



Non-invasive ventilation mask
product and manufacturing information



+49 178 145 3883

facemaskforcovid19@gmail.com

June 2020

Dear user, below are a few notes to consider before printing or using the mask. Please read the instructions and specifications carefully before using the mask, and use at your own risk.

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Introduction

The Soteria face mask was developed to reduce the supply shortage of the ventilation masks in pandemic situations. It was inspired by the Give a Breath Challenge by Munich Re and Fraunhofer-Gesellschaft. It has been designed, tested, and iterated over the past two months.

The Soteria mask is a fully 3D printable respiratory face mask for non-invasive ventilation. It allows for decentralized manufacturing utilizing FDM 3D printing technology. The modular design is especially suited for developing countries due to its low cost, ease of use, durability, and versatile use cases.

The mask is printed with two types of materials - PLA or PETG for rigid parts and TPE for flexible parts. This provides a high comfort for patients and increased safety due to a tight fit to the patient's face and filter capability of the exhaled air. There are, in addition to the mask, multiple connectors to non-invasive ventilation systems (i.e. for either one-tube or two-tubes systems) and different ventilation modes (i.e. CPAP and BiPAP). We have internally validated our mask to hold the required pressure for non invasive ventilation.

Disclaimer

This 3D model has not been approved by any regulatory agency and has not passed any official laboratory tests. It is a prototype designed by Team Soteria (a German student team), presented among many other works in the Give A Breath Challenge organized by Fraunhofer Gesellschaft and Munich Re, created with the aim of providing non-invasive ventilation for COVID-19 patients who need it, given the current global shortage of supplies. It is not intended to replace any homologated mask, but to provide protection during shortages. We cannot guarantee its operation, so use it at your own risk.

Medical Disclaimer

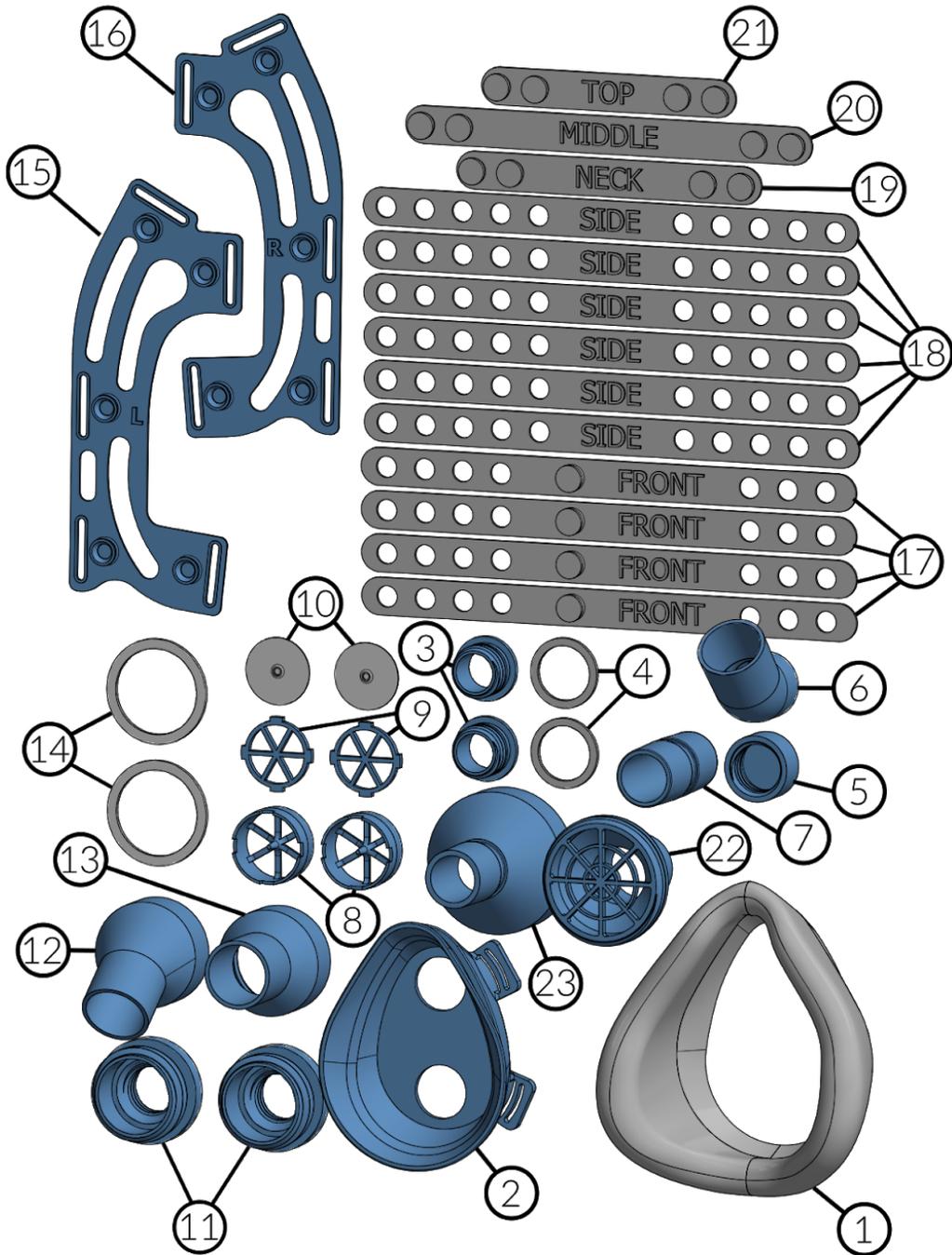
The information (including without limitation, advice and recommendation) within this product and support material, is provided solely as general educational and informational purposes. Use of this product and information contained herein is at the sole choice and risk of the user and reader.

