



Technical data sheet

Rev. 02/2022



OWANDY-RX^{AC}

PRECISION AND SIMPLICITY

AC INTRAORAL RADIOLOGY SYSTEM

A1. TECHNICAL SPECIFICATIONS

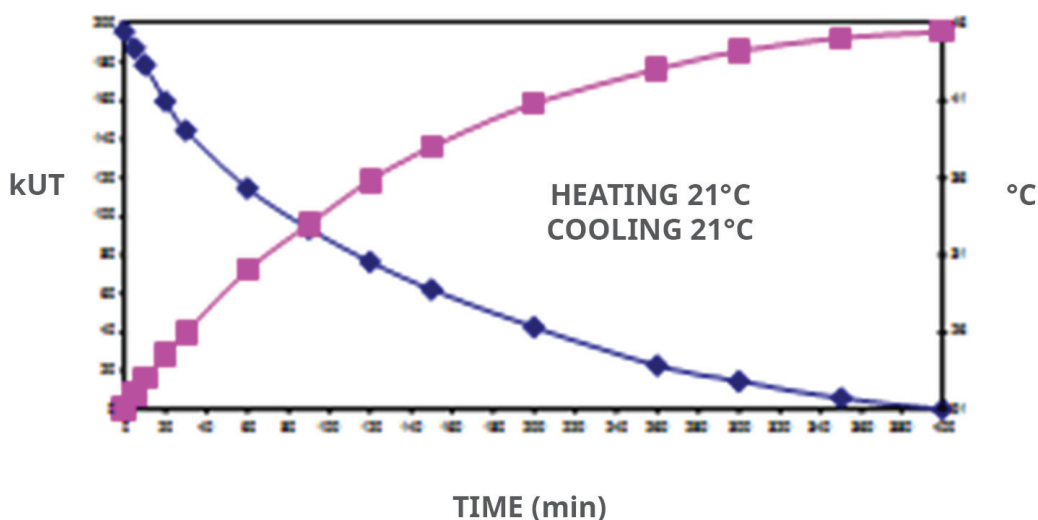
X-ray SOURCE ASSEMBLY

Half Value Layer (HVL) at 70 kV	2 mm Al
Total filtration at 70 kV	2,3 mm Al
Tube inherent filtration at 70 kV	> 1 mm Al
X-ray tube tension accuracy	±10%
X-ray tube current accuracy	±20%
Radiation linearity	±10%
X-ray emission time accuracy	±20 ms 0,020 s ≤ t ≤ 0,320 s ±5% 0,400 s ≤ t ≤ 3,2 s
Reproducibility	0,05
Generator	Single phase X-ray generator
X-ray tube nominal current	8 mA
X-ray tube nominal voltage	70 kV
Exposure times	0,080 s ÷ 3,2 s (17 steps)
Reference current-time product	0,8 mAs 8 mA 0,1 s
Intensity of radiation in the air	> 30 µGy/h at 1 m from focal spot
Leakage radiation (measured @ 70kV, 8 mA, 3,2 s)	< 0,25 mGy/h at 1 m from focal spot
Operating cycle	1:32
Loading factors related to the maximum specified energy input in one hour	70kV – 8mA

PLEASE NOTE

The measurements criteria are based on the requirements stated by the applicable standards listed in the annex A.3 of this manual.

HEATING AND COOLING CURVES

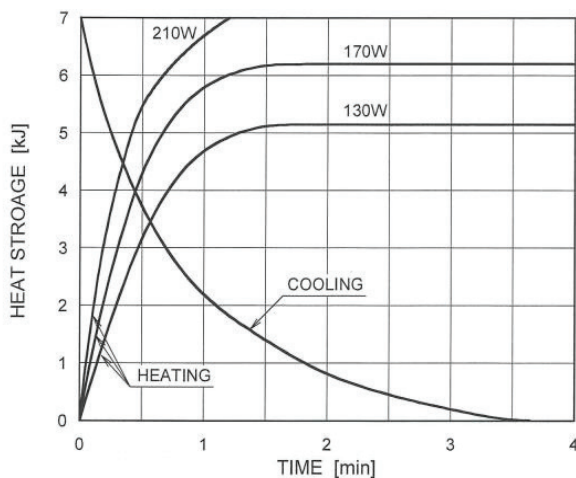


X-ray TUBE

X-ray tube model	CEI OX70-G7	TOSHIBA DG-073-AC
Focal spot size (IEC 336)	0,7 mm	0,7 mm
Anode angle	16°	20°
Anod material	tungsten	tungsten

