|  |  |
| --- | --- |
| 项目名称/变更编号  Project Name / CR No. | Nova |
| 产品名称Product Name | 牙科X射线机 |

批准列表Approval List：

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# 介绍 / Introduction

* 1. **目的 / Purpose of the document**

本文档描述了产品的软件需求。未经允许，不得转给其他人。软件需求只描述系统应该做什么，不包含如何实现部。This document contains the software requirements, which the product has to fulfill. This document is confidential and must not be given to any other without the permission. The requirements should only state WHAT the system shall do but NOT HOW it will be done or how it will be implemented.

# 引用文档 / Referenced documents

|  |  |
| --- | --- |
| **文档 / Document** | **文档编号 / Document number** |
| [1] 架构设计 / Architecture specification | [Name / Name - XXXXXXXX] |
| [2] 风险分析 / Risk analysis | [Name / Name - XXXXXXXX] |
| [3] PMF-RND015-010 Nova牙科X射线机产品需求规范 rev.B | PMF-RND015-010 |

## 定义 / Definitions

* + 1. 需求模板 / Requirements Template

本部分详细描述软件需求模板；需求模板模块化设计的好处在于：产品的软件需求可以多个工程师并行编写，并且可以复用。/ In the following section there will be a detailed description of the requirements template, which all the requirements are based on. A special benefit realized by the modular design of the template is, that requirements can be developed in parallel by more than one person and that the requirements can be easily reused.

|  |  |
| --- | --- |
| 缩写&术语/ terms | 详细介绍/Description |
| 医疗器械软件  Medical device software | 一种被开发成集成到目前正在开发的医疗设备中，作为独立的医疗设备使用的软件系统。A software system that was developed to be integrated in the medical device currently under development for use as an independent medical device. |
| 软件组件  Software components | 软件是软件系统或主软件的组成部分Software part of the software system or master software components |
| 软件单元  Software unit | 软件组件是不可分割的软件部分 Software part of a software component, which may not be dissected |

|  |  |  |  |
| --- | --- | --- | --- |
| **[SWR xxxxx\_yy]** | | | |
| Author: Richard Buerk | | Date: 23.05.2007 | Changed on XX.XX.XXXX by XXX |
| Safety relevant (y/n): x | | |  |
| Rationale |  | | |
| Source |  | | |
| Supporting materials |  | | |
| Description: | | | |
|  | | | |

这些字段使用特殊格式化样式来允许导出数据和生成不同的目录。 确保保留格式化样式，特别是在以文本复制时。The fields use special formatting styles to allow export of data and the generation of the different table of contents. Make sure that the formatting style is kept, especially when copying in text.

下面表格的一些内容使用field functions防止内容的意外覆盖。这些内容可以通过激活“edit field function”或者通过转换“field function on/off”状态进行编辑。Some of the fields (see below) use field functions to avoid accidental overwriting of the fields. They can only be edited by activating “edit field function” or by switching “field function on/off”.

