Passy-Muir Inc.

Clinical Inservice Outline

Passy-Muir Tracheostomy & Ventilator Speaking Valves **Clinical Inservice Outline**

I. Inventor, David Muir

- Α. 23 year-old ventilator dependent quadriplegic due to Muscular Dystrophy
- Developed PMV with help of his father
- C. David passed away in August 1990

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

- Closed position "no leak" patented design Α.
- B. The only speaking valves indicated for all of the following uses:
 - Communication
 - Ventilator Application*
 - Improved Oxvgenation
 - Decannulation & Weaning
- Improved Swallow/May Reduce Aspiration
- Facilitates Secretion Management Improved Olfaction

 - Restored Positive Airway Pressure
- Interchangeable between Tracheostomy and Ventilator Use*
- *The PMV 2020 (Clear) is for use on metal tracheostomy tubes (Pilling Weck metal Jackson Improved tracheostomy tubes sizes 4-6 or equivalent) and is not designed for in-line ventilator use.
- C. Small, lightweight and fit the universal 15mm hub of any size tracheostomy tube
- D. Safe to use with infants & adults from acute care to homecare
- E. Meet International Standards Organization (ISO) Standard
- F. Contain no latex.

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

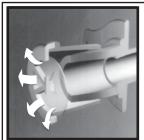
- PMV 005 (White) 15mm I.D./23mm O.D.
 - 1. Original low profile PMV
 - 2. Can be used on or off the ventilator
 - 3. Can be used in-line with flexible, rubber, non-disposable ventilator tubing
- B. PMV 007 (Agua) 15mm I.D./22mm O.D.
 - 1. Designed to fit in-line with standard, plastic, disposable ventilator tubing and adapters
 - 2. Can be used on or off the ventilator
- C. PMV 2000 (Clear) 15mm I.D./23mm O.D.
 - 1. Lower profile, lighter weight and smaller in size than the PMV 005
 - 2. Clear, less visible
 - 3. Opens easier upon inspiration than the PMV 005 or PMV 007
 - 4. Can be used in-line with flexible, rubber, non-disposable ventilator tubing
 - 5. Design includes a small ring built into the PMV that allows the PMV Secure-It™ to attach from the PMV to the trach tie to prevent valve loss
 - 6. Can be used with the PMA 2000 (O₂ adapter)
- D. PMV 2001 (Purple) 15mm I.D./23mm O.D.
 - 1. Identical to PMV 2000 except for color
 - 2. Bright purple color to facilitate staff awareness
- E. PMV 2020 (Clear) Tracheostomy Speaking Valve
 - 1. For use with the Pilling Weck metal Jackson Improved tracheostomy tubes sizes 4-6 or equivalent when utilizing the PMA 2020-S Adapter.
 - 2. Can be used on the Bivona (non-foam filled cuffed) tracheostomy tubes currently on the market without use of the PMA 2020-S Adapter.

- 4. Low profile design
- 5. Not designed for in-line ventilator use
- 6. Cannot be used with the PMA 2000 Oxygen Adapter
- F. PMV Secure-It[™] (Clear)
 - 1. Packaged for use with the PMV 2000, PMV 2001 and PMV 2020 Speaking Valves only
 - 2. Attaches the PMV to the tracheostomy tube tie to prevent valve loss
 - 3. Available separately for purchase (sets of five)
- G. PMA 2000 (O₂ adapter) (Clear)
 - 1. Small, lightweight, sold separately
 - 2. Allows for delivery of low flow supplemental oxygen up to 6 L/min.
 - 3. Snaps onto the PMV 2000 and PMV 2001 only
 - 4. O₂ flow delivered in front of the intake side of the PMV
 - 5. Allows for improved mobility
 - 6. Can be used with bubble humidifier
 - 7. Can only be used with the PMV 2000 and PMV 2001
- H. PMV Patient Care Kit (Color coded for easy PMV identification)
 - 1. Facilitates proper use and maintenance of PMV and continuity of patient care.
 - 2. Each PMV Patient Care Kit is a ziplock pouch containing:
 - One PMV
 - PMV Storage Container small plastic cup for storage of clean PMV
 - Instruction Booklet clinician's guide to use of the PMV
 - Chart Warning Labels adhesive labels for use in the patient's medical chart
 - Bedside Label durable, nonadhesive label to be placed near PMV user*
 - Pilot Balloon Labels warning labels for cuffed tracheostomy tube
 - Patient Parameters Chart Label adhesive label for use in patient's chart or care plan*
 - Patient Handbook comprehensive instruction booklet designed for patient, family and caregivers. This handbook is an excellent teaching tool useful for meeting JCAHO requirements.*
 - PMV Secure-It[™] packaged with the PMV 2000 Series Valves only. Clear, rubber attachment that connects the PMV to the tracheostomy tube tie to prevent valve loss.
 - PMA 2020-S Adapter included with the PMV 2020 Speaking Valve only
 - *except PMV 2020 Patient Care Kit

