Snorkel Mask 4 Life

Working towards emergency personal protection equipment against COVID19 virus

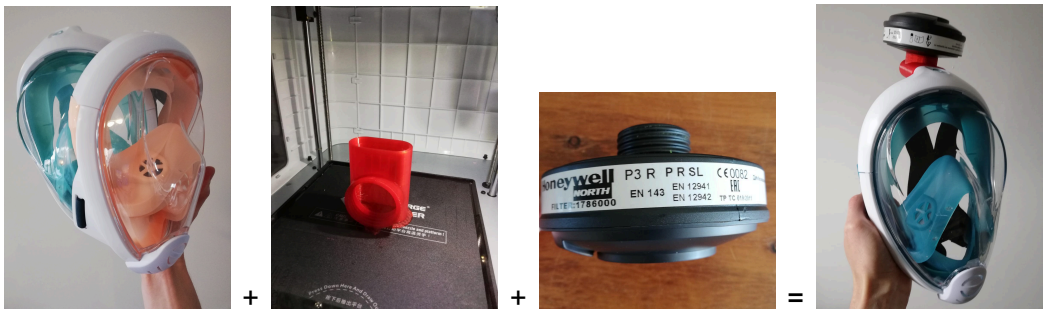

Figure 0: The Snorkel Mask 4 Life hypothesis: mask + coupler + filter = PPE ?

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Main Inspiration: ISINNOVA (Grazie Mille!!!) & Stanford Prakash Lab PneuMask

Introduction

As a result of the COVID19 pandemic there is a shortage in personal protection equipment (PPE) around the globe. In response to this global problem, our deepest concerns about situations in low-income countries, and the situation in The Netherlands we present the development of an emergency mask here. The goal of this document is to enhance collaboration and create a platform for sharing the progress of the project to the benefit of anyone in the world.

⚠️ DISCLAIMER / WARNING ⚠️
None of the work that is presented here is certified medical grade equipment. This is a work-in-progress open notebook. Use the information in this document at your own risk. We do not recommend the use of any of the information in practice until it is fully validated and peer-reviewed by independent experts.

Request a demo

In case you are interested in a Snorkel Mask 4 Life prototype for testing, validation or demonstration purposes, please contact pieter@snorkelmask4life.com

Problem definition

FFP2 mask shortage

FFP2 masks are running short all around the globe. In The Netherlands alone approximately 4,5 million masks are used every week. The world market has gone bonanza, corrupted with fraud and greed. As a result the many medical workers in The Netherlands are equipped with just a surgical masks or no protective equipment at all. Surgical masks do not protect against sub-micron COVID19 virus particles.[1] This problem concerns us deeply.

Comfortability issues

There are also many issues with the equipment that is available. For example, the currently used goggles are often regarded as uncomfortable and can cause bruises.

Figure 1: picture of a typical safety goggle

Planning

Under ideal conditions this project would follow a clear path from start to end. The truth is that we currently operate on a go-with-the-flow basis. In this part of the document we try to list what we are working on and see as our next steps.

Current research questions

- Is it possible to re-use P3 filters?
    - Expert opinion says so, validation on-going
- Is it possible to re-use second hand snorkel masks? Based on what criteria?
    -
- Is it possible to re-use the couplers? What material is best?
    - Depends on the material, validation on-going
- Could a rubber ring improve the sealing between the coupler and filter?
    - Face fit test show improved scores
- What is a suitable way to improve communication when wearing a mask?
    - Valve optimalisation or microphone/speaker
- What other usability issues arise when wearing the mask for a prolonged period of time?

