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# Deliverables Report - Translational Engineering Forum

*Project Title: SugarSense*

## Team Members

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# Stakeholder analysis

## 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. 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$.

## 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. 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.

## 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 instalments according to the funding terms and the amount of the devices needed by a time.

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

## Project Requirement

The requirement was to create a glucometer with fitness tracking which means to integrate blood sugar estimation with physical activity tracking using the Emstat Pico potentiostat.

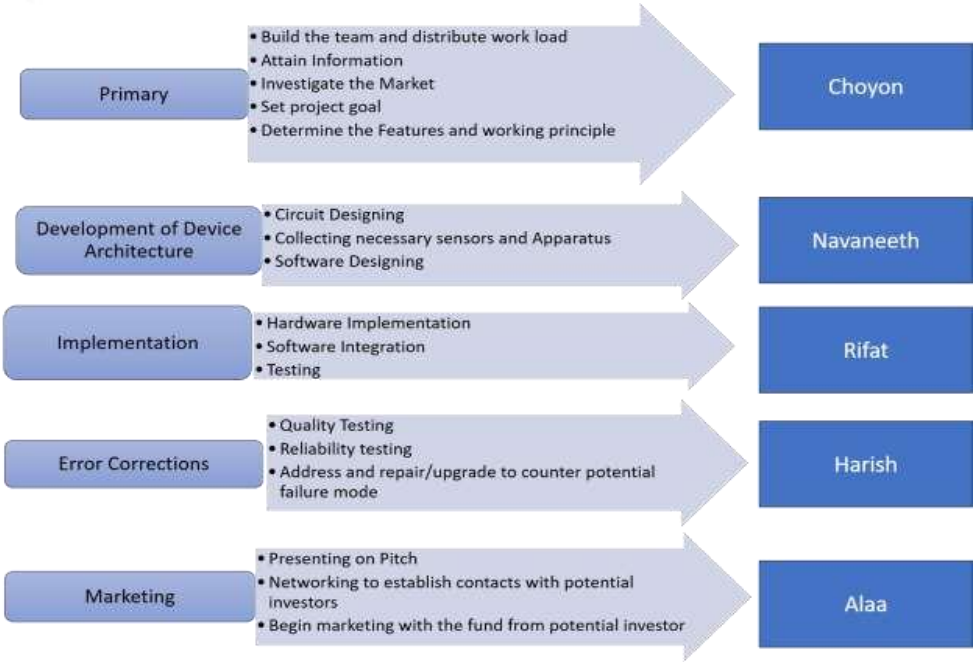
## High Level Risk

Faulty measurement in the device can impact the user directly through exchange of wrong information leading to potential health hazard. One dangerous situation is the no intake or unwanted intake of insulin by a diabetic patient based on the misinterpretation made by the device.

