



## **D²RS**

**Standard version**



## **D²RS 9090**

**Version with +/-90° table tilting**

**Digital Remote Controlled System with CANON dynamic flat panel detector**

### **Preface to the user's manual**

#### **SOFTWARE VERSIONS**

Shell software:

Control board software:

Control Console software:

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Tel: 00 33 4 77 47 81 60  
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# D<sup>2</sup>RS

## D<sup>2</sup>RS 9090

**Please read the whole documentation before using the medical device**



## REVISIONS HISTORY

| Revision | Date             | Reason for change                                                                                                                                                                        |
|----------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0        | 30 January 2015  | First edition<br>of reorganisation of the<br>manuals                                                                                                                                     |
| 1        | 12 February 2016 | New X-ray tubes<br>Graphical modification of<br>interface<br>CSA labels<br>Intervention Safety<br>Guepel Support<br>Acquisition console screen<br>Collimator key<br>Control footswitches |
| 2        | 09 October 2017  | New logo<br>Compression<br>Error Messages<br>Vigilance Message                                                                                                                           |
| 3        | 27 July 2018     | New computer<br>VAREX name                                                                                                                                                               |
| 4        | 08 November 2019 | New Table console                                                                                                                                                                        |
| 4-1      | 30 March 2020    | CE1639                                                                                                                                                                                   |
| 5        | 31 July 2020     | New design<br>New detector<br>Version with +/-90° tilting                                                                                                                                |
|          |                  |                                                                                                                                                                                          |

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.

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The CE mark on the system 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 of document: FRENCH

## **1 - SYSTEM INFORMATION**

### **1 – 1 Symbols**

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

| Symbol                                                                              | Description                                                                  |
|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 3N~                                                                                 | Three-phase alternating current with neutral conductor                       |
|    | 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                                                               |
|  | Not allowed for pregnant women                                               |

**1 – 2 System configuration**

| System elements                          | Type                         | Brand     | Title of corresponding user manual                                                                                |
|------------------------------------------|------------------------------|-----------|-------------------------------------------------------------------------------------------------------------------|
| Remote controlled Table (standard)       | D <sup>2</sup> RS            | STEPHANIX | Digital Remote Controlled Table with dynamic flat panel detector<br>USER'S MANUAL<br>Preface to the user's manual |
| Remote controlled Table (+/-90° version) | D <sup>2</sup> RS 9090       | STEPHANIX |                                                                                                                   |
| Console                                  | Console CC-XR_RCS            | STEPHANIX |                                                                                                                   |
| Secondary console                        | Secondary console CC2-XR_RCS | STEPHANIX |                                                                                                                   |
| Screen of table console                  | Touch screen 1002L           | ELO       |                                                                                                                   |
| Collimator                               | R225 ACS                     | RALCO     |                                                                                                                   |
| X-ray tube                               | RTM101 with C100XT housing   | IAE       | Tube documentation – RTM101<br>Tube assembly documentation – C100XT<br>X-ray tube assembly                        |
|                                          | RTC600 with C100XT housing   | IAE       | Tube documentation – RTC600<br>Tube assembly documentation – C100XT<br>X-ray tube assembly                        |
|                                          | RTC700 with C100XT housing   | IAE       | Tube documentation – RTC700<br>Tube assembly documentation – C100XT<br>X-ray tube assembly                        |
|                                          | RTC1000 with C100XT housing  | IAE       | Tube documentation – RTM101<br>Tube assembly documentation – C100XT<br>X-ray tube assembly                        |
|                                          | A-292 avec gaine B-147       | VAREX     | Tube documentation A-292 with B-147 housing                                                                       |
|                                          | G-292 avec gaine B-147       | VAREX     | Tube documentation G-292 with B-147 housing                                                                       |
|                                          | G-296 avec gaine B-147       | VAREX     | Tube documentation G-296 with B-147 housing                                                                       |
|                                          | G-892 avec gaine B-147       | VAREX     | Tube documentation G-892 with B-147 housing                                                                       |
|                                          | G-896 avec gaine B-147       | VAREX     | Tube documentation G-896 with B-147 housing                                                                       |

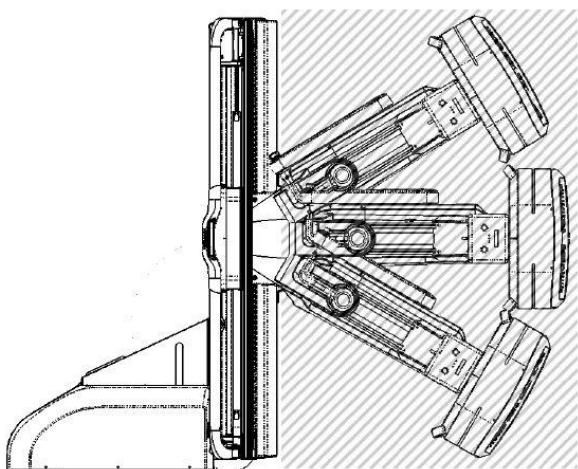
| <b>System elements</b>                | <b>Type</b>                            | <b>Brand</b> | <b>Title of corresponding user manual</b>                                                 |
|---------------------------------------|----------------------------------------|--------------|-------------------------------------------------------------------------------------------|
| Generator                             | N50HF-N                                | STEPHANIX    | Operation<br>HF Series generators<br>Generator Console for<br>CXDI Control Software<br>RF |
|                                       | N65HF-N                                | STEPHANIX    |                                                                                           |
|                                       | N80HF-N                                | STEPHANIX    |                                                                                           |
|                                       | N50HF                                  | STEPHANIX    |                                                                                           |
|                                       | N65HF                                  | STEPHANIX    |                                                                                           |
|                                       | N80HF                                  | STEPHANIX    |                                                                                           |
| Digital system                        | Computer PC unit                       | INFODIP      | Installation guide                                                                        |
|                                       | Computer Screen                        | EIZO         | Installation manual                                                                       |
|                                       | CCS_RF software<br>(user interface)    | CANON        | CXDI Controller RF                                                                        |
|                                       | CXDI-50RF Flat Panel<br>Detector (FPD) | CANON        | Dynamic/Static DR<br>CXDI-50RF<br>User's Manual<br>For System Integrator's<br>Reference   |
|                                       | B1 Flat Panel Detector<br>(FPD)        | CANON        | Dynamic/Static DR<br>B1<br>User's Manual<br>For System Integrator's<br>Reference          |
|                                       | Power box                              | CANON        | Dynamic/Static DR<br>Power Box<br>User's Manual<br>For System Integrator's<br>Reference   |
| Transformer<br>(for CSA version)      | 01240802                               | ABL TRANSFO  | NA                                                                                        |
| Transformer<br>(for CSA 9090 version) | MUSP 16F43WD                           | T-MARY       | NA                                                                                        |

**1 – 3 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.

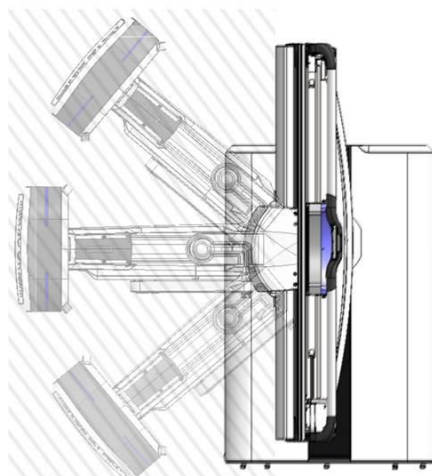
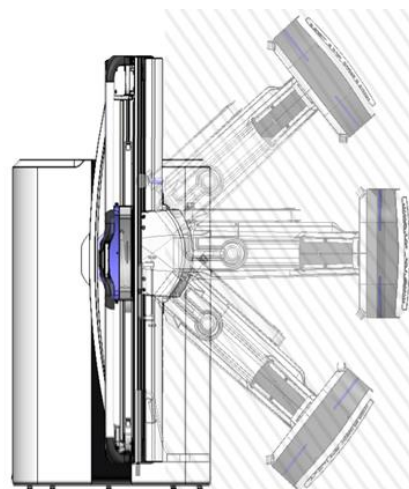
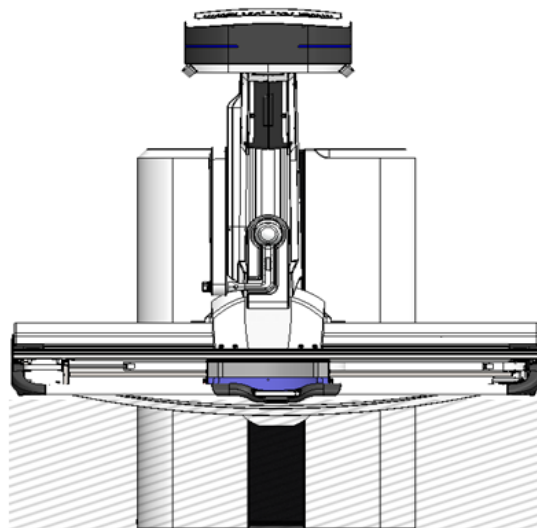
**D<sup>2</sup>RS**

