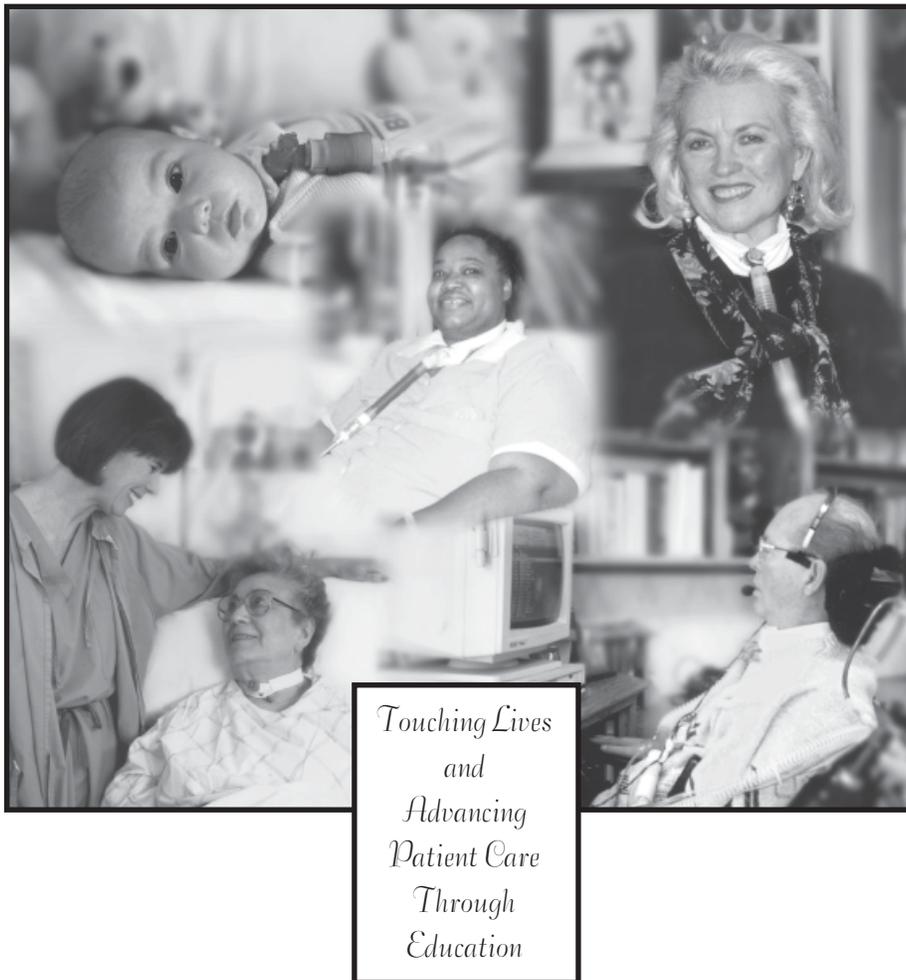


# Passy-Muir Tracheostomy and Ventilator Speaking Valve Resource Guide



*Passy-Muir Inc.*

Passy-Muir Tracheostomy and Ventilator Speaking Valves

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## THE PASSY-MUIR TRACHEOSTOMY AND VENTILATOR SPEAKING VALVES

### I. Inventor, David Muir

The Passy-Muir Tracheostomy and Ventilator Speaking Valves (PMVs) are the innovative invention of David Muir, who as a result of muscular dystrophy, was quadriplegic. In 1985 he required a tracheostomy and became ventilator dependent, which rendered him unable to communicate. He tried to utilize the communication products available at the time for tracheostomized individuals, however none of them worked to his satisfaction. With his own idea of how a one-way speaking valve should work and his father's assistance, David developed the PMVs which enabled him to speak normally both on and off the ventilator. These valves are indicated for in-line ventilator use and have a unique, patented closed position "no leak" design. For nearly six years this ingenious individual had the satisfaction of seeing both children and adults benefit from his invention. Unfortunately, David passed away in August, 1990, at the age of twenty-eight. David's legacy, the PMV, has returned independence and dignity to thousands of tracheostomized and ventilator dependent individuals all over the world.

### II. Description of the Passy-Muir Valves (PMVs)

The Passy-Muir Tracheostomy and Ventilator Speaking Valves (PMVs) are small, lightweight, and designed to fit the universal 15mm hub of tracheostomy tubes. The design of the PMV incorporates a larger diameter pathway so inspired air is not restricted as may occur with other one-way speaking valves. All PMVs can be used interchangeably by tracheostomized and ventilator dependent patients with the exception of the PMV 2020 Tracheostomy Speaking Valve for use with metal tracheostomy tubes which is not indicated for ventilator use. They are easily adapted for use in-line with a ventilator circuit and can be used in conjunction with closed suctioning systems, swivel adapters, supplemental oxygen, humidification, etc. All Passy-Muir Speaking Valves have the patented, closed position "no leak" design.

### III. Passy-Muir Valve Products and Accessories



PMV 005 (White)

#### A. PMV 005 (White) Tracheostomy and Ventilator Speaking Valve 15mm I.D./23mm O.D.

The PMV 005 is the original PMV. While it is more commonly used by non-ventilator dependent, tracheostomized persons and placed directly on the 15mm hub of the tracheostomy tube, it can also be used in-line with a ventilator using non-disposable, flexible, rubber tubing.



PMV 007 (Aqua)

**B. PMV 007 (Aqua) Tracheostomy and Ventilator Speaking Valve**  
15mm I.D./22mm O.D.

The PMV 007 is designed to fit inside adult 22mm I.D. disposable ventilator tubing. Use of an adapter may be needed to connect the PMV to pediatric ventilator tubing or various closed suctioning systems. It fits directly on the 15mm hub of the tracheostomy tube or can be used with various adapters (e.g. swivel, Omniflex™). The bright color makes it easier to see while in the ventilator tubing. The PMV 007 can also be used off the ventilator.



PMV 2000 (Clear)

**C. PMV 2000 (Clear) Low Profile - Lower Resistance Tracheostomy and Ventilator Speaking Valve**  
15mm I.D./23mm O.D.

The PMV 2000 is lightweight, smaller in size than the PMV 005 and PMV 007 and opens easier during inhalation. The PMV 2000 can be used directly on the 15mm hub of a tracheostomy tube as well as in-line with the ventilator using non-disposable, flexible, rubber tubing. The PMV 2000 is clear in color to make it less visible for use by the more ambulatory patient. The PMV 2000 is designed to be used with the PMV Secure-It™, a device that allows the PMV to remain connected to the tracheostomy tube tie to prevent PMV loss.



PMV 2001 (Purple)

**D. PMV 2001 (Purple) Low Profile - Lower Resistance Tracheostomy and Ventilator Speaking Valve**  
15mm I.D./23mm O.D.

The PMV 2001 is identical to the PMV 2000 (Clear) except for its color. This bright purple color makes it easier for staff/caregivers to identify the PMV while being worn as well as easier to locate if it becomes misplaced (e.g. in the bed sheets). It is also designed to be used with the PMV Secure-It™ and can be used on or off the ventilator utilizing non-disposable, flexible, rubber tubing.

**E. PMV 2020 (Clear) Low Profile-Lower Resistance Tracheostomy Speaking Valve and PMA 2020-S Adapter for Use on Metal Tracheostomy Tubes**  
15mm I.D./23mm O.D.



PMV 2020 (Clear) with the PMA 2020-S Adapter

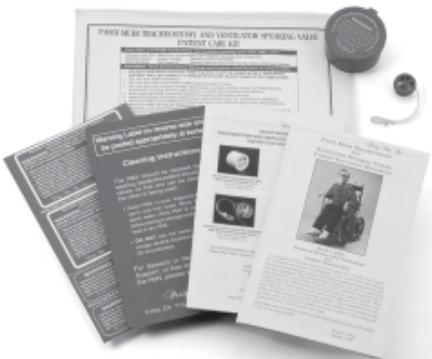
The PMV 2020 attaches to the Pilling Weck metal Jackson Improved tracheostomy tubes (sizes 4 - 6 or equivalent) with use of the PMA 2020-S Adapter. It can also be used on the adult, pediatric and neonatal Bivona non-foam filled cuffed tracheostomy tubes currently on the market. The PMV 2020 (Clear) is intended for use by both short-term and long-term adult, pediatric and neonatal non-ventilator dependent tracheostomized patients. The PMV 2020 and PMA 2020-S are sold as a set. Replacement PMA 2020-S Adapters are also sold in sets of three (3).



PMV Secure-It™ attached to the PMV 2000 (Clear)



PMV O2 Adapter attached to the PMV 2001 (Purple)



PMV Patient Care Kit

**E. PMV Secure-It™** - The PMV Secure-It™ is designed for use with the Low Profile - Lower Resistance PMV 2000 Series Valves [PMV 2000 (Clear), PMV 2001 (Purple) and PMV 2020 (Clear)]. The PMV Secure-It™ is a device that attaches the PMV to the trach tie to prevent valve loss. One PMV Secure-It™ is packaged with each of the PMV 2000 Series Valves. The PMV Secure-It™ is also sold separately from the PMV in sets of five (5).

**F. PMV O<sub>2</sub> Adapter (PMA 2000)** - The PMV O<sub>2</sub> Adapter allows for easy inhalation of low flow, supplemental oxygen and humidity through the Low Profile - Lower Resistance PMV 2000 Series Tracheostomy and Ventilator Speaking Valves. The PMV O<sub>2</sub> Adapter is small, lightweight, clear in color and easily snaps onto both the PMV 2000 (Clear) and PMV 2001 (Purple) Tracheostomy and Ventilator Speaking Valves. Oxygen is delivered in *front* of the intake side of the PMV to avoid complications associated with devices that provide continuous flow *behind* the valve which may include air trapping, drying of secretions and possible cilia damage.

The PMV O<sub>2</sub> Adapter allows the patient the opportunity to have improved mobility and is easily removed when not in use. The PMV O<sub>2</sub> Adapter is not for use with any valve other than the PMV 2000 (Clear) and PMV 2001 (Purple). The PMV O<sub>2</sub> Adapter is sold separately.

**G. PMV Patient Care Kit** - Each PMV comes packaged in a color coded PMV Patient Care Kit designed to facilitate proper use and maintenance of the PMV and to ensure patients have complete product information and instructions upon discharge.

**Each PMV Patient Care Kit contains the following items:**

1. **Ziplock Pouch** - a durable, ziplock pouch designed to hold all items in the PMV Patient Care Kit as well as provide extra room for any additional adapters and accessories that may be needed.
2. **PMV** - each Kit contains one of the following valves: PMV 005 (White) Tracheostomy and Ventilator Speaking Valve, PMV 007 (Aqua) Tracheostomy and Ventilator Speaking Valve, PMV 2000 (Clear) Low Profile - Lower Resistance Tracheostomy and Ventilator Speaking Valve PMV 2001 (Purple) Low Profile - Lower Resistance Tracheostomy and Ventilator Speaking Valve or PMV 2020 (Clear) Tracheostomy Speaking Valve with PMA 2020-S Adapter.
3. **PMV Storage Container** - a small plastic cup to allow for storage of a clean PMV when it is not being used.

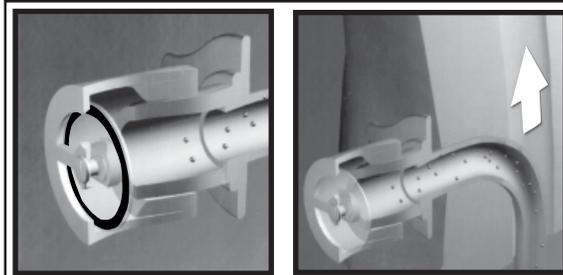
4. **Instruction Booklet** - a clinician's guide to use of the PMV. This booklet contains comprehensive, technical information about use of the PMV both on and off the ventilator as well as PMV cleaning guidelines.
5. **\*Chart Warning Labels (two)** - these adhesive labels can be placed in a patient's medical chart or care plan to alert all caregivers about PMV use.
6. **\*Bedside Label** - this nonadhesive, durable label is designed to be placed near the PMV user (i.e. at the head of the bed or on the wall). It provides important information to caregivers about the PMV.
7. **Pilot Balloon Labels (two)** - if the PMV user has a cuffed tracheostomy tube, these small durable stickers must be applied to the pilot balloon of the tracheostomy tube as a reminder that the cuff of the tracheostomy tube must always be *completely deflated* before wearing the PMV.
8. **\*Patient Parameters Chart Label** - this adhesive label can be used in the patient's medical chart or care plan to alert all caregivers about use of the PMV with a particular patient (i.e. how long it is worn, oxygen requirements, ventilator settings, eating recommendations, level of supervision needed, etc.).
9. **\*Patient Handbook** - this instruction booklet discusses use, care and cleaning of the PMV and is written in basic, non-technical terms. It is designed especially for patient, family and caregiver use.
10. **PMV Secure-It™** [Available only with PMV 2000 (Clear), PMV 2001 (Purple) and PMV 2020 (Clear)] - a clear, flexible, rubber attachment that connects the PMV to the tracheostomy tube tie to prevent PMV loss. (Use of the PMV Secure-It™ is optional).

*\*These items are not included with the PMV 2020 (Clear) Speaking Valve.*

#### IV. David Muir's Closed Position "No Leak" Design

Historically, concerns with the use of other one-way speaking valves have included: occlusion problems, safety, high resistance levels, size, adaptability, restriction during inspiration, leakage of exhaled air back out through the valve and noise. David successfully addressed these issues with the patented design of the PMVs.