IV. David Muir's Closed Position "No Leak" (Positive Closure) Design

- A. Only the PMVs have this patented design
- B. Opens only during inspiration with minimal, less than .05cm H_aO pressure
- C. Closes automatically before the end of the inspiratory cycle/beginning of the expiratory cycle. Air is exhaled through the oronasopharynx.
- D. No air leakage occurs through the PMV during exhalation
- E. A column of air is trapped in the PMV and in the tracheostomy tube that inhibits secretions from entering the tube and occluding the PMV
- F. Restores a more normal "closed respiratory system" resulting in many clinical benefits (see Section VI)
- G. Safe to use with tracheostomized and ventilator dependent patients of all ages (birth to geriatrics) Note: the PMV 2020 is not designed for use in-line with the ventilator
- H. Cost effective (see Section XIV)

V. Differences Between Closed Position "No Leak" (Positive Closure) PMVs and Open Position Valves



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





PMV Closed Position "No Leak" Design
(1) PMVs Close Completely At End Of Inhalation With No Air Leak,
Thereby Providing A Closed Respiratory System And More Normal
Breathing Pattern (2) 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

- A. Air leak occurs with open position valves
- B. Respiratory system is open (not closed), thus not providing clinical benefits available with closed position "no leak" valve design
- C. Open system creates a potential for secretions to move through the tracheostomy tube and occlude an open position valve

VI. Clinical Benefits of the Closed Position "No Leak" (Positive Closure) Passy-Muir Valves

- A. Improved Voice/Speech Production (Leder, 1994)
 - 1. Clearer voice with more normal phrasing, better vocal quality and increased volume
 - 2. Finger occlusion is not convenient or hygienic and not as feasible with pediatrics or quadriplegics
 - 3. Allows for clear, uninterrupted phonation and hands-free speech
 - 4. Ventilator dependent patients can produce stronger, louder speech, longer sentences and a more normal speech pattern while using the PMV
- B. Improved Swallow/Reduced Aspiration

(Scott, 1991; Baker, et al., 1994; Snyderman, et al., 1994; Gross, et al., 1994; Eibling and Gross, 1995; Dettlebach, et al., 1995; Stachler, et al., 1996; Eibling D. and Gross R. 1996; Gross, et al., 1997)

- 1. Tracheostomy may cause or exacerbate swallowing problems (dysphagia) and increase risk of aspiration due to:
 - a. Reduced positive subglottic air pressure
 - b. Reduced laryngeal/pharyngeal sensation
 - c. Anchoring of the larynx hindering laryngeal elevation (esp. with inflated trach cuff)
- 2. The PMV closed position "no leak" valve
 - a. Restores a "closed respiratory system"
 - b. Restores positive subglottic air pressure
 - c. Restores laryngeal/pharyngeal sensation
 - d. Reduces the "anchoring" effect of the tracheostomy tube due to the need for cuff deflation
- C. Facilitates Secretion Management

(Lichtman, et al., 1995)

- 1. Stronger more effective cough with oral expectoration and improved swallowing
- 2. Restores airflow through upper airway
 - a. Promotes evaporation of secretions
 - b. Facilitates sensation in oropharyngeal area
- 3. May reduce secretions and suctioning needs by restoring function of the bronchial hygiene system

- D. Restored Positive Airway Pressure
 - 1. Promotes restoration of physiologic Positive End Expiratory Pressure (PEEP)
 - 2. Facilitates increased oxygenation (Frev & Wood, 1991)
 - 3. Stronger cough (Dettelbach, et al., 1995)
 - 4. Improved ability to perform valsalva maneuver
 - 5. Facilitates improved swallow/reduced aspiration (as described previously in Section B)
- E. In-line Ventilator Use and Interchangeability*

(Prentice et al., 1989; Tucker et al., 1991; Manzano et al., 1993; Bell, 1996)

- 1. All PMVs are interchangeable between trach and vent use (with use of appropriate vent tubing)
- 2. Can be used in-line with adult, pediatric and neonatal patients who are non-ventilator dependent, weaning or ventilator dependent
- 3. Can be used with acute care and portable ventilators
- 4. Can be used in conjunction with conventional modes of ventilation

*Note: the PMV 2020 (Clear) is designed for use with the Pilling Weck metal Jackson Improved tracheostomy tubes sizes 4-6 or equivalent and not for in-line ventilator use

F. Expedites Weaning

(Frey and Wood, 1991)

- 1. Augmentative tool for weaning from mechanical ventilation
- 2. Physiological benefits
 - a. Reestablishes physiologic PEEP which in turn may improve oxygenation and may result in reduced atelectasis and lower mechanical PEEP requirements
 - b. More effective cough
 - c. Improves respiratory muscle strength
 - d. Restores a more normal breathing pattern
 - e. Improved assessment capabilities
 - f. Improved secretion management
- 3. Psychological Benefits
 - a. Patient confidence
 - b. Communication and socialization
 - c. Motivation and independence