**Standard version**



**D<sup>2</sup>RS 9090**

**Version with +/-90° table tilting**





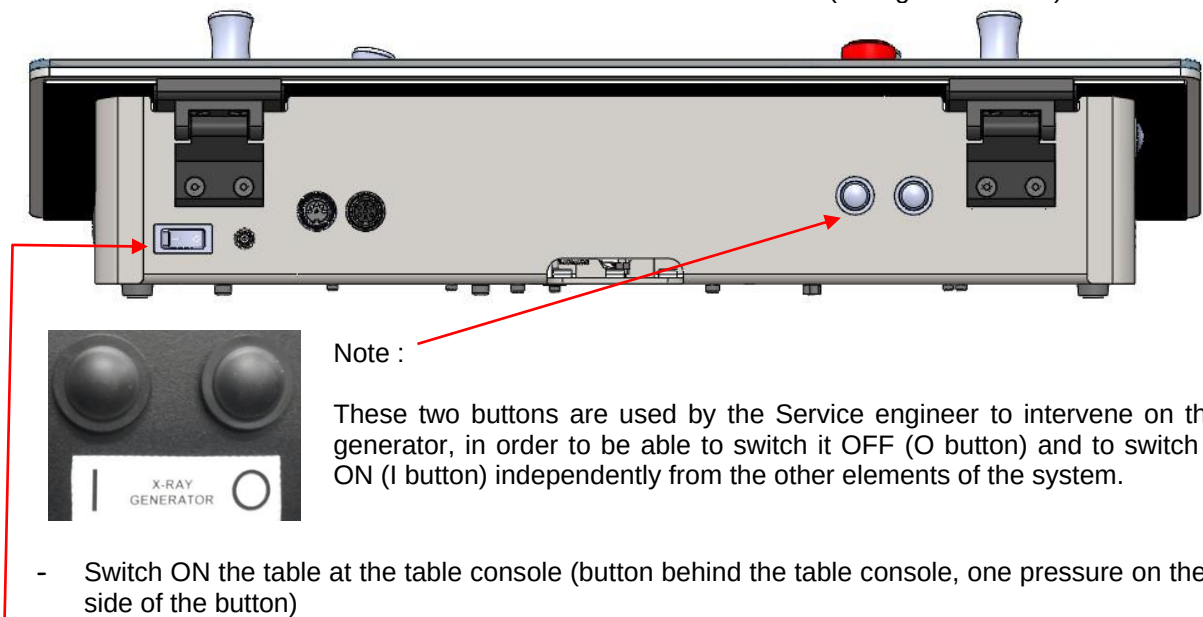
## 1 – 4 System switch on and off



### - Switch ON

**Note:** it is important to respect the order of startup.

- Switch ON the Power buttons on wall « Table and Generator » (red light indicators)

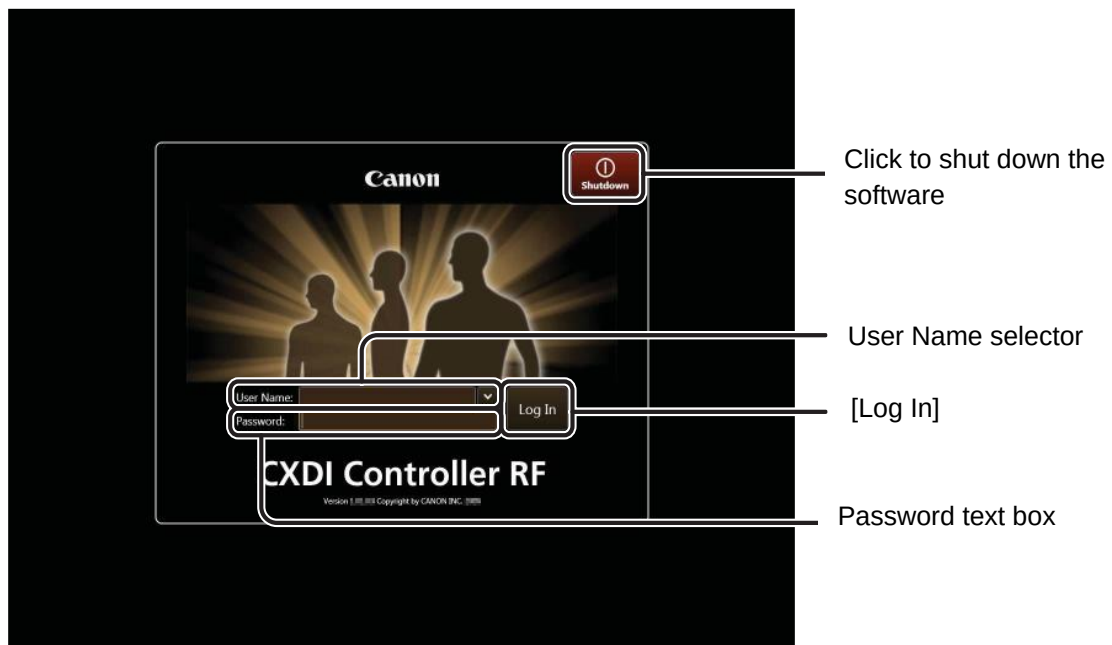


Note :

These two buttons are used by the Service engineer to intervene on the generator, in order to be able to switch it OFF (O button) and to switch it ON (I button) independently from the other elements of the system.

- Switch ON the table at the table console (button behind the table console, one pressure on the I side of the button)

- The button  on the front of the console turns green when the console is powered on, at 10% of the light intensity capacity.
- Switch on the system by pressing the button  on the front of the console for one second: it flashes green while communication is establishing between the table console and the table.
- The button  no longer flashes and remains green at 100% of the light intensity capacity when communication is established. All leds are lit at 10% of the light intensity capacity and confirm that the table console is ready for use.  
If some leds are off, it may mean that the corresponding movement is off.  
Contact Service department if necessary.
- The LCD touch screen displays Table and Generator interfaces (refer to corresponding chapter)
- Turn on the PC (and the screen) that will automatically start acquisition software
- Enter the password when requested



- Remember to check that the detector is turned on (blue LED on the detector)
- The system is now ready to use (no heating or calibration required, except x-ray tube warm-up)

**Warning: Beware; the error messages should never be ignored. Indeed, ignoring an error message can have serious consequences, such as loss of patient images.**

#### - Switch OFF

- Start by turning OFF the User interface software  
To do this, go to settings

Then, "Turn off" (red button at the top right)

The computer turns off then alone.

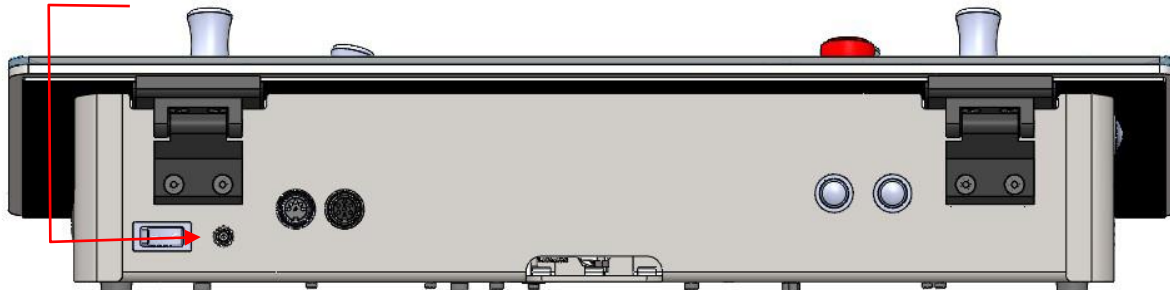


- By a short pressure (one second) on the button  on the front of the console, this button remains green at 10% of the light intensity capacity, you turn off the table and the generator and you put in stand-by the table console (its internal PC). The light strip of the console turns off.  
OR,
- By a long pressure (three seconds) on the button  on the front of the console, this button remains green at 10% of the light intensity capacity, you turn off the table console (its internal PC), the table and the generator. The light strip of the console turns off.



All buttons and LCD screen turn off.

- Switch OFF the table console with the same button as the switching on (button behind the table console), but this time by making a pressure on the O side.



- Finish by switching OFF the Power buttons on wall « Table and Generator » (green light indicators).

