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Prototype of an Insulin Dosing System

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**HOJA DE CALIFICACIÓN
DE TRABAJO DE FIN DE CARRERA**

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RESUMEN

La diabetes de tipo 1 es una enfermedad que requiere tratamientos invasivos que alteran el estilo de vida de los pacientes. Hoy en día las bombas de insulina son la mejor opción para hacer frente a esta enfermedad debido a su proximidad a la simulación de un páncreas real. Sin embargo, el coste de adquisición de este tratamiento y su mantenimiento requiere grandes sumas de dinero, por lo que su uso no es fácilmente accesible. El objetivo de este trabajo fue desarrollar un sistema de administración de insulina basado en un motor paso a paso lineal de bajo coste como unidad para la administración de insulina. Este sistema también contaba con una interfaz gráfica interfaz gráfica y un diseño mecánico basado en modelado 3D para de los componentes previstos. Además, este trabajo presenta una aplicación de la norma NEN-EN-IEC 60601-2-24 para caracterizar un dispositivo de infusión electro médica para la futura dispensación de insulina. La metodología de caracterización incluye el uso de una balanza con cuatro decimales de precisión para pesar cada gota que puede dispensarse desde el dispositivo. La caracterización permite dispensar el producto con precisión.

Palabras clave: Infusión de insulina, dispositivo electro médico de infusión, IEC 60601-2-24, modelado 3D.

ABSTRACT

Type 1 diabetes is a disease that requires invasive treatments that alter patients lifestyles. Nowadays insulin pumps are the best option to cope with this disease due to their proximity to the simulation of a real pancreas. However, the cost of acquiring this treatment and its maintenance requires large sums of money, so its use is not easily accessible. The objective of this work was to develop an insulin delivery system based on a low-cost linear stepper motor as an actuation unit for insulin delivery. This system also featured a graphical interface and a mechanical design based on 3D modeling for optimal matching of the intended components. Also, this paper presents an application of standard NEN-EN-IEC 60601-2-24 to characterize an electro-medical infusion device for future insulin dispensing. The characterization methodology includes the use of a scale with four decimals of precision to weight each drop that can be dispensed from the device. Accurate device characterization allows precise product dispensing.

Key words: Insulin infusion, infusion electro-medical device, IEC 60601-2-24, 3D modeling.

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I. Introduction

Diabetes is a major health problem that has reached alarming proportions. According to the International Diabetes Federation (IDF), in 2021, there were more than 500 million people living with diabetes worldwide [1]. Type 1 diabetes mellitus (T1D) is an autoimmune disease that results from the immunological destruction of insulin-producing β cells in the islets of the pancreas. The loss of these cells and the subsequent reduction of insulin causes a chronic rise in blood sugar levels, leading to serious complications [2]. For this reason, patients with T1D depend on exogenous insulin as treatment to control the disease. There are two principal treatments for this illness. The first is the multiple daily injections (MDI) and the second is the continuous subcutaneous insulin infusion (CSII) [3].

MDI is the insulin administration method mostly used for diabetes treatment, requiring at least three or more injections per day. To reduce complications and improve glycemic control, CSII has been used in recent years, as a popular option for diabetes management [4]. In 2020, COVID-19 lockdown made a radical change in the lifestyle of patients with T1D, especially in the glycemic control. CSII therapy showed an improved method in order to get lower mean glucose levels than MDI therapy under the lockdown period [5]. Thus, the performance of CSII control process seems to be the best platform to maintain an efficient control of the disease, even in adverse conditions.

The insulin pump, a CSII control process, is the object of this study. This pump is a compact and portable electronic device that must be permanently attached to the body in order to deliver required amounts of insulin through a catheter placed under the skin, usually in the abdomen. Insulin pump therapy is highly recommended, but the outrageous price prevents patients from using it. An insulin pump cost about $20 000 and a replacement insulin cartridge cost about $300 per month [6]. The insulin pump operation is based in bolus and basal dosing, in which an amount of insulin is injected through the pump system. Basal is a small dose of insulin injected at regular intervals. And bolus is a high dose of insulin injected before a meal to avoid a sudden rise in blood glucose [7].

