The separation of insulin pump hardware and software - a novel and low-cost approach to insulin pump design

Matthew Payne * **Francis Pooke** * **J. Geoffrey Chase** *
Jake Campbell * **Lui Holder-Pearson** * **Jennifer Knopp** *

* *Mechanical Engineering Department, University of Canterbury,*
Christchurch, New Zealand (e-mail: matt.payne@pg.canterbury.ac.nz,
francis.pooke@pg.canterbury.ac.nz, geoff.chase@canterbury.ac.nz).

Abstract: Insulin pumps are the most consistent and accurate means of regulating blood glucose levels in Types 1 and 2 diabetes. However, the technology is underutilised due to very high costs. A typical insulin pump costs US\$6500, which makes this gold standard of care inaccessible to many, reducing equity of access to care. Since insulin pumps were first introduced, the simple hardware has not changed significantly. Pump manufacturers couple the low-cost and simple hardware with their own software, removing consumer choice and locking value into the product. Using both a traditional motor-driven and novel spring-loaded approach, insulin pump hardware can be replicated for US\$100. Initial testing of the traditional motor-driven prototype proves the low-cost approach has comparable accuracy to commercially available pumps, with 85.1% of basal doses delivered within 5% of target. The results obtained indicate pump hardware and software can be separated with no significant loss in accuracy. If a separate market for pump software is established, costs can be driven down through market pressure given the increasing access to relatively extensive mobile and cloud computing. If open-source software is made accessible, a complete pump could be offered for US\$100. A 98.5% cost reduction would drastically improve pump accessibility, particularly in developing nations, and could lead to a global improvement in diabetes treatment, outcomes and costs.

Keywords: Diabetes, Healthcare management, Disease control, Critical care, Low cost technologies, Mechatronic systems, Open-source, Design methodologies

1. INTRODUCTION

1.1 Diabetes

Diabetes currently affects 463 million people worldwide, with this figure projected to rise to 700 million by 2045 (International Diabetes Federation, 2021). Diabetes disproportionately affects those least able to pay for their care, with a very large 80% of those with diabetes living in developing countries. Case numbers continue to rise rapidly in the developing world, such as in China, where the prevalence of diabetes has increased from 0.67% in 1980 to 11.2% in 2017 (Li et al., 2020; Grant, 2013).

The sharp rise in diabetes can be attributed to an increase in wealth, combined with greater urbanisation and mechanisation, which has resulted in more sedentary lifestyles and greater ability to purchase processed food items (Misra et al., 2019). With global health spending on diabetes currently at US\$1.3 trillion in 2015, and predicted to rise to US\$2.1 trillion by 2030 (Bommer et al., 2018), governments are facing a significant financial burden to treat those suffering with the condition. More generally, costs in developed nations are $\sim$1% GDP annually and rising towards 2% GDP by 2030 - 2035, which is unsustainable.

Diabetes patients are split into two groups, Type 1 and Type 2. Type 1 diabetes is characterised by the body's inability to produce insulin. Type 1 diabetes patients make up 5% to 10% of the total number of individuals with diabetes, and require exogenous insulin to be administered to control blood glucose levels. Type 2 diabetes is characterised by the patient's body either not producing enough insulin, or the patient's cells becoming resistant to insulin (Ministry of Health NZ, 2021a). While Type 2 diabetes can initially be controlled by diet and exercise, an increasing number of people need partial or full exogenous insulin support, rising from 7% to 15% of those affected by 2030 (Basu et al., 2019). In some countries 50% to 75% of those with Type 2 diabetes use at least basal background insulin. (Polinski et al., 2015), (Kusnik-Joinville et al., 2008). There is, accordingly, rapid growth in insulin demand and use, with insulin shortages forecast (Basu et al., 2019).

1.2 Insulin Pumps

The best, most convenient, and effective way to deliver insulin is using a wearable insulin pump. Insulin pumps continually release small doses of insulin to keep blood glucose levels steady throughout the day, reducing compli-

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cations while increasing quality of life. The better glycemic control associated with insulin pumps reduces the chance of becoming hypoglycaemic, or suffering keto-acidosis, (blood glucose becoming too high) (Karges et al., 2017). Even though insulin can be administered using a simple injection pen, there will be an increasing need for insulin pumps, which are considered the gold standard for out-patient insulin delivery and control, despite their high cost (Hirsch et al., 2005; Doubova et al., 2019).