[1] Van der Sande, 2013 Plos One

- What is the effect of wearing a mask, compared to other PPE?
    - Proposal for Clinical Trial submitted and others in development
- How can we best communicate our current results and future goals? Video?
    - New website in development

Future activities

- Check and improve mask sterilization protocols developed by Stanford
- Develop clear user instructions
- Design a manufacturing process for couplers

Completed activities

- 12-06-2020 Updated documentation on second hand masks
- 11-06-2020 SBIR Phase 1 proposal rejected
- 04-06-2020 SBIR Phase 1 funding proposal submitted
- 20-05-2020 Invited for SBIR proposal, made it to best 15 out of 96 proposals
- 17-05-2020 Drafting funding proposals
- 10-05-2020 Studying intensively peer-reviewed articles on PPE
- 06-05-2020 Logo design and draft website, to be launched soon
- 29-04-2020 Slide deck summary of findings and project
- 21-04-2020 Passed Qualitative Fit Test
- 21-04-2020 Improved coupler documentation, included clip
- 21-04-2020 Found and confirmed several large P3 RD40 filter suppliers
- 17-04-2020 Passed Quantitative Fit test
- 14-04-2020 Preparing prototype for quantitative Fit Tests with portacount
- 14-04-2020 Announce collection of Easybreath masks
- 13-04-2020 Publish coupler design on Thingiverse
- 12-04-2020 Publish RD40 thread and Easybreath coupler on Thingiverse
- 09-04-2020 Create an overview of all Easybreath types
- 08-04-2020 International meetup for snorkel mask initiatives
- 08-04-2020 Dry heat sterilization confirmed by experts as suitable sterilization protocol
- 08-04-2020 National Consortium cannot give insight into stock levels of filters or provide guidance on prioritizing a particular adapter
- 05-04-2020 Start documentation
- 04-04-2020 Deliver a second prototype to another hospital crisis team
- 03-04-2020 Deliver a prototype to the hospital crisis team
- 02-04-2020 Develop a prototype ready for testing
- 27-03-2020 Project initiation and acquisition of snorkel masks and filters

Engineering

Below we discuss several options and engineering challenges for each part of the project.

Parts

The Snorkel Mask 4 Life PPE that is project aims to develop consists of three parts:

1. Snorkel Mask
2. Passive Particle Filter
3. Coupler

Snorkel Masks

Several types and brands of snorkel masks could be used for making an emergency mask. Whereas the Prakash Lab Pneumask project focuses on the Dolfino Frontier and Ocean Reef ARIA mask, here we focus on the use of the Decathlon Subea Easybreath V1.

Advantages

- Decathlon is a major sports equipment outlet. Many people in The Netherlands probably already have a mask
- Snorkel masks cover the full face, thus combining the functionality of goggles and FFP2 masks
- Snorkel masks are widely available and do not increase the shortage in the current medical supply pool

Disadvantages

- Snorkel masks have been designed for under water usage. Above water gravitational force apply that might affect the fitting of the mask (to be tested)

Requirements / Standards

There are a number of standards that apply to PPE, that might be relevant to this project:

- FFP1, FFP2, FFP3 masks have to comply to NEN-EN 149:2001+A1:2009 en (Source: NHG)
- Surgical masks have to comply to NEN-EN 14683:2019+C1:2019 en (Source: NHG, updated to latest revision)
- Safety goggles have to comply to NEN-EN 166 (Source: NHG)
- Respiratory protective devices - half masks and quarter masks - requirements, testing, marking NEN-EN 140:1998/C1:2000 en

Decathlon Easybreath Mask

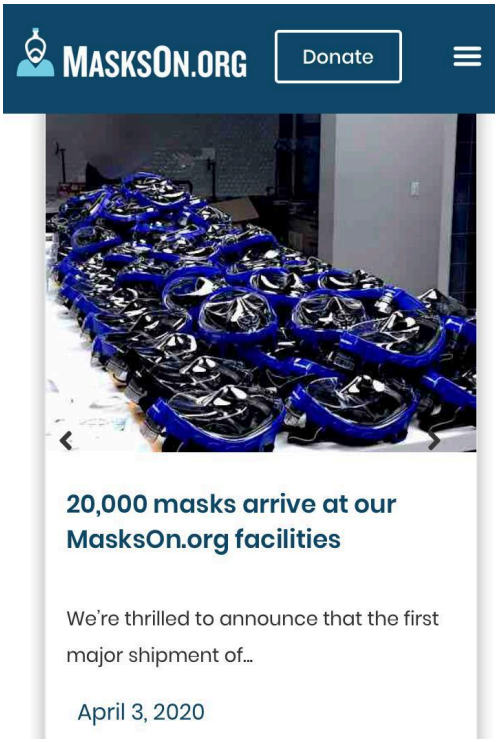
The Decathlon Subea Easybreath snorkel mask comes in several shapes and sizes. Three different sizes exist: XS, S/M and M/L.

