User's Manual for the Koning Breast CT System

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Caution:

United States Federal Law restricts this device to use by or on the order of a physician.

Warning:

This X-ray unit may be dangerous to patient, operator and others unless safe exposure factors and operating instructions are observed.

1. Introduction

1.1. Purpose of this Document

The purpose of this document is to provide instructions and guidance for the usage of the Koning Breast CT System (model# CBCT1000) by qualified medical professionals. Instructions for the guidance and usage of the corresponding KBCT Console program, as well as any Koning designed accessories, are also included. This manual is for Koning customers, technical representatives, and field service engineers. Any questions regarding these instructions should be brought to the attention of Koning Corporation or Koning's Authorized Representative.

1.2. Summary

This User's Manual contains all instructions for use of the CBCT1000, the KBCT Console program installed on the Operator's Console workstation, and all accessories designed by Koning for use with the CBCT1000. Important safety features, emergency and recovery procedures, cleaning instructions, labeling, specifications, routine quality control, troubleshooting, and more are all covered within this User's Manual. In general, this information has been organized as follows:

1. Safety related information, including emergency and recovery procedures, cleaning procedures, labeling, specifications, etc.

2. Instructions for use

3. Routine quality control

4. Troubleshooting

5. Information pertaining to accessories designed by Koning, including the information listed above, may be found in the Appendices.

This document assumes that the reader has at least a basic level of competency in using a computer, meaning that the reader knows how to use a mouse and keyboard, and is capable of using Microsoft Windows and mundane Windows programs.

For information on the room specifications expected for the CBCT1000, refer to the corresponding Pre-Installation Manual. For information regarding the installation of the CBCT1000, refer to the corresponding Installation Manual.

1.3. Contacting Koning

If you have any questions or feedback, or if you require assistance, contact Koning Corporation (or one of Koning's authorized representatives or sponsors, if appropriate).

Table 1.3-1: Contact List

Location	Contact
United States	**Koning Corporation** Lennox Tech Enterprise Center 150 Lucius Gordon Drive Suite 112 West Henrietta, NY 14586 Tel: (585) 214-2459 Fax: (585) 272-0054 e-mail: feedback@koningcorporation.com www.koningcorporation.com

2. CBCT1000 Overview

2.1. Indications for Use

Koning Breast CT (CBCT1000) is a cone beam computed tomography system intended to provide three dimensional images for diagnostic imaging of the breast. Koning Breast CT should be read along with standard 2-view mammography (CC and MLO views).

2.2. Device Description

The Koning Breast CT (KBCT) System (model # CBCT1000) consists of a Scanner, Operator's Console, Main Panel, and Isolation Transformer. Significant features include a horizontal CT scanner, a patient table assembly, X-ray/data acquisition components mounted on a rotating assembly, a reconstruction engine and 3D visualization/temporary DICOM storage package. The data acquisition is achieved by use of a flat panel detector, an X-ray tube, a 480 VAC high frequency generator, a frame grabber card and a PC workstation. Fig. 2.2-1 and Fig. 2.2-2 illustrate some of the basic components and principles of the system.

Figure 2.2-1: CBCT1000 Scanner and Operator's Console

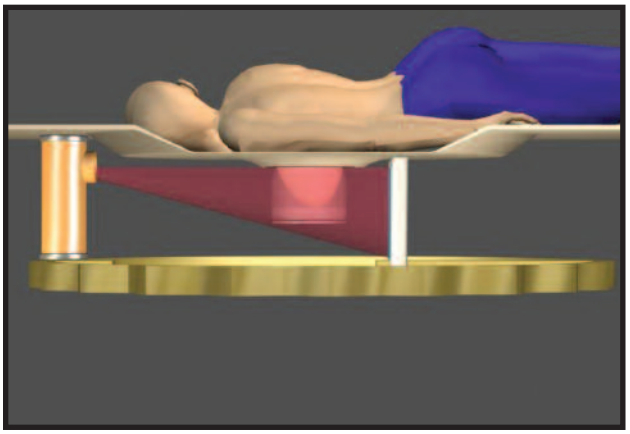


Figure 2.2-2: Principle of the System

The ergonomically-designed patient table can be moved vertically (up to approximately 5' (1.5 m) from the floor) to facilitate breast positioning for optimal coverage (especially near the chest wall and upper outer quadrant of the axilla region). This feature also enables the scanning of particularly long breasts (chest wall-to-nipple length >16 cm) by raising the table to scan the anterior end of the breast unable to be scanned in the low position. The table top includes a modular insert that has been optimized for coverage, especially near the chest wall and axillary region, as well as patient comfort. The tube/detector assembly is also able to move vertically to allow the system to take images for alignment with the patient table at maximum height. The covers on the Scanner protect the patient and clinicians from mechanical, electrical and radiation hazards during a scan. The cover doors allow an approximately 3' (1m) wide access simultaneously to both sides of the patient during positioning and other future procedures.

The table has an opening that allows a woman's breast to hang pendant in the imaging volume at the rotation axis. The tube/detector assembly rotates around the rotation axis and acquires multiple (300) 2D projection images of the breast located at the rotation axis. For a single scan, the total dose to the patient is similar to that of diagnostic mammogram. A 3D volume of the breast is reconstructed from this dataset of 2D images. The system also uses slip ring technology to achieve continuous rotation.

The system can acquire projection images of the breast that can be imaged in its 28 cm field of view at up to 30 fps. The system can acquire 397 mm x 298 mm projections at 30 fps with a matrix size of 1024 x 768 (2 x 2 binning) with >16-bit dynamic range. The flat panel detector is specifically designed to meet the needs of cone beam X-ray imaging applications. The number of reconstructed slices varies with the vertical length of the body part. The maximum vertical length for a single scan is 16 cm. This results in 586 slices for the standard slice thickness of 0.273 mm and 1032 slices for a high resolution slice thickness of 0.155 mm. The reconstructed volume is isotropic so that the same slice thickness is achieved in any orientation.

The 3D visualization/temporary DICOM storage package, the Koning Client/Server (CS), provides a solution that covers the entire imaging workflow. The Koning CS provides advanced visualization at the Operator's Console, physician's review station and other locations with simultaneous availability throughout the enterprise. With the inclusion of the PACS front-end, which supports seamless DICOM and HL7 connectivity, the Koning CS provides a link into the hospital HIS/RIS system for data entry and other functions. The PACS back-end provides full DICOM functionality to allow data to be pushed back to the PACS system for archiving and general data viewing. It also has raw data-to-DICOM conversion capability and approximately 1 TB of local storage.

Refer to Section 8 for the KBCT System specifications and parameters.

2.2.1. Software Description

The KBCT Console program is intended for use as part of the Koning Breast CT (KBCT) System (model # CBCT1000). It is intended to be used to control the KBCT System Scanner, and to perform 3D reconstructions of the images generated through that use. The KBCT Console program is only intended for use by qualified medical professionals. Use of the KBCT Console program for other purposes and/or by other persons is strongly discouraged, and Koning Corporation will not be held liable for any harm or damage caused by unintended use and/or by unintended users.

The KBCT Console program should come pre-installed on the workstation. If a KBCT System has been received without the KBCT Console program pre-installed, please contact Koning Corporation or Koning's Authorized Representative.

3. Cautions and Warnings

The KBCT System is designed to meet stringent safety standards. However, all medical electrical equipment requires proper operation and maintenance, particularly with regard to safety. It is vital that you read, note, and where applicable, strictly observe all **DANGER** and **WARNING** notices and other safety markings on the system. It is vital that you follow strictly all safety directions under the Safety headings and all Warnings and Cautions throughout this User's Manual to help ensure the safety of both patients and operators.

In particular, you must read, understand and know the Emergency Procedures described in this manual before attempting to use the equipment.

You should also note the following information given in this manual:

- Intended use (Sections 2.1)
- Contraindications (Section 4)
- Training for operators (Sections 11 through 17)

Caution:

United States Federal Law restricts this device to use by or on the order of a physician (or properly licensed practitioner).

Caution:

The printed circuit boards within some modules contain highly electrostatic sensitive components. If not regarded, the components could be damaged. Circuit boards should only be accessed by Koning Corporation's service representative. Refrain from using the System and contact Koning Corporation or the Koning's Authorized Representative if there is reason to suspect a circuit board may be malfunctioning.

Caution:

Do not spray the equipment. The cleaning fluid must not penetrate into the internal circuitry.

Caution:

The unpacking must be carefully performed. There's a risk for foot injuries when handling heavy parts. Wear safety footwear.

Caution:

If you press the Emergency stop button, you must reset the Emergency Stop button and power the KBCT System back on. The System takes approximately two minutes to recover once the System Power On Push Button has been pressed. See Section 10 (Resetting the Emergency Stop) and Section 11 (Recovery Procedure) for more information.

Caution:

Check the accuracy of the patient information every time. Edit the patient information, if needed, before **any** image acquisition to ensure corrected information is used in the DICOM headers of the reconstructed images.

Caution:

The X-rays emitted during normal operation of the System may interfere with the operation of implantable medical devices and body worn medical devices. Contact the manufacturers of such equipment for more information **prior** to imaging any patients who have had such a device(s) installed.

Caution:

Do not operate or observe the operation of this System if you have had an implantable medical device or body worn medical device installed.

Caution:

Do not power off the image detector and/or command processor except at the explicit direction of Koning Corporation or Koning's Authorized Representative.

Caution:

For quality control purposes use the tests described in Sections 51 through 63 of this document.

Caution:

Using high mA values significantly increases the dose delivered. Use the "Calculated Best mA" as described in Section 46.6.1 of this manual in order to reduce dose and preserve image quality. It is also recommended that the System be configured (see Section 47.1.1) to force use of the "Calculated Best mA" for normal users.

Caution:

The workstation and server computers provided as part of the CBCT1000 are **not** intended for personal use.

Caution:

While Koning Corporation has made an effort to secure the workstation and server computers, this is **not** a substitute for good IT and network security practices. Every precaution should be taken to avoid infection by viruses or other malware.

Warning:

Use of the CBCT1000 program for purposes other than its intended use is strongly discouraged, and may void the warranty. Koning Corporation will not be held liable for any harm or damage caused by unintended or abnormal use.

Warning:

KBCT is not intended to be used for breast cancer screening.

Warning:

This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.

Warning:

Disregarding the information on safety is considered abnormal use.

Warning:

Avoid using a rewritable DVD-ROM as permanent storage media. If a rewritable DVD-ROM is used, the data on the disc will be overwritten.

Warning:

Do not make any modifications to the System, unless at the explicit direction of Koning Corporation or Koning's Authorized Representative. Such modification will void warranties and service agreements and may lead to System behavior which is unpredictable and potentially hazardous and/or fatal to patients, operators and others.

Warning:

Do not attempt to service the System, unless at the explicit direction of Koning Corporation or Koning's Authorized Representative. To arrange for service, contact Koning Corporation or Koning's Authorized Representative.

Warning:

In case of problems operating the KBCT System according to the instructions for use, contact service, Koning Corporarion or Koning's Authorized Representative.

Warning:

If the acquired projection images are for some reason incomplete or not present, contact Koning Corporation or Koning's Authorized Representative. Do not diagnose the patient without first consulting with Koning. In the worst case, it may be necessary to reschedule the case/session.

Warning:

If the images look strange or the image backgrounds vary significantly throughout the series (as if flickering, for instance), contact Koning Corpotarion or Koning's Authorized Representative. Do not diagnose the patient without first consulting with Koning.

Warning:

To obtain the maximum information from the images, display them in their original resolution.

Warning:

DICOM printouts from the KBCT System must not be used for diagnostic purposes. Koning Corporation recommends viewing reconstructed images on 2MP clinical monitors for diagnostic purposes.

Warning:

Do not diagnose a patient before all images of the case have been loaded.

Warning:

Image quality must be checked after installation, service and maintenance. Be aware that use of the System may be prohibited if the image quality no longer meets specifications until such time as the problem can be resolved.

Warning:

Patient records are stored only temporarily in the local database. Since database space is limited, the oldest patient records and their associated images are periodically deleted to reclaim space for new patients. Koning Corporation **strongly** recommends that data be sent to an external long term storage device.

Warning:

Be aware there is a possible crushing hazard during motorized movements of the patient table and gantry lift. **Do not defeat safety interlocks. Do not attempt to initiate any motions while persons are working within the Scanner (such as when positioning the breast).**

Warning:

The Operator Console display is not suitable for primary diagnosis. Reconstructed KBCT images should be reviewed for primary diagnosis of KBCT images only on a standard workstation appropriate for primary diagnosis of KBCT images.

Warning:

Be aware there is a possible falling hazard when the patient gets on and off of the patient table. Some patients may require assistance getting onto and off of the patient table.

Warning:

Some components of disinfectants are detrimental to health. Their concentration in breathable air must not exceed safe and legal limits. Koning Corporation recommends that the instructions for use issued by the manufacturers of these agents be strictly observed.

Warning:

The ground conductor in the mains cable must **under no circumstances** be disconnected when operating the Scanner. A potentially life-threatening electric shock hazard exists.

Warning:

After pressing an emergency stop button (located at the Operator's Console control panel or Scanner) 120 VAC and 24 VDC voltages will still be present at the Scanner and at the Operator's Console. **Life-threatening electric shock hazard exists.** If needed, disconnect mains and comply with the information in the installation manuals.

Warning:

After shutdown of the system by emergency stop, there will still be 480 VAC present on the power distribution circuit. Life-threatening electric shock hazard exists.

Warning:

The operator should stand behind the radiation barrier provided for his/her protection during radiographic exposures.

Warning:

Do **not** attempt to image patients heavier than the patient table weight limit of 440 lbs.

Warning:

Special precautions, consistent with clinical needs, should be taken to minimize exposure of the embryo or fetus in patients known to be or suspected of being pregnant.

Warning:

To protect a pregnant or potentially pregnant patient, the abdominal region should be shielded with at least 0.25 mm lead equivalence. The risk/benefit ratio of the KBCT scan is a clinical decision and the scan must always be justified with the benefits outweighing the risks. If, after weighing risks of radiation exposure, the procedure is justified, careful attention must be paid to the pregnant woman's positioning to ensure comfort and adequate breast coverage.

Warning:

No additional electrical connections are to be made to the KBCT System other than network connections to the facility. Contact your Koning Corporation or Koning's Authorized Representative for guidance on adding network connections.

4. Additional Safety Information

4.1. Contraindications

There are no known contraindications for the CBCT1000.

4.2. Biocompatibility

Regarding the gelcoat applied to the patient table for the CBCT1000: The gelcoat that constitutes the outer surface of the table is Ashland's MAXGUARD®. This ISO-NPG resin was chosen for its superior hardness, smooth, glossy finish and its ability to withstand harsh chemicals and conditions. This product is used in many fiberglass applications similar to the patient table, including numerous products for spas and bathrooms. MAXGUARD® gelcoat is commonly used in the production of shower trays, sinks and counter surfaces and is applied to protect granite, onyx and cultured marble. It is a favorite of the marine industry and is used for below-water applications such as hull surfaces as well as above-water applications including decking and furniture.

Regarding the polyethylene table insert: No acute health hazards are known. It can be treated as inert organic waste.

4.2.1 Equipment Materials List

The following materials were used to make the patient table, table insert and patient safety cover.

Patient Table

- Polyester resin
- Polyester resin gel coat
- Fiberglass
- Two steel weldments incorporated in the underside of the table for mounting purposes and support

Table Insert

- Ultra high molecular weight polyethylene

Patient Safety Cover

- Stainless steel fasteners
- Aluminum ring
- Abs plastic
- PETG plastic

4.3. Potential Adverse Effects

The following is a listing of potential adverse effects that apply to computed tomography (CT) and are also applicable to the CBCT1000. To minimize the probability of these adverse effects, it is **strongly** recommended that the CBCT1000 is only used by properly trained personnel in accordance with this User's Manual.

- Excessive X-ray exposure
- Electric shock

4.4. Electrical Safety and Grounding

Koning Corporation recommends that all System covers and/or cables only be removed by qualified and authorized service personnel.

Only use this System in rooms or areas that comply with all applicable laws (or regulations having the force of law) concerning electrical safety for this type of medical equipment.

The System must be grounded to an earth ground by a separate conductor. The neutral side of the line is not to be considered the earth ground. On equipment provided with a line cord, the equipment must be connected to a properly grounded, three-pin receptacle. Do **not** use a three-to-two pin adapter.

4.5. Mechanical Safety

System covers should only be removed by qualified and authorized Koning service personnel.

4.6. Explosion Safety

This equipment **must not** be used in the presence of explosive gases or vapors, such as certain anesthetic gases. Use of electrical equipment in an environment for which it was not designed can potentially cause a fire or explosion.

4.7. Fire Safety

Use of electrical equipment in an environment for which it was not designed can potentially cause a fire or explosion. Conductive fluids that seep into the active circuit components of the System may cause short circuits that can result in electrical fires. Therefore, **do not** place any liquid or food on any part of the System. Fire regulations for the type of medical area being used should be fully applied, observed and enforced. Fire extinguishers should be provided for **both** electrical **and** non-electrical fires. All operators of this medical electrical equipment should be fully aware of and trained in the use of fire extinguishers, the use of any other available fire-fighting equipment and in local fire procedures.

If it is safe to do so, attempt to isolate the System from electrical and other supplies before attempting to fight a fire. This will reduce the risk of electric shock.

4.8. Radiation Safety

X-rays are dangerous to the patient, operator and others in the vicinity unless established safe exposure procedures are strictly observed. The useful and scattered beams can produce **serious or fatal** bodily injuries to patients and persons in the surrounding area if used by an unskilled operator. Adequate precautions must always be taken to avoid exposure to the useful beam, as well as to leakage radiation from within the source housing or to scattered radiation resulting from passage of radiation through matter.

Take the following protective measures to protect both yourself and the patient. Anyone who has to be near the patient during scanning must wear protective clothing (lead apron), wear a PEN dosimeter and/or film badge, and stay in the zone shielded by the system (At least 10’ (3 m) from the Scanner or behind a protective wall). **The physician is responsible for protecting the patient from unnecessary radiation.**

Those authorized to operate, participate in or supervise the operation of the equipment **must** be thoroughly familiar and comply completely with the current established safe exposure factors and procedures described in publications(for example, “Diagnostic X-ray systems and their major components,” section of subchapter J of Title 21 of the Code of Federal Regulations, and the National Council on Radiation Protection (NCRP) No. 102, “Medical X-ray and gamma ray protection for energies up to 10 MEV equipment design and use,” in the United States). Operators are **strongly** urged to comply with the current recommendations of the International Commission on Radiological Protection (ICRP).

4.9. Mobile Telephones and Similar Devices

The KBCT System complies with the requirements of applicable EMC standards. Other electronic equipment exceeding the limits defined in such EMC standards, such as certain mobile telephones, could affect the operation of the KBCT System.

You should not allow portable radio transmitting devices (such as mobile telephones) into the examination room – **regardless of whether the System is on or off**. Such devices could exceed EMC radiation standards and could interfere with the proper functioning of the KBCT System. This could, in extreme cases, lead to **fatal or other serious personal injury or to clinical misdiagnosis**. See Section 24 Electronic Compliance Information for guidance.

4.10. Regulatory Controls

Protect patient's health information

One of the most important assets to protect with security measures is the patient's health related information. Many governments require maintaining the confidentiality of this information. Therefore, strict security measures must be taken to guard this protected information. (Customers in the U.S.A. may find guidelines at http://www.hhs.gov/ocr/hipaa/.)

Prevent unauthorized device modification

Koning Corporation sells highly complex medical devices and systems and is thus required to follow government-regulated quality assurance procedures to verify and validate any and all modifications to the operation of Koning products. Operators and owners of this medical equipment must permit only Koning authorized changes to be made to these systems, either by Koning personnel or under Koning's explicit published direction. **Unauthorized changes will void warranties and service agreements and may lead to System behavior which is unpredictable and potentially hazardous and/or fatal to patients, operators and others.**

5. Labels

5.1. Warning Labels

Table 5.1-1 lists all caution and warning labels on the System. **DO NOT REMOVE** any labels. Follow the instructions and cautions contained in all labels. Regularly inspect labeling to ensure integrity. If any label needs to be replaced or repositioned, contact Koning Corporation or Koning's Authorized Representative.

Table 5.1-1: Warning Labels

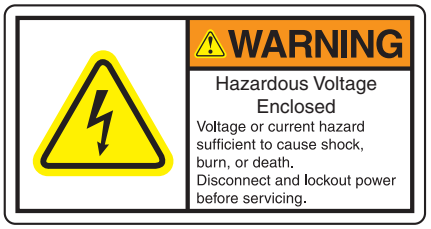
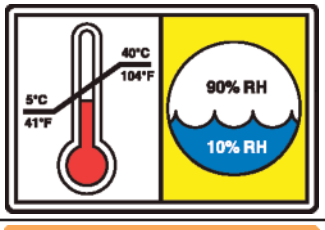
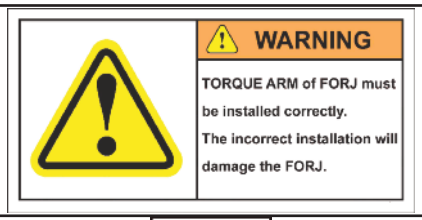
Label	English
	Warning, electrical shock, electrocution
	**WARNING** Hazardous Voltage Enclosed Voltage or current hazard sufficient to cause shock, burn, or death. Disconnect and lockout power before servicing.
	**WARNING** Crush hazard. Keep hands clear.
	**CAUTION** Laser radiation DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS Class 3A laser product.
	**DANGER** Hazardous voltage will cause severe injury or death. Turn off power and lock out before service.
	**WARNING** ONLY authorized personnel may service this equipment. See manual for safety information.
	Recommended temperature and humidity limits 41 °F - 104 °F 5 °C - 40 °C 10% - 90% RH
	480 VOLTS

Table 5.1-1: Warning Labels

Label	English
	**WARNING** This X-Ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.
	**WARNING** Do not connect items that are not part of the system.
	**WARNING** Read and understand operator's manual before using this machine. Failure to follow operating instructions could result in death or serious injury.
	**WARNING** TORQUE ARM of FORJ must be installed correctly. The incorrect installation will damage the FORJ.
	Protective conductor terminal (primary earth ground)

NOTE: Units shipped to other countries will have labels printed in that country's language. Koning Breast CT System units shipped to Canada will have both English labels and French labels.

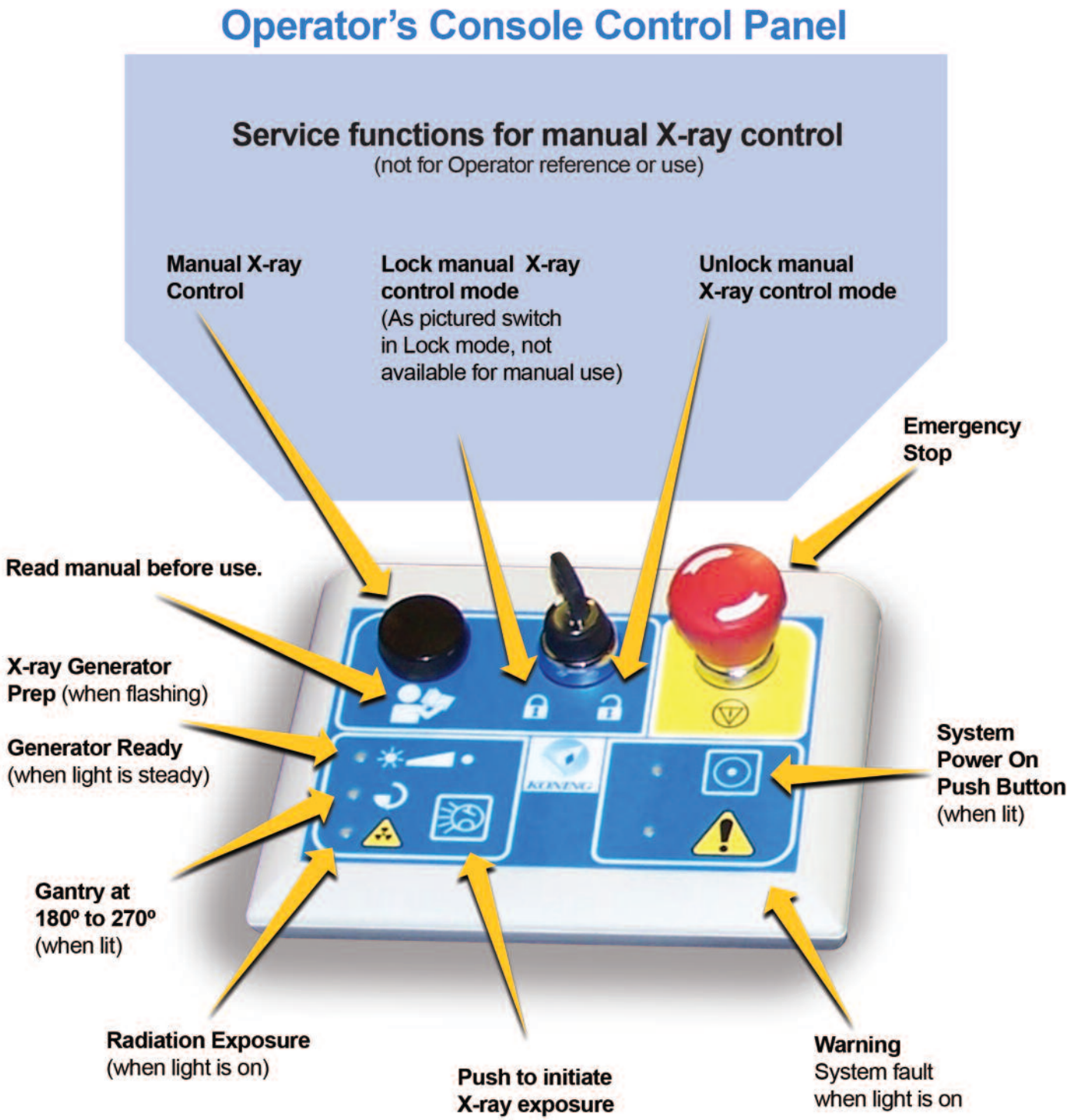


Figure 5.1-1: Operator's Console Control Panel

5.2. Identification Labels

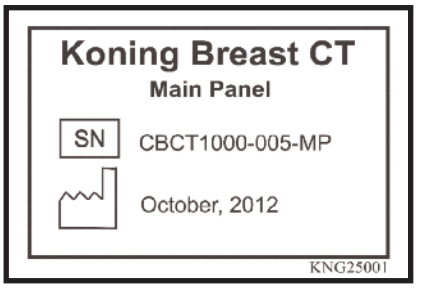


Figure 5.2-1: Main Panel nameplate

Description: Sub-system label for the Main Panel
Located inside the Main Panel on the upper left of the inside of the right door.
KNG25001

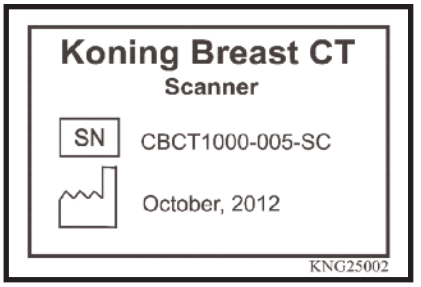


Figure 5.2-2: Scanner nameplate

Description: Sub-system label for the Scanner
Located inside the Scanner, on the junction box door above the connection plate (under the covers)
KNG25002

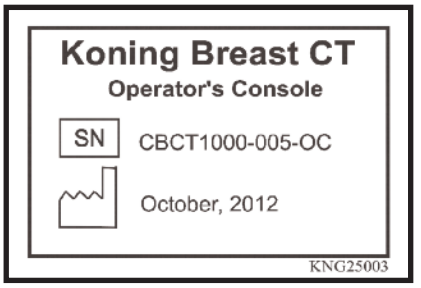


Figure 5.2-3: Operator's Console nameplate

Description: Sub-system label for the Operator's Console
Located inside the left side door of the Operator's Console, on the junction box door.
KNG25003

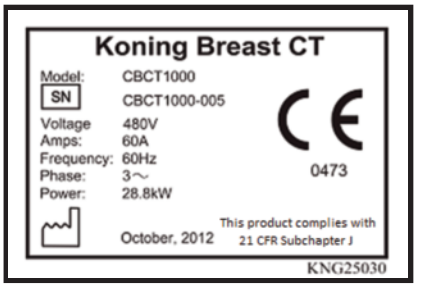


Figure 5.2-4: CBCT1000 nameplate

Description: System nameplate and power specifications
Located outside the Main Panel, above the power input hole.
KNG25030

Figure 5.2-5: Manufacturer address label

Description: Manufacturer address
Four used, each found adjacent to KNG25001, KNG25002, KNG25003, and KNG25030.
KNG25031

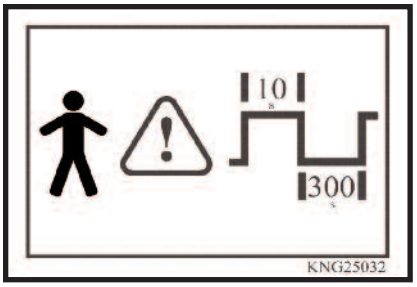


Figure 5.2-6: Duty cycle label

Description: Duty cycle information
Located adjacent to KNG25030.
KNG25032

Figure 5.2-7: ETL label

Description: ETL label
Located adjacent to KNG25030.
ETL control number: 3070059

6. Emergency Procedures

6.1. Emergency Stop

6.1.1. The Emergency Stop Buttons

In case of an emergency, push the red Emergency Stop button. Press down on a red Emergency Stop button to bring all gantry lift and patient table lift movements and X-ray production to an immediate halt. Gantry rotation will also come to a quick stop. The CBCT1000 has a total of 3 Emergency Stop buttons. One (1) Emergency Stop button is located on the control panel located at the Operator's Console, and two additional Emergency Stop button are located on the Scanner control panels located on either side of the Scanner. See Figure 6.1.1-1 and Section 9.2 in the Instructions for Use section of this manual.

Figure 6.1.1-1: Emergency Stop button

The Gantry control panel also allows manual raising and lowering both the patient table and the gantry and rotating the gantry, if the doors of the Gantry are closed.

6.1.2. Resetting the Emergency Stop

Use this procedure to reset from emergency stop:

1. Locate the Emergency Stop button that was pressed to initiate the stop.

2. Twist the button counter-clockwise until it disengages from the stop position and returns to its original position.

3. Press the System Power On Push Button (see Figure 6.1.2-1) on the Operator's Console control panel.

Figure 6.1.2-1: System Power On Push Button

4. Wait approximately 2 minutes for the System to recover.

5. Normal function should now be restored.

6.2. Power Outage Recovery Procedure

Use this procedure if the KBCT System loses power:

1. Assist the patient per standard facility procedures. Refer to Section 6.3 if the patient table is in a raised position.

2. Close the KBCT Console program if the workstation still has power. (See Figure 6.2-1.)

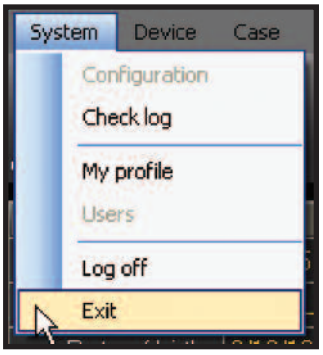


Figure 6.2-1: Closing the KBCT Console program

3. Wait for power to be restored to the facility. If the UPS backup power supply has been exhausted, use the procedure described in Section 6.4.

4. Press the System Power On Push Button on the control panel at the Operator's Console. (See Figure 6.1.2-1.)

5. Wait approximately 2 minutes for the X-ray generator to power back up and reboot.

6. Restart the KBCT Console program. (See Figure 6.2-2.)

Figure 6.2-2: Shortcut to KBCT Console program

7. The System should now be ready to resume normal operation.

6.3. Patient Recovery From a Raised Patient Table

In the event that the patient table is at or near maximum height and the vertical motion of the patient table fails due to an electrical or mechanical problem, the 3' x 4' (0.9 x 1.2 m) Single-Height Portable Stage Unit (Stage) must be used in combination with the standard 2-step step stool with hand rail (Stool) to get the patient down. The Stage must be stored in or near the KBCT System room and in such a way that it can be easily and rapidly obtained and deployed.

1. Deploy the Stage by unfolding the 3 sets of legs and locking them in place with the lock piece that slides over the top of each brace.

2. Position the Stage at the end of the Scanner.

3. Place the Stool on top of the Stage near the Scanner. The Stage and Stool should be aligned such that their longer dimensions are in parallel and centered on the end of the Scanner. The feet of the Stool should be at least 1" (2.54 cm) away from the edge of the Stage.

4. Confirm that the Stool and Stage are stable.

5. Stand on the Stage and assist the patient down from the table and onto the top step of the Stool.

6. Continue to help the patient down the Stool and off the Stage to the floor.

The Stage weighs 67 lbs. (30.4 kg) and has a heavy-gauge steel frame that supports its solid plywood deck. It folds to less than 2" (5 cm) high for storage and transport. Its carpet-covered platform is 16" (40.6 cm) above the floor when on its legs. Koning Corporation recommends that 2 able bodied personnel deploy the stage and assist the patient down from the patient table, one on each side of the Stool.

6.4. General Recovery Procedure

If the System is fully or partially off, use this recovery procedure. It may be desirable to have the assistance of the appropriate facility technical support personnel while performing this procedure.

1. Verify that the green light on the Isolation Transformer is on and that the main power switch is in the ON position. If the light is not on, contact the appropriate facility personnel to restore power to the CT room. If the light is on and the switch is in the OFF position (see Figure 6.4-1), pull it to the ON position.

Figure 6.4-1: Isolation Transformer is receiving power

2. Verify that the Main Panel disconnect is in the ON position. If it is not, turn it to the ON position.

3. Press the System Power On Push Button on the control panel at the Operator's Console. (See Figure 6.1.2-1.)

4. Open the doors to the Operator's Console cabinet. If necessary, obtain the keys from the appropriate facility personnel.

5. Turn on the Command Processor (see Figure 6.4-2). If the Command Processor is already on, turn it off, wait approximately 2 minutes, and turn it back on.

Figure 6.4-2: Back of Command Processor

6. If necessary, turn on the monitors.

7. Boot up the server PC. Use the KVM switch (see Figure 6.4-3) to move the display to the server PC and verify that it starts up correctly.

8. Boot up the workstation PC. Use the KVM switch to move the display to the workstation PC and verify that it starts up correctly.

9. Restart the KBCT Console program. (See Figure 6.2-2.)

10. The System should now be ready to resume normal operation.

Figure 6.4-3: KVM switch

7. Regulatory Information

7.1. IEC-60601 Classifications

Type of protection against electric shock . . . . . .Class I equipment

Degree of protection against electric shock . . . . . .Type B equipment

Degree of protection against harmful ingress of water . . . . . .Ordinary equipment

Possible interference with other equipment . . . . . .IEC 60601-1-2 + A1:2006
Group 1 Class A Device for Radiated Emission

Mode of operation . . . . . .Continuous mode with short time loading

Maximum Loading . . . . . .10 seconds ON per Five (5) minutes OFF

Input Power Requirement for:
CBCT1000 System . . . . . .480V 3 Phase @ 60 Amps

Isolation Transformer . . . . . .480V 3 Phase @ 60 Amps
OR
208V 3 Phase @ 120 Amps

7.2. Safety standards listed by Intertek-ETL for Koning Breast CT System (Model # CBCT1000)

- IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007), 3rd Edition ‘Medical Electrical Equipment, Part 1: General Requirements for Safety’
- IEC 601-1:1988 + A1:1991 + A2:1995, ‘Medical Electrical Equipment, Part 1: General Requirements for Safety’
- UL 60601-1 (2003), 'Medical Electrical Equipment, Part 1: General Requirements for Safety’
- CSA C22.2 No 60601.1:2008, 3rd Edition 'Medical Electrical Equipment, Part 1: General Requirements for Safety'
- IEC 60601-1-1:2000, 'Medical Electrical Equipment Part 1-1: General Requirements for Safety — Collateral Standard: Safety Requirements for Medical Electrical Systems'
- IEC 60601-1-2:2001 + A1:2006, ‘Medical Electrical Equipment — Part 1-2: General Requirements for Safety — Collateral Standard: Electromagnetic Compatibility — Requirements and Tests’
- IEC/EN 60601-1-2:2007, 3rd Edition ‘Medical Electrical Equipment — Part 1-2: General Requirements for Safety — Collateral Standard: Electromagnetic Compatibility — Requirements and Tests’
- IEC 60601-1-3:2008, 3rd Edition ‘Medical Electrical Equipment — Part 1-3: General Requirements for Safety — Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-ray Equipment’
- IEC 60601-1-4:2000, 'Medical Electrical Equipment Part 1-4: General Requirements for Safety — Collateral Standard: Programmable Electrical Medical Systems'
- IEC 60601-1-6:2010, ‘Medical Electrical Equipment — Part 1-6: General Requirements for Safety — Collateral Standard: Usability’
- IEC 60601-2-32:1994, 'Medical Electrical Equipment — Part 2-32: Particular Requirements for the Safety of Associated Equipment of X-Ray Equipment'
- IEC 60601-2-44:2009, 3rd Edition ‘Medical Electrical Equipment — Part 2-44: Particular Requirements for the Safety of X-ray Equipment for Computed Tomography’
- IEC 60601-2-45:2011, 3rd Edition ‘Medical Electrical Equipment — Part 2-45: Particular Requirements for the Safety of Mammographic X-ray Equipment and Mammographic Stereotactic Devices’

7.3. Electronic Compliance Information

The KBCT System is equipped for use in the electromagnetic environment specified below. The system shall be placed in an environment provided by the customer facility that meets these conditions. **Failure to provide such an environment will be considered abnormal use of the device.**

VARIAN
medical systems

X-Ray Products
1678 South Pioneer Road
Salt Lake City, UT 84104-4298
USA
tel 801 972 5000
fax 801 973 5050

Koning CBCT
User's Manual

Standards Compliance Statement
Varian Medical Systems

Koning Corporation May 1, 2013

STANDARDS COMPLIANCE STATEMENT

Varian Medical Systems, X-Ray Products is currently registered to ISO 9001:2008; Canadian Medical Device Regulation, P.C. 1998-783, 7 May, 1998; ISO 13485-2003; under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2 (MDD/CE Mark/Annex I - Essential Requirements). Compliance to IEC Standards is done through our design and internal testing. The MAMRAD 100H/RAD 70 meets the IEC Standards listed below. These X-Ray Tube Housing Assemblies model (Class I) have been registered with the FDA (CDRH) by supplement as per Code of Federal Regulations 21, Sub-chapter J. Product report number 7410266. The X-Ray Tube Housing is a recognized component per UL 60601-1: Medical Electrical Equipment Part 1: General Requirements for Safety, Third Edition. CSA 22.2 No. 601.1: Medical Electrical Equipment Part 1: Canada General Requirements for Safety, Am 90.

EN/IEC/UL/ANSI/AAMI Standards:

EN/IEC 60601-1: 2006/2005 (3rd Edition) Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1:1990 +A1:1993 +A2:1995
IEC 60601-1:1988 +A1:1991 +A2:1995
ANSI/AAMI ES60601-1:2005/C1:2009
UL 60601-1: 2003
EN 60522:1999 Determination of the permanent filtration of X-ray tube assemblies
EN 60601-1-3:2008 Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment.
EN 60601-2-28:1993, EN 60601-2-28:2010 Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis. (Over-pressure testing, Accompanying Documents and Labeling)
IEC 60336:2005 Medical electrical equipment – X-ray tube assemblies for medical diagnosis - Characteristics of focal spots
IEC 60526:1978 High-voltage cable plug and socket connections for medical X-ray equipment
IEC 60613:2010 Specifying and verifying the characteristics of rotating anode X-ray tubes and X-ray tube assemblies used in medical diagnosis

Pam Hunt
Regulatory Affairs Analyst

Figure 7.3-1: X-ray tube compliance statement

Compliance Statement

1. Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying Pre-Installation Manual.

2. Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

Cautions and Warnings

1. The System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.

2. The use of accessories, transducers and/or cables other than those specified by Koning Corporation may result in increased emissions or decreased immunity of the System.

Guidance and Manufacturer's Declaration – Emissions
All Equipment and Systems

The CBCT1000 is intended for use in the electromagnetic environment specified below. The customer or user of the CBCT1000 shall ensure that it is used in such an environment. **Failure to provide such an environment will be considered abnormal use of the device.**

Table 7.3-1: Emissions - all equipment and systems (Intertek Table 1)

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF Emissions CISPR11	Group 1	The CBCT1000 uses RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR11	Class A or B	A
Harmonics IEC 61000-3-2	Class A, B, C, D or N/A	N/A
Flicker IEC 61000-3-3	Complies or N/A	N/A
		The CBCT1000 is suitable for use in all establishments, **other than** domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Immunity
All Equipment and Systems

The CBCT1000 is intended for use in the electromagnetic environment specified below. The customer or user of the CBCT1000 shall ensure that it is used in such an environment. **Failure to provide such an environment will be considered abnormal use of the device.**

Table 7.3-2: Immunity - all equipment and systems (Intertek Table 2)			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
ESD IEC 61000-4-2	± 6kV Contact ± 6kV Air	As specified	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	As specified	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV Differential ± 2kV Common	As specified	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	As specified	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CBCT1000 requires continued operation during power mains interruptions, it is recommended that the CBCT1000 be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3 A/m	As specified	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Immunity Equipment and Systems that are NOT Life-supporting

The CBCT1000 is intended for use in the electromagnetic environment specified below. The customer or user of the CBCT1000 shall ensure that it is used in such an environment. **Failure to provide such an environment will be considered abnormal use of the device.**

Table 7.3-3: Immunity - equipment and systems that are **not** life-supporting (Intertek Table 4)			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(V1)=3Vrms	Portable and mobile communications equipment should be separated from the CBCT1000 by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) 150kHz to 80MHz D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5 GHz	(E1)=3V/m	

Recommended Separation Distances between portable and mobile RF Communications equipment and the KBCT Equipment and Systems that are NOT Life-supporting

The CBCT1000 is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the KBCT System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the CBCT1000 as recommended below, according to the maximum output power or the communications equipment. **Failure to provide such an environment will be considered abnormal use of the device.**

Table 7.3-4: Recommended separation distances between portable and mobile RF communications equipment (Intertek Table 6)

Maximum Output Power (Watts)	Separation (m) 150kHz to 80MHz D=(3.5/V1)(Sqrt P)	Separation (m) 80 to 800MHz D=(3.5/E1)(Sqrt P)	Separation (m) 800MHz to 2.5GHz D=(7/E1)(Sqrt P)
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

7.4. Interconnect Cable List

Note: Interconnect cable lengths are unique to each facility's individual layout.

Warning:

The use of accessories, transducers and/or cables other than those specified by Koning Corporation may result in increased emissions or decreased immunity of the equipment or system.

Table 7.4-1: Interconnect cables						
Line	**Generic Cable Part #**	**Specific Intertek EMC Tested Cable Part #**	**Tested Cable Length (Meters)**	**Origin Connection Point**	**Ending Connection Point**	**Purpose**
1	20000-001-XX	20000-001-05 Note: The "-05" suffix in this part # indicates this is a 5 meter cable. This is typical for all similar part #s.	5	Main panel connection plate	Scanner connection plate	PIN, 24DC I/O Signals to and from Pain Panel and Scanner
2	20000-007-XX	20000-007-05	5	Main panel connection plate	Scanner connection plate	480V Power Cable
3	20000-012-XX	20000-012-05	5	Main panel connection plate	Scanner connection plate	120V Power Cable
4	DRV1-PWR-2	KNG15351 This number applies to the 5 meter length only, typical for all DRV cables.	5	Main panel connection plate	Scanner connection plate	Gantry lift servo Motor power umbilical cable
5	DRV1-BRK-2	KNG15352	5	Main panel connection plate	Scanner connection plate	Gantry lift servo Motor brake umbilical cable
6	DRV1-ENC-2	KNG15353	5	Main panel connection plate	Scanner connection plate	Gantry lift servo Motor encoder feedback umbilical cable
7	DRV2-PWR-2	KNG15354	5	Main panel connection plate	Scanner connection plate	Dial rotate servo Motor power umbilical cable
8	DRV2-BRK-2	KNG15355	5	Main panel connection plate	Scanner connection plate	Dial rotate servo Motor break umbilical cable
9	DRV2-PWR-2	KNG15356	5	Main panel connection plate	Scanner connection plate	Dial rotate servo Motor encoder feedback umbilical cable
10	DRV3-PWR-2	KNG15357	5	Main panel connection plate	Scanner connection plate	Patient table lift (close) servo Motor power umbilical cable
11	DRV3-BRK-2	KNG15358	5	Main panel connection plate	Scanner connection plate	Patient table lift (close) servo Motor brake umbilical cable
12	DRV3-ENC-2	KNG15359	5	Main panel connection plate	Scanner connection plate	Patient table lift (close) servo Motor feedback umbilical cable
13	DRV4-PWR-2	KNG15360	5	Main panel connection plate	Scanner connection plate	Patient table lift (far) servo Motor power umbilical cable
14	DRV4-BRK-2	KNG15361	5	Main panel connection plate	Scanner connection plate	Patient table lift (far) servo brake umbilical cable
15	DRV4-ENC-2	KNG15362	5	Main panel connection plate	Scanner connection plate	Patient table lift (far) servo Motor encoded feedback umbilical cable
16	20000-002-XX	20000-002-13	13	Main panel connection plate	Operator's Console connection plate	40 Pin, 24 VDC 1/0 signal cable
17	20000-003-XX	20000-003-13	13	Main panel connection plate	Operator's Console connection plate	120V power cable
18	20000-041-XX	20000-041-13	13	Main panel connection plate	Ethernet hub (Inside Operator's Console)	Ethernet communications to PLC
19	20000-004-XX	20000-004-11	8	Operator's Console connection plate	Scanner connection plate	Communication between Scanner and operator console
20	20000-072-XX	KNG15129 This number applies to the 15 meter length only)	15	Command processor (Inside Operator's Console)	Scanner connection plate	Fiber optic cable for communication to X-ray detector
21			2.5	Isolation Transformer	Main Panel	Wiring and conduit providing conditioned power to the System

8. Specifications

8.1. Equipment Technical Specifications and Parameters

Table 8.1-1: CBCT1000 Specifications					
Item	**Test**	**Standard**			
1	Air Kerma	25 mGy ± 20% (Using CT ion chamber with 10-cm active area, in air, fully exposed at center of rotation). 1 Gy = 114 R (One 360° scan @ 49 kVp, 100 mA, 8ms/projection)			
2	Average Glandular Dose	7 mGy ± 20% for a normal breast (4.2 cm thick compressed or ~13 cm thick uncompressed, 50% glandular tissue, 50% adipose tissue)			
3	CT Number for Water	0 ± 10 HU			
4	Field Uniformity	≤ 15 HU @ 75% radius			
5	Low Contrast Resolution	6 mm @ 2%			
6	Spatial Resolution	Minimum value			
	a. MTF	50%	10%	5%	0%
		0.84 lp/mm	1.56 lp/mm	1.78 lp/mm	2.50 lp/mm
	b. Specks	290 µm (full group is visible)			
7	Noise	≤ 8 HU			
8	Half Value Layer	>0.49 mm Al at 49 kVp (FDA specification) 1.5 mm Al (± 10 %) at 49 kVp (typical)			
9	Quality Equivalent Filtration (Permanent)	≥99.9% pure Al			
10	Collimation Accuracy	The X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2% of the SID (1.85 cm)			
11	Patient Table Weight Limit	440 lbs. (200 kg)			

Table 8.1-2: CBCT1000 system parameters	
Parameter	**Value**
Scan time	10 seconds
Voxel size	$(0.155 – 0.273 \text{ mm})^3$
Focal spot size	~0.3 mm
Power	9.8 kW @ 30% DF
Source to rotation center distance	65.0 cm
Magnification	1.42
Pixel pitch	0.194 mm (0.388 with 2x2 binning for 30 fps)
Dynamic range	>16-bit
Projection number	300
Data acquisition rate	30 fps (with 2x2 binning)

Note:

1. The maximum acceptable number of isolated DEFECTIVE DETECTOR ELEMENTS in the entire IMAGE RECEPTION AREA and the maximum acceptable number in any subdivision with their distribution over the IMAGE RECEPTION AREA is 0

2. The maximum acceptable size and number of connecting DEFECTIVE DETECTOR ELEMENTS and their distribution in the entire IMAGE RECEPTION AREA and the maximum acceptable number in any subdivision and distribution over the IMAGE RECEPTION AREA of connecting DEFECTIVE DETECTOR ELEMENTS grouped by topology type (e.g., 2 adjacent detector elements, 3 adjacent detector elements, 2 x 2 adjacent detector elements, etc.) is 0

3. The maximum acceptable number of defective lines, columns and segments, and the minimum acceptable distance between defective lines or columns with their width, length and distribution over the entire IMAGE RECEPTION AREA and the maximum acceptable number in any subdivision and distribution over the IMAGE RECEPTION AREA is 0

These defects shall not significantly degrade the level of image quality required for the INTENDED USE

There are no acceptable properties, numbers, positions and arrangements of the DDE.

8.2. Power Ratings

The X-ray generator used in the CBCT1000 is rated to operate at a maximum voltage of 49 kVp. The maximum current is 200 mA and maximum output is 9.8 kW. Maximum loading time is eight millisecond pulses @ 30 Hz for 10 seconds with a maximum duty cycle of 10 seconds on, 300 seconds off.

8.3. X-Ray Specifications

Minimum Current Time Product (mAs)

- Minimum Current Time Product obtained at 0.1 s is 1 mAs.
- Minimum Current Time Product within the specified ranges of compliance for linearity and constancy is 0.1mAs.

Accuracy of Radiographic Parameters

Specified accuracy does not include test equipment accuracy.

Table 8.3-1: Radiographic accuracy

	Parameters	Accuracy (with 12 BITS HT Controller)
RAD	kVp	± (3% + 0.1 kV)
	mA	± (4% + 0.1 mA)
	Exposure Time (ms)	± (2% + 0.1 ms)

NOTE: Test data is available upon request.

8.4. Radiation Scatter Survey Information

Survey results were obtained under the following conditions:

- All measurements were taken during a 10 second normal circle scan at the indicated positions (see Figure 8.4-1) and at tabletop level (~4’ or ~1.2 m above the floor)
- Phantom: 16 cm diameter, 15 cm high acrylic phantom (CT head dose phantom) imaged at the axis of rotation
- No Pb mats on the table
- Maximum scan parameters (49 kVp, 200 mA, 8ms pulse width)
- 480 mAs for full scan (300 projection images)
- Typical average values for scans at the indicated positions are shown in Table 8.4-1 (measured with an Unfors Xi dosimeter system)

Table 8.4-1: Radiation scatter survey results			
Position	**Distance from axis of rotation (cm)**	**Value (mGy/h)**	**Air Kerma (Gy) per mAs**
A	50	12.72	73.62×10^{-9}
B	100	0.16	0.93×10^{-9}
C	150	0.01	0.04×10^{-9}
D	250	0.00	0.00×10^{-9}
E	300	0.00	0.00×10^{-9}
F	50	12.29	71.13×10^{-9}
G	100	3.72	21.54×10^{-9}
H	150	0.55	2.79×10^{-9}
I	300 (behind radiation barrier at Operato'rs Console)	0.00	0.00×10^{-9}

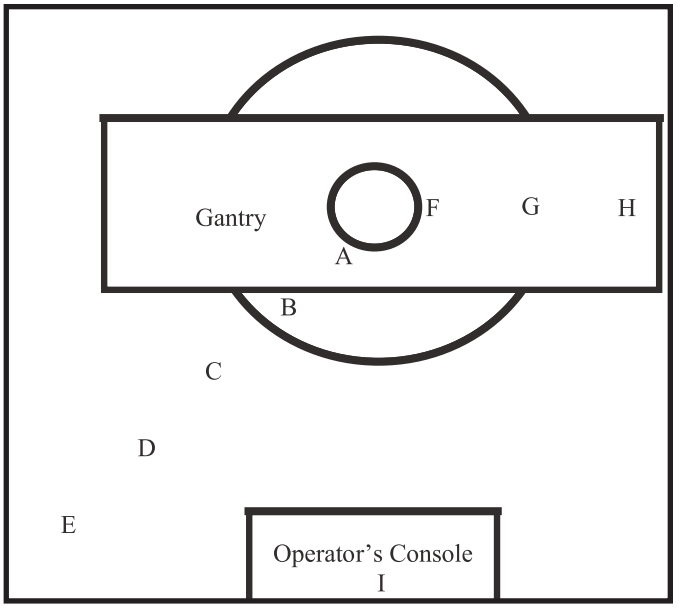


Figure 8.4-1: Measurement locations

8.5. Subsystem Dimensions

Refer to the Pre-Installation Manual, Section 11.2, for the dimensions of CBCT1000 subsystems.

8.6. Operating Temperature, Humidity & Pressure

Please refer to the Installation Manual, Section 3.1 Shipping and Storage of the Koning Breast CT System for the recommended limits on temperature and relative humidity for storage and shipping of this system.

Recommended limits on temperature, relative humidity and atmospheric pressure for the CBCT1000 are as follows.

- Temperature: 68°F to 75°F (20°C to 24°C)
- Relative Humidity: 30% – 60%
- Atmospheric Pressure: 10.9 psi – 14.5 psi (75 kPa – 100 kPa)

If these limits need to be exceeded, contact Koning Corporation or Koning's Authorized Representative for assistance.

8.7. Product Lifespan

The CBCT1000 is designed for a useful life of 7 years.

8.7.1. Disposal Guidelines

To properly remove and dispose of this system, follow environmental laws, codes, guidelines and requirements established Locally and by State or Provincial Authorities for the disposal of hazardous waste. Follow facility guidelines for proper and safe disposal of potentially hazardous materials and residues. Contact Koning Corporation or Koning's Authorized Representative for assistance.

8.8. Consumables

There are no consumable materials in the standard operation of the CBCT1000. However, the potential exists for the X-ray tube and PLC battery to require replacement prior to the end of the 7 year life cycle anticipated for the System. These can only be replaced by a trained service technician. Contact Koning Corporation or Koning's Authorized Representative for information.

8.9. Approved Accessories List

The following items are approved for use with the CBCT1000. For further information on Koning manufactured accessories, please refer to the appendices of this manual. For further information on accessories, contact Koning Corporation or Koning's Authorized Representative.

Table 8.9-1: CBCT1000 accessories

Koning Part #	Description	Manufacturer	Manufacturer's Part #
KNG10153	Patient positioning side pads, Skinfoam-coated (4 side pads total required per system)	POLYFORM	ET PF176
KNG10119	Lead Pad (for patient protection)	WOLF X-RAY CORPORATION	75057
KNG10120	Patient Mat (Patient mat is altered by cutting a hole in it.)	YOGADIRECT.COM	YP41MATXXXEL
KNG10124	Step Stool, 2-step, 600 lb. capacity with rubber feet	CLINTON INDUSTRIES	T-6850
KNG10132	Riser platform, single height, 4'x 3'x 16"	MIDWEST FOLDING PRODUCTS	MWF-3416C
KNG-BG-00000	Biopsy bracket (optional, see Appendix B)	KONING CORPORATION	KNG-BG-00000
KNG-CO-00000	Adjustable collimator (optional, see Appendix C)	KONING CORPORATION	KNG-CO-00000

9. Cleaning Procedure

9.1. General Cleaning Recommendations

Koning Corporation recommends that after each patient visit, all surfaces and panels the patient may have come in contact with – including the table top (fiberglass with polyester resin gel coat), safety cover (ABS plastic and PETG) and the table insert (ultra high molecular weight polyethylene)– be thoroughly cleaned using alcohol wipes containing a minimum 70% isopropyl alcohol.

When cleaning the buttons and the inside of the Patient Safety Cover, take care to avoid leaking liquid inside. Blood and other fluids are health risks. Take appropriate health and safety precautions when removing blood or other fluids.

Caution:

Do not use detergents or organic solvents to clean the system. Strong detergents, alcohol and organic cleaners may damage the finish and also may cause structural weakening over time.

9.2. Cleaning Guidelines for Table Insert (UHMW Polyethylene Surface) and Patient Safety Cover (PETG Surface)

Do rinse with warm water prior to cleaning process.
Do remove dust and dirt from Safety Cover (PETG) with a soft cloth or sponge and a solution of mild soap and/or liquid detergent in water.
Do follow the application with a lukewarm water rinse.
Do clean thoroughly using alcohol wipes (minimum 70% isopropyl alcohol).
Do Not use abrasives or high alkaline cleaners.
Do Not leave cleaners on for long periods of time, wash immediately.
Do Not apply cleaners in direct sunlight or at elevated temperatures.
Do Not use scrapers, squeegees or razors.
Do Not clean with gasoline.

The following cleaners will damage polyethylene:

- Diethylether
- Ethylenechloride
- Hydrogen peroxide
- Methylene chloride
- Acetylene dichloride

9.3. Cleaning Guidelines for the Patient Table (Gelcoat Fiberglass Surface, Patient Mat and Side Pads)

Koning Corporation recommends that after each patient visit, all tabletop surfaces (fiberglass with polyester resin gel coat) that the patient may have come in contact with, including the patient mat and side pads, be thoroughly cleaned using alcohol wipes containing a minimum 70% isopropyl alcohol.

Do Not use abrasive cleansers or solvents on gel coat surfaces.

Avoid cleaning products that contain the following chemicals, as they will damage a gel coat finish: Acetone; Ethyl alcohol; Amyl or ethyl acetate; Sodium hypochlorite; Toluene; Phenol.

9.4. Cleaning Guidelines for Countertops and Covers

Koning Corporation recommends that countertops and covers be cleaned with a mild soap and water solution once per week.

Do not use abrasive cleansers or solvents on countertops and covers.
Do not use scrapers, squeegees or razors on countertops and covers.

9.5. Cleaning Sheets, Pillow Cases and Other Items

Anything that comes in actual or potential contact with the patient during screening should be cleaned after each session, or the covering changed after each session in the case of covered items. This includes appropriate cloth bedding, sheets and pillow cases used to cover the Scanner which must be laundered between uses.

10. Maintenance

10.1. Rebooting the System

Koning Corporation recommends that the Operator Console's workstation be rebooted at least once a week. Follow the standard Windows restart procedure for the Operator Console's control computer.

10.2. Air Filter

Although the KBCT System is intended to be used in a clinical environment (note HVAC requirements in Section 3.5 of the accompanying Pre-installation Manual) the air filter in the intake fan on the Operator's Console will need to be cleaned over the life of the system. Koning Corporation recommends inspecting this filter weekly and cleaning it (not replacing it) as necessary. Contact Koning Corporation or Koning's Authorized Representative for assistance.

10.3. Annual Inspection

It recommended that you call your Koning Authorized Representative once a year from the date of installation to inspect and/or service the system, as required. In addition, on each anniversary date of the system installation, the facility's medical physicist must perform the various quality control computed tomography tests listed in Section 63 of this manual.

10.4. Service

Do not attempt to service the System. No alteration, substitution, modification or replacement of any kind is permitted, unless at the explicit direction of Koning Corporation or Koning's Authorized Representative. Changes and/or additions to the equipment that are carried out by persons without the appropriate training and/or using unapproved spare parts may lead to the Koning warranty being voided. As with all complex technical equipment, maintenance by persons not appropriately qualified and/or using unapproved spare parts carries serious risks of damage to the equipment and of personal injury.

In the event that a 3rd party performs servicing on Koning's behalf, Koning Corporation will make available circuit diagrams, component part lists, descriptions, calibration instructions and/or other information to that 3rd party as necessary to facilitate servicing.

10.4.1. X-ray Tube

The potential exists for the X-ray tube to require replacement prior to the end of the 7 year life cycle anticipated for the system. The X-ray tube can only be replaced by a trained service technician. Contact Koning Corporation or Koning's Authorized Representative for more information if X-ray tube failure is suspected.

10.4.2. PLC Battery

The potential exists for the PLC battery to require replacement prior to the end of the 7 year life cycle anticipated for the system. The PLC battery can only be replaced by a trained service technician. Contact Koning Corporation or Koning's Authorized Representative for more information.

10.4.3. Fuses

Contact Koning Corporation or Koning's Authorized Representative concerning replacement of worn or broken fuses. Replacement of any fuses by someone other than a Koning Technical Representative may void or alter any system warranties.

10.4.4. Software Updates

The KBCT Console program will be maintained by the Koning Corporation. As the software is updated, new versions will be made available. KBCT Console program upgrades may only be performed by authorized service representatives. Please refer to your contract with the Koning Corporation for more information.

11. Training Program

Users must ensure that they have completed the Koning training program described in the Koning Breast CT Training Manual prior to use of the System, especially prior to conducting patient exams. The Koning training program will address the personnel training requirements in the product labeling to assure that the prospective users are aware of the required training for any medical physicist, technologist, or interpreting physician. Please refer to the Koning Breast CT Training Manual for information about the training program.

For specific information about the CBCT1000 and the KBCT Console Program, please refer the appropriate section(s) of this User's Manual.

12. KBCT Console Program Introduction

12.1. System Roles/User Classes

Different users of the KBCT Console program will have different system roles. A system role is a predefined user class which correlates with specific positions in a real clinical environment. Examples include administrators and technicians. System roles are not mutually exclusive, so it is possible that a particular user may have one system role, many system roles, or even no system roles. Users assigned to different system roles will be able to access different portions of the KBCT Console program's functionality. For example, an administrator will be able to add and remove users, as well as modify a user's password and assigned system roles.

The system roles available are administrator, technician, and experiment. The absence of a system role denotes a normal user.

Table 12.1-1: System roles and the functionalities associated with them

System Role	Description	Functionality
(none)	A normal user, such as a technologist.	Standard functionality.
Administrator	A system administrator.	Standard functionality plus the ability to change the system settings and configuration, manage user accounts and view the total number of X-ray exposures performed.
Technician	A hospital or service technician (**not** to be confused with a technologist).	Standard functionality.
Experiment	A system role for performing radiographic experiments. **This system role is not intended for normal patient imaging.**	All functionality except the ability to manage user accounts. **Never bound to specific X-ray parameters. Not warned when using unusual X-ray parameters.**

12.2. User Interface Summary

This section provides a brief overview of the user interface.

12.2.1. The Main Screen

The main screen of the KBCT Console program as it appears when the application is started is shown at right. At the top of the screen you'll find the menus and toolbar buttons used to control the KBCT System, as well as the user name you are logged in with. Just below that, on the left side of the screen, is a table where information on a selected patient case (information on the patient and the procedure he/she is receiving as defined by the DICOM standard) will be displayed. To the right of that is where the information on each of the series (of medical images) acquired will be displayed. The large black area in the middle of the screen will be used to display scan settings, once the user indicates that a type of scan is to be performed, and images, once they are acquired. Lastly, at the bottom of the screen are several displays indicating the KBCT System's current status.

Figure 12.2.1-1: Main screen

12.2.2. System Status

Figure 12.2.2-1: System status

At the bottom of the main screen are several displays which are updated automatically when there is a change in the machine's status. Of these, the displays in the lower left corner of the main screen (those without a number or series of hyphens) display the system's status (Figure 12.2-1). The large display with the word "Ready" in it shows what the KBCT Console program is currently doing. When the top box (the one typically saying "Ready") changes, it flashes blue when all is well and yellow or red when there is a problem (yellow to indicate a warning state; red to indicate an error state).

The five small indicators in the lower-left corner are designed to mimic LED lights, and will display bright colors when "on" and dull colors when "off". They indicate whether or not the KBCT PLC is in a ready state (the green indicator on the far left), whether or not the X-ray generator is prepared to emit (the green indicator in the mid-left), whether or not it is time to tell the patient to hold still for a scan (the green indicator in the middle, see Section 46.6 for more information), whether or not X-rays are being emitted (the yellow indicator in the mid-right, displaying an icon), and whether or not there is an error (the red indicator on the far right).

While indicators on the screen go from left to right, LED lights on the control panel go from top to bottom (Figure 12.2-2). For example, this green indicator on the left and the topmost indicates whether or not the X-ray generator has been prepared for emission.

In figure 12.2-3, shown below, the KBCT Console program has connected to the KBCT System Scanner, the X-ray generator is not ready to emit X-rays, it is not a good time to tell the patient to hold still, no X-rays are being emitted, and there are no errors. Also, the KBCT Console program is currently performing an offset calibration. (For information on offset calibrations, refer to Section 46.3.1.)

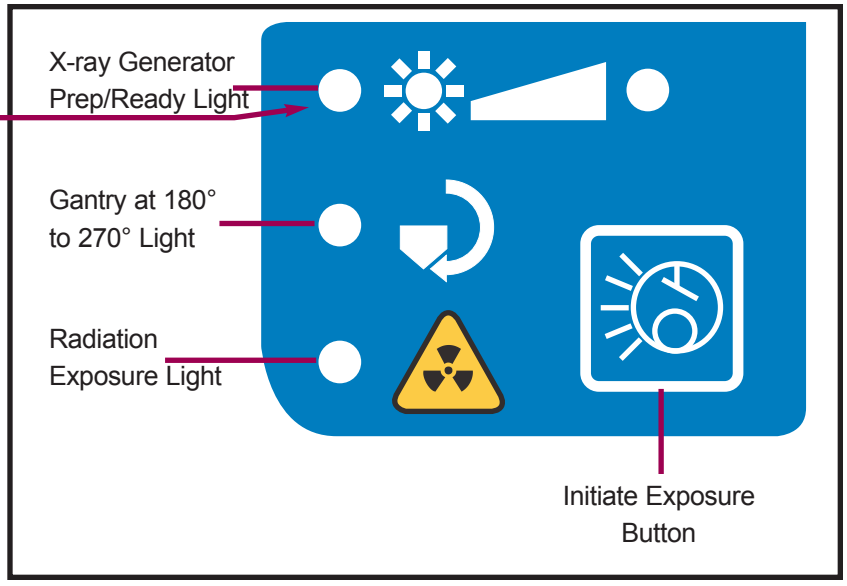


Figure 12.2.2-2: LED lights on the Operator's Console Control Panel

Figure 12.2..2-3: The system's status is automatically updated

In contrast, Figure 12.2-4 indicates that the system is homing the servos and an error has been encountered.

Figure 12.2.2-4: Homing servos

Clicking on the large display as shown at right will cause a box to appear above it containing a log of activity from the current session. A scrollbar will appear on the right side of the box when the log grows too long to fit in the box. Errors will be displayed in red text, warnings in yellow and normal messages in white. In the example shown in Figure 12.2-5, the System has been encountering problems communicating with the KBCT PLC.

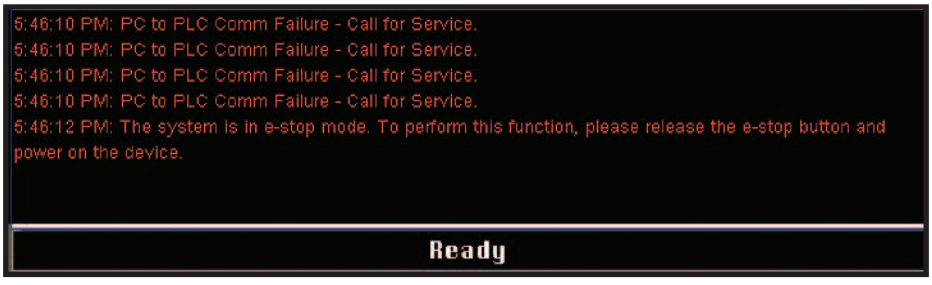


Figure 12.2.2-5: A log of the current session's activity

13. Standard Functionality Walkthrough

This section of the manual contains a walkthrough for the basic functionality which most users will make regular use of. It includes information pertaining to logging in, initializing the connection with the KBCT System Scanner, calibrations, selecting a patient case, motion control, specifying X-ray parameters, performing a scan, performing a reconstruction, viewing the results, publishing DICOM images and exiting the program. These tasks are explained in roughly the order in which the user would typically perform them.

For information on functionality which is unique to users with a particular system role, please refer to Section 47, Advanced Functionality.

13.1. Logging In and Related Tasks

This section deals with logging in to the KBCT Console program and tasks which serve a related purpose.

13.1.1. Starting the KBCT Console Program

To start the KBCT Console program, locate the icon shown at right on the workstation's desktop and double-click it. (For workstations running Windows 7, if prompted to allow the program to make changes on the computer click the "Yes" button.)

Figure 13.1.1-1:
Starting the program

13.1.2. Logging In

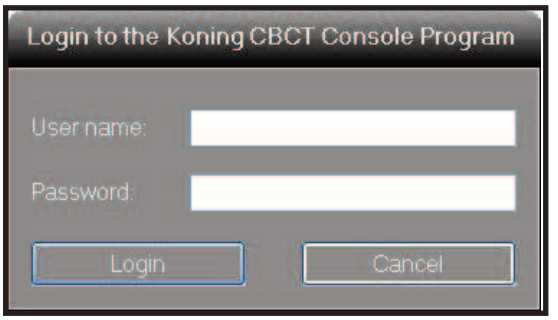


Figure 13.1.2-1: Log in

The very first thing you will see when starting the KBCT Console program is the log-in prompt shown below. To log in, type your user name in the box labeled "User name:" and your password in the box labeled "Password:", and then click the "Login" button (alternatively, you may hit Enter on the keyboard). Notice that the password is replaced by asterisks (*) for security. Clicking the "Cancel" button will cause you to exit the KBCT Console program (alternatively, you may hit Escape on the keyboard).

Note that you must be logged in to access the KBCT Console program's functionality.

Do not give out your password to others.

