INNO4COV-19

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Abbreviation and Acronyms

EMC – Electromagnetic Compatibility

GPSD – General Product Safety Directive

ICT – Information and Communications Technology

IEC – International Electrotechnical Commission

LVD – Low Voltage Directive

MDR – Medical Device Regulation

MDR – Medical Device Software

QMS – Quality Management System

RoHS – Restriction of Hazardous Substances

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Executive Summary

This document provides information about the relevant framework and specifications for Sensor and telemonitoring devices and telemedicine systems that are required to reach the market. The main objectives of this report are to provide i) more detailed information on the framework for development of devices in the context of COVID-19, ii) a Specifications Sheet template with instructions for use by test case providers/future users of the service platform, and iii) a guideline for implementation of the Specifications Sheet in the INNO4COV-19 service platform workflow.

This report describes the requirements needed for the technical specifications of electronic devices, instruments, and wearables for telemonitoring or telemedicine developed in the frame of INNO4COV-19 project.

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1. Framework for development of telemonitoring or telemedicine systems

The Specification Sheet templates consider several categories of emerging and existing technologies for telemonitoring, and telemedicine applications based on connected devices, instruments, or equipment and also wearables that can be used for parameters monitoring in order to increase the health security mechanism on public and private health systems and obtain more specific and relevant data from patients and users of this new and emergent technologies.

It is important to remark that all development needs to identify the potential market to be addressed and consider all regulation and legal requirements that they must achieve before to commercialize. In this context it is important to differentiate the telemonitoring system with and without medical grade.

1.1 Regulatory framework

All electronic equipment/devices are subjected at several regulations depending of the performances and the final application market. There are some common regulations that should be considered on electronic equipment:

- **RoHS:** RoHS is an EU Directive restricting the use of hazardous substances (e.g heavy metals) in electrical and electronic equipment. No matter what kind of electronic products you are importing, you must ensure that your products do not contain an excessive amount of restricted substances such as (Lead (Pb), Mercury (Hg), Cadmium (Cd), etc)
- **Low Voltage Directive (LVD):** overs electrical safety of electrical equipment operating with an input or output voltage between:
  A. 50 and 1000 V for alternating current
  B. 75 and 1500 V for direct current
- **EMC Directive:** Electrical devices might interfere when they are placed close to each other. In this aspect, the EMC Directive ensures that such side effects are kept under reasonable control. Moreover, the EMC Directive limits electromagnetic emissions to ensure that electrical equipment doesn't affect the functionality of nearby equipment.
- **Ecodesign Directive:** Ecodesign is an ecologic directive that encourages energy-efficient products imported in the European market. Under the directive, importers shall include energy labels on the product and its

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packaging. The label shall also include information such as energy savings information, ecodesign requirement, and the ranking of energy consumption.
- **CE Marking:** finally, if the electronic product is covered by any CE directives (e.g. LVD, RED, EMC). The CE mark indicates conformity with requirements when importing and selling in the EU market.

Other regulations to be considered are:

- **General Product Safety Directive (GPSD):** applies to all products placed in the EU market. GSPD ensure that product must be safe in order to protect consumers' health and safety. GSPD requires a self-issue risk assessment to prevent accidents and health issues.
- **Packaging Regulations (Directive 94/62/EC):** When selling products in the EU market, it is also essential to comply with the packaging regulations. For example, the packaging material shall not contain excessive amounts of heavy metal or any other hazardous substances.

Special regulation for medical devices:

- In Europe medical devices need to be developed and placed on the market in compliance with the new Medical Device Regulation MDR 2017/745 (replacing the current Directive 93/42/EEC). When assessing conformity with the legislation and prior to issuing a certification (CE mark), the manufacturer must evaluate the performance and safety of the device and capture the data in the instructions for use and Technical Documentation of the device.

  The collection of the safety and performance data in conformity with the European Harmonized Standards is considered state of the art. Many of these standards are ISO standards which are harmonized in Europe.

  In addition to conducting analytical and clinical performance studies, the performance of devices may be validated, e.g. in reference laboratories, academic institutions or national regulatory agencies. Such validation is not legally obligatory, but is highly recommended for public health decision making, especially in the context of the current COVID-19 crisis.

  MDCG 2019-11 on the classification of software provides guidance on the classification of computer aided detection systems as Decision Support Software, which combines general medical information databases and algorithms with patient-specific data. They are intended to provide healthcare professionals and/or users with recommendations for diagnosis, prognosis, monitoring and/or treatment of individual patients, and are qualified as Medical Device Software (MDSW).

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1.2. Medical device development life cycle

During its development life cycle, a medical device product goes through distinct phases, as depicted in Figure 1. These consist of i) conception and prototyping, ii) classification and development of a regulatory plan, iii) installation of a quality management system (QMS), iv) product development, including design control and risk management, and v) product launch, including technology transfer to enable production, product registration and marketing.

