Open-Source low-cost syringe pump system adapted to hospital use (#OpenSyringePump)

Problem and background

The Paris Hospitals Association (AP-HP) have an urgent need for Syringe Pump Systems (SPS), with the opening of many intensive care units (ICUs), due to the current SARS-Cov-2 crisis. Every single patient in the ICU needs 3 to 5 syringe pump systems in order to administrate multiple drugs simultaneously, for sedation, analgesia and circulatory support for example.

The shortage of SPS has already begun with phase 3 of the SARS-Cov-2 pandemic, as the need for intensive care keeps growing all around the world. As reported, in major hospitals in Paris, France (such as Hôpital Bichat or Lariboisière), there is a huge lack of syringe pump systems in ICUs. As a result, nurses are required to administrate all the drugs in a single intraveinous (IV) drip, which can be deleterious for the patient.

In other countries such as Africa for example, nurses have no choice but to push the syringe by hand during several hours continuously.

Solution summary in simple terms

The current cost and the manufacturing process of a standard Syringe Pump System (SPS) is not appropriate for the existing crisis, as we have to reinvent in a very short amount of time a new way to provide ICUs with a local and fast access to reliable SPS.

This SPS have to be cheap (regarding the amount needed and the cost of existing models), easy to make, intuitive to use, and as universal as possible, in order to be built in emerging countries as well.

Solution summary in technical terms

Our idea was to create a low-cost SPS, suited for a hospital use.

The Poseidon syringe pump system, made by Booeshaghi et al. is an open-source 3D-printable SPS design, initially created for laboratory purposes, but appears to be the ideal candidate for adaptation to hospital use. 

Specifications of a standard SPS used in ICU, the Injectomat MC Agilia F was used in order to make our product calibrated to usual standards.
State of advancement of the project

We recruited dozens of biomedical engineers and developers from different countries to work together and get this device ready for mass production as quickly as possible.

The first prototypes, ready for lab testing, were sent this week to AP-HP biomedical engineers and some engineering French universities such as Institut des Arts et Métiers.

We also planned an evaluation of our device by fifty nurses, who represent the main users of SPS, in order to compare our product to the Agilia/Fresenius model.

Project Timeline

- **April 2020**:
  - Adapt the design and technical specifications for hospital use
  - Run Lab testing of prototypes and user evaluation
  - Submit to AP-HP team for validating local mass production in case of critical shortage with emergency temporary certification

- **May 2020**:
  - Begin local production
  - Run clinical studies:
    - A cluster study (fast, sufficient in this context)
    - A non-inferiority study in the meantime
**Project Implementation**

**Solution :**
- Our answer to the growing need of syringe pump systems (SPS), in this context of SARS-CoV-2 pandemic, is to develop a reliable low-cost SPS, that can be produced massively and in a very short amount of time, in any place with basic and universal electronic equipment. The 3D-technology seems to be ideal in this context of lockdown and economical paralysis.

**Methodology :**
- We based our development on getting the Poseidon fit the required specifications to obtain a functional device
- We collected feedback from nurses in ICUs during this crisis, to build a product with the essential features only, free of unnecessary marketing details.
- We decided to strip down to the minimum features required for a fully functional and reliable device, so that it could be implemented in many countries and make our device more universal
- Our team was able, in a very short amount of time and thanks to the huge involvement of each member, to adapt the design and make a functional prototype. It has been submitted to specialized universities and companies to make a battery of tests, in order to validate the technical reliability.
- We also planned a user evaluation of the prototype by numerous nurses, in comparison with the Injectomat MC Agilia F. This assessment should take place in the next couple of weeks.

