DABI ATLANTE

Owner's Manual

Intraoral Scanner Eagle Scan

English

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PRESENTATION OF THE MANUAL

Technical Name: Intraoral Camera
Trade Name: Intraoral Scanner
Modelo: AXR-S
Marca: eagle.scan/Dabi Atlante

Technical Manager: Caetano B. Biagi
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ANVISA Registration Nº: 10101130094

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GENERAL INFORMATION

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1. GENERAL INFORMATION

1.1. DEAR CUSTOMER

Congratulations, thank you for your choice. Whenever you purchase an ALLIAGE quality product, rest assured that our products are of top quality and compatible with the best in the world in their class.

This manual offers you an overview of the equipment which includes a detailed description of important features that might aid you in its use, as well as in the troubleshooting of small issues that eventually might appear.

This manual must be read thoroughly and kept for future consultations.

1.2. INDICATION FOR USE

Intraoral scanner is a dental 3D scanner made to be used for digitally capturing the topographical features of teeth and adjacent tissues. The system generate 3D scans for use in computer-aided design and manufacturing of dental restorations.

1.3. CONTRAINDICATIONS

This equipment is contraindicated for people with polyphenylsulfone (PPSU) allergies, which is the material used in the scanner's probe tip, or for those allergic to polycarbonate (PC) and acrylonitrile butadiene styrene (ABS), materials used in the scanner body. These chemical compounds may cause allergic reactions or irritation in some people.

1.4. SYMBOLOGY

The following symbols are used both throughout this manual and on the product. Make sure you fully understand each symbol and follow the instructions that accompany it.

	Fragile, handle with care		Maximum stacking
	Protect from rain	60°C -12°C	Temperature limit
	This side up		Protect from sunlight
	Manufacturer		Date of Manufacture

	ON/OFF button Scan button		Optional print-screen function
	Type B applied parts		USB plug
	General warning		Attention
	Mandatory action		Follow the instructions for use
	Indicates that the product must be taken to a special waste collection site at the end of its useful life. Applies to both the device and its accessories.	NON STERILE	Non-sterile (scanner tips)
	Optical radiation		Direct current
	Recyclable	135°C	Sterilizable in a steam sterilizer (autoclave) at specified temperature
#	Reference / Product Code	SN	Serial number
MD	Medical device	MODEL	Model

LOT	Lot number		Electrostatic Sensitive Devices (ESD)
RoHS COMPLIANT LEAD FREE	Indicates that the equipment complies with Directives 2011/65/EU and 2015/863/EU on the Restriction of the use of certain hazardous substances in electrical and electronic equipment	UDI	Unique device identification

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WARNINGS, PRECAUTIONS AND RECOMMENDATIONS

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2. WARNINGS, PRECAUTIONS AND RECOMMENDATIONS

2.1. GENERAL WARNINGS

	Read and understand all instructions contained in these operating instructions before installing or operating this equipment.
	Only use equipment in perfect condition and protect yourself, patients and third parties against possible dangers.
	This equipment must be installed and operated by personnel familiar with the necessary precautions.

- Do not spill liquids on the body of the device.
- Never operate the device in a humid environment.
- Keep the device away from radiators and heat sources.
- Use the device only with the accessories provided.
- Do not modify the device or open the cases.

	General prohibition. The functionality of the system may be destroyed in the event of incorrect use. If unauthorized changes have been made to the system and accessories supplied, the manufacturer's warranty will be void. Alliage will not accept any responsibility or liability for improper functioning of the product in this case.

If any of the following conditions occur, unplug the device from the electrical outlet and contact authorized service personnel:

- The power cord or power adapter is damaged.
- The device has been exposed to water.
- The device has been damaged.
- The device does not operate properly when the operating instructions are followed.

	Modification of the system may result in physical injury to the patient and operator and damage to the system.
	The product must only be used with compatible and approved software.
	The product is sensitive to electrostatic discharge.
	If the system malfunctions or fails, avoid any contact between the scanner and the system. Store the system in a safe place and keep it out of reach to prevent use by unauthorized persons. Contact specialized technical service.

	There is a risk of electrical shock when opening or attempting to open any part of the system; only qualified service personnel should open parts of the system.
	Avoid installing the product in a way that makes its disconnection difficult.

2.2. DURING TRANSPORT

The equipment must be transported and stored, observing the following:

- Handle with care to avoid falls, excessive vibrations and impacts;
- The arrows on the packaging must be pointing upwards;
- Do not stack above the quantity indicated on the packaging;
- Protect against sunlight, humidity, water and dust;
- Observe the limits of temperature, pressure and relative humidity.

2.3. DURING EQUIPMENT INSTALLATION

- Place the equipment in a location where it will not be exposed to moisture or water.
- Install the unit in a location where it will not be damaged by pressure, temperature, humidity, direct sunlight, dust, salts or corrosive products.
- The equipment should not be subjected to excessive vibration or shock (including during transportation and handling).
- This equipment is not designed for use in the presence of flammable anesthetic mixture vapors or nitrous oxide.
- Recommendations must be followed.
- The *intraoral scanner* is factory calibrated and therefore does not require calibration when installed. If the *intraoral scanner* begins to have problems scanning and recognizing tooth models, the system should be examined, which may result in the system being returned for repair/calibration.

2.4. BEFORE USING THE EQUIPMENT

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

2.5. DURING USE OF THE EQUIPMENT

- Under no circumstances may the patient operate the equipment.
- The equipment should only be operated by qualified healthcare professionals.

To operate the equipment, operating personnel must:

- Read and understand the user manual.
- Be familiar with the structure and fundamental functions of this equipment.
- Be familiar with the emergency situation protocols for this equipment.
- Be able to recognize irregularities in the operation of the equipment and implement appropriate measures when necessary.
- The patient must not touch any parts other than those specifically intended for treatment.
- If this product is exposed to water, moisture or foreign substances, turn it off immediately and contact an Alliage Authorized Service Center.
- In the event of damage or malfunction, do not use the equipment and contact an Alliage Authorized Service Center.
- Do not use the equipment if any of its enclosures or parts are damaged, loose or removed. Contact an Alliage Authorized Service Center and have any damaged, loose or removed enclosures or parts repaired or replaced before using the equipment again.

- Do not touch or operate the equipment if it is being repaired or if the equipment enclosures have been removed.
- Do not open or remove any of the equipment enclosures. There are no user-serviceable parts inside.
- All moving parts are inside the handheld scanner, so do not open the unit.
- When not in use, always rest the handpiece on the base. Do not place the base on a slanted surface. Place the cables (power cable and USB cable) where people cannot accidentally get caught in them and potentially damage the system.
- In the event of a fall or impact to moving parts causing them to break, be careful when handling them, as there may be sharp parts.
- The operator must not come into contact with the patient when in contact with accessible connectors.
- The operator must not use tools to open the equipment.
- During system operation, the *intraoral scanner* may become slightly warm; this is normal.

	If the probe tip of the scanner is dropped, check if the mirror is not damaged or misaligned; if the probe tip is damaged, it should be immediately discarded. If the scanner falls or is subject to impact, check if any part of the system is damaged because it might affect its performance.
	The *intraoral scanner* system contains delicate optical and mechanical elements and should therefore be handled with care. Do not drop, knock or shake the handpiece or tip. Always place the handpiece in the base when not in use. Do not force the cable connecting the handpiece to the Base. Do not submerge the handpiece or Base in any liquid. Do not place the handpiece or Base on wet or heated surfaces. Hold the handpiece with a firm grip when handling.
	To prevent the system from overheating, the ventilation opening on the bottom of the handpiece should never be obstructed.
	Be careful to not use incorrect voltages in the cable of the system.
	Use only the cable supplied with the system.
	During operation, the system emits a bright, flashing light at the tip. Although the system complies with IEC 62471 (Phenomenological Safety of Lamps and Lamp Systems), prolonged exposure to flashing light may result in discomfort, seizure or eye irritation.

2.6. PREVENTION AGAINST CROSS-CONTAMINATION

	Appropriate cleaning and disinfection measures should be taken to prevent cross-contamination between patients, users and other persons.

- For each new patient, perform cleaning and disinfection procedures according to the instructions contained in this manual.

	To maintain patient safety, wear surgical gloves when handling any part of the system. Always verify that the tip is assembled into the handpiece before inserting it into the patient's mouth. Before using the system with a new patient, ensure that the system is disinfected and the tip is sterilized.

2.7. AFTER USING/OPERATING THE EQUIPMENT

- Turn off the equipment if it is not in use for a long time.
- All parts that have had contact with the patient must be cleaned and disinfected for each new patient to prevent the transmission of infectious agents that can cause serious illness.
- Perform cleaning and disinfection according to the instructions contained in this manual.
- Do not disconnect the cable or other connections unnecessarily.
- No modifications to this equipment are permitted.
- When it is not in use, always keep the handpiece on its support. Don't put the support on a slanted surface. Put the cable in a place where people accidentally trip over and possibly damage it.

2.8. PRECAUTIONS IN CASE OF CHANGES IN EQUIPMENT OPERATION

If the equipment shows any abnormality, check whether the problem is related to any item listed in the “Troubleshooting” topic of this user manual.
If the problem cannot be solved, turn off the equipment and contact an Alliage Authorized Technical Assistance Center.

	The manufacturer is NOT responsible for: - The equipment is used for purposes other than those for which it was designed. - Damage caused to the equipment, the operator and/or patient, as a result of incorrect installation and maintenance procedures not in accordance with the operating instructions accompanying the equipment.

