Translational Engineering Forum

Project Title: SugarSense

Team Members

Md Mashrur Sakib Choyon
Rashid Ahmed Rifat
Alaa Abdalla
Navaneeth Paliath
Sivakumar Harish

Contents

Aalto-yliopisto

Aalto-yliopisto

Abbreviations

NCGM: Non-Continuous Glucose Monitoring, **CGM**: Continuous Glucose Monitoring, **SMBG**: Self-Monitoring Blood Glucose, **PCB**: Printed Circuit Board, **MEMS**: Micro-ElectroMechanical Systems, **FMEA**: Failure Mode and Effect Analysis

1. Background

1.1 Diabetes – Definition, cause, and symptoms

Diabetes is a long-term illness that inhibits the body's ability to convert food into energy. Most of the food we eat gets converted to sugar and released into our circulation. When blood sugar levels rise, the pancreas is prompted to release insulin. Insulin functions as a key, allowing blood sugar to enter body cells and be used as energy. When a person develops diabetes, their bodies either don't produce enough insulin or cannot utilize it as effectively as they should. Too much blood sugar persists in the bloodstream when there isn't enough insulin or when cells cease responding to insulin. This can lead to significant health issues like heart disease, eyesight loss, and renal illness over time [1].

There are 4 types of diabetes: Type1, type2, gestational, and prediabetes. Type 1 diabetes cause is an autoimmune reaction that prevents the body from producing. Type 1 diabetes affects around 5-10% of people with diabetes. Its symptoms might appear suddenly. It's primarily found in children, teenagers, and young adults. If a person has type 1 diabetes, one needs to have insulin daily to stay alive. No one knows how to avoid type 1 diabetes right now [2].

In type 2 diabetes, the body cannot utilize insulin and maintain appropriate blood sugar levels properly. About 90-95% of people with diabetes have type 2. It takes many years to develop and is usually diagnosed in adulthood (but more and more in children, teens, and young adults). Since symptoms may go unnoticed, it's critical to have one's blood sugar checked if they're at risk. Type 2 diabetes can be avoided or delayed by adopting a healthy lifestyle that decreases weight, eats healthy foods, and stays active [3].

1.2 Statistics

Diabetes affects 422 million people worldwide, up from 108 million in 1980. Low- and middle-income countries have seen a faster increase in prevalence than high-income countries. Diabetic retinopathy, kidney failure, heart attacks, strokes, and lower limb amputation are all common complications of diabetes. There was a 5% increase in diabetes-related premature death between 2000 and 2016. Diabetes was the tenth largest cause of mortality in 2019, with an estimated 1.5 million fatalities caused directly by the disease. Diabetes is predicted to affect 463 million people worldwide in 2019, accounting for 9.3% of the global adult population (20–79 years). In 2030, this number is predicted to rise to 578 million (10.2 percent) and 700 million (10.9 percent) by 2045. Diabetes is predicted to affect 9.0 percent of females and 9.6 percent of males in 2019, as shown in Figure 1. Diabetes prevalence rises with age, with a prevalence of 19.9% (111.2 million) in adults aged 65 to 79 years [4].

Aalto-yliopisto

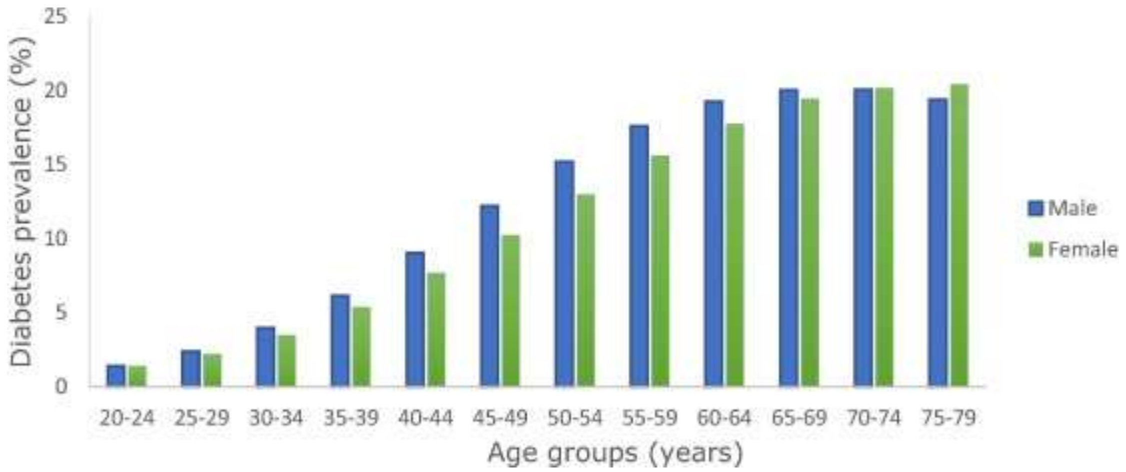

Figure 1. Diabetes prevalence in 2019 [4]

The most important thing one can do to manage type 1 or type 2 diabetes is to monitor the blood sugar levels on a regular basis. One will be able to see what causes the statistics to rise or fall, such as changing the diet, taking medicine, or exercising. With this information, patients and their healthcare team can decide on the optimal diabetes treatment plan. The doctor will determine when and how often the blood sugar levels are to be monitored [5].

1.3 Methods for blood sugar level monitoring

Whole blood, plasma, or serum (Serum and plasma both come from the liquid portion of the blood that remains once the cells like RBCs, WBCs, and platelets are removed) samples can all be used to assess glucose concentration, although the last two are preferred because whole blood values are typically 15% lower due to the high-water content in the blood cells. Standard procedures necessitate a specific volume of blood, making them invasive. Glucose measurement was initially only possible in laboratories due to glucose's reducing and condensation properties, but problems with non-specificity, toxicity, and cross-reaction with other drugs quickly drove them out of clinical use. Current methods rely on enzymatic and hexokinase procedures. While both provide excellent levels of accuracy, specificity, and minimal cross-reaction, the enzymatic approach is preferred for point-of-care and home monitoring due to its simplicity and relative price [6].

1.3.1 Laboratory techniques

The preferred methods for testing laboratory blood glucose concentrations are based on enzymatic reactions. It has reasonable specificity and sensitivity and can detect a wide range of glucose values. Laboratory testing forms the benchmark for glucose measurement because it is more accurate than home monitoring techniques. Furthermore, using different reagents or combined procedures, most laboratory equipment can detect and measure other sugar derivatives and chemical constituents, including lactose, methanol, and hydrogen peroxide; however, this is not included in this paper. The main disadvantages of laboratory methods include their inherent invasiveness. All of these methods require in-vitro testing, which necessitates the collection of blood samples from patients; the need for trained laboratory personnel, which adds to the cost; and long wait times for laboratory results.

1.3.2 Home monitoring techniques

Non-continuous glucose monitoring (NCGM) and continuous glucose monitoring (CGM) are the two types of devices designed for personal usage and self-assessment. NCGM devices, as the name implies, are used to monitor glucose levels only at particular times throughout the day, with the frequency varying depending on the person's diabetes type, food, medication dosage, and clinical state. On the other hand, CGM devices can automatically check glucose levels every few minutes, allowing for the monitoring of rapid changes and trends that SMBG testing cannot. Nonetheless, both systems' accuracy and reliability make them acceptable for use in point-of-care and self-assessment scenarios.

1.3.2.1 Self-monitoring blood glucose – SMBG

SMBG devices are the standard glucometers that require a lancet puncture to access capillary blood. After that, the glucose measurement method is essentially the same electrochemical methodology as before. The primary distinction is that the entire reaction and detection takes place in a glucose test strip coupled to a meter. Following the placement of a drop of blood on the test strip, the glucose oxidizes in the presence of an enzyme, resulting in the production of a certain amount of current proportional to the glucose level. The electrons are then sent to a meter with a current-to-voltage converter, which generates a voltage proportional to the glucose level. The enzyme is combined with three electrodes on the test strip, as shown in Figure 2. The working electrode detects the reaction's real current; the reference electrode maintains a steady voltage concerning the working electrode to facilitate the chemical reaction, and the counter electrode provides current to the working electrode. On the other hand, new designs just require the working and reference electrodes.

