EN Instructions for Use **ZH** 面罩

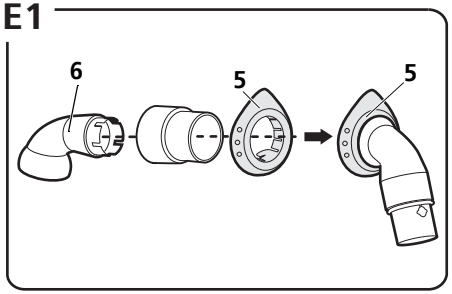
JOYCEeasy
JOYCEeasy Full Face
JOYCEeasy Full Face NV

Nasal Mask
Full Face Mask

面罩
使用说明书

LÖWENSTEIN
medical

E1



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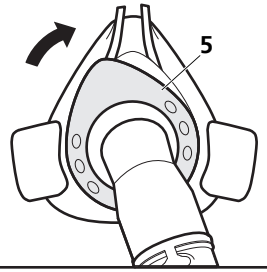

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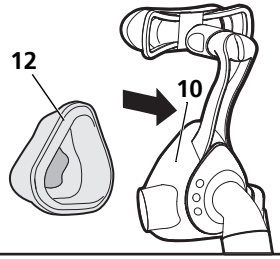

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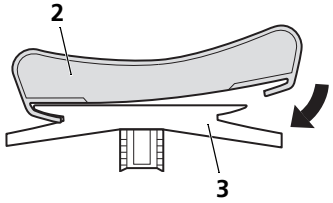

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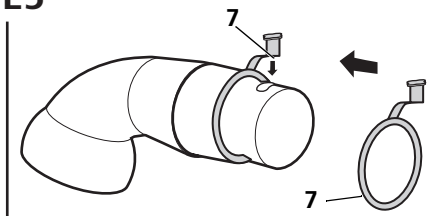

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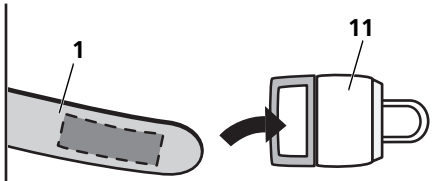

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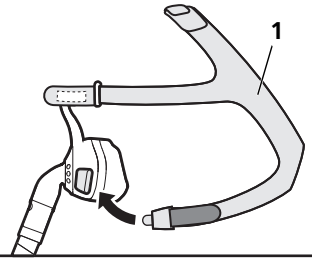

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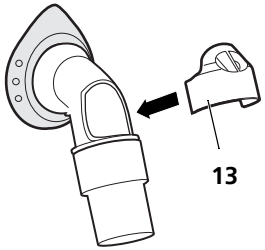

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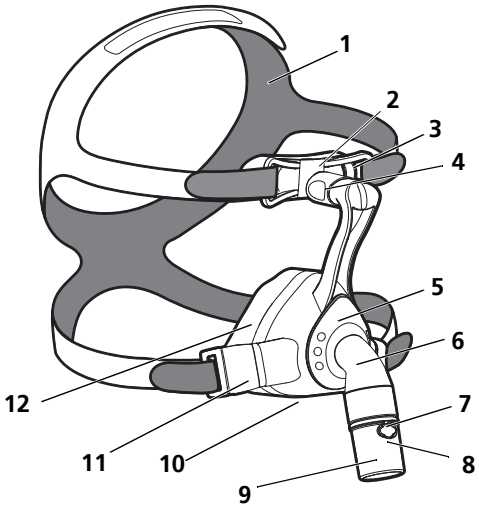

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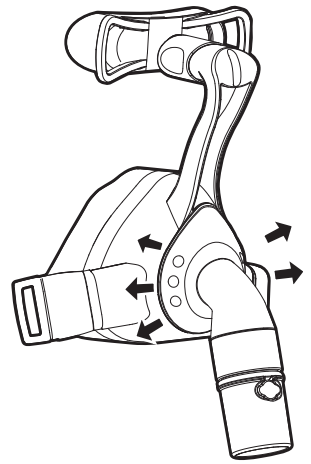

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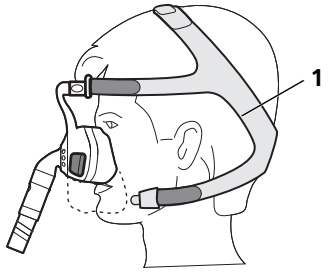

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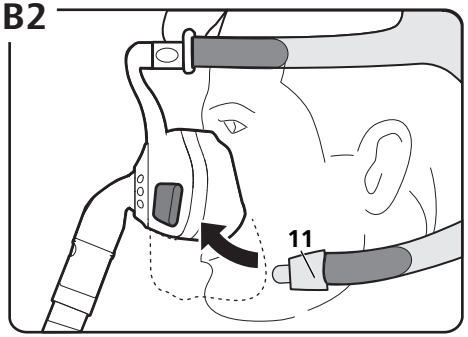

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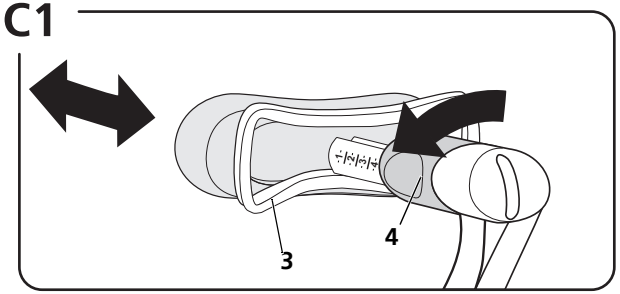
C1



