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To whom it may concern:

In response to the shortage of mechanical ventilators resulting from the global COVID-19 pandemic, several organizations have proposed or developed devices to ventilate two patients with one ventilator. Most of these devices involve flow-splitting adapters that are connected to the inspiratory and expiratory ports of the ventilator allowing for two patient breathing circuits to be connected to the ventilator simultaneously. **I am writing to urgently inform you of a hazardous situation that may result from the use of these devices.** A schematic of the ventilator configuration I am referring to is provided in Figure 1. Accessories such as monitors, humidifiers, and filters have been omitted for clarity.

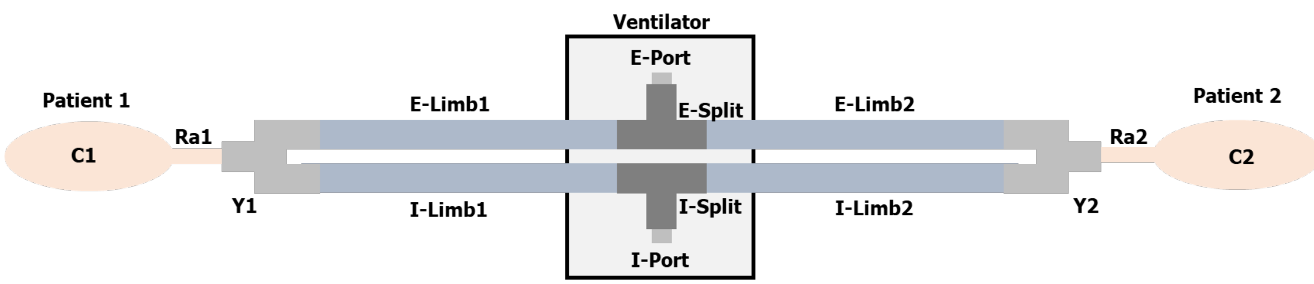

Figure 1: Schematic of ventilator configuration used to ventilate two patients with one ventilator. I-Port: Ventilator inspiratory port; E-Port: Ventilator expiratory port; I-Limb: Breathing circuit inspiratory limb; E-Limb: Breathing circuit expiratory limb; I-Split: Inspiratory flow splitting adapter; E-Split: Expiratory flow splitting adapter; Y: Patient wye piece; Ra: Airway resistance; C: Pulmonary compliance.

To adequately support a patient, a ventilator must meet two requirements. Firstly, the ventilator must deliver an adequate volume of gas to the patient's lungs. Secondly, the majority of gas inspired into the lungs must be fresh gas from the ventilator and not gas that has already been inspired by the patient and expired back into the breathing circuit.

The configuration shown in Figure 1, if used with a pressure-controlled mode of ventilation, will provide volume delivery to each patient that is similar to the volume that would have been delivered if the patient were on the same ventilator alone, with the same settings, without the splitters. However, if the two patients do not have identical respiratory physiology (airway resistance and pulmonary compliance) or breathing circuits (tubing, filters, etc.) then the patients may inspire gas from the expiratory limbs of the breathing circuit and expire gas into the inspiratory limbs of the breathing circuits. As a result, expired gas, instead of fresh gas, may be re-inspired during subsequent breaths. Expired gas has higher concentrations of carbon dioxide and lower concentrations of oxygen than fresh gas from the ventilator and, if rebreathed, **may result in hypercapnia and/or hypoxia**.

As a simple illustrative example, Figure 2 shows the flow of gas in the circuit if the connection to Patient 2 is fully occluded, which could occur due to a blocked airway filter, kinked endotracheal tube, or removal of Patient 2 from the ventilator and capping of the circuit.