If you attempt to log in with an incorrect name and/or password, a prompt will notify you of it as shown below.

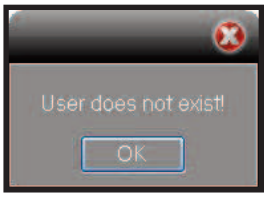


Figure 13.1.2-2: Incorrect user name

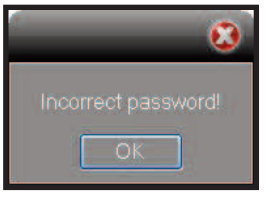


Figure 13.1.2-3: Incorrect password

13.1.3. Changing Your Password

To change your password, go to the "System" menu and click "My profile" as shown below.

It is **strongly** recommended that you change your password on a regular basis.

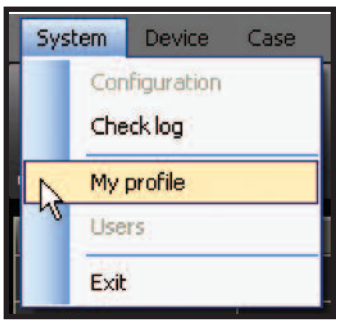


Figure 13.1.3-1:Changing your password

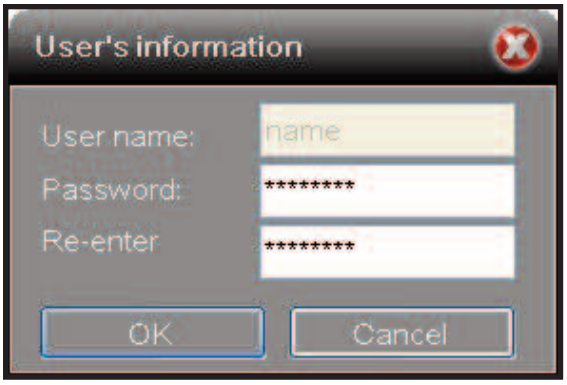


Figure 13.1.3-2: Entering a new password

The “User’s information” prompt shown below should appear. Its layout is similar to the log in prompt, with boxes for your user name and password, and two buttons.

Note that you may not change your user name. To change your password, type your new password into the box labeled “Password:” and also the box labeled “Re-enter password:”, and either click the “OK” button or hit Enter on the keyboard. When creating a password, it is recommended that you choose one which is not a commonly used word, is at least eight characters (letters) long, and contains a mix of letters (both capital and lowercase), numbers and symbols (such as @, # and $).

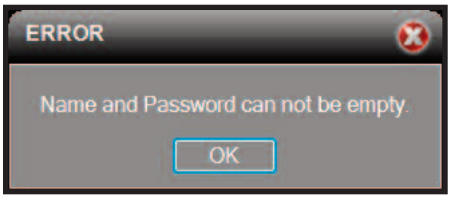


Figure 13.1.3-3: Password is empty

If you don’t want to change your password, either click the “Cancel” button, click the in the upper right corner of the prompt, or hit the Escape key on the keyboard.

If you clicked the “OK” button, the program will check to make sure that you typed the same password in each box. This is done to reduce the chance of a typo in the new password. If a password field is empty, the prompt shown in Figure 13.1.1.3-3 will appear. If the passwords do not match, then the prompt shown below in Figure 13.1.1-4 will appear. In either case clicking the “OK” button, clicking the in the upper right corner, or hitting “Enter” on the keyboard will return you to the “User’s information” prompt.

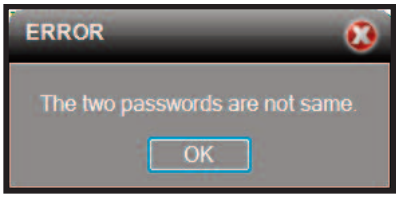


Figure 13.1.3-4: Passwords are not the same

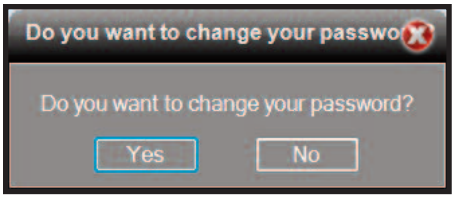


Figure 13.1.3-5: Confirm password change

If the passwords match, then the prompt shown at left (Figure 13.1.3-4) will appear asking if you want to change your password. Click the “Yes” button or hit Enter on the keyboard, and the change to your password will be complete. Click the “No” button if you don’t want your password changed.

13.2. Initializing the Connection

This section deals with initializing the connection to the KBCT System Scanner. The connection referred to throughout this section is a software connection, not the physical wiring and connections made between the workstation and the KBCT System Scanner. For information on physical connections, please refer to the Installation Manual.

Do not connect external devices to the System.

13.2.1. Connecting to the Device

To create a connection to the KBCT System Scanner, go to the “Device” menu and click “Connect to device” as shown at right (Figure 13.2.1-1).

Figure 13.2.1-2: Connect to device toolbar button

Alternatively, you may click the “Connect to device” toolbar button shown at left (Figure 13.2.1-2). The icon on the button resembles the symbol found on a computer’s power button. You will be unable to do this if there is already a connection.

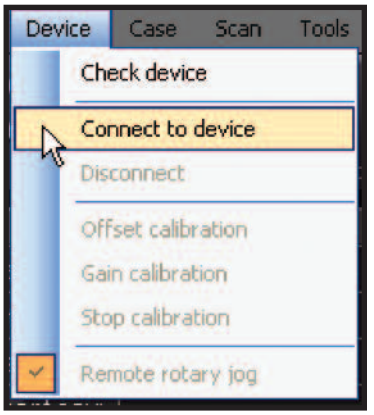


Figure 13.2.1-1: Connecting to the device

Note that this is a software connection which is being made, and that this procedure will always fail in the event of an absent physical connection.

The status indicator at the bottom of the main screen will begin to flash blue, and the text will change to read “Connecting to the device…” as shown in Figure 13.2.1-3. The KBCT Console program is now in the process of connecting to the KBCT PLC.

Figure 13.2.1-3: Beginning to connect to the device

If the Scanner doors are open, the prompt shown below (Figure 13.2.1-4) may appear. Close the Scanner doors and click the “OK” button in order to continue connecting. Alternatively, click the “Cancel” button or the in the upper right corner of the prompt to abort the attempt at establishing a connection.

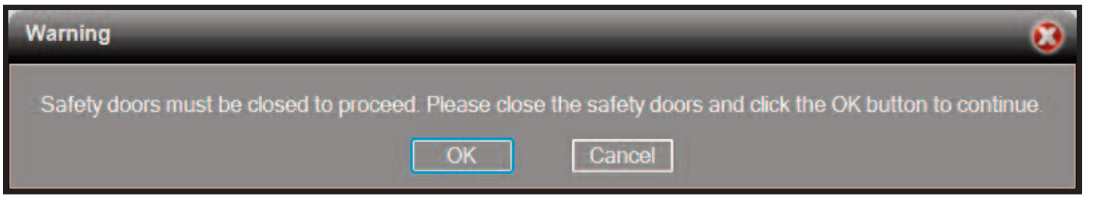


Figure 13.2.1-4: Scanner doors need to be closed

If the moving parts (servos) need to be homed in order to locate their home positions the dialog shown at right (Figure 13.2.1-5) will appear. Clicking the “OK” button or hitting Enter on the keyboard will cause the moving parts to move to their home positions. Clicking the “Cancel” button, clicking the in the upper right corner, or hitting Escape on the keyboard will cause the KBCT Console program to stop trying to open a connection.

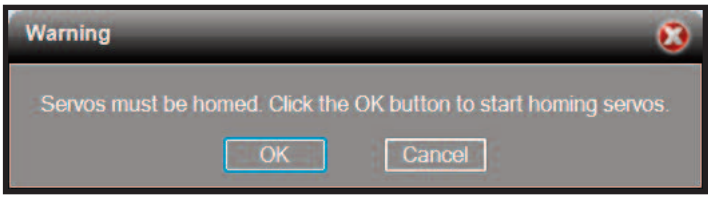


Figure 13.2.1-5: Servos need to be homed

Figure 13.2.1-6: Waiting for system to be ready to home servos

If the system is busy, the message shown at left (Figure 13.2.1-6) may appear. The system should begin homing the servos momentarily in such an event.

The status indicator will change to read “Homing servos…” as shown at right (Figure 13.2.1-7) once the system begins homing its servos. All servos will gradually return to their home positions automatically. This may take a few minutes.

Figure 13.2.1-7: Homing servos

Figure 13.2.1-8: Initializing the X-ray generator

If the servos do not need to be homed, or once the servos have been homed, the text will change to read “Initializing the X-ray generator” as shown in Figure 13.2.1-8. At this point, a connection is established with the X-ray generator.

Lastly, the message “Loading initial parameter values…” will be displayed as shown below (Figure 13.2.1-9). During this time, the X-ray parameters will be set to their default values. These initial values are 49.0 kVp, 16 mA, 8 ms, and 0.128 mAs. These default values may only be changed with administrative privileges. **Modifications to the initial/default X-ray parameters are not recommended.**

Figure 13.2.1-9: Loading preset X-ray parameters

Note that if the system has just come out of an e-stop then this will take some time since the X-ray generator takes a few minutes to reboot. If you find yourself in this situation, please be patient. The connection will be completed once the X-ray generator finishes booting.

Once the connection has been successfully made the green LED on the far left will turn on as shown at right (Figure 13.2.1-10).

Figure 13.2.1-10: Successful connection

Note that the positions of the servos and the X-ray parameters will display their current values once a connection has been established, instead of the hyphens (-) shown when disconnected.

13.3. Calibrations

This section deals with the calibrations which you may perform using the KBCT Console program. It is recommended that you perform these calibrations at the times suggested in table 13.3-1 to reduce the number of artifacts which may appear in scanned and reconstructed images.

Table 13.3-1 Calibration intervals

Calibration Type	Suggested Frequency
Offset calibration	Every 10 to 15 minutes (while system is in use)
Gain calibration	Once a month

13.3.1. Performing an Offset Calibration

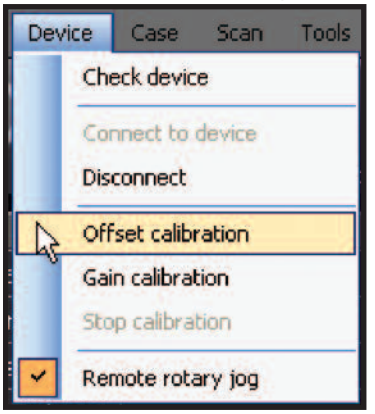


Figure 13.3.1-1: Performing an offset calibration

It is strongly recommended that you perform an offset calibration every 10 to 15 minutes while the KBCT System is in use. An offset calibration is a calibration which compensates for some of the irregularities in pixel brightness in the detector by acquiring images without firing X-rays. In order to perform an offset calibration on the KBCT System, go to the “Device” menu and click “Offset calibration” as shown at left (Figure 13.3.1-1).

Alternatively, you may click the “Offset calibration” toolbar button shown at right (Figure 13.3.1-2). The icon on the button is that of a balance (it resembles a circle resting on top of a triangle).

Figure 13.3.1-2: Offset calibration toolbar button

Note that if no connection has been made, you will be unable to perform an offset calibration.

Figure 13.3.1-3: Performing offset calibration

The status indicator at the bottom of the main screen will begin to flash blue and the text will change to “Performing offset calibration…” as shown in Figure 13.3.1-3.

As the dark images for the calibration are acquired, the message in the status indicator will change as shown at right (Figure 13.3.1-4).

Figure 13.3.1-4: The calibration is ongoing

Figure 13.3.1-5: Performing final calculations

Once the necessary images have been acquired, the KBCT Console program will perform some calculations using them, recording the results as the calibration finishes. The message in the status indicator will once again change as shown at left (Figure 13.3.1-5).

13.3.2. Gain Calibration

It is strongly recommended that a gain calibration be performed once a month, or if you begin to notice an increase in image artifacts (particularly “blotches” in projection images). Gain calibrations involve acquiring several images using various X-ray parameters with no objects in the beam in order to help ensure the uniformity of acquired images. In order to perform a gain calibration on the System, go to the “Device” menu and click “Gain calibration” as shown at right (Figure 13.3.2-1).

Note that if no connection has been made, or if the HU used (heat units) is too high, you will be unable to perform a gain calibration.

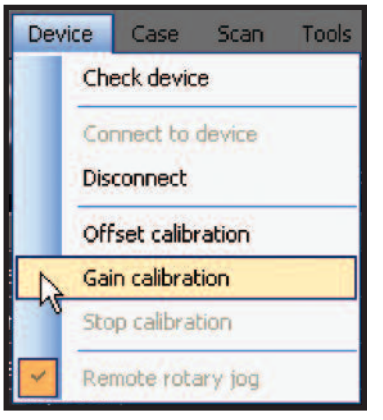


Figure 13.3.2-1: Performing a gain calibration

The text in the status indicator will change to “Doing gain calibration…” to indicate that the gain calibration has begun as shown in Figure 13.3.2-2.

Figure 13.3.2-2: Starting a gain calibration)

The gantry will then lower to the 0.0 mm position and the patient table will move to a position of 450.0 mm automatically, to prevent the patient safety cover from being in the beam during the gain calibration.

An offset calibration is then performed as the first step of the gain calibration. During this step, the message shown in Figure 13.3.2-3 will be displayed.

Figure 13.3.2-3: Offset calibration at start of gain calibration

Once the offset calibration images have been acquired, the X-ray parameters will automatically be set to values specified in the system configuration (the defaults are 49.0 kVp, 20 mA, and 5 ms). The message in the status indicator will change as shown at right (Figure 13.3.2-4), indicating that the ratio between high and low gain modes is calibrated as the next step of gain calibration. (For more information on gain modes and gain calibration, please contact Koning Corporation or Koning’s Authorized Representative.)

Figure 13.3.2-4: HL Ratio calibration, part of gain calibration

The gantry will begin to rotate and the X-ray generator will then prepare for emission. While the X-ray generator is preparing, the X-ray Generator Prep/Ready Light will blink on and off. When the X-ray generator is ready it will remain on steadily as shown in Figure 13.3.2-6.

Once the X-ray generator is ready, the operator may start X-ray emission and image acquisition for the gain calibration by pressing the “Initiate Exposure” button on the Operator’s Console control panel.

The light next to the radiation symbol on the control panel at the Operator’s Console will be on while X-rays are being emitted. Also, the corresponding icon in the KBCT Console program will light up as shown in Figure 13.3.2-7. You should be able to hear the X-ray generator working, as it will emit a steady, high-pitched sound.

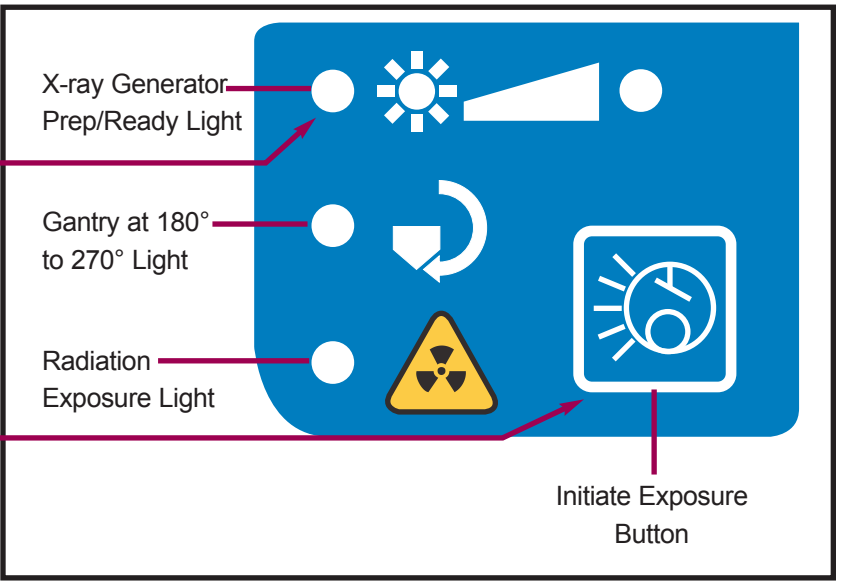


Figure 13.3.2-5: Controls and indicators for the X-ray

Figure 13.3.2-6: The X-ray generator is prepped

Note that similar sounds occur at other times, such as when the generator is initialized. Also, another sound occurs when the X-ray tube’s rotor is braking. This occurs approximately 2 minutes after X-ray exposure is taken if no subsequent exposure is performed. It is recommended that you avoid initiating an X-ray exposure during this time.

Figure 13.3.2-7: X-rays are being emitted

The operator should remain safely behind the radiation barrier while X-rays are being emitted.

Once the images for the HL ratio calibration step have been acquired, the X-ray parameters will automatically be set to some other set of values specified by the system configuration (49.0 kVp, 64 mA, and 8 ms by default). The status indicator’s text will change to “Lo img calibration…” as shown in Figure 13.3.2-8 to indicate that the next step of the gain calibration is starting. The X-ray generator will begin to prepare for emission again. Once it is ready, press the “Initiate Exposure” button on the control panel at the operator’s console as before.

Figure 13.3.2-8: Lo img calibration, part of gain calibration

Next, the X-ray parameters will automatically be set to a third set of values specified by the system configuration (49.0 kVp, 125 mA, and 8 ms by default). The status indicator will change as shown at right (Figure 13.3.2-9), and the X-ray generator will once again begin to prepare for emission. Once it is ready, press the emit button on the operator's console control panel as before. This is the final emission which occurs during gain calibration.

Figure 13.3.2-9: Hi img calibration, part of gain calibration

Lastly, the KBCT Console program will perform the calculations necessary to complete the calibration using the images which have been acquired. While these calculations are ongoing, the message shown in Figure 13.3.2-10 will be displayed.

Figure 13.3.2-10: Calculations at the end of gain calibration

13.3.3. Stopping a Calibration

If there is a need to stop an ongoing calibration, click "Stop calibration" under the "Device" menu as shown at right (Figure 13.3.3-1). The calibration will then stop shortly.

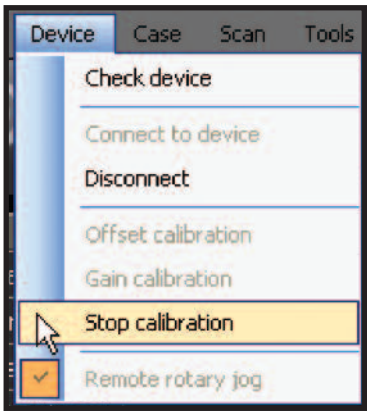


Figure 13.3.3-1: Stopping a calibration

Use of this functionality is **not** recommended in an emergency.

13.4. Patient Management

This portion of the manual deals with managing patient cases.

13.4.1. Loading a Patient Case from the RIS

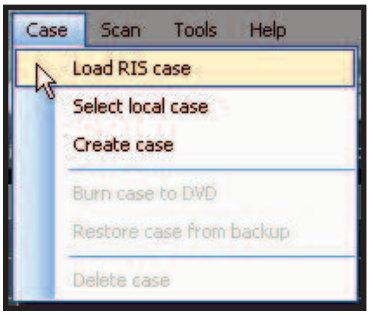


Figure 13.4.1-1: Loading a case from the RIS

In order to load a patient case from your organization's RIS, go to the "Case" menu and click "Load RIS case" as shown at left (Figure 13.4.1-1).

Alternatively, you may click the "Load RIS case" toolbar button shown below (Figure 13.4.1-2). The icon on the button shows a hand below a row of boxes above it, with the hand pointing at a box which has been checked.

The text in the status indicator will change as shown in Figure 13.4.1-3.

Figure 13.4.1-2: Check RIS toolbar button

Note that this functionality will not work properly if there is no connection to your facility's network, or if your organization does not use an RIS.

Figure 13.4.1-3: User is selecting a case from the RIS

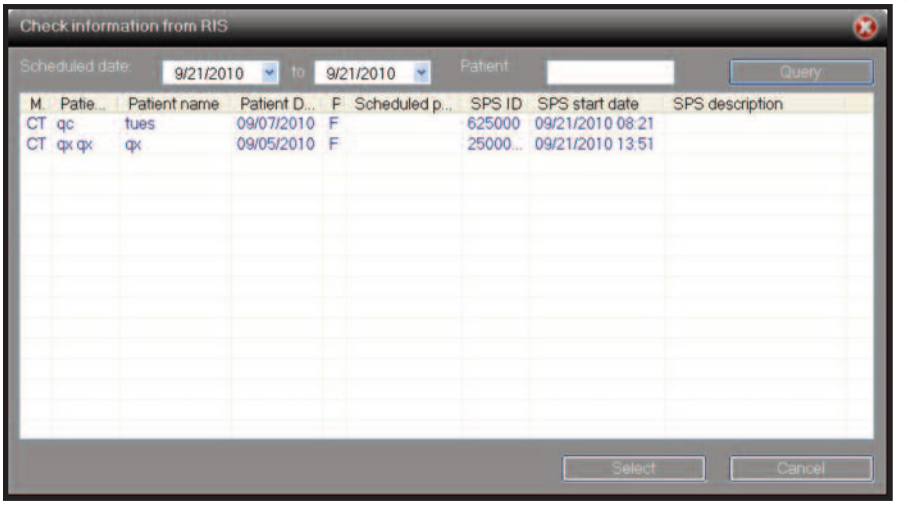


Figure 13.4.1-4: Cases found in the RIS

A window similar to the one shown below will appear. The majority of the window is taken up by a table which displays information from the patient cases retrieved from the RIS. Specifically, the modality, patient ID, patient name, patient date of birth, patient sex, scheduled physician, SPS ID, SPS start date/time and SPS description are shown. The cases are sorted by their SPS start date/time. If there are more patient cases than can fit in the window, a scrollbar will appear on the right side of the table. The column widths may also be adjusted if you cannot read a particular entry.

In order to limit which patient cases are displayed, you may use the controls at the top of the window. Change the dates in the dropdown boxes labeled “from” and “to” in order to specify a range of time. You may also search for a specific patient by typing a patient’s name into the box labeled “Patient name:”. Once you have specified the parameters for your search, click the “Query” button to search the RIS for patient cases matching the parameters you specified. Be aware that this may take some time depending on the number of results found and the speed of your network.

To load a patient case, click the case you wish to select and then click the “Select” button at the bottom of the window. Alternatively, you may double-click a case instead. Once you do, the window will close and the selected case will be transferred to the local database.

If you do not want to load a patient case, either click the “Cancel” button at the bottom of the window or click the  in the upper right corner. The window will close and no patient case will be loaded.

13.4.2. Selecting a Locally Stored Patient Case

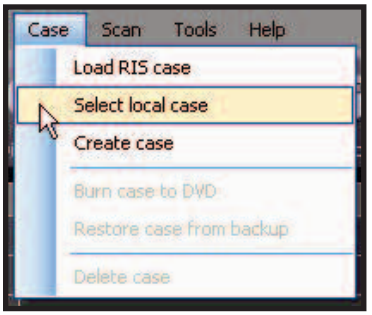


Figure 13.4.2-1: Selecting a case from the workstation’s local database

In order to select a patient case from the workstation’s local database, go to the “Case” menu and click “Select local case” as shown at left (Figure 13.4.2-1).

Alternatively, you may click the “Select local case” toolbar button shown at right (Figure 13.4.2-2).

Figure 13.4.2-2: Select case toolbar button

The text in the status indicator will change as shown below at right (Figure 13.4.2-3).

Figure 13.4.2-3: User is selecting a case

A window similar to the one shown at right (Figure 13.4.2-4) will appear. The majority of the window is taken up by a table which displays information from the patient cases retrieved from the workstation’s local database. Specifically, the modality, patient ID, patient name, patient date of birth, patient sex, scheduled physician, SPS ID, SPS start date/time, and SPS description are shown. The cases are sorted by their SPS start date/time. If there are more patient cases than can fit in the window, a scrollbar will appear on the right side of the table. The column widths may also be adjusted if you cannot read a particular entry.

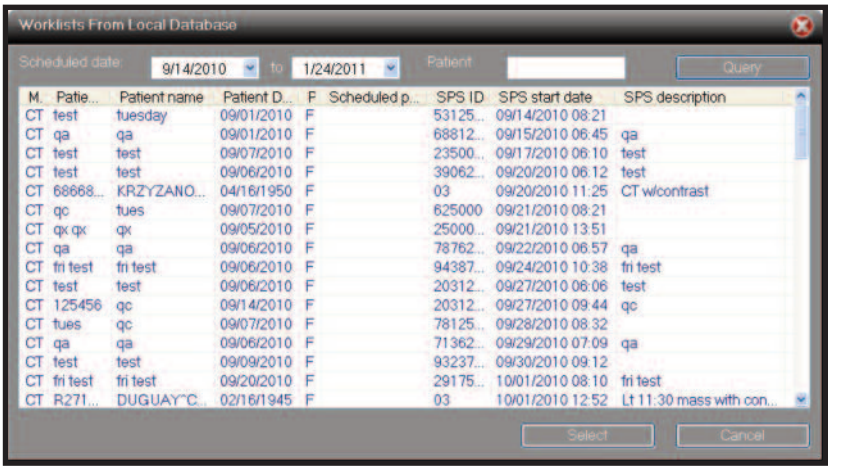


Figure 13.4.2-4: Patient cases found in the workstation’s local database

In order to limit what patient cases are displayed, you may use the controls at the top of the window. Change the dates in the dropdown boxes labeled “from” and “to” in order to specify a range of time. You may also search for a specific patient by typing a patient’s name into the box labeled “Patient name:”. Once you have specified the parameters for your search, click the “Query” button to search the workstation’s local database for patient cases matching the parameters you specified. Be aware that this may take some time depending on the number of results found.

To select a patient case, click the case you wish to select and then click the “Select” button at the bottom of the window. Alternatively, you may double-click a case instead. Once you do, the window will close and the information on the main screen will be updated to display the case information as shown in Figure 13.4.2-5. The table on the left is filled with the patient case’s information, and the table on the right is filled with the series associated with that patient case. A scrollbar will appear on the right side of the table if there are more series than can be displayed.

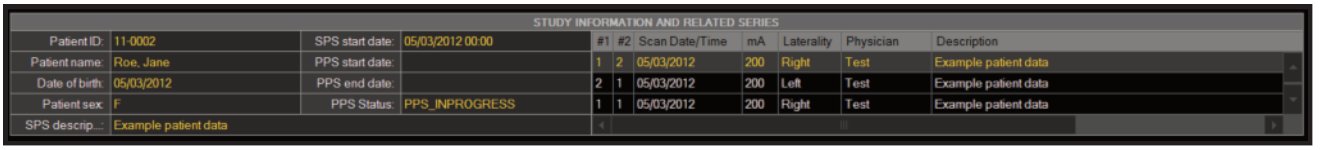


Figure 13.4.2-5: Main screen now displays selected patient case information

If you do not want to select a patient case, either click the “Cancel” button at the bottom of the window or click the in the upper right corner. The window will close and no patient case will be selected.

13.4.3. Creating a Patient Case

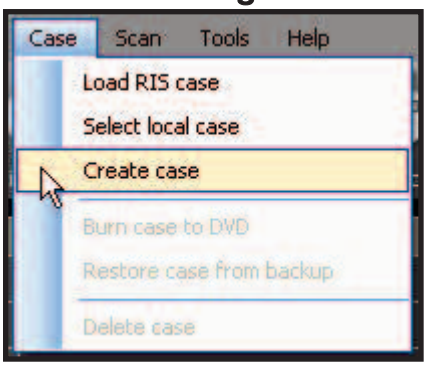


Figure 13.4.3-1: Creating a patient case

In order to create a new patient case, go to the “Case” menu and click “Create case” as shown at left (Figure 13.4.3-1).

Alternatively, you may click the “Create case” toolbar as shown in Figure 13.4.3-2.

Figure 13.4.3-2: Create case toolbar button

The text in the status indicator will change as shown below (Figure 13.4.3-3).

Figure 13.4.3-3: User is creating a new case

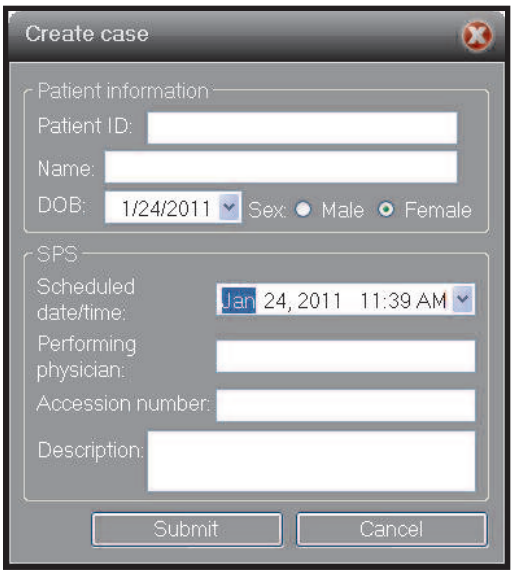


Figure 13.4.3-4: Filling in the new patient case’s information

The window shown at left (Figure 13.4.3-4) will appear. In order to create a new patient case, you will have to fill in the information (at minimum the patient’s ID number, name, date of birth, and sex, as well as the SPS’s scheduled date/time; optional information includes the SPS’s performing physician, accession number, and a brief description). When you are done, click the “Submit” button and the new patient case will be created. The newly created case will be stored locally in the workstation’s database.

If you do not want to create a patient case, either click the “Cancel” button or click the in the upper right corner of the window.

Note that if you create a new patient case, it will be selected automatically as a convenience, and added to the workstation’s local database. This is shown in the screenshots below (Figure 13.4.3-5 and Figure 13.4.3-6).

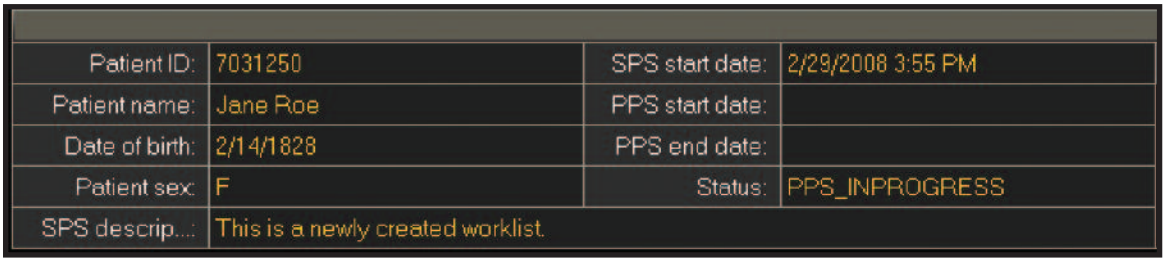


Figure 13.4.3-5: The newly created patient case is automatically selected

Figure 13.4.3-6: The newly created patient case is added to the workstation’s local database

13.4.4. Editing a Patient Case

Once the patient data has been loaded, it may still be edited until an image is acquired in case a mistake is found. In order to edit the patient information, right-click anywhere on the section of the main screen labeled “STUDY INFORMATION AND RELATED SERIES” and select “Edit case information” from the menu which appears as shown in Figure 13.4.4-1.

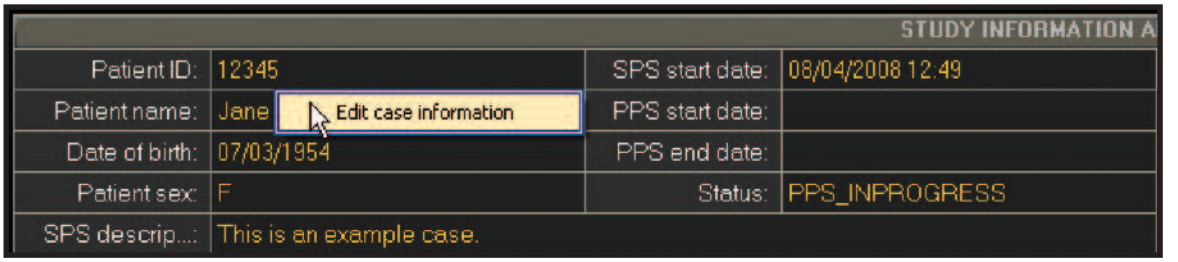


Figure 13.4.4-1: Right-click menu for the patient case

Note that if any images have already been acquired for the patient case, the prompt at right (Figure 13.4.4-2) will appear and you will be unable to edit the information.

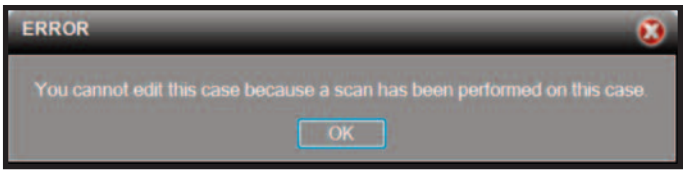


Figure 13.4.4-2: Cannot edit information

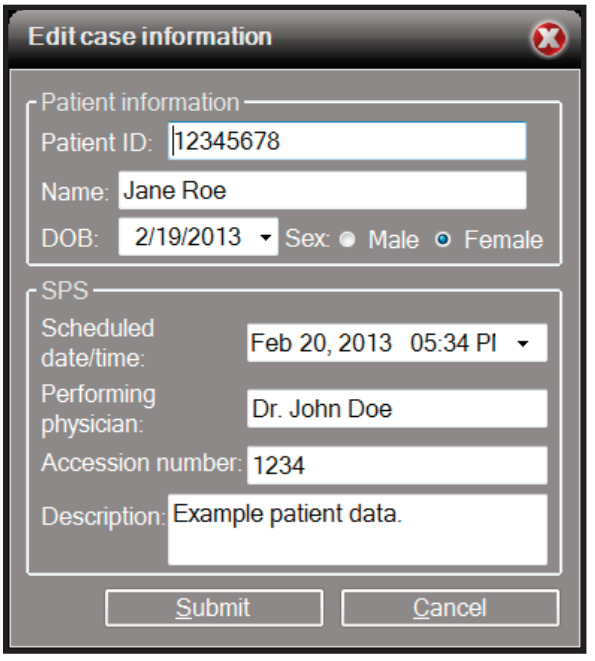


Figure 13.4.4-4: Editing the patient case

Figure 13.4.4-3: User is editing a case

The status indicator will show the message “Editing case...” shown above (Figure 13.4.4-3) and the form shown at left (Figure 13.4.4-4) will appear. The patient’s ID number, name, date of birth, and sex as well as the SPS’s scheduled date/time, performing physician, accession number, and description may be edited.

Note that this is essentially the same form used when creating a patient case.

Click the “Submit” button when done editing the patient case information close the window and update the case with the changes entered into the form. Figure 13.4.4-5 shows an example of updated case information. To close the form without changing the patient case information, either click the “Cancel” button or the in the upper-right corner of the form.

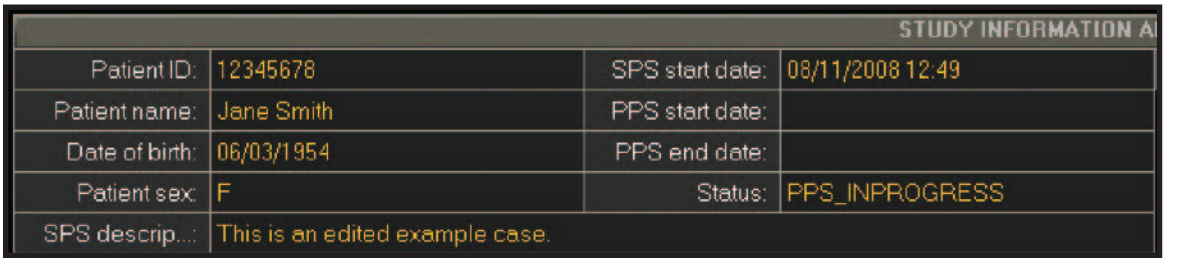


Figure 13.4.4-5: Updated information

13.4.5. Selecting a Series

Once a case has been selected, you will be able to select a series to work with. In order to select a series, click the desired series in the series list. Make use of the up and down arrows if the desired series is not visible. The currently selected series will be hi-lighted as shown in Figure 13.4.5-1.

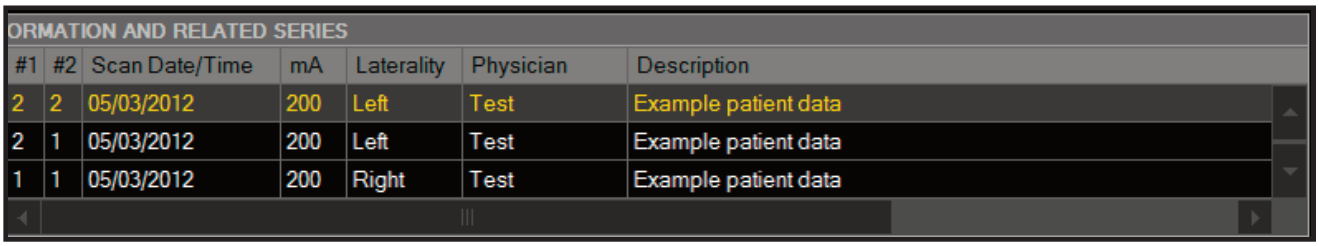


Figure 13.4.5-1: A series has been selected

Note that if no images associated with the current case have been acquired then no series will be available.

Note that when a new series is created (either due to a scan or reconstruction) it will be selected automatically.

13.5. Preparing for a Scan

This section of the manual deals with functionality typically used in direct preparation for a scan, such as motion control.

13.5.1. Motion Control

At the bottom of the screen are several displays. Of these, the ones shown below (the displays with green numbers seen in Figure 13.5.1-1) display the current position and motion of the KBCT System Scanner's moving parts (namely the patient table and gantry). The values displayed are the gantry's vertical position (in millimeters), the gantry's angular position (in degrees), the patient table's vertical position (in millimeters), and the gantry's rotation speed (in degrees per second).

Figure 13.5.1-1: Motion control gauges

In order to change one of these settings, click on the display of the setting you wish to change. The controls shown at right (Figure 13.5.1-2) will appear above the display. There are a few ways in which you may move a particular part. To move the part to a specific position, specify the desired position using either the dropdown box or the slider in the area labeled "Move to (mm)" and then click the "Move" button. To move the part by a specific amount, specify the desired change in position using the dropdown box or the slider in the area labeled "Move by (mm)" and then click the "Move" button. Keep in mind that the motion you specified (either using the "Move to (mm)" or the "Move by(mm)" controls) will not occur until you click the "Move" button, which has an icon showing a diamond with a vertical line in it. (Labels other than "Move to(mm)" and "Move by (mm)" are used when adjusting the gantry's angular position. The layout of the controls is the same though, with the controls for moving to a specific position located above the ones for moving by a specific amount.) You may also move a servo without specifying a destination or displacement. To move a part up, click the "Up" button and hold it until the part reaches the desired position. The motion will stop after the "Up" button is released. The "Down" button functions in the same way, except that the part will move down instead. The icons on the "Up" and "Down" buttons are arrows pointing in the corresponding directions. (In the case of the gantry's angular position, there are the "CW" and "CCW" buttons instead, that is clockwise and counter-clockwise, respectively.) Clicking the "Home all" button, which has the icon of a house, will cause all the parts to move to their home (zero) positions. Clicking the "Stop" button, which has the icon of an upside down triangle, will cause a moving part to stop moving.

Figure 13.5.1-2: Adjusting the gantry's vertical position

Keep in mind that since the value shown on the display is updated in real-time, it will gradually move toward the value you selected instead of changing immediately.

If no connection to the KBCT System has been made, then all values will be displayed as a series of hyphens and change you will be unable to access the controls to change them.

Note that the gantry's rotational velocity may not be adjusted in this way; the display only shows the current velocity of the rotation.

Note that you will be unable to use the "CW" and "CCW" buttons in the gantry's angular position controls if your administrator has disabled the "Remote rotary jog" feature.

The "Stop" buttons in the motion controls are not intended for emergency use.

Alternatively, you may initiate motion by means of the Scanner control panels located on either side of the Scanner where the doors meet (Figure 13.5.1-3). By pressing and holding the up or down arrow buttons at the bottom of the panel, you may move the selected moving part in the corresponding direction. Just as with the "Up" and "Down" buttons in the KBCT Console program, release the button to stop the motion. Note that the up and down arrow buttons also have circular arrows to indicate the corresponding direction of motion for gantry rotation. To change the selected moving part, press the select servo button (the second button from the top, which has a square arrow icon). The indicator lights in the middle of the panel indicate which moving part has been selected. From top to bottom, these are the gantry lift, gantry rotation, and patient table lift.

There are limits to the range of motions available. The patient table and the gantry may not move past each other, and the gantry may not move below the zero position. The patient table, likewise, may not move above a certain position (approximately 550.0 mm, though the exact value of this limit varies slightly from Scanner to Scanner). The gantry's angular position has no such limitations, as the gantry is capable of continuous 360° rotation.

Figure 13.5.1-3: Scanner control panel

Do not attempt to initiate motions while there is a danger of collision with the patient, operator, or other personnel. For safety reasons, the software will prevent you from initiating motions while the Scanner cover doors are open. You will also be unable to initiate motions in the absence of the patient safety cover (or other accessories designed to be attached to the hole in the patient table). Do not attempt to defeat these safety features.

Koning generally recommends that all scans be performed with all servos at their 0 positions, unless otherwise necessary to achieve sufficient coverage. Koning recommends confirming all servos are in the desired positions before initiating any scans.

13.5.1.1. Home Lights

There is a little box with an "H" in it to the left of each of the motion control displays (except for the one showing the gantry's rotation velocity). These are home lights, and they are used to indicate when a moving part is within a certain range of its home position. A home light will turn green when the corresponding part has reached the vicinity of its home position, and will turn black again once the corresponding part has moved away from its home position. Both cases are shown at right (Figure 13.5.1.1-1 showing an unlit home light and Figure 13.5.1.1-2 showing a lit home light).

Figure 13.5.1.1-1: Home light is not lit; gantry is not at its angular home position

Figure 13.5.1.1-2: Home light is lit; gantry is at its angular home position

13.5.2. Setting X-Ray Parameters

At the bottom of the main screen are several displays. Of these, the ones shown below (Figure 13.5.2-1) display the current X-ray parameters. The X-ray parameters are mGy (estimated), kVp, mA, ms, and mAs (that is, estimated dose, peak voltage, current, exposure time, and the electrons emitted from cathode to anode in one second). Their values are updated in real-time.

Figure 13.5.2-1: X-ray parameter gauges

Figure 13.5.2-2: Adjusting the mA

If the system is configured to allow normal users to directly set the mA, clicking on the mA display will cause controls similar to the ones shown at left (Figure 13.5.2-2) to appear above the display. You may then either select a new value from the list, or you may use the "Up" and "Down" buttons located below the list to increment and decrement the value used. The "Up" and "Down" buttons have icons of arrows pointing in the corresponding direction. The values you may specify for each parameter have been limited to help prevent damage to the KBCT System and/or excessive exposure to the patient.

Keep in mind that since the value shown on the display is updated in real-time, there may be a slight delay before the value shown is updated.

If the X-ray generator is off, or if a connection has not been made, then all values will be displayed as a series of hyphens and change you will be unable to access the controls to change them.

Note that only Experiments may adjust the kVp and ms (refer to Section 14.3 for more information).

Note that you may not adjust the mAs and estimated mGy in this way. Instead, these are calculated automatically from the current kVp, mA and ms values.

13.5.3. Checking the HU Used

The remaining display shown in Figure 13.5.3-1 (to the right of the mAs) indicates the HU Used. This is the percentage of HU (heating units) that have been consumed by the X-ray generator. Once the HU Used becomes too high, you will be unable to perform a scout image, scan or gain calibration. The HU Used will go down over time as the X-ray generator cools. It is recommended that you keep the HU Used below 50 at all times.

Figure 13.5.3-1: HU Used

13.6. Scanning the Patient

This section explains and provides instructions for the types of scans which the KBCT System may be used to perform on a patient.

Caution:

Loose or damaged cable connections may cause problems during scans, including loss of data and unnecessary X-ray exposure. For this reason, Koning strongly recommends keeping the Operator's Console doors locked and all connection covers in place at all times. Only qualified personnel should perform service on the machine.

13.6.1 Guidelines for Patient Positioning

1. Always explain the procedure before getting the patient on the table

2. Tell the patient at the beginning to expect the exam to take approximately 10 minutes

3. Inform the patient to remove all jewelry, especially necklaces, to ensure that they are not in the imaging field during the scan

4. The patient climbs the steps and either sits on the edge and turns down onto her stomach or crawls up on hands and knees to get to the hole

- Help steady the patient as needed while climbing onto the table
- **Always make sure the cross hairs are off before having the patient climb onto the table**
- **Instruct the patient not to put weight on the Scanner cover doors**

5. Make sure the patient's cape is unsnapped so that no material goes into the hole

6. The patient will position herself so that the correct breast is hanging through the hole

7. The arm on the scanned side should be down by the patient's hip, the other arm up at the patient's head as shown in Figure 13.6.1-1

8. Ask the patient to move until her shoulder is down into the groove of the white circle table insert (this maximizes imaging of the axillary region)

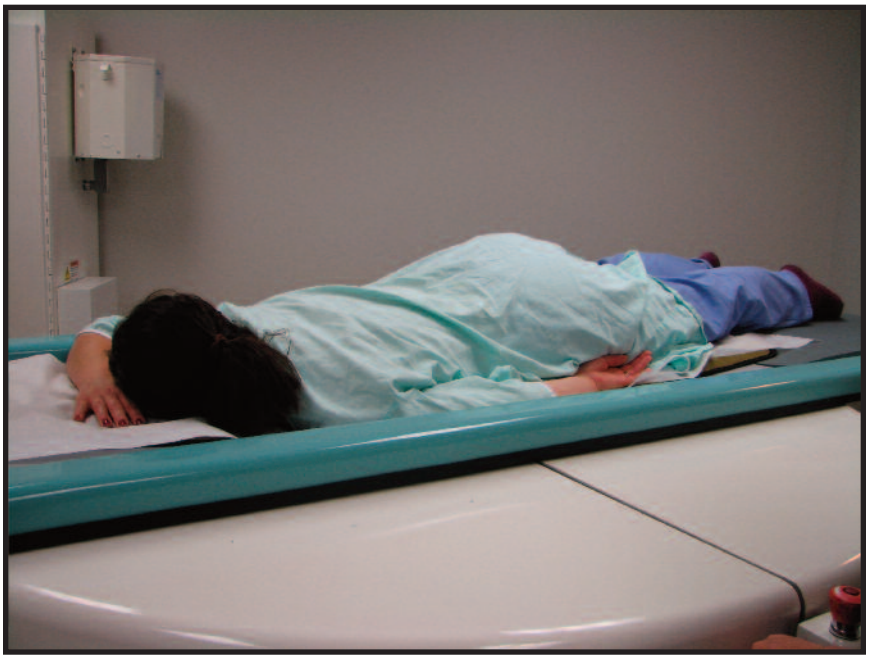


Figure 13.6.1-1: Patient on table

9. Open the Scanner cover doors on either side and check with the cross hairs that the breast is centered correctly

- The cross hairs are a laser which may be turned on and off by pressing the crosshair button at the top of either of the control panels located at the Scanner cover doors (see Figure 13.6.1-2)
- The cross hairs do not necessarily have to be on the nipple, but they should be fairly close
- **Do not look directly into the cross hair laser**

Figure 13.6.1-2: Scanner control panel

10. Use the foam pads provided to make the patient comfortable without compromising breast positioning in the hole

- Ask the patient where she is uncomfortable to position the foam pads

11. Tell the patient to lie as still as possible

- It is OK for the patient to breathe slowly

12. After the scan, the patient can get up by herself and move to the steps (reverse of what she did to get on the table)

- **Make sure the cross hairs are off before having the patient begin to climb off of the table**
- Help steady the patient as needed while climbing off the table
- Make sure the patient retrieves any jewelry before leaving the room

13.6.2. Acquiring a Scout Image

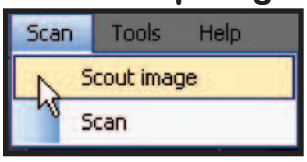


Figure 13.6.2-1: Acquiring a scout image

A scout image is typically used to confirm that everything is positioned correctly before performing an actual scan. To have the X-ray generator acquire a scout image, go to the "Scan" menu and click "Scout image" as shown at left (Figure 13.6.2-1).

Alternatively, you may click the "Scout image" toolbar button shown in Figure 13.6.2-2. The icon on the button shows a cone beam hitting a detector plane.

Figure 13.6.2-2: Scout image toolbar button

Note that you will be unable to perform a scan of any type until you've connected to the device and selected a patient case.

The message "Opening the scan controls…" may appear as shown at right (Figure 13.6.2-3). (Most likely you will not see it though, as this task is completed immediately under normal circumstances.)

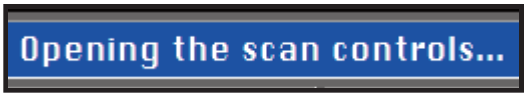


Figure 13.6.2-3: The scan controls are being opened

The large black area on the main screen will change as shown below (Figure 13.6.2-4). Along the left side you'll find the options and controls for acquiring a scout image. The large black box to the right is where you'll be able to view the image taken by the KBCT System.

Figure 13.6.2-4: The main screen, ready to acquire a scout image

At right below (Figure 13.6.2-5) is a closer look at the options and controls for a scout image.

Note that the “SERIES INFORMATION” box does not change based on the type of scan to be performed, and that the “Start” and “Stop” buttons in the “SCOUT SCAN CONTROL” box are present for all scans.

Note that the “Start” button may be a different color depending on the language settings in Windows.

Figure 13.6.2-5: The options for a scout image

The top box, labeled “SERIES INFORMATION”, allows you to specify the laterality of the series and provide a brief description of it. To specify the laterality, click either the “Left” or “Right” radio button. To provide a description, type it into the box below the “Description:” label.

Note that you must specify a laterality before you acquire any scout images, or the message shown below (Figure 13.6.2-6) will be seen when clicking the “Start” button.

Figure 13.6.2-6: User must select a laterality

Figure 13.6.2-7: Performing the scout image

The middle box is better explained after a scout image has been acquired, so the bottom box, labeled “SCOUT SCAN CONTROL”, will be explained next. Clicking the “Start” button, which has the icon of a diamond with a vertical line in it, will cause the X-ray generator to begin preparation for the scout image. The “Start” button will grey out as the “Stop” button becomes usable. The status bar at the bottom of the main screen will also begin to flash blue, displaying the text “Performing the scout image…” as shown in Figure 13.6.2-7.

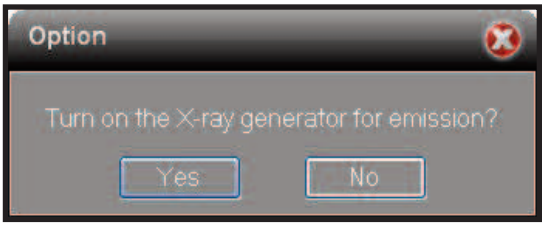


Figure 13.6.2-8: Experiments choose if X-rays are emitted

If you are logged in as an experiment user, the prompt shown at right (Figure 13.6.2-8) will appear. Clicking the  in the upper right corner will cause the scout image acquisition to be prevented. Clicking the “No” button will cause a scout image to be acquired without any X-ray exposure occurring: a dark image. Most of the time you will want to click the “Yes” button.

Figure 13.6.2-9: The X-ray generator is prepped

Whether you are a non-Experiment user or an Experiment user who clicked “Yes” the mid-left green indicator will begin to flash as the X-ray generator gets ready. It will remain steadily on when the X-ray generator has finished its preparations.

Clicking the “Stop” button (in the “SCOUT SCAN CONTROL” box), at any time during the preparation or the scout image itself, will stop the KBCT System Scanner.

The “Stop” button in the “SCOUT SCAN CONTROL” box is not intended for emergency use.

While the X-ray generator is preparing, this X-ray Generator Prep/Ready Light will blink on and off. When this indicator remains steadily on, the X-ray generator is ready.

Once this occurs, the operator may press the Initiate Exposure Button to acquire a scout image.

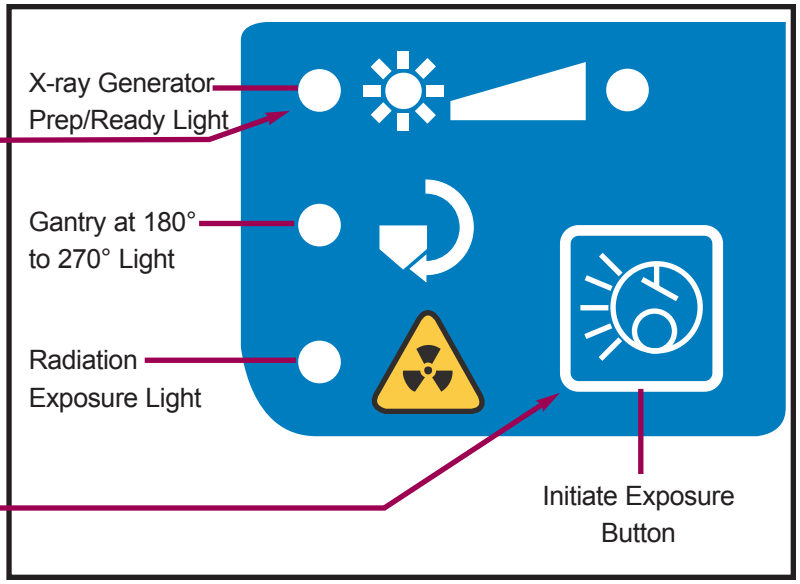


Figure 13.6.2-10: Controls for the X-ray

Do not press the Initiate Exposure Button while facility personnel or other persons are not safely behind the radiation barrier or out of the room. Only the patient should remain at the Scanner.

The light next to the radiation symbol on the control panel at the operator's console will be on while X-rays are being emitted.

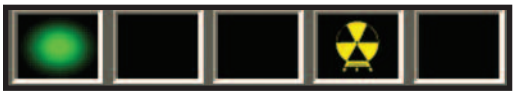


Figure 13.6.2-11: X-rays are being emitted

Also, the corresponding icon in the KBCT Console program will light up as shown in Figure 13.6.2-11. You should be able to hear the X-ray generator working, as it will emit a brief high-pitched noise.

Figure 13.6.2-12: The X-ray generator is done emitting

Note that similar sounds occur at other times, such as when the X-ray generator is initialized. Also, another sound occurs when the x-ray tube's rotor is braking. This occurs approximately 2 minutes after an X-ray exposure is taken if no subsequent exposure is performed. Avoid initiating an X-ray exposure during this time.

The operator and any other personnel present should remain safely behind the barrier while X-rays are being emitted.

When the scout image is completed (it should only take about a second), the light next to the radiation symbol on the control panel at the operator's console will turn off. The corresponding icon in the KBCT Console program will also turn off as shown above (Figure 13.6.2-12).

Once the scout image is acquired, you'll be able to see it in the image viewer to the right of the controls as shown in Figure 13.6.2-13.

Note that the X-ray generator will remain prepared for a few minutes after the acquisition of a scout image.

Figure 13.6.2-13: A scout image has been acquired

Going back to the scan controls, the middle box (labeled “SCOUT IMAGES”) allows you to work with the scout images you’ve acquired. The large grey box within will contain a listing of the scout images to be factored in to the best mA calculation. Click a scout image to select it; double-click a scout image to display it in the Image Viewer to the right of the controls. The “Calculate best mA” button is used after selecting a region of interest (ROI). When a scout image is being displayed in the image viewer, there will be a little orange box which may be moved by clicking and dragging it with the image moving tool to a desired ROI. (Please refer to Section 6.6.1.1 on controlling the image viewer for information on the image moving tool.) Once you’ve chosen your ROI, click the “Calculate best mA” button to perform the calculation for that area.

Figure 13.6.2-14: “SCOUT IMAGES” box

Figure 13.6.2-15:
The orrange box

Note that the best mA calculation is to some extent determined by the ROIs used.

This calculation is performed by solving for mA using 2000 adu, 49.0 kVp, and 8 ms for all scout images acquired (the selected ROIs are unique to each scout image) and then averaging the results. You will be asked whether or not you want to use the calculated mA as shown at right. Click the “Yes” button and the value of the mA used will be automatically changed to the calculated value. Clicking the “No” button or the will close the prompt without changing the current mA value.

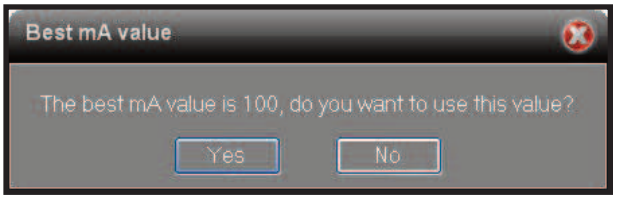


Figure 13.6.2-16: Do you want to use the calculated mA?

Click the “Delete” button to remove the currently selected scout image from the list. (Note that it is not deleted from the hard drive.)

13.6.3. Controlling the Image Viewer

Figure 13.6.3-1: Right-click menu

If you right-click on the image viewer, the menu shown at right (Figure 13.6.3-1) will appear. The icons displayed on the menu are tools used to manipulate the image currently displayed. They are, from left to right, the normal mouse pointer (the icon showing a mouse pointer), a tool for moving the image (the icon showing a cross made of arrows), a tool for resizing the image (the icon showing a magnifying glass), a tool for changing what frame is displayed (the icon of a line intersecting several planes), a tool for adjusting the window and level of the image (the icon of a circle which is half white and half black), a tool for playing the projections like a movie (the triangular icon of a green play button), and a tool for stopping the play button (the icon of a red stop button). The tool's name will appear if you have the mouse hover over its icon for a few seconds. To use one of these tools, click the icon of the tool you wish to use. The mouse pointer will change to match the tool's icon. For instance, if you clicked the window/level tool the mouse pointer will change to a circle that is half black and half white. Now, click and hold the mouse on the image and move the mouse to make the desired adjustments. For example, to zoom in you would right-click, click on the icon of a magnifying glass in the middle of the pop-up menu, and then click and hold on the image while moving the mouse downward. In the case of the play and stop tools, simply clicking the tool is sufficient to start or stop the playing of the images like a movie.

Note that the tool used for changing which frame is shown, as well as the play and stop buttons, will not do anything when viewing a scout image.

Figure 13.6.3-2: Information at the bottom of the image viewer

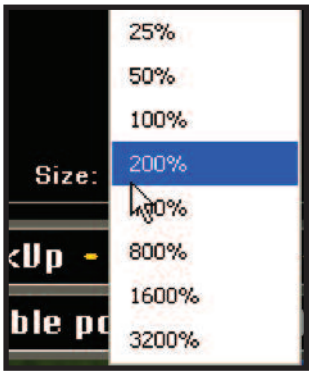


Figure 13.6.3-3: Quickly change the magnification of the image

There are also some quick convenience controls built in. You will notice that information about the image and the point the mouse is at may be found at the bottom of the image viewer as shown above in Figure 13.6.3-2.

Clicking on the size of the image (the number, not the word "Size:") causes the pop-up menu shown at left (Figure 13.6.3-3) to appear. This allows you to quickly change how much the image has been zoomed in on by selecting a magnification from the menu.

Figure 13.6.3-4: Quickly change the window/level of the image

Double-clicking on the window/level will cause the prompt shown at right (Figure 13.6.3-4) to appear. Either type the desired minimum and maximum into the "Minimum value" and "Maximum value" fields respectively, or type the desired window and level into the "Window width" and "Window level" fields. Click the "OK" button or hit the "Enter" key on the keyboard to quickly change the window and level of the image in the image viewer. Alternatively, click either the "Cancel" button or the  to close the prompt without changing the window and level of the image displayed.

13.6.4. Performing a Scan

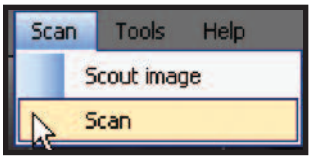


Figure 13.6.4-1: Performing a scan

To have the System perform a scan, go to the "Scan" menu and click "Scan" as shown at left (Figure 13.6.4-1). Alternatively, you may click the "Scan" toolbar button shown below at right (Figure 13.6.4-2). The button's icon is made up of a series of arrows which form a circle with two more arrows inside pointing down and up.

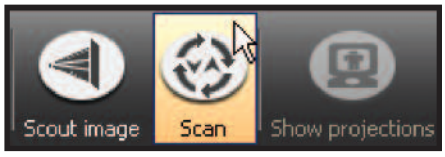


Figure 13.6.4-2: Scan toolbar button

Figure 13.6.4-3: The scan controls are being opened

The message “Opening the scan panel…” may appear as shown at left (Figure 13.6.4-3). (Most likely you will not see it though, as this task is completed immediately under normal circumstances.)

The large black area on the main screen will change as shown below (Figure 13.6.4-4). Along the left side you’ll find the options and controls for performing a scan. The large black box is where you’ll be able to view the images taken by the KBCT System, both before and after reconstruction.

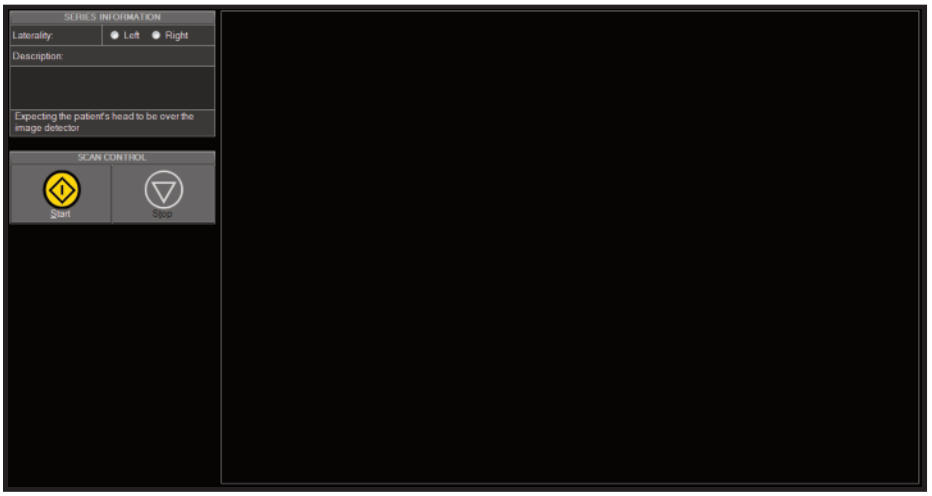


Figure 13.6.4-4: The main screen, ready to perform a scan

Note that the “SERIES INFORMATION” box does not change based on the type of scan to be performed, and that the contents of the “SCAN CONTROL” box are present for all scans though the name of the box changes depending on the type of scan being performed.

Note that you will be unable to perform a scan of any type until you’ve established a connection and selected a patient case.

At left is a closer look at the options and controls for a scan (Figure 13.6.4-5).

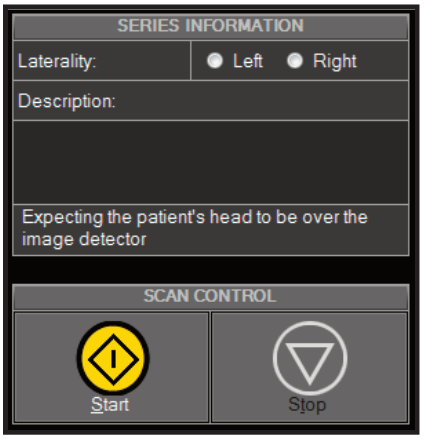


Figure 13.6.4-5: The options for a scan

The top box, labeled “SERIES INFORMATION”, allows you to specify the laterality of the series and provide a brief description of it. To specify the laterality, click either the “Left” or “Right” radio button. To provide a description, type it into the box below the “Description:” label.

The bottom box, labeled “SCAN CONTROL”, allows you to control the KBCT System Scanner. Clicking the “Start” button, which has the icon of a diamond with a vertical line in it, will cause the confirmation prompt shown in Figure 13.6.4-6 to be displayed. Koning strongly urges you to take this opportunity to confirm that the patient is oriented correctly, that the X-ray parameters are as expected, and that the scan is as desired. If everything is correct, click the “OK” button to continue. Otherwise, click the “Cancel” button or the  to abort the scan.

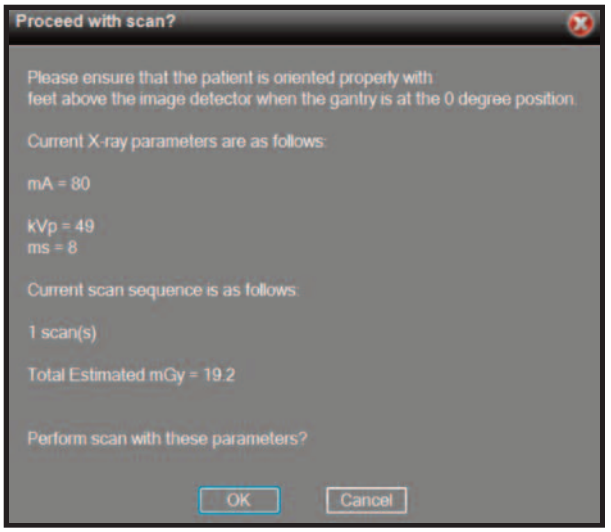


Figure 13.6.4-6: Confirmation prompt

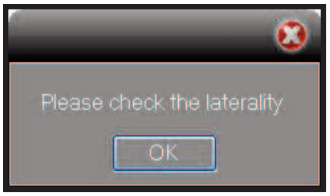


Figure 13.6.4-7: User must select a laterality

However, if the laterality has not yet been specified, the error message at left (Figure 13.6.4-7) will be shown and the scan will not start.

When the scan process starts the status display will begin to flash, displaying the text "Performing a scan…" as shown in Figure 13.6.4-8. The mid-left green indicator will begin to flash as the X-ray generator gets ready (not to be confused with the far left green indicator), and will remain steadily on when the X-ray generator has finished its preparations (Figure 13.6.4-9). Preparation will also include the automatic rotation of the gantry for a scan and preparation for acquisition (see Figure 13.6.4-10). Clicking the "Stop" button, which has an icon showing an upside down triangle, during the preparation or the scan itself, will stop the KBCT System Scanner and abort the scan.

The "Stop" button in the "SCAN CONTROL" box is not intended for emergency use.

Figure 13.6.4-8: Performing a scan…


Figure 13.6.4-9: X-ray generator is prepped

Figure 13.6.4-10: Preparing for acquisition

The Initiate Exposure button should be pressed and is only active when the "Gantry at 180° – 270° " light is on (a duration of approximately 3 seconds per rotation). This light is active only after the generator is ready, as shown at left (Figure 13.6.4-11). If the Initiate Exposure button is not pushed during that time then the operator will need to wait until the gantry passes the 180° position again. There is a 60-second time out period in which the Initiate Exposure button needs to be pushed after the generator is ready or the scan will automatically be terminated.

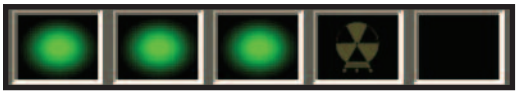


Figure 13.6.4-11: Tell the patient to hold still and press the Initiate Exposure button

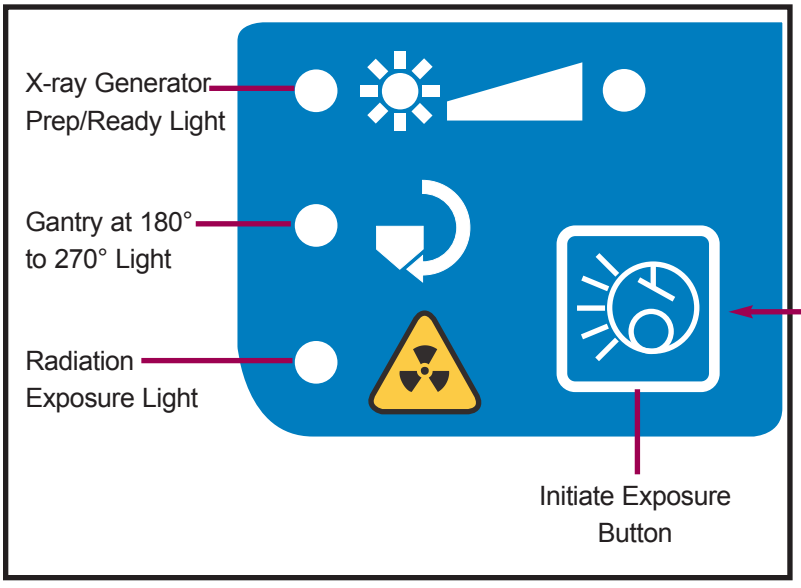


Figure 13.6.4-12: Controls for the X-ray

Press the "Initiate Exposure" button on the control panel at the operator's console when ready to begin X-ray exposure for the scan. When the "Gantry at 180° – 270° " light is on and the operator has pushed the Initiate Exposure button it is a good time to tell the patient to hold still since the scan will start in about 2 seconds.


Figure 13.6.4-13: X-rays are being emitted

Do not press the Initiate Exposure Button while facility personnel or other persons are not safely behind the radiation barrier or out of the room. Only the patient should remain at the Scanner.

The X-ray generator will begin emitting the next time the gantry passes the 0 degree position. The light next to the radiation symbol on the control panel at the operator's console will be on while X-rays are being emitted. The corresponding yellow icon in the KBCT Console program will also light up as shown above (Figure 13.6.4-13). You should be able to hear the X-ray generator working, as it will emit a steady high-pitched beeping noise. Additionally, the status display will change as shown at right (Figure 13.6.4-14).

Figure 13.6.4-14: Acquiring projections

The operator and any other personnel present should remain safely behind the barrier while X-rays are being emitted.

