

# Evaluation report ‘Splitting the ventilator’

## In vitro testing and risk analysis

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## 1. Purpose of this document

This document describes the evaluation process performed for ‘splitting the ventilator’: an off-label use setup for emergency situations during the peak of the Covid-19 crisis in case of life-threatening shortage of ventilators.

The intention of this document is to analyze the risks of the proposed setup and to provide relevant information, based on lab tests, that could be of value to healthcare professionals for decision making. Published experiences and warning of other groups (e.g. in New York<sup>1</sup>) that in some cases already applied this emergency solution to COVID-19 patients are also included in this report.

## 2. Disclaimer

Ventilators are not designed, nor registered to ventilate more than one patient at the same time. See also the joint statement of the American Society of Anesthesiologists<sup>2</sup>. The setup and tests described are a simulation of the clinical situation and the setup should not be duplicated for regular clinical application. The data presented are based on simulated lungs (Michigan Test Lung) and the interpretation and translation to a clinical situation are fully the responsibility of healthcare professionals.

## 3. In vitro testing data

### Dual Patient ventilation measurement report

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### Introduction

Due to the COVID19 pandemic there might be a shortage of ventilators in several parts of the world. In a worst-case scenario, one could theoretically ventilate two or more patients with one ventilator. Previous research has investigated that the Pressure Controlled (PC) mode of ventilation is the safest way to ventilate four sheep (ref 1) and two healthy adults (ref 2).

These studies showed several limitations in which one of the main questions is; how could you adequately ventilate two patients with different stages of pulmonary disease? Differences in respiratory mechanics, like lung- and chest-wall compliance and airway resistance, will lead to different lung volumes when the same ventilator pressure will be delivered to two patients simultaneously.

This leads to the main question:

Can two patients with unequal lung compliance be ventilated safely with one ventilator when splitting the inspiratory and expiratory hoses of the ventilator?

### Methods

Two ventilator circuits are connected to a ventilator (Draeger infinity V500) using T-connectors (Intersurgical, The Netherlands) with one-way valves to ventilate two patients with one ventilator. For schematic details see figure 1, for a real-life setup see figure 2.

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<sup>1</sup> <https://www.gnyha.org/wp-content/uploads/2020/03/Ventilator-Sharing-Protocol-Dual-Patient-Ventilation-with-a-Single-Mechanical-Ventilator-for-Use-during-Critical-Ventilator-Shortages.pdf>

<sup>2</sup> <https://www.asahq.org/about-asa/newsroom/news-releases/2020/03/joint-statement-on-multiple-patients-per-ventilator>

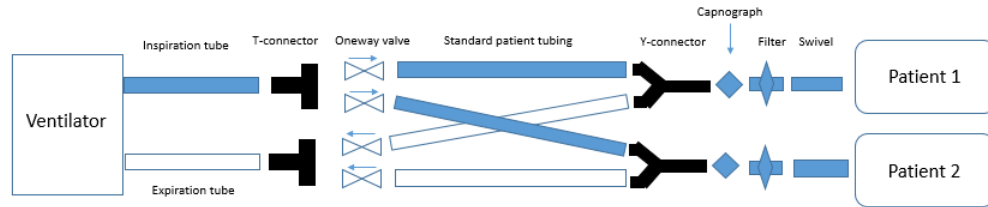


Figure 1: Setup with two patients on a single ventilator using T-connectors with one-way valves, bacteria filters and capnographs.

