English

OWNER´S MANUAL

Portable Dental X-Ray

SAEVO

Cód.:77000001704 - Rev.:01

MANUAL PRESENTATION

GMDN: 44606 Hand-held intraoral dental x-ray system, digital

Technical name: Dental X-ray Equipment

Trade name: Portable Dental X-Ray

Models: AXR60 H

Brand: Saevo Air X-Ray / Saevo

Basic UDI-DI: 78995813X-rayAXR60H79

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

ANVISA Registration nº: 10101130092

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REF 77000001704 - Rev.: 01 - November/22

Document originally written in Portuguese.

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The performance characteristics provided in this manual are for reference only and should not be considered as guaranteed specifications.

SUMMARY

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GENERAL INFORMATION

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1. GENERAL INFORMATION

1.1. DEAR CUSTOMER

Congratulations on your excellent choice. By buying ALLIAGE quality equipment, rest assured you have bought technology products compatible with the best in its class.

This manual offers you a general presentation of your equipment, describing important details that may guide you in its correct use, as well as in the solution of small problems that may eventually occur. No additional training is required beyond your own reading.

This manual should be read in full and kept for future reference.

1.2. INDICATION FOR USE

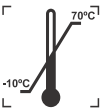
The Portable Dental X-Ray is intended for the production of oral anatomy radiological images, including teeth, maxillofacial areas, oral and bone structures, for exclusive dental use, and should be handled by qualified and trained health professionals.

1.3. CONTRAINDICATION

This equipment is contraindicated for people on radioiodine treatment of thyroid cancer.

1.4. SYMBOLS

The following symbols are used throughout this manual and in the product itself. Make sure you fully understand each symbol and follow the accompanying instructions.

	Fragile, handle with care		Maximum stacking
	Protect from rain		Temperature limit
	This side up		Protect from sunlight
REF	Catalogue number	MODEL	Model name
#	Model number	SN	Serial number
	Manufacturing date		Manufacturer
LOT	Lot number		Do not remove covers. Maintenance must only be carried out by an authorized technician.
MD	Medical device	UDI	Unique Device Identification
	Direct current		Type B applied parts

	Class II		It indicates that the product should be taken to a special waste collection site at the end of its useful life. It applies to both the device and accessories
	Presence or Potential presence of Ionizing Radiation/Physiological Effect		Focal Point
	Focal Point Position		General warning
	Warning; Electricity		Warning; Ionizing Radiation
	Refer to the instruction manual		Mandatory action
	Attention		Recyclable
	Electrostatic-sensitive devices (ESD)		It indicates that the product has undergone an assessment, and that standards or regulations developed for the product category have been observed in its design/manufacture/placement on the market
	It indicates that this product has been assessed for specific properties, a limited range of risks or suitability for use under limited or special conditions by the UL		Standby Starts or disables the equipment

	Selection		Patient profile
	Receiver		Tooth profile
	Increases		Decreases
	**Ready to operate** It indicates that the equipment is ready to receive any operation		Trigger
	Emission of ionizing radiation		Decreasing temperature (cooling)
	Error		**Free configuration** It indicates that the exposure time has been changed by the user
	Adult patient		Child patient
	Digital sensor		Analogue film

	Phosphorous plate		Occlusal
	Lower Molar / Lower Premolar		Upper Molar / Upper Premolar
	Lower Incisor		Upper Incisor
	Battery out of charge		Battery with reduced charge
	Battery with medium charge		Battery with full charge

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WARNINGS, CAUTIONS AND RECOMMENDATIONS

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2. WARNINGS, CAUTIONS AND RECOMMENDATIONS

General warnings

	Read and understand all instructions in these instructions for use before installing or operating this equipment.

	Use only the equipment in perfect condition and protect yourself, patients and others from possible dangers.

	This equipment must be installed and operated by personnel familiar with the necessary precautions to avoid excessive exposure to both primary and secondary radiation.

	The Portable Dental X-Ray has the following five different user interactions: - Identification and safety plate: Located at the bottom of the equipment; - LCD panel: located at the top of the equipment; - Membrane keyboard: located at the top of the equipment; - Local exposure button: located at the front of the equipment; - Remote exposure button: located outside the operating area;

During transport

The equipment must be transported and stored according to instructions:
- Handle with care to avoid falls and impacts.
- The arrows on the packaging should be pointing upwards.
- Do not stack above the quantity indicated on the package.
- Protect against sunlight, moisture, water and dust.
- Observe the temperature, pressure and relative humidity limits.

During equipment installation

	The installation instructions can be found in this user manual.

• The equipment must not be subjected to excessive vibration or shock (including during transport and handling).
• Install the equipment in a place where it will not be in contact with moisture, water, plants and animals.
• Install the equipment in a location where it will not be damaged by pressure, temperature, humidity, direct sunlight, dust, salts or corrosive products.
• This equipment was not designed for use in the presence of vapours from flammable anaesthetic mixtures or nitrous oxide.
• Place any other external devices at least 1.5 meters away from the X-ray unit so the patient cannot touch it while being X-rayed.
• This manual's recommendations regarding the EMC should be followed. Communications equipment and RF generating sources can affect the operation of the equipment.
• The equipment can cause radio interference or interrupt the operation of nearby equipment, making it necessary to take mitigating precautions, such as reorientation, relocation of equipment or shielding the location.
• Depending on local regulations, the remote exposure control should be installed in a radiation-protected area by means of a fixed barrier or an X-ray protection screen, so the operator is protected during the radiographic exposure process and has visual contact with the patient.
• Installation in Brazil must comply with the requirements of RDC No. 330, of 20 December 2019 and IN No. 57, of 20 December 2019 of the Agência Nacional de Vigilância Sanitária [Brazilian Health Regulatory Agency].

Before using the equipment

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

While using the equipment

	No part of the equipment should touch the patient during use.

	Do not remove the covers. High internal voltage. Danger of Electric Shock.

	Do not use hand straps and neck straps to transport and move the equipment.

• Under no circumstances can the patient operate the unit.
• The equipment should only be operated by qualified health professionals with knowledge regarding precautions against excessive radiation exposure.
• To operate the unit, operating personnel must:
- Read and understand the user manual.

- Be familiar with this unit's fundamental structure and functions.
- Be familiar with this equipment's emergency situation protocols.
- Be able to recognise irregularities in the operation of the unit and implement appropriate measures when necessary.
• The equipment has been designed in accordance with electromagnetic compatibility standards but, in very extreme conditions, it may cause interference with other equipment. Do not use this equipment together with other devices very sensitive to interference or with devices that create high electromagnetic disturbances.
• This equipment is not recommended for the display of cartilage structures and soft tissue exposure.
• Depending on local regulations, during exposure, the operator must position themselves at least 3 meters away from the X-ray unit, in order to reduce the amount of ionizing radiation absorbed, maintaining visual contact with the patient and the unit throughout the exposure.
• The equipment must always be operated with a protective shield close to the patient, aiming to block and protect the operator and third parties from the scattered radiation generated by the equipment during radiographic exposure.
• In case of risk to the patient, cancel the exposure immediately by releasing the exposure button.
• If this product is exposed to water, moisture or foreign substances, switch it off immediately and contact an Alliage Authorized Service Centre.
• In case of damage or defect, do not use the equipment and contact an Alliage Authorized Service Centre.
• Do not use the unit if any of its compartments or parts are damaged, lose or have been removed. Contact an Alliage Authorized Service Centre and request the repair or replacement of any damaged, loose or removed enclosures or parts of the unit before using it again.
• Do not touch the unit or use it if it is being repaired or if the unit's cabinets have been removed.
• Do not open or remove any of the unit's enclosures. No internal parts can be repaired by the user.
• In the event of a fall or impact causing the unit to break, be careful when handling them as there may be sharp parts.
• Do not touch connectors accessible when in contact with the patient.

During battery handling

	Batteries cannot be replaced by users.

For battery handling, operating personnel must:
• Charge the battery outside and away from the patient.
• Use only batteries supplied or approved by Alliage. If non-standard or damaged batteries are used, there is a risk of fire and explosion.
• Use only a battery charger supplied or approved by Alliage. Use of an unauthorized charger may result in battery damage.
• Do not expose batteries to heat or fire. Avoid storage under direct sunlight.
• Do not short-circuit, crush, puncture or disassemble the battery.
• Do not subject the battery to mechanical shock.
• Do not store the batteries in a place where they may come into contact with metallic objects and cause short circuit.
• Keep the battery away from children and pets.
• Do not wet the battery or leave it in the water. Keep the batteries clean and dry.

	If the equipment is not to be used for long periods of time, it is recommended to charge the battery before use. After long periods of storage, it may be necessary to charge and discharge the batteries several times for maximum performance.

	DO NOT leave the battery charging for long periods when not in use.

	In case of leakage of the battery cells, make sure the liquid does not come into contact with the skin or eyes. In case of leakage, wash the affected area with large amounts of water and seek medical assistance.

Radiation protection

	Protective measures against ionizing radiation and residual radiation to avoid side effects to users and operators must be taken. The country's legal guidelines should be followed to avoid unnecessary exposure.

	The lead apron and thyroid collar are not included with the equipment.

• Exposure to X-rays can cause damage to cells in the human body.
• Radiation protection equipment should be used to reduce the patient's radiation exposure, specifically paediatric and pregnant patients.
• The patient and operator should wear a lead apron and thyroid collar during exposures.
• The use of X-ray equipment in pregnant women is not recommended without medical authorization.
• A patient with a cardiac pacemaker or an implantable cardioverter-defibrillator (ICD) should consult its manufacturer before performing an exposure to confirm that the X-ray unit will not interfere with its operation.
• Exposure to X-rays can cause damage to cells in the human body. Thus, radiation protection equipment should be used in order to reduce the patient's radiation exposure, especially paediatric patients. It is recommended to wear a bismuth or a lead apron or vest during exposures.
• No person should remain in the room during an exposure, unless the patient needs to be restrained. In this case, a third person must be adequately protected against the emission of ionizing radiation.
• During an exposure, the operator must position themselves as follows:
- inside the protection area, immediately behind the protective shield wearing individual protection equipment and properly protected against the emission of ionizing radiation.
- as far as possible from the focus of the X-ray generator, maintaining a minimum distance of 3 m or
- behind a physical barrier, to reduce as much as possible the amount of ionizing radiation absorbed.
• Maximum protection against scattered radiation exists when the equipment is positioned close to the patient and perpendicular to the operator and the protective shield parallel to the operator.

Prevention against cross-contamination

	Appropriate cleaning and disinfection measures should be taken to avoid cross-contamination between patients, users and others.