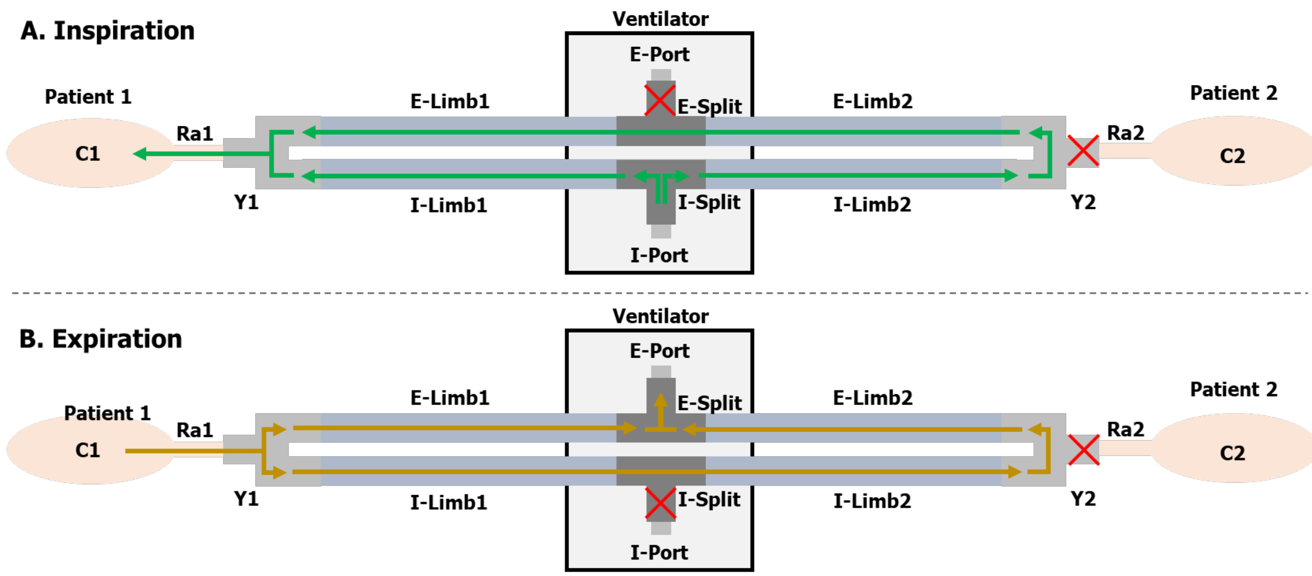

Figure 2: Flow of gas in the circuit when the connection to Patient 2 is fully occluded.

To demonstrate the effects of differing patient airway resistances, a computer simulation of the pneumatic circuit was executed. The parameters used for the simulation were a constant driving inspiratory pressure of 30 cmH_2O, positive end expiratory pressure of 5 cmH_2O, respiratory rate of 20 breaths/min, I:E ratio of 1:2, pulmonary compliance of 30 ml/cmH_2O for both patients, a resistance of 2 $cmH_2O/L/s$ for all limbs of the breathing circuits, and an airway resistance of 10 $cmH_2O/L/s$ for Patient 1. The circuit was simulated for three values of Patient 2 airway resistance: A) 10 $cmH_2O/L/s$ to represent the situation where Patient 1 and 2 are identical, B) 20 $cmH_2O/L/s$ to represent the situation where the patients are not matched, and C) infinite resistance to simulate the situation where the airway is fully occluded or the circuit is capped (as in Figure 2). Circuit compliance and compressibility of gas were neglected for simplicity.

The resulting gas flows to Patient 1 in I-Limb1 and E-Limb1 are shown in Figure 3. As can be seen in Figure 3A, when the patients are identical, inspiratory gas is delivered to the patient exclusively via the inspiratory limb and expiratory gas exits the patient exclusively via the expiratory limb. However, when the airway resistance of Patient 2 is higher than that of Patient 1 (Figure 3B), some expired gas in E-Limb1 is delivered to Patient 1 during inspiration and, during expiration, some expiratory gas from Patient 1 flows into I-Limb1 and will be inspired in the next breath. If the connection to Patient 2 is fully occluded, the retrograde gas flow and resulting rebreathing becomes more severe (Figure 3C).

