

# Production of 3D printed components for ventilation systems: practical hints

For further information please contact 3D4Med laboratory (<https://www.3d4med.eu/contacts/>)

3D printing or Additive Manufacturing (AM) can play a fundamental role in the context of Covid-19 emergency. Due to the unprecedented request of ventilation systems and related components, hospitals rapidly run out of many of them and are struggling to supply. Furthermore, the current emergency poses many new challenges which require a rapid response.

Shortening the time from design to production, AM can help to promptly produce the required stuff. We must underline that we are talking about the production of medical devices, which are subjected to strict certification processes before coming to the market (CE Marking).

The current emergency allows exceptions to the use of not certified medical devices, if it is proved that no certified choices are available and in accordance with the local ethical committee. Furthermore, due to the short time required for the production, it is not possible to run extensive testing campaigns on the components, but each AM operator must pay attention to the selection of materials and technologies that are suitable for the specific application, considering the risk classification of the components and the operational environment.

In the following we summarize the workflow we applied at 3D4Med (<http://www.3d4med.eu>) – the Clinical 3D Printing Laboratory of San Matteo Hospital in Pavia – and Protolab – its engineering counterpart – to produce some of the requested components, along with some practical examples.

1. Definition of the **required cleaning<sup>1</sup>-disinfection<sup>2</sup>-sterilization<sup>3</sup> procedures** [1]: **equipment used for respiratory therapy** (e.g. items that come into contact with mucous membranes) is considered semicritical<sup>4</sup>; such items should be cleaned and then receive at least **high-level disinfection** between patients [4]. High-level disinfection of respiratory equipment is accomplished by **chemical germicides or physical methods** [5]. In the case of plastic parts of respiratory equipment (i.e. connectors) safe methods of disinfection include [1]:

- heat for heat-resistant equipment that can withstand high temperature (e.g. 80 °C); such equipment can be disinfected using a washer–disinfector;
- if a washer or pasteurizer is not available, it is possible to use a high-end or commercial dishwasher with a “sanitize” feature that can reach 70 °C;
- for plastic equipment that may not tolerate 80 °C and for equipment that may be damaged by boiling, or in the absence of the equipment described above, it is possible to use chemical disinfection.

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<sup>1</sup> The removal of dirt from a device or surface, either by physically scrubbing with a surfactant or detergent and water, or through an energy-based process (e.g. ultrasonic cleaner) [1].

<sup>2</sup> A process that eliminates all viable pathogenic microorganisms (other than bacterial spores) from inanimate objects [1].

<sup>3</sup> A process that eliminates, removes, kills, or deactivates all microorganism on the surface of an article or fluid to prevent disease transmission [2].

<sup>4</sup> According to Spaulding's classification [3], semicritical items are devices that come in contact with non-intact skin or mucous membranes but do not penetrate them.

The simplest and fastest solution not requiring the availability of specific instrumentation is chemical disinfection using hospital disinfectants active against viruses [6].

2. Evaluation of available commercial **disinfectants against viruses**, tested on previous Coronaviruses (SARS-CoV, HCoV-229E, MHV-2, MHV-N, CCV, TGEV) [7]:
  - 0.1% sodium hypochlorite (dilution 1:50 if household bleach at an initial concentration of 5% is used) after cleaning with a neutral detergent;
  - 70% concentration of ethanol after cleaning with a neutral detergent, for surfaces that may become damaged by sodium hypochlorite;
  - Sodium dichloroisocyanurate dihydrate (NADCC). Avoid contact with easily oxidizable organic materials: ammonia, urea or similar nitrogen containing compounds; inorganic reducing compounds; floor sweeping compounds; calcium hypochlorite and alkalis [8].

3. Evaluation of the compatibility<sup>5</sup> of available commercial **disinfectants with 3D printed materials**.

As there is no perfect correspondence between commercially available disinfectants which have been proven effective in eliminating coronaviruses and the ones recommended by manufacturers of 3D printing materials, resistance tests to disinfection should be carried out.

Please refer to the technical datasheet of the 3D printing material or contact the material producer for further information.

According to our experience:

- Sodium dichloroisocyanurate dihydrate (NADCC): thermoplastic polymers Acrylonitrile Butadiene Styrene (ABS) and Acrylonitrile Styrene Acrylate (ASA) are proved to be chemical resistant.
- IsoPropyl Alcohol (IPA): IPA is quite similar to ethanol - one of the recommended disinfectants - and most photopolymer resins are proved to be chemical resistant to it. We commonly use pure IPA for the cleaning of Stratasys PolyJet Materials and Formlabs resins. Pay attention to the time required for disinfection: photopolymer resin have limited resistance in IPA.

4. **Mechanical resistance of 3D printed materials to disinfection**: even though a material is tested against a chemical agent, a reduction in static strength can still be present. For example, ABS and ASA can show a slight mechanical impairment after NADCC disinfection. We have successfully tested ABS components in low pressure devices without any mechanical impairment.