**Expected results :**
- Based upon the strong experience of some of the team members specialized in SPS, we should get a prototype fully functional and reliable within a week.
- As the current situation implies dangerous techniques to overcome the shortage of SPS, such as mixing drugs in a single IV drip, our device is expected to improve the accuracy of drugs’ administration flow rate, and lower the risks of overdose, thus decreasing the mortality due to SPS’ shortage around the world
- Funding from the OpenCovid 19 initiative would help with designing and testing the mechanical hardware, electronics and firmware, as well as conduct the clinical trials needed for certificating our device

**Safety, quality assurance and regulation**

**Have you planned the testing, verification and validation of your solution? How advanced are you?**

We are currently submitting the prototype, in order to verify the safety and functionality of the device. As soon as it is ready, the device will be tested by nurses who will answer a satisfactory questionnaire and help us refine the last details. We will then submit our project to AP-HP, in order to obtain the autorisation for local production in large amounts, with the help of industrials that took part in this project.
Have you talked to medical staff about the feasibility of your project? What did they say?

We have received a widespread excitement from nurses and doctors in ICUs, as they are worried about the shortage to come and the critical situation in Paris as well as in other countries, regarding the administration of sedative or vasoactive drugs and the “unappropriated” techniques used by default.

Will you need assistance with the regulation system? If not which Regulatory system do you plan on distributing the product?

Yes, we will need assistance from different organizations like WHO or FDA in order to help us build a device fully compatible with their standards. We will also need the help of individual countries’ administrations, in order to help with the regulation and distribution of the product.

Impact, issues and risk

According to the literature, the main issues and risks in using SPS are due to human mistakes in preparing the syringe with the correct amount of drugs, and doing the proper actions required by the system in case of blockage for example.

If we achieve to make a reliable open source 3D-printable SPS, we could share this technology with the entire world: anyone who has access to a 3D-printer and universal basic electronic material would be able to produce locally a functional SPS within hours, at a low cost and without shipment issues.

The risks are those related to the use of a classical syringe pump system. We are currently improving the safety disposals (such as the sensitivity of the alarm systems or the pressure sensors) in order to meet the standards and build a reliable product.

Team Experience

As the team is getting bigger, we decided not to mention individuals.

Our team includes engineers from all over the world (US, France, Netherlands…) who worked on SPS before, as well as programmers specialized in medical devices, and industrials who help us build and adapt some parts of the device.

We agreed to have a daily-basis meeting, in order to ensure the proper organisation of our team effort.

Our goal is to keep this project open-source in order to give it an access to everyone.
Funding

We need funding to keep building more prototypes and test them. We also need to provide the devices to the testers.

The estimated price per kit is just under 1000$ worth of equipment before the current round of testing. After this round of testing, as some of the parts are selected out by testing, the price per kit would fall lower to around $400 (3D printed parts excluded, to be printed by each builder or donated).

Here is the current estimation of the hardware testing plan:

- Order electronics components to test sensor and actuators and validate hardware design (Gotronic ordered by Caltech, sent to Arthur Wolf, lead on the electronics, 230 €)
- Order electronics components related to the electrical systems and battery backup systems (estimated at 300€ based on the current BOM).
- Once all electronics are validated, we would need to ship both hardware (mechanical) parts as well as electronics parts to all kit builders (currently estimated at $400 per builder).
  - 9 builders are currently planning to build a syringe pump system
  - This amount is adjustable: we can send less to some builders, more is simply better and would save time as well as add redundancy to the building and testing

Development of the firmware for the syringe pump system is based on the Open-Source and widely available « Smoothieware » CNC control system, as it contains a lot of code that can easily be adapted for this usage, greatly speeding up development, and because the Smoothieboard hardware is by chance a perfect match for this project, making hardware implementation and sourcing much easier.

One company (Robosprout, US) often assists with Smoothieware Open-Source code development, and is available to assist/speed up development of this new system. Estimated cost would be €1500 to assist with coding through third party devs, and assisting in testing the code as it is improved.

This is a sliding scale where less budget could be allocated to less help, and vice-versa.

In total, the first prototype is worth about 1000€ and each builder would need about at least 400€ (to order parts, make, test, adapt the prototype in their own lab) with the goal of making a functional, reliable and safe device ready for mass production. The idea is that builders should be able to adapt the prototypes themselves, avoiding shipping costs from different actors.

So the whole amount would be about 4600€ to start the testing process of the prototypes.

We thank you, sincerely, for your consideration.

#proj-syringe-pump Team

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