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

After using / operating the equipment

• Turn off the equipment if it is not in use for a long time.
• All parts that come into contact with the patient, operator or third parties or with bodily fluids such as saliva and blood should be cleaned and disinfected with each new patient to prevent transmission of infectious agents that can cause serious diseases.
• Clean and disinfect the equipment according to the instructions contained in this manual.
• Do not unplug the cable or other connections unnecessarily.

Precautions in case of changes to the equipment's operation

If the equipment has any abnormalities, check if the problem is related to any item listed in the "Troubleshooting" section of this user manual.

If the problem cannot be solved, disconnect the equipment, disconnect the cables and contact an Alliage Authorized Technical Assistance.

	The manufacturer is NOT responsible for: • The equipment being used for purposes other than those for which it was designed. • Damage caused to the equipment, operator and/or patient as a result of incorrect installation and maintenance procedures contrary to the operating instructions accompanying the equipment. • Improper equipment operation. • No changes to this equipment are permitted.

Precautions for reducing environmental impact

Alliage S/A aims to achieve an environmental policy to promote the supply of environmentally conscious medical and dental products that continuously minimize environmental impact and are more friendly to the environment and human health.

To maintain a minimal environmental impact, observe the following recommendations:
• After installation, dispose of the recyclable materials at a recycling station.
• During the life cycle of the equipment, switch it off when it is not in use.

	The Portable Dental X-Ray packaging consists of cardboard, plastic and polyethylene (PE) that are 100 % recyclable materials.

DIMENSIONS:
275 X 221 X 308 /MASS: Approximately: 3,0 Kg

Precautions in case of unusable equipment

To avoid environmental contamination or improper use of the Portable Dental X-Ray equipment, when rendered unusable, it should be disposed of (according to current legislation) in an appropriate place, since 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 the corresponding national laws. This directive demands that the product should be taken to a special waste collection site at the end of its useful life. It applies to both the device and accessories, including the battery.

Contact your dealer if a final product disposal is required.

	This equipment should not be disposed of as household waste.

	DO NOT dispose of batteries as household waste. Send the batteries for disposal or recycling in accordance with local government regulations.

3

SYSTEM OVERVIEW

Alliage S/A Industrias Médico Odontológica
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3. SYSTEM OVERVIEW

3.1. PRODUCT DESCRIPTION

The Portable Dental X-Ray is an X radiation controlled emissions generator system, i.e., once put into service, is intended to be moved from one location to another by a person, used together with appropriate capture devices to generate intraoral radiological images for dental assessment, diagnosis and treatment.

This equipment has exposure programmes that can be applied to a variety of patients and has predefined exposure parameters depending on the type of patient. The operator is free to change these parameters depending on the situation.

The equipment's human-machine interface consists of a control panel located on the top of the equipment, a local trigger button and a remote trigger. The triggers are “dead-man” triggers, meaning they release and interrupt the exposure.

The Portable Dental X-Ray was designed to be used in adult and children patients by trained dentists and dental technicians to produce X-ray images for diagnosis.

3.2. APPLICATION SPECIFICATION

The Portable Dental X-Ray is indicated for the production of intraoral medical images of teeth, mandible and oral structures; it assists in the diagnosis of diseases, planning of surgical treatment and monitoring of non-invasive and painless therapy; it is exclusively for dental use, and must be used and handled by qualified and trained health professionals according to the User Manual.

3.2.1. Principles of operation

The Portable Dental X-Ray is an autonomous X-ray emitting system, used to produce radiographic images. The X-ray beam passes through the patient's body, where a part of the X-rays is absorbed or spread by internal structures, and the rest of the X-rays are transmitted to a detector (e.g., a film, digital sensor or phosphorous plate) for recording or further processing by a computer. The mechanism that provides the generation of electromagnetic X-ray waves in the equipment is an X-ray ampoule or Coolidge tube. The interior of the glass ampoule is kept in vacuum and has two electrodes: a cathode and an anode. In the cathode, there is a filament that, when crossed by an electric current, generates heat. Once heated, the filament emits electrons through thermionic effect. These electrons are accelerated towards the anode due to a potential difference between these electrodes. When the electrons reach the anode, they suffer a sudden deceleration and their kinetic energy is, for the most part, converted into heat and X-rays by means of the Bremsstrahlung phenomenon.

3.2.2. Significant physical characteristics

The mechanism that generates the electromagnetic X-ray waves has a 60 kV power and an anodic current of 2.5 mA, generating hard and soft X-rays. For radiology purposes, soft X-rays are not adequate and the patient's exposure to them is unnecessary. To minimize this effect, the equipment has an aluminium bulkhead in its tube, which “filters” the radiation to which the patient is exposed.

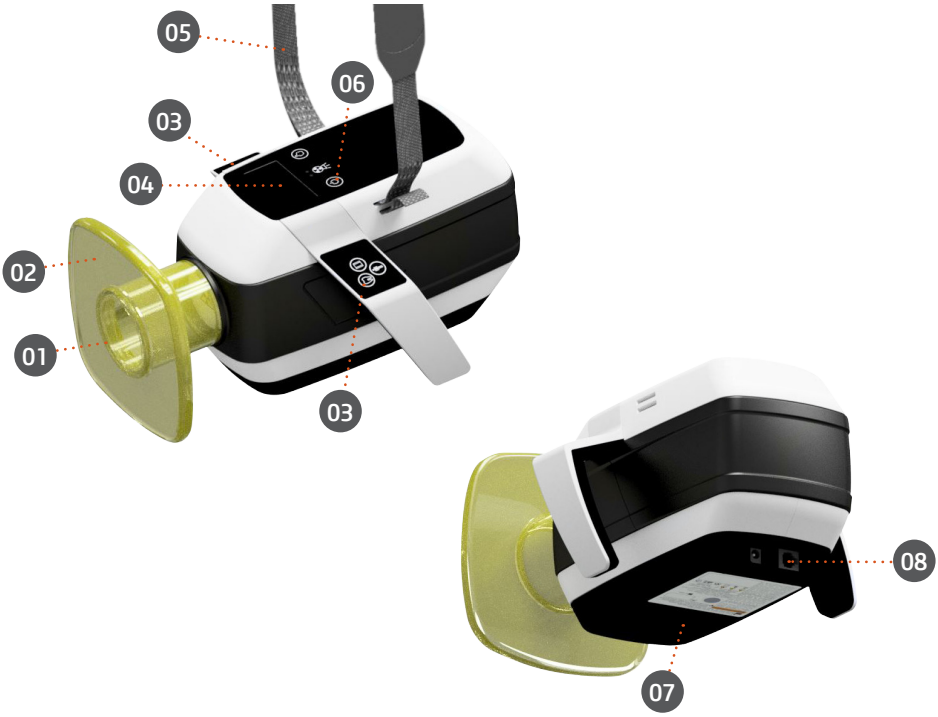
Finally, the radiation leak from the equipment is minimized by a collimator of radiopaque material, avoiding the user’s unnecessary exposure and directing the radiation to the exam target.

3.2.3. User profile

The Portable Dental X-Ray can be operated and handled by users of both sexes, with ability to read and understand images, symbols, icons, western Arabic characters (Arial font), alphanumeric characters, know how to distinguish intraoral part of the human body, not being able to present a degree of visual imperfection for reading and seeing and a medium degree of recent memory impairment, not being in a clear capacity to perform the activities and functions of the product in a correct way to the profession.

The user must be a qualified health professional and trained with technical competence in the area of health and dentistry.

3.3. MAIN PRODUCT COMPONENTS



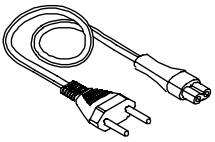
01 - Positioning cone
02 - Scattered radiation shield
03 - Control panel
04 - Interface display
05 - Neck strap
06 - On/off button
07 - Battery compartment
08 - Remote trigger compartment and battery charger connector

3.4. SETS AND ACCESSORIES

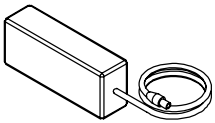
⚠	All parts, accessories and options described in the user manual are for exclusive use. The use of any parts, accessories or materials not specified in this manual is the sole responsibility of the user.

COMPONENTS ACCOMPANYING THE PRODUCT

01



02



01 - Power cable
02 - Battery charger

ACCESSORIES

01

*01 - Remote trigger

* Optional item

3.5. APPLIED PARTS

The following items may eventually come into contact with the patient during operation of the equipment and should, therefore, be treated as applied parts.

Applied part	Type of part	Type of contact	Contact duration
Plastic positioning cone covers	Fix	Skin	<10s

3.6. USER INTERFACE

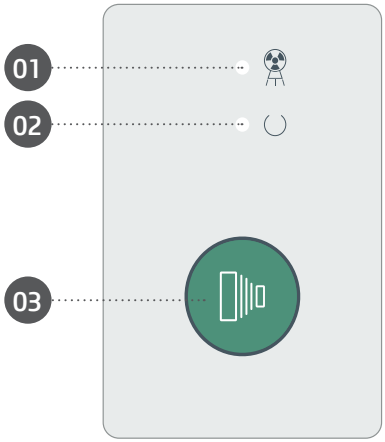
3.6.1. Interface display

ICON	FUNCTION
01 Patient	Patient type selection
02 Sensor	Receiver type selection
03 Tooth	Tooth type selection
04 Battery	Battery level indication
05 Time	Shooting time
06 Message	Message bar

3.6.2. CONTROL PANEL

BUTTONS	FUNCTION
01 Green LED	Indicates that the equipment is ready to operate
02 Yellow LED	Emission of ionizing radiation
03 Stand by	Starts or disables the equipment
04 Selection	Selects the menu item
05 Tooth Profile	Selects the tooth profile to be X-rayed
06 Receiver	Selects the type of image receiver that will be used in the acquisition
07 Patient Profile	Selects the patient profile
08 Exposure button	Trigger
09 Increases	Increases the exposure time
10 Decreases	Decreases the exposure time

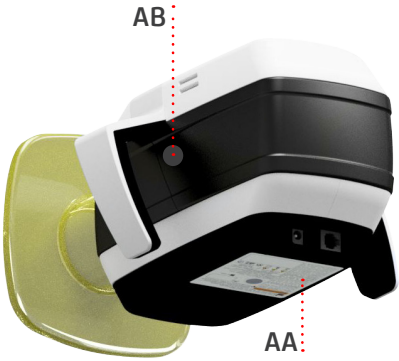
3.6.3. Remote trigger



BUTTONS / INDICATORS	FUNCTION
01 Yellow LED	Emission of ionizing radiation
02 Green LED	Indicates that the equipment is ready to operate
03 Exposure button	Trigger

3.7 LABEL PLACEMENT

The following image illustrates the location of the labels on the equipment.