|  |  |
| --- | --- |
| **内容名称Field** | **包含信息Stored information** |
| 需求内容编号  Requirements field  [SWR xxxxx\_yy]  or  [HWR xxxxx\_yy] | 该字段通过“field function”保护。Protected field via field function.  这部分包含唯一的requirement ID和一个关于需求的短标题（即需求名）。对于硬件需求，该ID由HWR和一个唯一的数字组成。对于软件需求，该ID由SWR和一个唯一的数字组成。This field holds the unique requirement ID and a short caption of the requirement (= requirement name). For hardware requirements, the ID consists of the abbreviation HWR and a unique number (HWR = Hardware Requirement). For Software Requirements, the ID consists of the abbreviation SWR and a unique number (SWR = Software Requirement).  编号机制Numbering scheme:  xxxxx = 唯一编号，以00010开头。通常以10为单位递增，为将来的需求预留一些空间。xxxxx = unique number, beginning with 00010. Usually incremented in steps of 10 to spare some space for future requirements.  yy = 需求记录或更改的版本信息。此字段跟踪该需求的版本，而不会使版**本的历**史记录显著增加。当该需求变更时，输入本文档的版本。此版本号易于跟踪本需求是在哪个版本中添加的。yy = document revision when the requirement was recorded or altered. This field allows tracking, which requirements were changed in which document revision without bloating the revision level history. Enter the document revision which the release version of the document will become. This revision number also allows an easy tracking, which feature was added in which revision.  典型例子Example of typical number : [SWR 00010\_00]  一旦文档发布和/或其他文档参考了需求，不能再更改ID部分xxxxx，因为其他文档依赖此ID以实现可跟踪性。非常重要的是，ID是唯一的。如果某个需求被删除，则该序曲的ID需要保持锁定以避免意外重复使用。Once the document is released and/or other documents refer to the requirements, the ID-part xxxxx must not be changed anymore because other documents rely on this ID for traceability! It is very important, that the ID is unique. If a requirement is deleted, the ID needs to be kept locked to avoid accidental re-use.  编号顺序没有特殊的相关性，不能用于分组要求。唯一重要的是数字是唯一的。The numbering sequence has no special relevance and shall not be used for grouping the requirements. The only important thing is that the number is unique. |
| 作者Author field | 该字段通过“field function”保护。Protected field via field function.  最初记录需求的人。The person who recorded the requirement initially. |
| 日期Date field | 该字段通过“field function”保护。Protected field via field function.  最初记录需求的日期。The date, when the requirement was recorded initially. |
| 更改Changed on … | 该需求最后一次更改/修订的日期和人员。如果该需求没有从初始记录修订/更改，则保留xxxx。The date and person, the requirement was changed / revised the last time. If the requirement was not revised / changed from initial recording a placeholder with xxxx exists. |
| 安全相关Safety relevant field | 标记为安全相关的需求需要在验证期间通过，并需要在每次验证发布中验证。Requirements marked as safety relevant need to be passed during verification and need to be verified in every release verification. |
| 来源Source field | 来源，即需求来自（国际标准，他人，经验，系统要求，风险分析，变更请求...）The source, the requirement came from (international standard, persons, experience, system requirements, risk analysis, change request, …) |
| 支持资料  Supporting materials field | 有关需求的更多信息的资料，或者完整规范（例如通信协议）或国际标准。A pointer to more information about the requirement or maybe a pointer to a complete specification (ex. communication protocols) or international standards. |
| 需求描述  Description field | 需求的描述。此字段包含在适当的情况下必须满足相关草图/绘图的要求。标记为注释的文本不是需求的一部分，但需要提供额外的背景信息、需求和提示的可能解决方案以及此需求可能产生的影响。The description of the requirement. This field holds the requirement, which has to be met along with related sketches / drawings where appropriate. Text marked as note is not part of the requirement, but gives additional background information, possible solutions for the requirement and hints, what effects this requirement may have. |

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| --- | --- | --- |
| **责任/ Liability** |  | **关键字/ Keyword** |
| 必须满足Obligation | 在任何情况下都必须满足这一要求。  This requirement has to be fulfilled in any case. | shall |
| 尽可能满足Wish | 如果没有重要的理由这些要求应该得到满足。  These requirements should be fulfilled, if there is no important reason to prevent this. | should |
| 希望满足Intention | 该需求希望以后应用，应该在设计期间最终被考虑。This requirement is an intention which will be applicable later and should be eventually regarded during design. | will |
| 建议满足Proposal | 该要求只是一个建议，如果不需要特别努力可以实现。This requirement is just a proposal that could be implemented if it requires no special effort. | may |

## 产品的目的 / Purpose of the product

产品的目的在架构规范[1]中描述。

The purpose of the product is described in the architecture specification [1].

## 产品的用户 / Users of the product

产品的用户在架构规范[1]中描述。

The users of the product are described in the architecture specification [1].

## 使用的缩写和术语 / Abbreviations and terms used

|  |  |
| --- | --- |
| 缩写，术语 / Abbreviation, term | 描述 / Description |
| DAP | Dose-area product (X射线束的横截面积与所致平均剂量的乘积) |
|  |  |

# 系统和软件概述/ System- and Software Overview

系统和软件概述在架构规范[1]中描述。

The system and software overview is described in the architecture specification [1]. /

# 需求 / Requirements

本章包含所有需求。This chapter contains the requirements.

