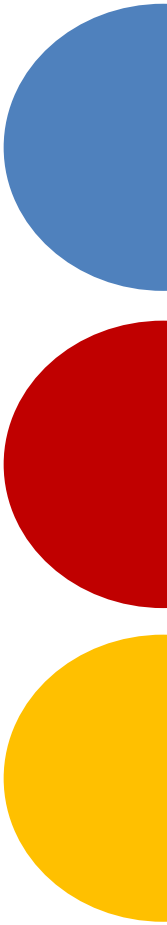
Use and Maintenance Manual

X-VIEW 3D PAN



trident

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This Manual was originally written in English. Versions in other languages are available, please contact the company to have more information.

Trident S.r.l. reserves the right to make changes in specification and features shown herein, or discontinue the product described at any time without notice or obligation.

Trident S.r.l. reserves the right to carry out technical modifications without updating this Manual.

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1 INTRODUCTION

Dear customer, X-VIEW 3D PAN is the result of many years of experience in the radiology field and meets the highest standards on design and functionality; we are certain that you will be pleased with our quality. Thank you for choosing our product and for trusting our company.

We made every effort to make all of the descriptions and instructions listed in this user manual as easy to understand as possible, in order to guarantee that you get maximum enjoyment from our product.

We are in any case at your complete disposal for any additional information you may require, as well as for any suggestion aimed at an improvement in the device performance or in the after sales service.

1.1 Purpose of this Manual

This manual is a comprehensive guide for installing and operating the X-VIEW 3D PAN unit. The manual describes the parts and components and explains how to correctly install, operate, and get the best performance from your unit. It is our intention to explain the proper use and all relevant safety measures to be adhered to when handling X-Ray equipment. The manual is limited to describe the unit, while the installation of digital acquisition system is provided in a related manual.

	This manual is updated to the current condition of the product, ensuring an appropriate reference to use the unit properly and safely.
	Changes in the product without impact on operating procedures and on safe use may not be included in this manual.

1.2 Icons and Symbols Used in this Manual

1.2.1 Icons

On this manual the following icons are used:

	Shows a "**NOTE**". We recommend paying particular attention when reading the arguments identified by this icon, because is referred to an operative conditioning that can be dangerous for the unit if ignored.
	Shows a "**WARNING**"; the arguments identified by this icon refer to the patient and operator safety.
	Consult the accompanying documentation

1.2.2 Symbols

This manual and the equipment use the following symbols:

SYMBOL	DESCRIPTION
	Unit with applied parts of type B. IEC 60601-1 uses the term "applied part" to refer to the part of the medical unit which comes into physical contact with the patient in order to carry out its intended function.
	The product, at the end of its useful life, cannot be thrown in the regular trash with other wastes and is subject to a separate collection.
	Alternating Current
N	Conductor connected to the neutral point
L	Connection point to the Power Line
	Grounding
	Functional earth connection
	ON/OFF
	POWER ON
	Power OFF
	Laser source
	Electric shock risk
	Product Reference
	Serial Number
	Manufacturing date
	Manufacturer address
	Total Filtration
	Tube head
	X RAY Tube
	Hand cleaning
CE	In compliance with requirements CE 93/42 and subsequent amendments.

1.3 To Users

	Read this manual to become familiar with the unit before putting it into service. Carefully follow the warnings and safety instructions.
	Always keep this manual handy, so that it can be consulted even after the first use.
	The unit must always be used in accordance with the procedures explained in the present manual, and shall never be used for purposes other than those it was designed for. Failure of the user to properly maintain the equipment may relieve Trident or its dealer, from responsibility for any injury, damage, or non-compliance, which may result.
	Promptly report to Trident or to its dealer any accident involving this unit or any alteration in features and/or performances which could cause death, injuries or health hazard to Patient and/or Operator.

1.4 Usability

All documentation accompanying the X-VIEW 3D PAN system is designed to facilitate the operator's operations.

2 ABOUT YOUR UNIT

2.1 General Description

X-VIEW 3D PAN manufactured by Trident S.r.l., is a cone-beam computed tomography system, or CBCT system that uses a cone-shaped X-Ray beam to take pictures of the skull and teeth. The system uses those pictures, along with the digital processing software (Deep-View), to reconstruct 3D images.

X-VIEW 3D PAN is essentially a digital X-Ray scanner mounted on a rotating arm. The machine uses a rotating X-Ray source, which emits a cone-shaped beam of radiation through the head, or alternative area of interest, onto an X-ray detector (a CMOS Flat panel sensor) on the opposite side. The X-ray source and detector rotate around a support located directly above the patient, positioned so the head is at the center of the system. The system takes a series of projection images over the course of a few seconds, taking the images in either a complete or partial arc, depending on the focus.

The process of images acquisition includes the following steps:

Patient Positioning: The patient's head will be stabilized with a restraint mechanism, such as a chin rest, to minimize movement during the scanning process.

Acquiring the Scan: The X-Ray source rotates around the head, while the flat panel sensor moves opposite, both rotating around a fixed support oriented directly over the patient's head. The frame rate, speed of rotation, field of view and completeness of the trajectory arc are all set to get the desired image. During this process, the machine emits radiation in short bursts, meaning the exposure time of the patient is only a fraction of the total scan time. This scan takes few seconds on average.

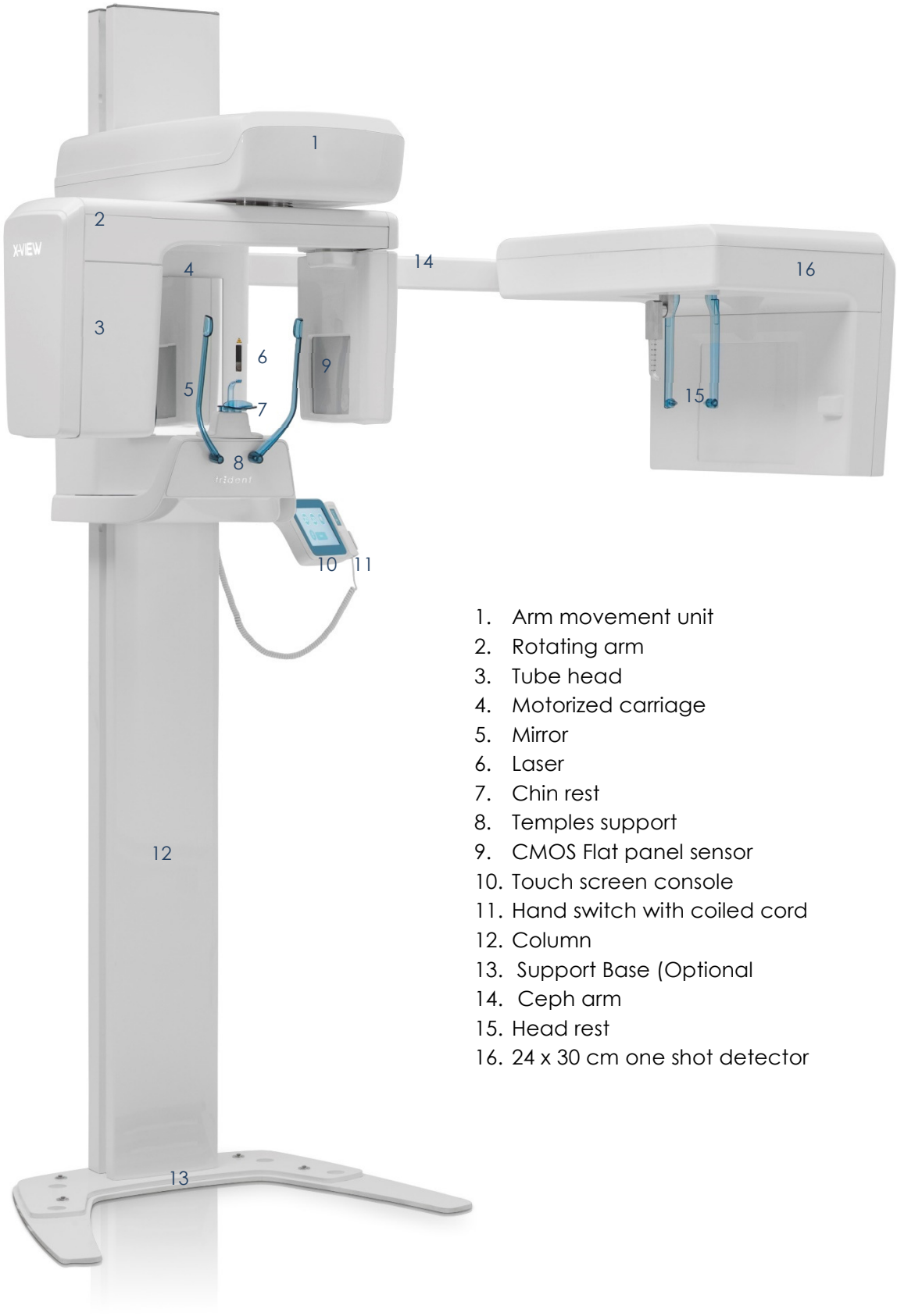
Detecting the Image: The flat panel sensor picks up the radiation emitted from the X-Ray and collects it as digital data. This data is then transmitted to and collected at a dedicated computer.

Reconstructing the Image: Once the projected images have been acquired and collected, the images are taken and used to construct a model of the skull. This is done with Deep-View software that uses reconstruction algorithms to build up a three dimensional model of the skull, teeth or other area of interest.

Displaying the Image: X-VIEW 3D PAN provides a complete digital model at the end of the process. Deep-View software also provides the doctors with a relatively large choice of display formats, allowing for 2D and 3D images of the mouth and head, along with other viewing options to help focus in on areas of interest.

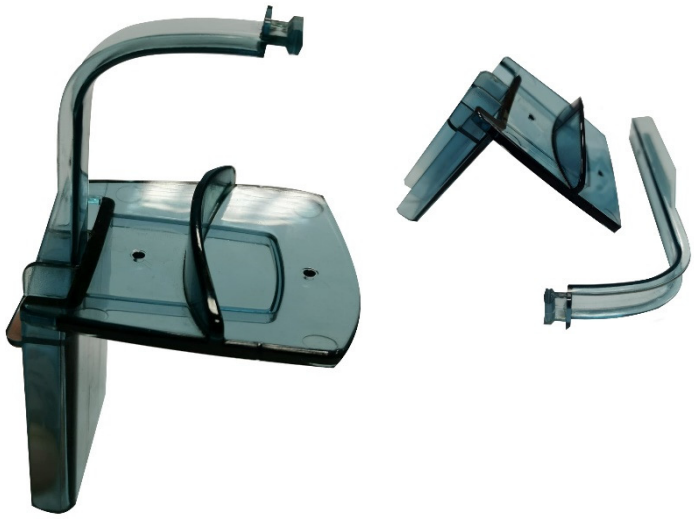
2.2 Parts

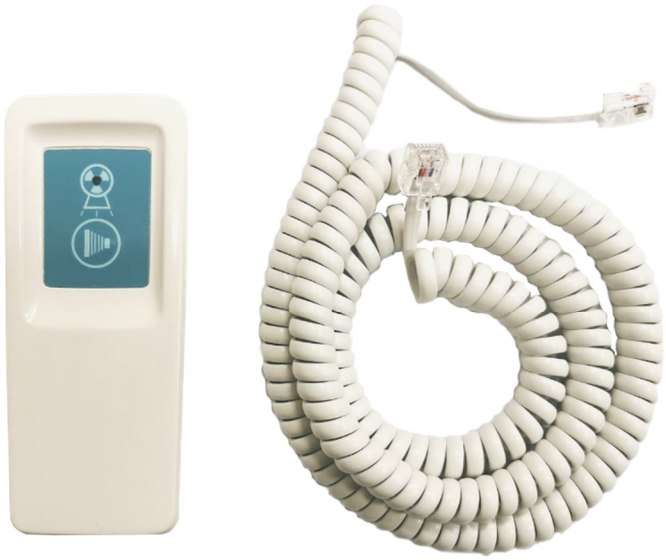
X-VIEW 3D PAN is composed of the following functional components.
The picture shows the integrated version with cephalometric arm.



1. Arm movement unit
2. Rotating arm
3. Tube head
4. Motorized carriage
5. Mirror
6. Laser
7. Chin rest
8. Temples support
9. CMOS Flat panel sensor
10. Touch screen console
11. Hand switch with coiled cord
12. Column
13. Support Base (Optional
14. Ceph arm
15. Head rest
16. 24 x 30 cm one shot detector

2.2.1 Detachable parts

Standard Bite block/Chin rest (2 pieces bite+chin rest)	

Condile's chin rest	
Only Bite block	
X-Ray remote control and telephone wire with 2 connectors RJ10, 4 poles and 4 contacts. The X-Ray remote control enables the operator to launch a radiological image acquisition via the exposure button from outside the x-ray room. The operator must press and hold the exposure button until the end of acquisition. Premature release of the exposure button interrupts the acquisition.	

2.3 Physical Principles of Operation

2.3.1 Flat Panel Sensor

The Flat Panel sensor generally operates as a normal digital sensor, converting the amount of dose that hits every single pixel into an electrical signal that can be processed through a system of analog-to-digital conversion.

While traditional sensors used for panoramic images put together several slices to build up an image, a Flat panel sensor deliveries the whole acquired information to create an image.

The flat panel sensor is comprised of a sensor board and a control board. Mounted on the sensor board is a CMOS image sensor chip made up of a two-dimensional photodiode array, row-scanning vertical shift register, and 8 charge amplifier arrays.

2.3.2 Cephalometric Detector

X-VIEW 3D PAN CEPH is equipped with a DR Ceph sensor,10×12-inch a-Si FPD for radiographic imaging. It features a 125 µm pixel pitch with direct deposition CsI and provides excellent image quality for single-shot cephalometric imaging.

2.3.3 3D Volumetric Images Acquisition

A 3D image is acquired during the movement of the rotating arm. In this type of capture, X-Ray generator is controlled in pulsed way with short pulses emitted at each degree fraction of the arm's rotation. A dedicated software processes the sequence of images obtained using mathematical algorithms to generate the volumetric images.

The spatial resolution of the image is the result of the size of the pixels of the sensor and of the reconstruction. In this case, the resolution is measured in "voxels" (acronym for Volume pixels). The volume thus rebuilt is returned to image viewing software, where there are several operations, which allow the operator or the doctor, among other functions, to select which part of the volume display or getting specific sections of a point.

2.3.4 2D Panoramic Images Acquisitions

Special Flat Panel functions allow reducing the sensor's sensitive area to get 2D images. In this mode, the X-Ray is continuous (not pulsed) and the image is obtained from a great sequence of single slides.

2.3.5 Dose Area Product (DAP)

Dose area product is a quantity used in assessing the radiation risk from diagnostic X-Ray examinations and interventional procedures. It is defined as the absorbed dose divided by the area irradiated, expressed in gray-centimetres squared (Gy/cm^2). DAP reflects the dose within the radiation field and also the area of tissue irradiated. It also has the advantage of being easily measured, with the permanent installation of a DAP meter on the X-Ray set.

The DAP values are calculated based on the effective exposure parameters by applying a mathematical formula obtained by data interpolation. DAP values vary from one unit to another in relation to the power of the X-Ray emission tube. The accuracy of DAP is 50%.

2.3.5.1 DAP for Volumetric 3D Exams

	X-VIEW 3D system allows manual variation of exposure parameters between minimum and maximum possible values: kV: from 61 to 85; step 3 kV mA: from 5 to 10; following R'20 standard. Considering that • Exposure time is fixed Principle of optimization of the dose suggests to limit values of exposure parameters that you can change • Adult patient: from 76 to 85 kV, from 6 to 10 mA • Child patient: from 73 to 79 kV, from 6 to 8 mA It is still operator's responsibility to set exposure parameters basing on his experience and preference.

DAP for X-VIEW 3D with 13x13 cm sensor

DAP (mGy*cm²) 3D Adult Dentition Exposure Time 3D = 10,5sec					
kV	mA				
	6,3	**7,1**	**8**	**9**	**10**
61	1971	2222	2503	2817	3129
64	2168	2443	2753	3098	3441
67	2370	2671	3010	3385	3761
70	2578	2905	3273	3681	4091
73	2790	3144	3543	3986	4429
76	3008	3390	3820	4297	4775
79	3232	3643	4104	4618	5131
82	3462	3901	4396	4945	5494
85	3696	4166	4694	5281	5868

DAP for X-VIEW 3D with 15 x 15 cm sensor

DAP (mGy*cm²) 3D Adult Dentition: Exposure Time 3D = 10,5sec					
kV	mA				
	6,3	**7,1**	**8**	**9**	**10**
61	1973,52	2224,12	2506,05	2819,31	3132,57
64	2170,09	2445,66	2755,67	3100,13	3444,59
67	2372,17	2673,40	3012,28	3388,82	3765,35
70	2579,76	2907,35	3275,89	3685,37	4094,86
73	2792,86	3147,51	3546,49	3989,80	4433,11
76	3011,47	3393,88	3824,09	4302,10	4780,11
79	3235,58	3646,45	4108,68	4622,26	5135,85
82	3465,21	3905,23	4400,26	4950,30	5500,33
85	3700,34	4170,23	4698,85	5286,20	5873,56

2.3.5.2 DAP for Standard Adult Panoramic

DAP (mGy*cm²) Exposure time PAN = 15sec							
kV	mA						
	5	**5,6**	**6,3**	**7,1**	**8**	**9**	**10**
61	58	64	74	83	93	105	116
64	63	71	81	90	101	114	127
67	69	78	87	99	112	125	139
70	76	85	95	108	121	137	152
73	83	92	104	117	132	148	166
76	90	100	113	128	144	161	179
79	98	109	123	138	155	175	194
82	106	118	132	150	169	190	210
85	114	128	144	161	182	205	228

For others 3D exams, DAP value is calculated multiplying values in the table for:

	Adult	Child
3D Dentition	1	1
TMJ R or TMJ L	0.92	0.92
Sinus 3D	1	1

For the rest of 2D exams, DAP value is calculated multiplying values in the table for:

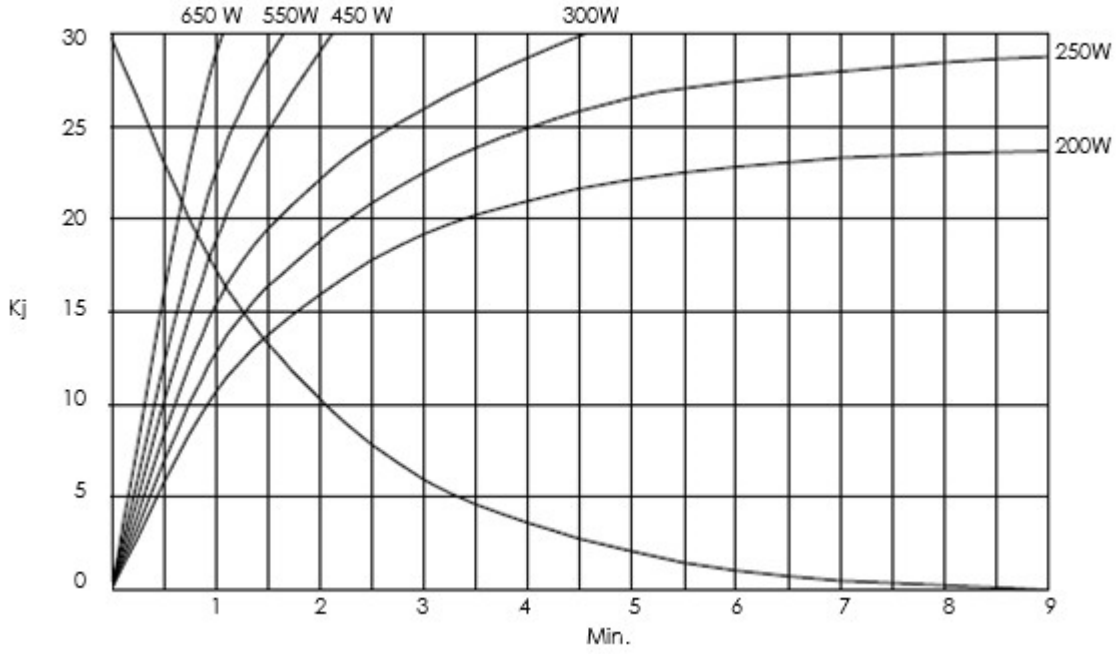
Type of exam	Adult	Child
Standard PAN	1,00	0,96
Right Hemi-Panoramic	0,54	0,51
Left Hemi-Panoramic	0,54	0,51
Frontal dentition	0,27	0,27
TMJ	0,43	0,43
Sinus	0,78	0,78
Low Dose Panoramic	0,78	0,78
Bitewing R	0,20	0,15
Bitewing L	0,20	0,15
Bitewing R + L total	0,39	0,30
Improved Orthogonality	0,83	0,78

2.3.5.3 DAP for 30 x 24 cephalometric exam

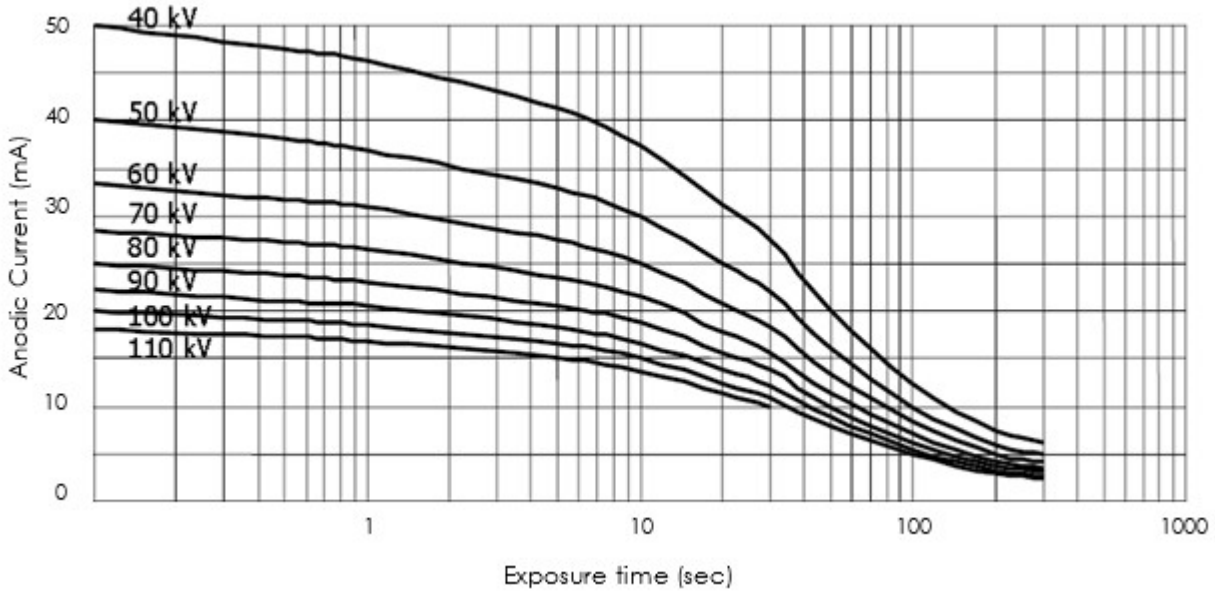
DAP (mGy*cm²) mA = 10									
Tiempo (s)	kV								
	61	**64**	**67**	**70**	**73**	**76**	**79**	**82**	**85**
0,20	22,37	24,71	27,08	29,48	31,92	34,38	36,88	39,41	41,97
0,22	24,61	27,18	29,79	32,43	35,11	37,82	40,57	43,35	46,17
0,25	27,96	30,89	33,85	36,85	39,90	42,98	46,10	49,26	52,46
0,28	31,32	34,59	37,91	41,28	44,68	48,14	51,63	55,17	58,76
0,32	35,79	39,53	43,33	47,17	51,07	55,01	59,01	63,06	67,15
0,36	40,26	44,48	48,74	53,07	57,45	61,89	66,39	70,94	75,55
0,40	44,74	49,42	54,16	58,97	63,84	68,77	73,76	78,82	83,94
0,45	50,33	55,59	60,93	66,34	71,81	77,36	82,98	88,67	94,43
0,50	55,92	61,77	67,70	73,71	79,79	85,96	92,20	98,53	104,93
0,56	62,63	69,18	75,82	82,55	89,37	96,27	103,27	110,35	117,52
0,71	79,41	87,72	96,13	104,67	113,31	122,06	130,93	139,91	149,00
0,80	89,48	98,84	108,32	117,93	127,67	137,53	147,52	157,64	167,88
0,90	100,66	111,19	121,86	132,67	143,63	154,73	165,96	177,35	188,87
1,00	111,84	123,54	135,40	147,42	159,59	171,92	184,41	197,05	209,85
1,60	178,95	197,67	216,64	235,87	255,34	275,07	295,05	315,28	335,76
2,00	223,69	247,09	270,80	294,83	319,18	343,84	368,81	394,10	419,71
3,00	335,53	370,63	406,20	442,25	478,76	515,75	553,22	591,15	629,56

2.3.6 Curves

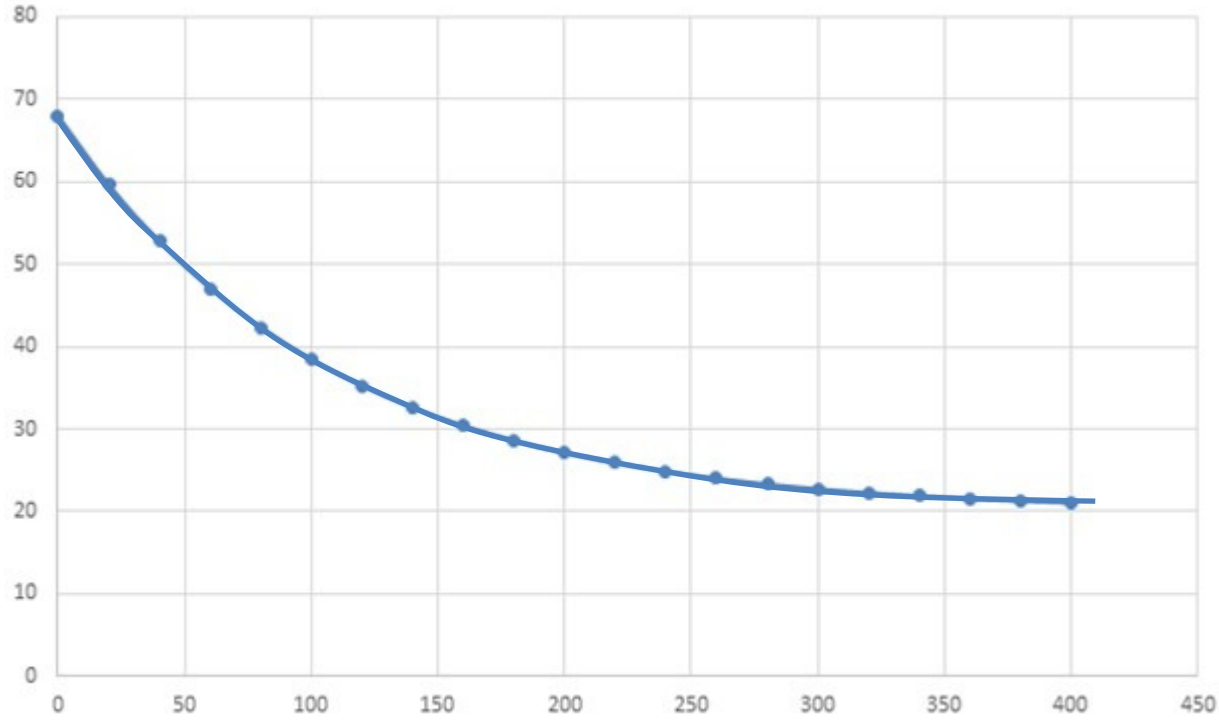
2.3.6.1 Loading Curve



2.3.6.2 Anode Cooling Curve



2.3.6.3 Tube Head Cooling Curve



2.4 Intended Use

X-VIEW 3D PAN must only be used to take panoramic, cephalometric and 3D images of the dento-maxillofacial complex of the human skull. It must not be used to take images of any other part of the human body, except for carpus.

2.4.1 Main Uses

X-VIEW 3D PAN is an important diagnostic tool for dentists and oral surgeons in everyday practice. Images obtained with X-VIEW 3D PAN, Panoramic (2D), cephalometric, or three-dimensional (3D), cover a wider area than a conventional intraoral X-Ray and, as a result, provides valuable information about the nasal area, maxillary sinuses, tooth positioning and gum and bone irregularities. These examinations are also used to plan treatment for full and partial dentures, braces, extractions and implants.

Oral and maxillofacial surgery
X-VIEW 3D PAN enables the analysis of jaw pathology, the assessment of impacted teeth, supernumerary teeth and their relation to vital structures. It is also helpful in analyzing and assessing paranasal sinuses and obstructive sleep apnea.
Endodontics
X-VIEW 3D PAN is a very useful tool in diagnosing apical and peri-apical lesions; it is also reliable for pre-surgical assessment of the proximity of the tooth to adjacent vital structures, size and extent of lesions as well as the anatomy and morphology of roots.
Implantology
X-VIEW 3D PAN enables the assessment of bone quality and bone quantity. This leads to reduced implant failure, as case selection can be based on much more reliable information. This advantage is also used for post-treatment evaluation and to assess the success of bone grafts.

Orthodontics

Orthodontists can use X-VIEW 3D PAN images in orthodontic assessment and cephalometric analysis, also in the assessment of facial growth, age, airway function and disturbances in tooth eruption.

Temporomandibular joint disorder

One of the major advantages of X-VIEW 3D PAN is its ability to define the true position of the condyle in the fossa, which often reveals possible dislocation of the disk in the joint, and the extent of translation of the condyle in the fossa. Another advantage is its ability to visualize soft tissue around the TMJ.

Periodontics

X-VIEW 3D PAN can be used in assessing a detailed morphologic description of the bone and to detect buccal and lingual defects.

2.5 User's Profile

The unit is designed to be used in radiology and dental offices. Only qualified personnel, dentists and radiologists must use it; all the users need to have a good knowledge on general radiology. X-VIEW 3D PAN needs a computer for its operation, so the users should be familiar with using computer (PC) and the specific software for the image acquisition and management. Radiologists and dentists need to have specific knowledge about:

- Ionizing radiation emissions
- Dangers of biological damage related to excessive use of ionizing radiation.
- Methods to reduce the risks of excessive radiation to the patient (use of leaded protections, etc.).

2.5.1 Training

After the installation, the operator must have training sessions on how to operate and maintain the unit. Trident Srl organizes, in cooperation with its dealers, a permanent training system for technicians. The schedule for these courses is done according to customer's needs.

2.6 Patient profile

X-VIEW 3D PAN is suitable for every type of patient. The exposure parameters of a test depend on patient's age, weight and height. X-VIEW systems allows the selection, in all examinations, between two kinds of patient, adult and child, and three sizes, small, medium and large. By combining these factors it is possible to obtain 6 different elements when selecting the patient. The patient's type and size may be selected from the operating console.

2.6.1 Child patient

Considering the normal use of the system, pediatric use considers an age range from 10 to 15 years old. The use on pediatric patients automatically will reduce the absorbed dose by reducing kV and mA; the exposure time is reduced only on PAN examinations and not on 3D ones.

2.6.2 Adult patient

A patient older than 15 years or, whose weight exceeds 81 kg is considered as "Adult". For a weight up to 70 kg, the adult is considered as "Small"; from 71 kg to 83 is considered "Standard", while an adult exceeding 84 kg is "Large".

2.7 Versions and Exams

X-VIEW 3D PAN can be configured from the factory in the following versions:

VERSIONS					
	Code	Sensor Type	FOV Exam	PAN	Ceph
3D Only	X3D-POY	Sensor 13X13	9 x 9	NA	NA
	X3D-POY1	Sensor 15X15	9 x 9	NA	NA
	X3D-POY2	Sensor 15X15	11 x 11	NA	NA
3D UP	X3D- SYD0	Sensor 15X15	9 x 9	15 x 30, 13 x 30	NA
	X3D- SYD2	Sensor 15X15	11 x 11	15 x 30, 13 x 30	NA
	X3D-SYD3	Sensor 15X15	MultiFOV 11 x 11 9 x 9 6 x 11 5x5	15 x 30 13 x 30	NA
3D PAN DR CEPH	X3D-DPH0	Sensor 15x15 + DR CEPH	9 x 9	15 x 30, 13 x 30	24X30
	X3D-DPH2	Sensor 15x15 + DR CEPH	11 x 11	15 x 30, 13 x 30	24X30
	X3D-DPH3	Sensor 15x15 + DR CEPH	MultiFOV 11 x 11 9 x 9 6 x 11 5x5	15 x 30 13 x 30	24X30

EXAMINATION PROCEDURES	
Technical factors selection for PAN	Automatic selection for Adult and Child, 3 sizes, with preset values.
	Manual selection for kV and mA
	Rotating collimator with automatic positioning
Volumetric 3D Panoramic	Automatic selection for Adult and Child, 3 sizes, with preset values
	Manual selection for kV and mA
	FOV Selection (optional)
	Image capture every 0.75 ° of rotation.
Panoramic	Adult/Child Standard Panoramic
	Adult /Child Right Hemi Panoramic
	Adult/Child Left Hemi Panoramic
	Frontal Dentition
Optional PAN	Adult/Child Reduced Dose Panoramic
	Adult/Child Improved Orthogonality Panoramic
	Right Bitewing
	Left Bitewing
	Right and Left Bitewing
TMJ	TMJ closed mouth
	TMJ open mouth
Sinus	Sinus P/A rotational projection
Cephalometric	LL CEPH 30 x 24

And Carpus	AP CEPH
	Carpus

2.8 Installation Type

The X-VIEW 3D PAN is designed for permanent installation; it must be connected to the main voltage via dedicated line equipped with security units.

2.9 Unit Classification According to EC 93/42

X-VIEW 3D PAN, based on classification rules contained in annex IX to Directive CE 93/42 and its modifications and additions is an active medical unit that releases energy (ionizing X-Ray) to the human body in a potentially hazardous form.

The emission of ionizing radiation is intended for diagnostics of diseases of maxillofacial complex. X-VIEW 3D PAN falls therefore, according to the rules above, in **Class IIb**.

2.10 Manufacturer Address

Headquarters and Production site
Via Artigiani 4
25014 Castenedolo (BS)
Italy
Tel +39 0302732485
Fax +39 0302731647
Web site: www.trident-dental.com

2.11 Package and Contents

X-VIEW 3D PAN system is shipped in a corrugated cardboard of triple wall:

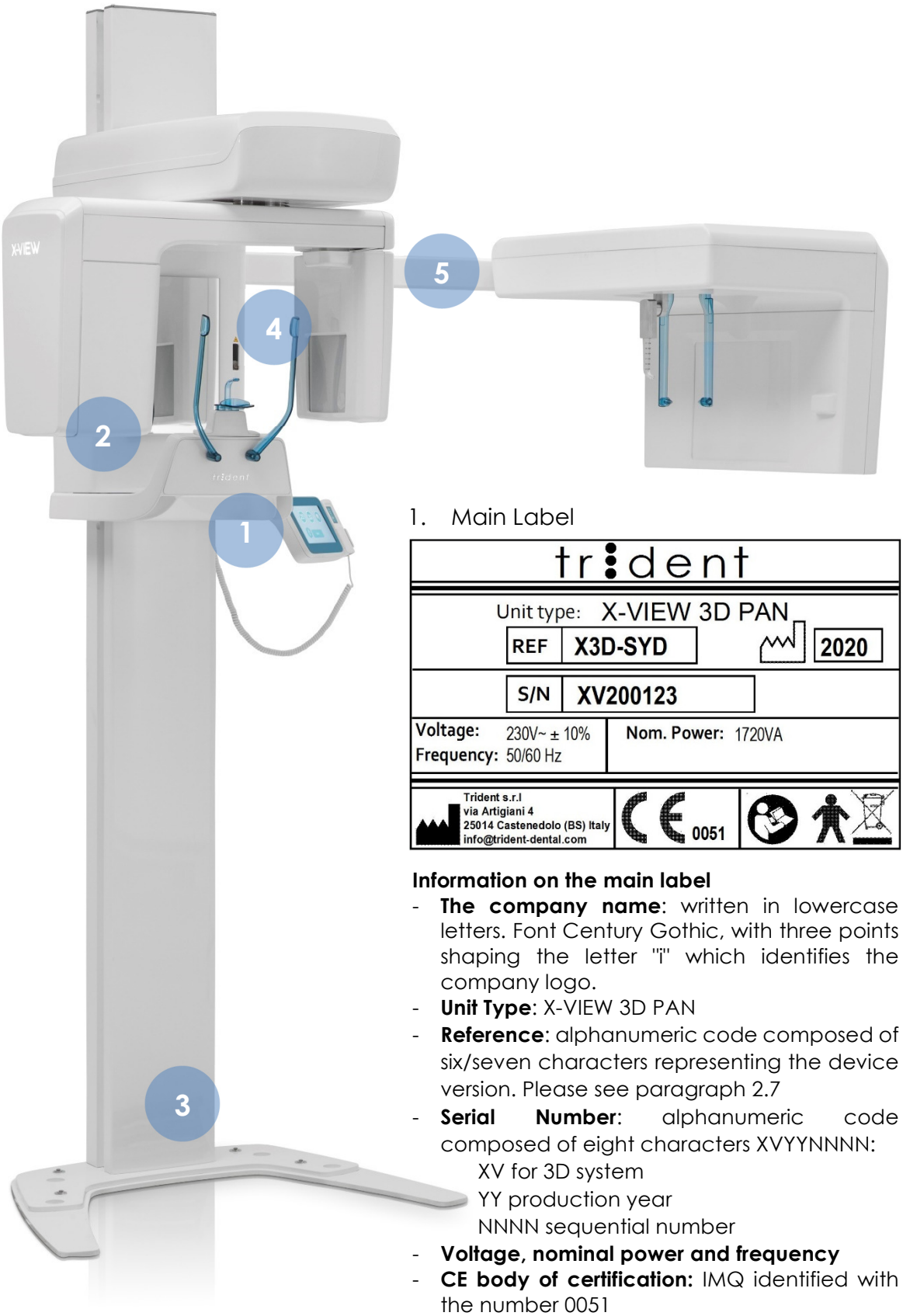
- It was designed to support considerable amounts of weight on its corrugated frame.
- Although the box is light it can carry heavy weight reducing transport costs.
- The triple wall will absorb any potentially damaging collision, abrasions and temperature changes
- 100% recyclable and totally reusable. Because of its heavy duty nature you have the possibility of re-use.

<table>
<tr><th>Box</th><th>Contents</th><th>W (Kg)</th><th>Size (cm)</th></tr>
<tr><td rowspan="5">  </td><td>Carriage
Column, with small base
Accessories</td><td>160</td><td rowspan="4">120 x 80 x 120</td></tr>
<tr><td>Large base (when included)</td><td>20</td></tr>
<tr><td>PC</td><td>10</td></tr>
<tr><td>Ceph sensor and arm (when included)</td><td>25</td></tr>
<tr><td colspan="3">The small base is mounted on the column, the large base (when included) is fixed to the floor of the pallet and the carriage is supported above a layer of polyethylene foam cushioning material.

The display group, the front cover, and the accessories bag (chin support, bite, small parts, etc.), are housed in a special packaging.</td></tr>
</table>

2.12 Labels for Identification

2.12.1 External Labels

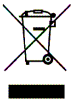


1. Main Label

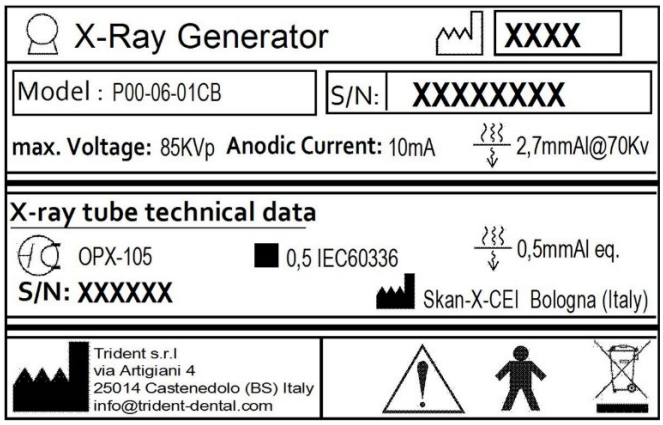
Information on the main label

- **The company name**: written in lowercase letters. Font Century Gothic, with three points shaping the letter "i" which identifies the company logo.
- **Unit Type**: X-VIEW 3D PAN
- **Reference**: alphanumeric code composed of six/seven characters representing the device version. Please see paragraph 2.7
- **Serial Number**: alphanumeric code composed of eight characters XVYYNNNN:
  - XV for 3D system
  - YY production year
  - NNNN sequential number
- **Voltage, nominal power and frequency**
- **CE body of certification:** IMQ identified with the number 0051

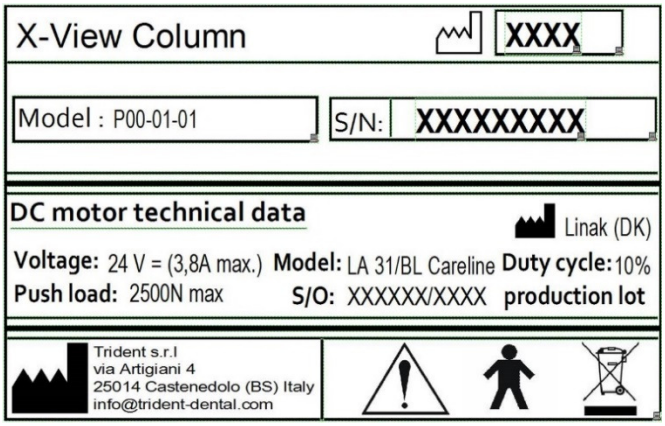
Other information in the main label:

Icon	Meaning
	Manufacturer address
	Read the instructions
	The device has some sensitive parts to electro-static.
	The product has some parts that come in contact with the human being
	Selective collection of electrical or electronic devices. At the end of its useful life do not throw this device in household waste

2. Tube Head Label

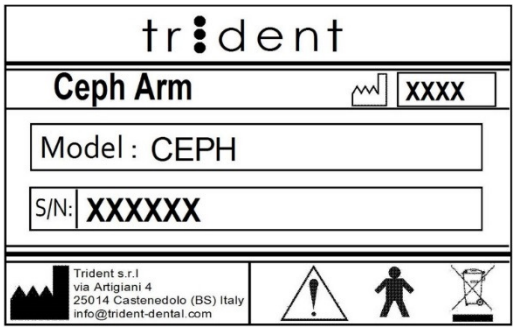


3. Column Label



4. Laser Label

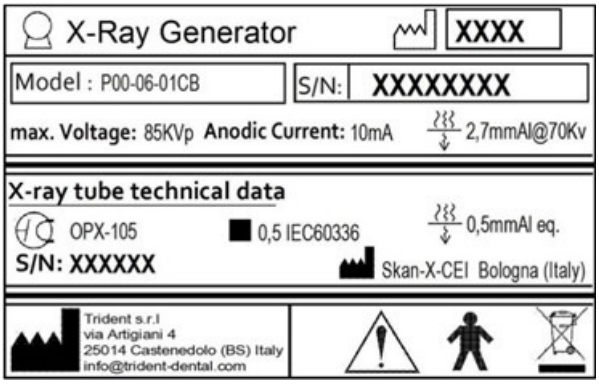
5. Ceph Arm Label



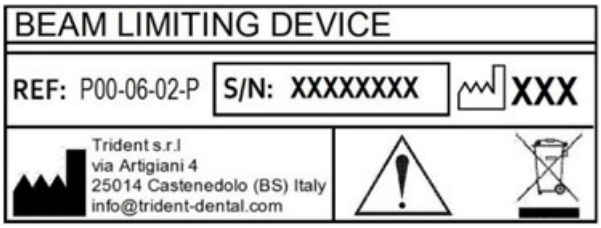
2.12.2 Labels Inside the Unit

6. Laser Label

7. Tube Head Label



8. Collimator Label



	For some Countries, labels may be different in order to follow local regulation. Please refer to labelling instruction to check.

