**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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| Requirement ID | Requirement Description |
| SRS | Software requirement specifications |
| SOUP | Software of unknown provenience |
| Endofill | Is a low-viscosity, injectable, hydrophilic, light-curable endodontic sealer |

# 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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| Requirement ID | Requirement Description |
| 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:***

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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 |

***System errors requirements:***

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| Requirement ID: | R1 |
| Requirement Description: | The system shall allow users to create an account. |
| Deficiency: | None |
| Requirement ID: | R2 |
| Requirement Description: | The system shall allow users to log in to their account. |
| Deficiency: | None |
| Requirement ID: | R3 |
| Requirement Description: | The system shall allow users to reset their password. |
| Deficiency: | None |
| Requirement ID: | R4 |
| Requirement Description: | The system shall encrypt user passwords for security. |
| Deficiency: | None |
| Requirement ID: | R5 |
| Requirement Description: | The system shall have a user profile page. |
| Deficiency: | The requirement does not specify what information should be displayed on the user profile page. |
| Requirement ID: | R6 |
| Requirement Description: | The system shall allow users to update their profile information. |
| Deficiency: | None |
| Requirement ID: | R7 |
| Requirement Description: | The system shall allow users to delete their account. |
| Deficiency: | 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." |
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***Charging base requirements:***

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| Requirement ID | Requirement Description |
| Title: | Charging battery - LED indicator |
| Description: | The charging base have LEDs that turns green when a battery is put in charge. |
| 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 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." |
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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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| Section: | 1. Introduction |
| Requirement: | The software shall be developed according to the IEC 62304 standard. |
| Deficiency: | None |
| Section: | 2. Scope |
| Requirement: | The software shall be used for monitoring vital signs in a hospital setting. |
| Deficiency: | The requirement does not specify if the software is intended for use in a clinical setting or for research purposes only. |
| Section: | 3. Functional Requirements |
| Requirement: | The software shall display real-time vital sign data on a graphical user interface. |
| Deficiency: | None |
| Requirement: | The software shall generate alerts when abnormal vital sign values are detected. |
| Deficiency: | The requirement does not specify the criteria for determining abnormal vital sign values. |
| Section: | 4. Non-Functional Requirements |
| Requirement: | The software shall have a response time of less than 2 seconds for displaying vital sign data. |
| Deficiency: | The requirement does not specify if the response time includes network latency. |
| Requirement: | The software shall be able to handle a maximum of 100 simultaneous users. |
| Deficiency: | The requirement does not specify how the software will handle additional users beyond the maximum limit. |

***User interfaces:***

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| Requirement ID: | RQ001 |
| Requirement Description: | The system shall allow users to create an account. |
| Deficiency: | None |
| Requirement ID: | RQ002 |
| Requirement Description: | The system shall allow users to log in to their account. |
| Deficiency: | None |
| Requirement ID: | RQ003 |
| Requirement Description: | The system shall allow users to reset their password. |
| Deficiency: | None |
| Requirement ID: | RQ004 |
| Requirement Description: | The system shall allow users to update their account information. |
| Deficiency: | Missing requirement for account deletion |
| Requirement ID: | RQ005 |
| Requirement Description: | The system shall allow users to view their account information. |
| Deficiency: | 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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| Requirement ID | Requirement Description |
| 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 |

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| Section: | 1. Introduction |
| 1.1 Purpose: | The purpose of this document is to specify the requirements for the software system. |
| 1.2 Scope: | This document applies to the software system developed for XYZ Medical Devices. |
| 1.3 References: | None |
| 1.4 Definitions: | None |
| 1.5 Abbreviations: | None |
| 1.6 Conventions: | None |
| 1.7 Intended Audience: | This document is intended for the development team, quality assurance team, and regulatory authorities. |

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| Section: | 1. Introduction |
| 1.1 Purpose: | To provide an overview of the software requirements |
| 1.2 Scope: | The software requirements apply to the XYZ medical device |
| 1.3 Definitions: | None |
| 1.4 References: | ISO 13485, IEC 62304 |
| 1.5 Overview: | This section provides an introduction to the software requirements and their scope. |

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| key: | value |
| key: | value |
| key: | value |
| Depth: | None |

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| Software Requirements: | The software requirements specified in IEC 62304 should be followed. |
| Software Development Process: | The software development process should adhere to the guidelines provided in IEC 62304. |
| Software Safety Classification: | The software should be classified according to the safety requirements specified in IEC 62304. |
| Software Risk Management: | A comprehensive software risk management process should be implemented as per the guidelines in IEC 62304. |

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| Software Requirement: |  |
| Software Requirement ID: |  |
| Software Requirement Description: |  |
| Software Requirement Type: |  |
| Software Requirement Priority: |  |
| Software Requirement Verification Method: |  |
| Software Requirement Verification Result: |  |
| Software Requirement Traceability: |  |
| Software Requirement Status: |  |
| Software Requirement Review Date: |  |