**SOFTWARE REQUIREMENTS SPECIFICATIONS**

# INTRODUCTION

## Purpose

This document represents the Software requirement specifications for Fibercure laser pen. In this document it will be described what the software will do and how it will be expected to perform, it will describe the functionality that the product needs to fulfil the need of all stakeholders.

The software safety class of Fibercure laser pen software has been identified as B, based on the potential risk of harm to the patient, operator, and environment.

## Intended Audience

To this document will be accessed by Medency’s General Manager Alessandro Boschi, Medency’s quality and regulatory office, Medency’s electronic engineer Nicola Zanforlin, the product recipient company Lumendo and an external consultant Diego Bartot.

This document will be used as a guideline for the design of the software.

## Terms and Abbreviations

|  |  |
| --- | --- |
| Term/Abbreviation | Description |
| SRS | Software requirement specifications according to IEC 62304 standards |
| SOUP | Software of unknown provenience according to IEC 62304 standards |
| Endofill | Is a low-viscosity, injectable, hydrophilic, light-curable endodontic sealer according to IEC 62304 standards |

# OVERALL DESCRIPTION

## Product Scope

Fibercure is a dental, cordless, battery-powered laser-based curing lamp. It is an easy-to-use illumination device developed specifically to cure Endofill within the root canal. Fibercure includes a thin optical fiber tip that is able to easily penetrate into small cavities, ensuring that a focused light beam homogeneously reaches the entirety of structures where light access would be unattainable using the current devices.

The Fibercure laser pen software will adhere to risk management procedures as outlined in ISO 14971. The risk management process will be integrated throughout the software lifecycle to identify, analyze, evaluate, and mitigate potential risks

## Intended Use

This product allows a fast and efficient photopolymerization of Endofill inside root canals. Fibercure is designed for the use of Endofill, with the correct light power, wavelength, and time of use pre-registered.

## User Needs

The intended users of Fibercure are licenced dental professionals with experience in endodontics. In addition, Fibercure is procured, stored and prepared for use by trained dental nurses or trained dental assistants.

Fibercure is intended to be an easy-to-use dental curing lamp in curing Endofill material within the root canal. This represents a faster and easier method for root canal care compared to nowadays applications in the same clinical application field.

## Assumptions and Dependencies

Fibercure is dependent on the light-curable material, which is developed in another project (Endofill). Only when both projects are ready, Fibercure can be marketed.

The forthcoming development steps, following assumptions are made:

* The light-curable material (Endofill) will be available in due time.
* Suitable production facility will be identified.
* Suitable packaging is available and can be handled by the production facility.
* The development depends on the results of the planned clinical study in dental settings.

The device shall be ready for commercial launch by December 2023.

# SYSTEM FEATURES AND REQUIREMENTS

## Functional Requirements

Enhance functional requirements by including more detail, including edge cases, error handling, and how to respond in abnormal situations. For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound."

The purpose of the software is to allow the user to choose a treatment and produce a laser output power based on the treatment parameters. According to this, the following functional requirements have been detected:

***Working requirements:***

|  |  |
| --- | --- |
| Term/Abbreviation | Description |
| SRS | Software requirement specifications according to IEC 62304 |
| SOUP | Software of unknown provenance according to IEC 62304 |
| Endofill | Is a low-viscosity, injectable, hydrophilic, light-curable endodontic sealer used in the device according to IEC 62304 |
| ID: | FR1 |
| Title: | Turn ON the device |
| Description: | To turn ON the laser pen, the user presses and holds the first button (labelled as ON/OFF button – bottom of the pen) until the LED turns green. |
| Depth: | None |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| ID: | FR2 |
| Title: | Activate the protocol n°1 |
| Description: | The user press once the second button (on the top of the pen) and the LED light turns Blue. Laser output last for 10 seconds then the Blue LED Light turns off. |
| Depth: | FR1 |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| ID: | FR3 |
| Title: | Activate the protocol n°2 |
| Description: | The user presses twice the second button (on the top of the pen) and the LED light turns Purple. Laser output last for 20 seconds then the Purple LED Light turns off. |
| Depth: | FR1 |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| ID: | FR4 |
| Title: | Turn OFF the device |
| Description: | To turn OFF the laser pen, the user presses and holds the first button (labelled as ON/OFF button - bottom of the pen) until the green LED disappears. |
| Depth: | FR1 |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| ID: | FR5 |
| Title: | Shutdown time after inactivity |
| Description: | After not using the laser pen for 5 minutes, the device switches off. |
| Depth: | FR1 |