We currently have two different models in our possession:

- Easybreath v1, item number: 2046935
- Easybreath 500, item numbers: 2398074 and 2382193

Since the Easybreath 500 is only on sale since March 2020, we focus on the Easybreath V1. The V1 also comes at slightly lower price point than the V500 (€ 19.99 vs 24,99). From other snorkel mask initiatives we have learned that the Easybreath 500 is also less suitable for PPE purposes, as it seems of lower quality.

Another type snorkel mask might also be a possibility, in the future. One snorkelmask initiative (https://maskson.org/) received instantly 20.000 masks. This indicated that snorkelmasks are still available in large amounts.



Eye - Chin distance:

- < 10 cm: XS
- 10 - 12 cm: S/M
- > 12 cm: M/L

Figure 3: Recommended use of variety in sizes by Decathlon

Figure 4: Easybreath V1 (left) and Easybreath 500 (right) front and back

Figure 5: Easybreath V1 connector with rubber ring. The center channel is for inhalation, the two outer channels for exhalation

Filters

Since we expect the health care sector to be confronted with shortages in filters, we include as many filters as possible in this project.

Requirements / standards

In this project we focus on FFP2-masks/FFP1-masks that have to comply to NEN-EN 149 + A1 standard. (Source: NHG)

Gas mask filter

Gas mask filters seem to be a very logical choice, since they were designed for filtering virus particles and to protect the users breath. Moreover, there are many different brands, so many supply chain options. So far we have included 3M, Draeger, Honeywell, Climax and Spasciani filters in this project.

3M

Figure 6: 3M filter connector and replacement filters

Product specifications
Acquired on March 27th and currently in evaluation by @Pieter

Advantage:

- 3M has a strong reputation as a brand
- Filter materials are replaceable

Disadvantage:

- Difficult to get, due to export restrictions in Germany

Draeger X-plore RD40

Product specifications

Acquired on March 27th, but not delivered due to export restrictions from Germany

Advantage:

- RD40 standard connector

Disadvantage:

- Difficult to get, due to export restrictions in Germany

Honeywell bus filter

Figure 8: product picture, and pictures of RD40 40mm 1/7" connector

Product specifications

Acquired on March 27th and currently in evaluation by @Pieter

Advantage:

- RD40 standard
- Still available in several stores

Climax

Figure 9: product picture and pictures of the connector

Product specification needs better link

Acquired on March 27th and currently in evaluation by @Pieter

Disadvantage:

- Strange connector

Spasciani

Figure 10: product picture and picture of the connector

Product specification needs better link
Acquired on March 27th and currently in evaluation by @Pieter

Disadvantage:

- Strange connector that has to perfectly fit

HME filter

There seem to be many snorkel mask PPE projects in development that are based on HME filters, but there is also discussion on whether these filters are suitable for this kind of application. In this project we are not interested in this type of filters.

In case you are interested in HME filter approaches in The Netherlands, take a look at COVID Life Saver Mask.

Coupler

Requirements / standards

- Disposable or re-use?

Prototyping

The main engineering challenge is to create a coupler between the mask and the filter. This is a typical challenge for which 3D printing can be used to create prototypes.

3D printing

All couplers in this project are currently produced by 3D printing in PLA material.

