Pre-Installation Manual

July 2024 / Rev. D

10198 Rev A

REVISION HISTORY

REVIEW DATE	RELEASE DATE	MODIFICATIONS	Revision
February 2021	04/02/2021	First release	A
June 2021	08/07/20221	Table information details	B
September 2021	30/09/2021	125cm grid => 140cm grid Correction of elevation values	C
July 2024	26/07/2024	Symbols update / Transformer / Speed / Footrest / Motorise Compression Device / Environmental specification / Electrical power distribution diagrams / Electrical connection for UL-CSA version	D

The manufacturer constantly strives to improve its products and, therefore, reserves the right to deliver, without prior notice, machines whose characteristics differ from those described here: nonetheless, these machines are still guaranteed to comply with regulations in force.

GUARANTEE CONDITIONS

It is the responsibility of the user to ensure that the government regulations respecting installation and operation of the equipment are observed.

Incorrect operation or failure of the user to maintain the equipment in accordance with the schedule of maintenance relieves the manufacturer or its agent from all responsibility for consequent non-compliance, damage, injury, defects and or other malfunction.

The installation and equipment must not be used if any mechanical, electrical or radiation-emitting component is defective, or if the procedures described in the schedule of maintenance have not been carried out.

Changes and additions to the equipment may only be carried out by the manufacturer or by third parties expressly authorized by the manufacturer to do so. Such changes must comply with local regulations and accepted standards of good practice.

In case the power lines do not meet the specifications given in section A “Preinstallation” of the Service Manual, the table cannot reach its maximum performance and the standard use cannot be guaranteed.

Technical files (diagram, parts list, measurement procedure and so on) are available on request to the manufacturer.

TRANSPORTATION CONDITIONS

Goods travel at owner’s risk.

No contestations shall be taken into account unless written reservations have been made on the consignment note, face to face to the carrier, upon receipt of the goods in case of apparent loss or damage.

During transportation and storage, the black cap of the H.T. tank must be neither unscrewed nor removed.

Crates and packing means made by the manufacturer cannot be used for other purposes than carriage.

SAFETY AND PROTECTION

X-rays are not innocuous and can be dangerous if used badly. Therefore, you must follow the instructions provided in this manual very carefully.

These X-ray units comply with the strictest safety standards in force throughout the world (Europe, Japan, USA, etc.). They guarantee optimum protection against radiation risks.

Nonetheless, you are handling a unit specifically designed to generate X-rays or allow medical diagnosis on a film or using a digital imaging system. Consequently, despite the inherent safety of our equipment, we recommend using conventional commercially available equipment to protect yourself and your patient against scattered radiation risks.

- The following instructions must be strictly observed:
  - Use the smallest as possible X-ray field
  - Use the shortest possible fluoroscopy time
  - Use focal spot to skin distances as large as possible in order to keep the absorbed dose to the patient as low as reasonably achievable.
  - Maintain the X-ray tube and flat panel detector in good condition.
  - Keep as far away from the beam as possible.
  - During exposure, staff members not directly involved with the patient must stand behind lead or lead-glass shielding.

- Should any part of the equipment be damaged, it must be repaired or replaced before the equipment is returned to service.

- Equipment described herein is unsuitable for operation where and when flammable gasses or vapors are present.

- The user must always electrically disconnect the equipment from the mains before cleaning or disinfecting.

- Do not allow water or any liquid to enter in the equipment, as such liquid may cause short circuits and/or some corrosion.

- It must be noted that some disinfectants vaporize, forming potentially explosive mixtures. Should such disinfectants be used, the vapors must first be allowed to disperse before the equipment is returned to use.

- Note that the equipment is not protected against anesthetic gases.

- In addition, it is important that the assembly, extension, adjustments, modifications and repairs be carried out by an authorized manufacturer distributor. Also your radiological unit must be installed in premises that comply with IEC provisions and the standards in force.

- Due care must be taken to prevent injury to the patient. Ensure that patient's clothing cannot be trapped in the equipment. It is important that the patient hands remain on the tabletop.

- While declining the table, the patient must be either fastened or secured using handgrips, footrest, straps…

- The user must always ensure that there are no obstacles that would interfere with the table. Ensure that accessories such as shoulder supports, leg supports or footrest are correctly fixed to the table.

- It is important that all persons dealing with X-radiation be fully acquainted with the radiation protection.

In the event of failure to comply with these instructions, the manufacturer shall not be held responsible for the safety, reliability and characteristics of the machine.

Your distributor will be pleased to help you with the initial use of your unit and to answer any subsequent questions you may have.

CE
1639

The CE mark on the remote-controlled table indicates that the unit is in compliance with the European Directive 93/42/CEE of the 14/06/93 concerning the medical devices.

Original language: ENGLISH

NOTE TO THE USER

You have just purchased our remote-controlled table. We congratulate you on your choice, and are sure you will be fully satisfied with its use and diagnostic capabilities.

This remote-control table is an universal X-ray examination table with variable height fully digitized & microprocessor controlled and developed for easy and fast examinations in fluoroscopy and radiography.
The table is suited for functional and for anatomical examinations with the patient in any position.
This multipurpose table is designed for performing following examination on adults, children and babies:

- ***With the detector inserted in the table:***

  - General x-ray procedures: skull, chest, abdomen, pelvis, spine, extremities …
  - Stitching
  - Tomography
  - Tomosynthesis

- ***With the detector inserted in the table, in dynamic mode:***

  - Full digestive tract
  - Uro-genital system
  - Endoscopy
  - Arthrography
  - Myelography
  - Paediatrics

- ***With an optionnal detector outside the table:***

  - Extremities (skyline patella, weight bearing exams …)
  - Paediatrics (baby pelvis …)
  - Direct exposures in the room (on stretcher, wheelchair …)

This list of procedures is not an exhaustive one, but gives an idea of the wide range of possibilities that the system offers.

The manufacturer units offer high quality and advanced technology.
We recommend reading the user's manual carefully before using your unit, to become familiar with its operation and make the most of its performance.

Keep this manual in a safe place so that you can easily refer to it in the future.

Thank you for placing your confidence in the manufacturer.

REGLEMENTARY INFORMATIONS

Some reglementary informations must be present in accompanying documents; this is the exhaustive list of items requested by the standard:

“WARNING: No modification of this equipment is allowed.”

“WARNING: Do not modify this equipment without authorization of the manufacturer.”

“WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.”

The assembly of medical equipment systems and modifications during the actual service life require evaluation to the requirements of the standard IEC 60601-1 3rd edition.

This table indicates the symbols that are used on the system.

Symbol	Description
	Three-phase alternating current with neutral conductor
	Alternating current
	Type B applied part
	Protective ground
	Ground
	“ OFF “ (power supply)
	“ ON “ (power supply)
	Dispose of electronic and electrical equipment separately from normal waste
	Dangerous voltage
	Warning: dangerous voltage
	Manufacturer
	Date of manufacture
	This system transmits RF (Radio Frequency) energy and non-ionizing radiation
	Caution – X-rays
	Caution
	Operating instructions
	Refer to instruction manual / booklet
	General warning sign
	Catalogue number
	Serial number
	Medical Device

IPX6	IP stands for dust protection and waterproofness. The first number indicates the level of protection against dust, and the second number indicates watertightness: X: No specified protection against dust. 6: Protected against strong water jets from any direction. Note: Where it is not required to specify a numerical, it is replaced by the letter "X" ("XX" if both digits are omitted).
IPX7	IP stands for dust protection and waterproofness. The first number indicates the level of protection against dust, and the second number indicates watertightness: X: No specified protection against dust. 7: Protected against the effects of temporary immersion in water. Note: Where it is not required to specify a numerical, it is replaced by the letter "X" ("XX" if both digits are omitted).

1. TECHNICAL DATA

1.1. Remote controlled table general informations

Power supply

Table: 230V, 50/60Hz, 1 phase + earth, 3kVA

Dimensions and weight

Table: 2260mm x 2350mm - 1500 kg (1650 kg with adaptation pallet)
Minimum ceiling height: 2500mm
Recommanded ceiling height: 2800mm

Type B equipment.
Class II equipment.

Caution! Consult included documentation.

1.2. Remote controlled table detailed caracteristics

Transformer (only for UL/CSA VERSION)
transformer 110V / 230V
5 kVA

Table top

Dimensions:	2250 x 810 (600 mm, net width)
Ground to tabletop distance:	380 mm to 1480 mm
Radiation attenuation:	0.55 mm eq. Al
Lateral movement:	Motorized: 7 cm/s Travel: + 180 mm/ -180 mm
Longitudinal movement:	Motorized at 4 cm/s in vertical position Motorized at 8 cm/s in horizontal position Travel: +1200 mm / -600 mm Or +600 mm / -1200 mm

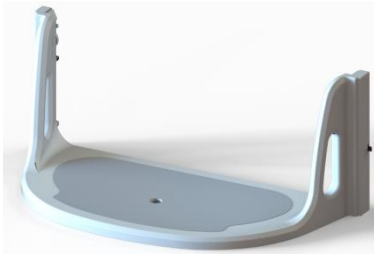
Collision safety done by software.

Tilting

Angulation:	+90° / -90° +/ -0.5°
Tilting time:	15 seconds from 0° to 90° (+/- 2°)

Collision safety done by software.
Mechanical safety done by micro switches.

Maximum patient's weight
The maximum patient load on the tabletop is 230kg (or 500 lbs) without any movement limitation.



The maximum patient load on the tabletop and on the removable footrest is 275 kg (or 600 lbs) with longitudinal movement limitation at -400mm or +400mm.

A patient having a maximum weight of 310 kg is also authorized with tabletop in horizontal centred position provided the user does not do the following movements: tilting, longitudinal tabletop movements and lateral tabletop movements.

1.3. Tube stand

Focus to Detector Distance
Motorized with continuous speed from 110 cm to 180 cm.

Tube rotation
Manual rotation with intermediate stops from + 180° to - 180°.
Stop controlled by photoelectric sensors.

Angulation
Motorized with progressive speed from + 40° to - 40° (+/- 0.5°).

Electronic parallax correction provided.
Angulation value displayed on the control console.
Mechanical safety done by micro switches.

Collimator
4 pairs of motorized lead shutters.
Can Bus.
High luminosity provided by a white power led (illumination provided at 100 cm cannot be less than: 160 lux)
Automatic, semi-automatic and manual modes.

1.4. Motorized Compression Device

Retractable compression type. **The compression can be used in horizontal and vertical table position.**
Motorized movement with maximum pressure control at 19 daN.
Compression settable until 13 daN.
Patient detection with movement limitations at 6 daN.

1.5. Tomography

One direction curvilinear tomography.

Angles:	40°, 20°, 10°
Exposure duration per angle:	0.5 s max for a 10° angle
	1 s max for a 20° angle
	2 s max for a 40° angle
Layer height:	from 0 to 300 mm.

Automatic layer height increase or decrease.

1.6. Stitching

An optional stitching mode is available with 2, 3 or 4 exposures mode.

1.7. Tomosynthesis

Tomosynthesis option is available with following parameters :

Layer height	from 10 to 300mm
Angles	from 0 to 70° (+/-35° regarding column centering)
FPS	See digital imaging system datasheet
Sweep time	See digital imaging system datasheet

1.8. Detector holder

Functionalities

Space available for automatic exposure chamber (AEC).

Grids

Trixell detector, 3 Grids are available:

- Extractable and non moving grid: 85lp/cm, ratio10:1, focus distance 125 cm (optional)
- Extractable and non moving grid: 90lp/cm, ratio10:1, focus distance 140 cm (included)
- Extractable and non moving grid: 85lp/cm, ratio10:1, focus distance 180 cm (optional)

Canon detector, 3 Grids are available:

- Extractable and non moving grid: 40lp/cm, ratio10:1, focus distance 110 cm (optional)
- Extractable and non moving grid: 40lp/cm, ratio10:1, focus distance 140 cm (included)
- Extractable and non moving grid: 40lp/cm, ratio10:1, focus distance 180 cm (optional)

Automatic detection of the grid.
No grid protocols available.

1.9. Carriage movement

Motorized: 135 cm travel.
Total scanning: 135cm (carriage travel) + 180cm (longitudinal tabletop travel).

Mechanical safety carriage done by micro switches.

1.10. Control console.

Dimensions: 600 x 270 x 120 mm 14.7kg

Class II Equipment
Type B Equipment

Caution! Consult included documentation.

Power supply: 110/230VAC 60/50 Hz 3.15A/2A

User interface: 10 inches Colour touch screen
All messages are displayed on this screen: Error messages, warning messages.
Movement of all axes with 4 joysticks and keys.
Infra-red remote control.
Control of X rays by mechanical keys.
Emergency switch. This switch stops all the movements in case of problem.

Collimator control.
Tomography control.
Table tilting and elevation.
FDD (focus to detector distance).
Compression.
Lateral and longitudinal tabletop control.
Interface with Digital Images System.
Automatic positionning system with MOVE button.

The control console must be installed so that all the movements are in the operator‘s field of view.

1.11. Remote controlled table data sheet

The following table provides approximate movements characteristics, provided that the movement was correctly calibrated and the closed loop control is tuned.

