PA (polyamide)
Headgear	Elastane, polyester, PU (polyurethane), CO (cotton)
Emergency exhalation system: Elbow, anti-asphyxia valve, valve safety device	PA (polyamide), SI (silicone), PP (polypropylene)

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
UDI	Unique device identifier (uniform product code for medical devices)
	Permitted temperature range for transport and storage
	Keep out of sunlight
REF	Order number
MD	Indicates the product is a medical device
LOT	Lot number
	Manufacturer and, if necessary, date of manufacture
	Follow the instructions for use
CE 0197	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 GmbH + Co. KG (Kronsaalsweg 40, 22525 Hamburg, Germany) hereby declares that the product complies with the relevant provisions of the Medical Device Regulations (EU) 2017/745. The unabridged text of the Declaration of Conformity can be found on the manufacturer's website.

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1 Operation

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

1 Putting on the mask
2 Adjusting the mask
3 Removing the mask
4 Dismantling the mask
5 Assembling the mask

2 Introduction

2.1 Intended use

The CARA 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.

2.2 Contraindications

The mask may not be used in the following situations: necessity for immediate intubation; 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 facial skin; 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

3.1 Safety information

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 can 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 re-inhaling CO_2!
If the mask is used incorrectly, CO_2 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.
⇒ Patients who are unable to take the mask off themselves must be monitored by qualified nursing staff.

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.

3.2 General information

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.

4 Product description

4.1 Overview

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

1. Headgear
2. Link
3. Elbow

4. Anti-asphyxia valve
5. Rotating sleeve
6. Mask body
7. Headgear clip
8. Mask cushion

4.2 Compatible devices

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

The mask has an integrated exhalation system. The link and mask body are shaped so that there is a gap between these parts. The exhaled air can escape through this gap.

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 CO_2 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. Dismantle mask (see Figure 4).
2. Clean mask in accordance with the table below:

Action	Daily	Weekly
Wash mask components with warm water and a mild detergent.	X	
When washing mask parts, clean thoroughly with a cloth or a soft brush. Or: Put the mask parts in the dishwasher.		X
Wash headgear by hand.		X

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

ℹ 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 damaged.	Replace mask cushion.
	Patient circuit leaking.	Check connectors, check tubes properly located.
	Anti-asphyxia valve defective (only vented).	Replace the mask.

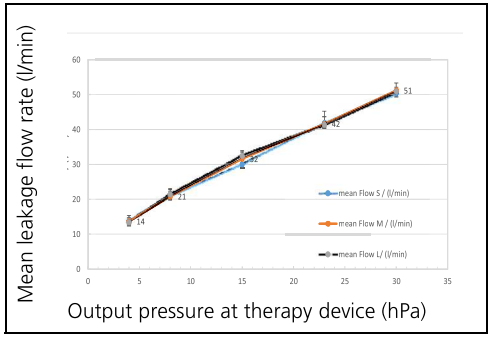
8 Technical specifications

Product class to (EU) Medical Device Regulations 2017/745	IIa
Dimensions (W x H x D) Size S Size M Size L	 93 mm x 145 mm x 89 mm 95 mm x 160 mm x 90 mm 95 mm x 174 mm x 91 mm
Weight Size S Size M Size L	 93 g 97 g 102 g
Dead space Size S Size M Size L	 180 ml 219 ml 244 ml
Therapy pressure range	4 hPa - 25 hPa
Tube connection: tapered connection to EN ISO 5356-1 vented	Ø 22 mm (male)
Temperature range: Operation Transport and storage	 +5 °C to + 40 °C -20 °C to +70 °C
Flow resistance at 50 l/min at 100 l/min	 0.15 hPa 0.5 hPa
Flow resistance, anti-asphyxia valve Inspiration at 50 l/min: Exhalation at 50 l/min:	 0.6 hPa 0.8 hPa
Switching pressure Anti-asphyxia valve • Open: • Close:	 0.5 hPa 2.2 hPa
Quoted two-figure noise emission value to ISO 4871: - Sound pressure level - Sound power level - Uncertainty factor	 19 dB(A) 27 dB(A) 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:

EN