In a future stage we will evaluate the use of other materials:
Sterile 3D printing material that withstand sterilization techniques

Gas mask filter couplers

Since pretty much every brand of filter comes with its own connector, thus we need a different coupler for each brand. The RD40 standard seems to be the most widely used, which is why the Snorkel Mask 4 Life project starts with focussing on this coupler.

Also, there are many Easybreath couplers to be found on the web, but only few designers share the CAD source files, but most of the time in proprietary formats. This limits the number of potential users and contributions. This is why this project present fully Open Source designs.

Snorkel Mask 4 Life Universal Open Source Easybreath V1 coupler

- Design by: Pieter van Boheemen
  Printed by Pieter on April 13th

Designed in OpenSCAD, fully parametric and open source. It can be easily modified to account for the tolerances of your 3D printer

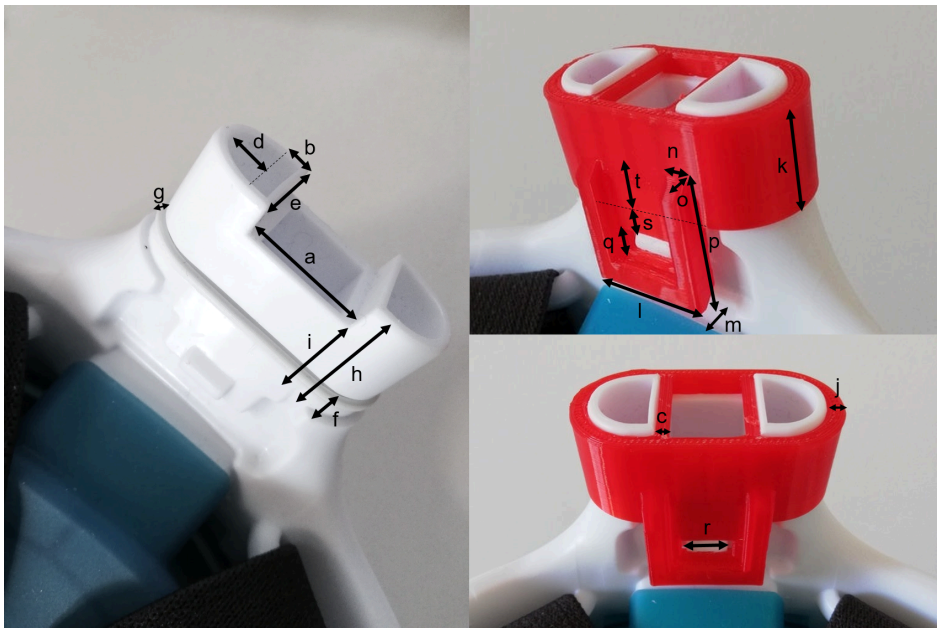


Figure X: Snorkel Mask 4 Life Universal Open Source Easybreath V1 coupler

The parameters in the OpenSCAD code correspond to the following dimensions indicated in the figure above:

- a: center_channel_width
- b: channel_straight_width
- c: channel_seperator_width
- d: side_channel_width
- e: depth
- f: rubber_height
- g: rubber_width

- h: male_connector_height
- i: coupler_center_delta
- j: coupler_thickness
- k: coupler_height
- l: clip_width
- m: clip_depth
- n: clip_reinforcement
- o: clip_reinforcement_depth
- p: clip_height
- q: clip_hole_height
- r: clip_hole_width
- s: clip_hole_distance
- t: clip_overlap

Stanford Universal Easybreath coupler

- Design by: Pollina Thibaut
  Printed by Pieter on April 7th and fits great. No CAD file available