**For more details concerning switching on / OFF for each element of the system, please refer to corresponding chapters in user's manuals of table, generator interface and digital system.**

## **1 – 5 Cleaning and disinfection**



***Warning: Turn off the equipment and disconnect the electrical supply before starting any cleaning or disinfection operations.***

### **GENERAL CLEANING INSTRUCTIONS:**

For any equipment, always clean painted or enameled parts by means of a soft and clean cotton cloth. Dampen the cloth with tepid water and/or mild detergent. Then, you should wipe the equipment with a dry cotton cloth.

*Do not use any abrasive powder, nor organic solvents, neither liquid detergent containing solvents (petrol, alcohol, stain removers) which could damage the materials.*

Do not immerse equipment parts that enclose electrical components. You should rather use a soft dampened cloth, taking care not to allow liquids to enter the equipment.

### **GENERAL DISINFECTION INSTRUCTIONS:**

In order to prevent any patient contamination, before each procedure, always clean parts of the equipment which are in contact with the patient with a bacterial, germicidal and antiviral solution.

If the room containing the equipment needs to be disinfected with an atomizer, it is recommended to follow these specific instructions:

- Switch all the equipment parts OFF.
- Allow them to cool down.
- Cover them with a plastic sheet

When the disinfectant mist has subsided, the plastic sheet may be removed and the equipment be disinfected by wiping.

Methods of disinfection used must conform to legal regulations and guidelines regarding disinfection and explosion protection.

### **CAUTION:**

Use the least possible amount of cleaning fluids. The fluids must not flow or run in or on the elements that compose the system.

If more than soap and water is required, it is recommended any one of the following:

- 10% chlorine bleach solution and water with one part commercially available chlorine bleach solution and nine parts water
- Commercially available isopropyl alcohol solution (70% isopropyl alcohol by volume, not diluted)
- 3% maximum concentration of hydrogen peroxide solution.

After you apply any of the above solutions, use a pad and apply a soapy solution to clean any parts that touch the patient.

### **Caution :**

To prevent damage to the electronic components, do not use disinfectant sprays on the system.

### **TO PREVENT POSSIBLE INJURY OR EQUIPMENT DAMAGE**

Do not use a corrosive solvent, abrasive detergent, or polish.

Select a cleaning/disinfecting agent that does not damage the elements of the apparatus such as plastics, aluminum, and carbon fiber parts.

Do not use strong detergents, abrasive cleaners, high alcohol concentration, or methanol at any concentration.

Do not expose equipment parts to steam or high temperature sterilization.

Do not let liquids enter the internal parts of the equipment.

Do not apply cleaning sprays

Preface to the user's manual

or liquids to the equipment. Always use a clean cloth and apply the spray or liquid to the cloth. If liquid enters the system, disconnect the electrical supply and examine the system before returning it to use.

**CAUTION**

Wrong cleaning methods can damage the equipment, decrease imaging performance, or increase the risk of electric shock.

Always follow instructions from the manufacturer of the product you use for cleaning.

The instructions include the directions and precautions for the application and contact time, storage, wash requirements, protective clothing, shelf life, and disposal. Follow the instructions and use the product in the most safe and effective method.

**SPECIFIC INSTRUCTIONS:**

**REMOTE CONTROL TABLE**

In order to clean chromium-plated parts, wipe them with a soft dry cotton cloth.

*Do not use any corrosive or abrasive polishes.*

The equipment, accessories and cables can be disinfected by wiping them with rag dampened with a disinfecting solution

*In any case, the remote controlled system is never to be exposed to any disinfecting gas.*

*Disinfection by spraying should be banned since the disinfectant may enter the equipment.*

If disinfectants which form explosive mixtures of gases are used, these gases must have evaporated before switching on the equipment again.

**RX GENERATOR**

Clean the equipment frequently, particularly if corroding chemicals are present.

*NEVER ATTEMPT TO CLEAN ANY PART OF THE UNIT WHEN IT IS SWITCHED ON.*

*DO NOT REMOVE ANY COVER, DISASSEMBLE OR MANIPULATE INTERNAL COMPONENTS IN THE UNIT.*

Never use anything other than soap and water to clean plastic surfaces. Other cleaners may damage the plastic.

Never use any corrosive, abrasive or solvent detergents or polishes.

Disinfection by spraying is not recommended because the disinfectant may enter the X-Ray generator.

If disinfectants which form explosive mixtures of gases are used, these gases must have evaporated before switching on the equipment again.

**CONSOLES, SCREENS AND PC CABINET**

External surfaces should be wiped to remove any foreign material that may have accumulated.

Painted surfaces should be cleaned using a clean cloth slightly moistened with a good mild cleaner.

Use a clean, soft cloth to wipe off any dirt or dust on the outside of the cabinet.

Use care when cleaning the outer surface of the LCD screen. Always use a clean, soft, lint-free cloth to clean the display area. Microfiber cloths are recommended.

- Never use a spray or flow a liquid
- Never apply any pressure to the display area
- Never use a detergent with fluorides, ammonia, alcohol, or abrasives
- Never use any bleach
- Never use any steel wool nor a sponge with abrasives

### Preface to the user's manual

There are many commercially available products to clean LCD displays. Any of the products free of the ingredients described above and used according to the directions of the manufacturer can be used.

Use a window or glass cleaning product to clean the screen. Apply the cleaning product to a cloth, then clean the screen. Do not apply the cleaning product to the screen without the cloth.

## FLAT PANEL DETECTOR

### COVER

When the instrument is going to be cleaned, be sure to turn OFF the power of each instrument, and unplug the power cable from the AC outlet.

Never use alcohol, benzine, thinner or any other flammable cleaning agents. Otherwise, fire or electric shock may result.

Clean the cover by the following procedure if it is dirty.

**(1)** Turn OFF the power of the power box.

Shut down the image capture computer, and press side "0" of the power switch.

**(2)** Turn OFF the power of each instrument.

Turn OFF the power of each instrument if connected.

**(3)** Unplug the power cables.

Unplug the power cables of each instrument from the AC outlet.

**(4)** Wipe the cover using neutral detergent.

Wipe the cover with a piece of cloth soaked in neutral detergent diluted in water and wrung dry.

**(5)** Wipe out neutral detergent.

Wipe the cover with a piece of cloth soaked in water and wrung dry whenever neutral detergent has been used.

### CFRP (Carbon Fiber Reinforced Plastic) Plate of the Detector Unit

Wipe the CFRP plate of the detector unit with ethanol or glutaraldehyde solution to disinfect it each time a different patient uses the instrument, in order to prevent infection.

If the optional grid unit is being used, disinfect its surface.

Please consult a specialist for the procedure for disinfection.

If you are using disinfectant other than those specified above, or you are mixing another disinfectant with ethanol, please also consult a specialist, because they may harm the CFRP plate and grid unit.

Disinfect the CFRP plate of the detector unit each time a different patient uses the instrument. If the optional grid unit is being used, disinfect its surface.

## **1 – 6 Environmental Specifications**

| Component<br>Of the<br>System | TRANSPORT AND STORAGE |       |                                       |      |                      |         |
|-------------------------------|-----------------------|-------|---------------------------------------|------|----------------------|---------|
|                               | Temperature           |       | Relative humidity<br>(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                 | +75°C | 30%                                   | 75%  | 700hPa               | 1060hPa |
| X-ray tube                    | -10°C                 | +80°C |                                       | 80%  | 700hPa               | 1050hPa |
| Generator                     | -40°C                 | +70°C | 10%                                   | 100% | 500hPa               | 1060hPa |
| Detector                      | -30°C                 | +50°C | 10%                                   | 95%  | 700hPa               | 1060hPa |
| Power box                     | -30°C                 | +50°C | 10%                                   | 95%  | 700hPa               | 1060hPa |
| Transformer                   | -20°C                 | +60°C | 10%                                   | 75%  | 700hPa               | 1060hPa |

| Component<br>Of the<br>System | IN-USE      |       |                                       |     |                      |         |
|-------------------------------|-------------|-------|---------------------------------------|-----|----------------------|---------|
|                               | Temperature |       | Relative humidity<br>(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 | 30%                                   | 75% | 760hPa               | 1060hPa |
| X-ray tube                    | +5°C        | +40°C |                                       | 80% | 760hPa               | 1050hPa |
| Generator                     | +10°C       | +35°C | 30%                                   | 75% | 760hPa               | 1060hPa |
| Detector                      | +5°C        | +35°C | 30%                                   | 80% | 760hPa               | 1060hPa |
| Power box                     | +5°C        | +35°C | 30%                                   | 80% | 760hPa               | 1060hPa |
| Transformer                   | +10°C       | +35°C | 30%                                   | 75% | 760hPa               | 1060hPa |

### **Transport conditions**

The merchandises travel at the recipient's risks.

Any dispute for losses or damage caused during the transport shall be mentioned in presence of the carrier during the delivery and indicated on the delivery notice.

