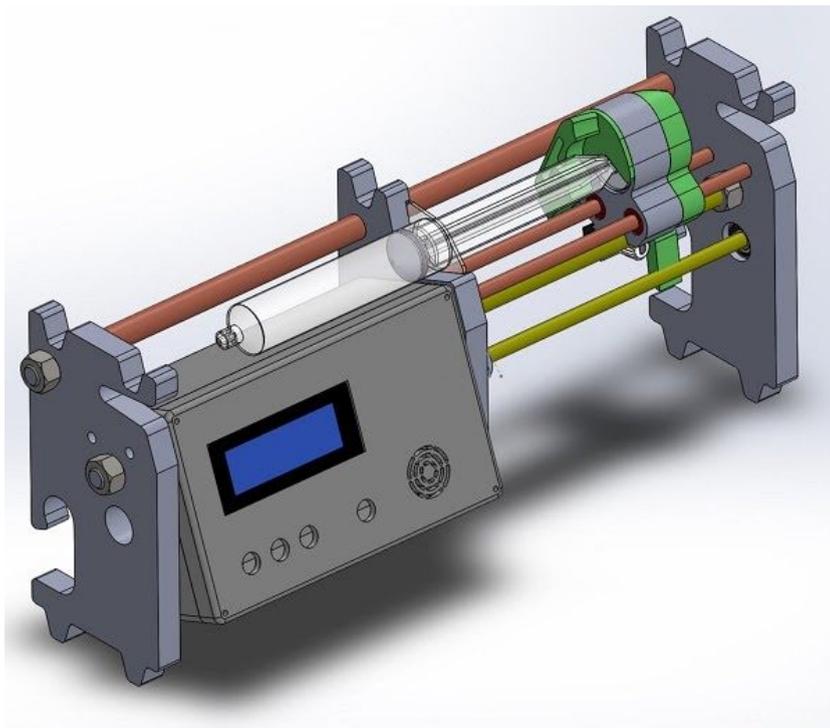


Open Syringe Pump

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Project summary



This project is supported by :



sous égide de la Fondation de l'Académie de Médecine



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Key words :

Electric syringe pump, electric syringe, auto push syringe, COVID-19, SARS-CoV-2, pandemic, medical equipment for emergency use, emergency situation, Open Hardware, Open Software, Free Software, Intensive care unit (ICU), non-profit initiative.

Introduction

L'association Electrolab

Electrolab (www.electrolab.fr) is a non-profit organization located in Nanterre whose social purpose is "the spreading of knowledge in the field of science and technology".

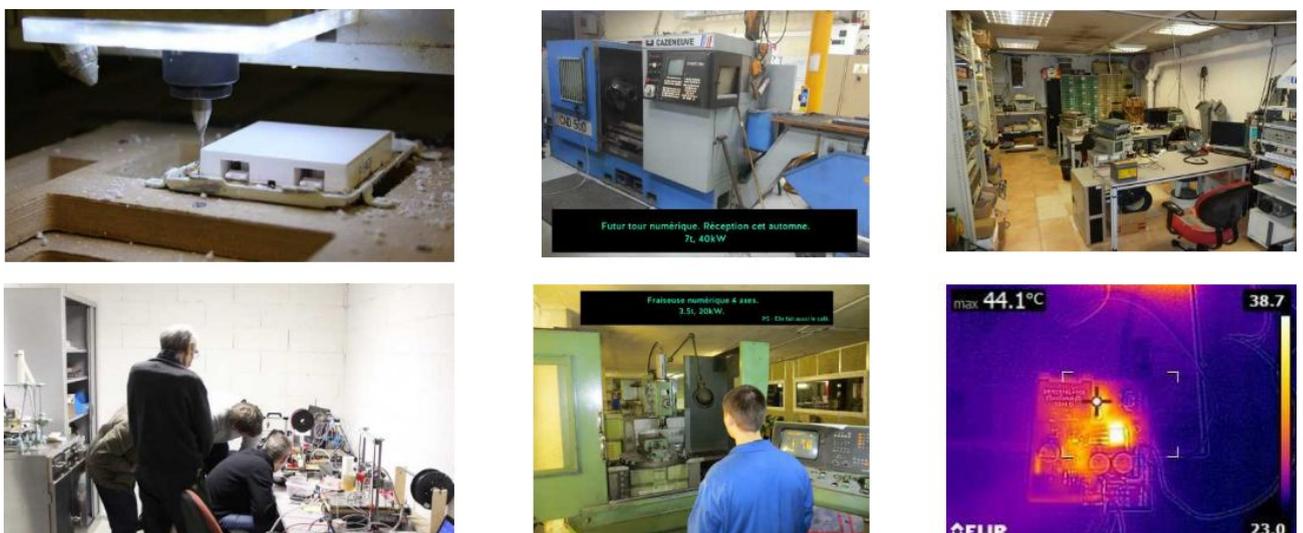
Founded in 2010 by enthusiasts from all backgrounds, it is a cultural institution (member of the AMCSTI, interprofessional network of scientific, technical and industrial culture) whose leitmotiv is the reappropriation of technologies and industrial means by citizens.