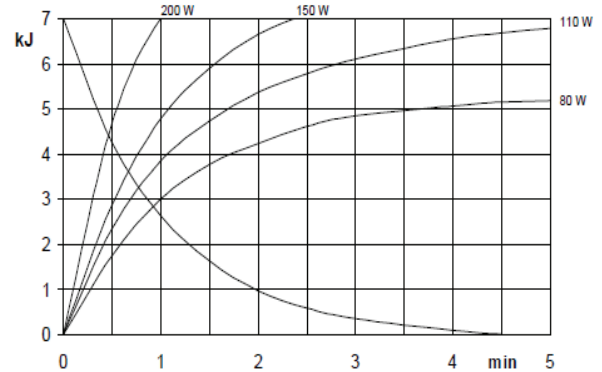
Heating/cooling curves

Anode Heating / Cooling Curve



TOSHIBA DG-073B-AC

THERMAL CURVES



CEI OX70-G7

DEVICE POWER SUPPLY

Type of power supply	single phase, alternate
Supply nominal voltage	115 V / 220V / 230V
Maximum voltage variation	±10%
Nominal current	3,5 A @ 220V / 230V 5,7 A @ 115V
Supply voltage frequency	50/60 Hz
Maximum line current (measured @ 70 kV, 8 mA, 3,2 s)	5,7 A @ 115V
Absorbed power	0,8 kVA at 230V 0,79 kVA at 220V 0,66 kVA at 115V
Apparent resistance	0,5 Ω at 220V / 230V 0,2 Ω at 115V
Protection fuses (F1 – F2 – F3 – F4)	F 8 A – 250 V at 220V / 230V F 12,5 A – 250 V at 115V
Circuit protection fuses	(F5) – n° 1 630 mA – 125 V (F6) – n° 1 500 mA – 125 V

ELECTRICAL CLASSIFICATION (IEC 60601-1)

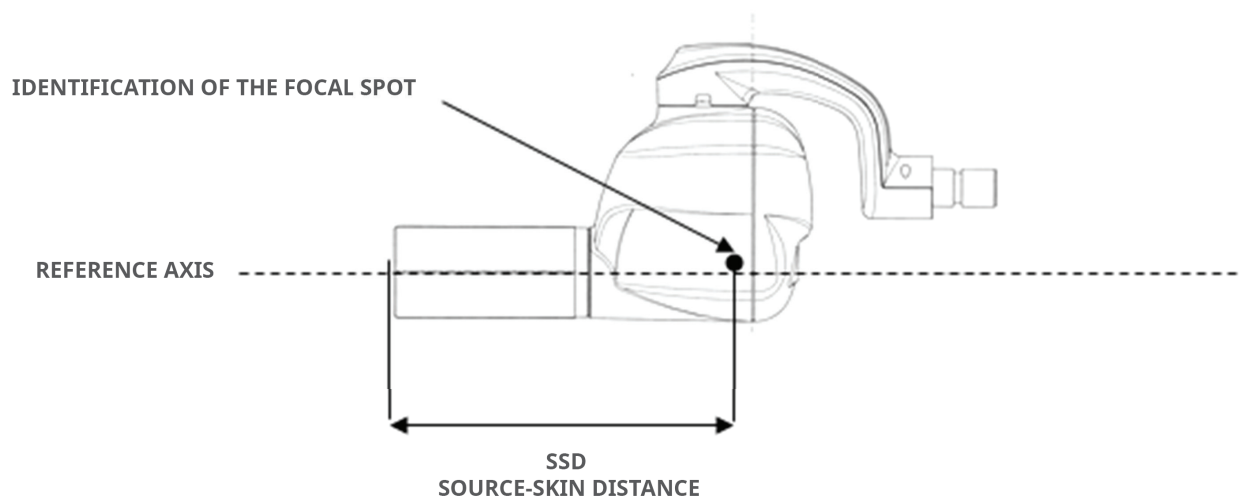
Protection against electrical shock (insulation class)	Class I
Degree of protection against electrical Shock (applied part)	Type B (collimator cone)
Protection against harmful ingress of water or particulate matter	IP 20
Use with flammable anaesthetics	Not for use in presence of flammable anaesthetic mixture with air, oxygen or nitrous oxide.
Sterilization and disinfection methods	The device is supplied not sterile and it must not be subjected to sterilization
Operation mode	Continuous operation with intermittent X-ray loading

