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"Universal mobile protection system for aerosol-generating medical interventions in COVID-19 patients"

Straube, F., MD, FESC, FHRS[1,2]; Wendtner, C., MD[3]; Hoffmann, E., MD, FESC[1, 2]

For the medical personnel of the Muenchen Klinik Hospital Group, Munich, Germany:
Volz S.[1], Dorwarth U. [1], Engel M. [1], Schneider N. [2], Lärmer J. [2], Nagel B.[2], Friederich P.[4], Fisch R.[4], Riess A.[4], Benedikter J.[5], Meyer F.J.[5,6], Lewerenz B.[7], Schepp W.[7], Schmid M.[8], Dodt C.[8], Schmidt W.[1], Weidenbach K.[1], Rogowski S. [1], Kossmann H. [1], Berger M. [1], Gatos C.[1], Wuerstl B.[9], Deichstetter M.[1]

1) Department of Cardiology and Internal Intensive Care Medicine, Munich Clinic Bogenhausen, Academic Teaching Hospital, Technical University of Munich (TUM), Munich, Germany
2) Department of Cardiology, Pneumology and Internal Intensive Care Medicine, Munich Clinic Schwabing, Academic Teaching Hospital, Ludwig-Maximilians-University (LMU), Munich, Germany
3) Department of Hematology, Oncology, Immunology, Palliative Medicine, Infectious Diseases and Tropical Medicine, Munich Clinic Schwabing, Academic Teaching Hospital (LMU), Kölner Platz 1, 80804 Munich, Germany
4) Department of Anaesthesiology, Munich Clinic Bogenhausen, Academic Teaching Hospital (TUM), Munich, Germany
5) Department of Pulmonology and Pneumological Oncology, Munich Clinic Bogenhausen, Academic Teaching Hospital (TUM), Munich, Germany
6) Department of Pulmonology, Gastroenterology and Internal Intensive Care Medicine, Munich Clinic Harlaching, Academic Teaching Hospital (LMU), Munich, Germany
7) Department of Gastroenterology, Hepatology and Gastrointestinal Oncology, Munich Clinic Bogenhausen, Academic Teaching Hospital (TUM), Munich, Germany
8) Department of Emergency Medicine, Munich Clinic Bogenhausen, Academic Teaching Hospital (TUM), Munich, Germany
9) Department of Hygiene and Prevention of Infectious Diseases, Munich Clinic Schwabing, Academic Teaching Hospital (LMU), Munich Germany

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¶**Corresponding Author:** Florian Straube, M.D., FESC, FHRS
Department of Cardiology and Internal Intensive Care Medicine
Muenchen Klinik gGmbH, Hospital Bogenhausen
Englschalkinger Str. 77, 81925 Munich, Germany
Phone +49-89-9270-702237, Fax +49-89-9270-4502
florian.straube@muenchen-klinik.de (for official use and third-party communications)

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Background and Rationale

SARS-CoV-2 can actively replicate in the upper respiratory tract, and is shed for a prolonged time after symptoms end [1]. The prolonged viral shedding in sputum is relevant for hospital infection control [1] and the necessary protective measures for the medical personnel.

Direct care for patients with infectious diseases might be a risk for nursing staff and treating doctors who can become infected [2]. For healthcare workers performing aerosol-generating procedures on patients with COVID-19 in the intensive care unit, using fitted respirator masks (N95 respirators, FFP2, or equivalent) in addition to other personal protective equipment (i.e. gloves, gown, and eye protection, such as a face shield or safety goggles) has been recommended [3].

However, medical personnel is at risk of becoming infected with severe illness due to high exposure to the virus (e.g. aerosol formation during intubation) [4]. This risk increases due to the fact that personal protective equipment of staff members is mainly based on disposable materials, and the supply is limited in the context of the pandemic [5,6].

The present report introduces a new type of mobile and reusable protection system that medical staff can use in addition to the personal protection measures already in operation. It might be used during medical procedures and medical examinations or procedures by doctors, where it is likely to be a high amount of aerosol from the patient. It is made up of several parts that together might help to protect medical staff, in addition to established protection measures.

Inventive steps

- The invention of protective equipment that is neither worn by staff nor patients, but is placed on the ground and can be moved around on castors.

- Development of a flexible system that can be used also in confined spaces (e.g., so-called isolation boxes in intensive care wards), in operating rooms or functional areas.
- The universally applicable transparent protective screen with an angled field of vision might deflect and prevent aerosols from being inhaled by the user
- Making openings that allow personnel to treat patients without significantly reducing protective function.

