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FullLife

INSTRUCTIONS FOR USE

PHILIPS
RESPIRONICS

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Package Contents

- FullLife
 - frame
 - mask cushion
- Headgear and chin support band
- Instructions for use
- Quick fit tips

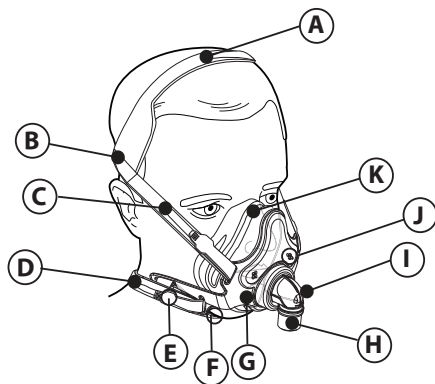


Note

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



Figure 1



- A = Top Headgear Strap
- B = Back Headgear Strap
- C = Side Headgear Strap
- D = Lower Headgear Band
- E = Strap Stop
- F = Chin Support Band
- G = Frame
- H = Tubing Quick Release
- I = Entrainment Valve with Fresh Air Inlet (large opening)
- J = Exhalation Vents
- K = Mask Cushion



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

Intended Use

The FullLife Full 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 (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.



Important Note: An exhalation port is built into the FullLife Full 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.

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.

 Warnings cont.

- 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 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 3cm 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.

 Warnings cont.

- This mask is not recommended for patients who are taking a prescription drug that may cause vomiting.
- 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.
- 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.

Contraindications

This mask may not be suitable for persons with the following conditions: impaired cardiac sphincter function, excessive reflux, impaired cough reflex, and hiatal hernia. It should not be used if the patient is uncooperative, obtunded, unresponsive, or unable to remove the mask by themselves.

Symbols

Symbol	Description
	Consult instructions for use
	Caution or Warning
	Tip
	Note
X1	System One Resistance Control Setting

Symbols cont.

Symbol	Description
	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.
- Make sure the cushion is securely attached to the frame. See the *Attaching the Cushion* section.
- Verify that the entrainment valve functions correctly, as noted below.
- Inspect the mask components for damage or wear; replace if necessary.

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.



Warning

Do not block the fresh air inlet on the entrainment valve. Ensure that the valve is not blocked with secretions and that the flapper is dry. Do not block or seal the exhalation vents in the mask cushion.

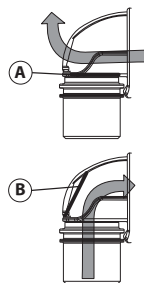


 Figure 2

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. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
3. 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 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.

Putting on the Mask and Headgear

1. Loosen the lower headgear band by peeling back the tabs and then open up to the strap stop.
2. Next, loosen the side headgear straps by peeling back the tabs and then open up to the strap stop.
3. Pull the lower headgear band over your head and onto your neck.
4. Adjust the chin support band so it is under your chin.
5. Place your nose and mouth into the cushion.
6. Pull the remaining headgear on over your head. The headgear stretches to make it easier to put on and take off the mask.

Achieving the Right Fit

Make sure your mouth remains slightly open as you begin adjusting the mask. The mask frame and headgear tabs are marked with numbers 1-4 (Figure 3), indicating the order for adjusting the straps. Hold the mask lightly against your face and tighten the straps and band.

1. Adjust the side headgear strap.
2. Adjust the lower headgear band.
The chin support band should still rest comfortably under your chin.

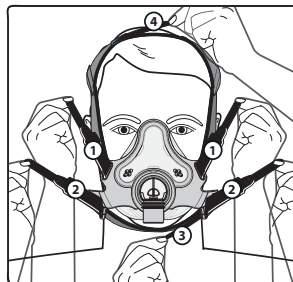


 Figure 3

Note

The chin support band is not intended to keep your mouth closed.

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** overtighten the top strap as it may cause the headgear to slip.

Achieving the Right Fit cont.

The mask and headgear should fit comfortably. The side headgear straps should rest just above your ears. The lower headgear band should rest on the back of your neck.

4. Connect the tubing that is included with your CPAP or bi-level device to the quick release.
5. With the airflow on, lie down and breathe normally with your mouth slightly open. Re-seat the mask by pulling it directly away from your face and gently setting it back into place.
6. Assume different sleeping positions and move your head around.
7. If there are any air leaks, make any final adjustments. Some air leakage is normal. Do not overtighten the headgear. Overtightening the headgear may cause discomfort, irritation, and/or additional leaks.



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

Achieving the Right Fit cont.



Comfort Tips

- The headgear should fit loose and comfortable. If your skin bulges around the mask, loosen the headgear. Over tightening the headgear can hinder the mask's performance and seal.
- Reseat the mask by pulling it directly away from your face and gently setting it back into place.
- Adjust the side headgear straps to eliminate leaks around your eyes.
- Adjust the lower headgear band to eliminate leaks at the sides of your mouth.
- Tighten the chin support band if the mask is leaking and/or riding into your eyes.
- Adjust the top headgear strap to lift the straps off of your ears.

Removing the Mask

1. Grasp the back headgear strap and pull the headgear forward over your head. The mask will rest on the front of your chest (Figure 4).
2. If necessary, undo one or both tabs of the lower headgear band and pull over the top of your head.