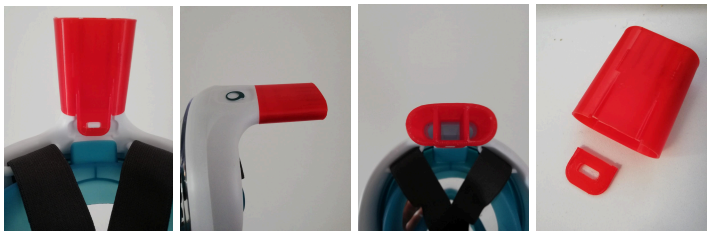


Figure 13: Pictures of assembly and broken clip

- Issue: clip breaks when trying to release the adapter

3M

- Design by: Alfredo Redondo
  Printed by Pieter on a FlashForge Adventure 3 on April 1st

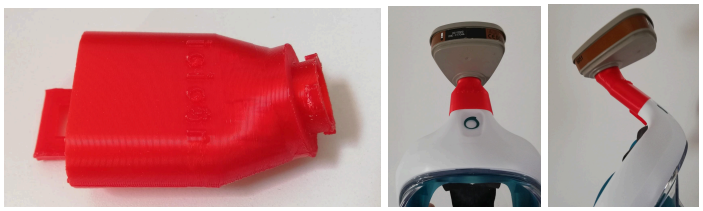


Figure 14: Pictures of print and assembly

- Issue: connector needed to be modified with a knife to fit a 3M filter on

RD40

Snorkel Mask 4 Life Universal RD40 thread

- Designed by: Pieter van Boheemen
  Printed on April 12th

This Universal thread allows anyone to easily design your own couplers for RD40 filters.

Figure X: Universal RD40 thread

It has been designed with the help of the SS-EN 148-1:2019 standard.

Snorkel Mask 4 Life RD40 coupler

- Design by: Pieter van Boheemen
  Printed on April 13th

Figure X: Snorkel Mask 4 Lfie prototype

- Issue: no clip yet, will be included in next version

Draeger X-plore RD40

- Design by: RealCharal and RealCharal V2.1
  Printed by Bart Bakker and Henk Buursen on March 31st
  Ordered at 3Dhubs on March 27th

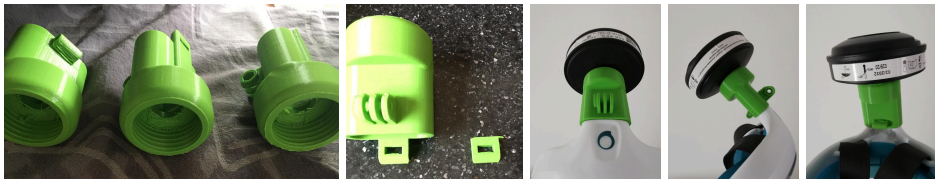


Figure 15: pictures of print and assembly

- Issue: clip breaks easily when fastening the adapter to the mask

These adapters are meant to be used with filters with a 40mm 1/7” connection.

There are also adapters that convert a 40mm 1/7” into a 3M connector and vice versa.

- 40mm 1/7” to 3M converter and vice versa by Ksantor

Honeywell

- Design by: RealCharal
  see above
- Design by: CovMask

Climax

- To be designed

Spasciani

- To be designed

Couplers for other filter types

Currently the couplers are out of scope of this project.

Draeger HME

- Designed by: COVID_LIFESAVER_MASK
  Printed by Bart Bakker and Henk Buursen on March 31st

Figure 17: 3D model and prints

We are NOT testing HME filter based PPE, nor recommending to use these.

Production

Once a prototype satisfies all requirements we will need to switch to mass production.

Injection molding

This production method seems most suitable for large scale production.

Usage

In this section we gather information on how to use the Snorkel Mask 4 Life equipment.

Communication

Initial test showed that it can be hard to communicate by voice when wearing the mask. A microphone / speaker setup might solve this issue.

Wireless clip on microphone

Jam Hang Up speaker with 3.5mm line in - CoolBlue MediaMarkt

Usage protocol

Example NHG Persoonlijk Beschermingsmiddel Werkafspraak

Mask sterilization protocol

We aim for reusing the snorkel mask. The couplers are probably going to be single use disposables.

