

DeVilbiss®
Horizon™ BiLevel
Nasal CPAP System
7355 Series
Instruction
Guide



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

MISE EN GARDE—Le droit fédéral (américain) limite ce modèle à être vendu ou commandé par un médecin.

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Specifications

Size	9.75" H x 9.75" W x 7.25" D (24.8cm x 24.8cm x 18.4cm)
Weight	8 lbs.(3.6 Kg)
Electrical Requirements	100-240V~, 50/60 Hz
Power Consumption	80 Watts maximum
IPAP Pressure Range	3-20 cm H ₂ O ± 1.0 cm H ₂ O*
EPAP Pressure Range	3-20 cm H ₂ O ± 1.0 cm H ₂ O*
Operating Temperature Range	40°-105° F (4.4° - 34°C)
Storage Temperature Range	-4°-140° F (-20° - 59°C)
Operating Humidity Range	95% RH (noncondensing)
Operating Atmospheric Conditions	Sea level to 10,000 feet
Warranty	One-year limited

Equipment classification with respect to protection from electric shock: Class I;

Degree of protection from electric shock: Type BF;


Degree of protection against ingress of liquids: None;

Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with nitrous oxide;


Mode of operation: BiLevel and Continuous.


*Must utilize mask and patient tubing assembly as detailed in manual to obtain prescription pressures within the specified tolerance range.

IEC Symbols

 Attention, consult instruction guide
Attention. Veuillez consulter votre guide

| On (power: connection to the mains)
On/En (l'appareil est alimenté)

 Off (power: disconnection from the mains)
Off/Hors (l'appareil n'est alimenté)

 Type BF equipment
Équipement de type BF

IMPORTANT SAFEGUARDS/ PRÉCAUTIONS IMPORTANTES

When using electrical products, basic safety precautions should always be followed.

Read all instructions before using. Important information is highlighted by these terms:

DANGER—urgent safety information for hazards that will cause serious injury or death.

WARNING—important safety information for hazards that might cause serious injury.

CAUTION—information for preventing damage to the product.

NOTE—information to which you should pay special attention.

READ ALL INSTRUCTIONS BEFORE USING. SAVE THESE INSTRUCTIONS.

Lors de l'utilisation d'un produit électrique, on doit toujours observer certaines mesures de sécurité essentielles. Lire la totalité des instructions avant d'utiliser l'appareil.

L'information importante est mise en valeur par les termes suivants:

DANGER—information d'identification des dangers susceptibles de provoquer des blessures graves ou un accident mortel.

AVERTISSEMENT—information de sécurité importante à l'égard des dangers susceptibles de provoquer de graves blessures.

MISE EN GARDE—information destinée à empêcher le produit de subir des dommages.

REMARQUE—information à considérer avec attention.

LIRE LA TOTALITÉ DES INSTRUCTIONS AVANT D'UTILISER L'APPAREIL. CONSERVEZ CES INSTRUCTIONS.

WARNING STATEMENTS:

- This is not a life support device and is intended to be used on spontaneously breathing adults.
- This CPAP machine should be used only with masks (and connectors) recommended by the manufacturer of the CPAP machine, or by your physician or respiratory therapist. A CPAP mask with tubing should not be worn unless the CPAP machine is turned on and operating properly. The vent hole(s) associated with the mask should never be blocked.

Explanation of the Warning:

This CPAP machine is intended to be used with special masks (or 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 mask vent hole. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some

circumstances lead to suffocation. This warning applies to most models of CPAP machines.

- To reduce the chances of rebreathing of expired gases, use only a nasal mask with exhalation ports sized for a minimum leak rate of 10 L/min at CPAP pressure of 3 cm H₂O and a maximum of 60 L/min for CPAP pressures of 20 cm H₂O.
- Some tubing is prone to kinking. Flow can be blocked causing apnea episodes to resume. Use only 22mm diameter smooth bore-type, kink-resistant tubing.
- Electric shock hazard. Unit must be used

with a wall outlet installed and grounded in accordance with all local codes and ordinances. The wall outlet must have the same configuration as the power cord's plug. If the plug does not fit properly into your wall outlet, do not modify the plug or wall outlet. Do not use an adapter, a qualified electrician should be contacted to install a correct outlet.

- To avoid electric shock, always unplug power cord from wall outlet power source before cleaning. Never rinse or place the unit in water. Never allow liquids to get into or around any of the ports, switches, or air filter.

- Electric shock hazard. Do not attempt to open or remove cabinet, there are no user-serviceable internal components. If service is required, return it to a qualified Sunrise Medical provider or an authorized service center.

- If oxygen is used with this CPAP machine, the oxygen flow must be turned off when the CPAP machine is not operating.

Explanation of the warning:

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

- Equipment not suitable in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Note: Equipment is suitable for use with oxygen if prescribed by your physician. See Supplemental Oxygen section in the following pages.

- Oxygen causes rapid burning. To avoid possible physical injury, do not smoke while setting up or using your nasal CPAP with supplemental oxygen. Do not use within 10 feet of hot, sparking objects or open sources of flame.

- The oxygen adapter assembly is for single-patient use.

- To ensure that an adequate level of supplemental oxygen is being delivered, make certain that the same interfacing technique be utilized in the home as was used in the clinic.

- The flow setting of the oxygen source shall be specified by a physician.
- The mask, patient tubing, and air intake filter are for single-patient use.

AVIS D'AVERTISSEMENTS

- Cet appareil n'est pas un respirateur artificiel, et est visé à être utilisé pour des souffles spontanés d'adulte.

