RADiant Therapy System

Operator Manual

CE 1434

Language: English

About Us

Xstrahl Limited produces specialist clinical solutions for medical practitioners and their cancer and dermatology patients by offering a range of superficial and orthovoltage X-Ray Therapy Systems.

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Trademark

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To improve reliability, function or design, Xstrahl reserves the right to change the product and/or this manual without notice.

Compliance

The design of Xstrahl Systems is in compliance with internationally recognised standards for safety. Xstrahl's range of X-Ray therapy systems are classified as Class IIb Medical Devices in accordance with the Medical Devices Directive.

RADiant has clearance by FDA for sale in the U.S.A and is manufactured in accordance with ISO13485 certified quality management system.

Classification of Equipment (ME)

Xstrahl's X-Ray Therapy Systems are classified as Class I Medical Electrical (ME) equipment and are classified for continuous operation with intermittent loading. With continuous operation of the system in standby. After 20min continuous treatment exposure allow 4min cooling time (80% Duty Cycle).

File No., Revision, Year

PHET_OP_GB, Version 10 ©2021

This document and all accompanying documents have been drafted in the English language.

Acknowledgments

All manufacturer tradenames and trademarks appearing in this document are hereby acknowledged.

Referenced Documents

Not all documents referred to in this document are part of the scope of delivery for the equipment. Xstrahl reserves the right to determine the documents delivered with the product.

Compatibility/Contra indications

Xstrahl X-Ray Therapy Systems must be used only in combination with components expressly recognised by Xstrahl as compatible with Xstrahl X-Ray Therapy Systems. Before using any equipment or component not supplied by Xstrahl, consult Xstrahl for advice on compatibility.

The use of components other than those specified by Xstrahl may affect electromagnetic compatibility (EMC) performance and result in increased emissions or decreased immunity of the equipment.

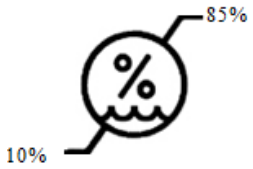
Modification of Equipment

Changes and/or additions to Xstrahl X-Ray Therapy Systems must be performed only by persons expressly authorised by Xstrahl. Such changes must comply with best engineering practice and all applicable laws and regulations within the jurisdiction.

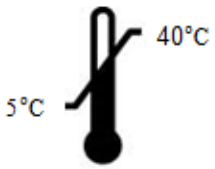
Any modifications during the service life of the equipment requires evaluation to the requirements of EN60601-1 and EN60601-2-8

Environmental Conditions

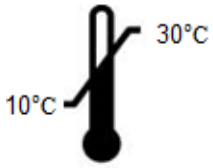
Xstrahl systems are designed to be operated and stored within the following environmental conditions:



Ambient Humidity



Storage Temperature



Operating Temperature

Note:	Ensure the shipping box for the system and generator are stored upright and the boxes are not stacked at any time.

Electromagnetic Compatibility

The Xstrahl Radiotherapy systems are suitable for use in a clinical or hospital environment, within a suitable lead shielded treatment room (for relevant X-Ray radiation protection).

Xstrahl has declared the following essential performance when subject to electromagnetic emissions or RFI immunity:

Treatment Mode

- X-Ray beam can carry on running and complete the correct treatment
- X-Ray beam can be interrupted or stopped
- X-Ray beam can be interrupted, and error messages are visible
- Electronic component failure prevents the X-Ray beam from running

Standby Mode

- X-Ray beam cannot be run
- Errors can be reported
- Power on fail LCD will still read with power off

WARNING: Use of Xstrahl equipment adjacent to or stacked with other equipment should be avoided to prevent improper operation.

WARNING: Equipment spare parts, cabling and accessories should only be replaced with Xstrahl specified parts to prevent increased EMC emissions or decreased immunity of the Xstrahl system.

WARNING: Portable RF communication equipment (example; antenna cables or antennas) should be used no closer than 30cm to any part of the Xstrahl system

Portable Personal Electronic Devices

Portable personal electronic devices (intravenous pumps, cardiac pacemakers, intravenous devices and other implanted devices) should not be placed in front of a radiation beam. Small doses of radiation could cause the devices to malfunction. Failure to observe this warning could cause these devices to malfunction which could result in serious injury or even death. Always monitor the operation of portable personal electronic devices during radiation treatment.

Intended Audience

The information contained in this manual is intended solely for the use of trained and competent medical operators preferably trained by Xstrahl or an authorised person. Training requirements vary by country. Operators must ensure that training is provided in accordance with all applicable local laws and regulations.

Training

All operators must have the required training before attempting to operate the Xstrahl X-Ray Therapy System. Because countries have different regulations for training, the operator must be compliant with the local laws and regulations of the jurisdiction in which the equipment is installed..

Warnings and Cautions

All potential hazards to the health of personnel and to the integrity of Xstrahl's equipment are presented as *Warning* and *Caution* notices.

All Warning and Caution notices in this manual will appear at the point of application.

Sample Warnings and Cautions:

WARNING: Warnings alert operators to potential hazards to personal health and safety. Each warning explains the nature of the hazard, states the means by which the risk can be avoided and explains the consequences of failing to observe the warning.

CAUTION: Cautions alert operators to the potential risk of damage to the equipment or the environment, but not of hazards to health and safety. Each caution explains the nature of the hazard, the means by which the risk can be avoided and explains the consequences of failing to observe the caution.

Specific Hazards

Xstrahl X-Ray Therapy Systems have system specific hazards that are a potential risk to both personnel and equipment. All Specific Hazard notices in this manual will appear at the point of application.

Sample specific hazards:

RADIATION: Xstrahl X-Ray Therapy Systems generate ionising radiation which can cause death or injury if precautions are not adhered to

WARNING: Warnings alert operators to potential hazards to personal health and safety. Each warning explains the nature of the hazard, states the means by which the risk can be avoided and explains the consequences of failing to observe the warning.

PROTECTIVE EARTH: Protective earth labels are placed next to protective earth terminal studs. Ensure earth terminals are connected to system earth at installation and before operating the equipment. If any protective earth point is disconnected, the equipment must not be used.

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with a protective earth.

