PROMETEUS

preterm brain-oxygenation and metabolic eu-sensing

D5.1

Specifications of the Cloud app

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History of Changes

Revision	Date (dd/mm/yyyy)	Author	Changes	Status (Draft/In review/Submitted)
V 1	19/04/2023	Alberto Scarpa (DAVE)	First draft	Draft
V 2	27/04/2023	Alberto Scarpa, Andrea Marson, Manuele Papais, Stefano Dal Poz (DAVE)	General improvements	In review
V 3	30/05/2023	Alberto Scarpa (DAVE)	Description of sensors	Submitted

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1 Executive Summary

This document is the deliverable D5.1 “Specifications of the cloud app” of the Prometeus Project.

The aim is to present the results of the user requirement and specification definition process performed from M1 (February 2023) to M4 (May 2023) for the Prometeus project within the activities of WP5.

The contents of this document are:

i) A description of the user methodology adopted to gather requirements.
ii) An analysis of the state-of-the-art related, the context of the project, the products with functionalities similar to subcomponents of Prometeus, and the epidemiology of prematurity.
iii) A high-level description of the architecture of the system, its components, and data.
iv) Collection of specifications: business requirements, user requirements and system requirements.
v) Development plan for the implementation of the collected specifications.

2 List of abbreviations

BR	Business Requirement
UR	User Requirement
SR	System Requirement
HCP	Health Care Professional
CGM	Continuous Glucose Monitoring
NICU	Neonatal Intensive Care Unit
NCA	Nutritional Clinical Advisor

3 Methodology

The collection of specifications for the Prometeus "cloud app" followed the standard product design processes starting from the high-level view of the *Business Requirements (BR)* and then going down to the user level with the *User Requirements (UR)* and at the least defining the *System Requirements (SR)* (Figure 1).

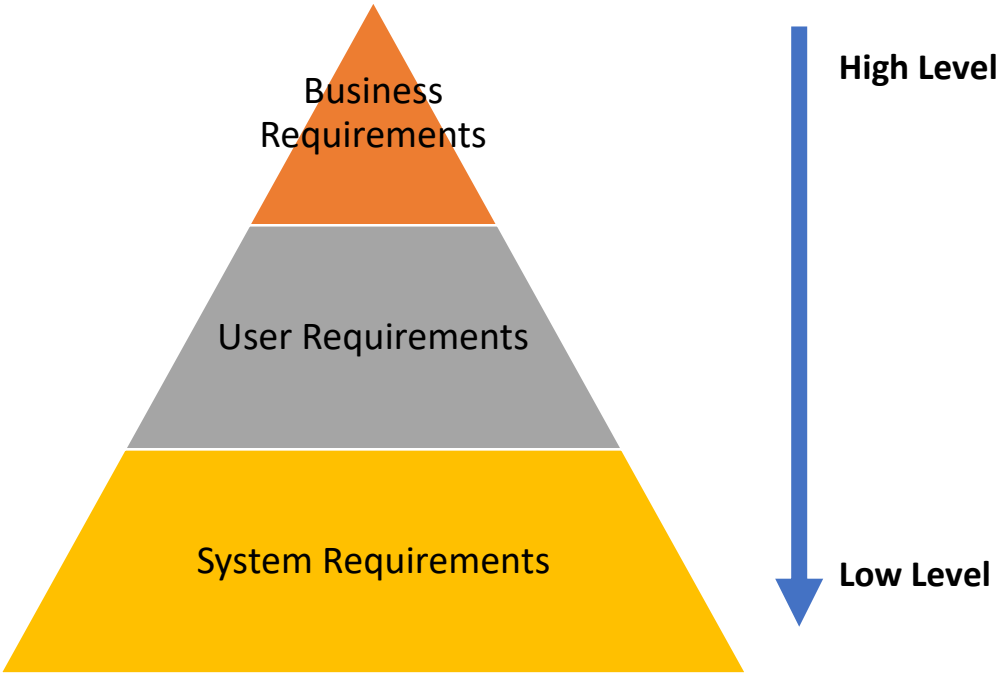


Figure 1 Requirements'' Pyramid

The process to collect requirements and specifications is:

- Identify the size of the prematurity problem.
- Identify stakeholders and users of the project.
- Identify high-level components and architecture of the system.
- Identify products with functionalities related to the project.
- Identify workflows of the system.
- Meet key users and project partners for brainstorming.
- Extract requirements and specifications.
- Design a draft of UI as input for a review with partners.

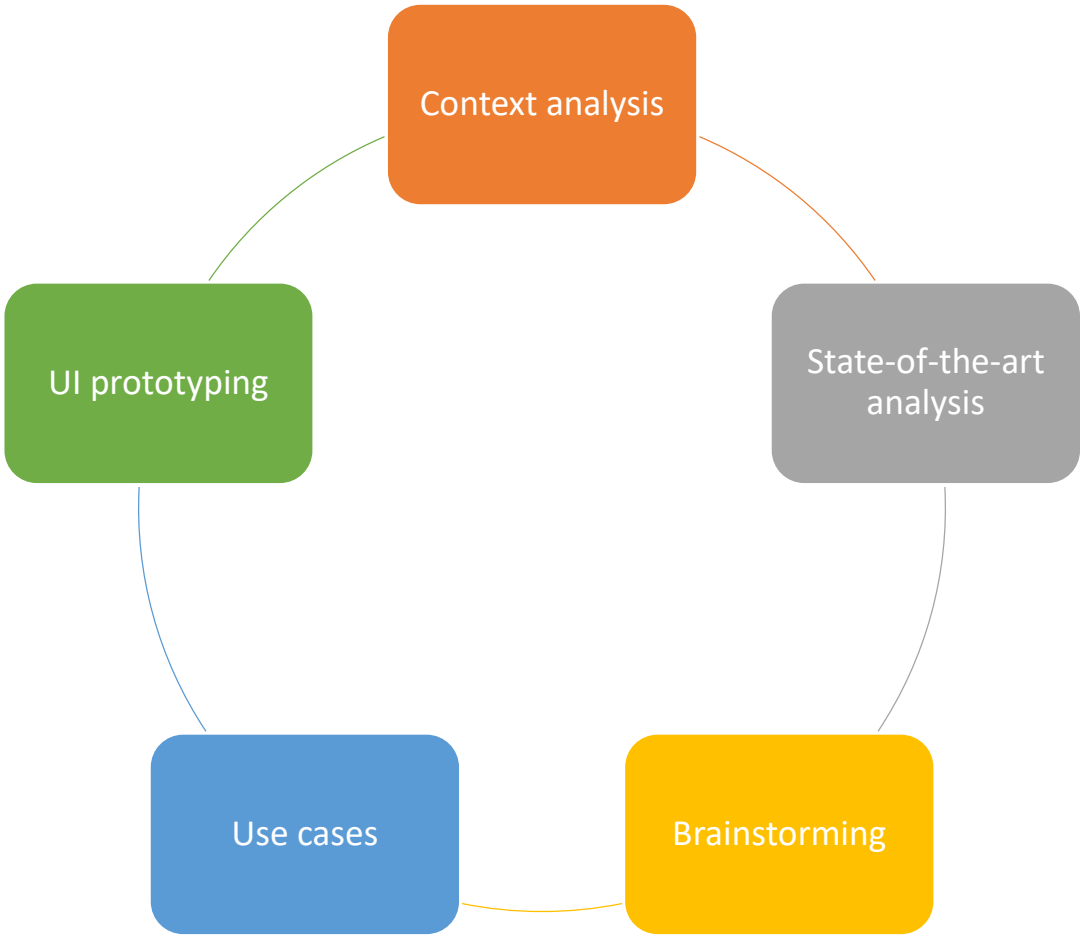


Figure 2 Activities to collect specification

3.1 Process

We managed the activities of the current task in three macro phases:

- **Specification gathering**: this is the first round of interviews and brainstorming with partners and experts to collect specifications and details about the system.
- **Specification drafting**: the specifications gathered in the previous phase are written in this document as business and user requirements. Then they are extended as system specifications to provide a complete set of specifications to be used on the development tasks 5.2, 5.3. The specifications are also used to create a first draft of the UI.
- **Specification review**: The draft specification and UI is used in this step to review the specification with the partners and the clinicians to create the final release of the specifications.

4 Context Analysis

4.1 Prematurity

According to WHO (World Health Organization):

"*Preterm is defined as babies born alive before 37 weeks of pregnancy are completed. There are sub-categories of preterm birth, based on gestational age:*

- *extremely preterm (less than 28 weeks)*
- *very preterm (28 to 32 weeks)*
- *moderate to late preterm (32 to 37 weeks).*

Babies may be born preterm because of spontaneous preterm labour or because there is a medical indication to plan an induction of labour or caesarean birth early.