Dry heat

works according to references from Prakash document:

[13] Darnell, M. E. R., & Taylor, D. R. (2006). Evaluation of inactivation methods for severe acute respiratory syndrome coronavirus in noncellular blood products. *Transfusion*, *46*(10), 1770–1777. https://doi.org/10.1111/j.1537-2995.2006.00976.x

[14] Rabenau, H. F., Cinatl, J., Morgenstern, B., Bauer, G., Preiser, W., & Doerr, H. W. (2005). Stability and inactivation of SARS coronavirus. *Medical Microbiology and Immunology*, *194*(1–2), 1–6. https://doi.org/10.1007/s00430-004-0219-0

Autoclaving

Tests by Parkash lab on the Ocean Reef mask look promising, but to our knowledge no such tests have been conducted on Easybreath masks

Ethanol

Tests by Parkash lab on the Ocean Reef mask look promising, but to our knowledge no such tests have been conducted on Easybreath masks

Bleech Soap

Tests by Parkash lab on the Ocean Reef mask look promising, but to our knowledge no such tests have been conducted on Easybreath masks

Regulatory Affairs (The Netherlands)

This section is about the regulatory aspects of the project and focuses on the required steps for use and approval in The Netherlands.

Testing, evaluation and certification

Testing the Snorkel Mask 4 Life concept

Full face masks can be tested in a qualitative and quantitative manner.

The qualitative face fit test was passed, tested on one female subject with Denatonium.

An independent biosafety expert is conducting a quantitative Fit Test with a TSI Portacount 8038 on a SM4L prototype, using the Quantitative Face Fit Test Method (QNFT) following the OSHA protocol. The test resulted in an overall Fit Factor of 146 (full report in image below). The test was repeated on a second male subject, resulting in a Fit Factor of 110. The publication of the results has led to a discussion on the method and threshold value. Some argue a fit factor of less than 500 or 1000 is the minimum. So although the diagram below shows the prototype passed the test, we await further testing before we conclude that the prototype passed

EXERCISE	DURATION (sec.)	FIT FACTOR	PASS
NORMAL BREATHING	60	125	Y
DEEP BREATHING	50	141	Y
HEAD SIDE TO SIDE	40	165	Y
HEAD UP AND DOWN	40	184	Y
TALK OUT LOUD	50	169	Y
GRIMAS	20	Excl.	
BENDING OVER	50	129	Y
NORMAL BREATHING	60	131	Y
OVERALL FF		146	Y

Figure X: Prototype that has been delivered to independent expert for Portacount validation and results

Identified issues:

- After 20 minutes the resistance in breathing increases slightly. THis is probably due to moisture from exhale breaths accumulating in the filter. Exhaling through a seperate (filtered) channel is therefore recommended.
- The mask has to sufficiently fastened in order to pass the bending over test

Testing refurbished Decathlon Easybreath masks

A shortage in Decathlon Easybreath masks could seriously limit the impact of this project. This is why we are evaluation whether used, second hand masks could be refurbished. This effort serves two goals. On the one hand we are considering whether it makes sense to conduct a large scale collection, on the other hand we would like to know what happens to masks when they are used for a prolonged period of time.

Establishing (exclusion) quality criteria

Based on a first batch of collected masks we are establishing criteria for evaluating second hand masks. These include:

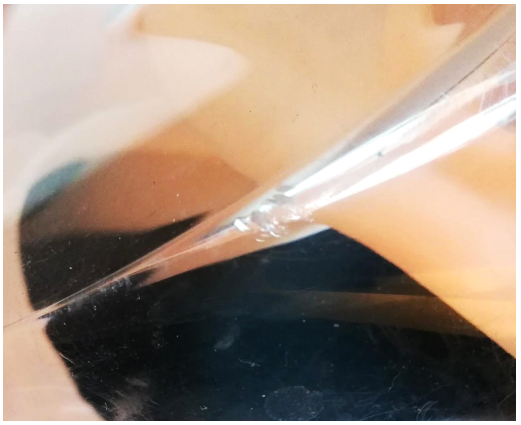
Visual inspection

- Silicone rubber:
  - Is the seal to the face intact?
  - Are the exhale ventilation channels fully connected?
- Visor:
  - Is it still clear?
  - No scratches?
- Connector:
  - Has it been deformed?
  - Is the rubber ring still intact?
  - Are all channels open, non-clogged?
- Valves:
  - Are these still functional?
  - Are all three valves still present? Two near the nose, one in the chin
- Elastic straps:
  - Are these still flexible and not overstretched?
  - Are there any signs of rapture in the straps?
- Dirt
  - Is the mask clean, and is there no dirt in between the rubber and plastic parts?

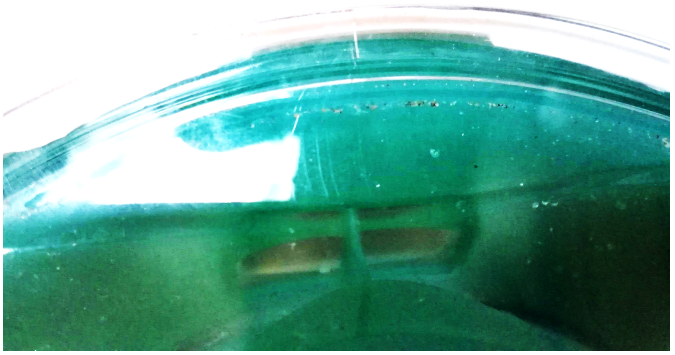
Common defects

In the masks donated to Waag were in a surprisingly good state. Some masks were more than 2 years old and were used for several weeks of snorkeling. Here are a few pictures of common (minor) defects:


Early signs of rapture in the elastic strap - Nose valve missing



Scratches on the visor



Dirt / sand stuck in between rubber and visor

Other validation efforts

- LUMC is conducting a qualitative Respirator Fit test with Denatonium
- TNO ProQares contacted on April 6th and forwarded us to a Notified Body for CE-marking, such as BSI, DEKRA or APAVE

Relevant authorities

- Inspectie Gezondheidszorg en Jeugd (IGJ Min VWS)
    - “Een fabrikant kan mondneusmaskers op de markt brengen als beschermingsmiddel en/of als medisch hulpmiddel. De IGJ houdt toezicht op medische hulpmiddelen conform 93/42/EEC; de Inspectie SZW is markttoezichthouder voor persoonlijke beschermingsmiddelen (EU 2016/425)” (Source: Toelating beschermingsmiddelen)

    - “de zorginstelling moet expliciet om de alternatieve middelen vragen en draagt de verantwoordelijkheid voor het gebruik ervan” (Source: Toelating zonder CE-markering)
    - Instructie verzoek leverantie alternatief medisch hulpmiddel
    - Contacted on April 6th

- Outbreak Management Team / RIVM
    - Advies Ademhalingsbescherming

- Landelijk Consortium Hulpmiddelen (LCH)

- Landelijk Netwerk Acute Zorg (LNAZ)
    - Regionaal Overleg Acute Zorg (ROAZ) per regio

Relevant scientific insights

Modified Full-Face Snorkel Mask as COVID-19 Personal Protective Equipment: Quantitative Results
https://www.preprints.org/manuscript/202004.0293/v1

Presymptomatic SARS-CoV-2 Infections and Transmission in a Skilled Nursing Facility >> https://www.nejm.org/doi/full/10.1056/NEJMoa2008457
Virus detected in pre- and asymptomatic patients, also high viral load found in those cases

Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. Cochrane Systematic Review 2020 >>
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011621.pub4/full
Evidence is low to very low. The sample sizes should be much bigger. There is a need for collaboration between organisations serving epidemic areas to carry out this important research in circumstances with limited resources, and during the throes of an outbreak.

