



EasyFit Full Face Mask, Silicone

EasyFit Full Face Mask, Gel

Device Description and Instructions for Use

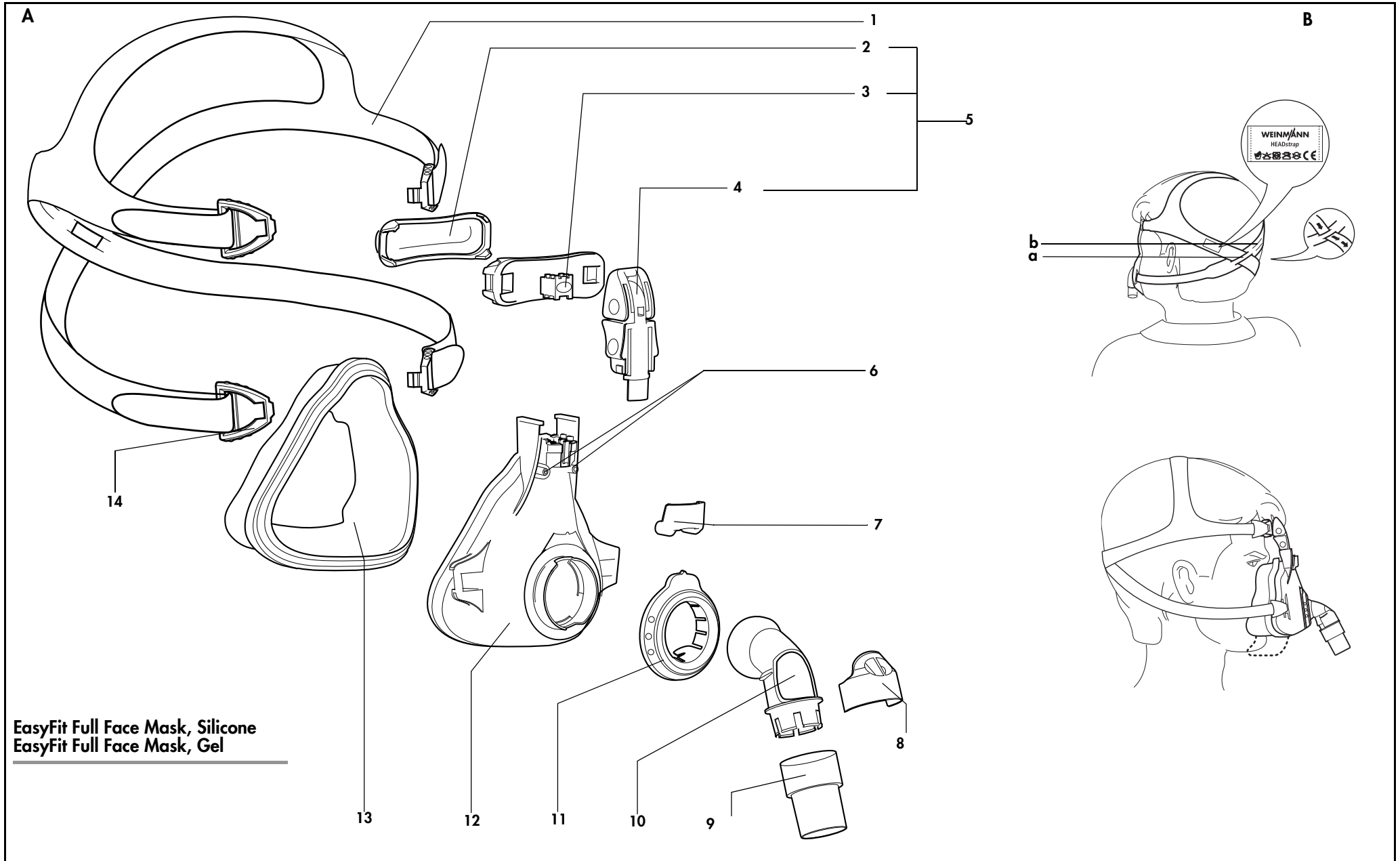
Caution

Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

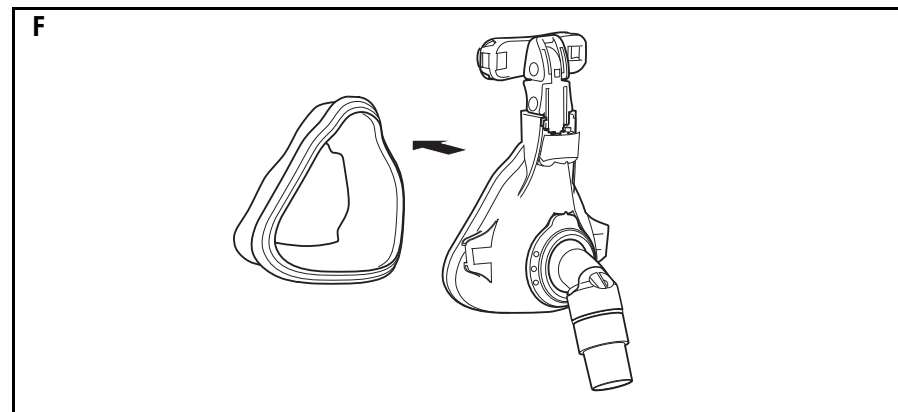
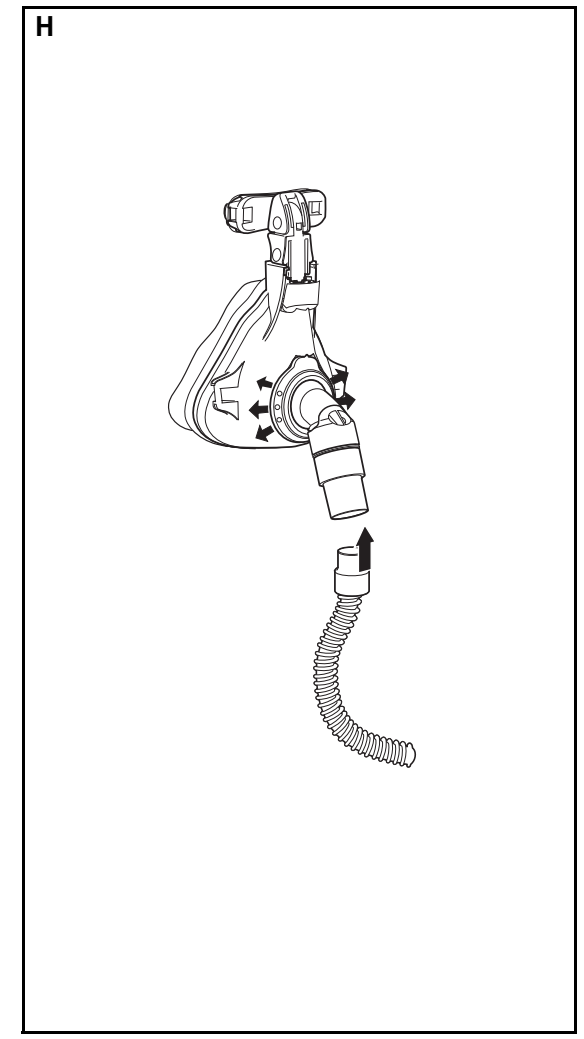
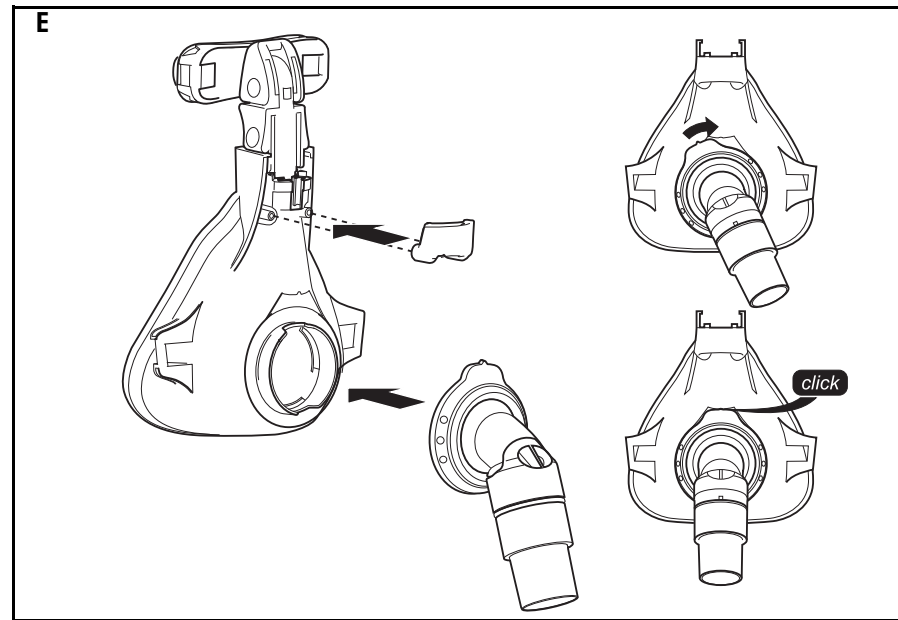
