Use and Maintenance Manual

RiX70 DC

X-Ray Intraoral System

trident

CE 0051 CISQ IQNet

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1 INTRODUCTION

Dear customer, thank you for trusting our company and choosing RiX-70 DC as your Intraoral X-Ray System. RiX-70 DC is the result of many years of experience in the radiology field and meets the highest standards on design and functionality.

1.1 Purpose of this Manual

The purpose of this manual is to provide you with a comprehensive guide for installing and operating your RiX-70 DC Intraoral X-Ray System. This manual describes the parts and components and explains how to correctly install, operate, and get the best performance from your RiX-70 DC. It is our intent to explain the proper use and all relevant safety measures to be adhered to when handling X-Ray equipment.

	This manual is updated to the current condition of the product to ensure an appropriate reference in the use of the device and with respect to all aspects related to safety.
	The manual may not reflect changes in the product without impact on operating procedures and on safe use.
	The device must always be used in accordance with the procedures explained in the present manual, and shall never be used for purposes other than those it was designed for.
	Read these manual to become familiar with the device before putting it into service. Carefully follow the warnings and safety instructions.
	Always keep this manual handy, so that it can be consulted even after the first use.

1.2 Icons and Symbols Used in this Manual

1.2.1 Icons

On this manual are used the following icons:

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

1.2.2 Symbols

This manual and the equipment use the following symbols:

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

1.3 *User Obligations*

	Carefully read and follow the warnings and safety instructions contained in this manual.
	Use the device in accordance with the procedures explained in the present manual, and do not use it for purposes other than those it was designed for. Failure of the user to properly maintain the equipment may relieve Trident or his dealer, from responsibility for any injury, damage, or non-compliance, which may result.
	Report promptly to Trident or to its dealer any accident involving this device or any alteration in features and/or performances which could cause death, injuries or health hazard to Patient and/or Operator.

2 SYSTEM PRESENTATION

2.1 General Description

RiX-70 DC is an intraoral X-ray system that emits ionizing radiation, X-Ray, for taking images of the oral cavity.

RiX-70 DC with a high technological development allows getting high quality images using both normal films and digital images receptors (intraoral sensor and phosphor plates).

This system has two version, wall mounted and mobile. This chapter explains the wall mounted version, for the stand mobile version, please refer to the paragraph 5.2.3

2.2 Parts

The device comprises (1) The DC X-ray head, (2) the hand switch, (3) the control panel (timer), (4) the support arm and (5)the scissor arm.

2.2.1 Optional

Remote Control Panel to facilitate the operation outside the X-Ray room.

35 x 43 mm Rectangular Collimator, that offers two advantages:

- Reduction of radiation dose to the patient.
- Reduction of scatter radiation thereby increasing image contrast.

2.2.2 Additional keypad

The additional keypad is located on the side of the Tubehead's support; it allows a fast and easy adjustment of

This keypad is part of the standard wall-mounting version. It is not available neither for the stand mobile version nor for systems with remote timer.

2.2.3 *The control Panel*

This is an easy-to-read control panel, with quickly identifiable icons for a faster and easier operation. The following are the function keys(buttons) present in the RiX-70 DC unit:

System ready (green light ON)

Emission in progress(yellow light ON)

Alarm(red light ON), the system has a problem, CAUTION. It can cause the interruption of the emission

Buttons to manually increase/ decrease the preset values.

Tooth Type selection, choose the tooth to be examined: lower incisors , lower canines, lower bicuspids, lower molars, upper molars, bicuspids, upper canines, upper teeth, bitewing.

Patient size selection, according to patient morphology choose between adult or child.

Image receptor selection, select the receptor from film, intraoral sensor and phosphor plate.

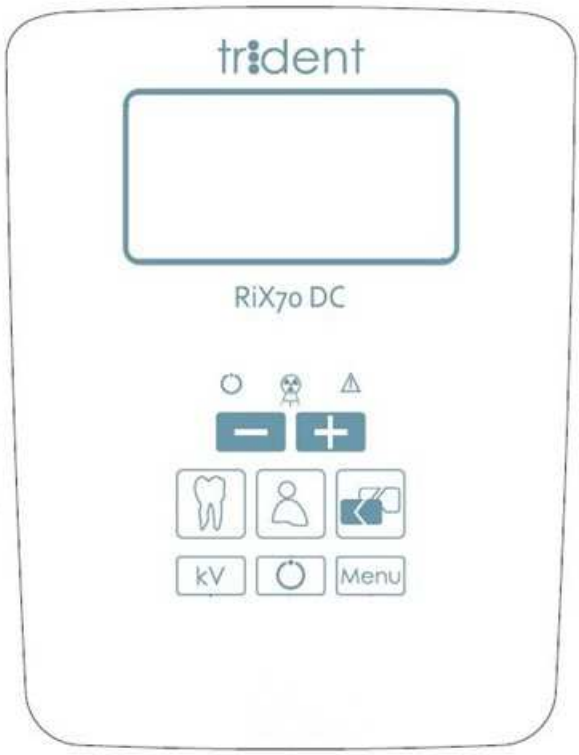
kV selection, allows to select the voltage from 60, 65 and 70 kVp

X RAY button Activation, pressing this button will be activated on the display a count down during which you can make expositions by pressing the X-Ray button.

Note: in the remote system, this button controls the X-Ray emissions too. Press  +  to activate the countdown, when you leave the  X-ray will be emitted. In case you leave both the buttons the X-ray will be interrupted

Menu, press this button for at least 2s to access the Menu. Allows to select those parameters that do not need to be set very frequently.

2.2.3.1 Disposition of the Function Keys on the control panel



2.2.4 Graphic display

The RiX-70 DC display has 2 zones: the left one indicates all the radiologic parameters (high voltage value, anodic current, exposure time); while the right one displays the anatomic settings and the type of receptor.
The following picture shows the display:

2.2.4.1 *Icons on the display*

ICON									
									
PATIENT TYPE		**TOOTH TYPE**					**IMAGE RECEPTOR**		
Pediatric	Adult	Incisor	Canine	Premolar	Molar	Bitewing	Film	Digital sensor	Phosphor plate

2.3 *Main Features*

RiX-70 DC offers the following exclusive features:

- The support arm come in two different lengths : 60 and 80 cm.
- Additional keypad installed near the tube head, for manual adjustment of the exposure time, tooth type and patient size.
- Hand switch provided with coiled cord extensible up to 3 m.
- Clear and intuitive remote control and timer, which includes pre-programmed exposure settings to set all the system parameters outside the examination room.
- RiX-70 DC applies a nearly constant potential to the tube. This constant potential supplies the tube with DC current, resulting in a constant stream of consistent radiation that maintains the preset kV values even with mains fluctuations.
- RiX- 70 DC can operate either 60, 65 or 70 kV allowing to reach excellent results : voltage 60 kV for caries detection or periodontal applications; 70 kV for endodontic applications, including visualization of canals, detection of root fractures and diagnosis of periapical lesions due to pulpal inflammation.

2.4 *Physical Principles of Operation*

RiX-70 DC is a direct voltage supply intra-oral X-Ray system based on the physical principles of X-rays generation, using a special component called "X-ray tube". The X-ray tube is a high vacuum glass ampoule, which contains a high voltage cathode and an anode. The cathode or negative pole is composed by the heater filament and the real cathode connected to the high voltage circuit . The anode or positive pole, located at the opposite pole of the ampoule, is made of tungsten and sometimes called the tungsten target.

The Tubehead, a metal sheath with lead shielding, contains the X-ray tube. The Tubehead is filled with dielectric oil, that allows dissipating the heat generated from the functioning tube and ensure the electrical insulation between the external contacts of anode and cathode. The oil is cooled with air. The sheath has two purposes: mechanical protection and heat conduction.

The X-rays emerge from a tube part not shielded by the metal sheath, called window. The aluminium filter (of a suitable thickness) filters the X-rays: the lower energies unnecessary for the image acquisition are filtered. In fact, the X-ray tube emits polychromatic X-radiation (of many different wavelengths); the wavelength depends on the anodic disc metal type and mainly on the operating voltage. The shorter wavelengths represent the hard radiation, more penetrating; while the longer ones are called soft X-rays and are reduced by the aluminium filters.

The first step for x-ray generation is to turn on the machine. When the unit is turned on, the filament of the cathode is heated by electrical current, causing it to emit electrons by thermionic effect. For the second step, high voltage is passed across the x-ray tube. When this is done, the electrons or electron cloud from the filament are drawn across the window toward the anode. The third and final step is the collision of electrons with the anode (tungsten target). This rapid deceleration of electrons produces x-rays, also referred to as photons.

A microprocessor card controls the whole system operation doing both interfacing with the operator and controlling the X-ray generating circuit.

2.4.1 Focal spot position

A relief on the plastic cover of the unit, as in the image, indicates the focal spot position within the Tubehead.

2.4.2 Dose Area Product

Patient exposure is displayed on the screen as Dose Area Product (DAP). Dose area product is a quantity used in assessing the radiation risk from diagnostic X-ray examinations and interventional procedures. It is defined as the absorbed dose multiplied by the area irradiated, expressed in gray on squared centimetres (Gy/cm^2). DAP reflects the dose within the radiation field and also the area of tissue irradiated. It also has the advantage of being easily measured, with the permanent installation of a DAP meter on the X-ray set. DAP value is measured considering the dose of air issued by the system at 22cm of distance from the Tubehead focus. See Annex 4 for DAP values

The following tables need to be analysed considering a 50% of possible error.

Exposure time	kV			Exposure time	kV		
	60	65	70		60	65	70
0,010	2,7	3,3	3,9	**0,160**	42,5	52,4	62,3
0,011	2,9	3,6	4,3	**0,180**	47,8	59,0	70,1
0,012	3,2	3,9	4,7	**0,200**	53,2	65,5	77,9
0,014	3,7	4,6	5,5	**0,220**	58,5	72,1	85,7
0,016	4,3	5,2	6,2	**0,250**	66,5	81,9	97,4
0,018	4,8	5,9	7,0	**0,280**	74,4	91,7	109,1
0,020	5,3	6,6	7,8	**0,320**	85,1	104,9	124,6
0,022	5,8	7,2	8,6	**0,360**	95,7	118,0	140,2
0,025	6,6	8,2	9,7	**0,400**	106,3	131,1	155,8
0,028	7,4	9,2	10,9	**0,450**	119,6	147,4	175,3
0,032	8,5	10,5	12,5	**0,500**	132,9	163,8	194,8
0,036	9,6	11,8	14,0	**0,560**	148,9	183,5	218,1
0,040	10,6	13,1	15,6	**0,630**	167,5	206,4	245,4
0,045	12,0	14,7	17,5	**0,710**	188,7	232,6	276,6
0,050	13,3	16,4	19,5	**0,800**	212,6	262,1	311,6
0,056	14,9	18,3	21,8	**0,900**	239,2	294,9	350,6
0,063	16,7	20,6	24,5	**1,000**	265,8	327,7	389,5
0,071	18,9	23,3	27,7	**1,100**	292,4	360,4	428,5

Exposure time	kV			Exposure time	kV		
	60	65	70		60	65	70
0,080	21,3	26,2	31,2	**1,125**	299,0	368,6	438,2
0,090	23,9	29,5	35,1	**1,400**	372,1	458,7	545,3
0,100	26,6	32,8	39,0	**1,600**	425,3	524,3	623,2
0,110	29,2	36,0	42,8	**1,800**	478,5	589,8	701,1
0,125	33,2	41,0	48,7	**2,000**	531,6	655,3	779,0
0,140	37,2	45,9	54,5				

DAP value when using the rectangular collimator (35x45mm) is the result of the values in the table multiplied by 0.56.

2.4.3 Exposure parameters measurement

The accuracy and consistency of exposure parameters can be performed in two ways: non-invasive method and invasive method, it means with access (or not) to those parts under voltage tension.

2.4.3.1 Non-invasive method

RiX-70 DC allows the measurement of the exposure parameters (kV, time and dose) using the so-called "non-invasive " method, which involves the use of a non-invasive tool. For this method follow these steps:

- Turn on the system.
- Select 70 kV and an adequate exposure time for a correct reading.
- Place the measuring tool, making sure the X-Ray beam completely irradiates the tool.

	**CAUTION** Now the system is ready to emit X-rays.

- Press the X-Ray button
- Verify the measured values.
- Repeat the check for 65 kV and 60 kV.

2.4.3.2 Invasive method

For the direct measurement of exposure parameters see **Acceptance Test** paragraph.

2.5 Deterministic Effects of X Radiation

No deterministic effects of X radiation used in dental intra-oral X-ray system.

2.6 Normal Intended Use

The unit is designed to get radiographs of the human oral cavity with the specific purpose of diagnose and identify multiple pathologies of mouth and teeth. Only qualified personnel, dentists and radiologist must use it. All the users need to have a good knowledge on general radiology. RiX-70 DC also works with digital sensors and phosphor plate scanners, so the users need to have a good knowledge of computer and software uses.

Radiologists and dentists need to have specific knowledges about:

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

2.6.1 Main Uses

- Conservative Dentistry
- Diagnosis of tooth decay, especially of proximal lesions.
- Endodontics
- Periodontology
- Denture
- Surgical Dentistry
- Implantology
- Orthodontics
- Oral and Maxillofacial Surgery

2.6.2 Contraindications

- Representation of cartilaginous structures.
- Representation of the soft parts' tissue.

2.7 Patient's profile

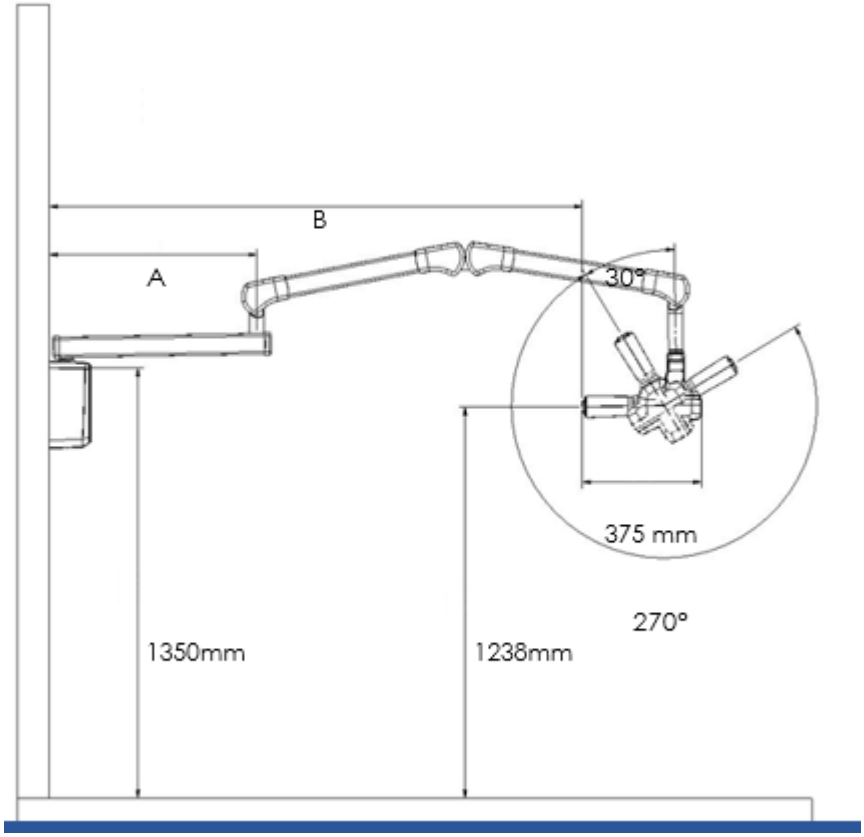
The device is suitable for use on any type of patient.