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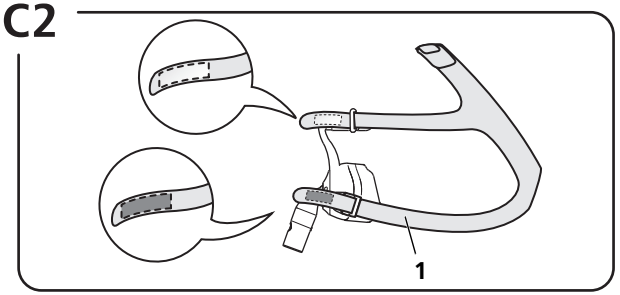

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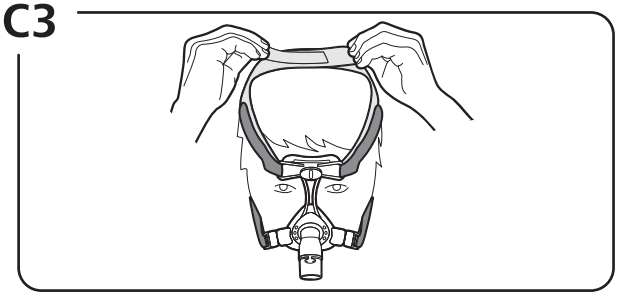

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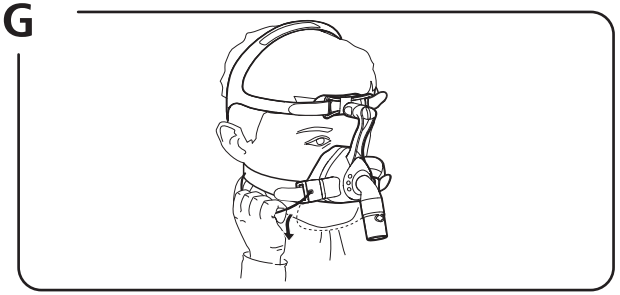

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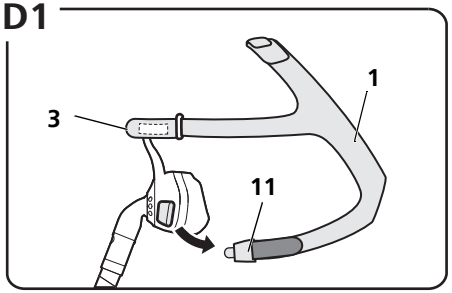

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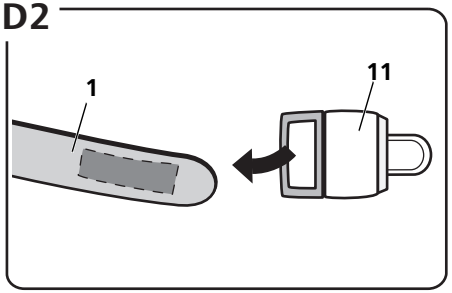

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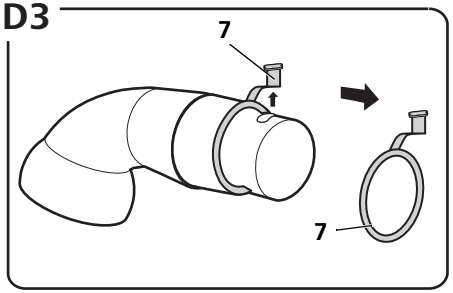

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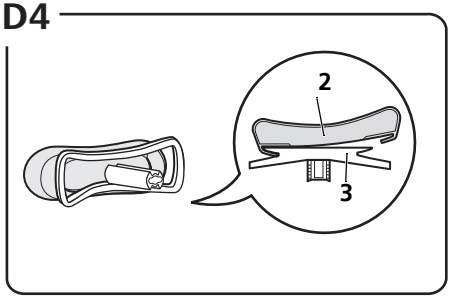

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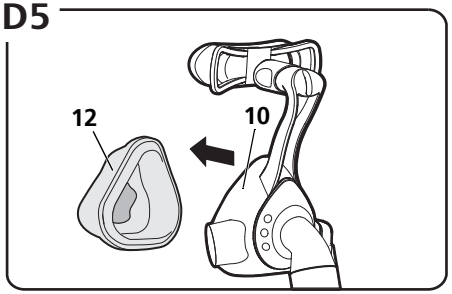

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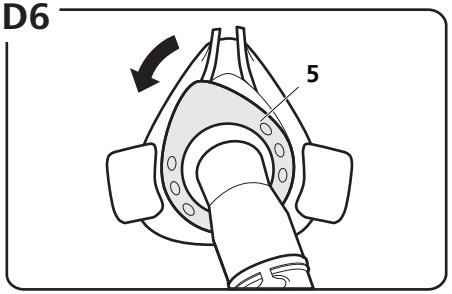

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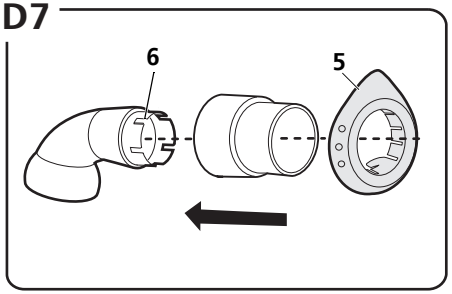

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Table of Contents

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1 Introduction

1.1 Model

JOYCEeasy, JOYCEeasy Full Face

1.2 Intended use

JOYCEeasy nasal masks and JOYCEeasy Full Face masks are 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.

