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FitLife

INSTRUCTIONS FOR USE

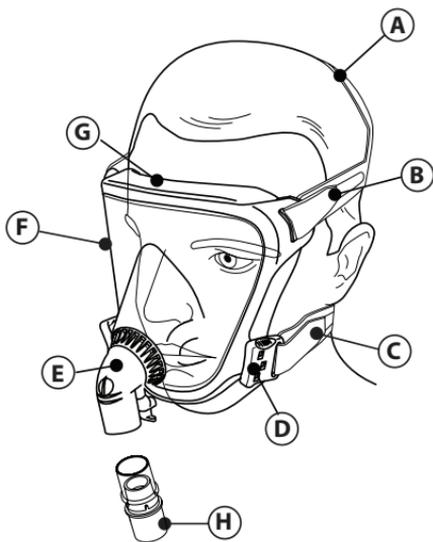
PHILIPS
RESPIRONICS

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Package Contents

- FitLife mask with entrainment elbow
- Headgear
- Instructions for use



Note

Not all packages contain listed items. Please contact your Home Care Provider or Respironics for additional items or replacement parts.

Figure 1

- A = Top Strap
- B = Side Strap
- C = Bottom Strap
- D = Headgear Clip
- E = Entrainment Valve with Fresh Air Inlet (large opening)
- F = Faceplate
- G = Cushion
- H = Accessory Swivel

 Caution

U. S. federal law restricts this device to sale by or on the order of a physician.

Intended Use

Small Size Intended Use: The small size of the FitLife Total Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients 7 years or older (>40 lbs/20 kg) for whom CPAP or bi-level therapy has been prescribed.

Large Size Intended Use: The large size of 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 mask is to be used on patients (>66 lbs/30 kg) for whom CPAP or bi-level therapy has been prescribed.

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

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

Warning

A warning indicates the possibility of injury to the user or operator.

Caution

A caution indicates the possibility of damage to the device.

Note

A note places an emphasis on an operating characteristic.

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 mask 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 4 cm H₂O (hPa) must be maintained when using this mask.
- This mask should not be used for patients who are uncooperative, obtunded, unresponsive, or unable to remove the mask by themselves.
- This mask is not recommended for patients who are 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.

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- 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.

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 by themselves.

Disposal

Dispose of in accordance with local regulations.

Symbols

Symbol	Description
	Consult instructions for use
	General caution or warning
	System One
	Tip
	Note
	Does not contain natural rubber latex
	Does not contain DEHP (bis (2-ethylhexyl) phthalate)

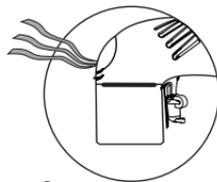
Before Use

- 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.

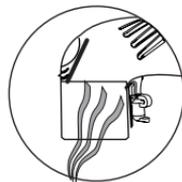
Entrainment Valve

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 elbow.



2a



2b



Figure 2

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

Cleaning Instructions

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 the mask and headgear in warm water with a mild liquid dish washing detergent.

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

2. Rinse thoroughly with drinking quality water and air dry out of direct sunlight. Make sure the mask is dry before use.
3. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
4. Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc). Replace the mask if the cushion becomes hardened.

For **multi-patient use** in the hospital/institutional environment, use the Mask Cleaning and Disinfection Instructions to reprocess the mask between patients. These instructions can be obtained by visiting www.sleepapnea.com or contacting Respironics Customer Service at 1-800-345-6443 (USA or Canada) or 1-724-387-4000.

System One Resistance Control

This mask uses the System One Resistance Control setting  ← X1. 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.

Comfort Tip

If you have sensitive skin, you can condition the mask cushion before use. To condition, create a bath of warm, soapy water and soak the cushion for 30-60 minutes. Use a mild detergent free of conditioners, moisturizers, or bleaching agents. Rinse thoroughly and air dry.

Sizing the Mask

To select the appropriate size mask, the mask cushion should surround your face without obstructing your sight and enclose your 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.