Therefore, this work aims to develop an insulin delivery system based on a low-cost linear stepper motor as the actuation unit for insulin supplies. The design of this system has two main parts. First, it is related to all the mechanic structure of insulin pump. This part uses 3D printing to develop the shell of the device. The second part involves the development of software controllers as well as the graphical interface between the user and the insulin pump. Each patient has a different amount of insulin to be supplied, so that through a touch screen, the user is able to enter the necessary insulin configuration for the treatment prescribed by his doctor.

This paper is organized in the following manner: section II presents a description of the system, including the bolus and basal dosing, volumes to be dosed, control signals, linear stepper motor, micro-controller, user interface and 3D printing. In section III, the results of insulin dosing are described. The overall findings are presented in the conclusions section.

II. METHODOLOGY

In this section, the insulin delivery system is explained as well as each part of the electronic design which includes the interface between the user and the insulin pump and its dosage forms.

A. Bolus and basal dosing

Basal-bolus insulin dosing (BBD) is proposed as a medical treatment which objective is that the patient achieves a normoglycemic level in his daily life through exogenous insulin infusion. BBD can be defined as the physiological replacement of basal and bolus insulin to achieve near-normal blood glucose levels without hypoglycemia and hyperglycemia scenarios which represents an improvement of the quality of life of the patients [8]. For this reason, it is important the design and the development of an insulin pump that can provide basal-bolus insulin dosing.

Basal insulin delivery is designed to optimize glucose concentrations between meals and overnight, while bolus insulin delivery counteracts postprandial hyperglycemia. Basal infusion rates are programmed with time-varying profiles over a 24-hour period to account for circadian variations in patient insulin sensitivity and activity. The bolus insulin infusion can also be delivered via different profiles (Standard, Extended/Square Wave, Combination/Dual Wave) to cope with different meal compositions or other circumstances such as stress and/or exercise [9].

In this article, we focused on creating a simple dosing mode. In other words, provide the basal and bolus programs so that the patient/user must know in advance which units of insulin are to be administered. As we have explained, the basal program works all the time, and the bolus program has a limited duration of two and three hours for this project. Thus, the basal and bolus programs are the goal to be achieved where the patient/user could manage their insulin dosages according to a general basal program and a limited duration bolus program [10].

B. Volumes to be dosed

The maximum and minimum volume to be dosed was calculated using the insulin-containing elements and the minimum and maximum step size of the actuator. These containers are called insulin reservoirs, and for this project we used the MiniMed™ Silhouette™ from Medtronic items, namely the 3.00 ml reservoir and its catheter [11].

The step size of the actuator results from the step mode used. In this case, our actuator works in 1/16 Step Mode, where its minimum step size is 0.000625[mm] and its maximum is 15[mm] [12]. The volumes were calculated according on the size of the selected elements.

1) $Vol_{min} = 0.09621\ [uL]$

2) $Vol_{max} = 2.30910[mL]$

In one hand, the minimum volume to be dosed is showed in the equation 1 and its units are microliters. This factor proves that our dosing system can deliver very small amounts of insulin. On the other hand, the maximum volume to be dosed is appreciated in the equation 2, this value gives us an idea of how much insulin our system can deliver, so the chosen size of the reservoir does not pose a problem for the storage of insulin.

C. Dosing design

The system is designed to work with two models. The first is the basal dose (BAD) and the second is the bolus dose (BOD). Both programs use the same configuration, their difference lies in the dosing time. So, calculation of volumes to be dosed give us an important equality, which is showed in the next equation.

3) $0.09621[uL] = 0.000625[mm]$

The equation 3 indicates the distance that the stroke of the motor must travel in order to supply the required volume. Now, we need the conversion factor between distance in [mm] and distance in [steps], speed in [mm/s] and speed in [steps/s], and insulin units in [units] and insulin units in [uL], which are showed in the next equations.

4) $15[\mathrm{mm}] = 24000[\mathrm{steps}]$

$$5)\ \ 1[\mathrm{mm/s}] = 1600[\mathrm{steps/s}]$$

$$6)\ \ 1[\mathrm{unit}] = 10[\mathrm{uL}]$$

All the equations presented in this section were used to determine the parameters needed for our dosing system in order to deliver the required insulin. The following subsection provides a detailed explanation of the parameters used in the dosing system depending on the selected actuator and controller.