Packaging made by the manufacturer mustn't be used in any case for any other purpose that transport.

## **1 – 7 Accessories**

### **STANDARD ACCESSORIES:**

Remote Control; Compression belt and winches; footrest; stool; handles; double fluoroscopy pedal

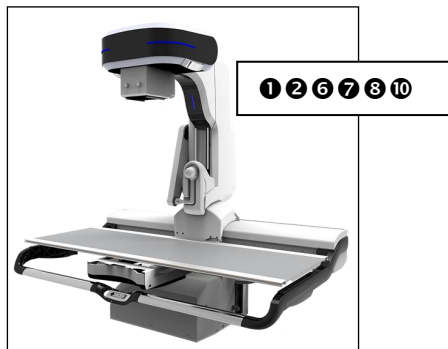
### **OPTIONAL ACCESSORIES:**

Triple fluoroscopy pedal; cup-holder; pair of shoulder rests; pair of gynaecology stirrups; pair of leg supports of Guepel ; retaining bar; IV-Pole; Multi FPD lateral support; 1m ruler for stitching; Ruler support for stitching; 10cm ruler for measuring; secondary console

### 2 - LABELLING

Labels identify the different components of the table (see examples below) according to the requirements of international standards.

**Note: the control cabinet components are integrated into the table**



Standard Version



+/- 90° Version



Capacitive control console

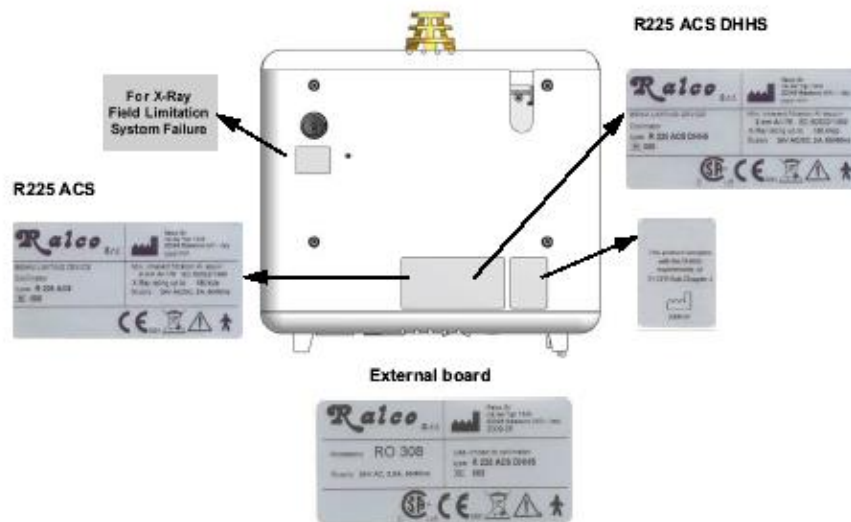


Transformer

| For CSA version |  |    |  |
|-----------------|--|----|--|
| 1               |  | 1  |  |
| 2               |  | 2  |  |
| 3               |  | 3  |  |
| 4               |  | 4  |  |
| 5               |  | 5  |  |
|                 |  | 9  |  |
| 6               |  | 9  |  |
| 7               |  | 10 |  |
| 8               |  |    |  |



Preface to the user's manual



**LABEL 1:**  
CAUTION, LASER RADIATION,  
DO NOT LOOK AT THE BEAM  
DIRECTLY

**LABEL 2:**  
Warns of the danger of the  
laser beam

**LABEL 3:**  
Indicates the OPENING from  
where the LASER beam goes  
out.

**LABEL 4:**  
AVOID ANY LASER RADIATION  
EMITTED FROM THAT OPENING  
CLOSED                      OPEN

**LABEL 5:**  
CAUTION, LASER RADIATION,  
DO NOT LOOK AT THE BEAM  
DIRECTLY

**CE Laser labels**

**LABEL 1**



**LABEL 3**



**LABEL 5**



**LABEL 2**



**LABEL 4**



**FDA Laser labels**

**LABEL 1**

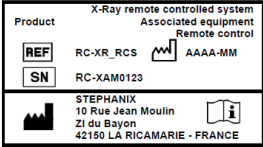
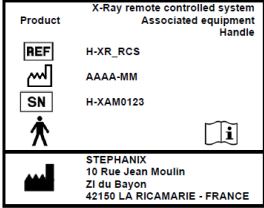
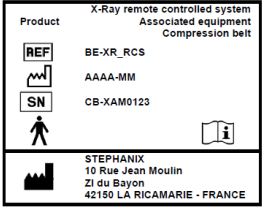
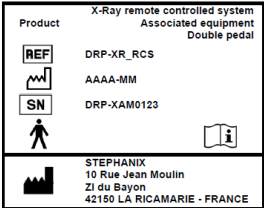
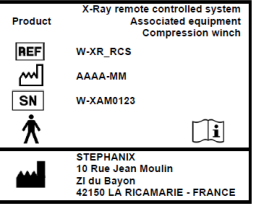
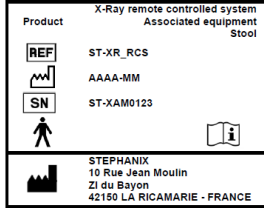
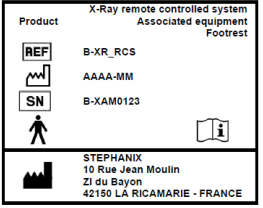


### CAUTION

**Use only the following accessories provided by the manufacturer:**

#### STANDARD ACCESSORIES:

Remote Control; Compression belt and winches; footrest; stool; handles; double fluoroscopy pedal

|                                                                                                                                  |                                                                                     |                                                                                                                  |                                                                                       |
|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| <b>Remote control</b><br>                       |    | <b>Handles</b><br>             |    |
| <b>Compression belt (label on packing)</b><br> |   | <b>Double fluoro pedal</b><br> |    |
| <b>Compression winches</b><br>                |  | <b>Stool</b><br>             |  |
| <b>Footrest</b><br>                           |  |                                                                                                                  |                                                                                       |

#### OPTIONAL ACCESSORIES:

Triple fluoroscopy pedal; cup-holder; pair of shoulder rests; pair of gynaecology stirrups; pair of leg supports of Guepel; retaining bar; IV-Pole; Multi FPD lateral support; 1m ruler for stitching; Ruler support for stitching; 10cm ruler for measuring; secondary console