- Cet appareil de ventilation spontanée en pression positive continue (CPAP) ne doit être utilisé qu'avec un masque (et des connecteurs) recommandés par le fabricant de l'appareil CPAP, ou par votre médecin ou le thérapeute en inhalothérapie. Le masque et le tube de l'appareil CPAP ne doivent être portés que si l'appareil est en position ON et fonctionne bien. La bouche (ou les bouches) de ventilation associée(s) au masque ne doit (vent) jamais être obstruée(s).

Explication sur l'avertissement:

Cet appareil CPAP a été conçu pour être utilisé avec des masques spéciaux (ou des connecteurs) munis de bouches de ventilation qui permettent la circulation continue de l'air dans le masque. Lorsque l'appareil CPAP est en position ON et qu'il fonctionne bien, un air renouvelé provenant de l'appareil CPAP nettoie l'air exhalé par le blais de la bouche de ventilation du masque. Toutefois, lorsque l'appareil CPAP n'est pas en marche, il n'y a pas suffisamment d'air qui circule dans le masque et il peut arriver que le patient respire à nouveau l'air expiré. La respiration de l'air exhalé plus que quelques minutes, peut, en certaines circonstances, provoquer la suffocation. Cet avertissement s'applique à la plupart des modèles d'appareils CPAP.

- Afin d'éviter de respirer à nouveau les gaz expirés et pour vous assurer que le système fonctionne adéquatement, n'utilisez qu'un masque nasal muni d'orifices d'exhalation permettant un écoulement minimum de 10 L/min pour des pressions CPAP (ventilation spontanée en pression continue) de 3 cm H₂O et un écoulement maximum de 60 L/min pour des pressions CPAP de 20 cm H₂O.

- Certains tubes sont enclins à s'entortiller. Le débit peut être obstrué et provoquer une reprise d'épisodes d'apnée. n'utilisez qu'un tube de 22 mm, à parois lisses, qui résiste à l'entortillement.

- Danger de choc électrique. L'appareil doit être utilisé avec une prise murale avec mise à la terre selon les codes et règlements locaux. La configuration de la prise murale doit être identique à celle de la fiche à trois branches du cordon d'alimentation. Dans le cas où la fiche ne s'insère pas bien dans la prise murale, ne modifiez pas la fiche ou la prise murale. Ne vous servez pas d'un adaptateur. Veuillez communiquer avec un électricien qualifié pour l'installation de la prise appropriée.

- Afin d'éviter tout choc électrique, débranchez toujours le cordon d'alimentation de la prise murale. Ne placez jamais l'appareil dans l'eau et ne le rincez jamais. Aucun liquide ne doit être répandu sur ou s'infiltrer dans les orifices, les interrupteurs ou le filtre à air.
- Risque de choc électrique. N'essayez pas d'ouvrir ou d'enlever le boîtier. L'utilisateur n'a aucunement besoin des pièces à l'intérieur de l'appareil. Si l'appareil doit être réparé, veuillez le retourner à un distributeur compétent ou un centre de services autorisé de Sunrise Medical.

- Si vous utilisez de l'oxygène avec cet appareil CPAP, vous devez placez le débit d'oxygène en position Off lorsque l'appareil CPAP ne fonctionne pas.

Explication sur l'avertissement:

Lorsque l'appareil CPAP n'est pas en marche, et que le débit d'oxygène est laissé en position ON, l'oxygène évacué dans le tube du ventilateur peut s'accumuler dans le boîtier de l'appareil CPAP. L'oxygène accumulé dans le boîtier de l'appareil CPAP peut provoquer un risque d'incendie. Cet avertissement s'applique à la plupart des modèles d'appareils CPAP.

- Cet équipement n'est pas approprié en présence d'un anesthésique inflammable mélangé avec de l'air ou avec de l'oxygène ou encore avec du protoxyde d'azote. REMARQUE— Cet équipement est approprié pour l'usage avec de

l'oxygène, seulement si votre médecin vous l'a prescrit. Voir Supplemental Oxygen dans les pages suivantes.

- L'oxygène peut rapidement causer des brûlures. Afin d'éviter toute blessure éventuelle, ne fumez pas en installant ou en utilisant votre appareil respiratoire nasal CPAP avec un supplément d'oxygène. Utilisez l'appareil à une distance minimale de 10 pieds de la chaleur, des objets étincelants ou des sources ouvertes de flammes.
- L'adaptateur d'oxygène est réservé à l'usage d'un seul patient.
- Pour vous assurer d'avoir un niveau de débit d'oxygène additionnel adéquat, utilisez la technique d'interface identique à celle qui fut utilisée à la clinique.
- Le réglage du débit de la source d'oxygène doit être déterminé par un médecin.
- L'usage du masque, du tube de patient et du filtre d'admission d'air est limité à un seul patient.

PRECAUTION STATEMENTS:

- At low CPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- 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 caution applies to most types of CPAP machines.

• The air flow for breathing produced by this device can be as much as 3°F higher than the temperature of the room when operating at an IPAP level of 14 cm H₂O and an EPAP level of 7 cm H₂O. This temperature difference may vary with various IPAP/EPAP ratios. Caution should be exercised if the room temperature is warmer than 90°F.

- Consult your physician if the temperature of the air creates discomfort.
- Oxygen is a prescription gas and should only be administered under the supervision of a physician.
- Always turn on the nasal CPAP device prior to turning on the oxygen flow and turn off the oxygen before turning the unit off.
- Do not place mask, headgear, tubing, or oxygen adapter in an automatic dishwasher. Some automatic dishwashing detergents contain chemicals that may damage these items. Also do not clean with alcohol or any alcohol-based solutions as damage will result.

