


RESPIRONICS


Instructions for Use

FitLife Total Face Mask

Intended Use

The FitLife Total Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. This mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The small size mask is to be used on patients 7 years or older (>20 kg) for whom CPAP or bi-level therapy has been prescribed. The large and extra large size masks are to be used on patients (>30 kg) for whom CPAP or bi-level therapy has been prescribed.

 **Note:** An exhalation port is built into the FitLife Total Face Mask so a separate exhalation port is not required.

 **Note:** This mask is not made with natural rubber latex or DEHP.

 **Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician.

Symbols



Consult instructions for use



Warning or Caution

X1

System One Resistance Control Setting



Note



Tip



Not Made with Natural Rubber Latex

Warnings

• This mask is not suitable for providing life support ventilation. • This mask is designed for use with CPAP or bi-level systems recommended by your health care

professional or respiratory therapist. Do not wear this mask unless the CPAP or bi-level system is turned on and operating properly. Do not block or try to seal the exhalation port. Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. This warning applies to most models of CPAP systems. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.

- If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Explanation of the Warning: When the device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the device enclosure. Oxygen accumulated in the device enclosure will create a risk of fire.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and bi-level machines.
- Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your healthcare professional.
- The patient's physician should be contacted if the patient experiences the following symptoms while using the masks or after removing it: Unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision. (Consult an ophthalmologist if symptoms persist.)
- At low CPAP or EPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- A minimum of 3 cm H₂O (hPa) must be maintained when using this mask.

- This mask should not be used on patients who are uncooperative, obtunded, unresponsive, or unable to remove the mask.
- This mask is not recommended if the patient is taking a prescription drug that may cause vomiting.
- Appropriate patient monitoring should be used as medically necessary.
- The mask contains small parts which could result in a choking hazard.
- If an additional exhalation device is added to the patient circuit, you may need to adjust the pressure level to compensate for the additional leak of the exhalation device.
- Hand wash prior to first use. Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.
- Use of a nasal or full face mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition. Consult your physician or dentist if symptoms occur.
- Do not block or try to seal the entrainment valve.
- If the mask is dropped, verify that the exhalation vents have not been obstructed prior to use.

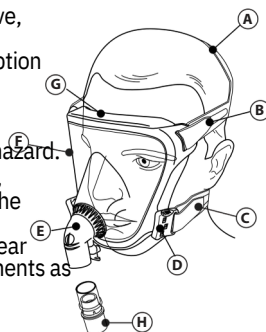


Figure 1

- A = Top strap
- B = Side strap
- C = Bottom strap
- D = Headgear clip
- E = Entrainment valve with fresh air inlet (large opening)
- F = Cushion
- G = Faceplate
- H = Accessory swivel

Contraindications

This mask may not be suitable for use on patients with the following conditions: glaucoma, recent eye surgery or dry eyes, nocturnal vomiting, hiatal hernia, impaired cardiac sphincter function, excessive reflux, impaired cough reflex, or on patients unable to remove the mask.

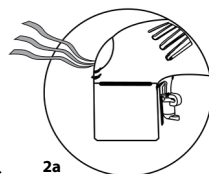
Before Use

- Read and understand the instructions completely.
- Hand wash the mask.
- Wash your face.
- Inspect the mask components for damage or wear; replace if necessary.
- Verify that the entrainment valve functions correctly.

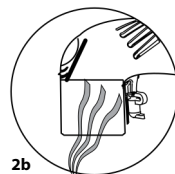
Entrainment Valve

With the airflow turned off, verify that the entrainment valve flapper is lying flat so that room air can flow in and out through the fresh air inlet in the valve (Figure 2a).

Next, with the airflow on, the flapper should now cover the fresh air inlet and air from the CPAP or bi-level device should flow into the mask (Figure 2b). If the flapper does not close or does not function properly, replace the mask.



2a



2b

Warning: Do not block or try to seal the entrainment valve.