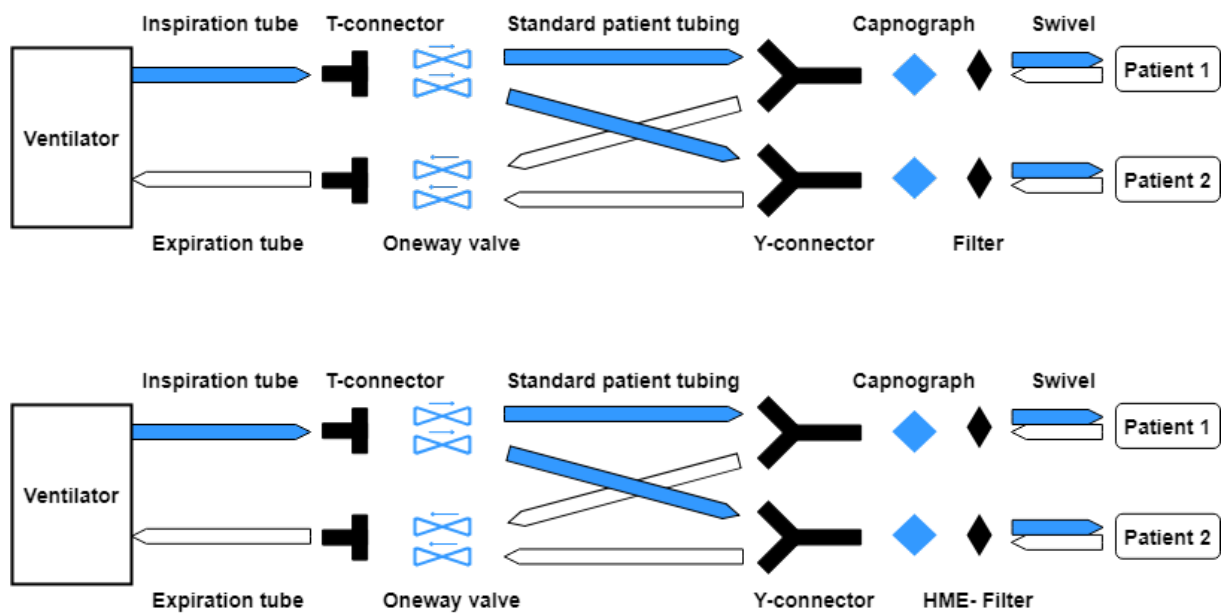


Figure 2: Set up, with a Draeger ventilator, two Fisher and Paykel tubing sets and two Vyntus Spiro PC pneumotachs, measuring the tidal volume delivered to each "patient".

Tidal volume measurements were measured for one minute per setting for:

- a) Equal compliances of both lungs while increasing peak inspiratory pressure (PIP)/PEEP (Positive End Expiratory Pressure) settings from 16/6 to 26/16 cmH<sub>2</sub>O in steps of 2 cmH<sub>2</sub>O with constant driving pressure;

- b) Unequal lung compliances to see the margin in which comparable tidal volumes are obtained at constant PIP/PEEP settings of 22/12 cmH<sub>2</sub>O;
- c) Added resistance in the inspiratory line of the patient with the higher lung compliance (the healthier patient) to investigate if tidal volumes of both patients could be matched despite their different lung compliances.

**Materials used:**

- Michigan test lung (pneuvue 3) with two independent “lungs” for which each lung the compliance (from 10-100 ml/cm H<sub>2</sub>O) as well as the airway resistance (from 0-500 cm H<sub>2</sub>O/L/sec) could be set independently.
- Spirometers   Vyntus Spiro PC Spirometer, Vyair (2x)
- Ventilators:   Draeger Evita Infinity V500 ventilator  
                  Philips Respironics V689 ventilator
- Tubing sets:   Adult ventilator circuit (RT380, Fisher and Paykel (2x) or  
                  S2000000, Intersurgical )  
                  Adult ventilator circuit (Intersurgical, The Netherlands) (2x)
- T-connectors with one-way valves (#1954000, Intersurgical, The Netherlands)
- Bacteria filters ( Intersurgical, The Netherlands)

## Results

In figure 3, both lungs had an equal compliance of 50 ml/cmH<sub>2</sub>O as well as an equal airway resistance of 5 cmH<sub>2</sub>O/L/sec mimicking the resistance of an intubated adult patient.

