***Tyndall National Institute***
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# DMask.ie Solution

## Supporting the Global fight against COVID19

*Reconfigured masks for non-invasive ventilation of COVID19 patients*

### Overview

The majority of ill people suffering from Covid19 do not need high-end invasive ventilators and are not admitted to the ICU. Many must be cared for in large open style medical wards and without isolation.

Reports from Wuhan, Italy and France indicate that up to 80% of patients can be treated with existing low end respiratory or non-invasive (NIV) equipment. This early intervention reduces the pressure on ICU.

However, the use of existing NIV masks in these environments is believed to have led to cross infection due to aerosolization of virus particles, impacting other patients and healthcare staff. This presents the biggest barrier to adoption of NIV for COVID-19 patients.

As a result, we have seen the emergency deployment of sealed masks fitted with filters to contain the aerosolized virus particles. The DMASK project has followed this experience and built capacity to provide a similar emergency capability in Ireland.

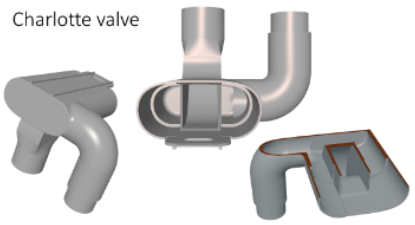


*Figure 1. Charlotte Valve*
https://www.isinnova.it/wp-content/uploads/2020/03/charlotte-valve.zip


*Figure 2. Charlotte Valve Snorkel Replacement*
https://www.decathlon.co.uk/C-2455105-easybreath-masks

### Background

Based on global data, up to 25% of COVID19 patients have been hospitalised. Statistics from Italy (n=19,166) suggest that ventilators are needed to treat critical patients only, representing 5% of all cases. In Italy at present, the standard of care is 40 to 50% FiO2 with 7.5 to10 cm H2O CPAP.

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This front-line data suggests that the global shortage of ICU ventilators could be radically addressed by applying less invasive and readily available respiratory support earlier in the course of treatment versus a step-up from a 4 LPM oxygen cannula to intubation on a high-end ventilator.

Based on feedback from Wuhan, two concerns need to be addressed to allow non-invasive ventilators (e.g. CPAP, BIPAP machines) to be deployed:

- Masks with leak ports cause the risk of aerosolization of virus particles, impacting patients and healthcare staff.
- Many basic CPAP systems do not support the delivery of elevated levels of FiO2.

Tyndall National Institute is part of an international, humanitarian consortium of volunteers with domain expertise in medical devices, clinical healthcare, R&D, 3D printing, international supply-chain logistics and high-volume production which is addressing these issues and delivering a graduated set of respiratory support solutions for emergency use in the global fight against COVID19.

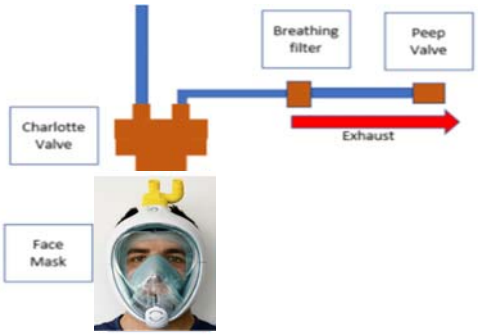


*Figure 3. Configuration*

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## Clinical Feedback

- Cork University Hospital (CUH): Dr. Marcus Kennedy consultant Respiratory Physician
- Beaumont Hospital, Dublin: Prof. Ross Morgan, Respiratory Medicine
- Mater Hospital, Dublin: Mr. Andrew Kennedy, Chief Biomedical Engineer

Feedback to date is positive. The following points are worth noting:

- All groups successfully connected the mask and charlotte valve into a circuit on their own and were able to test its performance and clinical use for initial feedback. The mask functions and aligns well with different ventilation circuits in common clinical use.
- This solution reduces the transmission of the virus through the exhalation of the patient. The patient exhaled air (aerosolization) is principally contained in the mask and it is exhaled through an outlet valve with a standard virus filter attached. This offers additional protection to staff and other non-infected patients who maybe nearby.
- The mask is useable in an emergency situation where there is no supply of standard NIV patient interfaces (masks and other vital circuit components).
  The mask solution may be particularly useful in the earlier stages of ventilation NIV as would be seen in an Emergency Dept. and where the level of patient supervision is higher.