3 SAFETY ASPECTS

	This chapter contains very important information concerning the unit, operator and patient safety. Read this chapter very carefully.

Trident S.r.l. have designed this device in compliance with all relevant safety requirements; it also provides all necessary information for appropriate use and warnings on the risks associated with using X-Rays for diagnostic purposes. Trident S.r.l. shall have no liability for:

- Misuse, neglect, abuse, accident, alteration, improper installation, or other acts that are not Trident's fault including damage caused by shipping, blown fuses, or spills of food or liquid.
- Damage to the unit, injuries to the operator or patient caused by either incorrect installation or maintenance that does not follow the procedures contained in the User and Service Manual provided with the unit, as well as incorrect operating techniques.
- Mechanical and/or electrical changes, made during or after installation, that differ from those listed in this Manual

3.1 General Warnings

Read carefully all the safety instructions to avoid potential hazards that could result in personal injuries or could damage your equipment.

	Personnel operating the device must be adequately trained with respect to the technological principles of operation and radiation protection.
	X-VIEW 3D PAN is built for continuous operation with intermittent load; therefore, it is required to observe the cycles of use allowing the dissipation of heat accumulated by the radiation source.
	X-VIEW 3D PAN must be switched off when using electro surgery or similar units.
	Make sure the installation of your X-VIEW 3D PAN unit is carried out only by qualified personnel. Absolutely avoid provisional electrical connections and verify that only the parts (screws, nuts, bolts, etc.) recommended by the manufacturer are used.
	The installation area must comply with the current regulations pertaining to radiology in the country of operation.
	Do not drop, knock, or shake the unit: rough handling or use beyond the recommendations may cause damage to internal circuitry.
	**In accordance with EN 60601-1, it is strictly forbidden to modify the equipment or its parts.** Only trained and qualified technicians are authorized to remove the covers giving access to the circuits. The cables of the power supply must comply with applicable laws and must be equipped with terminals for connecting to the protective earth.
	Carry out a proper cleaning and disinfection of all parts that come into contact with the patient.
	Check regularly (at least once a year) the state of correct operation of the system involving a specialist for any maintenance.
	Do not try to manually move the rotation arm unit. Only if the unit suddenly switches off (e.g. in case of electric power loss) the arm can be manually moved to let the patient out.

	X-VIEW 3D PAN must be connected to a PC for image capture and reconstruction. The system is equipped with a shielded Ethernet cable "cat.5E" or higher, which must only be used with the dedicated PC and GigaE network card. **NOTE** Do not use this connector to connect X-VIEW 3D PAN to LANs network.
	If the PC is placed within the patient's environment, it must comply with the requirements laid down in IEC 60601-1 medical units. If placed outside the patient environment, must conform to IEC 60950. **NOTE** The "patient environment" is defined as a distance of at least 1.5 m from the same patient. In case the PC is provided by Trident (optional part), this must be positioned outside the patient environment.
	**PRECAUTIONS WHEN USING A LASER CENTERING UNIT:** Although the laser centering unit used with the X-VIEW 3D PAN is classified in class 1 in accordance with IEC 60825-1 and attachments, it is recommended to follow this precautions: • Always keep the work area well lit. • Do not look inside the window of laser centering unit. • Do not look at the reflections of laser pointers. • Instruct the patient to keep his eyes closed during the activation of the laser pointers. • Before starting an exam, the patient should remove earrings, glasses, necklaces and anything else that can reflect the laser beam or be impressed on the radiographic image. • Do not open the laser centering unit with a gear as this could modify the optics of the same. • Only qualified service personnel must perform any cleaning operations. Carrying out procedures other than those listed above may result in emission of highly hazardous non-ionizing radiation.

3.1.1 Mechanical Risk

	Be careful not to pinch your fingers or any part of the body when the unit is in movement.

3.1.2 Explosion Risk

	Do not use the unit in the presence of vapours, oxygen and nitrous oxide, or flammable anaesthetic mixtures.

3.1.3 X-Rays Risk

	During the exposure, make sure no one except the patient and operator are present in the X-Ray area. Never leave the equipment unattended.

	Although the radiation dose of dental radiology equipment is, on average, lower and distributed on a reduced surface during exposure, the operator must take all precautions and provide appropriate protection to the patient and himself.
	The operator should take every reasonable precaution to maintain a safe and healthy working environment, minimizing the radiation hazard.

3.2 Electromagnetic Environment

Medical devices manufactured by Trident conform to EN60601-1-2:2007 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- X-VIEW 3D PAN is suitable for use in the electromagnetic environment that meets the conditions described below.
- The medical devices should not be used adjacent to or stacked with other equipment.
- The use of accessories and cables other than those specified by Trident, may result in increased emission or decreased immunity of the device.

The guidance below refers to the EMC environment in which the device should be used.

3.2.1 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

X-VIEW devices are intended for use in the electromagnetic environment specified below. The customer or the user of these devices should assure that they are used in such environment.

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT–GUIDANCE
RF Emissions CISPR 11	Group I	The unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The unit is suitable for use in all establishments other than domestic, and in those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not applicable	Not applicable
Voltage fluctuation / flicker emissions IEC/EN 61000-3-3	Not applicable	Not applicable

3.2.2 Guidance and Manufacturer's Declaration –Electromagnetic Immunity

X-VIEW devices are intended for use in the electromagnetic environment specified below. The customer or the user of these devices should assure that they are used in such environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	EMC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	Test level IEC 60601-1-2	Floors should be in wood, concrete or ceramic tile. If floor is cover with synthetic material, the relative humidity should be at least 30 %.
Electrical fast	2 kV for power supply		Mains power quality should be that of a typical commercial or hospital

transient/ burst IEC 61000-4-4	lines 1 kV for input/ output lines > 3 mm	Test level IEC 60601-1-2	environment.
Surge *IEC 61000-4-5*	± 1 kV line to line ± 2 kV line to earth	Test level IEC 60601-1-2	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines 61000-4-11	<5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (> 95% dip in UT) for 5 s	Test level IEC 60601-1-2	Mains power quality should be that of a typical commercial or hospital environment. If the user of the unit requires continued operation during power mains interruptions, it is recommended that the phototherapy unit be powered from an uninterruptable power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Test level IEC 60601-1-2	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Test level IEC 60601-1-2	Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1,2 √P 80 MHz to 800 MHz d = 2,3 √P 800 MHz to 2.5 GHz d = 1,2 √P Where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5 GHz	3 V/m	
Interference may occur in the vicinity of equipment marked with the symbol shown on the right 			
NOTE 1) At 80 MHz and 800 MHz, the higher frequency range applies. *NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.*			
(a) Field strength from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Trident devices are used exceeds the applicable RF compliance level above, the Trident device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Trident device. *(b) Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.*			
NOTE: *UT is the AC. mains voltage prior to application of the test level.*			

3.2.3 Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and X-VIEW 3D PAN

X-VIEW 3D PAN is intended for use in an environment in which radiated RF disturbances are controlled. The user of the unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters)

and the unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d = 1,2 √P	80 MHz to 800 MHz d = 1,2 √P	800 MHz to 2.5 GHz d = 2,3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

NOTES
For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3.3 Safety Regulations

X-VIEW 3D PAN is in accordance with the IEC 60601-2-65:2012 regulation and follows the next safety regulations.

3.3.1 General Safety

CEI EN 60601-1	Electromedical Equipment - Part 1: General requirements for basic safety and essential performance.
EN 60601-1:2006, IEC 60601-1:2005	Medical electrical equipment. General requirements for basic safety and essential performance
IEC 60601-2-63:2012	Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-Ray equipment.
IEC 60601-2-28 Ed. 2	Medical Electrical Equipment - Part 2-28: Particular requirements for basic safety and essential performance of X-Ray tube assemblies for medical diagnosis.
IEC 60336:2005	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots

3.3.2 Electromagnetic Compatibility

EN 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

3.3.3 Radiation Protection

IEC 60601-1-3 Ed.2	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-Ray equipment
IEC 60825-1:2007	Safety of laser products - Part 1: Equipment classification and requirements

3.3.4 Usability

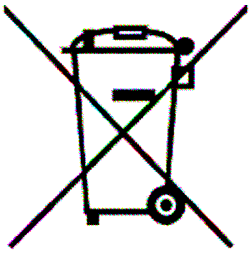
IEC 60601-1-6:2010 / CEI EN 62366:2008	Medical units - Application of engineering characteristics of medical units

3.3.5 Symbols

UNI CEI EN ISO 15223-1:2012	Medical units - Symbols to be used in the medical unit labels, labeling and information to be supplied - Part 1 : General requirements
UNI EN ISO 780:2001	Packaging -- Pictorial marking for handling of goods
CEI/IEC 60417-1: 2000	Graphical symbols for use on equipment – Part 1: Overview and application

3.4 Disposal at the end of its useful life

The device, its spare parts and accessories may include parts that are made of or include materials that are non-environmentally friendly or hazardous.



The symbol of the "crossed bin" as indicated on the label, means that when the product has reached the end of its useful life, it should not be disposed as household waste but must be collected separately and transferred to specialized operators for recycling or disposal of waste electrical and Electronic Equipment (WEEE), in accordance with the laws in force. This helps to avoid possible negative effects on health and environment, and promoting the recycling of the materials making up the product. The law provides penalties for illegal disposal.

Trident Dental and its local dealers, will assume the commitments associated with the management of WEEE from professional nature, according to the relevant standards applicable in the European Union and other European countries with separate collection systems, Article 13 of Legislative Decree 25 July 2005, n. 151 *"Implementation of Directive 2002/95 / EC, 2002/96 / EC and 2003/108 / EC on the restriction of use of hazardous substances in electrical and electronic equipment and the disposal of waste"*

4 TECHNICAL PARAMETERS

4.1 General Characteristics

Parameter	Value
Unit name	X-VIEW 3D PAN
Manufacturer	Trident Srl Castenedolo, 25014 (BS) Italy
Classification according to IEC 60601-2-63:2012	Medical Unit
Classification according to IEC 60601-1	Medical Unit Class I with type B applied parts
Classification according to Directive EC 93/42	Medical Unit Class II b
Working way	Continuous with adaptive duty cycle
Protection Rank	IPX0

4.2 System Supply

Parameter	Value
Line Voltage	115 V/230 V ± 10%
Frequency	50/60 Hz
Electric current	7.5 A @ 230V
Absorbed power	1720 VA @ 230V @ 50/60Hz
Apparent line resistance	0.5 Ω max
Main Power protection fuse (F1)	10 A T
Column actuator Protection fuse (F2)	5 A T
Rectifier Board protection fuse XRPSR	6,3 AT
Inverter Board protection fuse XRPSI	6,3 AT
Switching power supply protection fuse 24 V	2 x 3, 15AT
Switching power supply protection fuse 12 V	2 x 2, 15AT
High tension	61 to 85 kVp, at steps of 3 kVp (9 steps)
Anodic current	6,3 to 10 mA, according to R'20

4.3 X-Ray Tube Head

Parameter	Value
Model	P00-06-01
Manufacturer	Trident S.r.l. Via Artigiani 4, Castenedolo 25014 (BS)
Tube Voltage	85 kVp
Precision kVp	± 8 %
Maximum Anodic current	10 mA
Anodic current accuracy	± 10%
Radiation Output linearity	< 0.2 IEC 60601-2-63 paragraph 203.6.3.1.101
Duty cycle	Adaptive Duty cycle according to the exposure and dielectric oil temperature. Minimum 1:8, average 1:16
Nominal power	850 VA (85 kVp - 10 mA)
Total filtration	2.5 mm Al eq. @ 70 kVp

Parameter	Value
Half Value Layer (HVL)	> 2.0 mm Al eq. @ 61 kVp > 2.7 mm Al eq. @ 73 kVp > 3.05 mm Al eq. @ 85 kVp
Current transformer insulation	Oil bath
Cooling	As per convection
Focal spot	0.5 mm (IEC 60336)
Leakage radiation at 1 m	< 0.5 mGy/h @ 85 kVp - 10 mA – 3s duty cycle
Max thermal capacity of tube head	900 kJ

4.4 X-Ray Tube

Parameter	Value	
Manufacturer	Skan-X-CEI (Bologna) Italy	Kailong
Model	OPX 105	KLA-0.5-105
Nominal Focus size	0.5 IEC 60336:2005	5 IEC 60336:2005
Inherent filtration	0.5 mm Al eq.	0.6 mm Al eq.
Anode angle	5°	5°
Anode material	Tungsten	Tungsten
Nominal maximum tension	105 kVp	105 kVp
Nominal reverse tension	136 kVp	136 kVp
Maximum filament current	4 A	4.2 A
Maximum filament tension	8 V	8.2 V
Anode thermal capacity	30 kJ	30 kJ
Maximum anodic dissipation	250W	250W

4.4.1 X-Ray Tube Characteristics Respect to the Reference Axis

Inside the tube head, the X-Ray tube is rotated both horizontally and vertically, so that the X-Ray beam adequately covers the image receptor.

Parameter	Value
Focus nominal size	0.5 IEC 60336:2005
Anode angle	5° (IEC 69788)

4.4.2 Geometric Relationship

Parameter	Value
Focus - Sensor distance	512.5 mm
Focus – Centre of Rotation distance	377 mm
3D X-Ray beam size	130 x 130 mm (L x H)
Irradiated area size (PAN)	6 x 130 mm (L x H)

4.5 Digital Sensors para 3D

Characteristics	Value
Manufacturer	iRay technology
Model	Jupi 0505
Sensitive area	13 x 13 cm
Pixel dimensions (L=H)	85 µm, 85 µm
Pixel Number (H x L)	1536 x 1536
Scintillator	CsI

Characteristics	Value
Manufacturer	iRay technology
Model	Jupi 0606
Sensitive area	15 x 15 cm
Pixel dimensions (L=H)	100 µm, 100 µm
Pixel Number (H x L)	1536 x 1536
Scintillator	CsI

4.6 Ceph Sensor

DR (digital radiography) sensor	
Parameter	Value
Detector Technology	Amorphous Silicon
Scintillator	CSI
Sensitive area	30 x 25 cm
Pixel dimensions	125 µm
Image format	30 x25 and 25 x 25
Image dimensions (pixel)	2400 x 2000 for 30 x 25 cm image format

4.7 Centering Lasers

Parameter	Value
Wavelength	650 nm ± 10 nm
Divergence	< 2.0 mRad
Optical power	< 1 mW
Classification	Class 1 according to IEC 60825-1

4.8 Mechanical Characteristics

Parameter	Value
Focus-image receptor distance (3D, PAN, TMJ, Sinus)	52 cm
Focus-image receptor distance (CEPH)	145 cm
Patient centering movement	77 cm
Vertical column total height	223 cm
Bite centering height	105 to 182 cm

4.9 Exposure Times

Program	Exposure Time (in seconds)
Adult Panoramic	15.5
Child Panoramic	14.8
Adult Right/Left Hemi Panoramic	8.4
Child Right/Left Hemi Panoramic	8
Adult Reduced dose Panoramic	12.1
Child Reduced dose Panoramic	12.1
Adult Improved Orthogonality Dentition	12.8
Child Improved Orthogonality Dentition	12.1
Adult Right/Left Bitewing	3.0
Child Right/Left Bitewing	2.4
Adult Bitewing right left	6.0
Child Bitewing right left	4.8
TMJ open/close mouth	3.4 s for image right/left side joint in the open or closed condition
SINUS	12.1
Exposure times accuracy	± 10 %

	The filament warm-up time (3s) precedes the exposure times.
	The exposure parameters values (kV and mA) may be adequate to the patient morphology.

4.10 Images Magnification

Program	Value
Adult/Child Standard Panoramic	1 : 1.28
TMJ open/close mouth, 4 images	1 : 1.25 (nominal)
Sinus	1 : 1.27 (nominal)
CEPH	1: 1.10 on the median sagittal plane projection in LL Not quantifiable in Projection AP
Carpus	Not quantifiable enlargement.

4.11 Environmental Conditions

Parameter	Value
Minimum size of the room	L x P x H: 120 x 120 x 240 (cm)
Maximum operating temperature ranges	+ 10° to + 40°
Operating relative humidity range	30% to 75%
Operating atmospheric pressure	80 to 106 Pa(maximum higher ≤ 2000 m)
Transport and storage temperature	- 20° to + 70°
Transport and storage Maximum relative humidity	< 95% not condensed
Transport and storage Atmospheric pressure	63 to 106 Pa

5 INSTALLATION

	This chapter describes the installation requirements needed to guarantee a safe procedure.
	Before starting installation, please carefully read and follow all safety instructions in this chapter.

The following are the essential conditions for a proper installation of the system. The person responsible for installing the equipment is required to:

- Determine the type of wall and its bearing capacity as well as the eventual modification or installation of electric and mechanical structures required for a correct installation.
- Ensure that the supply voltage specified by Trident is available and within the given limits.
- Check that there is a safety switch breaker with the characteristics described in the technical sheet.
- Disconnect the power grid during installation.

5.1 Installation Pre-quirements

Unit Weights	
3D PAN	120 KG
Ceph Arm	25 KG

	Make sure the floor where the unit is to be installed can support this weight.
	The unit must be permanently attached to the wall.
	Make sure that the fixing hardware and wall can withstand pull-out strengths of at least 5000N.
	The place where the unit is to be installed and the position from the user takes exposures must be correctly shielded from the radiation. Follow the local radiation and safety requirements.
	When installing the unit make sure there is enough space at the front and sides of the unit to allow patients to enter and exit the unit easily.

5.1.1 Minimum Room Dimensions

See Annex 1 and 2

5.1.2 Fixing System and Required Tools

X-VIEW 3D PAN standard version must be fixed to the wall with the two brackets supplied by Trident. Each piece must withstand an extraction force of 120 kilograms (264 pounds).The screws to be used for each wall type are:

Wall Type	Fixing System	Screw Reference
Full solid brick or cement	Steel or nylon anchors	**M8x1,25 ISO 8.8** **M8x1 ISO 8.8**
Drilled Brick	Chemical anchors (not supplied)	**5/16" – 18 UNC SAE Degree 5**
Wood structure	Self-tapping screws(not supplied)	

	Using inadequate screws or not enough solid walls for installation, can resulting in serious injury to people, and serious damage of the unit.
	The system with Ceph arm, ought to be fixed to the wall or to the floor using the support base.

Tools	
Installation Tools	Electric drill Spanners Allen keys Flat blade screwdrivers Spirit level Pliers and wire cutters Scissor/knife Service tools sets
PAN calibration and setup tools	Trident supplies a PA2-05 tool

5.1.3 Electrical Requirements

	The unit is intended for a permanent installation. Do not connect the system to a traditional outlet plug in order not to compromise the operator and patient safety. Do not use mains extension cables.
	Safety distances between high voltage parts as specified by IEC 60601-1 ought to be respected in order to avoid electrical incidents.

5.1.3.1 Power Line Requirements

FEATURE	REQUIREMENT
Power supply: single-phase with neutral	115/230 V ± 10%
Frequency	50/60 Hz
Absorbed power	1720 VA
Current consumption	7,5 A (at 230 V), 15 A(at 115 V)
Apparent resistance line	0,5 Ω max

For the mains connection the room should be equipped with adequate wiring, complying with the following guidelines:

1. Minimum section conductors of 1.5 mm^2 (16AWG)
2. According to the standards, a reinforced protective ground connection must be ensured.

3. The electrical connection can be inserted into the wall; these connections should be made well in advance. The cable raceways must be properly sized for the passage of the connection cables.

	**WARNING** Poor quality ground connection may result in damage to the equipment and injury to the patient or the operator.

5.1.3.2 Differential Magneto-thermal Breaker Features

The differential magneto-thermal switch combines in a single unit the residual current function and the function of overload protection typical of magneto-thermal switches. The main features of the differential magneto-thermal breaker must be:

Parameter	Requirement
Working Voltage	115/230 V ~
Nominal Current	10 A (at 230V) 20 A (at 115V)
Differential Breaker Sensitivity	30 mA

5.1.3.3 Preparation of Signal Lamps, Remote Controls and Safety

X-VIEW 3D PAN is designed to accept the following remote signals:

1. **System Ready** external signal lamp: lits when the system is powered on and READY to perform the examination (N.O. contact, 230 V, 2A max). Remember to check the presence of a power supply or transformer for the related lamp.
2. **System in Emission** external signal lamp: is on when the system is running an exam (contact N.O., max 230 V, 2 A). Remember to check the presence of a power supply or transformer for the related lamp.
3. **Open Door** Safety sensor: this sensor consists of a switch that warns the system that the door of the X-ray room is open, so the exam cannot be acquired
4. Remote X-Ray command button: allows to control the emission from a protected area or outside the room.

	The safety signal **Open Door** can be deactivated from the interconnection card; sensor status is not reported on the Control Panel, so it is the responsibility of the installer and end user to control that access is not permitted during the execution phase of the examination.
	The protected location must be such that the operator can observe, during all the phase of emission, both the patient and the control panel, in order to interrupt the examination, releasing the button, in case of any problem.

For remote signals connection and remote X-Ray control, the following connectors will be required:

- No. 4-wires for remote reporting **System Ready** and **System in Emission**
- No. 2 wires for security signal **Open Door**
- No. 2 wires for the **Remote X-Ray button**

5.2 Step by step Installation

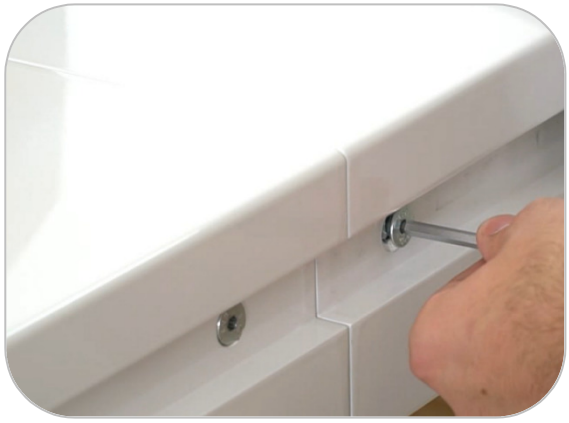
☞	We strongly recommend assembling the unit near the place for installation. Place the packing into the room where you plan to install the machine, considering that it will be necessary to connect the X-VIEW to a power supply to operate the lift.
	Save the packaging materials as they may be needed if you move the unit to a new location
	For the installation you will need these tools: • Screwdriver/electric screwdriver • Allen keys n°4, n°5 and n°6 • Electrical drill for wall holes

- Open the carton box and remove the high part of the column. Use the base of the pallet as support for the assembling operations.

- Assemble the bracket P00-01-00-021 on the top of the column using the two screws M8 x 20.

5.2.1 Installation with small base

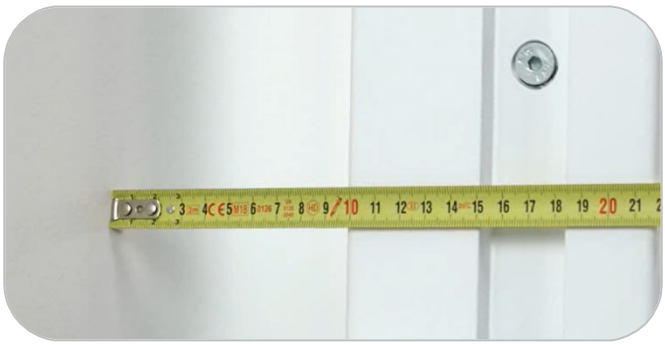
- Join the two parts of the column using the three brackets



Now the column is completed.

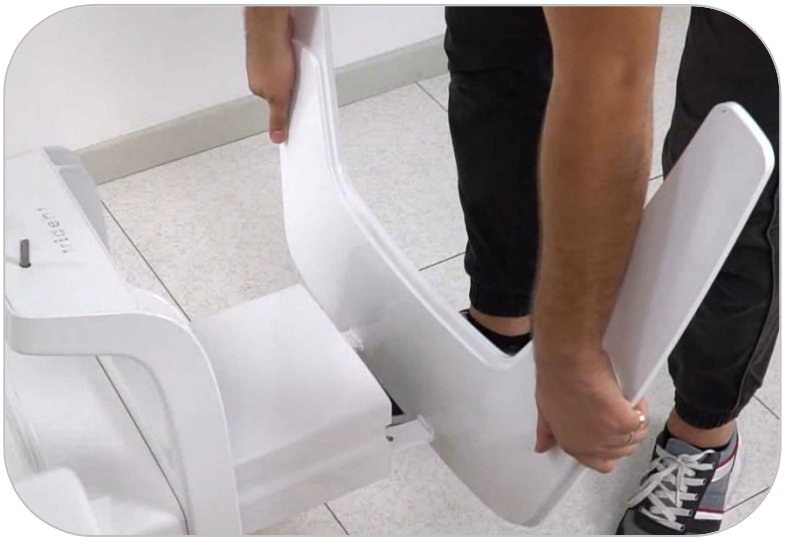
- Lift the column and stand it to the wall to prepare the holes

- Prepare the holes. Use the spirit level, a marker and a meter.

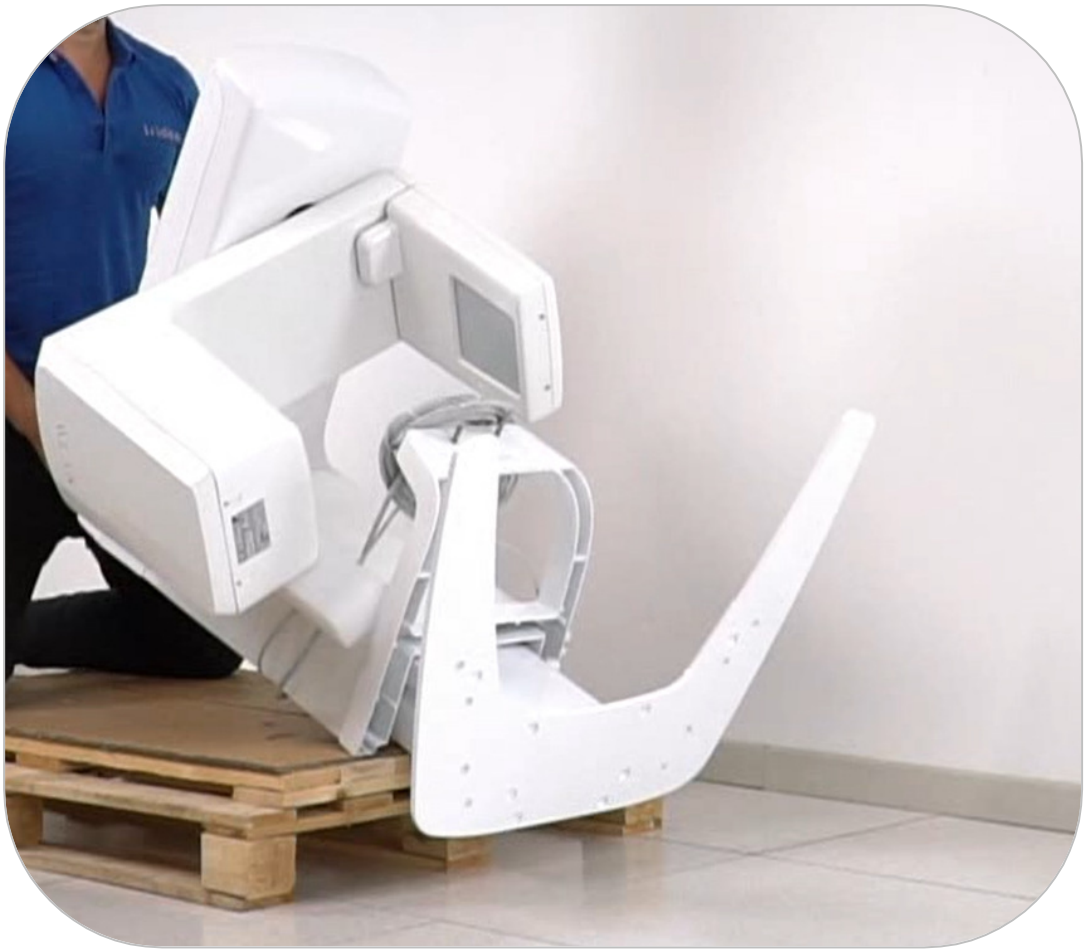


5.2.2 Installation with Large base

- Fix the large base to the half column with the holes in the rear.



- Once the large base is well fixed, lift the half column.



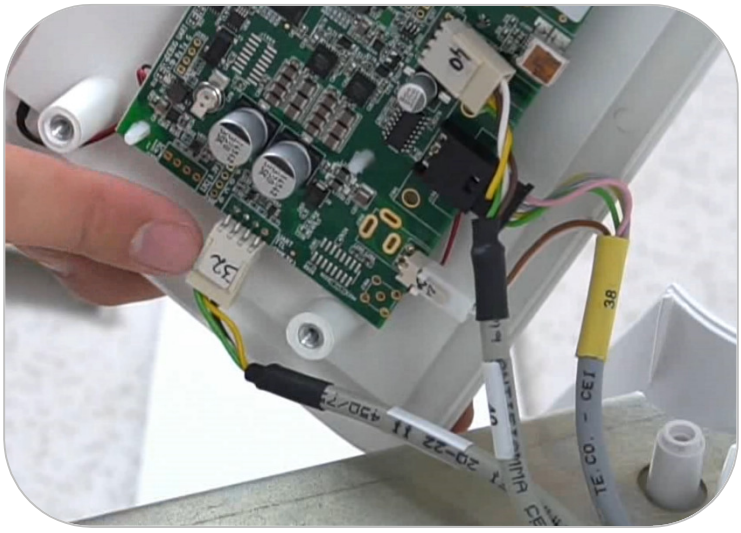
- Assemble the bracket P00-01-00-021 on the top of the column using the two screws M8 x 20.

- Join the two parts of the column using the three brackets.

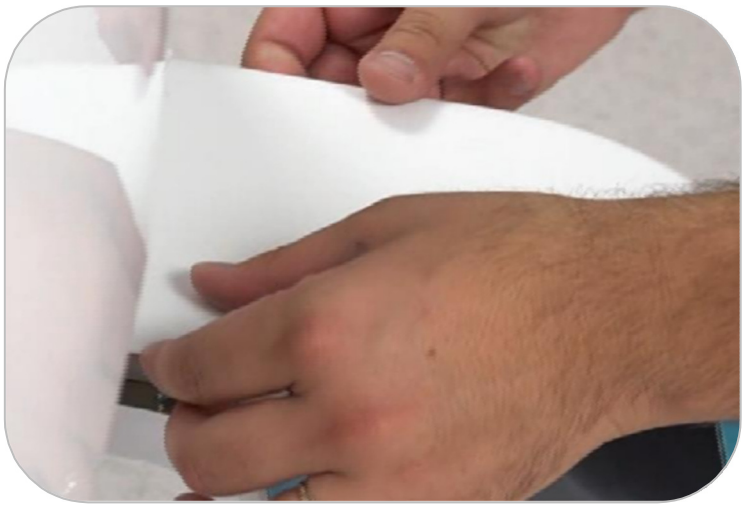
5.2.3 *Display and cable connection*

- Mount the display case on the device

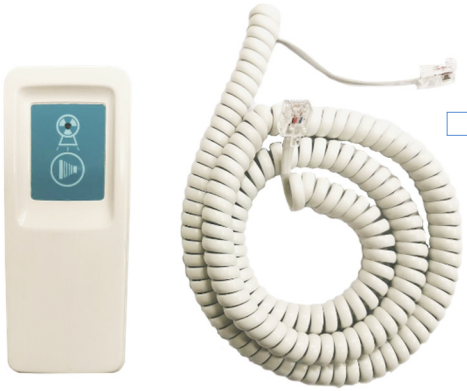
- Connect the cables following the numbers.



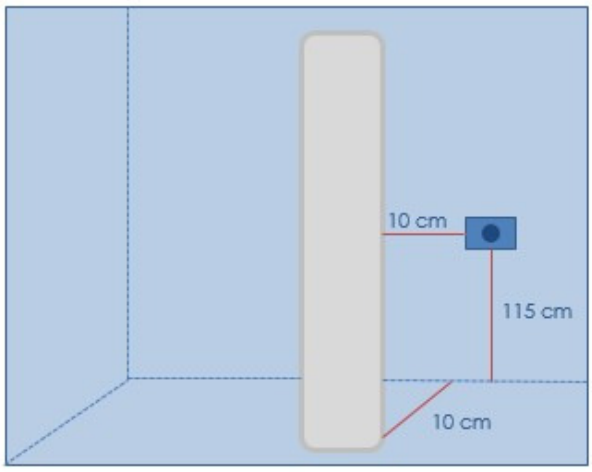
- Close all covers.



- Connect the X-Ray push button to the spiraled cable and plug it to the device



- Plug the device to the main power supply (check if the device is set for 230 V or 115V). Follow this distances recommendations:



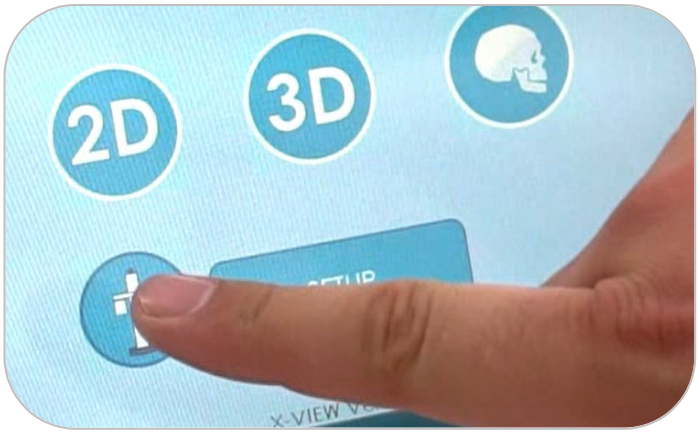
5.2.4 *Lifting the column*

- Plug one end of the PA2-29 cable to the column motor connector

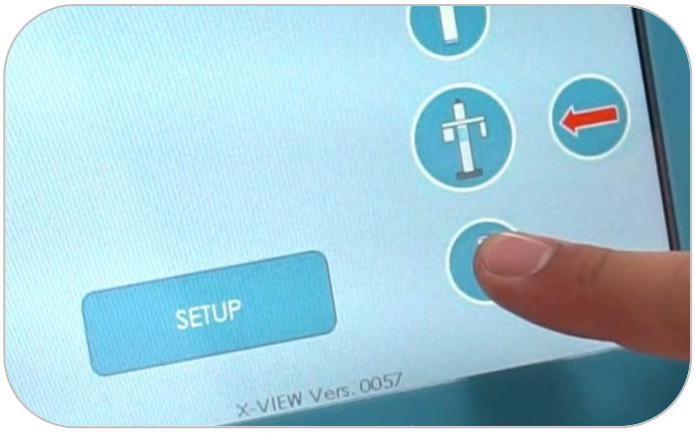
- Plug the other end of the cable to the column power supply

- Turn on the device and follow the display instructions to reset the axes

- Press the column icon



- Now press the “down” arrow to release the carriage hook



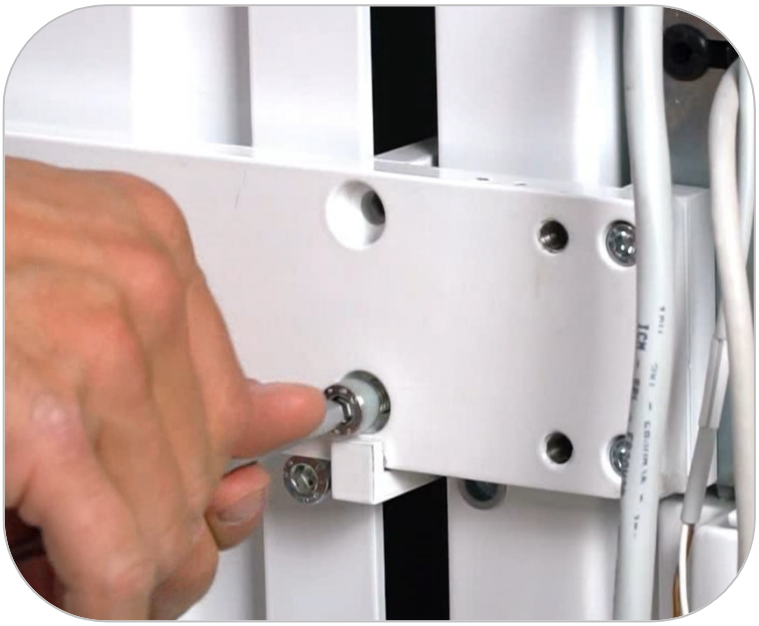
- On the back of the column remove the hook safety lock

- Connect the hook to the upper carriage crosspiece

- Lift the column pressing the upward arrow

- Once reached, put the safety screw under the low crosspiece.

- Unloose the chain and fix the hook properly with the 2 screws on the lower crosspiece.



- Disconnect the PA2-29 cable and directly connect power supply and motor

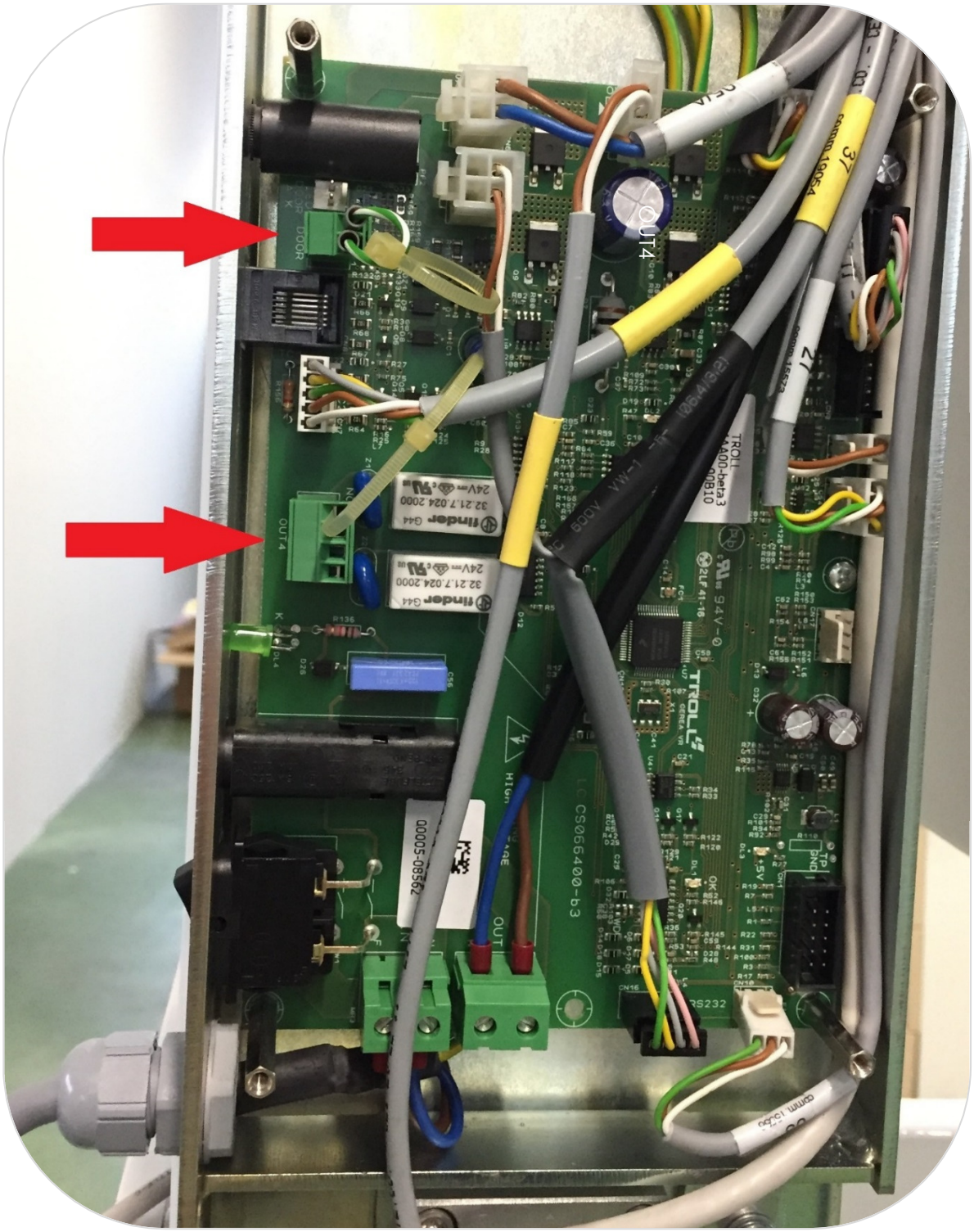
5.2.5 *Accessories*

- Fix the front sticks

- Position the bite and chinrest

5.2.6 *External Warning Signals Connection*

Connect the cable from the remote signal to the OUT 4 connector; the connector is equipped with screw terminals; see the connector position in the following picture:



Connect the external warning lights in this way:

- TERMINALS 1-2 for the **System Ready** Indicator
- TERMINALS 3-4 for the **Emission in Progress** indicator

	**WARNING** The connector only supplies the "clean" outputs of 2 single-phase relays, which controls switching on the safety warnings, **without power. The power must be supplied separately**.