2.8 Versions

RiX-70 DC intraoral X-Ray generator is available in two models:

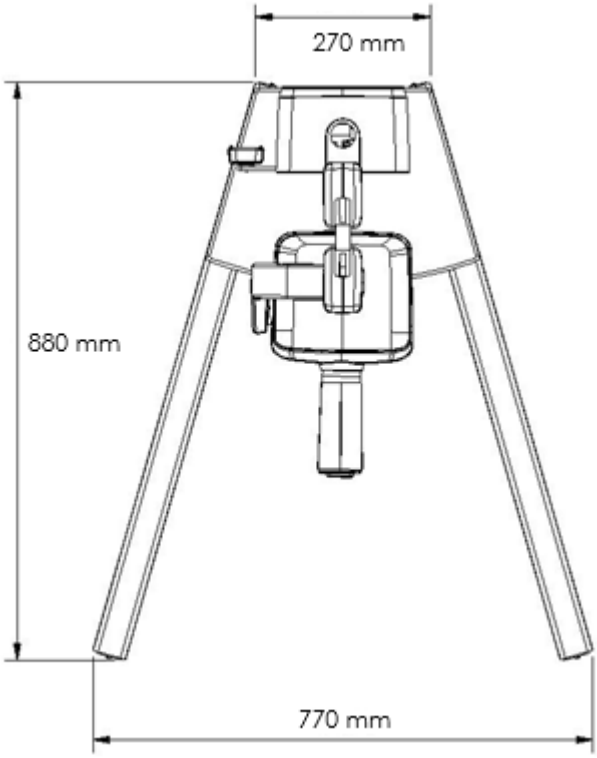
- RiX-70 DC wall mounted : Permanent Installation, connected to the power supply network through a dedicated line equipped with protection devices.
- RiX-70 DC mobile stand : Configuration for installation on mobile stand. This configuration does not have the horizontal support arm.

2.8.1 Overall Dimension for Wall Mounted Version



	Arm length 600 mm	Arm length 800 mm
Distance A	600 mm	800mm
Distance B	1615 mm	1815 mm

2.8.2 Overall Dimension for Mobile Stand Version



2.9 Device Classification

RiX-70 DC is a Class I device, Type B, conforms to IEC 60601-2-65: 2012. RiX-70 DC, according to the classification rules set out in Annex IX of EC Directive 93/42 and its amendments and supplements, is an active medical device that releases energy (ionizing radiation X Ray) and represents a potential hazard to the human body. Applicable Standards:

- **EN 60601-1:2005**
- **EN 60601-1-2:2007**
- **IEC 60601-2-65:2012**
- **Classification CND Z1103040101**
- **Nomenclature GMDN 42297**

2.10 Manufacturer Address

	Manufacturing site Via Artigiani 4 25014 Castenedolo (BS) Italy Web site: www.trident-dental.com

2.11 Device Identification and Labels

The device for its identification has four labels with all the information needed for the device traceability and its parts. See all the labels information on Annex 2.

3 SAFETY ASPECTS

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

Trident S.r.l. designs and manufactures RiX-70 DC in compliance with all relevant safety requirements. It also provides all necessary information for appropriate use and warnings on the risks associated with using X-rays for diagnostic purposes, therefore, Trident S.r.l. shall not be held liable for:

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

3.1 General Warnings

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

	RiX-70 DC is an electro-medical device that must be used under the supervision of a doctor or a person with vast experience in radiology.
	Do not modify the device mechanically and / or electrically during or after the installation.
	RiX-70 DC is built for continuous operation with intermittent load; therefore, it is required to observe the cycles of use allowing the dissipation of heat accumulated by the radiation source.
	RiX-70 DC must be switched off when using electro surgery or similar devices.
	Make sure the installation of your X-Ray unit is carried out only by qualified personnel. Absolutely avoid provisional electrical connections and verify that only the parts (screws, nuts, bolts, etc.) recommended by the manufacturer are used.
	The installation area must comply with the current regulations pertaining to radiology in the country of operation.
	Do not drop, knock, or shake the unit: rough handling or use beyond the recommendations may cause damage to internal circuitry.
	The operator should take every reasonable precaution to maintain a safe and healthy working environment, minimizing the radiation hazard.
	During the exposure, make sure no one except the patient and operator are present in the X-ray area.
	Always turn off the machine and unplug it from the mains whenever possible (with the switch) before cleaning and disinfection.

	**In accordance with EN 60601-1, it is strictly forbidden to modify the equipment or its parts.** Only trained and qualified technicians are authorized to remove the covers giving access to the circuits. The cables of the power supply must comply with applicable laws and must be equipped with terminals for connecting to the protective earth.
	Carry out a proper cleaning and disinfection of all parts which come into contact with the patient.
	Check regularly (at least once a year) the state of correct operation of the system by involving a specialist for any maintenance.
	Do not use the device in the presence of vapours, or flammable anaesthetic mixtures with air, or oxygen or nitrous oxide.
	When using digital sensors, if the PC is positioned within the patient environment, it must meet the requirements defined by the IEC 60601-1 medical device; if located outside it must be in compliance with IEC 60950. The size of the patient environment is defined as a minimum distance of 1.5 m from the patient.

3.2 *Electromagnetic Environment*

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to electromagnetic emissions information provided in this manual.

3.3 *Electromagnetic Emissions*

	RiX-70 DC meets the requirements of IEC 60601-1-2 concerning the electromagnetic emissions. It is suitable for use in the electromagnetic environment that meets the conditions described below.
	The device may cause radio interference and may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment, or shielding the location.
	The system comes with all the cables needed for its operation. Using other cables not supplied by the manufacturer or in addition to those provided by the manufacturer can significantly influence the electromagnetic behaviour of RiX-70 DC. It may result in increased emissions or decreased immunity of the device.

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

3.3.1 Electromagnetic Immunity

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	EMC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be in wood, concrete or ceramic tile. If floor is cover with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/ output lines > 3 mm	2 kV for power supply lines 1 kV for input/ output lines > 3 mm	Mains power quality should be that of a typical commercial or hospital environment.
Surge *IEC 61000-4-5*	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines 61000-4-11	<5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (> 95% dip in UT) for 5 s	<5% UT (> 95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (> 95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the phototherapy device be powered from an uninterruptable power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1,2 √P 80 MHz to 800 MHz d = 2,3 √P 800 MHz to 2.5 GHz d = 1,2 √P Where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5 GHz	3 V/m	
Interference may occur in the vicinity of equipment marked with the symbol shown on the right			
NOTE 1) At 80 MHz and 800 MHz, the higher frequency range applies. *NOTE 2) These guidelines may not apply in all situations.* *Electromagnetic propagation is affected by absorption and reflection from structures, objects and people*			
NOTE: *UT is the AC. mains voltage prior to application of the test level.*			

3.3.2 Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and RiX-70DC

RiX-70 DC is intended for use in an environment in which radiated RF disturbances are controlled. The user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

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

NOTES

For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

3.4 Safety Regulations

RiX-70 DC is in accordance with the IEC 60601-2-65:2012 regulation and follows the next safety regulations.

3.4.1 General Safety

EN 60601-1	Electromedical Equipment - Part 1: General requirements for basic safety and essential performance.
EN 60601-1:2006	Electromedical Equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-2-65:2012	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
IEC 60601-2-28 Ed. 2	Medical Electrical Equipment - Part 2-28: Particular requirements for basic safety and essential performance of X-ray tube assemblies for medical diagnosis.
IEC 60336:2005	Medical Electrical Equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots

3.4.2 Elecromagnetic compatibility

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

3.4.3 Radiation Protection

IEC 60601-1-3 Ed.2	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment

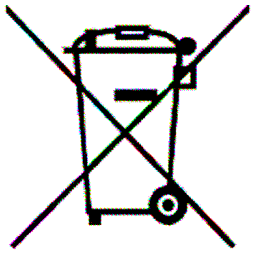
3.4.4 Usability

IEC 60601-1-6:2010	Medical devices - Application of engineering characteristics of medical devices

3.4.5 Symbols

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

3.5 Disposal Hazards



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

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

3.5.1 Information Concerning the Proper Disposal of the System or its Parts

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

PART	MAIN MATERIALS FOR DISPOSAL	RECYCLABLE MATERIAL	MATERIAL FOR THE DISPOSAL CENTER	HAZARDOUS MATERIAL
Structure and covers				
- Metal	Aluminium	x		
	Iron	x		
	Lead			x
- Plastic		x		
Electronic boards		x		
Monoblock				
- Oil	Dielectric oil		x	
- Metal	Copper	x		
	Iron	x		
	Lead			x
Package		x		

4 TECHNICAL DATA

4.1 System Supply

CHARACTERISTIC	VALUE
Manufacturer	Trident S.r.l. 25014 Castenedolo (BS) Italy
Voltage	AC100-240 V
Frequency	50/60 Hz
Electric current	2.1 A(@240V), 5.5 A (@100V)
Max power consumption	640 VA
Fuse	6.3 AT
Connection	7 wires cable with double insolation

4.2 X-Ray Head

CHARACTERISTIC	VALUE
Manufacturer	Trident S.r.l. 25014 Castenedolo (BS) Italy
Tube Voltage	60 kVp ± 8 % 65 kVp ± 8 % 70 kVp ± 8 %
Anodic current	7 mA± 10 %
Output radiation linearity	< 0.2 secondo IEC 60601-2-63
Duty cycle	1:30
Nominal power	490 W (70 kVp - 7 mA)
Total filtration	1.5 mm Al eq. @ 70 kVp
Current transformer insulation	Oil bath
Cooling	As per convention
Focal spot	0.4 mm (IEC 60336)
Leakage radiation at 1 m	< 1 mGy/h
Max thermal capacity of Tubehead	130 J
Distance focus to skin	20 cm
Beam diameter X Ray at 200 mm focus	60 mm
Bean limiting device (additional)	Rectangular 36 x45 mm
Dose intensity accuracy	< 50%

4.3 X-Ray Tube

CHARACTERISTIC	VALUE	
Manufacturer	**Toshiba(Japan)**	**Skan X - CEI (Italy)**
Model	D-045	OX70-4
Inherent filtration	< 1 mm Al eq.	0.5 mm Al eq.
Target angle	20	16°
Filament current	Max. 3 A	1.5 – 2.1 A
Max filament current	3 V	1.7 – 3.1 V
Anodic thermal capacity	4.3 kJ	7 kJ
Max anodic dissipation	100 W	110 W
X RAY beam covering at 200 mm from the focus	≥ ϕ 70 mm	
Focal spot	0.4 IEC 60336:2005	
Target material	Tungsten	
Max nominal voltage	70 kV	

4.4 Weights

CHARACTERISTIC	VALUE
Timer	4.00 kg
Support arm 60 cm	1.7 kg
Support arm 80 cm	4.5 kg
Scissor arm	11.4 kg
Tube head	4.3 kg
Mobile stand base	24 kg
Mobile stand column	4.00 kg
Wall mounted version with 80 cm arm support	25 kg
Mobile version	45 kg
Package	112 x 36 x h32.5 cm Weight: 27 kg

4.5 Working conditions

CHARACTERISTIC	VALUE
Max operative temperature	+ 10° ÷ + 40°
Operative humidity level	Max 80%
Operative atmospheric pression	80 ÷ 106 Pa (Max height ≤ 2000m lm)
Temperature range for transporting and storing	- 20° ÷ + 70°
Max humidity level for transporting and storing	< 95%
Atmospheric pression for transporting and storing	70 ÷ 106 Pa

5 INSTALLATION

5.1 Pre-Installation Requirements

	This chapter describes the installation requirements needed to guarantee a safe procedure.
	The following information is a prerequisite for a successful installation of your RiX-70 DC.
	Before starting installation, please carefully read and follow all safety instructions in this chapter.
	Safety is only guaranteed if the device is appropriately installed and operated. Personal injury or mechanical damage may result from insufficient attention or incorrect compliance of the directions contained in this manual.
	Trident Srl is not liable for any damage caused by faulty installation. Only qualified and trained personnel recognized by Trident must perform the installation.

Depending on the RiX-70 DC version you have purchased, the installation could be:

- Standard wall fixing system.
- Standard wall fixing system with remote timer.
- Mobile stand system.

5.1.1 Check up before Installation

The person responsible for installing the equipment is required to:

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

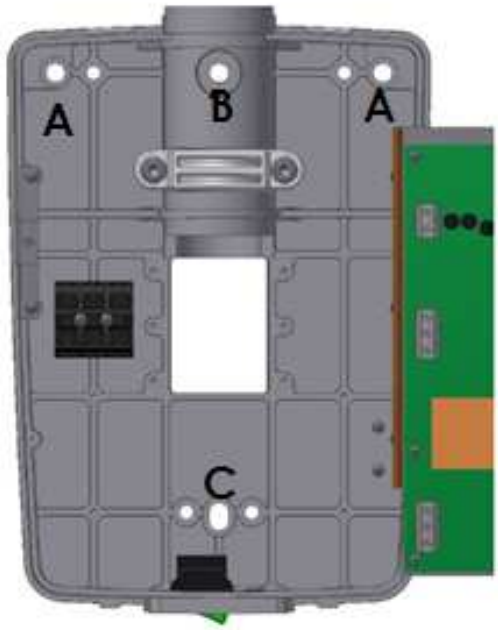
5.1.2 Wall Mechanical Requirements

The maximum extension of the system is 2078 mm from the wall (with a 100 cm support arm). Depending on the wall quality, this unit will be fixed using 1, 2 or 3 bolts in the upper side and one in the lower side. In some cases, it may be necessary to reinforce the wall with a special support (back plate) to hold the system; Trident provides two different types of support to embed in the wall.

	Before drilling a wall, make sure there is not electrical wiring or plumbing that interfere on the work surface.

5.1.3 Setting the fixing points

The fixing points are shown in the following figure:



5.1.3.1 Anchoring system with two points (single stud)

This system is normally used for individual uprights, generally wood. For single stud fixing use one bolt at the top, point “B”, and one at the bottom point “C”.

Considering the safety factor required, the bolt at the top must withstand a maximum load of about 5000 N, equal to 510 kg (1125 lb). Select appropriate screws for a stable anchorage. We recommend the classes ISO 8.8 (M 8, M 8x1, M 8x1,25) or SAE 5 (18UNC-5/16 ", 24 UNF-5/16"), while for wooden posts, wood screws (8x70 A 4.8).

5.1.3.2 Anchoring system with three points

For installation on solid walls (concrete walls) or on large metal plates, use two bolts at the top, point "A", and one in the lower point “C". With the required factor of safety, each bolt at the top must withstand a maximum load of 2650 N, equal to 251 kg (556 lb). Select appropriate expansion bolts for a stable anchoring to the concrete wall.

5.1.3.3 Recommended fastening systems

In order to ensure a proper bearing capacity we recommend to use the screws listed below:

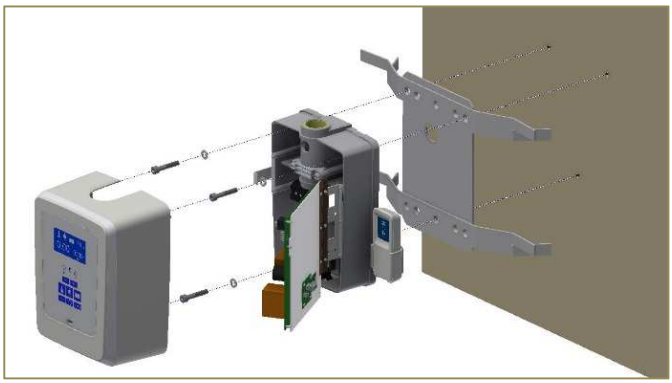
WALL TYPE	FIXING SYSTEM	SCREW REFERENCE
Concrete or full brick wall	Steel anchors	**M8x1,25 ISO 8.8** **M8x1 ISO 8.8**
Brick wall	Chemical anchors (not supplied)	**5/16” – 18 UNC SAE 5 5/16 – 24 UNF SAE 5**
Wood wall	Hex head wood screws zinc galvanized steel(not supplied)	**8x70 DIN 751-8,8**

⚠	**WARNING** INADEQUATE SCREWS OR NOT ENOUGH SOLID WALLS COULD RESULT IN THE REMOVAL OF THE WALL SUPPORT. The device may fall, causing serious injury, and serious damage to the device itself.