Always consult a physician or healthcare provider before using the mask. If you choose to use this information without prior consent of a physician, you are agreeing to accept full responsibility for your decisions and agreeing to hold harmless Soteria, its agents, contractors and any affiliated companies from any liability with respect to injury or illness to you or your property arising out of or connected with your use of the device or the information contained within this brochure. Furthermore, a medical professional must supervise the use of the mask.

Part List

Blue parts are PLA or PETG

Grey parts are TPE



PART-NR	QTY	DESCRIPTION	MATERIAL
1	1	Mask - Face	TPE
2	1	Mask - Front	PLA
3	2	Connector M20	PLA
4	2	Sealing Ring M20	TPE
5	1	Plug M20	PLA
6	1	Conical Connector F-D22	PLA
7	1	Conical Adapter M-M-D22 (Optional)	PLA
8	2	OWV - Rim	PLA
9	2	OWV - Lid	PLA
10	2	OWV - Flap	TPE
11	2	OWV - Adapter	PLA
12	1	OWV - Conical Connector F-D22-45	PLA
13	1	OWV - Conical Connector F-D22	PLA
14	2	Sealing Ring M36	TPE
15	1	Headmount Left	PLA
16	1	Headmount Right	PLA
17	4	Headstrap Front	TPE
18	6	Headstrap Side	TPE
19	1	Headstrap Neck	TPE
20	1	Headstrap Middle	TPE
21	1	Headstrap Top	TPE
22	1	Filter Adapter F-D22	PLA
23	1	Filter Lid M-D22	PLA

*PLA can be interchanged with PETG depending on material availability. Refer to the material recommendations on page 13.