Insulin pumps offer the best diabetes control, but 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 3-4 years. Pump users must also purchase consumables to use with their devices. Insulin, infusion sets, pump cartridges and filling syringes/needles cost between US$2000 and US$3000 per year (Skyler et al., 2007). Those without health insurance, or whose insurance only covers a percentage of these costs face a significant initial outlay and a continuing financial burden when opting for an insulin pump. In single payer health systems, this high cost leads to rationing of subsidised access.

For those living in developing countries the situation is more dire, with the cost of an insulin pump sometimes greater than the median salary. For example, in India the median salary is US$2130 (World Population Review, 2021). Therefore, the purchase of an insulin pump is an impossibility for many living in developing countries, making the best option for diabetes control unattainable.

Countries such as New Zealand, which have a government subsidised health system, require insulin pump users to contribute towards costs. Government subsidies only cover up to half the cost of a pump and required consumables, and only if an individual meets specific criteria, such as poor glyceamic control (Ministry of Health NZ, 2021b). Individuals must pay at least US$3500 per year to obtain the best level of treatment for their diabetes. When compared to the NZ median household income of US$72000, this represents a cost that is too high for many families, and people are forced to make a choice as to whether they can afford a better quality of life. 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"* (Selam, 2000).

In addition, the high cost of pumps limits their economic utility for moderately controlled patients. This loss of economic efficacy essentially vanishes if the cost of insulin pumps were halved (Pollard et al., 2018). There is thus a growing need for much lower cost insulin pumps offering similar utility as current products. The designs presented here offer potential reductions in cost up to 65x, increasing economic efficiency, as well as increasing the quality and equity of access to care.

The hardware design of an insulin pump is simple, and essentially unchanged since their inception. Insulin pumps are built from a core group of components: a motor to provide actuation, a battery for power, and electronics for control/user interfacing. If insulin pumps are non-complex hardware, then what drives the cost of these devices to be so high?

Insulin pumps are sold as a package where hardware and software are bundled together as a complete device. The hardware and software are sold as a single costly item, which locks profits into a complete device sold by the respective manufacturer. Hence, relatively low-cost hardware is sold at a premium due to the installed software. Forcing manufacturer software onto these devices also stifles innovation, as users have no choice regarding the software installed on their pumps. If it were possible to separate the hardware and software into two products, insulin pump hardware could be sold without software, and at a price more representative of the cost of manufacture.

If a cheap, open-source hardware design could be produced for an insulin pump, the cost currently locked into the combined hardware/software model could be drastically reduced. Computation could also be moved away from the pump, and onto one of many smart devices people carry with them everyday. With computation moved to smartphones, tablets, PCs and laptops, insulin pump hardware could be simplified, driving cost down further.

Although low-cost and open-source infusion pump hardware and software can be found in literature, there are currently no available designs which offer comparable functionality to commercially available insulin pumps, and, in a portable size suitable for everyday use.

Tenorio et al. (2021) have developed a prototype for a syringe pump for insulin delivery, which has achieved similar accuracy to commercially available pumps. However, the current device is not practical as a lightweight, wearable solution. It is also not clear whether this design will be made available on open-source platforms. An existing open-source pump is also too large for practical use as a wearable insulin pump, as it is not intended for insulin therapy (Poseidon, 2021). Additionally, there are currently no open source software solutions that provide the insulin pump specific functionality offered by commercially available systems, which are essential for good diabetes control. Bolus calculators are one such example of missing functionality, which automatically calculate the additional required dose of insulin based on carbohydrate intake. Overall, there is a real need for a complete open-source solution which offers users insulin pump specific hardware and software comparable in size, functionality, and appeal to commercial systems.

This conference paper presents research and test findings of two low-cost insulin pump hardware designs. A design is presented for a motor-driven pump, as well as a novel mechanically driven pump. Both designs are tailored specifically to facilitate open-source insulin therapy.

2. DESIGN AND METHODS

2.1 Traditional Motor-driven Pump

A traditional insulin pump uses a stepper motor to actuate a plunger which delivers insulin to the user. The device is powered by a battery and controlled with a simple PCB and micro-controller. Users are able to enter simple commands via buttons to control the insulin their pump delivers. A low-cost design that is simple to manufacture and is built from commonly available components is shown in Fig. 1. Bluetooth compatibility will be integrated in future development of the design, which will enable users to control their pump remotely from their phone or tablet.