G. Reduces Decannulation Time

(Light, et al., 1989; Parker, et al 1994)

- 1. Interim step in the decannulation process
- 2. Adjusting to a more normal breathing pattern
- 3. Easier to tolerate than plugging
- 4. Improved ability to assess the airway
- 5. Builds patient confidence
- 6. Vocal cord stimulation due to airflow through the oronasopharynx
- 7. Reestablishes physiologic PEEP which in turn may improve oxygenation and may result in reduced atelectasis

H. Facilitates Infection Control

- 1. Eliminates the need for finger occlusion
- 2. Provides protection from particulates entering the trachea
- 3. Redirects secretions through the upper airway allowing for oral expectoration and reducing contamination of the environment

I. Improved Olfaction

(Lichtman, et al., 1995)

- 1. Improved sense of smell by reestablishing airflow through the oral/nasal cavities
- 2. Improved sense of smell may facilitate improved sense of taste which may increase appetite and caloric intake
- 3. Improved appetite may lead to an improved nutritional status

- J. Facilitates Pediatric Speech/Language Development (Jackson & Albamonte, 1994)
 - 1. Supports normal speech and language development when PMV initiated at an early age
 - 2. Facilitates child/caregiver interactions when child is able to vocalize
 - 3. Can be utilized with children as early as one or two weeks of age

K. Quality of Life

- 1. Ability to regain control through communication
- 2. More normal voice/speech production
- 3. Less conspicuous than finger occlusion
- 4. Improved energy/well-being
- 5. Facilitates more active participation in life activities/socialization

VII. Indications For Use of the Passy-Muir Speaking Valve

- A. All tracheostomy and ventilator dependent patients should be assessed for PMV candidacy
- B. Adult, pediatric and neonatal patients
- C. Indications for use include but are not limited to:
 - 1. Ventilator Dependent Patients
 - 2. Neuromuscular Disease
 - 3. Quadriplegia
 - 4. Head Trauma
 - 5. Chronic Obstructive Pulmonary Disease
 - 6. Tracheomalacia
 - 7. Mild Tracheal and/or Laryngeal Stenosis
 - 8. Bilateral Vocal Cord Paralysis without significant airway obstruction
 - 9. Non-Obstructive Laryngeal Tumors (can include patients who have vocal cord function following surgical resection of the tumor)
 - 10. Sleep Apnea patients who are tracheostomized as an alternative to plugging when awake
 - 11. Patients who emotionally or physically are unable to tolerate tracheal plugging

VIII. Contraindications For Use of the Passy-Muir Speaking Valve

(The following contraindications are discussed in more detail under Section IX Pre-Placement Assessment)

- A. Unconscious and/or Comatose Patients
- B. Inflated Tracheostomy Tube Cuff
- C. Foam-Filled Cuffed Tracheostomy Tube
- D. Severe Airway Obstruction
- E. Unmanageable, Thick Secretions
- F. Severe Risk for Aspiration
- G. Severely Reduced Lung Elasticity
- H. This device is not intended for use with endotracheal tubes or other artificial airways
- I. Do not use during sleep

IX. Pre-Placement Assessment (Guidelines)

- A. Team approach
 - 1. Successful use of the PMV is facilitated by a team approach
 - 2. Each discipline brings to the assessment phase a unique understanding of the issues involved in regards to their area of expertise

B. Patient Assessment

- 1. Cognitive status
 - a. Awake, responsive, attempting to communicate
 - b. Not to be used while sleeping

2. Medical/Pulmonary Status

- a. The patient must have the appropriate lung mechanics to exhale passively around the tracheostomy tube
- b. Ideally, the patient should be medically stable via medications, mechanical ventilation or adjunctive treatment

3. Ability to Tolerate Cuff Delation

- a. Complete cuff deflation is mandatory
- b. Ability to tolerate cuff deflation during mechanical ventilation
- c. Assess swallowing status gross aspiration is contraindicated for PMV use
- d. Foam filled cuffed tracheostomy tube is contraindicated due to potential risk for airway obstruction

4. Secretion Management

- a. PMV can facilitate oral expectoration of secretions
- b. Aspiration may affect amount/consistency of secretions
- c. Humidification issues may affect consistency of secretions
- d. Reevaluate PMV use with secretion changes
- e. Overabundance or very thick secretions may be contraindicated

5. Swallowing Status

- a. Risk for aspiration should be evaluated
- b. PMV provides more normal closed respiratory system, restoring positive subglottic pressure
- c. PMV improves swallowing/may reduce aspiration
- d. Facilitates increased pharyngeal/laryngeal sensation due to restored upper airway airflow
- e. Contraindicated for gross aspiration