5.2.7 Open Door Safety Signal Connection

The **Open Door** safety indicator is triggered whenever the door is open during an examination. The emission is interrupted.

The safety indicator must be connected to the screw terminals of the door connector, located on the interconnection card as shown in the previous picture.

	The safety indicator is a digital signal.
	If you want to use the **Open Door** safety sensor, remove the jumper that disables the safety indicator.
	Failure to enable the **Open Door** safety sensor is not shown on the operator display; therefore, the user must control this fact.
	The **Open door** safety sensor can be disabled at the installation phase, in accordance with the user indications. The status of the enabled or disabled security is not displayed on the operator's interface.

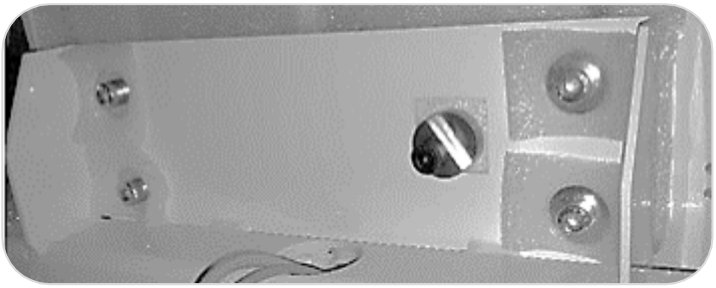
5.2.8 Remote X-Ray Button Connection

A RJ45 telephone type connector, accessible from the outside, connects the remote X-Ray button; it is located in the upper side of the interconnection card, above the button to turn on the system and the relative LED.

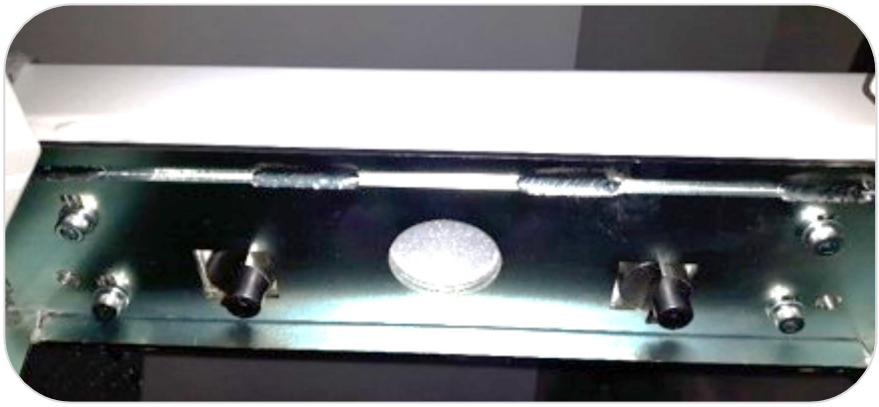
	The remote X-Ray button must be installed so that the patient can always be observed when the examination is being performed, during the emission phase.
	The remote X-Ray button is in parallel with the local X-Ray button, located near the display, which is not disabled. Thus, its operation is similar to that of the standard X-Ray button.

5.3 Cephalometric arm installation

– Fix the CEPH arm to the column using the four screws provided by Trident.



– Then, fix the sensor to the arm. Use the four screws provided by Trident.



⚠	**IMPORTANT: Once everything is installed, loosen the screws, use a spirit level to align the arm, and move the eccentric to leave the arm horizontal. Then tighten the screws.** **It is recommended to move the eccentrics from the sensor side ONLY if necessary. These are set in the correct position at the factory.**

- Connect power cable 56 to cable 47 on the back of the device
- Connect Ethernet cable from CEPH arm to your PC.

6 IMAGING SOFTWARE INSTALLATION & CONFIGURATION

Deep-View 3D is the software for the management (acquisition, modification and storage) of digital images developed by Trident for X-VIEW 3D PAN. Deep View comes in a portable USB marked with Trident logo.

The USB contains the following folders:

- DEEP-VIEW Installer
- DEEP-VIEW Manuals
- X-VIEW 3D SN Config
- X-VIEW 3D SN Instructions & Manuals
- Utilities

6.1 PC Specifications

Model	Personal Computer minimum Intel Core i7-6700 3.4 8M 4C
RAM	8 GB DDR4-2133 NECC
HDD	1 TB
OS	Windows 10 Pro
	1 DVDRW
Ethernet	2 Intel LAN 10/100/1000
USB ports	2 internal + 4 external
GRAPHIC CARD	PNY GEFORCE GTX 1660 TI 6 GB XLR8 minimum
Monitor	Monitor 24" HD

6.1.1 PC Installed Inside the X-Ray Room

In this case, prepare the following items:

- A 230 V or 115 V socket with a PERMANENT cables fixing system for the X-VIEW.
- A standard socket for the PC.
- A standard socket for the monitor.
- Ethernet cable for the connection with the acquisition PC (LAN gigabyte)
- RJ45 socket for the X-VIEW remote button cable (two cables)
- Passage for the multi-pole cable (six cables) for the **Open Door** safety switch, the 24V **X-Ray Emission in Progress** warning light and the 24V **System Ready for Acquisition** illuminated indicator.

These cables need to be connected between the PC and X-VIEW:

- Ethernet cable for acquiring images. If necessary, the cable supplied by Trident can be lengthened with cables of the same type -Ethernet CAT6- using female-female connectors.
- Bipolar connector for communication between X-VIEW and PC (supplied; with the following specifications: twisted bipolar cable 0,22mm2-cod. RS Components-660-4021). In this case, the installer will decide whether to pass the cables from the outside or inside the wall, through the appropriate passages.

6.1.2 PC Installed Outside the X-Ray Room

Follow the directions above, although this time consider that:

- The sockets for the PC and monitor do not need to be in the room.
- The cables between X-VIEW and the PC need to pass through the walls.

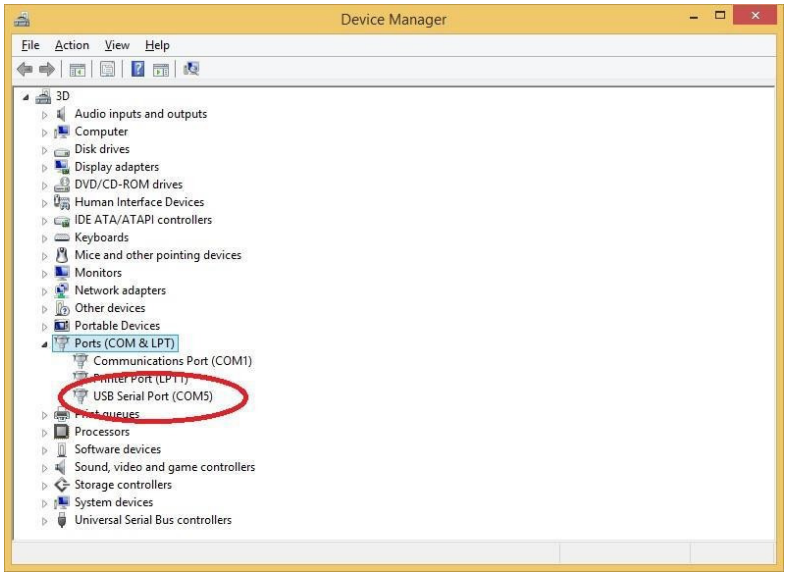
6.2 Software Configuration

- Connect the USB cable from X-VIEW to the PC
- Connect Ethernet cable (two, in case of Ceph arm) from X-VIEW to the PC

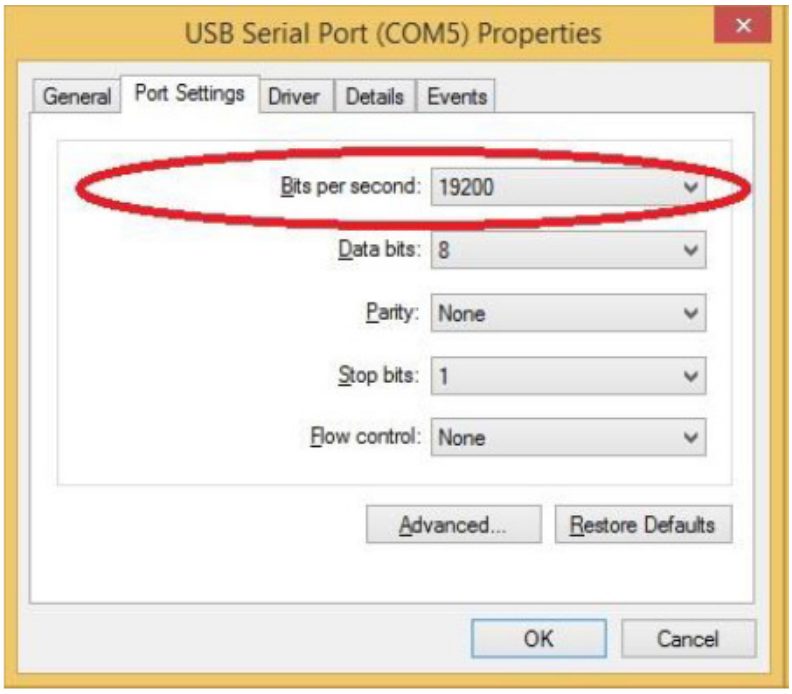
6.2.1 Ethernet configuration and IP Address setting

Please follow these steps:

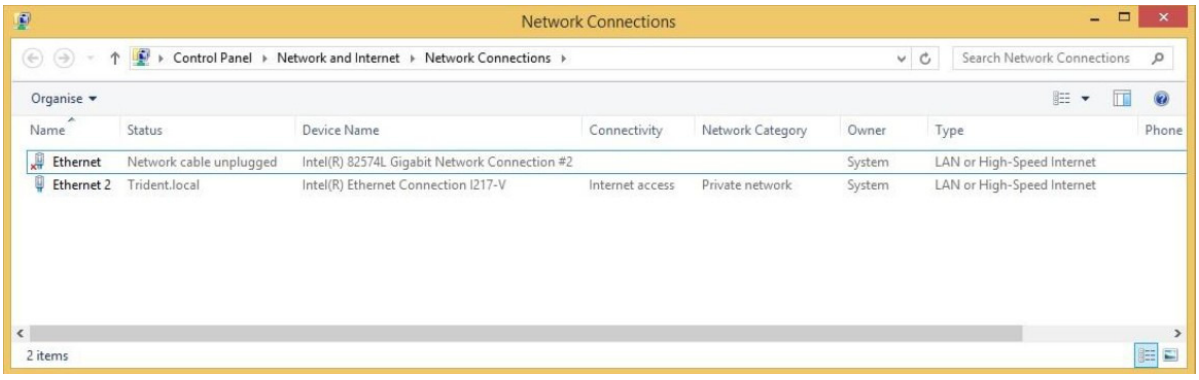
- Open **Device Manager** and write the COM port number and relative properties.



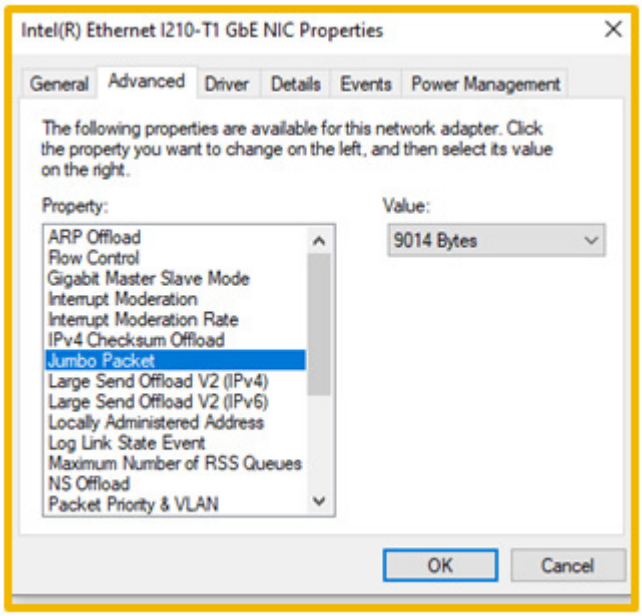
- Right click on the USB port (if it is not there, check the connection with the unit) and check the speed, which must be 19200 bps.



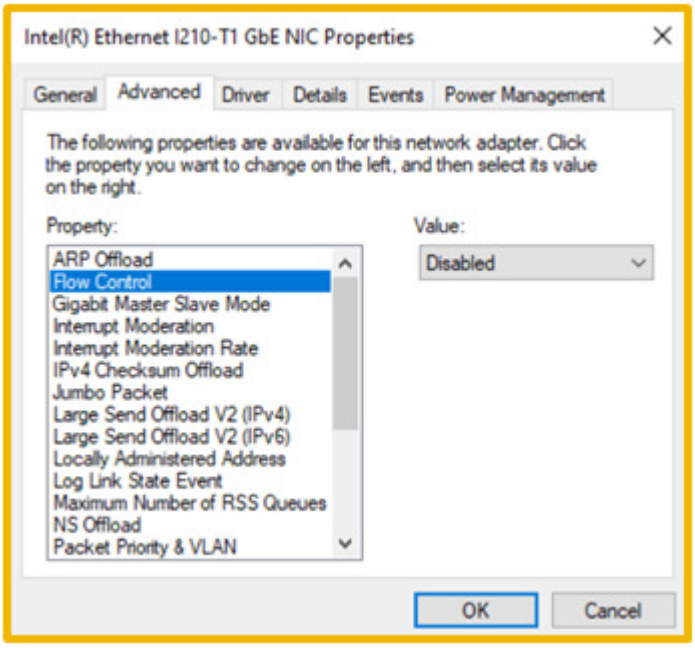
– Identify Intel Gigabyte Lan Adapter:



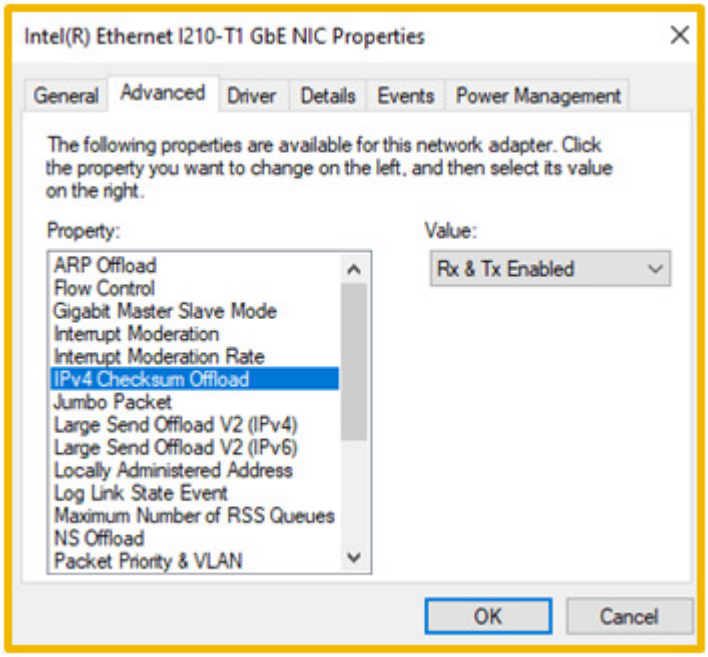
– Set the Ethernet Intel Gigabyte Lan adapter as follows:



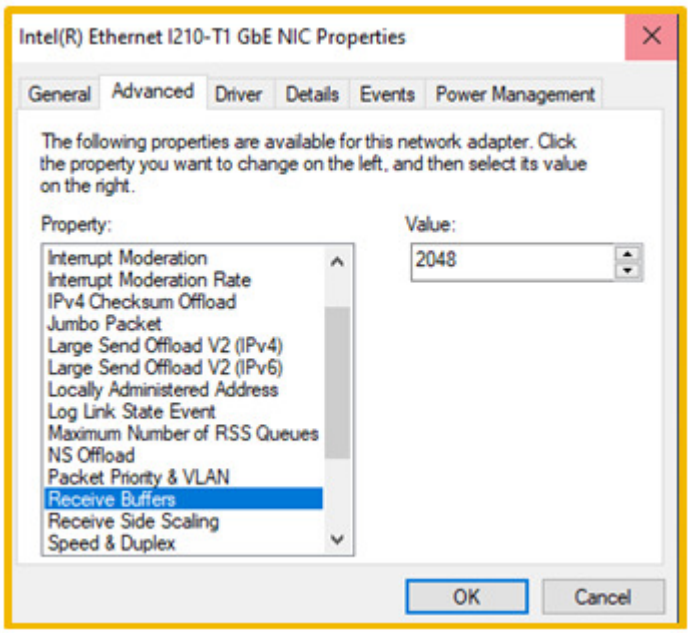
✓ Set the value of **Jumbo Packet** to 9014 bytes



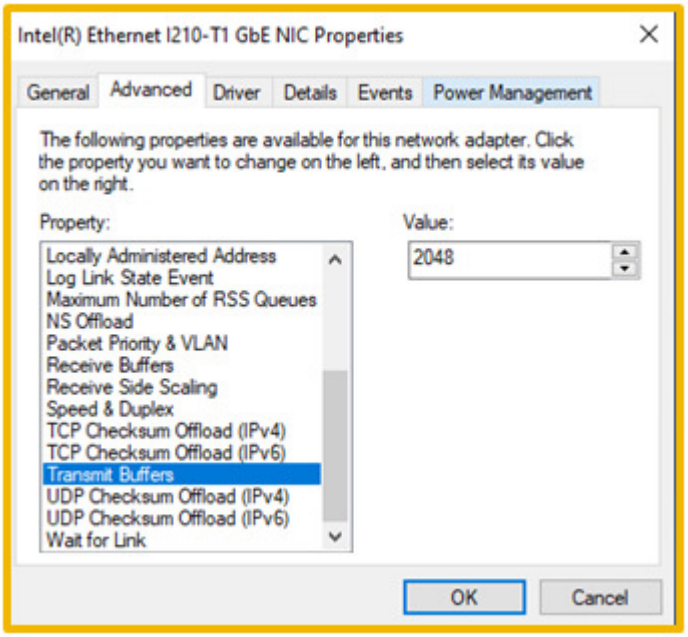
✓ Disable the **Flow Control**



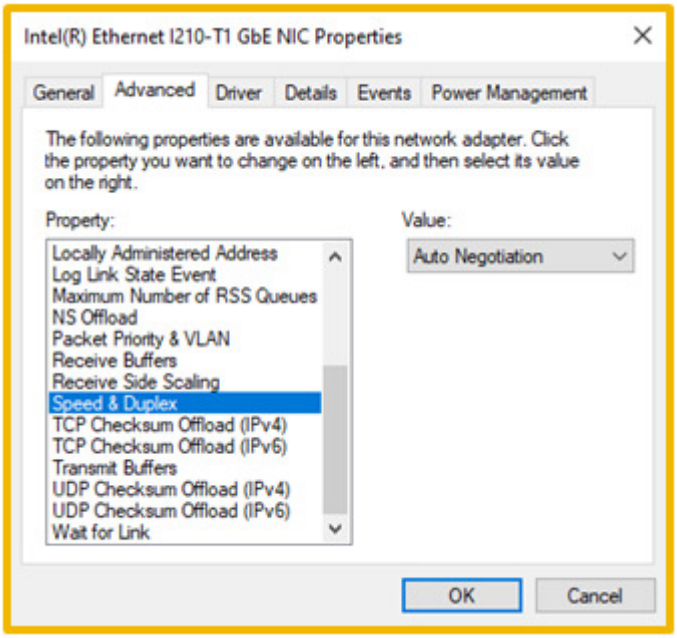
✓ Set **IPv4 Checksum Offload** to Rx & Tx Enabled



✓ Set **Receive Buffers** to 2048



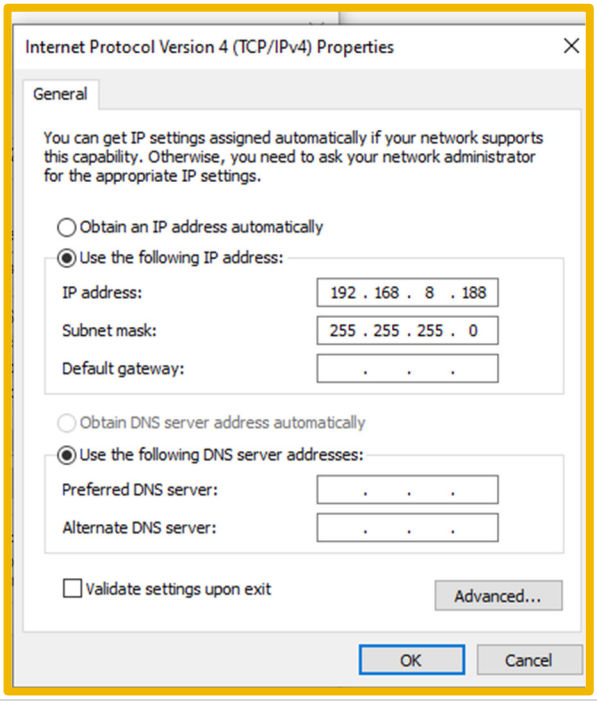
✓ Set **Transmit buffers** to 2048

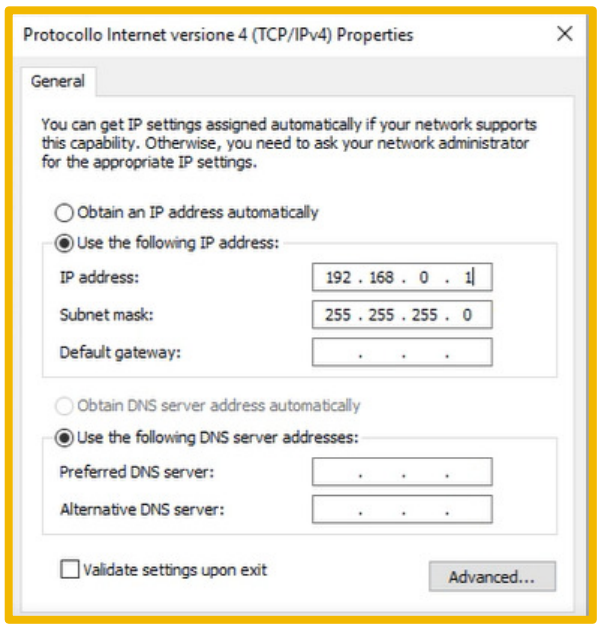
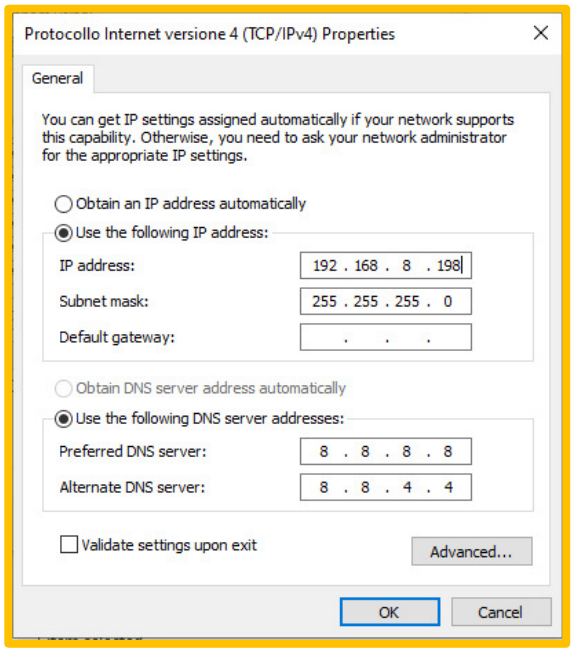


✓ Set **Speed & Duplex** as Auto Negotiation

Go to Control Panel
→ Network and Internet
→ Network Connections
Select the Network
Go to **Properties**
Select **Internet protocol version 4 (TCP/IPv4)**
Select **Properties** and set IP address on 192.168.X.YY, otherwise the connection with the unit will not work.

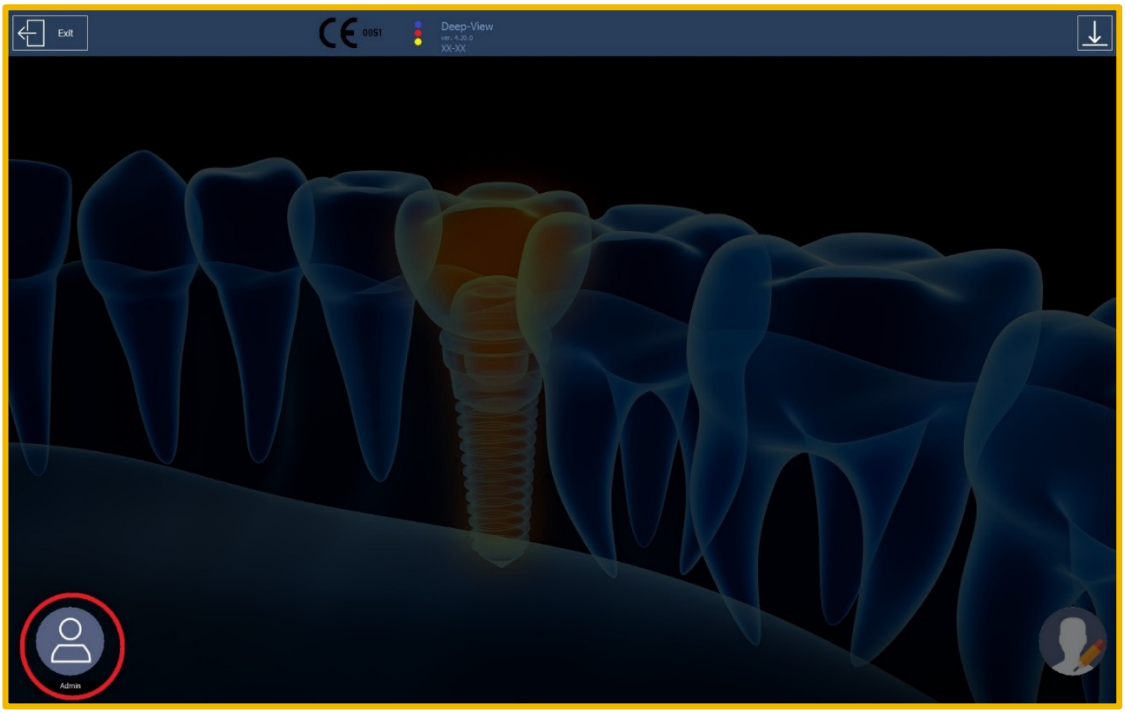
IP addresses:

3D	192.168.8.188	

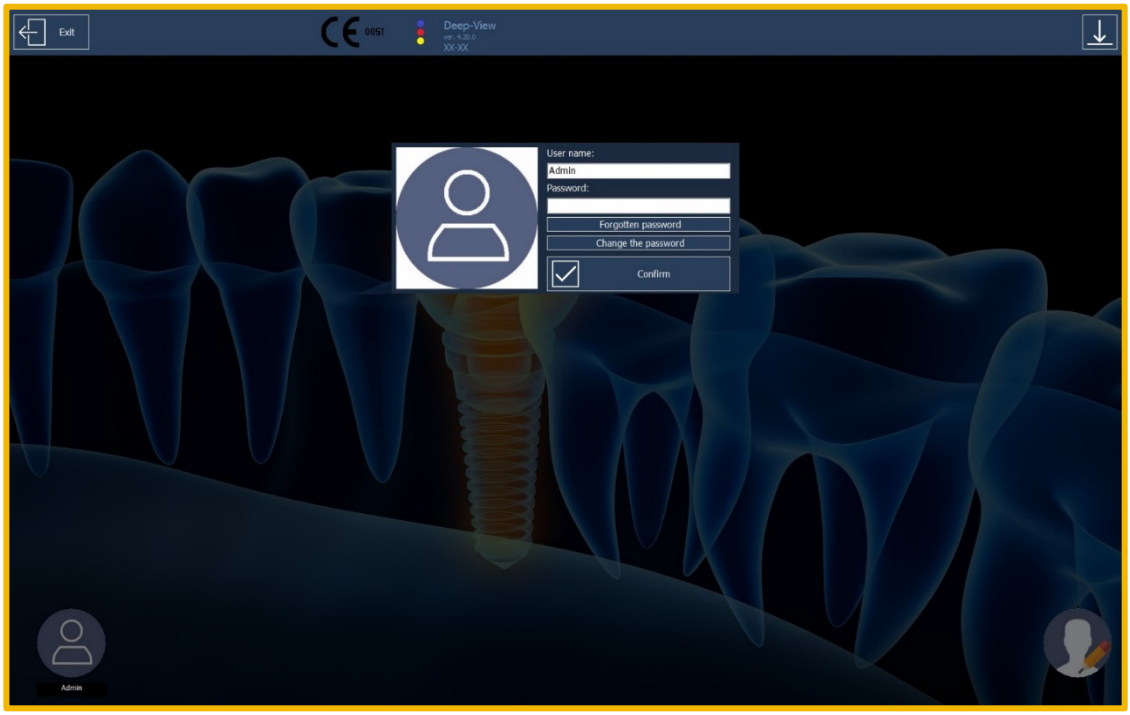
CPH	192.168.0.1	
DPH	192.168.8.198	

6.2.2 COM Port Setting

– Open Deep View

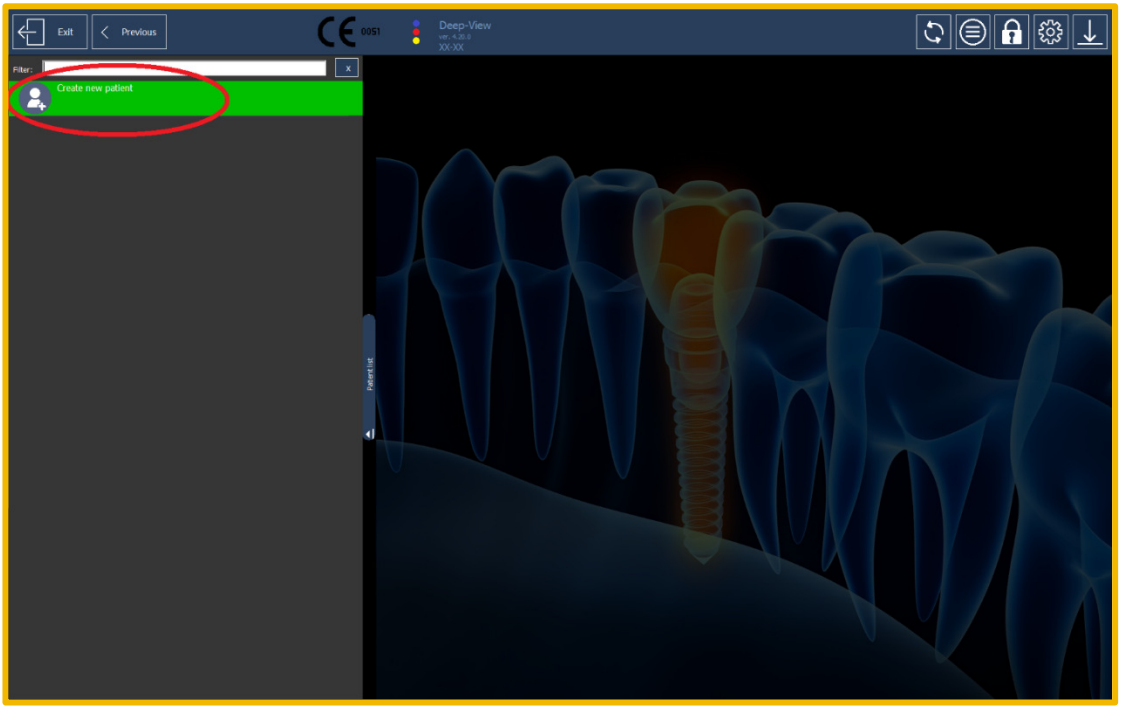


– Select Admin Icon

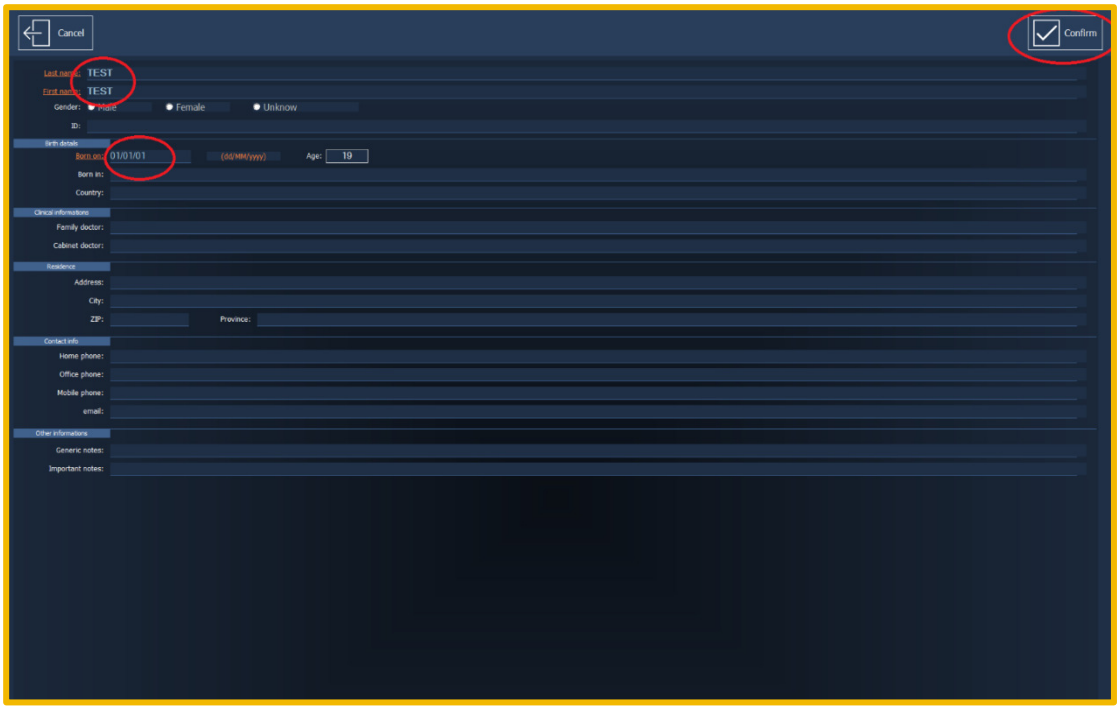


– Insert the password **12345678**

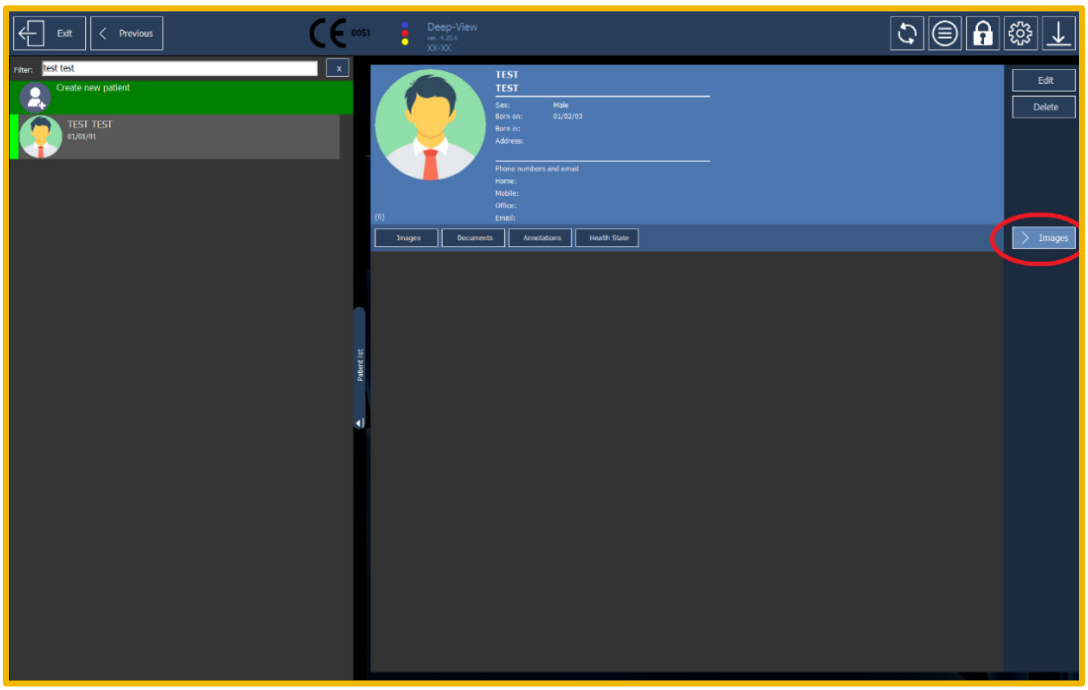
– Create a new patient



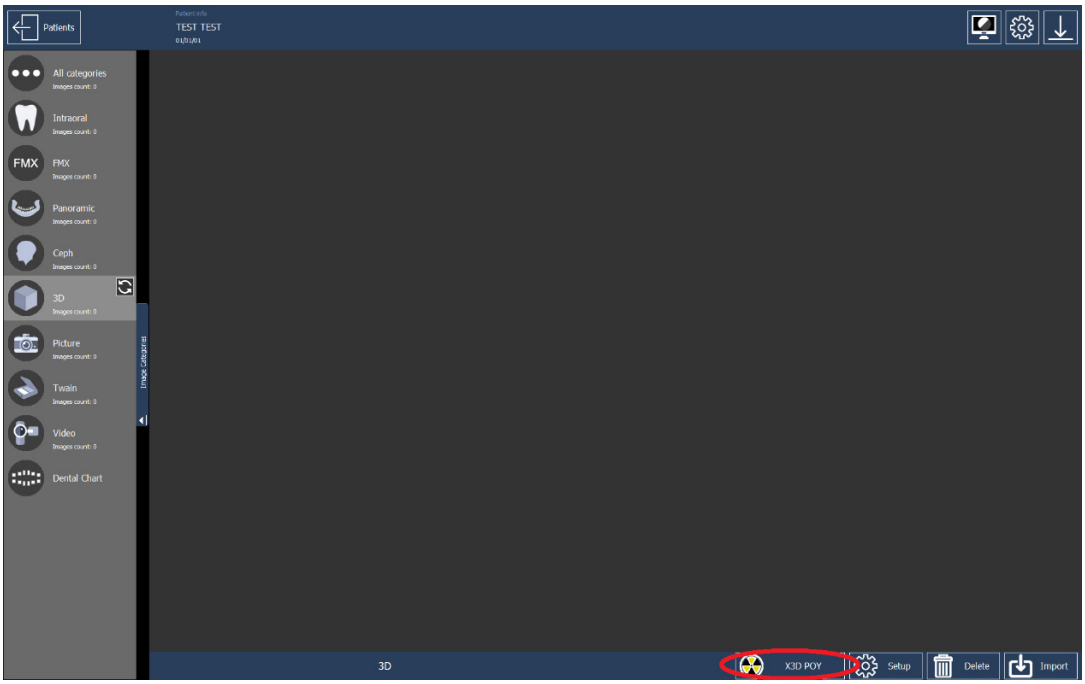
Example of Patient:
Insert the date of birth and confirm



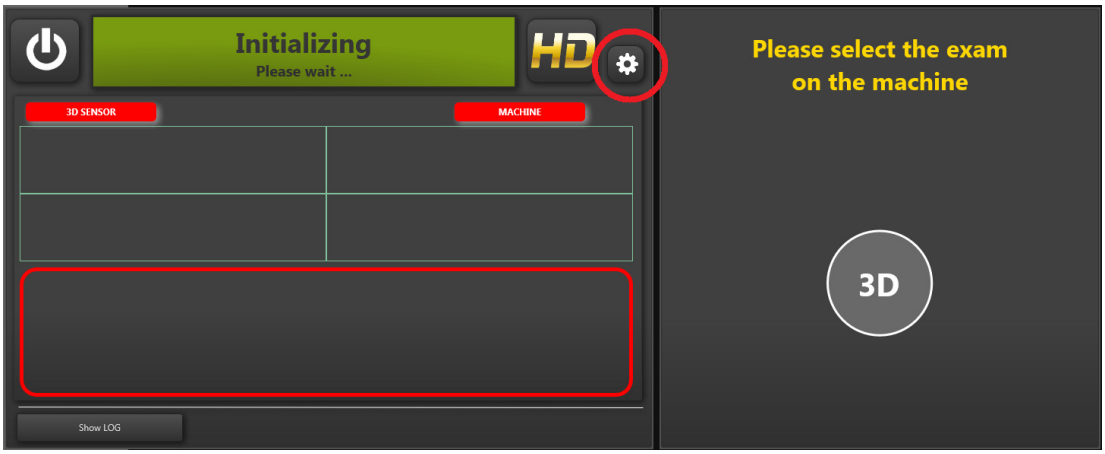
– Open the patient sheet and click on **Images**



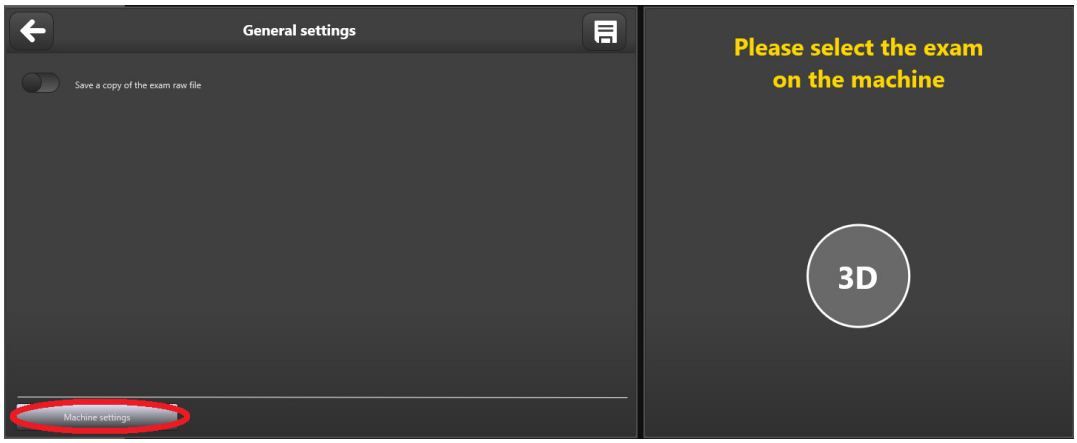
6.2.2.1 3D Option



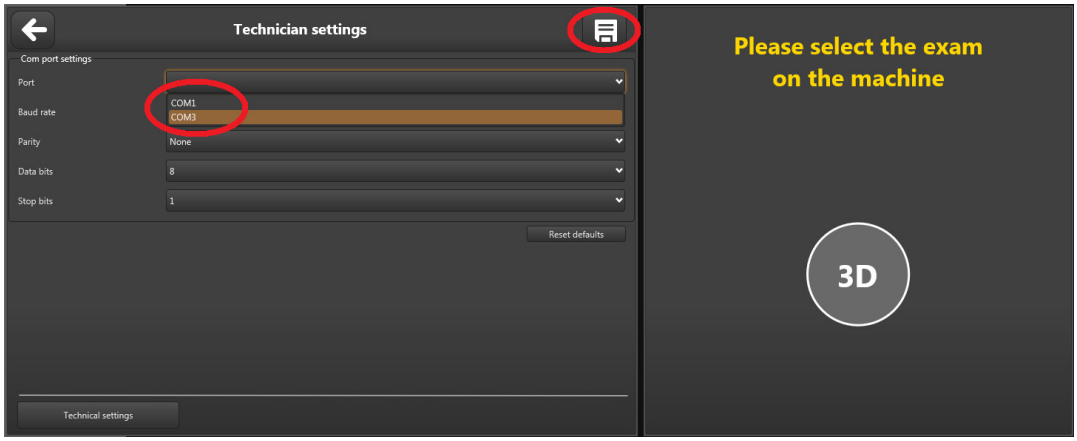
– Click on **Set up** button and insert the password **123456**



– Go inside and open **Machine setting** with the password **112358**



– Select the COM port in this menu. Save it and exit.