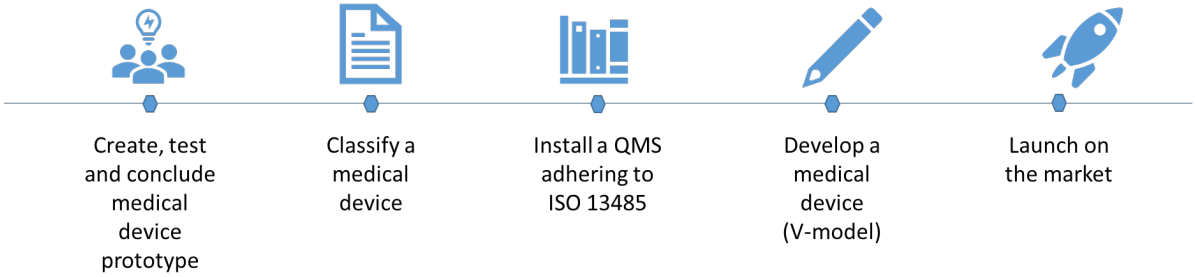

***Figure 1**: Medical device development life cycle*

Harmonized international standard EN ISO 13485:2016 is designed to be used by organizations involved in the design, production, installation and servicing of medical devices and related services. It contains a process-oriented approach and helps organizations to implement a quality management system.

For medical device software, international standard IEC 62304 defines software development life cycle requirements.

For both medical devices and medical device software a product development methodology and approach, described in the afore mentioned harmonized standards can be used as a guidance. An example of such approach is the V-model, shown in Figure 2, in which specifications related to user requirements, product functions and product design are represented. These have been taken into account in the Specification Sheet templates, described in section 2.

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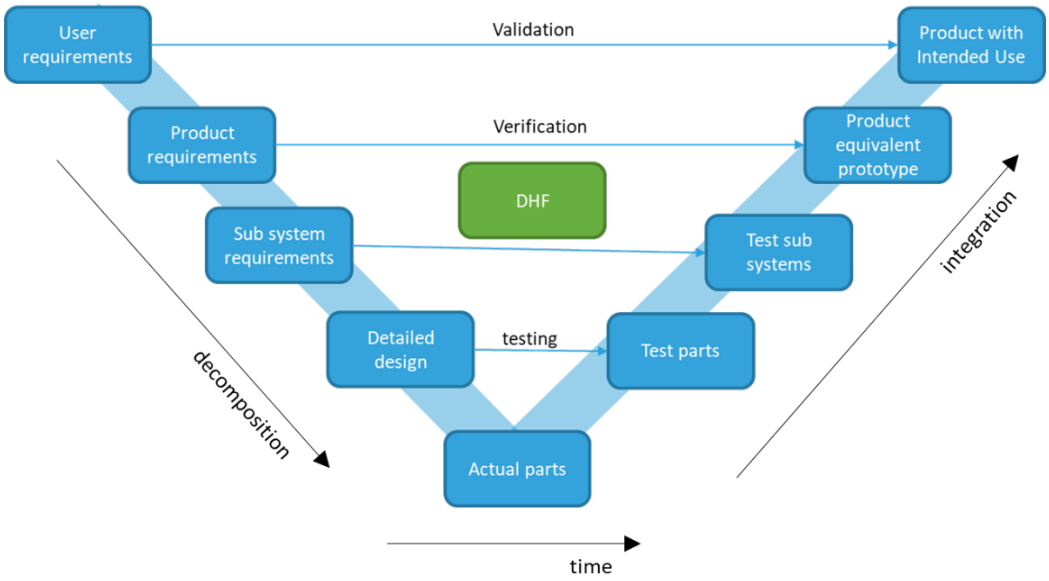

***Figure 2**: V-model of medical device development. Traceability of all design controls throughout the product development process, as required by the applicable regulations, are kept in the Design History File (DHF).*

2. Specifications Sheet template

The Specifications Sheet template for the telemonitoring and telemedicine systems are split in main seven fields:

1. Usability Aspects:
2. Electrical characteristics
3. Sensor performances
4. Data & Software
5. Connectivity & Traceability
6. Test Procedures
7. Regulatory Compliance

All fields are defined and explained on table 1, but it is important to remark that specification sheet defines seven main areas where telemonitoring systems o medical devices should be specify their characteristics, but it is clear, that not all field will be present at each system. For instance, one device can be a sensor array but not use a software or a wireless connection. In this case, must be necessary to complete fields 1,2,3,6 and 7 but will be not necessary the fields 4 and 5.

