Czech Technical University in Prague
Faculty of Electrical Engineering
Department of Circuit Theory

Bachelor thesis

Implementation of the Firmware for an Insulin Pump Control Unit

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Study program: Medical Electronics and Bioinformatics

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[2] Reznik, Yves: Handbook of Diabetes Technology. Springer International Publishing AG, 2019. ProQuest Ebook Central,
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Abstract

This thesis focuses on how people with type 1 diabetes mellitus interact with insulin pumps and what are the drawbacks of current insulin pumps. It finds that there is an obstacle of difficulty and dislike of insulin pumps within some MDI users, even though insulin pump could benefit them and allow them to enjoy greater health and life comfort. To decrease this obstacle, after analyzing the issues, a path to design an alternative dosing mechanism and provide a more supportive user interface was chosen. After describing the system conceptually, a part of the software function was tested in a simulation and compared with target outcomes.

Keywords

insulin pumps, diabetes software, medical device design

Abstrakt

Práce se zaměřuje na to, jak osoby s diabetem mellitem 1. typu používají inzulinové pumpy a jaké problémy se při využívání pump vyskytují. Po prozkoumání problematiky je identifikován problém přechodu z injekcí na inzulinovou pumpu. Někteří uživatelé pumpu odmítají kvůli její složitosti, možnému diskomfortu nebo nejsou dostatečně kvalifikování podle zdravotnického personálu. Nicméně inzulinová pumpa v případě správného zacházení může umožnit dosažení lepších zdravotních výsledků a flexibilnější životosprávu. Pro překonání této překážky byl zvolen cíl zmenšení pumpy, k čemuž byl navrhnut alternativní koncept podávácího mechanismu, a cíl lepší podpory uživatele softwarem inzulinové pumpy během rozhodování. Po konceptuálním popisu návrhu byla část softwaru otestována v simulaci.

Klíčová slova

inzulinová pumpa, software pro diabetes, návrh lékařských zařízení

List of Abbreviations

BG	–	Blood glucose
CGM	–	Continuous glucose monitoring
DIA	–	Duration of insulin action
DKA	–	Diabetic Ketoacidosis
FMCA	–	Failure Mode Criticality Analysis
GI	–	Glycemic index
HbA1C	–	Glycated hemoglobin
ICR	–	Insulin to carbohydrate ratio
IOB	–	Insulin on board
ISF	–	Insulin sensitivity factor
MDI	–	Multiple daily injections
MDR	–	Medical Devices Regulation
RPN	–	Risk Priority Number
SG	–	Sensor glucose
SOUP	–	Software of Unknown Providers
TDD	–	Total daily dose
TIR	–	Time in range

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1 Introduction

There are a great number of medical devices that are under development to match an even greater and growing need of various patients and users. Working to create such a device can be a long process involving understanding patients, healthcare actors, technology, and law, where none of the named requires less attention than the other. To get into the process of medical device design (and make as many mistakes during learning as soon as possible), I wanted to select a device that is simple enough to understand and yet vital to many people and has some aspects that could be worked on and redesigned for a better outcome. When I first interacted with the world of Type 1 diabetics and their insulin pumps it seemed like the right pick. Naturally, as time progressed, I understood that despite having simple mechanics, the insulin pump deals with situations that are anything but simple – the constant struggle between a low blood glucose and a high blood glucose, future planning and device handling is stressful, tiresome, and complex.

The aim of this thesis is to understand current issues and drawbacks that people using insulin pumps experience, attempt to find at least conceptual design solutions to them and test them out. The design process was mostly governed by the book Medical Device Design by Peter Ogrodnik, specifically the stages of research, specifications and development. Many of the practical insights and information were gained from a 'classic' book on the topic of infusion pumps, the Pumping Insulin by John Walsh. He guides the user through the whole life cycle of using a pump and adds his and his team comments and suggestions based on experience and research during the last decades. Another major source were interviews with both diabetics and a diabetologist which, hopefully, allowed the work to describe and address issues more at the root.

2 Managing Type 1 Diabetes

2.1 Diagnostics

In healthy people, pancreas produces the hormone insulin which reduces blood sugar levels. People with T1D often have an autoimmunity-induced destruction of the beta-pancreatic cells where insulin is made, or other forms of autoimmunity diseases detected by antibodies. In children, the main diagnostic symptom are high random plasma glucose values.[1]

2.2 Associated risks

Chronic vascular complications are generally usually associated with diabetes. Microvascular complications include kidney disease, blindness, and amputations. The progress of microvascular problems cannot be yet halted but can be significantly altered with early glycemic control.[2] Macrovascular complications include hypertension, blood pressure.[3] In the short term, if a patient stops administering sufficient amounts of insulin there is a risk of developing diabetic ketoacidosis which is an acute condition leading to coma and death if

[1] DEFRONZO, Ralph A. International textbook of diabetes mellitus. Chichester, England: Wiley Blackwell, 2015, 10.
[2] Ibid., 875.
[3] Ibid., 1007.

not treated.[4] Furthermore, if intaking too much insulin, severe reduction of blood glucose (hypoglycemia) could also lead to death.

2.3 Insulin therapy in a nutshell

Blood glucose (BG) has units mmol/L and is one of the main drivers of diabetic care. A person will determine a BG range with his medical team in which his aim is to stay, but for example the American Diabetes Association recommends staying between 3.9 and 7.2 mmol/L pre-meals, and circa less than 8.5 mmol/L post-meal.[5] In practice, that means estimating the carbohydrate content of each meal/drink consumed and adequately compensating for it, and also covering the non-meal sugar release. After injecting, usually to the subcutaneous tissue, the insulin will spread throughout the bloodstream, pick up blood glucose and store it in cells. There are various types of insulin-analogs with different speeds of action, so a user can, for example, combine 'fast-acting' and 'slow-acting' to cover the short term and long-term insulin requirements. However, even 'fastacting' insulin reacts slower than carbohydrate consumption and it is therefore important to time insulin delivery ahead. (Cite the Bolus timing article at bottom) Once insulin is delivered, it is also important to keep in mind that it shall be active for several hours and beware of potential insulin 'overstacking' and consequential overdose.

2.4 Measuring blood sugar

An essential part in management of diabetes is measuring blood sugar levels. One traditional option is using strips. The patient pinches usually his finger to acquire a drop of blood which he applies to the testing strip. A small electronic device reads the result from the strip and displays the result.[6] The newer option are continuous glucose monitoring (CGM) systems which are implemented as a subcutaneously injected sensor with a transmitter to send the data off to a device. Usually, a reading is sent out every five minutes. CGMs are very useful in that they can provide information about time spent in a healthy blood glucose range (TIR).[7]

2.5 Insulin-related metrics

To allow for correct dosing and compensation, several metrics are used. Insulin is standardized to units (u), a vial of insulin would tell how many units/ml it contains – typically 100 u/ml. Insulin sensitivity factor (ISF) describes how much do BG levels drop after injecting one unit of insulin. To handle carbohydrate corrections, insulin to carbohydrate ratio (ICR) is used which describes how many grams of carbohydrates are covered with one unit of insulin. As mentioned above, insulin acts relatively slowly and it is important to monitor its activity in the body. The amount of active insulin present at a given time is called insulin on board (IOB). Apart from BG, the amount of glycated hemoglobin (HbA1C) in percent is used as a long-term metric indicating therapy success.

[4] FAYFMAN, Maya, PASQUEL, Francisco J. and UMPIERREZ, Guillermo E. Management of hyperglycemic crises. Medical Clinics of North America. 2017. Vol. 101, 3p. 587–606. DOI 10.1016/j.mcna.2016.12.011.

[5] WALSH, John and ROBERTS, Ruth. Pumping insulin: Everything for success on an insulin pump and CGM. San Diego: Torrey Pines Press, 2017, 24, 182.

[6] REZNIK, Yves. *Handbook of Diabetes Technology*. Cham: Springer, 2019, 10–11.

[7] Ibid., 37–40.

2.6 Pump therapy

The insulin pump is a small, computerized device (or a system of devices) that contains a microcomputer controlling a delivery system – often a motorized piston pushing out insulin from a reservoir, which then travels to the body via a cannule. The user interacts with the system through a display, a set of buttons and/or touching the display. The system is powered by a battery and has alarm (vibration and sound usually) capacities.

2.6.1 Pump features

Unlike multiple daily injection (MDI) therapy, the pump therapy only uses 'fastacting insulin' which it delivers in small amounts according to a programmed plan to cover 'basal' insulin requirements. For greater flexibility, it is possible to temporarily override these base settings and change the basal delivery, a so called 'temporary basal'.

The user boluses via the pump for meals, similarly as during an MDI. However, the process of bolusing is usually easier, because the pump contains a user-interface where the user can input grams of carbohydrates, his current BG, target BG, current IOB and the pump software performs the calculation and suggests an insulin dose. During an MDI, this would have to be done by hand, or on an external device.

Another important feature is the ability to automatically calculate and display IOB which helps the user prevent overstacking. The pump also keeps a history of actions which the user can then discuss with his doctor. Pumps can integrate with CGMs which allows the user to view his BG trends and values on one device. The CGM data can also be used in newer pump versions to automatically adjust basal dosing, a so called 'hybrid closed-loop'.[8]

2.6.2 Pump types

There are two common approaches to pumps – tube and tubeless. Tube pumps came first and consist of a tubing exiting from the reservoir, with a cannule attached at its end. This 'infusion set' is usually required to be switched every 2–3 days (to prevent infection), or sooner if it gets blocked or kinked. The pump of this kind would usually have an integrated user interface and the relatively long tubing would allow the user to operate it.

The other, newer, and more trendy approach is a 'patch pump' which is attached directly to skin, has no direct user interface, and is controlled through a remote controller similar to a phone. The patch pump is usually partially, or fully, disposed off after 3 days of use. Regardless of type, the pump would typically take 150–300 units of u-100 insulin. The reservoir would be also typically one-use only.

2.6.3 The benefits of pump therapy over MDI therapy

Besides possibly allowing for a more flexible lifestyle, it has been found by various studies that glucose variability and insulin requirements decreased in groups using pump therapy. The reductions in HbA1C compared to MDI are usually below 1% at 8%, which is still above the 6.5% goal. There are also risk reductions in heart complications.[9]

3 Medtronic pump – a benchmark

The leading producer of insulin pumps in Europe is Medtronic.

[8] WALSH, John and ROBERTS, Ruth. Pumping insulin: Everything for success on an insulin pump and CGM. San Diego: Torrey Pines Press, 2017, 18–25.
9 Ibid., 14.

3.1 Medtronic 780g

The latest insulin pump produced by the Medtronic is the 780g model. It is a tube pump with a display and buttons as user interface. It can be paired with a Medtronic CGM. Because of its wide usage, the pump is considered a benchmark in throughout this text. [10]

3.1.1 Insulin delivery settings

Bolus operation is either manual – simply enter the amount of insulin to be delivered, or through a bolus wizard. The bolus wizard uses the latest BG reading, lets the user enter an amount of carbs eaten and with other settings (ISF, ICR, DIA) proposes a dosage. It also considers IOB. If the resulting amount of insulin would be negative, 0-unit bolus is recommended. The user can edit the dosage and then confirm. The following bolus wizard can be changed: insulin-to-carbohydrate ratio (ICR), insulin sensitivity factor (ISF), insulin active time, blood glucose target.

Also, except for the insulin active time, all named parameters can be set to vary for different times. The bolus operation can be stopped anytime. The bolus can be delivered as normal (all in at once), or square wave (extended bolus), or dual wave (combination). The bolus can be administered in two speeds (1.5 u/min, 15 u/min) and the increments can be tuned (0.025, 0.5, 0.1). Bolus profiles can be preset.

