# Portable Healthcare Device for Vital Measurements

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Department of Bioengineering

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# Medway

## Design and Development Plan

Document 001

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| Written by/updated by | | Date | Effective date / reference |
|---|---|---|---|
| Ana Ruiz Medina | | 08/10/2022 | |
| Reviewed by<br>Pooja Dandge | Signature | Date | 08/10/2022 |
| Approved by<br>Justin Bieber | Signature | Date | |

# 1. Introduction

## 1.1. Purpose of the Document

The purpose of this document is to define the goals, strategies, roles, responsibilities and methods for performing for the development of an all-in wearable vest called MedWay. This portable device, designed especially for bedridden patients and in need of continuous monitoring, measures oxygen levels in blood, pulse rate from an ECG lead and temperature all at the same time.

## 1.2. Intended audience

The intended audiences of this document are:

- Project Sponsor
- Product Manager
- Program Manager
- Clinical Manager
- Lead System Designer
- Manufacturing Leader
- Service Leader
- Supplier Quality Leader
- Sourcing Leader
- Quality Auditor Manager
- Regulatory Affairs Manager

### 1.3. Scope of the document

This design and development plan covers the design and development of the MedWay product to measure physiological activity of bedridden patients and patients in need of continuous monitoring.

# 2. Goals and objectives

## 2.1. Background and effect goal

The Patient Monitoring Market size was valued at $36.45 billion in the past year 2021 and is predicted to reach $77.56 billion by 2030, with a compound annual growth rate of $8.7 billion from 2022 to 2030. This fast annual growth has attracted new companies and sponsors to invest in this market. Due to this, the purpose of the project is to meet the increasing competition on the Patient Monitoring Market. The increasing rate of new products in this field makes the engaging task with both clients and sponsors much more difficult. The project develops a new product line that meets this threat and increases the market share while maintaining the same gross profit margin as before.

The MedWay product helps monitor the physiological activity of patients in critical conditions and keeps track of it. The product can be used to detect abnormalities and improvements and to export information to the doctor or clinician. The per-unit cost of one device will be $100 plus the service cost of approximately $60 for six months of usage.

## 2.2. Project objectives

The project has the following objectives:

1. Develop a portable and waterproof device according to the scope baseline of this project plan
2. Completed according to the budget specified in this plan, to make the device affordable
3. Complete the project no later than 2 years

### 2.3 Project objectives priority

The following priority should apply:

- To develop a medical device that is reliable, safe, accurate and uses sensor technology to track physiological activity and recovery for bedridden patients and patients under treatment.
- To make said device affordable and portable so that it can be used in the daily life of patients.
- To develop an application where all data coming from the device is stored and exported for a quick and easy follow-up process by doctors
- To present the device in conferences for the product to reach a higher audience
- To meet the budget of $25 million in the developing process of the device

## 3. Scope baseline

### 3.1. Product scope description

The product uses ECG and sensor technology to easily find heart rate signals, oxygen levels and body temperature in order to measure the physiological activity of patients in the intensive care unit or in need of continuous monitoring.

The system will have the following key features:

- Smart detection of abnormalities in the heart rate
- Smart detection of abnormalities in the body temperature
- Smart detection of abnormalities in oxygen levels in blood
- Algorithms to eliminate background noise
- Wireless technology for more freedom capability and easy and flexible usage
- Application development to keep track of the data stored and to facilitate the data exportation process to healthcare professionals

### 3.2. Product acceptance criteria

Our product, MedWay, is developed as per regulatory and documentation requirements as set out in the requirement specifications by regulatory authorities for the target markets in Europe, as specified in the project charter. Project deliverables shall be approved according to the product development procedure.

## 3.3. Major deliverables

The project has the following major deliverables:

- First prototype of the MedWay portable device
- Zero serial production of 10 units of the device that are validated and verified using the standard operating procedures
- Verification documents of the device
- Device History file that includes the device changes
- Completed documentation on device master record

## 3.4. Work breakdown structure

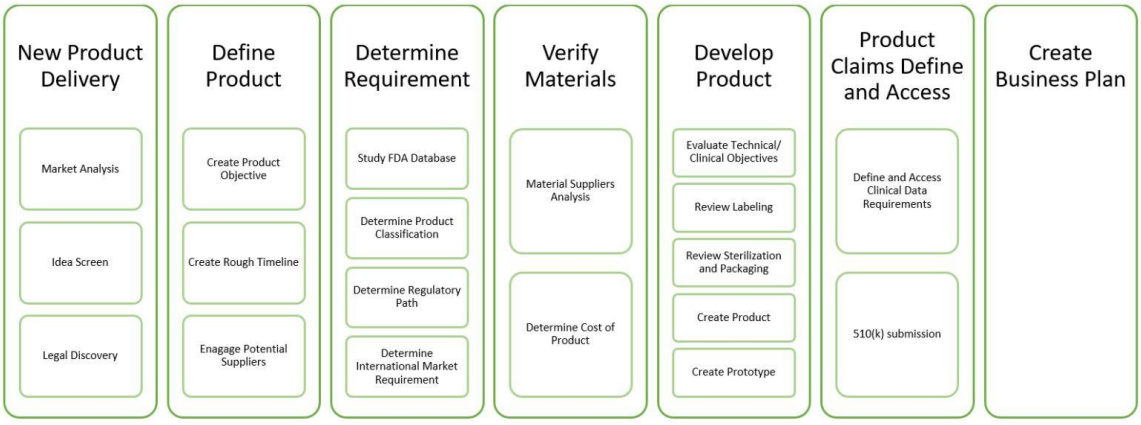


**Fig1: Work breakdown structure**

## 3.5. Exclusions

Clinical investigations and trials will not be performed and will not be a part of the project.

## 3.6. Constraints

Due to limited cash flow, some important physiological activities such as the detection of the breathing pattern, skeletal muscle activity or glucose blood levels will be excluded from this device. Despite this, with the budget allowed, the device will use sensors to precisely be able to detect heart rate patterns, oxygen blood levels and body temperature.

## 3.7. Assumptions

The following assumptions are considered to be true for planning purposes:

- Project managers, factory leaders, service personnel and the quality management system will be approved by the notified body throughout the duration of this project.
- No major changes with regard to the design and development of the Quality Management System will be done throughout the duration of the project.
- Key researchers will provide information in a timely manner during the course of the project.
- During the design phase, a contract manufacturer will be available to produce the device with a max six months lead-time.

## 3.8. Requirement documentation

The requirements for the product and processes can be found in the following documents:

- SOP 0001 Rev-00 Test procedure to get the ECG signals
- SOP 0002 Rev-00 Test procedure to detect abnormalities in the heart rate from the ECG
- SOP 0003 Rev-00 Test procedure to detect the body temperature sensor
- SOP 0004 Rev-00 Test procedure to detect the pulse oximeter sensor
- SOP 0005 Rev-00 Test procedure to record, integrate and export the signals
- SOP 0006 Rev-00 Test procedure to verify the application

# 4. Schedule

Baseline target dates are:

| Phase | Date |
|---|---|
| Start of Design Phase | 07/01/2023 |
| Start of Verification Phase | 10/01/2023 |
| Start of Validation Phase | 11/15/2023 |
| End of project, product release to clinical investigation | 05/01/2024 |

## 4.1. Phases and reviews

The development is done according to the phases defined in SOP-0007 Rev-00 Design and Development.

Design reviews will be performed according to SOP-XXX Design and Development and the table below:

| Design reviews/Decision points | Date | Review team |
|---|---|---|
| End of Design phase | 08/01/2023 | Ángela Moreno, Teresa Antropow, Isabel Nogales |
| Before Verification Phase | 15/09/2023 | Ángela Moreno, Teresa Antropow, Isabel Nogales |
| Before starting validation phase | 11/01/2023 | Ángela Moreno, Teresa Antropow, Isabel Nogales |
| Before end of project, product release to clinical investigation | 04/01/2024 | Ángela Moreno, Teresa Antropow, Isabel Nogales |

# 5. Project organization plan

## 5.1. Project organizational structure

The organization chart above also defines the organizational interfaces between various functions in the project:

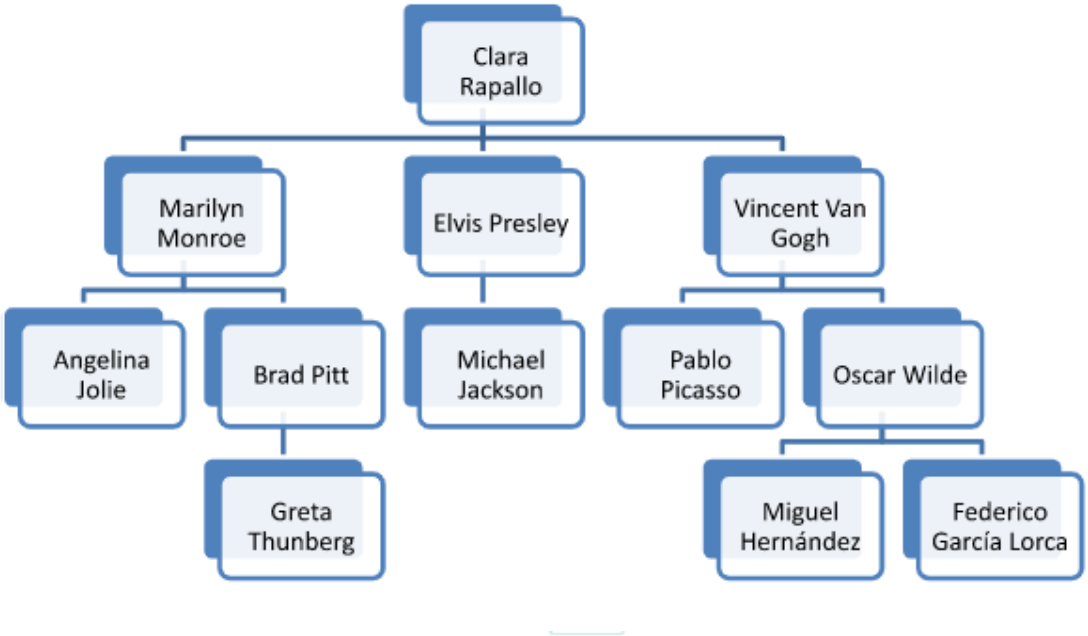


**Fig2: Project organizational structure**

## 5.2 Resources

The following personnel are working in the project:

- Alexandros Zografos Manos
- Ana Ruiz Medina
- Kiran Mehnaz Kaur
- Pooja Dandge
- Poulami Mondal
- Srishti Sanjay Arora

The following material resources will be used in the project:

- Heart rate detection thanks to 3 ECG leads
- Temperature detection sensor
- Pulse oximeter
- Materials for design

## 5.3 Responsibilities and authorities

These are the associated responsibilities and authorities who make up the team for MedWay:

| Role | Name |
|---|---|
| Project Sponsor | James Charles |
| Project Manager | Emma Chamberlain |
| Program Manager | Kendall Jenner |
| Clinical Manager | Beyoncé Knowles-Carter |
| Lead System Designer | Scott Disick |
| Manufacturing Leader | Amaia Romero |
| Service Leader | Taylor Swift |
| Supplier Quantity Leader | Bruno Mars |
| Sourcing Leader | Gerard Piqué |
| QA | Lionel Messi |
| RA | Justin Bieber |
| Software Developer | Kim Kardashian |

## 6. Design and development documentation

Documentation will be controlled according to the following SOPs:

- SOP-009 Rev-00 Document control
- SOP-010 Rev-00 Records Control
- SOP-011 Rev-00 Device Master Record

## 7. Change history

| Document Version | Author | Date | Description/Change |
|---|---|---|---|
| SOP-001 Rev-00 | Pooja Dandge | 11/01/2022 | To check if the device can detect the heart rate from the ECG leads |
| SOP-002 Rev-00 | Alex Zografos | 11/01/2022 | To check if the device can detect the body temperature from the temperature sensors |
| SOP-003 Rev-00 | Poulami Mondal | 11/06/2022 | To check if the device can detect oxygen levels from the pulse oximeter |
| SOP-004 Rev-00 | Srishti Arora | 11/06/2022 | To check if the device can store and integrate the signals |
| SOP-005 Rev-00 | Kiran Mehnaz Kaur | 11/10/2022 | To check the autonomy of the device with respect to battery conditions |
| SOP-006 Rev-00 | Ana Ruiz Medina | 11/10/2022 | To check the accuracy of the signals detected using different algorithms |
| SOP-007 Rev-00 | Srishti Arora | 11/10/2022 | To check the ability of the device to detect abnormalities in the physiological activity from the signals received |

| | | | |
|---|---|---|---|
| SOP-008 Rev-00 | Poulami Mondal | 11/23/2022 | To check if the data is exported correctly to the healthcare professionals |
| SOP-009 Rev-00 | Pooja Dandge | 11/29/2022 | Document Control |
| SOP-010 Rev-00 | Ana Ruiz Medina | 11/29/2022 | Record Control |
| SOP-011 Rev-00 | Alex Zografos | 11/29/2022 | Device Master Control |

Medway

# Integrated Design Plan

Document 002

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**Page No**

# 1. Purpose and Scope

## Basic Purpose

This Mobile Healthcare System device by Medway works as a patient monitoring system and measures vital parameters including ECG, heart rate, oxygen saturation (SpO2) and temperature. The device is specially targeted to cater patients in critical conditions and alert the user in case of any abnormalities from the comfort of their home. The hardware of the device consists of multiple sensors and microcontroller unit to detect and transform the received signal which is then transferred using transceiver modules and displayed on a monitor. Our device is going to be low-cost and portable.

