**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 specifications (SRS) is a document that captures the functional and non-functional requirements of the software system. It serves as a foundation for the software development process. |
| SOUP | Software of unknown provenience (SOUP) refers to any software component or module that is obtained from a third-party source and whose origin, development process, and quality cannot be fully verified or controlled by the software development organization. It is important to carefully assess and manage the risks associated with using SOUP in the software system. |
| Endofill | Endofill is a low-viscosity, injectable, hydrophilic, light-curable endodontic sealer. In the context of software development, it is not clear how this term is relevant. Please provide more information about its significance in the software requirement specifications. |

# 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: | Deficiency |
| FR1 | Depth is None |
| FR2 | Edge Cases is None |
| FR2 | Error Handling is None |
| FR3 | Edge Cases is None |
| FR3 | Error Handling is None |
| FR4 | Edge Cases is None |
| FR4 | Error Handling is None |
| FR5 | Edge Cases is None |
| FR5 | Error Handling is None |
| 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:***

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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 |
| Type: | Functional Requirement |
| Priority: | Medium |
| Verification Method: | Unit Testing |
| Traceability: | SRS-001 |
| 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 |
| Type: | Functional Requirement |
| Priority: | High |
| Verification Method: | Integration Testing |
| Traceability: | SRS-002 |
| 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 |
| Type: | Functional Requirement |
| Priority: | Low |
| Verification Method: | System Testing |
| Traceability: | SRS-003 |

***System errors requirements:***

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| --- | --- |
| Edge Cases | The edge cases for this requirement should be identified and described here. |
| Error Handling | The error handling procedures for this requirement should be described here. |
| 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. If this occurs, 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. If this occurs, 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 are out of the 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. If this occurs, the software should alert the user with a specific error message or sound. |
| 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." |
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***Charging base requirements:***

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| ID: | FR12 |
| Title: | Charging battery - LED indicator |
| Description: | The charging base has LEDs that turn green when a battery is put in charge. |
| Depth: | Low |
| Edge Cases | The LED should also turn red when the battery is fully charged. |
| Error Handling | 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. |
| How to respond in abnormal situations | If the LED continues to blink green for an extended period of time, it may indicate a charging error. The software should notify the user and provide guidance on how to resolve the issue. |
| 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 successful, the LED turns green. If the calibration is unsuccessful, the LED turns red. |
| Depth: | Medium |
| Edge Cases | The LED should also turn yellow if the calibration is in progress. |
| Error Handling | If the LED fails to turn green or red during calibration, the software should alert the user with a specific error message or sound. |
| How to respond in abnormal situations | If the LED continues to blink red after multiple calibration attempts, it may indicate a calibration failure. The software should notify the user and provide guidance on how to resolve the issue. |
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## 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. |

***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: | None |
| 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 |
| Requirements: |  |
| Functional Requirements: |  |
| 1. The device shall have buttons for turning it on/off. |  |
| 2. The device shall have buttons for performing the desired treatment. |  |
| Non-Functional Requirements: |  |
| 1. The buttons shall be easy to press and operate. |  |
| 2. The buttons shall have a tactile feedback to indicate successful press. |  |
| 3. The LEDs shall provide clear and intuitive indications of the device functioning. |  |
| Safety Requirements: |  |
| 1. The buttons shall not pose any risk of accidental activation. |  |
| 2. The LEDs shall not emit any harmful radiation. |  |
| Usability Requirements: |  |
| 1. The buttons and LEDs shall be positioned ergonomically for easy access and visibility. |  |

***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: | The description does not provide specific information on how the software will handle the compromise of sensitive information. It should include details on encryption, access controls, and data protection measures. |
| Depth: | None |
| ID: | NFR2 |
| Title: | Compatibility |
| Description: | The description states that the software does not need to be supported by an operating system because it is embedded into the medical device. However, it should also mention any compatibility requirements with other devices or systems that the software may interact with. |
| Depth: | None |
| ID: | NFR3 |
| Title: | Scalability |
| Description: | The description provides information on the microchip used in the device, but it does not mention any scalability requirements or considerations. It should include details on how the software can be scaled to support different hardware configurations or increased user load. |
| Depth: | None |
| ID: | NFR4 |
| Title: | Usability |
| Description: | The description mentions that usability will be evaluated, but it does not provide any specific criteria or metrics for evaluation. It should include details on how usability will be measured and what factors will be considered in the evaluation process. |
| Depth: | None |

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| ID: | NFR |
| Title: | Performance |
| Description: | The performance requirements specify the expected performance characteristics of the software. This includes factors such as response time, throughput, and resource utilization. |
| Depth: | High |

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| --- | --- |
| ID: | NFR |
| Title: | Maintainability |
| Description: | Maintainability refers to the ease with which the software can be modified or repaired to correct defects, improve performance, or adapt to changes in the environment. It includes factors such as modularity, code readability, and the use of design patterns. |
| Depth: | High |

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| ID: | NFR |
| Title: | Supportability |
| Description: | The supportability requirements specify the necessary measures to ensure the software can be supported throughout its lifecycle. This includes considerations for maintenance, troubleshooting, and updates. |
| Depth: | High |

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| --- | --- |
| ID: | NFR |
| Title: | Reliability |
| Description: | The reliability requirement specifies the expected level of performance and availability of the software. It should outline the acceptable failure rates and mean time between failures (MTBF). |
| Depth: | High |

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| --- | --- |
| ID: | NFR |
| Title: | Cybersecurity |
| Description: | The cybersecurity requirements specify the measures and controls that need to be implemented to protect the software system from unauthorized access, data breaches, and other cybersecurity threats. This includes encryption, authentication, access control, and secure communication protocols. |
| Depth: | High |