

MEDICAL DEVICE MANUFACTURING TECHNOLOGIES

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ABSTRACT: This article aims to present the main technologies for medical device manufacturing, advantages and disadvantages of these technologies. A concrete example of a device made with 3D printing technology is also presented: the design and assembly of the prototype of a medical dispenser.

KEYWORDS: injection molding, 3D printing, drug dispenser, 3D design.

1. Introduction

The evolving technology is not only economically beneficial but also capable of creating new industries or transforming existing ones, thereby potentially exerting significant economic and industrial impact on our society. There exists a range of technologies available for the development of medical devices, which may vary depending on the type and purpose of the device. In general, medical devices are manufactured through the utilization of specialized technologies that enable the production of high-quality components and products that are safe and efficient for users. The technologies employed in the production of medical devices constitute a highly significant and continuously advancing field within the medical industry, with the primary objective of aiding in the improvement of health and the quality of life for patients. The main technologies utilized for device fabrication include injection molding, 3D printing, stereolithography, CNC milling, and electrical discharge machining.

Injection moulding is the technique of producing identical products from a molten material in a mould and is the most widely used polymer processing operation. [1] The main advantage of injection moulding is that it is a very economical method of mass production. Ready-made parts with close tolerances can be produced in one step, often fully automatically, and generally no further processing steps are required. It is also possible to integrate different functions into a single part to avoid different components that would be more costly. [2] Compatibility with a wide range of materials and colours is a benefit, there are currently over 25,000 manufacturing materials that are compatible with injection moulding, including thermoplastics, thermosets, resins and silicones. A primary disadvantage is the high initial costs because custom tooling must be created for each injection moulded part, initial start-up costs are high, and this is not economical for low-volume production runs. Injection moulding has a longer lead time, often taking 5-7 weeks to manufacture tools and 2-4 weeks to produce and ship parts. For the most part, this long lead time can be attributed to the complexity of the moulds themselves. Another disadvantage would be in changing the design, you will probably have to create a new mould from scratch, which means extra cost. [3]

Of the various manufacturing processes currently adopted by industry, 3D printing is an additive technique. It is a process by which a three-dimensional solid object of virtually any shape is generated from a digital model.[4] 3D printing has the advantage of quickly manufacturing custom medical models at a lower cost because no tools are involved. 3D printed organ models primarily help doctors perform surgical analysis and pre-operative preparation. Such implants and printed organs not only fit perfectly with the patient's damaged tissue, but can also have microstructures of engineered materials and cellular arrangements to promote cell growth and differentiation. Thus, implants allow the desired tissue repair to be achieved and could ultimately solve the problem of donor shortage. Customised medical models with complex shapes that are made using 3D printing can provide doctors and engineers with a means of

communication and help with surgical planning and diagnosis. There is no requirement for biocompatibility of materials in such applications, which include medical models and in vitro equipment for pre-operative planning, prosthesis design, testing standards and so on, as the printed parts will not enter the body. [5] While it is difficult to specifically assign a cost to a process when considering the potential to save or improve quality of life, it is clear that all technologies have associated costs. Even where there are clear benefits in terms of improved medical service, the approach can be cost prohibitive. Many 3D printing machines are expensive to run, particularly in terms of material costs. [6]

However, in addition to the higher price, issues such as limited print resolution, longer printing time and few available materials similar to the target organ or tissue during the process need to be addressed. [5] Many materials are not even suitable for sterilisation and transport to operating theatres. [6]

A concrete example of a device created using 3D printing technology is the medication dispenser, whose components are entirely designed. These devices are utilized to assist patients in timely and accurate administration of prescribed medications. Traditionally, such devices are manufactured using rigid materials like metal or plastic through milling and casting processes. However, the utilization of 3D printing technology enables the rapid and precise production of a customized medication dispenser with precise shapes and dimensions to suit the patient's needs.

2. The practical implementation of a medicine dispenser

2.1. Medicine dispenser design

In designing the medication dispenser, the basic idea was to create a simple but effective device that would allow patients to take their prescribed medication in an organised and accurate way.

In the first stage of the design, we made preliminary sketches of the medicine dispenser. Once we had established the desired models we started to make the 3D design of the parts in the Onshape application. We created 3D models to ensure that the device would work in a proper way and to help us identify possible design issues. We then generated 2D drawings with associated dimensions for use in the manufacturing process.

The medication dispenser is composed of several designed components, including its housing, which accommodates the feed chute tube, the screw mechanism inside the tube, the support for the Arduino board and motor, as well as the pill collection tray.