## The Plan

This Integrated Design Plan (IDP) documents the strategies and plans that will be used for the Medway device. This document, together with the reference documents attached, is intended to provide program team members with a clear understanding of the program objectives, scope, deliverables, organization, and operating mechanisms such that the required work can be planned in detail and executed. It will follow "Design Controls Integrated Design Planning Work Instruction" and will be updated and released prior to each program milestone unless no required changes are identified at that time. Updates may also be made between milestones if the program leadership team determines an update is necessary for effective team communication.

## Business Impact

It is essential for any company to perform market research and analyze patterns to better strategize for their product. This device detects crucial parameters of patients in critical condition and needs constant monitoring. What makes this device different than other patient monitoring systems is its portability and low cost. It allows the patient to utilize our device from anywhere, in the comfort of their own home and alerts the user and the healthcare personnel in case of any anomaly and when emergency response is needed.

## Clinical Impact

This device detects crucial parameters including ECG, heart rate, temperature and SpO2 and transfers them to a visual display to alert the user of any abnormal condition. It is simple, non-invasive, portable, and cost-effective, and allows real-time testing by detecting any anomaly in the measured parameters. However, there are limitations in wearable patient monitoring devices due to inaccuracies while detecting the signal by the sensors, which must be addressed too. Hence, it is essential to perform adequate research and acquire favorable data to ensure the product is safe and reliable before releasing in the market.

## Competition

The competition of MedWay is Allyn 300 and Apple Watch Ultra, which have similar features to MedWay. MedWay measures ECG with 3 leads on the other hand Allyn 300 does not measure ECG and Apple Watch Ultra uses an electric heart rate sensor. The heart rate in MedWay is calculated from the ECG that is obtained, in Allyn 300 it is measured from the SpO2 probe which does not give the exact measurements and in the Apple Watch Ultra the electric heart rate sensor gives the heart rate. MedWay transmits the data to the doctor, but Allyn 300 and Apple Watch Ultra do not. MedWay has a compact size for easy portability which does not require additional costs, while Allyn 300 requires a mobility stand which can cost up to 125$. While the Apple Watch Ultra is very compact, it is also very expensive. The overall price of MedWay ranges from 100$ to 150$, Allyn 300 costs around 1050$ plus the mobility stand of 125$ and an Apple Watch Ultra costs around 700$ to 800$.

# 2. Device Description

## Hardware Requirements

- Battery
- Arduino Mega controller
- Transducers
- Wireless communication module
- Temperature sensor
- SpO2 sensor
- ECG Leads
- Display module
- ADC
- Amplifier
- USB Connector

## Software Requirements

- Operating systems
- Transducer controller for turning it on and off
- Transmitting data from controller to receiver
- Screen to display the vitals
- Real time data processing
- ADC
- Amplifier
- Modulator
- Transducer controller for input signals
- Filters
- Feature point extraction
- Heartbeat detector
- ECG curve
- Digital signal processing

We have a 3-Lead ECG detection system, pulse rate sensor, temperature sensor and oxygen saturation sensor, all equipped in a box. The ECG leads are placed on the left leg, left arm and right arm. When the patient places their hand into our sensor box, the temperature sensor detects the temperature of the patient from the back of the hand and oxygen saturation is measured using pulse oximeter sensor placed on the finger. The microcontroller processes the input signals and then displays it on the display system of our mobile patient monitoring system while the transceiver module transfers the data to the display system of the healthcare personnel. Medway provides real-time monitoring and alerts the users in emergent conditions.

## Picture:

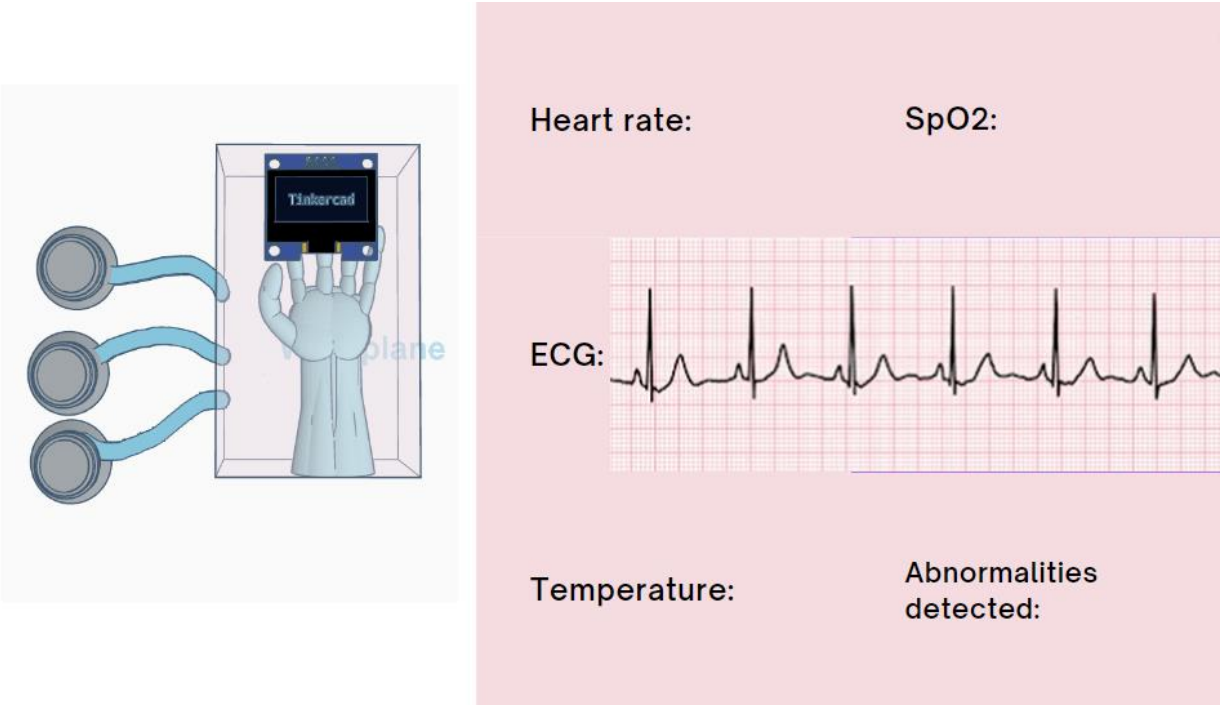



**Fig3: Device and measured parameters**

## Block Diagram:

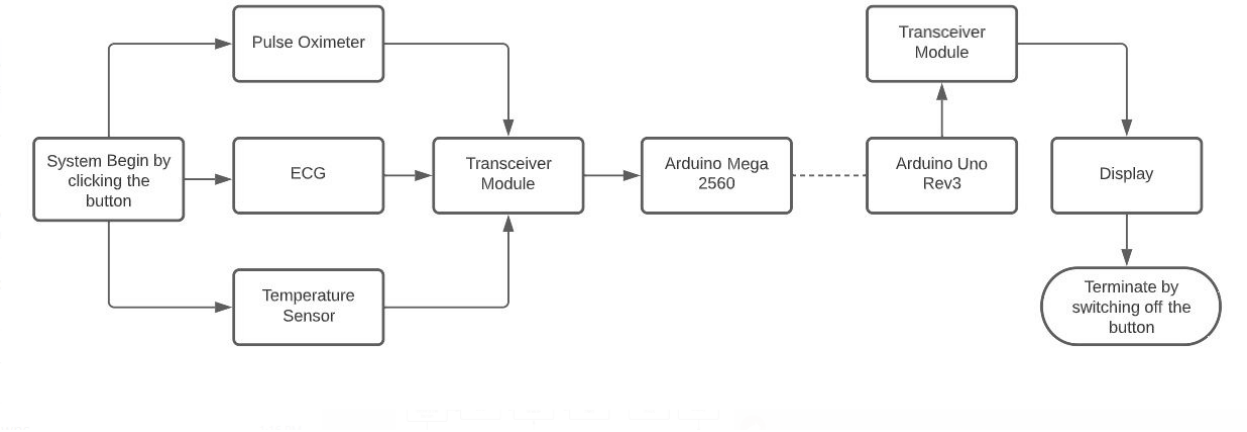



**Fig4: Block Diagram of the Hardware**

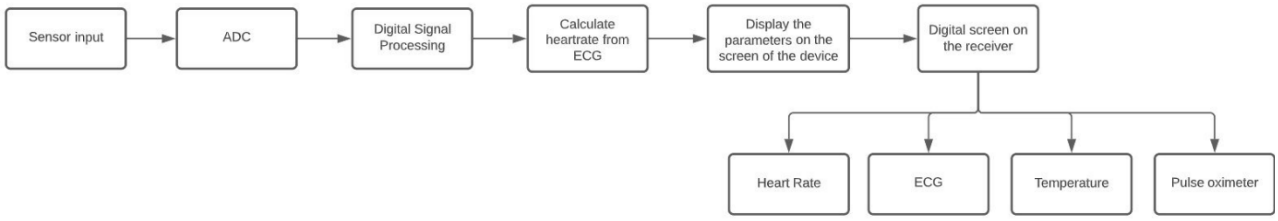



**Fig5: Block Diagram of the Software**

## Indications for use:

- This mobile healthcare system is intended to continuously monitor crucial health parameters- ECG waveform, pulse rate, temperature and SpO2 of patients from anywhere.
- The parameters measured are displayed on the screen for the patient and is also wirelessly transmitted to healthcare personnel.

## Text Description:

The Medway mobile healthcare system comprises of three parts:

- The sensors: to detect the different healthcare parameters.
- Microcontroller: to receive the signals, and process them for appropriate use
- Transceiver module and Display: to display the results to the user as well as wirelessly transmit them to healthcare personnel.

# 3. Risk Management

| Risk | Management |
|---|---|
| Excessive patient leakage current | Resistors 10kohms on each leads |
| Loose ECG Leads | Map each ECG lead before starting the procedure to measure ECG |
| Misplacement of temperature and SpO2 sensors | Marking on the device which shows ideal placement of the hand to detect good quality signal |
| Excessive/ Low signal | If the signal is not ideal for the microcontroller, it will display warning message to try again |
| Noise Cancellation | The microcontroller will be able to eliminate noise to measure the right parameters |
| Power Shortage | When the voltage supply from the battery is lower than ideal, the microcontroller will display a low battery symbol on the display |

| | |
|---|---|
| Communication | The signals will be transmitted wirelessly to the display of the healthcare personnel |
| Display | Under the circumstances that one of the displays (patient/ healthcare personnel) stops working, the data can be retrieved from the other display system |

# 4. Development Phases

## a) Design Inputs

**User Requirements:**

- Person of any age
- User friendly interface
- Patient history and data

**System Requirements:**

- Stable internet connection
- Power supply/ battery
- Portable
- Lightweight
- System memory
- Waterproof

## Hardware Requirements:

- Sensors
  - 3 ECG leads
  - Temperature sensor
  - SpO2 sensor
- Transmission receiver module
- ADC
- Booster circuit
- Voltage stabilizers
- 1 button
- Power amplifier
- Filters

### Software Requirements:

- ADC
- Digital signal processors
- Digital screen display
- Data storage
- Functionality supervision and auto detection for irregularities

## b) Design Outputs

- Digital screen displaying ECG, heart rate, temperature, and oxygen saturation in the blood
- Units of all the vitals
- Battery percentage

## c) Design Verification

All the parts of the design input will be verified step by step using its dedicated SOP as the prototype is being built.

## d) Design Transfer

Medway parts will be manufactured by Bio-health Industries as identified on the supply strategy and will follow the Bio-health Industries Site Quality Plan for Manufacturing processes.