1.3 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.

1.4 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.

1.5 Structure and components

The mask consists of a headgear, forehead cushion, forehead support, lock, retaining ring, elbow, plug for pressure measurement port, pressure measurement port, rotating sleeve, mask body, headgear clip, mask cushion and an anti-asphyxia valve (on full face masks only). The product is non-sterile and reusable.

2 Safety

Please read these instructions carefully. They are a constituent part of the mask and must be available at all times. In accordance with MDR (EU) 2017/745, observe the points below.

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2.1 Safety information

2.1.1Safety 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 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 deposit on clothing, bed linen and hair. In conjunction with smoking, naked flames or electrical equipment, it can cause fires and explosions.

⇒ Do not smoke.

⇒ Avoid naked flames.

⇒ Do not use electrically conductive tubes (exception: breathing tubes which can be heated electrically).

Risk of injury from oxygen therapy!

Oxygen therapies can lead to side effects in case of incorrect use or dosage.

⇒ Only administer oxygen as prescribed by a physician.

⇒ Follow the instructions for use of the oxygen system and therapy device.

Risk of injury from re-inhaling CO_2!

If the mask is used incorrectly, CO_2 may be re-inhaled.

⇒ Do not close the openings of the mask.

⇒ Only apply the mask for a prolonged 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 cannot take it off themselves.

⇒ Monitor patients with obstructive and restrictive lung diseases individually when using JOYCEeasy masks.

Risk of injury from slipping of the mask!

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.

⇒ Monitor patients with obstructive and restrictive lung diseases individually.

Patient endangerment through application of mask during anesthesia!

When the nasal mask is used during anesthesia, the anesthetic gas supplied can escape through the mouth and endanger the patient.

⇒ Do not use nasal mask during anesthesia.

Risk of injury from lack of cleaning!

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

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

⇒ Clean mask regularly.

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2.2 General information

- Use of third-party products may lead to functional failures and restricted fitness for purpose. Biocompatibility may also be compromised. Please note that in these cases, any claim under warranty and liability will be void if neither the accessories nor original replacement parts recommended in the instructions are used.
- To prevent infection, bacterial contamination or functional impairments, follow the instructions in the section "Hygiene preparation" (see "5 Hygiene preparation", page 10).
- 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.

3 Product description

3.1 Overview

Illustrations of the individual components can be found on the enclosed folding sheet (**figure A1**).

Key

1 Headgear
2 Forehead cushion
3 Forehead support
4 Lock
5 Retaining ring
6 Elbow
7 Plug for pressure measurement port
8 Pressure measurement port
9 Rotating sleeve
10 Mask body
11 Headgear clip
12 Mask cushion
13 Anti-asphyxia valve (on full-face masks only, see **figure F**)

3.2 Compatible devices

The mask can be used with all therapy devices which are not for life-sustaining treatment of patients with sleep apnea or ventilatory insufficiency.

With many combinations of device, the actual pressure in the mask will not correspond to the 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 the 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.

Quick-release cord (optional)

You can use a quick-release cord (accessory) to open the headgear in emergency situations (e.g. vomiting).

The quick-release cord consists of a special clip with a cord which you can fit to the mask instead of one of the bottom headgear clips.

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In an emergency, simply pull the quick-release cord. The special clip will detach itself from the mask. The headgear is now open and the mask can be removed (**figure G**).

3.3 Exhalation system

The mask has an integrated exhalation system. The retaining ring and mask body are shaped in such a way that a gap forms between these parts. The exhaled air can escape through this gap (**figure A2**).

3.4 Anti-asphyxia valve

⚠ WARNING

Risk of asphyxia if anti-asphyxia valve not working properly!
Residues may block the mask and jeopardize the success of therapy.
⇒ Check before each use that the anti-asphyxia valve is working properly.
⇒ Clean contact surfaces between the elbow and the rotating sleeve thoroughly.

Safety function of the anti-asphyxia valve

The anti-asphyxia valve has an opening to the atmosphere through which the patient can inhale ambient air if the therapy device fails. This significantly reduces the risk of breathing CO_2 back in and thus also the risk of asphyxia. Inside the anti-asphyxia valve is a membrane which can adopt one of two positions:

- as long as the therapy device is in operation, the air flow forces the membrane against the opening to the atmosphere and seals it completely. The patient breathes through the therapy device.
- if the therapy device fails or if the device is not connected, the membrane is in the rest position, in other words the opening to the atmosphere is free. The patient breathes ambient air through this opening.

3.5 Pressure measurement port

The mask has a connection **8** which can be used for measuring pressure or supplying oxygen. If you are not using the pressure measurement port, close it with the plug **7** to reach therapy pressure.

4 Operation

4.1 Applying the mask

1. Pull the headgear **1** over the head and place the mask on the face (**figure B1**).
2. Insert headgear clips **11** (**figure B2**).

4.2 Adjusting the mask

1. Undo lock **4** (**figure C1**).
2. Pull the forehead support **3** in or out of the lock **4** bit by bit as necessary (**figure C1**).

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> Remember the most convenient position. To do this, use the scale between the forehead support and the lock (figure **C1**).

3. Applying the mask (see "4.1 Applying the mask", page 8).
4. Adjust headgear **1** with the aid of the hook-and-loop fasteners so that the mask seals on the face but is not too tight (**figure C2**).
5. To adjust the hook-and-loop fastener on top of the head undo the hook-and-loop fastener, pull on the ends of the headgear with both hands and close the fastener again (**figure C3**).

