

# PPE Manufacture in a Pandemic: The Development of a Reusable Visor

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## Introduction

The COVID-19 pandemic resulted in a **highly publicised** shortage of appropriate personal protective equipment (PPE) for medical staff due to the unexpected and unplanned high usage of disposable PPE.

This resulted in a large increase in **single-use plastic waste** and improper use of disposable items, including **reusing single-use articles**.

A quality assurance (QA) group was formed in the Medical Devices Unit (MDU) early in the pandemic to test the large volume of disposable visors being donated to NHS GG&C with respect to regulations and standards. Over 70 different face shields were tested from large manufacturers, such as Airbus, to small community groups, including schools.

The vast numbers of disposable visors experienced by the QA group and discussions with infection control concerning safety identified a need for a **low-cost reusable visor** to reduce the pressure on NHS GG&C in obtaining large volumes of disposable visors.

Help was offered to NHS GG&C via industry partners and funding was granted by a consortium of companies in exchange for quick development and deployment of reusable visors.

## Aim

- To create a reusable visor to be used for PPE in protection against splashes of liquid in line with the requirements of British Standard 166:2002 for Personal Eye Protection.
- To create a reusable visor which could be easily disassembled, decontaminated and safely reused for over a month.
- To create documentation to satisfy clinical and technical requirements and to comply with local protocols and MDU **ISO 13485** quality management system (QMS) processes.

## Method

Specifications for single-use PPE had been created by the QA group in line with requirements of British Standard 166:20 for Personal Eye Protection.

These specifications were then **amended to satisfy the requirements of a reusable visor** in liaison with infection control specialists and chief nursing staff.

Engineers within MDU worked to modify the design of an open-source face shield released by Prusa Printers to suit the required specifications (Fig 1). Appropriate **risk assessment** steps were followed when completing the following design modifications:

- Improvement to side splash protection.
- Improvement to mechanism attaching visor shield to headband to ease disassembly for decontamination.
- Change to recommended manufacturing process from 3D printed to injection moulding to improve production volume, quality and production time.
- Change to recommended material to improve cost-effectiveness and comfort, maintain safety standards and comply with local decontamination protocols.

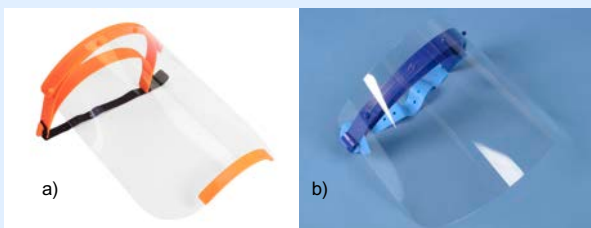


Figure 1. a) Original Prusa Printers open-source design with 3D printed headband; b) modified MDU reusable visor with injection moulded headband

## Results

MDU use Redmine software, a web-based project management tool, to comply with their QMS. A series of **design acceptance test** protocols were created, performed and documented on Redmine including:

- Accelerated decontamination tests
- Accelerated assembly and disassembly tests
- Component inspection

Evaluations carried out by the visor QA group, shown in Table 1, were also performed and documented.

Table 1. Technical and clinical evaluations carried out by QA group.

Technical Evaluation	
<b>Required Feature</b>	
Splash Protection	Does the device protect the user from splashes of liquid?
Sharp Edges	Does the device have any sharp edges?
Wipeable	Is the front surface of the device fully wipeable?
Viewing Depth	Is the length of the visor at least 150mm?
<b>Desirable Features</b>	
Adjustable Fit	Does the device have sufficient adjustability?
Robustness	How durable is the device?
Headband Width	Is the headband at least 10mm wide wherever it contacts the users head?
Glasses Clearance	Does the visor contact glasses when worn?
<b>Clinical Evaluation</b>	
Visual Clarity	Does the visor allow a clear view that has not been distorted or dimmed?
Comfort	Is it comfortable to wear during a clinical session (up to approx. 3 hours)?
Infection Control	Can it be cleaned?

Appropriate documentation was drafted including an **Instructions for Use (IFU)** which contained information regarding the intended use of the visors, decontamination and storage information and assembly and disassembly instructions.

A production line was set up at West Glasgow Ambulatory Care Hospital and members of the Department of Clinical Physics and Bioengineering (DCPB) were enlisted to help.

A series of different roles were established including assembling, bagging, packaging and documenting on Redmine software.

Within 3 days, around **4000 visors** were assembled and packaged to be sent to clinical areas.



Figure 2. DCPB staff photographed working on visor production line.

## Conclusion

The MDU were able to provide NHS GG&C with a significant volume of **safe and effective reusable visors** which comply with standards and regulations for use in PPE. Documentation was created in line with ISO 13485 certification and stored on QMS software.

Margaret Connolly, Assistant Chief Nurse, Governance & Regulation, NHS Greater Glasgow and Clyde said:

"We've been looking for a more sustainable solution to single-use visors for staff to use that's safe and reduces plastic waste. The design of the reusable visor used by single members of staff allows easy cleaning of the visors per NHSGGC infection control guidance. Staff can write their names on the front of the visors which is a helpful communicate aid to both staff and patients alike."



Figure 3. NHS GG&C clinical staff photographed wearing MDU designed reusable visor.