Movement Designation	Speed			Acceleration Ramp Time			Deceleration Ramp Time			Positioning accuracy	Position feedback accuracy	Travel length
	Min	Typ	Max	Min	Typ	Max	Min	Typ	Max			
Carriage (Detector holder + supports the column)	15 mm/s	120 mm/s	140 mm/s	100 ms	400 ms	400 ms	100 ms	400 ms	400 ms	1.6 mm	0.3 mm	1350 mm
Column (tube angulation)	2 °/s	6 °/s	10 °/s	100 ms	400 ms	400 ms	100 ms	400 ms	400 ms	0.5°	0.04 °	80°
Elevation	30 mm/s	60 mm/s	80 mm/s	100 ms	200 ms	400 ms	100 ms	400 ms	400 ms	0.8 mm	0.08mm	1100 mm
Tilting	3 °/s	6 °/s	6 °/s	100 ms	100 ms	400 ms	100 ms	400 ms	400 ms	0.15°	0.05 °	+/-90°
SID	20 mm/s	60 mm/s	60 mm/s	100 ms	100 ms	300 ms	100 ms	150 ms	400 ms	0.6 mm	0.2 mm	700 mm
Table top lateral movement	20 mm/s	70 mm/s	70 mm/s	100 ms	150 ms	1000 ms	100 ms	200 ms	400 ms	5 mm	0.11 mm	360 mm
Table top longitudinal movement	20 mm/s	80 mm/s	80 mm/s	100 ms	100 ms	400 ms	100 ms	100 ms	400 ms	5 mm	0.11 mm	1800 mm
Compressor	NA	83 mm/s	NA	NA	NA	NA	NA	NA	NA	5mm	2mm	300 mm
Collimator blades.	Automatic mode 110cm SID			Manual mode 110cm SID						NA	NA	430 mm
	43 cm/s			1.2 cm/s								

2. PREINSTALLATION DATA

2.1. Environmental specifications

2.1.1.System relative humidity and temperature

Component Of the System	TRANSPORT					
	Temperature		Relative humidity (non condensing)		Atmospheric pressure	
	MIN.	MAX	MIN	MAX	MIN	MAX
Table console	-20°C	+60°C	10%	75%	700hPa	1060hPa
Table	-20°C	+60°C	10%	75%	700hPa	1060hPa
Collimator	-40°C	+70°C	10%	95%	500hPa	1060hPa
X-ray tube	-10°C	+75°C	10%	80%	700hPa	1050hPa
Generator	-10°C	+70°C	5%	95%	500hPa	1060hPa
Detector	+5°C	+40°C	15%	95%	613hPa	1060hPa
Digital system	0°C	+50°C	20%	90%	700hPa	1060hPa
Multibox	+5°C	+40°C	15%	85%	613hPa	1060hPa
Transformer	-20°C	+60°C	10%	75%	700hPa	1060hPa
Secondary console	-20°C	+60°C	10%	75%	700hPa	1060hPa

Component Of the System	IN-USE					
	Temperature		Relative humidity (non condensing)		Atmospheric pressure	
	MIN.	MAX	MIN	MAX	MIN	MAX
Table console	+10°C	+35°C	30%	75%	760hPa	1060hPa
Table	+10°C	+35°C	30%	75%	760hPa	1060hPa
Collimator	+10°C	+40°C	10%	75%	700hPa	1060hPa
X-ray tube	+10°C	+40°C	10%	75%	700hPa	1050hPa
Generator	+10°C	+40°C	30%	75%	700hPa	1060hPa
Detector	+5°C	+35°C	15%	80%	613hPa	1060hPa
Digital system	+15°C	+35°C	20%	75%	760hPa	1060hPa
Multibox	+5°C	+35°C	15%	80%	613hPa	1060hPa
Transformer	+10°C	+35°C	30%	75%	760hPa	1060hPa
Secondary console	+10°C	+35°C	30%	75%	760hPa	1060hPa

2.1.2.SYSTEM HEAT OUTPUT

Components	Standby	In-use
Remote controlled table	150 W (1W=3.41BTU) 512 BTU/h	1000 W (3000W peak) 3415 BTU/h
RX Tube **IAE C100XT**	0 W 0 BTU/h	600W 2046 BTU/h
RX Tube **VARIAN B147**	0 W 0 BTU/h	600 W 2047 BTU/h
Monitors	8 W 28 BTU/h	80 W 273 BTU/h
System + 4 monitors	- W - BTU/h	560 W 1910 BTU/h
Detector TRIXELL	- W - BTU/h	105 W 358 BTU/h
Detector CANON	20 W 68 BTU/h	40 W 136 BTU/h
X-rays generator **N65HF**	52 W 177 BTU/h	160 W 546 BTU/h

2.1.3.EMC (IEC 60601-1-2: 2014)

Note: The radiodiagnosis system requires special precautions with respect to EMC and it must be installed and put into service according to information provided in this technical manual.

Note: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Note: It is not possible to exclude with absolute certainty the possibility that other high frequency electronic equipment, which is fully compliant to the EMC regulations, will not adversely, affect the operation of this radiodiagnosis system. If the other equipment has a comparatively high level of transmission power and is in close proximity to the radiodiagnosis system, these EMC concerns (the risk of interference) may be more pronounced. It is therefore recommended that the operation of equipment of this type such as mobile telephones, cordless microphones and other similar mobile radio equipment be restricted from the vicinity of this radiodiagnosis system.

IEC 60601-1-2: 2014 standard

Tests designation	Results	Comments
EMISSION		
• **Conducted emission**		
Power supply 230Vac 50Hz	PASS	Limits: CISPR 11, Group 1, Class A
Ethernet (under power supply 50Hz)	PASS	
Power supply 110Vac 60Hz	PASS	
Ethernet (under power supply 60Hz)	PASS	
• **Discontinuous disturbances**		According to CISPR 14-1
Power supply 230Vac 50Hz	N.A.	E.U.T. does not generate clicks
Power supply 110Vac 60Hz	N.A.	
• **Radiated electric field measurement**		Limits:
Frequency range: 30Mhz – 1GHz (50Hz)	PASS	CISPR 11, Group 1, Class A
Frequency range: 30Mhz – 1GHz (60Hz)	PASS	
• **Radiated magnetic field measurement**		Limits: CISPR 11, Group 1, Class A
Frequency range: 30Mhz – 1GHz	N.A.	
• **Harmonics current emission**		**Class A**
IEC 61000-3-2		
Power supply 110Vac 60Hz	PASS	**Result is given for information under customer's request**
Power supply 230Vac 50Hz	PASS	
• **Measurement of voltage fluctuation and flicker**		**Result is given for information under customer's request**
IEC 61000-3-3		
Power supply 230Vac 50Hz	PASS	
• **Measurement of human exposure to electromagnetic field**		Recommendation 99/519/EC of 12 July 1999 Directive 2013/35/CE of June 2013
Measurement of electromagnetic field in comparison of reference levels	PASS	

Tests designation	Results	Comments
IMMUNITY		Power supply frequency at 50Hz
• **Electrostatic discharge immunity**		
IEC 61000-4-2		
Indirect discharges VCP	PASS	Level: ± 8kV
Direct discharges	PASS	Level: ± 8kV
Air discharges	PASS	Levels: ± 2kV, ± 4kV, ± 8kV, ± 15kV (note 1)
• **Radiated, radio-frequency, electromagnetic field immunity**		
IEC 61000-4-3		
Level: 3V/m from 80MHz to 2.7GHz	PASS	Power supply under frequency 60Hz **On authorized ISM frequencies 433.05 to 434.79MHz** **2.4GHz to 2.5GHz**
Test specification for enclosure port immunity to RF wireless communications equipment		**Service**
Level: 27V/m in the band 380-390MHz	N.A.	TETRA 400
Level: 28V/m in the band 430-470MHz	PASS	GMRS 460, FRS 460 (note 2)
Level: 09V/m in the band 704-787MHz	N.A.	LTE band 13, 17
Level: 28V/m in the band 800-960MHz	N.A.	GSM 800/900, TETRA 800, LTE band 5…
Level: 28V/m in the band 1700-1990MHz	N.A.	GSM 1800/1900, DECT, UMTS, LTE band 1, 3, 4, 25…
Level: 28V/m in the band 2400-2570MHz	PASS	Bluetooth, WLAN, RFID 2450, LTE band 7…
Level: 09V/m in the band 5100-5800MHz	PASS	WLAN 802.11 a/n

Tests designation	Results	Comments
IMMUNITY		Frequency of repetition: 100 kHz
• **Electrical fast transient/burst immunity**		Power supply frequency 60Hz
IEC 61000-4-4		
Power supply 110Vac 60Hz	PASS	Level: ± 2kV
Console #1 link	PASS	Level: ± 1kV
Console #2 link	PASS	Level: ± 1kV
Computer link	PASS	Level: ± 1kV
• **Surge immunity**		
IEC 61000-4-5		
Power supply 110Vac 60Hz	PASS	Level: ± 2kV in common mode and Level: ± 1kV in differential mode
Power supply 230Vac 50Hz	PASS	Level: ± 2kV in common mode and Level: ± 1kV in differential mode
• **Immunity to conducted disturbances, induced by radio-frequency fields**		
IEC 61000-4-6		
Level applied: 3V from 0.15 to 230MHz and 6V in ISM Bands		Power supply frequency at 60Hz
110Vac 60Hz power supply cable	PASS	
Console #1 link	PASS	
Console #2 link	PASS	
Computer link	PASS	

Tests designation	Results	Comments
IMMUNITY		
• **Power frequency magnetic field immunity**		
IEC 61000-4-8	PASS	
Three axis exposed, power supply frequency 60Hz	PASS	
Table	PASS	Level applied: 30A/m than 3A/m
Console #1	PASS	Level applied: 30A/m than 3A/m
Console #2		Level applied: 30A/m than 3A/m
Computer		Level applied: 30A/m than 3A/m
• **Voltage dips and short interruptions immunity**		
IEC 61000-4-11		
230Vac 50Hz power supply cable		
0% x Un 0.5 cycle	PASS	
At 0°, 45°, 90°, 135°, 180°, 235°, 315°		
..0% x Un 1 cycle at 0°	PASS	
70% x Un 25 cycles at 0°	PASS	
0% x Un 250 cycles	PASS	
110Vac 60Hz console and computer power supply cable	PASS	
0% x Un 0.5 cycle		
At 0°, 45°, 90°, 135°, 180°, 235°, 315°	PASS	
..0% x Un 1 cycle at 0°	PASS	
70% x Un 25 cycles at 0°	PASS	
0% x Un 250 cycles		
• **ISO 7637-2**		
DC power supply cable	N.A.	

2.2. Compatibility

2.2.1.Generator compatibility

N50HF ; N65HF ; N80HF / (1 tube)
N50HF ; N65HF ; N80HF / (2 tubes)
N50HF-N ; N65HF-N ; N80HF-N / (1 tube)
N50HF-N ; N65HF-N ; N80HF-N / (2 tubes)

2.2.2.Digital imaging systems

Compatible with:

- ATS_RF43-TS, TRIXELL_PIXIUM 4343FL-P
- CANON_CCS-RF, CANON_CXDI-RF Wireless B1

2.2.3.Tube and collimator compatibility

Collimator: RALCO R225 ACS

X ray tube assembly: IAE equipped with housing C100XT
RTM 101 → focal spots (mm) 0.6/1.0 – 0.6/1.2 – 0.6/1.5
RTC 600 → focal spots (mm) 0.6/1.0 – 0.6/1.2 – 0.6/1.5
RTC 700 → focal spots (mm) 0.6/1.0 – 0.6/1.2
RTC1000 → focal spots (mm) 0.6/1.0 – 0.6/1.2

X ray tube assembly: VARIAN equipped with housing B147
A292 → focal spots (mm) 0.6/1.2
G292 → focal spots (mm) 0.6/1.2
G296 → focal spots (mm) 0.6/1.0
G892 → focal spots (mm) 0.6/1.2
G896 → focal spots (mm) 0.6/1.0

2.2.4.Cable length

The system can be delivered with the following cable length:

- Table to generator: 12m, 14m, 16m, 20m (this is the HT cable length, the internal length from tube to rear of foot is 10m)
- Table to console: 20m (this is the console cable length, the internal length from electrical part to rear of foot is 2.5m)

2.2.1.Compatibility with auxiliary equipment

Wall bucky (horizontal and vertical position)
Wall detector holder
Ceiling suspension (safety kit needed)

2.2.2.Options

Miscellaneous Accessories (see user manual)
Patient compressor device
4 screens option

2.3. Electrical connection

The electrical connection can be routed using one of the 3 following means:

- Inside trunking
- Inside suspended ceiling
- Inside floor trunking

When choosing the means to route the cables take care that there is no risk that

- the cables can be underwatered
- the cables routes can't be torned off by a moving part inside the room

2.3.1.EC version

The connection must be done to a single-phase AC power supply, 50 or 60Hz and 230V, 3kVA.

Push buttons emergency switches must be located close to the operator and the room exits to switch off the equipment in case of trouble.

A two-pole switch must be mounted in order to cut off the power in all live wires of the installation (without affecting other electrical equipment). The power line must be protected by a 20A / D curve / 230VAC / 10kA circuit breaker and by an SI differential of 30mA.

The switch shall comply with the creepage distances and air clearances as specified in IEC 61058-1 for a mains transient voltage of 4 kV.
The electrical installation must comply with all relevant legislation, recommendations and standards in use in the country.

Maximum peak current is 16A.

The control console is powered separately from the table by a cable ref. IEC 3x0.75mm². The power supply can be 110VAC or 230VAC. The control console power supply cable is not provided by the manufacturer with the installation.

The table power supply cable is not provided by the manufacturer with the installation. Use a 3G2.5mm² cable if the length between the installation power supply cabinet and the table foot is less than 7m, for a greater length (max. 15m), use a 3G4mm² cable.

These two cables will be provided by the installer or distributor of the equipment in accordance with the regulations in force in the country.

The line resistance, including the supply line of the distribution network and the connections to the system must be equal or less than 0.30 ohm.
Grounding (earth) quality is very important. Ground connection must be made with the same wire section as mains cables. Earth resistance must be less than 3 ohms.

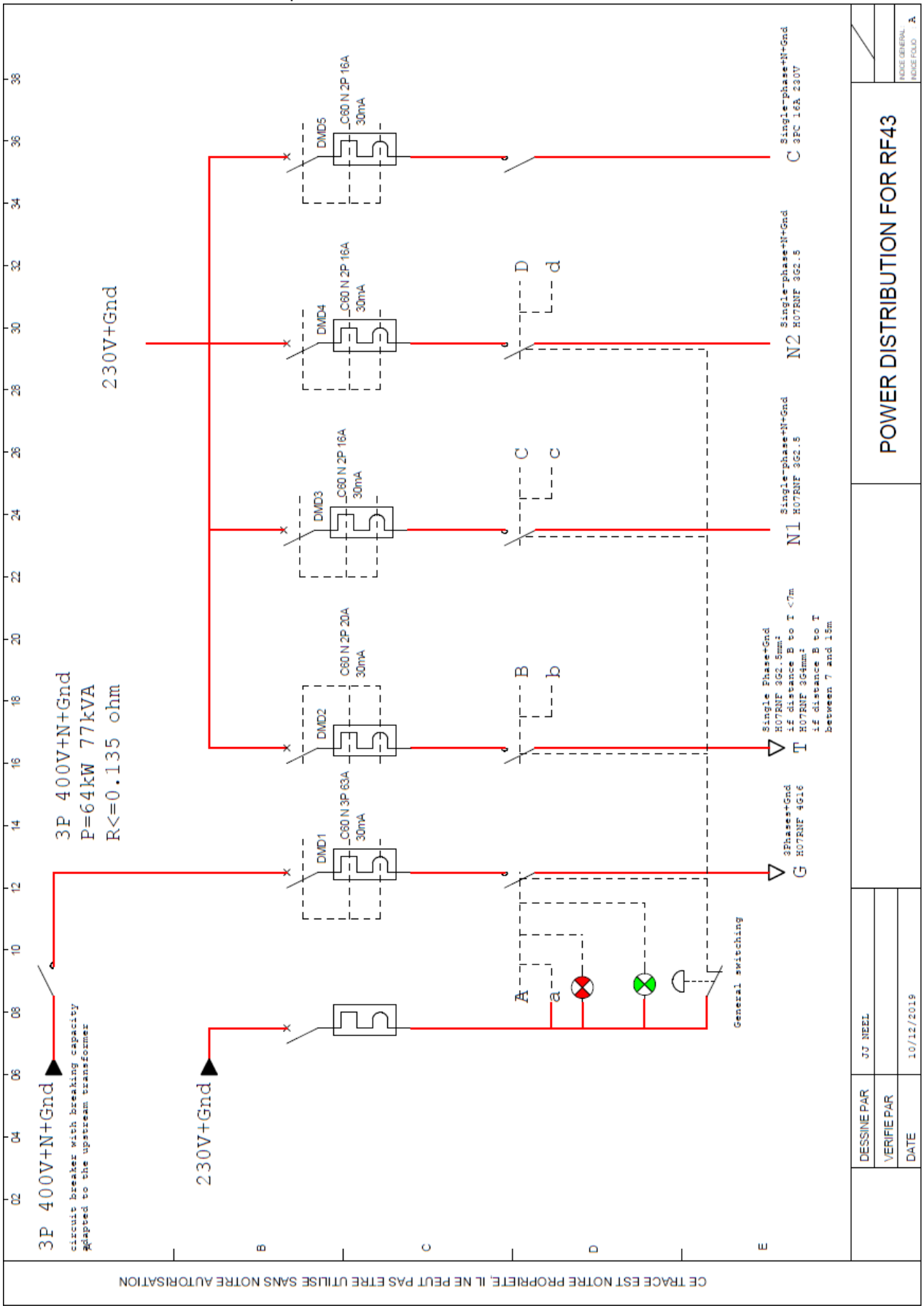
A red light indicator (25W, 230V) must be installed as shown on next page figure.

