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

deficiencies: None  
  
response:   
  
| Term/Abbreviation | 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:

deficiencies:   
1. The table lacks traceability to the requirements of IEC 62304.  
2. The table does not mention any safety requirements.  
3. The table does not mention any software requirements related to the device's safety.  
4. The table does not mention any software requirements related to the device's security.  
5. The table does not mention any software requirements related to the device's performance.  
6. The table does not mention any software requirements related to the device's reliability.  
7. The table does not mention any software requirements related to the device's usability.  
  
response:   
  
| 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. |  
| Traceability | This requirement is related to the safety requirements of the device as per IEC 62304. |  
| Safety Requirements | The device should not cause any harm to the user while turning ON. |  
| Software Requirements | The software should ensure that the device is turned ON safely. |  
| Security Requirements | None |  
| Performance Requirements | None |  
| Reliability Requirements | None |  
| Usability Requirements | None |  
  
| 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. |  
| Traceability | This requirement is related to the safety requirements of the device as per IEC 62304. |  
| Safety Requirements | The device should not cause any harm to the user while activating the protocol. |  
| Software Requirements | The software should ensure that the device is activated safely. |  
| Security Requirements | None |  
| Performance Requirements | None |  
| Reliability Requirements | None |  
| Usability Requirements | None |  
  
| 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. |  
| Traceability | This requirement is related to the safety requirements of the device as per IEC 62304. |  
| Safety Requirements | The device should not cause any harm to the user while activating the protocol. |  
| Software Requirements | The software should ensure that the device is activated safely. |  
| Security Requirements | None |  
| Performance Requirements | None |  
| Reliability Requirements | None |  
| Usability Requirements | None |  
  
| 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. |  
| Traceability | This requirement is related to the safety requirements of the device as per IEC 62304. |  
| Safety Requirements | The device should not cause any harm to the user while turning OFF. |  
| Software Requirements | The software should ensure that the device is turned OFF safely. |  
| Security Requirements | None |  
| Performance Requirements | None |  
| Reliability Requirements | None |  
| Usability Requirements | None |  
  
| ID: | FR5 |  
| ----- | --------------------------------------------------------- |  
| Title | Shutdown time after inactivity |  
| Description | After not using the laser pen for 5 minutes, the device switches off. |  
| Traceability | This requirement is related to the safety requirements of the device as per IEC 62304. |  
| Safety Requirements | The device should not cause any harm to the user while shutting down after inactivity. |  
| Software Requirements | The software should ensure that the device shuts down safely after inactivity. |  
| Security Requirements | None |  
| Performance Requirements | None |  
| Reliability Requirements | None |  
| Usability Requirements | None |

Battery requirements:

deficiencies:   
1. The table lacks information about the safety requirements for the device.  
2. The table does not mention any specific requirements for the battery to be used in the device.  
3. The table does not provide any information regarding the battery replacement process.  
  
response:   
  
[['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.\nLaser 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.\nLaser 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'],   
['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'],   
['Safety Requirements', 'The device should comply with IEC 62304 safety requirements.'],   
['Battery Requirements', 'The device should use a battery that complies with IEC 62304 requirements.'],   
['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'],   
['Battery Replacement', 'The software should provide instructions for battery replacement.'],   
['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:

|  |  |
| --- | --- |
| 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 | If the battery is running low during READY phase, the software shall display a warning message to the user indicating that the battery is low and needs to be charged or replaced. The software shall also log the event and its severity according to the risk classification of the error. |
| 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 | If the battery needs to be replaced, the software shall display a warning message to the user indicating that the battery needs to be replaced. The software shall also log the event and its severity according to the risk classification of the error. |
| 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 | If the battery is running low during OPERATE phase, the software shall display a warning message to the user indicating that the battery is low and the system will return to READY mode after the treatment is completed. The software shall also log the event and its severity according to the risk classification of the error. |
| 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 | If an electrical error occurs, the software shall display an error message to the user indicating that an electrical error has occurred and the system will stop the emission. The software shall also log the event and its severity according to the risk classification of the error. |
| 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 | If a system lock occurs, the software shall display an error message to the user indicating that a system lock has occurred and the system will stop the laser emission. The software shall also log the event and its severity according to the risk classification of the error. |
| 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 | If an overheating/temperature error occurs, the software shall display an error message to the user indicating that an overheating/temperature error has occurred and the system will go into safeguard mode. The software shall also log the event and its severity according to the risk classification of the error. |
| 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 have LEDs that turns green when a battery is put in charge. The charging process should follow the standards mentioned in IEC 62304. Safety measures such as using only the recommended charger and avoiding overcharging should be taken. |
| 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. The calibration process should follow the standards mentioned in IEC 62304. The expected accuracy of the calibration process should be mentioned. Safety measures such as wearing protective gear and avoiding direct exposure to the laser beam should be taken. |
| 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. It should comply with the IEC 62304 standard. |
| Communication interfaces | The requirements for the communication function your product will use, like emails or embedded forms. It should comply with the IEC 62304 standard. |
| 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. The interfaces will be implemented and tested according to the IEC 62304 standard. |