*An estimated **15 million babies** are born too early every year. That is more than 1 in 10 babies. Approximately **1 million children die each year** due to complications of preterm birth (1). **Many survivors face a lifetime of disability**, including learning disabilities and visual and hearing problems.*

Globally, prematurity is the leading cause of death in children under the age of 5 years. Inequalities in survival rates around the world are stark. In low-income settings, half of the babies born at or below 32 weeks (2 months early) die due to a lack of feasible, cost-effective care such as warmth, breastfeeding support and basic care for infections and breathing difficulties. In high-income countries, almost all these babies survive. Suboptimal use of technology in middle-income settings is causing an increased burden of disability among preterm babies who survive the neonatal period."[1]

Out of the **500,000 babies annually born before the term in Europe**, by the time they reach school age, **125,000 (25%) are expected to require a variable range of school support**, paid leave for families and caregivers and may not be able to achieve superior instructions due to a wide range of learning and motor disabilities that cannot be identified and effectively prevented during the early post-natal period. The prematurity-associated disability cost for the first two years of life in Europe is estimated to be more than **50,000 € per year per baby**. Addressing the global burden of preterm birth has been considered a pivotal task to achieve the third **WHO Sustainable Development Goal** – to ensure healthy lives and promote well-being for all at all ages – and to reduce preterm-related neonatal and child social burden[2].

4.2 Stakeholders

At the centre of the Prometeus ecosystem, there is the baby, as well as the doctor and the parents (main actors of the Prometeus solution).

The other members of the ecosystem related to Prometeus are:

1. medical device industry
2. IT industry
3. medical experts in the field of prematurity
4. the scientific community
5. diabetes and prematurity patient associations

[1] https://www.who.int/news-room/fact-sheets/detail/preterm-birth

[2] https://www.who.int/europe/about-us/our-work/sustainable-development-goals/targets-of-sustainable-development-goal-3

6. the mobile application industry
7. regulators
8. insurers
9. policymakers.

4.2.1 Users

The users of the systems are:

1. HCP and Nurses
2. Researchers
3. Parents
4. Hospital IT staff

4.3 EU-funded Research Projects

Several EU Projects were focused to improve the quality of life of pre-term babies both improving the detection of pre-term labour risk and monitoring the health condition of pre-term babies. Some examples of these projects are:

- **SHIPS**[3]: A new study from the Effective Perinatal Intensive Care in Europe (EPICE) cohort assessed the impact of follow-up and screening programmes on the health of very preterm infants after they are discharged home from the neonatal intensive care unit. The study also looked at the effects on their families, assessment tools and costs to society.
- **RECAP preterm**[4]: The project's overall aim is to improve the health, development and quality of life of children and adults born very preterm (VPT, < 32 weeks of gestation) or very low birth weight (VLBW, < 1500g) – approximately 50 000 births each year in Europe – by establishing an ICT platform to integrate, harmonise and exploit the wealth of data from 20 European cohorts of VPT/VLBW children and adults and their families constituted from the early 1980s to the present, together with data from national registries.
- **WISH**[5]: An estimated 15 million babies are born prematurely every year, posing a significant risk to both maternal and neonatal health. The EU-funded WISH project promotes a novel tool for monitoring the risk of preterm labour at home.
- **BABYLUX**[6]**:** An Optical Neuro-Monitor of Cerebral Oxygen Metabolism and Blood Flow for Neonatology – is a project that aims to provide an innovative and reliable tool to monitor and assess brain blood flow and oxygenation in extremely preterm neonates. The device can be brought to the bedside, measurements can be done in a few minutes and repeatedly, if the condition is critical. The project takes up complete R&D works and extends already tested prototypes to the level of demonstrator, bridging the gap between research products and commercialization.

[3] https://cordis.europa.eu/article/id/386879-follow-up-and-screening-to-improve-the-health-of-children-who-are-born-before-32

[4] https://cordis.europa.eu/project/id/733280

[5] https://cordis.europa.eu/article/id/436204-a-wearable-for-monitoring-prenatal-health-at-home

[6] https://www.babylux-project.eu/about/overview/

- **SafeBoosC[7]:** The primary objective of the SafeBoosC trial is to examine if it is possible to stabilise the cerebral oxygenation of extremely preterm infants during the first 72 hours of life through the application of cerebral NIRS oximetry and implementation of an rStO2-specific clinical treatment guideline. We hypothesise that by using the specified treatment guideline to respond to cerebral monitoring readings outside the target range, we would reduce the burden of hypo- and hyperoxia and consequently reduce brain injury.
- **OXYPREM[8]:** High-risk preterm infants need early oxygen (O2) monitoring. Quality medical devices are needed to monitor the precise level of O2 supply in their brain as even small O2 variations can produce irreversible damage. There is an urgent need to develop tissue oximeters designed for preterm infants to decrease avoidable deaths and chronic disabilities. The EU-funded OXYPREM project aims to introduce a brain oximeter created specifically for preterm infants and providing the degree of precision and reliability they need. The oximeter consists of a near-infrared spectroscopy sensor embedded in biocompatible silicone that is fixed to the preterm's head to monitor brain O2 levels and to run analysis algorithms transforming the signals into tissue oxygenation saturation measurements. The oximeter prototypes have shown the highest levels of precision in clinical studies and are currently in the commercialisation phase.
- **LIFECYCLE[9]:** Early life is an important window of opportunity to improve health across the full lifecycle. European pregnancy and child cohort studies together offer an unique opportunity to identify a wide range of early life stressors linked with individual biological, developmental and health trajectory variations, and to the onset and evolution of non-communicable diseases. LIFECYCLE will establish the EuroCHILD Cohort Network, which brings together existing, successful pregnancy and child cohorts and biobanks, by developing a governance structure taking account of national and European ethical, legal and societal implications, a shared data-management platform and data-harmonization strategies. LIFECYCLE will enrich this EuroCHILD Cohort Network by generating new integrated data on early life stressors related to socio-economic, migration, urban environment and life-style determinants, and will capitalize on these data by performing hypothesis-driven research on early life stressors influencing cardio-metabolic, respiratory and mental health trajectories during the full lifecycle, and the underlying epigenetic mechanisms. LIFECYCLE will translate these results into recommendations for targeted strategies and personalized prediction models to improve health trajectories for current and future Europeans generations by optimizing their earliest phase of life. To strengthen this long-term collaboration, LIFECYCLE will organize yearly international meetings open to pregnancy and child cohort researchers, introduce a Fellowship Training Programme for exchange of junior researchers between European pregnancy or child cohorts, and develop e-learning modules for researchers performing life-course health studies. Ultimately, LIFECYCLE will lead to a unique sustainable EuroCHILD Cohort Network and provide recommendations for targeted prevention strategies by identification of novel markers of early life stressors related to health trajectories throughout the lifecycle.

[7] https://www.clinicaltrials.gov/ct2/show/NCT01590316

[8] https://cordis.europa.eu/project/id/888943

[9] https://cordis.europa.eu/project/id/733206

5 Products in the market

There are no products with the same value proposition as Prometeus but some sub-components like the CMM are available.

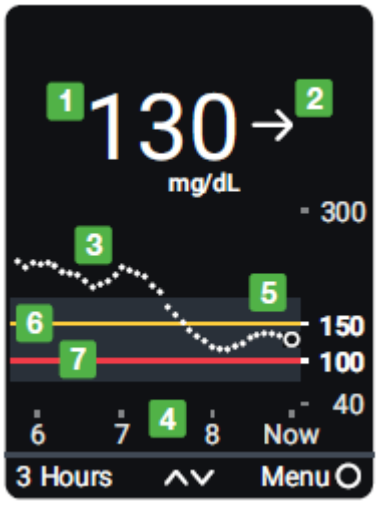
5.1 CMM

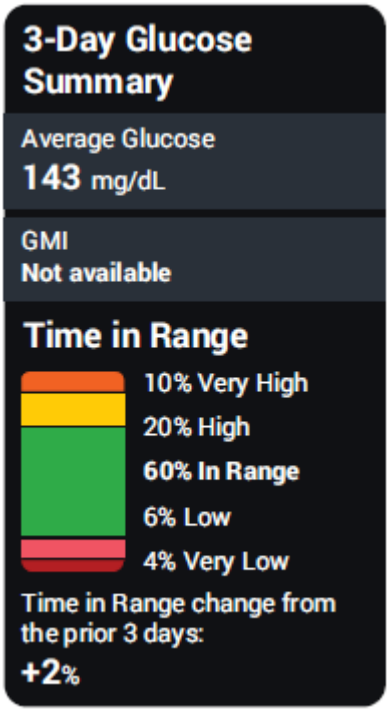
CMM sensors for glucose (also known as CGM – Continuous Glucose Monitoring) have been available on the market for a few years. CMM sensors for other metabolites are under development.