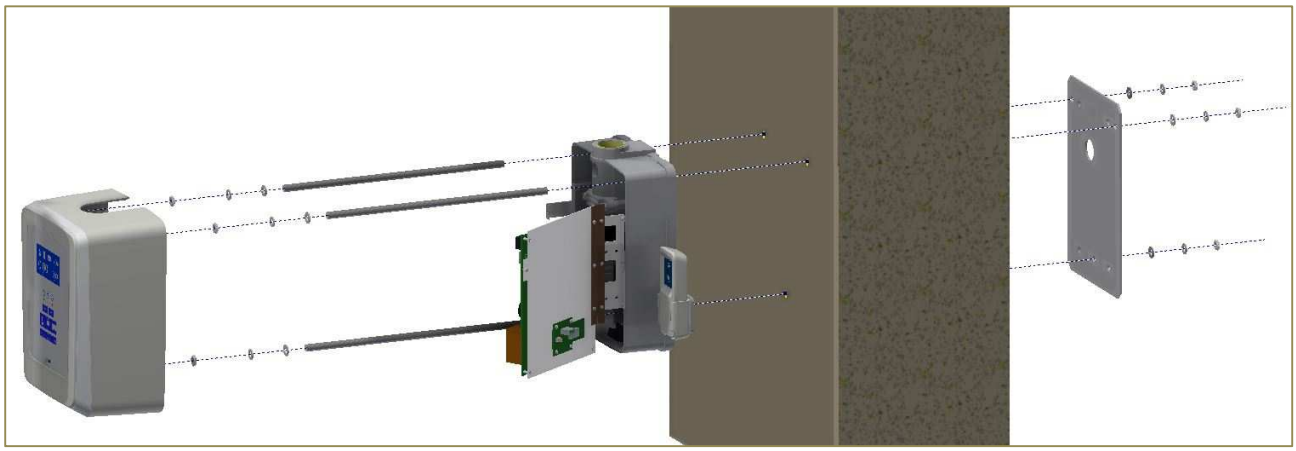
5.1.3.4 Anchoring with special supports

In case the wall cannot withstand the indicated load, it is mandatory the use of special supports. Trident provides two solutions: reinforcing plate or steel backing plate.

The reinforcing plate, as described in the following image, must be suitable fixed to the support wall, which will hold the system; the plate has a central hole for the passage of power cables and / or the remote control.



In the case of thin, wood or plasterboard walls, which are not solid enough, it is mandatory to use a steel backing plate, as described in the following image.



We recommend to install a second backing plate (one plate to each side of the wall) when a single plate is not enough to fasten the equipment.

5.1.4 Electrical requirements

⚠	The wall-mounted version requires a permanent installation. DO NOT INSTALL THE SYSTEM TO A TRADITIONAL OUTLET. FOLLOW THE INSTRUCTIONS FOR A SPECIAL CONNECTION.

⚠	The system must be connected to the power supply using a differential magneto-thermal switch to completely separate it from the mains.

5.1.4.1 Differential Magneto-thermal switch features

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

FEATURE	REQUIREMENT
Working Voltage	240 V
Rated Current	10 A
Differential Sensitivity	30 mA

5.1.4.2 Power Line requirements

FEATURE	REQUIREMENT
Power supply: single-phase with neutral	100-240 V
Frequency	50/60 Hz
Absorbed power	0,64 kVA
Current consumption	2 A (a 230 V)
Apparent resistance line	0,5 Ω max

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

1. Minimum section conductors of 2.8 mm2 (14AWG) or 3.31 mm2 (12 AWG).
2. According to the standards, a reinforced protective ground connection must be ensured.
3. The electrical connection can be inserted into the wall; these connections should be made well in advance. The cable raceways must be properly sized for the passage of the connection cables, depending on configuration chosen: fixed, with remote control or remote timer.

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

5.1.4.3 Remote control and remote security signals preparation

The system RiX-70 DC is designed to accept the following remote signaling:

1. Safety sensor "Open Door": this sensor consists of a switch that indicates to the system that the access door to the room where the system is installed is open, and the examination is not feasible or is interrupted.
2. Remote X-Ray push button: allows to control the emission from a protected location or from the outside of the room.

To connect the remote signaling and / or remote X-Ray control is necessary to provide the following connectors:

- No. 2 wires for security signal "Open Door"
- No. 2 wires for the remote X-Ray button

5.2 Assembly and mounting

5.2.1 Unpacking

Make sure that the packaging is intact and has not suffered damaged during transport. Unpack the system and check that:

• The version of the system matches the requirements.

• The package contents is intact and not damaged.

	Two people are required to safely assemble the wall mounted unit.
	After unpacking, save all the packaging materials in case you ever have to ship the unit.
	Before performing the following steps, check the power supply is disconnected.

5.2.2 Standard wall-mounted system

5.2.2.1 Wall plate mounting

- Select the mounting point. Remove the plastic cover and take the wall plate.
- Using the provided drill drawings as a template, mark on the wall where to open the holes.
- Drill the holes on the wall according to the fastening type, as described above.
- Remove the plastic cover and fix the wall plate using the appropriate anchoring system. In case of installation under track, make sure that the power cord enters from the back.
- With a spirit level, check the horizontal and vertical levelling, make sure to center the bubble. In case of incorrect leveling, the arm cannot remain in position.

5.2.2.2 Support and Scissor's arm mounting

	The following steps must be performed without inserting the arm's support on the plate.
	The springs of articulated arm are calibrated to withstand the Tubehead weight. Removing the safety rubber band when the Tubehead is not mounted, can cause injury to the user and damage the arm. REMOVE THE SAFETY BAND ONLY WHEN NECESSARY.

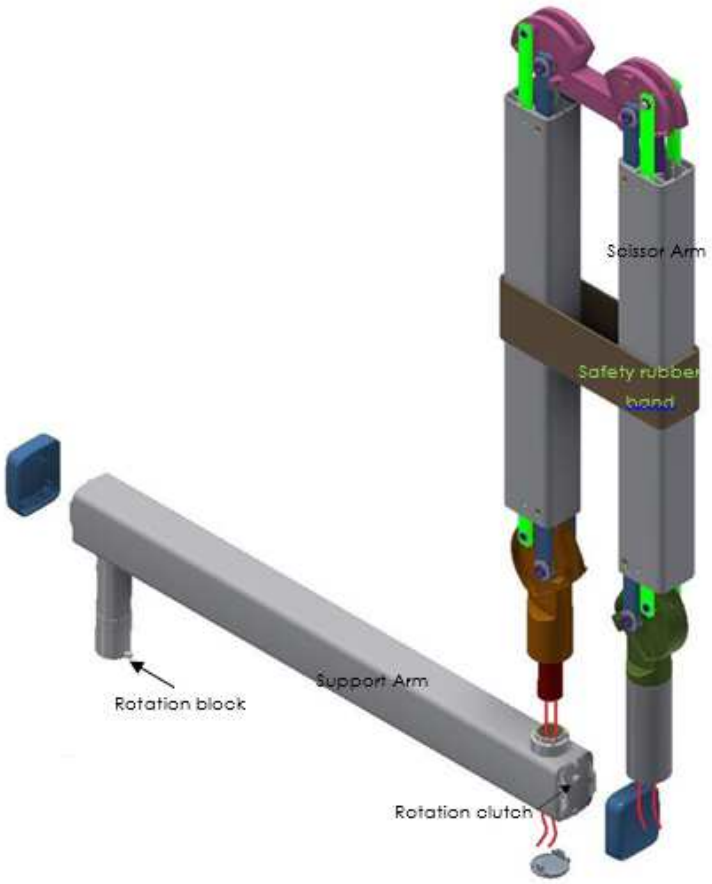
- Note: Trident RiX-70 DC can be supplied in 2 versions:

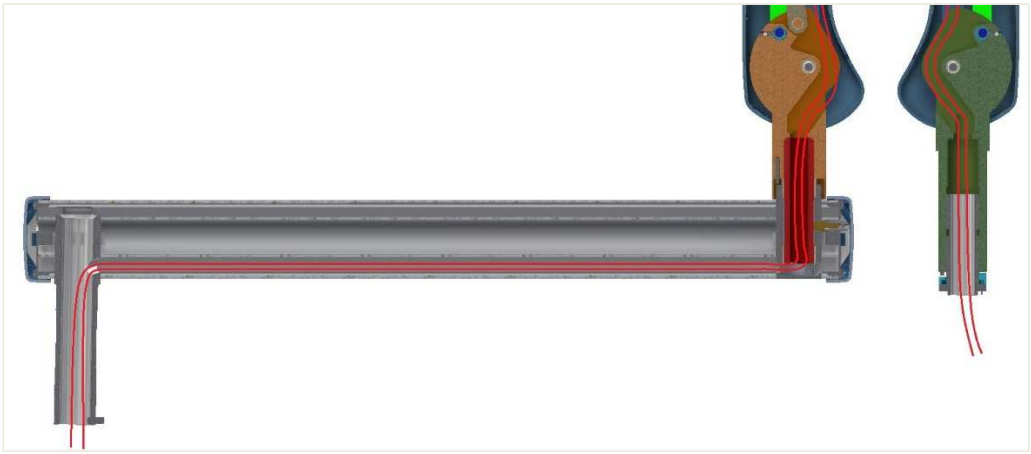
  V0 -> 2 cables not split between extension arm and scissor arm
  V1 -> 1 cable split in 2 parts between extension arm and scissor arm

- Remove the support arm from the packaging and check the integrity of its components. Do not remove the wire inside the scissor arm; it is a guide to insert the wires.
- Remove the scissor arm from the package. Do not remove the safety rubber band until the end of the assembly operation.

V0 model: assemble the scissor arm to the extension arm before placing them to the wall plate.

Place the arms on an appropriate working surface. To assemble the complete arm, insert the scissor arm into the support arm adjusting the length of the wires.



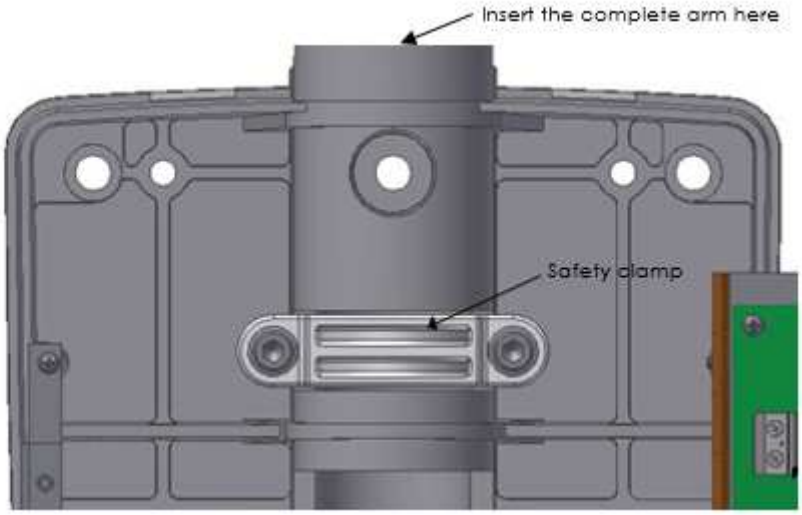


V1 Model : place the extension arm directly to the wall plate and after that easily install the scissor arm and connect the cables as shown below.

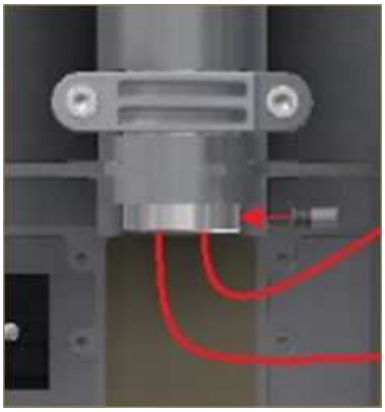
Adjust the length of the cable from the timer to easily connect the connector an safely close the metal cover.

5.2.2.3 Extension arm – wall plate assembly

- Unscrew the rotation block and the anti-sliding safety block from the support arm. Take care not to loose it.
- Unscrew the rotation clutch of the support arm and be sure that it does not get in touch with the rotation pin during insertion.
- Insert the complete arm into the socket of the wall plate.



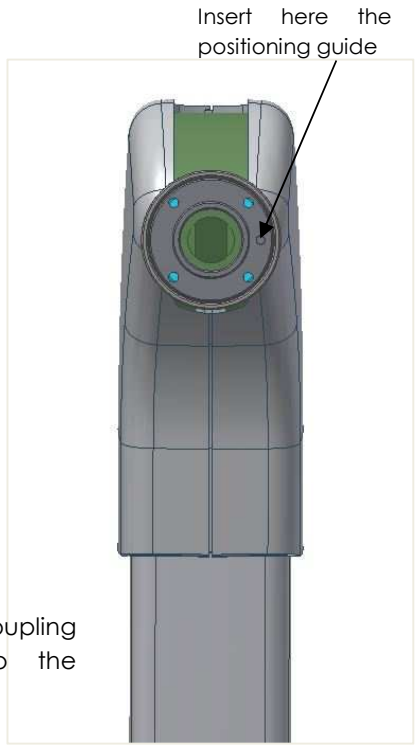
- Insert the rotation block and the anti-sliding safety inside its place and screw it accurately (As shown in the image)
- Screw the rotation clutch as needed.

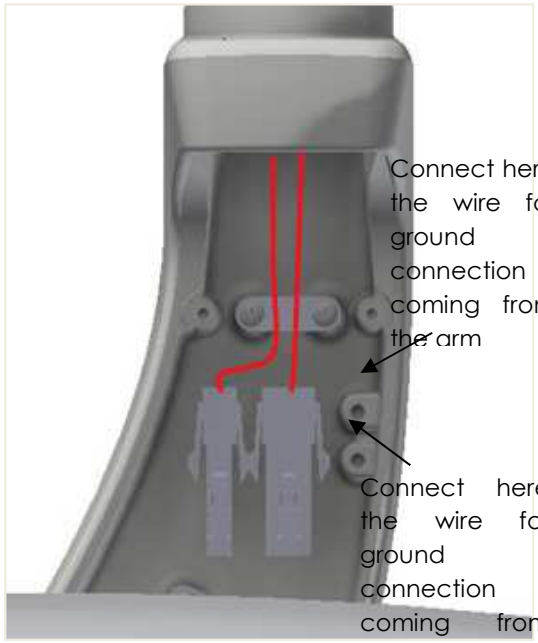


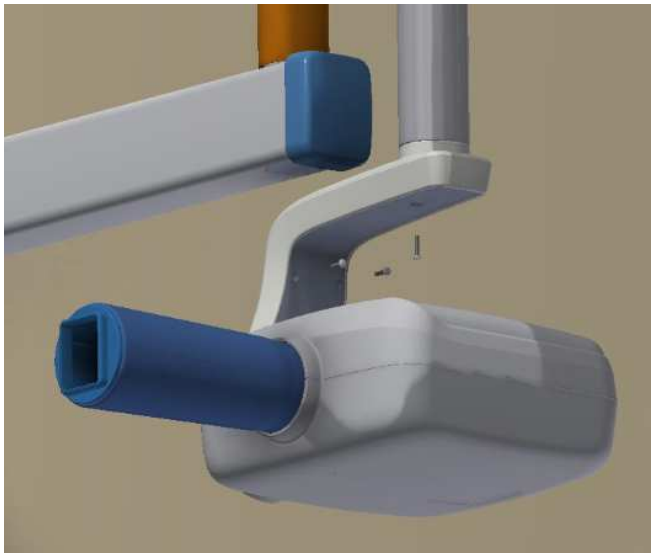
5.2.2.4 Monoblock Installation and connection

- Take out the Tubehead from the box. The Tubehead is coupled to a support. In this support is located the additional key pad for manual changing of exposure time and tooth type. This support comes without cover. Verify the cover is included in the package.
- Bring the support of the Tubehead near the pivot pin of the scissor arm; pass the cables coming from the scissor arm, through the Tubehead support. One of those wires is for grounding.
- Once the cables has been passed, connect them to the Tubehead wires. There are two wires for grounding: one coming from the scissor arm, one coming from the Tubehead.
- Insert the positioning guide of the Tubehead support into the hole on the pivot pin of the scissor arm; align the four holes and tighten screws.

The positioning guide is a reference to facilitate the coupling between the monoblock and the arm.







- Mount the protective cover of the support, fasten it with the provided screws
- Hold the mobile part of the articulated arm , carefully remove the safety block and slowly follow through the opening movement of the arm making sure that there are no people around .