## Approved Project Charter

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

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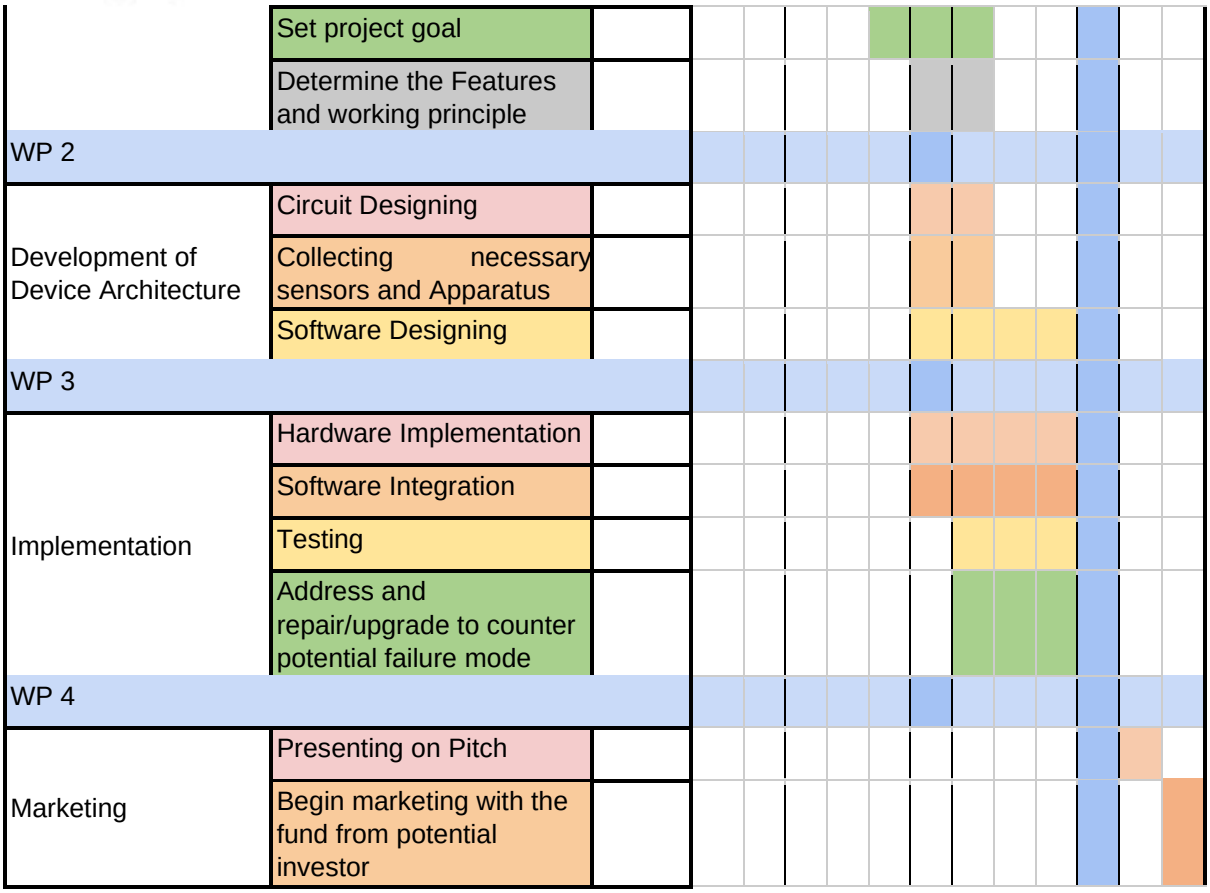



## Benefit Analysis

The primary benefit of the device is the increase in accuracy of glucose estimation achieved through the integration of glucometer and pedometer. This tight integration is achieved using an Emstat Pico 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.

## Gantt Chart

| 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 | | | | | | | | | | | | | | |




## Risk management plan

The project team members reviewed the business objective such as product development, budget framework or business collaborations. The risk management process goes hand in hand with the present scenario as well as the future developments of the project. The assets, vendors, data, software, hardware, supply chain etc. are reviewed. After reviewing these a catalogue was developed and the risks were identified from these and then categorized based on its impact for example financial risk, reputational risk, risk based on license etc. The severity of the risk was assessed and then an order of priority was prepared. The identified risks underwent a rating process where the risk priority number (RPN) for each risk was calculated based on its severity, occurrence and detection. The highest RPNs were given the first preference and subsequently the rest. Further, risk mitigation strategies were planned to reduce the impacts.

## Quality management plan

The project is divided into several smaller components and designated to different project members. The quality assurance for each subdivision is taken care by that individual circle. The quality standards are the “measures” used to determine a successful outcome for a deliverable. These standards may vary dependent on the type of information technology project. Once the product is developed, it will undergo a series of trials and tests and then be introduced to the customers. The initial set of products given among the customers is to understand the product functionality, based on their age and other health complications and lifestyle. User

reviews will be gathered on continuous basis and the project committee will try implementing some of the possible quality improvements on the product and relaunch it. This will be a repetitive process which will go along with the product launch and distribution to the market.

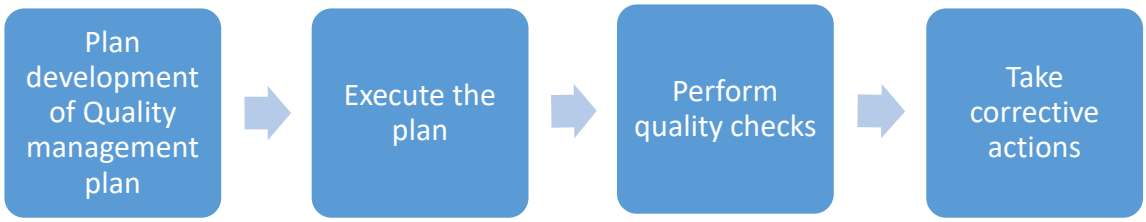



Figure 1. Steps involved in the quality management plan

## Communication management plan

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.