AA

WARNING

This X-ray unit can be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.

AB

AC

Alliage S/A Indústrias Médico Odontológica
Rodovia Abrão Assed, Km 53 + 450m - CEP 14097-500
Ribeirão Preto - SP - Brazil +55 (16) 3512-1212 MADE IN BRAZIL

Segurança

RAIO-X ODONTOLÓGICO PORTÁTIL / *PORTABLE DENTAL X-RAY*

Entrada / Input
22.2V ⎓ 500 VA

Operação / *Operation*
T.on: 1.0s - T.off: 60s

Potência Saída / *Power Output*
60kV +/- 10%, 2,5 mA +/- 20%

Tubo Raio-X / X-Ray Tube
E7696 / Canon **0.7mm**

Filtração Total / *Total Filtration*
> 2.05mm Al Eq.

Reg. Anvisa: 10101130092

This product conforms to DHHS radiation standards of 21 CFR subchapter J as of date of manufacture.

MODEL
#
SN
LOT

UDI
(01)
(11)
(10)
(21)

4

OPERATION

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4. OPERATION

4.1. INITIAL PREPARATION

	The equipment must be cleaned and disinfected before being used on a new patient, observing the instructions contained in this manual.

Before starting the equipment operation, insert the safety strap around the neck and hold the equipment with both hands.

	Handle the equipment carefully, always using the safety strap, avoiding falls and impacts.

	Do not use the neck strap to transport and move the equipment.

The Portable Dental X-Ray remains in standby mode and is activated via a single key. To turn on the equipment, just press and hold the Standby key for 2 seconds.

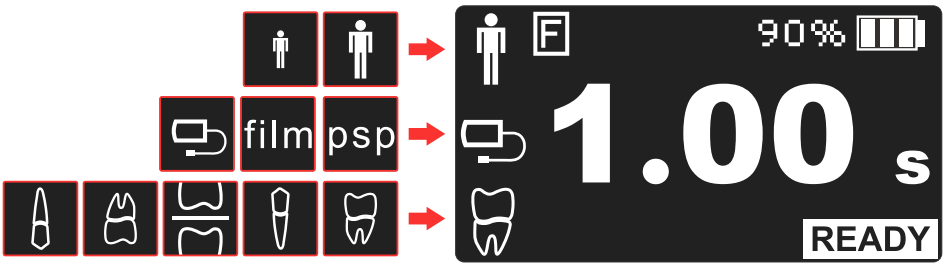
A QR Code will be displayed on the screen indicating that the equipment is being initialized. When the user scans the QR Code, they will be directed to the equipment manufacturer website.

To switch off, perform the same procedure of pressing and holding the Standby button for 2 seconds.

4.2. EXPOSURE TIME SELECTION

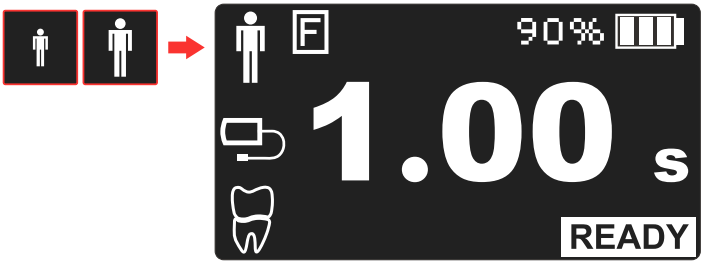
The equipment will indicate exposure time values according to the patient profile, X-rayed tooth and selected receiver. However, these values are only starting points to be replaced by more specific protocols developed by the user. The operator can manually adjust the exposure time values.

When the equipment is switched on, the last used screen is automatically restored. If the operator needs to set a different time, they can select the programs stored in the equipment's memory using the interface keys.



4.2.1. Patient Profile Selection

To select the patient profile, the operator must press the key . Each time the key is pressed, the patient field must alternate between Adult and Children, thus allowing selection according to the operator's needs.

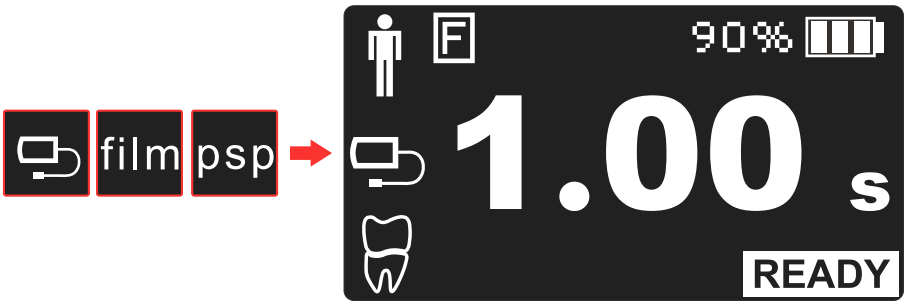


If the patient's biotype size is selected, the software will indicate exposure time values, which are just starting points to be replaced by more specific protocols developed by the user. The operator can manually adjust the exposure time.

4.2.2. Receiver type selection

To select the type of receiver, the operator must press the key .

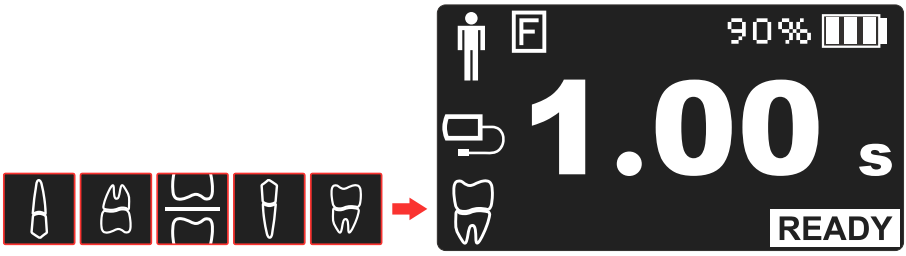
Each time the key is pressed, the receiver field must alternate between Digital sensor, Analogue film and Phosphorous plate, thus allowing selection according to the operator's needs.



4.2.3. Tooth type selection

To select the type of tooth to be X-rayed, the operator must press the key .

Each time the key is pressed, the tooth type field must alternate between Upper Incisor, Upper Molar/Upper Premolar, Occlusal, Lower Incisor and Lower Molar/Lower Premolar, thus allowing selection according to the operator's needs.



4.2.4. Automatic pre-selection parameters

The table below shows the exposure times for each patient type, tooth type and receiver type setting.

Type of patient	Tooth Type	Exposure time (s)		
		Digital Sensor	Phos-phorous Plate	Film
ADULT	UPPER INCISOR	0,12	0,16	0,30
	LOWER INCISOR	0,14	0,18	0,35
	OCCLUSAL	0,25	0,20	0,40
	UPPER MOLAR / UPPER PREMOLAR	0,16	0,19	0,38
	LOWER MOLAR / LOWER PREMOLAR	0,18	0,22	0,44
PAEDIATRIC	UPPER INCISOR	0,09	0,90	0,18
	LOWER INCISOR	0,10	0,10	0,21
	OCCLUSAL	0,14	0,16	0,32
	UPPER MOLAR / UPPER PREMOLAR	0,13	0,15	0,30
	LOWER MOLAR / LOWER PREMOLAR	0,15	0,17	0,35

4.2.5. Changing exposure time

It is also possible to change the exposure time using the △ increment and ▽decrement keys.

This mode allows adjustments of 0.01 seconds. If the current exposure time is far from the desired time, it is possible to increase the speed by incrementing or decrementing, allowing for a faster adjustment. For this function, simply press and hold the increment or decrement key.

When the user changes the time, the free configuration symbol F will be displayed. This symbol indicates that the exposure time has been changed by the user.

4.2.6. Saving exposure time

Once the exposure time has been changed, the new value can be saved in the equipment's memory. To do this, simply press the Selection key. A confirmation screen will appear and ask you to confirm the entry saved. If you really want to save a new value, select the option "**YES**" using the increment and decrement keys and press the selection key to confirm. If you select the option "**NO**", the value will not be saved and the application returns to the User Menu.

The new value will be saved in the Patient Profile, Receiver Type and Tooth Type position that was changed. After being saved, when selecting this setting, the value will be displayed.

4.3. POSITIONING

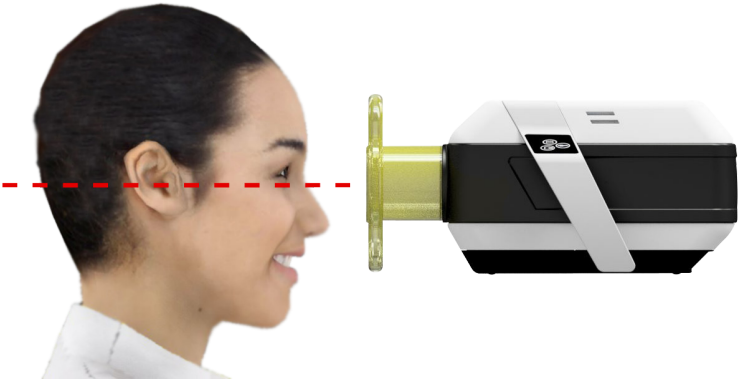
4.3.1. Preparing the patient

	Ask the patient to remove any objects such as glasses, hearing aids, prostheses and personal jewellery, such as earrings, necklaces and hair pins, among others.  Ask the patient to wear the protective apron over the body, especially paediatric patients, according to local legislation.  Ask the patient to sit in the chair with the sagittal plane vertical.

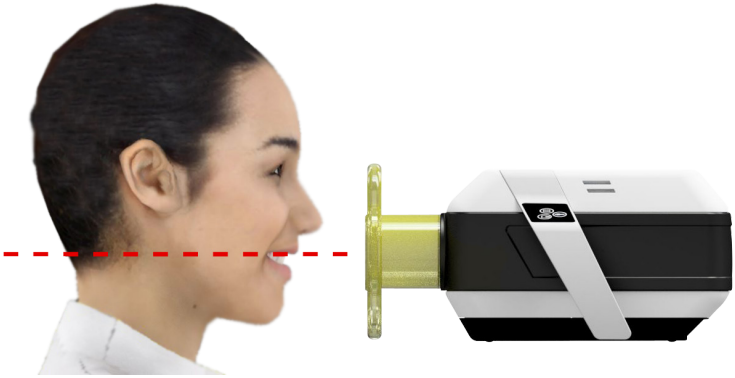
4.3.2. Positioning the patient

The proper positioning of the patient ensures better quality in the radiographic image, which is why the steps below should be followed.

