

## **AARC Clinical Practice Guideline**

### **Neonatal Time-Triggered, Pressure-Limited, Time-Cycled Mechanical Ventilation**

#### **TPTV 1.0 PROCEDURE:**

The application of time-triggered, pressure-limited, time-cycled mechanical ventilation (TPTV) to neonates--this Guideline does not address patient-triggered ventilation.

#### **TPTV2.0 DESCRIPTION/DEFINITION:**

The application of time-triggered, pressure-limited, time-cycled mechanical ventilation in the neonate is typically accomplished by the use of commercially available pressure-limited ventilators specifically designed for this population or of multipurpose, multimodal ventilators with the necessary capabilities. These ventilators permit precise management of ventilator settings.(1-8)

Pressure-limited ventilators commonly incorporate continuous flow to deliver a mixture of oxygen and air. The continuous flow supplies the patient with a fresh gas source for spontaneous breathing.(7,9-14)

Mandatory breaths are time-triggered and time-cycled, based on an adjustable frequency and inspiratory time. As the ventilator time-triggers inspiration, the exhalation valve closes, and the continuous flow is directed to the inspiratory limb of the patient circuit for the length of the inspiratory time.(7,11,12,14)

Once the pressure limit has been reached, remaining flow is diverted to a limiting mechanism. As the ventilator cycles to expiration, the exhalation valve opens to ambient and the continuous flow exits the expiratory limb of the circuit.(7,10,14)

Flow continues to enter the patient's lungs until pressure equilibrates or until the inspiratory time has elapsed, resulting in a decelerating flow pattern. Volume delivery is dependent on lung and chest-wall compliance and airway resistance, including the resistance of the endotracheal tube. As these variables change, deceleration of flow is

altered, and the tidal volume (VT) varies.(10,11,15-22) The VT achieved depends on the pressure limit, gas flowrate, inspiratory time (tI), and positive end-expiratory pressure (PEEP). Circuit characteristics that affect VT include compressible volume, presence of condensate, and obstruction of the artificial airway.(3,4,8-10,18,20,23)

### **TPTV 3.0 SETTINGS:**

TPTV is applied by trained personnel in acute care and subacute care hospitals.

### **TPTV 4.0 INDICATIONS:**

The presence of one or more of the following conditions constitutes an indication for TPTV.

**4.1** Apnea (24-27)

**4.2** Respiratory or ventilatory failure, despite the use of continuous positive airway pressure (CPAP) and supplemental oxygen (ie, FIO<sub>2</sub> > or = 0.60)(24,25,28)

**4.2.1** Respiratory acidosis with a pH < 7.20-7.25(8,25,29)

**4.2.2** PaO<sub>2</sub> < 50 torr(8,13,25,29,30)

**4.2.3** Abnormalities on physical examination

**4.2.3.1** Increased work of breathing demonstrated by grunting, nasal flaring, tachypnea, and sternal and intercostal retractions(5,27,29,31)

**4.2.3.2** The presence of pale or cyanotic skin and agitation

**4.3** Alterations in neurologic status that compromise the central drive to breathe:

**4.3.1** Apnea of prematurity(32)

**4.3.2** Intracranial hemorrhage(33)

**4.3.3** Congenital neuromuscular disorders(34)

**4.4** Impaired respiratory function resulting in a compromised functional residual capacity (FRC) due to decreased lung compliance and/or increased airways resistance,(12,35) including but not limited to

**4.4.1** Respiratory distress syndrome (RDS)(1,2,28,36-39)

**4.4.2** Meconium aspiration syndrome (MAS)(40)

**4.4.3** Pneumonia(41)

**4.4.4** Bronchopulmonary dysplasia(42-44)

**4.4.5** Bronchiolitis(41)

**4.4.6** Congenital diaphragmatic hernia(45)

**4.4.7** Sepsis(41)

**4.4.8** Radiographic evidence of decreased lung volume(27)

**4.5** Impaired cardiovascular function

**4.5.1** Persistent pulmonary hypertension of the newborn

(PPHN)(46,47)

**4.5.2** Postresuscitation(41)

**4.5.3** Congenital heart disease(48)

**4.5.4** Shock(6)

**4.6** Postoperative state characterized by impaired ventilatory function(45,49)

**TPTV 5.0 CONTRAINDICATIONS:**

No specific contraindications for neonatal TPTV exist when indications are judged to be present (Section 4.0).

**TPTV 6.0 HAZARDS/COMPLICATIONS:**

**6.1** Air leak syndromes due to barotrauma and/or volume overinflation (ie, volutrauma),(2,11,50-54) including

**6.1.1** Pneumothorax(16,55-59)

**6.1.2** Pneumomediastinum(55,56,58)

**6.1.3** Pneumopericardium(55)

**6.1.4** Pneumoperitoneum(55)

**6.1.5** Subcutaneous emphysema(55)

**6.1.6** Pulmonary interstitial emphysema(56,60-62)

**6.2** Chronic lung disease associated with prolonged positive pressure ventilation and oxygen toxicity(63,64) (eg, bronchopulmonary dysplasia(42,43,65-68))