6. Airway Patency

- a. Patient should be able to exhale efficiently and completely around the tracheostomy tube and through the upper airway
- b. Check history for diagnosis of airway obstruction (i.e. severe stenosis, granulation growth, traumatic intubation, etc.)
- c. Trach tube should be sized to allow for sufficient airflow around trach tube
- d. Trach tube cuff (even when deflated) may create bulk in the airway causing obstruction to exhaled airflow. Assess for cuffless tube or downsizing.
- e. Bedside assessment for airway patency
 - 1. Deflate trach tube cuff
 - 2. Instruct the patient to inhale through open trach tube
 - 3. Manually finger occlude during exhalation
 - 4. Encourage oral exhalation and voice
 - 5. Some patients may require repeated attempts to become accustomed to exhaling through the upper airway

7. Lung Compliance

- a. Altered compliance due to loss of lung elasticity requires careful assessment to prevent air trapping
- b. Prolonged exhalation potentially causing complications associated with air trapping
- c. PMV use may be limited to short periods of time

8. Level of Care

- a. Evaluation for PMV can occur as early as 48-72 hours post tracheotomy
- b. The PMV can be utilized across the healthcare continuum from the ICU to homecare
- c. Requires a physician order

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

A. Education

- 1. Patient and family
 - a. Reduces anxiety
 - b. Decreases transitioning time
- 2. Staff
 - a. All caregivers on all shifts

B. Patient Bedside Assessment

- 1. Assessment should be performed before, during and after PMV placement
- 2. Assessment should be based on the patient's normal baseline
- 3. Select acceptable patient parameters per physician direction
- 4. Assessment can include but is not limited to:
 - a. Oxygen saturation
 - b. Vital signs HR, RR, etc.
 - c. Breath sounds after PMV placement breath sounds should remain the same as before placement. Breath sounds that are decreased or a prolonged expiratory phase may indicate airway obstruction.
 - d. Color
 - e. Work of breathing
 - f. Patient responsiveness
 - g. Secretion status

C. Positioning

- 1. Position patient comfortably to facilitate diaphragmatic movement and to maintain a patent airway
- 2. Ensure proper position of the trach tube and accessory tubing to help maintain a patent airway

D. Suctioning

- 1. Tracheal suctioning, preferably while deflating the cuff, prior to PMV placement
- 2. Oral suctioning as needed to remove excessive oral secretions
- 3. Occasionally nasal suction may be required, especially for obligate nose breathers (i.e., infants)

E. Cuff Deflation

- 1. Slowly remove all air from the tracheostomy tube cuff
- 2. Cuff deflation often requires a physician's order
- 3. Attach warning label on the pilot balloon of the tracheostomy tube
- 4. Allow patient to adjust to cuff deflation. If the patient experiences a lot of coughing, allow the patient to relax before proceeding to the next step.

F. PMV Attachment (Please see appropriate PMV Instruction Booklet for complete instructions)

- 1. Attach PMV Secure-It™ (optional) to PMV before placing PMV on patient
- 2. If utilizing the PMA 2000 (O2 adapter), attach the PMA 2000 before placing PMV on patient
- 3. Gently stabilize the trach tube
- 4. Attach the PMV to the 15mm hub of the trach tube with a gentle 1/4 twist
- 5. If using the PMV 2020 Speaking Valve, press the PMA 2020-S Adapter onto the hub of the metal tube with the notch positioned underneath the ball lock mechanism. Place the PMV 2020 onto the PMA 2020-S Adapter.
- 6. Friction fit allows for secure connection
- 7. Observe the patient for adequate airflow during exhalation
- 8. Encourage exhalation through the upper airway
- 9. If patient exhibits signs of respiratory distress, remove PMV immediately and reassess for airway patency

G. Connections

- 1. Fenestrated Trach Tubes
 - a. A fenestrated trach tube is not mandatory for PMV use
 - b. If the fenestrated tube is cuffed, the cuff must be completely deflated before placing PMV

2. Inner Cannula

- a. The PMV 005 (White), PMV 007 (Aqua), PMV 2000 (Clear) and PMV 2001 (Purple) fit on the universal 15mm hub of adult, pediatric and neonatal trach tubes
- b. The PMV 2020 (Clear) fits on the 15mm hub of the Bivona non-foam filled cuffed tracheostomy tubes currently on the market without use of the PMA 2020-S Adapter

3. Metal Trach Tubes

- a. The PMV 2020 (Clear) is designed for use on Pilling Weck metal Jackson Improved tracheostomy tubes sizes 4-6 or equivalent in conjunction with the PMA 2020-S Adapter
- b. If the metal tube has an inner cannula with a 15mm hub, the PMV 005 (White), PMV 007 (Aqua), PMV 2000 (Clear) or PMV 2001 (Purple) should be utilized instead of the PMV 2020

4. Oxygen

a. O₂ can be delivered via T-piece, trach collar or PMA 2000 O₂ adapter [the latter can be used only in conjunction with the PMV 2000 (Clear) or the PMV 2001 (Purple)]