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| [SWR 00010\_00] | | | |
| Author: Leo Liu | | Date: 09.10.2019 | Changed on |
| Safety relevant (y/n): x | | |  |
| Rationale |  | | |
| Source: | Nova-712 | | |
| Supporting materials: |  | | |
| Description: | | | |
| 1. 系统支持胶片、影像板、和数字传感器3种成像方式 2. 界面能选择及显示 胶片、影像板、数字传感器3种成像方式 | | | |

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| [SWR 00020\_00] | | | |
| Author: Leo Liu | | Date: 09.10.2019 | Changed on |
| Safety relevant (y/n): x | | |  |
| Rationale |  | | |
| Source: | Nova-713， Nova-727， Nova-726 | | |
| Supporting materials: |  | | |
| Description: | | | |
| 1. 系统支持成人、儿童两种模式   2）界面能选择、设置成人、儿童两种模式  3）每种模式，软件有默认参数 | | | |

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| [SWR 00030\_00] | | | |
| Author: Leo Liu | | Date: 09.10.2019 | Changed on |
| Safety relevant (y/n): x | | |  |
| Rationale |  | | |
| Source: | Nova-722 系统应提供一个2.4” 的彩色液晶显示，黑色背景，黄色字体 | | |
| Supporting materials: |  | | |
| Description: | | | |
| 1）软件可以控制液晶显示黑色背景，黄色字体 | | | |

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| [SWR 00040\_00] | | | |
| Author: Leo Liu | | Date: 09.10.2019 | Changed on |
| Safety relevant (y/n): x | | |  |
| Rationale |  | | |
| Source: | Nova-744 液晶显示内容包含电压、电流、DAP、时间、电池电量、数字/模拟模式、报错、系统信息 | | |
| Supporting materials: |  | | |
| Description: | | | |
| 1）软件能够驱动液晶显示内容包含电压、电流、DAP、时间、电池电量、数字/模拟模式、报错、系统信息 | | | |

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| [SWR 00050\_00] | | | |
| Author: Leo Liu | | Date: 09.10.2019 | Changed on |
| Safety relevant (y/n): x | | |  |
| Rationale |  | | |
| Source: | Nova-724 系统提供如下指示：电源指示，系统状态（黄色-曝光；绿色-就绪；蓝色-报错），牙位指示（绿色）。 | | |
| Supporting materials: |  | | |
| Description: | | | |
| 1）软件可以根据系统状态，驱动不同的LED显示：（黄色-曝光；绿色-就绪；蓝色-报错），牙位指示（绿色）。 | | | |

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| [SWR 00060\_00] | | | |
| Author: Leo Liu | | Date: 09.10.2019 | Changed on |
| Safety relevant (y/n): x | | |  |
| Rationale |  | | |
| Source: | Nova-725 系统应提供数字和模拟模式选择，成人和儿童模式选择以及牙位（上下切牙、尖牙、磨牙及其咬翼和咬合）的选择。 | | |
| Supporting materials: |  | | |
| Description: | | | |
| 1）软件能够通过按键选择数字和模拟模式，成人和儿童模式以及牙位（上下切牙、尖牙、磨牙及其咬翼和咬合）。 | | | |

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| [SWR 00070\_00] | | | |
| Author: Leo Liu | | Date: 09.10.2019 | Changed on |
| Safety relevant (y/n): x | | |  |
| Rationale |  | | |
| Source: | Nova-728 系统应提供曝光时间的调节。 | | |
| Supporting materials: |  | | |
| Description: | | | |
| 1）软件能够通过按键调节曝光时间，曝光时间调节范围：大于等于0.1秒，小于等于2秒 | | | |

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| [SWR 00080\_00] | | | |
| Author: Leo Liu | | Date: 09.10.2019 | Changed on |
| Safety relevant (y/n): x | | |  |
| Rationale |  | | |
| Source: | Nova-730系统应提供一个独立的曝光按钮和电源开光按键 | | |
| Supporting materials: |  | | |
| Description: | | | |
| 1. 当曝光按钮按下时，软件驱动系统曝光 2. 当电源开关按钮按下时，软件可以让系统开关机。 3. 软件支持机器远程按键曝光和机器上曝光按钮曝光 | | | |

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| [SWR 00090\_00] | | | |
| Author: Leo Liu | | Date: 09.10.2019 | Changed on |
| Safety relevant (y/n): x | | |  |
| Rationale |  | | |
| Source: | Nova-688 | | |
| Supporting materials: |  | | |
| Description: | | | |
| 1）软件版本控制，版本号符合卡瓦版本号规则。 | | | |