







2D, CEPH PANORAMIC UNIT

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Language of original document: English.



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Revision history Manual code 6904916503

| Rev. | Date | Page/s | Modification description |
|------|------------|--------|--------------------------|
| 0 | 10/12/2019 | all | Initial release |
| | | | |
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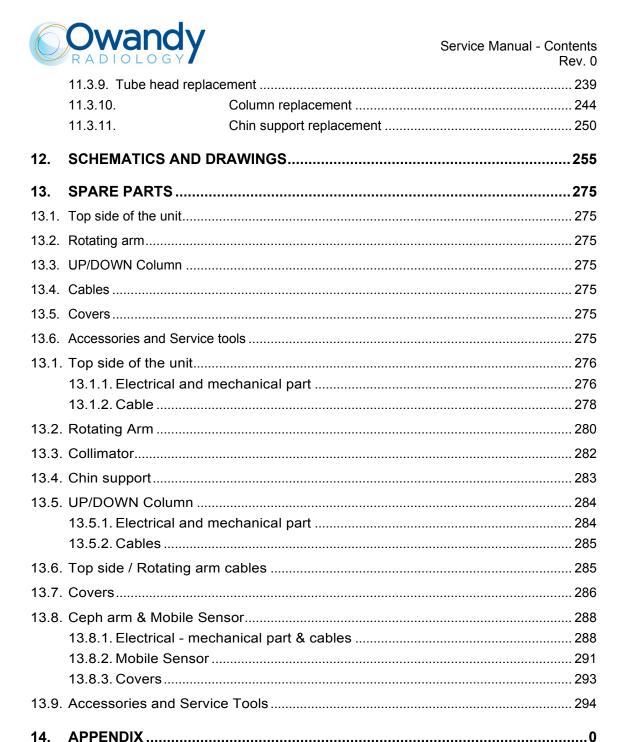
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1. INTRODUCTION

Note



The present manual is updated for the product it is sold with in order to grant an adequate reference in performing diagnostics and repair operations normally carried out by the service engineer.

The manual may not reflect changes to the product not impacting service operations.

This manual provides the instructions for proper and safe installation and maintenance of the appliance by technical personnel.

This manual is limited to the description of the radiographic equipment; the instructions for the image acquisition, manipulation and processing are given in the user manual supplied with the imaging software used with the I-Max unit.

Ŵ

Warning

- I-Max is an electro-medical device and it can be used only under the supervision of a physician or of highly qualified personnel, with the necessary knowledge on X-ray protection.
- The device must be used in compliance with the procedures described, and never be used for purposes different from those herewith indicated.
- The user is liable with regards to the legal fulfilment related to the installation and the operation of the device.
- Service engineers who install and maintain the device need knowledge of radiation protection and must read the Service Manual prior to use the X-ray equipment. They must be qualified and authorized by Owandy.

Icons appearing in the manual



This icon indicates a "NOTE": please read the items marked by this icon thoroughly.



This icon indicates a "WARNING": the items marked by this icon refer to safety aspects of the patient and/or operator.



How to contact OWANDY technical service

For any technical queries please contact the following:

- Telephone number +33(0)1 64 11 18 18
- Fax number +33(0)1 64 11 18 10
- E-mail: info@owandy.com

If a technical service intervention is required it is mandatory to provide OWANDY technical service the following information:

- Unit Serial Number
- Unit firmware & driver version: MCU, CCU, HF(XCU), OSP, QuickVision (see chapter 8)
- Other software version used with I-Max
- Problem description including: condition/unit-state, sequence in which the anomaly occurs and how it can be reproduced.
- If one or more errors messages are displayed:
 - Errors messages numbers.
 - Results of all the errors troubleshooting tests.
 - Part codes to be replaced (if required by the troubleshooting tests).
 - Additional information or data required by the troubleshooting of the displayed errors.





2. SAFETY INFORMATION



Warning

Please read this chapter thoroughly.

Owandy Radiology designs and manufactures its devices in compliance with safety requirements; furthermore, it supplies all information necessary for correct use, and warnings related to dangers associated with X-ray generating units.

Owandy Radiology cannot be held liable for:

- Use of I-Max other than its intended use
- Damage to the unit, the operator or the patient, caused both by installation and maintenance procedures other than those described in this Manual and in the Service Manual supplied with the unit, and by erroneous operations
- Mechanical and/or electrical modifications performed during and after the installation, other than those described in the Service Manual.

Installation and any technical operations must only be performed by qualified technicians authorised by Owandy Radiology.

Only authorised personnel may remove the covers and/or have access to live components.



Warning

In compliance with the IEC 60601-1 standard, the modification of the equipment or its parts is strictly prohibited.



Warnings

The device must be used in compliance with the procedures described and never be used for purposes different from those herewith indicated.

Before performing any maintenance operation, disconnect the unit from the power supply using the provided circuit breaker.

I-MAX is an electro-medical device and therefore it can be used only under the supervision of suitably qualified medical personnel, with the necessary knowledge on X-ray protection.

The user is responsible for the fulfillment of the legal requirements regulating the ownership, installation and use of the equipment itself.

This device has not been designed to be used in environments where vapours, anaesthetic mixtures flammable with air, or oxygen and nitrous oxide, can be detected.

Do not let water, or other liquids, into the device, as this could cause short-circuits and corrosion.

Before cleaning the device, be sure that the main power supply has been disconnected from the equipment. Pushing the ON/OFF button of the equipment, it mustn't switch on.

Wherever necessary, use the appropriate accessories, such as the leaded aprons, to protect the patient from radiation.

While performing the radiography, no-one, apart from the operator and the patient, must remain in the room.

I-MAX has been built to support a continuous operation at intermittent load; therefore please follow the described use cycles to enable the device to cool down.

I-MAX must be switched off while using electrosurgical devices or similar apparatus.



Warning

For safety reasons, it is prohibited to abnormally overload the patient support arm, for example by leaning on it. The traction force on the handle shall be less than 16kg.



Warning

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Please clean and disinfect, when necessary, all parts that can be in contact with the patient.

The centering bite, the bite protective sleeve and the ear pin covers must be replaced after each examination in which they were used.

Never try to rotate the moving arm manually when the unit is switched on, to avoid permanent damage to the unit.

Movement is only possible in case of Error 362 because motors are disabled to permit the patient exit.



Note

When the unit is switched on, do not move the rotating arm or the tube-head.



2.1.1. Precautions while using laser centring devices

For patient positioning, I-Max uses two laser diodes with optical power on the working surface < 1 mW.

The directive CEI-EN 60825-1 defines the laser as "any device that produces or amplifies electromagnetic radiation in a coherent manner which includes a wave lengths from 180 nm to 1 mm by means of a stimulated emission". In reference to this directive, the lasers present on the I-Max are parts of class 2.

A laser in class 2 can be potentially dangerous if the ray is reflected into not protected eyes by a mirror, watch, a ring etc.

The warning label below is affixed to I-Max to indicate a laser in class 2 is mounted internally and caution is advised:





Warning

- Always keep the room well lit.
- Do not look into the output windows of laser centring units.
- Do not stare at the reflections of laser pointers.
- Instruct the patient to keep his/her eyes closed as long as the laser pointers are active.
- Before starting an exam, the patient must remove earrings, glasses, necklaces and any other item that could reflect the laser beam or be impressed on the radiographic image.
- Do not clean the openings of laser centring devices with tools that could modify the optics. Any cleaning must only be performed by authorized technicians.
- Operations other than those indicated could cause the emission of dangerous non-ionizing radiation.



Protection against radiation

Although the dose supplied by dental X-ray units is quite low and distributed on a fairly small surface, the operator must adopt precautions and/or suitable protection for the patient and himself, during radiography.



Warning

Protection against radiation is regulated according to law. The equipment may only be used by specialised personnel.

It is advisable to control the X-ray emission from a protected area, by remote control. If it is necessary to operate near the patient, stay as far as the remote control cable allows, or at least 2 m both from the X-ray source and from the patient, as shown in the following figure.

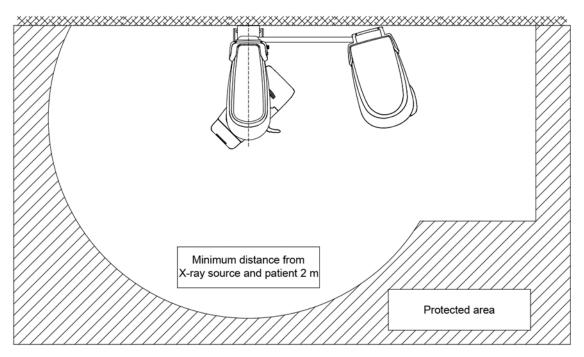


Figure 1





Information about **Electromagnetic** Compatibility

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Portable and mobile RF communications equipment can affect medical electrical equipment.

The equipment can be installed both in professional buildings (e.g. hospitals or clinics) and in residential buildings. Residential buildings, according to IEC 60601-1-2 4th edition, are intended to be connected to dedicated power supply system (normally fed by separation transformers). For the purpose of EMC environment classification according to IEC 60601-1-2 4th edition, both installations are classified as "Professional healthcare facility environment".

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment, even if it is usually permanently installed in X-Ray shield locations, might not offer adequate protection to radio-frequency communication services. If abnormal performance is observed, such as degradation of essential performance in the form of lack of accuracy of exposure parameters and lack of reproducibility of exposure parameter, additional measures may be necessary, such as re-orienting or relocating the device.

Warning

The use of cables other than:



- Ethernet cable CAT.6 L=5 m
- Ethernet cable CAT.6 L=10 m

with the exception those sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emission or decreased immunity of the equipment or system.

Warning



I-Max should not be used adjacent to or stacked with other equipment; if adjacent use is necessary, I-Max has to be observed to verify if it operates in a normal way.

Interference may occur in the vicinity of equipment marked with the symbol





Warning

Portable and mobile RF communications equipment should be used no closer to any part of I-Max, including cables. Minimum distance 30 cm.



2.1.2. Electromagnetic emissions

In accordance with the IEC 60601-1-2 Ed4 standard, I-Max is suitable for use in the electromagnetic environment specified below.

The customer or user of the system must ensure that it is used in the said environment.

| | 1 | |
|---|------------|---|
| Emissions test | Compliance | Electromagnetic environment |
| RF emissions | Group I | I-Max uses RF energy only for its internal function. Therefore, its R.F. emissions are very |
| CISPR 11 | | low and are not likely to cause any interference in nearby electronic equipment. |
| | Class A | I-Max is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonics emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |





2.1.3. **Electromagnetic immunity**

In accordance with the IEC 60601-1-2 Ed4 standard, I-Max is suitable for use in the electromagnetic environment specified below.

The customer or user of the system must ensure that it is used in the said environment.

| Immunity test | IEC 60601-1-2 test level | Compliance level | Electromagnetic environment |
|---|--|-----------------------------|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | 8 kV contact 2/4/8/15 kV air | IEC 60601-1-2 Test level | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% |
| Radiated electromagnetic field IEC 61000-4-3 | 3 V/m 80 MHz to 2.7 GHz | IEC 60601-1-2 Test level | Portable and mobile RF communications equipment should be used no closer to any part of I-Max including cables. Minimum distance 30 cm |
| Electrical fast transient/burst IEC 61000-4-4 | 2 kV for power supply lines 1 kV for input/output lines > 3 m | IEC 60601-1-2 Test level | Mains power quality should be that of a typical commercial or hospital environment |
| Surge IEC 61000-4-5 | 0.5/1 kV differential mode 0.5/1/2 kV common mode | IEC 60601-1-2 Test level | Mains power quality should be that of a typical commercial or hospital environment |
| Conducted disturbances induced by RF fields IEC 61000-4-6 | 3 V 150 kHz to 80 MHz 6 V ISM frequencies | IEC 60601-1-2 Test level | Portable and mobile RF communications equipment should be used no closer to any part of I-Max, including cables. Minimum distance 30 cm |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 10 ms – 0 % a 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 20 ms – 0% a 0° 500 ms – 70% a 0° 5 s – 0% | IEC 60601-1-2 Test level | Mains power quality should be that of a typical commercial or hospital environment. If the user of the EUT requires continued operation during power mains interruptions, it is recommended that the EUT be powered from an uninterruptible power supply or a battery |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | IEC 60601-1-2 Test level | Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment |



2.2. Cybersecurity measures

Like all computer-based systems, I-Max might be exposed to Cybersecurity threats.

I-Max is equipped with hardware provisions that make sure that no unwanted X-ray exposure, laser radiation or motorized movements can be activated even in case of cyber-attack or software failure.

Nevertheless, in order to minimize the possibility of cyber-attacks, it is user responsibility to make sure that the following protection measures are followed.

- The initial software installation and system set-up shall be done by authorized and trained personnel only and using the software provided with the machine.
- Any software or firmware upgrade of the equipment shall be done by authorized and trained personnel only.
- After any software or firmware upgrade, or any other maintenance operation, image quality checks shall be performed to ensure the system is working as expected. Instructions are given in User Manual, chapter 7.
- Password-protect each user account on the Windows login. Passwords shall be strong
 enough (at least made of 8 alphanumeric characters), shall be safely managed by every
 user (for example they have not been written down), and should be periodically changed (if
 the system is supplied with a PC, the Windows user is password-protected, but it is user
 responsibility to change the default password and set new ones for all the different users
 that will have access to the system).
- Activate a screensaver that requires a password to be unblocked after a timeout of 5-10 minute, giving this way an automatic timed method to terminate sessions, preventing an unauthorized access to the computer when it is not used (if the system is supplied with a PC, the screen saver is activated by default).
- Install an antivirus software and keep virus definitions up to date.
- Activate the windows firewall on the host PC (if the system is supplied with a PC, the Windows firewall is activated by default).
- It is recommended to activate a hardware firewall on the WAN router/modem used for internet connection, if present.
- Make sure that all other PCs in the network are protected by an anti-virus.
- Make a virus scan of USB pen drive or CD/DVD media before using them to check they are free from viruses, malware or any dangerous software.
- Avoid installation of an unknown or untrusted software since it may undermine performance and safety of the computer and the equipment.
- Keep the Windows operating system up to date by installing all security patches.
- Make regular copies (backup) of all your valuable data and store them in a safe place, separately from the host PC.





2.3. Environmental risks and disposal

Some parts of the device contain materials and liquids that, at the end of the unit's lifecycle, must be disposed of at appropriate disposal centres.

In particular, the device contains the following materials and/or components:

- Tube-head: dielectric oil, copper, iron, aluminium, glass, tungsten, lead.
- Collimator: lead
- Other parts of the device: non-biodegradable plastic materials, metal materials, printed circuits, iron-plastic materials, lead.



Note

Information for users of the European Community according to 2011/65/EU Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.



The symbol of the crossed waste container on the equipment or packaging shows that the product, at the end of its lifecycle, must be collected separately from other types of waste.

The separate collection of this equipment at the end of its lifecycle is organised and managed by the manufacturer. Users who need to dispose of this equipment should therefore contact the manufacturer and follow the procedure adopted by the manufacturer for the separate collection of the equipment at the end of its lifecycle.

Proper separate collection for subsequent recycling, treatment and compatible environmental disposal of equipment helps avoid possible negative effects on the environment and on health and encourages the reuse or recycling of materials the equipment is made from.

Illegal disposal of the product by the owner of the equipment will result in administrative sanctions, as provided for by applicable regulations.



2.4. Symbols used

In this manual and on I-Max itself, apart from the symbols indicated on the keyboard, the following icons are also used:

| Symbols | Description | |
|------------|---|--|
| <u> </u> | Device with type B applied parts | |
| | Some parts of the device contain materials and liquids that, at the end of the unit's lifecycle, must be disposed of at appropriate disposal centres. | |
| ~ | A.C. voltage | |
| N | Connection point to the neutral conductor | |
| L | Connection point to the line conductor | |
| (| Protection grounding | |
| <u></u> | Functional grounding | |
| | OFF; device not connected to the mains | |
| I | ON; device connected to the mains | |
| | Laser | |
| 4 | Dangerous voltage | |
| REF | Product identification code | |
| SN | Serial number | |
| | Manufacturing date (year and month) | |
| | Name and address of the manufacturer | |
| <u> </u> | Filtration | |
| \Box | Tube-head | |
| \bigcirc | X-Ray tube | |





| Symbols | Description |
|----------------------------|---|
| | Focal spot according to IEC 60336 |
| | Follow instructions for use |
| C € ₀₀₅₁ | Conformity to the Directive 93/42/EEC and its revised version and all other applicable Directives |
| Ċ | Exposure enabled status (the corresponding green LED is on) |
| Ф | Ceph sensor properly connected |
| <u> </u> | X-Ray emission (the corresponding yellow LED is on) |



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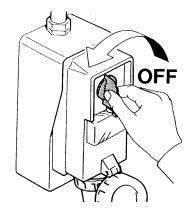
3. CLEANING AND DISINFECTION

In order to guarantee a good level of hygiene and cleaning, it is necessary to carry out the following procedures.



Warning

Disconnect the unit from the mains before performing any cleaning.



Do not let water or other liquids penetrate the unit, as these could cause corrosion or short circuits.

Use only a wet cloth and a mild detergent to clean the painted surfaces, accessories and connection cables and then wipe with a dry cloth; do not use corrosive, abrasive solvents (alcohol, benzine, trichloroethylene).



The centring bite or the bite protective sleeve and the cephalometric ear pin sleeves must be replaced after each exam.

Thoroughly clean the chin support, resting handles, temple clamps, ceph rods, nasion reference and carpus plate whenever they are used.

The chin support, resting handles temple clamps, ceph rods, nasion reference and carpus plate should be disinfected (when considered necessary) with a solution of 2% glutaraldehyde.



Note

To ensure a greater level of hygiene the handles of the equipment are covered with a special antibacterial paint which, thanks to the emission of silver ions, prevents the development of micro-organisms.





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4. DESCRIPTION

4.1. Identification labels and laser labels

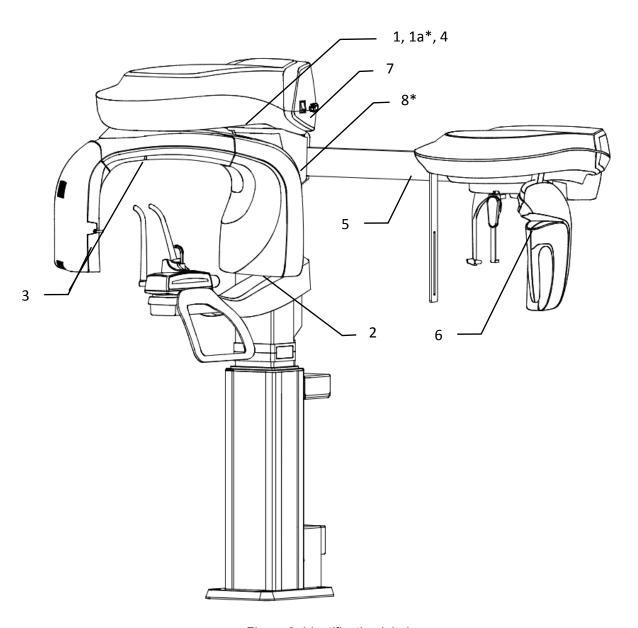


Figure 2: Identification labels

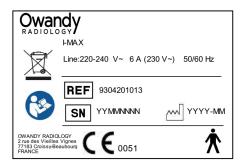
(*) Only for 110-120V version



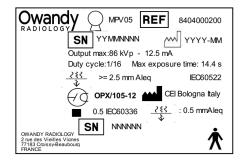


4.1.1. Identification plates and laser labels "220-240V" version

1 I-MAX identification label



2 Tube-head identification label



3 (No. 2) Laser symbol label



4 Laser WARNING label



3

CEPH ARM

REF 8104080200

SN 1907 40 18

CHIANDY RADOLLEY
Zrice does Welles Vignes
Zrice does Welles Vignes
Zrice does Welles Vignes
Zrice foes Welles Vignes
FRANCE

Cephalometric arm identification label

Ceph detector identification label



Column emergency switch

STOP

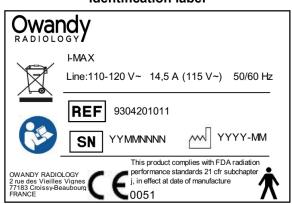
7





4.1.2. Identification plates and laser labels "110-120V" version

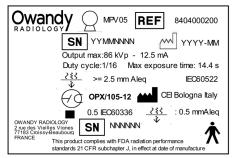
1 I-MAX identification label



1a
UDI label (only for110/120V version)



2 Tube-head identification label



3 (No. 2) Laser symbol label



4 Laser WARNING label

— RADIAZIONE LASER —

NON FISSARE IL FASCIO AD OCCHIO NUDO

APPARECCHIO LASER DI CLASSE 2 Norma IEC 60825—1:2007

Po ≤ 1mW Lungh. d'onda 650 nm ± 10 nm

— LASER RADIATION —

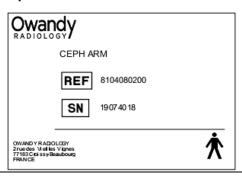
DO NOT STARE INTO BEAM CLASS 2 LASER PRODUCT
IEC Standard 60825—1:2007

Po ≤ 1 mW Wavelength 650 nm ± 10 nm



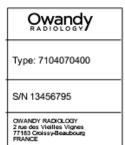
5

Cephalometric arm identification label



6

Ceph detector identification label



7

Column emergency switch



8 **WARNING label**

(only for110/120V version)

WARNING: THIS X RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS, OPERATING INSTRUCTIONS AND MAINTENANCE SCHEDULES ARE OBSERVED. ELECTRICAL SHOCK HAZARD - DO NOT REMOVE PANELS.

RISK OF EXPLOSION - DO NOT USE IN PRESENCE OF FLAMMABLE ANESTHETICS. FOR CONTINUED PROTECTION AGAINST RISK OF FIRE, REPLACE ONLY WITH SAME TYPE AND RATING OF FUSE.

DANGER:

DANGER:
CET APPAREIL DE RADIODIAGNOSTIC PEUT ETRE
DANGEREUX POUR LE PATIENT ET L' OPERATEUR
SI LES FACTEURS D'EXPOSITION, LES
INSTRUCTIONS ET LES PROGRAMMES DE
MAINTENANCE NE SONT PAS SUIVIS.
RISQUE DE CHOO ELECTRIQUE- NE PAS ENLEVER
LES CAPOTS.

LES CAPOTS.
RISQUE D'EXPLOSION - NE PAS UTILISER EN
PRÉSENCE D' ANESTHESIQUES INFLAMMABLES.
POUR ASSURER UNE PROTECTION CONTINUE
CONTRE LE RISQUE D' INCENDIE, UTILISER
UNIQUEMENT UN FUSIBLE DE RECHANGE
DE MEME TYPE ET DE MEMES CARACTERISTIQUES
NOMINALES.



4.2. Functions, models and versions

I-Max ceph, manufactured by Owandy Radiology, is a complete panoramic X-ray system that can perform the following exams:

- Panoramic adult or child exams, with 3 sizes and 3 types of biting for a total of 18 combinations with automatic selection; with manual selection, it is possible to select a high voltage between 60kV and 86kV, in 2kV steps and anodic current from 2 mA to 12.5 mA in the R20 scale steps.
- Sinus mode makes it possible to take exams of the paranasal sinuses with front projection (postero/anterior).
- TMJ closed/open mouth in lateral projection.
- Right or Left Emi-panoramic, to be used when the patient is known to have a problem only on one side of the arch, in order to reduce radiation.
- Reduced dose Panoramic, which reduces the dose radiated by excluding the TMJ's ascending rami from the radiograph.
- Frontal dentition, for a radiograph of the front part (roughly from canine to canine).
- Panoramic with improved orthogonality, which reduces teeth overlap, thereby improving the diagnosis of interproximal decay.
- Bitewing left or right, for lateral dentition (generally from eighth to fourth) with a trajectory that reduces teeth overlap
- Bitewing (left and right), which sequentially performs both bitewings, showing them on the same image.
- Cephalometric L-L projections in the formats 18x24, 24x24, 30x24 and 18x18, 24x18, 30x18; the selection between HS High Speed and HD High Definition is available;
- Cephalometric A-P projections in the format 24x24 and 24x18 the selection between HS High Speed and HD High Definition is available;
- Carpus Projection in the format 18x24, only in HD High Definition mode.

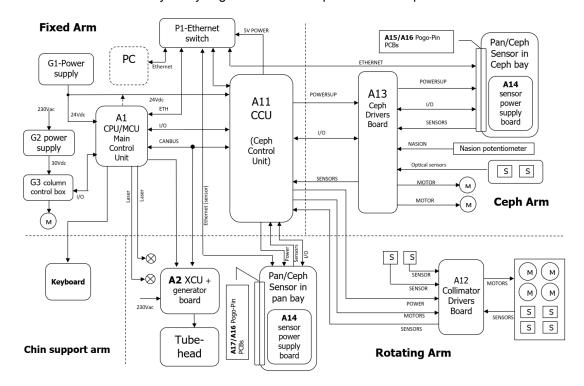
Note of cephalometric image formats:

For user convenience, the ceph projections are named following the conventional format of the film-cassettes (24 cm), although the vertical active area of the cephalometric sensor is 22.8 cm.



4.3. Block diagram

This paragraph provides a brief description, at block diagram level, of the I-MAX. Aim of this paragraph is to provide a brief description of the system. More details about the electronic circuits can be obtained by analysing the schematics provided in chapter 12.



MCU board A1 is the main CPU board that manages directly all the components of the unit. It is connected to the following components:

- Power supply assembly (G1)
- Zero position sensors
- X-ray button
- External signal board (A8)
- Lift motors control box (G3)
- Generator board XCU (A2) ---> (Tubehead)
- Ceph Control Board (CCU, A11)
- Collimator driver board (A12)
- Ceph Driver board (A13)
- Ceph Sensor power supply board (A14)
- Overlay keyboard
- Ceph sensor and host PC via a 5-ports ethernet switch

MCU board, CCU board and HF board are equipped with a local microcontroller that shares information using a CANbus transmission line and protocol.

An additional power supply assembly (G2) is directly connected to the column driver.

4.3.1. Power supply circuit

Owandy Radiology SAS





It is positioned in the top part of the unit and it is mainly composed by mains switch (S1), line filter (Z1), a 24Vdc 7.5A switching mode power supply (G1), located under the MCU board which supplies 24 Vdc to the logic boards, a 30Vdc power supply (G2) that supplies the lift motor.

- G2 power supply provides power to the motor control box (G3) which dirves the up/down motor (M1). located in the lower part of the unit.
- Safety switch S2 located in the top side of the unit (red button) cuts power ONLY to the up/down motor in case of malfunction
- Mains voltage is also provided to the Generator Board A2 used to generate High voltage to the tube head.



Note

The S2 emergency switch doesn't cut power to the X-ray generator or to other circuits, therefore mains voltage is still present in the unit even when the S2 emergency swith has been pressed..

The unit does not include a voltage selector circuit for the mains voltage. Therefore, the unit is manufactured in different versions, depending on the line voltage of the installation place.



4.3.2. **MCU board (A1)**

It is located on top of the unit. Main tasks are:

- General controlling of the unit, receiving the signals from the keyboard and from the different optical sensors.
- Communicating to the PC via ethernet connection.
- Driving of the stepper motors of Rotation, Y axis and chin rest.
- Monitoring the functioning of the motors through the analysis of the signals (zero position) coming from the zero position light sensors.
- Driving of the HF group (Generator board and tubehead) in order to provide the X-ray doses set by the operator on the PC (kV and mA set point) and in the meantime, check the functioning of this group through the managing of the relevant alarm signals.
- Driving of the x-ray button signal and the digital sensor board used to synchronize sensor acquisition with X-ray emission.
- Activation of the 2 laser centering devices.
- Managing of the alarms that can be generated by anomalous conditions present in the unit and caused by the operator or by a fault. These signals are sensed by the local MCUs and signal led using specific CANBus messages and reading temperature sensor placed on the sensor power board.

MCU includes also the configuration and calibration data stored in the EEPROM memory and the HW key to activate the optional XP exam package and extended volumes package.

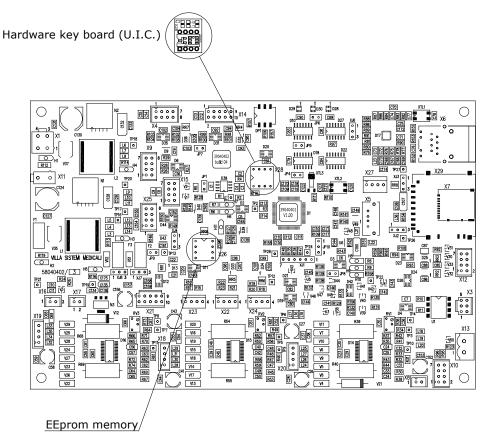


Figure 3



4.3.2.1. MCU board DIP Switches

The following table shows the different modalities of DIP Switches present on the MCU board.

| Code (*) | 1 | 2 | 3 | Function |
|----------|-----|-----|-----|---|
| 0 | ON | ON | ON | Normal mode |
| 1 | OFF | ON | ON | EEPROM reset (see paragraph 9.2.2.1) |
| 2 | ON | OFF | ON | Exhibition demo mode: allows rotation without X-ray emission (see paragraph 7.13.2) |
| 4 | ON | ON | OFF | Axis alignment service mode: used to check laser centering rotating between the arm 0°, 90° and 180° positions by pressing >0<. Collimator type setting (see paragraph 0). |
| 5 | OFF | ON | OFF | - MCU bootloader forced by DIP switches |

^{*} It is possible to see this code by keeping the MCU SD card log (see paragraph 11.2.1.2)

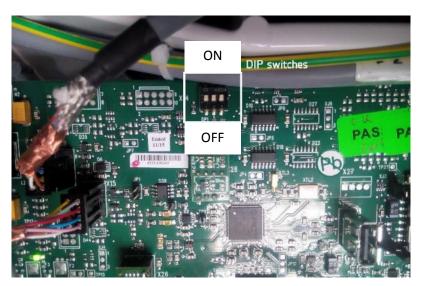


Figure 4



4.3.3. Generator board (A2) and Tubehead

The Generator board and the tubehead are located on the rotating arm. The power supply voltage is directly provided by the mains line.

Generator board includes a µprocessor which communicates with the MCU board (A1) through the CANBus cable (X15-X32). This cable also has a dedicated wire to bring the X-ray button signal to this board, so the "dead man switch" method is generated directly on the board.

The high frequency (HF) circuit is based on an inverter circuit working at the frequency about 100kHz, which drives the tubehead through an output stage based on IGBT components.

The Generator board receives the signals concerning the X-ray dose to provide (kV and mA), from the MCU board through CANBus messages; it is the Generator µprocessor that generates the commands used for the X-ray emission. The Generator board provides to the tubehead the voltages that drive the high voltage transformers that then drive anode and filament of the X-ray tube, also giving the relevant timing.

The tubehead is composed by the X-ray tube (CEI OPX 105-12) inserted in a sealed container, together with the high voltage transformers, filled with dielectric oil.

The Generator board controls the X-ray emission parameters feedbacks, generated by the tubehead. Any anomalies are then communicated to the MCU board (A1) which generates error codes to alert the operator.

4.3.4. CCU Ceph Control Board (A11)

Its main tasks are:

- Managing the stepper motors of the ceph arm and 4 blade primary collimator.
- Monitoring the functioning of these motors through the analysis of the signals (zero position) coming from the zero position light sensors.
- Managing the potentiometer on the nasion
- Managing the detection of the image sensor in the pan or ceph bays
- Driving of the HF group (Generator board and tubehead) for the ceph exams, in order to provide the X-ray doses set by the operator on the PC (kV and mA set point)
- Managing of the alarms that can be generated by anomalous conditions present in the cephalometric arm and collimator.

4.3.4.1. CCU board DIP Switches

The following table shows the different modalities of DIP Switches present on the CCU board.

| Code (*) | 1 | 2 | 3 | Function |
|----------|-----|----|----|---------------------------------------|
| 0 | ON | ON | ON | Normal mode |
| 1 | OFF | ON | ON | CCU bootloader forced by DIP switches |

^{*} It is possible to see this code by keeping the MCU SD card log (see paragraph11.2.1.3)

4.3.5. Collimator Driver Board (A12)



It is located in the rotating arm just above the collimator itself.

On this board there are the stepper motor drivers of the 4 blade collimator.

It is also an interconnection board to route the cables of collimator zero sensors and to the Control Units Boards.

4.3.6. Ceph Driver Board (A13)

It is located in the bottom part of ceph unit. It can be accessed after removing a dedicated cover in the bottom part of the ceph device.

- On this board there are the stepper motor drivers of the cephalometric arm.
- It is also an interconnection board to route the cables (power supply, signals and zero sensors) from the machine to the cephalometric arm.

4.3.7. Ceph sensor power supply board (A14)

It is located Inside the ceph sensor enclosure.

The main tasks are:

- Give the power supply (12V) to the Ceph Sensor.
- Give to the MCU the temperature of the Ceph Sensor, through which the system can manage the switching ON / OFF of its power supply.





4.4. Keyboard - Description and functions

Figure 5 shows a general view of I-Max control Interface.

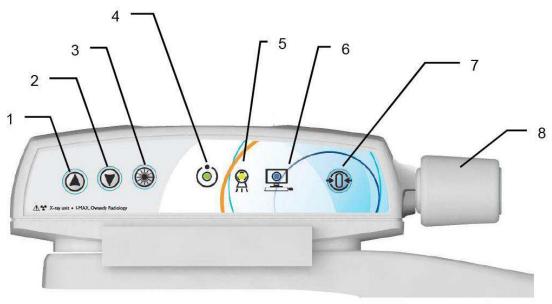


Figure 5 - Keyboard

| - | | | |
|-------|--|---|--|
| Label | Description | | |
| 1 & 2 | The up/down movement of the column is controlled by the corresponding keys. The movements are enabled during equipment setting. Column movement is not possible if the emergency button is pressed. | | |
| 3 | The "Luminous centring device" key turn the laser centring devices ON/OFF, allowing the correct positioning of the patient. | | |
| 4 | Light indicator of "Machine Ready" status: Green fixed, alerts the user that by pressing the X-ray button, X-ray emission will start Green blinking slowly, indicates that by pressing >0 button, axis reset will start, Green blinking fast, indicates the equipment cooling status. | | |
| 5 | Light indicator "X-Ray Emission" status. It indicates the emission of X-rays. | 8 | |





| Label | Description | |
|-------|--|--|
| 6 | Light indicator of "Computer connection" status: Blue fixed, computer connection established, Blue blinking slowly, waiting for computer connection. No X-ray emission available Blue blinking fast, the equipment is in error state. Refer to the GUI for error description. | |
| 7 | The "Centring/Patient Entrance" key is used to: Start/Stop the exam procedures Put the rotation arm in the patient entrance position at the end of the exam. | |
| 8 | Temple clasps closing/release knob. | |



5. TECHNICAL CHARACTERISTICS

| General features | | | | |
|--|--|--|--|--|
| Туре | I-Max Ceph | | | |
| Manufacturer | Owandy Radiology | | | |
| Class | Class I with type B applied parts according to IEC 60601-1 classification. | | | |
| Protection degree | IPX0 standard device | | | |
| Line voltage | 99-132 V 198-264V | | | |
| Rated line voltage | 110-120V 220-240V | | | |
| Line frequency | 50/60Hz | | | |
| Maximum line current | 14.5A @115V 50/60 Hz 6A @ 230V 50/60 Hz | | | |
| Technical factors for maximum line current | 86kV, 12.5mA | | | |
| Power consumption | 1.8kVA @ 115V 50/60 Hz 1.4kVA @ 230V 50/60 Hz | | | |
| Protection fuse (F1) | 20 A T 250V 6.3x32 mm 10kA @ 125V 8 A T 250V 6.3x32 mm 200A @ 250V | | | |
| Column protection fuse (F2) | 4 A T 250V 6.3x32 mm 10kA @ 125V 2.5 A T 250V 6.3x32 mm 100A @ 250V | | | |
| Maximum line apparent resistance | 0.4 Ω max (99-132V) 0.5 Ω max (198-264V) | | | |
| Rated output voltage (kVp) | 60 – 86 kVp, with 2 kVp steps | | | |
| Anodic current | 2 - 12.5 mA, with R20 scale steps (2, 2.2, 2.5, 2.8, 3.2, 3.6, 4, 4.5, 5, 5.6, 6.3, 7.1, 8, 9, 10, 11, 12.5) | | | |
| Additional filtration | ≥ 2 mm Al eq. | | | |





| Expo | osure times | |
|---|--|--|
| Panoramic exam (PAN) | 14 s Adult / 12.8 s Child | |
| Half panoramic exam | 7.7 s Adult / 7.1 s Child | |
| Ortho Rad panoramic exam | 11.5 s Adult / Child | |
| Low dose panoramic exam | 11.6 s Adult / 10.4 s Child | |
| Frontal dentition | 4.1 s Adult / Child | |
| Bitewing Right, Bitewing Left | 3.1 s Adult / Child | |
| Bitewing Right & Left | 6.2 s Adult / Child | |
| TMJ mouth closed/open | 10.6 s for left and right joint in open and closed condition | |
| TMJ single phase | 5.3 s | |
| Sinus P/A projection | 9 s | |
| Latero lateral 18x24 and 18x18 cephalometric exam | 9.1 s HD / 4.4 s HS | |
| Latero lateral 24x24 and 24x18 cephalometric exam | 12.1 s HD / 5.8 s HS | |
| Latero lateral 30x24 and 30x18 cephalometric exam | 15.1 s HD / 7.3 s HS | |
| Antero posterior 24x24 and 24x18 cephalometric exam | 12.1 s HD / 5.8 s HS | |
| Carpus | 4.4 s | |
| Exposure time accuracy | ± 5 % or ± 20ms whichever is greater | |
| Exa | am modes | |
| Exam selection | Automatic selection for Adult and Child 3 Sizes 3 biting modes (Panoramic exam) | |
| | Manual selection | |
| Panoramic exam | Standard panoramic | |
| | Half panoramic Left/Right | |
| | Ortho Rad panoramic | |
| | Low dose panoramic | |
| | Frontal dentition | |
| | Bitewing Left/Right | |
| | Bitewing Left and Right | |
| TMJ (Temporal Mandibular Joint) exam | TMJ open and closed mouth | |
| Sinus exam | Sinus P/A projection | |



| Cephalometric exams | | |
|------------------------------|---|--|
| Lateral projections | formats 18x24 cm, 24x24 cm, 30x24 cm and 18x18 cm, 24x18 cm, 30x18 cm | |
| Antero-posterior projections | format 24x24 cm and 24x18 cm | |
| Carpus exam | format 18x24 cm | |

Note of cephalometric image formats:

For user convenience, the ceph projections are named following the conventional format of the film-cassettes (24 cm), although the vertical active area of the cephalometric sensor is 22.8 cm.

| Image magnification | Geometric magnification | Magnification after software correction |
|----------------------------------|---|---|
| Adult / Child standard Panoramic | 1 : 1.23 (constant over dentition part) | 1:1(*) |
| TMJ open/closed mouth | 1 : 1.20 (nominal) | 1:1(*) |
| Sinus | 1 : 1.22 (nominal) | 1:1(*) |
| Cephalometric exams | 1 : 1.1 (nominal) | 1:1(*) |
| Carpus exam | 1 : 1.06 (nominal) | 1:1(*) |



(*) Warning

The declared image magnification value is valid after proper software calibration.



Note

I-Max is based on a standard dentition and ascending rami shape.

This shape, based on statistical studies, establishes a form for the dentomaxillofacial complex, adopted as "standard".

I-Max follows a rototranslation path which maintains the magnification factor as stated in the Technical Characteristics of each type of exam as constant along this "standard" shape only along the dentition area. The patient's anatomy can differ significantly from the statistical model, so the magnification factor is not maintained and may be different from the value stated. Based on experience and competence, the user has to judge this variation.

In any case, TMJ radiography cannot be used to perform calculations of distances, angles etc. on the film.

| Tube-head characteristics | |
|---------------------------|------------------|
| Model | MPV 05 |
| Manufacturer | Owandy Radiology |

Service Manual – Description Rev. 0



| Maximum tube voltage | 86 kVp |
|---|---|
| kVp accuracy | ± 8 % |
| Maximum anodic current | 12.5 mA |
| Anodic current accuracy | ± 10 % |
| Duty cycle | 1:16 |
| Reference loading conditions related to maximum energy input to the anode | 2812.5 mAs/h @86 kVp |
| Nominal power | 1.075 kW (86 kVp - 12.5 mA) |
| Total filtration | ≥ 2.5 mm Al eq. @ 86 kVp |
| HVL (Half value layer) | > 3.2 mm Al eq. @ 86 kVp |
| Transformer insulation | Oil bath |
| Target angle and reference axis | See |
| Cooling | By convection |
| Leakage radiation at 1 m | < 0.5 mGy/h @ 86 kVp - 12.5 mA - 3s duty cycle 1/16 |
| Tube-head maximum thermal capacity | 310kJ |

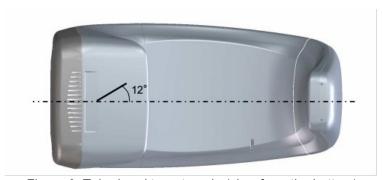


Figure 6: Tube-head target angle (view from the bottom)

| X-ray tube characteristics | | |
|--|---------------|--|
| Manufacturer | CEI | |
| Туре | OPX 105-12 | |
| Nominal focal spot | 0.5 EN 60336 | |
| Inherent filtration | 0.5 mm Al eq. | |
| Anode tilt | 12° | |
| Anode material | Tungsten | |
| Nominal maximum voltage | 110 kVp | |
| Filament max current | 4 A | |
| Filament max voltage | 6.7 V | |
| Anode thermal capacity | 30 kJ | |
| Anode thermal capacity during continuous operation | 300 W | |

Laser centring devices



| RADIOLOGI. | Rev. U |
|---|--|
| 2 laser beams are used for patient positioning; planes (please refer to relevant paragraphs for | |
| Wave length | 650 nm |
| Divergence | < 2.0 mRad |
| Optical power on the working surface | < 1 mW |
| Laser class | Class 2 laser product according to IEC standard 60825-1:2007 |
| 3D Digi | ital sensor |
| Detector type | CMOS flat panel |
| Sensitive Area (H x L) | 144 x 118.6 mm |
| Pixel dimensions | 120 μm 240 μm (2x2 binning) |
| Number of pixel (H x L) | 1200 x 988 600 x 494 (binning 2x2) |
| Voxel dimensions | 175 µm HD mode 87.5 µm XD mode |
| Grey levels | 65536 (16 bit) |
| Resolution | 4.16 lp/mm (non binning mode) |
| Sensor cover attenuation equivalent | < 0.4 mm Al eq. |
| Cephalometr | ic Digital sensor |
| Detector type | CMOS flat panel |
| Sensitive Area (H x L) | 228 x 6.7 mm |
| Pixel dimensions | 99 μm 198 μm (2x2 binning) |
| Number of pixel (H x L) | 2304 x 68 (non-binning mode) |
| gray levels | 16384 (14 bit) |
| Resolution (spatial frequency at CTF=5%) | 5 lp/mm (non-binning mode) |
| Sensor cover attenuation equivalent | < 0.4 mm Al eq. |
| • | ' |
| Mechanical | characteristics |
| Focal spot to image receptor distance (panoramic and) | 52 cm (20") |
| Focal spot to image receptor distance (cephalometric) | 165 cm (65") |
| Telescopic motorised column run | 70 cm (27"1/2) |
| Maximum total height | 223 cm (88") |
| Weight | 123 kg (271 lbs) |
| Environme | ntal conditions |
| Minimum room size (please refer to the Service Manual) | 186 x 121 cm (75"x49") |
| Recommended room size (please refer to the Service Manual) | 200 x 130 cm (80"x52") |
| | |

Service Manual – Description Rev. 0



| Working temperature range | + 10° ÷ + 35° |
|--|----------------------------|
| Working relative humidity (RH) range | 30% ÷ 75% |
| Working atmospheric pressure range | 700 ÷ 1060 hPa |
| Temperature range for transport and storage | - 20° ÷ + 70° |
| Humidity range for transport and storage | < 95% without condensation |
| Minimum atmospheric pressure for transport and storage | 630 hPa |



Note

The handles of the equipment are covered with a special antibacterial paint which, thanks to the emission of silver ions, reduces the development of micro-organisms.