5. Humidity

- a. The PMV can be used with nonmedical heated humidity via trach collar or T-piece
- b. Humidification does not affect the function of the PMV
- c. HMEs are low performing when used in conjunctions with the PMV
- d. Do not use PMV with medicated nebulizer treatments

H. Transitioning/Troubleshooting Issues

- 1. Some patients require a gradual transition to wearing the PMV and may first need to use it for short periods of time, gradually increasing use as tolerated
- Fear and anxiety about trying something new may require gradual use of the PMV, reassurance from the clinician, patient education and use of distraction techniques
- 3. Reeducation to breathing through the upper airway
- 4. Increased coughing
 - a. Due to airflow through the upper airway causing movement of secretions
 - b. If patient exhibits prolonged excessive coughing, PMV should be removed and airway patency should be reassessed
- 5. Motivation and control issues
 - a. Depression
 - b. Loss of autonomy
 - c. Anger

6. Troubleshooting

- a. If patient is unable to exhale adequately:
 - Check trach tube cuff to ensure complete deflation
 - Make sure the patient and trach tube are positioned appropriately
 - · Re-suction orally and tracheally as needed
 - For some patients nasal suctioning may be indicated
 - Assess for change to cuffless trach tube if cuff is too bulky
 - Assess trach tube size for possible downsizing
 - Physician assessment for upper airway obstruction
 - Bronchoscopy

I. Removing Valve

- 1. Gently stabilize the tracheostomy tube and remove the PMV with a gentle 1/4 twist
- 2. Remove the PMV Secure-It™, if applicable
- 3. Remove the PMA 2000 (O₂ adapter), if applicable
- 4. If using the PMV 2020 with a metal tracheostomy tube, remove the PMA 2020-S Adapter

XI. Ventilator Application

- A. The benefits of the closed position "no leak" design of the PMVs are maintained during all conventional modes of ventilation as well as during continuous flow, flow-by, PEEP or CPAP
- B. Can be used (with acute care and portable ventilators) in most conventional modes of ventilation
 - 1. A/C (Assist/control)
 - 2. SIMV (Synchronized Intermittent Mandatory Ventilation)
 - 3. Pressure Support
 - 4. CPAP (Continuous Positive Airway Pressure)
 - 5. PEEP (Positive End Expiratory Pressure)
- C. Use of the PMV in-line reduces deadspace as patients are exhaling out through the upper airway versus exhaling back into the ventilator circuit
- D. PMV In-Line Placement
 - 1. Review the PMV Placement (non-ventilator application) Section for the following:
 - a. Education
 - b. Patient Assessment
 - c. Suctioning
 - d. Positioning
 - 2. Ventilator Assessment record all ventilator settings before PMV placement (including but not limited to):
 - a. Mode of ventilation A/C, SIMV, CPAP, etc.
 - b. Tidal volume (V_T)
 - c. Rate mechanical and spontaneous
 - d. Fraction of Inspired Oxygen Content (F₁O₂)
 - 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)
 - 3. Cuff Deflation
 - a. Note Peak Inspiratory Pressure (PIP) before cuff deflation
 - b. Completely deflate trach tube cuff allow the patient time to adjust to the sensation of cuff deflation
 - c. PIPs that drop acutely from their normal range indicate volume loss is occurring through the upper airway during inspiration
 - d. If PIP drops from normal range, increase tidal volume $(V_{\scriptscriptstyle T})$ in small increments to achieve previous PIPs
 - e. If PIPs do not return to pre-cuff deflation levels with V_{T} increases, reinflate the cuff and consider program to strengthen oropharyngeal muscle tone such as gradual cuff deflation or glottal exercises
 - f. DO NOT EXCEED PRE-CUFF DEFLATION PIPs
 - g. No volume adjustments should be needed if PIPs stay within their normal range
 - h. After PMV has been placed, exhaled $V_{\scriptscriptstyle T}$ can be measured with a simple spirometer via the mouth and nose
 - i. Some mechanically ventilated patients may require slow weaning from the cuff
 - i. Reevaluate high and low pressure alarm settings

E. PMV Attachment

- 1. The PMV will attach to the 15mm hub of the tracheostomy tube. The distal end of the PMV is placed inside the ventilator tubing
- 2. Humidification devices
 - a. The PMV can be used with standard non-medicated heated humidity
 - b. Heat Moisture Exchange filters (HME) are low performing when used in conjunction with the PMV