2.9. PRECAUTIONS IN CASE OF EQUIPMENT FAILURE

To avoid environmental contamination or misuse of the equipment, when it is no longer in use, it must be disposed of (in accordance with current legislation) in an appropriate place, as the materials inside it can contaminate the environment.

For the European Economic Area (EEA), this product is subject to Directive 2012/19/EU, as well as the corresponding national laws. This directive requires that the product must be taken to a special waste collection site at the end of its useful life. It applies to both the device and the accessories.

Please contact your dealer if final disposal of the product is necessary.

	This equipment must not be disposed of as household waste.

2.10. PRECAUTIONS TO REDUCE ENVIRONMENTAL IMPACT

Alliage S/A aims to achieve an environmental policy to promote the supply of environmentally conscious medical and dental products that continually minimize environmental impact and are more friendly to the environment and human health. To maintain a minimum impact on the environment, please observe the recommendations below:

- After installation, forward recyclable materials to the recycling process.
- During the life cycle of the equipment, turn it off when it is not in use.
- To prevent environmental contamination, the disposal of waste and consumables should follow the normal procedure for biomedical waste.
- Biomedical waste includes non-acute materials that are likely to cause disease or are suspected of harboring pathogenic organisms that must be stored in a yellow bag properly labeled with a biohazard symbol, stored in a puncture-resistant, watertight container until collection and incineration.

	The product packaging is made of cardboard, plastic and expanded polystyrene (EPS), which are 100% recyclable materials.

DIMENSIONS: 140 x 360 x 370mm

WEIGHT: Approximately: 5 kg

3

SYSTEM OVERVIEW

Alliage S/A Industrias Médico Odontológica
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3. SYSTEM OVERVIEW

3.1. SYSTEM DESCRIPTION

The product is designed and developed to produce high-quality digital intraoral scans or models for dental restoration or analysis.

The scanner is lightweight, small and easy to use, allowing for fast and accurate scanning.

The product should be handled by qualified and properly trained healthcare professionals and can be used for the following indications:

- Anatomical crowns
- Copings
- Temporary crowns
- Anatomical pontics
- Reduced pontics
- Temporary pontics
- Inlays / Onlays
- Implant abutments
- 3-unit implant bridges
- Bridges up to 5 units
- Orthodontic aligners
- “Nightguards”
- Splints
- Retainers
- Bleach trays
- Sleeping aids

3.2. PRINCIPLES OF OPERATION

The *intraoral scanner* is an optical scanning system. It has as operating principle the confocal digital technology to capture images digitally along the optical axis. During the scanning process, 3D reconstruction is generated from the selection regions with the highest image quality associated to the focal plane, thus ensuring high precision in the depth estimates. It is used to capture the topographical features of teeth, dental impressions or physical models for use in projects designed by computer (PAT/CAD) and computer-aided manufaturing (FAC/CAM) of prosthetic devices used in dental restoration.

⚠	Unintended use of the system may result in physical injury to the patient and operator and damage to the system.

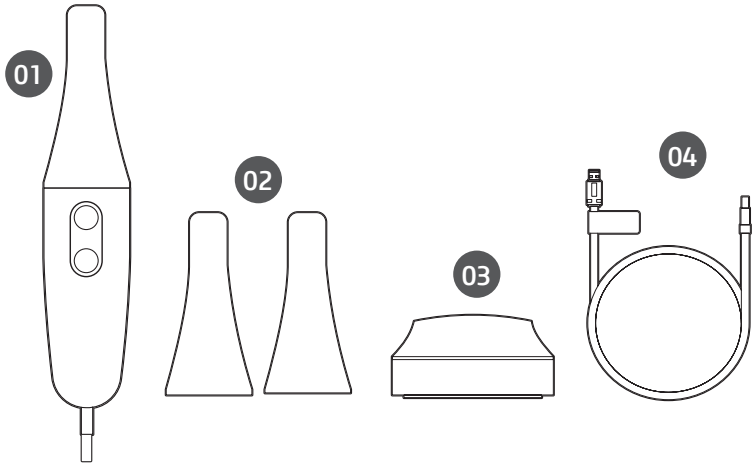
3.2.1. User profile

The product can be used by both sexes, with a minimum level of literacy and the ability to read and understand images, symbols, icons, Western characters (Arial font), alphanumeric characters, and must not have a degree of visual imperfection for reading or vision and a medium degree of impairment of recent memory, not being in a clear capacity to perform the activities and functions of the product correctly for the profession.

The user must be a qualified and trained healthcare professional to perform the activities and functions frequently used in the application of the *intraoral scanner* and its primary operating functions.

3.3. MAIN COMPONENTS OF THE PRODUCT

3.3.1. Parts accompanying the product



01 - Scanner
02 - Scanner tip (Type B applied part)
03 - Support Base
04 - USB 3.0 cable (Type C connector)

⚠	**Keep the box:** It is highly recommended that you keep the box in a safe place and do not throw it away. The box is ideal for any transport or shipping needs.

⚠	The body of the product consists of the Base and the Handpiece.

4

INSTALLATION

Alliage S/A Industrias Médico Odontológica
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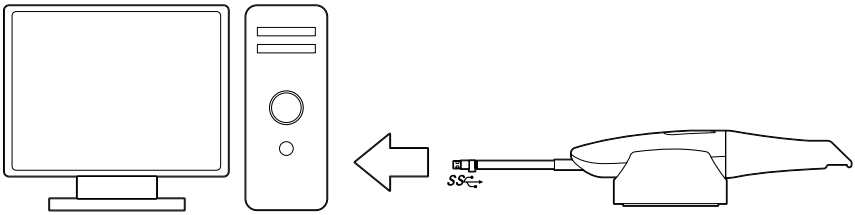
4. INSTALLATION

4.1. INTRAORAL SCANNER CONFIGURING AND CONNECTING



COMPUTER REQUIREMENTS	
Operating system	Windows 11 PRO
Disk space	M2 SSD 500GB
Port	USB 3.0 or higher
CPU Type	13th Gen Intel(R) Core(TM) i7 or higher
Memory	16GB Ram or higher
GPU (recommended)	NVIDIA RTX 4060 laptop, 6 VRAM or higher

⚠	The computer must be CE approved and comply with IEC 60950-1:2005 + AMD1:2009 + AMD2:2013, as well as the Low Voltage 2014/35/EU and EMC 2014/30/EU directives. In addition, for electrical safety reasons, the computer must have mandatory grounding for protection, in accordance with the requirements of IEC 60601-1 and the Brazilian standard NBR 5410, guaranteeing protection against electric shock and the correct functioning of the system. To ensure optimum performance, make sure that all installed programs are virus-free and have been properly tested, avoiding any impact on the image acquisition software after installation.

⚠	It is recommended that patient files and data be backed up periodically to avoid loss of history in the event of a computer system failure.

⚠	To comply with safety standards, do not operate non-medical equipment, such as personal computers, within the patient area. The presence of non-medical equipment outside the patient area is acceptable, provided that approved and certified IT equipment is used.

Install the system according to the following steps:

Step 1: Installation will be carried out through technical support, with a call being opened together with the customer, as specified in item 11.ALLIAGE AUTHORIZED SERVICES.

Step 2: Place the base on a flat, stable surface and place the *intraoral scanner* handpiece firmly on its base.

Step 3: Connect the supplied USB 3.0 cable to your computer; the connector socket is located below the handpiece.

⚠	Using a USB cable other than the one provided may result in system malfunction or reduced performance.

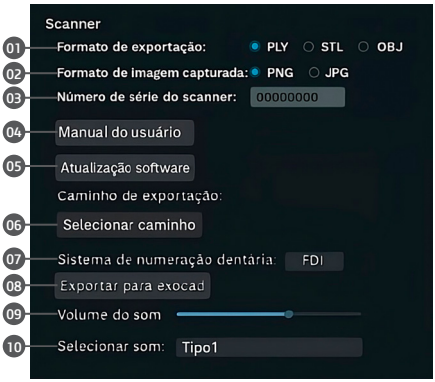
Step 4: Connect the other end of the USB cable to your computer.

⚠	Make sure to use a USB port that is USB 3.0 compatible; failure to do so may result in system malfunction or reduced performance. If you are using a laptop, make sure the power supply is plugged into a wall outlet and is not running on battery power.

⚠	Unsuitable installation locations: - Locations with excessive humidity or dust; - Locations subject to high temperature; - Locations subject to shaking or vibration; - Locations exposed to considerable electrical or magnetic noise or other forms of electromagnetic energy.

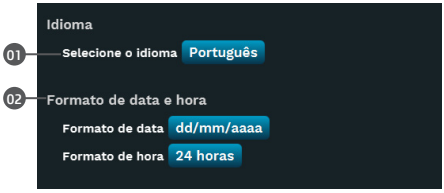
4.2. SETTINGS

4.2.1 Scanner



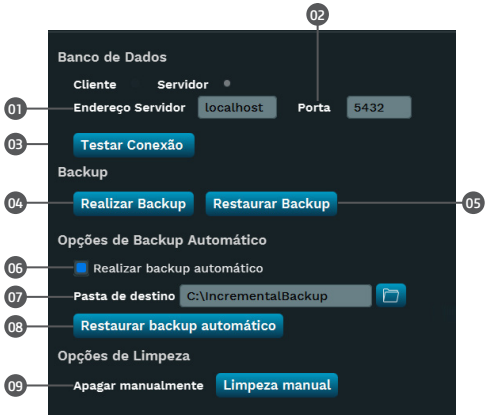
01. Exported format: The 3D output has three options, namely, STL, PLY, OBJ.
02. Captured image format: There are two image format options PNG and JPG.
03. Scanner Serial Number: Check the scanner serial number.
04. User's Manual: Link to user's manual.
05. Software Update: Link to the software update page.
06. Select the export path: Select automatic export path.
07. Dental numeration system: Select the type of numeration of teeth for display.
08. Export to exocad: Select the export path to exocad.
09. Sound volume: Control bar to set the volume level.
10. Select sound: Option to choose the alert sound during scanning.

