Blom-Singer®

voice restoration systems

Adjustable Tracheostoma Valve II

with optional HumidiFilter™ System

REF BE8024H, BE8025H, BE8026H

INHEALTH® TECHNOLOGIES

CE

Manufacturer
Hersteller/Fabricante/Fabricant/
Produttore/Fabrikant

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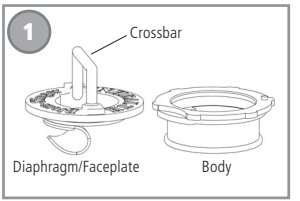
User's Information Data Sheet
37-433-01 Rev. A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Body


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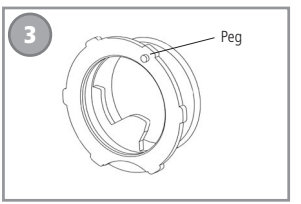
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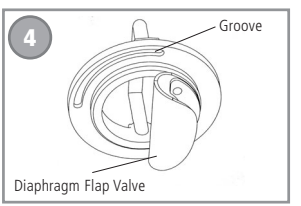
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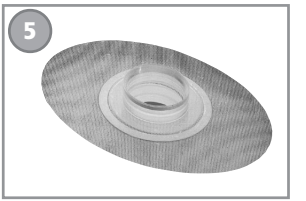
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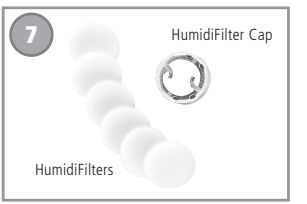
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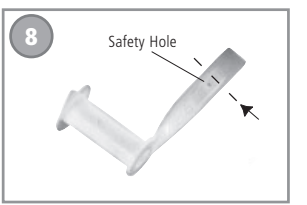
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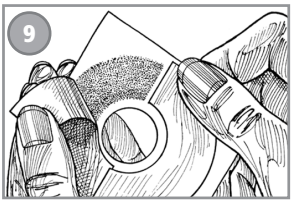
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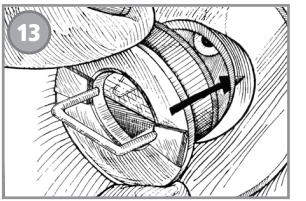
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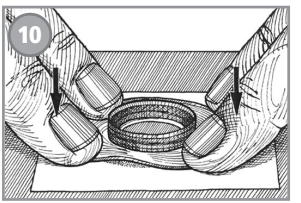
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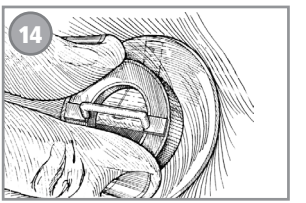
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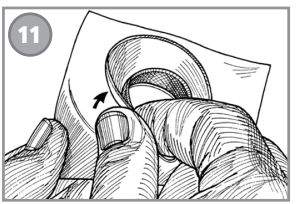
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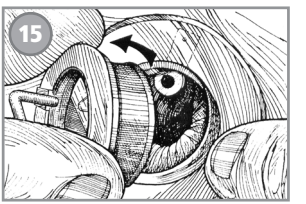
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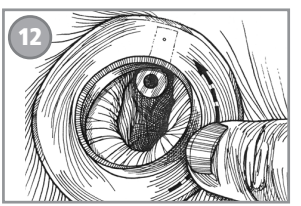
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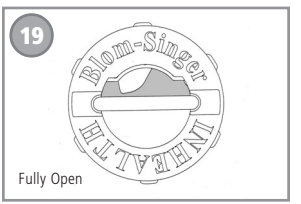
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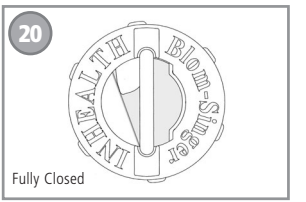
Blom-Singer
INHEALTH
Fully Open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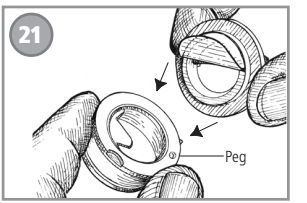
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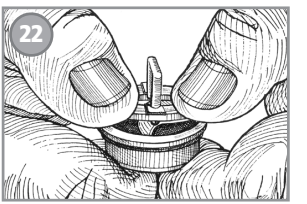
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ADJUSTABLE TRACHEOSTOMA VALVE II

