

Standard Operating Procedure (SOP) on Hubs

Change Log		
Date	Change Made	New Document Number
01/05/20	Effective Date has been updated.	SOP_3D_HUB_V1.1
03/05/20	P2:Addition of 'Aim', P2:Definition of hub expanded for distribution hubs P3:Coordinator Responsibilities wording updates P4:Materials and Equipment. Expanded list of key materials P4:Volunteer Safety. Clarified use of PPE in the hub P4:Volunteer Safety. Clarification around volunteering when you had symptoms or suspected Covid-19 previously. P6: Cleaning of Face Shields. Rationale added Throughout: sterilised change to Cleaning with Milton / IPA	SOP_3D_HUB_V1.2
05/05/20	P7: Update to numbering ref. in section 8b Link updated for Hub Dispatch and Stock Update Form P9:Hub to hub transfer procedure added to section 8g	SOP_3D_HUB_V1.3
10/05/20	P3: Updates removing reimbursement details P8: Hub to Hub transfers updated	SOP_3D_HUB_V2

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1 Purpose

The purpose of this SOP is to provide instructions on how to set up and run a hub.

2 Aim

- a. To uniformly provide the safest, cleanest face shields possible within the confines of the hub model run by volunteers during the COVID-19 pandemic.

3 Definition

- a. A hub is defined as a space where different elements of the PRUSA 3D Face Shield are brought together, cleaned and made ready for delivery. Makers send 3D printed parts to the hub. A hub may have one or more volunteers and may be in a person's home.

It is possible to split up the cleaning and distribution elements of a hub if it is not feasible to clean frames in the hub which will be supplying to the end user.

Please note this does not mean parts are allowed to be supplied uncleaned.

Parts must be cleaned as per this SOP before they can be supplied to an end user. If a hub is only performing distribution or drop off duties please see Appendix 3.

4 Scope

- a. This SOP covers the set up and operation of regional distribution hubs for distribution of PRUSA RC3 Face Shields. The latest revision of the SOP_3D_MAKE covers making of face shields.
- b. **Out of Scope:** This SOP is not suitable for use outside the COVID-19 pandemic.

5 Responsibilities

CEO Admin:

It is the responsibility of 3DCrowd CEO Admin to ensure that hubs are covered by insurance against public liability.

Hub Coordinator:

It is the responsibility of the Hub Coordinator to do the following:

- Provide a copy of this SOP to all Hub volunteers

- Check all Hub volunteers have read this SOP and have an opportunity to ask questions prior to starting
- Should ensure volunteers that need access to the order management system they need to complete the GDPR declaration first.
- Identify the orders required to be fulfilled at any one time with the Area / Regional Coordinator
- The Hub Coordinator should ensure an adequate system is in place to assign tasks for volunteers to complete.
- Organise delivery drivers. Ideally this should be volunteer drivers to keep costs low. Please check for volunteers in your region on the database.
- Ensure that adequate systems are in place to allow prompt a regular stock take of usable parts. This information is used centrally and locally to monitor supplies. Busy hubs are recommended to do this at least three times a week.
- Ensure that adequate systems are in place so that all order quantities are confirmed before dispatch to ensure that the order is still required, and delivery details are correct.
- Ensure that all dispatched orders are reflected as “fulfilled” in the order management system. This is done by completing a Hub Dispatch and Stock Update Form and then setting the status to fulfilled once you have confirmed the dispatched details have been matched to the order. Completion of this form ensures upload of delivery metrics into the central system.
- Hub Reimbursement: Please keep receipts for hub running cost expenses if you would like to be reimbursed for costs. Speak to your Regional or Area Coordinator regarding the reimbursement procedure.
 - Note: Reimbursement for hub costs currently only includes items for running and operating a hub. e.g. Milton Tablets, cleaning containers, IPA wipes, disposable gloves, blue roll, courier costs, sealed bags etc. Please note there is no reimbursement offered for locally sourced visors or elastic. If a hub is manufacturing head bands then they should fill out the makers dispatch form as well for all headbands they produce.
- Hub Coordinators must ensure an adequate system is in place to keep a register of volunteers in the hub each day and which orders left the hub on those days.
- Liaise with Central Logistics on visors, elastic and filament supply. Elastic must be wider than 15mm and preferably buttonholed. Please note there is no reimbursement offered for locally sourced visors or elastic.
- Ensures an adequate system is in place to oversee the packing and delivery of orders during hub operation.
- No eating, drinking or smoking/vaping is allowed during hub operations.

