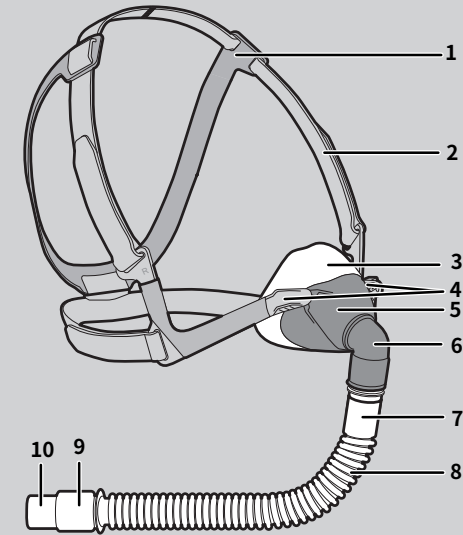


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# JULIA

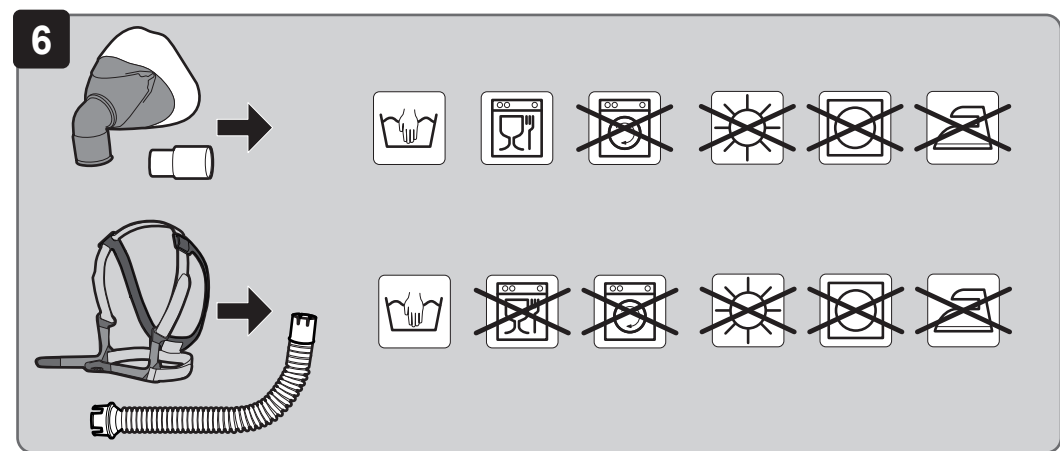
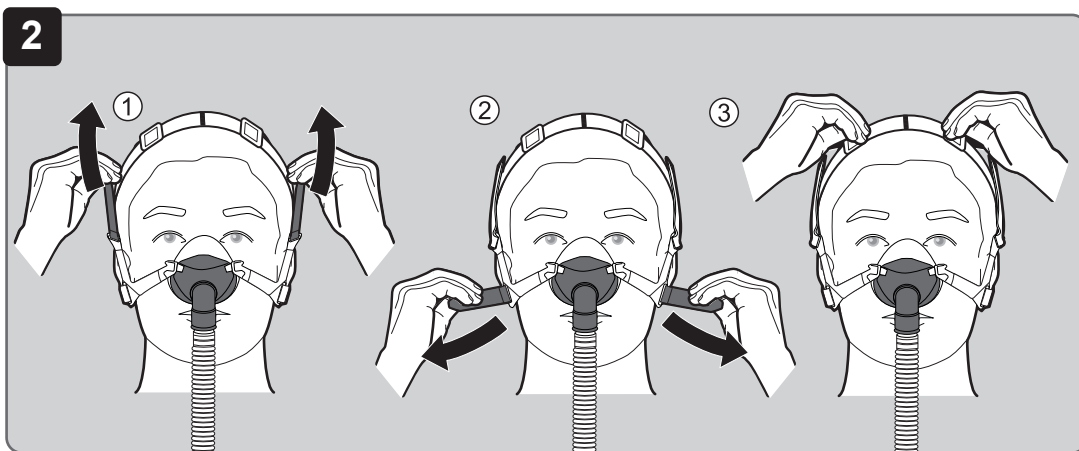
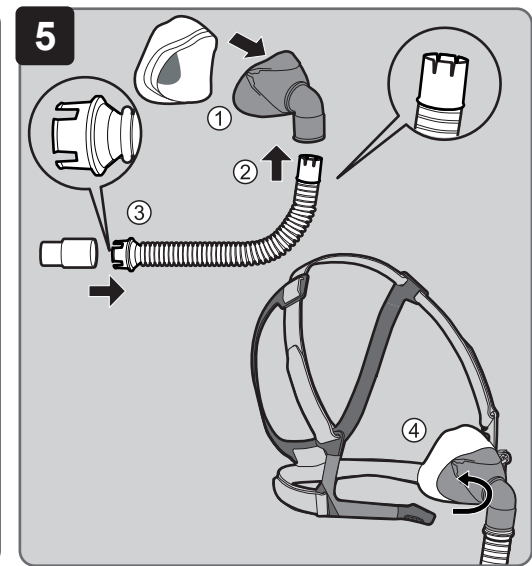
