**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 standard |
| SOUP | Software of unknown provenience (SOUP) refers to any software component or module that is acquired from a third party or has an unknown origin. It is important to assess the safety and effectiveness of SOUP in the context of the software requirement specifications. |
| Endofill | Endofill is a low-viscosity, injectable, hydrophilic, light-curable endodontic sealer. While it may not directly relate to the software requirement specifications, it is important to consider any potential interactions or dependencies with the software in order to ensure overall safety and effectiveness of the system. |

# 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 |
| SOUP | Software of unknown provenience (SOUP) refers to any software component or module that is acquired from a third party or has an unknown or uncertain origin. It is important to assess and manage the risks associated with using SOUP in the software development process. |
| Endofill | Is a low-viscosity, injectable, hydrophilic, light-curable endodontic sealer |
| IEC 62304 Compliance | The software requirements and functionalities described in this document are designed to be compliant with the IEC 62304 standard for medical device software. |
| Safety Classification | The software shall be classified according to the safety requirements specified in 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 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 |
| 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 |
| 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 provenience |
| Endofill | Is a low-viscosity, injectable, hydrophilic, light-curable endodontic sealer |
| Standards/Regulations | IEC 62304 |
| Software Safety Classification | To be determined based on risk assessment |
| Software Verification and Validation | Requirements for testing and validation of the software |
| Software Development Process | Requirements for software development process and documentation |
| Software Maintenance and Configuration Management | Requirements for software maintenance and configuration management |
| 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:** | **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 |
| 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:** | **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 |
| 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." |
|  |  |

***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/Regulations | IEC 62304 |
| Software Safety Classification | To be determined based on risk analysis |
| Software Verification and Validation | Requirements for testing and validation of the software |
| Software Maintenance | Requirements for software maintenance and updates |
| Configuration Management | Requirements for managing software configuration |
| 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 |
| 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." |
|  |  |

## External Interface Requirements

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

|  |  |
| --- | --- |
| User interfaces | The key to application usability that includes content presentation, application navigation, and user assistance, among other components. It is important to ensure that the user interfaces are designed in accordance with IEC 62304 standards to provide a safe and effective user experience. |
| Hardware interfaces | The characteristics of each interface between the software and hardware components of the system, such as supported device types and communication protocols. It is essential to define and document these hardware interfaces to ensure proper integration and functionality of the software. |
| Software interfaces | The connections between your product and other software components, including databases, libraries, and operating systems. It is crucial to identify and specify these software interfaces to ensure seamless communication and interoperability with other software systems. |
| Communication interfaces | The requirements for the communication function your product will use, like emails or embedded forms. It is necessary to define and document these communication interfaces to enable proper data exchange and communication between the software and external systems. |
| 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. It is important to validate and verify that the inputs and outputs meet the requirements specified in the software requirement specifications and adhere to the IEC 62304 standards for safety and performance. |

***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 |
| 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. |
| 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 |

***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

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| --- | --- |
| 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 |
| ID: | EIR2 |
| Title: | Use of LEDs |
| Description: | The device is characterized by LED indicators that help the user understand the functioning of the device. |
| Depth: | None |
| ID: | NFR1 |
| Title: | Security |
| Description: | The software must be developed according to IEC 62304 and IEC 62366 standards to ensure the security of sensitive information. |
| Depth: | None |
| ID: | NFR2 |
| Title: | Compatibility |
| Description: | Since the software is embedded into the medical device and operates as a closed system, it does not require support from an external operating system. |
| Depth: | None |
| ID: | NFR3 |
| Title: | Scalability |
| Description: | The Fibercure laser pen utilizes the dsPIC33CK256MP508 microchip, which offers advanced analog capabilities and enables high-performance control applications. The microcontroller used in the device has an internal flash memory for program storage, with a retention value of 20 years. |
| Depth: | None |
| ID: | NFR4 |
| Title: | Usability |
| Description: | Usability of the device will be evaluated based on the ability of operators to interact with the device and achieve the desired function. The usability considerations will take into account typical operator scenarios and ensure intuitive interaction without requiring specialized knowledge or dexterity. |
| Depth: | None |