4.2.2. Language and date/time



01. Select language: Language option for the software.
02. Date and time format: Format options to display date and time.

4.2.3. Database



01. Server Address: Database server's IP address.
02. Port: Database server's connection port.
03. Test Connection: Check the access to the database server.
04. Perform Backup: Save the backup file on the hard disk.
05. Restore Backup: Choose the backup file stored on the hard disk to restore the system data.
06. Perform automatic backup: Select it to start a periodical backup done automatically.
07. Target folder: The place where the periodical backup will be saved.
08. Restore automatic backup: Restore the system to the last periodical backup done.
09. Delete manually: Manually delete parts of the database by date.

⚠	If you need help with the installation, please contact Alliage's authorized technical support. Phone: +55 (16) 98227-0297 Address: Rodovia Abrão Assed, Km 53 + 450m - Recreio Anhangüera – Ribeirão Preto-SP/ Brazil CEP 14097-500

5

OPERATION

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5. OPERATION

5.1. INTRODUCTION

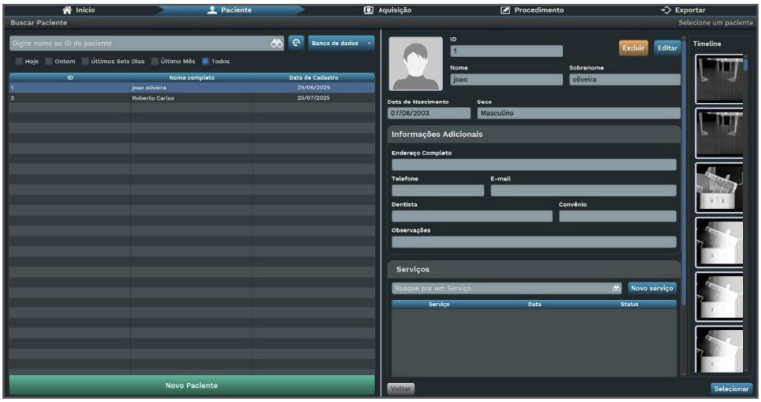
5.1.1. Log in and create a new account

A new user account can be created using the administrator account set up during software installation. To do this, log in with administrator credentials, then click “**Manage Users**” -> “**New User**” fill in the required fields with the new user's information, and finally click “**Confirm**”.

5.1.2. Case Management Software Overview

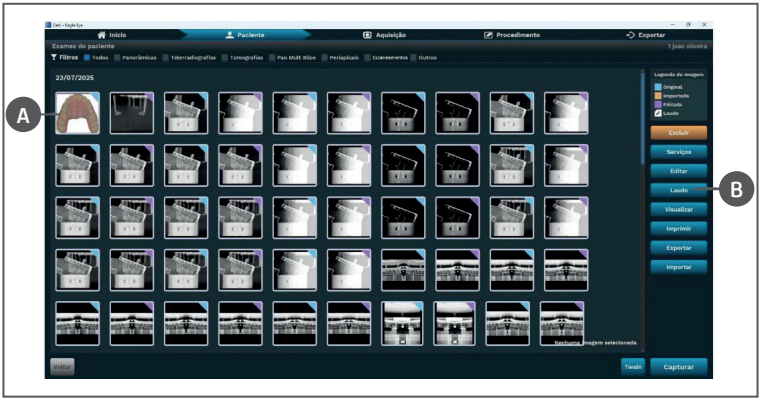
5.1.2.1. Patients

When connected, you will have access to a list of patients. Clicking once on a patient’s name in the table on the left will display basic information about the patient. Double-clicking the patient’s name will display that patient’s exams.



5.1.2.2. Patient cases

After selecting the patient, the exams screen will be displayed. To view a case already created, just click on the exams displayed **(A)** and click on "**Report**" **(B)** on the toolsbar on the right.



5.1.2.3. Filters

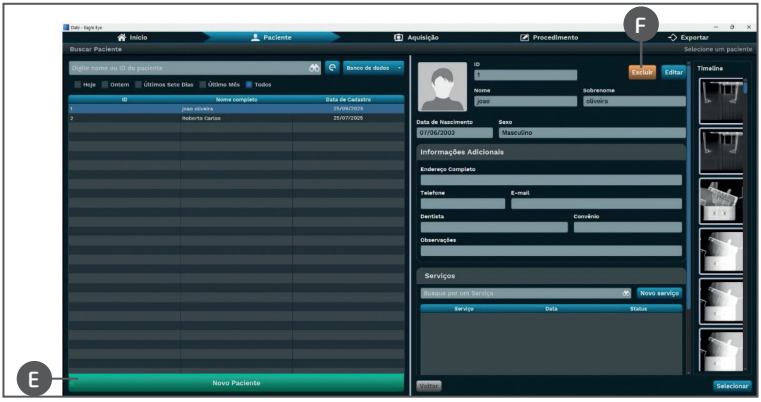
Cases can be filtered using predefined categories to make searching easier. Filters can be selected in the "**Filters**" section at the top of the screen. The available filters are: "**All**", "**Panoramic**", "**Teleradiographs**", "**Pan Mult Slice**", "**Periapicals**", "**Scans**" and "**Others**."

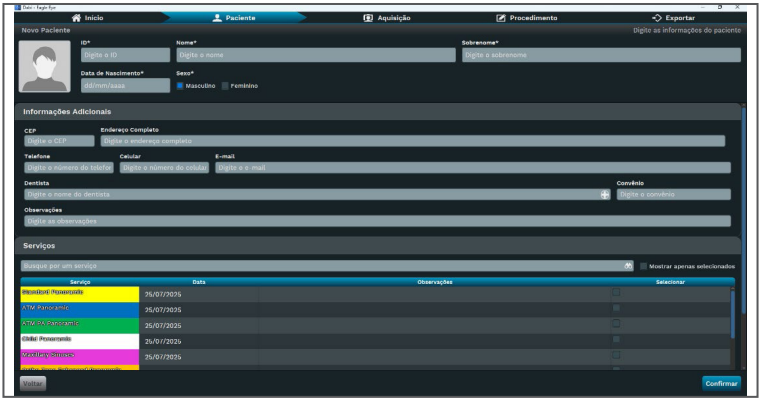
5.1.2.4. Settings

The settings can be found on the "**Home**" screen and can be accessed by clicking on "**Settings**" **(C)**. To switch the user just click on "**Exit**" on the lower left portion of the screen **(D)** and it will return to the login screen.

5.1.2.5. Creating a new patient

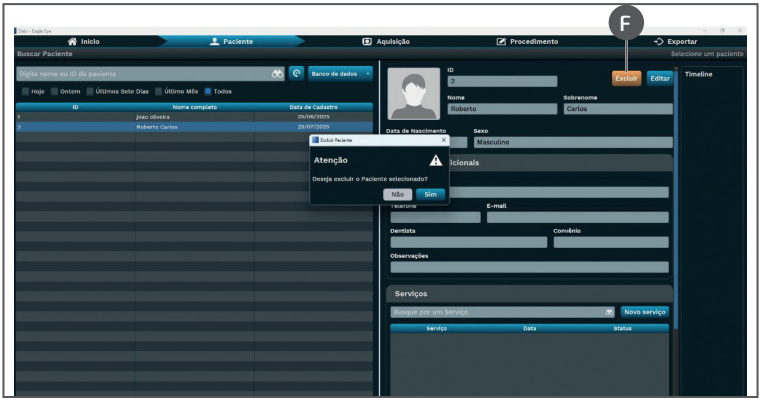
In order to add a new patient, access the "**Patient**" menu on the top bar in the software, and then click on "**New Patient**" **(E)**. Fill in the patient's details. Fields marked with * are mandatory.





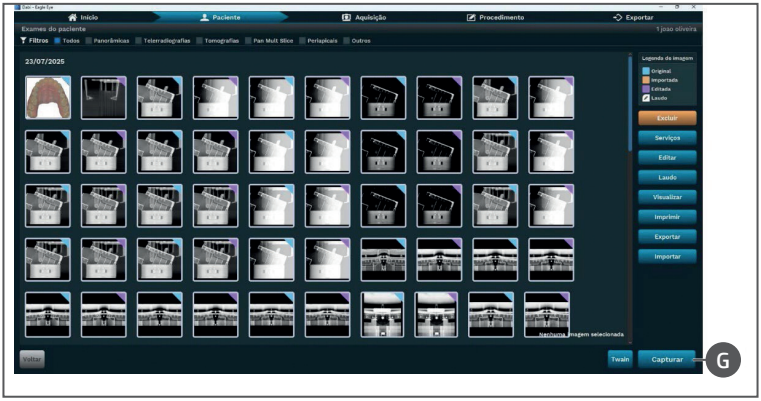
5.1.2.6. Delete a patient

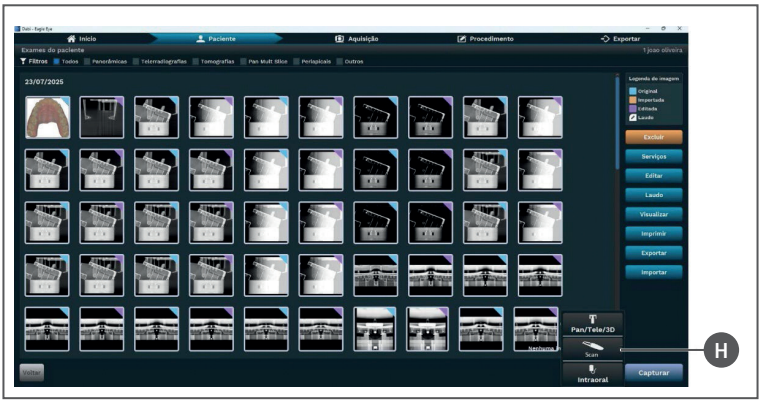
To delete a patient go to the "**Patient**" tab, select the patient to be deleted from the patients list and then click on the "**Delete**" button **(F)**, after that, click on "**Yes**" on the dialog box that will be displayed on the software screen to confirm the exclusion.