The closed position "no leak" design of the PMVs promotes the establishment of a more normal "closed respiratory system." These valves are designed in a biased-closed position. They open only during inspiration with less than  $.05\text{cmH}_2\text{O}$  [ $.02\text{cmH}_2\text{O}$  with the PMV 2000 (Clear), PMV 2001 (Purple) and the PMV 2020 (Clear) Speaking Valves] and start to close again before the end of the inspiratory cycle/beginning of the expiratory cycle (Fig. 1.A). There is no air leakage out of the PMV during expiration. Instead, the air is directed around the tracheostomy tube, up through the vocal cords, and then out through the oral and nasal cavities. Since the PMV remains closed except when the patient inspires, a column of air is trapped within the valve and tracheostomy tube which acts as a buffer to resist the movement of secretions up the tracheostomy tube and into the PMV (Fig. 1.B). This design makes the PMVs safe to use with tracheostomized and ventilator dependent patients of all ages including quadriplegics and infants.



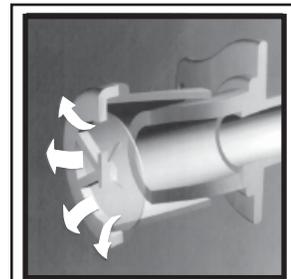
**Fig. 1 PMV Closed Position “No Leak” Design**

(A) PMVs Close Completely At End Of Inhalation With No Air Leak, Thereby Providing A Closed Respiratory System And More Normal Breathing Pattern. (B) Closed Position “No Leak” Design Maintains A Column Of Air In Tracheostomy Tube Redirecting Airflow And Secretions Up The Trachea (Airway) And Out Of The Mouth And/Or Nose.

## V. Differences Between Closed Position “No Leak” PMVs and Open Position Valves

All other one-way speaking valves available have an open position design that require expiratory pressure to close them. There is always some air leakage through these valves during expiration (Fig. 2) which precludes the benefit of a “closed system” that is obtained with the closed position “no leak” design of the PMVs. Increased work of breathing can also occur with open position speaking valves because the patient must both open and close these valves while the biased-closed PMV closes automatically. In addition, while the closed position “no leak” design of the PMV creates a buffer against secretions and resists occlusion, the open position design of other one-way speaking valves allows secretions to travel up the tracheostomy tube and potentially occlude these valves.

Since the PMVs became available in 1985, they have been used with patients of all ages, from newborns to the elderly, who are spontaneously breathing or ventilator dependent, and who have had a wide variety of diagnoses. In addition, many of these patients have been significantly medically compromised. While the PMV cannot be used by every tracheostomized patient, often patients who were initially considered unable to use the valve have ultimately been able to tolerate it very well. For example, successful use of the PMV has occurred following a downsizing of the tracheostomy tube to allow for more air leak around the tube, or after removal of granulation tissue from the upper airway, and/or with effective management of patient transitioning issues. Therefore, it is extremely important that the assessment process utilized to identify candidates for use of the PMV be thorough and that reassessments be performed as a patient’s status changes.



**Fig. 2 All Other Speaking Valves**

Open Position Speaking Valves Have Air Leak During Exhalation And Do Not Provide A Closed Respiratory System

## VI. Clinical Benefits of the Closed Position "No Leak" Passy-Muir Valves

The Passy-Muir Tracheostomy and Ventilator Speaking Valves were developed to allow tracheostomized and ventilator dependent patients to speak more normally. However, additional significant clinical benefits include:

- Restores Positive Airway Pressure
- Voice/Speech Production
- Swallowing
- Secretion Management
- Oxygenation
- In-line Ventilator Use & Interchangeability
- Weaning
- Decannulation
- Olfaction
- Infection Control
- Pediatric Speech/Language Development
- Quality of Life

**A. Restores Positive Airway Pressure:** The unique closed position “no leak” design of the PMV allows the patient to create a positive airway pressure without the need for manual occlusion of the tracheostomy tube. This creates a more normal closed respiratory system and in turn promotes louder voice, improved swallow, stronger cough and increased oxygenation.

**B. Improves Voice/Speech Production:** Air will take the path of least resistance. If a patient has a tracheostomy, air will move in and out of the tracheostomy tube, thus bypassing the vocal tract. Therefore, the patient must manually occlude the tracheostomy tube to redirect expired air up through the vocal cords and into the oral and nasal cavities to produce speech. This is neither convenient nor hygienic and is often not feasible due to a patient's cognitive and/or mobility status (e.g. infants, quadriplegics). Use of the PMV eliminates the need for finger occlusion and facilitates easier coordination of respiration with speech production. When the PMV is placed on the hub of the tracheostomy tube, all expired air is diverted through the oronasopharynx (with no leakage of air back out through the PMV) allowing the opportunity for louder, clear, uninterrupted phonation and increased length of utterances.

Due to the closed position “no leak” design of the PMVs, they are virtually “noiseless.” In an independent study conducted at Yale University Medical Center (Leder, 1994), listeners and the tracheostomized subjects themselves, rated speech quality (including presence of noise produced from the speaking valves) highest while wearing a PMV as compared to three other open position speaking valves.

When using the PMV, ventilator dependent patients are not limited to speaking one or two syllables with the ventilator cycle as they are when they use “leak speech.” Ventilator dependent patients can produce stronger, louder speech, longer sentences and a more normal speech pattern while using the PMV. This can contribute to their speech intelligibility so they can be heard and understood on the telephone or over background noises such as the ventilator. This in turn offers patients more security and control over their situation, as well as the ability to participate more actively in their health care and recovery.

**C. Improves Swallow/May Reduce Aspiration:** Tracheostomized patients often have difficulty swallowing and are at risk for aspiration. The presence of a tracheostomy tube abolishes the pressures normally generated during swallowing because air escapes through the tracheostomy tube. The tracheostomy tube (especially with an inflated cuff) also tends to anchor the larynx, interfering with laryngeal elevation and airway protection. Reduced sensation in the larynx and pharynx may also occur due to a lack of airflow through the upper airway.

Improved swallowing and reduced aspiration is another important benefit offered through use of the PMVs (Scott, 1991; Baker, et al., 1994; Snyderman, et al., 1994; Gross, et al., 1994; Eibling and Gross, 1995; Dettelbach, et al., 1995; Stachler, et al., 1996). This is due to the fact that the valves restore a “closed respiratory system” and upper airway airflow which in turn promotes restoration of subglottic air pressure and laryngeal and pharyngeal sensation. In addition, due to the need for tracheal cuff deflation when the PMV is utilized, the “anchoring” effect that an inflated cuff can have on laryngeal movement may be reduced.

- D. Facilitates Secretion Management:** Secretions generally increase with the presence of a tracheostomy tube. The body’s natural reaction to the introduction of a foreign body (the tracheostomy tube) into the system is to create more secretions in an attempt to flush out the foreign body. In addition, an individual normally produces one to two liters of oral secretions per day. Most of these secretions are swallowed or evaporated by the passage of air through the mouth and nose. When a tracheostomy tube is in place, these secretions do not evaporate and if not swallowed, can accumulate in the pharynx and eventually enter the trachea.

The PMVs restore airflow to the oral and nasal cavities and thus can contribute to the evaporation process. Furthermore, the “closed respiratory system” restored by the PMVs may enable tracheostomized patients to produce a stronger cough and improve their swallow so that they may not require tracheal suctioning as frequently. This improves secretion management and pulmonary hygiene. Physiologic PEEP (Positive End Expiratory Pressure) is another mechanism by which secretions are evacuated. Physiologic PEEP opens the alveoli, allowing air to move beneath secretions and push them upward toward the larger airways. Lichtman, et al., (1995) objectively measured and compared secretion levels in tracheostomized patients with and without the PMV in place. They found that there was a significant decrease (40%) in the amount of secretions suctioned from tracheostomized patients while using the PMV versus when the PMV was not being used.

- E. Improves Oxygenation:** The closed position “no leak” design of the PMVs restores a more normal “closed respiratory system.” As a result, PEEP is reestablished which facilitates improved oxygenation by opening up the alveoli for better gas exchange (Frey & Wood, 1991).
- F. In-Line Ventilator Use and Interchangeability:** The PMV 005 (White), PMV 007 (Aqua), PMV 2000 (Clear) and PMV 2001 (Purple) can be used both on and off the ventilator with adult, pediatric and neonatal patients. This includes non-ventilator dependent tracheostomized patients, patients who are weaning from the ventilator and patients who are ventilator dependent. When in-line, the PMVs can be used with acute care and portable ventilators and in conjunction with most conventional modes of ventilation. The PMV 007 (Aqua) is designed to fit readily into disposable ventilator tubing, whereas the PMV 005 (White), PMV 2000 (Clear) and PMV 2001 (Purple) require the use of non-disposable, flexible, rubber ventilator tubing. The PMV 2020 (Clear) is not indicated for use in-line.
- G. Expedites Weaning:** The PMV is the ideal augmentative tool for weaning the ventilator dependent patient. As ventilator dependent patients use the PMV, they resume using their diaphragm and respiratory muscles to exhale in conjunction with voicing. They also become accustomed to a more normal breathing pattern and to airflow in the oral/nasal chambers. Consequently, they are able to vocalize and develop confidence. All of

these factors help enable them to wean from the ventilator. Medical staff report that patients often experience faster weaning from the ventilator with PMV use due to the physiological benefits as well as the psychological benefits derived from improved communication, confidence and comfort. (Frey and Wood, 1991)

- H. Reduces Decannulation Time:** When the physician feels a patient no longer needs the tracheostomy tube, he/she must determine that the patient's airway is patent. This may be accomplished by plugging the tracheostomy tube (which can be traumatic and uncomfortable for the patient) or the physician may gradually reduce the size of the tracheostomy tube (which is costly and time consuming). By using the PMV as an interim step in the decannulation process, the patient has an opportunity to adjust to a more normal breathing pattern (expiring through the upper airway). This allows the patient to gain confidence while the physician can assess for airway patency. Utilization of the PMV for decannulation is more comfortable for the patient, more efficient for the physician and more cost effective since decannulation time is reduced (Light, et al., 1989).
- I. Improves Olfaction:** Tracheostomized patients usually lose the ability to smell and taste due to a lack of airflow through the nasal and oral cavities. Use of the PMV reestablishes this airflow during exhalation and as a result olfaction is stimulated (Lichtman, et al., 1995). Restoration of olfaction can also facilitate the sense of taste. In turn, patients may experience improvement in appetite which may lead to increased oral intake and improved nutritional status.
- J. Facilitates Infection Control:** When using the PMV, there is no need for finger occlusion, which can be a significant source of contamination. In addition, the PMV offers protection from airborne particulates entering the trachea, which helps to prevent contamination of the tracheobronchial tree.

Furthermore, due to the restoration of a "closed respiratory system" with use of the PMV, patients can cough and expectorate secretions orally, instead of through the tracheostomy tube, thus reducing contamination risk to others in the patient's environment.

- K. Pediatric Speech/Language Development:** The PMV can be used with children as young as a few days old if they meet the assessment criteria. Introducing the PMV as soon as possible after tracheotomy offers more normal speech/language development as the child is able to vocalize (e.g. cry, laugh, coo, and babble) which is an important precursor to speech and is important to the parent/child bonding process.
- L. Quality of Life:** A tracheostomy can raise many psychological/quality of life issues for patients. Finger occlusion is a very conspicuous action and prevents patients from using their hands while speaking. Difficulty with communication as well as secretion management and swallowing problems can discourage patients from attempting to socialize or interact with others. When using the PMV, patients can breathe, speak and use their hands more normally without drawing attention to the tracheostomy. Patients can use an ascot or scarf to cover the tracheostomy tube from sight if they wish to do so. Restoration of normal speech, reduced suctioning requirements and improved swallowing also facilitate return to a more normal lifestyle. Patients can function without feeling disabled and conspicuous because of their tracheostomy. Increased communicative ability can enable patients to regain control over their environment and facilitate an improvement in self-esteem and well-being.

## VII. Indications for Use of the Passy-Muir Speaking Valve

Tracheostomized (ventilator or non-ventilator dependent) adult, pediatric and neonatal patients who are awake and responsive should be considered candidates for PMV use if they meet the assessment guidelines discussed in sections IX, X and XI. During expiration, air passage must be sufficient around the tracheostomy tube and through the upper airway. The PMV is intended for single patient use only.

Indications for Use Can Include, But Are Not Limited To, The Following:

- Ventilator Dependent Patients\*
- Neuromuscular Disease
- Quadriplegia
- Brain Injury
- Chronic Obstructive Pulmonary Disease
- Tracheomalacia
- Mild Tracheal and/or Laryngeal Stenosis
- Bilateral Vocal Cord Paralysis without significant airway obstruction
- Non-Obstructive Laryngeal Tumors (can include patients who have vocal cord function following surgical resection of the tumor)
- Sleep Apnea patients who are tracheostomized (PMV is used as an alternative to plugging when awake)
- Patients who emotionally or physically are unable to tolerate tracheal plugging

(\*Utilize the PMV 005 (White), PMV 007 (Aqua), PMV 2000 (Clear) or PMV 2001 (Purple). The PMV 2020 (Clear) is for use with non-ventilator dependent tracheostomy patients only.)

## VIII. Contraindications for Use of the Passy-Muir Speaking Valve

- A. Inflated Tracheostomy Tube Cuff:** Controlling ventilation and gross aspiration are the two main issues that influence the decision to utilize a cuffed tracheostomy tube. If, for either of these reasons, the cuff cannot be deflated, then the PMV *cannot* be used as the cuff would cause an obstruction to exhaled air flow and the patient would be unable to exhale/breathe.
- B. Unconscious and/or Comatose Patients:** Ideally, the patient should be awake, responsive and attempting to communicate. However, some semi-comatose patients may have the ability to make sounds. In this case, it may stimulate further responses from the patient and bring them into a lighter state of consciousness (Eggleston, et al., 1990). These patients require constant monitoring when attempting PMV use. The PMV should not be used during sleep.
- C. Severe Medical Instability:** Ideally, the patient should be medically stable via medications, mechanical ventilation and/or adjunctive treatment. However, PMV usage is occurring more frequently with significantly medically compromised patients who may be terminally ill. Use of the PMV can allow patients an opportunity to give medical consent, direct their care and allow for brief periods of communication with family and friends. These situations require physician approval and continuous monitoring.

