OWNER´S MANUAL

INTRAORAL DIGITAL RADIOGRAPHIC SYSTEM SAEVO SLIM

SAEVO

PRESENTATION OF MANUAL

GMDN: 44905 - Dental digital imaging sensor, intraoral
Technical Name: X-ray imaging scanner
Trade Name: Sistema Radiográfico Digital Intraoral
Model: Saevo Slim
Brand: Saevo

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CREA-SP: 5062199650

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REF 77000001680 - Rev.: 01 - May/22

Document originally written in Portuguese.

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The performance characteristics presented in this manual are only for reference and mustn't be considered as secured specifications.

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EQUIPMENT IDENTIFICATION

DEAR CUSTOMER

Congratulations for your excellent choice. When buying equipment with the "Saevo" quality, you can be sure you purchased products with technology that is compatible with the best in the world from its class.

This manual offers you a general presentation of your equipment, describing important details that can guide you in its correct use, as well as in the solution of small issues that can eventually occur. There is no need of any additional training besides its own reading.

This manual must be read on the whole and preserved to future consultations.

USE INDICATION

The Intraoral dental digital imaging sensor Saevo Slim is aimed at the acquisition of intra-oral medical images from teeth, jaw and oral structure, only for exclusive dental use and must be handled by trained and qualified health professionals, observing the instructions included in this manual.

CONTRAINDICATION

The Intraoral dental digital imaging sensor Saevo Slim is contraindicated for patients with temporomandibular dysfunction who limit mouth opening.

Protective plastic covers contain polyvinyl chloride (PVC) and should not be used by persons with polyvinyl chloride (PVC) allergies or substances used in the manufacturing process of the same, such as bisphenol A, adipic polyester, Propylene glycol compound and ethylhexyl and who have anatomical characteristics that prevent their use as a low palate.

SYMBOLOGY

Use the icons above to identify the symbology of your equipment.

⚱	Fragile, handle with care	👤	Applied parts BF type
☂	Keep dry	▢	Equipment Class II
⇧	This side up	⚠	Attention
☀	Keep away from sunlight	⚠	General warning
⊠	Maximum stacking	❗	Mandatory action
🌡	Temperature limit		Temperature limit
%	Humidity limit	⇌	USB connection
♺	Recyclable	REF	Catalog number
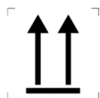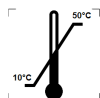
SYMBOLOGY

Do not re-use

SN Serial number

Indicates that the product must be taken to a special waste collection site at the end of its lifespan. Applies to the device and to the accessories.

Part Number

IP00 This product is not protected against harmful water infiltrations and particulate matter.

INMETRO Indicates that the product has passed an evaluation, and that standards or regulations developed for the product category have been observed in its design / manufacture / placing on the market.

Manufacturer

Manufacturer

MODEL Model

WARNINGS, CAUTIONS, AND RECOMMENDATIONS

!	Read and understand the instructions contained in these instructions for use before install or operate this equipment.

⚠	Operation of this device may be dangerous for the patient and the operator unless safe exposure factors and operating instructions are observed. Personal protective equipment should be used with this device.

⚠	Use the equipment only if in perfect conditions and protect yourself, patients and third parties against possible dangers.

⚠	This equipment must be installed and operated by personal acquainted to the necessary precautions to avoid excessive exposure to primary and secondary radiation.

⚠	The Saevo Slim has three different interactions with the user. They are: - Identification label: Placed in the lower part of the product package; - Security symbology: Placed in the upper part of the sensor on its identification; - Image acquisition software: Found installed with a computer where the sensor is connected.

DURING TRANSPORTATION AND STORAGE

The equipment must be shall be carried and stored according to the following:
• Handle with care to avoid falls and impacts.
• The arrows on the package must be pointing upwards.
• Don't stack items above the quantity indicated on the packaging
• Protect against sunlight, humidity, water and dust.
• Observe the limit of temperature, pressure and relative humidity

WARNINGS, CAUTIONS, AND RECOMMENDATIONS

BEFORE USING THE EQUIPMENT

To help and ensure a proper hygiene and to protect against infectious diseases, before first use, the equipment must be cleaned and disinfected according to the instructions enclosed in this manual.

DURING THE INSTALLATION OF THE EQUIPMENT

• Put the equipment in a place where it won't be in contact with humidity or water.
• Install the unity in a place where it won't be damaged by pressure, temperature, humidity, direct sunlight, dust, salt or corrosive products.
• Operators should follow all radiation protection guidelines for pregnant or suspected pregnancy patients, including the use of abdomen and thyroid protection.
• The equipment must not be subjected to excessive vibration or shock (including during transportation and handle).
• This equipment was not designed for use in presence of vapors from flammable anesthetics mixtures or nitrous oxide.
• The recommendations of this manual must be followed regarding the EMC. Communication equipment and sources that generate RF can affect the performance of the equipment.

DURING THE EQUIPMENT USE

⚠️	Proper hygienic measures must be taken to avoid cross contamination among the patient, users and other people.

• The equipment must be operated only by qualified healthy professionals including safeguard knowledge against excessive exposure to radiation.
• The equipment was manufactured to resist continuous and intermittent operation; therefore, follow the cycles described in the Owner's Manual.
• X-Ray exposure can cause damage to human body cells. It is recommended that no one stays in the radiographic examination room unless the containment of the patient is necessary. In this case, this person must be properly protected against ray emissions.
• The equipment was projected according to the electromagnetic compatibility standards, but in very extreme conditions, it can cause interference with other equipment. Don't use this equipment along with other devices that are sensitive to interference or with devices that create high electromagnetic disturbances.

⚠️	The manufacturer assumes NO liability: • If the equipment is used for purposes other than those for which it was designed. • For damages caused to the equipment, operator and/or patient as result of incorrect installation and maintenance procedures that are not in compliance with the operation instructions that comes with the equipment. • For inappropriate operation of the equipment.

WARNINGS, CAUTIONS, AND RECOMMENDATIONS

PREVENTION AGAINST CROSS CONTAMINATION
• To help to prevent the cross contamination among the patients, it is mandatory the use of disposable protective plastic covers.
• The covers must be properly disposed of for each new patient.
• The protective plastic cover must cover the sensor and at least 10 cm of the USB cable.
• Don't ever use damaged protective plastic covers.

AFTER USE / OPERATION OF THE EQUIPMENT
• Turn off the equipment when it is not being used for an extended period.
• The protective plastic covers must be disposed and the positioners, if used, must be sterilized for each new patient to avoid the transmission of infectious agents that can cause serious conditions.
• Perform the cleaning and disinfection according to the instructions contained in this manual.
• Don't modify any part of the equipment.

PRECAUTIONS IN CASE OF CHANGE IN THE PERFORMANCE OF THE EQUIPMENT
If the equipment presents any abnormality, verify id the problem is related to any item listed in the topic: "Error Diagnosis" of this user manual.
If it is not possible to solve the problem, turn off the equipment and disconnect the cables

⚠️	In case of damage or defect, do not use the equipment and contact an Alliage Authorized Technical Assistance.

PRECAUTIONS FOR THE REDUCTION OF ENVIRONMENTAL IMPACT
Alliage S/A aims to reach an environmental politics to promote the supply of medical and dental products environmental conscious that continuously minimize the environmental impact and that are more friendly to the environment and to the human health.
To keep a minimum impact on the environment, observe the following recommendations:
• After installation, forward the recyclable materials for the recycling process.
• During the life cycle of the equipment, turn it off when it is not being used.
• To prevent environmental contamination, the disposal of the protective plastic covers and other consumables must be according to the normal procedure of the dental office for biomedical waste.
The biomedical waste comprises nonhigh materials susceptible to cause diseases or suspect for housing pathogenic organisms that must be stored in a yellow bag properly labeled with the symbol of biological hazard, stored in a container resistant to perforation, tight and even recollection and incineration.

⚠️	The packaging[1] of the Saevo Slim is composed of cardboard and plastic, which are 100% recyclable materials. ♲

[1]DIMENSIONS: 185 x 160 x 71,5 mm /WEIGHT: Approximately: 100g

WARNINGS, CAUTIONS, AND RECOMMENDATIONS

PRECAUTIONS IN CASE OF DESTRUCTION OF THE EQUIPMENT

To avoid environmental contamination or inappropriate use of the Saevo Slim when it is destroyed, they must be disposed of (according to the current legislation) in an appropriate place, since the existent materials inside it can contaminate the environment.

To the European Economic Area (EEA), this product is subject to the Directive 2012/19/EU, ass well as to the correspondent national laws. This directive requires that the product must be taken to a special waste collection site at the end of its lifespan. Applies to the device and to the accessories Contact the retailer if the final disposition of the product is necessary.

⚠	This equipment must not be disposed of as domestic waste.

SYSTEM DESCRIPTION
PARTS THAT ACCOMPANY THE PRODUCT

01 - Sensor Saevo Slim
02 - Saevo Slim holder
03 - Installation flash drive (Software, Drivers, and Manuals)
04 - Capa de silicone

⚠	The Saevo Slim Sensor can be marketed in white or black. (Subject to commercial availability).

SYSTEM DESCRIPTION
ACCESSORIES THAT DON'T ACCOMPANY THE PRODUCT

*01 - Positioning kit
 02 - Protective plastic cover

SYSTEM DESCRIPTION

INTRAORAL SENSOR

The Intraoral dental digital imaging sensor Saevo Slim uses a sensor that employs the associated technologies from CMOS (Complementary Metal-Oxide-Semiconductor), protective optical fiber and scintillator. This sensor was developed to obtain a high-quality x-ray image from the human arch and its structures. The acquisition process is made by positioning the sensor inside the mouth, behind the structure you want to perform the exam. The structure must be exposed to an x-ray dose using an external source. Once exposed, the sensor performs a conversion of the x-ray photons into a digital sign and transfers it to a computer through USB connection (Universal Serial Bus).

