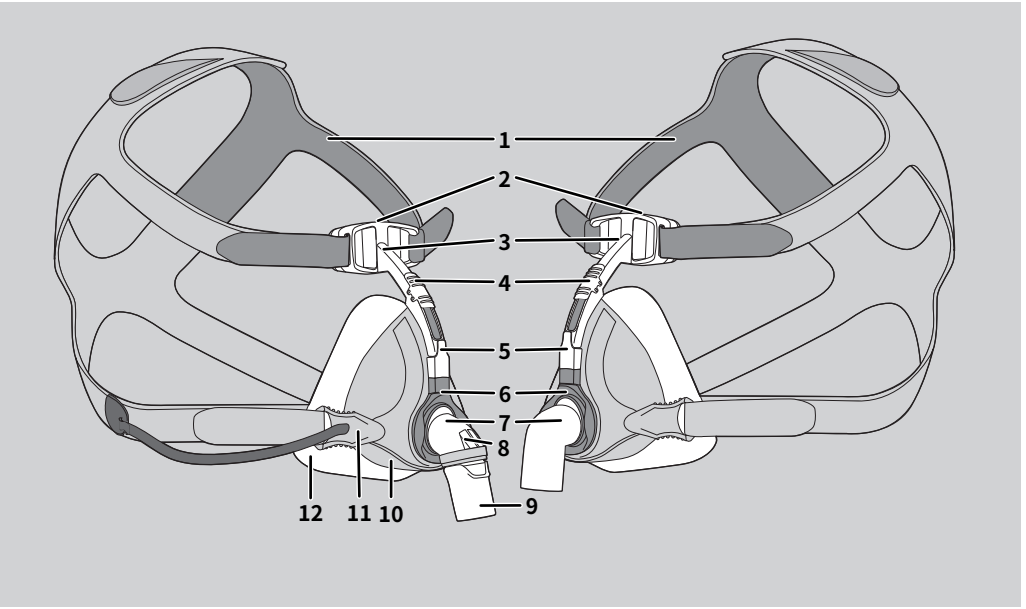
LMT 65886b 09/2023 ZH-CHT, EN-US



CE 0197

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LENA, LENA NV

Full Face Mask

LMT 65886b

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medical

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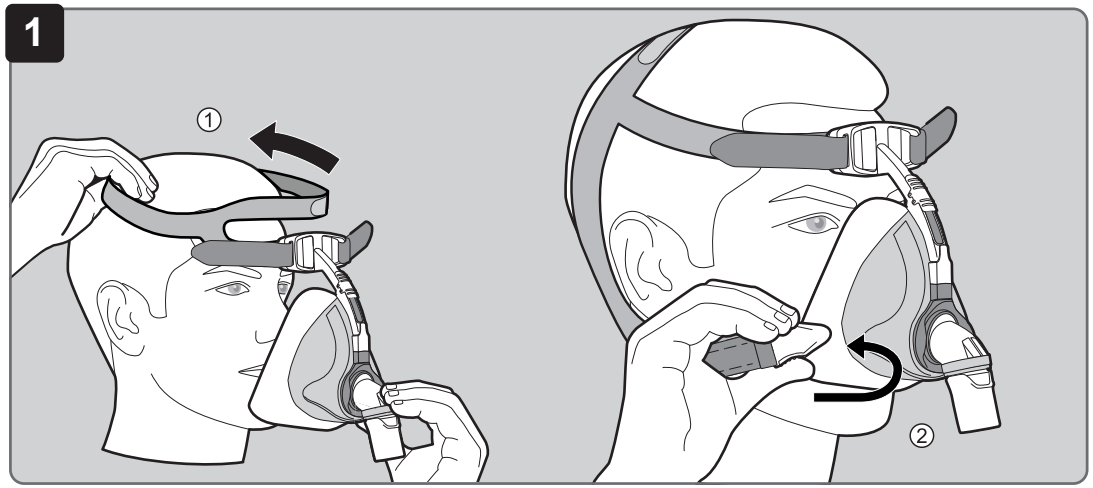