D. System design

As is presented in Fig. 1, the system consists of many components: (i) the actuator of Actuonix, which is managed by (ii) Tic T825 Controller, (iii) an ESP 32S as micro-controller in charge of collecting, processing and communicating data, (iv) a graphical interface, (v) battery module and two conditioning circuits to provide the required power for the elements selected.

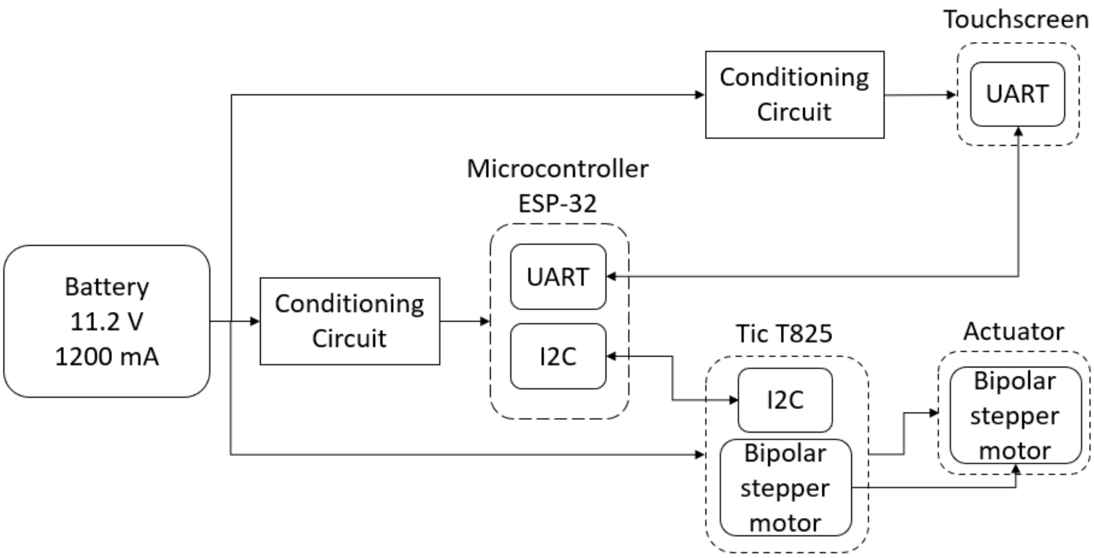

Fig. 1: System description diagram.

i. *Actuator*: The actuator used in this prototype is the S20- 15-38-B of Actuonix Motion Devices. This stepper motor was chosen by its step size of 0.01[mm], input voltage of $0 - 4.2$[V DC], and max current of 0.60[A]. The actuator is designed to push or pull a load axially along its full stroke length. The movement speed is determined by the step frequency and the maximum force by the applied current. If power is removed, the actuator will hold its position unless the applied load exceeds the back drive force. This stepper linear actuator is a superior alternative for designing many push/pull mechanisms in robotics, optics, diagnostic equipment, and industrial automation [13].

ii. *Tic T825*: This controller was selected for its size, 1.05 inches wide by 1.5 inches long, and the variety of interfaces it supports, such as USB for connecting directly to a computer, TTL and I²C serial for use with a microcontroller for manage our actuator. The Tic T825 is based on the DRV8825 IC from Texas Instruments. This driver IC supports microstepping up to 32 microsteps per full step and has three configurable decay modes. The Tic T825 can operate from 8.5[V] to 45[V] and has reverse polarity protection up to 40[V], a factor to consider because the other elements operate at different powers. It can deliver up to approximately 1.5[A] per phase without a heat sink or forced airflow. Additionally, this controller is suggested by the actuator manufacturer as it supports six control interfaces and can be easily customized to find the best configuration for each application [14].

iii. *ESP32S*: Its dimensions are 2.14 x 1.10 inches and are well adapted to the development of this prototype which requires small components. The presence of two serial and two I²C ports ensures connectivity between this on-board module and the rest of our components such as the touch module and the Tic T825 controller. In addition, power is supplied via 3.3V pin and this 3.3V pin supplies the regulated 3.3V directly to the board which fits our necessary power supply [15].

iv. *Graphical Interface*: This method was designed to activate the dosing systems as well as their cancellation, pause and restart. In addition, the user can enter and configure the insulin units to be dispensed. This is done through the Nextion 2.4” touchscreen which is a resistive touchscreen that connects to our microcontroller through its UART interface, and its operating voltage is 5V. The development of this interaction is shown in the Fig. 2, which shows the main options of the system created to have a friendly communication between device and user.