The following strategy documents are available:

- Medway Supplier Quality Strategy Doc- 003
- Medway Program Sourcing Strategy Doc- 004
- Medway Program Design Transfer Plan Doc- 005

## e) Software Development

The software team led by Kim Kardashian will work on software development. Software development includes OS, signal processing, analog to digital signal conversion, display and wireless transmission. The processes for software development are detailed in Software Development Plans that are

- Medway Software Development Plan Doc- 006
- Medway Software Verification and Test Plan Doc- 007

The following standards would be required:

1. ISO/IEEE 11073-10101:2020(en) Health informatics — Device interoperability — Part 10101: Point-of-care medical device communication — Nomenclature
2. IEC 62304:2006(en) Medical device software — Software life cycle processes
3. ISO/IEEE 11073-10441:2015(en) Health informatics — Personal health device communication — Part 10441: Device specialization — Cardiovascular fitness and activity monitor

## f) Hardware Development

The hardware team led by Emma Chamberlain will work on hardware development. Hardware development includes sensor placement, data collection, pre-processing, and monitoring. The processes for hardware development are detailed in Hardware Development Plans that are

- Medway Hardware Development Plan- 008
- Medway Hardware Verification and Test Plan Doc- 009

The following standards will be required:

1. ANSI/AAMI EC13-1992, "Cardiac monitors, heart rate meters, and alarms"
2. ANSI/AAMI EC38-1994, "Ambulatory electrocardiographs"
3. ANSI/AAMI ES1-1993, "Safe current limits for electromedical apparatus

## g) Usability

The Medway plan for Usability is detailed in Medway Usability Engineering Plan DOC- 010

## h) Design Validation

The Design would be validated based on its input design to verify whether all the inputs have been covered and the required functionality is achieved.

## i) Formal Design Reviews

- Design input review- 08/20/2023
- Design clinical evaluation review- 09/20/2023
- Design verification review- 10/20/2023
- Design validation review- 01/20/2024

## j) Clinical External Evaluations

The clinical testing would include acquiring data from the patients and testing them for abnormalities related to the measured parameters- cardiac health, temperature and SpO2.

## 5. Design History File Strategy

The Design History File Index (DOC-011) identifies the content of the Design History File for the Medway program. The Design History File Index is updated at each milestone at a minimum and is stored in the Cloud electronic data repository. The test procedures and results will be managed in HP ALM and released in MyWorkshop.

## 6. Change Management

- The Hardware Team would collaborate with the manufacturing Lead and the Supply Chain Lead for procurement of parts
- The Hardware Team would work with the Software Team to check the algorithms
- The validation and verification would be done by the QA Team

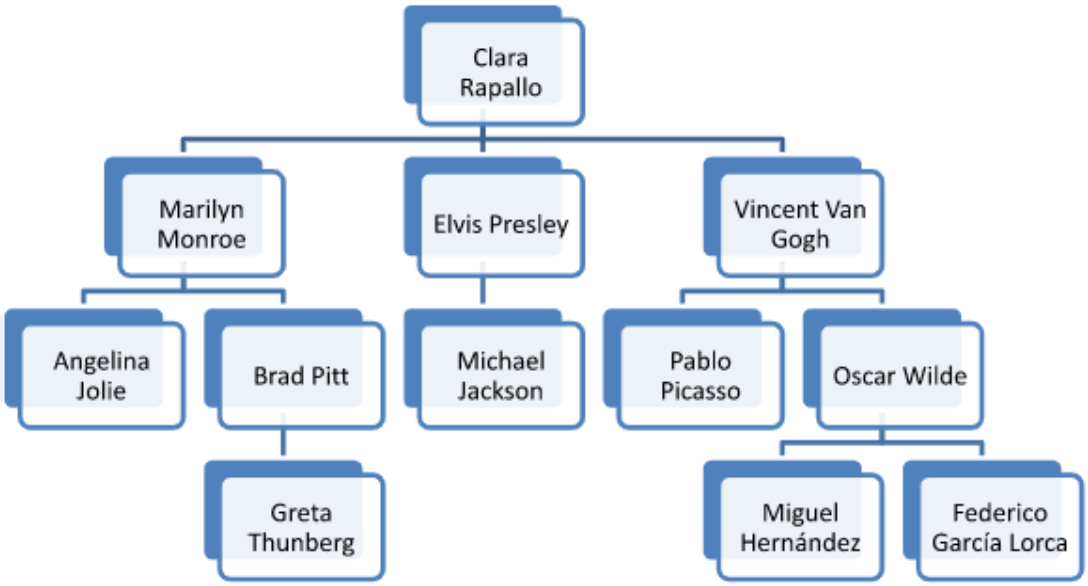
## 7. Program Team

These are the individuals who make up the team for Medway

| Role | Name |
|---|---|
| Project Sponsor | James Charles |
| Project Manager | Emma Chamberlain |
| Program Manager | Kendall Jenner |
| Clinical Manager | Beyoncé Knowles-Carter |
| Lead System Designer | Scott Disick |
| Manufacturing Leader | Amaia Romero |
| Service Leader | Taylor Swift |
| Supplier Quantity Leader | Bruno Mars |
| Sourcing Leader | Gerard Piqué |
| QA | Lionel Messi |
| RA | Justin Bieber |
| Software Developer | Kim Kardashian |

## 8. Team Organization

The Organization chart for the Medway team is as follows




## 9. Integrated Program Schedule

The Medway- Mobile Healthcare System Program Schedule is mentioned here-

| Task Name | Duration | Start Date | End Date |
|---|---|---|---|
| Medway Program Schedule | **515 days** | **12/04/2022** | **05/20/2024** |
| **Phase 1** | | | |
| Preliminary Requirements Document | **10 days** | **12/04/2022** | **12/14/2022** |
| Proof of Concept | **21 days** | **12/14/2022** | **01/04/2023** |
| Preliminary Plan | **10 days** | **01/04/2023** | **01/14/2023** |

| | | | |
|---|---|---|---|
| **Phase 2** | | | |
| Requirements Document | **10 days** | **01/14/2023** | **01/24/2023** |
| Detailed Project Plan | **25 days** | **01/24/2023** | **02/20/2023** |
| Risk Management Plan | **7 days** | **02/20/2023** | **02/27/2023** |
| Hazard Analysis | **7 days** | **02/27/2023** | **03/06/2023** |
| Clinical Plan | **30 days** | **03/06/2023** | **04/06/2023** |
| Manufacturing Strategy Plan | **25 days** | **03/16/2023** | **04/10/2023** |
| **Phase 3** | | | |
| Design review | **20 days** | **04/10/2023** | **04/30/2023** |
| DVT Report | **10 days** | **04/30/2023** | **05/10/2023** |
| Prototypes | **90 days** | **05/10/2023** | **08/10/2023** |
| Verification Protocols | **45 days** | **08/10/2023** | **09/25/2023** |
| **Phase 4** | | | |
| FMEA Report | **20 days** | **09/25/2023** | **10/15/2023** |
| Packaging Test Report | **15 days** | **10/15/2023** | **10/30/2023** |
| Design Transfer Plan | **30 days** | **10/30/2023** | **11/30/2023** |

| | | | |
|---|---|---|---|
| Clinical Pilot Builds | **50 days** | **11/30/2023** | **01/20/2024** |
| **Phase 5** | | | |
| Design Validation Report | **25 days** | **01/20/2024** | **02/15/2024** |
| DHF Audit Report | **30 days** | **02/15/2024** | **03/15/2024** |
| Process Validation Report | **30 days** | **03/15/2024** | **04/15/2024** |
| Clinical Summary Report | **15 days** | **04/15/2024** | **04/30/2024** |
| **Regulatory Submission** | | | |
| USA (Class II (510k)) | **180 days** | **04/30/2024** | **10/30/2024** |
| Canada (Class III (ISO-13485-2003)) | **120-150 days** | **04/30/2024** | **06/30/2024** |
| India (Class B (ISO-13485-2003)) | **510-900 days** | **04/30/2024** | **10/30/2026** |
| Australia (Class IIb) | **60-90 days** | **04/30/2024** | **07/30/2024** |
| Europe (Class IIb (93-42-EEC)) | **60 days** | **04/30/2024** | **06/30/2024** |

## 10. Product Configurations

One unit of Medway- mobile healthcare system will be offered to the customer where the patient data would be acquired from the ECG leads, temperature and SpO2 sensor and displayed on the monitor screen of the patient as well as the healthcare personnel.

## 11. Program Information

### Quality System:

For the device to meet the compliance for India, Australia, USA, Canada and Europe, the device should comply with ISO 13485:2016 Medical devices- Quality management systems- Requirements

### Manufacturing:

The manufacturer appointed would handle manufacturing of the device. It would require the manufacturer to have all the compliance documents for manufacturing medical devices.

### Regulatory:

| Country | Regulatory Body | Classification of Devices | Timeline |
|---|---|---|---|
| USA | Food and Drug Administration (FDA) | Class II | 180 days |
| Europe | CE Mark | Class IIb | 60 days |
| Canada | Canadian Medical Device Regulations (CMDR) | Class III | 120-150 days |
| Australia | The Australian Register of Therapeutic Goods (ATGA) | Class IIb | 90 days |
| India | The Central Drug Standards Control Organization (CDSCO) | Class B | 510-900 days |

| MEDICAL DEVICE SPECIFICATION<br>(Including information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| 1. | Version No. | 001 |
| 2. | Date of Initial Version | October 10, 2022 |
| 3. | Date of last modification | December 2, 2022 |
| 4. | Date of Publication | January 6, 2023 |
| 5. | Completed/Submitted by | Medway Working Group |
| **NAME, CATEGORY, AND CODING** | | |
| 1. | Proprietary Name(s) | Innovate Mobile Healthcare Ltd. |
| 2. | Generic Name | Mobile Healthcare System |
| 3. | Specific type or variation (optional) | N/A |
| 4. | GMDN Name | Imperative ECG, SpO2 and temperature monitor |
| 5. | GMDN Code | 35196 |
| 6. | GMDN Definition/Description | This mobile healthcare system is intended to continuously monitor crucial health parameters- ECG waveform, pulse rate, temperature and SpO2 of patients from anywhere. The parameters measured are displayed on the screen for the patient and are also wirelessly transmitted to healthcare personnel. |

| | | |
|---|---|---|
| 7. | Part Numbers | MHS-123-01 |
| 8. | Legal Manufacturer | Bio-health Industries |
| 9. | Target Countries | USA, Europe, Canada, Australia, India |
| 10. | Legal Manufacturer | Bio-health Industries |
| 11. | Manufacturing Sites | Michigan, USA and Pune, India |
| 12. | Country of Origin | USA |
| **PURPOSE OF USE** | | |
| 13. | Clinical or other purpose | To monitor ECG and measure Pulse Rate, Temperature and SpO2 |
| 14. | Level of use (if relevant) | Home Use / Health Centre / District Hospital / Provincial Hospital / Specialized Hospital |
| 15. | Clinical department / ward (if relevant) | Doctor's Office, Operating Room, Emergency Room, Intensive Care Unit |
| 16. | Indication for Use | Continuously monitor crucial health parameters- ECG waveform, pulse rate, temperature and SpO2. The parameters measured are displayed on the screen and alerts the user of any abnormalities |
| 17. | Overview of Functional Requirements | To acquire 3-Lead ECG data using 3 electrodes, 1 SpO2 sensor and 1 temperature sensor and display results on patient monitor and health care provider monitor using micro-controller and transceiver modules |
| **TECHNICAL CHARACTERISTICS** | | |

| | | |
|---|---|---|
| | | |
| 18. | Detailed Requirements | ECG leads, SpO2 sensor, temperature sensor, wireless transmission of processed signal |
| 20. | User Adjustable Settings | User shall be able to change filter, low battery, and connectivity to sensor settings |
| **PHYSICAL/CHEMICAL CHARACTERISTICS** | | |
| 21. | Components (if relevant) | ECG leads, SpO2 sensor, temperature sensor, microcontroller, transceiver module, battery, screen display |
| 22. | Mobility, portability (if relevant) | Portable Device |
| 23. | Raw Materials (if relevant) | N/A |
| **UTILITY REQUIREMENTS** | | |
| 24. | Electrical, water and/or gas supply (if relevant) | N/A |
| **ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS** | | |
| 25. | Accessories (if relevant) | N/A |
| 26. | Sterilization process for accessories (if relevant) | Supplier to describe any sterilization process required for accessories |

| | | |
|---|---|---|
| 27. | Consumables / Reagents (if relevant) | N/A |
| 28. | Spare Parts (if relevant) | N/A |
| 29. | Other Components (if relevant) | N/A |
| **PACKAGING** | | |
| 30. | Sterility status on delivery (if relevant) | The device must be sterile on delivery |
| 31. | Shelf Life (if relevant) | 4 years |
| 32. | Transportation and storage (if relevant) | Unit shall be supplied protectively packed for safe onward shipping |
| 33. | Labelling (if relevant) | Labelling includes name and place of the manufacturer, relevant contradictions, hazards, adverse effects, warnings, and precautions. |
| **ENVIRONMENTAL REQUIREMENTS** | | |
| 34. | Context-dependent requirements | Capable of operating and being stored continuously in ambient temperature of 40F to 140F and relative humidity of 15& to 95% |
| **TRAINING, INSTALLATION AND UTILISATION** | | |
| 35. | Pre-installation requirements (if relevant) | Generating Login ID |

| | | |
|---|---|---|
| 36. | Requirements for commissioning (if relevant) | N/A |
| 37. | Training of user/s (if relevant) | Training of users in operation and basic maintenance shall be provided. |
| 38. | User care (if relevant) | Unit layout to enable easy cleaning and sterilization of all surfaces before use |
| **WARRANTY AND MAINTENANCE** | | |
| 39. | Warranty | 1. Duration of warranty to be stated, minimum three years<br>2. Specific inclusions and exclusions to be listed<br>3. Contact details of local service agent to be provided |
| 40. | Maintenance tasks | Maintenance information shall be provided in the User Manual |
| 41. | Type of Service Contract | Costs and types of post-warranty service contract available shall be described |
| 42. | Spare parts availability post-warranty | Guaranteed period of availability of spare parts post-warranty shall be described |
| 43. | Software / Hardware upgrade availability | Sensors and Display shall be sold separately |
| **DOCUMENTATION** | | |
| 44. | Documentation requirements | User, technical and maintenance manuals to be provided in English, German, and French languages. |
| **DECOMMISSIONING** | | |

| | | |
|---|---|---|
| 45. | Estimated Life Span | 4 years |
| **SAFETY STANDARDS** | | |
| 46. | Risk Classification | Class B (India), Class II (USA), Class IIb (Europe and Australia), Class III (Canada) |
| 47. | Regulatory Approval / Certification | USA- Food and Drug Administration (FDA) Approval<br>Europe- CE Mark<br>Australia- The Australian Register of Therapeutic Goods (ATGA)<br>Canada- Canadian Medical Device Regulations (CMDR)<br>India- The Central Drug Standards Control Organization (CDSCO) |
| 48. | International Standards | 1. ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada, and EU)<br>2. ISO 14971:2019 Medical devices -- Application of risk management to medical devices<br>3. IEC 60601-1:2014 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance<br>4. IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems<br>5. IEC 60601-1-8:2012 (Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems)<br>6. IEC 80601-2-49:2018 (Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment)<br>7. IEC 60601-2-27:2011 (Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment) |