AVIS DE PRÉCAUTIONS

- Lorsque les niveaux de pression du CPAP sont bas, il est possible que le débit dans le port d'exhalation soit inadéquat et ne permette pas d'éliminer du tube tous les gaz exhalés. Il y a un risque que le patient respire à nouveau l'air exhalé.
- Lorsque le taux d'écoulement de débit additionnel d'oxygène est fixe, la concentration d'oxygène inhalé variera selon les réglages de la pression, le mode de respiration du patient, le type de

masque et le taux d'écoulement. Cette mesure de prudence s'applique à la plupart des appareils CPAP.

- Le débit d'air de respiration produit par cet appareil peut être de 3°F supérieur à la température de la pièce lorsque l'appareil est réglé à un niveau de pression positive inspiratoire de 14 cm H₂O et à un niveau de pression expiratoire de 7 cm H₂O. Cette différence de température peut varier selon le rapport pression inspiratoire/pression expiratoire. Veuillez être prudent si la température de la pièce dépasse 90° F. Veuillez consulter votre médecin si la température de l'air crée un inconfort.
- L'oxygène est un gaz fourni sur ordonnance seulement et ne devrait être administré qu'une fois sous la supervision d'un médecin.
- Mettez toujours votre CPAP nasal sous tension (On) avant de mettre le débit d'oxygène sous tension (On), et mettez l'oxygène hors tension (Off) avant de mettre l'appareil hors tension (Off).
- Ne placez pas le masque, le serre-tête, le tube ou l'adaptateur dans un lave-vaisselle automatique. Certains détergents de lave-vaisselle automatique contiennent des produits chimiques qui peuvent endommager ces pièces. De plus, n'utilisez pas d'alcool ou de solutions à base d'alcool pour nettoyer ces pièces. Vous risquez de les endommager.

International Travel

This unit is equipped with a universal power supply capable of accepting line voltages of 100-240V~, 50/60 Hz. No adjustments are required with the AC power connector or the line fuses

to accept this entire range of voltages. If traveling to another country where the line voltage is different than the domestic supply voltage, simply obtain a line cord configured for

that particular country with the appropriate international plug and substitute it for the standard plug. Operate unit as normal.

Introduction

What is Obstructive Sleep Apnea (OSA)?

Obstructive Sleep Apnea (OSA) is a condition where the upper airway relaxes during sleep causing the airway to obstruct. Apnea is the Latin word meaning "without breath." People diagnosed with sleep apnea stop breathing repeatedly during sleep resulting in extreme exhaustion. High blood pressure, cardiac enlargement, and cardiac arrhythmias are common, as are shortness of breath and loud snoring. In a 1993 report, the National Commission on Sleep Disorders Research states that as many as 18 million Americans may have signs and symptoms of obstructive sleep apnea.

How does the Horizon BiLevel CPAP system work?

The Horizon instrument provides non-invasive, continuous air pressure to your upper airway acting as an air "splint" to keep the airway passages open during sleep. This reduces and eliminates the obstructive events, allowing uninterrupted sleep. The DeVilbiss Horizon is designed to provide this therapy to you quietly and comfortably so that your sleep is restorative and refreshing. The bilevel mode provides two levels of pressure established by the physician. There is an inspiratory positive airway pressure (IPAP) and an expiratory positive airway pressure (EPAP) setting. These two pressures allow for a more comfortable breathing pattern

when a higher pressure is needed to treat your obstructive sleep apnea. In turn this should allow you to better comply with the therapy so you receive the most benefit from this treatment.

Indications for Use:

The Horizon BiLevel model #7355 is indicated for the treatment of obstructive sleep apnea in the adult patient population.

WARNING—This is not a life support device and is intended to be used on spontaneously breathing adults.

AVERTISSEMENT—Cet appareil n'est pas un respirateur artificiel, et est visé à être utilisé pour des souffles spontanés d'adulte.

Important Parts of Your Horizon

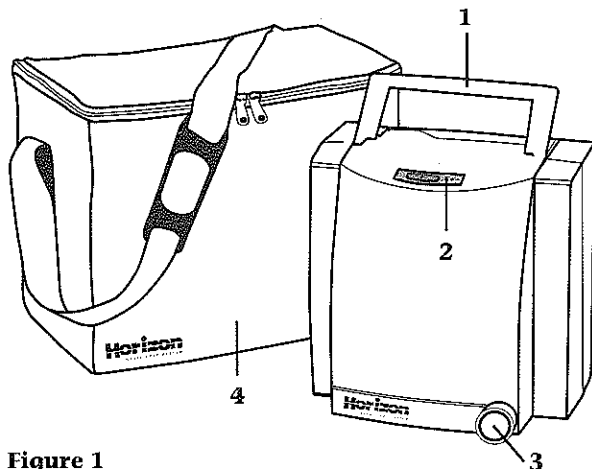


Figure 1

1. Flip-Up Handle
2. A/D (Activate/Deactivate) Button
3. Outlet Port
4. Carrying Case

WARNING—Equipment not suitable in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. **NOTE**—Equipment is suitable for use with oxygen if prescribed by your physician. See Supplemental Oxygen on page 8.

AVERTISSEMENT—Cet équipement n'est pas approprié en présence d'un anesthésique inflammable mélangé avec de l'air ou avec de l'oxygène ou encore avec du protoxyde d'azote. **REMARQUE**—Cet équipement est approprié pour l'usage avec de l'oxygène, seulement si votre médecin vous l'a prescrit. Voir Supplemental Oxygen sur la page 8.

