



# DualAdapter for "Easybreath"



## 1. Purpose

Due to the ongoing COVID-19 crisis all over the world the supply of certain medical devices is extremely low and industrial supply chains are struggling to scale up in order to meet actual demands.

This DualAdapter enables the Decathlon "Easybreath" snorkel mask to be modified for medical purposes. In order to provide maximum flexibility to the user the design of the DualAdapter meets the requirements of the following applications:

- Personal Protective Equipment (PPE) for health care workers and other potential users with increased risk of infection
- (Non-invasive) Ventilation Kit/Resuscitation Device as emergency alternative for non-invasive ventilation (NIV) assistance for COVID-19 patients

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## 2. Product Characteristics

## **Basic Information**

The Easybreath DualAdapter consists of medical grade PP and has been specifically developed for the adoption of the 1st generation Decathlon Easybreath full-face snorkel mask. The DualAdapters are produced via 3D-printing or injection moulding. It is part of a basic mask kit connecting a full-face snorkel mask to bacterial/viral standard filters already available on the market.



full face snorkel mask



DualAadapter (3D-printed/ injection moulded)



bacterial/viral filter



Figure 1 components of basic mask kits

Due to its design, the DualAdapter provides separated ducts for the fresh air supply and the exhaust air of the user. The fresh air supply is provided via port A, while exhaust air is deducted via port C. As indicated in the picture below, inhale and exhale air channels are separated via different chambers in order to secure a one-way flow of the air within the mask.

#### Figure 2: DualAdapter - air flow concept

**Please note:** Besides this basic mask kit further components/devices need to be purchased depending on the specific application. Please find further details regarding the proposed solutions in the respective chapters further below and the FAQs.





## Dimensions

Port A and port B are both designed to accept ISO standard 22 mm OD HME and viral filters. Thus, the DualAdapter connects the snorkel mask to a single standard respiratory filter which is already in supply at many hospitals or other medical facilities.

Please find detailed information regarding the dimensions of the DualAdapter in the technical drawing below.



Figure 3: DualAdapter – technical drawing

**Please note:** As the final assembly of the mask kit depends on the selected application case, the DualAdapter needs to be integrated accordingly. Please find detailed information regarding the different use cases, the respective parts list and assembly procedures in the explanations further below and the FAQs.





## Material

The adapter is made of polypropylene (PP) random copolymer (Bormed RF830MO), developed for healthcare applications: "This transparent grade is modified with a nucleating agent and is suitable for articles, which need post sterilisation with radiation. Bormed RF830MO is characterised by easy processability, high transparency, high gloss and a good stiffness-impact balance. Products moulded from this grade and radiated with the dose of 25 kGy have a shelf-life of 5 years, if properly stored. Material can also be sterilised with ethylene oxide and steam." [BOREALIS Product Data Sheet - RF830MO]

#### **Temperature & Cleaning Procedure**

Referring to the material data sheet, the provided DualAdapter is made for reutilization after cleaning with adequate procedures such as approved processes of steam sterilization. It is recommended to not exceed a cleaning temperature of 134 °C while a steam sterilization temperature of 143 °C may still be applicable.

Material	PP - Bormed RF830MO (polypropylene random copolymer)		
Density &	0,91 g / cm³		
Product Weight	27 g		
Temperature & Product sterilization	Melting: 150 °C Heat Deflection Temperature (0,45 MPa): 75 °C Cleaning: Steam sterilization at 121 °C or 134 °C is recommended		





## 3. Personal Protective Equipment (PPE)

The full-face snorkel mask can be adapted as personal protective equipment for health care workers and other potential users with increased risk of infection.

#### Components

The proposed solution consists of an off-the-shelf snorkel mask, a custom (3D-printed / injection-moulded) DualAdapter, and a bacterial/viral filter.



#### Figure 4: PPE mask kit - components

The DualAdapter connects the full-face snorkel mask with the bacterial/viral filter. When breathing in, the fresh air enters the filter and passes the DualAdapter after being filtered through port A and flows via port B into the mask.



When exhaling, the used air is blown out of the mask through the chin valve, according to the original design of the snorkel mask. In cases of PPE application, the user is considered to be healthy, which is why the exhaust air is directly blown out into the environment without any filtering.

As the proposed DualAdapter can also be used for further application cases, the outlet valve needs to be blocked at port C using a standard plug. The plug is provided together with the DualAdapters. In this use case, only inhalation air is meant to be channelled through the DualAdapter.

Figure 5: PPE – air flow concept (DualAdapter)





Additionally, a one-way valve can be placed between the DualAdapter and the filter to prevent any exhaled air from passing through the filter in the wrong direction (unless a two-way filter is used).

## Assembly

Please take into consideration the following information regarding the assembly process of the mask kit:

If installed, please first of all remove the snorkel from the full-face snorkel mask. Connect the DualAdapter at port B to the snorkel mask.