Figure 2

Cleaning Instructions for the Mask

Hand wash the mask before first use and daily. The headgear should be hand washed weekly, or as needed. The headgear does not need to be removed for daily cleaning of the mask.

1. Hand wash mask in warm water with a mild liquid dishwashing detergent.

Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

Caution: Any deviation from these instructions may impact the performance of the product.

2. Rinse thoroughly. Air dry completely before use. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.


⚠ Caution: Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.

Institutional Disinfection

For multi-patient use in the hospital/institutional environment, use the Disinfection Guide to reprocess the mask between patients. These instructions can be obtained by visiting us online at www.philips.com/respironics or by contacting Philips Respironics Customer Service at 1-800-345-6443 (USA or Canada) or at 1-724-387-4000.

System One Resistance Control

This mask uses the System One Resistance Control setting

 $\times 1$. This symbol may appear on your therapy device. This symbol represents the level of mask resistance compensation. Match the setting to the mask if appropriate.

⊖ Important Notes:

- Verify the System One setting if the mask or mask cushion changes.
- The System One setting is not compatible with masks requiring a separate/additional exhalation device.

If your provider has locked the resistance compensation setting, you can view the setting but cannot change it, and the screen will display a lock symbol. If your provider has disabled the resistance compensation, you will not see this setting.

Sizing the Mask

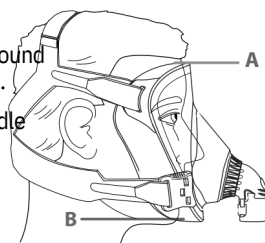
To select the appropriate size mask, the mask cushion should surround the patient's face without obstructing sight and enclose the mouth.


A—The top of the cushion should rest comfortably against the middle of the forehead above the eye brows.

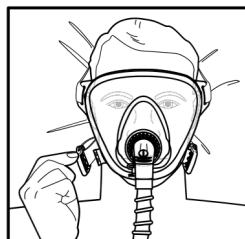
B—The bottom of the cushion should rest comfortably under the mouth and above the chin.


Putting on the Mask

1. Loosen the side headgear straps by peeling back the tabs and open the straps to a larger size.
2. Disconnect one or both of the bottom headgear clips. Grasp the clip with the thumb and index finger and in a turning motion, lift the clip upwards with the thumb while pulling the clip away from the mask faceplate.
3. Hold the mask against your face. The top of the cushion will contact your face just above the eyebrows. The bottom of the cushion will contact your face just above the chin. Be sure your mouth remains slightly open.
4. Pull the headgear over your head.
5. Attach one or both bottom headgear clips by finding the tab on the lower part of the mask faceplate with your thumb. Guide and gently push the headgear clip onto the tab with your middle and index fingers until it clicks into place.



 Figure 3



 Figure 4

Achieving the Right Fit

1. Tighten the side headgear straps. The top strap should lie at the crown of the head. The cross-strap should sit low on the back of the head.
2. Tighten the bottom headgear straps.
3. Adjust the top headgear strap, if necessary. If the side headgear straps are resting on your ears, adjust the top headgear strap to lift the straps slightly off of your ears. DO NOT over tighten as it may cause the headgear to slip.
Connect the accessory swivel to the mask elbow.
4. Connect the tubing that is included with your CPAP or bi-level device to the accessory swivel.
5. With the airflow on, lie down and breathe normally with your mouth slightly open. Reseat the mask
6. by pulling it directly away from your face and gently setting it back into place.
7. Assume different sleeping positions and move your head around.
8. If there are any air leaks, make any final adjustments. Some air leakage is normal.



Comfort Tips

- Re-seat the mask. Pull the mask by the sides of the faceplate directly away from the face then gently set it back into place. DO NOT pull the mask by the exhalation elbow. This allows the cushion to create a new seal on the face .
- Adjust the side headgear straps to eliminate leaks around the forehead and temples. • Adjust the bottom headgear straps to eliminate leaks around the cheeks and chin. • The most common mistake is over tightening the headgear. The headgear should fit loose and comfortable. If your skin bulges around the mask or if you see red marks on your face, loosen the headgear.

