HardwareX 12 (2022) e00375

Contents lists available at ScienceDirect

HardwareX

journal homepage: www.elsevier.com/locate/ohx

Design of an open source ultra low cost insulin pump

Matthew Payne *, Francis Pooke, Harrison Fulton, Hamish Shaw, Tom Coulson, Dr Jennifer Knopp, Lui Holder-Pearson, Jake Campbell, J. Geoffrey Chase

Department of Mechanical Engineering, University of Canterbury, Christchurch, New Zealand

ARTICLE INFO

Article history:

Keywords:
insulin pump
Bioengineering
Open source
Medical device
Electrical engineering
Mechanical engineering
Low-cost

ABSTRACT

In this report we present a design for an open source low cost insulin pump. The pump has been designed to provide an alternative to commercially available pumps costing upwards of US$6500, making them inaccessible to many. The hardware described in this article can be produced for a materials cost of US$89.85. Compared to other devices on the market, the design presented has the obvious advantage of being low cost, but is also highly customisable as it is run using open source software. The device is housed in a case of size 85 mm x 55 mm x 25 mm making it small enough to fit in a pocket, and equivalent to other devices on the market. The device is designed to work with insulin cartridges currently available on the market. Power is provided through the use of AAA batteries, and the pump is able to be recharged through a USB mini port. The accuracy of the pump has been tested and compared to data obtained from an in-warranty commercial insulin pump model using an identical testing methodology, with the ultra-low-cost pump performing similarly to the commercial model. The system can be readily extended to be controlled from external bluetooth or wired mobile devices using their built in security, offloading computation from the device and onto a phone.

Specifications table:

Hardware name	Ultra low-cost insulin pump
Subject area	• Biomedical Engineering • Electrical Engineering • Mechanical Engineering • Open Source Alternative to Existing Product
Hardware type	• Low Cost Medical Device for Controlled Insulin Delivery
Open source license	Creative Commons - Attribution 4.0 International - CC BY 4.0
Cost of hardware	US$89.85
Source file repository	https://data.mendeley.com/datasets/xb4tykn5gd/1 https://github.com/UCBioengineering/open_source_insulin_pump

* Corresponding author.
E-mail address: matt.payne@pg.canterbury.ac.nz (M. Payne).

https://doi.org/10.1016/j.ohx.2022.e00375
2468-0672/

Nomenclature

Abbreviation

Abbreviation	**Definition**
ADC	Analog to Digital Converter
CGM	Continuous Glucose Monitoring
FDA	Food and Drug Administration
GPIO	General Purpose Input Output
GST	Goods and Services Tax
IC	Integrated Circuit
IDE	Integrated Development Environment
JTAG	Joint Test Action Group
LED	Light Emitting Diode
MCU	Micro-Controller Unit
Ni-CD	Nickel Cadmium
Ni-MH	Nickel Metal-Hydride
NZ	New Zealand
PCB	Printed Circuit Board
RTC	Real-Time-Clock
SPI	Serial Peripheral Interface
SPR	Steps Per Revolution
SWD	Single Wire Debug

1. Hardware in context

Diabetes is a condition currently affecting 463 million people worldwide, and predicted to rise to 700 million by 2045 [1]. Diabetes is split into two groups, Type 1 and Type 2. Type 1 diabetes is characterised by the body's inability to produce insulin and comprise 5% to 10% of the total. Type 2 diabetes is characterised by the patient's body either not producing enough insulin and the patient's cells becoming resistant to insulin [2]. Type 1 diabetes requires exogenous insulin to be administered to control blood glucose levels. While Type 2 diabetes can initially be controlled by diet and exercise, increasing numbers are progressing to needing partial or full exogenous insulin support, rising from 7% to 15% of those affected by 2030 [3].

In particular, in some countries 50% to 75% of those with Type 2 diabetes use at least basal background insulin. [4,5]. There is thus rapid growth in insulin demand and use, with shortages forecast [3]. Even though insulin can be injected, there will be an increasing need for insulin pumps, the gold standard for out-patient insulin delivery and control.

The best and most convenient way to deliver insulin is using a wearable insulin pump. Insulin pumps release small doses of insulin to keep blood glucose levels steady throughout the day thus reducing complications and cost while increasing quality of life. The better glycemic control associated with insulin pumps reduces the chance of becoming hypoglycaemic (blood glucose becoming too low) or suffering keto-acidosis (caused by blood glucose becoming too high) [6].

Although insulin pumps offer the best control, their high cost makes them unaffordable to many. In the US the cost of an insulin pump is around US$6500 and the pump has a life expectancy of only 3–4 years. In addition, the annual cost of consumables is between US$2000 and US$3000 [7]. In addition, in the USA, access to pumps can be limited by cost and insurance coverage [8].

Even in countries such as New Zealand (NZ), which has a government subsidised health system, insulin pump users may need to fund their own pumps and consumables. PHARMAC (the organization responsible for deciding which treatments will be publicly funded in NZ) currently funds a limited number of pumps per year, and users must meet strict criteria to qualify. This outcome is a function of budget limitations leading to care rationing. Furthermore, access to insulin pump funding can also be removed should glycaemic control deteriorate from the criteria required for pump access [9]. If a pump is not publicly funded users are required to pay up to US$6000 for the insulin pump itself along with US$900/year for consumables [10,11]. Currently When compared to the NZ median household income of US$52000 this cost represents too high a cost for many families, and people must make a choice as to if they can afford a better quality of care for their diabetes.

There is thus a need for a very low cost alternative, to increase equity of access to these devices. These issues are equally well demonstrated in initiatives like OpenAPS, an open artificial pancreas solution [12]. Similar issues of economic inability to obtain access to gold standard devices and care persist, where this pump starts towards meeting those needs. Regarding the use and cost of insulin pumps one could note: *"Insulin infusion pumps are probably the most marginal, but also the most effective and the most expensive routine method of insulin therapy*" [13].