APPLIED PART: Type BF Applied Part

INSTRUCTIONS FOR USE: Consult Operator Manual for Instructions for Use.

DO NOT PUSH: Xstrahl X-Ray Therapy Systems can become unstable if pushed with the brakes applied or pushed against a lip higher than 20mm

Safety

All operators of this equipment must read, obey and understand all safety warnings, cautions, notes and safety labels on equipment.

All operators must read and understand all information in this document.

Intended Function (of equipment)

Xstrahl's range of superficial and orthovoltage X-Ray Therapy Systems are intended to assist in the delivery of radiation to a defined target area whilst sparing surrounding normal tissue

Intended Use (of equipment)

The Xstrahl 80, 100, 150, 200 and 300 therapy systems are intended to be used for Therapeutic surface X-Ray radiation treatment of a tumour/lesion and/or anatomical area for Non-Melanoma Skin Cancer, hyper proliferative benign diseases and to provide palliative radiotherapy for superficial and bony lesions, as determined by a licensed medical practitioner where the system is being used. They are intended to be used for single or fractionated treatment (dose or time depending on system). Treatment should always be determined by a licensed medical practitioner in the jurisdiction where the system is being used.

Note: In the United States, Federal law restricts the sale of these devices, distribution and use by, or on or order of, a licensed physician.

Intended Function (of document)

The intended function of this document is to assist the operator in the safe and correct operation, application and preventative maintenance of the equipment. The operator is the authority who has the control of the equipment and the person(s) who operates and works on the equipment.

Xstrahl recommends that this document is kept with the equipment at all times.

Quality Assurance

The RADiant defines the exposure in time and does not measure the output of the X-Ray tube for each exposure conducted. The output of each clinical energy needs to be measured during the acceptance of the unit and schedule in the daily quality assurance conducted on the machine.

The IPEM report 81, kilovoltage X-Ray units recommends that the following quality control checks are conducted on superficial systems

Table 1-1: Recommended Quality Control Checks[a]

Recommended Quality Control Checks[b]		
	Test Frequency	**Tolerance**
Daily	Output constancy check	**±** 5% If the daily output constancy check varies by more than **±**5% from the previous monthly output calibration, an investigation should be performed. This should include at least a measurement of HVL.
	Interlocks and warnings	
	Mechanical fixtures	
	Filter interlock	
Weekly (or following repair)	Filter interlock	
Monthly (or following repair	Output measurement	**±** 3%
	Timer accuracy	**±** 0.01 min.
	Filter interlocks	
	HVL constancy	**±** 10%
Annually (or following repair	Field uniformity	**±** 2%
	Half value layer	
	Focal spot alignment	**±** 10%

a .Where no quantitative action level is indicated, the assessment is subjective or based
on a yes/no decision.

b. Refer to IPEM (Institute of Physics and Engineering Medicine) report 81 for further details on recommended quality assurance checks

Document Amendment Table

Xstrahl, at their discretion, may update sections of this document after first issue. Updated document amendments will be marked by an identifying release date which can be found at the bottom of all document pages (for example, 22/5/14).

It is the responsibility of the operator to update the following Document Amendment Table as new document amendments are issued:

Document			
No.	**Section**	**Release Date**	**Authorised By**

Table of Contents

List of Figure and Tables

Preface

This is the Operator Manual for the Xstrahl RADiant System. This manual provides the information a medical operator requires to operate the Xstrahl RADiant.

- **Precautionary Information**

  This section provides an overview of important safety information and cautionary warnings which should be read and thoroughly understood prior to operating the Xstrahl RADiant.

- **RADiant System Description**

  This section provides an overview of the Xstrahl RADiant features, including the interface, filters and applicators, and illustrations of the base unit and tube stand.

- **RADiant Operation**

  This section provides an overview of how to power on, warm-up and power off the Xstrahl RADiant.

- **Concerto®**

  This section provides an overview of the Xstrahl RADiant main menu options, including file, treatment, system errors, system interlocks, reports and treatment database and errors.

- **System Errors**

  This section provides a description of the system messages and errors.

- **About Xstrahl**

  Refer to the About Xstrahl section at the front of this manual for more information about Xstrahl.

Section 1:

Precautionary Information

In this section

1 Precautionary Information

RADIATION: X-Ray equipment emits ionising radiation and is dangerous to both operator and personnel within close proximity. To avoid risk of injury, observe all safety measures and ensure you are adequately trained prior to operating this equipment.

1.1 Ionising Radiation

The instructions within this operator's manual should be thoroughly read and understood before operating the Xstrahl X-Ray Therapy System.

This equipment incorporates various safety features and components. Before using this equipment, operators must carefully read and thoroughly understand the instructions in this manual. The operator should pay special attention to all safety warnings. Failure to observe these instructions could result in serious injury to the operator and/or patient.

1.2 Maintenance of Equipment

As with all electro-mechanical equipment, the various components of the Xstrahl Systems require periodic maintenance to ensure both operational safety and optimum performance. Failure to observe periodic maintenance can present a serious safety risk which could result in serious injury to the operator and/or patient.

Please observe the *Preventive Maintenance Procedures* included in the Xstrahl Technical Manual provided with the equipment. Recommended maintenance intervals and schedules are also described in the Xstrahl Technical Manual.

1.3 Portable Personal Electronic Devices

WARNING: Portable personal electronic devices (intravenous pumps cardiac pacemakers, intravenous devices and other implanted devices) should not be placed in front of a radiation beam. Small doses of radiation could cause these devices to malfunction. Failure to observe this warning could cause these devices to malfunction, which could result in serious injury or death.

Always monitor the operation of portable personal electronic devices during radiation treatment.

Section 2:

RADiant System Description

In this section

2 Xstrahl RADiant System Description

The RADiant Therapy system is a superficial X-Ray therapy system producing X-Rays up to 80kV, the system may have a lower kV limit depending on configuration. The energy of the beam is defined as the half value layer, which is dependent on the kV selected and the filter materials placed within the X-Ray beam.

