**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 |
| SOUP | Software of unknown provenience |
| Endofill | Is a low-viscosity, injectable, hydrophilic, light-curable endodontic sealer |
| IEC 62304 | International standard for medical device software lifecycle processes |
| SDLC | Software Development Life Cycle |
| V&V | Verification and Validation |
| Hazard | Potential source of harm |
| Risk | Combination of the probability of occurrence of harm and the severity of that harm |
| Hazardous Situation | Circumstance in which people, property, or the environment are exposed to one or more hazards |
| Safety | Freedom from unacceptable risk of harm |
| Software Safety Classification | Classification of software based on the potential risk it poses to the patient, operator, or environment |
| Software of Unknown Provenance (SOUP) | Software that has not been developed under the organization’s quality management system |
| Endodontic Sealer | Material used in root canal treatment to fill and seal the root canal space |

# 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:***

|  |  |
| --- | --- |
| 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:***

|  |  |
| --- | --- |
| 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 | None |
| Error Handling | None |
| 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 | None |
| Error Handling | None |
| 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 | None |
| Error Handling | None |
| 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 | None |
| Error Handling | None |
| 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 |
| Edge Cases | None |
| Error Handling | None |
| 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: | 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 | None |
| Error Handling | None |
| 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 | None |
| Error Handling | None |
| 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 |
| Edge Cases | None |
| Error Handling | None |
| 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." |

***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 |  |
| Software Development Process |  |
| Software Verification and Validation |  |
| 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:** | **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:***

|  |  |
| --- | --- |
| ID: | FR12 |
| Title: | Charging battery - LED indicator |
| Description: | The charging base has LED indicators that turn green when a battery is being charged. This provides a visual indication to the user that the battery is being charged successfully. |
| 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: | FR13 |
| Title: | Calibration of laser beam - LED indicator |
| Description: | The user can perform a calibration of the laser beam by shooting it through the optical tip on the charging base calibrator. If the calibration is successful, the LED indicator turns green, indicating that the laser beam is properly calibrated. In case of a failed calibration, the LED indicator turns red, indicating that the laser beam needs to be recalibrated. |
| 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. |
| 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.** |

***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 |
| Standards: | The user interface design should follow the guidelines specified in IEC 62366-1:2015 for medical devices. |
| 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 |
| Standards: | The LED indicators should comply with the requirements specified in IEC 60601-1-8:2006 for medical electrical equipment. |
| 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. |

***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: | 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. The buttons should be designed and positioned in accordance with IEC 62304 standards for usability and safety. |
| 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. The LEDs should be designed and positioned in accordance with IEC 62304 standards for usability and safety. |
| Depth: | None |
| ID: | NFR1 |
| Title: | Security |
| Description: | Related to the compromise of sensitive information: the device is not intended to handle sensitive data. However, the software should still be developed according to IEC 62304 and IEC 62366 standards to ensure security measures are in place to protect against unauthorized access or data breaches. |
| Depth: | None |
| ID: | NFR2 |
| Title: | Compatibility |
| Description: | Since the software is embedded into the medical device and is a closed system, it does not need to be supported by an operating system. Therefore, this section is not applicable. |
| Depth: | None |
| ID: | NFR3 |
| Title: | Scalability |
| Description: | The microchip used in the Fibercure laser pen is dsPIC33CK256MP508. This microchip features a 100 MHz dsPIC® DSC core with integrated DSP and enhanced on-chip peripherals, making it suitable for high-performance control applications. The dsPIC33CK product family has hardware features that help simplify functional safety certifications for automotive and industrial safety-critical applications. The microcontroller used has an internal flash that is used only as program memory, with no data being saved during the life of the product. The retention value TRETD (Characteristic Retention) 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 based on the ability to interact with the device in relation to the function to be obtained, taking into account the operator who will have to use it. The device should be designed with intuitive controls and interfaces that can be easily understood and operated by operators with varying levels of expertise. Usability considerations should be made in accordance with IEC 62304 standards to ensure the device is user-friendly and meets the needs of the intended users. |
| Depth: | None |