with optional HumidiFilter™ System

The Blom-Singer® Adjustable Tracheostoma Valve II (ATSV II) is designed to enable hands free speech for users of Blom-Singer voice prostheses. The Adjustable Tracheostoma Valve II consists of a body and a removable diaphragm/faceplate (diagram 1). The assembled two-piece valve attaches to an adhesive housing that is applied to the skin surrounding the stoma (diagram 2). The ATSV II is designed and constructed to allow the user to achieve a full range of required sensitivity settings by simply rotating the faceplate to the most comfortable position. Disassembly of the silicone valve element is *not required* nor should it be attempted.

The ATSV II is compatible with the optional Blom-Singer HumidiFilter heat and moisture exchange system (diagram 7) that is designed to reduce dryness, mucous secretions, and coughing that occur in laryngectomized individuals.

Fitting and instructions for use of the ATSV II must be provided by a physician, speech pathologist or other trained and qualified medical professional. It is recommended that a supervised trial evaluation of the ATSV II be provided to the user to ensure effective independent operation.

INDICATIONS

The Blom-Singer Adjustable Tracheostoma Valve II is a medical device intended for use only by laryngectomees who have undergone surgical voice restoration and use a voice prosthesis. When used in conjunction with a voice prosthesis, the ATSV II eliminates the need for digital stoma occlusion to produce voice. The Blom-Singer Adjustable Tracheostoma Valve II should only be used by individuals trained in the use of tracheostomal prosthetic devices.

HOW SUPPLIED

The Blom-Singer Adjustable Tracheostoma Valve II is available in a Starter Kit or as individual components. The ATSV II and components are supplied non-sterile in a single-wrapped packaging system for use by a single user.

REF	DESCRIPTION
BE8024H	ATSV II Starter Kit with HumidiFilter Cap
BE8025H	ATSV II only
BE8026H	ATSV II Diaphragm/Faceplate Replacement

ATSV II AND COMPONENT PARTS

Please refer to the diagrams located at the front of this data sheet.

Body: The body is designed to hold the faceplate. It has a peg upon which the faceplate rotates (diagram 3).

Diaphragm/Faceplate

Faceplate: The faceplate has a groove that fits against the peg on the body (diagram 4). As the faceplate rotates along the groove, a small projection in the body positions the diaphragm flap valve to varying degrees of closure. The "further closed" the valve position, the easier it is to shut the valve completely to speak. The most wide-open setting is useful during periods of exercise when breathing rate increases.

Diaphragm Flap Valve: The silicone diaphragm flap valve is permanently attached to the undersurface of the faceplate (diagram 4). The diaphragm flap valve is normally in the open position, however, when the user exhales to speak, the airflow pushes the valve to the closed position, so that air is diverted through the voice prosthesis thus eliminating the need to manually occlude the stoma. The valve automatically returns to its fully open position when airflow is decreased at the end of the speech utterance.

Crossbar: The crossbar (diagram 1) is designed to prevent clothing from blocking the faceplate of the ATSV II as well as for holding the HumidiFilter system in place. It permits adjustment of the diaphragm flap valve for voicing or for periods of exercise when breathing rate increases. The crossbar should not be used as a handle for inserting or removing the ATSV II from the housing. Refer to "Valve Removal" to remove the ATSV II. **Clipping off the crossbar will make the valve unusable with the HumidiFilter System.**

TruSeal™ Adhesive Housing: The TruSeal (diagram 5) Adhesive Housing is a lightweight, disposable all-inclusive adhesive tape-disc/housing that eliminates the need for a tracheostoma valve housing, tape or adhesive foam disc. It is applied to the skin area surrounding the tracheostoma to attach the ATSV II over the stoma. The TruSeal Adhesive Housing is available in one size.