HOLDER FOR INTRAORAL SENSOR

The intraoral sensor support consists of a base where the sensor can be placed when it is not in use. The intraoral sensor support can be screwed close to the computer system using the two screws provided or other mounting material.

Alternatively, the support can be glued to a uniform surface, for example, using the required double-sided adhesive tape.

COMPUTER SYSTEM

The captured digital images are transferred to a computer system via a USB port.

SOFTWARE REQUIREMENTS

For the correct performance of the Saevo Slim software, some basic software described below is necessary:

.Net Framework 4.5.1: The NET Framework is essential to run several programs that were developed through the use of this technology from Microsoft. This framework offers a series of resources for the agile and robust development of applications. The 4.5.1 version requires the Windows Vista SP2 or superior and it's included in Windows 8.1 and in Windows Server 2012 R2.

wkhtmltopdf 0.12.3.2: It's an open-source command line tool (LGPLv3) to render HTML to PDF using the rendering mechanism from Qt WebKit. It works completely "headless" and it doesn't require an exhibition service or exhibition.

The required software for the performance of the Saevo Slim software will be automatically installed, in shape of prerequisites, during the installation of the application, offering more speed and convenience to the user.

SYSTEM DESCRIPTION

HARDWARE REQUIREMENTS
The computer system must meet the following requirements.

Operational System	Windows 7 (x86 e x64) - Home, Starter, Pro Windows 8 (x86 e x64) - Pro Windows 8.1 (x86 e x64) - Pro Windows 10 (x86 e x64) - Home, Pro
CPU	Intel i3 3.0 Ghz or superior
HDD	500 GB
RAM	2GB DDR2 SDRAM
Monitor	1024x768
USB connector	2 x USB 2.0 – 500mA

⚠️	The computer must be EC approved and compliant with IEC 60950-1: 2005 + AMD1: 2009 + AMD2: 2013 and the Low Voltage Directive 2014/35 / EU and EMC 2014/30 / EU. In addition, to help ensure optimum performance, make sure that all installed programs are virus-free and have been properly tested so that you do not influence the image acquisition software after installation.

⚠️	It is recommended the execution of regular backup in the files and patient data to avoid record loss in case of failure of the computing system.

ELECTRICAL REQUIREMENTS
The Saevo Slim doesn't require an external power supply since its power is supplied through the USB connection of the computer and it has approximate consumption of 300mA.

⚠️	Don't use USB ports available in keyboards or in the front or lateral side of the computer. These connections are frequently unable to deliver sufficient power for the proper operation of the sensor.

SYSTEM DESCRIPTION

INSTALLATION SITE

⚠️ To meet the safety regulations, don't operate non-medical equipment like personal computers inside the patient area. Outside the patient area, it's acceptable the presence of non-medical equipment as long as it's used computer equipment approved and certified by IEC 60950-1:2005 + AMD1:2009+AMD2:2013

Place your computer and video monitor outside the patient area, ensuring that there's enough space for proper ventilation.
Preferably, use the monitor in 4:3, with full HD features and place the screen to avoid direct light or reflexes that can make difficult the visualization of the images.
Place the sensor next to the patient, with a minimum distance of 1.5 meter from the computer. Only the sensor and medical equipment can be inside the patient area.

SOFTWARE
The dental image management software interfaces with the Saevo Slim system and the user, making it possible to view, improve, store, send, print, among other functions.

SOFTWARE INSTALLATION
Insert the sensor in the USB port of the computer.

Connect the flash drive that accompanies the Saevo Slim in the USB port, open the device and click on the file **setup_2_0_0_X**

SYSTEM DESCRIPTION

Select the desired language and click on **OK**
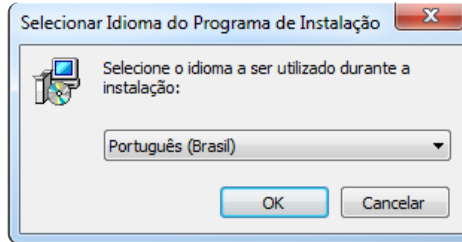
Read and understand the End User License Agreement and, if you accept, click on **I accept the terms of the Contract.**. Click **Next**.
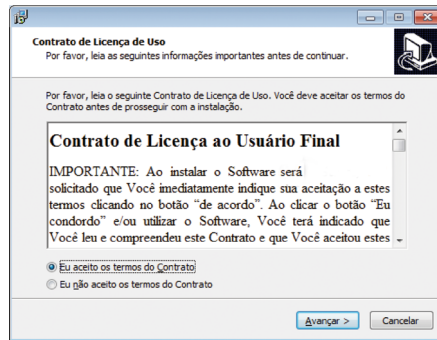
Select the dialog box if you want to create an icon on Desktop and click **Next**.
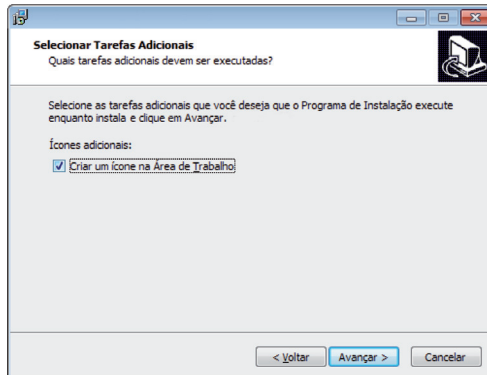
SYSTEM DESCRIPTION

Click **Install** to begin the installation process.
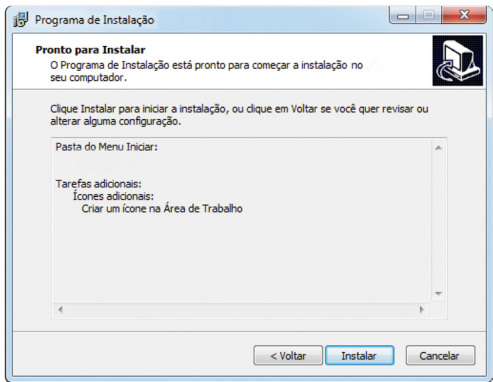
Setup will install .NET 4.5.1
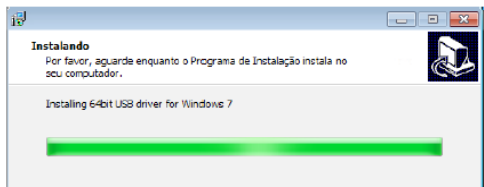
Setup will install the necessary tools to generate reports. Click "**I Agree**" to accept the terms of the software.
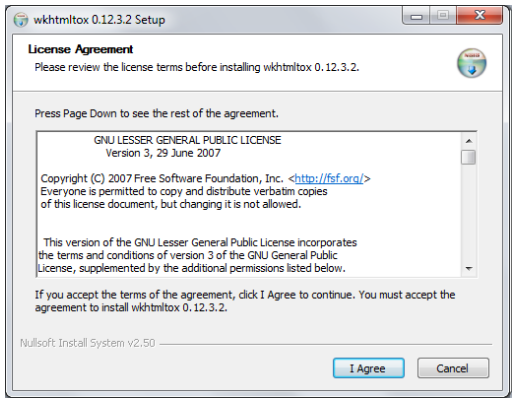
SYSTEM DESCRIPTION
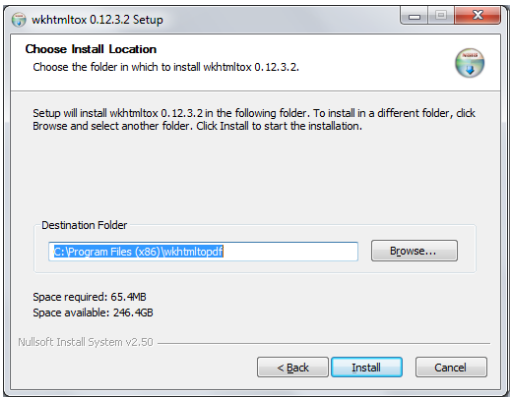
Click "**Install**"

Wait for the end of installation and click "**Close**"
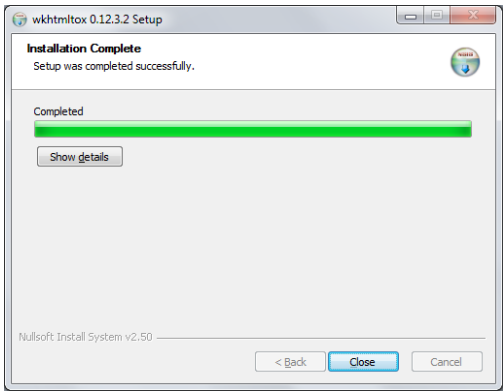
Setup will install the USB driver. Press **Install** to begin the installation process.
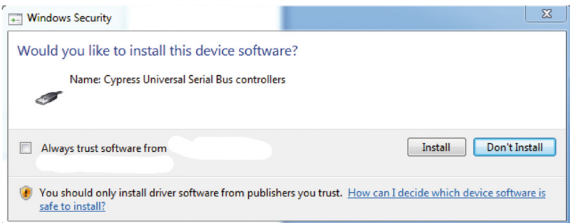
SYSTEM DESCRIPTION

Click **Finish** to end installation.
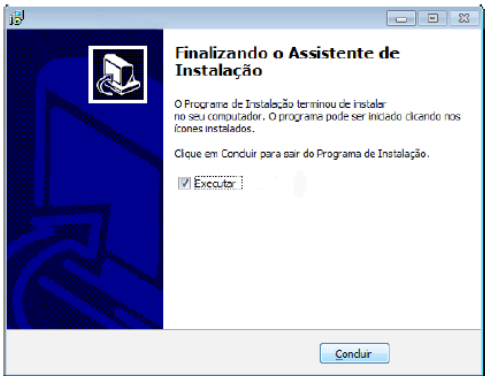
SYSTEM DESCRIPTION

