Problem

Because of the COVID-19 pandemic, there is a shortage of personal protective equipment. There is anecdotal evidence that healthcare providers are therefore approaching their (potentially) infected patients with insufficient protective equipment. For this reason, initiatives have already been taken to reuse FFP2 mouth masks (normally disposable) after sterilisation.

RIVM has conducted a limited fitness test to see whether a sterilised mask retains its fit, but it is in fact unknown how well such a reused mask protects against a viral infection.

In the context of this great uncertainty, other unconventional measures may also be worth considering. Over the past three days, a consortium of companies, experts and specialists has come up with a potential solution to the shortage of mouth masks: a full-face face mask assembly, a Powered Air Purifying Respirator (PAPR) from the welding industry and a hose connector.

It is important to stress that the consortium does not pursue commercial interests and this initiative was started out of a concern for care.

Methods

Our basic approach is to give health care employees the highest possible degree of protection. This means that we have not only looked at respiratory protection but also protection of the face and eyes as described in the RIVM protocol. One could draw a comparison with a welder in the heavy industry who, according to the Dutch Health and Safety Act, has to wear breathing air protection during his work. This protection consists of a fully approved PAPR in combination with a fully opaque face mask where the PAPR is equipped with E13-14 FFP2 or FFP3 filters in accordance with the EN1822 standard. The PAPR with hose is standardised under CE0194 EN12941:1998TH2P. For the face protection we searched for a full coverage mask in which air from the PAPR creates a seal and a membrane separates the exhaled air from the mouth and nose from the eyes. The mask is widely available in the consumer market. However, there is no CE certification for the assembly. Nevertheless, the face mask can be disinfected and the mask can be attached with a simple click closure.

In cooperation with the company ProCare Safety BV from Groningen we have performed a fit test on this assembly by means of a TSI ProACount Pro+8048. This is exactly the same test, performed by the same company, as the test published by RIVM with the sterilized FFP2 mouth masks.

Results

The fit test was carried out in accordance with the HSE Protocol in which the pass value was set to 100 in order to achieve a good and fair comparison with the current (non-sterilised) mouth caps that are currently frequently used in healthcare.

In short: the test shows that the assembly as offered by us passes the same standard that is set for FFP2 masks in a fit test - the fit factor is even several times higher than that of an unused FFP2 mask as tested by RIVM (see appendix 2020.03.23 ProCare Safety Fittest.pdf). It should also be mentioned

that the assembly appears comfortable and portable and that the sound of the ventilator makes a conversation somewhat difficult but not impossible. It is conceivable that the comfort is greater than with a regular FFP2 mask that is worn all day.

Plan

We would like to dedicate ourselves without commercial interest to obtain a large range of these devices on loan through our contacts in the Dutch industry. Good to know is that only in the Netherlands an estimated number of 100,000 - 150,000 of these types of PAPR units are in circulation at companies that are currently mostly stationary. We would like, in cooperation with the government, to set up a coordinated action and with maximum commitment from the Dutch industry to help as many care providers as possible to deal with the situation surrounding COVID19 .

<u>DISCLAIMER</u>

Initiators are active in industry and healthcare. Due to the scarcity of mouthmasks in healthcare, they have jointly investigated whether existing protection solutions within the industry can offer an alternative solution. On this basis, the initiators have put together a set, consisting of a PAPR filter that is connected to a swimming mask via a 3-d printed connector. Initiators have tested the system themselves and are confident that it will work. However, the system has not been tested or certified and does not have any (safety) standards. Initiators have made an effort to come up with a good solution quickly, but cannot give any guarantee on this. Anyone who wants a guarantee or certainty must have the system tested and standardised by an authorised testing institute.