Università Campus Bio-Medico di Roma (UCBM)

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SYRINGE PUMP FOR A DRUG DELIVERY SYSTEM

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1. Introduction

1.1 Objective

The aim of this project is to build a syringe infusion pump that can deliver a continuity of flow rate. The difference between the volume set and the volume recorded by the precision balance, will return an error. The pump shall be realized through an ARDUINO UNO [9] board, a motor driver, a NEMA 17 [8] motor and a worm.

1.2 Background

The infusion pump is an electronic device that allows intravenous or enteral therapy to be infused precisely in terms of time and dose. The therapy can be continuous, if it is administered continuously over a 24-hour period, or intermittent, if it is given at precise times of short duration. Through infusion pumps can be administered drugs, fluids, enteral nutrition and parenteral nutrition.
The main advantages related to the use of infusion pumps over common flow regulators or other devices are:

- Accuracy in the volume and drug being administered.
- Accuracy in the speed of administration.
- Ability to set and adjust even very small amounts of drug.

Generally, infusion pumps use a push mechanism that presses the plunger of the syringe filled with drug, which is pushed into the outflow and delivered to the patient.

1.3 Requirements

The Infusion Pump must meet various requirements imposed by the task it has to perform.
These objectives have been identified and hierarchized in an objectives tree indicated in the figure below.
The main objectives and functions have been summarized in four pairs of similar areas of interest: economy and availability, safety for both patients and users, skills and easy to use.

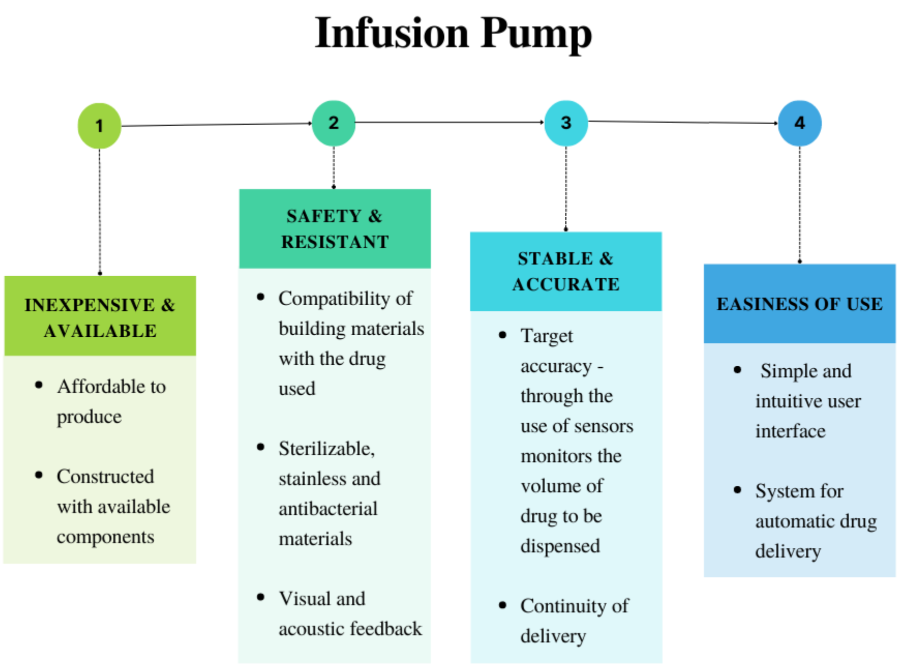

Figure 1: Tree of Requirements

2. Detailed Description

2.1 General Overview

As a mechatronic system, the syringe infusion pump contemplates an energy flow and an information flow. A general overview of how this system works is given by the following block diagram:

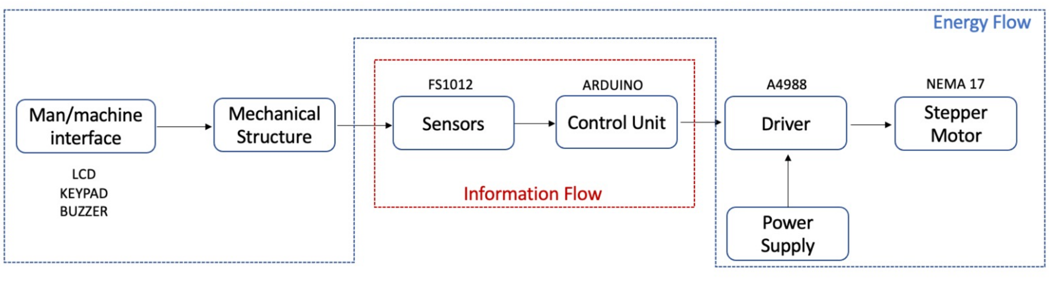

Figure 2: Block Diagram - General Architecture

2.2 CAD and Materials

Our device is conceived in two main parts: the upper one, which contains all the supports for the syringe and the motor connected with the worm, and the lower one which is a box that contains all the electronic components, the LCD and the keypad (see Attachment_01).

The CAD for this project has been designed via the software OnShape and Fusion360, and the final product has a total length 308 mm, an height 173 mm and the final weight is approximately 2.56 kg.

2.2.1 Materials

After evaluating different materials [1], in the first place we selected ABS and PLA, both FDA approved and FDM printable materials. Between the two, our choice has fallen on the PLA. This is a thermoplastic material, which has lower print temperatures than the ABS, and so it is less likely to deform after the cooling. In addition, the surfaces after the print result more polished, having a better print performance. PLA offers many advantages for our case study: it has good stiffness and resistance and it is affordable and sterilizable. Furthermore, the material we've chosen makes our device light, so that it is transportable.

In the end another great advantage of this material is that it is biodegradable, therefore resulting eco-sustainable [2][3].

2.2.2 Syringe Mobile Part

The Syringe Mobile Part is a 90x50 mm mobile platform, 5 mm thick.

The syringe plunger is pushed forward along with the movement of this part: the axial distance the part moves determines the volume of the drug dispensed.
The terminal part of the syringe plunger fits perfectly into the mechanical part to ensure that every movement of the syringe plunger follows the movement of the mobile platform, guaranteeing the best accuracy possible. In order to prevent friction as the platform slides, it has been chosen to leave an empty space between this part and the base. Two holes were drilled allowing to insert recirculating ball bearings through which steel support rods pass. The material has been selected to guarantee greater stability and lightness during the movement.

2.2.3 Syringe Support Part

The length of this component is 40 mm, with a height of 53 mm and a thickness of 5 mm. On the upper side there is a concavity that has the exact same size of the syringe diameter to maximize the adherence between the two parts. The syringe support part is connected to the base with two screws so that it keeps the syringe locked in place. This part is smaller in length than the others and needs just one hole in order to let the worm pass through.

2.2.4 Motor Support Part

The motor support part has 85 mm of length, a height of 64 mm and a thickness of 58 mm. It covers the motor and allows the connection between the motor and the warm through one hole of 22 mm. The connection between motor and worm screw is made via a flexible coupling. On the bottom there is a rectangular hole that allows the motor's power electrical wires to pass and reach the electronic components and power source located in the lower part. On the back, there is a removable component that allows accessibility to the motor and a step has been designed in order to thread it.

2.2.5 Terminal Part

This part has a length of 85 mm, a height of 53 mm and a thickness of 30 mm.
It supports the end of the syringe, guaranteeing full adherence between the syringe and the part, so that the syringe, which is pushed by the syringe mobile part, does not slip forward. Two holes in this part have been designed in order to wedge the metal support rods. There is also one central hole to attach the terminal part of the worm.
Two screws keep this component anchored to the base.