As the scan is performed, you will be able to view the projections acquired in the image viewer to the right of the controls (Figure 6.6.4-15). Projections are the raw images captured by the detector during a scan. A single scan will finish after the X-ray generator has emitted through a full 360 degrees of gantry rotation. The scan is now complete and ongoing emission and motion will cease and the gantry will rotate back to its home position.

Note that similar sounds occur at other times, such as when the generator is initialized. Also, another sound occurs when the X-ray tube's rotor is braking. This occurs approximately 2 minutes after X-ray exposure is taken if no subsequent exposure is performed. Avoid initiating an X-ray exposure during this time.

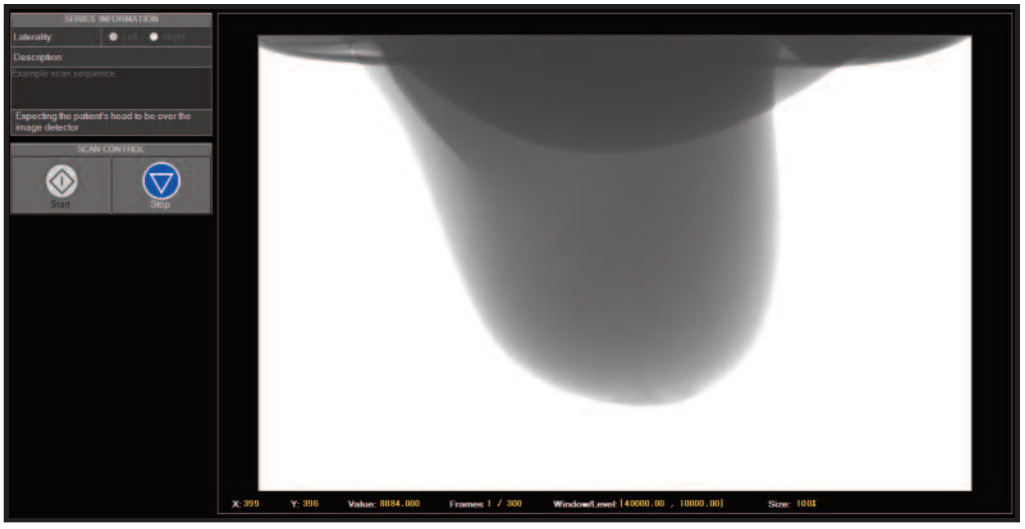


Figure 13.6.4-15: Projection images are being acquired

When the scan is completed, the light next to the radiation symbol on the control panel at the operator's console will turn off. The yellow indicator on the right will also turn off. The projection images and the corresponding series will automatically be added to the currently selected patient case. A series is created for the scan.

Note that the X-ray generator will remain prepared for a few minutes after the completion of a scan.

Note that as a safety precaution you will be unable to perform another scan until you have explicitly selected a patient case again.

In the event that there are problems with the acquired data, contact Koning Corporation or Koning's Authorized Representative for assistance. In some situations, Koning may be able to correct or otherwise compensate for problems and provide a reconstructed data set with reasonable diagnostic image quality. This includes issues caused by defective image detector elements.

13.6.5. Instructions on How to Perform a Minimal Overlap Scan

Warning:

There exists the risk of the increased radiation dose from a second scan to cover the anterior portion of the breast. This procedure should be done **only** if imaging this region is required for diagnosis, as determined by the physician. This may not be required since in some cases the region of concern may not be in the extreme anterior part of a long breast just missed by the initial scan. The risk/benefit ratio of the second (anterior) KBCT scan is a clinical decision and the scan must always be justified with the benefits outweighing the risks.

The maximum vertical coverage of Koning Breast CT is 16 cm. For patients with long breasts (chest wall-to-nipple length >16 cm) the initial scan would cover most of the breast including the posterior portion of the breast. The ergonomically-designed patient table is able to be moved vertically so that it can be moved up to enable the scanning of the anterior portion of the long breast (not scanned in the low position) with minimal overlap of that portion of the breast previously scanned.

Figure 13.6.5-1: Patient breast extends beyond imaged area

Since the maximum vertical coverage by Koning Breast CT System is 16 cm, Koning recommends for patients with breasts longer than 16 cm (160 mm) that after the initial scan the patient table should be raised by 15 cm (150 mm) and another scan performed to cover the missed anterior portion of the breast with minimal overlap (~1 cm).

Figure 13.6.5-2: Minimal overlap scan

13.7. Reconstruction and Viewing of Results

This section deals with performing a 3D reconstruction of the scanned object, viewing the results, and publishing DICOM files to the KBCT System 3D imaging server.

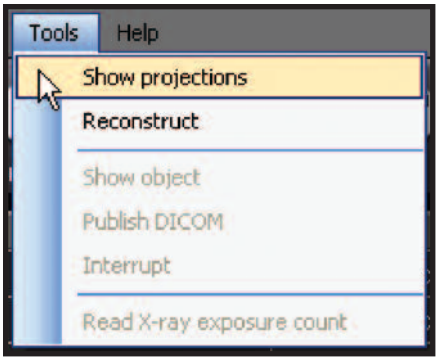


Figure 13.7.1-1: Show projections

13.7.1. Showing the Projections

To view the projections acquired during the scan, go to the “Tools” menu and click “Show projections” as shown in Figure 13.7.1-1 at left. Alternatively, you may click the “Show projections” toolbar button shown in Figure 13.7.1-2.

Figure 13.7.1-2: Show projections toolbar button

Note that if you have not selected a series, you will be unable to do this.

The status bar will begin to flash blue, and the text will change to indicate that projections are being loaded as shown in Figure 13.7.1-3.

Once the projections are loaded, they will be displayed in the image viewer as shown below (Figure 13.7.1-4).

Figure 13.7.1-3: Loading projections

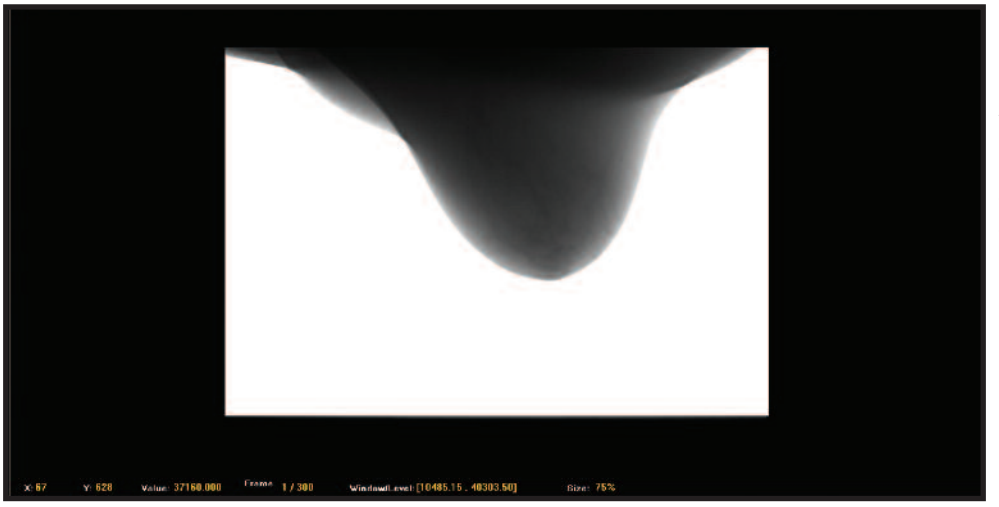


Figure 13.7.1-4: Image viewer displaying projections

Additionally, the bottom of the image viewer will now display information (Figure 13.7.1-5): the position of the mouse on the projection in x, y coordinates, the value of the point at the mouse’s position, the number of the projection being viewed, the overall value of the image, and the size of the image (as a percentage of the image’s actual size).

Figure 13.7.1-5: Information shown at bottom of image viewer

For information on how to manipulate the images displayed, please refer to Section 13.6.2 on controlling the image viewer.

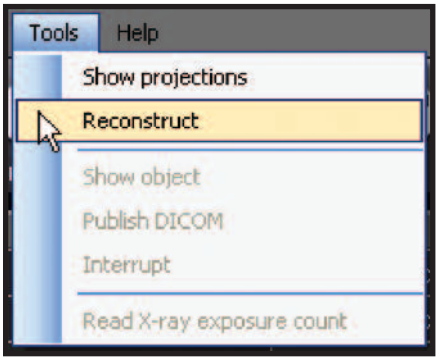


Figure 13.7.2-1: Performing a reconstruction

13.7.2. Performing a 3D Reconstruction

In order to perform a 3D reconstruction of the data acquired during a scan, go to the “Tools” menu and click “Reconstruct” as shown at left (Figure 13.7.2-1).

Alternatively, you may click the “Reconstruct” toolbar button shown below (Figure 13.7.2-2). The icon on the button resembles a calculator.

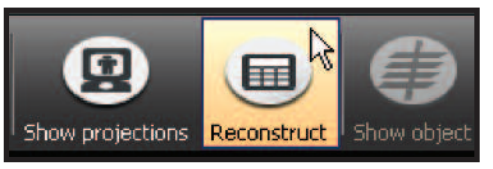


Figure 13.7.2-2: reconstruct toolbar button

Note that if you have not selected a series, you will be unable to do this. Reconstructions may be performed multiple times on the same series of projections, with each additional set of reconstructed images stored in its own series.

Figure 13.7.2-3: Starting the reconstruction

The status bar will begin to flash blue, and the message shown above (Figure 13.7.2-3) will appear.

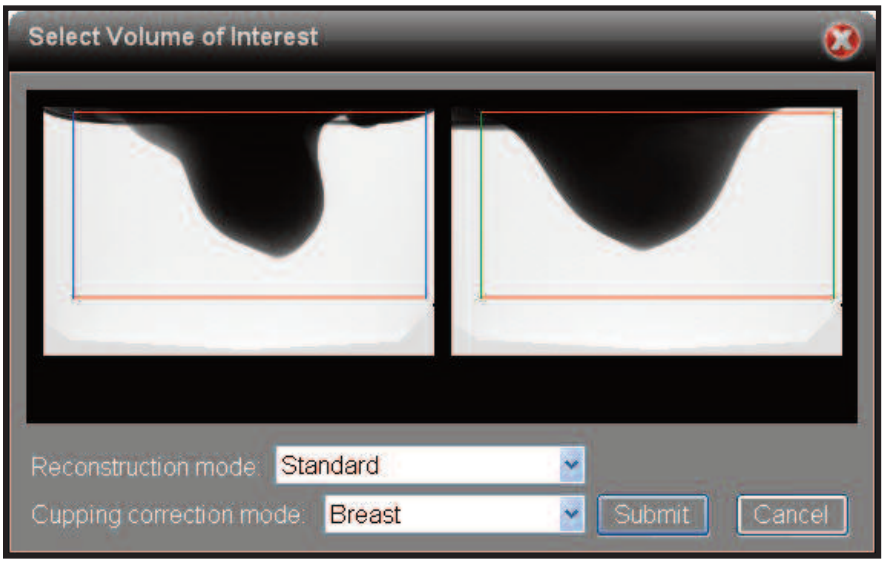


Figure 13.7.2-4: Selecting a region of interest

The window shown at left (Figure 13.7.2-4) will also appear. Shown within this window are two of the projection images associated with the series to be reconstructed, specifically the ones taken when the gantry was at the 0° (on the left) and the 90° (on the right) positions. Both images contain a box which is used to define the volume of interest (VOI): the volume which will be reconstructed. You may click and drag on the sides of the boxes to change their shape, thereby changing the area which is reconstructed. The sides of the box are color coded by which axis they represent (blue is x, green is y, and red is z; think of the body as being upright). Alternatively, you may directly type the VOI boundaries into the text boxes below the images (labeled X start, X end, Y start, etc.). Note that adjusting the VOI box updates the text fields and vice versa.

If no object can be found in the reconstruction results, make sure the VOI includes the object and perform another reconstruction without cupping correction.

The dropdown boxes below the images may be used to change the reconstruction mode and the cupping correction applied during reconstruction. The options available for the reconstruction and cupping correction modes are explained briefly at right (Table 13.7.2-1 and Table 13.7.2-2).

Table 13.7.2-1: Reconstruction Modes

Mode	Characteristics
Standard	Normal reconstruction
High Resolution	Produces larger images, emphasizes calcifications
Calcifications	Emphasizes calcifications

Be aware that the cupping correction algorithm assumes that the scanned object extends beyond the top of the imaged area. While not an issue when scanning patients, incorrect reconstruction results may be obtained for phantoms or other objects which have been positioned too low.

Table 13.7.2-2: Cupping Correction Modes

Mode	Characteristics
Breast	Best for patient data
Phantom	Best for phantom data
No Correction	Use when cupping correction is not desired

Once the VOI and other options are set, click the “Submit” button or hit “Enter” on the keyboard to perform the reconstruction. If you’ve changed your mind and no longer wish to perform a reconstruction either click the “Cancel” button or the in the upper right corner.

Once the reconstruction begins, the text will change to indicate how much progress has been made in the reconstruction. First the percentage of projection images processed will be shown as in the example at right (Figure 13.7.2-5). Once the processing of the projections has been completed, the percentage of slice images processed will be shown as in Figure 13.7.2-6 at right.

Figure 13.7.2-5: Progress of work with projections

Figure 13.7.2-6: Progress of work with slices

If no cupping correction was used, the reconstruction will end once the slices are done being processed. Otherwise, the KBCT Console program works with the projections and slices again as shown in the aforementioned figures, processing projections and slices a total of three times, with the first two times being completed very quickly. When the reconstruction is finished, the results will automatically be stored locally on the workstation in the form of DICOM slice images.

13.7.3. Showing the Reconstructed Object

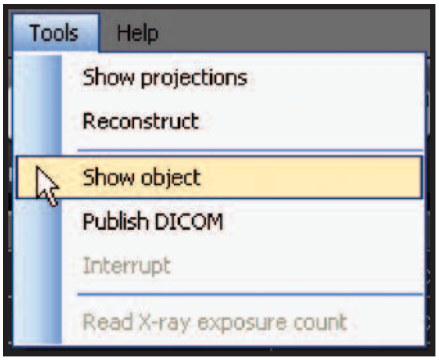


Figure 13.7.3-1: Showing the reconstructed object

To view the slices of a reconstructed object, go to the “Tools” menu and click “Show object” as shown at left (Figure 13.7.3-1).

Alternatively, you may click the “Show object” toolbar button shown at right (Figure 13.7.3-2).

Figure 13.7.3-2: Show object toolbar button

The status bar will begin to flash blue, and the text will change to indicate the progress in loading the slices of the reconstructed object as shown at right (Figure 13.7.3-3).

Note that you must have selected a series and performed a 3D reconstruction on the selected series before you will be able to view the slices of a reconstructed object.

Figure 13.7.3-3: Progress loading slices

Once the slices are loaded, they will be displayed in the image viewer as shown below (Figure 13.7.3-4). Additionally, the bottom of the image viewer will now display information: the position of the mouse on the slice in x,y coordinates, the value of the point at the mouse's position, the number of the slice being viewed, the overall value of the image, and the size of the image (as a percentage of the image's actual size) as shown in Figure 13.7.3-5.

For information on how to manipulate the images displayed, please refer to Section 13.6.2 on controlling the image viewer.

Note: Koning uses a corrected bad pixel map and regular gain calibrations to have the number of Defective Detector Elements (DDE) be 0 (the KBCT Console software corrects them all). If, for some reason, a scan occurs and a DDE is in the raw data it will produce an obvious artifact in the reconstructed image (circle or line). If this occurs contact Koning or its Authorized Representative to make arrangements to send in the defective data set. The images will be manually corrected by Koning to remove all DDE and the corrected data set will be returned to the customer for reconstruction. After reconstruction, inspect the newly reconstructed images for any obvious artifacts. Also, perform a gain calibration (Section 13.3.2.), perform the daily equipment warm-up procedure (Section 17.3) and ensure all artifacts are gone before scanning another patient. If the artifact persists, contact Koning Corporation or Koning's Authorized Representative to arrange for repairs.

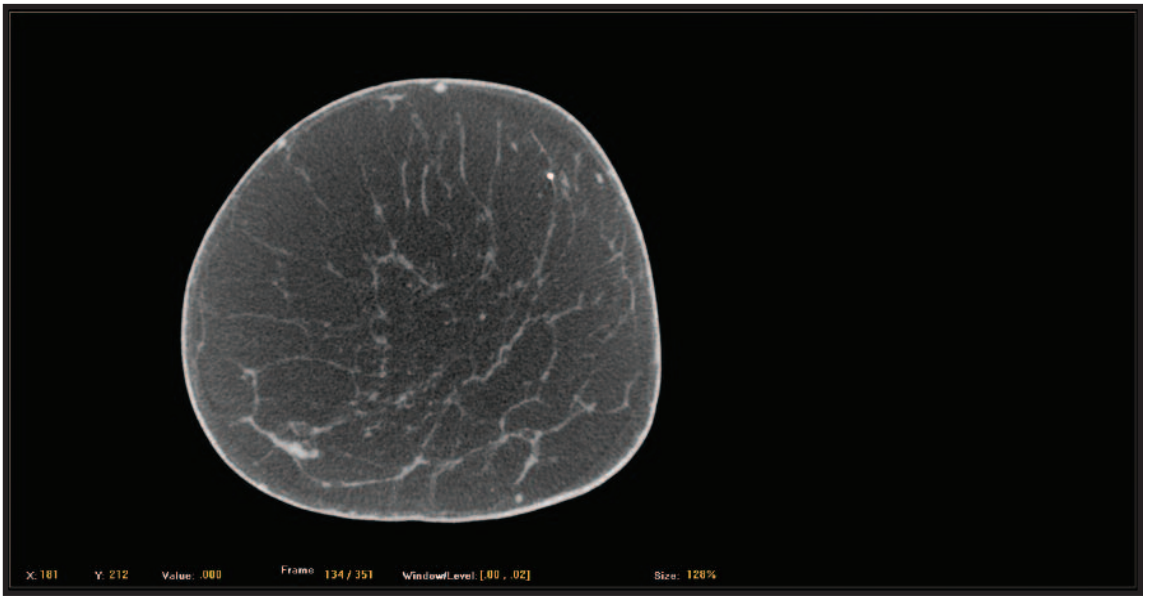


Figure 13.7.3-4: Image viewer displaying slices

Figure 13.7.3-5: Information shown at bottom of image viewer

13.7.4. Publishing DICOM Files to the KBCT System Client/Server

In order to publish the reconstructed DICOM files to the Koning Client/Server, go to the "Tools" menu and click "Publish DICOM" as shown at left (Figure 13.7.4-1).

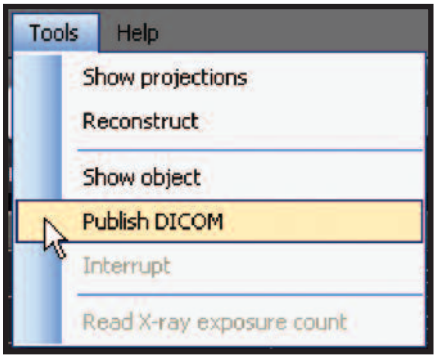


Figure 13.7.4-1: Publishing DICOM files to the Server

Alternatively, you may click the "Publish DICOM" tool bar button shown at right (Figure 13.7.4-2).

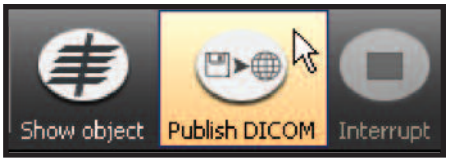


Figure 13.7.4-2: Publish DICOM toolbar button

The status bar will begin to flash blue and its text will change to "Publishing DICOM images…" as shown below (Figure 13.7.4-3).

The previously reconstructed slices will be processed into the DICOM files which are being created, and the text in the status bar will change to indicate the KBCT Console program's progress in this task (Figure 13.7.4-4).

Note that you must select a series which you've performed a 3D reconstruction on before this functionality will become available. If you've already published DICOM files from the series to the Koning Client/Server, the previously published data will be overwritten by the current publication.

Figure 13.7.4-3: Publishing DICOM images

Figure 13.7.4-4: Reconstructed slices are processed into the DICOM files

Once the DICOM files are published, they may be retrieved by radiologists using the separate Koning Client/Server.

13.7.5. Visage Primer

See Figure 13.7.5-1 for a primer on the user interface when viewing an image on the Koning Client/Server using Visage. When viewing a series, 4 views of the reconstructed breast are shown, with orientation markers at the edges of these views. Each view also includes a visual representation of the orientation being viewed from in the lower left corner. The views are as follows:

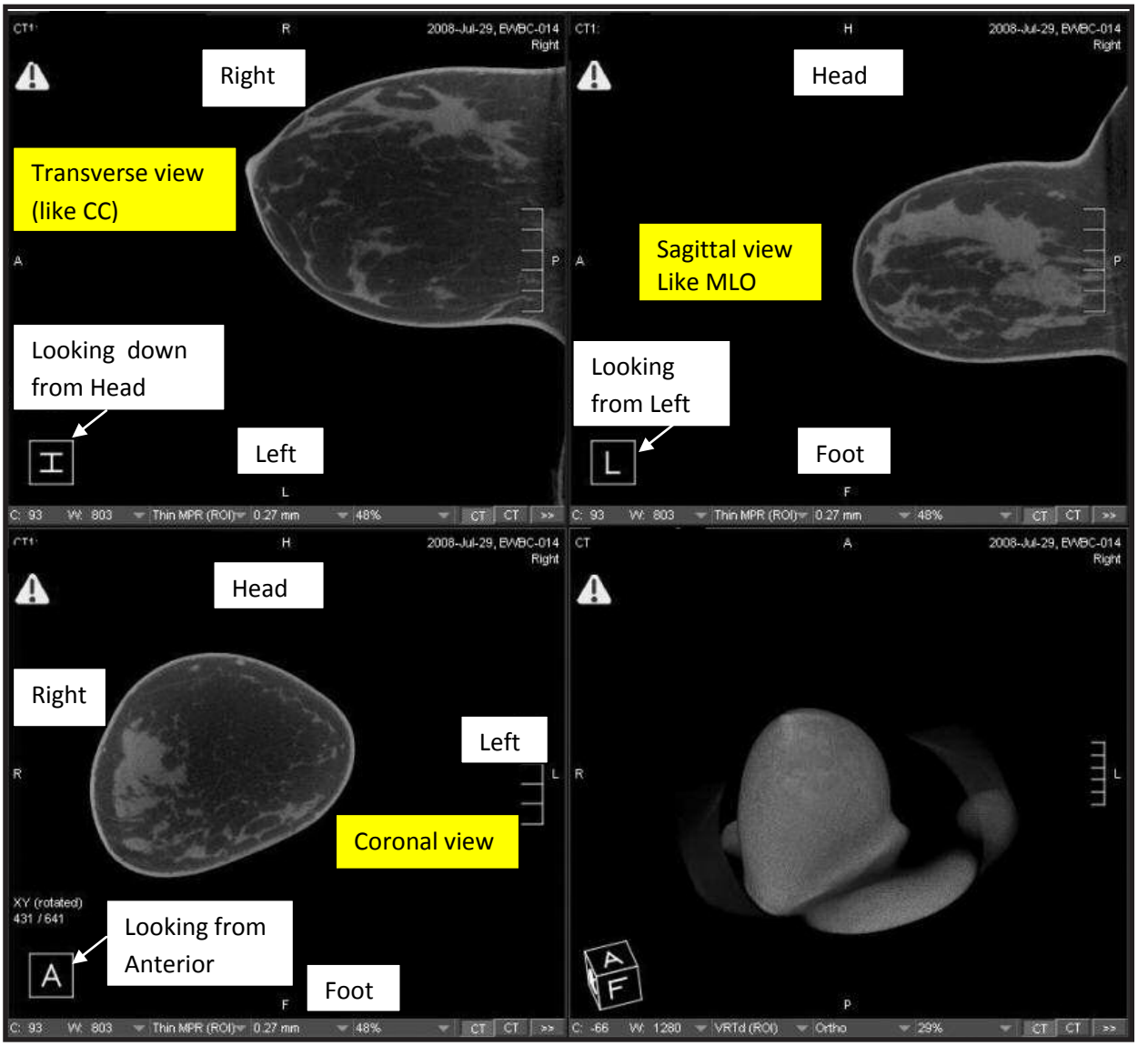


Figure 13.7.5-1: Visage image viewing primer

For instructions on how to use the Koning Client/Server, please refer to its instructions for use and other documentation available within Visage's "Help" menu.

1. Slices in the transverse view (comparable to the CC view in mammography)

2. Slices in the sagittal view (comparable to the MLO view in mammography)

3. Slices in the coronal view (this is the same view shown when viewing the reconstructed object in the Console program)

4. The reconstructed breast in 3D

13.7.6. Stopping a Reconstruction or DICOM Publication

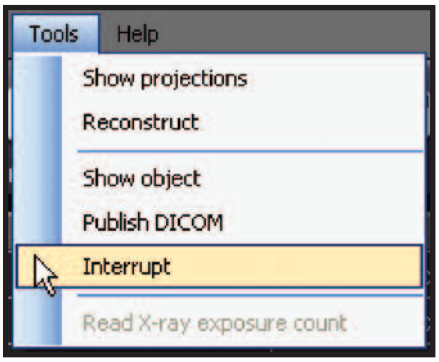


Figure 13.7.6-1: Interrupting a reconstruction or DICOM publication

If there is a need to halt an ongoing reconstruction or publication of DICOM files, you can stop the process by selecting “Interrupt” from the “Tools” menu as shown below.

Alternatively, you may click the “Interrupt” toolbar button shown at right. The ongoing reconstruction or DICOM publication will then cease.

Figure 13.7.6-2: The interrupt toolbar button

13.8. DVD Storage

This section deals with the KBCT Console program’s capabilities with respect to DVD storage.

13.8.1. Burning a Patient Case to a DVD

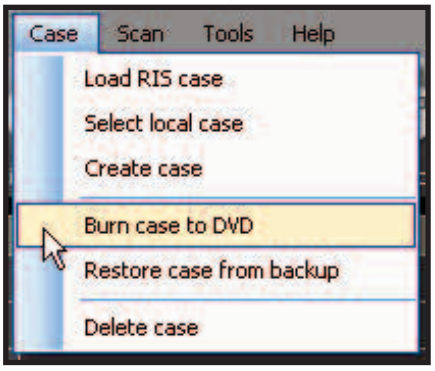


Figure 13.8.1-1: Burning images to DVD

In order to burn the images from a case to a DVD, insert a blank DVD into the workstation computer’s DVD drive and then click the “Burn case to DVD” option under the “Case” menu as shown at left (Figure 13.8.1-1).

The message “Burning the case...” will be displayed as shown in Figure 13.8.1-2 as the system prepares to burn the case. The status indicator will change to show the message “Checking content…” as shown at right (Figure 13.8.1-3) while the KBCT Console program ensures that there is adequate space on the DVD.

Figure 13.8.1-2: Burning the case

Figure 13.8.1-3: Checking the DVD’s free space

While the image files are actually being written to the DVD, the status indicator will display the message “Building content…” as shown in Figure 13.8.1-4.

Figure 13.8.1-4: Burning the images

Note that you will be unable to perform this task if a patient case has not yet been selected. This functionality will be ineffective if the images associated with the case have been deleted, or if no DVD has been inserted. If the case is too large for the DVD then you will be unable to burn that case. Contact Koning Corporation or Koning’s Authorized Representative for assistance in this situation.

13.8.2. Restoring Images from a DVD

In order to restore burned images from a DVD, insert the appropriate DVD into the workstation computer's DVD drive, select the patient case which you wish to restore the images to (see Section 13.4.2 on selecting a case), and click the "Restore case from backup" option from under the "Case" menu as shown at right in Figure 13.8.2-1.

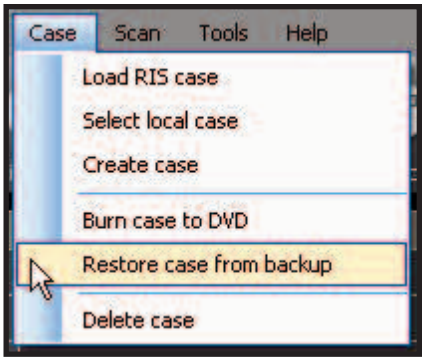


Figure 13.8.2-1: Restoring images from a DVD

> Note that this operation will not be available if you have not selected a patient case. You will be unable to restore images from a DVD without inserting the DVD.

The window shown at right (Figure 13.8.2-2) will appear so that you may select which image files are restored. Navigate to the directory on the DVD corresponding to the current case as shown in Figure 13.8.2-3 and click the "OK" button to begin the restoration. Alternatively, you may click the "Cancel" button or the in the upper-right corner to close the window without restoring any images. The message "Restoring the case…" will be displayed in the status indicator as shown below (Figure 13.8.2-4) as the KBCT Console program begins to restore the images from the DVD. If the currently selected case does not match the location selected, the error message shown below (Figure 13.8.2-5) will appear.

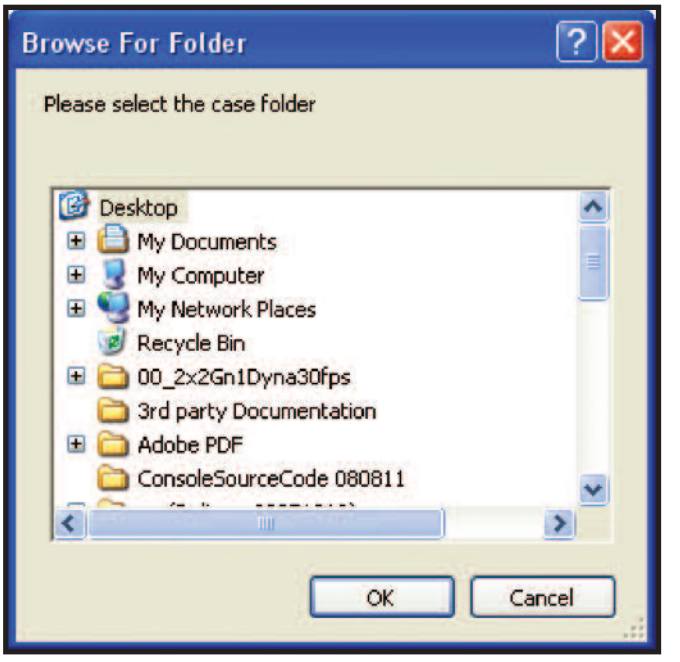


Figure 13.8.2-2: Selecting the directory of the images to restore

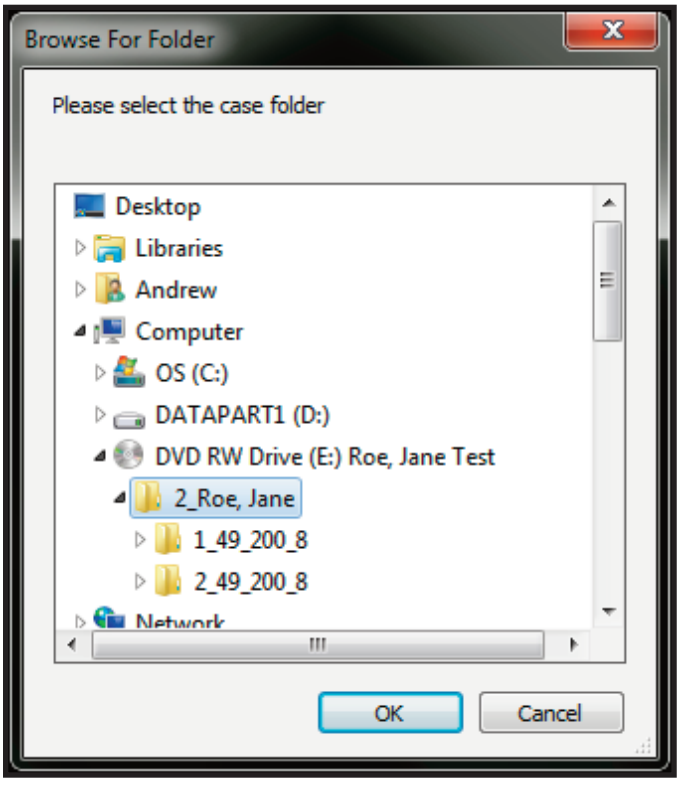


Figure 13.8.2-3: Directory of the images to restore

Figure 13.8.2-4: Image restoration has begun

As the images are restored from the DVD, the message in the status display will change to indicate where the images are being copied from. This is shown in Figure 13.8.2-6.

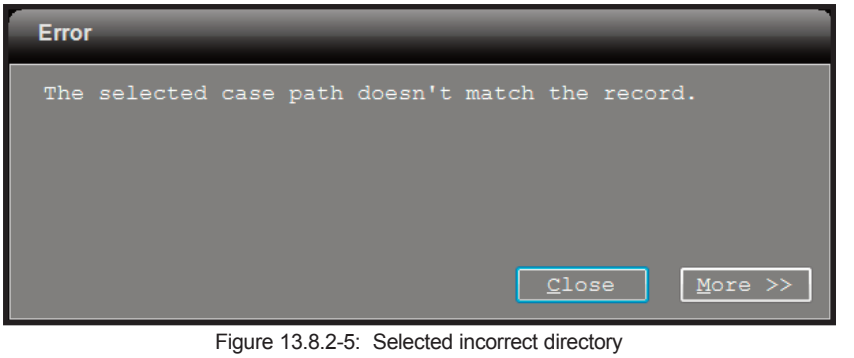


Figure 13.8.2-5: Selected incorrect directory

Figure 13.8.2-6: Copying images from the DVD

13.8.3. Deleting Images from a Patient Case

If there is a shortage of available hard disk space on the workstation, you may wish to delete image data which you are no longer using. This can be done by going to the “Case” menu and clicking “Delete case” as shown at left (Figure 13.8.3-1). The prompt shown below (Figure 13.8.3-2) will then appear, suggesting that you back up the images before proceeding and requesting confirmation. This is done to help prevent the accidental deletion of images. Click the “Yes” button to proceed with the deletion. Click the “No” button to prevent any information from being deleted. Once the KBCT Console program is finished deleting the images, the notification shown in Figure 13.8.3-3 will appear.

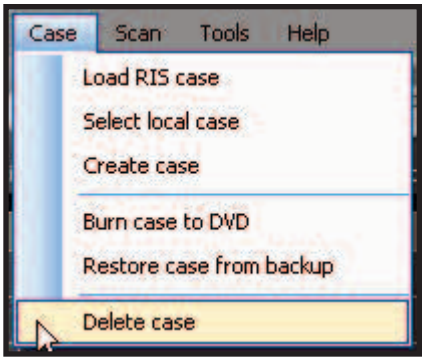


Figure 13.8.3-1: Deleting images from a case

Note that you will be unable to perform this operation if you have not yet selected a patient case to work with.

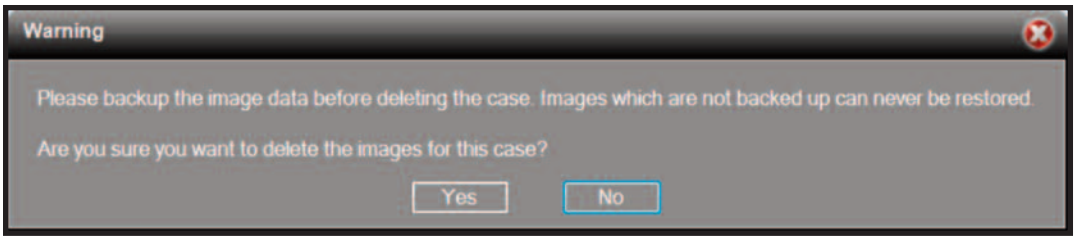


Figure 13.8.3-2: Confirm the deletion

Once the images are deleted, they are gone. **Do not delete images unless certain they are safely stored in another location.**

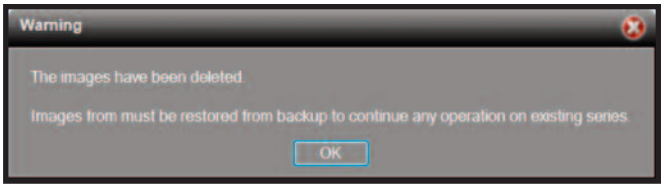


Figure 13.8.3-3: Images deleted

13.9. Exiting the Program and Related Tasks

This section deals with exiting the KBCT Console program and tasks which serve a related purpose.

13.9.1. Disconnecting from the Device

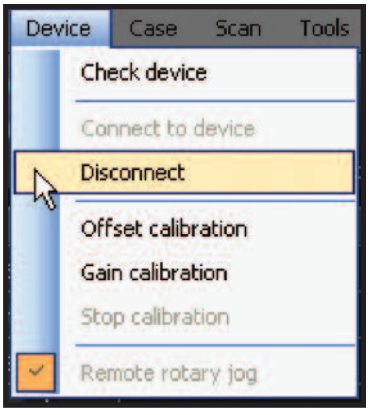


Figure 13.9.1-1: Closing the Connection

It is recommended that you disconnect from the device when you won’t be using the KBCT System for a time (for instance, an hour long gap between patients); if the KBCT System will be used again soon there is no need to do this. To close the connection with the KBCT System, go to the “Device” menu and click “Disconnect” as shown at left (Figure 13.9.1-1). Alternatively, you may click the “Disconnect” toolbar button shown above (Figure 13.9.1-2).

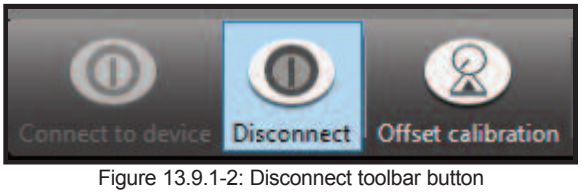


Figure 13.9.1-2: Disconnect toolbar button

Note that if no connection has been made, you will be unable to disconnect. Keep in mind that “disconnect” here refers to a connection in the software. **It is neither necessary nor recommended that you physically disconnect any wires.**

While disconnecting, the message “Disconnecting from device...” is displayed as shown at right (Figure 13.9.1-3).

Figure 13.9.1-3: Disconnecting from device

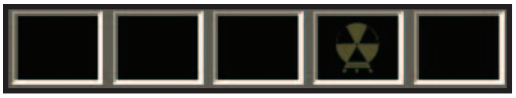


Figure 13.9.1-4: Disconnected from the system

Once the connection has been closed, the leftmost green indicator will turn off as shown at left (Figure 13.9.1-4). The positions of the servos and X-ray parameters will no longer display their values, but rather hyphens (-) to indicate that the value is unavailable due to the lack of a connection as shown in Figure 13.9.1-5 below.

Figure 13.9.1-5: Disconnected from the system - unable to display current X-ray parameters and servo positions

13.9.2. Exiting the KBCT Console Program

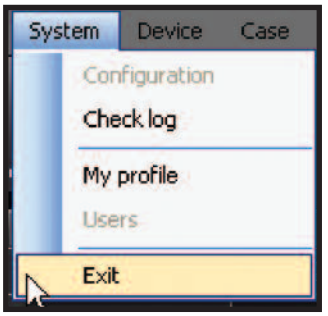


Figure 13.9.2-1: Exiting the program

To exit the KBCT Console program, go to the “System” menu and click “Exit” as shown at left (Figure 13.9.2-1). Alternatively, you may click the words “Exit console” in the upper right corner of the main screen as shown in Figure 13.9.2-2.

Figure 13.9.2-2: Another way to exit the program

The status indicator will change to display the message “Closing Console...” as shown at right (Figure 13.9.2-3).

Figure 13.9.2-3: The user is closing the program

The prompt shown at left (Figure 13.9.2-4) will appear, asking if you are sure you want to exit the KBCT Console program. If you wish to exit the KBCT Console program, click the “Yes” button or hit Enter on the keyboard, and the program will stop running (returning you to the Windows desktop). Otherwise, click the “No” button to close the prompt and the program will continue running.

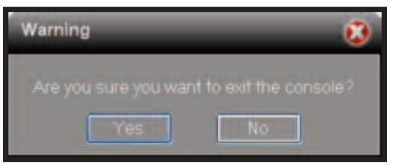


Figure 13.9.2-4: Confirming that you want to exit the program

In order to help prevent unauthorized use of the System, it is strongly recommended that you exit the KBCT Console program at shift changes and whenever you will be away from the CT room for a time (at lunch, for example).

14. Advanced Functionality

This section of the manual contains instructions for using functionality which a user with no system roles would be unable to access. The information in this section is organized by the system role required to access the corresponding functionality.

14.1. Administrator

Those with the system role of an administrator will have access to functionality which allows them to change the configuration of the KBCT Console program, to manage user accounts, and to read the exposure counter.

14.1.1. Changing the Configuration

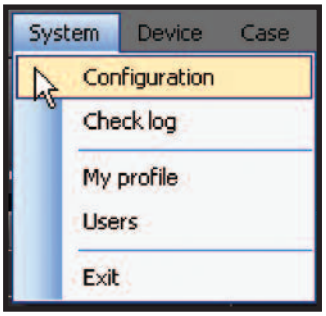


Figure 14.1.1-1: Changing the Configuration

To change the KBCT Console program's configuration, go to the "System" menu and click "Configuration" as shown at left (Figure 14.1.1-1).

Note that you will be unable to access this functionality unless you are an administrator or experiment.

This should cause the window shown below (Figure 14.1.1-2) to appear. There are several configuration settings you may change, and these are shown in a table which occupies most of the window. Not all of the settings are visible at once, so there is a scrollbar on the right side to allow you to navigate the table.

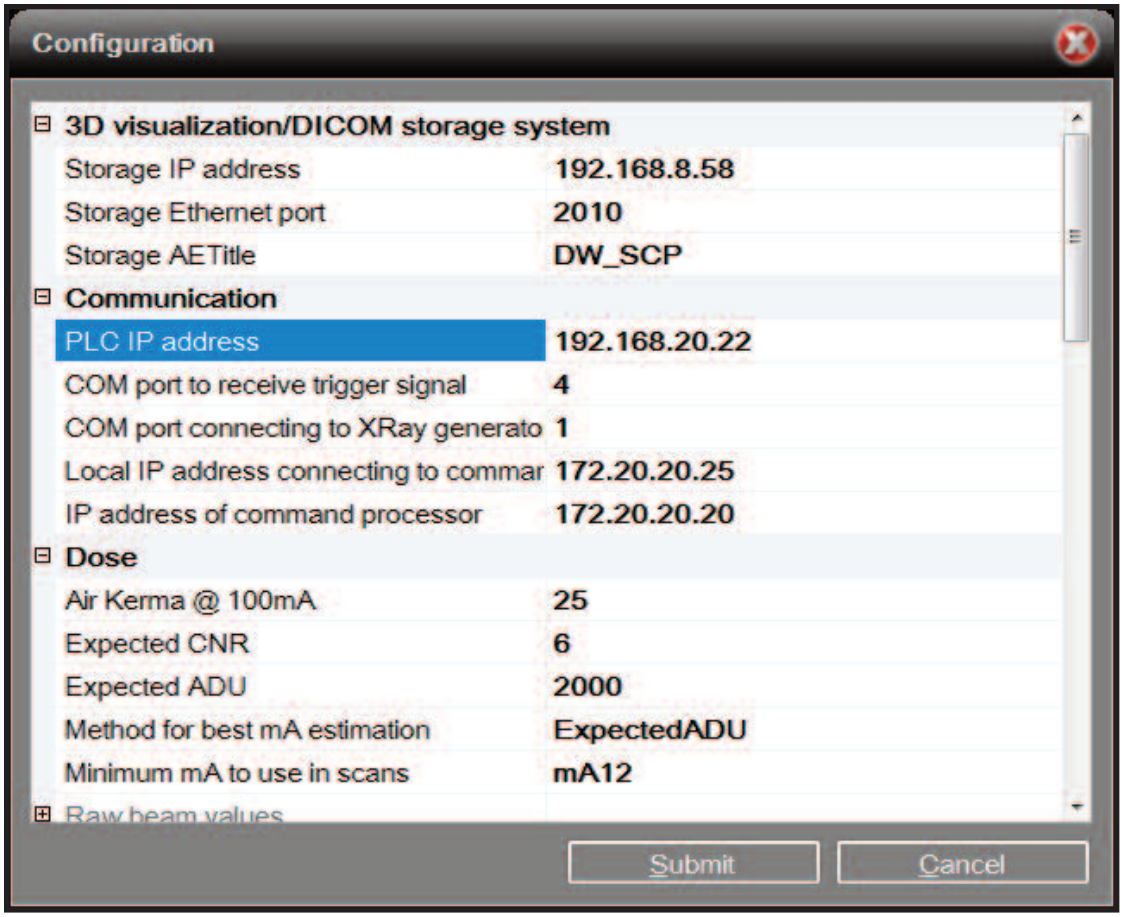


Figure 14.1.1-2: The Configuration Window

To change a setting, click the box with the value you want to change and type in the new value (remember to delete the old value by hitting Backspace on your keyboard). Some values may have to be selected in a dropdown box or some other prompt instead. When you are done making changes, click the "Submit" button to save your changes. If you make a mistake, you can correct it by changing the value again and then clicking "Submit" again.

You must click the “Submit” button for your changes to be saved. You will need to restart the KBCT Console program before the changes will be applied.

If you don’t want to change any configuration settings, click the “Cancel” button or click the  in the upper right corner of the window.

The settings you may change and their default values are listed in Table 14.1.1-1, along with the category they fall under. Note that changing a COM port connection setting merely changes which port the software is using, not which port is physically being used. Changing the physical connections without first consulting Koning is **strongly discouraged**.

Table 14.1.1-1: Configuration Settings

Category	Setting Name	Description	Default Value
3D Visualization / DICOM Storage System	Storage IP address	The IP address of the storage server	192.168.8.58
	Storage Ethernet port	The Ethernet port to use when publishing data to the storage server	2010
	Storage AETitle	The AETitle to use when publishing data to the storage server	DW_SCP
Communication	PLC IP address	The IP address of the PLC	192.168.20.22
	COM port to receive trigger signal	The COM port which receives the signal which triggers the acquisition of images during a scan	4
	COM port connecting to X-ray generator	The COM port which is connected to the X-ray generator	1
	Local IP address connecting to command processor	The IP address used by the workstation on its connection to the image detector	172.20.20.25
	IP address of command processor	The IP address of the image detector’s command processor	172.20.20.20
Gain Calibration Parameters	HL ratio calibration kVp	The kVp used during the HL ratio phase of gain calibration	kVp49
	HL ratio calibration mA	The mA used during the HL ratio phase of gain calibration	mA12
	HL ratio calibration ms	The ms used during the HL ratio phase of gain calibration	ms8
	Lo img calibration kVp	The kVp used during the lo img phase of gain calibration	kVp49
	Lo img calibration mA	The mA used during the lo img phase of gain calibration	mA64
	Lo img calibration ms	The ms used during the lo img phase of gain calibration	ms8
	Hi img calibration kVp	The kVp used during the hi img phase of gain calibration	kVp49
	Hi img calibration mA	The mA used during the hi img phase of gain calibration	mA125
	Hi img calibration ms	The ms used during the hi img phase of gain calibration	ms8

Table 14.1.1-1: Configuration Settings			
Category	**Setting Name**	**Description**	**Default Value**
Image Correction	Automatically set masks during gain calibration	Whether or not to automatically recalculate and update the “Remove bottom mask” setting during gain calibration	True
	Remove bottom mask	A mask defining an area of unusable data removed from the bottom of acquired projections	(None, varies from unit to unit)
Log	Type of logged message	How severe a message must be for it to go into the system log	Error
Path	Data path	The directory where all image data will be stored	D:\App\Data
	Detector imager path	The directory used for storing calibration data	C:\IMAGERs\6188-08\00_1x2Gn1Dyna30fps
Reconstruction	Do reconstruction after data acquisition	Whether or not a reconstruction will be performed automatically once a scan is completed	False
	Publish images after reconstruction	Whether or not DICOM files will be published to the Koning Client/Server automatically after a reconstruction has been completed	False
Scan Control	HU limit	The maximum HU used allowed before the KBCT Console program prevents X-ray emissions	30
WL/MPPS	Worklist server	The IP address of the RIS server	(None, varies from facility to facility)
	Worklist service port	The port used by the RIS server for communication	(None, varies from facility to facility)
	Worklist AE title	The AE title of the RIS server	(None, varies from facility to facility)

Caution:

If the configurable HU limit is set too low, the KBCT will never be able to perform scans. Koning strongly recommends that this setting be kept above 15.

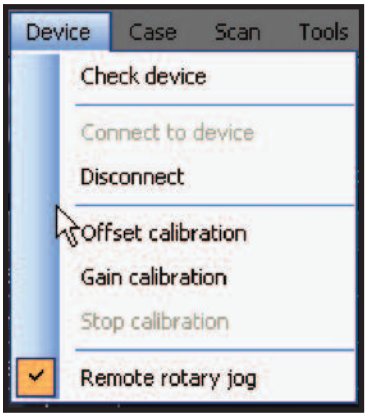


Figure 14.1.1.1-1: Toggling the remote rotary jog feature

14.1.1.1. Remote Rotary Jog

The remote rotary jog feature may be activated and deactivated by means of the “Remote rotary jog” item under the “Device” menu as shown at left (Figure 14.1.1.1-1). If the feature is currently activated, there will be a check mark next to the menu item. Clicking on the menu item will activate the feature if it is currently deactivated, and vice versa. Having the remote rotary jog feature enabled allows users to change the gantry’s angular position using the software’s motion controls.

14.1.2. User Management

To manage the KBCT Console program's users, go to the "System" menu and click "Users" as shown at left (Figure 14.1.2-1).

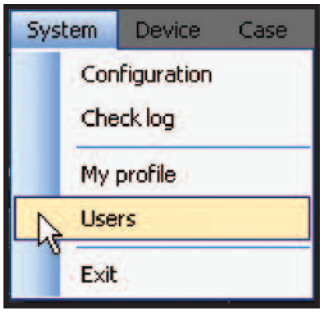


Figure 14.1.2-1: Managing users

Note that you will be unable to use this functionality unless you are an administrator.

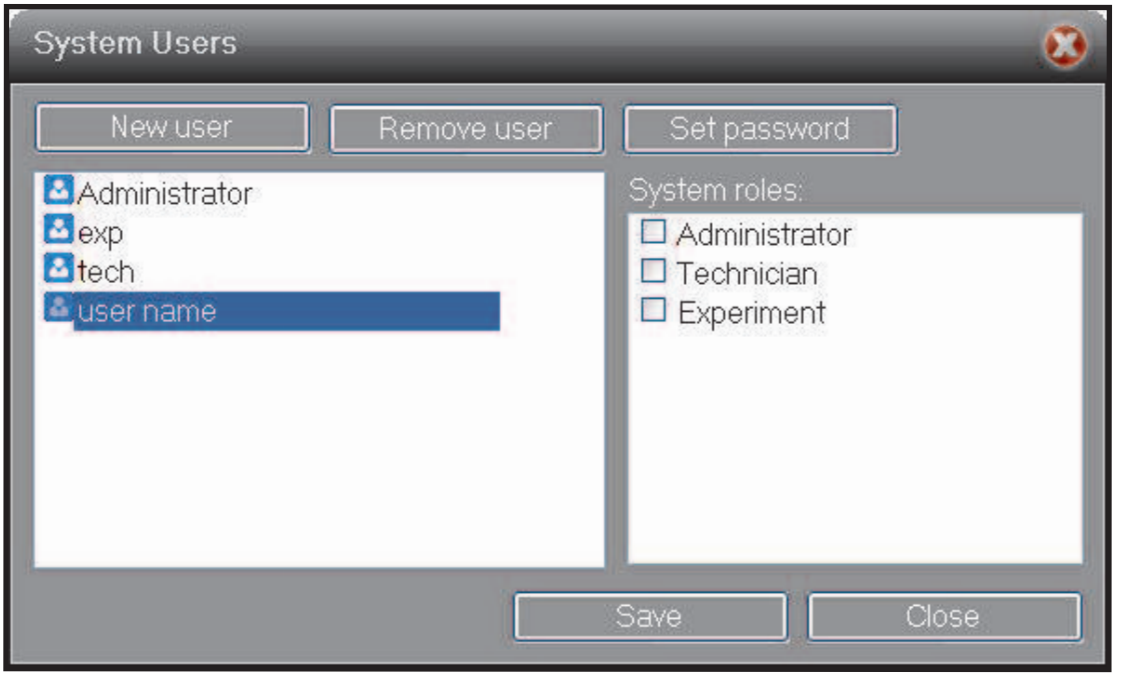


Figure 14.1.2-2: Current users

The window shown in Figure 14.1.2-2 above will appear. The large box on the left contains the names of the current users, and the box on the right contains the selected user's system roles. In the case shown below, the user named "user name" has no system roles. To change a user's system roles, use the checkbox next to each role. Clicking the "Save" button will make these changes permanent. To close the window click the "Close" button or the  in the upper right corner.

For information on adding and removing users, as well as changing their passwords, see the following subsections.

Note that you will be unable to change the system roles of the user named "Administrator".

14.1.2.1. Adding New Users

To add a new user, click the "New user" button. The prompt shown at right (Figure 14.1.2.1-1) will appear. Type the new user's name into the box labeled "User name:" and the new user's password into the boxes labeled "Password:" and "Re-enter password:", then click the "OK" button or hit Enter on the keyboard to create the new user. If the user name or password is blank, the error message shown in Figure 13.1.3-2 will appear.

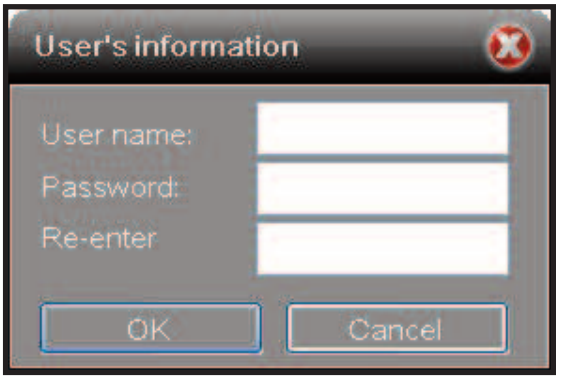


Figure 14.1.2.1-1: Adding a new user

Caution:

The user name will also be used as the Performing Physician's Name in the DICOM header of reconstructed images (DICOM tag 0008,1050). Koning strongly recommends that you manage your CBCT1000's user accounts accordingly by creating a unique account for each physician expected to utilize KBCT using their names as the user names for those accounts.

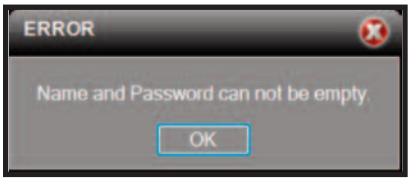


Figure 13.1.3-2: User name or password is empty

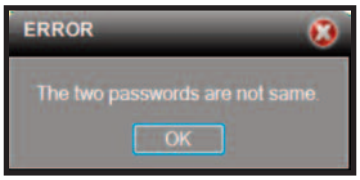


Figure 13.1.3-3: Passwords are not the same

Note that the passwords you type will be hidden by asterisks for security, and if they don't match an error message (Figure 13.1.3-3) will appear to notify you of this.

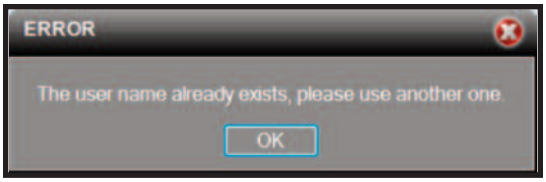


Figure 13.1.3-4: User already exists

Note that you will be unable to assign the same user name to multiple users (see Figure 13.1.3-4).

If you don't want to create a new user, you may click the "Cancel" button, click the  in the upper right corner of the prompt, or hit Escape on the keyboard.

14.1.2.2. Removing Users

To remove a user, select the user you wish to remove then click the "Remove user" button. The prompt shown at left will appear, asking if you are sure you want to remove the selected user. If you wish to remove the selected user, click the "Yes" button and the user will be removed from the list of users. Otherwise, click the "No" button and the user won't be removed.

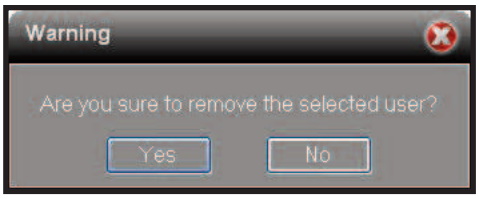


Figure 14.1.2.2-1: Confirming the removal of a user

Note that you will be unable to remove yourself, or the user named "Administrator".

14.1.2.3. Changing a User's Password

To change a user's password, select the user whose password you wish to change then click the "Set password" button. The prompt shown at right (Figure 14.1.2.3-1) will appear.

Note that you may not change the user's name.

Type the user's new password into the boxes labeled "Password" and "Re-enter password:", then either click the "OK" button or hit Entr on the keyboard to make the change. If you don't want to change the user's password click the "Cancel" button, click the  in the upper right corner of the prompt, or hit Escape on the keyboard.

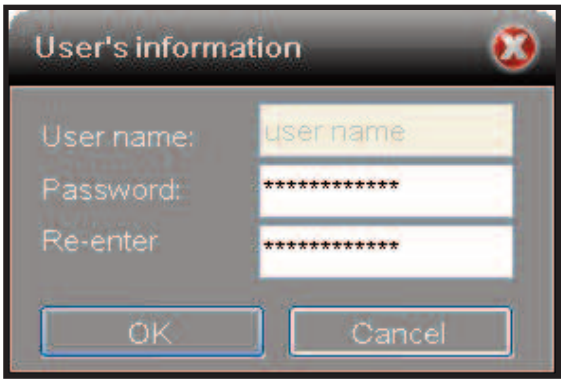


Figure 14.1.2.3-1: Changing a user's password

Note that the prompt is identical to the prompt for changing your own password.

14.1.3. Viewing the X-ray Exposure Count

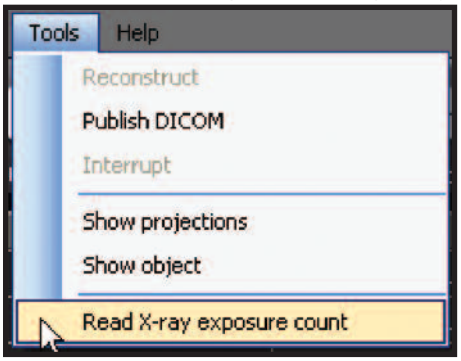


Figure 14.1.3-1: Read X-ray exposure count

In order to see the total number of X-ray exposures performed by the KBCT System, select “Read X-ray exposure count” from the “Tools” menu as shown at left (Figure 14.1.3-1).

Note that you must be an administrator or experiment to access this functionality.

The status bar will begin to flash blue, and the text will change to “Opening the X-ray generator’s control panel…” as shown below (Figure 14.1.3-2).

Figure 14.1.3-2: Reading the exposure counter

The prompt shown at right will appear, indicating the total number of X-ray exposures the KBCT System has performed. Click the “OK” button when you are done.

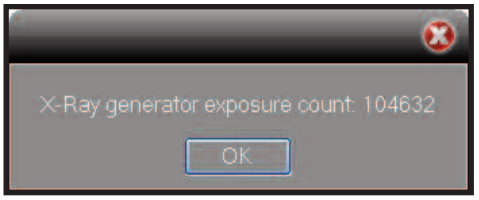


Figure 14.1.3-3: The X-ray exposure count

14.2. Technicians

The system role of technician corresponds to a hospital technician (not to be confused with a technologist) in real life. The functionality available to a technician relates to performing calibrations, hardware maintenance, and similar tasks. Currently technicians do not have access to any unique functionality.

14.3. Experiment

The system role of Experiment is a special system role for use in imaging experiments. An Experiment user has access to all the functionality of the other system roles (except for user management, only Administrators have access to that functionality). In addition to that, experiments have the following unique functionality.

14.3.1. Directly Specify X-ray Parameters

When logged in as an Experiment, the user is allowed access to the software controls for adjusting all X-ray parameters (kVp, mA, and ms). This freedom is applicable to both scout images and scans. The controls for changing an X-ray parameter may be used as described in Section 13.5.2 Setting X-Ray Parameters.

Note that the estimated mGy algorithm currently only works for 49.0 kVp. For other kVp values, the mGy field will be replaced with hyphens (-) to reflect this.

Note that you will be unable to use this functionality unless you are an experiment.

Be aware that the KBCT Console program tracks the X-ray parameters for scout images and scans separately, and will adjust the X-ray parameters accordingly whenever “Scout image” or “Scan” is selected from the menus or toolstrip buttons.

Be aware that use of the Experiment system role for the normal imaging of patients is strongly discouraged.

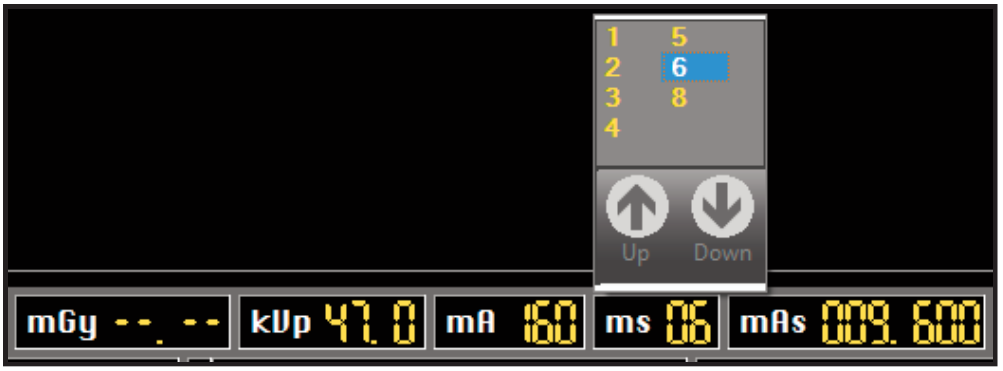


Figure 14.1.3-1: Custom X-ray parameters

14.3.2 Dark Image Acquisition

Experiment users have the ability to acquire dark images when performing a scout image acquisition, and will automatically be prompted as shown at right (Figure 14.3.2-1) whenever acquiring a scout image. A dark image is an image that has been acquired with no X-ray exposure (and thus appears to be black when viewed). For more information, refer to Section 13.6.2 Acquiring a Scout Image.

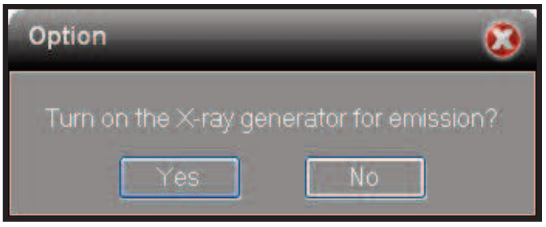


Figure 14.3.2-1: Experiments choose if X-rays are emitted

Note that you will be unable to use this functionality unless you are an experiment.

15. Getting Help

This portion of the manual deals with accessing and using the KBCT Console program's built-in help content, as well as related functionality.

15.1. Instructions for Use

Figure 15.1-1: Getting help

In order to view the help file for the KBCT System, go to the "Help" menu and click "Content" as shown at left (Figure 15.1-1). Doing so will open this User Manual.

The help content will be viewed in .pdf format as shown below (Figure 15.1-2). When you are done viewing the help content, click the in the upper right corner to close it.

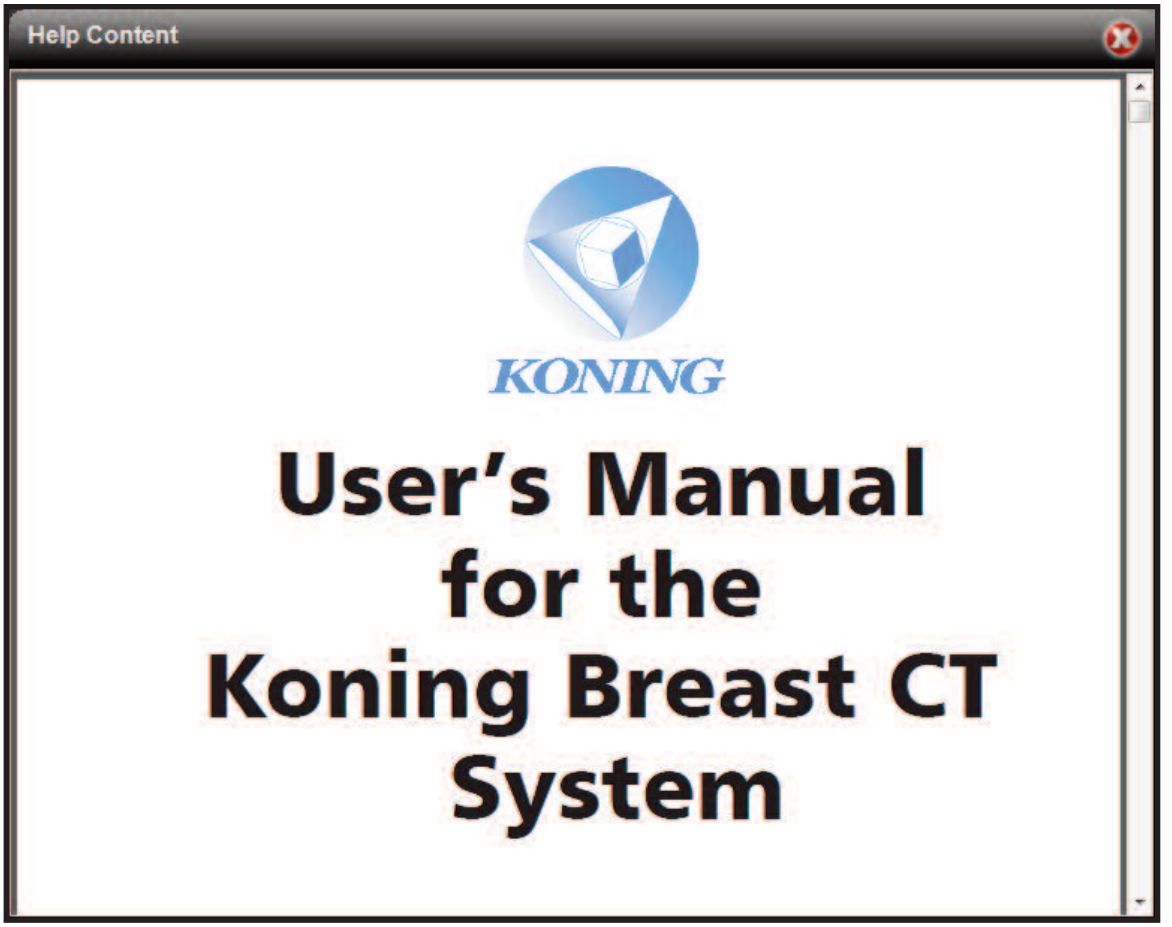


Figure 15.1-2: Help content

If this User Manual has failed to address a question or concern, please contact Koning Corporation or Koning's authorized representative.

15.2. About the KBCT Console Program

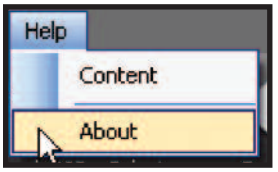


Figure 15.2-1: About the KBCT Console program

In order to view information about the KBCT Console program (such as the version, copyright, etc.), go to the "Help" menu and click "About" as shown at left (Figure 15.2-1).

This will cause the prompt shown below to appear. It contains information on the version of the KBCT Console program, the copyright, compatible versions of the Koning PLC, the operating system of the workstation, the workstation's processor, and the workstation's RAM. The prompt may be closed by clicking the "OK" button or clicking the in the upper right corner.

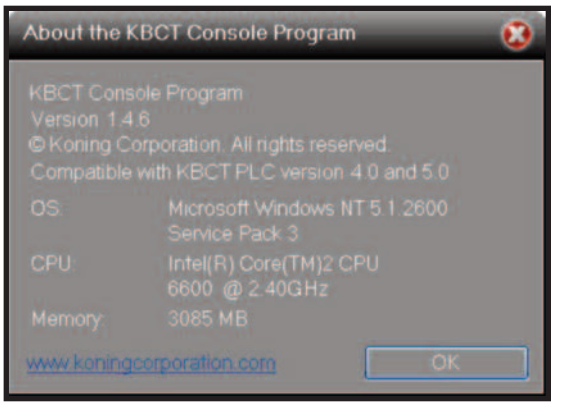


Figure 15.2-2: About the KBCT Console program

16. Troubleshooting

This section of the manual deals with what you should do when something goes wrong.

Note that this section only deals with stopping the Scanner, diagnosing problems, and possible resolutions in **non-emergency** conditions. **In the event of an emergency, please immediately refer to Section 6: Emergency Procedures.**

16.1. How to Tell When There is a Problem

16.1.1. Error Messages

If the KBCT Console program encounters an error, a prompt similar to the one shown at right (Figure 16.1.1-1) or below (Figure 16.1.1-2) may appear in order to notify you of the failure. This information is often helpful in determining what has gone wrong. In the example below, the user was unable to perform a task because an emergency stop button had been pressed. Releasing the emergency stop and pressing the System Power On Push Button on the control panel at the operator's console should solve the issue. Click the "Close" or "OK" button or the  in the upper right corner after reading the message to make it disappear. Alternatively, you may hit the Enter or Escape key on the keyboard.