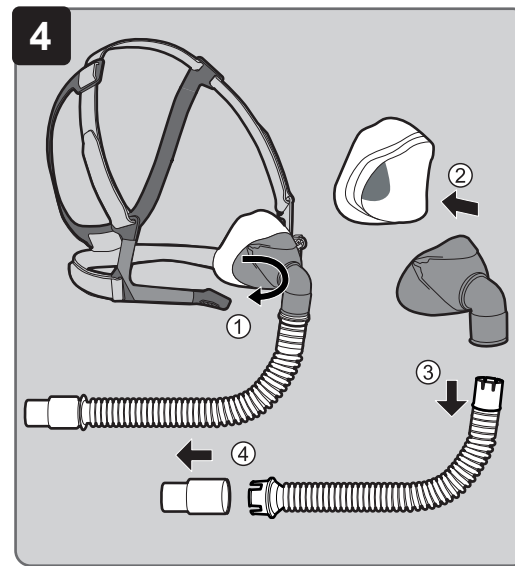
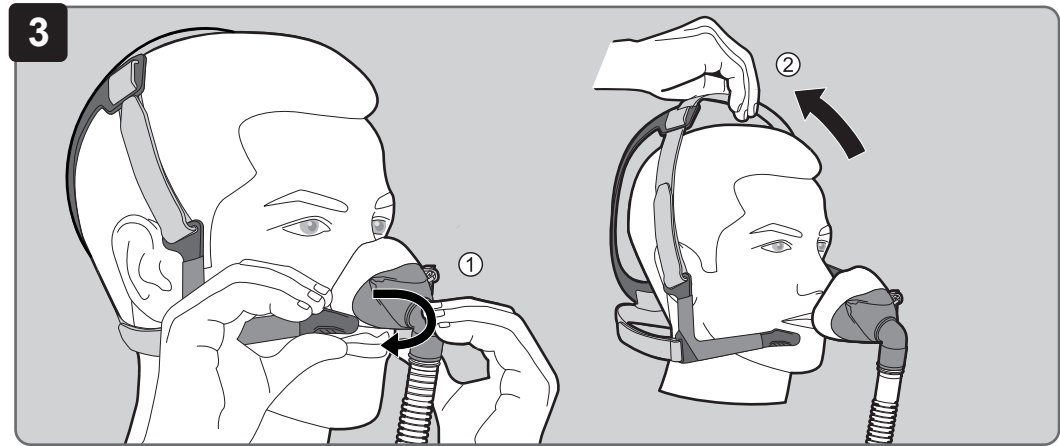
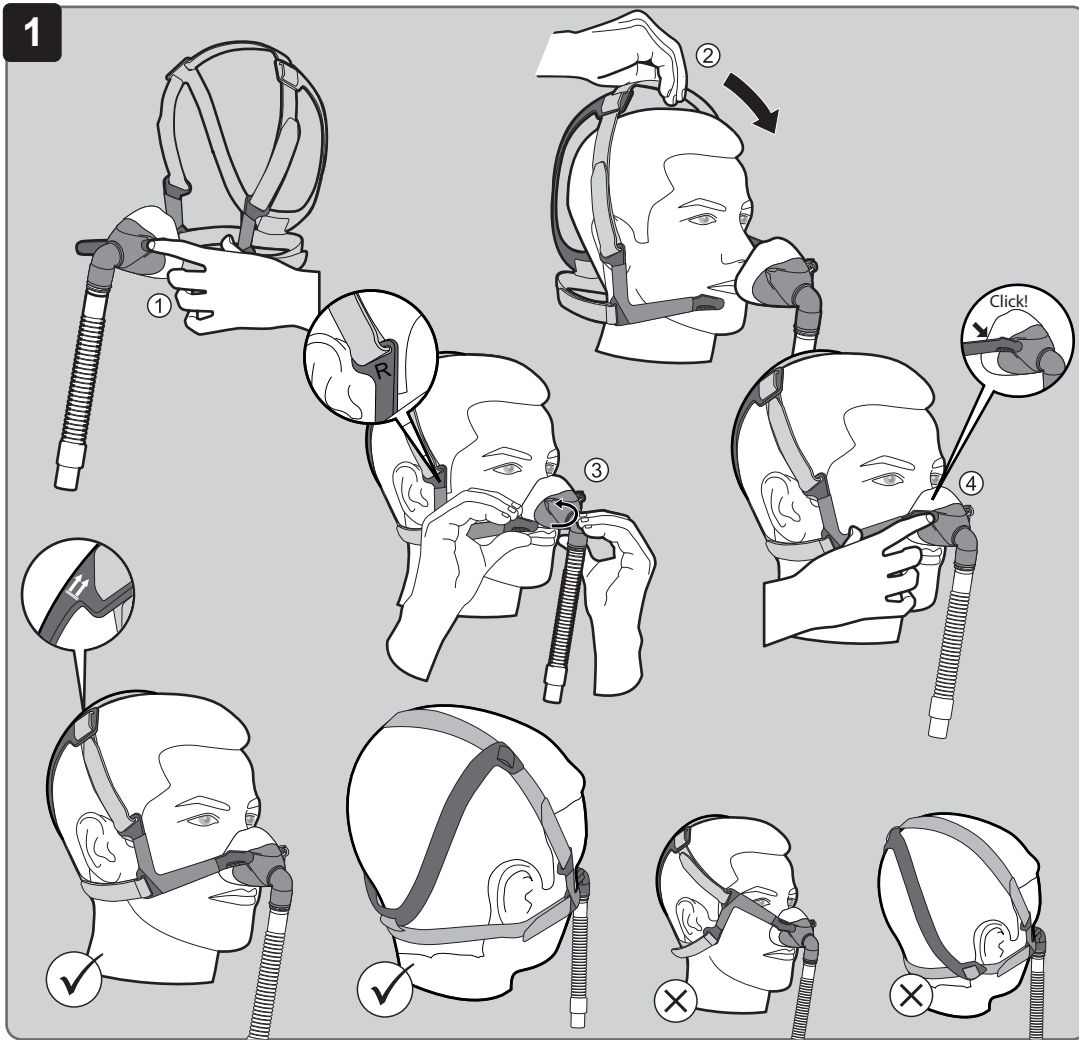
## Nasal Mask



