ISTITUTO ITALIANO DI TECNOLOGIA

Protective mask technical documentation – SEAC

Assembly and user manual

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Rev.	Author	Description	Date
0	M. Gesino	First edition	28/03/2020
1	L. Fiorio	First revision	29/03/2020
2	L. Fiorio	Cleaning section added, Unica mask added	31/03/2020
3	A. Pagnin	Filter details added	06/03/2020
4	L. Fiorio	Cleaning procedures results added	11/04/2020

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 usage, in protective devices for MP or patients.

In particular, IIT decided to transform full-face masks 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 air flow into the mask.

IIT technical solution, visible in Figure 1, consists of 3 main components:

- Full face mask SEAC Libera or SEAC Unica
- Adaptor
- Filter

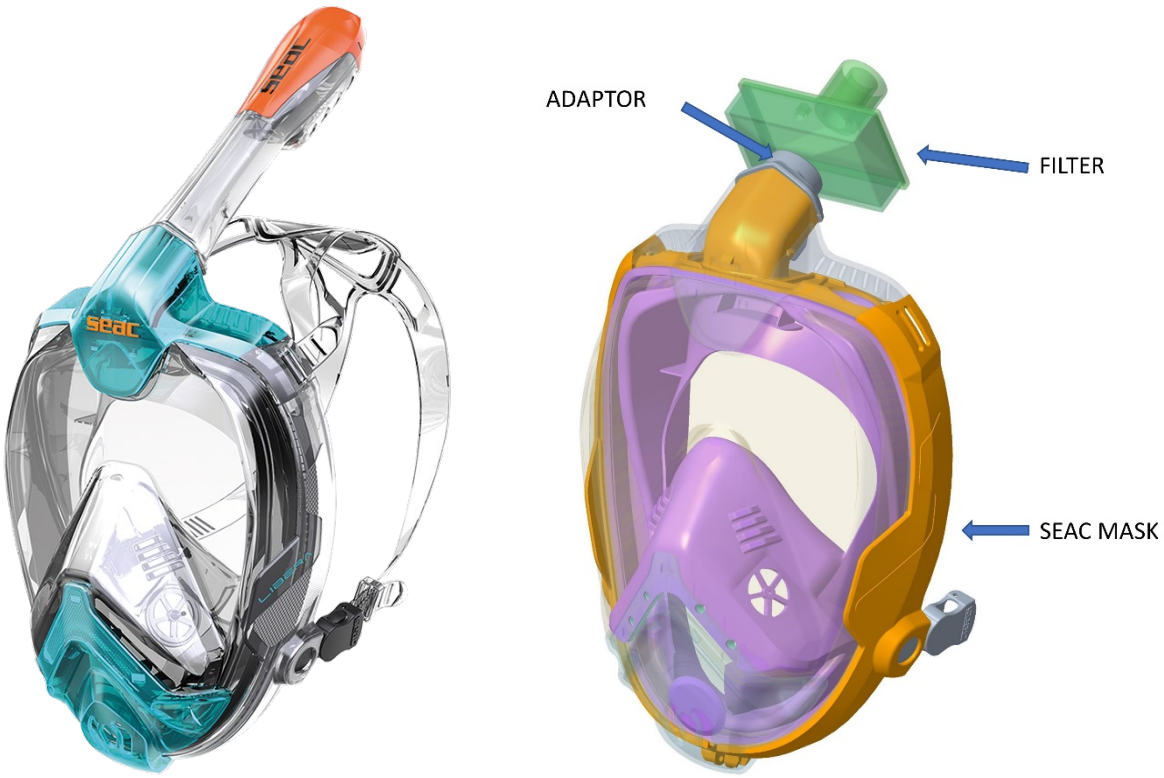

Figure 1 On the left, the original SEAC mask. On the right, the modified mask.

1.1 PRINCIPLE OF OPERATIONS

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.

