Market Requirement Specification/MRS

市场需求规范

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| Document Name文件名称 |  |
| Document No. & Rev.文件编号及版本 |  |
| Project Name项目名称 | Nova |
| Product Name产品名称 |  |

Approval List 批准列表：

|  |  |  |  |  |
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Change History更改历史记录:

|  |  |  |  |
| --- | --- | --- | --- |
| Revision  版本 | Change Description  更改描述 | Prepared by  起草人 | Effective Date  生效日期 |
| A | Initial release  初始发布 | Ya, Li 栗 亚 | Sep 12th, 2018  2018年9月12日 |
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# Product description/产品描述

## Overview/概述

Target country: China

目标国家：中国

In recent years, the emerging markets in China such as private dental hospital and clinic are changing greatly every day mainly for that MoH already loosened up the limitation of opening private dental hospital and clinic. Many KOLs also think that the number of private dental hospitals and clinics will double or more in the coming 5 ~ 8 years. On the other hand, currently, more than 80% customers, especially small dental hospitals (below Grade ǁ) and private dental clinics are still using analog X-ray, which will be the main markets chance for Nova.

近年来，新兴市场诸如中国的私立口腔医院和诊所每天都在经历着巨变，主要因为卫生部已经放宽了开设私立医院和诊所的限制。许多关键意见人物也认为私立口腔医院和诊所的数量在未来的5~8年内将翻倍。另一方面，现在超过80%的客户，尤其是二级以下的小医院和私立诊所还在用着模拟X光机，这些将是Nova主要的商业机会。

With Nova program Kavo China group is looking for growth in the emerging markets such as private dental hospital or clinic, as well as low-end existing markets like as Grade ǀ and ǁ dental public hospital, and winning market share in price sensitive developed markets with a product maintaining competitive price in the offering.

通过Nova项目，卡瓦集团在寻求私立医院和诊所这样的新兴市场，以及诸如一级和二级公立医院这样低端现有市场的增长，同时通过提供价格有竞争力的产品在价格敏感的发达市场赢得市场占有率

Nova program delivers an intraoral X-ray system that is easy to install and use reliable and affordable yet providing adequate clinical performance for the users.

Nova项目将发布牙片机，它易安装、易使用，可靠和性价比高，同时提供充分的临床表现给用户。

The product will be made available for only one brand: Soredex. Adequate brand differentiation is needed to position the product according to the brands and to avoid direct price comparison between the brands.

产品将只提供1个品牌：Soredex。充分的品牌差异是为了根据品牌定位产品，并且避免品牌间直接的价格比较

## Clinical applications and customer needs served/临床应用和客户需求

A targeted Nova customer has a small dental office running with a limited ability or willingness to invest in more than strictly required.

In the developed markets, the customer is typically running a solo office with private money. but in the emerging markets the customer is transitioning from analog to digital, Nova provides a cost-efficient solution. Nova provides good clinical image quality for basic intraoral radiography including bitewing, periapical and occlusal projection images.

Nova的目标客户，有一间牙科办公室，他不愿意或者不能投资得更多。

在发达市场，客户通常是典型地运营一间自负盈亏得办公室，但是在新兴市场客户正在从模拟向数字转变，Nova提供了一个高性价比的解决方案。Nova对于基本的口内放射提供良好的临床图像质量，它包括：咬翼、根尖和咬合等等。