X-ray tube characteristics

| Manufacturer | CEI |
|--|---------------|
| Туре | OPX 105-12 |
| Nominal focal spot | 0.5 EN 60336 |
| Inherent filtration | 0.5 mm Al eq. |
| Anode tilt | 12° |
| Anode material | Tungsten |
| Nominal maximum voltage | 110 kVp |
| Filament max current | 4 A |
| Filament max voltage | 6.7 V |
| Anode thermal capacity | 30 kJ |
| Anode thermal capacity during continuous operation | 300 W |

Laser centring devices

2 laser beams are used for patient positioning; beams that align the sagittal and Frankfurt planes (please refer to relevant paragraphs for a detailed explanation).

| Wave length | 650 nm | |
|--------------------------------------|--|--|
| Divergence | < 2.0 mRad | |
| Optical power on the working surface | < 1 mW | |
| Laser class | Class 2 laser product according to IEC standard 60825-1:2007 | |

Panoramic and Cephalometric Digital sensor

| Detector type | CMOS flat panel | |
|--|-------------------------------|--|
| Sensitive Area (H x L) | 228 x 6.7 mm | |
| Pixel dimensions | 99 μm 198 μm (2x2 binning) | |
| Number of pixel (H x L) | 2304 x 68 (non-binning mode) | |
| Grey levels | 16384 (14 bit) | |
| Resolution (spatial frequency at CTF=5%) | 5 lp/mm (non-binning mode) | |





Sensor cover attenuation equivalent

< 0.4 mm Al eq.





| Mechanical characteristics | | | | |
|--|----------------------------|--|--|--|
| Focal spot to image receptor distance (panoramic) | 50 cm (20") | | | |
| Focal spot to image receptor distance (cephalometric) | 165 cm (65") | | | |
| Telescopic motorised column run | 70 cm (27"1/2) | | | |
| Maximum total height | 223 cm (88") | | | |
| Weight | 118 kg (260 lbs) | | | |
| Working | conditions | | | |
| Minimum room size (please refer to the Service Manual) | 186 x 121 cm (75"x49") | | | |
| Recommended room size (please refer to the Service Manual) | 200 x 130 cm (80"x52") | | | |
| Working temperature range | + 10°C ÷ + 40°C | | | |
| Relative working humidity (RH) range | 30% ÷ 75% | | | |
| Temperature range for transport and storage | - 20°C ÷ + 70°C | | | |
| Humidity range for transport and storage | < 95% without condensation | | | |
| Minimum atmospheric pressure for transport and storage | 630 hPa | | | |
| | · | | | |



Note

The handles of the equipment are covered with a special antibacterial paint which, thanks to the emission of silver ions, reduces the development of micro-organisms.



5.1. PC requirements



Warning

PC to be used with the machine must comply with the standard IEC 60950-1:2005.

In the following paragraphs are listed the minimum and suggested PC characteristics.

5.1.1. PC minimum characteristics

- Mother board with at least one free PCI express X16 slot (mandatory for the Dual Port Network Card provided with the equipment).
- Processor Intel Core i5 2.66 GHz Quad Core
- RAM 8GB
- Hard drive 1TB
- Graphics card With dedicated VRAM, at least 1GB
- Operating system Windows 10 64bit
- Network Single port dedicated Giga-Ethernet



Note

Monitor characteristics: the PC and the monitor are not supplied with the equipment.

In order to properly view images taken with I-Max Ceph, the PC monitor must have the following minimum characteristics:

Resolution: 1366 x 768 pixelsColour depth: 16M of colour

Contrast: 500:1

Luminosity 200cd/m²





5.2. Software

The equipment Graphical User Interface can be run with the software provided with the machine or integrated in a third party imaging and database software that complies with the following specifications: it has to be CE marked as medical device of class IIa and integrate the equipment SDK according to what stated in the document PANOW API programmer's guide Vn (n is the document revision), contact Owandy Radiology to have the latest revision of the programmer's document.

5.3. I-Max – PC communication

I-Max requires connection to a host PC to transfer images and to exchange the machine status. The communication between I-Max and computer requires a dedicated Giga-Ethernet channel directly connected between the unit and the PC.

The information flow from I-Max includes image data and system status messages that are exchanged only with the host PC and with no other devices on the network. The communication requires fixed IP addresses.

The ethernet cable from the unit must be connected directly to the PC ethernet port for the unit to operate correctly.

In order to properly operate the unit follow carefully the instructions reported at paragraph 7.6. The system is provided with an Ethernet cat 5e cable in order to permit the PC connection. In case of replacement, cables of the same or superior category have to be used.

If the communication between I-Max and PC is not properly set problems in unit connection causing impossibility of acquisition or loss of frames causing distortion and artifacts on the images can occur.



Note

I-Max is not intended to transmit or receive information to/or from other equipment through network/data couplings.



5.4. Separate parts supplied with I-MAX

I-MAX comes with the following removable accessories:

Chin rest for standard panoramic (code 6104011508 + 5407098200), supplied with removable appendix for edentulous patients (code 5407098108)





Reduced height chin rest for standard panoramic (code 6104011708 + 5407098200)



Lowered chin rest for Sinus exam, made by lowered chin rest (code 6104011608) and appendix for edentulous patients (code 5407098108)

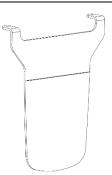


Standard TMJ positioning support (code 6104011800)





Hand plate support for carpus exam (code 6104081300)







Bites (code 6107110300), bite protective sleeves (code 6107110700), TMJ positioner (code protective sleeves 6107110800) and ceph ear pins sleeves (code protective 6104081500)

Disposable and unsterilized parts.

Replace after every use.



Note

These removable parts are considered "type B applied parts", in accordance with IEC 60601-1, edition 3.1.

Some of these parts do not carry identification codes due to their small size. The use of these parts on other devices is not possible, since they are parts designed specifically for the I-MAX.





5.5. Reference standard

Medical electrical equipment for extra-oral dental radiography I-Max complies with:

IEC 60601 1: 2005 (3rd ed.)

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601 1: 2005 (3rd ed.) + Am1:2012

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6:2010 (3rd Ed.)

Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices.

IEC 60601-1-6:2010 (3rd Ed.) + Am1:2013

Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices.

IEC 60601-1-2:2007 (3rd Ed.)

Electromagnetic compatibility - Requirements and tests.

IEC 60601-1-2:2014 (4th Ed.)

Electromagnetic disturbances - Requirements and tests.

IEC 60601-1-3:2008 (2nd Ed.)

Medical electrical equipment - Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment.

IEC 60601-1-3:2008 (2nd Ed.) + Am1:2013 (ed. 2.1)

Medical electrical equipment - Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment.

IEC 60601-2-63:2012 (1st ed.)

Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of extra-oral dental X-ray equipment.

IEC 60601-2-63:2012 (1st ed.) + Am1:2017 (ed. 1.1)

Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of extra-oral dental X-ray equipment.

IEC 62366:2007 (1st Ed.)

Medical devices – Application of usability engineering to medical devices.

IEC 62366:2007 (1st Ed.) + Am1:2013

Medical devices – Application of usability engineering to medical devices.

IEC 62304:2006 (1st Ed.) + Ac:2008

Medical devices software – Software life-cycle processes.

IEC 62304:2006 (1st Ed.) + Am1:2015 (ed. 1.1)

Medical devices software – Software life-cycle processes.

IEC 60825-1:1993 (1nd ed.)

Safety of laser product – Part 1: equipment classification and requirements.

IEC 60825-1:2007 (2nd ed.)

Safety of laser product – Part 1: equipment classification and requirements.





EN-ISO 14971:2012

Medical Devices - Application of Risk Management to Medical Devices.

CAN/CSA-C22.2 No 60601-1:08

Canadian National deviations to IEC 60601-1.

CAN/CSA-C22.2 No 60601-1:14

Canadian National deviations to IEC 60601-1.

ANSI/AAMI ES60601-1:2005/A2:2010

US National differences to IEC 60601-1.

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012 US National differences to IEC 60601-1.

C€₀₀₅₁

Guarantees the compliance of I-Max with Directives 93/42/EEC (as amended), 2011/65/EU, 2006/42/EC.

Classifications

I-Max is an electrical medical X-ray device classified as class I type B according to EN 60601-1, with continuous operation and intermittent load.

According to 93/42/EEC Medical Devices Directive, the equipment is classified as class II B.

According to Canadian MDR, the equipment belongs to class II.

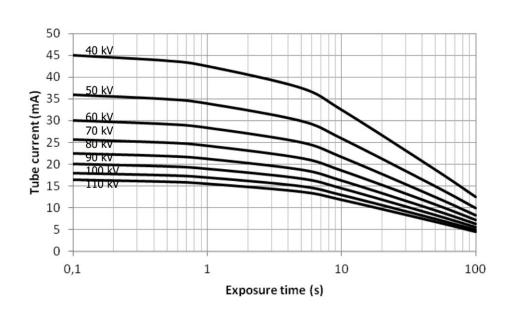
According to FDA 21 CFR, the equipment belongs to class II.



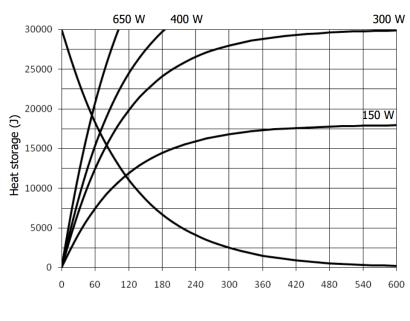


5.6. Loading curve of the tube and cooling curve of the anode

Tube "CEI OPX 105-12" (0.5 IEC 336) Load



Anode cooling curve

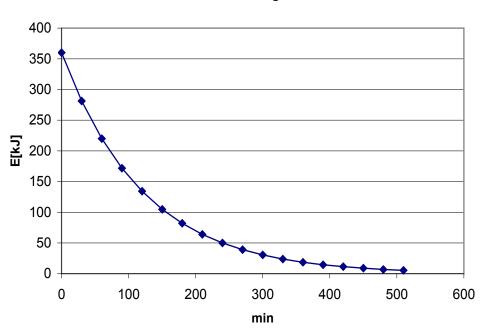


Time (s)



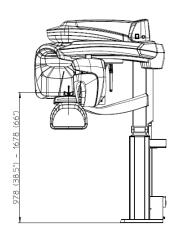


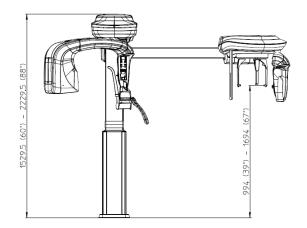
Tube head cooling curve





5.7. Dimensions





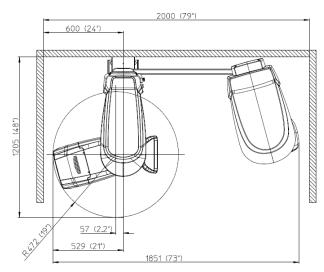


Figure 7: I-Max dimensions -Floor- Wall mounted version





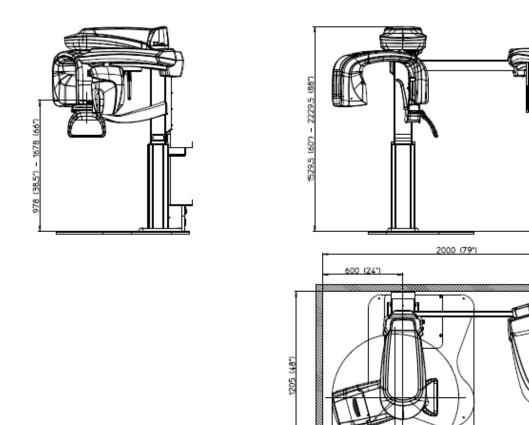


Figure 8: I-Max dimensions – Free standing version







6. PRE-INSTALLATION

The instructions indicated in this and in the following chapter enable to perform a correct installation in order to grant a regular operation of I-Max.

The supplier can supply the assistance and the necessary technical advice for pre-installation. All masonry works and the pre-installation phase are at the customer's charge and must be performed complying with the indications given below.

The requirements for a correct installation of I-Max are:

- minimum height of the room: 2.5 m (8.20') and a surface variable according to the configuration of I-Max to be installed
- No heating devices in close proximity of the unit
- the entrances in the room, for the transport of the unit (after unpackaging), must have a minimum width of 65 cm (25.6").

6.1. Packaging

The unit is delivered on one pallet containing three cardboard boxes

| Contonto | Daaliina dimaanian | Weight | |
|--|-------------------------------------|-----------|------------------|
| Contents | Packing dimension | Net | Gross |
| Complete unit | 150x100x H145 cm | 118 kg | 160 kg |
| | (59.1"x39.4"x57.1") | (260 lbs) | (353 lbs) |
| Main unit | 122x100x H63 cm | 96 kg | 125 kg |
| | (48"x39.4"x24.8") | (212 lbs) | (276 lbs) |
| Ceph arm | 150x92x H66 cm | 22 kg | 26 kg |
| | (59.1"x39.4"x26") | (48 lbs) | (57 lbs) |
| <empty> Filler box only for delivery</empty> | 100x26x H63 cm (39.4"x10.3"x26") | 0 | 2 kg (11 lbs) |







Note

A shock detector is applied to the packaging.



Upon receipt of the unit, check that the sensor has not been activated. In case the sensor has been activated, immediately notify the forwarder and sign the delivery note as "Provisionally accepted".



Warning

Owandy Radiology will not bear any responsibility for damages caused to the equipment due to improper unpackaging procedure, and for the relevant costs.



Note

The package will be used as a tool during the initial steps of the installation. Do not discard the packaging until installation has been completed and unit is fully operational.





6.2. Room layout

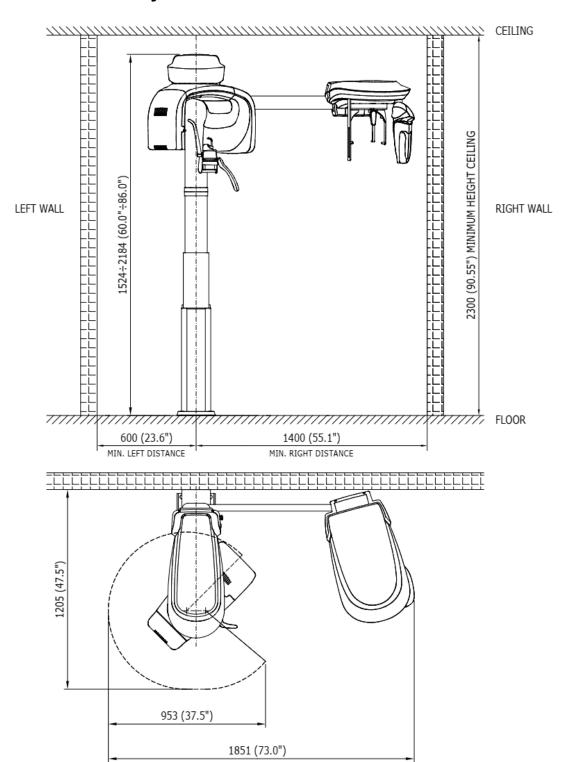


Figure 9



6.3. Drilling templates



Note

Although it is recommended to use the package as a tool to install the I-Max, here following the indication of the drill layout for the standard height in case it is necessary to prepare the room before you receive the unit.

The unit can be fixed in different ways:

- To the wall only, using the upper bracket (2 screws) and lower bracket (2 screws)
- To the wall and floor using the upper bracket (2 screws), lower bracket (2 screws) and the floor plate (4 screws). This installation is recommended when the wall strength is uncertain.
- bracket adapter is available for dual-stud installation on wooden walls.



A free-standing floor plate is also available for installations where drilling holes in the walls is not possible. Although this kind of installation provides the necessary structural safety, the unit might have higher vibrations and oscillations.

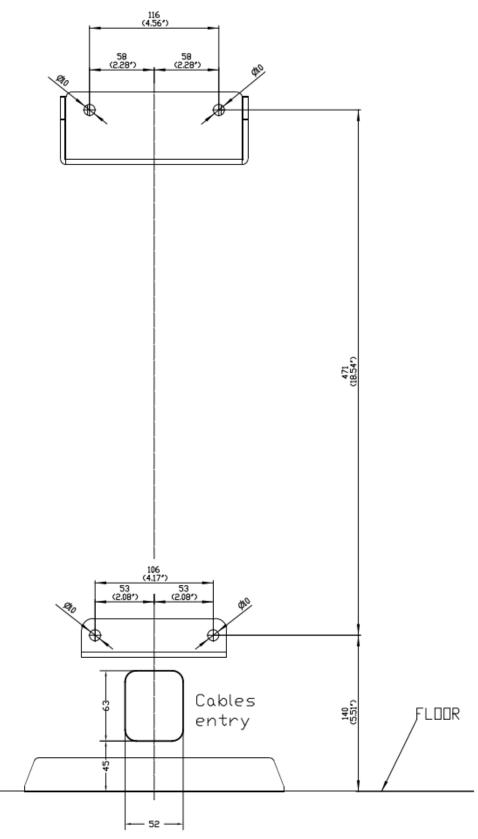


Warning for free standing floor mounted unit.

In case the unit shall be moved for service or other extraordinary operation, maximum caution shall be taken to prevent the unit from tilting and falling to the ground.



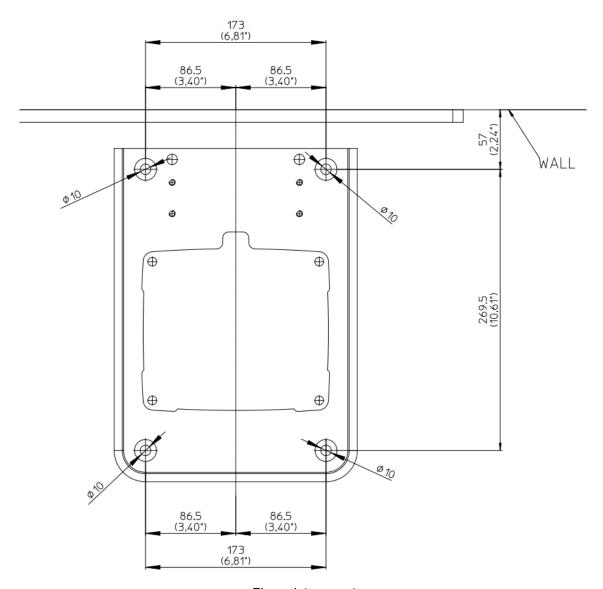




Standard Wall mount

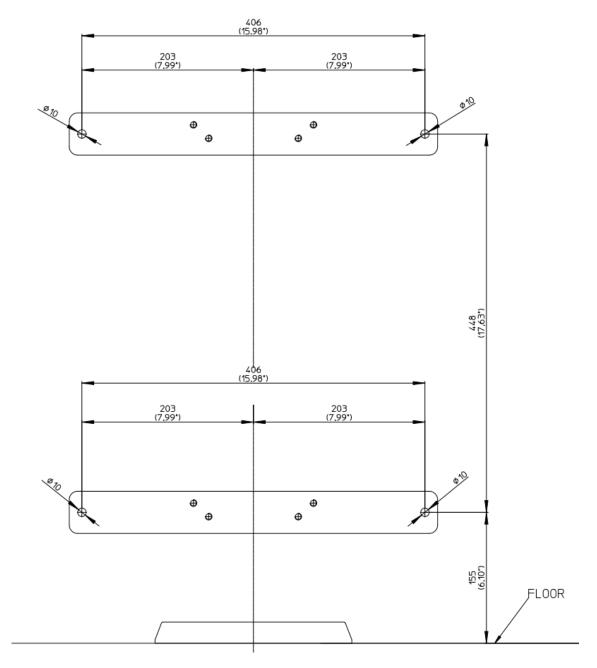






Floor plate mount





Wall mount with 16" Adapter





Warning

It is responsibility of the installer to verify the type of wall and use the correct fixing anchor.

Here following some suggestion that can help installer to find the correct method depending on wall and installation type.

- Standard wall installation. Unit is fixed using two screws on the upper bracket and two screws on the lower bracket. Extraction force on each anchor is about 55 kg.
 - In case of full concrete (class C20/C25 thickness >200mm): drill with Ø8 + Fischer Anchor FAZ II 8/10 (ordering code 6604100100). Tightening force 20Nm.
 - In case of full bricks: drill Ø14 + chemical Anchors FIS V-BOND 300T + Steel Insert FIS E 11X85 M6 + screws M6x25 (ordering code 6604100200).
 This solution permit to avoid the use of threated bars. Tightening force 4Nm.
 - In case of hollow brick: drill Ø16 + chemical Anchors FIS V-BOND 300T Plastic anchor FIS H 16X85 K + Steel Insert FIS E 11X85 M6 (ordering code 6604100200). This solution permit to avoid the use of threated bars. Tightening force 2Nm.
- Wall-floor installation. This installation is recommended when the wall strength is uncertain. Unit is fixed using two screws on the upper bracket, two screws on the lower bracket and four screws on the base plate. Extraction force on wall anchors is about 46 kg and on floor anchors is 73 kg.
 - In case of full concrete (class C20/C25 thickness > 200mm): drill with Ø8 + Fischer Anchor FAZ II 8/10 (ordering code 6604100100). Tightening force 20Nm.
 - In case of full bricks: drill Ø14 + chemical Anchors FIS V-BOND 300T + Steel Insert FIS E 11X85 M6 + screws M6x25 (ordering code 6604100200).
 This solution permit to avoid the use of threated bars. Tightening force 4Nm.
 - In case of hollow brick: drill Ø16 + chemical Anchors FIS V-BOND 300T Plastic anchor FIS H 16X85 K + Steel Insert FIS E 11X85 M6 (ordering code 6604100200). This solution permit to avoid the use of threated bars. Tightening force 2Nm.
- Wall installation with 16" adapter brackets (optional kit, p/n 6104101200).
 Unit is fixed using two screws on the upper bracket and two screws on the lower bracket. Extraction force on each anchor is about 25 kg.
 - Anchors shall be chosen according to the wall stud material.
- Free-standing floor plate (optional kit p/n 6104103000). No fixation is necessary.



Warning

Installation using only the 4 base plate holes doesn't provide structural stability and is STRICTLY FORBIDDEN





6.4. Electrical setting up

The main electrical characteristics of I-Max are:

Mains voltage
 220-240 V ~ with ground

110-120 V ~ with ground

• Frequency 50/60 Hz

Power consumption 1.8 kVA (at 115 V)

1.4 kVA (at 230 V)

• Current absorption 6 A (at 230 V)

14.5 A (at 115 V)

• Apparent line resistance 0.5 Ω max (for 220-240 V version)

0.4 Ω max (for 110-120 V version)

Line voltage regulation
 < 3 % at 99 V

(for 110-120 V version)



Warning

The unit is classified as "**Permanently Installed**" according to EN 60601-1, meaning that the mains cable shall be permanently connected to the mains line.

DO NOT connect the unit to the power using a detachable plug, to avoid compromising the electrical safety.



Warning

The unit is classified as "IPX0" according to EN 60529, meaning that the units provides NO protection against the ingress of liquids

The unit must be connected to a differential magneto-thermal switch, to separate the unit from the mains line in case of maintenance operations. This switch must comply with the electrical regulations in force in the country of installation.

The unit comes equipped with a 3-meters mains connection cable (13 AWG, 2.63 mm²) already connected to the unit mains terminals.

The installer is responsible for verification of the mains line characteristics in the installation site. The minimum recommended wire gauge is:

1.5 mm² (16 AWG) for 230V power supply.

AWG) for 115V power supply

The general grounding must comply with the rules in force; a wrong quality of the grounding could be dangerous for the patient and operator's safety and might cause malfunction of the unit.

Other than the power supply, I-Max provides the following connections.

All connections are located in the base of the unit and are protected by a metallic cover.

 RJ45 Ethernet connection for pan/ceph detector and system interface: point-to-point connection from the unit to the host PC. A Cat 6 cable

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(5m long) is supplied with the unit. In case a longer cable is needed, make sure the cable is Cat 6 or better.

- READY light: The signal is active when the unit is ready to perform the exam. Normally Open dry Contact, maximum load 24V, 40W. Contacts X11-1 and X11-2
- X-RAY ON light: The signal is active during X-Ray emission. Normally Open dry Contact, maximum load 24V, 40W. Contacts X11-3 and X11-4

The unit only provides dry contacts relative to the above mentioned functions. Power supply for the relevant devices has to be provided externally, making sure not to exceed the indicated ratings.

• Remote X-RAY button: An external pushbutton can be connected so that the operator can start exposure from outside the exam room. It is mandatory to use a MOMENTARY pushbutton in order to guarantee "dead man" operation. The standard X-ray button supplied with the unit has the above characteristic. Contacts X51-3 and X51-4. Only a dry contact shall be connected to this input.



Warning

It is installer's responsibility to check the characteristics of the remote X-ray button. No current or voltage must pass through remote control hand switch.

Wrong connections may damage the unit.

See Chapter 7.2 for details of the connections.



7. INSTALLATION



Note

The mechanical mounting consists in fixing the unit to the wall, install the ceph arm and complete the installation with few operations. Most of the adjustments are carried out at the factory.

A single technician will be able to install the unit as the package is used to support the unit during installation.



Mechanical installation 7.1.



1)





















Remove the straps and place the packaging of the Ceph arm on the floor (Warning! Don't overturn the box to avoid damaging the contents)

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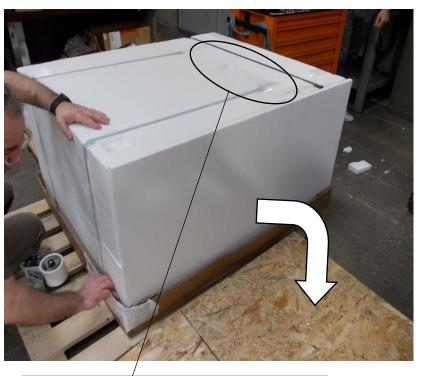




2) Remove the carton box from the packaging of the Pan machine and turn the package in the direction of the arrow, leaning on the floor.







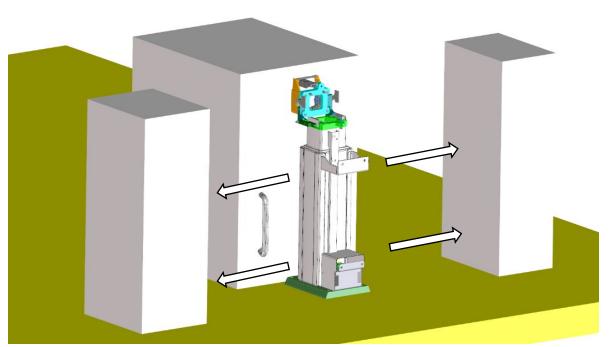
Warning! The handle compartment must be downwards after tilting



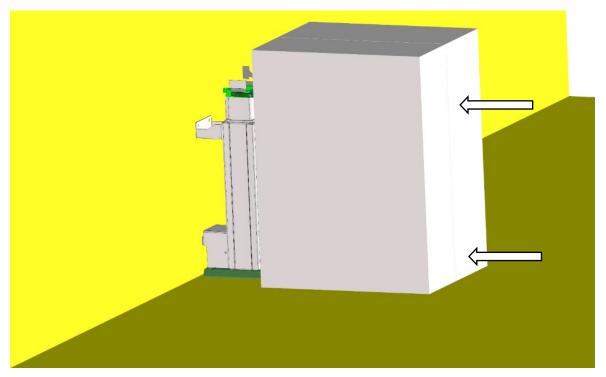
3) Cut the straps and remove the polystyrene rear sections
Owandy Radiology SAS







4) Slide the packaging to the wall in the position where the Unit will be installed

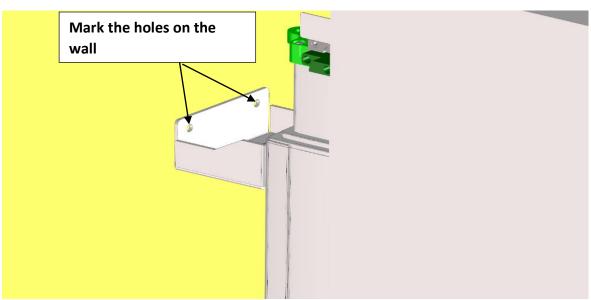


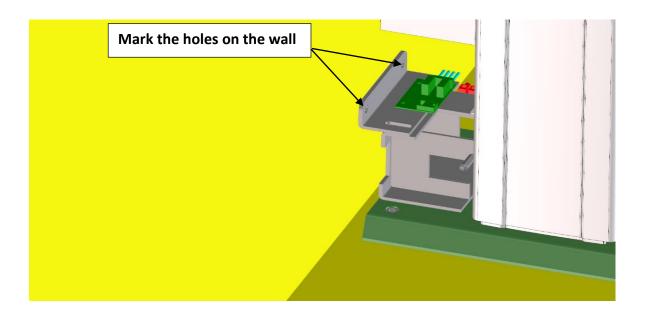
5) Push the package until the upper and lower wall bracket of the system are in contact with the wall, then mark the position of the screw holes on the wall,





alternatively, use the appropriate template to mark the holes. <u>Note: the standard fixing includes the upper and lower wall brackets, alternatively you can fix using the upper bracket and the holes in the floor base.</u>

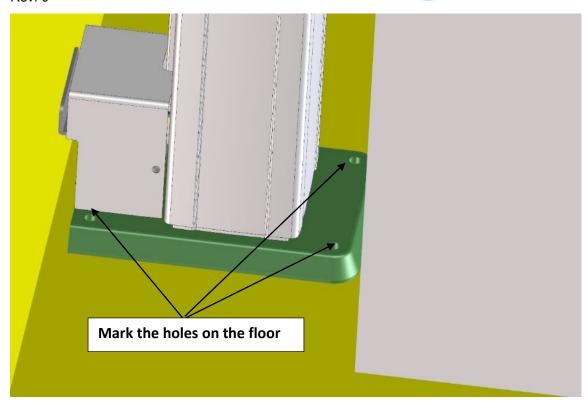




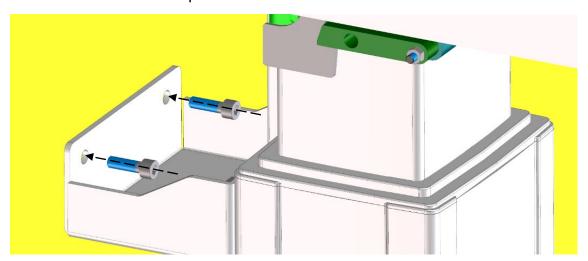
6) If necessary, mark the holes for fixing the base to the floor.

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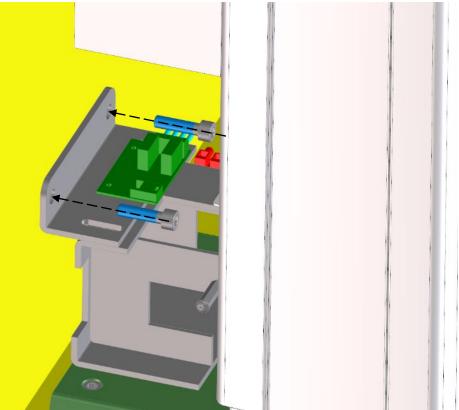


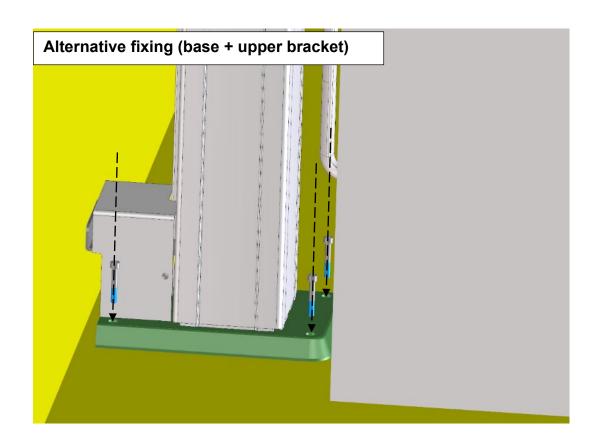
7) Move back the packaging, drill the wall and, if necessary, the floor, put the dowels, reposition the packaging against the wall and secure the wall bracket and the base plate with the screws.







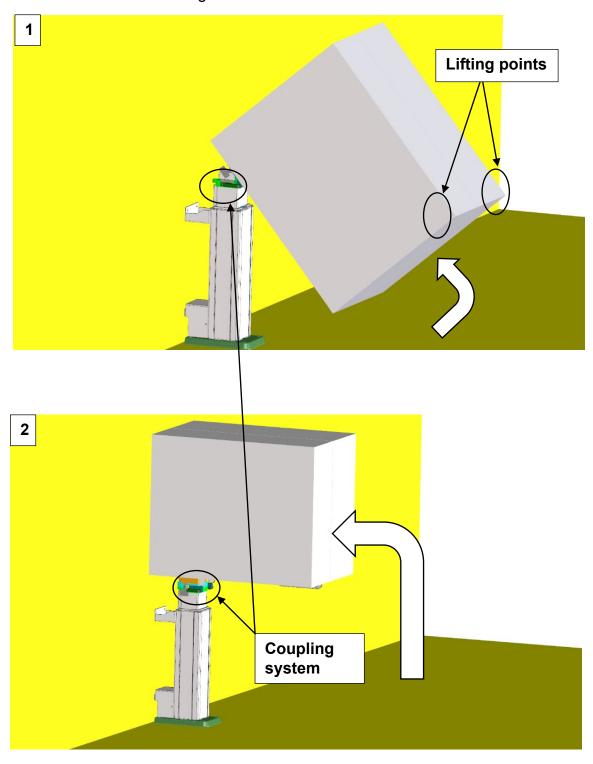






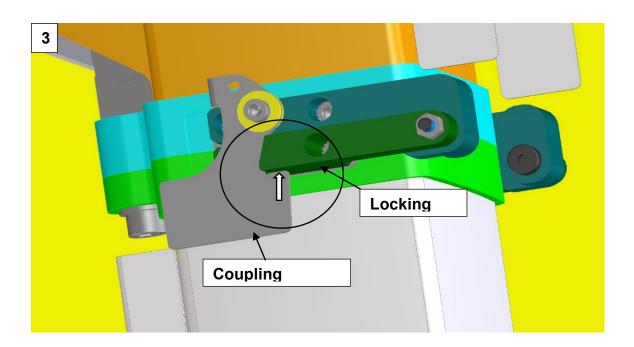
8) Grab the package and lift until the coupling system has engaged the locking bars on both sides, see figure 1-2-3-4).

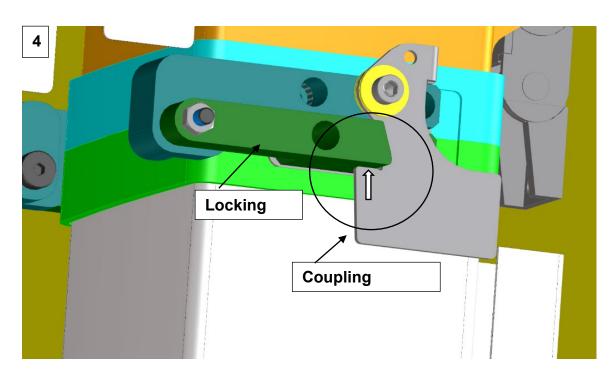
NOTE: The force necessary to lift the unit is about 20kg, so that a single technician can be enough to install the unit





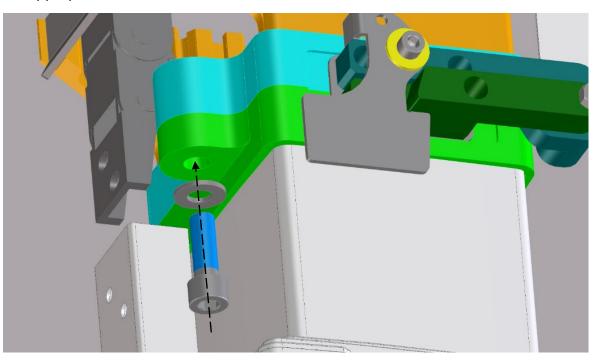




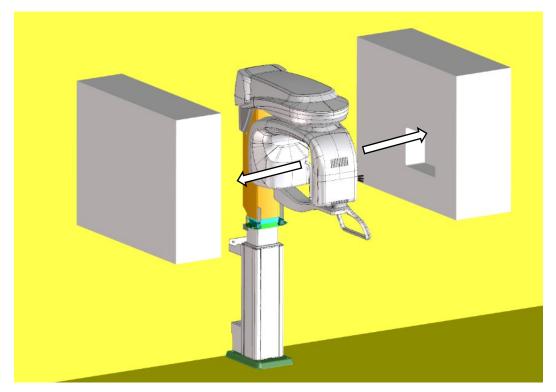




9) Lock the tilting movement of the machine head of the column with the appropriate screw



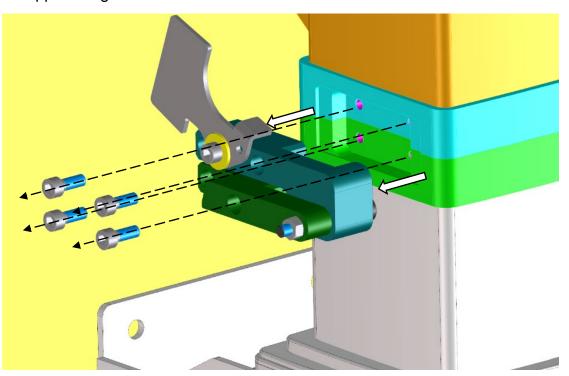
10)Cut the straps that join the two polystyrene elements and remove them. WARNING: inside the polystyrene elements, you can find the accessories of the machine and the wall plate cover)

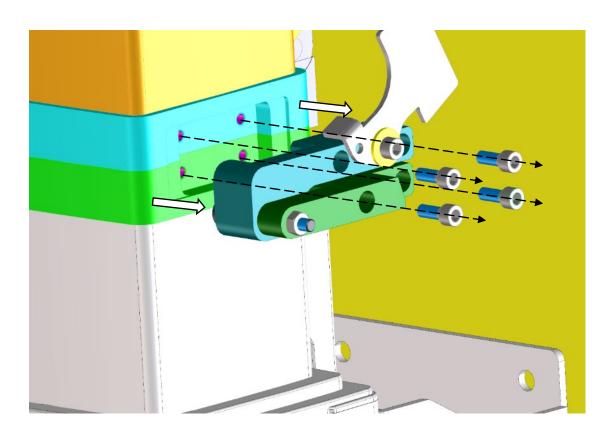






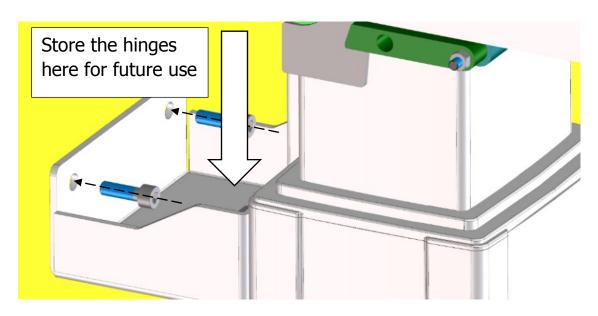
11) Remove the two hinges from the machine and store them in the upper fixing bracket of the column.



