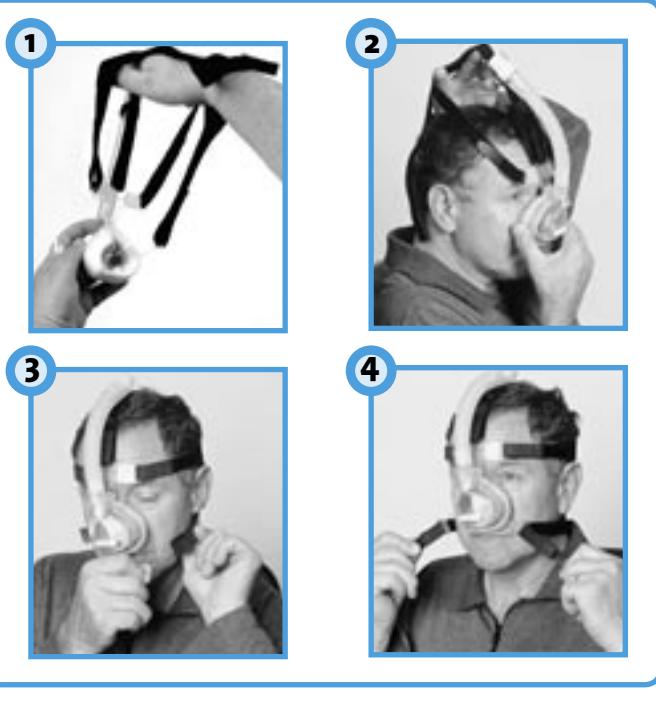


Acclaim®2 NASAL MASK PATIENT INSTRUCTIONS FOR USE

The Acclaim®2 Nasal Mask is intended for multiple patient or single patient adult use by individuals who have been diagnosed by a physician as requiring CPAP or Bi-level ventilator treatment.



FITTING YOUR MASK

- Remove plastic cover from Silicone Seal (C).
- Holding your mask in one hand, spread the Headgear (K) with your free hand, just enough to fit comfortably over your head.
- Lightly hold the mask against your face, covering the nose, then slowly pull the Headgear over your head.
- Attach the Headgear to the Glider™ Strap (E). Pull the lower straps as low as possible down the back of your neck. Gently tighten straps to remove slack. Connect to the CPAP/Bi-Level machine set at prescribed pressure.
- Adjust the tension in each strap for comfort and to ensure there are no leaks.
- If necessary, tighten the lower straps to eliminate any leak (avoid overtightening the straps).
- Use the Silicone Seal that provides the best fit for you. Small and Large are both provided with your mask.
- When you need to remove your mask, unhook the Headgear from the Glider™ Strap.

FITTING TIPS

- Forehead pads should rest gently on the forehead without top straps being pulled too tight.
- If there are any leaks after gently tightening the top and lower straps, pull the mask slightly out from the face while straps are still attached. This will allow Silicone Seal to inflate with air. Put the mask back onto the face.

CLEANING YOUR MASK

To ensure continuing safety and comfort from your Acclaim®2 Nasal Mask:

- BEFORE FIRST USE:**
 - Hand-wash the Headgear in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to dry out of direct sunlight.
 - Inspect the mask for deterioration. Do not use if damaged.
 - AFTER EACH USE:
 - Wash all parts except the Foam Cushion (D), Headgear (K) and Diffuser (G) in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to dry out of direct sunlight.
 - The Diffuser (G) should not be washed or rinsed. Simply replace it with a new Diffuser if it becomes noisy or deteriorates. It should last two to three months. Small dots may appear on the Diffuser - these do not affect its performance. The Acclaim®2 Nasal Mask may be used with or without the Diffuser and Diffuser Cap (H).
 - EVERY 7 DAYS:**
 - Hand-wash the Headgear in pure soap dissolved in lukewarm water. Do not soak for longer than 10 minutes, then rinse in fresh water and allow to dry out of direct sunlight.

CAUTIONS

- Do not soak the mask for longer than 10 minutes.
- Do not wash the mask in the dishwasher.
- Do not clean the mask with products containing alcohol, anti-bacterial agents, antiseptic, bleach, chlorine or moisturizer.
- Do not store the mask in direct sunlight.