5.1.2.7. Create a new case

When selecting a patient on the "**Patient**" tab, a view will be displayed with the already existing cases concerning this patient, in order to get a new capture, click on the "**Capture**" button **(G)**. When clicking, a submenu **(H)** will be displayed with the screen capture options, select Scan to start a scanning process.





5.2. WORKFLOW INDICATIONS

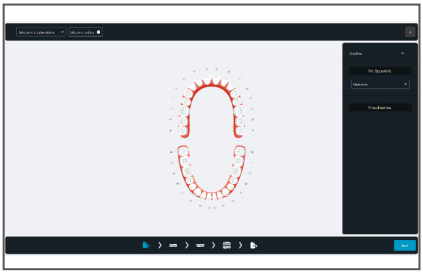
The product supports the following restorations and equipment:

- Anatomical crowns
- Copings
- Temporary crowns
- Anatomical pontics
- Reduced pontics
- Temporary pontics
- Inlays / Onlays
- Implant abutments
- 3-unit implant bridges
- Bridges up to 5 units
- Orthodontic aligners
- “Nightguards”
- Splints
- Retainers
- Bleach trays
- Sleeping aids

5.2.1. Create new case

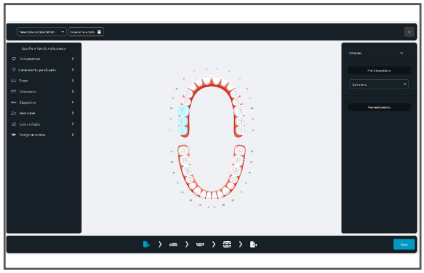
To create a new patient case for the above mentioned indications, follow the steps below.

When creating a new case, the order form will be displayed. Please verify the correct patient, selected lab, and desired lab delivery date.



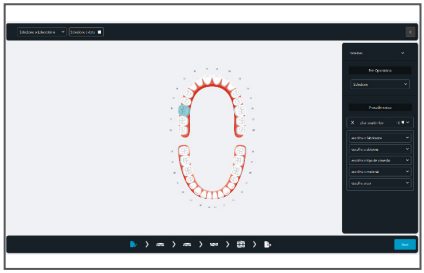
5.2.1.1. Selecting the restore

Select the teeth and choose the procedure type. Teeth can be selected by clicking on them, and multiple teeth can be selected at once. A pre-operative scan can be selected if desired.



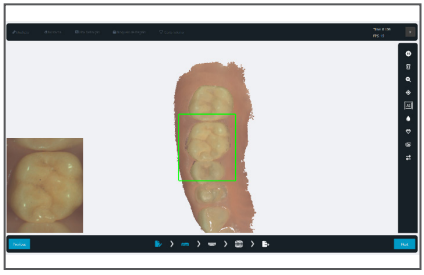
5.2.1.2. After selecting the procedure

Choose the color and material. Press "**Next**" when the request form is complete.



5.2.1.3. Scan Page

The live preview window in the lower-left corner shows the real-time view from the *intraoral scanner*. Its size can be set to Small, Medium, or Large. The 3D reconstruction is displayed in the center of the screen.



5.3. IMPORTANT TIPS BEFORE SCANNING

Before placing a crown, prepare the tooth with a gingival retraction cord. This is optional but highly recommended. Before scanning, remove the retraction cord and dry the surface of any blood or saliva using an air/water syringe or a 2x2 gauze pad.

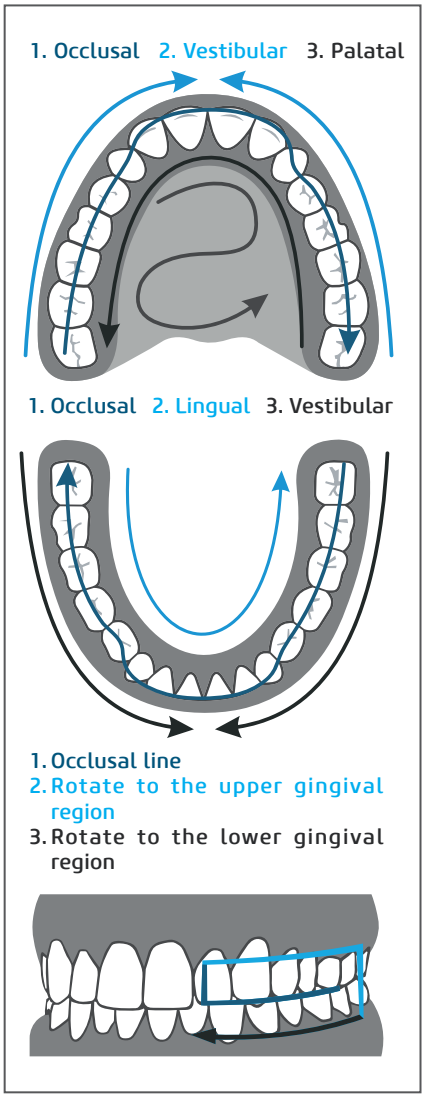
5.4. OPERATING THE SCANNER

5.4.1. Scanning strategy

- Soft tissue is the problem: Retract your lips, cheeks and tongue for a better experience.
- The first path (occlusal) is key: swipe a second per tooth.
- To be accurate, keep the scanner steady and stable.

Extra tips:

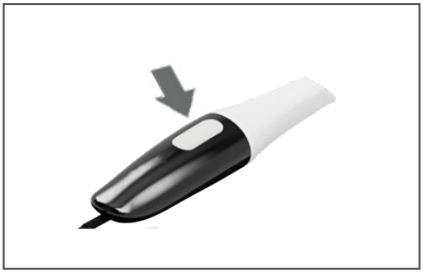
- For the maxilla: rotate the tip so that it is facing upwards.
- When scanning the occlusal surface, also scan part of the buccal surface especially in the incisor region alternating between lingual and buccal sides.
- To fill the holes correctly, tilt the scanner in different directions.
- For best results, control the scanning speed by reducing it when necessary.



5.4.2. Scanning

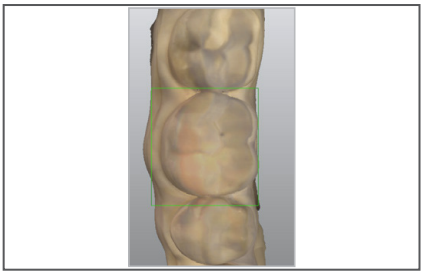
1. Start scanning:

To start scanning, press the button on top of the scanner or click "**Scan**" in the right-side toolbar.



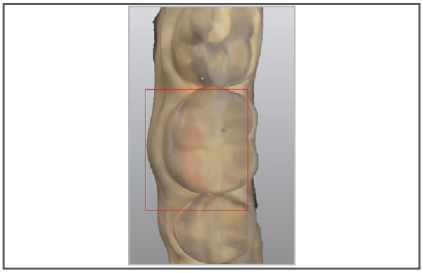
2. Green Image:

When the green box is present, it indicates that the scan is successful. To keep the green indicator, remain steady and precise with your movements.



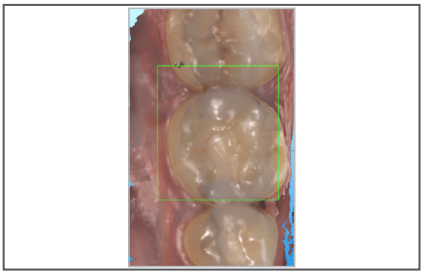
3. Red Image:

In the case of a red box, the scan has lost track and is no longer scanning. This is caused by jerky, unstable movements of the handpiece as well as lack of cheek/tongue retraction.



4. Restart:

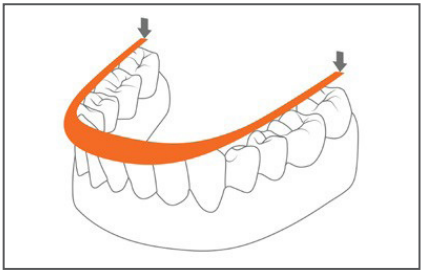
If your scan has lost its track, simply place the tip of the scan on the occlusal surface of an already scanned tooth. The occlusal surface has more detail and will allow the software to recognize its position quickly. Smooth surfaces are difficult to recognize because their surfaces are flatter.



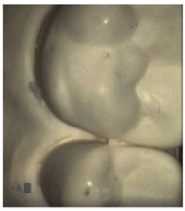
5.4.3. Mandibular and maxillary scanning

1. Begin your scan by starting with the chosen procedure arch. If you are scanning both arches, you can select either arch to start with.

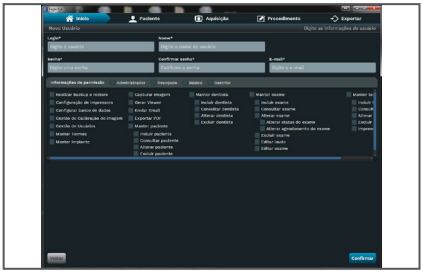
1a. For a full arch, follow an occlusal, linear, buccal scanning path. Starting at the posterior terminal molar, working across the occlusal plane of the arch, you will end at the opposite terminal molar. When scanning the anterior region, lightly roll the scanning tip at least 1 mm over the incisal edges to capture some smooth surface.