# Marketing requirements/市场需求

## Wins - Key features and benefits/赢的关键特征和益处

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| --- | --- | --- | --- | --- |
| **ID** | **Requirement**  **需求** | **Level**  **重要性** | **Benchmark**  **标杆** | **%Customer**  **%客户** |
| MRS 1-1 | Nova can be used as fixed type in X-ray room, also can be used as handy type anywhere according to customer's favorite  Nova可以根据客户的喜好，在铅房内作为固定式使用，也可以在任何地方作为手持式使用 | Mandatory  必须 | None  无 | Public:50%  Private:100% |
| MRS 1-2 | Nova is a high frequency intraoral X-ray with LCD, deliver good image quality  Nova是一个带有液晶显示屏的高频口内X射线机，提供良好的图像质量 | Mandatory  必须 |  | Public:100%  Private:100% |
| MRS 1-3 | Tube head specifications for Nova:  − Toshiba  − Nominal Focal spot size: ≤0.4 mm  − Tube voltage: 60 or 65kv, selectable on LCD  Nova的球管规格要求：  − 东芝  − 焦点尺寸: ≤0.4 mm  − 管电压: 60 or 65kv, 在液晶显示屏上可选 | Mandatory  必须 | Minray or ProX | Public:100%  Private:100% |
| MRS 1-4 | Nova has radiation shielding glass(backscatter shielding) to decrease the irradiation to the greatest extent for the purpose of protecting exposure personnel (nurse or dentist)  Nova具有反向散射防护以求最大限度地减少辐射，以达到保护曝光人员（护士或医生）的目的 | Mandatory  必须 | NOMAD PRO 2 | Public:50%  Private:100% |
| MRS 1-5 | Easy to install and use  No need to hit nails on the wall or floor, users only need to open the package box, and soon start to use with the help of operation video and quick guide  易安装和使用  无需在墙上或地板上钉钉子，用户只需要打开包装箱，就可以在操作视频和快速指南的帮助下迅速开始使用 | Mandatory  必须 |  | Public:100%  Private:100% |
| MRS 1-6 | Nova provides a seat for patient, while patient sitting nurse take exposure for him. The cushion color should be compatible with Soredex brand  Nova给病人提供一个座位，病人坐下时护士为其拍片。坐垫颜色应当与Soredex品牌相符 | Mandatory  必须 |  | Public:100%  Private:100% |
| MRS 1-7 | Nova has wireless, remote exposure control switch to protect exposure personnel(nurse or dentist)  Nova具有无线远程曝光按钮，以求保护曝光人员（护士或医生） | Mandatory  必须 |  | Public:100%  Private:100% |
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## Delivery contents/交付内容

**MRS 2-1 SOREDEX Nova**

* Intraoral X-ray unit
* Power supply unit
* Manuals & operation guide (DVD)
  + User manual
  + Operation guide(DVD)
* Printed quick guide (Installation & Operation)
* One printed user manual (Chinese)
* Launch date: July 2019
* 2 Standard configurations:

|  |  |  |
| --- | --- | --- |
|  | Fixed type | Handheld type |
| Cushion | Yes | No |
| Supporting column & arm | Yes | No |
| Remote exposure switch | Yes | No |
| Backscatter shielding | No | Yes |
| COGs (incl. DL, Labor, OH) | ≤ 6500 RMB | ≤ 6500 RMB |

**MRS 2-1 Soredex Nova**

* 牙片机
* 电源适配器
* 说明书和操作视频(DVD)
  + 说明书
  + 操作视频(DVD)
* 纸质快速指南(安装和操作)
* 纸质说明书 (中文)
* 上市日期：2019年7月
* 2个标准配置

|  |  |  |
| --- | --- | --- |
|  | 固定式 | 手持式 |
| 坐位 | 有 | 无 |
| 支撑立柱及平衡臂支架 | 有 | 无 |
| 远程曝光按钮 | 有 | 无 |
| 反向散射防护 | 无 | 有 |
| COGs (物料+工时+分摊) | ≤ 6500 RMB | ≤ 6500 RMB |