MECHANICAL DATA

Total weight	19,5 kg (wall mounting) 50 kg (mobile version)
Weight of the tubehead	5,5 kg
Mechanical configuration	Wall mounting, top and bottom / Mobile

COLLIMATOR CONE TECHNICAL DATA

Source-skin distance (SSD)	short cone long cone rectangular cone	20 cm (8") 31 cm (12") 31 cm (12")
X-ray beam dimension	short cone long cone rectangular cone	≤ 60 mm ≤ 60 mm 44x35 mm



A2. INTENDED ENVIRONMENT

⚠ CAUTION

Owandy-RX AC is for INDOOR USE ONLY.

If the Owandy-RX AC has been stored at a temperature below +10°C (+50° F) for more than a few hours, enough time must be allowed for the device to reach the room temperature before reconnecting it to the mains voltage and applying power.

CLINICAL ENVIRONMENT CONDITIONS (OPERATING CONDITIONS)

- Temperature: 10 °C (50°F) ÷ 40 °C (104°F);
- Relative humidity: 25 ÷ 75 %;
- Atmospheric pressure: 850 ÷ 1060 hPa.

TRANSPORTATION ENVIRONMENT CONDITIONS

- Temperature: 0 °C (32°F) ÷ 50 °C (122°F);
- Relative humidity: see clinical environment conditions
- Atmospheric pressure: 500 ÷ 1060 hPa

WAREHOUSE ENVIRONMENT CONDITIONS

- Temperature: -15 °C (5°F) ÷ 50 °C (122°F);
- Relative humidity: see clinical environment conditions
- Atmospheric pressure: 500 ÷ 1060 hPa

A3. LIST OF INTERNATIONAL STANDARDS AND DIRECTIVES

Owandy-RX AC: X-ray equipment for dental intraoral radiography is classified as:

Directive	MDD 93/42 EEC Annex IX, article 10	TG(MD) Regulations 2002 Schedule 2 part 4.3
Class	IIb	IIb

IEC/EN 60601-1:2005 + A1:2012 (3.1 edition)
IEC/EN 60601-1-3:2008 + A1:2013 (2.1 edition)
IEC/EN 60601-1-6:2010 + A1:2013 (3.1 edition)
IEC 62366: 2007
IEC 60601-2-65:2012 A1:2017 (1.1 edition)
IEC/EN 60601-1-2: 2014 (4 edition)
IEC 62304:2006 + A1:2015



A4. DOSIMETRIC INDICATIONS

The radiation exposure is reported in terms of Dose Area Product (DAP), which takes into account the entire area of the X-ray beam and the total amount of X-ray radiation incident on the patient. The DAP is obtained by multiplying the Air Kerma by the corresponding X-ray beam area, which is dependent by the typology of beam limiting device installed. It is independent by the measured location, because increases in beam area are compensated by the reduction of beam intensity (inverse square law).

The dosimetric values reported here are relevant to the following measured values of Total Filtration and Half Value Layer (HVL):

kV	HVL (mm Al)	Total Filtration (mm Al)
70	2,0	2,3

In the following tables the radiation exposure is indicated in terms of DAP [mGy cm²] for each setting of kV, beam limiting device length (SSD) and Beam Limiting Device type (circular or rectangular).

As per paragraph 203.6.4.5 of the IEC 60601- 2-65, the overall deviation from the estimated air kerma is within 50%.