Detailed description of the protection system

The mobile protection system is made up of several parts (Figure 1 - 3).

The protection system is ideally mounted on four **swivel castors** (between 2 to 20 castors). The castors have an conceptually designed diameter of 5 cm (between 4 and 10 cm) and can be equipped with a locking function. The material of the castors is durable stiff plastic, with or without rubber tyres. The load capacity of the castors at 4 km/h should be of order 75 kg (between 30 and 150 kg).

A **base plate** is mounted on the castors with mounting plates.
The base plate has an ideal width of 75 cm (between 40 and 220 cm), a height or thickness of 0.6 cm (between 0.2 to 4 cm) and an extend of 39 cm (between 30 and 80 cm). The base plate is ideally made of commercially available material, e.g. aluminium layers, which have been thermally bonded to a polyethylene core and are hereinafter referred to as "aluminum Dibond" (alternatively made of stiff durable plastic, wood, acrylic, and/or metal). Aluminum Dibond can be shaped with jigsaws, scroll saws, copy milling machines and water jet cutting systems as well as CNC machining centers. Templates for cutting the components can be found in Figure 2.

The base plate has a cut-out on the patient's side so that it can be pushed under the bed or the surgical table when being used. This enables close contact to the patient even if, for

example, the castors of the bed are positioned directly in front of the protective screen. The cut-out in the base plate has a designed width of 35 cm (0 to 140 cm) and an extend of 23 cm (between 0 and 70 cm).

Two customised **side plates** (stands) are mounted on the base plate for stabilisation. These have to be cut out according to use so that the protective screen can be moved close to the patient, still guaranteeing the system's stability. Ideally, the side wall on top is only 5 cm wide (3 to 20 cm). This can be made from the same materials as the base plate. The dimensions of the side plate depend on the base plate and the total height of the protection system in order to ensure stabilisation. Ideally, the side panels are 50 cm wide (between 20 and 100 cm) and 70.5 cm high (between 40 and 140 cm). The shape of the side plate defines an angle for the inclination of the protective screen. Ideally, the **inclination of the protective wall** is three degrees (between 0 and 20 degrees).

The protective wall consists of 3 mm (between 1 to 20 mm) thick clear polymethyl methacrylate, so-called "acrylic glass". Depending on the overall height and the material used, the lower area should ideally be stabilised with opaque aluminium Dibond (alternatively metal, wood, and/or hard plastic). The opaque stabilisation has an ideal height of 108 cm (from 60 to 160 cm).
The entire protective screen has an ideal height of 143 cm (between 110 to 200 cm). At this height, for example by forming the material using heat, the acrylic glass is bent forwards towards the patient at a 60° angle (from 0 to 120 degrees). This part of the protective screen is called **face protection** and then has an ideal length of 40 cm (from 0 to 50 cm).

The protective screen and **face protection** made of acrylic glass have an ideal width of 75 cm (between 40 and 220 cm). In the upper transparent part of the protective screen, **openings** can be cut into the acrylic glass if required. Depending on application and protection requirements, circular openings with an ideal diameter of 15 cm (between 5 and

30 cm) can be cut for people to put their arms through. The height of the openings depends very specifically on the screening and measures carried out, as well as on the medical staff's physical size. Ideally, the opening is between 115 cm (between 60 and 170 cm) and 130 cm (between 75 and 185 cm) from the floor. The opening can also be rectangular and is then ideally 50 cm wide (between 5 and 150 cm) and 15 cm high (between 5 and 40 cm).

On the patient's side, the openings can be optionally provided for with so-called **extensions ("gaiters")** or gloves made of artificial leather (alternatively disposable material, synthetic material or latex) to better shield off the examining personnel from the patient. These can be attached to the openings with adhesive or snap fasteners or Velcro.

The protective screen is stabilised on both sides by means of aluminium rails from the base plate to the bending of the acrylic glass. The optimal width of the rails is 2.5 cm (between 1 and 7 cm), the thickness is optimally 0.8 cm (0.5 to 2 cm). The height depends on the height from the base plate to the bending of the acrylic glass and is ideally 134 cm (between 50 and 180 cm).
The rails can be glued to the protective screen and should also ideally be fastened through holes in the protective screen, for example with Allen screws and nuts.

To stabilize the top of the system and to prevent aerosols to escape laterally, an 8 mm (from 3 to 11 mm) thick acrylic glass of triangular shape could be mounted by acrylic glass adhesive or with the help of screws on the patient’s side at the angle between protective screen and face shield. Steam tests with and without side shields suggest an improved protection with the latter. High resolution slow-motion video files from the tests are provided online as a supplement (https:// osf.io/7u2tv).

