Xstrahl 300 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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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.

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 ISO13485:2003 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

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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 operate within the following environmental conditions:

Ambient Humidity:	10 to 85% (non-condensing)
Operating Temperature:	10 to 30º Celsius

The storage temperature for all Xstrahl systems (non-operating conditions) must not exceed the following limits:

Ambient Humidity:	10 to 85% (non-condensing)
Storage Temperature:	5 to 40º Celsius

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

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 notices will appear at the point of application.

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.

HIGH VOLTAGE: High voltages are present in all Xstrahl X-Ray Therapy Systems when the system is connected to the mains electrical supply. Exercise extreme caution and isolate the mains electrical supply before attempting to connect any cables or open any service or access doors on equipment.

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)

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 preventive 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 this document be 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 Amendment Table			
No.	**Section**	**Release Date**	**Authorised By**

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Preface

This is the Operator Manual for the Xstrahl 300 X-Ray Therapy System. This manual provides the information a medical operator requires to operate the Xstrahl 300.

1

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 300.

2

Xstrahl 300 System Description

This section provides an overview of the Xstrahl 300 features, including the interface, filters and applicators, illustrations of the base unit and tube stand movements.

3

Xstrahl 300 Operation

This section includes information on how to power on, warm-up and power down the Xstrahl 300.

4

Concerto®

This section provides an overview of Concerto®, the clinical interface for the Xstrahl radiotherapy system. This section demonstrates how to create patients, define treatment parameters and deliver exposures, record values to a database and print hard copy patient reports.

5

System Errors

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

About

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 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 300 System Description

in this section

2 Xstrahl 300 System Description

The Xstrahl 300 is a superficial orthovoltage X-Ray therapy system which produces X-Rays up to 300kV. 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 300

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 software.

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

2.2 Filters and Applicators

The Xstrahl 300 uses an encoding system to detect treatment filters and applicators.

2.2.1 Filters

Figure 2–2: Xstrahl 300 Applicator/Filter Storage

The *Xstrahl 300* X-Ray Therapy System uses an encoding system to detect treatment filters within the filter storage unit. Each system can have up to ten filters—nine clinical filters and one warm-up filter. The clinical filters can be constructed in accordance with the half value layers, as defined by medical physics.

Each filter can be constructed from a maximum of three materials (aluminium, copper and tin), up to a maximum physical thickness of 4 mm. The materials and thickness in combination with the kV for the clinical filter give a resultant HVL measured by the physicist.

The HVL achieved will affect the percentage depth dose achieved. Please refer to the B*ritish Journal of Radiology* (supplement 25) for details on percentage depth doses for a range of HVLs, up to 3 mm copper.

Only the filter required for the treatment should be removed from the storage unit. Treatment delivery will be prohibited if the wrong filter is inserted into the machine head because all of the filters are interlocked.

2.2.2 Filter kV Settings

The following table demonstrates the standard filter set supplied with the Xstrahl 300 system:

Xstrahl 300 Filter kV Settings[a]									
Filter	**1**	**2**	**3**	4	**5**	6	7	8	9
kV	60	80	100	120	150	180	200	250	300
HVL1 (mm)	1.5 Al	2.5 Al	3.0 Al	5.0 Al	6.0 Al	0.5 Cu	1.0 Cu	2.0 Cu	3.0 Cu
Added filtration (mm)	1.0 Al	2.0 Al	2.0 Al	0.5 Al 0.10 Cu	1.00 Al 0.10 Cu	1.5 Al 0.15 Cu	1.0 Al 0.45 Cu	1.0 Al 1.10 Cu	1.5 Al 0.25 Cu 0.50 Sn

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

Figure 2–3: Filter Storage Unit

The Xstrahl 300 filters are housed in a wall-mounted storage unit. They are inserted into the individual slots for storage purposes only. Each filter consists of a main body to the filter holder, a filter holder ring and a handle. Contact with the filter material should be avoided to prevent damaging it.

On the front, handle end of the filter is the filter number, *R* (warm-up filter only) and the numbers *1* through *9* (depending on filter). The opposite end of the filter has a series of small holes which provide the filter encoding when inserted into the system sub-tube assembly, so that each filter is uniquely identified.

The warm-up filter has 6 mm of lead pre-installed in its holder to prevent unwanted X-Ray emissions during the warm-up phase of daily operation.

2.2.3 Removing the Filter

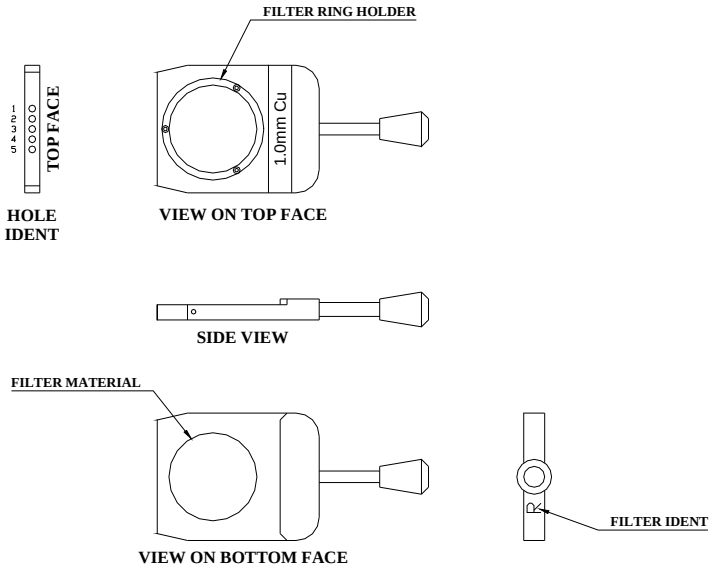
CAUTION: The filter holder should be manipulated by the handle. Contact with the filter material should be avoided to prevent damage to the filter.

To remove a filter from the storage unit:

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

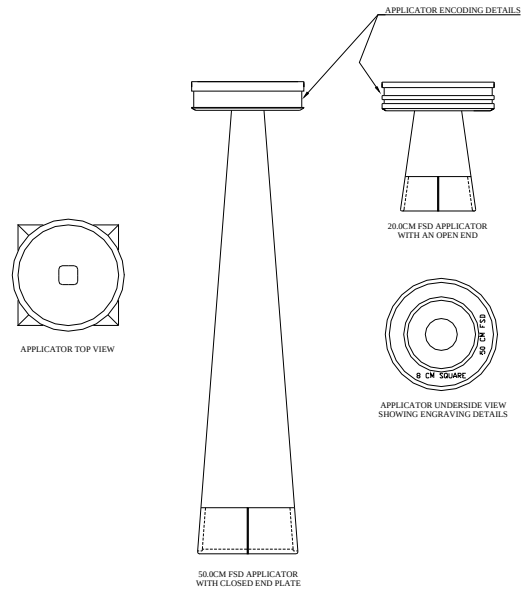
When the filter is no longer required, it should be returned to the filter storage unit. It is recommended that the warm-up filter be inserted into the sub-tube assembly overnight, thus enabling the system to be ready for its daily warm-up on the next working day.

Figure 2–4: Xstrahl 300 Filter Holder



2.2.4 Applicators

Figure 2–5: Xstrahl 300 Applicators



CAUTION: The Xstrahl 300 system applicators weigh up to 5.4 kgs. Care should be exercised when handling at all times.

The standard range of applicators supplied with the Xstrahl 300 are as follows:

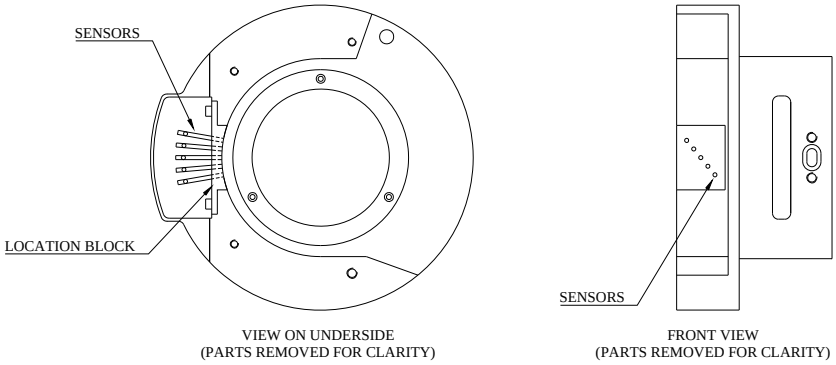
Xstrahl 300 Applicators	
30 cm FSD Open Applicators	**50 cm FSD Closed Applicators**
3 cm diameter	4 cm x 4 cm
4 cm diameter	6 cm x 6 cm
5 cm diameter	8 cm x 8 cm
10 cm diameter	10 cm x 10 cm
	15 cm x 15 cm
	20 cm x 20 cm

The weight of each applicator varies from 3.05 kg to (approximately) 5.4 kgs, with the heaviest type of applicator being the largest field size of 50 cm FSD.

The field size and FSD is engraved on the underside of the top element of each applicator. Each applicator is individually encoded by means of a series of grooves around the top element. The applicator recognition sensors lie along the inner rear surface of the sub-tube assembly and are diagonally staggered.

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. Most of the 30 cm FSD applicators are open-ended with clear viewing ends, but the 50 cm applicators are closed with clear viewing ends.

Figure 2–6: Applicator Sensor



2.2.5 Inserting the Applicator (Into the Sub-Tube)

CAUTION: Two hands should always be used to hold the applicator when carrying the applicator for insertion into the sub-tube assembly. The Xstrahl 300 applicators weigh up to 5.4 kgs and have an FSD of up to 50 cm. The field size and FSD is engraved on the underside of a series of grooves around the top element. The applicator recognition sensors lie along the inner rear surface of the sub-tube assembly and are diagonally staggered.

CAUTION: Do not touch the system ion chamber with the applicator or your fingers as it may cause damage to the ion chamber.

To insert the applicator:

1. Insert the applicator with the sub-tube assembly in the 0º position to enable the sub-tube assembly to take the weight of the applicator whilst inserting.
2. Rotate the door lever to the left until resistance to the movement can be felt.
3. Press the door catch release button, with the right forefinger, to release the locking catch. The sub-tube assembly door will open outwards, while the left hand utilises the grip on the door cover.
4. Rotate the door to the open position to allow for insertion of the chosen applicator.
5. Insert the applicator into the sub-tube assembly, ensuring the applicator locates into the sub-tube assembly with the applicator encoding ring sliding above the lower horseshoe element of the applicator holder (within the sub-tube assembly).
6. Carefully slide the applicator to the back of the sub-tube assembly.

7. Hold the door lever in your left hand, keeping the lever parallel to the X-Ray tube, and close the door with your right hand. This may require a firm push, depending on the applicator.
8. Push the button on the side of the assembly in; do not force the door shut without pushing the catch in as this will cause the catch to wear over time and become loose.
9. Tug on the door slightly to confirm that the door has latched. If not, then the door needs to be pushed a little harder to achieve proper latching.

Note: Ensure the lever is parallel to the X-Ray tube. It is not necessary to push the lever as far as it will go to lock the applicator sufficiently enough to prevent it from rotating within the sub-tube assembly.

10. Rotate the lever towards the door until some resistance is felt, then push the lever a little further.

When the applicator is locked it will not be possible to rotate the applicator within the sub-tube assembly. The inner door elements push the applicator to the back of the location and lift the applicator slightly to engage all of the detection sensors.

2.2.6 Rotation of the Applicator

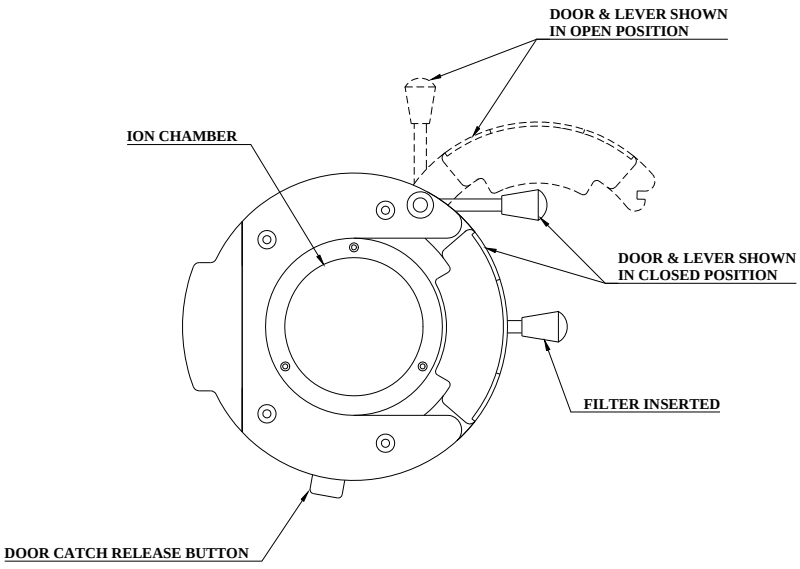
To release the applicator (to enable rotation of the applicator for patient set-up):

- Rotate the door lever slightly until the pressure is released.

