

SOFTWARE REQUIREMENTS SPECIFICATIONS

1 INTRODUCTION

1.1 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.

1.2 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.

1.3 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

2 OVERALL DESCRIPTION

2.1 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

2.2 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.

2.3 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.

2.4 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.

3 SYSTEM FEATURES AND REQUIREMENTS

3.1 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:	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	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."

situations	
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:

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	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."

situations	

Charging base requirements:

ID:	FR12
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."

3.2 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 <u>detailed design description document</u> .

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
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.

3.3 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."

3.4 Non-Functional Requirements

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:	<p>The microchip used into the Fibercure laser pen is dsPIC33CK256MP508.</p> <p>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.</p> <p>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.</p> <p>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</p>

	<p>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.</p> <p>As regards the life time it refers to the retention value TRET (Characteristic Retention). This value is identified by the manufacturer as equal to 20 years in the full range of voltage and temperature use.</p>
Depth:	None
ID:	NFR4
Title:	Usability
Description:	<p>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.</p> <p>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.</p>
Depth:	None

ID:	NFR
Title:	Performance
Description:	
Depth:	

ID:	NFR
Title:	Maintainability
Description:	
Depth:	

ID:	NFR
Title:	Supportability

Description:	
Depth:	None

ID:	NFR
Title:	Reliability
Description:	
Depth:	None

ID:	NFR
Title:	Cybersecurity
Description:	
Depth:	None