4.3 Removing the mask

1. Undo **11** the headgear clips.
2. Slip the headgear **1** over the head and remove the mask.

4.4 Dismantling the mask

1. Undo the headgear clips **11** (**figure D1**).
2. Release hook-and-loop fasteners from headgear clips **11** and forehead support **3** and remove the headgear **1** (**figure D1 + D2**).
3. Remove the plug for the pressure measurement port **7** (**figure D3**).
4. Remove forehead cushion **2** from forehead support **3** (**figure D4**).
5. Take mask cushion **12** off mask body **10** (**figure D5**).
6. Turn retaining ring **5** counterclockwise and remove it (**figure D6**).
7. Remove elbow **6** from retaining ring **5** (**figure D7**).
8. Take rotating sleeve **9** off elbow **6** (**figure D7**).
9. For full-face masks only: carefully take the anti-asphyxia valve off the elbow. In the process, please note: do not damage the membrane on the inside of the anti-asphyxia valve.

4.5 Assembling the mask

1. Push rotating sleeve **9** onto elbow **6** (**figure E1**).
2. Insert elbow **6** in the retaining ring **5** (**figure E1**).
3. Insert retaining ring in the mask body with position **5** at 11 o'clock and turn clockwise to a 12 o'clock position until it locks into place (**figure E2**).
4. Fit mask cushion **12** onto mask body **10** (**figure E3**).
5. Pull forehead cushion **2** over the forehead support **3** (**figure E4**).
6. Fit the plug for the pressure measurement port **7** (**figure E5**).
7. Attach the headgear **1** with the headgear clips using the lower hook-and-loop fasteners **11** (**figure E6**).
8. Attach the headgear **1** to the mask (**figure E7**).

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9. For full-face masks only: carefully push anti-asphyxia valve onto the elbow until it audibly engages on both sides of the elbow (figure **F**).
   In the process, please note: do not damage or trap the membrane on the inside of the anti-asphyxia valve.

> **i** You can tell whether the headgear is correctly attached by the hook-and-loop tabs. The hook-and-loop tabs on the forehead have the same color as the inside of the head bands.

5 Hygiene preparation

> **⚠ 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.
> ⇒ Thoroughly clean the contact surfaces between the elbow and the rotating sleeve.

- **This product may contain disposable items. Disposable items are intended for single use.** Therefore, use these items only once and do **not** reprocess them. Reprocessing disposable items may impair functionality and safety of the product and lead to unforeseeable reactions due to ageing, embrittlement, wear, thermal stress, the effects of chemical processes etc.

5.1 Cleaning the mask

1. Wash your hands before cleaning.
2. Dismantle the mask (see "4.4 Dismantling the mask", page 9).
3. Clean mask in accordance with the table below:

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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 (exception: mask cushion, anti-asphyxia valve and forehead cushion), 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.

NOTICE

Material damage due to abrasion!
Rubbing the mask cushion and forehead cushion can damage the coating.
⇒ Do not rub the mask cushion and forehead cushion dry.

NOTICE

Material damage due to careless use!
Careless handling can damage the anti-asphyxia valve.
⇒ Always handle the anti-asphyxia valve with care.

5. Allow all parts to air-dry.
6. Perform a visual inspection.
7. Replace damaged parts if necessary.
8. Assembling the mask (see "4.5 Assembling the mask", page 9).

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

5.2 Tips

- You can wash all parts (exception: anti-asphyxia valve and headgear) in a dishwasher at 65 °C.
- Do not dry parts in direct sunlight.
- Wash headgear before first use, as the color may run.
- Do not iron the headgear in order to keep the hook-and-loop fasteners intact.
- Do not dry the headgear in a tumble-dryer.

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5.3 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 Faults

Fault	Cause	Remedy
Facial pressure pain.	Mask fits too tightly.	Loosen headgear. Adjust position of forehead support.
Draft in the eyes.	Mask fits too loosely.	Tighten headgear. Adjust position of forehead support.
	Mask does not fit.	Use different mask size. Contact your specialist retailer.
Therapy pressure is not reached.	Mask is not adjusted correctly.	Re-adjust mask (see 4.2, p. 8).
	Mask cushion is damaged.	Replace mask cushion.
	Tube system is leaking.	Check connection and fit of tubes.
	Air is escaping from pressure measurement connection.	Close pressure measurement port with plug (included in scope of supply).
	Anti-asphyxia valve incorrectly fitted.	Fit anti-asphyxia valve correctly (see 4.5, p. 9).
	Anti-asphyxia valve defective	Replace anti-asphyxia valve

8 Replacement parts

A current list of replacement parts can be ordered on the internet site of the manufacturer or through your authorized specialist dealer.

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9 Technical data

	Nasal mask	Full-face mask
Product class according to directive MDR (EU) 2017/745	IIa	
Dimensions (W x H x D)	approx. 80 mm x 130 mm x 90 mm[1]	approx. 120 mm x 150 mm x 110 mm[1]
Weight	approx.72 g[1]	approx.103 g[1]
Therapy pressure range	4 hPa - 30 hPa	
Hose connection: Cone according to EN ISO 5356-1	Ø 22 mm (male)	
Pressure measurement port	Ø 4 mm	
Wide headgear clips	max. 20 mm	
Temperature range: Operation Storage	+5 °C to + 40 °C -20 °C to +70 °C	
Flow resistance at 50 l/min at 100 l/min	0.16 hPa 0.64 hPa	0.13 hPa 0.53 hPa
Anti-asphyxia valve flow resistance • Inspiration at 50 l/min: • Exhalation at 50 l/min:	-	0.5 hPa 0.5 hPa
Switching pressure for anti-asphyxia valve • Open: • Close:	-	≤ 1 hPa ≤ 2 hPa
Quoted two-figure noise emission value according to ISO 4871: -Sound pressure level -Sound power level, uncertainty factor:	18 dB(A) 23 dB(A) 3 dB(A)	
Service life	5 years[2]	
Standards applied	EN ISO 17510:2020	

[1] depending on size and variant.