The door will not open, but applicator rotation to the desired position will now be possible. When the applicator has been placed in the desired position the door lever can be rotated again (as before) to lock the applicator in place.

It is advisable, when rotating the applicator in the sub-tube assembly, that you push the applicator away from the bottom of the sub-tube assembly to ease the applicator off of the lower inner door element (where some friction may occur).

Figure 2–7: Applicator Movement



2.2.7 Removing the Applicator

To remove the applicator:

1. Place the sub-tube assembly at 0º axial rotation and the tube longitudinal rotation to 0º.
2. Rotate the door lever to the left until resistance is experienced, then press the door catch release button to open the door with the left hand, while utilising the grip on the door cover to the open position.
3. Using two hands, remove the applicator from the sub-tube assembly and return to the storage facility.

2.2.8 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 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 300 Tube Stand

Figure 2–8: Floor/Wall Mounted Tube Stand

Figure 2–9: Ceiling Track Mounted Tube Stand

The Xstrahl 300 can come with either a floor/wall mounted tube stand or mounted on a ceiling track. Electromagnetic brakes lock the tube stand movements. These brakes may be released, individually or in combination by depressing push buttons located on the front panel of the X-Ray tube assembly.

There are two motion enable buttons on the tube head handle. In order to enable movement, the operator must first press a movement brake button and depress a motion enable button(s). The movement brake is only released when the motion

enable buttons are depressed.

CAUTION: Never force a movement of the system without first releasing the brakes or motion enable buttons.

WARNING: When carrying out movements with the Xstrahl 300, 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.

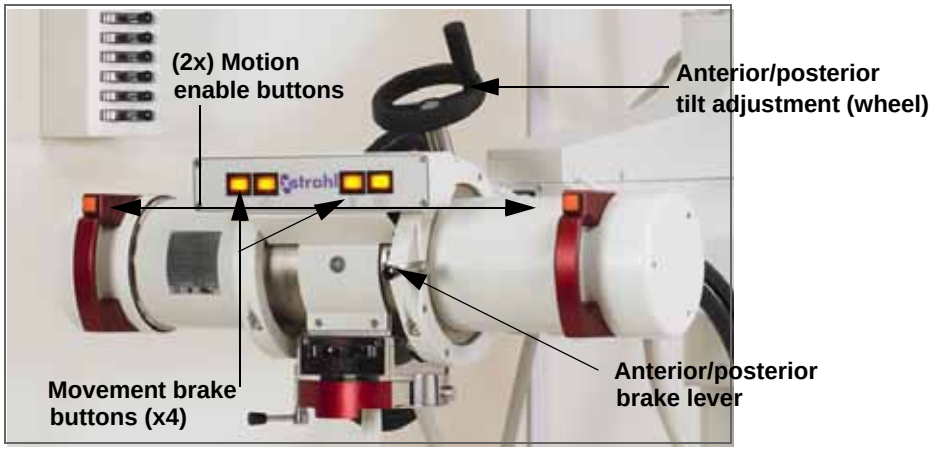
2.4 Movement Controls

Figure 2–10: Location of Movement Controls

The longitudinal and lateral movement brakes are identified by movement arrows. The column rotational movement brake button only works on a ceiling stand, enabling rotation about the vertical column. On an Xstrahl 300 floor/wall mounted stand, this button is green to indicate mains power to the stand.

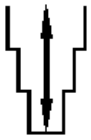
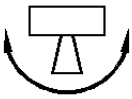
2.4.1 Floor/Wall Stand Systems (Movements)

Figure 2–11: Floor/Wall Tube Stand Controls



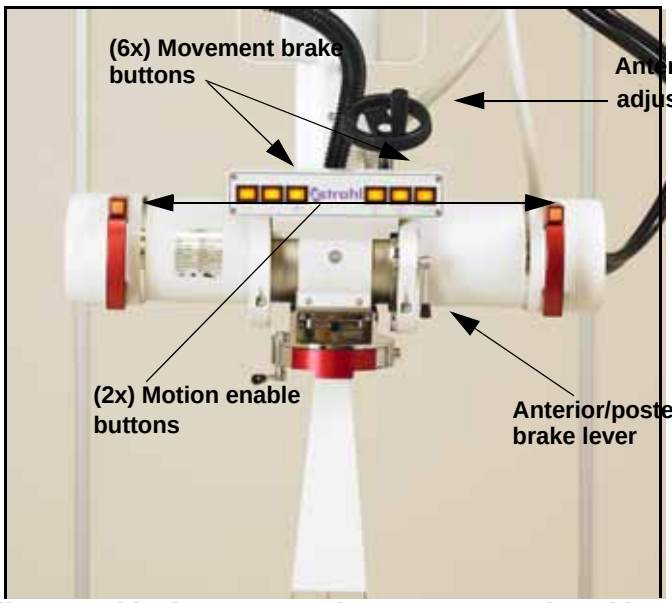
The following table demonstrates the movements achievable with an Xstrahl 300 floor/wall stand system:

Wall/Floor Stand Control Movements	
	**Tube Stand Longitudinal Movement:** 1. Press the longitudinal movement brake button. The button will illuminate to confirm your selection. 2. Press the motion enable button(s) to move the X-Ray tube longitudinally. 3. Release the motion enable button(s) when the desired position is achieved. 4. Release the longitudinal movement brake button to lock.
	**Column Rotation Movement:** 1. Press the column rotation movement brake button. This will illuminate the switch to confirm your selection. 2. Press the motion enable button(s) to enable rotation of the horizontal tube support arm around the vertical axis of the telescopic tube column. 3. Release the motion enable button(s) when the required position is achieved. 4. Release the column rotation movement brake button to lock. Detents are positioned at 90º for precise positioning, however the electromagnetic brakes allow locking of the rotation at any position. The maximum allowed rotation is 90º clockwise and anti-clockwise.

Wall/Floor Stand Control Movements	
	**X-Ray Tube Vertical Movement:** 1. Press the vertical movement brake button. This will illuminate the button to confirm your selection. 2. Press the motion enable button(s) to move the X-Ray tube vertically. 3. Release the motion enable button(s) when the required position is achieved. 4. Release the vertical movement brake button to lock.
	**Tube Head Rotational Movement:** 1. Press the rotation movement brake button to rotate the tube head. 2. Press the motion enable button(s) to move the tube head to desired position or angle. 3. Release the motion enable button(s) when the required position is achieved. 4. Release the rotation movement brake button to lock.
See Floor/Wall Illustration	**Anterior/Posterior Tilt Adjustment (Tube Rotation Wheel):** The rotation wheel on the horizontal arm enables the anterior/ posterior tilt to be adjusted
See Floor/Wall Illustration	**Anterior/Posterior Brake Lever:** Locks in the anterior/posterior movement.
See Floor/Wall Illustration	**Motion Enable Buttons:** Use to enable movement

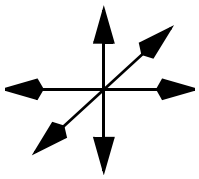
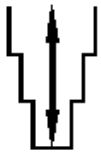
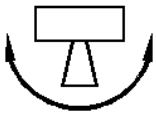
2.4.2 Ceiling Track Systems (Movement)

Figure 2–12: Ceiling Track System Controls



The following table demonstrates the movements achievable with an Xstrahl 300 ceiling track system:

Ceiling Track Movements	
	Lateral Movement: 1. Press the lateral movement brake button. This will enable the machine to move across the lateral rails. 2. Depress the motion enable button(s), while holding the handgrips. 3. Release the motion enable button(s) when the required position is achieved. 4. Release the lateral movement brake button to lock. The range of lateral movement is determined by the positioning of end stops on the rails.
	**Longitudinal Movement:** 1. Press the longitudinal movement brake button. 2. Depress the motion enable button(s), while holding the handgrips. 3. Release the motion enable button(s) when the required position is achieved. 4. Release the longitudinal movement brake button to lock. The range of longitudinal movement is determined by the positioning of end stops on the rails.

Ceiling Track Movements	
	**Longitudinal, Lateral and Vertical Movement (combined):** 1. Press the combined movement brake button. This will enable the tube support assembly to move along the longitudinal ceiling tracks and across the lateral ceiling tracks in a combined movement. 2. Depress the motion enable button(s), while holding the handgrips. 3. Release the motion enable button(s) when the required position is achieved. 4. Release the combined movement brake button to lock.
	**(X-Ray Tube) Vertical Movement:** 1. Press the vertical movement brake button. The button will illuminate to confirm selection. 2. Press the motion enable button(s), while holding the handgrips. This will enable the X-Ray tube to move vertically. 3. Release the motion enable button(s) when the required position is achieved. 4. Release the vertical movement brake button to lock.
	**Tube Head Axial Rotation Movement:** 1. Press the tube head axial movement brake button. 2. Press the motion enable button(s) and angle the tube head to the desired position. 3. Release the motion enable button(s) when the required position is achieved. 4. Release the tube head movement brake button to lock.

Ceiling Track Movements	
	**Rotation (about the) Vertical Column Movement:** 1. Press the rotation (about the) vertical column movement brake button. This will illuminate the switch to confirm your selection. 2. Press the motion enable button(s) to enable rotation of the horizontal tube support arm around the vertical axis of the telescopic tube column. 3. Release the motion enable button(s) when the required position is achieved. 4. Release the rotation (about the) vertical column movement brake button to lock. Detents are positioned at 90º for precise positioning, however the electromagnetic brakes allow locking of the rotation at any position. The maximum allowed rotation is 90º clockwise and anti-clockwise. Use the handgrips to rotate the tube arm, whilst depressing the movement enable button.
See Ceiling/ Track System Controls	**Anterior/Posterior Tilt Adjustment (Wheel):** The anterior/posterior tilt adjustment (wheel) on the horizontal arm enables the tilt to be adjusted.
See Ceiling/ Track System Controls	**Anterior/Posterior Brake Lever:** Use to lock in the anterior/posterior tilt adjustment.
See Ceiling/ Track System Controls	**Motion Enable Buttons:** Use to enable movement

2.4.3 Manual Height Override with 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 the event of an emergency it is possible to manually override the vertical movement by pushing the tube head vertically up the telescopic column (ceiling stand) or the floor stand column. It is only possible to push the tube up—the magnetic braking system will prevent the tube head from coming down, either automatically or manually.

In the event of a power loss or when the mains power is switched off, the brakes controlling the lateral and longitudinal movements of the tube support along the ceiling rails will be freed up, enabling the machine to be moved away from the patient. The vertical brake is a fail-safe mechanism and will not release.

2.5 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 or 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 300 Operation

in this section

3 Xstrahl 300 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 (this is either a key operation or a mechanical switch). The location of the mains isolator will vary between sites and is customer dependent (established during the installation process).

To power 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
   - Generator
   - Cooling System
   - Tube Stand (ceiling and floor) and
   - Safety Circuit.
2. Turn the key switch on the operator pod 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 classified as a controlled area in respect to the ionising radiation regulations.

3. *Power On* the Xstrahl PC
4. Double click the  icon.

3.2 System Warm-Up

The X-Ray tube requires a daily warm-up to be run. 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.

See the table below for standard warm-up times for all Xstrahl systems:

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

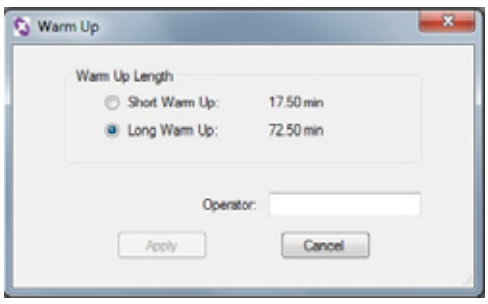
2. Double click the required Fisica or Concerto icon. The Xstrahl software applications provide the ability to conduct a system warm-up. If there is a problem with the communication between the PC and TP2 hardware, an error dialog will be displayed.

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

Figure 3–1: Warm-Up Window (200 Time Shown)



2. Enter the operator name into the operator field. The operator's name must be greater than 3 alphanumeric characters.
3. Select *Apply*. *Apply* checks the filter, applicator and status of the system.
4. Turn the operator 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 logon 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. The operator's name must be greater than three alphanumeric characters.
4. Select *Apply*. Apply checks the filter, applicator and status of the system.
5. Turn the operator pod 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: A warm-up will take longer if interrupted.

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 System Power Down

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.

To power down the system:

1. Select *File*, then *Exit* to close the application.
2. Power down the PC.
3. Turn the key switch to O (Off). This will shut down the mains power from the controller.

Note: The Xstrahl 300 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 (set in Fisica).

4. Once the cooling power has been removed from 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 routinely left overnight with mains power (prolonging the life of the cooling system pump).

1. Recorded in the Fisica database

Section 4:

Concerto®

in this section

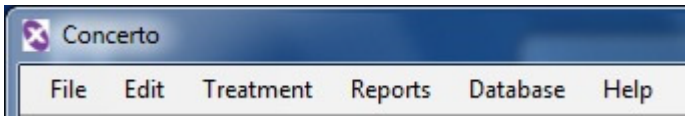
4 Concerto®

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.