Figure 2-1: System Schematic

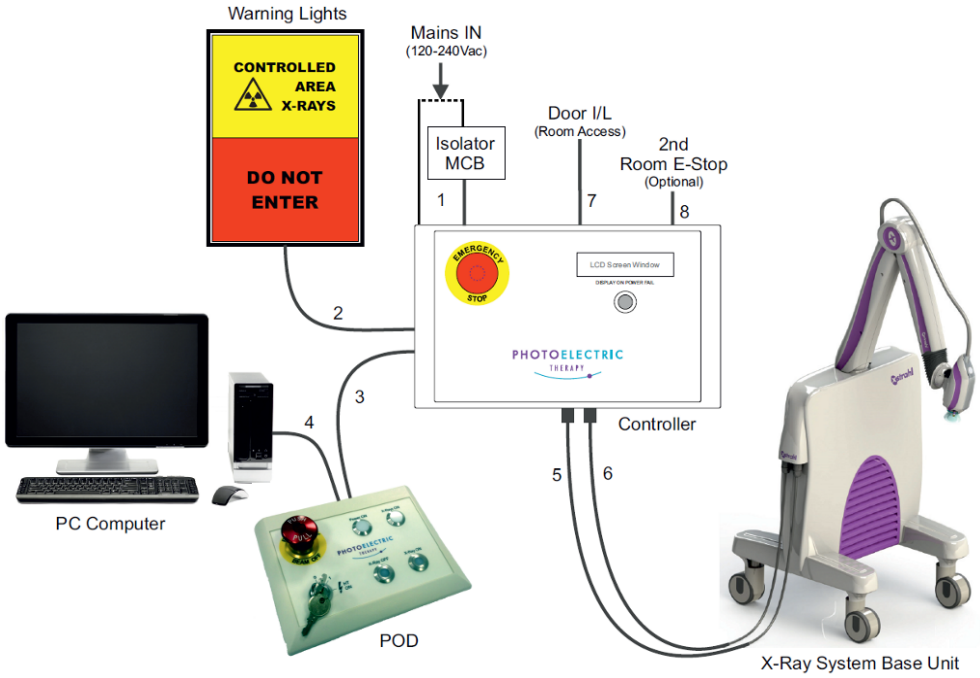


Table 2-1: System Schematic Descriptions

	Description	Location
1	Mains isolator and Circuit breaker or Maint socket	Treatment Room
2	Controller	
3	X-Ray System (Base Unit)	
4	Warning Lights	By Access Door to Treatment Room
5	Door Interlock	
6	Control POD	Control Room
7	PC Computer	

Figure 2-2: RADiant Therapy System

2.1 Operator Interface

The Xstrahl operator interface consists of two elements:

- A PC running Concerto (clinical software) and Fisica (physics software);
- An operator control pod.

2.1.1 Concerto

Concerto enables the clinical operator to:

- create patients;
- define and deliver treatment fields in time or dose and
- maintain records of all exposures.

More information can be found in the *Concerto* section in this manual.

2.1.2 Fisica

Fisica is database-driven physics software used to calibrate the system.

Note: More information on Fisica can be found in the *Xstrahl Technical Manual* provided with the equipment.

2.2 Filters

The Xstrahl RADiant Therapy system comes with interlocked filters.

Figure 2-3: RADiant Therapy System filter

Each Xstrahl RADiant Therapy system can have up to 9 standard filters — clinical filters and one warm-up filter. The system uses encoding to detect treatment filters fitted within the machine head.

The Xstrahl RADiant Therapy filter is made of aluminium and be up to a maximum physical thickness of 2.5mm. The materials and thickness, in combination with the kV for the clinical filter, give a resultant HVL as measured by the physicist; the HVL achieved will affect the percentage depth dose achieved.

Note: Please refer to the *British Journal of Radiology, Supplement 25* for details on percentage depth doses for a range of HVL's.

2.2.1 Filter Settings

The standard filters for the system configurations are described in the tables below. Additional filters can be added on request to better accommodate the departments clinical requirements.

Table 2-2: Xstrahl RADiant Therapy 80kV standard filter settings

Xstrahl RADiant Therapy Filter Settings[a]			
System Type	**80kV**		
	eBt	**SRT**	
Filter	**1**	**2**	**3**
kV	70	80	80
Thickness (mm)	2.5mm Al	1.5mm Al	2.5mm Al

Table 2-3: Xstrahl RADiant Therapy 50kV standard filter settings

Xstrahl RADiant Therapy Filter Settings[a]		
System Type	**50kV**	
	eBt	**SRT**
Filter	**1**	**2**
kV	50	50
Thickness (mm)	1.5mm Al	1.5mm Al

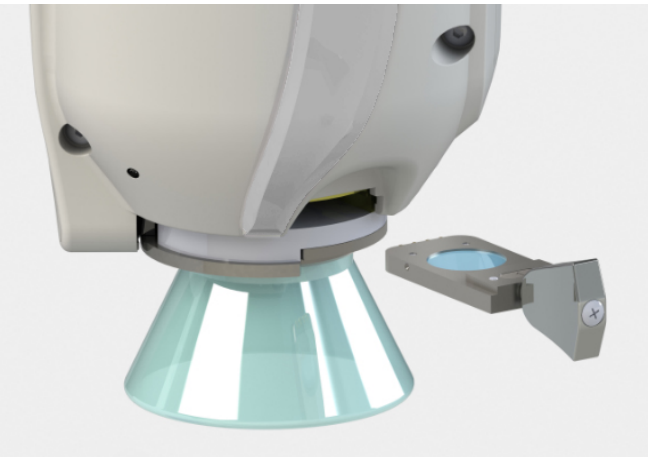
a. The kV, mA and HVL values must be checked and recorded in the acceptance test document.

2.2.2 Installing the filter

To remove the filter:

1. Select the required filter and insert into the fully into the sub-tube assembly, until it clicks into position. Each filter is numbered.

Figure 2-4: RADiant Therapy filter being fitted



2.2.3 Removing the filter

To remove the filter:

1. To remove the filter, pull the handle and remove it from the sub tube. Each filter is numbered.

2.3 Applicators

CAUTION: Care should be exercised at all times when handling applicators. Two hands should be used when carrying the applicator for insertion. The identification of each applicator is engraved on the top side of each applicator

Table 2-4: Xstrahl RADiant Therapy range of applicators

RADiant Therapy Applicators	
eBt Standard Applicator Set 5 cm FSD Applicators	**SRT Standard Applicator Set** 6cm FSD Applicators
1cm diameter	1cm diameter
1.5cm diameter	1.5cm diameter
2cm diameter	2cm diameter
3cm diameter	3cm diameter
4cm diameter	4cm diameter

System applicators are normally stored in the treatment room. They should be stored in the protective carry case.

