Xstrahl 150 X-ray Therapy System Operator Manual

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, as well as a comprehensive superficial therapy educational (STEP) program for training and support.

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Trademark

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Compliance

The design of Xstrahl Systems is in compliance with internationally recognised standards for safety.

All Xstrahl products have received CE marking approval for sale in Europe, clearance by FDA for sale in the U.S.A., are licensed for sale in Canada and are designed and manufactured in accordance with an ISO13485:2016 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.

All systems are specified IP0X for environmental protection.

File No., Revision, Year

150_OPMAN_GB Version 10 ©2019

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.

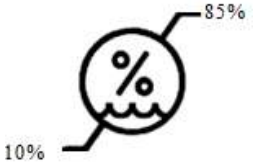
Modification of Equipment

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.

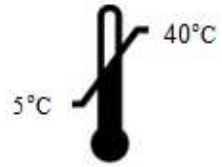
Any modification during the service life of the equipment requires evaluation to the requirements of EN60601-1 and EN60601-2-8.

Environmental Conditions

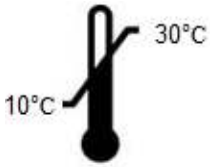
Xstrahl systems are designed to be operated and stored within the following environmental conditions:



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.

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.

Quality Assurance

The Xstrahl 150 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, kilo voltage X-Ray units recommends that the following quality control checks are conducted on superficial systems

Table 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

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)

Xstrahl® (100, 150, 200 and 300) X-Ray Therapy Systems are intended to be used for radiation treatment of superficial skin disorders, boney metastases and diseases of the skin, 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.

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, 16/4/14).

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

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Preface

This is the Operator Manual for the Xstrahl 150 X-Ray Therapy System. This manual provides the information a medical operator requires to operate the Xstrahl 150.

- **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 150.

- **Xstrahl 150 System Description**

  This section provides an overview of the Xstrahl 150 features, including the interface, filters and applicators, and illustrations of the base unit and tubestand.

- **Xstrahl 150 Operation**

  This section provides an overview of how to power on, warm-up and power off the Xstrahl 150.

- **Concerto®**

  This section provides an overview of the Xstrahl 150 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

Xstrahl 150 System Description

In this section

2. System Description

The Xstrahl 150 is a superficial X-Ray therapy system producing X-Rays up to 150kV. 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: Xstrahl 150

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 and Applicators

The Xstrahl 150 has interlocked filters.

2.2.1. Filters

The filter holder consists of a main body, filter holder ring and a handle.

Figure 2-2: Filter Carousel

Each Xstrahl 150 system can have up to ten filters—nine clinical filters and one warm-up filter. The system uses encoding to detect treatment filters within the filter storage unit. The clinical filters can be constructed in accordance with the half value layers defined by the medical department.

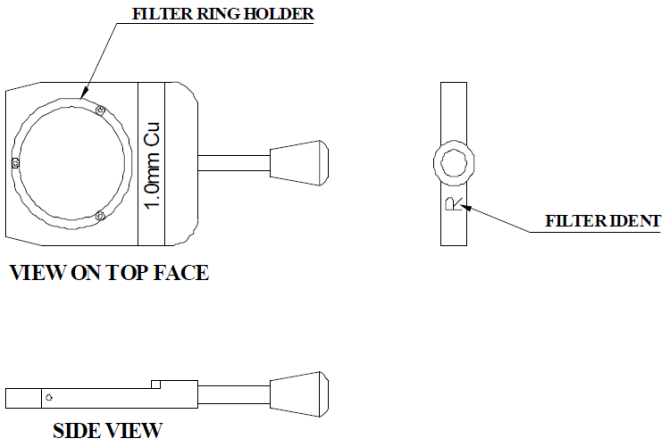
Each filter can be constructed from a maximum of three materials, up to a maximum physical thickness of 2 mm. The materials and thickness, in combination with the kV for the clinical filter give a resultant HVL as measured by the physicist; the HVL achieved will affect the percentage depth dose achieved.

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

The warm-up filter has 2 mm of lead pre-installed in the holder. The materials used in the filters are aluminium and copper. Only the filter required for the treatment should be removed from the storage unit. Treatment delivery will be prohibited if more than one filter is removed from the storage unit or the wrong filter is inserted into the machine head because all filters are interlocked within the storage box.