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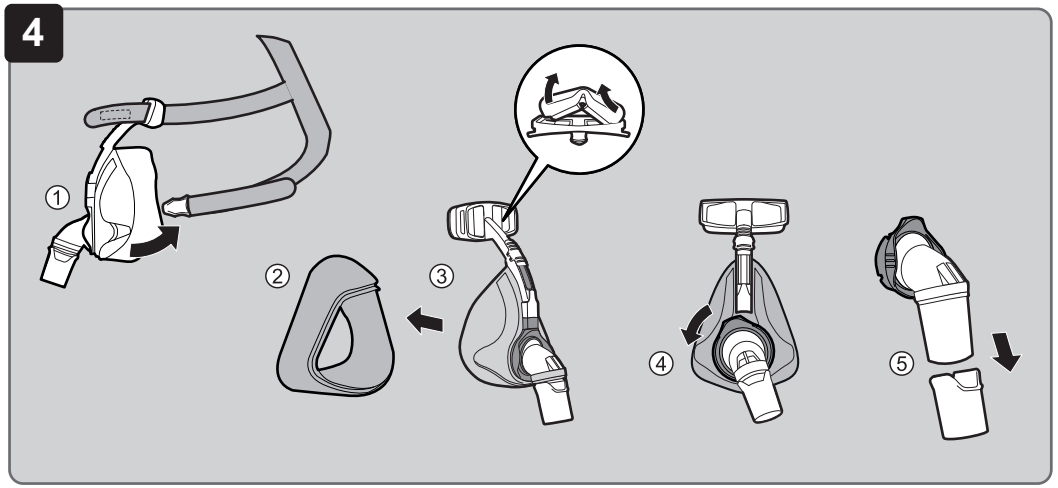
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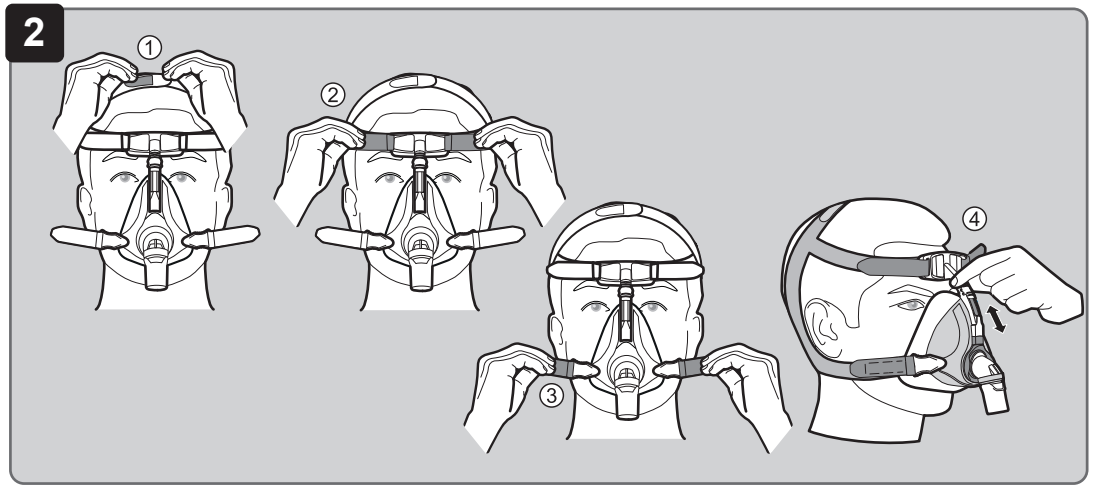
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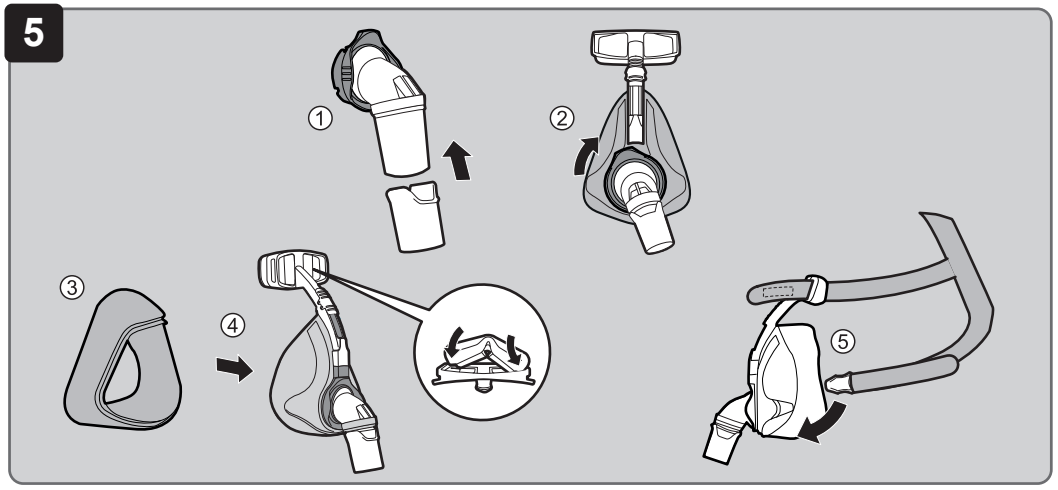
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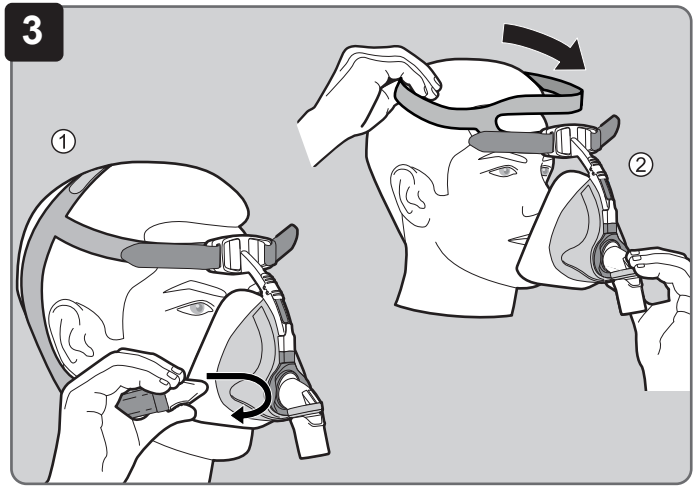