### International Feedback

We have also received significant feedback internationally, primarily from Italy, where the modified scuba mask has been used extensively in the red zone. The following is a commentary from one of the Biomed Engineers in a hospital in Italy:

'They (Clinicians) didn't notice any difficulty in the patients with respiratory problems as the masks with the Charlotte valve can guarantee a constant flow of air in the mask and can clear out the CO2 basically on its own. They use a PEEP valve to help the breathing anyway. They have measured the loss of oxygen and they haven't found any leak, it's almost perfect'.

## Tyndall and its collaborators can provide access to:

- Path to production of the solution in volume
- Optimised open-source 3D drawings of Charlotte valve adaptors
- 3D printing of appropriate Charlotte valve adaptor in prototype and small-to-medium volume quantities
- Interaction with hospital clinicians and consultants and medical device designers
- Detailed documentation of use-case scenarios and associated Bill of Materials in a range of emergency healthcare settings
- Access to experts in supply chain logistics and high-volume manufacturing in Ireland, Europe and China.

## DMask Use-case Scenarios:

The schematics on the following pages present connection and parts details for three application scenarios.

- Solution 1 – Basic Application with Mask and Valve Adaptor for Low-Flow O2 Supply
- Solution 2 – High-Flow CPAP Device or BiPAP/CPAP NIV System
  - Setup 1 – CPAP with Flow Generator
  - Setup 2 – CPAP/BiPAP Machine
- Solution 3 – Complete CPAP Solution

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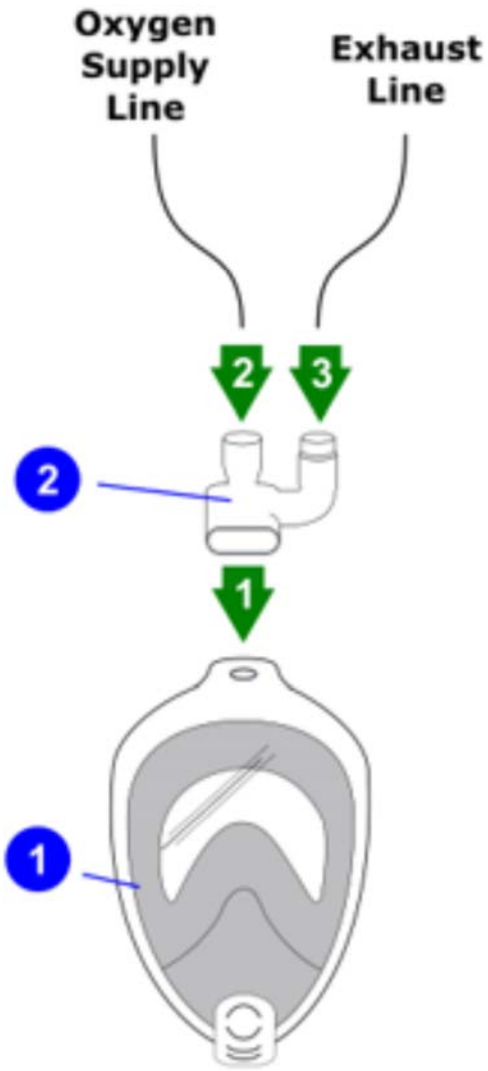
# DMask Use-case Scenarios

## Solution 1 – Basic Application with Mask and Valve Adaptor for Low-Flow O2 Supply




**Components**

1. Mask
2. Charlotte Valve Adaptor

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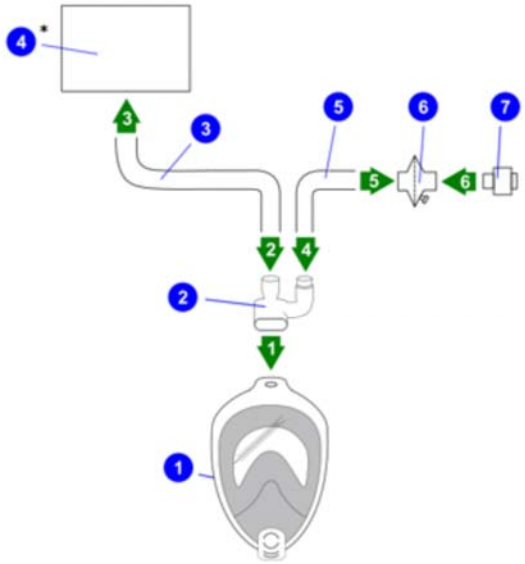
# DMask Use-case Scenarios