Cone type	Circular Long	Short Circular	Rectangular Long
SSD (mm)	310	200	310
kV	70	70	70
mA	8	8	8
Time (s)	DAP (mGy*cm ²)	DAP (mGy*cm ²)	DAP (mGy*cm ²)
0,08	5,559	13,597	3,458
0,1	6,949	16,996	4,323
0,125	8,686	21,246	5,403
0,16	11,118	27,194	6,916
0,2	13,897	33,993	8,646
0,25	17,372	42,491	10,807
0,32	22,236	54,388	13,833
0,4	27,795	67,986	17,291
0,5	34,744	84,982	21,614
0,63	43,777	107,077	27,234
0,8	55,590	135,971	34,582
1	69,487	169,964	43,228
1,25	86,859	212,455	54,035
1,6	111,179	271,942	69,165
2	138,974	339,928	86,456
2,5	173,718	424,910	108,070
3,2	222,358	543,885	138,329

A5. ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility (EMC) is assessed with reference to the following standards:

IEC/EN 60601-1-2: 2014 (4 edition)

EMISSION

- CEI EN 55011: 2013
- CEI EN 61000-3-2: 2015
- CEI EN 61000-3-3: 2014

IMMUNITY

- CEI EN 61000-4-2: 2011
- CEI EN 61000-4-3: 2007 + A1: 2008
- CEI EN 61000-4-4: 2013
- CEI EN 61000-4-5: 2007
- CEI EN 61000-4-6: 2011
- CEI EN 61000-4-8: 2013
- CEI EN 61000-4-11:2006

Guidance and manufacturer's declaration – electromagnetic emissions		
<p>Owandy-RX AC is intended to be used in the electromagnetic environment specified below. The customer or the operator of Owandy-RX AC must ensure that the device is used in this type of environment.</p>		
Emission test	Conformity	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	Owandy-RX AC uses RF energy only for internal operation. RF emissions are extremely and attenuated are not likely to generate interference with electronic equipment in the vicinity. Owandy-RX AC is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions CEI EN 61000-3-2	Class A	
Voltage fluctuations/flicker emissions CEI EN 61000-3-3	Complies	
<p>NOTE: Ensure that the device is not stack and location close to other EQUIPMENT please refer to the «Recommended separation distances between portable and mobile RF communication equipment and Owandy-RX AC medical device»</p>		

Guidance and manufacturer’s declaration – electromagnetic immunity			
<p>Owandy-RX AC is intended to be used in the electromagnetic environment specified below. The customer or Owandy-RX AC operator must ensure that the device is used in this type of environment.</p>			
Immunity test	CEI EN 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) CEI EN 61000-4-2	+/- 8 kV contact +/- 15 kV air	CEI EN 60601-1-2 Test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%
Electrical fast transient/burst CEI EN 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	CEI EN 60601-1-2 Test level	Mains power quality should conform to that of typical commercial or hospital applications.
Surge CEI EN 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	CEI EN 60601-1-2 Test level	Mains power quality should conform to that of typical commercial or hospital applications.
Voltage dips, short interruptions and voltage variations on power supply input lines CEI EN 61000-4-11	<5 % UT for 0.5 cycles (>95 % dip in UT) 40 % UT for 5 cycles (60 % dip in UT) 70 % U _T (30 % dip in U _T) for 25 cycles (50Hz) for 30 cycles (60Hz) <5 % UT for 5 onds (>95 % dip in UT)	CEI EN 60601-1-2 Test level	Mains power quality should conform to that of typical commercial or hospital applications. If the Owandy-RX AC operator requires continued operation even during mains power outage, we recommend powering the system using a UPS.
Mains frequency (50/60 Hz) magnetic field CEI EN 61000-4-8	30 A/m	CEI EN 60601-1-2 Test level	Power frequency magnetic fields must be at the typical level of standard mains for commercial or hospital use.
<p>Note: Ut is the AC mains voltage prior to the application of the test level.</p>			