The identification of each applicator, is engraved on the top side of each applicator, on the base shoe.

2.3.1 Inserting the Applicator

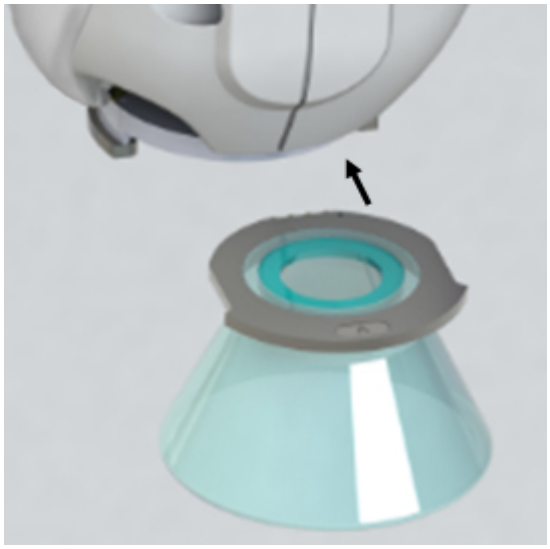
To insert the applicator:

1. Pick up the applicator.

Figure 2-5: RADiant Therapy Applicator

2. Insert the applicator into the sub-tube assembly (the applicator will only fit in one direction).

Figure 2-6: RADiant Therapy system applicator being fitted



3. Push the applicator fully into the sub-tube assembly. It is not possible to rotate the applicator within the sub-tube assembly.

Figure 2-7: RADiant Therapy system applicator fitted

2.3.2 Removing the Applicator

To remove the applicator:

1. Pull the applicator (gently) out from the sub-tube assembly.

Two hands should be used to remove the applicator from the sub-tube assembly before returning the applicator to the protective carry case.

2.3.3 Cleaning the Applicators

CAUTION: Contact with alcohol can damage the applicators. Xstrahl recommends that only products which are free from alcohol are used to clean the applicators

Due to the ends of the treatment applicators being constructed of Clear Cast Acrylic (PMMA), it is not recommended that products containing a high level of alcohol be used to clean the applicators after use. It is possible that alcohol could cause damage.

The applicator manufacturer recommends a product free from alcohol be used to clean the applicators, such as Sterets Unisept®, a sterile aqueous solution containing Chlorhexidine Gluconate 0.05% w/v.

If you have any queries regarding the suitability of various cleaning products, please contact Xstrahl Limited before using on the applicators.

2.4 RADiant Therapy Base Unit Tube Stand

The Xstrahl RADiant Therapy tube support is mounted on a base unit. The unit provides power distribution, generator control and power to tube stand peripherals.

Figure 2-8: RADiant Therapy System Base Unit

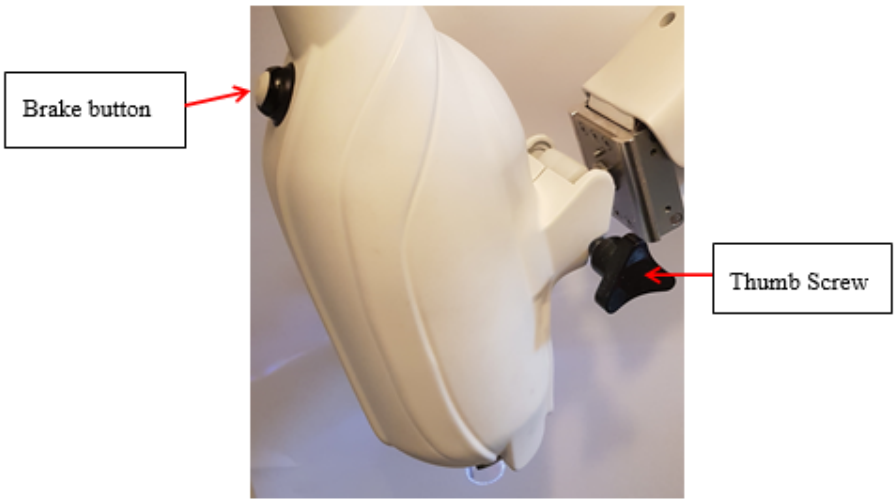
2.4.1 Movement Controls

CAUTION: Never try to force a movement of the arm without first releasing the brakes

WARNING: When carrying out movements with the RADiant Therapy system, avoid colliding with objects or persons within the room. Familiarise yourself with fixed collision hazards within the room and always check before making a movement that an object has not been moved into your intended path in order to avoid damaging the equipment. To avoid injury, always be on alert for movement into your intended path.

DO NOT PUSH: Xstrahl X-Ray Therapy Systems can become unstable if pushed with the brakes applied or pushed against a lip higher than 20mm

Figure 2-9: Brake Button



Tube Rotation and nod movements are achieved by means of releasing the manual pinch brake. Axial rotation and rotation about the vertical/horizontal axis are achieved by means of pressing the brake button located on the tube head to release the electromagnetic brakes.

Grip the tube head with left hand with the thumb located on the brake button, release the pinch brake using the 3 lobe thumb screw with the right hand and then press the brake button. The operator is then free to position the unit for treatment. Once in position tighten the 3 lobe thumb screw and release the button.

Electromechanical brake engagement and disengagement are signified by an audible click. The correct disengagement of the pinch brake will allow the tube head to move freely (tube head weight is then supported by the left hand) Correct engagement of the pinch brake ensures the tube head does not move during treatment.

2.4.2 The Support Arm

The support arm is fixed to the top of the base unit and consists of a two-part jointed arm and articulated 'wrist' joint.

2.4.2.1 Range of Movements

Details of the range of movements is summarised below in Figure 2-9.