Tracheostoma Valve Housing: The Tracheostoma Valve Housing (diagram 6) is a reusable, flexible circular housing that attaches the ATSV II over the stoma. It is applied to the skin area surrounding the tracheostoma with separate adhesive tape discs and Blom-Singer Silicone Adhesive. The Tracheostoma Valve Housing is available in two sizes, standard and large.

HumidiFilter Cap: The HumidiFilter Cap (diagram 7) is an optional attachment. It is specifically designed for the ATSV and ATSV II to hold the foam filters to facilitate heat and moisture exchange.

HumidiFilter Foam Filters: The disposable foam filters (diagram 7) are specially treated with an agent to inhibit bacterial growth and a salt to retain heat and moisture on the foam.

ADHESIVE HOUSING ATTACHMENT

The user may choose from one of two housing options for attaching the ATSV II to the tracheostoma: the TruSeal Adhesive Housing or the Tracheostoma Valve Housing. To ensure the successful use of the ATSV II, a full line of tracheostoma adhesive attachment supplies is also available from InHealth.

Blom-Singer Tracheostoma Adhesive Attachment Supplies

REF	DESCRIPTION	SIZE
BE6053	TruSeal Adhesive Housings	One size, 5 pack
BE6054	TruSeal Adhesive Housings	One size, 20 pack
BE6038	Tracheostoma Valve Housing	Standard, 1 each
BE6039	Tracheostoma Valve Housing	Large, 1 each
BE6034	Heavy Duty Tape Discs	Standard, 30 each
BE6035	Heavy Duty Tape Discs	Large, 30 each
BE6041	Regular Tape Discs	Standard, 30 each
BE6042	Regular Tape Discs	Large, 30 each
BE6043	Thin Tape Discs	Standard, 30 each
BE6044	Thin Tape Discs	Large, 30 each
BE6045	Regular Foam Discs	Standard, 30 each
BE6046	Regular Foam Discs	Large, 30 each
BE6047	Thin Foam Discs	Standard, 30 each
BE6049	Thin Foam Discs	Large, 30 each
BE6051	Adhesive Foam & Tape Disc Sampler Pack	Standard, 1 pack
BE6052	Adhesive Foam & Tape Disc Sampler Pack	Large, 1 pack
C29600	Alcohol Prep Pads	100 each
44700	Shield Skin® (protective skin barrier)	2 oz bottle
44005	Shield Skin (protective skin barrier wipes)	50 each
4204-00	Skin-Prep™ (protective skin barrier wipes)	50 each
BE6067	Silicone Adhesive	2 oz bottle
4031-00	Remove® (adhesive remover wipes)	50 each

INSTRUCTIONS FOR USE

Please refer to the diagrams located at the front of this data sheet.

The following procedure is provided by Eric D. Blom, Ph.D.

The user's hands should always be thoroughly cleaned to help avoid introducing contaminants into the stoma, puncture, or esophagus. Removal and attachment of any devices worn over the tracheostoma should only be done with the user positioned in front of a mirror with a bright light focused directly on the stoma.

For non-indwelling voice prosthesis users, the voice prosthesis safety strap may interfere with adequate tracheostomal sealing. To reduce the possibility of air leaks, trim the excess strap protruding outside of the housing. First, hold theTruSeal housing or the Tracheostoma Valve Housing, over the tracheostoma with the voice prosthesis in place. Mark the amount of voice prosthesis strap protruding outside the outer edge of the housing. Note the point where the strap meets the housing. Trim the excess strap just below this point so the remaining strap will be completely covered by the housing when it is properly in place. **Do not trim below the portion of the strap that has the small hole in it that attaches to the safety peg on the voice prosthesis inserter** (diagram 8).