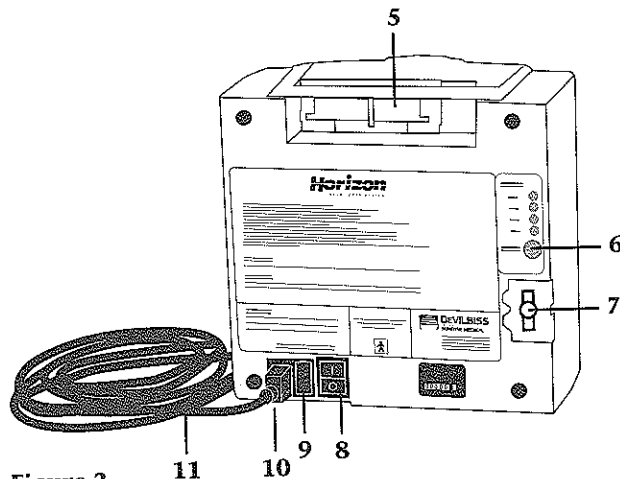
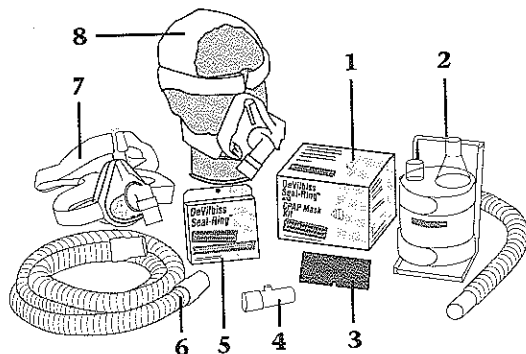


Figure 2

- 5. Air-Inlet Filter
- 6. Delay Select Button
- 7. Options Port
- 8. Power Switch
- 9. Fuse Holder
- 10. AC Power Connector
- 11. Power Cord (Assure proper configuration for outlet)

Accessory/Replacement Items



- 1. Nasal Masks
 - Small 7351D-668
 - Medium 7351D-669
 - Large 7351D-670
- 2. CPAP Humidifier 7352D-640
- 3. Air-Inlet Filter 7353D-602 (4pk)
- 4. Oxygen Adapter 7353D-601
- 5. DeVilbiss Seal-Ring™ (4/pk)
 - Small 7351D-658
 - Medium 7351D-659
 - Large 7351D-660
- 6. 8' 22 mm Tubing 7353D-603
- 7. Strap-Style Headgear 7351D-617
- 8. Cap-Style Headgear 7351D-627

These accessories can be obtained from the home medical equipment provider in your area or contact Sunrise Medical.

WARNING—To reduce chances of rebreathing of expired gases and to assure proper system operation, use only a nasal mask with exhalation ports sized for a minimum leak rate of 10 L/min at CPAP pressures of 3 cm H₂O and a maximum of 60 L/min for CPAP pressures of 20 cm H₂O **Diagram 1.**

AVERTISSEMENT—Afin de réduire les risques de respirer à nouveau les gaz expirés et pour vous assure que le système fonctionne adéquatement, n'utilisez qu'un masque nasal munl d'orifices d'exhalation permettant un écoulement minimum de 10 L/min pour des pressions CPAP (ventilation spontanéc en pression continue) de 3 cm H₂O et un écoulement maximum de 60 L/min pour des pressions CPAP de 20 cm H₂O **Diagram 1.**

How to Operate Your Horizon

DeVilbiss Mask Leak Rates

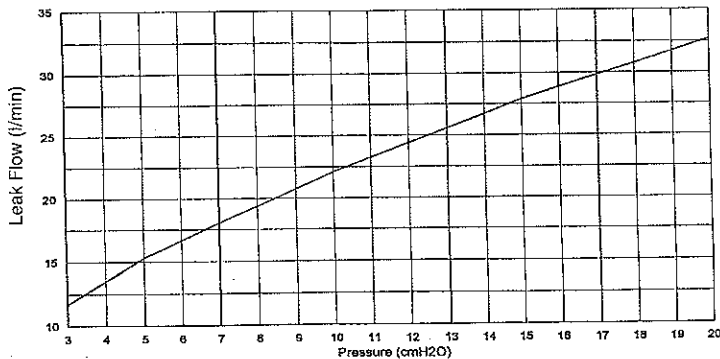


Diagram 1. DeVilbiss Small (7351D-668), Medium (7351D-669) & Large Mask (7351D-670)

NOTE—Refer to *Important Parts of Your Horizon* for part identification.

Step 1

- Place unit on a level, sturdy surface; i.e., nightstand or floor, away from heating vents, radiators, drapes, and bedspreads so that air intake is not restricted.
- Insert the appropriate power cord into the AC power connector **Figure 2**. Make sure the power switch is in the "Off" position. Plug the power cord into an appropriate grounded wall outlet.
- Connect the 22 mm diameter tubing to the outlet port on the front of the unit **Figure 4**. This is the port from which CPAP air supply is provided. Connect the opposite end of the 22 mm tubing to the mask and headgear assembly.

WARNING—Some tubing is prone to kinking. Flow can be blocked causing apnea episodes to resume. Use only

22 mm diameter smooth bore-type, kink-resistant tubing in lengths of 6-8 feet to assure delivery of accurate prescription pressure.

AVERTISSEMENT—

Certains tubes sont enclins à s'entortiller. Le débit peut être obstrué et provoquer une reprise d'épisodes d'apnée. N'utilisez qu'un tube lisse et antitortillement, de 22 mm de diamètre et de 6' à 8' de long, pour vous assurer que les niveaux de pression sont conformes à l'ordonnance de votre médecin.

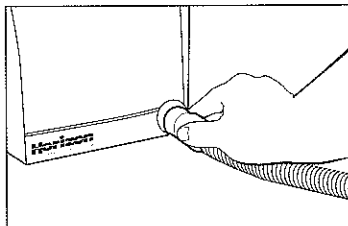


Figure 4

DANGER—Electric shock hazard. Unit must be used with a wall outlet installed and grounded in accordance with all local codes and ordinances. The wall outlet must have the same configuration as the power cord's plug. If the plug does not fit properly into your wall outlet, do not modify the plug or wall outlet. Do not use an adapter; a qualified electrician should be contacted to install a correct outlet.