2.2.6 Base Support

The base support contains electronic parts and the emergency battery and is made of three parts: the LCD and keypad part, the cover part and the support part.

In the first part:

- The PCB is allocated inside the part by means of an appropriate support.
- On the side wall of the piece, there are two openings that allow connection to the external power supply and USB.
- Looking from the front, it is possible to notice two windows: the left one is designed to connect the LCD and the other one is designed to connect the keypad. Due to the small thickness of the keypad, a support has been created in order to keep it in place.
- There are four pins that provide the interlocking with the cover part.

In the second part:

- There is a pipe holder on the side, in which the catheter [6] passes getting stuck in place.
- An opening has been planned in order to place the flowmeter which will control the flow.

The third part has been realized in order to place all the mechanical components of the syringe pump, making it easy to place or relocate it.

2.3 Mechanics

Nema 17, which is a bipolar permanent magnet stepper motor compatible with Arduino1, has been chosen for our application. Stepper motors operate on precise position control: each input pulse rotates the shaft through a fixed angle and the rotation angle of the motor is proportional to the input pulse.
In addition, stepper motors can hold a load in place having no vibrations and are able to generate high torque at low rpm.
One feature of stepper motors that differentiates them from other motor types, particularly servo motors, is that they exhibit holding torque.
Essentially, stepper motors offer excellent speed control, precise positioning, and repeatability of movement.
They require a motor driver: A4988 is the one used in this project. This device allows the connection between the power source and the motor itself, providing the required current and voltage. The A4988 Motor Driver [15] is used to convert the control signals from the Arduino microcontroller into suitable output signals for the NEMA17 Stepper Motor.
The motor's shaft is connected to a worm, whose rotation make the translation of the syringe mobile part possible.
In Attachment_02 all the dimensions of the motor, driver and worm are shown.

2.4 Electronics

2.4.1 PCB

In the realization of the infusion pump, has been realized one custom computer board in order to:

- Analyze the information coming from flowmeter sensor.
- Program the microprocessor located on the board.
- Manage the energy supply for motor handling and provide proper alimentation to electronic components.

The PCB features are (see Attachment_03 and Attachment_04):

- An advanced Virtual RISC (AVR) **ATmega328** [14] microcontroller that supports 8-bit data processing good performance, low power consumption, real time counter having separate oscillator, 6 PWM pins, programmable Serial USART.

- The **ATmega16U2** [11] is a low-power CMOS 8-bit microcontroller based on the AVR enhanced RISC architecture. By executing powerful instructions in a single clock cycle, the ATmega16U2 achieves throughputs approaching 1 MIPS per MHz allowing the system designer to optimize power consumption versus processing speed.

- A **USB port** and an **external connector** are provided for powering the PCB. Through a scheme featuring a mosfet, the voltage supplied to the PCB is controlled by selecting either the voltage given by the USB port, or the voltage given by the external connector.

- A voltage regulator **NCP1117** which allows you to lower the voltage of 12V supplied as input to PCB to 5V.

- The **flowmeter FS1012**[17], mass flow sensor module measures the flow rate using the thermo-transfer (calorimetric) principle. The FS1012 is capable of measuring gas or liquid. It features a 6-pin for an analog output. The analogical output of this sensor is amplified by a differential amplifier TL071D [7] with a gain of 40 (see Attachment_05).

- **Passive piezoelectric buzzer** [12] which is in charge of sound feedback. It provides an audible alarm indicating the start and the end of dispensing. It features a 2-pin (GND and a digital pin with a resistance of 100 Ω).

- The **microswitch** [16] is a mechanical component for disabling and locking the motor when the moving platform returns the syringe to its starting position. It features a 2-pin (GND and a digital pin).

- For the human-machine interface (HMI), an **LCD display** [13] has been implemented. It is used to provide visual feedback regarding the volume delivered from the syringe. It features 4-pin (VIN, SDA, SCL, GND).