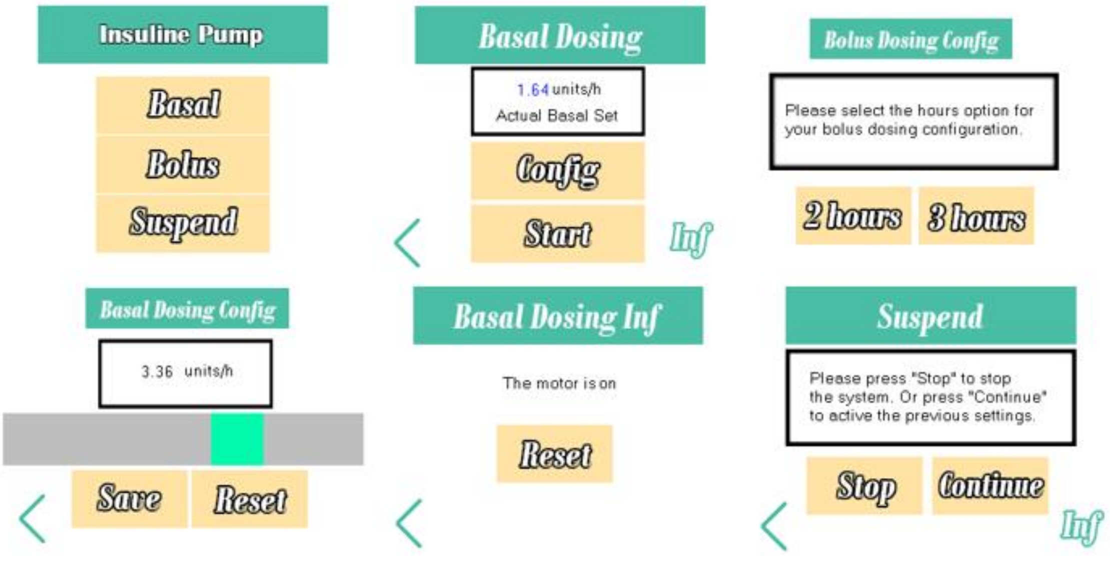

Fig. 2: Graphical interface menus.

v. *Power supply and conditioning circuits*: A lithium polymer (LiPo) battery supplies power to the system. The selected model has three cells and a capacity of 1200 mAh, which gives 11.1 V. In order to provide the required power for the elements selected such as the ESP32S with 3.3V and the touchscreen with 5V, two step-down voltage converter MP2307 was selected. It has a conduction capacity of 3 A. So, the battery module is used to energize the conditioning circuits, EPS32S microcontroller, and the Tic T825 which directly powers our stepper motor.

E. Insulin pump case 3D printing

This part consists of the construction of the insulin pump case. The main objective was to simulate a case like those existing in the market, that is to say, to have a case where its dimensions in centimeters are similar to 10.2 length x 5.8 width x 2.8 depth. According to the elements used for the design of the dosing system, the case had a dimension in centimeters of 14 length x 8 width x 3.5 depth. Finally, four compartments were modeled to locate the required elements, which consisted of three phases: base, top and securing.