MAIN SCREEN
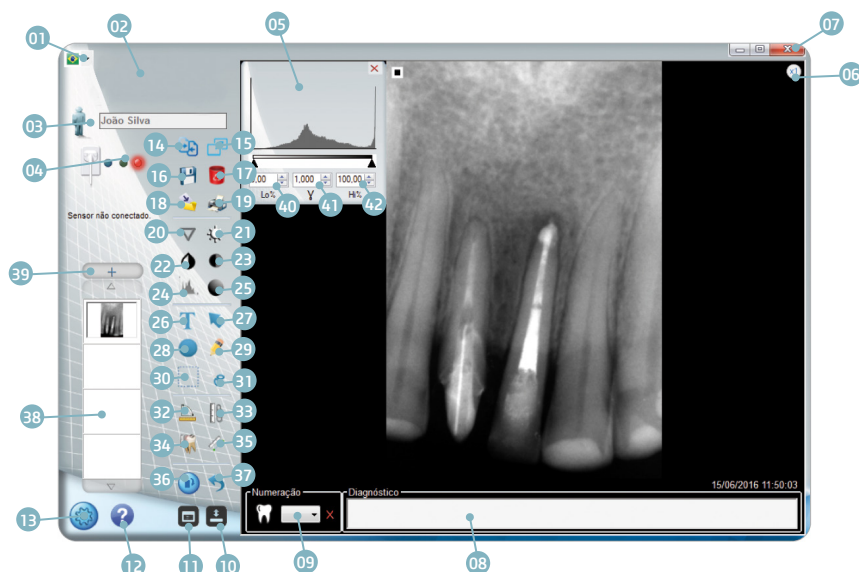
01 - Language selection
02 - Access to the manufacturer site
03 - Patient folder
04 - Sensor status
05 - Histogram window
06 - Fixed Zoom 1x or 2x
07 - Exit
08 - Number tagging and diagnosis
09 - Tooth selection
10 - Show / Hide toolbar
11 - Odontogram
12 - Help
13 - Setting
14 - Compare images in full screen
15 - Full Screen
16 - Save
17 - Delete
18 - Export image
19 - Print
20 - Sharpen
21 - Brightness setting

22 - Invert colors
23 - Contrast setting
24 - Histogram
25 - Gamma setting
26 - Insert Text
27 - Insert Arrow
28 - Insert circle
29 - Insert drawing
30 – Select
31 – Cropping
32 - Angular measurement
33 – Calibrate
34 - Multiple measurement
35 - Single Measurement
36 – Rotate
37 – Undo
38 - Open images
39 - Opening the Patient's Folder
40 - Histogram Adjustment – minimum
41 - Gamma Adjustment
42 - Histogram Adjustment - maximum

SYSTEM DESCRIPTION

INTERFACE ICONS

Icon	Features
	Exit To exit the application
	Maximize Maximize application
	Minimize Minimize application
	Create a new patient folder Allows to create a new folder (new patient)
	Open a patient Allows the access to the database of saved patients.
	Open the patient record Allows the access to the folder record showed on the interface and open previously saved files.
	Browse up Allows sliding images showed in the vertical library.
	Browse down Allows to slide images showed in the vertical library.
	Sequential capture. Defines the number of sequential captures to be done.
	Zoom x1 To show the whole cliché in the viewing window.
	Zoom x2 To expand the image
	Compare images Compare images in full screen
	Full Screen Change the viewing mode to full screen

SYSTEM DESCRIPTION
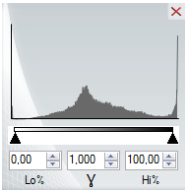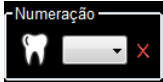
	Save Save image in patient's record
	Delete image Permanently delete the display image
	Export Allows saving a copy of the image with another name in several images standards.
	Print Print the image in DICOM or Conventional |	Print in standard printer
	Print in secondary printer | The setting of the main printer is made in the Setting menu
	Edge highlight Improve definition of the edge of the image. Available in 4 levels of density. Obs: Available only for TIFF images without marking. It is recommended to apply it right after the image capturing.
	Brightness setting Allows setting the brightness of the image.
	Inversion of colors Invert the color of the image.
	Contrast Setting Allows adjusting the contrast of the image.

SYSTEM DESCRIPTION

		Histogram Allows the setting of the image histogram
		Gamma Setting Allows the setting of the image gamma
		Insert text Insert a text on the image. The definition of color and width is made in the Settings menu
		Insert Arrow Insert an arrow in the image. The definition of color and width is made in the Settings menu
		Insert Circle Insert a circle in the image. The definition of color and width is made in the Settings menu
		Insert Freehand drawing Insert a freehand drawing in the image The definition of color and width is made in the Settings menu
		Selection Select an area of the image
		Cut Cut a selected area of the image
		Simple measurement Perform a distance measurement of two points on the image
		Multiple measurement Perform a distance measurement of multiple points on the image
		Angular measurement Perform an angular measurement on the image

SYSTEM DESCRIPTION

	Calibration Perform the calibration of the distance of the image
	Image rotation Allows 90 degrees rotation of the image.
	Undo |	Undo all
	Partial undo	
	Show/hide toolbar Show/hide toolbar with marking resources/association of the image
	Odontogram Access to Odontogram mode
	Histogram window Automatically opens when loading or capturing an image (configurable in the options menu)
	Tooth checkbox Used to check the tooth (teeth) showed in the image. Accompany "delete" button to undo checking.

SYSTEM DESCRIPTION

		Setting Allows the access to the parameters of your computer (format and file path of database of images, downloads)
		Help Shows tutorial on how to perform an acquisition

SETTING SCREEN

To set the application, press the icon . The following screen will appear.
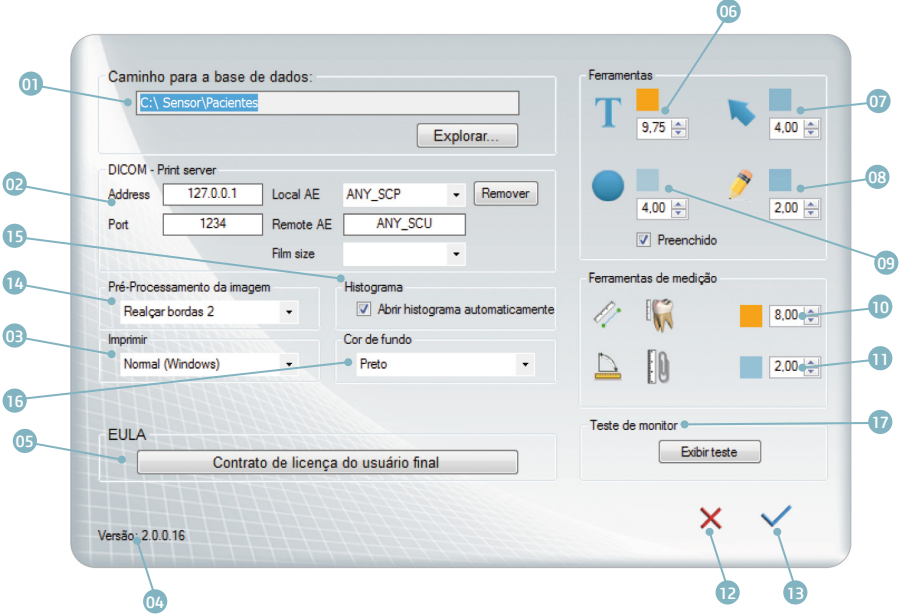
01 - Path of Database
02 - DICOM address
03 - Definition of the main printer
04 - Software version
05 - EULA
06 - Color and size of the text*
07 - Color and width of the arrow*
08 - Color and width of free-hand drawing*
09 - Color, width, and filling of the circle.*

10 - Distance measurement: Color and size of the text font.*
11 - Angular measurement: Color and size of font.*
12 - Cancel changes
13 - Confirm changes
14 - Preprocessing of image
15 - Histogram
16 - Background color
17 - Monitor test.

*Measurement unit in pixels.

SYSTEM DESCRIPTION

ODONTOGRAM

The Odontogram resource allows organizing images according to the tooth, building image record to each tooth and generating reports of the treatments.

It's possible to view the image records or start the capture of a new image by clicking the right button of the mouse on the desired tooth.