DANGER—Danger de choc électrique. L'appareil doit être utilisé avec une prise murale avec mise à la terre selon les codes et règlements locaux. La configuration de la prise murale doit être identique à celle de la fiche du cordon d'alimentation. Dans le cas où la fiche ne s'insère pas bien dans la prise murale, ne modifiez pas la fiche ou la prise murale. Ne vous servez pas d'un adaptateur. Veuillez communiquer avec un électricien qualifié pour l'installation de la prise appropriée.

Step 2

- Press power switch to the "On" position. The green indicator light located by the A/D button will illuminate indicating power on, and the blower will operate at a low pressure level. A yellow indicator light located in the A/D button may illuminate or flash **Figure 5**. This yellow light is a status light and is used to verify the current state of operation. Refer to the *Status Lights* in **Figure 8** on page 10 of this guide for further explanation.

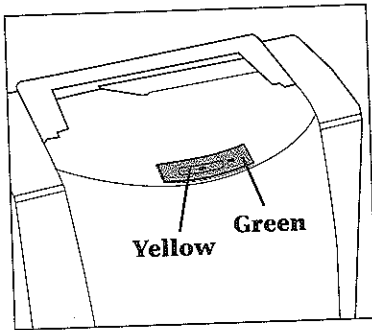


Figure 5

Step 3

- Position mask loosely on face. Adjust headgear straps so mask is snug and comfortable **Figure 6**.

NOTE—Excess facial oils will deteriorate mask material. To prolong mask life, wash face nightly before use. Refer to cleaning section of this manual for details.

NOTE—The Horizon BiLevel provides two different pressure levels while you are breathing on the device.

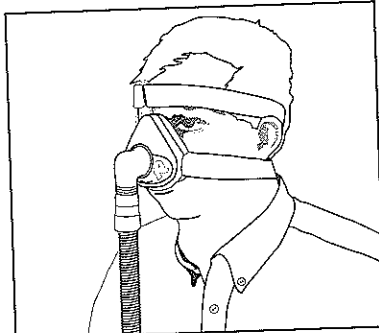


Figure 6

Step 4

- Breathe into the mask for approximately 30 seconds to activate the automatic start feature of the unit or press the A/D button to immediately start operation.

Pressure delay feature not activated: The yellow status indicator light of the A/D button will steadily flash, indicating that the unit is approaching the bilevel prescription pressures (IPAP and EPAP). The yellow status indicator light will then turn off once the prescription has been reached.

Pressure delay feature activated: The yellow status indicator light of the A/D button will slowly flash, representing the start of pressure delay. The yellow status indicator will continue to flash slowly while IPAP and EPAP increase toward the prescription setting. The yellow status indicator will turn off when the pressure delay time expires and IPAP/EPAP are at the prescription setting.

Figure 7.

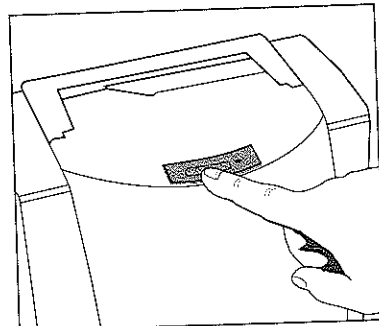


Figure 7

- Press the A/D button a second time to increase to bilevel pressures (IPAP and EPAP) and check mask seal. Once sealed, press the A/D button again to return to a low pressure state and begin operation. If the button is not pressed, the IPAP and EPAP pressures will automatically return to the low pressure state after one minute and standard operation will begin.

NOTE—If the pressure delay is active, refer to the *Pressure Delay Feature* on page 10 for a detailed explanation of the operating light sequence.

- The BiLevel mode will be maintained until the unit is turned off or the A/D button is activated.
- If the A/D button is activated, the unit will return to the low-pressure pause state of operation and the yellow indicator light will illuminate.

Pressure Delay Feature

Pressure delay is an optional feature used specifically during start up to ease the difficulty of falling asleep. Pressure delay allows you to fall asleep at low, more comfortable pressures. This procedure is defined as a gradual increase in system delivery pressure, starting at low pressures and slowly increasing to prescription pressures over a period of time **Figure 8**. The pressures will remain at the prescribed level for the remainder of the night if no patient interference is detected.

Mask check allows you to check your mask for leaks at the prescribed pressures before falling asleep, so you know there is a tight-fitting mask before you get to sleep.

Select the preferred pressure delay setting by pressing the delay select button on the rear of the unit. The choices are the preset pressure delay time or 0 minutes. The pressure delay time will be represented by the green indicator light.

When you turn the Horizon off, it will keep the last setting in memory so you do not need to reset the pressure delay each day.