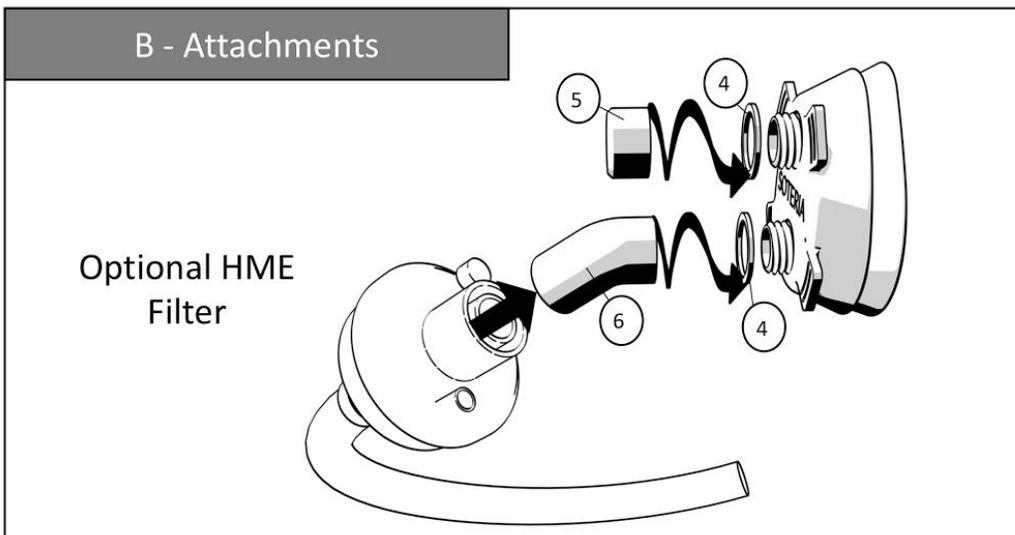
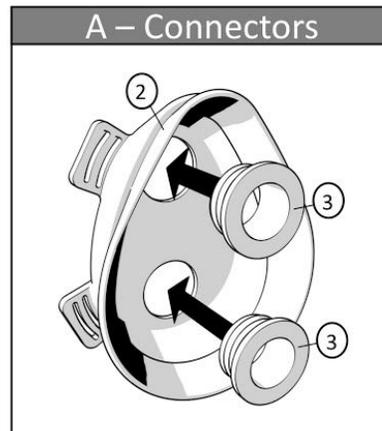
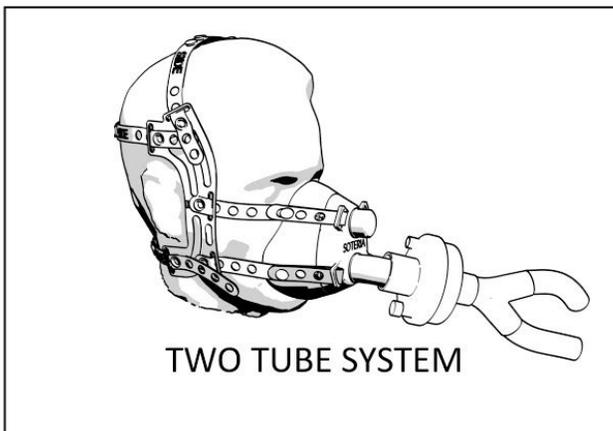
SOTERIA

Mask Assembly Manual

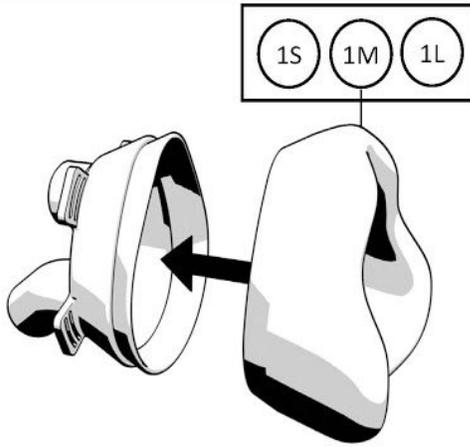
The Soteria face mask can be used for two types of ventilation systems:

One-tube ventilation systems and
Two-tube ventilation systems

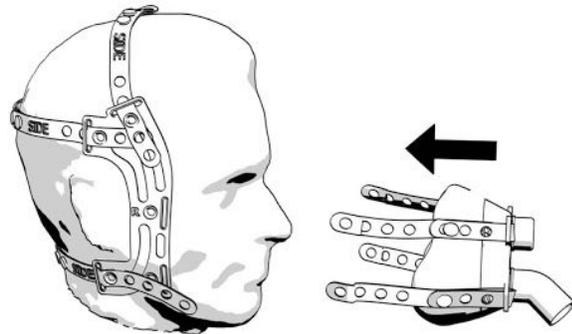
Video assembly instructions:



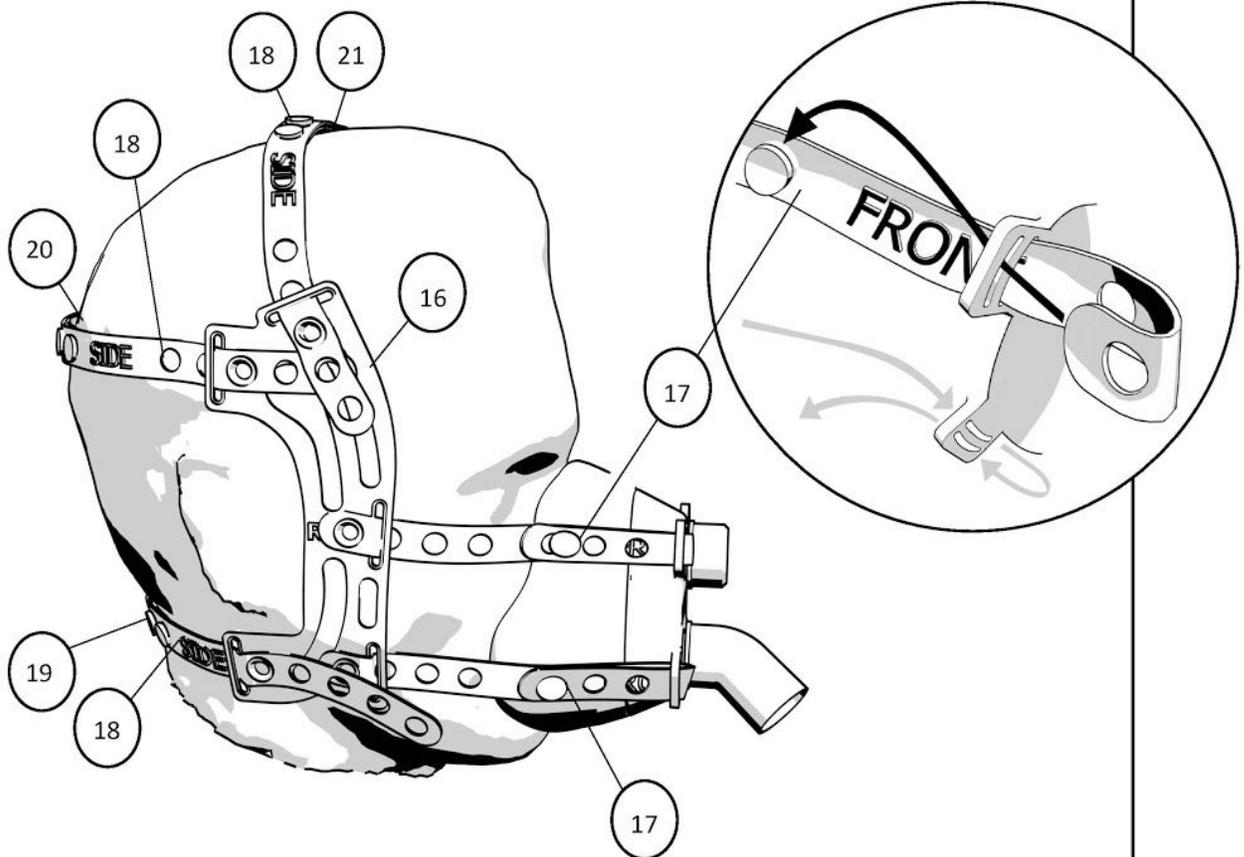
C – Mask Sizes

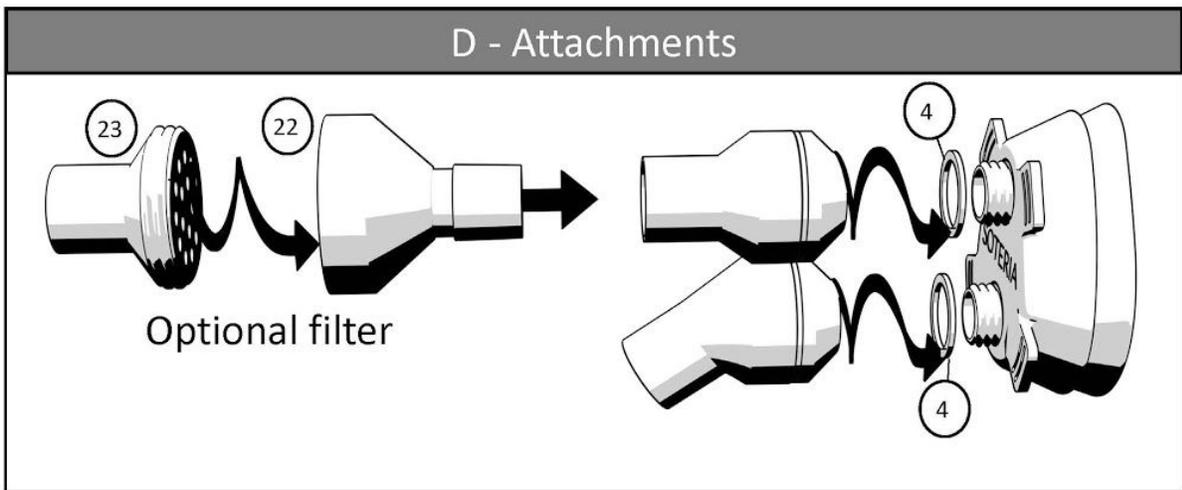
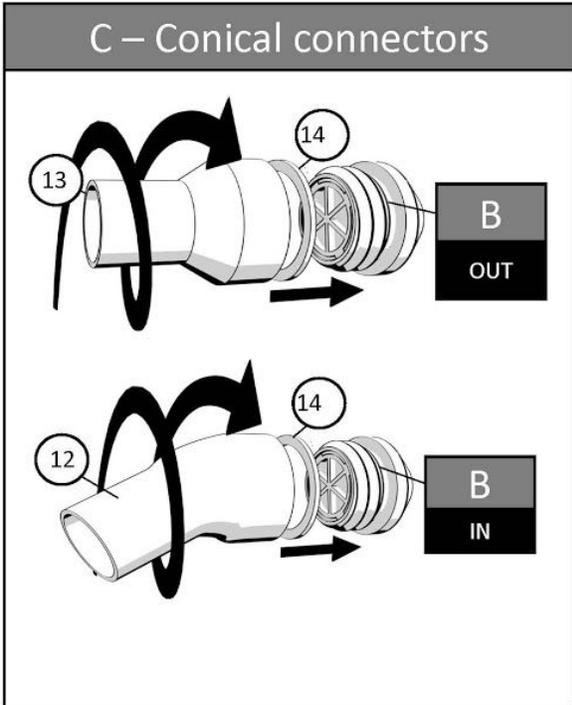