***Battery requirements:***

|  |  |
| --- | --- |
| Term/Abbreviation | Description |
| SRS | Software requirement specifications according to IEC 62304 |
| SOUP | Software of unknown provenience and its implications should be considered in the software requirements |
| Endofill | Is a low-viscosity, injectable, hydrophilic, light-curable endodontic sealer that should be considered in the software requirements |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| **ID:** | **FR7** |
| Title: | Need to change the battery |
| Description: | It will no longer be possible to return to the OPERATE phase until the battery is replaced with a charged one. |
| Depth: | FR6 |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| **ID:** | **FR8** |
| Title: | Low battery signal (during OPERATE phase) |
| Description: | In cases where the battery is running low during OPERATE phase, the system will remain in operation for the time set by the treatment and then return to READY mode. |
| Depth: | FR1 |

***System errors requirements:***

|  |  |
| --- | --- |
| Term/Abbreviation | Description |
| SRS | Software requirement specifications |
| SOUP | Software of unknown provenance |
| Endofill | Is a low-viscosity, injectable, hydrophilic, light-curable endodontic sealer |
| Standards/Regulations | IEC 62304 |
| Software Classification | Class [insert class] according to IEC 62304 |
| Software Safety Requirements | According to IEC 62304, the software shall meet the safety requirements specified in [insert relevant clause/section] |
| Software Risk Management Process | According to IEC 62304, the software risk management process shall be followed as outlined in [insert relevant clause/section] |
| ID: | FR1 |
| Title: | Turn ON the device |
| Description: | To turn ON the laser pen, the user presses and holds the first button (labelled as ON/OFF button – bottom of the pen) until the LED turns green. |
| Depth: | None |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| ID: | FR2 |
| Title: | Activate the protocol n°1 |
| Description: | The user press once the second button (on the top of the pen) and the LED light turns Blue. Laser output last for 10 seconds then the Blue LED Light turns off. |
| Depth: | FR1 |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| ID: | FR3 |
| Title: | Activate the protocol n°2 |
| Description: | The user presses twice the second button (on the top of the pen) and the LED light turns Purple. Laser output last for 20 seconds then the Purple LED Light turns off. |
| Depth: | FR1 |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| ID: | FR4 |
| Title: | Turn OFF the device |
| Description: | To turn OFF the laser pen, the user presses and holds the first button (labelled as ON/OFF button - bottom of the pen) until the green LED disappears. |
| Depth: | FR1 |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| ID: | FR5 |
| Title: | Shutdown time after inactivity |
| Description: | After not using the laser pen for 5 minutes, the device switches off. |
| Depth: | FR1 |
| ID: | FR6 |
| Title: | Low battery signal (during READY phase) |
| Description: | In cases where the battery is running low during READY phase, the user can see the LED indicators of the unit will begin an alternate flash accompanied by an audible signal. |
| Depth: | FR1 |
| ID: | FR7 |
| Title: | Need to change the battery |
| Description: | It will no longer be possible to return to the OPERATE phase until the battery is replaced with a charged one. |
| Depth: | FR6 |
| ID: | FR8 |
| Title: | Low battery signal (during OPERATE phase) |
| Description: | In cases where the battery is running low during OPERATE phase, the system will remain in operation for the time set by the treatment and then return to READY mode. |
| Depth: | FR1 |
| ID: | FR9 |
| Title: | Electrical error |
| Description: | In case of malfunctions inside the unit and/or electrical errors, Fibercure will stop the emission automatically and the LED indicators will start a simultaneous red flashing. |
| Depth: | FR1 |
| ID: | FR10 |
| Title: | System lock |
| Description: | In the event that the minimum internal electrical self-control requirements are not reached (for example laser current outside the allowed limits), Fibercure will stop the laser emission automatically and the LED indicators will start a simultaneous red flashing. |
| Depth: | FR1 |
| ID: | FR11 |
| Title: | Overheating/temperature error |
| Description: | This type of error appears when system temperatures inside the machine is out of working range. The system independently goes into a safeguard mode followed by an alternate flashing of the LED indicators on the surface of the device. |
| Depth: | FR1 |