In order to act, develop and carry out its missions, the organization has set up an essential tool: a 1500m² facility easily accessible by public transport. Organised in widely open thematic zones, the site brings together all the components of society on a daily basis: schoolchildren, artists, scientists, novice and experienced entrepreneurs, students, or the simply curious.

Within this framework, the association is involved in several projects aimed at fighting the COVID-19 pandemic (emergency protection visor, electric syringe pump, medical needs modelling...).

In the context of March 2020, offering a rapid response to healthcare operators essential.

This document describes the emergency production and industrialization process that Electrolab wishes to put in place for the electric syringe pump developed by its members.



Quelques images des locaux et projets menés à l'Electrolab.

Project summary

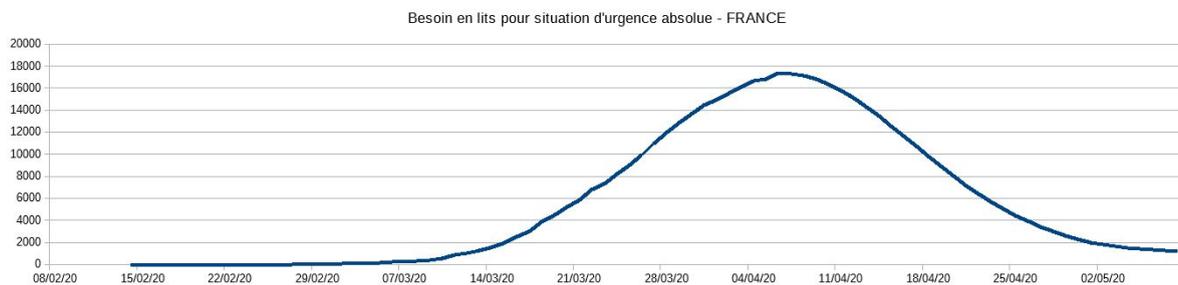
Historique du projet

Since March 11, 2020, WHO has qualified as a pandemic the 2019-2020 epidemic of coronavirus disease (called Covid-19) that began on November 17, 2019 in the city of Wuhan, central China.

With a provisional case-fatality rate of 1 to 2% of detected cases, the challenge identified is to prevent the saturation of intensive care units.

Predictive analyses of Covid-19-related deaths make it possible, from the beginning of March 2020, to anticipate a peak in the need for intensive care units (ICU) throughout France for 10 April 2020 (see graph below).

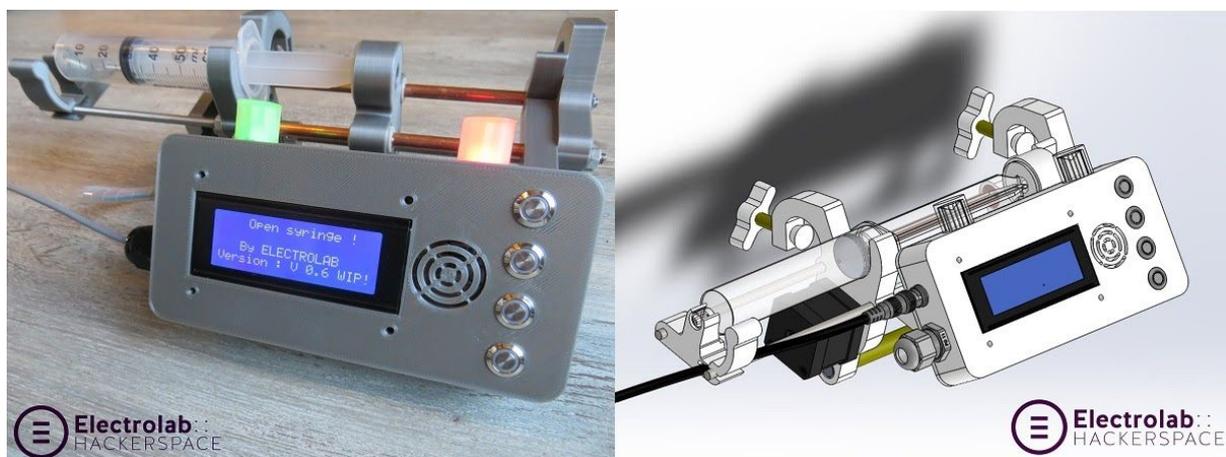
In these estimates, it is expected that the significant overrun of the ICU capacities usually available in France will be spread over a period from 24 March to 21 April 2020.