In addition, the high cost of pumps limits their economic utility for moderately controlled patients. This loss of economic efficacy essentially vanishes if pumps are halved in cost [14]. Whilst it can be difficult to estimate a retail price including full scale manufacturing and development costs for a new product, this value is often approximated at 3-5x the BOM cost (resulting in a potential retail price of US$269.55 - US$449.25 for this device). Therefore, the pump design presented offers potential reductions in cost between 14-25x, increasing economic efficiency as well as increasing the quality and equity of access to care. There is thus a growing need for much lower cost insulin pumps offering similar utility as current products.

2. Hardware description

A MCU (Micro-Controller Unit) controlled portable insulin pump has been designed and successfully tested to accurately deliver insulin automatically. The insulin pump is designed to be easily produced using simple equipment and can be built from commonly available low cost components. A system diagram is given in Fig. 1. Users can control the quantity and frequency of insulin delivery. The device is battery powered, and so is portable.

2.1. Motor

Insulin is required to be delivered in very small quantities. A single unit of U100 insulin is 0.01 ml, and a typical pump user may administer 100 units throughout a day (1 ml). A motor with a high resolution was chosen to allow these very small amounts of insulin to be delivered with accuracy. The motor chosen was a 20:1 stepper motor sourced from China (GA12BY15-M455 DC 5 V, Convienience Machines, Shenzhen, China). The motor can be supplied with a 50:1, 100:1 or 298:1 gearbox already attached giving output resolutions between 1000 and 5960 Steps Per Revolution (SPR).

The motor is required to be resilient enough to continue to function for multiple years, while maintaining accuracy, to match the performance of currently available pumps. Motors were tested for accuracy, and stress tested for the equivalent of up to 800 days of usage. Following stress testing, the motors were retested for accuracy. The second accuracy tests were to confirm extensive usage did not significantly affect motor accuracy.

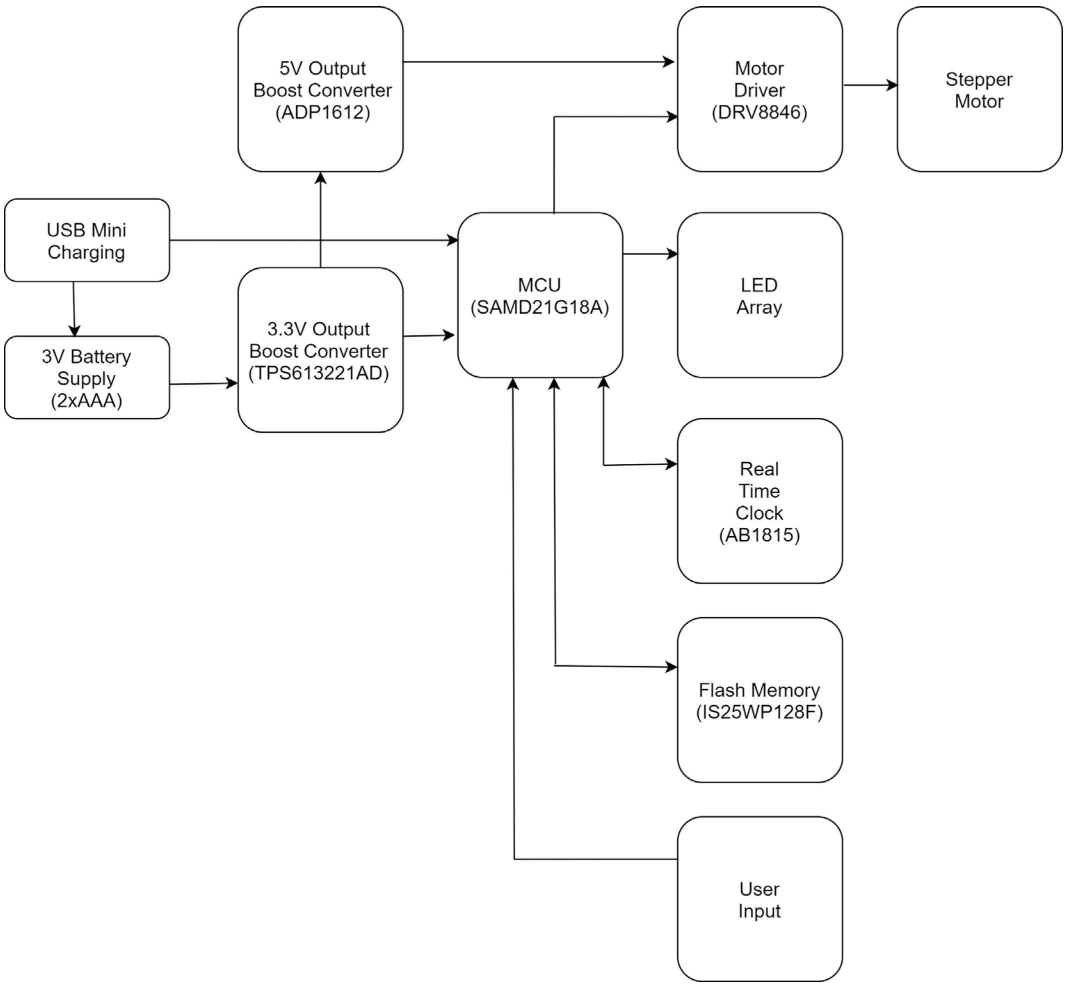


Fig. 1. High level system diagram for insulin pump hardware.