TruSeal Adhesive Housing Attachment

1. Gently clean the skin area around the tracheostoma with mild soap and warm water. Rinse and dry the skin completely. Next, gently wipe the skin area with an alcohol pad. Avoid inhalation of alcohol fumes which may cause coughing. Allow the skin area to dry completely. Apply one to two layers of a protective skin barrier, such as Shield Skin™ or Skin Prep™. Apply carefully to avoid inhalation of fumes which may cause coughing. Allow the skin area to dry completely.

If a more durable seal is necessary, a very thin coating of Blom-Singer Silicone Adhesive may be applied to the skin prior to attaching the TruSeal housing (step 4). Allow the adhesive to dry for at least 3 to 4 minutes before attaching the housing. **Note:** a thin coating of adhesive works better than a thick application. **Do not inhale the adhesive or permit it to enter the stoma.**

2. Carefully open the plastic bag containing the TruSeal housing. Remove the housing and place on a clean, dry surface.

3. Slowly peel the paper backing from the TruSeal housing to expose the adhesive. Avoid allowing the adhesive liner to fold onto itself.

4. Stretch the skin gently away from the stoma and affix the TruSeal housing to the

recessed area surrounding the tracheostoma.

5. Press the TruSeal housing against the skin surface to avoid air pockets between the skin and the housing. Gently rub the TruSeal housing against the skin to achieve maximum adhesive contact.

Removal and Cleaning: Carefully remove the TruSeal adhesive housing from the skin. Any residual adhesive on the skin surrounding the tracheostoma can be removed with medical grade adhesive remover, such as Remove, REF 4031-00, followed by gentle cleansing with soap and water. **Extreme care should be used to avoid entry of adhesive remover or fumes into the tracheostoma when cleaning the surrounding skin area.**

Tracheostoma Valve Housing Attachment

1. Gently clean the skin area around the tracheostoma with mild soap and warm water. Rinse and dry the skin completely. Next, gently wipe the skin area with an alcohol pad. Avoid inhalation of alcohol fumes which may cause coughing. Allow the skin area to dry completely. Apply one to two layers of a protective skin barrier, such as Shield Skin™ or Skin Prep™. Apply carefully to avoid inhalation of fumes which may cause coughing. Allow the skin area to dry completely.

2. Apply a very thin coating of Blom-Singer Silicone Adhesive to the skin area surrounding the tracheostoma where the valve housing will be positioned. **Note:** a thin coating of adhesive works better than a thick application. **Do not inhale adhesive or permit it to enter the stoma.** Allow the adhesive to dry for at least 3 to 4 minutes prior to positioning the assembled tape-disc/housing.

Tape Application

3. Using a tape disc, attach the disc to the housing by first slowly peeling the backing paper from one side of the disc. Avoid pulling the backing paper from the reverse side of the disc (diagram 9).

4. Place the circular housing on top of the disc.

5. Flatten the circular housing against the disc surface. Rub firmly against the entire circular area of the housing to ensure complete contact with the disc (diagram 10).

6. Remove the paper backing on the reverse side of the disc to expose the second adhesive surface (diagram 11).

Foam Disc Application (refer to diagrams 9—11)

7. Remove the backing paper from one side of the adhesive foam disc. Avoid pulling

the backing paper from the reverse side of the adhesive foam disc.

8. Place the circular housing on top of the adhesive foam disc.

9. Flatten the circular housing against the adhesive foam disc surface. Rub firmly against the entire circular area of the housing to ensure complete contact with the foam disc.

10. Remove the paper backing on the reverse side of the adhesive foam disc to expose the second adhesive surface.

Attaching Housing to Skin

11. Position the circular housing over the recessed area surrounding the tracheostoma. Press the housing flush against the skin surface to avoid air pockets between the skin and the housing.

