

## *Key Project Team\**

- Professor Richard Hague, Director, Centre for Additive Manufacturing, Faculty of Engineering, UoN (Lead)
- Mark East, Head Technician, Centre for Additive Manufacturing, Faculty of Engineering, UoN
- Shaun Beebe, Physics, Faculty of Science, UoN
- Professor Donal McNally, Head of the Bioengineering Research Group, Faculty of Engineering, UoN
- Peter Harris, Additive Manufacturing Lead, Matsuura Machinery Ltd
- Sean Skidmore, Prime Group Ltd
- Richard Higgins, BSI
- Hazel Buchanan, Nottingham NHS CCG

## *Background and why we're doing this*

The Centre for Additive Manufacturing (CfAM) at the University of Nottingham (UoN) have worked with colleagues within UoN's Bioengineering Research Group, Nottingham University Hospitals NHS Trust (NUH) and a host of external collaborators and contributors\* to develop a Personal Protective Equipment (PPE) FaceShield to meet the critical need for COVID-19 related PPE from healthcare professionals.

**Why?:** Our reason for undertaking this work was due to an approach from NUH and Nottingham's NHS Clinical Commissioning Group (CCG) asking if we could supply much needed COVID-19 PPE face protectors for both hospital and community-based healthcare worker (GPs, healthcare visitors, etc). This approach was made in response to the significant press and interest in the use of 3D printing to help fill the acute shortage of PPE - however, it should be noted that though there are several laudable 3D Printing (Additive Manufacturing (AM)) initiatives on face visors ongoing internationally, other designs and manufacturing routes had not been regulatorily tested and therefore do not necessarily meet current safety standards for PPE.

Therefore NUH and CCG approached the CfAM to see if we could quickly help use our expertise in 3D printing to produce FaceShield that are regulatorily approved, and therefore safe to use.



**Figure1: Images of completed FaceShield**

*\*Special thanks to Peter Harris (Matsuura UK – [matsuura.co.uk](http://matsuura.co.uk)), for the exceptional help provided in the production of HP Jet Fusion HeadBands, EOS UK for the supply of Laser Sintering material at reduced cost to UoN, Prime Group for their help in the production of the laser cut visors and Nottingham Trent University with their support in laser cutting the straps*

# COVID-19 FaceShield: UoN001 - CE 727826

## *What is Different in our Approach?*

In short, we have taken a comprehensive engineering approach where we have coupled the responsiveness of industrial-grade Additive Manufacturing (3D Printing) techniques (and laser cutting) alongside an expedited route to regulatory approval. As a result, within 10 days, the University of Nottingham were authorised to make and distribute a CE marked visor that has passed the relevant regulatory tests (*PPE for Healthcare Professionals 2020/403 – Eye protection Technical Specification*).

## *How is our FaceShield made?*

Our developed FaceShield (Fig 1 above) is made up of three components (see appendix for greater detail):

- A 3D printed headband, that is cleanable and reusable, made in PA12 (nylon)
- A laser-cut strap made from polypropylene
- A laser-cut, disposable, clear, antifog visor made from PET.

This design is an adaptation of an open-source design from HP, that was originally intended to have both a 3D Printed headband *and* strap, alongside a visor made from A4-sized sheets that are appropriately hole-punched to fit the pegs on the front of the headband. This particular design was chosen over other open-source variants as it importantly incorporates a cover over the top of the headband (from the front where the visor is connected, to the forehead strap) that stops splashes entering the eyes from above – this feature was deemed essential for safety reasons in discussions with healthcare professionals.

Adaptations were made to the original design to:

- aid comfort (modifications to the headband)
- lower manufacturing costs and improve fit (longer, laser cut strap)
- incorporate a wider, laser-cut visor to meet regulatory standards (see below).

3D Printing has been used for the headband as, if deployed appropriately, can give a highly responsive (quick) route to manufacture. Laser cutting for the visors and straps are used as it is the most appropriate technique in this instance for the volume of straps made.