[2] Useful life up to 12 months. The materials of the mask deteriorate if exposed to e.g. aggressive detergents. In individual cases, therefore, it may be necessary to replace mask parts sooner.

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9.1 Materials

Mask part	Material
Mask cushion, forehead cushion	Silicone, silicone coating
Plug for pressure measurement port	Silicone
Retaining ring (hard component)	PP (polypropylene)

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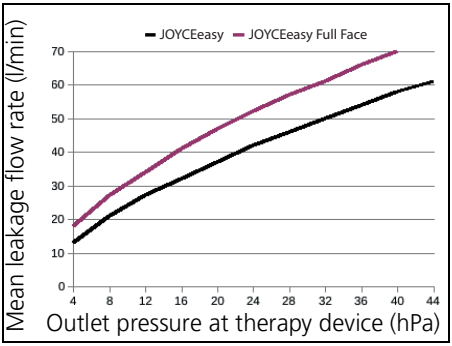
Mask part	Material
Retaining ring (soft component)	TPE (thermoplastic elastomer)
Headgear clip, lock	PA (polyamide), POM (polyoxymethylene)
Forehead support, rotating sleeve, mask body, elbow	PA (polyamide)
Headgear	Elastane, polyester, PU (polyurethane), UBL loop, cotton, PA (polyamide)
Anti-asphyxia valve	TPE, PP (polypropylene)
Quick-release cord	POM, polyester, PA (polyamide)

All parts of the mask do not contain latex, PVC (polyvinylchloride) and DEHP (diethylhexyl phthalate).

9.2 Characteristic pressure/flow curve

The characteristic pressure/flow curve shows the outlet flow in dependence with therapy pressure.



10 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
	Use by date
	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)

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11 Warranty

Löwenstein Medical gives the customer a limited manufacturer warranty on new original Löwenstein Medical products and any replacement part fitted by Löwenstein Medical 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

12 Declaration of conformity

The manufacturer Löwenstein Medical Technology GmbH + Co. KG (Kronsaalsweg 40, 22525 Hamburg, Germany) hereby declares that the product complies with the relevant regulations of 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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目录

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1 引言

1.1产品型号

JOYCEeasy，JOYCEeasy Full Face

1.2适用范围

产品与治疗仪连接，用于对有睡眠呼吸暂停和呼吸功能不全的患者进行无创、非维持生命的通气治疗。

1.3禁忌症

以下情形不得使用面罩：需要立即插管；失去知觉、剧烈呕吐。

以下情形应慎用面罩：面部皮肤瘀伤和严重损伤；面部皮肤过敏；面部或鼻咽腔变形；面部剧烈疼痛；咳嗽反射受限或无咳嗽反射；幽闭恐惧症；严重恶心。

如果您不确定这些情形中是否有符合自己的情况，请咨询您的主治医师或医护人员。请认真阅读治疗仪使用说明书中禁忌症的相关说明。

1.4副作用

使用面罩可能产生以下副作用：鼻塞、鼻干，清晨口干舌燥、鼻窦有压迫感、眼结膜刺激发炎，皮肤红斑、面部留有压痕、呼吸时有干扰杂音。
如果出现这些副作用，请咨询您的主治医师或医护人员。

1.5结构及组成

产品由头带、额垫、额部支架、额部支架的锁紧装置、固定环、弯头、测压接口堵头、测压接口、旋转套筒、面罩壳、带夹、呼吸面罩凸缘、急救呼吸阀（仅用于口鼻罩），拉绳（选配）。产品为非灭菌非一 次性使用产品。

2 安全须知

请仔细阅读本使用说明书，本使用说明属本鼻罩的重要组成部分，必须随时可供查阅。按照医疗产品条例 (EU) 2017/745 的要求，请注意以下事项。

2.1安全须知

2.2 安全提示

因面罩部件断裂造成受伤危险！
老化或过度使用的面罩部件可能会脱落，进而危及患者安全。
⇒ 请注意使用时长。
⇒ 定期检查面罩部件，如有必要及早更换。

因泄漏量太大而导致的受伤危险！
泄漏量太大可能导致患者供气不足。
⇒ 激活治疗仪上的低压 / 泄漏报警装置。
⇒ 使用正确的面罩尺寸并检查位置是否固定。

因输氧而构成的人员受伤危险！
氧气会沉积在衣服、床上用品以及头发上。遇有吸烟、明火和使用电气设备等因素会引起火灾和爆炸。
⇒ 禁止吸烟。
⇒ 切忌使用明火。
⇒ 请勿使用导电软管 （例外：可电加热的呼吸软管）。

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因氧气疗法而构成的人员受伤危险！
如果出现使用 / 计量错误，那么氧气疗法会产生副作用。
⇒ 只能遵医嘱施用氧气。
⇒ 请认真阅读氧气输入装置和治疗仪使用说明书。