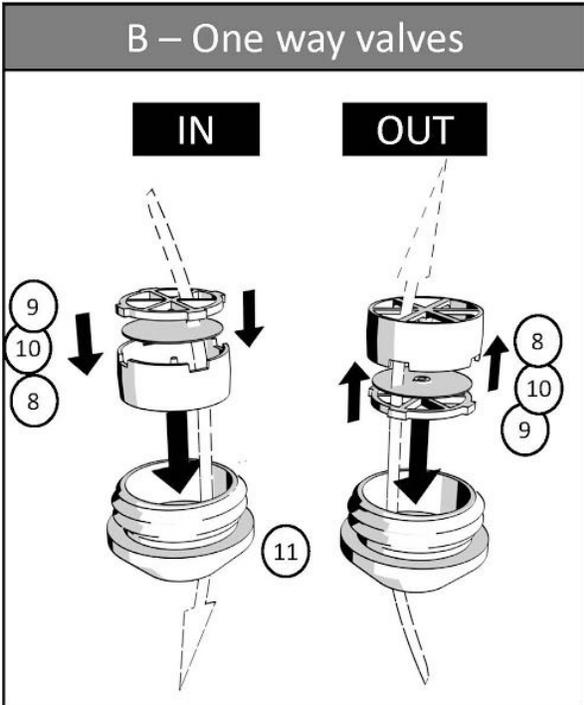
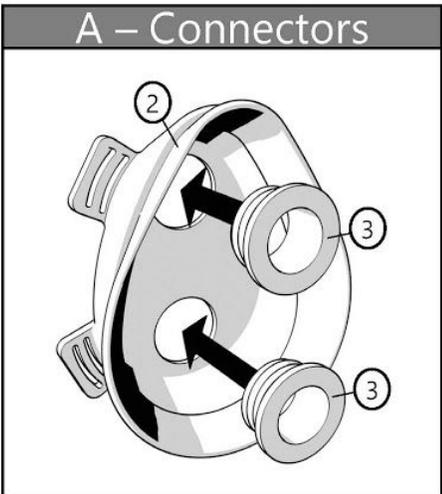
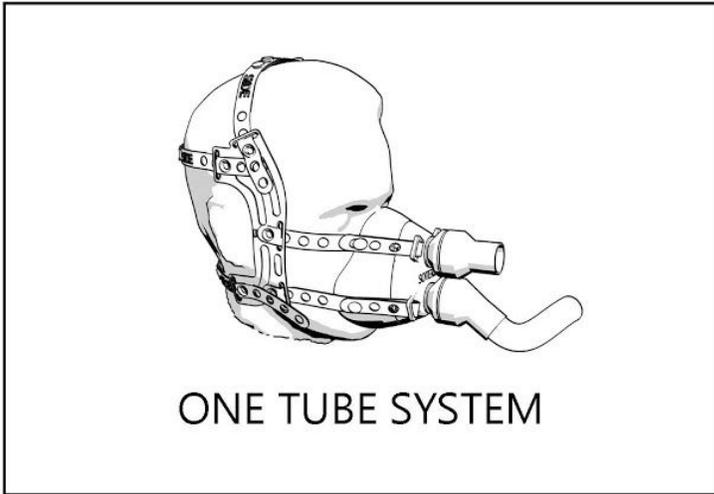