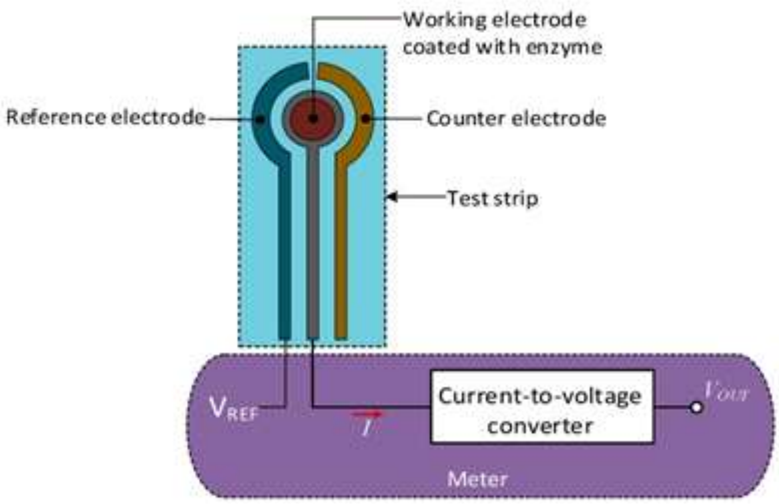

Figure 2. Glucose measurement system with electrode [6]

1.3.2.2 Continuous glucose monitoring – CGM

A wireless receiver, a transmitter, and a sensor are the three main components of CGM devices. The glucose reading is shown on a monitor in the receiver. The sensor is connected to the transmitter, which sends the measurements to the receiver via RF waves. The sensor is a small sensing device implanted into the subcutaneous tissue and extends just far enough into the interstitial fluid to provide access (ISF).

Even though CGM devices can continuously record glucose levels, they cannot be considered the best alternative for blood glucose monitoring because they still require calibration with the usual finger-pricking approach at least twice a day. Furthermore, CGM systems derive glucose from the ISF, assuming a lag time of 6 to 12 minutes, implying that ISF readings do not reflect the actual glucose level in the blood. Furthermore, there are concerns with erroneous readings owing to mishandling and poor self-monitoring skills, issues with the insertion of the sensor beneath the skin, skin irritation and discomfort when securing the device, and issues with the device itself.

Due to the relative ease of the measurement technique and their reliance on capillary blood to obtain accurate glucose readings, Finger-pricking, SMBG devices are currently the most reliable and accurate instruments for self-monitoring. Unfortunately, the pain and discomfort involved with multiple daily finger pricks, as well as the costs connected with the ongoing purchase of test strips, dissuade many patients from checking their glucose levels frequently [6].

1.4 Other factors that influence blood glucose level

An unconventional lifestyle is a significant cause of diabetes. Current trends show that people are diagnosed with diabetes due to their unhealthy lifestyle, making diabetes more of a lifestyle disease than hereditary. The prominent factors that influence blood glucose from a person's lifestyle are physical activity and diet. When a person engages in moderate exercises, such as walking, their heart beats quicker, and breathing becomes more difficult. Muscles consume more glucose, or sugar, from the bloodstream. This can help to reduce blood sugar levels over time. It also improves the efficiency of his or her body's insulin. On the other hand, strenuous activity might briefly raise blood sugar levels after one finishes exercising. Intense activity can cause the body to produce more stress hormones, raising blood sugar levels. Thus physical activity in the right amount is necessary to keep the blood glucose under control. Similarly, a balanced diet at the right time helps to prevent diabetes [7].

1.5 Challenges with blood glucose measurement

Although blood glucose measurement is popular, using a whole-blood sample brings challenges and compromises in terms of the assay principle, calibration method, and result expression. The majority of point-of-care systems are calibrated against a manufacturer-selected method for reference reasons, and assumptions are made, not always legitimate assumptions, that blood samples from various persons will behave similarly in both the reference and point-of-care procedures. While most traditional laboratory techniques measure blood glucose as a concentration in plasma or whole blood, direct-reading electrode systems measure it as molality in mmol/kg water, which is numerically more significant. However, the results are frequently factored and expressed, for example, as plasma glucose concentration. However, there is inconsistency, and the range of methodologies and concepts makes comparing the findings of different blood glucose measures problematic. It has been suggested that some uncertainty could be avoided by stating all data as plasma glucose concentration, regardless of specimen type or analytical method. Errors can be introduced by differences in blood collection sites, especially in point-of-care testing [8].

Aalto-yliopisto

1.6 Proposed Solution

We present an SMBG device that integrates glucose measurement with physical activity and diet analysis to provide many added benefits such as enhanced blood glucose estimation accuracy, which leads to a reduced number of tests per day, fitness tracking and reporting, glucose threshold notification, diet planner, and professional medical consultation as required.

This tight integration is achieved using an Emstat Pico [9] interfaced to determine glucose/sugar level, accelerometer, and heart rate sensor. The idea aims to decrease the number of daily measurement injections for diabetic patients and move away from artificial insulin intake by balancing it with monitored physical activity and a controlled diet. Emstat Pico is a tried-and-tested standalone potentiostat and impedance analyzer module that allows users to do electrochemical measurements using an electrochemical sensor without the need for programming. It is popular because of its advantages, such as compact size, measurement accuracy, and interfacing possibilities.

The proposed idea also houses an application into which the user initially feeds in primary data such as height, weight, age etc. The fitness data from the device is synchronized with the application and updated to a cloud database for processing and later retrieval. To receive accurate predictions and notifications, the user can also input diet information in the mobile application. Based on the calculations performed in the backend using the food intake and physical activity data, the application will be able to estimate the glucose level and send alerts to the user if the level exceeds a preset threshold. Figure 3 shows the overall functional structure of the system backend.

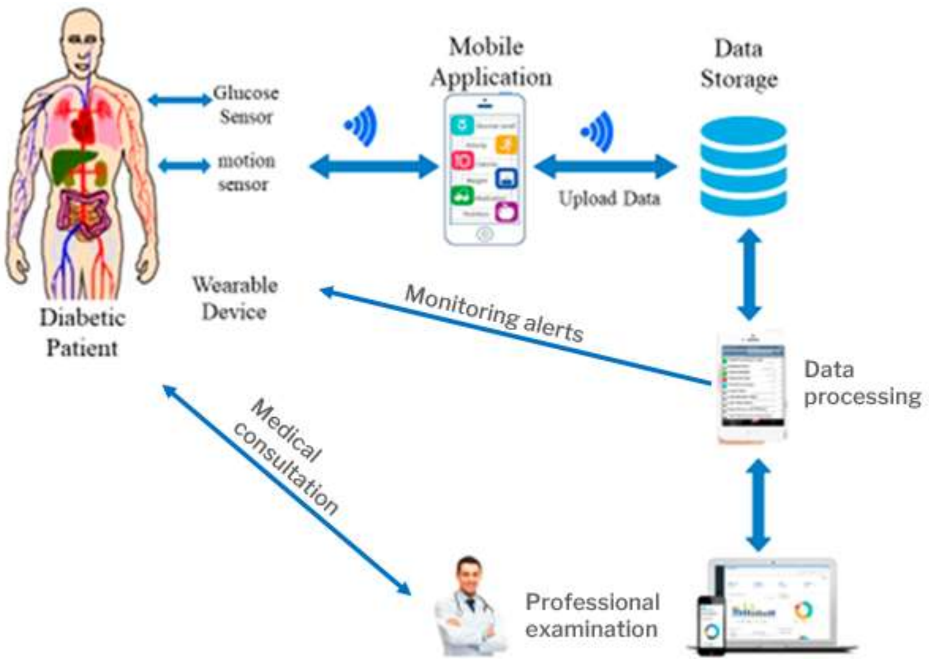

Figure 3. System functionality structure

2. Project team

Our project team consists of 5 key persons, all with different roles. The roles and tasks of these persons may be viewed in the adjacent Table 1.