Curve from the OpenCovid19Model project, led by members of Electrolab

Health care workers reported a predictable lack of syringe pumps in the intensive care units.

To participate in the effort to respond to this emergency, volunteer members of the Electrolab hackerspace, in collaboration with physicians, designed a first prototype of an “open source syringe pump”.



Picture and CAD view of the first OpenSyringePump prototype

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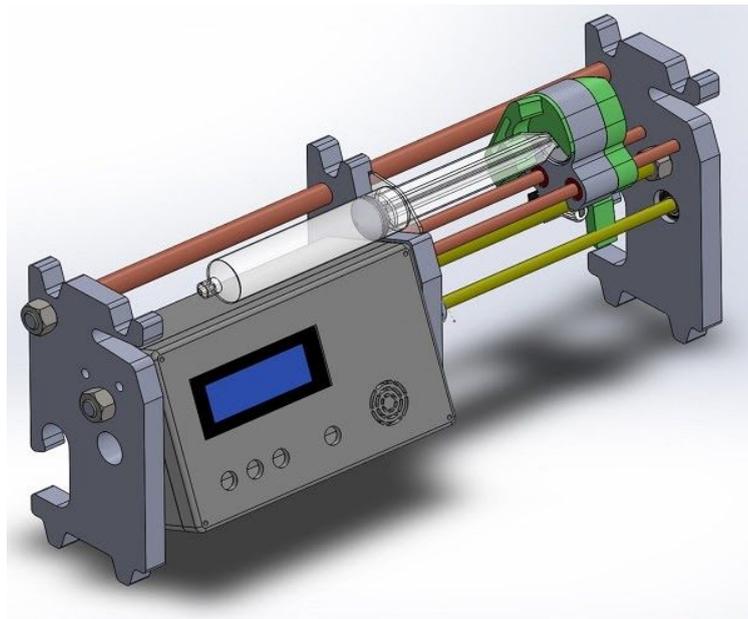
Ergonomic and preliminary functional tests of this prototype were carried out on Friday 3 April 2020 by several physicians from a major Parisian hospital.



Dr. Jona JOACHIM during the preliminary trials on April 3, 2020.

As a result of these tests, a new pre-industrial design was developed. While the first version uses - for its manufacture - exclusively 3D printing techniques, all plastic parts of the initial design have been modified to be feasible by traditional subtractive machining means (milling and turning).

The aim is to make the production of OpenSyringePump compatible with large volumes in a very short time frame.