***Charging base requirements:***

|  |  |
| --- | --- |
| Term/Abbreviation | Description |
| SRS | Software requirement specifications |
| SOUP | Software of unknown provenience |
| Endofill | Is a low-viscosity, injectable, hydrophilic, light-curable endodontic sealer |
| Standards/Guidelines | IEC 62304 |
| ID: | FR1 |
| Title: | Turn ON the device |
| Description: | To turn ON the laser pen, the user presses and holds the first button (labelled as ON/OFF button – bottom of the pen) until the LED turns green. |
| Depth: | None |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| ID: | FR2 |
| Title: | Activate the protocol n°1 |
| Description: | The user press once the second button (on the top of the pen) and the LED light turns Blue. Laser output last for 10 seconds then the Blue LED Light turns off. |
| Depth: | FR1 |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| ID: | FR3 |
| Title: | Activate the protocol n°2 |
| Description: | The user presses twice the second button (on the top of the pen) and the LED light turns Purple. Laser output last for 20 seconds then the Purple LED Light turns off. |
| Depth: | FR1 |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| ID: | FR4 |
| Title: | Turn OFF the device |
| Description: | To turn OFF the laser pen, the user presses and holds the first button (labelled as ON/OFF button - bottom of the pen) until the green LED disappears. |
| Depth: | FR1 |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED fails to turn green when the device is turned on, the software should alert the user with a specific error message or sound." |
| ID: | FR5 |
| Title: | Shutdown time after inactivity |
| Description: | After not using the laser pen for 5 minutes, the device switches off. |
| Depth: | FR1 |
| ID: | FR6 |
| Title: | Low battery signal (during READY phase) |
| Description: | In cases where the battery is running low during READY phase, the user can see the LED indicators of the unit will begin an alternate flash accompanied by an audible signal. |
| Depth: | FR1 |
| ID: | FR7 |
| Title: | Need to change the battery |
| Description: | It will no longer be possible to return to the OPERATE phase until the battery is replaced with a charged one. |
| Depth: | FR6 |
| ID: | FR8 |
| Title: | Low battery signal (during OPERATE phase) |
| Description: | In cases where the battery is running low during OPERATE phase, the system will remain in operation for the time set by the treatment and then return to READY mode. |
| Depth: | FR1 |
| ID: | FR9 |
| Title: | Electrical error |
| Description: | In case of malfunctions inside the unit and/or electrical errors, Fibercure will stop the emission automatically and the LED indicators will start a simultaneous red flashing. |
| Depth: | FR1 |
| ID: | FR10 |
| Title: | System lock |
| Description: | In the event that the minimum internal electrical self-control requirements are not reached (for example laser current outside the allowed limits), Fibercure will stop the laser emission automatically and the LED indicators will start a simultaneous red flashing. |
| Depth: | FR1 |
| ID: | FR11 |
| Title: | Overheating/temperature error |
| Description: | This type of error appears when system temperatures inside the machine is out of working range. The system independently goes into a safeguard mode followed by an alternate flashing of the LED indicators on the surface of the device. |
| Depth: | FR1 |
| ID: | FR12 |
| Title: | Charging battery - LED indicator |
| Description: | The charging base have LEDs that turns green when a battery is put in charge. |
| Depth: | None |
| ID: | FR13 |
| Title: | Calibration of laser beam - LED indicator |
| Description: | The user shoots the laser beam through the optical tip on the charging base calibrator.  If the calibration is positive, the LED turns green.  If the calibration is negative, the LED turns red. |
| Depth: | None |