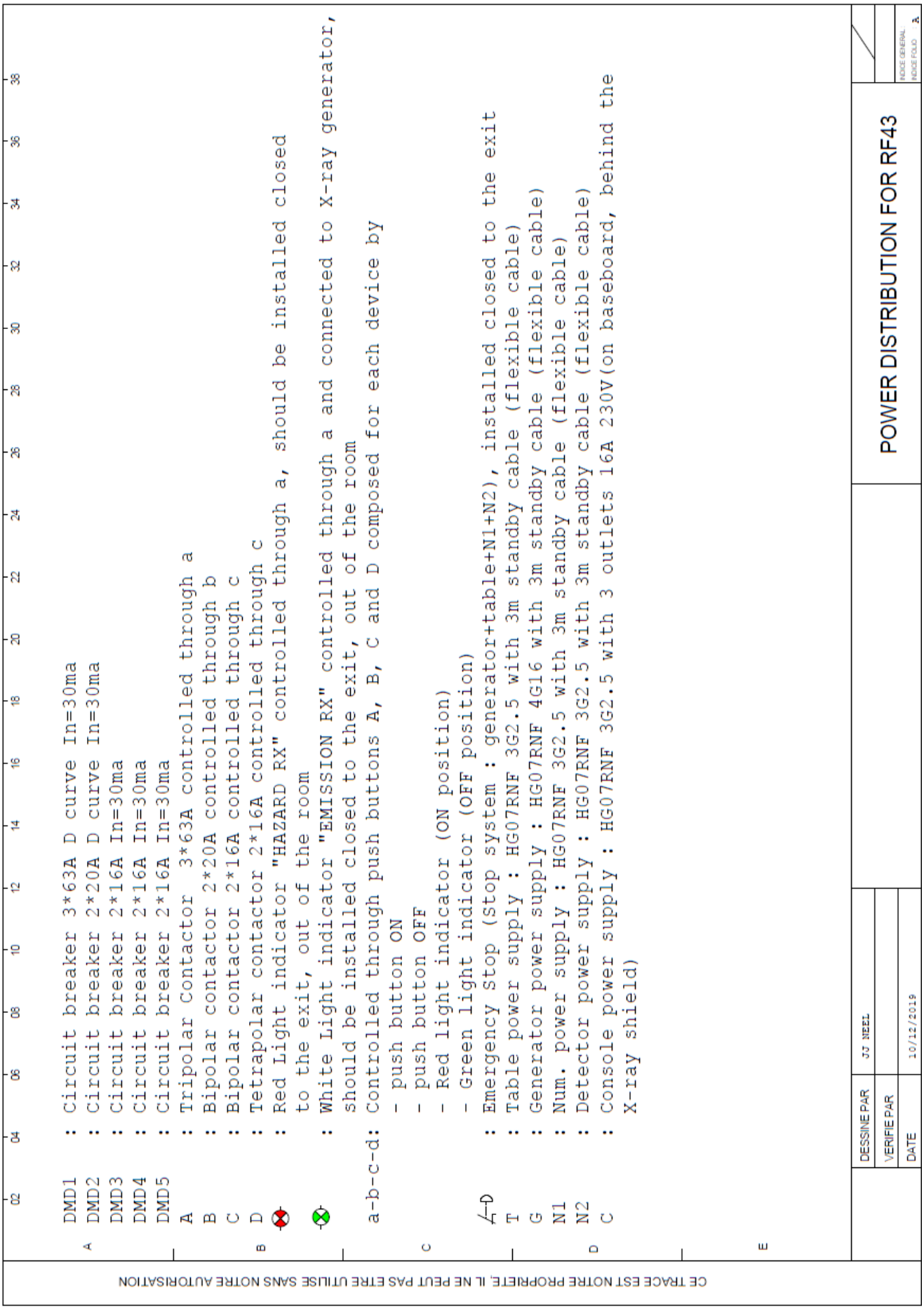
Any other equipment used in the same room, especially the generator, must have its own safety system according to the standards in use in the country. See the relevant service manual.

Warning: the electrical equipments of the system must be positionned in order to let the disconnection device always accessible.
It is the installer and user responsibility to comply with all relevant legislation, recommendations and standards in use concerning the installation and the use of this equipment.

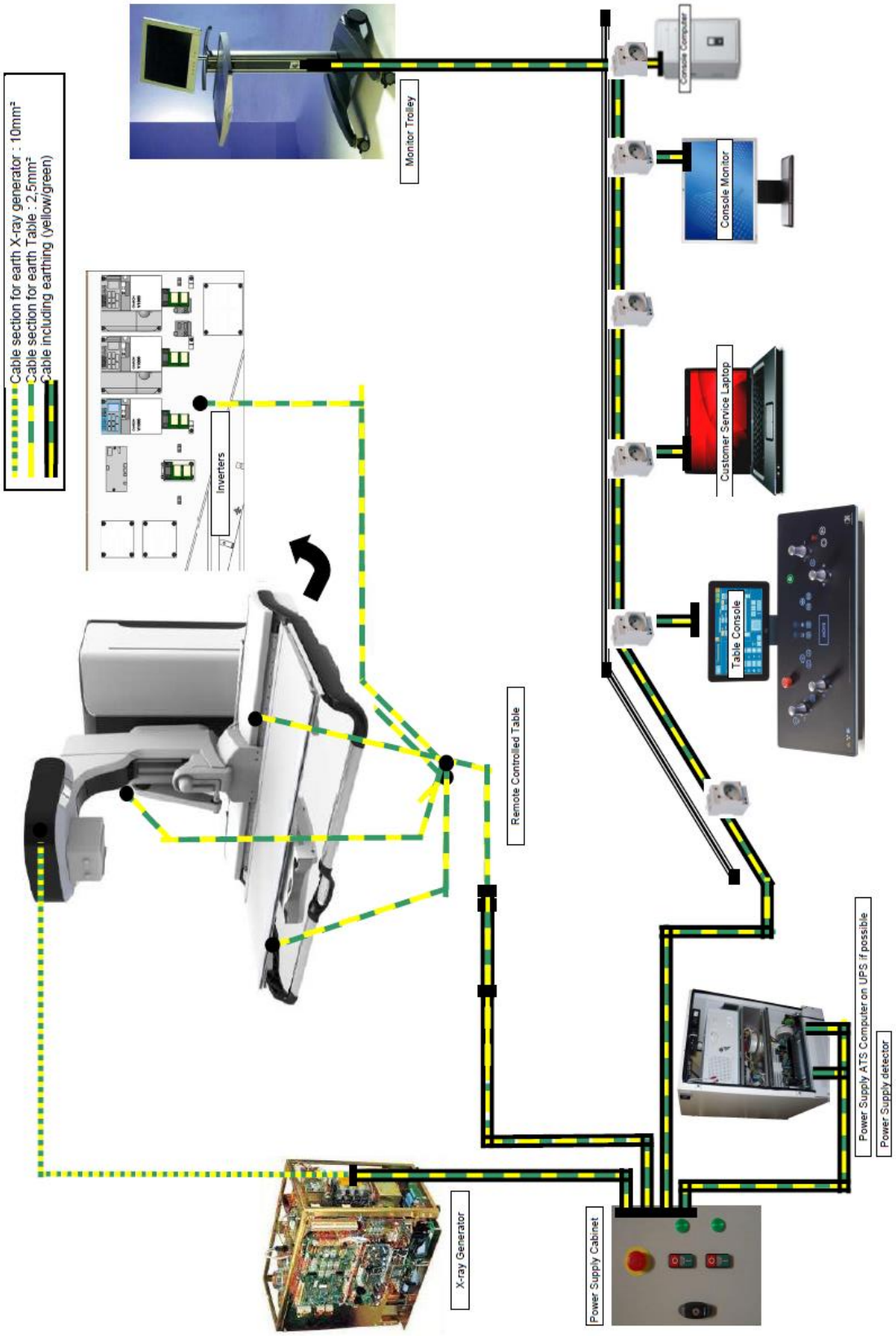
The schematic next page shows the table power supply distribution.

2.3.2.RF43 CE electrical power distribution

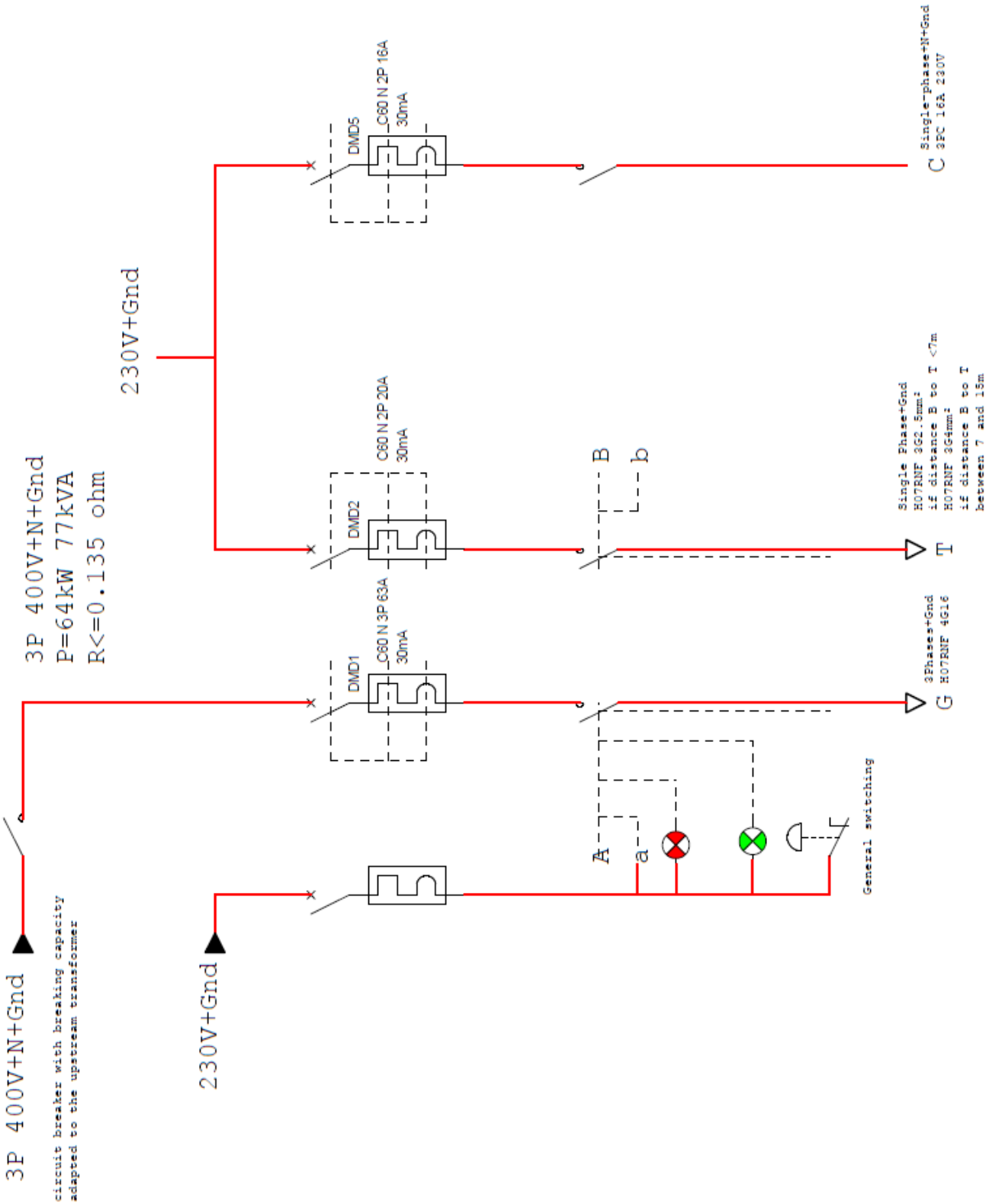



DMD1 : Circuit breaker 3*63A D curve In=30ma
DMD2 : Circuit breaker 2*20A D curve In=30ma
DMD3 : Circuit breaker 2*16A In=30ma
DMD4 : Circuit breaker 2*16A In=30ma
DMD5 : Circuit breaker 2*16A In=30ma
A : Tripolar Contactor 3*63A controlled through a
B : Bipolar contactor 2*20A controlled through b
C : Bipolar contactor 2*16A controlled through c
D : Tetrapolar contactor 2*16A controlled through c
: Red Light indicator "HAZARD RX" controlled through a, should be installed closed to the exit, out of the room
: White Light indicator "EMISSION RX" controlled through a and connected to X-ray generator, should be installed closed to the exit, out of the room
a-b-c-d: Controlled through push buttons A, B, C and D composed for each device by
- push button ON
- push button OFF
- Red light indicator (ON position)
- Green light indicator (OFF position)
: Emergency Stop (Stop system : generator+table+N1+N2), installed closed to the exit
: Table power supply : HG07RNF 3G2.5 with 3m standby cable (flexible cable)
: Generator power supply : HG07RNF 4G16 with 3m standby cable (flexible cable)
: Num. power supply : HG07RNF 3G2.5 with 3m standby cable (flexible cable)
: Detector power supply : HG07RNF 3G2.5 with 3m standby cable (flexible cable)
: Console power supply : HG07RNF 3G2.5 with 3 outlets 16A 230V(on baseboard, behind the X-ray shield)
POWER DISTRIBUTION FOR RF43
DESSINE PAR JJ NEEL
VERIFIE PAR
DATE 10/12/2019
CE TRACE EST NOTRE PROPRIETE, IL NE PEUT PAS ETRE UTILISE SANS NOTRE AUTORISATION