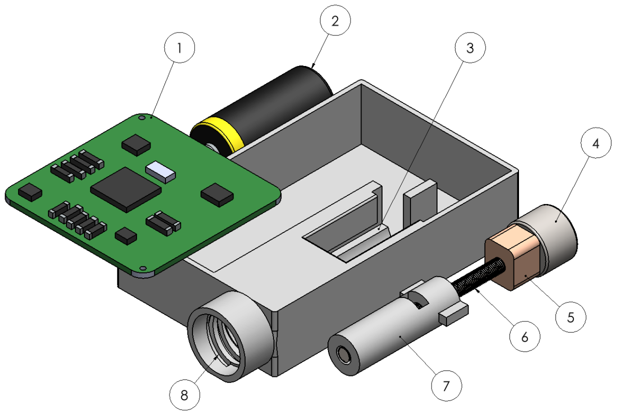

Fig. 1. CAD design of the traditional insulin pump with key components labelled

Fig. 1 presents an exploded view of the traditional insulin pump. The 20:1 stepper motor (GA12BY15-M455 DC 5V, Convenience Machines, Shenzhen, China) used to drive the pump (4) is connected to a 298:1 gearbox (5) giving a total output resolution of 5960 Steps Per Revolution (SPR). The output of the gearbox is connected to an M4 threaded shaft (6). As the shaft turns, a follower (7) moves along its length, and pushes on the plunger of an insulin pump cartridge. The cartridge is secured into the device using a thread (8) designed to fit Medtronic 3 ml and 1.8 ml insulin cartridges. The case design features tracks (3) used to stop the follower rotating with the motor shaft and guide it to push the insulin cartridge plunger. The device is powered via a Li-Ion battery (NITECORE RCR123A, Sysmax Innovations, Guangzhou, China) (2) and controlled with a custom designed PCB (1).

2.2 *Mechanical Pump*

An alternative design is also proposed which replaces the motor with a compression spring to achieve a fully mechanical drive mechanism. As shown in Fig. 2, the drive mechanism consists of a lead-screw (1), plunger attached to a lead-screw follower (2), and a compression spring (3). If rotation of the follower is restricted, the restoring force from the compressed spring will drive the plunger forwards, causing the lead-screw to rotate. Insulin dosage can be controlled by limiting the rotation of the lead-screw using a clockwork escapement mechanism (5), so that periodic release of an escapement gear delivers a set dose of insulin. The escapement is connected to the lead-screw through a 50:1 gearbox (4), so that one 'tick' of the escapement delivers a 0.1 unit (0.001 ml) increment of U-100 insulin. A solenoid will be used to actuate the escapement, so that dosage can be controlled via Bluetooth.

A mechanical pump mechanism aligns well to a low-cost approach, as, without the need for a motor, the pump electronics will be simpler and consume less power. Coupled with a basic housing design and generic drive components, the cost of manufacture will be significantly lower than commercially available pumps, and can thus be sold at a fraction of the price. In addition, the simplicity of the design and components promotes pump repair and maintenance, enabling a larger service life, which makes the long-term use of insulin pumps more affordable.

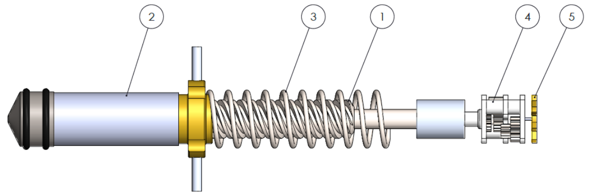

Fig. 2. CAD model of the mechanical insulin pump drive mechanism with key components labelled

3. PRELIMINARY RESULTS

3.1 *Traditional Pump*

A prototype suitable for initial testing was built. The design includes a custom PCB, and 3D printed housing. It is also connected to a universal giver interface to match typical infusion sets. Key specifications for the traditional pump prototype are included in Table 1.

Table 1. Prototype Pump Specifications

Specification	Electrical	Mechanical
Reservoir (unit)	300	300
Size (mm)	85 x 55 x 25	20 OD x 120
Weight (g)	100	90
Min Bolus Increment (unit)	0.05	0.1
Battery life (weeks)	1	52
Bluetooth Compatibility	Yes	Yes
Hardware Cost (USD)	\$100	\$100

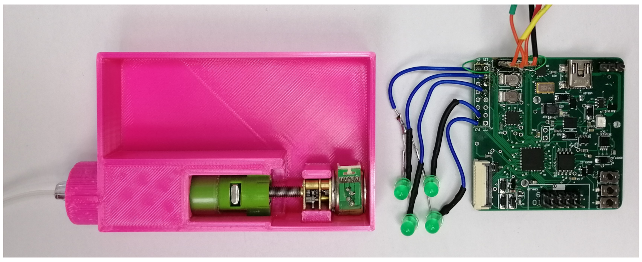

Fig. 3. Housing, drive mechanism, and PCB of the traditional insulin pump prototype

The insulin pump (presented in Figure 3) was tested using *Infusion pump testing to IEC 60601-2-24* UL (2021). Testing provided a highly promising result with overall accuracy recorded at -4.76%, which is within the range of $\pm 5\%$ currently targeted by commercial pumps (Ziegler et al., 2020).

