bunnell
INSPIRED INFANT CARE

GUIDANCE DOCUMENT – 6 April 2020

Non-traditional means of PEEP generation utilized in conjunction with the LifePulse Jet Ventilator (HFJV)

Given the current COVID-19 Pandemic, hospitals may be faced with inadequate numbers of conventional ventilators due to the reallocation to other patient units. Clinicians may need to utilize non-traditional methods for PEEP and Mean Airway Pressure generation for use with the LifePulse Jet Ventilator. Recommendations are below for these optional applications.

We encourage you to call the hotline at **800-800-4358 (HFJV)** should this situation arise.

WARNING:

- Alarms will only be activated by the LifePulse Jet Ventilator in all of the following set up scenarios. It is essential to respond to all alarms identified on the LifePulse HFJV.
- Use the PEEP display on the LifePulse HFJV to monitor PEEP.
- The following options are only recommended to be used on stable patients, as defined by the attending physician.
- Filter the exhaled gas in any of the following set up scenarios.
- Always provide proper humidification in any of the following set up scenarios.

Option One: Traditional Invasive CPAP. (***Diagram 1)*** Provide a blended gas source to a heated wire conventional ventilator circuit. At the interface on the distal end of the expiratory limb, utilize a PEEP valve. This set up would allow for the filtration of the exhaled gases, located before the PEEP valve. In addition, this option could also utilize a T-Piece Resuscitator to function as the PEEP valve and offer intermittent positive pressure breaths given via the clinician.

NOTE*: The position for some PEEP valves, i.e., vertical versus inverted, will affect the PEEP value displayed on a pressure manometer.*

NOTE*: During testing, we noticed an audible vibration when using a PEEP valve and filter together. This noise did not affect the functionality of this option.*

Option Two: Traditional Invasive Bubble CPAP. (***Diagram 2)*** Provide a blended gas source to a heated wire circuit using a flowmeter. Place the distal end of the circuit in either sterile water or acetic acid bath, to generate the desired CPAP level. ***NOTE:*** *Bubbles generated in the water column caused pressure fluctuations, which contributed to discrepancies between measured PEEP on the Jet and the set PEEP. Our recommendation, for this application specifically, is to use another pressure manometer for monitoring PEEP.*

Option Three: Utilizing a T-Piece Resuscitator. (***Diagram 3)*** It is strongly suggested to utilize flows between 8-10 liters per minute. It is essential to heat and humidify the inspiratory gas by utilizing the manufacturer's recommended heated wire circuit.

Option Four: Utilizing a T-piece circuit without the Driver. (***Diagram 4)*** Similar to Option Three. In this option, there is a T-piece, with a PEEP valve, placed before the humidifier to set the desired Peak Inspiratory / Pop-Off Pressure. To deliver a manual breath, the T-piece resuscitator, located on the expiratory limb near the filter, is occluded by the clinician. ***WARNING***: Having a PEEP Valve / Pressure Pop-Off, located at the humidifier, is critical in safely applying this option.

The methods described in this Bulletin are valid only for the duration of the Declared Public Health Emergency. These alternate methods of providing PEEP have not been cleared through the FDA. These methods are only to be used if a conventional ventilator is not available to provide PEEP or mean airway pressure. Although Bunnell Inc. has performed bench studies to confirm effectiveness and safety, full clinical validation with all set-ups has not been completed.

If the patient is positive for Coronavirus or is suspected to be positive, we recommend the use of an expiratory filter or a traditional conventional ventiltor.

Please call the hotline **800-800-4358 (HFJV)** for questions about applications.