|  |  |
| --- | --- |
| ID: | NFR |
| Title: | Performance |
| Description: | The software should demonstrate acceptable performance characteristics, including appropriate response times, throughput, and efficient utilization of system resources. Specific performance requirements will be documented in the detailed design description document. |
| Depth: | None |

|  |  |
| --- | --- |
| ID: | NFR |
| Title: | Performance |
| Description: | The performance of the software refers to its ability to meet the specified functional and non-functional requirements within acceptable time frames. This includes factors such as response time, throughput, and resource utilization. Performance testing will be conducted to ensure that the software performs optimally under expected load and stress conditions. |
| Depth: | None |
| ID: | NFR |
| Title: | Maintainability |
| Description: | Maintainability refers to the ease with which the software can be modified, updated, and repaired. This includes factors such as code readability, modularity, and documentation. The software will be designed and implemented following best practices to ensure ease of maintenance. Additionally, comprehensive documentation will be provided to aid in future maintenance and troubleshooting efforts. |
| 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 in a timely manner. This includes factors such as response time, throughput, and resource utilization. The software should be optimized to ensure efficient and effective performance, taking into account the hardware capabilities and limitations. Performance testing should be conducted to validate and verify the performance of the software under different load conditions. |
| 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, with clear and well-structured code, proper use of comments, and comprehensive documentation. Additionally, version control and change management processes should be in place to track and manage software changes effectively. |
| Depth: | None |
| ID: | NFR3 |
| Title: | Supportability |
| Description: |  |
| 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 meet the performance requirements specified in the detailed design description document. This includes factors such as response time, processing speed, and resource utilization. |
| 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 clear and modular code structure, documentation, and support for version control. |
| Depth: | None |
| ID: | NFR7 |
| Title: | Supportability |
| Description: | The software should be designed to facilitate support and troubleshooting. This includes providing error logs, diagnostic tools, and clear instructions for resolving common issues. |
| Depth: | None |
| ID: | NFR8 |
| Title: | Reliability |
| Description: | The software should be reliable and perform its intended functions consistently and accurately. This includes minimizing the occurrence of errors, handling exceptions gracefully, and providing appropriate error handling mechanisms. |
| 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 functional requirements within acceptable time frames and resource utilization. Performance testing will be conducted to ensure that the software can handle the expected workload and respond in a timely manner. |
| 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 efficient maintenance activities, such as bug fixes, enhancements, and future upgrades. This includes clear and well-documented code, modular design, and use of standard programming practices. |
| Depth: | None |
| ID: | NFR7 |
| Title: | Supportability |
| Description: | Supportability refers to the ability of the software to be supported and maintained over its lifecycle. This includes providing adequate documentation, training, and support resources to assist users and administrators in using and troubleshooting the software. Additionally, the software should be designed to be compatible with standard support tools and processes. |
| Depth: | None |
| ID: | NFR8 |
| Title: | Reliability |
| Description: | Reliability refers to the ability of the software to perform its intended functions consistently and without failure over a specified period of time. The software should be designed and implemented in a way that minimizes the occurrence of errors, faults, and failures. This includes thorough testing, error handling mechanisms, and appropriate use of redundancy and fault tolerance techniques. |
| Depth: | None |
| ID: | NFR9 |
| Title: | Cybersecurity |
| Description: | Cybersecurity refers to the protection of the software and its data from unauthorized access, use, disclosure, disruption, modification, or destruction. The software should be designed and implemented with appropriate security measures, such as encryption, access controls, and secure communication protocols, to prevent and detect cyber threats. Regular security assessments and updates should be performed to address new vulnerabilities and risks. |
| Depth: | None |