The pump intends to supply basal insulin 24 hours per day. The user can set dosages to vary every 30 minutes, using 0.025-unit steps and create multiple basal profiles. For a specified amount of time, is possible to set a temporary basal rate (0.5–24 hours), either in percentage, or in absolute rate. It is possible to cancel the temporary basal rate and return to the basal plan anytime. The temporary profiles can also be set, for example for higher activity.

All insulin delivery (both bolus and basal) can be suspended indefinitely, but the pump will issue warnings every 15 minutes. If there is a bolus in process, one cannot issue a new bolus or access insulin delivery settings. Maximum basal rate and single bolus amount is defined.

The settings are reset to factory values in reaction to certain pump errors. You have to use the start-up wizard to set up the pump again.[11]

3.1.2 Alerts and CGM

The main way of alerts is through sound (with adjustable volume) and vibration, which can be toggled on/off. Messages are also viewed on the main screen, and sent to a mobile app.

The pump has preset reminders, which the user can tune – low reservoir, set change, CGM calibration, bolus BG check, and missed meal bolus. Also, personal reminders can be set to occur daily at a given time.

If the user has a CGM, he or she can set up alerts for highs and lows. The highs alert can be set to notify the user at a specified time before the high, when the high is reached or to notify him if BG rises too fast. What is too high, or too fast is defined by the user.

The lows alarm work similarly. They also have an alert before (without an option to specify time) and when a low happens. It is also possible to turn on a function to automatically suspend insulin before/on low. The suspend takes at least 30 minutes or 2 hours in maximum, based on if BG levels rise sufficiently. After such event, the auto-suspend function is disabled for some time in order to prevent insulin under-dosing. The user can still resume/suspend basal manually at any time. If auto-suspend is on, alert on low is automatically on. Also, no matter the settings, the low alarm also always runs at 3.0 mmol/L.

[10] Medtronic Minimed 780G system user's manual. ManualsLib [online]. 5 February 2021. [Accessed 20 May 2022]. Available from: https://www.manualslib.com/manual/1971363/Medtronic-Minimed-780g.html.

11 Ibid., 49–68.

Sensor alerts for BG highs, BG highs and lows, or all alerts can be manually silenced for a specified duration. After issuing a high/low alert, the pump waits some time before repeating it (based on the user settings).

For certain alarms (highs, lows, no sensor data, basal resumed...) the pump will launch a siren if the alarm isn't cleared in 10 minutes. Before that, it beeps, vibrates or both. When a critical pump error occurs, pump siren is also activated and you must disconnect the pump immediately.[12]

3.1.3 Hardware operation and maintenance

The pump uses an infusion set composed of a detachable cannule, a tube with a connector and a reservoir. The reservoir is pushed by a piston on an electric motor. The whole pump runs on AA 1.5 V batteries. The routine to change the infusion set and reservoir is the following. First, wash your hands, remove the infusion set from the body and disconnect the tubing from the pump. Then rewind the piston via the pump, fill the new reservoir with room temperature insulin, lock it into the infusion set and then lock it into the pump. Next, hold load reservoir on the pump and fill the tubing and cannule with insulin until there is no air in it. Air bubbles are not harmful by themselves but can lead to lower insulin delivery than expected. Finally, insert the infusion set into the body. This process can be prone to errors and also infection by unclean hands. Generally, when filling a new reservoir, the infusion set has to be disconnected from the body in order to prevent accidental infusion of insulin. Without the battery, the pump doesn't deliver insulin. The user should also clear any active alarms or alerts before removing the battery.[13]

3.1.4 Safety

The Safety section of the pump manual recommends carrying an emergency kit glucose, batteries, reservoir, ketone meter, monitoring supplies, insulin syringe. It warns to beware of paracetamol and other medications that can alter blood glucose values from the sensor. The user shouldn't use an BG value from the sensor in case of a manual mode. The user should never insert a new reservoir into the pump if it is connected to the body, there is a risk of accidental insulin infusion. It further warns to not use the pump close (less than 30 cm from any source stronger than 1 W) to a radio frequency emitting device. This shouldn't cause wrong values to be sent, it simply blocks the communication. If symptoms don't agree with sensor readings, don't ignore them, but confirm them with a finger test reading. Don't insert the device into strong magnetic fields (like MRI) and also don't use magnets near the device (magnetic clasp on a pump belt). Don't expose the pump to radiation. The pump cannot detect leaks or insulin degradation. The pump is waterproof up to 3.6 meters for up to 24 hours. After pump reset, automatic basal control is disabled for 5 hours to allow any active insulin to get gone. Electrostatic discharge can cause a pump reset and a pump error alarm. The pump should be between 5 and 40 degrees, insulin should be kept above 0 degrees and below 37 degrees. Data sent and received are encrypted and protected by cyclic redundancy checks, however, pairing is a sensitive step in the process where other people can pair in.[14]

[12] Medtronic Minimed 780G system user's manual. ManualsLib [online]. 5 February 2021. [Accessed 20 May 2022]. Available from: https://www.manualslib.com/manual/1971363/Medtronic-Minimed-780g.html, 99–122.
[13] Ibid., 73–86.
[14] Ibid., 9–18.

3.1.5 Specifications

Operating range is 70.33 kPa to 106.18 kPa. Basal rates at 1.0 u/h are accurate +-5%. Relative humidity 20 to 90%. Essential performance – delivery accuracy, occlusion detection, empty reservoir detection, detection of power loss, pump therapy status, working notifications: speaker and LCD display. Occlusion is sensed at 90.67 kPa. It takes usually around 2.5 hours to detect an occlusion from 1.0 u/h basal or 95 seconds during a bolus. Single fault conditions make the pump stop insulin delivery (max infuse 0.2 units). The pump keeps a 90-day history. Weight around 100 grams without battery and consumables.[15]

4 Regulations and Development Standards

The main document that regulates medical devices in the EU is the Medical Devices Regulation (Regulation (EU) 2017/745), shortly MDR. Notably, it specifies the classification of devices to different risk classes and presents general requirements regarding the design and manufacture of the device. Several other standards are usually referred in medical device design, Quality Management for Medical Devices ISO 13485:2016 standard, the Risk Management for Medical Devices ISO 14971:2019 standard, the Software Development EN 62304:2006 standard and possibly the Electric Devices ISO 60601 standard.

4.1 Classification (MDR)

An important part of the regulation is the classification of the devices which drives the regulatory requirements. According to the Annex VIII of the MDR an insulin pump is an active device which delivers potentially hazardous medicinal products; hence Rule 12 applies:" All devices intended to administer...medicinal products...in a manner that is potentially hazardous...they are classified as class IIb."[16] The difference in classes is in the regulatory oversight of the device and in the documentation to be provided to the regulatory body. For class IIb devices that means obtaining the conformity assessment from a Notified body.

4.2 Requirements on Design and Manufacture (MDR)

In the Annex I, the MDR specifies requirements for various aspects of the device. It is the primary source of regulations for design and development. Only those requirements relevant to the project are included.[17]

General Requirements

The general imperative is to eliminate all unacceptable risk while keeping the device functional according to its intended use for the whole duration of its lifetime. The primary driver of risk reduction should be safe design and manufacture, secondary alarms, and training and safety information as a last resort. Benefits must clearly outweigh any known or foreseeable risks during its operation, considering standard user's capabilities.

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[15] Medtronic Minimed 780G system user's manual. ManualsLib [online]. 5 February 2021. [Accessed 20 May 2022]. Available from: https://www.manualslib.com/manual/1971363/Medtronic-Minimed-780g.html, 274–286.

[16] Regulation (EU) 2017/ 745 of the European Parliament. [online]. [Accessed 20 May 2022]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745., 188.

[17] Ibid., 123–141.

Materials

Materials must be chosen to be non-toxic, compatible with body in case of contact, compatible with administered substances and durable enough to withstand expected device use. The design should minimize the risk of device material releasing debris and of external substances unintentionally entering the device. In both cases, the risk of unwanted particles entering the human body should be minimized.

Infection

The risk of infection and microbial contamination should be minimized. If necessary, the device should be designed to allow for safe and efficient cleaning/disinfection/sterilization. A device with a sterile status has to be sterilized by validated methods and delivered in such state.

Mechanical and thermal risks

The user has to be protected from any mechanical risks which should be minimized, along with vibrations and noise. It should be impossible to misconnect any connecting parts of the device or to the energy source by virtue of design. Any part of the device in contact with the human body must not have dangerous temperatures under normal conditions.

Interaction with environment

If a device connects with other devices and a user performs such connections, risk of incorrect device combinations and connections must be minimized. If necessary, the user has to be able to adjust, calibrate and maintain the device safely and efficiently. Any display and measurement scales must be ergonomic/user-friendly with valid units.

Furthermore, the device shall not interfere with radio signals. The risk of the IT environment negatively impacting the device's software must be minimized.

Any influence of electric, magnetic fields or their combinations, electrostatic discharge, radiation, pressure, temperature, and other factors must be considered. Risk of flame or explosion must be mitigated.

When the life cycle of the device is finished, it must be disposable safely.

Active devices

All devices which use electrical energy must have single fault condition risks minimized, not the least risk of shocks. Generally, the user has to be alarmed in any situation which could cause death or severe harm – for example, the device must alarm the user about any power failure. Specifically, for batter-ran devices, the user must also have access to the battery level and be warned if the battery is running low.

Electromagnetic compatibility must be assured – the device should not be hampered by or interfere with other devices. Also, the device has to be protected from any unauthorized access.

Software

All software operations must be repeatable, reliable and perform according to the intended use. When tested for single fault conditions, no unacceptable risk shall arise. The software must be developed in alignment with procedures including risk management, information security, verification, and validation. Every device will set out minimum requirements for the hardware necessary for the software to run. If software is developed on a general IT platform, its characteristics have to be considered.

Devices delivering medicinal products

The medical substance which the device is delivering must be verified and evaluated for its interaction with the body and other medicinal products (as required by the conformity

assessment procedure). The dosing of the substance must be accurate and the user has to be able to set the dosage. When doing so, all controls and indicators must be clearly understandable. Further, the device must prevent and/or indicate dosing of dangerous levels of the substance – be it due to user error or device failure.

Lay person user risks

There is a considerable variation in user skill and capability, naturally, the device must work safely for all of them. The risk of misuse must be minimized, for example through training. The device should contain a procedure to assess whether it is able to work correctly as intended, and in case not, warn the user.

4.3 Product realization (ISO 13485:2016)

Apart from specifying requirements for documentation, management and setting up procedures, the standard provides a path for product realization in section 7.[18]

4.3.1 Planning

All requirements for the product must be determined, what resources are needed to accomplish the project, which tests shall be performed to verify the device and which documentation is necessary. Risk management should also be performed.

4.3.2 User-related processes

It is essential to determine all requirements for the device. What the user expects and requires from the device, what the regulations command, what is necessary technically and perhaps if any training shall be required. All requirements must be reviewed and confirmed, and they must not be contradictory. At the end of this step, it should be assessed whether it is possible to accomplish such product, including, for example, providing device training. As one must communicate with users for feedback, this "product design specification document" may change during the development.

4.3.3 Design and development

All procedures for design and development must be documented. Development must be planned and systematically reviewed throughout the processes, with checkpoints set for verification and validation. Any changes to the design have to be first assessed – how they impact the device function, performance, usability, safety or if they comply with regulatory requirements – and only then, if accepted, implemented.

Design inputs (requirements) must be well defined and be verifiable and also include risk management inputs. Design outputs (i. e. the device, technical documentation...) shall meet the inputs and include a clear specification of what is essential for the correct functioning of the device. Any design output has to be suitable for verification and has to be verified, which means confirming it passes the internally set requirements. Any measuring instruments used for verification must be verified themselves and calibrated, if necessary. Next, the device has to be validated, that is checking if the user requirements are met.

Every development step and change has to be documented in a "design and development file".