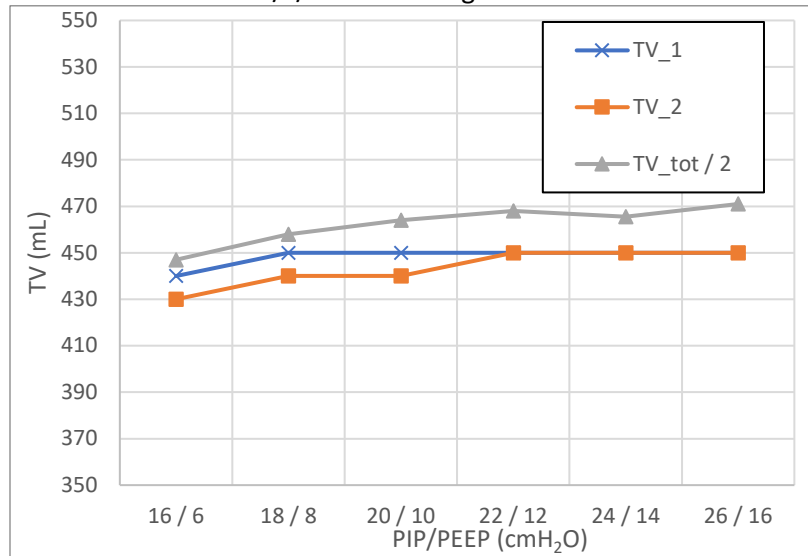


Figure 3: Tidal volume (TV in mL) delivered to patient 1 (TV\_1, blue crosses) and patient 2 (TV\_2, orange squares) and the total TV measured by the ventilator divided by 2 (TV\_tot/2, gray triangles) as function of different (PIP/PEEP) settings for the Draeger Infinity ventilator with the Fisher and Paykel tubing system.

In figure 4, the compliance (C1 = compliance patient 1, C2= compliance patient 2) of one lung was changed from 10 ml/cm H<sub>2</sub>O till 70 ml/cm H<sub>2</sub>O while the other lung compliance was changed from 70 ml/cm H<sub>2</sub>O till 10 ml/cm H<sub>2</sub>O). Airway resistance remained unchanged (5 cm H<sub>2</sub>O/L/sec for each lung). The grey line is the tidal volume measured by the ventilator divided by two (e.g. 330 ml at C1, C2 = 10, 70 mL/cm H<sub>2</sub>O matches the tidal volumes measured with the pneumotach systems: 330\*2 = 660 mL = 150 mL + 510 mL). All for the Draeger ventilator with the Fisher and Paykel tubing set. The shaded green colored bandwidth of 400-480 mL– comparable to a tidal volume of 5-6 mL/kg – shows that if tidal volumes lie within this bandwidth, the maximal difference in respiratory compliance is 20 mL/cm H<sub>2</sub>O.

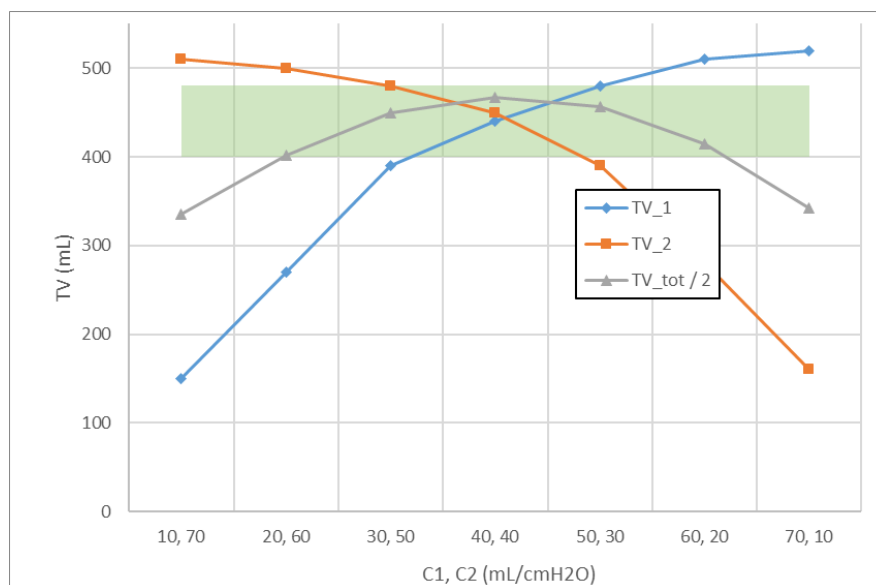


Figure 4: Tidal volume (TV in mL) delivered to patient 1 (TV\_1) and patient 2 (TV\_2) and the total TV measured by the ventilator divided by 2 (TV\_tot/2) as function of different test lung compliances in which **UNEQUAL** compliances are chosen: e.g. the first points at the left are with a respiratory compliance of 10 ml/cmH<sub>2</sub>O (resulting in a TV of 150 mL, blue line) and a compliance of 70 ml/cm H<sub>2</sub>O for patient 2 resulting in a tidal volume of 510 mL for that patient) for the Draeger Infinity ventilator with the Fisher and Paykel tubing system.