- 3. In-line Suction Systems
 - a. Most of these suctioning systems allow for direct PMV connection to the 15mm side port
 - b. T-piece style in-line suction systems can be used in conjunction with a 15mm x 22mm step down adapter
- 4. Swivel Adapter
- Omniflex
- 6. Disposable Ventilator Tubing
 - a. The PMV 007 is designed to fit readily into disposable ventilator tubing
 - b. Do not use the PMV 005, PMV 2000 or PMV 2001 with disposable ventilator tubing
- 7. Non-Disposable Ventilator Tubing
 - a. The PMV 005, PMV 2000 and PMV 2001 (all 15mm I.D./23mm O.D.) can be utilized in-line with non-disposable, rubber, flexible tubing
 - b. When using the PMV 2000 or PMV 2001 in-line, do not use PMV Secure-It™
- 8. Pediatric Circuitry
 - a. An adapter will be needed to fit the PMV in-line with a pediatric circuit
 - 1. 15mm I.D. X 15mm O.D. rubber adapter, or
 - 2. 15mm X 22mm step down adapter

F. Airway Pressure

- 1. Airway pressure may rise slightly with PMV use but should be within allowable limits for the patient
- 2. If peak pressures rise above the allowable limits, remove PMV immediately
- 3. PEEP requirements may be reduced

G. Ventilator Alarm Settings

- 1. Reevaluate all alarms for appropriate adjustments
- 2. Exhaled volume alarms air is not exhaled via the ventilator circuit and back to the machine, therefore the ventilator will not read any exhaled volumes
- 3. Pressure alarms reassess and adjust pressure alarms to ensure sensitive disconnect and sensitive high pressure alarms

H. F₁O₂

- 1. Due to the effects of physiologic PEEP, the F₁O₂ requirements may be reduced due to increased saturations
- 2. Remove the PMV and reassess the patient if there is significant desaturation or large increases in F_1O_2

I. Monitoring Devices

- 1. Pulse oximetry
- 2. Transcutaneous monitoring
- 3. End tidal CO₂
- 4. Spirometry
- 5. Arterial blood gases (ABG's)

J. Transitioning/Troubleshooting

- Transitioning issues with ventilator dependent patients are the same as those with the tracheostomized patient, however the degree to which they experience them may be much more profound
- 2. Feelings of anxiety are much more intense when a patient is dependent on a ventilator. Education, reassurance and support will help with transitioning
- 3. Severe depression
 - a. Solicitation of family involvement
 - b. PMV will allow patient to communicate their problems to another person
 - c. PMV may help patient to positively interact and regain more control over their life/environment
- 4. Patients unable to tolerate the PMV should be re-evaluated for airway patency to rule out any physical causes of discomfort before determination of any psychological issues are made

- 5. When using of the PMV, the patient exhales through the mouth and nose which may require the use of oral exhalation exercises and education to help them relearn upper airway exhalation
- 6. Increased/excessive airflow through the upper airway is experienced by some patients requiring mechanical ventilation. This may be corrected by a variety of methods such as glottal exercises or ventilator adjustments as per patient assessment, depending upon the reason for the increased airflow.
- 7. Increased coughing is usually due to secretions that have been redirected through the airways because of airflow changes. To help remove these secretions suctioning orally and/or tracheally may be beneficial. However if the patient has persistent coughing or a dry hacking cough, remove the PMV immediately and re-assess for airway patency
- 8. The PMV provides a closed respiratory system restoring certain physiologic functions which enhance the patient's ability to breathe more efficiently. Consequently, the amount of ventilatory support delivered via mechanical ventilation may require adjustments after a thorough assessment has been performed.

K. Removal of Valve

- Remove PMV from ventilator circuit and replace with the setup being used prior to PMV placement
- 2. Return ventilator settings and alarms to their previous levels prior to PMV placement
- 3. Inflate tracheostomy tube cuff, as indicated (Do not inflate tracheostomy tube cuff until ventilator settings are returned to their previous levels)

XII. Pediatric Application

A. Reaction time

Children are much more reactionary physically than adults. Careful assessment of patient history, medical stability, airway patency, tendency for air trapping, behavioral issues, motivation and patient preparation are important.

B. Airway Obstruction

- 1. Children have a higher incidence of airway obstruction, therefore it is important to assess for upper airway patency
 - a. Bronchoscopy is often performed to evaluate airway patency
 - b. Finger occlusion should also be used to assess airway patency
 - c. Techniques such as blowing bubbles, whistles, feather, etc. will help to evaluate and teach children to exhale through the upper airway
 - d. A tracheostomy tube that is too large will also cause an obstruction to the airway
- 2. If a child does not tolerate use of the PMV and it is not due to airway obstruction then working with the child to overcome behavioral issues is important to facilitate PMV use
 - a. Play therapy
 - b. Singing
 - c. Distraction techniques
 - coloring books
 whistles
 stuffed animals

C. Psychological Aspects

- a. Patient cooperation
- b. Positive attitude toward the patient
- c. Positive communication, genuine warmth, and friendliness are essential

D. Power of Communication

- a. Infants begin to communicate from the moment of birth via crying, babbling and cooing which provide them with auditory feedback as well as invites interaction from parents and caregivers
- b. Life is communication
- c. When one major area of development is affected (e.g., speech/language), it directly affects development in other areas (e.g., socialization)
- d. Several components of communication are fully developed and in place by the time a child is 18-24 months old