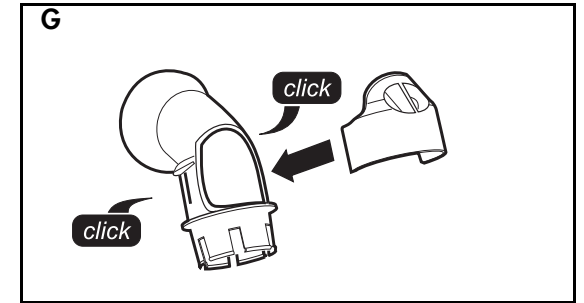
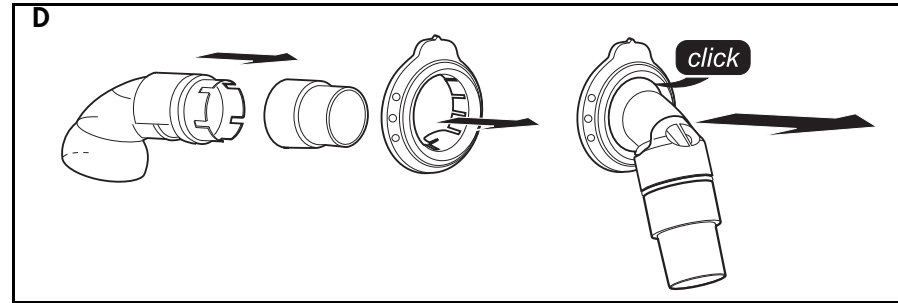
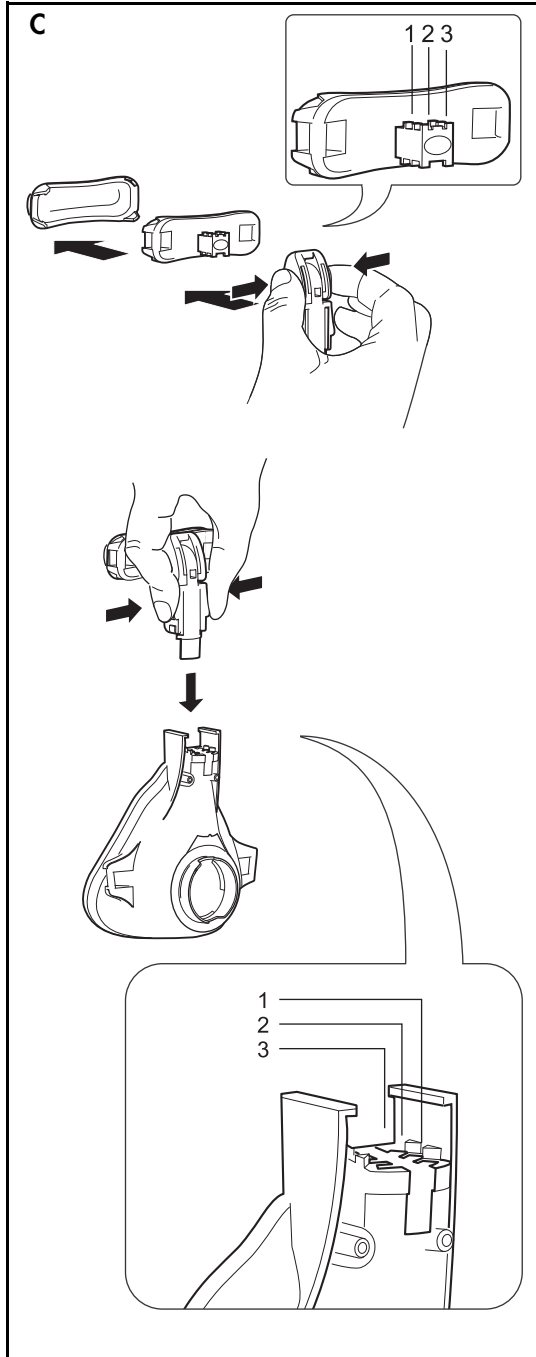
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Overview