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Table 1. Specifications Sheet template for *telemonitoring telemedicine systems* – description of key performance features

Key performance feature	Description
USABILITY ASPECTS	
Intended use	Identify and describe scope of product whose technical specifications are being documented and describe desired outcome.
Target use setting	Describe each type of device/equipment/wearable, including their settings, users and testers and outline which environments are required for its use. Specify the requirements of building, medical center or other specific point for the device/equipment/wearable deployment.
Target population/patient	Identify the specific target/s who are oriented the device/equipment/wearable. Depends directly the detection principle and the objectives of the device/equipment/wearable.
Detection principle	Define the objective of sensing device and which physical or physiological parameters are obtained. Define also if the measurement is directly (using sensors) or indirectly (using software analytics or artificial intelligence for a data processing).
Uses personal data	Indicates if a personal data is used during the normal operation.
End user profile	Also identify the end user profile. (Examples: Trained health care worker or lab technician, trained lay worker, patient self-administered, non-trained worker, etc.)
Necessary specific training for use it	Identify if the device/equipment/wearable needs a specific training, the duration and methodology of training course and also if this course will be virtual or presential form.
Need for maintenance/spare parts	Identify the parts of device/equipment/wearable that need to be replaced, changed or maintenance during the product lifetime.
Mechanical dimensions	Define the mechanical dimensions and other mechanical requirements as ergonomic and comfortability specially in the case of wearables.
Usability Conditions	All the usability modes and conditions must be defined and explained. Special requirements for each mode should be identified including the personnel involved and their training.
Cleaning and reuse requirements	Specify cleaning process required and when it is necessary in the normal equipment/device operation. If it is necessary to reuse or change any part of device/equipment is mandatory to explain which and when this operation should be done.
Waste/disposal requirements	Identify the waste generated during the current operation and if it possible to reuse and if not, which can of waste will be generated and how must be recycled, especially in case of biohazard waste or incineration of consumables, need for decontamination.

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Storage life	In case of uses some products or materials with specific date of Expiry, indicates the storage life and how will be indicated on the product.
Product Lifetime	Indicate the lifetime of product and the expiry date and also the fabrication/assembling date.
ELECTRICAL CHARACTERISTICS	
Power Supply	Indicates the maximum and minimum voltage operating Range.
Supply current	Indicates the maximum and minimum current operation Range.
Batteries	Define if device uses batteries and where technology is used. It is recommended also indicates the batteries operational ratings and also the operational conditions if this are lower than the specified for electronic devices, especially in environmental conditions.
Environment conditions temperature, humidity, vibration, shocks and acceleration	Define the environmental conditions where the device/equipment/wearable can be operated. Main environmental conditions to be defined: Temperature operation, humidity, and shocks. Other recommended conditions are: vibration, acceleration, UV protection, etc.
Operation/procedure conditions	Define the conditions of operations and the requirements for standard procedure and process of operation such as: pressure, light, number of samples etc. Define also the maintenance required for the equipment/device and the calibration period.
Electrical Isolation	Indicates the electrical isolation level for the electric/electronic component/ parts/ device/ equipment.
Bus interfaces	Define wired communication interfaces uses for the device/equipment and their communication protocols.
Other hardware interfaces	Define other interfaces like optical, magnetic, photonic, etc…
SENSORS PERFORMANCE	
Sensitivity/Limit of detection	It is the lowest detectable level of analyte distinguish able from zero, whereas analytical sensitivity is the slope of the calibration curve.
Robustness	Robustness of sensors is often defined as invariance degree of state, behaviour, and function or the adaptation/flexibility degree under interference of perturbations.
Precision	The concept of precision refers to the degree of reproducibility of a measurement. In other words, if exactly the same value were measured a number of times.
Reproducibility	Describes the maximum variability of precision where variations occur over longer time periods with different instruments and different operators. Error is the difference between a measurement and the true value of the measurand.
Calibration	Sensor calibration is an adjustment or set of adjustments performed on a sensor or instrument to make that instrument function as accurately. It is necessary to define calibration period or the maximum error assumed by sensor or instrument.