4.2 Main Menu

Figure 4–1: Concerto Main Navigation Menu

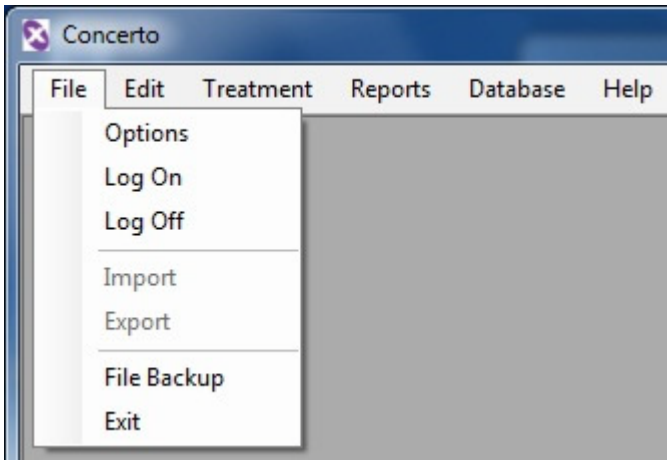


Concerto's Main Navigation Menu consists of File, Edit, Treatment, Reports, Database and Help.

4.2.1 File Menu

The *File Menu* is the primary menu for logging on/off the interface, housekeeping options, backing up files and exiting the software.

Figure 4–2: File Menu

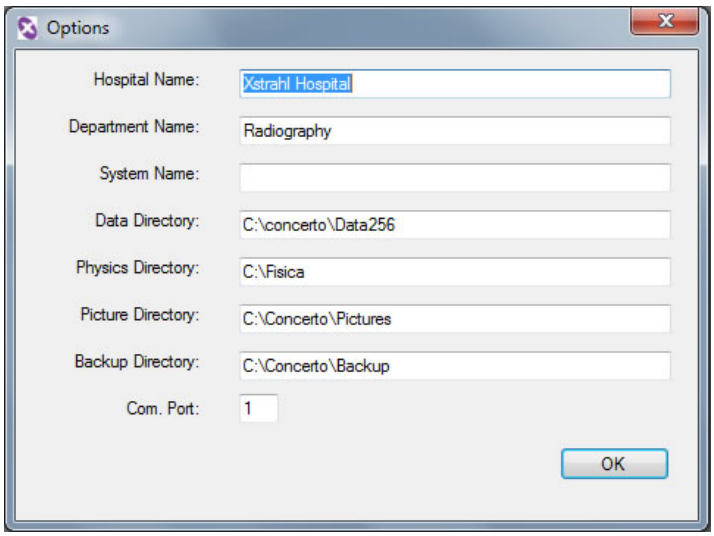


File Menu	Description
Options	Enables user to view or change system options; requires master password.
Log On	Enables user to log on and change a password; requires user ID and password.
Log Off	Logs the user off
Import	For future use
Export	For future use
File Backup	Backs up the treatment database
Exit	Exits the *Concerto* interface

4.2.1.1 Options Window

The user must enter the Master Password to access the *Options* window.

Figure 4–3: File Options Window



Option	Description
Hospital Name	The name of the hospital where this system is located.
Department Name	The name of the department where this system is located.
System Name	The name of this system.
Data Directory	The path and folder where data is stored.
Picture Directory	The path and folder where pictures are stored.
Backup Directory	The path and folder where backups are stored.
Com Port	The COM port on the controller that is connected to the system.

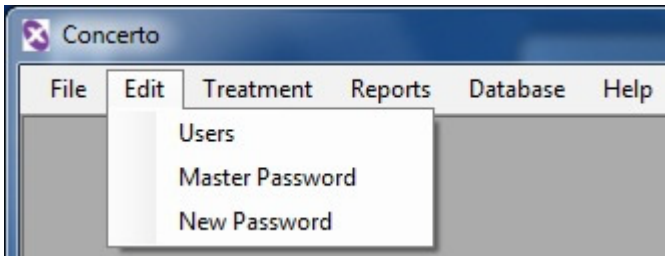
4.2.2 Edit Menu

The *Edit Menu* enables the management of users and passwords.

To manage users/passwords:

- Select *Edit*, then *Users*, *Master Password* or *New Password*

Figure 4–4: Edit Menu

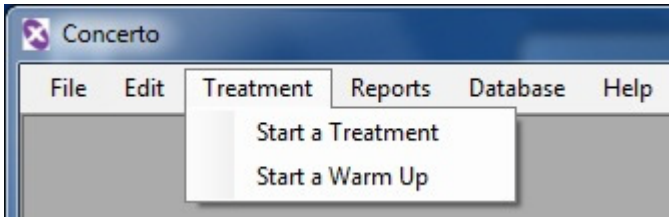


Edit Menu	Description
Users	Requires the master password; edit/adds user details
Master Password	Change the master password; enter the old password, new password and repeat. This is only for changing the master password. The master password is generic to the system and is used to access the user details.
New Password	Change a user password by entering a user name. This is only for changing a user password. Each user has a unique user name and password

Note: If the master password is changed and later forgotten, contact Xstrahl for assistance.

4.2.3 Treatment Menu

Figure 4–5: Treatment Menu



Start a Treatment

Start a Treatment requires a patient ID to create a new patient or a pre-existing patient ID to re-treat a patient. Patient treatment details required are the patient's first name, middle and last name, date of birth, clinician name and ID number. Adding a patient image is optional.

Once the patient information is completed, an operator ID entered and applied, a *New Patient Treatment Window* will appear requesting the treatment exposure information—this is the filter and applicator, time set (or MU if dose system), field, position and treatment image.

Start a Warm-Up

Starts a Warm-Up; select either a short warm-up (after 16 hours of inactivity) or a long warm-up (after 28 days of inactivity). The system will automatically default to the required warm-up.

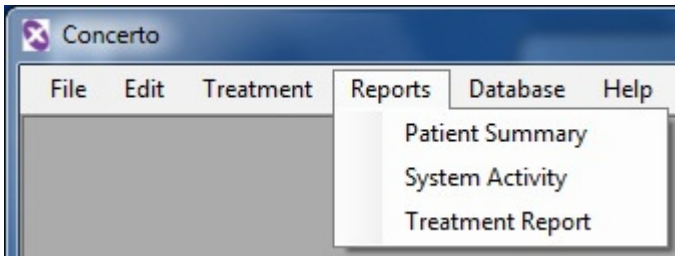
4.2.4 Reports Menu

Concerto provides three reports—a *patient summary*, *system activity* and *treatment report*. Each report has a top *navigation menu* which manages the report views (Figure 4–6:). Reports can be printed, saved as a PDF or exported to other file formats.

To generate a report:

- Select *Reports*, then either *Patient Summary* (Figure 4–46:), *System Activity* (Figure 4–49:) or *Treatment Report* (Figure 4–50:)

Figure 4–6: Reports Menu



Reports Menu	Description
Patient Summary	Patient treatment summary displaying the patient name, ID, date of birth, clinician and treatment series information, including the total time or MU of series, filter and applicator used and the date and time of exposures given.
System Activity	Activity of the system by date, time, filter, applicator, kV/mA, exposure minutes or MU, operator who ran the treatment and errors, if any.
Treatment Report	Displays the name, date of birth, patient ID and the date of previous exposures and the treatment time provided in minutes (or MU). This report is specific to a single exposure only.

4.2.5 Database Menu

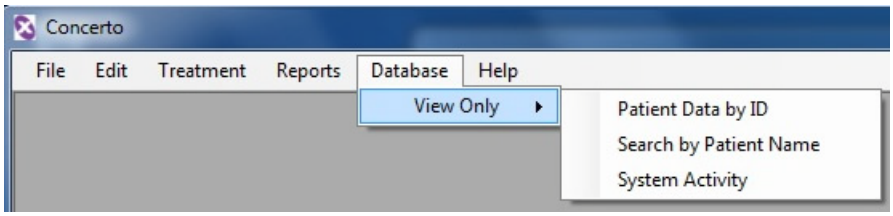
All patient data and treatment exposures are recorded in the *Concerto* treatment database. There are three ways to view data—searching by *patient data by ID*, *patient name* or *system activity* (calendar date).

The treatment database is *read only* and cannot be edited.

To view patient data in database:

- Select *Database*, *View Only*, then either *Patient Data by ID* or *Search by Patient Name* or *System Activity.*

Figure 4–7: Database Menu

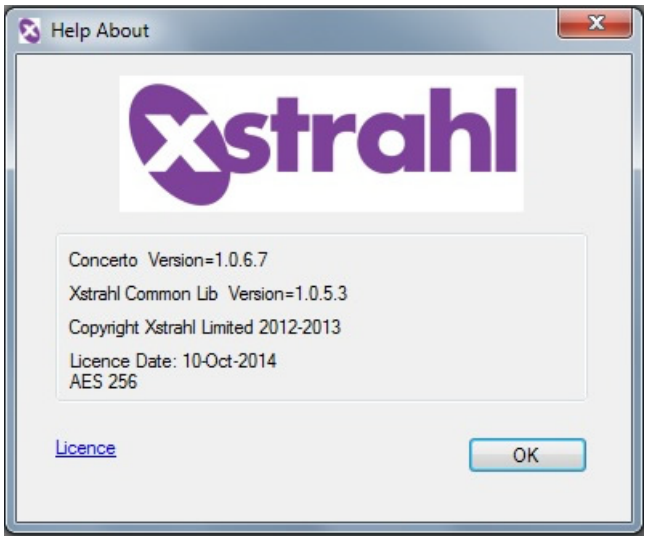


Database Menu	Description
Patient Data by ID	Searches for patient record by patient ID number
Search by Patient Name	Searches for patient record by patient name
System Activity	Searches for system activity (exposures) by calendar date. Data is specific to the machine and not to a particular patient.

4.2.6 Help Menu

The *Help Window* (Figure 4–8:) displays the software version, common library, copyright and licence information.

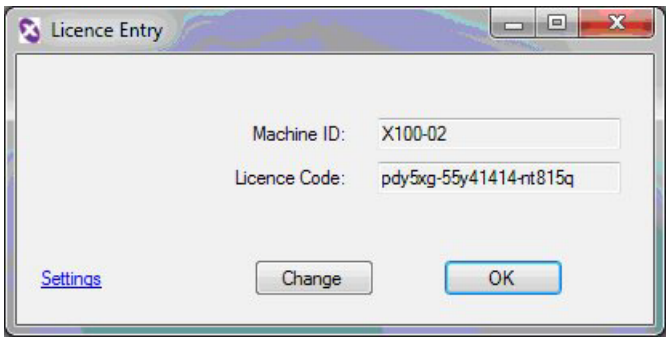
Figure 4–8: Help Window



Licence

The *Licence Window* displays the *machine identification number* and *licence code*. If this information is not entered, the software will not run.

Figure 4–9: Licence Window



4.3 Operator Guide to Concerto®

4.3.1 Powering On and Logging On

Note: Departmental variations may occur where there is a mains isolator switch present. If this is the case, the mains isolator will also need to be switched on. However, it is only necessary to power off the machine by the operator control pod at the end of the clinical day. The mains isolator can be left on (or switched off) to comply with departmental protocol.

Power on and log on to *Concerto*:

1. Turn the mains isolator to the *On* position (if present).
2. Turn the TP2 CCU mains switch clockwise to the | (ON) position.
3. Insert the mains key in the front of the operator control pod, then turn the key switch clockwise to *Standby* (|) (position 2). The *Power On* light will illuminate.
4. Turn on the PC. Double click the  icon on the desktop to launch *Concerto*. The *Main Navigation Menu* will display.
5. Log on by selecting *File*, then *Log On* (Figure 4–10:). Enter your user name and password and select *OK* (Figure 4–11:). You will now be logged on to the system and are ready to run a warm-up, if required.

Figure 4–10: Log On to Concerto

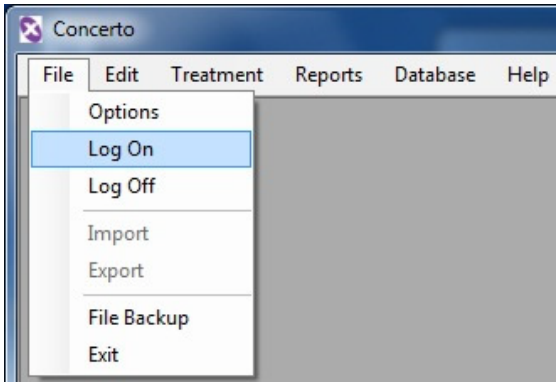
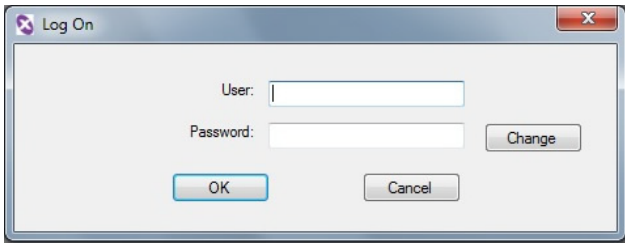


Figure 4–11: Enter User Name and Password



Note: It is not possible to carry out any exposures until the user is logged on.