## Solution 2 – High-Flow CPAP Device or BiPAP/CPAP NIV System

### Setup 1 – CPAP with Flow Generator



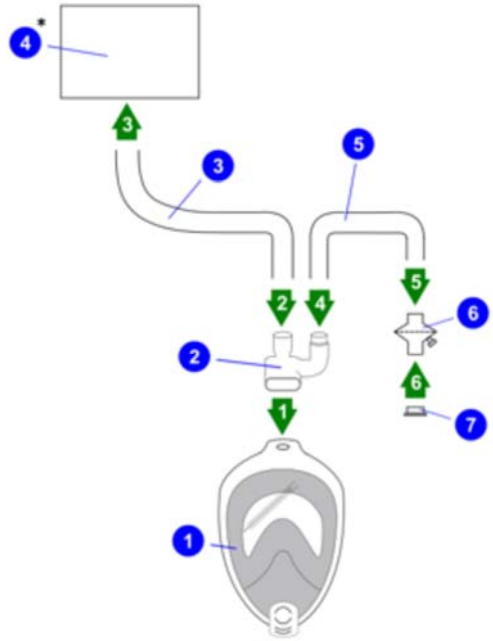
**Components**

1. Mask
2. Charlotte Valve Adaptor
3. 2m Tube
4. Generator*
5. ½m Tube
6. Ported Filter
7. Adjustable PEEP Valve

* Not included in the CPAP Procedure Pack

**Caution:** The port on item 6 must be closed.

### Setup 2 – CPAP/BiPAP Machine



**Components**

1. Mask
2. Charlotte Valve Adaptor
3. 2m Tube
4. CPAP/BiPAP Machine*
5. ½m Tube
6. Ported Filter
7. Cap End

* Not included in the CPAP Procedure Pack

**Caution:** The port on item 6 must be open for a bi-level configuration.

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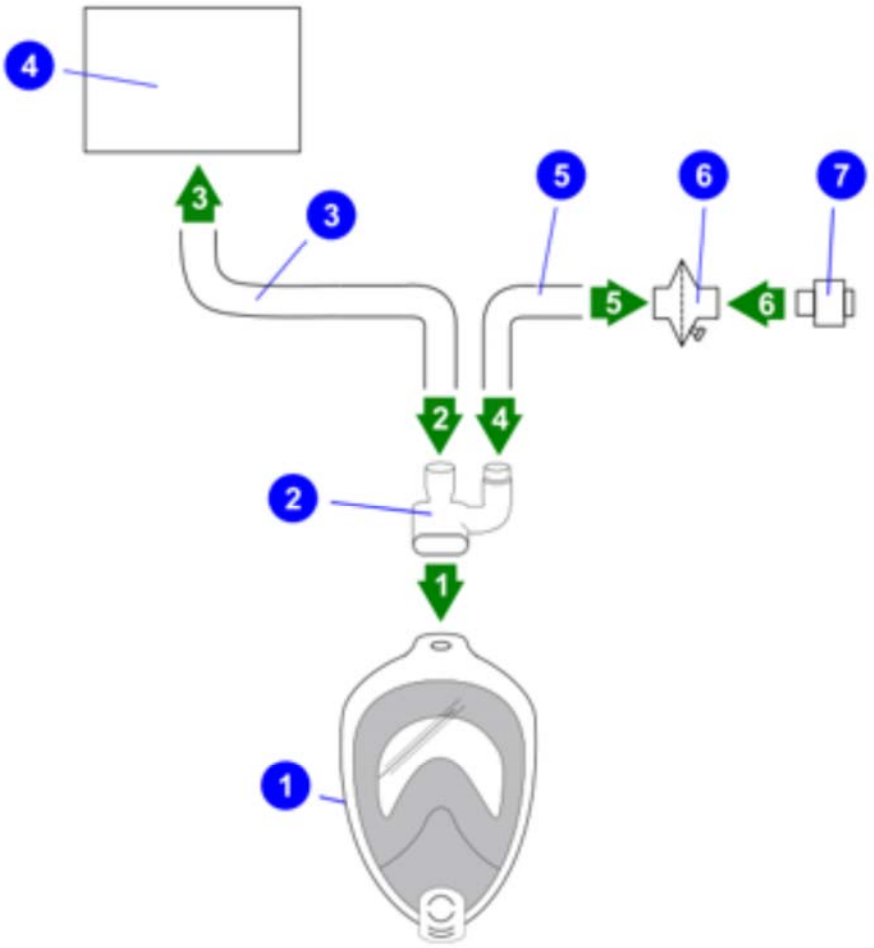
# Use-case Scenarios

## Solution 3 – Complete CPAP Solution (documentation in preparation)




**Components**

1. Mask
2. Charlotte Valve Adaptor
3. 2m Tube
4. Generator
5. ½m Tube
6. Ported Filter
7. PEEP Valve

**Caution:** The port on item 6 must be closed.