1.0 DESCRIPTION

1.1 Definition: Noninvasive Positive Pressure Ventilation (NPPV) is a ventilatory-assist technique used in the management of impending respiratory failure as an alternative to endotracheal intubation. BiPAP, (Bi-level Positive Airway Pressure), is a low pressure, electronically driven device intended for use as a ventilatory support system for patients who have an intact respiratory drive. The device provides non-invasive ventilatory assistance through the use of a nasal or face mask. The device may also be used for invasive ventilatory support (refer to the “Guideline for Invasive Applications with BiPAP® Vision Systems). The device uses an electronic pressure control sensing mechanism to sense patient breathing. It accomplishes this through its ability to monitor pressure differential in the patient circuit. This feedback allows for adjustment of the flow and pressure output to assist in inhalation or exhalation through the administration at two distinct levels of positive pressure. During inspiration, the level is variably positive and is always higher than the expiratory level. During exhalation, pressure is variably positive or near ambient.

In addition, this device has the ability to compensate for leaks through automatic adjustment of the trigger threshold. This capability allows for the application of BiPAP for mask-applied ventilation assistance.

1.2 Indications

1.2.1 Acute respiratory failure

1.2.2 Acute or chronic respiratory insufficiency

1.2.3 Documented sleep apnea

1.3 Contraindications

1.3.1 Patients with severe respiratory failure without a spontaneous respiratory drive

1.3.2 Noninvasive ventilation may be contraindicated for patients with the following:
1.3.2.1 Inability to maintain a patent airway or adequately clear secretions
1.3.2.2 Acute sinusitis or otitis media
1.3.2.3 Risk for aspiration of gastric contents
1.3.2.4 Hypotension
1.3.2.5 Pre-existing pneumothorax or pneumomediastinum
1.3.2.6 Epistaxis
1.3.2.7 Recent facial, oral or skull surgery or trauma
1.3.2.8 History of allergy or sensitivity to mask materials where the risk from allergic reaction outweighs the benefit of ventilatory assistance

1.4 Potential Complications

1.4.1 Cardiovascular compromise
1.4.2 Skin break down and discomfort from mask
1.4.3 Gastric distention
1.4.4 Increased intracranial pressure
1.4.5 Pulmonary barotrauma

2.0 EQUIPMENT AND SUPPLIES

2.1 BiPAP ST/D

2.1.1 BiPAP® ST/D Ventilatory Support System with Detachable Control Panel (DCP) and airway pressure monitor

2.1.2 BiPAP ST/D disposable circuit with disposable proximal pressure line and exhalation port

2.1.3 Main flow bacteria filter

2.1.4 Nasal or face mask and disposable headstrap (see the Respironics Inc.® Nasal; Mask and Accessories Guide or the mask package insert for specific information on sizing) or airway adapter

2.1.5 Smooth inner lumen tubing for use in connecting the humidifier system to the BiPAP unit

2.1.6 Oxygen enrichment adapter and extension tubing

2.1.7 Pulse oximetry equipment and supplies

2.1.8 Continuous Ventilation Record

2.1.9 Device-specific humidification system (if necessary)

2.1.10 BiPAP sizing guage for nasal masks
2.2 BiPAP Vision

2.2.1 BiPAP® Vision Ventilatory Support System

2.2.2 BiPAP Vision disposable circuit with disposable proximal pressure line and exhalation port

2.2.3 Main flow bacterial filter

2.2.4 Nasal or face mask and disposable head strap (see the Respironics Inc.® Nasal Mask and Accessory Guide, or the mask package insert for specific information on sizing) or airway adapter.

2.2.5 Smooth inner lumen tubing for use in connecting the humidifier system to the BiPAP unit

2.2.6 Pulse oximetry equipment and supplies

2.2.7 Oxygen analyzer with circuit adapter

2.2.8 Continuous Ventilation Record

2.2.9 Device-specific humidification system (NOTE: A heated humidification system must be used for all invasive ventilation)

3.0 PROCEDURE

3.1 BiPAP ST/D

3.1.1 Determine appropriate circuit adapter. If a nasal mask is required, use the mask sizing gauge to select the appropriate size. Assemble the circuit with exhalation port proximal to the patient.

3.1.2 Connect the mask with headstrap or airway adapter to the circuit. Oxygen may be added at two points in the circuit. For use with an airway adapter, an oxygen enrichment attachment should be placed between the mainstream bacteria filter and the tubing going to the patient. For use with a mask, oxygen tubing should be connected directly from a flow meter to one of the sample ports on the patient’s mask.