## Software Design

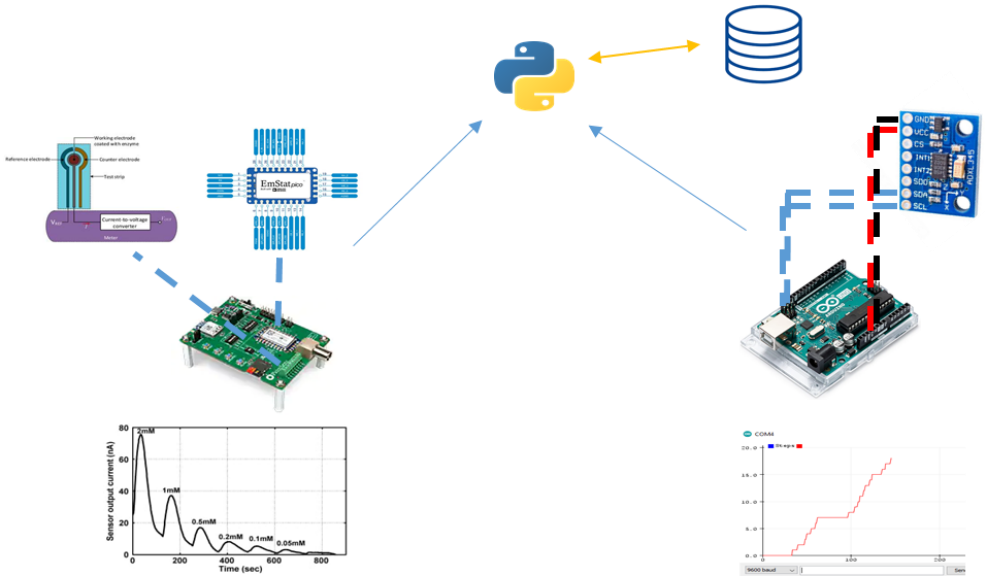
The requirement for the system was to measure the blood glucose level and track the fitness data of the user which were achieved on the prototype level using two independent hardware systems. The software design for the project starts with the proprietary software used to program these two hardware systems which are: PSTrace for EmStat Pico development board and Arduino for the Arduino Uno board. The PSTrace software helps create a complex series of experiments using a scripting window. Scripting allows to automate and perform batch analysis with full control over data manipulations and output, providing automation of all of the main functions of the PSTrace software. The interactive plot and a head-up-display of peaks while hovering over the plot in the graph makes post-measurement part of electrochemistry quicker and easier. The data can also be exported to excel. The glucose content in the electrolyte corresponds to a typical peak current flowing through it after it is dropped onto the measuring electrode. Value of peak current corresponds to the glucose

level of that particular fluid and the value may be extracted from the system using a script. The Arduino software allows for easy programming of the Arduino Uno development board to which the accelerometer can be interfaced to implement the pedometer functionality. The software implements an I2C communication between the board and the ADXL 345 accelerometer which can detect the acceleration in 3 directions. The change in acceleration is compared to the typical threshold value after removing the component corresponding to gravitational acceleration. When the pre-set threshold is crossed a step count is registered. To enhance the system and combine all the independent software components, the integration framework of the system can be developed in python. The peak electric current value of the system can be read out from PSTrace to Python using MethodScript and similarly the step count can be exported from Arduino to Python using PyFirmata or other libraries. A mobile application can be used to store the details of the step count, to retrieve basic user data such as height, weight, age etc. and to input the diet information of user. This data along with the determined step count can be given as inputs to an ML algorithm to estimate the amount of calories burnt by using a relevant regional diet database in python. Thus the entire system can be executed directly from Python and the reduction in glucose level through physical activity can be related to the measured glucose level to make better glucose level estimations and reduce number of tests per day.

## Proof-of-concept system

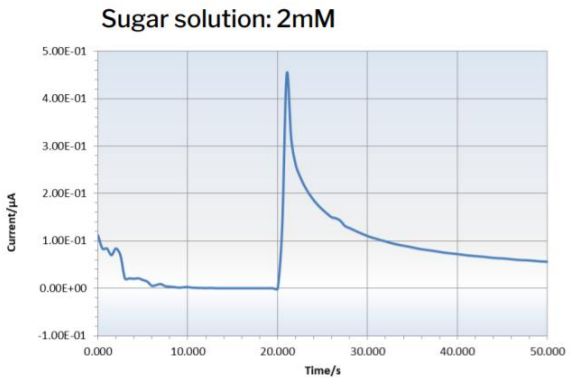
The proof-of-concept system consists of the EmStat Pico development board to which the measurement electrode is connected. The development board provides provision for directly interfacing the electrode. The glucose estimation was performed on given quantities of particular solutions whose glucose content was known such as apple juice, soft drinks etc. The peak current observed has a direct relation to glucose content of the solution and hence helps verify the same against the package description of these solutions. A pedometer developed using the 3-axis accelerometer ADXL 345 interfaced to an Arduino was the proof of concept for the physical activity tracker. The step count determined using the accelerometer can be used to estimate the amount of glucose that was reduced due to physical activity, according to a relation between steps walked and blood glucose reduced, which was established in few research papers. For example walking for 1 hour can correspond to the reduction of blood glucose level of about 35 mg/dL. Thus knowing the current glucose level using the EmStat Pico reading and reducing the glucose level with respect to the physical activity performed helps determine the glucose level during later part of the day accurately and hence avoids multiple test. This