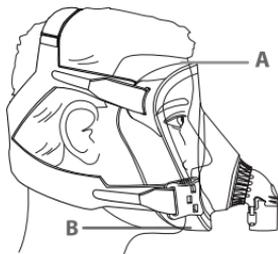
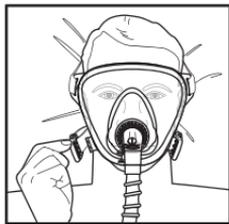


 Figure 3

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.



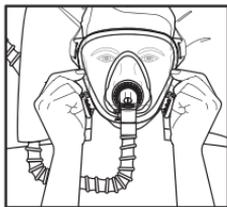
 **Figure 4**

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.
4. Connect the accessory swivel to the mask elbow.
5. Connect the tubing that is included with your CPAP or bi-level device to the accessory swivel.
6. With the airflow on, lie down and breathe normally with your mouth slightly open. Reseat the mask by pulling it directly away from your face and gently setting it back into place.

Note

Do not over tighten the headgear. Over tightening the headgear may cause discomfort, irritation, and/or additional leaks.



▲ Figure 5

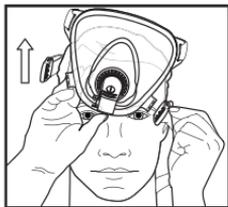
7. Assume different sleeping positions and move your head around.
8. If there are any air leaks, make any final adjustments. Some air leakage is normal.

Comfort Tips

- *Re-seat the mask. Pull the mask by the sides of the faceplate directly away from your 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 loosely and feel 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 the mask over the top of your head. By undoing the headgear clips instead of the tabs, you will preserve your adjustments.

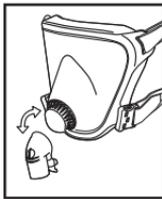


▶ Figure 6

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.

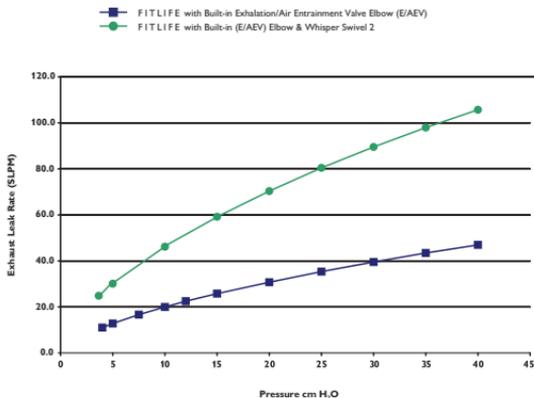


▶ Figure 7

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.

Intentional Leak



Pressure Drop cm H₂O (hPa)

	50 SLPM	100 SLPM
Small	0.52	1.07
Large	0.52	1.07

Deadspace Volume

Small	375 mL
Large	550 mL

Storage Conditions

-4° to +140° F (-20° to +60° C)
15% to 95% RH, non-condensing

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 non-transferable 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 states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS WARRANTIES. IN ADDITION, ANY IMPLIED WARRANTY, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS SPECIFICALLY DISCLAIMED. SOME STATES DO NOT ALLOW DISCLAIMERS OF IMPLIED WARRANTIES, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM STATE TO STATE.

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, 1-800-345-6443 (USA and Canada only) or 1-724-387-4000.

Reorder Numbers

1060801	SMALL FITLIFE MASK W/ HEADGEAR
1060802	LARGE FITLIFE MASK W/ HEADGEAR
1072530	SMALL FITLIFE MASK W/O HEADGEAR
1072531	LARGE FITLIFE MASK W/O HEADGEAR
1060807	FITLIFE HEADGEAR, SMALL
1060808	FITLIFE HEADGEAR, LARGE
1060809	FITLIFE ENTRAINMENT ELBOW
1060913	FITLIFE HEADGEAR CLIPS
7041	ACCESSORY SWIVEL

Visit us on-line at www.sleepapnea.com for a complete list of products and reorder numbers, or contact Customer Service at 1-800-345-6443 (USA or Canada only) or 1-724-387-4000.