English

OWNER´S MANUAL

eagle.IOS

CE

DABI ATLANTE

Cód.: 77000001633 - Rev.:08

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INTRODUCTION TO THE MANUAL

Technical Name: Intra-Oral/Extra-Oral Camera
Trade Name: Intraoral Scanner
Model: Eagle IOS
Brand: Dabi Atlante

Technical Responsible: Daniel R. de Camargo
CREA-SP: 5062199650

ANVISA Registration nº: 10101130093

Alliage S/A Indústrias Médico Odontológica
Rodovia Abrão Assed, Km 53 + 450m - CEP 14097-500
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EC REP
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REF 77000001633 - Rev.: 08 - September/22

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GENERAL INFORMATION

Alliage S/A Industrias Médico Odontológica
Telefone: +55 (16) 3512-1212
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brasil

1.GENERAL INFORMATION

1.1.DEAR CUSTOMER

Congratulations on the excellent choice. When purchasing equipment with ALLIAGE quality, you can be assured of acquiring products with technology compatible with the world's best in its class. This manual gives you an overview of your equipment, describing important details that can guide you in its correct use, as well as in solving small problems that may eventually occur.
This manual must be read in its entirety and kept for future reference.

1.2.INDICATION FOR USE

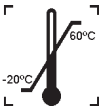
The Intraoral Scanner is a dental 3D scanner intended to be used to digitally record topographical characteristics of teeth and surrounding tissues. The system produces 3D scans for use in computer-assisted design and manufacturing of dentalrestorations.

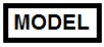
1.3.CONTRAINDICATION

None known.

1.4. SYMBOLOGY

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

	Fragile, handle with care		Maximum stacking
	Protect from rain		Temperature limit
	This side Up		Protect from sunlight
	Manufacturer		Manufacture Date
	ON/OFF button Turning the equipment on/off		Scanning process
	Stand by		USB plug
	General warning		Attention
	Mandatory action		Follow instructions for use
	It indicates that the product must be taken to a special waste collection point at the end of its useful life. It applies to both device and accessories.		Non-sterile (scanner tips)

	Optical radiation		Direct current
	Type B applied parts		Sterilizable in a steam sterilizer (autoclave) at specified temperature
	Recyclable		Serial number
	Model number		Model
	Catalog number		Electrostatic sensitive devices (ESD)
	Class II		Indicates that equipment complies with the regulation (EU) 2017/745 of the European Parliament and Council (MDR)
	Indicates which equipment complies with Directives 2011/65/EU and 2015/863/EU on the Restriction of Use of Certain Hazardous Substances in Electrical and Electronic Equipment.		Authorized representative in the European community

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WARNINGS, CAUTIONS AND RECOMMENDATIONS

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2. WARNINGS, CAUTIONS AND RECOMMENDATIONS

General warnings

	Read and understand all instructions contained in these instructions for use before installing or operating this equipment.
	Only use the 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 device body.
- Never operate the device in a humid environment.
- Keep the device away from radiators and heat sources.
- Use the device only with the supplied accessories.
- Do not alter the device or open the cabinets.

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

If one of the following conditions occurs, 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 work properly when the operating instructions are followed.

	Modification of the system could result in physical injury to the patient and operator and damage to the system.
	The Eagle IOS scanner should only be used with compatible and approved software. The Eagle IOS device is designed to operate with EagleClinic software.
	The intraoral scanner is sensitive to electrostatic discharge.

	In the event of a system malfunction or failure, you must: Prevent any contact between the system and the patient. Unplug the system from the electrical outlet and the computer. Store the system away so that it cannot be used by someone else. Contact the technical service.

	There is a risk of electric shock when opening or attempting to open any part of the system; only qualified service personnel should open parts of the system.

	Do not position the Intraoral Scanner in such a way that it is difficult to disconnect between the source and the power supply.

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 package must be pointing up;
• Do not stack above the amount indicated on the package;
• Protect against sunlight, moisture, water and dust;
• Observe temperature, pressure, and relative humidity limits.

During equipment installation

• Place the equipment in a location where it will not be in contact with 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 must not be subjected to excessive vibration or shock (including during transport and handling).
• This equipment is not designed for use in the presence of flammable anesthetic mixture vapors or nitrous oxide.
• Recommendations must be followed.
• Eagle IOS is factory calibrated and therefore does not require calibration when installed. If Eagle IOS starts having problems scanning and recognizing the tooth models, the system should be examined which may result in the system returning for repair/calibration.

Before using the equipment

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

While using the equipment

• Under no circumstances can 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's manual.
- Be familiar with the structure and fundamental functions of this equipment.
- Be familiar with the emergency protocols of this equipment.
- Be able to recognize irregularities in equipment operation and implement appropriate measures, when necessary.
• The patient should not touch parts other than those specified to be attended to.

• If this product is exposed to water, moisture, or foreign substances, turn it off immediately and contact an Alliage's Authorized Service Center.
• In case of damage or defect, do not use the equipment and contact an Alliage's Authorized Service Center.
• Do not use the equipment if any of its compartments or parts are damaged, lose or removed. Contact an Alliage's Authorized Service Center and request repair or replacement of any damaged, loose, or removed cabinets or parts from the equipment before using the equipment again.
• Do not touch the equipment or use it if it is being repaired or if the equipment cabinets have been removed.
• Do not open or remove any of the equipment cabinets. No internal parts are user serviceable.
• 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 an inclined surface. Place cables (power cord and USB cable) where people cannot accidentally get caught in them and potentially damage the system.
• In case of a fall or impact of moving parts causing them to break, be careful when handling them, there may be sharp parts.
• The operator cannot contact the patient when in contact with accessible connectors.
• The operator cannot use tools to open the equipment.
• During system operation, the handpiece and tip may become slightly hot; this is normal.

	If the scanner tip falls, check that the mirror is not damaged and not shifted; if the tip is damaged, it must be discarded immediately. If the scanner handpiece falls or collides, check that no part of the system is damaged as this may affect performance.
	The Eagle IOS system contains delicate optical and mechanical elements and therefore must be handled with care. Do not drop, bump, or shake the handpiece or tip. Always place the handpiece on 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 at the bottom of the handpiece must never be obstructed.
	Care must be taken not to apply unnecessary strain to the system cables, whether the power cable, the USB cable, or the cable between the handpiece and the Base.
	Only use the power adapter provided as part of 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.

Prevention of cross contamination

	Appropriate cleaning and disinfection measures must be taken to avoid crosscontamination between patients, users, and other people.

• For each new patient, perform cleaning and disinfection procedures as instructed in this manual.

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

After using / operating the equipment

• Turn off the equipment if not in use for a long time.
• All parts that have come into contact with the patient must be cleaned and disinfected with each new patient to prevent transmission of infectious agents that can cause serious illness.
• Carry out cleaning and disinfection according to the instructions contained in this manual.
• Do not disconnect the cable or other connections unnecessarily.
• Do not modify any part of the equipment.
• When not in use, always rest the handpiece on the base. Do not place the base on an inclined surface. Place cables (power cord and USB cable) where people cannot accidentally get caught in them and potentially damage the system.

Precautions in case of alteration of the equipment operation

If the equipment shows any abnormality, check if the problem is related to any item listed in the “Troubleshooting” topic of this user manual.
If it is not possible to solve the problem, turn off the equipment, contact an Alliage's Authorized Technical Assistance.

	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, because of incorrect installation and maintenance procedures not in accordance with the operating instructions accompanying the equipment.

Precautions in case of equipment failure

To avoid environmental contamination or misuse of the equipment, when it is rendered useless, they must be discarded (according to current legislation) in an appropriate place, as the materials inside can contaminate the environment.
For the European Economic Area (EEA), this product is subject to Directive 2012/19/EU as well as 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 device and accessories. Contact your dealer if final disposal of the product is required.

	This equipment must not be disposed of as household waste.

Precautions for reducing environmental impact

Alliage S/A aims to achieve an environmental policy to promote supply of environmentally conscious medical and dental products that continuously minimize environmental impact and that are friendlier to the environment and human health.
To maintain a minimal impact to the environment, consider the recommendations below:
• After installation, send the recyclable materials to the recycling process.
• During the life cycle of the equipment, turn it off when not in use.
• To prevent environmental contamination, the disposal of plastic protective covers and other consumables should follow the normal procedure for biomedical waste. Biomedical waste shall include non-acute materials which may cause diseases or suspicions of sheltering pathogenic organisms which should be stored in a yellow bag, duly labeled with a biohazard symbol, stored in a leak-tight, watertight container until collection and incineration.