LMT 67693

**LÖWENSTEIN**  
medical

**LÖWENSTEIN**  
medical



## 1 操作

口鼻罩操作如圖中的下列步驟所示：

- 1 戴上口鼻罩
- 2 調整口鼻罩
- 3 取下口鼻罩
- 4 拆分口鼻罩
- 5 組裝口鼻罩

**i** 面向盲人或視障使用者  
製造商網站上額外提供電子版使用說明。

## 2 序言

### 2.1 使用範圍

鼻罩作為儀器配件，用於治療睡眠呼吸障礙和呼吸衰竭時的非維持生命的通氣呼吸。鼻罩可以在家用環境中供患者重複使用。在臨床環境中鼻罩適用於多位患者，但需要重新處理。

### 2.2 禁忌症

口鼻罩不得用於體重 < 30 kg 的患者。

在下列情況中不得使用口鼻罩：需要立即插管；失去意識、嚴重嘔吐。

在下列情況中應特別小心地使用口鼻罩：面部皮膚留有壓痕和受到嚴重傷害、面部區域皮膚過敏、面部或鼻咽畸形、面部區域急性疼痛、咳嗽反射受限或缺失、幽閉恐懼症、嚴重噁心。

口鼻罩不適合結合噴霧器或作為麻醉面罩使用。

如不確定您是否適用上述情況之一，請聯絡您的醫務人員。另請注意儀器使用說明中的禁忌症。

### 2.3 副作用

使用口鼻罩時可能出現下列副作用：鼻塞、鼻乾、清晨口乾、鼻竇有壓迫感、眼結膜受刺激、皮膚發紅、面部留有壓痕、呼吸時有干擾噪音。

出現上述副作用時，請聯絡您的醫務人員。

### 2.4 臨床使用

將治療儀的治療效果傳遞給患者

## 3 Sicherheit

**⚠ 警告！** 格外危險的情況。不遵守採取下列資訊訊息可能導致不可逆的嚴重乃至致命傷害。

### 損壞或磨損的口鼻罩零部件會造成受傷危險！

- ⇒ 每次使用前和每次清潔後進行目檢。必要時更換口鼻罩零部件。
- ⇒ 注意有效壽命（參見技術參數章節）。

### CO<sub>2</sub> 再呼吸會造成受傷危險！

- ⇒ 僅能在治療時使用面罩。
- ⇒ 只能在規定的治療氣壓範圍內使用口鼻罩。
- ⇒ 無法自己取下口鼻罩的患者須由護理人員看護。
- ⇒ 不要封閉呼氣系統。

### 使用氧氣有受傷風險！

氧氣可能會黏附在衣物、床單和頭髮上。在沒有防護裝置的情況下輸入氧氣可能導致火災。

- ⇒ 使用氧氣安全閥。
- ⇒ 遵循氧氣供應系統的使用說明。
- ⇒ 禁止吸煙。
- ⇒ 避免明火。
- ⇒ 房間充分通風。
- ⇒ 保持口鼻罩無油脂。
- ⇒ 注意設備使用指南中的使用說明。

### 患者供氣不足造成受傷風險！

- ⇒ 在儀器上啟動壓力不足/洩漏警報。
- ⇒ 使用適當的面罩尺寸並檢查是否牢固就位。

### 清潔不足會造成受傷風險！

- ⇒ 首次使用之前清潔口鼻罩零部件（參見清潔和衛生處理章節）。
- ⇒ 定期清潔口鼻罩。
- ⇒ 臨床環境中更換患者時：遵循檔案 *面罩處理提示*（參見衛生處理章節）。

### 呼吸軟管敷設錯誤造成受傷風險！

- ⇒ 不要沿頸部敷設軟管。
- ⇒ 不要擠壓軟管。

**⚠ 小心！** 危險情況。不遵守採取下列資訊訊息可能導致輕度或中等傷害。

### 因過敏造成受傷風險！

- ⇒ 請注意口鼻罩使用的材料（參見材料章節）。使用口鼻罩前請先諮詢醫務人員。
- ⇒ 選擇清潔劑時注意可能的過敏問題。

## 4 產品描述

各個零部件的說明請參見標題頁。

1	卡箍（後腦勺）	6	彎管
2	頭帶	7	轉接器（彎管至面罩管路）
3	面罩軟墊（視類型而定，有兩個面罩軟墊）	8	面罩管路
4	卡箍（左）或卡箍（右），各帶有卡箍墊層	9	轉接器（旋轉套管至呼吸軟管）
5	面罩罩體	10	旋轉套管