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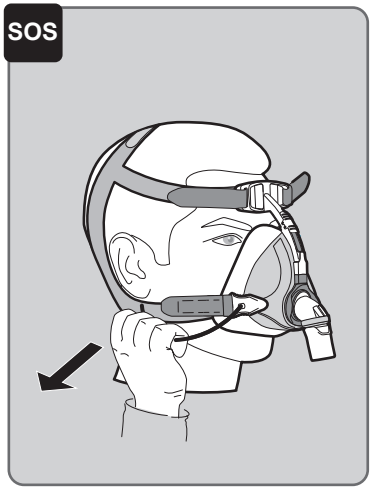
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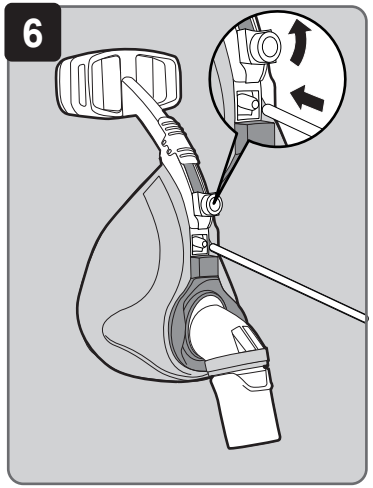
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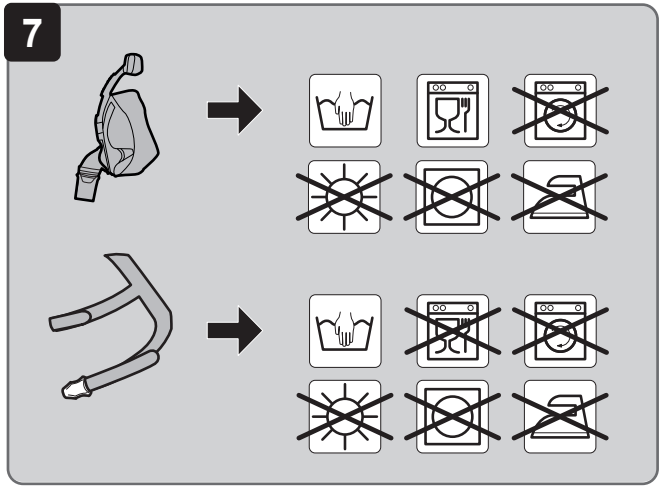
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1 操作