	The Intraoral Scanner packaging consists of cardboard, plastic and expanded polystyrene (EPS) which are 100% recyclable materials.

DIMENSIONS: 140 x 360 x 370mm / MASS: Approximately: 5 kg

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SYSTEM GENERAL DESCRIPTION

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3. SYSTEM GENERAL DESCRIPTION

3.1. SYSTEM DESCRIPTION

The Eagle IOS Intraoral Scanner is designed and developed to produce high quality digital intraoral exams or models for dental restoration or analysis.

The Scanner is light, small, and easy to use, allowing for fast and accurate scanning.

The Eagle IOS must be handled by qualified and properly trained healthcare professionals, it can be used for the following indications:

- Anatomical crowns
- Copings
- Temporary crowns
- Anatomical pontics
- Reduced pontics
- Temporary pontics
- Inlays / Onlays
- Pillars for implants
- 3-unit implant bridges
- Bridges of up to 5 units
- Orthodontic aligners
- “Nightguards”
- Splints
- Retainers
- Bleach trays
- Sleep device

3.2. PRINCIPLES OF OPERATION

Eagle IOS is an optical printing system. It is used to record the topographical features of teeth, dental impressions, or physical models for use in computer-drawn projects (CAD) and assisted by computerized manufacturing (CAM) of dental restorative prosthetic devices.

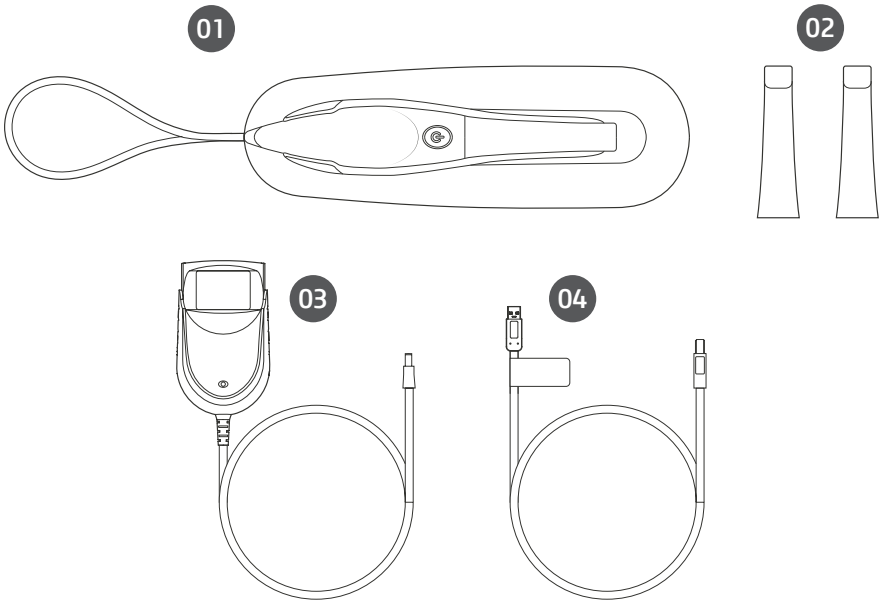
	Unintentional use of the system can result in physical injury to the patient and operator and damage to the system.

3.2.1. User Profile

The Eagle IOS Intraoral Scanner can be used by both sexes, with a minimum level of literacy with the ability to read and understand images, symbols, icons, western characters (Arial font), alpha numeric characters, and cannot present a degree of visual imperfection. for reading or vision and average degree of impairment of recent memory, not being in a clear capacity to perform the activities and functions of the product in a correct way for the profession. The user must be a qualified and trained health professional to perform the activities, functions frequently used in the application of the Intraoral Scanner and its primary operations functions.

3.3. MAIN PRODUCT COMPONENTS

3.3.1. Parts that come with the product



01 - Intraoral Scanner
02 - Scanner tip
03 - AC / DC power adapter
04 - 3.0 USB cable

⚠	Store the box: It is highly recommended that you store the box in a safe place and do not throw it away. The box is ideal for any necessary transportation or shipping of Eagle IOS.

⚠	The scanner body consists of the Base and Handpiece, connected by a flexible, non-removable cable.

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INSTALLATION

Alliage S/A Industrias Médico Odontológica
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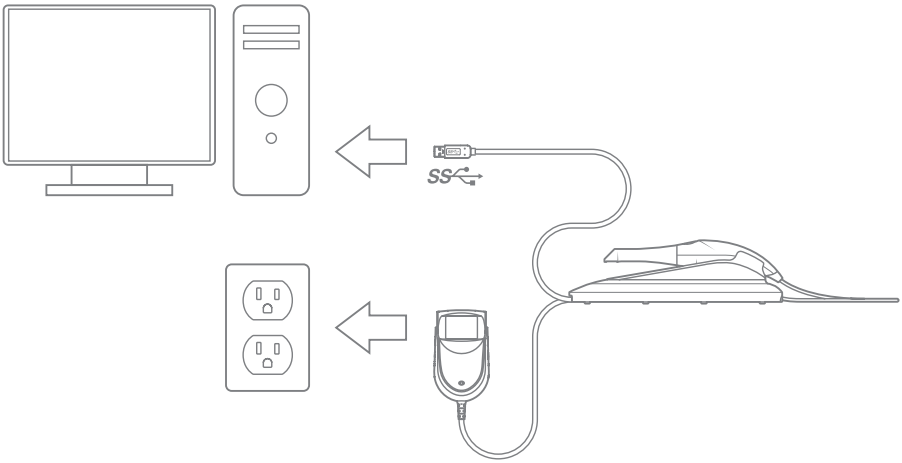
4. INSTALLATION

4.1. EAGLE IOS CONFIGURATION AND CONNECTION



COMPUTER REQUIREMENTS	
Operating system	Windows 10 or higher (excluding Windows 10 S, now defunct) Administrative rights required
Space on disk	100 GB of free disk space or more
Port	1 x USB 3.0 port (SuperSpeed)
CPU Type	Intel i7 - 4 cores or better (e.g., i7 8700)
CPU clock	2.8 GHz Clock or higher
Memory	16GB RAM or higher (DDR4 or higher)
GPU (Recommended)	Processador gráfico NVIDIA GeForce 10 Series (GTX): 1070 ou superior 10 Series (GTX): 1070 ou superior - Pelo menos 6 GB de memória de vídeo Série 20 (RTX): 2060 ou superior - Pelo menos 6 GB de memória de vídeo

	The computer must be approved by CE and must be in conformity with the standard EC 60950-1:2005 + AMD1:2009+AMD2:2013 and the Low Voltage 2014/35/EU and the EMC 2014/30/EU Directives. 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 to perform periodic backups on patient files and data to avoid loss of history in the event of a computer system failure.

	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. The computer equipments must be approved by CE and must be in conformity with the standard EC 60950-1:2005 + AMD1:2009+AMD2:2013 and the Low Voltage 2014/35/EU and the EMC 2014/30/EU Directives

Install the system according to the following steps:

Step 1: The installation will be done through technical support, with the opening of a ticket together with the customer.

Step 2: Place the base on a flat, stable surface and place the Eagle IOS Handpiece firmly on its base.

Step 3: Connecting the AC/DC power adapter cable to the database; the connector socket is located below the base.

Step 4: Connect the supplied USB 3.0 cable to the Base; the connector socket is located below the base.

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

Step 5: Connect the other end of the USB cable to the computer.