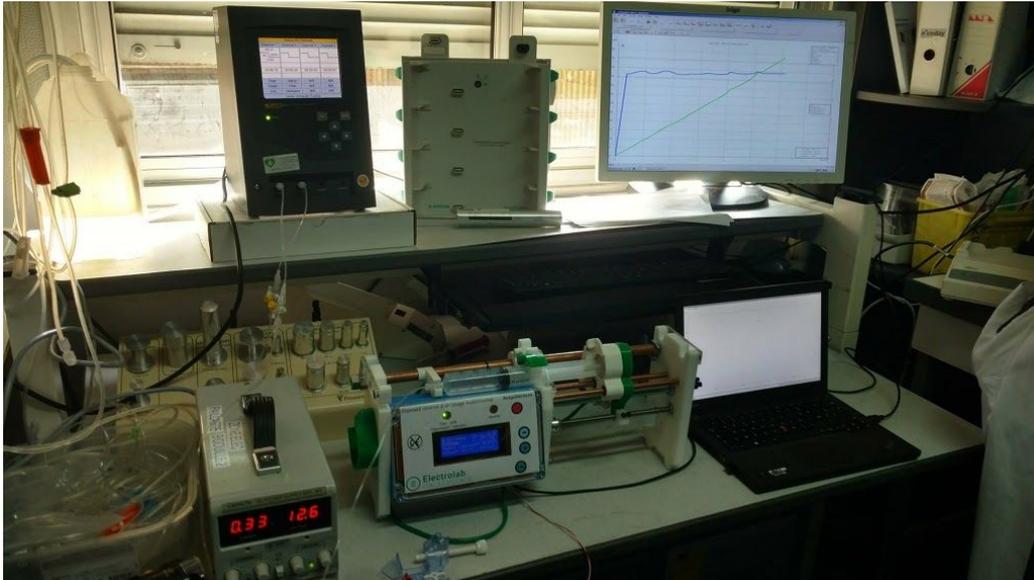


Vue CAO de l'OpenSyringePump V3.

Project summary

The prototype version 3 has been medically validated on a dedicated test bench in a major Parisian hospital:

- on April 8, 2020 for pre-qualification testing,
- on April 10, 2020 for formal testing by biotech engineers,
- on April 12, 2020 for a first real conditions user experience by a COVID ICU team.



Tests on a dedicated test bench, carried out in a Parisian hospital on April 8, 2020.



Dr Fabrice VALLEE during the trials on April 12, 2020.

OpenSyringePump project license

Documents, parts drawings, manufacturing files and software are gathered on Electrolab's GIT repository:

<https://code.electrolab.fr/covid-19/opensyringepump>

Hardware and documents

EN : The OpenSyringePump project led by the ELECTROLAB non profit organization, and all documents produced through the development process are under Creative Commons license:

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Software

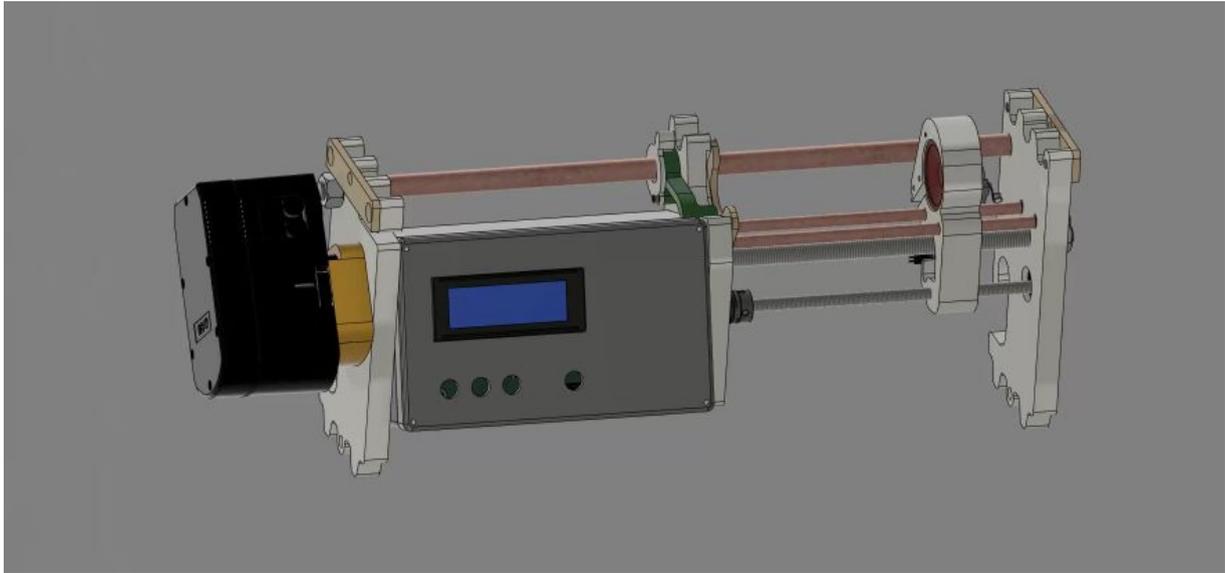
EN : The software developed for the needs of the OpenSyringePump project led by the ELECTROLAB non profit organization is under the GNU GPL version 3 license.