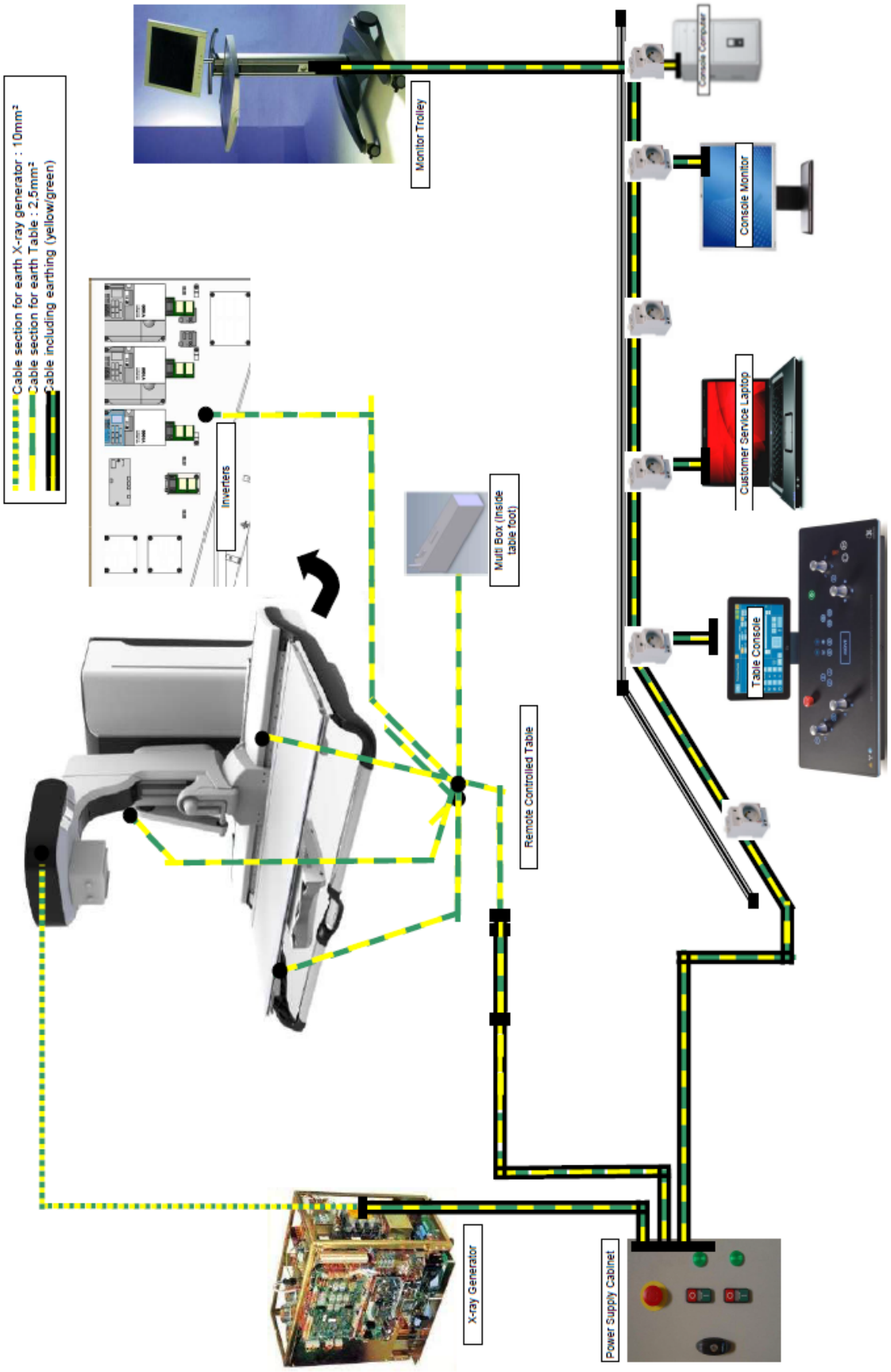
SYSTEM GENERAL GROUNDING DRAWING



2.3.3.CANON B1 CE electrical power distribution



```
DMD1  : Circuit breaker 3*63A D curve In=30ma
DMD2  : Circuit breaker 2*20A D curve In=30ma
DMD5  : Circuit breaker 2*16A In=30ma
A     : Tripolar Contactor  3*63A controlled through a
B     : Bipolar contactor 2*20A controlled through b
        : Red Light indicator "HAZARD RX" controlled through a, should be installed closed
          to the exit, out of the room
        : White Light indicator "EMISSION RX" controlled through a and connected to X-ray generator,
          should be installed closed to the exit, out of the room
a-b: Controlled through push buttons A and B composed for each device by
       - push button ON
       - push button OFF
       - Red light indicator (ON position)
       - Green light indicator (OFF position)
      : Emergency Stop (Stop system : generator+table+N1+N2), installed closed to the exit
T     : Table and Multibox power supply : HG07RNF 3G2.5 with 3m standby cable (flexible cable)
G     : Generator power supply : HG07RNF 4G16 with 3m standby cable (flexible cable)
C     : Console power supply : HG07RNF 3G2.5 with 3 outlets 16A 230V(on baseboard, behind the
        X-ray shield)
```


Cable section for earth X-ray generator : 10mm²
Cable section for earth Table : 2.5mm²
Cable including earthing (yellow/green)
Monitor Trolley
Console Computer
Console Monitor
Customer Service Laptop
Table Console
Inverters
Multi Box (Inside table foot)
Remote Controlled Table
X-ray Generator
Power Supply Cabinet

2.3.4.UL/CSA version

The primary of the 5KVA transformer **TR** must be connected to a single-phase power supply, 60Hz and 110VAC.

Please refer to Installation "TABLE ELECTRICAL CONNECTION" for the details of connection on the transformer.

A two-pole switch must be installed in order to cut off the power in all live wires of the installation (without affecting other electrical equipment). The primary of the transformer **TR** must be protected by a 25A / D curve / 230V / 10kA circuit breaker and by a GFP (Ground Fault Protector) of 30mA.

The switch shall comply with the creepage distances and air clearances as specified in IEC 61058-1 for a mains transient voltage of 4 kV. The switch must be easy to reach and located close to the operator, allowing an immediate switching off at any time.
The electrical installation must comply with all relevant legislation, recommendations and standards in use in the country.

Maximum entrance peak current is 30A.

The transformer is provided with the table. The table is only to be used with this transformer.

Push buttons emergency switches must be located close to the operator and the room exits to switch off the equipment in case of trouble.

The control console is powered separately from the table by a UL/CSA powercord (18AWGx3, SJT min, Hospital grade cord, rated 125V min, 10A) connected to the AC/DC adapter. Connector C13 on AC/DC adapter (fig.b) and NEMA5 plug on mains side (fig.a). The power supply is 110VAC. The control console powercord is not provided by the manufacturer with the equipment.

fig.a

The table power supply cable is not provided by the manufacturer with the equipment. Use a 13AWGx3 min cable upstream and downstream the transformer if the length of each cable is less than 7m, for a greater length (max. 15m), use a 11AWGx3 min cable.

These two cables shall be provided by the installer or distributor of the equipment in accordance with the country regulations.

fig.b

Line resistance, including connections to the meter and the mains supply line, must be equal or less than 0.30 ohm.

Grounding (earth) quality is very important. Ground connection must be made with the same wire section as mains cables. Earth resistance must be less than 3 ohms.

A red light indicator (25W) must be installed as shown on next page figure.

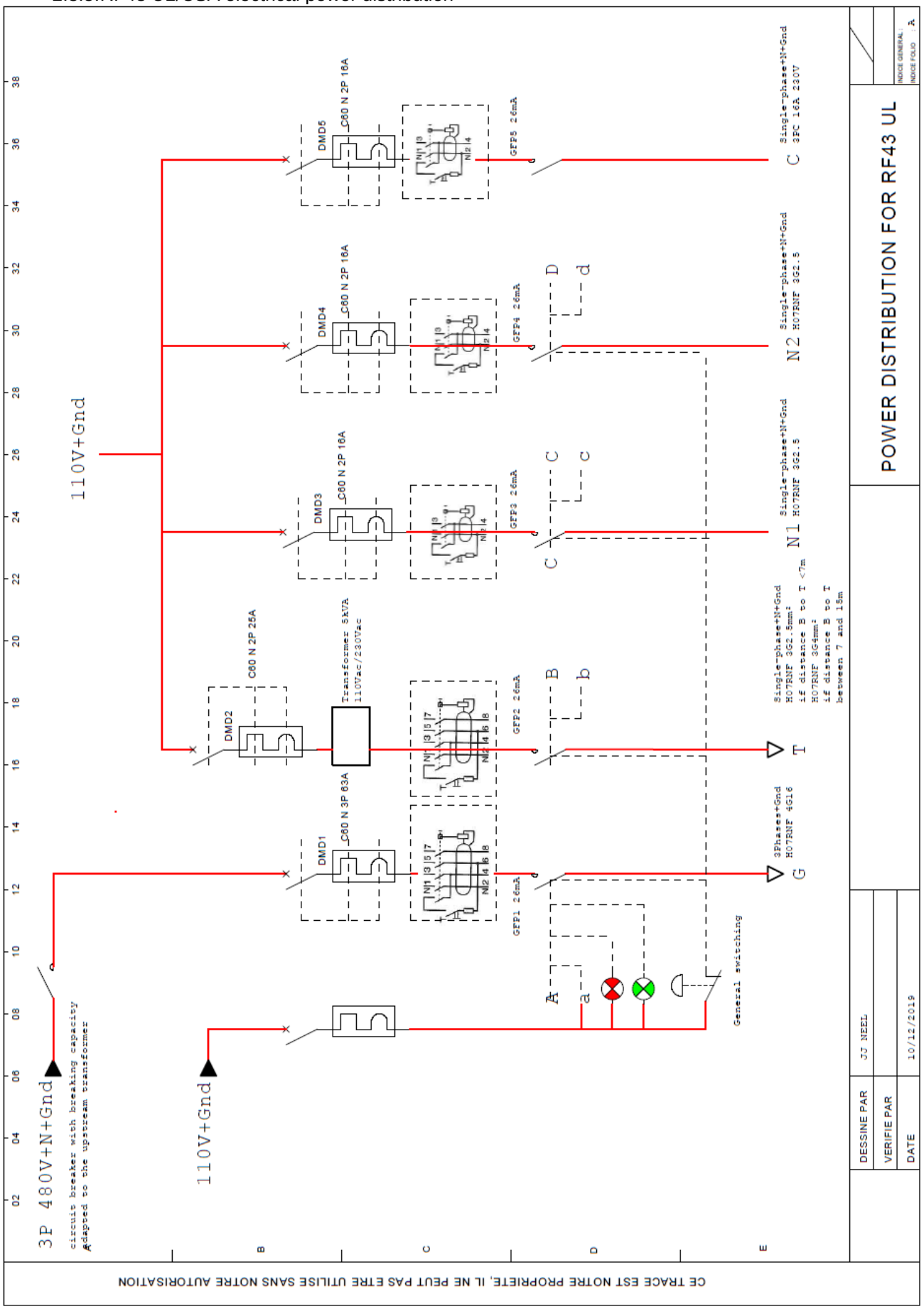
Any other equipment used in the same room, especially the generator, must have its own safety system according to the standards in use in the country. See the relevant service manual.

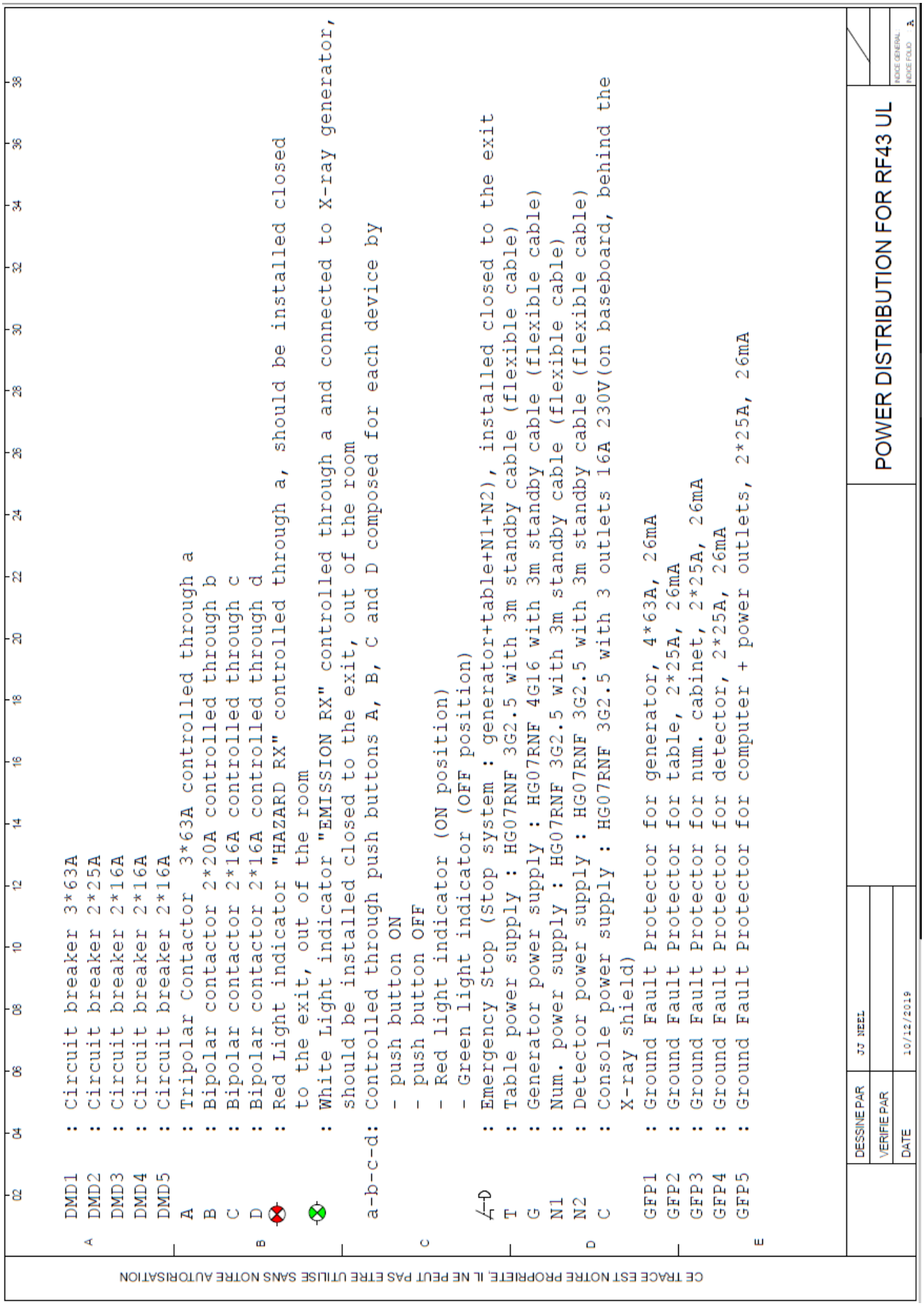
Warning: the electrical equipments of the system must be positionned in order to let the disconnection device always accessible.

It is the installer and user responsibility to comply with all relevant legislation, recommendations and standards in use concerning the installation and the use of this equipment.