## Preface to the user's manual

|                                                                                                                                       |                                                                                                                                                                                                                                              |                                                                                                                                       |                                                                                                                                                                                                                                                                                     |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Triple fluoro pedal (for versions with CINE)</p>  | <p>Product X-Ray remote controlled system<br/>Associated equipment Triple radioscopes pedal</p> <p>REF TRP-XR_RCS<br/>AAAA-MM<br/>SN TRP-XAM0123</p> <p>STEPHANIX<br/>10 Rue Jean Moulin<br/>ZI du Bayon<br/>42150 LA RICAMARIE - FRANCE</p> | <p>Retaining bar</p>                                | <p>Product X-Ray remote controlled system<br/>Associated equipment Retaining bar</p> <p>REF R-XR_RCS<br/>AAAA-MM<br/>SN R-XAM0123</p> <p>STEPHANIX<br/>10 Rue Jean Moulin<br/>ZI du Bayon<br/>42150 LA RICAMARIE - FRANCE</p>                                                       |
| <p>Cup holder (label on packing) *</p>               | <p>Product X-Ray remote controlled system<br/>Associated equipment Cup holder</p> <p>REF CH-XR_RCS<br/>AAAA-MM<br/>SN CH-XAM0123</p> <p>STEPHANIX<br/>10 Rue Jean Moulin<br/>ZI du Bayon<br/>42150 LA RICAMARIE - FRANCE</p>                 | <p>IV-pole</p>                                      | <p>Product X-Ray remote controlled system<br/>Associated equipment Intravenous pole</p> <p>REF IVP-XR_RCS<br/>AAAA-MM<br/>SN IVP-XAM0123</p> <p>STEPHANIX<br/>10 Rue Jean Moulin<br/>ZI du Bayon<br/>42150 LA RICAMARIE - FRANCE</p>                                                |
| <p>Pair of shoulder rests</p>                       | <p>Product X-Ray remote controlled system<br/>Associated equipment Pair of shoulder rests</p> <p>REF SH-XR_RCS<br/>AAAA-MM<br/>SN SH-XAM0123</p> <p>STEPHANIX<br/>10 Rue Jean Moulin<br/>ZI du Bayon<br/>42150 LA RICAMARIE - FRANCE</p>     | <p>FPD lateral support</p>                         | <p>Product X-Ray remote controlled system<br/>Associated equipment Multi FPD lateral support</p> <p>REF FPD-XR_RCS<br/>AAAA-MM<br/>SN FPD-XAM0123</p> <p>STEPHANIX<br/>10 Rue Jean Moulin<br/>ZI du Bayon<br/>42150 LA RICAMARIE - FRANCE</p>                                       |
| <p>Pair of gynecology stirrups</p>                 | <p>Product X-Ray remote controlled system<br/>Associated equipment Pair of gynaecology stirrups</p> <p>REF G-XR_RCS<br/>AAAA-MM<br/>SN G-XAM0123</p> <p>STEPHANIX<br/>10 Rue Jean Moulin<br/>ZI du Bayon<br/>42150 LA RICAMARIE - FRANCE</p> | <p>1m ruler for stitching (label on packing)</p>  | <p>Product X-Ray remote controlled system<br/>Associated equipment 1m ruler for stitching</p> <p>REF R1-XR_RCS<br/>AAAA-MM<br/>SN R1-XAM0123</p> <p>STEPHANIX<br/>10 Rue Jean Moulin<br/>ZI du Bayon<br/>42150 LA RICAMARIE - FRANCE</p>                                            |
| <p>Pair of leg supports of Guepel</p>              | <p>Product X-Ray remote controlled system<br/>Associated equipment Support legs of Guepel</p> <p>REF SLG-XR_RCS<br/>AAAA-MM<br/>SN SLG-XAM0123</p> <p>STEPHANIX<br/>10 Rue Jean Moulin<br/>ZI du Bayon<br/>42150 LA RICAMARIE - FRANCE</p>   | <p>Ruler support for stitching</p>                | <p>Product X-Ray remote controlled system<br/>Associated equipment Ruler support for stitching</p> <p>REF S1-XR_RCS<br/>AAAA-MM<br/>SN S1-XAM0123</p> <p>STEPHANIX<br/>10 Rue Jean Moulin<br/>ZI du Bayon<br/>42150 LA RICAMARIE - FRANCE</p>                                       |
| <p>10cm ruler for measuring</p>                    | <p>Product X-Ray remote controlled system<br/>Associated equipment 10cm ruler for measuring</p> <p>REF R2-XR_RCS<br/>AAAA-MM<br/>SN R2-XAM0123</p> <p>STEPHANIX<br/>10 Rue Jean Moulin<br/>ZI du Bayon<br/>42150 LA RICAMARIE - FRANCE</p>   | <p>Secondary console</p>                          | <p>Product X-Ray remote controlled system<br/>Associated equipment Secondary Capacitive Console</p> <p>Voltage 12VDC<br/>Intensity 5A<br/>REF CC2-XR_RCS<br/>AAAA-MM<br/>SN CC2-XAM0123</p> <p>STEPHANIX<br/>10 Rue Jean Moulin<br/>ZI du Bayon<br/>42150 LA RICAMARIE - FRANCE</p> |

\* for cup holder, use a lightweight cup only (plastic, cardboard) and do not fill more than 250 ml of liquid, that is to say an approximate weight of 250 g maximum

### **3 - RADIOPROTECTION AND IMAGING PERFORMANCE**

#### **3 – 1 Introduction**

##### Risks:

Risks associated with ionizing radiation depend on the dose delivered during an examination but also the accumulation of dose during several successive examinations. The purpose of radiation protection is to prevent or reduce these risks.

##### Nature of hazard:

The user is faced with the risks associated with ionizing radiation. Therefore, if the user does not respect safety regulations put in place, he can be exposed to a radiation hazard

##### Precautions:

Two main rules regarding radiation protection are daily implemented: justification and optimization.

The justification lies in the fact that, as with any medical procedure, the benefit must be greater than the risk. Although the risk of low doses is not demonstrated, caution is to consider that they can be responsible. Therefore the achievement of examination with ionizing radiation is well thought out and weighed.

The optimization of doses is the role of the users who need the least radiation necessary to obtain an examination to answer questions.

#### **3 – 2 Minimizing the possibility of exposing patients to radiation, optimising the radiation dose delivered to the patient and the operators**

To minimize the exposition of the patient to radiation, the following should be observed :

- collimate the radiated field to the minimum possible value.
- provide the patient with the best possible protection by using specific screens in leaded rubber if exposures are to be executed next to the patient genital organs.
- If the presence of a doctor or auxiliary personal near the patient during the X ray exams is required, they must wear the specific protective garments ( lead apron, gloves, thyroid shield, etc).
- If the presence of a doctor or auxiliary personal near the patient during the X ray exams is required, they must occupy only the significant zone of occupancy (see also the specific zone of occupancy section.
- wear your personal dosimeter.
- keep a proper distance from the X ray beam: The exposure should be done from the control desk which is normally placed behind a leaded shield, in this way the necessary distance to ensure an adequate protection is respected.

There are many ways to optimize the radiation delivered to the patient. Some General guidelines are:

- use the proper anti-scatter grid depending on the SID.
- use the spatial filters provided in the collimator

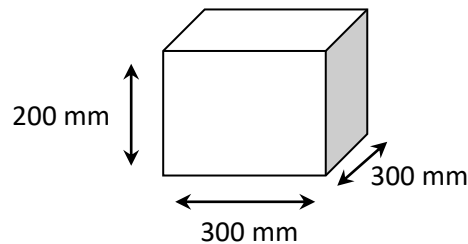
### **3 – 3 Quantitative information**

- For all the intended uses of the medical equipment, the radiation quantity delivered by the system is available to the user in terms of Dose Area Product (DAP) and AirKerma. The unit for the DAP in the system is mGy.cm<sup>2</sup>.

The unit for the Air Kerma is mGy.

This value is visible on the screen of the imaging system, next to the radiologic image. Depending on the imaging system, the accumulated DAP (also called Total DAP) and the accumulated Air Kerma are shown for the whole exam. In case of a static exposure (RAD exposure), the DAP for this exposure can also be shown, depending on the imaging system. More details about where the DAP and Total DAP is shown on the screen can be found in the imaging system user manual.

- A test object can be used to simulate an average patient. The object's total dimensions are:



The material used should be PMMA layers. If this is not available, you can use a plastic container filled with water (same thickness). When PMMA is used, the 20 cm thickness can be obtained by piling up several layers of PMMA.

- To measure the radiation quantity for the specified test object, proceed as follow:

For static RAD exposure:

Place the test object in the X-ray beam.

Set SID to 110 cm.

Start a new exam.

Set the collimator to get 20\*20 cms on the phantom entrance surface. Make sure that all three AEC chambers are selected and no spatial filter is set in the collimator. Set the exposure parameter to 70 kV.

Make a RAD exposure.

Read the Air Kerma displayed on the imaging system's screen.

For dynamic fluororoscopic exposure:

Place the test object in the Xray beam.

Set SID to 110 cms.

Start a new exam.

Set the collimator to get 20\*20 cms on the phantom entrance surface. Make sure that ABS is turned ON and no spatial filter is set in the collimator. Set exposure parameter to 15 fps

Make a fluoroscopic exposure for 20 seconds.

Read the Accumulated Air Kerma displayed on the imaging system's screen.

- In the above testing conditions, the displayed accumulated Air Kerma should be less than 10 mGy for RAD and less than 13 mGy for fluoroscopy.

- The main exposure settings having an impact on the radiation quantity delivered by the system are:

- the SID: the shorter the SID, the higher the dose.
- loading factors: the lower they are, the lower the dose will be. This is especially true for kVs
- fluoro mode of operation: Q-Detail should be kept OFF to keep the radiation quantity as low as possible. When Q-Detail is OFF, lowering the frame rate ("fps") will lead to a lower radiation quantity. When Q-Detail is turned ON, the radiation quantity will be the same regardless of the fps setting.

### **3 – 4 Dose indication**

The indications of the dose, as expressed in chapter 2 of this annex, are made on the imaging system screen. Usually, these indications are made on the corners of the Xray image. Refer to the specific imaging system user manual for more information.

### **3 – 5 Clinical protocols**

Upon installation and training, clinical protocols are preset in the system for body parts. These are set in order to get the best compromise between image quality and dose reduction. They constitute a recommendation to be applied directly. However, if needed, they can be modified by people who have been trained and have knowledge of the system. If such modifications are needed, contact the application specialist.

### **3 – 6 Automatic exposure control (AEC)**

The system is provided with AEC for radiography operation.

The nominal shortest irradiation time using AEC is 2 ms.

A way for the user to check the functioning of the AEC is by:

1. Insert a 1mm Cu plate on the rails at the Xrays output of the collimator
2. Set the exposure kV to 60 kV
3. Open collimator to 43 cm \* 36 cm
4. Set SID to 110 cm
5. Turn ON all 3 AEC.
6. Set backup time to 40 ms
7. Make a RAD exposure

The AEC must stop the exposure. In other words, there should be no error 50 (Backup Timer) message on the generator interface.