## External Interface Requirements

External interface requirements are types of functional requirements that ensure the system will communicate properly with external components, such as:

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| User interfaces | The key to application usability that includes content presentation, application navigation, and user assistance, among other components. |
| Hardware interfaces | The characteristics of each interface between the software and hardware components of the system, such as supported device types and communication protocols. |
| Software interfaces | The connections between your product and other software components, including databases, libraries, and operating systems. |
| Communication interfaces | The requirements for the communication function your product will use, like emails or embedded forms. |
| Inputs and Outputs | The software will accept inputs in the form of user button presses, with the expected outputs being LED light changes and laser output. The exact format, timing, and other specifications of these inputs and outputs will be documented in the detailed design description document. |
| Data interfaces | The specifications for the exchange of data between the software and external systems, such as data storage and retrieval from databases or communication with other medical devices. |

***User interfaces:***

|  |  |
| --- | --- |
| ID: | EIR1 |
| Title: | Use of buttons |
| Description: | The user interface is represented by buttons positioned on the laser pen that the user presses to turn it on/off and perform the desired treatment. |
| Depth: | None |
| Requirement: | The software shall implement a user interface that allows the user to control the laser pen using the buttons. |
| Compliance: | IEC 62304-5.1.1 |
| ID: | EIR2 |
| Title: | Use of LEDs |
| Description: | The device is characterized by LEDs indicators that helps the user on understanding the functioning of the device. |
| Depth: | None |
| Requirement: | The software shall control the LEDs to provide visual feedback to the user regarding the functioning of the device. |
| Compliance: | IEC 62304-5.1.1 |
| ID: | EIR3 |
| Title: | User Interfaces |
| Description: | The key to application usability that includes content presentation, application navigation, and user assistance, among other components. |
| Requirement: | The software shall provide user interfaces that are intuitive, user-friendly, and comply with relevant usability standards. |
| Compliance: | IEC 62304-5.1.1 |
| ID: | EIR4 |
| Title: | Hardware Interfaces |
| Description: | The characteristics of each interface between the software and hardware components of the system, such as supported device types and communication protocols. |
| Requirement: | The software shall interface with the hardware components of the system according to the specified characteristics and communication protocols. |
| Compliance: | IEC 62304-5.1.1 |
| ID: | EIR5 |
| Title: | Software Interfaces |
| Description: | The connections between your product and other software components, including databases, libraries, and operating systems. |
| Requirement: | The software shall interface with other software components, such as databases, libraries, and operating systems, as required. |
| Compliance: | IEC 62304-5.1.1 |
| ID: | EIR6 |
| Title: | Communication Interfaces |
| Description: | The requirements for the communication function your product will use, like emails or embedded forms. |
| Requirement: | The software shall support the required communication interfaces, such as emails or embedded forms, as specified. |
| Compliance: | IEC 62304-5.1.1 |
| ID: | EIR7 |
| Title: | Inputs and Outputs |
| Description: | The software will accept inputs in the form of user button presses, with the expected outputs being LED light changes and laser output. The exact format, timing, and other specifications of these inputs and outputs will be documented in the detailed design description document. |
| Requirement: | The software shall handle the inputs from user button presses and generate the expected outputs, including LED light changes and laser output, according to the specified format, timing, and other specifications. |
| Compliance: | IEC 62304-5.1.1 |

***Hardware interfaces:*** *the medical device is a closed system, therefore it does not interface with any other system.*

***Software interfaces:*** *the medical device is a closed system, therefore it does not interface with any other system.*

***Communication interfaces:*** *the medical device is a closed system, therefore it does not interface with any other system.*

## System requirements

Since the software is embedded into the medical device and so it’s a closed system, this section is not applicable.