Note: The complete user information consists of this leaflet and the instructions for use.



Operation



1 Device Description

Legend

(Description of individual parts: see enclosed leaflet, fig. A)

- 1 Headgear
- 2 Forehead cushion
- 3 Fine adjustment component
- 4 Coarse adjustment component
- 5 Forehead support
- 6 Ports for pressure measurement
- 7 Oxygen port cap
- 8 Anti-asphyxia valve
- 9 Rotating sleeve
- 10 Elbow
- 11 Retaining ring
- 12 Mask frame
- 13 Mask cushion
- 14 Headgear clip

Intended Use

The full face mask is intended for adult patients (>66 pounds or 30kg) prescribed continuous positive airway pressure (CPAP) or bi-level therapy for multiple-patient use in a hospital or clinic environment after high-level disinfection and for single-patient use in a home environment. The full face mask is offered in two versions:

EasyFit Full Face Mask, Silicone
EasyFit Full Face Mask, Gel

Before use by the patient

Patients must be instructed in the use of the mask by qualified personnel before therapy begins.

2 Safety Instructions

Warnings and cautions

For your safety, please observe the following points:



Warning

• Please read these instructions for use very carefully. They are a part of the product and should be available at all times.

- This mask should be used only with CPAP or bi-level systems recommended by your physician or respiratory therapist.
- If oxygen is used with the CPAP or bi-level system, the oxygen flow must be turned off when the CPAP or bi-level machine is not operating.

Explanation of the warning: When the CPAP or bi-level device is not in operation, and the oxygen flow is left on, oxygen delivered into the CPAP tubing may accumulate within the CPAP or bi-level machine enclosure. Oxygen accumulated in the CPAP or bi-level machine enclosure will create a risk of fire. This warning applies to most types of CPAP or bi-level systems.

- The mask should not be worn if the anti-asphyxia valve is damaged or missing. This valve ensures that CO₂ rebreathing is kept to a minimum in the event of power failure.
- The mask should not be worn by patients who are unable to remove it or are prone to vomiting. Wearing the mask under these conditions creates the risk of suffocation.
- The mask is designed for therapy pressure between 4 and 30 cm H₂O. The full face mask must not be used at higher or lower therapy pressures.
- Patients with limited spontaneous respiration must be monitored at all times. The appropriate negative pressure/leak alarm on the therapy device must be activated.

- Patients with obstructive and restrictive lung diseases should be examined on an individual basis during use of the mask, for example with regard to re-inhalation of CO₂.
- The mask is equipped with an integral exhalation valve. Do not connect any additional exhalation valves as desired therapy pressure may not be reached.
- Do not put the full face mask over your face for a prolonged period unless the therapy device is connected to the mask and switched on. The flow of air from the therapy device serves among other things to remove the exhaled air from the mask and hose. If the therapy device is not switched on, there is a risk of re-inhalation when you breathe through your nose. In some circumstances this may lead to suffocation.
- Do not close the openings in this mask except in situations described in these instructions for use. Otherwise there is a risk of re-inhaling CO₂ and suffocation.
- The connection to the device's hose system must be airtight and should not be allowed to loosen due to therapy pressure.
- Do not use a breathing hose that is electrically conductive.
- Clean the mask as described under Section 4 "Cleaning Instructions." Inappropriate cleaning procedures, unsuitable cleaning agents, or infrequent cleaning can result in an infection or bacterial contamination and can impede the functioning of the mask. If the mask cannot be cleaned, replace it with a new one.