Diagram 1

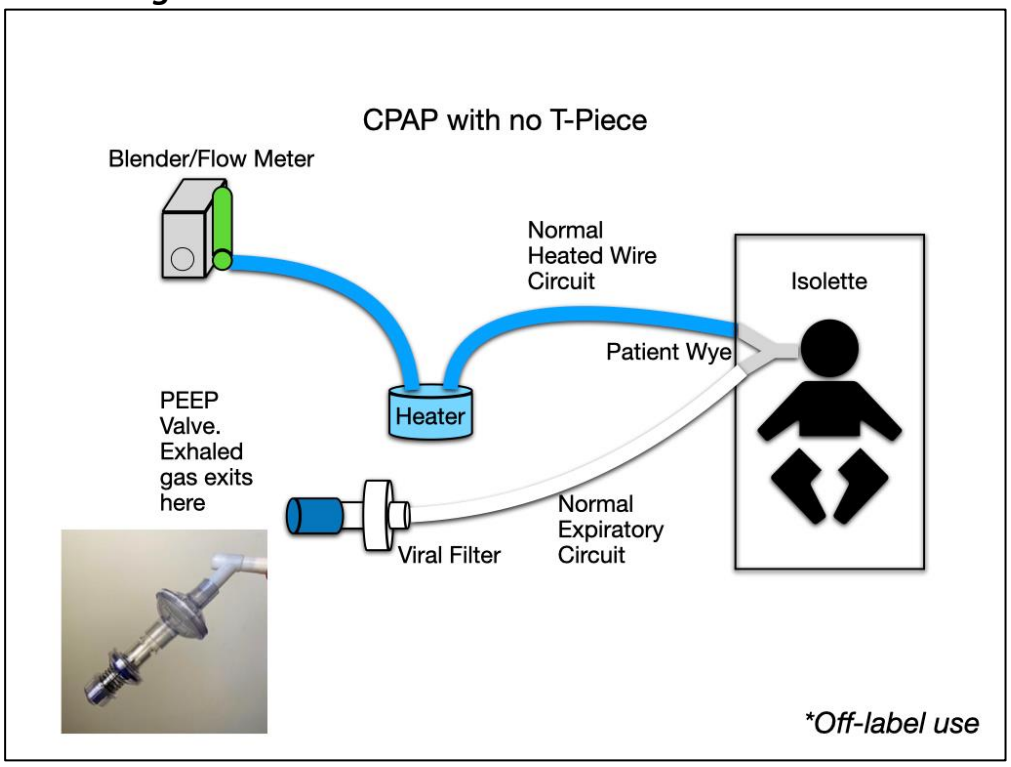

Diagram 2

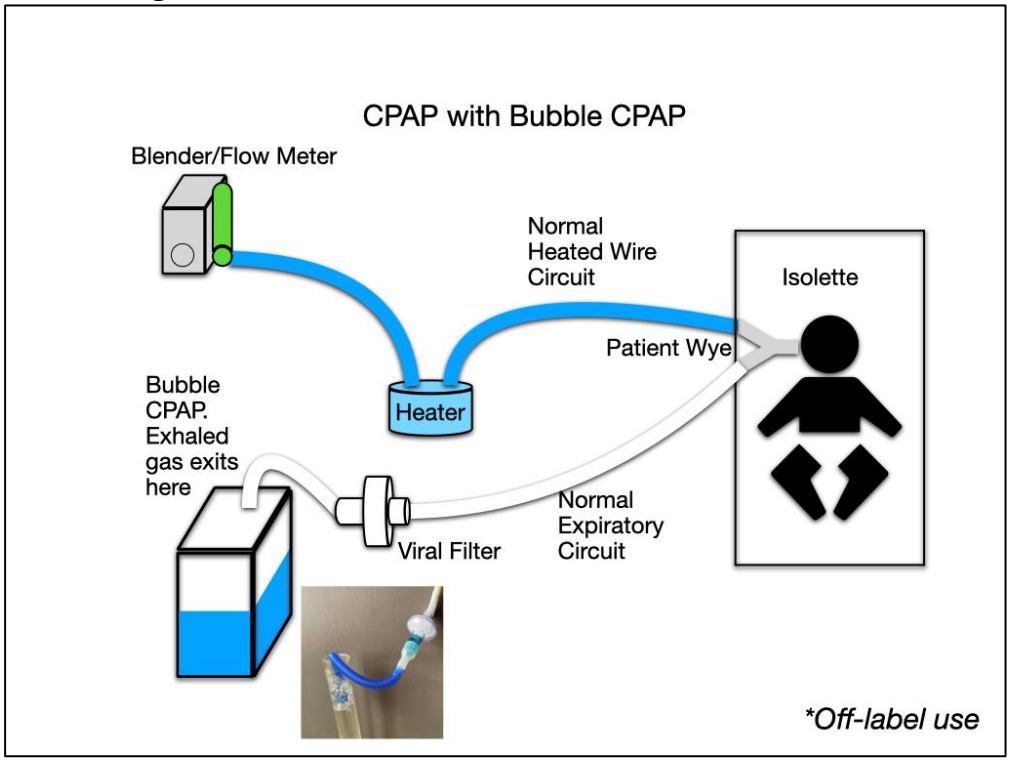

Diagram 3

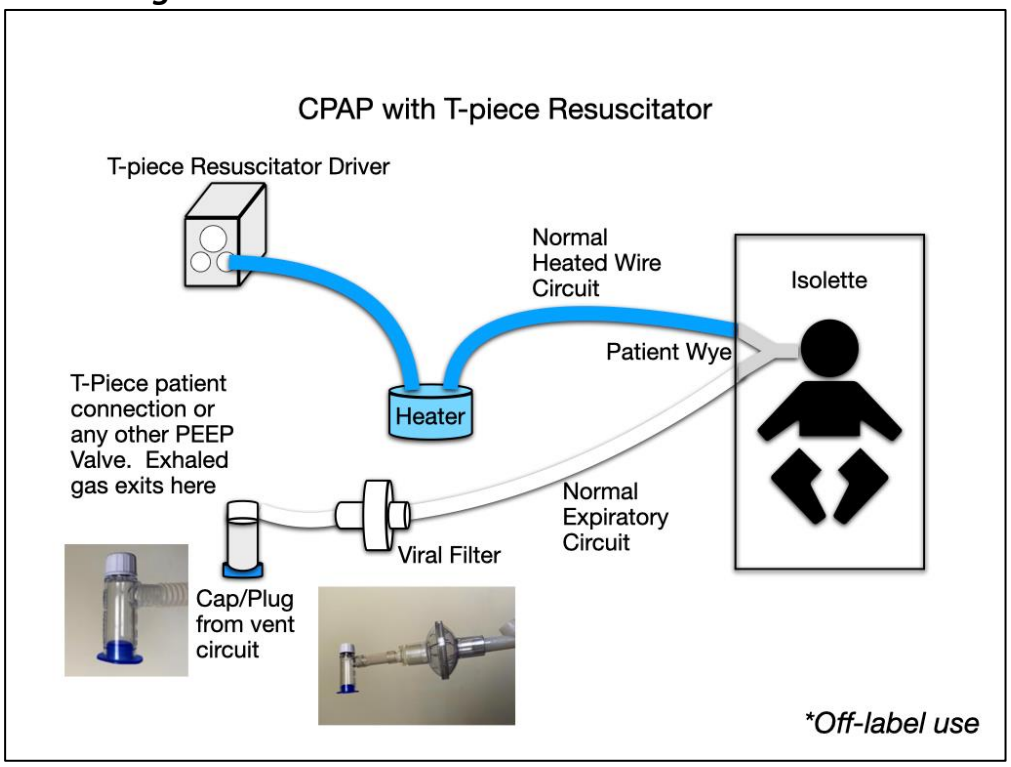

Diagram 4