- E. Behavioral Considerations
 - a. Unfamiliar with the normal exhalation process
 - b. Continual chin dropping
 - c. Popping the valve off
 - d. Direct or indirect education

XIII. Care and Lifetime of the Passy-Muir Tracheostomy and Ventilator Speaking Valves

- A. The PMV is packaged in single units. It is recommended however, that an additional PMV be available so that while one is being cleaned the other can be used. An extra PMV also provides the patient with a back up so if one PMV is lost the patient is not without voice.
- B. Cleaning Procedure for the PMV, PMV Secure-ItTM, PMA 2000 (0₂ Adapter) and PMA 2020-S Adapter: The PMV and accessories should be cleaned daily after wearing
 - Swish PMV and accessories in soapy, warm water (not hot water.) Rinse very thoroughly in warm running water. Allow PMV and accessories to air dry thoroughly before placing in storage container. Do not apply heat to dry PMV.
 - 2. DO NOT use hot water, peroxide, bleach, vinegar, alcohol, brushes or Q-tips to clean PMV or accessories. DO NOT autoclave.
- C. Each PMV is guaranteed to last a minimum of two months
 - 1. Lifetime cannot be guaranteed if cleaned or used improperly
 - 2. If PMV should become sticky, noisy or vibrate prior to or after two months, the PMV should be replaced
 - 3. 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

XIV. Reimbursement & Cost Effectiveness

- A. Medicare, Medicaid and MediCal reimbursable utilizing the HCPCS Prosthetic Code: L8501 communication prosthetic devices
- B. Reimbursable by California Children's Services using the following code: #7549
- C. Expedites staff/patient communication
- D. Facilitates improved infection control by eliminating the need for finger occlusion, which is a common source of patient and environmental contamination
- E. Facilitates secretion management and may reduce suctioning needs and associated costs by restoring function of the bronchial hygiene system (Lichtman, et al., 1995)
- F. Facilitates restoration of swallowing function, thus reducing the risk of aspiration (Dettelbach, et al., 1995; Gross, et al., 1994; Stachler, et al., 1994; Snyderman C. and Eibling D. 1994; Stachler, et al., 1996; Eibling D. and Gross R. 1996; Gross, et al., 1997)
- G. Enhances ventilator weaning strategies by reducing time needed for patients to successfully transition from ventilator dependency thus allowing patients to be transferred earlier from costly ICUs (Frey and Wood, 1991)
- H. Expedites decannulation process by serving as a transitional step toward tracheostomy tube removal [See Light, et al. (August, 1989). Decannulation Procedures for Patients with Chronic Tracheostomies. Chest. Vol. 96, Supp. 2, p. 257S]
- I. Improves nutritional status
- J. Contributes to an increase in patients' self-esteem, motivation and participation in therapy, which positively impacts their recovery process
- K. Supports normal speech/language development in children when valve use is initiated at an early age thus reducing the need for later intensive therapeutic intervention
- L. Restored physiologic PEEP may reduce patient oxygen requirements and may eliminate the need for mechanical PEEP or CPAP

XV. 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

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

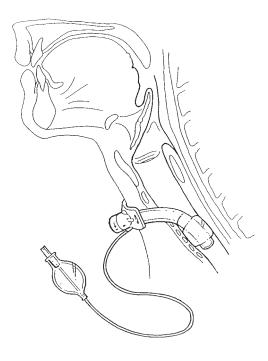
MALLINCKRODT, INC. (Nellcor Puritan Bennett) P.O. Box 5840 St. Louis, MO 63134 P (314) 654-2000 F (888) 222-9799 www.mallinckrodt.com

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

SMITHS MEDICAL 10 Bowman Drive Keene, NH 03431-0724 P (800) 258-5361 F (603) 352-3703

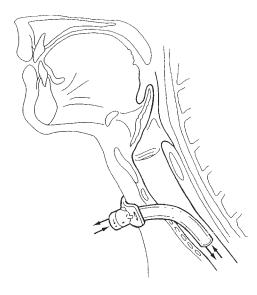
5700 West 23rd Avenue* Gary, IN 46406, USA* P (800) 348-6064* F (219) 989-7435* www.portex.com

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



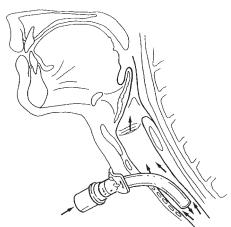
Cuffed Tracheostomy Tube

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



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 H₂O. 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 all exhaled air is redirected through the upper airway passing the vocal cords allowing the patient to speak.