Caution

- At low CPAP pressures (4 cm H₂O and lower) the flow through the exhalation slots may be inadequate to clear all exhaled gas from the tubing. Some re-inhalation may occur.
- If supplemental oxygen is used, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection and the leak rate.

- Malfunctions and a lack of biocompatibility may result if third-party articles are used. Bear in mind that in these cases any warranty entitlement and liability shall lapse if the accessories recommended in the instructions for use or original spare parts are not utilized.

Contraindications

In certain circumstances the full face mask should not be used or only with particular caution. In each case the decision whether to use the full face mask for therapy lies with the doctor in charge.

- Impaired cardiac sphincter function
- Excessive gastric reflux
- Impaired cough reflex
- Hiatal hernia
- Sedation
- Open facial wounds that are prone to infections
- Hemodynamic or cardiorespiratory instability
- Unconsciousness
- Claustrophobia or anxiety
- Facial or nasopharyngeal deformity
- Beard or other inability to fit mask and seal properly
- Facial trauma
- Barotrauma
- Need for ventilation or ventilatory support more than 12 hours per day
- Recent facial, esophageal or gastric surgery
- Patients under medication with a drug that may cause vomiting.
- Patients requiring immediate intubation

Side effects

The following side effects may occur during short-term or long-term use: nasal congestion, dry nose, dry mouth in the morning, sinus pressure, chest discomfort, shortness of breath, stomach distension, headache, irritation of the conjunctiva as well as irritating noises during exhalation.

Wearing the mask can also lead to tenderness of the face or reddening of the skin.

3 Operation

Fig. B-H: see enclosed leaflet.

3.1 Adjust forehead support (Fig. C)

Fine adjustment

Squeeze the upper side tabs of the coarse adjustment component inwards. Place the fine adjustment component in one of the stop positions shown.

The height of the forehead cushion can be adjusted (approx. 1 cm). To do this, turn the fine adjustment component through 180° and position it as described above.

Coarse adjustment

Squeeze the lower side tabs of the coarse adjustment component inwards. Place it in one of the slots in the mask frame.

3.2 Putting on the mask (Fig. B)



Warning

To minimize the risk of vomiting during sleep, avoid eating or drinking for three hours before using the mask.

1. Unhook one of the lower headgear clips on the mask.
2. Guide the headgear over your head and hook the headgear clip back onto the mask.
3. Position the mask on your face as shown in Figure B.
4. Adjust the upper and lower straps of the headgear so that the mask sits firmly, but not too tightly, on your face.

The headgear provides the following options for you to do this (see also "Overview" on the attached leaflet):

- coarse adjustments: slot "a" or "b" of the headgear.

- fine adjustments: four hook-and-loop straps.

5. If necessary, re-adjust the forehead support.

3.3 Exhaled air system (Fig. H)

The mask has an **integrated exhaled air system**: the retaining ring and mask frame are shaped in such a way that a gap is formed between these parts. Through this gap the exhaled air can escape. The special geometry of the parts guarantees that when putting on the retaining ring the gap cannot be closed. Do **not** connect an external exhaled air system, otherwise the therapy pressure will not be reached.

3.4 Anti-asphyxia valve (Fig. G)

The mask is equipped with an anti-asphyxia valve. In the event of a power failure this valve allows the patient to breathe room air keeping CO₂ rebreathing to a minimum and thus avoiding the risk of suffocation.

Caution

The anti-asphyxia valve is a delicate component. Always handle the valve with care and perform a function check before each use (See "Functional Checks" on page 7).

3.5 Gel-filled mask components

The EasyFit Full Face Mask, Gel, comes with gel-filled mask and forehead cushion. Gel forehead cushions and gel mask cushions are also available as replacement parts.

Caution

Gel-filled mask components are highly sensitive. Always handle them with care to prevent deformation and damage.