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

6 輸入氧氣

針對盲人或視障使用者
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

LENA 作為配件設計用於體重超過 30 kg 患者，其按醫生要求需要非侵入式呼吸道過壓治療（PAP 治療），如 CPAP/APAP、BiLevel 或 NIV。口鼻罩適合單個患者在家居環境下重複使用以及單個和多個患者在醫院/診所環境下重複使用。

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。
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 安全

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。
⇒ 注意有效壽命（參見技術參數章節）。
⇒ 必要時更換面罩零部件。

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。
⇒ 將氧氣源安置在距離儀器 1 m 以外的地方。
⇒ 禁止吸煙。
⇒ 避免明火。
⇒ 房間充分通風。
⇒ 保持口鼻罩無油脂。

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。
⇒ 須看護自主呼吸受限的患者。

CO_2 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。
⇒ 每次使用前檢查緊急呼氣閥的開口是否敞開。
⇒ 不要封閉呼氣系統。

麻醉氣體和霧化藥物外溢會造成受傷危險！

⇒ 麻醉期間禁止使用口鼻罩。
⇒ 切勿將口鼻罩用於霧化藥物。

清潔不足會造成受傷危險！

⇒ 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。
⇒ 選擇清潔劑時注意可能的過敏問題。
⇒ 在臨床環境中患者變更時：請遵循文檔*衛生處理提示*（參見清潔和衛生處理章節）。
⇒ 對於免疫系統弱或有特殊疾病的患者，需要諮詢醫務人員後每天消毒口鼻罩零部件。

4 產品描述

各個零部件的說明請參見標題頁。

1	頭帶	7	彎管
2	額部墊托	8	緊急呼氣閥
3	額部托架	9	旋轉套管
4	調節件	10	面罩罩體
5	O_2 輸入口	11	頭帶夾
6	鎖緊環	12	面罩軟墊（視類型而定，包含兩個面罩軟墊）

相容儀器

在一些儀器組閤中，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

帶有整合式呼氣系統的口鼻罩具有間隙，由此可以逸出呼出的空氣。

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不具備整合式呼氣系統（「NV」，鎖緊環和彎管為藍色）的口鼻罩只能搭配儀器使用，其具有主動式呼氣系統，還有針對可能出現的儀器故障情況的警報和安全系統。使用外部呼氣系統時，請遵守相關使用說明。

緊急呼氣閥 (AAV)

儀器故障時，緊急呼氣閥打開，患者呼吸的是環境氣體。

快速釋放索（可選）

藉助快速釋放索可以在緊急情況下快速、簡單地解鎖口鼻罩（參閱 **SOS** 圖示）。

5 清潔和衛生處理

5.1 清潔口鼻罩

1. 每次清潔前清洗雙手。
2. 拆分口鼻罩（參閱圖示 **4**）。
3. 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）。