4.3.2 Managing User Data (Adding Users and Editing Passwords)

You must enter a user's existing password before changing their password.

You must enter the *Master Password* before:

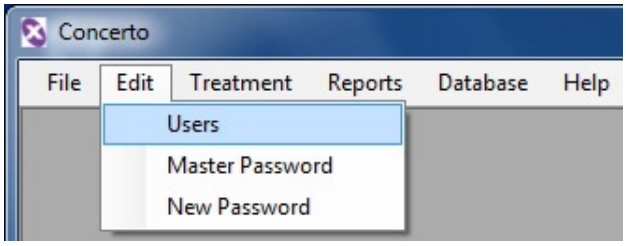
- adding a new user
- deleting a *User Password*
- changing the *Master Password*

4.3.2.1 Add a User

To add a user:

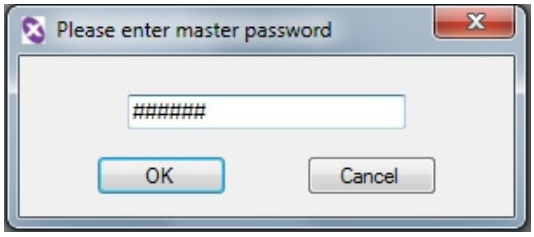
1. Select *Edit*, then *Users* (Figure 4–12:).

Figure 4–12: Add a User



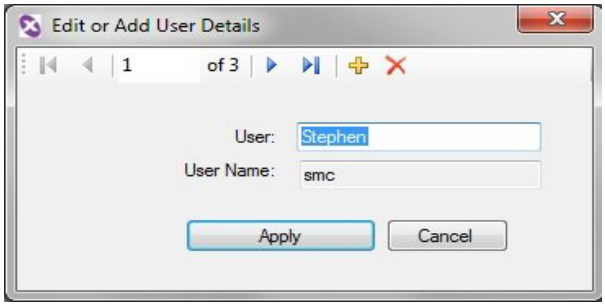
2. Enter the *Master Password* and select *OK* (Figure 4–13:).

Figure 4–13: Enter the Master Password



3. Select the "+" add icon, then enter the *name* of the new user and a *user name* and select *OK* (Figure 4–14:). The new user will be entered into the database.

Figure 4–14: Enter the Name and User Name



To scroll through the list of existing users, select the *forward/back arrows* in the navigation menu at the top of the window.

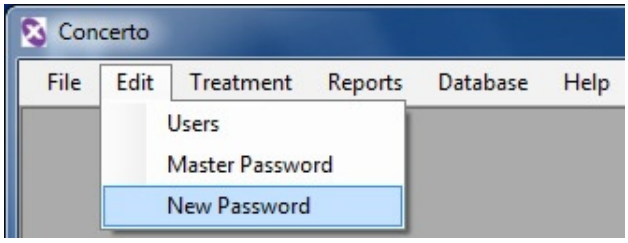
A password must now be created for the new user name.

4.3.2.2 Create a User Password

To create a user password:

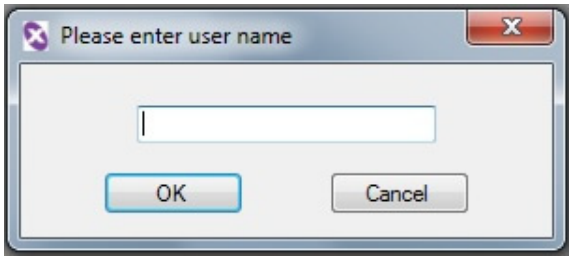
1. Select *Edit*, then *New Password*

Figure 4–15: Create a New Password



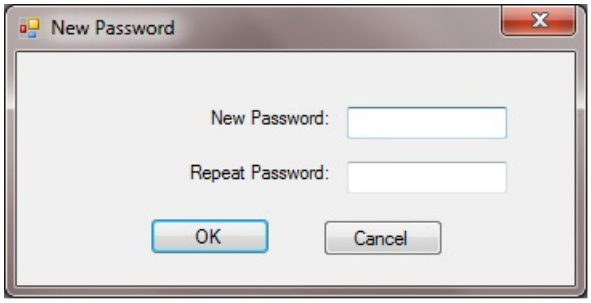
2. Enter the *User Name* and select *OK* (Figure 4–16:)

Figure 4–16: Enter the User Name



3. Enter the *new password* and *repeat*, then select *OK* (Figure 4–17:).
   Note that before a new password can be set for an existing user, the old password must be entered.

Figure 4–17: New Password



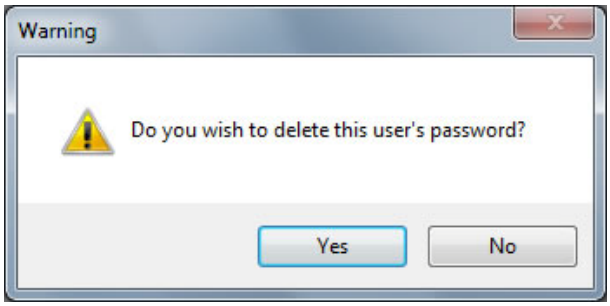
4.3.2.3 Delete a User Password

You can delete a user password to prevent that user from logging on. You can not delete the password of the user who is logged on.

To delete a user password:

1. Select *Edit*, then *Users* (Figure 4–12:).
2. Enter the *Master Password* and select *OK* (Figure 4–13:).
3. Scroll through the list of users until the required user is displayed.
4. Select the delete icon then select *Yes* (Figure 4–18:).

Figure 4–18: Delete the User Password



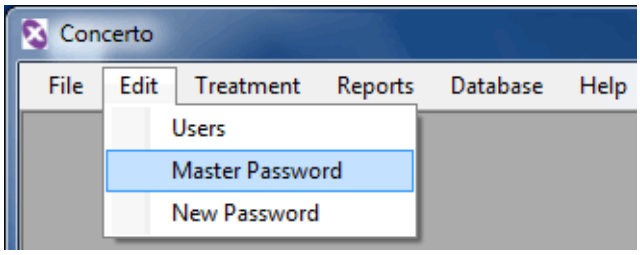
4.3.2.4 Change the Master Password

Note: If the master password is changed and forgotten, contact Xstrahl for further assistance.

To change the master password:

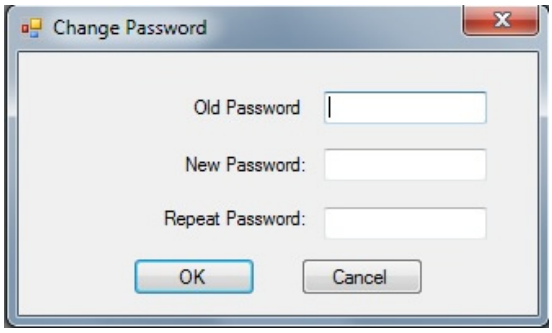
1. Select *Edit*, then *Master Password*

Figure 4–19: Master Password



2. Enter the *old password*, *new password* and *repeat password*, then select *OK*.

Figure 4–20: Enter Current Master Password



The master password will now be changed.

4.3.3 Warm-Ups

A daily warm-up must be completed before running any exposures; if the warm-up is bypassed, an error message is displayed. The warm-up can be carried out in either *Concerto* or *Fisica*. Both software applications know the other has completed a warm-up.

CAUTION: If a warm-up is bypassed, it will be recorded in the log. Bypassing the warm-up will invalidate the X-Ray tube warranty.

The following assumes you are already logged into the system (Section 4.3.1).

Run a warm-up:

1. Select *Treatment*, then *Start a Warm-Up* (Figure 4–21:). If a warm-up is required, the warm-up screen will appear—if a warm-up is not required, a *Warm-up is not required message* (Figure 4–22:) will appear providing the option to *continue* or *abort*.

Figure 4–21: Start a Warm Up

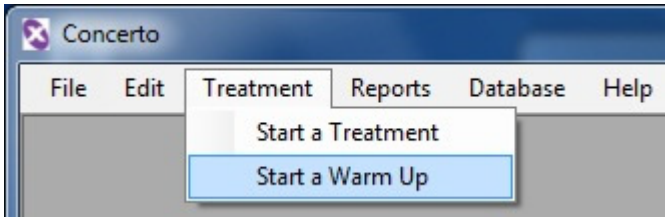
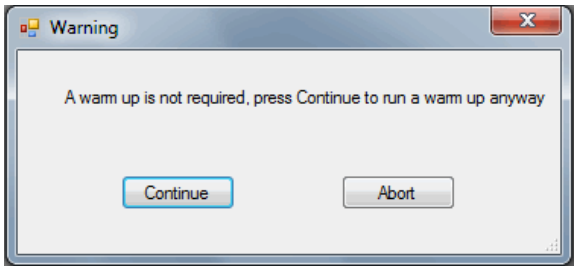
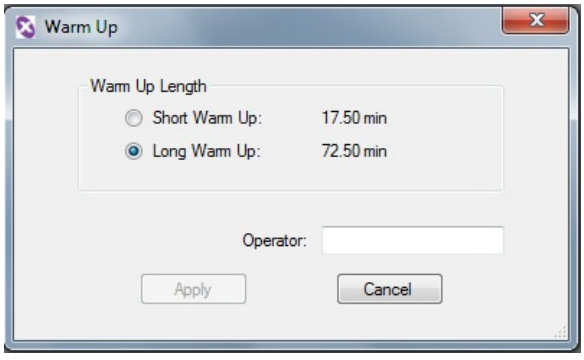


Figure 4–22: Warm-Up Not Required Message



2. Select either the *Short Warm-Up* or the *Long Warm-Up* (Figure 4–23:).A short warm-up is required after 16 hours of inactivity and a long warm-up is required after 28 days of inactivity.

Figure 4–23: Warm-Up Screen



3. Ensure the warm-up filter and any applicator are fitted to the unit. Enter your *Operator Name* and select *Apply* (Figure 4–23:). The system will check that the warm-up filter is fitted. The system checks if an applicator is fitted, but does not require a specific applicator.

4. When *Ready Status* displays on the *Warm-up Window* (Figure 4–24:), turn the key switch to *HT* (position 3). The *X-Ray On* button will now illuminate on the pod.

Figure 4–24: Warm-Up Screen: Ready Status

5. Press the *X-Ray On* button to initiate exposure and run the warm-up.

6. After the warm-up has completed, return the key switch to *Standby* (position 2) and select the OK button to close the window.

CAUTION: If a *long warm-up* is selected by the system, it is not recommended that you override it with a short warm-up.

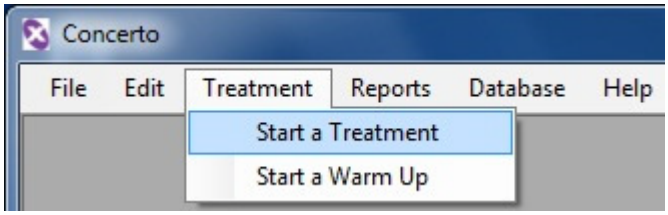
4.3.4 Creating a New Patient and Treatment Field

The following assumes you are logged on to the system (Section 4.3.1) and that a warm-up has already been run (Section 4.2.3). *Concerto* will warn the operator if a warm-up has not been run in either Concerto or Fisica. Warm-ups should not be overridden.

To create a new patient treatment field:

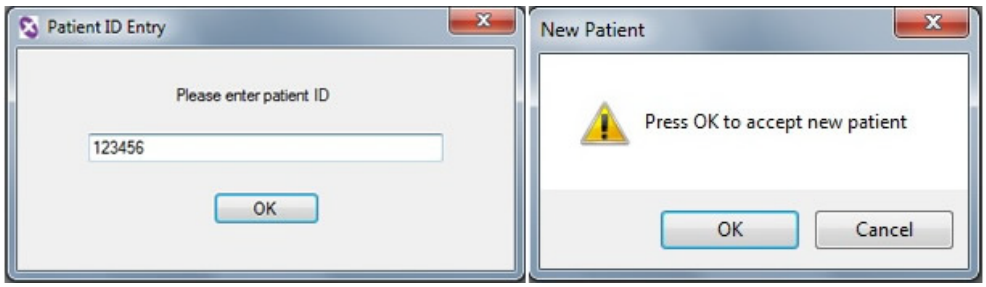
1. Select *Treatment*, then *Start a Treatment* (Figure 4–25:)

Figure 4–25: Start a Treatment



2. Enter the *patient ID* at the prompt and select *OK* (Figure 4–26:). The system will now check the database to see if this is a new ID. Select *OK* to the *Press OK to Accept New Patient* message.