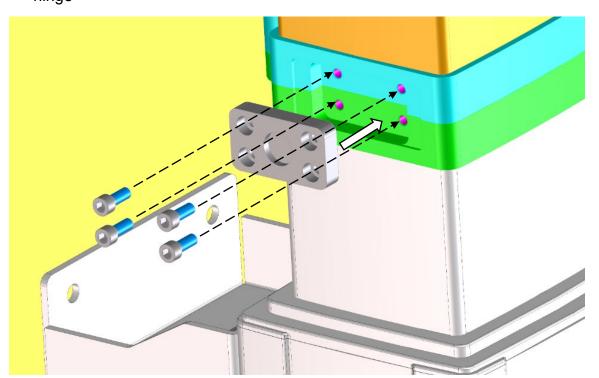




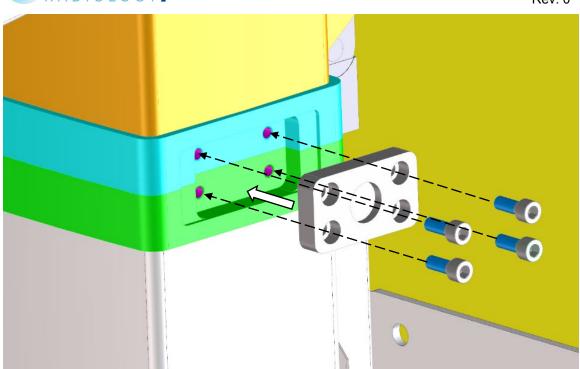




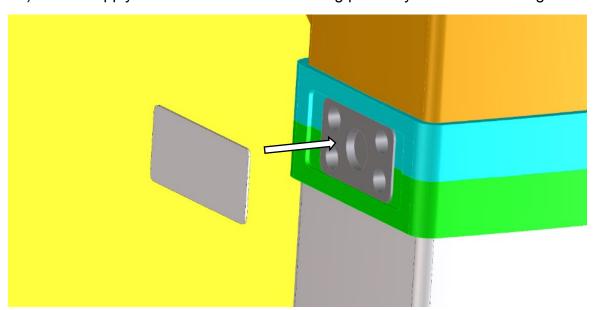
12) Fit the two joint locking plates using the same screws that fix the hinge





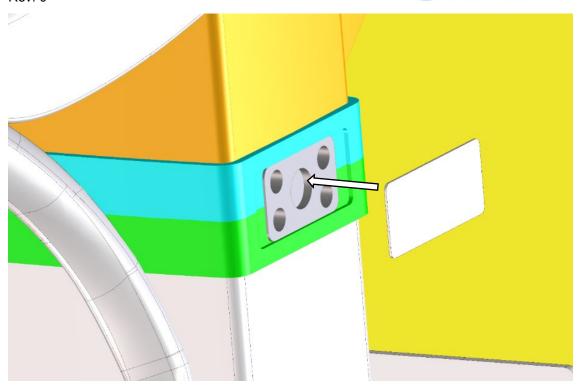


13) Apply the two covers on the locking plates by means of the magnets

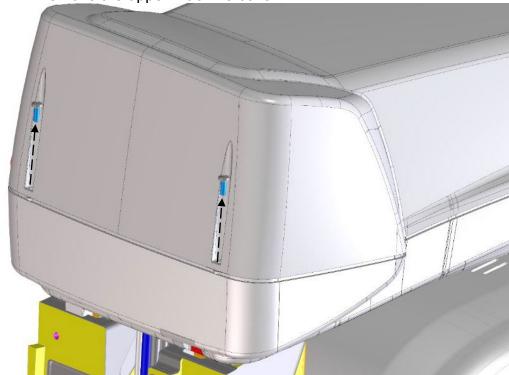


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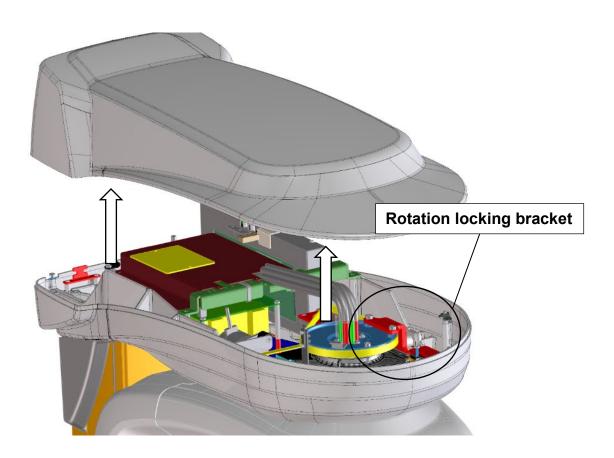


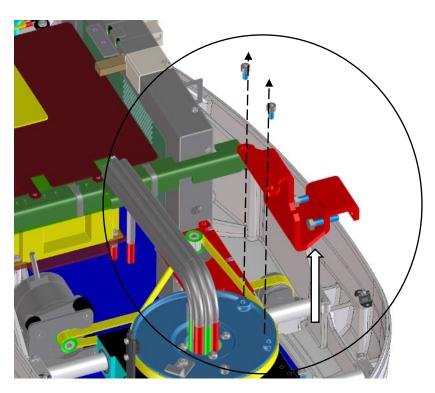






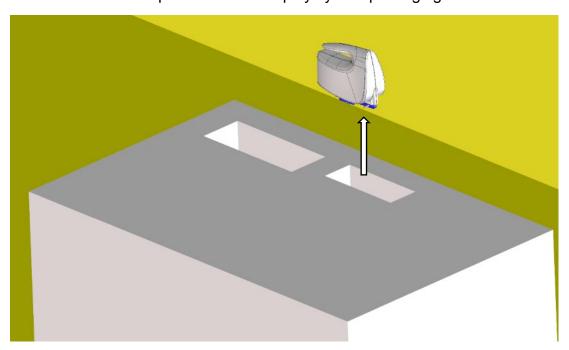
15) Remove the rotation locking bracket



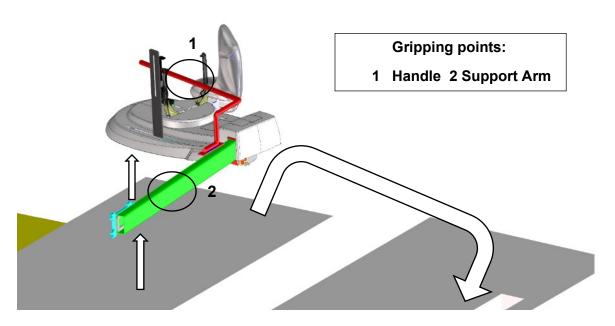




16) Remove the carton box from the Ceph package and remove the 2D sensor from the special seat in the polystyrene packaging.



17) Open the packaging and remove the Ceph arm using the handle and the support arm as gripping points. **DO NOT GRAB THE CEPH DEVICE IN ANY OTHER POINT.**



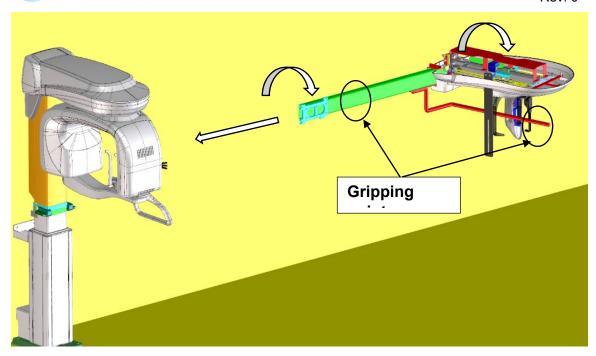
18) Using the handle and the support arm as gripping points, lift and rotate by 180 ° the Ceph arm approaching the rear of the machine.

(Warning! don't grab the arm from ceph clamps and sensor holder)

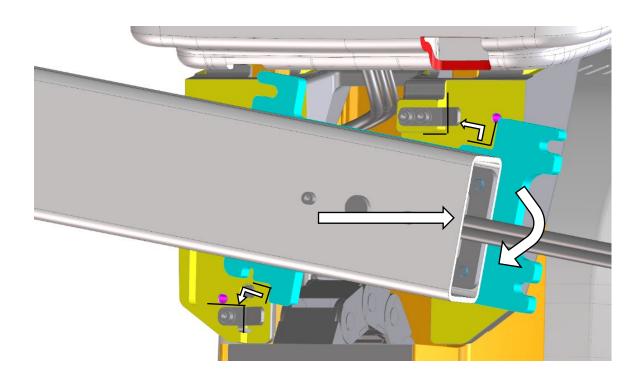






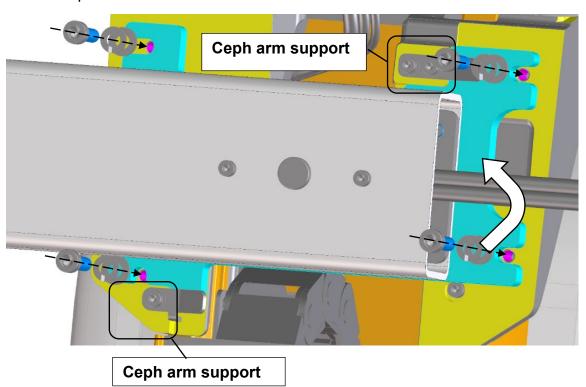


19) Insert the Ceph arm in its seat making the movement described in the following images

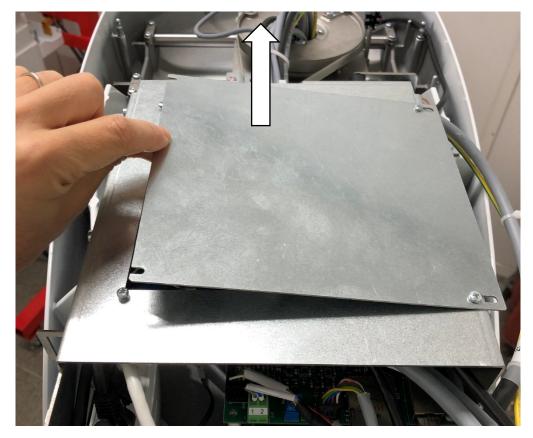




20) Put the Ceph arm in contact with the appropriate supports, then fix the Ceph arm to the machine with the screws and washers.



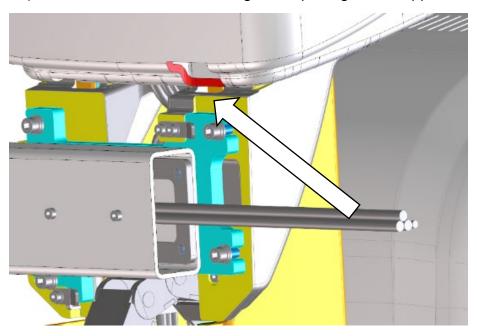
21) Remove the fire protection plate on top of the electronic boards



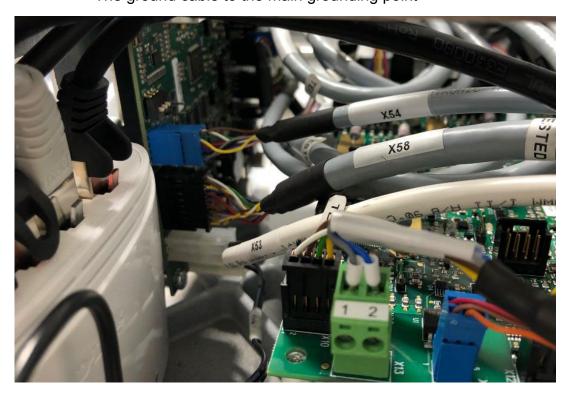




22) Pass the cables through the opening on the upper structure:

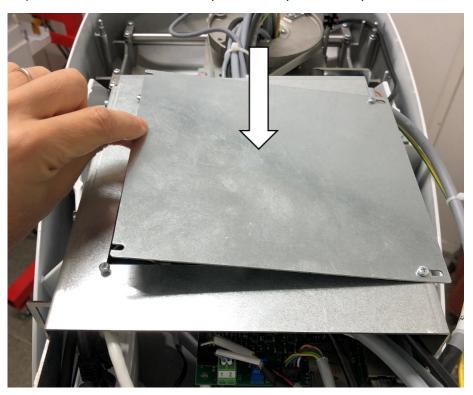


- 23) Connect the cables inside the fixed arm as follows:
 - X53, X54, X58 to the CCU board (A11)
 - The ethernet cable to the Ethernet switch
 - The ground cable to the main grounding point

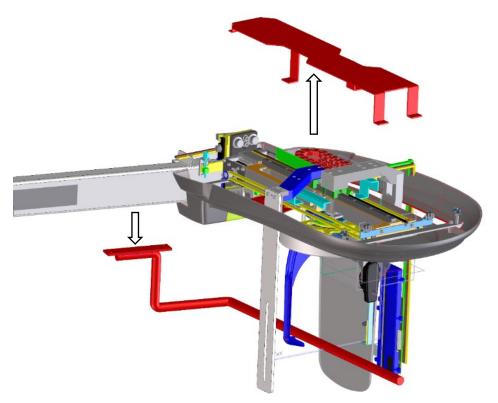




24) Reinstall the fire protection plate on top of the electronic boards



25) Remove the transport handle and the transport protection plate







7.2. Electrical connections

All external connections are located in the base of the unit.

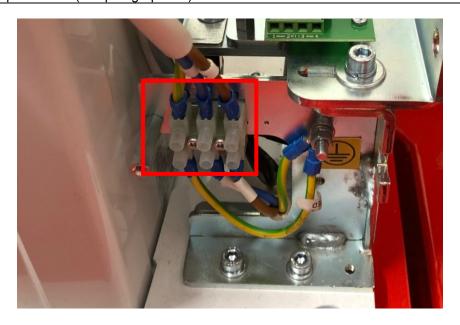
Mains Power Supply

The mains line shall be connected to the terminal block on the right side of the unit. The power supply cable is already connected inside the I-Max. It is only necessary to connect it to the dedicated power supply line.

1

Note

Before to connect main power supply, be sure that the main provided by the Customer is according to specification in terms of voltage, line resistance and safety protections (see paragraph 6.4).



X-RAY buttons:

Connections are located on the left side of the unit.

The main x-ray button shall be connected to X51-1 and X51-2.

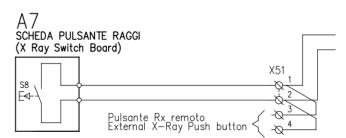
An external pushbutton can be connected so that the operator can start exposure from outside the exam room. It is mandatory to use a **MOMENTARY pushbutton** in order to guarantee "dead man" operation. The standard X-ray button supplied with the unit has the above characteristic. Contacts X51-3 and X51-4. Only a dry contact shall be connected to this input.



Warning

It is installer's responsibility to check the characteristics of the remote X-ray button. No current or voltage must pass through remote control hand switch. Wrong connections may damage the unit.





Internal button

External button

X-ray pushbuttons connection, located on the left side of the unit base.

External signaling lights.

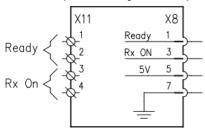
Connections are located on the right side of the unit.

- **READY light**: The signal is active when the unit is ready to perform the exam. Normally Open dry Contact, maximum load 24V, 40W. Contacts X11-1 and X11-2
- X-RAY ON light: The signal is active during X-Ray emission. Normally Open dry Contact, maximum load 24V, 40W. Contacts X11-3 and X11-4

The unit only provides dry contacts only. Power supply for the relevant devices has to be provided externally, making sure not to exceed the indicated ratings.



A8 SCHEDA SEGNALAZ. EXT. (External Signal Board)



- X11-1 / X11-2 contact closed when unit is ready
- X11-3 / X11-4 contact closed during X-ray emission



Warning lights connections, located on the right side of the unit base.

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Ethernet connection to the PC.

Connection is located on the left side of the unit.

• Ethernet detector and and system interface: point-to-point connection from the unit to the host PC.



A Cat 6 cable (5m long) is supplied with the unit. In case longer cables are needed, make sure the cable is Cat 6 or better.



Note

The ethernet cables shall be connected **DIRECTLY** to the corresponding ethernet port on the host PC. Connecting the cable to the local area network or to ethernet hubs will compromise the unit functionality.



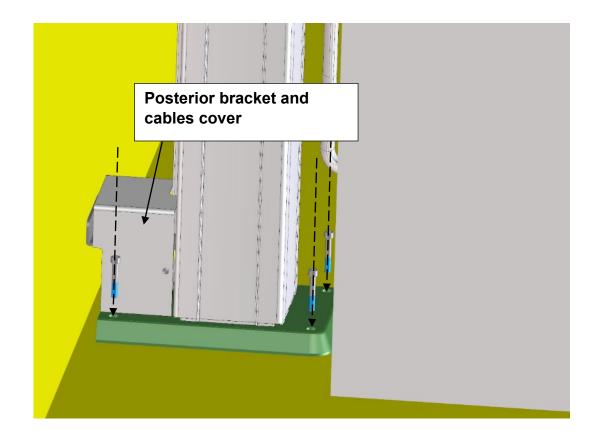
7.3. How to mount the covers



Note

Cover mounting is easier with the unit powered ON, mainly to move lift.

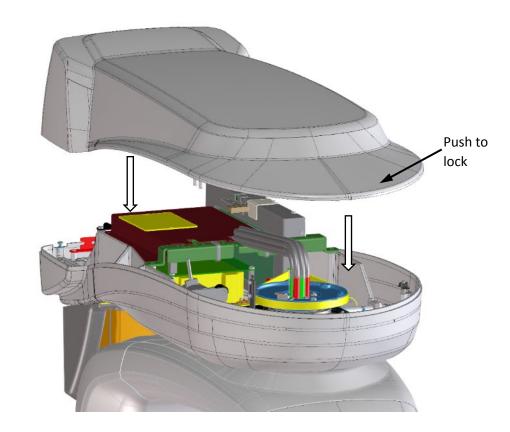
Wall plate cover

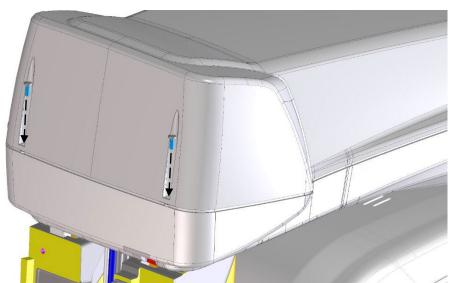






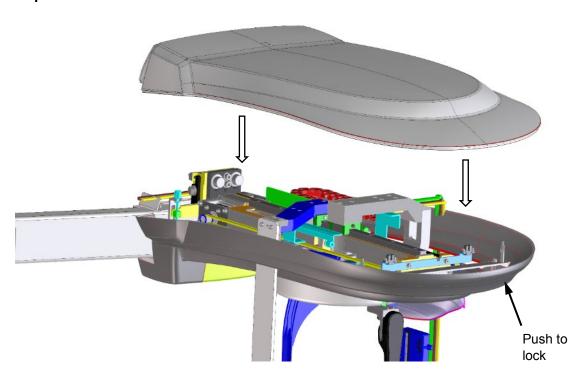
Upper cover



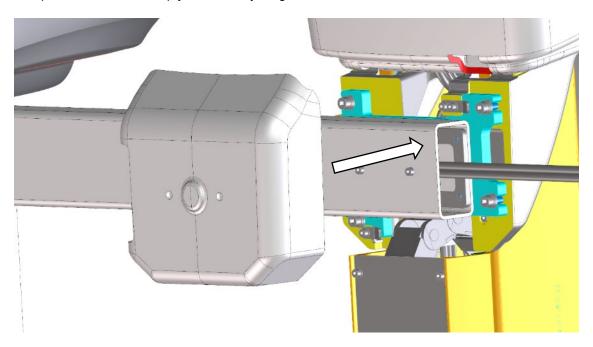




Ceph arm covers



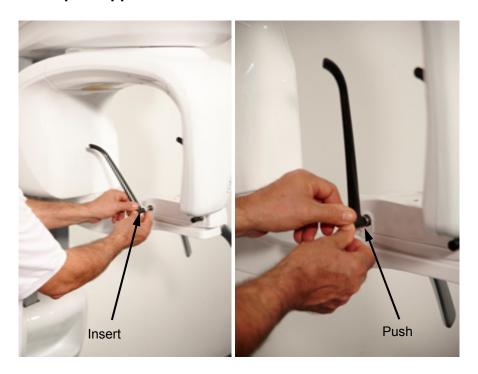
The posterior cover is simply attached by magnets.







7.3.1. **Temple supports**



Make sure that the convex side of the temple wands are facing inside and in contact with the patient.



7.4. PC configuration

7.4.1. Network Interface card configuration

In order to connect the I-Max to the PC it is necessary to configure the properties of the dedicated Network Interface Card in the PC following the procedure described below.

 Go to Control Panel > Network and Internet > Network and Sharing Center > Change adapter settings.

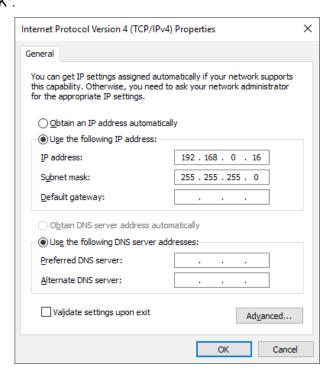


- Plug the Ethernet cable **DIRECTLY** to a giga-ethernet port of the PC. Connections through a network switch is not allowed.
- Switch on the unit. The network adapter connected to unit will become active.



- Right click on it and select "Properties".
- Select the item "Internet Protocol Version 4" and click on "Properties". Configure the IP address as follows:

IP address: 192.168.0.16Subnet Mask: 255.255.255.0 and then click "OK".





| ① | Note In any case to set the network card IP address avoid using the following values: • | 12 · |
|---|--|------|
| | 68.0.10 and 192.168.0.11 that are dedicated to the hootloader of MCLL: | and |
| | • | 2.1 |
| | 68.0.211 dedicated to MCU board. | |
| | •19 | 2.1 |
| | 68.0.99 dedicated to pan/ceph detector | |

 To check that the connection is properly configured, with the unit ON, run a command prompt and type "ping 192.168.0.211". Press Enter and verify that the unit replies to the ping as shown in the figure below.

```
Administrator: Command Prompt

Microsoft Windows [Version 10.0.14393]
(c) 2016 Microsoft Corporation. All rights reserved.

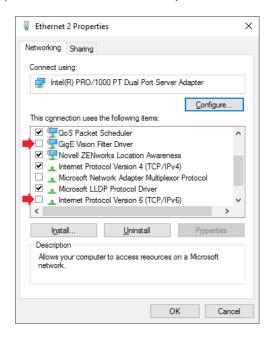
C:\WINDOWS\system32>ping 192.168.0.211

Pinging 192.168.0.211 with 32 bytes of data:
Reply from 192.168.0.211: bytes=32 time<1ms TTL=64
Ping statistics for 192.168.0.211:

Packets: Sent = 4, Received = 4, Lost = 0 (0% loss),
Approximate round trip times in milli-seconds:
Minimum = 0ms, Maximum = 0ms, Average = 0ms

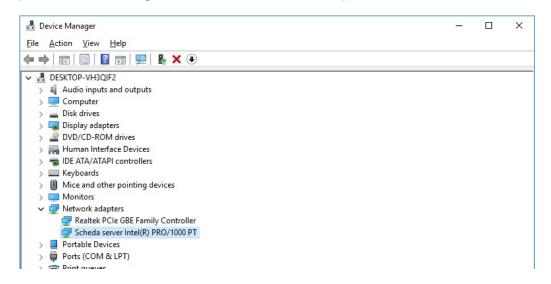
C:\WINDOWS\system32>
```

If the ping does not reply, unflag the items "GigE Vision Filter Driver" and "Internet Protocol Version 6" from the properties of all the network adapters.

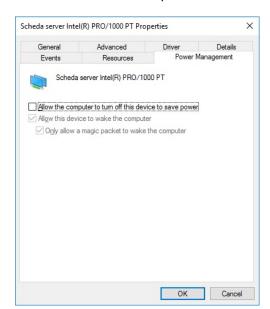




Open the Device Manager, double click on "Network adapters" to see the list of devices.



 Double click on the network card. Select the "Power Management" tab and unflag the box "Allow the computer to turn off the device to save power".







7.5. Software installation



Note

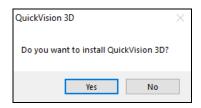
The windows user must have an administrator profile.

QuickVision requires that Windows 7, 8 or 10 is already installed on your computer and correctly configured.

- 1. Close all the running applications.
- Insert the USB pen drive or CD/DVD media. In case of USB pen drive, open the partition "SETUP" and double click on "Autorun.exe". In case of CD/DVD, the Installation wizard starts automatically, if this does not happen, double click on "Autorun.exe" at the root of the disc. In both cases, the window below opens:



- **3.** Click on "QuickVision" icon. The installation program starts; go through the installation procedure.
- **4.** At the end of QuickVision installation, a pop-up window will open asking to install "QuickVision 3D".



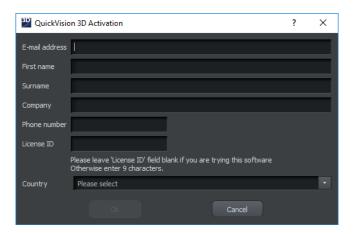
Confirm to proceed with the installation.





Note

When you open for the first time QuickVision 3D program, an activation window will be opened:



Fill with your data and press "Ok".

The activation of the program requires Internet connection.

- **5.** At the end of QuickVision 3D installation, click on "I-MAX ceph icon on the main QuickVision installation window to start drivers and utility software installation. Confirm until the installation is completed.
- 6. To check that the installation is correctly completed, open QuickVision, click on "Set up" icon and verify that in the digital panoramic field Owandy I-MAX is selected and click on save icon then click on "Mouth" icon (see arrow) and then on keyboard symbol (see circle) to open Virtual Keyboard of the unit.

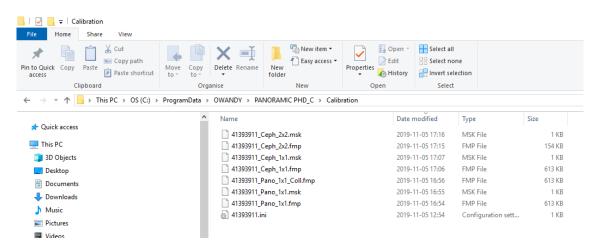




7.6. Detector Calibration files installation

Before starting unit operation, it is necessary to copy all the detector calibration files in the PC. Insert the USB pen drive or CD/DVD media containing the detector calibration files and open it. In case of USB pen drive, open the partition "CALIBRATION" and double click on "Install.bat". In case the automatic copy fails, copy all the files inside the folder "Calibration" in the directory C:\ProgramData\OWANDY\PANORAMIC PHD_C\Calibration (create the directory "Calibration" if not present).

In case of CD/DVD, copy all the files contained in the media support and paste them in the directory C:\ProgramData\OWANDY\PANORAMIC PHD_C\Calibration (create the directory "Calibration" if not present).





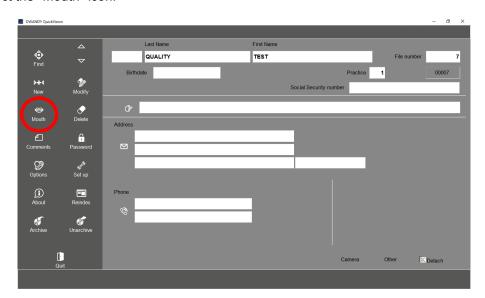
7.7. Verification of the PANORAMIC function



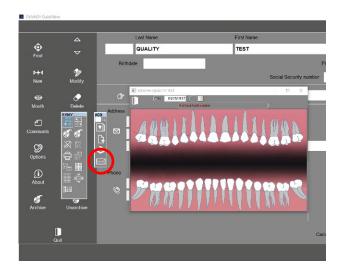
Warning

X-rays will be emitted during the performance of the following operations. Authorized Technicians are therefore recommended to use the greatest caution and to comply with the safety regulations and laws of their country.

- 1. Switch ON the unit and when the green LED starts blinking, press >0< button to perform axis reset.
- **2.** Open QuickVision software and open the patient "Quality Test". If not present, create a new patient (Name: "Quality"; Family name: "Test").
- 3. Select the "Mouth" icon.



4. From the "ACQ" toolbar, select the GUI icon to open the virtual keyboard.





5. Mount the centering tool on the support plate, and place it on the chin rest support.

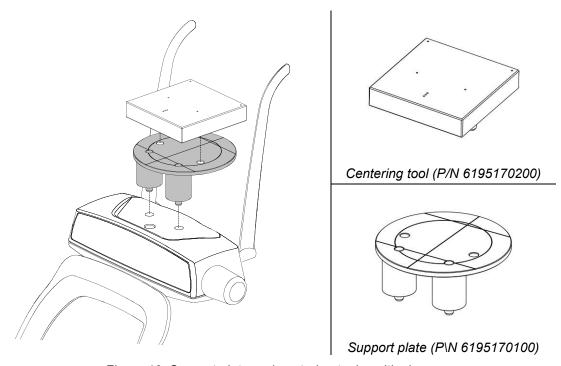
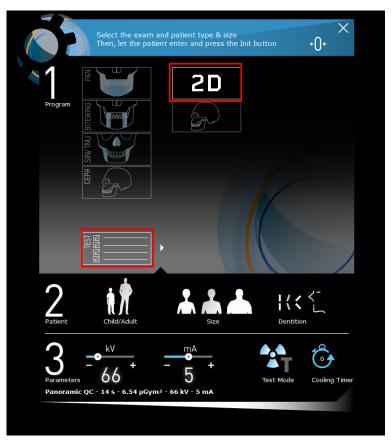


Figure 10: Support plate and centering tool positioning

6. On the main menu of the virtual interface, select "Test" exam, the following image will be displayed:

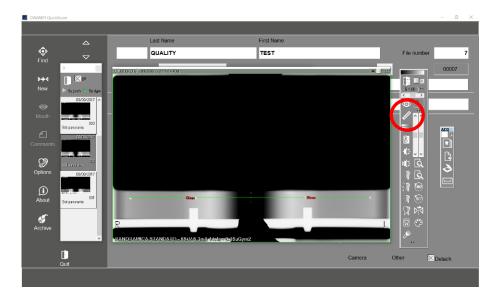








- 7. Select "2D" exam.
- 8. Make an exposure at 66kV, 6.3mA (see User's Manual chapter 9).
- **9.** Select the "Ruler" icon and measure the distance between the two external spheres; this value must be 168mm ± 2mm.



- **10.** If distance is outside the tolerance range, enter the service menu (see chapter 8) and adjust the Y axis offset (see paragraph 1.1) accordingly. Repeat the exposure.
- **11.** Measure also the two half of the image in order to check symmetry. The difference has to be max. 2mm.
- **12.** If distance is outside the tolerance range, perform the following test:
 - Visually check that the rotation offset is properly configured. This can be done by checking the laser alignment with the support plate as described in the User Manual, paragraph "Laser Alignment check"
 - If the rotation offset is correct, enter the technical setup and adjust the chin rest offset (see paragraph 1.1).

Repeat the exposure.

7.8. Verification of Ceph function

For adjustments of ceph device, see Chapter 11.2.9

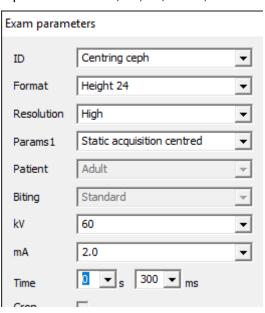


Warning

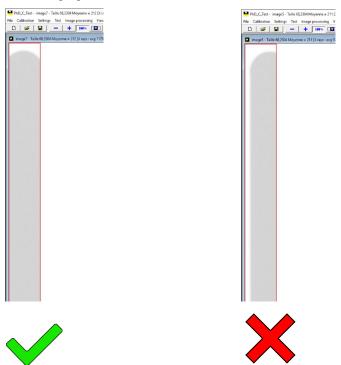
X-rays will be emitted during the performance of the following operations. Authorized Technicians are therefore recommended to use the greatest caution and to comply with the safety regulations and laws of their country.



- Switch ON the unit and when the green LED starts blinking, press >0< button to perform axis reset.
- 2. Open "PhD_C_Test.exe" service program (C:\Program Files (x86)\OWANDY\PANORAMIC PHD_C). See also Chapter 8.4for details).
- 3. In Exam parameters window select: ID: Centring Ceph; Format: Height 24; Resolution High; Params1: Static Acquisition Centered; kV; 60; mA: 2; time: 300ms



4. Take an X-ray emission and verify that the x-ray field is centered in the sensor area as shown in the following figure



NOTE to better view the sensor area, zoom in by clicking 2 times on the + icon in the program bar



- 5. If not centered adjust the offset according to paragraph...
- **6.** If the x-ray beam is properly centered open QuickVision software and open the patient "Quality Test". If not present, create a new patient (Name: "Quality"; Family name: "Test").
- 7. Select the "Mouth" icon.



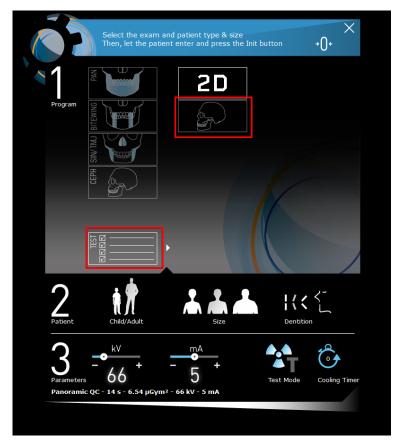
8. From the "ACQ" toolbar, select the GUI icon to open the virtual keyboard.



- 1. Remove any object (e.g. centering tool) from the chin rest.
- 2. Rotate the ceph head support in the lateral position
- 3. On the main menu of the virtual interface, select "Test" exam, the following image will be displayed:



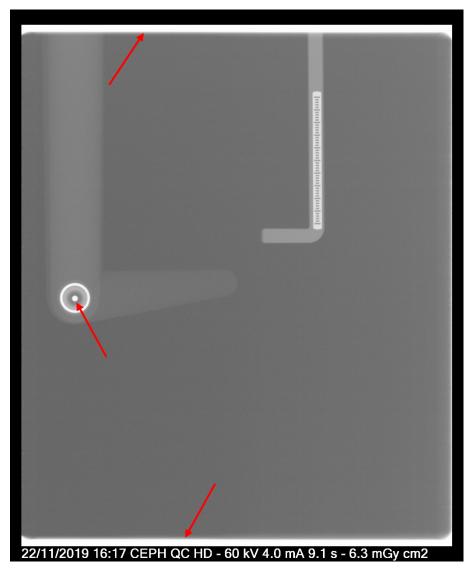




- 4. Select "Ceph" exam.
- 5. Prepare the machine to take a ceph exam.
- 6. Take an exposure at 60kV, 4mA.
- 7. In the acquired image using the QuickVision ruler verify:
 - In the ear centering pin: that the misalignment between the inner dot and the outer circle is not more than 1.5 mm
 - that the unexposed upper and lower border is 3mm +/-2mm







9. If distance is outside the tolerance range, enter the service menu (see chapter 8) to correct the problem.





7.9. Verification of exposure parameters

The exposure parameters (kV, time and dose) can be checked using two different methods:

- "invasive method" based on the measurement of the test points on HF board (requires the use of multimeter and oscilloscope for time) This method is tipically used during verification done by technical service engineers
- "non-invasive method" based on measurement with Dose meter. This is the typical method used by Physicist to verify periodically the unit

In order to make easier the exposure parameters measurements, I-Max has a dedicated modality that allows X-ray exposure without rotating the arm and without exposure parameters modulation that typically occurs in a standard exam.



7.9.1. Verification of Exposure parameters with invasive method

The exposure parameters (kV, mA and exposure time) can be measured directly on the Generator board (A2); this method has higher accuracy than the so-called non-invasive mode. The system accuracy is guaranteed by this measuring method.



Warning

By removing the HF group covers, internal parts where high voltage is present become accessible.

The Generator board has a working voltage of about 400V.

The exposure parameters can be checked with the following procedure:

- 1. Turn OFF the system.
- 2. Remove the cover on the back of the generator and remove the protection grid of the HF board.
- **3.** Identify the test point XJ8.

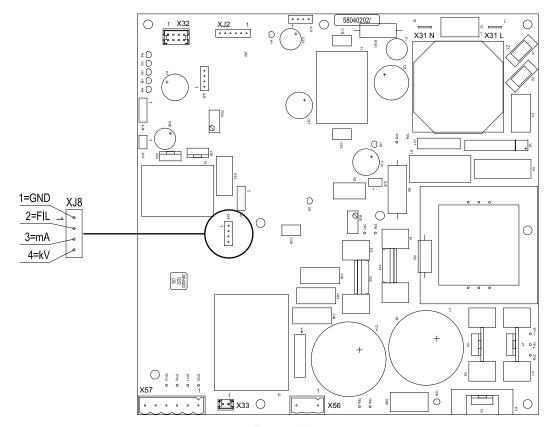


Figure 11



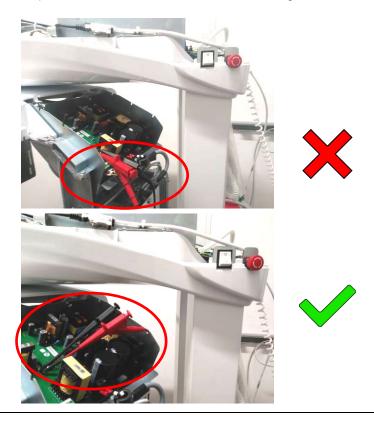
4. Place the clips of the instrument on the relevant pins according to the measurement to be performed as described in the following table, having care to avoid short circuits.

| Parameter | Instrument | XJ8 pins |
|-----------|----------------------------|---------------------|
| kV | Multimeter or oscilloscope | PIN 1 → GND |
| | | PIN 4 → kV feedback |
| mA | Multimeter or oscilloscope | PIN 1 → GND |
| | | PIN 3 → mA feedback |
| time | Oscilloscope | PIN 1 → GND |
| | | PIN 3 → mA feedback |



Warning

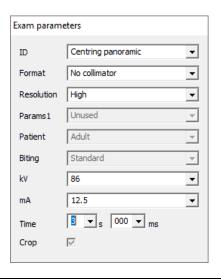
Beware that the probes do not interfere with columns during the rotation of the arm.



- **5.** Switch ON the system and as soon as the green led starts blinking, press >0< for initialization.
- **6.** Open the PhD_C_Test software (located at C:\Program Files (x86)\OWANDY\ PANORAMIC PHD_C) and check that the unit is connected to the PC (the message "MCU is connected" is displayed in the bottom left corner of the program window).



7. From the "Exam parameters" panel select the ID as "Centring Panoramic". Select format as "No collimator".

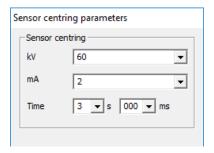




lote

The "Centring Panoramic" choice allows you to carry out the dosimetry test without the rotation of the tube-head arm.

8. In the "Sensor centring parameters" panel set the following exposure parameters: 60kV, 2mA, 3s.





Warning

The following operations involve the emission of X-rays, so the Authorized Technician must pay the greatest attention and respect the protection regulations in force in that country.

- **9.** Press the X-ray button to take an exposure and verify that the measured values are in the acceptance limits listed in the Table at point 10.
- **10.** Take a second exposure setting the following parameters: 86kV, 12.5mA, 3s and verify that the measured values are in the acceptance limits listed in the following table.

| Р | aramete | er | Acceptance range | | | | |
|----|---------|-------|--------------------|----------------------|----------------|--|--|
| kV | mA | t (s) | kV feedback (± 8%) | mA feedback (± 10 %) | Time (± 5 %) | | |
| 60 | 2 | 3 | 2.76 to 3.24 V | 0.9 to 1.1 V | 2.85 to 3.15 s | | |





| 86 | 12.5 | 3 | 3.96 to 4.64 V | 3.6 to 4.4 V | 2.85 to 3.15 s |
|----|------|---|----------------|--------------|----------------|
|----|------|---|----------------|--------------|----------------|

- **11.** In case the test fails (results do not match the indicated values), perform the following actions according to which parameter is out of the acceptance range:
 - kV out of range: follow the instructions described at paragraph 9.2.7.2
 - mA out of range: follow the instructions described at paragraph 9.2.7.4
 - time out of range: replace the generator board.



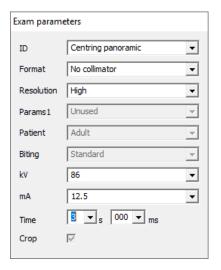


7.9.2. Verification of Exposure parameters with NON invasive method

The exposure parameters (kV, time and dose) can also be verified using the so called "non-invasive method".

The exposure parameters can be checked with a non-invasive instrument by performing the following procedure:

- 1. Place the probe of the dosimeter on the center of the sensor area (black rectangle on the sensor plastic cover).
- Open the PhD_C_Test software (located at C:\Program Files (x86)\OWANDY\
 PANORAMIC PHD_C) and check that the unit is connected to the PC (the message "MCU
 is connected" is displayed in the bottom left corner of the program window).
- **3.** From the "Exam parameters" panel select the ID as "Centring panoramic". Select format as "No collimator".

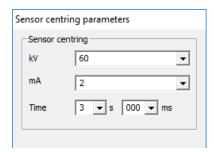




Note

The "Centring Panoramic" choice allows you to carry out the dosimetry test without the rotation of the tube-head arm.

4. In the "Sensor centring parameters" panel set the following exposure parameters: 60kV, 2mA, 3s.



5. Press the X-ray button to take an exposure and verify that the measured values are in the acceptance limits listed in the Table at point 6.









6. Take a second exposure setting the following parameters: 86kV, 12.5mA, 3s and verify that the measured values are in the acceptance limits listed in the following table.

| Parameter | | | Acceptance range | | |
|-----------|------|-------|----------------------|------------------------|--|
| kV | mA | t (s) | kV acceptance limits | Time acceptance limits | |
| 60 | 2 | 3 | 55.2 to 64.8 kV | 2.85 to 3.15 s | |
| 86 | 12.5 | 3 | 79.1 to 92.8 kV | 2.85 to 3.15 s | |

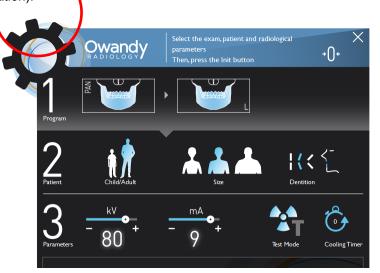
- 7. In case the test fails (result do not match the indicated values), proceed with the following actions:
 - Check the probe position and repeat the test
 - If the values are still out of range, perform the test using the invasive method as described in paragraph 7.10.1.



7.10. Storing of automatic exposure parameters

The preset exposure parameters of each specific exam can be modified according to the user's needs.

In order to modify the default exposure parameters, from the Main Menu select the symbol GEAR (configuration).

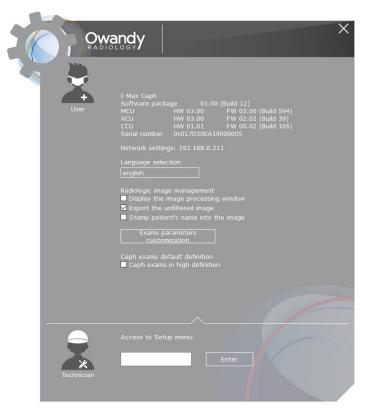


The following window will be displayed:

Select the button "Exam parameter customization".

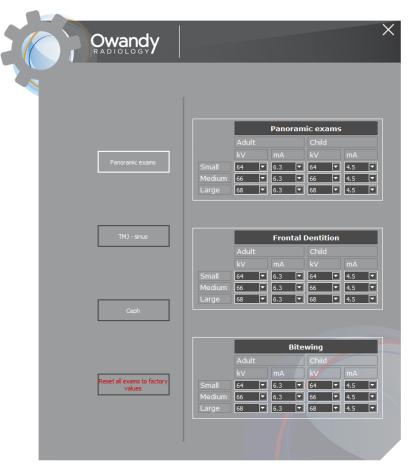






On the displayed window, use the buttons on the left to select the exam family and the tables to the right to customize the default parameters for each exam type, patient type and size.





At any time, it is possible to restore the factory preset for all the exams, clicking on the button on the bottom of the window "Reset all exams to factory values".



