User Manual

RiX-70 DC

X-Ray Intraoral System



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This is an English translation of the original document in Italian which may be obtained from the company.

The content of this document is faithful and accurately reflects the original version.

Castenedolo, 2017.

1 Introduction

Thank you for trusting our company and choosing RiX-70 DC as your Intraoral X-Ray System.

This manual, supplied with the system, is an integral part of the product; please keep it close to the unit's installation location; it describes the parts and components of your RiX-70 DC and explains the correct operation of the unit by observing all the relevant safety measures when handling X-ray equipment. The original language of the User Manual is Italian.

1.1 User Recommendations

3	Carefully read and follow the warnings and safety instructions contained in the User's 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.
3	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.

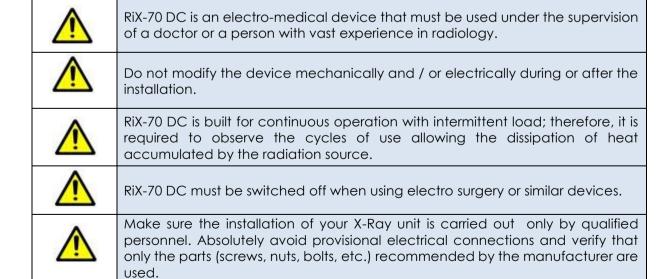
1.2 Safety Recommendations

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



This table contains important information regarding the system, the operator and the patient safety.

Please read this table very carefully.



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.



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.



Always turn off the machine and unplug it from the mains whenever possible (with the switch) before cleaning and disinfection.



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.

1.3 About your unit

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.

1.4 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.

2. TECHNICAL DATA

2.1 System Supply

Voltage	AC100-240 V
Frequency	50/60 Hz
Electric current	2-1 A(@240V), 5.5 A (@110V)
Max power consumption	640 VA
Fuse	6.3 AT
Connection	7 wires cable with double insolation

2.2 X-Ray Head

Tube Voltage	60 kVp ± 8 % 65 kVp ± 8 % 70 kVp ± 8 %
Anode 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 monoblock	130 kJ
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%

2.3 X-Ray Tube

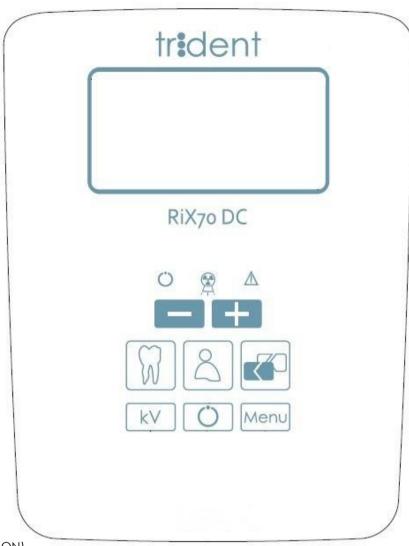
Manufacturer	Toshiba(Japan)	CEI(Italy)			
Model	D-045	OX70-4			
Inherent filtration	< 1 mm Al eq.	0.5 mm Al eq.			
Target angle	12.5°	16°			
Filament current	Max. 3 A	1.5 – 2.1 A			
Max filament current	3 V	1.7 – 3.1 V			
Anodic thermal capacity	4.3 kJ	7 kJ			
Max anodic dissipation	100 W	110 W			
X RAY beam covering at 200 mm from the focus	≥ ф 2	70 mm			
Focal spot	0.4 IEC 60336:2005				
Target material	Tungsten				
Max nominal voltage	70 kV				

2.4 Weights

Timer	4.00 kg
Support arm 60 cm	1.7 kg
Support arm 80 cm	4.5 kg
Support arm 100 cm	5.5 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

3. OPERATING INSTRUCTIONS

3.1 The Control Panel





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.



Menu, pressing this button for at least 2s allows to access the User's Menu. This menu contains the parameters that do not need to be adjusted frequently. To exit the user's menu it's necessary to push again "Menu" button.

3.2 Additional keypad

The system has an additional keypad installed near the tube head, which allows to adjust the exposure time, tooth type and patient size.

3.3 Beam Limiting Device

This device is suitable for either bisecting or paralleling radiographic techniques, once conveniently angled. Keep the rim of the collimator in touch with the film holder or with the face of the patient to reduce possible blur due to movement during irradiation.



3.4 Operation

Turn on the device with the switch 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 x-ray; 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.



When you manually change the exposure time, the information of the parameters that had contributed to calculate that time will disappear from the display; tapping again one of the parameter's symbol, the system will return to that exposure time.

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 μ Gy, 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 collimator in contact with the ring of the centering film (optional, not provided) or with the patient's face.
- 6. Take the exposure hand-switch and move to a convenient position of at least 2 m far from the patient.
- 7. Press the exposure pushbutton. The yellow light indicates X-ray emission. Keep the exposure pushbutton pressed until the yellow light are switched OFF to indicate the end of the exposure.
- 8. Hook back the exposure hand-switch and process the image receptor exposed.