[18] ISO 13485:2016(en) Medical devices — Quality management systems. ISO [online]. [Accessed 20 May 2022]. Available from: https://www.iso.org/obp/ui#!iso:std:iso:13485:ed-3:v1:en.

4.3.4 Purchasing

Any bought items have to come from valid supplier and be documented. Importantly, their function has to be verified.

4.4 Risk management (ISO 14971)

4.4.1 General Principles

The core idea of the standard for risk management is to assess risk based on two factors: the likelihood of occurrence and the severity of harm. The standard routine for risk analysis, in a simplified way, looks like this: Identify hazards, evaluate risks, adopt risk control measures; then ask if the residual risks are acceptable – if yes, compile a risk management report. If not, redo risk control measures.[19] Any residual risk must be clearly outweighed by the clinical benefits of the device. Notably, for every change in the design risk analysis must be performed.

4.4.2 Risk analysis

The common method applied to preform risk analysis is called Failure Mode Criticality Analysis (FMCA) which operates as following. First, hazards (a potential source of harm to the user) are identified. Annex C of the standard lists some examples of hazards categories which can be used for further hazard identification. An example of a hazard is routine violation by the user, which would be an operational hazard. For every hazard a potential effect is then determined. The effect could impact not only the user, but possibly also other people or the environment. Root-causes of hazards, i.e., which situations could lead to the hazardous situation, are found and consequently their likelihood. Severity is determined solely by the effect. Since a hazard can have multiple root-causes and each root-cause has to be assessed individually.

Usually, a 1–5 scale is used for both likelihood and severity. The Risk Priority Number (RPN) is obtained as the product of the likelihood (L) and the severity (S) scores: RPN = L*S. The scores can then be grouped into three general categories: unacceptable, significant, insignificant. It is necessary then to adopt control measures for the unacceptable and significant risk and calculate a new RPN based on the new residual risk likelihood. It should be also stated if the risk could be reduced any further and the answer should be usually "as far as possible". Furthermore, residual risk should be further mitigated by other measures. Importantly, it is necessary to look for any new hazards that may arise due to the control measures and assess them. [20] In the risk management folder in the technical file, it is necessary to state that clinical benefit outweighs residual risk, the complete documentation of risk assessments and ideally how hazards were pre-assessed.[21]

4.5 Software development (IEC 62304)

The development of software is considered as a special category for development as it is the main pilot of the insulin pump and has to run exactly as intended and adequately handle faulty situations. Generally, there has to be a development plan with well-defined

[19] OGRODNIK, Peter J. Medical device design: Innovation from concept to market. London : Academic Press, 2020.
[20] Ibid.
[21] Ibid.

software requirements. Meaningful milestones should be set, and the software verified at them. Risk management has to be performed throughout the process.[22]

4.5.1 Definition of Requirements

Mainly, the system has functional and capability requirements, for example regarding the performance or the processing unit, and a series of requirements for inputs and outputs. Usually, data is stored somewhere hence database requirements are also added and how the software will interface with other systems. The other part to consider is interaction with the user – specification of alarms/warnings and other operator messages and defining areas that could be prone to human error and could need training. Risk controls requirements should be also included but these might not be available at this point, and it is expected that they will be specified later in the development. The complete list of requirements has to be verified – especially that they are not contradictory and can be tested.

4.5.2 Software Architecture

The requirements then have to be transformed into software architecture containing smaller software items. The architecture of interfaces with external software and hardware has to also be constructed at this phase. In case any Software of Unknown Providence (SOUP) is used, functional hardware and software requirements have to be specified. At the end of this step, the architecture has to match the requirements and risk control measures and also possibly include segregation of software items for risk management.

4.5.3 Software Detailed Design

The software items are broken down into software units, which are the elementary building blocks of the software. For each software unit a detailed design has to be developed and also the interfaces are worked out. Again, it has to be checked if the detailed design matches the architecture correctly.

4.5.4 Implementation

Each software unit is then implemented. This includes having a process for unit verification with verified tests. Acceptance criteria have to be set and met before any unit integration, e. g. does the unit contain risk control measures, or does it conform to a coding standard. There are more criteria for high risk (Class C) software listed in the Standard. All verification results must be documented.

4.5.5 Integration

Integrate units according to an integration plan and verify the software throughout the process. Any hardware units are also integrated at this point. All software items are tested, including abnormal conditions, with integration test procedures which have to be verified. The next phase is to conduct regression tests to make sure the new integrated units don't cause dysfunction of the already integrated units. Testing records shall include the pass/fail results, and a list of anomalies which are then resolved in a separate process.

[22] EN 62304:2006(en) Medical device software — Software life cycle processes. [online]. [Accessed 20 May 2022].

4.5.6 Software system testing and release

Finally, established tests for software requirements with simulated stimuli and recorded output are performed. Any anomalies are resolved and all software tests are ran again. As usual, tests have to be verified and well documented.

Before releasing the software, the anomalies have to be evaluated if they don't pose an unacceptable risk. The residual risk of remaining anomalies has to be included in the documentation. After release, the software must be delivered to the user without any corruption or unauthorized change.

4.5.7 Software risk analysis

First, software items that could contribute to a hazardous situation have to be identified. This can include both software failure and risk control measure failure. The potential causes for such situation (e. g., failure or unexpected results from SOUP, reasonably foreseeable misuse...) have to be identified. If SOUP is the issue, one should check for SOUP anomalies list from the SOUP provider and evaluate them. All identified potential causes and sequences of events that could lead to hazard have to be documented.

4.5.8 Risk control measures

For each identified risk, measures have to be taken and new risks that could arise from this new measure have to be assessed too. Additionally, the measures have to be verified. In the documentation, every hazardous situation has to be traceable: situation – software item – specific software cause – risk control measure – verification of measure. Each software item should also have its software safety class rating based on risk assessment.

5 User experience

This section covers diabetic forum research, interviews with users and a medical professional, books, and academic works on the topic of insulin pump user experience and practice. It will be used as a basis for issue identification and design specification.

5.1 Diabetes Forum UK

The Diabetes Forum UK has approved with me using their forum as a source. The following points were taken from the pump subsection, during the year 2021–2022.[23]

5.1.1 Getting started problems

Several users shared that training to use the pump can be difficult and mentioned that using the pump requires a solid support from a health team. They also mentioned that setting up basals and other metrics might be complicated initially.

5.1.2 Infusion set and reservoir problems

Some users report problems with infusion set scarring and getting bent and clogged cannules. Sometimes, after changing an infusion set, BG goes high. Also filling the reservoir

[23] Insulin Pump Forum. Diabetes Forum • The Global Diabetes Community [online]. [Accessed 20 May 2022]. Available from: https://www.diabetes.co.uk/forum/category/insulin-pump-forum.14/.

might insert bubbles, which brings with it a risk of under-dosing, but air in itself is not dangerous.

5.1.3 Good practice

New insulin should be warmed to the room temperature before using. Users liked the suspend function and recommended always suspending for a definite time. They also advised to not correct post meal spikes with higher basal rates. When exercising, there should be little or none IOB before the activity. They remind that the user should halt insulin when taking off the pump, and prime the tubing when connecting it.

5.1.4 Wearable problems

Some people have problems with knocking off stuff on their arms. They further share that it can be annoying that the pump is permanently attached and difficult to hide. Some also mentioned that the pump reminds one that he or she is chronically ill. Other people discussed that they liked the freedom of being tubeless compared to tube-based systems.

5.1.5 Material and technical problems

The users shared their experience with having a lot of reserve material at home, partially due to risk of new materials arriving late or simply taking time to be delivered. It was also mentioned that sometimes frequently used buttons can wear out.

5.1.6 Sensor and algorithm problems

It was noted that sensor failure or bias means all smart algorithms produce bad decisions. One type of bias could be when a sensor is too near an injection site. They also reminded that sensors are 10–15 minutes lagged behind real blood glucose.

5.2 Books for Diabetics

5.2.1 Type 1 Diabetes: Answers at your fingertips

The book covers how to handle commonly happening situations.[24]

Sports. Eat sugars before sports, or lower insulin input and during sports carry sugars around. Blood glucose may drop even 2 or more hours after sport, which means frequent monitoring is important. It is good to have someone nearby to help.

When eating out in a restaurant, wait for the food to arrive to make sure you don't bolus to early or in wrong dose size. Pick foods that are not too sugary or fatty. Fasting is generally not recommended; one still needs to take insulin and eat carbs in case of overshooting.

Work. When running into a hypoglycemic episode, it is important that a non-diabetic person knows how to and can provide sugars or possibly suspend insulin.

Illness. During illness, blood sugars usually rise, and insulin dosage needs to be readjusted. It is important to never stop insulin delivery. Vomiting can be a sign of ketoacidosis – test frequently to find out if BG is high. Furthermore, when stressed out, BG levels also tend to rise. In case of emergency, other people should know you have diabetes.

[24] KILVERT, Anne, FOX, Charles and SÖNSKEN, Peter. Type 1 diabetes (answers at your fingertips). Class Publishing, 2008.

Alcohol. First comes a quick rise in BG, then a couple of hours delayed more severe hypoglycemia (in the morning, if drinking in the evening). Possibly eat sugars before sleeping or reduce morning insulin.

Emergencies. If you keep vomiting, call an ambulance, it could be an DKA which requires immediate medical attention.

5.2.2 Diabetes Dana: Artificial Pancreas Book

'Diabetes Dana' is DIY diabetes technology pioneer who has lately written a book on insulin pumps. She covers device expectations and situations and poses questions the user should be able to answer before choosing a pump. In general, she focuses on pumps with a hybrid loop system, but the remarks can be applied to non-looped pumps too.[25]

Bolusing. How do I bolus? Do I use the bolus wizard? What happens if I bolus on the pump or in the app? What happens if I don't use the bolus wizard? Do I enter carbs for meals? What happens if I don't enter carbs? What if I forget to enter or bolus for carbs? Should I enter carbs for hypoglycemia? What happens if I throw up after a meal bolus, and/or don't get to eat the meal I accounted for?

Basals. What should I do with my pump when I shower or swim? How does it account for, and handle, missing insulin during that time frame? When reconnecting and bolusing for the missed basals, the new insulin will start to be active after an hour or so, which may cause complications.

Monitoring and prediction. What is the pump predicting will likely happen? Will it alert me if I need to take action? How can I monitor it on a different display or device? What alarm controls do I have? Are my alarms for CGM glucose levels, or are there also predictive alerts and system status alarms? How common is it for the CGM reading to be blocked by the body?

Insulin delivery failure. If my pump site falls out or is not working well, how do I tell your system that I haven't actually received the insulin it thinks that I have gotten? Can I tell the system about other insulin sources, and if so, how?

Settings. When, and how, can I adjust my settings and preferences, or change which features I use? When, and how, should I change the time zone on my device when I'm traveling to a different time zone? How will this affect the pump system? Body sensitivity changes – does my pump allow to adjust settings for that, or perhaps does it automatically?

Tips. Most frequently, basal rates, ISF and ICR ratios are not well setup, but they consist of the core of improvements. The timing around sports activities is also important – low IOB before exercise, no carbohydrate intake pre-exercise – only take in correction carbohydrates during the run. Commonly, people have high basal rates but low ICR ratio and ISF to compensate that. When eating, it may be useful to set a temporary high target to start pumping insulin early on and then later (auto)correct post meal.

5.3 Interviews with diabetic people

Unstructured interviews were done with two young Type 1 patients. Adam and Alice are fictive names used to protect identity. Adam is currently on MDI isn't actively considering switching to pump therapy, while Alice has been using a pump for several years now. Both use CGM sensors. The discussions were mainly about how they perceived insulin pumps and in case of Alice, her experience with it.

[25] LEWIS, Dana. Artificial Pancreas Book, [online]. [Accessed 20 May 2022]. Available from: https://www.artificialpancreasbook.com/.

