Modification of a domiciliary ventilator to increase FiO_2;

an off label modification which may be of value in COVID-19.

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Running head: Modified domiciliary ventilators for the treatment of Covid-19

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Additional testing data

We tested the machine in spontaneous ventilation mode (S+Trigger). We used different size syringes (10ml, 20ml and 50ml) connected into the patient breathing circuit using a T- piece to simulate inspiratory effort at various trigger sensitivity settings. On the Vivo these are labelled 1-9 with 1 being the easiest to trigger and 9 the hardest. When a 10ml syringe was used the Vivo sensitivity needed to be set at 3 or less to trigger breath, while with a 20ml syringe the sensitivity needed to be set at <5. When using a 50ml syringe sensitivity can be set at 9 or less. We repeated this experiment with and without the modification. There were no measurable difference between the results obtained with the manufacturer's specification and the modified machine. This was expected, because according to the gas flow schematics shown in the revised manuscript, the modification assembly does not directly affect the patient breathing circuit volume to impact the patient inspiratory trigger.

Prompted by R#1 we also considered which other parameters could be potentially impacted by our modification. We reasoned that the modification assembly could potentially obstruct the air inlet port unless it provides enough gas supply at high inspiratory flow demands, and that therefore peak inspiratory phase and expiratory phase flows might be important. We set the Vivo 2 on a mandatory ventilation mode with a target to deliver large tidal volume (1L) at 20 breaths per minute to generate high inspiratory flow. We allowed 10 breaths without modification then placed the modification, without stopping the ventilation, then allowed a further 10 breaths. Both the inspiratory and expiratory peak flows did not change when the modification assembly is fitted. The measured inspiratory peak flow was 85LPM and expiratory peak flow was 68LPM.

In vivo testing

We undertook studies in a single healthy female. These studies were conducted under an ethical approval granted by the Science, Engineering and Technology Research Ethics Committee (SETREC) of Imperial College (20IC5960) and we used the Vivo 2 with and without the modification described in this MS. We measured CO_2 and O_2 (Philips Intellivue anaesthetic gas monitor G5), sampling from a port positioned close to the mask. Over a range of standard pressure settings and modes the average CO2 was 3.6 kPa

With the modification described in the paper we found the following at CPAP +15 cm H_2O; as is evident CO2 retention did not occur

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Ventilator condition	**Oxygen concentration**	**Breathing condition**	**CO_2 (kPa)**	**O_2 (%)**
Manufacturer spec	RA	Quiet Breathing	3.8	20
Modified device	RA	Quiet Breathing	3.5	20
Manufacturer spec	4 litres	Quiet Breathing	3.4	36
Modified device	4 litres	Quiet Breathing	3.8	37
Manufacturer spec	8 litres	Quiet Breathing	3.6	59
Modified device	8 litres	Quiet Breathing	3.8	60
Manufacturer spec	8 litres	Hyperventilation	3.8	30
Modified device	8 litres	Hyperventilation	3.8	46

It is evident that the value of the modification depends critically on the minute ventilation of the patient