7 ACCEPTANCE TESTS

X-VIEW 3D PAN as an electro medical device is subjected to inspection and testing in compliance with laws, regulations and supervisory directives applicable in the country where the installation is carried out.

7.1 Column Movement Check

- Turn on the system.
- Before setting any exam, please press the column icon 
- Repeat the operation with the other button.
- Press the first button and release it after a short run, ensuring that the movement stops.
- Verify that during the movement of the slide there is not metal rubbing noise.
- Exit using the red arrow 
- Run the system setup.

7.2 Exposure Parameters Check

Check if when selecting a test type, the corresponding values of exposure parameters (kV, mA, time and DAP) are correctly displayed.

7.3 Laser Centering and Exams Movements Check

- Set a PAN sequence in test mode (X-Ray disabled).
- Turn on the laser light pressing 

The lasers lighting is a commutative function; by pressing the button the lasers switch on and off repeatedly.

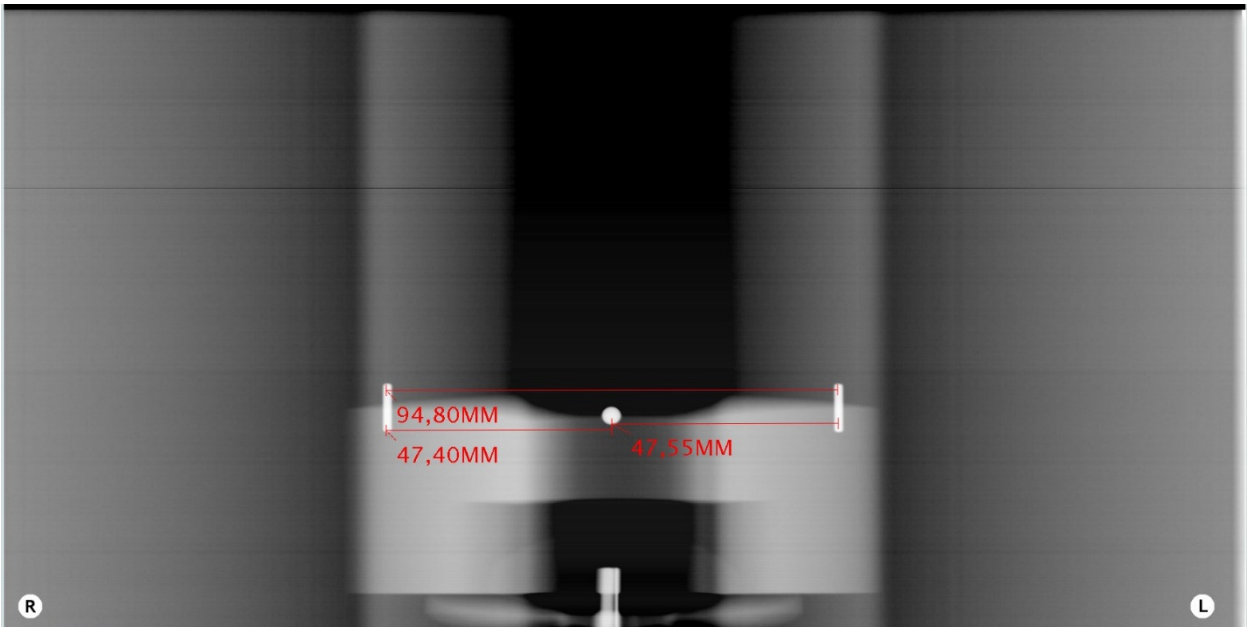
	**WARNING** **Do not look directly into the laser beam.**

- Switch off the laser-centering device and bring the rotating arm to the **Start Exam** position.
- Press the X-Ray button and run a rotation test; check the following points:
    1) You must move the two axes, rotation and translation, with a counterclockwise rotation.
    2) The rotation is continuous.
    3) The translational movement takes place at different speeds; then reverse, and go back to the starting point.
    4) At the end of the simulated exposure, the rotational arm moves perpendicularly to the median sagittal axis of the patient.
    5) Pressing the X-Ray button performs the **Return Entry Position**.

7.4 Focal Layer Position Check

	NOTE This examination requires the availability of Trident Phantom test PA2-05.

- Run DEEP-VIEW software and create a patient (for example “Acceptance Test”)
- On X-VIEW, select a standard adult panoramic exam with 64kV, 5mA.
- Insert PA2-05 tool.
- Add the 0,5 mm copper filer (provided) to the aluminium filter of the tube head cover.
- Perform an examination with real emission.
- Check the image obtained with DEEP-VIEW 3D software; make adjustments such as brightness or contrast to have good visibility of the markers.
- Verify that the circle is perfectly round and not oval.
- Select "Measure" and "Single", and measure the distance between the two pins: it must be 95 mm ± 1 mm.
- Verify that the tool is centered with respect of the dark vertical stripe in the middle.

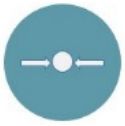


8 USER INTERFACE

The interface used by X-VIEW 3D PAN is a command driven Graphical User Interface (GUI). It is very intuitive; all options are easy to access through easy-to-understand commands. The control panel is an alphanumeric, digital soft touch console. All the information related to the system status and multiple functions is displayed on the screen allowing the operator to control certain unit functions. It also displays the operating parameters and error messages.

8.1 Icons and Symbols

8.1.1 Status Symbols

Symbol	Meaning
	System Ready for X-Ray emission: The unit is ready to emit X-Ray.
	Emission ON The system is emitting X-Ray, including the initial heating phase.
	Emission OFF The X-Ray emission is not enabled.
	X-Ray button emission This symbol also appears on the remote control. The operator should press it to activate the X-ray emission.
	Return to "Patient Centered". This button is active when the rotating arm is in **Start examination** position and allows returning to the **Entry patient** position, in order to allow the correct patient centering and/or modifying the selections.
	This symbol appears at the end of the exam. Press the x-Ray button to return the rotation arm to the **Entry patient** position.
	Confirm selection This button allows confirming the selections and going to the next screen.
	Change selection This button allows returning to the previous selection.

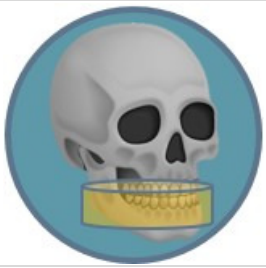
8.1.2 Icons

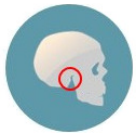
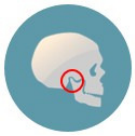
The following table shows the icons that symbolize each function.

8.1.2.1 Icons to Select the Exam Family

Icon	Description
	Icon for 3D volumetric exam
	Icon for Panoramic radiography
	Icon for Cephalometric (Available only with Ceph version)

8.1.2.2 Icons to select Standard Exams

3D Exams			
9x9	11x11	6 x11	5 x 5
			

Panoramic Exams						
Standard Panoramic	Hemi Panoramic Right	Hemi Panoramic Left	Frontal Dentition	TMJ closed mouth	TMJ open mouth	Sinus
						
Adult/Child panoramic exam	Segmented panoramic acquired only on the righ side	Segmented panoramic acquired only on the left side	Panoramic limited to the frontal dentition (canine to canine)	Left/right condyle, close mouth	Left/right condyle, open mouth	Projection, where both the maxillary sinuses are represented.

Cephalometric Exams		
Latero-Lateral Cephalometric 30x24 Image	Antero-Posterior Cephalometric Image	Carpus Image
		

8.1.2.3 Icons to Select Optional Exams

For this exam, the option **Additional exams** should be activated. If this option is enabled, these icons are displayed in the second panoramic type screen, otherwise they are not shown.

Additional Exams				
Reduced Dose Panoramic	Improved Orthogonality Panoramic	Right Bite Wing	Left Bite wing	Right and Left Bite wing
				
Panoramic with reduced angle of rotation to exclude the ascending ramus from the image. The result is a panoramic limited to the dentition area using a reduced patient dose.	The basic geometry of image processing is the same as in the standard panoramic program, but the X-ray beam is perpendicular to the maxilla.	Image that depicts the maxillary and mandibular crowns of the teeth, providing a clear image of the interproximal surfaces of the teeth and allowing for detection of interproximal caries. Simultaneously, the maxillary and mandibular alveolar crests are imaged, permitting the evaluation of their levels, contributing to the assessment of periodontal status.		Captures a double Bite-wing projection which performs both Bite-wing views in sequence, joining them on the same image.

8.1.2.4 Icons to select the Patient Size

The symbols on the left shows the non-active icons, while the ones on the right show the enabled feature.

Icon		Description
		Adult For adult patients radiographies.
		Children For underage youth patients radiographies.
		Thin patient. To expose adult thin patients.
		Standard patient. This selection is suitable for patients defined as "normal-sized".
		Big patient. Allows the selection for large and plus size patient.

8.1.2.5 Icons for Patient Centering

The following table shows the icons for the patient centering functions; the symbol on the left means the icon is not active, while the one on the right shows the corresponding symbol with the feature enabled.

Icon		Description
		Laser positioner. Turns ON/OFF the laser-centering unit to center the patient.
		Chin Rest Chin rest support height adjustment for a correct patient positioning.
		Frankfurt Plan(FFP) Adjustment of laser beam height for a proper patient positioning.

Icon	Description
 	Test function When active, the test mode is on; that means that during the rotation no X-Ray are emitted.
   	Selection of exposure parameters.
 	To increase/decrease exposure parameters value. This function works only for the selected parameter.
 	When chin support or FFP Icons are selected, lift or down the column/the laser by pressing the arrows .

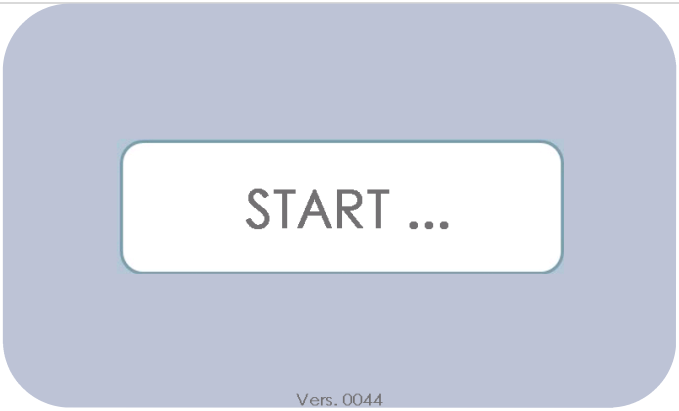
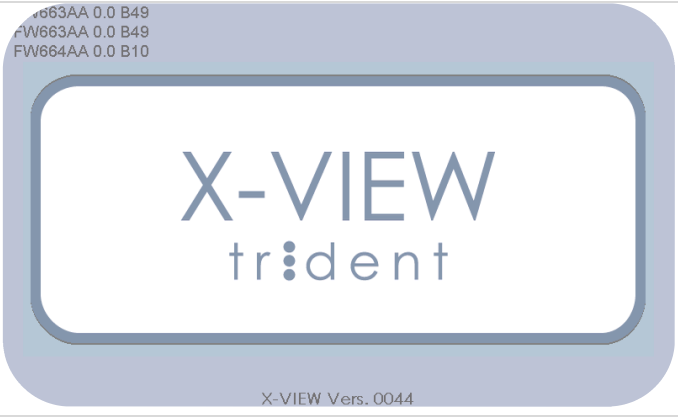
9 EXAM EXECUTION

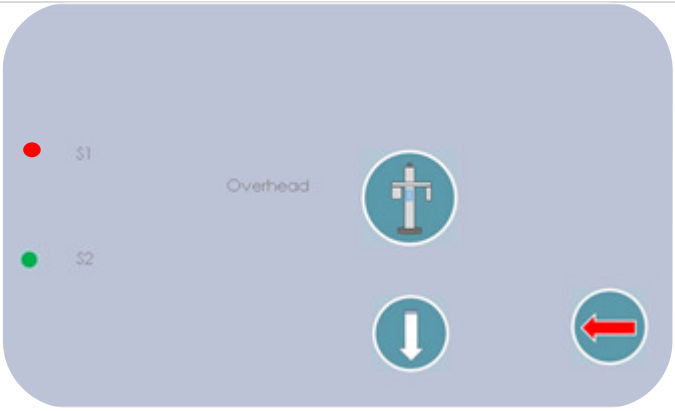
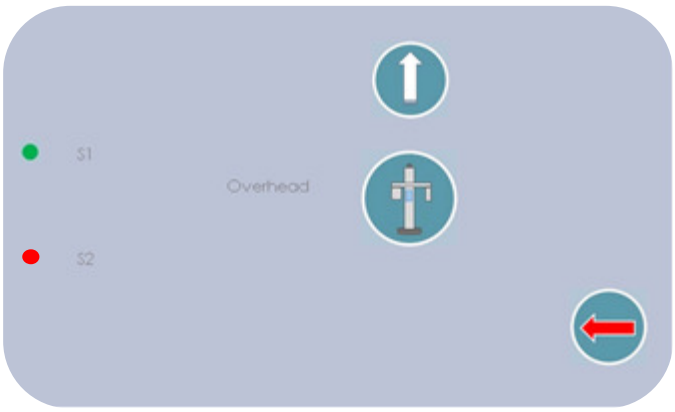
9.1 Switch on the Unit

Before switching on the unit, check that:

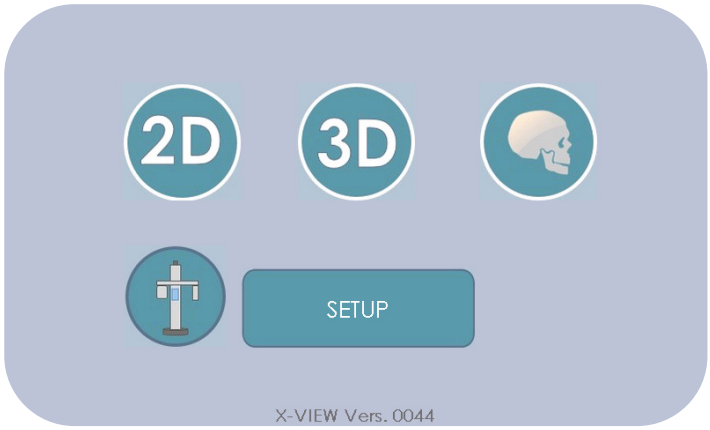
- The installation is complete.
- The PC is switched on.

	**WARNING** Switch on the PC before switching on the unit.

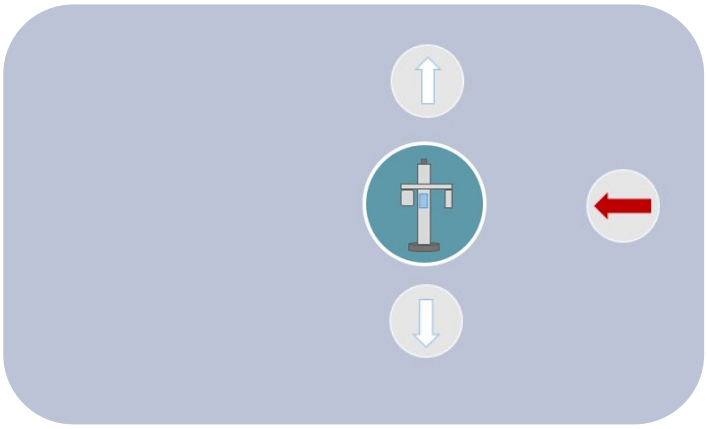
To switch on the unit, follow these steps: • Press the ON button, number 1 in the image. • Wait for a minute to establish the connection between the unit and the PC. Then, can proceed to run the imaging software. When the unit is switched on, the microprocessor performs the correct operation verification, ensuring the integrity of functional parts, which failure may eventually cause danger to the patient, operator or environment.	
This initial check, that also includes the program's integrity, takes around 40 seconds and is indicated by this screenshot.	
When the device is switched on the firmware checks the integrity of all the components: Fatal error User Interface Boards Firmware version	

If fatal errors are found, the nature of the error is properly shown. For example, this screenshot shows an alarm with an error detected. You can exit from this error only turning off the system.	
If no fatal errors are found, the unit checks for any other recoverable errors. In this case, the operator can fix the trouble working directly on the touch screen. The following example shows that the overhead is on the lower switch limited, to solve it the operator should simply press on the arrow and unlock the system.	
If no errors are found the system displays this image:	
Pressing the X-Ray button for two seconds the unit starts the initial set up operations.	

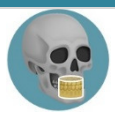
9.2 Selecting an Examination

SCREENSHOT	ICON	FUNCTION
		Button to select PAN exams
		Button to select Volumetric exams
		Button to select Cephalometric exams
		Button to move the chinrest support (adequate it to patient's height)
		Button to select the setup functions

By pressing the button,  the following screen appears:

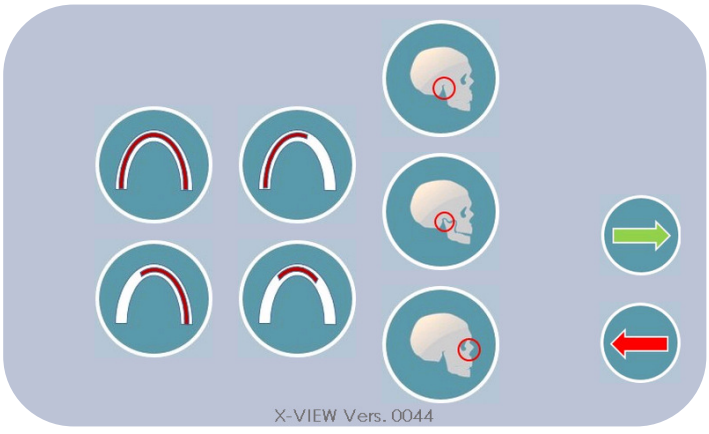
SCREENSHOT	ICON	FUNCTION
		When the column icon is active, using the arrows move the overhead to the desired position.
		Button to return to the previous option.

9.2.1 3D Volumetric Exam Selection

SCREENSHOT	ICON	FUNCTION
		3D Dentition 5 x 5
		3D Dentition 6 x11
		3D Dentition 9 x 9
		3D Dentition 11x11
NOTE: the selection of the type of exam may vary according to the X-VIEW model		Button to return to the previous info

9.2.2 2D Panoramic Type Selection

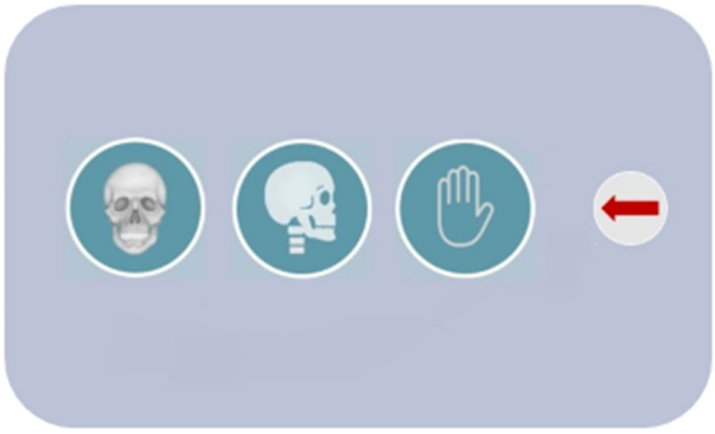
There are two types of 2D panoramic: standard and optional; the optional 2D panoramic are active only if they have been enabled. The standard 2D panoramic are the following:

SCREENSHOT	ICON	FUNCTION
		Close mouth TMJ
		Open mouth TMJ
		Sinus
		Standard Panoramic
		Hemi Panoramic Right
		Hemi Panoramic Left
		Frontal Dentition
		When optional features enabled, displays the optional examinations.
		Button to return to the previous option.

Go to Patient Selection by pressing any type of exam (for more details see "Patient Selection" paragraph).
The optional panoramic are displayed by pressing the green arrow:

SCREENSHOT	ICON	FUNCTION
		Left Bitewing
		Right and Left Bitewing
		Right Bitewing
		Reduced dose Panoramic
		Improved orthogonality panoramic
		Button to return to the previous option.

9.2.3 *Cephalometric Functions Selection*

SCREENSHOT	ICON	FUNCTION
		A-P cephalometric image
		Carpus image
		L-L cephalometric 30x24 image
		Button to return to the previous option.

Go to Patient Selection by pressing any type of exam.

9.3 Patient Selection

Patient selection involves two phases:

- Patient Type Selection
- Exposure Parameters Selection

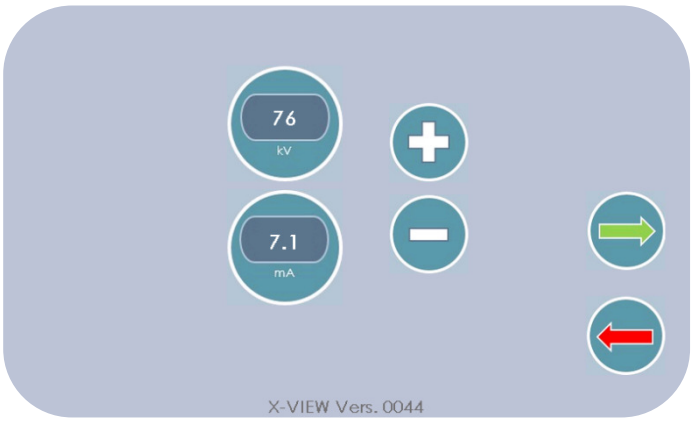
9.3.1 *Patient Type Selection*

This option considers two values: the patient type, adult or child; and the patient size, which refers to the patient morphology (small, normal, big) as, described in the image. Once pressed the icon frame becomes blue.

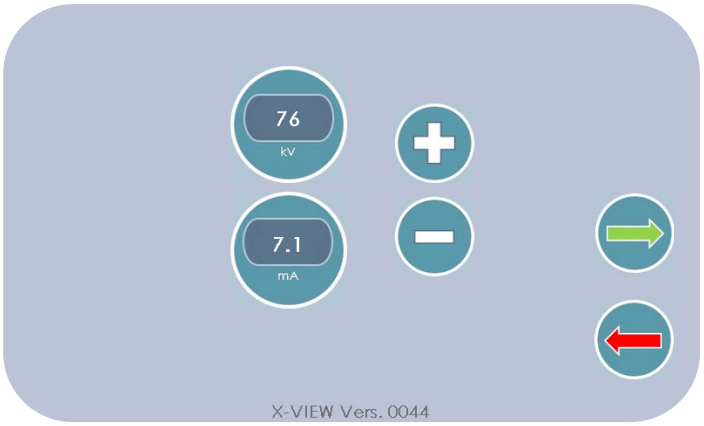
SCREENSHOT	ICON	FUNCTION
 In this screen the options Adult patient/Medium size are highlighted		Small size
		Medium size
		Large size
		Adult
		Child
		Display parameters
		Button to return to the previous option.

9.4 Exposure Parameters Selection

The default values for kV and mA are shown; eventually, the operator can adjust them using the "+/-" keys as shown in this screen:

SCREENSHOT	ICON	FUNCTION
		Change the kV value
		Change mA value
		Increase/decrease the parameter values
		Goes ahead
		Button to return to the previous option.

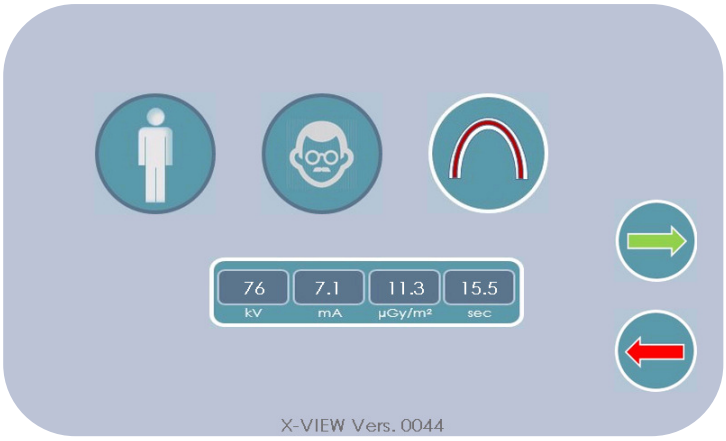
Example of exposure parameters:

SCREENSHOT	DESCRIPTION
	This image shows the set values of 76 kV and 7.1 mA.

9.5 Selected Values Summary Screen

This screen provides a summary of the selected parameters and the exam to execute; this information allows to confirm the information before the exam execution.

The summary screen is represented by the following image:

SCREENSHOT	DESCRIPTION
	This is an example of summary screenshot. The particular information refers to: • A standard panoramic • Adult/Medium size patient • Exposure parameters values: kV 76 mA 7.1 Dose expressed in mGy/m² 11.3 Exposure time 15.5 sec
	 Confirm all selections and moves to the patient centering menu.
	 Return to display parameters selection.

9.6 Patient Positioning

Please refer to Annex 5 to consult the Patient Positioning Guide

To obtain very clear and precise images, the stillness and good positioning of the patient are primary. To help patients keeping the right positioning X-VIEW 3D PAN uses the following tools:

9.6.1 Patient Centering Tools

a) Head Rest

The headrest is composed by two plastic curved pieces ending in a support for the temples (left and right). The headrest uses a lock mechanism that opens until the maximum capacity and then closes to fit the patient's head. The release mechanism is located under the bite-centering support. In order to ensure the proper performance of the examination, use the headrest in this way:

- For 3D Dentition, PAN, TMJ close/open mouth, Sinus and Ceph images, close the headrest.
- For 3D TMJ either right or left, open the headrest.

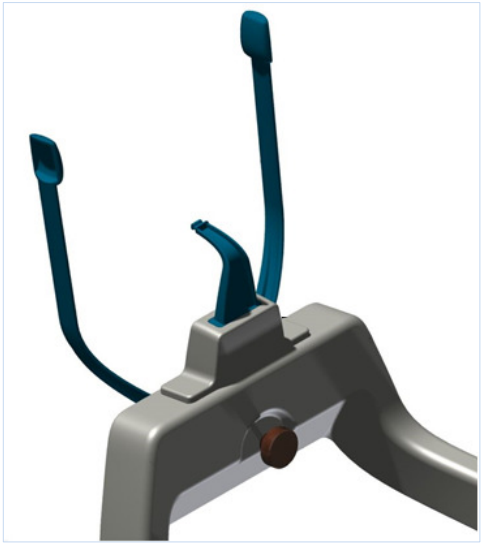
b) Bite Centering

X-VIEW 3D PAN uses a single bite centering and its respective support for all exams. This support may be removed for cleaning or to get the correct position for every type of exam. The bite support fits into one of the three slots of the chinrest.

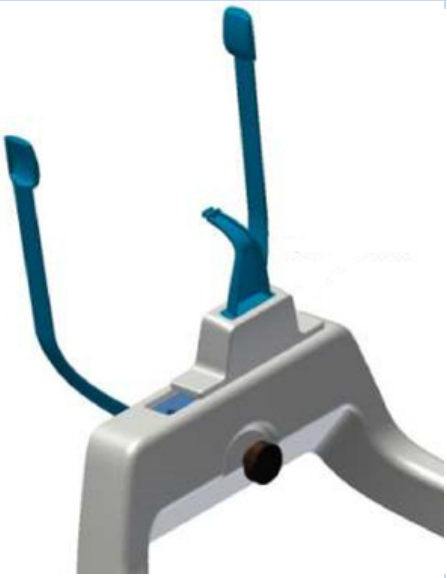
Chinrest + bite should be used for almost every exam. The operator can regulate and fit them to the patient height; with edentulous patients, the bite can be completely removed. For SINUS Trident provides a specific support.

The proper position for each type of exam is the following:

For 3D Dentition, PAN, TMJ close/open mouth and Sinus images, put the chinrest in the central position:



For TMJ 3D exam move the chinrest to the right/left position in order to center the affected articulation within the volume of reconstruction.

CHINREST POSITION **Right TMJ**	CHINREST POSITION **Left TMJ**
	

9.6.2 Anatomical Planes

The next step is to display the patient centering summary, which includes all operations necessary to place the patient in the correct position to perform the examination. The operations are different for 3D/PAN or cephalometric examinations. Correct centering operations of the patient will refer to the following anatomical planes:

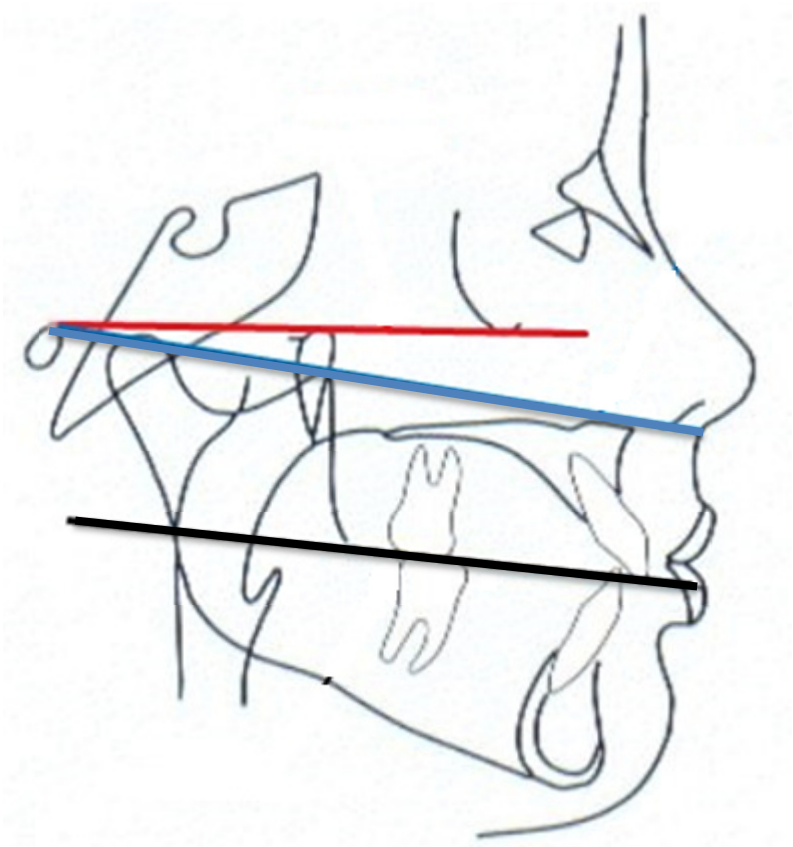
a) **Median Sagittal Plane**: is the plane that divides the skull vertically, in front/back direction and in two symmetrical halves. This plane is obtained by drawing lines through mid-palatal raphe at right angle to Frankfurt Plane.

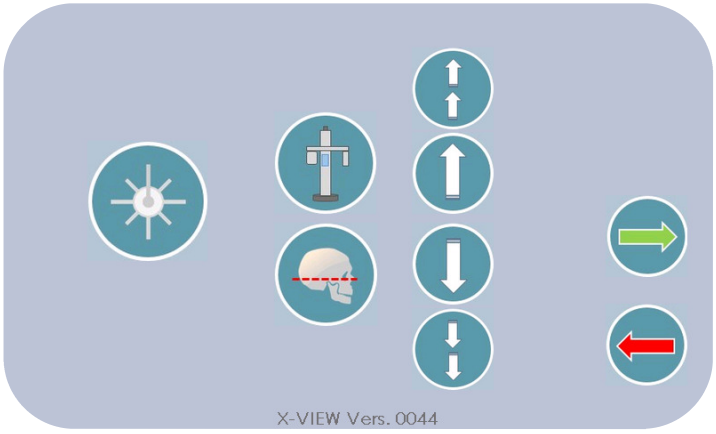
b) **Frankfurt Plane**: is a plane formed by drawing a straight horizontal line from the top of the ear canal to the bottom border of the eye along either side of the human skull. The plane is also called the auriculo-orbital plane because it passes through the auriculus, or ear, and the orbitales, or eye sockets. It was established in 1884 in Frankfurt, Germany, by the World Congress of Anthropology. The Frankfurt plane became the principal standard of skull measurement because it also identifies the normal plane in which the head is positioned parallel to the ground.

c) **Occlusal Plane:** an imaginary surface that is related anatomically to the cranium and that theoretically touches the incisal edges of the incisors and the tips of the occluding surfaces of the posterior teeth; it is not a plane in the true sense of the word but represents the mean of the curvature of the surface. Generally coincides with the closing line of the lips. Occlusal plane orientation is an important factor in the construction of a complete denture

d) **Camper's Plane or Ala-tragus Plane:** ideal plan that crosses the 2 points of the tragus and the anterior nasal spine. Many dentists have used camper's line as a reference in determining the plane of occlusion in edentulous patients. It is parallel to the occlusal plane and forms an angle of 15° with the Frankfurt plane.

The following image represents the planes



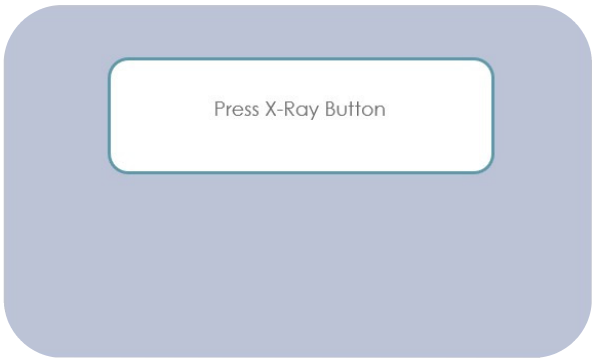
SCREENSHOT	ICON	FUNCTION
		ON/OF laser light centering device
		Vertical movement of the chinrest
		Frankfurt Plane centering
		UP/DOWN chinrest support
		Confirm the centering
		Return to the summary screen of the examination.

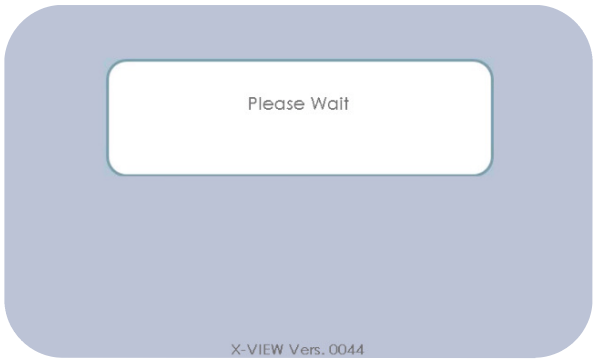
	Before entering the patient parameters and proceed to operations, the headrest must be open to the maximum extent.
	Moving the chinrest up or down requires keeping the UP /DOWN arrow key pressed. The chinrest's support movement has two speeds. Starts at a low speed, allowing a fine position adjustment; after 4 seconds the speed increases until releasing the key.

By pressing the laser button key, two laser beams illuminate the median sagittal plane and the horizontal line for the Frankfurt plane reference. Place the patient's head in such a way that these light beams fall on their anatomical references correctly, which are important points in function of the type of exams to run.

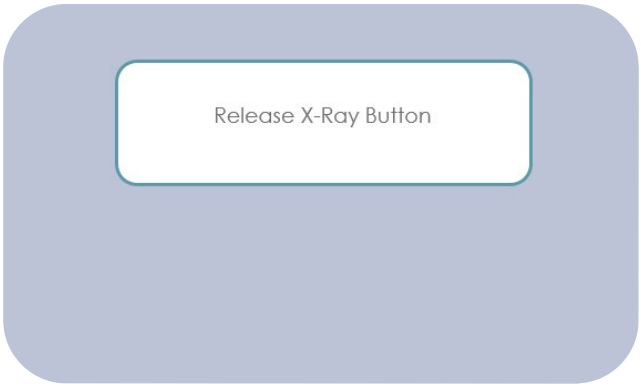
The Frankfurt plane beam can be adjusted according to the height of the patient; the position of the beam is only a reference; move the patient's head so that the Frankfurt plane is anatomically parallel to the laser beam. At the end of the centering operations, the headrest must be closed so that the patient is kept in place during the entire examination.

The rotating arm movement from the centering position to the start examination point is controlled by X-Ray button pressure, reported by the following screens:





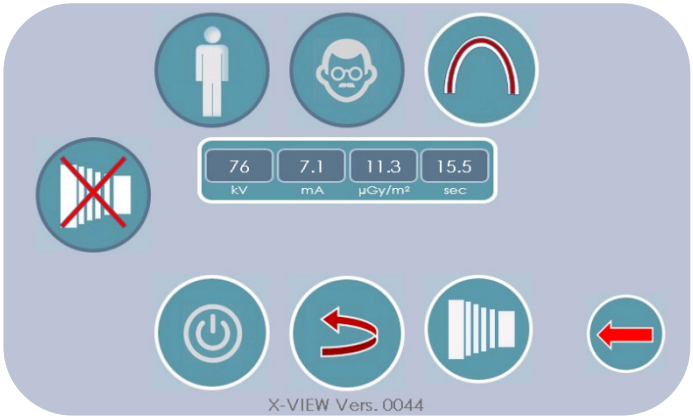
While at the end of the movement this screen appears, asking to release the X-ray button to continue.

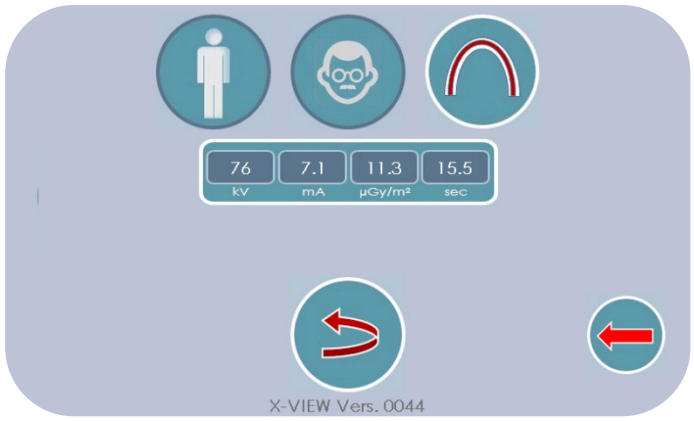


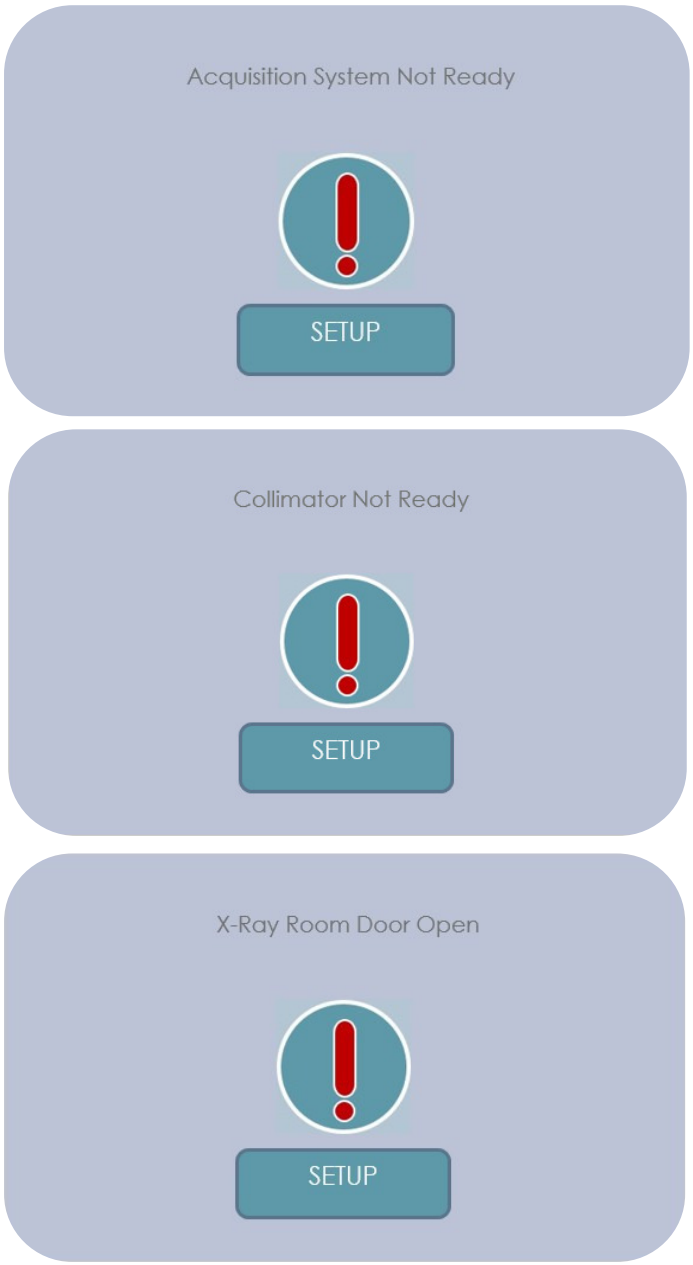
	**NOTE** A dead man switch commands the rotating arm movement. The X-Ray button must always be pressed during the movement. If the button is released, by mistake or intentionally for security issues, the movement stops and the alert screen appears on.

9.7 Start Menu Test

Once finished the rotation arm movement, and after releasing the X-Ray button, the screen with the examination information appears. On the screen are summarized the parameters selected for the examination.

SCREENSHOT	ICON	MEANING
		
		Medium size Patient
		Adult Patient
		Standard Panoramic
		System ready for X-Ray
		Indication for pressing the X-Ray button
		Test function; once pressed becomes green.
		Return to the previous option.