7.10.1. Table of pre-set anatomic parameters

| | Default exposure v | alues in 2D Pan | oramic modes | |
|--------|--------------------|----------------------------|--------------|-----------------------|
| | | Adult Patient (14 seconds) | | l Patient seconds) |
| | kV | mA | kV | mA |
| Small | 70 | 8 | 66 | 6.3 |
| Medium | 74 | 8 | 68 | 6.3 |
| Large | 76 | 8 | 70 | 6.3 |

| | Default exposu | re values in 2D S | inus mode | |
|--------|----------------|----------------------|-----------|----------------------|
| | | t Patient econds) | - | l Patient econds) |
| | kV | mA | kV | mA |
| Small | 68 | 8 | 64 | 6.3 |
| Medium | 72 | 8 | 66 | 6.3 |
| Large | 74 | 8 | 68 | 6.3 |

| | Default exposu | ure values in 2D | TMJ mode | |
|--------|----------------|-----------------------|----------|-----------------------|
| | | t Patient seconds) | 1 | l Patient seconds) |
| | kV | mA | kV | mA |
| Small | 70 | 8 | 62 | 6.3 |
| Medium | 74 | 8 | 66 | 6.3 |
| Large | 78 | 8 | 70 | 6.3 |

| | Exposure v | alues in Ceph L | L mode | |
|--------|------------|-----------------------------|--------|-----------------------|
| | | Adult Patient (4,4 seconds) | | d Patient seconds) |
| | kV | mA | kV | mA |
| Small | 74 | 8 | 72 | 7.1 |
| Medium | 76 | 8 | 74 | 7.1 |
| Large | 78 | 8 | 76 | 7.1 |

| | Exposure v | alues in Ceph Al | P mode | |
|--------|-----------------------------|------------------|--------------------------------|----|
| | Adult Patient (5,8 seconds) | | Child Patient (5,8 seconds) | |
| | kV | mA | kV | mA |
| Small | 76 | 12.5 | 74 | 11 |
| Medium | 78 | 12.5 | 76 | 11 |



Large 82 12.5 78 11

| Exposure values in Carpus mode | | | | | |
|--------------------------------|-----------------------------|----|--|--|--|
| | Child Patient (4,4 seconds) | | | | |
| | kV | mA | | | |
| Small | 62 | 8 | | | |
| Medium | 62 | 8 | | | |
| Large | 62 | 8 | | | |

(!)

Note

The exam parameters set as the default are values to be taken as the starting point. Users can optimise the parameters according to their needs.



Note

The type of biting does not affect the kV and mA values, but it affects the position of the focus layer, by adapting rotation movement to the patient's anatomy.





7.11. Data Backup

At the end of installation process, make sure that the following information and data are safely archived:

- IP address of the I-Max unit
- Setup Parameter Table containing the factory configuration
- Detector calibration files / Software installation CDs or USB pen drive media.

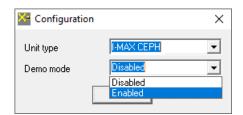
7.12. Exhibition mode setup

The I-Max system (unit and graphical user interface) provides three different demonstration modes in case it is to be used as demo (exhibitions or show room) where the X-ray emissions are not allowed.

7.12.1. Graphical User Interface (G.U.I.) demo (without unit connected)

The following procedure allows the demonstration of the Graphical Unit Interface (G.U.I.) without connection to the unit.

- **1.** Open "PhD_Conf.exe" program in C:\Program Files (x86)\OWANDY\ PANORAMIC PHD_C.
- 2. On the "Configuration" window select "Demo mode" as "Enabled":



Confirm with "OK".

3. Start QuickVision program and open the G.U.I. The user interface (G.U.I.) will work normally without the unit connected.



Note

In order to restore the normal functioning of the unit interface: close the G.U.I., open "PhD_Conf.exe" program and select "Demo mode" as "Disabled"; confirm with "OK" to restore the normal functioning of the interface.



7.12.2. Unit movements demo (without PC connection)

The following procedure allows the simulation of the panoramic exam movements without connection with the PC.

With this setting is possible to perform a single exam simulation or activate an automatic continuous movements program.

Set the MCU DIP-Switches to "Exhibition demo mode": ON-OFF-ON (see paragraph 4.3.2.1)





Note

In this mode the X-ray emissions are disabled and it is not possible to connect the unit to a PC.

7.12.2.1. Single exam simulation

- Switch ON the unit.
- 2. When the keyboard green LED blinks slowly (one pulse per second), press the >0< button and wait the end of the axis reset.
- **3.** To take a panoramic simulation press the >0< button and wait the end of the movements.
- **4.** Press the X-ray button until the end of the panoramic rotation.
- **5.** At the end of the rotation press the >0< button and the unit come back to the start position ready for another panoramic exam simulation.
- **6.** To take a ceph simulation move the sensor to ceph position, press the >0< button and wait the end of the movements.
- 7. Press the >O< button and wait the end of the movements.
- **8.** Press the X-ray button until the end of the ceph exam simulation.
- **9.** At the end the machine returns back to the patient entry position.





7.12.2.2. Automatic continuous movements program (Exhibitions)

- **1.** Switch ON the unit.
- 2. When the keyboard green LED blinks slowly (one pulse per second), press the >0< button and wait the end of the axis reset.
- **3.** Press together the column up and column down buttons on the keyboard.
- **4.** After 5 second release both buttons to start the automatic demo sequence.
- **5.** The unit then keeps on doing a demo sequence of a panoramic roto-translation, a ceph movement and a column movement.
- 6. In order to stop the movements, switch OFF the unit.



Note

To stop the column movements, press the red emergency button located on the upper part of the unit, near the power switch.



7.12.3. Unit and G.U.I. full demonstration (X-Ray emission permanently disabled)

The following procedure allows a full simulation of the unit and G.U.I. functioning without X-Ray emission (connection the PC required).

- 1. Enter service menu (see chapter 8).
- 2. Select the "Exposition" page (see paragraph 8.2).
- 3. Check "Disable permanently X-ray emission" box.
- **4.** Click on the gear and save the new configuration in the EEPROM memory.
- **5.** Wait the unit reboot and use the G.U.I. and unit normally; the system will perform the exam without the X-Ray emission.



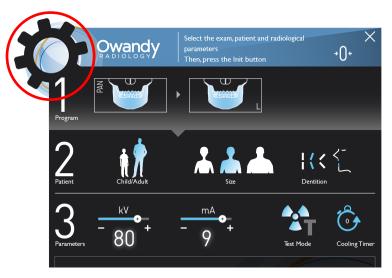


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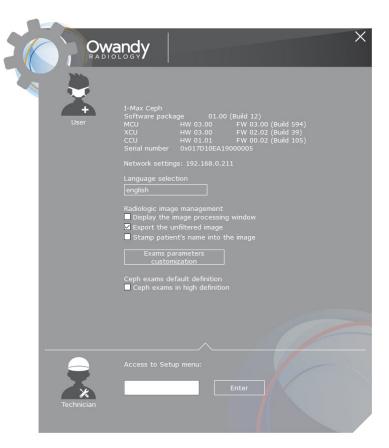


8. SERVICE PROGRAMS DESCRIPTIONS

In order to access Service Programs, from the main menu select the GEAR symbol (configuration).



The first page of the configuration window shows the SW versions present in the unit. This is useful in case it is required to know the current versions. This page doesn't require any password.





In order to enter in Configuration menu, type the password "TechAccess" in "Access to Setup menu" filed and press Enter.

This page is reserved only to authorized technicians: it allows access to the different functional parameters, as following:

- Network Setting: allows to set the IP address of the unit (see paragraph 8.1)
- Exposition: allows to disable the x-ray emission permanently (see paragraph 8.2)
- Logs: this page displays the exam counters (see paragraph 8.3)

Each time a parameter is modified, the unit will provide a confirmation window.





8.1. Network setting

Selecting "Network Setting" it is possible to modify the IP address used to communicate with the I-Max (see paragraph 11.2.8).



If necessary, change the IP Address according with the one present on the PC (same IP, but last 3 digits different; same Subnet mask).



8.2. Exposure inhibit and adjustment

This function allows:

- to disable X-ray emission permanently checking the box to disable X-rays;
- to set a corrective factor in % on the displayed DAP dose per area value.





8.3. Logs

In this page it is possible to see the exam counters and access the machine logs folder.



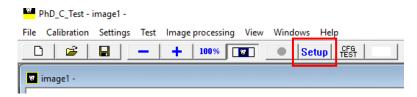
In order to keep the unit logs, refer to paragraph 11.2.1.

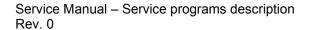
8.4. Machine configuration and setup

In addition to the Service Programs available in the Graphical User interface, other Service Programs and the machine configuration can be be done by running the **"PhD_C_Test"** program located in the directory C:\Program Files (x86)\OWANDY\PANORAMIC PHD_C.

To access the machine configuration:

- Run the software "PhD_C_Test"
- Click on the SET-UP button and in the windows that will open type the password PhdAccess.

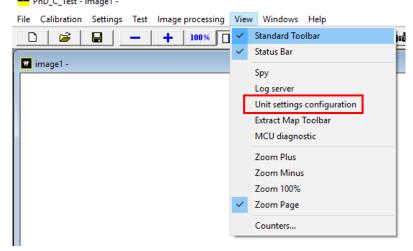




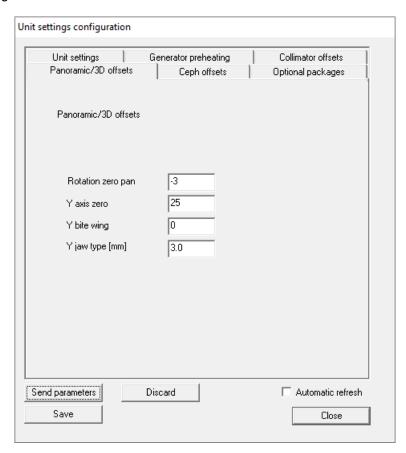




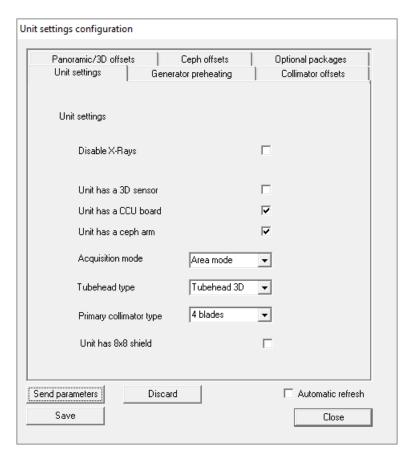
In the View menu select Unit Setting configuration
 PhD_C_Test - image1 -

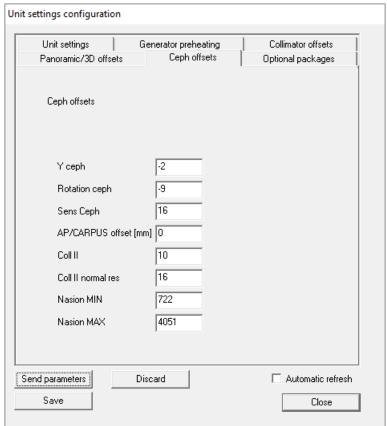


 The following window will open; there are several different tabs for different system settings







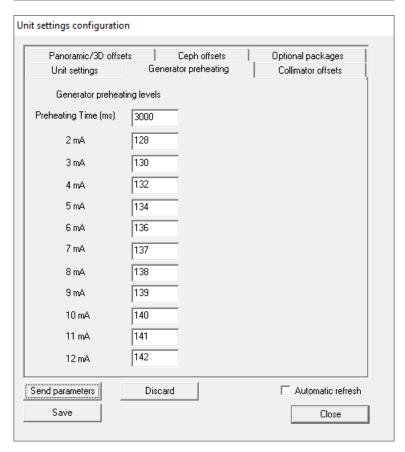




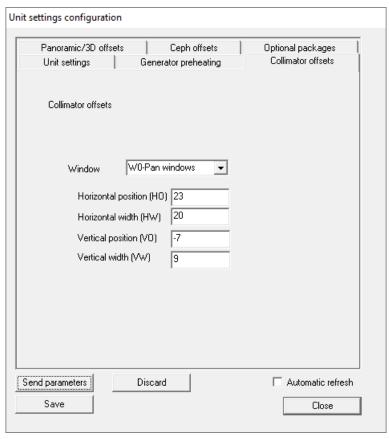
Service Manual – Service programs description Rev. 0



| Unit settings Panoramic/3D offsets | Generator preheating Ceph offsets | Collimator offsets Optional packages |
|---------------------------------------|--|---|
| Optional packages ac | tivation | |
| XP exams activation I | key 554C4CF655480511 | Enabled |
| Extended volumes ke | 55555555555555555555555555555555555555 | Disabled |
| | | |
| | | |
| 4 | | |
| d parameters | Discard | Automatic refresh |











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9. TROUBLESHOOTING



Note

If components have to be replaced or technical support is required, contact OWANDY Technical Service providing the mandatory information listed on paragraph 1.2 and the additional information required by the specific error description.

9.1. LEDs

9.1.1. MCU board A1 LEDs

The following table shows the LEDs that are present on MCU board A1, their functions and the recommended corrective actions in case of defects. To locate the LEDs, refer to the layout of the MCU board A1 (see chapter 12 - drawing 2).

| Led | Colour | Working status | Failure status | Main function | Corrective action |
|-----------------|--------|---|--|--|---|
| H1 | Green | ON | OFF | +24V | See paragraph 11.2.3 |
| H2 | Green | ON | OFF | +24V Motors and power supply | See paragraph 11.2.3 |
| H3 | Green | ON | OFF | +5V | Check cables: X22, X23, X24, X36, X15, X10, X25, X9 |
| H4 | Green | ON | OFF | + 3V Micro controller power supply | |
| H5 | Green | ON | OFF | Laser power supply | Check the laser cables X16 and X18 |
| H6 | Green | Flashing / lit weakly | Steady ON/OFF= error on CANbus | Can Bus communication | See Error E670 and E671 (paragraph 9.2.6.1) |
| H7 | Red | Flashing / lit weakly | Steady ON/OFF= error on CANbus | Can Bus communication | See Error E670 and E671 (paragraph 9.2.6.1) |
| H8 H9 H10 | Green | OFF | | These three LEDs when blinking indicate the MCU programming status | |
| H11 | Green | OFF=X-ray button not pressed ON=X-ray button pressed | OFF=X-ray button pressed ON=X-ray button not pressed | X-ray button activation | See Errors E360 and E760 (paragraphs 9.2.4.1 and 9.2.7.11) |



9.1.2. **Generator board A2 LEDs**

The following table shows the LEDs that are present on the Generator board, their functions and the recommended corrective actions in case of defects. To locate the LEDs, refer to the layout of the Generator board (see chapter 12, drawing 3).

| Led | Colour | Working status | Failure status | Main function | Corrective action |
|-----|--------|---|--|--|---|
| H1 | Green | ON | OFF = Failure | +5Vdc | See Error E750 (paragraph 9.2.7.1) |
| H2 | Green | OFF=X-ray button not pressed ON=X-ray button pressed | OFF=X-ray button pressed ON=X-ray button not pressed | X-Ray button activation | See Error E760 (paragraph 9.2.7.11) |
| НЗ | Green | Flashing / lit weakly | Steady ON/OFF= error on CAN-bus | CANbus communication | See Error E670 and E671 (paragraph 9.2.6.1) |
| H4 | Green | Flashing / lit weakly | Steady ON/OFF= error on CAN-bus | CANbus communication | See Error E670 and E671 (paragraph 9.2.6.1) |
| H5 | Red | OFF | ON | ON if during exposure there is a: - Filament failure - Backup timer intervention - Bad mA / kV feedback - X-ray button release | See Errors: E751, E753, E754, E758, E760 (paragraphs 9.2.7.2, 9.2.7.4, 9.2.7.5, 9.2.7.9, 9.2.7.11) |
| H6 | Yellow | OFF during stand-by ON during X-ray | ON during stand-by OFF during X-ray | X-ray emission active | |
| H8 | Green | ON | OFF | Auxiliary power supply | See Error E750 (paragraph 9.2.7.1) |
| H9 | Red | OFF | ON | X-ray exposure too long (backup timer intervention) | See Error E755 (paragraph 9.2.7.6) |
| H10 | Green | ON | OFF | Main power supply | See Error E750 (paragraph 9.2.7.1) |



9.1.3. CCU Ceph Control Board A11 LEDs

The following table shows the LEDs that are present on the CCU Ceph Control Board (A11), their function and the recommended corrective action in case of defect. To locate the LED, refer to the layout of the A11 board (see chapter 12 – drawing 4).

| | 1 | | | | _ |
|----------------|------------|-------------------------|--------------------------------------|--|--|
| Led | Colour | Working status | Failure status | Main function | Corrective action |
| H1, H2 | Green, Red | Flashing/ lit weakly | Steady ON/OFF= error on CANbus | Can Bus communication | Check cable X9 |
| H3 H4 H5 | Green | OFF | | These three LEDs when blinking indicate the CCU programming status | |
| H6 | Green | ON | OFF | +24 V input | Check 24V on cable X62. See also Error E750 (paragraph 9.2.7.1) |
| H7 | Green | ON | OFF | +5V | Check 24V on cable X62. If present, replace CCU board |
| Н8 | Green | ON | OFF | +3V | Check 24V on cable X62. If present, replace CCU board |
| H9 | Green | ON | OFF | +24 V output to collimator (A12) board | Check 24V on cable X62. See also Error E750 (paragraph 9.2.7.1) |

9.1.4. Collimator Driver Board A12 LED

The following table shows the LED that is present on the Collimator Driver Board (A12), its function and the recommended corrective action in case of defect. To locate the LED, refer to the layout of the A12 board (see chapter 12 – drawing 5).

| Led | Colour | Working status | Failure status | Main function | Corrective action |
|-----|--------|-------------------|-------------------|---------------|---|
| H1 | Green | ON | OFF | +5 V input | Check 24V on cable X62 of CCU board. See also Error E750 (paragraph 9.2.7.1) |

9.1.5. Ceph Driver Board A13 LEDs

The following table shows the LEDs that are present on the Ceph Driver Board (A13), their Owandy Radiology SAS

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function and the recommended corrective action in case of defect. To locate the LED, refer to the layout of the A13 board (see chapter 12 – drawing 6).

| Led | Colour | Working status | Failure status | Main function | Corrective action |
|-----|--------|-------------------|-------------------|---------------|---|
| H1 | Green | ON | OFF | +24 V output | Check 24V on cable X62 on CCU board. See also Error E750 (paragraph 9.2.7.1) |
| H2 | Green | ON | OFF | +24 V input | Check 24V on cable X62 on CCU board. See also Error E750 (paragraph 9.2.7.1) |

9.1.6. Ceph sensor power supply board A14 LED

The following table shows the LED that is present on the Ceph Sensor Power board (A14), its function and the recommended corrective action in case of defect. To locate the LED, refer to the layout of the A10 board (see chapter 12 – drawing 7).

| Led | Colour | Working status | Failure status | Main function | Corrective action |
|-----|--------|-------------------|-------------------|--------------------------|--|
| H1 | Green | ON | OFF | +12 Vsensor power supply | Check 24V on cable X62 on CCU board. Check connection X76 to CCU board. See also Error E750 (paragraph 9.2.7.1). Check pogo-pins connections |



9.2. Displayed messages

The I-Max operative states and any detected errors are signaled by the different activation of the three keyboard LEDs (see User Manual keyboard description) and by the displayed operational and error messages on the PC interface-G.U.I. (Graphical User Interface):

- Operational messages: are instructions which guides the operator in the correct use of the unit.
- **Error messages**: are displayed by the GUI and describe the last occurred error. There are two kind of errors messages:
 - 1. Messages that require a reset by clicking on OK button on the GUI and by pressing the >0< button on the unit keyboard.
 - 2. Messages that can only be reset after the turning OFF and ON of the unit.

The error messages are divided into different areas that can be distinguished by the error number; the following table contains the different errors with meanings.

| | Main MCU board | |
|-----------|--|---------------------|
| Code | Error description | Reference paragraph |
| 001 / 003 | Internal MCU error | 9.2.1 |
| 500 ÷ 505 | MCU Ethernet errors | 9.2.5 |
| | MCU EEPROM configuration | |
| Code | Error description | Reference paragraph |
| 100 / 101 | Configuration area parameter doesn't match the expected one | 9.2.2.1 |
| 102 | Wrong version number in configuration area | 9.2.2.2 |
| 103 / 104 | Timeout error occurred during an EEprom erase/write operation | 9.2.2.3 |
| | Rotation motor | |
| Code | Error description | Reference paragraph |
| 200 | Zero position optical sensor of rotation axis always activated | 9.2.3.1 |
| 201 | Zero position optical sensor never activated | 9.2.3.1 |
| 202 / 203 | Zero position optical sensor of rotation still active after exiting from zero sensor | 9.2.3.1 |
| 204 | Unexpected activation of rotation optical sensor | 9.2.3.2 |
| 205 | Timeout on rotation | 9.2.3.1 |





| | Y translation motor | |
|-----------|--|---------------------|
| Code | Error description | Reference paragraph |
| 240 | Zero position micro Y always active | 9.2.3.3 |
| 241 | Zero position micro Y never active | 9.2.3.3 |
| 243 | Timeout on Y axes | 9.2.3.3 |
| | Hardware key board (U.I.C.) | |
| Code | Error description | Reference paragraph |
| 270 / 271 | Hardware key fault | 9.2.3.5 |
| | X-ray Controls | |
| Code | Error description | Reference paragraph |
| 360 | RX button pressed on start-up or before exam | 9.2.4.1 |
| 362 | RX button released during emission | 9.2.4.2 |
| | Sensor ready | |
| Code | Error description | Reference paragraph |
| 370 | Sensor ready lost during exposure | 9.2.4.3 |
| 371 | Sensor not ready | 9.2.4.4 |

CCU Board

| Code | Error description | Reference paragraph |
|------------------|--------------------------------------|---------------------------|
| 600/601/ | | |
| 605 | CCU malfunctioning errors | 9.2.6.1 |
| 602 ÷ 604 | ceph operative errors | 9.2.6.1 |
| 606 | Nasion calibration error | Currently not implemented |
| 611 | Internal CCU error | 9.2.6.1 |
| 623 / 624 | CCU eeprom errors | 9.2.6.2 |
| 630 ÷ 635 | Sensor movement errors | 9.2.6.3 |
| 640 ÷ 645 | Secondary collimator movement errors | 9.2.6.4 |
| 650 ÷ 661 | 4 blade collimator movement errors | 9.2.6.5 |
| 670 / 671 | Can Bus errors | 9.2.6.6 |
| 680 | Ceph exam aborted | Restart the exam |

Generator Board



| Code | Error description | Reference paragraph |
|------|--|---------------------|
| 750 | Generator board initialization error | 9.2.7.1 |
| 751 | Alarm "overvoltage kV" | 9.2.7.2 |
| 752 | Alarm "overload on filament" on Generator board | 9.2.7.3 |
| 753 | Alarm "overload anodic current" | 9.2.7.4 |
| 754 | Alarm "filament not OK" | 9.2.7.5 |
| 755 | Alarm "backup timer" | 9.2.7.6 |
| 756 | Alarm "PFC not OK" | 9.2.7.7 |
| 757 | Alarm "Brown OUT" | 9.2.7.8 |
| 758 | Alarm "NO X-ray" | 9.2.7.9 |
| 759 | Alarm "unexpected emission" | 9.2.7.10 |
| 760 | Alarm "NO RX button command" | 9.2.7.11 |
| 761 | Alarm "NO X-ray emission" | 9.2.7.9 |
| 762 | Bad unit status: emission flag detected unexpectedly | 9.2.7.12 |
| 763 | kV analog feedback out of range | 9.2.7.13 |

Generator Board

| Code | Error description | Reference paragraph |
|------|--|---------------------|
| 764 | mA analog feedback out of range | 9.2.7.13 |
| 765 | Filament analog feedback out of range | 9.2.7.13 |
| 766 | Generator board reset due to a brown out | 9.2.7.8 |
| 767 | Generator board reset due to low voltage detection | 9.2.7.8 |
| 768 | Generator board reset due to a watchdog timeout | 9.2.7.8 |
| 769 | Generator board reset due to a stack overflow | 9.2.7.8 |
| 770 | Mismatch between generator board (A2) and MCU board (A1) types (2D / 3D) | 9.2.7.14 |

Keyboard

| Code | Error description | Reference paragraph |
|------|-------------------------------------|---------------------|
| 850 | One or more keycodes are pressed | 9.2.8.1 |
| 852 | Button >0< pressed during movements | 9.2.8.2 |





| | DC aeffware wear interface (CIII) | | |
|------|---|---------------------|--|
| Code | PC software user interface (GUI) Error description | Reference paragraph | |
| 1201 | Setup menu: write data EEPROM failure | 9.2.9.1 | |
| 1202 | Unespected value detected by the software | 9.2.9.2 | |
| 1203 | Software allocation failure | 9.2.9.1 | |
| 1204 | Exposure parameters failure | 9.2.9.2 | |
| 1205 | Image buffer allocation failure | 9.2.9.2 | |
| | PC driver interface (OSP) | | |
| Code | Error description | Reference paragraph | |
| 1401 | sensor connection lost during exam | 9.2.10.1 | |
| 1402 | sensor communication failure | 9.2.10.2 | |
| 1403 | Software watchdog error | 9.2.10.3 | |
| 1404 | sensor does not detect X-rays during exam | 9.2.10.4 | |
| 1405 | sensor frame lost during exam | 9.2.10.1 | |



9.2.1. Errors with code from E001 to E003

These errors are related to the MCU board and its firmware.

Power OFF the unit and, after 1 minute delay, power it ON again; if the error is displayed again, replace the MCU board and report the error and when it occurred to the technical service.

9.2.2. Errors with code from E100 to E104

These are errors related to the MCU board EEprom memory.

9.2.2.1. E100: Configuration area parameter (CRC-16) doesn't match the expected one /

E101: Configuration area parameter (magic number) doesn't match the expected one

These errors are shown when a corrupted configuration area parameter is found by the firmware of the I-Max.

- 1. Verify that on the MCU board the EEPROM memory is well inserted (Figure 3).
- 2. If the error is still present, reset the EEPROM memory as listed below:



Warning

All the factory calibrations offset will be lost.

Before performing this procedure, make sure that the equipment parameters table (supplied as paper copy with the unit documentation – see paragraph 14.1) with the factory setting offsets is available.

- Remove the MCU board metallic cover.
- **b.** Set the DIP-switch position on OFF-ON-ON (see paragraph 4.3.2.1).
- **c.** Switch ON the unit. The three keyboard LED blinks three times in sequence.
- d. The two alignment laser blinks three times.
- **e.** At this stage, if you press the X-ray button until 5 seconds, the EEPROM memory reset will be performed. The correct reset of the EEPROM is indicated by the laser blinking.
- f. Switch OFF the unit and restore the normal mode DIP-switch position (ON-ON-ON).
- g. If collimator is BELT type, perform the setting procedure (see paragraph 0).
- h. Switch OFF the unit and restore the MCU metallic cover.
- i. Switch ON the unit and restore the factory setting offsets reported in the equipment parameters table (see paragraph 14.1) following the procedures present on chapter 8.
- **3.** If the error persists, replace MCU board complete of EEPROM (see paragraph 11.3.2). Manually restoring of the unit configuration data will be requested.

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<u>Technical Service additional information required: MCU SD card log (see paragraph 11.2.1.2).</u>

9.2.2.2. **E102: Wrong version number in configuration area**

This error is shown when the version number of the configuration area doesn't match the MCU board firmware version.

- 1. Verify that the code printed on the MCU board match code 5804040600/XX. If it does not match, replace the MCU board with a correct one (see paragraph 11.3.2).
- 2. Contact OWANDY Technical Service to verify that the MCU firmware version is compatible with the unit configuration. If it is not, upload the MCU firmware with a compatible one (see paragraph 11.1.1).
- 3. If the problem is still present, reset the EEPROM following the procedure described in paragraph 9.2.2.1, point 2.

<u>Technical Service additional information required: MCU SD card log (see paragraph 11.2.1.2).</u>

9.2.2.3. E103: Timeout error occurred during an EEPROM erase operation / E104: Timeout error occurred during an EEPROM write operation

These errors are shown when a timeout occurred during an EEPROM erase or write operation. Power OFF the unit and, after 1 minute delay, power it ON again and verify the correct functioning of the unit.

If a new error is displayed, refer to the specific error paragraph description to fix the issue.





9.2.3. Errors with code from E200 to E299

These errors codes are concerning problems related to the movement axis of the unit.

9.2.3.1. **E200: Zero position optical sensor of rotation always active /**

E201: Zero position optical sensor of rotation never active /

E202 and E203: Zero position optical sensor of rotation still active

after exiting from zero sensor /

E205: Timeout on rotation

These errors are signals a problem on the rotation axis movement.

The position of rotation is controlled by the optical sensor B1, that is activated during the rotation axis reset movement; if this sensor is found active at the start up phase, and it is never sensed de-activated, the E200 message error is displayed, meaning that the sensor itself is broken or that the motor is not running.

In case that it is never sensed activated, the E201 is displayed, and the reasons are the same.

E202 or E203 is displayed when the rotation zero sensor B1 is still active after exiting from axis zero position.

E205 means that the optical sensor is never activated during the rotation axis reset.

In all cases, the optical sensor functionality can be checked placing an opaque thin material in the optical path and using a multimeter, verify that the voltage between pin X22-2 and pin X22-4 on the MCU board is about 5V when the optical path is covered by the thin material and about 0V when the optical path is not covered.

- If there is no variation and the arm does not move or moves with difficulty or jumps:
 - a. check the belt and verify that it is not broken; if the belt is loose, adjust its tension
 - b. check cable X18 of motor M3; there can be a short circuit or a broken wire; check also for a loosen contact. In case of short circuit, replace the cable, verifying also that no damage has been caused to the motor driver on the MCU.



Note

In the event of a short circuit on the X18 cable, the MCU board fuse F1 may be blown (the 24V power supply LED H2 OFF) and / or the motor driver (on the MCU board) may be damaged: if it is the case, replace the fuse F1 and then the MCU board.

2. If the arm moves but no variation of the signals is detected, replace the optical sensor B1 and if the problem is still present, the MCU board A1.

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- Audio / Video with the global view of the unit movement
- <u>Audio / Video of the view of the rotation motor group movement (with unit top cover removed)</u>

9.2.3.2. **E204:** Unexpected activation of zero position rotation sensor

This message means that there was an unexpected activation of the rotation optical sensor B1 during the exam or an another movement. Typically, the problem is due to a contact of the rotation arm with an object or patient shoulder.

 Verify if the unit had an interference with the patient or an object external to the unit; in this case remove all the object from the unit work space or instruct the patient to do not move during the exam.



Note

In the event of patient collision, it is recommended to perform a TEST examination without X-ray, with the patient in the correct exam position (see User's Manual – "Patient positioning" chapter), before performing another X-ray examination.

- 2. If the interference is not external to the unit (point 1.): remove the unit top cover, perform a panoramic Test exam and verify if there are interferences in the motor work spaces: remove the objects and repeat the test.
- 3. If the issue was not solved, refer to the Error E200 ÷ E205 troubleshooting.



9.2.3.3. **E240: Zero position sensor for Y axes always active /**

E241: Zero position sensor for Y axes never active /

E243: Timeout of Y axes

These errors are signalling a problem on the Y axis movement. The position of Y axis is controlled by the optical sensor B2, that is activated during the translation axis reset movement.

E240 is displayed when the sensor B2 is found active at the start-up phase and it is never sensed de-activated.

E241 is displayed when the sensor B2 is never sensed activated.

E243 means that the optical sensor B2 is never activated during the translation axis reset.

The above errors may mean that the sensor B2 is broken or that the motor system is not running (MCU driver or motor group fault).

- 1. If there is no variation and the arm does not move or moves with difficulty or jumps:
 - a. check the belt and verify that it is not broken; if the belt is loose, adjust its tension
 - **b.** check cable X19 of motor M4; there can be a short circuit or a broken wire; check also for a loosen contact. In case of short circuit, replace the cable, verifying also that no damage has been caused to the motor driver on the MCU.



Note

In the event of a short circuit on the X19 cable, the MCU board fuse F1 may be blown (the 24V power supply LED H2 OFF) and / or the motor driver (on the MCU board) may be damaged: if it is the case, replace the fuse F1 and then the MCU board.

2. If the arm moves but no variation of the signals is detected, replace the optical sensor B2 and if the problem is still present, the MCU board (see paragraph 11.3.2).

- Audio / Video with the global view of the unit movement
- <u>Audio / Video of the view of the translation motor group movement (with unit top cover removed)</u>



9.2.3.4. **E270** and **E271**: Hardware key board fault (U.I.C.)

These errors are shown when the firmware of the I-Max does not sense the presence of the U.I.C. (Unique Identification Code).

The hardware key board (Figure 3) is read during unit start-up; if the check is incorrect, the system displays one of the above error number: verify the presence of the key and that is well inserted.

The issue can be generated by a MCU board or hardware key fault.

- 1. Verify if the hardware key is well inserted on the MCU board: insert the key and verify if the issue is solved.
- 2. If the issue was not solved, replace the MCU board and then the hardware key.



Note

In case of MCU hardware fault, replace it following the instruction present at paragraph 11.3.2.





In case there is a fault on the hardware key itself, it must be replaced. All the optional features must be re-enabled with proper codes. To request a new hardware key, report to OWANDY the S/N of the equipment and / or the U.I.C code listed on the equipment parameters table (supplied as paper copy with the unit documentation – see paragraph 14.1).



9.2.4. Errors with code from E300 to E399

9.2.4.1. **E360: RX button pressed on start-up or before exam**

This message is displayed if, during the power ON phase or before starting of the exam, one of the connected X-ray button, has been sensed as pressed.

- **1.** Verify if one of the X-ray buttons was intentionally / unintentionally pressed: switch OFF the unit and release the button. Switch ON the unit and verify if the issue is solved.
- 2. Switch OFF and ON the unit, press the X-ray button and verify that the LED H11 on MCU board (A1) light-up according to the X-ray button activation: if is not ok, verify the connected X-ray buttons and their connections. If they are not ok, replace or fix the buttons and verify if the issue is solved. If the error is still present, replace the MCU board (see paragraph 11.3.2).

9.2.4.2. **E362: X-ray button released during emission**

The above error message is displayed if the X-ray button is unintentionally / intentionally released during an exam; the emission is stopped and all motors released in order to allow the patient's exit.

Verify if the X-ray button has been intentionally / unintentionally released during the exam:

- **a.** If it was intentionally released, press button >0< to reset the error on the unit and close the error window displayed on the GUI.
- b. If it was unintentionally released, refer to Error E360.





9.2.4.3. **E370: Sensor ready lost during exposure**

This error is displayed if the "sensor ready" signal is lost during the exposure.

With the unit powered OFF, proceed as follow:

1. Perform the troubleshooting tests listed on Errors E1401 and E1402 (see paragraphs 9.2.10.1 and 9.2.10.2).

<u>Technical Service additional information required</u>: try to reproduce the error keeping the following logs:

- <u>Software logs</u>
- <u>MCU SD card log</u> (see paragraph 11.2.1).

9.2.4.4. **E371: Sensor not ready**

This error is displayed when the user tries to perform an exam while the sensor connection has not yet been established.

Clear the error and wait for at least 5 minutes: if the sensor connection is not achieved, refer to troubleshooting of Error E370 (see paragraph 9.2.4.3).



9.2.5. Error with code from E500 to E505

This range of errors are dedicated to MCU – PC ethernet communication problems due to incompatibility between OSP software and MCU firmware version and/or ethernet hardware issues.

- 1. check the ethernet connection and the network card settings (see paragraph 7.4.1).
- 2. Power ON the unit and wait the connection to the PC-GUI. Verify the compatibility between MCU firmware and OSP versions: update/downgrade the FW-SW to a released/compatible configuration.



Note

Contact OWANDY Technical Service to verify that the firmware and software versions are compatible with the unit configuration.

<u>Technical Service additional information required</u>: try to reproduce the error keeping the following logs:

- Software logs
- <u>MCU SD card log</u> (see paragraph 11.2.1).

9.2.6. Error with code from E600 to E680

9.2.6.1. **E600 – 605, 611**

These errors are related either to a CCU board malfunction or to a CAN bus problem between MCU board and CCU board.



Note

It may happen that at the end of CCU board firmware upgrade the error E600 is displayed in the PhD_C_Test program. In this case power off the machine and restart the software. If the error is persistent continue the troubleshooting.

1. Check that CCU dip switches are all in the ON position (down), if not place them as in the picture and power off the machine and power it on again.

- 2. Check the CAN bus cable X9-X9 between CCU board and MCU board: replace or fix it if defective and then verify if the problem is still present.
- 3. Check the CCU voltage power supply and the CCU leds.



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<u>Technical Service additional information required:</u> try to reproduce the error keeping the following logs:

- Software logs
- MCU SD card log

(see paragraph 11.2.1).

<u>If it is not possible to reproduce the error, send at least the software logs indicating the time and</u> day when the issue occurred

9.2.6.2. **E623: timeout error during the CCU EEPROM erase operation** / **E624: timeout error during the CCU EEPROM write operation**

These errors are shown for a timeout during the CCU EEPROM erase or write operation. Power OFF the unit and, after 1 minute delay, power it ON again and verify the correct functioning of the unit, checking the machine configuration and the set-up data. In case the error is persistent replace the EEPROM.

If a new error is displayed, refer to the specific error paragraph description to fix the issue.

9.2.6.3. E630: Sensor holder zero position optical sensor always active /
E631 and E632: Sensor holder zero position optical sensor still active
after exiting from zero sensor /

E633: Sensor holder zero position optical sensor never active /

E634: Timeout on sensor holder movement

E635: Sensor holder motor overrun

These errors are signals of a problem on the ceph sensor movement.

The position of the sensor movement is controlled by the optical sensor B6, that is activated during the sensor holder axis reset; if this sensor is found active at the start up phase, and it is never sensed de-activated, the errors E630 - E632 are displayed, meaning that the sensor itself is broken or that the motor is not running.

In case that it is never sensed activated, the errors E633 and E634 are displayed.

In all cases, the optical sensor functionality can be checked placing an opaque thin material in the optical path and using a multimeter, verify that the voltage between pin X95-3 and pin X95-5 on the Ceph driver board A13 is about 5V when the optical path is covered by the thin material and about 0V when the optical path is not covered.

If there is no variation and the sensor holder does not move or moves with difficulty or jumps:

- a. check the belt and verify that it is not broken; if the belt is loose, adjust its tension
- **b.** check the 24V on the A13 board (led H2) if not present check the cable X53-X87 and the fuse F1.
- c. check cable X92 of motor M9; there can be a short circuit or a broken wire; check also for a loosen contact. In case of short circuit, replace the cable, verifying also that no damage has been caused to the motor driver on the A13 board.



Note

In the event of a short circuit on the X92 cable, the A13 board fuse F1 may be blown (the 24V power supply LED H2 OFF) and/or the motor driver (on the A13 board) may be damaged: if it is the case, replace the fuse F1 and then the board.



If the sensor holder moves but no variation of the signals is detected, replace the optical sensor B6, its cable and if the problem is still present, the A13 board.

In addition if the movement is just in one verse check also the cable X54-X88 between CCU A11 board and A13 board and finally replace the CCU A11 board.

- Audio / Video with the global view of the unit movement
- Audio / Video of the view of the ceph motor group movement (with unit top cover removed)





9.2.6.4. **E640:** Secondary collimator zero position optical sensor always active

E641 and E642: Secondary collimator zero position optical sensor still active after exiting from zero sensor /

E643: Secondary collimator zero position optical sensor never active /

E644: Timeout on Secondary collimator movement

E645: Secondary collimator motor overrun

These errors are signals of a problem on the secondary collimator movement.

The position of the secondary collimator movement is controlled by the optical sensor B5, that is activated during the sensor holder axis reset; if this sensor is found active at the start up phase, and it is never sensed de-activated, the errors E640 - E642 are displayed, meaning that the sensor itself is broken or that the motor is not running.

In case that it is never sensed activated, the errors E643 and E644 are displayed.

In all cases, the optical sensor functionality can be checked placing an opaque thin material in the optical path and using a multimeter, verify that the voltage between pin X95-4 and pin X95-6 on the Ceph driver board A13 is about 5V when the optical path is covered by the thin material and about 0V when the optical path is not covered.

If there is no variation and the secondary collimator does not move or moves with difficulty or jumps:

- d. check the belt and verify that it is not broken; if the belt is loose, adjust its tension
- e. check the 24V on the A13 board (led H2) if not present check the cable X53-X87 and the fuse F1.
- f. check cable X93 of motor M10; there can be a short circuit or a broken wire; check also for a loosen contact. In case of short circuit, replace the cable, verifying also that no damage has been caused to the motor driver on the A13 board.



Note

In the event of a short circuit on the X93 cable, the A13 board fuse F1 may be blown (the 24V power supply LED H2 OFF) and/or the motor driver (on the A13 board) may be damaged: if it is the case, replace the fuse F1 and then the board.

If the secondary collimator moves but no variation of the signals is detected, replace the optical sensor B5 its cable and if the problem is still present, the A13 board.

In addition if the movement is just in one verse check also the cable X54-X88 between CCU A11 board and A13 board and finally replace the CCU A11 board.

- Audio / Video with the global view of the unit movement
- Audio / Video of the view of the ceph motor group movement (with unit top cover removed)



9.2.6.5. E650 - E653: Primary collimator movement timeout /

E654 - E657: Primary collimator zero position optical always active /

E658 - E661: Primary collimator motor overrun

These errors are signals of a problem on the primary collimator axes.

Each axis is identified by a label on the collimator and in the following table the corrispondence between error and axis is reported:

| Error | FT1 axis | FT2 axis | FT3 axis | FT4 axis |
|--------------------|----------|----------|----------|----------|
| movement timeout | E650 | E651 | E652 | E653 |
| zero always active | E654 | E655 | E656 | E657 |
| overrun | E658 | E659 | E660 | E661 |

The position of the primary collimator axes is controlled by the optical sensors B7-B9, that are activated during the axes reset; if these sensors are found active at the start up phase, and are never sensed de-activated, the errors E654 - E657 are displayed, meaning that the corresponding sensor is broken or that the motor is not running.

In case that a sensor is never sensed activated, the errors E650 - E653 are displayed.

In all cases, the optical sensor functionality can be checked placing an opaque thin material in the optical path and using a multimeter, verify that the voltage between the following pins: for B7 pin X84-5 and pin X84-3, for B8 pin X84-5 and pin X84-4, for B9 pin X85-5 and pin X85-3 and for B10 pin X85-5 and pin X85-4 on the Collimator driver board A12 is about 5V when the optical path is covered by the thin material and about 0V when the optical path is not covered. Check the X77-X59 cable.