**Type of 3D Printing used:** Importantly, we have utilised industrial grade AM systems (known as “powder bed fusion” techniques), as opposed to low cost, home/office orientated printers (using the “filament extrusion” approach) that have been the focus of many 3DP visor initiatives. These more industrial-type systems – in our case, either using HP Multi Jet Fusion or EOS Laser Sintering systems - are used in preference to the low-cost fused-filament systems as they:

- Are faster and capable of building many components in one build (i.e. are “batch-able”)
- Have increased design freedoms (allowing features such as the eye cover)
- Are able to use materials that can be cleaned and reused (whereas the home printers produce parts that are generally considered to be single use).

## *Initial design and issues with accreditation / BSI feedback*

A key aspect of our final design is in the width of the laser-cut visor that we have used, which is in contrast to many of the 3DP face shields being produced that utilise hole-punched, A4-sized acetate-type sheets as the clear-visor element. Indeed, our visor was initially tested at BSI (*PPE for Healthcare Professionals 2020/403 – Eye protection Technical Specification*). Figure 2(a), below, shows that for this particular design of headband, A4-sized visors are not wide enough to sufficiently cover the face, where it can be seen that the laser mark from the lateral test falls outside the visor and therefore constitutes a fail.

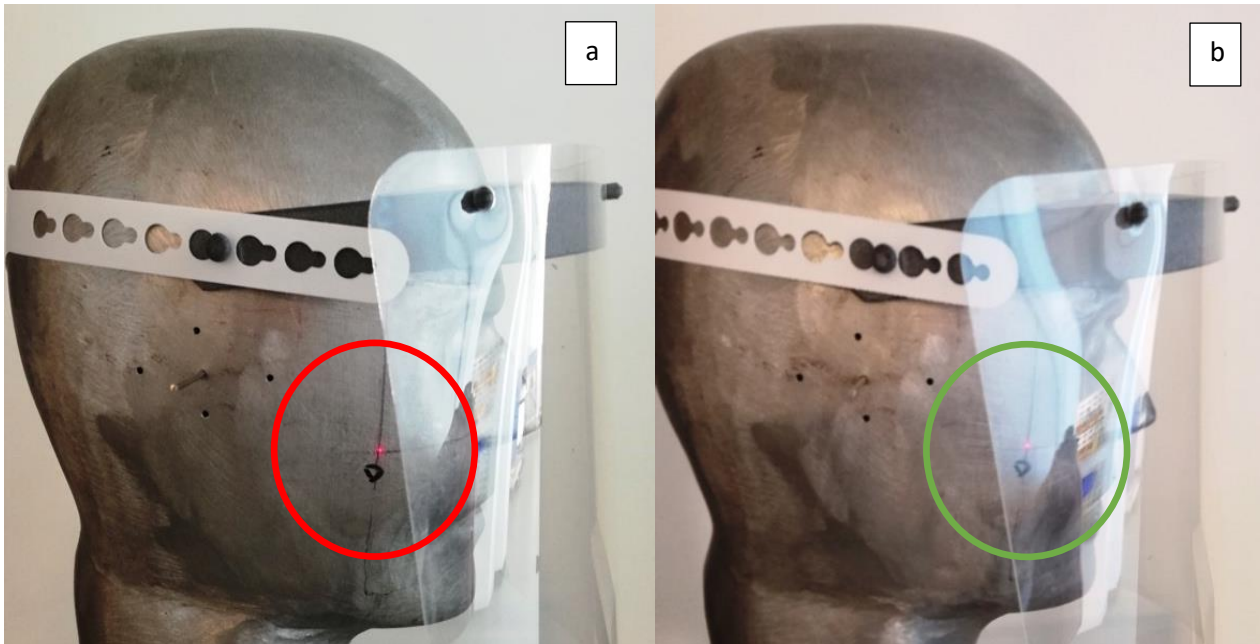


Figure 2: BSI CE tests (to Technical Specification, Annex II of the PPE Regulation (EU) 2016/425) showing for this design of visor that (a) A4 sized visors are not wide enough to meet the test standards whereas (b) a 350mm wide visor passes the test and is therefore safe to use

Also shown in Figure 2 (b) is the results from the regulatory tests at BSI where a 350mm wide visor has been used, and it can be clearly seen that the laser mark from the lateral test now falls upon the visor element itself, therefore constituting a pass.