12. Rub the circular housing firmly against the skin to achieve maximum adhesive contact (diagram 12).

Removal and Cleaning: Carefully remove the reusable circular housing from the skin. Peel back the tape and adhesive foam disc from the housing. Residual adhesive on the skin surrounding the tracheostoma can be removed with medical grade adhesive remover, such as Remove®, REF 4031-00, followed by gentle cleansing with soap and water. **Extreme care should be used to avoid getting adhesive remover or fumes in the tracheostoma when cleaning the surrounding skin area.**

Clean any residual adhesive from the surface of the housing with Remove®, or by soaking the housing overnight in water and then rubbing off the adhesive under warm tap water.

Replace housing when flexibility decreases with age.

ATSV II INSERTION, REMOVAL AND CLEANING

Insertion: To insert the ATSV II, grasp its rim and insert it partially into the lower rim of the housing (diagram 13). Press the ATSV II firmly inward until it is completely positioned and locked into the housing (diagram 14).

Removal: The ATSV II is designed for instant removal without detaching (untaping) the housing from the skin. Place the index finger firmly against the housing to prevent pulling the tape loose. Grasp the ATSV II by the rim and pull to remove (diagram 15). Avoid using the crossbar as a handle.

The ATSV II must be removed before sleeping in order to avoid a possible obstruction of the airway should the valve stick in the closed position

due to an accumulation of phlegm around the valve diaphragm.

Cleaning: Periodically the ATSV II should be removed and soaked in warm water for 2-3 minutes to dissolve any phlegm that may be lodged in the device. Carefully clean the surfaces of the diaphragm/faceplate and body with a small brush or cotton tip applicator and mild soap to remove phlegm. Do not use strong detergents or any other chemical that may be damaging. Failure to clean thoroughly may cause dried phlegm to interfere with the proper function of the diaphragm flap valve. Rinse with clean water before drying with a lint-free material, or air-dry. Never use facial or toilet tissue to dry the ATSV II, as it may leave particles of lint or fabric on the unit that can be aspirated into the airway. **Do not attempt to clean or soak the ATSV II if the HumidiFilter is attached.**

ATSV II WITH HUMIDIFILTER SYSTEM

The ATSV II is compatible with an optional Blom-Singer HumidiFilter System, so the user can incorporate the many benefits of a heat and moisture exchanger into the hands free method of speech.

The HumidiFilter System is available as separate components and also in the ATSV II starter kit, BE8024H.

REF	DESCRIPTION
BE1010	HumidiFilter Cap & 7 Foam Filters
BE1020	Replacement Foam Filters, 7 each
BE1030	Replacement Foam Filters, 30 each

HumidiFilter Cap Assembly: Always handle the device with clean hands. To attach the HumidiFilter Cap and insert the foam filters, first tuck the filter under the crossbar on the ATSV II so that one of the slits on the foam filter is lined up with one end of the crossbar as (shown in diagram 16). Next, pull the filter through so the second slit is lined up with the opposite end of the crossbar. Place the HumidiFilter Cap over the crossbar and rotate counterclockwise to lock it into position. (See diagrams 17 and 18.) Attach the ATSV II/HumidiFilter into the housing in the usual manner. **Be sure to wash hands after handling the filter** as it contains substances that may be irritating to skin and eyes.

The user should be able to breathe normally through the unit, however, a slight increase in resistance may be felt. See "ATSV II Sensitivity Adjustments" in this data sheet.

A properly attached ATSV II/HumidiFilter system provides an airtight seal around the stoma. Breathing through the filter system should be comfortable and easy. If breathing

is not easy, remove the tracheostoma valve/filter system and replace the filter if necessary.

Replacing Foam Filters: First, remove the ATSV II/HumidiFilter from the housing. Then remove the HumidiFilter Cap by rotating the cap clockwise and lifting it off from the diaphragm/faceplate. Grasp the foam filter and pull it out from under the crossbar. **Be sure to wash hands after handling the filter** as it contains substances that may be irritating to skin and eyes. **The filter should be replaced once every 24 hours.** The package containing the filters must be resealed after every opening to preserve the effectiveness of the filters.