- A **4×4 keyboard** is a 16-key keyboard consisting of a combination of four rows and four columns. It gives the possibility to set the volume delivered. It features an 8-pin (digital pins) [5].

The LCD screen and keypad use I2C as communication protocol for data transfer with PCB

2.4.2 Computation of powers

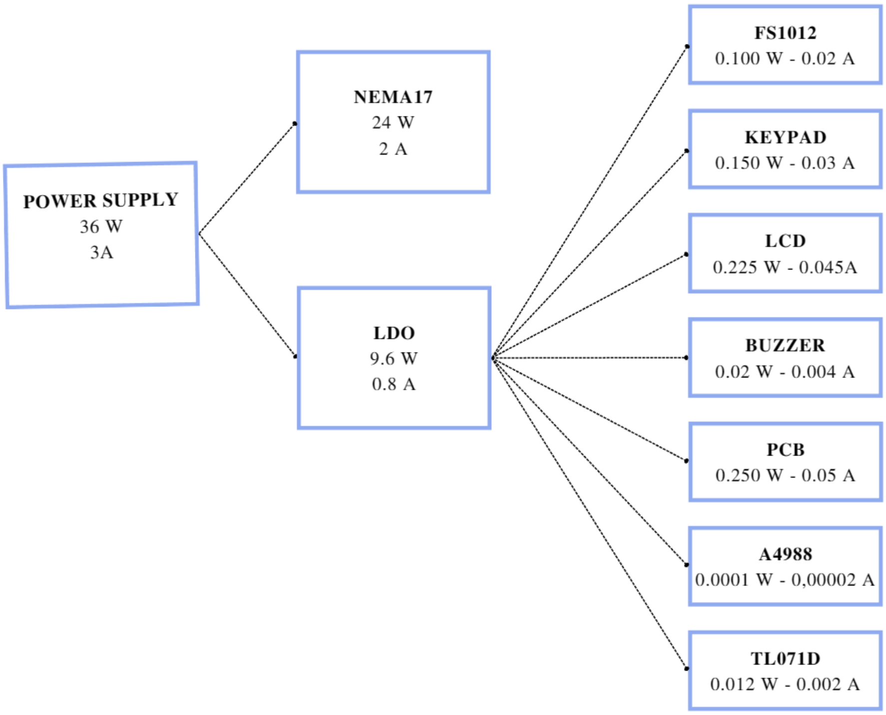

Figure 4: Power Supply Division

To select an appropriate alimentation for the device, we consider:

- The power absorbed by the motor **NEMA17** is 24 watts, considering a voltage of 12 V and a current of 2 A.

- The power absorbed by the Arduino Uno **voltage regulator** (**LDO**) [10] is equal to 9,6 W, considering a voltage of 12V and a current of 800 mA.

$$Power\ supply > P_{NEMA17} + P_{LDO} = 24\ W + 9.6\ W = 33.6\ W \tag{2.1}$$

The supply current and voltage of each active device were taken into account to verify that the LDO is able to supply the right power to all electronic components:

- The power absorbed by the **PCB** is 250 mW, considering a voltage of 5V and a current of 50 mA.

- The power absorbed by the **flowmeter FS1012** is 100 mW, considering a voltage of 5V and a current of 20 mA.

- The power absorbed by the **LCD** screen is 225 mW, considering a voltage of 5V and a current of 45 mA. 45 mA is the supply current for backlight considering a power supply of 5V.

- The power absorbed by the **buzzer** is 20 mW, considering a voltage of 5V and a current of 4 mA.

- The power absorbed by the **keypad** is 150 mW, considering a voltage of 5V and a current of 30 mA

- The power absorbed by the **motor driver A4988** is 0.1 mW, considering a voltage of 5V and a current of 20 μA. Its power is much lower the other sensors power, so it can be considered negligible.

- The **microswitch** is not included in the power calculation since this component does not dissipate energy, since its resistance is close to zero, thus negligible.