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|---|---|---|
| | | 8. IEC 60601-2-47:2012 (Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems)<br>9. ISO 80601-2-61:2011 (Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment) |
| 49. | Regional / Local Standards | 1. AAMI/ANSI EC38:2007 (Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems) (USA)<br>2. IEEE Std 11073-10406-2011 (Health informatics - Personal health device communication Part 10406: Device specialization - Basic electrocardiograph) (USA)<br>3. EN 12470-4:2000 Clinical thermometer performance of electrical thermometers for continuous measurement (UK, Ireland) |
| 50. | Regulations | US Regulations 21 CFR part 820; EU Regulations Council Directive93/42/EEC Directive 93/68/EEC (CE Marking) Directive 98/79/EC Directive 2001/104/EC Directive 2007/47/EC |

## Technical Specification Document

- **Hardware requirements**
  - Battery
  - Arduino Mega controller
  - Transducers
  - Wireless communication module
  - Temperature sensor
  - SpO2 sensor
  - ECG Leads
  - Display module
  - ADC
  - Amplifier
  - USB Connector

- **Software requirements**
  - Operating systems

- Transducer controller for turning it on and off
- Transmitting data from controller to receiver
- Screen to display the vitals
- Real time data processing
- ADC
- Amplifier
- Modulator
- Transducer controller for input signals
- Filters
- Feature point extraction
- Heartbeat detector
- ECG curve
- Digital signal processing

## List of Verification document to verify Design History File

**SOP-001 Rev-00** To check if the device can detect the heart rate from the ECG leads

**SOP-002 Rev-00** To check if the device can detect the body temperature from the temperature

**SOP-003 Rev-00** To check if the device can detect oxygen levels from the pulse oximeter

**SOP-004 Rev-00** To check if the device is able to store and integrate the signals

**SOP-005 Rev-00** To check the autonomy of the device with respect to battery conditions

**SOP-006 Rev-00** To check the accuracy of the signals detected using different algorithms

**SOP-007 Rev-00** To check the ability of the device to detect abnormalities in the physiological activity from the signals received

**SOP-008 Rev-00** To check if the data is exported correctly to the healthcare professionals

**SOP-009 Rev-00** Document Control

**SOP-010 Rev-00** Record Control

**SOP-011 Rev-00** Device Master Record

**All other documents:**

**DOC-001 Rev-00** Design and Development Plan

**DOC-002 Rev-00** Integrated Design Plan

**DOC-003 Rev-00** Medway Supplier Quality Strategy

**DOC-004 Rev-00** Medway Program Sourcing Strategy

**DOC-005 Rev-00** Medway Program Design Transfer Plan

**DOC-006 Rev-00** Medway Software Development Plan

**DOC-007 Rev-00** Medway Software Verification and Test Plan

**DOC-008 Rev-00** Medway Hardware Development Plan

**DOC-009 Rev-00** Medway Hardware Verification and Test Plan

**DOC-010 Rev-00** Medway Usability Engineering Plan

**DOC-011 Rev-00** Medway Design History File Index

# Procedure to validate the device

# Requirements

- Medway Unit
- Screen
- Sensor simulator


Note: These tests are supposed to be performed at ambient temperatures or room temperatures while making sure that the device is checked thoroughly for physical damages before testing.

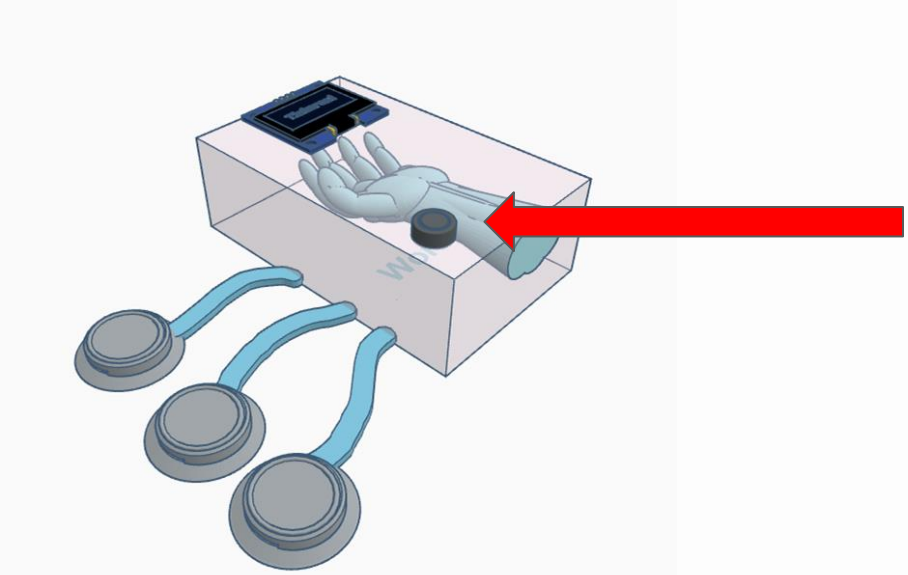
# Scope

To validate the vitals obtained from the sensors and transfer them wirelessly to the healthcare providers.

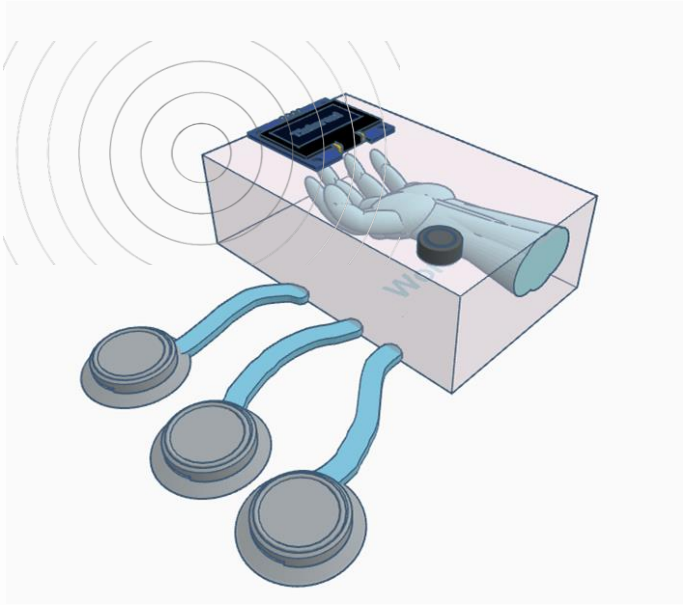
# Procedure

1. Turn on the MedWay unit with a button.

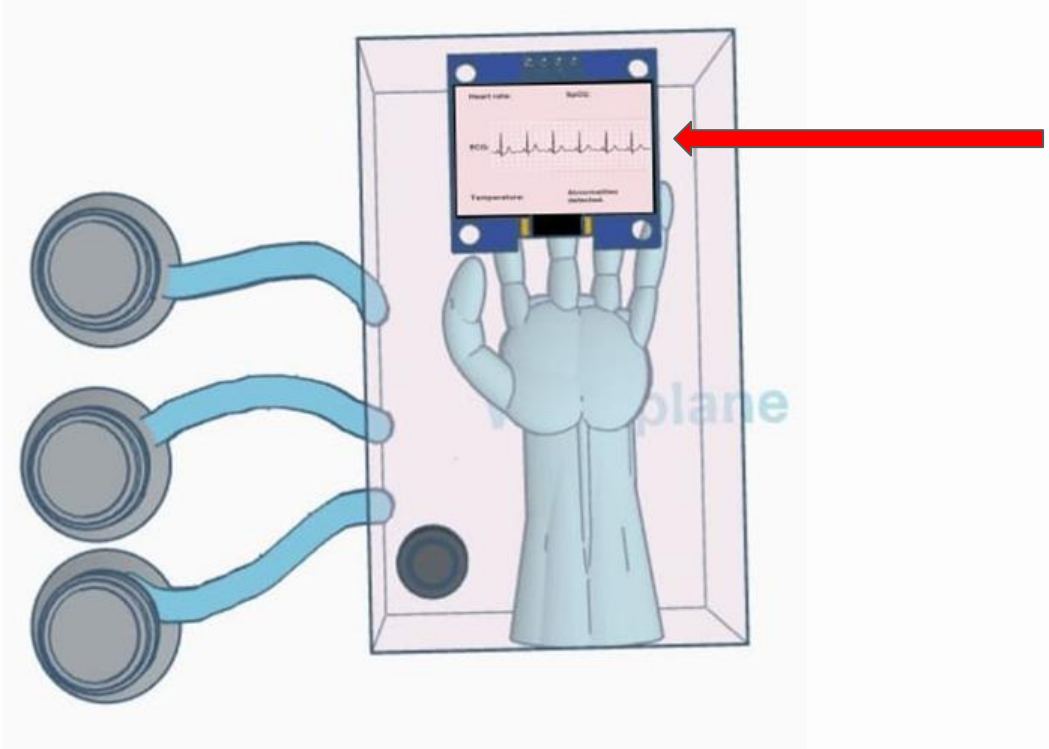
   The power button is indicated with an arrow in the image below.



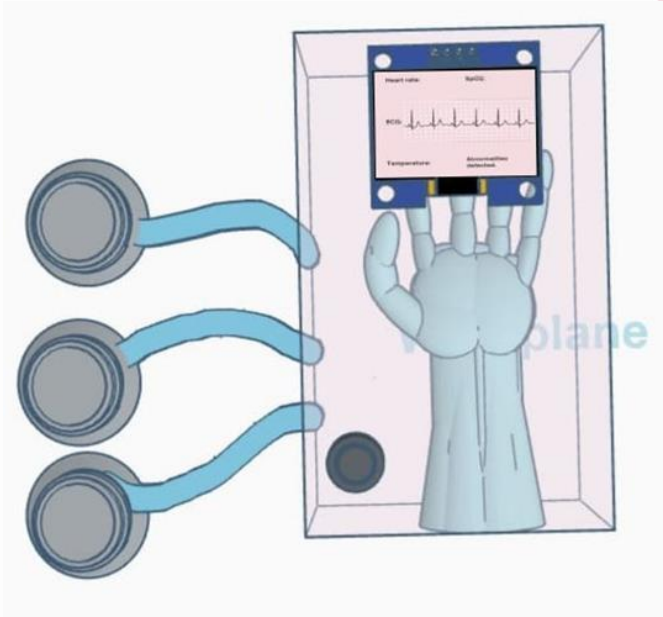
2. At the transmitter end, test the radio setup for the communication module.



3. Test the initial data with seeing the microcontroller output to check if the sensors are working



4. Radio write all the values from the sensors for sending the data to the receiver’s screen, at the receiver end, read the values from the transmitter module and display it on the screen.