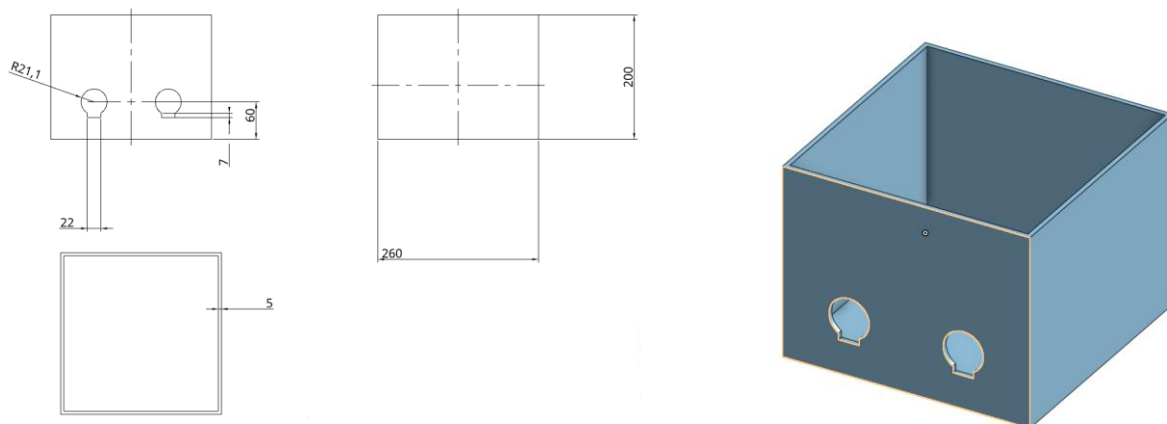


Fig. 1. 2D/3D medicine dispenser housing

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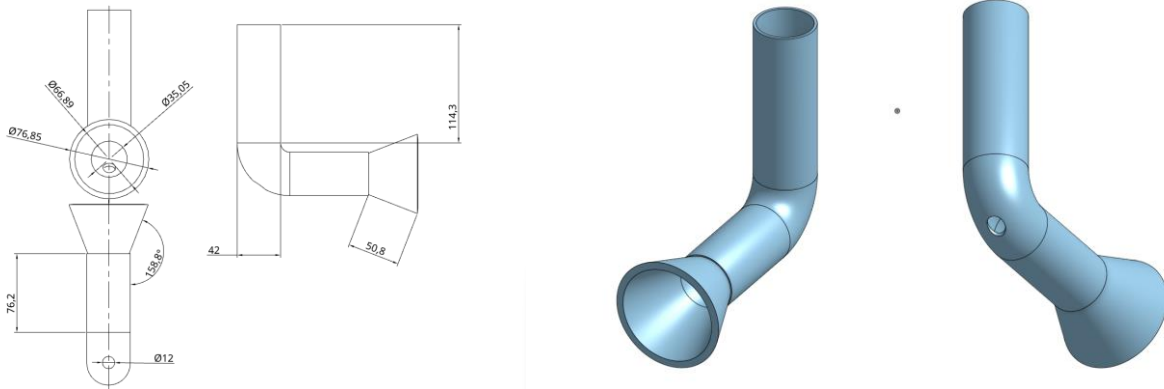