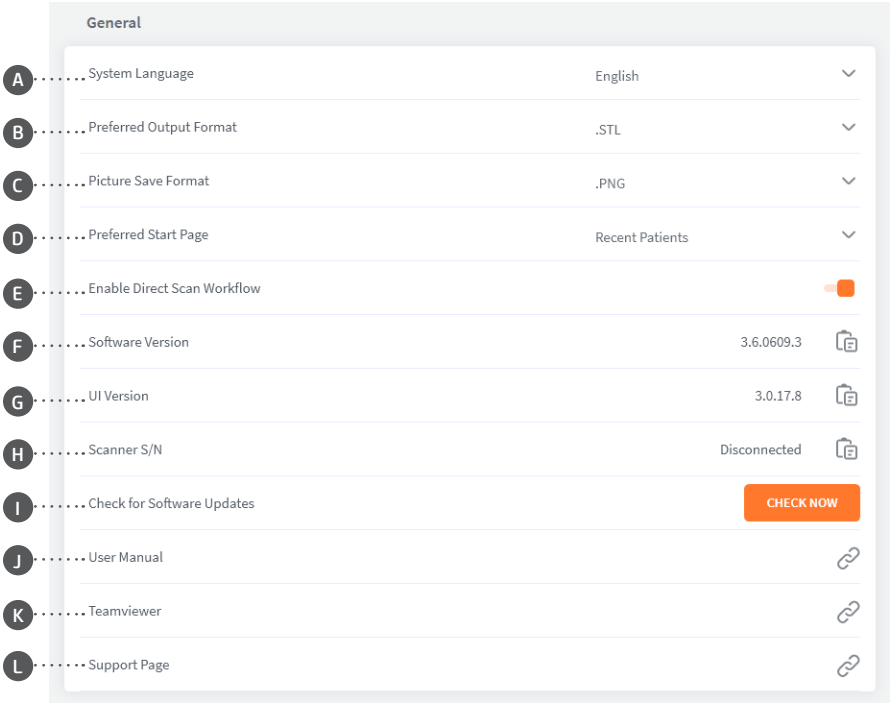
	It is highly recommended to connect the USB cable to a USB port located on the back of the computer; failure to do so may result in system malfunction or reduced performance. Be sure to use a USB 3.0 compliant USB port, failure to do so may result in system malfunction or reduced performance. If using a laptop, make sure the power supply is plugged into an outlet and not running on battery power.

Step 6: Plug the AC/DC power adapter into an outlet.

	Inappropriate installation locations: • Places with excessive humidity or dust; • Places subject to high temperature; • Places subject to agitation or vibration; • Locations exposed to considerable electrical or magnetic noise or other forms of electromagnetic energy.

4.2. SETTINGS

General



A. Language.

B. The 3D output format can be STL, PLY, OBJ.

C. Image formats can be PNG, JPG.

D. The preferred homepage can be chosen as Recent Patients or Recent Cases.

E. The Workflow Fast Scan can be enabled if Patient or If not required.

F. View software version (copy function on the right).

G. View UL version (copy function on the right).

H. View scanner serial number.

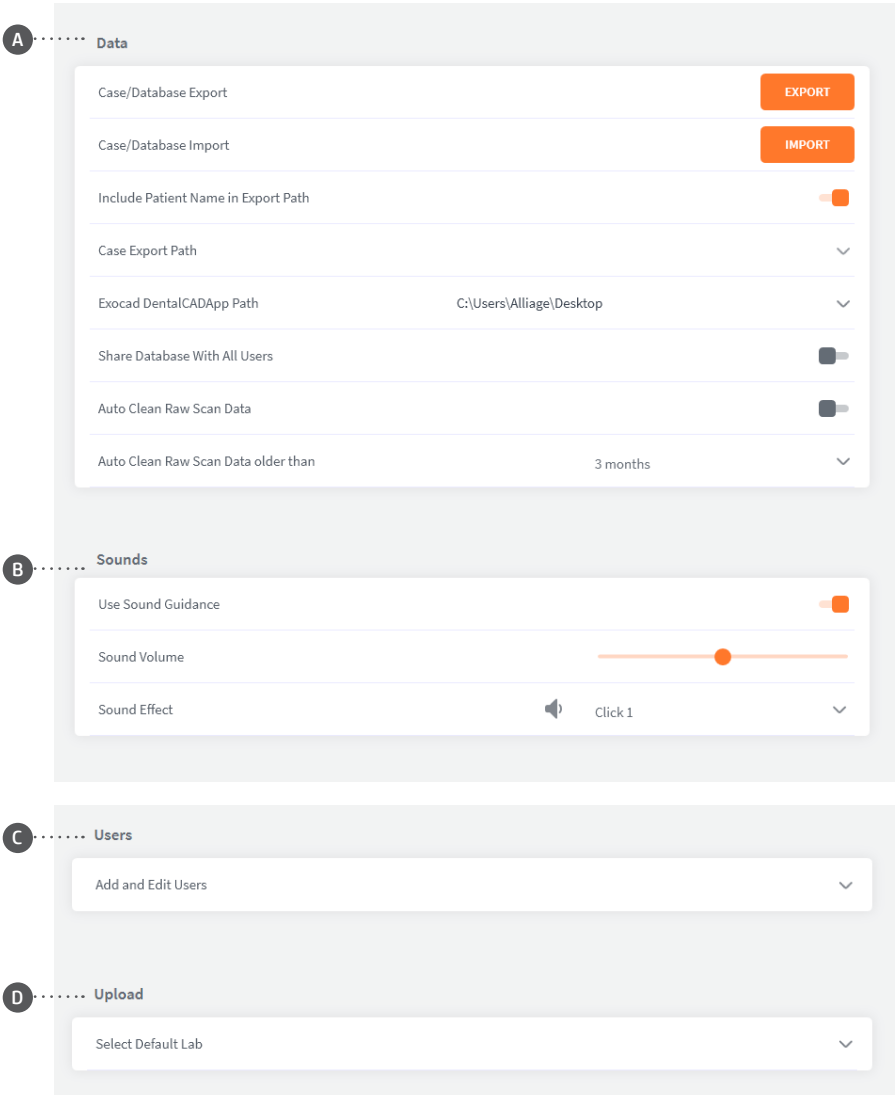
I. Manual software update check. Automatic verification is done on every release.

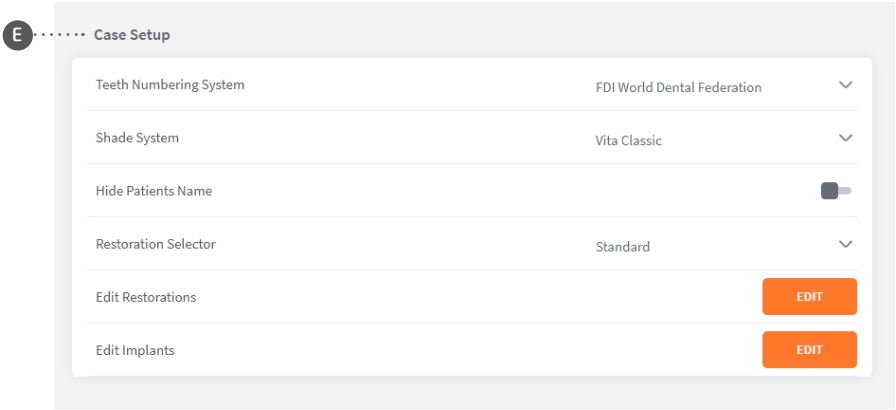
J. Link to user manual.

K. Link to remote access.

L. Link to support page.

System


A
Data
Case/Database Export
EXPORT
Case/Database Import
IMPORT
Include Patient Name in Export Path
Case Export Path
Exocad DentalCADApp Path
C:\Users\Alliage\Desktop
Share Database With All Users
Auto Clean Raw Scan Data
Auto Clean Raw Scan Data older than
3 months
B
Sounds
Use Sound Guidance
Sound Volume
Sound Effect
Click 1
C
Users
Add and Edit Users
D
Upload
Select Default Lab



A. System: The option to export or import the patient's database.

B. Sounds: Select to use sound during scanning. Pre-select volume and select between different sound effects.

C. Users: Add, edit, and delete users with name and image, it is also possible to add password to the user.

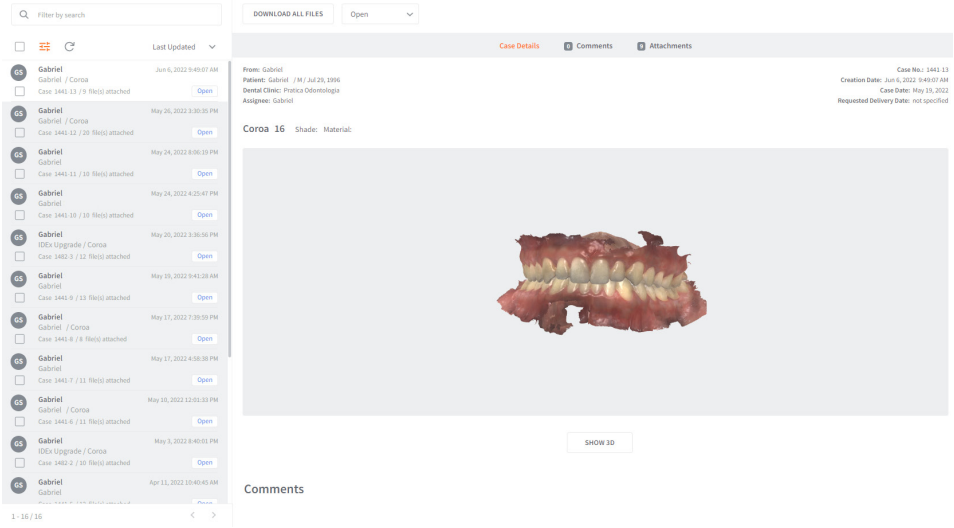
D. Lab Connections: Configure and select connections to the Lab. Also set the preferred lab as the default.