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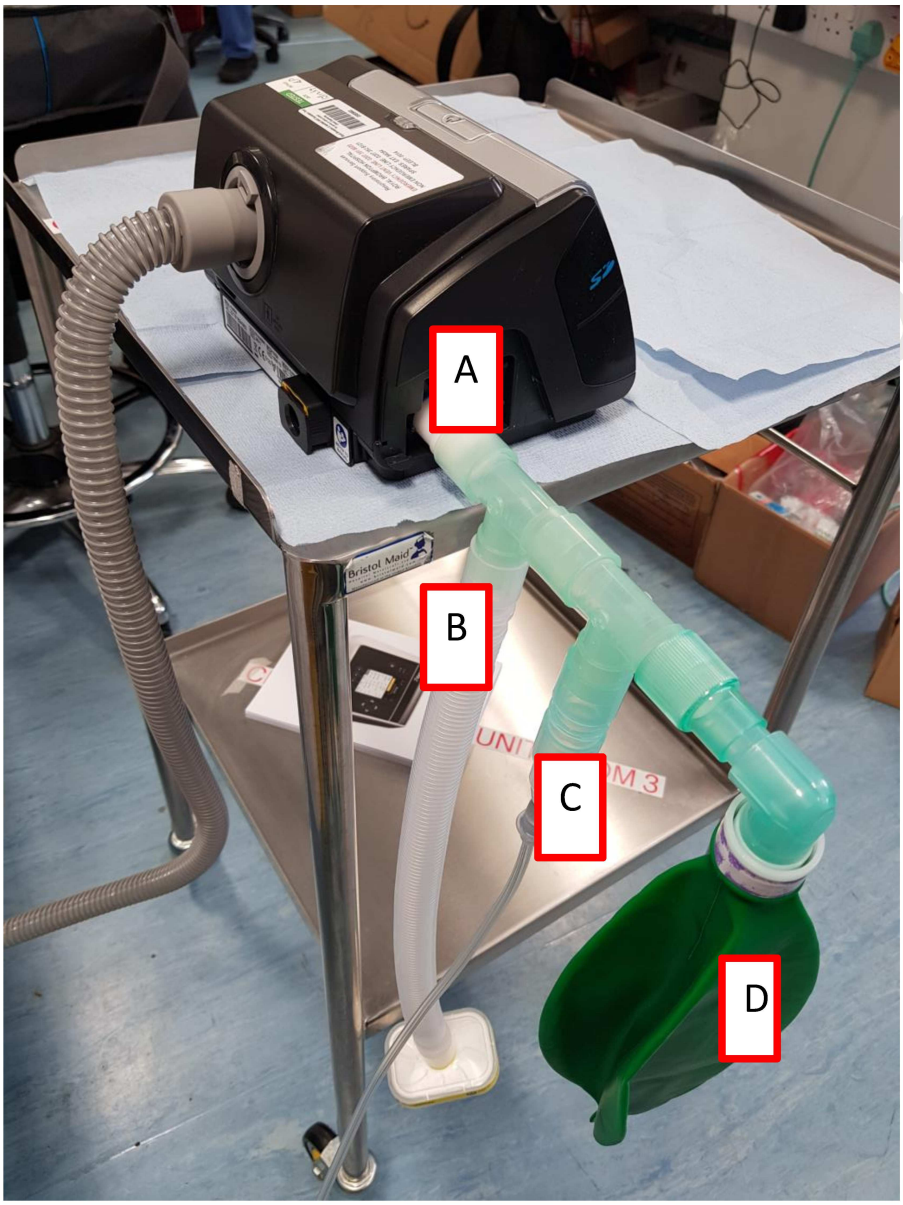
Figure E1

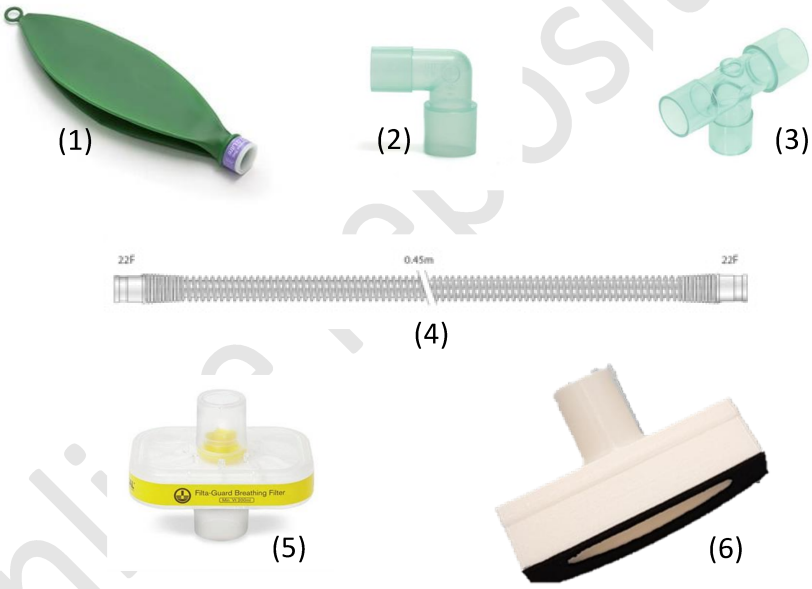
Because the Lumis 150 ventilator, in common with other devices, lacks a dedicated air inlet facility we designed and printed an adaptor for the air inlet (A). Air can till enter via filter protected T piece (B) placed proximal to the oxygen source (C) with the reservoir (D) placed adjacent to this.