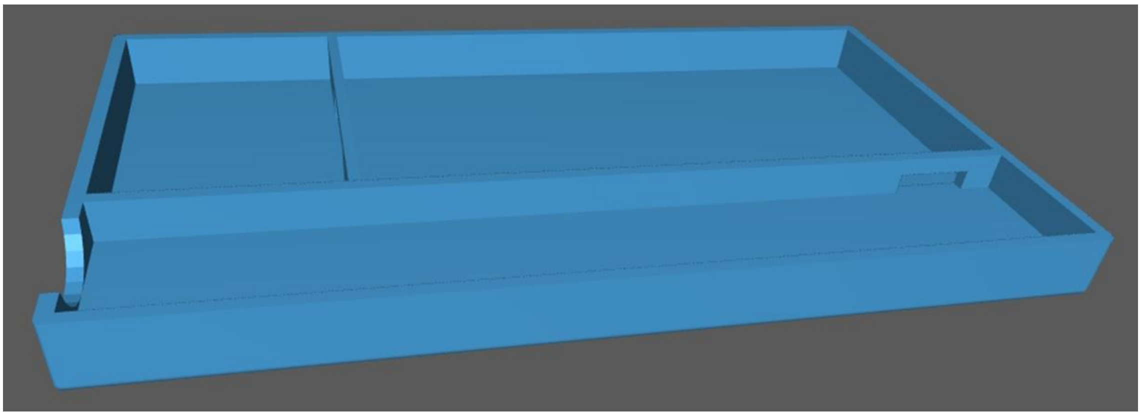

Fig. 3: Case bottom.

As is presented in Fig. 3, the first phase consisted in sectioning the ideal location of each element where the necessary coupling for the mechanical system is highlighted, since the model had to ensure the immobility of the actuator and the reservoir. Therefore, the compartments were custom designed to fit exactly where they were required. In addition, an extra support was added to fix the actuator, so the planned system was not sufficient.

The system was improved during the securing phase by zip ties because the reservoir must be changed repeatedly unlike the actuator which should not interact directly with user. This solution proposes to build a base to secure the actuator where the holes present will allow the correct operation of the zip ties. This secures the important part of our dosing system since an abrupt displacement of the actuator or reservoir would cause significant changes in the dosing parameters. Thus, it is expected to obtain the estimated results since the design depends on these elements not moving.

Finally, the other elements were placed as follows. According to Fig. 3, the reservoir and batteries are placed on the left side due to the temporary replacement of these elements, so their upper part of the case will be movable. The actuator and the rest of the elements such as the microcontroller, the driver and the conditioning circuits were placed on the right side. This was done to make the interaction with the user less accessible and to keep the upper part of the case fixed, since the display would be placed on top of it.

F. Characterization and calibration of the actuator

This section presents an application of standard NEN-ENIEC 60601-2-24 to characterize an electro-medical infusion device for future insulin dispensing. The characterization methodology includes the use of a scale with four decimals of precision to weight each drop that can be dispensed from the device. This methodology was used in a previous work and is presented in [16], and this one used the design used in this study, so it is a continuous work that guarantees the best performance of the prototype to be developed.

III. EXPERIMENTATION AND RESULTS

This section reports the experimentation and results of the process developing system. The actuator used in this work has a full step size of 0.01mm. Using the driver, it is possible to select different step modes. The selected mode is 1/16 of a step, which is equivalent to 0.000625mm of displacement and a speed of 2 steps/s. The theoretical operation of the actuator under these conditions is shown in Fig. 4. In this way, it is expected that the results produced by the prototype will resemble the data shown in the figure below.

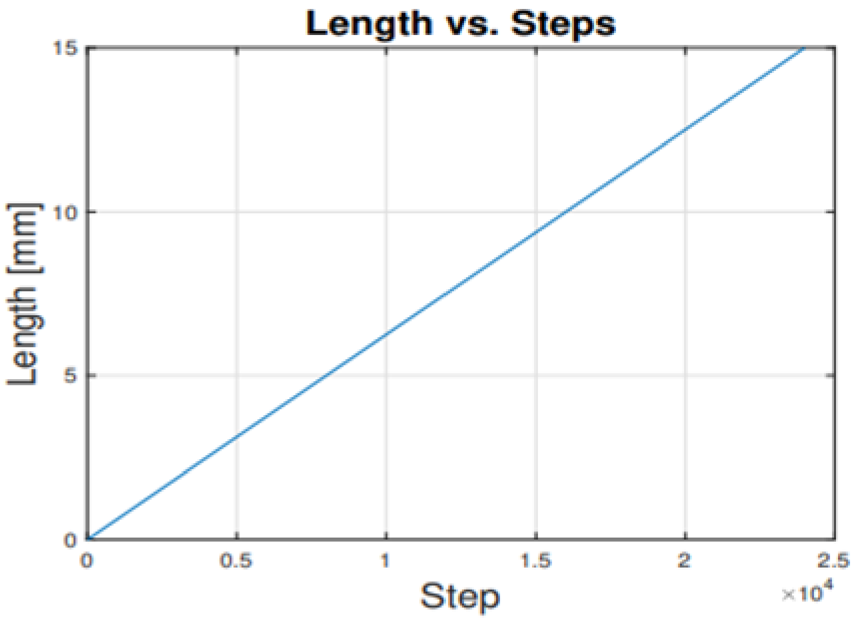

Fig. 4: Actuator stem length vs. motor step.