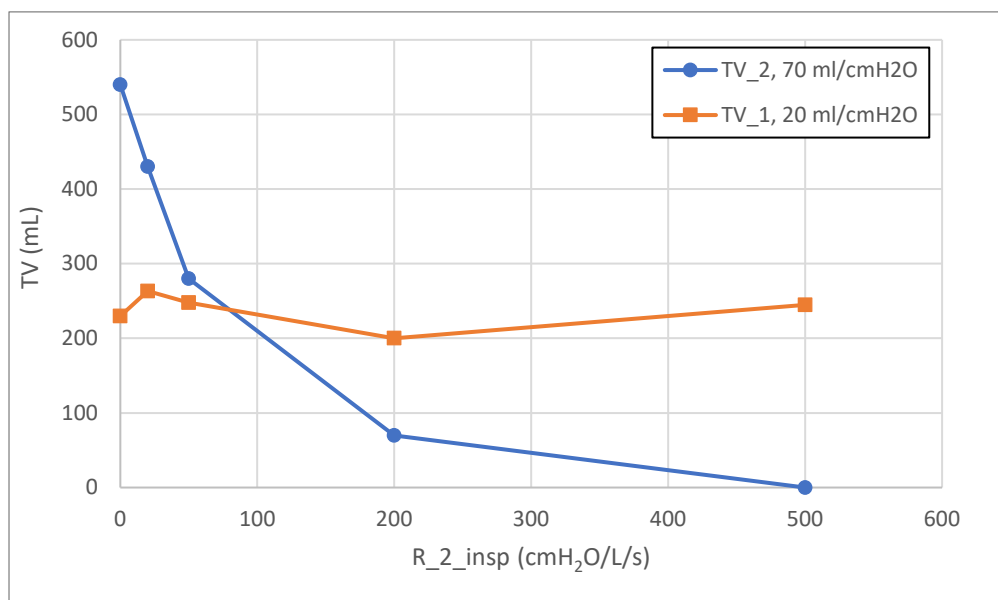


Figure 5: No resistance in the lung with the low lung compliance (red, 20 mL/cm H<sub>2</sub>O), increasing resistance in the lung with the high lung compliance (blue, 70 mL/cm H<sub>2</sub>O). Without resistance the lung with the high lung compliance receives more than double the volume (around 550 mL) as the lung with the low compliance. Adding a resistance of approximately 80 cm H<sub>2</sub>O/L/s show that both tidal volumes become almost equal (around 220 mL) despite the large difference in lung compliance.

## Discussion

This study shows that, in vitro, technically two simulated patients can be ventilated with one ventilator, however, with limits. The tidal volume delivered to the lungs of each “patient” depends on the compliance of the respiratory system of that patient. The ventilators and tubing systems tested showed that the tidal volume measured by the ventilator was the sum of the two tidal volumes delivered within 10% (figure 3). When both lung compliances were equal, an equal tidal volume was delivered to each lung as expected. This tidal volume was almost independent of the peak/PEEP setting provided that the driving pressure was constant.

When unequal lung compliances were chosen only a very limited range of acceptable tidal volumes for both patients could be obtained (figure 4). By adding a resistance in the inspiratory limb of the lung with the highest compliance the tidal volume of this patient was lowered and could be brought in line with the tidal volume delivered to the lung of the patient with the low lung compliance (figure 5).

As the effects are achieved by altering the “resistance · compliance time” (RC-times) of the limbs in question, choosing the resistances adequately, is an highly precarious operation, especially when the respiratory mechanics of the patients are not fully known. Therefore, clinical implementation of such is not recommended and even highly discouraged.

With the investigated setup the PEEP, Peak pressure and FIO<sub>2</sub> cannot be regulated per patient. The ventilator will show the sum of the tidal volumes delivered to the two “patients” within 10% margin, but not the tidal volume delivered to each individual patient. If a flow/pressure sensor would be installed between the T-connector and the patient this could be solved. Ideally such flow/pressure sensor is also capable of measuring the end tidal CO<sub>2</sub> (capnograph).

To ensure patient safety in the described setup, adequate measures should be put in place. Ventilation parameters of both patients should be closely monitored, since for instance partly disconnection of one patient might not give an alarm while the other patient is still ventilated. Moreover, bacteria filters and one-way valves should be placed adequately while otherwise air of one patient (e.g. when coughing) could enter the tubing system of the other patient.