1b. The live view window on the left is the main reference point. During scanning, what is shown in the live window will appear in the 3D image. Make sure the tooth anatomy is centered in the view window with little to no cheek or tissue present.



2. When you have finished scanning the occlusal area, starting at the terminal molar, slightly rotate the scanner 45 degrees, scanning the entire lingual surface of the arch, ending at the opposite terminal molar.



3. To scan the buccal surface, starting again at the posterior terminal molar, you will rotate 45 degrees scanning the buccal segment, stopping at the midline. You will repeat the process on the opposite terminal molar to connect the midlines. Be sure to scan the entire arch on the smooth buccal surfaces. Finish scanning the buccal side of the molars with the scanner at a 90 degree angle, making sure to capture at least 5 mm of gingiva.

4. When the scan is complete, turn off the scanner using the power button on the top of the scanner. If you are scanning both arches, select the other arch now in the software.
5. Repeat the same path and scanning strategy for the remaining arch.

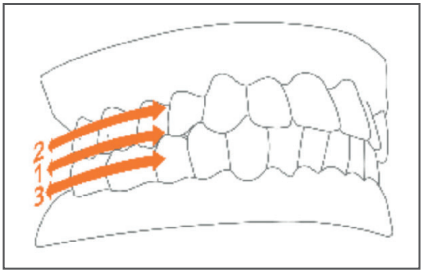
5.4.4. Bite alignment

For a quadrant scan, you will be prompted to scan only the lateral side of the quadrant. When scanning the entire arch, you will be prompted to scan bilaterally.

When selecting "**bite**", wait a few seconds for the arch scans to load.

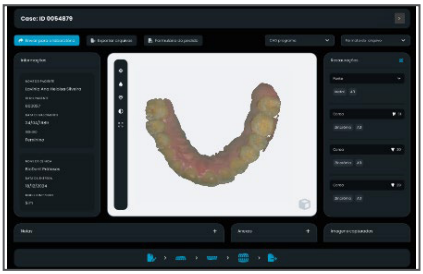
1. Scanning the occlusion.

1a. To capture the bite, start by scanning the central molars, capturing both mandibular and maxillary teeth in the first pass. Scan a region containing 3 to 4 molars in each arch. Repeat this movement until both arches are registered. Once the first bite is complete, begin scanning the second bite following the same procedure.



1b. Once bite alignment is complete, you can rotate the 3D image to confirm the patient's correct occlusion.

2. Finishing
Once the scan is complete, we get an overview of the case, including a 3D view of the scans. Additional notes can be added and pictures or similar can be attached to the case. If connected to a laboratory via cloud storage, the entire case can now be sent to the laboratory. In addition, the scans and the order form can be exported to a different location on the PC.



3D Viewer

Each of the scans can be opened in the full-screen 3D viewer for a more detailed investigation.

3. If you want to export the case to send it manually, access the files using the export file button.

⚠	If the equipment disconnects or turns off without operator intervention, disconnect it from the power supply and restart the entire operation. If the problem persists, contact authorized technical assistance.

5.4.5. Automatic Soft Tissue Identification

The intraoral scanning system features a new AI-based functionality for accurate identification of soft tissues during the scanning process. This function aims to facilitate more efficient and accurate scanning by ensuring that soft tissue regions such as the cheek, tongue, spacer, finger and glove are properly excluded from the resulting 3D model.

The AI integrated into the system analyzes each image captured during the intraoral scan. Using advanced image processing algorithms, the AI automatically identifies the areas corresponding to the aforementioned soft tissues.

This AI-based automatic soft tissue identification functionality brings a number of significant benefits to the intraoral scanning process. Firstly, by performing a thorough analysis of the images, the AI ensures improved accuracy in identifying soft tissue regions, significantly reducing the likelihood of including imperfections in the resulting 3D model mesh. Furthermore, by automating this process, operational efficiency is maximized, allowing users to save valuable time that would otherwise be spent on manual adjustments. Finally, by ensuring that soft tissue areas are properly excluded, AI functionality promotes consistent, high-quality results with every scan, resulting in cleaner, more reliable 3D models.

In the example below, AI accurately identifies the presence of a glove and soft tissue areas in the image captured during the scan. These areas are then automatically masked by AI prior to reconstructing the 3D model, ensuring the integrity and quality of the final result.

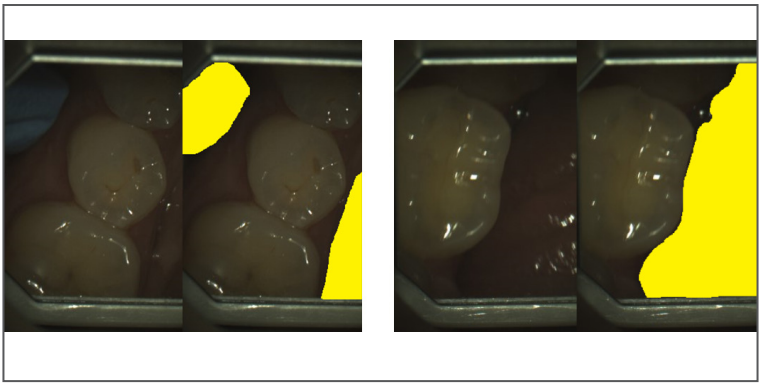
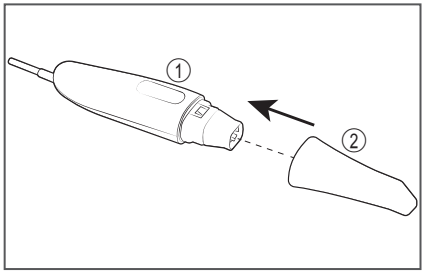


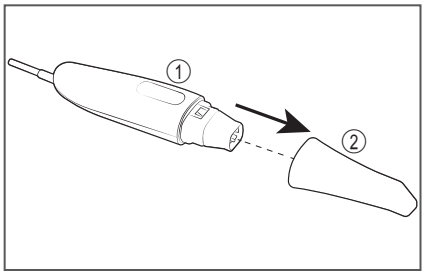
Figure 1 - Example of an intraoral scanning image with soft tissue regions identified (tongue and glove).

5.4.6. Tip

1. Position the tip ② with the mirror side facing down along with the scanner ①. Press it firmly the tip into the scanner until it is connected to the scanner.



2. Hold the scanner ① with one hand and the tip ② with the other hand and pull to move the scanner tip.



⚠	There is no need to rotate the tip for maxillary scanning.

5.5. SCANNING TOOLS

01 - Scan: Allows you to start and pause the data acquisition.

02 - Reset: Deletes the current digitalization.

03 - Adjust the zoom level.

04 - Center the digitalization on the screen.

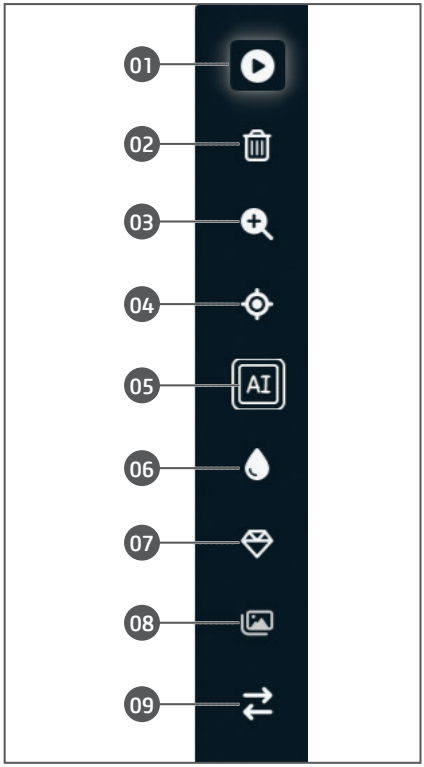
05 - Toggle AI on/off for removing soft tissue.

06 - Switch between color and black & white digitalization.

07 - Switch between color digitalization and quality map.

08 - Save the camera image.

09 - Invert the camera or tip orientation.



6

CLEANING, DISINFECTION AND STERILIZATION

Alliage S/A Industrias Médico Odontológica
Phone: +55 (16) 98227-0297
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brasil

6. CLEANING, DISINFECTION AND STERILIZATION

6.1. INTRODUCTION

⚠	For your protection, during the equipment cleaning and disinfection process, use PPE such as disposable gloves and protective glasses.

The cleaning and disinfection process must be carried out with each patient change.
To clean, use a clean, soft cloth moistened with mild soap and then dry with a clean, soft cloth or paper towel.

6.2. CLEANING THE HANDPIECE

For the disinfection process, use disinfectant detergent foam that has active components based on didecyldimethylammonium chloride.

Apply the disinfectant detergent foam to the surface or to a clean cloth and spread over the surface to be treated. Respect the antimicrobial contact time indicated by the manufacturer.

After application, let it dry. Do not rinse. Do not use disinfectant on the tip.

⚠	All scanner components (except the tips) must be clean and not sprayed. Avoid moisture, alcohol or disinfectant inside the open chamber of the scanner.