The experimentation consisted of collecting the data of the 10 proposed process cycles, data is processed in order to calculate the variance and deviation. The experimental setup is shown in Fig 5. As can be seen in Fig. 6, measurements exhibit the same behavior as compared with the theoretical curve. The variance is 0.1153 g which represents 1.64 drops and the deviation is 0.3396 compared with theoretical model.

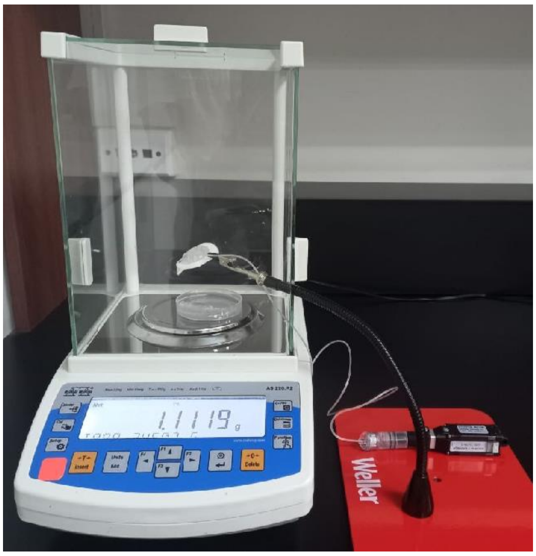

Fig. 5: Set up.

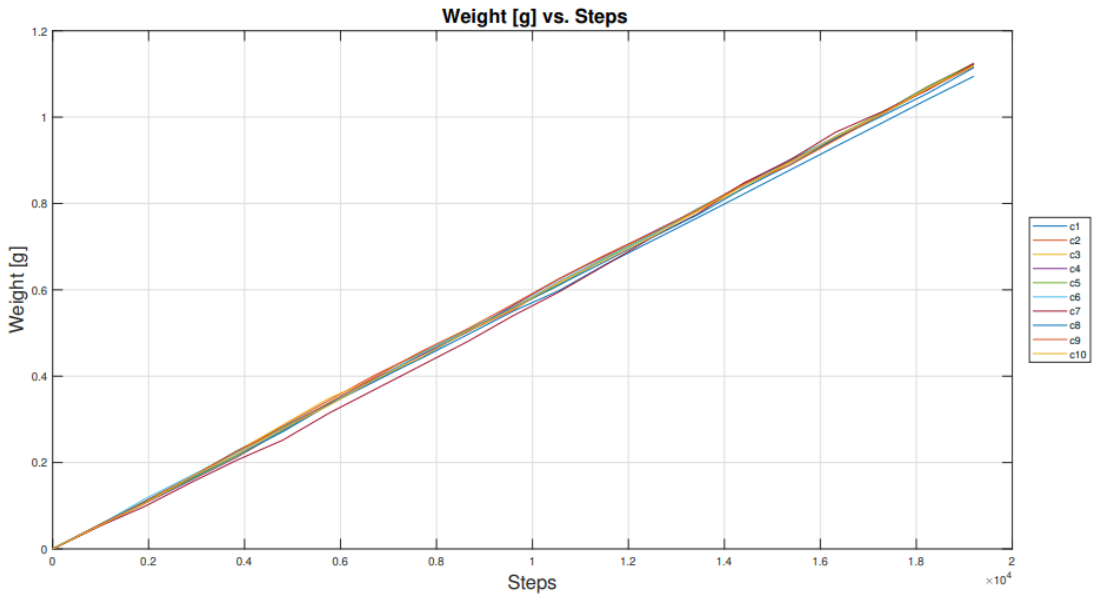

Fig. 6: Ten samples curves.