Instruction on how to build a Vivo 2 modification assembly to improve FiO_2

Components required:

1. One 2 litres reservoir bag with 22 mm female connector neck – e.g. Intersurgical, part number – 2820000.
2. One fixed elbow 22 mm female – 22 mm male connector – e.g. Intersurgical, part number – 1992000
3. One T-piece connector 22mm male – 22 mm male – 22 mm female – e.g. Intersurgical, part number – 1982000
4. A short (~ 40 cm) breathing tube with 22 mm female on either end – e.g. Intersurgical, part number – 8746004
5. Breathing filter – e.g. Intersurgical, part number – 1944000 Filta-Guard
6. A manufactured or 3D printed adapter that snuggly fit in the air inlet port of the Vivo 2 machine presenting a 22 mm connector end, externally. An STL file is provided as a supplemental file: Vivo Filter adapter -REV C- v2.



Assembling:

a) Connect the reservoir bag (1) with 22F to the 22M of the elbow connector (2)
b) Connect the other end of the elbow connector 22F to the 22M end (not the middle connector) of the T-piece connector (3)
c) Connect one end of the short breathing tube (4) with 22F to the middle 22M connector of the T-piece
d) Connect the other end of the breathing tube 22F to the bacterial filter (5) with 22M end
e) Remove the air filter and its holder from the Vivo 2 and place the 3-D printed adapter snuggly into the air inlet port location as shown below

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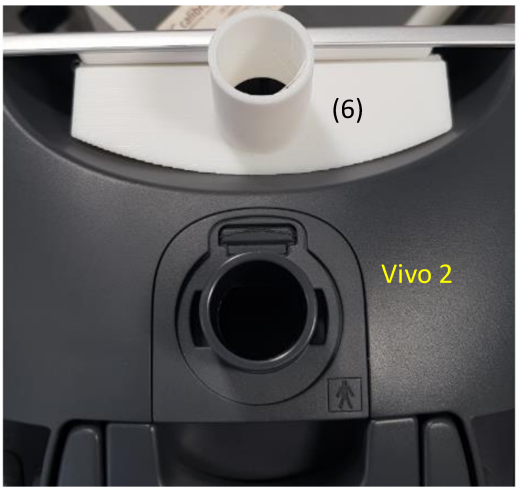

f) Connect the 22F end of the T-piece to the 22M end of the 3-D printed adapter that has already been attached to the Vivo 2 as shown below

g) The Vivo 2 has now been modified. Oxygen can be supplied as normal through the supplemental oxygen port and the machine can be operated as usual using the desired ventilation mode and settings.

*Other connectors may be employed to achieve the same result, for example straight sex changer connectors can be utilised where necessary.

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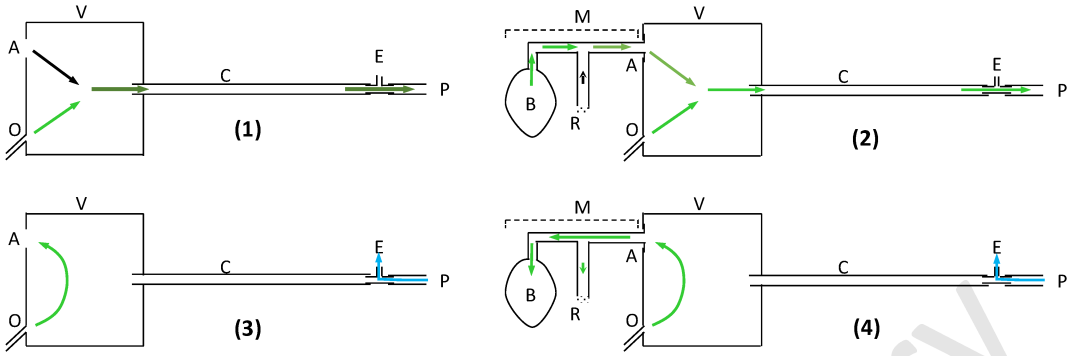
Below is a simplified gas flow schematics of the Vivo 2 modification.



Supplemental Figure 1: Simplified gas flow schematics of the Vivo 2 ventilatory system pre and post modification.

Panels (1) and (2) show the gas flow schematics of the inspiratory phase before and after modification, respectively. Panels (3) and (4) show the expiratory flow schematics before and after modification, respectively.