- The power absorbed by the amplifier TL071D is 12.5 mW, considering a voltage of 5V and a current of 2.5 mA. Its power is lower than the other sensors power, so it can be considered negligible.

The total current absorbed by all electric components is equal to:

$$I = I_{FS1012} + I_{PCB} + I_{LCD} + I_{BUZZER} + I_{KEYPAD} = 149\ mA \qquad (2.2)$$

It is verified that:

$$I < I_{LDO} \rightarrow 149\ mA < 800\ mA \qquad (2.3)$$

The total Current absorbed by the device is:

$$I_{TOT} = I_{NEMA17} + I_{FS1012} + I_{PCB} + I_{LCD} + I_{BUZZER} + I_{KEYPAD} = I_{NEMA17} + I = 2A + 149\ mA = 2.149\ A \sim 2.2\ A \qquad (2.4)$$

A voltage regulator that provides a voltage of 12 V and a current of 3 A [4] is required to power the system. The voltage chosen for the transformer comes from the maximum value with which we supply the device (which is the voltage supplied to the motor NEMA17 and the LDO).

In the event that the power supply provided by electricity fails, a battery with a nominal voltage 12V and with nominal capacity of 3.2Ah [18] can be provided.

The estimated battery life is the following:

$$BL = \frac{Battery\ capacity}{Total\ supply\ current} = \frac{3.2\ Ah}{2.2\ A} \sim 1.45h \tag{2.5}$$

2.5 Firmware

The code implemented to control the device (Attachment_06) is described by the block diagram in the following figure. It was written using Arduino language on an ATmega328P chip (which is the processor of Arduino Uno) which communicates with the A4988 Motor Driver to control the motor.

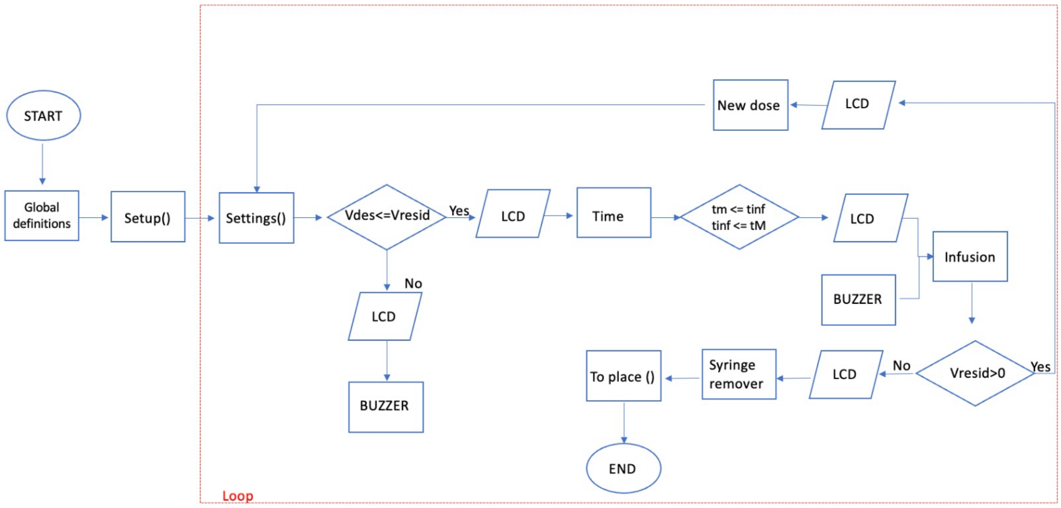

Figure 5: General Code Block Diagram

2.5.1 Global Definitions

The first block of the firmware description includes the libraries and declares the global variables and constants needed for the program's operations. The libraries used are:

- Wire.h: for I2C communication between ATmega328P and A4988
- LiquidCrystal_I2C.h: for I2C communication between ATmega328P and LCD and therefore for the operation of the display
- Keypad.h: it configures the pins to recognize the rows and columns of the pressed buttons
- Math.h: used to perform mathematical operations

2.5.2 Setup

In the *Setup()*, via *pinMode()*, pins referred to the motor (which are used in the change of its direction and for the generation of the PWM) and the pin of the buzzer (which is used to control its state – *HIGH/LOW*) are set as output. The buzzer is used as an alarm in different situations. Each specific sound is supported by visual feedback via LCD, which is also initialized in this part of the firmware (*lcd.init()*).