- D. Foam-Filled Cuffed Tracheostomy Tube:** Foam-filled cuffed tubes are designed to inflate when the pilot line is open to the atmosphere. When deflated, the pilot line of this type of tube must be plugged in order to keep the cuff from reinflating. Because inadvertent reinflation of the cuff can potentially occur, maintenance of cuff deflation cannot be ensured. Therefore, use of the PMV is contraindicated with this type of tracheostomy tube.
- E. Severe Airway Obstruction:** The patient must have the ability to exhale passively around the tracheostomy tube and through the upper airway. If an airway obstruction is severe enough to prevent adequate airflow via this route, then PMV use is contraindicated at that time. As is true with every aspect of PMV assessment, airway patency must be evaluated on a patient by patient basis. Many airway obstructions can be corrected and when corrected, the patient should be reevaluated for PMV placement.
- F. Unmanageable Secretions:** Research has validated that the PMV can help reduce secretions, however, the presence of thick and copious secretions in the airway can make breathing difficult for patients. Use of the PMV with a patient who has unmanageable secretions is contraindicated. Keep in mind that the type, amount and manageability of secretions will vary from patient to patient. When secretions become more manageable, the patient should be reassessed for PMV use. Aggressive pulmonary hygiene, including increased humidity therapy, mucolytics and postural drainage are often used to help loosen and mobilize thick secretions.
- G. Severe Risk for Aspiration:** The PMV has been shown to improve swallowing and may help to reduce aspiration. However, for patients who grossly aspirate an inflated cuff is often utilized to prevent large amounts of aspirated material from entering the lungs. The PMV *cannot* be utilized with an *inflated* cuffed tracheostomy tube.
- H. Severely Reduced Lung Elasticity:** Critically ill and chronic pulmonary patients have lungs with altered compliance. Therefore, PMV usage may be limited to short periods of time during the day with close monitoring. Severe obstructive lung disease causes a loss of lung elasticity and poor natural recoil. Exhalation is thus prolonged. Careful assessment for PMV use is needed to avoid potential complications associated with air trapping that can occur with non-elastic lungs. The appropriate sized tracheostomy tube is especially crucial for these patients when considering PMV use as it can facilitate exhaled air flow.
- I. This device is not intended for use with endotracheal tubes or other artificial airways.**
- J. This device should not be used during sleep.**
- IX. Pre-Placement Assessment (Guidelines)**

Prior to placing the PMV on a patient, a pre-placement assessment should be performed to determine patient candidacy as well as to identify and correct any problems that may temporarily prevent PMV use.

**A. Team Approach**

Patient assessment is most efficient when a team approach is taken. Each discipline brings to the assessment phase unique skills and expertise enabling safe, effective use of the PMV. A team approach offers the tracheostomized and ventilator dependent patient

the support needed to tolerate cuff deflation and transition to wearing the PMV. According to Bell (1996) “a multidisciplinary team approach in developing a communication program can be used to promote a positive patient outcome in any mechanically ventilated tracheostomized patient.”

Although team members will vary within each healthcare setting, the team should include, but is not limited to, the following members: patient, family, physician, respiratory therapist, speech-language pathologist and nurse.

It is essential that education regarding the PMV and its use be provided to all team members working with the patient. This will help to ensure appropriate use of the PMV and facilitate achievement of the patient's maximum communication potential. The following are guidelines for PMV pre-placement assessment:

## **B. Patient Assessment**

1. Cognitive Status: Patient must be awake, responsive and attempting to communicate. The PMV should not be used while the patient is sleeping.
2. Medical/Pulmonary Status: Patient must have the appropriate lung mechanics necessary to exhale around the tracheostomy tube and out the oral and nasal cavities. The patient should be medically stable via medications, mechanical ventilation or adjunctive treatment.
3. Ability to Tolerate Cuff Deflation: Cuff deflation is mandatory when utilizing the PMV in order to allow expired air to pass around the tracheostomy tube and through the oronasopharynx. If it is determined that the patient cannot tolerate cuff deflation initially (i.e., due to risk of gross aspiration or need for intensive critical control over mechanical ventilation), the patient should be reassessed for cuff deflation as changes in his/her medical condition occur. An alternate means of communication should be provided to the patient in the interim.
4. Secretion Management: Use of the PMV can facilitate movement and oral expectoration of secretions by the patient. However, overabundance of secretions, changes in viscosity and/or ongoing infection affect secretion manageability. The ability to manage increased and/or different viscosities of secretions will vary with each patient. PMV use may need to be limited or deferred temporarily until secretions become manageable (e.g. following treatment such as increased humidity therapy, mucolytics, postural drainage, etc.).
5. Swallowing Status: The patient's risk for aspiration should be evaluated as this can influence the amount, thickness and manageability of secretions.

The safety and efficiency of the swallowing process can be negatively affected by the presence of a tracheostomy tube. While some tracheostomized individuals exhibit no swallowing difficulties, many will experience dysphagia and aspiration even though their primary diagnosis would not typically indicate swallowing problems. Use of the PMV improves the safety and efficiency of swallowing and may reduce aspiration. The closed position “no leak” design of the PMV restores the patient to a more normal “closed respiratory system” which improves swallowing as it facilitates increased pharyngeal/laryngeal sensation and restores positive subglottic air pressure.

Presence and/or risk of gross aspiration is an important factor in determining a patient's appropriateness for cuff deflation and PMV use. While use of the PMV can facilitate improved swallow, severe aspiration risk may contraindicate cuff deflation and PMV use.

6. Airway Patency: The patient must be able to exhale efficiently around the tracheostomy tube, up through the larynx and pharynx and out the nasal and oral cavities in order to wear the PMV. The following can assist in determining airway patency:
  - a. Check diagnosis to ensure that there are no known airway obstructions (e.g. tumors, stenosis, granulation tissue).
  - b. Tracheostomy tube size plays an important role in the patient's ability to exhale efficiently. The tracheostomy tube should be sized to allow for sufficient airflow around the tracheostomy tube to facilitate speech and use of the PMV. The cuff on a tracheostomy tube can also create an obstruction even when deflated and should be taken into consideration during airway patency assessment.
  - c. Bedside assessment of airway patency (non-ventilator dependent patients).
    1. Deflate tracheostomy tube cuff completely, if present.
    2. Instruct the patient to inhale through the tracheostomy tube.
    3. Manually/finger occlude the tracheostomy tube with a gloved finger as you instruct the patient to exhale through the mouth and nose to ensure adequate exhalation. This may be observed by having the patient blow on a tissue, mirror, feather, etc. Encourage the patient to vocalize (e.g. say "Ah", count, etc.), to determine presence and quality of voicing. Although some patients may be able to exhale adequately, they may not be able to vocalize initially and may require voice assessment and/or retraining.
    4. Some patients may require repeated attempts of steps 1-3 to become accustomed to exhaling through the upper airway. Upon determination that the patient is able to exhale and/or voice adequately, you may consider PMV placement if other assessment criteria are met.
  - d. Bedside assessment of airway patency (ventilator dependent patients).
    1. Slowly and completely deflate the cuff if present. Follow the guidelines suggested in section XI, Ventilator Application, part C.
    2. Adjust tidal volume, if needed. Follow procedures described in Section XI, *Ventilator Application*.
    3. Instruct the patient to allow normal inhalation of the ventilator breaths.
    4. During exhalation, instruct the patient to exhale through the mouth and nose to ensure adequate exhalation. This may be observed by having the patient blow on a tissue, mirror, feather, etc. Encourage the patient to vocalize (e.g. say "Ah," count, etc.), to determine presence and quality of voicing. Although some patients may be able to exhale adequately, they may not be able to vocalize initially and may require voice assessment and/or retraining.
    5. Some patients may require repeated attempts of steps 1-4 to become accustomed to exhaling through the upper airway. Upon determination that the patient is able to exhale and/or voice adequately, you may consider PMV placement if other assessment criteria are met.

7. **Lung Compliance:** As discussed earlier, critically ill and chronic pulmonary patients have lungs with altered compliance. Therefore, PMV usage may be limited to short periods of time during the day with close monitoring. Severe chronic obstructive lung disease causes a loss of lung elasticity and poor natural recoil. Exhalation is thus prolonged. Careful assessment for PMV use is needed to avoid potential complications associated with air trapping that can occur with non-elastic lungs. An appropriately sized tracheostomy tube is especially crucial to these patients when considering PMV use as it can facilitate exhaled air flow.

During mechanical ventilation, those patients with decreased lung compliance (stiff lungs) may have difficulty tolerating cuff deflation as airflow will take the path of least resistance. Therefore, the patient may not be adequately ventilated thus preventing PMV use. As pulmonary status changes reassess the patient's ability to tolerate cuff deflation.

8. **Level of Care:** Utilization of the PMV can occur in the ICU, rehabilitation, subacute and home settings. Evaluation for PMV use can be performed as early as 48-72 hours post tracheotomy. PMV placement can occur with physician's order as soon as the patient has stabilized and is attempting to communicate, depending upon the degree of tracheal edema and secretions present.

## X. Initial Placement of the PMV (Non-Ventilator Application)

After pre-assessment criteria have been met, PMV placement should occur in conjunction with a physician's order using, but not limited to, the following guidelines:

- A. **Patient and Staff Education:** To reduce anxiety and ensure successful transition to the PMV, the patient, family and all personnel working with the patient (all shifts) should be instructed on the use of the PMV including contraindications, cautions and warnings. Review all package inserts and labeling with patient, family and staff. Free patient information and clinical inservice videos are available from Passy-Muir, Inc. to assist you with your educational efforts.
- B. **Patient Bedside Assessment:** The patient should be assessed before, during and after PMV placement for the following:
  - Oxygen saturation
  - Vital signs, (e.g. heart rate, respiratory rate)
  - Breath sounds
  - Change in patient's color and responsiveness
  - Work of breathing
  - Tracheal and oral secretion status
  - Patient reaction
  - Airway patency

When determining the appropriate patient parameters during the bedside assessment, they should be based upon the patient's normal baseline and per physician direction.

- C. **Positioning:** To insure successful use of the PMV, the patient should be positioned comfortably, usually at a 45° angle or sitting position to facilitate proper diaphragmatic movement and maintenance of a patent airway. Not only should the *patient* be positioned

properly but the *tracheostomy tube* should be correctly aligned in the trachea to maintain a patent airway and patient comfort. Appropriate positioning may vary from patient to patient.

- D. Suctioning:** Suctioning should be performed on an as needed basis prior to placement of the PMV. If the patient has secretion accumulation it is recommended that both tracheal and oral suctioning be administered before deflating the cuff. If the patient has an inflated cuffed tracheostomy tube, suctioning during cuff deflation is desirable to catch secretions that have been sitting on top of the cuff which may penetrate to the lower airway if suctioning intervention is not provided. In some cases, such as with obligate nose breathers (infants), nasal suctioning may be required to allow air to flow freely through the nasal passages.
- E. Cuff Deflation:** If the patient has a cuffed tracheostomy tube, it is imperative that the cuff be fully deflated prior to PMV placement. This is required to maximize the amount of space existing between the tracheostomy tube and the tracheal wall through which the patient must be able to adequately exhale. Slow deflation of the cuff often facilitates a smoother transition for the patient to adjust to the feeling of airflow in the upper airway and secretions being dislodged in his/her trachea.

Deflate cuff slowly allowing the patient to acclimate to the sensation of airflow through the upper airway. Per physician direction, changing to a smaller and/or cuffless tracheostomy tube may be necessary to provide sufficient airflow around the tube to facilitate use of the PMV. Attach warning labels provided with the PMV to the pilot balloon of the patient's cuffed tracheostomy tube, at the patient's bedside and/or in the patient's chart.

**It should be noted that the Passy-Muir Valves are contraindicated for use with foam-filled cuffed tracheostomy tubes due to safety issues regarding inadequate deflation of this type of cuff.**

- F. PMV Attachment:** The following discusses attachment of the PMV 005, PMV 007, PMV 2000 and PMV 2001 only. Please see the Passy-Muir Instruction Booklet provided with the PMV 2020 for instructions on use of this product.

The PMV 005 (White), PMV 007 (Aqua), PMV 2000 (Clear) and PMV 2001 (Purple) fit directly onto the 15mm hub of adult, pediatric and neonatal tracheostomy tubes.

To attach the PMV to the tracheostomy tube, gently stabilize the tracheostomy tube with one hand while attaching the PMV to the 15mm hub of the tracheostomy tube with the other hand using an approximate 1/4 twist. The PMV has a friction fit for secure placement.

Observe the PMV to ensure that the diaphragm of the PMV opens during inspiration and remains closed during expiration. Observe the patient with the PMV in place to ensure the patient has adequate airflow around the tracheostomy tube. If the patient exhibits signs of respiratory distress, remove the PMV immediately and reassess for airway patency. To remove the PMV, gently stabilize the tracheostomy tube with one hand and twist the PMV off gently with the other hand.