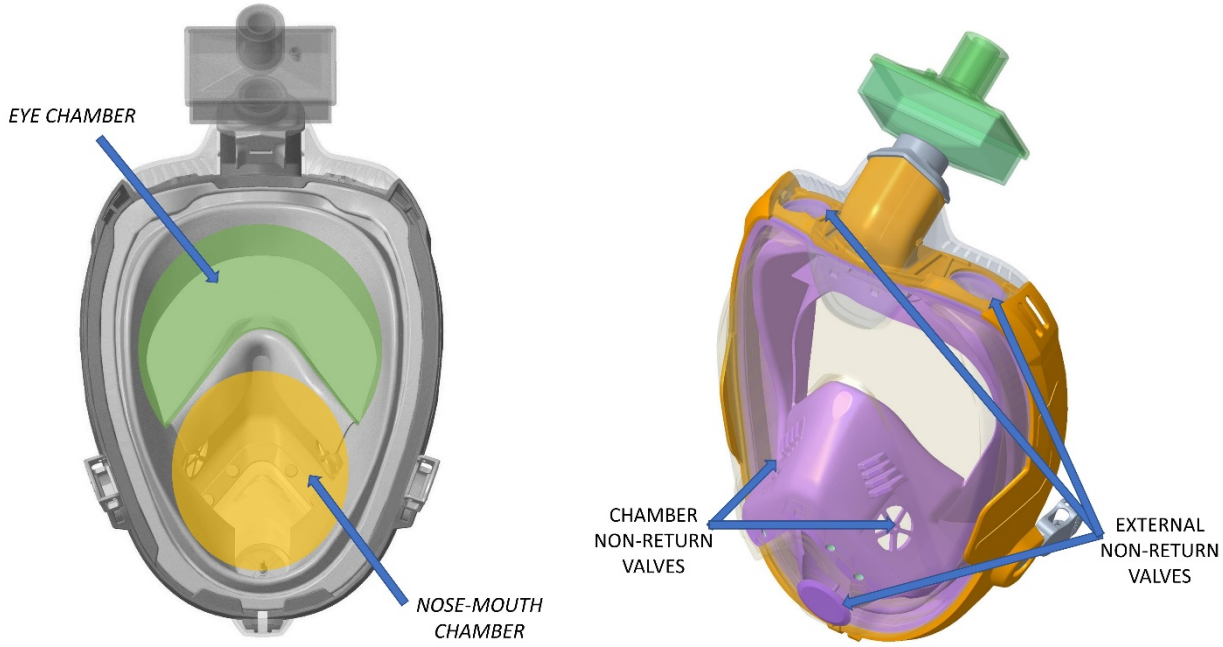

Figure 2 Left: hermetic spaces. Right: non-return valves.

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.

While the MP breaths out the airflow, as shown in Figure 3 (right), returns to the surrounding environment (green arrows) through non-return valves.

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

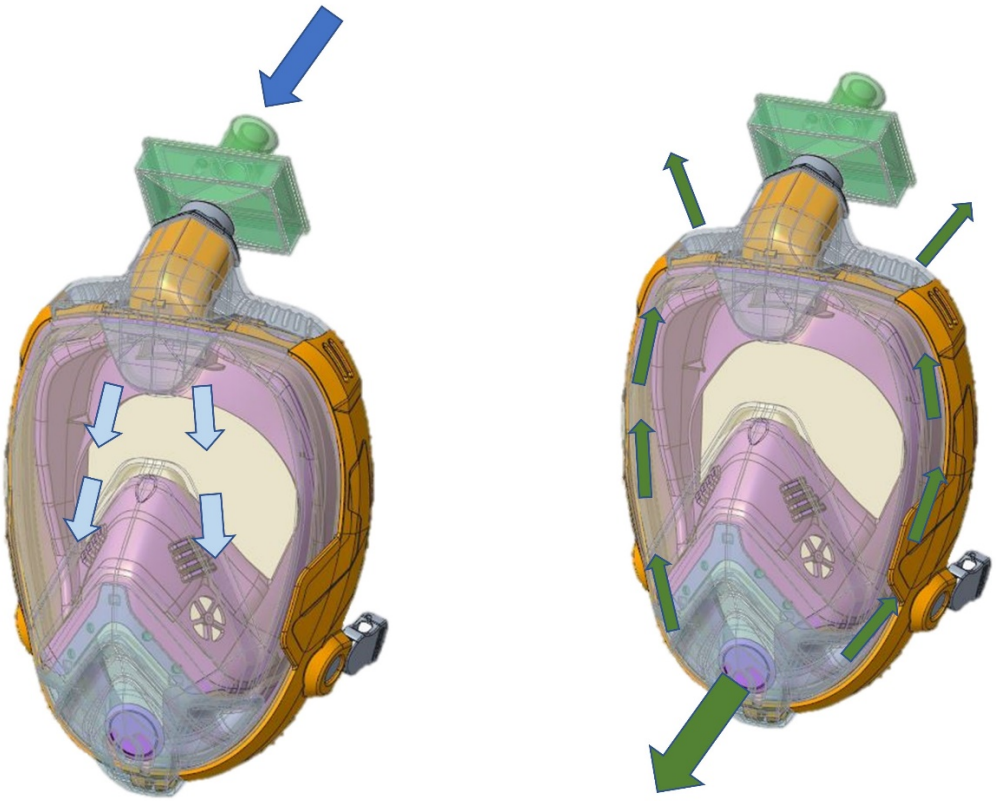

Figure 3 Left: Air flow during inspiration phase. Right: Air flow during exhalation phase.