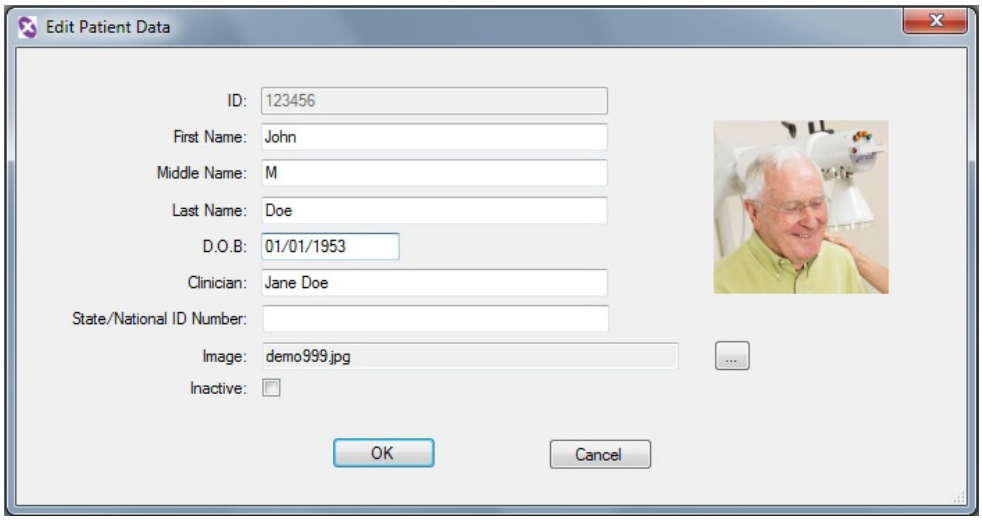
Figure 4–26: Enter New Patient



3. Enter the new patient's details in the *Edit Patient Data Window* (Figure 4–27:)—this includes the first name, middle and last name, date of birth, clinician name and ID number; then select the "..." field to insert the patient's ID photo. Selecting the *Inactive box* will inactivate the patient so they cannot be called up for treatment. Select *OK* to display the *New Patient Treatment Window* (Figure 4–28:).

Note: *First Name*, *Last Name* and *Date of Birth* (D.O.B.) fields are compulsory. *Middle Name*, *Clinician*, *State/National ID Number* and image are not compulsory.

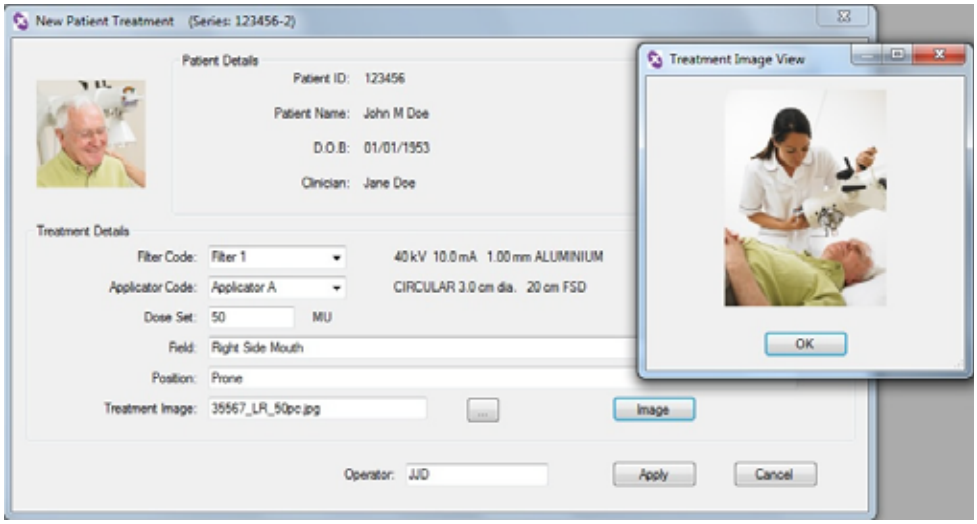
Figure 4–27: Enter Patient Data



Note: Once an exposure has been delivered it is only possible to edit the *Clinician* and *State/National ID Number*.

4. Enter the treatment exposure parameters in the *New Patient Treatment Window* (Figure 4–28:)—select the *filter* and *applicator* from the drop-down menu (the filter and applicator must be fitted before the *Apply* button is activated), the time set (or MU for dose systems), field, position and treatment field image[1]. Only filters and applicators *in use* in *Fisica* will be visible in the drop-down menus. Only calibrated filter/applicator combinations are allowed for a dose system.

Figure 4–28: New Patient Treatment



5. Enter *operator name* (more than 3 characters) and select *Apply.*

The system checks the status. If a *safety interlock* is not satisfied, the *Treatment of Current Field Window* will not be available.

1. Errors will display if the maximum number of characters entered in each field is exceeded.

6. Turn the key switch to *HT* (position 3). The green *X-Ray On* button will illuminate. If the *Ready Status* message is displayed on the *Treatment of Current Field Window* (Figure 4–29:), press the green *X-Ray On* button on the pod to commence the exposure. Once the exposure has completed, return the key switch to *Standby* (position 2).

Note: The green *Set Values* are the primary values entered for the exposure. For time systems these values are minutes, kV and mA. For dose systems, these values are MU, kV and dose rate. The *Actual Values* are the real time values, which are monitored while the exposure is delivered. The back-up time is monitored and updated in real time as the exposure is delivered.

Figure 4–29: Treatment of Current Field Window: Ready Status

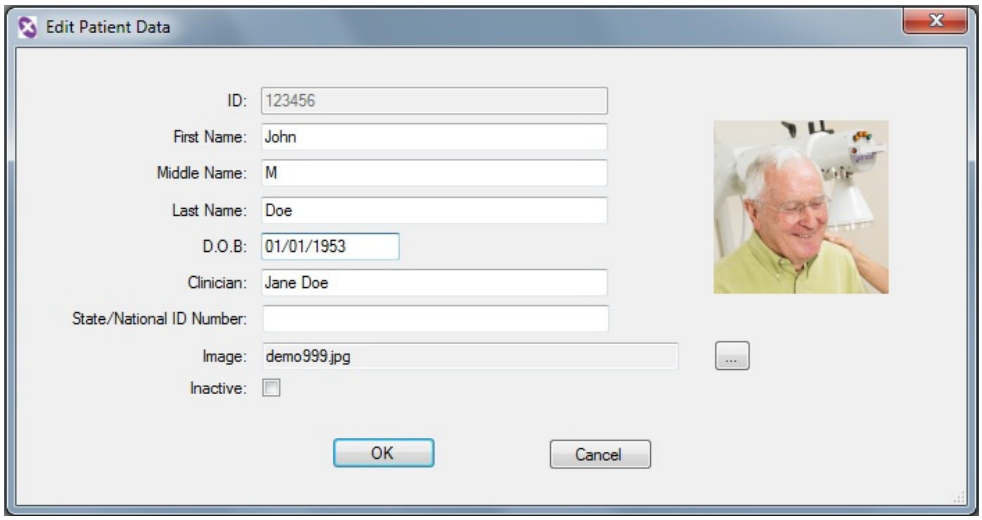
7. Select *Print* to render a treatment report, which can be printed or exported. The details of the exposure will be written to the patient database.

8. Select *OK* to close the exposure window.

4.3.5 Patient Images

Concerto provides the operator with the ability to attach a patient ID image to the patient data and also attach a treatment field image to the treatment data. Patient and treatment images can be uploaded as jpgs in the pictures folder and then added from the *Edit Patient Data* window (Section 4.3.4) or the *New Patient Treatment* window. You can change the location of the pictures folder from the *Options* menu (Section 4.2.1).

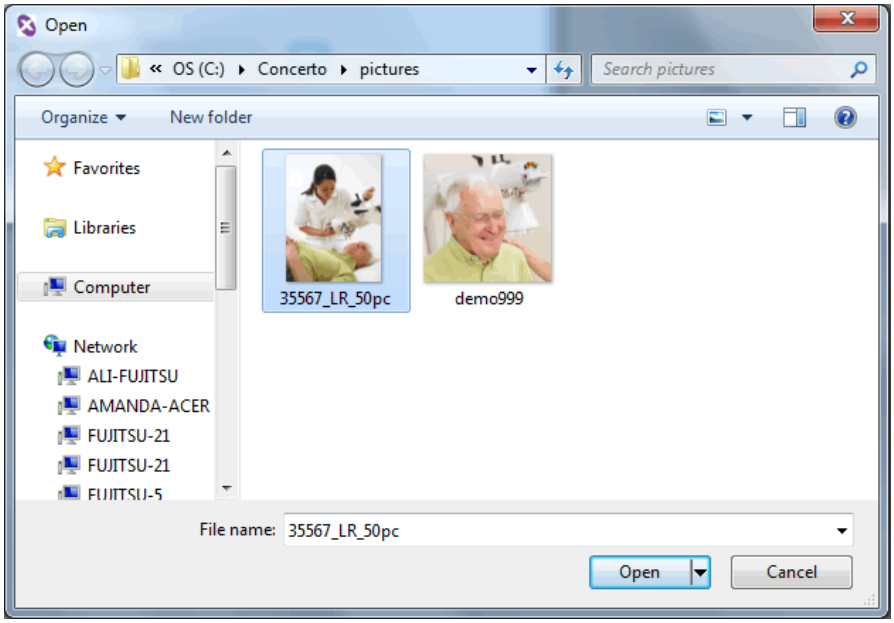
Figure 4–30: Edit Patient Data: Adding an Image.



To add an image (from the *Edit Patient Data* window):

1. Select the "..." (Figure 4–30:). This opens the pictures folder.
2. Highlight an image (previously saved in this folder) and select *Open* (Figure 4–31:). The image will be placed in the patient record.

Figure 4–31: Select an Image



3. Select *OK* to save the image to the record.

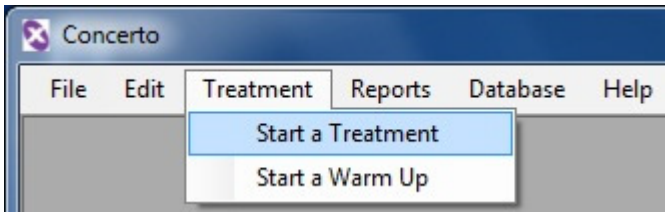
4.3.6 Retreating an Existing Patient

The following assumes you are logged on to the system, a warm-up has already been run, and a patient has already been treated.

To recall a patient treatment field for delivery:

1. Select *Treatment*, then *Start a Treatment*

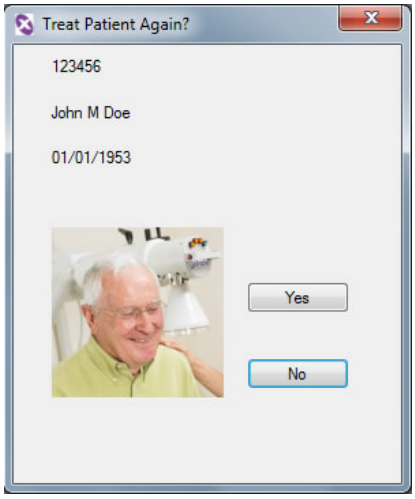
Figure 4–32: Start a Treatment to Re-Treat a Patient



2. If the patient has just been treated, *Concerto* will prompt to retreat the same patient—A *Treat Patient Again Window?* will display (Figure 4–33:).

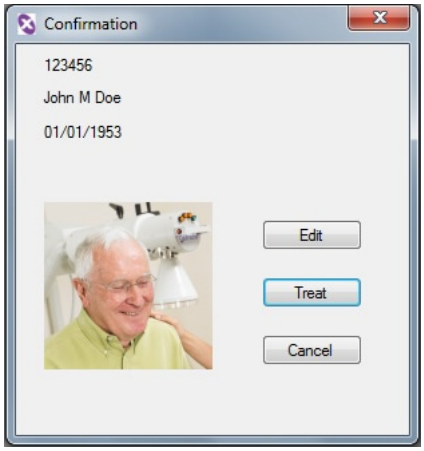
3. Select *Yes* in the *Treat Patient Again?* window.

Figure 4–33: Treat Patient Again?



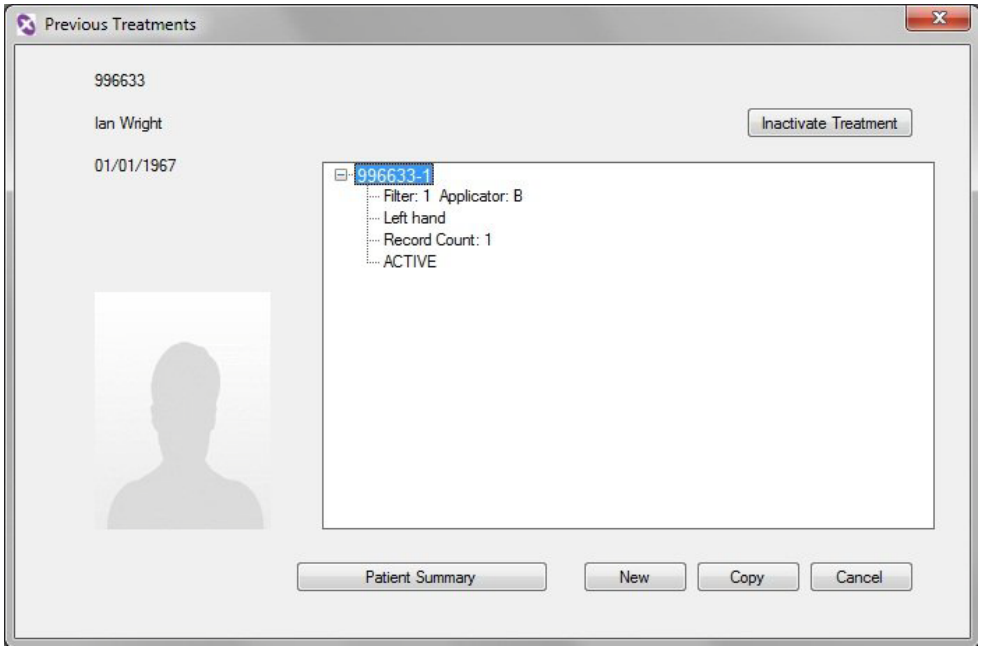
4. Select *Treat* from the *Confirmation Window* (Figure 4–34:). The *Previous Treatments Window* will display (Figure 4–35:).