2.2. Integrated Circuits

MCU [15] An ATSAMD21G18A MCU was chosen for the device due to its multiple Serial Peripheral Interface (SPI) bus connections, Analog–Digital Conversion (ADC) hardware, 38 General Purpose Input–Output (GPIO pins), and on-board Flash memory.

Flash Memory [16] A 128 MB flash memory is included in the design to record data whenever insulin is delivered. The memory is sufficient to record one year of insulin deliveries (date, time and quantity).

Real Time Clock [17] The Real Time Clock (RTC) is used to maintain the correct time, as the MCU is set to sleep mode after administering insulin to save energy. The clock is powered by a 70 mF capacitor so can maintain time for short periods between battery changes. The clock has an inbuilt alarm tied to the reset of the MCU, so when a user defined time is reached the MCU is reset, and the insulin delivery process begins.

LED Array The Light Emitting Diode (LED) array provides a low energy solution to give the user feedback regarding the delivery rates currently programmed into the device.

Motor Driver [18] The motor driver controls the stepper motor direction, and activation of the two phases of the stepper motor. Control signals are sent from the MCU.

User Input User input is provided from three buttons. The buttons are tied to external interrupts on the MCU and so are able to wake the device at anytime, to respond to user requirements. The foundation design presented is able to be extended to external control via wired or blue-tooth connectivity to a range of mobile and personal computing devices which contain built in communications and security protocols. Breakout pins and a second SPI bus has been left for this purpose. Alternative uses for the device include:

- Exact measurement of liquid substances. For example, determining the quantity of one substance added to another during a titration.
- Programmable automated delivery of liquid substances or medicine. For example, delivery of drugs to patients where oral administration is non-viable.

3. Design files

Design files for both hardware and software are provided in Table 1. Software has been made available at *github.com/UCBioengineering* in the *open_source_insulin_pump* repository, while software and hardware files are available from *https://data.mendeley.com/datasets/xb4tykn5gd/1*.

4. Bill of materials

A full bill of materials can be found at *https://data.mendeley.com/datasets/xb4tykn5gd/1*. The total cost provided is inclusive of NZ GST of 15%, and prices were converted at an exchange rate of NZ$1 = US$0.71. All costs given in this document are correct as of March 23rd 2021 for the New Zealand region. Cost of 3D printing has been estimated based on the current price of printer filament and was performed using a US$349 3D printer (*PRUSA MINI, Czechoslovakia*). Printed Circuit Boards (PCB) were ordered in batches of 10 and the average price for a single PCB unit is given in the table. Designators are referenced to the *Altium* schematic available at *https://data.mendeley.com/datasets/xb4tykn5gd/1*. The total cost for the bill of materials is US $89.85.

5. Build instructions

There are three stages required to complete the build of the device. The first stage requires the PCB to be assembled. The PCB uses only SMT (Surface Mount Technology) components so requires the use of a pick and place machine for assembly.

Table 1
Location of design files for hardware and software documentation in project.

Filename	Software	Open Source License	Web-link
Battery and Charge Management 2.0.SchDoc	Altium	CC-BY-4.0	https://data.mendeley.com/datasets/xb4tykn5gd/1
Eink.SchDoc	Altium	CC-BY-4.0	https://data.mendeley.com/datasets/xb4tykn5gd/1
Flash Memory.SchDoc	Altium	CC-BY-4.0	https://data.mendeley.com/datasets/xb4tykn5gd/1
MCU.SchDoc	Altium	CC-BY-4.0	https://data.mendeley.com/datasets/xb4tykn5gd/1
Motor Driver.SchDoc	Altium	CC-BY-4.0	https://data.mendeley.com/datasets/xb4tykn5gd/1
Peripherals.SchDoc	Altium	CC-BY-4.0	https://data.mendeley.com/datasets/xb4tykn5gd/1
RTC.SchDoc	Altium	CC-BY-4.0	https://data.mendeley.com/datasets/xb4tykn5gd/1
PCB Layer Files	Altium	CC-BY-4.0	https://data.mendeley.com/datasets/xb4tykn5gd/1
CAM Files	Altium	CC-BY-4.0	https://data.mendeley.com/datasets/xb4tykn5gd/1
PCB Layout Files	Altium	CC-BY-4.0	https://data.mendeley.com/datasets/xb4tykn5gd/1
Software	Microchip	CC-BY-4.0	https://data.mendeley.com/datasets/xb4tykn5gd/1

The second stage requires loading the code onto the MCU. A ten pin header is provided for connection to a debugger/programmer for this purpose. The software has been written in *Atmel Studio*, a free embedded C Integrated Development Environment (IDE). An *Atmel ICE* debugger/programmer is recommended for ease of use, but any compatible programmer/debugger can upload code to the device. The final stage is to 3D print the case for the device, and connect external components to the board.

5.1. PCB Build and Component Choice

The PCB assembly requires components to be placed on both sides of the board. It is recommended to place the components on the back of the PCB first as most of the parts are small passive components. These small components are unlikely to fall off when the board is turned upside down and reheated to set the topside components thus it is recommended to complete the back of the board first. The ferrite bead, inductors and larger decoupling capacitors should not be placed on the back initially, due to their large size meaning they are likely fall off when the board is reheated.

When assembling the top side of the PCB, care should be taken when placing diodes and bulk decoupling capacitors to ensure correct polarity. All integrated circuits have some form of marker on the chip to denote pin one, which should be lined up with the marking on the PCB to ensure correct orientation.

Motor and LED connections are soldered directly to the board. Motor wires should be connected left to right in the order green, yellow, red, black, when viewing at the board from the top. If required, the 5 mm LEDs should be connected as shown in Fig. 2.

Once both sides of the PCB have been completed all through hole connections should be added. The larger inductors and capacitors which were not able to be placed previously should now be hand soldered to the PCB. There is an option to add header pins to the board. However, it is recommended to solder wires directly, so the board fits more snugly in the case. The only exception to this choice is a ten pin header required for programming, which should be added.