The bacterial/viral filter has to be installed at port A.

**Attention**: Please be aware, that not all standard bacterial/viral filters available on the market can be used bi-directional. For one-way filters, the correct assembly is crucial for the effectiveness of the whole solution.

Port C of the DualAdapter has to be blocked with a port plug, available on the market as a standard part. Alternatively, a second bacterial/viral filter can be installed. Again, correct installation is crucial for the effectiveness of the solution.





## 4. (Non-invasive) Resuscitation Device

The full-face snorkel mask can also be adapted to provide an emergency alternative for non-invasive ventilation (NIV) assistance for COVID-19 patients.

## Components

The mask kit consists of an off-the-shelf snorkel mask, a custom (3D-printed / injectionmoulded) DualAdapter, and two bacterial/viral filters.



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assembled mask kit
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## Figure 6: ventilation kit components

Besides this mask kit, the following standard parts/devices are needed: an oxygen system, a venturi valve and a PEEP valve.

The **oxygen system** and the **venturi** valve are needed to provide fresh air with a stable and regulated proportion of oxygen, individually adjusted to the patients' needs. To avoid pressure drop within the lungs of the patient to the level of environmental pressure after exhaling, a **PEEP valve** (PEEP, positive end-expiratory pressure) needs to be installed.

Please find examples illustrated for these components in the picture below. As these components are available as standard parts on the market, they are not part of the provided mask kit itself.



Figure 7: ventilation kit - additional equipment





Additionally, a one-way valve can be placed between the DualAdapter and the filter to prevent any exhaled air from passing through the filter in the wrong direction (unless a two-way filter is used).

## Assembly

Please take into consideration the following information regarding the assembly process of the mask kit as well as the whole solution which is proposed as alternative, non-invasive resuscitation device.

As shown in the illustration, the oxygen system needs to be connected via the venturi valve to a bacterial/viral filter. The filter for the inhale air flow is connected to the custom DualAdapter to provide  $O_2$  enriched, fresh air to the patient via the full-face snorkel mask.

After breathing the exhaust air leaves the mask via the DualAdapter and is filtered by a second viral/bacterial filter. This second filter is connected to the PEEP valve, which is passed by the exhaust air before it is blown out into the environment.



#### Figure 8: assembly concept [ventilation device]

**Attention**: Please be aware, that not all standard bacterial/viral filters available on the market can be used bi-directional. For one-way filters, the correct assembly is crucial for the effectiveness of the whole solution.

The air flow within the DualAdapter is illustrated in the picture below: the fresh air enters the DualAdapter via port A and flows is channelled via port B into the full-face snorkel





mask. After breathing, the exhaust air is routed via a separated chamber from port B to port C into the second viral/bacterial filter.



#### Figure 9: ventilation kit - air flow concept

As shown in Figure 10 the full-face snorkel mask itself needs to be slightly adjusted to be usable for resuscitation application:

- The **chin valve [X]** must be blocked to prevent exhaled, contaminated air from being deducted into in the environment without being filtered. While it is strongly recommended to hermetically seal the chin valve, it is a possible alternative to simply revert the valve to achieve the same functionality.)
- The **side valves [Y] and [Z]** need to be removed as inhalation and exhalation air flows are both channelled via the upper port of the mask. Please be aware, that due to this design the fogging is increased within the mask, which does not impact the functionality and effectiveness of the proposed solution.



Figure 10: adjustment of full-face snorkel mask





## 5. Standards & Approvals

This is a non-profit initiative where we want to help in the best possible way by providing different solution concepts and parts/kits together with our partners. We are not able to provide any officially approved solutions, parts or kits as the proposed solutions are designed and developed as an alternative to existing, approved solutions, that cannot be provided in a sufficient amount during the COVID-19 crisis. Please be aware, that neither we nor any of our partners assume any liability for the correct design, assembly or use of the illustrated solutions, parts and kits. (Further details please find here: Medical Disclaimer)

Please also take into consideration relevant rules and regulations for certification, development and use of medical devices and parts within your own country before using.

## 6. Medical Disclaimer

The provided content, including but not limited to project descriptions, preliminary test results, figures/images, and prototypes, published here is meant to maximize potential public benefit during this SARS-CoV-2 (formerly CoVID-19) crisis, specifically in addressing the urgent need around PPE and resuscitation/ventilation shortage.

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The content/device has not been used in formal testing with human subjects at this time.





## 7. Get in touch

If any further information is needed, please feel free to contact the below mentioned colleagues. As one of our key competences is 3D printing, we might also be able to adopt the proposed solution to individual needs and requirements.

Besides that, we are currently searching for partners regarding

- Organizations like NGOs/IGOs especially with contacts to developing countries to obtain local demands and support with the local distribution
- Medical companies willing to support with the process of certification and / or professional distribution of the kits
- Funding for the purchasing of parts (mask and filters), assembly and distribution of the kits on a non-profit basis.