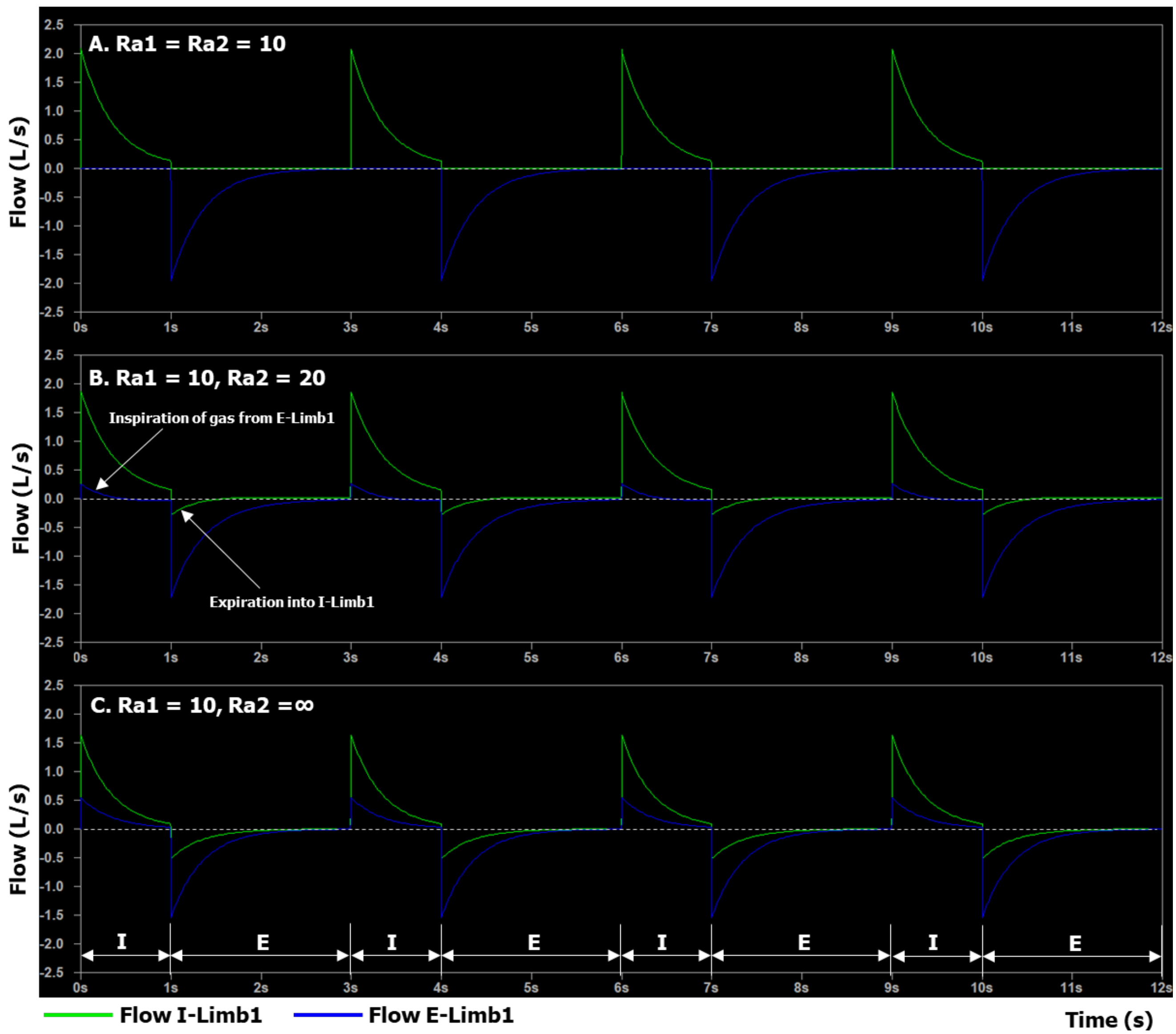

Figure 3: Flow to/from Patient 1 via I-Limb1 and E-limb1 when A) Patient 1 and Patient 2 have identical respiratory physiology; B) the airway resistance of Patient 2 is higher than Patient 1; and C) the connection to Patient 2 is fully occluded. Ra1: Airway resistance of Patient 1; Ra2: Airway resistance of Patient 2.

