**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

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| --- | --- |
| Term/Abbreviation | Description |
| SRS (Software Requirement Specification) | A document that describes the functional and non-functional requirements of the software system. It provides a detailed description of what the software should do and how it should behave. |
| SOUP (Software of Unknown Provenance) | Refers to software components or modules that have been obtained from a third-party source whose origin, integrity, and reliability are unknown. It is important to assess and manage the risks associated with using SOUP in the software system. |
| Endofill | Is a low-viscosity, injectable, hydrophilic, light-curable endodontic sealer used in endodontic procedures to fill and seal the root canal space. It provides a hermetic seal to prevent bacterial reinfection and promote healing. |

# 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:***

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| --- | --- |
| ID: | FR6 |
| Title: | Low battery signal (during READY phase) |
| Description: | In cases where the battery is running low during the 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 | N/A |
| Error Handling | N/A |
| How to respond in abnormal situations | 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 | N/A |
| Error Handling | N/A |
| How to respond in abnormal situations | 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 the 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 |  |
| 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:***

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| ID: | FR6 |
| Title: | Low battery signal (during READY phase) |
| Description: | In cases where the battery is running low during the READY phase, the software shall provide a visual indication to the user by flashing the LED indicators and an audible signal. |
| Depth: | FR1 |
| Priority: | Medium |
| Classification: | Class B |
| References: | IEC 62304 |
| Edge Cases: | None |
| Error Handling: | None |
| How to respond in abnormal situations: | 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: | If the battery is low and needs to be replaced, the software shall prevent the system from returning to the OPERATE phase until a charged battery is inserted. |
| Depth: | FR6 |
| Priority: | High |
| Classification: | Class C |
| References: | IEC 62304 |
| Edge Cases: | None |
| Error Handling: | None |
| How to respond in abnormal situations: | 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 the OPERATE phase, the software shall allow the system to continue operation for the time set by the treatment and then transition back to the READY mode. |
| Depth: | FR1 |
| Priority: | Medium |
| Classification: | Class B |
| References: | IEC 62304 |
| Edge Cases: | None |
| Error Handling: | None |
| How to respond in abnormal situations: | 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:***

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| 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 |
| 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: | 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 |
| 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: | 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:***

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| 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: | FR1 |
| Edge Cases | The software should handle the case where the LED fails to turn green or turns red during the calibration process and provide a warning message to the user. |
| Error Handling | The software should handle any errors that occur during the calibration process and provide appropriate error messages to the user. |
| How to respond in abnormal situations | For example, "If the LED fails to turn green or turns red 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 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:

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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. |
| Safety requirements | The software shall comply with the safety requirements specified in IEC 62304 standard. |
| Risk management | The software shall undergo a risk management process as per the requirements of IEC 62304 standard. |
| Software development process and lifecycle | The software development process and lifecycle shall be in accordance with the guidelines provided in IEC 62304 standard. |
| Software verification and validation | The software shall undergo verification and validation activities as per the requirements of IEC 62304 standard. |
| Software maintenance and configuration management | The software shall be maintained and managed in accordance with the guidelines provided in IEC 62304 standard. |

***User interfaces:***

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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: | According to IEC 62304, the use of buttons should be designed to ensure safe and reliable operation of the device. |
| 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: | According to IEC 62304, the use of LEDs should be designed to provide clear and unambiguous feedback to the user about the device status. |

***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: | 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 standards. It should implement appropriate security measures to protect against unauthorized access and ensure the confidentiality, integrity, and availability of data. |
| Depth: | None |
| ID: | NFR2 |
| Title: | Compatibility |
| Description: | Since the software is embedded into the medical device and it is a closed system, it does not need to be supported by an operating system. However, it should be compatible with the hardware components of the device and any external systems it interacts with. |
| Depth: | None |
| ID: | NFR3 |
| Title: | Scalability |
| Description: | The software should be designed to be scalable, allowing for future enhancements and updates. It should be able to handle increased data volume and user load without compromising performance or stability. |
| Depth: | None |
| ID: | NFR4 |
| Title: | Usability |
| Description: | Usability will be evaluated based on the ability to interact with the device and achieve the intended function. The software should have a user-friendly interface and intuitive controls to facilitate ease of use. It should consider the needs and capabilities of the typical operator, ensuring that they can interact with the equipment without requiring specialized knowledge or skills. Additionally, the software should comply with relevant usability standards and guidelines. |
| Depth: | None |

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| ID: | NFR |
| Title: | Performance |
| Description: | The software shall meet the performance requirements specified in the system requirements document. |
| Depth: | N/A |

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| ID: | NFR |
| Title: | Maintainability |
| Description: | The software shall be designed and implemented in a modular and well-structured manner to facilitate ease of maintenance. This includes clear separation of components, use of standardized coding practices, and documentation of the software architecture. |
| Depth: | N/A |

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| ID: | NFR |
| Title: | Supportability |
| Description: | The supportability requirement ensures that the software is designed and implemented in a way that allows for easy maintenance, troubleshooting, and support. This includes providing clear documentation, error logging, and remote access capabilities for support personnel. |
| Depth: | Level 1 |

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| --- | --- |
| ID: | NFR |
| Title: | Reliability |
| Description: | The software shall be designed and implemented to ensure reliable operation of the system. This includes minimizing the occurrence of errors, faults, and failures, as well as providing appropriate error handling and fault tolerance mechanisms. |
| Depth: | Level 1 |

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| --- | --- |
| ID: | NFR |
| Title: | Cybersecurity |
| Description: | The software shall be designed and implemented to protect against unauthorized access, data breaches, and other cybersecurity threats. This includes implementing secure authentication and authorization mechanisms, encryption of sensitive data, secure communication protocols, and regular security updates and patches. |
| Depth: | None |