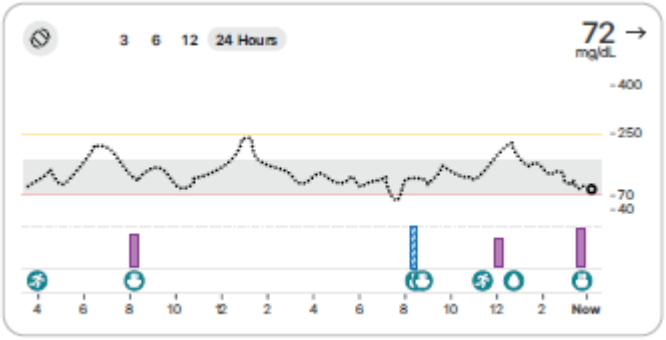
5.1.1 Dexcom G7

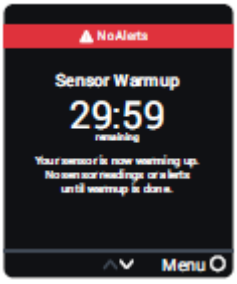
Dexcom is one of the leading companies in the development of CMM for glucose.

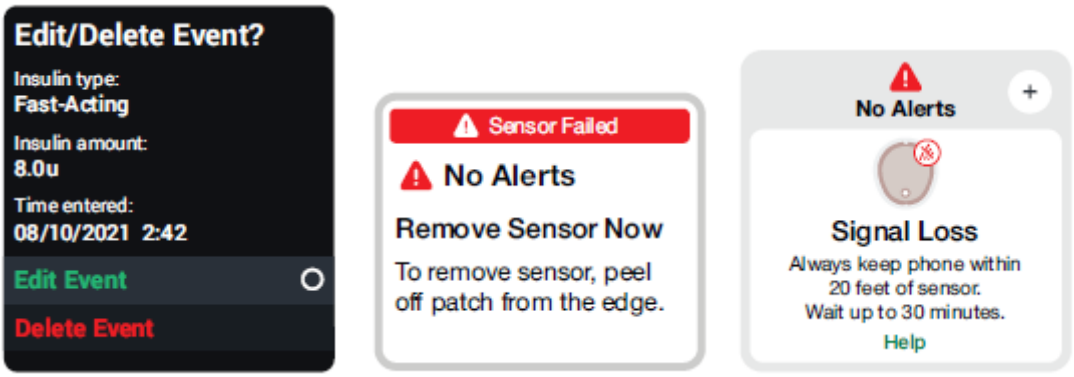
The G7 is their best product. The following screenshot reports the UI of this device.





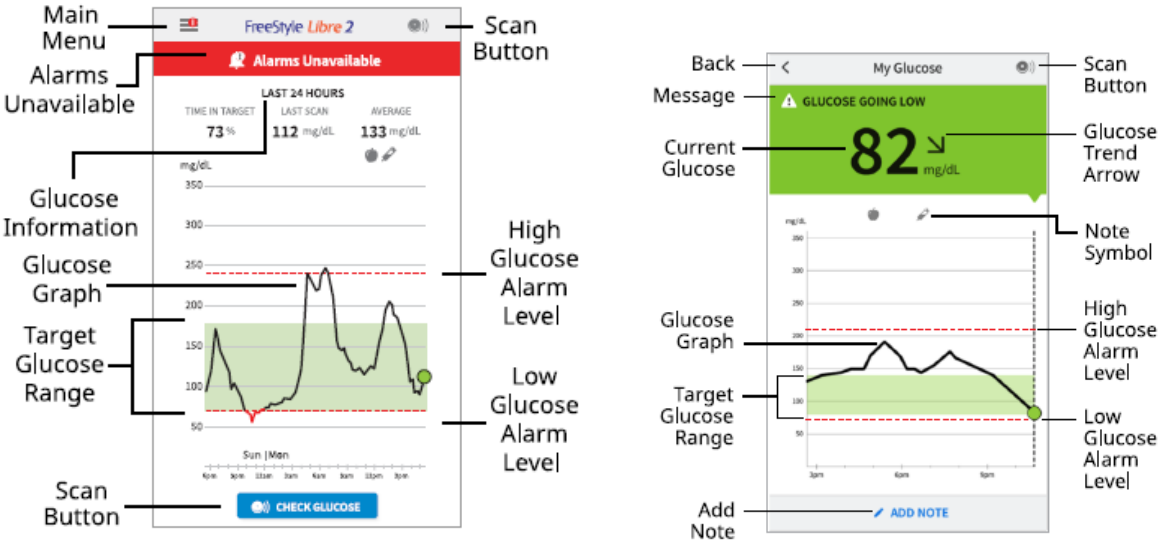






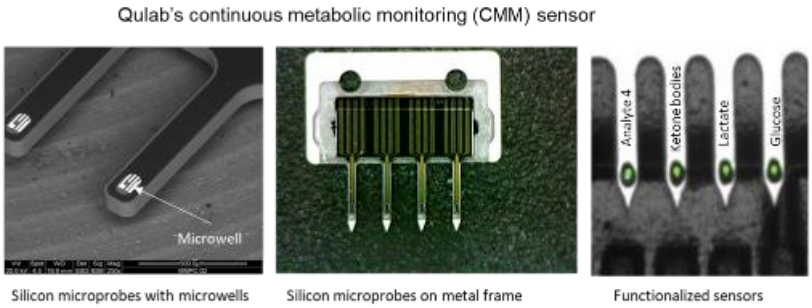
5.1.2 Freestyle Libre 2

Freestyle Libre 2 is another leading product in glucose monitoring.



5.1.3 CMM from QuLAB

The partner of the project QuLAB is developing a CMM sensor for premature babies.



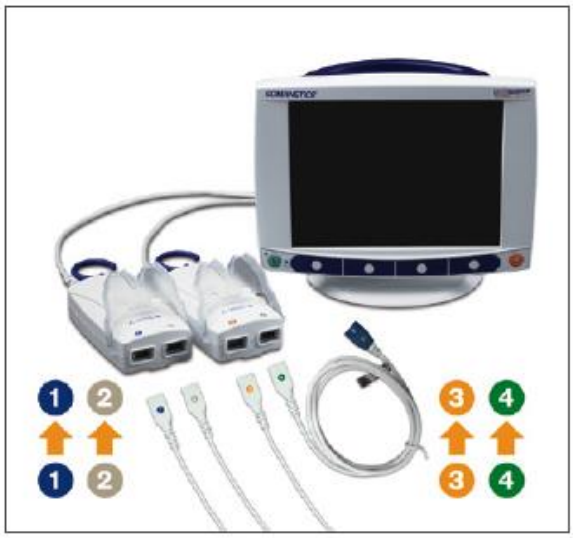
5.2 Brain oxygenation

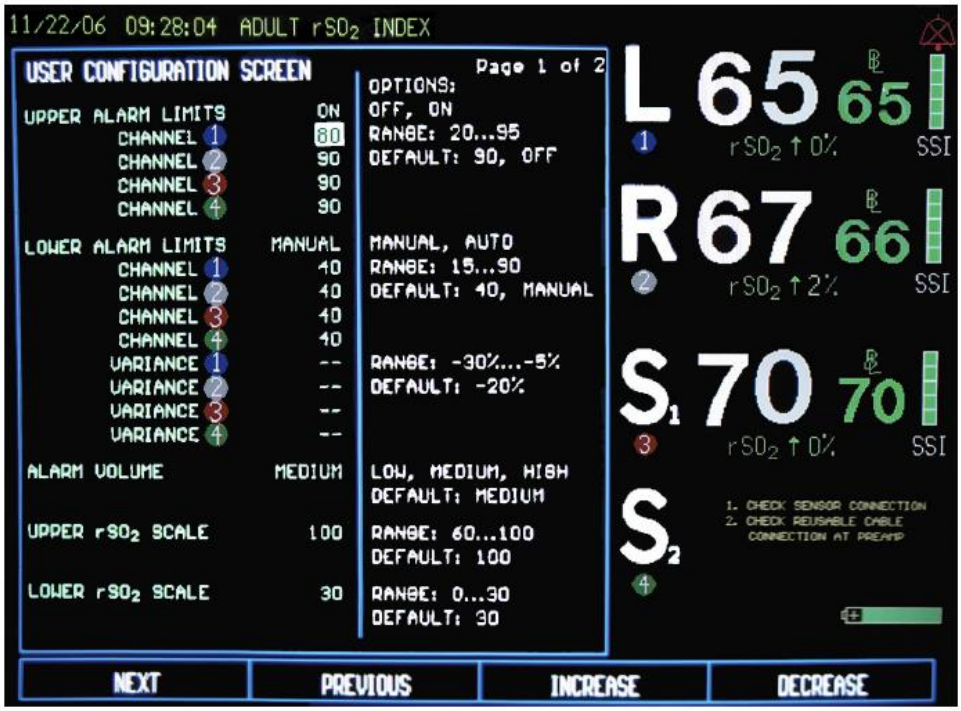
Few brain oxygenation devices are available on the market, but they are not designed for prematurity neither they provide monitoring of multiple regions of the brain.