## Summary

UoN are now very happy to be in the position of being official manufacturers of a BSI approved, CE marked PPE FaceShield. As well as manufacturing the 3DP element ourselves, for greater scale we are working with a network of suppliers who are providing the components either FoC or at cost.

Having delivered 1000 to Nottingham NHS CCG, we have been requested to make a further 4000 and are ramping up production to meet this target within two weeks so that we can supply a total of at least 5000 FaceShields to aid healthcare workers in the Nottingham areas in their efforts to treat people with COVID 19.

We are also making the designs open-source for others to implement.

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This face shield has been approved under the BSI's PPE for Healthcare Professionals 2020/403 – Eye protection Technical Spec. BSI Assurance UK Ltd (Notified Body 0086), Kitemark Court Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, United Kingdom. This face shield is not a PPE device for general use and shall not be used for purposes other than protection against COVID-19. It has been manufactured for COVID-protection only.

## *Assembly Instructions and Operating Conditions*



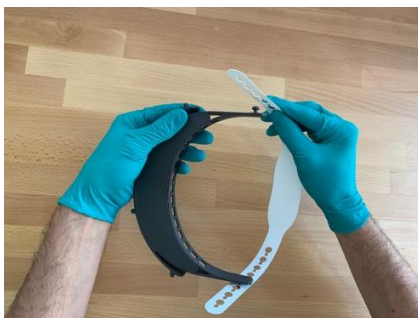
### **Components**

- 1 x HEADBAND, made using Additive Manufacturing on HP Jet Fusion or Laser Sintering in PA12
- 2 x Polypropylene adjustable BACKSTRAP (one for use, one for spare)
- At least 5 pre-cut clear VISOR (PET Sheets with Antifog coating) that are replaceable when required. (Please note that A4-sized acetate-type sheets **MUST NOT** be used as they do not meet this design's CE accreditation)

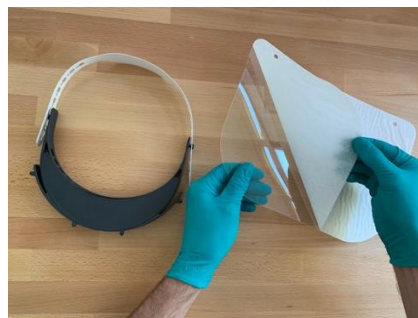
### **Tools**

- Vinyl Gloves – to be used throughout the assembly process

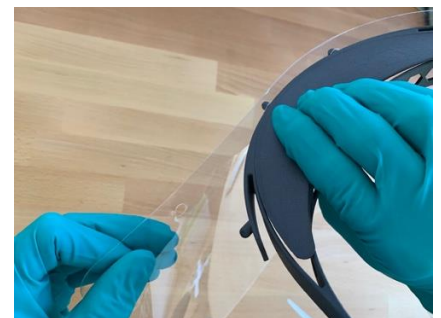
### **Assembly**



1. Locate the adjustable BACKSTRAP onto the headband by inserting the pins on the side of the HEADBAND through the larger diameter holes of the backstrap. Pull the strap towards the small diameter hole to lock it in position. Repeat both sides and adjust to fit the head of the user.



2. On the replaceable VISOR sheet provided, remove the protective paper covering the antifog coating of the visor. (n.b.: some visors may not be shipped with this protective paper covering and so this step can be ignored if this is the case).



3. Attach the VISOR sheet to the HEADBAND by placing the pins on the front of the headband through the holes in the visor. Care should be taken whilst positioning (particularly) the final locating pin through the visor so as not to tear the material (see above).

### **Operating Conditions**

This face shield visor should not be worn for more than one shift. Contaminated visors may be removed from the headband and a replacement attached prior to the headband and backstrap being appropriately cleaned following guidelines defined by your local working practices. However, it is strongly suggested that the item is regularly cleaned with appropriate surface cleaning techniques and /or sporicidal wipes.