## General requirements/通用需求

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| **ID** | **Requirement**  **需求** | **Classification**  **分类** | **Level**  **重要性** |
| MRS 3-1 | Nova is targeted for price sensitive users running small dental offices such as private dental clinics or low-end public dental hospital like Grade ǀ & Grade ǁ.  Nova定位于价格敏感的用户，他们开着私立牙科诊所或诸如一级和二级的低端公立医院 | Design target  设计目标 | Mandatory  必须 |
| MRS 3-2 | Nova is targeted for customers who are often using their first digital IO X-ray  Nova定位于通常是首次用数字牙片机的客户 | Design target  设计目标 | Mandatory  必须 |
| MRS 3-3 | The industrial design of the Soredex product shall follow Soredex industrial design guide lines, DAP item in the LCD.  Soredex产品的工业设计应当遵循Soredex工业设计的准则，在液晶显示屏有DAP参数 | Branding  品牌 | Mandatory  必须 |
|  |  |  |  |
| MRS 3-5 | Nova shall be compatible with the current films, imaging plates of PSP, digital sensors and hygiene accessories.  Nova应当支持现有的胶片、牙片宝的影像板、数字传感器和卫生附件 | Design target  设计目标 | Mandatory  必须 |
| MRS 3-6 | System is intended to be used only by dentist and other qualified dental professionals to take x-ray images, exposed to the imaging plates of PSP, films and digital sensors from the intraoral complex of the skull.  系统的预期用途：医生或其他有资质的口腔专业人员拍摄X片，X射线成像在牙片宝的影像板、胶片和数字传感器上，他们用以显示头颅的口内结构 | Design target  设计目标 | Mandatory  必须 |
| MRS 3-7 | System shall be operated in dental office and X-ray rooms intended for dental care.  系统被用在口腔办公室或者铅房内，用于口腔关注 | Design target  设计目标 | Mandatory  必须 |
| MRS 3-8 | Nova will be operated indoor only in normal daylight  Nova仅仅在普通的日光下的室内操作 | Design target  设计目标 | Mandatory  必须 |
| MRS 3-9 | The product can be operated in the clinical environments (temperature, humidity and pressure) typical to the countries of the targeted markets.  产品在目标国家的典型临床环境（温度、湿度和气压）中使用 | Design target  设计目标 | Mandatory  必须 |
| MRS 3-10 | Product meets all applicable standards and requirements for safety and other regulatory clearance to be sold the targeted markets  产品满足待售市场的所有的安全和法规豁免所需的实施标准和需求 | Design target  设计目标 | Mandatory  必须 |
| MRS 3-11 | Operator of the unit is for dental professional, a dentist or a dental nurse. There can be only a little experience in using digital systems.  设备的操作者是口腔专业人员，诸如牙医或者护士。他们可能是在数字系统方面经验并不充分 | Design target  设计目标 | Mandatory  必须 |
| MRS 3-12 | The Nova system typical installation is in the X-ray room. The height of the user(nurse) is typically 155-175 cm high, the sitting height of patient is 40-60cm  Nova系统的典型安装是在铅房内，用户（护士）的典型身高是155-175cm，病人的坐高是40-60cm | Design target  设计目标 | Mandatory  必须 |
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## User needs/用户需求

The customer has decided to purchase a Nova and has received the delivery package at the place of use. The user, after ensuring that there is no damage during the transportation, unpacks the product using only household tools (knife, scissors). With the information inside the delivery package he is able to place the intraoral X-ray unit in an appropriate place, and ensure that the system is ready for the use by the operator(s).

客户决定购买Nova，并在使用地收到交付包。用户在确认运输过程中没有损害之后，仅仅使用家用工具（刀、剪刀）打开产品包装。根据包装箱内提供的信息，他能够把牙片机放到恰当的地方，并确定设备可以用于操作者使用。