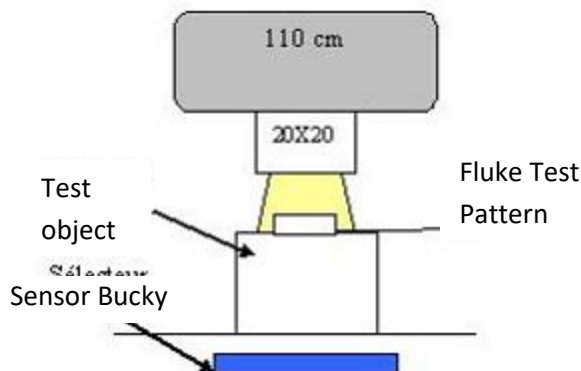
### 3 – 7 System Performance

The following procedure allows assessing the system performance.

*For Static imaging (RAD):*

Put 25mmAl or 20cm of PPMA in the center of the field, with the FLUKE Biomedical test pattern (ref 1-800-850-4608, 15x5cm) above at 45°.

Put SID at the lowest point. Collimation at 20cm side, 70kV to get a minimum dose level of EI = 250



Use the small focus and do an exposure after selecting the middle cell on the AEC. The visualization must be done in diagnostic console (not on the acquisition computer). Identify the last group of lines that can be distinguished.

You should be able to identify a resolution of at least 2 pl/mm.

*For Fluoroscopic image:*

Required equipment: test pattern FLUKE Biomedical 1-800-850-4608 (15\*5 cm).

Center the test pattern on the patient support, placed at 45° on the table top

SID set to 110 cms.

Work in auto fluoro if possible, the most used mode

Collimate the closest to the test pattern

Work in the standard conditions with minimum kV without added filters

Make a fluoro and identify the first group of lines merged on the screen

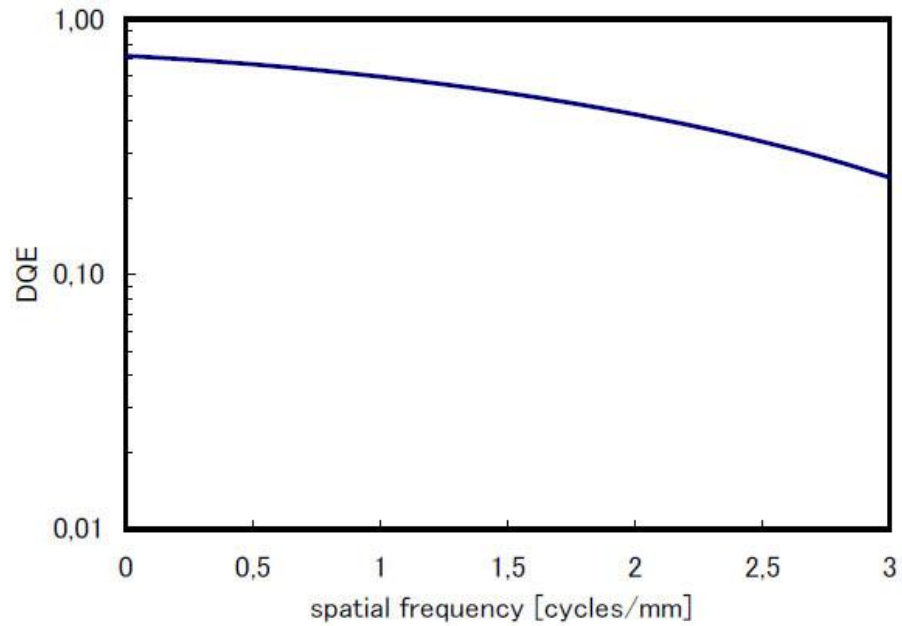
Depending on the chosen zoom, the minimum spatial resolution you should be able to read is:

| Zoom  | minimum spatial resolution |
|-------|----------------------------|
| 35X43 | 0,71                       |
| 35X35 | 0,90                       |
| 30X30 | 1,00                       |
| 23X23 | 1,40                       |

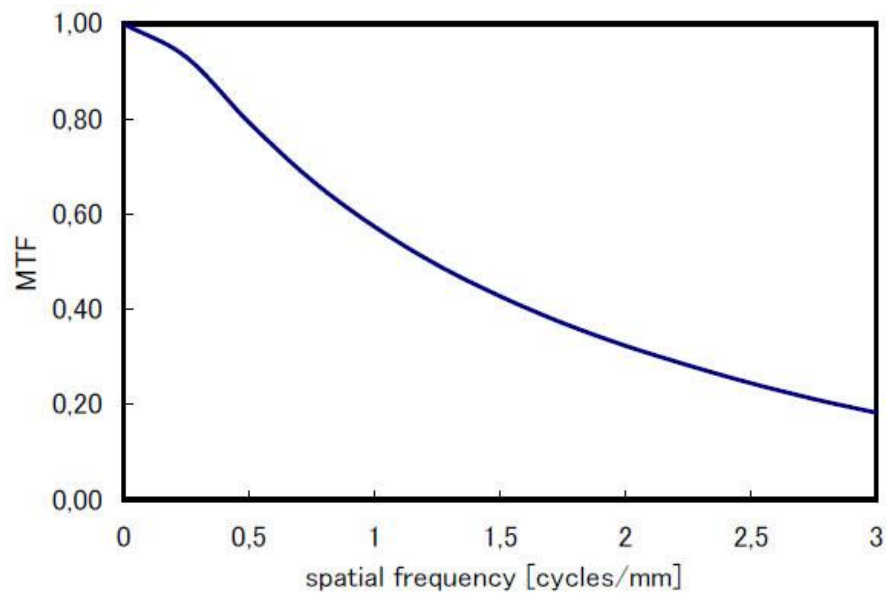
The digital X-ray image receptor integrated in the system contributes to the imaging performance. They are given here as pixel pitch, Detective Quantum Efficiency (DQE), Modulation Transfer Function (MTF):

➤ Pixel Pitch = 160  $\mu\text{m}$

➤ DQE:



➤ MTF :



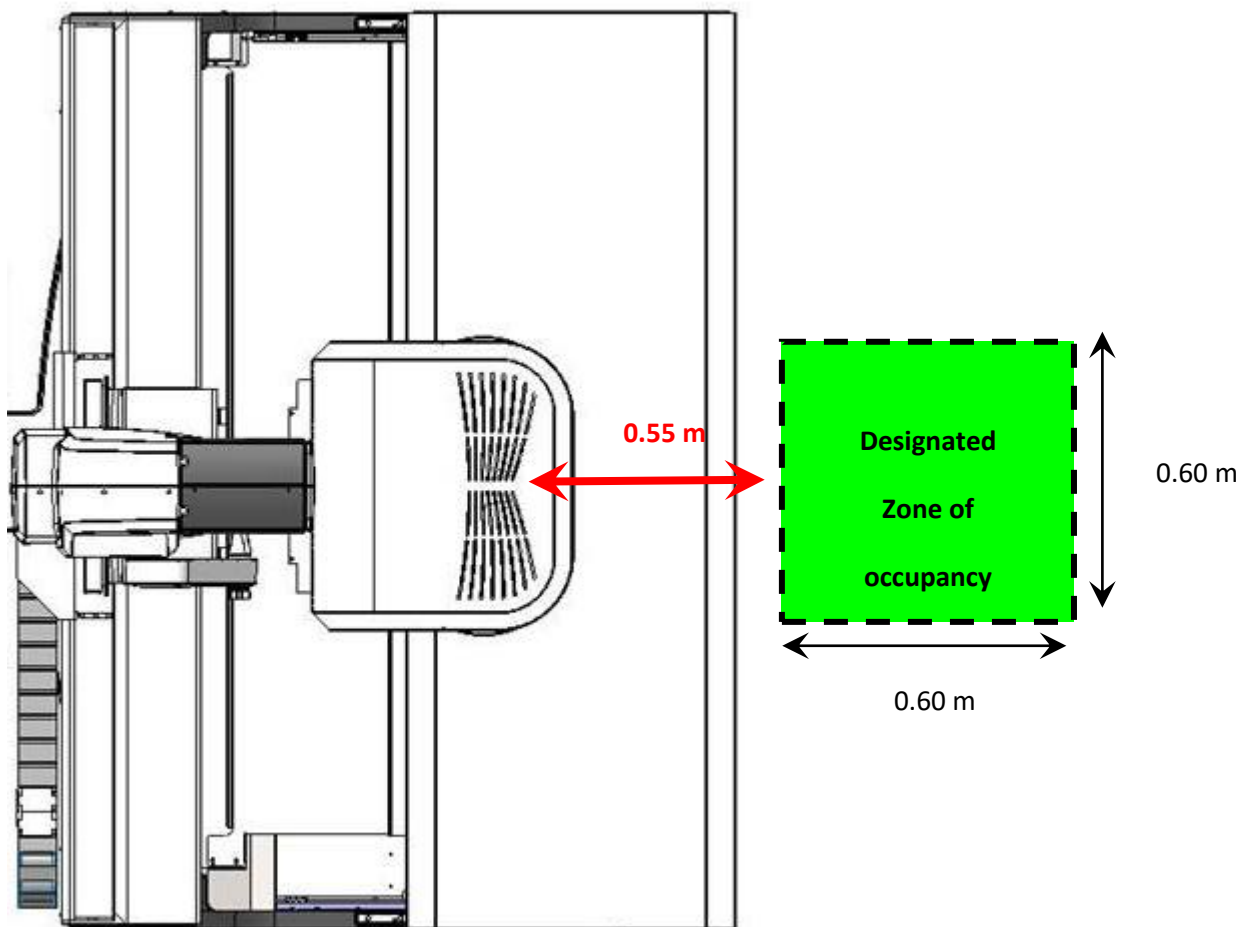


### **3 – 8 Designated significant zones of occupancy**

Some examinations, including but not limited to :

- Hystero-graphy
  - Arthro-graphy of joints such as shoulder, knee, wrist...
- may require the operator or staff to be close to the patient.