### 相容儀器

在一些儀器組閥中，實際壓力與儀器顯示的治療氣壓不一致。請醫務人員設定儀器，確保口鼻罩內的實際壓力與治療氣壓一致。應以治療期間使用的面罩類型完成設定。

### 呼氣系統

口鼻罩具有整合的呼氣系統。透過該間隙可以逸出呼出的空氣。

## 5 清潔和衛生處理

### 5.1 清潔口鼻罩

- 每次清潔前清洗雙手。
- 拆分口鼻罩（參閱圖示 **4**）。

**i** 將卡箍墊層保留在卡箍上，並使用卡箍進行清潔。在受到較重污染或損壞時：移除並更換卡箍。

- 按照以下表格用手清潔口鼻罩（最大 30 °C，1 ml 清潔劑加 1 l 水）：

面罩零部件	頻率	操作
面罩罩體、面罩軟墊、旋轉套管、彎管	每天	浸泡 15 分鐘並清洗。使用柔軟的清潔刷清潔 3 分鐘。
面罩管路	每天	浸泡 15 分鐘並清洗。
	每星期	日常清潔後，使用柔軟的清潔刷清潔面罩管路內側 3 分鐘。
頭帶，帶卡箍墊層的卡箍	每星期	清洗 15 分鐘。

**i** 面罩罩體、面罩軟墊、旋轉套管和彎管可每週放入洗碗機清洗（最大 70 °C，溫和的洗碗精，最長程式時間 90 分鐘，上方碗籃，單獨沖洗）。

- 用清水沖洗所有零部件。
- 晾乾所有零部件。
- 掛起面罩管路晾乾。
- 目視檢查有無裂紋和變形。更換損壞的零部件。變色沒有影響。
- 如果面罩軟墊損壞或嚴重髒污：更換面罩軟墊。如果沒有附帶第二個面罩軟墊，請聯絡專業經銷商。
- 組裝口鼻罩（參閱圖示 **5**）。

### 5.2 衛生處理（臨床環境）

如果更換患者，請遵循文檔**面罩處理提示**。文檔位於製造商網站上。我們也可應要求向您傳送文檔。

### 5.3 棄置處理

禁止將口鼻罩作家庭垃圾廢棄。在臨床環境：根據醫院規定棄置處理口鼻罩。

## 6 故障

故障	原因	措施
面部壓痛	口鼻罩太緊。	調鬆頭帶。
眼部感覺有氣流	口鼻罩太松。	調緊頭帶。
	口鼻罩不合適。	聯絡專業經銷商。

故障	原因	措施
未達到治療氣壓。	口鼻罩未正確調整。	重新調整口鼻罩。
	面罩軟墊損壞。	更換面罩軟墊。
	軟管系統受損。	檢查軟管系統以及軟管系統位置是否正確。

## 7 技術參數

尺寸，單位 mm (寬 x 高 x 長)	
型號 S	50 x 61 x 75
型號 M	57 x 61 x 73
型號 L	63 x 65 x 73
重量	
型號 S	78 g
型號 M	78 g
型號 L	79 g
死腔容量	
型號 S	65 ml
型號 M	71 ml
型號 L	87 ml
軟管接頭：依據 EN ISO 5356-1 的錐體	Ø 22 mm (錐頭)
阻流性	
50 l/min 時	0.8 hPa
100 l/min 時	2.9 hPa
使用壽命	5 年
有效壽命	最長 12 個月 <sup>1</sup>
治療氣壓	4 hPa - 30 hPa
依據 ISO 4871 規定的雙噪音排放值：	
聲壓級	18 dB(A)
聲功率級	26 dB(A)
不確定因數	3 dB(A)
溫度：	
工作	+5 °C 至 +40 °C
運輸與存放	-20 °C 至 +70 °C
應用的標準	EN ISO 17510 : 2020
依據 MDR (EU) 2017/745 的產品類別	IIa

