A bench study comparison of volume delivery in the presence of leak

**Study objective**
To compare the volume delivery of the Trilogy100 ventilator to the volume delivery of the LTV 1200 as a representative of a portable ventilator.

**Study design**
Bench test comparison

**Measurements and Results**
Bench testing was performed on an ASL 5000 lung model (Ingmar Medical Inc, Pittsburgh, Pa.) with the Ingmar SBLVM to simulate a leak. The NiCO monitor (Respironics, Wallingford, Ct.) was used to measure tidal volume and flow. There was a significant drop in tidal volume with the introduction of a leak in the portable ventilator.

**Conclusions**
Tidal volume delivery is affected by leak and the Trilogy100 ventilator with the passive exhalation device is able to maintain the desired Vte in the presence of a leak as compared to the portable ventilator.

**Abbreviations**
Vte – Expired Tidal Volume
MinVent – Minute Ventilation
R – resistance
C - Compliance

**Key words:**
mechanical ventilation, non-invasive ventilation, invasive ventilation, passive exhalation device

---

**Introduction**
The main purpose of a mechanical ventilator is to artificially assist or replace the patient’s muscles in performing the work of breathing. Mechanical ventilation was first used during the polio epidemic in Scandinavia and the United States. The most common ventilators used during that time were negative pressure ventilators, such as the iron lung. After the end of the Polio epidemic, invasive mechanical ventilation via endotracheal tube or tracheostomy became more predominant largely because of a higher level of reliability and direct access to the airway. Invasive ventilation has traditionally required the use of an active exhalation device. An active exhalation device releases gas from the patient breathing circuit during the expiratory phase by creating an intermittent leak (e.g. deflating a balloon through a small opening, then re-inflating it to seal the opening during the inspiratory phase).

In noninvasive ventilation, gas is delivered to the airway via a mask or “interface”, rather than an invasive conduit (endotracheal or tracheostomy tube). With noninvasive ventilation, the gases are passively released via exhalation ports on the mask or other type of passive exhalation device (e.g. Whisper Swivel, Respironics, Murrysville, Pa). The passive exhalation device allows gas to continuously flush from the patient breathing circuit.

Invasive mechanical ventilation is indicated when the patient’s spontaneous ventilation is not adequate to sustain life.
Some common indications for employing mechanical ventilation include, but are not limited to:

- Lung infections
- Acute lung injury
- Chronic obstructive pulmonary disease (COPD)
- Post-operative states
- Congestive heart failure
- Chronic restrictive pulmonary disease
- Neuromuscular disease

Many of these disease states require mechanical ventilation outside of the hospital or institution and may also be needed in the home and other transitory environments. Patients suffering from such diseases require mechanical aid for breathing to augment or replace spontaneous ventilatory efforts to achieve medical stability or to maintain life. An individual that requires invasive mechanical ventilation in the home may require a tracheostomy tube for ventilatory support, but may no longer require intensive medical and monitoring services.

Advances in the field of mechanical ventilation have been rapid in the last few years with concentration in addressing the need of a portable lightweight ventilator providing accurate therapy under various conditions. Modern ventilators make use of blower technology combined with active exhalation devices or passive exhalation devices for better control and delivery of accurate therapy to the patients.

**Trilogy ventilator**

The Trilogy ventilator is a small, lightweight, and portable, device for use as an invasive and noninvasive ventilator. It is intended to ventilate adult and pediatric patients weighing at least 5kg (11lbs) through their disease progression and provides both pressure and volume control modes of therapy, as outlined in Table 1.

### Table 1

<table>
<thead>
<tr>
<th>Pressure modes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous positive airway pressure (CPAP)</td>
</tr>
<tr>
<td>Spontaneous pressure support (S)</td>
</tr>
<tr>
<td>Spontaneous/timed pressure support (ST)</td>
</tr>
<tr>
<td>Pressure control pressure support (PC)</td>
</tr>
<tr>
<td>Timed pressure support (T)</td>
</tr>
<tr>
<td>Pressure control synchronized intermittent mandatory ventilation (PC-SIMV)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Volume control modes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synchronized intermittent mandatory ventilation (SIMV)</td>
</tr>
<tr>
<td>Assist control (AC)</td>
</tr>
<tr>
<td>Control ventilation (CV)</td>
</tr>
</tbody>
</table>

In addition to the different modes of therapy available, the Trilogy ventilator offers user selectable features that allow the caregivers to provide mechanical ventilation with different patient circuits that may include either an active exhalation valve or a passive exhalation device. The therapy in all modalities of the Trilogy ventilator is comparable in both pressure and volume modes regardless of the exhalation device being used.