6 Materials and Equipment

The hub will receive deliveries of 3D printed parts from makers, and materials from central. This includes:

- 3D printed headbands
- 3D printed bottom reinforcement
- Visors
- Elastic: This may be received pre-cut. If the elastic is not pre-cut, it should be cut to the length required (350mm for buttonhole, 400mm for non buttonhole) with a cutting tool cleaned with Milton/IPA

All remaining materials required to adhere to the SOP should be sourced by the Hub Coordinator and expensed as per this SOP. These materials are:

- Milton Tablets (see 8c for link to exact ones) or IPA
- Container with lid for cleaning
- Drying Rig and clean drying cloth(s)
- Necessary equipment to clean down hub space
- Mask and Gloves for volunteers (Volunteers can bring their own PPE)
- Plastic sealable bags

Any issues with supply of remaining materials please contact your Area or Regional Coordinator.

7 Volunteer Safety

- Only volunteers who are not considered to be “vulnerable persons” and are not living in a household with a vulnerable person, can work at a hub (Check Gov UK guidance on Social Distancing and Vulnerable People, see Appendix)
- Volunteers and Covid-19
 - A volunteer who has had a confirmed case of Covid-19 previously, may not volunteer in a hub as there is insufficient scientific data on the duration of contagiousness.
 - If you have had a suspected case of Covid-19 review and ensure you have followed the NHS Guidelines before volunteering in a hub.
 - Volunteers should NOT take part if they are showing symptoms of Covid-19.
 - Should volunteers develop symptoms while working, they should stop ALL hands-on work and inform the Hub Coordinator immediately.
- For hubs with more than 1 volunteer, it is recommended that prior to starting hub operations, the Hub Coordinator designates a backup who can deputise as required.
- Should the Hub Coordinator develop symptoms, they should stop ALL hands-on work immediately and inform the Area / Regional Coordinator.

- If any person develops Covid-19 symptoms during kit assembly, all parts of the kits MUST be disposed of. These parts CANNOT be reused.
- All volunteers who are not from the same household, must maintain a distance of two metres apart.
- Personal equipment such as bags and mobile phones should not be brought into the working area of the distribution hub.
- All volunteers should wash hands thoroughly with soap or hand gel before distribution operations begin and end.
- PPE in the Hub
 - Mask: A face mask, gloves and face shield to be worn while in the room where cleaning is taking place and until all Face Shield parts are sealed in a bag. Volunteers should avoid touching their face or mask unless removing the mask.
 - Reusable face masks should be hot washed or cleaned in Milton before each session. (It is therefore advisable to have multiple reusable face masks)
 - Gloves: All volunteers must wear protective gloves made from nitrile or vinyl. NB: Latex gloves are NOT allowed. This is because latex can cause allergic reactions. Instructions on how to use protective gloves. (See link to How to Use Protective Gloves video in Appendix). Gloves must be disposed of once removed.
 - Face Shields: Hubs will provide Face Shields for hub volunteers.