E. Order Form: Select tooth numbering system. The shadow system can be selected. Patient names can be hidden if necessary. New materials can be imported and exported. Special materials can also be created and edited.

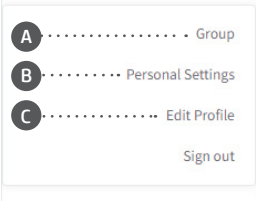
Cloud Storage

Eagle IOS has a file transfer cloud service which can be found at **eagleioscloud.com**.
Labs and users create an account and share files for free via the cloud, cases are stored for a period of 03 months in the cloud. Login will provide an overview of user created cases or cases sent to user with current status.
The interface supports the following languages: Portuguese, English and Spanish.

Connections with laboratories and dentists is managed by clicking the connections button.



Options for the Cloud

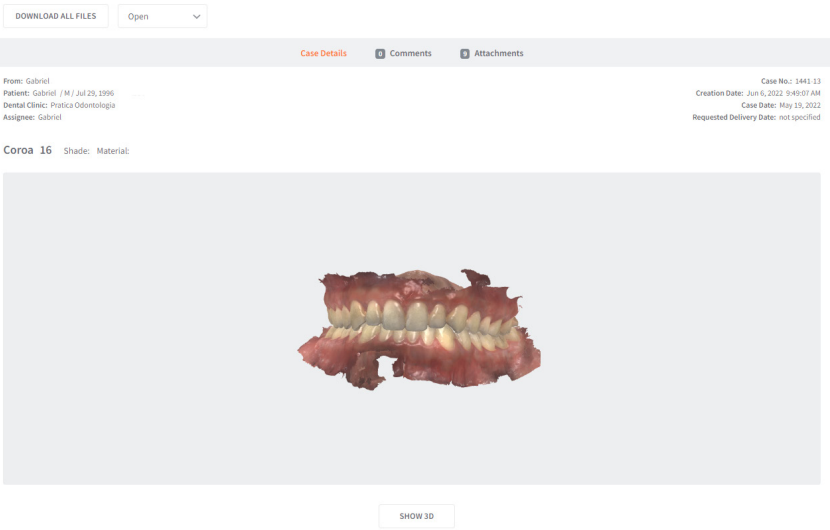


A. Groups can be created.

B. Settings can change the appearance of the case view.

C. Edit profile, allows you to edit data like name and email.

Opening a case from the list will show all the necessary information. Possibilities to change status, view scans in 3D Viewer, download and add files are found.



	If you need installation assistance, contact Alliage authorized technical support. Phone: +55 (16) 3512-1212 Address: Rodovia Abrão Assed, Km 53 + 450m - Recreio Anhangüera – Ribeirão Preto-SP/ Brazil CEP 14097-500

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OPERATION

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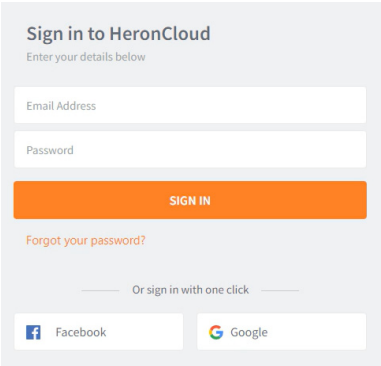
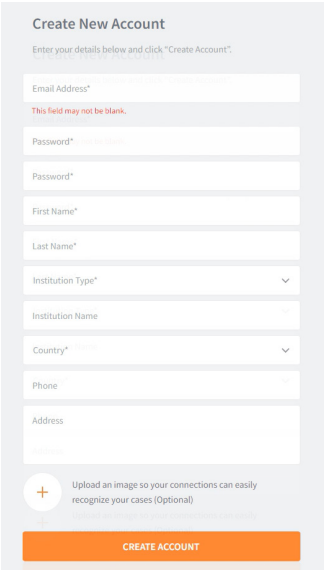
5. OPERATION

5.1. INTRODUCTION

Log in and create a new account

A new account must be created before it can be linked to a user in the software. On **eagleioscloud.com**, click "Create New Account". Fill in the required fields (marked with a red *) and click "Create". An email will be sent to confirm the email address. Click the confirmation link and you are ready to log in to the cloud.





5.1.1. Communication with the laboratory

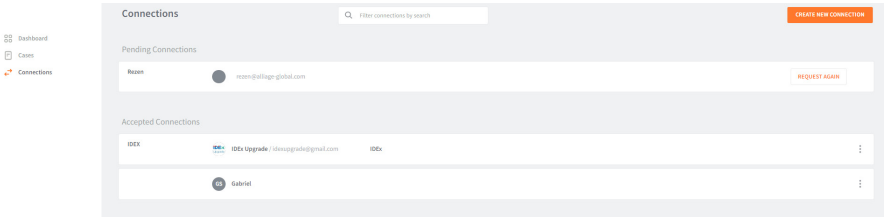
The EagleClinic application contains two internal methods of communicating with the laboratory. You can also:

1. Access the scans directly by clicking the "export files" tab. Select the desired files, drag and drop them on the desired platform;

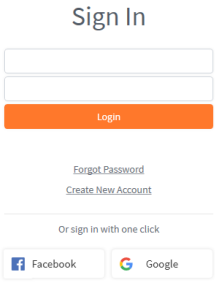
2. Use cloud storage;

2.a. Share files directly by locating the file in the "open in explorer" tab and copying the file to Dropbox, wetransfer.com, email etc.;

2.b. After creating your account, you can now connect to a lab by going to the connections menu and adding the connection;



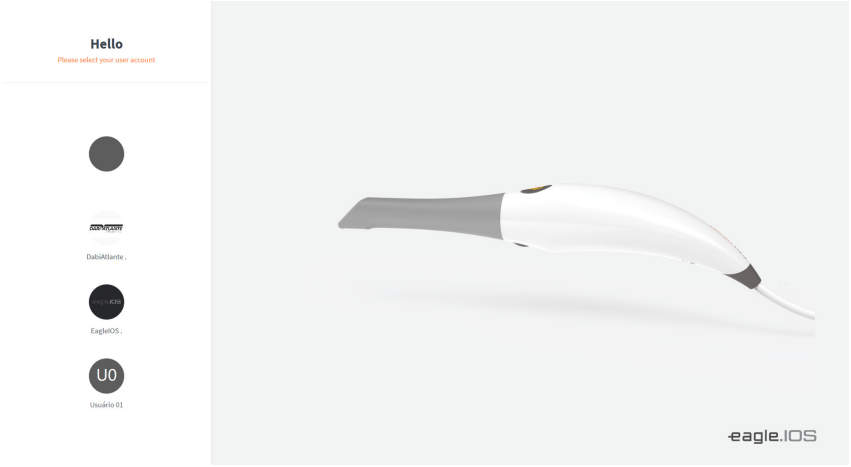
2.c. Add your cloud storage connection to the settings, your connected labs will now appear as options.



2.d. Submit cases via cloud storage on the checkout page, linking your cloud account to the software.

Login screen

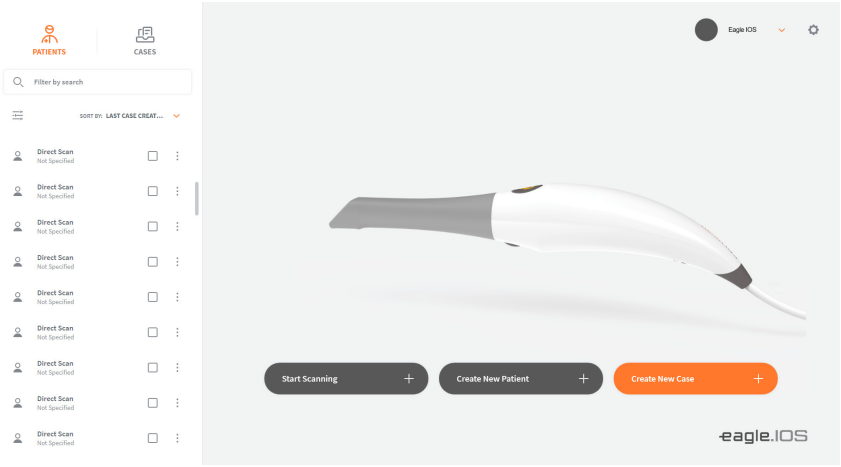
The user login page is the first page when the software starts. Select the user and enter the password if it is already configured.