<https://www.gnu.org/licenses/gpl-3.0.txt>



Overview

A stand-alone electronic controller drives a stepper motor which moves a sliding block by means of a threaded rod, and actuating the syringe pusher.



The man-machine interface is made up of a keyboard (4 push buttons), an alphanumeric display (4 x 20 characters), 2 leds and a buzzer. Parameter setting and supervision are performed through this interface.

Several control mechanisms are provided to continuously check the correct operation of the unit and alert in case of problems (pressure sensor on the syringe plunger, carriage position sensor and electronic watchdog).

The unit is powered by an external 12V power supply.

Optionally, a battery (similar to a cordless tool battery) can be installed in order to give autonomy to the device in case of power failure or patient displacement.



Description

Syringes

Three types of syringes can be installed in the device: 10 ml, 20 ml and 50 ml.

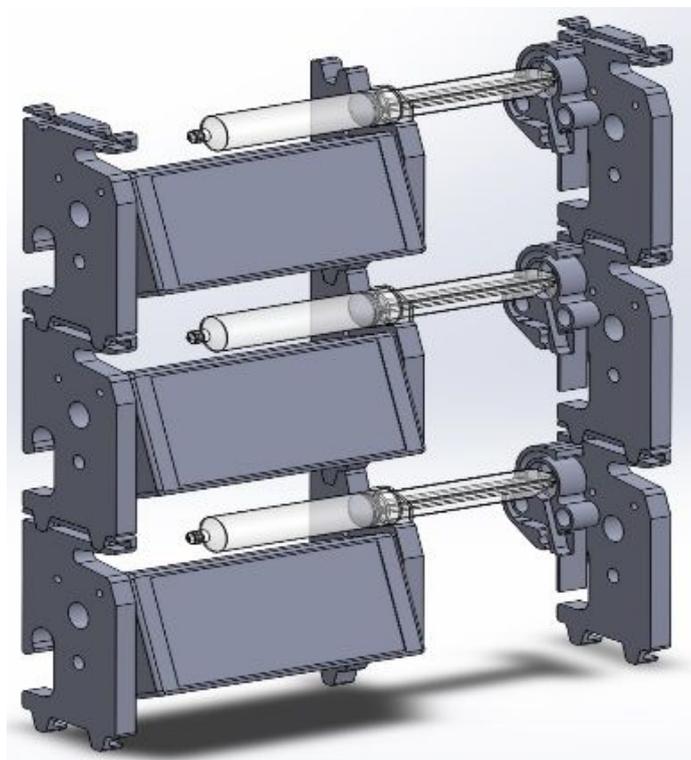
The selection of the syringe type is made by the user via the keypad. A confirmation is requested to minimize the risk of wrong selection (human error).

The selected syringe type is permanently displayed on the screen.

Stacking

In some situations several simultaneous injections are necessary for the same patient (up to 6).

The mechanical design of the supports allows stacking the devices.



Project summary

The electronic assembly has dedicated connectors allowing the chaining of the power supply in order to use only one PSU for the whole unit. The power supply unit is dimensioned accordingly.

Power supply section

In the usual operating configuration, the device is powered by an external 12V DC power supply unit.

It is possible to run the device with an external battery (Ryobi 18V type, reference RB18Lxx) to temporarily take over the power supply in case of power failure or patient displacement.

On power-up, the device starts spontaneously and displays an alarm status. This alerts the practitioner that a restart has occurred, either following a power failure or following a restart due to a technical problem.

The device is able to save its settings and its instantaneous operating information, thus making it possible - in the event of a loss of power - to resume injection where it was interrupted, i.e. at the precise moment when the lack of electrical power was detected.

If there is a dual power supply (mains + battery), the presence of the mains disconnects the battery. The device does not recharge the battery. The battery is removable and must be recharged in its original charger.

This design allows, when several OpenSyringePumps are used, a high degree of flexibility regarding the power source:

- use of only one battery for the entire syringe pump battery,
- hot swapping of batteries using the battery holder of another OpenSyringePump battery on the stack
- In extreme situations, full battery operation is possible. One battery allows an OpenSyringePump to run autonomously for 10 hours on a 15 minute charge. In this case, the battery is replaced when the syringe is changed.