The above actions may deteriorate or damage the mask and shorten its life. If your Acclaim®2 Nasal Mask weakens or cracks, discontinue use and seek replacement immediately.

ASSEMBLING YOUR MASK

Your Acclaim®2 Nasal Mask is fully assembled and ready to use. However, when you need to clean your mask, use the following instructions for reassembly: Refer to the diagram on the left.

- Place the Foam Cushion (D) into the Mask Base (A).
- Starting at the top of the mask, fit the Silicone Seal (C) over the Foam Cushion and onto the Mask Base, finishing at the bottom.
- Fit the small end of the Flexitube Assembly (B) onto the Mask Base.
- Fit the Diffuser (G) into the Diffuser Cap (H) and snap the assembly onto the Mask Base.

5. Lay the Headgear (K) flat, with the loop side down. Position the assembled mask over the Headgear and attach the five straps to the corresponding slots in the Forehead Rest (J) and Glider™ Strap (E). Finally, secure the Flexitube Assembly with the tab attached to the top strap.

OXYGEN/PRESSURE PORT CONNECTOR

If pressure readings and/or additional oxygen are required, an Oxygen/Pressure Port Connector is available (Code 900HC452).

- Connect the large end of the Connector (T) to the Swivel (I) on the mask and the small end of the Connector to the main Breathing Tube (R).
 - Open the Port Caps (P) and place the pressure and/or oxygen tube (S) firmly over the Port(s) (Q).
- (The two ports are identical; either port may be used for oxygen or pressure measurement. Only remove the Port Cap from ports that are being used.)
- Note:** At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient's breathing pattern, mask selection, and the leak rate.
 - Warning:** If oxygen is used with CPAP/Bi-Level machine, the oxygen flow must be turned off when the CPAP/Bi-Level machine is not operating.
 - Explanation of Warning:** When the CPAP/Bi-Level device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the CPAP/Bi-Level machine enclosure. Oxygen accumulated in the CPAP/Bi-Level machine enclosure will create a risk of fire.
 - Warning:** Do not smoke while using or in the vicinity of someone using oxygen with this mask.
 - Warning:** Do not use Polyvinyl Chloride (PVC) pressure and/or oxygen tubing. PVC tubing instead.
 - Explanation of Warning:** Contact with PVC can cause premature cracking of ports.

WARNINGS

- This mask should be used only with CPAP or Bi-Level equipment recommended by your physician or respiratory therapist. A mask should not be used unless the CPAP or Bi-Level machine is turned on and operating properly.
- Explanation of Warning:** CPAP and Bi-Level machines are intended to be used with special masks which have exhaust flow holes to allow continuous flow of air out of the mask. When the CPAP/Bi-Level machine is turned on and functioning properly, new air from the CPAP/Bi-Level machine flushes the exhaled air out through the exhaust flow holes. However, when the CPAP/Bi-Level machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be re-breathed. Re-breathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation.
- At low CPAP/Bi-Level pressures the flow through the exhalation ports may be inadequate to clear all exhaled gas from the tubing. Some re-breathing may occur.
 - Do not block the gas exhalation ports or use alternative diffusers, other than those manufactured by Fisher & Paykel Healthcare. Before use, always ensure that gas is flowing out the exhalation ports or through the Diffuser (if it is being used).
 - Do not use the mask if vomiting or feeling nauseous.
 - Discontinue using the mask if there is an allergic reaction to any part of the mask. Consult your physician if this occurs.
 - If reusing the Acclaim®2 Nasal Mask between different patients, refer to the Multi-Patient Cleaning Instructions for the Acclaim®2 Nasal Mask.

CAUTIONS

- Use the mask for its intended use only as directed in this booklet.
- US Federal Law restricts this device to sale by, or on order of a physician.

The Acclaim®2 Nasal Mask and accessories are Latex free. Many people find CPAP/Bi-Level therapy causes dryness of the nose and throat. Heated humidification can substantially reduce these symptoms.

US PATENT NUMBER 6 615 834
OTHER PATENTS PENDING

FOR ADDITIONAL INFORMATION CONTACT YOUR LOCAL HOMECARE PROVIDER

TECHNICAL SPECIFICATIONS

EXHAUST FLOW

Nasal masks for CPAP and Bi-Level machines have exhaust flow holes to expel the air that you exhale from the mask. The Acclaim®2 Nasal Mask has a unique Diffuser system that is designed to diffuse the air that is expelled from the mask. This reduces the draft.