To access the odontogram, click on the icon . The following screen will appear.
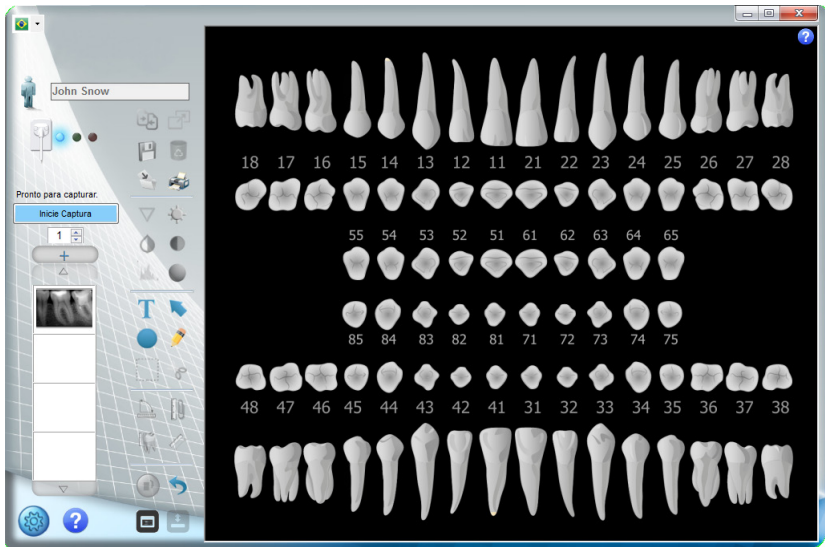
SYSTEM DESCRIPTION

a. Associate image to the odontogram

Perform an image capturing
Select numbering of the tooth you want to associate with the image. If you want, insert diagnosis information in the text field.
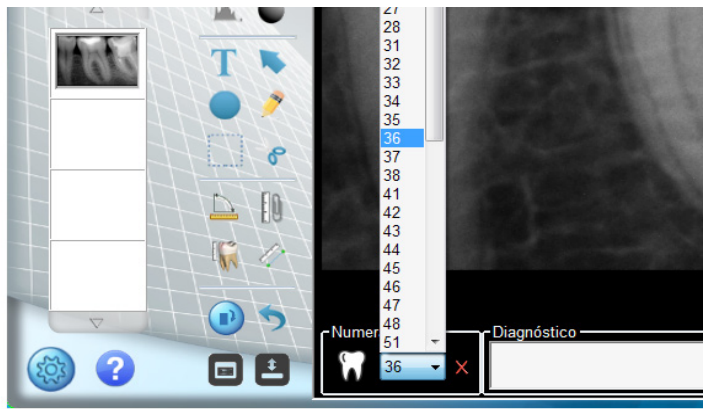
Click on to associate the image with the patient record.

SYSTEM DESCRIPTION

The tooth whose image is associated will be pointed in YELLOW.
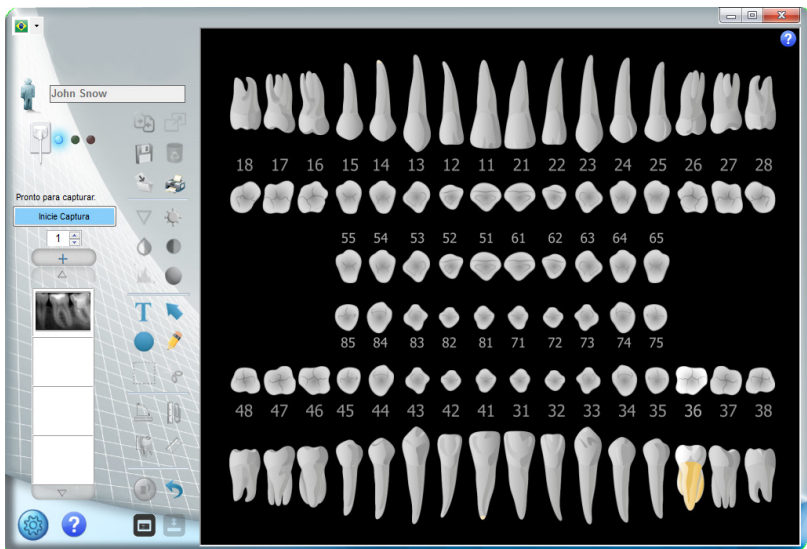
b. Capture through odontogram

To start a capture, click the right button of the mouse and after that, on start capture.
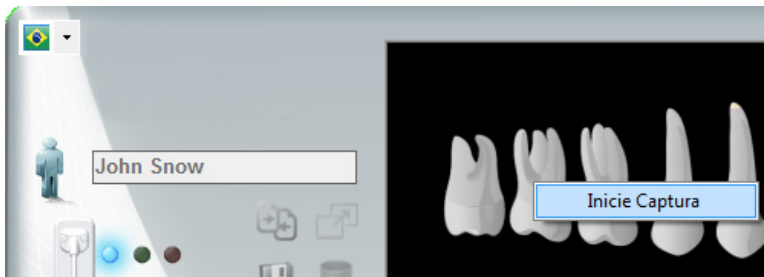
SYSTEM DESCRIPTION

c. Opening image through odontogram

Click on a tooth that has an image on the odontogram with the right button of the mouse. Select the day and time of the image you want to open.
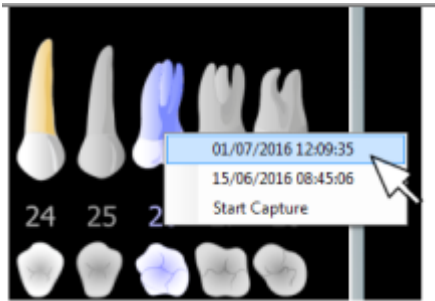
Click with right button to open an image.

d. Help odontogram

The icon opens a window with an illustrated guide to help with the use of tools on the Odontogram.
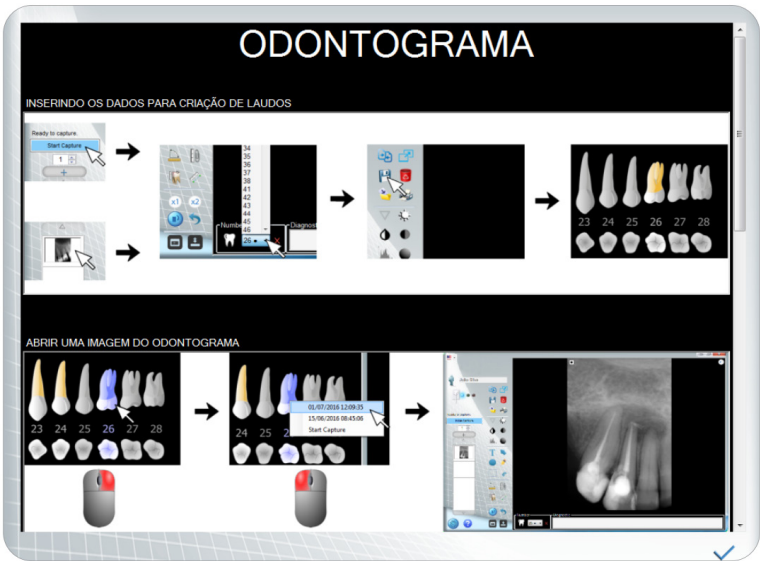
SYSTEM DESCRIPTION

e. Generating report through odontogram

With the odontogram open, click on the icon [icon] . The following screen will be displayed.
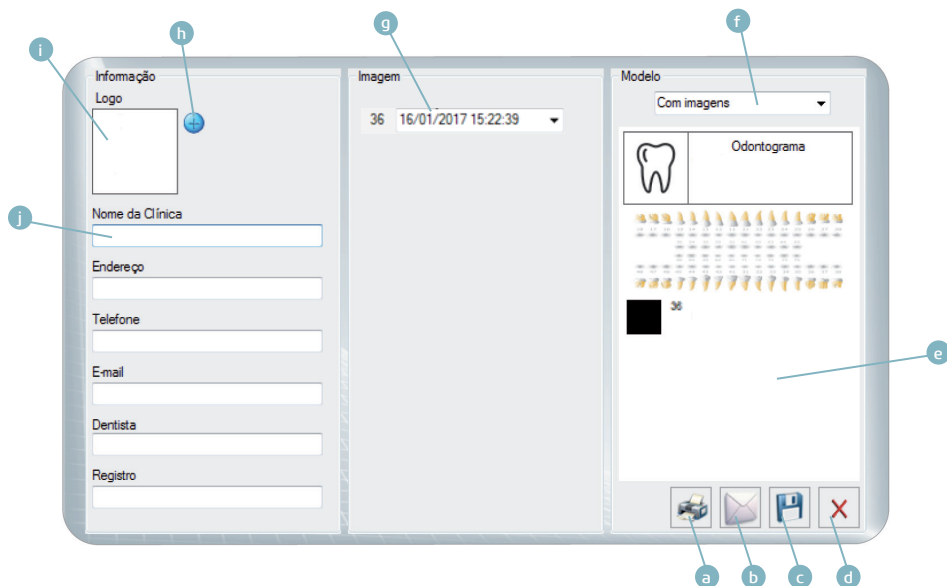
a - Print report
b - Send by email
c - Save report on pdf
d - Delete report
e - Preview report
f - Selection of report model (with images or without images)

g - Select the image to be inserted in the report*h
h - Add logo
i - Preview logo
j - Clinic data

*In case of more than an image associated with the tooth

SYSTEM DESCRIPTION

CONSUMABLES

Protective plastic covers are used as an additional measure to avoid contamination between patients, users and others.

This equipment should be used with plastic protective covers, specific for use with intraoral dental sensors.

Protective plastic covers are single use consumables that should be discarded for each new patient.

⚠	The protective plastic covers don't accompany the product.

⚠	When buying a protective plastic cover, make sure they are CE approved, always follow the items listed below: • Always use protective plastic covers manufactured with non-cytotoxic, non--irritant and non-sensitizing polyethylene film, in accordance with ISO 10993-1. • Always use products for exclusive dental use. $R\!\!\!/\;only$ • Always use single use products. Ⓧ

This equipment can be used with autoclavable intraoral radiographic positioner, specific for use with dental intraoral sensors.

In each new patient, the procedure of cleaning and sterilization recommended by the manufacturer must be performed.

⚠	The positioners don't accompany the product.

⚠	Always use autoclavable positioners manufactured with non-cytotoxic, nonirritant and nonsensitizing in accordance with ISO 10993-1.