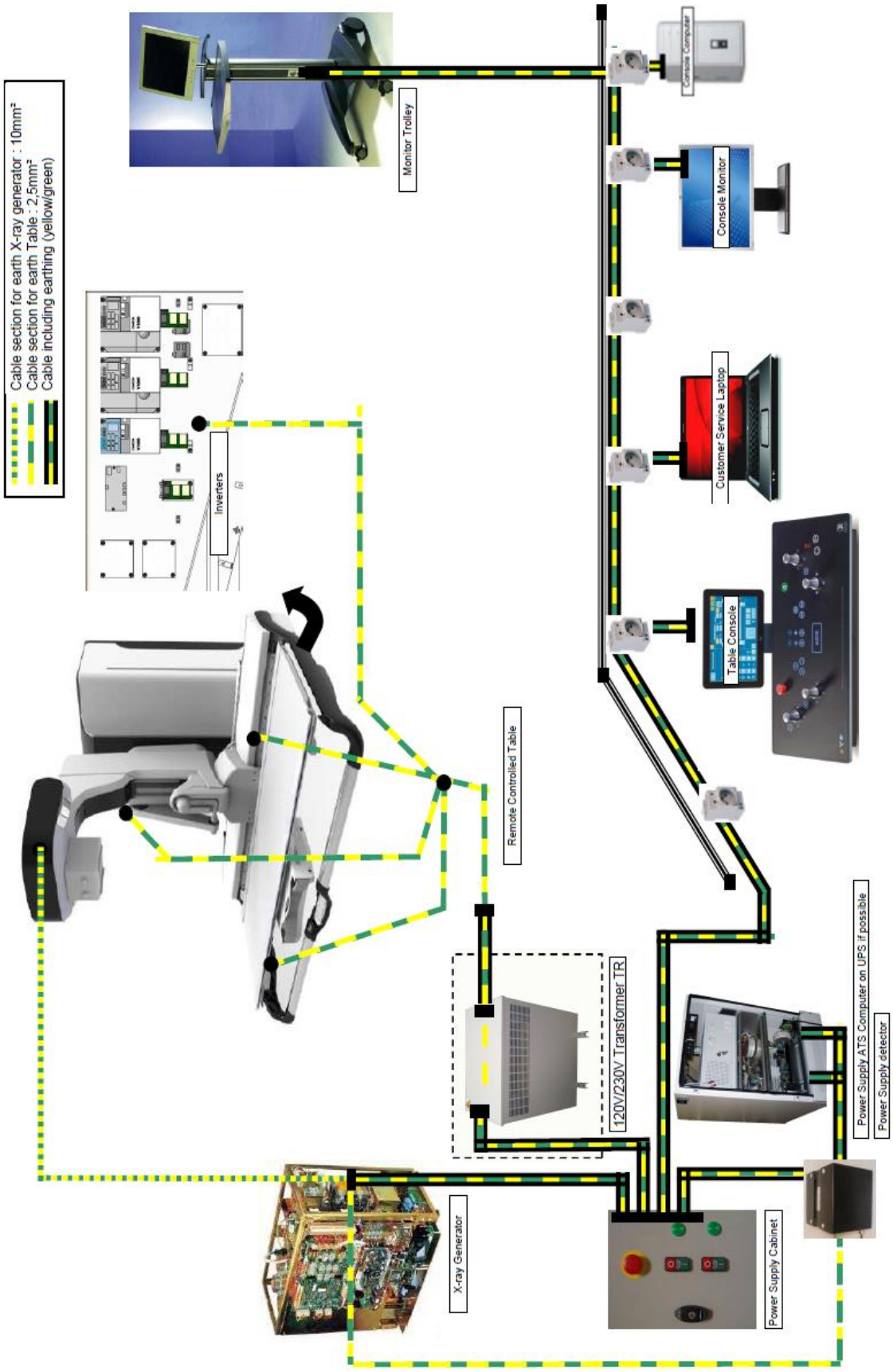
The schematic next page shows the table power supply distribution.

2.3.5.RF43 UL/CSA electrical power distribution

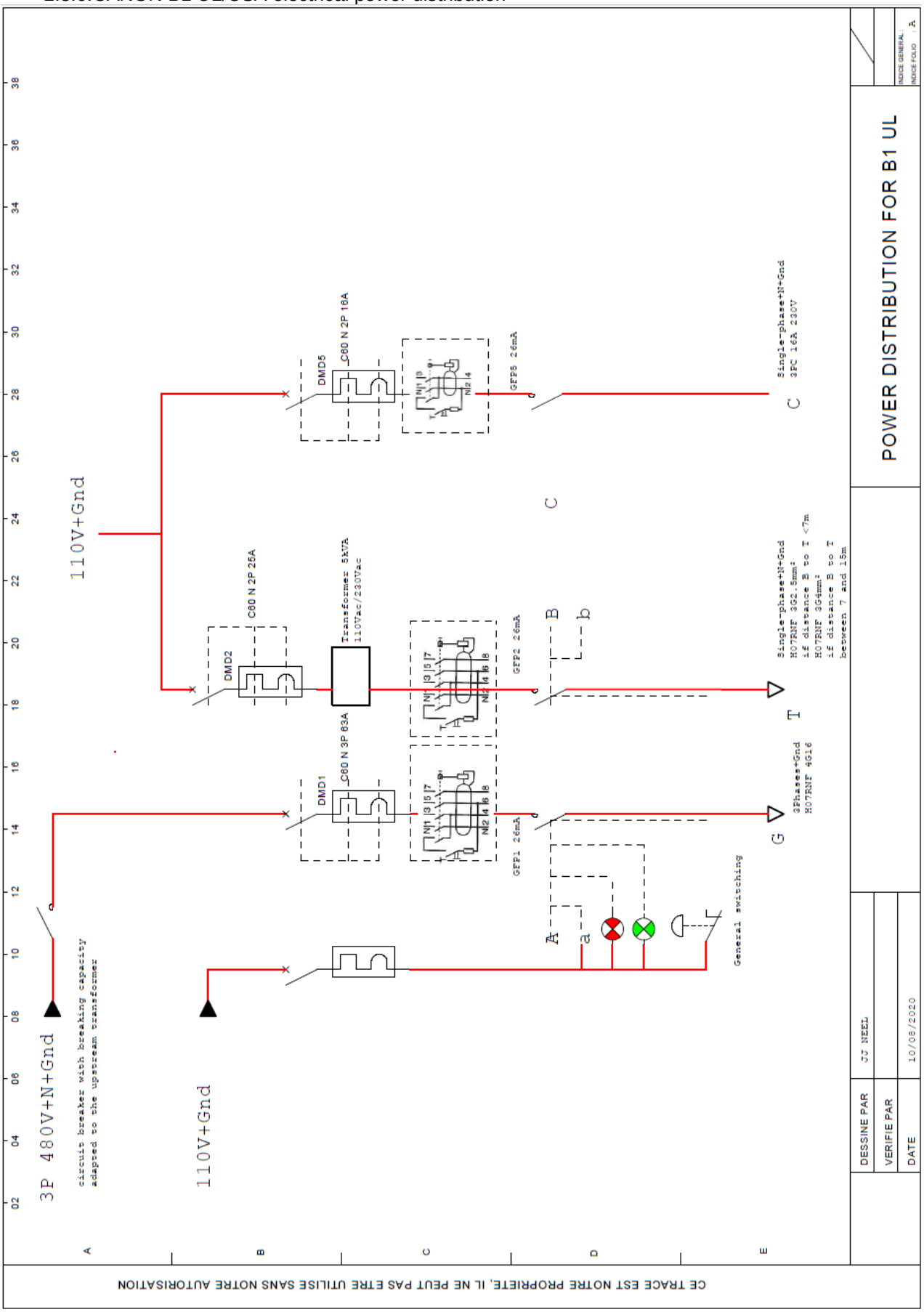



DMD1 : Circuit breaker 3*63A
DMD2 : Circuit breaker 2*25A
DMD3 : Circuit breaker 2*16A
DMD4 : Circuit breaker 2*16A
DMD5 : Circuit breaker 2*16A
A : Tripolar Contactor 3*63A controlled through a
B : Bipolar contactor 2*20A controlled through b
C : Bipolar contactor 2*16A controlled through c
D : Bipolar contactor 2*16A controlled through d
: Red Light indicator "HAZARD RX" controlled through a, should be installed closed to the exit, out of the room
: White Light indicator "EMISSION RX" controlled through a and connected to X-ray generator, should be installed closed to the exit, out of the room
a-b-c-d: Controlled through push buttons A, B, C and D composed for each device by
- push button ON
- push button OFF
- Red light indicator (ON position)
- Green light indicator (OFF position)
: Emergency Stop (Stop system : generator+table+N1+N2), installed closed to the exit
T : Table power supply : HG07RNF 3G2.5 with 3m standby cable (flexible cable)
G : Generator power supply : HG07RNF 4G16 with 3m standby cable (flexible cable)
N1 : Num. power supply : HG07RNF 3G2.5 with 3m standby cable (flexible cable)
N2 : Detector power supply : HG07RNF 3G2.5 with 3m standby cable (flexible cable)
C : Console power supply : HG07RNF 3G2.5 with 3 outlets 16A 230V(on baseboard, behind the X-ray shield)
GFP1 : Ground Fault Protector for generator, 4*63A, 26mA
GFP2 : Ground Fault Protector for table, 2*25A, 26mA
GFP3 : Ground Fault Protector for num. cabinet, 2*25A, 26mA
GFP4 : Ground Fault Protector for detector, 2*25A, 26mA
GFP5 : Ground Fault Protector for computer + power outlets, 2*25A, 26mA
CE TRACE EST NOTRE PROPRIETE, IL NE PEUT PAS ETRE UTILISE SANS NOTRE AUTORISATION
DESSINE PAR JJ NEEL
VERIFIE PAR
DATE 10/12/2019
POWER DISTRIBUTION FOR RF43 UL