2. ASSEMBLY

2.1 MATERIALS

Necessary components to assemble the prototype:

- Full-face mask SEAC
- Specific adapter to connect the SEAC full face mask to filter
- O-ring (usually not supplied, though retrievable from the SEAC mask snorkel)
- Disposable filter

In particular, as shown in Figure 4, the adapter interface is an ISO 22 F. Nevertheless, it is easy to modify the 3D model for different filters.

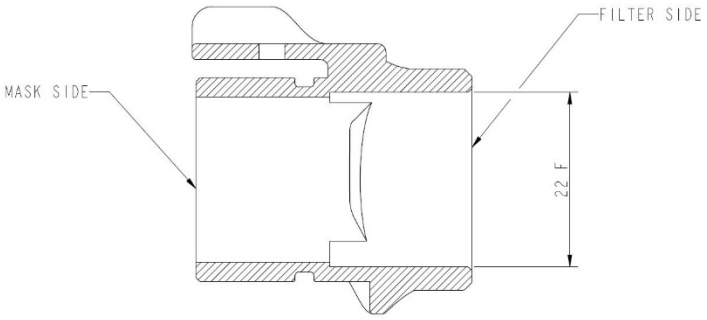

Figure 4 Adapter section.

The filter used for this prototype is a commercial component. In particular, it is the *Mechanical Filter Compact* model *351U5878*, manufactured by Medtronic. This filter is made of polystyrene with a ceramic filtering stage capable of retaining ≥99,9999% of bacteria and viruses. The filter is certified and commonly employed in hospitals as a filtering device for patients in intensive and sub-intensive care units.

2.2 ASSEMBLY DIAGRAM

Firstly, the snorkel is removed from the SEAC full face mask. As shown in Figure 5, the mask (1) should be separated from the snorkel (2) by pressing on the highlighted flap.