5.2. Board Programming

The board can be programmed with any debugger/profiler device. However, for ease of use, an Atmel Ice is recommended. Connect the octopus cable to the 10 pin header[1] per page 22 in the Atmel Ice datasheet [19].

Atmel provide all the firmware files required for programming the board from their website, *Atmel Start*. Provided in the Git repository is a file named *InsulinPump.atstart*. Navigate to the web page *https://start.atmel.com/*, and click on *Load project from file*, located at the bottom left of the page. The file contains all pin connection data for the MCU, and allows Atmel Start to generate firmware files for all required peripherals. Once the project is loaded click *Export Project* at the top of the screen and choose support for Atmel Studio and Microchip Studio. Double click on the downloaded file to open it in Microchip Studio. The *.h* amd *.c* code files from Mendeley Data should be included in the folder created by Microchip Studio, which has the name that was given to the project when the software was first opened. (The correct folder will already contain files with the names *atmel_start*, *driver_init* and *main.c*). When done correctly added files will be viewable in the solution explorer on the right hand side of Microchip Studio. To program the board, the code should be built using the "hammer" icon and can then be loaded to the device using the green "play" icon.

Care must be taken when uploading code multiple times to the device, as the Atmel Ice rewrites all flash memory pages of the MCU when uploading code. Therefore, retrieving data values from the non volatile memory can result in unexpected behaviour. The best option when reloading code to the MCU is to connect the positive side of the 70mF capacitor (C26) to ground to discharge it. C26 acts as a temporary power supply to the RTC when batteries are disconnected, and discharging the capacitor cuts power to the device resulting in all internal data being reset. The MCU checks a general purpose register in the clock to determine if the device has been power cycled so draining the capacitor as stated will result in predictable performance when reloading code.

5.3. Mechanical Assembly

5.3.1. Plunger Sub-assembly

Fig. 3 shows how the motor and plunger should be assembled before use. A square M4 nut should be inserted in the slot in the plunger, and in the centre and ends of the plunger. Once the square M4 nuts are in place, the threaded shaft of the plunger can be screwed through both nuts, allowing the plunger to travel along the motor shaft as it turns. A small amount of lubricant can be placed on the shaft to allow smoother travel. The plunger should be wound back to the motor to allow the parts to slot into the case, as detailed in Section 5.3.2.

5.3.2. Pump assembly

Fig. 4 shows the steps to assemble the device. Bracketed numbers throughout this paragraph refer to the numbered steps in Fig. 4. The plunger and motor sub assembly (1) should be inserted into the channel (2) in the case, ensuring the 'wings' fit

[1] Note, the board is designed to be programmed through the JTAG SWD interface only, thus only five of the 10 pins are used

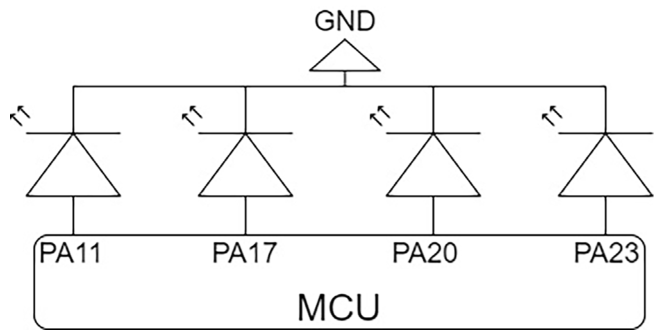


Fig. 2. Wiring diagram for LED array.

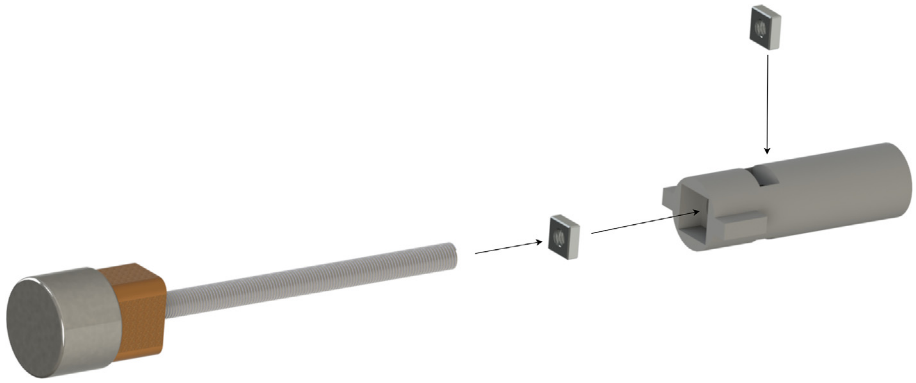


Fig. 3. Build instructions for Plunger Sub-assembly.