Removing the Mask

Undo one or both bottom headgear clips and pull over the top of the patient's head. By undoing the headgear clips, instead of the tabs, you will preserve your adjustments.

Replacing the Mask Elbow

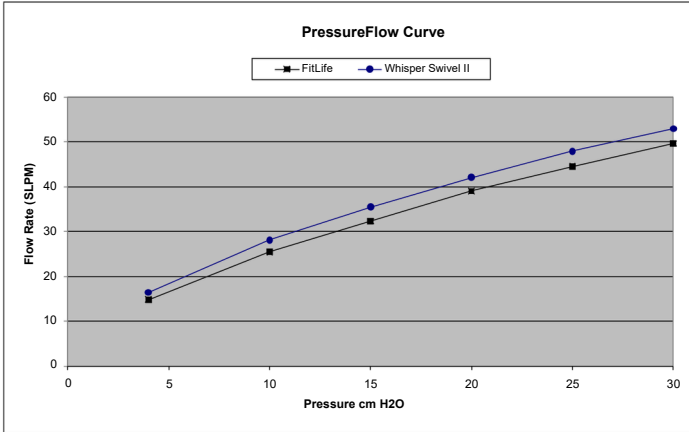
To remove: Hold the faceplate swivel and gently pull the elbow from the faceplate swivel.

To replace: Press the mask elbow into the faceplate swivel. Do not use excessive force or any tools.

Specifications

⚠ Warning: The technical specifications of the mask are provided for your healthcare professional to determine if it is compatible with your CPAP or bi-level therapy device. If used outside these specifications, or if used with incompatible devices, the mask may be uncomfortable, the seal of the mask may not be effective, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect device function.

Pressure Flow Curve



Resistance with Anti-Asphyxia Valve Closed to Atmosphere
Drop in Pressure at

	50 SLPM	100 SLPM
Small/Large/Extra Large	0.4 cm H ₂ O	0.9 cm H ₂ O

Inspiratory and Expiratory Resistance with Anti-Asphyxia Valve Open to Atmosphere

	50 L/min
Inspiratory Resistance	1.5 cm H ₂ O
Expiratory Resistance	0.9 cm H ₂ O

Deadspace Volume

Small	375 mL
Large	550 mL
Extra Large	717 mL

Sound Levels

A-weighted Sound Power Level

≤ 38 dB

A-weighted Sound Pressure Level at 1 m ≤ 30 dB

Storage Conditions

Temperature: -20° to +60° C

Relative Humidity: 15% to 95% non-condensing

Disposal

Dispose of in accordance with local regulations.

Limited Warranty

Respironics, Inc. warrants that its mask systems (including mask frame and cushion) (the “Product”) shall be free from defects of workmanship and materials for a period of ninety (90) days from the date of purchase (the “Warranty Period”).

If the Product fails under normal conditions of use during the Warranty Period and the Product is returned to Respironics within the Warranty Period, Respironics will replace the Product. This warranty is nontransferable and only applies to the original owner of the Product. The foregoing replacement remedy will be the sole remedy for breach of the foregoing warranty.

This warranty does not cover damage caused by accident, misuse, abuse, negligence, alteration, failure to use or maintain the Product under conditions of normal use and in accordance with the terms of the product literature, and other defects not related to materials or workmanship.

This warranty does not apply to any Product that may have been repaired or altered by anyone other than Respironics. Respironics disclaims all liability for economic loss, loss of profits, overhead, or indirect, consequential, special or incidental damages which may be claimed to arise from any sale or use of the Product. Some jurisdictions do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

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To exercise your rights under this limited warranty, contact your local authorized Respironics, Inc. dealer or Respironics, Inc. at 1001 Murry Ridge Lane, Murrysville, Pennsylvania 15668, USA, or Respironics Deutschland GmbH & Co KG, Gewerbestraße 17, 82211 Herrsching, Germany.