**Passive exhalation device**

As previously stated, invasive ventilation has traditionally required the use of an active exhalation device with a volume control mode of therapy. Volume control therapy is divided into two parts: 1) the inspiratory phase when the precise amount of flow is controlled until the prescribed volume has been delivered, and 2) the expiratory phase, when a set pressure is delivered according to the positive end expiratory pressure (PEEP) set point.

It has been standard practice to use an active exhalation device is needed when ventilating volume control modes of therapy. No ventilator in the past has offered volume mode therapy with a passive exhalation device. In those therapy modes, the passive exhalation device complicates the control algorithms for both measurement and delivery of the set volume. Leak flow during the inspiratory phase changes with the pressure at any give instant which is not typical when compared to circuits with a closed active exhalation valve.

The Trilogy ventilator has been designed to model the leak characteristics of the passive exhalation device to provide a flow waveform that, when measured at the patient, is indistinguishable from that provided by an active exhalation device. The set volume is maintained on a breath-by-breath basis regardless of the exhalation device being used. Furthermore, the flow sensing technology can accurately account for additional leaks and provide automatic leak detection and compensation. The Trilogy ventilator is currently the only ventilator capable of delivering volume ventilation with a less complicated passive exhalation circuit.

**Leak compensation**

The Trilogy ventilator provides leak compensation. Other portable ventilators available today do not compensate volume delivery based on varying leak, and deliver the prescribed setting only in the exceptional case where there is no leak. When leaks develop, the delivered volume to the lung is smaller. The Trilogy ventilator overcomes this condition by combining accurate leak estimation algorithms and precise control of air flow from the blower to provide accurate respiratory volume delivery without the use of an active exhalation valve. It makes use of a simple circuit containing only a passive leak device instead of the bulky circuitry that is found with an active exhalation valve.
Method
The Trilogy ventilator allows for volume control delivery in both active and passive modes of ventilation. A simple control system incorporated into the Trilogy ventilator is shown in Figure 1. The blower delivers a set tidal volume to the patient based on the command flow signal which includes the estimated leak flow.

In the volume control mode, the pressure is not controlled directly, but a flow controller provides the therapy. The applied pressure observed is simply an artifact of the flow/volume prescription. In contrast to traditional volume ventilators, the setting in Trilogy when using a passive circuit refers to the patient flow and not the total flow. The control flow is constantly adjusted for instantaneous leak. Therefore as leak increases or decreases, the machine estimates the leak and compensates delivery such that patient flow is delivered according to the setting.

Test procedure
To illustrate and compare the behavior of the Trilogy ventilator against other ventilators available in the market, a bench test comparison between Trilogy and the LTV 1200 volume ventilator was performed on the Ingmar Medical Inc. ASL 5000 lung model and the Michigan test lung. The Ingmar SBLVM leak orifice was used to simulate leak in the patient interface or cuff. In all tests, the NICO monitor was positioned to measure the volume expired (Vte) and inspired (Vti) by the test lung. Two TSI flow meters were positioned at the device outlet and proximal to the test lung to monitor the delivered and patient flow waveforms. A Druck pressure gauge monitored the applied pressure to the lung.

Both the Trilogy and the LTV 1200 ventilators were set to deliver 500 ml over a 1.0 second inspiratory time in passive mode with a PEEP of 4 cm H$_2$O to a Michigan test lung. The outputs of two TSI flow meters placed at the input and the output of the leak device were sampled at 100 Hz respectively. The pressure gauge was also sampled by the same computer and data was recorded. The lung was configured with a compliance of 50 ml/cm H$_2$O and connected with an Rp=20 restriction. Figure 2 shows the set up used for bench testing of the Trilogy ventilator. Figure 3 shows the setup used for bench testing of the LTV ventilator. Note the addition of the exhaust valve control and pressure sensing line, which is part of the LTV 1200 active exhalation valve circuit.

All flow measurements were translated to liters per minute (lpm) BTPS by the computer for volume delivery measurement. The passive exhalation device used for this experiment was the Whisper Swivel II design from Respironics. The device was first tested with no additional leak and later with an additional leak of 10 lpm during PEEP.
**Results and discussion**

The waveforms obtained from the Trilogy and the LTV ventilators, for one illustrative patient simulated with and without leak, are shown in the figures 4, 5, and 6. Figure 4 shows the Trilogy waveforms of total flow and patient flow measured using the TSI flow meter. The difference in the two flows is the leak due to whisper Swivel II. Figure 5 shows the patient pressure and measured Vti as reported by the NICO. Figures 6 and 7 show that when leak was introduced in the system, the Trilogy ventilator provided more flow and pressure. The total flow of the system increased to compensate for the additional leak. The patient flow was unchanged from that shown in Figure 3 when the device was tested without additional leak. The same test performed on the LTV ventilator produced very different results as explained below.