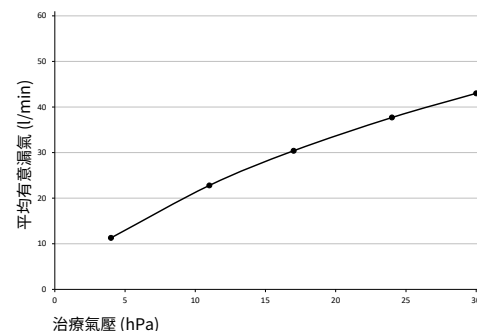
<sup>1</sup> 有效壽命取決於清潔及所用清潔劑、每日佩戴時長、治療氣壓及個人出汗情況。使用第二個面罩軟墊（可選）不會延長有效壽命。

## 8 材料

口鼻罩的所有零部件都不含乳膠、PVC（聚氯乙烯）和 DEHP（鄰苯二甲酸二乙基己酯）。

面罩罩體	PA（聚醯胺）
面罩軟墊	SI（硅酮）
面罩管路	POP（聚烯烴塑性體）
頭帶	PA（聚醯胺）、PU（聚氨酯）、P（聚酯纖維）
後腦勺卡箍	PP（聚丙烯）
卡箍（左/右）	PA（聚醯胺）
卡箍墊層	P（聚酯纖維）
轉接器（彎管至面罩管路）	MABS（甲基丙烯酸甲酯丙烯腈丁二烯苯乙烯）
轉接器（旋轉套管至呼吸軟管）	MABS（甲基丙烯酸甲酯丙烯腈丁二烯苯乙烯）
彎管	PA（聚醯胺）
旋轉套管	PA（聚醯胺）

## 9 壓力/流量特性曲線



## 10 標識與符號

產品、配件或其包裝上可能附加了以下標識與符號。

符號	描述
	製造商和製造日期（如可能）
	產品識別碼（醫療器材統一產品標識）
	訂購貨號
	將產品標識為醫療器材
	遵循使用說明

符號	描述
	許可的運輸與存放溫度範圍
	可使用至指定日期
	避免日曬
	批號
	CE 標誌（證明該產品符合現行的歐盟指令/規定）

## 11 保固

Löwenstein Medical Technology 依據適用於相應產品的保固條款和以下所列之保固期，自購買之日起向全新原裝 Löwenstein Medical Technology 產品與 Löwenstein Medical Technology 所安裝備件的客戶提供有限的製造商保固。保固條款請參閱製造商網站。我們也可應要求向您傳送保固條款。

請注意，如未使用本使用說明所建議的配件和原裝備件，那麼對於產品保固及製造商責任的任何權利要求將失效。如需保固，請聯絡特許經銷商。

產品	保固時間
包括配件在內的面罩	6 個月











## 12 符合聲明

製造商 Löwenstein Medical Technology GmbH + Co. KG，（Kronsaalsweg 40，22525 Hamburg，德國），在此鄭重聲明，本產品符合歐盟醫療器械法規 (EU) 2017/745 中的相關規定。完整的符合聲明文字可在製造商網站上獲取。

在歐盟：作為使用者和/或患者，您必須向製造商和主管當局報告與產品相關的所有嚴重事故。

## 10 Markings and symbols

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

Symbol	Description
	Manufacturer and, if necessary, date of manufacture
	Unique device identifier (unique product code for medical devices)
	Order number
	Indicates the product is a medical device
	Follow the instructions for use
	Permitted temperature range for transport and storage
	Use by date
	Keep out of sunlight
	Lot number
	CE symbol (confirms that the product conforms to the applicable European directives/regulations)

## 11 Warranty

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

Please bear in mind that any claim under warranty and liability shall be void if neither the accessories recommended in the instructions for use nor original spare 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 (Kronsaalweg 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.

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 figures show the following steps for operating the mask:

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

**i** **For blind and partially-sighted users**  
An electronic version of the instructions for use is also available on the manufacturer's website.