D – Headmount

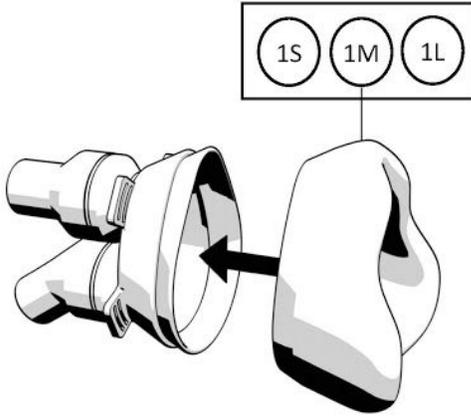


E – Headstraps, Symmetric

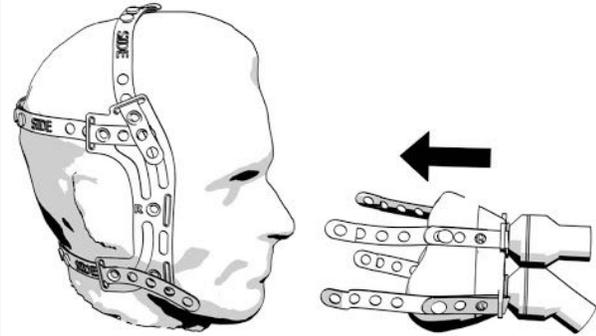




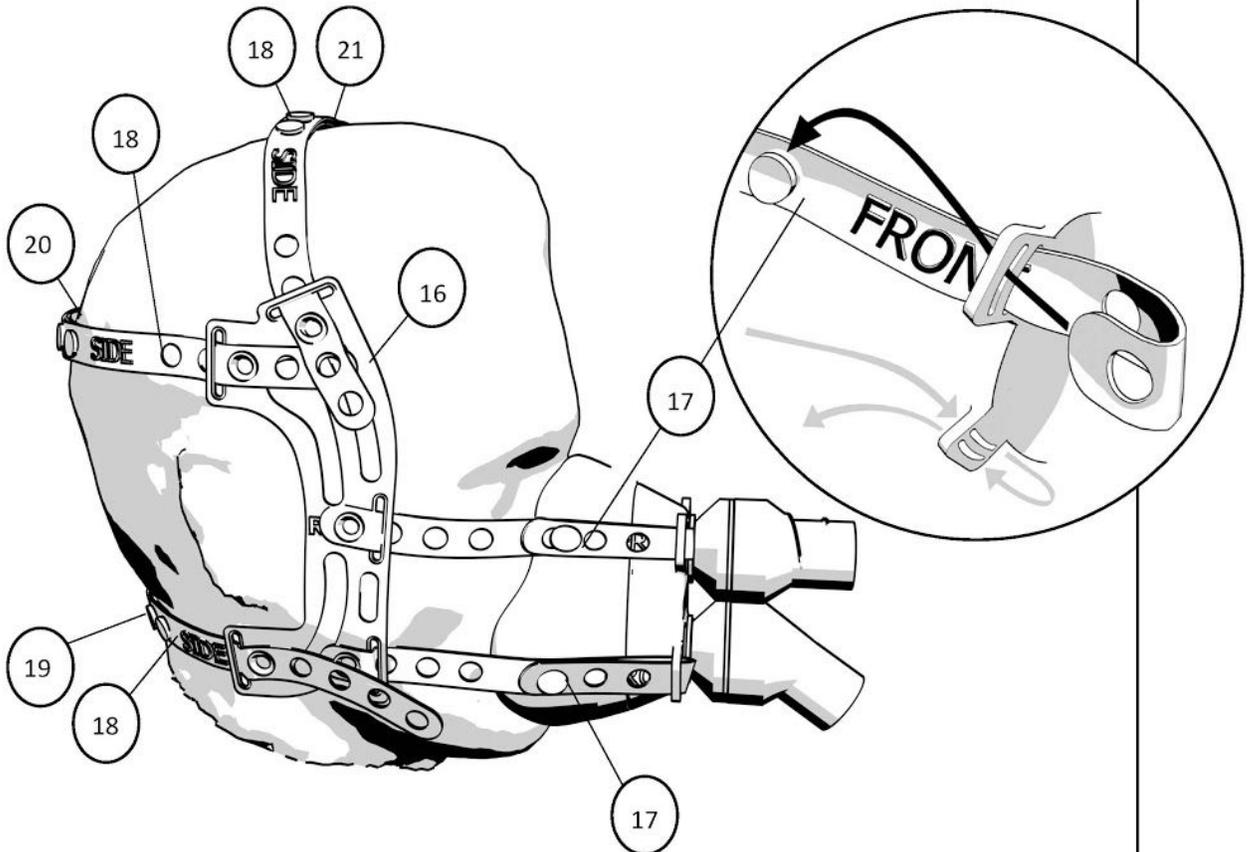
E – Mask Sizes



F – Headmount



G – Headstraps, Symmetric



Before Printing

The design of the mask is optimized for fused Fused Deposition Modeling (FDM 3D printers). If you intend to use the STL-files with different printing methods feel free to contact us.