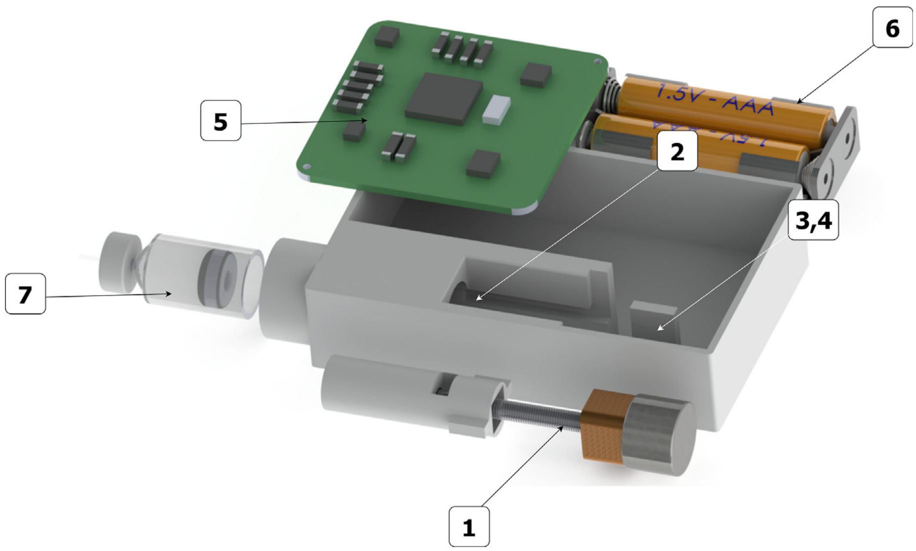
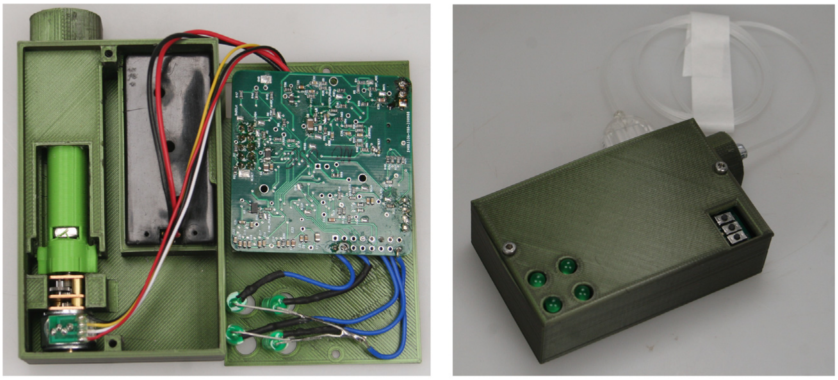


Fig. 4. Build instructions for Ultra-low-cost insulin pump.

into the slots provided. The body of the motor should be placed into its slot at the opposite end of the case (3). When placing the motor into the case ensure the gearbox sits inside the housing built into the case (4). The PCB should be placed inside the top of the case (5). The battery holder can be placed in the slot inside the case (6). A standard MiniMed 180U Reservoir insulin cartridge and Silhouette infusion set (Medtronic, Northridge, California, USA) can be screwed directly into the case (7). Final assemblies of the device are shown in Figure 5.



(a) (b)

Fig. 5. Internal components fitted into case (a) and final design with closed case and commercial insulin cartridge and infusion set fitted (b).

6. Operation instructions

6.1. Device Setup and Usage

The device is powered by two AAA batteries, to be placed in the battery compartment provided in the design. A standard size insulin cartridge should be loaded into the device and the baffle turned until it rests against the back of the cartridge, readying the device for use. Before the software is loaded onto the device the user must set the current time and date by modifying values in the C function *rtc_set_current_time()*. This task is achieved by setting values into the function call in the module *rtc.c* as follows:

- Year entered as number of years passed since 2000
- Month entered as a value between 1 and 12
- Day entered as a value between 1 and 31
- Hour entered in 24 h format
- Minute entered as a value between 1 and 60
- Seconds entered as a value between 1 and 60

For example, the date and time 16/10/2020, 9:08 pm, would be entered into the device by using *rtc_get_current_time(20, 10, 16, 21, 8, 0)*.

The frequency at which the pump should wake up and deliver insulin can also be customised by the user, by writing relevant values to the RTC using functions provided in the Git repository. When changing alarm values a user must write all relevant registers in the RTC. Default functions are provided to allow insulin delivery once per minute, or once per hour. Code has been commented extensively and so modifications should be easy to make in conjunction with Integrated Circuit (IC) data-sheets, links to which are given in the references section.

The background rate of insulin delivery can be changed using buttons one to increase the rate and button two to decrease the rate. Pressing button three allows a user to change between basal and bolus rates of insulin. The device has four LEDs, so can display rates up to four units however the software will record insulin rates up to 255 units per hour.

Some parameters for pump control can only be modified by altering values in the source code meaning the pump currently requires knowledge of the C programming language for a deeper level of user customisation.

6.2. Health and Safety Considerations

It is likely uncovered needles will be used in conjunction with the device. Users should be careful not to harm themselves or others when handling the device, and dispose of used needles appropriately. The device is designed to operate from a 3 V supply. Use of a voltage outside of the recommended level may cause the device to behave unexpectedly or cause irreparable damage to circuitry. If using disposable batteries an alkaline variety is recommended. If using rechargeable batteries only Ni-MH and Ni-Cd chemistry batteries are compatible with the device.

The insulin pump presented in this paper would be rated as a class II medical device by the FDA, as it does not provide options for integration with a Continuous Glucose Monitor (CGM) [20]. The design is provided as a foundation or platform design. It thus provides fundamental capability to build upon. However, despite initial testing it is not a certified or regulated medical device.

7. Validation and Characterization

7.1. Test Procedures

Insulin pump accuracy is validated using a micro-gravimetric method, as outlined in IEC60601-2–24, the unit standard for infusion pump testing [21]. Data is collected by setting the insulin pump to deliver Class III water into a beaker, which is placed on a microscale (Mettler Toledo XP105 DeltaRange, Columbus, Ohio, USA) with a readability of 0.01mg, or 5 decimal places. The weight of the displaced fluid is measured and used to calculate the dose size delivered by the pump.

The data collection method outlined in IEC60601-2–24 was followed closely through testing with two modifications made to improve the accuracy of the results. Firstly, a small layer of oil was floated on top of the water in the beaker to prevent evaporation from the beaker during testing. Secondly, water was placed in a vacuum chamber to degas it before use and prevent air bubbles forming in the insulin cartridge and infusion set line. Both modifications stated have been used in other literature [22,23] and shown to be effective.