Role	**Designated person**	**Reasoning as to why this person**	**Tasks**
CTO	Choyon	Have an overview of the technical specification and operation of such devices.	Overseeing the project's technological development for external customers and other clients to improve and grow the business.
Project manager	Harish	Overall grasp on the project and previous experience on project management.	Manage the overall management of the project
Technical analyst	Alaa	Having a thorough analytical capability on the overall project.	Error tracing and providing solution
Hardware specialist	Rifat	Have prior experiences in hardware such as Arduino, Raspberry-Pi.	Hardware Implementation of the Project
Software specialist	Navaneeth	Having prior knowledge on programming.	Software Implementation of the Project

Table 1: Project team roles

3. Project charter

3.1 Customer base

The customer base for the SugarSense device is quite large, and if we can make a strong position in the market, there could be a huge success. The increasing number of diabetes patients are the primary potential customers of the product. Furthermore, the product could be extended to other customers such as people concerned about their blood glucose level/diabetes, health-conscious customers, athletes, health professionals, etc. In recent times, the users rely not only on getting their glucose level measured from a health service point, clinic, or hospital. Instead, they are more focused on getting their blood glucose level self-monitored regularly.

The rate of diabetes patients is increasing with every passing year. The majority of death from health-related issues worldwide is due to diabetes. As there is no permanent treatment to cure this disease, the effective method is to keep diabetes under control by monitoring the blood glucose level and staying physically active.

The most potential group of customers for the SugarSense device are the people with diabetes. The initial plan is to get the SugarSense device to have a strong market position across the European region and expand it globally to other regions in the future. Moreover, SugarSense will target fitness and healthy lifestyle enthusiasts. Figure 4 shows a brief idea about the diabetes patients in 2021 and the predicted number of patients in 2030 globally and the European region [10]. In Figure 5, we can look at the numbers of diabetes patients in Europe over the years and the predicted number for the future [11]. By 2025, the total market value of the continuous blood glucose monitoring device in Europe alone is predicted to be at 2.3 billion US$ [12].

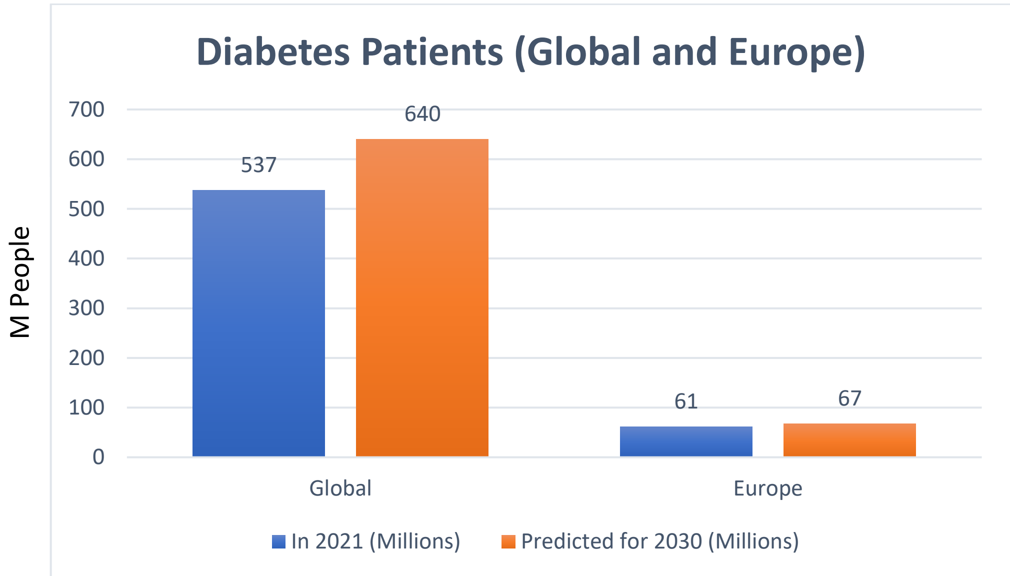

Figure 4. Number of Diabetes Patients Globally and at European Region in 2021 and prediction for 2030 [10]

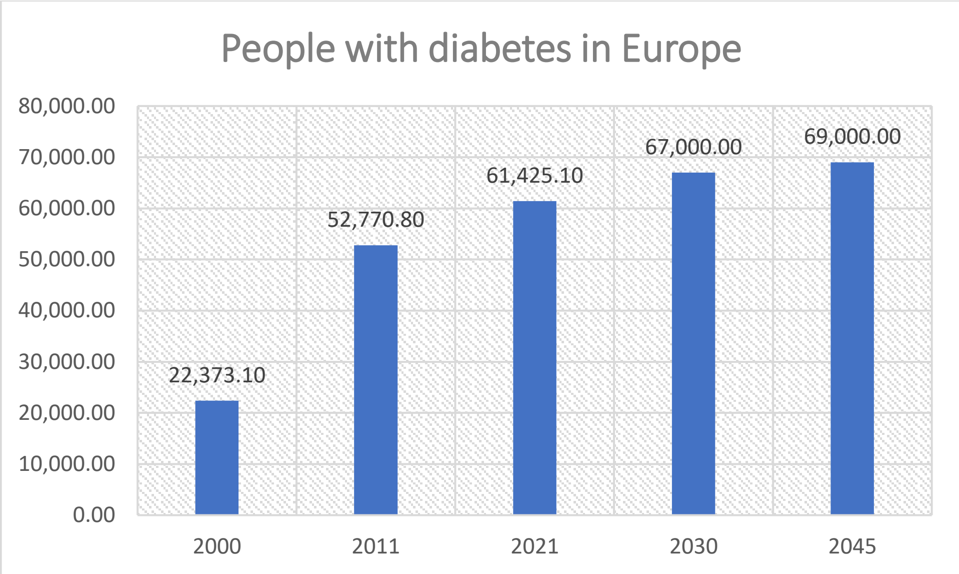

Figure 5. People with diabetes in Europe over Years and Predicted Numbers for Future (in thousands) [11]

3.2 Competition

Along with the increasing market size of the blood glucose measuring devices, there are many competitions to have a bigger presence in the market. Some big companies occupy a large portion of the market share. The big companies selling the blood glucose level measuring devices in the European market are: Dexcom, Medtronic, Abbott, and Sanseonics [12]. These companies together hold a significant portion of the European market share, and they also have their presence in other regional markets as well. The rest of the market shares are occupied by the regional or local manufacturer holding a relatively more minor market share.

Therefore, taking on big companies would not be feasible for our SugarSense product. Instead, proving the high potential of our product and collaborating with the big companies would be a more strategic option to enter the market and grow.

3.3 Suppliers

The suppliers for the SugarSense device would be from various sectors. There should be suppliers for the device's hardware and software sides in the big picture. Table 2 shows the potential suppliers for different parts of the device prototype. However, for large-scale manufacturing and production, we aim to scale down the device design to smaller packages and sensors on a single PCB that can replace the parts in the prototype and maintain higher performance. In order to reduce the cost and maintain bulk manufacturing, the plan is to carry out the manufacturing process in China.
The software cost will be divided by the hosting and infrastructure cost, which will be paid instantly, and the team cost included in the salaries cost.
The hardware cost will be divided to be reimbursed by installments according to the funding terms and the amount of the devices needed by a time.

	Parts	Supplier
Hardware	Microprocessor	PalmSens
	Sensors	Arduino
		PalmSens
	Glucose Measuring Strips	PalmSens
Software	Platform	PalmSens
	Database	Git
	App Development Platform	Flutter

Table 2: Different Suppliers for the Development of the Device Prototype

3.4 Customer promise

We promise our customers to provide advanced and reliable solutions for quality assurance of the products they will buy from us. We have made specific operational goals to do this, as shown in Table 3 below.

Operational goal	**Process design objectives**	**Benefits of goals**
Quality	Maintaining the EU Derivatives, ISO Standards, EU regulations, CE certification standards	Ensuring proper quality and have certification of the high standard
Speed	Using the EmStat Pico module or maintaining the similar quality microprocessor	Low power consumption with higher data transfer and data processing speed in the device
Reliability	Conducting quality control procedure, reliability testing, and FMEA analysis to increase the reliability	Higher durability, performance, and reliability will increase the efficiency and popularity of the device
Flexibility	Utilize user-friendly design method, easy controlling method, and easy installation procedure	The user-friendly device will increase the popularity of the device among users
Expenses	Maintaining lower production cost and relatively lower selling price in the market	Higher sales and significant profit

Table 3: Operational goals

3.5 Tasks & timeline

The project's tasks have been categorized into four different levels, and they can be viewed in Figure 6 below. Furthermore, each level has one assigned contact person who can provide all updates regarding the particular task.