Figure 4–34: Confirmation Window



5. Select the treatment series, then select a previous exposure to re-treat (Figure 4–35:) and select *Copy*. This will display the previous treatment's parameters. When an exposure is copied, it is not possible to edit any of the parameters. The parameters will remain the same as the previous exposure. To confirm how many treatments the patient has received, select *Patient Summary* to display a patient summary report.

Figure 4–35: Previous Treatments Window



6. If the treatment parameters are correct (Figure 4–36:), enter your operator name and select *Apply*. The *Treatment of Current Field Window* will now display the *Ready Status* message (Figure 4–37:).

Figure 4–36: Repeat Treatment Window

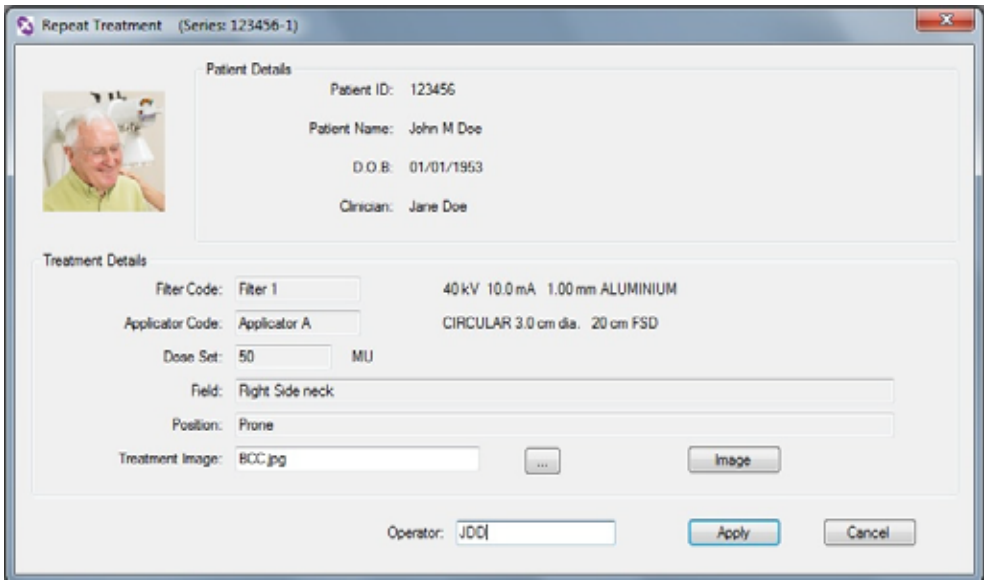


Figure 4–37: Treatment of Current Field Window: Ready Status

7. Turn the safety key switch to *HT* (position 3), then press the illuminated *X-Ray On* button to commence the exposure. The exposure will now run. Once the exposure has completed, return the key switch to *Standby* (position 2).

8. Select *Print* to produce a hard copy report of the exposure.

9. Press *OK* to close the exposure window. The details of the exposure will be written to the patient database.

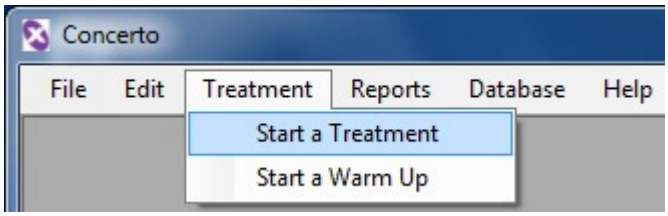
4.3.7 Creating a New Treatment Field for an Existing Patient

The following assumes you are logged on to the system and that a warm-up has already been run.

Create a new treatment field for an existing patient:

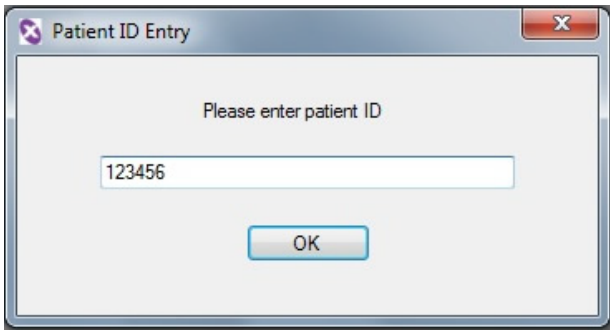
1. Select *Treatment* ➢ *Start a Treatment*

Figure 4–38: Start a Treatment Window



2. Enter the existing *Patient ID* (Figure 4–39:) and select *OK*

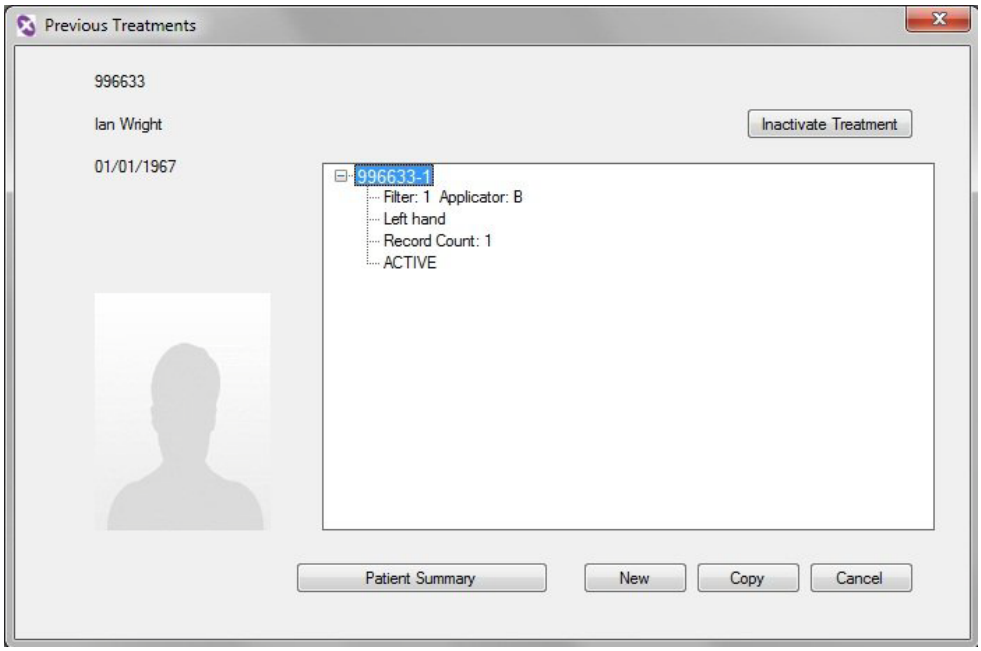
Figure 4–39: Patient ID



3. Select *Yes* in the *Treat Patient Again? Window* (which will only display if the patient has *just been* treated). The *Previous Treatments Window* will appear (Figure 4–40:) with previous treatment exposure highlighted.

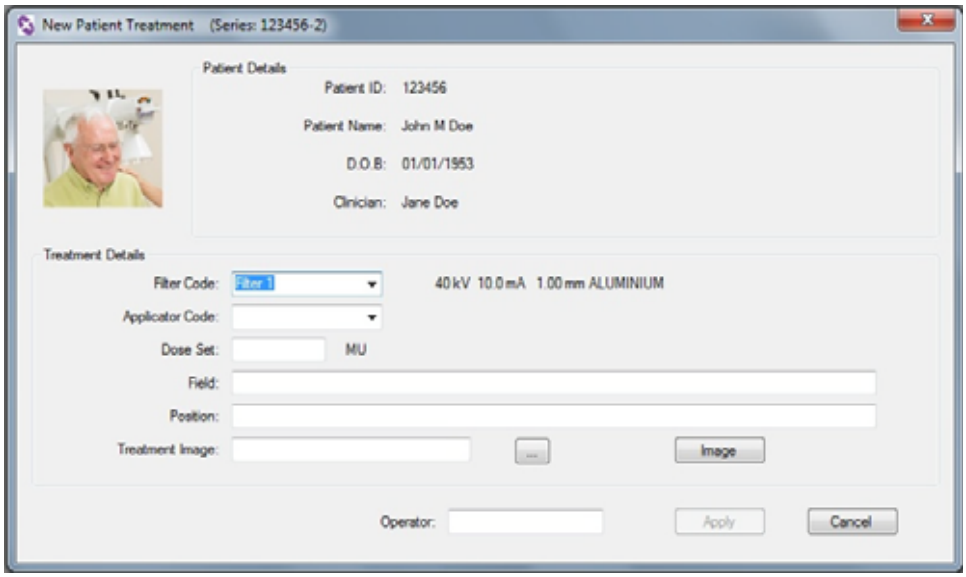
4. Select *New* in the *Previous Treatments Window* (Figure 4–40:). The *New Patient Treatment Window* will display and the new exposure information can then be entered.

Figure 4–40: Previous Treatments Window: Select New



5. Enter the new treatment exposure parameters—select the *filter* and *applicator* from the drop-down menu (the filter and applicator must be fitted before the *Apply* button is activated), the time set (or MU for dose systems), field, position and treatment image. Only filters and applicators *in use* in *Fisica* will be visible in the drop-down menus. Only calibrated filter/ applicator combinations are allowed for a dose system.

Figure 4–41: Enter Treatment Parameters of New Treatment



6. Turn the key switch to *HT* (position 3). The green *X-Ray On* button will illuminate. If the *Ready Status* message is displayed on the *Treatment of Current Field Window* (Figure 4–42:), press the green *X-Ray On* button on the pod to commence exposure. Once the exposure has completed, return the key switch to *Standby* (position 2).

Figure 4–42: Treatment of Current Field Window: Ready Status

7. Select *Print* to generate a treatment report or select OK to close the exposure window. After the exposure has completed, the details will be written to the database and stored.

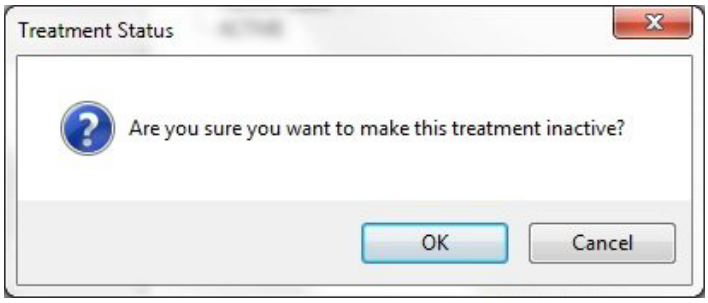
8. Select *OK* to close the exposure window.

4.3.8 Making a Treatment Field Inactive

To stop a treatment from being selected and delivered, it can be set to INACTIVE:

1. Select the treatment series, then click on the *Inactivate Treatment* button (Figure 4–35:).
2. On the Treatment Status window, click OK to confirm that the treatment should be made inactive (Figure 4–43:).