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

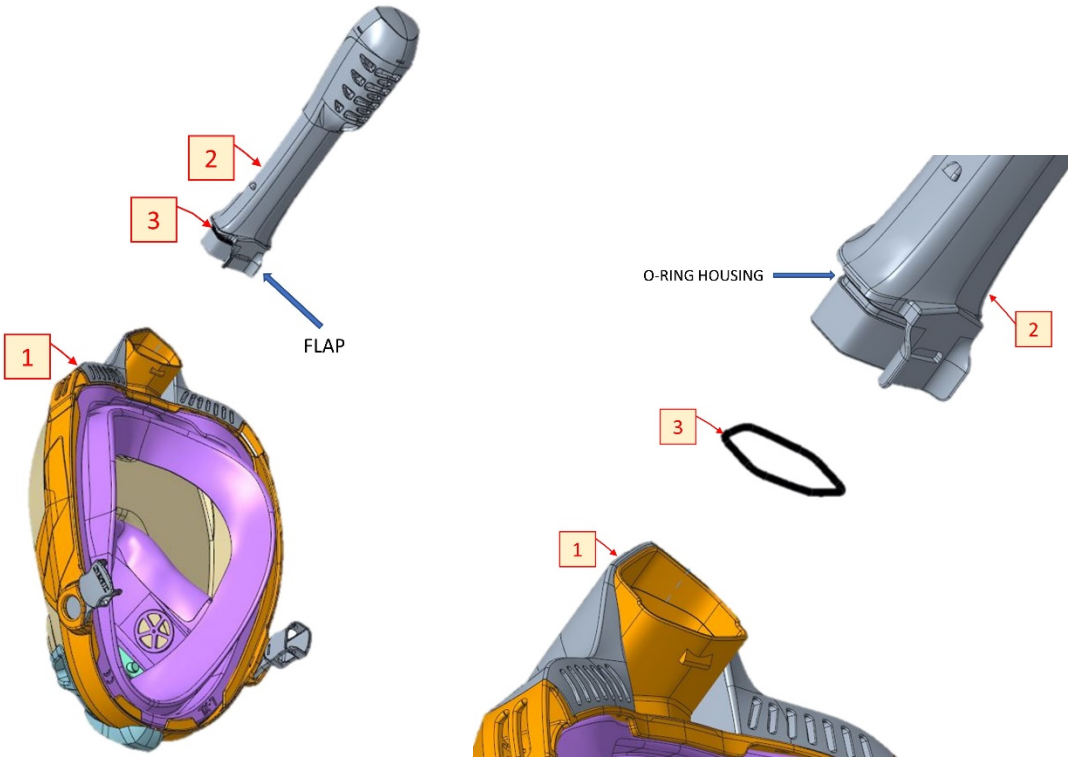

Figure 5 Left: Removal of the snorkel. Right: Removal of the o-ring.

The following steps is to assemble the modified mask. All the additional components needed are highlighted in the assembly diagram in Figure 6: The filter (5), a commercial component, and the adapter mask-filter (4).

Firstly of all, the o-ring and the adapter are assembled, as shown in Figure 6.

Then, o-ring and adapter must be connected to the mask. Finally, the filter is inserted.

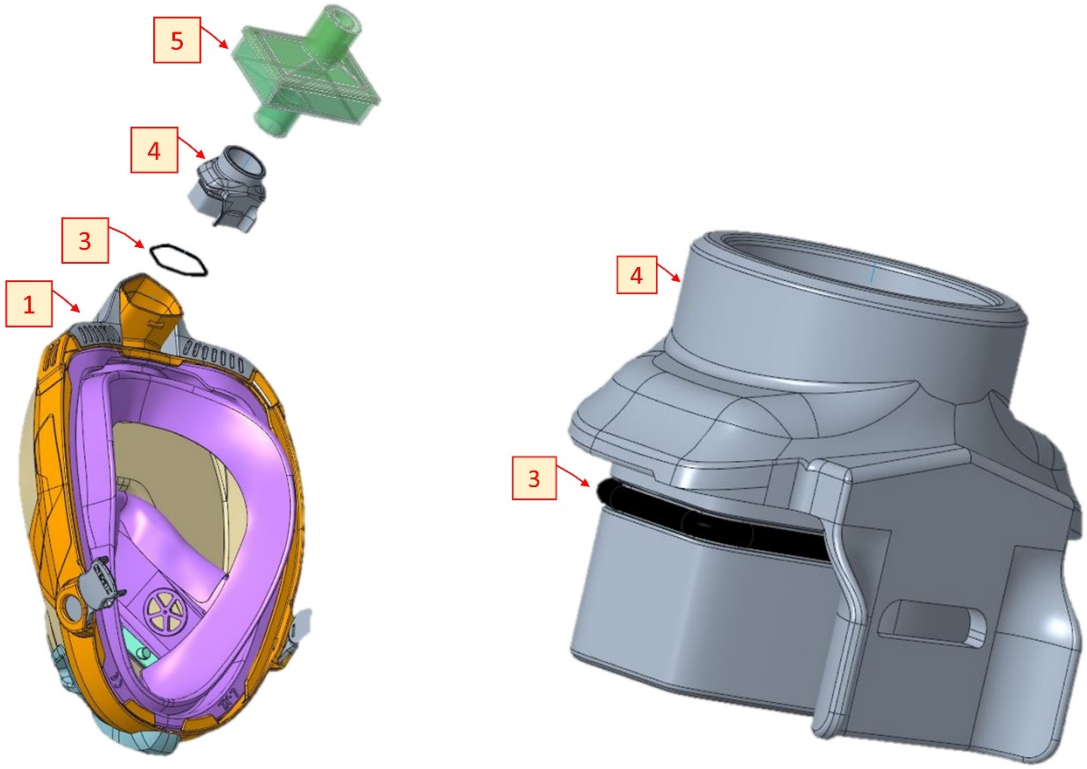

Figure 6 Left: Assembling of transformed Seac full face mask. Right: Close up of adapter and o-ring.

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 7 shows the masks before and after the 5 cycles.

Figure 7 Top the mask SEAC Libera, bottom the mask SEAC Unica. On the left the masks before the cycles, on the right the masks front and back sides after the 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 8 shows the masks before and after each cycle.

Figure 8 Top the mask SEAC Libera, bottom the mask SEAC Unica. On the left the masks before the cycles, moving to the right the masks after each cycle.