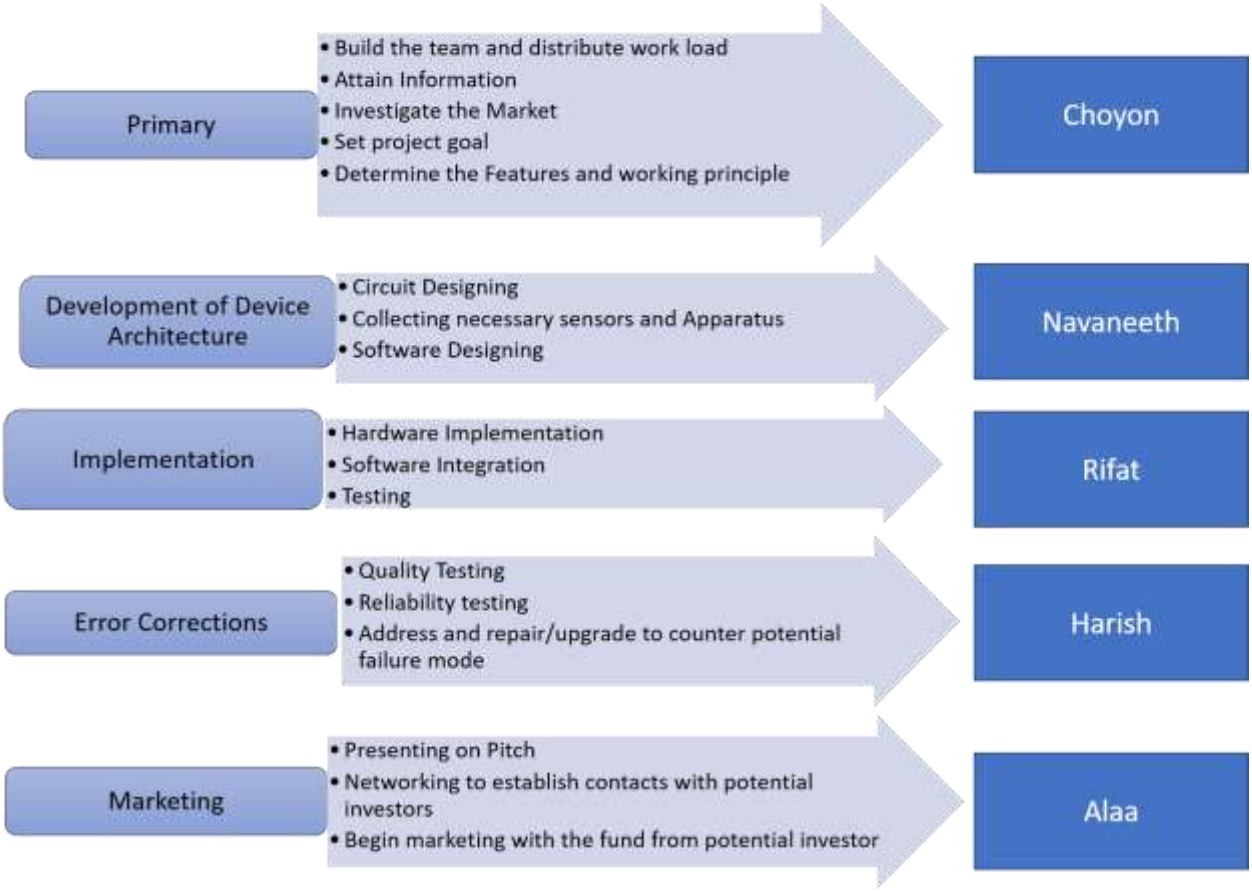

Figure 6. Task diagram of the Project

The timeline for planning and implementing a functioning prototype can be viewed below in Table 4.

Course: Translational Engineering Forum	Project Title: SugarSense	Detailed schedule												
			Month		Month				Month				Month	
Work Package	Tasks	Hours	39	40	41	42	43	44	45	46	47	48	49	50
WP 1														
Primary	Build the team and distribute work load													
	Attain Information													
	Investigate the Market													
	Set project goal													
	Determine the Features and working principle													
WP 2														
Development of Device Architecture	Circuit Designing													
	Collecting necessary sensors and Apparatus													
	Software Designing													
WP 3														
Implementation	Hardware Implementation													
	Software Integration													
	Testing													
	Address and repair/upgrade to counter potential failure mode													
WP 4														
Marketing	Presenting on Pitch													
	Begin marketing with the fund from potential investor													

Table 4 Timeline of different project tasks

Aalto-yliopisto

3.6 Communication

In developing the project prototype, there have been several types of communication between the group members, Course Instructor, and course TA.

The group members have always been in contact with each other through a virtual messaging group. All the project's development phases were being discussed in the group to reach a satisfactory conclusion on each issue. There also have been several live sessions that took place among the group members on the ‘Zoom’ platform to discuss more interactively specific topics related to the project. Furthermore, the workload was distributed among group members according to individual members' choice and expertise to have a better outcome of the project.

On the other hand, there have been specific issues regarding the project in which we couldn’t find a solution, and we required some help or further guidelines. In such cases, we reached out to the course instructor and course TA through email to get proper guidelines and clarification regarding the project work.

In addition, the group members had several physical sessions/meetings to develop the project's prototype. There have also been multiple sessions with the course instructor to have some guidance regarding the project tasks. The team has realized that the physical meetings proved to be more fruitful than previously held online sessions/meetings. As a result, the rapid development of the project was observed towards the end.

4. Production process

4.1 Production process as a whole

The production process of the device comes from a series of different development phases. The Production Process of the project is shown in Figure 7.