## 2 Introduction

### 2.1 Intended use

The nasal mask is used as an accessory for devices for treating sleep-related breathing disorders or for non-life-support ventilation in the case of respiratory insufficiency. The nasal mask is suitable for re-use for patients in the home environment. In the clinical environment, the nasal mask is suitable for multiple patients after reprocessing.

### 2.2 Contraindications

The mask must not be used for patients weighing < 30 kg.

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 in the facial area, facial or nasopharyngeal deformities, acute pain in the facial area, cough reflex restricted or absent, claustrophobia, acute nausea.

Mask is not suitable for use with a nebulizer or as an anesthetic mask.

If you are not certain whether one of these situations applies to you, consult your healthcare professional. Please observe the contraindications in the instructions for use of your 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.

If these side effects occur, contact your healthcare professional.

## 2.4 Clinical benefit

Transfers the therapeutic efficacy of the therapy device to the patient.

## 3 Safety

**⚠ WARNING!** Unusually hazardous situation. If you ignore the following instructions, severe, irreversible or fatal injuries may result.

### Risk of injury due to damaged mask parts or those under strain!

- ⇒ Perform a visual inspection before every use and after every cleaning operation. Replace mask parts if necessary.
- ⇒ Note useful life (see section entitled "Technical data").

### Risk of injury from re-inhaling CO<sub>2</sub>!

- ⇒ Only use the mask when therapy is in progress.
- ⇒ Only use the mask within the quoted therapy pressure range.
- ⇒ Patients unable to remove the mask themselves must be monitored by a nurse.
- ⇒ Do not close off exhalation systems.

### Risk of injury due to the use of oxygen!

Oxygen can accumulate in clothing, bed linen, and hair. Supplying oxygen without a safety device can lead to fire.

- ⇒ Use an oxygen safety valve.
- ⇒ Follow the instructions for use for the oxygen supply system.
- ⇒ Do not smoke.
- ⇒ Avoid naked flames.
- ⇒ Ventilate the room well.
- ⇒ Keep mask free from oil and grease.
- ⇒ Observe the safety instructions in the instructions for use of the device.

### Risk of injury due to insufficient supply to the patient!

- ⇒ Activate low pressure/leakage alarms on device.
- ⇒ Use the correct mask size and check that it fits tightly.

### Risk of injury from inadequate cleaning!

- ⇒ Clean mask parts before using for the first time (see section entitled "Cleaning and reprocessing").
- ⇒ Clean the mask regularly.
- ⇒ In case of a change of patient in the clinical environment: Follow the document *Mask reprocessing instructions* (see section entitled "Reprocessing").

### Risk of injury if tubes are routed incorrectly!

- ⇒ Do not route tubes along the neck.

⇒ Do not crush tubes.

**⚠ CAUTION!** Hazardous situation. If you ignore these instructions, mild or moderate injuries may result.

#### Risk of injury due to allergies!

- ⇒ Be aware of the materials used in the mask (see section entitled "Materials"). Only use a mask following consultation with a healthcare professional.
- ⇒ When selecting the detergent, consider potential allergies.

## 4 Product description

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

1	Frame (back of head)	6	Elbow
2	Headgear	7	Adapter (elbow to mask tube)
3	Mask cushion (two mask cushions included, depending on variant)	8	Mask tube
4	Frame (left) and frame (right), each with frame cover	9	Adapter (rotating sleeve to breathing tube)
5	Mask body	10	Rotating sleeve

#### Compatible devices

In some device combinations, the actual pressure does not correspond to the therapy pressure displayed by the device. Have the device adjusted by a healthcare professional so that the actual pressure in the mask corresponds to the therapy pressure. This adjustment should be made with the type of mask that will be used during therapy.

#### Exhalation system

The mask has an integrated exhalation system. The exhaled air escapes through a gap.

## 5 Cleaning and reprocessing

### 5.1 Clean mask

1. Wash your hands before starting cleaning.
2. Dismantle mask (see Figure 4).

**i** Leave the frame covers on the frames and clean them together. If they are very dirty or damaged, remove the frame covers and replace them.