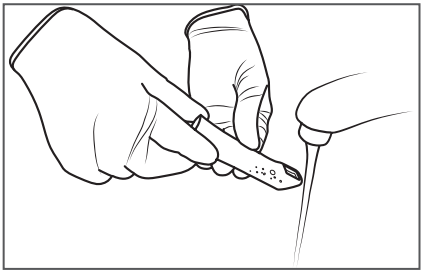
6.3. CLEANING AND STERILIZATION OF THE TIP

⚠	The included tips must be autoclaved before use as they are not pre-sterilized. The scanner tip is autoclavable up to 250 times in a steam autoclave.

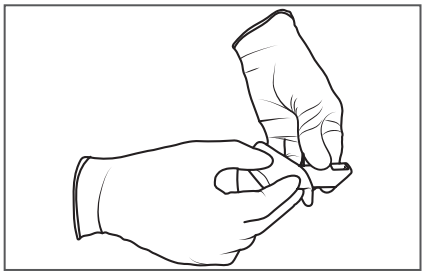
⚠	Make sure the mirror surface does not show any residue, stains, scratches or any damage as this would affect the performance of the device.

6.3.1. Step by step procedure

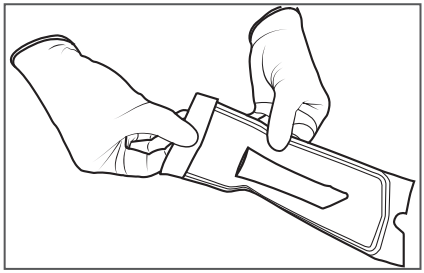
1. Clean the tip with soap and water, ensuring that the mirror is clean and free of dirt, stains or any residue. Avoid using abrasive materials on the cloth as this will scratch the mirror.



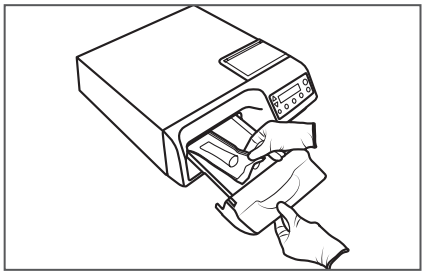
2. After drying the outside of the tip, carefully dry the inside and the mirror with lint-free wipes, making sure not to scratch the surface. The mirror should be free of any visible debris or water spots.



3. Insert and seal the tip into a sterilization pouch with the tip facing down so that no water droplets collect on the mirror. Make sure the seal is airtight. Each tip should be individually wrapped.



4. Sterilize the wrapped tip in a steam autoclave.



135°C	Minimum sterilization time 30 minutes at 121°C or minimum 3 minutes at 135°C, with equivalent temperature and time parameters within this range being able to be used. Maximum sterilization temperature 135°C.

5. Ensure the drying cycle is complete before removing the tip from the autoclave. If the pouch is moist, adequate sterilization cannot be guaranteed.

⚠	Always autoclave the tip wrapped in a sealed sterilization pouch; failure to do so will result in permanent stains on the mirror.
⚠	Do not autoclave the device handpiece.

	Tips should not be placed in an ultrasonic cleaner or any cold sterile solution. Sterilizing solutions will leave a sticky residue or film on the mirror while drying.
	Do not remove the bag before the autoclave has completed its full drying cycle. If the bag is wet or shows any signs of moisture, it may leave water spots on the mirror, which may affect the image quality during scanning.
	Be very careful when cleaning the mirror as it is very delicate and prone to scratches.

7

TROUBLESHOOTING, INSPECTION AND MAINTENANCE

Alliage S/A Industrias Médico Odontológica
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7. TROUBLESHOOTING, INSPECTION AND MAINTENANCE

7.1. TROUBLESHOOTING

If you encounter any problems during operation, please follow the instructions below to check and fix the problem, and/or contact your representative.

IMPREVISTOS	SOLUÇÕES
There is a memory full error message that appears when the software is open.	Clear some space on the C Drive
The status in the live view window is "**Disconnected**".	Make sure you have external power for the *intraoral scanner* and that the USB cable is plugged into a USB 3 port.
Scanning is very slow.	Make sure your laptop is plugged into an external power source.
The corners are cut off in the live view window.	Make sure the tip is mounted correctly and that it clicks into place when you turn it.
There is a red square in the scan window	Go back to a tooth that was scanned and start from there again
No image appears when scanning, but everything else (e.g. live view image, sounds, FPS) works fine.	The scanner may need to be recalibrated. Contact your local dealer for support.
There are dots in the live view window.	Check and clean the tip mirror
Where can I get the *intraoral scanner* software and manuals?	Software is included with the product and the manual is available for download on the manufacturer's website (www.dabiatlante.com.br).

If the problem persists, contact the Alliage Service Department.

	Corrective, preventive or service maintenance procedures may only be performed by a technical service authorized by the manufacturer. The *intraoral scanner* cannot be disassembled or repaired in the field.

All instructions for using the equipment as intended are provided in this user guide.

If a problem is detected that cannot be corrected using the instructions in the troubleshooting section, please contact the Alliage Service Department.

7.2. PERIODIC INSPECTION

It is imperative that this equipment be inspected regularly to ensure operational safety and functional reliability. This inspection should be carried out by personnel familiar with the precautions necessary to avoid patient exposure to risk.

Periodic inspection should be carried out at regular intervals (at least once a year) to ensure that the product is permanently safe and operational. All components subject to normal wear and tear must be checked and, if necessary, replaced.

The manufacturer and the assembler/installer are exempt from liability if the standard results are not in accordance with the user's failure to carry out the maintenance recommended by the manufacturer.

Neither inspection nor service is part of the equipment warranty.

The maintenance carried out must be documented and kept with the equipment.

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

ITEM	DESCRIÇÃO DA INSPEÇÃO	FREQUÊNCIA RECOMENDADA
Operation / Safety system	On/off button actuation (Visual).	Daily
Electrical parts	Overheating/Noise/Burning smell (Audible and visual).	Monthly
Parts and pieces	Operation/Noise/Vibration/Breakages (Audible and visual).	Monthly

If problems are detected during the inspection, contact the Alliage Service Department.

7.3. PREVENTIVE MAINTENANCE

In addition to the annual inspection, to ensure the long life and proper functioning of your equipment, it is important to perform preventive maintenance every three (3) years.
Contact the Alliage Service Department about our periodic inspection and preventive maintenance program.

7.4. CORRECTIVE MAINTENANCE

	Do not open the equipment or attempt to repair it yourself or with the help of someone without training or authorization. This may aggravate the problem or produce a failure that may compromise the safety of the equipment.
	Power cables and electronic boards can only be replaced by an authorized technician.
	The equipment or any of its parts may not be repaired, maintained or serviced while it is being used on a patient.
	The service manual is only available to Authorized Technical Assistance.

Alliage declares that the provision of circuit diagrams, component lists or any other information providing technical assistance on behalf of the user, may be requested provided that this has been previously agreed between the user and Alliage.

The warranty will be void if original parts are removed/replaced by unauthorized service technicians.

8

RULES AND REGULATIONS

Alliage S/A Industrias Médico Odontológica
Phone: +55 (16) 98227-0297
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brasil

8. RULES AND REGULATIONS

This equipment was designed and manufactured to meet the following standards:

ABNT NBR IEC 60601-1:2010+A1:2016+A2:2022	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
ABNT NBR IEC 60601-1-2:2017+A1:2022	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances
ABNT NBR IEC 62471:2008	Photobiological safety of lamps and lamp systems
ABNT NBR IEC 80601-2-60:2021	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment
ABNT NBR IEC 60601-1-6:2011 + A1:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ABNT NBR IEC 60601-1-9:2008+A2:2020	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally responsible design
ABNT NBR ISO 15223-1:2021	Graphic symbols for electrical equipment in medical practice
ABNT NBR 20417:2021	Information provided by the manufacturer of medical devices.
ABNT NBR ISO 13485:2016+A11:2021	Quality management systems - Requirements for regulatory purposes.
ABNT NBR ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Assessment and testing.
ABNT NBR ISO 14971:2019	Medical devices - Application of risk management to medical devices.

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TECHNICAL SPECIFICATIONS

Alliage S/A Industrias Médico Odontológica
Phone: +55 (16) 98227-0297
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brasil

9. TECHNICAL SPECIFICATIONS

9.1. EQUIPMENT CLASSIFICATION

EQUIPMENT CLASSIFICATION	
Classification according to ANVISA	Class I
Classification class according to CE	Class I

EQUIPMENT CLASSIFICATION ACCORDING TO EN IEC 60601-1 STANDARD	
Product Classification for Applied Parts	Type B
Protection Against Electric Shock	Class II
Protection Against Harmful Water Penetration	IPXO - Product not protected against harmful penetration of water and particulate matter
Degree of application safety in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide	Equipment not suitable
Mode of Operation	Continuous

9.2. DEVICE INFORMATION

GENERAL INFORMATION SCANNER	
Voltage (Power Supply)	5VDC (USB 3.0), compatible with dual-voltage powered computers
Power Required	4,5W
Base Dimensions Size	Diameter: 88mm, Height: 56mm
Scanner Dimensions Size	Length: 220mm, Width: 47mm, Height: 36mm
Scanner Weight	Handpiece with tip: 145g, Base: 400g
Scanner Tip	Reusable, sterilized using steam autoclave
Optional modules for image manipulation	Dental implant, Bite, Temporary, Articular, Rendering, and Patient Progression

DIGITIZATION PROCESS	
Acquisition method	Video scanning with confocal digital technology, LED-illuminated
Captured video area	14x20 mm
Color scanning	24 bits (8 bits per channel)
File formats	STL, PLY e OBJ
File resolution	0,5 µm
Tooth preparation	No powder or spray needed
Field depth	20mm
Possible duration of contact by the patient	10min
Workpiece accessible to the operator	Handpiece
Possible duration of contact by the patient	10min
Workpiece accessible to the patient (applied part type B)	Tip

9.3. COMPUTER REQUIREMENTS

NECESSARY AND MISCELLANEOUS SOFTWARE	
Operating system	Windows 11 PRO
Disk space	M2 SSD 500GB
Port	USB 3.0 or higher

REQUIRED HARDWARE	
CPU Type	Notebook: 13th Gen Intel(R) Core(TM) i7 or higher
Memory	16GB Ram or higher
GPU	NVIDIA RTX 4060 laptop, 6 VRAM or higher

⚠	AMD GPUs are not compatible with the *intraoral scanner* Failure to meet the minimum hardware requirements will affect scanner performance.