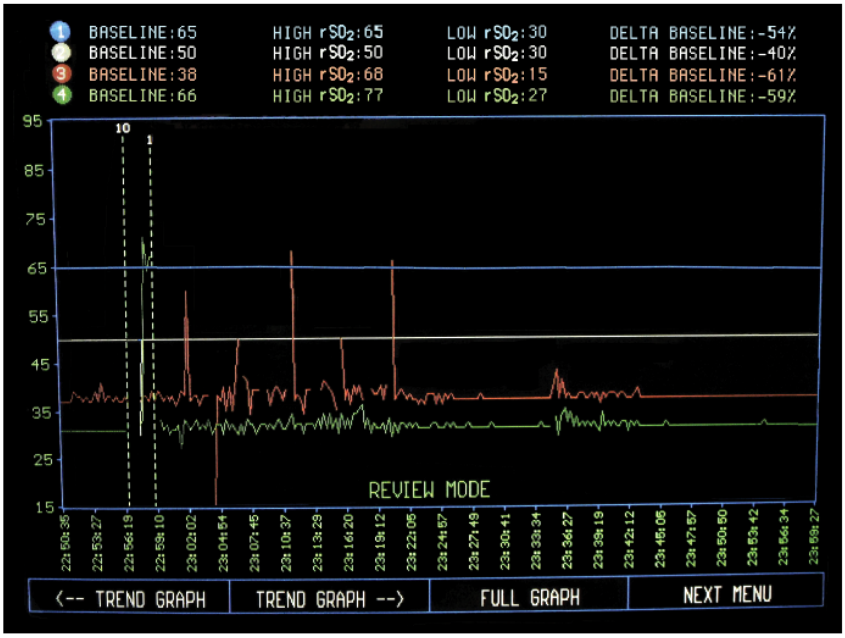
5.2.1 Medtronic INVOS

Medtronic INVOS cerebral somatic oximeter is one of the leading products for monitoring brain oxygenation.

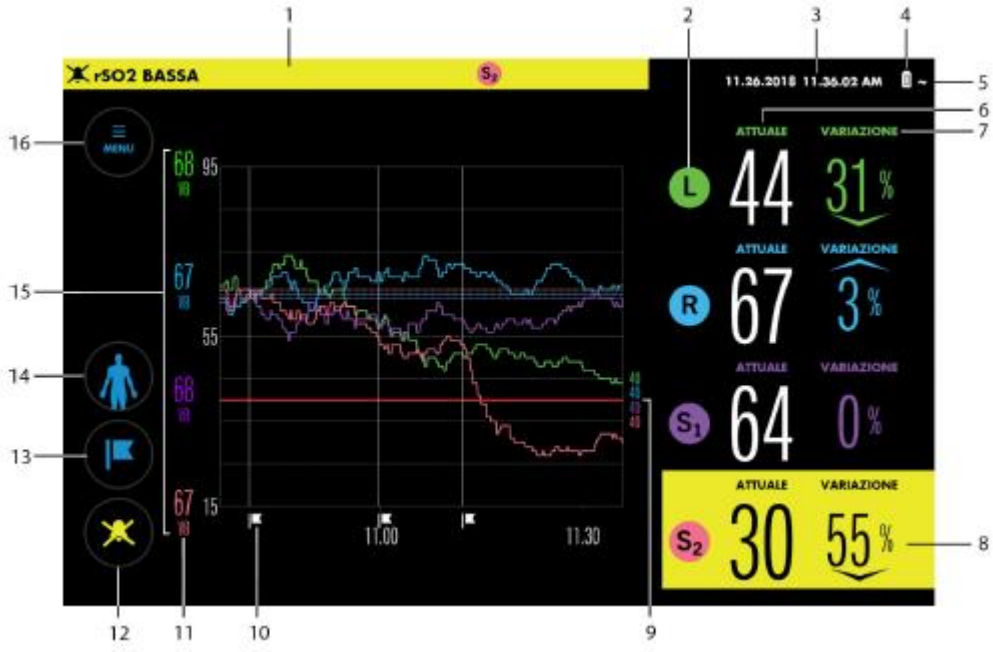
The images below show the device and its user interface.

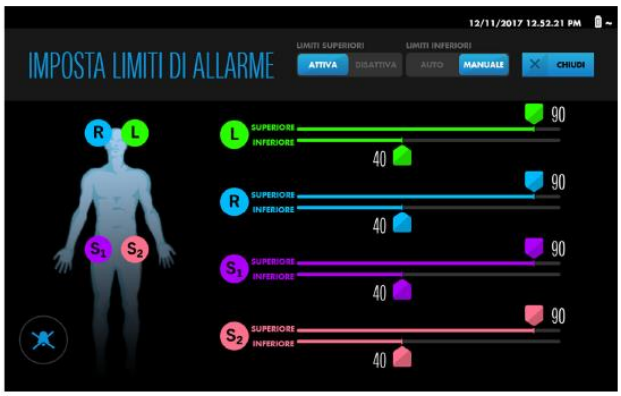



11/22/06 09:28:04 ADULT rSO2 INDEX
USER CONFIGURATION SCREEN
Page 1 of 2
UPPER ALARM LIMITS ON
CHANNEL 1 80
CHANNEL 2 90
CHANNEL 3 90
CHANNEL 4 90
LOWER ALARM LIMITS MANUAL
CHANNEL 1 40
CHANNEL 2 40
CHANNEL 3 40
CHANNEL 4 40
VARIANCE 1 --
VARIANCE 2 --
VARIANCE 3 --
VARIANCE 4 --
ALARM VOLUME MEDIUM
UPPER rSO2 SCALE 100
LOWER rSO2 SCALE 30
OPTIONS:
OFF, ON
RANGE: 20...95
DEFAULT: 90, OFF
MANUAL, AUTO
RANGE: 15...90
DEFAULT: 40, MANUAL
RANGE: -30%...-5%
DEFAULT: -20%
LOW, MEDIUM, HIGH
DEFAULT: MEDIUM
RANGE: 60...100
DEFAULT: 100
RANGE: 0...30
DEFAULT: 30
L 65 65
rSO2 ↑ 0% SSI
R 67 66
rSO2 ↑ 2% SSI
S1 70 70
rSO2 ↑ 0% SSI
S2
1. CHECK SENSOR CONNECTION
2. CHECK REUSABLE CABLE CONNECTION AT PREAMP
NEXT
PREVIOUS
INCREASE
DECREASE


BASELINE:65 HIGH rSO2:65 LOW rSO2:30 DELTA BASELINE:-54%
BASELINE:50 HIGH rSO2:50 LOW rSO2:30 DELTA BASELINE:-40%
BASELINE:38 HIGH rSO2:68 LOW rSO2:15 DELTA BASELINE:-61%
BASELINE:66 HIGH rSO2:77 LOW rSO2:27 DELTA BASELINE:-59%
95
85
75
65
55
45
35
25
15
REVIEW MODE
<-- TREND GRAPH
TREND GRAPH -->
FULL GRAPH
NEXT MENU