因 CO_2 反复呼吸而构成的人员受伤危险！
呼吸面罩处置不当时，CO_2 会被反复呼吸。
⇒ 请堵住呼吸面罩上的开口。
⇒ 只有当治疗仪运行较长时间时，方可佩戴上呼吸面罩。
⇒ 仅限于在规定的治疗气压范围内使用呼吸面罩。
⇒ 切勿给不能自己摘下呼吸面罩的患者佩戴呼吸面罩。
⇒ 在使用 JOYCEeasy 鼻罩的过程中，对患有阻塞性和限制性肺疾病的患者单独检查。

因呼吸面罩滑脱而构成的人员受伤危险！
如果呼吸面罩滑脱或脱落，治疗无效。
⇒ 对患有限制性自发呼吸困难的患者要进行监测。
⇒ 激活治疗仪上的负压 / 泄漏报警装置。
⇒ 对患有阻塞性和限制性肺疾病的患者单独监测。

在麻醉状态下使用呼吸面罩对患者有危害！
如果在麻醉状态下使用鼻罩，导入的麻醉气体会通过口腔泄漏，对患者构成危险。
⇒ 切忌在麻醉状态下使用鼻罩。

因缺少清洁而导致的受伤危险！
面罩可能带有污染物，这些可能会危及患者安全。
⇒ 首次使用面罩前请进行清洁 （参见清洁与消毒一章的内容）。
⇒ 定期清洁面罩。

2.3 一般提示

- 使用其它厂商的产品可能导致器件功能障碍以及适用性受到限制。另外，还会导致设备不能符合生物相容性的要求。请注意：如果既没有使用说明书中所推荐的配件也没有使用原装备件，有此类情况发生时，本公司对产品出现的任何问题恕不承担产品保修和责任。
- 为了防止感染、细菌感染或功能受损，请参阅 “ 卫生处理 ” （参见 “5 卫生处理 ”，第 21 页）一章。
- 在欧盟：所有用户和 / 或患者必须在产品发生严重意外时通知制造商和主管部门。

3 产品说明

3.1 概览

零部件图示，请参见随产品附上的折页说明书 （**插图 A1**）。

图例说明

1 头带
2 额垫
3 额部支架
4 额部支架的锁紧装置
5 固定环
6 弯头
7 测压接口堵头
8 测压接口
9 旋转套筒
10 面罩壳
11 带夹
12 呼吸面罩凸缘
13 急救呼气阀 （仅用于口鼻罩，参见**插图 F**）

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3.2仪器适配

可以将此呼吸面罩与所有治疗仪器结合使用，这些治疗仪器均不用于患有睡眠呼吸暂停综合症和呼吸功能不全的患者的生命维持治疗。

在有些仪器组合上，其呼吸面罩中的实际气压与规定的治疗气压不一致，即使治疗仪器上显示的是正确的气压。请医师或特约经销商对仪器组合进行调节，以使面罩中的实际气压与治疗气压一致。所需治疗压力可能在不同型号面罩之间存在差异。因此，为了确定合适的治疗压力，应使用在治疗本身期间也使用的面罩型号进行治疗设置或调整。

拉绳 （选用）

为了在紧急情况 （例如呕吐）下打开头带，您可以使用拉绳 （配件）。

拉绳由一个带线的专用夹组成。该夹子可以代替其中一个下带夹安装在鼻罩上。

在紧急情况下拉动拉绳，专用夹就从鼻罩上松开。头带现在处于打开状态，然后就可以取下鼻罩了 （**插图 G**）。

3.3呼气系统

面罩配有一个内置呼气系统。安全环和面罩壳的造型使在部件之间产生一个间隙，呼出的气体可以通过这一间隙泄漏 （**插图 A2**）。

3.4急救呼气阀

⚠ 警告

由于不正常工作的急救呼气阀而产生的窒息危险！
残渣会使鼻罩堵塞，影响治疗效果?
⇒ 请在每次使用前检查急救呼气阀是否正常工作。
⇒ 彻底清洗弯头和旋转套筒之间的接触面。

急救呼气阀的安全功能

急救呼气阀配有一个大气开口，患者可以在治疗仪器发生故障的情况下吸入室内空气。这明显减少了二氧化碳重复吸入的危险和因此导致的窒息危险。急救呼气阀内，有一个可以设置两个位置的膜片：

- 只要治疗仪器工作，膜片就在大气开口前被气流压迫并使其完全关闭。患者可以通过治疗仪器呼吸。
- 在治疗仪器发生故障或设备未连接时，膜片位于原始位置，即大气开口打开。患者可以通过此开口呼吸室内空气。

3.5测压接口

呼吸面罩配备 1 个接头 **8**，以便对压力进行测量或导入氧气。当不使用测压接口时 **7**，请用堵头将其封闭，以达到治疗气压。

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4 操作

4.1 戴上面罩

1. 将头带 1 在头上并且将呼吸面罩置于面部 （**插图 B1**）。
2. 将带夹 11 推入 （**插图 B2**）。

4.2 调整呼吸面罩

1. 将锁紧装置 4 松开 （**插图 C1**）。
2. 根据需求，将额部支架 3 逐个地从锁紧装置 4 中取出或将其推入锁紧装置 4 内 （**插图 C1**）。

> 请记住您感觉最舒适的位置。为此请使用额部支架和锁栓之间的刻度 （**参见插图 C1**）。

3. 戴上面罩 （参见 “4.1 戴上面罩 ”，第 20 页）。
4. 借助尼龙搭扣调节头带 1，使呼吸面罩封闭，但又不过紧贴附在面部上 （**插图 C2**）。
5. 为了调整头顶部上的尼龙搭扣：松开尼龙搭扣，双手将其略微拉到头带末端，然后将尼龙搭扣再次按压 （**插图 C3**）。