5.3.1 Interview with Adam

According to Adam, the user shouldn't notice the pump during normal operation unless he wants something from it, or it has an issue. Generally, he says, things must be simple – when I deal with my diabetes, I want to have it done as fast and simple as possible. Control must be swift, and that's why he likes the idea of a dedicated control device. He likes having his sensor on a distant body place where there is little interaction with other objects and thinks the pump should behave similarly.

He judges the current tube pumps ugly, and thinks the tubing is probably annoying but adds that he would possibly get used to it eventually. Even though visually patch pumps are better, he would choose the tubed one, if he were to throw out the device every couple of days as patch pumps are often one-time use. He also dislikes the idea that he would have to charge the device often. The pump seems to him difficult to manage and set-up in contrast with the sensor. Color-wise, he would choose a white option which seems natural to him. He also adds that anything on the body should generally be round and outside the body rectangular.

5.3.2 Interview with Alice

Alice recalls that the main fear, when transitioning to a pump, was of the unknown, cannule pain, fear of not being able to detach from the pump. She also wondered how is the pump going to go with sports.

She shares that overall, the pump has worked for her very well, but notes that it is still the responsibility of the person that makes the difference.

From Alice's point of view, the tube pump design isn't nice – the pump should be as flat as possible. Still, she prefers the tube system – she questions whether a patch pump wouldn't cause excessive sweating. Controlling the pump through a phone could be okay to her if she could do critical operations also on the pump. She is used to having the pump running for a month before changing the battery. She also notes that it would be nice to see the reservoir level directly on the pump.

5.4 Healthcare professional input

The Czech doctor (diabetologist and endocrinologist) has youth and children as her patients and is proficient in both pen and pump therapy. She considers the current technology (hybrid loop with a CGM) a big leap, especially for children, and adds that a proactive approach is still necessary. One of the main hurdles she notices is that when people switch from finger-prick blood tests to a CGM, they don't think in terms of BG 'trends' (rising, falling down, stable) but in terms of individual numerical values. Sometimes, the patients tend to become more leisure about their diabetes on a pump, missing important therapeutic steps, such as bolusing, and compensating later through higher temporary basal rate. Nevertheless, other patients view the pump as an opportunity for better control. Interestingly, some teenage patients refuse the CGM system due to sharing their BG values with their parents and rather than sorting it out, they switch back to finger-prick tests.

She encourages her patients to experiment and find out how exactly their body reacts in different situations. The pump training is provided by the companies is mostly excellent hence they should have a good basis for further experimentation. Generally, it is important to think in a preventive way, not in reactive way. Yet before considering a pump, she usually would have patients for 6 months on an MDI therapy to acquire base diabetes skills. She describes the goal of the diabetic patients as simply to be able to live normally as far as possible.

The doctor thinks the current technology should gradually improve in the same direction as until now. From the interview it was apparent how important is it to have a reliable CGM, which are currently active between 7 and 14 days, yet there are still some products which fail relatively frequently before this range. Interestingly, in the Czech Republic, only one patch pump (from a minor company) is currently available, all others are tube pumps. At least for the child and youth patients, the insurance covers a full hybrid loop set up.

5.5 Academic texts

5.5.1 Training and selection in non-looped pump and MDI therapies

In this group of studies from the UK, participants without a strong preference for either kind of therapy (pump, MDI) were recruited, diabetes-trained and followed for 2 years. The pump group had greater quality of life (diet restrictions, daily hassle, treatment satisfaction) but not statistically significant better HbA1C scores. It appears that when trained well, the pump technology without CGM and a hybrid loop provides greater comfort but not greater control.[26]

Throughout the same experiment, the healthcare staff (nurses, diabetologists) were questioned about their views on who would be a suitable candidate for a pump. They wouldn't generally recommend a user for a pump, if they didn't comply with management rules previously, were old, were not technical. After completing the trial, where users were assigned a pump randomly, they have agreed that people who they wouldn't recommend on the pump could use the pump well. The key issue seems to be the patient's motivation (and view of the pump as a fresh opportunity).

5.5.2 Trainer observations in first-time pump users

In this dissertation work, the author interviews insulin pump trainers and identifies common issues that occur during a first-time pump training. The trainings are always flexible as the users have varying capabilities and motivations. The trainers commonly experience that people don't read the manual before the session or understand the terminology, e. g. what is active insulin. Also, sometimes they lack base diabetes management skills, like carbohydrate counting. Still, they try to make it work and most of the time, they are able to teach the user how to use the pump.

Mostly, the users come in for the training nervous and stressed and that's why the trainers consider a key moment when the patient feels like "I can do this". They would usually drill basic activities, like administering a bolus, and discuss safety, for example sensing and reacting to an occlusion. Some trainers think that changing the set is the most critical procedure. They also focus on explaining that an insulin pump is not a toy, and the user has to think ahead and avoid things like stacking insulin, or bolusing for low-BG-compensation food. Sometimes, the patient loses his or her attention during the training, possibly due to being overwhelmed by information and training length.

Switching from MDI to an insulin pump can be complicated, as in the beginning the amount of attendance needed is higher and gradually decreases until benefits become clearer. Also, the users tend to override pump settings in the beginning, being used to the way MDI works. Some people tend to get lost in the menu hierarchy – an 'escape' button is very useful in this case. Some users are annoyed and frustrated by the amount of button pressing that needs to be done, describing the buttons as hard to press. It can happen that a

[26] Relative effectiveness of insulin pump treatment over multiple daily injections and structured education during flexible intensive insulin treatment for type 1 diabetes: Cluster Randomised Trial (repose). BMJ. 2017. DOI 10.1136/bmj.j1285.

user is overwhelmed by alarms and ignores them all together. For some people, memorizing tasks is difficult. [27]

5.5.3 Alternative pump design, Georgia Tech

Harper in his Masters insulin pump project for Georgia Tech researched what kind of situations people experience and what technology they consider important. He found that a small wireless controller is important for many users, combined with a good system of haptic/vibration feedback alerts. In the survey, the users also mention how alarms often intrude into social situations, such as school classes or movies. Sometimes it can also be difficult to access the pump, like when driving a car. [28]

6 Device Specification

6.1 Main identified issues

Summarizing the information from previous section, I have identified the following points to be the key issues with using pumps or problems discouraging the users from trying pumps out. The identified issues were validated with Alice and Adam.

Main issues:

1. **Difficult** – It is generally complicated to learn to use the pump. The pump is considered more difficult to handle compared with the simplicity of pens.
2. **Clumsy** – The pumps are relatively big and unfashionable, and can be complicated to wear, especially during activities and sleep.
3. **24/7** – The users are afraid of having something attached practically nonstop.
4. **Unknown** – There is a fear of dealing with something foreign and unknown when considering switching to a pump.

Secondary issues:

1. **Site Issues** – Pump sites fail quite frequently, sometimes being difficult to prevent and notice. The skin gets irritated and scarred sometimes too.
2. **Spares** – Lot of pump reserve material is needed; the user is always dependent on shipments arriving on time.
3. **Price** – Depending on health insurance, the pump operation can be expensive.

6.2 Analysis of identified issues

In order to better understand how the primary issues and how they influence each other, binary relations between main issues were explored. The most important drivers were selected.

[27] Hernandez, H.B., Dringus, L.P., Snyder, M., & Wang, L. (2019). Usability Challenges with Insulin Pump Devices in Diabetes Care: What Trainers Observe with First-time Pump Users.

[28] Harper, A.: Exploring the Challenges & designing potential solutions for Insulin Pump Technologies [online]. [Accessed 20 May 2022]. Available from: https://smartech.gatech.edu/bitstream/handle/1853/63025/Harper_MSProject_Book.pdf?sequence=1&isAllowed=y.

6.2.1 Difficult vs others

If the pump is simple to use and learning curve isn't steep, it can be expected that fear of the unknown should reduce. Also, the 24/7 attachment should be more bearable knowing that one can handle various pump situations easily. However, making the device easier to use could mean increasing its size and clumsiness – for example by adding extra buttons or a display.

The issue of difficulty generally comes away after the user learns how to operate the pump, usually during weeks or months. Nevertheless, it still remains one of the main discouragements from switching to a pump. Adam noted that since he uses insulin pens and an CGM, it would be useful to make the pump user interface work similarly to his current skills and experience.

6.2.2 Clumsy vs others

The size and bulkiness of the pump can make it unpractical to be worn throughout the daily range of activities. Reducing its clumsiness could lead to the users being more willing to wear it for extended periods of time.

The reduction of clumsiness is practically limited not only by price, but also by other factors, such as usability. Alice also pointed out that a smaller pump could mean more frequent parts changes, such as battery and reservoir.

6.2.3 24/7 vs others

When the user wouldn't have to wear his pump almost all the time, the fear of the unknown should play a lesser role. Wearing the pump less could also make the user more tolerant to its size and decreased comfort. Furthermore, having an opportunity to take a rest from the pump (especially at the beginning) could make the user more accepting of mastering its difficulties.

However, Alice emphasized that frequent disconnecting should not be seen as a solution to linked problems, because the pump works the best if it is connected almost 24/7.

6.2.4 Unknown vs others

If the device wouldn't feel unknown, acceptance of the 24/7 attachment could be increased. Furthermore, once perceived as known even objectively difficult user interactions could be simple due to previous related experience.

Adam also shared that in order to accept the device, aesthetics are important. Alice recalls that when she got on the pump, she felt that pump benefits weren't explained well enough to her and that this would be very beneficial for any person considering pump therapy.

6.3 General design goals

6.3.1 Issues and Intended Use Relations

There is a risk of not including pump performance in the analysis of issue relations. For example, making the device easy to use could mean reducing the options available for diabetes management. Hence, I will add constraints from the Intended use section, control and safety.

By greater control I mean the ability of the device to administer insulin in a more flexible and/or precise way. Usually, greater control requires a more experienced user to handle it and could feel overwhelming for the new user. It would also probably mean increase in price. The effects on safety could be mixed – complicated user interaction could

result in more mistakes that would outweigh any flexibility/precision benefits. Proper control also possibly puts mechanical constraints on the size of the device.

Safety means that the device doesn't pose any unacceptable risk under intended use and expected situations. Making the device safe is necessary and could mean making it more clumsy and increase its price.

6.3.2 Statement of need

The statement of need is a part of the design process recommended by Ogrodnik to define who and why will be the user of the medical product.[29]

It appears that people can benefit from the pump significantly if they are trained properly and are motivated to do so. However, quite naturally, only those deemed responsible and involved are suggested for a pump, as it is considered a complex device requiring care and attention in order for it to have an impact and not harm. Commonly, teenagers could struggle on an MDI and skim through their diabetes management. [30] Nevertheless, it also seems that the pump can be a breaking point between bad control and proactive good control, which can especially for younger people pose a positive turning point in their lives. My goal then is to lessen these transitional barriers and produce a design for a pump, that would be and appear to be to both the users and diabetologists as simple, and consequently worth giving a shot even if the user doesn't have a good diabetes record. After gaining experience, self-confidence, and the trust of the diabetologist, he or she could progress to the current, more advanced commercial pumps.

Based on this approach and identified issues in the research, these are the design goals:

1. The young user could ignore diabetes management on MDI most of the time (e. g. not counting carbs, forgetting to bolus). The pump design shall take these people on board.
2. It will take into account and build on any previous MDI routines in order to minimize the learning gap.
3. It shall be designed not only to prevent bad decisions, but especially to help the user make good decisions.
4. The pump shall look and be comfortable to wear.
5. Any pump-related potentially socially awkward situations shall be minimized (unexpected alarms, not being able to disconnect for certain activities).
6. The benchmark is to achieve greater control than on MDI. At the same time, the pump shall be and appear to be simpler to use than an MDI from the first glance, through training, to usage.

