ISTITUTO ITALIANO DI TECNOLOGIA

Protective mask technical documentation – CRESSI

Assembly and user manual

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Author:	Michele Gesino (michele.gesino@iit.it)
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Reviser:	Luca Fiorio (luca.fiorio@iit.it)
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0	M. Gesino	First edition	06/04/2020
1	L. Fiorio	First revision	06/04/2020
2	A. Pagnin	Filter details added	06/04/2020
3	L.Fiorio	Updated cleaning section	11/04/2020
4	L.Fiorio	Modified with plug solution	23/04/2020

Contents

1. OVERVIEW

CAUTION: The technical solution contained in this document was developed in response to the emergency of SARS-Cov-2 virus pandemic and did not go through all tests and controls normally required for the development of medical surgical devices.

In order to address the emergency situation caused by SARS-CoV-2 pandemic and the consequent deficiency of PPEs (Personal Protective Equipment) to preserve Medical Personnel (MP) and patients health, IIT decided to apply its Staff know-how to modify existing equipment, meant for other usages, in protective devices for MP or patients.

In particular, IIT decided to transform full-face snorkeling masks, into medical personnel protection masks. Assuming that the medical personnel is healthy and breaths out pathogen-free air, we focused on optimizing the filtration of the airflow into the mask.

IIT technical solution, shown in Figure 1, consists of 4 main components:

- Full face mask Cressi Duke - Gran Facciale
- Adaptor
- Filter
- Plug for adaptor

Figure 1 On the left, the original Cressi Duke Gran Facciale mask. On the right, the modified mask.

1.1 PRINCIPLES OF OPERATION

The full-face mask, sticking to the MP face, creates two hermetic areas: one surrounding the eyes, the other nose and mouth (Figure 2). The airflow, between these two spaces and the external environment, is regulated by check (non-return) valves.

Figure 2 Left: hermetic spaces. Right: non-return valves.

Figure 3 (left) shows the **inhalation** phase**.** During inhalation pressure decreases in the nose-mouth space. Consequently, air from outside the mask (blue arrows) goes through the filter and (light-blue arrows), reaches into the eyes space. Afterwards, the airflow goes into the nose-mouth space through two non-return valves.

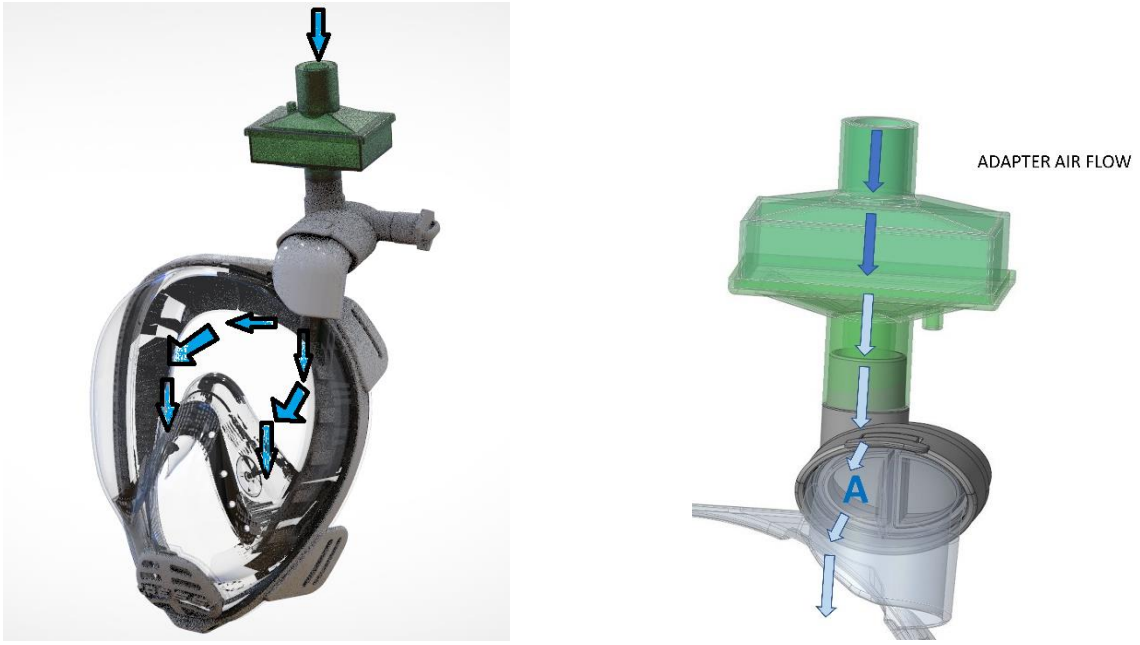

Figure 3 on the left the airflow during inhalation; on the right a detail of the adaptor section

While the MP breaths out the airflow, as shown in Figure 4, returns to the surrounding environment (green arrows) through the non-return valve.