5.1.2. Case management software overview

Patients on the home screen

When logged in, you will have Patients or Cases as the default view (selected in settings). Select an already created patient on the left side of the screen to view and/or create new cases for the patient.



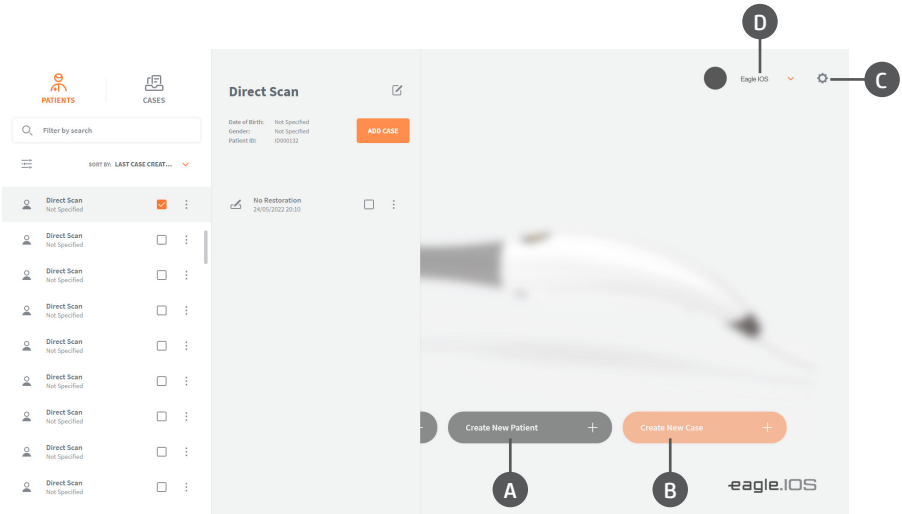
Home screen cases

Select an already created case to view the scans and proceed with all cases for the same patient.

Create a new patient (A) or case (B) using the buttons on the main part of the screen.

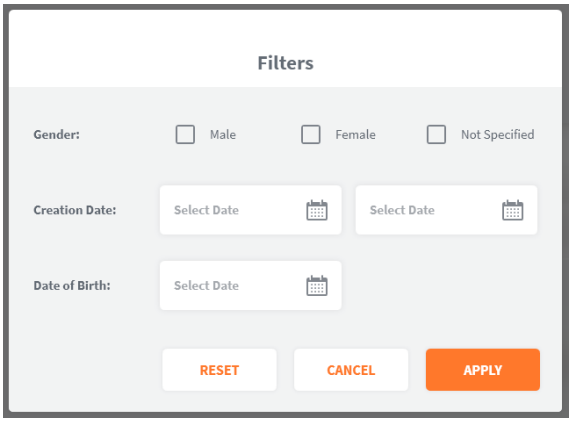
Settings

The settings are found in the upper right corner by clicking on the gearwheel (C). By clicking on the user in the upper right corner (D), you will be given the option to log out.



Filters

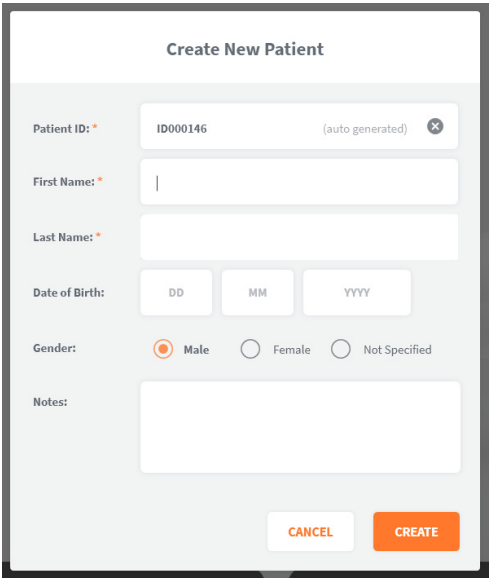
Patients and cases can be sorted with filters or with a search for a specific word/name. Filters are accessed through this buttono and have these options.



Creating a new patient

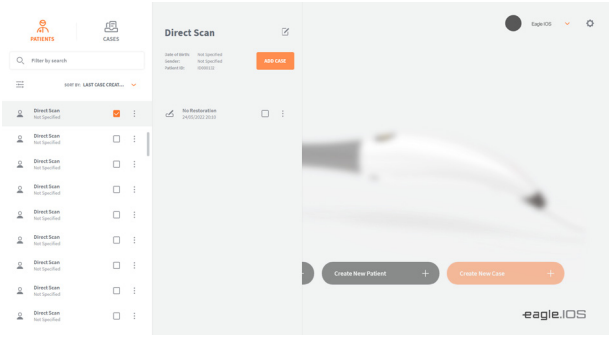
Creating a new patient will open the screen below. Fill in the data. The patient ID is created automatically, but you can switch to a different ID if necessary. First and Last name are required.

When filled in, click create and you are ready to create cases.



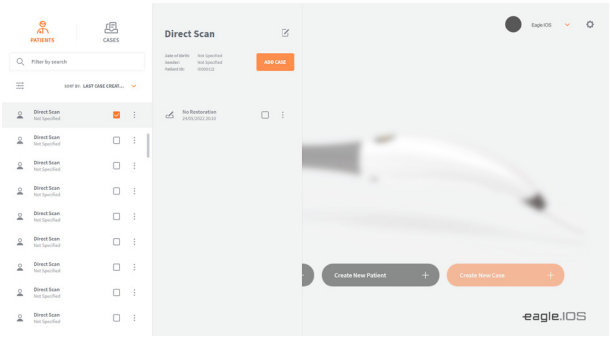
Delete a patient

You can delete a patient by clicking on the 3 dots to the right of the name and selecting Delete. Note that only patients without cases can be deleted, so any cases below the patient must be deleted first. This is done by clicking on the 3 dots next to the case. Multiple cases can be deleted simultaneously.



Create a new case when the patient is selected

When a patient is selected, a preview will be displayed with the name and the cases already existing in the patient. Here you also have the option to create a new case for the same patient by pressing "add case".



5.2. WORKFLOW INDICATIONS

EagleClinic supports the following restorations and equipment:

- Anatomical crowns - Copings - Temporary crowns - Anatomical pontics - Reduced pontics - Temporary pontics - Inlays / Onlays - Pillars for implants	- 3-unit implant bridges - Bridges of up to 5 units - Orthodontic aligners - Nightguards - Splints - Retainers - Bleach trays - Sleep device

5.2.1. Create new case

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

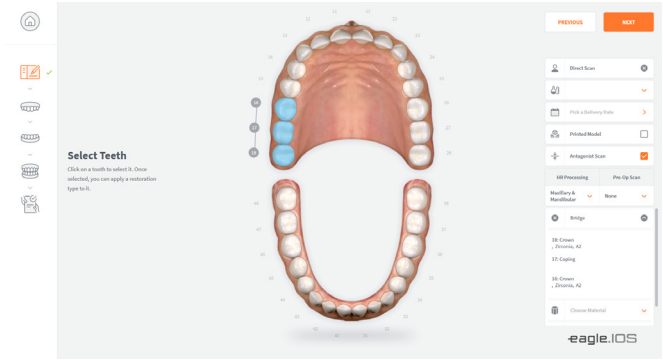
When creating a new case, the order form will be displayed. Verify the correct patient, selected laboratory, and desired laboratory due date.

Selecting the restoration

Select the teeth and choose the type of procedure. Teeth are selected by clicking on them and multiple teeth can be selected simultaneously. The antagonist is automatically selected but can be deselected if needed. Preoperative scanning can be selected if desired.