口鼻罩零部件	頻率	操作
所有口鼻罩零部件	每天	浸泡 15 分鐘並清洗，使用柔軟的清潔刷清潔 3 分鐘。
頭帶	每星期	清洗 15 分鐘。

所有零部件（例外：彎管及緊急呼氣閥）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）。

4. 用清水清洗所有零部件。
5. 晾乾所有零部件。
6. 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。
7. 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。
8. 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*衛生處理提示*。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。
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。
未達到治療氣壓。	緊急呼氣閥損壞。	更換緊急呼氣閥。

7 技術參數

	通氣版	NV
尺寸，單位 mm（高 x 寬 x 長） 型號 S 型號 M 型號 L	 155 x 100 x 95 165 x 100 x 95 175 x 100 x 100	 155 x 100 x 105 165 x 100 x 105 175 x 100 x 110
重量 型號 S 型號 M 型號 L	 137 g 141 g 150 g	 135 g 139 g 148 g
死腔容量 型號 S 型號 M 型號 L	 246 ml 288 ml 326 ml	 252 ml 270 ml 321 ml
軟管接頭：依據 EN ISO 5356-1 的錐體	Ø 22 mm（錐頭）	Ø 22 mm（錐套）
阻流性 50 l/min 時 100 l/min 時	 0.32 hPa 0.67 hPa	 0.04 hPa 0.14 hPa
呼氣閥阻流性 50 l/min 時吸氣 50 l/min 時呼氣 公差：± 1 hPa	 0.6 hPa 0.8 hPa	 - -
呼氣閥開關壓力 打開 關閉	 0.5 hPa 2.2 hPa	 - -

使用壽命	5 年
有效壽命	最長 12 個月[1]
治療氣壓	4 hPa - 35 hPa
依據 ISO 4871 規定的雙噪音排放值： 聲壓級 聲功率級 不確定因數	 12 dB(A) 20 dB(A) 3 dB(A)
溫度： 工作 運輸與存放	 +5 °C 至 + 40 °C -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

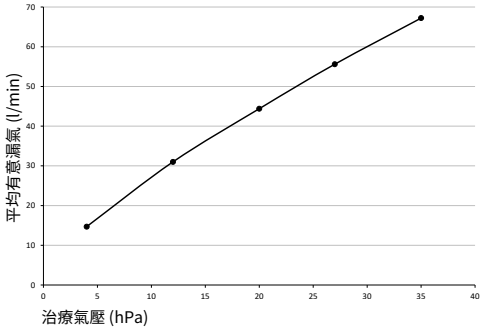
[1] 有效壽命取決於清潔及所用清潔劑、每日佩戴時長、治療氣壓及個人出汗情況。使用第二個面罩軟墊（可選）不會延長有效壽命。

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）。如對所列材料過敏，使用口鼻罩前請先咨詢醫務人員。

頭帶	PA（聚酰胺）、P（聚酯纖維）、PU（聚氨酯）
頭帶夾	POM（聚甲醛）
快速釋放索	PET（聚對苯二甲酸乙二醇酯纖維）、PA（聚酰胺）
快速釋放索夾	POM（聚甲醛）
調節件	POM（聚甲醛）
氧气輸入口	SI（硅酮）
鎖緊環	POM（聚甲醛）
面罩罩體	PA（聚醯胺）
面罩軟墊	SI（硅酮）
彎管	PA（聚醯胺）
旋轉套管	PP（聚丙烯）
緊急呼氣閥	SI（硅酮）
閥門鎖緊件	PP（聚丙烯）

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
UDI	產品識別碼（醫療器材統一產品標識）
REF	訂購貨號
MD	將產品標識為醫療器材
LOT	批號
	製造商和製造日期（如可能）
	遵循使用說明
CE	CE 標誌（證明該產品符合現行的歐盟指令/規定）
	許可的運輸與存放溫度範圍
	可使用至指定日期
	避免日曬