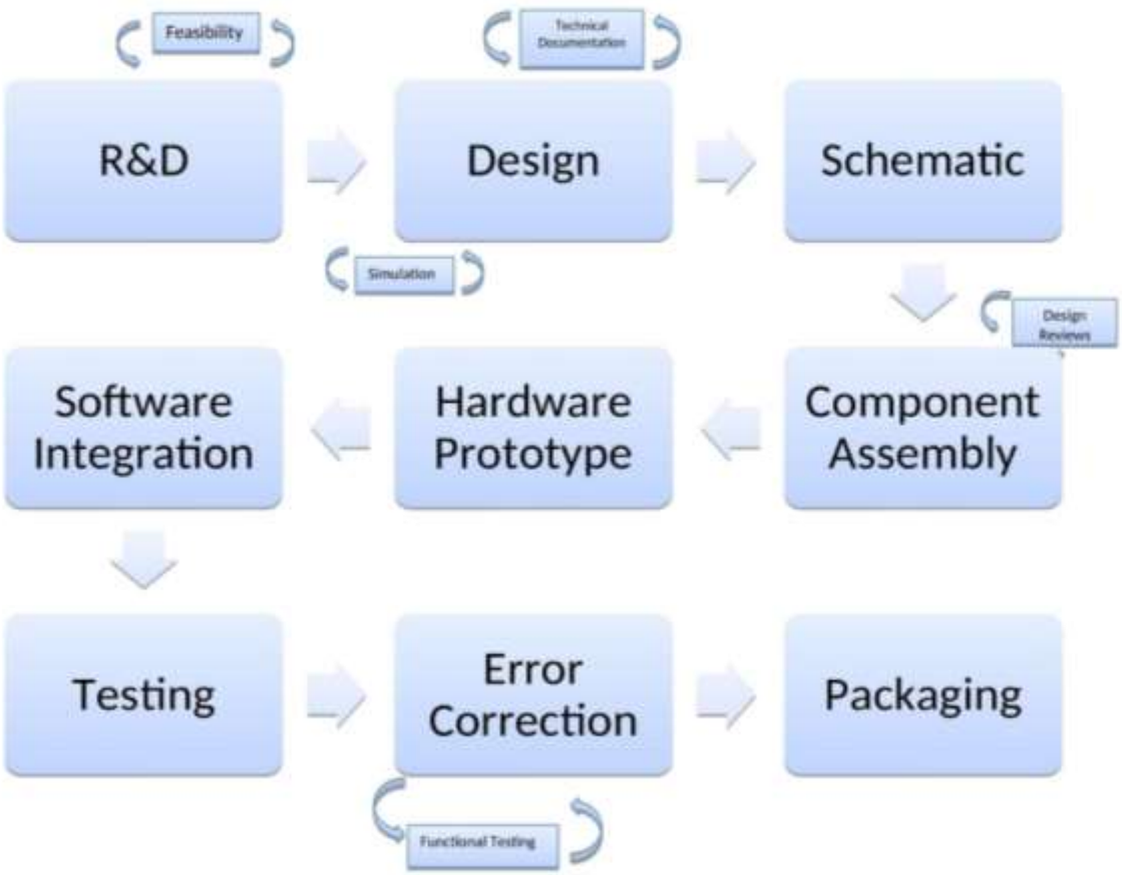

Figure 7. Block diagram of the Production Process

In order to carry out the production process successfully in a distributive manner, the operation process was defined in such a way that it can produce maximum efficiency in the final product. Figure 8 shows the operational process as a whole.

Aalto-yliopisto

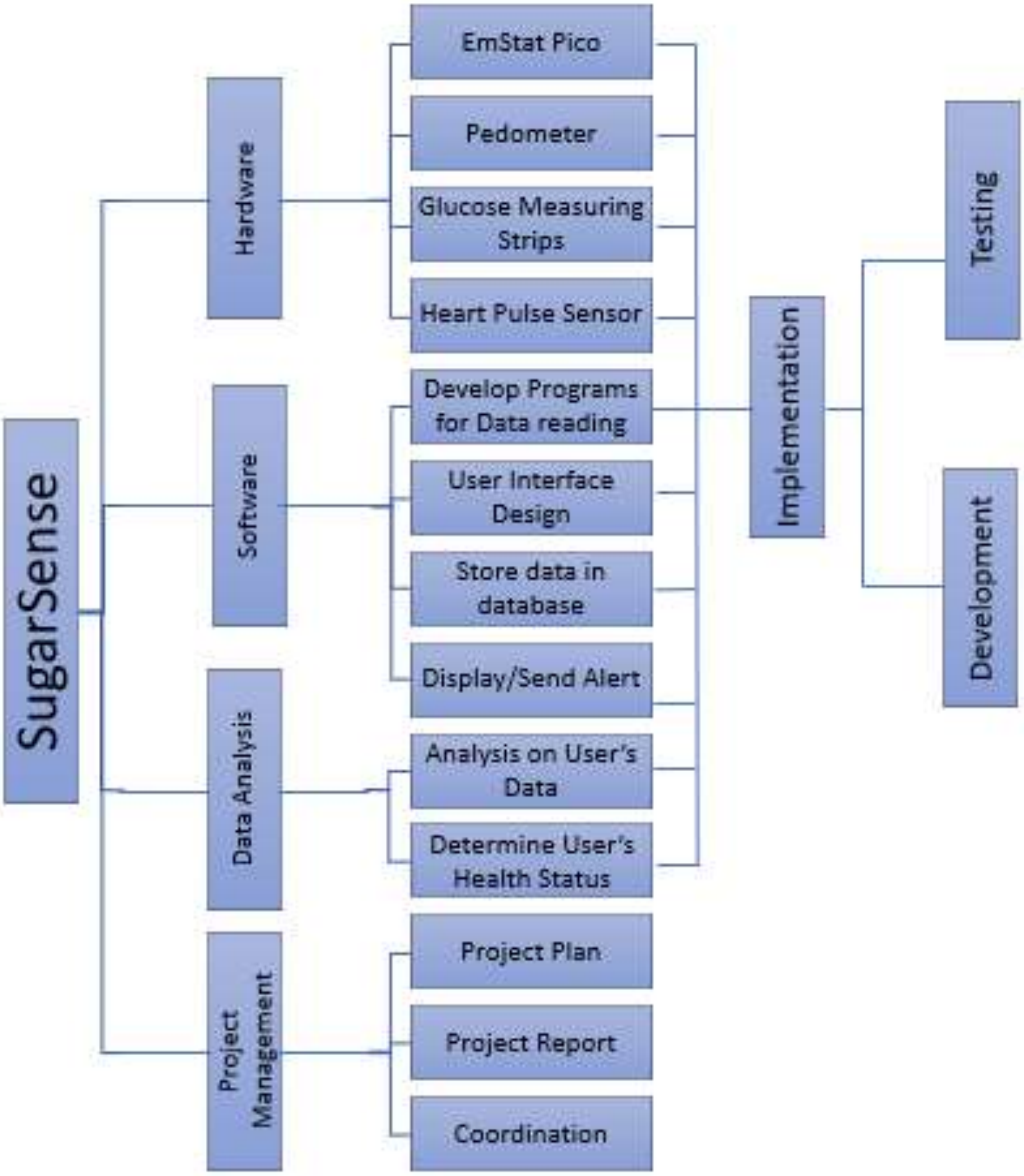

Figure 8. Operational process of SugarSense Project

4.2 Hardware consideration

In developing the SugarSense project, we have considered the best performing hardware. The main processing unit of the project prototype is the EmStat Pico module. Furthermore, we have decided to use pedometer, heart pulse sensor, and glucose level measuring strips for the project prototype. Some of the aspects of our hardware consideration are mentioned in Figure 9.

