HARDWARE METAPAPER

A Novel Dual Non-Invasive Ventilator Continuous Positive Airway Pressure Non-Aerosolization Circuit for Emergency Use in the COVID-19 Pandemic

Ted J. Vaughan*, Frank Kirrane†‡, Kevin M. Moerman*§, Tara Cahill†‡, Anthony O’Regan†‡ and Derek T. O’Keeffe*†‡

The COVID-19 pandemic is a public health emergency of unprecedented scale. The surge in clinical cases of patients with severe respiratory illness has overwhelmed the traditional capacity of healthcare systems worldwide. Continuous Positive Airway Pressure (CPAP) delivered through Non-Invasive Ventilation (NIV) has been shown to be useful in caring for patients with COVID-19. In particular patients with early stage milder acute hypoxemic respiratory failure can benefit from NIV CPAP therapy, though there is an acknowledged risk of COVID-19 aerosolization with traditional circuit use. Furthermore, given the surge in clinical care demand, there is an acute global shortage of ventilators, including NIV devices and therefore innovative methods are needed to increase NIV capacity and ameliorate infectious aerosolization. This paper outlines an emergency use modified dual NIV CPAP Circuit that uses a 3D printed splitter designed to work with traditional international NIV CPAP tubing standards and a 3D printed respiratory face mask knuckle to allow for distal expiratory breath exhalation through a viral filter rather than through an open to air proximal valve, which is the traditional NIV CPAP configuration. We expect that this work will increase global NIV CPAP capacity and ameliorate aerosolization of COVID-19 in patients undergoing therapy in an emergency scenario.

Keywords: COVID-19; NIV; 3D Printing; Ventilation; Aerosolization; Respiratory

Metadata Overview
• Project repository: https://github.com/3DNIV/3DNIV
• Archived version DOI: http://doi.org/10.5281/zenodo.3818306
• Licenses: All hardware is licensed under the CERN-OHL v2 S (CERN Open Hardware Licence Version 2 – Strongly Reciprocal) (see also: https://cern-ohl.web.cern.ch/). All project documentation content is licensed under CC-BY-4.0. The G-code is licensed under the GNU Affero General Public License.
• Target group: medical professionals and biomedical engineers
• Skills required: 3D printing – easy; assembly of ventilation circuit and tubing – relatively easy
• Replication: No other builds known to the authors so far.

(1) Overview
Introduction
Coronavirus disease 2019 (COVID-19) is an infectious disease caused by a newly discovered coronavirus: SARS-CoV-2. COVID-19 is an unprecedented global health emergency. In the first half of 2020, over 9 million humans have been infected with over 500,000 deaths (https://coronavirus.jhu.edu/map.html). The COVID-19 virus primarily causes a respiratory infection and is mainly transmitted through aerosolized droplets (e.g. coughs, sneezes, breathing) or contact with contaminated surfaces. About 1:6 people who contract COVID-19 become seriously ill and develop difficulty breathing, requiring hospitalisation (WHO, 2020).

The initial stage of COVID-19 severe acute respiratory infection (SARI) is Type 1 respiratory failure (T1RF), which is characterised by low blood oxygen levels (hypoxemia, $\downarrow P_{O_2}$) with either normal (normocapnia, $\leftrightarrow P_{CO_2}$) or low levels of blood carbon dioxide (hypocapnia, $\downarrow P_{CO_2}$). In COVID-19, this T1RF occurs due to inadequate gas exchange by the respiratory system due to lung parenchymal disease causing a diffusion problem for
oxygen entering the capillaries (WHO, 2020). TIRF usually requires respiratory support which includes methods such as High Flow Nasal Cannulae (HFNC) O$_2$ therapy to achieve P$_{O_2}$ (8-10kPa), S$_{O_2}$ >90%. Lack of a response to oxygen therapy requires escalation to machine based Non-invasive Ventilation (NIV) and ultimately Invasive Mechanical Ventilation (IMV) where required. However, one of the challenges of COVID-19 pandemic has been the global shortage of ventilators (Truog et al., 2020) and subsequent rationing of resources due to limited capacity (FDA, 2020). NIV CPAP has emerged as preferred form of NIV support in the management of the hypoxaemic for COVID-19 patients outside of ICU, with some data suggesting that it can result in the avoidance of IMV (McEnery et al., 2020).