5.2.2.5 Arm-Driver connection

Trident RiX-70 DC is supplied in 2 versions, please check on your model the version descripted below:

-**V0 cable version**: 2 cables pass inside the arm (cables with no junction between the scissor arm and extension arm)

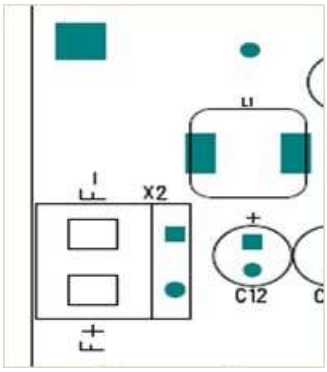
-**V1 Cable version**: only one cable with colored wires passes inside the arm (the cable is split in 2 pieces joint between the scissor arm and the extension arm)

V0 cable version

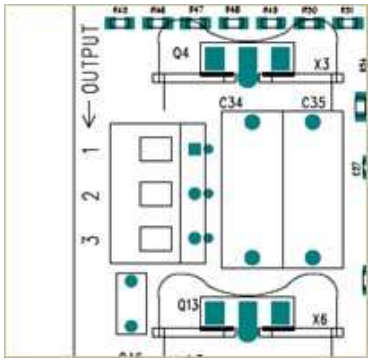
1. High voltage supply/filament/ground -> the wires are black with a printed number on each wire.

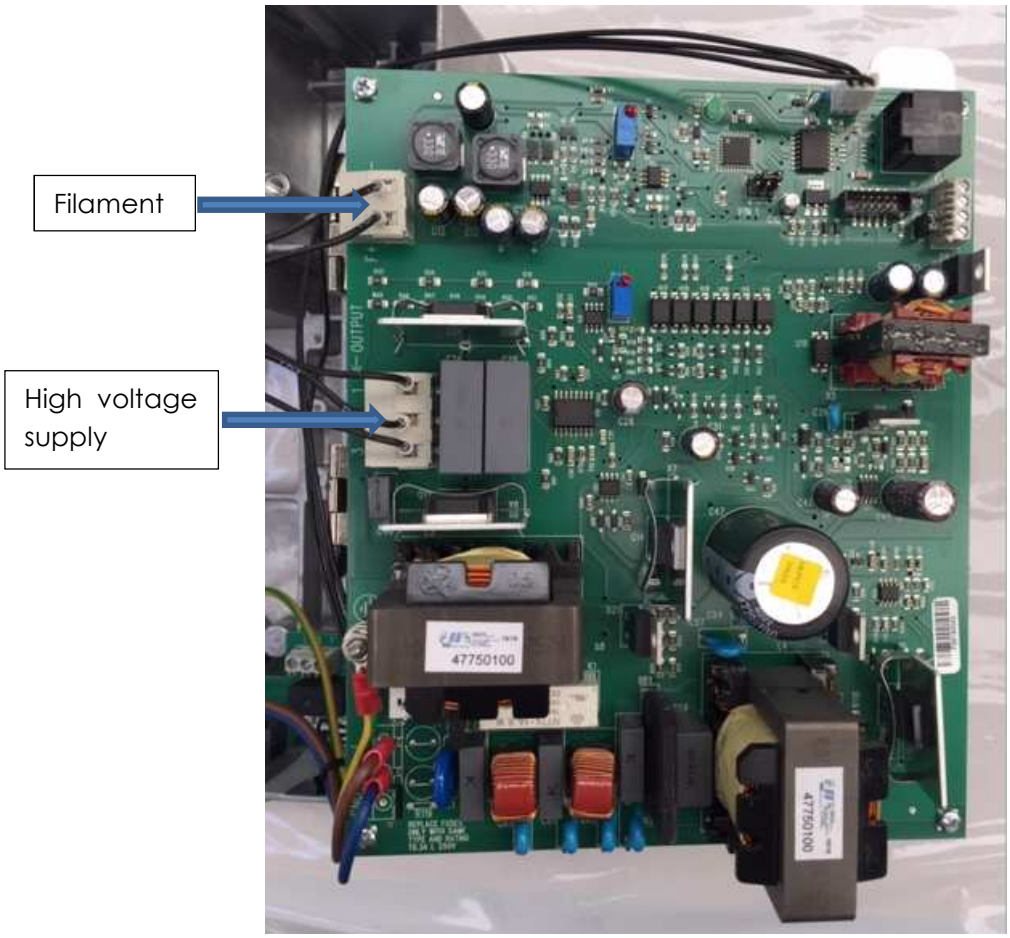
Connect wires 4 and 5 to F+ and F- connector:

Cable 4 to F-
Cable 5 to F+

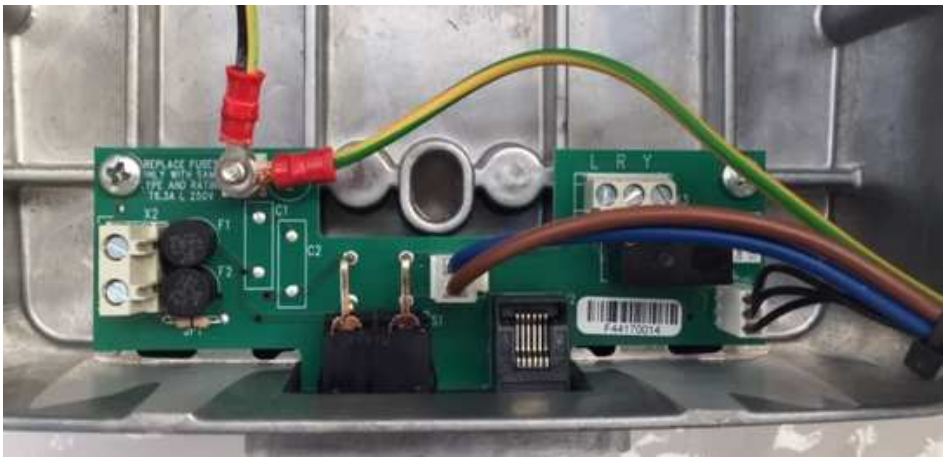


Connect cables 1, 2 and 3 to the corresponding connectors of the driver board:





Connect the yellow-green cable to the ground point



⚠	**CAUTION** The message "Error filament power supply" can be caused by switching the connections of the filament's cables.
⚠	**CAUTION** Be sure to safely connect the ground protection wire (yellow-green wire) **A defective connection to the grounding protection can cause damage to the operator, to the patient and to the technician.**

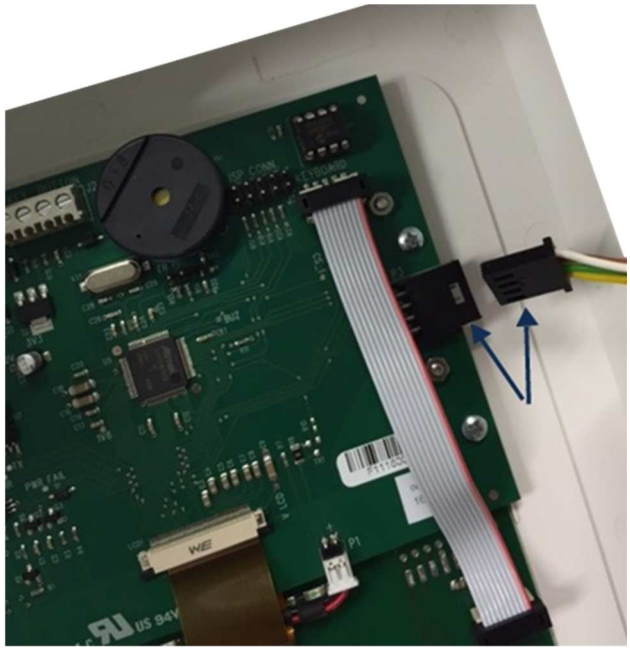
2. Additional keypad

The additional keypad must be connected to the main keypad on the CPU board.

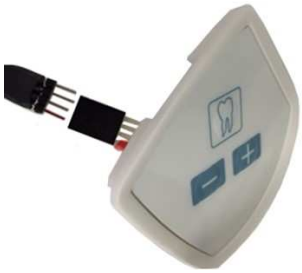
CPU side:

Connect the output connector to the corresponding CPU board connector.

Be careful to insert the pin in the right way.



Generator side:



To connect correctly the keypad please refer to the model version:

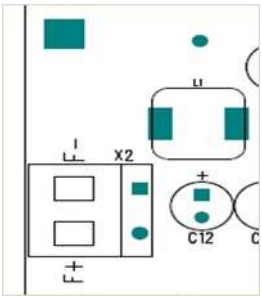
V0: connect the red marked pin of the wire to the arrow printed on the plastic connector (or to the red dot mark)

V1: connect wire 6 of the cable to the arrow printed on the plastic connector (or to the red dot mark).

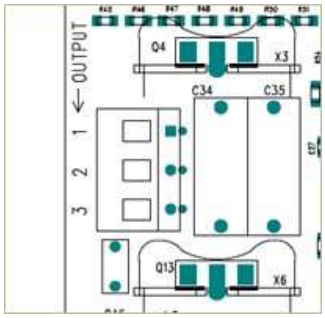
⚠	**CAUTION** The keypad entrance is protected against a possible wrong connection, thus avoiding a system failure; in this case only the keypad will fail.

V1 Cable version

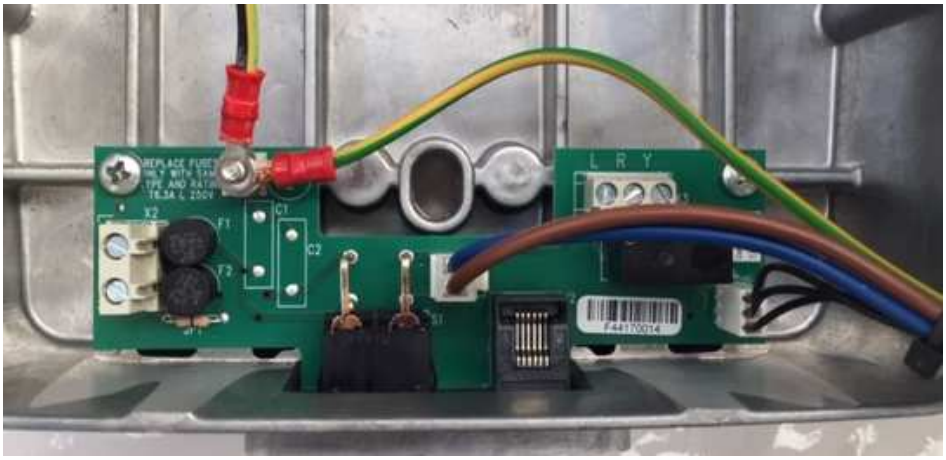
Red -> F-
Black -> F+



Pink -> 1
Blue -> 2
Grey -> 3



Connect the yellow-green cable to the ground point

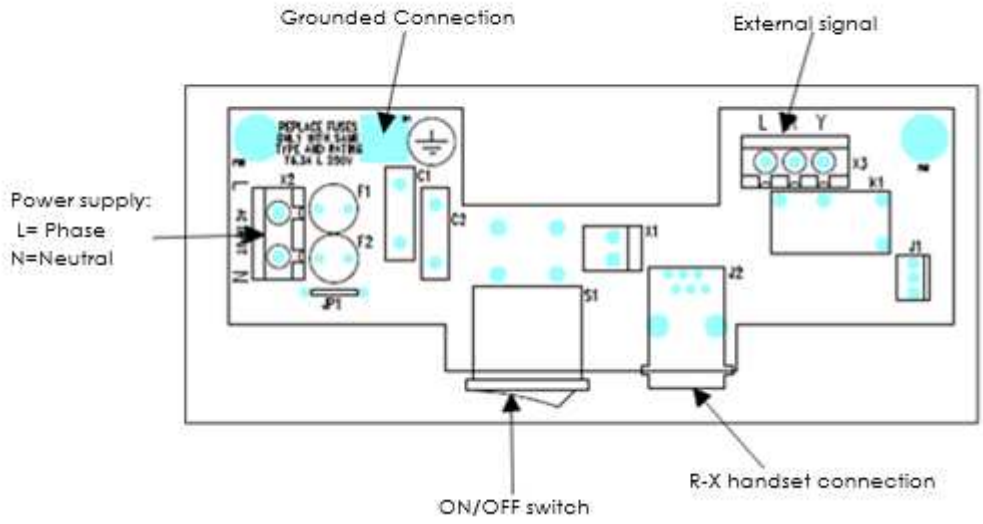


⚠	**CAUTION** The message "Error filament power supply" can be caused by switching the connections of the filament's cables.
⚠	**CAUTION** Be sure to safely connect the ground protection wire (yellow-green wire) **A defective connection to the grounding protection can cause damage to the operator, to the patient and to the technician.**

Additional keypad: close the driver metal cover and connect the additional keypad connector to the CPU board as shown in the picture

5.2.2.6 *Power supply connection*

- Connect the three wires of the power line to their own connectors, respecting the position of phase and neutral as indicated next to the terminals of the connector.
- Ensure that the thread of the protective ground is connected to your terminal.



5.2.2.7 *Remote wall system*

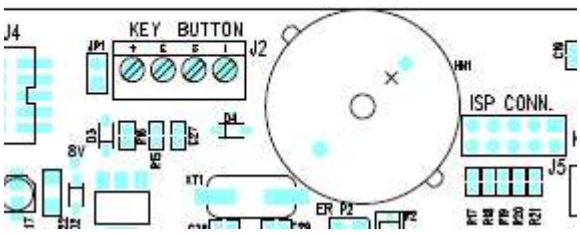
The system can be operated from a remote protected position outside the room using a remote control panel.

5.2.2.8 *Remote control panel installation*

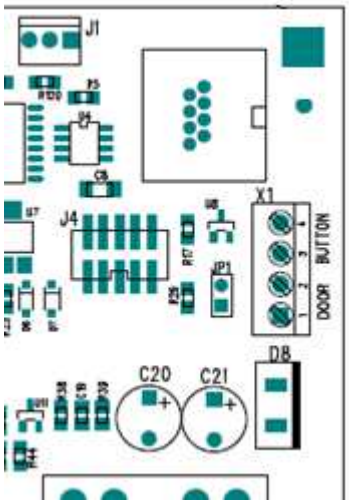
For mounting the remote control panel, follow the instructions for mounting the wall plate at paragraph 5.2.2.1. Note that the weight of the remote control is less than the weight of the wall plate, so you can use plastic expandable anchors.

5.2.2.9 *Remote control panel connection*

This panel has to be connected to the terminals 1 and 2 of J2 connector of the CPU board.



It is also possible to connect the remote panel to the terminals 3 and 4 of X1 connector on the Driver board, as in the following figure.



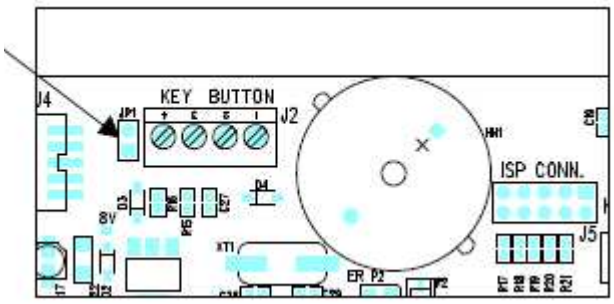
⚠	**CAUTION** Both these inputs are in parallel with the emission's standard button, that will be active as usual. No firmware configuration is required to use the remote button and the normal button.

5.2.2.10 Protection Key Connection

To ensure controlled emissions(not accidentally emissions), the remote control panel can be enabled using an extra protection key. The following instructions show how to set this key.