8 Process

8a. Set Up

- Area Coordinators and Regional Coordinators must agree on location of hubs in a region and what areas the distribution hub serves.
 - Refer to the [3DCrowd Regions Map](#) for guidance.
 - Please also consider where most orders and volunteers are based when selecting the location.
- Volunteers should also complete the GDPR Data Privacy forms if they are accessing order information.
- Ideally, choose a large area such as a warehouse or large school room for the hub. A volunteer's home is also acceptable to use as a hub.
- The hub should have enough space to safely store materials and allow packaging and distribution to occur while following social distancing.
- Consider the need for the hub to be accessible for deliveries and people coming and going. i.e search for a space where outside access is nearby.
- Different areas should be considered for different parts of the process: for example, cleaning face shield parts, kit assembly, packaging etc

- All benches, tables and surfaces should be thoroughly cleaned with a 70% alcohol based cleaner before starting kit assembly and afterwards. Note: Concentrations of above 70% may not work as well. Covid-19 has been shown to live on surfaces for days. IPA wipes may also be used for this process.
- Thorough hand washing before and after setup is essential.

8b. Quality Control

- All face shield components can be removed from their packaging to undergo Quality Control, parts should then be cleaned as per instructions in section 8c.
- Prior to cleaning, all component parts must undergo Quality Control assessment
- Please use the latest version of the Quality Control document (QC_3D_MAKE) to check the suitability of the incoming maker parts and how to rectify any build quality issues.

8c. Cleaning of Face Shield Parts:

Rationale

To address the concerns identified in the risk assessment completed as part of the CE Mark application process.

Many viruses and bacteria can survive 72 hours in a sealed bag. Plastic particulate and other debris are a potential source of harm to the end user and the patients they treat. This procedure is intended to minimize that harm by requiring all shields are bathed in a cleaning solution to both minimize the threat from infection and remove as much debris as possible.

Room:

The room should be well ventilated either mechanically or through sufficient open windows. The cleaning area should not be near a heat source or in direct sunlight.

Components for Cleaning:

RC3 Headband, bottom reinforcement, and visor. (Note that the elastic does not need cleaning)

Solutions for Cleaning:

[Milton tablets](#) (available in many outlets in the baby section) made into solution per the instructions for use or IPA (Isopropyl Alcohol) (70%) may be used to clean the components. The solution must be changed at least every 24 hours, or every 200 components whichever is the sooner.

Container:

A container made of plastic or stainless steel that has a lid and is of sufficient size to completely submerge each component shall be used. The lid needs to be something you can clean. Cling film is sufficient if you have nothing else but replace with each clean. Suggested minimum container size 30cmL x 30cmW and at least a volume of 10L. Components may be cleaned in batches in larger sized containers. The container should be emptied and cleaned at least every 24 hours, or more often if in high usage.

Procedure:

- The container should be cleaned and dried prior to use.
- Read the instructions for use on either the Milton or IPA container carefully before use.
- Add prepared Milton solution or IPA to the container.
- Fully submerge the components in the solution and wait 15 minutes for a Milton solution or 2 minutes for IPA.
- All components must be allowed to dry (air dry) thoroughly and without any visible sign of moisture for a minimum of 2 hours for PETG and 4 hours for PLA.
 - Please attempt to wash, dry and pack all components within 8 hours of being removed from the cleaning solution.
 - A washing line safely strung up makes a good way to dry visors. Small (cleaned with Milton/IPA) hooks can be used to hang visors. These could also be made from stainless steel wire cleaned with Milton/IPA.
 - Ensure volunteers don't slip on potential wet patches below the drying area.
- To prevent marks or streaking visors without any protective film must be wiped down with a fresh paper towel/kitchen roll/blue roll which has been opened up by a PPE protected volunteer in the hub. If there is a protective film leave this in place throughout the procedure and allow the end user to remove if delivering in unassembled kit form.
- Tongs cleaned with Milton/IPA could be used to remove components from the solution for ease.