GENERAL GUIDELINES FOR A TEAM-ORIENTED PASSY-MUIR SPEAKING VALVE (PMV) EVALUATION

1 of 3

		I. GENERAL PAT	TIENT INFORM	ATION					
Name:		Ad	mission Date:	DOB: Age: _					
Primary Dx:		Sec	condary Dx:						
Attending Physician:		Rei	ferring Physician:						
Referral Date:									
Current Status:									
Medical History:									
Precautions:									
Pre PMV Assessment Pa	tient E	ducation Completed:	Yes No	Date:					
<u>Intubation</u>		RECENT DIAGNOSTIC PROCEDURES							
Date performed: Type (circle one): Emergency yes Oral Nasal	no	Chest X-Ray Bronchoscopy	Date Results						
Extubation Date performed:		Laryngoscopy Other							
Length of Intubation:		Sputum Culture —							
Comments:			Arterial Blood Ga	as Results Date:					
Tracheotomy		рН		BE					
Date performed:				Sa0 ₂					
Comments:		Pa0 ₂		$F_I O_2$					
Comments.		HC0 ₃							
		II. BEDSIDE AS	SSESSMENT	Date: Time:	_				
<u>Vital Signs</u>	Trac	cheostomy Tube	Secretions	Supplemental Oxygen	<u>n</u>				
Oxygenation Pulse Oximeter —— TCM ———	ygenation Track		Oral Amount Consistency	Fi02 LPM Delivery Method					
Other		ffed vs. Cuffless	Color	——— Blow by ———					
Te-mp RR		atus of Cuff (circle): Inflated Deflated	Trachael	Trach mask ——— Nasal cannula ———					
BP		heal Plugging (circle):	Tracheal Amount	Respiratory Therapy					
HR ——	ye			Type					
Other	•	ration	Color	Meds					
	Brea	th sounds		Frequency ————Other ————					

Ventilator Mode	Vent	ilator Settings		Ventilator Weaning					
Control A/C IMV SIMV CPAP PS Other Type of ventilator Date artificial ventilation initiated	Tidal Volum Rate PEEP F10 ₂ Other Spontaneou Date VT	us Ventilation	-	Method: SIMV T-piece CPAP Other PS Dates Spontaneous Weaning Parameters VT VC MV RR NIF Length of weaning trial Tolerance of weaning					
Nutritional Stat	us			Swallowing S	status				
Oral (Diet Level)		Tolerate curre History of asp History of ref	ent diet piration lux prob Swallowir t copy	Date	yes no yes no yes no				
	Cogni	tive-Communica (please circle)		tus					
Alertness Orientation Attempts to communicate Following simple command RLAH Level Current mode of communication used:	S	Not Observed Not Observed Not Observed Not Observed cal (type)		Inconsistent Inconsistent Inconsistent Inconsistent	WFL WFL WFL type) — s assistance? Yes No				
Comments:	1			1					
	0	ral Motor/Vocal (please circle)							
Oral Motor Strength/Coordi Phonation with cuff deflatio Phonation with finger occlu-	Nonfunctional Nonfunctional Nonfunctional		Inconsistent Inconsistent Inconsistent	WFL WFL WFL					
Comments:	Do «!4	ioning Status/Pr		20					
Tolometer study and the territory					Hans for 20				
Tolerates sitting up in bed Comments:	yes	по	HOW IOI	ng?	How far?				
Tolerates sitting in chair Comments:				ng? How far?					
Is head control *WFL?	yes			ents:					
Is trunk control WFL?	yes	no	Comme	nts:					

^{*}within Functional Limits

]	II. PM	V PLA	CEMEN	NT DATA	4					
Date	te Time O ₂ SAT of Day Before During		After	Respirations/min After Before During After			Heart Before	Heart Rate (hi/low) Before During After			Breath Sounds Before During After			
	Coughir	ng (amou	nt)		S	ecretions	s (amoun	t)			A	Anxiety (d	lescribe)	
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 = anh	nonic, 5 = W	NI												
0 = api	iome, 3 = w			Г	v. EVA	LUATI(ON SUN	MMARY	7					
Summa	ary of Resu	ılts												
Follow-	-up Recom	mendat	ions (cire	cle all tl	hat apply	and des	scribe re	ason for 1	reco	mme	ndations	s):		
Broncho	oscopy													
Laryngo														
	stomy Tube		ing											
	up Chest X-I	Ray												
ABGs														
	ing Evaluati		_											
_	e Evaluation Iuir Valve	1												
	stomy Tube	Plugging												
	ocal Commu													
	cal Commun		Device											
Treatm	ent Plan:													
Patient	Observation	ns/Patie	nt Comm	ents (re	: Assessi	ment): _								
				S	ignature			Da	ate					
	Tembers: SLP, OT, PT,	MD)								_				
										-				
Patient:										-				



PMB 273, 4521 Campus Drive, Irvine, CA 92612 • (949) 833-8255 • (800) 634-5397 • FAX (949) 833-8299 www.passy-muir.com • email: info@passy-muir.com