SYSTEM DESCRIPTION

LABELS

IDENTIFICATION LABEL
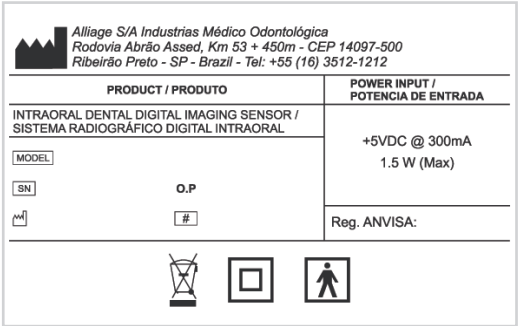
*DEMONSTRATIVE PICTURE REAL DIMENSIONS 100 x 63 mm

SAFETY LABEL

*DEMONSTRATIVE PICTURE REAL DIMENSIONS 50 x 23 mm

CONSULTATION LABEL AND INSTRUCTION MANUAL

*DEMONSTRATIVE PICTURE REAL DIMENSIONS DIAM. 10 mm

SYSTEM DESCRIPTION

INTRAORAL RADIOGRAPHY EQUIPMENT

The intraoral digital image sensor is compatible with intraoral x-ray equipment with an electronic timer that complies with current standards EN 60601-1, EN 60601-1-2, EN 60601-1-3 and IEC 60601-2-65 and meets the following requirements:
• The intraoral X-ray generator must operate at a voltage between 60 and 70kV and anode current of 7mA.
• The intraoral X-ray generator must be installed according to the manufacturer's instructions and requirements.

⚠️	Do not use generators with power less than 60KV

SPECIFICATIONS AND TECHNICAL CHARACTERISTICS

GENERAL INFORMATION

Alliage S/A Industrias Médico Odontológica **Telephone:** +55 (16) 3512-1212 **Address:** Rodovia Abrão Assed, Km 53 - Recreio Anhanguera Ribeirão Preto – SP - Brazil CEP 14097-500	
Name	Intraoral Dental Digital Imaging Sensor
Model	Saevo Slim
Equipment Classification	
Classification class according to ANVISA	Class I
Classification class according to CE/FDA	Class
Classification of the Equipment according to the NBR IEC 60601-1 regulation	
Classification of the product for applied parts	Applied parts BF type
Protection Against Electrical Shock	Class II
Protection Against Harmful Water Infiltration	IP00 - This product is not protected against harmful water infiltrations and particulate matter.
Degree of application security in presence of one flammable anesthetic mixture with the air, oxygen or nitrous oxide	Inappropriate equipment
Operation Mode	Continuous operation
Input Voltage	+5 Vdc
Input Current	300 mA
Power Consumption	1,5 W
Cable length	3m +/- 0,5m

SYSTEM DESCRIPTION

CHARACTERISTICS OF THE SENSOR

Size*	0	1	2
Sensor resolution (pl/mm)	25	25	25
External dimensions (mm)	21,7 x 30,3	24,7 x 38,3	30,6 x 44,2
Active surface dimensions (mm)	17 x 22	20 x 30	26 x 36
Matrix dimension	850 x 1100	1000 x 1500	1300 x 1800
Pixels number (Mega-Pixels)	0,93	1,50	2,34
Technology	CMOS	CMOS	CMOS
Gray level	4096	4096	4096
Image resolution	12 bits	12 bits	12 bits
Image format	TIFF, JPG, PNG, BMP DICOM	TIFF, JPG, PNG, BMP DICOM	TIFF, JPG, PNG, BMP DICOM
Optical Fiber	1	1	1
Weight	60 g	65 g	70 g
Connection	USB2 – High speed	USB2 – High speed	USB2 – High speed
Cable lenght	3m +/- 0,5m	3m +/- 0,5m	3m +/- 0,5m

* **Order on request.**

ENVIRONMENTAL CONDITIONS FOR TRANSPORTATION AND STORAGE

Room temperature range for transportation and storage	+4ºC to +40ºC
Relative humidity range for transportation and storage	< 85% RH
Atmospheric pressure band	797 hPa to 1013 hPa (598 mmHg to 760 mmHg)

CONDITIONS FOR INSTALLATION AND OPERATION OF THE EQUIPMENT

Operating room temperature band	+10˚C to +30˚C
Operating relative humidity range (non-condensing)	< 75% RH
Atmospheric pressure band	797 hPa to 1013 hPa (598 mmHg to 760 mmHg)
Operating altitude	≤ 2000 m

SYSTEM OPERATION

⚠️	Never let the patient unattended during the acquisition process.

PREPARATION FOR USE

❗	The equipment must be cleaned and disinfected before the use by a new patient, observing the instructions included in this manual.

❗	To prevent cross-contamination, use hygienic covers that must be disposed of for each new patient, always observing if they are not damaged.

Cover the sensor with the disposable plastic cover, also covering the cable to ensure that it will not be in contact with the patient.

The sensor can be positioned manually or using intraoral positioners.
In the case of manual placing, introduce the sensor in the mouth of the patient in the deeper possible part.

Active Area
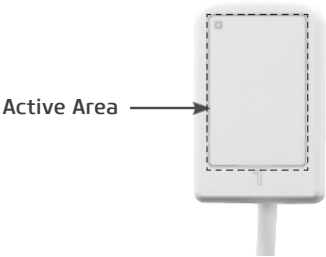
The active surface of the sensor must be placed towards the source of X-Rays.

⚠️	Ao inserir o sensor dentro da boca do paciente tenha cuidado para evitar que o paciente aspire ao plástico protetor causando a obstrução das vias aeras. Em caso de náusea, retire imediatamente o sensor da boca do paciente.

SYSTEM OPERATION

⚠️	During the examination, take the necessary precautions to prevent the patient from biting the sensor cable.

POSITIONERS

ⓘ	In each new patient, the procedure of cleaning and sterilization recommended by the manufacturer must be performed.

The positioners of the Saevo Slim intraoral sensor are tools that help the correct positioning of the intraoral sensor in an easy, practical and precise way. Its use is not mandatory and depends on the technique used by the operator.

When it's used with the Intraoral dental digital imaging sensor Saevo Slim, follow the procedure below:

Mount the sensor in the positioner and lock it on the side wings.

Introduce the positioner inside the patient's mouth. A roll of cotton can be placed between the biteblock and the opposite tooth to improve the comfort and stability.
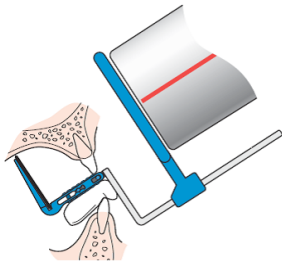
Place the sensor and the device inside the patient's mouth in the deeper possible part.

Ask the patient to slowly bite the positioner, being careful to not bite the sensor cable. Place the x-ray tube parallel to the arm and centered with the ring.

The positioners are usually made in different colors that represent the exam that the positioners must be used.

The colors of the positioners are:
Blue: Previous
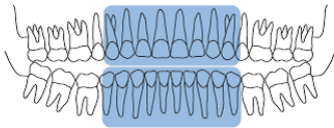
Yellow: Next
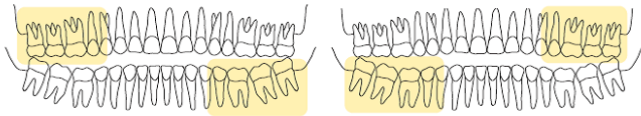
Green: Endo
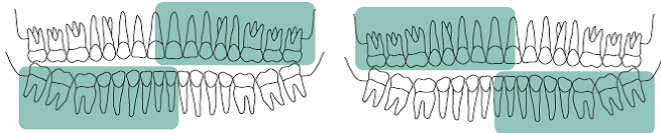
Red: Bitewing
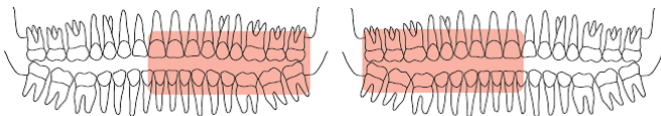
ACQUISITION OF RADIOGRAPHIC IMAGES

To use the Intraoral dental digital imaging sensor Saevo Slim, start the computer and verify if it's on.

Start the software of image capturing clicking on the shortcut icon on the Desktop or Start **->** All programs **->** Saevo Slim

The home screen of the application will appear.
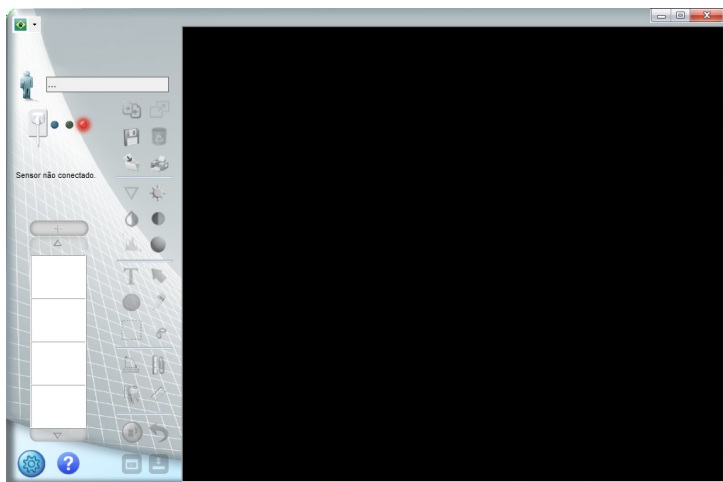
SYSTEM OPERATION

CREATE A NEW REGISTRATION OF PATIENT

Click on icon the next screen will be shown.
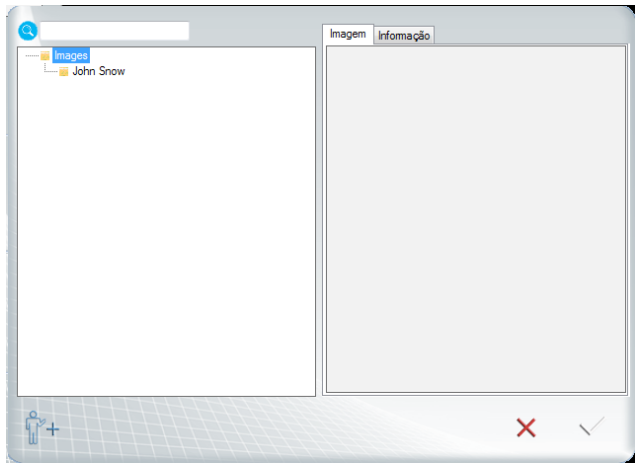
Next, click on icon

Fill the fields to do the registration of the new patient (Name and Last name are obligatory fields).
Next, click "OK"

SYSTEM OPERATION

Select the file that you created and click OK.
The name of the folder appears in the capture window. The images will be stored in this folder.