Cleaning: The HumidiFilter Cap should be cleaned with mild soap and warm water on a regular basis and rinsed with water. It should be dried with a lint-free material or air-dried. Never use facial or toilet tissue to dry the HumidiFilter Cap, as it may leave particles of lint or fabric on the unit that can be aspirated into the airway. **Do not wash the specially treated foam filter!** It is designed for single use only. **Never clean the HumidiFilter Cap or replace the filters while the ATSV II/ HumidiFilter is in position in the neck. Always clean the HumidiFilter Cap, or replace the filters, after the cap has been removed.**

Inspect the filter and cap for structural damage, such as cracks or tears resulting from prolonged use. Do not use a device that is damaged. **The ATSV II/HumidiFilter must be removed before sleeping in order to avoid a possible obstruction of the airway.**

ATSV II FUNCTION

During normal quiet breathing and routine physical activity the diaphragm flap valve remains in an open position permitting normal speech. When properly adjusted, a slight increase in the exhaled airflow causes the diaphragm flap valve to close and seat against the faceplate to provide an airtight seal during speech. The diaphragm flap valve automatically reopens as breathing airflow decreases when the speaker stops talking.

With the extremely high pressure of a cough, the diaphragm flap valve may be forced partially through the opening in the faceplate. This will be accompanied by the loud noise of pressure being released. If this happens, pull the ATSV II from the circular housing and reseat the diaphragm flap valve with a fingertip. Preferably the ATSV II/HumidiFilter should be removed from the housing prior to coughing to avoid expelling phlegm into the diaphragm flap valve. Failure to do so causes loosening of the housing seal.

ATSV II SENSITIVITY ADJUSTMENTS

The Adjustable Tracheostoma Valve is designed to accommodate the speech and breathing requirements of each individual user by rotating the faceplate clockwise or counterclockwise (diagrams 19 and 20). **Clockwise** rotation adjusts the diaphragm flap valve to a more closed position rendering it easier to close the rest of the way during speech. **Counterclockwise** rotation adjusts the diaphragm flap valve to a more widely open position thus requiring greater effort (respiratory airflow) to close it to speak. Most users set the ATSV II to a near closed position during speech and adjust it to a wide-open position during increased respiratory exertion (i.e., during physical exercise). Intermediate positions can be selected in accordance with varying speech and breathing requirements of the user.

Valve sensitivity adjustment is most easily accomplished when the ATSV II is removed from the adhesive housing. To adjust the ATSV II while it is in position in the adhesive housing, the user should first stabilize the base of the ATSV II between the index finger and thumb to prevent movement while simultaneously rotating the faceplate. Note: The ATSV II may have to be removed temporarily during instances of extreme physical activity and respiratory exchange.

A physician, speech pathologist or other qualified professional can assist the user in assessing appropriate valve diaphragm settings.

DIAPHRAGM/FACEPLATE REPLACEMENT

If the diaphragm flap valve becomes worn or damaged it may be replaced. A replacement diaphragm/faceplate, REF BE8026H, is available from InHealth.

To remove the old diaphragm/faceplate from the ATSV II body, insert a coin into the slot located on the side of the ATSV II. Gently twist to detach the diaphragm/faceplate from the body. Align the peg on the body (diagram 21) with the groove in the rim of the diaphragm/faceplate replacement and "snap" these two components together (diagram 22).

The diaphragm flap valve should curl over the small "arm-like" projection in the interior of the ATSV II. Always check the ATSV II and the diaphragm flap valve prior to use to assure that they are properly assembled and structurally sound.

TROUBLESHOOTING CHART

The following information is provided by Eric D. Blom, Ph.D.

Problem

ATSV II housing will not adhere securely to skin for a 12-14 hour period.

Causes and Remedies

1. Excessive resistance to airflow through the voice prosthesis and/or throat. See surgeon or speech pathologist for assessment.
2. Insufficient tracheostoma valve housing application and/or use. Review application steps in **Adhesive Housing Attachment** in this data sheet.
3. Failure to allow the liquid silicone to dry thoroughly, at least 3-4 minutes, prior to attaching the housing.
4. Failure to carefully remove the ATSV II prior to coughing.
5. Excess internal pressure against the housing seal caused by trying to talk too loudly.
6. The valve adjustment is set "too open" for user needs. Always set the adjustment in easiest-to-close position that does not cause inadvertent closure.