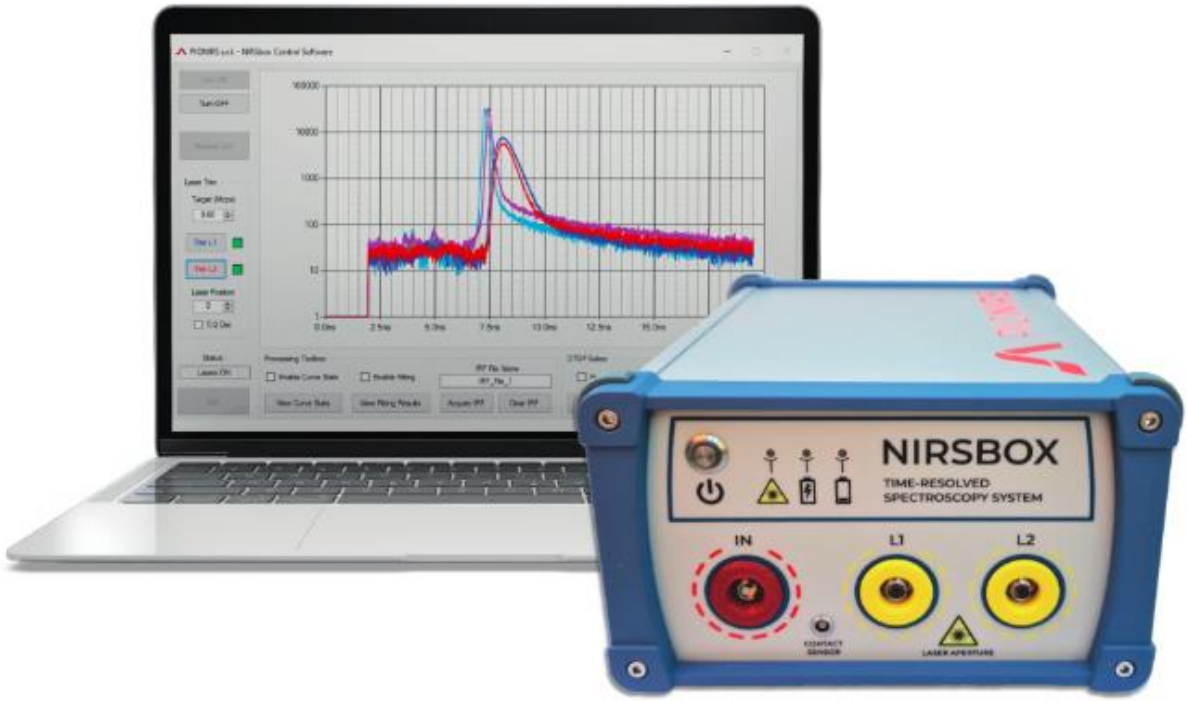
5.2.2 Medtronic INVOS New version

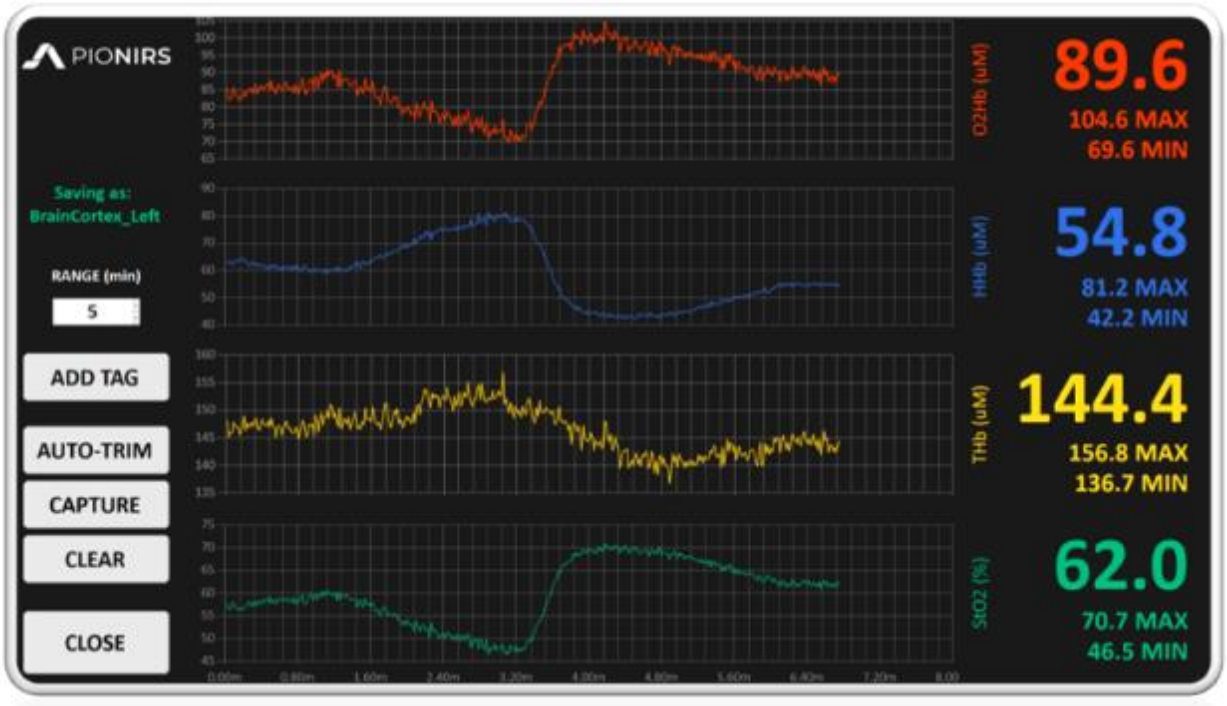




5.2.3 PIONIRS NIRSBOX

The partner of Prometeus Pionirs has a solution for monitoring brain oxygenation.

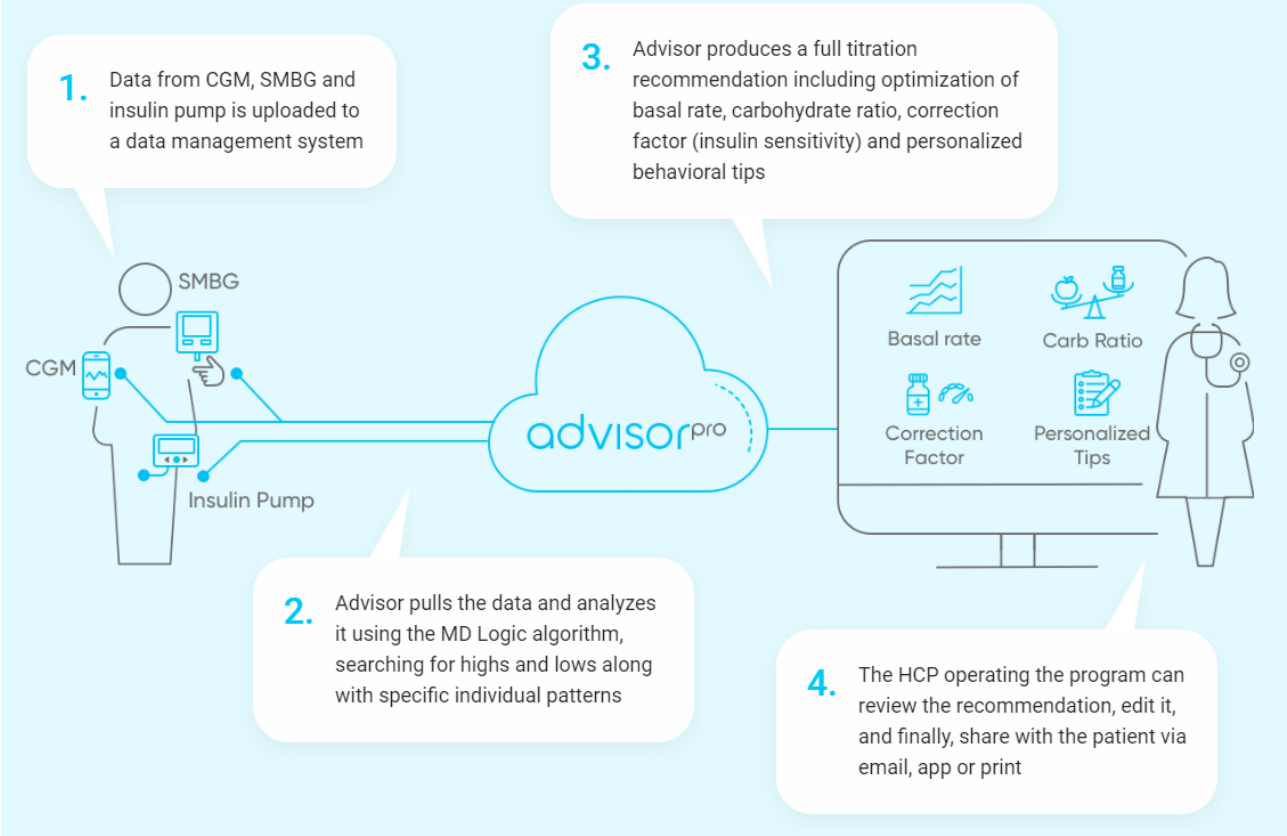




5.3 NCA

There are no nutritional advisors on the market for babies.