When using the PMV 2000 (Clear), PMV 2001 (Purple) and PMV 2020 (Clear) Speaking Valves, place the PMV Secure-It™ on the PMV before placing the PMV on the tracheostomy tube. Do not use the PMV Secure-It™ when using the PMV 2000 (Clear)

or PMV 2001 (Purple) in-line with mechanical ventilation. Attach the PMV Secure-It™ using the following steps (use of the PMV Secure-It™ is optional):

1. Thread the long, thin end of the PMV Secure-It™ through the small hole on the side of the PMV.
2. Pull it through the hole until the PMV rests between the two notches on the PMV Secure-It™.
3. Place the other (thicker) end of the PMV Secure-It™ around the tracheostomy tube tie close to the neckplate of the tracheostomy tube.
4. Fasten like a button in a button hole.

(Please see Passy-Muir Valve Clinical Instruction Booklet for diagrams).

## G. Connections:

1. **Fenestrated Tracheostomy Tubes:** The PMV can be used with fenestrated tracheostomy tubes although a fenestrated tube is not required. If using an inner cannula to connect the PMV, it is necessary that both the inner and outer cannula be fenestrated to take advantage of the fenestration. If the fenestrated tube is cuffed, the cuff must be completely deflated. Using the PMV with a fenestrated tube may offer the advantage of further improvement in voice/speech volume along with the other benefits of the PMV discussed in Section VI.
2. **Inner Cannula:** The PMVs fit on the universal 15mm hub of adult, pediatric and neonatal tracheostomy tubes with a friction fit. Some tracheostomy tube designs may provide the 15mm hub as part of the inner cannula and some as part of the outer cannula. When using the PMV 005 (White) on tracheostomy tubes that have a disposable inner cannula with a grasp ring, it is necessary to ensure that the grasp ring does not extend beyond the 15 mm hub of the tracheostomy tube. If it does extend beyond the 15mm hub, the inner cannula should be removed prior to PMV use. **CAUTION:** If the grasp ring is sprung outward it may obstruct diaphragm movement of the PMV 005 (White).
3. **Metal Tracheostomy Tubes:** Most metal tracheostomy tubes do not offer a 15mm hub and instead have a low profile hub which prevents direct connection with the standard PMVs (PMV 005, PMV 007, PMV 2000 and PMV 2001). However, the PMV 2020 (Clear) Speaking Valve and Adapter set (Fig. 3) is designed to be used with the Pilling Weck metal Improved Jackson tracheostomy tubes sizes 4-6 or equivalent.

Some metal tracheostomy tube manufacturers offer an optional 15mm hub on the inner cannula which will allow for connection of the standard PMVs, as well as other respiratory equipment. These can be ordered from the manufacturer or distributor. For those metal tubes that cannot accommodate the PMV 2020 and do not have a 15mm hub, a plastic endotracheal tube adapter may be sized to fit a low-profile metal tracheostomy tube to create a 15mm hub that will allow for placement of the standard PMV. (Fig. 4)



Fig. 3 PMV 2020 (Clear) Tracheostomy Speaking Valve and PMA 2020-S Adapter on a Pilling Weck Metal Jackson Improved Tracheostomy Tube

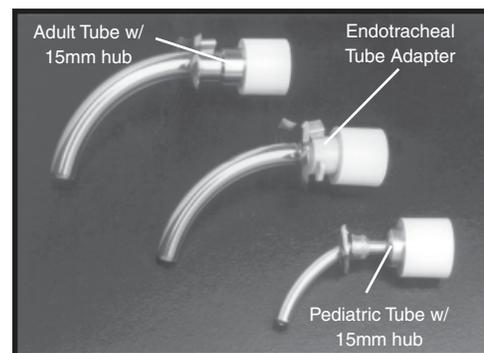
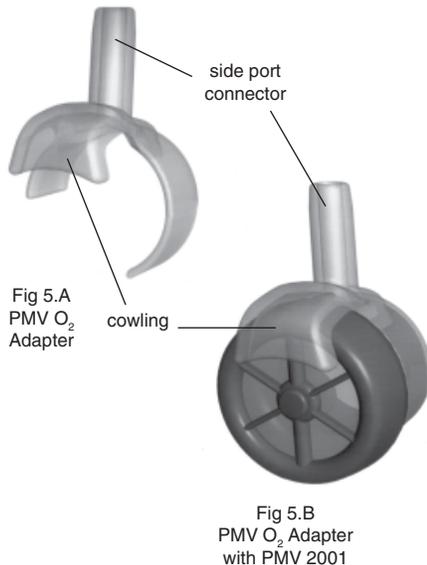


Fig. 4 Metal Tracheostomy Tubes

4. **Oxygen:** Oxygen can be administered while the PMV is in place at the tracheostomy tube site via mask, trach collar or PMV O<sub>2</sub> Adapter. If using the PMV 2000 (Clear) or PMV 2001 (Purple) Speaking Valves, low flow ( $\leq 6$  L/min) oxygen can be applied using the PMV O<sub>2</sub> Adapter (PMA 2000).

PMV O<sub>2</sub> Adapter Placement:



- Place the oxygen tubing securely onto the side port connector (Fig 5.A) that protrudes from the side of the PMV O<sub>2</sub> Adapter to ensure a secure attachment.
  - Snap the PMV O<sub>2</sub> Adapter gently into place against the side of either the PMV 2000 (Clear) or PMV 2001 (Purple) Speaking Valves, making sure the curvatures of the two parts match tightly to one another, with no gaps or interference from the small ring that is molded into the side of the valve. When properly installed, the cowling of the PMV O<sub>2</sub> Adapter should overhang the front edge of the PMV, in order to deliver oxygen directly in front of the diaphragm (Fig 5.B).
  - Once the PMV O<sub>2</sub> Adapter (with oxygen tubing attached) has been snapped onto the PMV, the PMV can then be placed on the hub of the tracheostomy tube in the conventional manner.
  - Titrate the oxygen liter flow using methods such as pulse oximetry to ensure adequate oxygenation. The PMV O<sub>2</sub> Adapter is an open oxygen system, therefore the F<sub>I</sub> O<sub>2</sub> will be variable, depending upon patient status.
5. **Humidity:** Humidity (non-medicated heated aerosol) can be applied at the tracheostomy tube site with the PMV in place via the use of a trach collar or T-piece. Heat moisture exchange filter (HME) performance may be reduced when used in conjunction with the PMV as exhaled air no longer passes through the filter providing airflow to trap moisture. A secondary humidification system may be needed. If an HME is used, it is important that it be placed between the PMV and the patient so that some moisture may be gained. Hygroscopic condensing humidification (HCH) devices are designed to create a higher percentage of humidity which may provide slightly improved humidification with the PMV as compared to the HME. Patients utilizing HME or HCH devices with the PMV should be evaluated to ensure that adequate humidification is being delivered to the patient.
6. **Monitoring During Valve Placement:** The baseline measurements, described earlier, should be carefully monitored for significant changes while the patient is wearing the PMV. If significant negative changes are observed, the valve should be removed immediately and the patient given appropriate assistance. **CAUTION:** If the patient experiences difficulty utilizing the valve, remove the valve immediately as the patient may have an airway obstruction due to stenosis, masses, secretions, or a tracheostomy tube that is oversized for the patient's trachea. With correction of the obstruction, the valve can be used. Some patients can wear the valve for 15 to 30 minutes or longer on the first attempt. Other patients will need to increase the time that the

valve is worn a few minutes at a time. Ideally, patients will gradually reach the point where they can tolerate the PMV during all waking hours. It should be noted that due to a patient's fluctuating respiratory status (e.g. presence of infection, thick secretions, etc.), his/her tolerance of the PMV could vary from day to day and week to week.

7. Facilitating Voice/Speech: If the patient appears to be tolerating the PMV, he/she should be encouraged to exhale through the mouth and attempt to vocalize an "ahhhh." Next, he/she should count to ten and then repeat some phrases and sentences of gradually increasing length. Many patients will be able to speak quite well immediately after the PMV is placed. However, other patients will need to practice these simple activities to improve their speech and voice production possibly due to vocal cord atrophy, damage or neurological deficits.

## H. Troubleshooting and Transitioning Issues

Many patients adjust immediately and easily to the PMV, tolerating it during all waking hours (e.g. 16-18 hours per day). However, some patients may require a gradual transition to wearing the PMV. Re-education of breathing pattern and voice/speech production may be needed if the patient has not vocalized for a prolonged period of time. Patients will experience more normal respiratory sensations such as airflow in the oral/nasal cavities, and the effects of increased respiratory muscle activity. Patients may initially experience increased coughing due to restoration of a more normal, "closed respiratory system," which re-establishes subglottic pressure and normal exhaled airflow in the oronasopharynx. Therefore, secretion management and clearing of tracheal secretions is facilitated, which aids in pulmonary hygiene.

1. Airway Patency: If the patient is unable to exhale adequately through the upper airway, remove the PMV and consider the following for reassessment:
  - Check to ensure that the tracheostomy tube cuff is completely deflated. Although not required, a cuffless tracheostomy tube may provide optimal airway patency for use with the PMV and should be considered if the patient is an appropriate candidate.
  - Reassess to insure optimal patient and tracheostomy tube positioning.
  - Evaluate tracheostomy tube to determine whether downsizing the tube is necessary as the size of the tracheostomy tube or bulk of the deflated cuff may prevent adequate exhalation.
  - Physician assessment (e.g. bronchoscopy for presence of unknown airway obstruction, stenosis, granulation, mass, vocal cord paralysis, etc.) should be considered.

Methods for checking airway patency may include: 1) listening to breath sounds before and after finger occlusion and/or PMV placement. Absent or decreased breath sounds during finger occlusion or PMV placement may indicate air trapping. The PMV should be removed until further evaluation of the airway is performed. 2) Observing for exhaled air through the mouth and nose using items such as a tissue, mirror, feathers, etc. 3) Monitoring saturation levels can be helpful in detecting problems with gas exchange that may be due to airway obstruction.

2. **Breathing Pattern Changes:** Long-term tracheostomized and ventilator dependent patients who are no longer used to breathing through their upper airway may actually “forget” how to exhale through the mouth and nose, requiring the clinician to work on various exhalation techniques such as blowing a feather or counting. Other helpful tools are biofeedback, relaxation techniques and abdominal breathing exercises. Once the patient relearns upper airway exhalation, tolerance of the PMV may increase significantly.
3. **Increased/Excessive Coughing:** Initial placement of the PMV may stimulate patients to cough due to airflow through the upper airway. When airflow is absent, as with an inflated cuff, there is a tendency to pool secretions due to lack of sensation. If patients do not feel secretions in the airway they will not cough or dry swallow, therefore the secretions will pool. Placement of the PMV redirects air through the upper airway moving the secretions upward. Patients can feel this movement and a cough is triggered. Coughing will continue until the secretions settle or have moved into a position that will allow patients to swallow or expectorate them. This is beneficial as patients have a more effective secretion clearing mechanism in place with PMV use. Usually, coughing subsides and the patient becomes comfortable with the PMV. If coughing persists and/or a patient exhibits distress, remove the PMV and suction the airway.

If the patient exhibits prolonged dry or excessive coughing, the patient may be air trapping. Remove the PMV immediately and reassess for airway patency.

4. **Patient Anxiety:** Tracheostomized patients may experience anxiety with initial PMV placement. Patient education prior to placement of the PMV may help reduce some of this anxiety. This should include an explanation that the patient will experience the sensation of airflow through the upper airway upon exhalation, and may initially experience movement of secretions through the airway and out of the mouth. Distraction techniques may also be used to facilitate exhalation and/or voice (e.g. talking to friends, watching TV, talking on the phone), as well as visual techniques such as simple spirometry or use of mirrors, cotton, feathers, whistles or bubbles to assist with the oral exhalation process. A patient/clinician information video is available free of charge from Passy-Muir Inc., which may assist in patient education and motivation.

## **I. Removing The PMV (PMV 005, PMV 007, PMV 2000 & PMV 2001)**

When removing the PMV from the tracheostomy tube, place one hand gently on the tracheostomy tube neckplate (to keep the tracheostomy tube from moving) and with the other hand gently twist the PMV in a clockwise motion off the hub of the tube. If using a tracheostomy tube that has a hub that rotates it may be necessary to use a rocking rather than twisting motion to remove the PMV.

### **1. Removing the PMV Secure-It™**

- a. Unbutton the PMV Secure-It™ from the tracheostomy tube tie.
- b. Remove the PMV from the hub of the tracheostomy tube as described above.
- c. Gently pull the PMV Secure-It™ out of the small hole on the side of the PMV.

## 2. Removing the PMV O<sub>2</sub> Adapter

- a. Remove the PMV from the hub of the tracheostomy tube.
- b. Remove the PMV O<sub>2</sub> Adapter from the PMV with a gentle pulling motion.
- c. Remove the oxygen tubing from the PMV O<sub>2</sub> Adapter.

## XI. Ventilator Application

The PMV 005 (White), PMV 007 (Aqua), PMV 2000 (Clear) and the PMV 2001 (Purple) can all be used interchangeably on or off the ventilator depending upon the type of ventilator tubing being utilized (see Section D: *PMV Connections* in this section). The PMVs can be used with acute care and portable ventilators and in conjunction with most conventional modes of ventilation including pressure support ventilation (PSV), synchronized intermittent mandatory ventilation (SIMV), assist/control (A/C), pressure control (PC), continuous positive airway pressure (CPAP) and control (C) ventilation. The benefits of the closed position “no leak” design of the PMVs are maintained during all conventional modes of mechanical ventilation as well as during continuous flow, flow-by, PEEP or CPAP.

When utilizing the PMV with continuous flow or flow-by, the flow of air from the ventilator travels from the inspiratory limb of the ventilator circuit to the expiratory limb of the circuit and does not flow to the patient unless a drop in pressure occurs at the patient's airway, as with the beginning of inspiration. This drop in pressure redirects the flow to the patient's airway and opens the diaphragm of the PMV. At the end of inspiration, pressures in the lungs are equal to or greater than the pressure in the circuit. At this time the PMV returns to its normally closed position, this causes a redirection of flow back to the ventilator circuit.