Table 2-5: Support Arm Range of Movement

Treatment Arm Specification	
Maximum Weight Supported	4.5kg
Counterbalanced Spring Arm	
Rotation about the base unit	± 180°
Vertical range	59.5cm to - 23cm [b & c]
Horizontal range	43 cm to 105cm [b & c]
Radiation Head	
Rotation of the Radiation Head	± 90° [c]
Tilt of the Radiation Head	+ 90° to - 15° [c]

Figure 2-10: Support Arm Range of Movement

The design enables the unit to be moved to a suitable location within the treatment room for a clinical session.

Once the machine has been moved into position, the foot brake can be applied to prevent wheel movement. At the end of the clinical session, the foot brake can be released, and the base unit moved to a storage position.

2.5 Warning Lights and Door Interlock

The RADiant Therapy System has warning lights on access to the treatment room.

Controlled Area X-rays illuminated (Yellow) when the system is powered. Do Not Enter illuminated (Red) and flashing when X-rays are on.

Door interlock switches located on the access door to the treatment room.

Figure 2-11: Warning Lights (at access to treatment room)

2.6 Cleaning and Disinfecting

WARNING: Always carry out cleaning procedures with the mains power switched off. When using disinfectants, do not use agents that when mixed with air produce flammable or explosive vapours. Do not subject this equipment to liquid spills, ingress of liquids or harmful substances

Carry out cleaning and disinfecting as necessary. Dust metallic parts as required. If soiling or more stubborn stains exist, use a non-abrasive cleaning agent and apply with a damp, *not wet*, cloth.

Use a cleaning wipe such as Clinell Universal Wipes, for surface disinfection of the medical device (NHS Supply Chain: VJT118), and dry after use.

Follow the manufacturer's recommended instructions supplied with cleaning agent or disinfectant.

2.6.1 Cleaning the Applicators

CAUTION: Due to the ends of the treatment applicators being constructed of clear cast acrylic (PMMA), it is not recommended that products with high quantities of alcohol be used to clean the applicators after use. Using alcohol can result in the applicator end tips becoming cloudy and cracked in appearance.

The applicator manufacturer recommends a product free from alcohol be used to clean the applicators, such as Sterets Unisept®, a sterile aqueous solution containing chlorhexidine gluconate 0.05% w/v.

If you have any queries regarding the suitability of various cleaning products, please contact Xstrahl Limited before using on the applicators.

2.7 Service Life and Disposal

The X-ray tube contains a beryllium window. At the end of the useful life of the X-Ray tube (with Be-window) must be disposed in accordance with your local regulations.

Fumes or dust of Beryllium metal can be hazardous if inhaled. During use corrosion deposition on the Be-window can occur. These should not be scraped off, machined, or otherwise removed.

Equipment capable of producing ionising radiation must be rendered inoperable before disposal.

Section 3:

Xstrahl RADiant Operation

In this section

3 Xstrahl RADiant Therapy System Operation

Note: Operating environment limits for Xstrahl equipment is 10 to 35ºC, with 20 to 80% ambient relative humidity (non-condensing).

3.1 Power On

If the Xstrahl System has been installed with a connection to a mains isolator, the isolator needs to be placed in the *On* position. The location of the mains isolator will vary between sites and is customer dependent (established during installation process). If th Xstrahl System has been connected to a mains socket, insert plug into socket. If socket is switch, place in the *On* position.

To power on your Xstrahl System:

1. Turn On the mains power isolator switch or plug the mains cable into the socket.

This applies mains power to the following system components:

- Generator
- Cooling system
- Tube stand
- Safety interlocks

2. Turn the key switch on the operator control pod to *Standby* (position 2) to initiate power. The Power On indicator will illuminate to indicate the power on status.

Note: Power will also be applied to the controlled area warning lights to indicate the area is classified as a controlled area in respect to the ionising radiation regulations.

3. Power on the Xstrahl PC and monitor screen located in the control area.
4. Select either Fisica or Concerto.
5. Using the mouse, double click the  icon.

3.2 System Warm-Up

The X-Ray tube requires a daily warm-up to be conducted. The system performs a fully automated warm-up.

Note: If the warm-up sequence is bypassed, it is recorded in the system log and will invalidate the manufacturer's warranty on the X-Ray tube

The following table provides the standard warm-up times for the system:

Table 3-1: Warm up times

Xstrahl RADiant Therapy Warm-Up Times		
Xstrahl System	**Short Warm-Up**	**Long Warm-Up**
80kV	1.15 minutes	20.25 minutes
50kV	1.15 minutes	15.00 minutes

Note: If the system is limited to another value of kV not shown above please contact Xstrahl for confirmation of you long and short warmup

The long warm up is defaulted to if the system is left inactive for >28 days.

Once the system is powered on, a warm-up should be conducted.

To conduct a warm-up:

1. Fit the warm-up filter and a small aperture applicator onto the system. The system requires an applicator to be fitted to the sub-tube assembly, but does not require a specific applicator.

2. Double click the icon (either Fisica or Concerto).

Both Xstrahl software applications provide the ability to conduct a system warm-up. If there is a problem with the communication between the PC and TP2 hardware, an error dialog will be displayed.

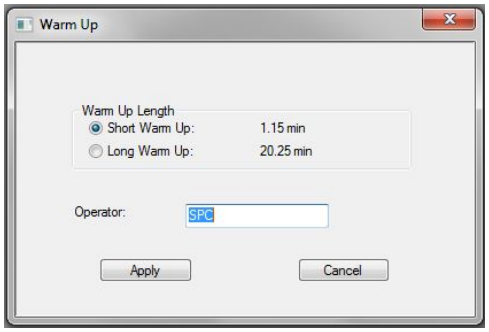
Please follow the Concerto or Fisica heading, depending on which interface you are using to conduct the warm-up.

Using Concerto:

1. Log on to Concerto. Select *Treatment* then *Start a Warm-Up*

*Figure 3-1: Warm-Up Window**

*Values shown are subject to you system kV limit



The system will default to the warm-up required by the system. Use the radio buttons to select a different warm-up if required.