Dreamed commercializes an advisor for type 1 diabetic patients.



6 Brainstorming with partners

Several discussions have been performed between the partners of the consortium through conference calls, emails, and meetings (e.g., the kick-off meeting, on 2023/02/28). Through these discussions, clinical and technical expertise was combined to define the user requirements that the Prometeus solution and its cloud app should fulfil.

The discussions were focused on requirements for 'common' environments. Later in the lifecycle of the project and after its end, due to the potential of the system, these requirements could be adapted to specific/particular medical/working environments.

The participants in these discussions, considered:

- the users' expectations,
- the existing solutions (either the commercially available ones or prototypes under development),
- requirements for the systems

The topics addressed in the brainstorming were:

Partners	**Main topics**
DAVE – UniPD Clinicians	High-level architecture of the system, clinical and research needs, best practices in NICU, review of medical devices used in NICU, review of CGM systems.
DAVE - QuLab	CMM requirements for installation, calibration, connectivity with the main unit, errors and warning detection, commands, security procedures involving HCP, and data formats.
DAVE – PoliMi	Neo-opticap requirements for installation, calibration, connectivity with the main unit, errors and warning detection, commands, security procedures involving HCP, and data formats.
DAVE – UniPD Math Model - UDG	Metabolic mathematical model, configuration, personalization, inputs from sensors, inputs and outputs of NCA, error management of NCA
DAVE – UniPD Clinicians	Specification review, UI/UX review, workflow review,

7 Use Cases

The uses cases were prepared by the Prometeus consortium considering the users of the system and the activities that the users should do during their interaction with the system.

All these use cases involved the usage of the Prometeus solution and cloud app inside the NICU by the HCP or at home by the parents.

7.1 Use Case 1 - Setup

This use case includes the activities needed to configure the system before starting a monitoring session. The steps are:

- Turn on PEU and wait for the main interface.
- Login with admin credentials.
- Verify internet connection.
- Turn on CMM and neo-opticap.
- Perform the pairing/connection procedure for the CMM.
- Perform the pairing/connection procedure for the neo-opticap sensor.
- Start a “system check” procedure.

7.2 Use Case 2 - Monitoring and NCA

This use case is the core functional usage of the system.

- HCP turns on the Prometeus system and put it on the baby.
- HCP sets the baby’s information (Patient ID, weight, gender, days of life, gestational age, …) on the system.
- HCP starts the monitoring session.
- Real-time data from the sensors are shown on the local app.
- NCA generates suggestions for the HCP and HCP records the real feeding information provided to the baby.

7.3 Use Case 3 – Interactions of the Parents

This use case describes how the parents at home use the Prometeus system to monitor the health status of their babies while they are hosted at the NICU.

- Parent login on the Prometeus cloud portal (PCS)
- Parents see an interface with the overall status of their babies and with some additional information.
- The parent interface is automatically updated reporting the latest information of the baby.

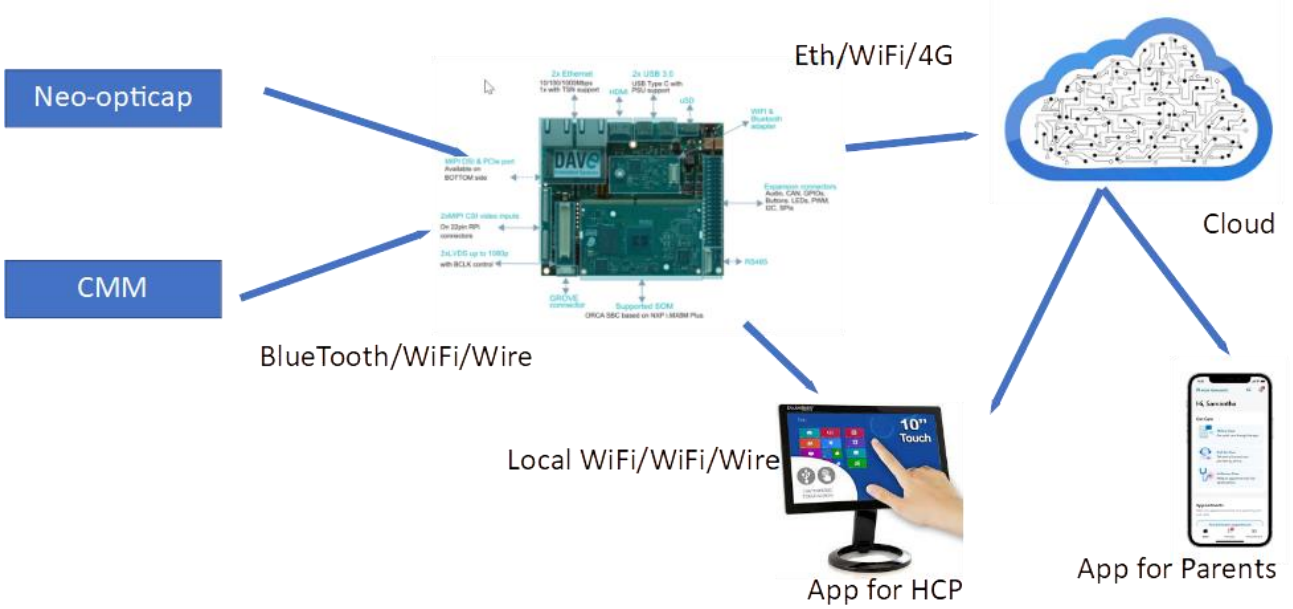
7.4 Use Case 4 - data review by HCP

This use case describes the interaction of an HCP with the PCS online to review data from a previous monitoring session.

- The HCP login to the cloud interface of the PCS.
- HCP has a list of monitoring sessions ordered by date with the most recent sessions first.
- The HCP can filter the list of sessions by patient ID or by date.
- HCP opens a monitoring session.
- HCP scrolls the time of the session and clicking on a single data stream they can gather more information about that sensor.

8 Architecture

8.1 High-level Architecture



8.2 Components

8.2.1 Neo-opticap sensor

The neo-opticap is a cap for the baby. The cap measures 6 parameters per each of the 6 brain regions (FR, FL, BR, BL, R, L). Raw signal from the cap is elaborated with a custom electronic system that sends elaborated data to the PEU. It communicates via REST API over the network with the PEU. The sensor generates a sample (6x6 measurements) every minute.

8.2.2 CMM sensor

The CMM is a patch sensor worn by the baby. It measures 3 analytes: glucose, lactate, beta hydroxybutyrate. The sensor communicates via Bluetooth with the PEU. The sensor generates a sample every 5 mins.

8.2.3 PEU (Prometeus Edge Unit)

PEU (Prometeus Edge Unit): field device which is in proximity to the sensing devices and the patients and interoperates with the sensors through their docking stations, manages the Controller execution, and interoperates with field equipment and other ICT platforms.

8.2.4 PCS (Prometeus Cloud Service)

PCS (Prometeus Cloud Service) is the cloud platform of the Prometeus system. It provides functionalities like user management, data storage, frontend for HCP, and frontend for parents.

8.2.5 Metabolic Model

The Metabolic Model is a software component that receives the data from sensors and the information about the baby as input and provides the forecast of metabolism as output. Internally the model creates the digital avatar of the metabolism of the baby. The model is used to simulate the effect of active actions (like nutrition) on the baby.

8.2.6 NCA (Nutritional Clinical Advisor)

NCA is the algorithm responsible to find the best nutrition for the baby based on the current health status and using the forecast of the metabolic model.

8.2.7 Local App for HCP

HCP has a local interface to interact with the Prometeus system. The local interface guarantees the system can work even if the internet connection is not available. With the local app, the HCP monitors the information coming from the sensors and receives suggestions from the NCA. The local app shows the alarms from the whole system to the HCP.

8.2.8 Webapp for HCP

The WebApp is the Prometeus' front-end UI for HCP users both with local and remote sessions. It is used to review old monitoring sessions and to perform advanced data analysis.

8.2.9 WebApp for Parents

The webapp for parents is used by the parents to monitor the overall status of their baby while he/she is in the NICU. The webapp for parents may be the same one used for HCP with different levels of access/functional availability.