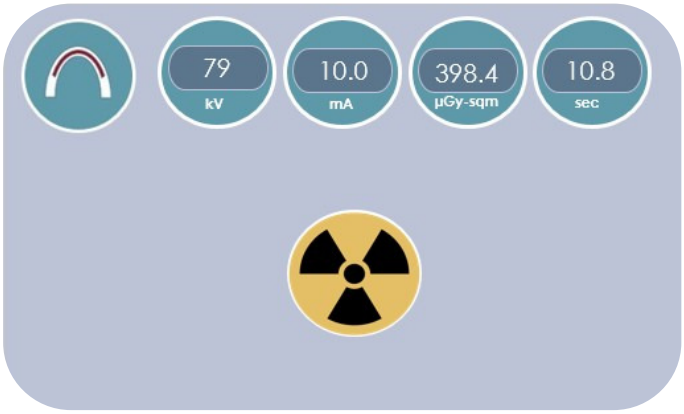
SCREENSHOT	MEANING
	During **Ready for X-Rays** message, the system checks the validity of all the necessary safety conditions for a correct examination; these conditions include: • Collimator position • No errors on the X-Ray Generator • System of acquisition ready to acquire • X-Rays room door closed If those conditions are not met, the **Ready for X-Ray** and **Press X-Ray** icons will not appear, as shown in this screen.



The message **System not ready** appears when the X-Ray button is pressed and the system is not ready, as shown in these screenshots.

9.8 Exam Execution

	**WARNING** During X-Rays emission, protection for operator and other personnel, must comply with the regulation in force. In any case, it is recommended that during X-Rays release, if bulkheads do not protect the operator, she/he should be located at least 2 meters away and in the opposite direction of X-Rays releasing.

SCREENSHOT	MEANING
	During the exam execution this screen appears. The screen displays: • Type of ongoing examination • Exposure parameters • Exposure dose. The X-Ray exposure is also signaled by a beep sound.
	A dead man switch commands the exam execution, meaning the operator ought to press and hold the X-Ray button until the exam is completed. The system shows when to release the button.
	If the button is released, by mistake or intentionally for security issues, the exam stops and the alert screen appears.

	If test function is selected, the X-Ray output is disabled and this screen will appear.

9.8.1 End of the Examination

SCREENSHOT	MEANING
	The end of the examination is reported by an acoustic signal followed by this image.

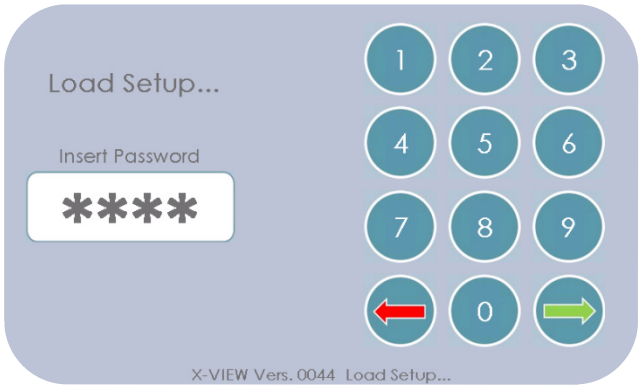
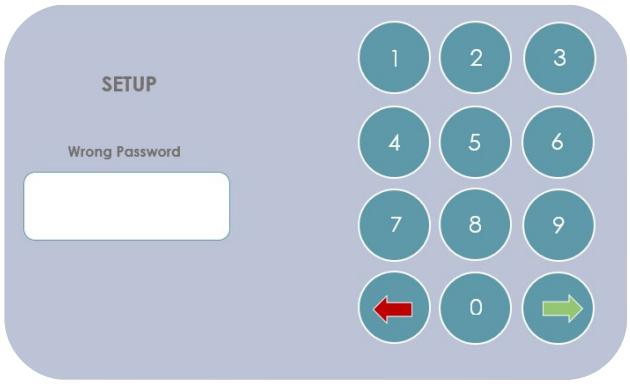
At the end of the examination and after pressing the X-Ray button, the system returns to **Entry Patient** position.

10 SETUP FUNCTIONS

	Consult the accompanying documentation before proceeding with setup functions.

The system has two types of setup functions protected by different passwords.

1. User Setup Functions.
2. Service Technician Setup Functions.

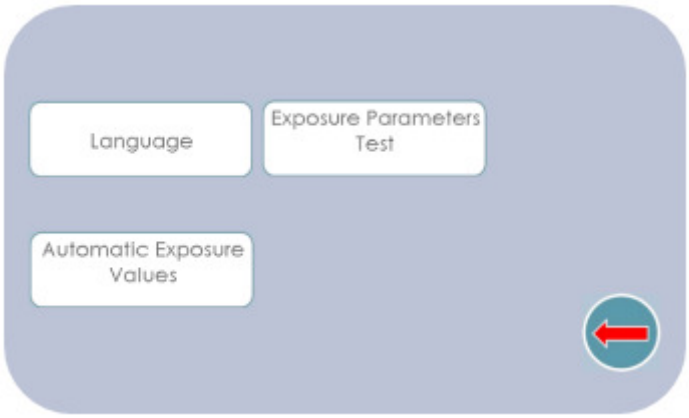
The setup functions can be accessed from all the screens where the SETUP tab is displayed. By pressing it, the system requires to enter the password, as shown in the image. At this point, insert the password and press the green arrow to confirm.	
If the entered password is incorrect, the following message appears:	

	In all Setup screens:  Allows exit the SETUP functions.  Confirms the selections and move to the next screen.

10.1 User Setup Functions

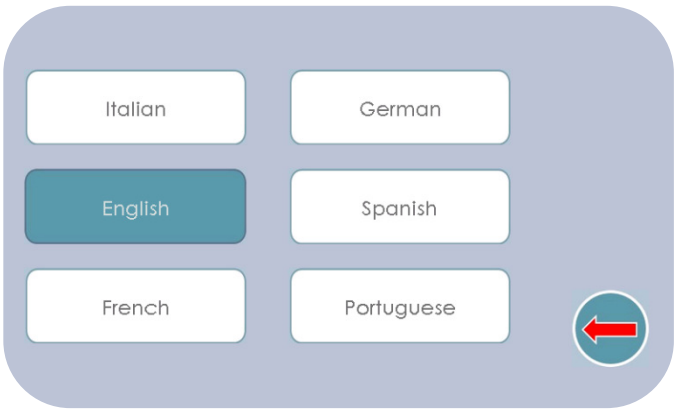
These functions reserved to the final-user are useful to improve the use of the system or check its correct operation. The password to access this feature is: **1234.**

The available functions are shown in this screen:



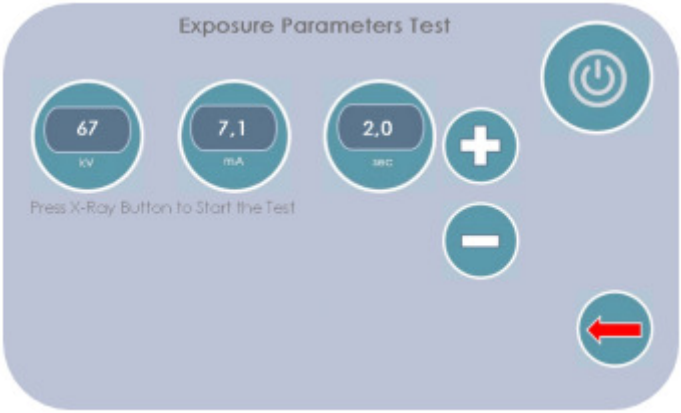
10.1.1 Language

This option allows choosing the language for all the messages used inside the program. It is possible to select among six languages; once selected, the language icon becomes green, as shown in the image where English is the selected language.



10.1.2 Exposure Parameters Test

Technicians mainly use this function during the acceptance inspection or periodic verification and sensor calibration. Trident recommends to test the exposure values using this dedicated menu because in the exam the measurement could be affected by X-ray pulsation or dose modulation (see note (a) and (b)of point 10.1.2.1). The following screen shows the parameters to check:



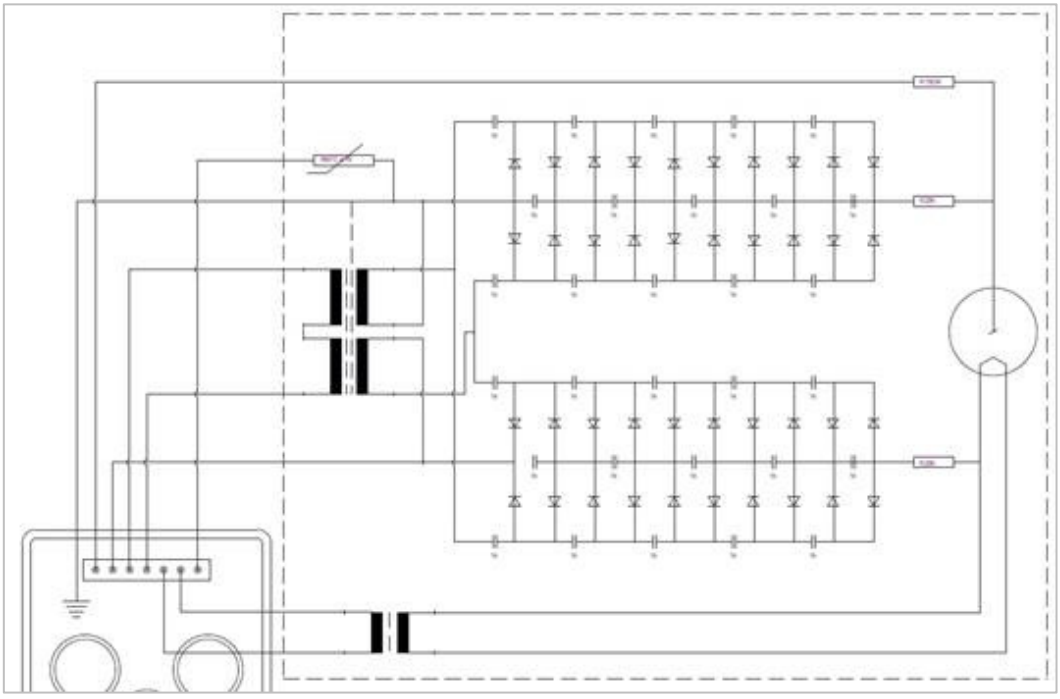
	Trident recommends using the Exposure Parameters Test menu to measure Kv, mA, time and DAP values using the invasive method, otherwise 50% tolerance is not guaranteed.
	If the technician or qualified expert decides to proceed with the measurement of the parameters directly onto 3D or 2D examination, they should consider this method to be highly imprecise.

Technicians and qualified experts can measure the exposure parameters using either a non-invasive method or an invasive method.
Note: the emission is in continuous mode

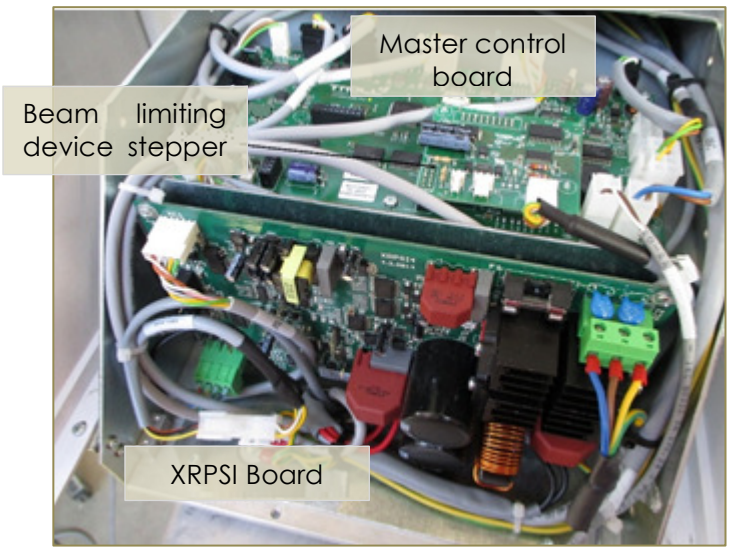
a) Invasive Testing Method

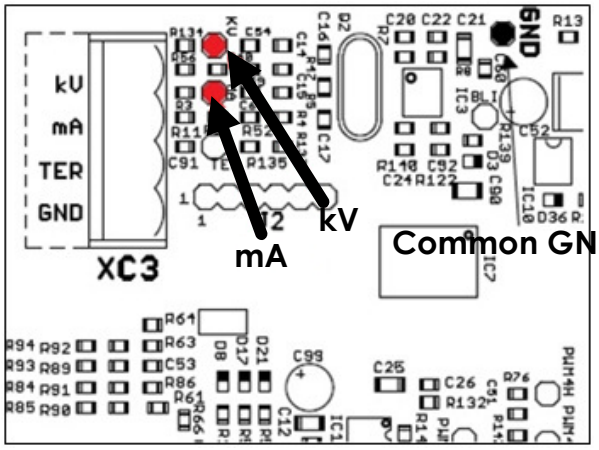
The invasive method is highly recommended and the only one legally accepted by the manufacturer since it is the most precise exposure parameters measurement method. With this method it is possible to measure directly on the generator the real dose values using a calibrated DC voltage multimeter.

The X-ray tube voltage and current values are directly measured on the generator circuit using resistors to convert the kV and mA values to DC tension.



Generator scheme - mA and kV feedback for measurements





	The execution of the measure with the invasive method requires accessing the control board where there are dangerous voltages, so that only qualified service technician must perform the procedure.
	Qualified Service technicians are defined as follows: -Personnel that have been attended a Training Course regarding X-VIEW equipment. -Personnel authorized by Trident.
	WARNING Exposure parameters measurement using an invasive method provides a real emission.
	The invasive method is performed using a digital multimeter, which must have an input impedance of at least 10 MΩ, in order to obtain a reliable reading.
	High Voltage on the board

To measure the parameter values:

- Remove the tube-head plastic cover and the metal sheet of the X-Ray control board to access the XRPSI board (located on the rotating arm).
- Pay attention to capacitors C29 and C30, they could still be charged.
- Make the following connections:
  Connect the "–" pole of the multimeter (or oscilloscope) to the common ground (GND)
  Connect the "+" pole to mA -> 1 measured Volt DC = 1mA
  Connect the "+" pole to kV -> 1 measured Volt DC = 10 kV

b) Non-Invasive Testing Method

Technicians or qualified experts can measure the exposure parameters values using an X-ray calibrated dosimeter, even if Trident recommend to use the "Invasive method" described above. This method is not a direct method and the result could be affect by environment, device, positioning and time response leading the result to be inaccurate.

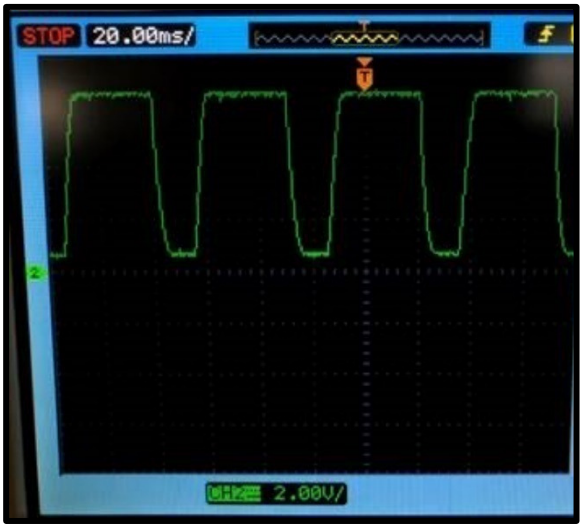
	If the test is performed in PAN mode the measuring system must be properly adequate, i.e. equipped with a narrow-beam probe which must be correctly positioned on the X-Ray beam, in the center of digital sensor.
	It is better to check the probe's correct position using the special measuring instrument, or with the help of a fluorescent screen, running one or more tests for emissions test probe's centering.
	We suggest testing the tube current using an invasive method, since the non-invasive method could be inaccurate.
	WARNING The unit is in "Ready to Release Rays" mode. The operator ought to observe all precautions for radiation protection.

10.1.2.1 Testing the exposure parameters directly in the 3D or 2D exam

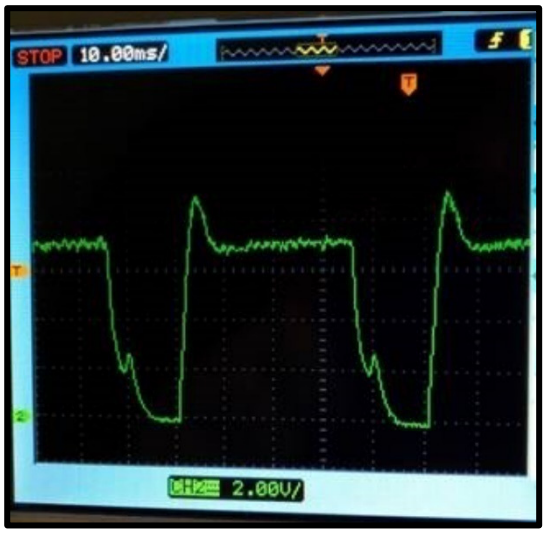
a) Directly in the 3D exam: pulsed radiation

In case the technician or qualified expert want to test the dose directly on the 3D exam they must consider that to improve the quality of the image and reduce the dose, X-VIEW family devices work with high frequency pulsed radiation.

- Measurement must consider it because it could be affected by method/tools imprecision.
- During the exam voltage and current are applied with high frequency and the X-Rays are emitted for the 70% of the period of each impulse.
- Multimeter (when an invasive method is performed) or dosimeters (when non-invasive method is performed) could read the average value of the radiation and show 70% of real parameters, not the peak.
- Only with oscilloscope it is possible to get exactly the correct dose values and curve.



kV impulse curve



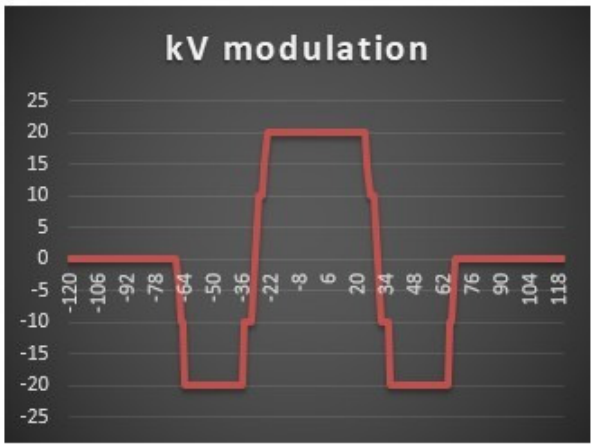
mA impulse curve

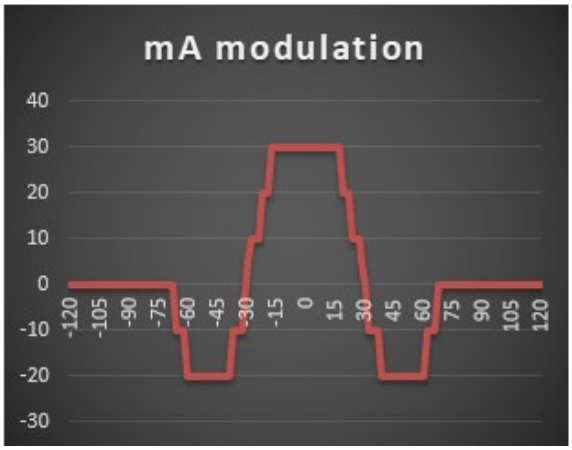
b) Directly in the panoramic exam: dose modulation

In case the qualified technician or expert wants to test the dose directly on the 2D exam, they should consider that to improve image quality and reduce dose, X-VIEW family devices work with dose modulation during exam panoramic to compensate for X-rays absorbed by the spine.

To guarantee the best quality/dose ratio, in fact during the emission the machine modulates the dose, it is reduced where not needed (sinus slices) and increased to pass thick bones (back bone).

The following graphics show the real dose profile used during adult Panoramic exam from -120° to +120° starting from the reference mean value selected for the exam.





For each degree, the modulation is calculated as follows:

*Voltage (kV) = (RV * 100 + MP * 10) / 100*
*Current (mA) = (RV * 1000 +MP * 100) / 1000*

RV: reference value
MP: modulation parameter

The following table shows the selected reference values with the minimum/maximum parameters value that will be measured on the exam.

kV	20	-20	mA	30	-20
61	63	59	5	8	4
64	66	62	5,6	8,6	4
67	69	65	6,3	9,3	4,3
70	72	68	7,1	10	5,1
73	75	71	8	10	6
76	78	74	9	10	7
79	81	77	10	10	8
82	84	80			
85	87	83			

For higher doses, the central part of the curve will be reduced or flat down, it is considered in fact not useful to exceed 10 mA during the exam.

It is not appropriate to go below 4 mA for low dose exam, so the minimum-maximum peaks will be contained between 4 and 10 mA.

The modulation could vary fast during the exam leading to measurement error due to the time responding and imprecision of the measurement tool.

This is the reason why it is considered mandatory to use the "dose parameters test" to know exactly the generator emission.

10.1.2.5 Exposure Time Measurement

The exposure time is normally measured with the non-invasive method.

c) The measurement with the invasive method can be made with a memory oscilloscope, analyzing the voltage feedback signal.
d) To perform this measure, use a probe having a 10 MΩ impedance input, with a ratio of 1:10.
e) Perform an exposure with the oscilloscope probe connected to mA.

	Standard IEC 60601-2-63 (paragraph 203.4.101.1) defines the emission time as the time interval between the instant when the Air Kerma rate exceeds 50% of its steady state value and the instant when it finally drops below the same value.

10.1.2.6 Half Value Layer (HVL) Check

The HVL is the thickness of the aluminum (Al) absorber that is required to reduce the output to half of its initial value. To check the HVL follow this procedure:

1. Enter Setup and select Exposure **Parameters Test**
2. Place the dose meter probe on the center of the digital sensor facing the tube head.
3. Set these exposure parameters: 85 kV, 10 mA, 1 s exposure time.
4. Check the correctness of the probe centering by performing an exposure and repeat it if necessary.
5. Perform three exposures, recording the measured doses and calculate its average value.
6. Place an aluminum filter of 3.05 mm thickness in the X-Ray path.
7. Perform another three exposures, recording the measured doses and calculate its average value.
8. Check that this value is higher than the half value of the one measured on the point 5 above.
9. Check on the digital image that there are no abnormal scratches both horizontal and vertical.

	NOTE: The test is performed in PAN mode, so that the measuring system must be equipped with a narrow-beam probe, which must be correctly positioned on the x-ray beam, in the center of digital sensor. It is recommended to use a special probe with a reduced sensitive area. It may be helpful to use a fluorescent screen to locate the beam of rays and thus place the probe of the instrument.
	To perform this procedure, place the filter in front of the sensor probe, taking care of completely covering the probe.

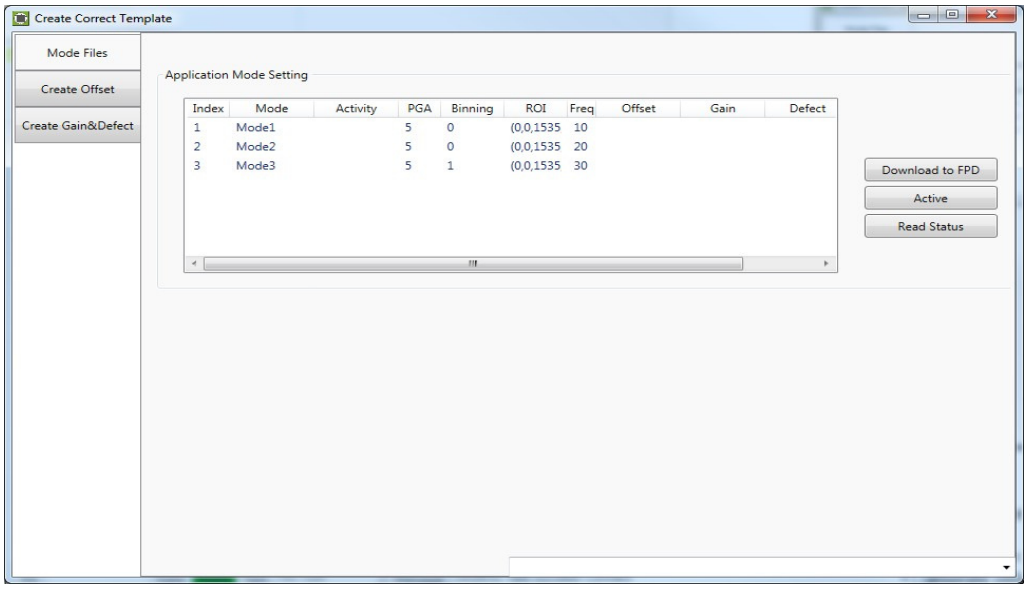
If the above measures are not correct, please refer to the dedicated functions of Technical service for X-axis and rotation centering.

10.2.1.7 Sensor calibration function

To calibrate the 3D sensor:

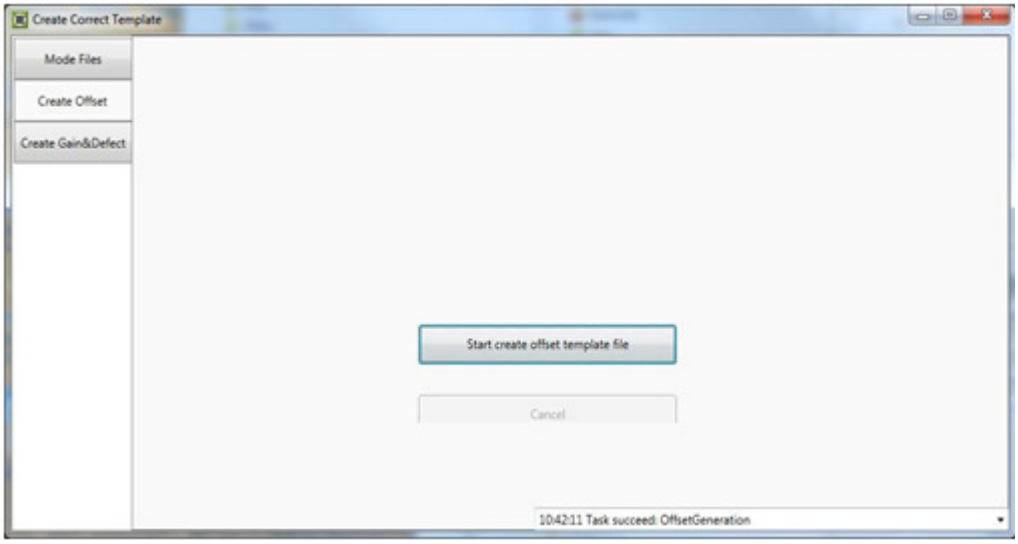
- Go inside C:\ProgramData\TRIDENT_xView_3D_v4\infSensor3D.
- Open the file **iDetector.exe.**
- Select the only one sensor possibility, the **Jupy0505X**, enter inside and go to **Detector.**
- Select the **Sync Out** mode.
- Go to **Calibrate.**

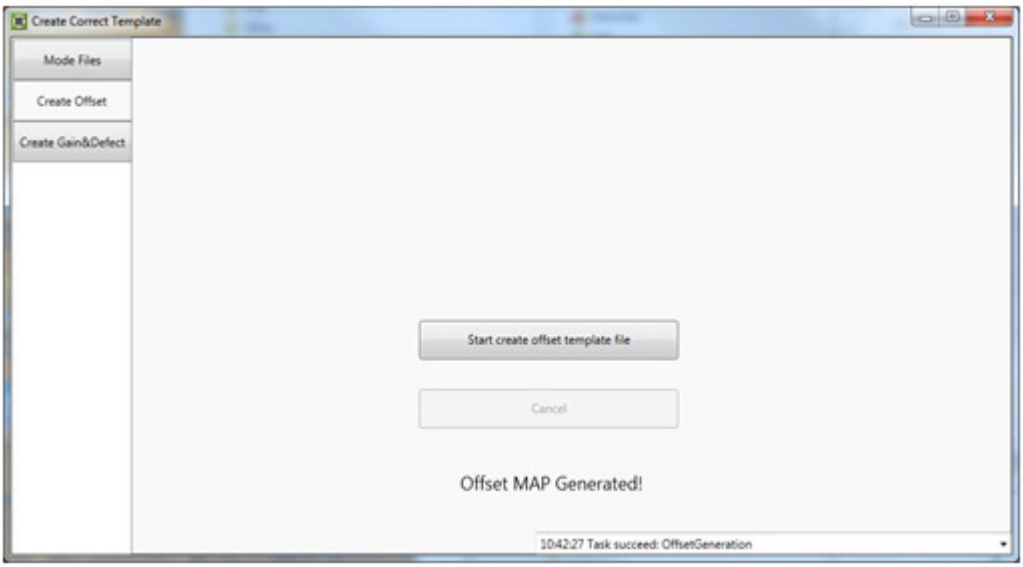
On **Application Mode Setting,** please select **Mode1**. After that, PGA, Binning mode, Frame rate, Zoom and template file storage location are defined.



The Offset template generation process is shown below.

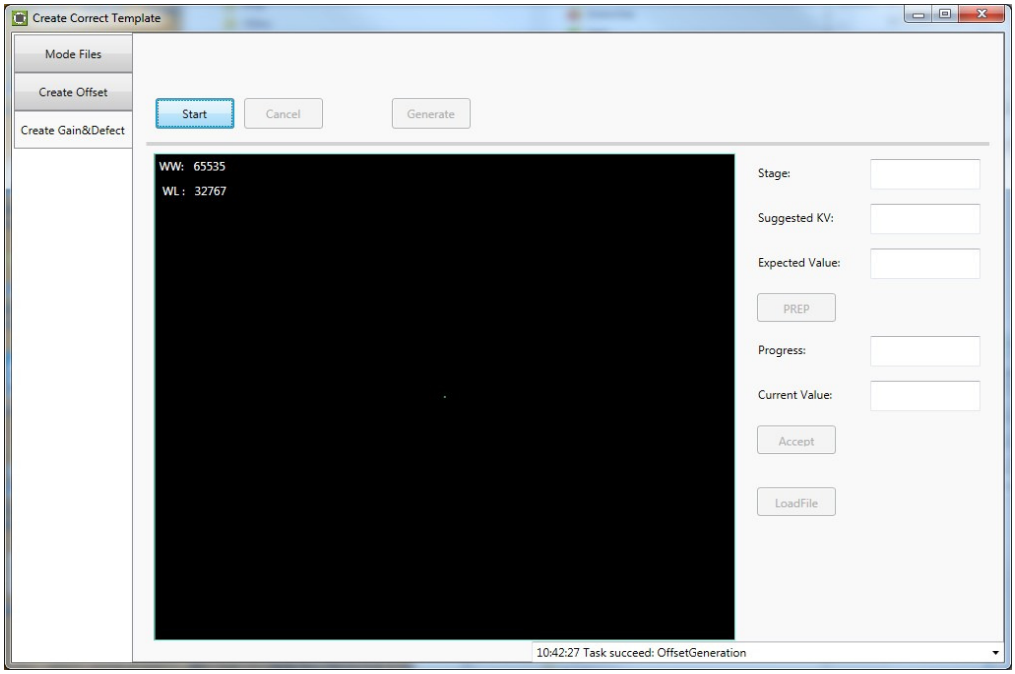
- Click "**Start create offset template file**" to generate offset template file.



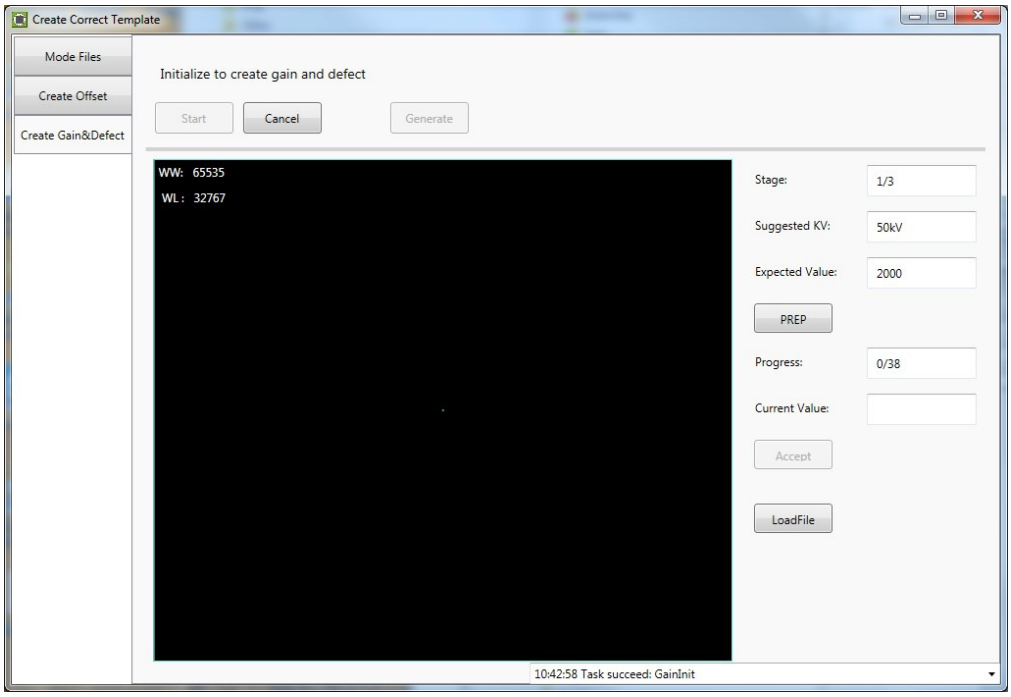


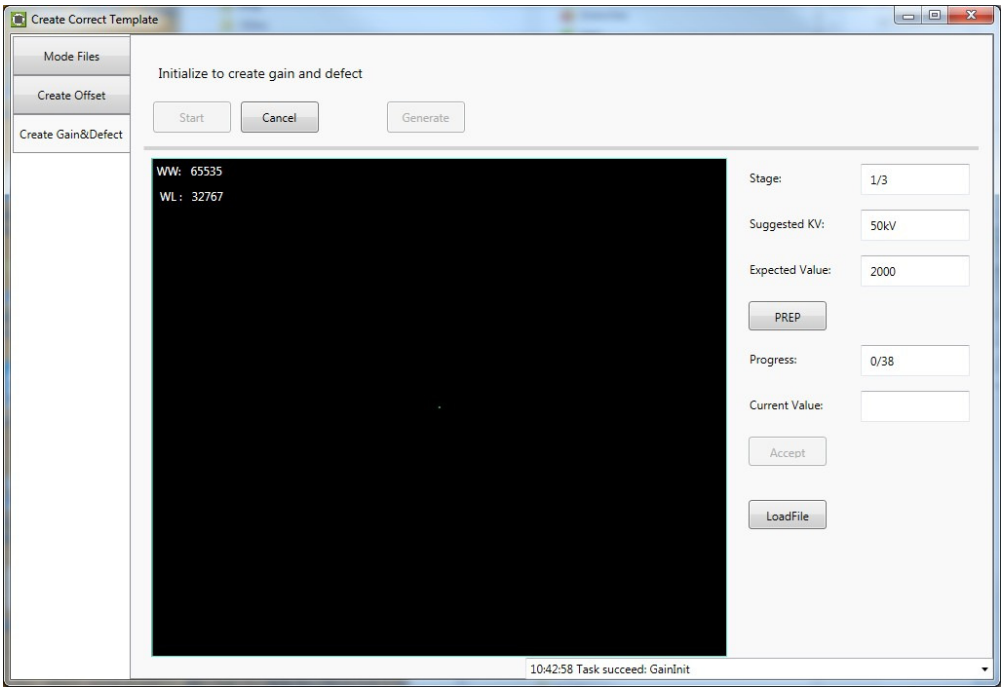
Dynamic detector will generate both Gain template and Defect template together.

- Click **Start** button.



- Click **PREP** button. Exposure and acquire image.
- Click **Select** button.
- Select **Light field image**.
- Then "**Stop exposure**" message box will appear. Begin to acquire dark field image after close message box.
- Click "**Accept**". Repeat step 2, step3, step4 until all images are acquired.
- Click "**Generate**" button. Generate Gain and Defect template.


Create Correct Template
Mode Files
Create Offset
Create Gain&Defect
Initialize to create gain and defect
Start
Cancel
Generate
WW: 65535
WL : 32767
Stage:
1/3
Suggested KV:
50kV
Expected Value:
2000
PREP
Progress:
0/38
Current Value:
Accept
LoadFile
10:42:58 Task succeed: GainInit

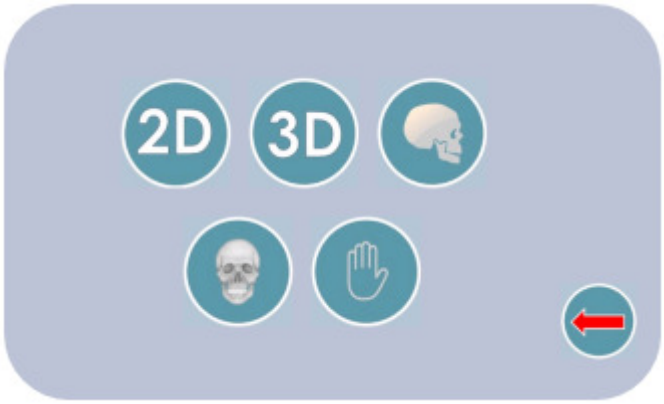

Create Correct Template
Mode Files
Create Offset
Create Gain&Defect
Initialize to create gain and defect
Start
Cancel
Generate
WW: 65535
WL : 32767
Stage:
1/3
Suggested KV:
50kV
Expected Value:
2000
PREP
Progress:
0/38
Current Value:
Accept
LoadFile
10:42:58 Task succeed: GainInit

10.1.3 Automatic Exposure Values

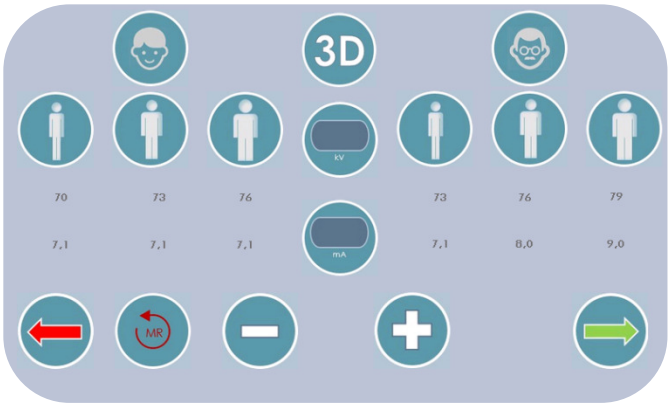
X-VIEW 3D PAN comes with a set of default exposure parameters for each exam. The manufacturer has chosen and set these values based on considerations and tests of image quality. Radiological image quality, however, is strictly dependent on the user's personal considerations, and also environmental installation conditions. In particular, the presence of light sources affect the perception of the image quality.

Pre-set exposure values can be modified to get contrasted images according to the needs of the user. To change the parameters select the function **Auto Exposure**:

1) **Select the examination family** to be modified:



2) **Select the parameters** to be modified:



This screenshot displays the values for a 3D examination parameters, for each type of patient (adult/child) and size (normal, small and large). Proceed as follows:

- Select the patient's type and size to modify.
- Select the parameter kV and/or mA and using the "+" or "-" buttons change the values.
- Store, temporarily, the selected values using the green arrow.
- Pressing the red arrow returns to the function selection **without saving** the changes.
- To recall the preset values and cancel the modifications press the red arrow in the shape of a semicircle

10.2 Service Technician Functions

This menu allows the following functions:

- Specific System properties Configuration
- Troubleshooting operations and system maintenance consult.

The **password** to access the menu dedicated to the service technician is **0000**. If the password is incorrect, the operator will be prompted to insert it again or return to the main menu. If the password is correct the following screen appears:

10.2.1 Language

Please refer to point 10.1.1

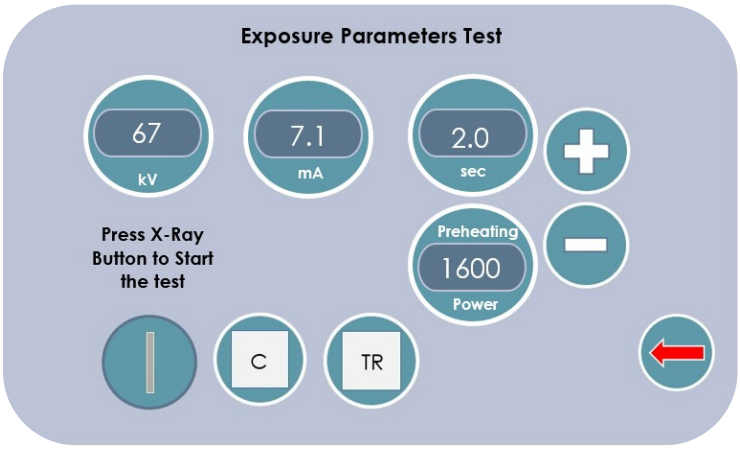
10.2.2 Exposure Parameters Test

This option in the **Service Menu** allows some more functions compared to the same option of **User menu**:

Preheating. The preheating value drives the energy supplied to the generator to preheat the tube filament. It should not be modified without the authorization of Trident Technical Service.

Collimator selection. This option allows technicians to select the X-ray beam and emission modality:

- Panoramic beam – continuous X-ray emission
- 3D beam – continuous X-ray emission
- 3D beam – pulsed emission

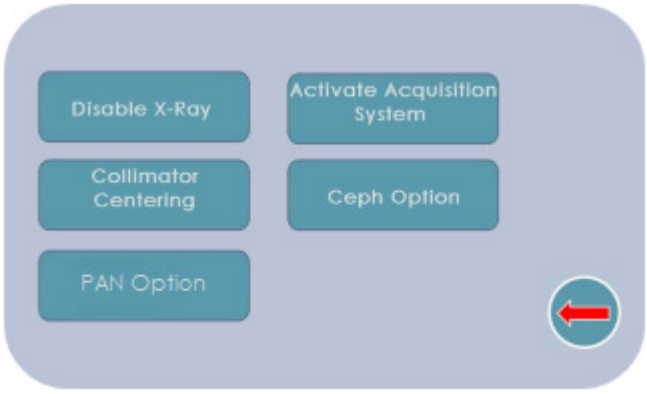
SCREENSHOT	ICON	MEANING
		Choose Collimator
		Continuous X-Ray emission
		Triggered X-Ray emission
		Buttons to increase/decrease de values
		Button to exit

10.2.3 Automatic Exposure Values

Please refer to point 10.1.3

10.2.4 Settings

This section includes the following options:

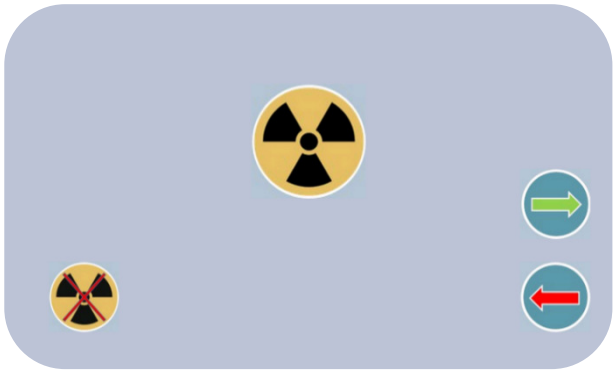


10.2.4.1 Disable X-RAY

This function is used to enable or to disable the X-Ray emission. Inhibition of the rays is mainly used for exhibitions and/or trainings when you want to show how the system works without exposure.

