In-house production of personal protective equipment to assist in the frontline response to Covid-19

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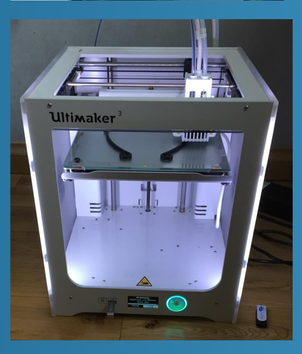
Background

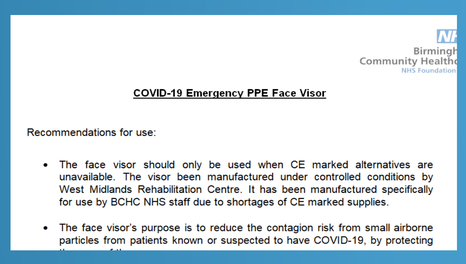
The coronavirus pandemic of 2020 resulted in worldwide shortages of PPE (BBC news, 2020). Guidance issued by the government recommended the use of goggles/visors for all aerosol generating procedures (UK Government, 2020) and it was confirmed that healthcare workers had the right to refuse to administer treatment without the provision of suitable PPE (Royal College of Nursing, 2020).

Due to difficulty obtaining sufficient supplies of PPE a prototype visor was designed, tested and batch production started within 4 days.

Prototyping and design



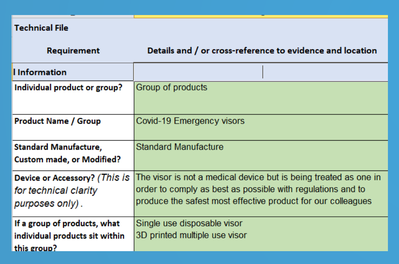
Open source 3D printed designs were trialled and used, but could not keep up with numbers required .Therefore a foam and elastic version was reverse engineered from trust stocks. Technical files and user instructions were also created.



COVID-19 Emergency PPE Face Visor

Recommendations for use:

- The face visor should only be used when CE marked alternatives are unavailable. The visor been manufactured under controlled conditions by West Midlands Rehabilitation Centre. It has been manufactured specifically for use by BCHC NHS staff due to shortages of CE marked supplies.
- The face visor's purpose is to reduce the contagion risk from small airborne particles from patients known or suspected to have COVID-19, by protecting

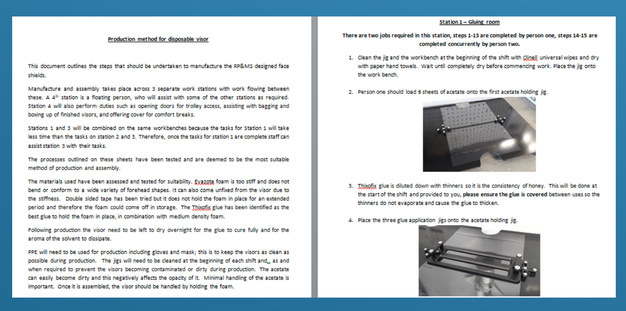


Technical File

Requirement	Details and / or cross-reference to evidence and location
l Information	
Individual product or group?	Group of products
Product Name / Group	Covid-19 Emergency visors
Standard Manufacture, Custom made, or Modified?	Standard Manufacture
Device or Accessory? *(This is for technical clarity purposes only)*.	The visor is not a medical device but is being treated as one in order to comply as best as possible with regulations and to produce the safest most effective product for our colleagues
If a group of products, what individual products sit within this group?	Single use disposable visor 3D printed multiple use visor

Scaling up – Jig production and Quality

Jigs were produced to ensure continuity of product, for gluing the foam and acetate and cutting of elastic.



Production method for disposable visor

This document outlines the steps that should be undertaken to manufacture the RP&MS designed face shields.

Manufacture and assembly takes place across 3 separate work stations with work flowing between these. A 4th station is a floating person, who will assist with some of the other stations as required. Station 4 will also perform duties such as opening doors for trolley access, assisting with bagging and boxing up of finished visors, and offering cover for comfort breaks.

Stations 1 and 3 will be combined on the same workbenches because the tasks for Station 1 will take less time than the tasks on station 2 and 3. Therefore, once the tasks for station 1 are complete staff can assist station 3 with their tasks.

The processes outlined on these sheets have been tested and are deemed to be the most suitable method of production and assembly.