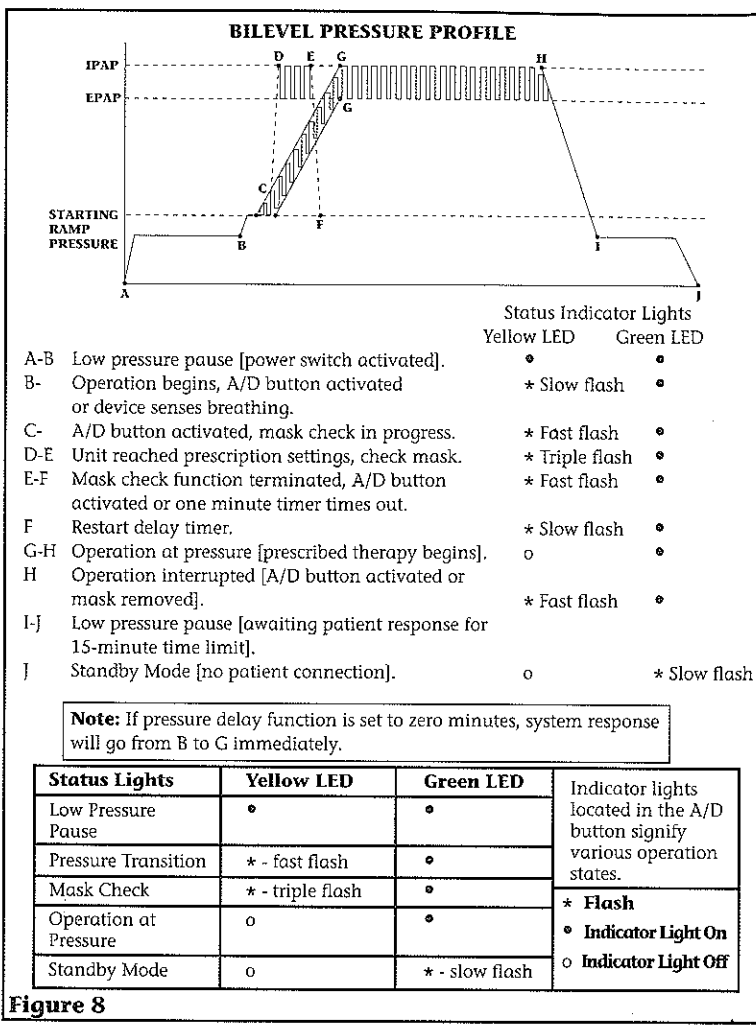


Figure 8

Standby Mode

This state of operation is reached if the main power switch is activated and there has been no user intervention for a 15-minute

time period. The green "power on" light will flash, the yellow LED will be off, and the power will be discontinued to the blower

drive circuit. It is recommended that the power switch be in the "Off" position when the unit is not in use.

Supplemental Oxygen

Supplemental oxygen may be prescribed along with nasal CPAP for treatment of obstructive sleep apnea.

CAUTION—Oxygen is a prescription gas and should only be administered under the supervision of a physician.

MISE EN GARDE—L'oxygène est un gaz fourni sur ordonnance seulement et ne devrait être administré qu'une fois sous la supervision d'un médecin.

WARNING—Oxygen supports combustion and causes rapid burning. To avoid possible physical injury, do not smoke while setting up or using your nasal CPAP for supplemental oxygen. Do not use within 10 feet of hot, sparking objects or open sources of flame.

AVERTISSEMENT—L'oxygène est un combustible et peut brûler rapidement. Afin d'éviter tout risque de blessure corporelle, ne fumez pas lorsque vous installez votre CPAP nasal pour un apport d'oxygène. Maintenez l'appareil à une distance d'au moins 10 pieds de la chaleur, des objets étincelants et de toutes sources ouvertes de flamme.

CAUTION—Always turn nasal CPAP on prior to turning on the oxygen flow and turn off the oxygen before turning the unit off.

MISE EN GARDE—Mettez toujours votre CPAP nasal sous tension (On) avant de mettre le débit d'oxygène sous tension (On), et mettez l'oxygène hors tension (Off) avant de mettre l'appareil hors tension (Off).

1. Activate power switch and connect the optional oxygen adapter (part #7353D-601) to the outlet port of the unit. Always turn Horizon on before the oxygen source and turn the oxygen source off before turning off the Horizon.
2. Connect one end of the 22 mm diameter tubing to the remaining open end of the "T" adapter and the other end to the CPAP mask.
3. Oxygen may be injected into the air supply by connecting one end of standard oxygen tubing to the oxygen "T" adapter and the other end to the oxygen source **Figure 9**.

WARNING—The oxygen adapter assembly is for single-patient use.

AVERTISSEMENT—L'adaptateur d'oxygène est réservé à l'usage d'un seul patient.

WARNING—To ensure that an adequate level of supplemental oxygen flow is being delivered, make certain that the same interfacing technique is utilized in the home as was used in the clinic.

AVERTISSEMENT—Pour vous assurer d'avoir un niveau de débit d'oxygène additionnel adéquat, utilisez la technique d'interface identique à celle qui fut utilisée à la clinique.

WARNING—The flow setting of the oxygen source shall be specified by a physician.

AVERTISSEMENT—Le réglage du débit de la source d'oxygène doit être déterminé par un médecin.

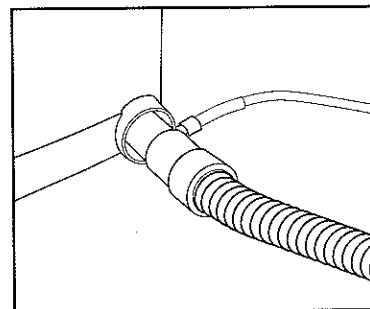


Figure 9

Cleaning

WARNING—The mask, 22mm diameter patient tubing, and air-inlet filter are for single-patient use.

AVERTISSEMENT—L'usage du masque, du tube du patient de 22mm et du filtre d'admission d'air est limité à un seul patient.

WARNING—To avoid electric shock, always unplug power cord from wall outlet power source. Never rinse or place the unit in water. Never allow liquids to get into or around any of the ports, switches, or air filter.

AVERTISSEMENT—Afin d'éviter tout choc électrique, débranchez toujours le cordon d'alimentation de la source d'alimentation de la prise murale. Ne placez jamais l'appareil dans l'eau et ne le rincez jamais. Aucun liquide ne doit être répandu sur ou s'infiltrer dans les orifices, les interrupteurs ou le filtre à air.