OPENING A PATIENT REGISTRATION
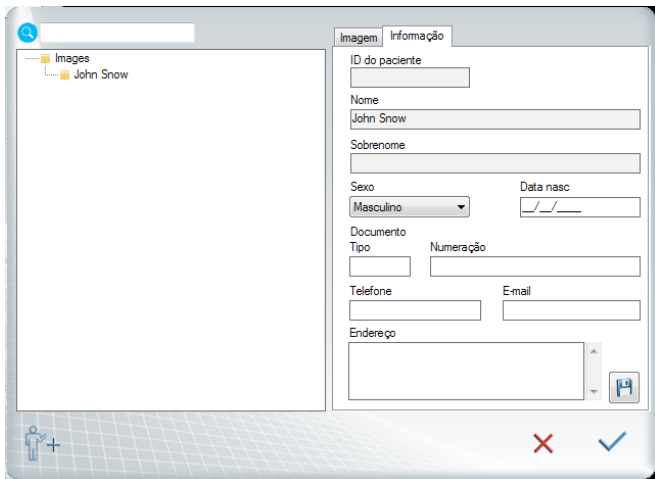
Click on the icon
Select the patient directory that you want to open.

Click on ✔ to confirm or click on ✘ to go back to the initial interface.

CHANGING A PATIENT REGISTRATION

Click on the icon
Select the patient directory that you want to open.
Click on the information tab and fill the fields you want to change.

Click on 🖫 to save the changes.

Click on ✔ to confirm or click on ✘ to go back to the initial interface.

SYSTEM OPERATION

SENSOR STATUS

Symbol	Cor	Sensor status
	Blue icon	The sensor is connected and was recognized by the application. Waiting for Start command to activate the sensor.
	Green icon	The sensor is active and able to receive X-Rays.
	Red icon	The sensor is not connected, canceled acquisition, patient folder not selected or sensor error.

PROCESS OF IMAGE CAPTURING

Verify if the sensor status has the **BLUE light.**
Select the necessary exposition time on the timer of the periapical X-Ray.

⚠	**Selecting the X-Ray exposition setting, verify if they are all appropriate The setting depends on multiple variables, such as… the X-Ray tube, patient anatomy, distance between the sensor-font and location of the sensor in the oral cavity. As a reference, it must be considered that the Saevo Slim sensor requires an 85% dose less that the movie "Tipo-D".**

On the application interface, click on **INITIATE CAPTURE**.
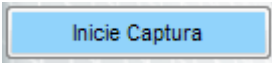
The icon of the sensor turns **GREEN**. The sensor will be activated and waiting for the X-Ray exposure, being kept active during 120 seconds. An indicative progress bar shows the counter.

At the end of this period, if there`s no X-Ray emission, the sensor will be back to standby mode. Just click START CAPTURE to reactivate it.

SYSTEM OPERATION

The activation of the sensor can be interrupt at any moment, just by clicking CANCEL CAPTURE.

Cancelar a captura

⚠️	Before the shot, to avoid unnecessary X-Ray exposure to the patient, make sure that the sensor status shows a GREEN icon and has the message "Waiting to expose" in it.

Perform the exposure with the X-Rays generator to capture the image.

After the exposure, the image will appear on the screen of the application.
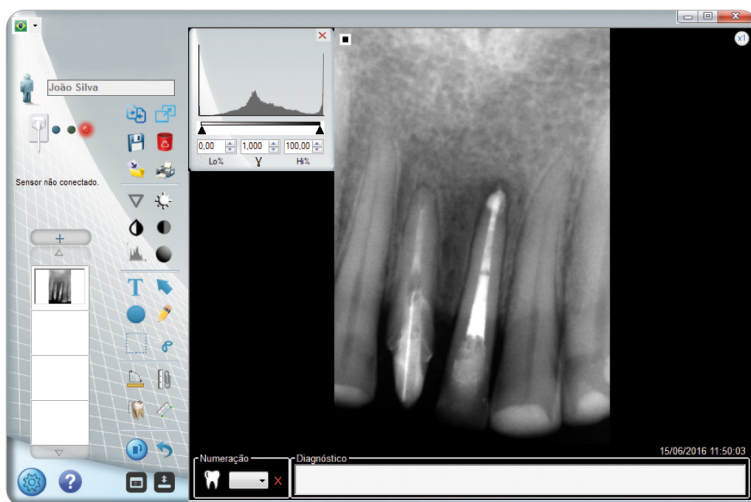
If the captured image is suitable for diagnosis, click the icon to save it in the patient folder, otherwise, delete the image clicking on the icon and perform new exposure.
At the end of the exam, remove the sensor from the mouth of the patient and dispose the plastic protection following the recommendations included in this manual.

⚠️	**Keep the sensor in its box when it's not in use.**

SYSTEM OPERATION

IMAGES OF THE PATIENT'S REGISTRATION

To access the registered images of a patient, open the register of him clicking on the icon 👤 the following screen will appear
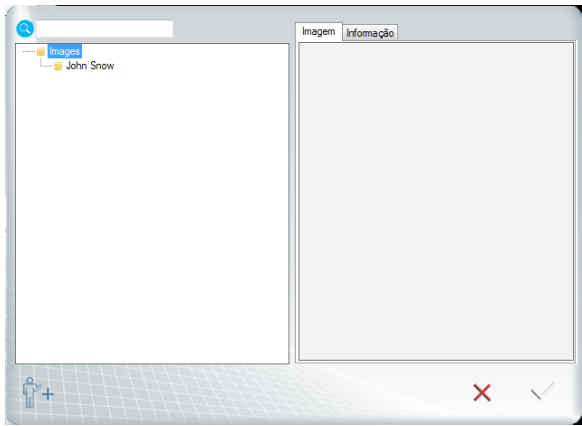
Select the patient folder and after, click on the icon ⬜➕ . The following screen will be displayed.

All images with date information and time of the capture will be exhibited.

SYSTEM OPERATION

a. Add a new image to the register

To add a new image to the patient register, click on the icon [icon] . A search window will be opened.

Select the image you want to add to the register and click "Open".

b. Delete an image from the register

To delete an image, select the image you want and click [icon] to delete it permanently.

c. Open an image from the register

To open an image from the register, select the image that you want to open and click on the icon. [icon]

METRIC CALIBRATION

[icon]	The process of metric calibration must be performed at least one time after installation.

[icon]	The metric calibration depends on the radiographic technique used. The metric technique must be performed every time the technique is changed.

The intraoral calibration is unique for any device and it depends on the radiographic technique used. There are two basic periapical radiographic techniques: the Bisector Technique and Parallelism Technique

a. Radiographic techniques

Parallelism Technique or Long cone

In this technique, the Saevo Slim is placed in parallel to the axis plan of the tooth with the help of a positioner and the focal point of the x-ray generator must be positioned at a distance around 40cm of the sensor.
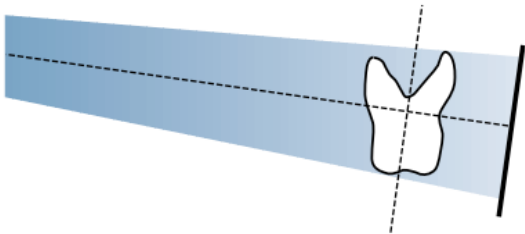
This technique produces radiograph with minimum distortion, showing objects that are being x-rayed in their true anatomic relation and size.

SYSTEM OPERATION

Bisector Technique or Short Cone

In this technique, the Saevo Slim is placed in a way that the beam of the central X-Ray must fall upon in a perpendicular way over an imaginary plan of the bisector of the angle formed between the long axis of the tooth and the sensor capture surface, according to the isometric law from Cieszinski. For this, the focal point of the X-Ray generator must be placed at a distance of appro-ximately 20cm of the sensor.
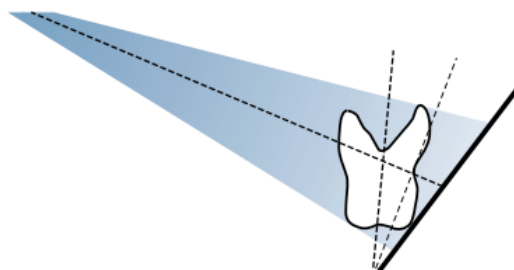
This technique produces radiographs with distortion, regardless of the technique and precision of the operated. However, it also provides a relatively simple, fast and comfortable positioning to the patient.

b. Metric calibration procedure

To perform the metric calibration, first perform the capture of an image of an object that can be physically measured, using the radiographic technique that will be used with the sensor.
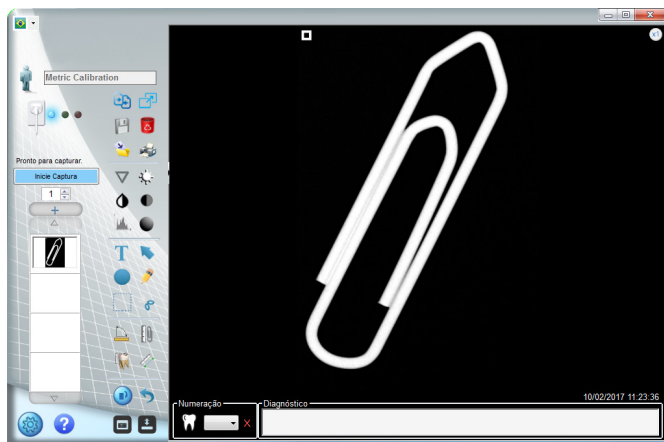
SYSTEM OPERATION