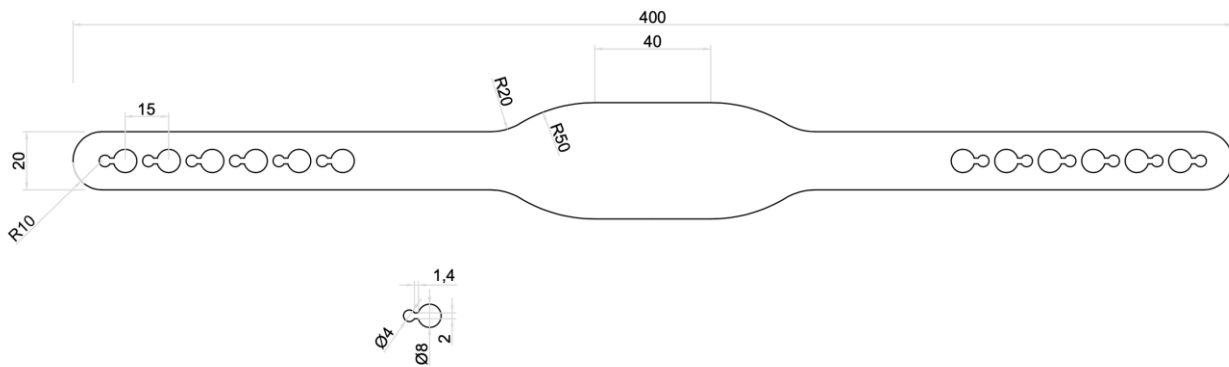


## Appendix – Further information

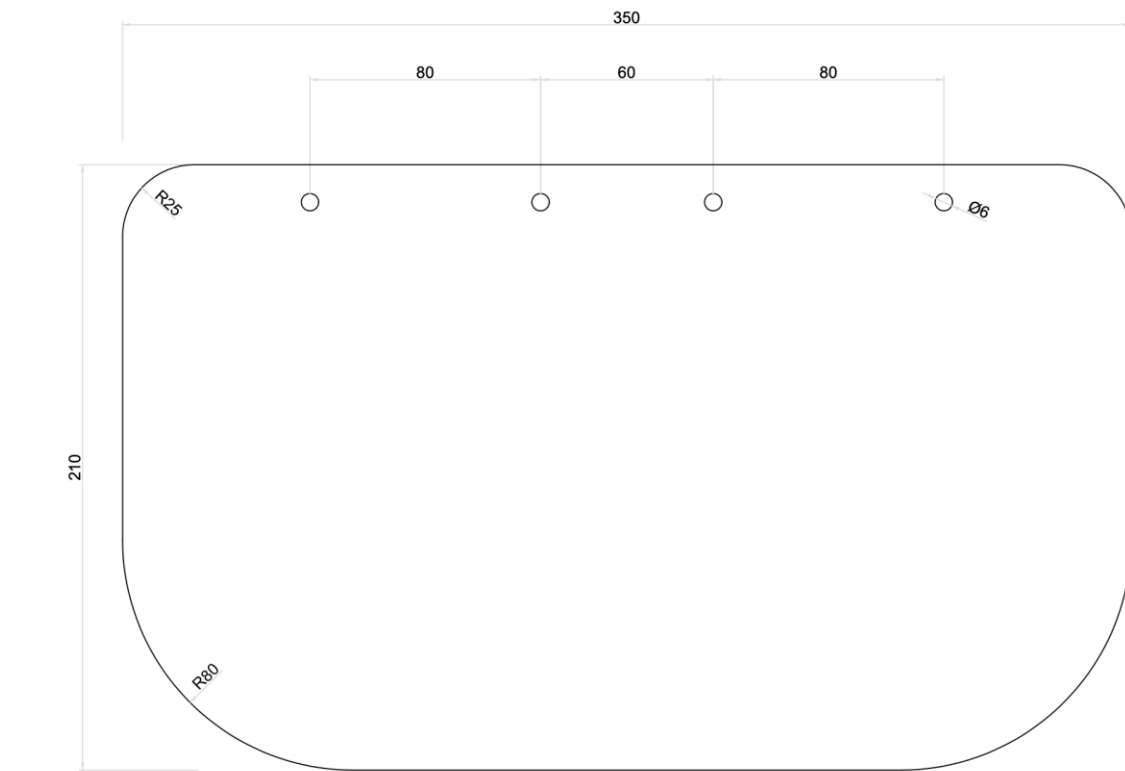
### How we're producing, with which partners and at what scale