The Diffuser does not significantly change the amount of air flowing from the mask, therefore the mask can be used with or without the Diffuser.

PRESSURE (cmH₂O) 3 5 7 9 11 13 15 17 19 21 23 25
FLOW (L/MIN) 15 19 23 26 28 31 33 35 37 39 41 43

RESISTANCE TO FLOW

Pressure drop through mask @ 50 l/min 0.1cmH₂O

Pressure drop through mask @ 100 l/min 0.5 cmH₂O

MASK DEAD SPACE

800cc

OPERATING CONDITIONS

- Operating pressure is 3-25 cm H₂O
- Operating temperature range is 5-50°C (40-120°F)

MULTI-PATIENT CLEANING INSTRUCTIONS

Your Acclaim®2 Nasal Mask is provided patient-ready. To reuse between patients please follow the guidelines below.

CLEANING / DESOILING

- Before disinfection, remove visible soil by disassembling and thoroughly cleaning the mask with a small brush under running potable tap water.

FAILURE TO PROPERLY CLEAN THIS DEVICE MAY RESULT IN INADEQUATE DISINFECTION.

HIGH-LEVEL DISINFECTION PARAMETERS

- NB : Pour les cycles de stérilisation à l'autoclave ou à l'oxyde d'éthylène, les composants doivent être placés dans une poche de stérilisation.

MASK BASE

Autoclave, 30 minutes' exposure at 121°C (250°F).

OR

STERRAD® 100S

Follow manufacturer's instructions for Sterrad® 100S sterilization system.

SILICONE SEAL

Follow manufacturer's instructions for high-level disinfection.

Immerse for 30 minutes at 20°C (68°F).

Rinse thoroughly in potable water.

OR

SPOROX® II

Follow manufacturer's instructions for high-level disinfection.

Immerse for 6 hours at 20°C (68°F).

Rinse thoroughly in potable water.

FLEXITUBE & SWIVEL

SOAK parts in hot-water bath for 30 minutes at 70°C (158°F).

OR

STERRAD® 100S

Follow manufacturer's instructions for Sterrad® 100S sterilization system.

CIDEX® OPA

Follow manufacturer's instructions for high-level disinfection.

Immerse for 30 minutes at 20°C (68°F).

Rinse thoroughly in potable water.

HEADGEAR

Hand-wash the Headgear in pure soap dissolved in lukewarm water. Dry out of direct sunlight.

FOAM CUSHION

Replace with new part.

DIFFUSER

If continuing use with the Diffuser, replace with a new part.*

DIFFUSER COVER

If continuing use with the Diffuser, replace with a new part.*

*Use of the Diffuser and Diffuser Cap is optional on the Acclaim®2 Nasal Mask.

Disclaimer: It is the users responsibility to qualify any deviations from the recommended method of reprocessing.

The Acclaim®2 Nasal Mask can be reprocessed 20 times using the above methods. Do not use if damaged.

CONTACT YOUR LOCAL HOMECARE PROVIDER FOR ADDITIONAL INFORMATION.

Acclaim®2 Bias Flow

Graph showing Bias Flow (LPM) vs Pressure (cmH₂O). The curve shows a linear increase from approximately 15 LPM at 5 cmH₂O to 45 LPM at 25 cmH₂O.

Bias Flow (LPM) 50
40
30
20
10
0
0 5 10 15 20 25 30
Pressure (cmH₂O)

MASQUE NASAL Acclaim®2 MODE D'EMPLOI POUR LE PATIENT

Le masque nasal Acclaim®2 a été développé pour des patients adultes à qui il a été prescrit un traitement par pression positive continue ou VNDP. Ce masque est conçu pour une utilisation à patient unique ou multiple.