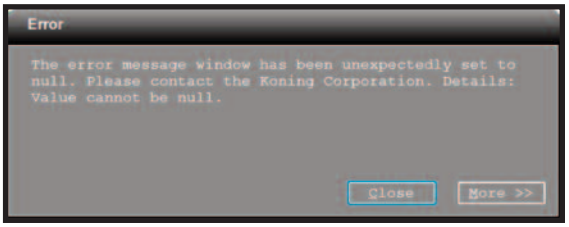


Figure 16.1.1-1: A task failed because of an unexpected null value

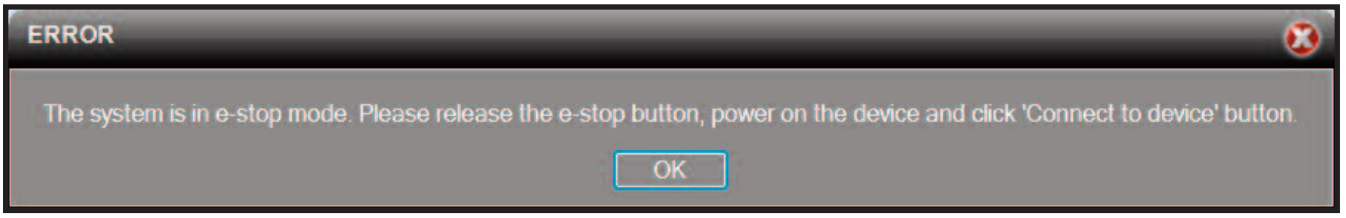


Figure 16.1.1-2: A task failed because the system is in emergency stop mode

If unable to resolve the problem from the information given, Koning Corporation strongly encourages you to write the error message down. Providing this information to Koning Corporation or Koning's Authorized Representative will facilitate efforts to resolve the issue.

16.1.2. Status Indicator

As previously mentioned, if the status indicator begins to flash yellow or red a problem has occurred. More accurately, this means that the PLC has encountered a problem. In the examples shown at right (Figure 16.1.2-1 and Figure 16.1.2-2), a problem was encountered while trying to home servos which has left the PLC in a warning and error state, respectively.

Figure 16.1.2-1: The PLC is in a warning state

Figure 16.1.2-2: The PLC is in an error state

Clicking on the status display brings up a log of the recent activity. Errors are recorded in red, warnings in yellow, and other messages in white. This may be used to help determine the cause of the problem. The example below (Figure 16.1.2-3) shows an instance of each type of message.

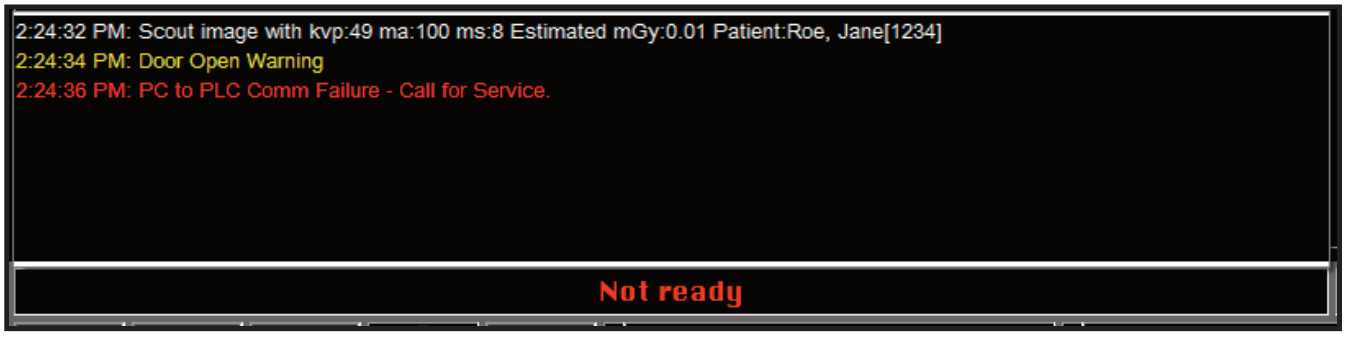


Figure 16.1.2-3: A log of the PLC's recent activity

16.1.3. Error Indicator & Warning Light

As previously mentioned, if an error occurs, the red indicator on the far right may turn on as shown at right (Figure 16.1.3-1).

Figure 16.1.3-1: Error indicator is on

Figure 16.1.3-2: Warning light on the control panel at the operator's console

Another indicator of whether or not something has gone wrong is the corresponding warning light next to the caution label located on the control panel at the operator's console shown at left (Figure 16.1.3-2). When there is a problem, the warning light will be lit.

Note that this light may also be lit before you've opened a connection to the KBCT Scanner. This is normal, and not necessarily indicative of a problem.

16.2. Stopping the KBCT System

There are several ways of stopping the KBCT System. An emergency stop button is located at the top of the control panel found on either side of the KBCT System Scanner (mounted on the Scanner cover, near the point where the doors meet). It is the large, red button in the picture at right (Figure 16.2-1). The emergency stop buttons located on the Scanner have a red light on them which will be active if the button was pressed.

Figure 16.2-1: Emergency stop button found on the side of the Scanner

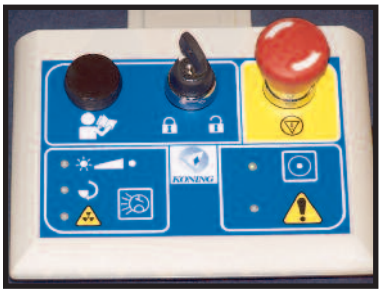


Figure 16.2-2: Emergency stop button found on the control panel at the Operator's Console

Another emergency stop button may be found on the Operator's Console Control Panel located at the workstation. It is in the upper-right corner of the control panel (in the yellow box), as shown at left (Figure 16.2-2).

To use the emergency stop button, press it down. All moving parts and any emission from the X-ray generator will come to a stop as brakes are applied and power to the X-ray generator is removed. Note that the emergency button will be locked, meaning it will remain pressed down after being used, so as to prevent the KBCT System Scanner from starting to move or emit X-rays again at an undesired time.

To unlock the emergency button, twist it in the direction shown by the white arrows on top of it. The button will then be released and pop back up, allowing the KBCT System to function again, after pressing the System Power On Push Button (it has a circle with a dot on it) on the control panel at the operator's console shown at right (Figure 16.2-3). The LED light next to the System Power On Push Button will be on if the power is on.

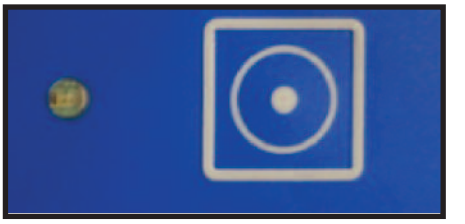


Figure 16.2-3: System Power On Push Button found on the control panel at the Operator's Console

The software contains various stop buttons shown below (Figure 16.2-4 and Figure 16.2-5) to halt scans and servo motions. Their use is **not** recommended in an emergency situation as they only stop some individual functionality rather than halting the entire KBCT System. Additionally, the KBCT System will stop a scan or servo motion automatically if errors are received from the PLC.

Figure 16.2-4: Stopping the X-ray generator

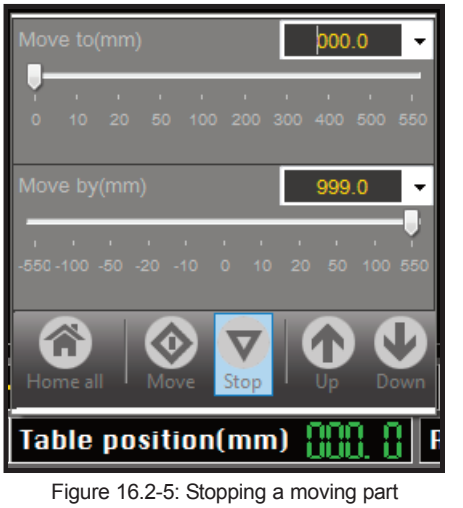


Figure 16.2-5: Stopping a moving part

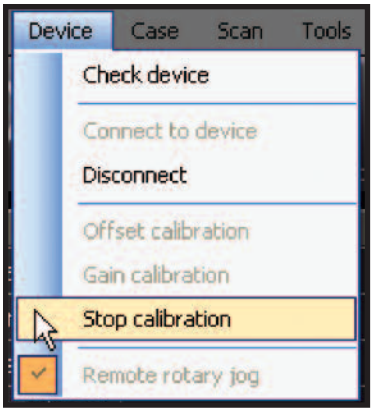


Figure 16.2-6: Stopping a calibration

Calibrations may be stopped using the “Stop calibration” option under the “Device” menu at right (Figure 16.2-6). Once again, relying on this feature is **not** recommended in an emergency.

Reconstructions and DICOM publications may be stopped using the “Interrupt” option under the “Tools” menu, or by clicking the corresponding toolbar button. Their use is **not** recommended in an emergency.

Figure 16.2-8: The interrupt toolbar button

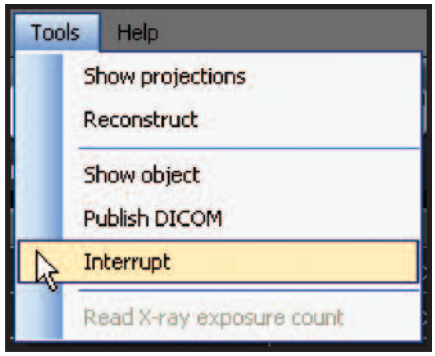


Figure 16.2-7: Interrupting a reconstruction or DICOM publication

Remember, only the Emergency Stop button is to be considered reliable in an emergency situation.

16.3. Checking the Hardware’s Connection

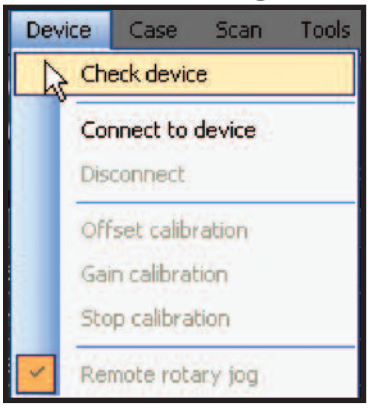


Figure 16.3-1: Checking the hardware’s connections

The KBCT Console program is able to check its connections to the other components of the System, which may prove useful when determining the cause of a problem. In order to have the software perform these checks, go to the “Device” menu and click “Check device” as shown at left (Figure 16.3-1). Any user may access this functionality.

The status indicator will change to display the message shown at right below.

Figure 16.3-2: The connections are being checked

The window shown in Figure 16.3-3 at right will appear. The KBCT Console program will begin testing the connections to the KBCT System’s sub-systems, and the window will automatically be filled with text indicating what is being tested and whether the test succeeds or fails. This ends with a message stating that the connection check is finished. In the example below, the connection with the PLC and the X-ray generator have both failed, but the connections to the detector and the frame grabber card appear to be functional.

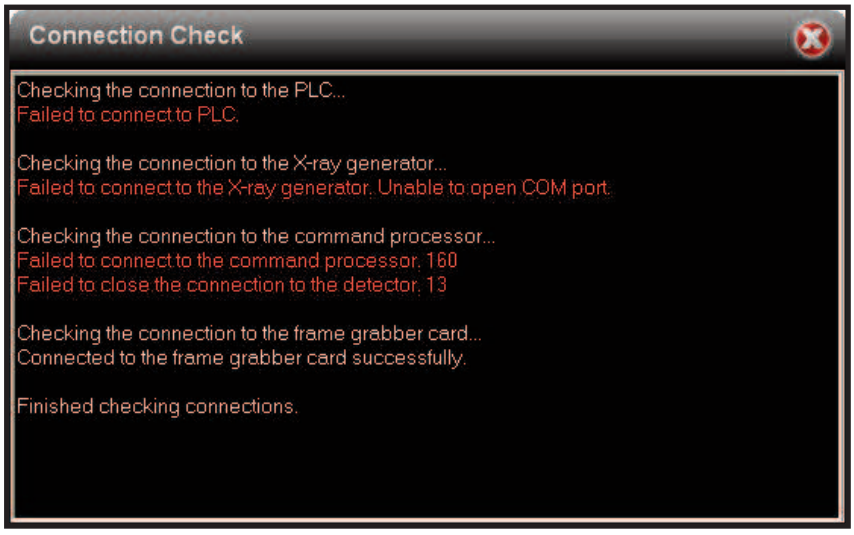


Figure 16.3-3: Output from checking the hardware’s connection

You can close the window by clicking the in the upper right corner.

Depending on the connection check being performed, it may take some time for the results to be determined.

16.4. Checking the System Log

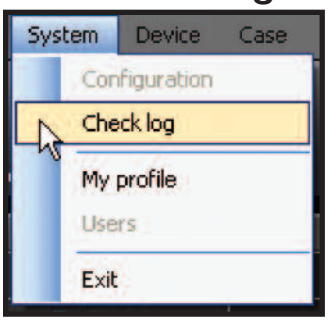


Figure 16.4-1: Checking the system log

The system log contains messages recorded by the KBCT Console program, which may be helpful when troubleshooting. To check the system log, go to the “System” menu and click “Check log” as shown at left (Figure 16.4-1). Any user may view it.

The window shown below (Figure 16.4-2) will appear. The majority of the window is taken up by a table displaying messages from the system log. If there are more messages than can be displayed in the window, a scroll bar will appear on the right side of the table. For each message, the time it was recorded, the user in control of the KBCT System at the time, the type of the message, the software module that wrote it, and the message’s contents are displayed.

All messages which were recorded from all modules over the last two days will be displayed initially.

Note that the messages are sorted by their date. Also note that messages from normal operation are present in addition to warning and error messages.

However, using the controls at the top of the window, you may specify what messages are retrieved. Using the leftmost dropdown box will allow you to specify what types of messages are retrieved. To retrieve messages from a specific range of dates, use the “from” and “to” checkboxes and dropdown boxes. To specify which module of the KBCT Console program to display messages from, type the name of the module into the box to the right of the word “for”. Once you’re done specifying what messages you would like to retrieve, click the “Retrieve” button, and the table will display the messages you specified (this may take some time depending on the number of messages are being retrieved).

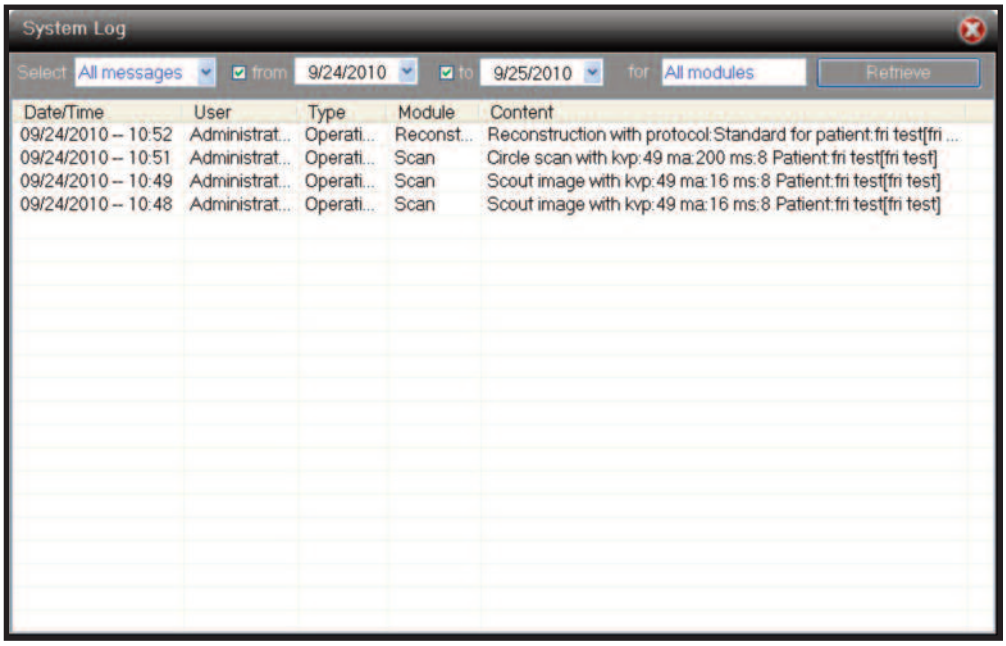


Figure 16.4-2: The system log

Note that the types of messages recorded are determined by the System configuration.

Note that if “to” is not checked and “from” is, all messages from the “from” date until the present are retrieved. Conversely, if “from” is not checked and “to” is, all messages recorded before the “to” date will be retrieved. If neither box is checked, messages recorded at any and all times will be retrieved.

When you are done viewing the system log, click the  in the upper right corner of the window to close it.

16.5. Common Problems & Possible Solutions

Check the known bugs listed in the release notes

- For each version of the KBCT Console Program released, Koning includes release notes. Among other things, these release notes contain a list of known software defects, their impact, what to do if they occur, and known work arounds.
- If you encounter a software issue not found in the list of known bugs in the release notes, please contact Koning to report the issue.

Unable to log in

- Try again, typing in your user name and password slowly.
- If the log in prompt is not visible, confirm that it is not hidden by other windows.
- Contact your System Administrator and request that your password be reset (refer to Section 14.1.2.3).

Unable to open a connection to the device

- Check the emergency stop buttons. One of them may be in a locked position.
- Confirm that there is power going to the KBCT System Scanner by checking the LED light next to the System Power On Push Button.
- Have a technician confirm that all wires are connected properly.
- Have a technician confirm that the command processor is turned on.

Motion or scan controls are unresponsive

- Check the emergency stop buttons. One of them may be in a locked position (refer to Section 6.1.2).
- If you were using the software controls, confirm that a connection to the device has been opened (refer to Section 16.3).
- If you were using the software controls try the hardware controls, and vice versa.
- If you were attempting to rotate the gantry by jogging, ask your System Administrator if the remote rotary jog feature is enabled (refer to Section 14.1.1.1).
- If you were attempting to start a scout image or scan, confirm that a patient case has been selected.
- If you were using a physical button, wait 5 seconds and try again.
- In the software, try disconnecting from and reconnecting to the System (refer to Sections 13.2.1 and 13.9.1).
- Have a technician confirm that all wires are connected properly.

Unable to perform a 3D reconstruction

- Confirm that a series has been selected.
- Confirm that you are able to view the projections associated with the series (refer to Section 13.7.1).
- If the images associated with the series have been removed from the System, restore them from back-up and try again (refer to Section 13.8.2).
- Close all other open programs and try again.

Unable to view projections

- Confirm that a series has been selected.
- If the projections were loaded to the image viewer, try adjusting the window/level of the image (refer to Section 13.6.2).
- Try viewing other frames (refer to Section 13.6.2).
- If the images associated with the series have been removed from the System, restore them from back-up and try again (refer to Section 13.8.2).

Unable to view object

- Confirm that a series has been selected and that a 3D reconstruction has been completed on it.
- If the slices were loaded to the image viewer, try adjusting the window/level of the image (refer to Section 13.6.2).
- Try viewing other frames (refer to Section 13.6.2).
- If the images associated with the series have been removed from the System, restore them from back-up and try again (refer to Section 13.8.2).
- Perform another reconstruction with the same VOI and other options (refer to Section 13.7.2).

Unable to publish a DICOM file

- Confirm that a series has been selected and that a 3D reconstruction has been completed on it.
- Have a technician confirm that the server is on.
- Have a technician confirm that all Ethernet cables are connected properly.

When all else fails…

- In the software, try disconnecting from and reconnecting to the device (refer to Sections 13.2.1 and 13.9.1).
- If the software is completely unresponsive, you can use Windows Task Manager to stop the program. Koning strongly recommends that this be avoided if there is an ongoing operation (such as a patient scan) that is still behaving normally (screen still updates, images still being saved). This is not a means of stopping the program in an emergency. Windows Task Manager may be accessed by pressing Ctrl, Alt, and Delete simultaneously on the keyboard.
- Press an emergency stop button and then release it. Wait a minutes, restore power to the System, wait a few more minutes and then reconnect to the System (refer to Section 6.1.2).
- Reboot the workstation.
- Have a technician confirm that all wires are connected properly.
- Check the system log (refer to Section 16.4).
- Write down what you were trying to do when the problem occurred, and the sequence of events leading up to it. This may be helpful in determining the cause of the problem.
- Contact your facility's technicians.
- Contact Koning Corporation or Koning's Authorized Representative.

16.6. Product Complaints

Any customer or user of this system of products who has any complaints or has experienced any dissatisfaction in the quality, durability, reliability, safety, effectiveness, and/or performance of this product is encouraged to notify Koning Corporation or Koning's Authorized Representative.

If the device malfunctions, please notify Koning Corporation or Koning's Authorized Representative. In such an event, please be prepared to describe the nature of the malfunction, the sequence of events leading up to it, and the complete text of any associated error messages. This information may be vital to Koning's ability to assist in resolving the issue. Additionally, please be aware of the information in Section 16 for guidance on what to do in the event of a malfunction and initial steps toward identifying and resolving the problem.

If the device may have caused or contributed to the **death or serious injury** of a patient, Koning Corporation **must** be notified **immediately** by telephone, fax, or written correspondence.

17. Quality Control for the CBCT1000

This section provides information, instructions, and guidance for:

- General guidance for Quality Control (Section 17.1)
- The Quality Control test procedures to be performed (Sections 17.2 through 17.12)
- The frequency of each test (Table 17.1-1)
- Record retention (Table 17.1-2)
- Acceptability limits for each test performed (Table 17.1-3?)
- Sample forms for QC tests (Section 17.13)
- Medical Physicist's QC Survey (Section 17.12)

The procedures in this guide are not the only way to perform the tests. Alternative test procedures may be used. Contact Koning Corporation or Koning's Authorized Representative for more information.

17.1. Compliance Guidance for Quality Control

Regulatory requirements state that facilities performing diagnostic X-ray procedures (such as computed tomography using the KBCT System) develop and continually implement a Quality Assurance (QA) program. The regulations apply to equipment used on humans in hospital, medical, podiatric, chiropractic, industrial, school, and government facilities. The establishment and maintenance of a Quality Assurance program will help ensure consistent image quality over the lifetime of the CBCT1000.

A Quality Assurance program, which includes Quality Control (QC) tests, helps ensure that high quality diagnostic images are consistently produced while minimizing radiation exposure. A detailed description of each required test may be found in the following sub-sections. This Quality Assurance program will enable the facility to recognize when parameters are out of specification, resulting in poor quality images and increasing the risk of unnecessary radiation exposure to patients. Early intervention could save time, money and prevent unnecessary patient exposure to radiation.

Simply performing the Quality Control tests is not sufficient. When Quality Control test results exceed established operating parameters, appropriate corrective actions must be taken immediately and documented. This section provides guidance for performing Quality Control tests for KBCT System Model # CBCT1000 **only**.

FREQUENCY

Due to the importance of quality control in diagnostic imaging, it is recommended that each facility with the Koning Breast CT (KBCT) System Model CBCT1000 equipment perform the tests in Table 17.1-1 "Koning Breast CT Quality Control Requirements" (located in the following section). The frequencies of quality control tests specified in Table 17.1-1 are the minimum frequencies. The tests may need to be performed more often depending on many factors, including the age and stability of the X-ray equipment. Tests may always be performed at a greater frequency but not at frequencies less than specified by regulatory requirements.

COMPETENCY

The registrant must ensure that all individuals performing any of the CBCT1000 quality control tests have an appropriate level of training to perform the tests competently. The registrant shall ensure that the individual performing the Quality Control tests described in this section is a licensed radiological technologist, a qualified medical physicist or a trained service technician. The facility must ensure that sufficiently trained personnel are always available (i.e. to cover vacation and sick time) to perform necessary testing.

RESPONSIBLE INDIVIDUAL(S)

The facility must identify the individual who will have the overall responsibility of the QC program. It is recommended that the responsibility for the quality control tests be assigned to a Quality Control program coordinator to ensure consistency in test methodology and in the interpretation of data. More than one person may perform the tests, but one person should assume overall responsibility for the operation of the QA program. This leads to better understanding of when to repeat tests, call for service or consult with the practitioner or medical physicist.

The facility must also specify which individuals will be responsible for the X-ray unit, the annual physics survey and each quality control test. The physician, medical physicist and Quality Control personnel, working together as a team, are the key to providing optimum quality radiographic images.

RECORDS

All procedures being used must be documented in the facility's QA manual and meet all applicable regulatory requirements. Records of Quality Control test results, corrective actions, and the Medical Physicist's QC Survey must be maintained for at least the time period specified in Table 17.1-2 **or** per regulatory requirements, whichever is **longer**.

Note that all QC tests will be initially performed at installation of the System. These initial QC test records are to be retained permanently to provide a baseline for System performance.

REVIEW

Quality Assurance begins with baseline performance data acquired during KBCT System installation, and includes scanning a QC phantom (see Appendix A) under a prescribed set of conditions. These baseline images should be saved and used as a visual comparison with the weekly and monthly Quality Control checks. The baseline values will provide an objective way to monitor quality by repeating these tests or procedures on a regular frequency to detect changes in image quality values before patient images are affected.

It is additionally recommended that the appropriate facility personnel review the control tests, data and images quarterly.

Table 17.1-1: CBCT1000 Quality Control Requirements

The below tests are to be performed by a licensed radiological technologist, a qualified medical physicist or a trained service technician.

Section	Required Test or Procedure	Frequency	Standard
17.3	Equipment Warm-Up Procedure	Daily, each day X-rays are emitted	Must work properly
17.4	CT Number for Water	Weekly	Koning Specification: 0 ± 10 HU
17.5	Field Uniformity	Weekly	Koning Specification: Maximum CT # difference ≤15 HU (at 75% of the radius)
17.6	Low Contrast Resolution	Monthly	Koning Specification: 6 mm @ 2% (≤ 20 HU)
17.7	Spatial Resolution	Monthly	Koning Specification for MTF: See Table 17.7-1. Koning Specification for Calcification Specks: 290 µm (full group is visible)
17.8	Noise	Monthly	Koning Specification: 8 HU ± 5 HU
17.9	Table Position Indicator Accuracy	Monthly	Koning Specification: actual position of patient table within ± 2.0 mm of position on screen at the ~mid and ~max table positions
17.10	Gantry Position Indicator Accuracy	Monthly	Koning Specification: actual position of gantry within ± 2.0 mm of position on screen at the ~mid and ~max gantry positions
17.11	Alignment Light Accuracy	Monthly	Koning Specification: <5.0 mm
17.12	Medical Physicist's QC Survey	Annually	All Tests Pass

Table 17.1-2: Records Retention	
Record Type	**Minimum Retention Time**
EACH corrective action, repair and service	2 Years
Equipment Warm-Up Procedure	A record of this test is not required
Radiation Safety Survey of the Environs	As long as machine is owned plus 1 year
INITIAL Medical Physicist QA Survey and other tests	Permanently maintained
ANNUAL Medical Physicist QA Survey	2 Years
Test Results for all other tests listed in Table 17.1-1 Koning Breast CT Quality Control Requirements.	1 Year

17.2. Data Acquisition, Reconstruction & Display Common to All QC Tests

Follow these steps for data acquisition, reconstruction and display with the KBCT QC phantom for all QC tests:

1. Place the KBCT QC phantom (see Appendix A) in the "safety jar" under the patient table with Insert 1 facing up and Insert 2 facing down. The upper edge of the phantom should be at the same level as the detector's upper edge. Carefully position the phantom so that its axis is aligned to the gantry rotation axis. Use the laser alignment light to verify the phantom's position.

2. Use the X-ray parameters 49 kVp, 125 mA and 8 ms to acquire a scan of the phantom. Choose the standard reconstruction mode for all tests except Spatial Resolution (choose "Calcification" mode instead). Perform all reconstructions on the whole imaging field (largest possible VOI) and leave the "Remove Skin" box unchecked. Choose "Phantom" from the Cupping Correction Mode drop down list for all tests.

Follow these steps to adjust the image stack appearance and perform image measurements with ImageJ (which comes pre-installed on the Console workstation) for all QC tests:

1. Import image sequence
- **a.** Go to File->Import->Image Sequence
- **b.** Select image folder
- **c.** Click on any file and the Sequence Options will pop up

2. Adjust the window width and level
- **a.** Go to Image->Adjust->Window/level
- **b.** Enter the value for window and level

For further instruction on how to use ImageJ, please refer to its separate instructions for use.

3. Average a set of slices
- **a.** Go to Image -> Stacks -> Z Project
- **b.** Enter the first slice number and the last slice number
- **c.** Choose "Average Intensity" then click "Ok" to get the averaged image

4. Measure mean value and standard deviation
- **a.** Draw a rectangular ROI box on the image you want to perform the measurement
- **b.** Go to Analyze -> Measure
- **c.** The Results window should contain the mean and standard deviation of the ROI (if not, go to Edit -> Set Measurements, check the "Mean Gray Value" and "Standard Deviation", click OK and redo the measurement)

17.3. Equipment Warm-up Procedure

Each day before performing other QC testing and before scanning the first patient, check for visual indication of X-ray beam-on, patient alignment light indication (cross hairs), table and gantry mechanical integrity and the electrical safety of the CT system. Malfunctions and unsafe conditions must be corrected before the System can be considered safe to use.

Test Frequency
Once Each Day of Operation (Prior to Operation)

Standard
Must work properly

Equipment Required
Koning QC phantom (see Appendix A) or other suitable imaging phantom

Note: Koning uses a corrected bad pixel map and regular gain calibrations to have the number of Defective Detector Elements (DDE) be 0 (the KBCT Console software corrects them all). If, for some reason, a scan occurs and a DDE is in the raw data it will produce an obvious artifact in the reconstructed image (circle or line). If this type of artifact is observed during the test, perform a gain calibration (Section 13.3.2.), and repeat this test to ensure all artifacts are gone before scanning a patient. If the artifact persists, contact Koning Corporation or Koning's Authorized Representative to arrange for repairs.

Procedure
1. Have a technician turn on system (if not already on)
2. Perform an Offset Calibration
3. Acquire and review Scout Images at 0 and 90 degrees
4. Acquire and review a Scan dataset (both projections and reconstructed slices)
    a. Examine all reconstructed images using a Window Width (WW) = 200 and a Window Level (WL) = 0 to check for gross artifacts
    b. If there are obvious image artifacts, report the problem for further diagnosis and do not proceed to the other QC tests after completing this test
5. Verify mechanical motion of Gantry and Patient Table
    a. All movements must be smooth
    b. Gantry and Patient Table must remain in the positions they are placed in
6. Verify operation of the cross hairs
7. All controls and indicators on the Operator's Console Control Panel and Scanner Control Panels must function
8. All text and symbols on the monitors and control panel must be legible
9. All labels must be legible
10. Ensure cleanliness of all surfaces

Corrective Action
If an unusual noise, spark or other unexpected event is noted, or if obvious artifacts are seen in the images, the equipment should not be used until the situation has been investigated and the equipment deemed to be operating normally. Contact Koning Corporation or Koning's Authorized Representative for assistance and possibly repair. All corrective actions must be documented and records of each corrective action, repair and service maintained for at least 2 years.

Records
Records of daily equipment warm-up are required, although keeping the resulting images is only recommended to document the testing in the event that the test **failed** due to an obvious artifact or other image defect. (This is due to the amount of disk space the daily images would consume.) Koning recommends keeping a written record, such as the form found in Section 17.13.

17.4. CT Number for Water
This test is the weekly consistency check of KBCT calibration number for water. The KBCT system assigns numbers, in Hounsfield Units (HU, not to be confused with heat units), to the attenuation values of an X-ray passing through a variety of material densities. The KBCT Console program makes the attenuation visible by assigning shades of gray to the selected groups of numbers. The test for CT Number for Water in the phantom represents the standard against which you can track the system constancy.

Test Frequency
Weekly

Standard
Koning Specification: 0 ± 10 HU

Equipment Required
KBCT QC phantom

Procedure
1. Scan and reconstruct the KBCT QC phantom as directed in Section 17.2

2. Find the center of the uniform water section between Insert 1 and Insert 2

3. Perform a 36 slice (from 17 slices above to 18 slices below the center, a total of 10 mm) average to reduce noise (see Section 17.2 step 3)

4. Place an ROI of approximately 8 mm by 8 mm at the center of the image and the four edge positions as shown in Figure 17.4-1. For the edge ROIs, place the center of the ROI at approximately 75% of the radius.

5. Record the mean CT number of the ROIs on the Weekly CT Equipment Tests Form (see Section 17.13)

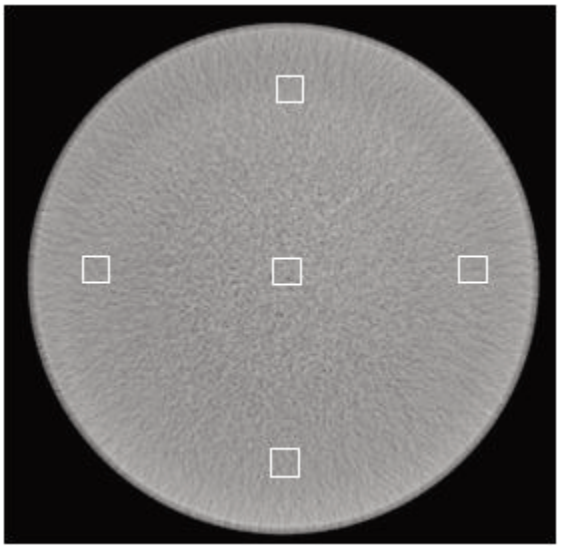


Figure 17.4-1: ROIs for CT number for water

Corrective Action
If there are any obvious image artifacts, or if the CT number for water is not within specification, stop testing and report the problem for further diagnosis. Have the imaging physicist run more detailed tests or contact Koning Corporation or Koning's Authorized Representative. Steps to repair the KBCT equipment to meet standards must be documented. All corrective actions must be documented and records of each corrective action, repair and service maintained for at least 2 years.

Records
Permanently maintain a written copy and digital copy of the initial CT number for water test results. Weekly test results must be documented and maintained for at least 1 year. The CT number for water should be recorded and compared each week to established specifications, and the recorded values examined to check for trends.

17.5. Field Uniformity
This test determines the spatial uniformity of CT numbers in a uniform medium. The uniformity test is a simple and direct approach to determining the accuracy of the image reconstruction process. To evaluate the axial plane uniformity, the QC phantom is scanned under simulated clinical conditions. The uniformity image can be very helpful in identifying the presence of image perturbations such as scattering, beam hardening artifacts, detection non-uniformity rings, etc.

Test Frequency
Weekly

Standard
Koning Specification: Maximum CT # difference ≤15 HU (at 75% of the radius)

Equipment Required
KBCT QC phantom

Procedure
1. Scan and reconstruct the KBCT QC phantom as directed in Section 17.2.

2. Find the center of the uniform water section between Insert 1 and Insert 2.

3. Perform a 36 slice (from 17 slices above to 18 slices below the center, a total of 10 mm) average to reduce noise (see Section 17.2 step 3).

Note: The same data set as was used for the CT number for water test described in Section 17.4 may be used if already acquired and prepared. If this is the case, start at step 2.

4. Place an ROI of approximately 8 mm by 8 mm at the center of the image and the 4 edge positions as shown in Figure 17.5-1. For the edge ROIs, place the center of the ROI at approximately 75% of the radius.

5. Calculate and record the field uniformity value (the absolute value of [the center mean CT number minus the edge mean CT number of the 4 edge ROIs]) on the Weekly CT Equipment Tests form (see Section 17.13).

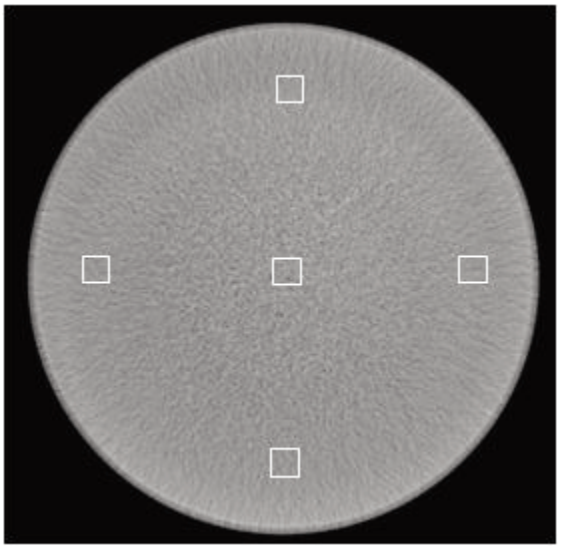


Figure 17.5-1: ROIs for field uniformity

Corrective Action

If the measurements indicate a change in values for uniformity > 15 HU for 75% of the radius, have the imaging physicist run more detailed tests or contact Koning Corporation or Koning's Authorized Representative. Steps to repair the CT equipment to meet standards must be documented. All corrective actions must be documented and records of each corrective action, repair and service maintained for at least 2 years.

Records

Permanently maintain a written and digital copy of the initial Field Uniformity test results. Weekly test results must be documented and maintained for at least 1 year. The change in values for uniformity should be recorded and compared each week to the established specifications.

17.6. Low Contrast Resolution

This test determines the capability of the Scanner to discriminate low contrast objects. Since much relevant soft tissue detail is low contrast in nature this is perhaps the most clinically important test. The visibility of low contrast objects is constrained mainly by the amplitude and frequency characteristics of the image noise. In CT, contrast is defined as the difference in CT numbers values between two structures. Subject contrast in CT is simply the difference in average CT numbers between two adjacent regions of the image.

Test Frequency

Monthly

Standard

Koning Specification: 6 mm @ 2% (20 HU)

Note: The same data set as was used for the CT number for water test described in Section 17.4 may be used if already acquired and prepared. If this is the case, start at step 2.

Equipment Required

KBCT QC phantom

Procedure

1. Scan and reconstruct the KBCT QC phantom as directed in Section 17.2.

2. Find the center slice of the insert 2 low contrast objects using a window width (WW) of 200 and a window level (WL) of 0. Note that there are 7 "tumors." That is 1 each of following diameters: 10, 8, 6, 5, 4, 3.2 and 2.5 mm.

3. Perform a 5 slice average (from 2 slices above to 2 slices below the center) to reduce noise.

4. View the image on the monitor with the room lights lowered, and determine the smallest tumor that can be fully visualized. The 3 large "tumors" (10, 8 and 6 mm diameters) should be seen with clear boundaries.

5. For each visible tumor...

a. Place an ROI within the tumor such that the distance between opposite corners is the diameter of the tumor. Place another ROI in the background material such that no tumors are within the ROI. See Figure 17.6-1.

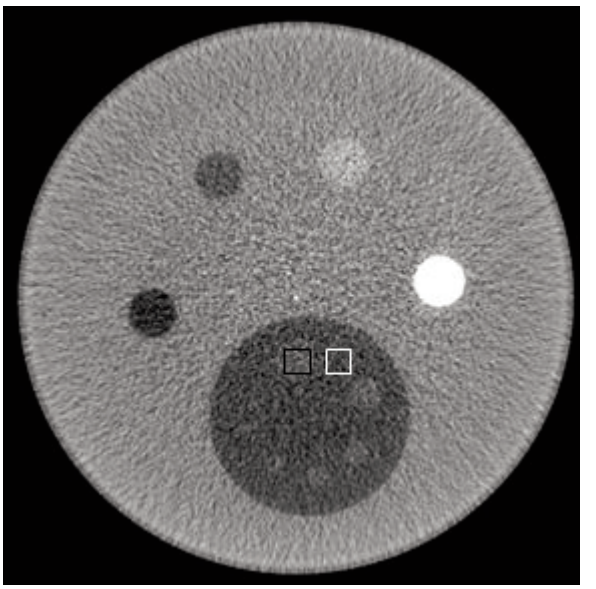


Figure 17.6-1: ROIs for low contrast resolution

b. Calculate the absolute value of the difference between the means of the 2 ROIs.

6. Record the diameter of the smallest visible tumor, as well as the calculated contrast for each visible tumor on the Monthly CT Equipment Tests: Imaging form (see Section 17.13).

Corrective Action

If the measurements indicate that the low contrast resolution does not meet specification, have the imaging physicist run more detailed tests or contact Koning Corporation or Koning's Authorized Representative. Steps to repair the CT equipment to meet standards must be documented. All corrective actions must be documented and records of each corrective action, repair and service maintained for at least 2 years.

Records

Permanently maintain a written copy and digital copy of the initial Low Contrast Resolution test results. Monthly test results must be documented and maintained for at least 1 year. Low Contrast Resolution results should be recorded and compared each month to established specifications.

17.7. Spatial Resolution

This test determines the capability of the Scanner to discriminate small high contrast objects by measuring the system's modulation transfer function (MTF) at contrasts of 50%, 10%, 5% and 0% (cut-off). A visual inspection of calcification "specks" is also performed. Since anatomical structures have important spatial resolution details (such as calcifications in the breast) this is a clinically important test. The visibility of small high contrast objects is constrained mainly by the blurring of images due to the focal spot size, detector pixel size, geometry (magnification) and reconstruction algorithm. This test helps to track any changes in these factors.

Table 17.7-1: Frequencies at which the MTF has the given minimum value

50%	10%	5%	0%
0.84 lp/mm	1.56 lp/mm	1.78 lp/mm	2.50 lp/mm

Note: lp/mm is line pair per millimeter.

Test Frequency

Monthly

Note: The same data set as was used for the CT number for water test described in Section 17.4 may be used if already acquired. If this is the case, start at step 2.

Standard

Koning Specification for MTF: See Table 17.7-1.

Koning Specification for Calcification Specks: 290 µm (full group is visible)

Equipment Required

KBCT QC phantom

Procedure

Part 1: Calcification Specks

1. Scan the KBCT QC phantom as directed in Section 17.2.

2. Reconstruct the QC phantom using the "Calcification" mode and the "Phantom" Cupping Correction Mode. Leave the "Remove Skin" box unchecked.

3. View the reconstructed slices at the center of Insert 1 using WW = 400 and WL ≈ 50. The WL can be adjusted slightly to optimize visualization of the calcification specks; if the WL necessary is below 40 or above 60 the results should be considered abnormal. Note that there are 6 speck patterns, containing calcifications of 375, 320, 290, 231, 195 and 165 µm diameters.

4. Carefully view the images with the room light lowered. Since the calcification specks may not all be in the same frame, the reconstructed images should be examined slice by slice to check for the complete visibility of each speck. See Figure 17.7-1.

5. Determine the smallest speck of which all 6 calcification grains are visualized.

6. Record the diameter of its calcifications on the data sheet. You should be able to see the 3 largest specks (375, 320 and 290 µm).

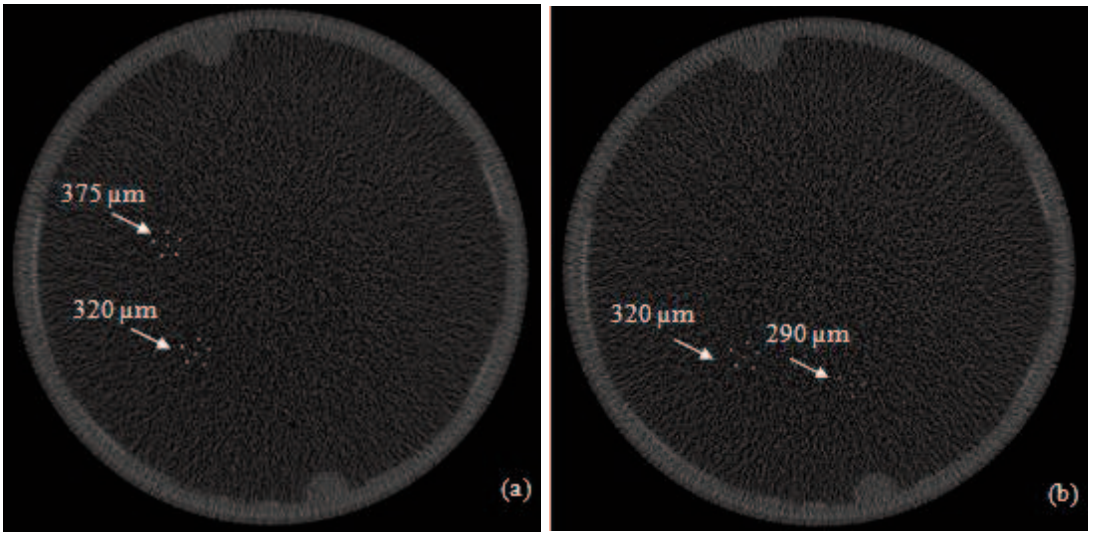


Figure 17.7-1: Calcification specks

Part2: MTF

1. View the reconstructed images of Insert 2 using a WW = 500 and WL = 150. The 50 µm tungsten wire should appear as a white dot at the center of the phantom. Place an ROI of approximately 24 mm by 24 mm to cover the wire and the surrounding background such that only the wire and background material are in the ROI (see Figure 17.7-2).

2. Go to Plugins -> Koning -> Koning MTF. Enter 0.273 for the pixel size and the start/stop slice number in the dialog, then click "OK" to calculate MTF. The slice range (start/stop, starting approximately 10 mm from the top of the imaged field) should cover 60 slices (17 mm).

3. Record the MTF values on the Monthly CT Equipment Tests: Imaging form (see Section 17.13).

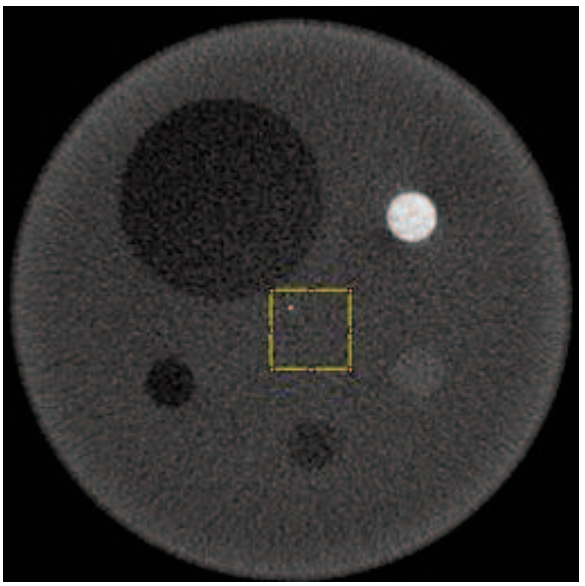


Figure 17.7-2: ROI for MTF measurement

Corrective Action

If the measurements indicate the values for high contrast are below the minimum values for any of the frequencies measured, or if the indicated specks are not seen, have the imaging physicist run more detailed tests or contact Koning Corporation or Koning's Authorized Representative. Steps to repair the CT equipment to meet standards must be documented. All corrective actions must be documented and records of each corrective action, repair and service maintained for at least 2 years.

Records

Permanently maintain a written copy and digital copy of the initial Spatial Resolution test results. Monthly test results must be documented and maintained for at least 1 year. The change in values for high contrast should be recorded and compared each month to established specifications.

17.8. Noise

This test assesses the level of noise and its variation with different scanning parameters under simulated clinical conditions. Noise refers to the fluctuations in CT numbers in a uniform medium around its average value. Image noise is analogous to quantum mottle in conventional radiography and is a part of the signal which does not add information. Noise limits the perceptibility of low contrast detail. The lower the noise, the better visibility of low contrast objects.

Test Frequency

Monthly

Standard

Koning Specification: 8 HU ± 5 HU

Note: The same data set as was used for the CT number for water test described in Section 17.4 may be used if already acquired and prepared. If this is the case, start at step 2.

Equipment Required
KBCT QC phantom

Procedure
1. Scan and reconstruct the KBCT QC phantom as directed in Section 17.2.

2. Find the center of the uniform water section between Insert 1 and Insert 2.

3. Perform a 36 slice (from 17 slices above to 18 slices below the center, a total of 10 mm) average to reduce noise (see Section 17.2).

4. Place an ROI of approximately 8 mm by 8 mm at the center of the image and the four edge positions as shown in Figure 17.8-1. For the edge ROIs, place the center of the ROI approximately 75% of the radius.

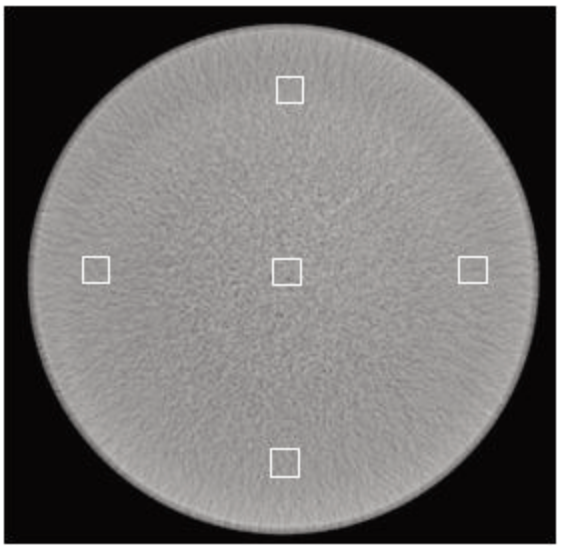


Figure 17.8-1: ROIs for field uniformity

5. Calculate and record the noise level (the average of the standard deviations of the 5 ROIs) on the Monthly CT Equipment Tests: Imaging form (see Section 17.13).

Corrective Action
If the measurements indicate a change in values for noise greater than 8 HU ± 5 HU, have the imaging physicist run more detailed tests or contact Koning Corporation or Koning's Authorized Representative. Steps to repair the CT equipment to meet standards must be documented. All corrective actions must be documented and records of each corrective action, repair and service maintained for at least 2 years.

Records
Permanently maintain a written and digital copy of the initial Noise test results. Monthly test results must be documented and maintained for at least 1 year. The change in values for noise should be recorded and compared each month to established specifications.

17.9. Table Position Indicator Accuracy
This test assesses the amount of relative table displacement by measuring the actual displacement the table traveled compared to the indicated value shown on the KBCT Console program. The CT operator must be able to accurately move patients to the desired elevation.

Test Frequency
Monthly

Standard
Koning Specification: the actual position of the patient table should agree to within ± 2.0 mm of the indicated position on screen at the ~mid table position and within ± 2.0 mm of the indicated position on screen at the ~max table position.

Equipment Required
Tape measure

Procedure
1. Using the KBCT Console program, move the patient table to 0.0 mm (lowest position). It may be necessary to move the gantry to 0.0 mm first.

2. Measure the distance from the base of the patient table frame to the floor (Y).

3. Using the KBCT Console program, move the patient table to 254.0 mm (approximately half of the maximum height).

4. Measure the distance from the base of the patient table frame to the floor (X_{mid1}).

5. Compare the difference of the measurements from step 4 and step 2 with the position indicated on screen. The difference (Z_{h1}) should be within ± 2 mm of the position indicated on screen ($X_{mid1} – Y = Z_{h1}$).

6. Using the KBCT Console program, move the patient table to 550.0 mm (approximately the maximum height).

7. Measure the distance from the base of the patient table frame to the floor (X_{max}).

8. Compare the difference of the measurements from step 7 and step 2 with the position indicated on screen. The difference (Z_{h2}) should be within ± 2 mm of the position indicated on screen ($X_{max} – Y = Z_{h2}$).

9. Using the KBCT Console program, move the patient table back to 254.0 mm.

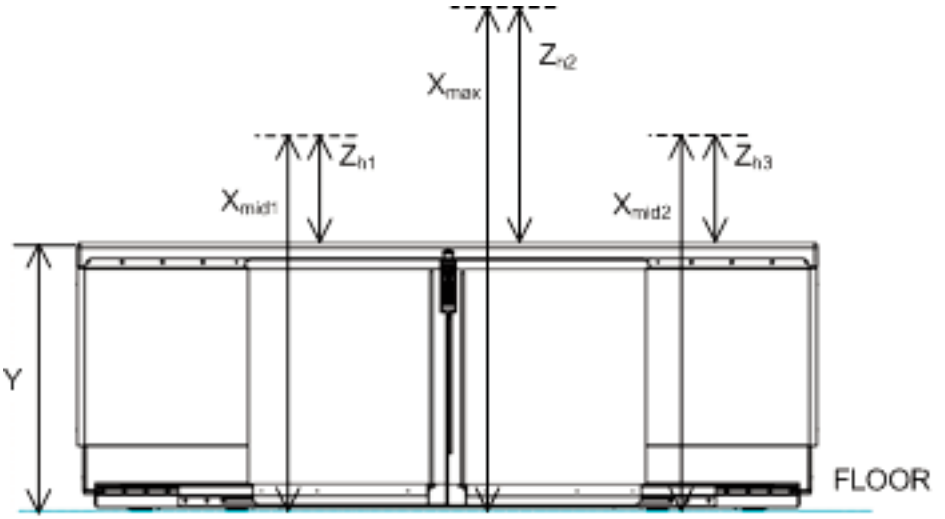


Figure 17.9-1: Table position indicator accuracy

10. Measure the base of the patient table frame to the floor. (X_{mid2})

11. Compare the difference of the measurements from step 10 and step 2 with the position indicated on screen. The difference (Z_{h3}) should be within ± 2 mm of the position indicated on screen ($X_{mid2} – Y = Z_{h3}$).

12. Record the results on the Monthly CT Equipment Tests-Mechanical form.

13. Using the KBCT Console program, move the patient table back to 0.0 mm (lowest position).

Corrective Action

If the differences between measured distances calculated during the steps above differ from the corresponding on screen positions by more than ± 2.0 mm, have the imaging physicist run more detailed tests or contact Koning Corporation or Koning's Authorized Representative. Steps to repair the CT equipment to meet standards must be documented. All corrective actions must be documented and records of each corrective action, repair and service maintained for at least 2 years.

Records

Permanently maintain a written copy of the initial Table Position Indicator Accuracy test results. Monthly test results must be documented and maintained for at least 1 year. The change in results should be recorded and compared each month to established specifications.

17.10. Gantry Position Indicator Accuracy

This test assesses the amount of relative table displacement by measuring the actual displacement the gantry traveled compared to the indicated value shown on the KBCT Console program. The CT operator must be able to accurately move the gantry to the desired elevation.

Test Frequency

Monthly

Standard

Koning Specification: the actual position of the gantry should agree to within ± 2.0 mm of the indicated position on screen at the ~mid gantry position and ± 2.0 mm of the indicated position on screen at the ~max gantry position.

Equipment Required

Tape measure

Procedure

1. Using the KBCT Console program, move the patient table the highest position possible.

2. Using the KBCT Console program, move the gantry to 0.0 mm (lowest position).

3. Measure the distance from the base of the gantry frame to the floor (Y).

4. Using the KBCT Console program, move the gantry to 254.0 mm (approximately half of the maximum height).

5. Measure the distance from the base of the gantry frame to the floor (X_{mid1}).

6. Compare the difference of the measurements from step 5 and step 3 with the position indicated onscreen. The difference (Z_{h1}) should be within ± 2 mm ($X_{mid1} – Y = Z_{h1}$).

7. Using the KBCT Console program, move gantry to 550.0 mm (approximately the maximum height).

8. Measure the distance from the base of the gantry frame to the floor (X_{max}).

9. Compare the difference of the measurements from step 8 and step 3 with the position indicated onscreen. The difference (Z_{h2}) should be within ± 2 mm ($X_{max} – Y = Z_{h2}$).

10. Using the KBCT Console program, move the gantry back to 254.0 mm.

11. Measure the distance from the base of the gantry frame to the floor (X_{mid2}).

12. Compare the difference of the measurements from step 11 and step 3 with the position indicated on screen. The difference (Z_{h3}) should be within ± 2 mm of the position indicated on screen ($X_{mid2} – Y = Z_{h3}$).

13. Record the results on the Monthly CT Equipment Tests-Mechanical form.

14. Using the KBCT Console program, move the gantry and patient table back to 0.0 mm (their lowest positions).

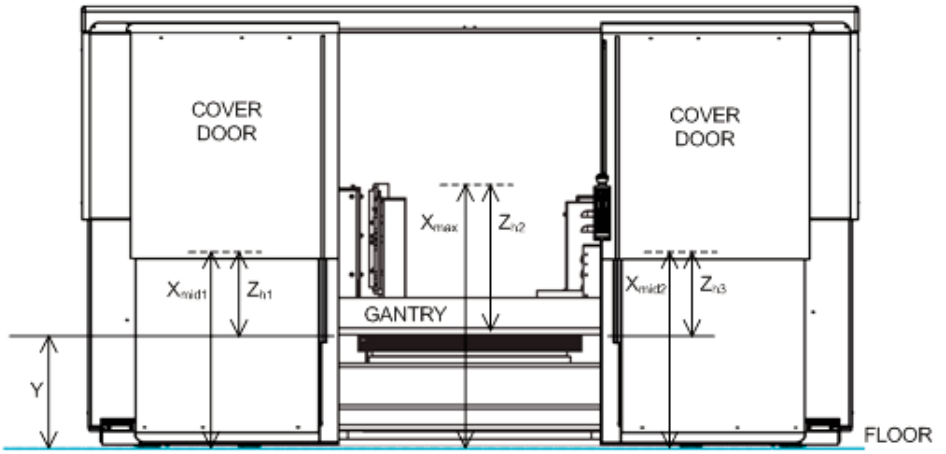


Figure 17.10-1: Gantry position indicator accuracy

Corrective Action

If the differences between measured distances calculated during the steps above differ from the corresponding on screen positions by more than ± 2.0 mm, have the imaging physicist run more detailed tests or contact Koning Corporation or Koning's Authorized Representative. Steps to repair the CT equipment to meet standards must be documented. All corrective actions must be documented and records of each corrective action, repair and service maintained for at least 2 years.

Records

Permanently maintain a written copy of the initial Gantry Position Indicator Accuracy test results. Monthly test results must be documented and maintained for at least 1 year. The change in results should be recorded and compared each month to established specifications.

17.11. Alignment Light Accuracy

This quality control test shows the congruence of the alignment light and the rotation axis of the gantry. Patient anatomy to be scanned is located using the alignment light (see Section 13.6-1). Alignment light is located within the gantry at the rotation axis.

Test Frequency

Monthly

Standard

Koning Specification: <5.0 mm

Equipment Required

Paper, Pen, Scotch Tape, Ruler

Procedure

1. Tape a piece of paper over the opening in the patient table
2. Using the KBCT Console program, rotate the gantry to the 0.0° position.
3. Turn on the patient alignment light and mark the center of the cross hairs on the paper.
4. Using the KBCT Console program, rotate the gantry to the 90°, 180° and 270° positions, marking the center of the crosshairs at each position.
5. Remove the paper from the patient table.
6. Using a straight edge, connect the four points on the paper into a parallelogram.
7. Using a straight edge, draw lines connecting the opposite corners of the parallelogram. The lines should intersect at the center.
8. Measure the distance from the center to the corners. Each distance should be <5 mm.
9. Record the results on the Monthly CT Equipment Tests-Mechanical form.
10. Using the KBCT Console program, rotate the gantry back to the 0° position.

Corrective Action

If any of the measured distances are greater than 5.0 mm then have the imaging physicist run more detailed tests or contact Koning Corporation or Koning's Authorized Representative. Steps to repair the CT equipment to meet standards must be documented. All corrective actions must be documented and records of each corrective action, repair and service maintained for at least 2 years.

Records

Permanently maintain a written copy of the initial Alignment Light Accuracy test results. Monthly test results must be documented and maintained for at least 1 year.

17.12. Monthly Physicist's Koning Breast CT QC Review

The QC Review is a routine review of past test results to check for emerging issues.

Test Frequency

Monthly

Standard

No issues found

Equipment Required

None

Procedure

The facility must ensure that a qualified medical physicist for the supervision of quality assurance programs for computed tomography equipment has performed and documented all the tests in Table 17.12-1. Once a month, the qualified medical physicist is to review all QC test results. If the review was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

Corrective Action

If a problem is found, the imaging physicist should run more detailed tests or contact Koning Corporation or Koning's Authorized Representative. Steps to repair the CT equipment to meet standards must be documented. All corrective actions must be documented and records of each corrective action, repair and service maintained for at least 2 years.

Records

Permanently maintain a written record of all findings.

17.13. Medical Physicist's Koning Breast CT QC Survey

The QC Survey is a series of measurements performed by the physicist to verify that a CT system conforms to manufacturer's specifications and state regulations. The physicist's primary concerns are image quality, radiation dose and radiation protection. The QC Survey will test performance characteristics that can be quantified by a medical physicist using widely available instruments and phantoms.

Test Frequency

Annually

Standard

All Tests Pass

Equipment Required

Calibrated Dosimeter, KBCT QC Phantom, Paper, Pen, Scotch Tape, Ruler, Tape Measure

Procedure

The facility must ensure that a qualified medical physicist for the supervision of quality assurance programs for computed tomography equipment has performed and documented all the tests in Table 17.13-1. The Medical Physicist's Computed Tomography QC Survey must include the tests identified in the Table 17.13-1, an evaluation of the facility quality assurance program, any corrective actions taken, their results, a summary of the review and recommendations for necessary improvements. The report shall list the start and completion dates of the survey and be signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

Table 17.13-1: Medical Physicist's Koning Breast CT QC Survey

Item	Test	Standard			
1.	Air Kerma	25 mGy ± 20% (Using CT ion chamber with 10-cm active area, in air, fully exposed at center of rotation) 1 Gy = 114 R (One 360° scan @ 49 kVp, 100 mA, 8ms/projection)			
2.	Average Glandular Dose	7 mGy ± 20% for a normal breast (4.2 cm thick compressed or ~13 cm thick uncompressed, 50% glandular tissue, 50% adipose tissue)			
3.	CT Number for Water	0 ± 10 HU			
4.	Field Uniformity	≤ 15 HU @ 75% radius			
5.	Low Contrast Resolution	6 mm @ 2% (≤ 20 HU)			
6.	Spatial Resolution	Minimum value			
	a. MTF	**50%**	**10%**	**5%**	**0%**
		0.84 lp/mm	1.56 lp/mm	1.78 lp/mm	2.50 lp/mm
	b. Specks	290 µm (full group is visible)			
7.	Noise	≤ 8 HU			
8.	Half Value Layer	>0.49 mm Al at 49 kVp (FDA specification) 1.5 mm Al (± 10 %) at 49 kVp (typical)			
9.	Quality Equivalent	Filtration (Permanent) ≥99.9% pure Al			
10.	Collimation Accuracy	The X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2% of the SID (1.85 cm)			

Corrective Action

If any test results indicate that the CT equipment does not meet the standards established in Table 17.12-1, you must immediately contact Koning Corporation or Koning's Authorized Representative in order to initiate corrective actions to meet the standards. The medical physicist should decide if patients can safely be scanned before the corrective actions are completed and the system meets all specifications. Document all steps to repair the CT equipment to meet standards. Please contact Koning Corporation or Koning's Authorized Representative regarding any specification issue.

Records

The facility must ensure that record of the initial Medical Physicist's Koning Breast CT QC Survey is permanently maintained. Annual Medical Physicist's Koning Breast CT QC Survey records must be maintained for at least 2 years.

Notes

Medical Physicist report of results and recommendations should be communicated to registrant once each year (or earlier if there are non-compliance issues).

17.14. QC Forms for CBCT1000

The following pages include sample QC forms which could be used to fulfill the recordkeeping requirements of the tests described in the previous subsections. Note that comparable alternatives may be used instead.

X-RAY EQUIPMENT **CT X-RAY Equipment to be Tested:**
List the Equipment Registered: Koning Breast CT system Manufacturer: Koning Corporation Model #: CBCT1000
Serial #: _____
Tube Serial #: _____
Registration # _____
Facility Designation: _____

Daily CBCT1000 Equipment Tests			
Date	**Person Responsible for Test**	**Equipment Function**	**Comments**

Weekly CBCT1000 Equipment Tests				
Date	**Person Responsible for Test**	**CT Number for Water**	**Field Uniformity**	**Comments**

Monthly CBCT1000 Equipment Tests: Imaging					
Date	**Person Responsible for Test**	**Low Contrast Resolution**	**High Contrast Resolution**	**Noise**	**Comments**

Monthly CBCT1000 Equipment Tests: Mechanical					
Date	Person Responsible for Test	Table Position Indicator Accuracy	Gantry Position Indicator Accuracy	Accuracy Alignment Light	Comments

APPENDIX A. Koning Breast CT Quality Control Phantom

A.1 Introduction

The Koning Breast CT (KBCT) Quality Control (QC) phantom has been designed specifically for the Koning Breast CT systems to perform quality control tests on a broad range of system parameters. These include:

- CT Number for Water
- Field uniformity
- Low contrast resolution
- Spatial resolution (MTF and Speck)
- Image noise

A.2 Specifications

The phantom includes one cylindrical container and two inserts. The container (13 cm in diameter and 10 cm in height) is constructed from acrylic, which is close to a water-equivalent material. It's filled with water to measure the water attenuation coefficient, image uniformity, and noise.

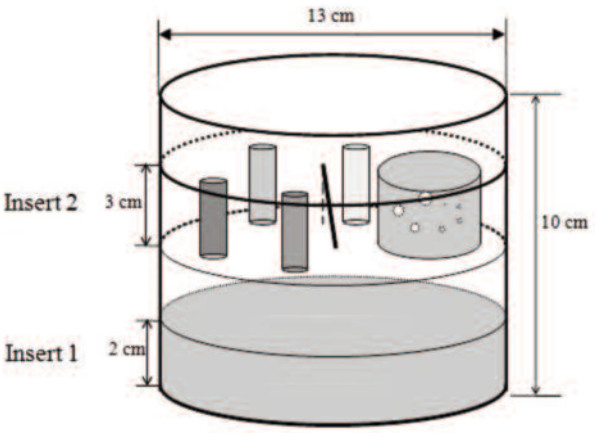


Figure A.2-1: Koning Breast CT QC phantom diagram

Insert 1 is a high-contrast resolution insert. It is made of BR12, which is equivalent to 50%/50% adipose/glandular tissue, and contains six calcification speck patterns simulated by calcium carbonate grains of 375, 320, 290, 231, 195, and 165 microns in diameter. Each speck pattern size is ~10 mm * 10 mm. The six calcification speck patterns are evenly spaced along a 3.0 cm radius circle at the same slice plane in the insert.

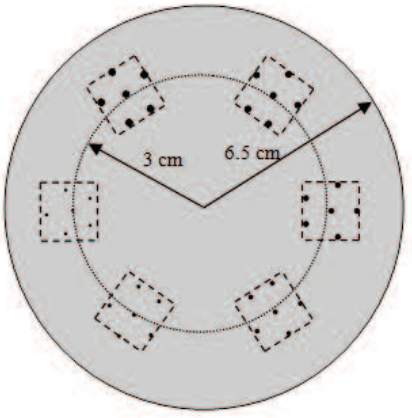


Figure A.2-2: Insert 1

Insert 2 contains three sections: a low-contrast resolution section, a CT number-linearity section, and a MTF measurement section. The low-contrast resolution section is made of BR12 and contains seven spherical "tumors" of different sizes. The tumors are made of a special material that gives ~30 HU contrast against the background. The diameters of the tumors are 10, 8, 6, 5, 4, 3.2, and 2.5 mm. The CT number-linearity section consists of four rods (1.2 cm diameter) made of different materials: adipose, breast, muscle, and 200mg/cc hydroxyapatite (HA). The MTF measurement section consists of a 50 micron tungsten wire that is vertically tilted by 3° to achieve a smooth MTF curve.

A.3 Acceptable Alternatives

If the Koning Breast CT Quality Control phantom is not available, the following may be used as an acceptable alternative:

A similar diameter and wall structure container filled with clean water (for instance, a 13 cm Tupperware container) may be used as a makeshift alternative to the QC phantom's water section in order to check uniformity, noise, the CT number of water, and to check for artifacts. All readings should be taken ~10 mm down from the top of the imaged field to avoid an edge effect. If the container has an embossed label on the bottom, noting good edges and examining the label can be used to make a subjective reading of low contrast and spatial contrast

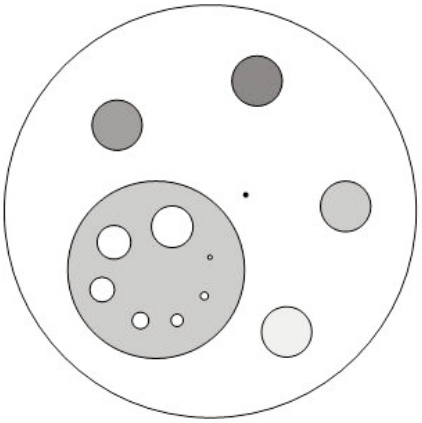


Figure A.2-3: Insert 2

Note that other alternatives may be appropriate. Please contact Koning Corporation or Koning's Authorized Representative before using an alternative phantom not listed above to confirm that it is acceptable.

Appendix B. Biopsy Bracket User Guide: Optional Accessory for Koning Breast CT

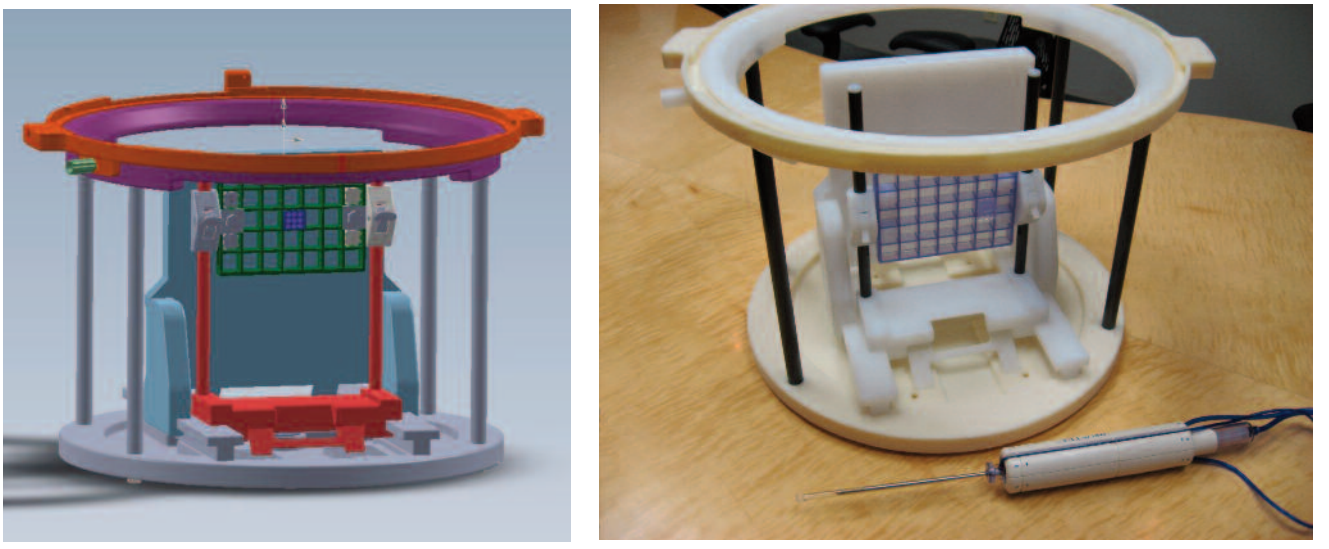
B.1. Introduction

The Biopsy Bracket will enable a Koning Breast CT-Guided Biopsy (KBCT-GBx) procedure using standard KBCT imaging and standard commercial vacuum-assisted percutaneous core breast biopsy systems.