With 5000 packs in total being produced, the FaceShield is made of three components

- **A 3D Printed headband** (1 per pack – 5000 in total) – cleanable and re-useable: We are taking two approaches for the manufacture of the headband
  1. EOS Laser Sintering using a P100 system, based at the CfAM, UoN
  2. HP MultiJet Fusion, HP MultiJet Fusion, 4200 and 5200 systems at Matsuura UK(Design adapted from HP open source design, with modified design file in STL format is downloadable [here](#) )
- **An adjustable Strap** (2 per pack – 10,000 in total) – laser cut from Polypropylene (Priplak Basik, 450um thick). Made by PrimeGroup and Nottingham Trent University. (Design of the strap as per below (NOT TO SCALE) and downloadable [here](#) )



- **Clear visor** (5 per pack – 25,000 in total) - laser cut from anti-fog coated PET, at least 175um thickness, (Design of the visor as per below (NOT TO SCALE) and downloadable [here](#) )



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## FAQs for UoN Face Shield

### **Why does a CE mark matter?**

A CE mark demonstrates that the product is compliant with the relevant EU and UK standards or technical specifications. NHS trusts have a duty of care to their employees and may therefore not want to make use of PPE that is untested and unregulated.

### **Does my product need a CE mark?**

Not necessarily, for a limited period, new COVID-19 PPE need not have a CE marking or a Declaration of Conformity, in line with EU Recommendation 2020/403. However, a manufacturer must have contacted a Notified Body and begun conformity assessment procedures before PPE specifically necessary for protection in context of COVID-19 outbreak can be placed on the market. Conformity assessment procedures must be completed as soon as possible unless the following paragraph applies.

Where PPE necessary for protection in the context of the COVID-19 outbreak is being manufactured for healthcare workers and being purchased by the Government/ NHS bodies, it can be purchased without conformity assessment. Such products may not be placed on the wider market.

### **If I use the UoN design, can I put a CE mark on my product?**

No, there is an obligation upon manufacturers to ensure the products they issue are the same as those tested by the Notified Body. Anything you produce is outside of our control. You would therefore need to have your own products tested.

### **Can I use the UoN face shield as general PPE?**

No, the UoN face shield was not evaluated against the full Personal eye-protection — Specifications standard (EN 166) but against a technical specification put in place in response to Commission Recommendation (EU) 2020/403. It can therefore only be used by healthcare professional for protection during the treatment and control of COVID-19.

### **What is Commission Recommendation (EU) 2020/403?**

This is a recommendation by the EU Commission which relaxes some of the regulation for PPE and medical devices used for the treatment and control of COVID-19 whilst ensuring an adequate level of protection corresponding to the applicable essential health and safety requirements.

### **Can I use the UoN design with an A4 sized transparent visor component?**

No. Our initial prototype device had an A4 sized face shield. Whilst it passed all the requirements of the BSI 'PPE for Healthcare Professionals 2020/403 – Eye protection Technical Specification' it failed the lateral protection test by 5cm. This means that the design did not protect the face from liquid splashes coming from the sides. This was why we redesigned the visor to protect more of the face.

### **Are any face shield designs that use an A4 sized transparent visor component safe?**

This is not for us to say, but our experience of the failed prototype demonstrates the importance of following the BSI certification process. Our implemented design mounts the visor 40mm away from the face (to prevent fogging). The visor also has a large radius of curvature. It is possible that other designs where the visor is closer to the face, and/or that wrap more tightly around the head, could be compliant with the technical standard. However, this would need to be tested and we would strongly recommend testing to the correct standard before using A4-sized sheets

### **Where can I find out more about manufacturing or supplying PPE for COVID-19?**

The Government Office for Product Safety and Standards has produced a guidance document for PPE regulation and COVID-19.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/879095/Guidance-for-businesses-ppe-regulations-version-2.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879095/Guidance-for-businesses-ppe-regulations-version-2.pdf)