Each filter has a unique place in the filter storage unit as defined by the mechanical shape of the storage unit and filter holders. Partial insertion of a filter into any holder position is possible, but the electronic recognition will not occur. The Xstrahl system will display the error message: *two filters out of box*.

Figure 2-3: Filter Holder Illustration



CAUTION: The filter shoulder should only be manipulated by the handle. Contact with the filter material should be avoided to prevent damage to the filter material.

The filter material is held in place in the filter holder by a ring, which is fixed by screwing through the ring and the filter material into the filter holder body. The front handle end of the filter bears the filter holder identification R for the warm-up filter and 1 to 9 for all of the other filters.

The warm-up filter has 2 mm of lead pre-installed in its holder to prevent unwanted X-Ray emissions during the warm-up. When either the warm-up filter or any of the treatment filters are required for use, they need to be removed from the filter storage unit.

2.2.1.1. Removing the Filter

To remove a filter from the filter ladder:

1. Gently pull on the filter, then, holding the filter by its integral handle, insert the holder into the filter slot in the system sub-tube assembly.
2. Gently push the filter into the slot until a distinctive click sound can be heard to indicate the filter holder is correctly located (by a ball/indent locating mechanism).

When the filter is no longer required, it should be returned to the filter storage unit. It is recommended that the warm-up filter be inserted into the sub-tube assembly overnight, thus enabling the system to be ready for its daily warm-up on the next working day.

2.2.1.2. Filter kV Settings

Xstrahl 150 filter settings:

Xstrahl 150 Filter kV Settings[a]									
Filter	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
kV	30	40	50	80	100	120	120	140	150
HVL (mm)	0.2 Al	0.5 Al	1.0 Al	2.0 Al	3.0 Al	4.0 Al	5.0 Al	8.0 Al	0.5 Cu
Added filtration (mm)	0.25 Al	0.55 Al	1.2 Al	2.0 Al	2.5 Al	1.1 Al 0.05 Cu	0.8 Al 0.1 Cu	1.4 Al 0.2 Cu	0.5 Al 0.25 Cu

a. The kV, mA and HVL values must be checked and recorded in the Acceptance Test Document.

2.2.2. Applicators

CAUTION: Care should be exercised at all times when handling the applicators so as not to damage the applicator.

Figure 2-4: Applicator Illustration

Standard range of applicators for the Xstrahl 150:

Xstrahl 150 Applicators	
15 cm FSD Open Applicators	**25 cm FSD Open Applicators**
1.5 cm diameter	10 cm diameter
2 cm diameter	15 cm diameter
2.5 cm diameter	
3 cm diameter	
4 cm diameter	
5 cm diameter	

Note: Applicators are not interlocked in the sub-tube assembly. The operator must ensure the correct applicator is fitted to the machine before enabling X-Rays On..

System applicators are normally stored in the treatment room. They should be stored with the stainless steel top, face down on a protective fabric surface. Usually, the 15 cm and 25 cm FSD applicators are open-ended with clear viewing ends.

CAUTION: Care should be exercised at all times when handling applicators. The weight of each applicator varies (0.45 to 1.1 kg) with the heaviest being the largest field size at 25 cm FSD. The identification of each applicator in terms of the field size and FSD is engraved on the underside of the top element of each applicator.

2.2.2.1. Inserting the Applicator

Note:	Two hands should always be used to hold the applicator when carrying the applicator for insertion into the sub-tube assembly. The applicator should only be inserted with the sub-tube assembly in the 0º position.

Figure 2-5: Inserting the Applicator Illustration

Inserting the Applicator:

1. Align the applicator with the sub-tube assembly opening.
2. Push the applicator up into the assembly and twist anti-clockwise until the spring locking system engages and a click is heard as it is locked in place. It is not possible to rotate the applicator within the sub-tube assembly. *Figure 2–7:* Applicator Movement

2.2.2.2. Removing the Applicator

Removing the applicator:

1. Twist the applicator clockwise within the sub-tube assembly until the locking system disengages. Care should be taken when removing the applicator because the sub-tube assembly does not support the applicators weight.
2. Use two hands to remove the applicator from the sub-tube assembly and return the applicator to the storage facility.