The average behavior of the dosing system is depicted in Fig. 7.a, and Fig. 7.b shows the behavior of the average of the last measurements. These results exhibit a difference equivalent to 0.005 g with an error of 0.4451% or 0.7142 drops.

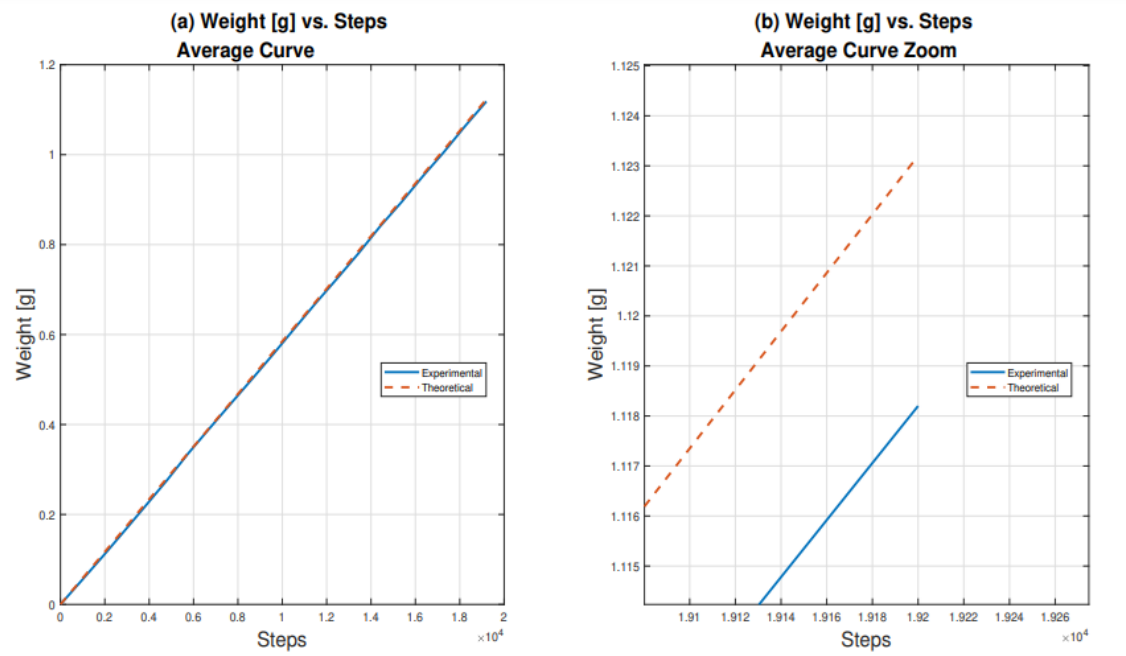

Fig. 7: Average curves.

IV. CONCLUSIONS

The design and implementation of a low-cost based insulin delivery system was presented. A linear stepper motor was selected as the actuation unit for insulin deliveries because it has a full step size of 0.01 mm, and its controller helps achieve a step of 0.000625 mm with a speed of 2 steps/s. In addition, the 3D modeling makes the developed prototype can be equipped in a portable way as its electronic connections allow a day-to-day interaction between the user and the device.

Initial results indicate that the mechanical design allows for proper operation of the elaborated dosing device. However, the design developed for easy replacement of the reservoir should be improved since its essence is rudimentary. The graphic configuration of the display is extremely basic, which means that the power consumption is not significant, so this first design meets the minimum requirements. A power saving system must be added to this, which can be applied directly to the display since it does not have a sleep mode protocol.

Also, the present study was designed to characterize an electromedical infusion device based on the standard NEN-ENIEC60601-2-24. After experimentation, the results obtained indicate that the system has a linear behavior and presents a similarity of 99.5524% compared with theoretical model. It is important to highlight that this result is thanks to the fact that the operation of the actuator is based on steps.

Analyzing the system after the 10 tests performed, it can be seen that the system has a tendency to accumulate error as is shown in Fig. 7.b; however, after analyzing the variance and deviation, the systems work well. As a general conclusion, the device developed was satisfactorily characterized and showed promising results.

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