Fig. 2. 2D/3D medicine supply system

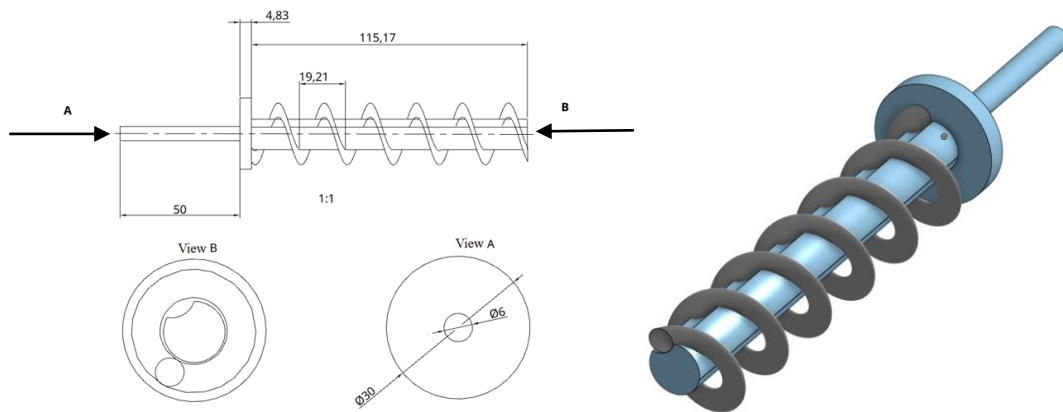


Fig. 3. The screw in 2D/3D

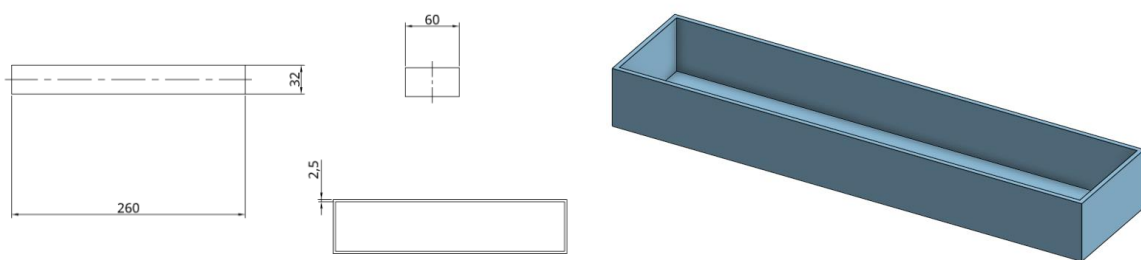


Fig. 4. 2D/3D pill collection tray

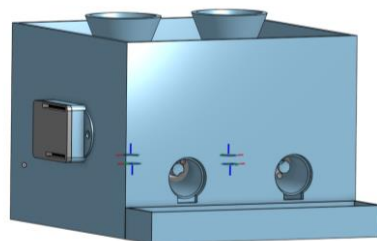


Fig.5 Assembled medical device

2.2. 3D printing of the medicine dispenser

We used 3D printing technology to create the prototype of the medicine dispenser. This process allows us to obtain a 3D image of the device so that we can analyse and adjust it before final manufacture.

The printing of the components was done with the ANYCUBIC MEGA 3D printer which uses molten plastic filament to build the object in a layer-by-layer process. The printer has a print area of 300mm x 300mm x 305mm and can print in a variety of materials. In our case we chose TPU (Thermoplastic Polyurethane) filament, it is a flexible, soft and pliable material, but at the same time quite durable, impact and abrasion resistant.

In order to achieve a high quality print, we set the extrusion temperature at 180°C and set a print speed of 75 mm/s to ensure that the object is printed in a reasonable time, but without sacrificing quality. In total, printing took about 15 hours.



Fig. 6. ANYCUBIC MEGA 3D printer

Following the 3D printing process, we got the components needed to assemble the prototype medicine dispenser. These components were of high quality and quite accurate, so they could be assembled and tested to verify the correct functioning of the device.

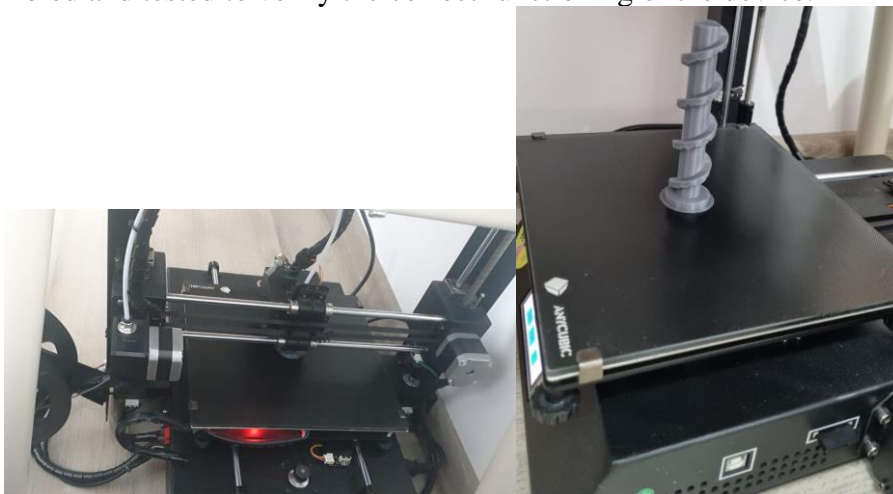


Fig. 7. The printing process of the medicine dispenser parts

2.3. Medication dispenser programming

We connected the motors and infrared sensors to the Arduino board via digital pins. The motors are connected to digital pins 3 and 5 respectively and the power pins, and the infrared sensors are connected to digital pins 4 and 6 respectively.

The code is written in the Arduino Integrated Development Environment - or Arduino Software (IDE), which is a software platform specifically designed for Arduino boards, in which programs can be developed and created.

This code will cause the two motors to start 3 minutes apart and wait 5 seconds to reach maximum speed. If one of the two infrared sensors detects a signal while the motors are running, they will stop immediately and wait for the next start 3 minutes apart.