2.2.2.3. Cleaning the Applicators

WARNING: 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 Lucite® (Perspex®), 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 significant damage to the Lucite®.

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 before using on the applicators.

2.3. Xstrahl 150 Tube Stand

Figure 2-6: Floor/Wall Mounted Xstrahl 150 Illustration

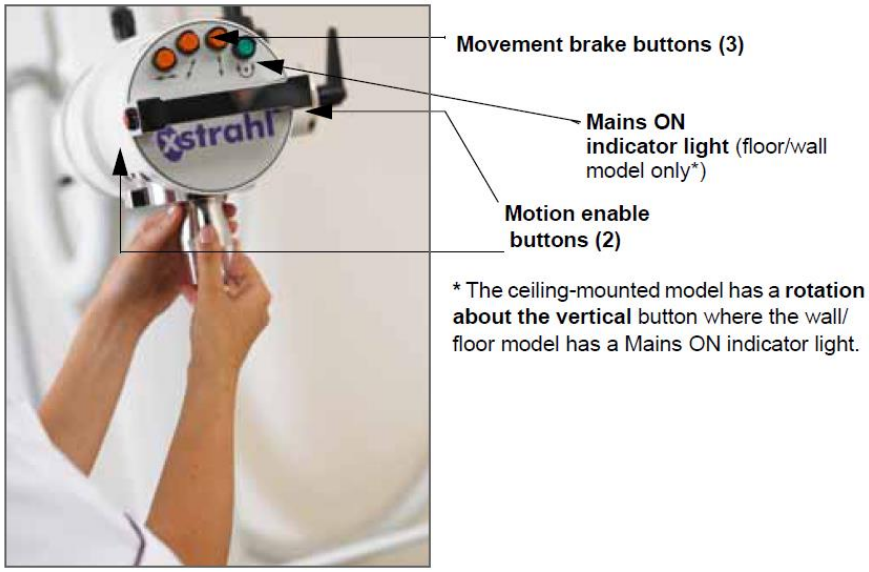
The Xstrahl 150 can be supplied with a floor/wall mounted tube stand or on a ceiling track. Electromagnetic brakes lock the tube stand movements. These brakes can be released individually or in combination, by pushing the buttons located on the front panel of the X-Ray tube assembly.

CAUTION: Never try to force movement of the system without releasing the brakes.

WARNING: When carrying out movements with the Xstrahl 150, 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 persons moving into your intended path.

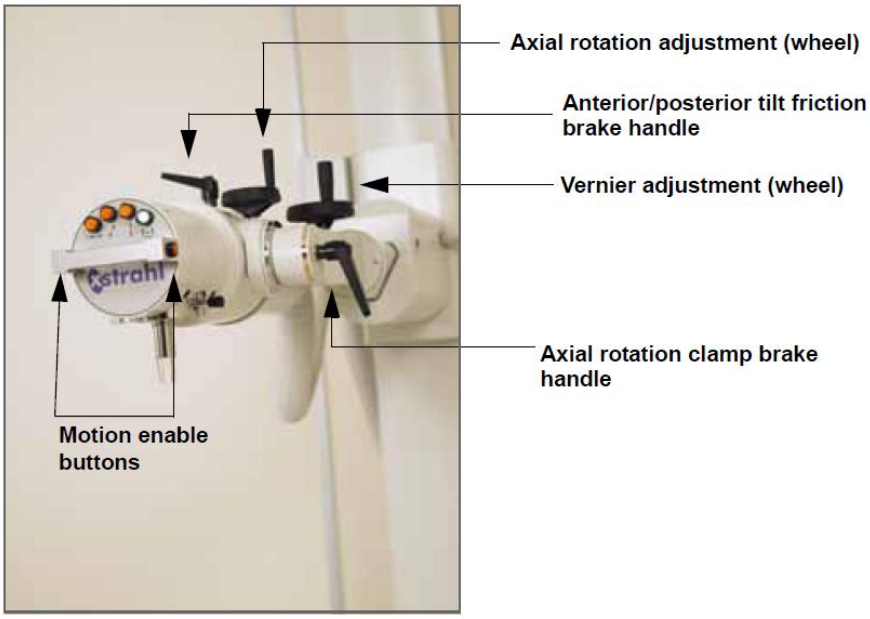
The vertical, longitudinal and lateral movement brakes are identified by movement arrows. The rotational button only works on the ceiling stand, allowing rotation about the vertical column. On a floor/wall stand, this button will be blue to indicate mains power to the stand.