To demonstrate the effects of differing patient breathing circuit resistances, again, a computer simulation of the pneumatic circuit was executed. The parameters used for the simulation were a constant driving inspiratory pressure of 30 cmH_2O, positive end expiratory pressure of 5 cmH_2O, respiratory rate of 20 breaths/min, I:E ratio of 1:2, pulmonary compliance of 30 ml/cmH_2O for both patients, an airway resistance of 10 cmH_2O/L/s for both patients, and a resistance of 2 cmH_2O/L/s for all limbs of the breathing circuits except E-Limb1. The circuit was simulated for three values of E-Limb1 resistance: A) 2 cmH_2O/L/s to represent the situation where all limbs of the circuits are identical, B) 5 cmH_2O/L/s to represent a small mismatch that may occur, for example, if an expiratory limb filter becomes damp or is a higher resistance model, and C) 15 cmH_2O/L/s to simulate a highly obstructed limb as may occur with a clogged expiratory limb filter or kinked tube. Circuit compliance and compressibility of gas were neglected for simplicity.

The resulting gas flows to Patient 1 in I-Limb1 and E-Limb1 are shown in Figure 4. As can be seen in Figure 4A, when the circuits are identical, inspiratory gas is delivered to the patient exclusively via the inspiratory limb and expiratory gas exits the patient exclusively via the expiratory limb. However, when the expiratory limb resistance of Patient 1 is slightly higher than that of the other circuit limbs (Figure 4B), during expiration, some expiratory gas from Patient 1 flows into I-Limb1 and will be inspired in the next breath. If the expiratory limb of Patient 1 is highly obstructed, the expiratory flow of Patient 1 into I-Limb1 becomes more severe, exceeding the expiratory flow into E-Limb1 (Figure 4C).