## 8. Contact

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## 9. Parts Catalogue

In Table 1 please find a list of the components used during the concept phase by our initiative.

**Please note:** Neither the initiative of Fraunhofer IAPT & CompriseTec nor any of our partners take over responsibility for the correct supply and use of the complementary parts for any of the proposed solutions.

#### Table 1: Parts Catalogue

Component	Product Details	Illustration
DualAdapter	<ul> <li>Product Name: DualAdapter for Easybreath</li> <li>Product ID:</li> <li>Manufacturer: Fraunhofer IAPT &amp; CompriseTec</li> <li>Application: <ul> <li>PPE</li> <li>Resusitation/Ventilation</li> </ul> </li> </ul>	
full-face mask	Product Name: Subea Easybreath Snorkelling Mask         Product ID: 8304667 / 8315702         Manufacturer: Subea [Decathlon]         Application:         • PPE         • Resusitation/Ventilation         Link: <a href="https://www.decathlon.com/products/surface-snorkeling-easybreath-mask-500?">https://www.decathlon.com/products/surface-snorkeling-easybreath-mask-500?</a>	
bacterial/viral filter	Product Name: HME TwinStar ® filter         Product ID: MP 01805         Manufacturer: Dräger         Application:         • PPE         • Resusitation/Ventilation         Link: https://www.draeger.com/en_uk/Products/Filter-and-Heat-and-moisture-exchanger	
air port plug	Product Name: Closure plug Product ID: GPN 300 F 21 Manufacturer: Pöppelmann Application: • PPE Link: https://www.poeppelmann.com/de/unternehmen/service/do wnloads/	





## 10. FAQs

## a. Which parts are provided by the initiative of Fraunhofer IAPT & CompriseTec cooperation?

As this concept is developed and provided by a non-profit initiative of the Fraunhofer IAPT and CompriseTec we would like to support other initiatives with the following parts:

- EASYBREATH DualAdapter
- Air port plug (GPN 300 F 21)

Further Details regarding these components please find here: **Parts Catalogue** In case of further questions please feel free to contact us: **Contact** 

b. Which full-face snorkel masks can be used?

The Easybreath DualAdapter is designed for a specific full-face snorkel mask, namely the Subea Easybreath Surface Snorkelling Mask by Decathlon/Subea.

Further Details regarding these components please find here: Parts Catalogue

**Attention**: Please note that the manufacturer Decathlon/Subea offers different full-face masks. In order to avoid confusion please make sure that the correct snorkel mask as illustrated in the **Parts Catalogue** is purchased. This is crucial for the adaptability of the provided Easybreath DualAdapter.

**Please note:** The DualAdapter is <u>not</u> compatible with the newer generation of Subea "Easybreath 500" snorkel mask system as the design and dimensions of the respective snorkel is differing.

## c. Is it possible to develop/provide adapters for other full-face snorkel masks than the Subea Easybreath Surface Snorkelling Mask by Subea/Decathlon?

As the initiative is a cooperation of Fraunhofer IAPT & CompriseTec the current design is based on the technology of 3D printing and injection moulding. As the tooling for the proposed solutions and parts is available right now, we are able to provide bigger amounts of these parts in short term.

Anyways, we are open to discuss also the option to adopt/adjust the parts design and components to individual need. Please feel free to **Contact** us.





## 11. References, Literature & Links (internal use only)

References

#### Product Data Sheet\_RF830MO\_Borealis\_20200505

## (further) Literature

Pneumask	Project:	Reusable	Full-Face	Snorkel	Mask	PPE	Project
Theumusik	rioject.	neusuble	runruce	JHORKCI	IVIUSI		rioject

#### Links

- <u>https://www.pneumask.org/</u>
- Pneumask Project: Reusable Full-Face Snorkel Mask PPE Project Assembling instructions <u>https://www.youtube.com/watch?v=xJ6sbaqU3Vw&feature=youtu.be</u>
- Pneumask Project: Reusable Full-Face Snorkel Mask PPE Project Full documentation (April 2020) (Link: <u>https://www.medrxiv.org/content/10.1101/2020.04.24.20078907v1.full.pdf</u>)
- Example of 3D-printed Charlotte Valve (predecessor of current adapter) Assembling instructions https://www.youtube.com/watch?v=-KBeC53oMo0&feature=youtu.be

## **12.** Illustrations, Pictures

Figure 1 components of basic mask kits	2
Figure 2: DualAdapter - air flow concept	2
Figure 3: DualAdapter – technical drawing	3
Figure 4: PPE mask kit - components	5
Figure 5: PPE – air flow concept (DualAdapter)	5
Figure 6: ventilation kit components	7
Figure 7: ventilation kit - additional equipment	7
Figure 8: assembly concept [ventilation device]	8
Figure 9: ventilation kit - air flow concept	9
Figure 10: adjustment of full-face snorkel mask	10
Table 1: Parts Catalogue	13