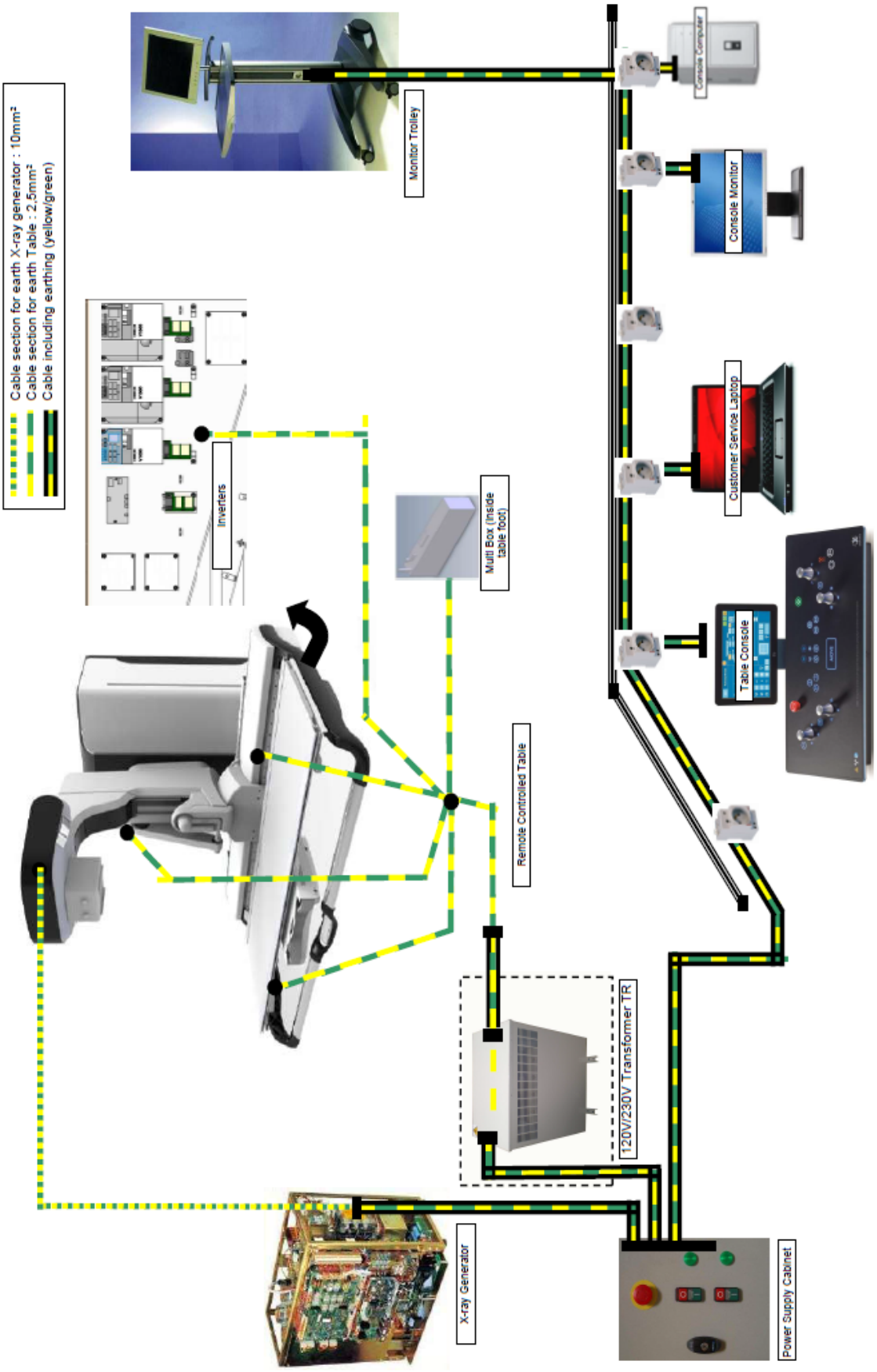
SYSTEM GENERAL GROUNDING DRAWING



2.3.6.CANON B1 UL/CSA electrical power distribution

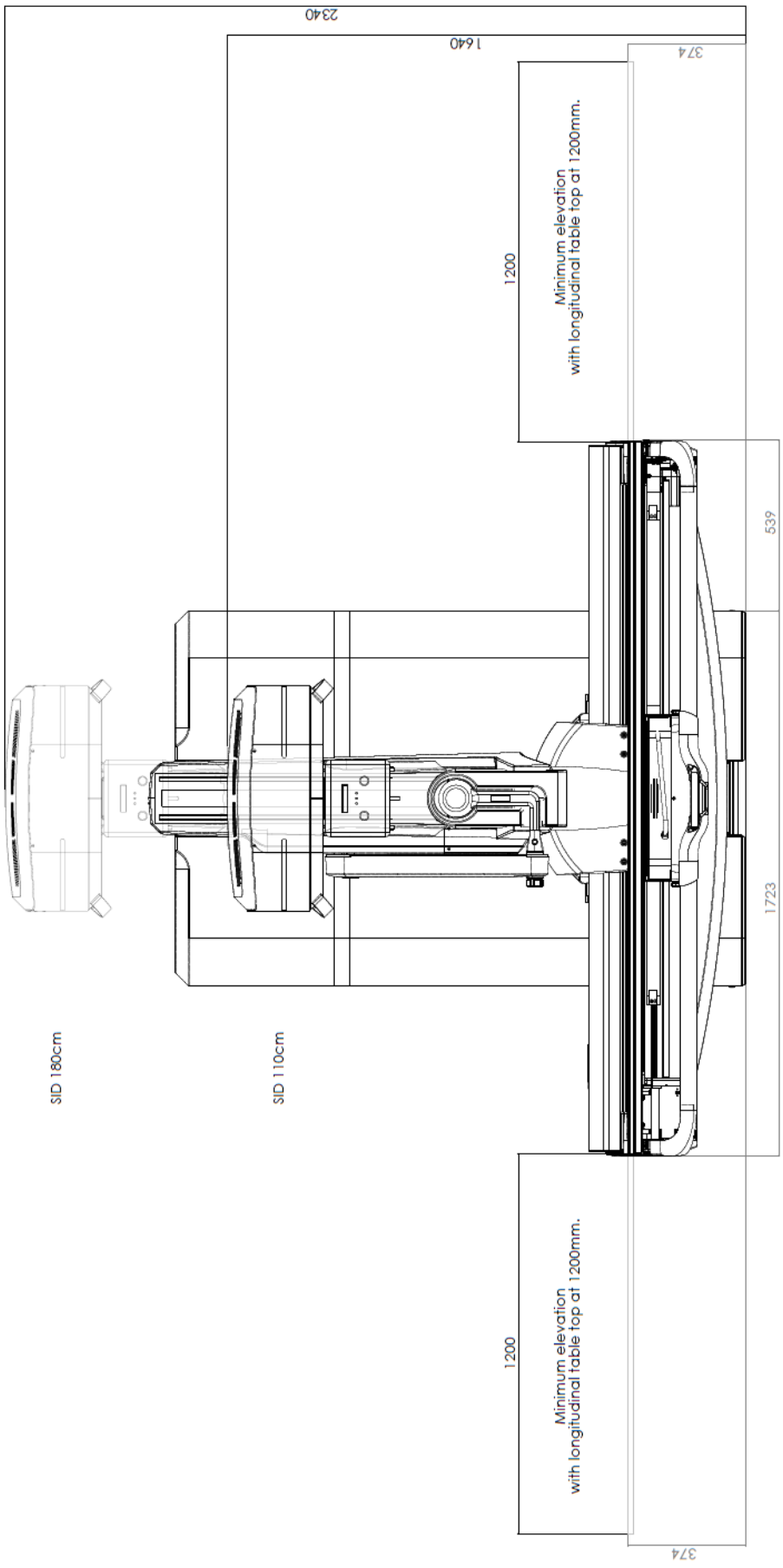


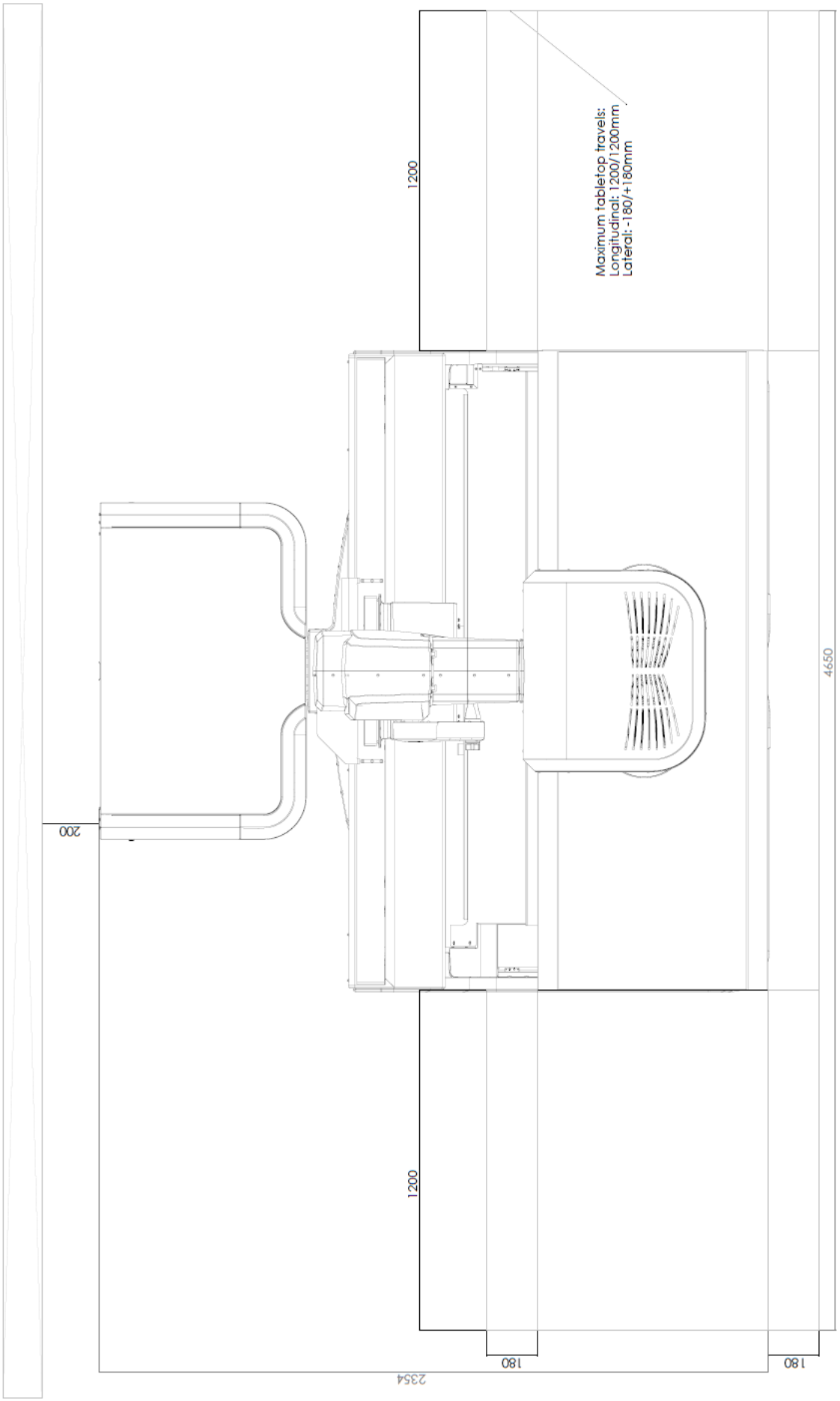
```
DMD1  : Circuit breaker 3*63A
DMD2  : Circuit breaker 2*25A
DMD5  : Circuit breaker 2*16A
A     : Tripolar Contactor  3*63A controlled through a
B     : Bipolar contactor 2*25A controlled through b
        : Red Light indicator "HAZARD RX" controlled through a, should be installed closed
          to the exit, out of the room
        : White Light indicator "EMISSION RX" controlled through a and connected to X-ray generator,
          should be installed closed to the exit, out of the room
a-b     : Controlled through push buttons A and B composed for each device by
          - push button ON
          - push button OFF
          - Red light indicator (ON position)
          - Green light indicator (OFF position)
        : Emergency Stop (Stop system : generator+table+N1+N2), installed closed to the exit
T       : Table and Multibox power supply : HG07RNF 3G2.5 with 3m standby cable (flexible cable)
G       : Generator power supply : HG07RNF 4G16 with 3m standby cable (flexible cable)
C       : Console power supply : HG07RNF 3G2.5 with 3 outlets 16A 230V(on baseboard, behind the
          X-ray shield)
GFP1  : Ground Fault Protector for generator, 4*63A, 26mA
GFP2  : Ground Fault Protector for table and Multibox, 2*25A, 26mA
GFP5  : Ground Fault Protector for computer + power outlets, 2*16A, 26mA
```

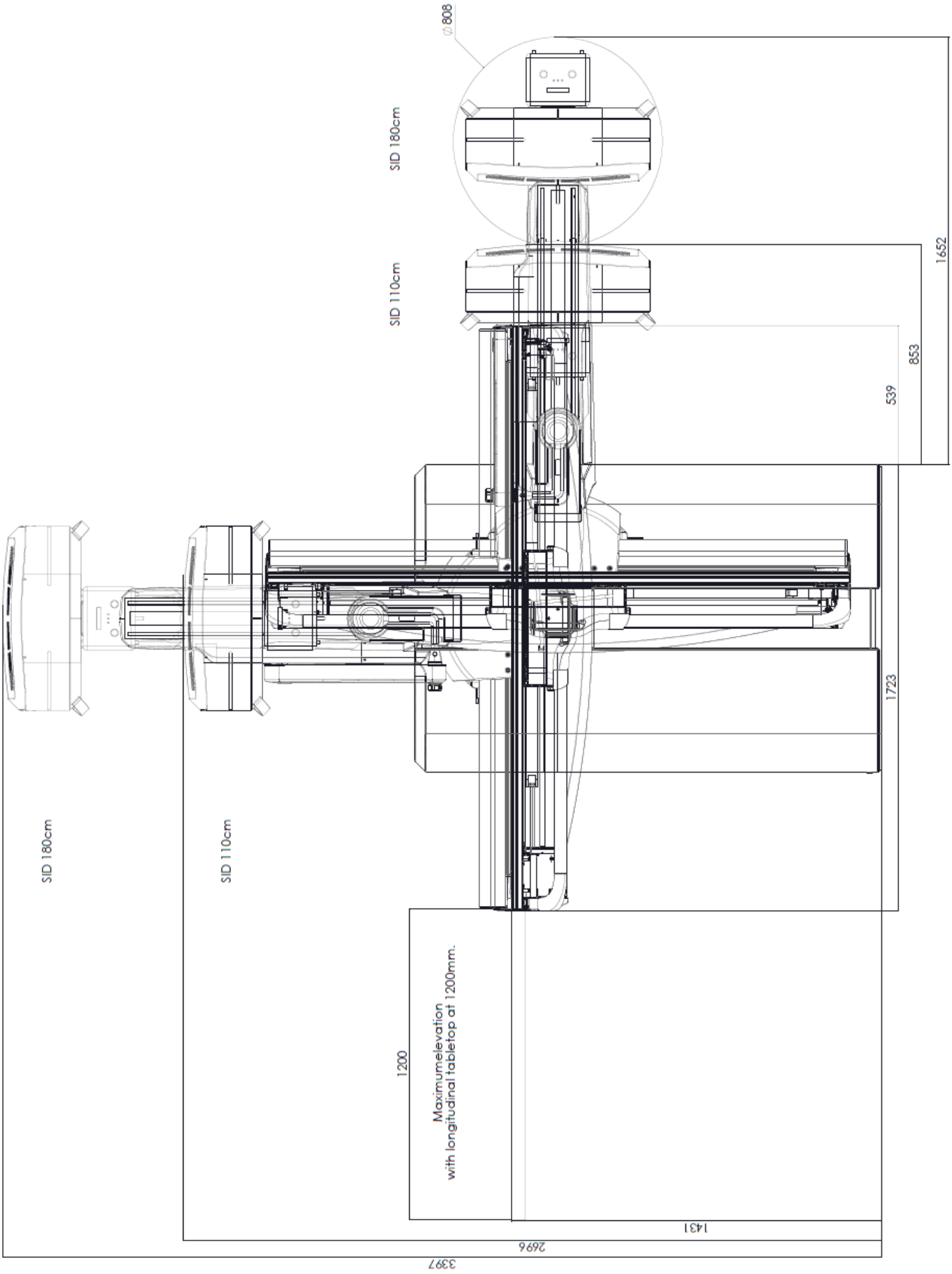

Cable section for earth X-ray generator : 10mm²
Cable section for earth Table : 2,5mm²
Cable including earthing (yellow/green)
Monitor Trolley
Console Computer
Console Monitor
Customer Service Laptop
Table Console
Inverters
Multi Box (inside table foot)
Remote Controlled Table
120V/230V Transformer TR
X-ray Generator
Power Supply Cabinet

2.4. Clearance and space requirements

The minimum room height is 2500mm, however it is recommended to have a room height of 2600mm in order to have no limitation on the movements.
These minimum room heights are given with a table fixed directly on the floor and shall be increased according to the table support used (palett, repartition plate…).

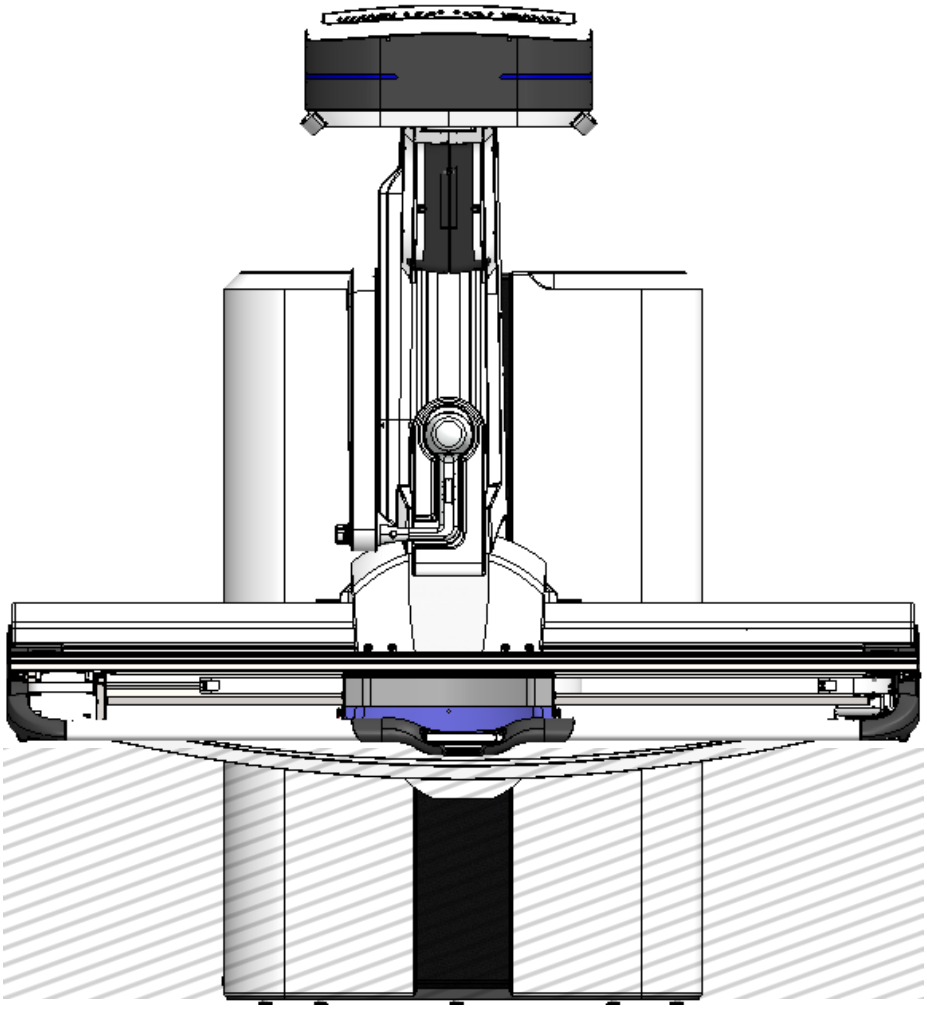

2340
1640
374
1200
Minimum elevation
with longitudinal table top at 1200mm.
539
1723
SID 180cm
SID 110cm
1200
Minimum elevation
with longitudinal table top at 1200mm.
374