After this phase, click on Calibration icon.
Draw a line between the two points that will be measured later.
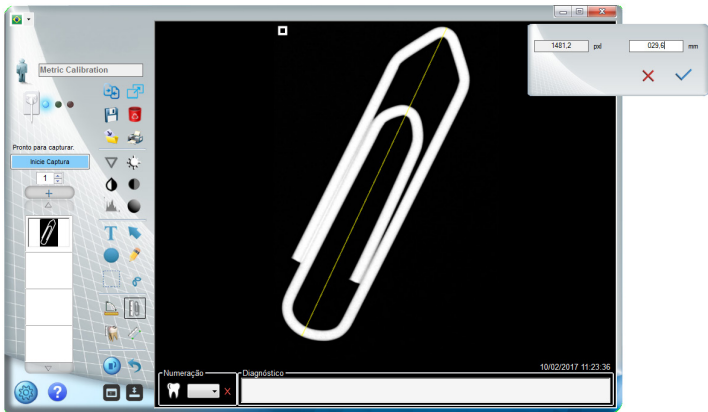
The system will show a standard distance in pixel and mm.
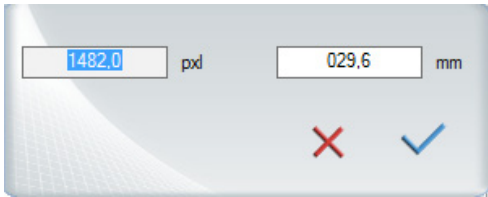
Perform the physical measurement of the x-rayed object.

SYSTEM OPERATION

Type the distance measured in mm.
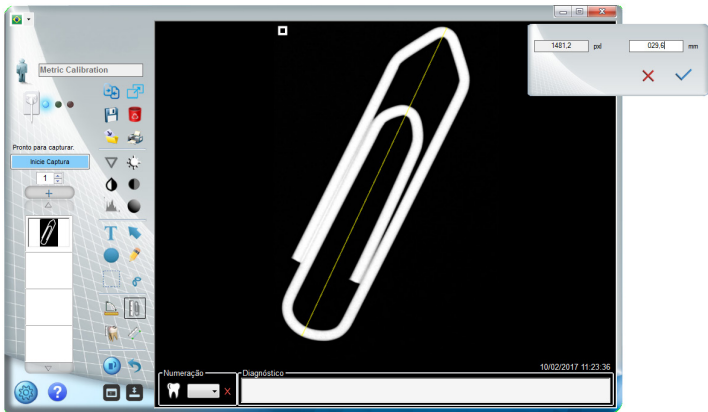
After entering the distance, click on ✓.

PRECISION OF THE MEASUREMENT

Parameter	Range	Precision
Distance	0 to 99,9 mm	0,1mm
Angle	0,00 to 179,99°	0,01°

SYSTEM OPERATION

RECOMMENDATION FOR EXAMS

The radiographs must be performed only when there's a diagnosis expectation that will affect the treatment of the patient. The dentist shall consider the benefits of getting radiographs against the risk of exposing the patient to radiation.

Due to the effects of radiation accumulation over time, all efforts must be done to minimize the patient exposure.

Use lead apron and thyroid collar.

Use pediatric profile or low usage and select the lowest permissible time of exposure.

There may be clinical circumstances for which a radiography is indicated, but a diagnosis image can't be obtained. For example, the patient may not be able to cooperate with the dentist.

TYPE OF CONSULTATION	PATIENT AGE AND STAGE OF DENTAL DEVELOPMENT[1]				
	Children with primary dentition (before the eruption of the first permanent tooth)	Children with transitory dentition (after the eruption of the first permanent tooth)	Teenager with permanent dentition (before the eruption of the third molars)	Adult toothed or partially edentulous	Adult, Edentulous
New Patient* being evaluated for oral diseases	Individualized radiographic exam which consists of periapical / Occlusal view and/or posterior bitewings if the proximal surface can't be viewed or probed. Patients with no indication of the disease and with open proximal contacts may not require a radiography	Individualized radiographic exam which consists of posterior bitewings with panoramical exam or posterior bitewings and selected periapical images.	Individualized radiographic exam which consists of posterior bitewings with panoramical exam or posterior bitewings and selected periapical images. A complete intraoral radiography exam from the mouth is preferable when the patient has clinical evidence of generalized oral disease or an extensive record of dental treatment.		Individualizes radiography exam, based on signs and clinical symptoms.
Patient follow-up* with decay or increased risk of decay**	Posterior bitewing exam in intervals of 6-12 months if the proximal surfaces can't be visually examined or with a probe			Posterior bitewing exam in intervals of 6-18 months	Non-applicable

SYSTEM OPERATION

Patient follow-up* **without decay or increased risk of decay**	Posterior bitewing exam in intervals of 12-24 months if the proximal surfaces can't be visually examined or with a probe	Posterior bitewing exam in intervals of 18-36 months	Posterior bitewing exam in intervals of 24-36 months	Non-applicable
Patient follow-up* **with periodontal disease**	Clinical judgment related to the need and type of radiographic images for the evaluation of the periodontal disease. The image can consist, but not be limited to, bitewing and/or periapical images from areas where the periodontal disease (except non-specific gingivitis) can be clinically demonstrated.			Non-applicable
Patient (New and Return) **for growth monitoring and dentofacial development, and/or evaluation of the dental/ skeletal relations**	A clinical judgment about the need and type of radiographic images for evaluation and/or monitoring of the growth and development or evaluation of dental and skeletal dentofacial relations.	A clinical judgment about the need and type of radiographic images for evaluation and/or monitoring of the growth and dentofacial development or evaluation of dental and skeletal relations. Panoramic or periapical exam to evaluate the development of the third molars	It is usually not indicated for growth and development monitoring. A clinical judgment about the need and type of radiographic images for evaluation of dental and skeletal relations.	

SYSTEM OPERATION

Patient with other circumstances including, but not limited to, proposed or existent implant, other dental and craniofacial pathologies, restoration / endodontic care, treatment for periodontal diseases and remineralization of the decay	Clinical judgment about the need and type of radiographic images for evaluation and/or control of these conditions

⚠️	This recommendation is subjected to the clinical judgment and is not applicable to every patient. It is the dentist responsibility to follow the ALARA principle (as low as reasonably possible) to minimize the exposure of the patient.

*Clinical situations in which the radiograph is indicated includes, but it's not limited to:

a. History of positive discoveries
1. Previous periodontal or endodontic treatment
2. History of pain or trauma
3. Family history of dental abnormalities
4. Post-surgery evaluation for healing
5. Remineralization monitoring
6. Implant presence, pathology related to previous implants or evaluation for implant placement

SYSTEM OPERATION

b. Clinical positive - Signs and Symptoms

1. Clinical evidence of periodontal disease
2. Big or deep restoration
3. Injury from deep cavity
4. Crooked or broken teeth
5. Swelling
6. Evidence of dental or facial trauma
7. Teeth mobility
8. Fistula
9. Clinical suspect of sinus pathology
10. Growth anomalies
11. Oral involvement in the known or suspicious systemic disease
12. Neurological positive findings in the head or neck
13. Evidence of strange objects
14. Pain or ATM dysfunction
15. Facial asymmetry
16. Pillar for prosthesis partially removable or fix
17. Unexplained bleeding
18. Inexplicable teeth sensibility
19. Unusual eruption, spacing or teeth migration
20. Morphology of the unusual tooth, calcification or color
21. Inexplicable absence of teeth
22. Clinical Acid Erosion
23. Peri-implanting

**The factors that increase the risk for caries can be available using the ADA forms for caries risk assessment (0 - 6 years old and older than 6 years old).

[1]U.S. Department of Health and Human Services. **Dental Radiographic Examinations**: **Recommendations for Patient Selection and Limiting Radiation Exposure**. Available in http://www.ada.org/~/media/ADA/Member%20Center/FIles/Dental_Radiographic_Examinations_2012.ashx. Accessed on November 2, 2015.

[2]The American Academy of Pediatric Dentistry. **Guideline on Prescribing Dental Radiographs for Infants, Children, Adolescents, and Persons with Special Health Care Needs**. Available in http://www.aapd.org/media/policies_guidelines/e_radiographs.pdf. Accessed on November 2, 2015.

[3]U.S. Department of Health and Human Services. **Pediatric X-ray Imaging**
Disponível em http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm. Accessed on November 2, 2015.

CLEANING AND DISINFECTION

!	Before starting the cleaning and disinfection procedure, disconnect the sensor from the USB port of the computer to avoid damage to your equipment.

⚠	For your protection, during the cleaning and disinfection process, it´s mandatory the use of IPEs such as disposable gloves and safety glasses.

The cleaning and disinfection process must be performed at each patient change and before the storage of the product.
When starting the process, check the existence of visible dirt, such as blood or saliva.
Clean carefully the Saevo Slim and the first 30cm of the USB cable.
For the cleaning, use a clean and soft cloth damp with neutral soap and then perform the drying with a clean and soft cloth or with a paper towel.
For the disinfection process of the Saevo Slim, use disinfectants towels that have active components based on Didecyldimethylammonium chloride respecting the contact time indicated by the manufacturer.
There's no cycle limits or time of application that the Saevo Slim and its parts can tolerate during the cleaning and disinfection process, following the instructions of this manual.