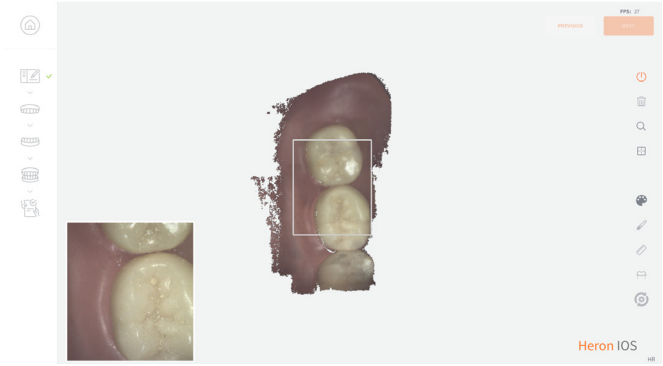
After selecting the procedure

Color and material are chosen. Note that a bridge is shown by the outer lines and dots beside the colored teeth.
Press Next when the Order Form is complete.



Scan Page

The live view window in the lower left corner shows what Eagle IOS is seeing. It can be changed in size, Small, Medium, and Large. The 3D construction of the scan is shown in the middle of the screen. You can capture 2D images by pressing “C”.



5.3. IMPORTANT TIPS BEFORE SCANNING

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

5.4. OPERATE THE SCANNER

5.4.1. Scanning Strategy

- Moving tissue is the issue:
Retract the lips, cheecks and tongue for a better experience.

- First path (Occlusal) is Key:
spend a sec per tooth.

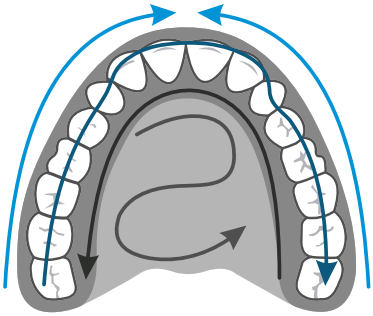
- To be precise, keep the scanner steady and steady.

Extra Tips:
- For Maxillary: rotate the tip so it's facing up.

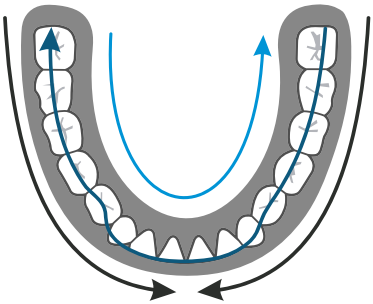
- When scanning the occlusal surface, also scan the buccal surface a little, especially in the region of the incisors.

- To fill the holes correctly, tilt the scanner in different directions.

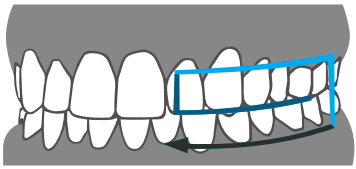
1. Occlusal 2. Buccal 3. Palatal



1. Occlusal 2. Lingual 3. Buccal

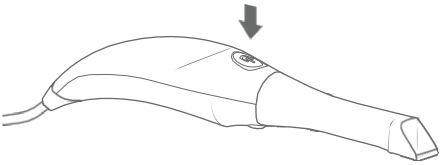


1. Line occlusal 2. Rotate to the upper gingival region 3. Rotate to the lower gingival region

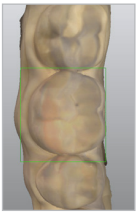


5.4.2. Scanning

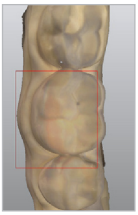
1. Start scanning:
To start scanning, press the button at the top of the scanner or click 'scan' in the right toolbar window. The recommended tip-to-tooth distance is 0 to 12 mm.



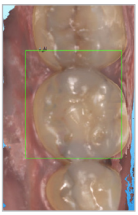
2. Green Image:
When the green box is present, it indicates that the scan is being performed successfully. To keep the indicator green, stay steady and precise with your movements.



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, unsteady handpiece movements, as well as a lack of cheek/tongue retraction.



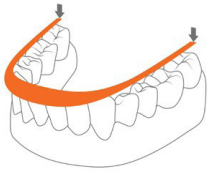
4. Restart:
If your scan has lost track, simply place the scan tip on the occlusal surface of an already scanned tooth. The occlusal surface has more detail and will allow the software to recognize its position quickly. Smooth surfaces are difficult to recognize as their surfaces are flatter.



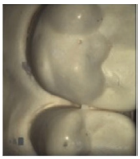
5.4.3. Mandibular and maxillary scanning

1. Start your scan starting at the arc of the chosen procedure. If you are scanning both arcs, you can select one of the arcs to start.

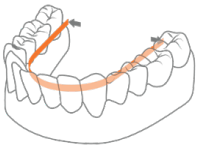
2.a. For a full arc, follow an occlusal, linear, and buccal scan path. Starting at the posterior terminal molar, working across the occlusal plane of the arc, you will end up at the opposite terminal molar. When scanning the anterior region, lightly roll the scanning tip at least 1 mm over the incisal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



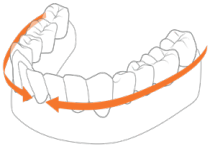
2.b. The live view window on the left is the main point of reference. During scanning, what is shown in the live window will appear in the 3D image. Make sure the anatomy of the tooth is centered in the viewport with little or no cheek or tissue present.



3. When finished scanning the occlusal, 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.



4. 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 arc on the buccal smooth 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 gum.



5. When scanning is complete, turn off the scanner by the power button on the top of the scanner. If scanning both arcs, select the other arc now in the software.

6. Repeat the same scan path and strategy for the remaining arc.

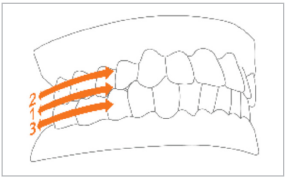
5.4.4. Bite alignment

In the case of a quadrant sweep, you will be prompted to sweep only the side of the quadrilateral. When scanning the full arc, you will be prompted to scan bilaterally.

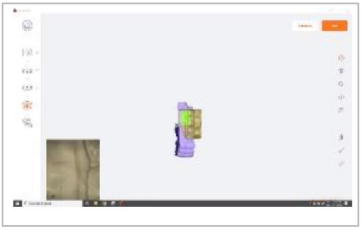
When selecting "bite", wait a few seconds for the arc sweeps to load.

1. Scanning the occlusion.

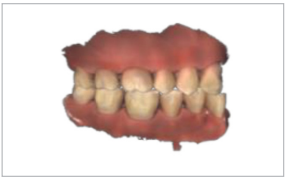
1.a. To capture the bite, you will begin scanning the central molars, capturing the mandibular and maxillary teeth on the first pass. Then scan only the maxillary molars and gum up to the arc.



1.b. When the arc is locked, the arc will get the initial sweep overlaid and a green checkmark will be displayed as described on the side, indicating that you have finished digitizing that arc. When the arc is complete, repeat the process for the opposite arc.

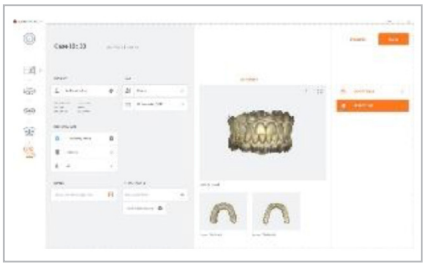


1.c. Once the bite alignment is complete, you can rotate the 3D image to confirm correct patient occlusion.



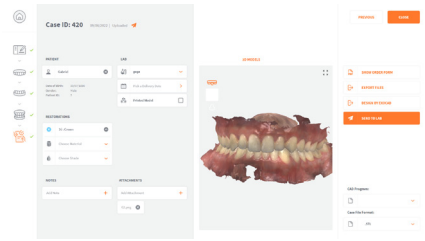
2. Wrapping Up

When the scan is complete, we get the overview of the case, including the 3D preview of the scans. Additional notes can be added and figures or similar can be attached to the case. If connected to a lab via cloud storage, the entire case can now be sent to the lab. In addition, scans and order form can be exported to a different location on the PC.

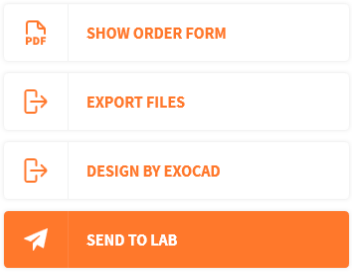


3D Viewer

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



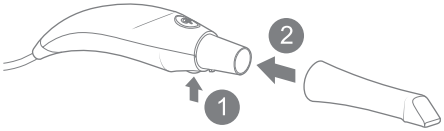
3. If you wanted to export the case to send it manually, access the files via the export file button.