As per the unit standard, brand new cartridges and infusion sets were used for each test. Testing results were obtained for the Ultra-low-cost pump and an in warranty Medtronic 640G (Medtronic, Northridge, California, USA).

7.2. Basal Rate Accuracy

Basal rate accuracy for the ultra-low cost and commercial pumps was tested over a 72 h period using a basal rate of 1 IU/h. The unit standard specifies the pump should be run at a "typical rate" when testing. Therefore, 1 IU/h was chosen as a basal rate at which an insulin may be used, and also because literature exists presenting data at this basal rate, allowing for a point of comparison [22]. A testing period of 72 h was used for two reasons: Firstly, this was the testing period used in other literature and replication of the method used allows for better comparison of results. Secondly, it is generally recommended that patients change infusion sets every 2–3 days [24], and so assessing accuracy over a 72 h testing period better imitates the way those with diabetes use their insulin pumps. All testing was conducted assuming an insulin concentration of U100. Data was processed by splitting the testing period into 72 1-h windows and calculating how many individual windows presented an accuracy within 5%, 10% and 15%. Box and whisker plots of results are presented in Figure 6 and hourly accuracy data in Table 2.

7.3. Bolus Accuracy

Bolus testing is conducted by delivering 25 boluses successively, and weighing each one. The weight of each bolus is recorded and the maximum positive and negative errors are calculated as a percentage of the target. Boluses of 0.1 IU, 1 IU and 5 IU were tested. All testing was conducted assuming an insulin concentration of U100. Table 3 and Table 4 show these results presented as per IEC60601-2–24 for the Ultra-low-cost insulin pump and commercial insulin pump respectively.

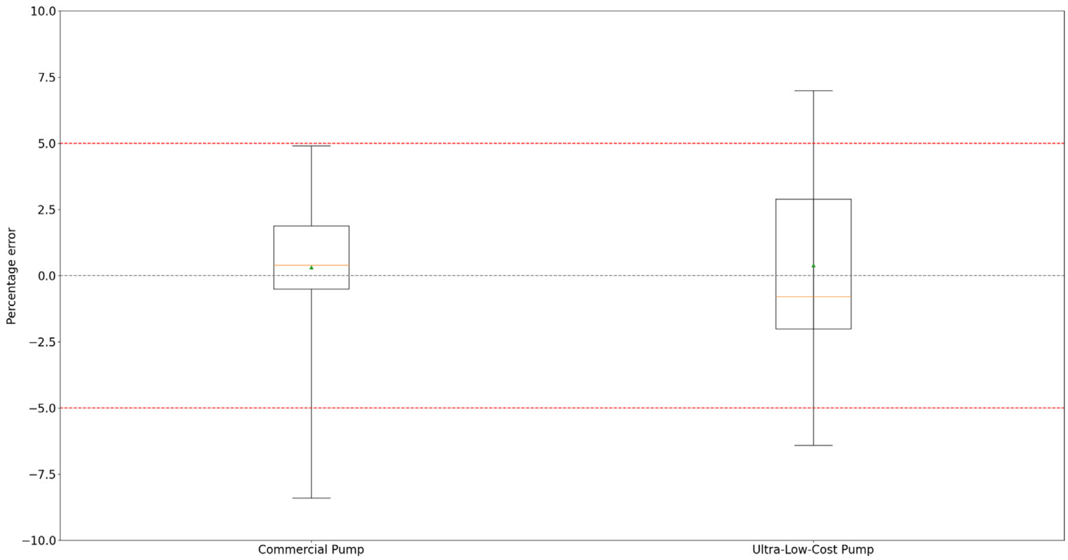


Fig. 6. Box and whisker plot showing different error parameters for the Commercial Pump and Ultra-low-cost insulin pump. Median error is denoted by an orange line, mean by a green triangle, first and third quartile by a black box and 95% range by the whiskers. The red dashed lines indicate ±5% error.

Table 2
Compiled table of basal results, displaying the number of accuracy windows the low cost pump and commercial pump were able to meet during a 72 h test.

Insulin Pump	Individual doses within		
	$\pm 15\%$	$\pm 10\%$	$\pm 5\%$
Commercial Pump	93.8%	93.8%	85.7%
Ultra-low-cost pump	98.6%	98.6%	84.7%

Table 3
Compiled table of bolus results, displaying mean delivery volume and maximum positive and negative error at each tested bolus size for the Ultra-low-cost insulin pump.

	Bolus Size		
	0.1 IU	**1 IU**	**5 IU**
Mean delivery	0.0987 IU	1.0182 IU	5.1176 IU
% deviation of mean from set rate	1.33%	1.82%	2.35%
Max positive error as % of set rate	14.0%	5.50%	4.02%
Max negative error as % of set rate	21%	1.60%	1.18%

Table 4
Compiled table of bolus results, displaying mean delivery volume and maximum positive and negative error at each tested bolus size for the commercial insulin pump.

	Bolus Size		
	0.1 IU	**1 IU**	**5 IU**
Mean delivery	0.0939U	0.9818U	4.9796U
% deviation of mean from set rate	6.08%	1.82%	0.41%
Max positive error as % of set rate	39.0%	4.30%	1.58%
Max negative error as % of set rate	41.0%	11.9%	2.22%

7.4. Assessment of Validation

Collection of data was conducted using a micro-gravimetric method as per IEC60601-2–24, with some testing parameters modified to increase accuracy of results. The results obtained for the commercial pump were similar to those presented by Ziegler et al. [25], with data for 5%, 10% and 15% accuracy windows being within $\pm 2\%$ of the previous literature. Such a result provides validation for the testing methodology used and allows comparison of the results obtained from the Ultra-low-cost pump with greater confidence.