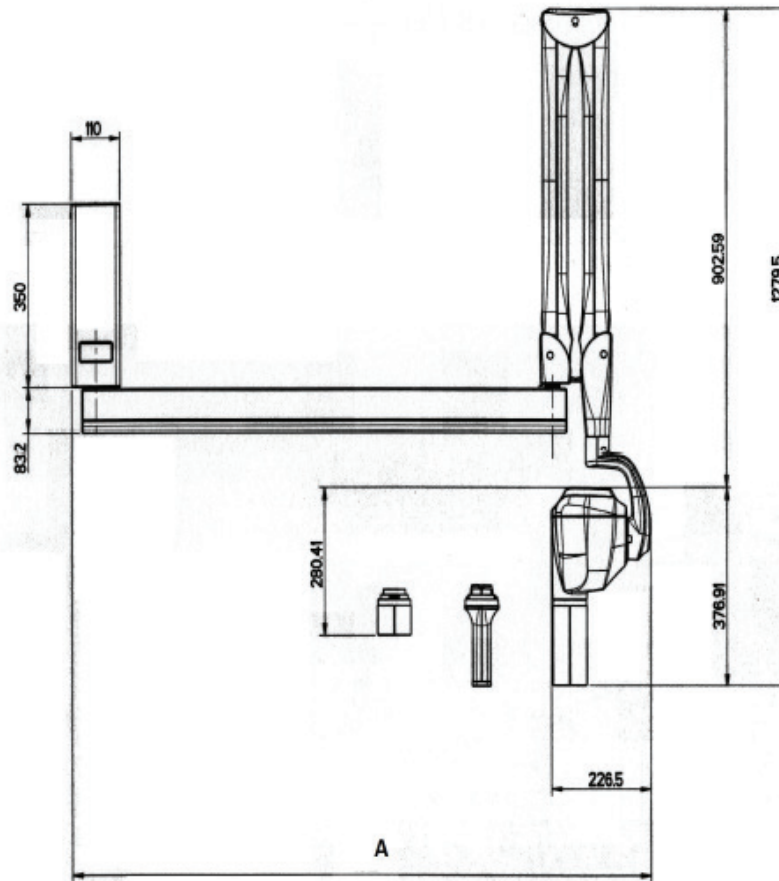
Guidance and manufacturer's declaration – electromagnetic immunity			
Owandy-RX AC is intended to be used in the electromagnetic environment specified below. The customer or Owandy-RX AC operator must ensure that the device is used in this type of environment.			
Immunity test	CEI EN 60601 test level	Compliance level	Electromagnetic environment guidance
⚠ CAUTION Portable and mobile RF communication equipment should be used no closer than 30 cm (12 inches) to any part of the Owandy-RX AC, including cables than the recommended separation distance, calculated according to the equation corresponding to the frequency of the transmitter.			
Conducted RF CEI EN 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V RMS in the ISM (Industrial, Scientific and Medical) band	3 Vrms	Recommended separation distance $d = 1,2 \sqrt{P}$
Radiated RF CEI EN 61000-4-3	10 V/m 80MHz to 2.5GHz	3 V/m	$d = 1,2 \sqrt{P}$ 80 MHz - 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz - 2.5 GHz 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 metres (m). Field strength from fixed RF transmitters as determined by an electromagnetic site survey ^a must be below the compliance level corresponding to each frequency range. ^b Interference can occur in the proximity of equipment marked with the following symbol : 
Notes: • At 80 MHz and 800 MHz the higher frequency range applies. • These guidelines may not apply in every situation. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a - Field strength from fixed RF transmitters, such as base stations for radio (cellular/wireless) telephones and land mobile radios, amateur radio, AM and FM radio and TV broadcast cannot be predicted with accuracy on a theoretical basis. To assess the electromagnetic environment created by fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the place where the equipment is used exceeds the corresponding RF compliance level (see above), it is important to ensure regular equipment operation. In the event of abnormal operation, additional measures may be required, such as redirecting or relocating Owandy-RX AC. b - Over the frequency range between 150 kHz and 80 MHz, the field strength must be below 10 V/m.			

Recommended separation distances between portable and mobile RF communication equipment and Owandy-RX AC medical device			
These devices are intended to be used in environments where radiated RF interference is controlled. The customer or Owandy-RX AC operator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and Owandy-RX AC, as indicated below, according to the maximum output power of the communication equipment.			
Rated maximum output power of the transmitter [W]	Separation distance according to transmitter frequency [m]		
	150 kHz - 80 MHz $d = 1,2 \sqrt{P}$	80 MHz - 800 MHz $d = 1,2 \sqrt{P}$	800 MHz - 2.5 GHz $d = 2,3 \sqrt{P}$
0.01	0.12	0.12	0.24
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
<p>In the event of transmitters whose maximum nominal output power coefficient does not fall within the indicated parameters, the recommended separation distance in metres (m) can be determined by means of the equation corresponding to the frequency of the transmitter, where P is the maximum output power coefficient of the transmitter in watts (W) according to the information provided by the manufacturer.</p> <p>Note 1: At 80 MHz and 800 MHz apply the separation distance corresponding to the highest frequency range.</p> <p>Note 2: These guidelines may not apply in every situation. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>⚠ CAUTION Pay attention to take any precautions to be taken to prevent adverse events to the PATIENT and Operator due to electromagnetic disturbances.</p>			