### **Conclusion**

In vitro, technically, two simulated patients can be ventilated with one ventilator. The tidal volume delivered to lungs of each “patient” depends on the compliance of the respiratory system of both patients. The ventilators and tubing systems tested showed that the tidal volume measured by the ventilator was the sum of the two tidal volumes delivered within 10%. When both lung compliances were equal, an equal tidal volume was delivered to each lung as expected. This tidal volume was almost independent of the peak/PEEP setting, provided that the driving pressure was constant. If respiratory compliances were unequal, only a very limited combination of compliances gave a comparable tidal volume. Adding an adequate resistance in the inspiratory limb of the patient with the highest lung compliance can solve this problem and deliver similar tidal volumes to the two patients despite a highly unequal lung compliance. However, clinical implementation of such an adaption is not recommended and highly discouraged.

**Our study shows that dual patient ventilation should only be considered when no other options are available.**

### **Literature**

1. Paladino L, Silverberg M, Charchaflieh JG, Eason JK, Wright BJ, Palamidessi N, Arquilla B, Sinert R, Manoach S. Increasing ventilator surge capacity in disasters: ventilation of four adult-human-sized sheep on a single ventilator with a modified circuit. *Resuscitation* 2008; 77: 121-126.
2. Neyman G, Irvin CB. A single ventilator for multiple simulated patients to meet disaster surge. *Acad Emerg Med* 2006; 13: 1246-1249.

#### 4. Risk analysis

A risk analysis was performed in several phases during the evaluation project. Since this setup was developed under high time pressure, verification was done in combination with validation. The following activities were performed:

- Intended use defined and characteristics identified.
- Known or foreseeable hazards identified.
- Risks for hazardous situations estimated.
- Decided on risk reduction necessity.
- Appropriate risk control measures identified.
- The risk control measures were implemented and verified.
- After the risk control measures were applied, any residual risk was evaluated using the criteria defined in the risk management plan.
- The results of all risk management activities were recorded in the risk management file and in this evaluation report.



Members of the risk management team were:




| Expertise required  | Name                   | Organization            | Function  |
|---|------------------------|-------------------------|---|
| Knowledge of Technology   | Ruud Verdaasdonk       | University of Twente    | Professor of Health Technology Implementation   |
| Knowledge of Technology and clinical impact                           | Jonne Doorduyn         | Radboudumc              | Assistant Professor   Technical physician   |
| Knowledge of Technology and clinical impact                           | Frans de Jongh         | Medisch Spectrum Twente | Pulmonary physiologist  |
| Knowledge of Clinical impact  | Eline Mos              | University of Twente    | Assistant Professor   Technical physician at Cardiovascular and Respiratory Physiology (CRPH) group |
| Knowledge of Technology   | Saskia Aarnink         | Medisch Spectrum Twente | Medical physicist   |
| Knowledge of Technology   | René ter Wee           | Medisch Spectrum Twente | Medical physicist in training   |
| Knowledge of investigational products                                 | Monique van Lier       | AMC – Sigmascreening    | Clinical application scientist  |
| Knowledge of Risk management on Medical Devices according to ISO14971 | Lisette van Steinvoren | Holland Innovative      | Sr. PM. MedTech   |

Input of ventilation practitioners of the Medisch Spectrum Twente (MST), Enschede, was obtained by an interview and comments were added to the risk analyses table.










The risk management was reviewed during the standard, daily team meetings, hosted by Remke Burie of the University of Twente, and joined by a multiple set of specialists of University of Twente, MST, Radboudumc & Holland Innovative. The risk management files were updated when needed.








The table below shows the resulting warnings, cautions and notes from the risk analysis. These should be taken into account when applying dual patient ventilation in COVID-19 emergency situations.

#### Definitions:

|   |   |
|---|---|
|  | <p><b>WARNING:</b></p> <p>Warnings are directions which, if they are not followed, can cause fatal or serious injuries to a user, engineer, patient or any other person or can lead to a mistreatment.</p>            |
|  | <p><b>CAUTION:</b></p> <p>Cautions are directions which, if they are not followed, can cause damage to the device described in this manual or any other equipment or goods and can cause environmental pollution.</p> |
|  | <p><b>NOTE:</b></p> <p>Notes provide advice and highlight unusual points. A note is not intended as an instruction.</p>   |