3.6 Connecting the mask to a therapy device (Fig. H)

Push the hose of your therapy device onto the rotating sleeve.

Ensure that the connection to the hose is secure and airtight. The connection must not be loosened by the therapy pressure.

If you want to detach the mask temporarily from the hose, pull the rotating sleeve off the elbow.



Warning

In situations where the risk of contamination between the patient and the therapy device is high, a bacteria filter should be placed between the therapy device and the patient. Also refer to the instructions for use of your therapy device.

3.7 Ports for pressure measurement (Fig. E)

The mask is fitted with two ports that can be used to measure pressure or to feed in oxygen.

Caution

- Oxygen therapy can have side-effects if incorrectly administered or used in the wrong dosage. Use oxygen therapy only as prescribed by a physician.
- When carrying out oxygen therapy, strictly follow the instructions for use of your O₂ system and your therapy device.

When the oxygen ports are not in use, always close them with the cap provided, otherwise air will escape from the ports and the therapy pressure will not be reached.

3.8 Combining the mask with other devices

Therapy devices

The mask can be combined with all devices designed for carrying out the therapies described under "Intended Use."

Note that if unsuitable device combinations are used, the actual pressure in the mask may not correspond to the therapy pressure you have been prescribed.

This may also happen even if the correct pressure is indicated on the therapy device. Have your device combination adjusted by a physician or homecare provider so that the pressure in the mask corresponds to your therapy pressure.

Take account of the specifications in the instructions for use for the devices you intend combining with the full face mask.

Using the mask with humidifiers

The full face mask system can be used with a cold-air or warm-air humidifier.

The degree of humidity you choose should not be so high that water condenses in the air hose. Please be sure to read the instructions for use for your humidifier and your therapy device.

3.9 After use

1. Unhook one of the lower headgear clips from the mask, and guide headgear over your head to remove.
2. Proceed as described in section 4 "Cleaning Instructions".

3.10 Disassembling/reassembling the mask

Disassembling the mask (Fig. F - C)

1. Detach the mask cushion from the mask frame.
2. Remove the cap from the pressure measurement ports.
3. Rotate the retaining ring counter-clockwise to the 11 o' clock position. Now pull the retaining ring and the elbow away from the mask frame.
4. Press the elbow through and out of the retaining ring and pull the rotating sleeve off the elbow.
5. Remove the anti-asphyxia valve from the elbow. Ensure that the inside membrane does not get damaged.
6. Detach the coarse adjustment component from the mask frame.
7. Detach the fine adjustment component from the coarse adjustment component. Then detach the forehead cushion from the fine adjustment component.

Reassembling the mask (Fig. C-F)

1. Attach the forehead cushion to the fine adjustment component. Then attach the fine adjustment component to the coarse adjustment component.
2. Attach the coarse adjustment component to the mask frame.
3. Push the anti-asphyxia valve onto the elbow until it clicks into place on both sides of the elbow. Ensure that the inside membrane does not get damaged.
4. Push the rotating sleeve onto the elbow until you hear it click into place.
5. Press the elbow into the retaining ring until you hear it click into place.
6. Attach the retaining ring and elbow onto the mask frame (11 o' clock position). Turn the retaining ring clockwise to the 12 o' clock position.
7. Push the cap onto the pressure measurement ports.
8. Attach the mask cushion to the mask frame.
9. Fasten the headgear to the mask with the clips.

4 Cleaning Instructions

4.1 Schedule

Daily

Disassemble the mask before cleaning. Immerse all mask components in warm water. Use a mild cleaning agent (e.g., hand dishwashing detergent). Use a piece of soft cloth to remove residue. To clean cavities use a soft brush.

After cleaning, rinse all parts carefully with clean water.



Warning

For patients with a weakened immune system or a special medical history, daily disinfection may be necessary. In this case, please consult your physician.

Caution

Take great care when cleaning the contact surfaces between the mask frame and the retaining ring. Residues on these surfaces can reduce the success of the therapy and the functioning of the integrated exhaled air system.

Note

This mask system is indicated for multiple-patient use in sleep laboratories, provided that appropriate hygienic measures are taken. Please contact your distributor to obtain detailed cleaning and disinfection instructions for multiple patient use (order no. DV67108).