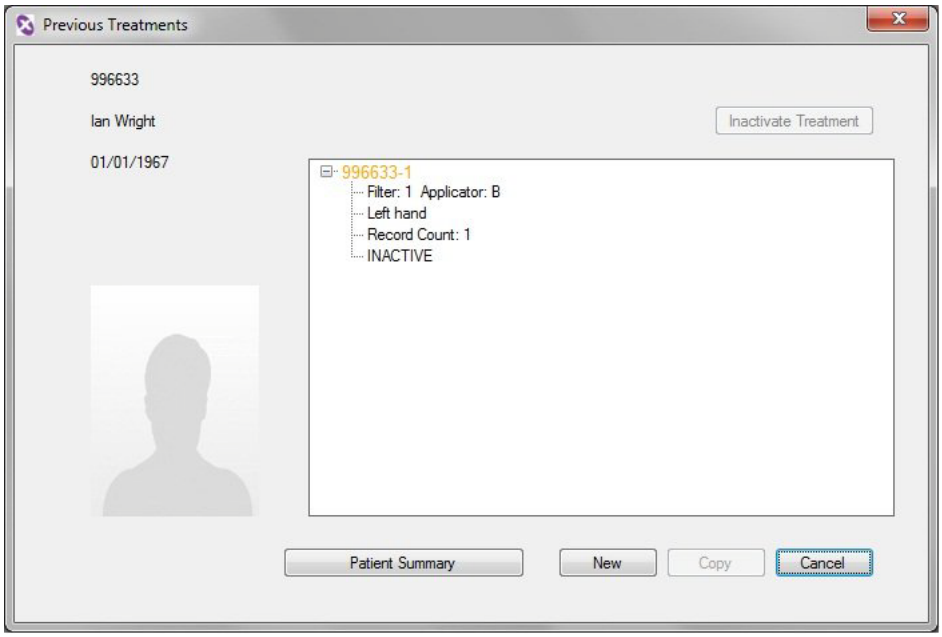
Figure 4–43: Treatment Status



The Previous Treatments window is updated. It shows:

- the treatment series name in a different colour
- the status is changed to INACTIVE
- the *Copy* function is not available:

Figure 4–44: Previous Treatments- Inactive Treatment

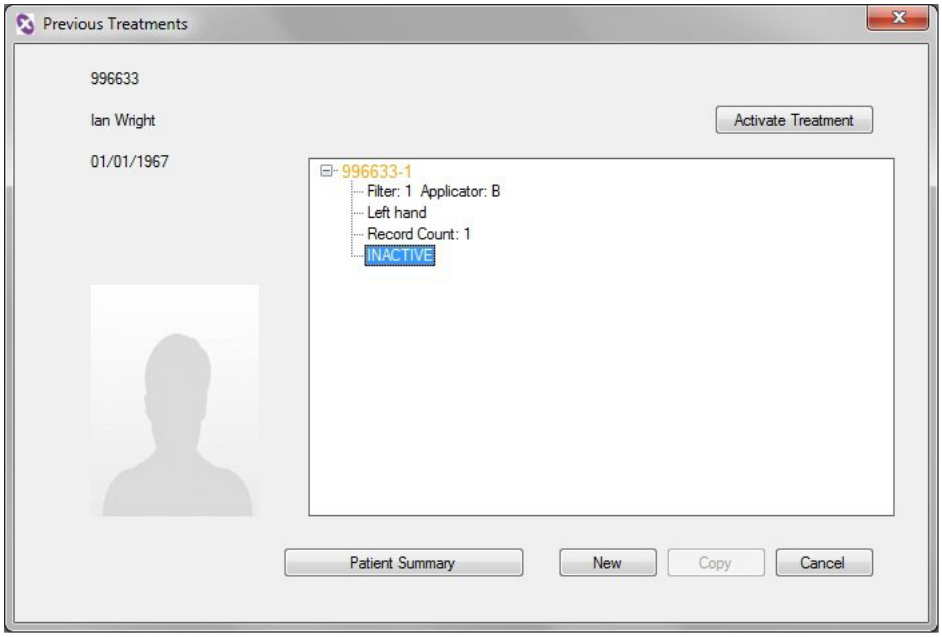


4.3.8.1 Activating a Treatment

Once a treatment is inactive, it must be activated before it can be used again. To activate a treatment:

1. Select the treatment series, then click on the INACTIVE status (Figure 4–45:).
2. Click the *Activate Treatment* button.

Figure 4–45: Previous Treatments- Activate Treatment



3. On the Treatment Status window, click *OK* to confirm that the treatment should be made active.

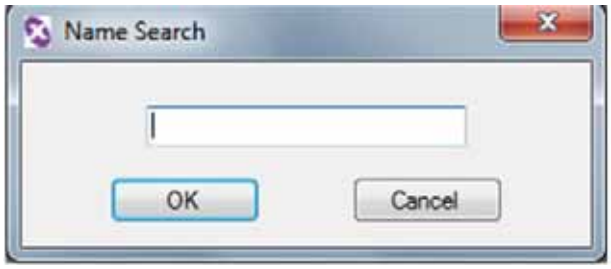
The Previous Treatment window is displayed, showing the treatment is ACTIVE, and the *Copy* function is available.

4.3.9 Producing Reports

4.3.9.1 Patient Summary

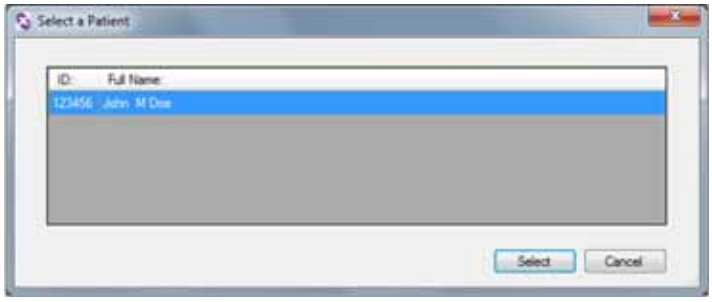
1. *Select Reports*, then *Patient Summary*.

Figure 4–46: Name search



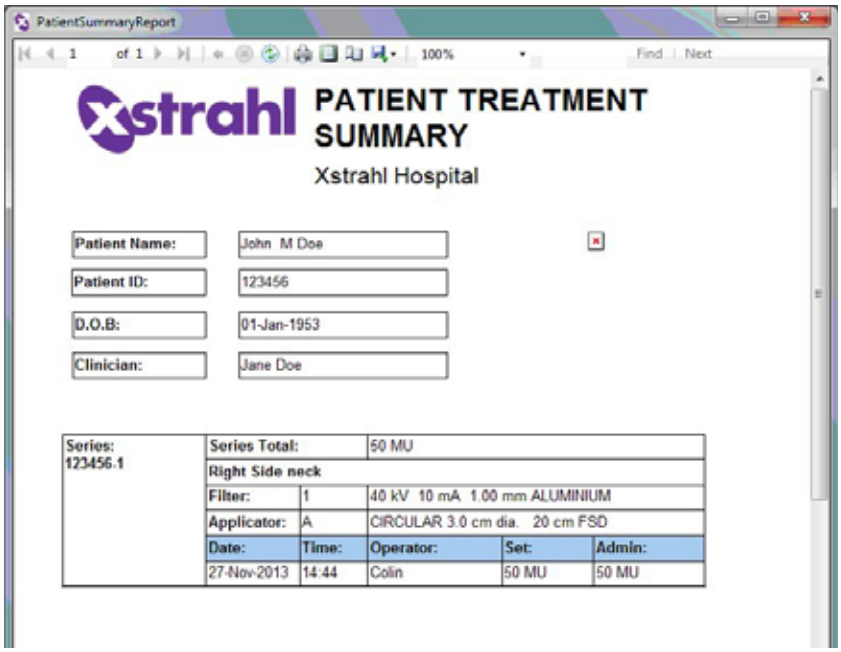
Enter your patient's name and press Enter or click OK to display the names matching your search:

Figure 4–47: Select a Patient



2. Highlight the correct patient if there is more than one displayed, and press Select. The Patient Treatment Summary is displayed:

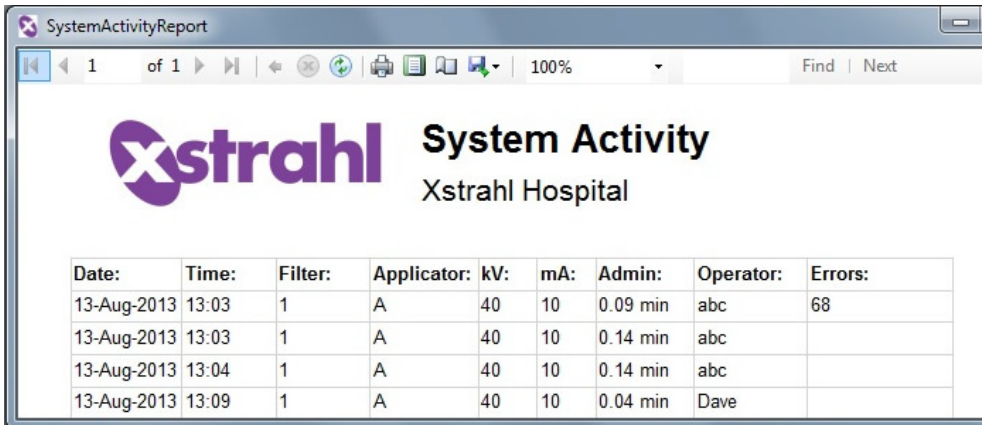
Figure 4–48: Patient Treatment Summary



4.3.9.2 System Activity

1. Select *Reports*, then *System Activity.*
2. Enter a start date from the date picker and select OK.

Figure 4–49: System Activity Report

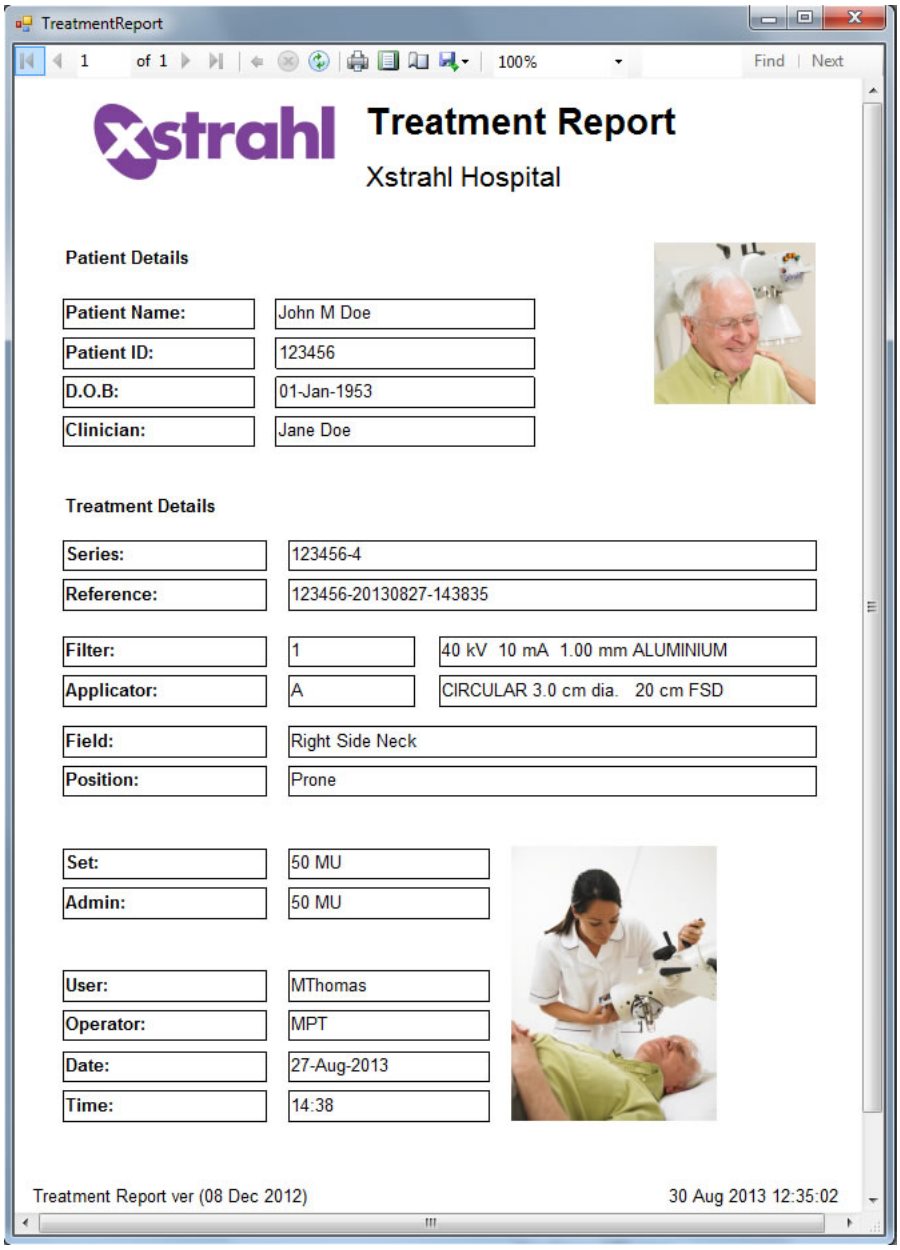


Date:	Time:	Filter:	Applicator:	kV:	mA:	Admin:	Operator:	Errors:
13-Aug-2013	13:03	1	A	40	10	0.09 min	abc	68
13-Aug-2013	13:03	1	A	40	10	0.14 min	abc	
13-Aug-2013	13:04	1	A	40	10	0.14 min	abc	
13-Aug-2013	13:09	1	A	40	10	0.04 min	Dave	

4.3.9.3 Treatment Report

1. Select *Reports*, then *Treatment Report.*
2. Enter the name of your patient in the dialog box, or enter the first letter of their name and press *Enter.*
3. Select the correct patient and press *Select*. The Treatment Report for the patient is displayed:

Figure 4–50: Treatment Report



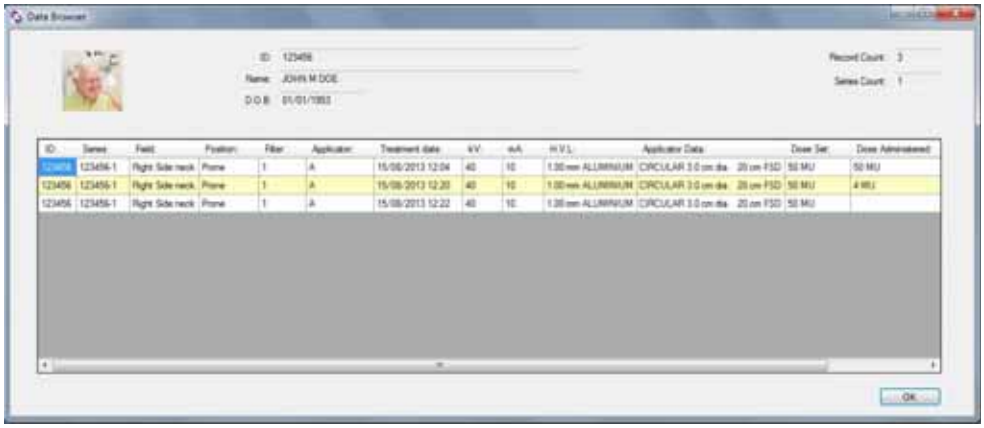
4. Expand the treatment series required and select the treatment record to be printed.
5. Print the selection.