In normal use of the pre-modification inspiratory phase (panel 1) the ventilator 'V' mixes room air (black arrow) entrained through the room air inlet port 'A', with the supplemental oxygen (green arrow) supplied through the dedicated constant flow oxygen inlet port 'O'. The mixed gas (pine arrow) is delivered to the patient 'P' through the patient breathing circuit 'C'. During the expiratory phase of the unmodified system (panel 3), the CO_2 rich expired gas (blue arrow) from the patient 'P' escapes through the exhalation leak port 'E'. Meanwhile, the constantly flowing supplied oxygen through port 'O' escapes to the atmosphere through the air inlet port 'A'. In the modified system, during expiration (panel 4) the oxygen that normally would have escaped to the atmosphere through the air inlet port 'A' is trapped in the modification assembly 'M'. The majority of the oxygen flows into the reservoir bag 'B'. In the event that excess pressure builds in the bag 'B' some amount of oxygen may escape to the atmosphere through an air inlet port with a fitted bacterial filter 'R'. During this expiratory phase, the CO_2 rich expired gas (blue arrow) from the patient 'P' escapes through the exhalation leak port 'E' same way as the pre modified system (panel 3). In the modified system, during the inspiratory phase (panel 2), the supplemental oxygen (green arrow), supplied through the constant flow oxygen inlet port 'O', mixes with the already oxygen rich gas (pine arrow) from the modification assembly 'M' (captured in the reservoir bag 'B' during the previous respiratory cycle). This provides a higher oxygen concentration gas mixture to be delivered by the ventilator to the patient 'P' compared with the gas mixture of pre modification.

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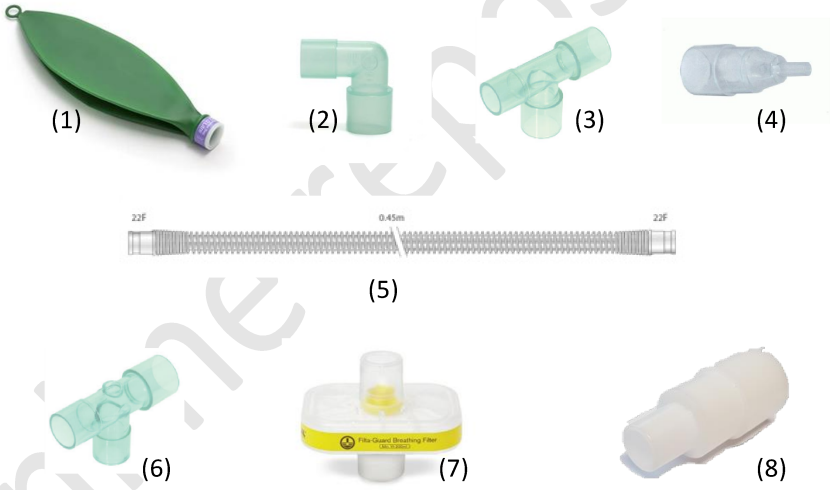
Instruction on how to build a Lumis 150 modification assembly to improve FiO_2

Components required:

7. One 2 litres reservoir bag with 22 mm female connector neck – e.g. Intersurgical, part number – 2820000.
8. One fixed elbow 22 mm female – 22 mm male connector – e.g. Intersurgical, part number – 1992000
9. One T-piece connector 22mm male – 22 mm female – 22 mm female – e.g. Intersurgical, part number – 1983000
10. One straight connector 22mm male – 6mm oxygen stem – e.g. Intersurgical, part number - 1968000
11. A short (~ 40 cm) breathing tube with 22 mm female on either end – e.g. Intersurgical, part number – 8746004
12. One T-piece connector 22mm male – 22 mm male – 22 mm female – e.g. Intersurgical, part number – 1982000
13. Breathing filter – e.g. Intersurgical, part number – 1944000 Filta-Guard
14. A manufactured or 3D printed adapter that snuggly fit in the air inlet port of the Lumis 150 machine presenting a 22 mm male connector end, externally. An STL file is provided as a supplemental file: Lumis filter adapter v2



Assembling:

h) Connect the reservoir bag (1) with 22F to the 22M of the elbow connector (2)
i) Connect the other end of the elbow connector 22F to the 22M end of the T-piece connector (3)
j) Connect the straight connector (4) 22M to the middle connector of the T-piece (3) 22F, leave the other side of the straight connector available as oxygen inlet port
k) Connect the third connector of the T-piece (3) 22F to the 22M of the second T-piece (6) – (not the middle connector)
l) Connect one end of the short breathing tube (5) with 22F to the middle 22M connector of the second T-piece (6)
m) Connect the other end of the breathing tube 22F to the bacterial filter (7) with 22M end

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n) Remove the air filter and its holder from the Lumis 150 air inlet port and place the manufactured or 3-D printed adapter snuggly into the air inlet port location as shown below

o) Connect the 22F end of the second T-piece (6) to the 22M end of the 3-D printed adapter that has already been attached to the Lumis 150 as shown below

p) The Lumis 150 has now been modified. Oxygen can be supplied through the 6mm oxygen stem (4) port. The machine can be operated as usual using the desired ventilation mode and settings.