9.4. ENVIRONMENTAL CONDITIONS

ENVIRONMENTAL CONDITIONS OF TRANSPORTATION AND STORAGE	
Ambient temperature range for transport or storage	-20ºC a +60ºC
Relative humidity range for transport and storage	10% ~ 80% (non-condensing) For indoor use only
Atmospheric pressure range	700 hPa a 1060 hPa (525 mmHg a 795 mmHg)

ENVIRONMENTAL CONDITIONS OF INSTALLATION AND OPERATION	
Ambient operating temperature range	+10ºC a +40ºC
Operating relative humidity range (non-condensing)	10% ~ 80% (non-condensing)
Atmospheric pressure range	700 hPa a 1060 hPa (525 mmHg a 795 mmHg)
Operating altitude	≤ 2000 m

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WARRANTY

Alliage S/A Industrias Médico Odontológica
Phone: +55 (16) 98227-0297
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brasil

10. WARRANTY

10.1. WARRANTY TERMS

Pursuing continuous improvement and customer satisfaction, this section provides all the necessary information for any eventual need to claim the warranty for products purchased from Alliage S/A or any other official sales channel.

The Warranty Policy applies to all products designed, manufactured, and marketed by Alliage S/A Indústrias Médico Odontológica and is in accordance with current consumer protection laws.

The product warranty is the responsibility assumed by the supplier/manufacturer to deliver the product free from defects and in proper working condition, as provided in Article 445 of the Civil Code. The warranty consists of two distinct coverage periods: the first is the legal warranty, and the second is the contractual warranty offered by the supplier/manufacturer, counted from the date of issue of the sales invoice to the final customer.

The warranty coverage period varies according to the product purchased.

For countries where the legal warranty period is 12 months or more, the contractual warranty coverage periods may be modified; therefore, it is recommended to contact the responsible branch to confirm such coverage.

Alliage S/A Indústrias Médico Odontológica warrants its products against any manufacturing defect, whether in materials or workmanship, provided it is identified within the warranty period..

NOTE: Carefully read the instructions contained in the User Manual before using the equipment for the first time.

This equipment is covered under the warranty terms starting from the date of issue of the sales invoice/bill of sale, as specified below.

- **WARRANTY PERIODS (including the legal period):** 01 (one) year against manufacturing defects.
- **WARRANTY VOIDED IF:** A) Any attempt at repair using inadequate tools or by unauthorized technicians; B) Installation of the equipment by an unauthorized technician; C) Damage resulting from improper storage or signs of tampering; D) Incorrect use of the equipment; E) Use of cleaning products not recommended by the manufacturer; F) Drops, impacts, or failure to follow the instructions in the User Manual; G) Failure to perform preventive maintenance according to the Preventive Maintenance Plan available on the websites. Repair or replacement of parts during the warranty period will not extend the original warranty term.
- This warranty does not exempt the customer from paying the service fee for the visit and the technician's travel expenses, as well as transportation charges (round trip) when the customer sends the equipment for servicing at the authorized technical assistance center. (Consumer Defense Code – Article 50, sole paragraph).
- This warranty does not cover parts subject to natural wear during normal product use, such as the plastic tip.
- In the event of product replacement, the new equipment will be covered for a legal period of 03 (three) months from the date of issue of the **INVOICE** for the replacement equipment, without prejudice to any ongoing contractual warranty.

WARRANTY CERTIFICATE

Manufacturer - Alliage S/A Indústrias Médico Odontológica
Rod. Abrão Assed, Km 53+450m - CEP 14097-500 - Ribeirão Preto - SP - Brasil
Telefone 55 (16) 98227-0297 - www.alliage-global.com

DATE OF PURCHASE	INVOICE

DELIVER THIS COPY WITH RECEIPT TO THE CUSTOMER.

THE TERMS OF THE WARRANTY CERTIFICATE ARE PRINTED ON THE BACK OF THIS DOCUMENT.

SERIAL NUMBER	BARCODE	PRODUCT NAME

RESELLER NAME

CUSTOMER NAME	TELEPHONE

CUSTOMER TAX IDENTIFICATION NUMBER	CUSTOMER ADDRESS

CITY	ZIP CODE	STATE (PROVINCE)	COUNTRY

E-MAIL

ACADEMIC ☐ PROFFESSIONAL ☐

THIS WARRANTY WILL ONLY BE VALID IF ALL FIELDS ARE COMPLETED BY AN AUTHORIZED TECHNICIAN AND SIGNED BY BOTH THE TECHNICIAN AND THE CUSTOMER ON THE INSTALLATION DATE AND SENT TO THE MANUFACTURER.

CUSTOMER'S SIGNATURE	INVOICE ISSUANCE DATE	INVOICE	SELLER NAME

THE WARRANTY TERMS ARE PRINTED ON THE REVERSE SIDE. DELIVER THIS DOCUMENT TO THE CUSTOMER.

RG 061/10

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ALLIAGE AUTHORIZED SERVICES

Alliage S/A Industrias Médico Odontológica
Phone: +55 (16) 98227-0297
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brasil

11. ALLIAGE AUTHORIZED SERVICES

All services performed on the *intraoral scanner* must be performed by an Authorized Technical Services Provider, otherwise they will not be covered by the warranty.

If you need to request electrical diagrams and/or specifications of components that are not stated in the user manual, use Alliage Customer Service to make the request.

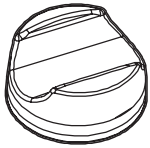
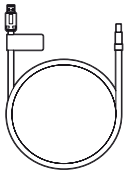
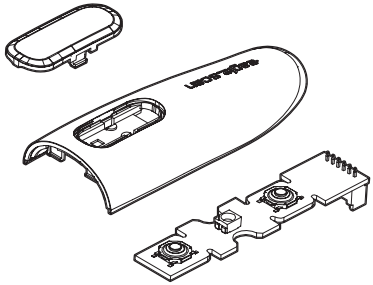
Opening a service call: https://alliageglobal.movidesk.com/form/2995

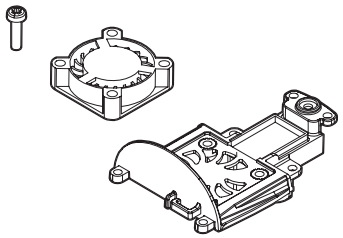
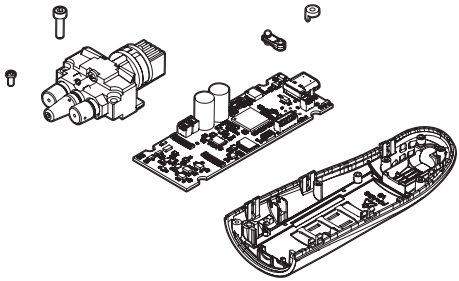
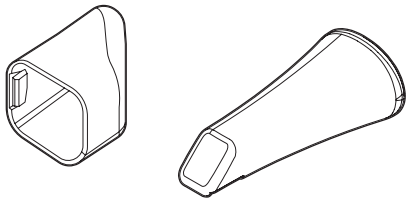
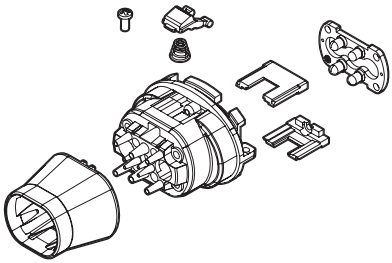
Phone: +55 (16) 98227-0297

Address: Rodovia Abrão Assed, Km 53 + 450m - Recreio Anhangüera – Ribeirão Preto-SP/ Brazil CEP 14097-500

11.1. PARTS LIST

Parts approved for replacement during maintenance. These parts can be purchased by contacting an Authorized Technical Service Center.

PART	DESCRIPTION	PART NUMBER
	AXRS SCANNER BASE KIT	16000004752
	AXRS SCANNER USB CABLE KIT	16000004661
	AXRS SCANNER BUTTON AND TOP COVER KIT	16000004784

PART	DESCRIPTION	PART NUMBER
	AXRS SCANNER COOLER KIT	16000004584
	AXRS SCANNER MAIN BOARD AND BLOCK KIT	16000004783
	AXRS SCANNER TIP KIT	16000004169
	AXRS SCANNER LED TIP KIT	16000004571

11.2. FAULT DIAGNOSIS

11.2.1. Power and Heating

ROOT CAUSE CLASS	PROBLEM				POSSIBLE CAUSE	SOLUTION
	SLOWNESS	OVERLAPPING	LOW FILLING LEVELS	SOFTWARE NOT OPENING		
Power and Heating	X	X	X		Laptop connected to the power supply. Whenever the laptop is not connected to the power supply, the performance drops drastically and it should not be used for scanning.	Connect the laptop to the power supply.
	X	X	X		Is the laptop battery charger rated for a sufficient power output? Similar laptops might present physically similar power chargers, yet with different power outputs.	Make sure that the charger rated power is equal to the scanner's rated power.
	X	X	X		In case of using a desktop, the power supply is adapted to use the maximum capacity of a graphics card (1000W usually is enough).	Check the power supply's rated power.
	X	X	X		Dirt inside the laptop might hinder its cooling capabilities even resulting in overheating of the system.	Clean the cooling parts and properly reapply thermal paste whenever it is applicable.