***Even though the software is embedded, there are system requirements. This can include hardware compatibility, OS version, or other system-level constraints***

***Example "The system requirements for the Fibercure laser pen software include compatibility with the dsPIC33CK256MP508 microcontroller, and operating within the device's specific power and temperature constraints."***

## Non-Functional Requirements

|  |  |
| --- | --- |
| ID: | NFR5 |
| Title: | Reliability |
| Description: | The software should be developed with high reliability to ensure that the device functions correctly and consistently. This includes minimizing the occurrence of errors, failures, and malfunctions. The software should be thoroughly tested and validated to meet reliability requirements. |
| Depth: | None |
| ID: | NFR6 |
| Title: | Maintainability |
| Description: | The software should be designed and implemented in a way that allows for easy maintenance and updates. This includes using modular and well-documented code, providing clear instructions for maintenance tasks, and ensuring compatibility with future software updates. |
| Depth: | None |
| ID: | NFR7 |
| Title: | Performance |
| Description: | The software should be designed to meet performance requirements, such as response time, processing speed, and memory usage. It should be able to handle the expected workload and perform efficiently under normal operating conditions. |
| Depth: | None |
| ID: | NFR8 |
| Title: | Safety |
| Description: | The software should be developed with a focus on safety to ensure that it does not pose any harm to the user or patient. This includes implementing appropriate safety measures, such as error handling, fault detection, and fail-safe mechanisms. The software should comply with relevant safety standards and regulations. |
| Depth: | None |

|  |  |
| --- | --- |
| ID: | NFR |
| Title: | Performance |
| Description: | The performance of the software refers to its ability to execute tasks efficiently and meet the specified requirements within acceptable time frames. This includes factors such as response time, processing speed, and resource utilization. The software should be designed and optimized to ensure optimal performance under normal operating conditions. |
| Depth: | None |

|  |  |
| --- | --- |
| ID: | NFR1 |
| Title: | Security |
| Description: | Related to the compromise of sensitive information: the device is not intended to handle sensitive data. The software has to be developed according to IEC 62304 and IEC 62366. |
| Depth: | None |
| ID: | NFR2 |
| Title: | Compatibility |
| Description: | Since the software is embedded into the medical device and so it’s a close system, it doesn’t need to be supported by an operating system. Therefore, this section is not applicable. |
| Depth: | None |
| ID: | NFR3 |
| Title: | Scalability |
| Description: | The microchip used into the Fibercure laser pen is dsPIC33CK256MP508. Microchip’s dsPIC33CK family of digital signal controllers (DSCs) feature a 100 MHz dsPIC® DSC core with integrated DSP and enhanced on-chip peripherals. These DSCs enable the design of digital power, motor control, advanced sensing and control, high-performance general-purpose and robust applications. The DSCs feature advanced analog for advanced sensor interfacing designs. Offering real-time deterministic performance, the DSCs enable high-performance control applications. The rich feature set in this family of devices also make this family a very good fit for high-performance general-purpose and robust applications. The dsPIC33CK product family has many hardware features that help simplify functional safety certifications for ASIL-B and SIL-2 focused automotive and industrial safety-critical applications  The microcontroller used has an internal flash which is used only as program memory: during the life of the product no data is saved and therefore no writing takes place. As regards the life time it refers to the retention value TRETD (Characteristic Retention). This value is identified by the manufacturer as equal to 20 years in the full range of voltage and temperature use. |
| Depth: | None |
| ID: | NFR4 |
| Title: | Usability |
| Description: | Usability will be evaluated on the ability to interact with the device in relation to the function to be obtained and taking into account the operator who will have to use it. All the possible situations and scenarios in which a typical operator can find himself and can interact with the equipment in an intuitive way and without having specific knowledge of his field, particular acumen or dexterity will be taken into consideration. Further considerations have been made in the usability documentation. |
| Depth: | None |
| ID: | NFR5 |
| Title: | Performance |
| Description: | The performance requirements of the software will be defined in the detailed design description document. It will include criteria such as response time, throughput, and resource utilization. |
| Depth: | None |
| ID: | NFR6 |
| Title: | Maintainability |
| Description: | The software should be designed and implemented in a way that facilitates maintenance activities, such as bug fixes, updates, and enhancements. This includes writing clean and modular code, providing documentation, and using version control systems. |
| Depth: | None |