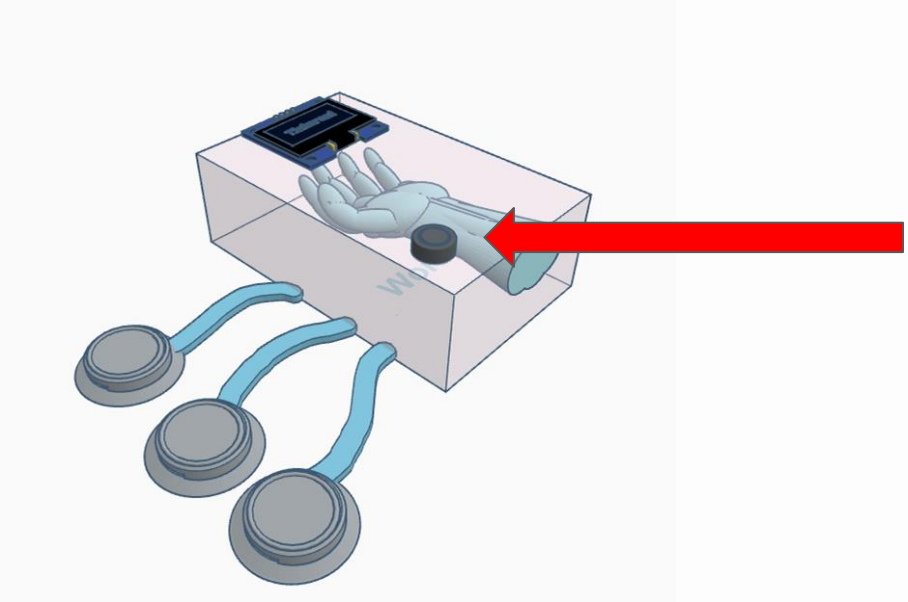


Heart rate: SpO2:

ECG:

Temperature: Abnormalities detected:

5. End the procedure by clicking the power button to switch it off and retain the data towards the receiver end.



# Outcome

If the device measures all the values accurately then record the values in the device verification document.

If there were any deviations or unexpected behavior is noticed from the device then it should be recorded in the device verification document and a FMEA report should be created.

# EU MDR (EU 2017/745) Annex I General Safety and Performance Requirements

## Chapter 1 - General Requirements

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.<br><br>They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. | ☐ | ☒ | **Design and development of the devices are carried out under a comprehensive quality management system in accordance with ISO 13485**<br><br>**Risk analysis is done in accordance with ISO 14971** | |
| 2. The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio. | ☐ | ☒ | **Risk analysis is done in accordance with ISO 14971** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 3. Manufacturers shall establish, implement, document and maintain a risk management system.<br><br>Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:<br><br>a) establish and document a risk management plan for each device;<br><br>b) identify and analyse the known and foreseeable hazards associated with each device;<br><br>c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;<br><br>d) eliminate or control the risks referred to in point (c) in accordance with the requirements of item "Order of Risk Controls";<br><br>e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit- risk ratio and risk acceptability; and<br><br>f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of "Order of Risk Controls". | ☐ | ☒ | **Risk analysis is done in accordance with ISO 14971** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 4. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art.<br><br>To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable.<br><br>In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:<br><br>a) eliminate or reduce risks as far as possible through safe design and manufacture;<br><br>b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and<br><br>c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.<br><br>Manufacturers shall inform users of any residual risks. | ☐ | ☒ | **Risk analysis is done in accordance with ISO 14971** | |
| 5. In eliminating or reducing risks related to use error, the manufacturer shall:<br><br>a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and<br><br>b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users). | ☐ | ☒ | **Risk analysis is done in accordance with ISO 14971** | |
| 6. The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions. | ☐ | ☒ | **ISO 13485 and ISO 14971 standards are followed.** | |
| 7. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer. | ☐ | ☒ | **ISO 13485 and ISO 14971 standards are followed.** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 8. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use. | ☐ | ☒ | **ISO 13485 and ISO 14971 standards are followed.** | |
| 9. For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons. | ☐ | ☒ | **ISO 13485 and ISO 14971 standards are followed.** | |

## Chapter 2 - Requirements regarding design and manufacture

### Chemical, physical and biological properties

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 10.1 Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to:<br><br>a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;<br><br>b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion;<br><br>c) the compatibility between the different parts of a device which consists of more than one implantable part;<br><br>d) the impact of processes on material properties;<br><br>e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;<br><br>f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;<br><br>g) surface properties, and;<br><br>h) the confirmation that the device meets any defined chemical and/or physical specifications. | ☐ | ☒ | **ISO 10993-18:2005 Biological evaluation of medical devices** | |
| 10.2 Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure. | ☐ | ☒ | **ISO 10993-1:2009 Biological evaluation of medical devices.** | |
| 10.3 Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use. | ☐ | ☒ | **ISO 10993-17:2002 Biological evaluation of medical device** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| 10.4.1 Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.<br><br>Devices, or those parts thereof or those materials used therein that:<br><br>- are invasive and come into direct contact with the human body,<br><br>- (re)administer medicines, body liquids or other substances, including gases, to/from the body, or<br><br>- transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,<br><br>shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:<br><br>a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council<br><br>(Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ( OJ L 353, 31.12.2008, p. 1).)<br><br>, or<br><br>b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH).<br><br>or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market of and use of biocidal products (OJ L 167, 27.06.2012, p. 1).<br><br>, in accordance with the criteria that are relevant to human health amongst the | ☐ | ☒ | **ISO 10993-17:2002 Biological evaluation of medical devices** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| criteria established therein. | | | | |
| 10.4.2 The justification for the presence of such substances shall be based upon:<br><br>a) an analysis and estimation of potential patient or user exposure to the substance;<br><br>b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives;<br><br>c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and<br><br>d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4. | ☐ | ☒ | **ISO 10993-17:2002 Biological evaluation of medical devices** | |
| 10.4.3 Guidelines on phthalates<br><br>For the purposes of Section 10.4., the Commission shall, as soon as possible and by ... [one year after the date of entry into force of this Regulation], provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before the date of the application of this regulation.<br><br>The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1.<br><br>The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments.<br><br>When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated. | ☐ | ☒ | | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 10.4.4 Guidelines on other CMR and endocrine-disrupting substances<br><br>Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate. | ☐ | ☒ | | |
| 10.4.5 Labelling<br><br>Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances.<br><br>If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used with Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 10.5 Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used. | ☐ | ☒ | **ISO 10993-17:2002 Biological evaluation of medical devices** | |
| 10.6 Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials. | ☐ | ☒ | **ISO 10993-17:2002 Biological evaluation of medical devices**<br><br>**Risk analysis is done in accordance to ISO 1497** | |

**Infection and microbial contamination**

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 11.1 Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:<br><br>a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,<br><br>b) allow easy and safe handling,<br><br>c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and<br><br>d) prevent microbial contamination of the device or its content such as specimens or fluids. | ☐ | ☒ | **ISO 16142-1 Medical Devices - Recognized Essential Principles Of Safety And Performance Of Medical devices** | |
| 11.2 Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation. | ☐ | ☒ | | |
| 11.3 Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer. | ☐ | ☒ | **ISO 11135:2014 Sterilization of health-care product** | |
| 11.4 Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use.<br><br>It shall be ensured that the integrity of that packaging is clearly evident to the final user. | ☐ | ☒ | **ISO 11135:2014 Sterilization of health-care products**<br><br>**ISO 15223-1:2016 Symbols to Be Used with Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 11.5 Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 11.6 Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities. | ☐ | ☒ | **ISO 11135:2014 Sterilization of health-care products** | |
| 11.7 Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination;<br><br>the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used with Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 11.8 The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile. | ☐ | ☒ | **All devices shall be sterilized before placing in the market** | |

## Devices incorporating medicinal product substances

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 12.1 In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation. | ☒ | ☐ | **The device does not fit the definition since no medicinal product are incorporated** | |
| 12.2 Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation. | ☒ | ☐ | **The device does not fit the definition since no medicinal product are incorporated** | |

## Devices incorporating materials of biological origin

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 13.1 For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply:<br><br>a) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC;<br><br>b) processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process;<br><br>c) the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC. | ☒ | ☐ | **The device does not incorporate derivatives of human tissue** | |
| 13.2 For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply:<br><br>a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers;<br><br>b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device;<br>in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply. | ☒ | ☐ | | **The device does not incorporate animal tissues or cells** |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 13.3 For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain.<br><br>In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. | ☒ | ☐ | | **No biological substances are used** |

## Construction of devices and interaction with their environment

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 14.1 If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices.<br><br>Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.<br><br>Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection. | ☐ | ☒ | **ISO 13485 and ISO 14971 standards are followed.** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 14.2 Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:<br><br>a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;<br><br>b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;<br><br>c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;<br><br>d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;<br><br>e) the risks of accidental ingress of substances into the device;<br><br>f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and<br><br>g) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism. | ☐ | ☒ | **ISO 13485 and ISO 14971 standards are followed.** | |
| 14.3 Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition.<br><br>Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion. | ☐ | ☒ | **ISO 14971 standard is followed** | |
| 14.4 Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively. | ☐ | ☒ | **ISO 13485 and ISO 14971 standards are followed** | |
| 14.5 Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe. | ☐ | ☒ | **ISO 13485 and ISO 14971 standards are followed.** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 14.6 Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used. | ☐ | ☒ | **ISO 13485 and ISO 14971 standards are followed.** | |
| 14.7 Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person.<br><br>To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use.<br><br>Such procedures shall be described in the instructions for use. | ☐ | ☒ | **ISO 13485 and ISO 14971 standards are followed** | |

## Devices with a diagnostic or measuring function

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 15.1 Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods.<br><br>The limits of accuracy shall be indicated by the manufacturer. | ☐ | ☒ | **ISO 13485 is followed** | |
| 15.2 The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 039, 15.2.1980, p. 40). | ☐ | ☒ | **ISO 13485 is followed** | |

## Protection against radiation

*General*

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 16.1 a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. | ☒ | ☐ | **IEC 60601-1-2:2007 Medical electrical equipment - Part 1- 2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests** | |
| 16.1 b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate.<br><br>Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified. | ☒ | ☐ | | **The device does not emit hazardous radiation** |

*Intended radiation*

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 16.2 a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non-ionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions.<br><br>Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance. | ☒ | ☐ | | **The device does not emit hazardous radiation** |
| 16.2 b) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions. | ☒ | ☐ | | **The device does not emit hazardous radiation** |
| 16.3 Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.<br><br>Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected. | ☒ | ☐ | | **The device does not emit hazardous radiation** |

*Ionising radiation*

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 16.4 a) Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. | ☒ | ☐ | **The device does not emit ionizing radiation** | |
| 16.4 b) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment. | ☒ | ☐ | **The device does not emit ionizing radiation** | |
| 16.4 c) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user. | ☒ | ☐ | **The device does not emit ionizing radiation** | |
| 16.4 d) Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation. | ☒ | ☐ | **The device does not emit ionizing radiation** | |

**Electronic programmable systems / Software**

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 17.1 Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use.<br><br>In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance. | ☐ | ☒ | **IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance** | |
| 17.2 For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation. | ☐ | ☒ | **IEC 62304:2006 Medical device software — Software life cycle processes** | |
| 17.3 Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise). | ☐ | ☒ | **IEC 62304:2006 Medical device software — Software life cycle processes** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 17.4 Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended. | ☐ | ☒ | **IEC 62304:2006 Medical device software — Software life cycle processes** | |

## Active devices and devices connected to them

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 18.1 For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks. | ☐ | ☒ | **IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance**<br><br>**IEC 60601-1-1:2000 Medical electrical equipment - Part 1- 1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems** | |
| 18.2 Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical.<br><br>If necessary, such warning or indication shall be given prior to the power supply becoming critical. | ☐ | ☒ | **IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance**<br><br>**IEC 60601-1-1:2000 Medical electrical equipment - Part 1- 1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 18.3 Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure. | ☐ | ☒ | **IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance**<br><br>**IEC 60601-1-1:2000 Medical electrical equipment - Part 1- 1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems** | |
| 18.4 Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. | ☐ | ☒ | **IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance**<br><br>**IEC 60601-1-1:2000 Medical electrical equipment - Part 1- 1: General requirements for safety - Collateral standard: Safety requirements for medical electrical system** | |
| 18.5 Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment. | ☐ | ☒ | | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 18.6 Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended. | ☐ | ☒ | **IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance**<br><br>**IEC 60601-1-1:2000 Medical electrical equipment - Part 1- 1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems** | |
| 18.7 Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer. | ☐ | ☒ | **IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance**<br><br>**IEC 60601-1-1:2000 Medical electrical equipment - Part 1- 1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 18.8 Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended. | ☐ | ☒ | **IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance**<br><br>**IEC 60601-1-1:2000 Medical electrical equipment - Part 1- 1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems** | |

## Particular requirements for active implantable devices

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 19.1 Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible:<br><br>(a) risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,<br><br>(b) risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment, and<br><br>(c) risks which may arise where maintenance and calibration are impossible, including:<br>– excessive increase of leakage currents,<br>– ageing of the materials used,<br>– excess heat generated by the device,<br>– decreased accuracy of any measuring or control mechanism. | ☒ | ☐ | **The device is not implantable** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 19.2 Active implantable devices shall be designed and manufactured in such a way as to ensure:<br><br>- if applicable, the compatibility of the devices with the substances they are intended to administer, and<br><br>- the reliability of the source of energy. | ☒ | ☐ | **The device is not implantable** | |
| 19.3 Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts. | ☒ | ☐ | **The device is not implantable** | |
| 19.4 Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation. | ☒ | ☐ | **The device is not implantable** | |