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| **ID** | **Requirement**  **需求** | **Classification**  **分类** | **Level**  **重要性** |
| MRS 4-1 | The delivery package is easy to carry and lift by one person.  交付物应当满足一人条件下的搬运和抬高 | System  系统 | Mandatory  强制的 |
| MRS 4-2 | Everything for a functional system is included in the delivery package.  交付物中包含用于可正常工作的所有物件 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-3 | It is possible to complete the installation and operation of the system using the visual quick guide and operation video.  通过使用快速指南和操作视频，能够完成系统的安装和使用 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-4 | Nova has 2 modes for exposure: adult mode and child mode  Nova有2种拍摄模式：成人和儿童模式 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-5 | Control Touch Panel:  Allow the user to set specific exposure values based on the anatomical area and system conditions  控制面板：  允许用户根据解剖区域和系统条件设定特定的曝光值 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-6 | Control Touch Panel:  Exposure Time Display  控制面板：  显示曝光时间 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-7 | Control Touch Panel:  Anatomy Selection (Anatomical Time Selector)  控制面板：  牙位选择（对应该牙位的曝光时间自动设定） | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-8 | Control Touch Panel:  Tube voltage: 60 or 65kv, selectable  控制面板：  球管电压：60和65kv，界面上可选择 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-9 | Control Touch Panel:  Patient Selector: Adult/Child  控制面板  患者选择：成人/儿童 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-10 | Control Touch Panel:  Imaging Type Selector: Incisor, Bicuspid, Bitewing, Lower Molar and Upper Molar  控制面板：  成像类型选择：切牙、尖牙、咬翼、以及上下磨牙 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-11 | Nova should has beam limiting cones  Nova应当有限束筒 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-12 | User interface is clear and understandable  用户界面是清楚的，易理解的 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-13 | Potential use errors are prevented by design as far as possible  从设计上应当尽可能地防止潜在的使用错误 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-14 | Exposure time: 0.1 - 2.0s  曝光时间：0.1 - 2.0s | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-15 | Nova’s battery should be chargeable, it is being charged while fixed on the stand of arm  Nova的电池应当是可充电的，当其固定在平衡臂的支架上时就为其充电 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-16 | The tubehead assembly entirety can be removed from the stand of arm, and can be standalone used as handy type.  球管组件单元整体可从平衡臂的支架上移除下来，并且可作为手持式单独使用 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-17 | It has backscatter to decrease the scatter irradiation for the purpose of protecting the operator  Nova有反向防护装置以减少散射辐射，来达到保护操作者的目的 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-18 | Nova is designed for min 8 years life time in normal use  Nova被设计为在正常使用情况下的寿命为8年 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-19 | Product is very reliable (MTBF: 2 years)  产品具有很好的可靠性（平均无故障时间：2年） | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-20 | Nova withstands poor electrical supply conditions present in the target markets  Nova能够承受目标市场下的糟糕供电情况 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-21 | Nova is compatible with typical environmental operating conditions at targeted markets  Nova能够与目标市场的典型环境操作条件兼容 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-22 | No field maintenance is required  无需现场维护 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-23 | More than 80% error conditions must be clearly detected by the system, others or unknow errors should be ≤ 20%, and show clear error code in the LCD  80%以上的错误必须能够被明确检测出来，其它或未知错误应低于20%，并在液晶屏幕上清楚显示错误代码 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-24 | All critical parts can be field replaced in calibrated modules  在校准模块中，所有的关键元器件是现场可替换的 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-25 | The field engineer can identify defect parts and order replacing modules with the help of telephone support.  现场工程师能够确定损坏件，并在电话支持的帮助下，下替换模块的订单 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-26 | Maximum 5 service modules, with reasonable cost / price compared to the total unit price.  最大5个服务模块，相对于设备整体价格较为合理的成本和售价 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-27 | Standard cost(Direct material +Labor+Overhead), is below 6500RMB  标准成本（物料+工时+分摊）低于6500元 | Design target  设计目标 | Mandatory  强制的 |
| MRS 4-28 | Initial investment includes all necessary but nothing extra to take a functional system into use  初期投资只包含可以投入使用必须的东西，没有任何不必要的附加物 | Design target  设计目标 | Mandatory  强制的 |
|  |  |  |  |