|  |  |
| --- | --- |
| ID: | NFR |
| Title: | Performance |
| Description: | The performance requirement specifies the expected performance characteristics of the software, such as response time, throughput, and resource utilization. It ensures that the software meets the performance needs of the users and operates efficiently. |
| Depth: | None |

|  |  |
| --- | --- |
| ID: | NFR |
| Title: | Performance |
| Description: | The performance of the software refers to its ability to meet the specified functional requirements within the given constraints, such as response time, throughput, and resource utilization. It is important to ensure that the software performs efficiently and effectively to provide a satisfactory user experience. Performance testing and optimization techniques should be employed to identify and address any performance issues. |
| Depth: | None |
| ID: | NFR |
| Title: | Maintainability |
| Description: | Maintainability refers to the ease with which the software can be modified, repaired, or enhanced. It is important to design the software in a modular and well-structured manner, using standard coding practices and documentation. This will facilitate future maintenance activities, such as bug fixes, updates, and feature additions. Additionally, the use of version control systems and proper documentation will aid in maintaining the software over its lifecycle. |
| 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 performs efficiently and effectively under normal and peak load conditions. |
| 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. Documentation, modular design, and adherence to coding standards are important factors in ensuring maintainability. |
| Depth: | None |
| ID: | NFR7 |
| Title: | Supportability |
| Description: | Supportability encompasses the ability of the software to be supported throughout its lifecycle. This includes providing adequate documentation, training, and support resources to assist users in effectively using the software. Supportability also involves the ability to diagnose and resolve issues that may arise during the use of the software. |
| 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. Performance testing will be conducted to ensure that the software performs efficiently and effectively under normal and peak load conditions. |
| Depth: | None |
| ID: | NFR6 |
| Title: | Maintainability |
| Description: | Maintainability refers to the ease with which the software can be modified, repaired, or enhanced. The software should be designed and implemented in a way that allows for easy maintenance, including clear and well-documented code, modular design, and use of standard coding 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 documentation, training, and technical support to users and ensuring that the necessary resources and infrastructure are in place to support the software. |
| Depth: | None |
| ID: | NFR8 |
| Title: | Reliability |
| Description: | Reliability refers to the ability of the software to perform its intended functions consistently and accurately over time. The software should be designed and implemented in a way that minimizes the occurrence of errors, failures, and downtime, and includes mechanisms for error detection, handling, and recovery. |
| Depth: | None |

|  |  |
| --- | --- |
| ID: | NFR1 |
| Title: | Performance |
| Description: | The performance of the software should meet the specified requirements, such as response time, throughput, and resource utilization. Performance testing should be conducted to ensure that the software performs optimally under different load conditions. |
| Depth: | None |
| ID: | NFR2 |
| Title: | Maintainability |
| Description: | The software should be designed and implemented in a way that allows for easy maintenance and future enhancements. This includes using modular and well-documented code, following coding standards, and providing appropriate documentation for troubleshooting and maintenance tasks. |
| Depth: | None |
| ID: | NFR3 |
| Title: | Supportability |
| Description: | The software should be designed to be easily supported by the development team and other stakeholders. This includes providing clear and comprehensive documentation, offering support channels for users to report issues and seek assistance, and ensuring that the software can be easily updated or patched. |
| Depth: | None |
| ID: | NFR4 |
| Title: | Reliability |
| Description: | The software should be reliable and able to perform its intended functions without failure or errors. This includes implementing error handling mechanisms, conducting thorough testing to identify and fix bugs, and ensuring that the software can recover gracefully from failures or errors. |
| Depth: | None |
| ID: | NFR5 |
| Title: | Cybersecurity |
| Description: | The software should be designed and implemented with strong cybersecurity measures to protect against unauthorized access, data breaches, and other security threats. This includes implementing secure authentication and authorization mechanisms, encrypting sensitive data, and regularly updating the software to address known security vulnerabilities. |
| Depth: | None |