In this case, the operator or staff should work from the following designated significant zones of occupancy:

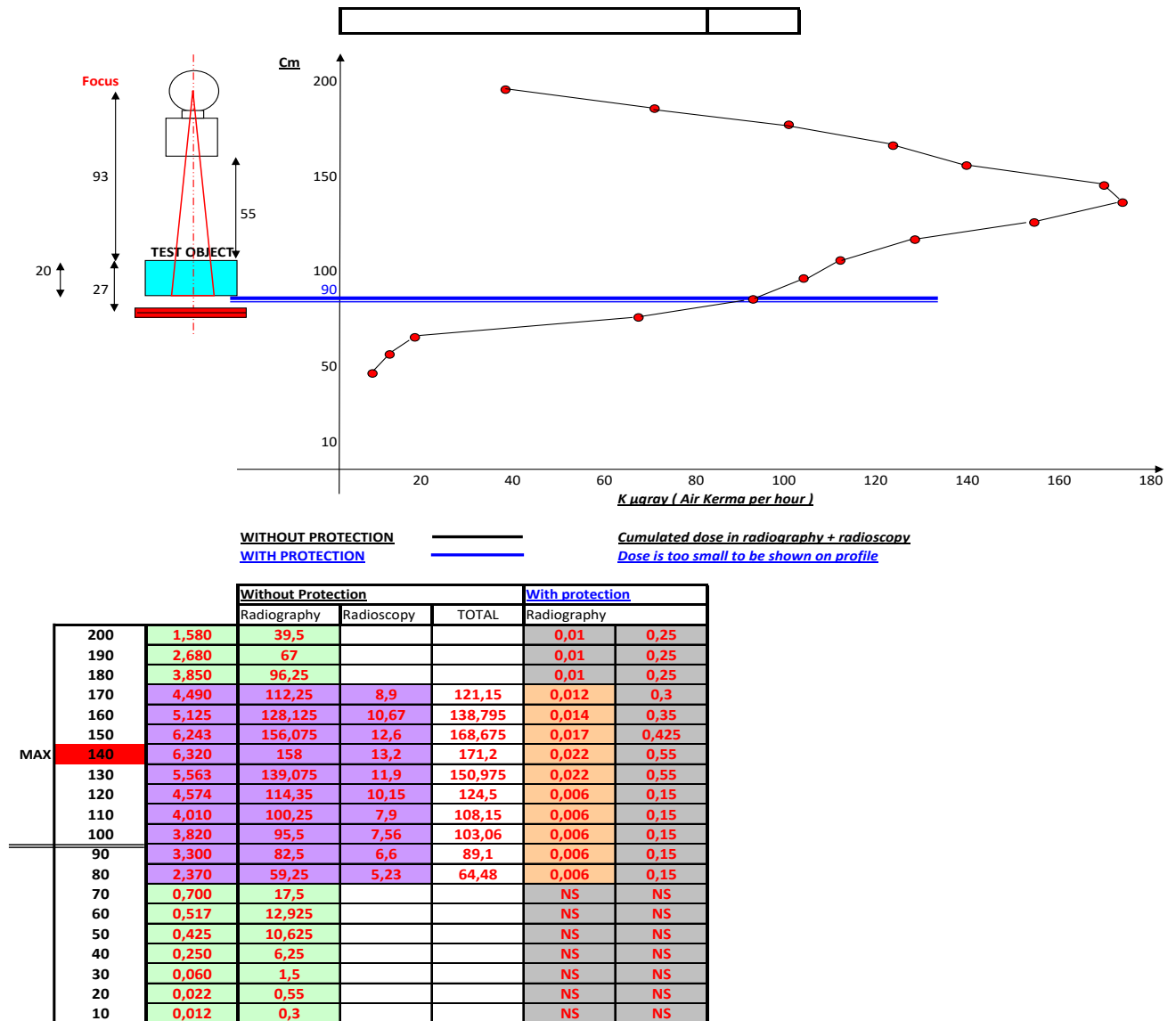


Wearing appropriate protection when present in the designated zone of occupancy reduces greatly the stray radiation received. Such protection includes leaded gloves, thyroid protection, apron etc.

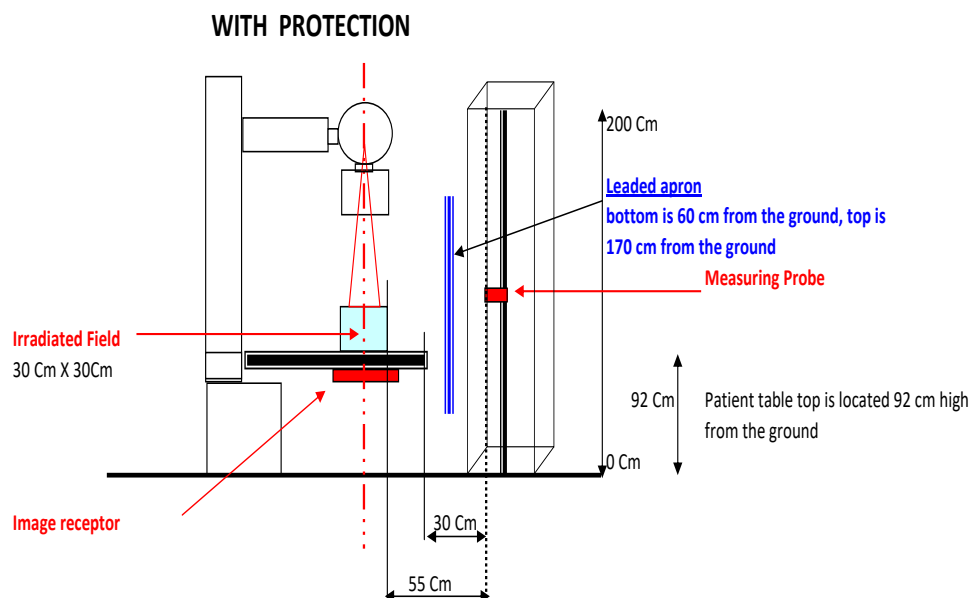
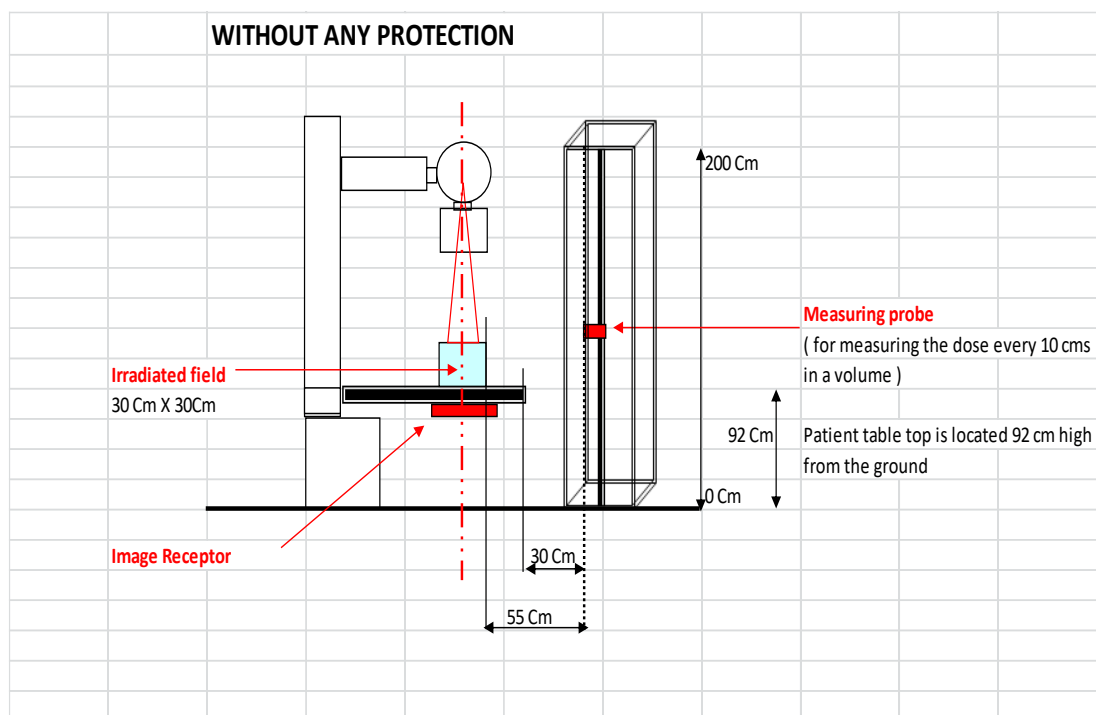
Also note that the use of the optional second console in room should be done within the significant zone of occupancy, or a greater distance from the x-ray beam.