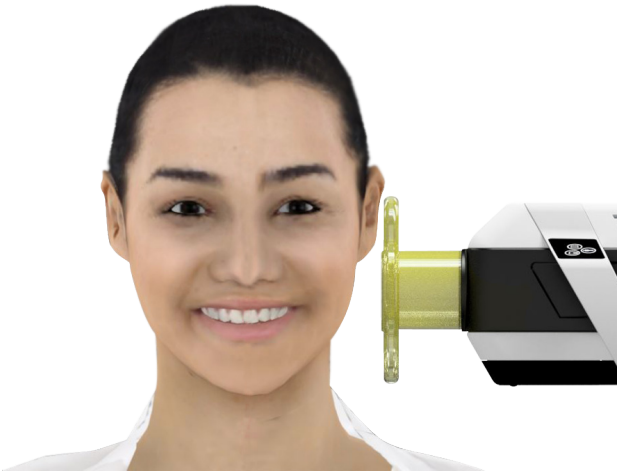
To X-ray the upper jaw, the Frankfurt plane should be horizontal.



To X-ray the lower jaw, the occlusal must be horizontal.

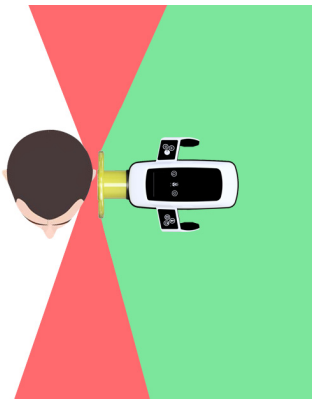


Position the cone in the exposure area you wish to X-ray.

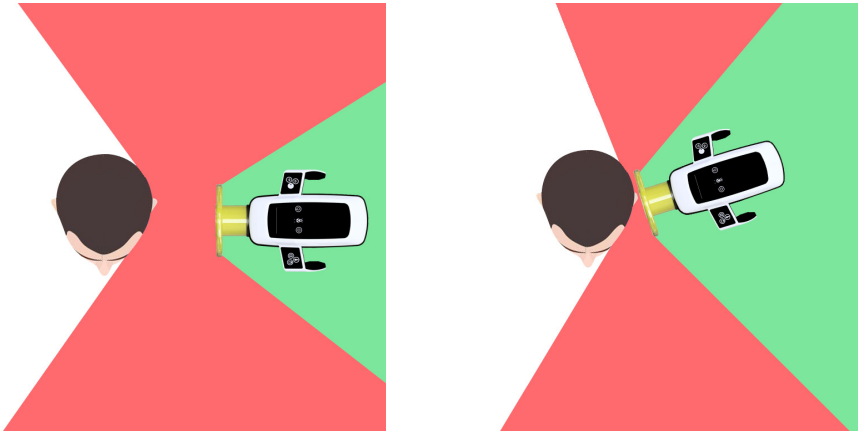


The Portable Dental X-Ray has a protective shield against scattered radiation. This shield protects the operator and third parties by creating a protection area against scattered radiation from the equipment due to a 0.35 mm lead equivalent shielding.

The graphic representation below shows the protection area (green area) versus scattered radiation (red area). Maximum protection exists when the equipment is positioned close to the patient, perpendicular to the operator.



If the equipment is moved away or not perpendicular, the protection area is reduced.

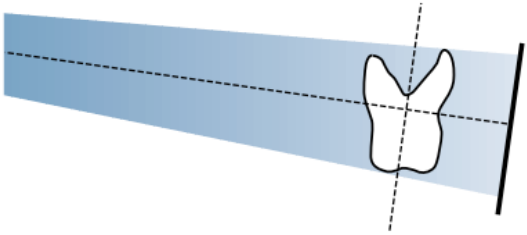


When performing an X-ray exposure, the operator must stand behind the unit, in the safety area.

4.3.3. Radiographic techniques

Paralleling Technique or Long-Cone Technique

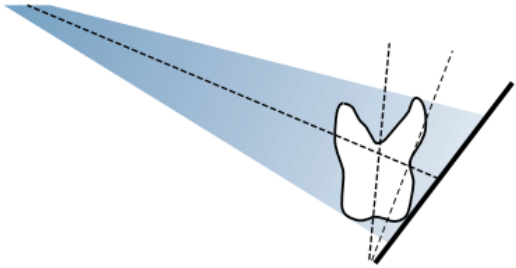
In this technique, the receiver is positioned parallel to the plane of the tooth axis with the assistance of a positioner and the focal point of the X-ray generator must be positioned approximately 40 cm away from the receiver.



This technique generates X-rays with minimal distortion, showing the objects being X-rayed in their true anatomical relationship and size.

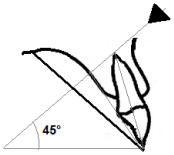
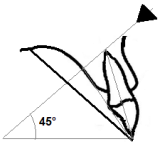
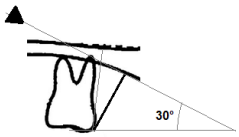
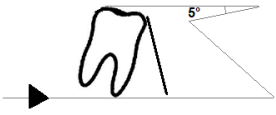
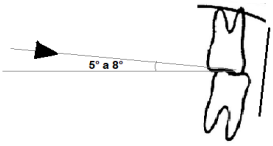
Bisecting Technique or Short-Cone Technique

In this technique, the receiver is positioned so that the central X-ray beam is perpendicular to an imaginary plane of the bisector of the angle formed between the long axis of the tooth and the sensor capture surface, according to Cieszynski's Rule of Isometry. For this, the focal point of the X-ray generator must be positioned approximately 20 cm away from the receiver.



This technique generates X-rays with distortions, regardless of the technique and accuracy of the operated; however, it also provides a relatively simple, fast and comfortable positioning for the patient.

The table below indicates specific angles and directions for the X-ray beam in order to obtain the best images of a particular tooth using the bisector technique.

TOOTH	INCLINATION ANGLE OF THE X-RAY BEAM	REPRESENTATION
Maxillary incisor	Directed downward at a 45°.	
Mandibular incisor	Directed upward at a 25°.	
Maxillary canine	Directed downward at a 45°.	
Mandibular canine	Directed upward at a 20°.	
Maxillary molar and premolar	Directed downward at a 30°.	
Mandibular molar and premolar	Directed upward at a 5°.	
Bitewing	Directed downward at a 5° to 8° angle and the patient clenches their jaw during exposure.	

4.4. EXPOSURE

	Ask the patient to remain still during exposure.

	Before performing an exposure, make sure the battery has a charge indicator above 11 %.

	Maintain visual contact with the patient during exposure. If a problem occurs during exposure, immediately release the trigger to stop exposure.

	If the trigger button is released, the exposure will stop.

4.4.1. Local trigger

After selecting the desired exposure time, the visible green LED will light up indicating that the equipment is ready for operation. Press and hold the trigger.

During exposure, a visible yellow LED and a continuous audible signal will indicate the presence of X-rays, in addition the message "**EXPOSING**" on the display.

A beep of two long beeps will indicate the end of the emission.

If the operator interrupts the exposure, the equipment will emit three short beeps.

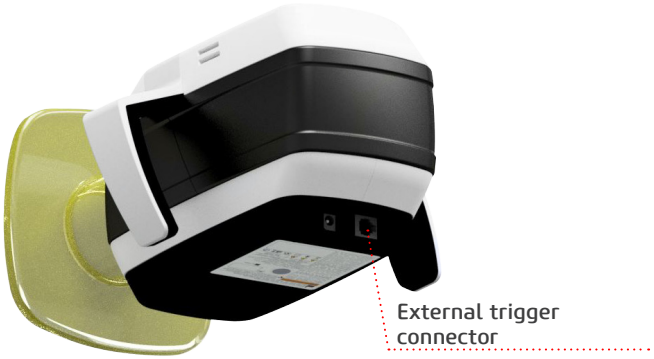
In the event of an interruption of exposure by the equipment, it will emit five short beeps.

After the X-ray exposure has ended, the trigger can be released and the equipment will go into cooling mode.

4.4.2. Remote trigger

The remote trigger allows the operator to perform the exposure distant from the equipment.

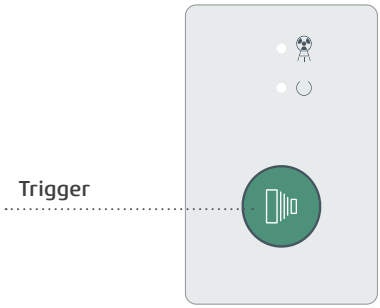
To use it, open the bottom compartment of the equipment to connect the external trigger.



Position the trigger 3 meters away from the equipment and behind a physical barrier to reduce the amount of ionizing radiation absorbed as much as possible.

⚠	No other type of cable may be connected to this connection other than the intended cable.

After selecting the desired exposure time, the visible green LED will light up indicating that the equipment is ready for operation. Press and hold the trigger.



During exposure, a visible yellow LED and a continuous audible signal will indicate the presence of X-rays, in addition the message "**EXPOSING**" on the display.

A beep of two long beeps will indicate the end of the emission.

If the operator interrupts the exposure, the equipment will emit three short beeps.

In the event of an interruption of exposure by the equipment, it will emit five short beeps.

After the X-ray exposure has ended, the trigger can be released and the equipment will go into cooling mode.

4.4.3. Shooting interruption

If an emergency situation occurs where the user interrupts the exposure by releasing the trigger, the message "**INTERRUPTED**" will appear on the display.

4.4.4. Movement during exposures

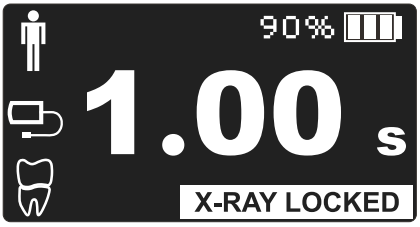
Like the emitters of a conventional intraoral X-ray system, the equipment can process a small amount of movement by the patient during real exposures. Always use both hands to hold the equipment during exposure and keep it stable.

The degradation or blurring of an image does not result from movement of the Portable Dental X-Ray source.

4.4.5. Protection against an accidental shooting

To prevent an accidental shooting, the Portable Dental X-Ray has a lock mode in order to avoid unwanted activations. This lock mode is activated by pressing the selection key and the patient profile key, which must be pressed within 2 seconds. The status is indicated at the bottom of the display with the message "**X-RAY LOCKED**".

To unlock, perform the same procedure. When repeating the procedure, the message at the bottom of the display reading "**X-RAY LOCKED**" should be replaced by the message "**READY**", indicating that the device is ready for operation.



4.5. ENERGY SAVING

4.5.1. Standby mode

If the equipment is not used within 5 minutes (standard), it will enter standby mode to reduce battery consumption. The time to enter standby mode can be set by the user, with a minimum of 3 minutes and a maximum of 10 minutes.