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。

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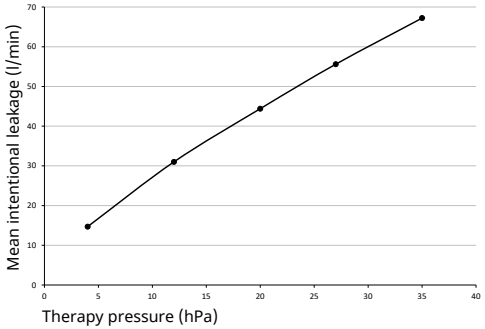
9 Characteristic pressure/flow curve



10 Markings and symbols

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

Symbol	Description
UDI	Unique device identifier (uniform product code for medical devices)
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	CE symbol (confirms that the product conforms to the applicable European directives/regulations)
	Permitted temperature range for transport and storage
	Use by date
	Keep out of sunlight

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 genuine 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 (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.

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.

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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

6 Supplying oxygen

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

LENA is designed for use as an accessory by patients weighing over 30 kg who have been prescribed non-invasive positive airway pressure therapy (PAP therapy) - CPAP/APAP, BiLevel or NIV, for example. The mask is suitable for reuse for individual patients in the home environment and for reuse for individual and multiple patients in the hospital/care home environment.

2.2 Contraindications

The mask must not be used on patients weighing < 30 kg.
The mask must 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 sure whether one of these situations applies to you, consult your healthcare professional. 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 ventilator to the patient

3 Safety

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

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

Risk of injury due to the use of oxygen!
Oxygen can become deposited in clothing, bedlinen, 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.
⇒ Set up oxygen sources at a distance > 1 m from the device.
⇒ Do not smoke.
⇒ Avoid naked flames.
⇒ Ventilate the room well.
⇒ Keep mask free from oil and grease.

Risk of injury due to patient receiving inadequate supply!

⇒ Activate low pressure/leakage alarms on the ventilator.
⇒ Use the appropriate mask size and check that it is securely in position.
⇒ Monitor patients with restricted spontaneous breathing.

Risk of injury from re-inhalation of CO_2!

⇒ 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.
⇒ Check before every use that the openings of the anti-asphyxia valve are clear.
⇒ Do not close off exhalation systems.

Risk of injury due to escape of anesthetic gas or atomization of drugs!

⇒ Do not use the mask during anesthesia.
⇒ Do not use the mask to atomize drugs.

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.

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⇒ When selecting a detergent, consider potential allergies.
⇒ On change of patient in a hospital environment: Comply with the document entitled *Information on reprocessing* (see section entitled "Reprocessing").
⇒ For patients with a compromised immune system or particular background of illness, disinfect mask parts daily following consultation with the healthcare professional.

4 Product description

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

1	Headgear	7	Elbow
2	Forehead cushion	8	Anti-asphyxia valve
3	Forehead support	9	Rotating sleeve
4	Adjusting element	10	Mask body
5	O_2 inlet	11	Headgear clip
6	Retaining ring	12	Mask cushion (two masks may be included, depending on variant)

Compatible devices

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

Exhalation system

Masks with an integrated exhalation system have a gap through which exhaled air escapes.

Only use masks without an integrated exhalation system ("NV", blue retaining ring and elbow) with devices that have an active exhalation system as well as alarms and safety systems for the event of the device failing. If using external exhalation systems, follow the associated instructions for use.

Anti-asphyxia valve (AAV)

If the device fails, the anti-asphyxia valve opens and the patient breathes ambient air.

Quick-release cord (optional)

The quick-release cord allows the mask to be released quickly and easily in emergency situations (see **SOS** illustration).