A system-level diagram of a standard NIV CPAP circuit that would typically be found in a hospital setting is shown in Figure 1A. A pressure-control ventilator machine (e.g. Figure 1B, see device A in Table 1) is used to deliver a fixed positive pressure of 10 cm H$_2$O (FiO$_2$ 0.6) to patients through a face mask (e.g. Figure 1D, see device B in Table 1), which is connected through 22mm corrugated tubing (e.g. Figure 1C, see component C in Table 1). The circuit contains an inspiratory viral filter (component D in Table 1) at the ventilator connection and an anti-asphyxiation, knuckle vented valve at the tubing – face mask connection, which expires to the room.

NIV CPAP supplies a constant fixed positive pressure airflow at 10 cm H$_2$O (FiO$_2$ 0.6) to stent the airways open in patients who are breathing spontaneously. It is important to note that CPAP systems do not cycle, but instead provide a positive pressure throughout inspiration and expiration respiratory phases. Patients must initiate their own breaths and CPAP systems do not provide pressures above the level of the set CPAP level (NIH, 2020). In March 2020, the US Food and Drug Administration
The overall design and implementation of the modified Dual NIV CPAP circuit.

**Overall implementation and design**

The modified Dual NIV CPAP circuit is shown below in Figure 2. This circuit introduces two novel components: 1) a single 3D printed T-piece splitter with dual inspiratory viral filters at the ventilator end, and 2) a modified 3D printed non-vented knuckle at the tubing – face mask interface. Instead of having an anti-asphyxiation valve, the knuckle connects to the tubing through an expiratory viral filter to prevent harmful aerosolised particles being transmitted to the outer environment.

We proposed to use our open source 3D printed splitter and respiratory knuckle in any globalised standard NIV CPAP circuit, thereby allowing maximum impact of our proposal. Currently only the 3D printed components are designed and provided open source. Combined with the commercial/standard (non-open source) clinical hardware they provide a rapid solution to increase capacity in the emergency situation that is the COVID-19 pandemic. In principle open source ventilator alternatives can be proposed. However, what is proposed here, is a much more rapid solution, and requires a minimal amount of clinical validation of non-standard components.

**Computer Aided Design (CAD) and 3D printing**

The two novel components were designed using the open source Computer Aided Design (CAD) software FreeCAD (version 0.19, revision 20802, https://www.freecadweb.org/). Both parts are 3D printed from Polylactic Acid (PLA) with an Ultimaker S5 (Ultimaker BV, The Netherlands) using an extrusion-based layer-by-layer process at a resolution of 200 micron and 100% infill to prevent air leaks (note however that the ventilator employed does

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**Table 1:** Required standard/commercial devices and components.

<table>
<thead>
<tr>
<th>ID</th>
<th>Device/component</th>
<th>#</th>
<th>Product, manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Ventilator</td>
<td>1</td>
<td>Philips Respironics Trilogy 202™, Koninklijke Philips NV</td>
</tr>
<tr>
<td>B</td>
<td>Face mask</td>
<td>2</td>
<td>BiTac MaxShield™, Pulmodyne</td>
</tr>
<tr>
<td>C</td>
<td>Respirator tubing</td>
<td>1</td>
<td>BiTac™ Circuit, Pulmodyne</td>
</tr>
<tr>
<td>D</td>
<td>Inspiratory filter</td>
<td>2</td>
<td>Servo Duo Guard™, Maquet Getinge</td>
</tr>
<tr>
<td>E</td>
<td>Expiratory filter</td>
<td>2</td>
<td>VIROBAC II™ viral/bacterial filter, 20801, King Systems</td>
</tr>
<tr>
<td>F</td>
<td>Disinfectant</td>
<td>1</td>
<td>Actichlor™ Plus, Ecolab</td>
</tr>
<tr>
<td>G</td>
<td>Test lungs</td>
<td>2</td>
<td>Adult 190 (1 Liter) 6006832, Maquet Getinge</td>
</tr>
</tbody>
</table>
automatically compensate to keep the required pressure if minor leaks occur i.e. by increasing its output volume). The Cura Ultimaker Projects and G-Code files have also been made available in the project repository.