3.1.3 Plug electrical cord into A/C outlet. Turn the power switch “ON” to the unit (located on the top right corner).

3.1.4 Assess appropriateness of physician’s orders and set ventilatory parameters accordingly. Initial settings as well as changes to ventilatory parameters must be accompanied by a physician order.

3.1.5 Adjust the DCP according to the desired mode, IPAP, EPAP, frequency (BPM) and %IPAP (Timed mode only). Consult the BiPAP® Ventilatory Support System Clinical Manual for specific information on the modes of operation and set parameters. Occlude the end of the circuit to adjust the ventilating pressures. NOTE:
The IPAP and EPAP controls are electrically coupled. The unit will not deliver an EPAP level that is higher than the set IPAP level [If the EPAP control is set higher than IPAP pressure, the unit will be locked to the IPAP setting and the IPAP Light Emitting Diode (LED) will remain lit]. The maximal achievable peak inspiratory pressure is 20 cm H₂O. **NOTE**: If the unit fails to read zero when not connected to the patient circuit (i.e., in ambient pressure), mechanically zero the pressure gauge using the zero adjust screw at the rear of the monitor.

3.1.6 Connect the patient to the circuit. Adjust headstrap to minimize leaks at the patient-mask interface. Assess the patient for tolerance and the ventilator system for proper function and adjust accordingly.

3.1.7 Adjust the oxygen liter flow as needed to achieve an appropriate oxygen saturation. **NOTE**: The BiPAP system should be turned ON prior to the introduction of oxygen to the circuit; the oxygen should be turned OFF prior to turning the BiPAP unit off.

3.1.8 Set high and low airway pressure monitor alarms as appropriate.

3.1.9 Observe the estimated exhaled tidal volume (Est Vte). The number should approximate the desired tidal volume. If the Est Vte flashes beyond 15 respiratory cycles there is a leak too great for compensation to occur. If this is observed, adjust the patient-unit interface as needed to achieve a steady Est Vte. The Est. Leak Display may be utilized to aid in correcting a persistent leak.

3.1.10 Perform a thorough assessment of the patient-ventilator system according to the CCTRCS Patient Assessment Policy. Monitor the patient continuously via cardiopulmonary monitor and pulse oximetry. Perform blood gas analysis as necessary per physician order.

3.1.11 Administration of aerosolized medications through the BiPAP system: Small volume nebulizers or adapters allowing the use of metered dose inhalers (MDI) may be added to the patient circuit. The liter flow used to drive the nebulizer does not impact on the functioning of the BiPAP system provided the nebulizer or MDI is added to the circuit on the patient side of the exhalation valve. A main flow bacteria filter must remain in-line during the treatment to prevent the aerosol from entering the BiPAP unit via the patient circuit. The use of a mouthpiece during the treatment may aid in treatment efficacy.

3.2 BiPAP® Vision

3.2.1 Assemble the circuit with exhalation port proximal to the patient. A bacterial filter and oxygen analyzer should be placed between the machine’s patient interface port and the patient circuit. If using the O₂ module, connect to a 50psi O₂ source.
3.2.2 Plug electrical cord in A/C outlet. Press START on the back of the machine. The Vision will perform a self-test as indicated by the display screen, “System Self-Test in Progress.”

3.2.3 Perform the “Test Exh Port”, second button from top, left of screen.

3.2.3.1 Occlude circuit with thumb throughout the test.
3.2.3.2 Press START TEST, top button, right of screen. This tests the leak of the circuit.

3.2.4 Assess appropriateness of physician’s orders and set ventilatory parameters accordingly. Initial settings as well as changes to ventilatory parameters must be accompanied by a physician order.

3.2.5 Select the proper mode by first selecting the mode button at the bottom of screen.

3.2.5.1 Choose CPAP or S/T mode, top button, right side of screen, per physician’s order.
3.2.5.2 Activate view mode by pressing the “Activate View Mode” button, bottom right of screen.

3.2.6 Select the “parameters” button below the screen.

3.2.6.1 Choose a parameter from the left and right sides of screen. Press the soft button for the parameter of choice. Once it is highlighted, spin knob clockwise to increase value, and counter clockwise to decrease value in the parameter block. Repress the button for that particular parameter to activate the new value.

NOTE: Consult the BiPAP® Vision Ventilatory Support System Clinical Manual for specific information on the modes of operation and set parameters.

3.2.7 Connect the patient’s properly fitted mask or airway adapter to the BiPAP Vision Circuit, and then apply the mask to the patient.

3.2.8 Select “alarms” button, below the screen. Set values for Hi Pressure, Lo Pressure, Lo Pressure Delay, Apnea, Lo MinVent, Hi Rate, and Lo Rate as appropriate for the patient.