2. Enter the *operator name* into the Operator field[1]
3. Click *Apply*. Apply checks the filter, applicator and the status of the system.
4. Turn the operator pod key switch to *HT* (position 3).
5. Press *X-Rays On*

Using Fisica:

1. Enter the *username and password* at the prompt and select *OK* on the log on screen. Once logged in, the username will be displayed on the left hand side of the screen. The warm-up can only be conducted if the system is synchronised.
2. Select *Tools* then *Warm-Up* to launch the warm-up screen. The system will default to the required Warm-Up. The radio buttons can be used to select a different warm-up (see Figure 3–1:).
3. Enter the operator name
4. Click *Apply*. Apply checks the filter, applicator and the status of the system.
5. Turn the operator pod key switch to *HT* (position 3).
6. Press X-Rays On

Note: Do not perform interlock checks (e.g. on doors or the key switch) during a warm- up.

Note: Warm-ups will take longer if interrupted

Note: If a warm up has been completed another cannot be requested without removing removing power to the system.

3.3 Interrupting an Exposure During the Beam Ramp Up

If the X-Ray beam is interrupted in any way (for example Door opened, E-stop,

Ray off) during the kV ramp (that is, without the mA to load the kV), it will take 5-8 seconds for the kV to drop below the 5kV level. In this situation the HT ON indication continues (even though the beam is interrupted) until the kV drops below 5kV. This is the correct operation of the system in this circumstance.

If possible, the beam should only be interrupted when the kV has ramped all the way up and the mA has started or stabilised. This can be seen in the 'actual' kV and mA values on the exposure screen.

1. Operator name must be at least three alphanumeric characters.

3.4 Power Down Procedure

The *Xstrahl X-Ray Therapy System* can be left powered on with the operator pod key switch in *standby* (position 2). During the clinical session this leaves the system with mains power. The key should be removed if the machine is left unattended.

After the last exposure of the day has been conducted, the Xstrahl System should be powered down, however the main isolator does not have to be switched off.

To power down the TP2 system:

1. Select *File* ➢ *Exit* to close down the application.
2. Power down the PC
3. Turn the key switch on the operator pod to '0' (OFF) to shut down mains power from the controller.

Note:

The Xstrahl system has an internal clock which records the time elapsed since the last exposure was conducted. The cooling system power will be maintained until

the shut down delay value has elapsed. When the operator pod is powered OFF, the cooler may remain on due to the shut down delay. This is defined in Fisica.

It is strongly advised to not turn off system power at the mains isolator until the cooler run-on time has elapsed, and the X-Ray tube optimally cooled following the last exposure.

4. Once the cooling power has been removed by the system, you can turn the system off at the mains isolator.

Powering down the system:

When the operator pod is powered OFF (key-switch position '0') the mains light will no longer be illuminated and the operator will hear the safety interlock drop out. The auxiliary supply to the base unit and cooling system will remain *On*. The cooling system will remain *On* until the cooler run on time after the last exposure[2] has elapsed.

This has two functions:

- Allows adequate cooling of the tube after the last exposure and
- turns off the cooling system automatically if the system is routinely left overnight with mains power (to prolong the life of the cooling system pump).

2. Recorded in the Fisica database.

Section 4:

Concerto®

4 Concerto®

4.1 Overview

Concerto is the clinical interface for the Xstrahl system. Concerto enables the operator to create patients, define treatment parameters and deliver exposures, record values to a database and print hard copy patient reports. The Concerto interface can be used without the X-Ray system being powered on, which can be useful for data housekeeping.

All user information for Concerto® is contained within its own user manual. A copy will be printed and located after this page in the operator manual.

CON03 – DE Operator Manual

CON04 – EN Operator Manual

Section 5:

System Errors

5 System Errors

Xstrahl system errors are displayed on the bottom right side of the exposure screens in Concerto and Fisica.

Types of Errors	
Normal Errors	Will persist whilst the problem exists; for example, a filter encoding error will remain until the correct filter is fitted.
Latching Errors	These will persist after the problem goes away, but require further action to clear. Pressing the X-Ray On button will clear this type of error.
Fatal Errors	Errors which cannot be cleared without turning the TP2 power off and then back on at the isolator.
Faults	Error classification similar to Fatal errors and identifies if they are a latching error

5.1 System Error Table

Error Code Table		
No.	**Message Displayed**	**Description**
2	Division by Zero	Displayed if an internal computation results in a division by zero. Requires the power to be recycled.
3	Divide Overflow	Displayed if an internal computation results in a division of zero. Requires power to be recycled.
4	kV too High	Generator error. Displayed when the generator kV exceeds the desired value. Latching error.
5	mA too High	Generator error. Displayed when the generator mA exceeds the desired value. Latching error.
9	Focal Spot Error	Generator error. Displayed after power up if the sense of a dual focal spot filament setting changes.
10	Bipolar Status Error	Generator error. Displayed after power up if the sense of an anode tank changes.
11	Generator Over kV	Generator error. Displayed when the generator kV exceeds a value set in the combination of X-Ray tube and generator data. Latching error.
12	Generator Over mA	Generator error. Displayed when the generator mA exceeds a value set in the combination of X-Ray tube and generator data. Latching error.
13	Converter Current	Generator error. Displayed when an internal current limit is exceeded in the generator drive electronics. Latching error.
14	Converter Voltage	Generator error. Displayed when an internal voltage limit is exceeded in the generator drive electronics. Latching error.
15	No Cooler Flow	Displayed when the coolant flow rate is less than the internal setting. Non-latching error; will reset automatically. This error will disconnect the safety contactor.
16	Check Cooling System	Displayed when the coolant temperature exceeds the internal cooler limit. Non-latching error; will reset automatically. This error will disconnect the safety contactor.
18	kV too Low	Generator error. Displayed when the generator kV fails to reach the desired value within a defined period of time. Latching error.
19	mA too Low	Generator error. Displayed when the generator mA fails to reach the desired value within a defined period of time. Latching error.
22	X-Ray Decay too Slow	Generator error. Displayed if the decay of the kV at the end of the exposure takes too long. The system status will remain as X-Ray ON until the kV threshold is reached.