We suggest testing the component at least from a qualitative point of view after disinfection, to assess its performance, for example checking possible gas leakages (see following point).

5. **Gas permeability tests of 3D printed components**: considering the specific application, gas permeability should be avoided in order to not interfere with the therapy. Photopolymer based technologies (Material Jetting/Vat photopolymerization) and powder-based technologies (Binder Jetting and Powder Bed Fusion) can provide a good impermeabilization of the component, thanks to the way 3D printing material is cured. On the other hand, the most widespread FDM and FFF machines suffer more this issue. As for FFF printers, we successfully tested 3D printed ABS components at low pressure without any gas leakage. Further investigations may be necessary for fluids' applications. The use of a heated building volume, high infill and at least 2 perimeters is recommended.

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<sup>5</sup> No degradation problems nor release of toxic substances.

Currently, we are working on the following clinical applications.

### **Adapters to Connect Ventilation Systems Outflow to the Anesthetic Gas Scavenging System**

**Aim:** to reduce the environmental contamination of the personnel working in with Covid-19 patients who require ventilation.

We developed adapters to enable the connection between ventilation systems exhaust and the scavenging system, employed to avoid environmental contamination in case of use of inhalational anesthetic agents. Normally, ventilation systems are not intended for a connection with gas scavenging, thus proper adapters are not available.

Adapters are made in compliant material, using a photopolymer-based machine. We produced two versions, with and without a lateral port to enable pressure measurement. The lateral port is useful to study the pressure effect of the gas suction flow with respect to the expiratory output of the ventilation system, which normally must be exposed to atmospheric pressure.

#### **Materials:**

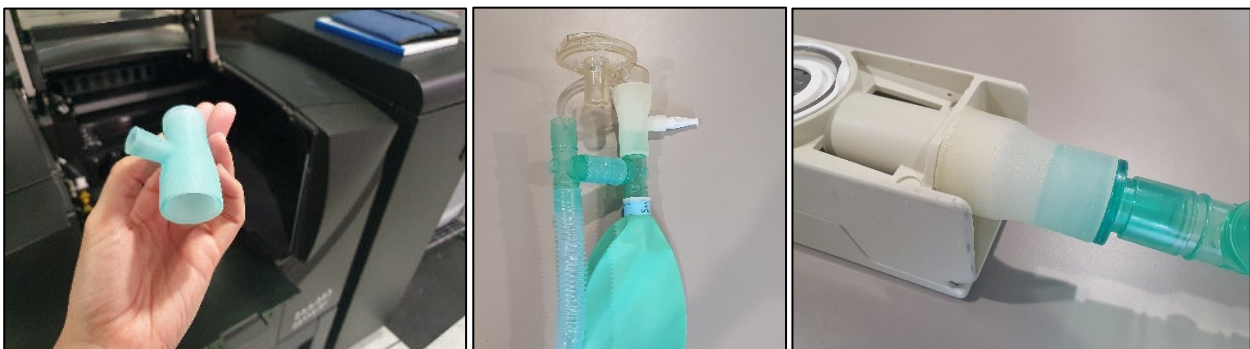
3D Printer: Stratasys Objet 260 Connex 3

Material: FLX-MT-S40-DM mixture of Agilus30 Clear (compliant) and VeroMagenta (rigid opaque) material, or another material from Verofamily, heavy support, matte finishing. Orient the component with the lateral port at 90° with respect to plate, to avoid distortions.

**Readiness Level:** adapters already in use on mechanical ventilators Hamilton G5 [Hamilton Medical, Switzerland] and Servo-i [Maquet, Inc, Wayne, N.J.]

**Requirements:** no sterilization/disinfection constraints. The device is placed in a ventilation circuit that has no return to the patient.

**If interested in the 3D model or if you need further information, please contact 3D4Med laboratory (<https://www.3d4med.eu/contacts/>)**



## Tubing Connector for Continuous Positive Airway Pressure (CPAP) Systems

**Aim:** to provide substitutes for a tubing connector which has rapidly run out of stock in the hospital due to the unprecedented high demand.

### **Materials:**

3D Printer: 3NTR A4v3 FFF printer

Material: 3NTR black ABS, layer thickness 0.25 mm, extrusion width 0.4 mm, infill rectilinear 50%, 2 perimeters, no support in the lateral port, heated environment at 80°, plate temperature 110°. High layer thickness is intended to increment yielding strength of the part and to reduce printing time.

**Readiness Level:** tubing connectors already in use.

### **Requirements:**

- Disinfection: tested with BIONIL (NADCC) at 10.000 ppm. No mechanical impairment occurred (qualitatively tested for the specific application);
- No gas leak: the device should avoid any gas leak to not impair the therapy. No gas leak occurred with the following parameters: 2 perimeters of 0,4 mm, 33% of infill (raised to 50% for the sake of safety), printing in heated environment at 80 °C.