Project summary

Force sensor

The device is equipped with a force sensor placed on the movable pusher and measures the pressure applied to the syringe plunger.

This system ensures a supervision of the operation and allows to alert in case of possible anomalies:

- Abnormal overpressure (blocked plunger, misplaced syringe, occlusion...)
- Insufficient contact pressure (missing syringe, poor physical contact of the mobile carriage with the syringe plunger)



Force sensor integrated between two constituent parts of the pusher carriage.

Project summary

Position sensor

The device is equipped with a position sensor (encoder) to know the position of the mobile pusher.

This system ensures a supervision of the operation and triggers an alert in case of movement inconsistent with the commands.

For example:

- Blocking
- Incoherent pusher displacement

An automatic calibration allows the device to reset the mechanical origin of the pusher thanks to a limit switch at the beginning of each cycle.

An automatic calibration mode allows the precision of the electromechanical assembly to be calibrated.

Sliding pusher

The sliding pusher is driven by a stepper motor. The speed of movement for injection is determined according to the user-defined parameters.

The plunger is equipped with force and position sensors.

Specifications

- Operating temperature: 15-35 °C
- Storage temperature: 5-45 °C
- Power supply 230 V (external power supply unit 12V 1.5A)
- Compatible syringes: 10, 20, 50 ml
- Adjustable dosage from 1 to 300 ml/h in steps of +/- 0.1 ml/h
- Bolus function
- Slide travel: 170 mm
- Force sensor: analogue 0.15 to 20 N
- Position sensor: 0.6 mm resolution

Project summary

End of injection alarm adjustable from 0 to 120 minutes or from 0 to 10 ml before the end of injection

- LCD display and simple user interface (3 push buttons + 1 dedicated to security)
- Indication of the remaining injection time, the quantity already administered and the percentage of syringe filling
- Possibility of chaining three EPS supplied with 12V DC by a single mains supply sized accordingly.
- Protection of the external 12V DC power supply against short-circuits: by an internal fuse with automatic reset.
- Mounting on hospital bed or mobile vertical column

Hardware security functions

The device integrates various hardware security functions:

- Monitored power supply with anti-pullout plug
- Possibility to install a backup battery
- Syringe position sensor for monitoring the injection speed in relation to the demand (motor fault or blocking)
- Force sensor for detecting occlusion
- Hardware monitoring and self-checking system for detecting software failures

Project summary

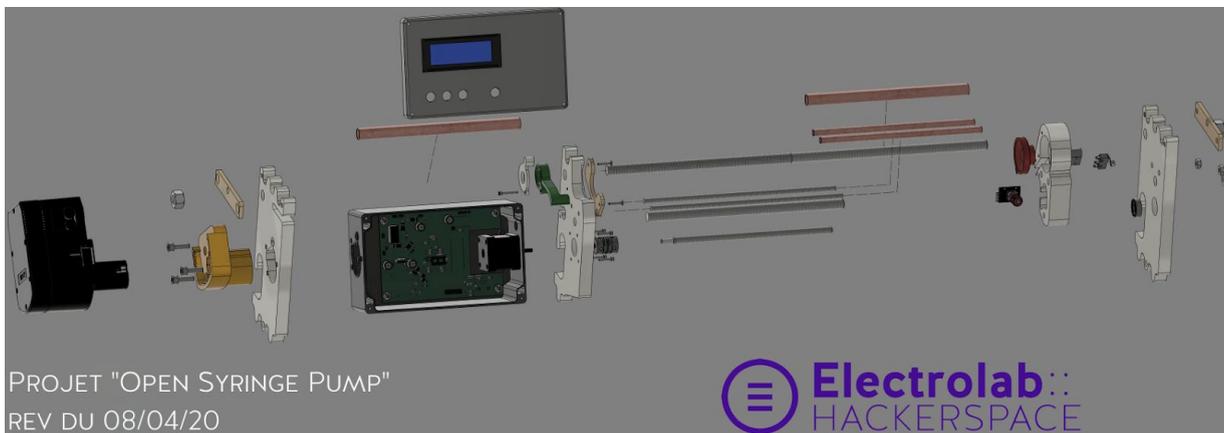
Safety function against human error

Functions to combat human error are also included:

- Visual (LEDs) and audible (buzzer) hardware alarms
- Backup of parameters and states for recovery after hardware failure or power failure
- Safe interface design prevents unintentional injection
- Dual validation of all injection-related operations with parameter recall

Project Parts

The objective is a design that goes to the essentials, oriented towards simple and rapid industrialization. Components have been chosen preferentially according to their ease of supply.