Basal testing shows both pumps performed to a comparable degree of accuracy, with the mean dose size and range of both pumps being similar. However, the commercial pump exhibited a lesser spread between the first and third quartile suggesting greater consistency between doses than the Ultra-low-cost pump. Table 2 shows the accuracy for individual 1-h windows during the testing period, with the commercial pump showing greater accuracy in the $\pm 5\%$ range and the ultra-low-cost pump showing better accuracy in the $\pm 10\%$ and $\pm 15\%$ ranges. However, under real usage conditions both pumps are likely to perform similarly with the small differences in their dosing unlikely to be clinically relevant [26].

When examining bolus accuracy, Table 3 and Table 4 both show larger dose sizes are delivered with a higher accuracy and this result is consistent with that presented in other literature [25,23,27]. Additionally the range between the maximum and minimum error values for both pumps decreases as the requested bolus size increases. These results suggest the pump has a slight tendency to over deliver, but the absolute error does not increase linearly with dose size, becoming a smaller percentage of the total as the dose size increases. Overall, the commercial pump showed a tendency to under-deliver, whilst the Ultra-low-cost pump showed a tendency to over-deliver.

An extension to the validation of the Ultra-low-cost insulin pump would be to repeat the accuracy testing with a wider range of commercially available insulin pumps, or multiple models of the same commercial insulin pump. This would provide a larger data set for comparison and negate any potential effects of manufacturing differences causing atypical results for any one device. Additionally it should be noted the Ultra-low-cost pump was calibrated using the same scale and methodology used for accuracy testing, which may have helped the pump achieve the results presented in this document. Finally, the Ultra-low-cost insulin pump does not provide many of the features present in the commercial pump, such as occlusion detection and CGM compatibility. It is possible that if extra hardware or software was added to the prototype device to match the feature set of the commercial pump, the accuracy of the device may be affected.

The Ultra-low-cost pump was also not tested for performance after use in real world conditions. Insulin pumps are worn externally throughout the day and as a result are subject to wear and tear. Insulin pumps may be knocked against doors, dropped, and subject to water damage as a result of everyday use. The Ultra-low-cost insulin pump was not subjected to any such factors, and it is unknown how the pump would perform if this was the case. In contrast, the commercial pump used for comparison underwent drop testing from a height of ~1 meter onto concrete, as well as altitude, humidity and electrostatic discharge testing [28]. It is possible additions to the Ultra-low-cost pump to match the robustness of the commercial pump may affect accuracy of the device also.

8. Conclusion

This paper has presented a design for a low-cost, open source insulin pump. Testing of the pump has shown a high overall level of accuracy. When compared to a commercially available pump, test results have shown the per dose accuracy is comparable. Future research would benefit from comparing the Ultra-low-cost pump to a wider range of commercial pumps, to provide more points of reference for the device. Additionally, the design put forward can be produced using easily obtainable parts and materials. A full set of code files have also been provided for use with the low cost pump design. Finally, only basic pump control is offered as part of the design. Future designs would benefit from the ability to connect a phone or a computer to allow users to modify pump parameters through a simple interface, rather than requiring users to modify the source code.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

This work was supported by the NZ National Science Challenge 7, Science for Technology and Innovation (2019-S3-CRS), and a University of Canterbury Doctoral Scholarship.