Aerodynamic analysis of SARS-CoV-2 in two Wuhan hospitals

Recognition of aerosol transmission of infectious agents: a commentary
Aerosol transmission is often underestimated

Airborne transmission of SARS-CoV-2: The world should face the reality
Discussion on whether transmission via air is likely or not

Turbulent Gas Clouds and Respiratory Pathogen Emissions
COVID19 possibly travels 8 meters in the air when a patient sneezes

News

A list of news items related to snorkel mask PPE initiatives:

Overheid kocht bijna tien miljoen ongeschikte mondkapjes
World market still wild wild west

https://www.npostart.nl/vpro-tegenlicht/03-05-2020/VPWON_1310220
Tegenlicht: The Bigger Picture. To put things into perspective… we should improve globalisation.

Hoofd IC Amsterdam UMC: 'Opschalen naar 3000 IC-bedden is een fata morgana'
Nog steeds tekort

Pneumask: Modified Full-Face Snorkel Masks as Reusable Personal Protective Equipment for Hospital Personnel

Hoog spel in een louche wereld: hoe Nederland faalde in de jacht naar mondkapjes

Mondkapjes bereiken thuiszorg en verpleeghuizen niet ondanks nieuw verdeelmodel
https://www.rtlnieuws.nl/nieuws/nederland/artikel/5102611/mondkapjes-beschermende-middelen-zorg-verpleeghuis-thuiszorg

https://www.npostart.nl/maurice-de-hond-over-zijn-data-analyses-over-corona-en-de-reactie-van-ab-osterhaus/18-04-2020/POMS_BV_16087802 (translated from dutch) Dutch expert prof dr A.D.M.E. Osterhaus stated “with some expiration maneuvers droplets ánd aerosols are formed”.

Vloeistoffysicus: virusdruppels vliegen veel verder dan anderhalve meter
https://newscientist.nl/blogs/vloeistoffysicus-virusdruppels-vliegen-veel-verder-dan-anderhalve-meter/

‘Onderzoek is de hand aan de kraan’
https://www.groene.nl/artikel/onderzoek-is-de-hand-aan-de-kraan
A call for more grass roots approaches in The Netherlands

https://maskson.org/
crowd funding, they raised over 2.000.000 milion US dollars!

Brandbrief KNOV aan minister De Jonge over PBM verloskundigen
Midwives need PPE!

‘Zorgverleners grootste risicogroep’
Clearly health care workers are at risk and need more protection

Duikmasker Decathlon omgebouwd tot mondmasker
Example from Brussels - Albert De Beir, based on different kind of filter approach

Decathlon snorkeling mask: Use Cases in Covid epidemics explained.
Overview of several Decathlon Easybreath initiatives in the world, take not of the warnings!

Met dit simpele snorkelmasker kunnen coronapatiënten zuurstof krijgen
Waiting for approval by Inspectie Gezondheidszorg en Jeugd

Makers van snorkelmasker tegen corona zoeken filters
Call for donating Damen Air-Wave filters

Other initiatives

Snorkel mask PPE

⚠️ **WARNING:** We do not endorse or suggest to use any of the work presented on the following websites. This list is intended to gain an overview of other (more or less) related snorkel mask PPE initiatives only.

Kennis Alliantie 3DQ

PneuMask Community Map

PneuMask - USA

COVID Mask Project status update

MedShield19 - Germany

Filip Kober - Poland

COVID19 Emergency Face Mask - USA

COVID-19 Swim Mask HEPA PAPR - USA

ARTA - Italy

CovMask - Czech Republic

- Potential supplier https://www.ec-covid.eu/index.php/en/

PezyGroup - Netherlands

… - India

Snorkel mask ventilator

ISINNOVA Easy COVID 19 - Italy

Project Open Air - Netherlands

UTwente Best vs COVID - Netherlands

History

Easybreath PPE solutions were pioneered by the Yellow Vest movement, as shown in this design by FrenchCivilian