PEEP and CPAP are both maintained via an exhalation valve that is either designed within the ventilator or added externally. Exhalation valves cause pressure to remain within the lungs by not allowing it to escape. In most cases, flow is not required to maintain this pressure. However, in some instances (e.g. presence of an air leak through the upper airway created by a deflated cuff) flow may be needed to help the exhalation valve maintain positive pressure within the airway. When this occurs, flow will follow the same principle as described above.

**A. Patient Assessment/PMV Placement Section Review:** Review Sections IX, *Pre-Placement Assessment* and Section X, *Initial Placement of the PMV (Non-Ventilator Application)* for the following information:

### Section IX Pre-Patient Assessment

- Team Approach
- Patient Assessment

### Section X Initial Placement of the PMV (Non-Ventilator Application)

- Patient and Staff Education
- Patient Bedside Assessment
- Positioning
- Suctioning
- Cuff Deflation

**B. Ventilator Assessment:** Record all ventilator settings before, during and after PMV placement including:

- a) Mode of Ventilation (A/C, SIMV, CPAP, etc.)
- b) Tidal Volume ( $V_T$ )
- c) Respiratory Rate (RR)- mechanical and spontaneous
- d) Fraction of Inspired Oxygen Content ( $F_{I,O_2}$ )
- e) Positive End Expiratory Pressure (PEEP)
- f) Peak Inspiratory Pressure (PIP)
- g) Sensitivity
- h) Alarm Settings - volume and pressure alarms
- i) Follow ventilator manufacturer's guidelines for self testing (e.g. PB 7200 Short EST Test)

**C. Ventilator Adjustments:** PMV use may require adjustments to be made to the alarms and/or parameter settings and should be evaluated by the treating physician and clinician. Before proceeding with PMV placement, perform patient assessment, educate the patient to valve use and suction tracheostomy and mouth as needed.

1. Volume Compensation During Cuff Deflation - Before placing the PMV, the cuff of the tracheostomy tube **must be completely deflated**.

The PMVs are increasingly used as part of the treatment plan for ventilator dependent patients. With valve use and cuff deflation, upper airway functions can be assessed and tracheal cuff complications reduced. This application may require learning techniques for cuff deflation, such as weaning the patient from use of the cuff.

Patients can be ventilated with the cuff deflated according to a study by Drs. Bach and Alba (1990) entitled, "Tracheostomy Ventilation: A Study of Efficacy with Deflated Cuffs and Cuffless Tubes." Of 104 patients with different diagnoses, 91 patients were able to tolerate a deflated cuff or cuffless tracheostomy tube during mechanical ventilation. "This study indicates that the vast majority of tracheostomized patients with severe respiratory insufficiency and reasonably competent oropharyngeal muscles can be safely and adequately ventilated up to 24 hours a day with their cuffs deflated or removed."

Prior to cuff deflation, exhaled volumes and peak inspiratory pressures (PIP) should be noted and then compared to measurements post cuff deflation. This is necessary to determine approximate inspiratory volume losses to the patient.

Volumes entering the lungs should generate a fairly consistent range of PIP's but are dependent upon the patient's pulmonary status. During exhalation (prior to PMV placement), air is directed back through the circuit to the ventilator where exhaled volumes can be measured. However, when the cuff is deflated air may be exhaled through the upper airway as well as through the circuit. Consequently, the PIP is a more accurate guide for monitoring ventilation because exhaled volume measurements will be less precise. Prior to cuff deflation, PIP should be noted and then compared to measurements post cuff deflation. PIP will assist in determining approximate inspiratory volume loss to the patient.

As exhaled air is redirected through the mouth and nose, it cannot be measured via the ventilator. Therefore, it is important for post cuff deflation PIPs to be assessed

and incremental volume adjustments made to match baseline peak pressures (do not exceed pre-cuff deflation PIP's). Once the PMV has been placed, exhaled volumes can be measured with a spirometer via a mask or mouthpiece and nose clips. Changes in volume may or may not be required and should be evaluated by the physician and treating clinician based upon pre and post cuff deflation PIP's as well as physical symptomatology. During cuff deflation before PMV placement, if a large decrease in PIP occurs, reinflate the cuff and begin a slow cuff deflation technique as described in section XI.E.3, *Increased/Excessive Airflow through the Upper Airway*. This technique facilitates increased oropharyngeal muscle tone by using a slow leak to introduce air to the upper airway.

## 2. Alarm Assessments

All alarms on a ventilator need to be re-evaluated for appropriate adjustments before, during and after use of the PMV. Some acute care ventilators may have a return demand alarm for exhaled volumes. Microprocessor sensors within the ventilator insist upon air return through the ventilator system or an alarm will sound as no exhaled airflow is detected when the PMV is in place. These alarms can be adjusted to cease unnecessary alarming per physician direction. Use of pressure support can also be of benefit as airflow is provided to the ventilator system to help satisfy sensor demands. Low volume alarm demands that cannot be satisfied do not necessarily preclude valve use. The valve can be worn during therapies when the alarms can be reset manually by the clinician, allowing the patient the opportunity for periods of verbal communication, socialization, and vocal cord strengthening.

When the patient has successfully weaned, changed to another mode of ventilation or a different ventilator is used, continuous PMV use can be reassessed. Two sets of alarms are available on most acute care ventilators, the first set being the exhaled volume alarms and the second set being the pressure alarms. Even if exhaled volume alarm adjustments are needed during PMV use, the pressure alarms remain intact and should be properly adjusted (set tighter) to detect and alert caregivers to disconnects or increasing pressures. Follow the ventilator manufacturer's recommendations for ventilator self testing as this may relieve any unnecessary alarming (e.g. a short EST should be performed with circuit changes on some acute care ventilators). Some of the newer model ventilators have a speaking valve mode that will measure the appropriate parameters. Contact your ventilator representative for more information.

## 3. Airway Pressures

Airway pressures may rise slightly with patients using the PMV due to the establishment of a closed respiratory system and exhalation through the oronasopharynx which creates (natural) physiologic PEEP. Consequently, mechanical PEEP requirements may be able to be reduced. Although airway pressures may rise, they should remain within the prescribed limits for a patient.

When peak pressures are above the allowable limits, the PMV should be removed and assessment for upper airway patency performed. In addition, due to a slight increase in airway pressure experienced with some patients it is necessary, as with any modification to the ventilator circuit, to re-evaluate low pressure settings for disconnect to ensure that these levels are appropriate.

#### 4. Fraction of Inspired Oxygen ( $F_{I}O_2$ )

In the article, “Weaning from Mechanical Ventilation Augmented by the Passy-Muir Speaking Valve,” J.A. Frey, RN and S. Wood, RRT (1991) compared oxygen saturation ( $SaO_2$ ) levels in patients before and during PMV use. Saturations in all cases increased during PMV use or remained the same. The physiologic PEEP that is restored when the PMV is placed allows for better oxygenation by opening up the alveoli for improved gas exchange.

Occasionally,  $SaO_2$  levels may decrease requiring small increases in  $F_{I}O_2$ . Significant desaturation requiring large increases in  $F_{I}O_2$  can indicate airway obstruction or air leak during ventilation. If significant desaturation should occur, remove the PMV and reassess the patient. (Review Section X *Initial Placement of the PMV (Non-Ventilator Application)* for Troubleshooting and Transitioning Issues).

#### 5. Levels of Ventilatory Support

The PMV can be comfortably utilized in conjunction with most conventional modes of mechanical ventilation. Occasionally, patients may require an extra level of support and in some cases may require a decrease in the level of support. These changes may include modification of respiratory rate and/or mode of ventilation (all changes require a physician’s order). Changes in ventilatory support should be based on the patient’s needs and assessed on an individual basis.

#### 6. Deadspace

The closed position “no leak” design of the PMV causes the valve diaphragm to close at the end of inspiration. Therefore, no air is exhaled through the tracheostomy tube or ventilator tubing. This reduces the amount of deadspace in the circuit so the patient is not rebreathing  $CO_2$ .

**D. PMV Connections:** All PMVs (with the exception of the PMV 2020) can be utilized in-line during mechanical ventilation. The PMV 007 (Aqua) is designed to fit into disposable ventilator tubing, therefore it is often the valve of choice for in-line ventilator use. However, the PMV 005 (White), PMV 2000 (Clear) and PMV 2001 (Purple) can be utilized in-line with non-disposable, flexible, rubber tubing. When placing the PMV in-line, the PMV should be placed on or as close to the tracheostomy tube as possible to prevent added deadspace. When using the PMV 2000 Series Valves in-line, do not use the PMV-Secure-It™ or PMV O<sub>2</sub> Adapter.

1. 15mm Hub: The PMV fits onto the universal 15mm hub of tracheostomy tubes including neonatal, pediatric and adult tubes.
2. Humidification: Humidification devices such as the cascade or concha do not affect PMV use. Heat moisture exchange filter (HME) performance may be reduced when used in conjunction with the PMV as exhaled air no longer passes through the filter providing airflow to trap moisture. A secondary humidification system may be needed. If an HME is used, it is important that it be placed between the PMV and the patient so that some moisture may be gained. Hygroscopic condensing humidification (HCH) devices are designed to create a higher percentage of humidity which may provide slightly improved humidification with the PMV as compared to the HME. Patients utilizing HME or HCH devices with the PMV should be evaluated to ensure that adequate humidification is being delivered to the patient.

3. **In-line Suction Systems:** The PMV can be utilized with in-line closed suctioning systems (Fig. 6). The PMV should be connected to the side port to prevent the suction catheter from obstructing or damaging the PMV. Most in-line closed suctioning systems allow for direct connection of the PMV to the side port however, some may require use of a 15mm X 22mm step-down adapter to provide the connection.

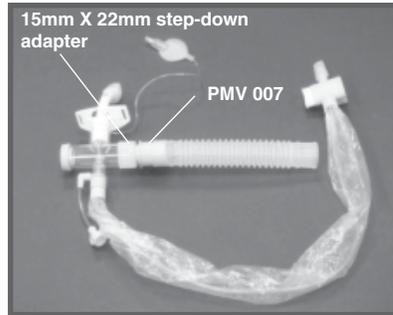


Fig. 6 In-line Closed Suction Catheter with the PMV 007 (Aqua)

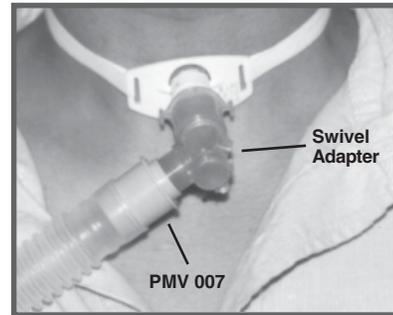


Fig. 7 Swivel Adapter with the PMV 007 (Aqua)

4. **Swivel Adapters:** Swivel adapters attach directly to the tracheostomy tube and then slope at a 45° angle (Fig. 7). These adapters have the ability to rotate thereby providing more comfort to the patient by creating less torque on the airway.

All PMVs will attach directly onto the 15mm (distal) end of the swivel adapter. Ventilator tubing is then connected to the PMV. Caution: If the PMV 005 (White) is placed on the swivel adapter with excessive force, it may cause occlusion of the PMV.

5. **Omniflex™:** The PMV attaches readily onto the 15mm (distal) end of the Omniflex™ adapter (Fig. 8). Ventilator tubing is then connected to the PMV. The Omniflex™ adapter increases patient comfort due to its flexibility, creating less torque on the airway.

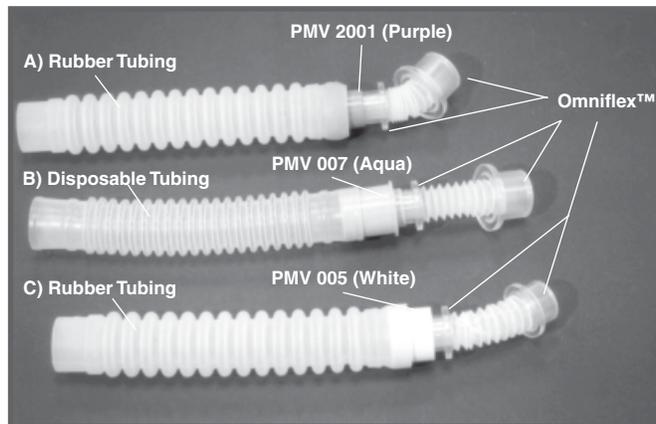


Fig. 8 PMV 005, PMV 007 and PMV 2001 in-line with the Omniflex™ adapter using non disposable, flexible rubber ventilator tubing (8A, 8C) and disposable ventilator tubing (8B)

6. Disposable Ventilator Tubing: The PMV 007 (Aqua) has a 22mm O.D. tapered design to fit directly into disposable ventilator tubing most commonly used in acute care settings (Fig. 8). The PMV 2000 (Clear), PMV 2001 (Purple) and PMV 005 (White) cannot be used with this type of tubing.
7. Non-Disposable Ventilator Tubing: Application of the PMV 2000 (Clear), PMV 2001 (Purple) and PMV 005 (White) requires use of non-disposable, flexible, rubber tubing that allows for insertion of these PMVs (15mm I.D./23mm O.D.) into the ventilator circuit (Fig. 8). The PMV 007 (Aqua) can also be utilized with this tubing.
8. Pediatric Circuitry: Pediatric circuits are too small to allow for direct insertion of a PMV. An adapter may be needed, such as a rubber adapter with a 15mm I.D. and a 22mm O.D., to convert to the smaller tubing requirements (Fig. 9). A 15mm x 22mm stepdown adapter is another example of an adapter that has appropriate dimensions to allow utilization of the PMV 007 (Aqua) with a pediatric circuit.