3. Clean the mask by hand (max. 30 °C, 1 ml mild detergent to 1 l water) in accordance with the following table:

Mask part	Frequency	Action
Mask body, mask cushion, rotating sleeve, elbow	Daily	Soak for 15 minutes and wash. Clean for 3 minutes with a soft cleaning brush.
Mask tube	Daily	Soak for 15 minutes and wash.
	Weekly	After daily cleaning, clean the inside of the mask tube for 3 minutes with a soft cleaning brush.
Headgear, frame with frame cover	Weekly	Wash for 15 minutes.

**i** Mask body, mask cushion, rotating sleeve and elbow can be cleaned weekly in the dishwasher (max. 70 °C, mild dishwashing detergent, max. 90 minutes program duration, upper basket, separate rinse cycle).

4. Rinse all parts with clean water.
5. Allow all parts to air-dry.
6. Hang up the mask tube to dry it.
7. Carry out a visual inspection for cracks and deformations. Replace damaged parts. Discoloration is harmless.
8. If the mask cushion is damaged or heavily soiled: Replace mask cushion. If a second mask cushion is not enclosed, contact your specialist dealer.
9. Re-assemble mask (see Figure 5).

### 5.2 Reprocessing (clinical environment)

In the event of a change of patient, follow the instructions in the document entitled *Information on reprocessing*. The document can be found on the manufacturer's website. We will send you this document on request.

### 5.3 Disposal

Dispose of the mask in domestic waste. In the clinical environment: Dispose of the mask in accordance with hospital regulations.

## 6 Troubleshooting

Fault	Cause	Action
Pain due to pressure on the face	Mask too tight.	Adjust headgear so that it is looser.
Draft in the eye	Full face mask fits too loosely.	Adjust headgear so that it is tighter.
	Mask does not fit.	Contact your specialist dealer.
Therapy pressure is not reached.	Mask is not correctly adjusted.	Re-adjust mask.
	Mask cushion is damaged.	Replace mask cushion.
	Circuit is damaged.	Check circuit and the correct fit of circuit.

## 7 Technical data

Dimensions in mm (W x H x D)	
Size S	50 x 61 x 75
Size M	57 x 61 x 73
Size L	63 x 65 x 73
Weight	
Size S	78 g
Size M	78 g
Size L	79 g
Dead space	
Size S	65 ml
Size M	71 ml
Size L	87 ml
Tube connection: Tapered connection to EN ISO 5356-1	Ø 22 mm (male)
Flow resistance at 50 l/min	0.8 hPa
at 100 l/min	2.9 hPa
Service life	5 years
Useful life	Up to 12 months <sup>1</sup>
Therapy pressure	4 hPa - 30 hPa
Quoted two-figure noise emission value according to ISO 4871:	
Sound pressure level	18 dB(A)
Sound power level	26 dB(A)
Uncertainty factor	3 dB(A)

Temperature: Operation	+5 °C to + 40 °C
Transport and storage	-20 °C to +70 °C
Standards applied	EN ISO 17510: 2020
Product class to MDR (EU) 2017/745	IIa

<sup>1</sup> Useful life depends on cleaning and on the cleaning agents used, on the amount of time worn daily, on therapy pressure, and on individual secretion of sweat. The use of the second mask cushion (optionally included) will not extend the useful life.

## 8 Materials

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

Mask body	PA (polyamide)
Mask cushion	SI (silicone)
Mask tube	POP (polyolefin thermoplastic)
Headgear	PA (polyamide), PU (polyurethane), P (polyester)
Frame, back of head	PP (polypropylene)
Frame (left/right)	PA (polyamide)
Frame cover	P (polyester)
Adapter (elbow to mask tube)	MABS (methylmethacrylate acrylonitrile butadiene styrene)
Adapter (rotating sleeve to breathing tube)	MABS (methylmethacrylate acrylonitrile butadiene styrene)
Elbow	PA (polyamide)
Rotating sleeve	PA (polyamide)

## 9 Characteristic pressure/flow curve