5 Cleaning and reprocessing

5.1 Clean mask

1. Wash your hands before starting cleaning.
2. Dismantle mask (see Figure **4**).
3. Wash mask by hand (max. 30 °C, 1 ml mild detergent in 1 l water) in accordance with the table below:

Mask part	Frequency	Action
All mask parts	Daily	Soak and wash for 15 minutes and clean for 3 minutes using a soft cleaning brush.
Headgear	Weekly	Wash for 15 minutes.

All parts (exception: elbow and anti-asphyxia valve) can be washed in a dishwasher once a week (max. 70 °C, mild detergent, max. program length 90 minutes, top basket, separate rinse).

4. Rinse all parts with clean water.
5. Allow all parts to air-dry.
6. Perform a visual inspection for cracks and deformation. Replace damaged parts. Discoloration is not a problem.
7. If the mask cushion is damaged or heavily soiled: Replace mask cushion.
   If a second mask cushion is not enclosed, contact your specialist dealer.
8. 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 the 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.	Loosen headgear.
Draft in the eye	Mask too loose.	Tighten headgear.
	Mask does not fit.	Contact your specialist dealer.
Therapy pressure not reached.	Mask not correctly adjusted.	Re-adjust mask.
	Mask cushion damaged.	Replace mask cushion.
	Patient circuit damaged.	Check circuit and correct fit of circuit.
Therapy pressure not reached.	Anti-asphyxia valve defective.	Replace anti-asphyxia valve.

7 Technical data

	Vented	NV
Dimensions in mm (H x W x D) Size S Size M Size L	 155 x 100 x 95 165 x 100 x 95 175 x 100 x 100	 155 x 100 x 105 165 x 100 x 105 175 x 100 x 110
Weight Size S Size M Size L	 137 g 141 g 150 g	 135 g 139 g 148 g
Dead space Size S Size M Size L	 246 ml 288 ml 326 ml	 252 ml 270 ml 321 ml
Tube connection: Tapered connection to EN ISO 5356-1	Ø 22 mm (male)	Ø 22 mm (female)
Flow resistance at 50 l/min at 100 l/min	 0.32 hPa 0.67 hPa	 0.04 hPa 0.14 hPa
AAV flow resistance Insp. at 50 l/min Exsp. at 50 l/min Tolerance: ± 1 hPa	 0.6 hPa 0.8 hPa	 - -
AAV switching pressure Open Close	 0.5 hPa 2.2 hPa	 - -

Service life	5 years
Useful life	Up to 12 months[1]
Therapy pressure	4 hPa - 35 hPa

Quoted two-figure noise emission value according to ISO 4871: Sound pressure level Sound power level Uncertainty factor	 12 dB(A) 20 dB(A) 3 dB(A)
Temperature: Operation Transport and storage	 +5 °C to + 40 °C -20 °C to +70 °C
Standards applied	EN ISO 17510: 2020
Product class to MDR (EU) 2017/745	IIa

[1] Useful life depends on cleaning and on the detergents used, on the amount of time worn daily, on therapy pressure, and on individual secretion of sweat. Using the second mask cushion (included as an option) does not extend useful life.

8 Materials

No parts of the mask contain latex, PVC (polyvinyl chloride) or DEHP (diethylhexyl phthalate). In the event of allergies to the materials listed, only use the mask following agreement with the healthcare professional.

Headgear	PA (polyamide), P (polyester), PU (polyurethane)
Headgear clip	POM (polyoxymethylene)
Quick-release cord	PET (polyethylene terephthalate fiber), PA (polyamide)
Quick-release cord clip	POM (polyoxymethylene)
Adjusting element	POM (polyoxymethylene)
O_2 inlet	SI (silicone)
Retaining ring	POM (polyoxymethylene)
Mask body	PA (polyamide)
Mask cushion	SI (silicone)
Elbow	PA (polyamide)
Rotating sleeve	PP (polypropylene)
Anti-asphyxia valve	SI (silicone)
Valve safety device	PP (polypropylene)

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