Other studies have tested the accuracy of commercially available pumps, including an in-depth analysis by Ziegler et al. (2020). The accuracy of the proposed design was compared to three commonly available pumps tested in that study. A summary of the results is included in Table 2.

As shown in Table 2, the traditional pump prototype delivered 85.1% of individual basal doses to within $\pm 5\%$

Table 2. Accuracy comparison to commercially available pumps for basal doses

Pump System	Doses delivered to accuracy	
	±10%	±5%
Tandem tSlim	98.9%	91.4%
Medtronic 640G	93.1%	84.0%
Omnipod	71.2%	46.6%
Low-Cost Insulin Pump	86.3%	85.1%

of the intended accuracy. When comparing bolus doses of insulin, the pump delivered 100% of doses to within ±5% for both a 1 unit and a 10 unit bolus. The recorded accuracy of 100% for bolus tests is the same as the Tandem tSlim and the Medtronic 640G, and is greater than the Omnipod, which recorded an accuracy of 76.9% for a 1 unit bolus and 100% for 10 unit bolus.

3.2 Mechanical Insulin Pump

A prototype was built to test the viability of the mechanical insulin pump concept. The drive mechanism was constructed using off-the-shelf components, and is contained within a housing machined from aluminium, as shown in Fig. 4.

Fig. 4. Housing and drive mechanism of the mechanical insulin pump prototype

The spring-loaded mechanism simultaneously delivered 300 units of insulin through a standard infusion set, and rotated the input shaft of a 1:50 gearbox, which are two key forces the pump must overcome. Although the escapement mechanism to control the release of insulin has not yet been tested, the initial results indicate a working mechanical pump can be built for under US$100, which meets the ultra low-cost objective.

In addition, it is predicted a battery life of up to 1 year could be achieved due to the low-power approach. This increased battery life offers a significant improvement over motorised pumps, which require weekly battery replacement. Key specifications for the mechanical pump design are included in Table 1.

4. DISCUSSION

The traditional and mechanical pump prototypes demonstrate that the hardware for insulin pumps can be built for less than US$100. With the average insulin pump costing approximately US$6500, it is clear that manufacturers are able to add significant value to their product by coupling the inexpensive hardware with software otherwise inaccessible to the user. Slight updates and modifications to software can be repackaged with the same hardware as a simple means of bringing new devices to market, driving up the cost of pumps and locking in profits. By providing users separate access to both the software and hardware components of insulin pumps, this cycle can be broken. Separating pump design into software and hardware components will have immediate technical, clinical, and long-term economic implications. The accessibility and flexibility of insulin pumps stand to be greatly improved if the hardware and software components can be separated.

4.1 Technical Implications

If the low-cost hardware is extended to have Bluetooth capability, software and hardware could be integrated without the need for an on-board micro-controller. Computation could be shifted from the pump to a device, such as a phone, or laptop, which would allow significant simplification of the hardware by harnessing the computational power already available on these smart devices. Many of the peripheral components required for on-board processing could be removed and replaced by those available on the connected device. The current Bluetooth protocol is safe from a security standpoint, and devices would not need to be connected 24/7. Users would only need to connect to update pump settings, or download data from the pump when required. Simplification of the hardware would help to further reduce pump costs.

Splitting the hardware from the software would allow a completely separate market for the software to be established. For individuals who are willing and able to pay for complex features and technical support, commercial software packages could be purchased. Different software packages at varying levels of complexity could be offered, which will enable pump users to select which version of software best suits their needs at a particular price point. For low-income families, or those in developing nations where cost is critical, open-source software could be downloaded, which would reduce the price of a complete pump to as little as US$100 (the price of the hardware alone). Although open-source software may initially start with limited features, the technical capabilities of the software will develop over time as more contributors become involved in the development process. For individuals with limited financial means, very basic pump functionality will still greatly improve their glucose control and level of diabetes care.

4.2 Clinical Implications

A complete insulin pump could cost as little as US$100, which represents a 98.5% decrease on the current average market price. The implications of a 98.5% cost reduction are significant, with an immediate increase in pump accessibility. Diabetes care in developing nations could be completely transformed, such as in India where access to insulin pumps for the general population is impossible. Reducing pump prices to US$100 would greatly improve the affordability of insulin pumps, which in turn will improve life for those with diabetes in developing countries through better glycaemic control. Advancing the management of diabetes also has the potential to reduce the occurrence of common complications such as heart failure and blindness, which makes treating diabetes a costly challenge for all healthcare systems.