Air-Inlet Filter

1. The air-inlet filter should be checked daily. The filter is located directly under the handle. Press the filter grill down 45° and pull out from the unit **Figure 10**.

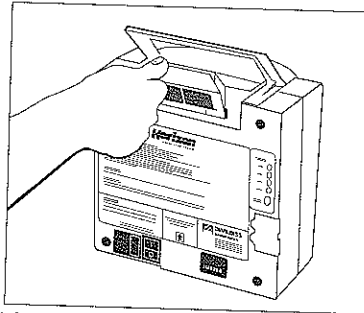


Figure 10

2. Slide the grill to the rear of the unit releasing it from the hinge **Figure 11**.

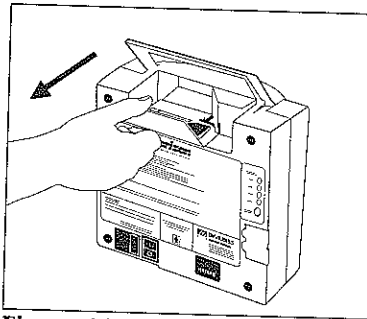


Figure 11

3. Remove the dirty foam filter from the frame.
4. Wash the filter in a solution of warm water and dishwashing detergent and rinse with tap water. Allow the filter to completely dry. If the filter (part #7353D-602) is damaged, contact your home medical equipment provider for a replacement.
5. Insert clean filter into filter frame and install **Figure 12**.

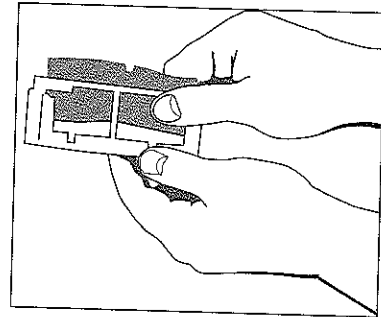


Figure 12

Mask, Headgear, and Tubing

CAUTION—Do not place mask, headgear, or tubing in an automatic dishwasher. Some automatic dishwashing detergents contain chemicals that may damage these items. Also do not clean with alcohol or any alcohol-based solutions as damage will result.

MISE EN GARDE—Ne placez pas le masque, le serre-tête ou le tube dans un lave-vaisselle automatique. Certains détergents de lave-vaisselle automatique contiennent des produits chimiques qui peuvent endommager ces pièces. De plus, n'utilisez pas d'alcool ou de solutions à base d'alcool pour nettoyer ces pièces. Vous risquez de les endommager.

Cleaning continued

1. Remove the tubing and headgear from the mask.
2. Each of these items may be washed as often as needed by using a solution of warm water and dishwashing detergent. Wash item individually, rinse with clean, warm tap water, and allow to air dry before using. Hang the tubing vertically to allow the water to drain and **dry completely**.

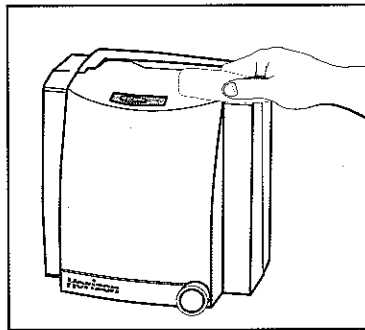


Figure 13

Oxygen Adapter

1. Remove oxygen adapter from the tubing assembly and wash as often as needed

Figure 14.

2. Wash with warm water and dishwashing detergent. Air dry.

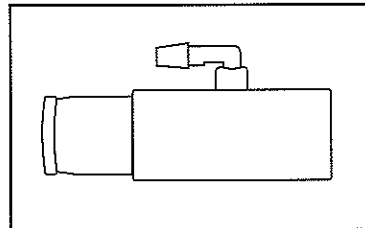


Figure 14

Cabinet

1. Unplug power cord from wall outlet.
2. Wipe the cabinet with a clean, damp cloth and mild dishwashing detergent every few days to keep dust free

Figure 13. Do not use alcohol or any alcohol-based solutions to clean the unit. These cleaning solutions may damage the plastic cabinet. Allow the unit to dry completely before plugging the unit into a power source.

CAUTION—Do not place oxygen adapter in an automatic dishwasher. Some dishwashing detergents contain chemicals that may damage this item.

MISE EN GARDE—Ne placez pas l'adaptateur dans un lave-vaisselle automatique. Certains détergents pour lave-vaisselle contiennent des produits chimiques qui peuvent endommager cet appareil.

Troubleshooting

NOTE—The Horizon 7355 Series contains no user-serviceable parts. If you believe your unit is not working properly, **BEFORE YOU RETURN IT TO THE HOME MEDICAL EQUIPMENT PROVIDER WHERE YOU PURCHASED IT OR TO SUNRISE MEDICAL**, please take a few moments to check for these possible causes:

Troubleshooting continued

Symptoms	Possible Causes	Remedies
Unit does not turn on; green LED in A/D button not illuminated.	<ol style="list-style-type: none"> 1. Unit not connected to a live power source. 2. Power cord not attached properly. 3. Fuse has blown in AC power connector. 	<ol style="list-style-type: none"> 1. Plug unit into a live receptacle. 2. Firmly attached power cord. 3. Replace fuse in AC power connector (fuse rating displayed on label) or contact your Sunrise Medical provider or authorized service center.
Low level of air flow out of the unit, yellow indicator light flashing.	<ol style="list-style-type: none"> 1. Pressure delay feature in operation. 	<ol style="list-style-type: none"> 1. Allow unit to complete the pressure delay cycle or change the delay setting.
No air flow emitted from flow generator when power is turned on, green LED illuminated and motor runs.	<ol style="list-style-type: none"> 1. Air filter may be occluded by dirt or bed clothing. 2. Defective Horizon BiLevel 	<ol style="list-style-type: none"> 1a. Clean or replace filter. b. Move unit away from loose material. 2. Contact your Sunrise Medical provider or service center.
Symptoms of OSA have recurred.	<ol style="list-style-type: none"> 1. Air filter may be occluded. 2. Incorrect air pressure setting. 3. Sleep apnea condition has changed. 	<ol style="list-style-type: none"> 1. Clean or replace the air filter; re-locate unit away from drapes, etc. 2. Contact your Sunrise Medical provider or authorized service center. 3. Call your physician; you may need to be retested.
Skin becomes irritated where mask touches skin.	<ol style="list-style-type: none"> 1. Headgear is too tight. 2. Incorrect mask size. 3. Allergic reaction to the mask material. 4. Worn mask. 	<ol style="list-style-type: none"> 1. Loosen the headgear 2. Contact your Sunrise Medical provider. 3. Call your physician. 4. Replace mask.
Dryness of throat or nose.	<ol style="list-style-type: none"> 1. Inadequate room humidity. 2. Room temperature too high. 	<ol style="list-style-type: none"> 1. Increase room humidity or add CPAP humidifier. (See page 5.) 2. Decrease room temperature.
Air from flow generator and mask seems warm.	<ol style="list-style-type: none"> 1. Air filter may be occluded. 2. Air filter and/or outlet port may be obstructed. 3. Unit or 22mm diameter patient tubing located too close to a heat register or radiator. 	<ol style="list-style-type: none"> 1. Clean or replace the air filter. 2. Move the unit away from obstruction. 3. Move the unit away from heat source.
Nasal, sinus, ear pain or runny nose.	<ol style="list-style-type: none"> 1. Reaction to air flow pressure, sinus infection or nasal congestion. 	<ol style="list-style-type: none"> 1. Discontinue use. Contact your physician.

DECLARATION OF CONFORMITY

Manufacturer's Name: Sunrise Medical Ltd.
Address: Sunrise Business Park
High Street
Wollaston, West Midlands DY8 4PS
ENGLAND

Sunrise Medical
Respiratory Products Division
100 DeVilbiss Drive
Somerset, Pennsylvania 15501
USA

Product Designation: CPAP
Type, Model: DeVilbiss® Horizon™ 7355 Series

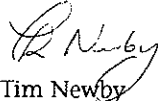

We herewith declare that the above-mentioned product complies with:

Quality System Standards Applied: ISO9001

Safety Standards Applied: IEC 601-1 / EN60601-1
DIN VDE 0750 TEIL 1/12.91

EMC Compliance To: EMC Directive 89/336/EEC
IEC 801-2, IEC 801-3.
IEC 801-4, IEC 801-5
CISPR 11/EN55011

Place: Wollaston, West Midlands Somerset, PA

Signature:  

Name: Tim Newby Carolyn D. Troast
Title: European new product development manager Director of quality and regulatory affairs

European Contact: Sunrise Medical Ltd.
Sunrise Business Park
High Street
Wollaston, West Midlands DY8 4PS
ENGLAND
44-138-444-6688



Maintenance

DANGER—Electric shock hazard. Do not attempt to open or remove cabinet, there are no user-serviceable internal components. If service is required, return it to a qualified Sunrise Medical provider or an authorized service center. Opening or tampering with the unit will void warranty.

DANGER—Risque de choc électrique. N'essayez pas d'ouvrir ou d'enlever le boîtier. L'utilisateur n'a aucunement besoin des pièces à l'intérieur de l'appareil. Si l'appareil doit être réparé, veuillez le retourner à un distributeur compétent ou un centre de services autorisé de Sunrise Medical. Un appareil qui a été ouvert ou qui a été altéré aura pour effet d'annuler la garantie.

One-Year Limited Warranty

DeVilbiss Horizon BiLevel 7355 Series is warranted to be free from defective workmanship and material for a period of one year from date of purchase. Any defective part(s) will be repaired or replaced at Sunrise Medical's option if the unit has not been tampered with or used improperly during that period. Make certain that any malfunction is not due to inadequate cleaning or failure to follow the instructions. If repair is necessary, contact your Sunrise Medical provider or Sunrise Medical Service Department for instructions: U.S.A. **800-333-4000**, Canada 905-660-2459, Europe 44-138-444-6688. **NOTE**—This warranty does not cover providing a loaner unit, compensating for costs incurred in rental while said unit is under repair, or costs for labor incurred in repairing or replacing defective part(s).

THERE IS NO OTHER EXPRESS WARRANTY. IMPLIED WARRANTIES, INCLUDING THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED TO THE DURATION OF THE EXPRESS LIMITED WARRANTY AND TO THE EXTENT PERMITTED BY LAW ANY AND ALL IMPLIED WARRANTIES ARE EXCLUDED. THIS IS THE EXCLUSIVE REMEDY AND LIABILITY FOR CONSEQUENTIAL AND INCIDENTAL DAMAGES UNDER ANY AND ALL WARRANTIES ARE EXCLUDED TO THE EXTENT EXCLUSION IS PERMITTED BY LAW. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS OR THE LIMITATION OR EXCLUSION OF CONSEQUENTIAL OR INCIDENTAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION 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.

FOR SERVICE CALL YOUR AUTHORIZED SUNRISE MEDICAL PROVIDER:

Phone _____ Purchase Date _____ Serial # _____



Respiratory Products Division

100 DeVilbiss Drive • Somerset, Pennsylvania • 15501-0635 U.S.A. • (814) 443-4881



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