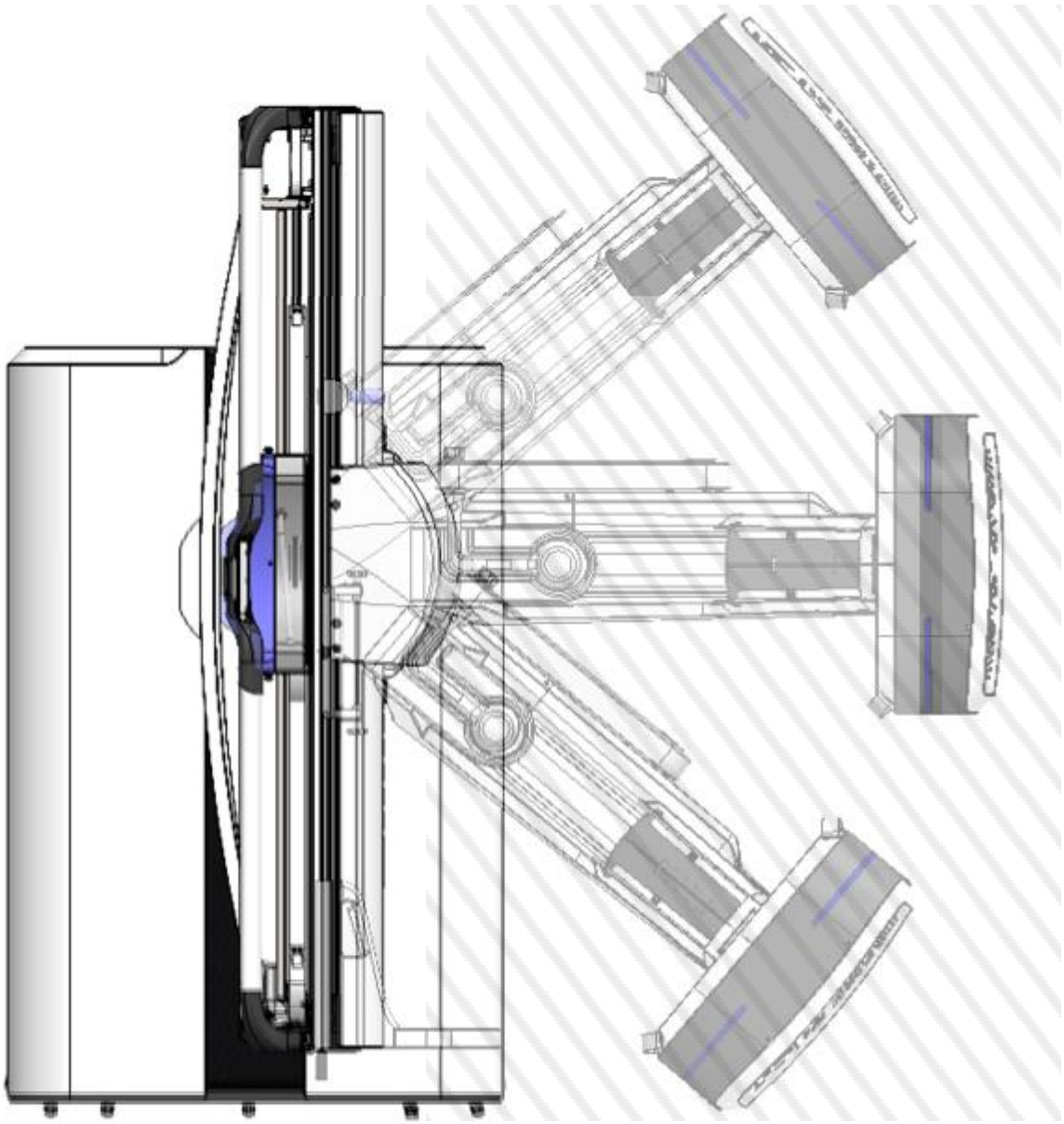

Maximum tabletop travels:
Longitudinal: 1200/1200mm
Lateral: -180/+180mm
1200
4650
200
1200
180
180
2354

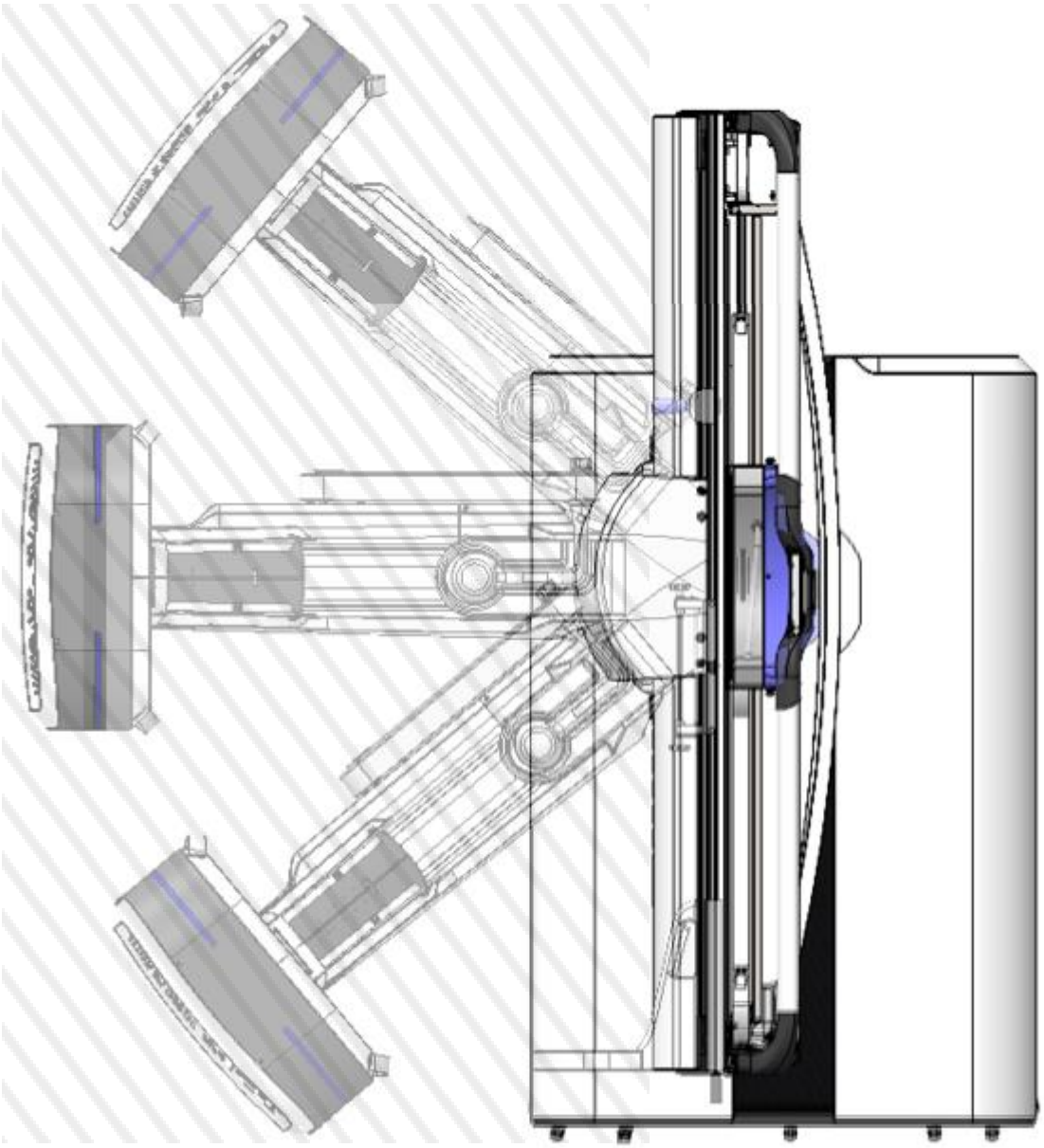

Ø 808
SID 180cm
SID 110cm
1652
853
539
1723
SID 180cm
SID 110cm
1200
Maximumelevation
with longitudinal tabletop at 1200mm.
1431
2696
3397

2.5. Mechanical safety

Since the table moves, some areas around the table should always be kept clear of any equipment. It is the operator's responsibility to make sure that there is no obstacle to the movements of the table.
The dangerous areas are dashed on the drawings below.



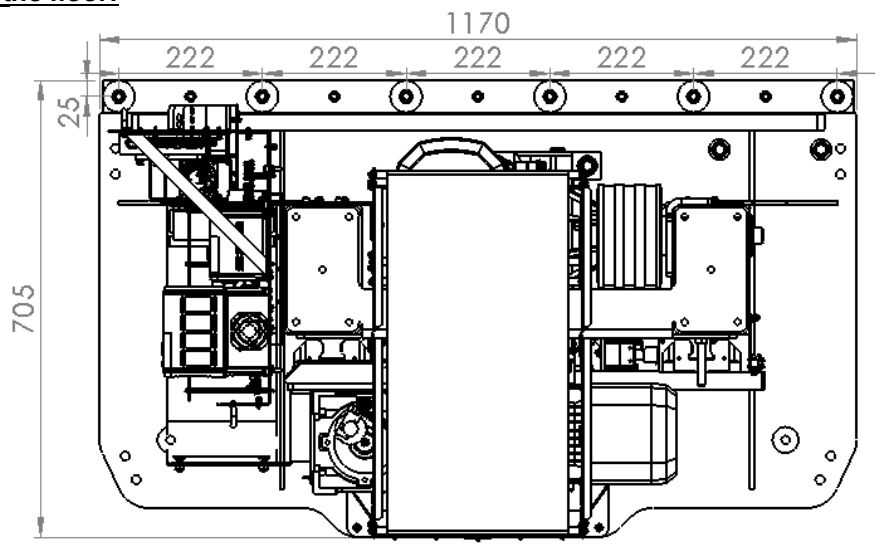




2.6. Ground layout

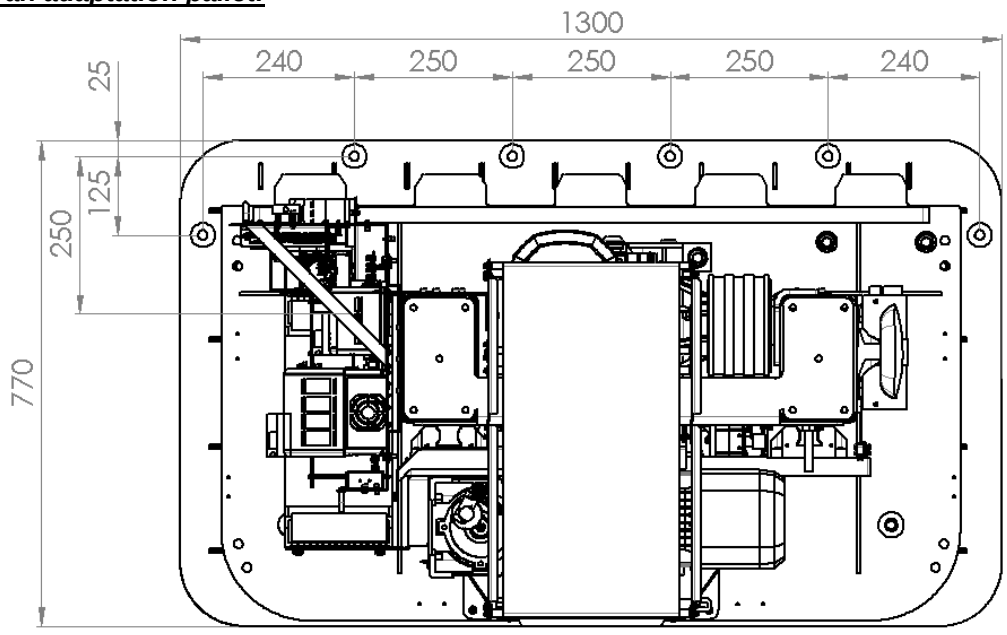
All dimensions are in mm.

Direct fixation on the floor:



The floor loading of the table is 1810kg/m².
The floor plate fixation must support a 11500N wrenching force at each fixing point.
A 200mm space between end of concrete slab and the chemical anchors should be used.

Fixation with an adaptation pallet:



The floor loading of the table is 1650kg/m².
The floor plate fixation must support a 6500N wrenching force at each fixing point.
A 125mm space between end of concrete slab and the chemical anchors should be used.

Depending on the concrete slab met, there are different solutions to fix the equipment.

The way used to fix the floor plate must comply with the relevant legislation, recommendations and standard in force in the country, including the seismic safeties. It must be done according to the ground characteristics as well as possible.

A free space of 100 mm minimum must be reserved at the back of the table to easiest maintenance. The recommended space is at least 200mm.

If the concrete floor is thick and strong enough (cracked or uncracked and thickness minimum 120mm), the equipment can be fixed to the floor using 6x threaded rod Ø12mm (Ø14mm drilling) HILTI chemical anchors and 2x M8x40 (Ø12mm drilling) HILTI HSL-3 mechanical anchors. The selected chemical anchors must be chosen in the following table:

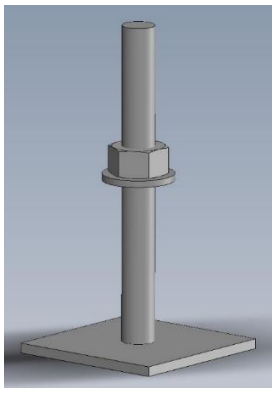
Concrete quality	Concrete state	Selected anchorage
C20/25 or higher	Cracked	HIT-HY 200-A + thread rod class 8.8
C20/25 or higher	Uncracked	HIT-HY 200-A + thread rod class 8.8
C20/25 or higher	Unknown	HIT-HY 200-A + thread rod class 8.8
C16/20	Cracked	HIT-HY 200-A + thread rod class 8.8
C16/20	Uncracked	HIT-HY 200-A + thread rod class 8.8
C16/20	Unknown	HIT-HY 200-A + thread rod class 8.8
C12/15	Cracked	Not possible
C12/15	Uncracked	HIT-HY 200-A + thread rod class 8.8
C12/15	Unknown	Not possible

If the concrete floor thickness is less than 120mm but more than 70mm and the quality of the concrete is at least C12/15 cracked or not cracked it is possible to install the foot with an adaptation pallet.

If the concrete floor thickness is less than 70mm or the quality of the concrete is less than C12/15 it is not possible to install the foot.

WARNING : read carrefully anchors datasheet and instruction before use

If it is not possible to use the different fixing types previously explained, then it is possible to use metal plate and threading rods to fix the equipment fom side to side of the floor. (See picture hereafter).



If the floor is not strong enough to support the loading of the table an optional dispatching plate can be ordered. Please contact your reseller for more details.

3. TOOLS AND PERSONNEL REQUIRED FOR ASSEMBLY

3.1. Tools

- Tools needed to fix the table directly to the floor or with an adaptation pallet:

Designation	Quantity
Hammer drill	1
Ø12 Drill bit – Depth mini 120	1
Ø14 Drill bit – Depth mini 230	1
HIT-RB Brush	1
HIT Blower pump	1
Manual injection pump dispenser HDM 500 + Cartridge holder HIT-CR 500 + HIT-RE-M Mixer	1
KIT - HAT-28 Tester	1
Gloves	1 pair
Protective glasses	1

- a standard tools set including :

A set of open end wrench, including 13, 14, 17 and 22 mm
An open end wrench of 17 mm, thickness: 3 mm
A set of pipe-wrench, including 8 mm
A set of Allen key
An Allen key of 4 mm with long handle
Hammer, cutter, screwdrivers,
Grease and talc
Loctite glue 242
A torque wrench (from 5 Nm to 100 Nm)

- a crowbar
- a spirit level
- a digital multimeter, input impedance : 10 MΩ, 5000 points
- a digital memory oscilloscope, two channels, 50 MHz
- two insulated oscilloscope probes

3.2. Person

For delivery, uncrating, positioning and mounting of the table frame, 4 people are needed.