The measures given in the next pages were made with no protection and with a “120 KV-Pb/le.0.5 mm” apron.

The profile of stray radiation in the significant zone of occupancy is as follows:

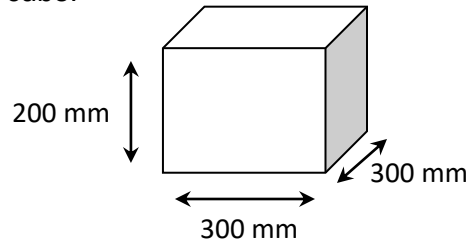


This profile was established using the following test arrangement:



Test Object:

30cm\*30cm\*20cm PMMA cube:



Irradiated field: 30cm \*30cm

Radiography loading factors:

- 80 kV
- 400 mA
- Large Focus
- AEC ON
- 16 mAs

Radioscopy loading factors :

- 87 kV
- 100 mA
- Small Focus
- ABS ON
- « High » curve selected
- 15 frames per second
- 5ms pulse width

No additional spatial filter.

In these conditions, the maximum dose output is 1.333 mGy/s

Using the worst the scenario where the most dose is delivered (hystero-graphy), 6 radiographic exposures are made, and 30 seconds of radioscopy. This averages to 25 radiographic exposures and 150 seconds of radioscopy per hour.

### **3 – 9 Dose levels**

Repetitive and prolonged exposure of the skin to X-rays may cause tissue reactions.

The skin dose levels can be lowered by following the recommendations in part 2

(Quantitative information) of this annex.

In this document, the patient entrance reference point is located 30 cm above the patient support.

The highest dose is delivered by the system when the following settings are set:

For Radioscopy:

- kV=120
- pps = 30
- Q Detail ON

For Radiography:

- kV=100
- mA = 500
- exposure time = 1000 ms
- mAs = 500
- AEC OFF

Minimum focal spot to image receptor distance of 110cm in normal use.

Maximum focal spot to image receptor distance of 180cm in normal use.

In these cases, the entrance skin dose level is 49.7 mGy for a single radiographic exposure and 59 mGy/mn for radioscopy.

There are three ABS curves that can be selected for automatic exposure regulation in radioscopy. The effect of these curves on the air kerma rate is the following:

|        |            | KERMA RATE mGy/min | KV  |
|--------|------------|--------------------|-----|
| LOW    | STD        | 24,98              | 103 |
|        | filtre 1   | 18,86              | 107 |
|        | coll 10x10 | 31,09              | 118 |
|        | 5pps       | 9,195              | 112 |
| MEDIUM | STD        | 35,4               | 120 |
|        | filtre 1   | 24,9               | 120 |
|        | coll 10x10 | 33,6               | 120 |
|        | 5pps       | 11,2               | 119 |
| HIGH   | STD        | 35,4               | 120 |
|        | filtre 1   | 24,6               | 120 |
|        | coll 10x10 | 34                 | 120 |
|        | 5pps       | 11,36              | 120 |

## 4 - TECHNICAL DATA

### **4 – 1 General**

#### ***MANUFACTURER***

STEPHANIX, 10 rue Jean Moulin, Z.I. du Bayon, 42150 LA RICAMARIE, FRANCE

#### ***MAINS***

Table, +90°/-25° version: 400 Vac, 50/60 Hz, three phases + neutral + ground, 5 kVA

Note: for 480V, the power is provided via an optional three-phase transformer 480V+N / 400V+N, 60 Hz

Table, +90°/-90° version: 230 Vac, 50/60 Hz, single phase

Note: for the 230Vac, the power is provided via an optional three-phase transformer 480V+N / 230V, 60 Hz

Table control console: 100/240Vac, 50/60 Hz, single phase

The power supply plug must be kept accessible in case to disconnect the console from power supply.

Digital system acquisition control console: 120/230Vac, 50/60 Hz, single phase

CLASS II EM EQUIPMENT with isolated internal screens

External means of isolation

Non-automatic discharging device for internal capacitors

Computer Network requirements for acquisition console, refer to corresponding DICOM Conformance Statements

#### ***DIMENSIONS AND WEIGHT***

Table, +90°/-25° version 226 x 159 x 216 cm minimum, table in horizontal position, lower tabletop height, minimum SID and column at 0°, 980 kg

Table, +90°/-90° version 226 x 235 x 189 cm minimum, table in horizontal position, lower tabletop height, minimum SID and column at 0°, 1600 kg

Table cabinet is integrated into the table

Table control console 60 x 27 x 12 cm, 15 kg

Table X-ray tube 52,4 x Ø 19 cm, 29 kg

Generator cabinet 60 x 36 x 69 cm, 95 kg

Generator control console is integrated into table console

Acquisition console /computer 18 x 45 x 47 cm, 9.8 kg

Acquisition console /colour LCD monitor 47 x 21 x 46 cm, 9.7 kg

### **4 – 2 Remote control table**

Class 1 equipment, Type B equipment

Caution! Consult inclosed documentation



#### ***TABLETOP***

Dimensions: 225 x 81 cm

Table, +90°/-25° version Variable Floor - tabletop distance motorised at 6 cm /s from 64 cm to 93 cm typically

Table, +90°/-90° version Variable Floor - tabletop distance motorised at 6 cm /s from 38 cm to 148 cm typically

Longitudinal movement motorized at 8 cm/s typically

Choice of movement between 120 / 60 cm or 50 / 50 cm or 70 / 30 cm

Lateral movement: motorized at 7 cm/s typically, clearance: + 180 mm / - 180 mm

The tabletop equivalent filtration is 0.55 mm Al at 100 kVp

Radiolucent width 600 mm

Accessories: two handles, two compression winches and the belt, one removable footrest, one stool

#### **TILTING**

Table, +90°/-25° version Incidence: + 90° / - 25° (+/- 0.5°);

Table, +90°/-90° version Incidence: + 90° / - 90° (+/- 0.5°);

Tilting time: 15 seconds from 0° to + 90° (+/- 2°), 6° /s typically

Collision safeties done by internal software

#### **4 – 3 Tube stand**

SID

Motorized at 6 cm /s typically with continuous speed from 110 cm to 180 cm

#### **TUBE ROTATION**

+/- 180° stop each 90° and electrical break on 360°

#### **INCIDENCES**

+/- 40° up to 150 cm motorised 6°/s typically, then 0° up to 180 cm

#### **COLLIMATOR**

4 pairs of motorized lead shutters and automatic filters

LED light beam

Automatic, semi-automatic and manual mode

X-ray tube and collimator assembled by the manufacturer

#### **COMPRESSION DEVICE (option)**

Motorized movement with pressure control

#### **4 – 4 Detector Support**

#### **FUNCTIONS**

Automatic centring with X-ray tube and detector format displayed on the control console

#### **MOVEMENT**

Motorised carriage (at 15 cm /s) about 135 cm from X-ray beam axis

#### **REMOVABLE GRID**

Fixed grid ratio 10/1, one focused at 125 cm and other optional one focused at 180 cm

#### **4 - 5 Control console**

The control console is electrical class I, type B



Caution! Consult enclosed documentation



User interface: 10 inches colour LCD touch screen

All messages regarding operation (warning, error) appear on this screen. Refer to chapter « error messages » in user manual.

Movements controls with four joysticks and soft keys, capacitive.

Soft keys also on remote handswitch.

Capacitive key for X-ray preparation, soft key for X-ray emission.

Emergency switch (red) located at the top of console. This button permits to stop all the table movements immediately in case of fail.

Refer to chapters “table console” and “switching on” of the user manual.

Collision safeties done by internal software