Instead, the microswitch is initialized as a pull-up input and, via *attachInterrupt()* function, the interrupt pin is defined to capture PWM's falling edge (it is used in the positioning part). Finally, the initial motor condition is specified: the engine starts off(*motorDisable()*).

2.5.3 Loop

The *settings()* function allows the healthcare provider to choose the drug dose to infuse and the desired infusing time. These commands are, initially, set through a keypad (*getKey()*) and, after an appropriate conversion (*atof()*), used as control parameters by the firmware.

An alarm tone and a message on the LCD will alert the user if the chosen drug dose exceeds syringe's available volume. Thus, the drug infusion can't start and a new volume has to be set.

Otherwise, if the drug dose to infuse is less than syringe's available volume, the infusion can start. Due to safety reasons, however, the drug is effectively dispensed by pressing a specific keypad button to confirm the operation.

2.5.4 Motor Control and Functions

The Nema17 motor is automatically controlled by FS1012-1001-LQ flow sensor's feedback by **v_fs** function. Once the operation is confirmed, the *infusion()* function allows the desired volume **v_des** to be infused.
Starting from desired volume v_des, via the expression (2.1), it's possible to evaluate the number of revolutions needed by the motor to deliver the desired volume.

$$numStepMotor = \frac{1000 * V_{des} * microstepping\_number}{\pi * \left(D/_2\right)^2 * screw\_feed} \qquad (2.6)$$

Knowing that, it's also possible to evaluate the time in which the PWM should remain high.

$$t = \frac{60 * 10^6}{speed * 200} * \frac{1}{2} \tag{2.7}$$

Until the required number of revolutions of the desired volume is reached, if the volume output from the sensor is less than the target volume the motor rotates, incrementing one step at a time (x++) and updating the data output from the sensor (v_fs) at each step.
Otherwise, if this condition (**V_fs < V_des**) is not verified, the motor stop (*motorDisable()*) is detected with visual and audible signals. These operations are performed within a *while* loop, ensuring the continuity of the process.
At the end of each infusion, the remaining dose **v_resid** is updated by the firmware and shown on the display. This process allows the healthcare provider:

- To set a new infusion volume by selecting '**D**' from the keypad;
- To stop the drug run by selecting '**C**' from the keypads. In this case, after a LCD's warning, the user must remove the syringe and the system automatically replace a new one via the *toPlace()* function. This procedure is also performed even if syringe's available is over.