The top and front part of the system including the face shield might be extended with adhesive strips or Velcro and disposable plastic covers if longer procedures are planned and if a full shielding of the patient is required.

All **joints** on the design are sealed with commercially available jointing material so that the protection system can be cleaned and disinfected. Special instructions for disinfecting and cleaning the material are provided by the manufacturer of the materials.

All **corners and edges** should be rounded off with a radius of 5 to 50 cm in order to protect the patients and staff. All cut-outs should be made in such a way that there are no sharp edges. Protruding edges can be marked with warning colours and/or made safe with soft plastic (rubber) in the form of attachments. Attachments are fixed with adhesive.

Cleaning and surface disinfection

The acryl surface of the shield is sensitive to alcohol based disinfection. The manufacturer of the acryl material can provide detailed information on resistance to certain substances. We used Polymethylmethacrylat (PMMA) and performed a gradual exposure attempt over up to 24 hours with two different commercially available non-alcoholic surface disinfection products. The endpoint was visible alteration on the glass after the disinfection and drying. On 6 pieces of glass we exposed the material to water with rinse aid (negative control), 1% solution Peracetic acid (in-situ) > 750 ppm (ULTRASOL® ACTIVE, Dr. Schumacher GmbH, Malsfeld, Germany), or 1.5% solution Hydrogen peroxide with Glycolic acid (Incidin OxyWipe S®, Ecolab Deutschland GmbH, Monheim am Rhein, Germany). We repeated a standard surface disinfection up to 10 times and incubated one piece of glass in both of the test substances overnight in a sealed plastic bag. No permanent visible changes of the material were observed with both products. After drying of the ultrasol® active little white specks were observed on the glass when holding the glass up to the light. These residues were washable, no permanent damage of the glass was visible. After drying of the Incidin OxyWipe S®,

almost invisible, somewhat sticky smudges without any white specks were noticeable when holding the glass up to the light. These residues were washable, no permanent damage of the glass was visible. No long-term exposure >24h was tested, no technical tests were performed. Therefore, we cannot exclude that those substances affect the resistance and the usability of the PMMA material in case of repeated use over time. Both of the products, ultrasol® active and Incidin OxyWipe S® have been approved to be used with PMMA by the manufacturers.

Occupational safety

The mobile protection system has not yet been assessed by one of the well-known technical inspection organisations. The inventor and the authors of the manuscript assumes no responsibility for using the system with humans. There is no scientific data on the effectiveness of protection against an infectious disease for the user, nor are there any data to prove that patients can be treated as well behind the protection system as without it. This is personal protective equipment and not a medical device. The application may only be carried out together with the officially recommended protective measures. The protection system is used at the user's own risk.

Possible benefits of the invention

Additional protection for medical staff when working close to patients when diagnosing and treating patients suffering from acute contagious infectious diseases such as the coronavirus diseases SARS-CoVid-2/CoVid-19.

Possible locations of use

- In hospitals: accident and emergency unit, intensive care unit, non-invasive and invasive diagnostic/treatment units (e.g. cath lab), operating theatre, isolation ward, monitoring ward, normal ward
- Doctor's office e.g. outpatient surgery

- Might be used for the protection of the staff at airports, in stores or on markets

Possible application of the protection system and examples of work close to patients and screening with high aerosol formation

- Mouth care with ongoing high-flow or non-invasive ventilation therapy
- Exchange of the breathing circuit tubes or disconnection of the masks
- Intubation and reintubation
- Bronchial lavage, bronchoscopy
- Placement and exchange of a tracheostomy tube
- Upper GI endoscopy, gastric tubing
- Transesophageal echocardiography
- Placement of a central venous catheter or any puncture in non-intubated patients
- Placement and initiation of an Extra Corporeal Membrane Oxygenation (ECMO) system
- Placement of a drainage e.g. pleura, pericardium
- Diagnostic and treatment in ophthalmology, ENT, dentistry
- Might be used in any longer lasting direct face-to-face contact situations <1.5 m of distance

Authors and collaborators contributions

F.S., S.V., and M.D. had the idea, F.S. developed the prototype, drafted and revised the manuscript, and the figure. On 27 March 2020 the employer informed F.S. that the decision to publish is up to him. The co-authors C.W. and E.H. gave medical advice, revised, and approved the manuscript.