## Warnings, cautions and notes

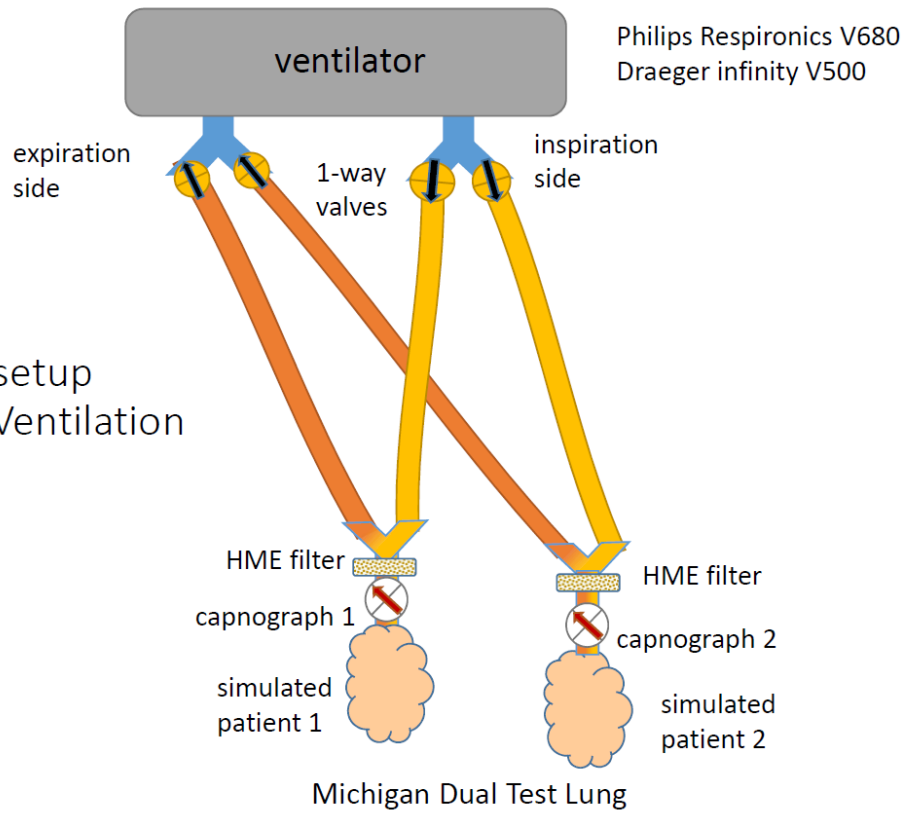
|   |   |  |
|---|---|--|
| 1 |    | <b>WARNING:</b><br>This setup is considered off-label use of a mechanical ventilator and is not clinically tested. Be aware that conventional self-tests of the ventilator might give errors.  |
| 2 |    | <b>WARNING:</b><br>This setup must only be used in emergency situations when no other option is available. The responsible healthcare professional remains responsible for the decision to implement this setup.   |
| 3 |    | <b>WARNING:</b><br>Only <u>pressure-controlled</u> ventilation must be used while splitting the ventilator for two patients <ul style="list-style-type: none"> <li>- No individual patient airway pressure or tidal volume monitoring is possible using the ventilator. Dedicated equipment should be used</li> <li>- Patients should NOT have respiratory effort.</li> </ul>  |
| 4 |    | <b>WARNING:</b><br>Equal inspiratory pressure, PEEP (Positive End Expiratory Pressure), and FiO <sub>2</sub> will be administered to both tubing systems; only in case the flow does not reach zero at end expiration, inspiratory pressures between patients will differ. Differences in individual patient respiratory compliance and resistance will lead to different delivered tidal volumes.   |
| 5 |  | <b>WARNING:</b><br>Additional capnography and ideally tidal volume monitoring must be added to this setup for each individual patient.   |
| 6 |  | <b>WARNING:</b><br>This setup must be assembled by a mechanical ventilation expert. <ul style="list-style-type: none"> <li>- All one-way-valves, as used in the setup, must be placed correctly to provide airflow in the <u>right direction</u> and thereby prevent backflow due to possible coughing, suctioning and other procedures.</li> <li>- Always test the setup with a test lung <u>before</u> connecting a patient and make sure all connections are tightly secured</li> </ul> |
| 7 |  | <b>CAUTION:</b><br>Be aware that in case one or both patients do not fully expire before a new inspiration is started, auto PEEP is build up.  |
| 8 |  | <b>CAUTION:</b><br>Be aware to adapt the tidal volume alarm settings to two patients.  |
| 9 |  | <b>CAUTION:</b><br>Be aware that ventilator tubing is not interchanged between patients, to prevent cross infectious contamination.  |