4.3.10 Viewing Data

4.3.10.1 Patient Data by ID

1. Select *Database*, *View Only*, then *Patient Data by ID*.
2. Enter the ID in the search box and click OK to display a complete treatment history for the patient:

Figure 4–51: Search by Patient ID



4.3.10.2 Search by Patient Name

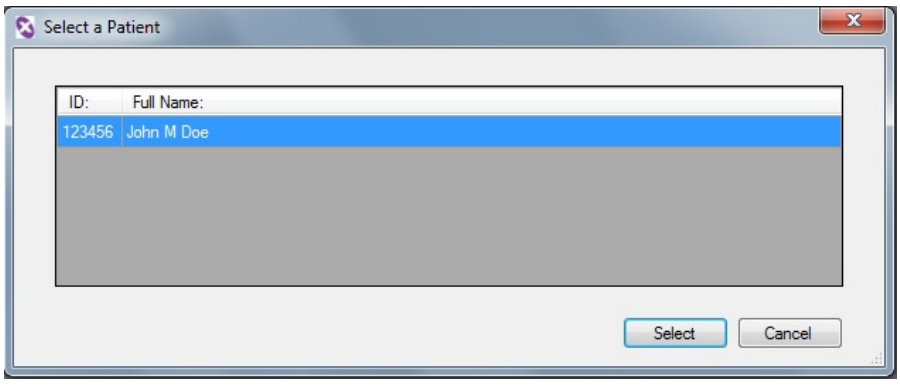
1. Select *Database*, *View Only*, then *Search by Patient Name*.

Figure 4–52: Name search

2. You can either:

- enter the full patient name or a few characters from the name. For example, entering *John Doe*, *Joh*, *John*, or *Doe* will display all patients with matching names; or
- enter a space, which will display a list of all the patients.

Figure 4–53: Select a Patient

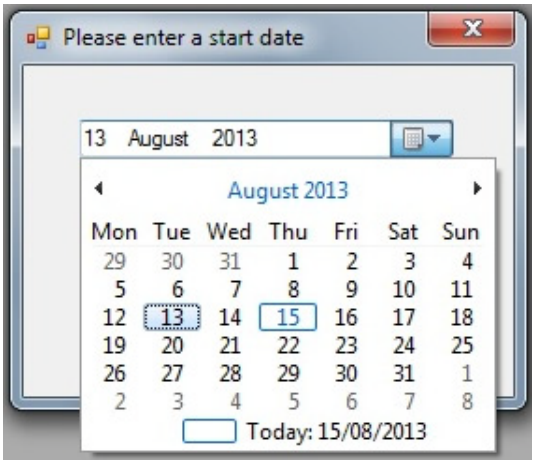


3. Select the patient from the list and a complete treatment history will be displayed (Figure 4–51:).

4.3.10.3 System Activity

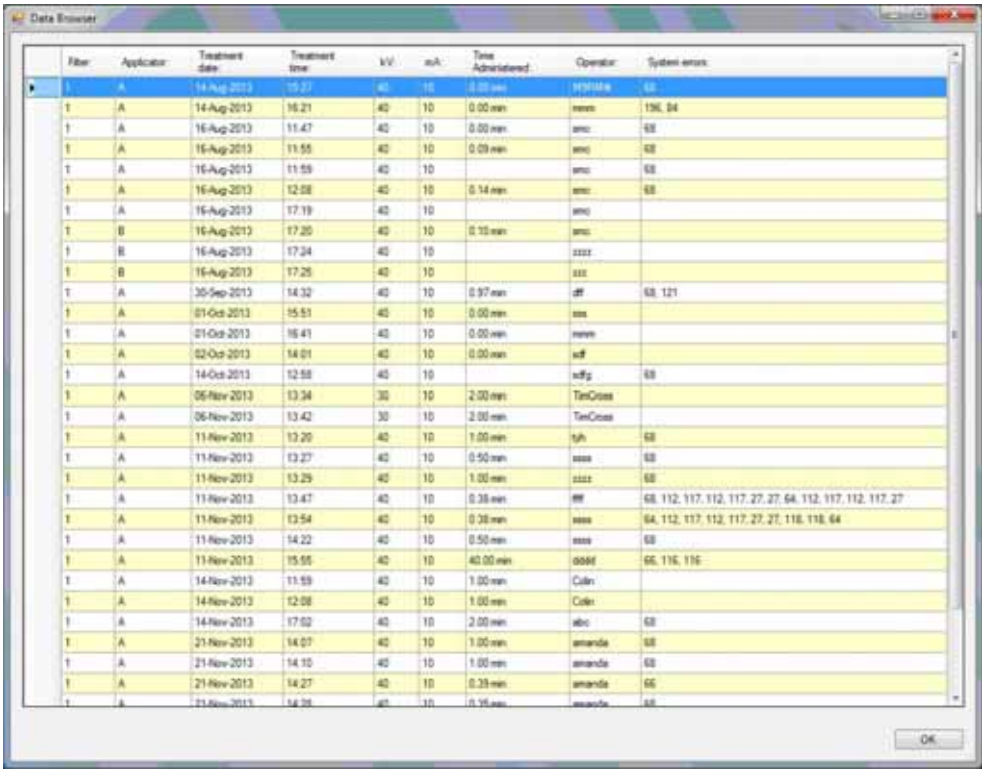
1. Select *Database*, *View Only*, then *System Activity.*

Figure 4–54: System Activity: Search by Date



2. Enter a start date from the date picker and select OK.

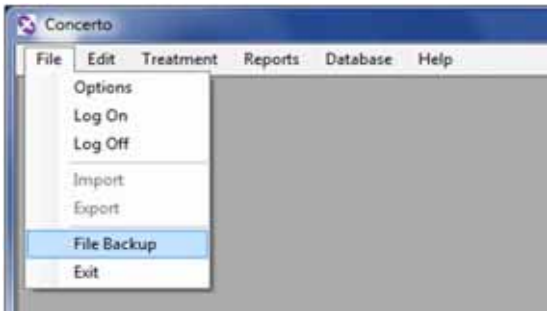
3. Records of all exposures since the start date will be displayed:.



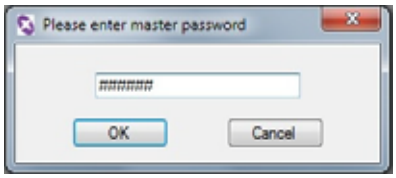
4.3.11 File Backup Procedure

This section explains the procedure for making a backup of the patient and treatment records that are held on the Concerto database.

1. Select the *File* menu, then *File Backup*



2. Enter the master password at the prompt.



3. The system backs up the Concerto database to the defined location as specified in the options.
4. The Success window is displayed when the file backup is completed:

4.3.12 Power Down Procedure

The *Xstrahl X-Ray Therapy System* can be left powered on with the operator pod key switch in *Standby* (position 2). This leaves the system with mains power during a clinical session. The key should be removed if the machine is left unattended—it can also be removed while in *Standby* (position 2).

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

To power down the TP2 system:

1. Select *File*, then *Exit* to close the application
2. Power down the PC
3. Return the key switch on the operator pod to *O* (Off) to shut down mains power to the controller. Best practice is to remove the key from the pod and store it securely.

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 (set in *Fisica*).

The mains light will no longer be illuminated on the operator pod 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 after the shutdown delay period (set in Fisica) has elapsed.

This has two functions:

- Allows adequate cooling of the tube 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).

4.4 Errors and Interlock Message Display

4.4.1 System Errors

System errors causing an interruption to an exposure will be recorded in the *Concerto* database. Errors display as orange interrupt messages specifying the error details.

Some errors are recorded through procedural or power failure. If the filter or applicator is altered after the treatment process has begun, then a filter/applicator encoding error will appear. It is not possible to continue with the exposure until the correct filter or applicator is refitted. If power is lost during treatment, then power lost will be recorded in the database files.

If the key switch on the operator control pod is turned to *Standby* (position 2) during an exposure, an error message will display. To continue with the exposure, return the key switch to *HT* (position 3) and press the green *X-Ray On* button.

Figure 4–55: Error Messages (orange)

4.4.2 Interlock Messages

Safety interlock messages are displayed as blue messages on the treatment screen. Interlocks interrupt the system and prohibit X-Rays from running.

Interlock Messages	
Door Open	The treatment door is open
Room Interlock Open	The interlock buttons mounted inside the treatment room
PC Data	The signal between the PC and the TP2 CCU

4.5 Emergency Off (Lost Power Recovery)

If power to the system is lost or the *Emergency Stop Button* on the operator control pod is pressed, power will be removed from the system and only the PC will remain powered on. *Concerto* will detect a loss of power and the exposure will be interrupted with a *system power loss error*.

To confirm status of the system at the time of power loss:

1. Press and hold the *Display On Power Fail* button on the TP2 CCU's LCD display. The filter and applicator in use, as well as the treatment time or MU value delivered at the exact point of power loss will be displayed.

Figure 4–56: LCD Display

2. If power loss is a result of the *Emergency Stop button* being pressed, power must be restored by releasing the button by turning the red knob on the TPU pod in the direction of the arrows. The system will then re-initialise and display values recorded at the time of power loss. It will then be possible to continue with the exposure.

3. Press *X-Ray On* to continue with the exposure.

Note: The *power loss error messages* will remain on the screen until the exposure is continued or the next exposure is commenced.

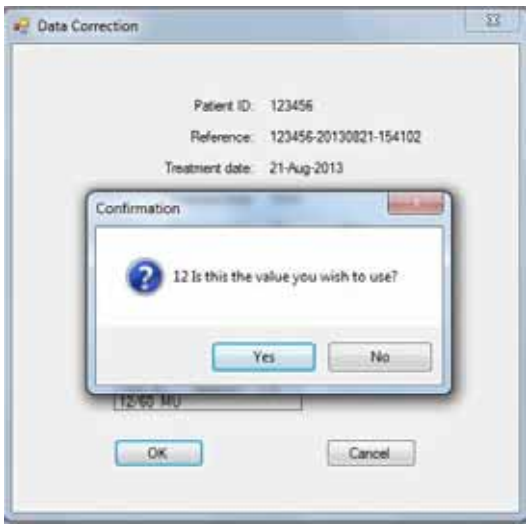
4.6 Data Loss

If power fails during an exposure, Concerto provides an option to correct the delivered dose, to ensure the patient record is accurate. When the operator logs onto Concerto after a power failure, the *Data Correction Window* opens (Figure 4–57:).

Figure 4–57: Data Correction window

1. Compare the TP2 Status displayed in the *Data Correction Window* with the delivered dose shown in the LCD display on the TP2 CCU.
2. Enter the delivered dose from the LCD display into the *Treatment Received* box in the *Data Correction Window*.
3. Click *OK*. A window opens asking the operator to confirm that the correct value has been entered (Figure 4–58:).

Figure 4–58: Data Correction confirmation window



4. If the value is correct, click *Yes* to close the window and write the new value to the database. A confirmation window opens to confirm the data has been updated (Figure 4–59:).

Figure 4–59: Data Correction is successful

5. If the value is incorrect, click *No* to enter a new value.
6. If required, generate a patient summary report, or check the patient database, to confirm that the data has been successfully updated.

Section 5:

System Errors

in this section

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.
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.

Error Code Table		
No.	**Message Displayed**	**Description**
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.
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)

Error Code Table		
No.	**Message Displayed**	**Description**
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 centigrade) 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.
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.

Error Code Table		
No.	**Message Displayed**	**Description**
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).
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.

Error Code Table		
No.	**Message Displayed**	**Description**
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.

Error Code Table		
No.	**Message Displayed**	**Description**
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.

Error Code Table		
No.	**Message Displayed**	**Description**
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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