8d. Bagging

- Bag the components as soon as is reasonably practical once they are dry.
- Face shields can be sent out in unassembled kits or fully assembled face shields.
- Face Shields can be sent out in one of the following ways depending on user requirements:
 - **Fully Assembled Face Shield(s)** placed in a sealed bag, with a label containing the date of bagging.
 - This method is most suited to much smaller numbers and end user needs but if your hub has the capacity to assemble in large numbers and suitable packaging is available it's fine to do so. (See appendix 2 for large bagging example)
 - **Unassembled Individual Kit.** 1 visor (with protective film/ or in a separate bag if it does not have a film), 1 headband, 1 bottom reinforcement, and 1 elastic strap placed in a sealed bag, with a label containing the date of bagging.
 - **Unassembled Multipack Kit.** If you intend to supply larger volumes it can be easier to pack like items in the same bag. Check with your end user as to quantities per bag. Then create 3 bags per kit. 1 bag with visors, 1 bag with 3D printed components, and 1 bag with elastic. Ensure EACH bag has a label containing the date of bagging.
- Bags can be placed into boxes for delivery
- If deliveries are not being made immediately, face shields or components should be kept in a secure, ideally locked area to avoid sealed bags being reopened

8e. Dispatch

- If delivery boxes are being reused, ensure there are not previous names or delivery details visible on the box.
- It is recommended that kits or components are packaged to be as small as possible.
- Avoid using oversized boxes to aid delivery and storage.
- Ensure [The Face Shield Instructions](#) are included in EACH box.
- Ensure that each box in a delivery has a [Delivery Note](#) attached to the outside in a visible place with the delivery address clearly marked.
- There is an optional [Thank You Note](#) that we'd love as many hubs to use as possible, it has 4 variations to allow you to find one that fits with your end user. Recommend that it's stuck to the box in a visible place.

8f. Delivery

- Delivery Drivers must wear a face mask and gloves as soon as they leave the vehicle
- Delivery drivers must observe social distancing guidelines when delivering orders and make a non-contact delivery. This means having no physical contact with another person.

- Should a delivery be required in a hospital setting, please use the antibacterial gel provided immediately on arrival. On exit, gloves must be disposed of immediately and antibacterial gel must be applied, or hands washed as soon as possible.
- On delivery, the driver should remind the recipient that Face Shields must only be used 72 hours AFTER the Date of Seal on each bag

8g. Post Delivery

- Hub to End User: Hub coordinators must complete the [Hub Dispatch and Stock Update Form](#) as soon as possible after the package has left the premises. Stock updates can also be done using the Slack Hub Stocktake.
- Hub to Hub Stock Transfers:
 - When stock is moving between hubs there is no need to complete a dispatch form but you must complete a stock update either via the Hub Dispatch and Stock Update Form or the Slack Hub Stockbot. This is the case for both the sending and receiving hub.
- The order system should be checked and updated as to whether the order is fulfilled or partially fulfilled.

Copies of all documents are located at www.3dcrowd.org.uk/wiki/docs Hub Dispatch and Stock Update Form is accessed directly from the link in section 8g.

See next page for Appendices

9 Appendices

Appendix 1 - Useful Links

- Guidelines on social distancing and vulnerable people [UK GOV Guidance on Social Distancing](#)
- NHS Website / Recognising Coronavirus symptoms [NHS Coronavirus Symptoms](#)
- Video on How to Use Gloves. NB: We do NOT allow use of latex gloves [Video How to use protective Gloves](#)

Appendix 2 - Bagging Example

Bagging up Assembled Kits - large bagging example



Appendix 3 - Distribution Hubs and Drop Off Points

When collecting cleaned Face Shield components: A distribution hub should take the bagged and sealed cleaned Face Shield components and package up into orders without opening any plastic bags.

Only while handling and boxing for delivery to an end user should you wear gloves and a face mask.

Whilst bagged cleaned face shields components are being stored in a distribution hub and they are not in a sealed off room they should be stored in boxes with a lid.

Drop off points: drop off point, please minimise handling of components before they are dropped to a Hub for cleaning.