We recommend a fine calibration of your printer before starting printing the mask and its parts. Further we recommend the use of direct drive for better results. To optimize the printing quality drying of the filaments can be useful.

Print Settings

Plate Adhesion

Brim for Parts 6, 7, 12, 22

Skirt for all other Parts

Speed

TPE: 20mm/s

PLA: 60mm/s

PETG: 60mm/s

Retraction

TPE: None.

PLA: as recommended for your Printer

PETG: as recommended for your Printer

Temperature (refer to Material Recommendation)

TPE: 210-245°C

PLA: 190-220°C

PETG: 225-245°C

Supports

None!

Resolution

Layerheight: 0.2mm

Nozzle: 0.4mm

Infill

TPE: 100%

PLA: 20%

PETG: 20%

Material Recommendation

It is necessary to use flexible material (TPE) for the flexible parts of the mask (e.g. Part 1, part 10, parts 17-21,, for detail refer to the part list on p. 5) in order for the mask to work properly.

PLA/PETG - Rigid Parts

We recommend using transparent materials. This allows the caregiver to check easily, whether sputum has been released, which can reduce the ventilation flow or could even cause suffocation of the patient.

For rigid parts, we recommend using PETG or other materials suited for healthcare applications if available. Otherwise we suggest using PLA. PETG and special medical 3D printable filaments are easier to disinfect and allow the parts to be reused. Alternatively, PLA is also a good material as it is more economical and is more available in developing countries and during supply shortages.

1. Verbatim PETG blue transparent

[Data sheet](#)

Printing Temperature: 225-245°C

Bed Temperature: 80°C



2. BASF Innofil3D PLA Iceblue

[Data sheet](#)

Printing Temperature: 205-220°C

Bed Temperature: 65°C



3. RepRap PLA transparent

[Data sheet](#)

Printing Temperature: 200-220°C

Bed Temperature: 60°C



TPE - Flexible Parts

We recommend TPE with a Shore hardness of 85A.

Different Shore hardness can be considered but we suggest to only use those if there is no 85A available. With increasing hardness such as 95A the flexibility of the mask design will be highly reduced. With more flexible TPE such as 82A the printing process is made more challenging and is not suitable for all low-cost printers, but will result in more comfortable masks.

1. BASF Ultrafuse TPU 85A

[Data sheet](#)

Printing Temperature: 210-230°C

Bed Temperature: 30°C



2. NinjaTek NinjaFlex 85A Snow

[Data sheet](#) , [chemical resistance sheet](#)

Printing Temperature: 225-245°C

Bed Temperature: 30°C



3. Recreus Filaflex Original 82A

[Data sheet](#)

Printing Temperature: 235°C

Bed Temperature: 35°C



4. Recreus Filaflex Medium 95A

[Data sheet](#)

Printing Temperature: 230°C

Bed Temperature: 35°C



Acknowledgement

This project was called into life by Munich Re and Fraunhofer Gesellschaft. Because of this, we would like to give a warm thank you to these two organisations for arranging the #Giveabreathchallenge and for supporting research teams in helping fight COVID19.

Beyond these two organisations, we would like to thank everyone who has participated during this challenge and all the experts who have helped our team with the design and iteration of the mask. Thank you so much for your help and support.

We are a team of 7 students and are grateful for the opportunity to work on such a pressing problem. We have put hundreds of hours into this project and would be very excited to see this mask distributed to the people in need.

With any questions, contact us any time.

Team Soteria



Moe Koeppenkastrop-Lueker
M.Sc. Medical Engineering
Student (TUM)



Lukas Peschel
M.Sc. Medical Engineering
Student (TUM)



Mira Mahavadi
M.Sc. Mechanical Engineering
M.Sc. Politics & Technology
Student (TUM)



Louis Krause
Medical Student (UMG)



Robert Roth
M.Sc. Medical Engineering
Student (TUM)



Thomas Wegele
M.Sc. Mechanical Engineering
Student (TUM)



Georg Lubins
M.Sc. Medical Engineering
Student (TUM)