Problem

Air leak through or around diaphragm flap valve during speech.

Causes and Remedies

1. Disassemble ATSV II and thoroughly clean any phlegm that may prevent the diaphragm flap valve from completely closing during speech.
2. Replace diaphragm/faceplate if it has become worn or inoperable.

Problem

Skin irritation from adhesive tape.

Causes and Remedies

1. Avoid repeated application of the housing in the same day.
2. Remove housing slowly and carefully to avoid irritation.
3. Apply Skin-Prep to skin surrounding tracheostoma prior to applying adhesive and housing.

Problem

Diaphragm flap valve is not easily closed during speech.

Causes and Remedies

1. Valve sensitivity setting is too firm for user's breathing requirements. Rotate faceplate clockwise to adjust diaphragm flap valve to close easier.
2. Consult physician or speech pathologist regarding ATSV style.

Problem

Diaphragm/faceplate closes inadvertently during moderate physical activity.

Causes and Remedies

1. Valve sensitivity setting is too light for user's breathing requirements. Rotate faceplate counterclockwise to adjust the diaphragm flap valve setting to a more open position.

If difficulty with the ATSV II cannot be easily remedied, your physician or speech pathologist should be consulted for assistance.

WARNINGS AND PRECAUTIONS

If there are tears, cracks, or structural damage, do not continue to use the product. Extreme care should be used to avoid getting adhesive remover or fumes in the tracheostoma when cleaning the surrounding skin area. The ATSV II must be removed before sleeping in order to avoid a possible obstruction of the airway should the valve stick in the closed position due to an accumulation of phlegm around the valve diaphragm. The package containing the filters must be resealed after every opening to preserve the effectiveness of the filters. Hands must be washed after handling the filters to avoid irritation of the skin and eyes. Do not wash the specially treated foam filter. Never clean the HumidiFilter ATSV Cap or replace the filters while the ATSV II/ HumidiFilter assembly is in position in the neck. Always clean the HumidiFilter ATSV Cap, or replace the filters, after the cap has been removed.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or licensed speech pathologist.

SPECIAL ORDER PRODUCTS

If this data sheet accompanies a special order product there will possibly be differences in the physical characteristics between the product enclosed and the product descriptions in this data sheet. These differences will not affect the safety or efficacy of the special order product. Special order products are nonreturnable.

ORDERING INFORMATION

USA & Canada

Blom-Singer products can be ordered directly from International Healthcare Technologies (InHealth) at the following toll free number (800) 477-5969, Monday—Thursday, 6:30 am—4:00 pm; and Friday, 6:30 am—2:00 pm, Pacific Time. (The toll free number can be used from the continental USA, Alaska, Hawaii, Puerto Rico, and the Virgin Islands. The toll free number for Canada is (800) 461-0991.) Products also may be ordered at the InHealth website: www.inhealth.com

If you have any questions or dissatisfaction with the product please contact customer service via telephone, fax, post, or e-mail: Tel: (800) 477-5969; Fax: (888) 371-1530; Post: 1110 Mark Avenue, Carpinteria, CA 93013-2918; E-mail: order@inhealth.com

International

For a list of international distributors, please contact International Healthcare Technologies, 1110 Mark Avenue, Carpinteria, CA 93013-2918, USA. Tel: +01(805) 684-9337, Fax: +01(805) 684-8594.

RETURNED GOODS POLICY

All returned merchandise must have a Return Merchandise Authorization number (RMA), and must be unopened and undamaged. RMA numbers are obtained from InHealth Customer Service. Returns without an RMA will not be accepted. Products must be returned in unopened packages, with manufacturer's tamper evident seals intact to be accepted for replacement or credit. Products will not be accepted for replacement or credit if they have been in possession of the customer for more than 90 days. Special order products are nonreturnable. There is a 20% restocking fee on all returned merchandise.

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