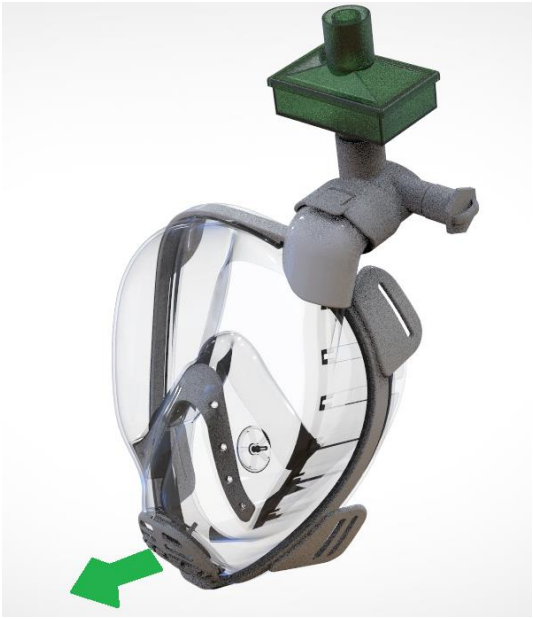

Figure 4 airflow during exhalation.

The airflows (in and out of the mask) are always kept separate

2. ASSEMBLY

2.1 MATERIALS

Components needed for the prototype:

- Cressi DUKE - Gran Facciale face musk
- Adapter to connect Cressi DUKE - Gran Facciale face musk to the filter
- Plug for the adapter
- Single use (disposable) antibacterial/antiviral filter
- O-ring (usually not supplied, though retrievable from the CRESSI mask snorkel)

In particular, as shown in Figure 5, the adaptor is designed for a filter with a plug-in 22 M, but it results quite easy to adapt the 3D model to different plug-ins.

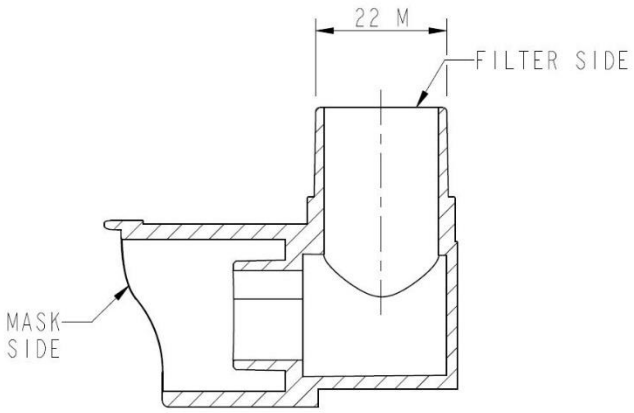

Figure 5 Adapter section and filter plug-in.

The filter used for this prototype is a commercial available component. In particular, it's the *Mechanical Filter Compact* model *351U5878*, manufactured by Medtronic. This filter is made of polystyrene and employs a mechanic filter made of ceramic pleated microfiber able to retain ≥99,9999% of bacteria and viruses. The filter is certified and commonly used in hospitals as a filtering device when treating patients in intensive and sub-intensive care units with supplementary oxygen.

2.2 ASSEMBLY DIAGRAM

First, remove the original snorkel from the CRESSI full-face mask. As shown in Figure 6, the mask (1) should be separated from the snorkel (2) by pressing on the highlighted flap.

CAUTION: during this operation is necessary to remove (and keep aside) the o-ring (3).