Weekly

Wash the headgear weekly by hand in warm water. Use a mild detergent. Then rinse all parts in clean water and allow to air-dry.

Note

- Wash the headgear before using for the first time, as the color might run.
- The headgear may only be washed by hand!
- Do not iron the headgear, otherwise the hook-and-loop closures will no longer work.

4.2 After cleaning

Dry all parts thoroughly after cleaning. Check the components for residual contamination or damage. If necessary, repeat the cleaning. Replace damaged parts. Reassemble the mask.

5 Functional Checks

Before each use

Before each use check the anti-asphyxia valve as follows:

1. Make sure that valve and membrane are dry and free from cracks or secretions. If the membrane shows any damage (e.g. cracks or deformation), do not use the mask. In this case replace the anti-asphyxia valve. See section 7 for replacement parts.
2. Verify that the inside membrane is not blocking the opening in the valve so the room air can flow into the mask.
3. Connect the hose system (included with your therapy device) to the elbow of your mask and the outlet on the therapy device.
4. Turn the airflow on. The membrane should now cover the opening in the valve so that air can flow from the therapy device into the mask.
5. If the valve or the membrane do not function properly, do not use the mask. In this case replace the anti-asphyxia valve. See section 7 for replacement parts.

After cleaning

Always perform a visual check after cleaning. If the mask cushion is no longer airtight due to cracks or splits, replace it with a new one. Yellowing of the mask cushion and forehead cushion does not indicate malfunction or damage.

Please check the functional capacity and air tightness of the ball-and-socket joint. If it no longer moves easily or is no longer airtight due to cracks or splits, replace the elbow connection and/or the body of the mask accordingly.

See section 7 "Item List" for information regarding replacement parts.

Parts no longer used can be disposed of as normal household waste.

6 Troubleshooting

| Problem | Cause | Solution |
|----------------------------------|--|--|
| Painful pressure on the face. | Mask is too tight. | Loosen headgear slightly. Adjust position of forehead support. |
| Draft in the eyes. | Mask is too loose. | Tighten headgear slightly. Adjust position of forehead support. |
| | Mask does not fit. | Use a different size mask; contact your provider. |
| Therapy pressure is not reached. | Mask not adjusted correctly. | Adjust headgear. Adjust position of forehead support. |
| | Mask cushion is damaged. | Replace mask cushion. |
| | Hose system is leaking. | Check rotating sleeve and hose fit connection. |
| | Air is escaping from pressure measurement ports. | Cover pressure measurement ports with cap (included in package). |

7 Item List

Note

All masks are supplied fully assembled and ready for use. Headgear and instructions for use DV67107 are included.

Complete System

| Frame, Cushions, and Headgear | | |
|-------------------------------|----------|------------------|
| Description | Item No. | Fig. A Label No. |
| Silicone, Small | DV97310 | 1-14 |
| Silicone, Medium | DV97320 | 1-14 |
| Silicone, Large | DV97330 | 1-14 |
| Silicone, X-Large | DV97340 | 1-14 |
| Gel, Small | DV97412 | 1-14 |
| Gel, Medium | DV97422 | 1-14 |
| Gel, Large | DV97432 | 1-14 |
| Gel, X-Large | N/A | |

Replacement Cushions

| Description | Item No. | Fig. A Label No. |
|----------------------------|----------|------------------|
| Silicone, Small | DV97410 | 13 |
| Silicone, Medium | DV97420 | 13 |
| Silicone, Large | DV97430 | 13 |
| Silicone, X-Large | DV97440 | 13 |
| Forehead Cushion, Silicone | DV97300 | 2 |
| Gel, Small | DV97212 | 13 |
| Gel, Medium | DV97222 | 13 |
| Gel, Large | DV97232 | 13 |
| Gel, X-Large | N/A | |
| Forehead Cushion, Gel | DV97227 | 2 |