6.3.3 Intended use

The insulin pump is a part of an invasive glucose device. The aim of the pump is to administer insulin in a safe and controlled manner to people with diabetes mellitus requiring insulin. Its goal is to also give advice in some of the typical situations a user might be in, but

[29] OGRODNIK, Peter J. Medical device design: Innovation from concept to market. London: Academic Press, 2020.
[30] WALSH, John and ROBERTS, Ruth. Pumping insulin: Everything for success on an insulin pump and CGM. San Diego: Torrey Pines Press, 2017, 301–302.

it always remains the responsibility of the user to judge whether an advice should be followed.

6.4 Specifications

6.4.1 Skill building

The software will aim to build and support gaining skills to be able to handle these situations:

1. Think ahead given current BG value and trend, IOB and other non-pump context (activity, stress, infection, sensor failure...) – where will my BG probably be?
2. How many carbohydrates, fats and proteins does this food have? How fast will it raise my BG?
3. When I approximated my future BG, what should I do with this information?
4. What should I do in a critical situation with a severe high, severe low, or a failed infusion set?
5. How should I reflect my long-term BG values and trends into my pump settings?

6.4.2 Administering insulin

When administering insulin, the software will:

1. contain a software tool, a bolus calculator, for calculating a correct dosage to cover a meal or a high BG and will account for the varying glycemic index of foods.[31]
2. adjust the recommended bolus dose for current BG, target BG, IOB, BG trends, carbohydrates, proteins and fats and glycemic index (GI).[32]
3. prevent and minimize: bolusing and missing food, eating and not bolusing, eating and bolusing but not timing the events well; (maximum 9.0 mmol/L post-meal high as a general benchmark).
4. allow the user to tell the pump if it took any other insulin than through a pump, including long-acting insulin, it will be possible to manually override current IOB.
5. let the user cancel any bolus in progress; and also stop insulin delivery in general but only for a limited amount of time and then issue warnings.
6. provide a simple way to help the user estimate food carbohydrates, proteins, and fats correctly; and deal with not entered carbs.
7. allow the user to change the speed of delivery, even to 'borrow' from future basals, max at 2.5 hours.
8. suggest an amount of carbohydrates to be eaten in case of excessive IOB.
9. consider flexibly possible solutions to a situation, e. g. reducing insulin vs. eating carbs, delaying food.

[31] WALSH, John and ROBERTS, Ruth. Pumping insulin: Everything for success on an insulin pump and CGM. San Diego: Torrey Pines Press, 2017.
[32] Ibid.

10. provide a temporary basal feature (in percentage and absolute value), limited in time (0.5 to 24 hours), temporary basal insulin underdosage or overdosage must be estimated and user warned.

6.4.3 Setting up personal metrics and basals

1. The following personal metrics shall be adjustable: total daily dose (TDD, default = 40 units), user weight (default = 65 kg) insulin sensitivity factor (ISF, default = 4.4 mmol/L), insulin to carbohydrate ratio (ICR, default = 11), duration of insulin action (DIA, default = 5 hours), basal rates; basals will be able to vary throughout the day, with 30-minute blocks.
2. The user can set multiple profiles with different basal rates and personal metrics.
3. The default setting for high BG will be 11.1 mmol/L, for low BG 3.9 mmol/L.
4. The default target range will be 4 to 7 mmol/L, and target 5.4 mmol/L,
5. There shall be maximal settings for basal rates/hour, bolus, TDD.
6. As a guideline, assuming frequent hypoglycemia or severe hyperglycemia is not present, TDD shall be used to suggest personal metrics settings. This is intended for adults and might differ for teens.
7. In case of frequent lows, total TDD shall be recommended for a raise, and settings adjustment proposed accordingly. The criteria for this shall be no severely low readings (threshold fixed to = 3.05 mmol/L) and less than 7 below a low threshold (default = 3.9 mmol/L) during the week.
8. In case of frequent (more than 7 per week) BG highs over a high target (default = 9.0 mmol/L), but without lows, a higher TDD shall be suggested.
9. The smallest rate of change for basal rates shall be 0.1 u/hour, for boluses 0.1 in dosage.

6.4.4 Other software feature requirements

1. The pump shall use 24-hour time format and mmol/L units for BG.
2. The pump will use a real time based on user set time.
3. When disconnecting (to take a shower, change a set/reservoir), the pump will ask for how long the user wants to disconnect a suggest a plan depending on the length of disconnecting. Generally, it will compensate for the missed insulin.
4. BG values, insulin doses, pump settings, set changes, carbohydrate intake, and pump settings shall be documented for at least two months.
5. It will be possible to manually enter a BG value.
6. The software will contain information regarding production and a serial number, a version, technical parameters, and other information.

6.4.5 Alarms, alerts, notifications, and information

1. Any alarms and alerts shall be maximally functional in order to minimize the risk of alarm burnout.
2. All sound alerts can be silenced, and vibrations weakened for a specified duration.
3. A low alarm shall be issued at 3.1 mmol/L automatically.
4. When issuing a low/high alarm it will wait some time before reissuing it.

5. The user must have access to information about the battery level, and the amount of insulin remaining, at least roughly, and shall be alarmed when any of them goes low.
6. The user must be alarmed in case of power failure.
7. If the pump thinks there will is a set failure, it will alarm the user.
8. The software shall be able to remind at least: set changes, meal boluses.
9. CGM, and generally BG data, must be viewable.
10. Key metrics shall be viewable, such as average TDD and TIR.

6.4.6 Hardware requirements

1. The pump must have these parts: battery, refillable reservoir, microprocessor, audio beeper, vibration generator, Bluetooth module, button for manual insulin delivery and a control button.
2. The pump shall have sensors to monitor the following: reservoir level, battery level.
3. The immediate surroundings of the insulin reservoir must not fall under2 degrees Celsius or pass 32 degrees Celsius for 5+ hours. However, it can temporarily heat to 37 degrees for max 3+ hours.
4. The pump will deliver insulin with precision at least 0.1 units +- 5%.
5. The actual insulin delivered over time has to be at least +- 5% correct.
6. The pump should be big maximally 4x7x1 cm, ideally smaller, the goal is to approach a CGM sensor size-wise.

6.4.7 Safety requirements

1. Hypoglycemia has to be prevented and the user must be warned about it.
2. The pump will track and display active insulin in body (insulin on board– IOB) in order to prevent insulin stacking.
3. In case of hypoglycemia, the pump will recommend how many carbs to eat and how often.
4. Hyperglycemia must be prevented and the user must be warned about it.
5. The pump shall detect insulin delivery failure, especially for occlusion and leakage, using both BG values and mechanical sensors.
6. In case of an infusion set failure, there shall be a simple way to inform the pump manually, which shall in turn suggest a plan and a coverage dose.
7. If the BG shall be rising, or falling rapidly, the user shall be alarmed and recommended what to do.
8. In case the pump wasn't operated by the user for more than 12 hours, it will automatically switch off.
9. The pump will check if incoming CGM data are missing and warn the user in such case.

6.4.8 MDR Requirements

As listed above, MDR requirements also have to be fulfilled.

7 Proposed Solution

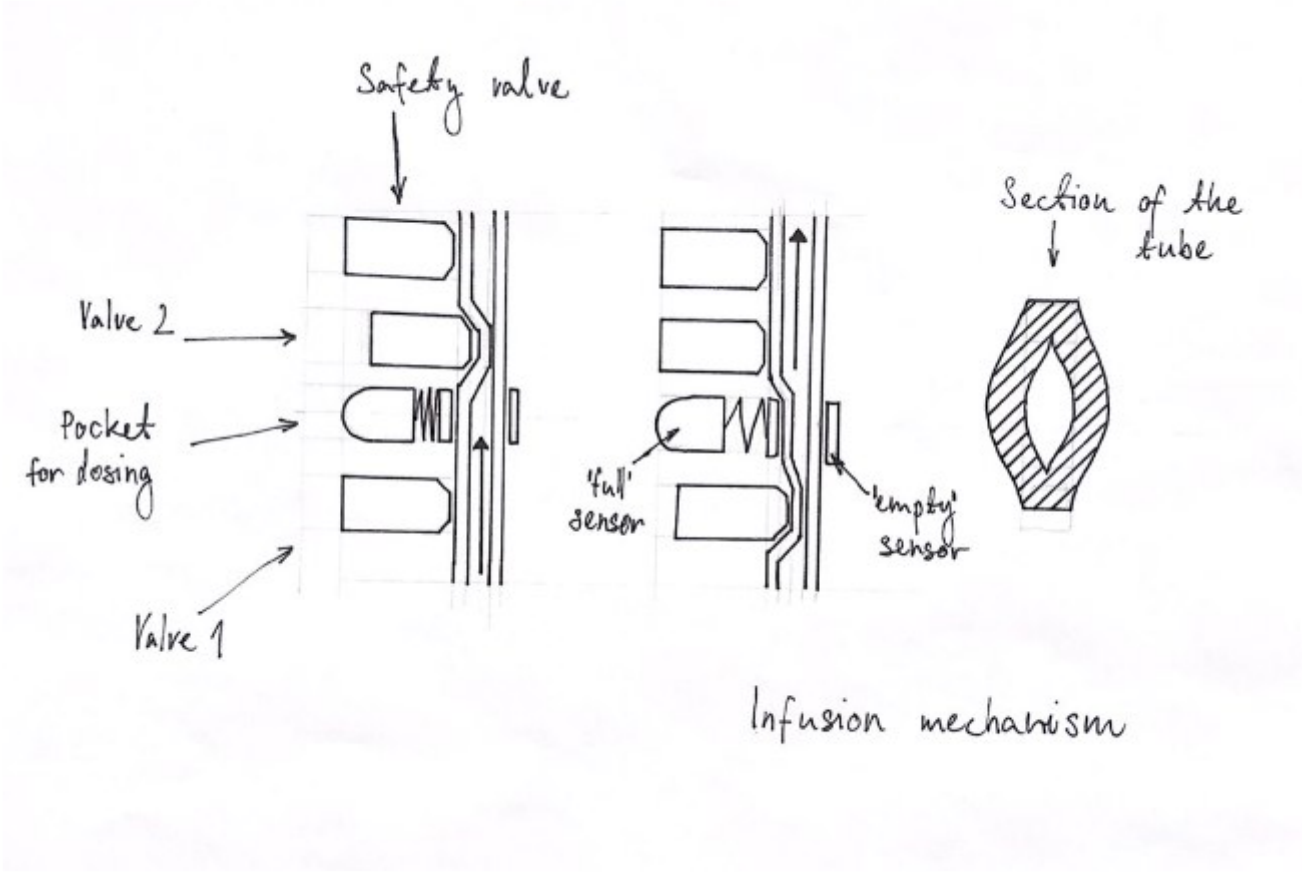
Based on goals stated above, the general approach of the solution is in two main areas – reduce the pump size and propose a system that would help the user learn to manage different pump situations quicker.

Apart from the display, the first issue arises mostly from the fact, that pumps have a piston delivery system powered by a motor or a rotational mechanism in general. This puts practical constrains on size. The second problem is possibly because pumps interact with the user as if he or she was already experienced with handling them.

As a general framework, the system will be composed of 3 units – a CGM, an insulin patch pump and a phone controller.