4.5.2. Hibernation mode

If the equipment is not used within 1 hour, it will be deactivated and it will enter hibernation mode. To resume normal operation in the energy saving mode, switch it back on by pressing the Standby button.

4.6. SETTINGS MENU

The Portable Dental X-Ray contains a user menu where you can customize some options according to your preferences.

To access the menu, the operator must press and hold the Selection key for approximately 2 seconds. After entering the user menu, the interface will appear as shown. To navigate between the menu options, use the increment and decrement keys. The Selection key within the user menu is used to confirm the current option that the cursor is in.

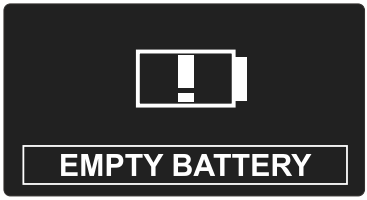
Item	Description
INFORMATION	View information such as firmware and serial number
COUNTER	Show the global and user shooting count.
STANDBY	Set the time in minutes for the equipment to enter standby mode (3, 5 or 10 minutes)
LANGUAGE	Select your preferred language between English, Portuguese and Spanish
FACTORY SETTING	Restore system parameters. In this menu, it is possible to delete the exposure counter and restore the factory setting. The latter will erase any exposure time values saved by the user.
EXIT	Return to the main menu.

4.7. BATTERY

4.7.1. Battery status

To identify the current status of the battery charge, locate the battery symbol, with the percentage of charge remaining at the top right of the display.

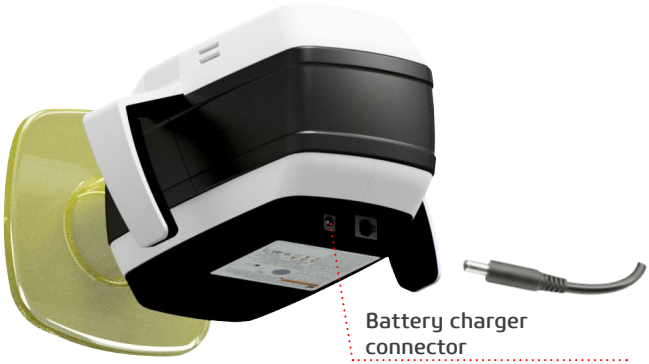
If the battery is empty, the message "**EMPTY BATTERY**" will appear on the display.



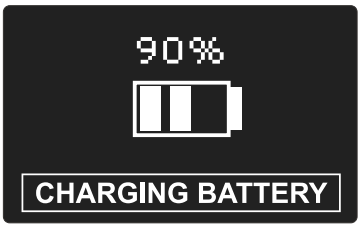
4.7.2. Charging the battery

	Charging the battery outside and away from the patient.

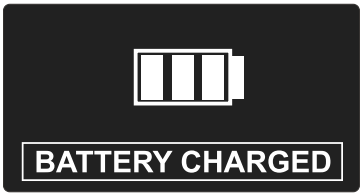
To start charging the battery, open the bottom side compartment of the equipment and connect the battery charger to the connector.



When connected to the battery charger, the message "**CHARGING BATTERY**" and the current battery charge level will automatically appear on the display. While the charger is connected to the equipment, the user will not have access to the interface menu.



The end of the battery charge cycle is indicated by the message "**BATTERY CHARGED**". The user can remove the power supply, close the lower compartment and use the equipment.



	The user will not be able to perform any exposure when the charger is connected. If the battery is empty, it is recommended to keep the equipment charging for close to 2 hours to fully charge it. When battery charging is complete, remove the charger.

4.7.3. Battery Protection and Safety

If the battery temperature reaches 50 ºC, the user interface will be disabled and the message "**BATTERY OVERHEAT**" will be displayed. In this case, wait until the battery temperature is normalized.

If it occurs again, it is recommended to replace the battery.

4.7.4. Replacing the battery

	The battery can only be replaced by the technical service authorized by the manufacturer

4.8. RECOMMENDATIONS FOR EXAMS

X-rays should only be taken when there is an expectation of diagnosis that will affect the patient's treatment. The dentist should weigh the benefits of obtaining X-rays against the risk of exposure to radiation from the patient.

Due to the effects of radiation build-up over time, every effort should be made to minimize patient exposure.

Wear a lead apron and thyroid collar.

The use of equipment and exposure settings designed for an adult may result in excessive radiation exposure for smaller patients, namely paediatric patients. Paediatric patients may be more sensitive to radiation than adults (i.e., the risk of cancer per unit dose of radiation is higher) and, therefore, unnecessary radiation exposure is a particular concern for paediatric patients. Use paediatric profile or a low dosage and select the shortest permissible exposure time.

There may be clinical circumstances for which an X-ray is indicated, but a diagnostic image cannot be obtained. For example, the patient may not be able to cooperate with the dentist.

PATIENT'S AGE AND STAGE OF DENTAL DEVELOPMENT[1]					
TYPE OF MEDICAL APPOINTMENT	**Child with primary dentition** (before eruption of the first permanent tooth)	**Child with transient dentition** (after the eruption of the first permanent tooth)	**Adolescent with permanent dentition** (before the eruption of the third molars)	**Adult, Toothed or partially Edentulous**	**Adult, Edentulous**
New Patient* **under assessment for oral diseases**	Individualized radiographic exam consisting of periapical / occlusal views and/or posterior bitewings if the proximal surfaces cannot be viewed or probed. Patients with no evidence of disease and with open proximal contacts may not require an X-ray	Individualized radiographic exam consisting of posterior bitewings with panoramic exam or posterior bitewings and selected periapical images.	Individualized radiographic exam consisting of posterior bitewings with panoramic exam or posterior bitewings and selected periapical images. A full mouth intraoral X-ray exam is preferred when the patient has clinical evidence of generalized oral disease or a history of extensive dental treatment.		Individualized radiographic exam based on clinical signs and symptoms.
Patient Return* **with caries or increased risk of caries** **	Posterior bitewing exam at 6-12 month intervals if the proximal surfaces cannot be examined visually or with a probe			Posterior bitewing exam at 6-18 month intervals	Not applicable
Patient Return* **without caries and without increased risk of caries** **	Posterior bitewing exam at 12-24 month intervals if the proximal surfaces cannot be examined visually or with a probe		Posterior bitewing exam at 18-36 month intervals	Posterior bitewing exam at 24-36 month intervals	Not applicable
Patient Return* **with periodontal disease**	Clinical judgement regarding the need and type of radiographic images for the assessment of periodontal disease. Imaging may consist of, but not limited to, bitewing and/or periapical images of areas where periodontal disease (except non-specific gingivitis) can be clinically shown.				Not applicable

Patient (New and Returning) **for monitoring of dentofacial growth and development and/or assessment of dental/skeletal relationships**	Clinical judgement regarding the need and type of radiographic images for assessment and/or monitoring of growth and development or assessment of dental and dentofacial skeletal relationships	Clinical judgement regarding the need and type of radiographic images for assessment and/or monitoring of dentofacial growth and development or assessment of dental and skeletal relationships Panoramic or periapical exam to assess the development of third molars	Usually, it is not suitable for monitoring growth and development. Clinical judgement regarding the need and type of radiographic images for assessment dental and skeletal relationships.
Patient **with other circumstances including, but not limited to, proposed or existing implants, other dental and craniofacial pathologies, restoration/endodontic care, treatment of periodontal diseases and remineralization of caries**	Clinical judgement regarding the need and type of radiographic images for assessment and/or control of these conditions		

These recommendations are subject to clinical judgement and do not apply to every patient.
It is the dentist's responsibility to follow the ALARA principle (as low as reasonably possible) to minimize patient exposure.

*** Clinical situations in which X-rays may be preferential include, but are not limited to:**

A. History of positive findings
1. Anterior periodontal or endodontic treatment
2. History of pain or trauma
3. Family history of dental anomalies
4. Postoperative healing assessment
5. Remineralization monitoring
6. Presence of implants, Pathology related to previous implants or assessment of implant placement

B. Clinical positive - Signs or Symptoms
1. Clinical evidence of periodontal disease
2. Large or deep restoration
3. Deep caries injury
4. Crooked or impacted teeth
5. Swelling
6. Evidence of dental or facial trauma
7. Teeth's mobility
8. Fistula
9. Suspected clinical sinus pathology
10. Growth anomalies
11. Oral involvement in known or suspected systemic disease
12. Positive neurological findings in the head and neck
13. Evidence of foreign objects
14. Pain or dysfunction in the TMJ
15. Facial asymmetry
16. Partially removable or fixed prosthesis abutment
17. Unexplained bleeding
18. Unexplained teeth sensitivity
19. Unusual eruption, spacing or migration of teeth
20. Unusual tooth morphology, calcification or colour
21. Inexplicable absence of teeth
22. Clinical dental erosion
23. Peri-implantitis

****The factors that increase the risk of caries can be assessed using ADA Caries Risk Assessment forms (age 0-6 and age >6).**

[1]U.S. Department of Health and Human Services. **Dental Radiographic Examinations**: **Recommendations for Patient Selection and Limiting Radiation Exposure**. Available at http://www.ada.org/~/media/ADA/Member%20Center/FIles/Dental_Radiographic_Examinations_2012.ashx. Accessed on 2 November2015.

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

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

5

DOSE INFORMATION

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5. DOSE INFORMATION

5.1. DOSE CALCULATION

For time values selected by the operator, the air kerma indications must be calculated using the following calculation.

$$Kair = 2{,}76 * time$$

The radiation dose was measured using one of specific ionization chambers for such a method that meets the IEC 60580:2019 standard for the radiation quality of the product, mounted juxtaposed to the radiation emitter, dispensing with the use of a test object representative of an average patient.

The formula below allows you to calculate the Dose-Area Product (DAP) for all exposure times. The Dose-Area Product (DAP) measure is calculated considering that the size of the output field at the end of the collimator cone at 20 cm from the focal point is 6 cm.

$$DAP = Kair * \pi * \left(\frac{6\ cm}{2}\right)^2$$

Where DAP is in mGy.cm^2

Based on the above equations, the table below was prepared with some dose values.

kV	mA	Exposure time (s) (Irradiation time (s))	Kerma in the air (mGy) @20cm	DAP (mGy.cm²)
60	2,5	0,01	0,02	0,57
		0,05	0,14	3,90
		0,10	0,28	7,80
		0,15	0,41	11,71
		0,20	0,55	15,55
		0,25	0,69	19,51
		0,30	0,83	23,41
		0,35	0,97	27,31
		0,40	1,10	31,10
		0,45	1,24	35,12
		0,50	1,38	39,02
		0,55	1,52	42,92
		0,60	1,66	46,94
		0,65	1,79	50,72
		0,70	1,93	54,63
		0,75	2,07	58,53
		0,80	2,21	62,49
		0,85	2,35	66,33
		0,90	2,48	70,23
		0,95	2,62	74,14
		1,00	2,76	78,04

Please use this information as a reference only. If necessary change the values according to your needs.