The following screenshot shows the current status of the emission system enabled.

Press the left bottom corner icon to enable/disable the x-ray emission.

SCREENSHOT	ICON	MEANING
		The emission is enabled
		Emission disabled
		Confirm selection
		Return to the previous option.

10.2.4.2 Activate Acquisition System

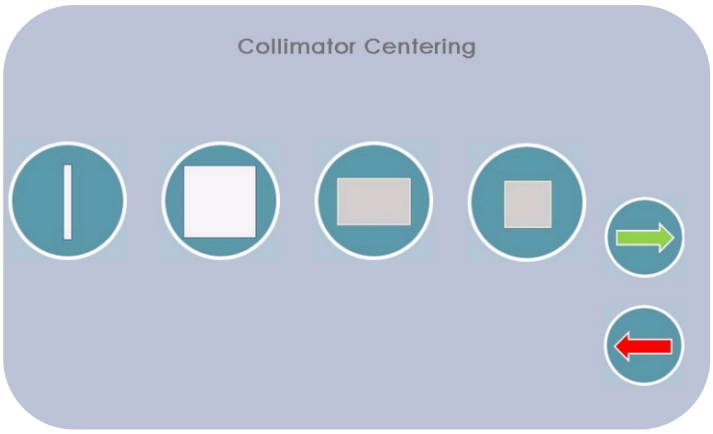
This function enables or disables communication with PC. It is used in exhibitions to show X-VIEW without its acquisition PC; if disabled, "Ready" signal from PC is not required, therefore the machine allows the customer to take exams (with or without X-Rays) but obviously no image will be shown. In normal operations this function must be enabled.

Press the left bottom corner icon to enable/disable PC communication.

10.2.4.3 Collimator Centering

	**WARNING** Only qualified service technician can perform the X-Ray alignment. The system is always in **Ready for X-rays release**. Please observe all precautions for radiation protection and press X-RAY emission button only safely.

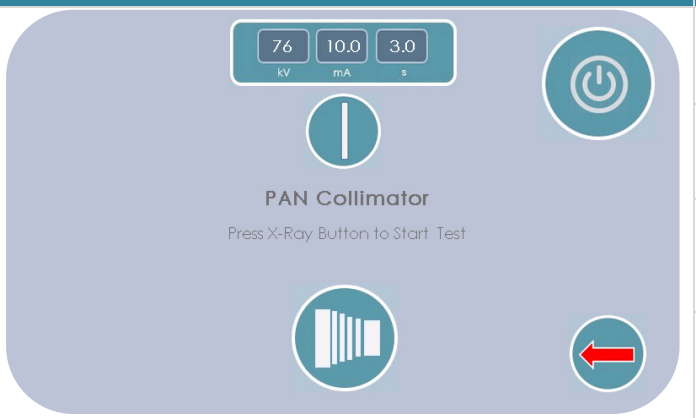
This function allows to center the collimator; this can be done by pressing the adult PAN collimator icon; to calibrate the sensor press the 3D collimator icon.

SCREENSHOT	ICON	MEANING
		Adult PAN Collimator
		3D Collimator
		Store the offsets and return to the main menu.
		Back to main selection menu **without changing the offsets already present in the system.**

Before accessing the menu, disable PC communication (see paragraph10.2.4.1).

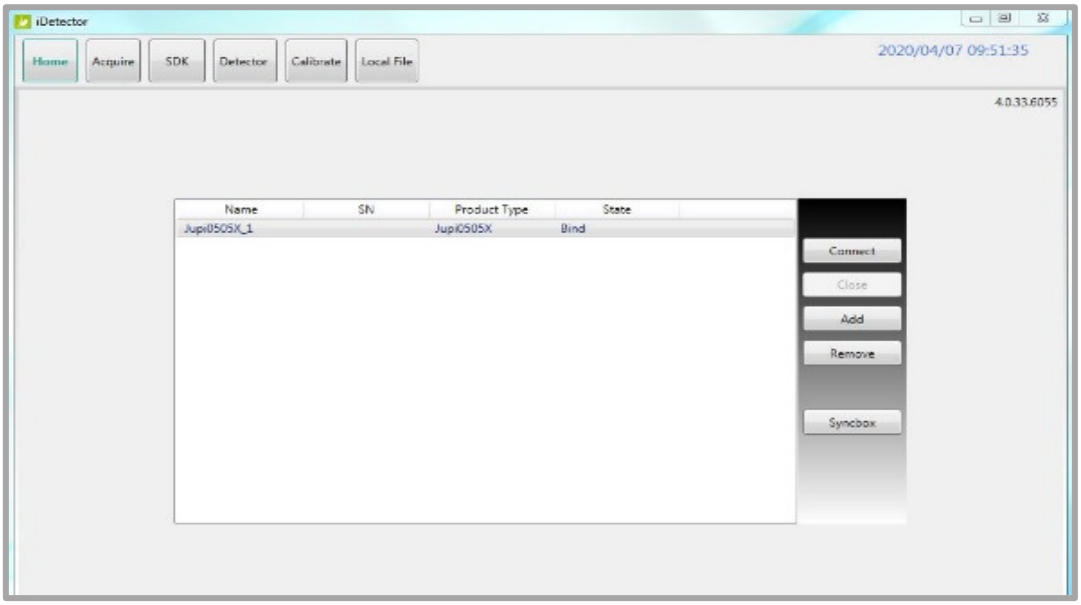
Once selected the collimator, the display shows the following information:

- Exposure Parameters settings
- The slit under test
- The **System Ready to emit** symbol
- The symbol informing to press the X-Ray button to start emission

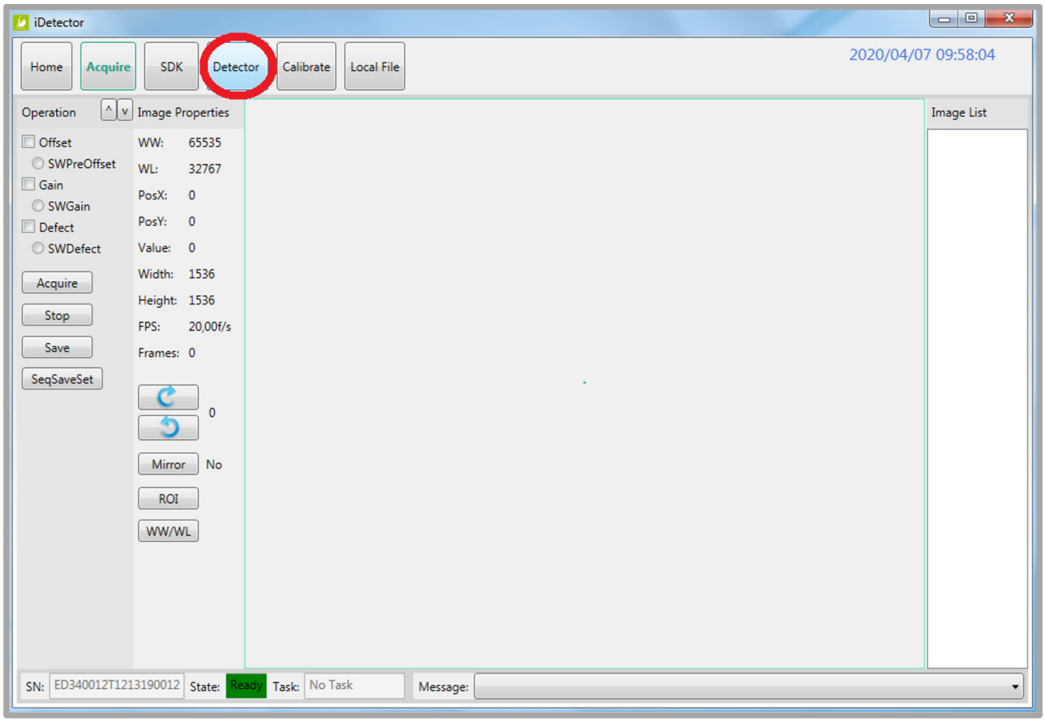
SCREENSHOT	ICON	MEANING
		System is ready to emit rays
		Select Adult Pan collimator
		Press X-Rat button to start
		Back to main selection menu

Instructions shows, in addition to the exposure parameters, that the system is ready for emission and that after pressing the X-Ray button, the exposure will start. But before to see the emission result, it is necessary to set the software following these steps:

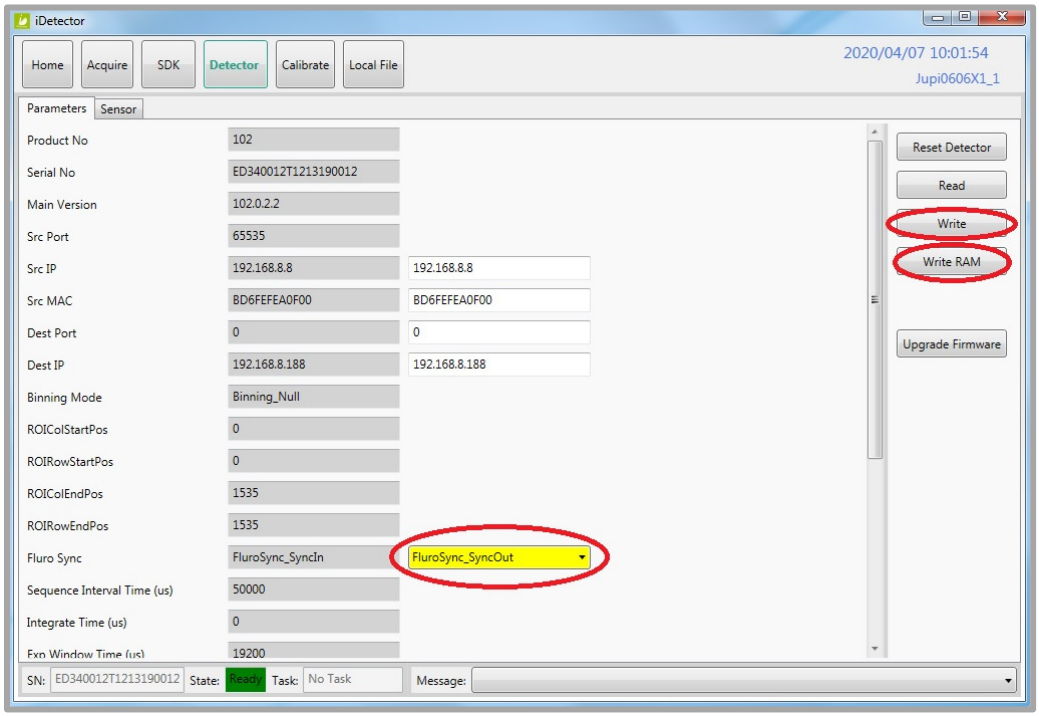
- Go to C:\ProgramData\TRIDENT_XView_3D_v4\inpSensor3D
- Open the file iDetector.exe.
- Select the sensor and click on **Connect.**



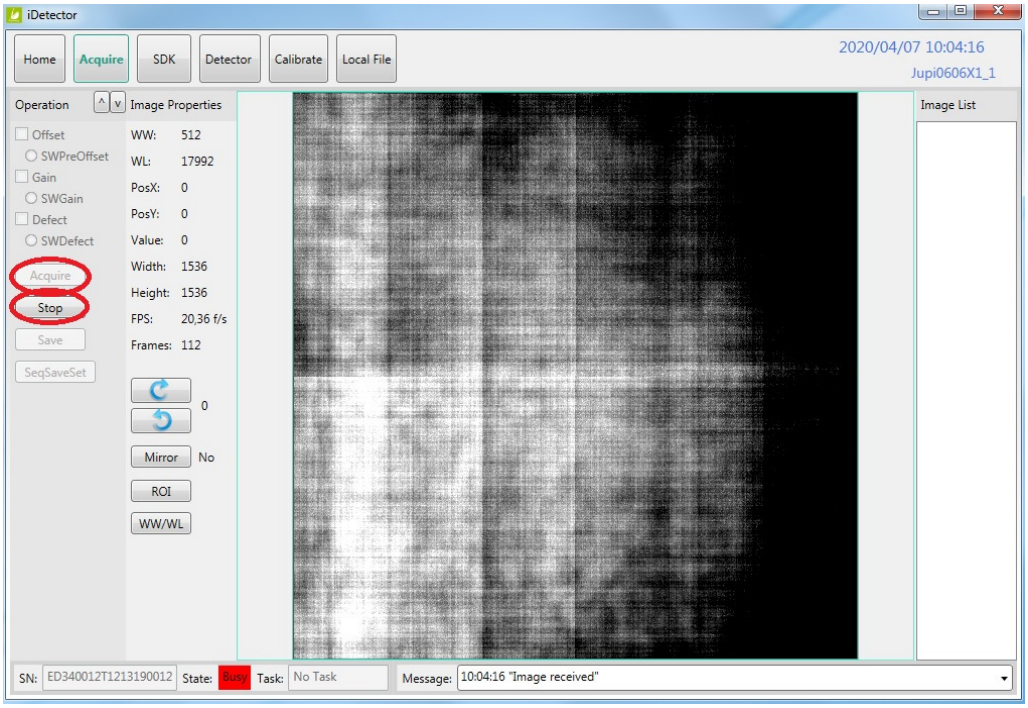
- Click on **Detector** and open the menu.



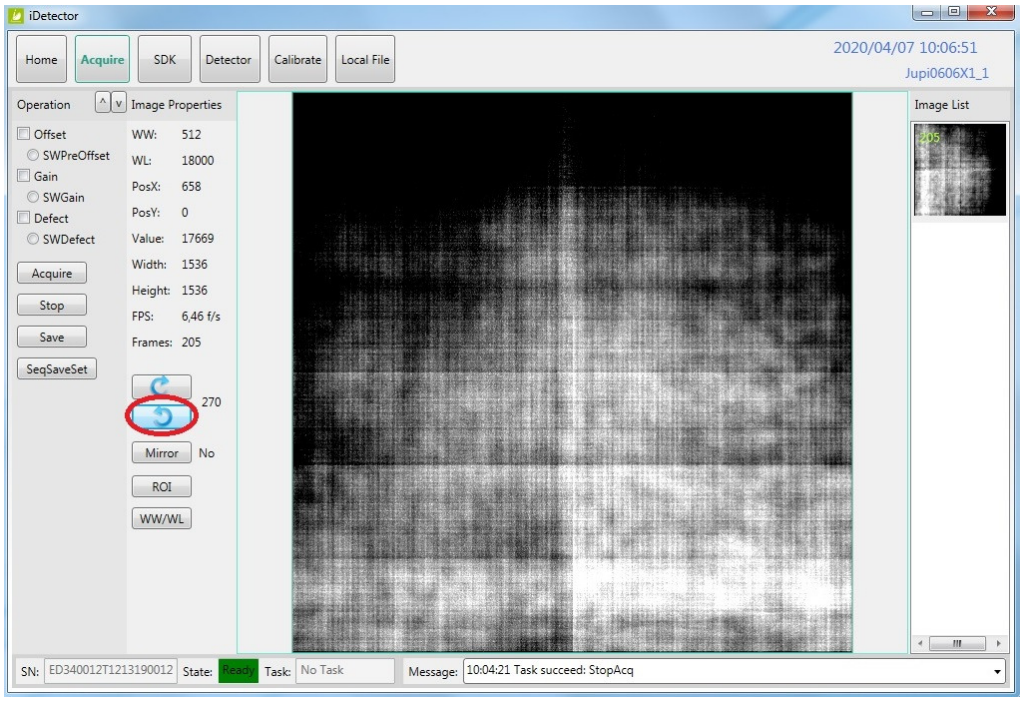
- Put the Sync of the sensor in **SyncOut**.
- Press on both, **Write** and **Write RAM**.



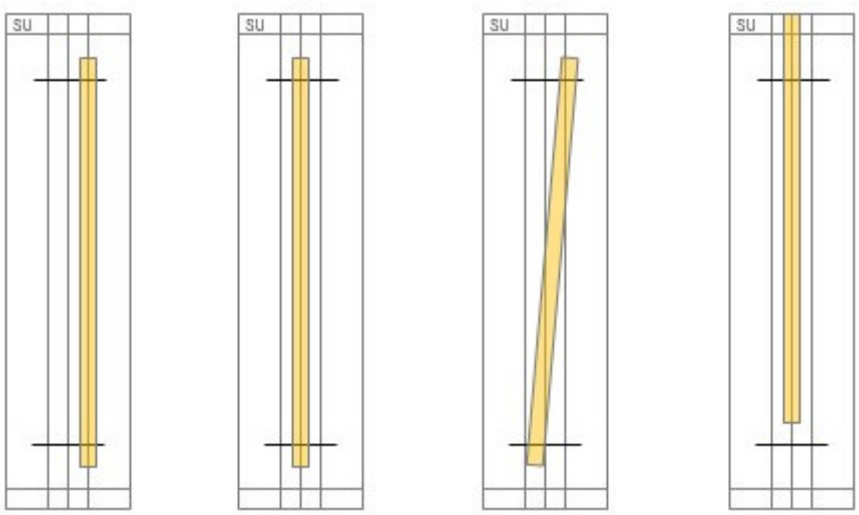
- Go inside **Acquire**.
- Press **Acquire** button and as the image appears, press **Stop**.



- Rotate the image. When a black area at the corner or at any side of the image is visible, the collimator must be moved. To move the collimator, follow the instruction of the 3D SYD and contact us.



The image may present one of the centering situations shown in the following figure:



The **optimal centering condition**, which is described in case B, occurs when the exposed field is within the reference area i.e., the highlighted line is perfectly positioned in the middle of the white area.
When one of the other situations, A, C or D occurs, the collimator must be accessed to center it.

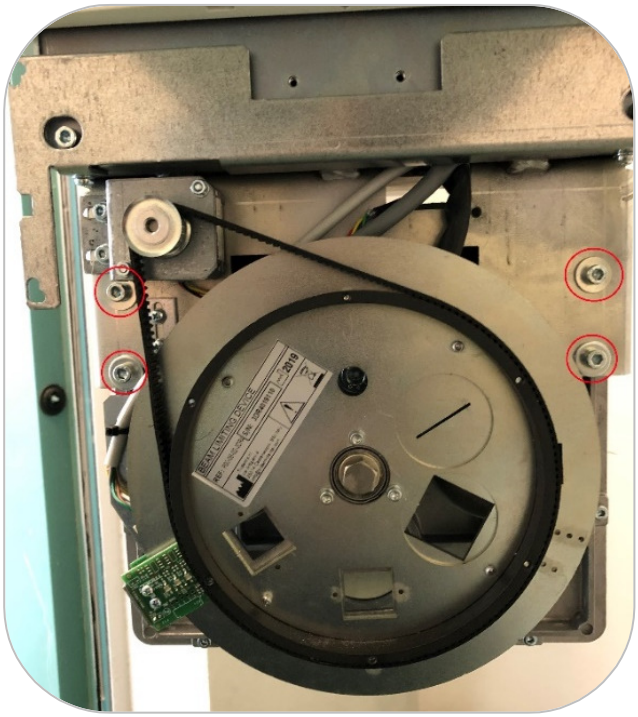
⚠	**WARNING** Only qualified service technician can perform the X-Ray alignment. The system is always in **Ready for X-rays release**. Please observe all precautions for radiation protection and press X-RAY emission button only safely.

To access the collimator, proceed as follows:

- Remove the cover:

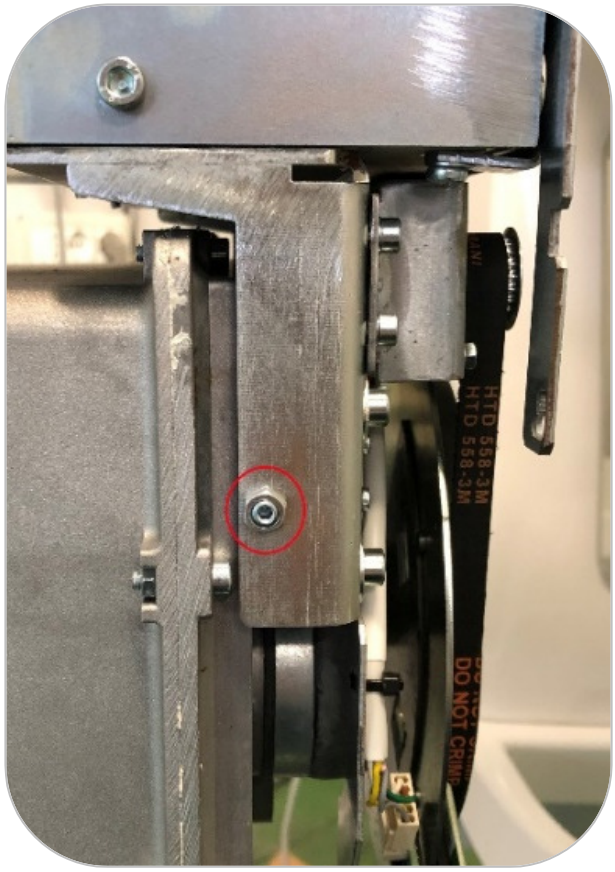
- Now, remove the X-ray tube cover:

- Slightly loose the four screws shown in the picture:



At this point, the correction actions are carried out according to the centering of the image:

1. For centering case A:
Here the exposed field is to the right of the reference area. To correct this position, move the tube in the direction opposite to the image using the set screw indicated in the photo.



To move the tube to the right, adjust the screw to the left.

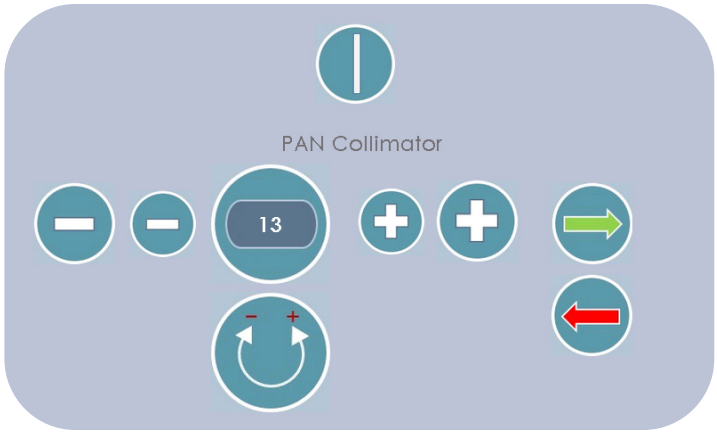
To move the tube to the left, adjust the screw to the right.

After moving the tube, check that the beam position reached the situation described in case B.

Before closing the covers of the machine, make sure you have properly tightened the 4 screws.

Notice: Avoid jerks and strong, fast movements when centering the tube. Move it little by little until the desired position is reached.

2. For centering case C:
When the image looks like centering situation C, rotate the collimator using the motor, use the "+" and "- " symbols to move it. If the correct centering position is not reached, proceed to move it right or left. The following screen appears and shows the current offset of the collimator examined:

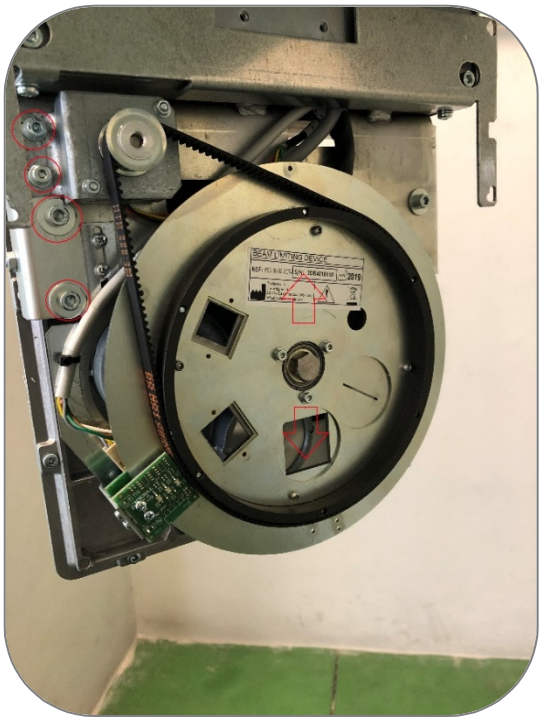


- Using the + and - symbols reach the position described in case B.
- Run an exposure to check the effects of the correction.
- Press the green arrow to save the settings.
- By pressing the red arrow, **return to the menu without storing the last collimators offset value.**

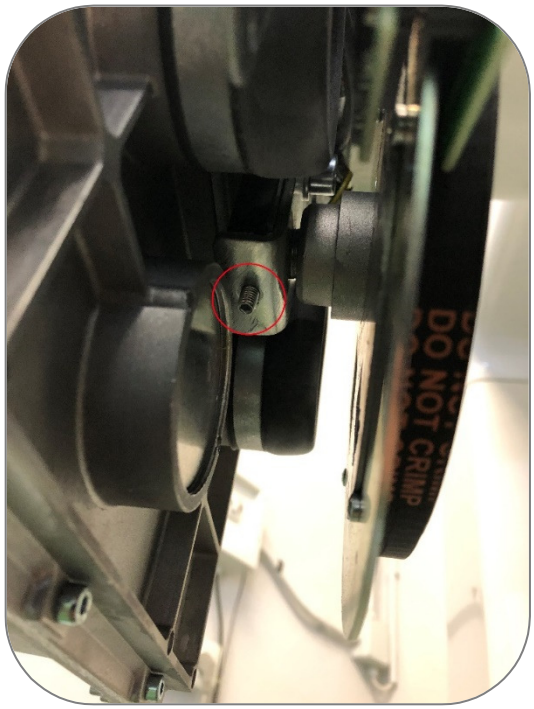
After calibration, the yellow line must be perfectly positioned in the middle of the white area, (situation B, **which** is **the optimal centering condition).**

3. For centering case D:

If the collimator is too high or too low move it directly up and down, as follows:



The set screw under the collimator eases the up/down movement. To move the collimator down, slightly loose the screw of the motor to avoid the belt to be tight.



To finish the process:

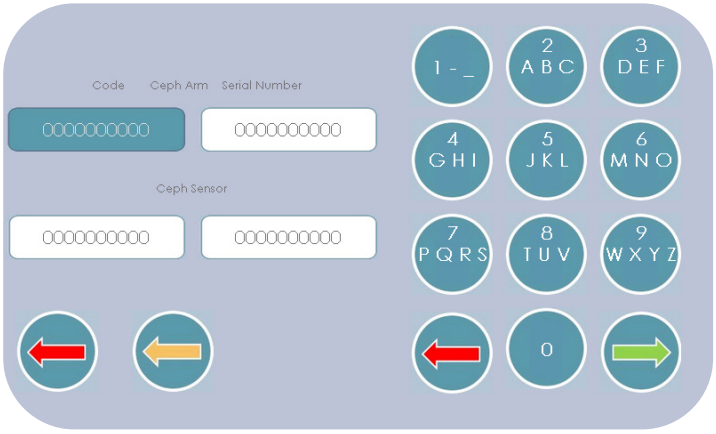
- Fix the motor screw and tight the belt.
- Set up the machine and the software to acquire an image with the new collimator.
- Check the result. If the result is as good as expected, fix the screws and put on the cover again. Now, the collimator centering process is finished.

10.2.4.4 CEPH Option

This function allows enabling the CEPH arm and to align the X-ray beam of the Ceph sensor.

Once selected this option, the system ask for the Ceph arm data. Using the keypad the user ought to introduce the following four codes:

- Ceph arm code
- Ceph arm serial number
- Sensor code
- Sensor serial number



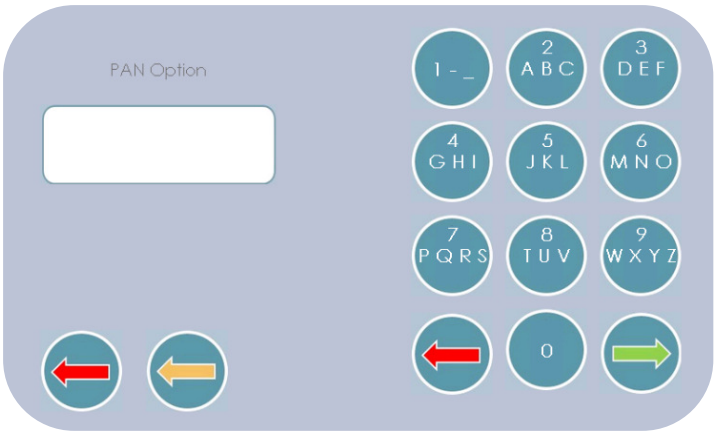
The keyboard has the same logic of a common mobile keypad. By pressing repetitively the same button, it will scroll the number and the letters associated with that key, e.g. pressing button 2 in succession will scroll the number 2 and letters a, b and c. To insert the same character twice, for example twice the number 2, press the button 2, wait 3 sec and press it again.

The green arrow confirms the data and enable the option, while the red arrow disables CEPH, erases the data and returns to the **Settings** menu.

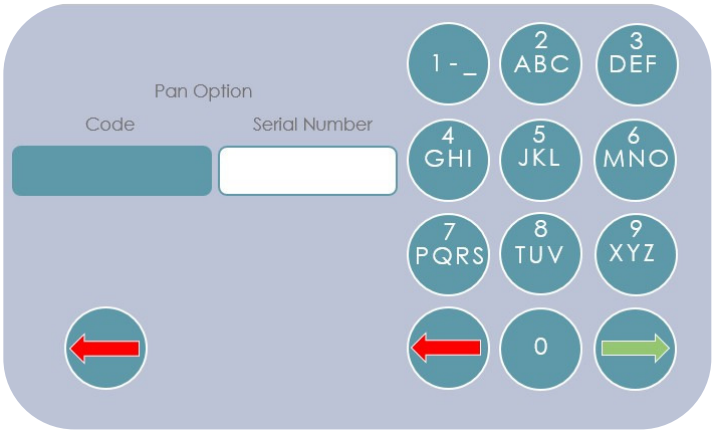
	The system does not recognize the presence or absence of the cephalometric arm and its sensor. Enable the CEPH option **only when** CEPH **arm** is installed.
	Enabling a CEPH arm on a system already installed, as well as the arm parts replacement, requires realigning the system.

10.2.4.5 PAN Option

This function enables the optional panoramic type examinations by entering the activation code sent by Trident under request. By pressing the **Select** button this screen appears:



If the code entered is correct, the optional PAN exams are available. The next screen with the boxes to enter the code and serial number that Trident has sent you will appear:



Using the numeric keypad enter the Code and Serial Number sent by Trident. Confirm the process by pressing the green arrow.
To delete wrong data, use the red arrow. To exit without saving the codes, use the red arrow on the far left.

10.2.5 Show Log

This function allows visualizing all the device reports and upload/download firmware and setting from/to and USB storage key.

10.2.5.1 Exposure counter

This table displays the total number of the exams carried out according to type of examination and patient type.

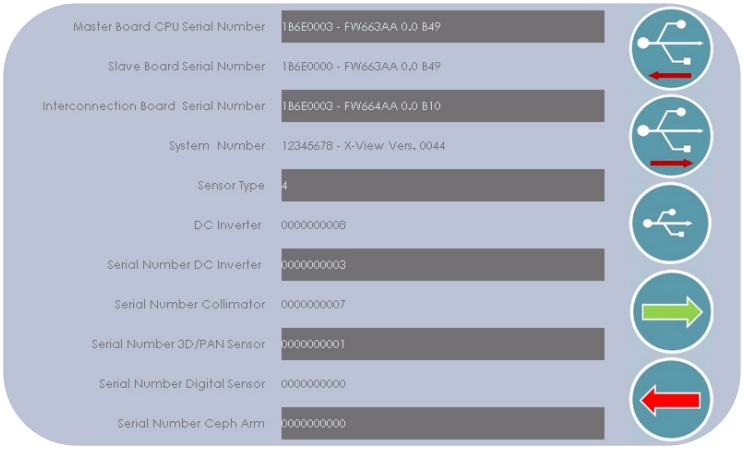
10.2.5.2 Number of Errors

This menu shows number of errors occurred on the device split by type.

10.2.5.3 Configuration

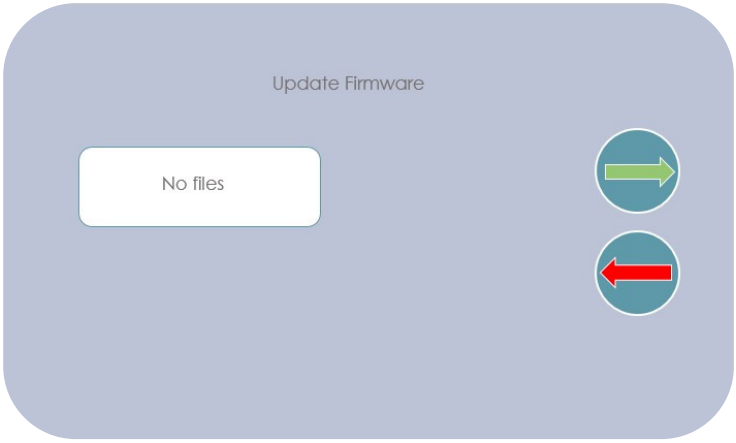
This section displays the account code values, the set serial numbers and allows the operator to upload/download the device settings and update the machine Firmware.

Configuration is shown in two pages, sliding with the green arrow goes from page 1 to page 2, and with the red arrow return from page 2 to page 1. The green arrow displays every page details.

SCREENSHOT	ICON	MEANING
		Loading settings from USB to XVIEW
		Exporting settings from XVIEW- to USB Exports the defaults of examinations, the ratings, the queues and S/N of components and offsets. These values will be the same that will be loaded when write from USB.
		Update the firmware of the master and slave board, retrieving the file from an external USB memory connected to the USB port.

This screen shows the saved setup.

While the following screen shows a firmware upgrade operation that could not be performed due to lack of update files.



10.2.5.4 Not Avalaible exposure

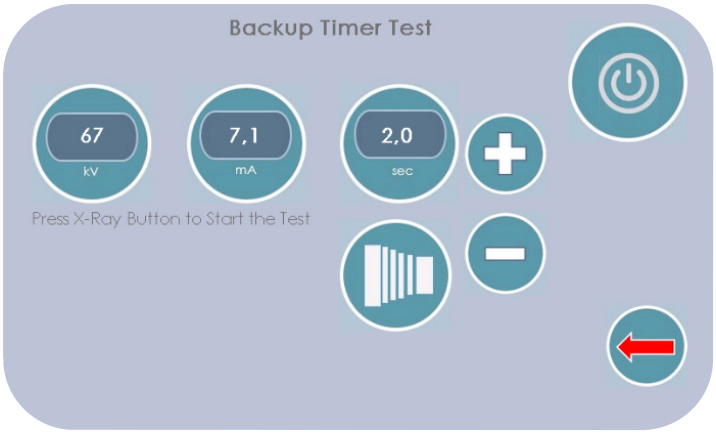
This menu shows the failed exams occurred on the machine.

10.2.5.5 Inverter Parameters

This menu shows all the Inverter parameters useful in case of X-ray generator trouble shooting.

10.2.6 Backup Timer Test

This function is used for periodic testing operation or after replacing the master CPU.

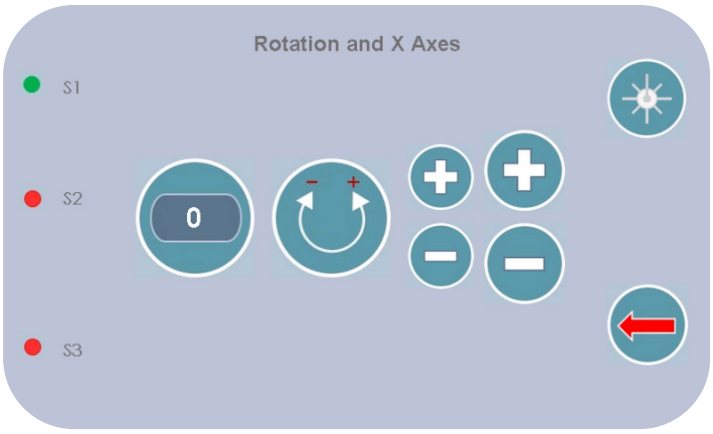


The test is similar to that described for the measurement of the exposure parameters but in this case, the exposure is not interrupted at the end of the set time, but continues until the backup safety timer, verifying the accuracy of the intervention.

	Do not release the X-Ray button until the end of the timer backup; it is signaled by a special message.
	Backup timer's intervention is considered a fatal error, shut down the system and turn it on again.

10.2.7 Rotation and X Axes

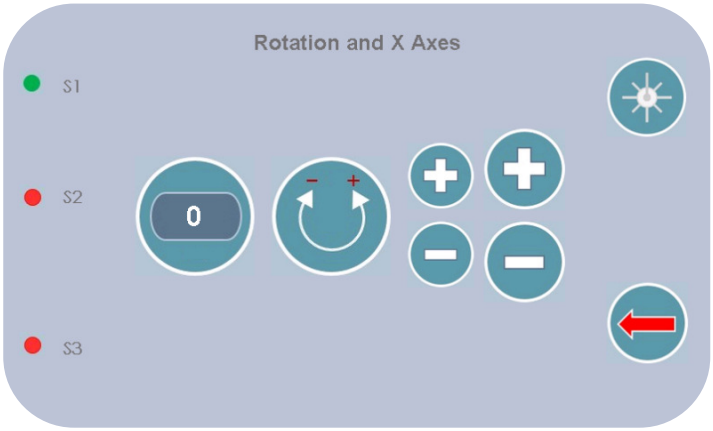
Pressing the **Rotation and X-axes** key allows the centering and storing offset axes operations. For a correct centering of the system, execute first the mechanical reset. If the mechanical reset is not been executed a screen requiring the test execution appears, as shown below.

SCREENSHOT	ICON	MEANING
		Laser button
		Rotation
		Optical sensors related to the selected Axis
		Decrease/increase values
		Return to the previous option.

The left side of the screen shows the state of the optical sensor. Pressing the X-Ray button the axis reset will start. Then the following screens will appear:

10.2.7.1 Rotation Axis

By selecting **Rotation,** the arm rotates to Zero position considering the previously stored offset.



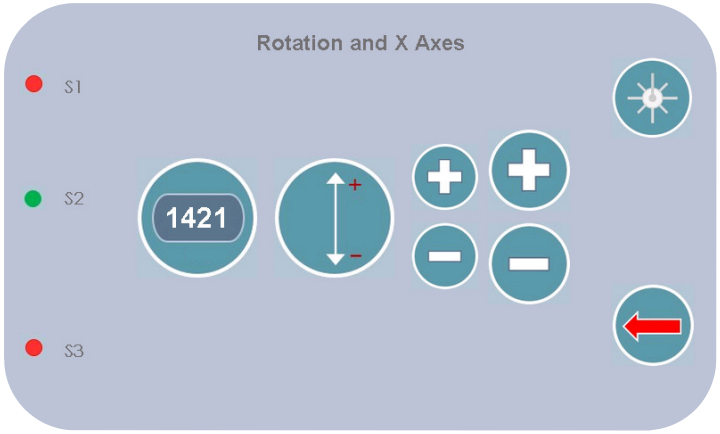
- If available, install the centering laser on system.
- The rotation movement search the Zero position in counterclockwise.
- Replace the bite center block with the centering tool (PA2-04) and verify that the centering laser line corresponds to the centering reference tool line.
- The "+" and "-" keys move the rotation arm in the desired direction to align the arm with the reference line. During the movement, the offset value is upgraded.

- The red arrow allows coming back to the main menu, without any consideration on the movement previously made.
- The green arrow allows saving the rotation offset and continuing to centering X Axis.

10.2.7.2 X Axis

	Until now the rotation offset is not been upgraded but is temporarily stored into erasable memory.

The following screen shows how to adjust the X Axis position:

SCREENSHOT	ICON	MEANING
		Laser button
		Axis centering
	S1 S2 S3	Optical sensors related to the selected Axis
		Adjustment values
		Return to the previous option.

1. Press the Axis centering button to activate this task. The centering Position is performed when the rotation arm moves perpendicularly to the mid sagittal axis while considering the offset rotation value defined with the above procedure.
2. The system searches "Zero" position with an external movement that apply offset already memorized.
3. Press the "+" and "-" keys to move the arm on desired direction to align the same with the reference. During the movement, the actual offset value is upgraded.
4. Press the red arrow to return to main menu, without saving or considering neither the rotation axis movement nor the offset (already modified); while pressing the green arrow will store rotation and offset and will return to operation selection menu.

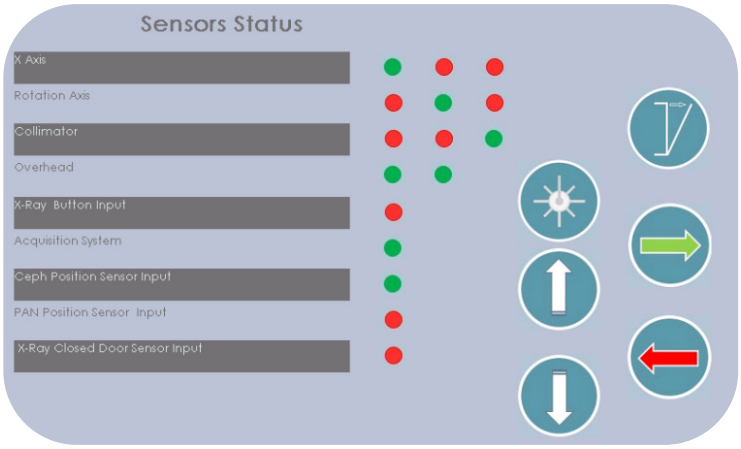
10.2.8 Troubleshooting

The troubleshooting function searches every solution to any fault. The first operation executed is a view of the sensors system status.