Fig. 9 PMV 007 (Aqua) in-line with pediatric ventilator circuitry utilizing a rubber adapter

## E. Troubleshooting and Transitioning:

1. Airway Patency: If the patient is unable to exhale adequately through the upper airway, the following may need to be considered for reassessment:
  - a. Cuff Status: Check to ensure that the tracheostomy tube cuff is completely deflated. Although not required, a cuffless tracheostomy tube may provide optimal airway patency for use with the PMV and should be considered if the patient is an appropriate candidate.
  - b. Tracheostomy Tube Size: Evaluate tracheostomy tube size to determine whether downsizing the tube is necessary. The size of the tracheostomy tube or bulk of the deflated cuff may prevent the patient from adequately exhaling through the upper airway.
  - c. Airway Obstruction: Physician assessment (e.g. bronchoscopy) for presence of unknown airway obstruction (e.g. stenosis, granulation tissue, vocal cord paralysis, etc.) should be considered.
  - d. Positioning: Reassess to ensure optimal patient and tracheostomy tube positioning.

- e. Suctioning: Movement of secretions in the airway due to increased airflow through the oronasopharynx may create some discomfort. Repeat tracheal and oral suctioning.
2. Breathing Pattern Changes: Long-term tracheostomized and ventilator dependent patients who are no longer used to breathing through their upper airway may actually “forget” how to exhale through the mouth and nose, requiring the clinician to work on various exhalation techniques such as blowing a feather or counting. Other helpful tools are biofeedback, relaxation techniques and abdominal breathing exercises. Once the patient relearns upper airway exhalation, tolerance of the PMV may increase significantly.
3. Increased/Excessive Airflow through the Upper Airway: Some patients may experience a continuous rushing of air through the upper airway which may be uncomfortable. Drying of the mucous membranes, inability to adequately ventilate and increased noise levels are associated with excessive airflow. Listed below are possible causes and corrective measures:
  - a. Decreased pharyngeal/laryngeal tone and sensation: Muscles that are not used for prolonged periods of time begin to atrophy and lose tone. Lack of airflow through the upper airway decreases pharyngeal/laryngeal tone and sensation and prevents effective glottic closure.

Besides decreased tone and atrophy, lack of airflow causes the vocal cords to remain in a relaxed, open position. These factors combined create a situation that allows air to flow readily past the vocal cords during both the inspiratory and expiratory ventilatory cycle because there is loss of glottic function and the path of least resistance is taken. A goal of the clinician will be to work on strengthening the laryngeal/pharyngeal muscles through glottic exercises, increased airflow and verbal communication.

- b. Failure of the ventilator to cycle off when in the pressure support mode: Decreased pharyngeal/laryngeal tone and poor glottic function create a potential for a large leak through the upper airway. When a leak occurs during inspiration, pressure in the airways may not rise to the levels that have been set on the ventilator. Therefore, the ventilator will continue to deliver flow, in an attempt to reach the preset pressure level, sense that flow has slowed or that an allotted time limit has passed (usually 3 seconds). Adjusting the ventilator from pressure support to the pressure control mode will allow adequate delivery of the pressure required without excessive flow. As glottal function improves the pressure support mode should be more easily tolerated.

An effective method of increasing pharyngeal/laryngeal tone is to go through a slow cuff deflation process. This may mean taking 1/2 cc of air out of the patient’s cuff every minute, letting the patient gradually acclimate to airflow through the upper airway. This allows the airway to gradually increase tone creating resistance in the upper airway, thus preventing air leak.

4. Increased/Excessive Coughing: Initial placement of the PMV may stimulate the patient to cough due to airflow through the upper airway. When airflow is absent, as with an inflated cuff, there is a tendency to pool secretions due to lack of sensation. If patients do not feel secretions in the airway they will not cough or dry swallow,

therefore the secretions will pool. Placement of the PMV redirects air through the upper airway moving the secretions upward. Patients can feel this movement and a cough is triggered. Coughing will continue until the secretions settle or have moved into a position that will allow patients to swallow or expectorate them. This is beneficial as patients have a more effective secretion clearing mechanism in place with the PMV. Usually, coughing subsides and patients become comfortable with the PMV. If coughing persists and/or a patient exhibits distress, remove the PMV and suction the airway.

If the patient exhibits prolonged dry, tight or excessive coughing, the patient may be air trapping. Remove the PMV immediately and reassess for airway patency.

5. Assessment of the Level of Ventilator Support: If a patient is having difficulty utilizing the PMV in-line and it is not due to airway obstruction, air leak, or anxiety, assessment and adjustment of the ventilator may help facilitate PMV use. This should be done based on the patient's status, good respiratory assessment skills and with a physician's order.
6. Voicing During Inspiration: Occasionally, a patient may attempt to communicate during the inspiratory cycle of the ventilator breath. This may be due to the lack of sensation which may occur with SCI patients. It is important to discourage vocalization during inspiration as it redirects the air from entering the lungs where it is needed for ventilation and instead diverts the air through the upper airway for speech production. Consequently, the patient is not ventilating appropriately and if not monitored, the CO<sub>2</sub> levels may rise. Patient education, timing cues during exhalation and relaxation techniques are useful tools to help the patient learn to voice normally during exhalation.
7. Anxiety: Patients who have been mechanically ventilated for an extended period of time sometimes react with anxiety to the initial placement of the PMV. It is extremely helpful to have the assistance of a speech-language pathologist to transition these patients to successful PMV usage. The speech-language pathologist can help patients optimize vocal/speech production, assess and treat swallowing problems, and instruct them in producing a cough, blowing their nose, etc. In addition, it can be effective to gradually transition a patient to wearing the PMV, starting with short periods of time and slowly increasing PMV use as tolerated.

Education is essential prior to PMV placement so that patients will know what to expect, thereby reducing anxiety. Goal setting charts can be useful, allowing patients and staff to measure progress of PMV use.

8. Depression: Ventilator dependent patients often experience severe depression and may not want to participate in therapy or conversation. Solicitation of family involvement with visits and therapies can be helpful in motivating patients. Psychological intervention may also be necessary. Patients unable to control their environment and/or their own physical functions can sometimes exhibit control issues by obstructing rehabilitation efforts and quality care. Patient anxiety and depression can be obstructive to any pulmonary rehabilitation process. Using the PMV for family visits, physician consults, therapy times and telephone calls may help motivate patients

to communicate. The ability to interface with nursing, physicians and therapists can help patients participate more actively in their care which can benefit health care providers by saving time and meeting patient needs more expeditiously.

## F. Monitoring Devices

The following devices are useful in monitoring patient status before, during and after PMV use:

1. Pulse Oximetry: Provides continuous, non-invasive monitoring of oxygen saturation and is routinely used for PMV placement.
2. Transcutaneous Monitoring (TCM): Non-invasive monitoring commonly used in the neonatal and pediatric arena. The TCM will offer trending information of  $PCO_2$  and  $PaO_2$  levels.
3. Capnography (ETCO<sub>2</sub>): Capnography measures the level of  $CO_2$  at the patient's airway during exhalation.
4. Spirometry: When the PMV is placed in-line, exhaled volumes can be measured via the mouth and nose with simple spirometry.
5. Arterial Blood Gases (ABGs): An arterial blood gas is an invasive method of obtaining information about the patient's  $PO_2$ ,  $PCO_2$  and oxygen saturation at a given point in time. The ABG results can be used for correlation with other monitoring devices.

## G. Removing the PMV

Remove the PMV from the ventilator circuit and replace with the set-up being used prior to PMV placement. After the PMV is removed and the original ventilator tubing is put into place, all ventilator settings should be returned to levels they were prior to PMV placement and then the tracheostomy tube cuff (if present) should be reinflated. Do not inflate the tracheostomy tube cuff until ventilator settings are returned to previous levels. The PIP, after removing the PMV, should be the same as it was before placing the PMV.

## XII. Weaning and Decannulation

- A. Ventilator Weaning:** The PMV has proven to be a useful, augmentative weaning tool, providing a positive transition step for patients to expedite their pulmonary rehabilitation process both psychologically and physiologically.

Frey and Wood (1991) reported improved oxygen saturations and greater tolerance for weaning attempts, eventually leading to independent breathing, through use of the PMV.

Utilization of the PMV provides several benefits that augment weaning. The following are specific issues related to weaning and use of the PMV:

1. Physiologic PEEP: Back pressure that is provided when a patient exhales against the upper airway structures. This back pressure assists in maintaining alveolar patency.
  - a. Oxygenation: can improve as a result of the alveolar recruitment that occurs with the restoration of physiologic PEEP.

- b. **Mechanical PEEP requirements:** physiologic PEEP may allow the mechanical PEEP provided via the ventilator to be reduced. The amount of physiologic PEEP generated through use of the PMV will vary from patient to patient depending on their own physical needs.
  - c. **Atelectasis:** back pressure achieved with use of the PMV can facilitate maintenance of airway patency which may help to prevent and reverse atelectasis.
2. **Effective Cough:** The ability to create subglottic pressure provides the opportunity for a stronger cough and more effective expectoration of secretions. It also facilitates improved clearance of lower lung lobe secretions that cannot be suctioned. This facilitates pulmonary hygiene and reduces the potential for complications caused by retained secretions (e.g. infection, atelectasis and mucus plugging). Reducing such complications allows weaning to progress more rapidly.
  3. **Psychological Enhancement:** Psychological well-being should never be overlooked as a weaning issue because a patient's ability to wean may be significantly impacted by depression, anxiety and/or fear.
    - a. **Communication and Socialization:** PMV use can facilitate improved patient/staff interaction, as well as expedite care and encourage patient participation in the rehabilitation process. Terminal patients can have the opportunity to address important personal issues as well as direct their care.

By facilitating the ability to communicate, PMV use can positively impact emotional status, feelings of well-being and family interaction. In addition, with the ability to verbally communicate, patients suffering from extreme depression can better utilize psychological counseling.

- b. **Patient Confidence Building:** The ability to communicate and utilize the upper airway can help to build patient confidence in their ability to wean.
  - c. **Motivation and Independence:** Patient motivation plays an important role in the weaning process. The PMV provides patients with the opportunity to interact with others and to actively participate and direct their care. This in turn can assist in patient motivation and independence. In addition, for those patients who will not be able to wean from the ventilator, PMV use provides the opportunity for verbal communication which can facilitate a dramatic improvement in their quality of life.
4. **Vocalization and Muscle Retraining:** Vocalization is a volitional process which incorporates the use of musculature that remains passive in the absence of voice. PMV use promotes utilization of these muscles, building strength and stamina for both vocalization and weaning efforts.
  5. **Improved Assessment Capabilities:** Airway patency and pulmonary stability can be more readily assessed with PMV use as successful restoration of the normal exhalation process is an indicator of a patent airway and stable pulmonary status.

**B. Decannulation:** Physicians utilize different methods to achieve decannulation. The PMV offers a transitioning tool to help assist patients and their physicians in the decannulation process. The following are specific reasons why use of the PMV can save time in the decannulation of tracheostomized patients:

1. Reduces Decannulation Time: According to R.W. Light, et al. (1989), the median time for decannulation was reduced to 18 days with the PMV as compared to 23 days with standard capping. It was also reported that patient comfort was greater with the PMV.

Utilization of the PMV reintroduces exhalation through the oronasopharynx while allowing inhalation via the tracheostomy tube. PMV use also provides patients with the ability to access upper airway functions such as expectoration, swallowing and speech.

2. Easier to Tolerate than Capping or Plugging: Long before a cap or plug can be tolerated, the PMV can be used to gain access to the upper airway during exhalation. The work of breathing around the tube during inhalation and exhalation can be substantially harder to tolerate with a plugged tracheostomy tube because of the size of the tube and upper airway resistance. The work of breathing can be reduced by use of a PMV as it allows the patient to inhale through the tracheostomy tube and passively exhale through the upper airway.
3. Airway Patency Assessment: PMV use can assist in airway patency assessment as airflow is reintroduced through the oronasopharynx during the exhalation cycle. Thus, exhaled flows and volumes can once again be measured orally.
4. Builds Patient Confidence and Reduces Anxiety: Patient confidence builds as exhalation is felt and tolerated. The patient is reoriented to the upper airway functions of voice/speech, secretion management/expectoration, and a more normal swallowing process. Anxiety in response to decannulation can be reduced dramatically if the PMV is incorporated as soon as possible after the tracheotomy procedure.
5. Vocal Cord Stimulation: Patients and clinicians report PMV use can assist in the assessment and restimulation of vocal cord function due to the return of airflow through the larynx. Valve use may also help improve any temporary dysfunction that is the result of vocal cord atrophy or damage from the original intubation.
6. Airway Pressure Support: Through use of the PMV, the intratracheal airway pressures generated and the reestablishment of upper airway usage help provide support for patients with tracheomalacia. In addition, patients regain glottal control and thus atelectasis may be reduced or prevented due to the back pressure created when the glottis is closed.

### **XIII. Pediatric Application**

**The aforementioned specifics of the adult application of the PMV apply to pediatric assessment and usage of the PMV with the following additional considerations:**

- A. **Reaction time**: It is important to remember that the physical reactions of pediatric patients are generally much quicker and more dramatic than adult tracheostomized or ventilator dependent patients. Even slight changes in treatment (even those assessed to have a known positive impact) may initially cause an instant compromising pulmonary reaction in the child. The understanding that children can “crash” quickly means there is less response time when working with children than there is when working with adults. This means that when putting a PMV on a pediatric patient, careful assessment of patient

history, medical stability, upper airway patency, tendency to air trap, behavioral issues, motivation and patient preparation is important. Even on complex, multiple diagnosed children, the PMV can potentially be utilized if the health care team is properly prepared and has prepared the patient and caregivers.