8.3 Data

8.3.1 Data Classification: Sensitive, Personal, generic

The Prometeus system will manage the following type of data:

- Generic data: data strictly related to the devices, sensors, and cloud of the system to monitor the correct work conditions. These data are not related to the exam or the patients. Some examples of this data are the temperature of the CPU, network usage, BT and Wi-Fi connection status, number of exams performed, uptime, etc.
- Personal data: data related to the users like username and password, email, and location.
- Sensitive data: data related to health status like brain oxygenation, and glucose levels. The sensitive data recorded in the Prometeus system cannot be used to identify a person. Sensitive data are related to the patient using an anonymous patient ID. The relation between patient ID and patient personal information is managed by clinicians outside the Prometeus system.

8.3.2 Data Storage: local app, cloud, app

Data is stored both on PEU and synced with the PCS. Local app on PEU stored data from sensors and inputs from the HCP in local storage. The local storage on the PEU is automatically synced with the PCS.

The app for Parents will use a cache of the parents' credentials just for usability reasons.

8.3.3 Security

Data should be protected at rest and in transit. Personal data, sensitive data and generic data should be stored according to best practices for data security.

8.3.4 Backups

The Prometeus system should have a backup system to guarantee no data loss for the whole duration of the project.

The system should provide a backup procedure on the PEU if the network connection between PEU and PCS is not available.

9 Specifications

The specifications of the Prometeus system are split into levels from the business level to the system level. The topics addressed for each type of requirement are:

Type of requirements	Main topics
Business Requirements	High-level requirements describe the goal and the value of the project/product.
User Requirements	User requirements describe what the system should do and how it should work according to the user's point of view. User requirements are designed to satisfy the business requirements.
System Requirements	System requirements are the technical requirements needed to satisfy the user requirements.

The specification and the requirements are listed using the MoSCoW[10] method and RFC 2119 for prioritization[11]:

- **MUST**: This word, or the terms "required" or "shall", mean that the definition is an absolute requirement of the specification.
- **MUST NOT**: This phrase, or the phrase "shall not", means that the definition is an absolute prohibition of the specification.
- **SHOULD**: This word, or the adjective "recommended", means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
- **SHOULD NOT**: This phrase, or the phrase "not recommended" means that there may exist valid reasons in particular circumstances when the particular behaviour is acceptable or even useful, but the full implications should be understood, and the case carefully weighed before implementing any behaviour described with this label.
- **MAY**: This word, or the adjective "optional", means that an item is truly optional.

9.1 Business Requirements

BR_001. The Prometeus system MUST provide nutritional suggestions for pre-term babies based on neo-opticap and CMM sensors.

BR_002. The system MUST be used by the HCP in NICU.

BR_003. The system MUST be used by parents at home to monitor their babies.

BR_004. The Prometeus system SHOULD be designed to help the development of the metabolic model of the neonatal brain using oxygenation and metabolic sensors and the development of the NCA.

BR_005. The system SHOULD be compliant with medical regulations like ISO 13485, MDR, and GDPR.

BR_006. At the end of the Prometeus project, the PEU and PCS MUST reach at least TRL 4.

BR_007. The UI/UX SHOULD be similar to other products in the market to simplify usability and acceptance by the HCP.

[10] https://en.wikipedia.org/wiki/MoSCoW_method

[11] https://www.ietf.org/rfc/rfc2119.txt

9.2 User Requirements

Starting from the business requirements and using the methodology described in the previous chapters we create the list of "User Requirements" for the project.

At the time of writing this deliverable the sensors, the metabolic model and the NCA are in a study phase so this document presents high-level specifications of them, and details will be provided by partners during the development of WP 1, WP 2, WP 3 and WP 4.

9.2.1 User Requirements for Prometeus System

UR_001. PEU MUST be easy to install and move on the bedside or near the incubator.

UR_002. PEU MUST have a display of at least 15 inches in FHD with a touchscreen.

UR_003. PEU MUST be connected with the CMM sensor.

UR_004. PEU MUST be connected with the neo-opticap sensor.

UR_005. PEU MUST be secure and safe for use.

UR_006. PEU MUST be connected to the internet via ethernet or Wi-Fi.

UR_007. PEU MUST run the Prometeus local app at startup.

9.2.2 User Requirements for Prometeus App for HCP

UR_008. The Prometeus app for HCP MUST start showing the most relevant information of the system like patient and HCP IDs, date-time, system notification, the status of the sensors, last readings from sensors, and last advice from NCA.

UR_009. The Prometeus app for HCP MUST start showing the most used actions of the system like recording a case, recording a nutritional giving, viewing the history of cases, and configuring the system.

UR_010. The Prometeus app for HCP SHOULD have a tag system to record special events like a change of diaper or ventilation.

UR_011. The Prometeus app for HCP MUST receive readings from sensors, store them and sync them with PCS.

UR_012. The Prometeus app for HCP MUST generate alarms based on thresholds for sensor values. Alarms MUST be accepted by HCP and the same alarm MUST not be triggered if inside a "managing" time.

UR_013. The Prometeus app for HCP MAY generate alarms based on trends of sensor parameters.

UR_014. HCP MUST change views on the app to analyse the chart of a value.

UR_015. HCP MUST set information about the baby like gestational age, age, weight, and gender. This information will be provided to sensors and NCA.

UR_016. Prometeus app for HCP MUST have a configuration screen for NCA.

UR_017. Prometeus app for HCP MUST show the advice generated by NCA as 1) changes of the infusion (protein, lipids and glucose) and 2) urgent requirement of glucose/insulin.

9.2.3 User Requirements for Prometeus App for Parents

UR_018. Parents' app MUST be available outside the hospital. It SHOULD be a web portal or a mobile app.

UR_019. Parents MUST log in to the app in a secure way.

UR_020. Parents MUST set the ID of their baby to get information.

UR_021. Parents MUST have access to only the information of their baby.

UR_022. The Parents' app MUST show the most relevant information about the health status of the baby.

UR_023. The Parents' app MUST show the overall status of the baby.

UR_024. The Parents' app MUST refresh/update automatically the UI to show the most recent data.

UR_025. The Parents' app MUST show some information about the baby's life like diaper changes.

9.3 System Requirements

System requirements are designed in this phase to meet the user requirements, but they can change during the development to solve technical constraints.

System requirements can be categorized as either functional requirements (FR) or non-functional requirements (NFR). System requirements describe what the system must do. Non-function requirements describe how the system works.

9.3.1 FR PEU and PCS

SR_001. PEU MUST send data to the PCS.

SR_002. Technicians MUST configure the clock of PEU.

SR_003. PEU MUST synchronize the clock of all subsystems and sensors.

SR_004. Technicians MUST configure the network of PEU.

SR_005. The electronics of the PEU SHOULD be all integrated into a single device.

SR_006. PEU MAY have an internal battery.

9.3.2 FR Prometeus app for HCP

SR_007. The Prometeus app for HCP SHOULD have a backend and a frontend service both on PCS and PEU.

SR_008. The Prometeus app for HCP MUST record data coming from sensors in local storage on PEU.

SR_009. The Prometeus app for HCP MUST receive data and warnings from the CMM sensor via BT/BTLE and send configurations and commands to it.

SR_010. The Prometeus app for HCP MUST receive data warnings from the neo-opticap sensor via network API calls and send configurations and commands to it.

SR_011. The Prometeus app for HCP MUST provide a secure authentication system for HCP and technicians.

SR_012. The Prometeus app for HCP MUST provide network configuration to the technician.

SR_013. The Prometeus app for HCP MUST provide clock configuration to the technician.

SR_014. The Prometeus app for HCP MUST have an internal database organized to record data coming from sensors and associated with a case and with a patient.

SR_015. Prometeus app for HCP SHOULD check the sensors' status and configuration of all components before starting a recording session.

SR_016. The Prometeus app for HCP SHOULD have a chart layout with the thresholds for alarms.

SR_017. Prometeus app for HCP MUST generate alarms for value received from sensors that are out of configured ranges. The alarms MUST be easy to understand on the screen.

SR_018. Errors/warnings MUST have a severity level. Based on the severity the errors/warning should change their evidence on the screen and their severity SHOULD trigger an audio alarm.

SR_019. The Prometeus app for HCP MUST feed the NCA algorithm with the values coming from the sensors. The execution time of the NCA algorithms SHOULD be less than the interval between two samples from sensors.

SR_020. The Prometeus app for HCP MUST display the advice generated by the NCA on the screen.

9.3.3 FR Prometeus app for parents

SR_021. The Prometeus app for parents MUST be available as a web portal or mobile app.