PLA is a biodegradable thermoplastic material commonly used in medical products (e.g. sutures [Madhavan Nampoothiri et al., 2010; Ulery et al., 2011]). While PLA is one of the most widely-used filament materials for desktop 3D printing, it should be noted that the final parts will vary across printing platforms depending on the constitutive PLA formulation, the addition of dyes to filaments, and/or the processing parameters used during the printing process itself (e.g. temperature, feed rate). In this case, we used the Ultimaker Tough PLA 2.85 mm black filament (see also the filament data-sheet), which was the recommended filament for the Ultimaker S5 printer. While PLA is biodegradable, this only takes place in the presence of water, with the process taking well over 2 years. PLA will remain in-tact for very long periods when stored in a cool, dry place.

The 3D printed T-Piece splitter

The T-piece splitter (Male-Male-Female) design is highlighted in Figure 3A. The part was designed to be compatible with the standard 22mm breathing circuit tubing. This female port of the T-piece attaches directly to the ventilator outflow port and splits the airflow into two channels. Standard respirator tubing is used to create the two limbs of the dual circuit, which is connected to the male ports of the T-piece splitter via two separate inspiratory viral filters (component D in Table 1) to protect the patient against potential harmful particles originating from the ventilator end.

The CAD design (Figure 3A) includes two thin features, which are also labelled in the technical drawing, which are not part of the final design but are “enforced” print support regions. These manually defined print support features were used to avoid the Ultimaker 3D printing software from proposing a sub-optimal amount of support material in these regions, and should be removed after 3D printing is completed.

The 3D Printed non-vented mask-tubing connector knuckle

The knuckle valve component is highlighted in Figure 4 and was designed to fit the 22mm circuit tubing to the 32mm swivel port on the face mask. This modified design replaces the standard version that typically includes an anti-asphyxiation valve that has the potential to expire harmful viral particles to the room. Instead, this modified respiratory knuckle is a closed section that connects to the 22mm circuit tubing via a virus filter (component E in Table 1) prior to expiration, thereby reducing the risk of viral aerosolization being released during operation.

(2) Quality control

Safety

To facilitate the emergency use of the bespoke design & 3D printed components to clinical use, the Galway University Hospital Medical Device Equipment Management Policy (Ref EF-SD-0052, Nov 2019), which is based on national Health Service Executive (HSE) policy (HSE, 2020), was consulted, particularly the sections on the modification of medical devices. A risk assessment was carried out to ensure the safety of the innovative circuit proposal, with particular consideration to robustness, disinfection, design dimensions, leak appraisal and evaluation of legal and ethical considerations during emergency use. The 3D printed components were disinfected by soaking in chlorine-based disinfectant (F in Table 1) for 2 hours at 1000ppm using 1 × 1.7g tablet in 1 Litre of water. These components underwent manual assessment
for robustness and visual checks carried out for unwanted deformation or material damage post-disinfection.

**General testing**

The Dual NIV CPAP Circuit was tested using a standard NIV machine (device A in Table 1) in CPAP configuration to ensure it could deliver 10 cm H₂O to two 1L test lungs (device G in Table 1) (see Figure 5), for a duration of at least 5 minutes. The 1L test lungs had a compliance of 16 mL/cm H₂O and a resistance of 20 cm H₂O/L/s. Based on this it was established that the dual NIV CPAP circuit maintained a pressure of 10 cm H₂O with both lungs inflated for the duration of the testing timeframe.

It may be important to note that this would be a standard test used to verify the operation of a single arm NIV CPAP circuit in a hospital setting. Under normal operation, NIV CPAP is typically designed to accommodate a certain amount of leakage in the circuit, in particular around the face mask. In particular, NIV CPAP automatically regulates the air flow in the circuit to ensure that pressure being delivered remains at 10 cm H₂O in normal circumstances. This was a motivating factor in splitting the NIV CPAP circuit as it was hypothesized that the ventilator would automatically regulate the flow, maintaining it at 10 cm H₂O, and facilitating delivery to both test lungs. Following the above testing, developers manually verified the function and ease of breathing with the NIV CPAP circuit (featuring both the splitter and the filtered expiratory valve), by simply wearing the mask and breathing through the system normally.