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Analysis of interference	For each sensor identify the interferences that can be affect in a conventional measurement. In case of cross interference with other sensors and the measurement correction using external probes or software, please indicate the methodology.
CE Marked	Identify the sensor origin and if these sensors are calibrated, certified (who is the certification entity) and if the sensors have the CE marking.
DATA & SOFTWARE	
Uses personal data	Define the data maturity and identify if it is used patient/personnel data under specific EU Data Protection Regulation (GDPR)/Regulation (EU) 2016/679. Indicates how the data is capture, managed and stored and the security mechanism applied in all lifetime of personnel data.
Data protection strategies (Security)	Define specific considerations and mechanisms developed under project as a security strategy for data protection.
Logical Data Flow	Define data flow from data source to their storage and management.
Servers Storage & network	Indicate the architecture of ICT systems and the configuration of servers, clouds and their scalability in terms of product.
Application memory requirements	Where a device/equipment/wearable has local electronics, specify the memory requirements for their standard operation.
Expected application transaction volume	Define the maximum volume of data involved in the transactions and define the requirements for support them. Also indicates the interrelation between other devices or ICT interfaces.
Operating System	Where a device/equipment/wearable has local electronics, specify the operating system requirements for their standard operation.
application CPU requirements	Where a device/equipment/wearable has local electronics, specify the hardware and CPU requirements for support the software and their standard operation.
Software Interfaces	Describe product / other software interface characteristics, including component names and versions, databases, operating systems, libraries, tools, etc. Specify any constraints, along with nature of communications and what data is coming in and being disseminated.
Software Quality	List other characteristics crucial to success of product. List each by describing its relation to product, being quantitative, specific, and verifiable.
Maintenance and Support	Define the maintenance and support periods for each product or each part of system.
Ethical approval	Define the ethical considerations taken in the data management and their usability and third parties. Specially attention with the personnel data and their conditions and usability.
CONNECTIVITY & TRACEABILITY	

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Remote connectivity capacity for data capture	Define the communication requirements of remote equipment in terms of the data transfer using the standard and maximum data rate required for the communication system.
Emision bands covered	Define the emission/reception bands covered by device/equipment.
Accessibility	Define the accessibility requirements for wireless communications considering the holistic system.
Critical Ancillary equipment & Connections	Define the connections required for the wireless communications and all critical ancillary equipment required such as gateways, repeaters etc.
EMC compliance	Identify the EMC standard to be accomplished for device and equipment: ISO, SAE, IEC, European standards concerning unwanted electrical emissions (EN 50 081, EN 55 011, etc)
	TEST PROCEDURE
Testing strategy	Define testing strategies for each area and sub-area to include all the functional and quality (non-functional) requirements.
Test methodology	Define the methodology applied during the testing campaign of overall system and each device or parts.
Certification and facility required	Identify the required external facilities for the testing campaign in order to certify the device/equipment/wearable.
Number of samples/devices for testing	Define the number of samples required for the testing campaign.
Environmental test procedures	Define the test procedures and conditions for the environmental test
System integration testing	Define the test procedures and conditions for the system integration
Usability Testing	The purpose of usability testing is to ensure that the device/equipment/wearable and features will function in a manner that is acceptable to the customer.
Performance and Stress Testing	Describe how Performance & Stress testing will be conducted. Who will done the stress test (external advisor, owner to company). Identify which parts of systems will tested in performances and which under stress test.
User Acceptance Testing	Describe how the User Acceptance testing will be conducted. Who will used for the validation procedure of user acceptance test
Quality Test	Identify the quality standards involved in the quality tests for each part of system.
Iteration/Regression Testing	During the repeated cycles of identifying bugs and taking receipt of new builds (containing bug fix code changes), there are several processes which are common to this phase across all projects. These include the various types of tests: functionality, performance, stress, configuration, etc. Special case for software applications.

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Final release Testing	End-users participates in this milestone process as well by providing confirmation feedback on new issues uncovered, and input based on identical or similar issues detected earlier. Special case for software applications
Regulatory compliance	
Target Regulatory classification	Identify the device classification and regulatory required as a function of scope. In case of medical grade device ((EU) 2017/745)
Quality management system	ISO 13485:2016 compliance
Status of regulatory approval	CE mark (or FDA approval), WHO or stringent regulatory authority (SRA) emergency use listing/authorization, WHO prequalification, or other approval identified.

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3. Guidelines for implementation in INNO4COV-19 service platform

The Specifications Sheet templates must be used for the three product categories, portable devices, equipment or instruments, and wearables. Specification Sheet aims to be a guide to harmonize the information regarding a future telemonitoring system and try to identify the technical restrictions and critical parts or key points for their intended use. Completing the technical requirements, technology providers can identify the missing parts for scale -up their products and reduce the time to market.

Moreover, specification sheet wants to collect information on the current development status of new emerging technologies and open a collaboration between technology providers and INNO4COV-19 partners through the offering services from the INNO4COV-19 platform.

As important part of specification sheet is to related the regulation requirements of telemonitoring systems, especially in the medical grade device due to this part is mandatory for achieve the market and needs a good assessment and planification for reduce time to market.

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4. Summary

In this report, specifications related to user requirements, electrical characteristics, connectivity, Data protection, test procedures and regulation requirements for a telemonitoring devices are presented and defined with the aim to offer at the selected technological providers in the frame of INNO4COV-19 project a guideline for complete a specification sheet of its technology.

The report is split in two areas:

- information on the framework for development of devices in the context of COVID-19 for telemonitoring and telemedicine.
- Define each filed contained on the Specifications Sheet templates and provide an instruction for complete them.

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Annex

D4.1_SP3_Specification Sheet Sensors_V3.xlsx

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