- The hardware protection's key has to be connected to the JP2 terminals 3 and 4 of the CPU board.
- Remove the JP1 jumper from the CPU (located next to the J2 connector)

Jumper to enable the security key

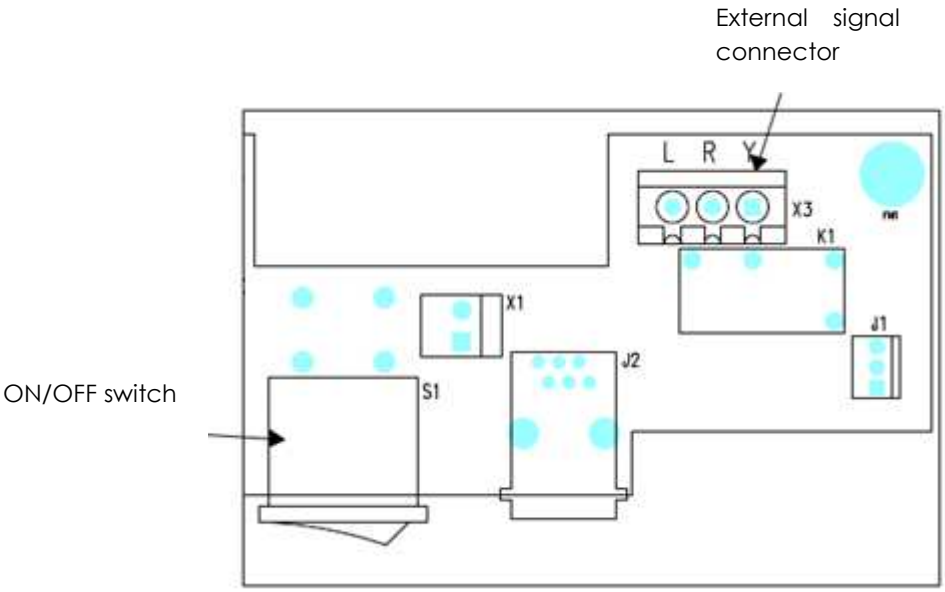


⚠	**CAUTION** The hardware protection's key works only if the JP1 jumper on the CPU has been removed.

5.2.2.11 External signaling connection

The device has an external signaling output for "System Ready" and "Emission in Progress"; the first one is activated when the machine is switched on; the second is activated during the emission (pre-heating time comprised).

The board has 3 connections, driven by relays, and these have the following points of contact on the X3 connection of the input board "Mains".



Make the following connections:

- L = common phase for both lights.
- R = neutral to switch on the red light, it indicates that the machine is ready to be used.
- Y = neutral commuted from the K1 relay, it indicates that the emission is in progress.

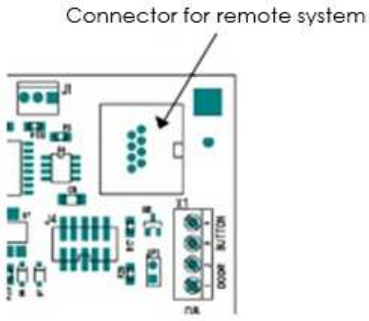
5.2.2.12 Remote timer connection

"Remote timer models" have no PCB on the wall plate, driver and remote timer should be connected using an Ethernet cable (not supplied by Trident)

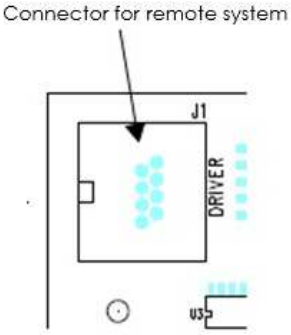
The remote timer is connected directly to the driver board through a coaxial Ethernet cable(not included in the package, you must buy the cable according to your needs). During the installation, the cable needs to be already connected.

To connect the remote system, follow these steps:

- Switch off the system
- Remove the remote timer plastic cover and the wall mounted cover, in order to access to the CPU board of the remote system and to the power driver board mounted and the support arm.
- Connect the coaxial cable to the J1 connector of the CPU board and J2 of the driver board, as per following image.
- Switch on the system and verify that the machine complete the initialization process.
- Switch off the system and place the cover.
- Enable the remote Timer (see 6.3 "Service Menu")
- See *7.3.1 "Function Keys on the control panel"*



Driver board



CPU board

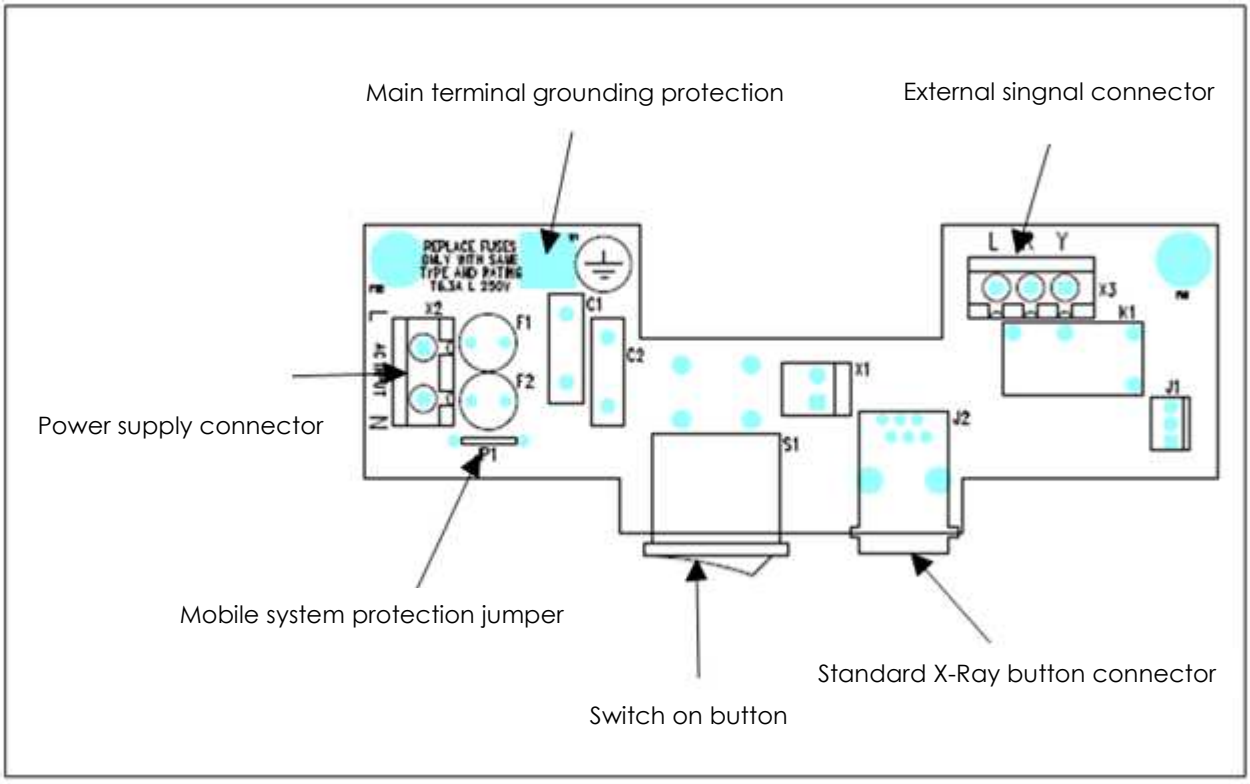
Ethernet cable connection to the driver

Ethernet cable connection to the remote panel

5.2.2.13 Protection fuse enabling

The driver board has two fuses; a zero resistance wire (JP1), as shown in the following picture bypasses one of them.

Remove jumper JP1 to enable the F2 protection's fuse



	Patient and operator's protection is guaranteed only if the JP1 jumper is disconnected
	Fuses have the following characteristics: 6.3 A T, 250V Fuses are the radial type; they need to be mounted on a printed circuit board, welded directly on it.

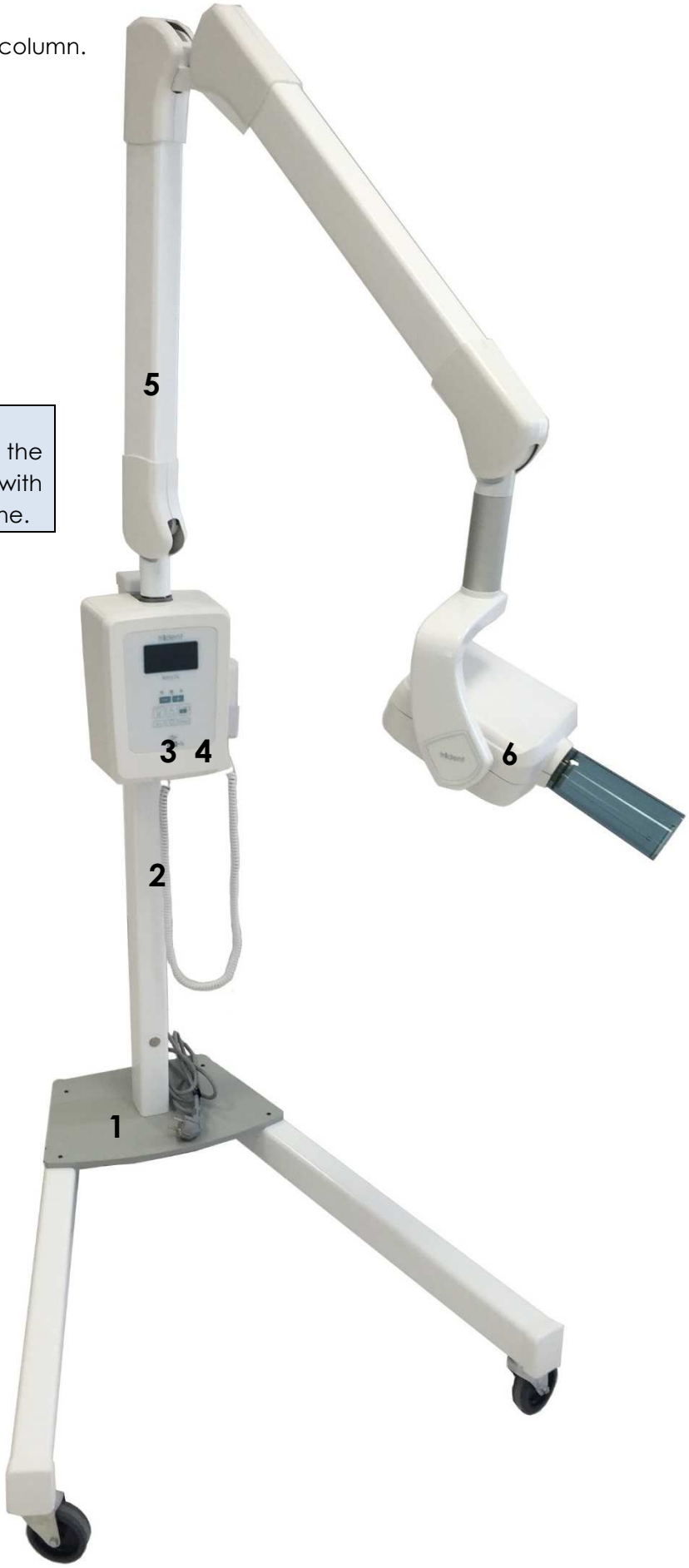
Verify the presence of the second fuse F2 and if the JP1 bridge is cutted, in order to guarantee the protection on both supply's wire.

5.2.3 *Mobile system mounting*

This version does not have the support arm.
The scissor arm is directly assembled to the column.

- Assemble the support legs with the stand base.
- Mount the rear castor wheels and the anterior wheels with the brakes.
- Fix the column to the plate.
- Complete the mounting of the fairlead and the timer.

	**CAUTION** To guarantee the stability of the system, mount the wheels with brakes in the front of the machine.



1. Mobile stand with support legs
2. Column
3. Timer
4. Handswitch with cable
5. Scissor arm
6. Monoblock with cone

5.2.3.1 Articulated arm mounting

- Loosen the mobile support rotation clutch so it does not prevent the articulated arm's mounting.
- Verify the presence of the rotation blocking system and its correct installation.

⚠	**CAUTION** The articulated arm's rotation blocking system has the function to locate the barycenter of the machine (with the arm completely extended) inside mobile system's area. **A wrong installation of this part can cause damage to the patient, to the operator and to the environment.**

- Insert the articulated arm's pivot inside its support, paying attention to let the cables (that come from the arm) passing through the proper hole on the support plate.

5.3 Acceptance test

The acceptance test of the system provides the measurement of the following parameters:

- Anodic current
- High voltage
- Exposure Time

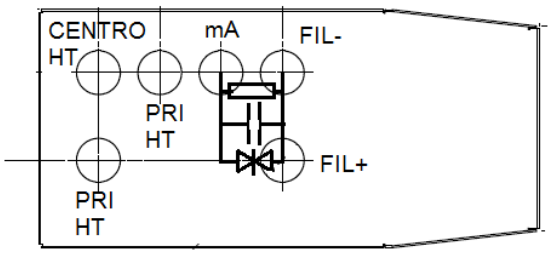
⚠	During the test there is emission of X-Ray, please take all necessary measures to ensure an adequate and safe operation.
☞	The measurement of these parameters require appropriate equipment and must be performed by qualified experts.

5.3.1 Anodic current measurement

Measurement of anodic current is an invasive method.

⚠	The invasive method requires access to the Tubehead by removing the cover. Therefore, only a trained technician can carry out this test.

The anodic current, expressed in mA, indicates the value of current in the X-ray tube reached after the pre-heating time.



- Get access to the Tubehead.
- The readability of the anodic current requires a voltmeter for continuous current, connected to the 1 kΩ resistor mounted on the Tubehead.
- Voltmeter characteristics:

a. Needs to be set to read a voltage of 10 V full scale, which corresponds to 1 V 1 mA .
b. Has to be able to memorize the value.

- Set an exposure of 500 ms or adequate time to permit reading of the value. The measurement has to be done for the three levels of high voltage.

5.3.2 High voltage value measurement

Measurement of high voltage is a non- invasive method.

	The non-invasive method does not require access to the Tubehead, it can be done using an external measuring instrument.

The kV_p level indicates the peak value of the anode's voltage. It increases until the preheating time ends and then becomes constant. The kVp level can be measured with a non-invasive instrument placed in front of the collimator. A correct measurement can be performed with an exposure time of at least 500 ms having introduced a delay of the reading instrument of about 100 ms to allow the stabilization of the voltage level after the preheating time.

The measurement needs to be done for the three levels of high voltage, selecting them appropriately from the operator interface.

1. Set an exposure time of 500 ms , insert the probe of the instrument in contact with the cone collimator, removing any rectangular collimator .
2. Ensure that all the sensitive part of the probe gets hit by the rays.
3. Make three exposures for each value of the set voltage, store the values for each exposure.
4. The value of the high voltage measured is represented by the average exposure for each value of high voltage.

5.3.3 Exposure time measurement

Measurement of high voltage is a non- invasive method.

	The non-invasive method does not require access to the Tubehead, it can be done using an external measuring instrument.

The paragraph 203.4.101 of IEC 60601-2-65 defines the exposure time as the time that elapses between the instant in which the dose in the air exceeds 50% of its peak value (excluding initial and overvoltage) and the instant at which it falls definitely below 50%. For this reason, the exposure time measurement can be performed with a noninvasive tool of kVp and exposure time able to hook up to 50% of the maximum level of kVp.

The procedure for measuring the exposure time is similar to the one reported for the measurement of the value of high voltage, selecting the exposure time that you want to check using the user interface in manual mode.

6 AVAILABLE MENUS

RiX-70 DC has three menus. The user can access two of them: the System Menu and the User's Menu. Only the technical service staff can manipulate the third menu (Service Menu).

The functions available to the user allow access to the less frequent operations. The technical service menu allow the configuration of the system; for this reason, a password (sequence key) protects the access to this area.

6.1 User's Menu

Pressing the button Menu for at least two seconds, access the User's Menu, identified by the words User's Menu at the top, which groups together the parameters that do not need to be frequently adjusted, according to the sequence below.

DISPLAYED MESSAGE	DESCRIPTION
Language	Changing Language
Collimator	Using the rectangular collimator
Sens. Film	Changing the sensitivity of the film
Sens. Dig.	Changing the sensitivity of the digital sensor
Sens. Fosf.	Changing the system sensitivity Phosphor Plate
Exposure Counter	Displaying the Counter
Contrast	Changing the display contrast
Reset	Reset settings

- Press the button **Selection kV** to select the correct item
- Press the button **Activation X-Ray** to confirm the selection.
- Press **Menu** to exit the User's Menu.