|    |   |   |
|----|---|---|
| 10 |    | <p><b>CAUTION:</b></p> <p>Use disposables, use the same disposables for both patients on the same ventilator, use them no longer than the end-of-life stated by the supplier and preferably use disposables from the same supplier, brand and type, to assure optimal connections.</p>  |
| 11 |    | <p><b>CAUTION:</b></p> <p>When disconnecting one of the patients from the setup, replace the patient with a test lung or tubing cap. Use a HEPA filter at the endotracheal tube to prevent test lung contamination.</p>   |
| 12 |    | <p><b>CAUTION:</b></p> <p>There is a risk of infectious contamination between both patients. This risk could be mitigated by the addition of HEPA filters and valves, but infectious risks, especially in case of longer-term usage of this emergency solution, should be analyzed and monitored by infection prevention experts.</p>   |
| 13 |    | <p><b>NOTE:</b></p> <p><u>Always</u> make sure that a healthcare professional continuously monitors both patients. In this setup, conventional monitoring is lacking and possible instability of the connections and tubes in the setup may occur. Oxygen saturation monitoring of both patients should be included.</p>  |
| 14 |  | <p><b>NOTE:</b></p> <p>Anticipate on patients possibly suitable for splitting the ventilator by placing them in the same room. Make sure to place them with equal distance to the ventilator.</p>   |
| 15 |  | <p><b>NOTE:</b></p> <p>The use of this setup, should be reported to the hospital board of directors and to the local authorities, according to National requirements.</p> <p>Follow hospital guidelines and make a trackable recording of 1) Considerations and decisions to use the 'Splitting the Ventilator' set-up, including an analysis of alternatives, 2) Refer to this Evaluation report and any other relevant literature, and 3) The components that are used.</p> |
| 16 |  | <p><b>NOTE:</b></p> <p>Applying this setup should be documented in the Medical Patient File and (if possible) patient and his/her family should be informed.</p>  |

5. Appendices

a) Component list as used in test setup

Scheme test setup  
Dual Patient Ventilation



Test setup

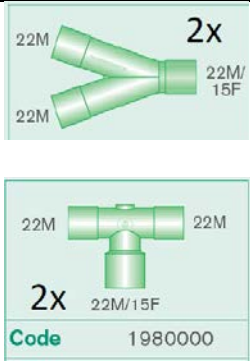

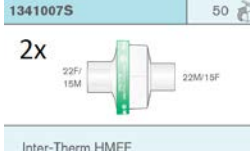

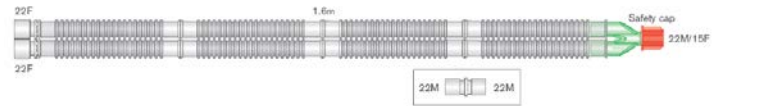


Michigan dual test lung



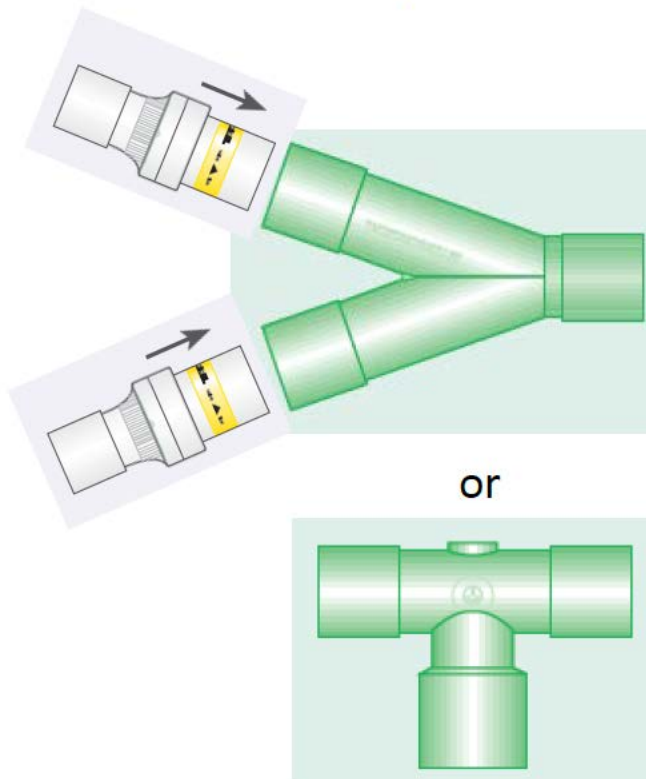
## Components

The following components are used to build the setup used for this evaluation.