If there is no variation and an axis does not move or moves with difficulty:

- g. check that the correspondent actuator is not broken;
- h. check the 24V on the A12 board (check led H6 of CCU A11 board) if not present check the cable X67-X75 and the fuse F1 on CCU A11 board.
- i. check the specific cable among X80-X83 of motor M5-M8; there can be a short circuit or a broken wire; check also for a loosen contact. In case of short circuit, replace the cable, verifying also that no damage has been caused to the motor driver on the A12 board.



Note

In the event of a short circuit on one of the cable among X80-X83, the CCU A11 board fuse F1 may be blown (the 24V power supply LED H6 OFF) and/or the motor driver (on the A12 board) may be damaged: if it is the case, replace the fuse F1 and then the boards.

If the arm moves but no variation of the signals is detected, replace the optical sensor B7-B8 or B9-B10 their cables and if the problem is still present, the A12 board.

In addition if the movement is just in one verse check also the cable X66-X76 between CCU A11 board and A12 board and finally replace the CCU A11 board.

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- Audio / Video with the global view of the unit movement
- Audio / Video of the view of the ceph motor group movement (with unit top cover removed)

9.2.6.6. **E670 / E671 Can Bus**



Note

This error can be related to the Generator board errors E750 and E761 or a Generator board power supply fault. Therefore, in these cases the CAN-Bus is not able to assure the communication between the unit boards (MCU, CCU and Generator).

This message is displayed when the CAN bus line has been interrupted, due to a hardware or a power voltage problem. Therefore, the communication between the boards (CCU, MCU, Generator) is interrupted.

- **4.** Check the CAN bus cable X9-X9 between CCU board and MCU board: replace or fix it if defective and then verify if the problem is still present.
- **5.** Check the CAN bus cable X15-X32 between MCU board and Generator board: replace or fix it if defective and then verify if the problem is still present.
- **6.** Verify the Generator board status performing the test listed for error E750 (see paragraph 9.2.7.1) and E761 (see paragraph 9.2.7.9).
- 7. Perform the tests reported by Error E760 (see paragraph 9.2.7.11).
- 8. Perform the test of the Error E761 (see paragraph 9.2.7.9).
- **9.** If the error is still present, replace first the MCU board (see paragraph 11.3.2) and then the CCU board (see paragraph 11.3.3).

<u>Technical Service additional information required:</u> try to reproduce the error keeping the following logs:

- Software logs
- MCU SD card log

(see paragraph 11.2.1).

If it is not possible to reproduce the error, keep at least the software logs.



9.2.7. Error with code from 750 to 770



Warning

Those errors are related to the X-ray generator.

In case of Error messages E759 and E755, the system must be immediately powered off, because an unexpected emission (E759) can be present or the emission has not been terminated into the expected time.

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Warning

On the Generator board (A2) there are dangerous high voltage, 230 VAC / 120 VAC and 400 VDC.

Before accessing the Generator board, it is mandatory to switch OFF the unit, disconnect it from the mains and wait up to 4 minutes in order to allow the discharge of the capacitor (LED H10 on the Generator board steady OFF).

9.2.7.1. **E750: Generator board initialization error**

This message is signalling that the MCU board is not able to initialize the Generator board (A2). This error can be generated by and hardware failure on the CAN-Bus or on the Generator board main power supply connection.

With the unit switched OFF (at least since 4 minutes), perform the following tests:

- Check fuse F1 (T1A 250V) on the Generator board: if the fuse is blown, replace it and redo the test.
- 2. Check integrity of the CAN-Bus cable X32-X15 between MCU board and Generator board: if NOT OK, replace it and redo the test.

If the error is still present after tests 1 and 2, switch ON the unit and proceed as follow:



Warning

During the following tests, pay attention to the dangerous High Voltage on the Generator board.

- 3. Verify the main power LED H8 on the Generator board:
 - **a.** if the LED H8 is OFF, check with a multimeter that between pins X31-L and X31-N the unit power provide AC voltage is present (eg. 230V or 120V):
 - if the power supply X31-L and X31-N is OK, replace the Generator board
 - if the power supply X31-L and X31-N is NOT OK, check the integrity and proper connection between Line filter Z1 and Generator board; fix or replace the faulty component
 - b. if the LED H8 is BLINKING, replace the Generator board
 - **c.** if the LED H8 is ON, replace the Generator board and then the MCU board (see paragraph 11.3.2).



Note

The error E750 (Generator board power supply fault) can be related to the Error E670 / E671, related to a fault on the CAN-Bus line is detected.



9.2.7.2. **E751: kV over voltage**

This message is displayed when a value higher than expected has been detected on the Generator board (A2).

With the unit switched OFF (at least since 4 minutes), perform the following tests:

- 1. Check that connector X57 is well connected: connect it and verify if the error is still present.
- 2. With the connector X57 CONNECTED, using a multimeter, perform the measures listed in the following table:

| Parameter | Connection | Value |
|---------------|----------------------|-------------|
| Feedback kV + | X57-4(GND) and X57-2 | 13.3kΩ ± 2% |
| Feedback kV - | X57-4(GND) and X57-3 | 14.3kΩ ± 2% |

3. With the connector X57 DISCONNECTED perform the measures (connector side) listed in the following table:

| Parameter | Connection | Value |
|--|-------------------------------------|----------------|
| Insulation between the PINs of the power tube filament | X57-5/6 and X57-4 | Infinite |
| Insulation between primary H.V. winding and GND | X56-1/2 and GND (Tubehead shell) | Infinite |
| Feedback kV + | X57-4 and X57-2 | 19.8 ÷ 20.2 kΩ |
| Feedback kV - | X57-4 and X57-3 | 19.8 ÷ 20.2 kΩ |

IF values measured at point 3 are incorrect, replace the tubehead (see paragraph 11.3.5).

IF values measured at point 2 are incorrect, while values measured at point 3 are correct, replace the Generator board.

IF values measured at point 2 and 3 are correct, the X57 connector is well inserted and its connections to the tubehead are OK, replace the Generator board and then the tubehead.

9.2.7.3. **E752: Filament overload**

This message is displayed when a filament overload is detected by the Generator board during preheating time or X-ray exposure.

If the error is displayed, contact OWANDY Technical Service.



9.2.7.4. **E753: Overload on Anodic current**

This message is displayed when an abnormal value of the anodic current has been detected.

With the unit switched OFF (at least since 4 minutes), perform the following tests:

- **1.** Check that connectors X56 and X57 are well connected: connect it and verify if the error is still present.
- **2.** With connector X57 CONNECTED, using a multimeter, perform the measures listed in the following table:

| Parameter | Connection | Value |
|-------------|----------------------|-------------|
| Feedback mA | X57-4(GND) and X57-1 | 326Ω ÷ 334Ω |

3. With the connector X57 DISCONNECTED perform the measures (connector side) listed in the following table:

| Parameter | Connection | Value |
|-------------|----------------------|-------------|
| Feedback mA | X57-4(GND) and X57-1 | 326Ω ÷ 334Ω |

IF values measured at point 2. and 3. are incorrect, replace the tubehead (see paragraph 11.3.5) and the Generator board.

IF value measured at point 2. is incorrect and value measured at point 3. is correct, replace the Generator board.

IF value measured at point 3. is incorrect and value measured at point 2. is correct, replace the tubehead

IF the tests listed at point 1., 2. and 3. do not solve the error, replace the Generator board and then the tubehead.



9.2.7.5. **E754: Broken filament**

This message is displayed when there is a fault on the power circuit of the filament, not only the filament itself.

With the unit switched OFF (at least since 4 minutes), perform the following tests:

- 1. Verify the continuity (max Ohmic value $\leq 0.5\Omega$) between pins the X57-5 and X57-6: if there is no continuity, replace the tubehead (see paragraph 11.3.6).
- 2. Verify that the pre-heating parameters stored in the MCU EEPROM memory matches the ones listed in the equipment parameters table (supplied as paper copy with the unit documentation see paragraph 14.1) (see paragraph 1.1); correct them and verify if the error is still present.



Note

If the tubehead is a spare part, the new pre-heating values are printed on the tubehead label.

3. If the error was not solved by point 1. and 2., replace the tubehead and then the Generator board.

9.2.7.6. E755: Alarm "Backup timer intervention"

The emission is controlled through a safety backup timer that interrupts the power to the tubehead in case of a fault (hardware or software). The intervention of the backup timer, is signalled also by a lighting on of the red LEDs H5 and H9.



Warning

This error can be safety related. In case of Error messages E755, the system must be immediately powered off and not been used, because an emission has not been terminated into the expected time.

In any case it is mandatory to contact Owandy Technical Service and not use or switch ON the system anymore.

9.2.7.7. **E756: PFC (Power Factor Control) failure**

This message is signalling that the PFC (Power Factor Control) circuit functioning is not correct.

If the error is displayed, contact OWANDY Technical Service.





9.2.7.8. **E757: Brown out alarm /**

E766: Generator board reset due to a brown-out /

E767: Generator board reset due to a low voltage detection / E768: Generator board reset due to a watchdog timeout / E769: Generator board reset due to a stack overflow

These messages are displayed when the Generator board microcontroller is reset due to the displayed issue.

If the error is displayed, contact OWANDY Technical Service.

9.2.7.9. **E758: Alarm "No X-ray"** /

E761: Alarm "No X-ray emission"

These errors are displayed when the anodic current has been interrupted during or at the beginning of the emission and may indicate that the Generator board is in a safety status (eg. due to a discharge inside the tubehead, a broken tube or any other tubehead damage). Error E761 may be displayed / associated with others errors (i.e. E362 and E760) that can explain the main cause of the X-ray interruption occurred during the previous exposure (refers also to the associated error paragraph).

In order to reset these errors:

- 1. Switch OFF the unit and wait at least 4 minutes.
 - **a.** Switch ON the unit, perform an exposure and verify if the error is still present.
 - b. Switch OFF the unit, wait at least 4 minutes and switch it ON again: verify that the pre-heating parameters stored in the MCU EEPROM memory matches the ones listed in the equipment parameters table (supplied as paper copy with the unit documentation see paragraph 14.1) (see paragraph 1.1); correct them and verify if the error is still present.
- 2. With the unit switched OFF (at least since 4 minutes), verify the proper connection of the connectors X56 and X57; fix them, switch ON the unit and verify if the error is still present.
- **3.** With the unit switched OFF (at least since 4 minutes), perform the following tests:
 - **a.** Verify the primary winding continuity (max Ohmic value $\leq 0.5\Omega$) on the pins X56-1 and X56-2
 - **b.** Verify the filament continuity (max Ohmic value $\leq 0.5\Omega$) on the pins X57-5 and X57-6
 - c. Verify the mA feedback Ohmic resistance on the pins X57-1 and X57-4, it should be between $326\Omega \div 334\Omega$.

If one of the above tests (a., b. or c.) fails, replace the tubehead (see paragraph 11.3.5).

4. If the error is still present, replace both the tubehead and Generator board.

<u>Technical Service additional information required:</u> try to reproduce the error keeping the following logs:

- Software logs
- MCU SD card log

(see paragraph 11.2.1).





9.2.7.10. E759: Alarm "Unexpected emission"



Warning

In case of Error message E759, the system must be immediately powered OFF because an unexpected emission can be present.

An unexpected emission has been detected by the Generator board.

- **1.** With the unit switched OFF (at least since 4 minutes), verify the proper connection of the pins X57-1 and X57-4; connect them and verify if the error is still present.
- 2. With the unit switched OFF (at least since 4 minutes), verify the Ohmic resistance between the TP10 (mA feedback) and GND (TP13), it should be between $326\Omega \div 334\Omega$. If it is NOT OK, remove the connector X-57 and repeat the Ohmic test on the connector (tubehead side).
 - IF the test is NOT OK, replace the tubehead (see paragraph 11.3.5).
 - IF the test is OK, replace the Generator Board.
- If the error is still present, it is mandatory NOT use or switch ON the system anymore and contact OWANDY Technical Service.

9.2.7.11. **E760: Alarm "NO RX button command"**

This message is displayed when the Generator board (A2) is not detecting the X-ray button during the emission.

If the X-ray button was NOT intentionally released, switch OFF and ON the unit. Wait the keyboard blinks (DO NOT press the >0< button) and perform the following checks:

- 1. Press the X-ray button and verify that the LED H11 on MCU board (A1) light-up according to the X-ray button activation.
 - IF the test is NOT OK, verify the connected X-ray buttons and their connections: replace or fix them and verify if the error is still present. If still present, replace the MCU board (see paragraph 11.3.2).
- 2. Press the X-ray button and verify that the LED H2 on the Generator board (A2) light-up according to the LED H11 on the MCU board and to the X-ray button activation. IF the test is NOT OK, verify the integrity of the cable X15-X32 (Pin 2 = X-ray button signal) between MCU and Generator board: replace the cable if not OK and if the error is still present, replace the MCU board.
- 3. If the above tests are OK and/or the error is still present, replace the Generator board.



9.2.7.12. **E762: "Bad Generator board unit status, emission flag detected unexpectedly**

This message is displayed when the MCU detect a wrong status of the Generator board.

If the error is displayed, contact OWANDY Technical Service.

9.2.7.13. E763: kV channel analog feedback out of range / E764: mA channel analog feedback out of range / E765: Filament channel analog feedback out of range

These messages are displayed when Generator board detect a wrong kV, mA or Filament analog level.

If the error is displayed, contact OWANDY Technical Service.

9.2.7.14. E770: Mismatch between the Generator board (A2) and MCU board (A1) types (2D / 3D)

This error is displayed when the Generator board or MCU board is not configured as 3D type.

With the unit powered OFF, wait at least 4 minutes and verify that the codes printed on the two boards matches the following ones:

Generator board: 5804020200/XX

MCU board: 5804040700/YY

Replace the wrong board.



9.2.8. Errors with code E850 and E852

These errors indicate a keyboard fault.

9.2.8.1. E850: One or more buttons pressed during power ON

During the power ON phase, one or more keyboard buttons have been sensed as pressed by the MCU board (A1).

- **1.** With the unit switched OFF, check that no keyboard buttons are pressed: power the unit ON and verify if the error is still present.
- 2. With the unit switched OFF, disconnect cable X12 on MCU board, power ON the unit, wait the connection with the GUI (about 3 minutes) and verify that error E850 is no more displayed.
 - **a.** If the error is still present, replace the MCU board (see paragraph 11.3.2)
 - **b.** If the error is no more displayed, verify:
 - integrity of the cable X12-X12 between MCU and keyboard: replace the cable and verify if the error is still present
 - **c.** If the above tests are OK, replace the keyboard (* see Note).



(*) Note

In order to check / replace these components, it will be necessary to open the keyboard following the chin rest replacement procedure.



Keyboard



9.2.8.2. **E852: One key pressed during the movement**

During the system movements, the keyboard is inactive, but at the pressure of >0< button all movements are stopped and this message is displayed.

This function allows the user to stop the system movements in case an unexpected system behavior or a collision during the system positioning.

- 1. Make sure that >0< button was not intentionally/unintentionally pressed during a unit movement: reset the unit and verify if the error is still present.
- 2. Check that the >0< button is not stuck: replace the keyboard membrane if the >0< button is faulty.
- **3.** If the tests are OK, refer to error E850 (see paragraph 9.2.8.1).





9.2.9. **Error with code from E1201 to E1205**

These errors are related to the system PC software application issues or the communication with unit's boards.

9.2.9.1. E1201: Failed to write data in EEPROM from Setup menu / E1203: Error detected in software allocation

These messages are displayed when a software error has been detected.

If the error is displayed, contact OWANDY Technical Service.

Technical Service additional information required:

- Condition/unit state/sequence in which the error occurs/can be reproduced
- Software logs (see paragraph 11.2.1.1).

9.2.9.2. **E1202:** Unexpected value encountered by the software /

E1204: Error detected in exposition parameters / E1205: Error detected in image buffer allocation

These messages are displayed when a Software or Firmware error has been detected.

If the error is displayed, contact OWANDY Technical Service.

<u>Technical Service additional information required:</u>

- <u>Software logs</u> (see paragraph 11.2.1).



9.2.10. Error with code from 1401 to 1404

9.2.10.1. E1401: Sensor connection lost during the exam /

E1405: Sensor frame lost during exam

This message is displayed if the unit drivers on PC detects less frame than expected during the exam acquisitions.

The error is related to a bad transmission of the image from the unit sensor to the PC. The cause can be a bad ethernet connection or a fault in the sensor itself.

- Check the Ethernet connections (cables, junctions, PC network board) and PC network board settings (see paragraph 7.4.1).
 - Check also if the cables and the network board interface are compliance with the mandatory characteristics reported below:
 - The Ethernet cables must be the ones supplied with the unit or CAT 6 cables (or higher category)
 - The unit must be directly connected to the PC; no Ethernet hub/switch are allowed between the sensor and the PC.
- Check if the detector is well inserted and aligned in its holder.
- Check if the pogo-pins contacts on the detector holders and on the detector itself are clean.
- Check the cables from the detector holder to the ethernet switch on both ceph and pan stations.
- Verify if the tubehead connector X56 is well inserted and then perform the tests of the Error E761 (point (see paragraphs 9.2.7.1 and 9.2.7.9).

Contact OWANDY Technical Service providing the following additional information:

- Software logs
- Ceph Sensor logs

(see paragraph 11.2.1)

- Last RAW files folder stored (see paragraph 0)





9.2.10.2. **E1402: sensor configuration failure**

This error is related to a communication problem between the image sensor and the PC or to a problem of the boards A11, A13 and A14.

Perform the exam in which the error was displayed (pan or ceph) in a test mode (without X-ray) and verify, during the movements the status of the Ethernet connection (Control Panel→Network and Internet→Network Connections).

1. IF the Ethernet connection is steady ACTIVE:



- a. Perform the checks described for Error E1401 (see paragraph 9.2.10.1).
- **b.** Activate the sensor logs (see paragraph 11.2.1.5) and perform an acquisition in order to reproduce the error.
- **2.** IF the Ethernet connection is DISABLED:



Right click on Network board icon and click on "Enable".

3. IF the Ethernet connection is NOT steady ACTIVE:



a. Check the Ethernet connections (cables, junctions, PC network board): replace the faulty components (see Error E1401 – paragraph 9.2.10.1).

Contact OWANDY Technical Service providing the following additional information:

- Software logs
- Sensor logs

(see paragraph 11.2.1)

Last RAW files folder stored (see paragraph 0)



9.2.10.3. **E1403: Software watchdog**

This message is displayed if the software did not periodically reset the Ethernet watchdog timer.

It may be related to a wrong machine configuration (e.g. the ceph option has been disabled). Refer to paragraph 8.4to check machine configuration.

Refer also to Error E1402 (see paragraph 9.2.10.2).

Technical Service additional information required:

- Software logs
- Sensor logs

(see paragraph 11.2.1).



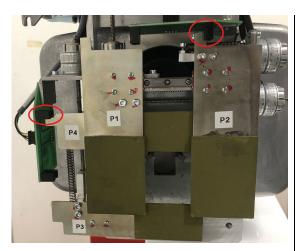
9.2.10.4. **E1404: Sensor does not detect X-rays during exam**

This message indicates that the sensor has not received X-rays during the last exposure. The problem may be related to the generation of X-rays (generator board or tubehead problem), to a bad positioning of the collimator or a radiopaque object may be in the X-ray field.

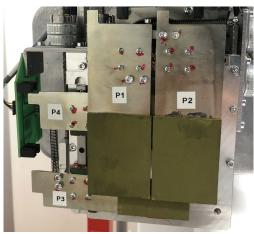
If this error is displayed during a panoramic go to point 2.

- 1. If the error is displayed during a ceph exam, perform a ceph exam test and verify:

 IF the secondary collimator and the ceph sensor move accordingly to the exam selected. If they do not move refers to E630-E635 (ceph sensor problems) or E640-E645 (secondary collimator problems)
 - If the error is still present, verify the ceph offsets stored in the EEPROM (compare them with the ones reported on the set parameters tables provided with the unit documentation). If they are not the same, correct them and then repeat the ceph exam test. (see paragraph 7.8).
 - If the error is still present, verify if the issue is present also in a panoramic exams.
 - If the issue is not present in a panoramic exam, verify the ceph axis alignment (paragraph 11.2.9)
 - o If the issue is present also in a panoramic exam, go to next point.
- 2. Remove the tubehead internal cover, open Phd_C_Test application and select the "Centering emission" ID and verify if the collimator move accordingly (the biggest collimator window is in front of the X-ray exit). "Centring panoramic" ID with "panoramic collimator" format and verify if the collimator is correctly positioned on panoramic window (the narrower collimator window is in front of the X-ray exit).



Centering emission collimator position Note that the P2 and P4 blades are positioned close their light barriers



Panoramic exam collimator position

IF the collimator movements are NOT OK, refer to errors E650-E661 (see paragraph 9.2.6.5).

- If the error is still present, verify the X-ray beam alignment (see paragraph 11.2.9.1).
- **3.** Verify if a radiopaque object is present in the X-ray field, remove it and verify if the problem is still present.





- **4.** Verify the collimator offsets stored in the EEPROM (compare them with the ones reported on the set parameters tables provided with the unit documentation). IF the offsets does not matches, fix them (see paragraph 8.4).
- 5. Perform the X-ray beam alignment check tests provided by paragraph 11.2.9.1
- **6.** IF the acquired images are completely white (without X-rays), perform the exposure parameters verifications with non-invasive and then with invasive method (see paragraph 7.10). If the non-invasive method is NOT OK but the invasive method is OK, replace the tubehead.

Contact OWANDY Technical Service providing the following additional information:

- Software logs (see paragraph 11.2.1)
- Last RAW files folder stored (see paragraph 11.2.2)
- Panoramic static acquisitions



9.3. User Interface (G.U.I.) messages

9.3.1. "Unit and computer not synchronized"

- 1. Can happen if the KV or mA parameters are modified from the G.U.I. to fast.
- 2. The message may be displayed while the G.U.I. is closing the Service Menu. If the problem persist contact Owandy Radiology Technical Service.
- **3.** If the problem is not the one described in the above points, refer to Error E1404 (paragraph 9.2.10.4).

9.3.2. "Sensor not ready"

Refer to Error E370 (paragraph 9.2.4.3), Error E1402 (paragraph 9.2.10.2) and Error E1401 (paragraph 9.2.10.1).

9.3.3. "Software error"



9.4. System Anomalies

9.4.1. White panoramic image

Panoramic white image

Figure 12

- 4. Verify the presence of the correct calibration files (8 files named as the SN of the sensor mounted on the unit) in the calibration folder C:\ProgramData\OWANDY\PANORAMIC PHD_C\Calibration and that all the calibration options in the image processing menu of the in PhD_C_Test.exe are checked (see paragraph 10.2).
- **5.** Perform tests of Error E760 (paragraph 9.2.7.11).
- **6.** Verify the integrity of tubehead X57 connector, pin 5 and 6.



9.4.2. Panoramic acquisition with less frames

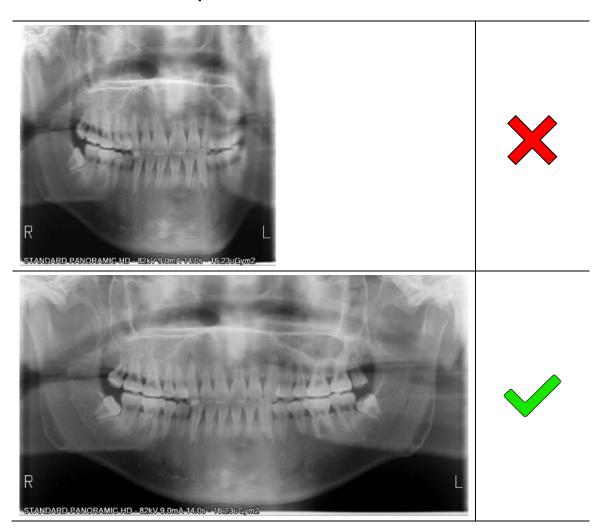


Figure 13

- 1. The panoramic acquisition above (X) may be indicate an acquisition with less frame than expected. In this case verify the Sensor Ethernet connections (cables, junctions, PC network board). Refer to Error E1401 point 1 (see paragraph 9.2.10.1).
- 2. If the error is still present, send the acquired RAW file (see paragraph 11.2.2) to Owandy Radiology Technical Service.

9.4.3. Asymmetries on the panoramic images

- 1. Check the orthogonality of the unit lasers (se User Manual paragraph 7.3).
- 2. Perform the verification of the panoramic function (see paragraph 7.7).



9.4.4. Unit/MCU connection problems

- 1. Verify if MCU DIP switches are set in normal mode (see paragraph 4.3.2.1).
- 2. Check the unit power supply (see paragraphs 6.4 and 11.2.3).
- 3. Verify the unit Ethernet connection status (Control Panel→Network and Internet→Network Connections):
 - a. IF the Ethernet connection is steady ACTIVE:



Verify the correct network interface board configuration (see paragraph 7.4.1).

b. IF the Ethernet connection is DISABLED:



Right click on Network board icon and click on "Enable".

c. IF the Ethernet connection is NOT steady ACTIVE:



Check the Ethernet connections (cables, junctions, PC network board).

- 4. Plug a functioning Ethernet CAT 6 (or higher) cable to the MCU and connect it directly to the PC network interface:
 - **a.** If the problem, in this configuration, disappears: there may be a faulty Ethernet cable or junction or the machine ethernet switch connected between the PC and MCU.
 - b. If the problem is still present, try to connect the MCU Ethernet cable to another network interface port (setting the right IP address on the network interfaces see paragraph – see paragraph 7.4.1).

If the problem is solved, it can be related to the network interface board.





9.4.5. The column does not move

- 1. Verify that the safety red switch is released in the top side of the unit.
- 2. If the problem persists, power off the machine and wait for about 20-30 seconds, then power on again the machine.
- 3. Verify the main power supply and columns driver board connection (see paragraph 6.4 and 7.2).
- 4. Verify the column fuse (see paragraph 11.3.1).

If the problem is still present, contact Owandy Radiology Technical Service.



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10. PERIODIC MAINTENANCE



Note

Maintenance and inspection procedure must be performed without patient positioned in the equipment.

As with all electrical appliances, this unit must be used correctly and maintenance and inspections must be made at regular intervals. Such precautions shall guarantee the safe and efficient function of the appliance.



Warning

Preventive and/or corrective operations must only be carried out by personnel authorised and properly trained on part replacement and maintenance.

The inspections made directly by the operator are the following:

| Frequency | Type of check | Method | |
|----------------|---|---|--|
| Daily | Functioning of the indicator lights | Visual inspection | |
| Daily | Check that the cables do not show signs of breaking or wear | Visual inspection | |
| Daily | Check that the unit is not damaged externally in such a way that the safety of protection from radiation is compromised | Visual inspection | |
| Daily | Check that there are no traces of oil on the tube-head | Visual inspection | |
| Daily | Check that arm movement is smooth | Practical inspection | |
| Monthly | Integrity of equipment and labels | Visual inspection | |
| Every 6 Months | QC test | Refer to paragraph 7.5 of User's Manual | |



Warning

If the operator detects irregularities or failures, he must immediately call Technical Service.

The appliance's performance is checked and, where necessary corrected, during the maintenance activities performed by the Technical Service Department, in accordance with the indications provided in the following chapters.



The periodic maintenance performed by the Technical Service Department comprises the performance of the following additional inspection activities:

| Frequency | Type of check | Method | |
|-----------|--|----------------------------------|--|
| Annually | General visual inspection Visual inspe | | |
| Annually | Grounding of all the conductive parts and cables | Practical inspection | |
| Annually | Condition of the internal and external cables: wear and tear and fastenings | Visual and practical inspection | |
| Annually | Tightening of the primary bolts and screws such as the wall fastening systems, the moving mechanisms and the chin rest arm | Practical inspection | |
| Annually | Correct equipment centring See paragray 7.7, 7.8 and | | |
| Annually | Check technical factors | See paragraphs 7.10.1 and 7.10.2 | |
| Annually | Perform sensor calibration | See paragraph 10.2 | |



Warning

Only use original spare parts if components need to be replaced. The relevant replacement instruction is supplied with the spare part.



Note

The Service Engineer has to take special care for all what concerns electrical safety of the device and must make sure of restoring all provisions for electrical safety which may be affected during a service intervention and to solicit the customer to have the electrical safety tests repeated every time the intervention has caused the replacement of important parts or the intervention has significantly affected safety provisions of the device.



Note

Interventions carried out by the Service Engineer must be noted in the Maintenance Record page at the end of the User Manual, with a short description of the actions done.





10.1. Service tools

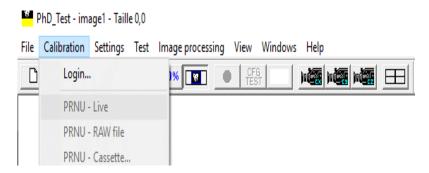
In order to perform a correct system calibration, is necessary the use of the following tools:

| Code | Description | Function |
|------------|----------------------|---------------------------------------|
| 6107900100 | Laser centering tool | Laser alignment check |
| 6195170100 | Support plate | Support for panoramic centering tools |
| 6195170200 | Centering tool | Panoramic function adjustment |
| 5607900800 | 1.5mm copper filter | Sensor calibration |

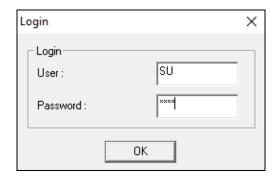


10.2. Sensor Calibration

- 10. In order to perform calibration, place a copper filter of 1.5mm in front of the tubehead in such a way as to cover the entire X-ray beam.
- 11. Open the "PhD_C_Test.exe" service program (C:\Program Files (x86)\OWANDY\PANORAMIC PHD_C).
- 12. Open the "Calibration" panel from the menu, and select "Login".



13. In the "User" field type in capital letter "SU". In the "Password" field type the password (see password generation on paragraph 10.2.1).



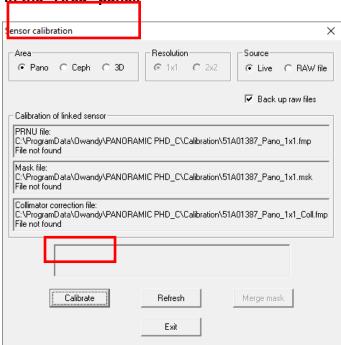
14. Open the "Calibration" panel and select "PRNU- Live".



15. Insert the detector in the PAN holder. Make sure that no objects are present in the X-ray field.



16. Select "Pano" in the "Area" panel.



- 17. Press the button "Calibrate".
- 18. Each time the calibration window displays the message "Waiting for an acquisition" press the X-ray button until the end of the exposure.





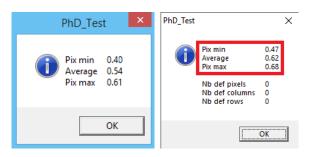
Note

If during calibration, the message "Sensor not ready" or "Time out" is displayed by the "Sensor calibration" window, click on "Calibrate" button and repeat the last performed calibration (Pano, ceph 1x1 or 2x2).

Note

During the calibration, when one of the following windows is displayed, verify that the values reported are within the tolerances:

- Pix min: > 0.20Pix max: < 0.90and then press OK.
- (!)

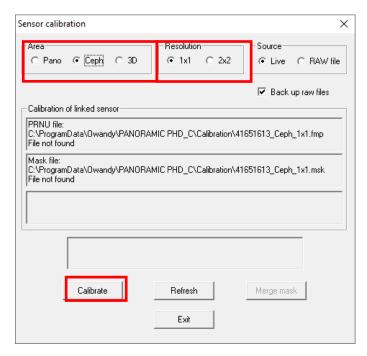


If they are not in the above limits, verify the copper filter positioning and that no objects are present in the X-ray field; repeat the calibration.





- 19. When the Panoramic area calibration is completed, the message "Calibration finished. Remove the 1.5 mm Cu filter " is displayed. This calibration will generate the following files in the folder C:\ProgramData\OWANDY\ PANORAMIC PHD C\Calibration:
 - [Sensor S/No]_2D_1x1.fmp
 - [Sensor S/No]_2D_1x1.msk
 - [Sensor S/No]_2D_1x1.Coll
 - [Sensor S/No].ini (if not present)
- **19.** Don't remove the copper filter, rotate the ceph head holder to antero posterior position, fold up the nasion
- 20. Select "Ceph" in the "Area" panel, "1x1" in the "Resolution" panel.



- 21. Press the button "Calibrate".
- **20.** Press >O< on the machine on the keyboard, when the machine stop moving and the blue and green leds blink move the sensor to ceph position; the machine goes in calibration position; Wait until the machine stops moving;
- **22.** Each time the calibration window displays the message "Waiting for an acquisition" press the X-ray button until the end of the exposure.
- 23. When the ceph 1x1 resolution area calibration is completed, the message "Calibration finished. Remove the 1.5 mm Cu filter " is displayed. This calibration will generate the following files in the folder C:\ProgramData\OWANDY\PANORAMIC PHD C\Calibration:
 - [Sensor S/No]_Ceph_1x1.fmp
 - [Sensor S/No]_Ceph_1x1.msk
 - [Sensor S/No].ini

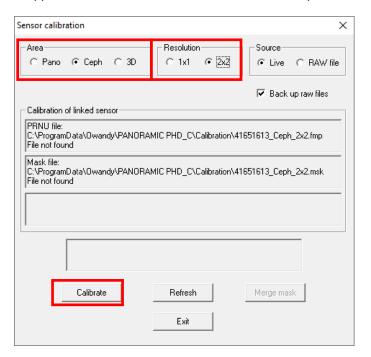




Note

If during calibration, a message "Error while computing the defect mask" is displayed, check that the ceph head holder is in antero posterior position. Then quit the current calibration procedure and repeat a new calibration by clicking on "Calibrate" button.

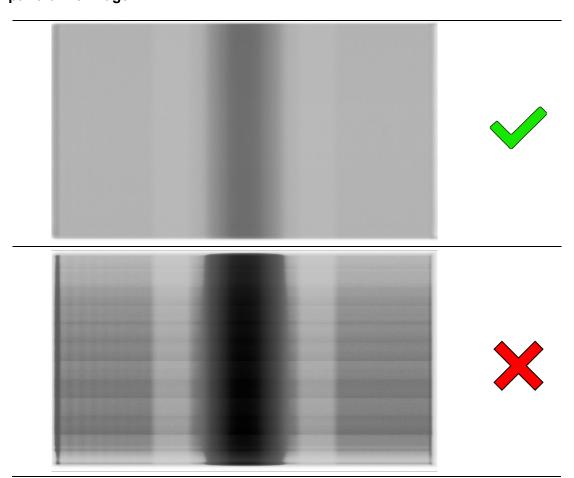
24. Don't remove the copper filter and Select "2x2" in the "Resolution" panel.



- 25. Press the button "Calibrate".
- **26.** Each time the calibration window displays the message "Waiting for an acquisition" press the X-ray button until the end of the exposure.
- 27. When the ceph 2x2 resolution area calibration is completed, the message "Calibration finished. Remove the 1.5 mm Cu filter " is displayed. This calibration will generate the following files in the folder C:\ProgramData\OWANDY\PANORAMIC PHD_C\Calibration:
 - [Sensor S/No] Ceph 2x2.fmp
 - [Sensor S/No]_Ceph_2x2.msk
- 28. When the Panoramic, Ceph 1x1 and 2x2 calibrations are completed, click "Exit".
- 29. Select the following filters from the "Image processing" menu:
 - Dark signal correction
 - PRNU correction if possible
 - Collimator correction if possible
 - Defect pixels correction if possible
- 30. Remove the copper filter from the tubehead, switch OFF the unit and close the "PhD C Test.exe" service program.
- 31. Switch ON the unit.



- 32. Open the "PhD_C_Test.exe" service program and make an exposure at 60kV 2.2mA without objects in the X-ray field.
- 33. Verify that there are no defect lines or inhomogeneous bands on the panoramic image:



- **34.** Select a ceph30x24LL, High resolution, position the ceph head holder in latero lateral position, place the nasion in field and take an exposure at 60kV3.2mA without objects in the X-ray field.
- **35.** Verify that there are no defect lines or inhomogeneous bands on the image.
- **36.** Select a ceph30x24LL, Normal resolution, position theceph head holder in latero lateral position, place the nasion in fieldand take an exposure at 60kV3.2mA without objects in the X-ray field.
- 37. Verify that there are no defect lines or inhomogeneous bands on image
- **38.** If artifacts are present in the image, redo the calibration...





10.2.1. Password generation

| Date | Value | Month | Value | Year | Value |
|------|-------|-----------|-------|------|-------|
| 1 | 53 | January | а | 2003 | С |
| 2 | 56 | February | b | 2004 | d |
| 3 | 59 | March | С | 2005 | е |
| 4 | 62 | April | d | 2006 | f |
| 5 | 65 | May | е | 2007 | g |
| 6 | 68 | June | f | 2008 | h |
| 7 | 71 | July | g | 2009 | i |
| 8 | 74 | August | h | 2010 | J |
| 9 | 77 | September | i | 2011 | k |
| 10 | 80 | October | j | 2012 | I |
| 11 | 83 | November | k | 2013 | m |
| 12 | 86 | December | I | 2014 | n |
| 13 | 89 | | | 2015 | 0 |
| 14 | 92 | | | 2016 | р |
| 15 | 95 | | | 2017 | q |
| 16 | 98 | | | 2018 | r |
| 17 | 01 | | | 2019 | s |
| 18 | 04 | | | 2020 | t |
| 19 | 07 | | | 2021 | u |
| 20 | 10 | | | 2022 | ٧ |
| 21 | 13 | | | 2023 | W |
| 22 | 16 | | | 2024 | Х |
| 23 | 19 | | | 2025 | У |
| 24 | 22 | | | 2026 | Z |
| 25 | 25 | | | | |
| 26 | 28 | | | | |
| 27 | 31 | | | | |
| 28 | 34 | | | | |
| 29 | 37 | | | | |
| 30 | 40 | | | | |
| 31 | 43 | | | | |

Example:

- if the actual day is 22 you have do digit "16"
- if month is April you have to digit "d"
- if year is 2016 you have to digit "p"

Password for this date will be "16dp" but will be displayed "****".





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11. CORRECTIVE MAINTENANCE

11.1. Firmware upgrade



Note

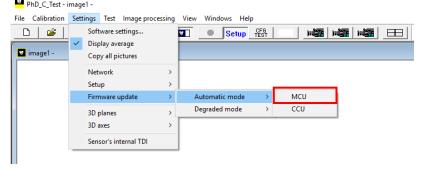
To update MCU and CCU boards be sure the ehternet board connected to the machine is properly set as described in paragraph 7.4.1

11.1.1. MCU Firmware upgrade

- 1. Copy in a working directory of the PC the MCU firmware to upload (the file name is in the form MCUet-YYYY-MM-DD-vM.mm.bbb.hex).
- 2. Power ON the machine. Open "PhD_C_Test.exe" service program (C:\Program Files (x86)\OWANDY\PANORAMIC PHD_C).
- Click on SETUP button and in the Login windows that will open insert the password PhdAccess and click OK



4. From the menu Settings select Firmware update>Automatic mode>MCU

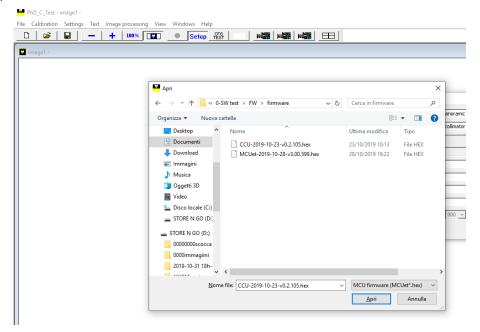


5. in the Login window that will open insert the password **EthUpload** and click OK

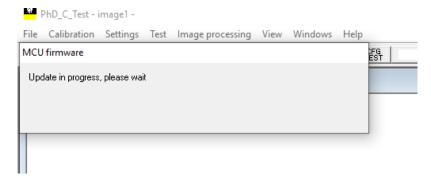




6. Browse the working folder where the firmware to upload has been copied, select it and click Open



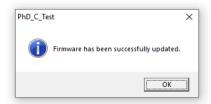
7. The firmware upload will start and the progress will be indicated by the message window. The upgrade progress might take up to two minutes.



8. When the upload process has been completed, the following window is displayed. Click on OK button.







- 9. Switch OFF the unit.
- 10. Click on OK button of the information window



11. Switch ON the unit and check on the first page of the GUI service program (chapter 8) the current MCU firmware version.





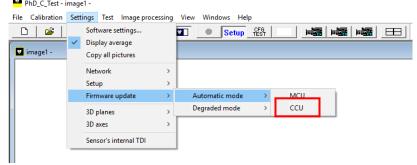
11.1.2. CCU Firmware upgrade

- 1. Copy in a working directory of the PC the CCU firmware to upload (the file name is in the form CCU-YYYY-MM-DD-vM.mm.bbb.hex).
- 2. Power ON the machine. Open "PhD_C_Test.exe" service program (C:\Program Files (x86)\OWANDY\PANORAMIC PHD_C).
- Click on SETUP button and in the Login windows that will open insert the password PhdAccess and click OK



4. From the menu Settings select Firmware update>Automatic mode>CCU

→ PhD_C_Test - image1 -



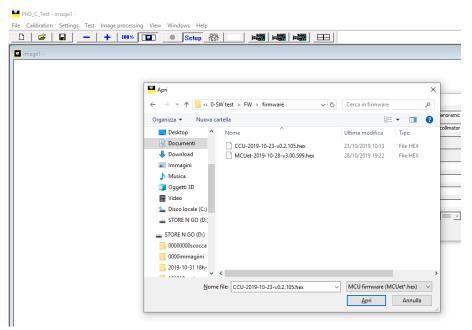
5. in the Login windows that will open insert the password EthUpload and click OK



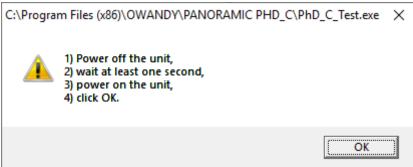
6. Browse the working folder where the firmware to upload has been copied and select it and click Open



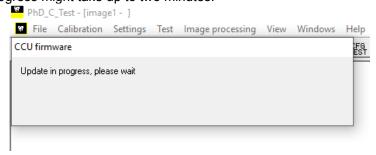




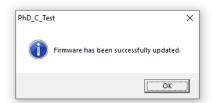
The software asks to power OFF the unit, wait for at least one second, power ON the unit again and click OK



8. The firmware upload will start and the progress will be indicated by the message window. The upgrade progress might take up to two minutes.