Warning

If the exposure pushbutton is released before the end of the requested time, the radiation emission is terminated and an alarm is generated.



To use the rectangular collimator it's necessary to select the right setting from the User's Menu

3. 5 Pre-set exposure time

RiX70 DC calculate exposure times as per the following tables:



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		Digital	sensor	Film type D		Film type E		Film type F		Phosphor system	
	size	Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child
_	Molars	0.100	0.063	0.320	0.200	0.125	0.080	0.100	0.063	0.320	0.200
Maxilla	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
<u>o</u>	Incisors	0.056	0.020	0.125	0.080	0.050	0.032	0.040	0.025	0.125	0.080
Mandible	Premolars	0.063	0.036	0.160	0.100	0.063	0.040	0.050	0.032	0.160	0.100
W	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										
To	oth/Patient	Digital	sensor	Film type D		Film type E		Film type F		Phosphor system	
	size	Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child
_	Molars	0.125	0.071	0.450	0.320	0.180	0.125	0.160	0.110	0.450	0.320
Maxilla	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
e	Incisors	0.063	0.025	0.180	0.125	0.071	0.050	0.063	0.045	0.180	0.125
Mandible	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		Digital	Digital sensor		Film type D		Film type E		Film type F		Phosphor sensor	
	size	Adult	Child	Adult	Child	Adult	Child	Adult	Child	Adult	Child	
ō	Molars	0.200	0.125	0.630	0.400	0.250	0.160	0.200	0.125	0.630	0.400	
Maxilla	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	
e	Incisors	0.110	0.040	0.250	0.160	0.100	0.063	0.080	0.050	0.250	0.160	
Mandible	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	

3.6 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			

4 CARE AND MAINTENANCE

4.1 Cleaning

Always disconnect the line voltage supply before cleaning the unit. Use a mild soap to remove finger or other dirty marks paying attention not to have liquids enter into the equipment.



Clean painted surfaces, accessories and connection cables only by hand with a damp cloth and mild detergent, making sure to wipe with a dry cloth; Do not use solvents (alcohol, benzene, trichlorethylene), corrosive and abrasive.

4.2 Disinfecting

Parts in touch with the patient must be cleaned with a detergent (such as 2% solution of ammonia) making sure not to use solvents or corrosive disinfectants, which can cause cracks on the plastic covers.

4.3 Maintenance

Maintenance of RiX-70 DC to be done regularly by a service technician at least once every 24 months, in addition to regular checks performed by the operator every year.



RiX-70 DC system not contain parts that can be repaired by the user. The system must be opened and maintained by qualified personnel.

5. DISPOSING OF OBSOLETE EQUIPMENT

A radiological system is made of different materials which include many kinds of metals (iron, aluminum, lead, copper and others), plastic materials, electronic components and dielectric oil in the tank of the X-ray tube. The "crossed-out wheeled bin" symbol on the product indicates that the product at the end of its useful life must not be disposed of as unsorted municipal waste but has to be collected separately and delivered to specialized operators for recycling or disposal of waste of electrical and electronic equipment (WEEE), in compliance with existing laws.



6. ELECTROMAGNETIC COMPATIBILITY

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.



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.

6.1 Electromagnetic Emissions



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

6.2 Electromagnetic Immunity

Immunity test	IEC60601 1-1-2 Test Level	Compliance level	EMC environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	Test level IEC 60601-1-2	Floors should be wood, concrete or ceramic tile. If floors are covered 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	Test level IEC 60601- 1-2	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN61000-4-5	± 1 kV differential mode ± 2 kV common mode	Test level IEC 60601- 1-2	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 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 sec	Test level IEC 60601- 1-2	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, the device needs to be powered from an uninterruptible power source.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	Test level IEC 60601- 1-2	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	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
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5 GHz	3 V/m	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.



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



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

For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** in metres (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.