7.1 Hardware concept

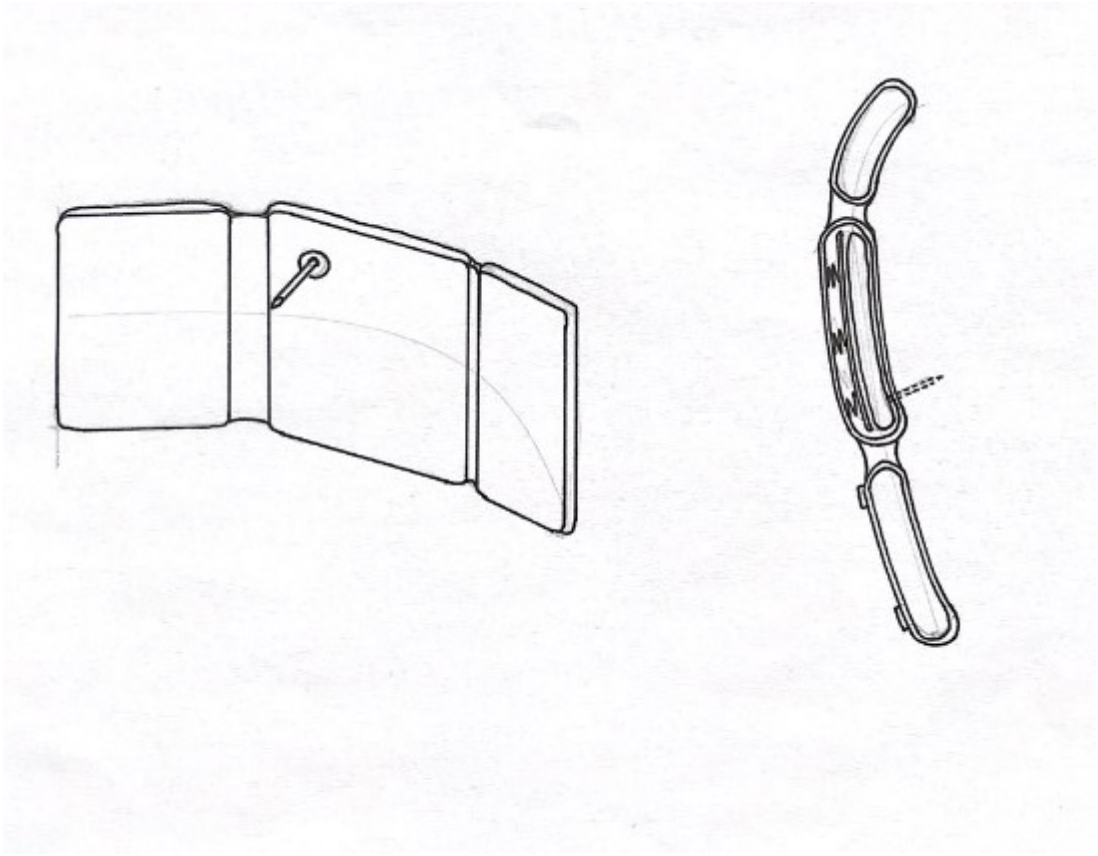
The patch pump will be divided into three functional parts – electronics, infusion, and battery. The alternative infusion system works as a combination of valves and a dose pocket and a self-emptying reservoir.



The insulin is forced to the tubing in the direction of arrows from a reservoir. In each operation, the pocket is filled and emptied, which is governed, by a forcing spring mechanism and the two sensors that sense pocket's state. The two valves serve as gates to the pocket. The biggest risk of this mechanism is that when both valves would open or leak, then insulin would be pushed without restraint into the user, which could pose a deadly risk. Another limitation of this system is that delivery is fixed to a constant discrete dose, but I will attempt

to handle this in the software system. That is why there is a safety valve that would get activated in the hazardous situations. The valves could possibly be controlled with shape memory alloys or electromagnets.

Nevertheless, this mechanism should allow the pump to become considerably flatter as shown in the following figure.



The pump would be reusable and hence would use an infusion set with an adhesive and a cannule to which it would attach to. When changing the infusion set, only the bottom part (on the left in the figure) would be disposed of. In theory, with an adapted infusion set, it would be also possible for the pump to be tubed. The right side of the figure shows a cross-section of the pump. The central part contains a reservoir and the regulative mechanism (not shown in the device), the bottom part would contain electronics and user control buttons, and the top part the battery.

7.2 User interaction – block overview

This section describes how the pump should function to allow for more intuitive and helpful user control, the second branch of the solution. The pump shall be display-less, and the separate controller will be based on a regular phone device. Phone-like wireless controllers have much better user control capacities and the user can rely on already gained skills with using his smartphone. Furthermore, the potential to connect to the internet and utilize other diabetes information and tools is enormous – all in one device. The CGM will pair directly with the pump and the pump in turn will send complete information to the phone controller and receive commands (bolus, temp basal...) from it. Additionally, the CGM may pair also with the phone.

The operation of the system can be subdivided into two areas –routine and special processes. The core concept of routine is to mimic a standard decision process and guide the user through it repeatedly. Specifically, it contains these procedures:

1. Observation – Given BG value and trend, IOB, (future) food on board, (future) activity, stress, illness (...), where it will probably be in 2 hours? The output options are – I will probably be low/high/OK/emergency. If the current BG is already high or low, what should I do now?
2. Decision – What will I do with the observation? The pump should list options and possible values, taking into account short term (less than 1 hour) and long term (1+ hours) options.
3. Deliver – Choose and action a specific decision. This includes bolusing, setting a temporary basal, canceling insulin delivery or eating carbs; or any combination of these.
4. Review – Check whether an action (or generally the pump) is working. From the users perspective, this is close and software-wise identical with the Observation.
5. Auto-monitoring – Throughout operation, the pump will evaluate if the BG is running as expected, especially after bolusing; check CGM validity, highs/lows, test infusion set, battery and reservoir levels...

Special procedures contain:

1. Emergencies – hypoglycemia and hyperglycemia alarms (both with protocols and recommendations)
2. Settings – as defined in the settings section of specifications.

7.3 Phone Control User Interface

The following subsections describe user interface on the phone controller.

7.4 Observation

The basic conception of the screen shall be the following.
Top status symbols...
Top: “What will my BG do in the following two hours?”
Middle left: Graph with BG values, and selected actions (bolus, temp basal...). An arrow will be drawn at the last point projecting the current rate of growth to help the user estimate short-term views.
Middle right: Three buttons in column: High, OK, Low. These will lead to the “Decision” procedure. The buttons correspond to the graph parts. Bottom:

1. “Did my previous actions work out?”
2. “Isn’t my insulin on board excessive? (Arrow down) (IOB value and time?)”
3. “Will I be eating/have I eaten? (Arrow up)”
4. “Will I be active/have I been active? (Arrow down)”
5. “Anything else? Stress (Arrow up), illness (Arrow up)”

An emergency button shall appear, instead of the regular low/high, if BG values are beyond a critical range. This will take the user straight to the corresponding emergency

screen. The graph screen shall be enlargeable and movable. In the morning it shall give an overview of night BG values. The user (or the doctor?) potentially could change the questions to his own.

7.5 Decision

Depending on which section (Low, OK, High) the user presses, a set of short time and long-time recommendations will appear on the screen. There shall be a button to the 'Action' screen, and 'OK' button which will return user back to the previous (home) screen.

7.5.1 Low

First, the question: "I'm I low right now or will be within an hour, or will it come probably later?"
"Right now, or soon: Consider eating approximately 15 grams of quick carbohydrates (an apple) or reducing temporary basal."
"Later: Consider setting a temporary basal rate to 80–95%, eat longer acting carbs."
"You can also think about cancelling any excessive running bolus."

7.5.2 High

Same question as above but replacing 'low' with 'high'.
"Right now, or soon: Consider delivering a correction bolus, or raising a bolus for food (by approx. 15 %?).
"Later: Consider setting a temporary basal rate to 105–120% In both cases,
you can also consider increasing activity.

7.6 Deliver

The deliver part will serve to manage bolus, temporary basal delivery, possibly get recommended carbs to eat or to cancel insulin delivery.

7.6.1 Food bolusing modes

Standard bolus delivery delivers a particular dose of insulin in a very short time window, practically immediately. However, sometimes it might be beneficial to deliver part of the bolus now and a part gradually during a given timespan – a combined bolus (CB).[33] The user will be able to select with sliders how many percent of the dose (0–100%) will be delivered later and the corresponding time window (1 hour to 4 hours). This delayed bolus part will be converted to a temporary basal increase to utilize existing tools efficiently.

Other bolusing scenario, 'a basal-borrowing bolus', is when a lot of insulin is needed to be delivered as soon as possible without later overdosing, for example to cover a quick acting carbs food. The solve this, the user can take future basal insulin, up to two hours, based on the current rate (including temporary changes) and add it to the standard bolus and cancel basals for the same amount of time.[34] The user will have a slider (0–100%) that will allow him or her to set the amount of future basal to borrow.

[33] WALSH, John and ROBERTS, Ruth. Pumping insulin: Everything for success on an insulin pump and CGM. San Diego: Torrey Pines Press, 2017,
[34] Ibid.,

7.6.2 Food bolus timing

For food bolusing, it is generally important to handle timing well. If BG is normal, 20 minutes before food is generally an ideal time to start a bolus dose. [35] However, the user should be flexible and adapt the dosage if his or her BG is low or high.[36] Forgetting to bolus can be solved by issuing a bolus reminder but people with erratic schedules might find it difficult to pinpoint a time when they will eat. The potential solution to this problem is to deliver a portion of the food covering insulin beforehand and a portion of it later. The situation should work as follows:

1. At a selected time, usually hour or two before estimated lunch time window, issue a 'food coming' notification to the user.
2. In the notification, the pump will suggest to the user: To raise his basal rate (for the following one hour, which will be fixed), but when doing so, consider his current BG trend and value. The user is reminded that it is best to deliver bolus 20 minutes before the meal.
3. After an hour passes, if the user didn't bolus yet, the pump will issue an alarm and cancel basal delivery for the next 3 hours or until the extra basal insulin matches the canceled insulin, whichever limit is hit first.
4. If the user boluses within the hour, the temporary basal rate gets cancelled with the bolus. If he or she boluses during within three hours from the initial notification, any extra basal insulin will be subtracted from the estimated bolus.

7.6.3 Bolus calculator

The 'Deliver' section will be also connected to a food database that will also contain carbohydrate counts. This is expected to help especially beginners to learn carbohydrate counting by example instead of having to rely on their own counting or unsorted internet resources. The database will also include the glycemic index of foods, so that insulin could be delayed (combined bolus) or hastened (basal-borrowing bolus) as needed. By default, the pump will consider that the user boluses 10 minutes before the meal. If the CGM is broken, you can manually enter a BG value. The user can override any recommended insulin amount. The net amount of insulin to be delivered with the bolus N is calculated as follows:

$$N = \frac{C_1}{ICR} - \frac{BG - G}{ISF} - BolOB - EBasOB \quad (1)$$

Where C_1 is carbohydrate input, G is target BG, *BolOB* is bolus insulin on board and *EBasOB* is extra basal insulin on board. If N is positive, then this is the amount of bolus to be delivered. If N is negative, then it is calculated as the amount of carbs the person should eat extra to inputted carbs:

$$C_2 = -N \cdot ICR \quad (2)$$

[35] COBRY, Erin, MCFANN, Kim, MESSER, Laurel, GAGE, Victoria, VANDERWEL, Brandon, HORTON, Lauren and CHASE, H. Peter. Timing of meal insulin boluses to achieve optimal postprandial glycemic control in patients with type 1 diabetes. Diabetes Technology & Therapeutics. 2010. Vol 12, no. 3p. 173–177. DOI 10.1089/dia.2009.0112.

[36] WALSH, John and ROBERTS, Ruth. Pumping insulin: Everything for success on an insulin pump and CGM. San Diego: Torrey Pines Press, 2017.

7.6.4 Correction bolus

If the user enters zero carbohydrates, it is considered a correction bolus, governed by the same mathematics as above.

7.6.5 Temporary basal

A core feature of insulin delivery is the temporary basal rate. The user will be able to see the currently running (temporary) basal rate. By either sliding the percent bar or absolute value bar can set a temporary basal rate. The above-mentioned boluses will automatically set the values in this section.