Note: The irradiation times defined above follow the sequence and variation of 0.05 s as a reference for the doses of Kerma in Air, which can be changed to other times within this variation of 0.05 s.

⚠	DAP and Air kerma values may vary due to measurement errors, as well as system and instrument variations. To compensate for such errors, a tolerance of 50 % must be taken into account.

5.2. RADIATION LEAKAGE

In the loading state, air kerma due to radiation leak from the equipment, at 1 m from the focal point, measured in an area of 100 cm2 of which no main linear dimension exceeds 20 cm, when operated under normal load conditions, does not exceed 0.25 mGy in one hour according to IEC 60601-2-65.

⚠	Air kerma values may vary due to measurement errors, as well as system and instrument variations. To compensate for such errors, a tolerance of 50 % must be taken into account.

RADIATION LEAKAGE	RANGE ALLOWED
60 kVp, 2,5 mA, 1 s (Maximum Condition of Exposure) 1 m distance to the focal point Work cycle 1:60	< 0,25 mGy/h

The following exposure tables were established in a unit equipped with a cone corresponding to focus distance to the skin of 200 mm. Leakage doses were measured with a 70 mm diameter lid and 5 mm lead thickness, all results were ND (Not Detected). The raw data are shown in the table below.

TEST RESULT		
DIRECTION	Horizontal Plane	Vertical Plane
	[mGy/h]	[mGy/h]
0º	ND	ND
30º	ND	ND
60º	ND	ND
90º	ND	ND
120º	ND	ND
150º	ND	ND
180º	ND	ND
210º	ND	ND
240º	ND	ND
270º	ND	ND
300º	ND	ND
330º	ND	ND

Voltage of the ampoule: 60 kV
Anodic current of the ampoule: 2.5 mA
Exposure time: 1.0 s

Measuring device: Radcal Corporation Ionization Chamber Model 9010 - SN: 5001383
Method: Elevation measurement at the level of the phantom skull in each position during the duration of exposure.
Accuracy of the radiation output: ±4 % of reading.

5.3. DIFFUSION RADIATION

The following exposure steps were established with a unit equipped with a cone corresponding to focus distance to the skin of 200 mm, respectively.

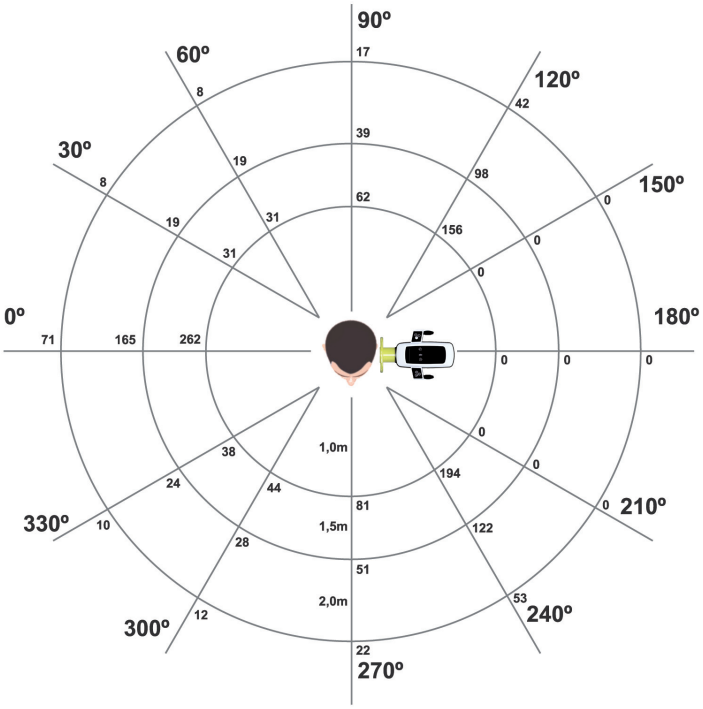
Method

The phantom skull was positioned 280 mm away from the focal point (with a position indication device), at maximum condition of exposure.

Measurement points: 1.0, 1.5 and 2.0 m of the phantom skull.

Below are the results found.

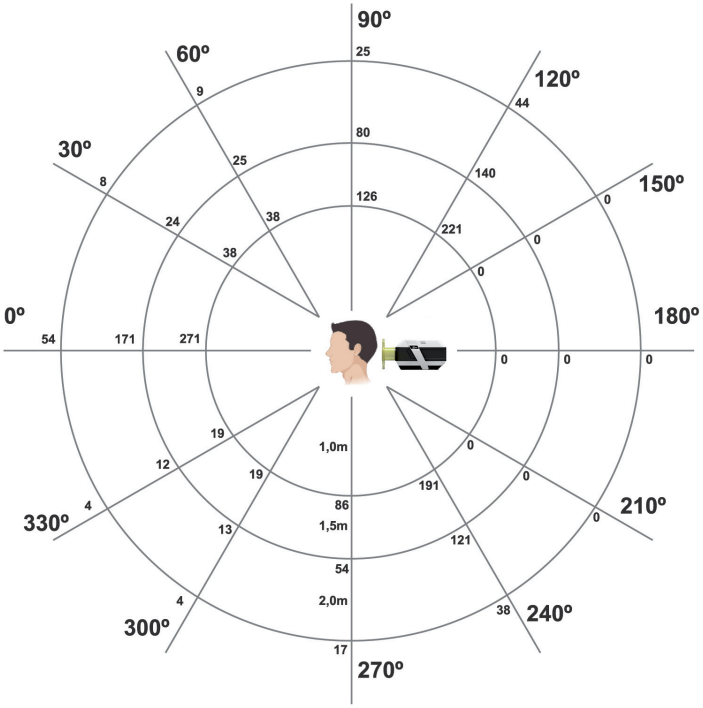
SCATTERED RADIATION - HORIZONTAL PLANE



Measuring unit: nGy
Voltage of the ampoule: 60 kV
Anodic current of the ampoule: 2.5 mA
Exposure time: 1.0 s

Measuring device: Radcal Corporation Ionization Chamber Model 9010 - SN: 5001383
Method: Elevation measurement at the level of the phantom skull in each position during the duration of exposure.
Accuracy of the radiation output: ±4 % of reading.

SCATTERED RADIATION - VERTICAL PLANE



Measuring unit: nGy
Voltage of the ampoule: 60 kV
Anodic current of the ampoule: 2.5 mA
Exposure time: 1.0 s

Measuring device: Radcal Corporation Ionization Chamber Model 9010 - SN: 5001383
Method: Elevation measurement at the level of the phantom skull in each position during the duration of exposure.
Accuracy of the radiation output: ±4 % of reading.

⚠	Diffusion radiation measurements are highly dependent on environmental conditions such as the composition of the walls and their locations. Therefore, under certain circumstances, the values can be significantly different.

6

CLEANING AND DISINFECTION

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6. Cleaning and Disinfection

	Before starting the cleaning and disinfection procedure, switch off the equipment and make sure it is not connected to the charger to avoid permanent damage.

	For your protection, during the equipment cleaning and disinfection procedure, use PPE such as disposable gloves and safety glasses.

The cleaning and disinfection procedure should be performed at each patient change.

When starting the process, check for visible dirt such as blood or saliva on the outside of the equipment, including the protective shield.

For the cleaning and disinfection procedure, the applicable parameters below must be followed.

For the cleaning, use a clean, soft, moist cloth with mild soap. Dry using a clean, soft cloth.

For the disinfection process, use disinfectant wipes with active Didecyldimethylammonium chloride based components respecting the contact time indicated by the manufacturer.

After application, allow to dry. Do not rinse.

There is no limit on cycles or application time that the Portable Dental X-Ray and its parts can tolerate during the cleaning and disinfection procedure, following the instructions in this manual.

	Do not spill liquid disinfectant on the equipment or use spray cleaning agents.

7

DIAGNOSIS OF PROBLEMS

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7. DIAGNOSIS OF PROBLEMS

7.1. ERROR MESSAGE

Occasionally, malfunctions may occur during use. In the case of an error code between 0x100 and 0x899, these errors relate to a generator failure during the exposure process.

Press the equipment selection button and return to operation. If the problem persists, write down the error displayed and contact the authorized technical service.

7.2. TROUBLESHOOTING

Failure	Possible causes	Solutions
The equipment does not start	The internal protection fuse is damaged	Contact your service representative
	The battery is empty	Connect the battery to the charger and wait for the battery to charge
	The battery does not start the charging cycle	Check if there is electricity where the charger was connected
	Damaged battery	Contact your service representative
The equipment does not emit X-rays	The generator is cooling.	Wait for cooling
	The local or remote trigger button is damaged	Contact your service representative
	X-ray generator failure	Contact your service representative
	End of tube life cycle	Contact your service representative
The X-rays perform an exposure but the image produced is very dark.	The exposure time is too long	Reduce the exposure time
	Inadequate development time	Check the development time
	Developer with inadequate mixture	Redo the mixture
The X-rays perform an exposure but the image produced is very light.	The exposure time is too short.	Increase the exposure time
	The sensor/film is incorrectly positioned	Position the X-ray cone correctly, use a positioner to assist in taking the X-rays
The X-ray has a dark stripe.	The developing chamber has a light penetration.	Avoid light entering the chamber.
There is a semi-circle on the X-ray.	Error in cylinder positioning.	Take the X-rays using the paralleling technique, making use of the auxiliary lines of the collimator cylinder.

8

DIAGNOSIS OF QUALITY

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8. DIAGNOSIS OF QUALITY

This section will, occasionally, use the procedures described in the previous sections. Please refer to these sections when necessary.

During installation or after a repair, this quality control procedure will generate baseline performance data.

Make a periodic assessment and compare against the baseline data.

If degradation in image quality or a change in values is noticed, contact the Alliage Service Department.

8.1. QUALITY CONTROL

8.1.1. Accuracy

The Portable Dental X-Ray is calibrated and tested at the factory before release and there are no adjustment options. However, the checks listed below must be performed by a qualified technician.

Set a performance metre calibrated according to manufacturer specifications to detect and report the following: X-ray rube tension (average kVp and PPV kV), Radiation time (ms Effective mode) and Dose (mR Medium mode).

Measurement method: Final performance measurements are made using a calibrated performance metre. Exposure time is measured from the time when X-rays are detected until they are no longer detected (meaning that the 90 % crossing configuration is selected without timer delay).