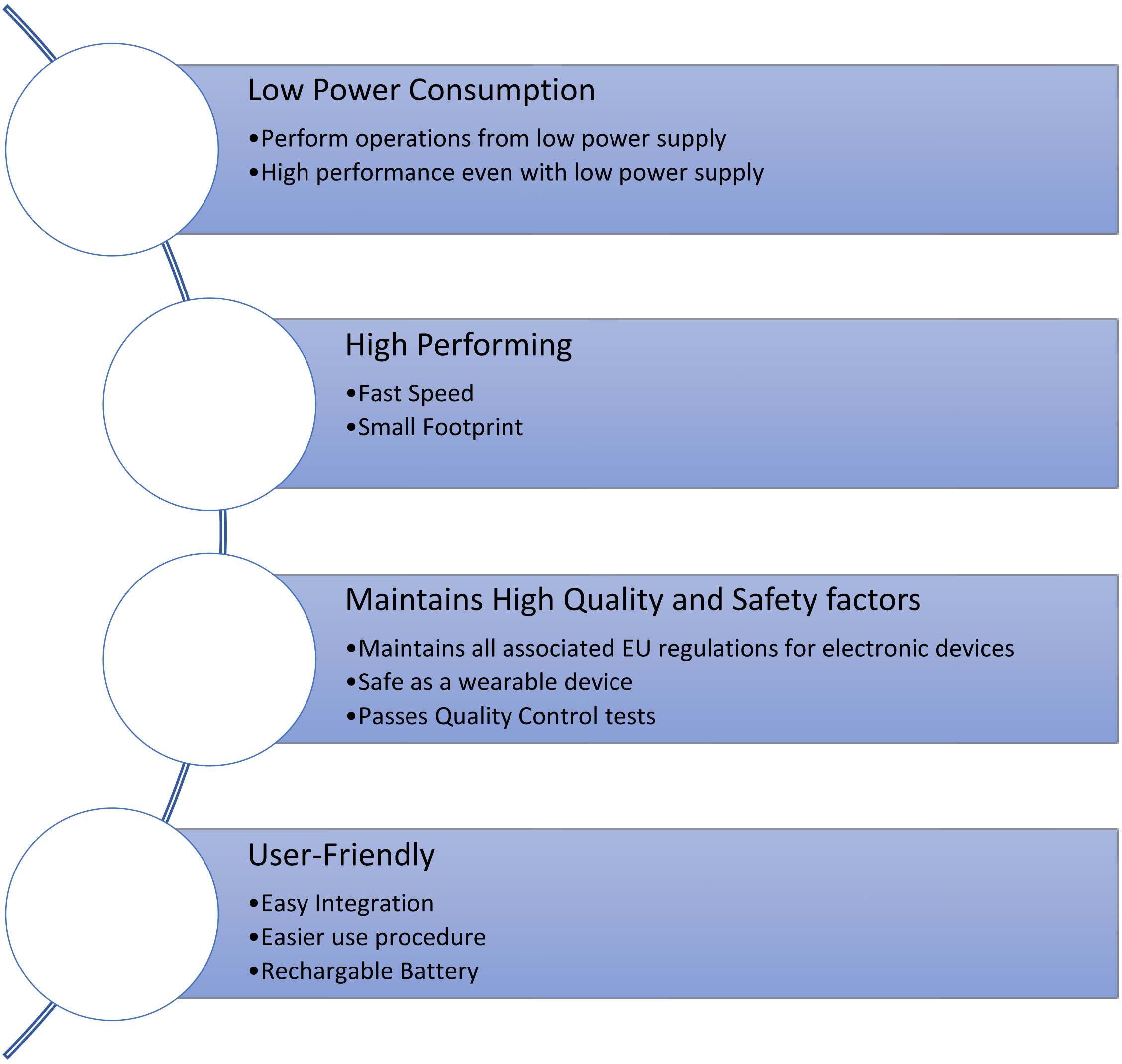

Figure 9. Different aspects of Hardware considerations

The EmStat Pico is the world's smallest and lowest power general purpose electrochemical interface module. Therefore, the module was chosen and used in the SugarSense project to achieve the desired goal. Figure 10 shows the EmStat Pico development kit module sample.

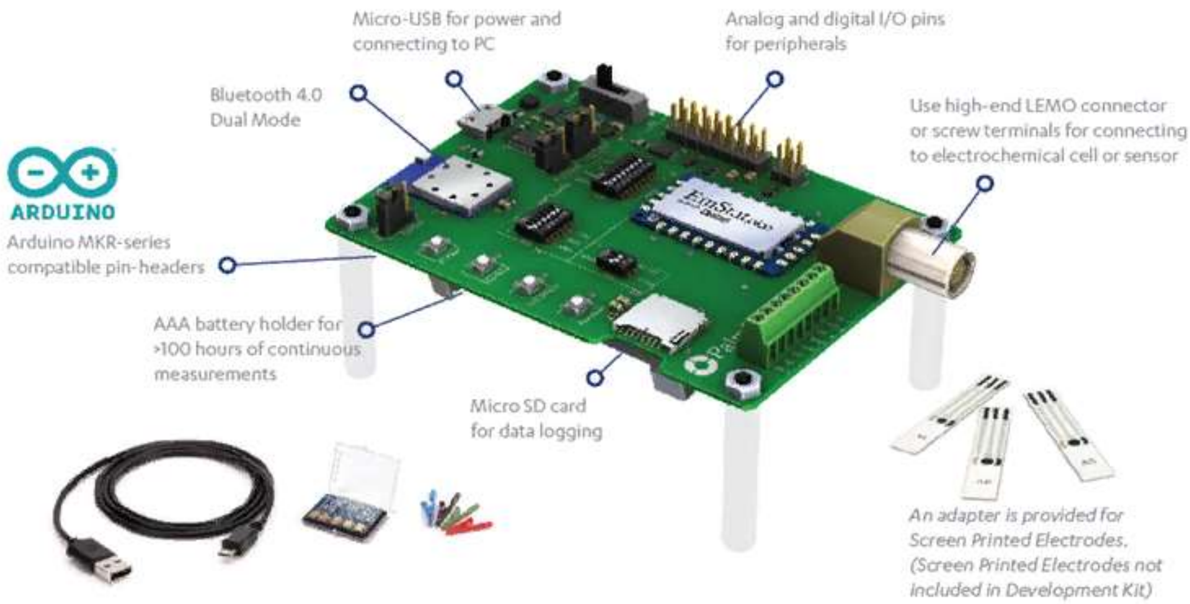

Figure 10. EmStat Pico Development kit Module [13]

In addition, the use of accelerometer and heart pulse sensor is also taken into account to avail the feature of pedometer and detecting heart pulse of the user. All the data collected through these sensors and modules would be stored in the cloud database to further analyze them. Figure 11 shows a sample of the accelerometer and heart pulse sensor.

Figure 11. Accelerometer and Heart Pulse Sensor [14]

4.3 System design

The entire system enables user-friendly features, fast processing, accurate data collection/processing, and accurate results/recommendations. The entire system design shown in Figure 12 can also give a much better idea about the operational structure of the SugarSense Device.

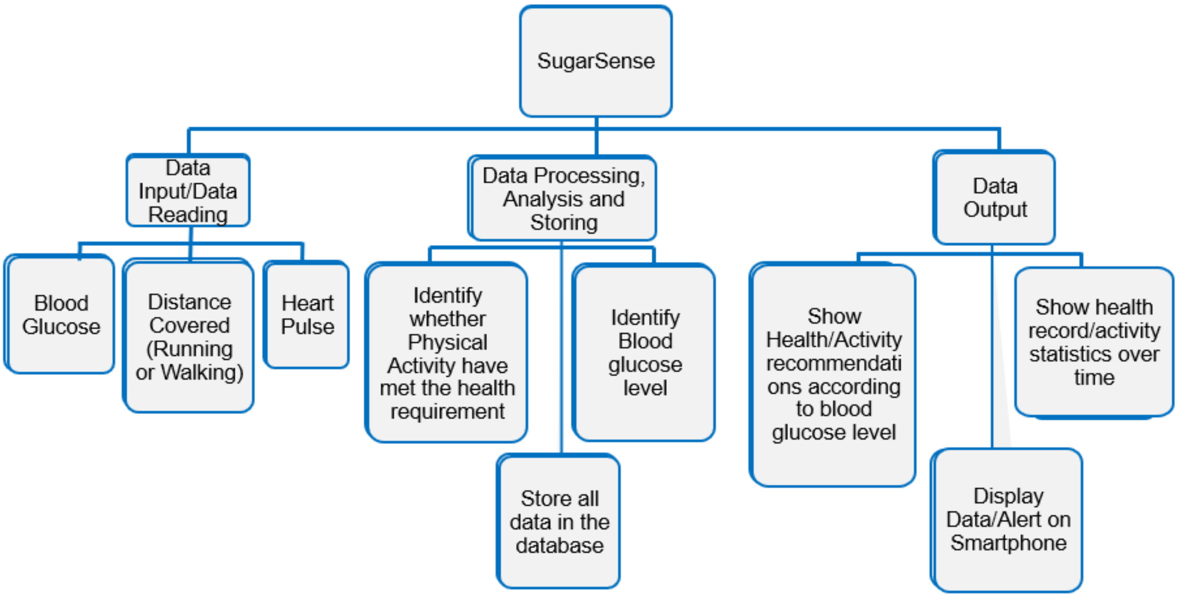

Figure 12. System Architecture of the Project

4.4 Acquired Result from Prototype

After implementing the project prototype, different sets of results were attained on different parameters. First, tests were carried out with the EmStat Pico measuring the sugar level of different solutions. Figure 13 shows the resultant data of the sugar levels in different solutions; thus, proving that the implemented prototype is functional to perform the task. Here, the graph shows a sudden peak, indicating that the solution was dropped on the testing strip, and later, it decays at a more stable rate.

Furthermore, the performance of the pedometer feature was implemented through the accelerometer by integrating it with the Arduino Uno. Figure 14 shows the resultant data of accelerometer as it measures the steps a person takes while walking for a certain period.