- B. Airway Obstruction:** There is a higher incidence of airway obstruction in children than in adults. Therefore, it is important to assess for airway patency. Many institutions will perform a bronchoscopy to evaluate airway patency. A less precise, more informal method of evaluating upper airway patency includes: finger occluding the tracheostomy tube for the child using a gloved finger while observing that the patient can exhale through the upper airway, and listening for exhaled breath sounds. Techniques for training children to orally exhale include: blowing bubbles, whistles, feathers, etc. Frequently, the tracheostomy tube will be too large and will need to be sized down one size to allow for improved exhalation. Children undergo bronchoscopy more often than adults and the incidence of tissue edema may be higher; therefore, it may be necessary to wait a few days for the edema to subside before using the PMV. If upper airway obstruction is not an issue and the child's pulmonary status is stable, then working with the child to eliminate anxiety and overcome behavioral issues is important and should be addressed. This may take some time. Successful transitioning techniques include play therapy and distraction. Coloring books, whistles and stuffed animals/dolls with tracheostomy tubes are all playful devices that help the child adjust to the tracheostomy tube and the PMV.

Inasmuch as very young children cannot communicate discomfort, observing them with the PMV to assure they are exhaling completely and are not air trapping is important. If a child is fussing or crying, one should remove the PMV immediately and assess the child to eliminate the possibility of upper airway obstruction or other physiological problems before assuming it is a behavioral reaction.

- C. Psychological Aspects:** Achieving patient cooperation is a significant issue with the pediatric population. Delivery of respiratory therapy interventions provided by a respiratory team requires patient cooperation. The inability of many pediatric patients to cooperate in the same manner as adults poses a challenge to the caregiver charged with delivering medical care. When approached correctly, however, an amazing level of cooperation is possible from infants and children of all ages.

A prerequisite for achieving cooperation is a positive attitude toward the patient. Children are particularly sensitive to detecting hostility or other negative attitudes. Positive communication, genuine warmth, and friendliness are essential. Simple acts such as: brushing a child's hair; rocking an infant; taking a few extra moments to communicate without rushing through a treatment; holding a child for support during procedures and treatments; explaining the use of equipment and procedures carefully and in terms a child can understand, and showing pictures of pilots or astronauts with hoods or mouth pieces and assuring the child that the procedure will make them feel better, are all possible ways to humanize medical intervention with children. Children respond to play names for their tracheostomies and ventilators, as well as the use of tracheostomized dolls or stuffed animals with PMVs. Communication via eye contact and/or touching is also important to help develop trust and a working rapport with children. They may have some awareness of their environment and still need affection and communication.

- D. Power of Communication:** Children begin to communicate from the moment of birth. Language develops in five areas: pragmatics, semantics, syntax, morphology, and phonology. Research has confirmed that there are no longer “prerequisites” to communication. Life is communication. Communication is an innate component of every human being who interacts with his or her environment. It is also evident, from the communication research of the 1970's and 1980's that speech and language development is interactive and interdependent on cognitive and motoric development. When one major area is affected, it directly affects development in the other areas.

Several components of communication, including eye gaze and social communication, are fully developed and in place by the time a child is 18-24 months old. The interactions that take place between caregivers and children to facilitate these processes begin at birth, with some complete by three months of age. Thus, it becomes extremely important to address communication via a speaking valve or if a vocal option is not appropriate, an augmentative communication system, as early as possible to avoid speech, language, and social developmental delays. A child's communicative development has a direct impact on later academic and social development.

- E. Behavioral Considerations:** Pediatric patients will demonstrate several challenges to the treatment team that are unique to age. These children are unfamiliar with the normal exhalation process and require additional “show and tell” to comprehend physically how to manage the use of a PMV with their tracheostomy or ventilator. Continual chin dropping affects the air flow and use of the PMV. Popping the PMV off for attention and treating it as a foreign item are additional problems that may also arise. The list of such unique behavioral issues continues to grow as the population of tracheostomized and ventilator dependent children increases.

Pediatric patients require either direct or indirect education concerning secretion management. They frequently require constant suctioning and may transition to normal secretion control and less frequent suctioning as respiratory and communication options are attempted. Research has shown that one of the remarkable benefits of using the PMV (aside from the result of speech) with adults and pediatric tracheostomized patients is the decrease in secretions and improved secretion management. An additional benefit is the protection from foreign particles such as bugs and dust that can infiltrate an open tracheostomy system.

## **XIV. Psychosocial Issues**

### **A. Importance of Communication**

The tracheostomy and/or ventilator dependent patient is extremely affected by loss of control over almost everything in his/her life; attributable to the fact that the very essence of life, breathing, is controlled by a tracheostomy and/or a ventilator. When the patient is intubated or tracheostomized and ventilator dependent, he/she has lost control, self esteem, independence, and the ability to express his/her personality. The very “person” of the patient is threatened. Expression, participation and control are as important to a patient as medications, physical therapy, and breathing treatments. They should not and need not be exclusive of each other.

Medicine is coming full circle as we refocus on birthing rooms with family in attendance, family care physicians, hospice and home care. We are returning to caring for the “person” rather than the “patient”. This can now extend into the most high tech environment, the Intensive Care Unit (ICU).

The ICU may be the most significant environment in which we can assist the patient by restoring some of the “person”. The ICU is the most controlled environment in the hospital and when the patient’s health is most critically compromised. It is paramount that this patient be able to express his needs and desires. It is necessary that a patient be able to ask for medication, nutrition and hygiene assistance as well as participate in the most significant decisions involving direction of care, life support, consent for treatment, and if the patient is dying, closure issues.

When the patient is medically stable and is attempting to communicate, it is the responsibility of each caregiver to assist in the appropriate intervention to ensure a method of communication for the patient. Whether in the ICU or home care setting, the patient’s personality and rights are compromised without an effective way to communicate.

Legal mandates and professional guidelines are now incorporating the issues of communication into their policies. However as we focus more on the quality of care and outcome issues for patients, we are also compelled by compassionate and ethical reasons to advocate communication for this patient population. It isn’t enough to save a life, we must also strive to restore quality. This cannot be done without ensuring the patient’s control and participation through his own expression.

Sometimes in medicine, recovery and cure are not possible and especially in these circumstances, communication is critical. Dr. Trudeau, a pioneer in tuberculosis treatment and research and the founder of what is today the American Thoracic Society, when discussing the role of the health care professional and patient care, quoted an old French saying that translates:

“to cure sometimes, to relieve often, to comfort always.”

As a health care professional one cannot always cure or relieve but there is always the opportunity to comfort and improve the quality of life for each patient. Even if it is only in the last few hours or minutes of life, if a patient is able to communicate his/her “I Love You’s” and “Good-byes”, it is immensely important to the patient and his/her loved ones. Giving comfort, dignity, and independence to a patient may be, in the end, all we have to give and may be the most important gift of all for the patient and his/her family.

According to the Bergbaum-Engberg and Haljamäe study (1989) “Assessment of Patients’ Experience of Discomforts During Respirator Therapy”, the need for communication was the main instigator for feelings of anxiety and fear during mechanical ventilation (occurring in 47% of patients studied). The isolation due to communication difficulties was a greater problem than direct airway related nursing care activities. Isolation, fear, panic, anxiety, anger, depression, loss of control and self esteem are issues for the adult and pediatric ventilator dependent patient alike. It is critical to the outcome of the patient that the medical team address the patient’s needs and right to communicate as diligently as they address the medical issues. The ability to communicate allows the patient participation and control in his/her medical care. The patient is, after all, the most significant team member. The treatment plan becomes more difficult to implement and

successful outcome more challenging if the patient is not able to communicate valuable information to the team as to his/her responses to therapy, need for changes in medications, emotional issues, etc.

Essential to quality of care is quality of life. Without communication the patient's quality of life is severely compromised. We must make communication a standard of care.

## B. Legal Mandates

The following are the 1995 Joint Commission on Accreditation of Health Care Organization (JCAHO) Guidelines involving communication needs for patients. Hospitals must ensure an adequate level of communication for all patients and have a procedure in place which documents that every patient can communicate at an adequate level. This requirement supports the need for a speech-language pathologist as a team member even in the initial stages of hospitalization. This would indicate that, even if a patient were terminal or death is imminent, communication must be addressed to insure the patient has the opportunity to ask questions, give consent and control the direction of his/her medical care. The speech-language pathologist, working with the respiratory and nursing team members, can establish some level of communication and increase the level as appropriate.

1. JCAHO GUIDELINES, 1995 STANDARDS as referred to in M. Spemulli's (1995) "Informed Consent and Communicative Competency," article in *Advance for SLPs*.
  - RI.1.3 Mechanisms that provide for consideration of the patients' other needs;
    - RI.1.3.1 Confidentiality of information;
    - RI.1.3.2 Privacy and security;
    - RI.1.3.3 Communication needs; and
    - RI.1.3.4 Resolution of complaints
2. TITLE 22 § 70707. PATIENTS' RIGHTS.

**Patients' rights are mandated nationally. The following is a list of patient's rights required by Title 22. Several of these "rights" require an adequate level of communication to be achieved with appropriate intervention (e.g. speech-language pathologist consult).**

Hospitals and medical staffs adopt a written policy on patients' rights. A list of these patients' rights shall be posted in both Spanish and English in appropriate places within the hospital so that such rights may be read by patients. This list shall include but not be limited to the patients' rights to:

- a. Exercise these rights without regard to sex or cultural, economic, educational, or religious background or the source of payment for care.
- b. Considerate and respectful care.

- c. Knowledge of the name of the physician who has primary responsibility for coordinating the care and the names and professional relationships of other physicians and non-physicians who will see the patient.
- d. Receive information about the illness, the course of treatment and prospects for recovery in terms that the patient can understand.**
- e. Receive as much information about any proposed treatment or procedure as the patient may need in order to give informed consent or to refuse this course of treatment. Except in emergencies, this information shall include a description of the procedure or treatment, the medically significant risks involved in this treatment, alternate courses of treatment or nontreatment and the risks involved in each and to know the name of the person who will carry out the procedure or treatment.**
- f. Participate actively in decisions regarding medical care. To the extent permitted by law, this includes the right to refuse treatment.**
- g. Full consideration of privacy concerning the medical care program. Case discussion, consultation, examination and treatment are confidential and should be conducted discreetly. The patient has the right to be advised as to the reason for the presence of any individual.
- h. Confidential treatment of all communications and records pertaining to the care and the stay in the hospital. Written permission shall be obtained before the medical records can be made available to anyone not directly concerned with the care.
- i. Reasonable responses to any reasonable requests made for service.**
- j. Leave the hospital even against the advice of physicians.
- k. Reasonable continuity of care and to know in advance the time and location of appointment as well as the identity of persons providing the care.
- l. Be advised if hospital/personal physician proposes to engage in or perform human experimentation affecting care or treatment. The patient has the right to refuse to participate in such research projects.**
- m. Be informed of continuing health care requirements following discharge from the hospital.
- n. Examine and receive an explanation of the bill regardless of source of payment.
- o. Know which hospital rules and policies apply to the patient's conduct while a patient.
- p. Have all patients' rights apply to the person who may have legal responsibility to make decisions regarding medical care on behalf of the patient.
- q. Procedure shall be established whereby patient complaints are forwarded to the hospital administration for appropriate response.
- r. All hospital personnel shall observe these patients' rights.

## **XV. Care and Lifetime of the Passy-Muir Tracheostomy and Ventilator Speaking Valves and Accessories**

The PMVs are packaged in single units. Ideally, the patient should have an additional PMV to serve as a back-up so that one can be worn while the other is in a cleaning cycle. The PMV, PMV Secure-It™ and PMV O<sub>2</sub> Adapter should be cleaned daily after wearing.

### **A. Cleaning Procedure:**

The following cleaning instructions apply to the PMV, PMV Secure-It™ and PMV O<sub>2</sub> Adapter. Each part should be cleaned individually.

- Swish each item in pure, fragrance-free soap and warm (not hot) water. Rinse thoroughly with warm water. Allow to air dry thoroughly before placing in the storage container. Do not apply heat to dry the PMV, PMV Secure-It™ or PMV O<sub>2</sub> Adapter.
- DO NOT use hot water, peroxide, bleach, vinegar, alcohol, brushes or Q-tips to clean the PMV, PMV Secure-It™ or PMV O<sub>2</sub> Adapter. Do not autoclave.

### **B. Lifetime of the PMV:**

Each PMV is guaranteed to last a minimum of two months. Lifetime cannot be guaranteed if cleaned or used improperly. Due to conditions of use and maintenance beyond the control of the manufacturer, if the PMV should become sticky, noisy or vibrate prior to or after two months, the PMV should be replaced. The PMV can continue to be used as long as it does not exhibit stickiness, noise, vibration, increased resistance on inspiration, or any other difficulties.

## **XVI. Cost Effectiveness & Reimbursement**

The benefits of PMV use which were previously discussed (Section VI) can contribute significantly to cost effective treatment for tracheostomized and ventilator dependent patients. Use of the PMV can expedite staff/patient communication, facilitate improved infection control, reduce suctioning needs, improve swallowing and reduce ventilator weaning and decannulation time. As a result, the costs involved in these areas of patient care can be reduced.

The PMVs are prescription devices that can be purchased through patient care facilities, physicians and durable medical equipment companies. They are sold in single units and are Medicare and Medicaid reimbursable utilizing the HCPCS Prosthetic Code: L8501. They should be billed as communication prosthetic devices. The PMVs are also reimbursable by California Children's Services using the following code: #7549. MediCal also reimburses for the PMVs by using Misc. Supply Code #9981K with modifier ZZ (include copy of invoice with re-order number). If there are any questions regarding third party reimbursement of the PMVs, please contact our clinical specialists at (800) 634-5397.