## Protection against mechanical and thermal risks

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 20.1 Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts. | ☐ | ☒ | **ISO 13485 and ISO 14971 standards are followed** | |
| 20.2 Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance. | ☒ | ☐ | **No such risks are identified** | |
| 20.3 Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance. | ☒ | ☐ | **ISO 13485 and ISO 14971 standards are followed.** | |
| 20.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks. | ☒ | ☐ | **No such risks are identified** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 20.5 Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.<br><br>The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk. | ☒ | ☐ | **No errors are identified** | |
| 20.6 Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use. | ☒ | ☐ | **No such risks are identified** | |

## Protection against the risks posed to the patient or user by devices supplying energy or substances

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 21.1 Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user. | ☐ | ☒ | **ISO 10993 BIOLOGICAL EVALUATION OF MEDICAL DEVICES** | |
| 21.2 Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger.<br><br>Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source. | ☐ | ☒ | **ISO 10993 BIOLOGICAL EVALUATION OF MEDICAL DEVICES** | |
| 21.3 The function of the controls and indicators shall be clearly specified on the devices.<br><br>Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient. | ☐ | ☒ | **ISO 10993 BIOLOGICAL EVALUATION OF MEDICAL DEVICES** | |

## Lay persons as users

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 22.1 Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment.<br><br>The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply. | ☐ | ☒ | **ISO 10993 BIOLOGICAL EVALUATION OF MEDICAL DEVICES** | |
| 22.2 Devices for use by lay persons shall be designed and manufactured in such a way as to:<br><br>– ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information,<br><br>– reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and<br><br>– reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results. | ☐ | ☒ | **ISO 10993 BIOLOGICAL EVALUATION OF MEDICAL DEVICES** | |
| 22.3 Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person:<br><br>- can verify that, at the time of use, the device will perform as intended by the manufacturer, and<br><br>- if applicable, is warned if the device has failed to provide a valid result. | ☐ | ☒ | **ISO 10993 BIOLOGICAL EVALUATION OF MEDICAL DEVICES** | |

## Chapter 3 - Requirements reg. the information supplied with the device

### Label and instructions for use

*General requirements regarding the information supplied by the manufacturer*

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.1 Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate.<br><br>Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.1 a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s).<br><br>In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.1 b) The information required on the label shall be provided on the device itself.<br><br>If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.1 c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.1 d) Instructions for use shall be provided together with devices.<br><br>By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.1 e) Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.1 f) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.1 g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.1 h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols.<br><br>Any symbol or identification colour used shall conform to the harmonised standards or CS.<br><br>In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

*Information on the label*

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.2 a) The label shall bear the name or trade name of the device; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 b) The label shall bear the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 c) The label shall bear the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.2 d) If the manufacturer has its registered place of business outside the Union, the label shall bear the name of the authorised representative and address of the registered place of business of the authorised representative; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 e) Where applicable, the label shall bear an indication that the device contains or incorporates:<br><br>– a medicinal substance, including a human blood or plasma derivative, or<br><br>– tissues or cells, or their derivatives, of human origin, or<br><br>– tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012; | ☒ | ☐ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 f) Where applicable, the label shall bear information in accordance with Section 10.4.5.; | ☒ | ☐ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 g) The label shall bear the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.2 h) The label shall bear the UDI carrier referred to in Article 27(4) and Part C of Annex VII; | ☒ | ☐ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 i) The label shall bear an unambiguous indication of the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| Where there is no indication of the date until when it may be used safely, the label shall bear the date of manufacture.<br><br>This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 k) The label shall bear an indication of any special storage and/or handling condition that applies; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 l) If the device is supplied sterile, the label shall bear an indication of its sterile state and the sterilisation method; | ☒ | ☐ | | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.2 m) The label shall bear warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person.<br><br>This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 n) If the device is intended for single use, the label shall bear an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 o) If the device is a single-use device that has been reprocessed, the label shall bear an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 p) If the device is custom-made, the label shall bear the words 'custom-made device'; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.2 q) The label shall bear an indication that the device is a medical device.<br><br>If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation'; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 r) In the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the label shall bear the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.2 s) For active implantable devices, the label shall bear the serial number, and for other implantable devices, the serial number or the lot number. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

*Information on sterile packaging*

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.3 The following particulars shall appear on the sterile packaging:<br><br>a) an indication permitting the sterile packaging to be recognised as such,<br><br>b) a declaration that the device is in a sterile condition,<br><br>c) the method of sterilisation,<br><br>d) the name and address of the manufacturer,<br><br>e) a description of the device,<br><br>f) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations',<br><br>g) if the device is custom-made, the words 'custom-made device',<br><br>h) the month and year of manufacture,<br><br>i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and<br><br>j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

*Information in the instructions for use*

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.4 a) The instructions for use shall contain all of the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2 of MDR. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.4 b) The instructions for use shall contain the device's intended purpose with a clear specification of indications, contra- indications, the patient target group or groups, and of the intended users, as appropriate; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.4 c) Where applicable, the instructions for use shall contain a specification of the clinical benefits to be expected. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.4 d) Where applicable, the instructions for use shall contain links to the summary of safety and clinical performance referred to in Article 32 | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.4 e) The instructions for use shall contain the performance characteristics of the device. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.4 f) Where applicable, the instructions for use shall contain information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.4 g) The instructions for use shall contain any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.4 h) The instructions for use shall contain specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.4 i) The instructions for use shall contain details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.4 j) The instructions for use shall contain any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.4 k) The instructions for use shall contain the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:<br><br>- details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection,<br><br>- identification of any consumable components and how to replace them,<br><br>- information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and<br><br>- methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.4 l) If the device is supplied sterile, the instructions for use shall contain instructions in the event of the sterile packaging being damaged or unintentionally opened before use. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.4 m) If the device is supplied non-sterile with the intention that it is sterilised before use, the instructions for use shall contain the appropriate instructions for sterilisation. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.4 n) If the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market.<br><br>Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses. | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.4 o) The instructions for use shall contain an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.4 p) If the device bears an indication that it is for single use, the instructions for use shall contain information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used.<br><br>This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail.<br><br>If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |
| 23.4 q) For devices intended for use together with other devices and/or general purpose equipment, the instructions for use shall contain:<br><br>- information to identify such devices or equipment, in order to obtain a safe combination, and/or<br><br>- information on any known restrictions to combinations of devices and equipment; | ☐ | ☒ | **ISO 15223-1:2016 Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.4 r) If the device emits radiation for medical purposes, the instructions for use shall contain:<br><br>- detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation,<br><br>- the means of protecting the patient, user, or other person from unintended radiation during use of the device | ☒ | ☐ | | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.4 s) The instructions for use shall contain information that allows the user and/or patient to be informed of any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device.<br><br>That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device.<br><br>The information shall cover, where appropriate:<br><br>- warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety,<br><br>- warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects,<br><br>- electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,<br><br>- warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,<br><br>- if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered,<br><br>– warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and<br><br>– precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user; | ☐ | ☒ | **ISO 20417 and ISO 18113 for labelling and packaging** | |

| | NA | A | Applicable Norms and Standards | Qualification |
|---|---|---|---|---|
| 23.4 t) In the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, the instructions for use shall contain warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra-indications, undesirable side-effects and risks relating to overdose; | ☐ | ☒ | **ISO 20417 and ISO 18113 for labelling and packaging** | |
| 23.4 u) In the case of implantable devices, the instructions for use shall contain the overall qualitative and quantitative information on the materials and substances to which patients can be exposed; | ☐ | ☒ | **ISO 20417 and ISO 18113 for labelling and packaging** | |
| 23.4 v) The instructions for use shall contain warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any.<br><br>This information shall cover, where appropriate:<br><br>– infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and<br><br>– physical hazards such as from sharps.<br><br>If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request; | ☐ | ☒ | **ISO 20417 and ISO 18113 for labelling and packaging** | |
| 23.4 w) For devices intended for use by lay persons, the instructions for use shall contain the circumstances in which the user should consult a healthcare professional; | ☐ | ☒ | **ISO 17664 for processing instructions** | |
| 23.4 x) For the devices covered by this Regulation pursuant to Article 1(2), the instructions for use shall contain information regarding the absence of a clinical benefit and the risks related to use of the device; | ☐ | ☒ | **ISO 20417 and ISO 18113 for labelling and packaging** | |
| 23.4 y) The instructions for use shall contain date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use; | ☐ | ☒ | **ISO 20417 and ISO 18113 for labelling and packaging** | |
| 23.4 z) The instructions for use shall contain a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established; | ☐ | ☒ | **ISO 20417 and ISO 18113 for labelling and packaging** | |
| 23.4 aa) The instructions for use shall contain information to be supplied to the patient with an implanted device in accordance with Article 18; | ☐ | ☒ | | |
| 23.4 ab) For devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, the instructions for use shall contain minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended. | ☐ | ☒ | **ISO 17664 for processing instructions** | |

# Portable Healthcare Device for Vital Measurements

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BIOE5250 12789 Design of Medical Devices
December 6, 2022
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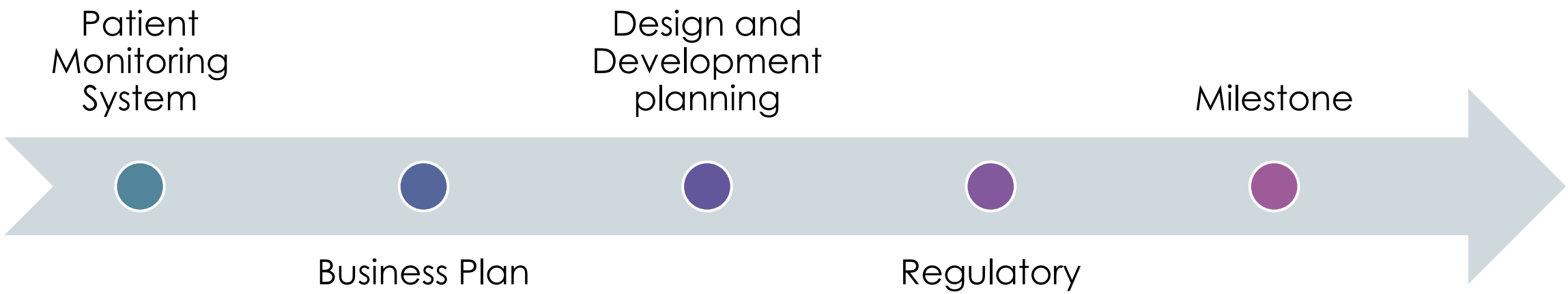
# Outline



# 1.Patient Monitoring Device

# Key Features of MedWay

- ECG, Heart rate, Oxygen Saturation (SpO2) and Temperature
- Targeted to cater patients in critical conditions
- Portable device/Easy to use
- Real time testing and alerting
- Wireless transmit of data to clinicians

# Patient Monitoring System- How it works

| Sensors | Microcontroller | Transceiver module and Display |
| --- | --- | --- |
| • Detect healthcare parameters | • Receive Signals<br>• Process for use | • Display Results<br>• Wireless transmitting to healthcare provider |

# Disadvantage of Current Systems

- Large systems
- Expensive
- No communication between the patient and the healthcare provider
- Inaccurate measurement of all vital signs