The Biopsy Bracket has been verified by phantom studies to meet the design requirements to:

- Attach to KBCT patient tables and allow for standard biopsy procedures
- Firmly but comfortably hold the breast by compressing by feel in small (~1 mm) steps
- Have low x-ray attenuation materials, quick compression release, and simple construction
- Rotate 360 degrees around the breast before compression to obtain the shortest skin-to-lesion distance
- Allow for disassembly and cleaning with standard clinical cleaning agents
- Work with commercially available grids, needle blocks and introducer sets
- Accommodate various breast lengths (chest wall to nipple) up to 22 cm

The Biopsy Bracket is shown in Figure B.1-1 below.



(a) (b)

Figure B.1-1: Biopsy Bracket. (a) 3D CAD engineering model; (b) photo of the Biopsy Bracket product.

B.1.1 Indications For Use

The Biopsy Bracket is an optional accessory to the standard Koning Breast CT System intended to enable a Koning Breast CT-Guided Biopsy (KBCT-GBx) procedure using standard KBCT imaging and standard commercially available vacuum-assisted percutaneous core breast biopsy systems and disposables.

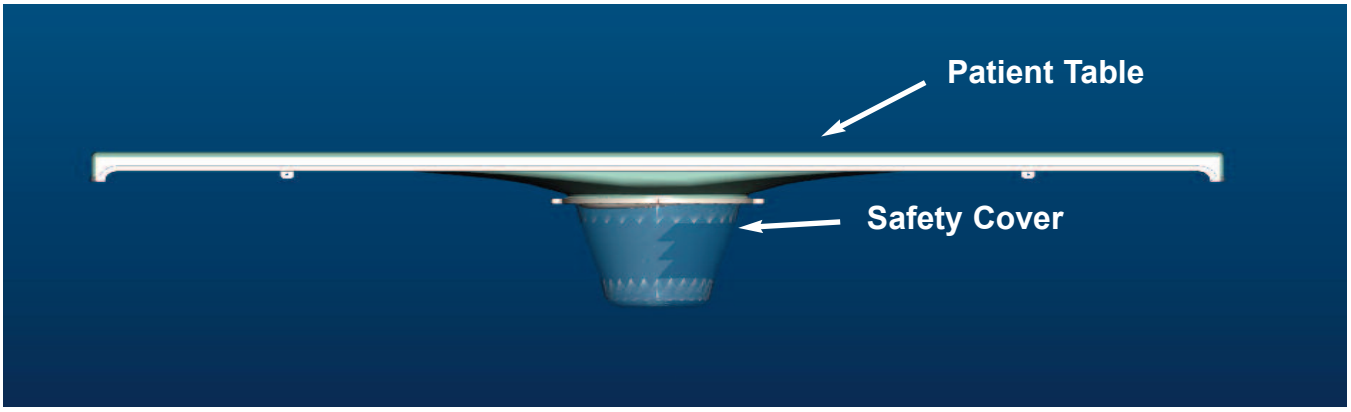
B.1.2 Accessory Lifetime & Disposal

The Biopsy Bracket is designed to last for the duration of the Koning Breast CT System's lifetime (that is, 7 years for a CBCT1000).

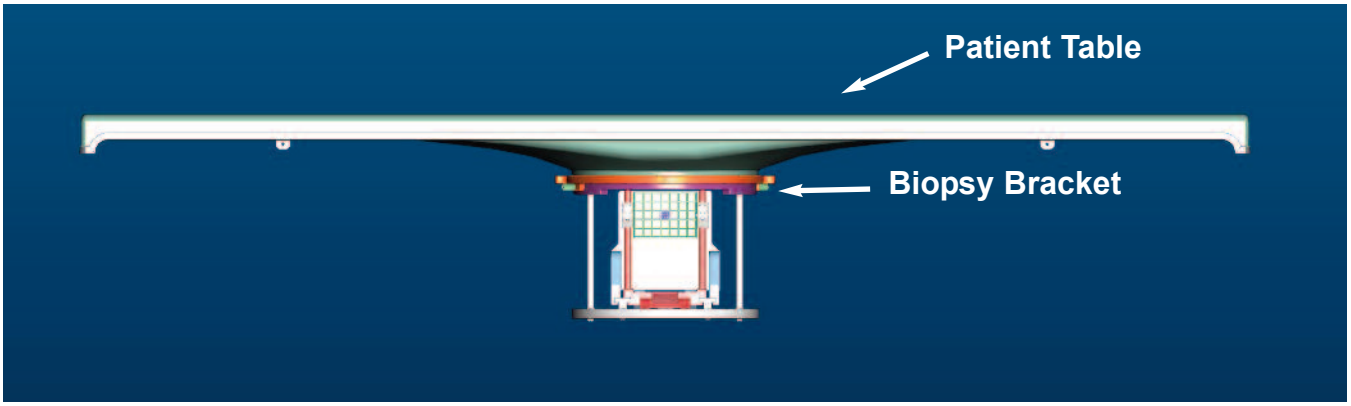
[redacted] To properly remove and dispose of this accessory, you must follow the environmental laws, codes, guidelines and requirements established locally and for your state or province for the disposal of hazardous waste. Follow your company's guidelines for proper and safe disposal of potentially hazardous materials and residues. Contact Koning Corporation or Koning's Authorized Representative for assistance.

B.2. Mounting the Biopsy Bracket on the Patient Table

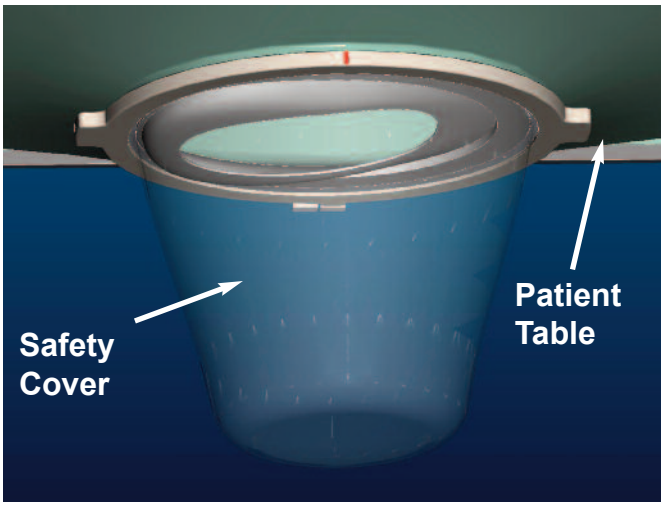
In standard KBCT imaging, the Safety Cover is mounted on the bottom of the patient table below the opening for the breast (Figure B.2-1a, c). It is interlocked with motion and X-ray control and is required for safe operation of standard KBCT imaging. The Biopsy Bracket will replace the Safety Cover before the KBCT-GBx procedure (Figure B.2-1b, d). Both use a simple ¼ turn ring to clamp to a flange on the underside of the patient table and have magnetic interlock “keys”.



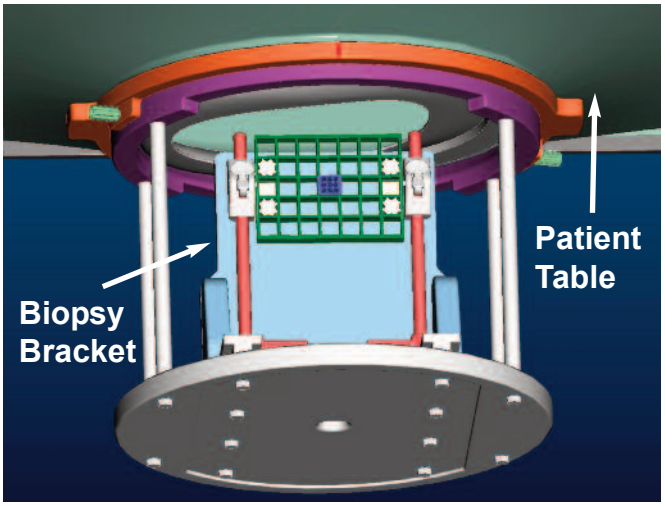
(a)



(b)



(c)



(d)

Figure B.2-1. Biopsy Bracket replaces Safety Cover and mounts to the bottom of the patient table (a, b c, d)

B.3. KBCT-Guided Biopsy (KBCT-GBx) Method Using the Biopsy Bracket

Koning has developed a KBCT-GBx method using the Biopsy Bracket and standard KBCT imaging to successfully use standard commercial vacuum-assisted percutaneous core breast biopsy systems and disposables to perform the biopsy procedure. The KBCT-GBx method is similar to standard MRI-guided biopsy and has been verified by phantom studies.

B.3.1 Procedure for KBCT-GBx Using the Biopsy Bracket

The step-by-step procedure for KBCT-GBx uses the Biopsy Bracket and a commercially-available biopsy grid, introducer set and vacuum-assisted biopsy system (shown in Figure B.3.1-1).

Although the biopsy grid is designed to minimize the chances of spillage, the gantry is to be covered with surgical drapes prior to performing a biopsy.

(a)

(b)

(c)

(d)

Figure B.3.1-1: Commercially available standard biopsy equipment and disposables used for KBCT-GBx using the Biopsy Bracket
(a) Introducer set, (b) Grid, (c) ATEC Pearl vacuum assisted biopsy system, (d) hand-piece

- The patient's breast is immobilized (Figure B.3.1-2) by the Koning Biopsy Bracket by compression with the grid oriented to give the minimal skin-to-lesion distance, as determined from previous imaging
- A pre-biopsy KBCT scan is performed (Figure B.3.1-3
- From this scan, the optimal grid location and needle-guide hole is determined that gives the best trajectory of the biopsy needle to the lesion while avoiding major vessels
- Skin-to-lesion depth is determined from the KBCT 3D imaging
- The patient's skin is prepped using an aseptic technique at the appropriate block of the grid
- The skin and deep to the lesion is anesthetized

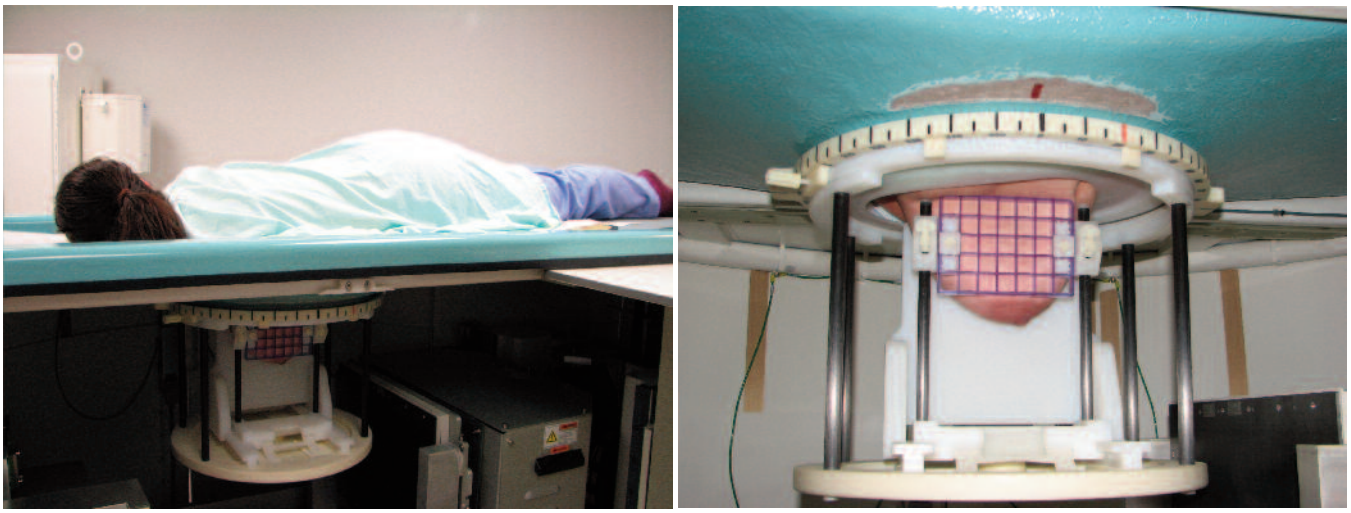


Figure B.3.1-2: Patient's breast is immobilized by the Koning Biopsy Bracket

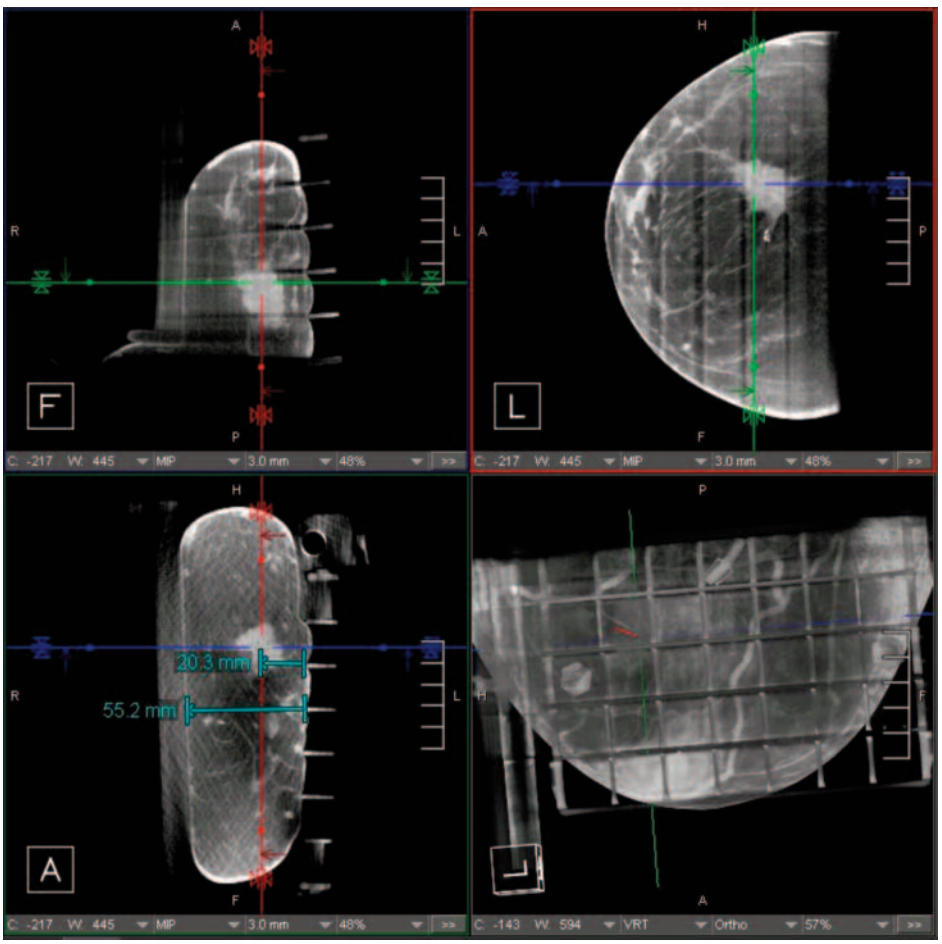


Figure B.3.1-3 Pre-biopsy images for targeting

- The needle guide block is inserted into the appropriate block of the grid. An introducer stylet is inserted and hubbed to the introducer sheath; a 'depth stop' on the introducer sheath is placed in the appropriate location based on the skin-to-lesion depth determined from the KBCT 3D imaging
- The introducer sheath with the introducer stylet is inserted into and through the needle guide to the depth stop

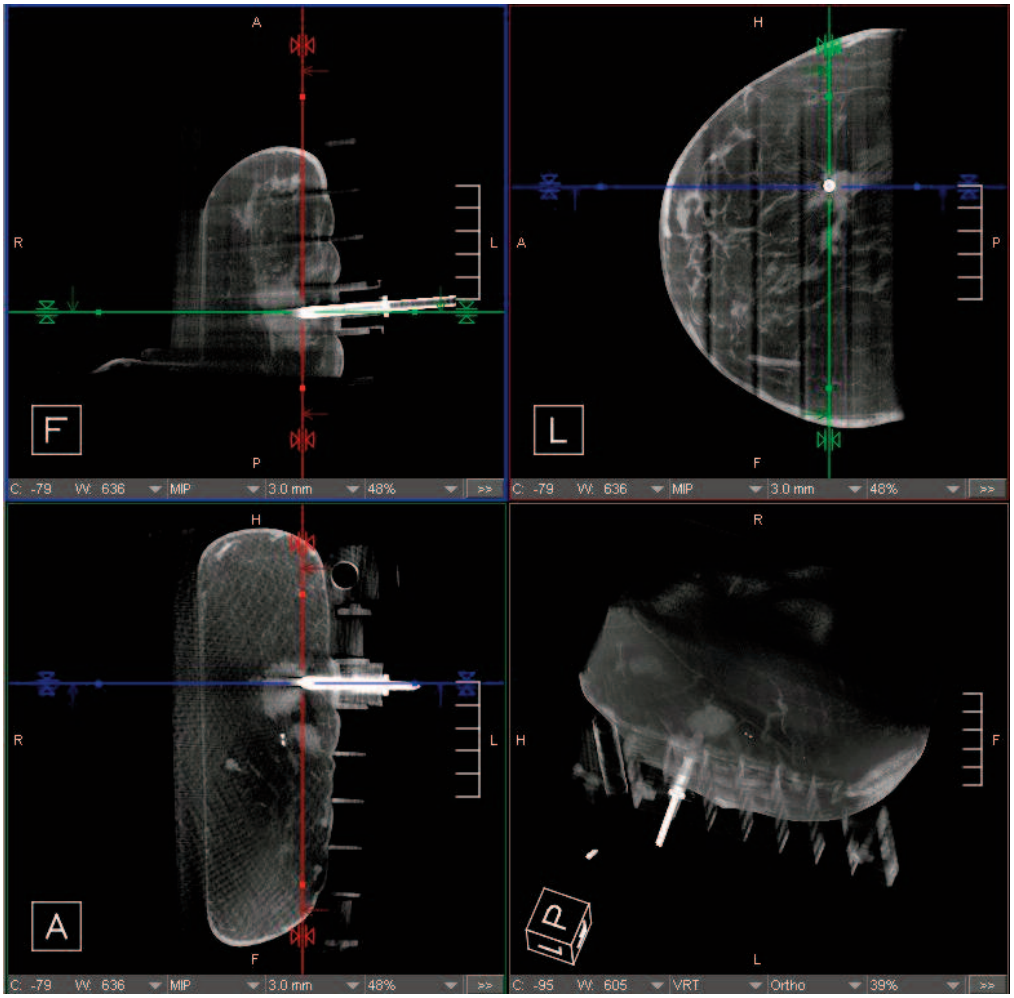


Figure B.3.1-4: Pre-biopsy images to confirm obturator position

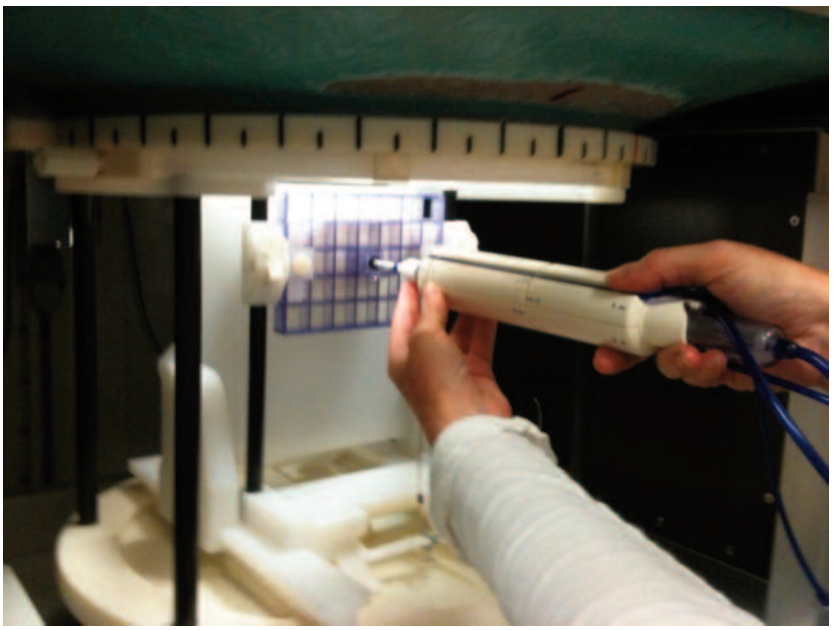


Figure 3.1-5: Biopsy needle inserted through introducer sheath

- The stylet is removed from the introducer sheath leaving the introducer sheath in place. The localizing obturator is inserted into the introducer sheath, and the patient is imaged to confirm accuracy (Figure B.3.1-4)
- The localizing obturator is removed and the biopsy needle is inserted (shown without patient in Figure B.3.1-5) and the area of interest biopsied
- Once the biopsy is completed, the biopsy needle is removed (leaving the introducer sheath in place) and post-biopsy KBCT imaging is performed to confirm the biopsy of the suspect area (Figure B.3.1-6). Pathology will be confirmed in the standard way
- For all lesions, a radiopaque marker will be placed at the biopsy site and the location verified with KBCT imaging for future intervention or treatment localization (Figure B.3.1-7)
- The breast is removed from compression, pressure is applied to the biopsy area to stop bleeding; a sterile gauze bandage will be applied for pressure as well as ice to minimize bruising

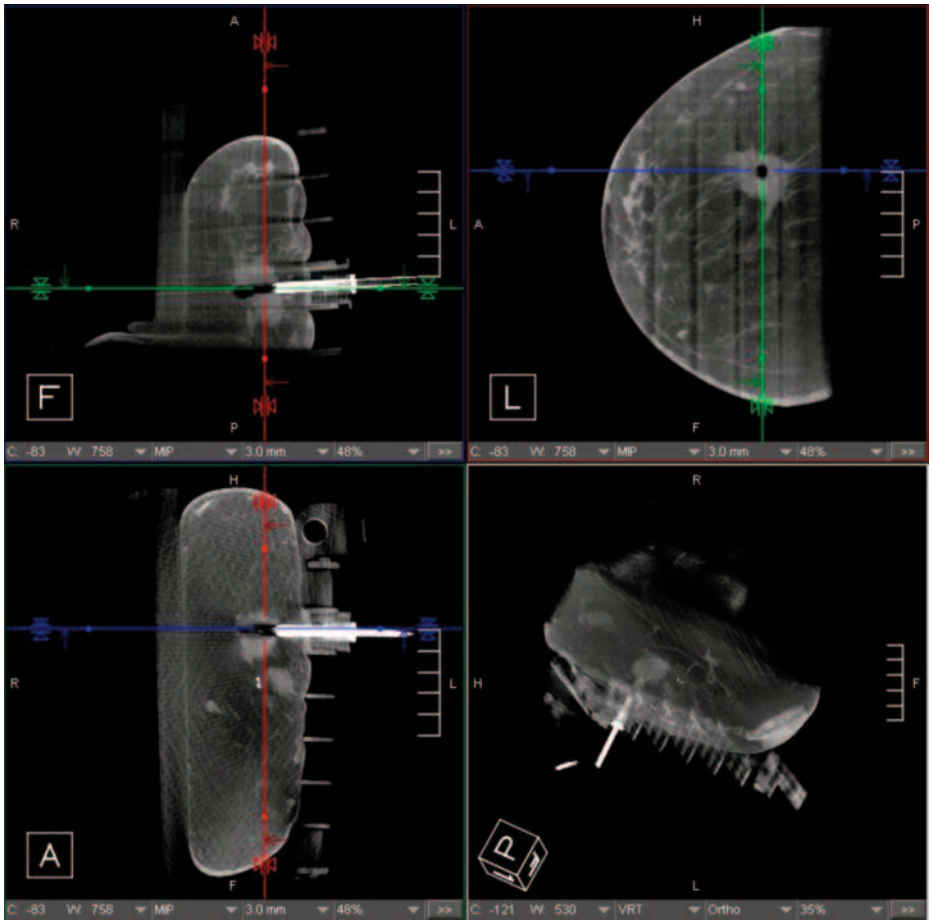


Figure B.3.1-6: Post-biopsy images to confirm biopsy

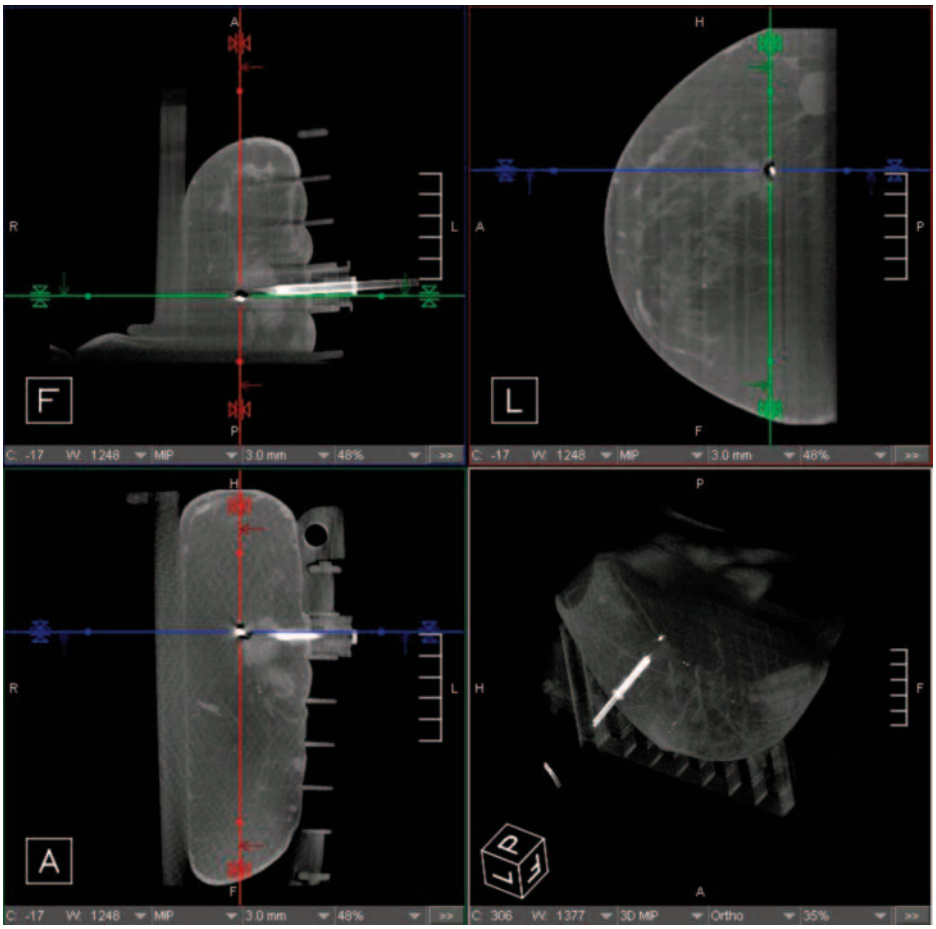


Figure B.3.1-7: Post-biopsy images to confirm clip placement

B.3.2 Simulation of KBCT-GBx Using a Breast Biopsy Phantom

This section shows screenshots from the KBCT standard 3D workstation during a simulated KBCT-GBx procedure using a biopsy phantom and Biopsy Bracket. It is intended to be a guide to the user for the procedure.

Koning offers a biopsy phantom set (See Figure B.3.2-1) that can be used as a training tool and practice medium. The anthropomorphic phantoms have the following characteristics:

Figure B.3.2-1: Biopsy Phantom Set

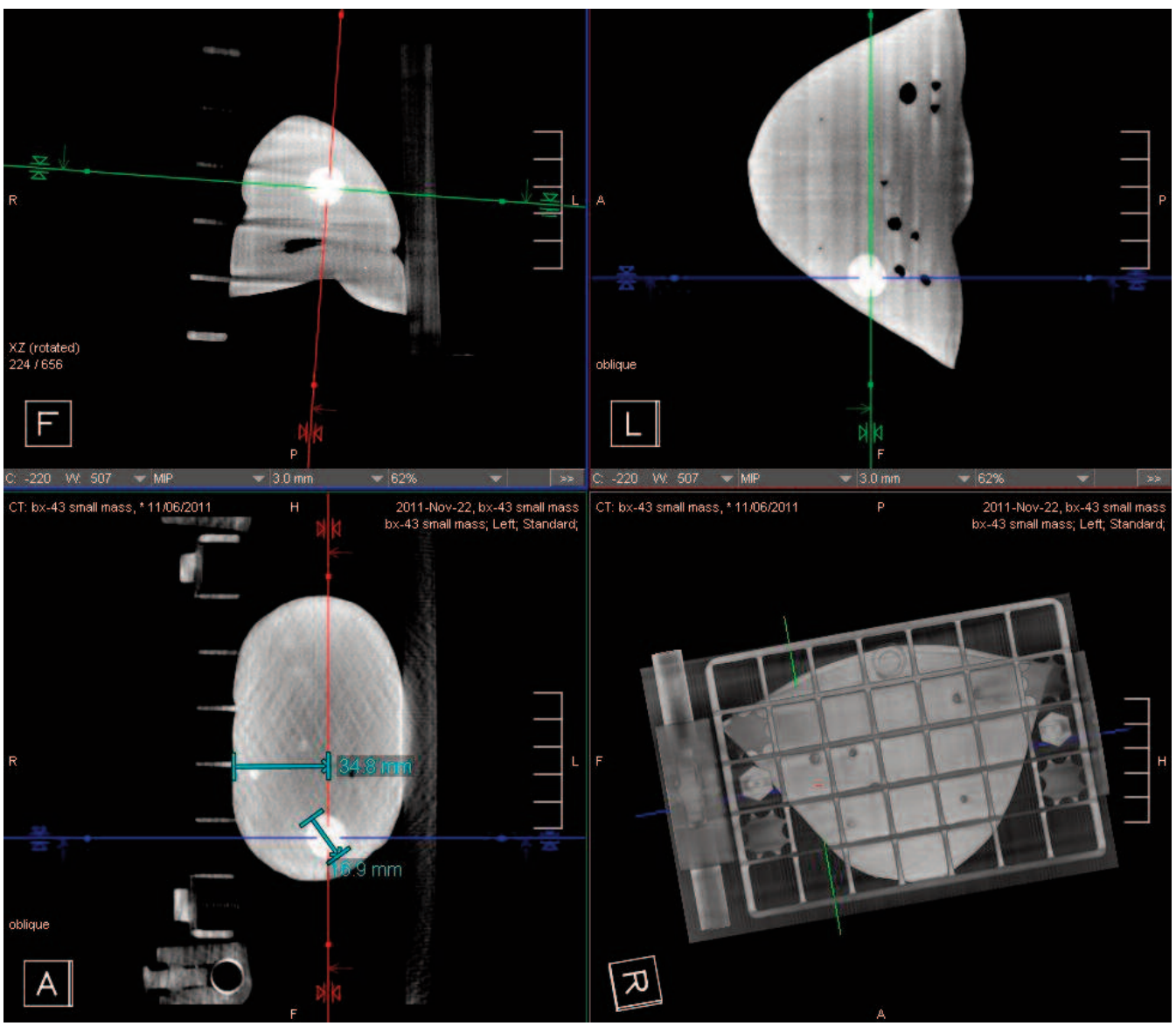


Figure B.3.2-2: KBCT-guided targeting of mass in the small phantom (Bx-43). Previous biopsies are evident (holes).

• Each set contains a small (B cup, 12 x 10 x 9 cm), medium (C cup, 18 x 15 x 9 cm) and large (D cup, 21.5 x 17 x 10 cm) phantom

• Each phantom contains 10 masses (2 to 15 mm in diameter) and 5 calcification clusters (3 to 11 mm in diameter)

• Background composition: 50% glandular/50% adipose

• Background material, masses and calcifications have similar image characteristics as actual breast tissue under KBCT and Stereotactic imaging conditions and can be retrieved with a standard vacuum-assisted biopsy system and hand-piece

• Phantoms are compressible

The small phantom is shown in this example KBCT-GBx simulation. Figure B.3.2-2, Figure B.3.2-3 and Figure B.3.2-4 are screenshots of the KBCT-GBx, targeting, pre-biopsy and post-biopsy scans, respectively, obtained during the biopsy procedure (Bx-43) of a mass in the small phantom using the Biopsy Bracket. Evidence of successful tissue harvest by KBCT-GBx was obtained through imaging by Faxitron. Figure B.3.2-5 shows the Faxitron image and photo of the biopsied mass (Bx-43).

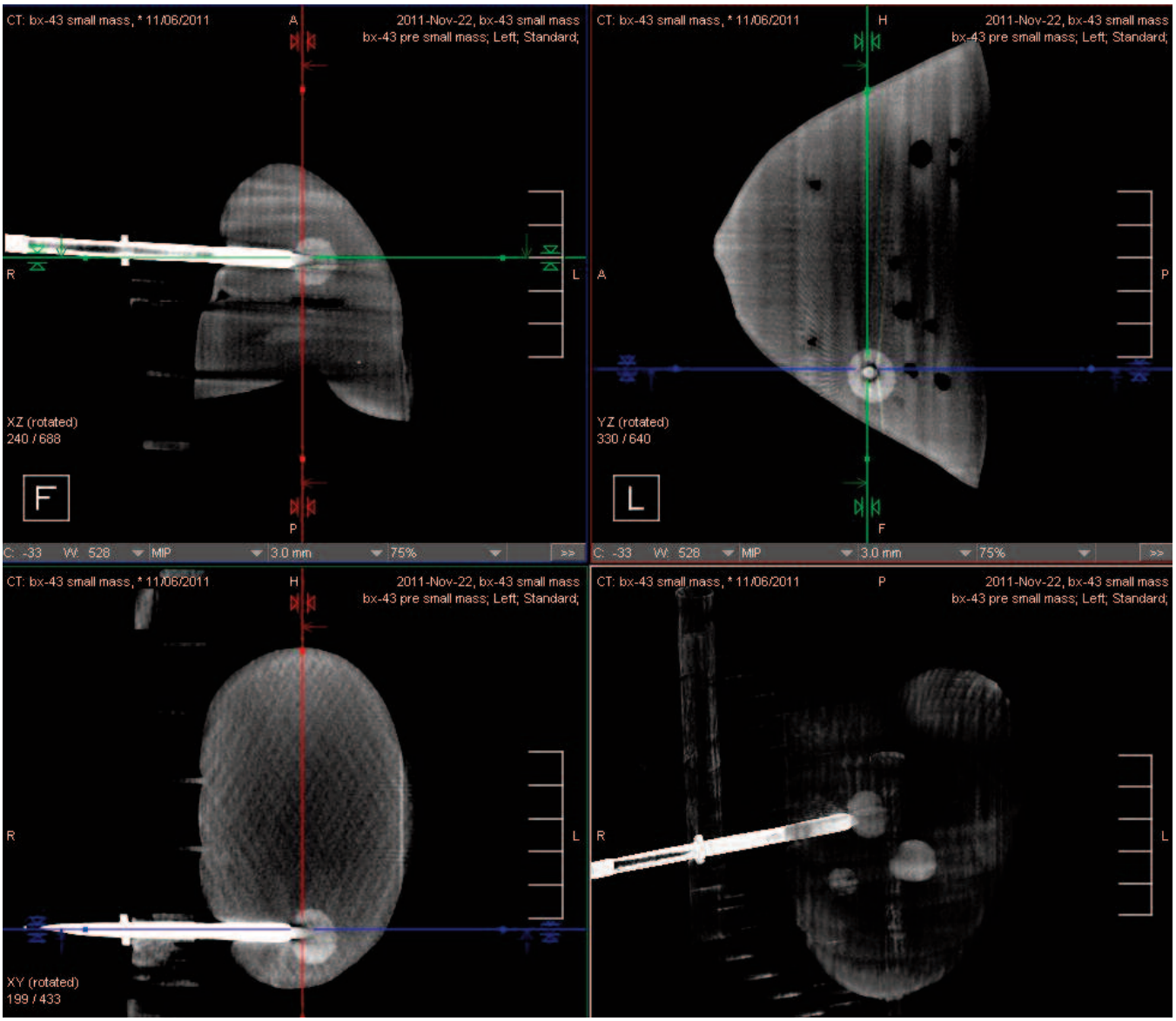


Figure B.3.2-3: KBCT-guided pre-biopsy scan of mass in the small phantom (Bx-43). Tip of obturator (crosshairs) indicates the location of the harvesting trough in the biopsy needle when the actual biopsy is performed

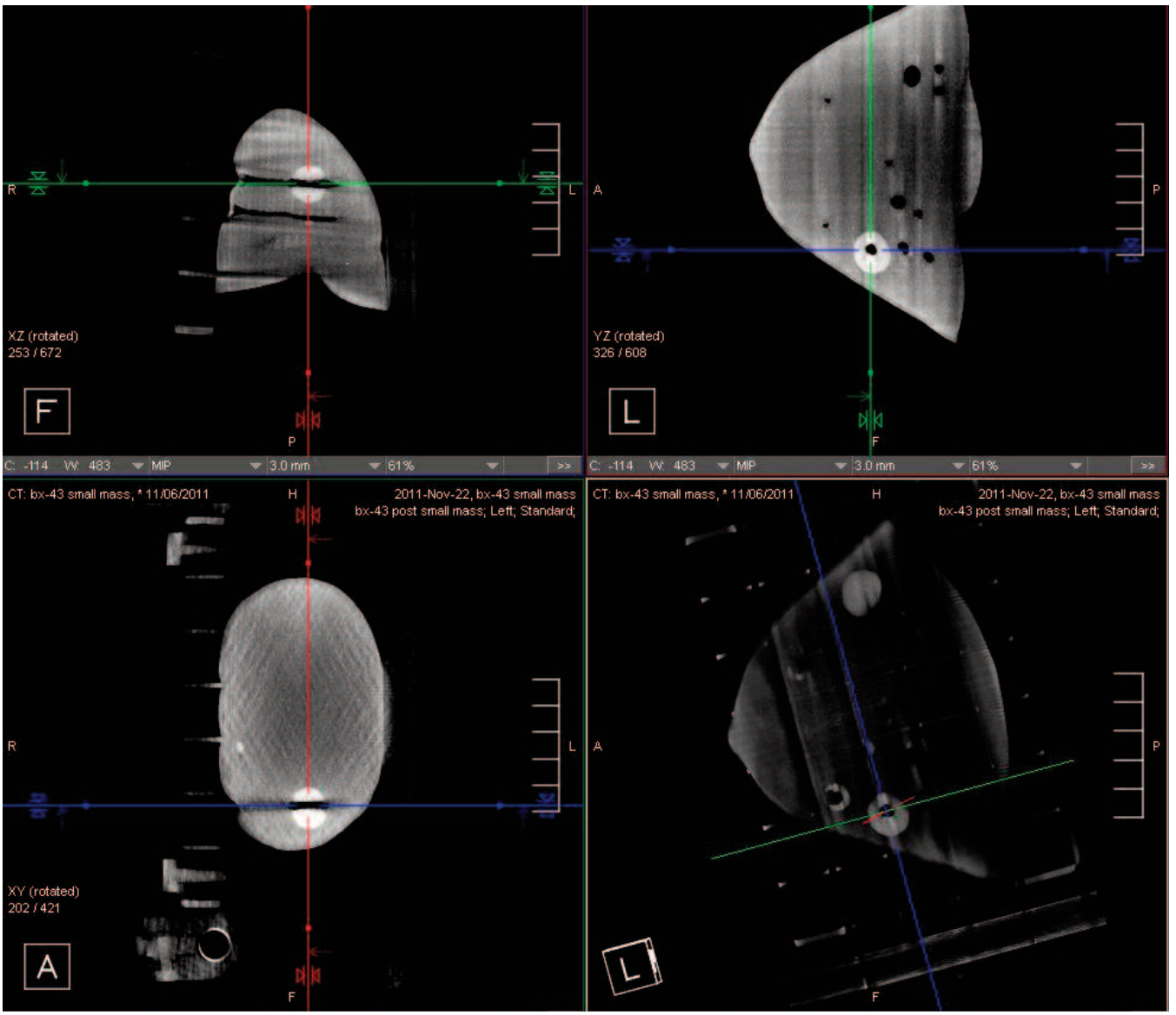


Figure B.3.2-4: KBCT-guided verification post-biopsy scan of mass in the small phantom. Cavity (crosshairs) indicates the area of tissue harvested by vacuum-assisted biopsy

Figure B.3.2-5: Faxitron image (left) and photo (right) of mass (arrows) harvested from the small phantom (Bx-38) using KBCT-guided biopsy

B.4. Dose Considerations

The standard stereotactic-guided biopsy procedure generally requires at least 9 exposures: the stereotactic-guided Scout, targeting (+/-15°), pre-fire (+/-15°), post-fire (+/-15°) and post-biopsy (+/-15°) images.

For KBCT-GBx, the average absorbed dose per scan (+/-20%) is dependent on the mA used (kVp and ms are constant during typical use). See Table B.4-1 for the dose associated with typically used mA values. Which mA to use is determined by the "Best mA" procedure (see Section 13.6.2) on the KBCT Console program calculated from the scout images. As indicated above in Section B.3.1, 3 scans are required for this procedure.

Table B.4-1: KBCT Dose vs. mA

mA	Dose (mGy) +/-20%
64	5.1
80	6.4
100	8
125	10
160	12.8
200	16

The average doses obtained during phantom imaging are shown in Table B.4-2.

Table B.4-2: Stereotactic vs. KBCT dose for biopsy for Small and Medium Phantoms

Modality	Dose per image (or scan) Average (mGy)		# of images (or scans)		Total Dose Average (mGy)	
	Small	Medium	Small	Medium	Small	Medium
Stereotactic	3.8	6.9	9	9	34.2	62.5
KBCT	5.1	10	3	3	15.4	30.0

B.5. Cleaning the Biopsy Bracket

The Biopsy Bracket's materials (polyethylene, ABS plastic and carbon fiber) have been selected to be cleaned with the standard hospital-grade antiviral cleaning solutions used to clean standard biopsy equipment. These hospital-grade cleaning solutions include: bleach, instrument detergent and disinfectant. The Biopsy Bracket should be fully disassembled (see Figure B.5-1) and cleaned after each biopsy procedure. The front grid holder section and back compression plate slide off the main frame.

When cleaning the inside of the Scanner, take care to avoid leaking liquid inside. Blood and other fluids are health risks. Take appropriate health and safety precautions when removing blood or other fluids.

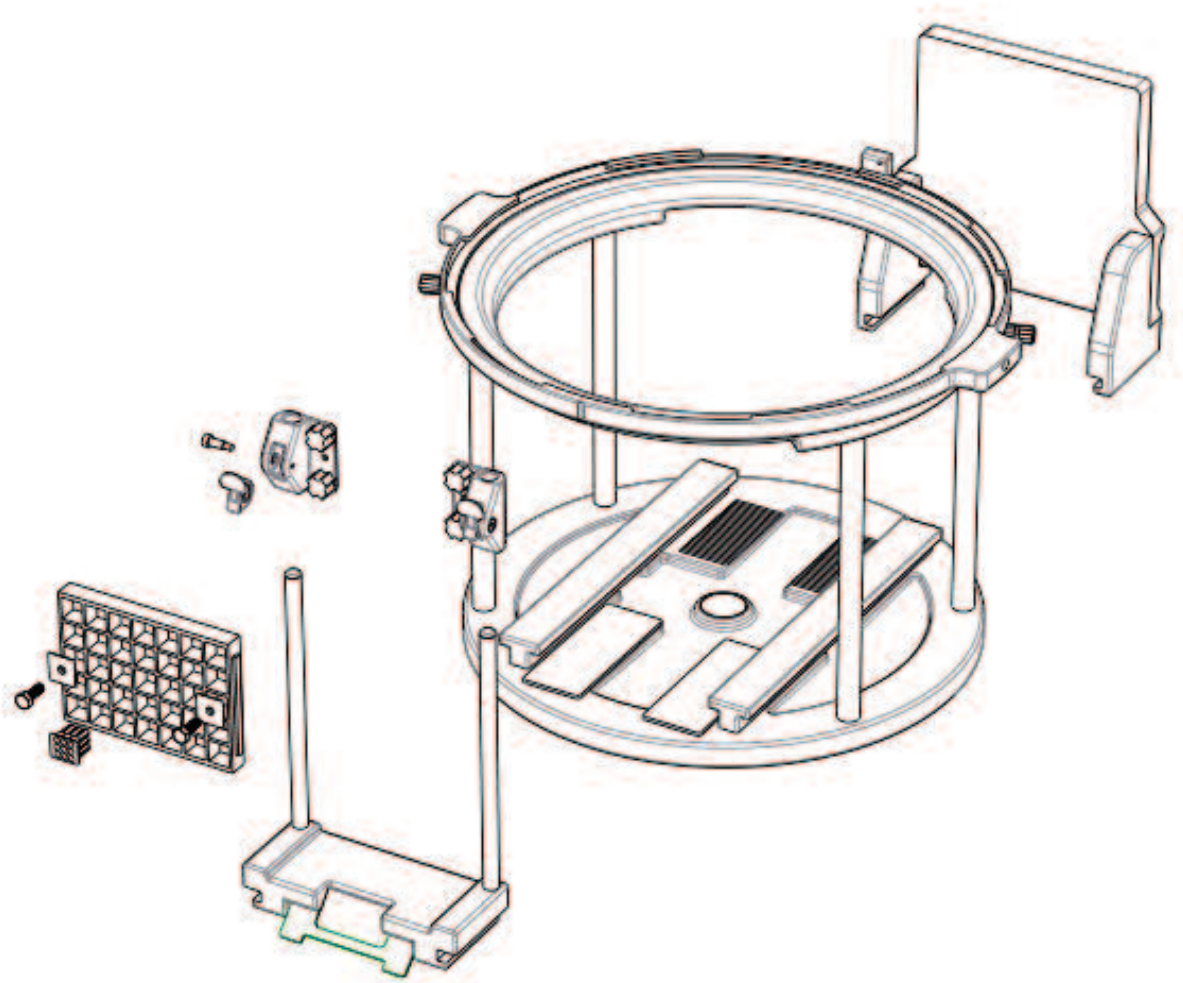


Figure B.5-1: Exploded view of the Biopsy Bracket. The Biopsy Bracket disassembles for easy cleaning.

Caution:

Do not use detergents or organic solvents to clean the system. Strong detergents, alcohol and organic cleaners may damage the finish and also may cause structural weakening over time.

B.6. Special Instructions for Using the Biopsy Bracket on Long Breasts

Although the vertical field of view at the object plane is limited to 16 cm, the Biopsy Bracket can be used with long breasts (chest wall to nipple up to 22 cm). The grid is mounted to the vertical carbon-fiber rods with clamp bearings that have a quick release tab. In this way the grid can be raised or lowered on the vertical rods to be in the correct location on the breast that contains the lesion of interest then locked in place. The patient table can be raised to the appropriate height to put the lesion within the 16 cm vertical field of view. Position would be verified with standard low-dose scout imaging before the biopsy procedure.

Appendix C. Collimator User Guide: Optional Accessory for Koning Breast CT

C.1 Introduction

The Collimator is used to limit the beam to an area of interest to minimize dose to the breast during standard KBCT imaging. The Collimator uses two (2) manually adjusted screw slides to move two (2) Pb shields, one located above and one located below the X-ray beam. The slides have 6 cm travel with an accuracy of 0.01 mm. A coated Pb shield is mounted to each carriage. Each shield has the ability to block all, none, or a portion of the X-ray beam. Their positions are independently controlled. The Collimator mounts to the front of the X-ray tube assembly with the existing holes.

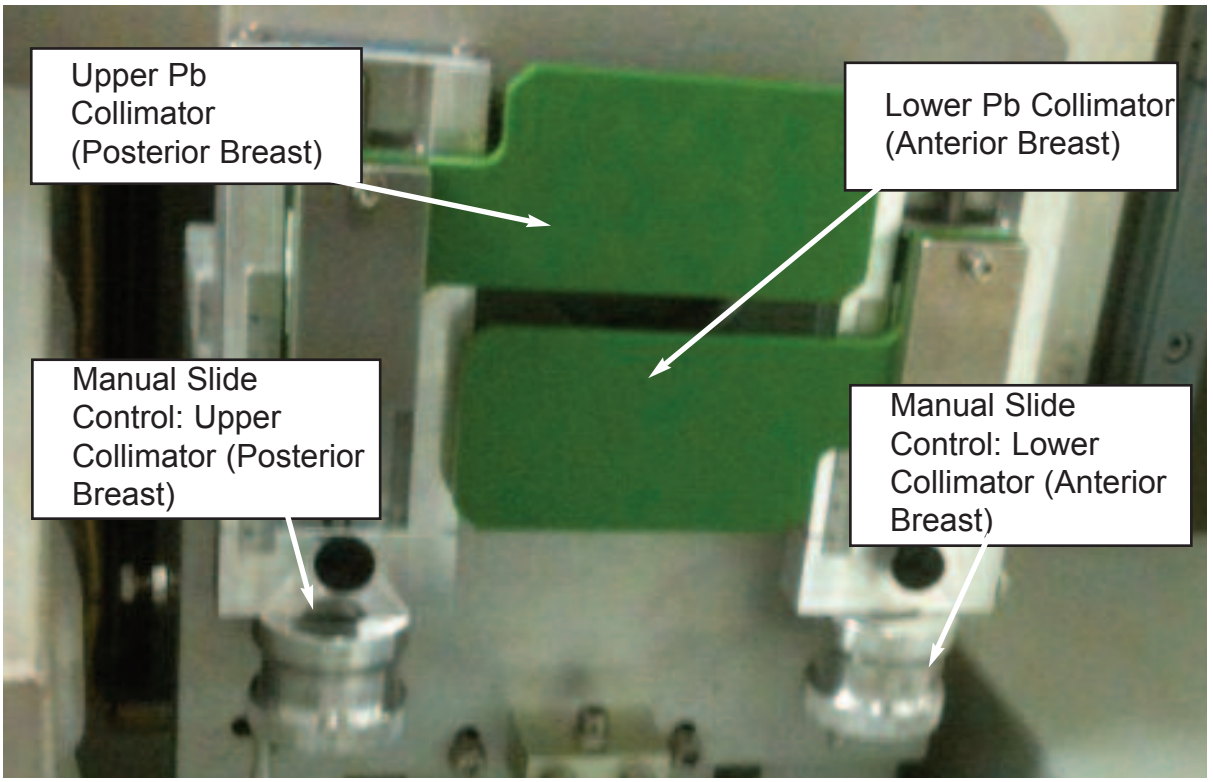


Figure C.1-1: Photo of Collimator mounted on the x-ray tube assembly

C.1.1 Indications for Use

The Collimator is an optional accessory to the standard Koning Breast CT system intended to limit the extent of X-ray exposure to the region of interest of the breast and reduce overall radiation dose to the breast.

C.1.2 Accessory Lifetime & Disposal

The Collimator is designed to last for the duration of the Koning Breast CT System's lifetime (that is, 7 years).

To properly remove and dispose of this accessory, you must follow the environmental laws, codes, guidelines and requirements established locally and for your state or province for the disposal of hazardous waste. Follow your company's guidelines for proper and safe disposal of potentially hazardous materials and residues. Contact Koning Corporation or Koning's Authorized Representative for assistance.

C.2. Calibration

This set of calibration images shows how the increments on the manual slides that control the lead blades positions can be used to give the user an idea how to set the collimator blades' positions. All images are low-dose scout images.

The upper collimator controls collimation at the posterior part of the breast. Its major scale is from 0 to 6 cm. The lower collimator controls collimation at the anterior part of the breast. Its major scale is from 6 to 0 cm. Both collimator slides have position indicators with 10 minor increments for each 1 cm of travel (0.1 cm or 1 mm resolution). The barrel of the manual slide control also has 100 increments (0.01 mm resolution). The positions noted in all the figures below were with the barrel set to 0. Change in position at the collimator results in a factor of about 6X at the object (breast).

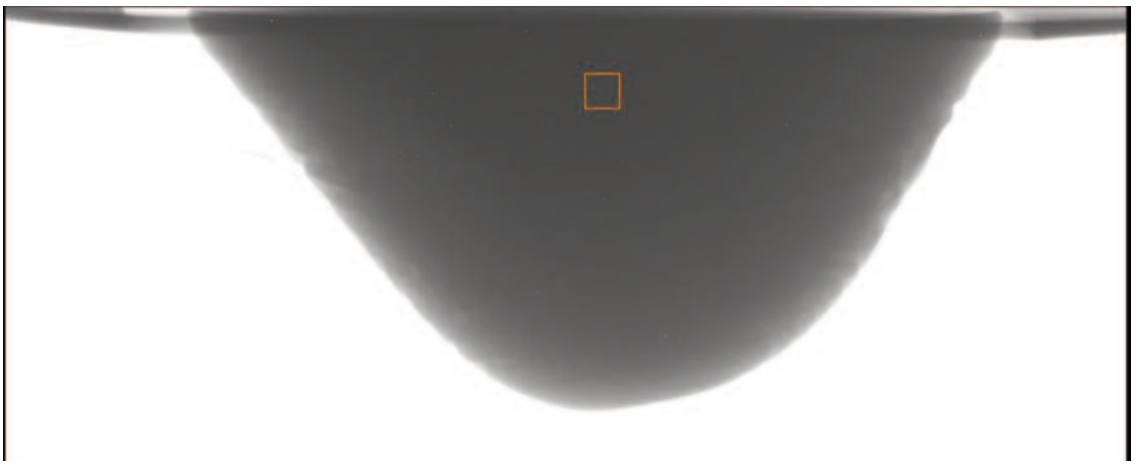


Fig C.2-1: No collimation. U(0.0) L(6.0)

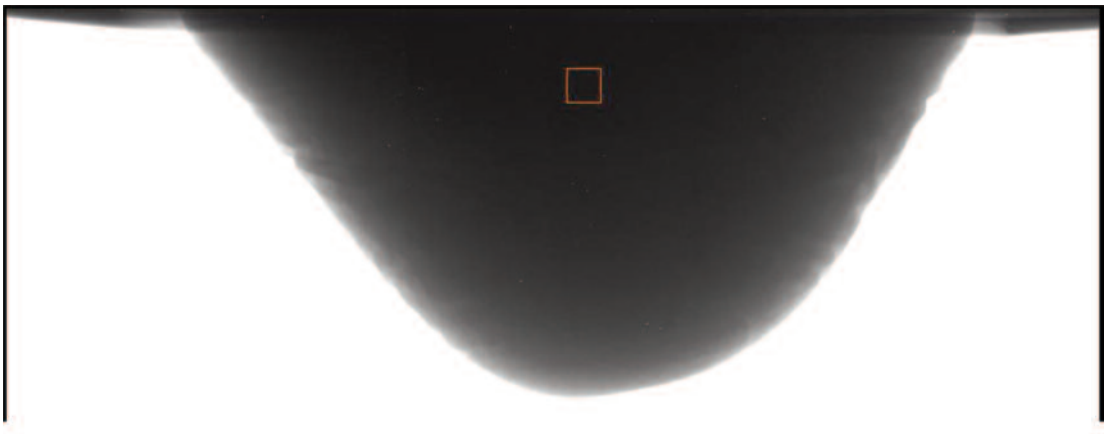


Figure C.2-2: U(0.1) L(6.0)

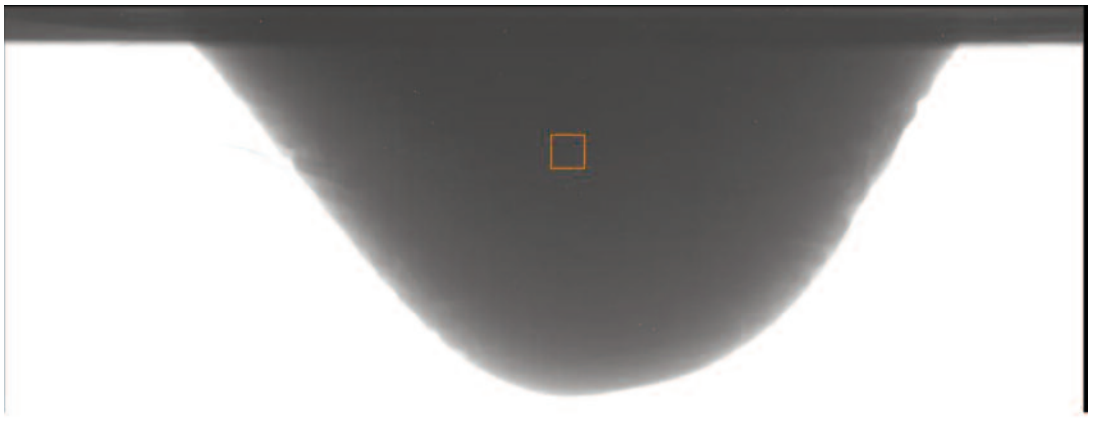


Figure C.2-3: U(0.3) L(6.0)

C.2.1 Upper Collimator (Posterior Breast)

Figure C.2-1, Figure C.2-2 and Figure C.2-3 were taken without the Biopsy Bracket in place. U(value) indicates the position of the upper (or posterior) collimator. L(value) indicates the position of the lower (or anterior) collimator. The lower collimator is completely out of the imaging field at position L(6.0).

Figure C.2.1-1, Figure C.2.1-2, Figure C.2.1-3, Figure C.2.1-4 and FIgure C.2.1-5 were taken with the Biopsy Bracket (see Appendix B) in place. The lower collimator was completely out of the field. For scale, the grid sections are 2 cm.

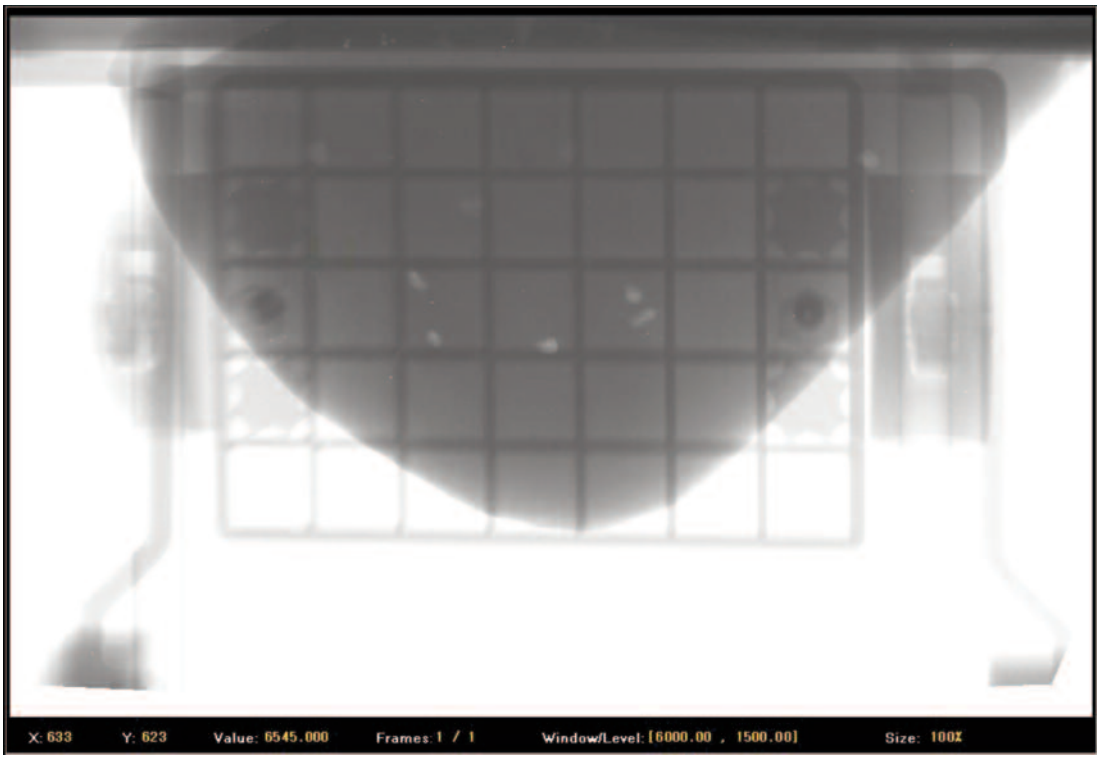


Figure C.2.1-1: U(0.0) L(6.0)

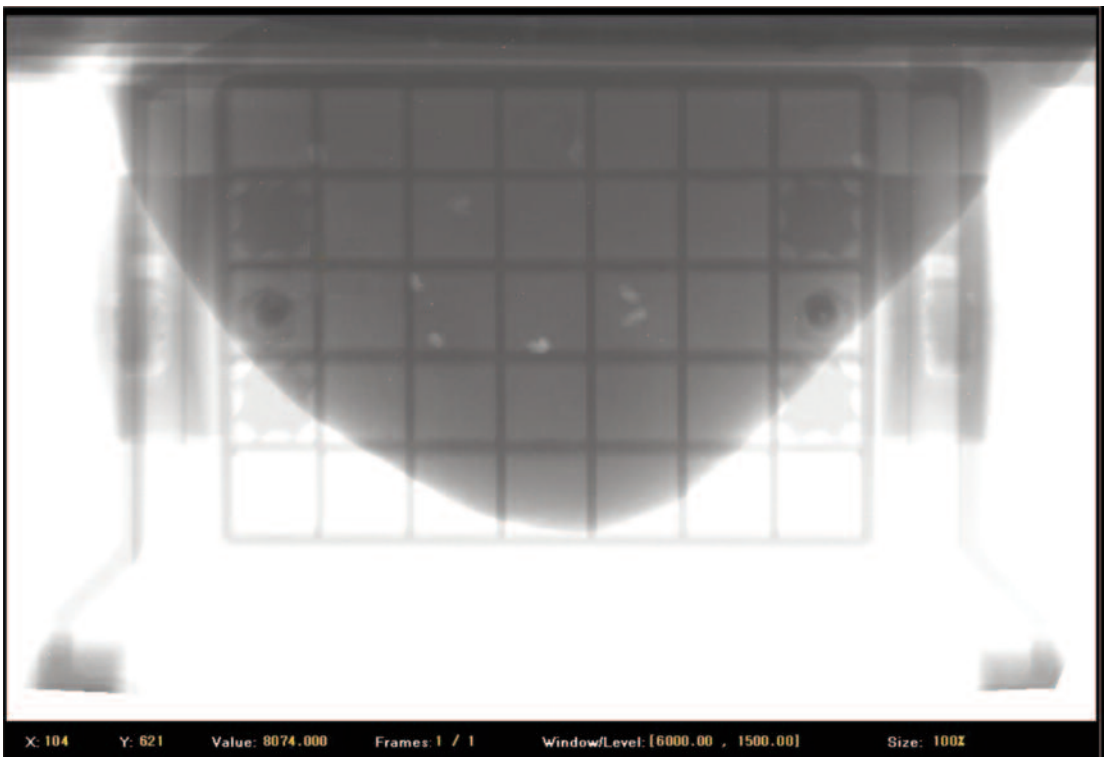


Figure C.2.1-2: U(0.1) L(6.0)

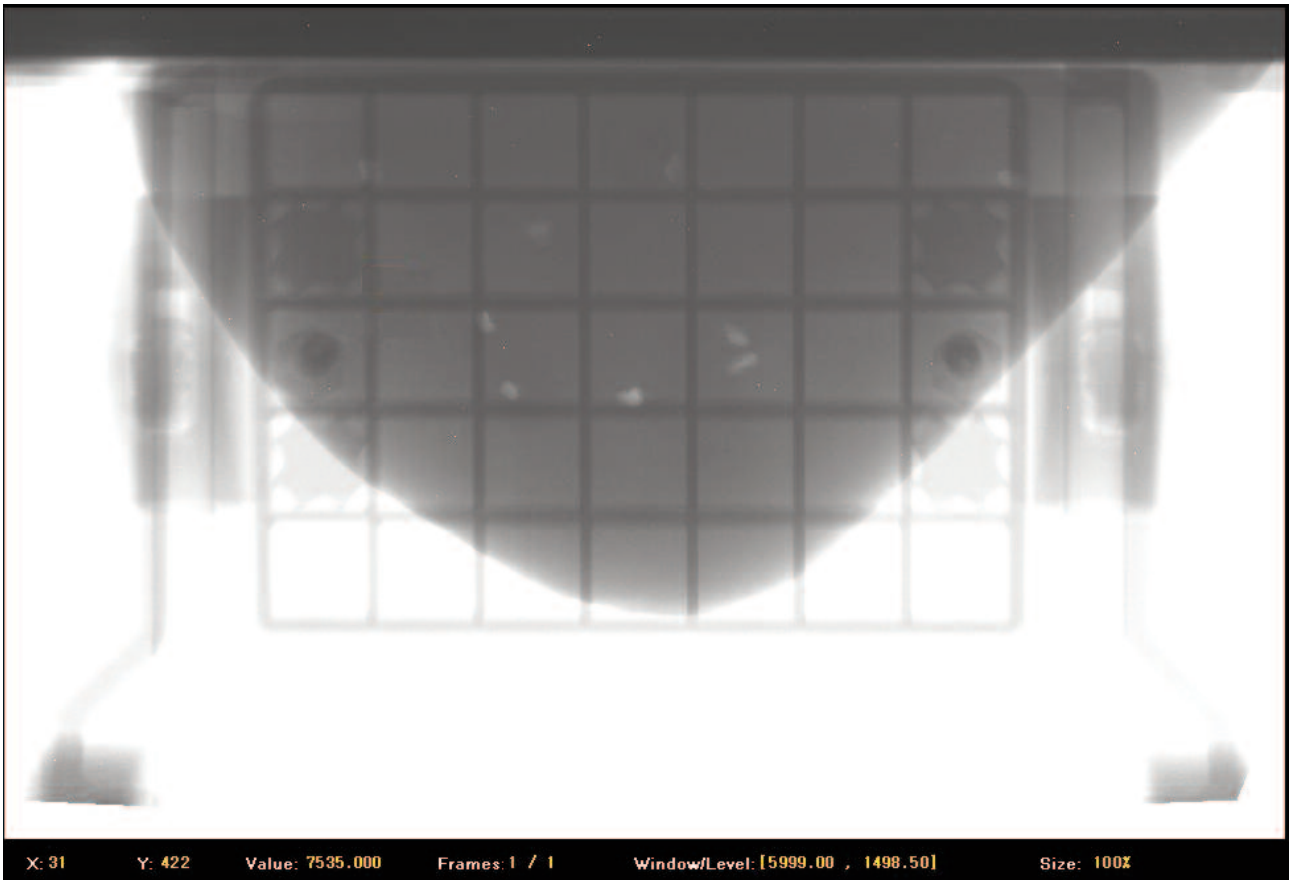


Figure C.2.1-3: U(0.3) L(6.0)

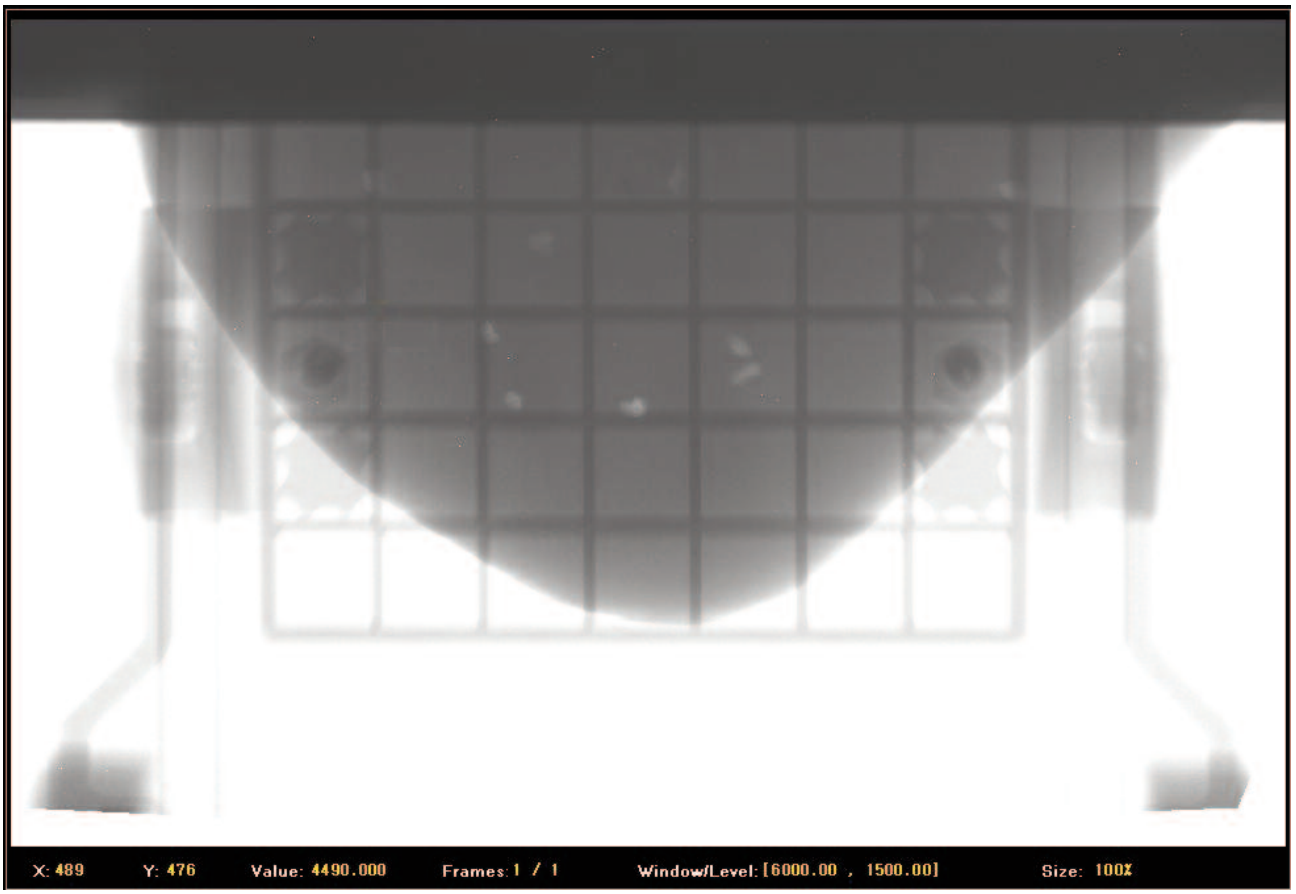


Figure C.2.1-4: U(0.5) L(6.0)

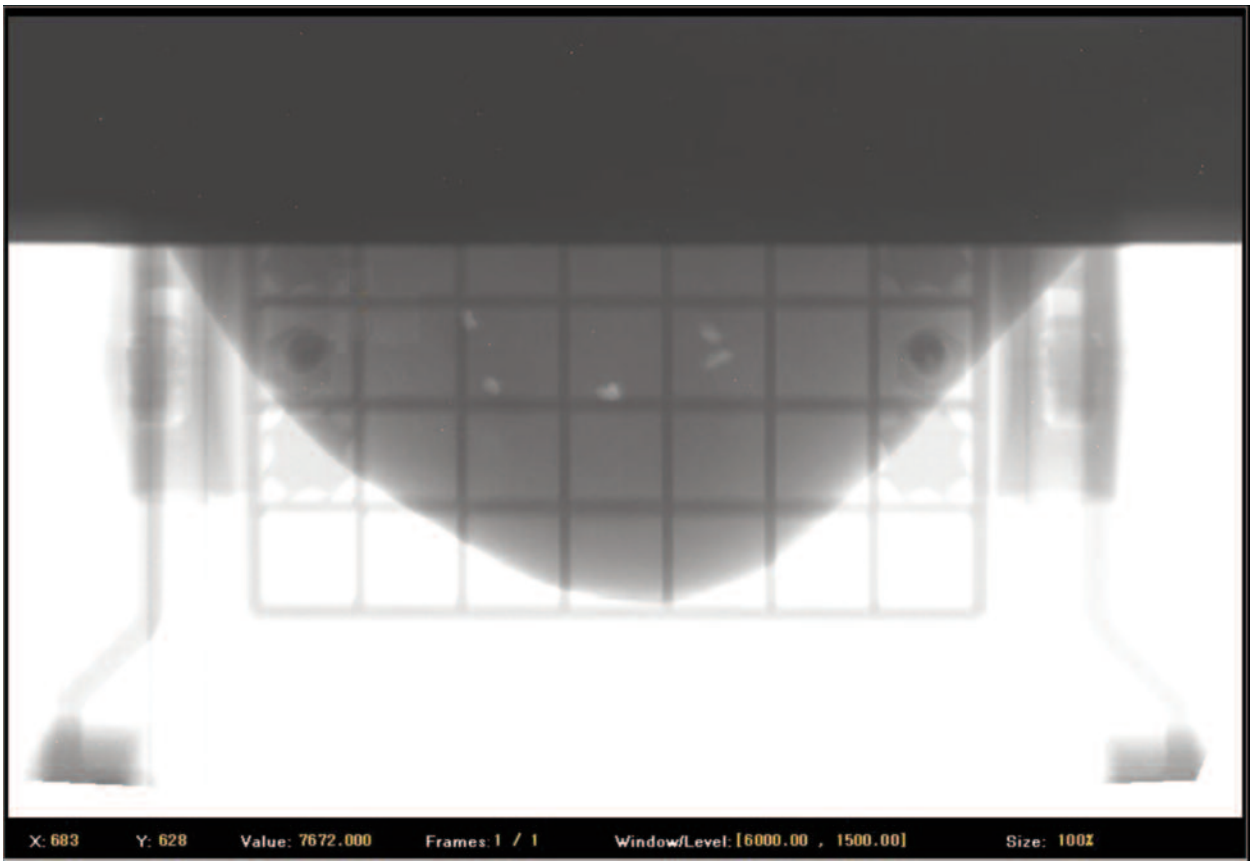


Figure C.2.1-5: U(1.0) L(6.0)

C.2.2 Lower Collimator (Anterior Breast)

Figure C.2.2-1, Figure C.2.2-2, Figure C.2.2-3 and Figure C.2.2-4 were taken with the Biopsy Bracket in place. For this series of figures the upper collimator blade was kept at U(0.3). For scale, the grid sections are 1 cm.