9. When the upload process ends the following windows is displayed. Click on OK button of the information window.





- 10. Power off the unit
- 11. Click on OK button of the information window



12. Switch ON the unit and check on the first page of the GUI service program (chapter 8) the current MCU firmware version.





11.2. Checks, settings and adjustment

11.2.1. Logs files recover

The I-Max firmware and software record some of the events that occurs during the unit functioning, stored in files called "Logs". These files have to be provided to the Owandy Radiology Technical Service as required by the different error descriptions.

The following table lists all the logs file names and their path location, while the paragraph below explains the procedures for activating and collecting them.

| | File name | Path location | Active by default |
|---------------------|---------------------------|---|-------------------------|
| Software package | LogsServer_yyyy.mm.dd.log | C:\ProgramData\OWANDY\LogServer\Logs | Yes |
| MCU | eeprom.dump mcu.log | [SDCARD]:\mcu\Logs | ON |
| noo | ccu.log | SDCARD]:\ccu\Logs | ON |
| Pan/Ceph sensor | - | C:\Program Files (x86)\Teledyne DALSA\Sapera\Bin\logview.exe | Yes |



11.2.1.1. Software package (OSP) logs

These logs record the events that occurs during the OSP (installed on the PC) execution. These logs are always active by default after any I-Max OSP installation.

The logs file are stored in the folder path: C:\ProgramData\OWANDY\LogServer\Logs. In this folder, every day a .log file named LogsServer_yyyy.mm.dd.log is store (where yyyy=year, mm=month and dd=day).





11.2.1.2. **MCU logs**



Note

The SD card MUST has the following characteristics:

- Capacity ≤ 32Gb
- Formatted as FAT32.

This log record the events that occurs during the MCU firmware execution, even if the unit is not connected to the computer.

- 1. Insert an SD card in the MCU SD card reader.
- 2. Switch ON the unit.
- 3. Wait at least 30s (10 minutes if sensor power on issues occur, related to sensors overheating) or use the unit normally, or reproduce the error/problem to be logged.
- 4. Switch OFF the unit.
- 5. Read the SD card. The "Logs" folder contents the following files:
 - eeprom.dump
 - mcu.log

The main information listed in the "imax.log" file are:

| Log | Description |
|---|---|
| MCU version numbers | MCU Firmware (SW) version |
| DIP switch code | MCU DIP-Switches position (see paragraph 4.3.2.1) 0 = Normal mode |
| S/N | MCU hardware key number (U.I.C.) |
| Acquisition mode | Area mode / DTDI |
| Tubehead type | 2D/3D |
| machine offsets | |
| MCU IP = 192.168.0.211 Netmask = 255.255.255.0 | MCU Ethernet IP and Netmask addresses |
| XP-PACK option | XP exam option ENABLED or DISABLED |
| XCU version numbers | Generator board Firmware (SW) version |
| CCU version numbers | CCU board Firmware(SW) version |
| Sensor temperature | |





11.2.1.3. **CCU logs**



Note

The SD card MUST has the following characteristics:

- Capacity ≤ 32Gb
- Formatted as FAT32.

This log record the events that occurs during the CCU firmware execution, even if the unit is not connected to the computer.

- 6. Insert an SD card in the CCU SD card reader.
- **7.** Switch ON the unit.
- **8.** Wait at least 30s (10 minutes if sensor power on issues occur related to ceph sensor overheating) or use the unit normally, or reproduce the error/problem to be logged.
- 9. Switch OFF the unit.
- 10. Read the SD card. The "Logs" folder contents the following files:
 - ccu.log

The main information listed in the "imax.log" file are:

| Log | Description |
|----------------------------------|--|
| CCU version numbers | CCU Firmware(SW) version |
| Nasion potentiometer readout | |
| DIP switch code | CCU DIP-Switches position (see paragraph4.3.2.1) 0 = Normal mode |
| Position of the imaging detector | |



11.2.1.4. Pan/Ceph sensor log

This log records the events that occur in the communication between the pan/ceph sensor and OSP software.



Note

Before recording the log, check that the network interface board connected to the unit is configured properly (see paragraph7.4.1).

To save the log:

- 1. In the folder C:\Program Files (x86)\Teledyne DALSA\Sapera\Bin\ run the program logview.exe
- 2. Then try to replicate the issue and save the log file selecting in the File menu the option save all messages.



Note

If the issue is rare open logview.exe, select the menu Options -> View GUI settings and set 50000 in *Maximum messages shown* box.

3. In addition in the folder C:\Windows\SysWOW64 retrieve the file logs.dat.



11.2.2. RAW files recovery

In case of image quality or sensor problems, it is required to send these raw folders to Owandy Radiology Technical Service.

The raw folders of the last ten acquired exams (pan, ceph and static) are stored in C:\ProgramData\OWANDY\PANORAMIC PHD_C\AcquisitionSave folder. The sub-folders are organized in folders named with time and date of the ten acquisitions.

Only the last ten acquisitions are stored.





11.2.3. **24V Power supply check**



Warning

The switching power supply can have dangerous voltage. Wait for at least 5 minutes before carrying out any action.

Before performing the following procedure, verify the main fuse integrity (see paragraph 11.3.1.1) and the main power supply line (see paragraph 4.3.1 and chapter 12 – General Diagram).

Verify if the MCU LED H1 is ON

- 1. If MCU H1 is OFF, remove the cable X1 and verify the 24V between X1-pin1 and X1-pin2.
 - IF X1 24V is NOT OK, fix or replace the cable X1 and then the switching power supply G1.
 - IF X1 24V is OK, unplug the connector X11 and verify if the MCU LED H1 light up:
 - IF MCU H1 is still OFF, replace the MCU board A1
 - IF MCU H1 is now ON, verify the integrity and the insulation between pin1 and pin2 of cable X11-X37. If the problem is still present, replace the 3D sensor power board.
- 2. If MCU H1 is ON, verify if the MCU LED H2 is ON.
 - a. IF MCU LED H2 is OFF, verify that fuse F1 is not blown:
 - IF fuse F1 is blown, replace it and verify if the error is still present (* see Note below).
 - IF fuse F1 is NOT blown, disconnect the motors connectors (X18, X19, X20 and X34) and verify if the LED H2 lights up:
 - IF MCU H2 is still OFF, replace the MCU board A1
 - IF MCU H2 is now ON, connect one at a time the motors connectors and verify which ones are the origin of the problem. (* see Note below).





(*) Note



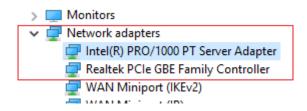
Before replacing, a burned fuse or any other parts verify that there are no short-circuit on motors (M3, M4, M5, M6) and theirs cables as described in the troubleshooting of the Errors E200 ÷ E205 (paragraph 9.2.3.1), E240 ÷ E243 (paragraph 9.2.3.3), E260 (paragraph 1.1.1.1) and E265 ÷ E268 (paragraph 9.2.3.4). Verify also that there are no short-circuits on cables X8-J8 and X11-X37.



11.2.4. Network interface board drivers upgrade

In case of Ethernet connection problems (Errors E1400÷1404, E371 and E370), a verification of the network board driver update is suggested:

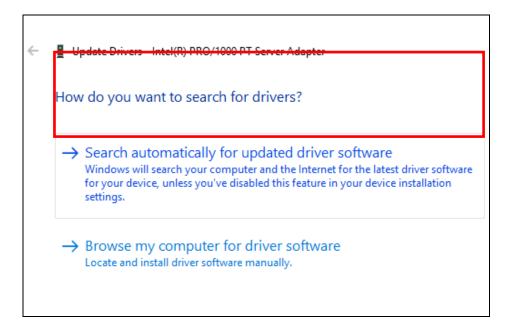
- 1. Connect the PC to Internet.
- 2. Open the system "Device Manager" (Control Panel→System and Security→System).
- 3. Click on Network adapters and right click on all the boards names connected to the unit:



4. Click on Update driver:



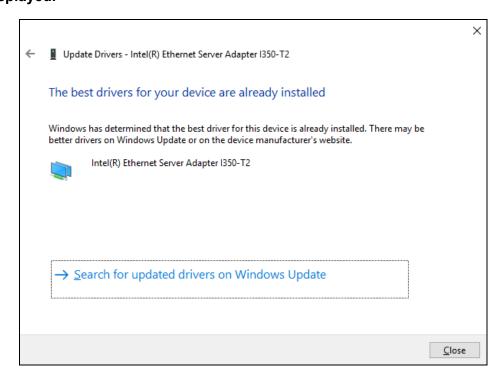
5. Click on "Search automatically for updated driver software":





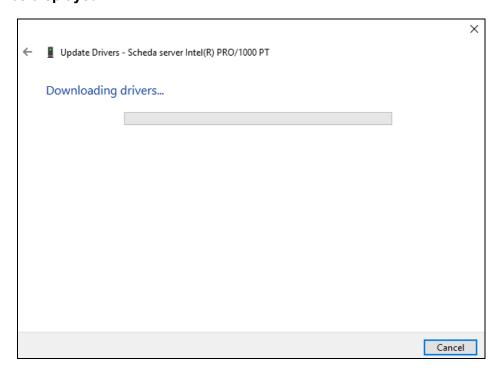
HUEL X LOW !

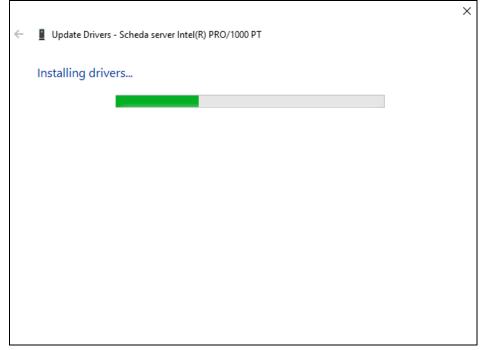
6. If the installed drivers are already updated the following window will be displayed:





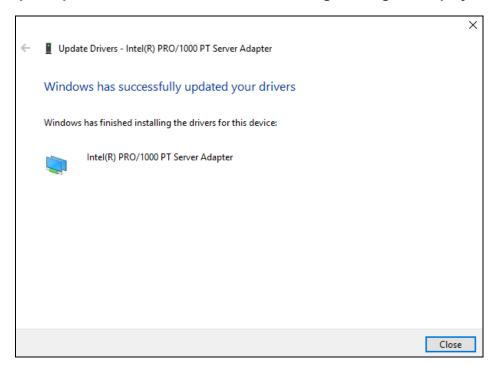
Otherwise, if the search found a driver to be updated, the following windows will be displayed:







7. The update process is finished when the following message is displayed:



8. Repeat the above procedure on all the PC network interface boards.





11.2.5. **EEPROM Memory values verification and modification**

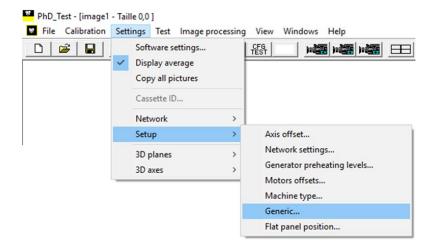


Note

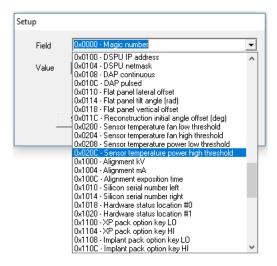
DO NOT CHANGE ANY EEPROM VALUES DIFFERENT FROM THE ONES REQUIRED BY THIS MANUAL (eg. required by a troubleshooting or Errors procedures).

An incorrect and improper modification of an EEPROM value may affect the correct functioning of the unit. The service technician is responsible for the following operations.

- 1. Switch ON the unit and when the green keyboard LED blinks slow press the >0< button.
- 2. Open the "PhD_C_Test.exe" (folder path: C:\Program Files (x86)\OWANDY\PANORAMIC PHD_C) and wait the unit connection.
- 3. Click on the menu Settings→Setup→Generic:

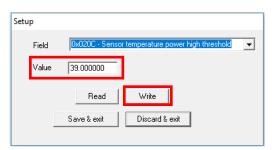


4. In the "Setup" window select the field needed value: 0x#### - [name of the EEPROM variabiles]:





The EEPROM stored values will be displayed in the "Value" field. If the value number is not correct, manually write the correct <u>DECIMAL number</u> in the white "Value" field and then press the button "Write":





Note

If in the "Value" field the number is preceded by the prefix "0x", means that that it is expressed in hexadecimal base. In this case refer to the DECIMAL values reported on the right of the field:



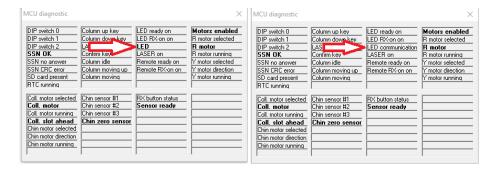
If the value must be changed, write in the white filed the correct DECIMAL number and then press the button "Write".

5. Wait the blue keyboard LED blink.



Note

In case of remote technical session: the BLU LED blinking state it signaled also in the "MCU diagnostic" window through the loop-variation between the bold "LED" text and the "LED communication" text in the field indicated by the red arrow in the Figure below:







6. Press "Save& exit" button and wait the unit reboot (green LED blink slow).



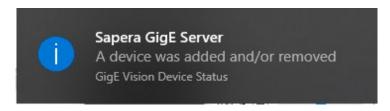
7. Switch OFF the unit.





11.2.6. Pan/Ceph sensor IP address modification

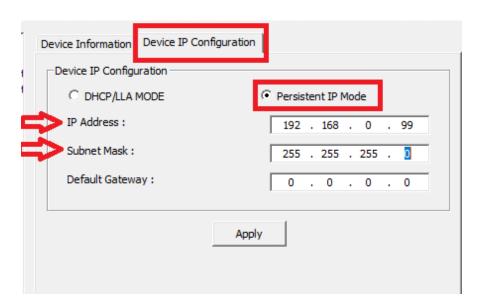
- Check that the network card connected to the unit is configured with a static IP in the family of the current sensor IP. The factory default is: IP address:192.168.0.16, Subnet Mask: 255.255.255.0 (refer to paragraph 7.4.1)
- Switch ON the unit
- Wait until connection with the sensor presence is recognized by the PC, i.e. when this message is displayed by windows:



- Start the program "CorNetConfigApp.exe" present on desktop (C:\Program Files (x86)\Teledyne DALSA\Network Interface\Bin)
 - In the left side select the item with the S/N of the sensor (check that it is matching with the S/N present on your sensor)



- In the right side of the menu select the window "Device IP Configuration". Select "Persistent IP Mode"
- In the field "IP Address" set the IP static to: 192.168.0.99
- In the field "Subnet Mask" set the value: 255.255.255.0
- Click on Apply

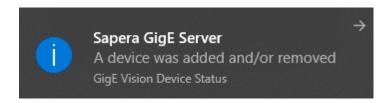








Wait the end of the process
 Connect the sensor to the Ethernet cable going to the HUB and wait the connection of the sensor to the PC; once connected, close "Nework Configuration Tool"



If the sensor IP family has been changed to connect again to the machine also MCU IP address (refer to paragraph 11.2.7) and PC network ethernet card are to be changed.

11.2.7. MCU IP address modification and factory reset

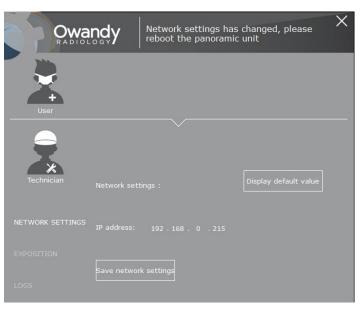
11.2.7.1. MCU IP address modification

- 1. Enter service menu (see chapter 8).
- 2. Select the "Network Settings" page (see paragraph 8.1).



3. Change the IP address; click on Save IP address, the following message will be displayed:





- **4.** Change the Network interface board IP with a valid one (see paragraph 7.4.1).
- **5.** Power OFF the unit and power it ON again and check the connection.



Note

You can verify the current MCU IP address by the MCU SD card log (see paragraph 11.2.1.2).

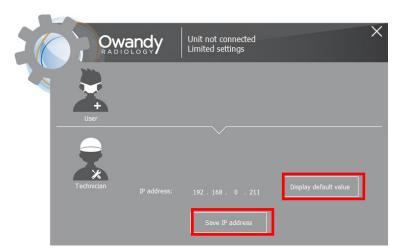




11.2.7.2. MCU IP address factory reset

Follow the procedure below to restore the factory MCU IP address 192.168.0.211.

- 1. Switch OFF the unit.
- 2. Press column UP and column DOWN keyboard buttons switch ON the unit and keep pressed column UP and column DOWN keys until the keyboard green LED blinks.
- 3. Switch the unit OFF and then power it ON again.
- **4.** Set a compatible IP address on the Network interface board IP (eg. 192.168.0.16, see paragraph 7.4.1).
- **5.** Enter service menu (see chapter 8).
- **6.** Select the "Network Settings" page (see paragraph 8.1).



- 7. Click on "Display default value" button and then on "Save IP address" button.
- 8. Wait the unit connection.
- 9. Exit the service menu by clicking on the gear.



Note

You can verify the current MCU IP address by the MCU SD card log (see paragraph 11.2.1.2).



11.2.8. Primary collimator alignment

11.2.8.1. Primary collimator beam alignment check

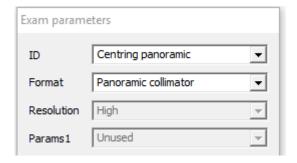
In order to make an exposition without rotating the arm it is necessary to use the software "PhD_C_Test" you can find in the directory C:\Program Files (x86)\OWANDY\PANORAMIC PHD_C. This function is useful to verify and adjust the x-ray beam alignment on the digital sensor and also to measure exposure parameters (see par. 9.7). This function is required in case of tubehead or digital sensor replacement.



Note

Before acquiring and image <u>remove</u> any object from the x-ray beam field including the chin support and the panoramic temple clamps

- Panoramic collimator checks
- From the "Exam parameters" window select the exam ID "Centring panoramic" and the Format "Panoramic collimator".

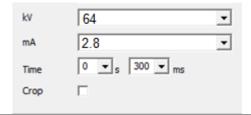




Note

The recommended ID for the measurement of exposure parameters with non-invasive method is "Centering emission"

2. Set the exposure parameters from the "Exam parameter" window.





Note

Place a 1.5mm Cupper filter on the tubehead X-ray beam exit. Be careful not to place the cupper filter on the front side of the collimator as the collimator blades must move during the following tests

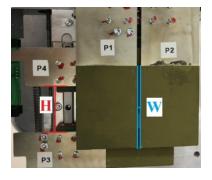




- 3. Once the green led on the keyboard gets solid, press the X-ray button to make an exposition. The acquired image will be displayed.
- 4. If needed, the images can be saved by clicking the button "Save" . To save the image in bitmap format, put ".bmp" at the end of the file name while saving.
- 5. With the panoramic collimator format selected, verify that:
 - In the panoramic acquisition a white border is visible on each side of the image
 - In the panoramic acquisition the irradiated area is **not tilted** and **centered** in the acquisition area
 - The width of the panoramic collimator window (distance between leads edge of P1 and P2) is **W=1mm +/-0.2mm**
 - The maximum distance between the iron part of the P3-P4 blades is **H≤ 35mm**

The x-ray beam coaligned: a white b

The x-ray beam **correctly aligned:** a white border is visible on each side of the image

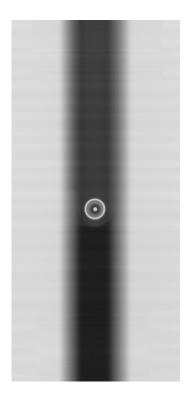




Collimator Width and Height physical measurement

Ceph collimator checks

- **6.** In the "Exam parameters" window set the "Centring ceph" ID and the following options:
 - Format: Height 24
 - Resolution: High
 - Param1="View of primary collimator field"
 - 70kV 8mA
- 7. In the image processing menu set the option "Dynamic adjustment" and remove the 1.5mm copper filter
- 8. Rotate the ceph head support in the lateral position
- 9. Prepare the unit to acquire a ceph exam
- **10.** Acquire the centring ceph exam by pressing the X-ray button
- **11.** In the acquisition verify that:
 - The dot and the outer circle are inside of the main exposed area
 - The top and bottom border of the acquired area are fully exposed
 - The width of the ceph collimator window (distance between leads edge of P1 and P2) is W=2mm +/-0.2mm









11.2.8.2. Primary collimator beam alignment adjustment

Warning



In case of tubehead replacement or digital sensor replacement the x-ray beam should be aligned using mechanical regulations: do not perform the following instructions.

Perform the following operations only in case of collimator replacement, collimator light

Perform the following operations <u>only in case of collimator replacement, collimator light</u> barrier or motors replacement or if the above verification checks failed

1. If the collimator position has to be adjusted, enter the SET-UP mode, open "Unit setting configuration" window and select "Collimator offsets" tab (refers to paragraph 8.4)





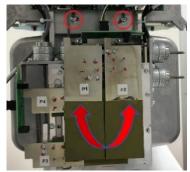
Select "W0-Pan windows" if you want to adjust the panoramic collimation windows



Note

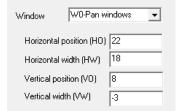
Perform first the Panoramic collimator adjustment (as explained below) and then proceed with the exact sequence of he operations reported in the following paragraphs

3. If the irradiated area in the panoramic acquisition is tilted with respect to the sensor area, adjust the collimator rotation through its fixing screws indicated by the red circles in the image below.



Collimator fixing-regulations for tilting adjustment

4. If the tilt of the irradiated area is ok, but the position is not: modify the offsets following the conventions reported below and then press on send parameter, save



5. Once an offset value has been changed, before acquiring a new static image, press the >o< button on the keyboard in order to perform a collimator reset and apply the new parameters to the to the collimator position.





COLLIMATOR OFFSETS (HO, HW, VO, VW) CONVENTIONS

The horizontal position (HO) offset allows to move the window on the right or left of the acquisition area without modifying the window width (P1 and P2 blades distance remains unchanged)

| OFFSET | EFFECT ON ACQUIRED IMAGE |
|--------|---|
| HO [+] | Move the collimator window on the LEFT of the sensor acquired area |
| HO [-] | Move the collimator window on the RIGHT of the sensor acquired area |

 The horizontal width (HW) offset allows to increase/ decrease the collimator width by moving only the P1 collimation blade

| | wing only the F F commutation state | |
|----------|---|--|
| OFFSET | EFFECT ON ACQUIRED IMAGE | |
| HW [+] | INCREASE the window width by moving the P1 blade on the Left of the | |
| 1144 [1] | sensor acquired area without moving the P2 blade | |
| HW [-] | DECREASE the window width by moving the P1 blade on the Left of the | |
| | sensor acquired area without moving the P2 blade | |

 The vertical position (VO) offset allows to move the window towards the Top/Bottom border of the acquisition area without modifying the window height (P3 and P4 blades distance remains unchanged)

| OFFSET | EFFECT ON ACQUIRED IMAGE |
|--------|---------------------------------|
| VO [+] | Move the collimator window DOWN |
| VO [-] | Move the collimator window UP |

• The vertical width (VW) offset allows to increase/ decrease the collimator height by moving only the P3 collimation blade

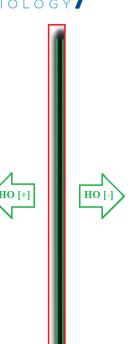
| OFFSET | EFFECT ON ACQUIRED IMAGE |
|------------|---|
| \/\A/ F. 7 | INCREASE the window height by moving the P3 blade on towards the |
| VW [+] | bottom edge of the sensor acquired area without moving the P2 blade |
| VW [-] | DECREASE the window width by moving the P3 blade towards the top |
| | edge of the sensor acquired area without moving the P4 blade |

• Pixel-Offset Conversion

1 offset \simeq 2 pixel (0.198mm) if ID= "Centring panoramic" (Resolution= Hight)

*Note: The symbols [+] and [-] mean, respectively, an increase and a decrease of the offset value.

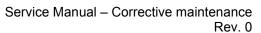


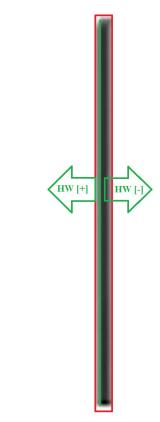


Horizontal Offset (HO) convention

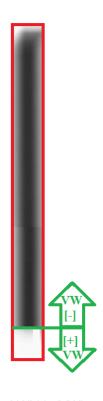


Vertical Offset (VO) convention





Horizontal Width (HW) convention



Vertical Width (VW) convention



- Repeat the tests prescribed by paragraph 11.2.8.1 "Panoramic collimator checks"
- 7. Once the panoramic collimator has been correctly adjusted, in the tab "Collimator offsets" of the "Unit setting configuration" window assign to the "W6 Ceph windows" the same HO, HW, VO and VW offsets values assigned to the "W0 Pan windows"
- 8. Repeat the tests prescribed by paragraph 11.2.8.1 in "Ceph collimator checks" part
- 9. If the tests failed again referring to the ceph alignment paragraph 11.2.9



Note

After any changes to the offset values, update the paper copy of the equipment parameters table in Appendix A with the new values.

11.2.9. Ceph Axis alignment

All the following sub-paragraphs of this chapter are organized in checks and adjustments procedures.



<u>Before making any adjustment</u> (mechanical regulation or offsets modification), it's mandatory to ensure that the <u>checks required by the previous sub-paragraphs</u> are within the prescribed tolerances. If they are not in the tolerances, first perform the adjustments prescribed by the previous sub-paragraphs

If during the following paragraph an offsets adjustment is required:



- refer to chapter "Machine configuration and setup" chapter 8.4
- After the changes update the paper copy of the equipment parameters table (supplied as paper copy with the unit documentation) with the new offset values (see Appendix A at paragraph 14.1)

11.2.9.1. Ceph ear rods adjustment

Checks

- 1. Rotate the ceph head support in the lateral position
- 2. Open "PhD_C_Test.exe" service program
- 3. And select the following parameters:
 - Format: No collimator
 - Resolution: High
 - Param1: View of Primary collimator field
 - 70kV 8mA
- 4. In the image processing menu select: "Dynamic adjustment"
- 5. Prepare the unit to take the ceph exam and then press the X-Ray button until the end of the exposure





6. Save the image as "Rods.bmp"

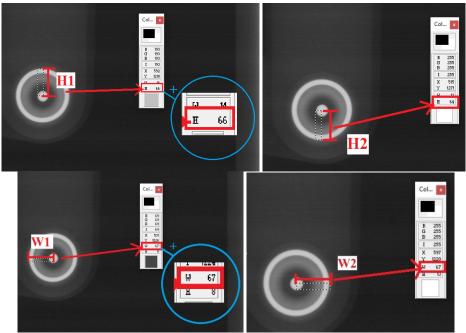


- 7. Open the image in SyMage software application (C:\Program Files (x86)\OWANDY\PANORAMIC PHD_C\SyMage)
- 8. In the menu bar select the "Rectangle Selection"



9. Verify that the that the misalignment between the centres of the inner dot and the outer circle is not more than 15 pixel (0.099mm/pixel) both in vertical and horizontal directions:

|H1-H2|≤15pixels |W1-W2|≤15pixels



Adjustments

• Vertical ear rods corrections:



The vertical regulation of the ear rods will affect also the projection of the secondary collimator on image plane, which will vary the upper and lower not exposed borders position. Therefore after this adjustment repeat the tests images requested by paragraph 7.8

- 1. Remove the ceph upper cover (refer to paragraph 7.3.3)
- 2. Lose the fixing screws F and act on regulation screw R according the table below
- 3. Tighten the fixing screws F and acquire again a check image
- 4. Iterate the procedure until the required tollerance on |H1-H2| measure is reached





| ACT of regulation screws | Effect on measure of H1-H2 |
|--------------------------|--|
| R [clockwise] | INCREASE segment H1 on the acquired image, move RING UP |
| R [anti-clockwise] | DECREASE segment H1on the acquired image, move RING DOWN |

R screw turn-pixels "conversion"

1 complete screw R turn→ add/remove 7 pixels to the measure of |H1-H2| on acquired image

Furthers checks after the adjustment

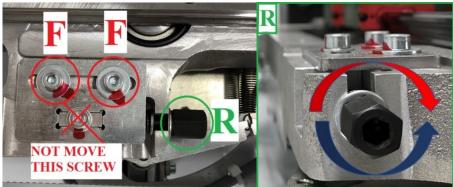
If the vertical regulation has been modified perform all the checks required by paragraph 7.8

• Horizontal ear rods corrections:

- 1. Remove the ceph upper cover (refer to paragraph 7.3.3)
- 2. Lose the fixing screws F and act on regulation screw R according the table below
- 3. Tighten the fixing screws F and acquire again a check image
- 4. Iterate the procedure until the required tolerances of |W1-W2| are reached.







| ACT of regulation screws | Effect on measure of H1-H2 |
|--------------------------|---|
| R [clockwise] | INCREASE segment W1 on the acquired image, move RING on the LEFT of the acquired image |
| R [anti-clockwise] | DECREASE segment W1 on the acquired image, move RING on the RIGHT of the acquired image |

R screw turn-pixels "conversion"

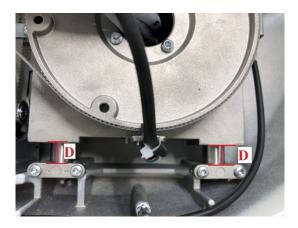
1 complete screw R turn→ add/remove 14 pixels to the measure of |W1-W2| on acquired image

11.2.9.2. **Y ceph offset**

Checks

- 1. Verify if the numerical value of the "Y ceph offset" stored in the unit EEPROM memory (see paragraph 8.4) is the same one reported by the equipment parameters table (supplied as paper copy with the unit documentation see paragraph 14.1). If it's not the same correct it.
- 2. Remove the unit upper covers, select a "Ceph" exam, prepare the unit to take a ceph exam, once the unit is positioned and ready to make an exposure (green keyboard LED steady ON) and verify that the distance between the slide of the Y axis and the back run limits (D in the following figure) is:

D=13mm± 2mm



Adjustments



The Y ceph offsets regulations will affect the position of the projection of the primary collimator on the ceph image plane. Therefore after the Y axis adjustment it's recommended to perform all the ceph checks requested by the following paragraphs (in the exact numeric



sequence).

If an adjustment is required modify the Y Ceph offset according to the following convention:

| OFFSET | Effect on measure of segment D |
|-------------|--------------------------------|
| Y ceph [+]* | INCREASE the segment D length |
| Y ceph [-]* | DECREASE the segment D length |

*Note: The symbols [+] and [-] mean, respectively, an increase and a decrease of the offset value. Offset Conversion

Furthers checks after the adjustment

If the offset has been modified perform all the checks of the following paragraphs following the numeric sequence.

11.2.9.3. Primary collimator W6-Ceph window



Warning

Before proceeding with following points perform the primary collimator alignment checks/adjustments requested by paragraph 11.2.8

Checks

- 1. Rotate the ceph head support in antero-posterior (AP) position
- 2. Open "PhD C Test.exe" service program
- 3. Select the following parameters:
 - Format: Height Custom
 - Resolution: High
 - Param1: View of Primary collimator field
 - 70kV 8mA
- 4. In the image processing menu select: "Dynamic adjustment"
- 5. Prepare the unit to take the ceph exam and then press the X-Ray button until the end of the exposure
- 6. Save the image as "Primary custom.bmp"
- 7. Open the image in SyMage software application (C:\Program Files (x86)\OWANDY\PANORAMIC PHD C\SyMage)
- 8. In the menu bar select the "Rectangle Selection"



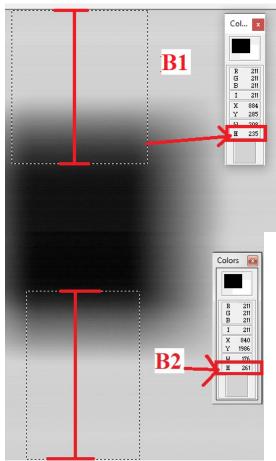
9. Verify that the that the upper (B1) and lower (B2) **not exposed borders** are (measured in High resolution 0.099mm/pixel):

B1>210pixels B1>210pixels

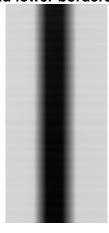


¹ offset \simeq 0.2mm measured on the Y axis





- 10. Select the following parameters:
 - Format: Height 24
 - Resolution: High
 - Param1: View of Primary collimator field
 - 70kV 8mA
- 11. Prepare the unit to take the ceph exam and then press the X-Ray button until the end of the exposure
- 12. Save the image as "Primary-full.bmp"
- 13. Verify that the upper and lower borders are fully irradiated.



Adjustments



If the B1 and B2 measures are not in the prescribed tolerances and/or the upper and lower borders are of the Primary-fully.bmp image are not fully irradiated:

- 1. Enter the SET-UP mode, open "Unit setting configuration" window and select Collimator offsets" tab (refer to paragraph 8.4)
- 2. Adjust the W6-ceph window "Vertical position VO" and "Vertical width VW" according to the following conventions:

The vertical position (VO) offset allows to move the window towards the Top/Bottom border of the acquisition area without modifying the window height (P3 and P4 blades distance remains unchanged)

OFFSET EFFECT ON ACQUIRED IMAGE (measuer of B1 and B2)

VO [+]* Move the collimator window DOWN

Increase B1 and decrease B2 of the same distance

VO [-]* Move the collimator window UP

Decrease B1 and increse B2 of the same distance

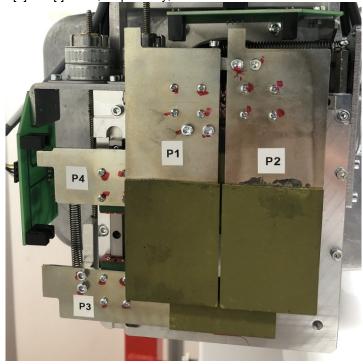
The vertical width (VW) offset allows to increase/ decrease the collimator height by moving only the P3 collimation blade

OFFSET EFFECT ON ACQUIRED IMAGE (measuer of B1 and B2)

VW [+]* REDUCE B2 by moving the P3 blade towards the bottom edge of the sensor acquired area without moving the P2 blade

VW [-]* INCRESE B2 by moving the P3 blade towards the top edge of the sensor acquired area without moving the P4 blade

*Note: The symbols [+] and [-] mean, respectively, an increase and a decrease of the offset value.



Primary collimator blades numbering

• Pixel-Offset Conversion

1 offset \approx 6 pixel (0.099mm) if ID= "Centering ceph" (Resolution= High)







Note

After any changes to the offsets values, update the paper copy of the equipment parameters table (supplied as paper copy with the unit documentation) with the new offset values (see Appendix A paragraph 14.1)

Furthers checks after the adjustment

If the offset has been modified perform all the checks of the following paragraphs following the numeric sequence.

11.2.9.4. Rotation ceph offset

Checks

- 1. Rotate the ceph head support in the lateral position
- 2. Open "PhD_C_Test.exe" service program
- 3. Select the following parameters:
 - Format: Height Custom
 - Resolution: High
 - Param1: View of Primary collimator field
 - 70kV 8mA
- 4. In the image processing menu select: "Dynamic adjustment"
- 5. Prepare the unit to take the ceph exam and then press the X-Ray button until the end of the exposure
- 6. Save the image as "Rotation.bmp"



7. Verify that the that the dot and ring projections are centred to the primary collimator beam

Adjustments

If the ring-dot are not centred to the primary X-ray beam perform the following procedures:

 Verify if the numerical values of the "W6-Ceph window" collimator offsets "HO, HV,VO,VW" stored in the unit EEPROM memory (see paragraph 8.4) are the same ones reported by the equipment parameters table (supplied as paper copy with the unit documentation – see paragraph 14.1). If they are not the same correct them.



2. Verify if the numerical value of the "Rotation ceph offset" stored in the unit EEPROM memory (see paragraph 8.4) is the same one reported by the equipment parameters table (supplied as paper copy with the unit documentation – see paragraph 14.1). If it's not the same correct it.



Before proceeding with following points perform the panoramic primary collimator alignment checks requested by paragraph 11.2.8)

3. If an adjustment of the Rotation ceph offset is required modify its values according to the following convention:

| OFFSET | Effect on position of x-ray beam |
|-----------|-------------------------------------|
| Rotation | Move the X-ray beam on the RIGHT of |
| ceph [+]* | the ear rods/ image |
| Rotation | Move the X-ray beam on the LEFT of |
| ceph [-]* | the ear rods/ image |

^{*}Note: The symbols [+] and [-] mean, respectively, an increase and a decrease of the offset value.

Offset Conversion

1 offset \simeq 37pixel (3.7mm) measured on the image (Resolution:High)

Furthers checks after the adjustment

If the offset has been modified perform all the checks of the following paragraphs following the numeric sequence.

11.2.9.5. Secondary Collimator offset

Checks

- 1. Rotate the ceph head support in lateral position
- 2. Open "PhD_C_Test.exe" service program
- 3. Select the following parameters:
 - Format: Height 24
 - Resolution: High
 - Param1: View of sec. collimator field
 - 70kV 8mA
- 4. In the image processing menu select: "Dynamic adjustment"
- 5. Prepare the unit to take the ceph exam and then press the X-Ray button until the end of the exposure
- 6. Save the image as "Secondary.bmp"





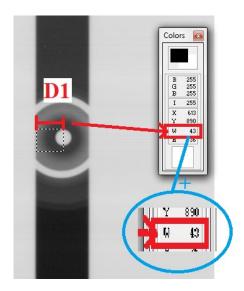


- 7. Open the image in SyMage software application (C:\Program Files (x86)\OWANDY\PANORAMIC PHD_C\SyMage)
- 8. In the menu bar select the "Rectangle Selection"

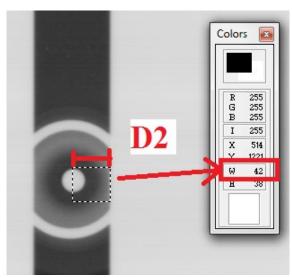


9. Verify that the that the dot of the ceph support is positioned in the center of the exposed area and the difference between D1 and D2 is in the following tolerance

|D1-D2| ≤ 4 pixels











Adjustments

If an adjustment is required modify the "Coll II" offset according to the following convention:

| OFFSET | Effect on measure of segments D1 and D2 |
|--------------|---|
| Coll II [+]* | INCREASE the segment D1 length on the image |
| Coll II [-]* | DECREASE the segment D1 length on the image |

*Note: The symbols [+] and [-] mean, respectively, an increase and a decrease of the offset value.

Offset Conversion

1 offset \simeq 3 pixel of shift of the secondary collimator position measured on the acquired image

Furthers checks after the adjustment

If the offset has been modified perform the checks/adjustments required by "Sensor ceph offset" chapter 11.2.9.6.

11.2.9.6. Sensor ceph offset

Checks

- 1. Rotate the ceph head support in lateral position
- 2. Open "PhD_C_Test.exe" service program
- 3. Select the following parameters:

- Format: Height 24

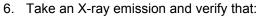
- Resolution: High

- Param1: Static acquisition centred

- 70kV 8mA
- 300ms
- 4. Prepare the unit to take the ceph exam and then press the X-Ray button until the end of the exposure
- 5. Save the image as "Static-ceph.bmp"







- There aren't not exposed borders on the sides of the acquired area (on the right and left)
- The dot of the ceph patient support is centred to the sensor area



Adjustments

If an adjustment is required modify the "Sens Ceph" offset according to the following convention:

| OFFSET | Effect on the image acquisition (position of projections of dot and secondary collimator) |
|-----------|---|
| Sens Ceph | Move the dot/Ring the LEFT of the image; |
| [+]* | Remove a not exposed edge on the LEFT of the image |
| Sens Ceph | Move the dot/Ring the RIGHT of the image; |
| [-]* | Remove a not exposed edge on the RIGTH of the image |

^{*}Note: The symbols [+] and [-] mean, respectively, an increase and a decrease of the offset value. Offset Conversion

Furthers checks after the adjustment

If the offset has been modified perform the checks required by "Verification of ceph function" chapter 7.8

 $^{1 \}text{ offset} \simeq 2 \text{ pixel}$ of shift of the secondary collimator position measured on the acquired image





11.3. Parts replacement

11.3.1. Fuses replacement

Before replacing fuses, turn the unit OFF and disconnect it from the mains (by turning OFF the mains power supply breaker dedicated to the unit).

Replace the broken fuse with one of the same specification.

11.3.1.1. **Main fuses**

The main fuses F1 and F2 are located on the top side of the unit.

The fuse F1 cuts the mains supplied to the switching power supply (G1) in case of overcurrent. The fuse F2 cuts the mains supplied to the motor column driver (G2) in case of overcurrent.

Fuses type:

- F1: 6.3x32 F fuse. Refer to chapter 5 Technical Characteristics for the value
- F2: 6.3x32 F fuse. Refer to chapter 5 Technical Characteristics for the value.

11.3.1.2. MCU board (A1) fuse

The MCU board fuse F1, in case of overcurrent, cuts the 24V supplied to the motors (M3, M4, M5, M6).

Fuse type: 2 A FF (125V)

Refer to chapter 12 – drawing 2 - for fuse position.



11.3.1.3. Generator board (A2) fuse

The Generator board fuse F1, in case of overcurrent, cuts the Generator board main power supply.

Fuse type: 1 A T (250V) TR5

Refer to chapter 12 – drawing 3 - for fuse position.



11.3.2. A1 MCU board replacement



Warning

The board shipped as replacement carries the Hardware key and the EEPROM not configured.

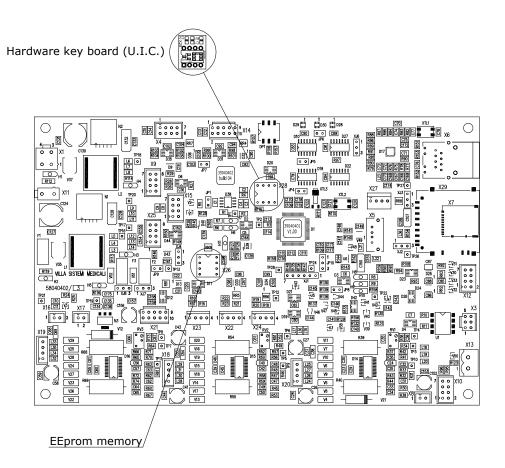
To make the system working, the Hardware key must be retrieved from the failed board and positioned on the new board. This component includes the U.I.C. (Unique Identification Code) which determines the enabling codes for the radiological exams.

Moreover on the EEPROM the system configuration data are stored; remove the EEPROM from the new board and replace it with the one present on the failed board. In case the old EEPROM was not functioning, it will be necessary to mount the not configured EEPROM and restore manually the configuration data present on the equipment parameters table supplied with the Service Manual (see paragraph 14.1), following the procedure present on chapter 8 - "Service programs description".