10.2.8.1 Sensors Status

This screen shows the encoder and input channels status.

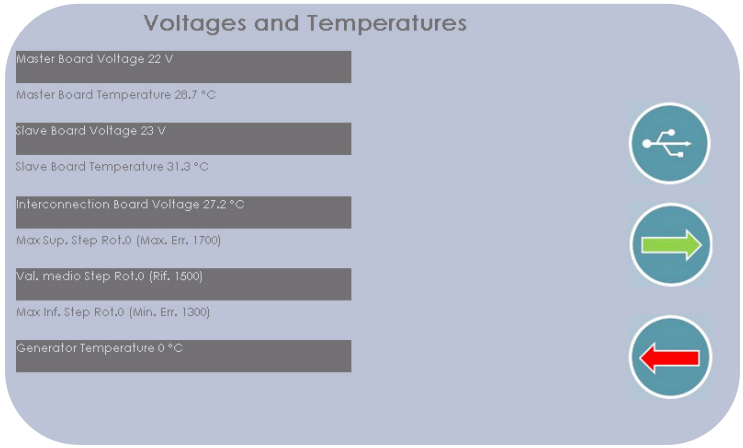
To enter this section, the motor ought to be unlocked, but not the column motor, so that it is possible to manually move all components to verify the encoder commutation status. Through this screen, it is possible to also check the overhead movement and its limit position as well as the input signals and laser functionality.



10.2.8.2 Voltage and Temperature Status

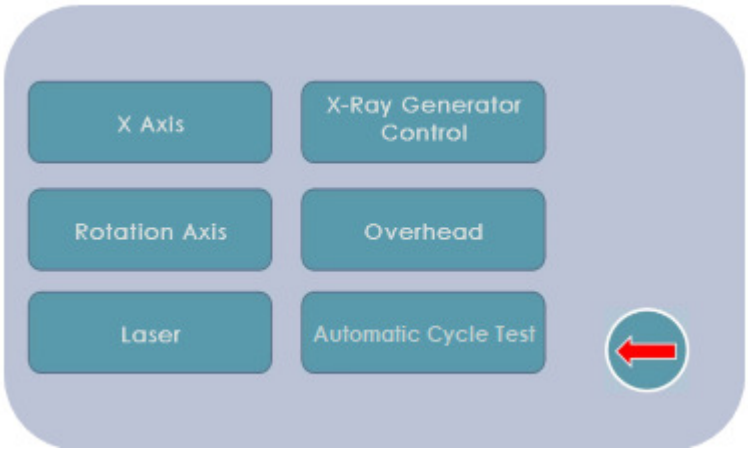
By pressing the green arrow, pass to the analysis of the voltage and temperature tabs. This screen displays the following data:

- The average step of the rotation encoder between one hole and the other for the last examination.
- The maximum difference towards the upper limit, between the average value and the real one, between two holes.
- The maximum difference toward the lower limit.



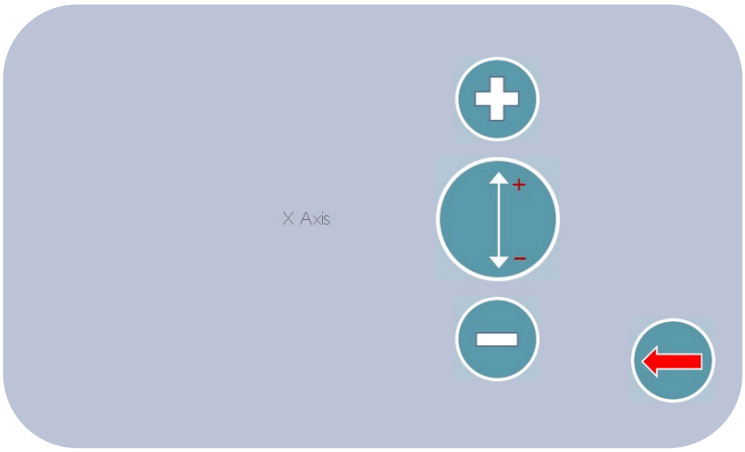
10.2.8.3 Troubleshooting Submenu

Press the green arrow to access the Troubleshooting submenu.



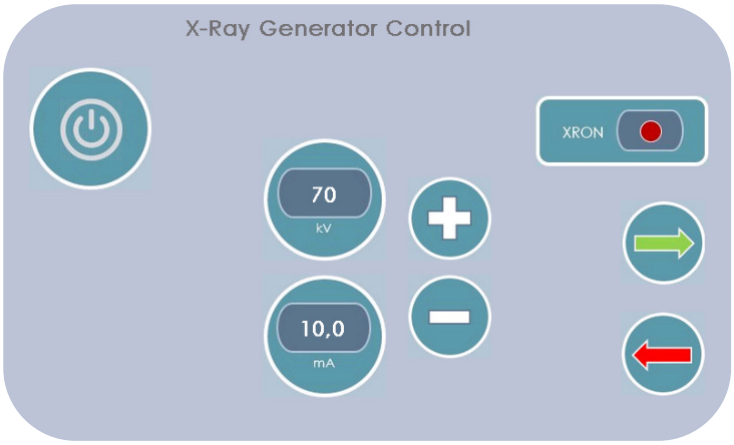
10.2.8.3.1 X Axis

In this phase, it is possible to test the arm's movement along the X-axis, making a motion step by step, showing at the same time the encoders' status.

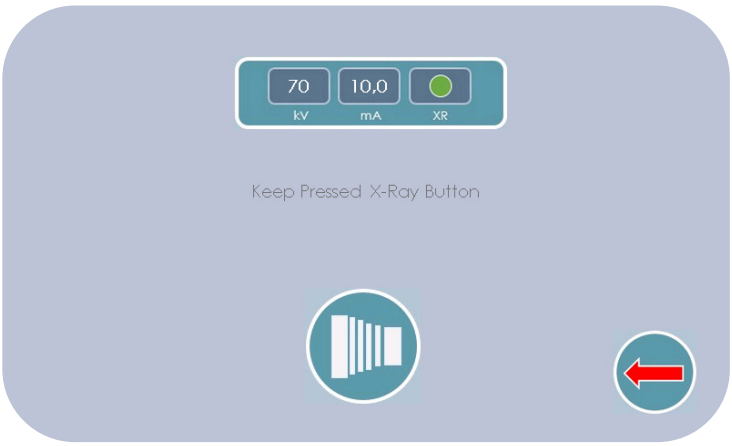


10.2.8.3.2 X-Ray Generator Control

This function allows the verification of emission generation chain. The screen is the following:



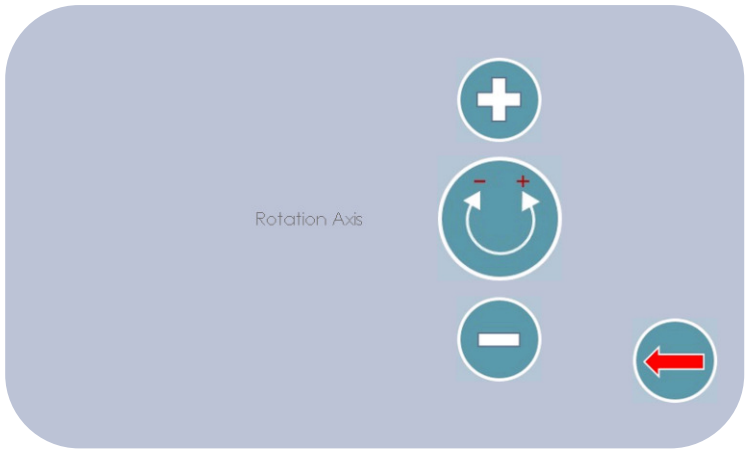
From here it is possible to set the parameters for an examination. Once selected the desired parameters, by pressing the green arrow the screen shows the information for emission process. The screen displays a real-time status of the return signal from the XRPSI card, XRON, and the return values of the feedback of kV and mA, always from the inverter Board.



Once the emission phase is complete, introduce the data back from the XRPSI card, from which can return to the request screen and make a new test, if needed. By pressing the red arrow, the unit returns to the Troubleshooting sub menu screen.

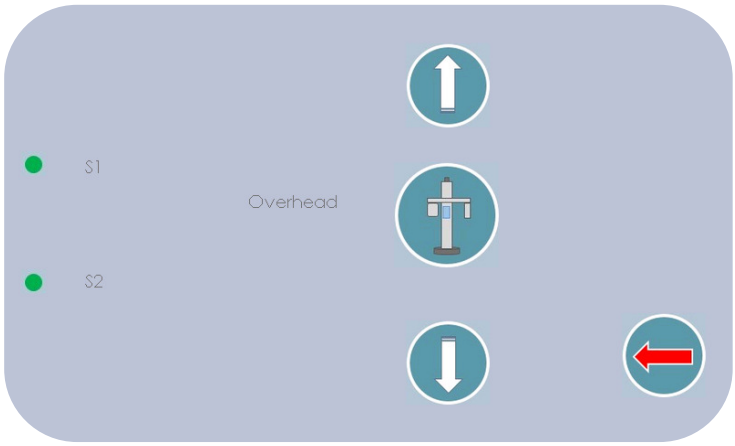
10.2.8.3.3 Rotation Axis

In this phase, it is possible to test the rotation arm movement, performing a gradual movement on distance, showing at the same time the encoders Status.



10.2.8.3.4 Overhead Support

This function allows checking the overhead movement; the operator can move the overhead upwards or downwards, also checking the status of the limiting switch.

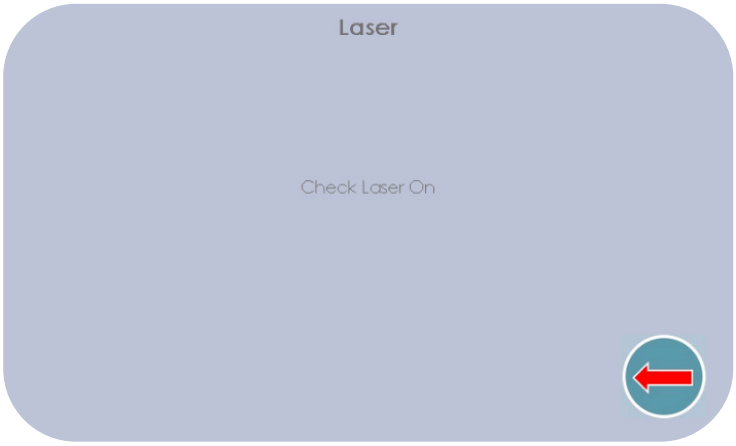


The arrows control the movement; here it is possible to check:

- The overhead movement. If it does not move, probably there is a motor failure or a vertical movement failure.
- Whether the direction of movement follows rightly the pressed key, otherwise there is a fault in the motor command.
- Whether the limit switches are correctly activated. When active, the movement will stop and the overhead can be shifted only in opposite direction.

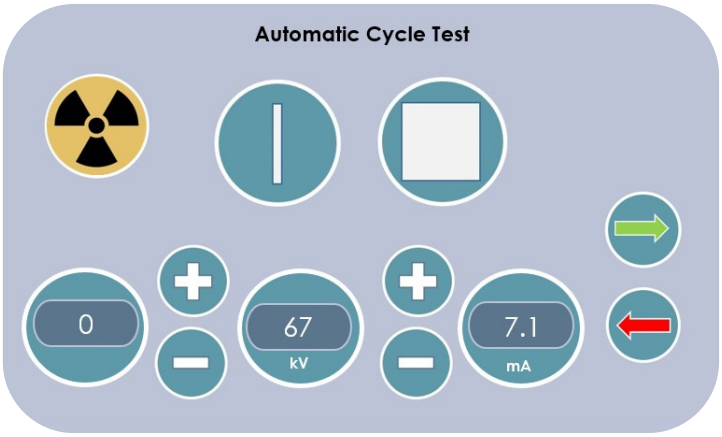
10.2.8.3.5 Laser

This function allows turning on the centering lasers. This operation in addition to the control of laser centering feature allows the alignment verification.



10.2.8.3.6 Automatic Cycle Test

This function can be used to repeatedly test the exam with or without X- ray emission. Select number of cycles, X-ray parameters, type of exam and press green arrow to launch the **Automatic Cycle Test**.



11 MESSAGES

X- VIEW 3D PAN shows messages for the system status, error messages and some actions to be performed. The operator must follow the directions and messages.

11.1 Power On Messages

During the starting phase, on powering, the unit automatically runs a check to verify the proper operation.

11.2 Unrecoverable Errors

Code	Message	Explanation	Action
A01	EEPROM	Program/Data checksum error	Master board error: replace it.
A02	XRON outside the exam	X-Ray emission outside the exam	Tubehead/cable/Esika board problem. Power cycle or replacement.
A10	Backup Timer	X-Ray stopped for safety reasons	Safety intervention. Possible master board failure (microprocessor).
A14	Collimator Hardware Fault	Hardware error	Possible short circuit (output); Check engine cable, master and driver on the master.
A21	Overhead limit error	Both limit switches are active	Check microswitch, cable, mounting
A22	Error rotation encoder	Encoder error	Check encoder operation via service menu; Mechanical impediments, belt, motor, collision with patient
A23	Error X axis encoder		

11.3 Reversible Errors

Code	Message	Explanation	Action
A03	Slave communication error	There is no serial link between master and slave	Cable / Board – Verify fuse on board / power (eg update firmware error)
A04	Interconnection communication error	There is no serial link between master and interconnections	
A05	Button Released	Release during any movement	Cable and / or button or card problem. Try changing the input
A06	Error with slave during motion	Error between master and slave during movement	Possible interruption of signal / cable or momentary disturbance. Check cards and cable
A07	Arm movement timeout	Does not respected timing (timeout)	Mechanical obstructions that slow down the movement / belt / motor
A08	Rotation limit switch error	The limit switches are active	Power cycle. Limit switch reached, possible mechanical problem / incorrect offset / motor failures
A09	X Axis limit switch		
A11	Communication error with Esika	Preheating error	Communication error between tubehead and Esika board (incorrect signal received by Troll); Check Esika board, master, cable
A12	Error Received from Esika board	X-ray emission error	
A12 Exit value 1	Low input voltage <240V		
A12 Exit value 2	High input voltage >370V		
A12 Exit value 3	Timeout Session		
A12 Exit value 4	Timeout X- Ray pulse -too long XREN pulse		
A12 Exit value 5	kV over 93 kV		
A12 Exit value 6	mA over 14 mA		
A12 Exit value 7	After 2 ms signal kV under 20 kV - maybe feedback signal kV disconnected		
A12 Exit value 8	After 1 ms signal mA<2 maybe feedback signal mA disconnected		

Code	Message	Explanation	Action
A12 Exit value 9	Negative average bridge current in duration of regulation bridge		
A12 Exit value 10	Unknown state session - software error of state machine		
A12 Exit value 11	Too high deviation of calibration A/D converter Average Filament Current		
A12 Exit value 12	Too high deviation of calibration A/D converter End Filament Current		
A12 Exit value 13	Too high deviation of calibration A/D converter Average Bridge Current		
A12 Exit value 14	Too high deviation of calibration A/D converter End Bridge Current		
A12 Exit value 15	Too high current filament - detected in software - no HW FAULT		
A12 Exit value 16	If 3x125us no measured data Kv + mA from Sensing/Watchdog controller		
A12 Exit value 17	If 3x125us current under <39mA - probably tubehead FIL disconnected		
A12 Exit value 18	If 3x125us current under <1.3A - no XREN or tubehead HT disconnected		
A12 Exit value 19	Too high current bridge PWM1 - detected by HW comparator - HW FAULT		
A12 Exit value 20	Too high current bridge PWM2 - detected by HW comparator - HW FAULT		

Code	Message	Explanation	Action
A12 Exit value 21	Too high current filament PWM6 - detected by HW comparator - HW FAULT		
A12 Exit value 22	Unknown HW FAULT		
A12 Exit value 23	Too high current filament - detected in software - no HW FAULT		
A12 Exit value 24	Filament heating >25W more than 100ms - filament burning protection		
A12 Exit value 25	Session finished by max. run time		
A12 Exit value 26	Session finished by count of pulses		
A12 Exit value 27	Session finished by command stop		
A13	Timeout Collimator	Collimator motion error	Verify possible mechanical obstructions, encoder, belt, motor, offset; Check that the collimator type is correct
A15	Open door	Open circuit	Check door closure; 6-pole cable interrupted (interconnections - master); Missing or damaged bridge jumper
A16	Timeout laser FF plane	Movement timeout	Verify possible mechanical obstructions, motor, cable, micro, interconnections
A17	Ready Signal 2D sensor not received	Missing signal	Verify PC / Sensor Connection, SW Error, Sensor, Cable, Connector on Master; Verify (in case of 2D) that "2D new" has been selected on the touch panel in the system configuration
A18	Communication error with Remote PC	Missing signal	Verify PC side configurations (Remote Communication missing) or Ready signal by PC missing

Code	Message	Explanation	Action
A19	Sensor support position error	Position error for Ceph	Both position sensors are active (intermediate position); Check microswitch, cable, master
A20	Touch Master communication error	Touch panel / master card connection	Communication problems (touch panel cable to master card)
A24	Switching off from ready state to acquisition of Remote PC	The PC does not switch from "ready" to "emitting"	Check SW: Communication is there but the PC does not change status

12 CLEANING AND DISINFECTION

In order to ensure a thorough cleaning and hygiene, the following procedures should be scrupulously respected.

Clean painted surfaces, accessories and connection cables with a damp cloth and mild detergent. In case a spray detergent is used, first spray the liquid on the cloth, then wipe.

	Always disconnect the system from mains before cleaning .
	Prevent equipment from water penetrating to avoid corrosion or short circuits. When using spray liquids, make sure that the liquid flowing along the surface does not penetrate into the ventilation slots.
	After each examination, thoroughly clean all parts in contact with the patient: chinrest, headrest and handles support. To clean the parts in contact with the patient: • Use a cloth moistened with the choose liquid and rub the not removable parts (handles, etc.) • The removable parts can be cleaned as above or by immersion in liquid. Follow the instructions of the liquid manufacturer without exceeding in the immersion time.
	WARNING Products for care and cleaning can contain aggressive components. Use of not proper products can results injurious to health and danger to the surfaces of the unit. **DO NOT USE: agents containing phenol, peracetic acid, peroxide and other agents that split up the oxygen, sodium hypochlorite and other agents that split up the iodine.**
	Do not use scouring pads or abrasive cleansers (alcohol, benzene, trichlorethylene). Use only soft clothes to avoid scratches.
	Do not use any colored cloths for cleaning, since they may cause discoloration of the surfaces in combination with disinfectants.
	Do not clean the labels with abrasive cleansers.
	To clean the touchscreen, use a clean cloth dampened with mild detergent and water.

12.1 Cleaning products compatible with X-VIEW 3D PAN

- Mild detergent for painted surfaces, accessories and connection cables.
- Disinfectant's liquids for surfaces and parts that come or may come into contact with the patient.

13 MAINTENANCE

X-VIEW 3D PAN system is designed to furnish reliable performance and customer satisfaction for many years. In order to ensure safe performance, this radiographic equipment needs a preventive Maintenance program. It is your responsibility to arrange for this service, which must be carried out only by trained and qualified personnel from Trident; to do this you need to consult your dealer to arrange this service.

13.1 Monthly periodical Maintenance made by the user

The user must carry out the following checks monthly:

1. Visually check that all labels are visible and readable: If needs request a copy of the same to the manufacturer.
2. Check that there are no external damage to the equipment may affect the safety of radiation protection.
3. Visually inspect the exposure indicator LED is switched on for the duration of exposure.
4. Check that there are no oil traces on the block covers.
5. Verify that the acoustic emission indicator is active for the duration of the exposure.

	**NOTE** In case of programs requiring an interrupted emission (such as TMJ examination open/closed mouth), the acoustic signal is interrupted at the time of issue between the two sides of the TMJ.

6. Verify that the exposure button must be pressed continuously during the exposure cycle.
7. Verify that, if the exposure is terminated due to premature X-Ray button release, the display will display its Error Message.
8. Check out all of the proper performance of the functions (selection and execution of tests) on the display panel with touch screen.

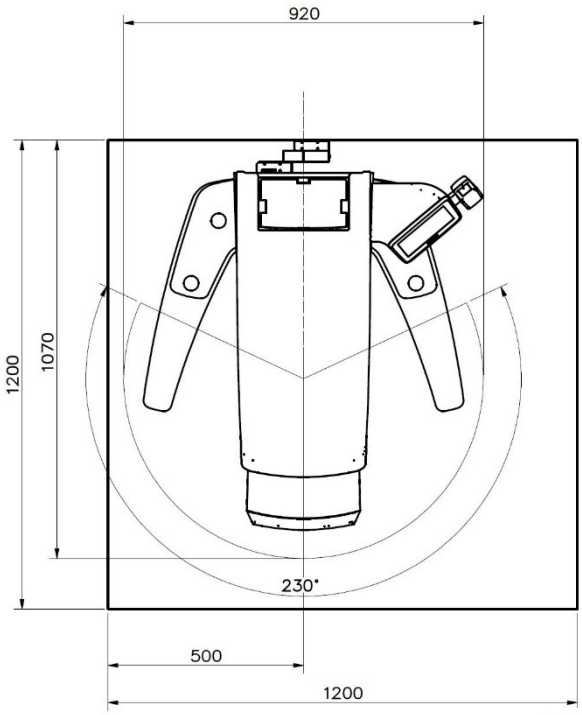
13.2 Scheduled Maintenance

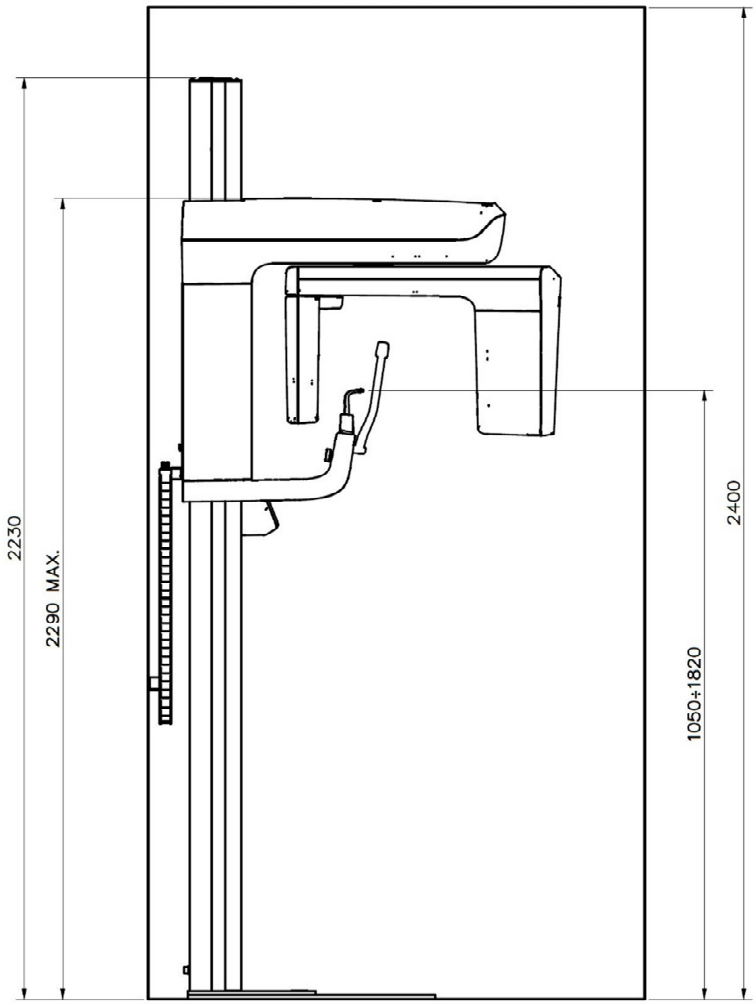
We recommend performing the scheduled Maintenance of X-VIEW at the installation and annually.

The scheduled Maintenance will include the following:

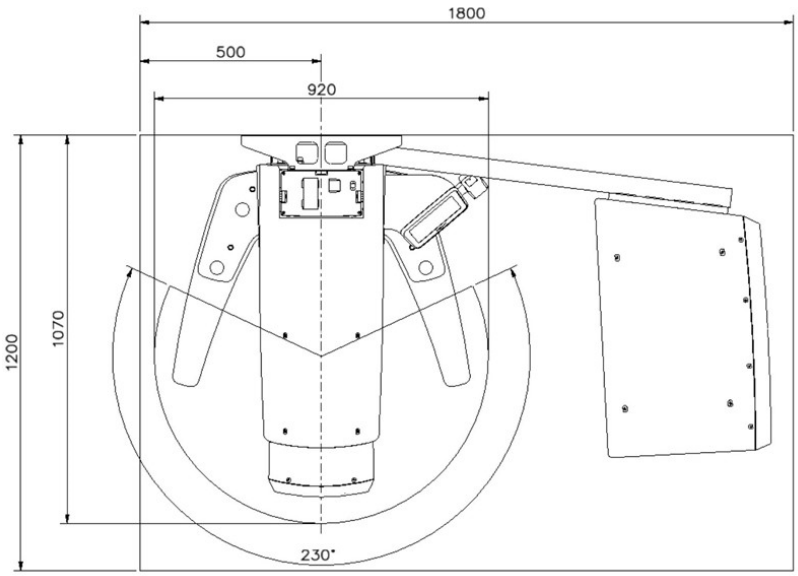
1. All the procedures for regular Maintenance by the user.
2. Verification of the Beam centering X-Ray for PAN.
3. Verification of the overhead movement
4. Correct visualization of the exposure parameters
5. Lasers brightness
6. Focus layer position
7. Exams movements

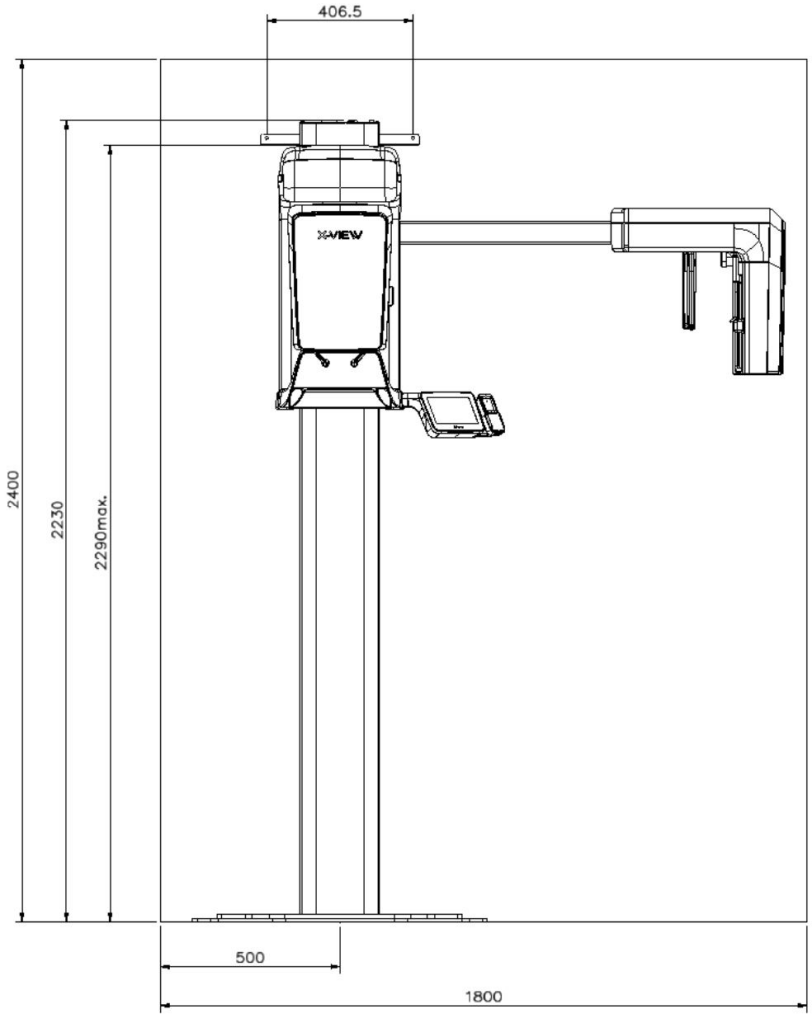
ANNEX 1
Dimensions
X-VIEW 3D
POY/SYD



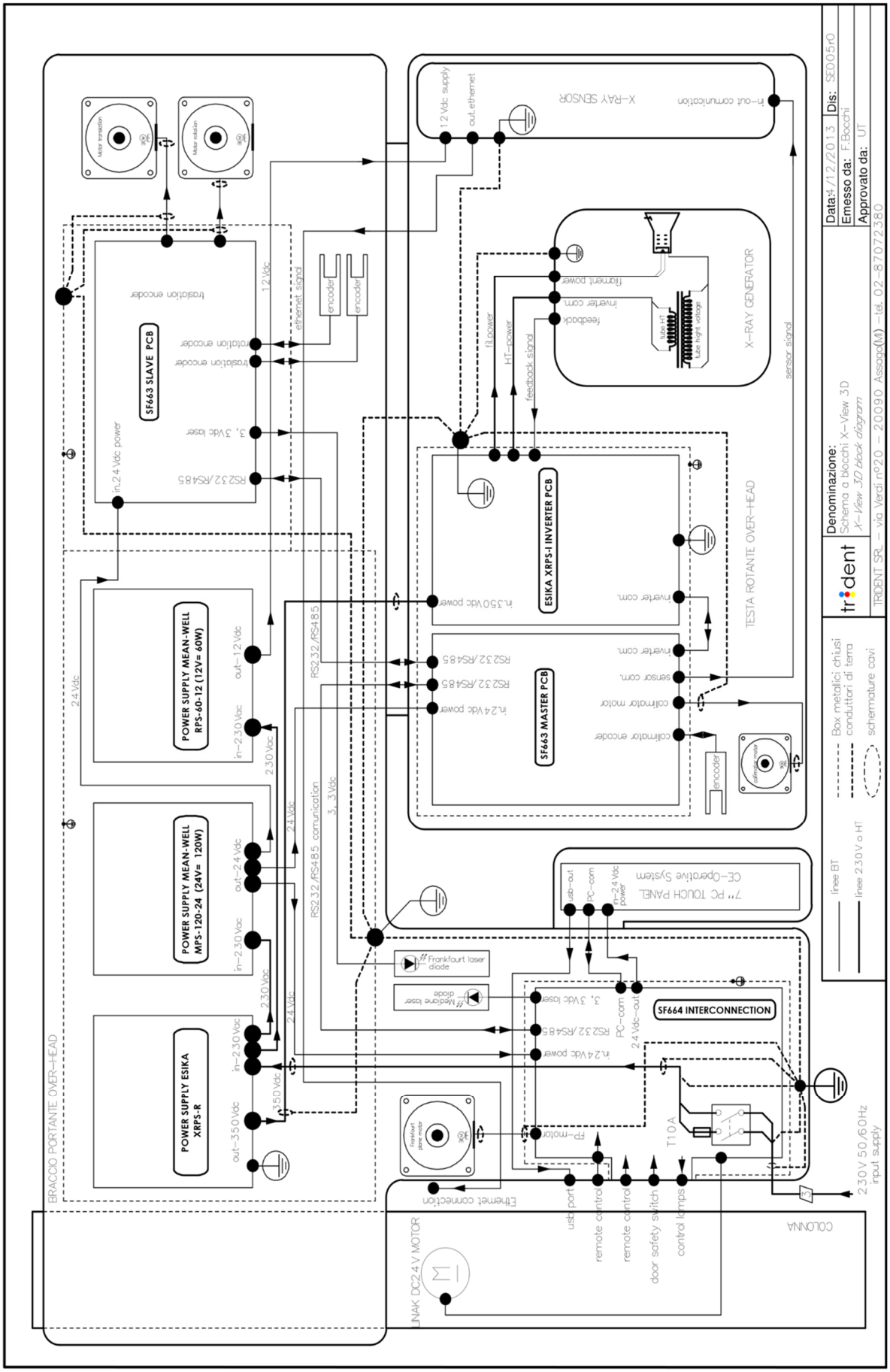


ANNEX 2
Dimensions
X-VIEW 3D
CPH/DPH





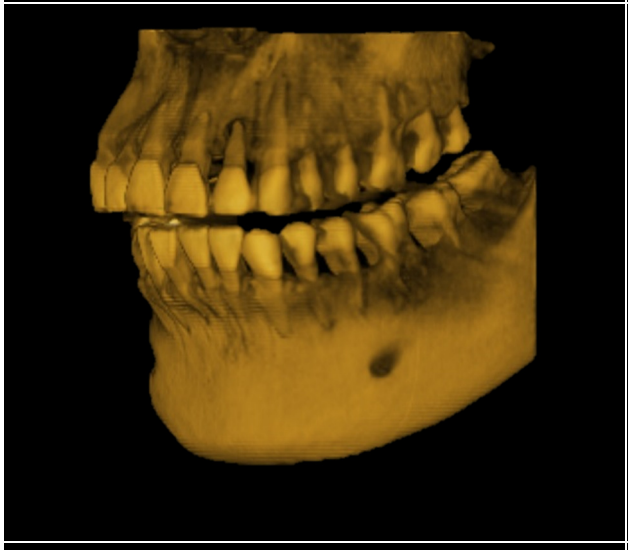
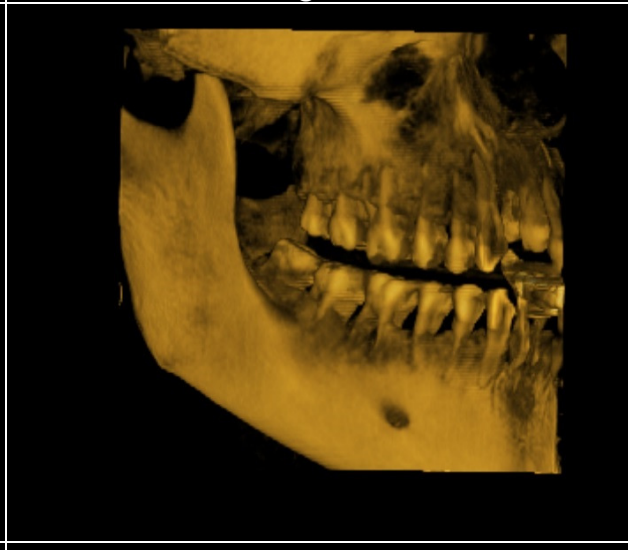
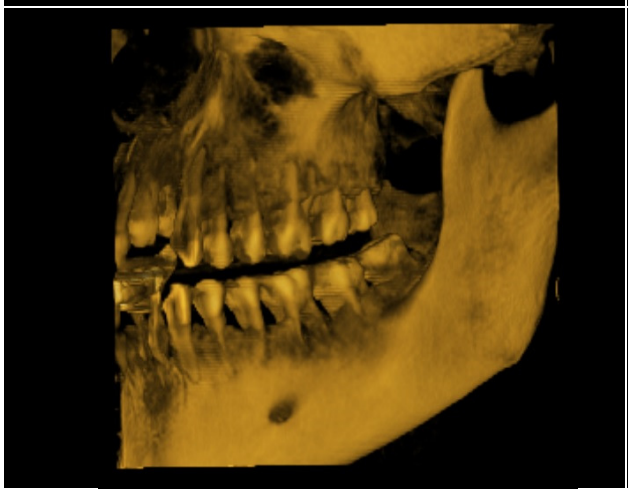
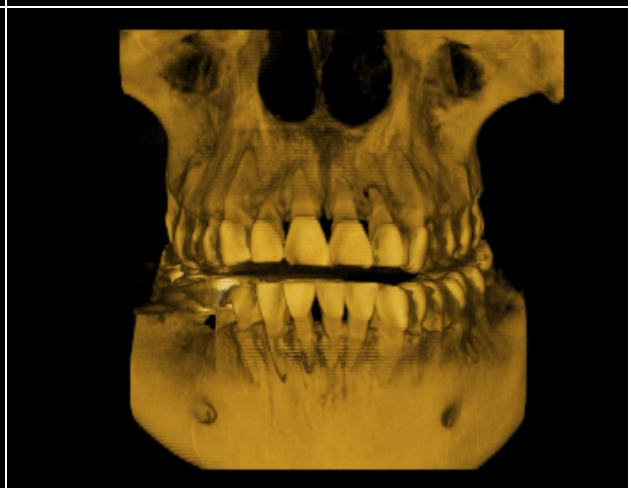
ANNEX 3
Schematics