References

[1] International Diabetes Federation, International Diabetes Federation - Facts & figures, https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html, Mar. 2021..
[2] Ministry of Health NZ, Diabetes, https://www.health.govt.nz/your-health/conditions-and-treatments/diseases-and-illnesses/diabetes, Mar. 2021..
[3] S. Basu, J.S. Yudkin, S. Kehlenbrink, J.I. Davies, S.H. Wild, K.J. Lipska, J.B. Sussman, D. Beran, Estimation of global insulin use for type 2 diabetes, 2018–30: A microsimulation analysis, The Lancet Diabetes & Endocrinology 7 (1) (Jan. 2019) 25–33.
[4] J.M. Polinski, S.C. Kim, D. Jiang, A. Hassoun, W.H. Shrank, X. Cos, E. Rodríguez-Vigil, S. Suzuki, I. Matsuba, J.D. Seeger, W. Eddings, G. Brill, B.H. Curtis, Geographic patterns in patient demographics and insulin use in 18 countries, a global perspective from the multinational observational study assessing insulin use: Understanding the challenges associated with progression of therapy (MOSAIc), BMC Endocrine Disorders 15 (1) (Sep. 2015) 46.
[5] O. Kusnik-Joinville, A. Weill, B. Salanave, P. Ricordeau, H. Allemand, Prevalence and Treatment of Diabetes in France: Trends between 2000 and 2005, Diabetes & Metabolism 34 (3) (Jun. 2008) 266–272.
[6] B. Karges, A. Schwandt, B. Heidtmann, O. Kordonouri, E. Binder, U. Schierloh, C. Boettcher, T. Kapellen, J. Rosenbauer, R.W. Holl, Association of Insulin Pump Therapy vs Insulin Injection Therapy With Severe Hypoglycemia, Ketoacidosis, and Glycemic Control Among Children, Adolescents, and Young Adults With Type 1 Diabetes, JAMA 318 (14) (Oct. 2017) 1358–1366.
[7] J.S. Skyler, S. Ponder, D.F. Kruger, D. Matheson, C.G. Parkin, Is There a Place for Insulin Pump Therapy in Your Practice?, Clinical Diabetes 25 (2) (Apr 2007) 50–56.
[8] Disparities in Insulin Pump Therapy Persist in Youth With Type 1 Diabetes Despite Rising Overall Pump Use Rates — Elsevier Enhanced Reader, https://reader.elsevier.com/reader/sd/pii/S0882596318301945?token=9B8DFFA900419ED394852F1A0DE922ACF98399F282BC3AC28D64DE3695E25E7BEF131CFE693F4406FF281CC2268B2A6F&originRegion=us-east-1&originCreation=20220915230410..
[9] L.D. Hennessy, M. De Lange, E.J. Wiltshire, C. Jefferies, B.J. Wheeler, Youth and non-European ethnicity are associated with increased loss of publicly funded insulin pump access in New Zealand people with type 1 diabetes, Diabetic Medicine 38 (1) (2021) e14450.
[10] L. Holder-Pearson and J.G. Chase, Socio-Economic Inequity: Diabetes in New Zealand, Frontiers in Medicine, vol. 9, 2022..
[11] P. N.Z. NZ Government, Schedule Online - Insulin Pumps, https://schedule.pharmac.govt.nz/ScheduleOnline.php?code=A011512&edition=2022-06..
[12] OpenAPS.org – #WeAreNotWaiting to reduce the burden of Type 1 diabetes..
[13] J.-L. Selam, External and implantable insulin pumps: Current place in the treatment of diabetes, in Transplantation and Changing Management of Organ Failure: Proceedings of the 32nd International Conference on Transplantation and Changing Management of Organ Failure, 25–26 May, 2000, ser. Transplantation and Clinical Immunology, P. Cochat, Ed. Dordrecht: Springer, Netherlands, 2000, pp. 131–138..
[14] D.J. Pollard, A. Brennan, S. Dixon, N. Waugh, J. Elliott, S. Heller, E. Lee, M. Campbell, H. Basarir, and D. White, Cost-effectiveness of insulin pumps compared with multiple daily injections both provided with structured education for adults with type 1 diabetes: A health economic analysis of the Relative Effectiveness of Pumps over Structured Education (REPOSE) randomised controlled trial, Open Access, p. 15, 2018..
[15] ATSAMD21G18A-MUT Microchip Technology — Integrated Circuits (ICs) — DigiKey, https://www.digikey.co.nz/product-detail/en/microchip-technology/ATSAMD21G18A-MUT/ATSAMD21G18A-MUTCT-ND/4878880, Mar. 2021..
[16] IS25LP128-JBLE ISSI, Integrated Silicon Solution Inc — Integrated Circuits (ICs) — DigiKey, https://www.digikey.co.nz/product-detail/en/issi-integrated-silicon-solution-inc/IS25LP128-JBLE/706-1341-ND/5189776, Mar. 2021..
[17] AB1815-T3 Abracon LLC — Integrated Circuits (ICs) — DigiKey, https://www.digikey.co.nz/product-detail/en/abracon-llc/AB1815-T3/535-11936-1-ND/3661487, Mar. 2021..
[18] DRV8846RGER Texas Instruments — Integrated Circuits (ICs) — DigiKey, https://www.digikey.co.nz/product-detail/en/texas-instruments/DRV8846RGER/296-40083-1-ND/5177960, Mar. 2021..
[19] Atmel-ICE, https://www.microchip.com/DevelopmentTools/ProductDetails/ATATMEL-ICE, Mar. 2021..
[20] Insulin Pump Risks and Benefits: EASD/ADA Joint Statement, http://www.medscape.com/viewarticle/842369, Mar. 2021..
[21] IEC 60601–2-24:2012: Standards New Zealand, https://www-standards-govt-nz.ezproxy.canterbury.ac.nz/shop/iec-60601-2-242012/..
[22] R. Ziegler, D. Waldenmaier, U. Kamecke, J. Mende, C. Haug, G. Freckmann, Accuracy assessment of bolus and basal rate delivery of different insulin pump systems used in insulin pump therapy of children and adolescents, Pediatric Diabetes 21 (4) (2020) 649–656.
[23] G. Freckmann, U. Kamecke, D. Waldenmaier, C. Haug, R. Ziegler, Accuracy of Bolus and Basal Rate Delivery of Different Insulin Pump Systems, Diabetes Technology & Therapeutics 21 (4) (Apr. 2019) 201–208.

[24] D. Deiss, P. Adolfsson, M. Alkemade-van Zomeren, G.B. Bolli, G. Charpentier, C. Cobelli, T. Danne, A. Girelli, H. Mueller, C.A. Verderese, E. Renard, Insulin Infusion Set Use: European Perspectives and Recommendations, Diabetes Technology & Therapeutics 18 (9) (2016) 517–524.
[25] R. Ziegler, D. Waldenmaier, U. Kamecke, J. Mende, C. Haug, G. Freckmann, Accuracy assessment of bolus and basal rate delivery of different insulin pump systems used in insulin pump therapy of children and adolescents, Pediatric Diabetes 21 (4) (Jun. 2020) 649–656.
[26] E. Campos-Náñez, J.E. Layne, H.C. Zisser, In Silico Modeling of Minimal Effective Insulin Doses Using the UVA/PADOVA Type 1 Diabetes Simulator, Journal of Diabetes Science and Technology 12 (2) (Mar. 2018) 376–380.
[27] K. Laubner, E. Singler, J. Straetener, T. Siegmund, G. Päth, J. Seufert, Comparative Dose Accuracy of Durable and Patch Insulin Pumps Under Laboratory Conditions, Diabetes Technology & Therapeutics 21 (7) (Jul. 2019) 371–378.
[28] Will You Drop it on The Floor? Will You Catch It On A Door? https://www.medtronicdiabetes.com/loop-blog/will-you-drop-it-on-the-floor-will-you-catch-it-on-a-door/, Jul. 2011..

Matthew Payne received a Bachelor of Electrical Engineering with First Class Honors from the University of Canterbury, New Zealand, in 2021. He is currently working towards his Ph.D in Bio-Engineering at the same university. His research interests include finding ways to develop low cost medical hardware, to increase equity of care.