The test results show that for the Trilogy device, the patient flow measured by the second TSI and that which is entering the test lung is identical regardless of the leak.

![Comparison of patient flow to TSI flow in Trilogy with no leak](image1)

![Comparison of patient flow to TSI flow in Trilogy with additional leak](image2)

![Plot of patient pressure and leak in Trilogy with no leak](image3)

![Plot of patient pressure and leak in Trilogy when additional leak was introduced](image4)

![Figure 5: NICO reported 502 ml VTI (unit set to 500 ml)](image5)

![Figure 6: Total machine flow and patient flow measured with two TSI flow meters. Tested with additional unintentional leak.](image6)

![Figure 7: NICO reported 505 ml VTI (unit set to 500 ml)](image7)
The NICO monitor verified that the volume delivered to the test lung was accurately leak compensated and remained the same with and without leak.

The LTV ventilator delivered 487 ml of tidal volume in the absence of leak, but when the leak orifice from the Trilogy test setup was inserted, the NICO monitor reported that the delivered tidal volume was only 238 ml. The LTV 1200 ventilator measured the tidal volume accurately and announced a low tidal volume alarm.

The waveforms below (Figure 8) show how the therapy from the LTV 1200 was affected by the leak.

In addition to the setup with 500 ml of volume, comparisons were also completed at a tidal volume of 300 ml and those volumes are depicted in Table 2. The percentage of error in the volume delivery was also computed for all settings and is included in the table.

![Comparison of patient flow to TSI flow in LTV with no leak](image)

Figure 9: NICO reported 487 ml VTI (unit set to 500 ml).

![Comparison of patient flow to TSI flow in LTV with additional leak](image)

Figure 10: Total machine flow and patient flow measured with two TSI flow meters. Tested with leak added at the patient interface.

![Plot of patient pressure and leak in LTV with no leak](image)

Figure 11: NICO reported 238 ml VTI (unit set to 500 ml).
The bench test comparison of the Trilogy and the LTV1200 ventilators showed a marked difference in volume delivery and triggering in the presence of leak. As shown in Table 2, the percentage of error in volume delivery in the presence of leak in Trilogy was superior as compared to LTV 1200.

**Conclusion**

The Trilogy ventilator is able to maintain the desired volume delivery in the presence of a leak, whereas, the LTV 1200 as a representative example of a portable ventilator was only able to deliver half of the set volume.

### Table 2

<table>
<thead>
<tr>
<th>Ventilator</th>
<th>Target volume (ml)</th>
<th>Ti secs</th>
<th>BPM</th>
<th>Unintentional leak (lpm)</th>
<th>NICO Vti</th>
<th>% error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trilogy</td>
<td>500</td>
<td>1.0</td>
<td>20</td>
<td>0</td>
<td>502</td>
<td>0.4</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>1.0</td>
<td>20</td>
<td>10</td>
<td>505</td>
<td>0.0%</td>
</tr>
<tr>
<td>LTV 1200</td>
<td>500</td>
<td>1.0</td>
<td>20</td>
<td>0</td>
<td>487</td>
<td>2.6%</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>1.0</td>
<td>20</td>
<td>10</td>
<td>238</td>
<td>52.6%</td>
</tr>
<tr>
<td>Trilogy</td>
<td>300</td>
<td>0.9</td>
<td>20</td>
<td>0</td>
<td>311</td>
<td>3.74%</td>
</tr>
<tr>
<td></td>
<td>300</td>
<td>0.9</td>
<td>20</td>
<td>10</td>
<td>326</td>
<td>8.81%</td>
</tr>
<tr>
<td>LTV 1200</td>
<td>300</td>
<td>0.9</td>
<td>20</td>
<td>0</td>
<td>274</td>
<td>8.67%</td>
</tr>
<tr>
<td></td>
<td>300</td>
<td>0.9</td>
<td>20</td>
<td>10</td>
<td>87</td>
<td>71%</td>
</tr>
</tbody>
</table>

### References


4. Price, June and Edward Anthony Oppenheimer, MD, Focus on ALS. Pulmonary and Critical Care Medicine, Los Angeles, Ca.

5. AARC Clinical Practice Guidelines. Long-Term Invasive Mechanical Ventilation in the Home. Respir Care; revised 2007.