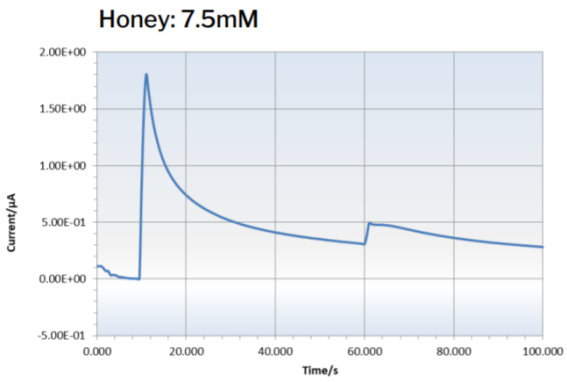
proof of concept established can be scaled in multiple ways to improve blood glucose calculation, fitness tracking etc. However a mature system would require more inputs such as the user diet, basic user data etc.



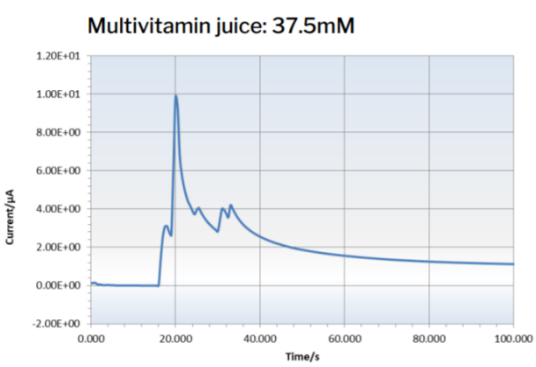

## Evaluation results:

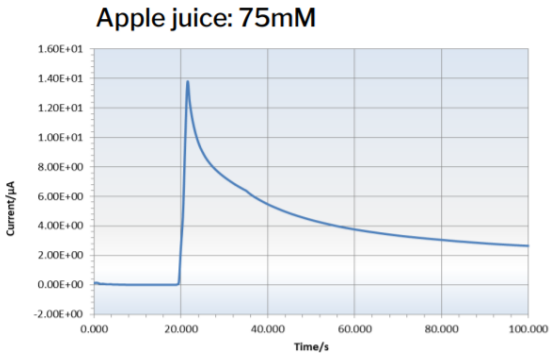
We started by measuring and understanding the results of the glucose measures of the EmStat-pico module, we tried different solutions to differentiate the level of the glucose, the following results are for several solution:



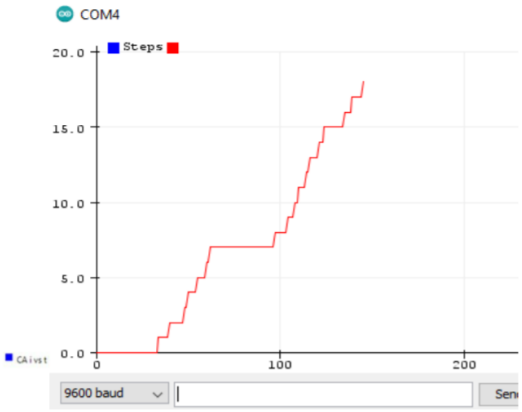
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A drop from the solution is placed in the sensor and the time for measuring is adjustable, the first noise appears in every measurement is neglectable and then we take the read after the line stabilizes. By knowing that 40nA of current corresponds to 1mM of glucose concentration we made the previous calculations.

The following graph indicates the steps counter calculated by sensing the acceleration of the user, the step is counted if the acceleration exceeded a certain threshold.




These results are the beginning of the project, afterward we will be able to calculate the number of calories burnt according to the accelerometer/pedometer results to achieve the goal of the project.

