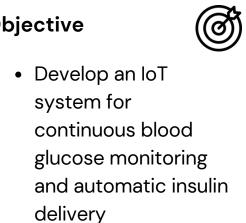
# Justifications

- Manual measurement of glucose levels
- Manual control over insulin application
- High physical and mental demand for DM1 patients
- High variations in glucose rate
- Damage to the quality of life of DM1 patients





# **Benefits**

 Automated control of glucose and

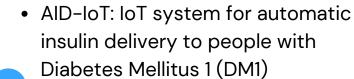
insulin delivery levels

- Less variation in blood glucose levels (the system simulates the function of a healthy pancreas)
- Reducing patient workload with treatment

1. Why

 Improving the quality of life of DM1 patients

## **Product**



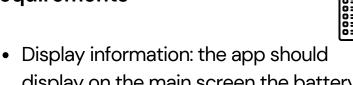


# Components



- Hardware
  - Continuous Glucose Monitor (CGM)
    - Glucose sensor/transmitter + glucose monitor/receiver
  - Insulin pump (IP)
  - Smartphone Android/iOS
- Software
  - User app for continuous glucose monitoring
  - Embedded CGM and insulin pump systems
  - Server: cloud database
  - Application for remote monitoring

# Requirements



- display on the main screen the battery levels, current insulin level (CGM), amount of remaining insulin (BI), date, time, and any malfunction alarms.
- Configure and activate infusion profiles: the user can configure different basal infusion profiles for each 24 hours.
- Configure and activate rapid infusion (bolus infusion): the user can configure the amount of insulin they want to infuse at the moment.
- Critical alerts: For each problem, such as a low battery or a lack of insulin, the APP (and component) must use an audible signal and visible alerts.

## Connectivity

- CGM/app: Bluetooth Low Energy (BLE)
- App/IP: Bluetooth Low Energy (BLE)
- App/server: 4G/5G or Wi-Fi

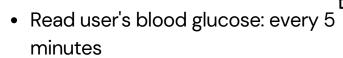
# Data



- Patient's blood glucose (source: CGM)
- Amount of insulin (source: IP)



## **Actions**



- Check insulin need: every reading
- Apply insulin: when necessary
- · Send data to the server: every reading
- Notify caregivers (health professionals, family, etc.)



# **Assets**



- User with Diabetes Mellitus 1 (DM1)
- Critical components: CGM, IP and app



## Losses

- Patient death due to system failures
- Patient hypoglycemia or hyperglycemia
- Damage to the patient's health or physical integrity due to component failures
- Defects or malfunctions of the CGM, IP or control algorithms
- Corruption, leakage or loss of patient



# **Stakeholders**



- DM1 patients (users)
- Healthcare professional who oversees the treatment (domain experts)
- Anvisa (external)



Team

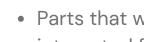
# **Delivery**



15



completed



**Assumptions** 

Assumptions about the

future and relatively

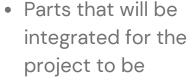
uncertain scenario

Security specialist

Requirements engineer

- Project manager
- Developers

**Constraints** 



• Concrete, measurable and verifiable deliverables

19

18

**Timeline** 

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**Project Risks** 

Uncertainties that may

affect project

Deadline for each

planned delivery

• It does not aim for

precision, but

estimation

objectives

# **Costs**



- Estimated per delivery
- Work + materials + acquisitions



# System Risks (intentional or unintentional)

• Limitations of any origin imposed on work

• They can originate from external entities, by team members

Reduce the team's freedom of choice

or components internal to the project



- Excessive bolus infusions, which can cause overdose (and hypoglycemia) or insufficient, underdosage (and hyperglycemia)
- Lack of notification to the holder in case of lack of insulin in the pump reservoir (or defective, broken, leaking reservoir)
- BI real-time clock (RTC) lagging or fasting
- Communications transmitted in clear text (glucose level and insulin dosage)
- Weak pairing protocol between devices (CGM, APP, BI)
- Lack of replay attack prevention or transmission guarantee
- Possibility of triggering unauthorized insulin injections







4. Who

5. How

6. When and how much