The acceleration voltage (kV) is calculated using the kVp average and the practical peak value in kV (PPV kV). Linearity is calculated according to IEC 60601-2-65.

Enable the Portable Dental X-Ray and, with the positioning cone perpendicular to the test detector, test some exposures on the test detector and capture the data resulting from the table below.

Compare the result with the factory release parameters (shown in the table below). For results outside these parameters, discontinue use and contact the Alliage authorized service network.

Test description	Acceptable Limit
kVp	60kV ±10%
Time	Set time ± 5 % + 50 ms

It is necessary to respect the work cycle after each X-ray shooting to avoid damage by overheating the X-ray tube.

8.1.2. Image quality

To assess the image quality, ask a qualified technician to perform an image acquisition using a test tool, specific for intraoral dental radiology. An image of the test tool must be produced, to be used as a reference using an image receiver (Phosphorus plate, Digital sensor or Analog sensor).

The image should be stored to compare the results with previous or optimal values

Every two years, an image test tool image should be produced, with the same technique used to produce the reference image.

Quantitative and qualitative assessments should be carried out based on the reference image and the test tool specifications.

The presence of artefacts in the images should also not be observed.

8.1.3. Dose measurement

For periodic dose measurement, use one of specific ionization chambers for such a method that meet the IEC 60580:2019 standard with an active area greater than 6 cm.

Position the dosimeter at the tube outlet 200 mm from the focal point and perform an exposure for all configurable times and record radiation dose.

9

INSPECTION AND MAINTENANCE

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9. INSPECTION AND MAINTENANCE

Maintenance or service procedures may only be performed by a technical service authorized by the manufacturer.

All instructions regarding use of the equipment as intended are provided in this user manual.

If any problems are detected and cannot be corrected with the instructions in the problem diagnosis section, contact the Alliage Service Department.

9.1. PERIODIC INSPECTION

This equipment must be regularly inspected to ensure operational safety and functional reliability. This inspection must be done by personnel familiar with the necessary precautions to avoid excessive exposure to both primary and secondary radiation. This equipment has a protection to limit both the primary and secondary radiation produced by the X-ray beam. However, this protection cannot prevent carelessness, negligence or lack of knowledge.

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.

The manufacturer and the assembler/installer are exempt from liability that the standard results are not compliant in cases where the user does not perform the maintenance recommended by the manufacturer.

Neither inspection nor service is part of the equipment warranty.

The maintenance performed must be documented and maintained with the equipment.

Item	Description of the inspection	Recommended frequency*
Security system	Warning and operation lights, audible signals, warning labels.	Every day
Internal and external trigger	Operation	Every day
Electrical parts	Overheating / Noise / Burning smell	Every month
Battery	Overheating / Burning smell / Charging / Load retention / Liquid leakage	Every month
Membrane keyboard	Operation / Damage	Every year
Accessories	General damage that may cause risk	Every year
Quality[1]	Accuracy, Image Quality and Dose	Every two years

*Recommendation according to ICRP Publication 129

[1]Refer to the procedures described in 'Dose measurement'

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

9.2. PREVENTIVE MAINTENANCE

In addition to the annual inspection, to ensure a long service life and smooth operation of your equipment, it is important to carry out preventive maintenance over a maximum period of three (3) years.

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

9.3. CORRECTIVE MAINTENANCE

	Corrective maintenance cannot be performed by the user. Do not open the equipment or try to repair it yourself or with the help of someone without training or authorization. This can aggravate the problem or cause a failure that can compromise the safety of the equipment.

	The equipment or any of its parts may not be maintained or serviced during use with a patient.

	The equipment contains parts under high voltage. Risk of electric shock. Switch it off and disconnect the charger before servicing.

Alliage declares that the provision of component lists or any other information that provides technical assistance by the user, may be requested as long as previously agreed, between the user and Alliage Company.

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

9.4. ALLIAGE AUTHORIZED SERVICE NETWORK

All services performed on Alliage equipment must be performed by an Authorized Technical Assistant. Otherwise, they will not be covered by the warranty.

If you need to request electrical schematics and/or components specifications not included in the user manual, contact the Alliage Customer Service with our request.

Telephone: +55 (16) 3512-1212

Address: Rodovia Abrão Assed, Km 53 - Recreio Anhangüera – Ribeirão Preto-SP/ Brasil CEP 14097-500

10

WARRANTY

Alliage S/A Industrias Médico Odontológica
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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 comes with the product.

11

TECHNICAL SPECIFICATIONS

Alliage S/A Industrias Médico Odontológica
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11. TECHNICAL SPECIFICATIONS AND CHARACTERISTICS

11.1. EQUIPMENT CLASSIFICATION

EQUIPMENT CLASSIFICATION	
Framework class according to ANVISA	Class III
Framework class according to CE	Class IIb

EQUIPMENT CLASSIFICATION OF ACCORDING TO IEC 60601-1 EN STANDARD	
Product classification for applied parts	Type B
Electric Shock Protection	Class II
Internally Energized Electromedical Equipment	
Protection Against Harmful Water Penetration	IP00 - Product not protected against harmful water and particulate matter penetration
Degree of safety of application in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide	Equipment not suitable
Operation Mode	Non-continuous operation Maximum exposure time: T on: 1,0 s / T off: 60 s ***Note:*** *The "T off" can be changed by the following control measures listed in the notes below.*

Note: If the temperature inside the pumphead reaches 40 °C, the X-ray exposure will be interrupted and a message will be displayed. Exposure will be enabled again after the internal temperature of the generator reaches 38 °C.

Note 2: If the battery temperature reaches 45 °C during the battery charging process, exposure will be enabled again after the generator's internal temperature reaches 40 °C.

Note 3: If the battery temperature reaches 60 °C during the battery charging process, exposure will be enabled again after the generator's internal temperature reaches 55 °C.

11.2. DEVICE INFORMATION

ITEM	DESCRIPTION
Supply voltage	22,2 Vd.c.
Power consumption	500 VA
Maximum grid impedance	0,1 Ω
Net weight	2,4kg
X-ray equipment for intraoral dental radiography model AXR60 H IEC 60601-2-65:2012	

11.3. ENVIRONMENTAL CONDITIONS

ENVIRONMENTAL TRANSPORT AND STORAGE CONDITIONS	
Transport or storage ambient temperature range	-18ºC to +60ºC
Humidity range regarding transport and storage	20% to 90% RH
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 +35ºC
Operating humidity range (non-condensing)	30% to 75% RH
Atmospheric pressure range	700 hPa to 1060 hPa (525 mmHg a 795 mmHg)
Operating altitude	≤ 2000 m

11.4. RADIOLOGICAL INFORMATION

GENERAL INFORMATION	
Ampoule Voltage	60kV
Ampoule Current	2,5 mA
Maximum energy accumulated in 1 hour	150 mAs.
Work factor	1 : 60
Selectable irradiation time range	0.01 to 1 second (With 0.01s steps)

LOAD PARAMETER ACCURACY	
Voltage	± 10 %
Anodic current	± 20 %
Irradiation Time	± 5 % + 50 ms
Accuracy of radiation output - Beam reproducibility (CV)	< 0,05

11.5. BATTERY

BATTERY	
Model	LBP6S1PAXR
Type	Rechargeable li-ion
Rated voltage	21,6V – 2.50Ah
Charging voltage	24 V
Cutting voltage	16,5 V
Power	54Wh
Weight	≤290g
Operating temperature	Loaded: 0° to 40°C Unloaded: -20° to 75°C
Storage temperature	1 month: -20° to 60°C 6 months: -20° to 45°C 1 year: -20° to 20°C
Maximum operating height	1,5m

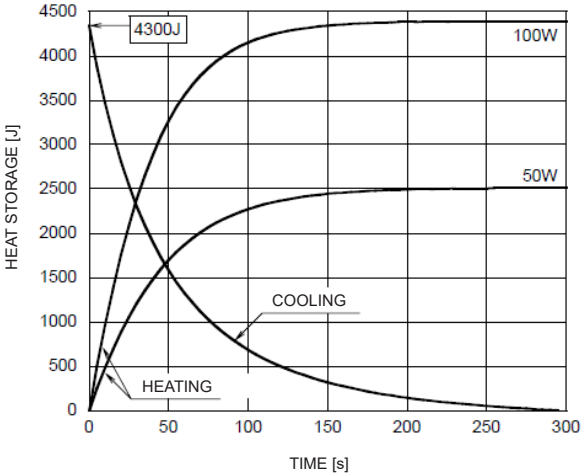
BATTERY CHARGER	
Model	Power Cord
Manufacturer	MEAN WELL
Condition	Input: 100-240 V~, 50-60 Hz, 0,8A
	Output: 24 V d.c., 1,5A
Frequency	50-60 Hz
Standard	IEC 60950-1
Power Cord	Flexible Cable PP Flat 500V 2X0,75mm²

11.6. X-RAY GENERATOR

GENERAL INFORMATION	
Generator type	Constant power high frequency generator
Maximum operating voltage (Intensity)	60 kVp
Heating and cooling curve	Refer to pumphead cooling characteristics graph
Maximum output power	150 W (60kV x 2,5mA)
Total filtration	> 2,05 mm Al eq. @ 60kVp
Permanent filtration	Glass: > 1,0 mm Al eq. @ 60kVp
	Plastic: > 0,05 mm Al eq. @ 60kVp
	Aluminum filter: > 1,0 mm Al @ 60kVp
Radiation leakage	< 0,2 mGy/h @ 60kV, 2.5 mA
Maximum kerma in the grip area in 1 hour (120 mm focal point)	0,00 mGy/h
Target angle	16°
Focal point as specified in IEC 60336, measured in the central X-ray beam:	0,7 x 0,7 mm
Reference axis	In the centre of the positioning cone
Nature of radiation	Undulating
Type of radiation	X-Ray
Focus-skin distance	200 mm
Focus-receiver distance	220 mm
The X-Ray generator is manufactured and assembled by Alliage S/A Indústrias Médico Odontológica.	
Portable Dental X-Ray with radiation protection according to ABNT NBR IEC 60601-1-3: 2010	

The equipment emits ionizing radiation only when subjected to a charge.