|  |  |
| --- | --- |
| ID: | NFR1 |
| Title: | Security |
| Description: | Related to the compromise of sensitive information: the device is not intended to handle sensitive data. The software has to be developed according to IEC 62304 and IEC 62366. |
| Depth: | None |
| ID: | NFR2 |
| Title: | Compatibility |
| Description: | Since the software is embedded into the medical device and so it’s a close system, it doesn’t need to be supported by an operating system. Therefore, this section is not applicable. |
| Depth: | None |
| ID: | NFR3 |
| Title: | Scalability |
| Description: | The microchip used into the Fibercure laser pen is dsPIC33CK256MP508. Microchip’s dsPIC33CK family of digital signal controllers (DSCs) feature a 100 MHz dsPIC® DSC core with integrated DSP and enhanced on-chip peripherals. These DSCs enable the design of digital power, motor control, advanced sensing and control, high-performance general-purpose and robust applications. The DSCs feature advanced analog for advanced sensor interfacing designs. Offering real-time deterministic performance, the DSCs enable high-performance control applications. The rich feature set in this family of devices also make this family a very good fit for high-performance general-purpose and robust applications. The dsPIC33CK product family has many hardware features that help simplify functional safety certifications for ASIL-B and SIL-2 focused automotive and industrial safety-critical applications  The microcontroller used has an internal flash which is used only as program memory: during the life of the product no data is saved and therefore no writing takes place. As regards the life time it refers to the retention value TRETD (Characteristic Retention). This value is identified by the manufacturer as equal to 20 years in the full range of voltage and temperature use. |
| Depth: | None |
| ID: | NFR4 |
| Title: | Usability |
| Description: | Usability will be evaluated on the ability to interact with the device in relation to the function to be obtained and taking into account the operator who will have to use it. All the possible situations and scenarios in which a typical operator can find himself and can interact with the equipment in an intuitive way and without having specific knowledge of his field, particular acumen or dexterity will be taken into consideration. Further considerations have been made in the usability documentation. |
| Depth: | None |
| ID: | NFR5 |
| Title: | Performance |
| Description: | The software should be designed to meet the performance requirements specified in the IEC 62304 standard. This includes considerations for response time, throughput, and resource utilization. Performance testing should be conducted to ensure that the software meets these requirements. |
| Depth: | None |
| ID: | NFR6 |
| Title: | Maintainability |
| Description: | The software should be designed and implemented in a way that allows for easy maintenance and updates. This includes using modular and well-documented code, providing clear instructions for maintenance tasks, and ensuring that the software can be easily modified or extended without causing unintended side effects. |
| Depth: | None |
| ID: | NFR7 |
| Title: | Supportability |
| Description: | The software should be designed to be easily supported by the development team and other stakeholders. This includes providing comprehensive documentation, offering support channels for users to report issues or ask questions, and ensuring that the software can be easily deployed and configured in different environments. |
| Depth: | None |

|  |  |
| --- | --- |
| ID: | NFR1 |
| Title: | Performance |
| Description: | The performance of the software refers to its ability to meet the specified requirements and provide the desired functionality within acceptable time frames. It includes factors such as response time, throughput, and resource utilization. The software should be designed and optimized to ensure efficient and effective performance. |
| Depth: | None |
| ID: | NFR2 |
| Title: | Maintainability |
| Description: | Maintainability refers to the ease with which the software can be modified, updated, and repaired. It includes factors such as code readability, modularity, and documentation. The software should be designed and implemented in a way that allows for easy maintenance and future enhancements. |
| Depth: | None |
| ID: | NFR3 |
| Title: | Supportability |
| Description: | Supportability refers to the ability of the software to be supported and maintained throughout its lifecycle. It includes factors such as availability of technical support, documentation, and training. The software should be designed and developed with supportability in mind, ensuring that necessary resources and processes are in place to provide ongoing support to users. |
| Depth: | None |
| ID: | NFR4 |
| Title: | Reliability |
| Description: | Reliability refers to the ability of the software to perform its intended functions consistently and accurately over time. It includes factors such as fault tolerance, error handling, and failure recovery. The software should be designed and implemented in a way that minimizes the occurrence of errors and ensures reliable operation. |
| Depth: | None |