# Overcoming the Drawbacks

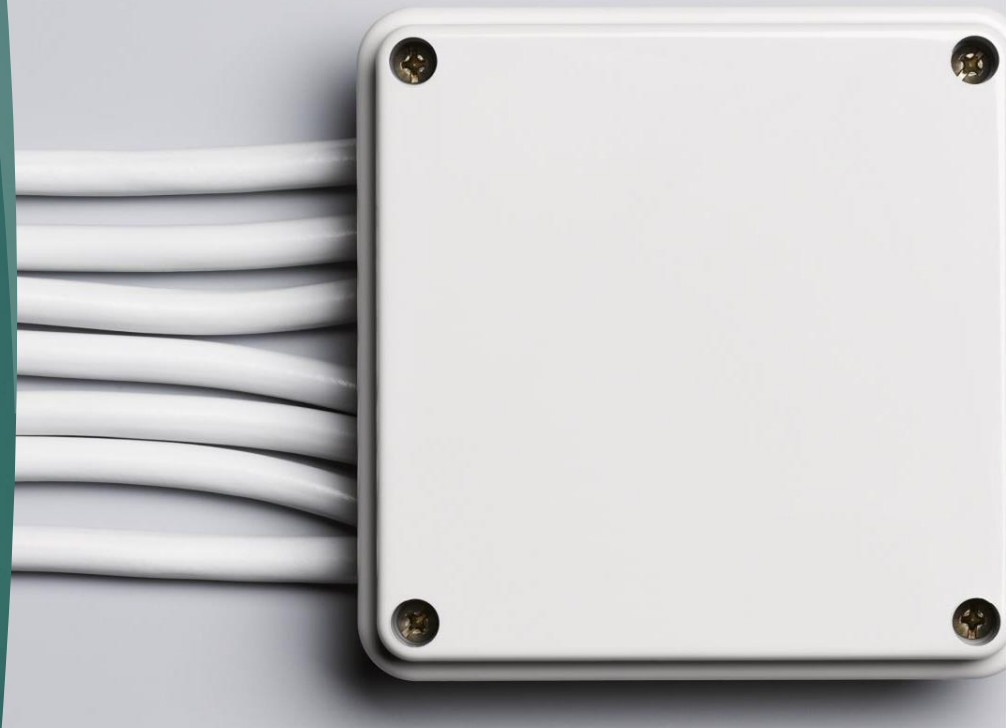
MODIFICATIONS MADE TO EXISTING DEVICE

PORTABLE/HOME USE, EASY TO OPERATE

WIRELESS AND REAL TIME CONNECTION WITH CLINICIANS

# Design Input Specifications

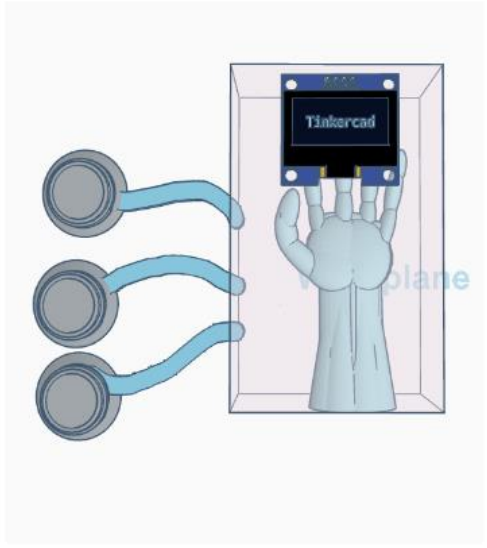
- Pulse Rate Sensor
- 3-Lead ECG
- Temperature sensor
- Pulse Oximeter
- Microcontroller
- Transceiver Module
- Display System
- Battery



# Design Output Specifications

- Digital screen displaying ECG, heart rate, temperature and oxygen saturation in the blood
- Units of all the vitals
- Battery percentage

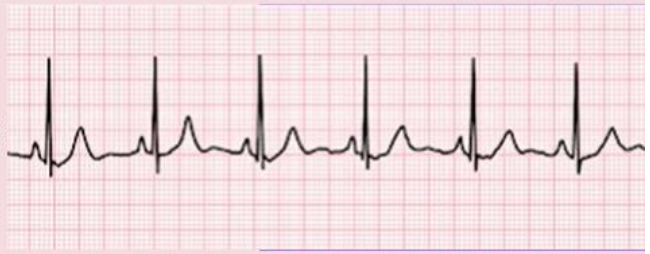
# System model




Heart rate:

SpO2:

ECG:



Temperature:

Abnormalities detected:

# 2. Business plan

# BUSINESS PLAN

It is essential for any company to perform market research and analyze patters to better strategize for their product.

This device detects crucial parameters of patients in critical condition and need constant monitoring.

What makes this device different than other patient monitoring system is its portability and low cost.

It allows the patient to utilize our device from anywhere, in the comfort of their own home and alerts the user and the healthcare personnel in case of any anomaly and when emergency response is needed.

# Competitors

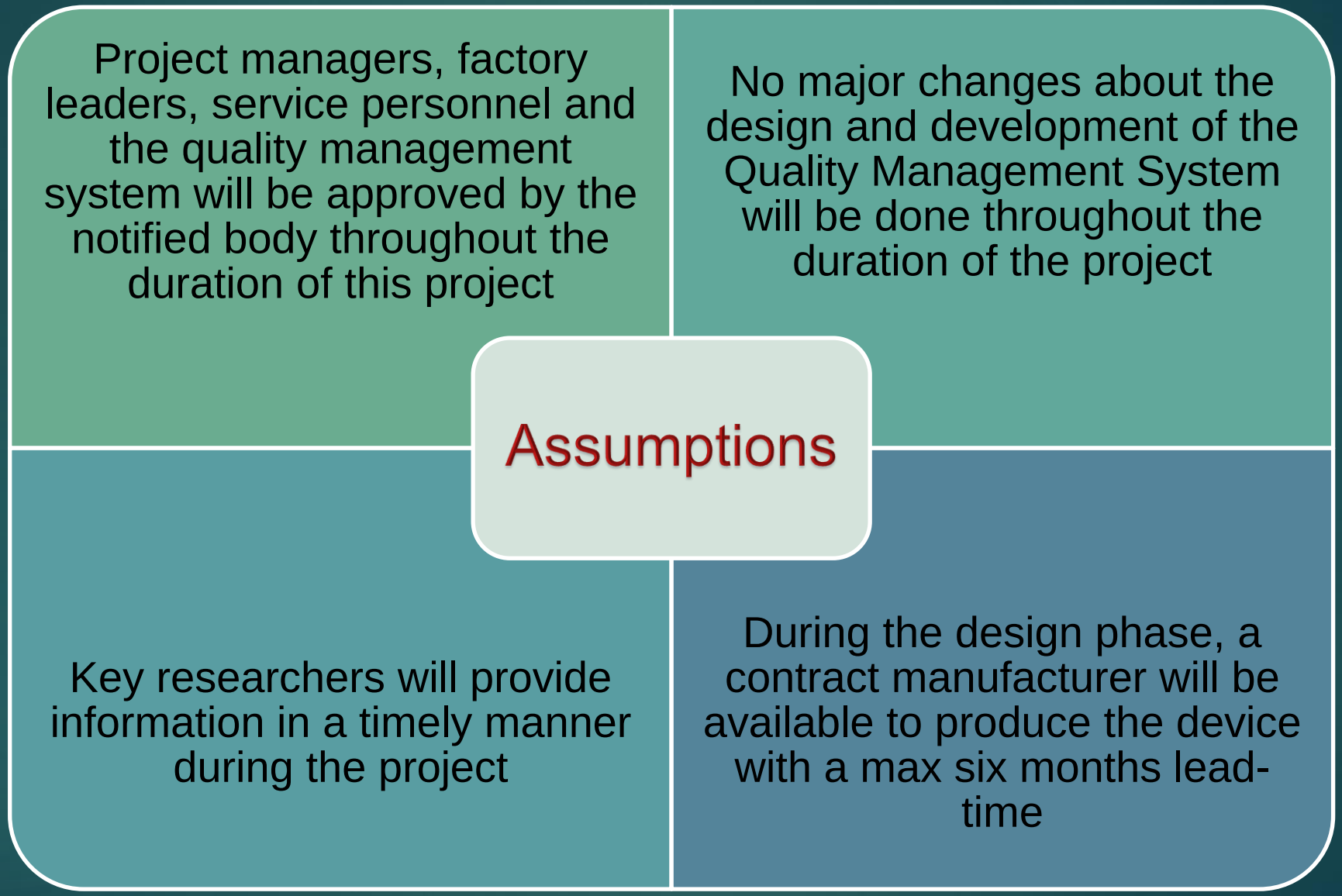
- 1.Allyn 300
- Temperature Probe
- SpO2 probe
- Heart rate not accurate
- No transmission
- Expensive

- 2. Apple Watch Ultra
- Electric heartrate sensor
- Wrist temperature – Not accurate
- Blood oxygen sensor
- No transmission
- Expensive

# Revenue target estimates

- The total cost for FDA clearance will be around 1 million dollars.
- If the device is being launched in 2026 or 2027 and with consideration of inflation and market costs
- The device will oversee revenue generation of around 15%
- The actual device price will stay around 150$ per unit and additional service charges will be applied if required.

# 3. Design and Development



## User Requirements:

- Person of any age
- User friendly interface
- Patient history and data

## System Requirements:

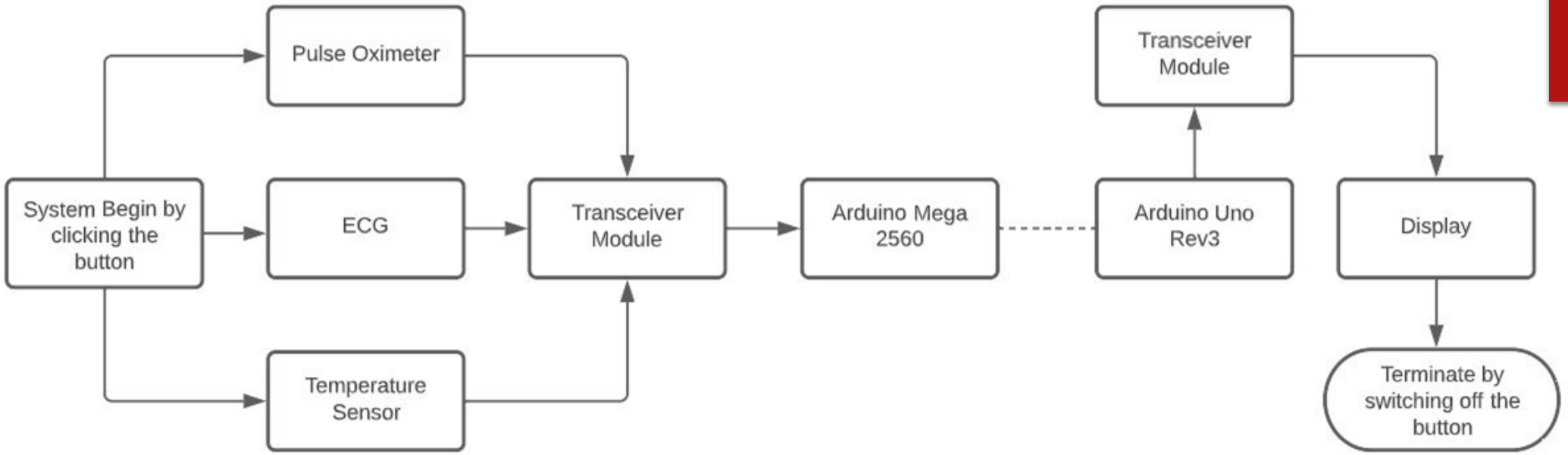
- Stable internet connection
- Power supply/ battery
- Portable
- Lightweight
- System memory
- Waterproof

## Hardware Requirements:

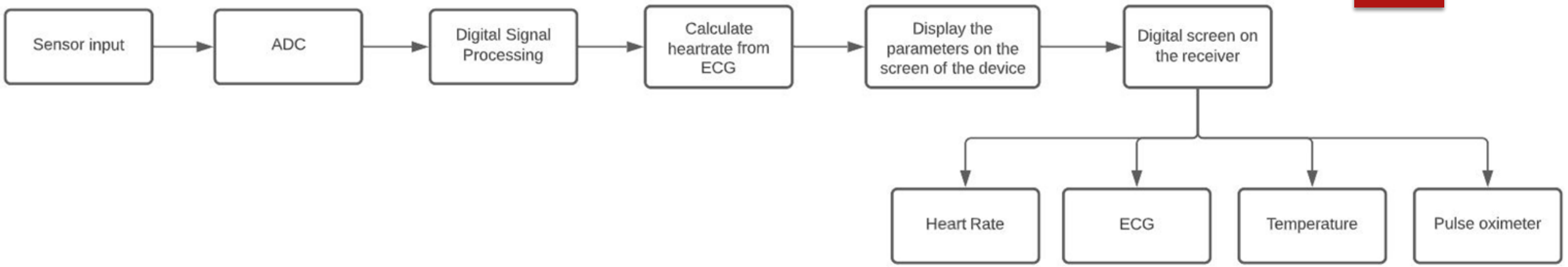
- Sensors
  - 3 ECG leads
  - Temperature sensor
  - SpO2 sensor
- Transmission receiver module
- ADC
- Booster circuit
- Voltage stabilizers
- 1 button
- Power amplifier
- Filters

## Software Requirements:

- ADC
- Digital signal processors
- Digital screen display
- Data storage
- Functionality supervision and auto detection for irregularities




# Hardware requirements




# Software requirements

# Project Risks

| | |
|---|---|
| Excessive patient leakage current | •Resistors 10kohms on each leads |
| Loose ECG Leads | •Map each ECG lead before starting the procedure to measure ECG |
| Misplacement of temperature and SpO2 sensors | •Marking on the device which shows ideal placement of the hand to detect good quality signal |
| Excessive/ Low signal | •If the signal is not ideal for the microcontroller, it will display warning message to try again |
| Noise Cancellation | •The microcontroller will be able to eliminate noise to measure the right parameters |
| Power Shortage | •When the voltage supply from the battery is lower than ideal, the microcontroller will display a low battery symbol on the display |
| Display | •Under the circumstances that one of the displays (patient/ healthcare personnel) stops working, the data can be retrieved from the other display system |
| Communication | •The signals will be transmitted wirelessly to the display of the healthcare personnel |