SR_022. The Prometeus app for parents MUST provide a secure authentication system for parents.

SR_023. The Prometeus app for parents MUST allow parents to set the id of their baby.

SR_024. The Prometeus app for parents MUST show all the relevant information about the health status of the baby on one page.

SR_025. The Prometeus app for parents MUST have an aggregated indicator of the health status of the baby. The indicator MAY be set by the HCP using the Prometeus app for HCP.

9.3.4 NFR PEU Operating Conditions

SR_026. PEU power supply SHOULD be in the range of 100 V CA a 240 V CA ± 10% with a frequency between 50 to 60 Hz.

SR_027. PEU standard operating temperature SHOULD be in the range of +5° C to +40° C.

SR_028. PEU standard operating altitude SHOULD be in the range of -500 m to 4.000 m.

SR_029. PEU standard operating pressure SHOULD be in the range of 1.075 hPa to 616 hPa.

SR_030. PEU standard operating humidity SHOULD be in the range of 15% to 95% without condensation.

9.3.5 NFR Regulatory

SR_031. PEU design process SHOULD be compliant with ISO 13485.

SR_032. SW development process MAY be compliant with ISO 62304 - Medical device software — Software life cycle processes.

SR_033. UI/UX MAY be designed following the ISO 62366 - Medical devices Application of usability engineering to medical devices.

SR_034. PEU MAY be compliant with IEC 60601-1-2 and IEC 60601-1-2.

SR_035. Prometeus solution SHOULD have a risk assessment according to ISO 14971.

9.3.6 NFR Usability

SR_036. HCP MUST access the most used actions with one click action.

SR_037. Parents MUST have a visual overall indicator of the health status of their baby.

9.3.7 NFR Performance

SR_038. PEU SHOULD collect and show data coming from the sensors in real-time. The max frequency from a sensor is 1 sensor sample per minute. Asynchronous events like errors and warnings must be processed and shown on the local app in less than 3 secs.

SR_039. PEU SHOULD execute metabolic model and NCA in soft real-time.

9.3.8 NFR Reliability

SR_040. PCS SHOULD be hosted on a cloud platform with more than 95% of uptime.

SR_041. PCS MUST detect abnormalities on its components and restart from a working condition.

SR_042. PEU MUST detect abnormalities on its components and restart from a working condition.

SR_043. PEU MUST manage electric power interruption restarting from a consistent status. No more than 10 seconds of data from sensors of user interactions must be lost.

SR_044. PEU MUST have an expected lifetime at a minimum of 2 years and 2000 power-on under standard operating conditions.

SR_045. PCS SHOULD have a backup system generating a full back every week.

SR_046. PCS MAY have a disaster recovery system to restart the system in no more than one week after a disaster.

9.3.9 NFR Security

SR_047. PEU MUST allow console login only with password protection.

SR_048. PEU MUST expose only the network service needed for the project. Available services MUST be protected with a password.

SR_049. PEU SHOULD log any login attempt.

SR_050. PCS MUST protect admin access with two-factor authentication.

SR_051. PCS MUST provide only authenticated user access.

SR_052. PCS SHOULD be protected against login brute force attacks and request flooding.

SR_053. PCS MAY follow OWASP best practices.

9.3.10 NFR APIs

SR_054. The PCS MAY have an open API to be integrated with other software/services.

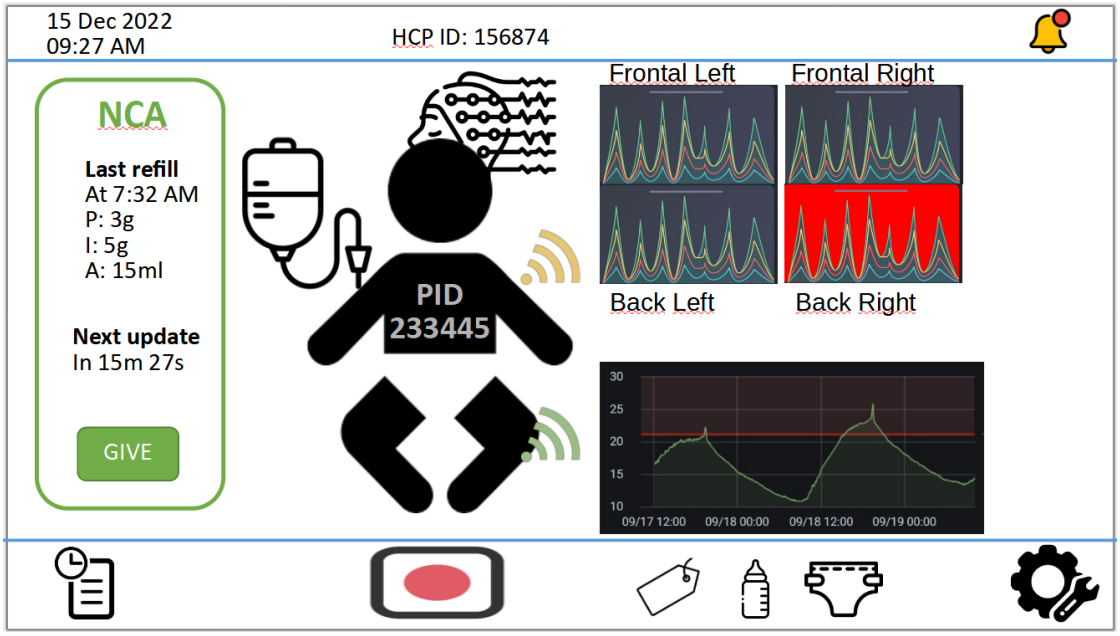
SR_055. The PCS API MUST be secure and protected by user/password and app key for B2B integration.

10 UI Prototyping

Using the requirements collected in the previous chapter, we designed a draft of the UI to put in one single image the most relevant information for the users (HCP).

This draft was used to tune requirements with clinicians and find an agreement on the macro functionalities of the system.

This draft will also be used as high-level input for the UI/UX experts.

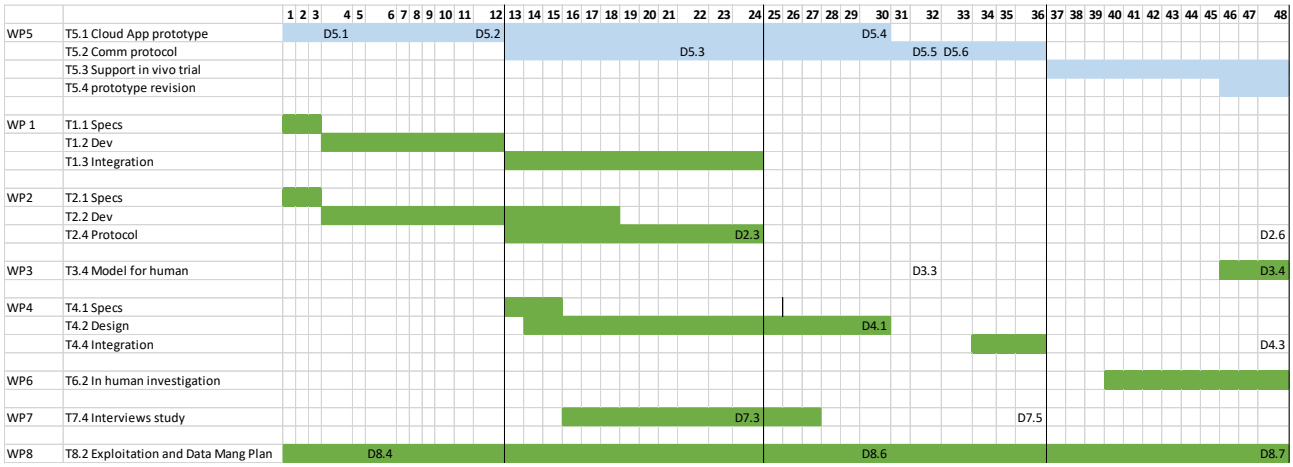


The review with the clinicians generated the following result:

- The drafted UI is a good starting point for the development.
- NCA should be updated with infusion advice and urgent advice.
- Tags should be extended with ventilation information.

11 Development Plan

The development of the specifications collected in this document will follow the DoA. The following Gantt shows in blue the tasks and deliverables of WP5 and in green its direct related tasks and deliverables.



The sensors (WP1 and WP2) and the NCA (WP3 and WP4) are under development, and they will be available after the first year of the project.

The prototype of the cloud app developed in Task 5.2 (deliverable D5.2), due in M12, will use a simulator of these components to show a fully working system. The integration with the real sensor will be developed during the second year.