**6.3** Airway complications associated with endotracheal intubation

**6.3.1** Laryngotracheobronchomalacia(69)

**6.3.2** Damage to upper airway structures(66,69,70)

**6.3.3** Malpositioning of endotracheal tube (ETT)(69,71)

**6.3.4** Partial or total obstruction of ETT with mucus(69,71,72)

**6.3.5** Kinking of ETT(69,71)

**6.3.6** Unplanned extubation(69,71,73)

**6.3.7** Air leak around uncuffed ETT

**6.3.8** Subglottic stenosis(69)

**6.3.9** Main-stem intubation(69)

**6.3.10** Pressure necrosis(74)

**6.3.11** Increased work of breathing (during spontaneous breaths) due to the high resistance of endotracheal tubes of small internal diameter(75)

**6.4** Nosocomial pulmonary infection (eg, pneumonia(76))

**6.5** Complications that occur when positive pressure applied to the lungs is transmitted to the cardiovascular system(77,78) or the cerebral vasculature resulting in

**6.5.1** Decreased venous return(77,78)

**6.5.2** Decreased cardiac output(77,78)

**6.5.3** Increased intracranial pressure leading to intraventricular

hemorrhage(27,33,79)

**6.6** Supplemental oxygen in conjunction with TPTV may lead to an increased risk of retinopathy of prematurity (ROP)(80,81)

**6.7** Complications associated with endotracheal suctioning(82)

**6.8** Technical complications

**6.8.1** Ventilator failure(10,83)

**6.8.2** Ventilator circuit and/or humidifier failure(38,70) (Condensate in the inspiratory limb of the ventilator circuit may result in a reduction in VT(23,84) or inadvertent pulmonary lavage.)

**6.8.3** Ventilator alarm failure(10,38,69,83)

**6.8.4** Loss of or inadequate gas supply

**6.9** Patient-ventilator asynchrony(85,86)

**6.10** Inappropriate ventilator settings leading to

**6.10.1** auto-PEEP

**6.10.2** hypo- or hyperventilation

**6.10.3** hypo- or hyperoxemia

**6.10.4** increased work of breathing

**TPTV 7.0 LIMITATIONS OF METHOD:**

Rapid changes in lung compliance and airways resistance may result in alterations in VT delivery that may significantly alter minute ventilation (VE).(3,4,9,11,19-21)

**TPTV 8.0 ASSESSMENT OF NEED:**

Determination that valid indications are present by physical, radiographic, and laboratory assessment

**TPTV 9.0 ASSESSMENT OF OUTCOME:**

Establishment of neonatal assisted ventilation should result in improvement in patient condition and/or reversal of indications (Section 4.0):

**9.1** Reduction in work of breathing as evidenced by decreases in respiratory rate, severity of retractions, nasal flaring and grunting

**9.2** Radiographic evidence of improved lung volume(41)

**9.3** Subjective improvement in lung volume as indicated by increased chest excursion and aeration by chest auscultation(87)

**9.4** Improved gas exchange

**9.4.1** Ability to maintain a PaO<sub>2</sub> > or = 50 torr with FIO<sub>2</sub> < 0.60(8,30)

**9.4.2** Ability to reverse respiratory acidosis and maintain a pH > 7.25(8,30)

**9.4.3** Subjective improvement as indicated by a decrease in grunting, nasal flaring, sternal and intercostal retraction, and respiratory rate(31)

## **TPTV 10.0 RESOURCES:**

**10.1** Equipment--recommended equipment based on individual patient need includes the following. (For a given patient, all mentioned equipment may not be necessary.)

**10.1.1** Commercially available continuous-flow infant ventilator equipped with TPTV mode or suitably equipped multipurpose, multimodal ventilator, low and high airway pressure alarms, high-pressure release-to-ambient pressure capability, loss of power and gas source alarms, low and high oxygen concentration alarms--alarms may be integral to the ventilator or an add-on.(21,38,83)

**10.1.2** Servo-regulated humidifier with low compressible volume chamber and preferably a continuous water source(21,38,83)

**10.1.3** Low-compliance infant ventilator circuit with heated inspiratory and expiratory wires compatible with the servo-regulated humidification system is recommended.(19,23,38,83,88,89)

Comparable circuits that permit continual drainage of condensate may also be used.

**10.1.4** Endotracheal tube with associated intubation equipment or tracheostomy tube with associated insertion and cleaning accessories and supplies for securing the tube

**10.1.5** Suction source, suction catheters, and normal saline for instillation to ensure patency of artificial airway(82)

**10.1.6** Standby resuscitation apparatus with airway manometer and masks of appropriate size(83) and supplies for chest-tube insertion

**10.1.7** Continuous noninvasive monitoring of oxygenation by either transcutaneous monitor or pulse oximeter with high- and low-alarm capabilities(90,91)

**10.1.8** Continuous noninvasive monitoring of carbon dioxide by transcutaneous CO<sub>2</sub> monitor with high- and low-alarm capabilities is also recommended(38,92) for the unstable baby requiring frequent ventilator changes. Measurements of end-tidal CO<sub>2</sub> may also be useful in these infants.(93,94)

**10.1.9** Continuous cardiorespiratory monitoring (eg, ECG and respiratory rate) with high- and low-alarm capabilities(38)

**10.1.10** Appropriate and adequate compressed gas supply

**10.1.11** Graphic display of airway pressure, flow, and tidal volume may be useful.

**10.2** Personnel: TPTV should be applied under the direction of a physician by trained personnel who hold a recognized credential (eg, CRTT, RRT, RN) and who competently demonstrate

**10.2.1.** proper use, understanding, and mastery of the technical aspects of management of artificial airways, mechanical ventilators, and humidification systems;

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.