4.0 POST PROCEDURES

4.1 Cleaning and sterilization for the BiPAP ST/D:

4.1.1 Disconnect the BiPAP and DCP before cleaning. Do not immerse in water. Unplug the DCP unit.

4.1.2 Discard the disposable circuit parts.

4.1.3 Wipe the outside of the DCP enclosure using a standard hospital disinfectant. Do not allow liquids to enter the DCP enclosure. The protective plexiglass cover should always be covering the DCP.
except when setting changes are being performed. The DCP should be thoroughly dry before reconnection.

4.1.4 Using a cloth slightly dampened with water and mild dish detergent, wipe the outside of the BiPAP enclosure. The BiPAP unit should be thoroughly dry before reconnection.

**Note:** DO NOT clean any parts of the system with alcohol or cleaning solutions containing alcohol. Do not clean the system by steam or gas sterilization methods. These cleaning processes may harden or deform the flexible plastic parts of the system and adversely affect the performance of the DCP.

4.2 Cleaning and sterilization for the BiPAP Vision

4.2.1 Before cleaning the unit turn the “Start/Stop” switch to the “Stop” position and unplug the electrical cord from the wall and from the rear of the unit.

4.2.2 Clean the front panel with water or 70% Isopropyl Alcohol only. **Do not immerse the Vision unit in water.**

4.2.3 Clean the exterior of the enclosure with a Clinical Center approved disinfectant. **Do not allow any liquid to enter the inside of the ventilator.**

4.3 Routine maintenance: Changing the intake filter:

In order to protect the patient from breathing dirt and other irritating particles, an air intake filter should be in place at all times when the BiPAP is being used. The white filter (on the front of the BiPAP ST/D and the back of the BiPAP Vision) is disposable and needs to be replaced after thirty days of use and in between patients.

**Caution:** Failure to replace a dirty filter may produce high operating temperature in the BiPAP unit, may reduce the flow, and may reduce the output pressure.

4.3.1 BiPAP ST/D

4.3.1.1 Turn off the unit and unplug the electrical cord.
4.3.1.2 Discard the dirty filter. **NOTE:** The filter is not washable.
4.3.1.3 Center a new filter over the filter holder. Carefully push in on the center button and tuck the filter in on all four sides.
4.3.1.4 Release the button. The filter should be intact and fit securely, covering the entire holder. Remove and re-adjust the filter as necessary.

4.3.2 BiPAP Vision

4.3.2.1 Refer to the BiPAP® Vision Ventilatory Support System Clinical Manual, Chapter 15 “Cleaning and Routine Maintenance”, 15.3 “Replacing the Inlet Filter”.
4.4 Equipment Readiness

The following should be with the device to assure it is “ready for use”:

4.4.1 Patient circuit

4.4.2 Variety of nasal and face masks with headstrap

4.4.3 Continuous Ventilation Record with clipboard

4.4.4 Plastic equipment cover over unit.

5 DOCUMENTATION

5.3 Documentation of parameters should be performed on the “Continuous Ventilation Record” at least every two hours on patients requiring BiPAP for full ventilatory support and every four hours on patients using Clinical Center BiPAP equipment for sleep apnea. Documentation should include the following:

5.3.1 Ventilator settings comply with physician order

5.3.2 Ventilator is functioning properly as evidenced by a check of measured volumes, rates, pressures and FiO₂.

5.3.3 Alarms are set appropriately

5.3.4 Measured inspired gas temperature (invasive ventilation only)

5.3.5 Oxygen saturation

5.3.6 Signature or initials of person performing the patient-ventilator system check

5.4 A proper record of ventilator care should include documentation of the following, at least every twelve hours in the MIS via the “Bipap” reporting pathway:

5.4.1 Ventilator settings (mode, rate, pressure, FiO₂)

5.4.2 Alarm settings

5.4.3 Airway temperature (invasive ventilation only)

5.4.4 Vital signs (pulse, respiratory rate, oxygen saturation, breath sounds)

5.4.5 Patient tolerance to therapy

5.4.6 Manual resuscitator and appropriate size mask at patient bedside and functional

5.5 For those patients using their own BiPAP/CPAP systems, a thorough patient assessment should be performed once every twelve hours and documented in the MIS via the “Respiratory Care Assessment/Consult” pathway.
5.6 A proper record of ventilator care should include documentation of the following as needed:

5.6.1 Ventilator circuitry and/or manual resuscitation equipment change

5.6.2 Changes to ventilatory parameters

6.0 REFERENCES

6.1 BiPAP® Ventilatory Support System Clinical Manual
6.3 Guideline for Invasive Applications with BiPAP® Systems
6.4 Respironics Inc.® Nasal Mask and Accessories Guide
6.5 CCTRCS Physical Assessment Policy