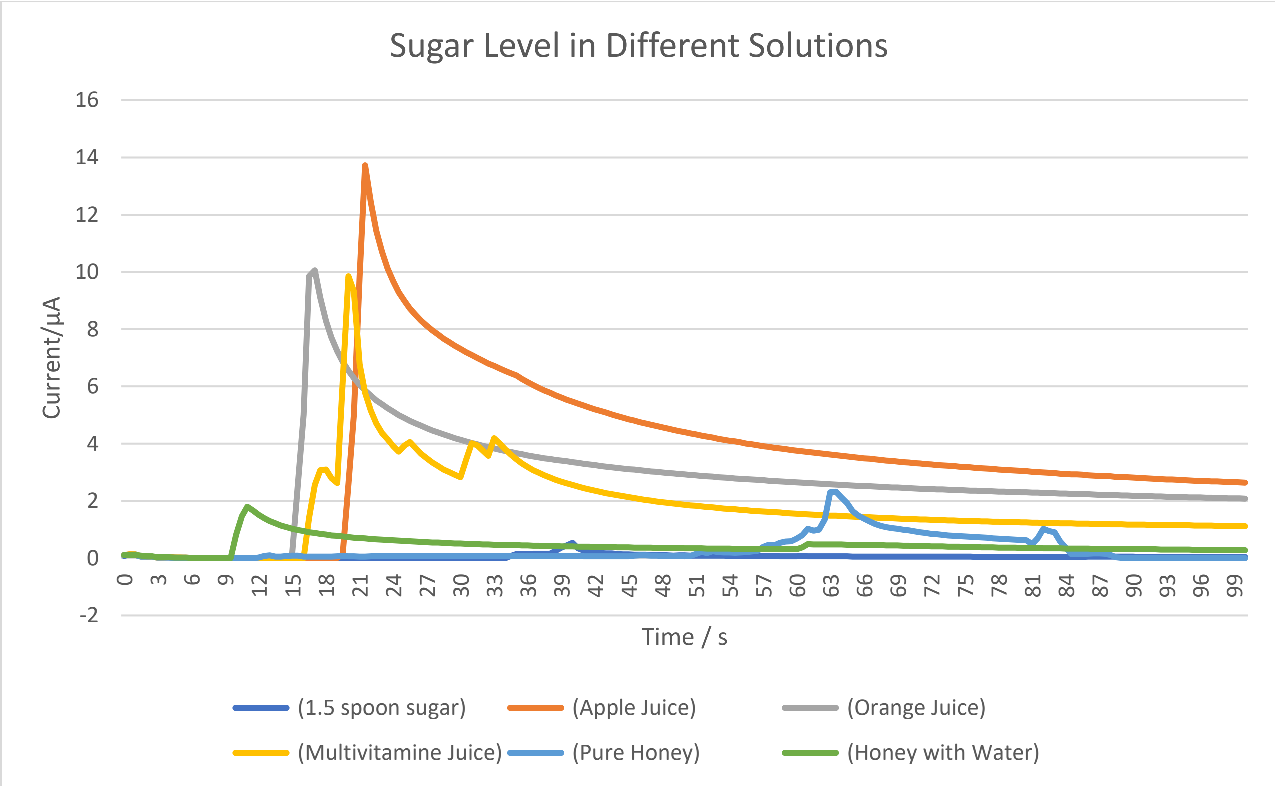

Figure 13. Resultant sugar level data from different solutions

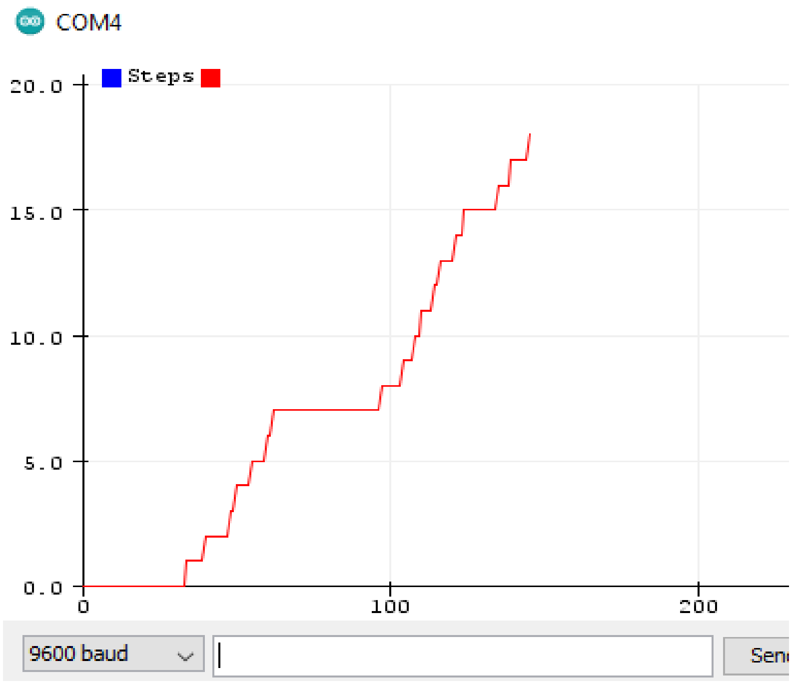

Figure 14. Steps and Distant count from the Accelerometer performing Pedometer's feature

4.4 Quality assurance

The quality of the SugarSense device would be ensured through various testing and analysis. After implementing the device on both hardware and software, these testings would take place to ensure that the product has reached the targeted standard on each of its sectors.

For Quality control, the device's risk assessment and FMEA analysis are carried out to ensure different parts and features of the device work better. Furthermore, different assessments in terms of reliability testing were also carried out to ensure better implementation of the device.

5. Costs

The cost of the product is an important consideration to think of from the initial stage. Many companies are well established and can reduce the final cost of the products they manufacture. As for our product we have divided the cost in terms of two phases 1. First phase cost for prototype, 2. Final development phase i.e., product ready for selling to consumers.

In the first phase of the development, the cost of the EmStat Pico module is not to be included because we have plans to develop a chip that will have all the technical features of EmStat Pico that were utilized in the project prototype. Also, all other sensors used for the project will be integrated together in PCB assembly or in a better method to produce a compact product that is convenient for consumer usage. Table 5 shows a cost detail of the prototype.

Item	**Description Links**	**Quantity**	**Price (Euro)**
1. ZP Glucose Sensor Test Kit	https://www.palmsens.com/product/zp-glucose-sensors-test-kit/	1	150.00
2. Pulse Sensor	https://www.sparkfun.com/products/11574	1	21.80
3. SparkFun Triple Axis Accelerometer and Gyro Breakout - MPU-6050	https://www.sparkfun.com/products/11028	1	26.17
4. Jumper Wire Kit	https://www.sparkfun.com/products/124	1	5.20
5. Hama SLIM5-HD Power Pack	https://www.prisma.fi/fi/prisma/hama-slim5-hd-power-pack-varavirtalahde-5000-mah-valkoinen	1	7.00
6. Miscellaneous			20.00
Total			**240.17**

Table 5: Device's Prototype cost details

Aalto-yliopisto

6. Legislative considerations

Glucose measurement in Sugar Sense is achieved through invasive methods by drawing a blood sample from the user. Product development shall strictly adhere to the governing bodies' standards and regulations relating to developing and using in-vitro medical devices. Quality components shall be used within the product from registered suppliers, and each of these parts, in turn, shall be ensured to comply with the legislative guidelines established for the use of electronics in medical devices. Since the components are purchased within the EU states for current development, the parts already comply with the RoHS and REACH regulations for the use of materials in electronic development. The assembly and distribution of the product are targeted within the EU states, and so the device as a whole shall comply with the following:

6.1 Regulations

Regulation (EU) 2017/745 on medical devices (MDR) for human use, established in 2017 (revised from the Directive 93/42/EEC established in 1993), concerning the placing of the product on the market and its clinical investigation. Under the regulation, the product falls in the category (1) medical device providing information through specimen derived from the human body like blood and shall comply with the requirements as detailed in [15].

In addition, since the product involves the collection and processing of user data and encompasses electronic components that operate in the radio frequency range, which could cause interference, it shall adhere to the following directives:

- Low voltage directive (LVD) (2014/35/EU) applicable since 2016: covers health and safety risks on electrical equipment operating with an input/output voltage of 50-1000 V AC or 75-1500 V DC [16].
- Electromagnetic Compatibility (EMC) Directive 2014/30/EU: limits electromagnetic emissions from equipment to ensure that equipment does not disturb radio and telecommunication, as well as other equipment [17].
- Radio equipment and telecommunication directive (RED) 2014/53/EU: requirements for safety and health, electromagnetic compatibility, efficient use of the radio spectrum, protection of privacy, personal data, and the protection against fraud [18].