6.1.1 Changing Language

The possibility of changing the language is always the first choice in the User's Menu. You can choose the display language from the available languages: English, Italian, French, Spanish and Portuguese. To change the language:

- Enter the User's Menu and press **Selection kV**.
- Go to the row "Language".
- Press "+" or "-" to change it. The system instantly change the content of the display in the selected language.
- Press **Activation X-Ray** to confirm the selection, which is now stored.
- Press **Menu** to exit the User's Menu

6.1.2 *Selecting the collimator*

The system allows the use of the optional rectangular collimator to be used on both standard cone and long cone. The presence of the rectangular collimator changes the DAP value, as a function of the exposed area. To select the collimator:

- Enter the User's Menu.
- Press **Selection kV**.
- Go to the row "Collimator", next to which is displayed the type of limiter currently set: "Absent", "Size 1" and "Size 2 ".
- Press the button "+" or "-" to change the option.
- Press **Activation X-Ray** to confirm the selection.
- Press **Menu** to exit the User's Menu

6.1.3 *Changing the sensitivity of the image receptor.*

This feature allows adapting the emission time to the image receptor in use. The system has the emission parameters preset for the sensitivity of the common use analogue films, type D, E and F, also for digital sensor and PSP . To change the sensitivity of the image receptor:

- Enter the User's Menu.
- Press **Selection kV**.
- Move to the type of image receptor you want to change the sensitivity ("Sens. Film" or "Sens. Dig." Or "Sens. Phos.")
- Press **Activation X-Ray** to confirm the selection.
- Press **Menu** to exit the User's Menu

When the image receptor is "Film", the sensitivity is shown by the type of film (D, E or F) followed by some "+" which correspond to the times the set exposure time is greater than the pre-set time.

When the image receptor is "Digital sensor" or "PSP", the sensitivity is shown by the symbol "0" (zero) preceded or followed by some "∗" corresponding to the times the exposure time is longer or shorter than the pre-set time.

6.1.4 *Displaying the exposures counter*

This option allows displaying the number of exposures already done. Users cannot change or enter the number of exposures. This operation is performed during the final test of the system.

6.1.5 *Changing the display contrast*

The contrast of the LCD display can be changed to suit the user's preference in order to have optimum readability settings. To change the contrast of the display,

- Enter the User's Menu.
- Press **Selection kV**.
- Move to the line "Contrast". Pressing "+" or "-" the contrast of the display changes.
- Press **Activation X-Ray** to confirm the selection.
- Press **Menu** to exit the User's Menu

6.1.6 *Reset Settings*

With this option, the unit returns to the original parameter's values. All the modification made by the user will be lost. This option will bring the system at its status before the first use:

- Language: English
- Use of the collimator: None

- Sensitivity for film, digital sensor or PSP scanner go back to the initial value.
- Contrast go back to the initial value.

To return the system to the original values:

- Enter the User's Menu.
- Press **Selection kV**.
- Pressing **Activation X-Ray** the message "Reset values: I proceed?" is shown.
- Press **Activation X-Ray** to confirm the selection.
- Press **Menu** to exit the User's Menu

6.2 *System's Menu.*

This menu is only for displaying some system parameters. To access the system menu, press **Menu** and **Selecting Receptor** buttons simultaneously for about two seconds. Pressing these buttons clears the display and shows the following parameters:

- CPU keyboard Firmware version
- EEPROM data Version
- Power board Firmware version
- Number of exposures done
- Total time of issue, with the format "day: hh: mm: ss: tenths"

6.3 *Service Menu*

This menu contains the selections that usually are set during the installation and do not require frequent modifications.

To access the service menu it is necessary to use a password (a key sequence) in order to avoid manipulations by no qualified personnel. This password consists in pressing **Menu** and **"**  **"** buttons simultaneously for about three seconds.

The Service Menu selection appears on the first line of the screen and is shown until the user leaves the Service Menu. Service Menu's possible operations are:

OPERATION	MENU MESSAGE
Modification of the activation time "System Ready for XR"	XR activation
System type setting	System type
Setting of Kv values limitation	Kv value
Visualization of exposure counter	Counter
Setting reset	

To select the parameter that you want to modify:

- Press the button **kV selection** scrolling up to the desired line; the chosen parameter is displayed in reverse. Any selection can have its own screen, related to the possible choice.
- Inside the menu it's always possible to scroll between the selections pressing the buttons "+" or "-".
- To exit the menu press **Menu**.

6.3.1 *Changing the activation time*

Pressing **System Ready** (green light on) the unit starts a countdown during which the user can press the X-Ray emission button. It is possible to set the maximum time or eliminate it in case of a remote control installation.

The activation timer could work on 30, 60, 90 or 120 seconds (the default time is 120 seconds). To set this parameter:

- Access the Service Menu.
- Press **Selection kV** up to Activation X-Ray.
- Press the button "+" or "-" to change the value.
- Press **Activation X-Ray** to confirm the selection.
- Press **Menu** to exit.

6.3.2 *Setting system type*

This parameter shows the system configuration as a standard or as a remote system. To change the parameter:

- Access the Service Menu.
- Press **Selection kV** up to "Type system".
- Pressing the button "+" or "-", changes the type of system.
- Press **Activation X-Ray** to confirm the selection.
- Press **Menu** to exit

6.3.3 *Setting the limitation of kV value*

This setting is required to comply with some local regulations, which impose lower limits on the value of anode voltage greater than that specified by IEC.

To set the kV choice, choose one parameter according to your needs:

PARAMETER	60KV	65KV	70KV
0	Available	Available	Available
1	Available	Not Available	Not Available
2	Not Available	Not Available	Available

To change the parameter,

- Access the Service Menu.
- Press **Selection kV** up to "kV value".
- Press the button "+" or "-" to change the value.
- Press **Activation X-Ray** to confirm the selection.
- Press **Menu** to exit.

6.3.4 *Expositions counters display*

The system has two counters:

- Total exposures counter
- Total exposure time counter

To display the counter exposures:

- Enter the Service Menu.
- Press **Selection kV** up to “Counter”.

To reset the exposures counter without resetting the counter of the total time of exposition:

- Press **Select Tooth** and **Select Size** buttons simultaneously .
- Press **Activation X-Ray** to reset the counter.
- Press **Menu** to return to the main screen.

6.3.5 Settings reset

It is possible to reset the device with the default parameters.

- Enter the Service Menu.
- Press **Selection kV** up to “Reset”.
- Once the message "Reset values: I proceed?" appears, press **Activation X-Ray** to confirm the procedure.
- Press **Selecting kV** to choose the value to reset:
  - Activation time X-Ray: 60
  - Setting system type: Standard
  - Setting limit values kV: 0 (no limitation)
- Press **Menu** at any stage to return to the previous menu.

7 OPERATOR'S INTERFACE

7.1 Starting the system

The ON/OFF switch is placed on the bottom of the timer. A green light indicates when the device is ON.

Every time the device is accessed, the following tests are performed:

- The system health monitoring (program memories, data storage , etc..)
- The Display turns on for 2 seconds.
- All the indicator LEDs turn on for 2 seconds.
- The buzzer control tweets for 1 second.
- Check that X-Ray button is not pressed
- Check that no other button is pressed
- Logo display
- Displaying the software versions for around 5 seconds.

	Do not press the X-rays button when accessing the device. In case it would happen, the device should be re-started.
	Do not press any button when accessing the device. In case it would happen, the device should be re-started.
	In case any error occurs during the automatic test, an error message will appear with its corresponding error code (see the Annex with error messages). A red LED indicates the activation of the alarm. The system is not ready to start. Restart the device.
	Error message after a new automatic test. In case an error occurred again, contact the technician.

7.2 Shutdown the system

RiX-70 DC does not require special care during shutdown procedure. Press the main switch to turn it off, the green signal lamp and the graphic display will turn off.

8 OPERATION

Turn on the device (the switch is below the timer). Immediately an automatic auto-diagnosis will be displayed. The software version is shown. At the end of the autodiagnosis procedure, the display will show the exposure parameters of the last exposition.

1. Pressing the kVp button select the kVp from 60, 65 or 70 according to your needs.
2. Select the image receptor from film, intraoral sensor or phosphor plate: touch the symbol "Image Receptor Selection" to make your choice and the display will show the symbol of your selection; in the case of analog receptor, it is also indicated the sensitivity of the selected film.
3. Select the patient size and type of tooth.
   - Tooth type: touch the symbol corresponding to the tooth you want to expose; the display will show the symbol corresponding to the selection.
   - Patient size: touch the symbol for the patient size (large, small); the display will show the symbol corresponding to the selection.

Once you select these parameters, RiX-70 DC automatically selects the output time for the type of X-Ray to be performed; the exposure time will appears on the display, whether you need increase or decrease it, use the "+" or "-" buttons.

1A Yellow light
1B Yellow light
2 Exposure pushbutton
3 Line-Switch On/Off below the unit

When you manually change the exposure time, the information of the parameters to calculate that value, will disappear. Tapping again one of the parameter's symbol, the system will return to the default values.

Every time a parameter is changed, the system recalculates the appropriate exposure time; the display shows the exposure time and the estimated air absorbed dose in µGy, delivered to patient.

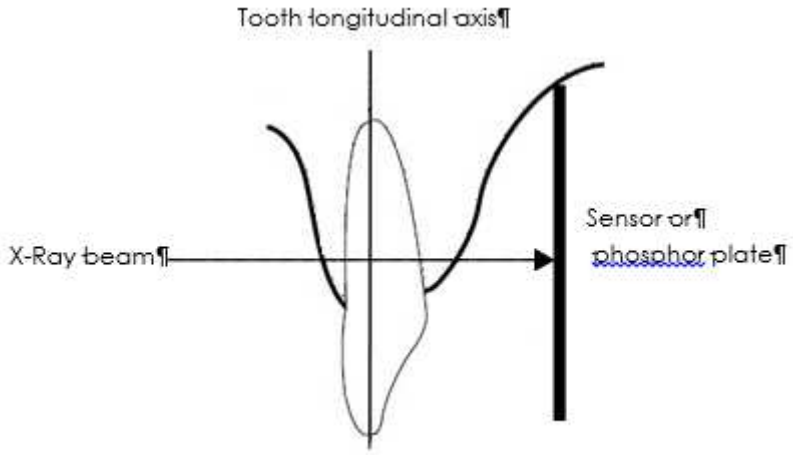
4. Place the patient, who must wear the appropriate protective lead apron (not supplied by Trident Dental), in the right position.
5. Position the image receptor where needed and orientate the tube-head accordingly. Operate with the edge of the cone in contact with the patient's face or the ring of the centering film (optional, not provided).
6. Take the exposure hand-switch and move to a convenient position (at least 2 m far from the patient).
7. Press the exposure button. The yellow light indicates the X-ray emission. Keep pressed the exposure button until the yellow light switches OFF (this indicates the end of the exposure).
8. Hook back the exposure hand-switch and process the image.

⚠	**Warning** If the exposure button is released before the end of the requested time, the radiation emission finishes. An alarm is shown.
⚠	To use the rectangular collimator is necessary to select the right setting from the User's Menu

8.1 Exposure's Techniques

8.1.1 Parallel exposure technique

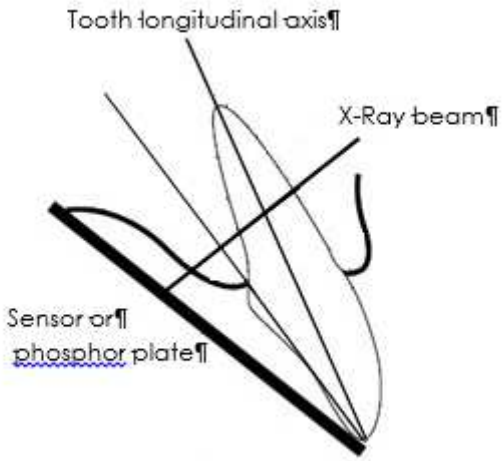
Position the image receptor (film, PSP or digital sensor) in a holder suitable to align to the longitudinal axis of the tooth. The X-Ray beam is perpendicularly oriented to the longitudinal axis of the tooth and the image receptor.



8.1.2 Angle bisector technique

The patient should hold the PSP or film with his finger.

The X-ray beam is directed perpendicularly towards an imaginary line that bisects the angle between the longitudinal axis of the tooth and the image receptor plane.



8.1.3 *Tilt angle*

- The X-Ray beam tilt angle depends on the occlusal plane of the patient.
- The angle value is indicated on the protractor placed between the Tubehead support and the Tubehead itself.

TILT ANGLES	
Jaw	
Molars	35°
Premolars and canines	45°
Front teeth	55°
Bitewing radiograph	10°
Mandible	
Bitewing radiograph	0°
Front teeth	-20°
Premolars and canines	-10°
Molars	-5°

8.2 *Exposure Time*

CAUTION
The following values, set as default values, are based on the quality image evaluation. The effective set of those values depends on many aspects as per the user preference (contrast, brightness etc..) and per patient mouth anatomy.

70 kV											
Tooth/Patient size		**Digital sensor**		**Film type D**		**Film type E**		**Film type F**		**Phosphor system**	
		Adult	**Child**	**Adult**	**Child**	**Adult**	**Child**	**Adult**	**Child**	**Adult**	**Child**
Maxilla	Molars	0.100	0.063	0.320	0.200	0.125	0.080	0.100	0.063	0.320	0.200
	Premolars	0.080	0.050	0.250	0.160	0.100	0.063	0.080	0.050	0.250	0.160
	Incisors	0.063	0.032	0.200	0.125	0.080	0.050	0.063	0.040	0.200	0.125
Mandible	Incisors	0.056	0.020	0.125	0.080	0.050	0.032	0.040	0.025	0.125	0.080
	Premolars	0.063	0.036	0.160	0.100	0.063	0.040	0.050	0.032	0.160	0.100
	Molars	0.080	0.050	0.250	0.160	0.100	0.063	0.080	0.050	0.250	0.160
	Bitewing	0.100	0.063	0.400	0.250	0.160	0.100	0.125	0.080	0.400	0.250

65 kV											
Tooth/Patient size		**Digital sensor**		**Film type D**		**Film type E**		**Film type F**		**Phosphor system**	
		Adult	**Child**	**Adult**	**Child**	**Adult**	**Child**	**Adult**	**Child**	**Adult**	**Child**
Maxilla	Molars	0.125	0.071	0.450	0.320	0.180	0.125	0.160	0.110	0.450	0.320
	Premolars	0.100	0.063	0.360	0.250	0.160	0.110	0.125	0.090	0.360	0.250
	Incisors	0.080	0.040	0.320	0.220	0.125	0.090	0.100	0.071	0.320	0.220
Mandible	Incisors	0.063	0.025	0.180	0.125	0.071	0.050	0.063	0.045	0.180	0.125
	Premolars	0.090	0.045	0.250	0.180	0.090	0.063	0.080	0.056	0.250	0.180
	Molars	0.100	0.063	0.360	0.250	0.160	0.110	0.125	0.090	0.360	0.250
	Bite-wing	0.160	0.100	0.630	0.360	0.250	0.180	0.200	0.140	0.630	0.360

60 kV											
Tooth/Patient size		Digital sensor		Film type D		Film type E		Film type F		Phosphor sensor	
		Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child
Maxilla	Molars	0.200	0.125	0.630	0.400	0.250	0.160	0.200	0.125	0.630	0.400
	Premolars	0.160	0.100	0.500	0.320	0.200	0.125	0.160	0.100	0.500	0.320
	Incisors	0.125	0.063	0.400	0.250	0.160	0.100	0.125	0.080	0.400	0.250
Mandible	Incisors	0.110	0.040	0.250	0.160	0.100	0.063	0.080	0.050	0.250	0.160
	Premolars	0.125	0.071	0.320	0.200	0.125	0.080	0.100	0.063	0.320	0.200
	Molars	0.160	0.100	0.500	0.360	0.200	0.125	0.160	0.100	0.500	0.360
	Bite-wing	0.200	0.125	0.800	0.500	0.320	0.200	0.250	0.160	0.800	0.500

8.2.1 Manual selection of Exposure time

The user can manually modify the pre-set exposure times for any type of receptor, pressing one of the buttons "+" or "-" from the main keyboard or on the optional keyboard. Times can move of 47 steps from 0.010 to 2s as per the following table:

0.010	0.011	0.012	0.014	0.016	0.018	0.020	0.022	0.025	0.028
0.032	0.036	0.040	0.045	0.050	0.056	0.063	0.0710	0.080	0.090
0.100	0.110	0.125	0.140	0.160	0.180	0.200	0.220	0.250	0.280
0.320	0.360	0.400	0.450	0.500	0.560	0.630	0.710	0.800	0.900
1.000	1.100	1.250	1.400	1.600	1.800	2.000			

8.3 Getting Images

⚠	Pay attention to the disposition regarding radiation protection. Press the X-Ray button only at a safe distance (at least 2 meters from the patient).