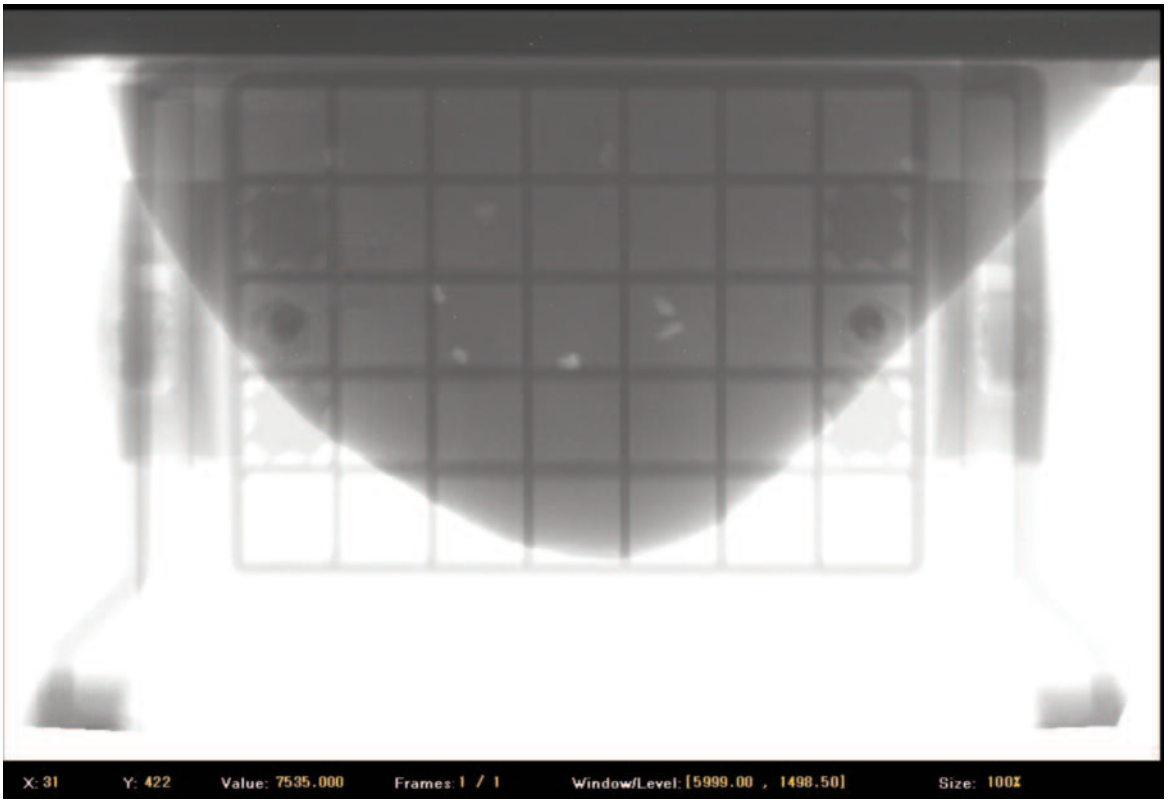


Figure C.2.2-1: U(0.3) L(5.0)

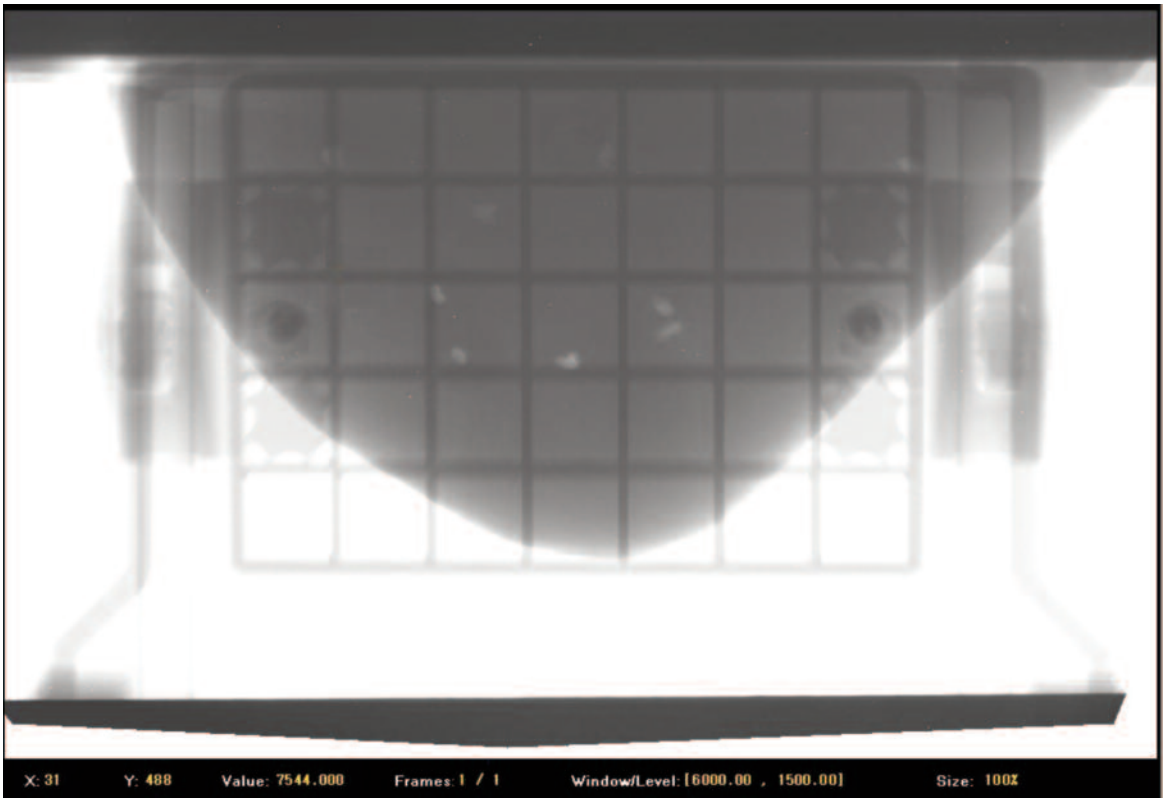


Figure C.2.2-2: U(0.3) L(3.0)

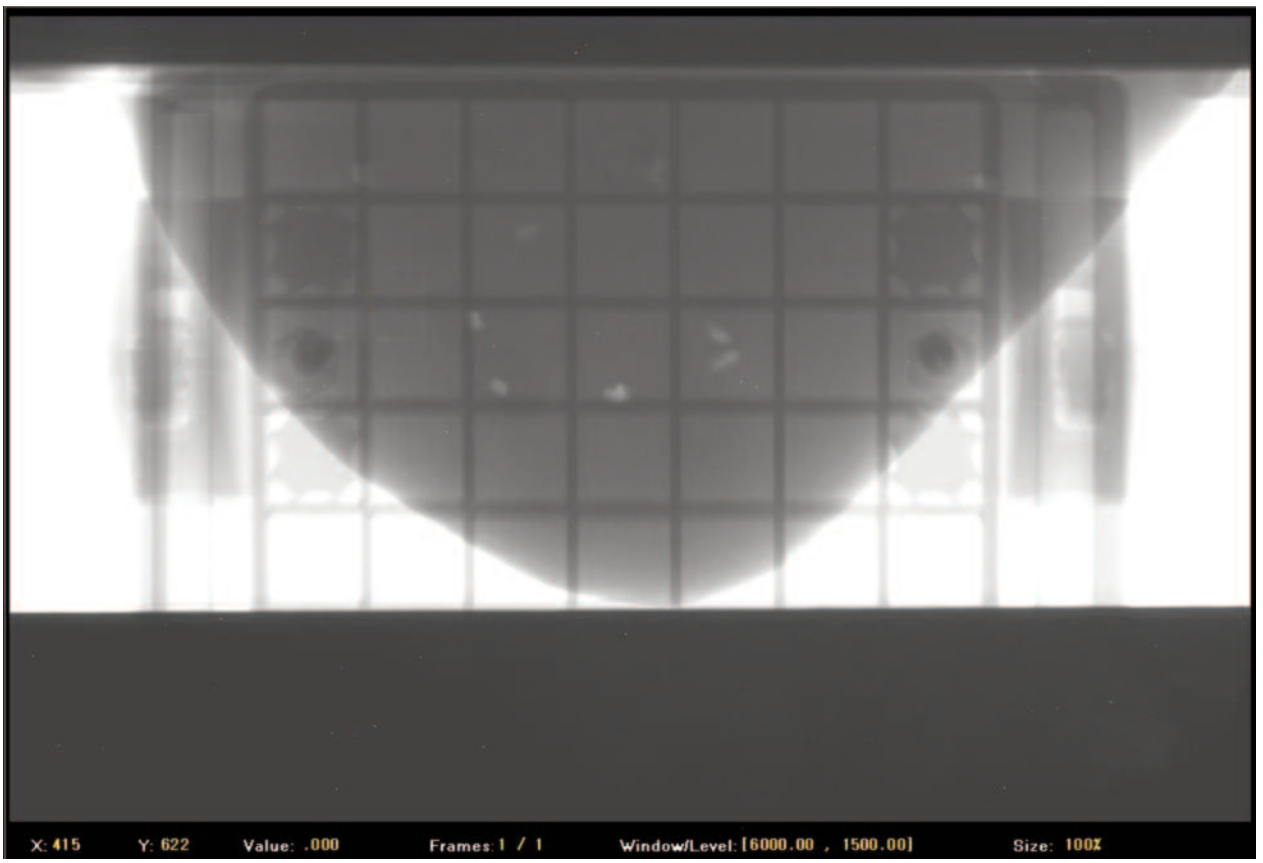


Figure C.2.2-3: U(0.3) L(2.5)

Figure C.2.2-4: U(0.3) L(2.0)

C.3. Dose Reduction with Collimator

The main purpose of the collimator is to limit X-ray radiation during the KBCT scan to the part of the breast which includes the lesion of interest so as to minimize dose to the unaffected parts of the breast (typically the nipple and chest wall). This dose reduction is in proportion to the length of the active area of the CT ion chamber exposed with and without collimation.

Some truncation artifacts are expected near the edges of the collimator blades, but they should not interfere with lesion characterization (in treatment monitoring) or in localization in biopsy for lesions at least 1 cm from the edges.

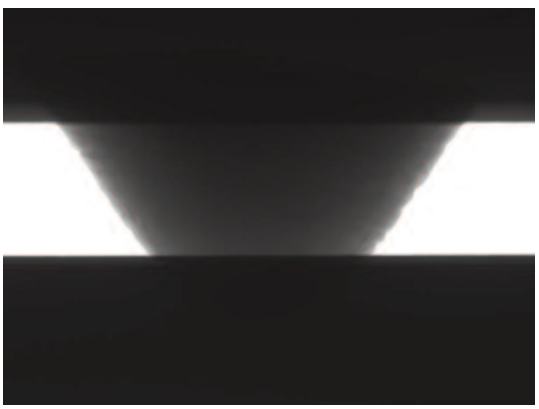


Figure C.3-1: Scout Image of breast phantom with X-ray collimation

As an example (Figure C.3-1), the collimator blades were centered on the masses in the anthropomorphic breast-imaging phantom (1 cm spacing at the blades, ~6 cm spacing at the phantom). Dose ($CTDI_{weighted}$) was measured with and without collimation with a 10 cm active area CT ion chamber.

- Using FDA-approved PMMA head dose phantom
- 49 kVp, 8ms/pulse, 100 mA
    - Dose with no collimation: 6.63 mGy
    - Dose after collimation: 3.32 mGy

In this example, the average glandular dose is cut in half and the anterior (nipple) and posterior (chest wall) regions are spared unnecessary radiation.

Figure C.3-2 shows the multi-planar and 3D views of the reconstructed breast phantom with X-ray collimation as shown in Figure C.3-1.

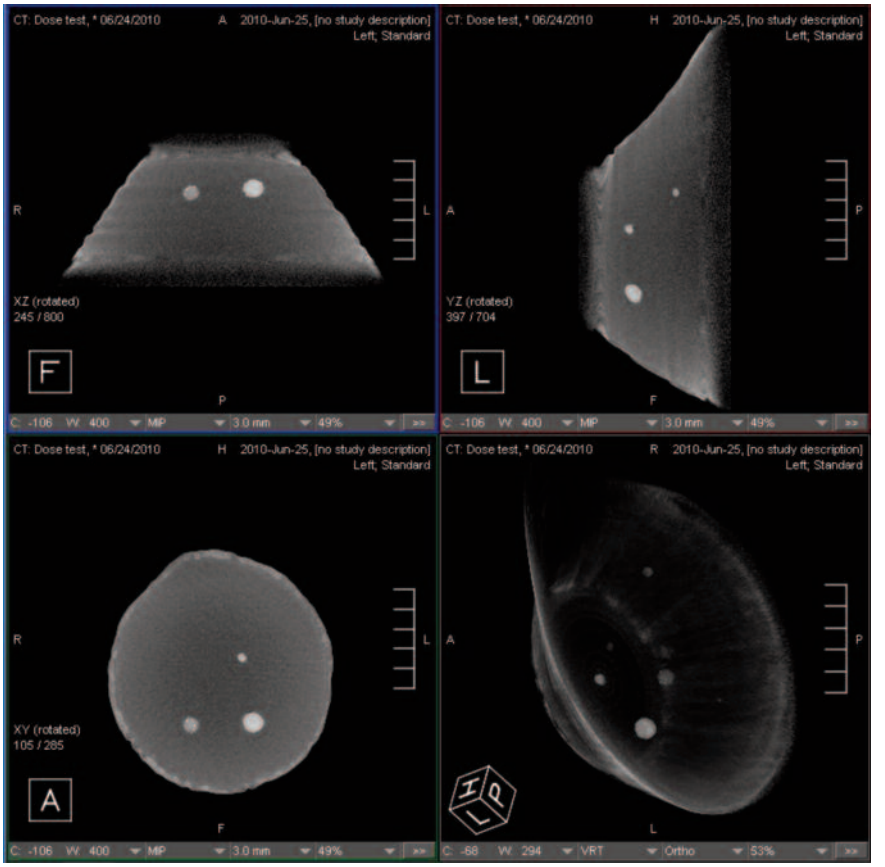


Figure C.3-2: Multi-planar and 3D views of the reconstructed breast phantom scanned with X-ray collimation as shown in Figure C.3-1

Appendix D Pivotal MRMC Study Summary

A pivotal Multi-Reader/Multi-Case (MRMC) study using images of BIRADS 1, 2, 3, 4, 5 diagnostic cases from the acquired non-contrast datasets from the acquisition studies at Elizabeth Wende Breast Clinic (EWBC) and University of Rochester Medical Center (URMC) was performed at the Medical University of South Carolina (MUSC) from June 2012 until April 2013 (IRB protocol # 00011686).

The pivotal MRMC study consisted of 18 readers and 236 cases. Subsequently, one case was excluded from the MRMC analysis because of a protocol violation (age was 37 [<40, per URMC protocol]; this was found and reported to the IRB), 7 cases were excluded from the MRMC analysis due to missing reader's response, so there were 228 cases valid for MRMC analysis. All radiologists were MQSA qualified interpreting physicians.

The study population was women presenting for diagnostic breast imaging, not a screening population

The KBCT images were read along with standard 2 view mammograms (Craniocaudal (CC) and Mediolateral Oblique (MLO) views). The Diagnostic Mammography includes CC and MLO views and any additional views needed for diagnostic workup.

D.1 Primary Analysis

The stated primary analysis of the pivotal MRMC study was to compare the performance of KBCT with diagnostic mammography with respect to the diagnosis of breast cancer of lesions using a 100 point Probability of Malignancy Score as the assessment of the visualized lesions and the ability to consistently assess these across various readers. The Area Under the Receiver Operating Characteristic Curve (AUC) was the primary performance measure for this assessment.

Table D.1-1: Primary Analysis

Modality	Mean Area	95% Confidence Interval
KBCT + 2-view Mammography	0.791	(0.740, 0.841)
Diagnostic Mammography	0.792	(0.739, 0.844)

The overall empirical ROC curves for KBCT+2 view Mammography and Diagnostic Mammography is presented in Fig. D.1-1.

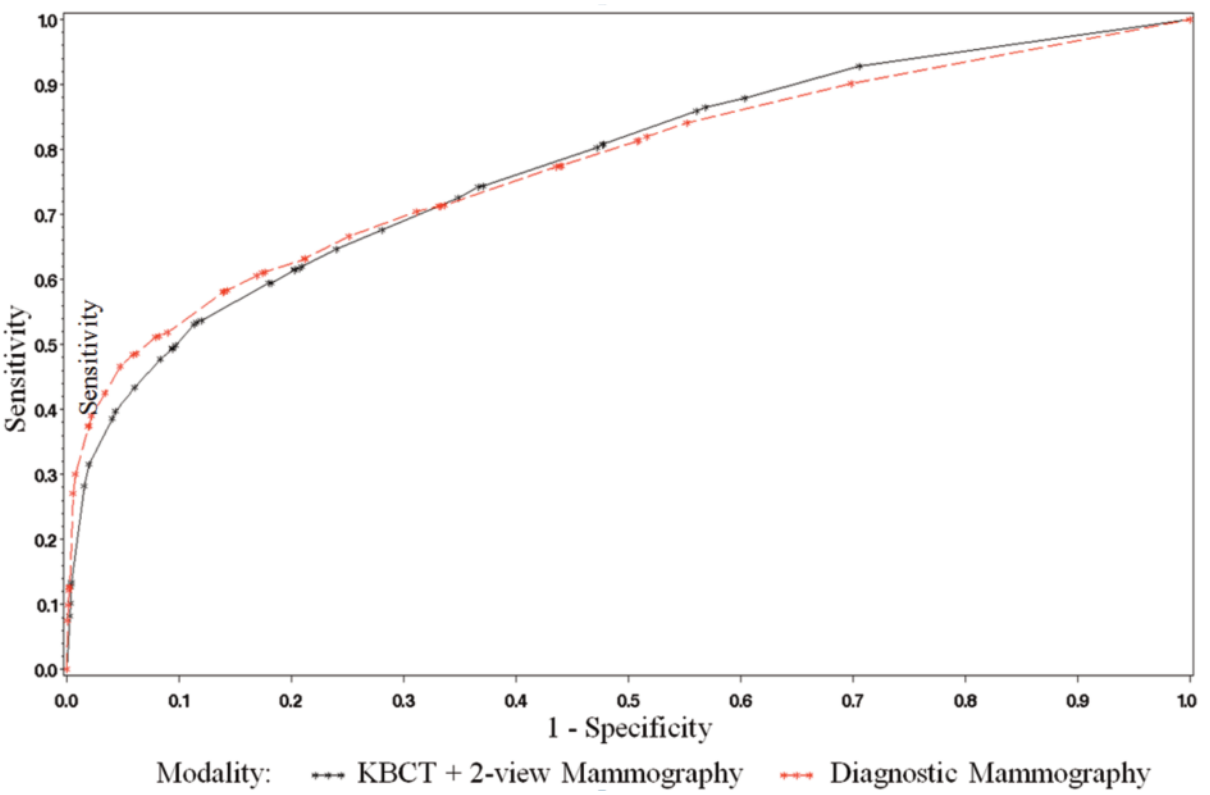


Figure D.1-1: Overall empirical ROC curves for KBCT+2 view Mammography and Diagnostic Mammography

D.2 Dose Analysis

For both Diagnostic Mammography and KBCT + 2-view Mammography to operate and be effective, a minimal amount of radiation must be used. The following table presents the radiation dose to the 220 patients in the pivotal MRMC study.

Note: 236 cases were originally included in the MRMC study in which: one case was excluded due to acquisition protocol violation; 15 cases were excluded from the dose analysis due to missing dose information on mammography images, so there are 220 cases included for dose analysis.

Table D.2-1: Dose Analysis

Statistic	KBCT	Diagnostic Mammography
N	220	220
Mean (mGy)	10.60	9.57
Std (mGy)	3.89	5.16
Median (mGy)	9.85	8.67
Minimum (mGy)	3.28	1.61
Maximum (mGy)	21.62	39.99

Here the represented dose for “KBCT” is from KBCT alone (without CC and MLO mammography views), and the represented dose for “Diagnostic Mammography” is from any additional views needed for diagnostic workup (without CC and MLO mammography views).

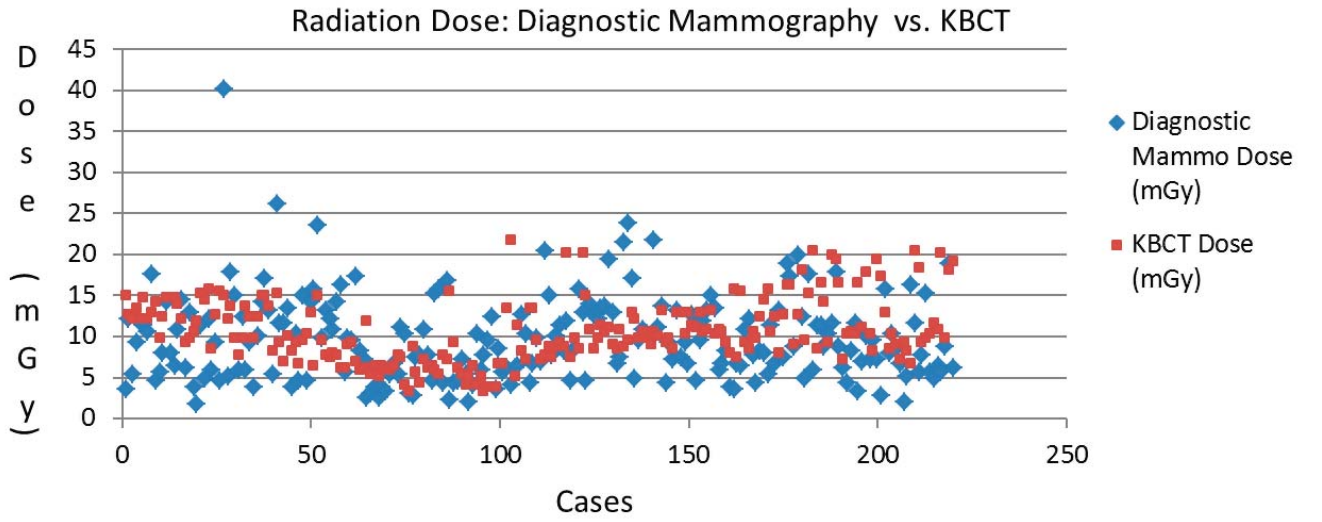


Figure D.2-1: Comparison of KBCT dose to diagnostic mammography dose for each patient.

D.3 Secondary Analysis

There were several secondary performance measures analyzed in the pivotal MRMC study. Several of these that highlight the performance of KBCT are presented below.

- The performance of KBCT + 2-view Mammography and Diagnostic Mammography in diagnostic accuracy (sensitivity and specificity) using the BIRADS score as the condition.
- The AUC for lesion subtype (mass, calcifications).
- The lesion based FROC analyses.
- The performance of KBCT alone and KBCT + 2-view Mammography.

D.3.1 Sensitivity and Specificity

The condition BIRADS ≥ 4 is used as the criteria to calculate the sensitivity and specificity.

- Negative cases and case with benign biopsies for which a reader scored below BIRADS 4 will be counted as true negatives (TN).
- Negative cases and case with benign biopsies for which a reader scored BIRADS 4 or above will be counted as false positive (FP).
- Cases with cancer for which a reader scored below BIRADS 4 will be counted as false negatives (FN).
- Cases with cancer for which a reader scored BIRADS 4 or above will be counted as true positives (TP).

Estimated sensitivity = number of TP / (number of TP + number of FN)
Estimated specificity = number of TN / (number of TN + number of FP)

The estimation technique is logistic regression with treating readers and cases as random.

Table D.3.1-1: Sensitivity and Specificity Analysis

Parameter	Modality	Mean Estimate	95% Confidence Interval
Sensitivity	KBCT + 2-view Mammography	88.03	(85.54, 90.15)
	Diagnostic Mammography	82.78	(79.74, 85.44)
Specificity	KBCT + 2-view Mammography	34.45	(31.76, 37.25)
	Diagnostic Mammography	41.00	(38.12, 43.94)

D.3.2 The AUC by Lesion Subtype

The POM scores by each of the 18 readers for each lesion type were analyzed using an MRMC analysis of the AUC based on the POM scores. Lesion types are defined as:

- Mass (architectural distortion is included in the mass category; if a mass is associated with calcifications, the lesion is classified as a mass)
- Calcifications

Table D.3.2-1: AUC by Lesion Subtype

Lesion Subtype	Modality	Mean AUC	95% Confidence Interval
Mass	KBCT + 2-view Mammography	0.831	(0.778, 0.885)
	Diagnostic Mammography	0.833	(0.778, 0.887)
Calcification	KBCT + 2-view Mammography	0.713	(0.601, 0.826)
	Diagnostic Mammography	0.757	(0.645, 0.868)

D.3.3 The Area Under the Free Response Operating Curve (FROC)

Specific lesions identified across multiple readers were determined from lesion locations and snapshots that were recorded in the electronic case report forms (eCRF) to provide lesion mapping. The data was organized and collected so that an FROC analysis could be conducted.

There are two approaches to the analysis of imaging data that are based on the detection of a disease, where the truth of the disease state (i.e. lesion or lesions) is known through some outside agency. The first type of analysis is a case or patient based approach. In this approach, if any lesion detected is rated by the observer to be malignant, then the patient or case is rated as malignant. Otherwise the patient or case is considered normal. The ROC curve is the plot of true positive fraction (sensitivity) vs. false positive fraction (1-specificity). In this current setting, the ROC analysis measures the ability of the evaluator to separate normal from abnormal patients or cases. The probability of correct classification is the area under the ROC curve (AUC).

The second approach is the lesion based analysis. In this approach each lesion is noted and given a confidence rating as to malignant or not. Based on the truth standard, it is determined whether the malignant lesions noted are in fact a malignant lesion and qualifies as lesion localization (LL) – (like a case based location-level "true positive") – or not a malignant lesion and is classified as non-lesion localization (NL) – (like a case based location-level "false positive").

The FROC curve is defined as the plot of lesion localization fraction (LLF) vs. non-lesion localization fraction (NLF), where LLF is defined as the total number of lesion localizations at a given threshold divided by the total number of lesions, and NLF is defined as the total number of non-lesion localizations at that threshold divided by the total number of images.

Since the AUC for the ROC curve is a probability, the total curve is contained in a unit square. The FROC curve is not contained within the unit square. While the y-axis is the probability that a lesion localization occurs, estimated by LLF, the x-axis is the mean number of non-lesion localizations per image, estimated by NLF. Thus, the x-axis can potentially tend to large values, especially if the total lesion area is much smaller than the total image area. Partial area measures, such as the area under the FROC curve to the left of a predefined abscissa value or the value of the ordinate at the predefined abscissa have been used as figures of merit.

The FROC plot for the average reader results of KBCT + 2-view mammography and diagnostic mammography alone for a predefined cut off value for NLF of 0.6 is presented in Fig. D.3.3-1.

Table D.3.3-1: Area Under the Free Response Operating Curve

Difference	FROC Figure of Merit	Std Err
(KBCT + 2-view Mammography) - (Diagnostic Mammography)	-0.068	0.0187

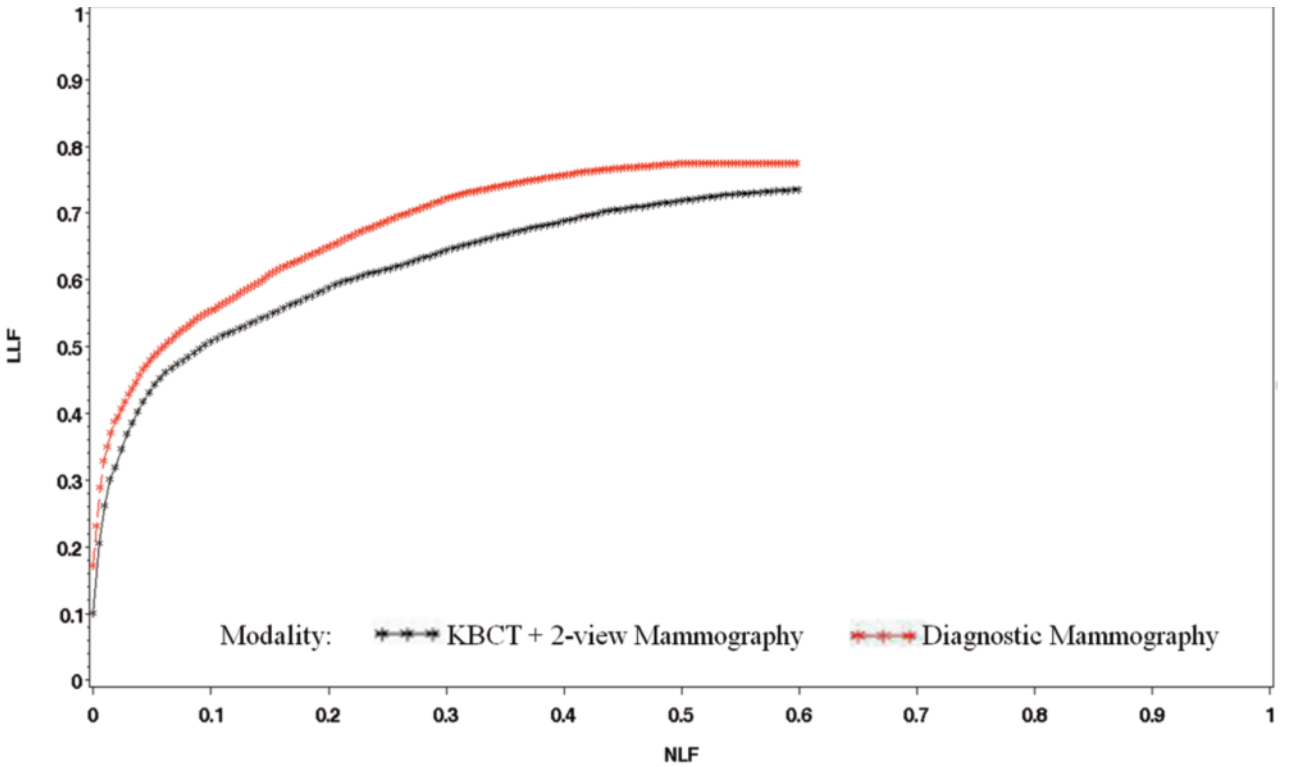


Figure D.3.3-1: The FROC plot for the average reader results of KBCT + 2-view mammography and diagnostic mammography alone for a predefined cut off value for NLF of 0.6

D.3.4 KBCT and KBCT + 2-view Mammography

D.3.4.1 AUC

The Probability of Malignancy (POM) scores provided by each of the 18 readers in the MRMC study were analyzed using an MRMC analysis for the AUC based on the POM scores.

Table D.3.4.1-1: AUC Analysis

Modality	Mean AUC	Std Err	Confidence Interval
KBCT	0.770	0.026	(0.718, 0.821)
KBCT + 2-view Mammography	0.791	0.026	(0.740, 0.841)

D.3.4.2 Sensitivity and Specificity

Sensitivity and specificity for each of the 18 readers were estimated using the criteria of BIRADS score ≥ 4 as the indication of positive result. Please refer to Section D.3.1 for the calculation of sensitivity and specificity.

The estimation technique is logistic regression with treating readers and cases as random.

Table D.3.4.2-1: Sensitivity Analysis

Modality	Sensitivity	Confidence Interval
KBCT	79.4	(76.1, 82.4)
KBCT + 2-view Mammography	88.0	(85.5, 90.2)

Table D.3.4.2-2: Specificity Analysis

Modality	Specificity	Confidence Interval
KBCT	47.3	(44.3, 50.3)
KBCT + 2-view Mammography	34.5	(31.8, 37.3)

D.3.4.3 Lesion Type Sub-Set Analysis

The POM scores for each lesion type were analyzed using an MRMC analysis for the AUC based on the POM scores. The results are presented below for the 18 readers for the two conditions KBCT alone, KBCT plus standard 2-view mammograms (CC and MLO).

Table D.3.4.4.3-1: Calcification Analysis

Modality	Mean AUC	Std Err	Confidence Interval
KBCT	0.667	0.058	(0.552, 0.781)
KBCT + 2-view Mammography	0.713	0.057	(0.601, 0.826)

Table D.3.4.4.3-2: Mass Analysis

Modality	Mean AUC	Std Err	Confidence Interval
KBCT	0.813	0.028	(0.757, 0.869)
KBCT + 2-view Mammography	0.831	0.027	(0.778, 0.885)

Appendix Z. Message Listing

The following tables contain a listing of all system, warning, and error messages which the KBCT Console program may display.

Z.1 System Messages

All messages output by the System during normal operation are listed and explained in Table Z.1-1 below.

If a message is received which is not listed in the following tables, please contact Koning Corporation or Koning's Authorized Representative for assistance.

Table Z.1-1: System messages

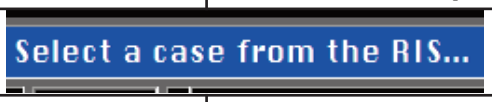
Message ID	Text	Explanation
CM-101		
	Select a case from the RIS...	Seen when querying for a case to load from the RIS.
CM-201		
	Select a case from the local database...	Seen when querying for a case in the Console workstation's local database.
CM-301		
	Creating a new case...	Seen when creating a new case.
CM-401		
	Editing case...	Seen when editing existing case information.
CM-501		
	Loading projections...	May be seen when loading acquired projections images for viewing.
CM-701		
	Loading the slices... x loaded	May be seen when loading reconstructed slices for viewing. Indicates progress by showing how many images have been loaded.
CM-702		
	Loading slices...	May be seen when loading reconstructed slices for viewing. Typically shown very briefly prior to message CM-701.

Table Z.1-1: System messages

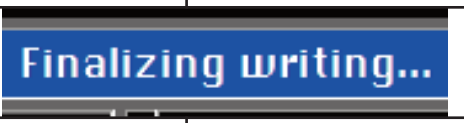
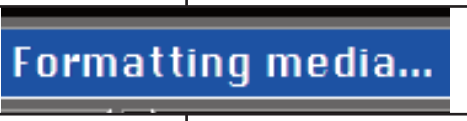
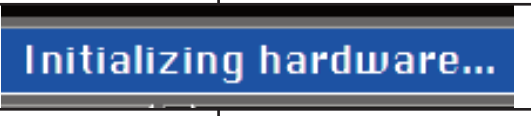
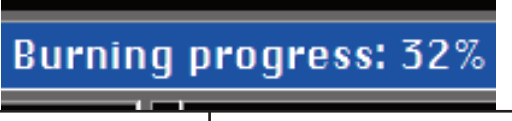
Message ID	Text	Explanation
CM-901		
	Building content...	Seen when burning a case to DVD, while the files are being burned.
CM-902		
	Burning the case...	Seen when burning a case to DVD, at the start of operation.
CM-903		
	Checking content...	Seen when burning a case to DVD, when determining available space on the DVD.
CM-904		
	Completed!	May be seen when burning a case to DVD, when the burn operation is completed. Typically not seen.
CM-905		
	Finalizing writing...	May be seen when burning a case to DVD, when the burn is being finalized. Typically not seen.
CM-906		
	Formatting media...	May be seen when burning a case to DVD, when the DVD is being formatted. Typically not seen.
CM-907		
	Initializing hardware...	May be seen when burning a case to DVD, when the DVD drive is being initialized. Typically not seen.
CM-908		
	Optimizing laser intensity...	May be seen when burning a case to DVD, when the DVD drive's laser intensity is being optimized. Typically not seen.
CM-909		
	Burning progress: x%	May be seen when burning a case to DVD, while the DVD is being burned. Typically not seen.

Table Z.1-1: System messages

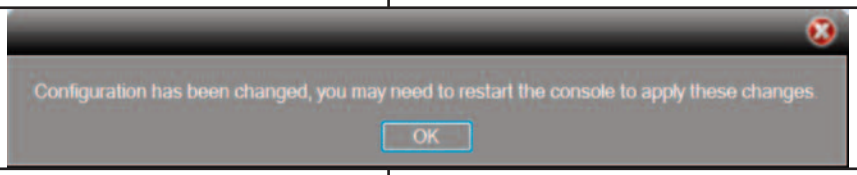
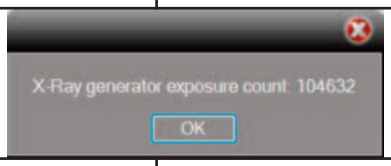
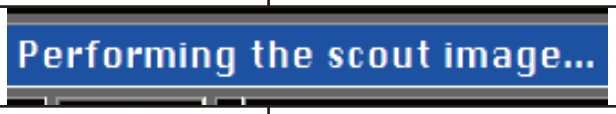
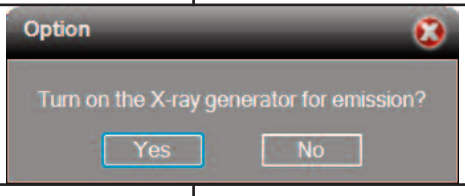
Message ID	Text	Explaination
CM-910		
	Validating current media...	May be seen when burning a case to DVD, when validating that the disc in the drive is supported. Typically not seen.
CM-1001		
	Restoring the case...	Seen when restoring images from DVD backup.
CO-101		
	Configuration has been changed, you may need to restart the console to apply these changes.	Seen when saving changes to the system configuration.
DA-001		
	X-ray generator exposure count: x	Seen when viewing the exposure count. Displays the exposure count.
DA-002		
	Reading exposure count...	Seen when viewing the exposure count.
DA-003		
	hh:mm:ss (AM/PM): No warnings from X-ray generator	Message logged when the X-ray generator clears a warning.
DA-201		
	Performing the scout image...	Seen when acquiring a scout image.
DA-202	12:01:33 PM: Scout image with kvp:49 ma:16 ms:8 Estimated mGy:0.001 Patient:Roe, Jane[1234]	
	hh:mm:ss (AM/PM): Scout image with kvp: x ma: y ms: z Estimated mGy: w Patient: (patient name) [(patient ID)]	Message logged when a scout image is acquired. (DA-204 is logged instead for dark scout images.)
DA-203		
	Turn on the X-ray generator for emission?	Appears when logged in as an Experiment and acquiring a scout image. Select “No” to acquire a dark image.

Table Z.1-1: System messages

Message ID	Text	Explaination
DA-204		
	hh:mm:ss (AM/PM): Scout image without exposure	Message logged when a dark scout image is acquired.
DA-301		
	Calculating...	Seen during calibrations (all kinds). Indicates that the system is performing calculations necessary to the calibration.
DA-302		
	Hi img calibration...	The system is in the process of performing high image calibration. This is one of the steps of gain calibration.
DA-303		
	HL Ratio calibration...	The system is in the process of performing HL ratio calibration. This is one of the steps of gain calibration.
DA-304		
	Lo img calibration...	The system is in the process of performing low image calibration. This is one of the steps of gain calibration.
DA-305		
	Offset calibration...	The system is in the process of performing an offset calibration.
DA-306		
	Doing gain calibration...	Seen at the start of a gain calibration.
DA-307		
	Performing offset calibration...	Seen at the start of an offset calibration...
DA-308		
	Acquisition finished. Moving data from temporary path to target path.	May be seen at the end of a scan, just before the software begins moving the acquired data from the temporary path to the data path. (Both locations are specified by the system configuration.)

Table Z.1-1: System messages

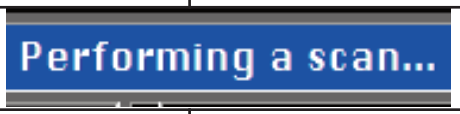
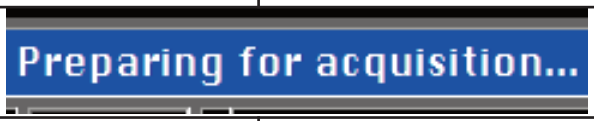
Message ID	Text	Explanation
DA-309		
	Opening the scan controls...	May be seen while the scan controls are loading. This operation typically completes before the message can be perceived.
DA-310		
	Performing a scan...	Seen when performing a scan, prior to the start of data acquisition.
DA-311		
	hh:mm:ss (AM/PM): Scan sequence with kVp:x mA:y ms:z Estimated mGy:w Patient: (patient name) [(patient ID)]	Message logged when a scan is completed.
DA-312		
	hh:mm:ss (AM/PM): Interrupted scan sequence with kvp: x ma: y ms: z Estimated mGy: w	Message logged when a scan sequence is stopped prior to the start of exposure. Note that where exposure has begun, DA-313-ER is logged instead.
DA-313		
	Copying file from [x] to [y]	May be seen at the end of a scan, while the software is moving the acquired data from the temporary path to the data path. (Both locations are specified by the system configuration.)
DA-314		
	Preparing for acquisition...	Seen during a scan, prior to acquisition of images.
GN-001		
	Closing console...	May be seen when exiting the KBCT Console program.
IR-201		
	hh:mm:ss (AM/PM): Reconstruction with protocol:(Reconstruction Mode) for patient: (Patient Name)[(Patient ID)]	Message logged when a reconstruction is performed.
IR-202		
	Processing the projections... x% complete	Seen during reconstruction. Indicates % completion of operations on projection images.

Table Z.1-1: System messages

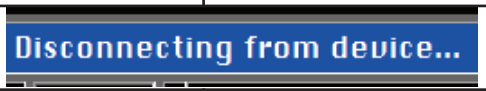
Message ID	Text	Explanation
IR-203		
	Processing the slices... x% complete	Seen during reconstruction. Indicates % completion of operations on slice images.
IR-204		
	Performing the reconstruction...	Seen during reconstruction, while selecting a VOI, reconstruction mode, and cupping correction protocol.
IR-301		
	Publishing DICOM images...	May be seen when publishing DICOM images. Typically shown very briefly prior to message IR-302.
IR-302		
	Publishing images x% complete	Seen when publishing DICOM images. Indicates progress in terms of % completed.
LM-001		
	Ready	Seen when the System is in a ready state.
MC-001		
	Connecting to the device...	Seen when establishing a connection with the Scanner.
MC-002		
	Disconnecting from device...	Seen when disconnecting from the Scanner.
MC-003		
	Homing servos...	The system servos are in the process of finding their home positions. May be seen when eastablishing a connection.
MC-801		
	Checking connections...	Seen when using the KBCT Console program's built in connection checks.

Table Z.1-1: System messages

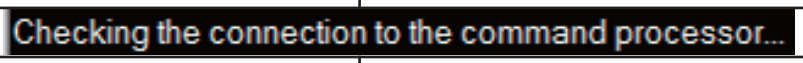
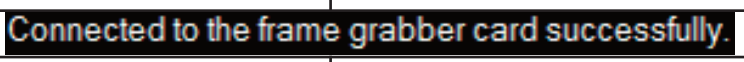
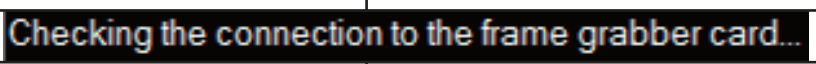
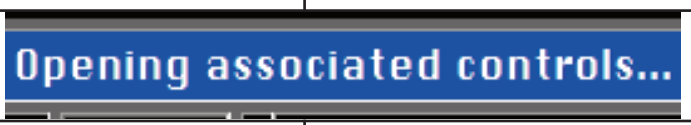
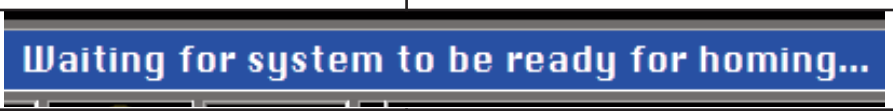
Message ID	Text	Explaination
MC-802		
	Connected to the command processor successfully.	Seen when using the KBCT Console program's built in connection checks. Indicates a successful attempt to connect to the command processor.
MC-803		
	Checking the connection to the command processor...	Seen when using the KBCT Console pogram's built in connection checks, prior to attempting a connection to the command processor.
MC-804		
	Finished with connection tests.	Seen at the conclusion of KBCT Console program's built in connection checks. This message is also logged with a time stamp.
MC-805		
	hh:mm:ss (AM/PM): Beginning connection tests.	Message logged when beginning the KBCT Console program's built in connection checks.
MC-806		
	Connected to the frame grabber card successfully.	Seen when using the KBCT Console program's built in connection checks. Indicates a successful attempt to connect to the frame grabber card.
MC-807		
	Checking the connection to the frame grabber card...	Seen when using the KBCT Console pogram's built in connection checks, prior to attempting a connection to the frame grabber card.
MC-008		
	Opening associated controls...	May be seen when opening the software controls for a servo's motion or an X-ray parameter value. Normally not visible.
MC-009		
	Connected to the PLC successfully.	Seen when using the KBCT Console program's built in connection checks. Indicates a successful attempt to connect to the PLC.
MC-010		
	Checking the connection to the PLC...	Seen when using the KBCT Console pogram's built in connection checks, prior to attempting a connection to the PLC.
MC-011		
	Waiting for system to be ready for homing...	May be seen when establishing a connection. Indicates that the servos need to be homed, and that the System is preparing to home them.

Table Z.1-1: System messages

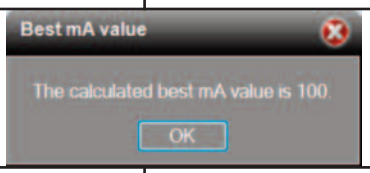
Message ID	Text	Explaination
MC-012		
	Initializing the X-ray generator...	The system is initializing the X-ray generator. This is one of the steps in establishing a connection.
MC-013		
	Loading initial parameter values...	The system is loading the initial X-ray parameter values. This is one of the steps in establishing a connection.
MC-014		
	Connected to the X-ray generator successfully.	Seen when using the KBCT Console program's built in connection checks. Indicates a successful attempt to connect to the X-ray generator.
MC-015		
	Checking the connection to the X-ray generator...	Seen when using the KBCT Console pogram's built in connection checks, prior to attempting a connection to the X-ray generator.
SC-101		
	The calculated best mA value is x.	Seen once a best mA calculation is completed. The calculated best mA is as displayed.

Table Z.1-1: System messages

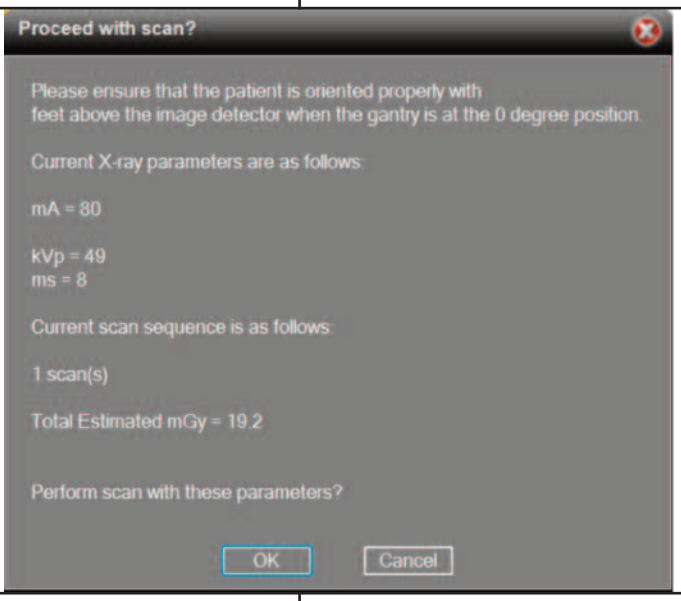
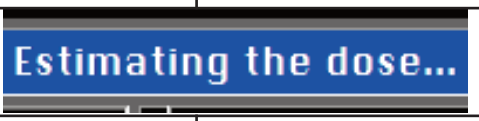
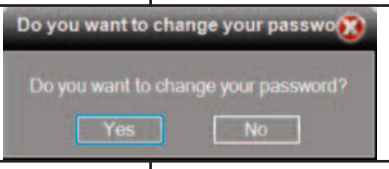
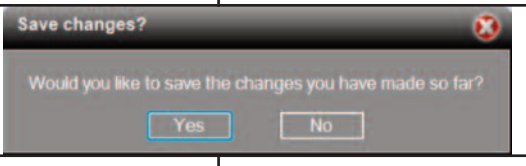
Message ID	Text	Explanation
SC-401		
	Please ensure the patient is oriented properly with (head or feet) above the image detector when the gantry is at the 0 degree position. Current X-ray parameters are as follows: mA = x kVp = y ms = z Current scan sequence is as follows: 1 scan(s) Total Estimated mGy = w Perform scan with these parameters?	Seen once the “Start” button in the SCAN CONTROLS is clicked. Gives the opportunity to confirm patient positioning, X-ray parameters, and scan sequence prior to performing the scan.
SC-501		
	Acquiring projections for scan x	Seen during a scan or scan sequence while acquiring projections.
SC-502		
	Waiting for scan x -- y seconds remaining	This message should not be seen. Contact Koning if this message is observed.

Table Z.1-1: System messages

Message ID	Text	Explanation
SC-701		
	Estimating the dose...	Shown when an Experiment uses the dose estimation tool. See Section 14.3.3.
SC-702	2:29:27 PM: Estimated dose 16.5 mGy for patient:Roe, Jane[12345]	
	hh:mm:ss (AM/PM): Estimated dose x mGy for patient (Patient Name) [(Patient ID)]	Message logged when an Experiment uses the dose estimation tool. See Section 14.3.3.
SC-801		
	Opening the scout image...	May be seen when loading a scout image to the Image Viewer. This operation typically completes before the message can be perceied.
UM-301		
	Do you want to change your password?	Appears when changing your password. Confirmation is required in order to reduce the chance of accidental changes.
UM-401		
	Would you like to save the changes you have made so far?	May appear when administering user accounts. This prompt reduces the chance of accidental loss of changes.

Z.2. Warning Messages

All warning messages output by the System are listed and explained in Table Z.2-1 below, along with possible resolutions.

Table Z.2-1: Warning messages

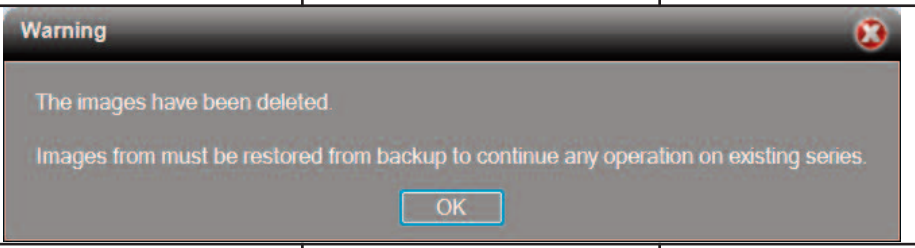
Message ID	Text	Explanation	Possible Resolution
CM-1101-WA			
	The images have been deleted. Images must be restored from backup to continue any operation on existing series.	Seen upon deletion of a case.	Images may be restored from backup if necessary, assuming a backup exists.

Table Z.2-1: Warning messages

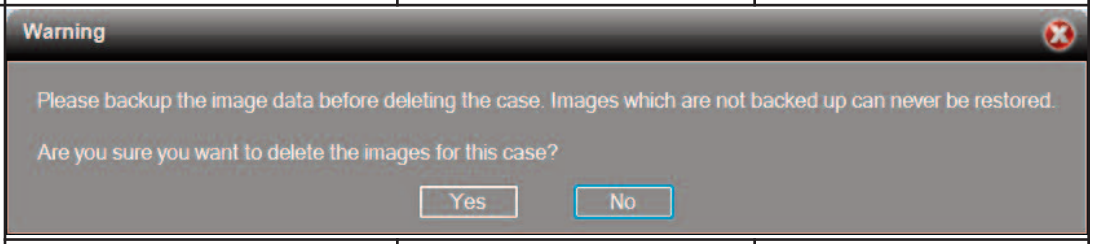
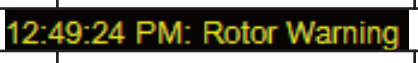
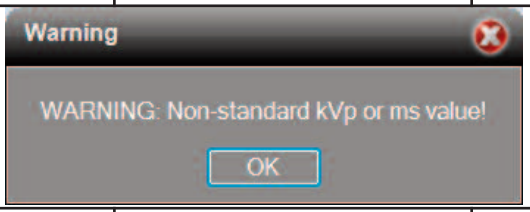
Message ID	Text	Explanation	Possible Resolution
CM-1102-WA			
	Please back up the image data before deleting the case. Images which are not backed up can never be restored. Are you sure you want to delete the images for this case?	Seen when attempting to delete a case. Provides a reminder to make a backup prior to deletion and requests confirmation to reduce the chance of accidental deletion.	Select no if no backup exists, or if you do not wish to delete the case.
DA-001-WA			
	hh:mm:ss (AM/PM): Collimator Warning	This message is logged if the X-ray generator reports an issue with the collimator.	Contact Koning for assistance.
DA-002-WA			
	hh:mm:ss (AM/PM): Filament Error	This message is logged if the X-ray generator reports an issue with lack of current on the filament.	Contact Koning for assistance.
DA-003-WA			
	hh:mm:ss (AM/PM): Rotor Warning	This message is logged if the X-ray generator reports an issue with the rotor.	Contact Koning for assistance.
DA-004-WA			
	hh:mm:ss (AM/PM): Technique Warning	This message is logged if the X-ray generator reports an issue with the calibration of a given parameter.	Contact Koning for assistance.
DA-301-WA			
	WARNING: Non-standard kVp or ms value!	Non-Experiment users will see this message before initiating a scan with non-default kVp or ms values.	Koning strongly suggests use of the default kVp and ms for non-Experiment users.
DA-302-WA			
	hh:mm:ss (AM/PM): A warning from BitFlow was received: (Additional information)	This message is logged during a scan if a warning is received from the frame grabber card.	Determine the condition of the acquired series. Contact Koning for assistance if frames are missing, or if this is a chronic issue.

Table Z.2-1: Warning messages

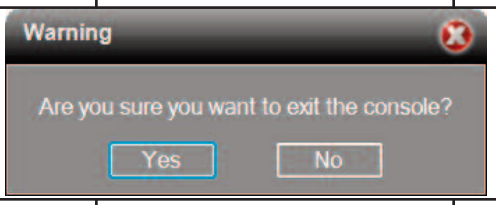
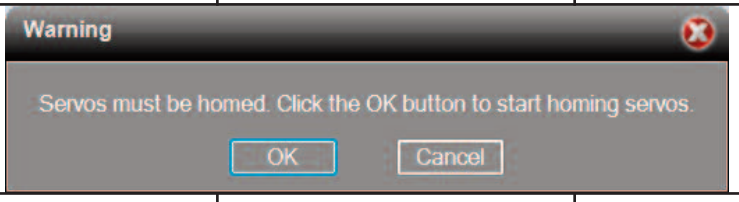
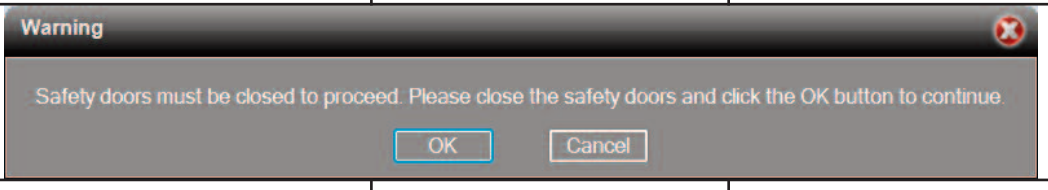
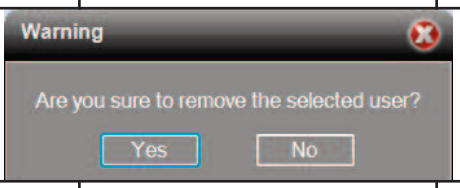
Message ID	Text	Explanation	Possible Resolution
DA-303-WA	11:44:07 AM: An unexpected warning was received from BitFlow. Warning code: 99999 Frame number: 234		
	An unexpected warning was received from BitFlow. Warning code: x (Additional information, if available)	This message is logged during a scan if an unknown warning is received from the frame grabber card.	Write down the warning code and any additional information and contact Koning for assistance. Be prepared to recount the series of events which led to this message.
GN-001-WA			
	Are you sure you want to exit the console?	Seen when exiting the KBCT Console program. Prompts for confirmation in order to reduce the chances of accidentally exiting the program.	If you do not intend to exit the program, click “No”.
MC-001-WA			
	Servos must be homed. Click the OK button to start homing servos.	May be seen when establishing a connection. Indicates that the servos need to locate their home positions.	Click the OK button to begin the homing process. It will be necessary for the servos to find their home positions before a connection may be established.
SF-001-WA			
	Safety doors must be closed to proceed. Please close the safety doors and click the OK button to continue.	May be seen when attempting functionality while the Scanner doors are open.	Close the Scanner doors and click “OK” to proceed. Contact Koning for assistance if the doors are not open.
SF-002-WA	11:26:57 AM: DC Bus Too High		
	hh:mm:ss (AM/PM): DC Bus Too High	This message is logged if the X-ray generator reports excessive DC bus voltage.	Contact Koning for assistance.
SF-003-WA	11:53:58 AM: Door Open Warning		
	hh:mm:ss (AM/PM): Door Open Warning	This message is logged if the Scanner cover doors are open.	Open and close the Scanner cover doors. Contact Koning if the issue persists.

Table Z.2-1: Warning messages

Message ID	Text	Explanation	Possible Resolution
SF-004-WA	12:14:16 PM: Generator Overload Warning		
	hh:mm:ss (AM/PM): Generator Overload Warning	This message is logged if the X-ray generator gives an overload warning.	Contact Koning for assistance.
SF-005-WA	12:39:23 PM: Overheat Warning		
	hh:mm:ss (AM/PM): Overheat Warning	This message is logged if the X-ray generator gives a warning that the X-ray tube is overheating.	Contact Koning for assistance.
SF-006-WA	1:02:24 PM: Tube Overload Warning		
	hh:mm:ss (AM/PM): Tube Overload Warning	This message is logged if the X-ray generator gives a tube overload warning.	Contact Koning for assistance.
UM-201-WA			
	Are you sure you want to remove the selected user?	Seen when removing a user account. Confirmation is requested to reduce the chances of accidentally removing a user.	If you do not intend to remove the user account, click “No.”

Z.3. Error and Fault Messages

All error and fault messages output by the System are listed and explained in Table Z.3-1 below, along with possible resolutions.

Table Z.3-1: Error messages

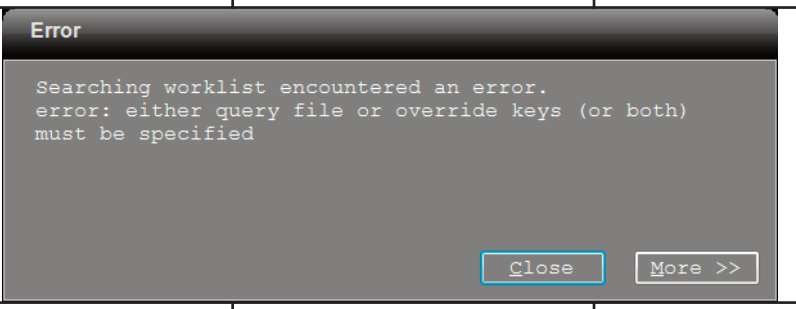
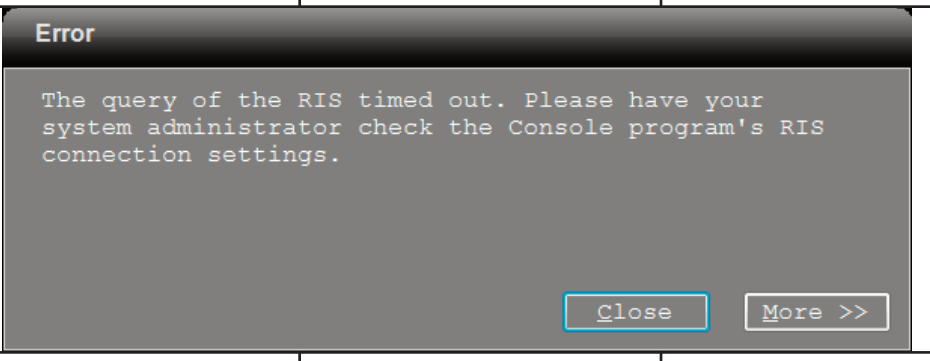
Message ID	Text	Explanation	Possible Resolution
CM-101-ER			
	Searching worklist encountered an error. (Additional text describing the error.)	Seen when querying the RIS for cases if the software encounters a problem. There are a variety of circumstances which may cause this error to appear.	Have your system administrator verify the configuration settings pertaining to the RIS. Write down the error message. If the settings are correct, contact Koning for assistance.
CM-102-ER			
	The query of the RIS timed out. Please have your system administrator check the Console program's RIS connection settings.	Seen when querying the RIS for cases if no response is received from the RIS.	Have your system administrator verify the configuration settings pertaining to the RIS. If the settings are correct, have the facility's IT department verify that there is not a network issue. If still unresolved, contact Koning for assistance.

Table Z.3-1: Error messages

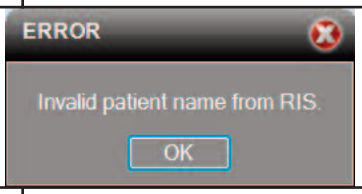
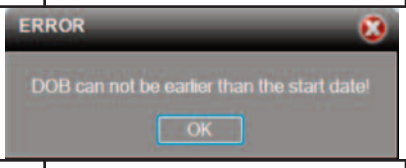
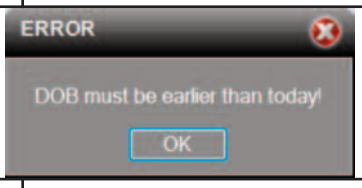
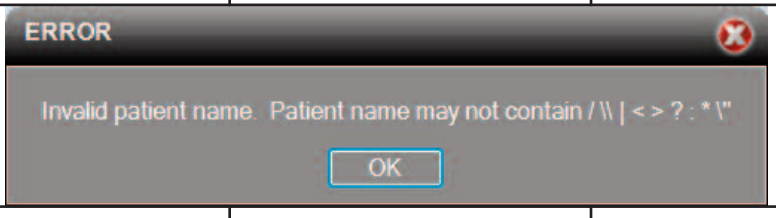
Message ID	Text	Explaination	Possible Resolution
CM-103-ER			
	Invalid patient name from RIS.	May appear when importing a case from the RIS. Indicates that the patient's name as it exists on the RIS is unusable by the KBCT Console program.	Contact facility IT staff for assistance. Contact Koning Corporation for assistance if this is a chronic problem, or if there is no problem with the data on the RIS.
CM-301-ER			
	DOB can not be later than the start date!	Seen when attempting to create or edit a case such that the SPS start date precedes the patient's DOB.	Verify case information and re-enter.
CM-302-ER			
	DOB must be earlier than today!	Seen when attempting to create or edit a case such that the patient's DOB is the current date or later.	Verify case information and re-enter.
CM-303-ER			
	Invalid patient name. Patient name may not contain / \ | < > ? : * “	Seen when attempting to create or edit a case such that the patient information includes the special characters indicated.	Verify case information and re-enter. In the unlikely event that the patient's name includes one of these characters, contact Koning for assistance.