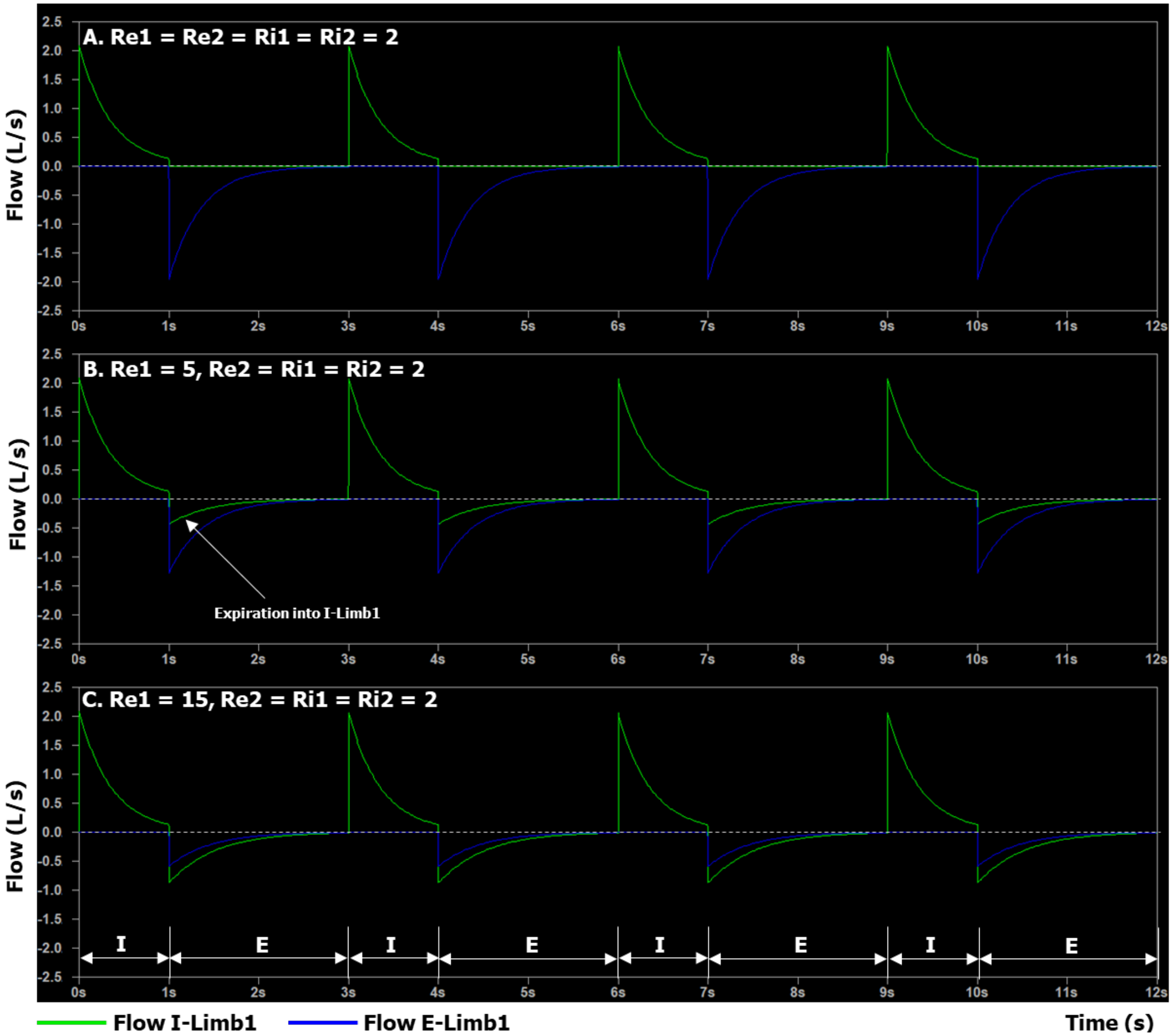

Figure 4: Flow to/from Patient 1 via I-Limb1 and E-limb1 when A) Patient 1 and Patient 2 have identical expiratory limb resistances; B) the expiratory limb resistance of Patient 1 is slightly higher than the other limbs of the breathing circuits; and C) the expiratory limb of Patient 1 is highly obstructed. Re1: Resistance of Patient 1 expiratory limb; Re2: Resistance of Patient 2 expiratory limb; Ri1: Resistance of Patient 1 inspiratory limb; Ri2: Resistance of Patient 2 inspiratory limb.

In order to prevent this potentially hazardous rebreathing, the patient connection ports of the flow-splitting adapters should be fitted with low-resistance respiratory check valves, as shown by the green boxes with blue arrows in Figure 5. Examples of such valves are produced by Qosina (https://www.qosina.com/) under part numbers 97351 and 97352.

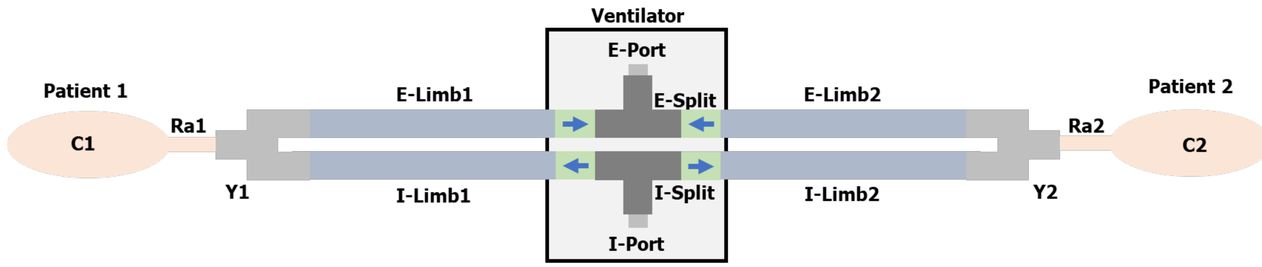

Figure 5: Schematic of ventilator configuration used to ventilate two patients with check valves to prevent rebreathing.

To demonstrate the effect of these check valves, the worst-case conditions of Figure 3C and Figure 4C were simulated again with the addition of check valves to the circuit. The results are shown in Figure 6A and Figure 6B, respectively. These results demonstrate that, with the addition of check valves, inspiratory gas is delivered to the patient exclusively via the inspiratory limb, expiratory gas exits the patient exclusively via the expiratory limb, and no rebreathing occurs, even when the patients and/or breathing circuits are highly mismatched.