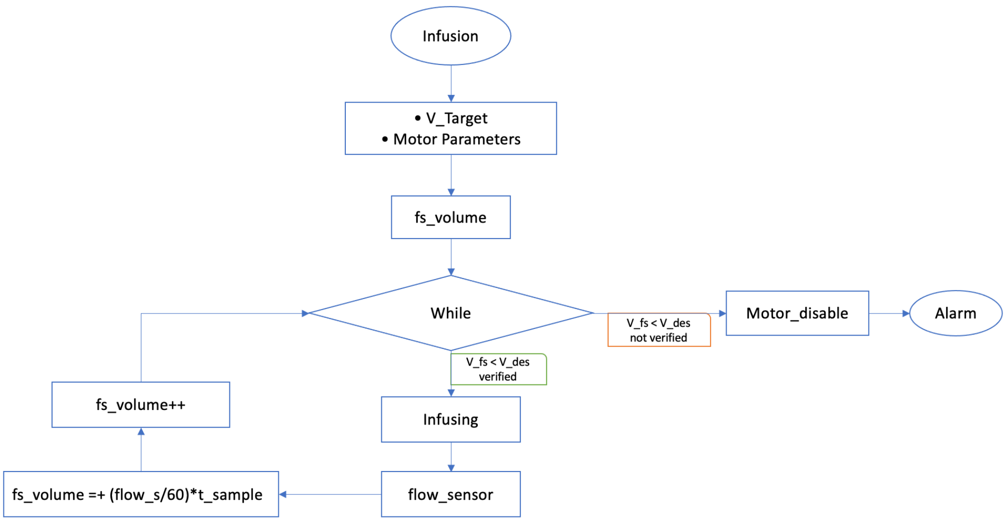

Figure 6: Motor Control Block Diagram

3. Cost Analysis

1. COMPONENT	COST [€]
NEMA17	15.84
USB Cable	2.99
Transformer	11.99
Microswitch	1.49
Buzzer	1.10
LCD	6.99
Keypad	3.79
Battery	18
Flowmeter	41.11
PCB	35
CAD Materials	357
Support	29.99
Recircolating x2	10
Steel support	4
TOTAL	539.29

Table I: Prices for Syringe Infusion Pump

Syringe price, tube price, and needle price, which are single-patient components, are not considered in this study.

4. Results

The proposed solution is an infusion pump, built following the guidelines of the ISO 11608-1 standard, taking products already on the market as a reference.
The overall dimensions are 308x173x190 mm.
The material chosen offers advantages in terms of stiffness and strength in addition to being economical and sterilizable.
These two features make the device lightweight, biodegradable, and easily transportable.
The main objective of the infusion pump is to deliver extremely fine amounts of volume, and this was possible using a flow sensor: thus, a motor control was implemented.
A flowmeter FS1012-1001-LQ was chosen for the following characteristics: response time 5ms, measurable flow range 0-0.5 SLPM, working frequency 200 Hz. The minimum detectable flow is 0.029 ml.
Since the application is of the slow-varying type, the working frequency required by the sensor must be greater than or equal to 2 Hz ($f_{sample} > 2f_{max}$), so the sensor chosen is optimal for our device.
To get visual and acoustic feedback were used: an LCD screen that shows all useful information about the dispensing status and quantities; a passive buzzer that emits alerts when there are problems and when dispensing starts (the two cases are differentiated by the sound emitted as required in the ISO).
A keypad for setting volumes and dispensing times and a microswitch used for syringe positioning for the preparation phase have also been implemented.
The liquid that this device can dispense will have the same rheological properties as water.
Therefore, the device thus produced meets the required specifications, allows different qualities of drug to be dispensed with high precision and could be used with different needles (Attachment_07).

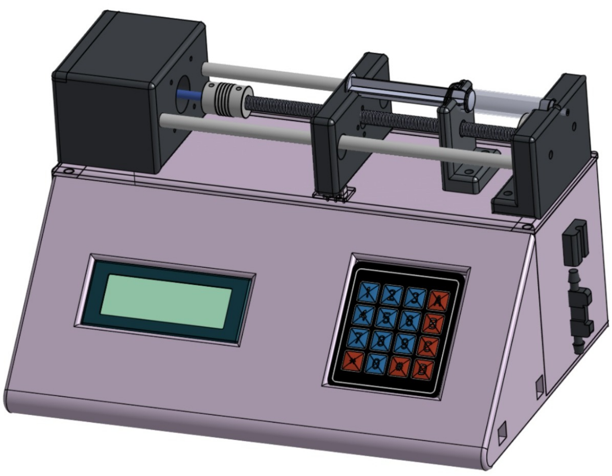

Figura 1: Final CAD

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Attachments

https://drive.google.com/drive/folders/1awqZA72FC8uWsam-Gl-ehFd0FOfLQZ12