The collaborators S.V., M.D., and M.E. gave substantial medical advice. S.V., M.D., N.S., J.L., B.N., P.F., R.F., A.R., J.B., B.L., W.S., M.S., W.S., K.W., S.R., H.K., and E.H. assessed the prototype in a test track to simulate representative clinical scenarios. In addition, they were test models for the size dimensions, especially for the positioning of the passage

openings. All of them gave practical and medical advice. All collaborators read and approved the manuscript.

Conflicts of Interest / Disclosures:

Authors and collaborators: Nothing to declare.

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The authors ethical opinion

Due to the SARS-CoVid-2/CoVid-19 virus pandemic declared by the World Health Organization (WHO) on 11 March 2020 and the resulting humanitarian emergency situation[6], the applicant would like to ensure that the intellectual property of the inventor does not fall into the wrong hands where third parties could profit from it at the expense of those affected and society. The applicant also wants to prevent the invention from being patented by others, which would slow down the availability of the protection system, hence costing lives.

Conclusion

A universal, reusable, easy-to-clean, and mobile protection system medical interventions in acute infectious diseases with aerosol formation including COVID-19 has been developed. It is considered useful by the main medical disciplines involved in the treatment of COVID-19 patients. In those times, disposable protection gear is scarce, and the robust, reusable protection system might be helpful for medical personnel to work more safely in vulnerable situations.

Figures

Figure 1

Drafts of the mobile protection system

The schematic drawing of the mobile protection system in frontal, lateral and bottom view. Red arrows depict certain important components of the system. Dimensions, materials, and instructions are presented in the text.

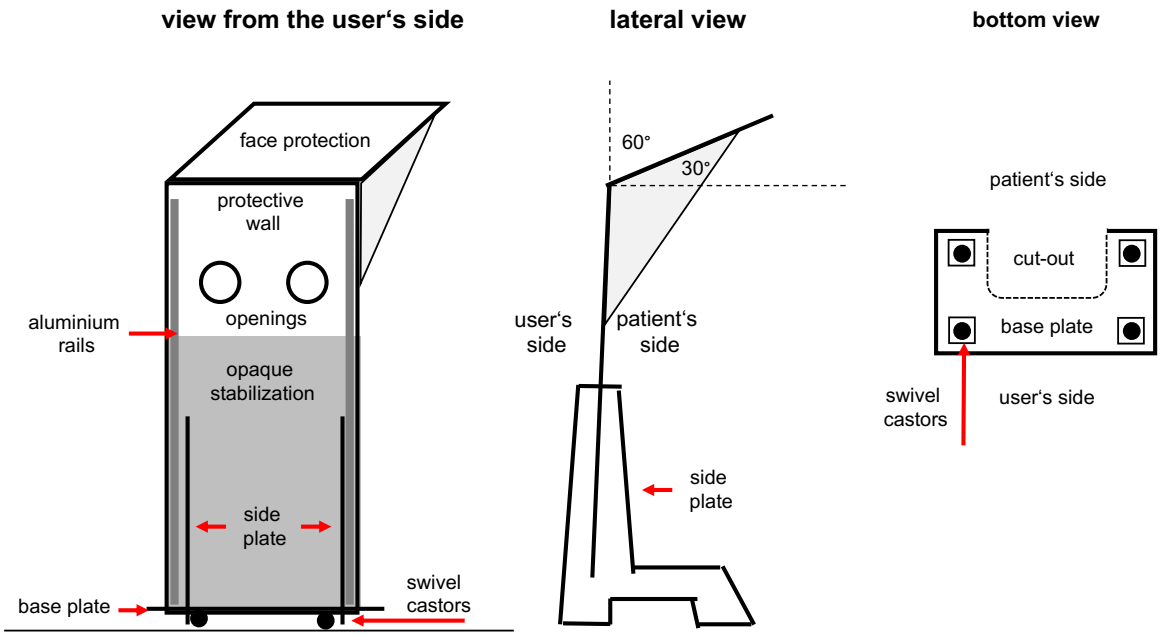

Figure 2: Technical draft with milling contours

The figure shows a technical sketches of the milling contours from the production of the prototype.