*Other connectors may be employed to achieve the same result, for example straight sex changer connectors can be utilised where necessary.

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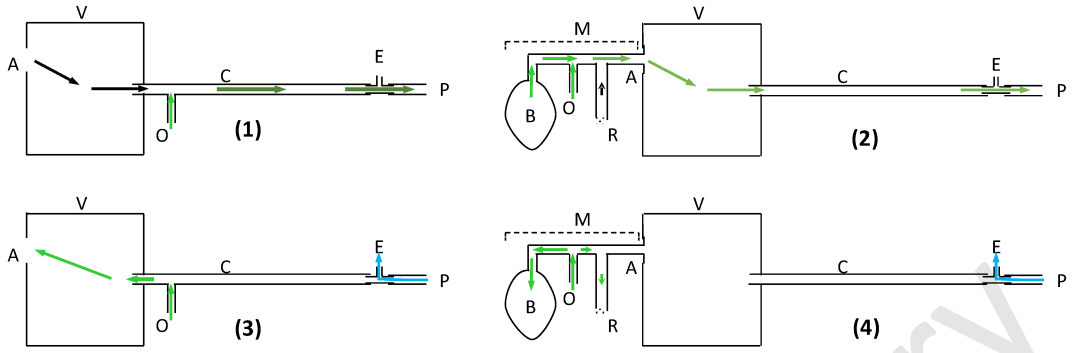
Below is a simplified gas flow schematics of the Lumis 150 modification.



Supplemental Figure 2: Simplified gas flow schematics of the Lumis 150 ventilatory system pre and post modification.

Panels (1) and (2) show the gas flow schematics of the inspiratory phase before and after modification, respectively. Panels (3) and (4) show the expiratory flow schematics before and after modification, respectively.

In normal use the Lumis 150 does not have a dedicated supplemental inlet port. Oxygen is commonly introduced into the patient circuit using a T-piece. If the oxygen flow introduced in the patient circuit is high (e.g. 15 LPM), there is a potential that the ventilator to alarm 'rebreathing' and in some cases cease to operate.

In the pre-modification inspiratory phase (panel 1) the ventilator 'V' entrains room air (black arrow) through the room air inlet port 'A', this is mixed with the supplemental oxygen (green arrow) supplied at a constant flow through a T-piece inlet 'O' connected in the patient breathing circuit. The mixed gas (pine arrow) is delivered to the patient 'P' through the patient breathing circuit 'C'. During the expiratory phase of the unmodified system (panel 3), the CO_2 rich expired gas (blue arrow) from the patient 'P' escapes through the exhalation leak port 'E'. Meanwhile, the constantly flowing supplied oxygen through port 'O' escapes to the atmosphere through the ventilator air inlet port 'A'.

In the modified system, the T-piece inlet 'O' is connected into the modification assembly 'M', rather than the patient breathing circuit. During expiration in the modified system (panel 4) the oxygen that normally would have escaped to the atmosphere through the air inlet port 'A' is trapped in the modification assembly. The majority of the oxygen flows into the reservoir bag 'B' because of the slightly higher resistance of the bacterial filter at the room air outlet 'R'. In the event that excess pressure builds in the bag 'B' some amount of oxygen may escape to the atmosphere through the air inlet port with a fitted bacterial filter 'R'. During this expiratory phase, the CO_2 rich expired gas (blue arrow) from the patient 'P' escapes through the exhalation leak port 'E' same way as the pre modified system (panel 3). In the modified system, during the inspiratory phase (panel 2), the ventilator draws gas through the modification assembly 'M'. The gas is drawn primarily from the constantly supplied oxygen through port 'O' (green arrow) mixed with the high oxygen mixture gas that was trapped in the reservoir bag during the previous breathing cycle (green arrow from bag). Some amount of room air may be drawn into the mixture through the room air inlet port 'R' (small black arrow - this depended on the tidal and minute volume of the respiration – light green arrow). This provides a higher oxygen concentration gas mixture to be delivered by the ventilator to the patient 'P' compared with the gas mixture of pre modification.

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