Only qualified field service engineers approved by the manufacturer should be authorized to work for the installation and the troubleshooting of this remote controlled table.

One engineer is needed for the remaining of the assembly, helped by another person on occasion.

4. SAFETY RULES

4.1. Instruction for installation safety

✓ The system must work only in rooms which are used for medical aims (refer to regulations in force). The unit is not planned to be used in rooms which are subject to explosions risks.

✓ Do not position or use the system in a location where it may be subject to splashed or spilled liquids.

✓ Cables between the table, the control desk, the x-ray generator and the Imaging system must be protected by a cable duct, or whatever means it is, if they follow a wall or the ceiling for example. In no case these cables between the different sub-assemblies must be unprotected.

✓ The system must be grounded as specified in the power connection instructions.

✓ High voltages capable of causing death are present within the system.

✓ The system has been tested and complies with the electromagnetic regulations. However, it is advised to keep a reasonable distance between the different electrical parts of the system in order to avoid any interference. This is especially true for the PC cabinet, which should be kept far from other electrical devices.

✓ This system is interfaced to X-ray generating equipment. Be certain to follow the X-ray manufacturer's instructions and specifications for wearing proper shielding.

✓ During the installation, do not bypass the mechanical, electrical or software safeties provided by the x-ray generator.

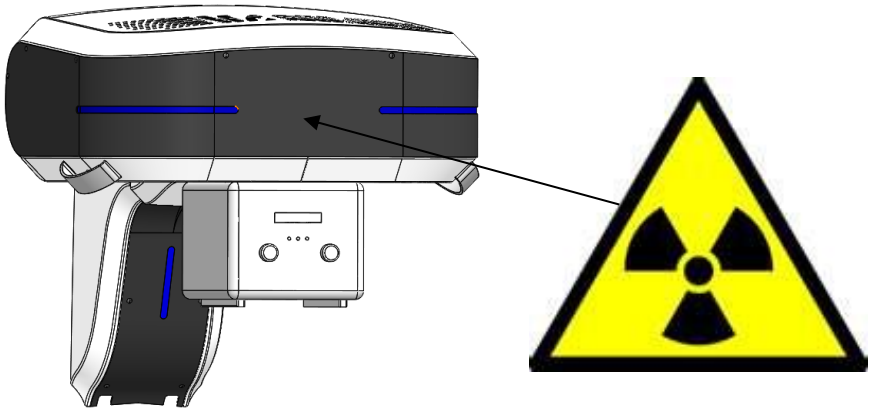
✓ All personnel must wear Dosimeters during every phase of the installation of the system.

✓ The control console must be installed so that all the movements are in the operator‘s field of view.

4.2. Radiation safety

All persons present in the X-ray room must comply with radiation safety rules common to any radiological system.

For patient safety, the user should, if necessary, employ accessories for radiation protection in addition to those provided on the equipment itself (e.g. collimator, spacer, and filter).



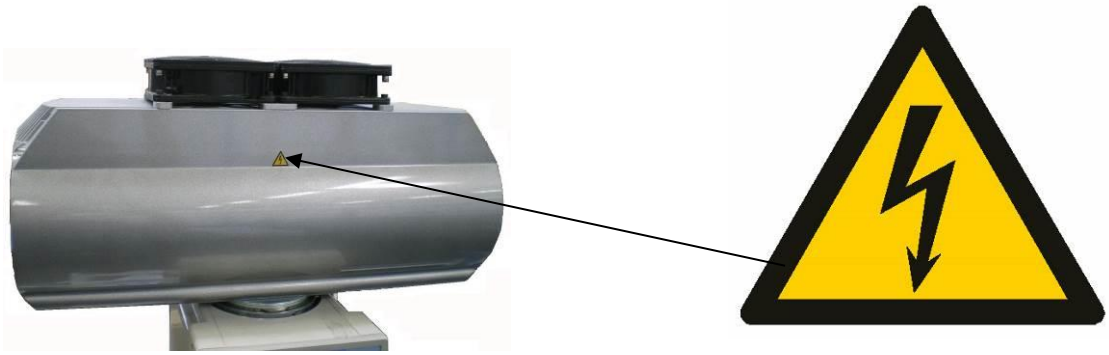
Safety interlocks preventing the emission of X-radiation under certain conditions must never, under any circumstances, be removed nor modified.

The equipment described in this manual may not be used in combination with other equipment unless such other equipment has been specifically designed as compatible by the manufacturer or by his agent.

Users of this equipment must wear a personal radiation dosimeter for safety reasons when operating this equipment.

4.3. Electrical safety

Only qualified field service engineers approved by the manufacturer should be authorized to remove the high voltage cables from the X-ray housing or high voltage tank of the x-ray generator.
Only the manufacturer qualified service representatives are authorized to remove the covers off or otherwise to access the high voltage generator or RX housing tube.



The equipment may only be used in rooms in compliance with the relevant national legislation and with the recommendations concerning electrical safety in rooms used for medical purposes like, for exemple the presence of an additional protective earth (ground) terminal for equipotential connection. (Refer to IEC 60601-1).

The equipment is not designed for use in the presence of gas or in a flammable environment.
Remember that some disinfectants may be explosive mixtures, if such disinfectants are used, it will be necessary to let the fumes dissipate before the equipment is switched on again.
Avoid penetration of water or any liquids int the equipment, as they may cause short-circuits or corrosion.

Always switch off the X-ray room (generator and stands) from the mains:

- Before cleaning or disinfecting.
- Before any servicing or maintenance on the equipment:

Always switch off the power supply, and open the main switch before connect or disconnect a plug or a PCB, otherwise the input transformer will remain under voltage.

Be careful when working on the PCB areas noted as High Voltage present.

In the microprocessor boards:

- Never use a soldering iron.
- Take protection against electrostatic discharge.
- These parts cannot be repaired in the field.

✓ No additional multiple portable socket outlet or extension cord shall be connected to the system.
✓ Do not connect items which are not specified as part of the system.
✓ When a non medical electrical equipment, which has been supplied as a part of the system, is directly connected to the wall outlet, the user does not benefit from the specific protections of the system power supply, notably concerning the leakage currents.
✓ When an electric equipment, which has not been supplied as a part of the electro medical system is connected to a socket outlet dedicated to the system, it can be prejudicial to the safety of the system.

4.4. Network safety

This system implements the necessary DICOM services to download work lists from an information system, save acquired images to a network storage device, print to a networked hardcopy device and inform the system about the work actually done.

It is the IT-Network integrator's responsability to assess and address the hazards that are likely to arise from integrating this system into the IT-Network. All the instructions needed for implementing the connection of this system to the IT-Network are provided in the system's DICOM Conformance Statement.
Failure of the IT-Network to provide the characteristics required to meet the purpose of this system connection to the IT-Network can result in unforseen risks to the patient.

Warning:
- ✓ The RESPONSIBLE ORGANIZATION should identify, analyze, evaluate and control these risks.
- ✓ Subsequent changes to the IT-NETWORK could introduce new RISKS and require additional analysis.
- ✓ Changes to the IT-NETWORK include:
  - Changes in the IT-network configuration;
  - Connection of additional items to the IT-NETWORK;
  - Disconnecting items from the IT-NETWORK;
  - Update of equipment connected to the IT-NETWORK; and
  - Upgrade of equipment connected to the IT-NETWORK.

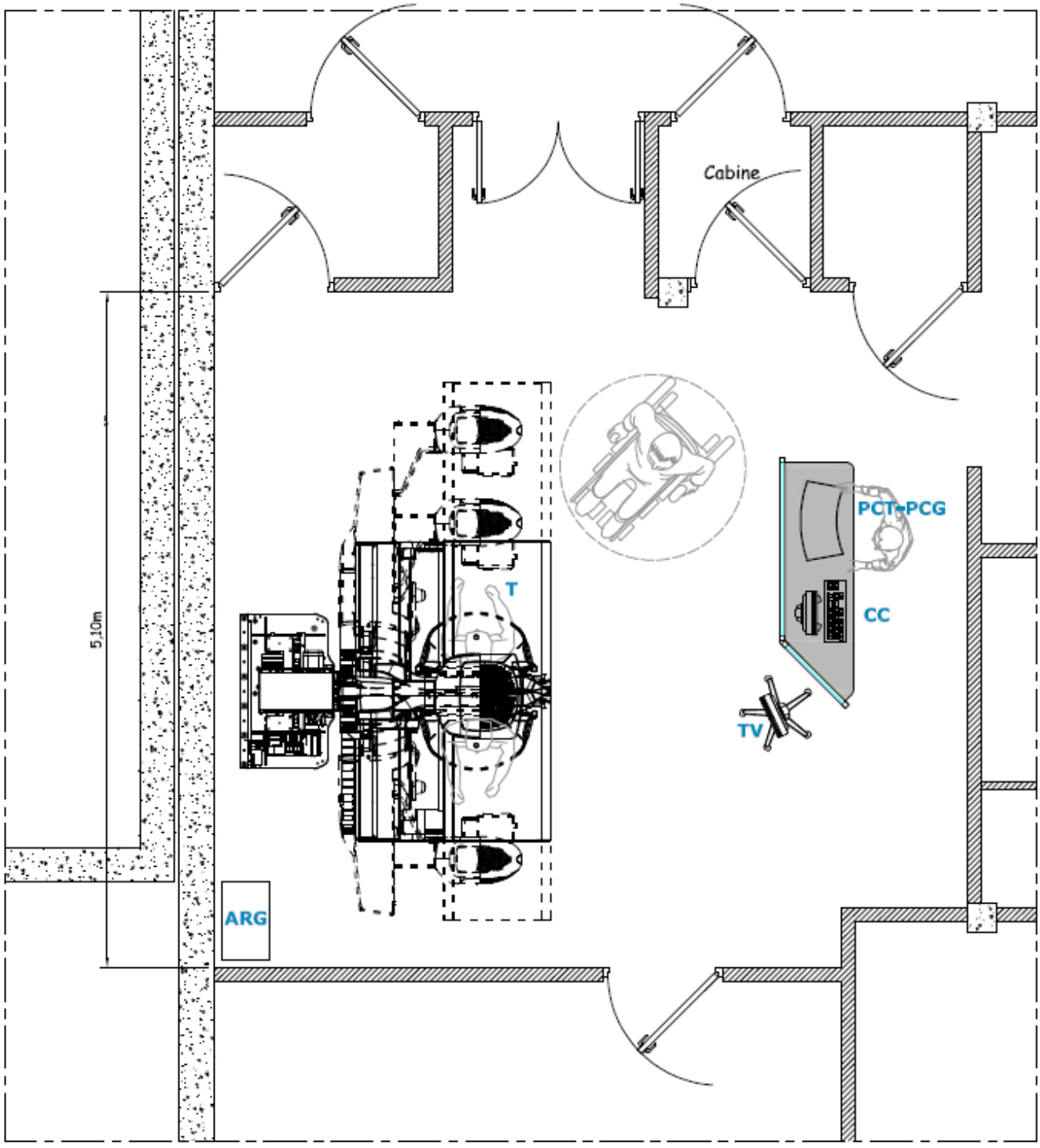
5. ROOM EXAMPLE AND PATIENT ENVIRONMENT

MARKS

SH	X-RAY SHIELD
PCT- PCG	TABLE AND GENERATOR CONTROL CONSOLE
T	REMOTE CONTROLLED TABLE
ARG	GENERATOR CABINET
PC	DIGITAL IMAGING SYSTEM COMPUTER
CC	DIGITAL IMAGING SYSTEM MONITOR AND KEYBOARD/MOUSE
TV	VIDEO MONITORS (2)
TR	TRANSFORMER 480/400VAC (only for UL/CSA VERSION)

NOTE: WALL LEADING SHOULD BE MADE ACCORDING TO THE REGULATIONS IN FORCE IN THE COUNTRY OF INSTALLATION.

IT IS RECOMMENDED THAT THE ROOM BE EQUIPPED WITH AUDIO AND VIDEO COMMUNICATION MEANS BETWEEN THE OPERATOR (PLACED AT THE MAIN CONSOLE) AND THE PATIENT. You can order the optional kit.


Cabine
5,10m
T
PCT-PCG
CC
TV
ARG

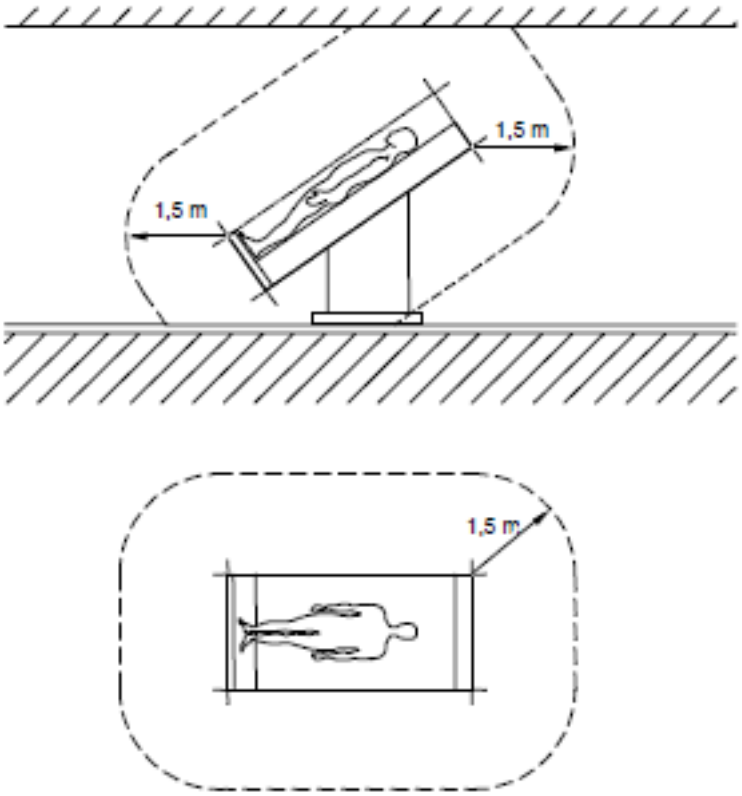
PATIENT ENVIRONMENT

✓ Devices installed in the patient environment are restricted to electrical medical devices conforming to IEC60601-1 3rd edition.

✓ The patient environment described below is an example cited from the IEC60601-1 3rd edition. The measurements are only guidelines. However, the IEC60601-1 3rd edition example must be treated as the standard.

✓ However, computer unit (PC and monitor) of digital system must be installed in an area outside the area described below (outside the patient environment).
However, the power box, the second monitor in X-ray room and the secondary console can be found in the patient's environment.

INSIDE THE PATIENTENVIRONMENT	OUTSIDE THE PATIENT ENVIRONMENT
Room fluoroscopy monitor	Table console
4 screens option	Transformer 110V/230V TR (only for UL version)
Remote controlled table and collimator	Canon computer
Digital detector	
X-ray tube assembly	
Measuring dose device	
Generator cabinet	
Digital detector power box	
Secondary console	



Note: the dimensions in the figure show minimum extent of the PATIENT ENVIRONMENT in a free surrounding.

6. DETAILLED LISTS OF ASSEMBLY PROCEDURES

Depending on the installation contraints, the remote-controlled table will be delivered disassembled with different packing size.

Contact your local representative for detailed packing size and installation instructions.