Note

At the end of the replacement, restore the metallic cover and the ground connection. Both parts has to be recovered from failed board.







11.3.3. A11 CCU board replacement

Replacement of this board doesn't require any adjustment. Take care of cable connections

11.3.4. **A2 Generator board replacement**

Replacement of this board doesn't require any adjustment. Take care of cable connections Refer to par. 11.3.9 steps 1-4 for more informationi

11.3.5. A12 Collimator driver board replacement

Replacement of this board doesn't require any adjustment. Take care of cable connections

11.3.6. **A13 CEPH driver board replacement**

Replacement of this board doesn't require any adjustment. Take care of cable connections

11.3.7. A14 Pan/Ceph sensor board replacement

Replacement of this board doesn't require any adjustment. Take care of cable connections

11.3.8. Pan/Ceph sensor replacement

Once replaced the PAN/ CEPH sensor, make a complete centering check as described in par. 7.9



11.3.9. Tube head replacement

- 1. Switch OFF the unit.
- 2. Remove the tubehead external and internal cover.
- 3. Remove the Generator board metallic cover:

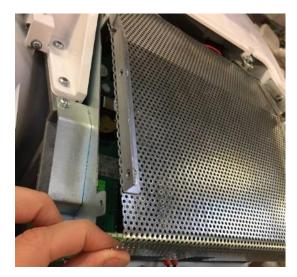


Figure 14

4. Unscrew the cables fixing clamps "A" and then disconnect X57 and X56 connectors from Generator board. Unscrew the 4 generator board support screws "B":

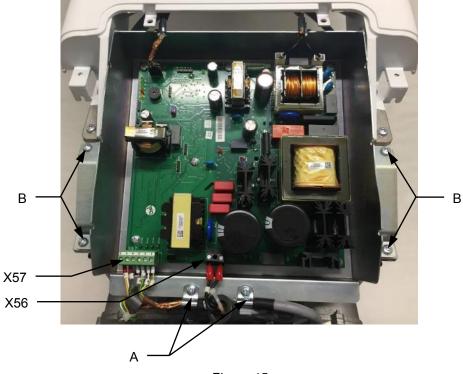


Figure 15

HAST X DU-1

5. Pull up the generator board.

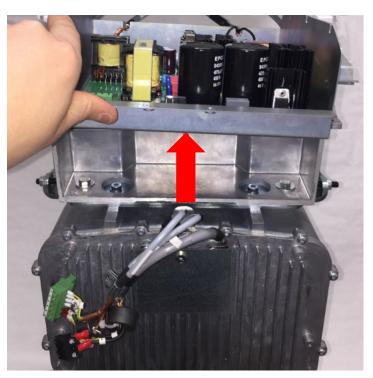


Figure 16



Note

The presence of a second operator is required during the following steps.

6. While the first operator hold the tubehead with two hands, the second unscrew the generator board screws "C".

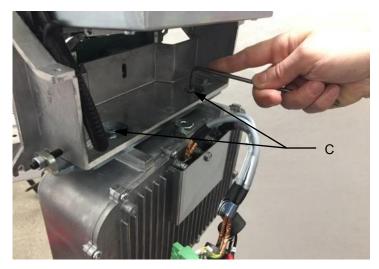


Figure 17



7. Mount the new tubehead, taking care to push it with one hand in the direction of the sensor while tightening the screws "C" (Figure 25).

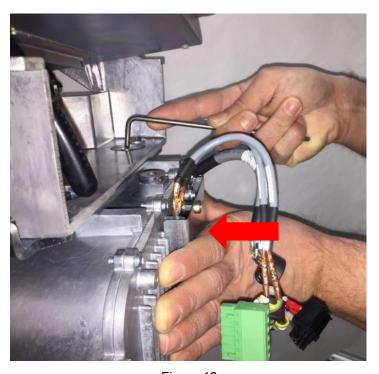


Figure 18

- 8. Connect X56 and X57 connectors and fix the cables fixing clamps "A" (Figure 23).
- **9.** Mount the generator board metallic cover and tighten its fixing screws.
- 10. Switch ON the unit and wait the G.U.I. connection.
- **11.** Insert the preheating values reported on the label of spare tubehead in the EEPROM memory (see paragraph 8.4).



Warning

Wrong settings of preheating parameters may damage X-ray tube.

12. Perform the X-ray beam centering verification (see paragraph 8.4).





- **13.** In case the beam is not centered to the sensor, loosen the screws "C" (Figure 25) and act on screws "D" and "E" (Figure 28) following the convention reported below:
 - Screw "E" to move the X-ray beam on the right (on the image)
 - Screw "D" to move the X-ray beam on the left (on the image)

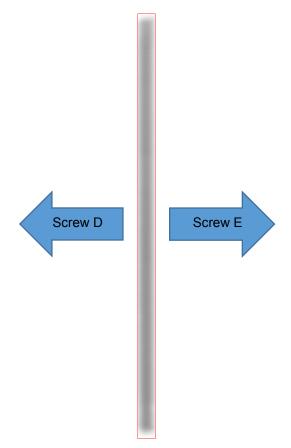


Figure 19



Note

In order to act on a screw (D or E) on one side, loosen the other screw on the opposite side.



Figure 20



- **14.** Tighten screws "C" and repeat the static acquisition.
- **15.** Once X-ray beam has been well centred, tighten all the screws.
- **16.** Mount the tubehead internal cover.
- 17. Mount the tubehead external cover paying attention to insert first the lower pins of the cover in the guide present in the tube head internal cover and then fix the upper part of the covers.

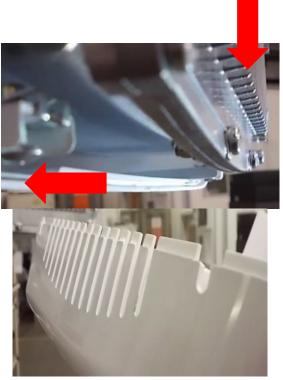




Figure 21

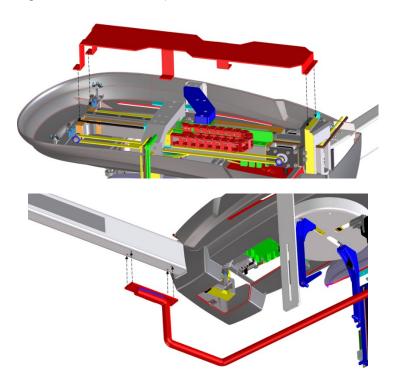
- 18. Perform the sensor calibration and verification (see paragraph 10.2).
- **19.** Perform a panoramic symmetry verification (see paragraph 7.7).





11.3.10. Column replacement

- 1. Remove the CEPH arm upper cover
- 2. Install the CEPH arm protection plate and CEPH arm handle (these tool have been removed during installation of the unit)



3. Fix secondary collimator and sensor arms to the protection plat.

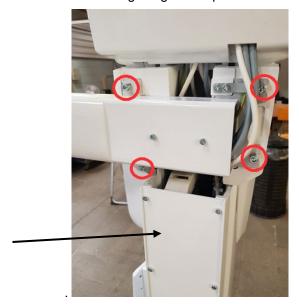




- 4. Remove the upper cover of the unit and the MCU cover to access the connectors
- 5. Disconnect cables coming from CEPH arm



6. Remove the screws of the following image and open the back cover



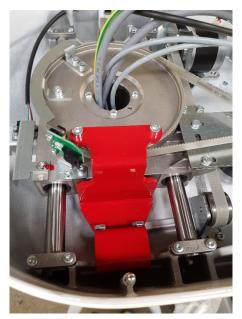




7. Remove the CEPH arm and position it up-side down, if possible inside the original package



8. Fix the rotating arm installing the support provided with the unit (that was removed during installation)





Protect the unit with plastic film and install the package. Fix it using adhesive tape





10. Remove fixing screws.









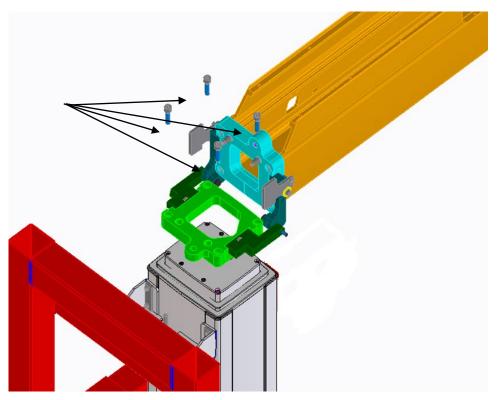
11. Tilt down the upper part of the unit. Disconnect cables and remove the back plates from the column



12. .Remove the top side screws and the cable channel

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- **13.** Replace the column and the T Motion control box (in the tilted part of the column).
- **14.** Once replaced, it is necessary to repeat the complete installation as for par. 7
- **15.** Repeat all the verification before to use the unit with patients as for par.7.7



11.3.11. Chin support replacement

- 1. Remove the upper cover. Remove cover from MCU board.
- 2. Set DIP-switch 3 to OFF (1 and 2 ON) in order to enter in Service Mode (see paragraph 4.3.2.1).
- 3. Switch ON the unit and wait until the green LED blinks.



Note

In service mode NEVER press up/down column keys as they change rotating position.

4. Unplug the "broken" cable X12 and connect the X12 of the new chin support. Use its keyboard for the next step.



Figure 22

- 5. Press the >0< button
- **6.** Position the panoramic tool on chin support.



7. Turn ON laser and press >0< button on the keyboard until sagittal laser is on the middle of tool. Use adhesive tape and mark the laser position (using a pen).



Figure 23

- 8. Put adhesive tape between the extremities of the tool.
- **9.** Press >0< button on the keyboard until sagittal laser is parallel to chin support arm. On adhesive tape mark the laser position (using a pen).

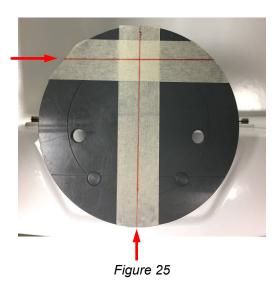


Figure 24





Rotation references are present on the tool and it has to be used as reference to position the unit in the same position.



10. Unplug the X12 cable and the ground.



Figure 26



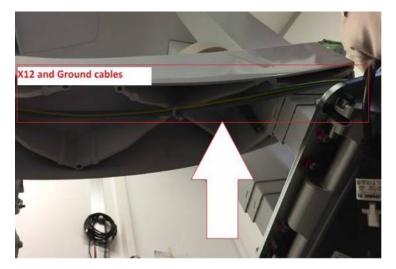


Figure 27

11. Unscrew the two screws under the arm.

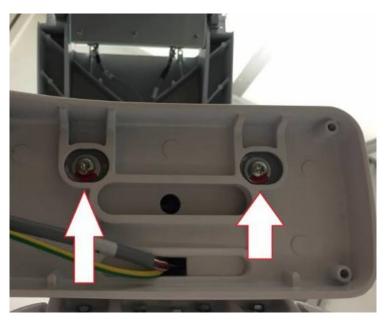


Figure 28

- 12. Remove the group "key board-handle".
- 13. Position the new group.
- 14. Turn ON the unit in Service mode.
- **15.** Turn ON the laser and press >0< button on the keyboard to rotate the unit.
- **16.** Verify that the sagittal laser is projecting on the reference on the tape and than lightly tighten the screws under the arm. Verify that the horizontal line is on the horizontal line on the tape.
- 17. If both the sagittal and horizontal line are aligned, hard tighten the screws.
- 18. Turn OFF the unit.
- **19.** Set DIP-switch 3 to OFF to set the unit in normal mode (see paragraph 4.3.2.1).
- 20. Turn ON the unit.



21. Make exposure and verify the image quality as described in paragraph 7.7.

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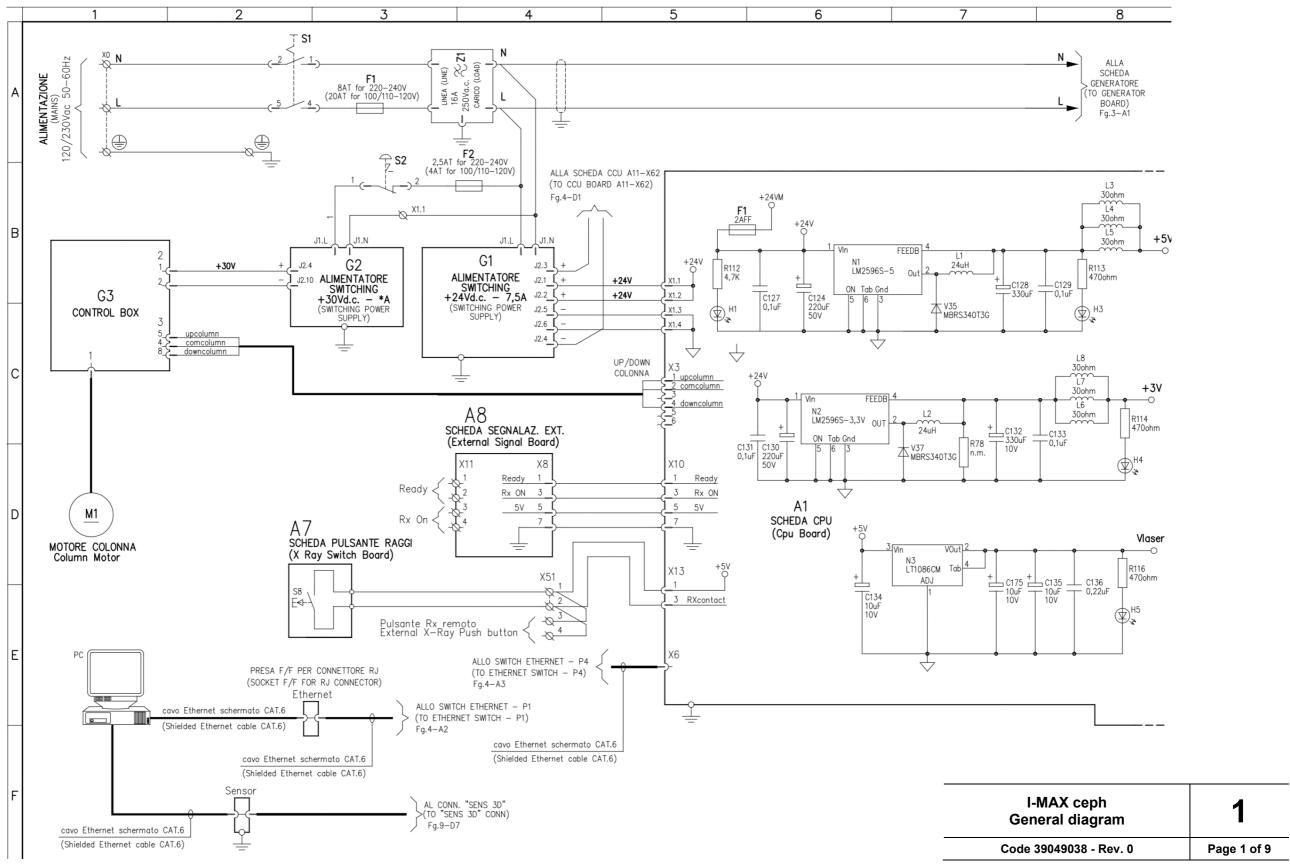
12. SCHEMATICS AND DRAWINGS

- 1. I-Max-Ceph General diagram
- 2. MCU-CPU board A1 layout
- 3. Generator board A2 layout
- 4. CCU board A11 layout
- 5. Collimator driver board A12
- 6. Ceph drivers board A13
- 7. Ceph sensor power supply board A14



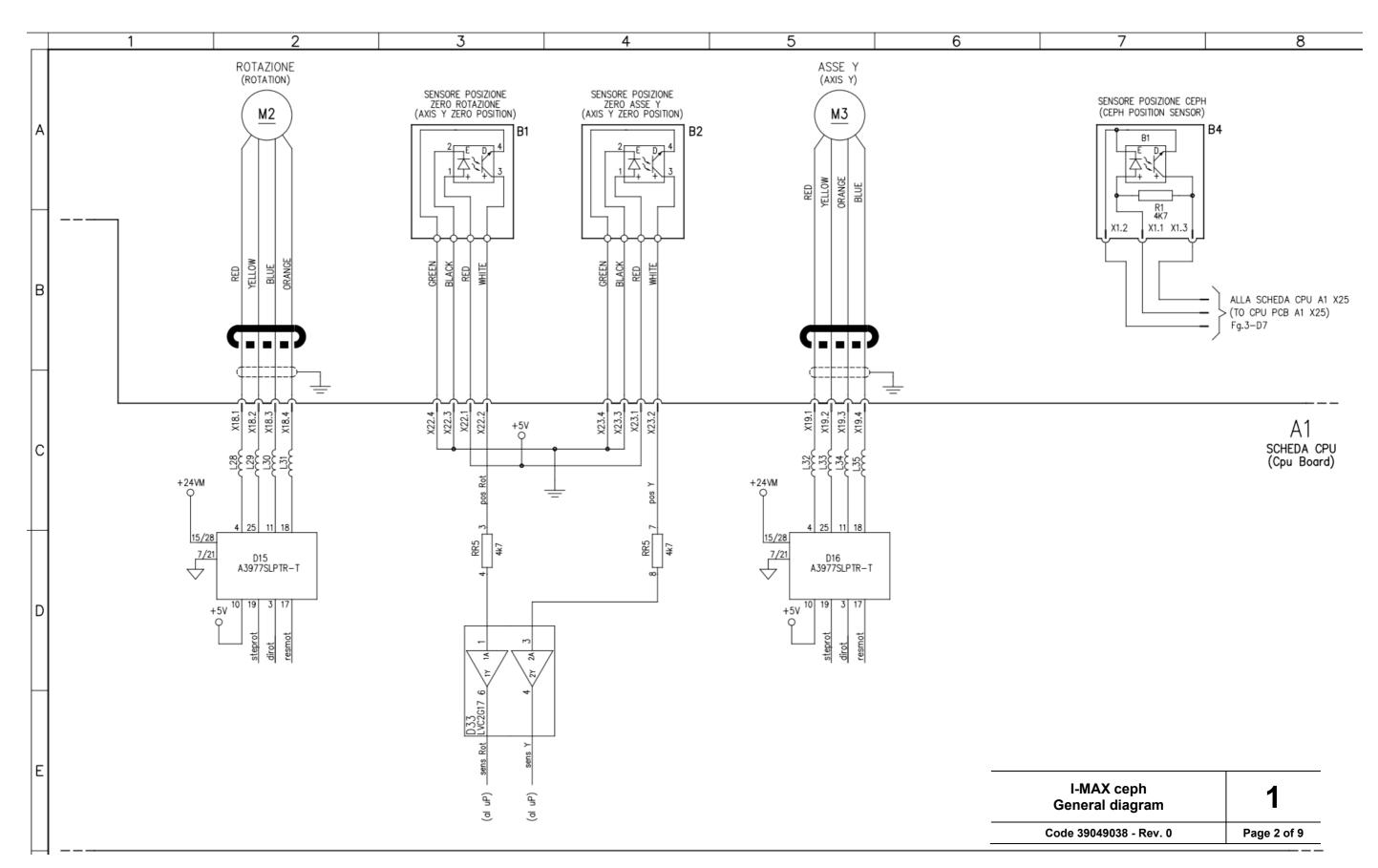
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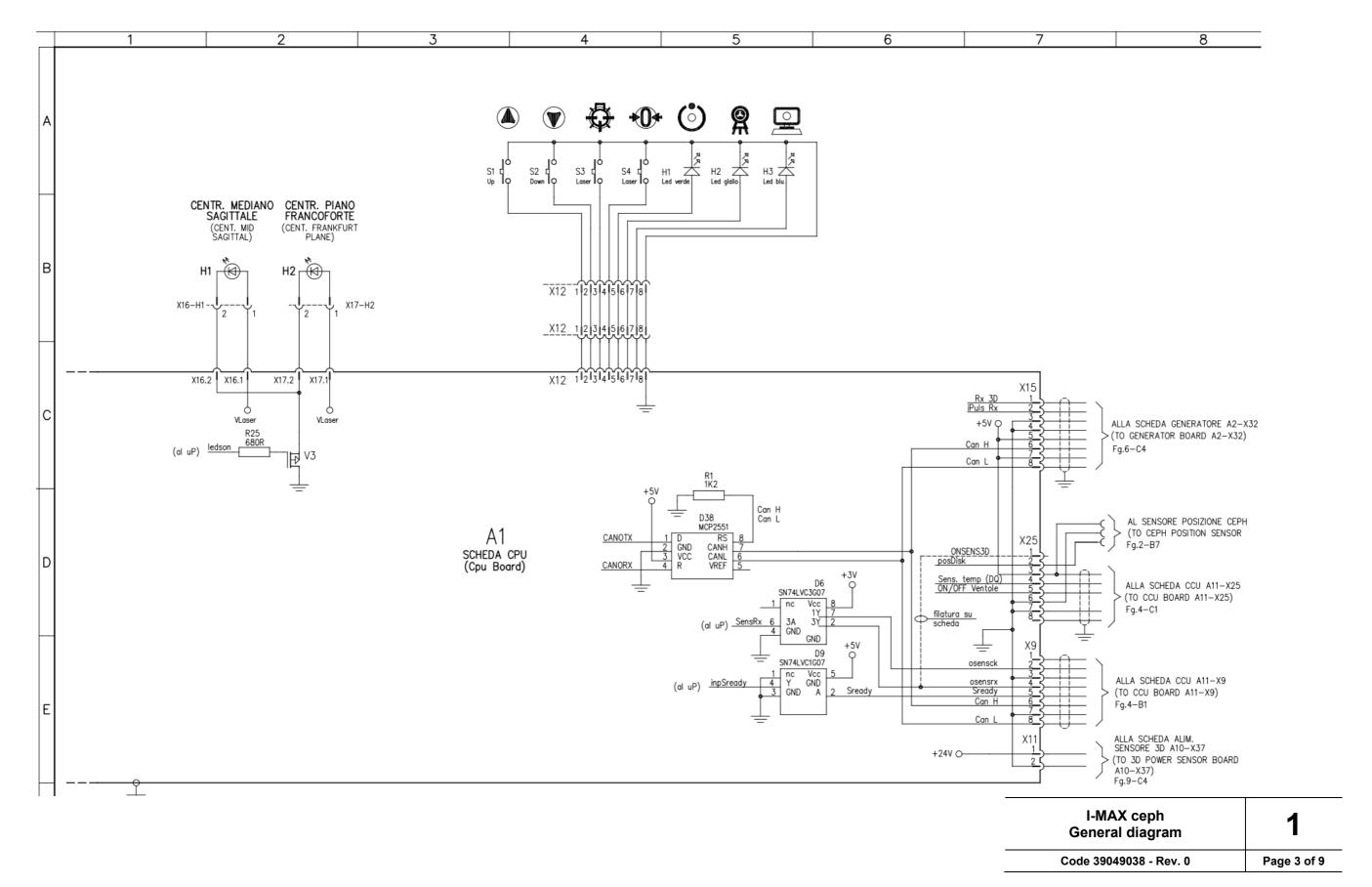
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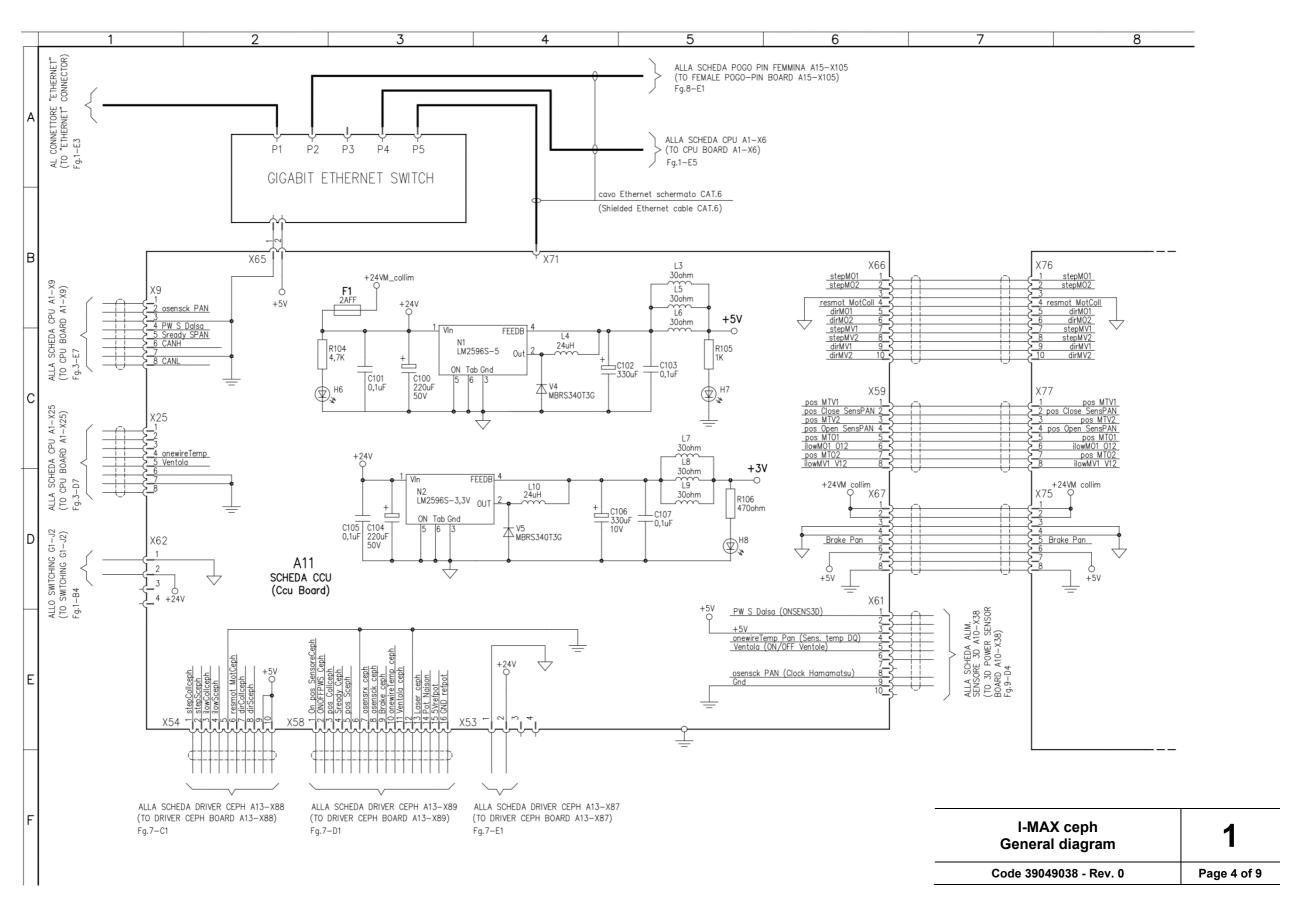






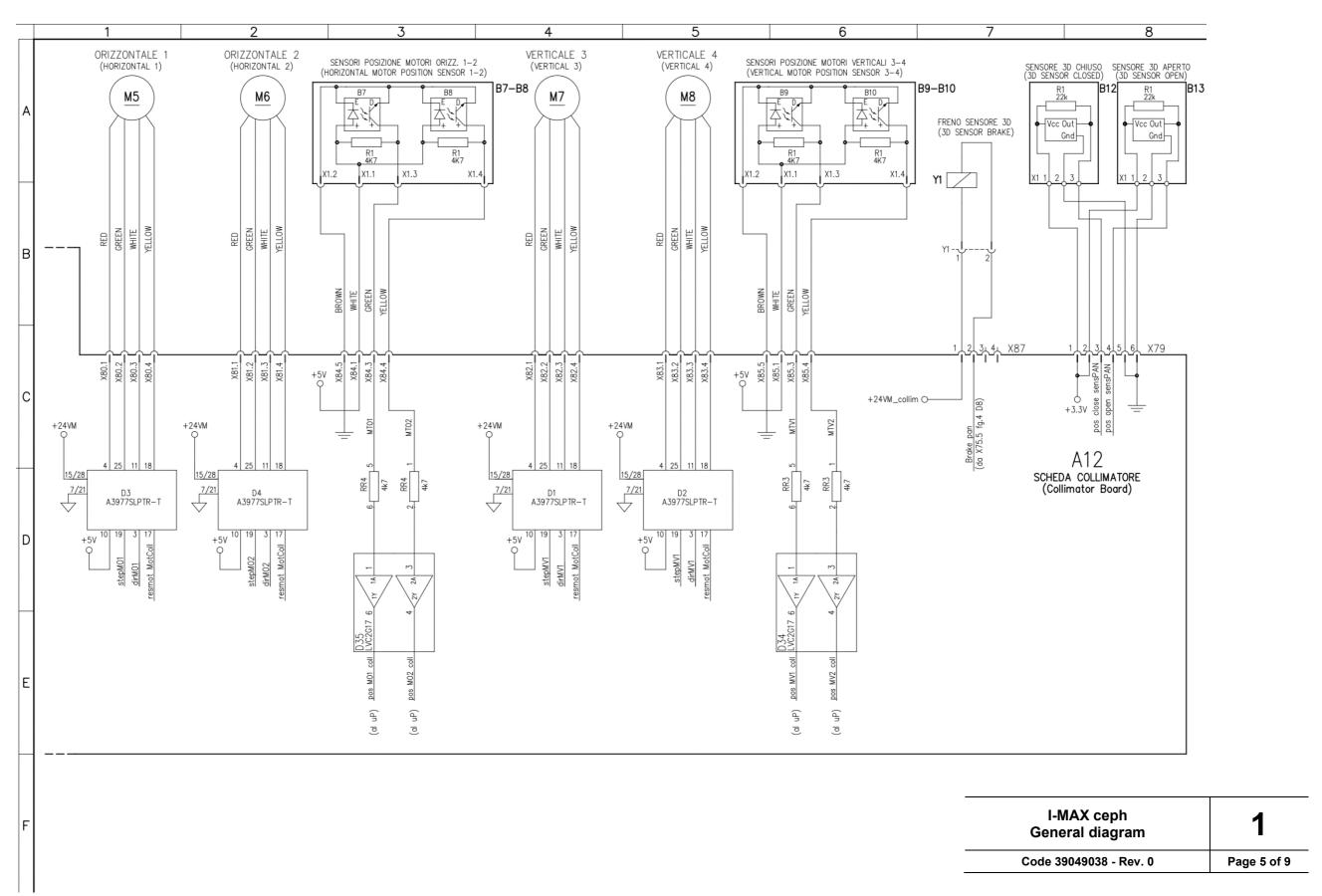






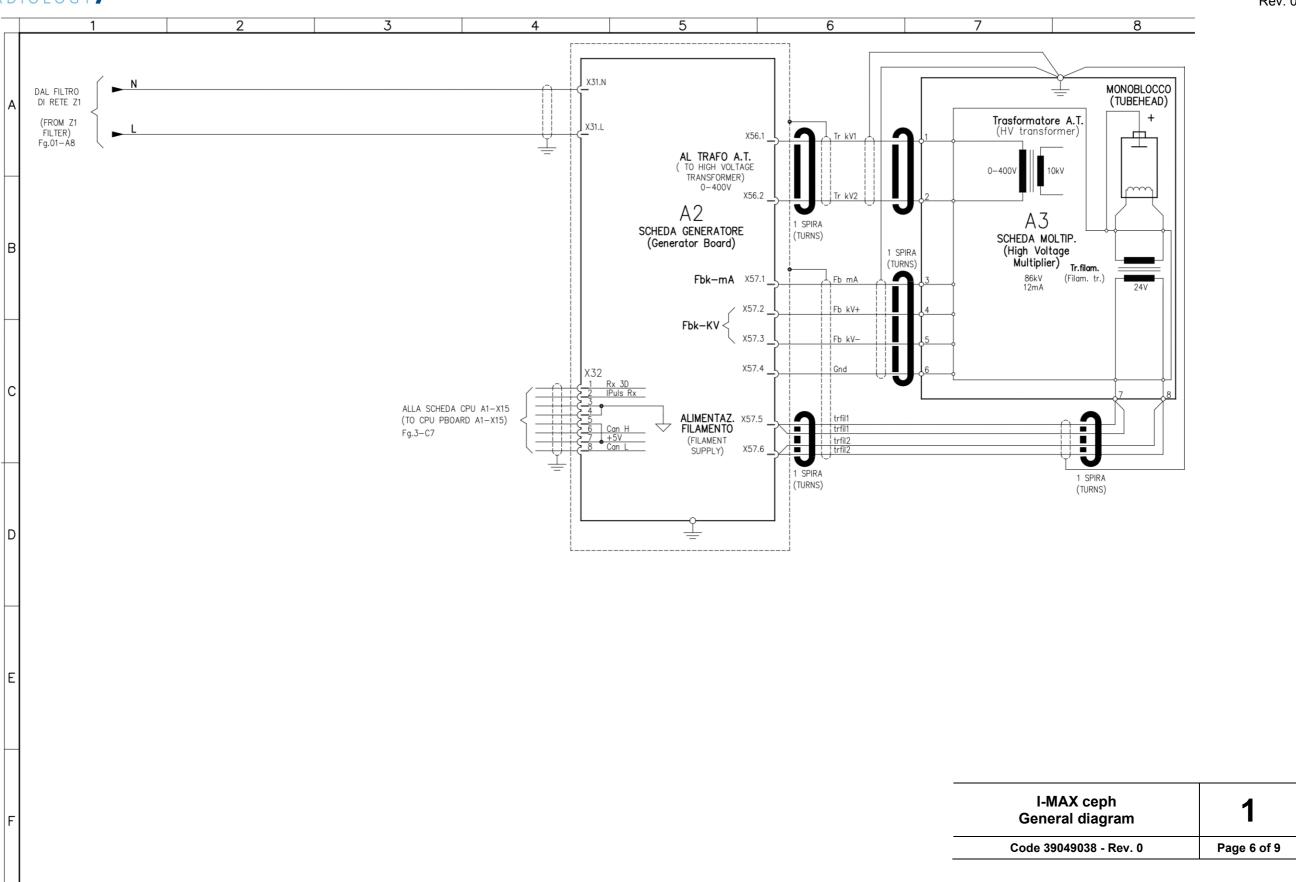






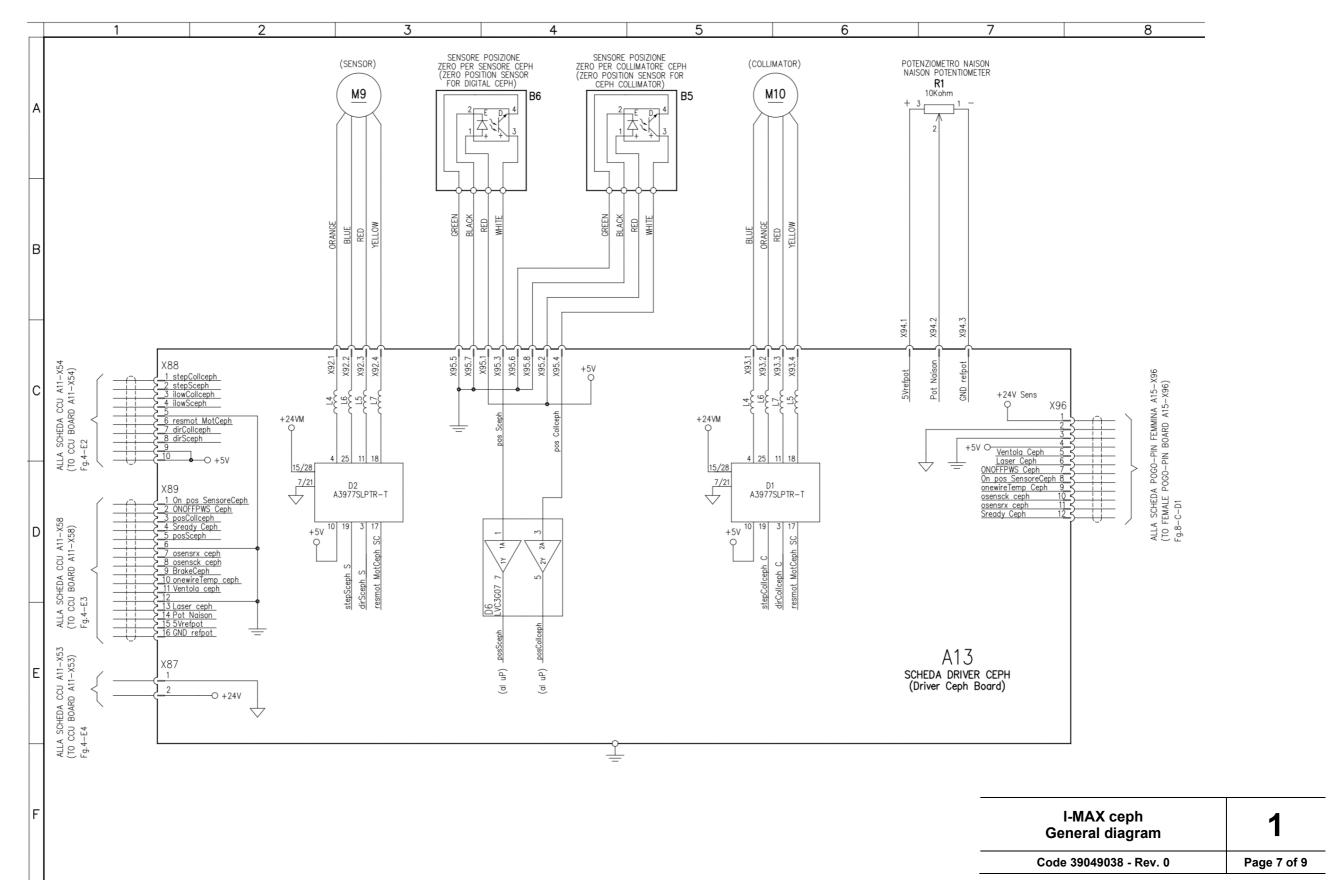
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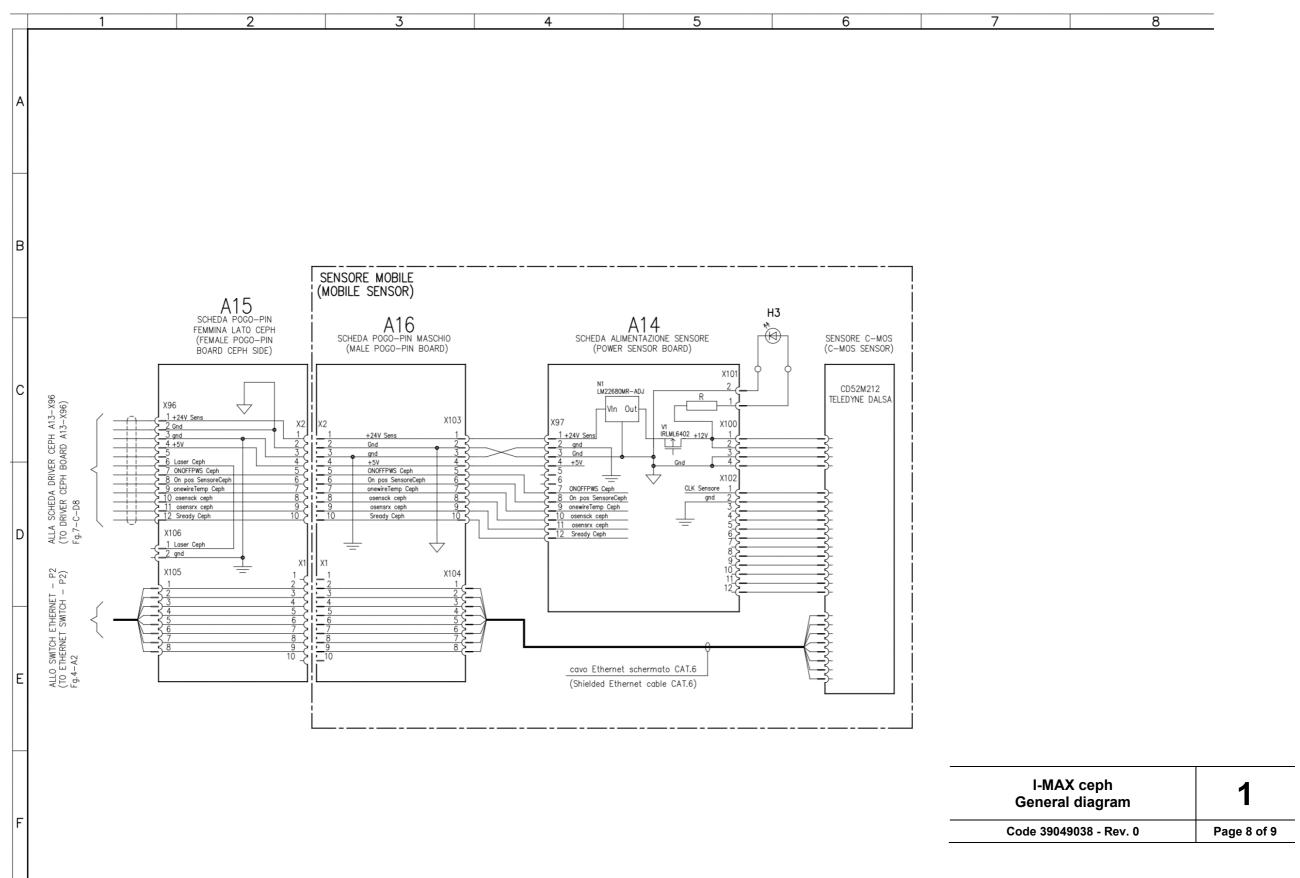
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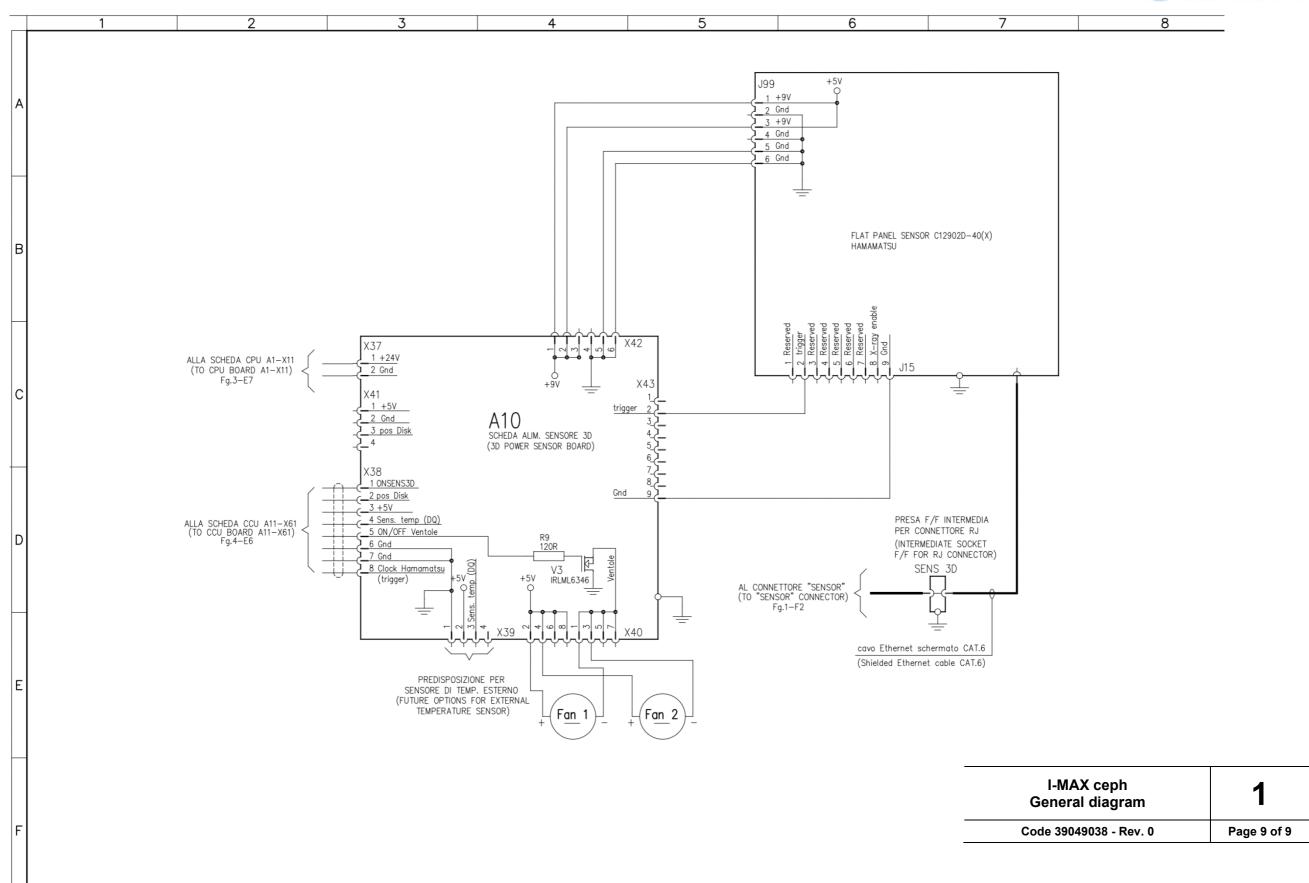