Table Z.3-1: Error messages

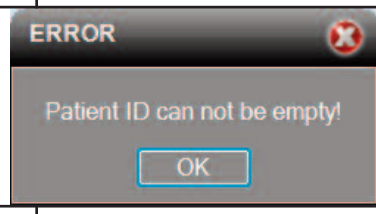
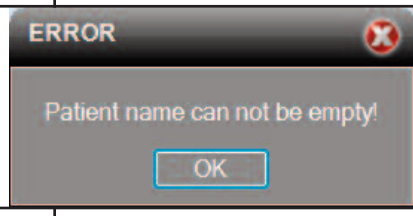
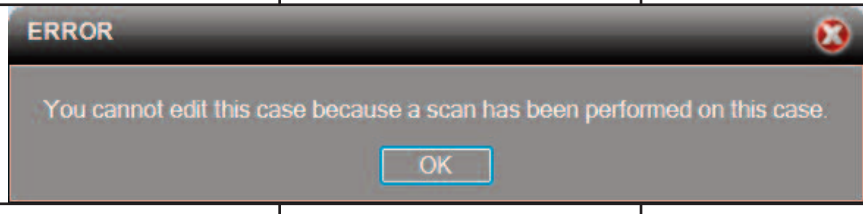
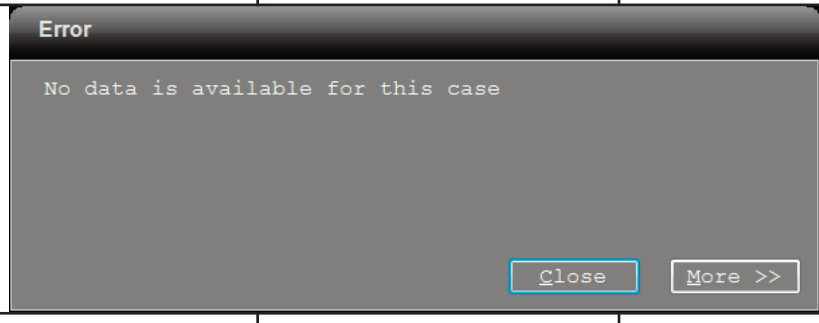
Message ID	Text	Explanation	Possible Resolution
CM-304-ER			
	Patient ID can not be empty!	Seen when attempting to create or edit a case such that the patient ID number is left blank.	Verify the case information and re-enter. If the patient ID is unknown, defer to your facility's procedures.
CM-305-ER			
	Patient name can not be empty!	Seen when attempting to create or edit a case such that the patient name is blank.	Verify the case information and re-enter. If the patient's name is unknown, defer to your facility's procedures.
CM-401-ER			
	You cannot edit this case because a scan has been performed on this case.	May be seen when attempting to edit the information of the currently selected case. Appears when 1 or more images associated with the case have been acquired.	Contact Koning for assistance if it is vital that the information be edited.
CM-901-ER			
	No data is available for this case	Shown when attempting to burn a DVD backup of a case which has no associated images.	Verify the currently selected case. If images have been acquired for the selected case, contact Koning for assistance.

Table Z.3-1: Error messages

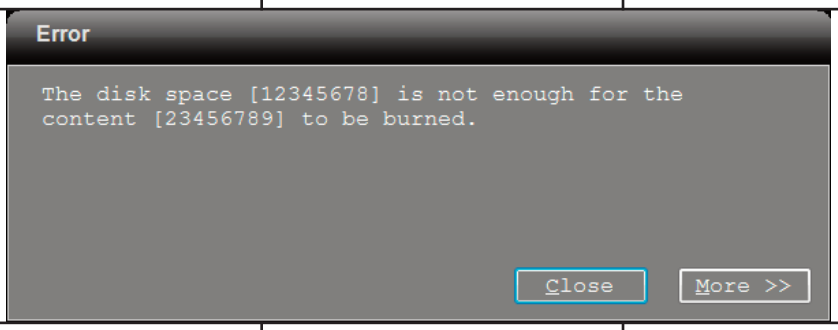
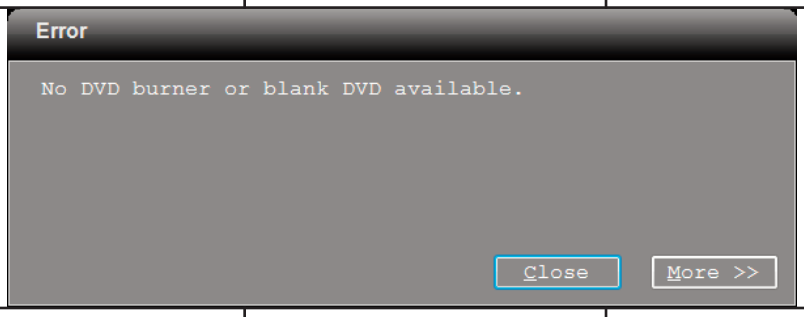
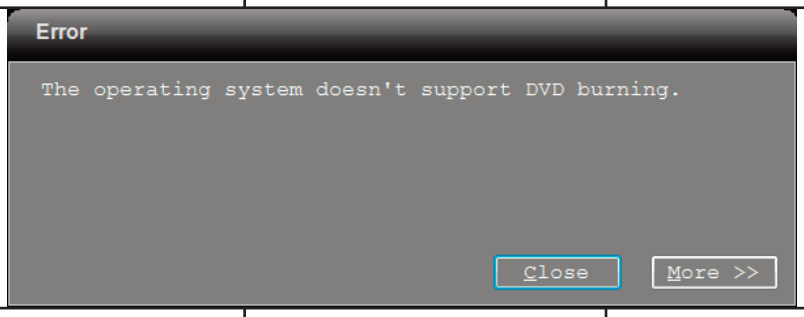
Message ID	Text	Explanation	Possible Resolution
CM-902-ER			
	The disk space [x] is not enough for the content [y] to be burned.	Shown when attempting to burn a DVD backup of a case onto a disc with insufficient free space.	Use a blank DVD with a larger storage capacity. Contact Koning for assistance.
CM-903-ER			
	No DVD burner or blank DVD available.	May appear when attempting to burn a case to DVD back-up. Normally appears if no blank DVD has been inserted.	Verify that a blank DVD has been inserted into the workstation. Contact Koning for assistance if this message is received once a blank DVD has been inserted.
CM-904-ER			
	The operating system doesn't support DVD burning.	Shown if the operating system of the Console workstation does not support the KBCT Console program's DVD burning functionality.	Contact Koning for assistance. Be aware that any unauthorized modification of the operating system voids your service agreements.

Table Z.3-1: Error messages

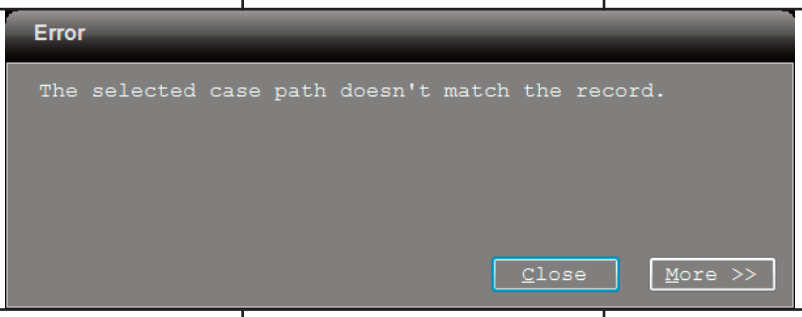
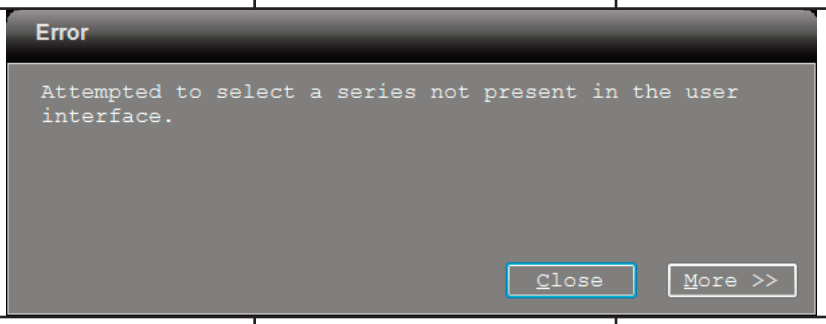
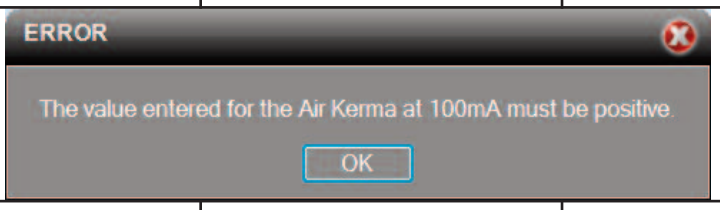
Message ID	Text	Explanation	Possible Resolution
CM-1001-ER			
	The selected case path doesn't match the record.	Shown when attempting to restore a case from DVD backup if the wrong location is selected.	Verify that the correct back-up directory has been selected. The directory name should include the case's patient name and patient ID (for instance "2_Roe, Jane"). If the correct directory has been selected, contact Koning for assistance.
CM-1201-ER			
	Attempted to select a series not present in the user interface.	The KBCT Console program attempted to select a series which does not exist. (Note that no error should be displayed when using the up and down arrow buttons to select a series.)	Contact Koning for assistance. Please notify Koning if this error is received even if it does not impede normal function.
CO-101-ER			
	The value entered for the Air Kerma at 100mA must be positive.	May be seen when changing the system configuration. An invalid value for Air Kerma at 100mA was entered.	Confirm the value entered is positive.

Table Z.3-1: Error messages

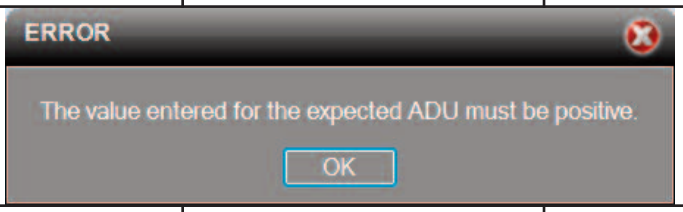
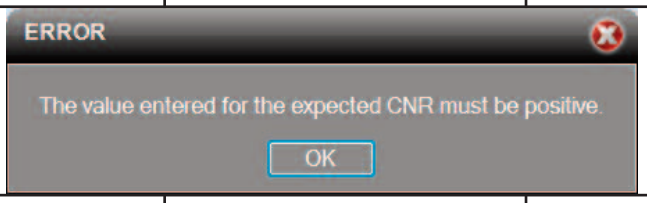
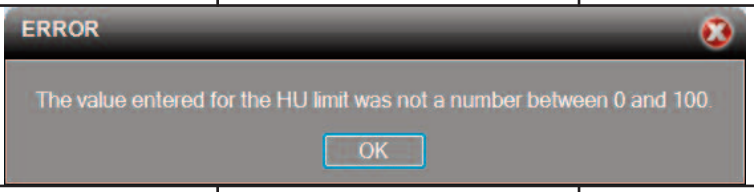
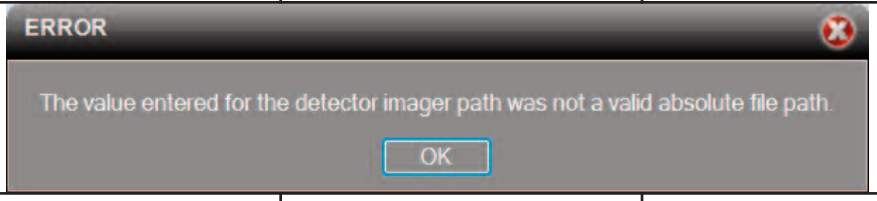
Message ID	Text	Explaination	Possible Resolution
CO-102-ER			
	The value entered for the data path was not a valid absolute path.	May be seen when changing the configuration. Appears when attempting to set the data path to an invalid location.	Contact Koning for assistance.
CO-103-ER			
	The value entered for the expected ADU must be positive.	May be seen when changing the configuration. Appears when attempting to set the target ADU to an invalid value.	Confirm the value entered is positive.
CO-104-ER			
	The value entered for the expected CNR must be positive.	May be seen when changing the configuration. Appears when attempting to set the target CNR to an invalid value.	Confirm the value entered is positive.
CO-105-ER			
	The value entered for the HU limit was not a number between 0 and 100.	May be seen when changing the configuration. Appears when attempting to set the HU limit to an invalid value.	Confirm the value entered is a number between 0 and 100.
CO-106-ER			
	The value entered for the detector imager path was not a valid absolute file path.	May be seen when changing the configuration. Appears when attempting to set the imager path to an invalid path.	Contact Koning for assistance.

Table Z.3-1: Error messages

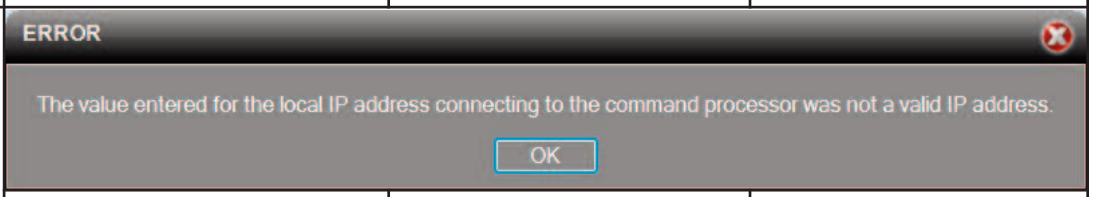
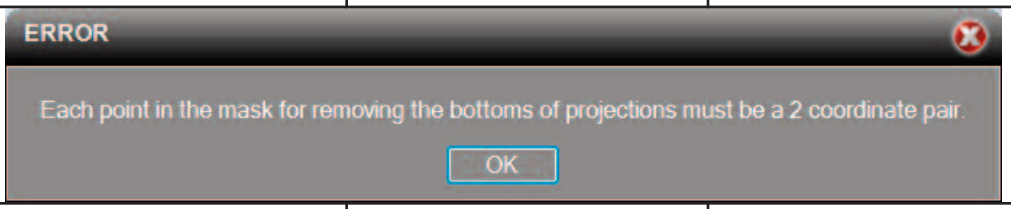
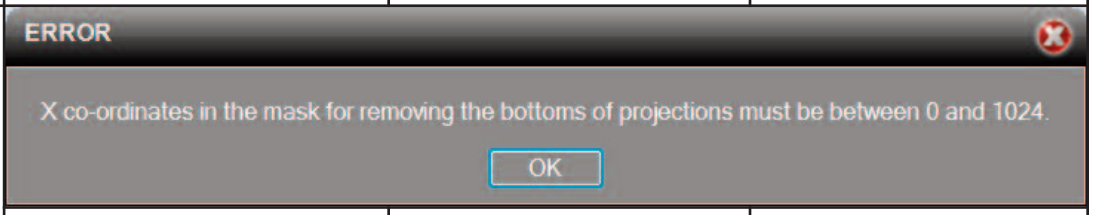
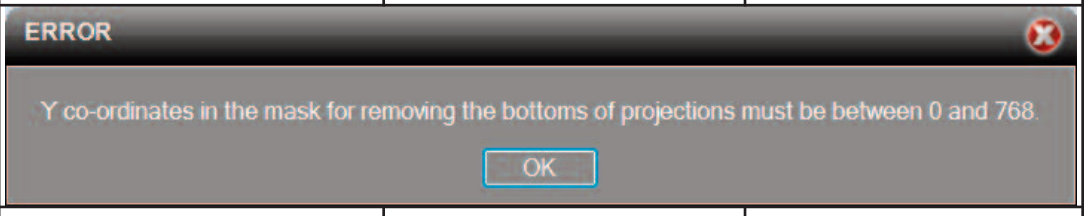
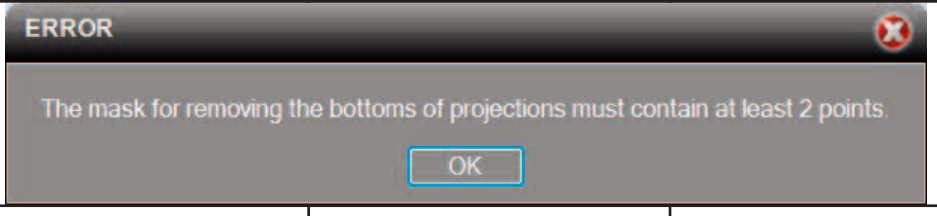
Message ID	Text	Explaination	Possible Resolution
CO-107-ER			
	The value entered for the local IP address connecting to the command processor was not a valid IP address.	May be seen when changing the configuration. Appears when attempting to set an invalid local IP connecting to the command processor.	Verify that the value entered is a valid IP address.
CO-108-ER			
	Each point in the mask for removing the bottoms of projections must be a 2 coordinate pair.	May be seen when changing the configuration. Appears when attempting to set an invalid mask.	Verify the format of the desired mask. Contact Koning for assistance.
CO-109-ER			
	X coordinates in the mask for removing the bottoms of projections must be between 0 and 1024.	May be seen when changing the configuration. Appears when attempting to set an invalid mask.	Verify that all desired X coordinates are numbers between 0 and 1024. Contact Koning for assistance.
CO-110-ER			
	Y coordinates in the mask for removing the bottoms of projections must be between 0 and 768.	May be seen when changing the configuration. Appears when attempting to set an invalid mask.	Verify that all desired Y coordinates are numbers between 0 and 768. Contact Koning for assistance.
CO-111-ER			
	The mask for removing the bottoms of projections must contain at least 2 points.	May be seen when changing the configuration. Appears when attempting to set an invalid mask.	Verify that the desired mask consists of at least 2 points. Contact Koning for assistance.

Table Z.3-1: Error messages

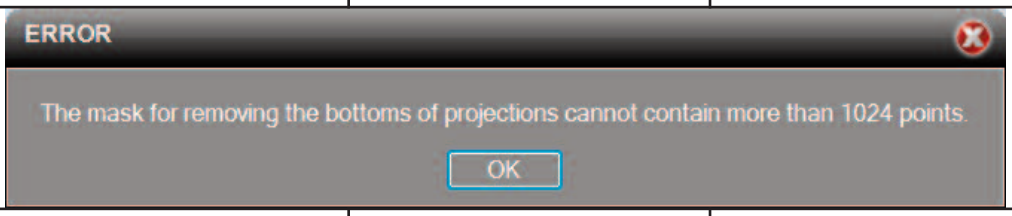
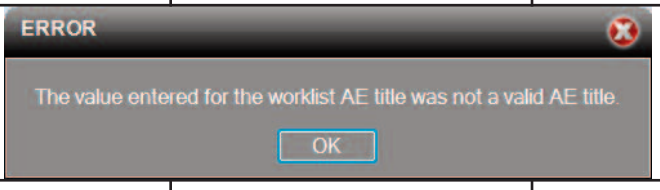
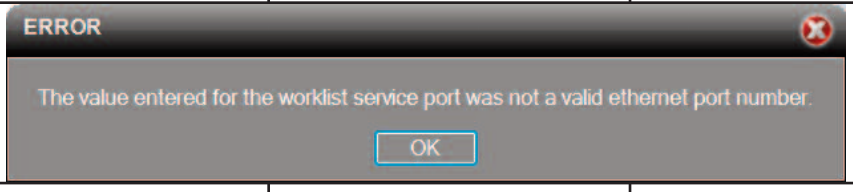
Message ID	Text	Explaination	Possible Resolution
CO-112-ER			
	The mask for removing the bottoms of projections cannot contain more than 1024 points.	May be seen when changing the configuration. Appears when attempting to set an invalid mask.	Verify that the desired mask consists of at most 1024 points. Contact Koning for assistance.
CO-113-ER			
	The value entered for the COM port to receive the trigger signal was not a valid COM port number.	May be seen when changing the configuration. Appears when attempting to set an invalid trigger COM port.	Verify that the desired port is a positive number.
CO-114-ER			
	The value entered for the PLC IP address was not a valid IP address.	May be seen when changing the configuration. Appears when attempting to set an invalid PLC IP address.	Verify that the desired IP address is valid.
CO-115-ER			
	The value entered for the worklist AE title was not a valid AE title.	May be seen when changing the configuration. Appears when attempting to set an invalid RIS AE title.	Verify the desired RIS AE title.
CO-116-ER			
	The value entered for the worklist service port was not a valid Ethernet port number.	May be seen when changing the configuration. Appears when attempting to set an invalid RIS port.	Verify the desired RIS port number.

Table Z.3-1: Error messages

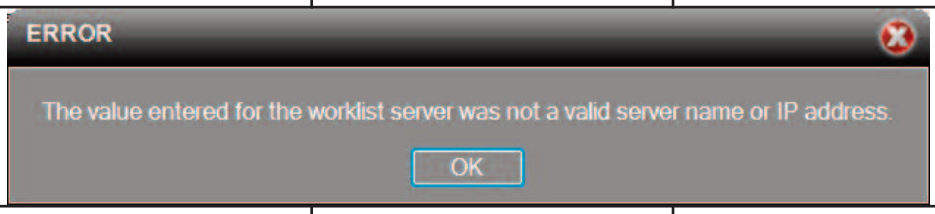
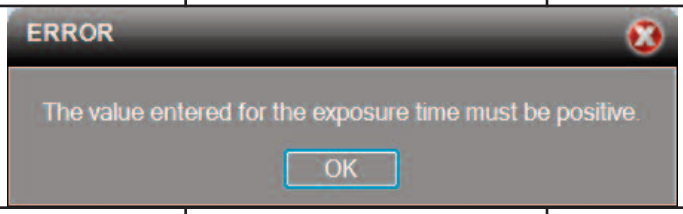
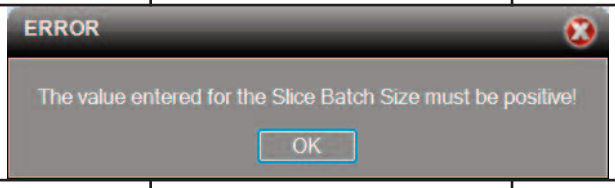
Message ID	Text	Explanation	Possible Resolution
CO-117-ER			
	The value entered for the worklist server is not a valid server name or IP address.	May be seen when changing the configuration. Appears when attempting to set an invalid RIS server name or IP address.	Verify the desired RIS server name or IP address.
CO-118-ER			
	The value entered for the exposure time must be positive.	May be seen when changing the configuration. Appears when attempting to set an invalid scout exposure time.	Verify the desired scout exposure time is a positive number.
CO-119-ER			
	The value entered for the Slice Batch Size must be positive!	Appears when an invalid Slice Batch Size has been set.	Contact Koning Corporation for assistance.
CO-120-ER			
	The value entered for the 3D visualization / DICOM storage system's AETitle is not a valid AETitle.	May be seen when changing the configuration. Appears when attempting to set an invalid storage server AETitle.	Contact Koning Corporation for assistance.
CO-121-ER			
	The value entered for the 3D visualization / DICOM storage system's IP address is not a valid IP address.	May be seen when changing the configuration. Appears when attempting to set an invalid storage server IP address.	Contact Koning Corporation for assistance.

Table Z.3-1: Error messages

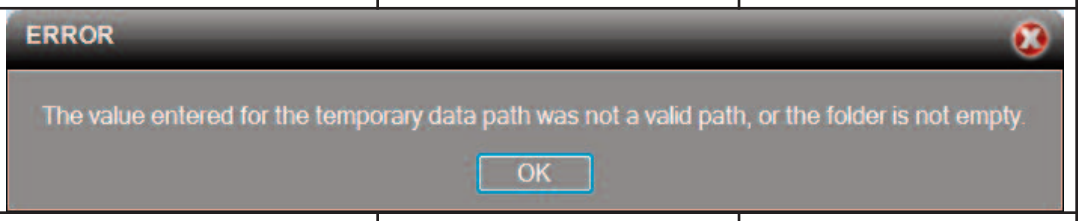
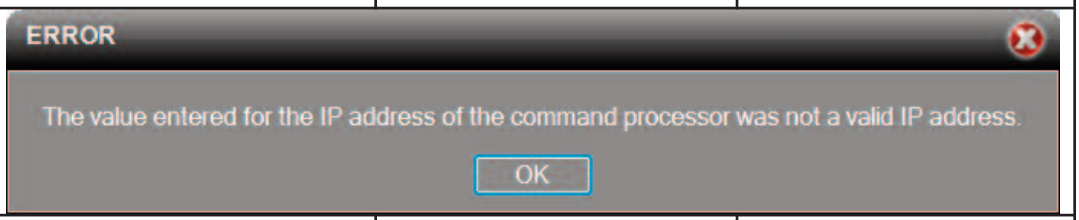
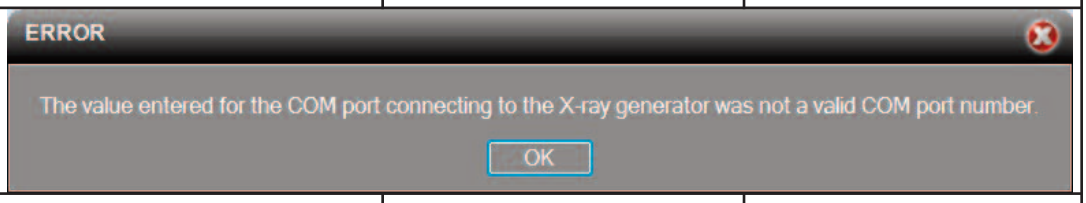
Message ID	Text	Explaination	Possible Resolution
CO-122-ER			
	The value entered for the 3D visualization / DICOM storage system's port is not a valid Ethernet port.	May be seen when changing the configuration. Appears when attempting to set an invalid storage server port.	Contact Koning Corporation for assistance.
CO-123-ER			
	The value entered for the temporary data path was not a valid path, or the folder is not empty.	May be seen when changing the configuration. Appears when attempting to set an invalid temporary data path.	Contact Koning Corporation for assistance.
CO-124-ER			
	The value entered for the IP address of the command processor was not a valid IP address.	May be seen when changing the configuration. Appears when attempting to set an invalid command processor IP address.	Contact Koning Corporation for assistance.
CO-125-ER			
	The value entered for the COM port connecting to the X-ray generator was not a valid COM port number.	May be seen when changing the configuration. Appears when attempting to set an invalid X-ray generator COM port number.	Contact Koning Corporation for assistance.
DA-001-ER	2:53:14 PM: The X-ray generator has recovered from an error.		
	hh:mm:ss (AM/PM): The X-ray generator has recovered from an error. (Additional text may follow.)	Message logged if the X-ray generator recovers from an error before it can report it.	Generally, no action should be necessary. Notify Koning if this message is encountered often.

Table Z.3-1: Error messages

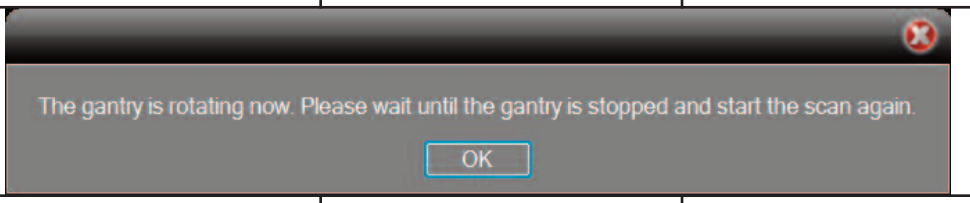
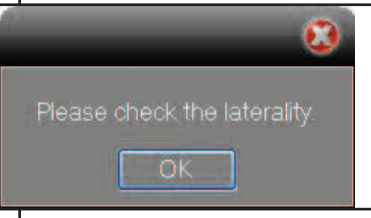
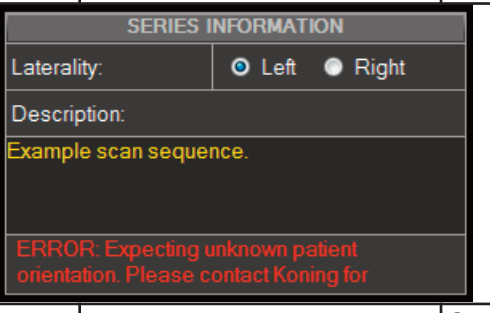
Message ID	Text	Explanation	Possible Resolution
DA-002-ER			
	hh:mm:ss (AM/PM): X-ray generator has encountered error x. (Additional information may be provided, if available.) Please contact your Koning service representative for technical support.	Message logged when the X-ray generator reports and error. There are a variety of circumstances which may cause this message to appear.	Contact Koning for assistance.
DA-003-ER			
	The gantry is rotating now. Please wait until the gantry is stopped and start the scan again.	Seen when attempting to initiate a scout image or scan while the gantry is rotating.	Wait for the gantry's motion to finish, then try again. If gantry rotation is continuing abnormally, press an emergency stop button and notify Koning.
DA-004-ER			
	Please check the laterality.	Seen when attempting to initiate a scout image or scan without having selected a laterality.	Select a laterality and try again.
DA-005-ER			
	ERROR: Expecting unknown patient orientation. Please contact Koning for assistance.	Displayed in place of the expected patient orientation if the expected orientation is undefined. Indicative of configuration issues.	Contact Koning for assistance. Be aware that any unauthorized modification of the system files voids your service agreements.

Table Z.3-1: Error messages

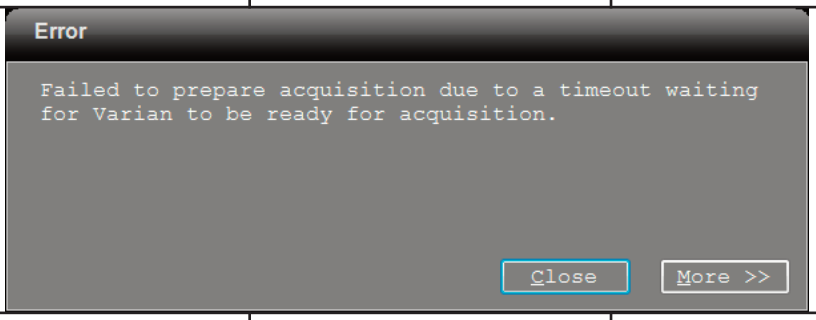
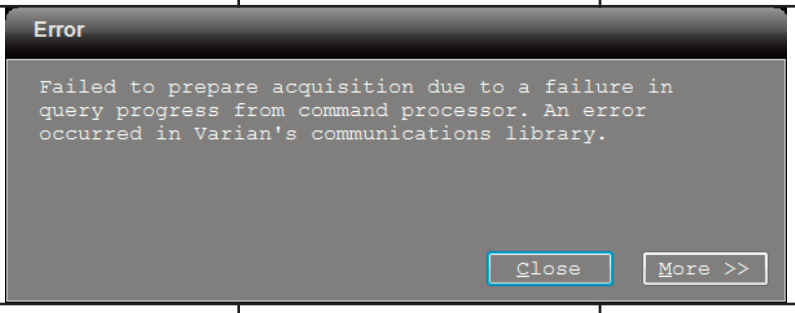
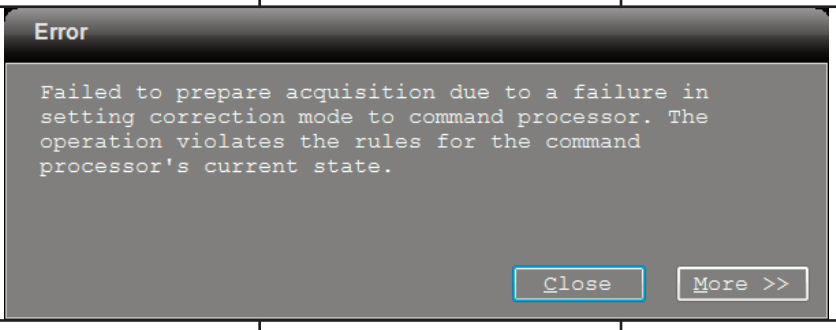
Message ID	Text	Explaination	Possible Resolution
DA-006-ER			
	Failed to prepare acquisition due to a timeout waiting for Varian to be ready for acquisition.	May be seen while preparing for a scout image or scan if the command processor fails to prepare for emission within a certain amount of time.	Have facility IT staff verify that no physical cable connections are loose. Contact Koning if the issue persists.
DA-007-ER			
	Failed to prepare acquisition due to a failure in query progress from command processor. (Additional information)	May be seen while preparing for a scout image or scan if the command processor fails to report its status.	Write down the additional information word for word and contact Koning for assistance.
DA-008-ER			
	Failed to prepare acquisition due to a failure in setting correction mode to command processor. (Additional information)	May be seen while preparing for a scout image or scan if the KBCT Console program fails to set the correction mode of the command processor.	Write down the additional information word for word and contact Koning for assistance.

Table Z.3-1: Error messages

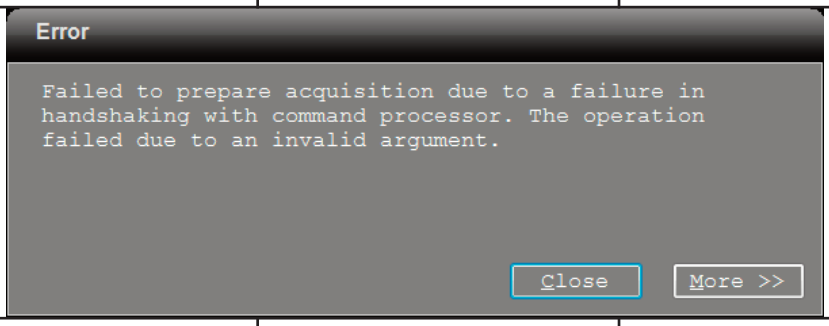
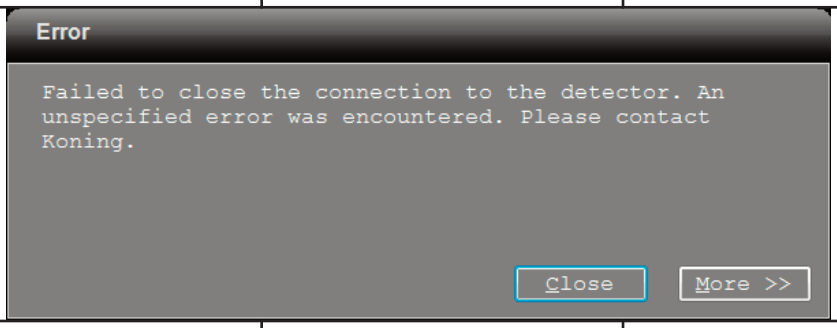
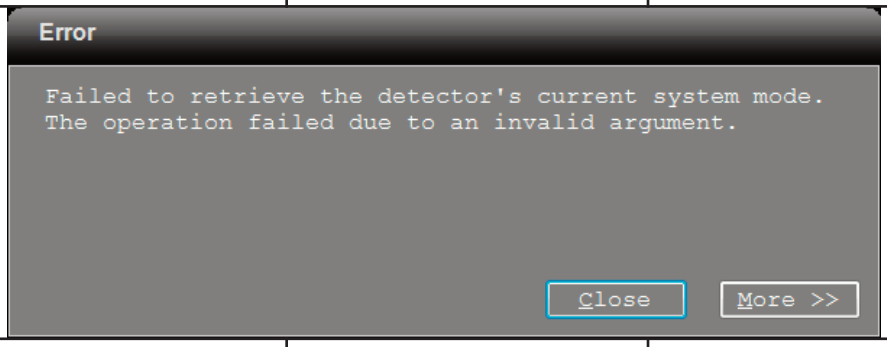
Message ID	Text	Explanation	Possible Resolution
DA-009-ER			
	Failed to prepare acquisition due to a failure in handshaking with command processor. (Additional information)	May be seen while preparing for a scout image or scan if there is a problem sending a handshaking signal to the command processor.	Write down the additional information word for word and contact Koning for assistance.
DA-010-ER			
	Failed to close the connection to the detector. (Additional information)	May be seen during a variety of operations if there is a failure to close the link to the command processor.	Write down the additional information word for word and contact Koning for assistance.
DA-011-ER			
	Failed to retrieve the detector's current system mode. (Additional information)	May be seen during a variety of operations if the KBCT Console program is unable to retrieve the command processor's current mode.	Write down the additional information word for word and contact Koning for assistance.

Table Z.3-1: Error messages

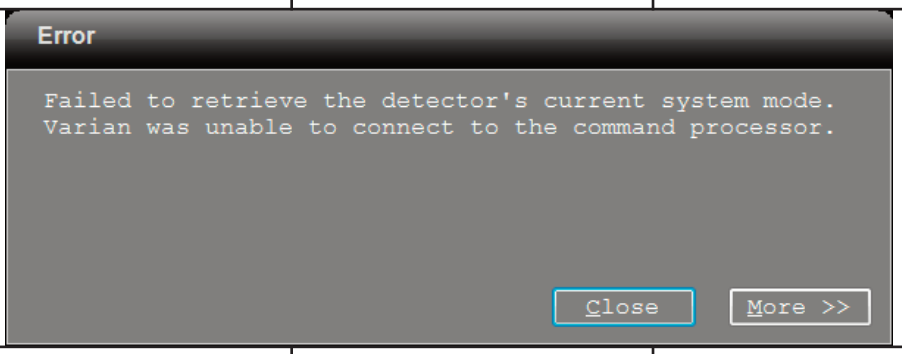
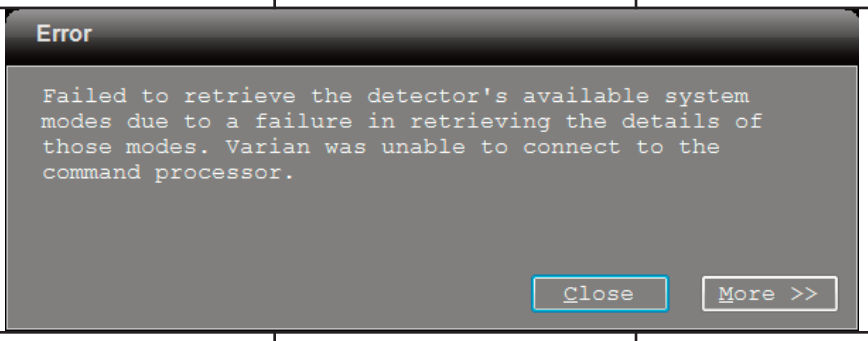
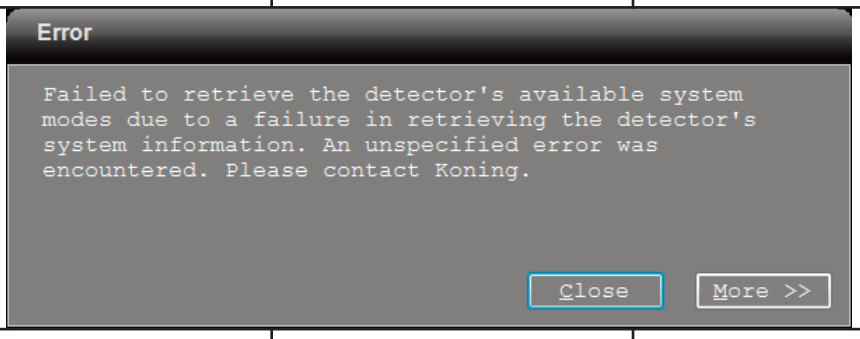
Message ID	Text	Explaination	Possible Resolution
DA-012-ER			
	Failed to retrieve the detail information of the detector's current system mode. (Additional information)	May be seen during a variety of operations if the KBCT Console program is unable to learn the details of the command processor's current mode.	Write down the additional information word for word and contact Koning for assistance.
DA-013-ER			
	Failed to retrieve the detector's available system modes due to a failure in retrieving the details of those modes. (Additional information)	May be seen under rare circumstances.	Write down the additional information word for word and contact Koning for assistance.
DA-014-ER			
	Failed to retrieve the detector's available system modes due to a failure in retrieving the detector's system information. (Additional information)	May be seen under rare circumstances.	Write down the additional information word for word and contact Koning for assistance.

Table Z.3-1: Error messages

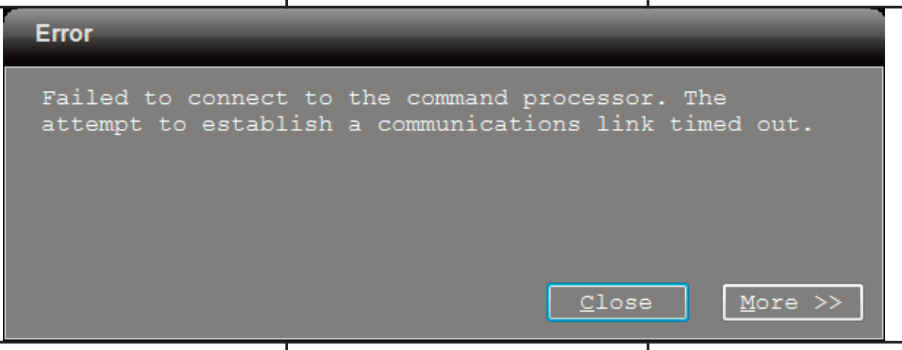
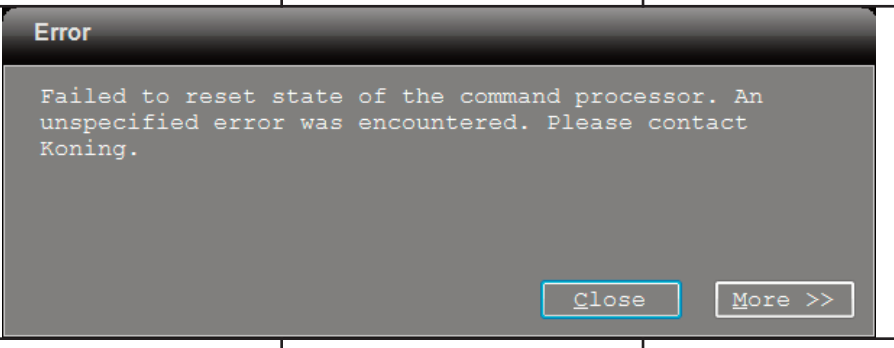
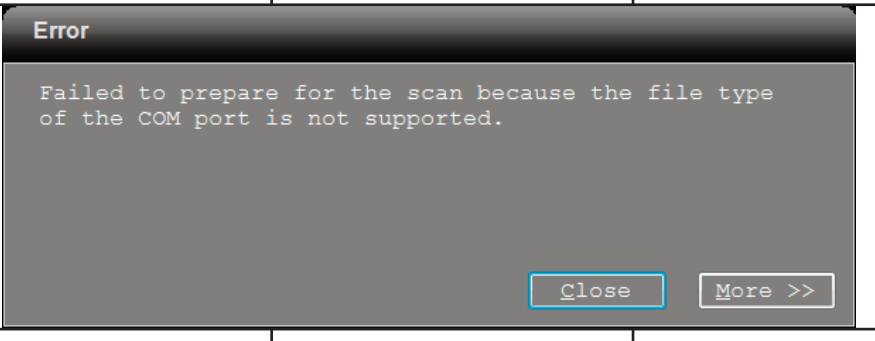
Message ID	Text	Explanation	Possible Resolution
DA-015-ER			
	Failed to connect to the command processor. (Additional information)	May be seen during a variety of operations if the KBCT Console program is unable to open communications with the command processor.	Write down the additional information word for word and contact Koning for assistance.
DA-016-ER			
	Failed to reset state of the command processor. (Additional information)	May be seen during a variety of operations if the KBCT Console program is unable to reset the state of the command processor.	Write down the additional information word for word and contact Koning for assistance.
DA-017-ER			
	Failed to prepare for the scan because the file type of the COM port is not supported.	May be seen during a variety of operations if the KBCT Console program is unable to access the COM port for the trigger signal.	Contact Koning for assistance.

Table Z.3-1: Error messages

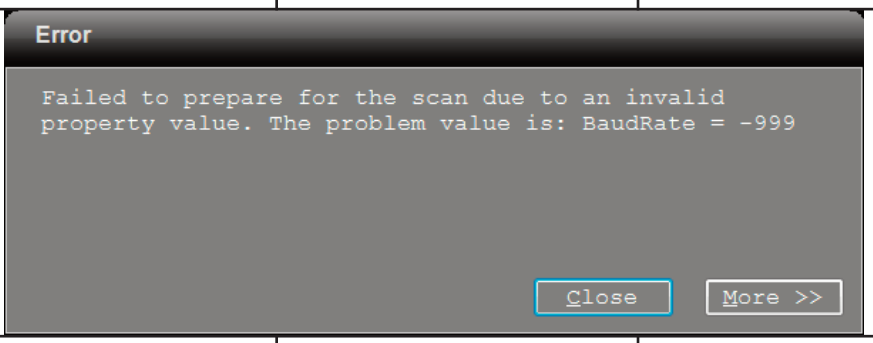
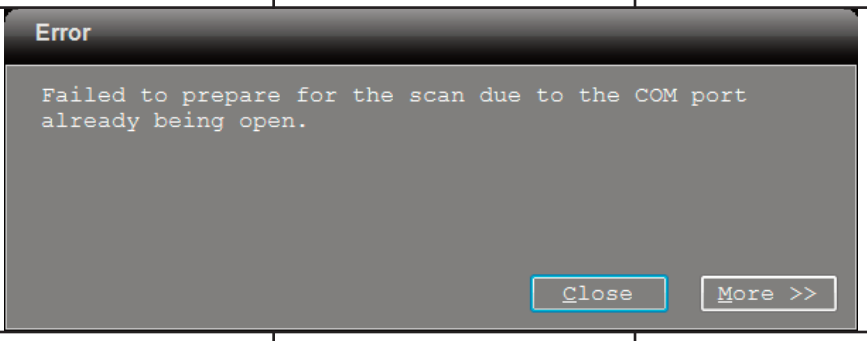
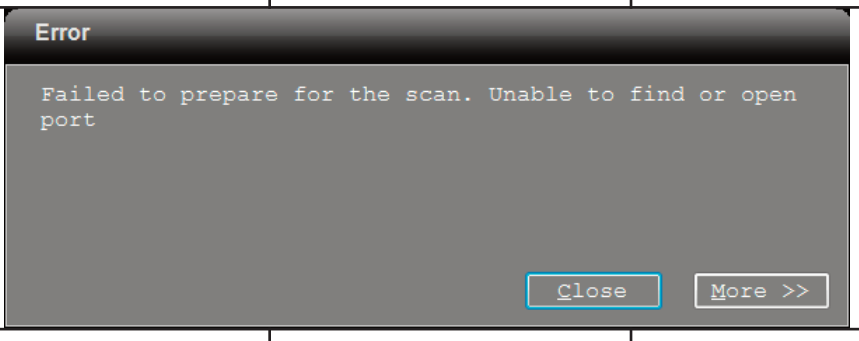
Message ID	Text	Explaination	Possible Resolution
DA-018-ER			
	Failed to prepare for the scan due to an invalid property value. The problem value is: (additional information)	May be seen during a variety of operations if the KBCT Console program encounters an internal problem with the COM port for the trigger signal.	Write down the additional information word for word and contact Koning for assistance.
DA-019-ER			
	Failed to prepare for the scan due to the COM port already being open.	May be seen during a variety of operations if the trigger signal COM port is unexpectedly already open.	Contact Koning for assistance.
DA-020-ER			
	Failed to prepare for the scan. Unable to find or open port	May be seen during a variety of operations if the KBCT Console program is unable to locate or open the trigger signal COM port.	Contact Koning for assistance.

Table Z.3-1: Error messages

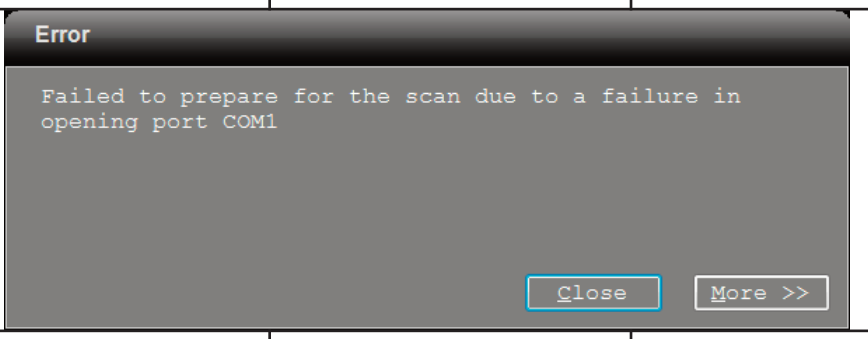
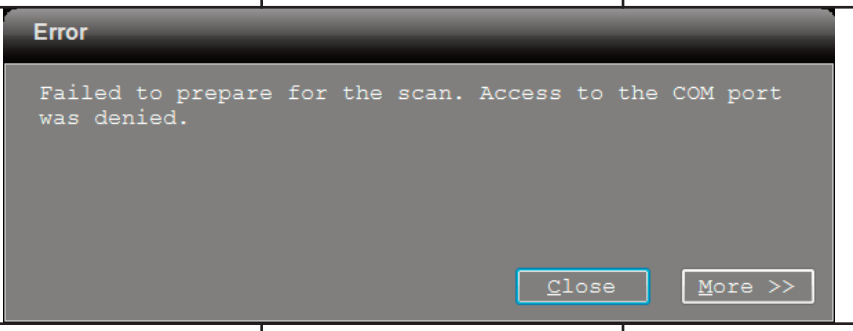
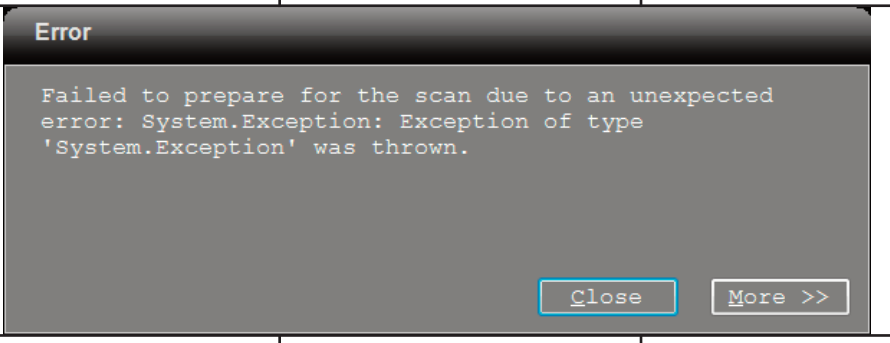
Message ID	Text	Explanation	Possible Resolution
DA-021-ER			
	Failed to prepare for the scan due to a failure in opening port x.	May be seen during a variety of operations if the KBCT Console program fails to open the trigger signal COM port.	Contact Koning for assistance.
DA-022-ER			
	Failed to prepare for the scan. Access to the COM port was denied.	May be seen during a variety of operations if the KBCT Console program does not have sufficient privileges to access the trigger signal COM port.	Contact Koning for assistance.
DA-023-ER			
	Failed to prepare for the scan due to an unexpected error: (additional information)	May be seen during a variety of operations if the KBCT Console program fails to open the trigger signal COM port for an unexpected reason.	Write down the additional information word for word and contact Koning for assistance.

Table Z.3-1: Error messages

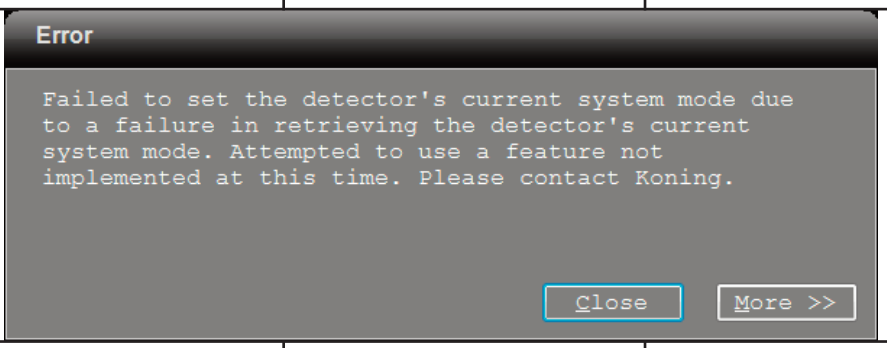
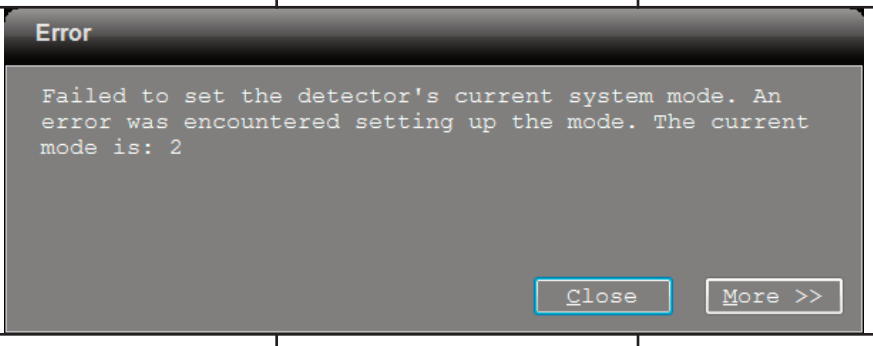
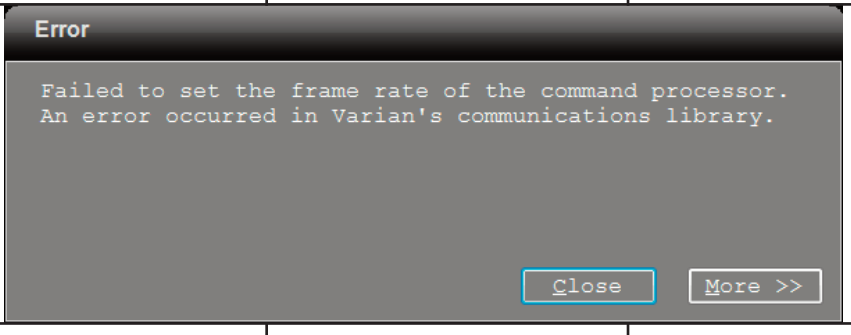
Message ID	Text	Explaination	Possible Resolution
DA-024-ER			
	Failed to set the detector's current system mode due to a failure in retrieving the detector's current system mode. (Additional information)	May be seen under rare circumstances while setting the command processor's mode if an error is received while requesting the command processor's current mode.	Write down the additional information word for word and contact Koning for assistance.
DA-025-ER			
	Failed to set the detector's current system mode. (Additional information)	May be seen under rare circumstances while setting the command processor's mode if an error is received while setting the command processor's current mode.	Write down the additional information word for word and contact Koning for assistance.
DA-026-ER			
	Failed to set the frame rate of the command processor. (Additional information)	May be seen during a variety of operations when setting the frame rate of the command processor if an error is received.	Write down the additional information word for word and contact Koning for assistance.

Table Z.3-1: Error messages

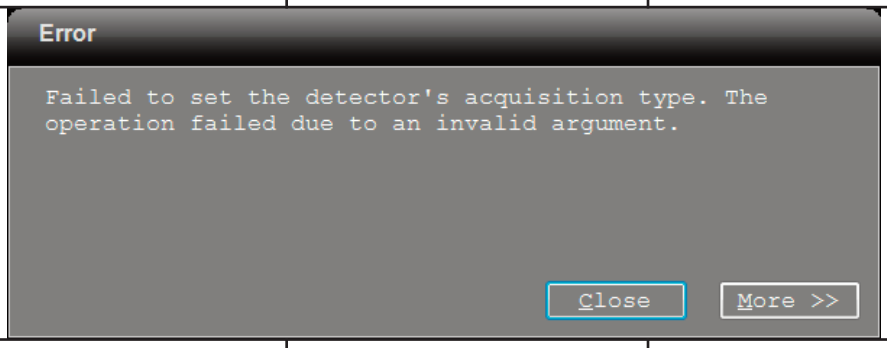
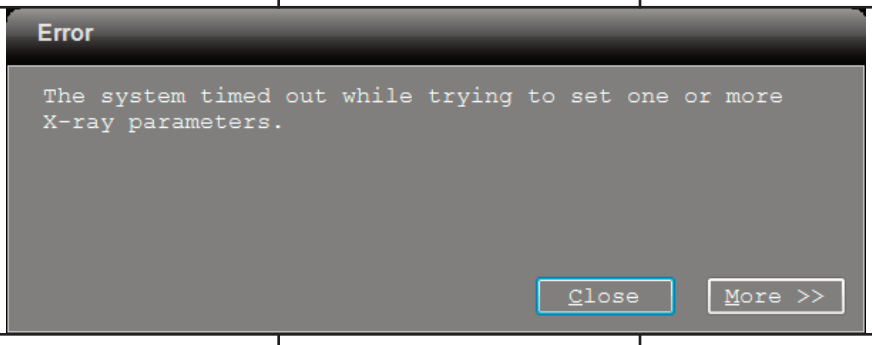
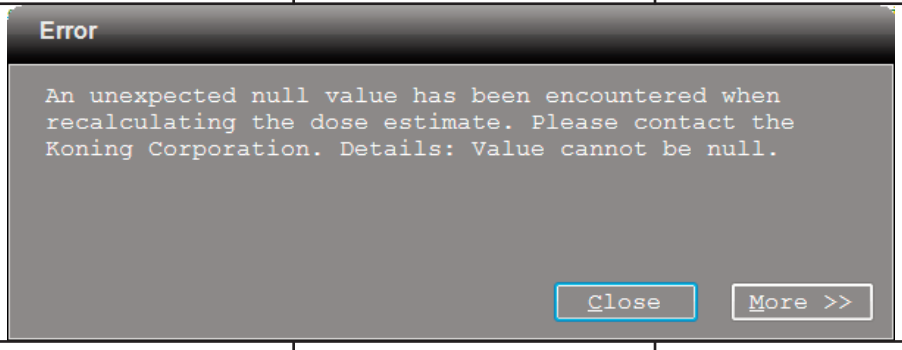
Message ID	Text	Explanation	Possible Resolution
DA-027-ER			
	Failed to set the detector's acquisition type. (Additional information)	May be seen during a variety of operations when setting the command processor's acquisition mode if an error is received.	Write down the additional information word for word and contact Koning for assistance.
DA-101-ER			
	The system timed out while trying to set one or more X-ray parameters.	This message is displayed if the X-ray generator takes too long to set an X-ray parameter.	Have facility IT staff verify that no physical cable connections are loose. Contact Koning if the issue persists.
DA-102-ER			
	An unexpected null value has been encountered when recalculating the dose estimate. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.

Table Z.3-1: Error messages

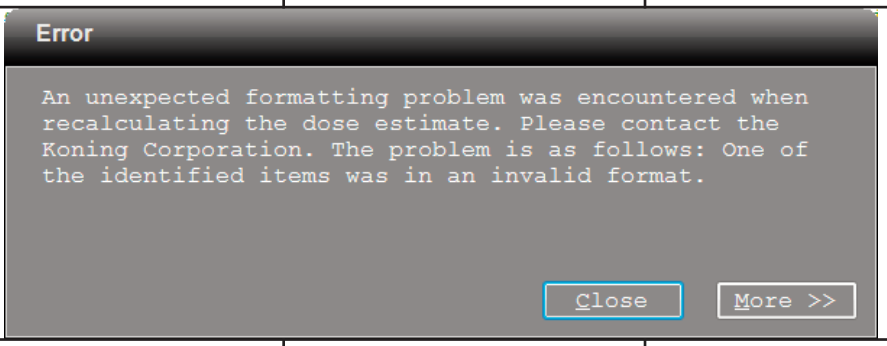
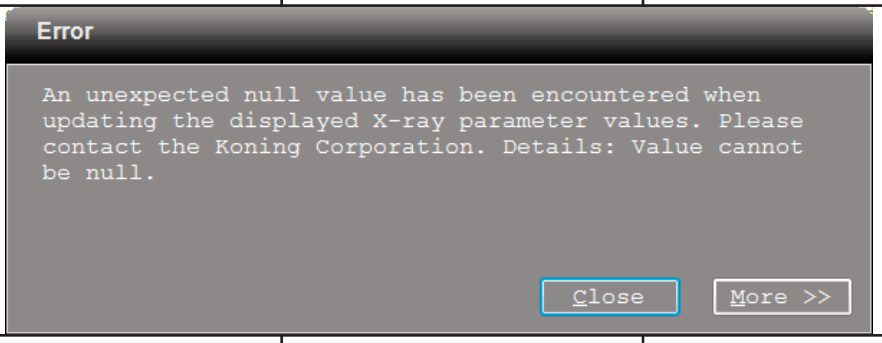
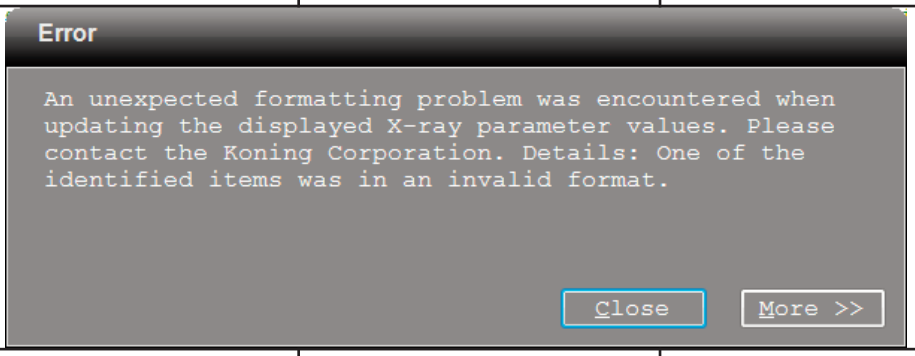
Message ID	Text	Explaination	Possible Resolution
DA-103-ER			
	An unexpected formatting problem was encountered when recalculating the dose estimate. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.
DA-104-ER			
	An unexpected null value has been encountered when updating the displayed X-ray parameter values. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.
DA-105-ER			
	An unexpected formatting problem was encountered when updating the displayed X-ray parameter values. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.

Table Z.3-1: Error messages

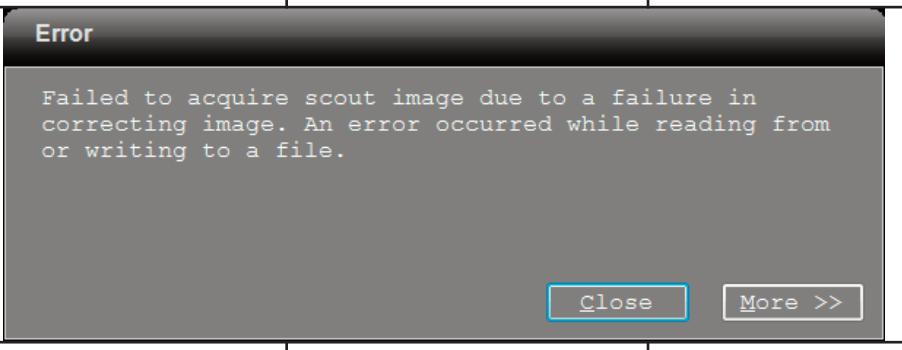
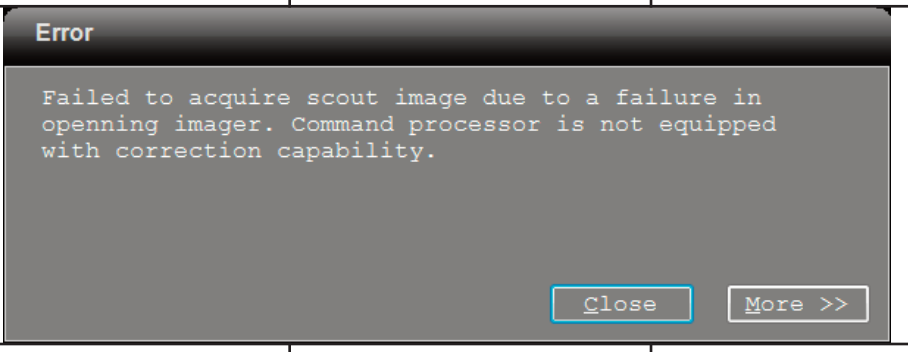
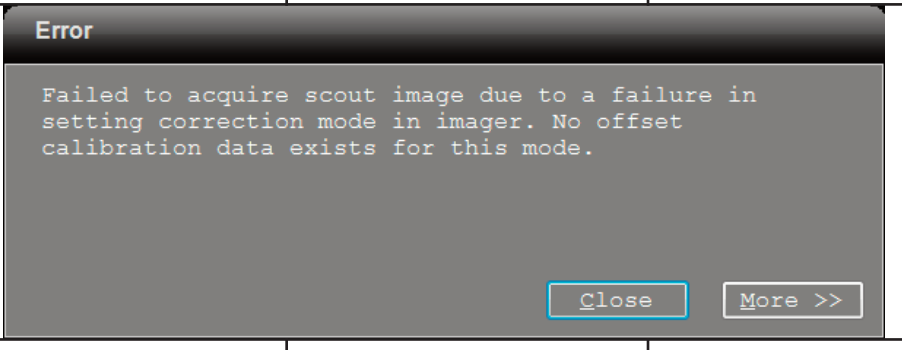
Message ID	Text	Explanation	Possible Resolution
DA-201-ER			
	Failed to acquire scout image due to a failure in correcting image. (Additional information.)	May be seen when acquiring a scout image if image correction fails. A variety of circumstances can cause this error.	Write down the additional information word for word and contact Koning for assistance.
DA-202-ER			
	Failed to acquire scout image due to a failure in openning imager. (Additional information)	May be seen when acquiring a scout image if the command processor is unable to access the imager path. A variety of circumstances can cause this error.	Write down the additional information word for word and contact Koning for assistance.
DA-203-ER			
	Failed to acquire scout image due to a failure in setting correction mode in imager. (Additional information)	May be seen when acquiring a scout image if the KBCT Console program is unable to set the command processor's image correction mode.	Write down the additional information word for word and contact Koning for assistance.

Table Z.3-1: Error messages

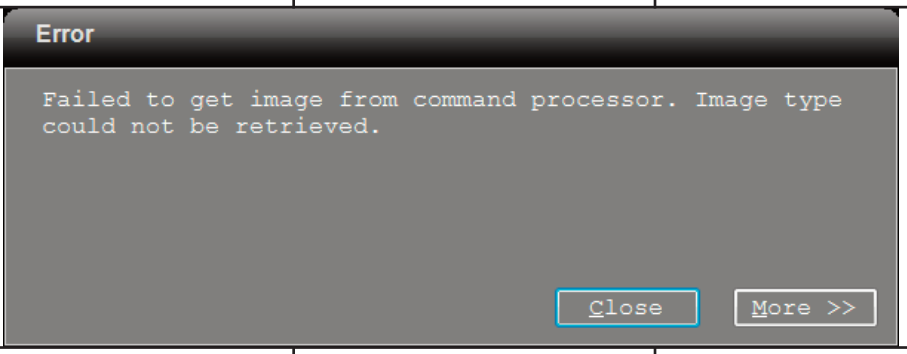
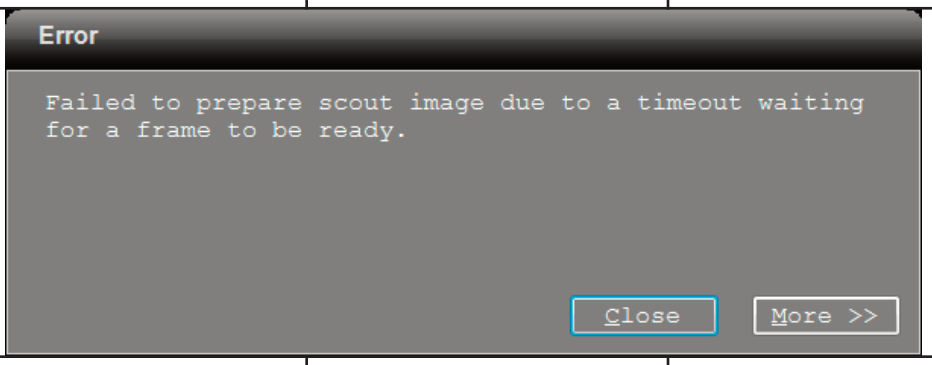
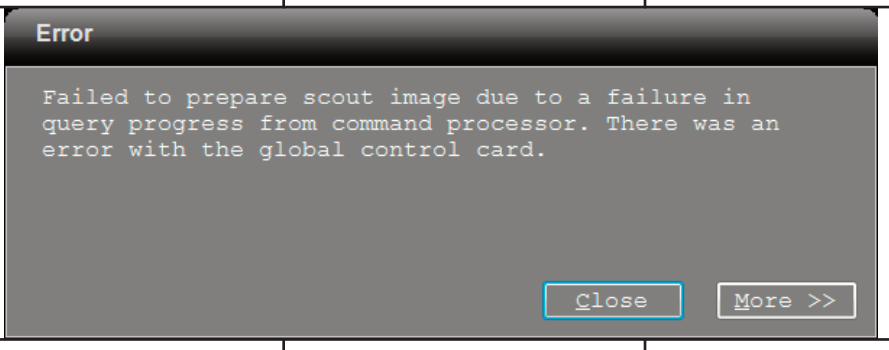
Message ID	Text	Explaination	Possible Resolution
DA-204-ER			
	Failed to get image from command processor. (Additional information)	May be seen when acquiring a scout image if the KBCT Console program fails to acquire the image.	Write down the additional information word for word and contact Koning for assistance.
DA-205-ER			
	Failed to prepare scout image due to a timeout waiting for a frame to be ready.	May be seen during preparation for a scout image acquisition if the command processor does not prepare a frame within a certain amount of time.	Contact Koning for assistance.
DA-206-ER			
	Failed to prepare scout image due to a failure in query progress from command processor. (Additional information)	May be seen during preparation for a scout image if the command processor gives an error when queried for its status.	Write down the additional information word for word and contact Koning for assistance.