ANNEX 4

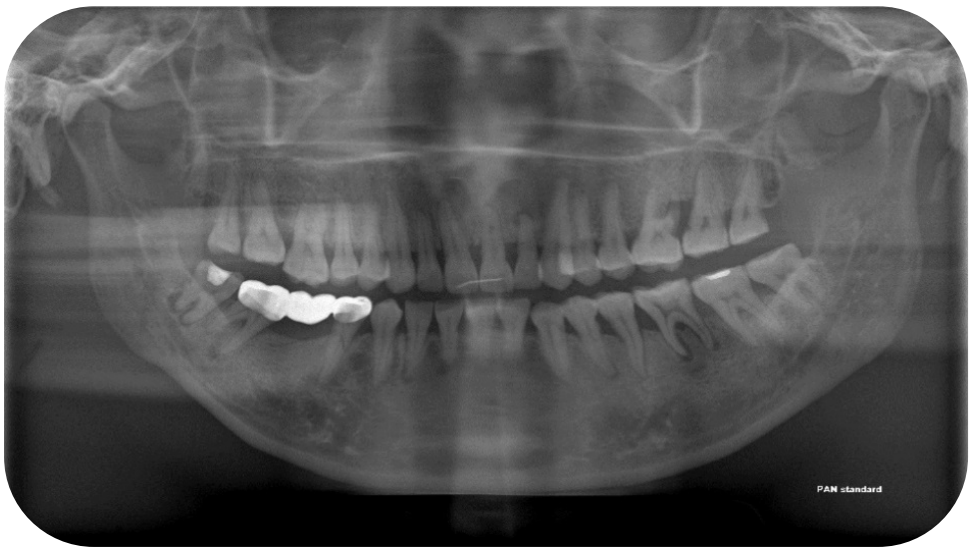
Album

3D Standard Exams

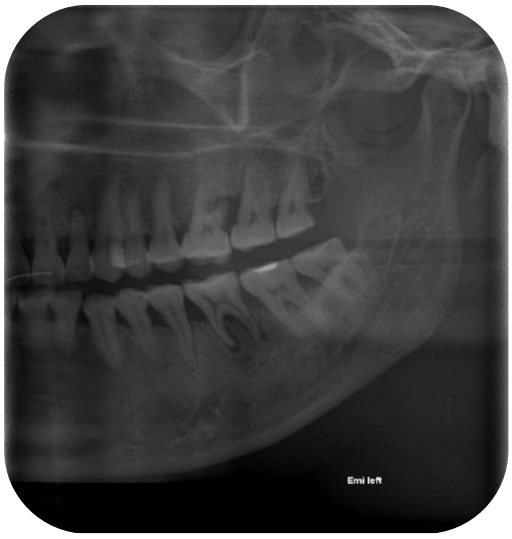
3D Dentition	3D Right TMJ
	
3D Left TMJ	**3D Sinus**
	

Panoramic Exams

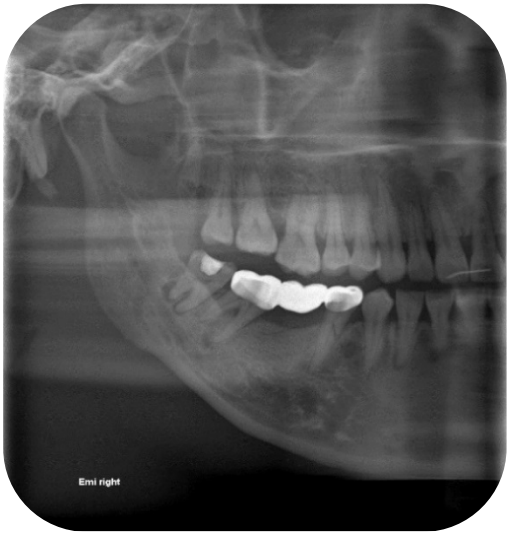
Standard Panoramic



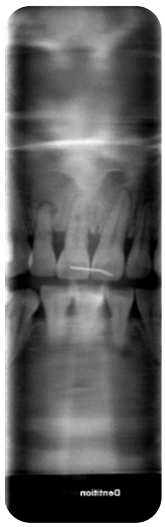
Hemi Panoramic Left



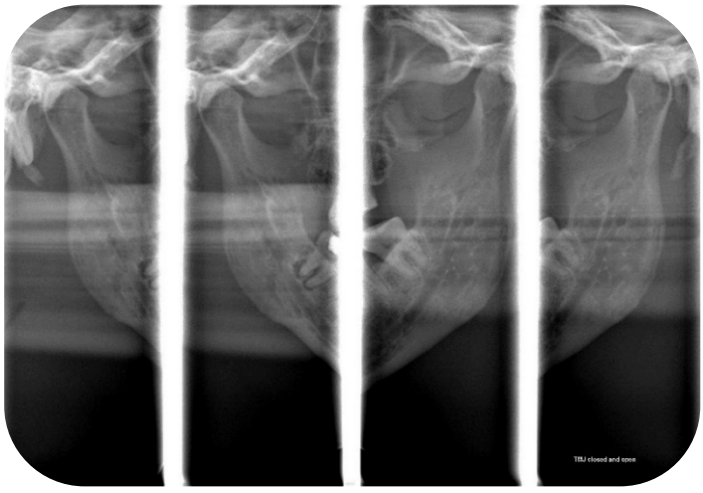
Hemi Panoramic Right

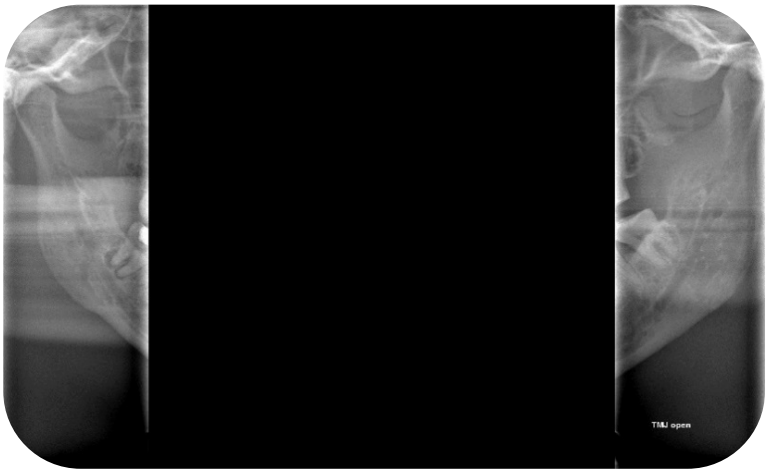


Frontal Dentition

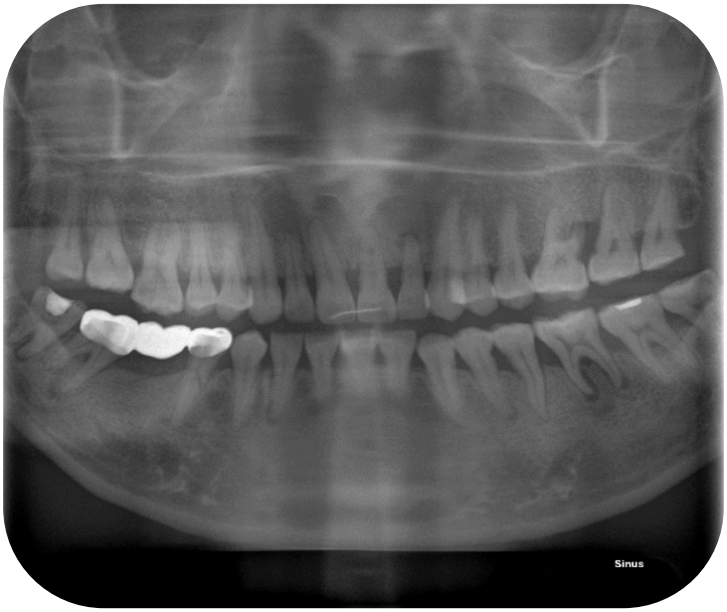


TMJ Closed and Open Mouth



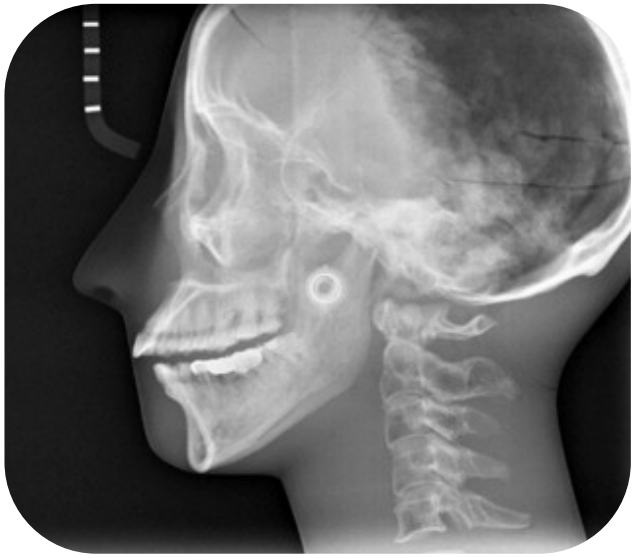


Sinus

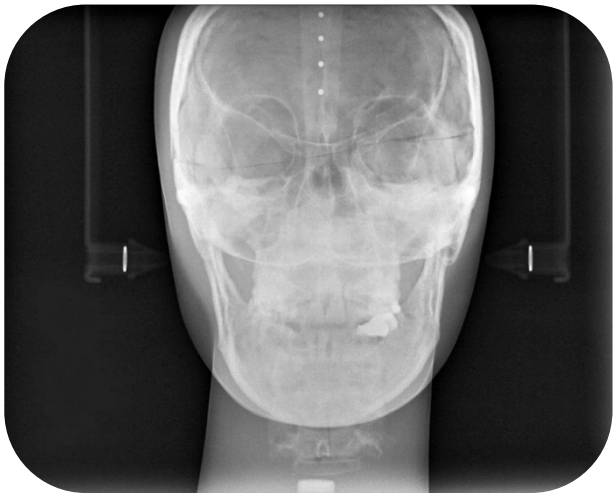


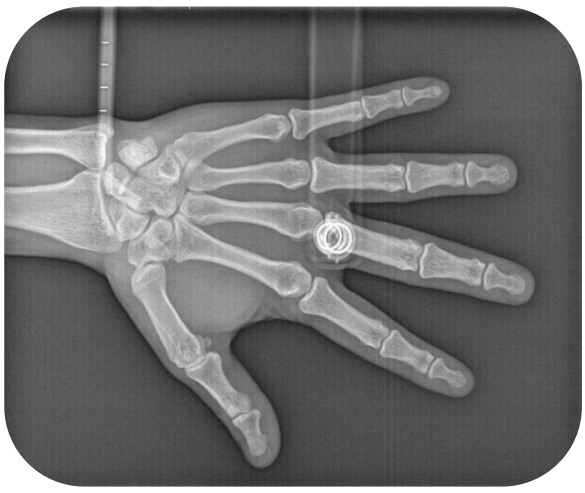
Cephalometric Exams

CEPH LL 30x24



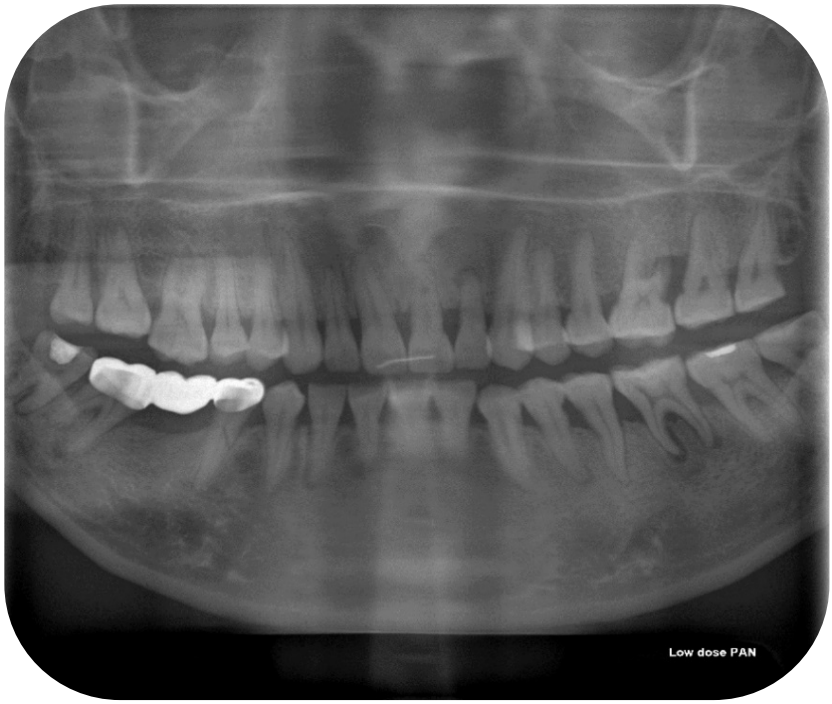
CEPH AP	Carpus



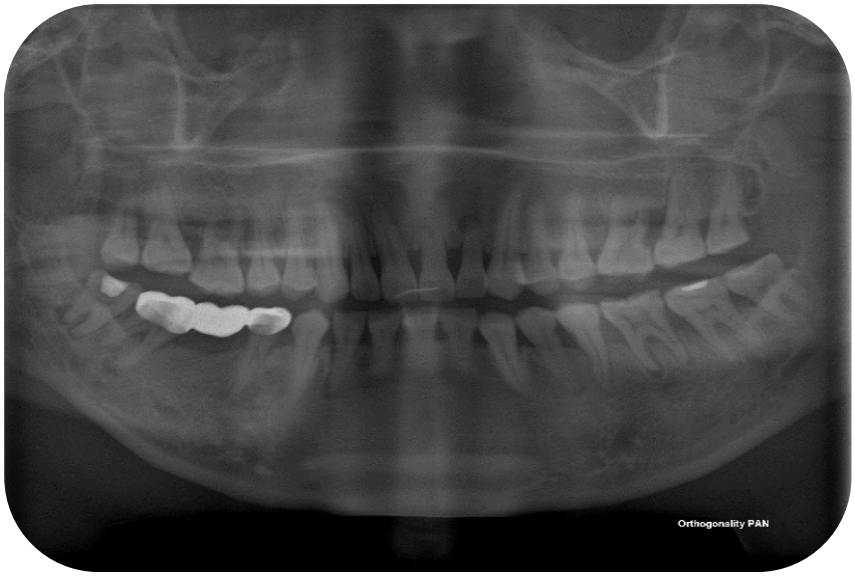


Optional Exams

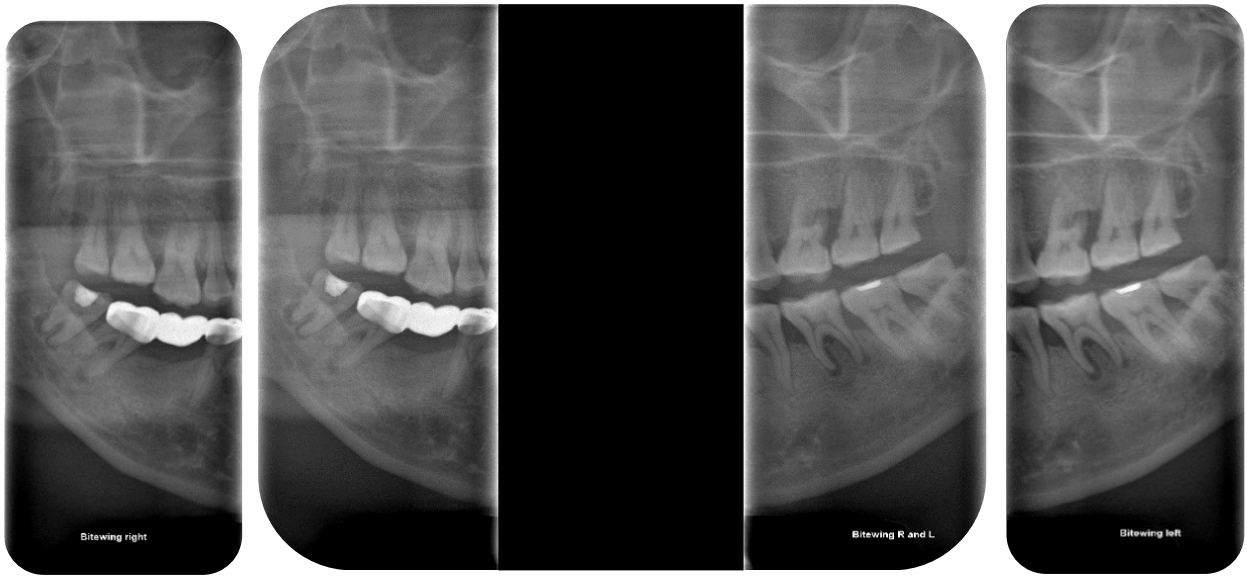
Reduced Dose Panoramic



Improved Orthogonality Panoramic



Right Bitewing	Right + Left Bitewing	Left Bitewing



ANNEX 5

Graphic Guide for Patient Positioning

Panoramic images that are sharp or detailed and have minimal distortion, a lack of artifacts, good density, and adequate contrast are of good quality. Radiographs that do not meet these criteria indicate that a mistake occurred during radiographic imaging.

Technical errors are the main errors that occur during panoramic radiographs: **patient positioning, exposure factors, artifact appearance, and technical performance** are the most observed errors in decreasing order.

The most common mistake, patient positioning, is related to the instructions given to patients and their preparation for the exam; therefore, the operator must have a thorough understanding of how to operate the machine and a clearly established patient management protocol. In this way, positioning errors are reduced, seeking to minimize the number of unsatisfactory radiographs and the unnecessary exposure of the patient to X-ray radiation. Some common patient positioning errors follow:

Error	Appearance on Image	Correction
Ghost images	Ghost image resembles real image Projected on opposite side of film and is higher	Have patient remove all radiodense objects before exposure
Lead apron artefact	Radiopaque, cone-shaped artifact in center of image	Use lead apron without thyroid collar
Patient lips not closed	Dark radiolucent shadow around anterior teeth	Remind patient to close lips around bite block
Patient chin too high	Condyles may not be visible Maxillary incisors appear blurred and magnified Reverse smile line (frown)	Keep Frankfort plane parallel with floor
Patient chin too low	Exaggerated smile line (Joker) Condyles higher on image Mandibular incisors appear blurred; roots appear short	Keep Frankfort plane parallel with floor
Patient too far forward (anterior to focal trough)	Anterior teeth are narrowed Spine is visible on film	Make sure patient's teeth are in bite block notches
Patient too far back (posterior to focal trough)	Anterior teeth appear magnified Ramus isn't entirely visible	Make sure patient's teeth are in bite block notches
Patient head not centered	Ramus and posterior teeth appear unequally magnified Side farthest from receptor appears magnified Side closest to receptor appears smaller Example: Patient turned to right will produce image with magnification on left side and overlapping of contacts	Keep midsagittal plane perpendicular to floor & ensure indicating light is located at center of patient's nose
Patient spine isn't straight	Cervical spine appears as radiopacity in center of image	Have patient stand as tall as possible. Seat patient if necessary.

Patient Preparation

Patient preparation is extremely important for ensuring high-quality images and error avoidance. For instance, incorrect patient preparation can lead to "ghost images" which can render the radiographic image undiagnostic. While ghost images often occur due to metallic objects, they can also occur due to anatomical structures located outside the image layer or focal trough. Ghost images always appear higher and distorted on the opposite side of the radiographic image. Some errors are unavoidable due to the patient's stature, facial asymmetry, or difficulty following instructions.

An important item to include when preparing the patient is the use of a lead apron, which is recommended for all radiographic procedures. Lead aprons help provide protection for radiosensitive tissues in the neck, chest, reproductive areas, and blood forming tissue. In addition, lead aprons stop nearly 98% of scattered radiation from reaching reproductive organs.

The following are some tips to help the patient stay safe and comfortable throughout the entire procedure.

- Provide clear directions or guide the patient gently into position if needed.
- Ask the patient if he or she is comfortable.
- Guide the patient to place their mouth on the bite stick, which should be positioned slightly above the level of the head.
- Maneuver the bite block so that the chin points down slightly, with the forehead reaching forward.

Remind the patient to not move throughout the X-ray process to minimize blurring of the images.

Standing/Sitting	If patient can stand, have their stand erect without the spine being slumped. If patient is seated, ask them to be as upright as possible. It helps to do a test run with your X-VIEW unit, to make sure it will not hit the patient's shoulders.
Mouth position	Patient needs to place maxillary/mandibular incisors correctly on bite block in order to achieve proper alignment of the teeth.
Midsagittal Plane	The patient's head must be straight and not tilted. The midsagittal plane must be kept perpendicular to the floor.
Frankfort Plane	Keep the Frankfort plane parallel with the floor.
Tongue	Instruct the patient to place the ENTIRE tongue on the hard palate and not to move it during the whole exposure procedure.
Lips	Instruct patient to keep their lips together for the duration of the exposure.

Equipment Preparation

As with any dental procedure, it is important to properly prepare the equipment beforehand. Setting the proper exposure time in advance will help improve efficiency and reduce the possibility of over-exposing the patient to unnecessary radiation.

X-VIEW preparation includes selection of items such as bite block, exposure settings, and patient selection. Open your patient's records or create a new one prior to the exposure. Otherwise, the image will be stored in the wrong location.

In order to properly protect patients, the exposure setting must be tailored for each individual patient. X-VIEW exposure settings can be adjusted as height and mass increases.

Select patient	X-VIEW allows to choose from two types of patient, adult and child, and three patient's sizes, small, medium and big, obtaining 6 different combinations of patient automatic settings.
Bite-block	In order to protect from cross infection, for every new patient cover the bite with disposable plastic sleeves.
Exposure Settings	Set according to the manufacturer's recommendations, which are pre-programmed considering the size of the patient.
Height	Adjust the column to the correct height for the patient.

Accessories for patient positioning

Image	Name	Use
	Standard Bite Block	For standard panoramic It should be used as standard positioner; the patient will bite it with the incisors just inside the central slot laying the chin on the chinrest seat.
	Chin Rest	Only with edentulous patients. The chin rest can be used alone taking off the bite
	Fixed Bite Block	Usable instead of standard bite block or in case of chin disease or morphologic distortion. To be used for 2D TMJ (open mouth/closed mouth): the patient will just touch the bite between nose and lips outside the mouth.
	Low Chin Rest	For sinus, use the central position. For 3D Condyle exams the sled of the machine will be moved right or left

Patient Positioning

Before the patient entry

Prepare the patient.

The patient should not dress clothes that may interfere with the X-ray beam, also to leave more space between the patient's shoulders and the rotating arm of the machine. Avoid interferences between the X-ray beam and the protective apron (when used).Remove all metal objects from the patient's head and neck (glasses, necklace, earrings, hair pins, removable prosthetics, piercings, fasten long hair up) this objects not only create radio-opaque images in their own position but also false images projected in other parts of the radiography, so disturbing the correct view of the anatomy.

If local regulations require, protect the patient with a lead apron (check that the lead apron or fastener is not covering the neck).

Prepare the unit

- Make sure the unit is in the ENTRY position.
- Open an existing patient or create a new one (enter the name, ID, date of birth etc.).
- Select the type of examination on the touchscreen.
- Select type and patient size or manually adjust exposure parameters (kV and mA).
- Depending on the type of exam to be performed, choose the proper tools (bite block, chin rest, etc.)
- Cover the byte with a disposable cover.

Ask the patient to approach the unit (do not position yet)

Considering the patient height, approximately adjust the column to the patient height.

Patient entry

Ask the patient to:

- Go inside the machine.
- Grasp the handlebars.
- Make one step forward.
- Bite the central groove of the bite block.

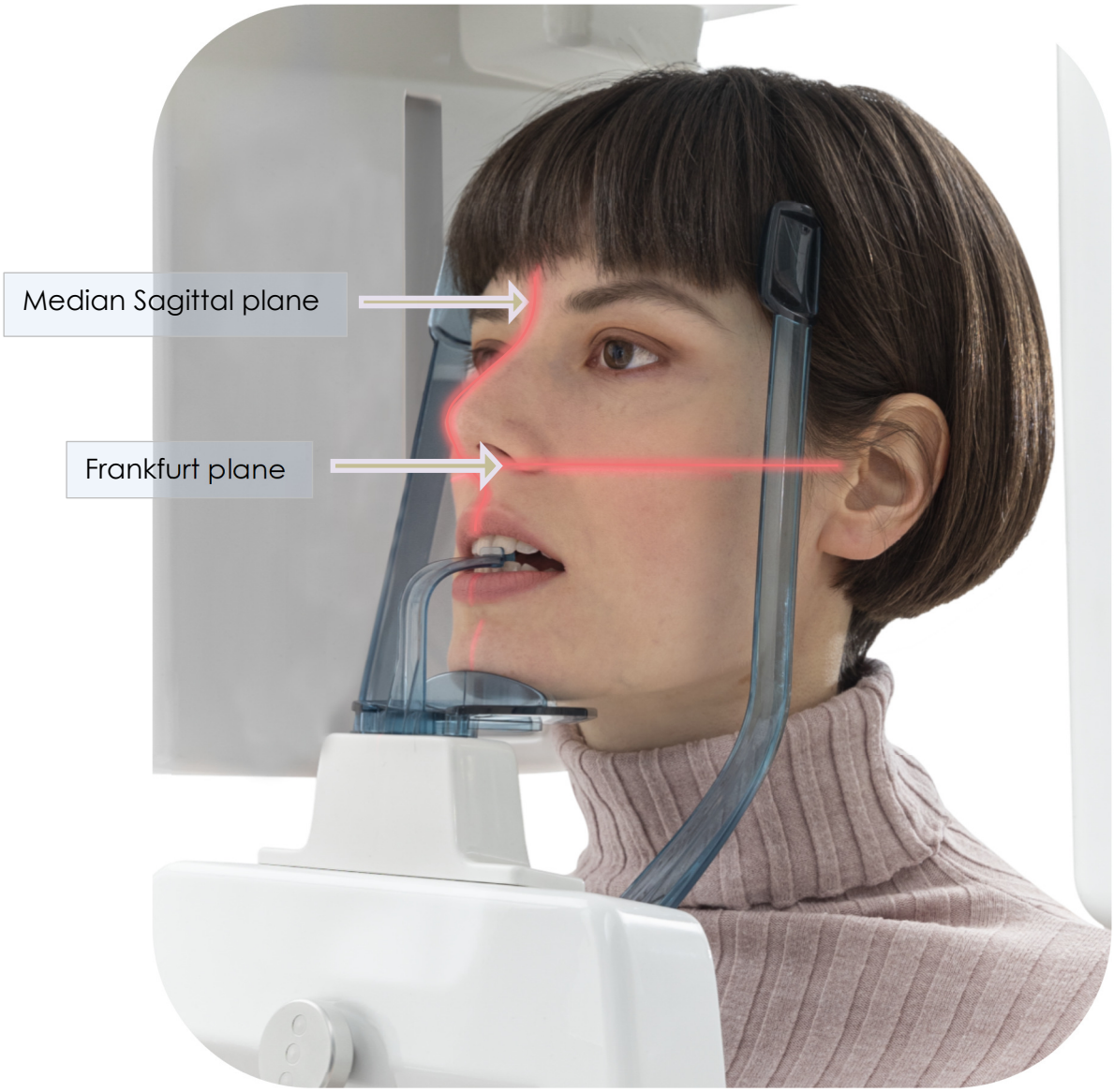
If you think there is potential that the unit will touch the patient shoulders during acquisition, ask patient to cross over his/her arms on the handle.

Teeth and chin positioning

Incisors must be placed exactly in the groove of the bite block and chin must lay exactly on the support seat

For standard panoramic and 3D exams use the standard bite block + chinrest.
For sinus and condyle, use the low chin rest.

Adjusting lasers



Median Sagittal plane

Using the mirror, check if the vertical mid-sagittal laser is aligned with the patient's mid sagittal plane. Adjust the position by moving patient's head, if necessary.

Frankfurt plane

Optimize the column height and gently move the patient's head, so that the horizontal Frankfurt plane is aligned with the bone chick and tragus.

- The patient's head must be lightly tilted downward in order to have the Frankfurt plane horizontal. In this way, the hard palatal ceiling will be projected slightly over the superior apex of anterior teeth. If the patient has a low palatal ceiling, slightly increase the tilting downward.
- Align the middle sagittal plane with centre of the chin support, normally indicated by the relevant light beam.
- Check that the vertical light beam falls on the canine and lays between the third and fourth teeth. This will ensure that the apex of the anterior teeth are positioned within the focussed area and therefore will be properly reproduced on the radiography.

Examples of positioning


TMJ close Mouth


TMJ open Mouth


Bitewing

Anterior Posterior Ceph

Position the head supports and the naseon as shown in the picture.

LL Ceph

This type of examination can be performed from both right and left side:

Taking images

After preparing the device and software the unit is ready to perform the exam.
Ask the patient to:

- Position the tongue against the palate, otherwise the air between the tongue and the palate will create a lower absorbance area which will result on the film as a darker area which in turn will hide the apex of the superior incisor teeth.
- To step forward and extend the spine making sure that all other conditions are unchanged. If not properly extended, the spine will cause the appearing of a lower exposed area (clearer) in the front part of the film.
- Watch his/her nose tip in the mirror.
- Breath normally through their nose and relax.
- Not move throughout the X-ray process to minimize blurring of the images.

Go behind the radiation shielded area (from where you should be able to see the patient).

Take the hand switch and press the **exposure button**. A beep sound and the **X-Ray emission light signal** indicate the radiation is in progress. Release the exposure button **JUST** when the beep sound and the unit stop.

Once finished the exam ask the patient to leave the unit.

The image appears on the monitor.

ANNEX 6

Troubleshooting in Panoramic radiography

The most common errors in panoramic radiography are related to the positioning of the patient. Therefore, positioning errors should be reduced to minimize the number of unsatisfactory radiographs and avoid unnecessary exposure of the patient to X-ray radiation. Incorrect patient posture and movement can produce a "ghost image" that appears as blurred areas in the image and forms large step defects in the inferior border of the mandible.

Consider the following points when positioning the patient:

Patient's head positioning

During radiographic examination, patients commonly tilt or turn their head to the right or left. When patients tilt their head, the structures imaged become asymmetrical (the side toward the slope appears reduced in size compared with the opposite side), and the proximal surfaces become substantially overlapped.

When patients turn their head to one side, the teeth appear to be extended on one side of the midline and the sharp proximal surfaces appear overlapped, whereas the teeth on the opposite side appear shortened. Furthermore, the ascending mandible on one side appears much larger than that of the other, and the condyles appear to be of different sizes.

Patient's head positioned in front of the focus. Leads to an image with dental arches, particularly the front teeth, with a blurred, shortened, and narrowed appearance. Furthermore, the proximal area around the premolars and the column of the ramus can overlap.

Patient's head positioned behind the plane of focus. The dental arches, especially in the anterior teeth, appear blurred and expanded in the horizontal direction. In addition, the condyles appear at the lateral edges of the film.

Patient's head tilted back. The occlusal plane becomes flattened or reversely curved as the apexes of the upper incisors appear out of focus. In addition, the condyles were projected out of the imaged area due to an increase in the intercondylar distance**.**

Patient's head tilted forward. The occlusal plane becomes excessively curved. In this scenario, the apexes of the lower incisors also appear out of focus. In addition, overlapping images of the hyoid bone in the anterior mandible can be apparent. However, this may be because the upper regions of the condyles may not be visible, and the intercondylar distance could be narrowing.

Chin Positioning

The patient's chin and the occlusal plane must be positioned correctly to avoid distortions. The occlusal plane should be angled at -20° to -30° from the horizontal plane. One way to position the chin is to set as the line connecting the tragus of the ear to the outer corner of the eye is parallel to the ground.

If the chin is elevated, the occlusal plane on the radiograph will appear flat or inverted, and the image would be distorted. Furthermore, the shadow of the radiopaque palate bone can overlap the roots of the maxillary teeth.

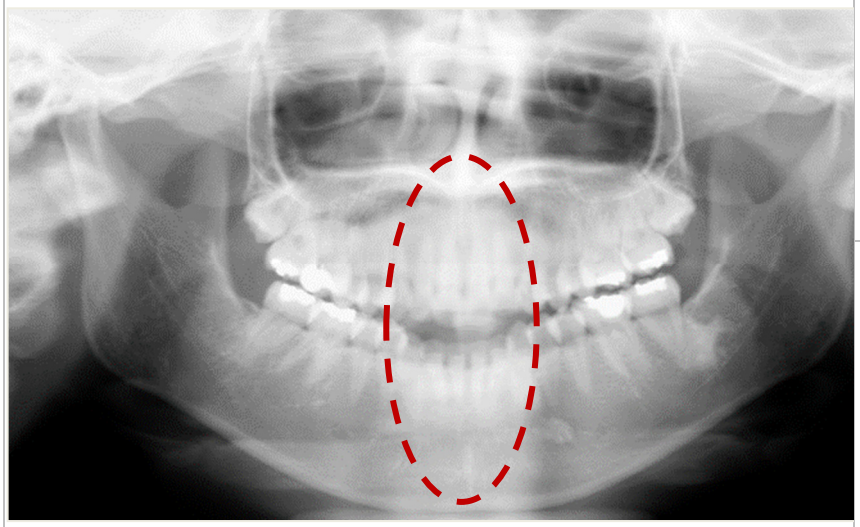
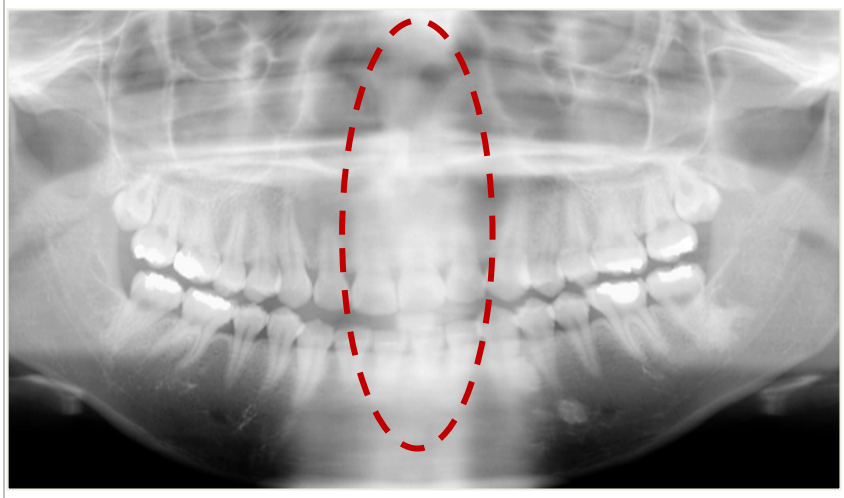
If the chin is tilted down, the teeth will overlap, and the symphysis of the jaw may not be visible. In addition, both mandibular condyles may appear to be projecting out of the upper edge of the image.

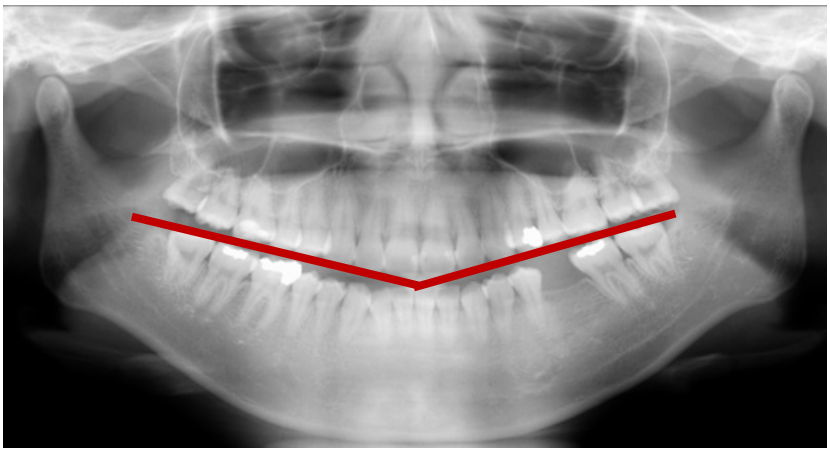
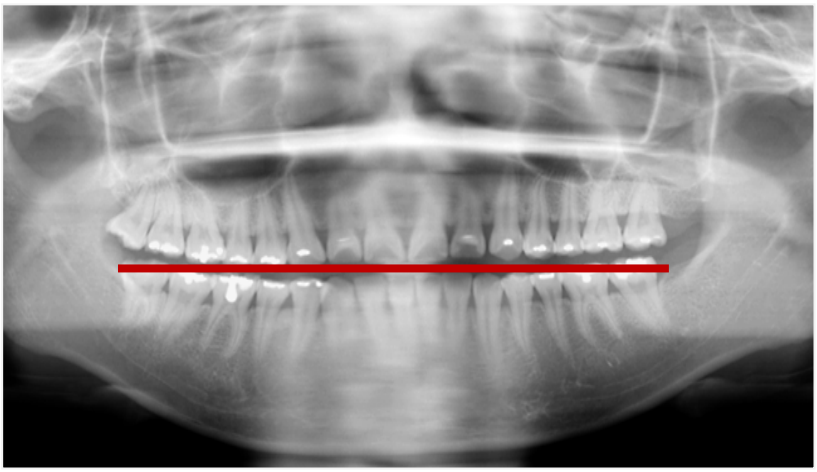
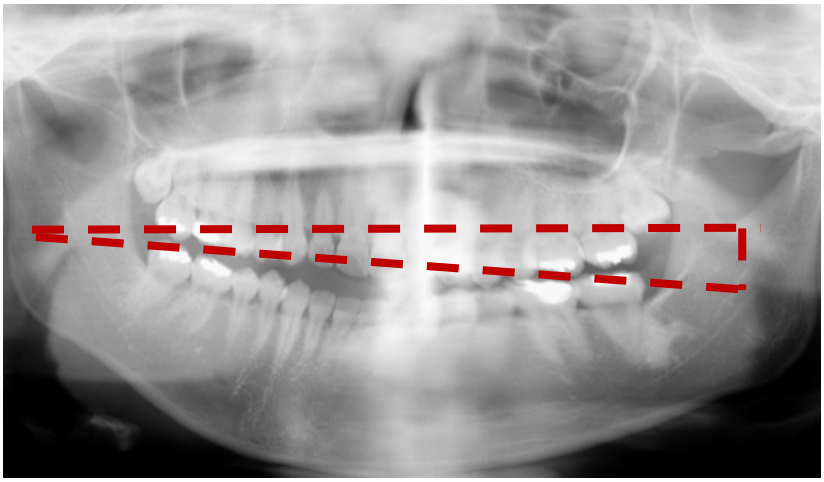
The position of the tongue

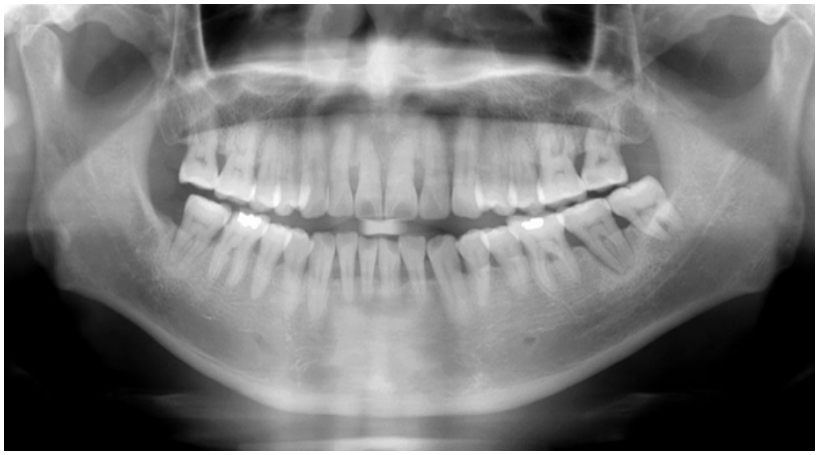
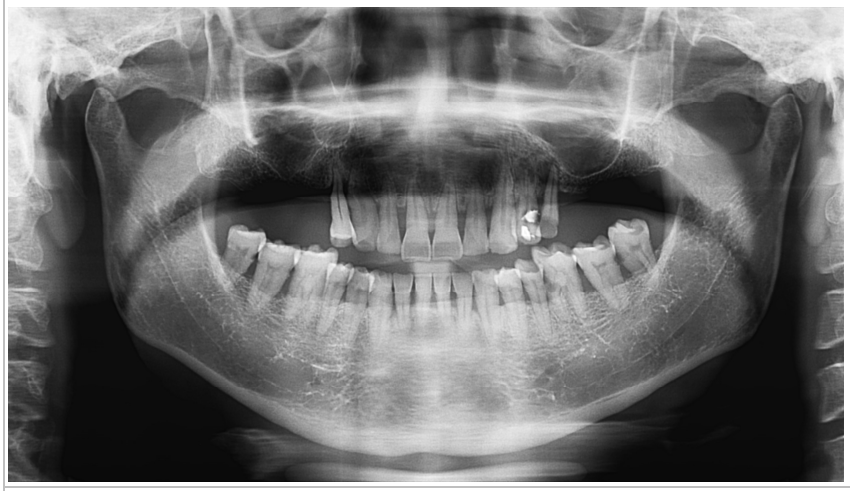
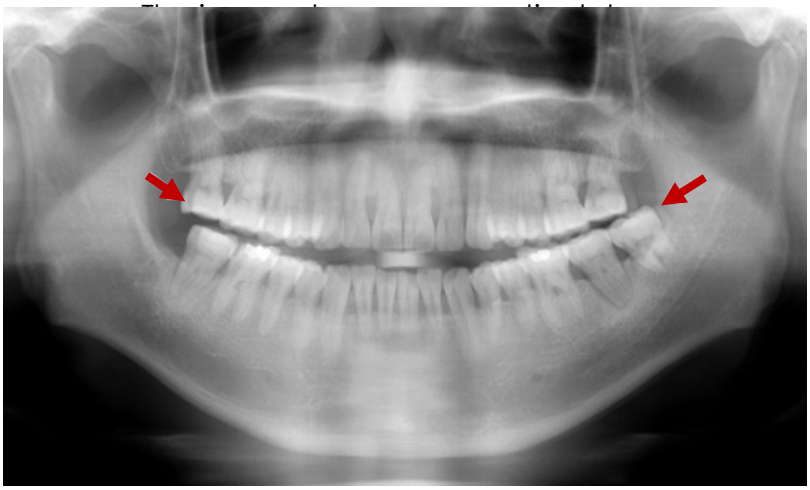
In the panoramic, the presence of a radiolucent band at the apex of the upper teeth is an indication that tongue contact with the upper palate was not sufficient. In addition, if the tongue is not placed on the palate or the lips remain open, the incisal area on the crowns may become obscured by the air space. A dark air space between the dorsum of the tongue and the hard and soft palates (palatoglossal air spaces) obscures the apical region of the maxillary teeth.

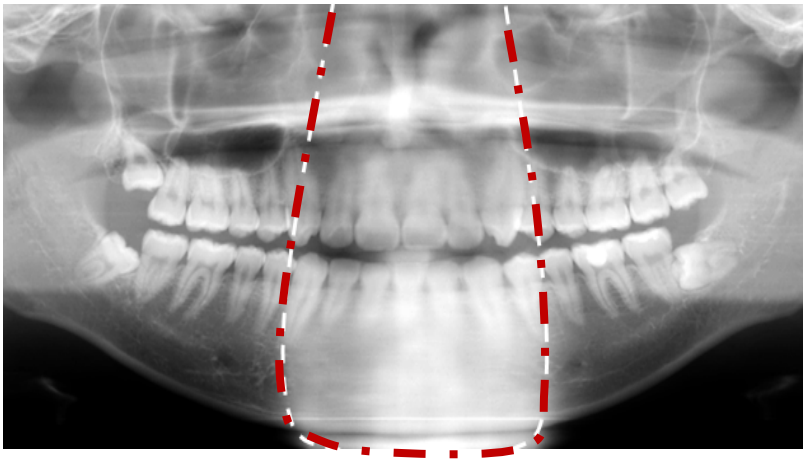
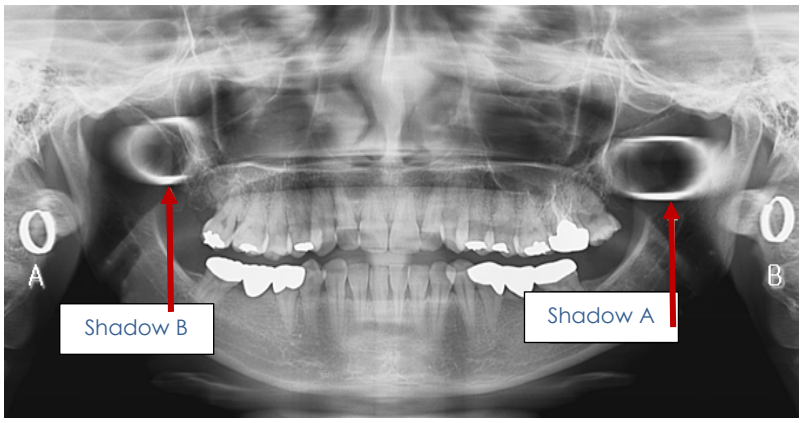
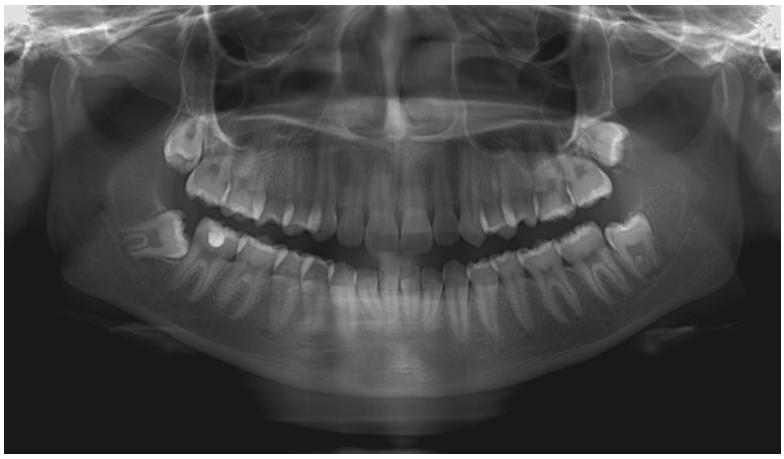
To avoid this error-prone situation, which would cause the central incisor apex to be misdiagnosed, the patient should be asked to position their tongue so that it adheres to the palate (roof of the mouth) and to not swallow saliva to prevent tongue movement during radiography.

Troubleshooting

Situation	Cause	Solution
Blurred incisors and narrow/little central teeth 	Patient bites too much the bite block	Relax while biting
	Patient too close to the column	Patient should bite correctly inside the groove of the bite block
Blurred and big incisors, maxillary bone could be dark 	The patient is too far from the column	Patient should correctly bite the bite and recoil a little. Patient should go back a little with the body

Situation	Cause	Solution
The incisors root is not on focus Premolars are not clear 	Device too low, patient's head too lean forward	Pull up the overhead of the device and rotate the head a little backward. Abnormal morphology or not standard dentition can cause the same situation with no solution.
Flat Profile. Incisors root are not on focus. 	Patient's head leans back	Pull down the overhead of the device Lean forward the patient's head
Tilted image. The lateral magnification is different and blurred 	Patient's head is tilted on one side	Use the Sagittal laser to center the patient on the median plane

Situation	Cause	Solution
Lateral magnification is different from one part to the other 	Patient's head is rotated on the vertical axes	Use the median-sagittal laser to center better the patient. Check on the mirror if the patient is well centered
Upper maxillary bone is dark 	Patient's tongue is not on the palate.	Ask the patient to position the tongue against the palate during the exposure.
The whole image is not on focus 	The patient moved	Before scanning kindly ask patient to be relaxed and quite

Situation	Cause	Solution
The image shows a pyramidal shadow in the middle 	The patient's shoulders are curved	The patient needs to straighten his back The shoulders must be down and relaxed Set the overhead at the correct height
Image with shadows or artefacts 	The most common cause for the presence of these artefacts is the presence of metal objects worn by the patient (ear-rings, necklace).	Ask the patient to remove all the objects from the neck up.
Image is too dark 	Exposure parameters too high with respect to the patient size.	Decrease the values of kVp e mA related to the patient's body

ANNEX 7

SYSTEM MAINTENANCE OPERATIONS REGISTER

Installation		
Serial Number	**Date**	**Installer Technician**

Maintenance	
Description of activities	**Date**
	Technician

Maintenance	
Description of activities	**Date**
	Technician

Maintenance	
Description of activities	**Date**
	Technician