# Manufacturers

- Legal Manufacturer : DVP Therapeutics

- Pune, India
  - IT center
  - Major companies for manufacturing
  - Easy connectivity for transportation
  - Low cost

- Michigan, USA
  - Easy accessibility hence shipping time is reduced

# Distributors

| Country | Distributor | Representatives |
|---|---|---|
| USA | Oxus America, Inc. | James Corden |
| Europe | ATMOS Medical Ltd | Harry Williams |
| Canada | MKS Instruments | James Martin |
| Australia | Genesys Electronics Design | Connor Hellen |
| India | Operon Strategist | Ananya Pandit |

# 4.Regulatory

# Regulatory Clearance pathway

| Country | Regulatory Body | Classification of Devices | Timeline |
|---|---|---|---|
| **USA** | Food and Drug Administration (FDA) | Class II | 180 days |
| **Europe** | CE Mark | Class IIb | 60 days |
| **Canada** | Canadian Medical Device Regulations (CMDR) | Class III | 120-150 days |
| **Australia** | The Australian Register of Therapeutic Goods (ATGA) | Class IIb | 90 days |
| **India** | The Central Drug Standards Control Organization (CDSCO) | Class B | 510-900 days |

# Quality System Considerations

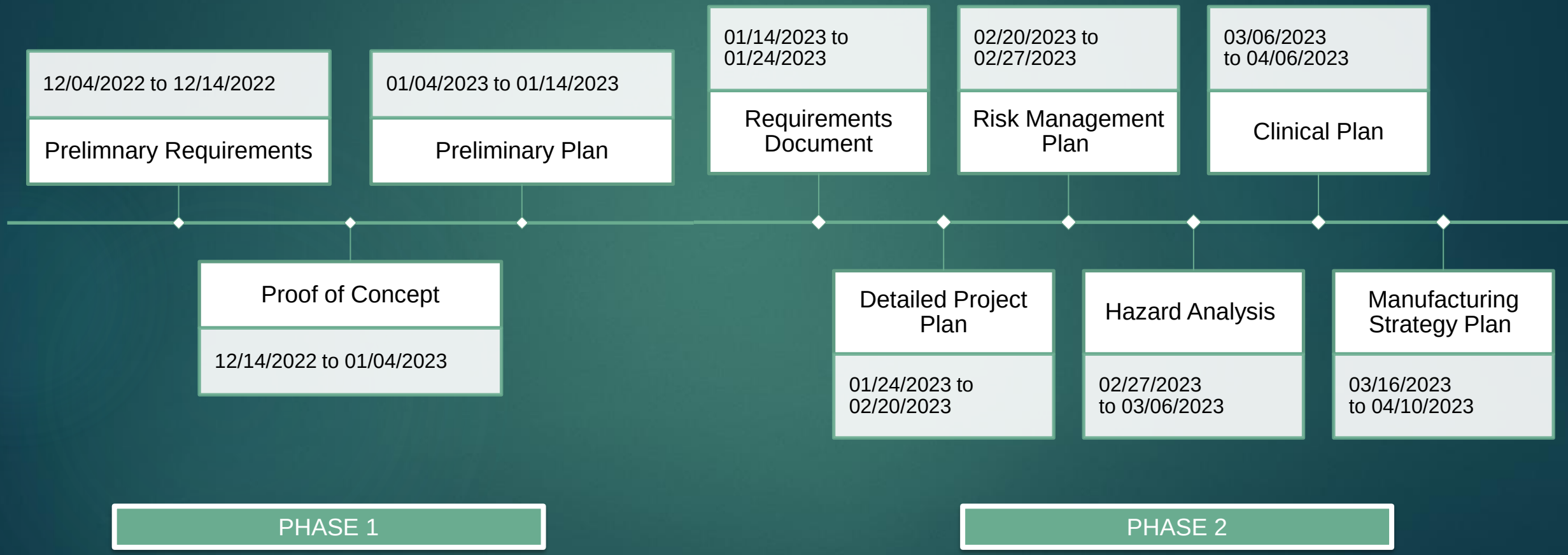
- MedWay follows cGMP guidelines 21 CFR 820 as per the FDA regulations
  - 21 CFR 820 covers "the design, manufacturing, the packaging, labeling, storage, installation and servicing of all the finished devices intended for human use", including the facilities and designs used for these processes.
- Meets the international standards ISO 13485 as per EU, Canada, Australia
  - Quality management system, organization needs to demonstrate its ability to provide medical devices and related services which consistently meet customer requirements and regulatory requirements
- Meets requirements of IEC 60601-1
  - Manages basic safety and performance requirements of the device which serves to ensure that no form of signal shall harm the patients or the operator

# Labeling and Translations

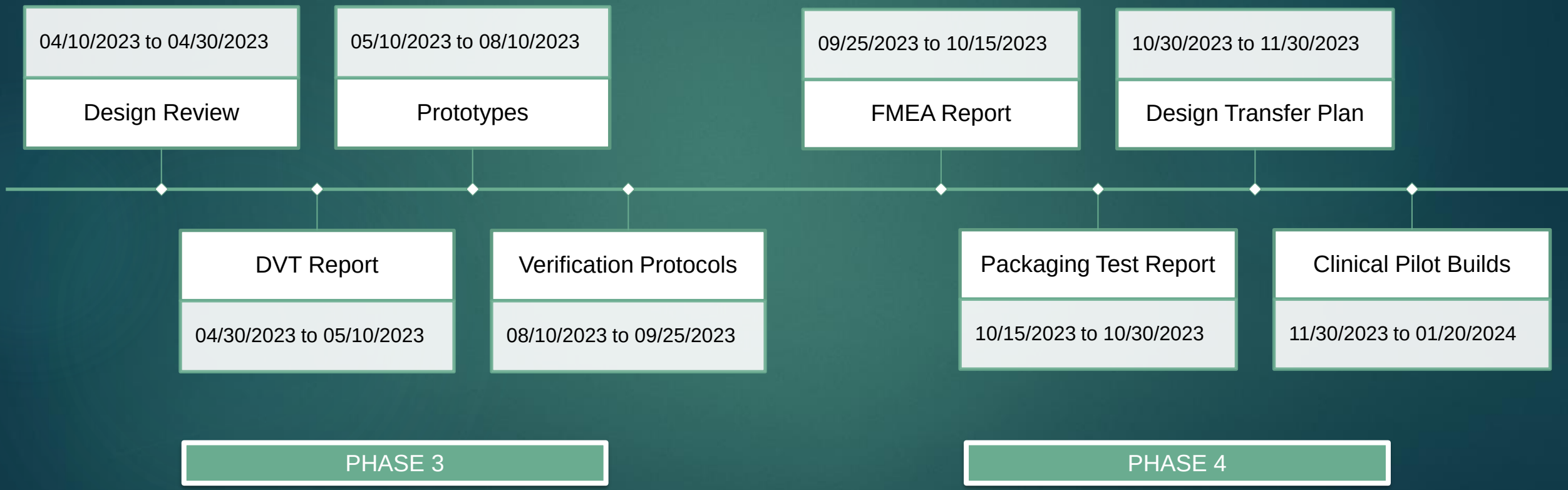
- Labelling includes name and place of the manufacturer, relevant contradictions, hazards, adverse effects, warnings and precautions.
- Languages : English, Spanish, Italian
- Unit shall be supplied protectively packed for safe onward shipping
- The device must be sterile on delivery

# 5. Milestones

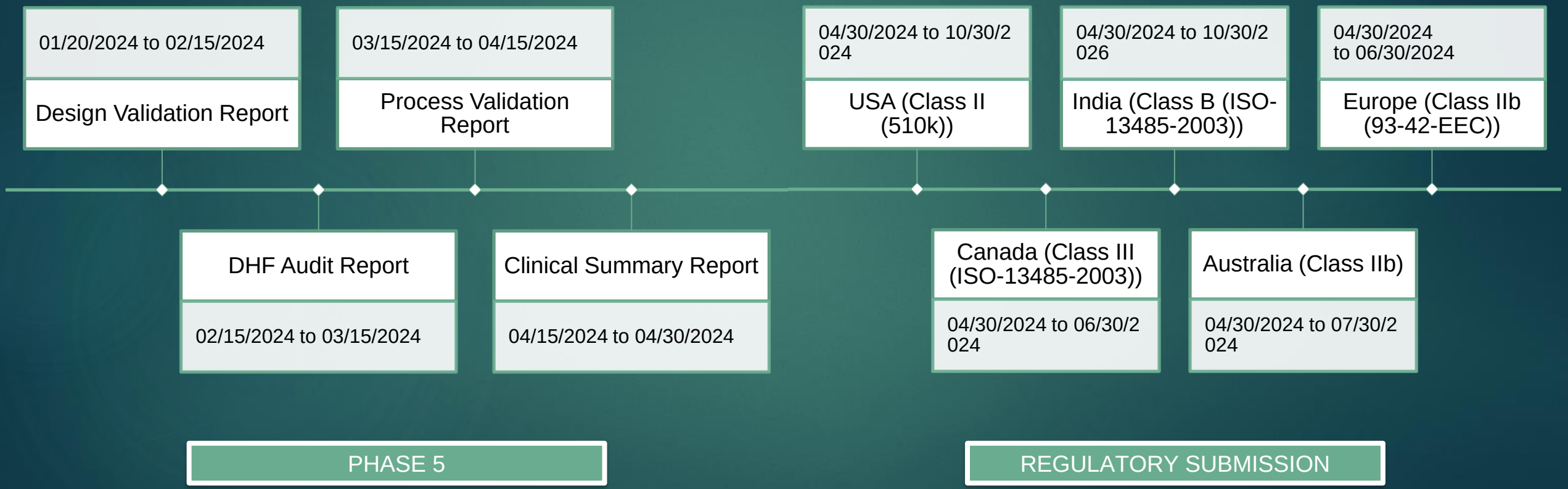
# Design Plan



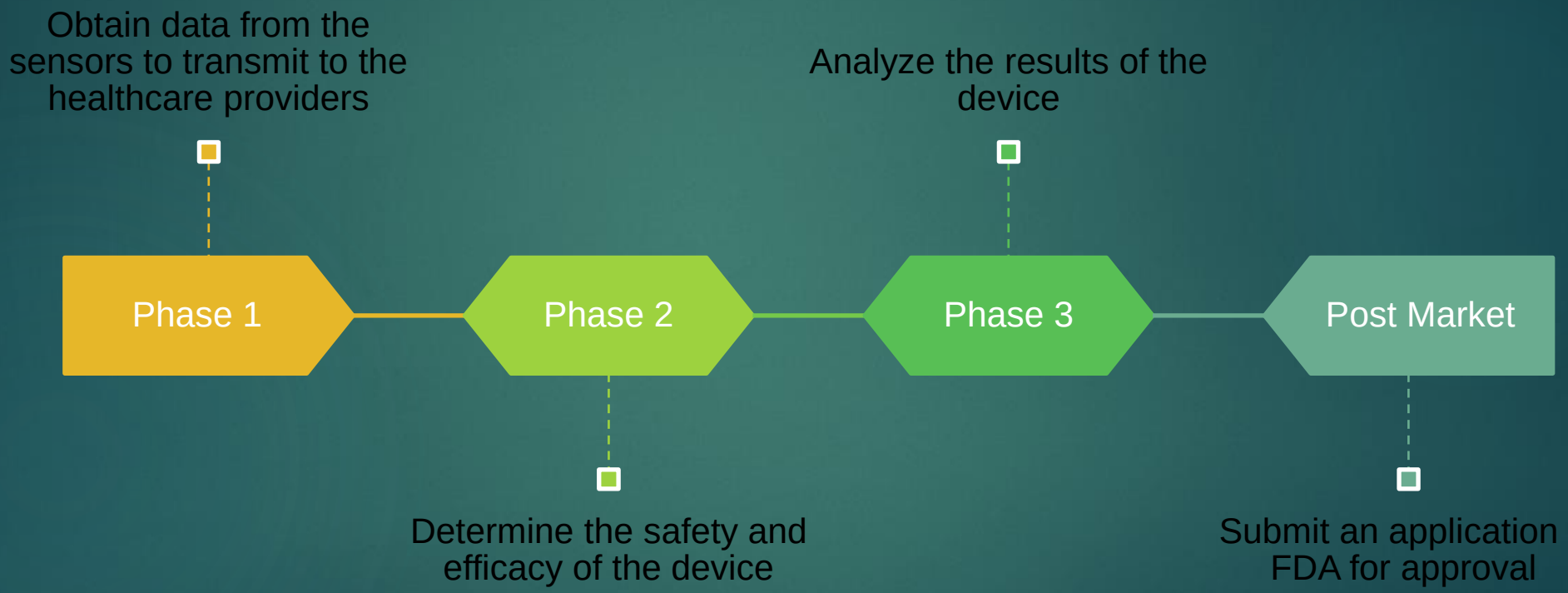
# Design Plan



# Design Plan



# Clinical Trials



# Thank You!