All parts can be machined in with standard techniques (milling/turning), and all supplies are standard industrial supplies, available off the shelf in large quantities.

Only the position sensor gearwheel requires specific manufacturing, either by machining with a specialized tool, or by 3D printing (stereolithography process - SLA, for example).

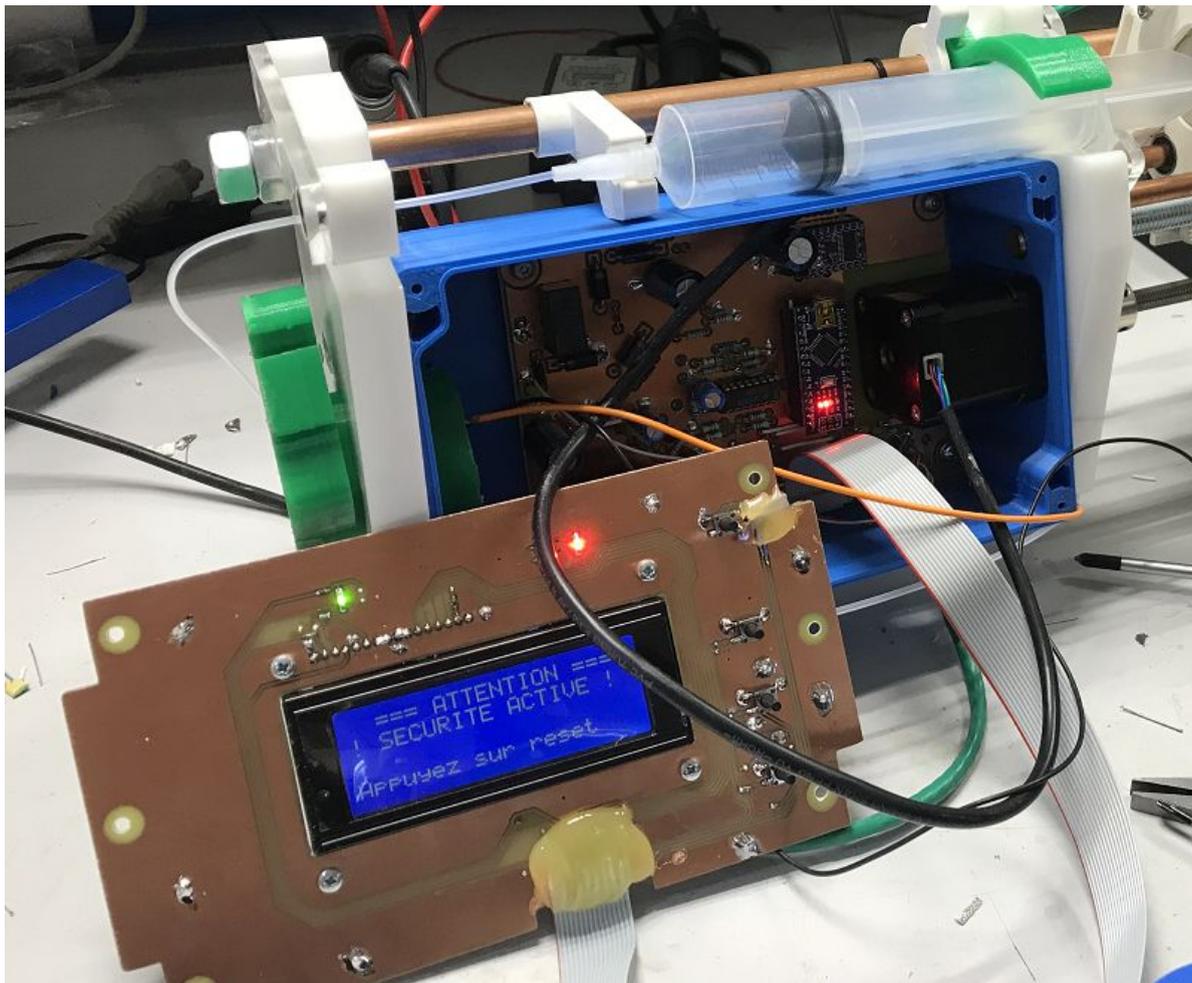
Project summary

Electronics

The system consists of two electronic boards:

- A user interface board (UI), with 3 NO and 1 NC buttons, a green LED, a red LED, and a 4 lines 20 characters LCD display.
- A motherboard (MB), with all the functions of the OpenSyringePump, excluding the power supply.