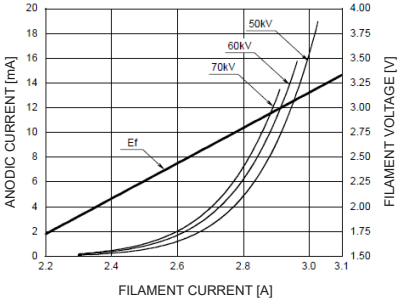
Characterization of X-radiation emitter-array



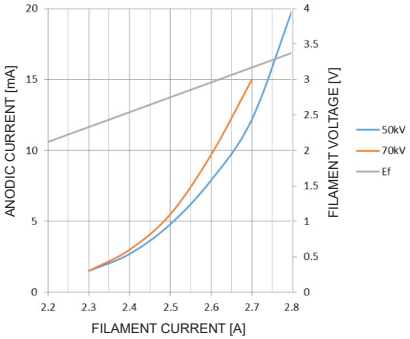
11.7. X-RAY TUBE

GENERAL INFORMATION		
Manufacturer	CANON	RADII
Model	E7696	KL21-0.7-70
Maximum operating voltage	70 kVp	70 kvp
Focus size	0,7mm	0,7mm
Anode angle	16°	16°
Equivalent filtration	1,0 mm Al equiv. @ 70kV	0,8 mm Al equiv. @ 70kV
Anode material	Tungsten	Tungsten
Anodic input power	600W	1000W
Thermal capacity	4,3 kJ	7,0 kJ
Maximum thermal capacity and cooling curve	Refer to anode thermal characteristics graph	Refer to anode thermal characteristics graph
Maximum current	19 mA	20mA
Maximum filament current	3,1A	2,8A
Frequency	Continuous Current	Continuous Current
Maximum continuous thermal dissipation	250 W	130W

EMISSION AND FILAMENT CHARACTERISTICS

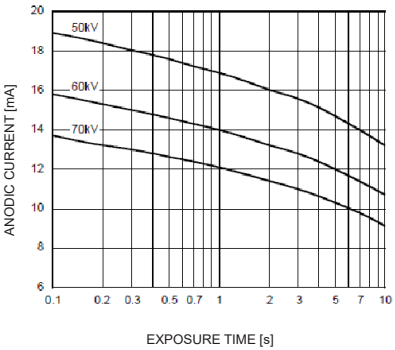


E7696



KL21-0.7-70

MAXIMUM LOAD CHARTS



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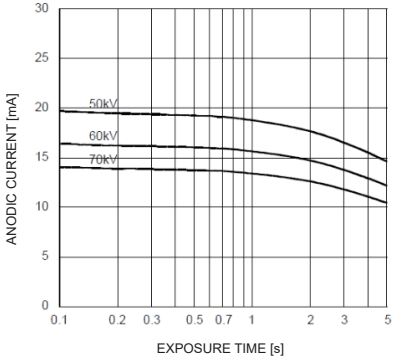

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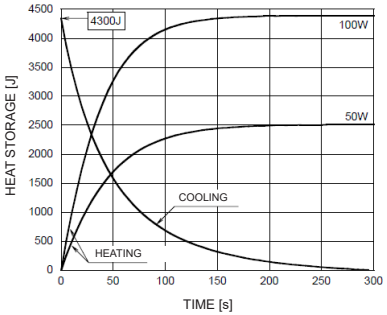
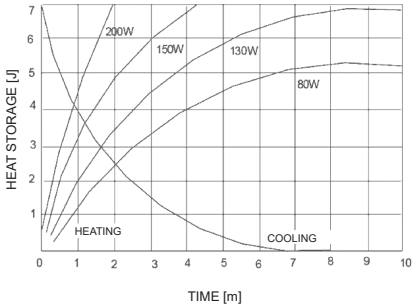
ANODE THERMAL CHARACTERISTICS



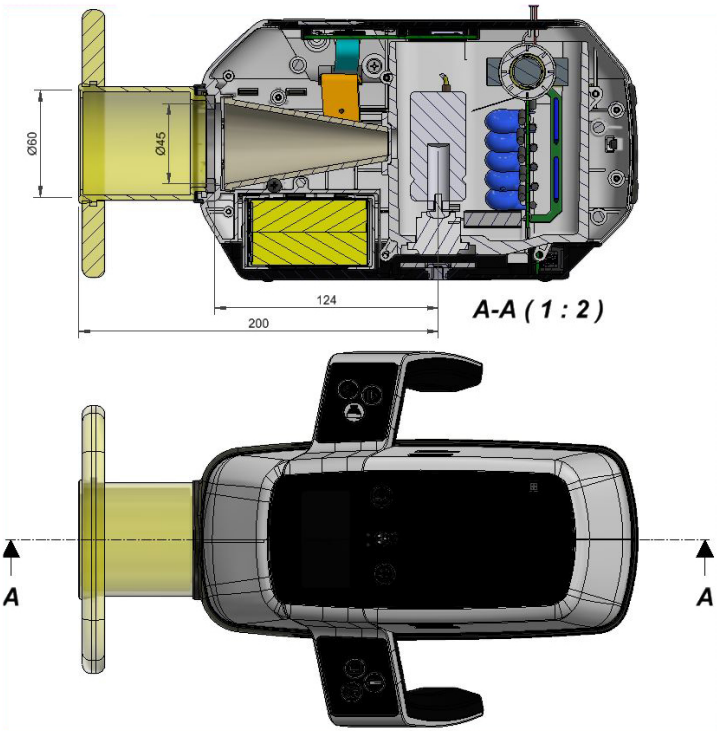
E7696



KL21-0.7-70

⚠	X-ray ampoules are for the exclusive use with the Portable Dental X-Ray.

BEAM LIMITER



11.8. STANDARDS AND REGULATIONS

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

ABNT NBR IEC 60601-1:2010 Amendment 1:2016	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.
ABNT NBR IEC 60601-1-2:2017	Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
ABNT NBR IEC 60601-1-3:2010	Medical Electrical Equipment, Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.
ABNT NBR IEC 60601-1-6:2011 Corrected Version:2013	Medical Electrical Equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability.
IEC 60601-1-9:2007+AMD1:2013	Medical Electrical Equipment, Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design.
IEC 62304:2006	Medical device software - Software life cycle processes.
ABNT NBR IEC 60601-2-65:2014	Electromedical equipment Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
ISO 15223-1:2016	Graphic symbols for medical practice electrical equipment.
EN 1041:2008	Information provided by the manufacturer of medical devices.
ABNT NBR ISO 13485:2016	Quality management systems - Requirements for regulatory purposes.
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing.
ABNT NBR ISO 14971:2009	Medical devices - Application of risk management to medical devices.
21 CFR 1020.30	Diagnostic X-ray systems and their major components.
21 CFR 1020.31	Radiographic equipment.
(EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

2011/65/EU Directive	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2).
2015/863/EU Directive	Amendment to Directive 2011/65/EU, regarding the restriction on the use of 10 dangerous substances (RoHS 3).
2012/19/EU Directive	Directive on waste electrical and electronic equipment.
80/181/ECC Directive	Directive on the approximation of the laws of the Member States relating to units of measurement.
ANSI / AAMI ES60601-1:2005 / (R) 2012 and A1:2012, C1:2009/ (R) 2012	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.
CAN / CSA-C22.2N° 60601-1:14	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

12

ELECTROMAGNETIC COMPATIBILITY

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12. ELECTROMAGNETIC COMPATIBILITY (EMC)

The Portable Dental X-Ray is intended for use in the specified electromagnetic environment below. It is advisable that the buyer or user ensure that it is used in such an environment.

The Portable Dental X-Ray is appropriate for use in a professional healthcare environment, not including areas where sensitive equipment or sources of intense electromagnetic disturbances are present, such as the room shielded against a system's RF for magnetic resonance imaging, operating rooms near active AF surgical equipment, electrophysiology laboratories, shielded rooms or areas where shortwave therapy equipment is used.

The following tables provide information on equipment compliance with ABNT NBR IEC 60601-1-2:2017.

12.1. GUIDANCE AND DECLARATION FOR ELECTROMAGNETIC EMISSIONS

EMISSIONS TESTS	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENTS - GUIDELINES
CISPR 11 RF Emissions	Group 1	The **Portable Dental X-Ray** uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are unlikely to cause any interference with nearby electronic equipment.
CISPR 11 RF Emissions	Class A	The **Portable Dental X-Ray** is suitable for use in all establishments, except households and those directly connected to the public low voltage power supply network that powers buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuation/ Scintillation emissions IEC 61000-3-3	Compliance	
Note: The emission characteristics of this equipment make it suitable for use 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 the equipment.		

12.2. ORIENTATION AND DECLARATION FOR ELECTROMAGNETIC IMMUNITY

PHENOMENON	BASIC EMC STANDARD OR TEST METHOD	IMMUNITY TESTING 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 irradiated 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 proximity from RF wireless communication equipment	IEC 61000-4-3	Refer to table	Refer to table
Fast/saved electrical transients	IEC 61000-4-4 c.c. power input	± 2 kV 100 kHz frequência de repetição	± 2 kV 100 kHz frequência de repetição
	IEC 61000-4-4 signal input/output	± 1 kV 100 kHz repetition frequency	± 1 kV 100 kHz repetition frequency
Line by line outbreak	IEC 61000-4-5	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV
Earth line outbreak	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	± 0,5 kV, ± 1 kV, ± 2 kV
Magnetic fields at declared power 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 800 MHz, the higher frequency range is applicable. NOTE 2 These guidelines may not apply to all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects and people. NOTE 3 RF field induced disturbance testing not applicable, once the equipment is internally powered 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 TESTING LEVEL (V/M)
385	380-390	TETRA 400	18 Hz 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	LTE 13, 17 Band	217 Hz Pulse modulation	0,2	0,3	9
745						
7480						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE 5 Band	18 Hz Pulse modulation	2	0,3	28
870						
930						
1720	1700 -1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE 1, 3, 4, 25 Band; UMTS	217 Hz Pulse modulation	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE 7 Band	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						

LIST OF CABLES USED		
CABLES	DESCRIPTION	LENGTH
Remote trigger	Data cable, U/UTP, Category 5, AWG24	15 m
Battery charger cable	PP Flat Flexible Cable 500 V 2X0.75 mm²	1,8 m

	The Portable Dental X-Ray is intended to obtain oral anatomy radiological images, including teeth, maxillofacial areas, oral and bone structures, for exclusive dental use. In case of MS disorders, the operator can experience locking the equipment interfaces.
	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 validated for the equipment.
	The use of this equipment adjacent to other equipment should be avoided as it may result in improper operation. If this use is necessary, it is advisable that this and the other equipment be observed to verify that they are operating normally.
	Do not use accessories, transducers, internal component parts and other cables other than those previously specified by the manufacturer. This may result in an increased emission or decreased electromagnetic immunity and result in improper operation.
	Portable RF communication equipment (including peripherals such as aerial cables and external antennas) should not be used within 30 cm of any part of the Portable Dental X-Ray, including cables specified by the manufacturer. Otherwise, performance degradation of this equipment may occur.
	To maintain basic safety regarding 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.
	The pins, connector sockets or elements carrying the ESD warning symbol must not be touched or interlocked without ESD protection measures.

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