⚠	Don't use sanitizing or cleaning agents as a spray.

⚠	Don't dip the Saevo Slim sensor in liquid sanitizing.

⚠	Don't sterilize the Saevo Slim sensor using an autoclave, thermal sterilizer.

MAINTENANCE

> ⚠️ The Saevo Slim sensor or any of its parts can't receive maintenance or assistance during its use with a patient.

PERIODIC INSPECTION

It is mandatory that this equipment be inspected regularly to ensure the operational safety and functional reliability.

The periodical inspection must be performed at regular intervals (at least once a month) to ensure that the product is permanently safe and operational. All components subject to the normal wear must be verified and, if necessary, replaced.

The manufacturer is exempt from liability for uncommon results, in case the user don't perform the maintenance recommended by him.

Inspection and service are not part of the warranty of the equipment.

The inspections performed must be documented and kept with the equipment.

The following table shows a description of the main inspection items and recommended frequency.

Item	Control description
USB cable	Connection / Physical damage
Intraoral sensor	Communication / Operation / Overheating / Physical Damage
Accessories	General damage that can cause risk

In case are detected problems during the inspections, contact us, with the Alliage Service Department.

PREVENTIVE MAINTENANCE

Besides the periodical inspection, to ensure a long durability and good functioning of your equipment, it's important to perform a preventive maintenance for a period of at most three (3) years. Contact the Alliage Service Department for our periodical review and program of preventive maintenance.

CORRECTIVE MAINTENANCE

All instructions about the use of the equipment as intended are provided in this user manual. If a problem is detected and can't be corrected with the instructions in the error diagnosis section, contact Alliage Service Department.

Alliage states that the supply of circuit diagrams, components lists or any other information that provides technical assistance for the user can be requested if previously agreed between him and Alliage Enterprise.

The warrant will be annulled if the original parts are removed/replaced by technicians from non authorized services.

MAINTENANCE

 The corrective maintenance that can be performed by the Intraoral dental digital imaging sensor Saevo Slim user is limited to the replacement of the USB cable.

ERROR DIAGNOSIS

In the case of problems with the functioning of your sensor, verify the following:

Symptoms	Diagnosis and solutions
Red status of the sensor, indicating that it is not connected	The sensor was not recognized by the computer or it is off. - Verify if the USB cable is properly connected to the computer - Restart the computer - Verify if the drivers of the sensor are correctly installed.
Red status of the sensor, indicating that it is not connected and start capture button doesn't appear	Patient folder was not selected
Blue status of the sensor and there's no image.	- Make sure the sensor is activated (button "Start capture" before the X-Ray shots. - Verify the correct performance of the generator. - Make sure the sensor surface is oriented to the x-rays source and that is correctly aligned.
Green status of the sensor and there's no image.	- Verify the correct performance of the X-Ray generator. - Make sure the active sensor surface is oriented to the x-rays source and that is correctly aligned.
Error "TransfersThread() - pre-capture(0) SafeHandle was closed"	Fail in USB communication during the capture of the sensor. - Verify if the USB cable shows any damage indicative - Verify USB connection with the computer - Verify if the USB port of the computer has the capacity to supply enough power for the proper operation of the sensor.

MAINTENANCE

Error "Saevo Slim has stopped working A problem made the program stop working correctly. Windows will close the program and will notify if there's an available solution"	Fail in USB communication during the setting of the sensor. - Verify if the USB cable shows any damage indicative - Verify USB connection with the computer - Verify if the USB port of the computer has the capacity to supply enough power for the proper operation of the sensor.
	Fail in RAM memory - Verify the RAM memory of the computer
Warning "There's a difference between the serial number of the Saevo Slim sensor and the calibration files. If the calibration files belongs to this sensor, please ignore this message	Calibration file doesn't belong to the sensor - Contact the technical service
	Calibration file belongs to the sensor, but it was generated with a wrong serial number. - Ignore warning
Error "To run this application, it is necessary to install one of the following versions of .NET Framework v4.0"	Fail to install.NET 4.5.1. - Install Microsoft.NET 4.5.1 or reinstall software
Very clear image	- Very long exposure time. - Adjustment of your monitor. (brightness and contrast)
Very dark image	- Insufficient exposure time. - The tension of the generator is insufficient (<60kV). - Adjustment of your monitor. (brightness and contrast)
Image completely dark	- The active area of the sensor was not exposed to the X-Rays - Insufficient X-Ray dose
Image with artifacts or lines	Calibration file doesn't belong to the sensor - Contact the technical support
Image failure	USB cable failure - Verify if the USB cable shows any damage indicative - Verify USB connection with the computer - Verify if the USB port of the computer has the capacity to supply enough power for the proper operation of the sensor.
	Fail in the sensor due to physical damage (impact) - Contact the technical service

In the case of pending issues, contact Alliage authorized technical service.

MAINTENANCE

CABLE REPLACEMENT

!	Before starting the cable replacement procedure, disconnect the sensor from the USB port of the computer to avoid damage to your equipment.

⚠	The electronic circuits of Intraoral dental digital imaging sensor Saevo Slim are susceptible to electrostatic discharge (ESD). During the cable replacement, measures must be taken to protect the device against possible damage by ESD.

With the help of a screwdriver with the tip of 3 x 0,8mm, remove the finishing cover of the screw.

With the screwdriver with the tip of 3 x 0,8mm, remove the screws that attach the cable.

Remove the USB cable and perform the replacement.

MAINTENANCE

Attach the screws again.

⚠	It is recommended the use of a torquemeter adjusted for 10 N.cm

Make sure there's no space between the plastic parts.

INCORRECT   CORRECT

Place the cover of the screws available in the kit and press them until they fit in the plug.

MAINTENANCE

AUTHORIZED SERVICE NETWORK ALLIAGE

All services performed in the Alliage equipment must be done by an Authorized Technical Assistant, because, otherwise, they won't be covered by the warrant.
If you need to request electrical schemes and/or components specifications that are not declared in the user manual, use the Alliage Customer Attendance Service to make the request.

Telephone: +55 (16) 3512-1212
E-mail: imagem.eagle@alliage-global.com
Address: Rodovia Abraão Assed, Km 53 - Recreio Anhangüera - Ribeirão Preto-SP/ Brasil   CEP 14097-500

WARRANTY

This equipment is covered by the warranty periods, terms and conditions contained in the Warranty Certificate that comes with the product.

ELECTROMAGNETIC COMPATIBILITY TABLES (EMC)

The **Intraoral Dental Digital Imaging Sensor** is intended for use in the electromagnetic environment specified below. Buyer or user should ensure that it is used in such an environment.

The **Intraoral Dental Digital Imaging Sensor** is suitable for use in a professional health care environment, not including areas where there are sensitive equipment or sources of intense electromagnetic disturbances, such as the RF shielded room of an imaging system magnetic resonance imaging, in operating rooms near active AF surgical equipment, electrophysiology laboratories, armored rooms or areas where short wave therapy equipment is used.

The following tables provide information on compliance of the equipment according to the standard EN 60601-1-2:2015.

GUIDANCE AND DECLARATION FOR ELECTROMAGNETIC EMISSIONS

Emission Essays	Conformity	Electromagnetic environments - guidelines
RF emissions CISPR 11	Group 1	The Intraoral Dental Digital Imaging Sensor uses RF energy only for its internal functions. Therefore, your RF emissions are very low and probably will not cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Intraoral Dental Digital Imaging Sensor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuation/ Scintillation Emissions IEC 61000-3-3	Not applicable	

ELECTROMAGNETIC COMPATIBILITY TABLES (EMC)

GUIDANCE AND DECLARATION FOR ELECTROMAGNETIC IMMUNITY

Phenomenon	Basic standard of EMC	Immunity test level	Level of conformity
Electrostatic discharge	IEC 61000-4-2	±8 KV contact ± 2 KV, ± 4 KV, ± 8 KV, ± 15 KV air	±8 KV contact ± 2 KV, ± 4 KV, ± 8 KV, ± 15 KV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See table	See table
Electrical Fast / Transients bursts	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency	± 1 kV 100 kHz repetition frequency
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz

ELECTROMAGNETIC COMPATIBILITY TABLES (EMC)

GUIDANCE AND DECLARATION FOR ELECTROMAGNETIC IMMUNITY

Proximity fields from wireless RF communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1,8	0,3	27
450	430-470	GMRS 460,FRS 460	FM ± 5 kHz deviation 1kHz sine	2	0,3	28
710	704-787	Banda LTE 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
7480						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, Band LTE 5	Pulse modulation 18 Hz	2	0,3	28
870						
930						
1720	1700 -1990	GSM 1800; CDMA 1900; GSM 1900; DECT; Band LTE 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, Band LTE 7	Pulse modulation 217 Hz	2	0,3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5500						
5785						

⚠ The Intraoral Dental Digital Imaging Sensor is intended for the acquisition of intra-oral medical images of teeth, mandible and oral structures, and it is for exclusive dental use only. In case of EM disturbances, the operator may experience loss of communication between the device and the computer.

ELECTROMAGNETIC COMPATIBILITY TABLES (EMC)

⚠	The compliance with EMC and EMI regulations can't be guaranteed by the use of modified cables or those which doesn't comply with the same standards under what the equipment was validated.

⚠	This equipment must not be used adjacent or supported by other equipment. The recommendations of this manual must be followed.

⚠	Don't use accessories, transducers, internal parts of components and other cables other than those previously specified by the manufacturer. This may result in increased emission or decreased electromagnetic immunity and result in improper operation.

⚠	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the Intraoral Dental Digital Imaging Sensor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠	To maintain basic safety in relation to electromagnetic disturbances during the expected service life, always use the equipment in the specified electromagnetic environment and follow the maintenance recommendations described in this manual.