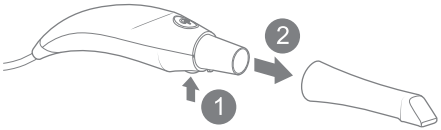
⚠	If the equipment disconnects or turns off without the operator's intervention, disconnect it from the electrical network and restart the entire operation. If the problem persists, contact the authorized technical assistance.

5.4.5. Tip

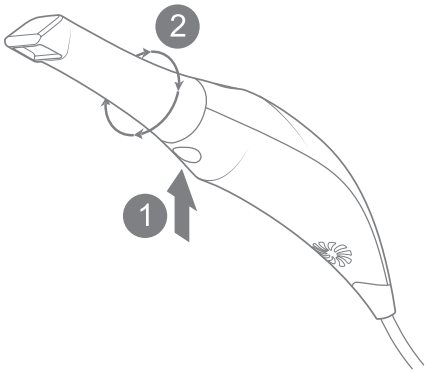
1. Secure the end with the mirror side facing down. Firmly press the tip into the scanner until you hear a click.



2. Release the tip by pressing the button located on the bottom of the handpiece (1) while moving away from the scanner (2).



3. Rotate the tip 180 degrees for maxillary scanning by pressing the button (1) located at the bottom of the handpiece.



⚠	It is not necessary to rotate the tip for maxillary scanning.

5.5. SCANNING TOOLS

A. Scanning
It allows scanning to start as well as scan pause.

B. Reset
Reset will delete the current scan.

C. Adjust the zoom level
You can change the zoom level (useful for touchscreens).

D. Screen centered scanning
Moves the scan to the center of the screen.

E. Color on/off
Switches between color scanning and thermal vision, highlighting poorly scanned areas.

F. Brush tool
Used to mark areas in the scan for modification/deletion.

G. Measuring tool
Place points to measure the distance.

H. Undercut Tool
It identifies retentive areas of the model through an insertion axis determined by the professional model or in general in the professional model.

6

CLEANING, DISINFECTION AND STERILIZATION

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6. CLEANING, DISINFECTION AND STERILIZATION

6.1. INTRODUCTION

	For your protection, during the cleaning and disinfection process of the equipment, use PPE such as disposable gloves and goggles.

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

6.2. CLEANING THE HANDPIECE

For the disinfection process of the equipment, use disinfectant detergent foam that has active components based on didecyldimethylammonium chloride.
Apply the disinfectant detergent foam on the surface or on a clean cloth and spread it over the surface to be treated. Respect the antimicrobial contact time specified by the manufacturer.
After application, let it dry. Do not rinse. Do not use disinfectant on the tip.

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

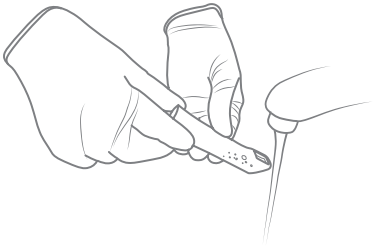
6.3. CLEANING AND STERILIZATION OF THE TIP

	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.

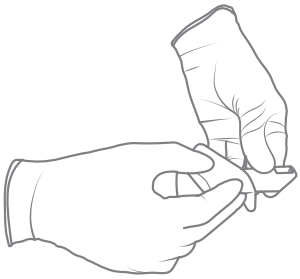
	Make sure the mirror surface does not show any residue, smudges, scratches, or any damage as this would affect the performance of the device.

Step by step procedure

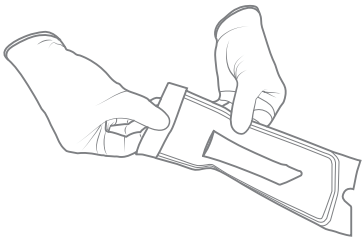
Step 1: Clean the tip with soap and water, ensuring the mirror is clean and free of dirt, smudges or any residue. Avoid using abrasive materials on cloth as this will scratch the mirror.



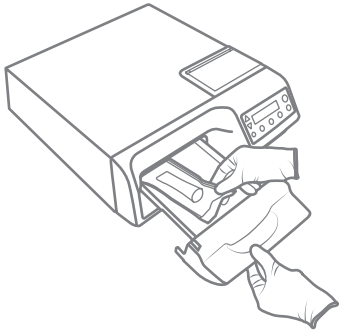
Step 2: After drying the outside of the tip, carefully dry the inside and mirror with lint-free wipes, ensuring you don't scratch the surface. The mirror must be free of visible debris or water spots.



Step 3: Insert and seal the tip in a sterilization package with the tip facing down so that water droplets do not accumulate on the mirror. Make sure the seal is airtight. Each tip must be individually packaged.



Step 4: Sterilize the wrapped tip in a steam autoclave.



135°C	Sterilization time minimum 30 minutes at 121 °C or minimum 3 minutes at 135 °C, and equivalent temperature and time parameters may be used within this range. Maximum sterilization temperature 135 °C.

Step 5: Make sure the drying cycle is complete before removing the tip from the autoclave. If the bag is damp, proper sterilization cannot be guaranteed.

⚠	Always autoclave the tip wrapped in a sealed sterilization bag; failure to do so will result in permanent smudges 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 during drying.
⚠	Do not remove the bag until the autoclave has completed its full drying cycle. If the bag is wet or shows any signs of moisture, it can leave water spots on the mirror, which can affect the image quality when scanning.
⚠	Be very careful when cleaning the mirror as it is very delicate and prone to scratches.

7

PROBLEM DIAGNOSIS, INSPECTION AND MAINTENANCE

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7. PROBLEM DIAGNOSIS, INSPECTION AND MAINTENANCE

7.1. TROUBLESHOOTING

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

UNFORESEEN CIRCUMSTANCE	SOLUTIONS
There is a memory full error message that appears when the software is open.	Clear some space on C Drive
The status in the live view window is "Disconnected".	Make sure you have external power for Eagle IOS and that the USB cable is plugged into a USB 3 port.
Scanning is too slow.	Make sure the laptop is connected to an external power source.
Corners are cropped in the live view window.	Make sure the tip is mounted correctly and when you turn it, it clicks into place.
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 scanned, but everything else (e.g., live window image, sounds, FPS) works fine.	The scanner may need to be recalibrated. Contact your local reseller for support.
There are dots in the live view window.	Check and clean the tip mirror.
Where can I get Eagle IOS software and manuals?	The Software accompanies 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's 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 any issues are detected and cannot be fixed with the instructions in the Troubleshooting section, 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 done by personnel familiar with the necessary precautions to avoid exposing the patient 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 should be checked and, if necessary, replaced.

ITEM	DESCRIPTION OF THE INSPECTION	RECOMMENDED FREQUENCY
Operation / Security System	Activation of the on / off button (Visual).	Daily
Electrical parts	Overheating/Noise/Burn Smell (Auditory and Visual).	Monthly
Parts and pieces	Operation/Noise/Vibration/Breaks (Auditory and Visual).	Monthly

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

7.3.PREVENTIVE MAINTENANCE

In addition to the annual inspection, to ensure a long durability and proper operation of your equipment, it is important to perform preventive maintenance in a maximum period of three (3) years.

Contact the Alliage Service Department about our periodic review and preventive maintenance program.

7.4.CORRECTIVE MAINTENANCE

	Do not open the equipment or try to fix it yourself or with the help of someone without training or authorization. This can aggravate the problem or produce a failure that may compromise the safety of the equipment.

	Power cables and electronic boards can be changed only by the authorized technician.

	The equipment or any of its parts may not be repaired, maintained, or assisted while being used on a patient.

	The service manual is only available for Authorized Technical Assistance.

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

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

8

STANDARDS AND REGULATIONS

Alliage S/A Industrias Médico Odontológica
Telefone: +55 (16) 3512-1212
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brasil

8. STANDARDS AND REGULATIONS

This equipment has been designed and manufactured to meet the following standards:

EN 60601-1:2006+A2:2021	Medical electrical equipment - Part 1: General basic safety and essential performance requirements
EN 60601-1-2:2015+A1:2021	Medical Electrical Equipment - Part 1-2: General Basic Safety and Essential Performance Requirements - Collateral standard: electromagnetic disturbances
EN 62471:2008	Photobiological safety of lamps and lamp systems
EN 80601-2-60:2020	Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment
EN 60601-1-6:2010+A2:2021	Electromedical Equipment - Part 1-6: General requirements for basic security and essential performance - Collateral standard: Usability;
EN 60601-1-9:2008+A2:2020	Medical electrical equipment - Part 1-9: General requirements for basic security and essential performance - Collateral standard: Requirements for environmentally conscious design
EN ISO 15223-1:2021	Graphic symbols for electrical equipment in medical practice
EN 20417:2021	Information provided by manufacturer of medical devices.
EN ISO 13485:2016+A11:2021	Quality management systems - Requirements for regulatory purposes
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and tests.
EN ISO 14971:2019	Medical Devices - Application of risk management to medical devices.

