Printing the future; an iterative process for medical device management

Background

3D printing is a technology that is becoming increasingly used within our industry; however, it has its challenges. We have found going 'too hard' too quick can lead to many issues including; limited traceability, repeatability issues and catastrophic machine failures. Through trial and error, we are evolving internal processes to improve repeatability and traceability better and reduce failures. To achieve this we have followed the same route we would take for traditional manufacturing methods with some additional information added, specifically relating to 3D printing as a process.

Aims

The aims of this project were to create a process to improve control method's for 3D printed parts in line with our ISO 13485 accreditation and BS EN ISO 21856;2022 assistive products general requirements and test methods. This will ensure we are able to reliably and accurately repeat the work we produce. There are many benefits of 3D printing including, the ability to produce low cost prototype designs, reduce waste material, the ability to recycle certain plastics, and the ability to print more intricate shapes including letters, numbers and symbols. If you are going to invest in a 3D printer, we have some suggestions on how to optimise your procedure's to ensure the above problems do not cause issues.

Technical drawings and additional information

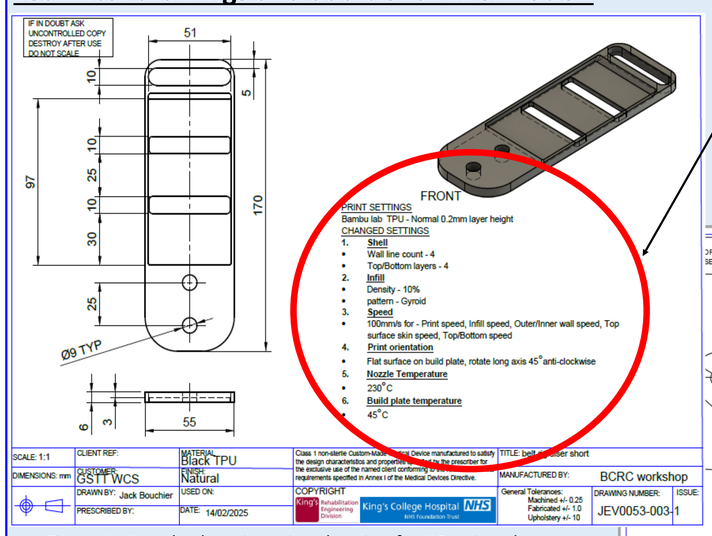

Figure 1: Standard engineering drawing for 3D printed parts

Figure 1. shows a List of standard settings for **ALL issued** 3D printed parts to include typically changed settings including material type and manufacturer, wall line count, infill, speed, orientation, nozzle and build plate temperature

Figure 2 shows additional information that is part specific to be added when required.

For example, build plate adhesion, support settings or assembly instructions.

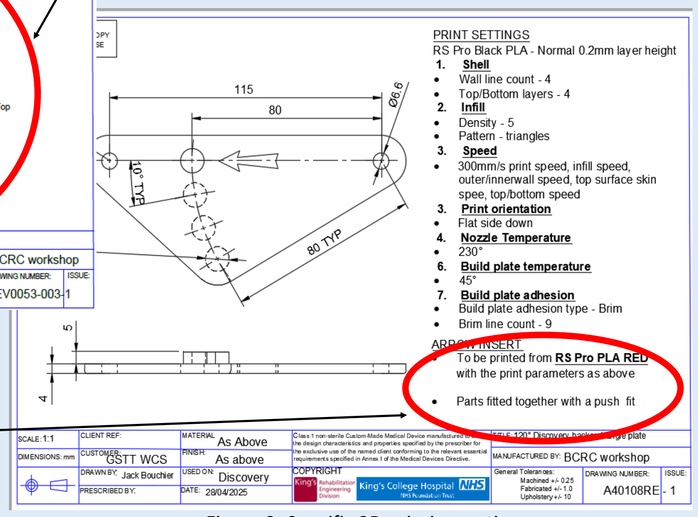

Figure 2: Specific 3D printing settings

Design procedure & printing considerations

When designing for 3D printing, there are key design and print considerations that can be incorporated either into your design or applied when slicing components. Print orientation can be a simple and effective way of reducing print time, the need for support and it can also affect component strength. The use of support can be an important print option for components with overhangs and complex geometry. The amount and style of infill needed to support top surfaces, is often a key print parameter that gets altered along with the number of walls/top and bottom layers to either help improve/reduce strength or increase/decrease print time. Clear documentation of edited settings is crucial to ensure repeatability.

Material selection for use

The material you choose to print with is a key decision when 3D printing. There are hundreds of different material characteristics to consider based on the environment and usage of the component. Depending on the material selection, there is a variety of different technical specifications that can be modified to get the best quality component e.g. print speed and temperature. Our favoured material is PLA , as it provides most of the physical properties we are after and is cost effective. We have found flexible materials such as TPU present more challenges when printing, especially when trying to print multiple objects on the same print bed due to stringing between components. This coupled with difficulties in post processing can lead to poor quality prints.