## XVII. Program Development

- A. Tracheostomy Team:** A tracheostomy team serves to ensure continuity of care to patients with a tracheostomy (on or off a ventilator) and to increase the quality of the care delivered throughout the entire institution. It increases collaboration among disciplines with the physician and enhances discharge teaching and discharge planning efforts. Specific team functions will vary according to setting however could include: policy formation, identifying resource persons for other staff, providing a forum for questions on care of tracheostomized patients, setting standards of care and development of critical pathways, setting up Tracheostomized/Ventilator Patient Rounds, and even increasing the appropriate use of devices such as the PMV, artificial noses, etc.
- B. Marketing of the PMV:** Introducing and developing a tracheostomy and ventilator program at a facility can be greatly enhanced by incorporating use of the PMV. The cost effectiveness of this device (e.g. speech, improved swallow, reduced secretions, reduced weaning and decannulation time), its ease of use, its positive impact on patient care and on patient recovery and psychological well-being has made it a vital component in most every progressive tracheostomy and ventilator program nationwide. Please contact our clinical specialists at (800) 634-5397 if you would like additional information on program development and the PMV.

**XVIII. Manufacturers Resource List**

The following are companies that manufacture respiratory accessory items that can be used in conjunction with the Passy-Muir Tracheostomy and Ventilator Speaking Valves.

**BALLARD MEDICAL PRODUCTS**  
12050 South Lone Peak Parkway  
Draper, UT 84020  
P (801) 572-6800  
F (801) 572-6999  
www.bmed.com

- 15mm O.D. x 22mm I.D. Artificial Nose Adapters (prod. # 112)  
*(Can be used to attach the PMV to the Ballard T-piece type suction catheter)*
- Closed Tracheal Suction Systems

**CARDINAL HEALTH**  
1660 Iowa Ave., Suite 100  
Riverside, CA 92507  
P (800) 321-3832  
F (909) 686-7967  
www.cardinal-health.com

- Omniflex Connectors  
*(A flexible adapter similar in function to a swivel adapter)*  
(Prod. # 3222 - Adult)  
(Prod. # 3215 - Pediatric)

**MALLINCKRODT, INC.**  
(Nellcor Puritan Bennett)  
P.O. Box 5840  
St. Louis, MO 63134  
P (314) 654-2000  
F (888) 222-9799  
www.mallinckrodt.com

- Ribbed flex tubes (Prod # 4-000057-00)  
*(Rubber, flexible, non-disposable ventilator tubing for use with the PMV 005 (White), PMV 2000 (Clear) and PMV 2001 (Purple) speaking valves in-line during mechanical ventilation)*
- Tracheostomy Tubes

**PILLING WECK**  
2917 Weck Drive  
Research Triangle Park, NC 27701  
P (800) 234-9325  
F (800) 932-5329  
www.pillingweck.com

- Metal tracheostomy tubes

**PORTEX (BIVONA)**  
10 Bowman Drive  
Keene, NH 03431-0724  
P (800) 258-5361  
F (603) 352-3703

- 15mm Endotracheal Tube Connectors  
*(An adapter that may be used to create a 15mm hub allowing for PMV use on tracheostomy tubes without a 15mm hub)*

5700 West 23rd Avenue\*  
Gary, IN 46406, USA\*  
P (800) 348-6064\*  
F (219) 989-7435\*  
www.portex.com

- In-line Suction Catheters
- Tracheostomy Tubes
- Trach Wedges  
*(The disconnect wedge is designed to remove items from the hub of a tracheostomy tube)*
- Custom Tracheostomy Tubes\*

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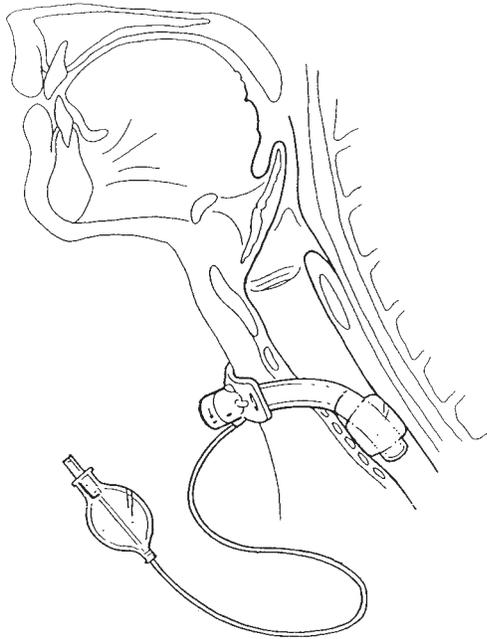
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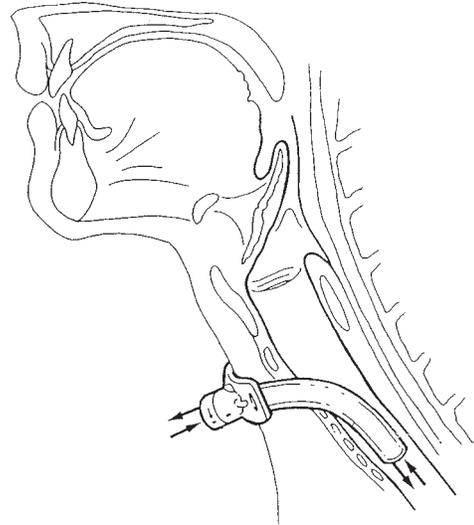
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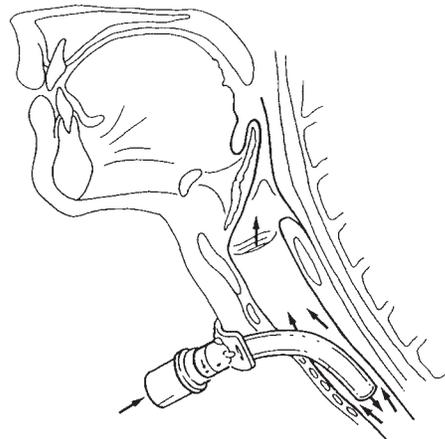
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**XX. RESOURCE FORMS****Cuffed Tracheostomy Tube**

With the cuff inflated, inspiratory and expiratory air flow will only travel in and out of the tracheostomy tube. Exhaled airflow is prevented from exiting the upper airway due to presence of the cuff.

**Uncuffed Tracheostomy Tube**

Inspired and expired airflow predominately occurs through the tracheostomy tube following the path of least resistance; however, some air may leak around the tracheostomy tube and up through the upper airway.



**Uncuffed Tracheostomy Tube with  
Passy-Muir Closed Position "No Leak"  
Speaking Valve (PMV)**

The PMV opens with less than .05cm H<sub>2</sub>O during inspiration. Air is directed through the tracheostomy tube and to the lungs. At the end of inspiration, the PMV returns to its naturally closed position and exhaled air is redirected through the upper airway passing the vocal cords and exiting the mouth and nose allowing the patient to speak.



Ventilator Mode	Ventilator Settings	Ventilator Weaning															
Control _____ A/C _____ IMV _____ SIMV _____ CPAP _____ PS _____ Other _____  Type of ventilator _____  Date artificial ventilation initiated _____	Tidal Volume _____ Rate _____ PEEP _____ F <sub>I</sub> O <sub>2</sub> _____ Other _____  Spontaneous Ventilation Date _____ VT _____ RR _____	Method: SIMV _____ T-piece _____ CPAP _____ Other _____ PS _____  Dates _____  Spontaneous Weaning Parameters VT _____ VC _____ MV _____ RR _____ NIF _____  Length of weaning trial _____  Tolerance of weaning _____															
Nutritional Status		Swallowing Status															
<u>Mode of Intake</u>  NPO _____ Oral (Diet Level) _____ Food Consistency _____ N-G Tube _____ PEG _____ G-Tube _____ J-Tube _____ Parenteral _____ Restrictions _____ Comments: _____		Tolerates secretions (oral/pharyngeal)    yes    no Tolerate current diet                            yes    no History of aspiration                            yes    no History of reflux problems                    yes    no  <p style="text-align: center;"><u>Swallowing Assessments Performed</u></p> <table style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:60%;"></th> <th style="width:20%;">Date</th> <th style="width:20%;">Results</th> </tr> </thead> <tbody> <tr> <td>Blue Dye Test</td> <td>_____</td> <td>_____</td> </tr> <tr> <td>Videofluoroscopy</td> <td>_____</td> <td>_____</td> </tr> <tr> <td>FEES</td> <td>_____</td> <td>_____</td> </tr> <tr> <td>Scintigraphy</td> <td>_____</td> <td>_____</td> </tr> </tbody> </table>		Date	Results	Blue Dye Test	_____	_____	Videofluoroscopy	_____	_____	FEES	_____	_____	Scintigraphy	_____	_____
	Date	Results															
Blue Dye Test	_____	_____															
Videofluoroscopy	_____	_____															
FEES	_____	_____															
Scintigraphy	_____	_____															
Cognitive-Communication Status (please circle):																	
Alertness	<i>Not Observed</i>	<i>Inconsistent</i>															
Orientation	<i>Not Observed</i>	<i>Inconsistent</i>															
Attempts to communicate	<i>Not Observed</i>	<i>Inconsistent</i>															
Following simple commands	<i>Not Observed</i>	<i>Inconsistent</i>															
RLAH Level _____																	
Current mode of communication uses	non-vocal (type) _____ requires assistance? Yes No	vocal (type) _____ requires assistance? Yes No															
Comments: _____																	
Oral Motor/Vocal Status (please circle):																	
Oral Motor Strength/Coordination	<i>Nonfunctional</i>	<i>Inconsistent</i>															
Phonation with cuff deflation	<i>Nonfunctional</i>	<i>Inconsistent</i>															
Phonation with finger occlusion	<i>Nonfunctional</i>	<i>Inconsistent</i>															
Comments: _____																	
Positioning Status/Precautions																	
Tolerates sitting up in bed	yes _____ no _____	How long? _____ How far? _____															
Comments: _____																	
Tolerates sitting in chair	yes _____ no _____	How long? _____ How far? _____															
Comments: _____																	
Is head control *WFL?	yes _____ no _____	Comments: _____															
Is trunk control WFL?	yes _____ no _____	Comments: _____															

\*within Functional Limits

**III. PMV PLACEMENT DATA**

Date	Time of Day	O <sub>2</sub> SAT			Respirations/min			Heart Rate (hi/low)			Breath Sounds		
		Before	During	After	Before	During	After	Before	During	After	Before	During	After

Coughing (amount)	Secretions (amount)	Anxiety (describe)

Vocal Intensity 0 1 2 3 4 5	Speech Intelligibility 0 1 2 3 4 5	Vocal Quality 0 1 2 3 4 5

0 = aphonic, 5 = WNL

**IV. EVALUATION SUMMARY**

**Summary of Results** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Follow-up Recommendations (circle all that apply and describe reason for recommendations):**

- Bronchoscopy \_\_\_\_\_
- Laryngoscopy \_\_\_\_\_
- Tracheostomy Tube Downsizing \_\_\_\_\_
- Follow-up Chest X-Ray \_\_\_\_\_
- ABGs \_\_\_\_\_
- Swallowing Evaluation \_\_\_\_\_
- Cognitive Evaluation \_\_\_\_\_
- Passy-Muir Valve \_\_\_\_\_
- Tracheostomy Tube Plugging \_\_\_\_\_
- Other Vocal Communication Device \_\_\_\_\_
- Non-Vocal Communication Device \_\_\_\_\_
- Other \_\_\_\_\_

**Treatment Plan:** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Patient Observations/Patient Comments (re: Assessment): \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

	Signature	Date
Team Members:	_____	_____
(e.g. RT, SLP, OT, PT, MD)	_____	_____
	_____	_____
	_____	_____
Patient:	_____	_____



**David A. Muir**

Inventor of the Passy-Muir  
Tracheostomy Speaking Valve  
December 6, 1961 - August 30, 1990

*I was diagnosed with muscular dystrophy at age five. Over the years I gradually weakened and became a quadriplegic. I was 23 and studying biochemical engineering in college when I had a respiratory arrest and became ventilator dependent. I had accepted the other difficulties of my disease. However, when I realized I could not talk, I wanted to give up. Then I realized I was not ready yet. I said to myself, 'Wait a minute, you've never given up this easily before and you're not going to this time. There has to be a way around this problem.' These thoughts became my theme for three agonizing months while I was working on my design for the speaking valve.*

*As corny as it sounds, every rain cloud has a silver lining, this is absolutely true. Ask me, I know first hand.*

*It has been very rewarding to know my valve has helped to improve the quality of life for so many people."*

David A. Muir  
January 1990

*We at Passy-Muir Inc. believe that communication is the essence of the human spirit, it is essential to individual rights and dignity. We are committed in our efforts to offer tracheostomized and ventilator dependent patients a step toward independence and dignity through speech.*

Patricia E. Passy  
President

## **Passy-Muir Educational and Clinical Support**

- Free Clinical Video, Research Literature and Benefits CD available upon request at (800) 634-5397.
- Respiratory and Speech Clinical Specialists at Passy-Muir are available to assist you by phone or email (see below) with clinical assessment, treatment questions and technical support.
- National Educational Consultants are available to provide Passy-Muir Inservices at your facility.
- Visit our website for updated information and Online Continuing Education (CEU) courses:
  - **website:** [www.passy-muir.com](http://www.passy-muir.com)
  - **e-mail:** [info@passy-muir.com](mailto:info@passy-muir.com)



*Passy-Muir Inc.*

Passy-Muir Tracheostomy & Ventilator Speaking Valves

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