To take an image do as follows:

- Properly prepare the patient.
- Choose the exposure parameters and set the unit.
- For X-Ray emission, keep pressed the X-ray button during the entire exposure. Be sure to enable the exposure countdown if enabled.
- The green LED switch off, while yellow LED and buzzer indicate the x-ray emission.
- Keep pressed the button (or the emission button in case of remote system) until the yellow LED and the buzzer stopped to indicate the end of the emission.

☞	If during the countdown the emission has not been done, the green LED will turn off and the emission will not be possible. Restart the process.
⚠	RiX-70 DC has a sensor for "Door open" that can be disabled. This status is not displayed on the display but if the door is open an error message appears.
⚠	**CAUTION** Do not release the command button before the end of the set exposure time, otherwise, stops the emission and emits an alarm.

At the end of any emission, the system takes a rest long 30 times the length of the emission time, not less than 10 sec. During this rest is not possible to make other emission but it's possible to modify the system's setting to prepare it for a new emission.

9 MAINTENANCE AND CLEANING

In the interest of safety and health of patients, users or third parties, is necessary to make periodic inspection and maintenance, in order to ensure the safe operation of the product.

1. The operator has to grant the execution of inspections and maintenance.
2. If the operator fails to comply with the obligation to carry out inspections and maintenance or ignores the fault messages , Trident Dental and / or its exclusive representative assume no liability for the resulting damage.
3. As manufacturers of medical equipment , we consider ourselves responsible for the technical safety of the device only if maintenance and repairs are performed by us or by centers approved by us and if the components, in case of failure , are replaced with original spare parts .
4. In the case of intervention on the device , we recommend to ask to the company making such intervention to show a certificate with all the identification datas of the company itself and the type of intervention.

9.1 Maintenance

	**Only trained personnel can open the unit.**
	RiX-70DC does not have parts subject to external maintenance.

9.1.1 Monthly maintenance

Users should perform the following monthly checking:

1. Visually inspect all visible labels that are intact and legible; if not, you should request a copy of these to the manufacturer.
2. Check the unit has no external damage that may affect the safety.
3. Visually check the exposure indicator LED is lit for the duration of exposure.

4. Check that there are no traces of oil on the Tubehead covers.
5. Verify that the acoustic indicator is active for the duration of exposure.
6. Check that the exposure button is held down continuously during the exposure cycle.
7. Check if the exposure is terminated prematurely by issuing the command button X-Ray, the display shows the appropriate error message.
8. Check all the proper performance of the functions of selection and performance of tests on the keyboard.
9. At regular intervals, at least once a year, the operator shall assess the quality of the image.

9.1.2 Performance verification

To guarantee the functionality of the unit, the user needs to perform at least once a year:

- Checking the following parameters:
  - Value and accuracy of high tension
  - Value and accuracy of anodic current
  - Value and accuracy of exposure time
- These verifications have to be done following what described in paragraph **5.3**

9.1.3 Mechanical maintenance

Every six months is necessary to check:

• Arm and shelf's joints: verify the absence of noise, roughness of the movement; the movement has to be fluid, with no shots, the unit must remain in the position where it is placed when performing an X-Ray;

- Wall plate with absolute zero detachment from the wall.

9.1.4 *Image's quality verification*

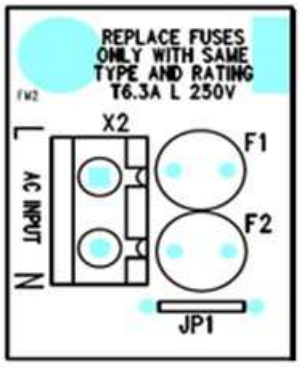
At least once a year, the operator shall evaluate the image quality. For film, follow the manufacturer instructions regarding the exposure time.

For sensor, it is used as a criterion for evaluation the growing number of image processing that require subsequent adjustments to brightness or contrast of the image processing software used.

9.1.5 *Electrical Maintenance*

The electrical system of RiX 70 DC does not require maintenance. However, it is necessary to provide periodic inspections of the electrical connections, in particular as regards the efficiency of the system of grounding protection, the conditions of the insulation and the good general conditions of the supply line. We suggest annual audits of the electrical system.

9.1.6 *Fuses substitution*



The power board is equipped with two fuses , one of which is bypassed by a resistance wire (JP1) that, in the case of the mobile system , it is cut so as to ensure the protection of both the power cables.

The fuses have the following characteristics : T 6.3 A , 250 V. To replace the fuses

- Remove the timer plastic cover to access the board.
- Switch off the system.
- Using a digital multimeter set to Ω find the burned fuse (or fuses)and replace it.
- An eventual rupture of the fuse normally identifies a catastrophic failure , so it's necessary to proceed with troubleshooting and replacement of the power supply board .

⚠	The fuses are radial type mounting on circuit board and are directly welded onto it. Cannot be replaced on field.

9.1.7 *Arm adjustment*

The RiX- 70 DC X-Ray unit is adjusted at the factory for normal use. It may be necessary, during the installation or the useful life of the unit, to perform an adjustment of the support arm to eliminate any oscillation or movement that interferes with the normal unit operation . For a correct adjustment of the arm, proceed as follows:

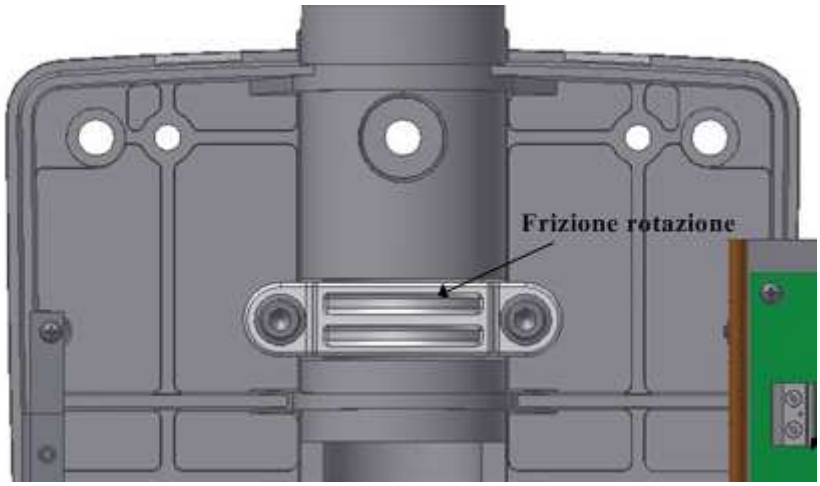
9.1.7.1 Adjusting the horizontal rotation.

The horizontal rotation can be adjusted whether on the rotation pin of the support arm or on the rotation of the scissor arm.

9.1.7.2 Adjustment of the horizontal rotation on the support arm.

The clutch of the support arm is adjusted by tightening / loosening the clutches on the arm.

- Remove the timer cover
- Open the support of the driver tab to access the pivot pin and the clutches
- Adjust the clutch using the two screws at every side of the pin.
- When the adjustment is completed, restore the system to its original condition



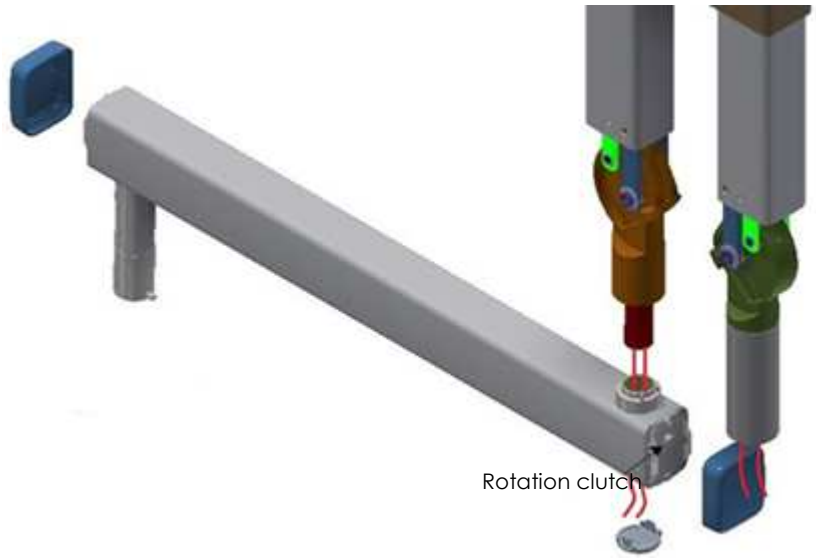
Warning

The rotation's lock and the rotation's clutch have an anti-slipping safety function.
They are essential for a safer operation of the unit.

9.1.7.3 Support arm rotation adjustment

(This adjustment cannot be performed in the mobile stand version)

- *Remove the support arm plastic cover to access the rotation clutch.*
- *Adjust the clutch with an Allen key, making sure that the arm does not make a strong resistance to the movement and at the same time maintains its position when released. After the adjustment, replace the plastic cover of the extension arm.*



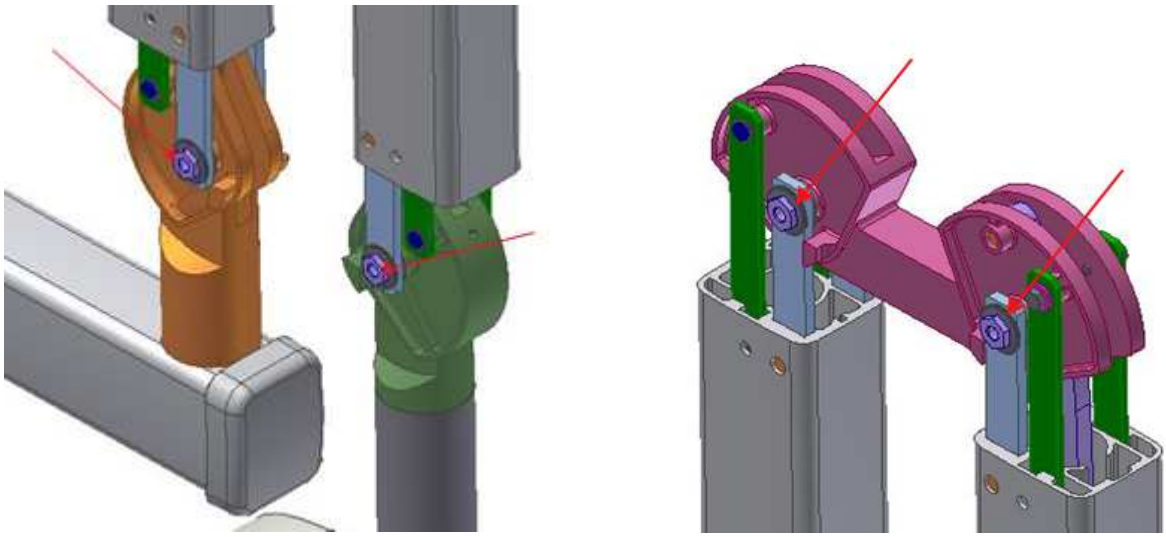
9.1.7.4 Adjustment of the horizontal rotation on the scissor arm

The scissor arm is composed by two pieces, the first piece is connected to the support arm, the second piece is connected to the Tubehead.
The adjustment of the scissor arm is necessary when:

1) The scissor arm movement makes resistance during the opening / closing. In this case is necessary to adjust the arm's clutches.
2) The Tubehead oscillates or can not keep a stable positioning. In this case is necessary to adjust the tension of the spring of the scissor arm's first piece.

9.1.7.5 Arm clutch adjustment

- *Remove the plastic covers of the central joint of the arm and the bottom shell.*
- *The position of the arm clutches are indicated in the following figures.*



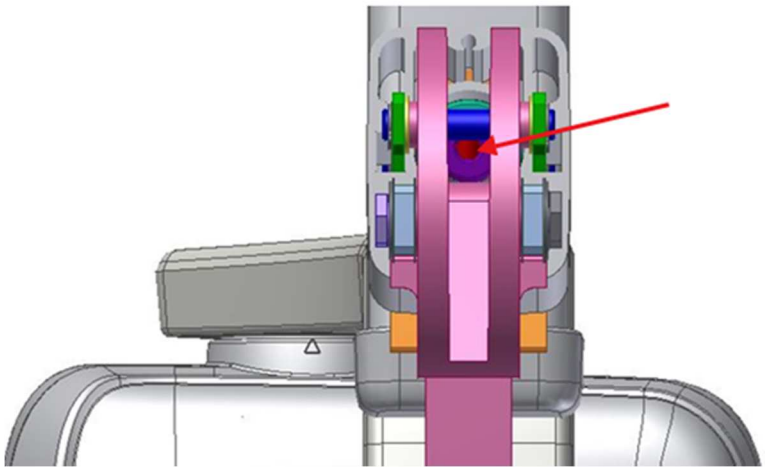
- *Using a 3mm hex key loosen the M6 dowel inserted inside the telescopic screw.*
- *With a spanner 13 adjust the clutch until obtain the desired fluidity in the movement.*
- *Warning: screw the M6 grain to avoid loosening the clutch.*

9.1.7.6 *Adjustment of the first arm's spring*

It is necessary to adjust the first arm' spring when:

- *The scissor arm oscillates excessively or when needs a long time to stabilize it at the desired position.*
- *To perform this operation the arm must be vertically positioned.*

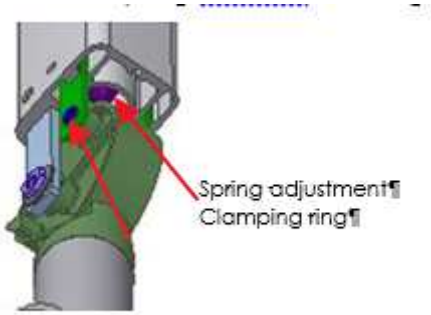
The position of the adjusting pin is shown in the following image (view from above)



- *Using a 6 mm Allen key inserted in the respective slot adjust the clutch.*
- *The adjustment is considered satisfactory when the forces needed to carry out the opening and closing movements are objectively of equal value.*

9.1.7.7 *Adjustment of the second arm' spring*

The position of the second arm' spring is shown in the figure:



The adjustment must be performed with the first arm in a vertical position and the second arm open. Using pliers remove the retaining ring and remove the pin from its seat to allow access to the spring adjustment.

Using a 6 mm Allen key, inserted into the joint slot, perform the adjustment of the second arm' spring. The adjustment is considered satisfactory when the forces needed to carry out the opening and closing movements are objectively of equal value.

9.2 Cleaning

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

	Always disconnect the system from the network (the local switch) before cleaning .
	Do not use scouring pads or abrasive cleansers (alcohol, benzene, trichlorethylene). Use only soft clothes to avoid scratches.
	Do not use any colored cloths for cleaning, since they may cause discoloration of the surfaces in combination with disinfectants.
	Do not clean the labels with abrasive cleansers.
	To clean the timer, use a clean cloth dampened with mild detergent and water.
	To clean the parts in contact with the patient use a damp cloth with the chosen liquid and rub the non-removable parts of the system (handle, tube, etc.)

9.2.1 Cleaning products compatible with RiX-70 DC

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

10 TROUBLE SHOOTING

Problem: the device does not switch on
Solution: Check the fuses integrity

	CAUTION: In case of mobile version, before checking the fuses , make sure the power cord is intact , and fully plugged in . If necessary, try another power outlet that you know works

The power board is equipped with two fuses , one of which is bypassed by a resistance wire (JP1) that in the mobile version, is cut so as to ensure the protection of both the power cables.