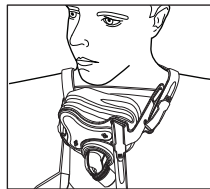


 Figure 4

Tubing Quick Release

The entrainment valve is equipped with a quick release for the CPAP tubing. Simply pull on the release with the tubing attached (Figure 5) and the tubing will release from the entrainment elbow.

Home Care Providers: If a nasogastric (NG) tube or similar device is in place, use an optional nasogastric tube sealing pad. Position the pad so that its flat surface is against the wearer's face and the C-shaped opening surrounds the tube.

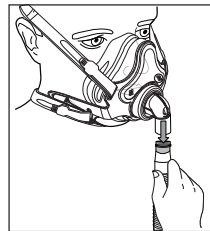


 Figure 5

Removing the Mask Cushion

The mask cushion can be removed from the mask frame (Figure 6). Grasp the top of the mask cushion and peel it off of the frame. The cushion can now be washed or replaced as needed.

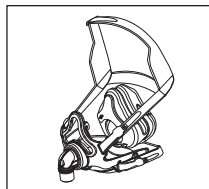


 Figure 6

Attaching the Mask Cushion

1. Place the raised triangular section of the mask cushion against the back of the mask frame (Figure 6).
2. Use your thumbs to press the mask cushion past the retaining tabs on the mask frame and press into place.
3. Use your thumbs to press the round hole in the cushion around the circular hub on the frame (Figure 7). Start at the top of the cushion opening and work your thumbs around the opening until the cushion completely surrounds the frame hub.

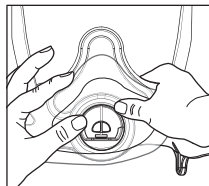
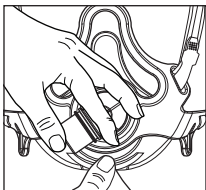


 Figure 7

Walk thumbs along inside of cushion until the circular hub is flush with the cushion

Attaching the Mask Cushion cont.

4. At the bottom of the frame, pull the cushion forward and over the edge of the frame until the frame slides into the lip of the cushion (Figure 8). The front of the mask cushion should be flush with the front of the mask frame.



◀ Figure 8

The cushion must be flush along the front of the frame. The tabs along the triangle area will slide into the mask cushion and the bottom curve of the mask frame will slide into the groove on the mask cushion.

Disposal

Dispose of in accordance with local regulations.

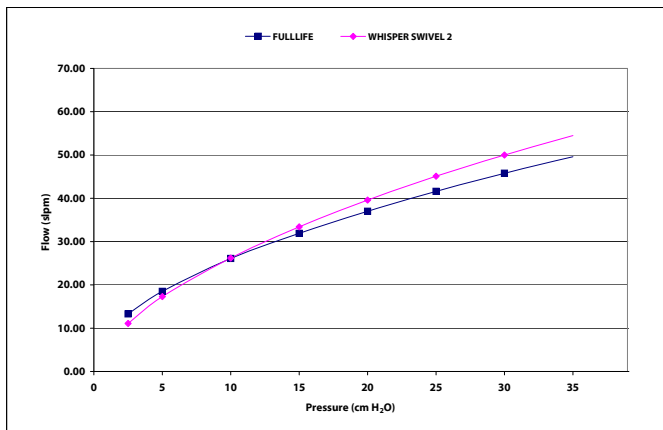
Specifications



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.

Specifications cont.

Intentional Leak



FullLife

Specifications cont.

Pressure Drop cm H₂O

	50 SLPM	100 SLPM
S/M/MW/L	0.5	1.1

Deadspace Volume

Small	260 mL
Medium	310 mL
Medium Wide	315 mL
Large	380 mL

Storage Conditions

Temperature: -4° to +140° F (-20° to +60° C)

Relative Humidity: 15% to 95%, 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.

LIMITED WARRANTY cont.

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 Respiroics, Inc. dealer or Respiroics, Inc. at 1001 Murry Ridge Lane, Murrysville, Pennsylvania 15668, 1-800-345-6443 (USA and Canada only) or 1-724-387-4000.

Reorder Numbers

1047916	S FULLLIFE MASK W/HEADGEAR
1047917	M FULLLIFE MASK W/HEADGEAR
1067584	MW FULLLIFE MASK W/HEADGEAR
1047918	L FULLLIFE MASK W/HEADGEAR
1047919	S/M/MW/L FULLLIFE FITPACK W/HEADGEAR
1052149	S/S FULLLIFE DUOPACK W/HEADGEAR
1052153	M/M FULLLIFE DUOPACK W/HEADGEAR
1067585	MW/MW FULLLIFE DUOPACK W/HEADGEAR
1052156	L/L FULLLIFE DUOPACK W/HEADGEAR
1052158	S FULLLIFE MASK W/O HEADGEAR
1052159	M FULLLIFE MASK W/O HEADGEAR
1067586	MW FULLLIFE MASK W/O HEADGEAR
1052160	L FULLLIFE MASK W/O HEADGEAR
1047922	S FULLLIFE CUSHION
1047923	M FULLLIFE CUSHION
1067604	MW FULLLIFE CUSHION
1047924	L FULLLIFE CUSHION
1047975	FULLLIFE HEADGEAR

Visit us on-line at www.respironics.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.

FullLife