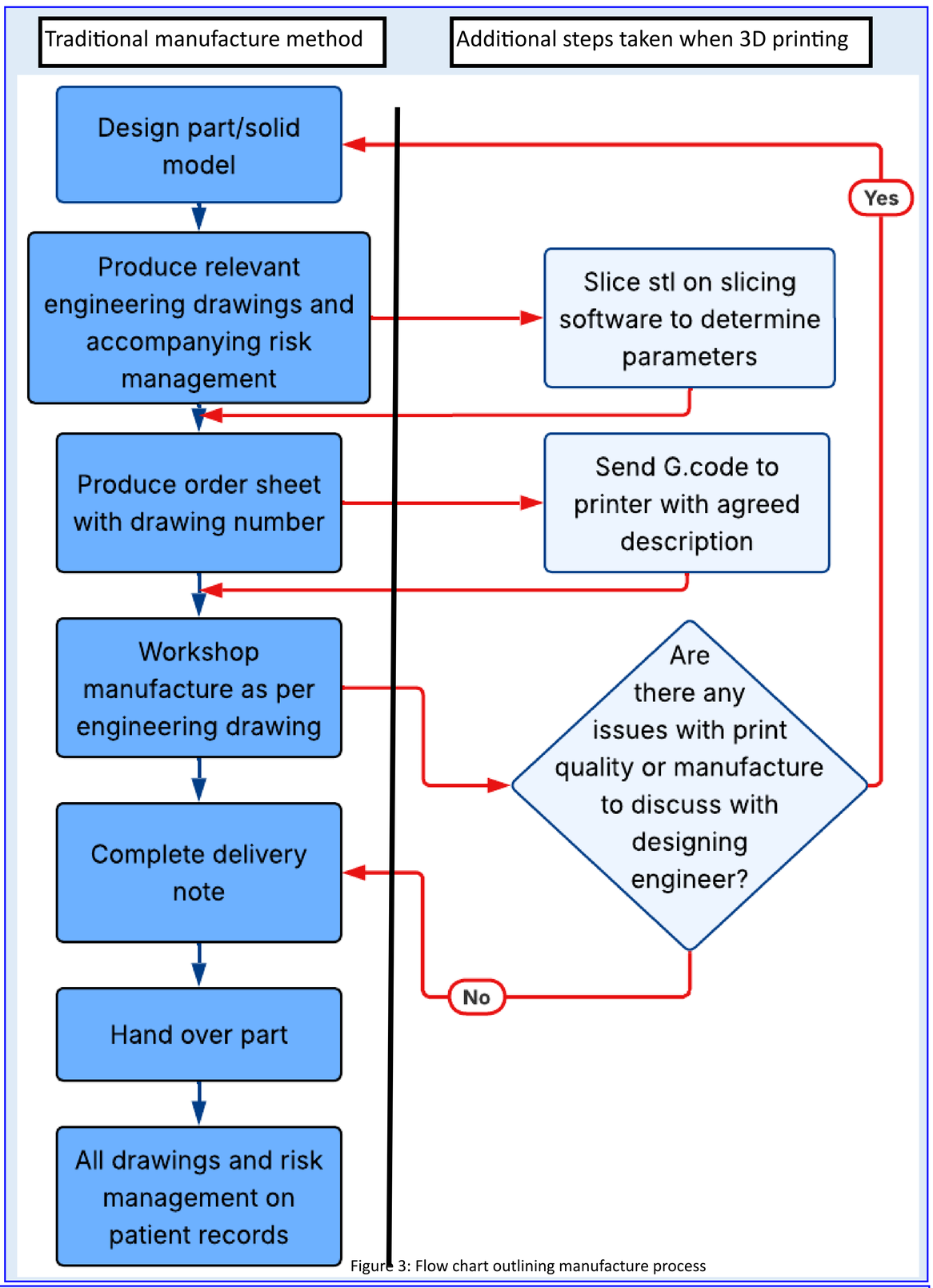

Figure 3: Flow chart outlining manufacture process

Limitations to 3D printing

Although there are many advantages to 3D printing, there some major limitations that can reduce reliability. It is imperative to have some knowledge of your printer, what can and will go wrong and how to fix it. Due to there being many smaller electrical components, lots of moving parts and extreme operating temperatures, failures can often come in ways you don't expect and the smallest things can affect your printer, such as a tiny piece of material debris stuck in the print head as seen in figure 4 that stopped our printer from functioning. The user's ability to design the components they want to print and how to use the printer to get the best results is critical. Having the ability to design the components and use the printer to generate the best quality finish is something that comes through experience and trial and error. Further limitations of 3D printing are, limited ability to post process, being restricted by the size of your printer and the components you want to create and inconsistencies due to material shrinkage and expansion. If not properly controlled these issues can cause major machine or component failures so it is key they are managed through your agreed service procedures to avoid disruption.

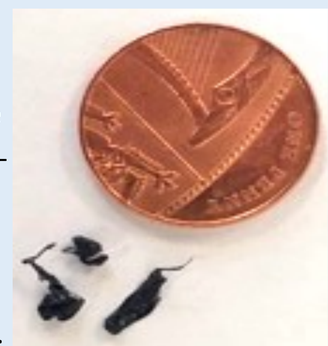

Figure 4: Debris size in print head

Parts we've Printed

Rem 211 blanking plate **JE0073**

Belt rigidiser arm **JEV0053**

Buggy transport restrictor **A40089RE-1**

RNET Gyro mount **A40090RE**

XLR charger plug adapter **A40103RE-1**

Vent tube routing clip **A40060RE**

Discovery recline indicator **PW0018-1**

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