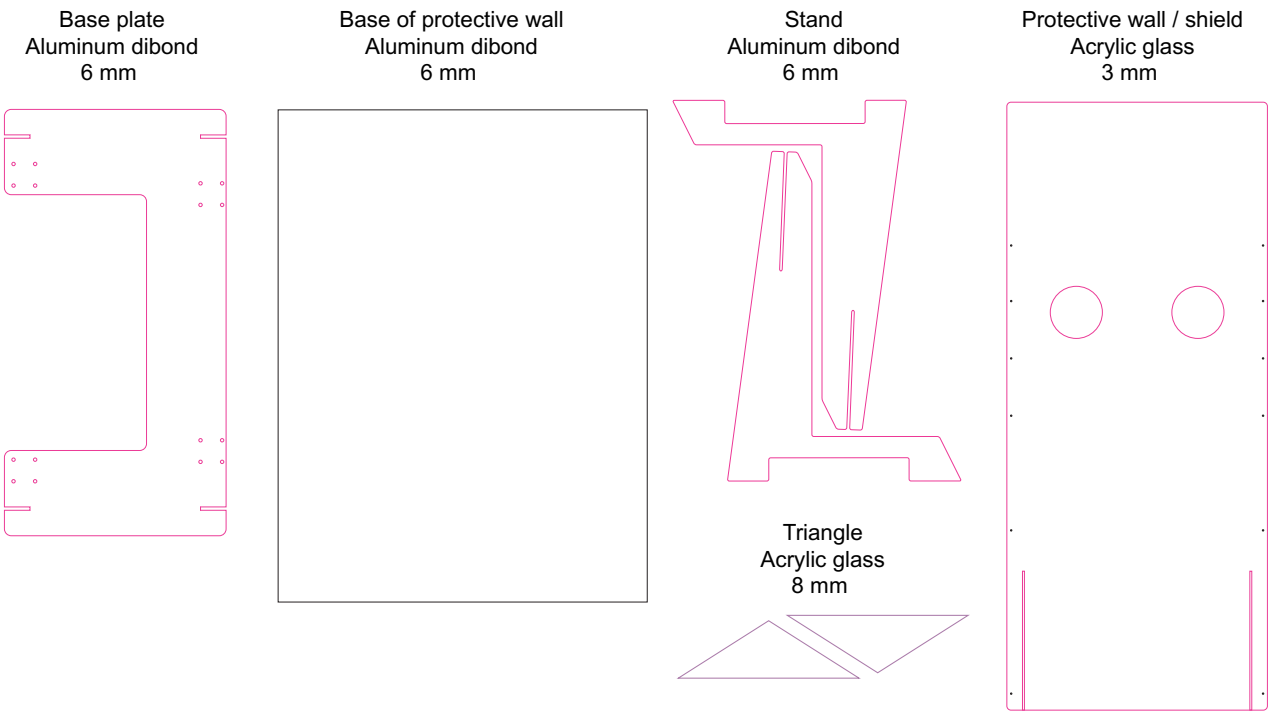

Figure 3: Detailed pictures of the prototype without side shields

Left picture: lateral view (user's side is left, patient's side is right) with inclined face protection shield; middle picture: frontal view from the user's side with openings for the operator's hands in the protection wall. Top right picture: view from the bottom side on the base plate with four mounted swivel castors. Bottom right picture: lateral view with one hand of the user in the opening towards the patient.

The prototype was created by WENZEL GmbH druck - kopie – media (Managing Director: Matthias Wenzel, Commercial Register: Munich District Court HRB60067) according to the instructions.

Figure 4: Pictures from the test track: initial evaluation of the prototype

Left hand picture: The prototype was tested for the dimensions at Munich Schwabing hospital. Middle picture: test track with videolaryngoscopy guided rapid sequence intubation of a dummy at Munich Clinic Bogenhausen. Right picture: extubation of a patient after successful surgery with the personal protection system in between a healthy patient and the physician.

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Supplement

Online Supplement 1

Steam test videos: Protection system with and without side shields

Video 1 (lateral view) and 3 (frontal view) shows the prototype of the protection system without side shields. The water vapor is deflected forward and upward, and water vapor escapes on both sides at the level of the face shield.

Video 2 (lateral view) and 4 (frontal view) shows the modified protection system with side shields. The water vapor is deflected forward and upward. The steam is stopped on the left and right side.

Video Files: DOI 10.17605/OSF.IO/7U2TV, Open Access Download: https://osf.io/7u2tv

filetype: .mp4; 1920×1080, codecs: H.264, AAC

1 Protectionsystem no side shields _ lat view

2 Protectionsystem with side shields _ lat view

3 Protectionsystem no side shields _ frontal view

4 Protectionsystem with side shields _ frontal view

Online Supplement 2:

Information sheet in English and German language.

DOI 10.17605/OSF.IO/7U2TV, Open Access Download: https://osf.io/7u2tv

filetype: PDF