Figure 2-7: Movement Control Illustration



2.3.1. Xstrahl 150 Wall/Floor Stand Systems

Figure 2-8: Xstrahl 150 Brake/Movement Illustration



Wall/Floor Stand Control Movements	
	**X-Ray tube (vertical movement):** 1. Press the vertical movement brake button. The button will illuminate to confirm your selection. 2. Press at least one of the motion enable buttons to move the X-Ray tube vertically. 3. Release the motion enable button(s) when the required height is achieved. 4. Release the vertical movement brake button to lock.
	**Tube stand (longitudinal movement):** 1. Press the longitudinal movement brake button. The button illuminates to confirm your selection. 2. Press at least one of the motion enable buttons to move the X-Ray tube longitudinally. 3. Release the motion enable buttons when the required longitudinal position is reached. 4. Release the longitudinal movement brake button to lock.
	**Tube stand (lateral movement):** 1. Press the lateral movement brake button. The button illuminates to confirm your selection. 2. Press at least one of the motion enable buttons to move the X-Ray tube laterally. 3. Release the motion enable button when the desired position is reached. The range of movement is 200 mm for the floor stand. 4. Release the lateral movement brake button to lock.
	**Mains On Indicator Light** Illuminates blue to indicate Mains On power
See Brake/ Movement Illustration	**Motion Enable Buttons** Enables movement
See Brake/ Movement Illustration	**Axial Rotation Adjustment (Wheel)** Axial rotation adjustment on the horizontal arm controls the axial rotation of the tube head. 1. Release the axial rotation clamp break 2. Turn the rotational wheel to adjust the tube head 3. Release axial rotation clamp brake to lock
See Brake/ Movement Illustration	**Vernier Adjustment (Wheel)** There is a rotational wheel on the horizontal arm which allows the vertical height to be adjusted. The

	process of winding back up can be stiff due to the weight of the tube head. 1. Turn the rotational wheel to lower the tube head 2. Wind the handle back in the opposite direction to raise the tube head back up
See Brake/ Movement Illustration	**Anterior/Posterior Tilt Friction Brake** Enables the tilt to be adjusted. Always release this brake gently to avoid the weight of the tube moving too quickly. Always reapply the brake to lock down the movement of the tube.
See Brake/ Movement Illustration	**Axial Rotation Clamp Brake** Controls the axial rotation. Use the axial rotation clamp brake to lock the axial rotation adjustment wheel.

2.3.2. Xstrahl 150 Ceiling System

Figure 2-9: Ceiling Mounted System

Ceiling System Movements	
	**X-Ray tube (vertical movement):** 1. Press the vertical movement brake button. The button will illuminate to confirm your selection. 2. Press at least one of the motion enable buttons to move the X-Ray tube vertically. 3. Release the motion enable button(s) when the required height is achieved. 4. Release the vertical movement brake button to lock.
	**Tube stand (longitudinal movement):** 1. Press the longitudinal movement brake button. The button illuminates to confirm your selection. 2. Press at least one of the motion enable buttons to move the X-Ray tube longitudinally. 3. Release the motion enable buttons when the required longitudinal position is reached. 4. Release the longitudinal movement brake button to lock.

	**Tube stand (lateral movement):** 1. Press the lateral movement brake button. The button illuminates to confirm your selection. 2. Press at least one of the motion enable buttons to move the X-Ray tube laterally. 3. Release the motion enable button when the desired position is reached. The range of movement is 200 mm for the floor stand. 4. Release the lateral movement brake button to lock.
	**Column Rotation Brake** Column rotation brake (white button); works in combination with the enable movement buttons (side of handle)
See Brake/ Movement Illustration	**Motion Enable Buttons** Enables movement
See Brake/ Movement Illustration	**Axial Rotation Adjustment (Wheel)** Axial rotation adjustment on the horizontal arm controls the axial rotation of the tube head. 1. Release the axial rotation clamp brake 2. Turn the rotational wheel to adjust the tube head 3. Release axial rotation clamp brake to lock
See Brake/ Movement Illustration	**Axial Rotation Adjustment (Wheel)** Axial rotation adjustment on the horizontal arm controls the axial rotation of the tube head. 1. Turn the rotational wheel to lower the tube head 2. Wind the handle back in the opposite direction to raise the tube head back up
See Brake/ Movement Illustration	**Anterior/Posterior Tilt Friction Brake** Enables the tilt to be adjusted. Always release this brake gently to avoid the weight of the tube moving too quickly. Always reapply the brake to lock down the movement of the tube.