A6. DRAWINGS AND DIMENSIONS

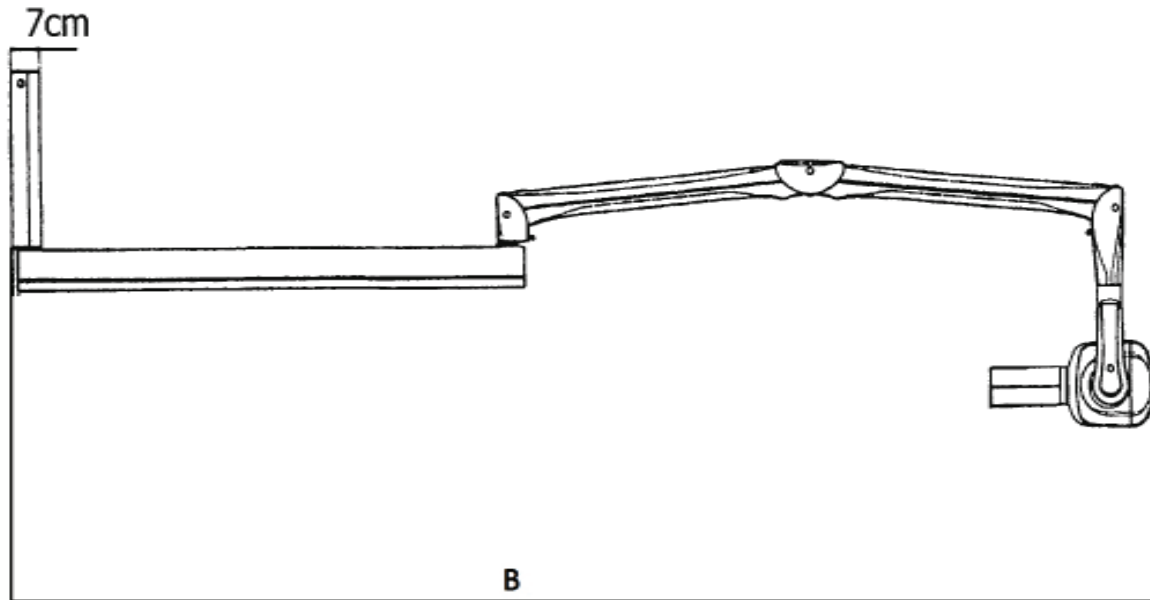
WALL INSTALLATION

Lateral view (rest position)
Bottom mount



A	
40 cm (16") bracket	63 cm
80 cm (31") bracket	104 cm
110 cm (43") bracket	132 cm

Lateral view (open)
Bottom mount



B	
40 cm (16") bracket	178 cm
80 cm (31") bracket	220 cm
110 cm (43") bracket	247 cm

The system can also be mounted with the timer on the top. For details, refer to the Installation and Maintenance Manual.

MOBILE INSTALLATION

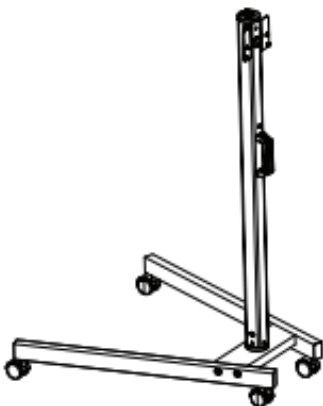
Owandy-RX AC exists also in the mobile version and it is sustained by the stand shown in the following figure:

Only for the mobile version of Owandy-RX AC

It is allowed to connect the equipment to the main supply using a plug supplied by the manufacturer.