Further to the above functional testing, the University Hospital Galway Ireland approved the use of our design, and we can report the system was successfully deployed in patient care during the COVID-19 pandemic.

(3) Application

**Use case(s)**

The modified Dual NIV CPAP Circuit is intended for use in emergency situations only, where clinical demand for NIV CPAP machines exceeds hospital capacity. The modi-
Reused respiratory knuckle used at the distal end may also be used on single circuit devices to reduce the risk of viral aerosol being released during general operation of NIV CPAP.

Reuse potential and adaptability
The project repository (found on GitHub https://github.com/3DNIV/3DNIV), and the archived version (Vaughan et al., 2020), contain the CAD source files, G-CODE, and documentation needed for this project. Users may reuse and adapt these files, as outlined in the open source licenses used. The source CAD files are for the open source software FreeCAD (available through https://www.freecadweb.org/). To maximise the potential for others to use and build upon this work, the project repository contains the following CAD files:

- The FreeCAD source files (.FCStd) which can be reused, altered by others.
- The CAD vendor-neutral Initial Graphics Exchange Specification (IGES) format (.IGES)
- STL (stereolithography) files (.STL)
- 3D Manufacturing Format files (.3mf)

In addition detailed technical drawings have been provided.

The proposed T-piece and knuckle components are here 3D printed in PLA using an Ultimaker S5 (Ultimaker BV, The Netherlands), and with settings (200 micron layers, 100% infill) to ensure an air-tight material is obtained. Others may wish to manufacture these parts using different 3D printers and different materials (such as ABS). Furthermore, the designs can be altered to suit available materials and manufacturing methods. The documentation is available at the GitHub project repository, and contains easy to follow assembly instructions. The GitHub repository includes an issue tracker where issues, comments, questions, and feature

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**Figure 4:** The novel knuckle component. A CAD file view (A), part of the technical drawing showing characteristic dimensions (B), the PLA 3D printed knuckle (C), and the knuckle connected to a face mask and tubing (D).
Dual NIV CPAP circuit is compatible with a wide range of similar equipment/hardware models. Furthermore, since the CAD source files have been provided the parts can easily be adjusted to fit the dimensions of other hardware components used.

Hardware documentation and files location
The project repository is where the active development for this project takes place and where the community may interact with the content and the developers. The content of the repository, for the first version of the hardware proposed, has also been archived on ZENODO (Vaughan et al., 2020).

Project repository: https://github.com/3DNIV/3DNIV
Hardware licence: CERN Open Hardware Licence Version 2 – Strongly Reciprocal (see also: https://cern-ohl.web.cern.ch/).
Content licence: CC-BY-4.0
Persistent identifier for archived release: 10.5281/zenodo.3818306
Archived release tag: v1.0
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(5) Discussion
Due to the COVID-19 pandemic and potential emergency clinical need, we have developed and described a potential methodology for doubling NIV capacity and preventing viral aerosolization using standard and bespoke 3D printed components. Our innovative dual circuit design from a single NIV CPAP machine uses a custom made splitter and incorporates a novel bespoke respiratory knuckle using 3D printed components, which we have made available through open access repositories. We have carried out a comprehensive local risk assessment which has confirmed that the 3D printed components are safe and suitable for use in an emergency.

Here we present the use of simple 3D printed components to double the capacity of a NIV CPAP circuit in emergency situations. The limiting factor is the actual NIV CPAP machines’ capability to provide the clinician selected pressure (e.g. 10 cm/H₂O). Here we verified that our NIV CPAP machine, through the use of the test lungs and user assessment, can compensate sufficiently to deliver the set-pressure to an additional face mask by monitoring the NIV CPAP machine pressure display. Splitting the NIV CPAP machine output to more than the two facemask circuits that we have done, could be explored by others but would be NIV CPAP machine dependent.

Acknowledgements
Construction and testing of the novel NIV circuit was completed at Galway University Hospital Ireland in conjunction with input from the Biomedical Engineering department at the National University of Ireland Galway.

Competing Interests
The authors have no competing interests to declare.

Figure 5: Testing of the T-piece splitter component with a NIV CPAP machine and test lung setup.
References


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