Stand mobile version

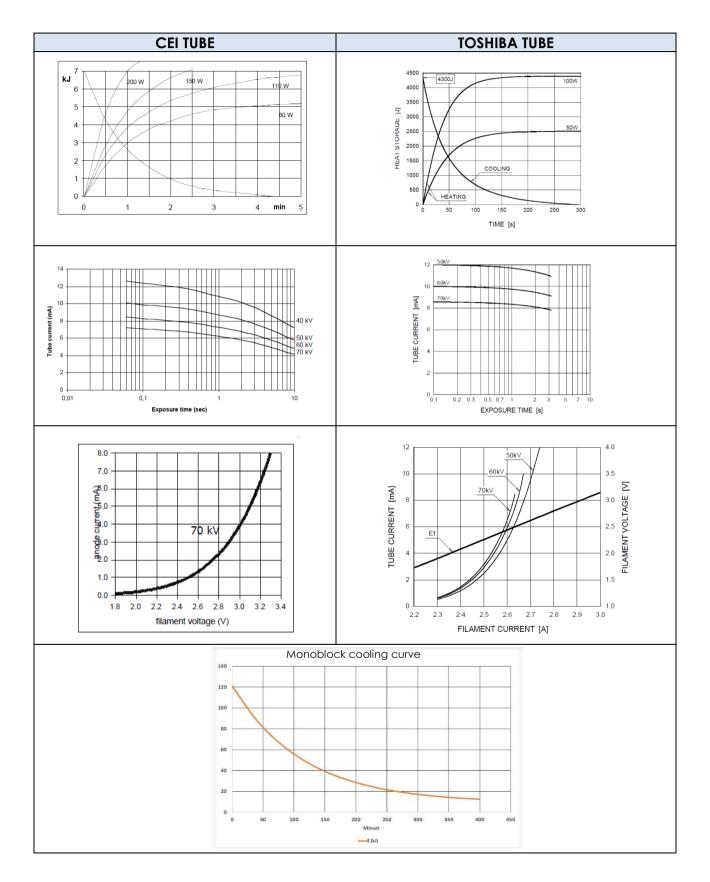
- 1 Mobile stand base
- 2 Mobile stand column
- 3 Control unit (timer) + hand switch with cable
- 4 Scissor arm
- 5 Monoblock with cone collimator



Appendix B Icons

SYMBOL	DESCRIPTION	
Ť	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.	
\sim	Alternating Current	
N	Conductor connected to the neutral point	
L	Connection point to the Power Line	
	Grounding	
<u></u>	Functional earth connection	
	ON/OFF	
- 1	POWER ON	
	Power OFF	
B	Electric shock risk	
REF	Product Reference	
SN	Serial Number	
للم	Manufacturing date	
•••	Manufacturer address	
<u> </u>	Total Filtration	
	Monoblock	
1	X RAY Tube	
	Hand cleaning	

Appendix C Heating and cooling curves



Appendix D 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 9	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 9	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 1	X-Ray button pressed	No operating system Release the keys eventually pressed; turn the system off and on again. Consult the Maintenance Manual.
Error 5	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.

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 1	Button pressed without enabling	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.

Display info	Description	Cause / Solution
Error 1	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 7	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.

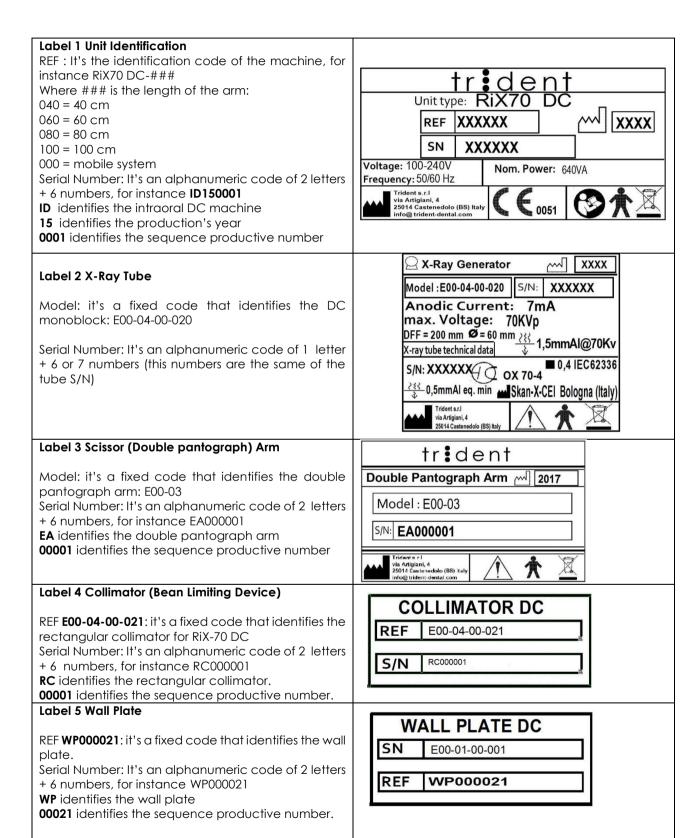
Error during X RAY emission

Display info	Description	Cause / Solution	
Error 2	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 1	The X RAY button is already pressed and, accidentally, another button is pressed. X-RAY button pressed If the error message doesn't disappear, even af switching off and on the system, please consult the Maintenance Manual.		
Error 8	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.	

Blocking messagesThese 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 3	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 6	Overvoltage security intervention The system has detected that high voltage value 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 4	Error filament power supply	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.

Appendix E Labels



IMPORTANT

Please do not try to open your unit.

Only trained and qualified technicians authorized by Trident can remove the covers giving access to the circuits.

Please contact an authorized Trident distributor responsible for the technical assistance of your device.