The materials used have been assessed and tested for suitability. Evazote foam is too stiff and does not bend or conform to a wide variety of forehead shapes. It can also come unfixed from the visor due to the stiffness. Double sided tape has been tried but it does not hold the foam in place for an extended period and therefore the foam could come off in storage. The Thixofix glue has been identified as the best glue to hold the foam in place, in combination with medium density foam.

Following production the visor need to be left to dry overnight for the glue to cure fully and for the aroma of the solvent to dissipate.

PPE will need to be used for production including gloves and mask; this is to keep the visors as clean as possible during production. The jigs will need to be cleaned at the beginning of each shift and, as and when required to prevent the visors becoming contaminated or dirty during production. The acetate can easily become dirty and this negatively affects the opacity of it. Minimal handling of the acetate is important. Once it is assembled, the visor should be handled by holding the foam.

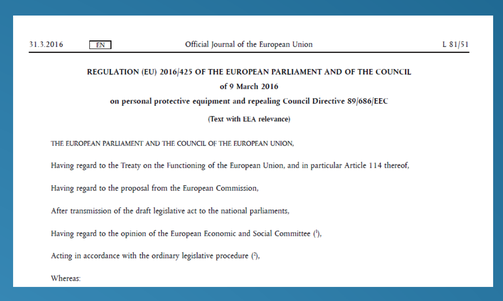
Station 1 – Gluing room

There are two jobs required in this station, steps 1-13 are completed by person one, steps 14-15 are completed concurrently by person two.

1. Clean the jig and the workbench at the beginning of the shift with Clinell universal wipes and dry with paper hand towels. Wait until completely dry before commencing work. Place the jig onto the work bench.
2. Person one should load 6 sheets of acetate onto the first acetate holding jig.
3. Thixofix glue is diluted down with thinners so it is the consistency of honey. This will be done at the start of the shift and provided to you, **please ensure the glue is covered** between uses so the thinners do not evaporate and cause the glue to thicken.
4. Place the three glue application jigs onto the acetate holding jig.

A team of 25 healthcare scientists from a range of trust departments were redeployed to work in shifts on the production line. Clear processes and quality checking were used to give the best possible quality.

Testing and conformance



31.3.2016 EN Official Journal of the European Union L 81/51

REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 9 March 2016
on personal protective equipment and repealing Council Directive 89/686/EEC
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

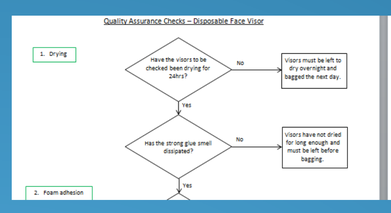
Having regard to the proposal from the European Commission,

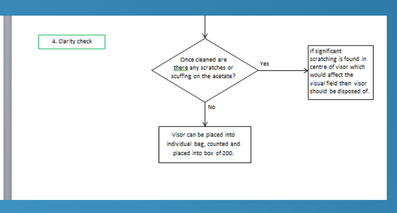
After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:





Destruction testing and fit testing were carried out as per requirements for CE marking and as extensively as possible in the timescale. Quality checking procedures and risk assessments were also complied alongside technical files to ensure the safest possible product for our end users.

Discussion

These were, unprecedented times, and there are some ethical concerns as to whether we should be manufacturing PPE, which is both outside of our scope of practice, and not possible to certify, in the time period required. Should we have done it?

It was assumed that something is better than nothing when it comes to PPE. It was discussed with the head of risk management for the Trust as well as with the lead for infection prevention and control, and quality protocols were put into place to minimise the risks.

Overall it was felt there was a greater element of control in the manufacturing processes in-house compared with the other avenues of sourcing 'off-label' PPE made by potentially unregulated local suppliers. In addition it was agreed with the Trust to provide only to meet the shortfall in CE marked devices, and that these would be used once available.

Conclusion

Average 800 disposable foam topped visors per day with 99% passing QI.

45,000 visors produced over 3 months

350 reusable 3D printed visor frames each with 25 visor fronts.

8,000 3D printed 'ear savers'.

Delivered for use by BCHC NHS staff, and over 750 nursing homes supported by the trust.

Conflicts of Interest and Thanks

The author declares the following conflicts of interest, and also expresses gratitude for their help and support to:

Consolor Ltd for providing the foam, pre-cut to size at cost and for cutting 10,000 elastic straps at minimal cost.

Active Design Ltd for donating their entire stock of 1" elastic for use, and helping to source further supplies.

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