Replacement Frame

| Includes Everything Except Cushions and Headgear | | |
|--|----------|------------------|
| Description | Item No. | Fig. A Label No. |
| Silicone, Small | DV97314 | 1-12 |
| Silicone, Medium | DV97324 | 1-12 |
| Silicone, Large | DV97331 | 1-12 |
| Silicone, X-Large | DV97341 | 1-12 |
| Gel, Small | DV97316 | 1-12 |
| Gel, Medium | DV97326 | 1-12 |
| Gel, Large | DV97336 | 1-12 |
| Gel, X-Large | N/A | |

Replacement Headgear

| Description | Item No. | Fig. A Label No. |
|--------------------------|----------|------------------|
| Headgear, Universal Size | DV97360 | 1 |

Parts and Accessories

| Description | Item No. | Fig. A Label No. |
|------------------------------|----------|------------------|
| Exhalation Port Assembly | DV97408 | 8-11 |
| Oxygen Port Cap | DV97213 | 7 |
| Headgear Clips Set, 4 Pieces | DV97218 | 14 |
| Forehead Support, Silicone | DV97217 | 5 |
| Forehead Support, Gel | DV97216 | 5 |
| Rotating Sleeve | DV97229 | 9 |

Instructions

| Description | Item No. | Fig. A Label No. |
|---------------------------|----------|------------------|
| Instructions for Use | DV67107 | N/A |
| Disinfection Instructions | DV67108 | N/A |

8 Technical Data

Specifications

| Parameter | Value |
|--|--|
| Dimensions (WxHxD)*: | c. 107 x 160 x 106 mm c. 4.21 x 6.3 x 4.17" |
| Weight*: | c. 93 grams c. 3.3 oz |
| Therapy pressure range: | 4 to 30 cm H ₂ O |
| Hose connector: | male Ø 22 mm conical connector |
| Pressure measurement ports: | Ø 4 mm = 0.157" |
| Width of headgear clip: | max. 20 mm = 0.787" |
| Temperature range Operation: | + 5 °C to + 40 °C 41 °F to 104 °F |
| Storage: | - 20 °C to + 70 °C -4 °F to 158 °F |
| Dead space | |
| Size S | 180 ml (10.98 in ³) |
| Size M | 220 ml (13.43 in ³) |
| Size L | 270 ml (16.48 in ³) |
| Size XL | 310 ml (18.92 in ³) |
| Gel, Size S | 160 ml (9.76 in ³) |
| Gel, Size M | 200 ml (12.20 in ³) |
| Gel, Size L | 250 ml (15.25 in ³) |
| Flow resistance at 50 l/min | 0.02 cm H ₂ O |
| at 100 l/min | 0.26 cm H ₂ O |
| Sound pressure level at 10 cm H ₂ O | 27.5 dB(A) |

*depending on size and type

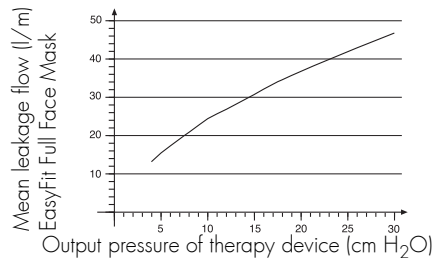
Material

| Article | Material |
|---|--|
| Mask cushion, oxygen port cap | Silicone |
| Mask cushion Gel | Silicone, silicone gel |
| Forehead cushion, retaining ring | TPE, Polypropylene |
| Forehead cushion Gel | Silicone, silicone gel, polycarbonate |
| Mask frame, elbow | Polycarbonate |
| Headgear | Nylon/ Spandex Polyurethane Polyester/Lycra |
| Rotating sleeve, forehead support coarse adjustment component, forehead support fine adjustment component | Polypropylene |
| Headgear clips | POM |

All mask components are latex-free.

Characteristic pressure/flow graph

The characteristic pressure/flow graph shows outlet flow as a function of therapy pressure.



9 Warranty

DeVilbiss warrants that on delivery your mask system including its components: mask cushion, mask frame, elbow, anti-asphyxia valve, oxygen port cap, forehead cushion, forehead support, retaining ring, rotating sleeve, headgear clips and headgear is free from defects in material and workmanship.

Patents

US 5,715,814 and other US patents pending.