The UI board is designed to be very simple which can be fabricated by hand if required on a standard double-sided PCB.

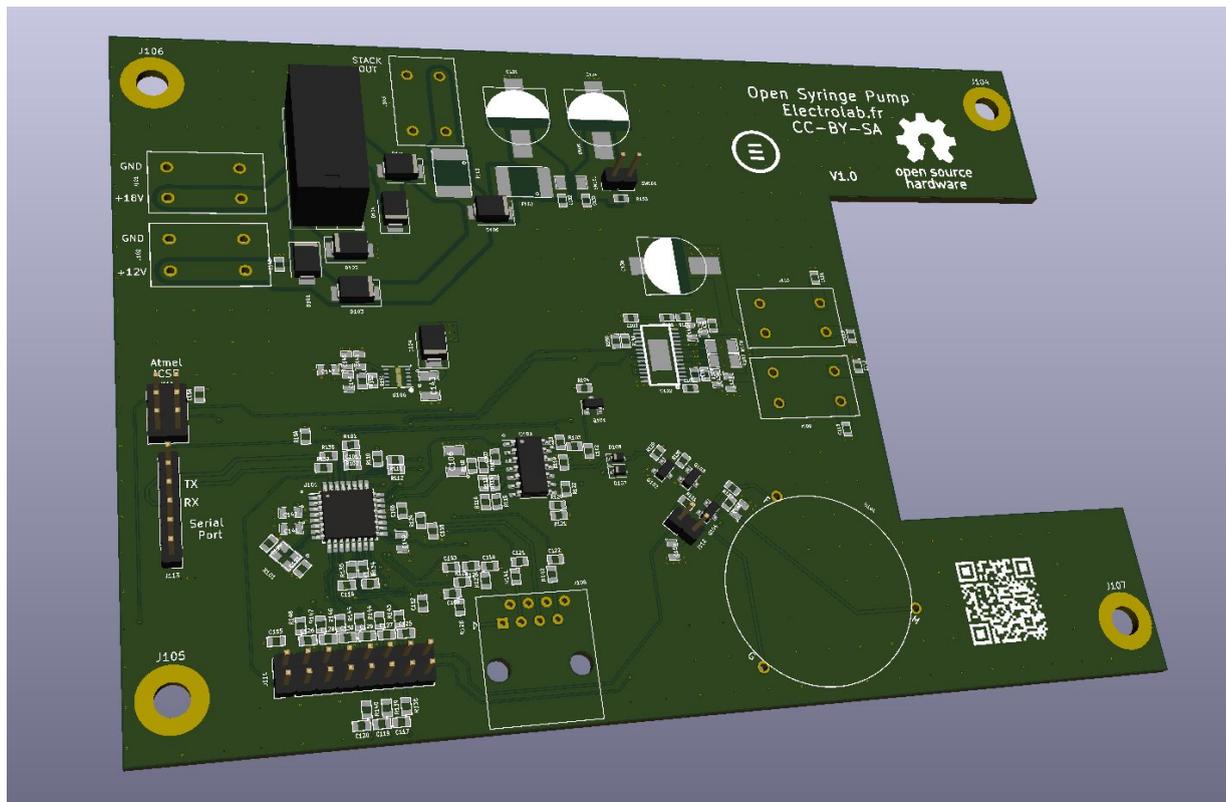


In the foreground, the UI board and in the background the motherboard (MB) "maker" version placed inside the blue case.

Project summary

The motherboard is available in two versions:

- A **"Maker" version**, double sided with through-hole parts, on which an Arduino Nano module is implanted, and a Pololu module. This PCB can be manufactured by hand if necessary on a standard double sided board.
- An **"Industrial" version**, optimized for production and capable to meet a high level of requirements in terms of EMC and electrical safety. This version consists of a 6C class 4 layer PCB.



Motherboard (MB) of the OpenSyringePump - "Industrial" version