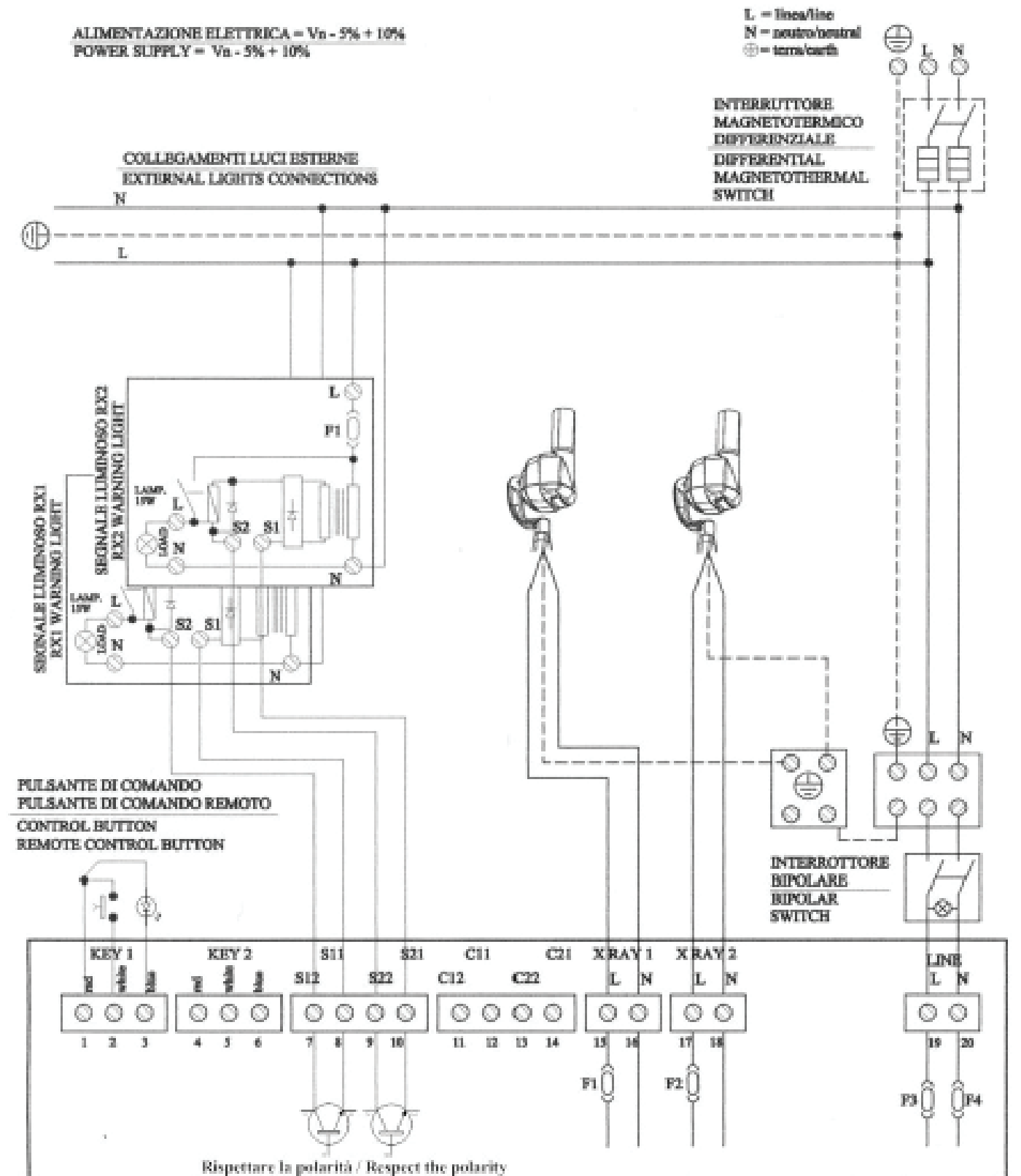
⚠ CAUTION

Repairs and replacements of any component included cables, must be carried out solely by authorized and highly qualified personnel and only using genuine spare parts supplied by Owandy Radiology. using other cables may negatively affect EMC performance.



For details, refer to the Mobile Unit Technical Note, supplied with this structure.

A7. INSTALLATION ELECTRICAL SCHEME



DIGITAL WORKFLOW OWANDY RADIOLOGY

A COMPREHENSIVE RANGE TO MEET ALL YOUR REQUIREMENTS