9

TECHNICAL SPECIFICATIONS

Alliage S/A Industrias Médico Odontológica
Telefone: +55 (16) 3512-1212
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brasil

9.TECHNICAL SPECIFICATIONS

9.1.EQUIPMENT CLASSIFICATION

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

EQUIPMENT CLASSIFICATION ACCORDING TO EN IEC 60601-1	
Product classification for applied parts	Type B
Protección Contra Descargas Eléctricas	Class II
Protection Against Harmful Water Penetration	IPX0 - Product not protected against harmful penetration of water and particulate matter
Safety degree of application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide	Equipment not suitable
Operation Mode	Continuous

9.2.DEVICE INFORMATION

GENERAL INFORMATION	
Connection to proper power supply network	External power supply
Network voltage	100-240 Vac (Bivolt)
Power	5 Vcc
Power network frequency	50 / 60 Hz
Current	4 A
Permissible fluctuation	+/- 10 %
Number of phases	Biphasic
Power consumption (VA)	120 VA - Momentary
Maximum network impedance	0,2 Ω
Base dimensions	Size: L 306mm, W 98mm, H 98mm
Scanner dimensions	Size: L 256mm, W 43mm, H 43mm
Scanner weight	150 grams
Scanner tip	Reusable, sterilized using steam autoclave (See item 6 of this manual)
Acquisition method	Intraoral camera - active stereo imaging
Color scanning	24-bit (8 bits per channel)

SCANNING PROCESS	
Tooth preparation	No powder or spray needed
Scanning principle	Continuously digitizing and accumulating (stitching) depth and color data
Scanner distance - tooth	0 - 12mm
Possible duration of contact by the operator	T ≤ 10 min Note: may vary depending on hardware configuration
Operator accessible part	Handpiece
Possible duration of patient contact	T ≤ 10 min
Patient accessible part (type B applied part)	Tip
Computer - Scanner Interface	USB 3.0

SOFTWARE AND LABORATORY INTEGRATION	
Output file format	STL, PLY, OBJ
Compatibility with CAD and CAM systems	Open architecture STL, PLY and OBJ output format. Compatible with most dental CAD systems
Application interface – case management	Touchscreen support

9.3.COMPUTER REQUIREMENTS

NECESSARY AND MISCELLANEOUS SOFTWARE	
Operating system	Windows 10 or higher (excluding Windows 10 S, now defunct) Administrative rights required
Space on disk	100 GB of free disk space or more
Port	1 x USB 3.0 port (SuperSpeed)

REQUIRED HARDWARE	
CPU Type	Intel i7 - 4 cores or better (e.g., i7 8700)
CPU clock	2.8 GHz Clock or higher
Memory	16GB RAM or higher (DDR4 or higher)
GPU	NVIDIA GeForce 10 Series (GTX): 1070 or better 10 Series (GTX): 1070 or better - At least 6GB of video memory 20 Series (RTX): 2060 or better - At least 6GB of video memory

	AMD GPUs are not compatible with Eagle IOS. Failure to meet the minimum hardware requirements will affect scanner performance.

9.4.ENVIRONMENTAL CONDITIONS

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

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

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WARRANTY

Alliage S/A Industrias Médico Odontológica
Telefone: +55 (16) 3512-1212
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brasil

10.WARRANTY

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

11

ALLIAGE'S AUTHORIZED SERVICES

Alliage S/A Industrias Médico Odontológica
Telefone: +55 (16) 3512-1212
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brasil

11.ALLIAGE'S AUTHORIZED SERVICES

All services performed on the Intraoral Scanner must be performed by an Authorized Technical Assistant, otherwise they will not be covered by the warranty.
If you need to request electrical diagrams and/or specification of components that are not stated in the user manual, please use Alliage's Customer Service to make the request.

Phone: +55 (16) 3512-1212
Address: Rodovia Abrão Assed, Km 53 + 450m - Recreio Anhangüera – Ribeirão Preto-SP/ Brazil CEP 14097-500

12

ELECTROMAGNETIC COMPATIBILITY

Alliage S/A Industrias Médico Odontológica
Telefone: +55 (16) 3512-1212
Rodovia Abrão Assed, Km 53 – CEP 14097-500 –Ribeirão Preto – SP –Brasil

12. ELECTROMAGNETIC COMPATIBILITY

The **Intraoral Scanner** is intended for use in the electromagnetic environment specified below. It is advisable that the buyer or user ensure that it is used in such an environment.

The **Intraoral Scanner** is suitable for use in a professional healthcare environment, not including areas where there are sensitive equipment or sources of intense electromagnetic disturbances, such as the RF-shielded room of a system for magnetic resonance imaging, in operating rooms near active PA surgical equipment, electrophysiology laboratories, armored rooms, or areas where shortwave therapy equipment is used.

The following tables provide equipment compliance information at EN 60601-1-2:2015+A1:2021.

12.1. ORIENTATION AND DECLARATION FOR ELECTROMAGNETIC EMISSIONS

<table>
<tr><th>EMISSIONS TESTS</th><th>COMPLIANCE</th><th>ELECTROMAGNETIC ENVIRONMENTS - GUIDELINES</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The Intraoral Scanner use RF energy only for their internal functions. Therefore, its RF emissions are extremely low and are unlikely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">The Intraoral Scanner are suitable for use in all establishments, except domestic ones and those directly connected to the public low voltage power supply network that powers 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 /
Scintillation 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 areas and hospitals (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 provide adequate protection for radio frequency communication services. The user may need to take mitigation measures, such as relocating or redirecting equipment.</td></tr>
</table>

12.2. GUIDANCE AND DECLARATION FOR ELECTROMAGNETIC IMMUNITY

PHENOMENON	BASIC EMC 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 air	± 8 KV contact ± 2 KV, ± 4 KV, ± 8 KV, ± 15 KV air
EM fields of radiated RF	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
Fields in the vicinity from RF wireless communications equipment	IEC 61000-4-3	See table	See table
Fast / saved electrical transients	IEC 61000-4-4 alternating current 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
Outbreak Line by line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV
Land line outbreak	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	± 0,5 kV, ± 1 kV, ± 2 kV
Magnetic fields at the stated feed frequency	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz
NOTE 1 At 80 MHz and 800MHz, the higher frequency range is applicable. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. NOTE 3 Conducted Disturbances Induced by RF Fields Test not applicable, as the equipment is internally energized and cannot be used during battery 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	18Hz pulse modulation	1.8	0.3	27
450	430-470	GMRS 460,FRS 460	FM deviation of ± 5 kHz 1kHz sinusoidal	2	0.3	28
710	704-787	Band LTE 13, 17	217 Hz pulse modulation	0.2	0.3	9
745						
7480						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, Band LTE 5	18Hz pulse modulation	2	0.3	28
870						
930						
1720	1700 -1990	GSM 1800; CDMA 1900; GSM 1900; DECT; Band LTE 1, 3, 4, 25; UMTS	217 Hz pulse modulation	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, Band LTE 7	217 Hz pulse modulation	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	217 Hz pulse modulation	0.2	0.3	9
5500						
5785						

The Intraoral Scanner is intended to produce high quality digital intraoral exams or models for dental restoration or analysis, and it is for dental use only. In case of EMC disturbances, the operator may experience equipment interface crash.

Compliance with EMC and EMI standards cannot be guaranteed by the use of altered cables or cables that do not meet the same standards as the equipment has been validated.

	The use of this equipment adjacent to other equipment should be avoided as this may result in improper operation. If this use is necessary, it is advisable that this and other equipment be observed to verify that they are operating normally.

	Do not 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, resulting in improper operation.

	Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used less than 30 cm from any part of the Intraoral Scanner, including cables specified by the manufacturer. Otherwise, performance degradation of this equipment may occur.

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

	Pins, connector sockets, or elements bearing the ESD warning symbol must not be touched or interconnected without ESD protection measures.

LIST OF USED CABLES		
CABLES	DESCRIPTION	LENGTH
Power	Power supply cable AWM 1185 16AWG, 80ºC, 300V, 2 Way	1,75 m

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