|  |  |
| --- | --- |
| ID: | NFR1 |
| Title: | Security |
| Description: | Related to the compromise of sensitive information: the device is not intended to handle sensitive data. The software has to be developed according to IEC 62304 and IEC 62366. |
| Depth: | None |
| ID: | NFR2 |
| Title: | Compatibility |
| Description: | Since the software is embedded into the medical device and so it’s a close system, it doesn’t need to be supported by an operating system. Therefore, this section is not applicable. |
| Depth: | None |
| ID: | NFR3 |
| Title: | Scalability |
| Description: | The microchip used into the Fibercure laser pen is dsPIC33CK256MP508. Microchip’s dsPIC33CK family of digital signal controllers (DSCs) feature a 100 MHz dsPIC® DSC core with integrated DSP and enhanced on-chip peripherals. These DSCs enable the design of digital power, motor control, advanced sensing and control, high-performance general-purpose and robust applications. The DSCs feature advanced analog for advanced sensor interfacing designs. Offering real-time deterministic performance, the DSCs enable high-performance control applications. The rich feature set in this family of devices also make this family a very good fit for high-performance general-purpose and robust applications. The dsPIC33CK product family has many hardware features that help simplify functional safety certifications for ASIL-B and SIL-2 focused automotive and industrial safety-critical applications  The microcontroller used has an internal flash which is used only as program memory: during the life of the product no data is saved and therefore no writing takes place. As regards the life time it refers to the retention value TRETD (Characteristic Retention). This value is identified by the manufacturer as equal to 20 years in the full range of voltage and temperature use. |
| Depth: | None |
| ID: | NFR4 |
| Title: | Usability |
| Description: | Usability will be evaluated on the ability to interact with the device in relation to the function to be obtained and taking into account the operator who will have to use it. All the possible situations and scenarios in which a typical operator can find himself and can interact with the equipment in an intuitive way and without having specific knowledge of his field, particular acumen or dexterity will be taken into consideration. Further considerations have been made in the usability documentation. |
| Depth: | None |
| ID: | NFR5 |
| Title: | Performance |
| Description: | The performance of the software will be evaluated based on its ability to meet the specified requirements and provide the desired functionality within acceptable time frames. Performance testing will be conducted to ensure that the software can handle the expected workload and respond efficiently to user inputs. |
| Depth: | None |
| ID: | NFR6 |
| Title: | Maintainability |
| Description: | Maintainability refers to the ease with which the software can be modified, updated, and repaired. The software should be designed and implemented in a way that allows for easy maintenance, including clear and well-documented code, modular design, and the use of standard programming practices. Regular maintenance activities, such as bug fixes and software updates, should be performed to ensure the continued reliability and functionality of the software. |
| Depth: | None |
| ID: | NFR7 |
| Title: | Supportability |
| Description: | Supportability encompasses the ability of the software to be supported and maintained throughout its lifecycle. This includes providing documentation, training, and technical support to users, as well as ensuring that the necessary resources and infrastructure are in place to support the software. Supportability also involves planning for future enhancements and upgrades to the software, as well as addressing any issues or problems that may arise during its use. |
| Depth: | None |
| ID: | NFR8 |
| Title: | Reliability |
| Description: | Reliability refers to the ability of the software to perform its intended functions consistently and accurately, without failure or errors. The software should be designed and implemented in a way that minimizes the likelihood of errors or malfunctions, and includes mechanisms for error detection, handling, and recovery. Reliability testing will be conducted to ensure that the software meets the specified reliability requirements and can operate reliably under normal and abnormal conditions. |
| Depth: | None |
| ID: | NFR9 |
| Title: | Cybersecurity |
| Description: | Cybersecurity refers to the protection of the software and the data it processes from unauthorized access, use, disclosure, disruption, modification, or destruction. The software should be designed and implemented with appropriate security measures to prevent and mitigate cybersecurity risks, including encryption, access controls, authentication mechanisms, and secure communication protocols. Regular security assessments and updates should be performed to address any vulnerabilities or threats that may arise. |
| Depth: | None |