7.6.6 Organization of items on the screen

This Deliver section contains many features and they should be well-organized. From top to bottom:

1. Select food: (a typing space)
2. How is my portion big: (slider – 0–200%, default 100%)
3. Carbohydrates: (automatically filled in from food)
4. BG: (automatically filled in from CGM)
5. Target: (automatically filled in from settings)
6. Extra Basal on Board: (automatically calculated)
7. Bolus on Board: (automatically filled in)
8. Recommended bolus insulin: (calculated based on the information above)
9. Recommended extra carbs: (calculated based on the information above)
10. Deliver later: (slider 0–100 %) – if this is non-zero, the next point is
11. Later time: (slider 0–100 %)
12. Temporary basal: (current value and two sliders (in percent and in absolute value)
13. Confirmation button.

7.7 Emergency

The emergency screen will contain these sections – severe high, severe low, infusion set failure. It should cover base emergency situations and how to handle them.

7.7.1 Severe high

1. Drink water, 300 ml every 30 minutes (Set reminder).
2. Bolus correction insulin. If you think your infusion set is bad, use pen insulin and then change the set.
3. If you can, measure blood ketones. If they are over 1.5 mmol/L, contact your doctor. If they over 3.0 mmol/L, call an ambulance.
4. Once BG falls below 11.1 mmol/L consume 20–30 grams of carbohydrates and cover them with bolus. (This decreases blood ketones)

7.7.2 Severe low

1. Don't overeat. Use the 15–15 rule.
2. Eat 15 grams of carbohydrates (half of cup of a sugar drink, 1 tablespoon of honey or sugar)
3. Wait 15 minutes. Then check BG.
4. If BG is still low, eat again 15 carbs, and wait 15 minutes.

This section will also include a 15-minute timer to help the user track time more easily.

7.7.3 Infusion set failure

1. Go to the change set guide.
2. Give a standard correction bolus.
3. Check after 2 hours if the new set works. (Button – remind me to).

7.8 Stats and Settings

Every time the user enters settings, it can be useful to have relevant statistics at the same place to help make meaningful changes. After displaying statistics, settings come, some with suggested changes. Any settings changes will be sent directly to the pump and their acceptance confirmed.

7.8.1 Stats

As Walsh describes in his book, it is important to consider 'out-of-range' episodes – very low, low and high. Base values are 3.05, 3.9 and 9.0 mmol/L. Anytime 3 consecutive BG values pass the threshold, a +1 count and a timestamp based on the first values is added to the corresponding category. The counting will snooze the category for 30 minutes after adding a new count to it. The result will be information of how many extreme lows/lows/highs the user experienced during a given time frame and can be further used for settings adjustments. Weekly counts will be the default unit. These counts should be a robust estimate of how an average week looks like, therefore the best and the worst day in each category will be cut of and substituted by the remaining average.

For a complete overview, time in range with high, low and extreme low sections will also be viewed.

The second important piece of information is TDD and its components basals, carbohydrate boluses and correction boluses. Based on average TDD, a new TDD can be set and consequently ICR and ISF changed.

7.8.2 Basal Settings

Based on the TDD, according to Walsh, average basal rate is estimated as avgbasal = 0.02*TDD. The user will be notified of how much will his TDD raise both in units and percentage if he makes any changes to basal rates, based on last week of data. The user will be able to edit multiple basal profiles in this section and selected a one to activate.

7.8.3 Target and Range

Next, the thresholds for low and high and also screen visualizations are set. The minimum for a low will be 3.05 mmol/L, the maximum for a high will be 12.0 mmol/L, and

the low has to be lower than the high threshold. The user will also set a target that will be used for bolusing.

7.8.4 Settings – ICR, ISF and others

The first setting that is core and might change in the beginning is TDD in units of insulin. From it, default values for ICR and ISF are estimated by these formulas:[37]

$$ICR = ICR_{study} \cdot \frac{2.2 \cdot m \cdot s_{study}}{TDD} \quad (3)$$

where ICR_{study} = 10.8 is the average ICR from the study participants, s_{study} = 0.24 is average study insulin sensitivity per pound of weight, m is user weight in kilograms. The numerical constant is for kg to pound conversion.

$$ISF = \frac{F}{TDD \cdot 18} \quad (4)$$

where F = 1960 is correction factor rule number in mg/dL and the numerical constant is to convert it to mmol/L.

The user can change these values anytime he or she wants and always revert to default values.

DIA is usually underestimated according to Walsh and should be generally set to circa 5 hours.

The maximal basal rate will be 2.0 u/h by default, max. 20 u/hour – this will affect all basal rates, temporary basal rates. Maximum bolus by default 10 u, max. 20 u.

7.8.5 Personal information

Weight, age and other attributes of the user can be set here and be used for a better estimation of parameters. However, these are not utilized yet in this scheme.

7.9 Pump control unit architecture

The following subsections describe the software architecture on the pump control unit. The pump receives CGM data every 5 minutes and with a new BG data point does a system check, evaluates if the user should be alarmed. Every hour, the pump and the phone exchange data unless immediate exchange is needed.

7.10 System check

The pump will periodically check the system status, BG and its trends. The alarms will have three levels of urgency – high, middle and low.
The high alarm will make the pump beep and repeatedly vibrate.
The middle alarm will repeatedly vibrate.
The low alarm will vibrate once.

In all cases, information will be sent to the phone controller. If multiple alarms should be issued, only the highest priority alarms will get sent. Alarms can be also silenced to pass only high-level alarms.

[37] WALSH, John and ROBERTS, Ruth. Pumping insulin: Everything for success on an insulin pump and CGM. San Diego: Torrey Pines Press, 2017.

7.10.1 BG validity

If there is no BG value received, BG related check will be skipped. If the last BG value received was 45 minutes or older, a high-level alarm will be issued.

7.10.2 Delivery failure

If the user issued a correction bolus, the BG should have a downward trend after 120 minutes, when insulin activity peaks. If this doesn't happen, a delivery occlusion could be under way. In case yes, this is a middle level alarm.

7.10.3 Temporary commands

Check if any overriding of settings – alarm silence,.. – finished, and if yes, reset it to base settings. Issue an immediate confirmation of any changes to the phone controller.

7.10.4 BG values and trends

If a BG value surpasses a threshold (either low or high), an alarm output will be issued. High level alarm for severe low, middle level alarms for the other cases. Similarly for BG trends.

7.10.5 Insulin and battery

Insulin and battery levels will be checked, and if they drop below 20% of maximum, a middle level alarm will be issued.

7.10.6 IOB tracking

The pump will track basal and bolus IOB separately based on actually delivered insulin and send it to the pump controller. The model to estimate insulin on board will be a logistic curve dependent on the duration of insulin action (DIA). It will be fixed to be 0.99 at $t = 0$, and 0.01 at $t = DIA$, where t is time.

$$IOB = \frac{-1}{1 + e^{-\frac{2}{DIA}\ln(99)(t-\frac{DIA}{2})}} + 1 \qquad (5)$$

Both parts of IOB will be reported to the pump every 30 minutes they will be compared with the target IOB.

7.10.7 Auto-off

Whether user interacted and when is sent automatically every hour. If more than 12 hours passed, the pump will issue an alarm.

7.10.8 Special circumstances

In case of a power failure, very low battery (5%), or very low insulin, high level alarm is activated outside regular checks. If power failure is the case, delivery valves are forced closed.

7.11 Insulin delivery

In this subsection, basal and bolus delivery is described along with the micro dosing operation. The maximum number of cycles is set to 360 per hour, in 10 second intervals.

7.11.1 Basal delivery

As the system will have 0.1 u fixed delivery, it will mainly deal with the period of delivery of these 'micro doses'.

Basal rates will function in 10 second blocks (360 per hour). The base cycles/hour will be calculated:

$$T = round(\frac{c * 360}{r}) *_{10} \quad (6)$$

where T is the micro dose period in seconds, c = 0.1[u] is the micro dose constant, r[u/h] is the hourly basal rate, 360 is the maximum number of micro dose basal cycles per hour.

Since the dosing is discreet and not continuous, the software will have to correct the amount of insulin delivered in real time. Insulin is still relatively slow acting and therefore its precise timing in basal rates isn't as important as the total dose. The software will use the following algorithm to manage the error circa every 15 minutes. First, calculate new error:

$$\epsilon = A - T + \epsilon_{old} \quad (7)$$

Where A is actual insulin, T is target insulin during the last time segment (circa 15 minutes), and epsilon is the previous segment error. If the new error surpasses 0.1, issue an extra micro dose as soon as possible. If the new error is lower than -0.1, skip the next planned micro dose.

When the basal rate changes, there will be a forced update of error, but no corrections shall be issued.

When the user wants to suspend insulin delivery, this will be issued as a temporary basal command set to 0 u/h and a cancel bolus command.

7.11.2 Bolus delivery

The standard bolus will be delivered with a 2-minute delay to let the user cancel it in time if he or she has bolused by accident.

As explained above, the pump software will treat the deliver-later bolus part as a temporary basal increase. The phone controller will calculate the corresponding hourly rate as total units divided by the bolus delivery time. This combined bolus rate will be added to the existing temporary basal rate and a new resulting temporary basal rate will be issued. That means it will increase the micro dosing frequency. It will also send a future command to resume any previous temporary basal rate once the bolus is delivered.

For the basal-borrowing bolus, the phone controller will do the calculations and send a zero temporary basal rate for the specified time and a bolus command.

For each scenario, the phone controller will also send an information regarding which scenario is happening so it can be identified properly. Otherwise, a temporary basal rate unrelated to a bolus would look the same as the one that does.

7.11.3 Micro dose operation

The micro dosing operation consists of the following steps:

1. Check that both valve 1 and valve 2 are closed.
2. If valve 2 is closed, open valve 1.
3. Wait, until the dose pocket is full. During this process check that valve 2 is still closed.

4. Close valve 1.
5. If valve 1 is closed, open valve 2.
6. Wait, until the dose pocket is empty. Frequently check that valve 1 is still closed.
7. Close valve 2.
8. Check that both valve 1 and valve 2 are closed.

If there is an error in any of these steps, all valves are force closed and an alarm issued.

7.11.4 Pump History

Detailed history should be stored mainly on phone, the pump will only store the following information. The error states, hourly state of the pump, amount of insulin delivered during each hour, basal rate changes, blood glucose values, exchanged commands and messages with the phone controller.