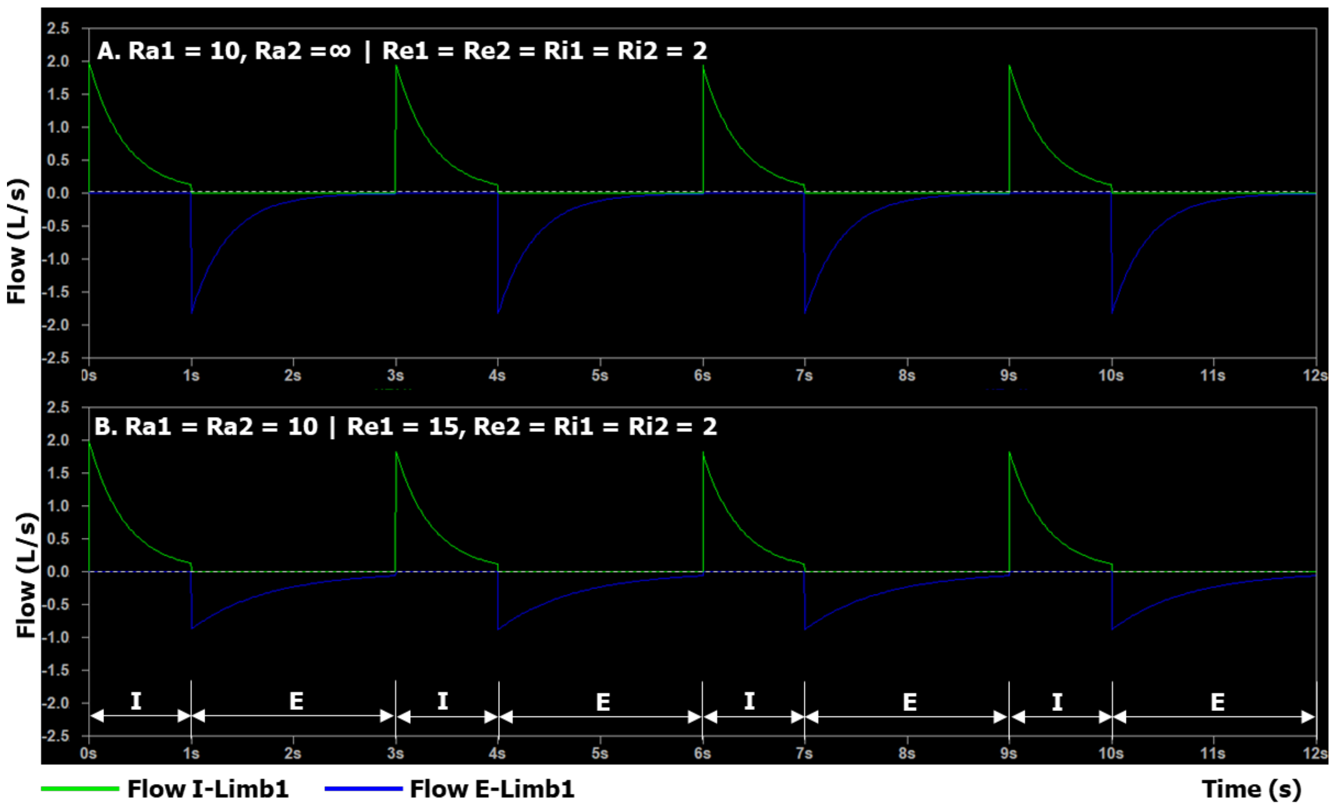

Figure 6: Simulation results of mismatched patients and circuits with the addition of check valves to the circuit. Ra1: Airway resistance of Patient 1; Ra2: Airway resistance of Patient 2; Re1: Resistance of Patient 1 expiratory limb; Re2: Resistance of Patient 2 expiratory limb; Ri1: Resistance of Patient 1 inspiratory limb; Ri2: Resistance of Patient 2 inspiratory limb.

I hope that you will carefully consider the information provided and take all appropriate actions to mitigate the identified risks. Please do not hesitate to contact me with any questions.

Sincerely,

Michael Klein, BASc, MSc