2.3.3. Manual Height Override (Power Off)

WARNING: To ensure safety, push the bottom of the vertical column (ceiling track) or the bottom of the horizontal arm (floor stand) closest to the vertical column and not the tube head. Always observe local handling procedures if performing manual height overrides.

In an emergency, it is possible to manually override the vertical movement by pushing the tube stand horizontal arm vertically up the telescopic column (ceiling stand) or the floor stand column.

If a power loss occurs or alternatively when the mains power is switched OFF, the brakes which control the lateral and longitudinal movements of the tube support along the ceiling rails will be freed, allowing the equipment to be moved away from the patient. The vertical is a fail-safe mechanism and will not release.

2.4. 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.

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

Section 3:

Xstrahl 150 Operation

In this section

3. Xstrahl 150 System Operations

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 (this is either a key operation or a mechanical switch). The location of the mains isolator will vary between sites and is established during the installation process.

Powering on the Xstrahl System:

1. Rotate the mains isolator switch from O (OFF) to | (ON) on the side of the TP2 CCU hardware box. This switch is usually located inside the treatment room. *This switch applies mains power to the following system components:*
    - Generator
    - Cooling System
    - Tube Stand (ceiling and floor)
    - Safety Circuit
2. Turn the key switch to *Standby* (position 2) to initiate power. The mains power bulb will illuminate to indicate Power on status.

Note: Power will also now be applied to the controlled area warning lights to indicate that the area is 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 the required interface – Fisica or Concerto will now be available.
5. 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 exponential 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 time required for the short or the long warm-up will depend on the Xstrahl Systems installed.

Standard warm-up times:

Standard Warm-Up Times		
System	**Short Warm-Up**	**Long Warm-Up**
100	10 min	30 min
150	10 min	30 min
200	17.5 min	72.5 min
300	16.43 min	62.18 min

After 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 on the Xstrahl system. The Xstrahl system requires an applicator to be fitted to the sub-tube assembly, but does not require a specific applicator.

2. Double-click the Fisica *or* Concerto icon  .

All of the Xstrahl software applications provide the ability to conduct a system warm-up. If there is a problem with the communication between the PC and the 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: Example Warm-Up Window (Xstrahl 150)

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 (greater than 3 alphanumeric characters)

3 Click *Apply*. Apply checks the filter, applicator and the status of the system.

4 Turn the 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 on, the username will be displayed at 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 warm-up required by the system. The radio buttons can be used to select a different warm-up, if required.
3. Enter the Operator name (more than 3 alphanumeric characters).
4. Select *Apply*. Apply checks the filter, applicator and status of the system.
5. Turn the key switch to *HT* (position 3).
6. Press *X-Rays On.*

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, X-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.

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; it can also be removed while in *Standby*.

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.

Power down the TP2 system:

1 Select File, then Exit to close the application.

2 Power down the PC

3 Turn the key switch on the operator pod to O (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 shutdown delay value has elapsed. When the operator pod is powered OFF, the cooler may remain on due to the shutdown delay. (set in Fisica).

4 Once the cooling power has been removed by the system, turn the TP2 CCU base unit off inside the treatment room. This removes power from the tube stand and TP2 hardware.

The mains light will no longer be illuminated and the operator will hear the safety interlock drop out. The auxiliary supply to the tube stand and cooling system will remain on. The cooling system will remain on until the time lapse after the last exposure[1] has elapsed.

This has two functions:

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

1. Recorded in the Fisica database.

Section 4:

Concerto®

4. Concerto®

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	Convertor 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.

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	Heatsink Temperature	Generator error. Displayed whilst the heat 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.

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 opencircuit 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.
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 I/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).
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.
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.
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 retrigger 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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