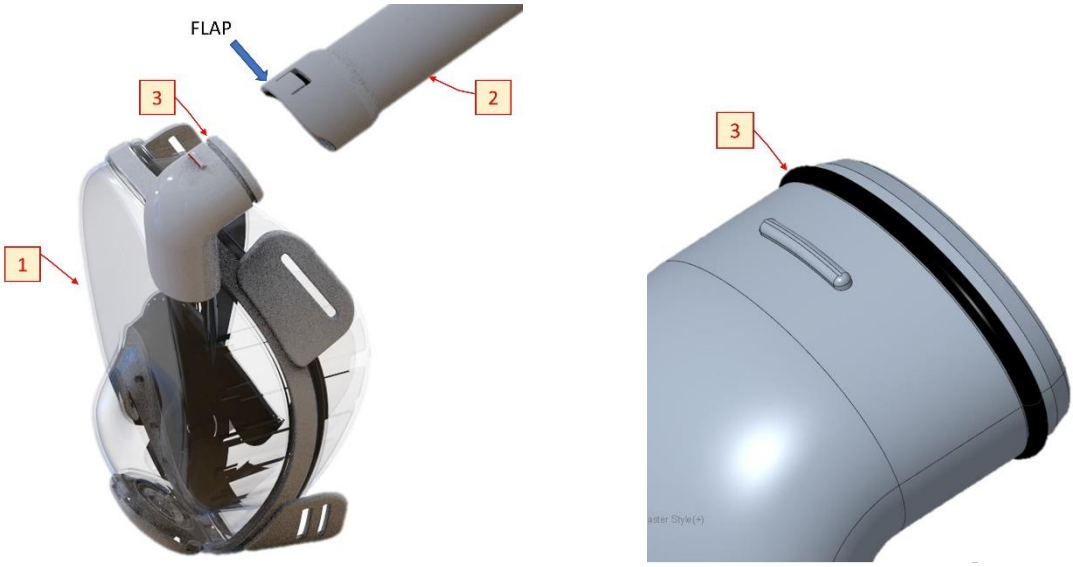

Figure 6 On the left how to remove the CRESSI snorkel. On the right a detail of the frontal o-ring.

The following step consists in assembling the modified mask as shown in Figure 7. Insert the adaptor (4) on the front part and after insert the filter (5) and the plug (6)

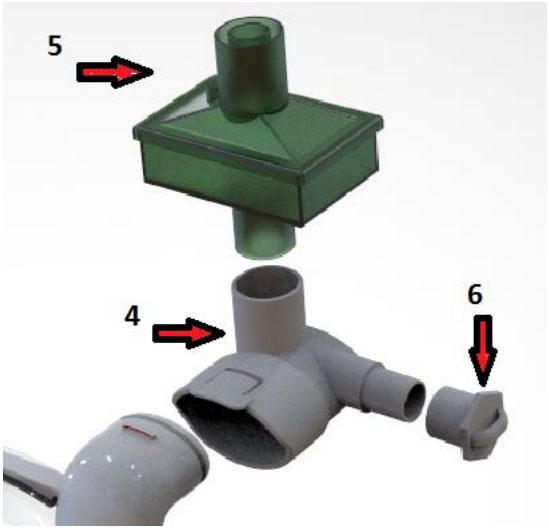

Figure 7 Assembling of modified CRESSI mask

3. CLEANING PROCEDURES

To clean the mask the manufacturer suggests NOT using products containing chlorine, hydrocarbon, alcohol or very aggressive surfactants.

In order to facilitate identifying an effective cleaning procedure, we tested different cleaning procedures in order to assess possible mask damages. In particular, for each cleaning procedures applied, many cleaning cycles have been performed. At the end of each cycle the mask was checked for macroscopic defects.

In order to assess the cumulative damage caused by the cleaning procedures, each testing cycle has been performed on a new mask.

Combined different cleaning procedures have not been tested.

3.1 PASTEUR OVEN

Tests were performed using the THERMOSCIENTIFIC HERAEUES UT12 device in accordance with the following procedures:

- Treatment temperature: 70 °C
- Treatment duration: 2 hours

We performed 5 cycles that did not cause any macroscopic defect on the masks. Figure 8 shows the masks before and after the 5 cycles of test.

Figure 8 On the left a new mask. On the right the mask after the 5 test cycles.

3.2 VAPOR PHASE HYDROGEN PEROXIDE (VPHP)

Tests were performed using the BIOQUELL CLARUS device connected to the TECNIPLAST RW900 device, in accordance with the following procedures:

- Treatment temperature: 65 °C
- Airflow: 25 m^3/h
- "Gassing Dwell" concentration: 350 ppm
- Post processing ventilation time: 24 hours

We performed 3 cycles that did not cause any macroscopic defect on the masks. Figure 9 shows the masks before and after each cycle.

Figure 9 On the left a new mask and after 1,2 and 3 cycles of test.

3.3 AUTOCLAVE

Tests were performed using the SELECTA PRESOCLAVE II 50 device, in accordance with the following procedures:

- Treatment temperature: 115 °C
- Treatment duration: 20 minutes

We performed 5 cycles that did not cause any macroscopic defect on the masks, just a slight decoloring of the printed brand on the elastic band. Figure 10 shows the masks before treatment and after 5 cycles.

Figure 10 On the left the new mask, on the right the mask after the treatment (front and rear view)