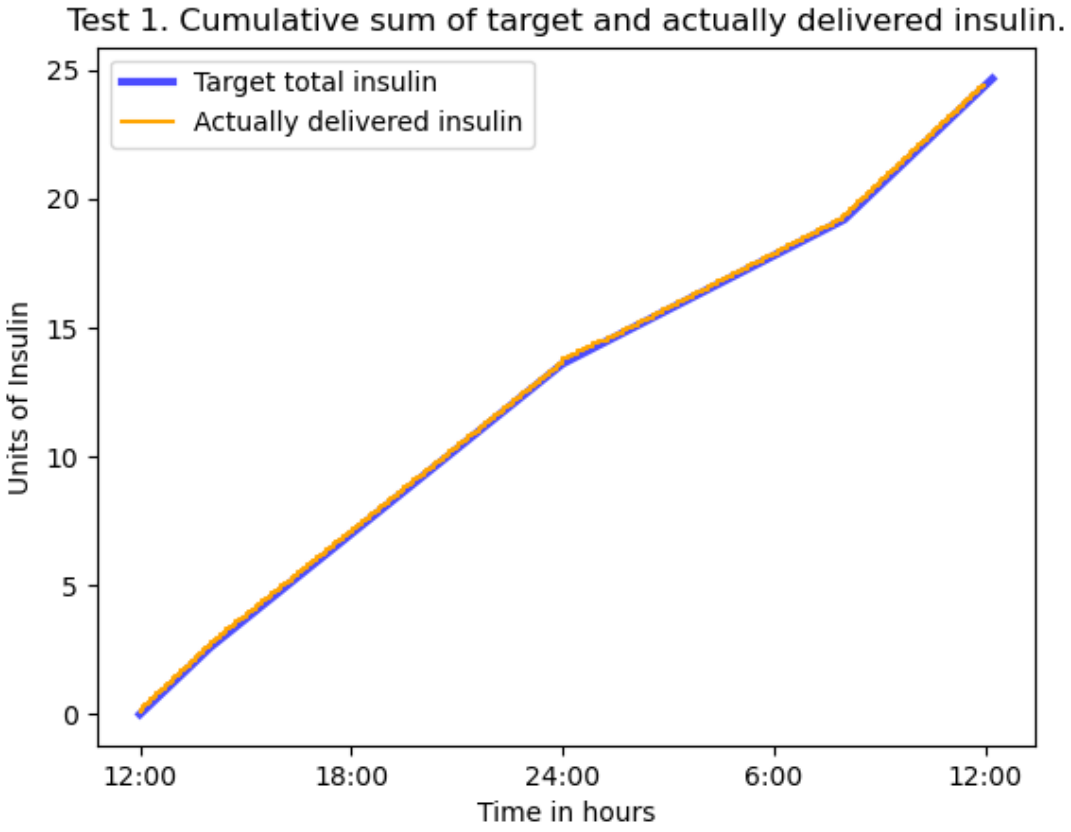
8 Implementation and testing

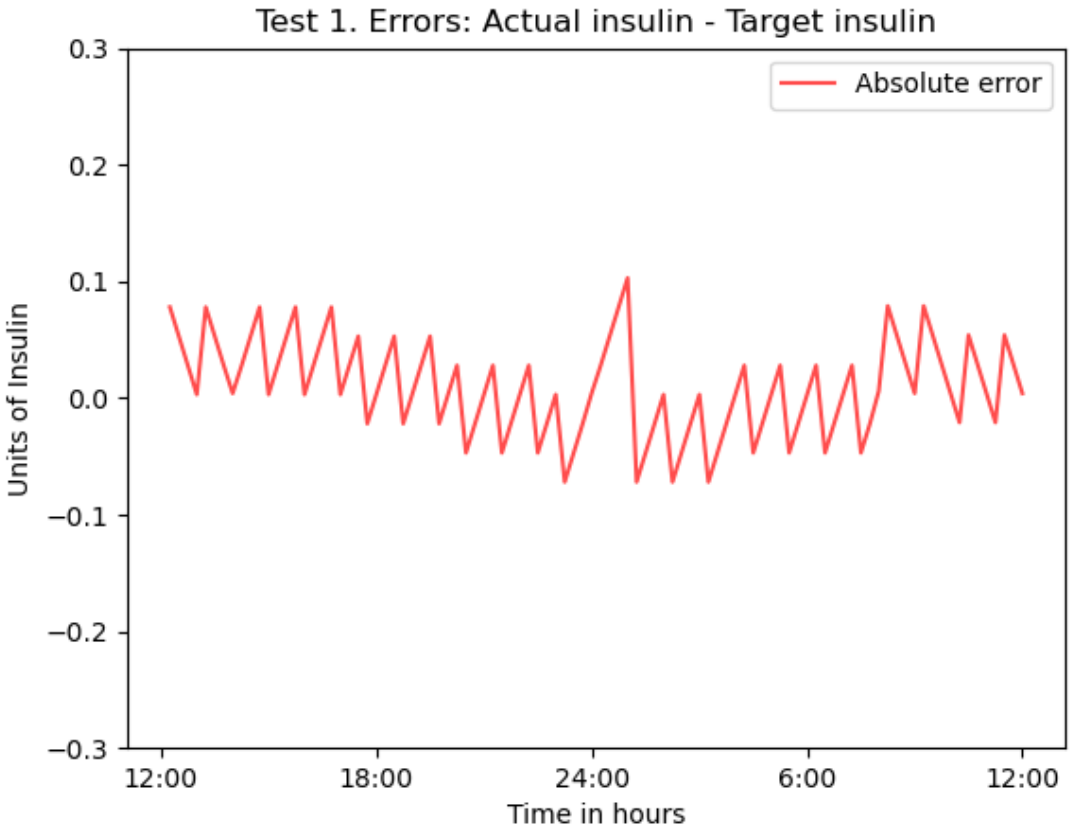
The planned basal delivery and micro dosing operation was developed in the programming language Python, version 3.9, and tested as documented below. The only library used was the time library.

8.1 Test 1: 3 basal rates

For testing regular operation, 3 basal rates 0.7, 1.3 and 1.1 u/h with end times at 8:00, 14:00 and 00:00 were selected. The simulated start time was at 12:00 and the simulation ended at 12:15 the next 'day'. The following figures display the total insulin delivered through time and the absolute error through time.

As can be seen, the current error is contained within the -0.1, 0.1 boundary and the delivery curve matches the target curve very closely.

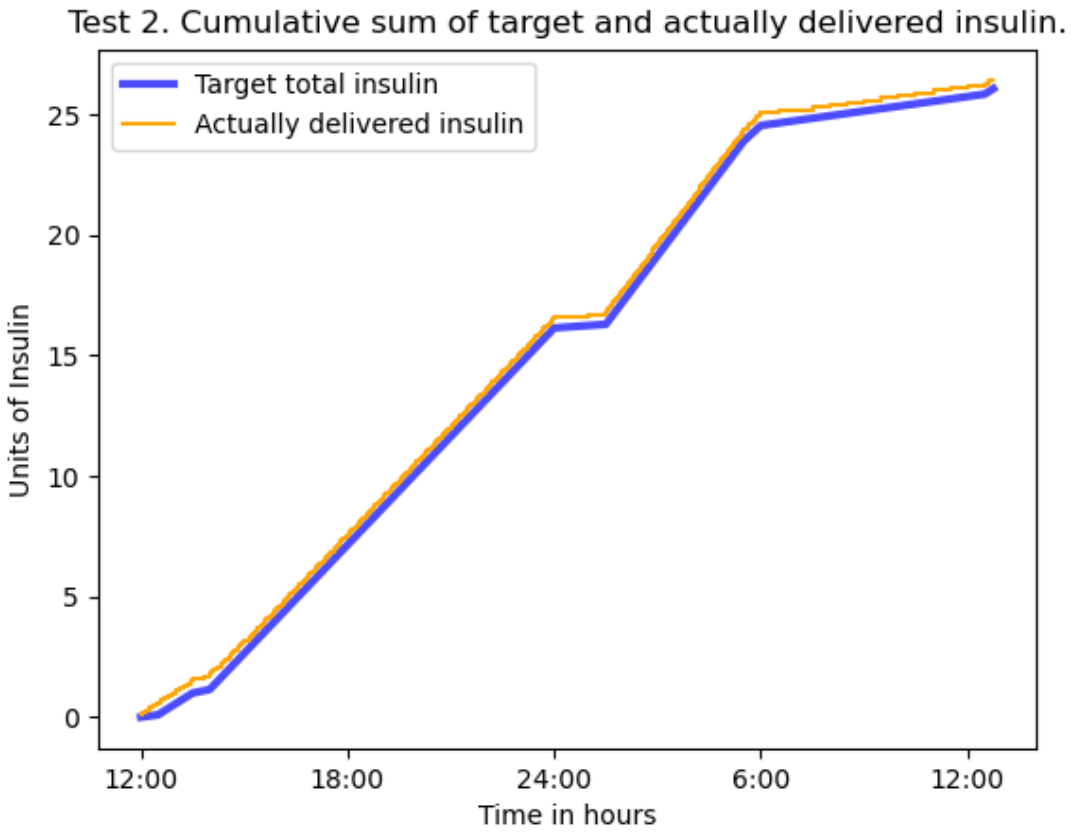

Test 1. Cumulative sum of target and actually delivered insulin.
Target total insulin
Actually delivered insulin
Units of Insulin
25
20
15
10
5
0
12:00
18:00
24:00
6:00
12:00
Time in hours

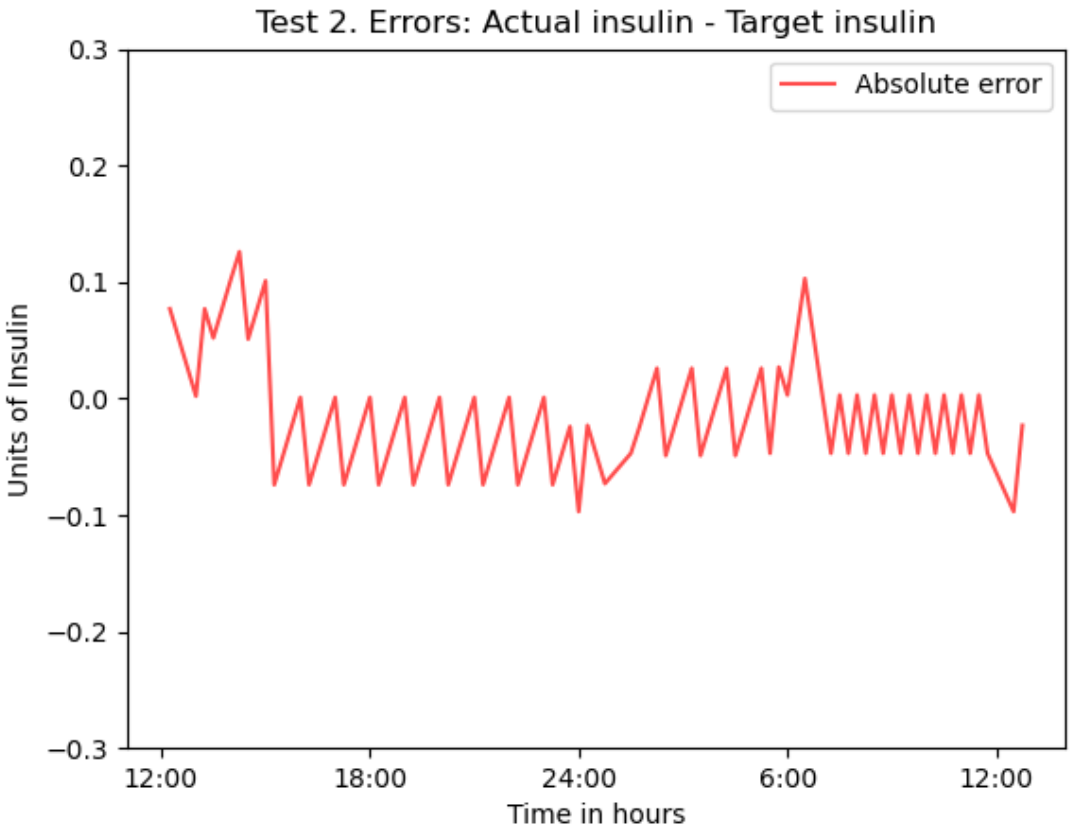

Test 1. Errors: Actual insulin - Target insulin
Absolute error
Units of Insulin
0.3
0.2
0.1
0.0
−0.1
−0.2
−0.3
12:00
18:00
24:00
6:00
12:00
Time in hours

8.2 Test 2: 7 basal rates

As a more complicated scenario, the following rates were chosen: (0.1, 1.9, 1.3, 0.2, 0.9, 0.3, 1.5) with end times (1:30, 5:30, 6:00, 12:30, 13:30, 14:00, 00:00). The timespan was selected from 12:00 to 12:45 the next 'day'. The figures have the same meaning as figures from Test 1.

Unlike in the case before, there is a tendency to over-deliver insulin in the short parts with a slower rate, with the cumulative error getting bigger at basal switches. The final error was slightly over 0.3 units, which isn't fatal but still requires optimization.





9 Conclusion

In this thesis, the insulin pump user experiences were explored, and issues identified from them. A target group of young people with Type 1 Diabetes on MDI was identified as potential beneficiaries of an insulin pump redesign. To address this group, two new approaches were presented - a 'guiding' pump software and a delivery mechanism that can be made flat. A part of the requirements defined was programmed and tested in a simulation.

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