MISE EN PLACE DE VOTRE MASQUE

- Enlevez le cache plastique de la jupe en silicone (C).
- Tenez le masque d'une main et de l'autre tirez suffisamment sur le harnais (K) pour pouvoir le mettre sur la tête sans difficultés.
- Maintenez le masque légèrement contre votre visage, en couvrant le nez, puis ramenez doucement le harnais sur votre tête.
- Fixez les sangles à la glissière (E). Tirez sur les sangles inférieures pour les amener aussi bas que dans votre narine. Serrez les sangles sans forcer pour éliminer le jeu. Raccordez à l'appareil de PPC / VNDP, réglez sur la pression prescrite.
- Ajustez le serrage de chaque sangle de manière à ce que le masque soit confortable et qu'il n'y ait pas de fuites.
- Si nécessaire, serrez les sangles inférieures pour éliminer toute fuite éventuelle (éviter de tirer sur les sangles excessivement).
- Utilisez la jupe qui vous convient le mieux. Deux tailles de jupe (Small et Large) sont fournies avec votre masque.
- Lorsque vous devrez retirer le masque, il vous suffit de détacher le harnais de la glissière.

ASTUCES DE MISE EN PLACE

- Il n'est pas nécessaire de tirer fortement le harnais pour positionner correctement les appuis frontal.
- Si des fuites persistent, tirez sur le masque pour décoller du visage (harnais en place). Cette opération permet de regonfler la jupe. Puis remettez le masque.

NETTOYAGE DE VOTRE MASQUE

Pour garantir la sécurité et le confort de votre masque Acclaim®2 :

- AVANT LA PREMIÈRE UTILISATION :**
 - Lavez à la main le harnais dans l'eau savonneuse tiède. Ne pas immerger plus de 10 minutes, puis rincer à l'eau claire et laisser sécher à l'air libre, à l'abri de la lumière du soleil.
- AVANT CHAQUE UTILISATION :**
 - Vérifiez que le masque n'est pas détérioré. Ne l'utilisez pas s'il est endommagé.
- APRÈS CHAQUE UTILISATION :**
 - Nettoyez toutes les pièces du masque sauf la mousse (D), harnais (K) et le diffuseur (G) dans de l'eau savonneuse tiède. Ne pas immerger pendant plus de 10 minutes, puis rincer à l'eau claire et laisser sécher à l'air libre, à l'abri de la lumière du soleil.
 - Le diffuseur (G) ne doit pas être lavé ou trempé. Le remplacer s'il est détérioré ou devient bruyant. Des petits points peuvent apparaître sur le diffuseur. Cela n'affecte pas ses performances. L'Acclaim®2 peut être utilisé avec ou sans diffuseur (H).
 - UNE FOIS PAR SEMAINE :**
 - Laver à la main le harnais dans l'eau savonneuse tiède. Ne pas immerger plus de 10 minutes, puis rincer à l'eau claire et laisser sécher à l'air libre, à l'abri de la lumière du soleil.

ATTENTION

- Ne pas immerger le masque plus de 10 minutes.
- Ne pas laver le masque au lave-vaisselle.
- Ne pas laver le masque avec des produits contenant de l'alcool, des agents antibactériens, des antiséptiques de la javel, du chlore ou de la crème hydratante.
- Stockez à l'abri de la lumière directe du soleil.
- Les actions citées ci-dessus peuvent détériorer ou endommager le masque. Si votre masque nasal Acclaim®2 se craquelle ou se fissure, ne l'utilisez plus et remplacez-le immédiatement.

MONTAGE DE VOTRE MASQUE

Votre masque Acclaim®2 est entièrement assemblé et prêt à l'emploi. Néanmoins, lorsque vous devrez le nettoyer, suivez les instructions suivantes pour le remettre:

- Retirez-vous au schéma de gauche.
- Placez la mousse (D) sur la coque du masque (A).
 - En commençant par le haut du masque et en finissant par le bas, placez la jupe (B) sur la structure de coque du masque en faisant passer par-dessus le coussin en mousse.
 - Placez la petite extrémité du tuyau flexible (B) sur la coque du masque.
 - Placez le diffuseur (G) dans son logement (H) et enclenchez l'ensemble sur la coque du masque.
 - Mettez le harnais (K) à plat avec la boucle vers le bas. Placez le masque assemblé sur le harnais et fixez les cinq sangles aux fentes correspondantes du support frontal (I) et de la glissière (E). Pour finir, fixez le tuyau flexible à l'aide de la languette de la sangle supérieure.

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