1. Switch off the system.
2. Remove the timer plastic cover to access the board.
3. Using a digital multimeter find the burned fuse (or fuses)and replace it.
4. If the fuses are working, go to **Step 11**
5. Reconnect the power line and turn on the system .
6. Ignore any error messages about failures with the Tubehead.
7. Turn off the system again and check the connections.
8. Turn on the system.

If the problem persists , probably the Tubehead is broken; replace it .
If the fuses are intact, the likely reason is the CPU / display

9. Check the two wires between driver board and CPU board
   a) For standard system , from the driver board J4 to CPU board J4
   b) For remote system , from driver board J2 to J1 remote CPU
10. Check the position of the display on the CPU board .
11. If the problem persists, replace the CPU and display.

Display message: Error 05	**Problem: X-Ray button pressed during switching on**
This message appears in both standard and remote control. For the wall system, the handset is connected to the driver board, terminals 1 and 2 of X1. For the remote system, the X-Ray trigger is connected to the CPU board , terminals 1 and 2 of J2 . **Solution** 1. Turn off the device and disconnect the X-Ray handset. 2. Turn on the system and verify that the message has disappeared; in this case replace the handset. 3. If the message persists, perform the following steps : a) For remote system, check the wiring between driver J2 to J1 remote CPU; if the wires are connected, replace the X-Ray hand set. If the problem persists, replace the CPU board. b) For standard system, replace the X-Ray hand set. If the problem persists, replace the CPU board.	

Display message: Error 05	Problem: One or more buttons pressed during switching on.

Solution

1. Switch off the system.
2. Switch on the stystem and verify that the message disappeared; if not:

a) Check if the wiring between the CPU board (J3) and card display / keyboard (J1) is fully inserted and not damaged.

b) If necessary, replace the wiring or the card display / keyboard

c) Turn on the system and verify the message has disappeared; otherwise replace the CPU board.

Display message: Error 01	Problem: X-Ray button pressed at the end of cooling time.

This error identifies that the X-Ray button still pressed after the end of the cooling period.

Solution

Release the button and check that the message disappears when you press the "Menu" button. If the problem persists follow the same instruction indicated at “RX botton pressed during switching on”

Display message: Error 07	Problem: RS485 Communication error

This message identifies a communication error between the boards.

Solution

Check the correct insertion of all wiring

1. Check the two wires between driver board and CPU board
    a. For standard system, from the driver board J4 to CPU board J4
    b. For remote system , from driver board J2 to J1 remote CPU
2. Check the cable between J3 CPU board and J1 display/keyboard.
3. If every single cable is regularly connected and not damaged, replace the wires one at a time. Turn on the unit after each replacement checking the message has already disappeared.

Display message: Error 01	Problem: Button pressed without authorization

This message indicates that the X-Ray button has been pressed without enabling.

Solution

To start the operative reset of the system, without hardware protection key, just press Menu.
If the system alarm is repeated, verify the presence of the JP1 jumper on the CPU board(in case the hardware’s key is not provided).
When the system is provided with the hardware’s protection key and the message is repeated:

1. Verify the correct functioning of the hardware’s protection key.
2. Verify the connection between the hardware’s protection key and the terminals 3 and 4 of the CPU's J2 connector.

Display message: Error 08	Problem: Door open

The door of the room, if equipped with its proper sensor. The door has been open and the emission interrupted.

Solution

Close the door and restart the operations pressing "Menu" button.

a) In case of film or phosphor receptor change the receptor.
b) For digital sensor: the image can be not diagnostic, repeat the operation

If the system has been prepared for this situation:
Verify the correct door micro switch functioning and the wiring to the driver board.
Check the wiring between the driver board and CPU board

a) In the case of the standard system , from the J4 driver board to J4 CPU board
b) In the case of remote system, from J2 driver board to J1 remote CPU

If wiring is correct and not damaged , replace the driver board and turn on the system by checking if the message is disappeared , otherwise replace the CPU board.

Display message: Error 04	Problem: Error filament power supply

This message appears when the control system detects a power supply failure on X-ray tube's filament, which does not necessarily mean a filament breakage. In fact, the message also identifies an interruption of the wiring between the driver board and Tubehead.

Solution

1. Turn off the system and access the driver board.
2. Remove the cover of the Tubehead .
3. Disconnect the cable connector X2 on the driver board and also disconnect the connector with two wires in the Tubehead support.
4. Check the two wires ohmic continuity; if there is a break change the cable, if not, go to step 7.
5. After replacing the cable , restore the connection between the connector and the X2 block.
6. Turn on the system and check the display to verify if the the error message disappeared.
7. Check the ohmic continuity of the wiring between the connector and terminal filament " FIL + " and " FILTER " welded to the Tubehead .
8. If any interruption occurs, replace the wiring, otherwise replace the Tubehead.
9. Restore all covers and check the proper performance of the X-Ray.

11 ANNEX 1

11.1 Alarms

DISPLAY INFO	DESCRIPTION	CAUSE / SOLUTION
------	The display is completely black	No power. Reset and switch on again ; if the error persists, please consult the Maintenance Manual If the power switch and the indicator lights are switched on, probably the main fuse is broken . Consult the Maintenance Manual.
-------	The display is completely blank even if the switch is on (green light on)	Likely failure of the main fuse. Consult the Maintenance Manual. If the error persists, fatal error of the program memory. Call the tech assistance to Replace the CPU board.
Error 09	Memory Error EEPROM 1	Control error of the first memory bank data ; the system is operating as it has restored the data from the second memory bank . Press " Menu " to continue checking. **Call the tech assistance to replace the CPU board if the problem occurs frequently**
Error 09	Memory Error EEPROM 2	Control error of both the first and the second memory bank; the system is operating as it has restored the data from the program memory. Press " Menu " to continue checking . **Call the tech assistance to replace the CPU board if the problem occurs frequently**
Error 10	Non congruent configuration	The system detected that the system configuration does not match the specifications. Repeat the configuration of the system. **Call the tech assistance to replace the CPU board if the problem occurs frequently**
Error 01	X-Ray button pressed	No operating system Release the keys eventually pressed; turn the system off and on again. Consult the Maintenance Manual.
Error 05	More than one button pressed during the switching on.	**System inoperative.** Release the buttons; turn the system off. On again. If the problem persists, please consult the Maintenance Manual.

11.1.1 Error during pre-exposure phase

DISPLAY INFO	DESCRIPTION	CAUSE / SOLUTION
	Mains voltage too low.	The system supply voltage has dropped below the minimum level allowed for the security of the system. Press " Menu " to delete the message . If it reappears or if the situation frequently happens, verify that the office's supply voltage is within the tolerances.
Error 01	Button pressed without authorization	The system is protected by a hardware protection key that was not correctly positioned before pressing the X-Ray button . Release the button, press the "Menu" button to resume the system operation of and turn the security key to the enabled position before repeating the exposure.
		Release the button and press the "Menu" button to resume operation of the system. Enter the state of "Ready for X-Rays" before performing the exposure.
		In the remote system. X-Ray button was not simultaneously pressed with "+" button to enable the emission.

Error 01	X RAY Button pressed after the end of the cooling break	Release the X RAY button and press "Menu" button. If the condition persists , there is a probable damage in the X RAY button. To see more information please refer to the Maintenance Manual.
Error 07	Communication error RS485	Caution: blocking error. Communication between system boards does not work correctly. Turn the system off and on again; If the error persists, please consult the Maintenance Manual.

11.1.2 Error during X RAY emission

DISPLAY INFO	DESCRIPTION	CAUSE / SOLUTION
Error 02	Exposure ended by the operator	Releasing of X-Ray button during the emission has interrupted the emission. • In case of phosphor or analogic receptor: change the film and repeat the emission. • In case of digital sensor: The image obtained can be not diagnostic, repeat the operations.
Error 01	X-RAY button pressed	The X RAY button is already pressed and, accidentally, another button is pressed. If the error message doesn't disappear, even after switching off and on the system, please consult the Maintenance Manual.
Error 08	Open door	The room's door, if equipped with the proper sensor, has been opened during the phase "Ready for X RAY". Close the door and restart the operations pressing "Menu" button.

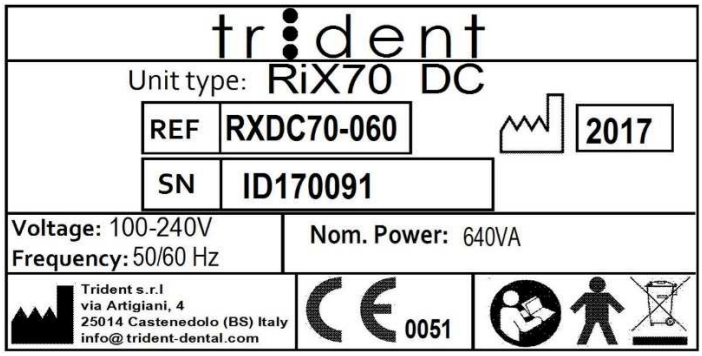
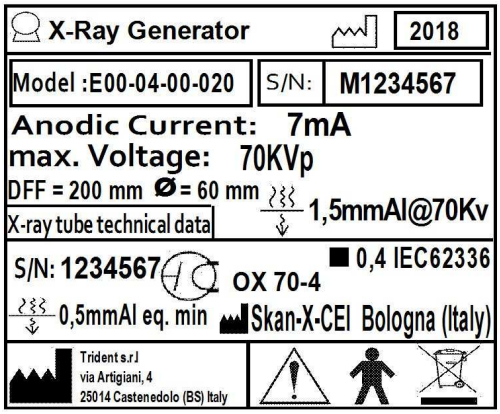
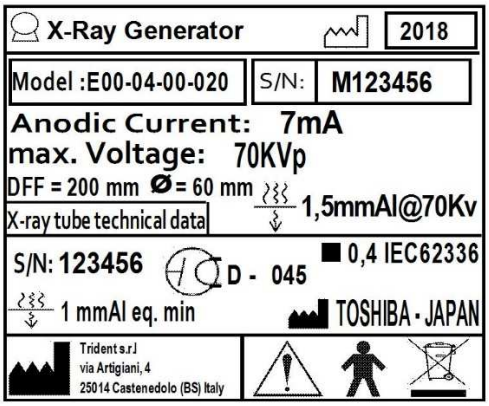
11.1.3 Blocking messages

These messages identify warnings situations for the patient, the operator and other persons located close to the machine. For these reason these errors block the machine.

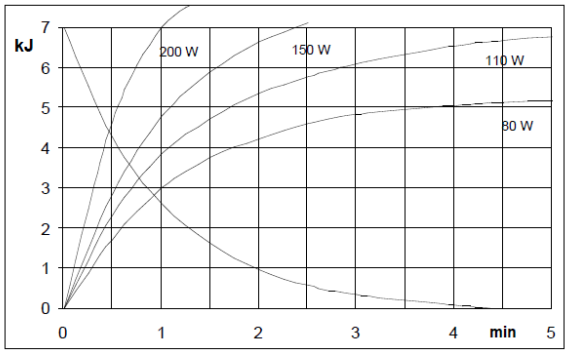
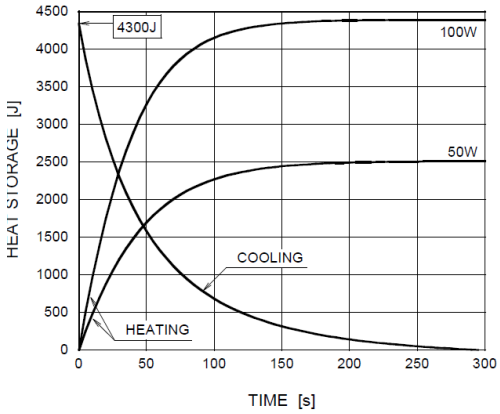
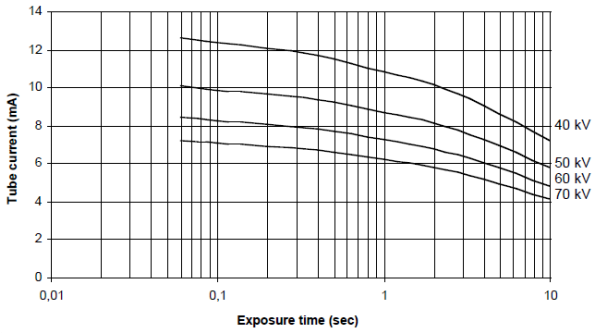
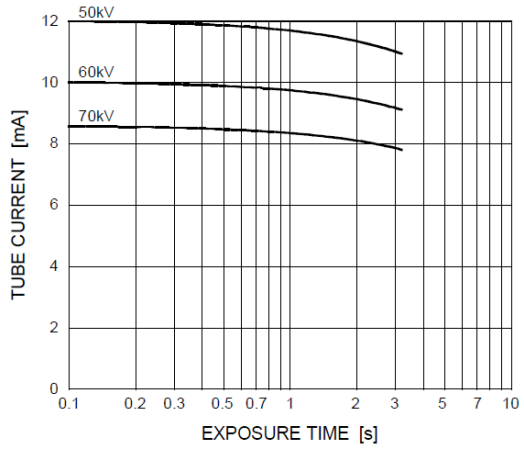
DISPLAY INFO	DESCRIPTION	CAUSE / SOLUTION
Error 03	End of exposure by security timer	The emission did not end normally and was interrupted by the safety timer . The audio signal will be active until the intervention of the security . **The image is not diagnostic.** The system is blocked: switch off and on again . If the problem persists please call tech assistance to replace the driver board.
Error 06	High Voltage regulation error	The system has detected that high voltage values are too high; the emission was interrupted. **The image is not diagnostic.** The system is blocked: switch off and on again. If the problem persists, call tech assistance to replace the driver board.
Error 04	Filament supplì error	The system detected the lack of the anode current feedback signal. The emission cannot start or was cancelled. The image is not diagnostic. The system is locked: turn off and on again. If the problem persists, please consult the Maintenance Manual.

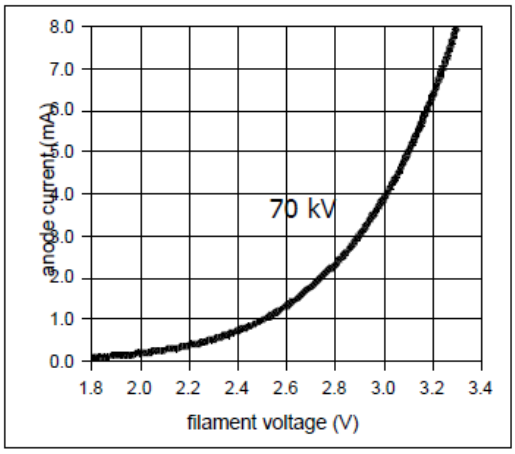
12 ANNEX 2

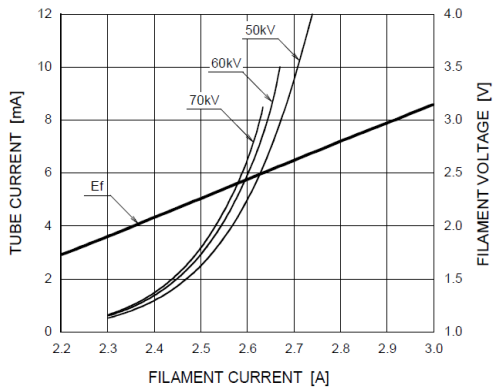
12.1 Labels

Label type	Label	Position
Main label		On the right side of the control panel (timer)
Tubehead label (as per the X+ray tube used)	 	On the lower side of the tubehead plastic cover. The S/N holds the same X-Ray tube S/N

12.2 Thermal curve

Scan X CE RX Tube	Toshiba RX Tube
	
	


anode current (mA)
8.0
7.0
1.0
0.0
70 kV
1.8
2.0
2.2
2.4
2.6
2.8
3.0
3.2
3.4
filament voltage (V)


TUBE CURRENT [mA]
FILAMENT VOLTAGE [V]
50kV
60kV
70kV
Ef
12
10
8
6
4
2
0
4.0
3.5
3.0
2.5
2.0
1.5
1.0
2.2
2.3
2.4
2.5
2.6
2.7
2.8
2.9
3.0
FILAMENT CURRENT [A]

12.3 Tubehead Cooling curve