6.2 Standards

ISO 15197:2013: This standard is the predecessor to the ISO 15197:2003 standard, which laid out the specifications for system accuracy and performance of the medical systems for human use. Under the current standard ISO: 15197:2013, blood glucose meters need to ensure that 95% of blood glucose results obtained on the device fall:

- Within ± 0.83 mmol/L of laboratory results at concentrations of under 5.6 mmol/L
- Within ± 15 mg/dl of laboratory results at concentrations of under 100 mg/dL
- Within ± 20% of laboratory results at concentrations of 5.6 mmol/L (100 mg/dL) or more

The 2013 guidelines also now stipulate that 99% of readings must fall within zones A and B of the Consensus Error Grid for type 1 diabetes [19], as depicted in Figure 15.

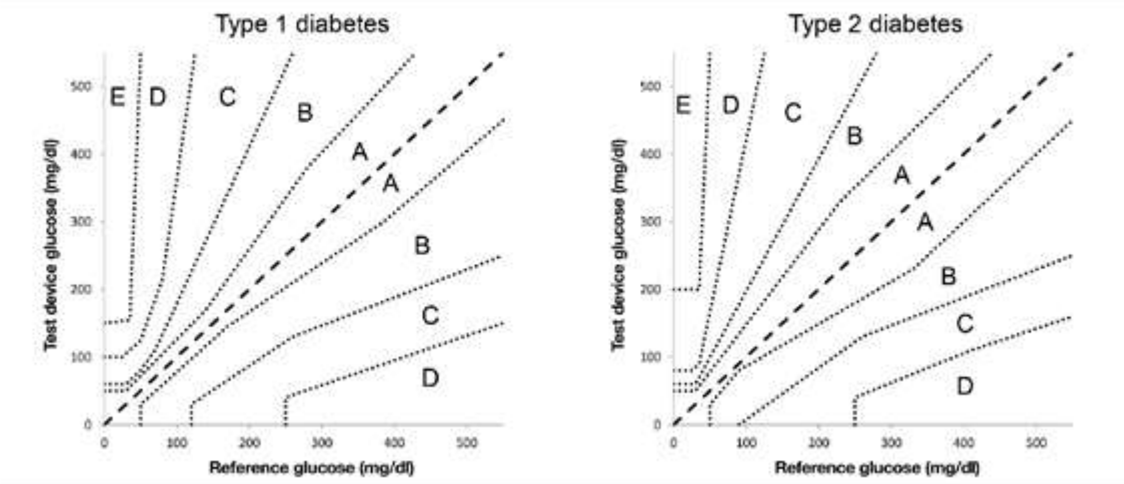

Figure 15. Zones in Error grid for type-1 and type-2 diabetes [19]

A declaration of conformity of the above legislative considerations shall be established concerning the device as a whole, and a CE marking shall be procured for the product.

6.3 Certification

We aim to have the patent on the SugarSense device according to its novel features. Furthermore, we aim to have the product CE certified and have other certifications from related standards in the near future.

7. Upscaling plan

The scaling plan considers different aspects as mentioned in the following points:

7.1 Market

We target the European market for the first phase as the European market for the glucose meters is considered to be 3.75 billion USD in 2020 and is expected to reach 5 billion USD by 2025.

The scaling will include the US market while keeping the Chinese manufacturing for the second phase. The North American market is expected to be 10 billion USD by 2025.

The Asia-Pacific is the third phase target as the glucose meter market is growing by 7.88%, and it's estimated to be 4.13 billion USD in 2021.

7.2 Upscaling features of the Product

New features will be added to the mobile application, such as: connecting patients to diabetes doctors for consultancy and advice from nutritionists for the healthy diet the patient should consider. Moreover, the app will recommend training that aims to burn more calories to reach the expected glucose level in the blood.

The fitness application market in North America is 11.52 billion USD by 2025 which will be taken under consideration in the second phase to launch with the device to increase the profit.

7.3 Product evolvement

The technology used in the device will be developed into one chip, and this miniaturization will allow us to sell the newly developed chip to manufacturers such as the innovative watch manufacturers to add the glucose measurement feature to their device.

Integrating with the smartwatches will exclude the usage of all other sensors, but the glucose sensor and that will reduce the cost of the device by 40%, but the cost will consider the technology development as well in the new price.

Aalto-yliopisto

References

[1] "What is diabetes? | CDC." https://www.cdc.gov/diabetes/basics/diabetes.html (accessed Dec. 09, 2021).

[2] "Diabetes statistics: Read the facts," *The Checkup*, Sep. 29, 2020. https://www.singlecare.com/blog/news/diabetes-statistics/ (accessed Dec. 09, 2021).

[3] "Diabetes." https://www.who.int/news-room/fact-sheets/detail/diabetes (accessed Dec. 09, 2021).

[4] P. Saeedi *et al.*, "Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9th edition," *Diabetes Research and Clinical Practice*, vol. 157, Nov. 2019, doi: 10.1016/j.diabres.2019.107843.

[5] "Monitoring Your Blood Sugar," Aug. 11, 2021. https://www.cdc.gov/diabetes/managing/managing-blood-sugar/bloodglucosemonitoring.html (accessed Dec. 09, 2021).

[6] W. Villena Gonzales, A. T. Mobashsher, and A. Abbosh, "The Progress of Glucose Monitoring—A Review of Invasive to Minimally and Non-Invasive Techniques, Devices and Sensors," *Sensors*, vol. 19, no. 4, Art. no. 4, Jan. 2019, doi: 10.3390/s19040800.

[7] E. Greenlaw, "Exercises to Lower Your Blood Sugar," *WebMD*. https://www.webmd.com/healthy-aging/features/exercise-lower-blood-sugar (accessed Dec. 09, 2021).

[8] "Principles and problems of blood glucose measurement." https://acutecaretesting.org/en/articles/principles-and-problems-of-blood-glucose-measurement (accessed Dec. 09, 2021).

[9] "EmStat Pico Module - Palmsens | DigiKey." https://www.digikey.com/en/product-highlight/p/palmsens/emstat-pico-module (accessed Dec. 09, 2021).

[10] "IDF Diabetes Atlas | Tenth Edition." https://diabetesatlas.org/ (accessed Nov. 12, 2021).

[11] "Europe diabetes report 2000 — 2045." https://diabetesatlas.org/data/ (accessed Nov. 12, 2021).

[12] "Europe Continuous Glucose Monitoring Market| Growth, Trends, and Forecasts (2020 - 2025)." https://www.mordorintelligence.com/industry-reports/europe-continuous-glucose-monitoring-market (accessed Nov. 12, 2021).

[13] "PalmSens - Compact Electrochemical Interfaces," *PalmSens*. https://www.palmsens.com/ (accessed Dec. 09, 2021).

[14] "Sensors," *Arduino Official Store*. http://store.arduino.cc/collections/sensors (accessed Dec. 09, 2021).

[15] *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.)*, vol. 117. 2017. Accessed: Dec. 09, 2021. [Online]. Available: http://data.europa.eu/eli/reg/2017/745/oj/eng

[16] "Low Voltage Directive (LVD)." https://ec.europa.eu/growth/sectors/electrical-and-electronic-engineering-industries-eei/low-voltage-directive-lvd_en (accessed Dec. 09, 2021).

[17] "Electromagnetic Compatibility (EMC) Directive." https://ec.europa.eu/growth/sectors/electrical-and-electronic-engineering-industries-eei/electromagnetic-compatibility-emc_fi (accessed Dec. 09, 2021).

[18] "Radio Equipment Directive (RED)." https://ec.europa.eu/growth/sectors/electrical-and-electronic-engineering-industries-eei/radio-equipment-directive-red_fi (accessed Dec. 09, 2021).

[19] A. Pfützner, D. C. Klonoff, S. Pardo, and J. L. Parkes, "Technical Aspects of the Parkes Error Grid," *J Diabetes Sci Technol*, vol. 7, no. 5, pp. 1275–1281, Sep. 2013.