4.3 取下面罩

1. 将带夹 11 取下。
2. 轻触头顶上的头带 1，然后将呼吸面罩取下。

4.4 拆分面罩

1. 将带夹 11 拔出 （**插图 D1**）。
2. 将尼龙搭扣从带夹 11 和额部支架 3 松开，然后将头带 1 取下 （**插图 D1 + D2**）。
3. 将测压接口上的堵头 7 移除 （**插图 D3**）。
4. 将额垫 2 从额部支架 3 取下 （**插图 D4**）。
5. 将呼吸面罩凸缘 12 从面罩壳 10 上松开 （**插图 D5**）。
6. 将安全环 5 逆时针方向旋转，并且取下 （**插图 D6**）。
7. 将弯头 6 通过安全环 5 取出 （**插图 D7**）。
8. 从弯头 6 上取下旋转套筒 9 （**插图 D7**）。
9. 仅适用于口鼻罩：小心地将急救呼气阀从弯头松开。
   其间注意：不要损坏急救呼气阀内侧的膜片。

4.5 组装面罩

1. 将旋转套筒 9 插在弯头 6 上 （**插图 E1**）。
2. 将弯头 6 通过安全环 5 导入 （**插图 E1**）。
3. 将安全环 5 插入面罩壳 11 点钟的位置，顺时针方向旋转到 12 点钟的位置，直至听到卡住声 （**插图 E2**）。
4. 将呼吸面罩凸缘 12 插在面罩壳 10 上 （**插图 E3**）。

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5. 将额垫 2 套在额部支架 3（**插图 E4**）。
6. 插上测压接口上的堵头 7（**插图 E5**）。
7. 将头带 1 与带夹上的下面尼龙搭扣 11 固定住（**插图 E6**）。
8. 将头带 1 固定在呼吸面罩（**插图 E7**）。
9. 仅适用于口鼻罩：小心地将急救呼气阀按下在弯头上，直到清晰地听到它两侧锁入弯头（**插图 F**）。
   其间注意：不要损坏或挤压急救呼气阀内侧的膜片。

> 通过拉扣，患者可以识别头带是否戴好。前额上的拉扣颜色与头带内侧颜色相同。

5 卫生处理

警告

因清洗不彻底而构成的人员受伤危险！
残渣会使呼吸面罩堵塞，对内置呼出系统产生不利影响，影响治疗效果。
⇒ 对于免疫系统衰弱或有特殊病史的患者，在与医师协商之后，每天对呼吸面罩部件进行消毒处理。
⇒ 彻底清洗弯头和旋转套筒之间的接触面。

- **本产品可能含有一次性用品。一次性用品仅限于一次性使用，**因此，仅一次性使用，**无法**再次回收利用，一次性用品的再次回收利用会对本产品的性能及安全性构成危险，会造成因老化、脆化、磨损、热负荷、化学作用过程等不可预见的反应

5.1 清洁呼吸面罩

1. 清洗前洗手。
2. 拆分面罩 （参见 “4.4 拆分面罩”，第 20 页）。
3. 将呼吸面罩按照以下表格执行清洁：

操作	每日	每周
用热水（大约 30 ° C）和温和的清洁剂（1 ml 兑 1 l 水）手洗面罩部件 15 分钟。	X	
清洗时（例外：鼻罩凸缘、急救呼气阀和额垫），用布或软刷彻底清洁面罩部件至少 3 分钟。 或：将面罩部件放入洗碗机上面的篮子中。选择最高温度 70 ° C 以及持续时间最长 90 分钟的清洗程序。使用温和的洗碗清洗剂（1 ml 洗碗清洗剂兑 1 l 水）。 在洗碗机中单独清洗面罩部件，不要与脏的碗筷混洗。		X
用热水（大约 30 ° C）和温和的清洁剂（1 ml 兑 1 l 水）手洗头带 15 分钟。		X

4. 将所有部件用清水冲洗。

注意

因磨损而造成仪器受损！
面罩凸缘和额垫的摩擦会损坏涂层。
⇒ 切勿干燥摩擦面罩凸缘和额垫。

注意

由于不小心使用而造成财产损失！
不小心操作会损坏急救呼气阀。
⇒ 始终小心操作急救呼气阀。

5. 将所有部件风干。
6. 进行目检。
7. 如果有必要：更换损坏部件。
8. 组装面罩 （参见 “4.5 组装面罩 ”，第 20 页）。

呼吸面罩部件变色不会对呼吸面罩的功能产生不利影响。

5.2 提示

- 患者可以将所有部件 （例外：急救呼气阀和头带）在 65 ° C 条件下放入洗碗机中进行清洗。
- 晾干时，切勿将部件在阳光下直接暴晒。
- 在第一次使用之前，将头带湿洗，原因是头带会有退色现象。
- 切勿熨烫头带，以保持尼龙搭扣完好。
- 切勿将头带在干燥机内烘干。

5.3 卫生处理 （临床领域）

更换患者时，卫生处理不彻底可能导致患者发生感染的危险。如果更换患者，则按照 “ 关于卫生处理的说明 ” 手册进行卫生处理。可在制造商的网站上找到该手册。根据用户要求，本公司可将资料手册寄送给用户。