2.4. Electrical part of medical dispenser

In addition to the printed components, we utilized the following components for the operation of the device: two DC motors, two infrared sensors, and an Arduino board. The motors were connected to the Arduino board using a dual H-bridge, L298N, which enables us to control the speed and direction of rotation. The infrared sensors were connected to the board using jumper wires. The power supply can be provided either by batteries or directly from the power source.

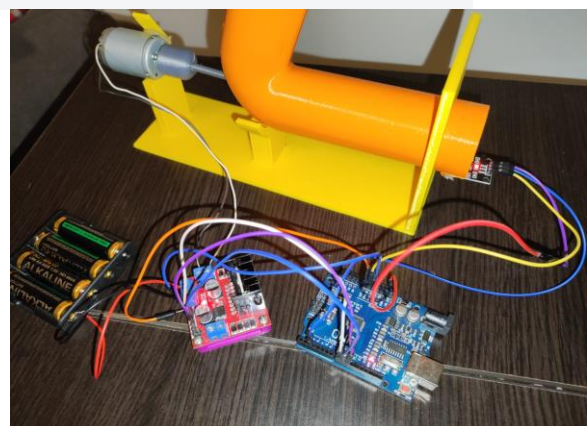
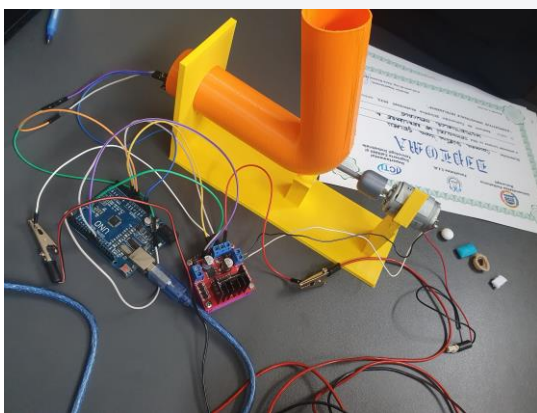
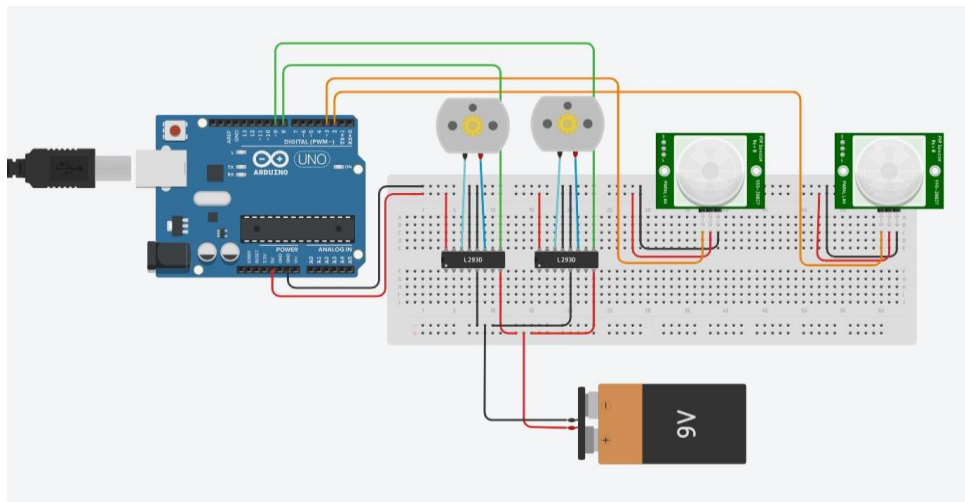


Fig.8. Electrical diagram with battery power/supply

3. Conclusions

The medication dispenser represents a precise method of medication administration, providing assistance for patients with daily treatment or elderly individuals. The device is designed for two types of pills and utilizes a motor-controlled screw to distribute the medications efficiently and in the appropriate dosage. Moreover, the components are crafted to ensure a pleasing aesthetic appearance while facilitating easy handling for the user, its dimensions allow for convenient storage. This type of device proves useful in hospitals and nursing homes, alleviating the burden on healthcare professionals. For instance, during the pandemic, this device could have been valuable for patients who did not require meticulous monitoring but only medication administration, thereby reducing contact with patients.

Regarding potential improvements, we believe that adding certain additional features could be beneficial. For instance, incorporating a touch screen interface would allow for personalization of the administration time and pill quantity, either directly on the device or through a remote programming application. Additionally, implementing an alarm system to notify both patients and caregivers when the medication is due or when pill supplies are running low would be advantageous. Expanding the capacity to accommodate a greater variety of pill types is another potential modification. Furthermore, integrating a notification system to alert users when the collection tray needs to be emptied and providing confirmation of medication intake could enhance the functionality of the device.

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