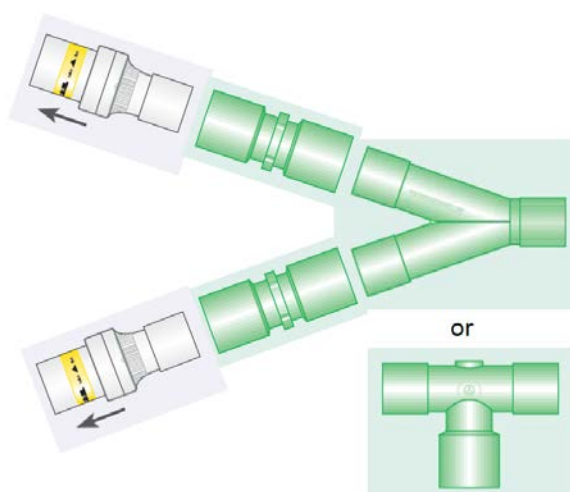
| Amount | Description  | Manufacturer                       | Reference                | Image  |
|--------|--|------------------------------------|--------------------------|--|
| 2      | 22mm<br>Traditional<br>Y-piece<br>22M/15F<br><br><b>OR</b><br>Tracheotomu<br>T-piece,<br>22M-<br>22M/15F-<br>22M | Intersurgical<br><br>Intersurgical | 1900000<br><br>1980000   |   |
| 2      | Straight<br>connector<br>22F-22F   | Intersurgical                      | 1967000                  |  |
| 2      | Inter-<br>Therm™<br>HMEF, sterile  | Intersurgical                      | 1341007S                 |  |
| 4      | One-way<br>valve 22M<br>(flow in) -<br>22M (flow<br>out)   | Intersurgical                      | 1950000                  |  |
| 2      | 22mm<br>Flextube™<br>ventilation<br>system 1.6m,<br>sterile<br><br><b>OR</b><br>22mm<br>Flextube™                | Intersurgical                      | 2000000S<br><br>2002000S |  |

|  |  |  |  |  |
|--|--|--|--|--|
|  | <p>ventilation system 1.6m with 0.8m extratube</p> |  |  |  |
|--|--|--|--|--|

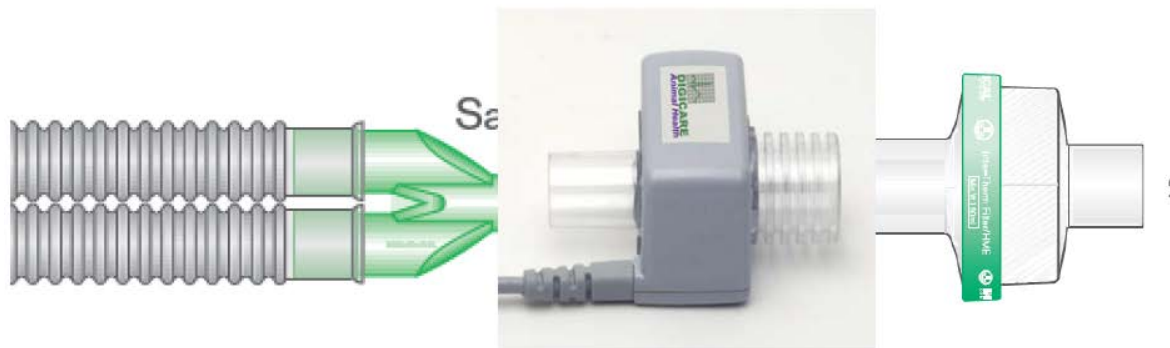
**Composition of parts – expiration**



**Composition of parts – inspiration**



Composition of parts – patient



Capnography – Flow and CO<sub>2</sub> or combined

- Philips Respironics
- Hamilton



Add-ons: test lung (e.g. Draeger)



b) Ventilator specific guidelines

Based on the performed tests on Draeger (Evita Infinity V500) and Philips (Respironics V689) ventilators:

- Switch off 'Automatic Tube Compensation' when using Draeger ventilator.
- The driving pressure needed to ventilate with a specific tidal volume was higher using a Philips ventilator than with a Draeger ventilator to get the same tidal volume.