## Investment pitch:

We SySmart present our product SugarSense. The product aims to help people with diabetes for both type 1 and type 2, according to International Diabetes Federation, number of people with diabetes in Europe is increasing steadily throughout the years and it's expected to reach 70 million diabetic persons by 2030 In Europe only. The most affected countries in Europe are Germany, France and Spain.

The present routine for diabetics is to measure their glucose level for -in average- 11 times a day, moreover, they rely on the artificial insulin intake. This protocol is very expensive and for instance it costed Kela -The healthcare system in Finland- 120M euro in 2020.

We present Our product which is an integrated system consists of several sensors and a mobile application. The device measures the glucose level by the glucometer and the heart rate, and the activity done by the patient

throughout the day by the pedometer, the patient is asked to input their meals daily to the mobile app so the system can calculate the number of calories taken, and according to the physical activity done the system will calculate the number of calories burnt.

The patient measurements per day will be reduced to be 2-3 measures a day and the device will monitor the perfect time for the insulin intake so the cost of the protocol will be reduced in an efficient way.

Our customer segment is not only diabetic patients, but we also target healthy lifestyle enthusiast and will reach them by the sports events like marathon and gyms, moreover we can go to the nursing houses as diabetes is proven to be more distributed among old age people.

We have competitors as Veri and Dexcom and we present lower price and easier usage in addition to the accurate results.

# 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 medical device providing information through specimen derived from the human body like blood and shall comply with the requirements. 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.

➢ 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.

➢ 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.

## 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:

Ø Within ± 0.83 mmol/L of laboratory results at concentrations of under 5.6 mmol/L

Ø Within ± 15 mg/dl of laboratory results at concentrations of under 100 mg/dL

Ø 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.

# 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

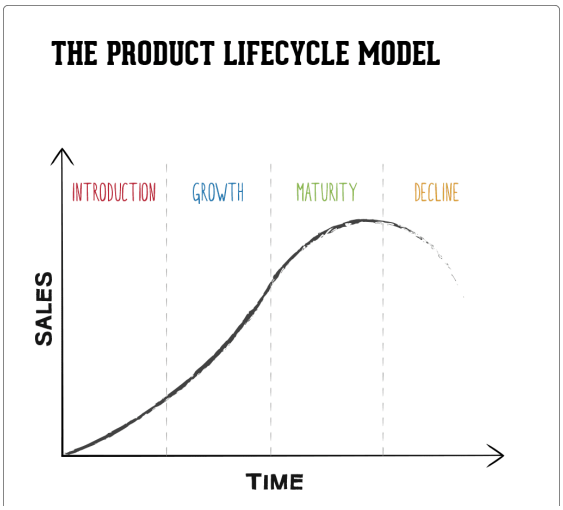
New features will be added to the mobile application, such as: connecting patients to diabetes doctors for consultancy and advice from nutritionists for the healthy diet the patient should consider. Moreover, the app will recommend training that aims to burn more calories to reach the expected glucose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

# Future Modifications

For future, 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, that will reduce the cost of the device by 40%, but the cost will consider the technology development as well in the new price. Adding to that, we planned for different versions of the devices with extra features like consultation with the doctors, diet plan from professionals, extra accessories, etc. Also, we have plans to apply for patent of the technology of integrating the glucose sensor module into the smart watches.

# Product Lifecycle Plan

The product lifecycle has 4 distinct stages, each with its own characteristics that mean different things for business that are trying to manage the life cycle of their particular products.




## 1. Introduction Stage (2022-2023):

- Product launch in April 2022
- Launch SugarSense Standard & Premium
- Compete with Veri and Dexcom who have similar products
- SugarSense Standard price € 600 and SugarSense Premium price € 800
- Place




- Promotion policy includes discount in special occasions, world fitness day, world diabetes day etc.
- Offer good amount of backend profit to retailers.
- Targeted advertisement in social media.

## 2. Growth Stage (2023-2025)

- Web subscription feature enhanced.
- SugarSense 2.0 launch in 2024 for elite customers.
- Fix bugs, introduce advanced features, add more doctors and hospitals for consultation with users.
- Place: same as the introduction stage.
- Provide competitive price for the users.
- Affiliation with insurance companies for more market penetration.
- Introduce more accessories for user ease.

## 3. Maturity Stage

- Focus on growth rate more than 50%.
- File patent for the technology.
- Collaborating with tech giants for use of Sugar Sense technology.
- Introduce single chip solution for integrating with existing smartphones.

- Place:




- Special offers for credit card payment. EMI introduced.
- Discount coupons introduced.
- Target for bulk sales and less profit.
- Aim for being market leader.