6 废弃物回收处理

您可将所有废弃部件扔到生活垃圾中处理。

7 故障及排除方法

故障	原因	排除
面部压迫疼痛。	呼吸面罩贴得过紧。	将头带松弛一些。调整额部支架的位置。
眼睛通风。	呼吸面罩贴得过松。	将头带调整得略紧一些，调整额部支架的位置。
	呼吸面罩不匹配。	请使用其他尺寸大小的呼吸面罩。联系特约经销商。
未达到治疗气压。	呼吸面罩调整得不得当。	重新调整呼吸面罩 （参见 4.2，第 20 页）。
	呼吸面罩凸缘受损。	更换呼吸面罩凸缘。
	软管系统不密封。	检查插接器和软管是否插好。
	测压接口漏气。	用堵头将测压接口 （包含在供货范围内）堵住。
	急救呼气阀安装不正确。	正确安装急救呼气阀 （参见 4.5，第 20 页）。
	急救呼气阀损坏。	更换急救呼气阀。

8 备件

必要时您可以另行订购备件。您可以在公司网站 www.lowensteinmedical.de 上或通过特许经销商索取最新的备件清单。

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9 技术数据

	鼻罩	口鼻罩
产品等级符合 MDR (EU) 2017/745 法规	IIa	
外形尺寸（宽 x 高 x 深）	约80 mm x 130 mm x 90 mm[1]	约120 mm x 150 mm x 110 mm[1]
重量	约 72 g[1]	约 103 g[1]
治疗气压范围	4 hPa - 30 hPa	
软管接头：锥销符合 EN ISO 5356-1	Ø 22 mm （公）	
测压接口	Ø 4 mm	
带夹宽度	最大 20 mm	
温度范围： 工作 存放	 +5 ° C 至 +40 ° C −20 ° C 至 +70 ° C	
急救呼气阀气在 50 l/min： 在 100 l/min：	 0.16 hPa 0.64 hPa	 0,13 hPa 0,53 hPa
急救呼气阀气流阻力 • 在 50 l/min 时的吸气： • 在 50 l/min 时的呼气：	–	 0.5 hPa 0.5 hPa
急救呼气阀控制压力 • 打开： • 关闭：	–	 ≤ 1 hPa ≤ 2 hPa
表明的两位数噪声发射值按照 ISO 4871 执行： - 声压等级 - 声功率等级 （不确定因素：	18 dB(A) 23 dB(A) 3 dB(A)	
使用期限	5 年[2]	
履行准则	EN ISO 17510:2020	

[1] 取决于规格和结构。

[2] 最佳佩戴期限：12 个月 . 例如：如果呼吸面罩受到具有腐蚀性洗涤剂的腐蚀，那么呼吸面罩的材料会老化，个别特殊情况下，需要提前更换呼吸面罩部件。

CE 0197

设计改进，恕不通知。

9.1 原材料

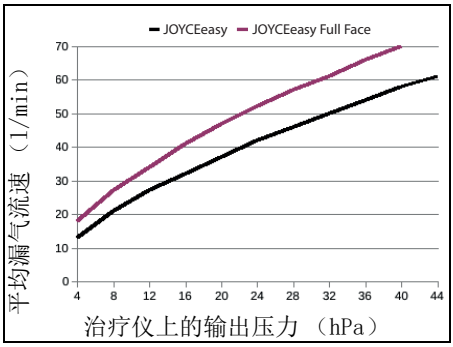
呼吸面罩部件	原材料
呼吸面罩凸缘、额垫	硅胶、硅树酯涂料
测压接口堵头	硅胶
固定环 （硬部件）	PP （聚丙烯）
固定环 （软部件）	TPE （热塑性弹力计）
带夹、锁紧装置	PA （聚酰胺） POM （聚甲醛）
额部支架、旋转套筒、面罩壳、弯头	PA （聚酰胺）

呼吸面罩部件	原材料
头带	氨纶弹性纤维、聚酯纤维、PU（聚氨酯）、UBL 环、棉、PA（聚酰胺）
急救呼气阀	TPE、PP（聚丙烯）
拉绳	POM、聚酯纤维、PA（聚酰胺）

面罩的所有部件不含乳胶、PVC（聚氯乙烯）和 DEHP（邻苯二甲酸二异辛酯）。

9.2 压力流速特性曲线

压力流速特性曲线示意排放流速与治疗气压的关系。



10 标识和符号

产品、产品标牌、配件或其包装上可能带有以下符号。

符号	说明
UDI	医疗器械唯一标识（医疗器械统一的产品标识）
	允许进行运输和存放的温度范围
	可在指定日期之前使用
	避免阳光直射
REF	产品编号
MD	表示本产品为医疗产品
LOT	批次号
	制造商和生产日期（如适用）
	遵循使用说明书
CE 0197	CE 标识（证明本产品符合现行的欧盟指令 / 法规）

11 保修期

Loewenstein Medical 为新的原装 Loewenstein Medical 产品及 Loewenstein Medical 内置备件用户承担有限的制造商保修责任，按照适用于各种产品的保修条件以及下列从购货之日起的保修期执行。保修条件可在制造商的网站上查询。根据用户要求，本公司也可将关于保修条件的资料寄送给用户。

请注意，如果不使用本操作说明书中所推荐的配件或者原装备件，那么对于产品保修和制造商责任的任何权利要求将无效。

保修时，请向特许经销商垂询。

产品	保修期
包括配件的面罩	6 个月

WM 67630h 04/2022

12 合格声明

制造商 Löwenstein Medical Technology GmbH + Co. KG（地址 Kronsaalsweg 40，22525 Hamburg，德国）在此郑重声明，本公司产品符合医疗产品条例（EU）2017/745 中的相关规定。关于本合格声明的全部内容，请访问制造商的网站。

产品技术要求编号：
国械注进 20152080249
医疗器械注册证编号：
国械注进 20152080249

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原产地：德国

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