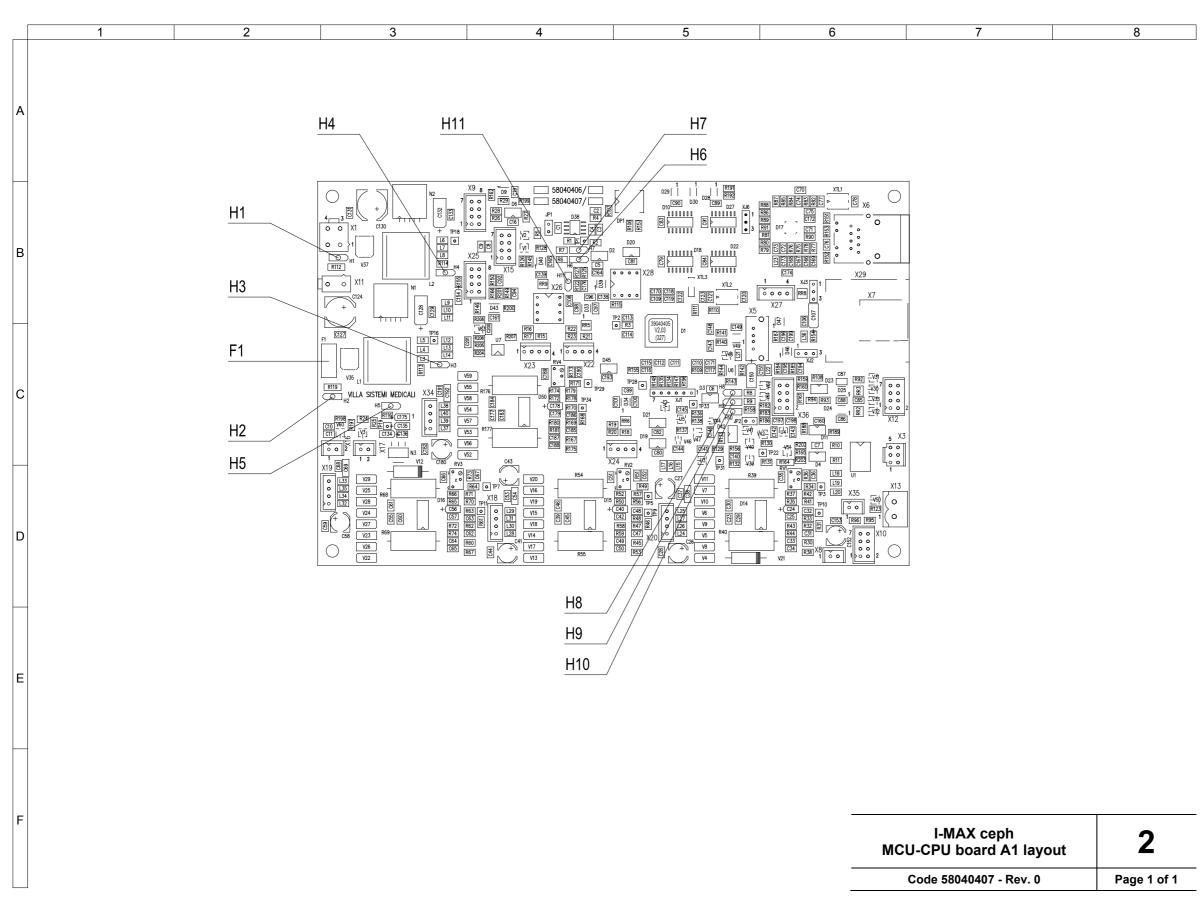






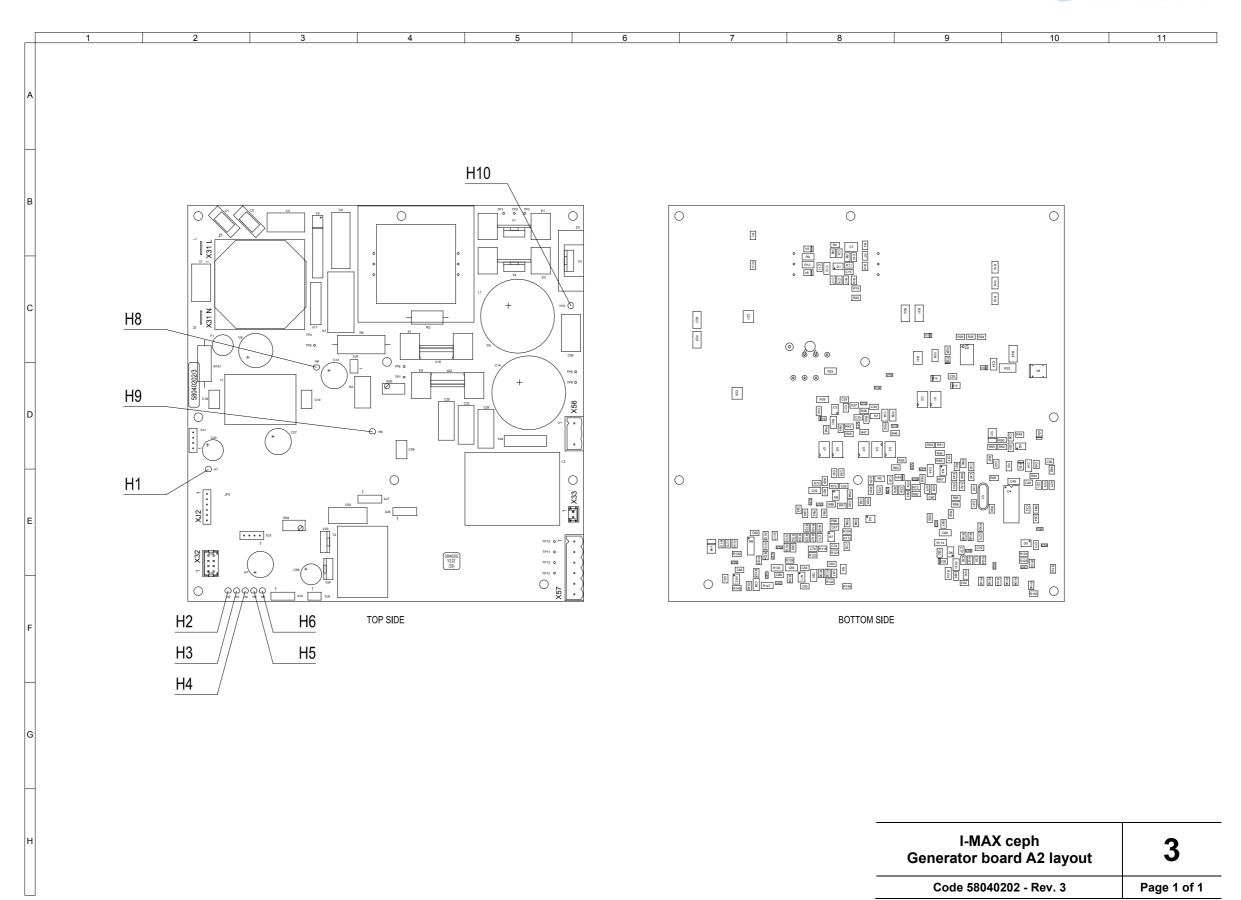






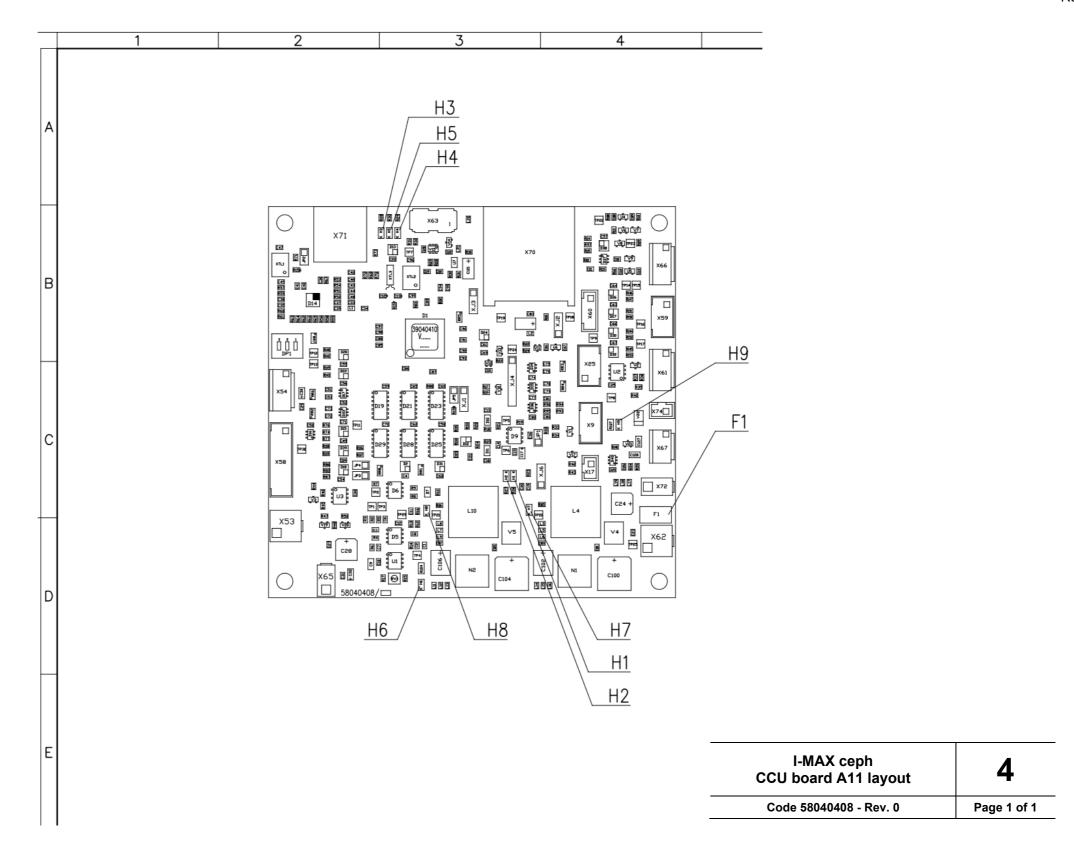




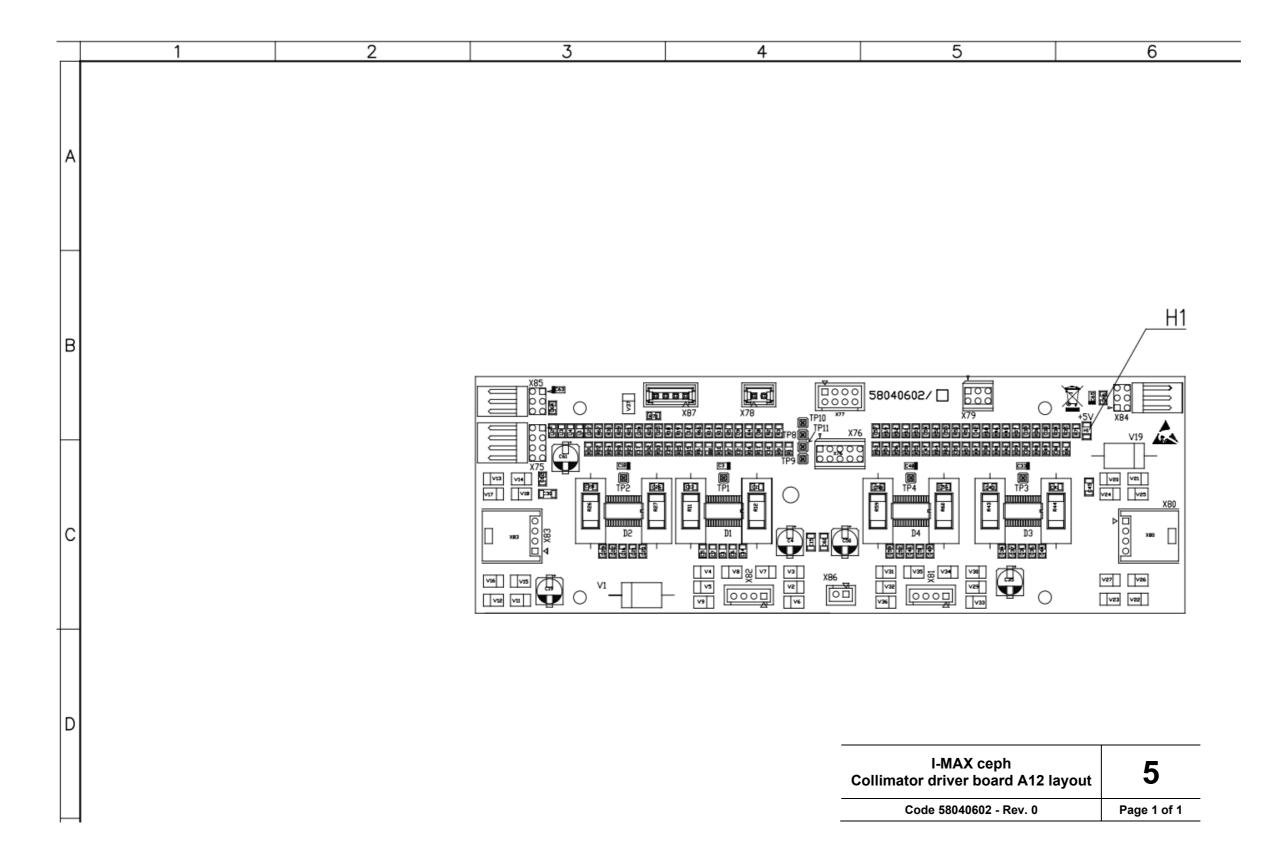




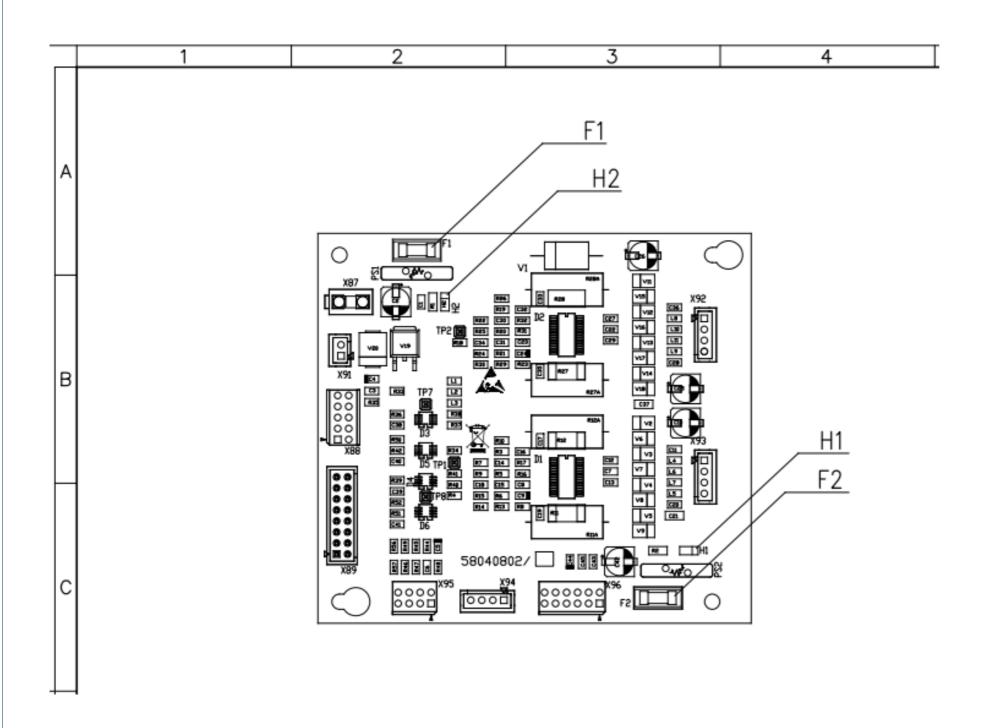






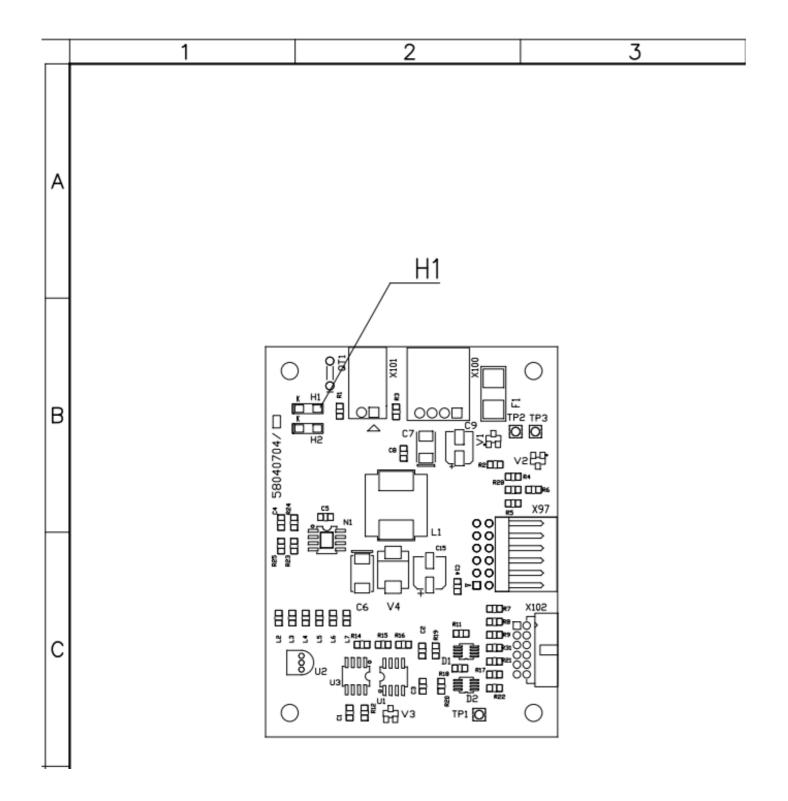






| I-MAX ceph Ceph driver board A13 layout | 6 |
|--|-------------|
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| I-MAX ceph Ceph Sensor power board A14 layout | 7 |
|---|-------------|
| Code 58040704 - Rev. 0 | Page 1 of 1 |



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13. SPARE PARTS

- 13.1. Top side of the unit
- 13.2. **Rotating arm**
- 13.3. **UP/DOWN Column**
- 13.4. **Cables**
- 13.5. Covers
- 13.6. **Accessories and Service tools**



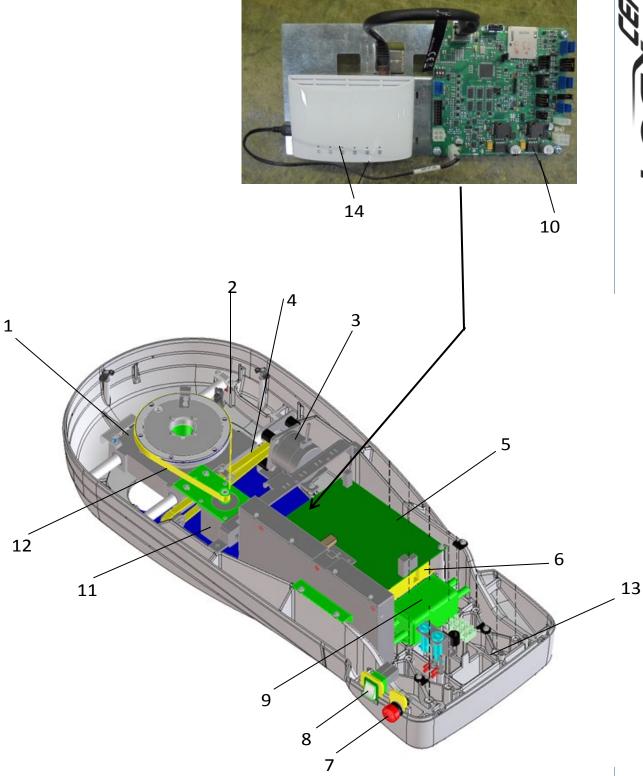
13.1. Top side of the unit

13.1.1. Electrical and mechanical part

| Ref. | Order code | Description | Note |
|------|------------|------------------------------------|------|
| 1 | 6204041000 | Light sensor assy Y axis | |
| 2 | 6204040900 | Light sensor assy rotation | |
| 3 | 6604041200 | Y axis motor assy | |
| 4 | 4990807000 | Y movement belt | |
| 5 | 5804040700 | A1 - CPU (MCU) board | |
| 6 | 4492824900 | G1 - Power supply board | |
| 7 | 4291421400 | Emergency pushbutton | |
| 8 | 4291422000 | ON/OFF Switch | |
| 9 | 4192212200 | Mains filter | |
| 10 | 5804040800 | A11 CCU board | |
| 11 | 6604041100 | Rotation motor assy | |
| 12 | 4990806900 | Rotation belt | |
| 13 | 6104042100 | Fuse kit wide range | |
| 14 | 4695456700 | 5 port Gigabit Switch | |
| 15 | 5804041000 | Optical sensor board Ceph position | |
| | | | |









13.1.2. **Cable**

| 16 | 6204042300 | MCU board power supply cable X1- X62 /J1 |
|----|------------|---|
| 17 | 6204042400 | Canbus CPU Ceph board cable X9/X9 |
| 18 | 6204042500 | One wire CPU Ceph board cable X25/X25 |
| 19 | 6204043100 | Optical sensor cable X25 / X1 |





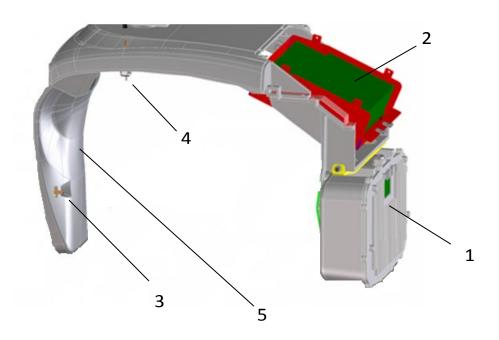






13.2. Rotating Arm

| Ref. | Order code | Description | Note |
|------|------------|----------------------------|------|
| 1 | 8404000200 | Tubehead assy | |
| 2 | 5804020200 | HF board | |
| 3 | 6604020000 | Sagittal laser assy | |
| 4 | 6604020400 | Frankfurt laser assy | |
| 5 | 5804070600 | A15 - Fixed Pogo-pin board | |



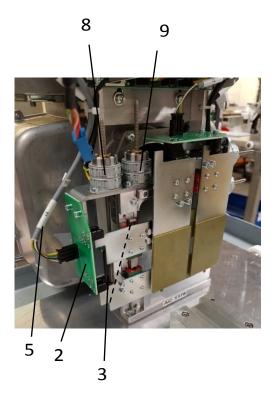


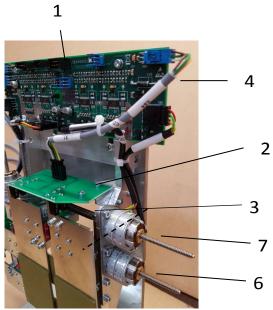




13.3. Collimator

| 1 | 5804060200 | A12 - Collimator driver board |
|---|------------|-------------------------------|
| 2 | 5804060400 | Optical sensor board |
| 3 | 5704060100 | Traction spring T31030 DIM |
| 4 | 6204060100 | Horizontal sensor motor cable |
| 5 | 6204060200 | Vertical sensor motor cable |
| 6 | 6204060300 | Horizontal motor 1 |
| 7 | 6204060400 | Horizontal motor 2 |
| 8 | 6204060500 | Vertical motor 3 |
| 9 | 6204060600 | Vertical motor 4 |
| | | |

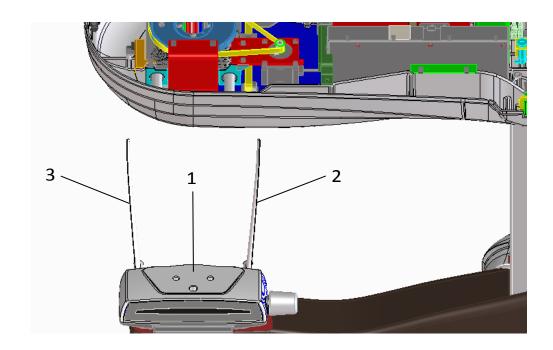






13.4. Chin support

| Ref. | Order code | Description | Note |
|------|------------|--------------------|------|
| 1 | 6604010500 | Chin support assy | |
| _ | 6104020600 | Keyboard assy | |
| 2 | 6604010112 | Temple clasp right | |
| 3 | 6604010212 | Temple clasp left | |

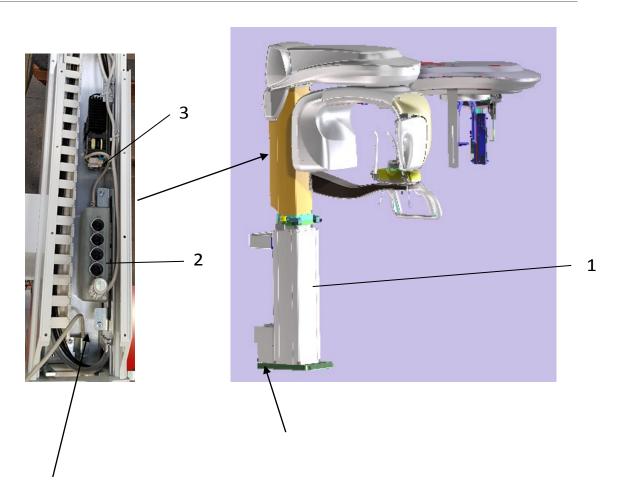




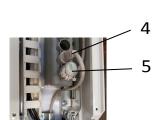
13.5. UP/DOWN Column

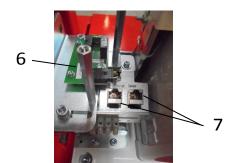
13.5.1. Electrical and mechanical part

| Ref. | Order code | Description | Note |
|------|------------|----------------------------------|------|
| 1 | 4391100205 | Lifting column T-Motion | |
| 2 | 4492825200 | T-Motion control box G3 | |
| 3 | 4492825100 | G2 Power supply | |
| 4 | 5004101800 | Control box/Lifting column cable | |
| 5 | 5004101900 | Control box signal cable | |
| 6 | 5859301200 | A8 - External signal board | |
| 7 | 4591851000 | RJ45 Cat6 adapter | |
| | | | |









13.5.2. **Cables**

| Ref. | Order code | Description | Note |
|------|------------|------------------------------------|------|
| 1 | 6204043200 | X-ray push button with cable | |
| 2 | 6204011000 | Keyboard cable X12/X12 | |
| 4 | 6204101200 | Power switching cable J1 | |
| 5 | 6204101000 | Power cable | |
| 6 | 6204101100 | Signal & Rx cable X8-X51 / X10-X13 | |
| 7 | 5007080200 | Ethernet cable CAT 6 | |
| | | | |

13.6. Top side / Rotating arm cables

| Ref. | Order code | Description | Note |
|------|------------|---------------------------------------|------|
| | 6204040500 | Laser 1 cable X16 | |
| | 6204040600 | Laser 2 cable X17 | |
| | 6204040100 | HF board power supply cable Z1 / X31 | |
| | 6204040200 | HF board signals cable X15 / X32 | |
| | 6204042600 | Collimator signal cable X59/X77 | |
| | 6204042700 | Collimator power cable X67/X75 | |
| | 6204042800 | Collimator motor signal cable X66/X76 | |
| | 6204043400 | Signal 2D sensor cable X96/ X61-X72 | |
| | 5004040300 | Ethernet cable CAT 6 | |
| | | | |



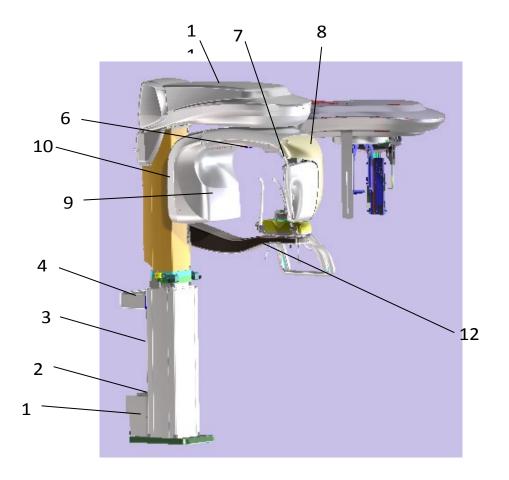


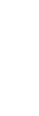
13.7. Covers

| Ref. | Order code | Description | Note |
|------|------------|-----------------------------------|------|
| 1 | 5604101405 | Rear base cover | |
| 2 | 5604101505 | Base cover | |
| 3 | 5604101605 | Duct | |
| 4 | 5604101705 | Upper cover | |
| 5 | 5604103305 | Lateral cover | |
| 6 | 6604020305 | Rotating arm lower cover | |
| 7 | 6604020805 | Sensor internal cover | |
| 8 | 6604020921 | Sensor external cover | |
| 9 | 6604020205 | Tube head internal cover | |
| 10b | 6604020605 | Tube head external cover (Owandy) | |
| 11 | 6604041105 | Upper cover | |
| 12 | 5404090105 | Lower guard 2D chin rest arm | |
| | | | |











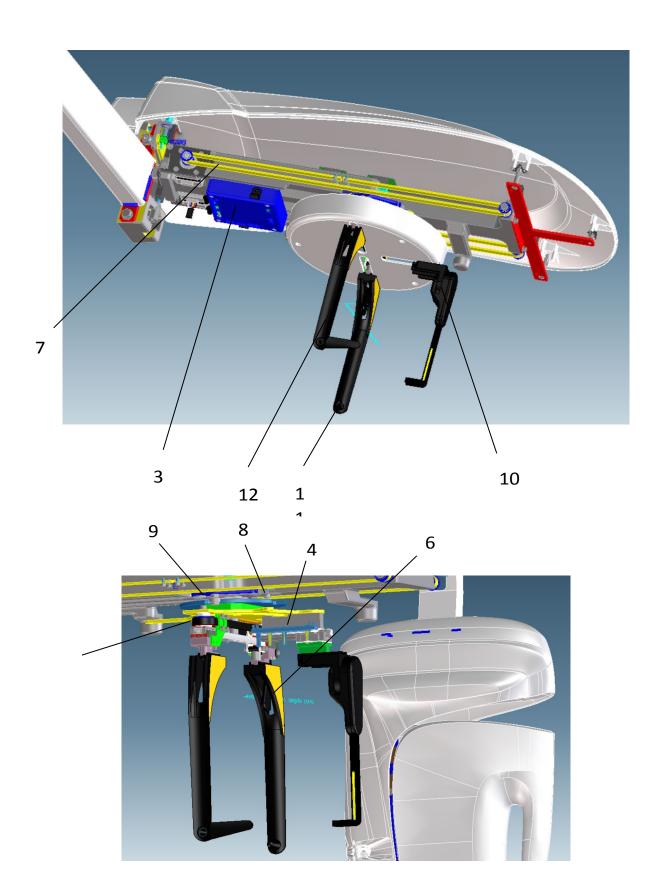
13.8. Ceph arm & Mobile Sensor

13.8.1. Electrical - mechanical part & cables

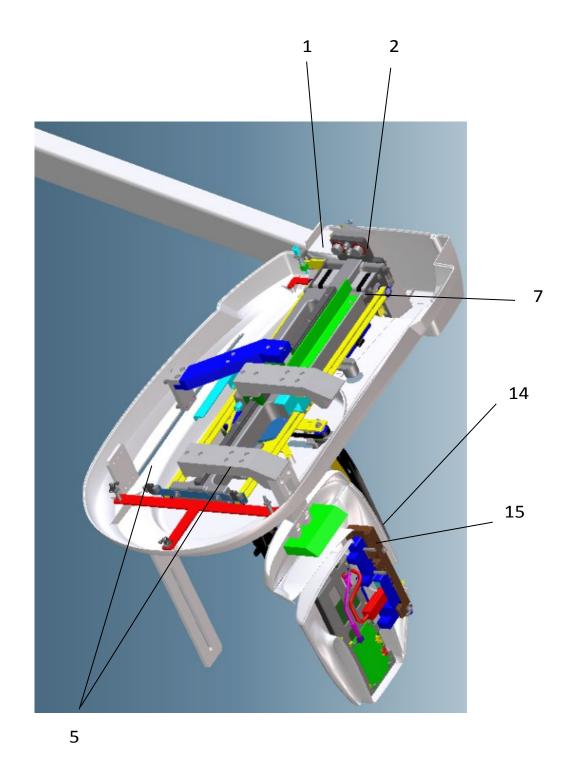
| Ref. | Order code | Description | Note |
|------|------------|--------------------------------------|------|
| 1 | 6204080300 | Ceph collimator motor with cable X93 | |
| 2 | 6204080400 | Ceph sensor motor with cable X92 | |
| 3 | 5804080200 | A13 - Driver Ceph board | |
| 4 | 6204080500 | Nasion potentiometer with cable X94 | |
| 5 | 6204080600 | Ceph motor sensor cable | |
| 6 | 5404081312 | Brake lever | |
| 7 | 4990804800 | Open belt 10 T2.5 roll 1.025m | |
| 8 | 5711418800 | Traction spring 6,6x33,5x0,7 | |
| 9 | 4910322900 | Radial bearing 4x13x5 | |
| 10 | 6107080700 | Nose rest group | |
| 11 | 6104080900 | Right head support Assy | |
| 12 | 6104081000 | Left head support Assy | |
| 13 | 4990806900 | Belt | |
| 14 | 5404070400 | Fixed part sensor connection | |
| 15 | 5804070600 | A15 - Fixed Pogo-pin board | |
| | 6204080800 | Signal ceph cable X58 / X89 | |
| | 6204080900 | Signal motor ceph cable X54 / X88 | |
| | 6204081000 | Power ceph cable X53 / X87 | |
| | 6204080700 | Signal sensor ceph cable X96 / X96 | |
| | 5007080200 | Ethernet cable CAT 6 | |
| | 6104081300 | Hand support plate for carpus exam | |













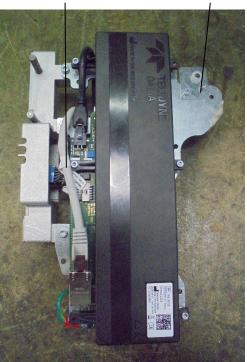
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13.8.2. Mobile Sensor

| 1 | 5804070400 | A14 Power sensor board |
|---|------------|---|
| 2 | 6204070400 | Power & signal pogo pin-sensor cable X103 / X97 |
| 3 | 6204070500 | Signal sensor cable X102 / Sync |
| 4 | 6204070600 | Power sensor cable X100 / Pwr |
| 5 | 5004070100 | Ethernet cable CAT 6 |
| 6 | 6104070800 | Sensor led assy |
| 7 | 7104070400 | 2D Ceph Mobile sensor OWD Assy |
| | | |



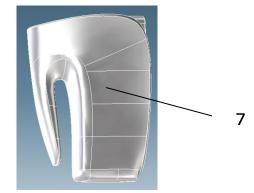


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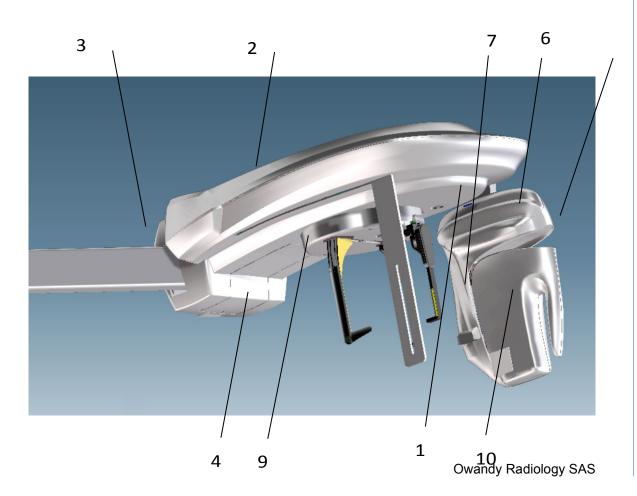


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13.8.3. **Covers**

| 1 | 5404080205 | Ceph lower cover |
|-----|------------|--------------------------|
| 2 | 6104081100 | Ceph upper cover |
| 3 | 6104081200 | Ceph rear arm cover |
| 4 | 5404080305 | Ceph CS cover |
| 5 | 5404080505 | Ceph cover arm |
| 6 | 5404080405 | Ceph sensor cover |
| 7 | 5404070700 | Ceph fix cover – 1 - |
| 8 | 5404070800 | Ceph fix cover – 2 - |
| 9 | 5404080605 | Head rest rotation cover |
| 10 | 5404070200 | Sensor cover |
| 10b | 5404070900 | Sensor cover Owandy |







13.9. Accessories and Service Tools

| Ref. | Order code | Description | Note |
|------|------------|--|------|
| | 6607090100 | PAN centering bites (50 pcs) | |
| | 6107110700 | Disposable bite protective sleeves (100 pcs) | |
| | 6604011519 | Panoramic standard chin support | |
| | 6604011719 | Panoramic chin support (reduced height) | |
| | 5407098119 | Edentulous patients appendix | |
| | 6604011619 | Maxillary-Sinus chin support | |
| | 6604011800 | TMJ positioner | |
| | 6107110800 | TMJ positioner protective sleeves (60 pcs) | |
| | 6695190000 | Service tools kit | |
| | 4695488300 | Ethernet board Intel i350-T2 | |
| | 6104081500 | Ear protection pack (300 pcs) | |
| | | | |







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14. APPENDIX

14.1. Appendix A: Setup parameters table

The following table lists those adjustment parameters stored in the unit during factory testing and that must be re-entered into the non-volatile memory in case of replacement of the MCU board (A1). This is due to the fact that the new MCU board, provided as a spare part, has been factory tested from the functional point of view, but contains only default parameters which are not related to the unit where it will be installed.

Entering of the listed parameters can be performed through the service programs (see chapter 8).



Note

The information listed in the table are the technical parameters set during factory testing. Preferences set by the user (e.g. exposure parameters different than the default ones) are not listed.

The table also has columns with blank cells. These cells must be filled in when, during installation or during the life on the unit, any of the listed parameters will be modified (e.g. after replacing a motor or a positioning sensor).





I-MAX - Ceph

| Unit code: | | |
|------------|--|--|
| Unit S/N:_ | | |
| U.I.C.: | | |

| Parameter | | Factory setting | New setting | New setting | New setting | New setting |
|--|-----------------|--------------------|----------------|----------------|----------------|----------------|
| Date | | | | | | |
| | Panoramic Exams | | | | | |
| Rotation axis motor offset | | | | | | |
| Y axis motor offset | | | | | | |
| Bitewing Y offset | | | | | | |
| Y Jaw type [mm] | | | | | | |
| Ceph Exams | | | | | | |
| Rotation axis motor offset | | | | | | |
| Y axis motor offset | | | | | | |
| Ceph sensor motor offset | | | | | | |
| AP-Carpus Offset [mm] | | | | | | |
| Secondary collimator motor | | | | | | |
| Secondary collimator normal resolution | | | | | | |
| Nasion | Min | | | | | |
| potentiometer calibration | Max | | | | | |



| Parameter | | Factory setting | New setting | New setting | New setting | New setting |
|-----------------------------------|--------------|--------------------|-----------------|-----------------|----------------|----------------|
| | | Primary | collimator | offsets | | |
| W0 Panoramic windows | НО | | | | | |
| | HW | | | | | |
| | VO | | | | | |
| | VW | | | | | |
| | НО | | | | | |
| W6 Ceph | HW | | | | | |
| windows | VO | | | | | |
| | VW | | | | | |
| HO=Horitzontal o | ffset, HW=Ho | orizontal width, V | O=Vertical offs | set, VW=Vertica | l width | |
| | Tubehe | ead preheat | ing values | (Filament | levels) | |
| | 2mA | | | | | |
| | 3mA | | | | | |
| Tubehead pre-heating values | 4mA | | | | | |
| | 5mA | | | | | |
| | 6mA | | | | | |
| | 7mA | | | | | |
| | 8mA | | | | | |
| | 9mA | | | | | |
| | 10mA | | | | | |
| | 11mA | | | | | |
| | 12mA | | | | | |