Error Code Table		
No.	**Message Displayed**	**Description**
23	Contactor Dropout	Displayed because the user has pressed the X-Ray ON button too quickly. Wait for the X-Ray ON button to illuminate green, and for the PC screen to show Ready for an exposure, before pressing the X-Ray ON button.
24	Residual kV too High	Generator error. Displayed if the generator kV exceeds a certain value in X-Ray OFF.
25	Residual mA too High	Generator error. Displayed if the generator mA exceeds a certain value in X-Ray OFF.
27	Communication Delay	Displayed if the communications from the generator fails. This will inhibit or terminate X-Rays ON.
28	All Filters in Box	Displayed when all *filters* are in the wall box when a *filter* is selected (only certain systems). Non-latching error; will reset automatically.
29	Two Filters Removed	Displayed when more than one *filter* is missing from the wall box when a *filter* is selected (only certain systems). Non-latching error; will reset automatically.
30	Please Fit Filter	Displayed when no *filter* is fitted to the sub-tube assembly when a *filter* is selected. Non-latching error; will reset automatically.
34	Bipolar kV Matching Failure	Generator error. Displayed in bipolar systems when the anode and cathode kV measurements differ by a defined amount. Latching error.
35	Bipolar mA Matching Failure	Generator error. Displayed in bipolar systems when the anode and cathode mA measurements differ by a defined amount. Latching error.
36	Feedback Open Circuit	Generator error. Displayed whilst the connection to the control PCB from the filament feedback PCB is open circuit (CP Models).
37	Heatseat Sink Temperature	Generator error. Displayed whilst the heatseat sink thermostat indicates a high temperature.
38	High Calibration Error	Generator error. Displayed when the value of calibration voltage entered in an initializing process is too high.
39	Low Calibration Error	Generator error. Displayed when the value of calibration voltage entered in an initializing process is too low.
40	Anode Over mA	Generator error. Displayed in bipolar systems when the anode tank mA exceeds the desired value. Latching error.
41	Anode Under mA	Generator error. Displayed in bipolar systems when the anode tank mA fails to reach the desired value within a defined period of time. Latching error.

Error Code Table		
No.	**Message Displayed**	**Description**
42	Less than 5 kV reached	Generator error. Displayed when the generator fails to reach 5 kV within a defined period of time after receiving an X-Ray ON command. Latching error.
43	Interlock to Generator Lost	Generator error. Displayed when an exposure is terminated by the removal of the interlock input to the generator. Latching error
45	Prohibited Exposure	Displayed when the time entered in a *Time* treatment exceeds the set time limit. This error will persist until a compliant time is entered. (can be caused in a *Dose* treatment)
46	Uninitialized Filter	Displayed when an uninitialized *filter* is selected or zero values detected for any of the following: kV, mA, HVL, Type HVL, Dimension or encoding.
47	Bad Applicator Data	Displayed when an uninitialized applicator is selected; non-valid shape or zero values in any of the following: width, breadth for rectangular applicator, length or encoding.
48	Bad Dose Calibration	Displayed when a *filter* is selected for a dose exposure with a non-valid reference applicator or zero values for counts/second or counts/MU.
49	Exposure Not Entered	Displayed when the X-Ray button is pressed and the internal NEEDS status indicates the *exposure* is not set. This error will persist until another treatment is set.
50	No Filter Selected	Displayed when the X-Ray button is pressed and the internal NEEDS status indicates the *filter* is not set. This error will persist until another treatment is set.
51	No Applicator Chosen	Displayed when the X-Ray button is pressed and the internal NEEDS status indicates the *applicator* is not set. This error will persist until another treatment is set.
52	Bad Temperature	Displayed when the temperature (in degrees centrigrade) read from the transducer is less than a *minimum* (10) or greater than a *maximum* (35). *Dose systems only*. This error will persist whilst the temperature is invalid.
53	Bad Pressure	Displayed when the pressure (in milli-bars) read from the transducer is less than a *minimum* (700) or greater than a *maximum* (1200). *Dose systems only*. This error will persist whilst the pressure is invalid.
55	X-Ray Off Signal Open to Power Up	Displayed if the X-Ray OFF button is open-circuit at power up.
56	Shutdown by Safety1	Displayed if the X-Ray beam is stopped by the door contact being open. Latching error requires a new X-Ray ON signal to be reset.

Error Code Table		
No.	**Message Displayed**	**Description**
57	Shutdown by Safety2	Displayed if the X-Ray beam is stopped by the second door/room interlock contact being opened. Latching error requiring a new X-Ray ON signal to be reset.
58	Shutdown by Cooler Flow	Displayed if the X-Ray beam is stopped by the cooler flow contact being opened. Latching error requiring a new X-Ray ON signal to be reset.
59	Shutdown by Cooler Temp	Displayed if the X-Ray beam is stopped by the cooler temp contact being opened. Latching error requiring a new X-Ray ON signal to be reset.
60	Contactor Closed at Power Up	Displayed at start-up if the *safety* contactor is engaged but not enabled.
64	System has RESET	Generator error. Displayed if the processor in the generator has reset.
66	Key Turned During Exposure	Displayed if the X-Ray beam is stopped by the control pod key being moved from *HT* (position 3), the X-Ray enable position. Non-latching error.
67	High kV Demand in XOff	Generator error
68	High mA Demand in XOff	Generator error
71	Droop Cal. too High	Generator error
72	DAC Offset too High	Generator error. Displayed if the *digital* to *analog converter* (DAC) offset voltage is too high. This will inhibit an exposure.
73	DAC Range Problem	Generator error. Displayed if the *digital* to *analog converter* (DAC) range data is incorrect. This will inhibit an exposure.
74	ADC Zero Offset too High	Generator error. Displayed if the *analog* to *digital converter* (ADC) offset voltage is too high. This will inhibit an exposure.
75	ADC Range Problem	Generator error. Displayed if the *analog* to *digital converter* (ADC) range data is incorrect. This will inhibit an exposure.
76	ADC Calibration Lost	Generator error. Displayed if the *analog* to *digital converter* (ADC) calibration is lost. This will inhibit an exposure
77	Bad Generator Table in PROM	Generator error. Displayed if the generator type data is corrupt. This will inhibit an exposure.
78	kV Breakdown Lockout	Generator error. Displayed if the X-Rays have been terminated by three events at successively lower kV values. This will inhibit an exposure.
79	X-Ray Off | / O Problem	Generator error. Displayed if the generator receives an X-Ray ON initiation, but the X-Ray OFF interlock line is not enabled (sourced with current).