11.2.2. Specifications and Settings

<table>
<tr><th rowspan="2">ROOT CAUSE CLASS</th><th colspan="4">PROBLEM</th><th rowspan="2">POSSIBLE CAUSE</th><th rowspan="2">SOLUTION</th></tr>
<tr><th>SLOWNESS</th><th>OVERLAPPING</th><th>LOW FILLING LEVELS</th><th>SOFTWARE NOT OPENING</th></tr>
<tr><td rowspan="9">Specifications and Settings</td><td>X</td><td>X</td><td>X</td><td>X</td><td>Are the minimum specifications of the laptop met?
<table>
<tr><th colspan="2">COMPUTER REQUIREMENTS</th></tr>
<tr><td>Operating system</td><td>Windows 11 PRO</td></tr>
<tr><td>Disk space</td><td>M2 SSD 500GB</td></tr>
<tr><td>Port</td><td>USB 3.0 or higher</td></tr>
<tr><td>CPU Type</td><td>13th Gen Intel(R) Core(TM) i7 or higher</td></tr>
<tr><td>Memory</td><td>16GB Ram or higher</td></tr>
<tr><td>GPU (recommended)</td><td>NVIDIA RTX 4060 laptop, 6 VRAM or higher</td></tr>
</table></td><td>Use a laptop with minimum specifications required.</td></tr>
<tr><td>X</td><td>X</td><td>X</td><td></td><td>Power Mode Settings different from the “Performance Mode”.</td><td>Set it using: Settings -> System -> Power and Battery -> Power Mode: Performance</td></tr>
<tr><td>X</td><td>X</td><td>X</td><td></td><td>Economy Mode Settings different from the “Turned Off Mode”</td><td>Set it using: Settings -> System -> Power and Battery -> Economy Mode: Turned Off</td></tr>
<tr><td>X</td><td>X</td><td>X</td><td></td><td>Graphic card drivers are outdated.</td><td>Update the graphic card drivers.</td></tr>
<tr><td>X</td><td>X</td><td>X</td><td></td><td>In desktop computers with more than one HDMI port, the monitor is connected to a HDMI port that is not connected to the NVIDIA graphic card.</td><td>Identify the HDMI port connected to the graphic card and connect the monitor correctly.</td></tr>
<tr><td>X</td><td>X</td><td>X</td><td></td><td>Scanner is connected to a 2.0 USB port instead of a 3.0 USB port.</td><td>Find the 3.0 USB port and connect the scanner to it.</td></tr>
<tr><td>X</td><td>X</td><td>X</td><td></td><td>Windows is outdated.</td><td>Update your windows.</td></tr>
<tr><td></td><td></td><td></td><td>X</td><td>There is an antivirus improperly deleting system files.</td><td>Install the software again and add the software to the antivirus exceptions.</td></tr>
</table>

11.2.3. Proper use of resources

ROOT CAUSE CLASS	PROBLEM				POSSIBLE CAUSE	SOLUTION
	SLOWNESS	OVERLAPPING	LOW FILLING LEVELS	SOFTWARE NOT OPENING		
Proper use of resources	X	X	X		Computer has been turned on for many days.	Restart the computer.
	X	X	X		The computer has other softwares working on the background along with the scanner. Softwares as the web browser, virtual drivers, windows automatic updates, etc. reduce the performance.	Keep only the scanner's software working.
	X	X	X		Has the computer an active antivirus consuming ram processing storage?	Deactivate the antivirus consuming the system storage resources or consider choosing a better hardware option.
	X	X	X		The computer is sharing its screen while doing the scanning process. Sharing the screen or streaming videos of the the power WiFi screen may reduce the performance significantly depending on the computer hardware capabilities.	During scanning, ensure that only the laptop's built-in display or the desktop's primary monitor is in use.
	X	X	X		Small amount of free storage available on the hard disk.	Delete some files in order to have more storage available on the hard disk.
	X	X	X		The scanner's calibration may have been compromised in the event of a fall or impact.	Perform fine calibration using the dedicated probe.

11.2.4. Guidelines

ROOT CAUSE CLASS	PROBLEM				POSSIBLE CAUSE	SOLUTION
	SLOWNESS	OVERLAPPING	LOW FILLING LEVELS	SOFTWARE NOT OPENING		
Guidelines	X	X	X		USB cable is not directly connected to the computer. Usage of hubs or similar devices is not recommended.	Connect the scanner directly to the computer using a 3.0 USB port.
	X	X	X		Is the scanner's mirror dirty?	Clean the scanner.
	X	X	X		The scanning guidelines are not being followed.	Do the scanning process following the guidelines defined at a constant speed, smoothly.
	X	X	X		AI functionality is disabled to scan the patient's mouth.	Please, enable the AI to scan the patient's mouth
	X	X	X		AI is enabled to scan plaster models or prosthetic elements.	Disable the AI to scan plaster models or prosthetic element if necessary.
	X	X	X		The scanning location is highly illuminated. This scanner is an optical instrument and light interferes with the scanning process.	Reduce the local illumination.

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ELECTROMAGNETIC COMPATIBILITY

Alliage S/A Industrias Médico Odontológica
Phone: +55 (16) 98227-0297
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brasil

12. ELECTROMAGNETIC COMPATIBILITY (EMC)

The *intraoral scanner* is intended for use in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in such an environment.

The *intraoral scanner* is suitable for use in a professional healthcare environment, excluding areas where sensitive equipment or sources of intense electromagnetic disturbances are present, such as the RF-shielded room of a magnetic resonance imaging system, in operating rooms near active HF surgical equipment, electrophysiology laboratories, shielded rooms or areas where shortwave therapy equipment is used.

The following tables provide information on the equipment's compliance with EN 60601-1-2:2015+A1:2021.

12.1. GUIDANCE AND DECLARATION FOR ELECTROMAGNETIC EMISSIONS

<table>
<tr><th>EMISSIONS TESTS</th><th>COMPLIANCE</th><th>ELECTROMAGNETIC ENVIRONMENTS GUIDELINES</th></tr>
<tr><td>CISPR 11 RF emissions</td><td>Group 1</td><td>The intraoral scanner uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>CISPR 11 RF emissions</td><td>Class A</td><td rowspan="3">The intraoral scanner is suitable for use in all establishments except domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation/
Flicker emissions
IEC 61000-3-3</td><td>Compliant</td></tr>
<tr><td colspan="3">Note: The emission characteristics of this equipment make it suitable for use in industrial and hospital areas (IEC/CISPR 11, Class A). If used in a residential environment (for which IEC/CISPR 11, Class B is normally required), this equipment may not offer adequate protection to radio frequency communications services. The user may be required to take mitigation measures, such as relocating or reorienting the equipment.</td></tr>
</table>

12.2. GUIDANCE AND DECLARATION FOR ELECTROMAGNETIC IMMUNITY

PHENOMENON	EMC BASIC STANDARD OR TEST METHOD	IMMUNITY TEST LEVEL	COMPLIANCE LEVEL
Electrostatic discharge	IEC 61000-4-2	± 8 KV contact± 2 KV, ± 4 KV, ± 8 KV, ± 15 KV ar	± 8 KV contact ± 2 KV, ± 4 KV, ± 8 KV, ± 15 KV ar
Campos EM de RF irradiada	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM a 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM a 1 kHz
Nearby fields from RF wireless communications equipment	IEC 61000-4-3	See table	See table
Electrical fast transients/bursts	IEC 61000-4-4 ac power input	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency
	IEC 61000-4-4 signal input/output	± 1 kV 100 kHz repetition frequency	± 1 kV 100 kHz repetition frequency
Line-to-line surge	IEC 61000-4-5	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV
Ground-line surge	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	± 0,5 kV, ± 1 kV, ± 2 kV
Magnetic fields at the stated power frequency	IEC 61000-4-8	30 A/m 50 Hz ou 60 Hz	30 A/m 50 Hz ou 60 Hz

NOTE 1 At 80 MHz and 800MHz, the higher frequency range is applicable.

NOTE 2 These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 3 Conducted disturbances induced by RF fields are not applicable, since the equipment is internally powered and cannot be used while the battery is charging.

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 desvio de ± 5 kHz Senoidal de 1kHz	2	0,3	28
710	704-787	Band 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 scanner* is intended to produce high-quality digital intraoral examinations or models for dental restoration or analysis, and is for exclusive dental use. In case of MS disorders, the operator may experience the equipment interface locking up.

Compliance with EMC and EMI standards cannot be guaranteed by using altered cables or cables that do not comply with the same standards as the equipment was validated against.

Use of this equipment adjacent to other equipment should be avoided as this may result in improper operation. If such use is necessary, both this equipment and the other equipment should be observed to ensure that they are operating normally.

	Do not use accessories, transducers, internal component parts and cables other than those previously specified by the manufacturer. This may result in increased electromagnetic emission or decreased electromagnetic immunity and result in improper operation.
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used within 30 cm of any part of the *intraoral scanner*, including cables specified by the manufacturer. Failure to do so may result in degradation of the performance of this equipment.
	To maintain basic safety against electromagnetic disturbances during its expected service life, always use the equipment in the specified electromagnetic environment and follow the maintenance recommendations described in this manual.
	Pins, connector sockets or elements bearing the ESD warning symbol must not be touched or interconnected without ESD protective measures.

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