In developed countries, such as New Zealand, government agencies could fully subsidise insulin pumps and consumables, or remove the criteria for funding which requires individuals with diabetes to have a history of poor glycaemic control. Diabetes care would be transformed to take a proactive approach, where everyone is provided with the optimal level of care from diagnosis. For current pump users, fully funded care would remove a large financial burden, and enable families to live without common sacrifices to meet the high yearly cost of running an insulin pump. The low-cost of the proposed designs would also enable each pump user to have a reserve device, which could be immediately substituted if needed. Widely accessible replacement parts will allow users to carry out maintenance and repair of their own pumps, which is not currently possible with commercial insulin pumps available today. Users would then have peace of mind knowing their care will not be compromised in the event their primary pump fails or is misplaced.

Moving computation, and hence user settings and data storage away from the device would allow users to easily switch pumps. If settings were able to be stored *"in the cloud"*, pump users would only need to connect their smart device to the new pump to update user settings, or download insulin usage data after a period of use. With very low-cost hardware, users could maintain multiple pumps, keeping spares on hand or using one pump while another charges. Equally, pharmacies or local doctors could stock emergency spares.

If the design was made fully open-source, users could achieve a far greater level of flexibility and control over their care compared to commercially available pumps, as both the hardware and software can be customised to each individual's needs. Hardware such as the pump housing could be modified to fit a desired cartridge size, or type of cartridge which is funded or accessible. Software could also be selected by each individual based on the features it provides, such as inbuilt alarms, or continuous glucose monitor (CGM) compatibility. As new versions of the pump are released, changes to both the software and hardware could be made by the user without the need for a new pump. The decision to update or upgrade the pump is ultimately down to the owner, who may not see any value in changing their device. Therefore, the open-source approach gives control back to those who use the pumps.

4.3 Future Implications

If the pump design is made open-source, technically minded individuals who are passionate about improving pump technology have the opportunity to modify the software or hardware, which promotes innovation. If these changes are documented and shared on accessible platforms, other users would be able to implement the same changes if desired. The rate at which pump technology advances will increase greatly, due to input from many collaborators with an invested interest of improving the technology of insulin pumps.

Further value could be added to software by harnessing the data being obtained from the pump. If this data were stored remotely it could be accessed not only by users, but also medical professionals. If specialists had access to patients pump data, care could be remotely monitored, reducing the need for in-person consultation. Changes could be made to the patients control remotely, based on the data uploaded from their pump. Equity of access and care would increase for people with diabetes in rural communities, who do not have access to the specialist endocrinologists working in major population centres.

Once a solid pool of data has been established, software developers would have the option to implement machine learning algorithms, and train these algorithms on available data. Efforts could be made to develop processes which flag pump users who have poor control with their insulin pump, and bring these patients to the attention of diabetes specialists. Care could be targeted to those who need it, without manual data analysis. With medical professionals better able to identify those with poor control and intervene early, there will be a reduction in hospitalisation due to diabetes related complications. With models predicting worldwide diabetes cases to rise to 700 million by 2045 there is a critical need to reduce the costs of treating diabetes.

While a low-cost insulin pump represents the bare minimum hardware requirement for improved diabetes control, a significant next step would be the introduction of low-cost CGM. 'Closing the loop' offers even better control of diabetes, and would expand the pool of data available to specialists, creating more opportunities to identify and help those not getting the best control from their insulin pump.

5. CONCLUSION

Insulin pumps are currently significantly overpriced considering the low complexity of their hardware and operating software. Through combining the simple hardware with software into one packaged device, manufacturers are able to sell insulin pumps at a significant premium. Modern smart devices have significant processing power and are easily able to cope with the computing requirements of an insulin pump. Therefore, computation could be moved away from the pump itself and onto one of the many smart devices carried by people everyday. Communication protocols such as Bluetooth already come with standardised security and data transfer methods, so the basic infrastructure for this change is already in place.

Once software has been separated from the insulin pump, only an inexpensive, relatively simple piece of hardware remains. Test results presented in this paper have shown that it is possible to create a low-cost insulin pump ($<$ \$100), which has comparable accuracy to those currently on the market. If users are free to choose which software to use with their pump hardware, cost will be driven down significantly, and the quality and equity of access to care will be equally significantly increased.

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