Error Code Table		
No.	**Message Displayed**	**Description**
80	Anode Decay too Slow	Generator error. Displayed in bipolar systems if the decay of the anode kV at the end of the exposure takes too long. The system status will remain as X-Ray ON until the kV threshold is reached.
81	Interlock Dropout	Generator error. Displayed if an exposure is terminated by the loss of the interlock signal. Latching error.
82	Interrupted by HS Temp	Generator error. Displayed if an exposure is terminated by the heatsink thermostat. Latching error.
83	Not Used	Generator error. Displayed if the *unipolar* or *bipolar* tables are incompatible.
84	Dual Door Interlock Failure	Displayed if the two door sensors fail to operate together when configured to do so. This will prevent X-Ray ON.
85	Overriding Mandatory WU	Generator error. Not used in this system.
86	Exposure Param Error	Generator error
87	Anode Residual kV	Generator error. Displayed in bipolar systems if the anode generator tank kV exceeds a certain value in X-Ray OFF.
88	Anode Residual mA	Generator error. Displayed in bipolar systems if the anode generator tank mA exceeds a certain value in X-Ray OFF.
89	No mA at Switch On	Generator error. Displayed if the mA measured remains at zero after a specified time.
91	Shutdown by Residual kV	Generator error. Latching error. Displayed if a residual kV error has terminated X-Rays.
92	Shutdown by Residual mA	Generator error. Latching error. Displayed if a residual mA error has terminated X-Rays.
93	Timer Interrupt Late	Generator error
94	Generator Not Ready	Generator error
95	High Energy Discharge	Generator error
107	Generator Interlock Problem	Displayed if the control of the interlock relay does not result in the correct response from the generator.
108	App Factor Required	Displayed when the applicator is selected for a *Dose* exposure and the applicator factor for the selected applicator is out of range. (Must be greater than or equal to 0.8 and less than or equal to 1.2.)
109	Dose Requested too High	Displayed when the dose entered in a *Dose* treatment exceeds the set dose limit. This error will persist until a compliant dose is entered.
110	LCD Failure	Displayed if the TP2 fails to read data from the LCD. This error will persist until rectified.

Error Code Table		
No.	**Message Displayed**	**Description**
111	Low Dose Rate Error	Displayed when the dose rate monitored in a *Dose* treatment is less than the calibrated dose rate by more than 3%. The ratio of actual mA to desired mA will be used to modify the calculation on the switch on mA ramp. The error will terminate X-Rays. The error requires the control pod key to be counter-rotated to *standby* (position 2) and then back to *HT* (position 3) to clear before X-Rays are enabled.
112	Emergency Off	Displayed if the X-Ray beam is stopped by the Emergency OFF button being pressed. X-Rays will not automatically resume after the Emergency OFF has been manually reset, but may after the X-Ray ON button is pressed.
113	Power On Light Failed	Displayed if the external Power ON lamp fails to draw current. This will prevent X-Ray ON.
114	X-Ray On Light Failed	Displayed if the external X-Ray ON lamp fails to draw current. This will terminate X-Ray ON.
115	Program Not Specified	Displayed when the X-Ray button is pressed and the internal NEEDS status indicates the program is not set. This error will persist until another treatment is set.
116	Exposure Stopped by Key	Displayed if the X-Ray beam is stopped because the control pod key has been moved from *HT* (position 3), the enable position. Latching error requires new X-Ray ON signal to be reset.
117	Power Lost	Displayed when the program monitoring the TP2 through the series communications fails to receive data. The program will indicate POWER LOST and wait for the TP2 to recover and, if possible, resume. Resumption of X-Rays will only be possible by operator control.
118	mA Value Not Available	Displayed if the generator mA limit (for the desired kV) is less than the required *Treatment mA*. This will prevent X-Rays ON.
119	kV Value Not Available	Displayed if the generator kV limit is less than the required *Treatment kV*. This will prevent X-Rays ON.
120	Stopped by Backup Timer	Displayed when the exposure is stopped by the back-up timer. The calculation of the limit will vary between *Time* and *Dose* treatments. No further exposure is allowed. X-Rays ON will be allowed, but termination will be repeated as soon as the timer starts.

Error Code Table		
No.	**Message Displayed**	**Description**
121	High Dose Rate Error	Displayed when the dose rate monitored in a *Dose* treatment is greater than the calibrated dose rate by more than 3%. The error will terminate X-Rays. The error requires the control pod key to be counter-rotated to *standby* (position 2) and then back to *HT* (position 3) to clear before the X-Rays are enabled.
122	Applicator Encoding Error	Displayed when the *applicator* bits do not match those of the specified applicator.
123	Filter Encoding Error	Displayed when the *filter* bits do not match those of the specified filter.
124	Generator Not Stopping	Displayed if the generator does not turn OFF within two seconds.
125	Generator Not Starting	Displayed if the generator does not turn ON within two seconds.
127	Generator Not Setup	Displayed if the generator cannot be set to the required kV or mA. This will prevent X-Rays ON.
129	Maintenance Due	Generator error. Displayed if the current date exceeds the date chosen for routine maintenance. Will not inhibit X-Rays ON.
193	Generator Interlock Open	Displayed when the interlock to the generator is open; suppressed unless the interlock relay is enabled.
195	PC Data Interlock	Displayed when the TP2 fails to receive a software interlock from the PC at less than one second intervals with the control pod key in *HT* (position 3).
196	Door Open	Displayed when the first safety signal is not sensed at the TP2. This error will disconnect the *safety contactor*.
197	Room Interlock Open	Displayed when the second safety signal is not sensed at the TP2. This error will disconnect the *safety contactor*.
228	Watchdog Failure	Displayed when the TP2 software fails to re-trigger the watchdog in time. The error is not resettable. *Fatal error.*
229	Background Lockup	Displayed when the TP2 background software fails to execute in time. The error is not resettable. *Fatal error.*
234	Other Trap	Displayed if an unexpected fault occurs. The error is not resettable. *Fatal error*
236	Bad Code Executed	Displayed if a bad instruction is detected. The error is not resettable. *Fatal error*
238	No Real Time Clock	NOT USED
243	Processor Clock Fault	Displayed if an internal processor clock fault arises. The error is not resettable. *Fatal error.*

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