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 |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the user presses the wrong button, the software should alert the user with a specific error message or sound." |
| 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 |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED indicators fail to function properly, the software should alert the user with a specific error message or sound." |
| ID: | EIR3 |
| Title: | User interface requirements |
| Description: | The user interface shall be designed to be easy to use and understand. The buttons shall be of a suitable size and color for easy identification and use. |
| Depth: | None |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the user interface fails to function properly, the software should alert the user with a specific error message or sound." |
| ID: | EIR4 |
| Title: | LED indicator requirements |
| Description: | The LED indicators shall be of a suitable size, color, and brightness for easy identification and use. |
| Depth: | None |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the LED indicators fail to function properly, the software should alert the user with a specific error message or sound." |
| ID: | EIR5 |
| Title: | Safety requirements for buttons and LEDs |
| Description: | The buttons and LEDs shall be designed and tested to ensure they are safe for use by the intended user population. |
| Depth: | None |
| Edge Cases |  |
| Error Handling |  |
| How to respond in abnormal situations | For example, "If the buttons or LEDs are found to be unsafe, the software should alert the user with a specific error message or sound and prevent further use of the device." |

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: | NFR1 |
| Title: | Security |
| Description: | The software should be developed according to IEC 62304 and IEC 62366 standards. It should include authentication, authorization, and data encryption to ensure the confidentiality, integrity, and availability of the data. |
| 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 software should be easily upgradable and maintainable to support future enhancements and changes. It should be designed to meet the requirements of IEC 62304 and IEC 62366 standards. |
| Depth: | None |
| ID: | NFR4 |
| Title: | Usability |
| Description: | The software should be designed with user-centered design principles, such as user feedback and usability testing, to ensure ease of use and user satisfaction. 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: | 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: | Performance requirements will be evaluated based on the response time, processing speed, accuracy, and reliability of the software. These parameters will be documented in the detailed design description document. |
| Depth: | None |

|  |  |
| --- | --- |
| ID: | NFR5 |
| Title: | Maintainability |
| Description: | The software should be designed to facilitate maintenance, repair, and software updates. The software should be modular and well-documented to allow for easy modification and debugging. The expected downtime for maintenance should be minimized, and procedures for performing maintenance tasks should be clearly documented. |
| 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 software shall be designed to meet the performance requirements specified in the detailed design description. The performance requirements shall be based on the intended use of the device and shall include, but not limited to, response time, processing time, and throughput. |
| Depth: | None |
| ID: | NFR6 |
| Title: | Maintainability |
| Description: | The software shall be designed to be maintainable throughout its life cycle. The software design shall be modular and well-structured, with clear and concise documentation. The software shall be designed to facilitate testing, debugging, and modification. |
| Depth: | None |
| ID: | NFR7 |
| Title: | Supportability |
| Description: | The software shall be designed to be supportable throughout its life cycle. The software shall be designed to facilitate troubleshooting, repair, and replacement of components. The software shall be designed to be compatible with standard diagnostic tools and techniques. |
| 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 software shall be designed to operate with the specified performance characteristics under all conditions of use specified in the user documentation. |
| Depth: | None |
| ID: | NFR6 |
| Title: | Maintainability |
| Description: | The software shall be designed to be maintainable throughout its life cycle. |
| Depth: | None |
| ID: | NFR7 |
| Title: | Supportability |
| Description: | The software shall be designed to be supportable throughout its life cycle. |
| Depth: | None |
| ID: | NFR8 |
| Title: | Reliability |
| Description: | The software shall be designed to operate reliably under all conditions of use specified in the user documentation. |
| Depth: | None |

deficiencies: The table\_text for NFRs is incomplete. We need to add more information for each NFR category based on IEC 62304 standards.  
  
response:   
  
Here is the updated table for NFRs:  
  
[['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 software should be designed to be scalable to accommodate future upgrades and changes. The software should be modular and designed with a clear separation of concerns to allow for easy modification and maintenance.'], ['Depth:', 'None'],   
['ID:', 'NFR4'], ['Title:', 'Usability'], ['Description:', 'The software should be designed with usability in mind to ensure that it is easy to use and understand for the intended users. The software should be designed with clear and concise user interfaces and should be intuitive to use.'], ['Depth:', 'None'],   
['ID:', 'NFR5'], ['Title:', 'Performance'], ['Description:', 'The software should be designed to meet the performance requirements specified in the SRS. The software should be optimized for speed and efficiency to ensure that it can perform its intended functions in a timely manner.'], ['Depth:', 'None'],   
['ID:', 'NFR6'], ['Title:', 'Maintainability'], ['Description:', 'The software should be designed to be maintainable to ensure that it can be easily updated and modified as needed. The software should be designed with clear and concise code that is easy to read and understand.'], ['Depth:', 'None'],   
['ID:', 'NFR7'], ['Title:', 'Supportability'], ['Description:', 'The software should be designed to be easily supported to ensure that it can be maintained and updated as needed. The software should be designed with clear and concise documentation to ensure that it can be easily understood and supported by other developers.'], ['Depth:', 'None'],   
['ID:', 'NFR8'], ['Title:', 'Reliability'], ['Description:', 'The software should be designed to be reliable to ensure that it can perform its intended functions without failure. The software should be designed with clear and concise error handling mechanisms to ensure that errors are handled in a timely and efficient manner.'], ['Depth:', 'None'],   
['ID:', 'NFR9'], ['Title:', 'Cybersecurity'], ['Description:', 'The software should be designed to be secure to ensure that it can protect sensitive information and prevent unauthorized access. The software should be designed with clear and concise security mechanisms to ensure that it can prevent cyber attacks and other security threats.'], ['Depth:', 'None']]