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## Venturi System Suction Unit

**Aim:** to provide substitutes for a commercial Venturi System Suction Unit which has rapidly run out of stock in the hospital due to the unprecedented high demand.

**Materials:**

3D Printer: Stratasys Objet 260 Connex 3

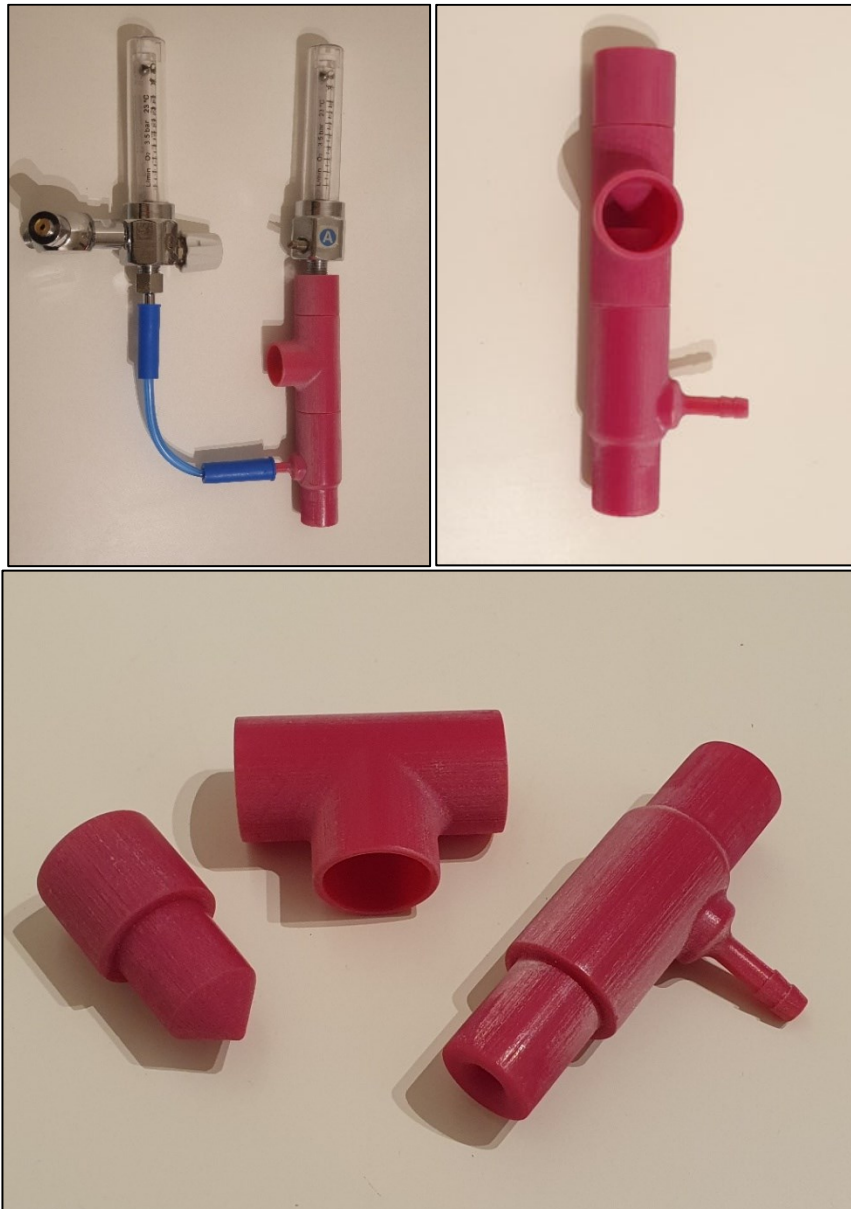
Material: VeroCyan (rigid opaque) material

**Readiness Level:** under testing. Other 3D printing technologies to be tested.

**Requirements:**

- Disinfection: under testing with IPA;
- No gas leak: under testing.

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## Scavenging System for CPAP outflow

**Aim:** to reduce the environmental contamination of the personnel working in with Covid-19 patients who require CPAP systems.

We are currently developing a system to scavenge the expiratory gas from CPAP through system normally employed to avoid environmental contamination in case of use of inhalational anesthetic agents. As for ventilation systems, CPAPs are normally not intended for a connection with gas scavenging.

The system under development should host a PEEP valve, avoid any depressurization that can interfere with the normal respiratory activity and avoid any environmental contamination, sucking away the expiratory gas.

**Materials:** under testing.

**Readiness Level:** under testing.

**Requirements:** no sterilization/disinfection constraints. The device is placed in a ventilation circuit that has no return to the patient.

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### **References**

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