Table Z.3-1: Error messages

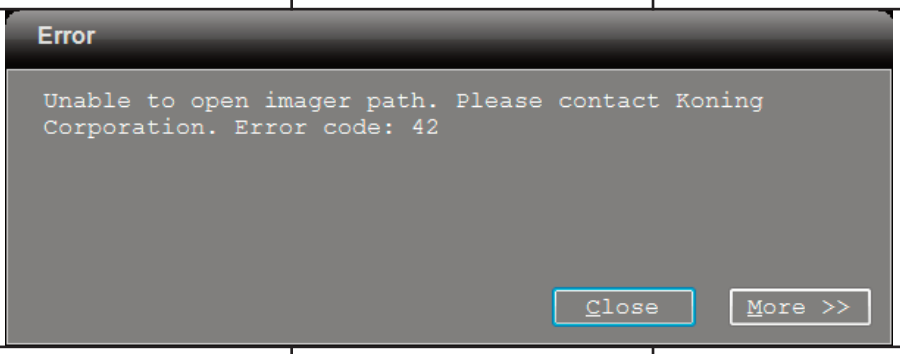
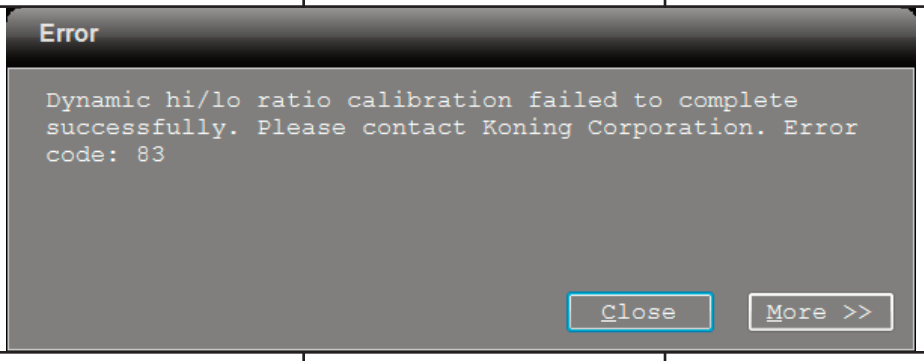
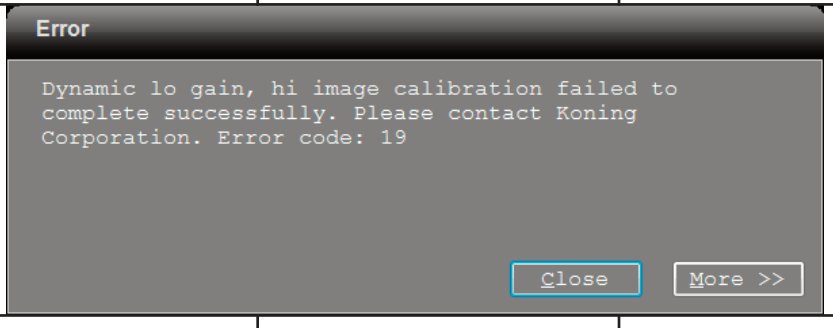
Message ID	Text	Explanation	Possible Resolution
DA-301-ER			
	Unable to open imager path. Please contact Koning Corporation. Error code: x	The software is unable to access some of the files stored on the workstation which are necessary for imaging. There are a variety of circumstances which may cause this message to appear.	Write down the error code and contact Koning for assistance.
DA-302-ER			
	Dynamic hi/lo ratio calibration failed to complete successfully. Please contact Koning Corporation. Error code: x	The software was unable to generate a calibration file for the dynamic hi/lo ratio calibration. There are a variety of circumstances which may cause this message to appear.	Write down the error code and contact Koning for assistance.
DA-303-ER			
	Dynamic lo gain, hi image calibration failed to complete successfully. Please contact Koning Corporation. Error code: x	The software was unable to generate a calibration file for the dynamic low gain high image calibration. There are a variety of circumstances which may cause this message to appear.	Write down the error code and contact Koning for assistance.

Table Z.3-1: Error messages

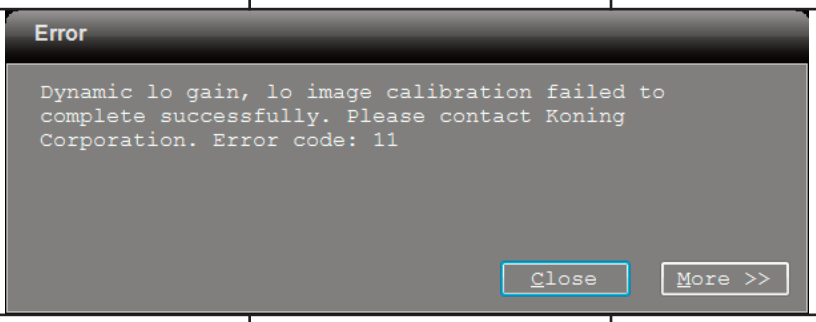
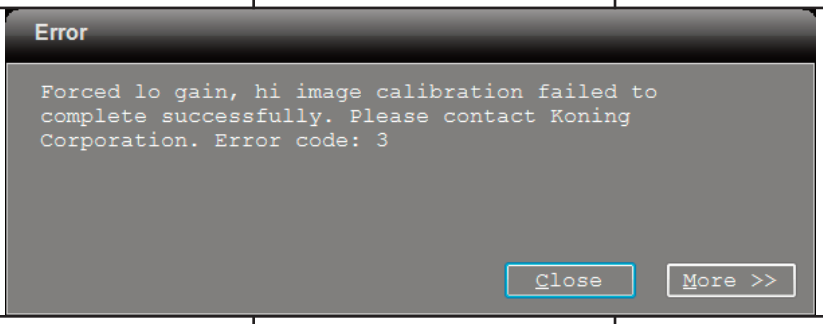
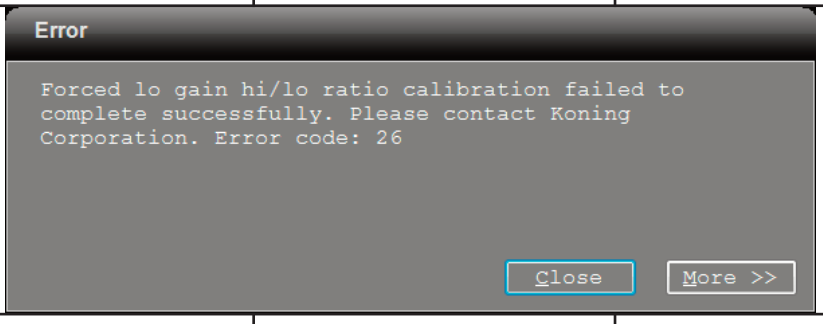
Message ID	Text	Explaination	Possible Resolution
DA-304-ER			
	Dynamic lo gain, lo image calibration failed to complete successfully. Please contact Koning Corporation. Error code: x	The software was unable to generate a calibration file for the dynamic low gain low image calibration. There are a variety of circumstances which may cause this message to appear.	Write down the error code and contact Koning for assistance.
DA-305-ER			
	Forced lo gain, hi image calibration failed to complete successfully. Please contact Koning Corporation. Error code: x	The software was unable to generate a calibration file for the forced low gain high image calibration. There are a variety of circumstances which may cause this message to appear.	Write down the error code and contact Koning for assistance.
DA-306-ER			
	Forced lo gain hi/lo ratio calibration failed to complete successfully. Please contact Koning Corporation. Error code: x	The software was unable to generate a calibration file for the forced low gain high/low ratio calibration. There are a variety of circumstances which may cause this message to appear.	Write down the error code and contact Koning for assistance.

Table Z.3-1: Error messages

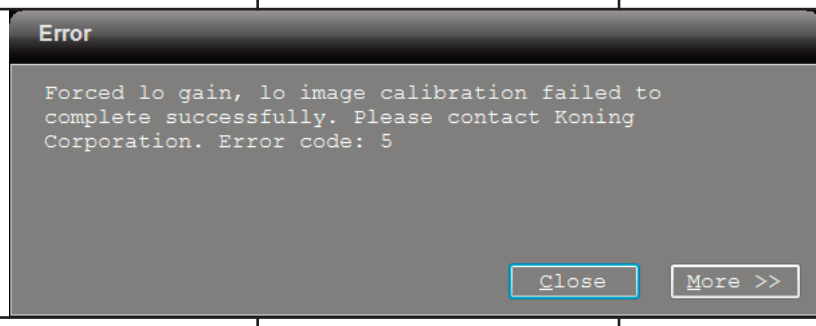
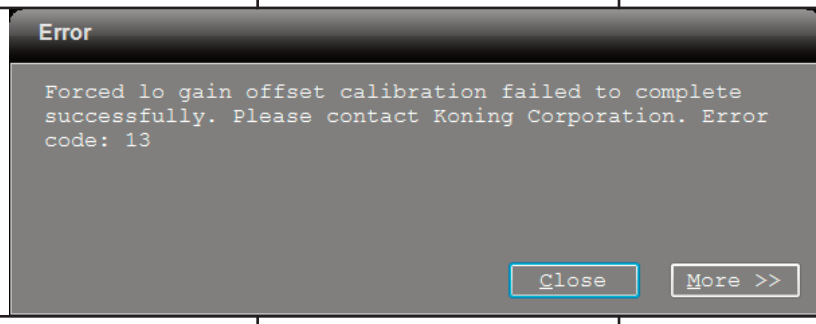
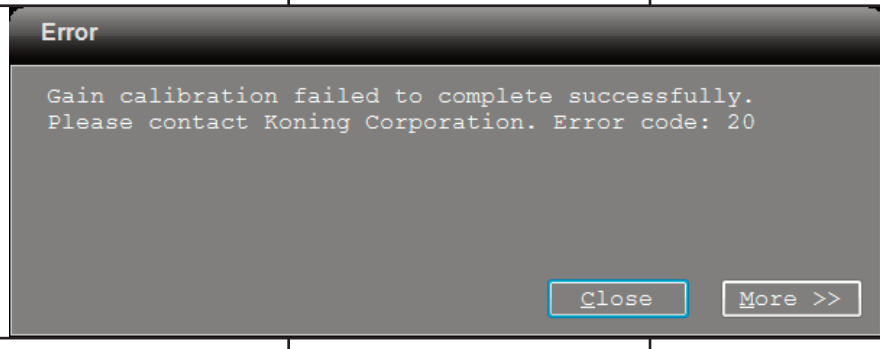
Message ID	Text	Explanation	Possible Resolution
DA-307-ER			
	Forced lo gain, lo image calibration failed to complete successfully. Please contact Koning Corporation. Error code: x	The software was unable to generate a calibration file for the forced low gain low image calibration. There are a variety of circumstances which may cause this message to appear.	Write down the error code and contact Koning for assistance.
DA-308-ER			
	Forced lo gain offset calibration failed to complete successfully. Please contact Koning Corporation. Error code: x	The software was unable to generate a calibration file for the forced low gain offset calibration. There are a variety of circumstances which may cause this message to appear.	Write down the error code and contact Koning for assistance.
DA-309-ER			
	Gain calibration failed to complete successfully. Please contact Koning Corporation. Error code: x	The software was unable to perform a gain calibration. There are a variety of circumstances which may cause this message to appear.	Write down the error code and contact Koning for assistance.

Table Z.3-1: Error messages

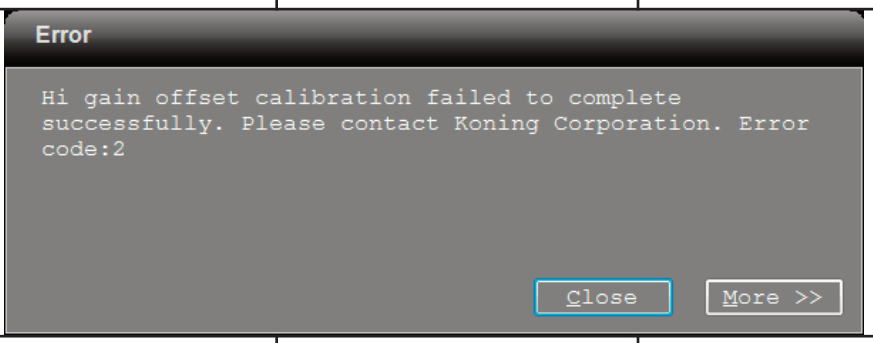
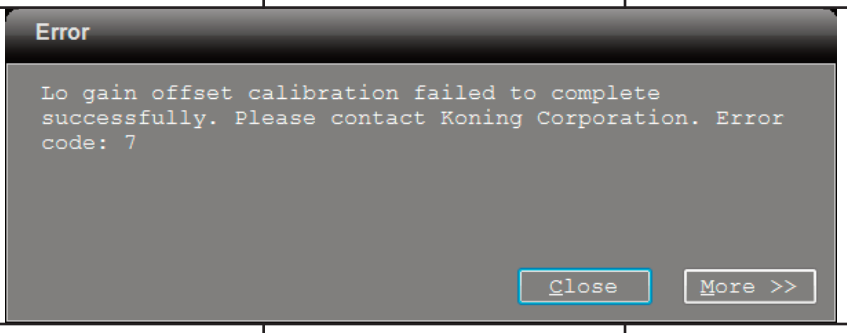
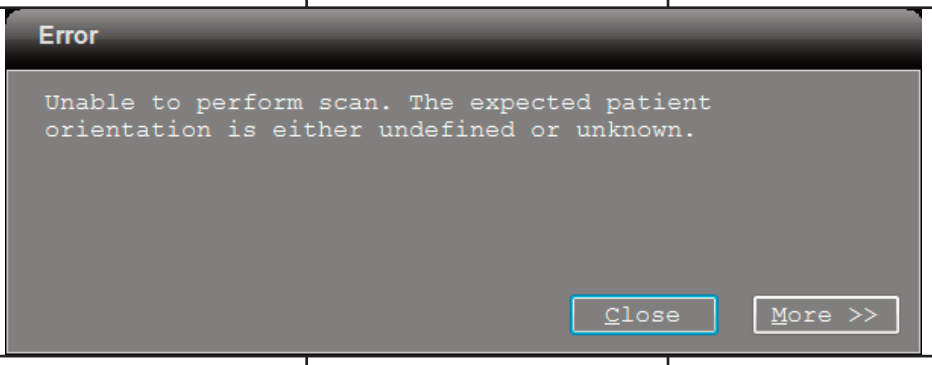
Message ID	Text	Explaination	Possible Resolution
DA-310-ER			
	Hi gain offset calibration failed to complete successfully. Please contact Koning Corporation. Error code: x	The software was unable to generate an offset calibration file for the high gain mode. There are a variety of circumstances which may cause this message to appear.	Write down the error code and contact Koning for assistance.
DA-311-ER			
	Lo gain offset calibration failed to complete successfully. Please contact Koning Corporation. Error code: x	The software was unable to generate an offset calibration file for the high gain mode. There are a variety of circumstances which may cause this message to appear.	Write down the error code and contact Koning for assistance.
DA-312-ER			
	Unable to perform scan. The expected patient orientation is either undefined or unknown.	This message will appear if a scan is attempted while the KBCT Console program is not aware of the intended patient orientation. Indicative of configuration problems.	Contact Koning for assistance. Be aware that any unauthorized modification of the system files voids your service agreements.

Table Z.3-1: Error messages

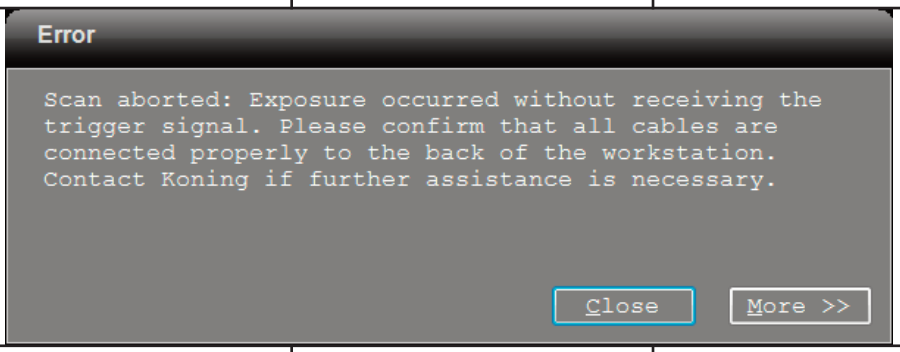
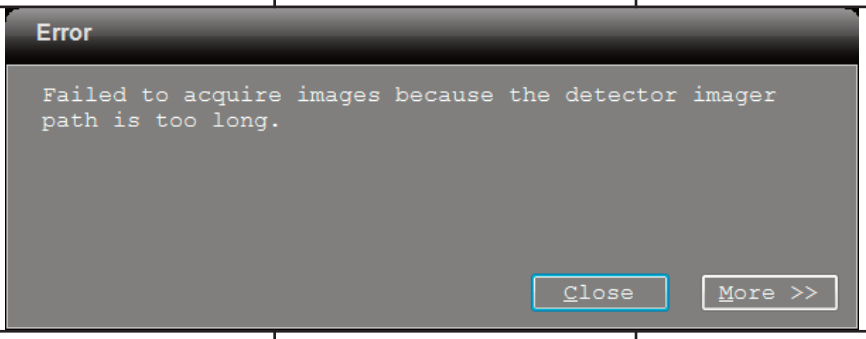
Message ID	Text	Explaination	Possible Resolution
DA-313-ER	3:54:07 PM: Interrupted scan sequence with kVp:49 mA:160 ms:8 Estimated mGy:12.8 Patient:Roe, Jane[1234]		
	Interrupted scan sequence with kVp: x mA: y ms: z Estimated mGy: w Patient: (patient name) [(patient ID)]	This message is logged if a scan is interrupted.	Any images acquired should be stored. Contact Koning for assistance in determining if they are usable, or if this is a chronic issue.
DA-314-ER	4:09:30 PM: No COM connection for receiving trigger signal. Please make sure all cable connections to the back of the workstation are secured.		
	hh:mm:ss (AM/PM): No COM connection for receiving trigger signal. Please make sure all cable connections to the back of the workstation are secured.	This message may be logged during a scan if the COM connection for the trigger signal is lost.	Have facility IT staff verify that no physical cable connections are loose. Contact Koning if the issue persists.
DA-315-ER			
	Scan aborted: Exposure occurred without receiving the trigger signal. Please confirm that all cables are connected properly to the back of the workstation. Contact Koning if further assistance is necessary.	This message may appear during a scan if exposure occurs without receiving a trigger signal.	Have facility IT staff verify that no physical cable connections are loose. Contact Koning if the issue persists.
DA-316-ER			
	Failed to acquire images because the detector imager path is too long.	May be seen during scans if the detector imager path specified by the system configuration is too long.	Contact Koning for assistance.
DA-317-ER	3:08:45 PM: BitFlow failed to acquire a frame because the worker thread could not be created. Frame number: 234		
	hh:mm:ss (AM/PM): BitFlow failed to acquire a frame because (additional information)	May be seen during a scan if the frame grabber fails to acquire a frame.	Write down the additional information word for word and contact Koning for assistance.

Table Z.3-1: Error messages

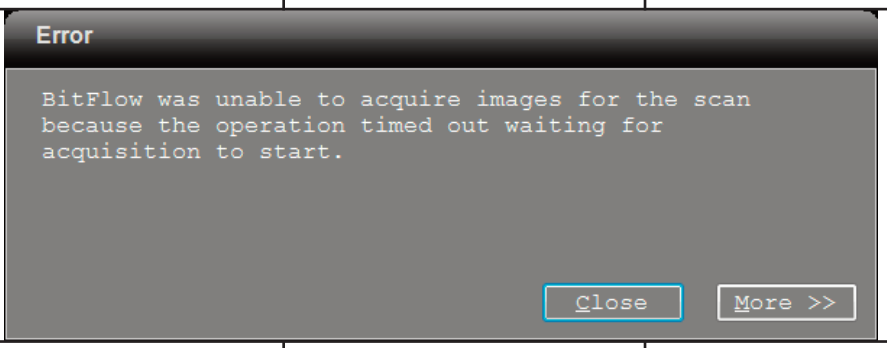
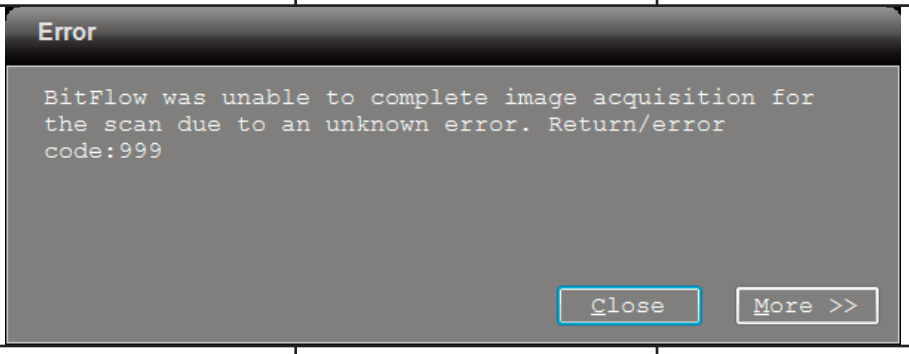
Message ID	Text	Explaination	Possible Resolution
DA-318-ER			
	BitFlow was unable to acquire images for the scan because (additional information)	May be seen during a scan if the frame grabber card is unable to acquire images.	Write down the additional information word for word and contact Koning for assistance.
DA-319-ER			
	BitFlow was unable to complete image acquisition for the scan due to an unknown error. Return/error code: x (Additional information may be provided)	May be seen during a scan if the frame grabber gives an unknown error.	Write down the error code and contact Koning for assistance. Be prepared to recount the sequence of events which led to this message.
DA-320-ER	3:28:19 PM: The Koning CBCT Console program was unable to display a frame due to the following problem: System.Exception: Exception of type 'System.Exception' was thrown. Frame number: 234		
	hh:mm:ss (AM/PM): The Koning CBCT Console program was unable to display a frame due to the following problem: (additional information)	May be seen while acquiring images for a scan if the image viewer does not function properly.	Write down the additional information word for word and contact Koning for assistance. Verify that all images were acquired properly. Depending on the situation, no action may be necessary.

Table Z.3-1: Error messages

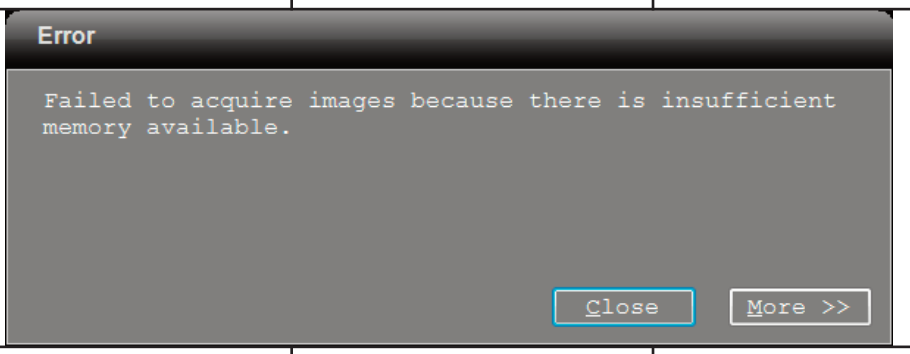
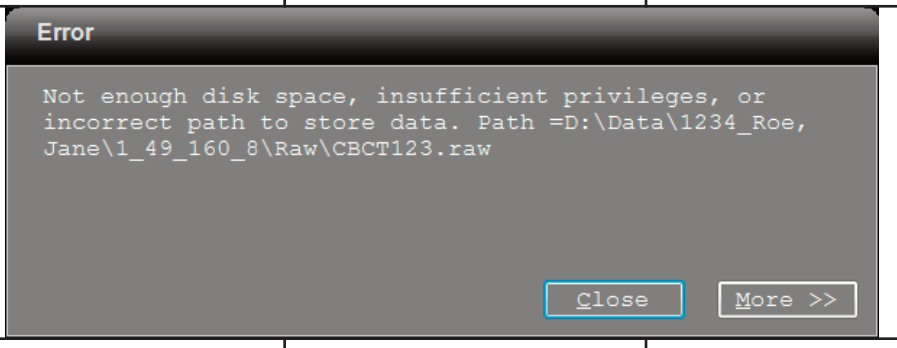
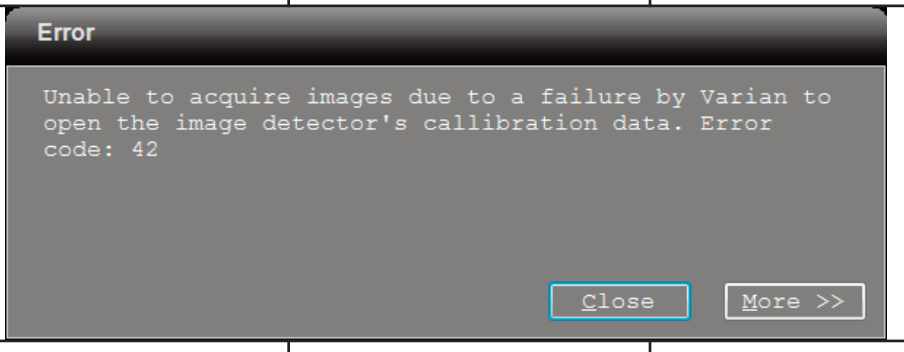
Message ID	Text	Explanation	Possible Resolution
DA-321-ER			
	Failed to acquire images because there is insufficient memory available.	May be seen while acquiring images for a scan if insufficient RAM is available on the Console workstation.	Close all unnecessary programs and try again. Contact Koning for assistance if the issue persists or is chronic.
DA-322-ER			
	Not enough disk space, insufficient privileges, or incorrect path to store data. Path = x (additional information if available)	May be seen during a scan if the KBCT Console program fails to save an image file.	Check the remaining free space on the hard disk. If it is low, backup and remove old case data. Contact Koning for assistance.
DA-323-ER	3:55:21 PM: Unable to correct frame due to a failure by Varian. Error code: 42 Frame number: 234		
	hh:mm:ss (AM/PM): Unable to correct frame due to a failure by Varian. Error code: x (additional information)	May be seen during a scan if corrections on an acquired image fail.	Write down the error code and contact Koning for assistance.
DA-324-ER			
	Unable to acquire images due to a failure by Varian to open the image detector's callibration data. Error code: x	May be seen during a scan if there is a problem accessing the calibration files.	Write down the error code and contact Koning for assistance.

Table Z.3-1: Error messages

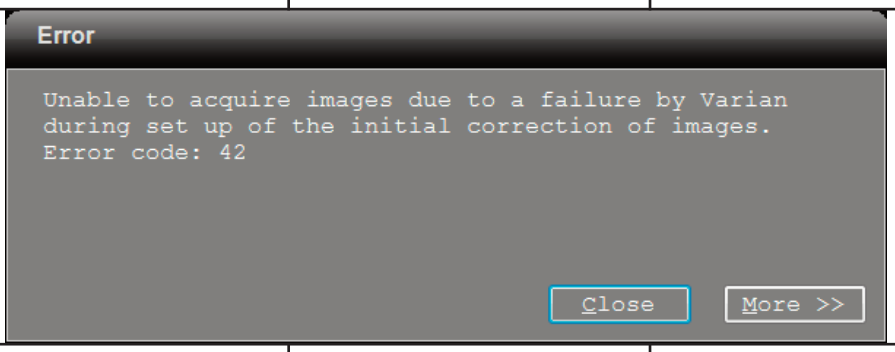
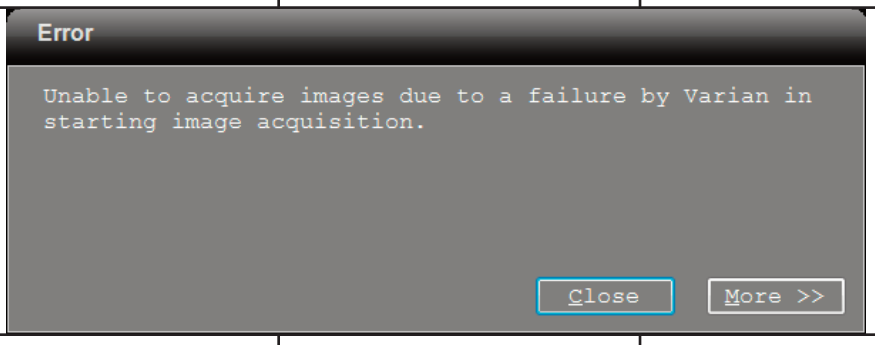
Message ID	Text	Explanation	Possible Resolution
DA-325-ER			
	Unable to acquire images due to a failure by Varian during set up of the initial correction of images. Error code: x	May be seen during a scan if there is a problem getting set up for image correction.	Write down the error code and contact Koning for assistance.
DA-326-ER			
	Unable to acquire images due to a failure by Varian in starting image acquisition.	May be seen during a scan if there is a problem starting image acquisition.	Contact Koning for assistance.
DA-327-ER	4:22:15 PM: BitFlow encountered an unexpected problem during clean up after the scan. Error code: 42		
	hh:mm:ss (AM/PM): BitFlow encountered an unexpected problem during clean up after the scan. Error code: x	This message is logged after a scan if an unexpected error is received from the frame grabber during post-acquisition clean up.	Write down the error code and contact Koning for assistance.
DA-328-ER	4:31:58 PM: BitFlow was unable to complete clean up after the scan because the overflow signal could not be freed.		
	hh:mm:ss (AM/PM): BitFlow was unable to complete clean up after the scan because (additional information)	This message is logged after a scan if an error is received from the frame grabber during post-acquisition clean up.	Write down the additional information word for word and contact Koning for assistance.
DA-329-ER	4:37:47 PM: An unexpected problem was encountered during clean up after the scan. Unexpected error: System.Exception: Exception of type 'System.Exception' was thrown.		
	hh:mm:ss (AM/PM): An unexpected problem was encountered during clean up after the scan. Unexpected error: (additional information)	This message is logged after a scan if an unexpected error is received during post-acquisition clean up.	Write down the additional information word for word and contact Koning for assistance.

Table Z.3-1: Error messages

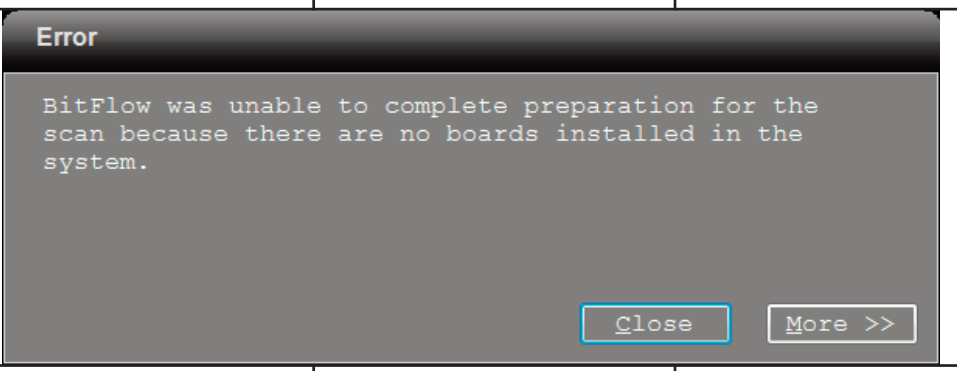
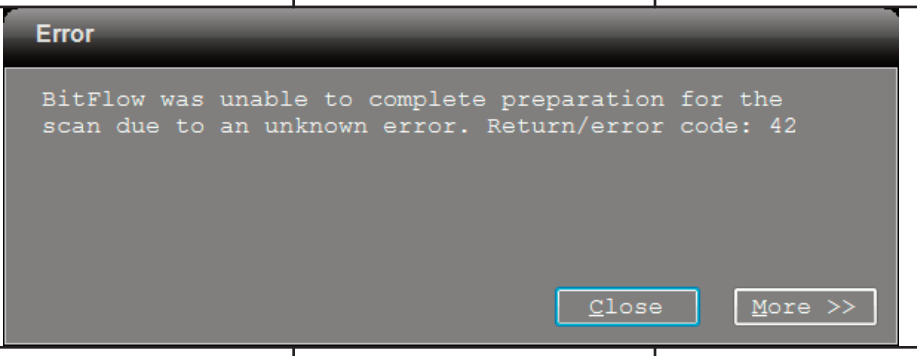
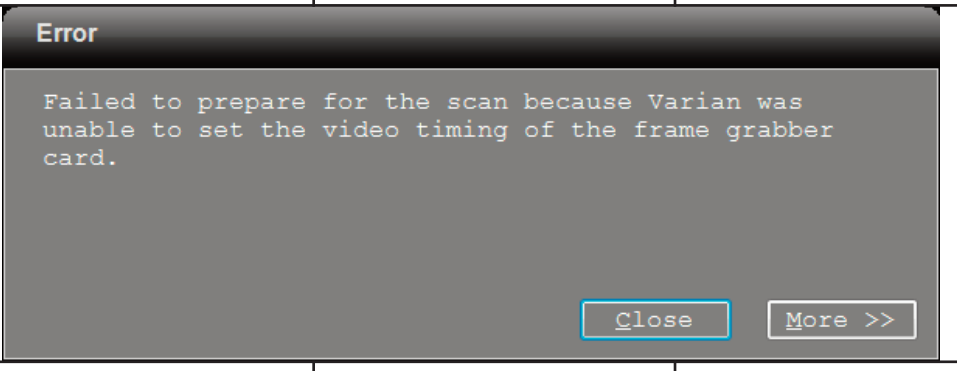
Message ID	Text	Explanation	Possible Resolution
DA-330-ER			
	BitFlow was unable to complete preparation for the scan because (additional information)	This message may be seen during a scan if the frame grabber fails to prepare for the scan due to a variety of reasons.	Write down the additional information word for word and contact Koning for assistance.
DA-331-ER			
	BitFlow was unable to complete preparation for the scan due to an unknown error. Return/error code: x	This message may be seen during a scan if the frame grabber fails to prepare due to an unknown error.	Write down the error code and contact Koning for assistance.
DA-332-ER			
	Failed to prepare for the scan because Varian was unable to set the video timing of the frame grabber card.	This message is displayed when preparing for a scan if the command processor is unable to synchronize with the frame grabber card.	Contact Koning for assistance.

Table Z.3-1: Error messages

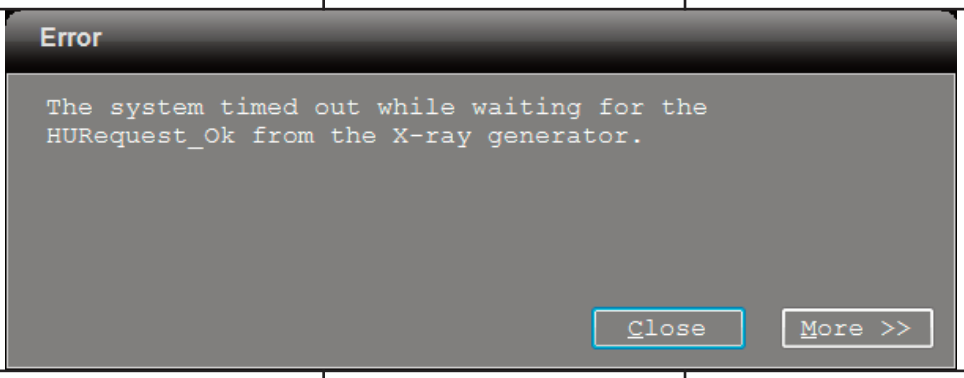
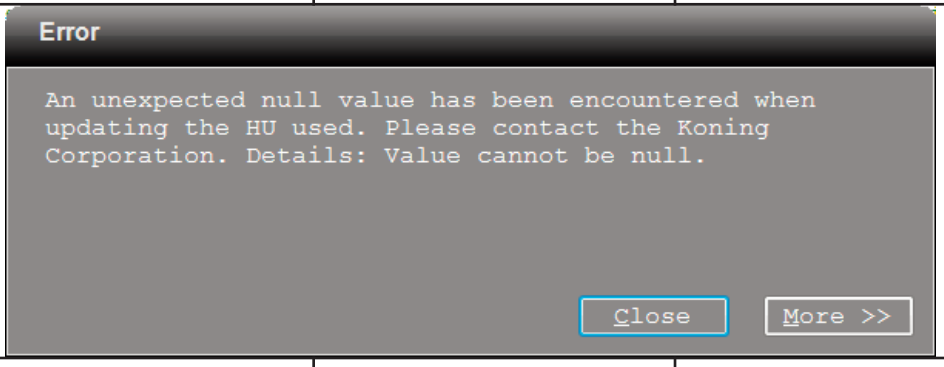
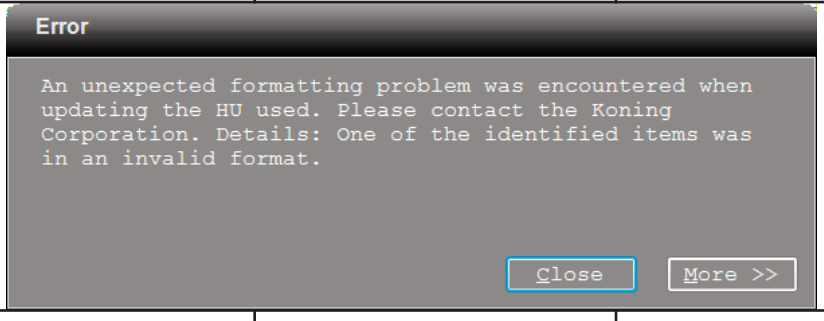
Message ID	Text	Explaination	Possible Resolution
DA-501-ER			
	The system timed out while waiting for the HURequest_Ok from the X-ray generator.	May be displayed while establishing a connection if the request for permission to query the X-ray generator for the HU used does not receive a response.	Have facility IT staff verify that no physical cable connections are loose. Contact Koning if the issue persists.
DA-502-ER			
	An unexpected null value has been encountered when updating the HU used. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.
DA-503-ER			
	An unexpected formatting problem was encountered when updating the HU used. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.

Table Z.3-1: Error messages

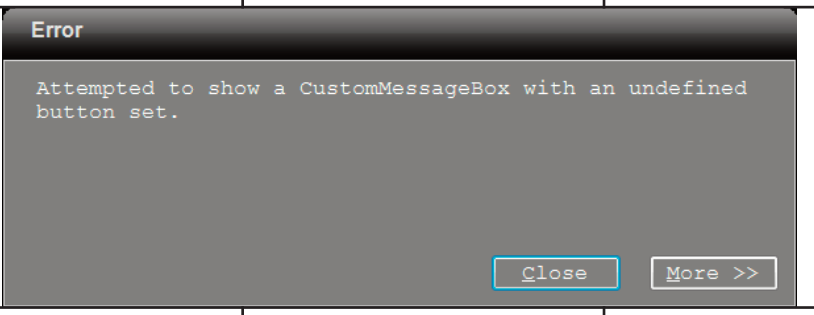
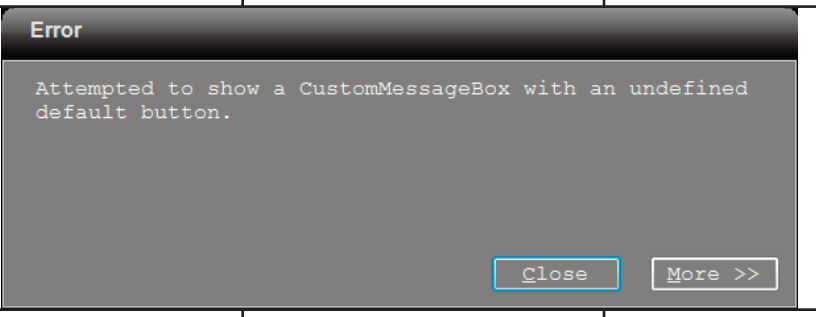
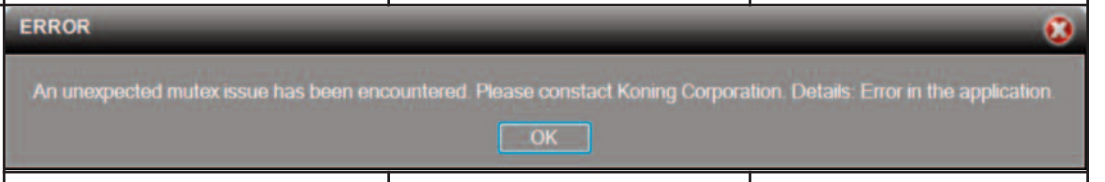
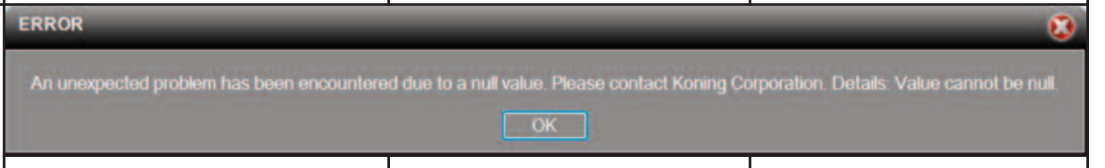
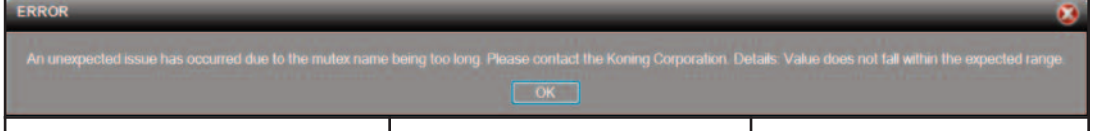
Message ID	Text	Explanation	Possible Resolution
GN-001-ER			
	Attempted to show a CustomMessageBox with an undefined button set.	Indicates failure to display a message.	Contact Koning for assistance. Be prepared to recount the series of events which led to this message.
GN-002-ER			
	Attempted to show a CustomMessageBox with an undefined default button.	Indicates failure to display a message.	Contact Koning for assistance. Be prepared to recount the series of events which led to this message.
GN-003-ER			
	An unexpected mutex issue has been encountered. Please contact Koning Corporation. Details: (Details)	On rare circumstances, may be seen when the KBCT Console program first starts.	Contact Koning for assistance.
GN-004-ER			
	An unexpected problem has been encountered due to a null value. Please contact Koning Corporation. Details: (Details)	On rare circumstances, may be seen when the KBCT Console program first starts.	Contact Koning for assistance.
GN-005-ER			
	An unexpected issue has occurred due to the mutex name being too long. Please contact Koning Corporation. Details: (Details)	On rare circumstances, may be seen when the KBCT Console program first starts.	Contact Koning for assistance.

Table Z.3-1: Error messages

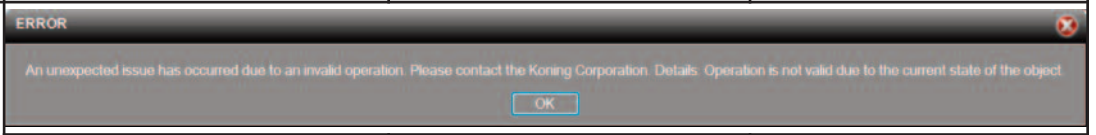
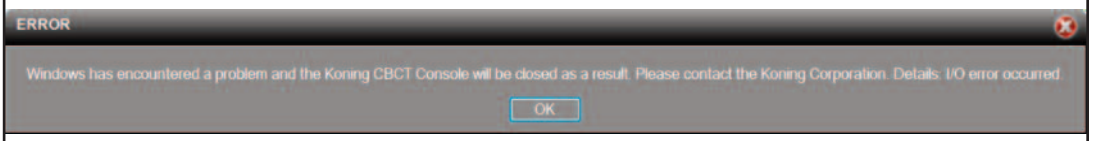
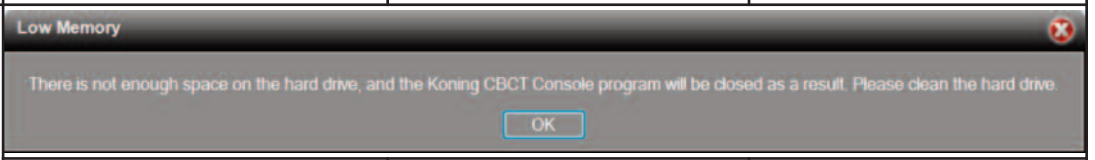
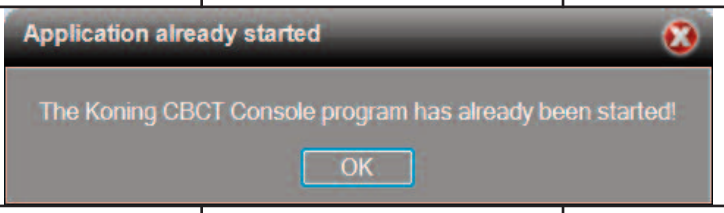
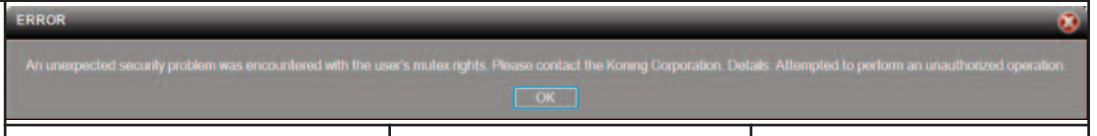
Message ID	Text	Explanation	Possible Resolution
GN-006-ER			
	An unexpected issue has occurred due to an invalid operation. Please contact Koning Corporation. Details: (Details)	On rare circumstances, may be seen when the KBCT Console program first starts.	Contact Koning for assistance.
GN-007-ER			
	Windows has encountered a problem and the Koning CBCT Console will be closed as a result. Please contact Koning Corporation. Details: (Details)	On rare circumstances, may be seen when the KBCT Console program first starts.	Contact Koning for assistance.
GN-008-ER			
	There is not enough space on the hard drive, and the Koning CBCT Console program will be closed as a result. Please clean the hard drive.	This message may be seen when the workstation is low on hard disk space.	Check free space available. Back up and remove old cases. Contact Koning for assistance if the problem persists.
GN-009-ER			
	The Koning CBCT Console program has already been started.	This message may be seen when starting the program if another instance of the program is already running.	Do not open the KBCT Console program if it is already running. If the program does not appear to be running, contact Koning for assistance.
GN-010-ER			
	An unexpected security problem was encountered with the user's mutex rights. Please contact Koning Corporation. Details: (Details)	On rare circumstances, may be seen when the KBCT Console program first starts.	Contact Koning for assistance.

Table Z.3-1: Error messages

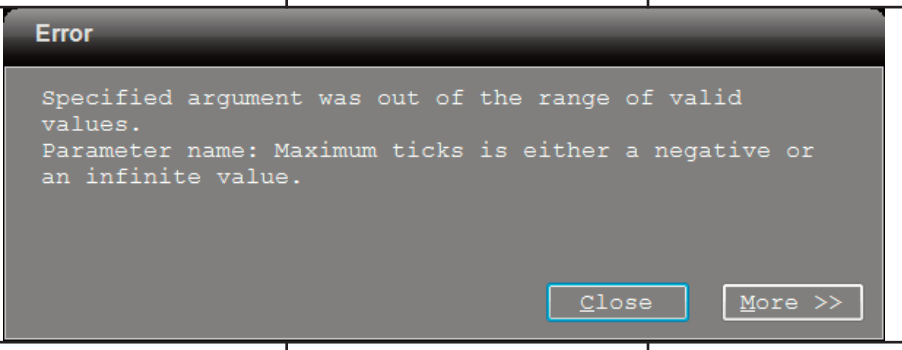
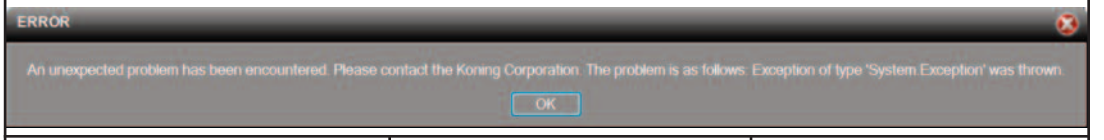
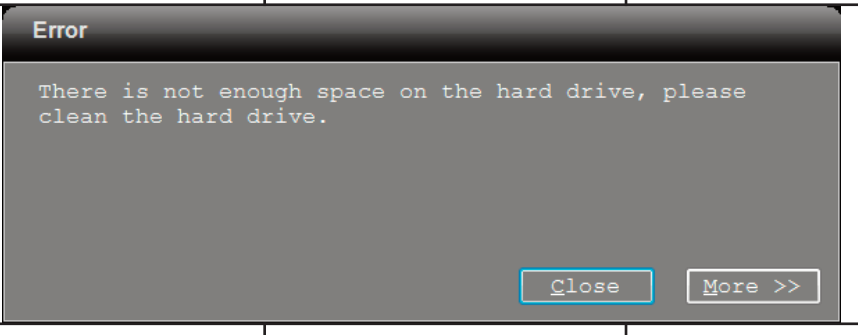
Message ID	Text	Explanation	Possible Resolution
GN-011-ER			
	Specified argument was out of the range of valid values. Parameter name: (additional information)	Indicative of an internal program failure.	Contact Koning for assistance. Be prepared to recount the series of events which led to this message.
GN-012-ER			
	An unexpected problem has been encountered. Please contact Koning Corporation. The problem is as follows: (Details)	May be seen under rare circumstances. Indicates an unexpected error has occurred.	Contact Koning Corporation for assistance. Be prepared to recount the series of events which led to this message.
GN-013-ER			
	There is not enough space on the hard drive, please clean the hard drive.	This message may be seen when the workstation is low on hard disk space.	Check free space available. Back up and remove old cases. Contact Koning for assistance if the problem persists.

Table Z.3-1: Error messages

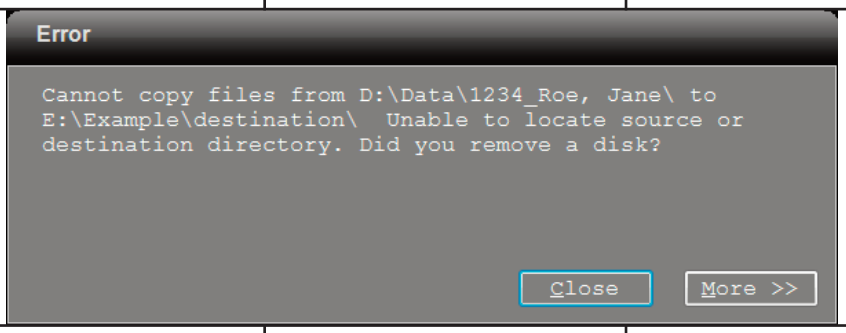
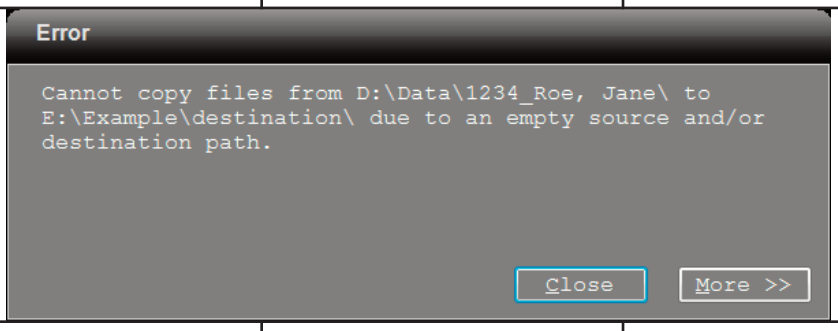
Message ID	Text	Explaination	Possible Resolution
GN-014-ER			
	Cannot copy files from x to y. Unable to locate source or destination directory. Did you remove a disk?	May be seen during operations involving the copying of files if either the source or destination (or both) directories cannot be located.	If either the source or destination is a DVD, verify that it wasn't ejected. Contact Koning for assistance. Be aware that any unauthorized modification of the Console workstation voids your service agreements.
GN-015-ER			
	Cannot copy files from x to y due to an empty source and/or destination path.	May be seen during operations involving the copying of files. Possibly indicative of configuration issues.	Contact Koning for assistance. Be aware that any unauthorized modification of the system files voids your service agreements.

Table Z.3-1: Error messages

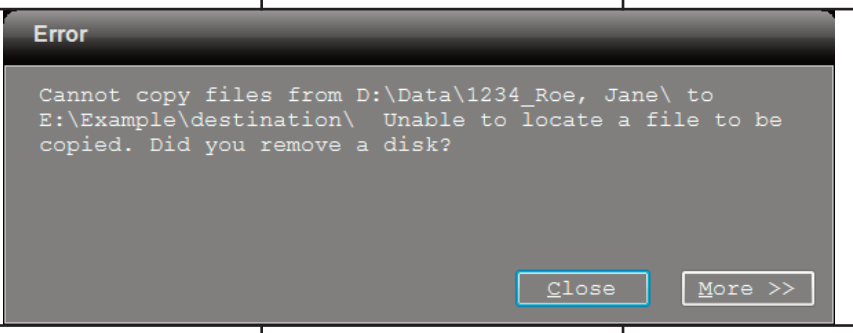
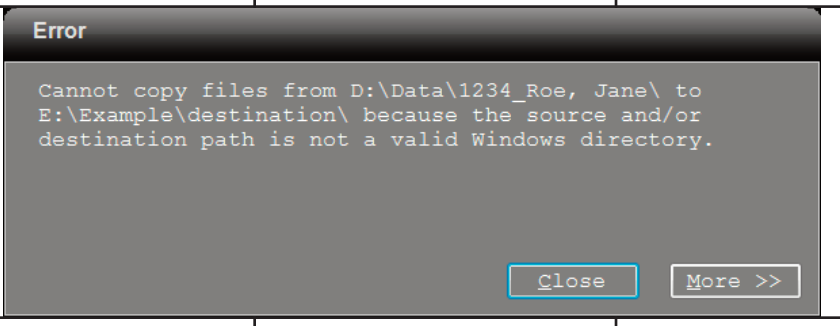
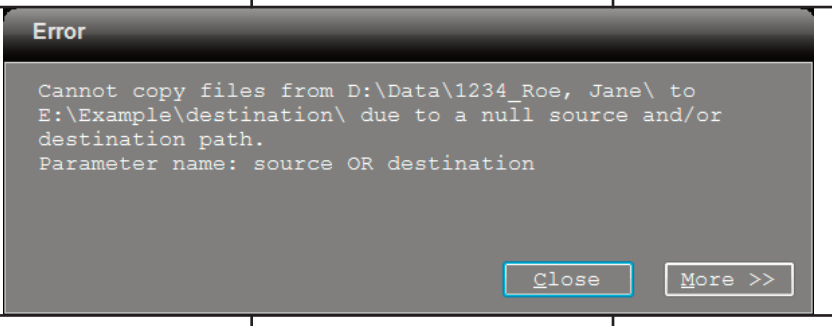
Message ID	Text	Explanation	Possible Resolution
GN-016-ER			
	Cannot copy files from x to y. Unable to locate a file to be copied. Did you remove a disk?	May be seen during operations involving the copying of files if a source file cannot be located.	If the source is a DVD, verify that it wasn't ejected. Contact Koning for assistance. Be aware that any unauthorized modification of the Console workstation voids your service agreements.
GN-017-ER			
	Cannot copy files from x to y because the source and/or destination path is not a valid Windows directory.	May be seen during operations involving the copying of files. Possibly indicative of configuration issues.	Contact Koning for assistance. Be aware that any unauthorized modification of the system files voids your service agreements.
GN-018-ER			
	Cannot copy files from x to y due to a null source and/or destination path. Parameter name: source OR destination	May be seen during operations involving the copying of files. Possibly indicative of configuration issues.	Contact Koning for assistance. Be aware that any unauthorized modification of the system files voids your service agreements.

Table Z.3-1: Error messages

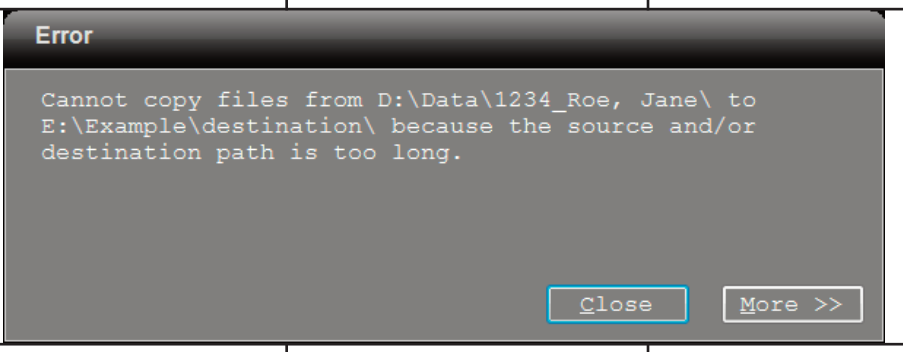
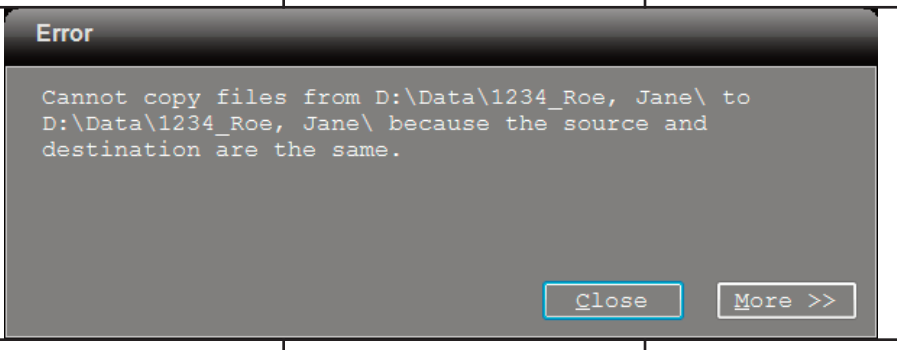
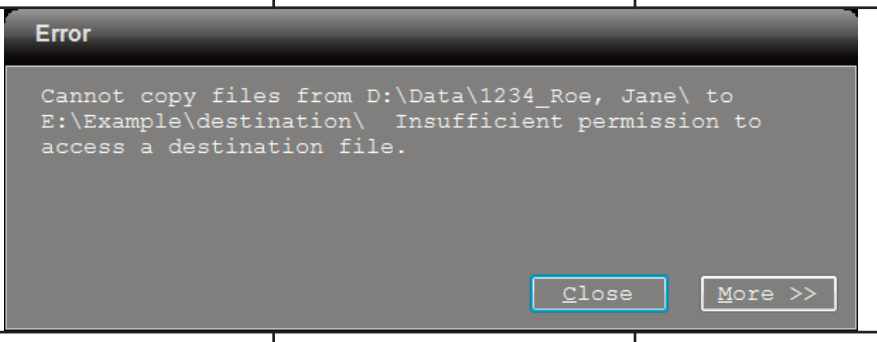
Message ID	Text	Explanation	Possible Resolution
GN-019-ER			
	Cannot copy files from x to y because the source and/or destination path is too long.	May be seen during operations involving the copying of files. Possibly indicative of configuration issues.	Contact Koning for assistance. Be aware that any unauthorized modification of the system files voids your service agreements.
GN-020-ER			
	Cannot copy files from x to x because the source and destination are the same.	May be seen during operations involving the copying of files. Possibly indicative of configuration issues.	Contact Koning for assistance. Be aware that any unauthorized modification of the system files voids your service agreements.
GN-021-ER			
	Cannot copy files from x to y. Insufficient permission to access a destination file.	May be seen during operations involving the copying of files. Possibly indicative of configuration issues.	Contact Koning for assistance. Be aware that any unauthorized modification of the system files voids your service agreements.

Table Z.3-1: Error messages

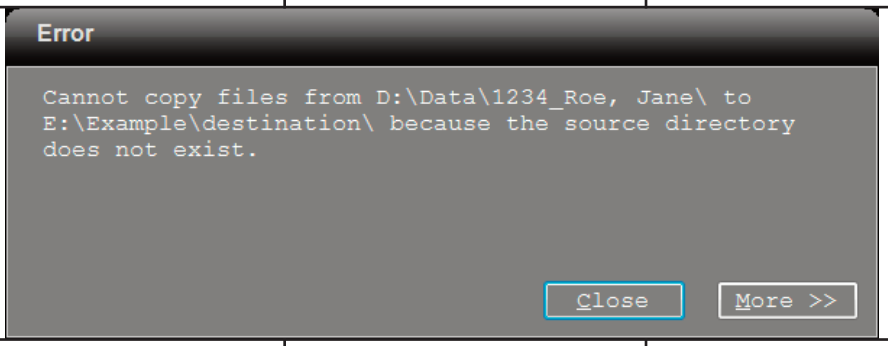
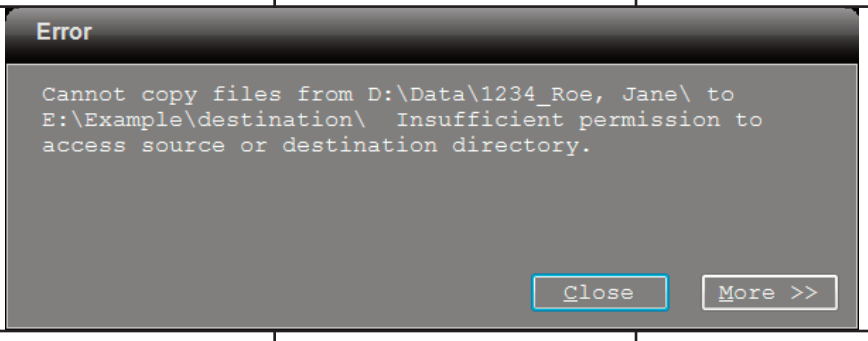
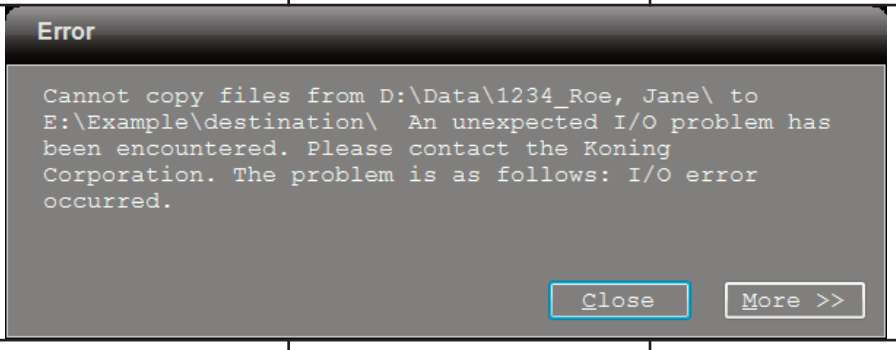
Message ID	Text	Explanation	Possible Resolution
GN-022-ER			
	Cannot copy files from x to y because the source directory does not exist.	May be seen during operations involving the copying of files. Possibly indicative of configuration issues.	Contact Koning for assistance. Be aware that any unauthorized modification of the system files voids your service agreements.
GN-023-ER			
	Cannot copy files from x to y. Insufficient permission to access source or destination directory.	May be seen during operations involving the copying of files. Possibly indicative of configuration issues.	Contact Koning for assistance. Be aware that any unauthorized modification of the system files voids your service agreements.
GN-024-ER			
	Cannot copy files from x to y. An unexpected I/O problem has been encountered. Please contact Koning Corporation. The problem is as follows: (additional information)	May be seen during operations involving the copying of files under a variety of rare circumstances.	Contact Koning for assistance.

Table Z.3-1: Error messages

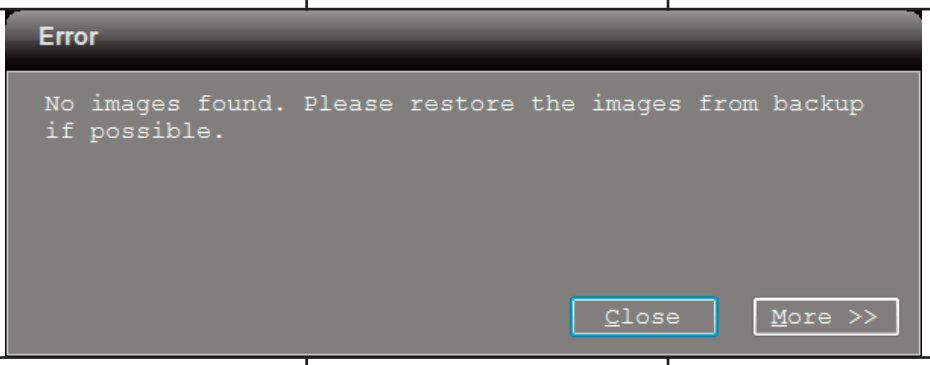
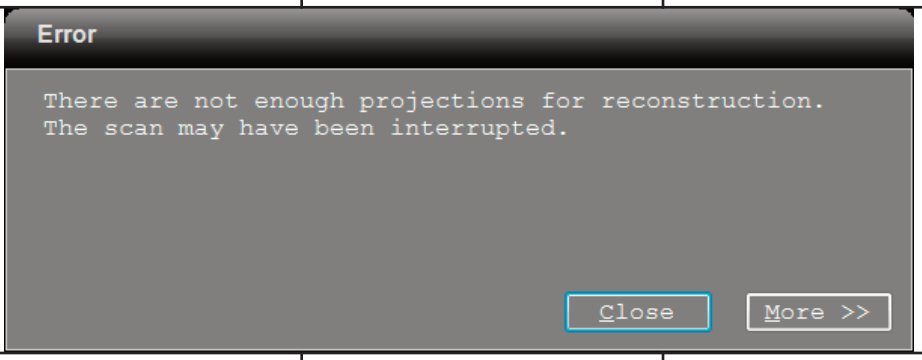
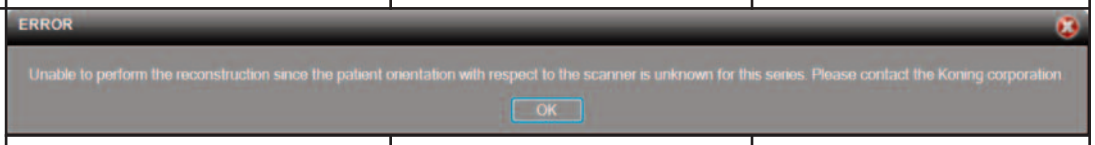
Message ID	Text	Explaination	Possible Resolution
IR-201-ER			
	No images found. Please restore the images from backup if possible.	Shown if attempting to view or otherwise perform an operation requiring images no longer stored on the Console workstation.	If the images were backed up previously, restore them and try again.
IR-202-ER			
	There are not enough projections for reconstruction. The scan may have been interrupted.	Shown if attempting reconstruction on a series where fewer than 300 projection images are present.	Contact Koning for assistance. Depending on the number of missing projections, Koning may be able to reconstruct the data set for you. If this is a chronic issue, Koning recommends avoiding use of the System until the problem is resolved.
IR-203-ER			
	Unable to perform the reconstruction since the patient orientation with respect to the scanner is unknown for this series. Please contact Koning Corporation.	On rare circumstances, may be seen when attempting a reconstruction. Indicates that there is no orientation data associated with the series.	Contact Koning Corporation for assistance.

Table Z.3-1: Error messages

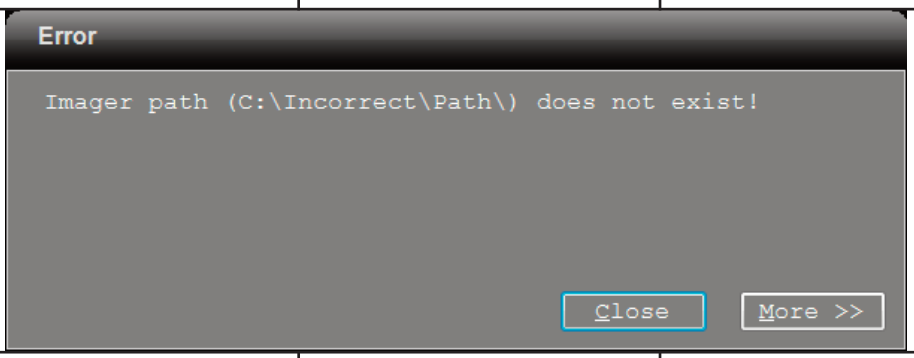
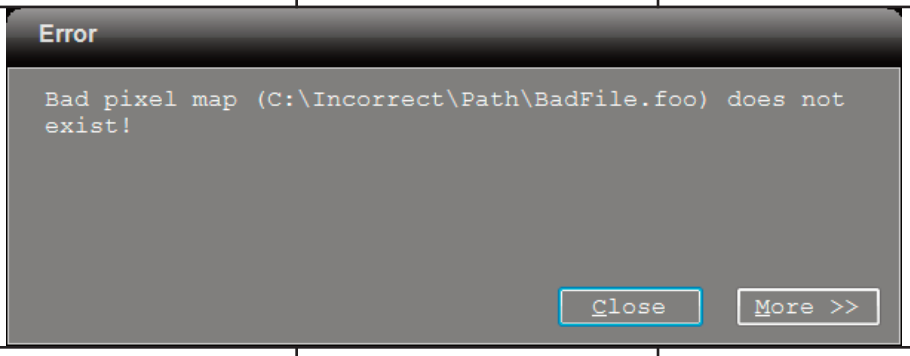
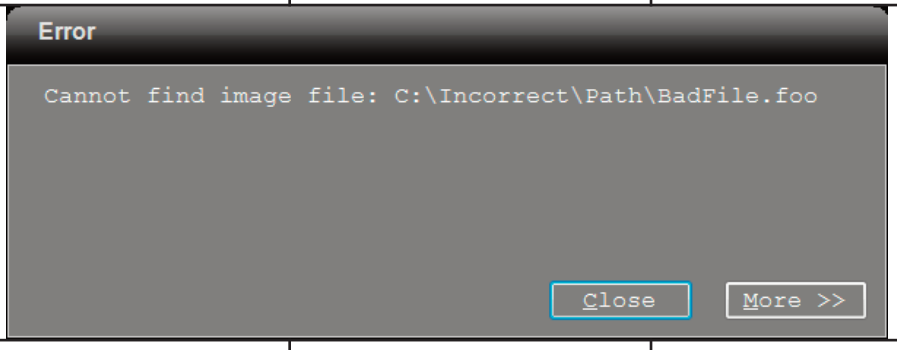
Message ID	Text	Explanation	Possible Resolution
IR-204-ER			
	Imager path (x) does not exist!	This message may appear during reconstruction under rare circumstances.	Contact Koning Corporation for assistance.
IR-205-ER			
	Bad pixel map (x) does not exist!	This message may appear during reconstruction under rare circumstances.	Contact Koning Corporation for assistance.
IR-206-ER			
	Cannot find image file: x	This message may appear during reconstruction if the KBCT Console program is unable to locate an image file.	Contact Koning Corporation for assistance.

Table Z.3-1: Error messages

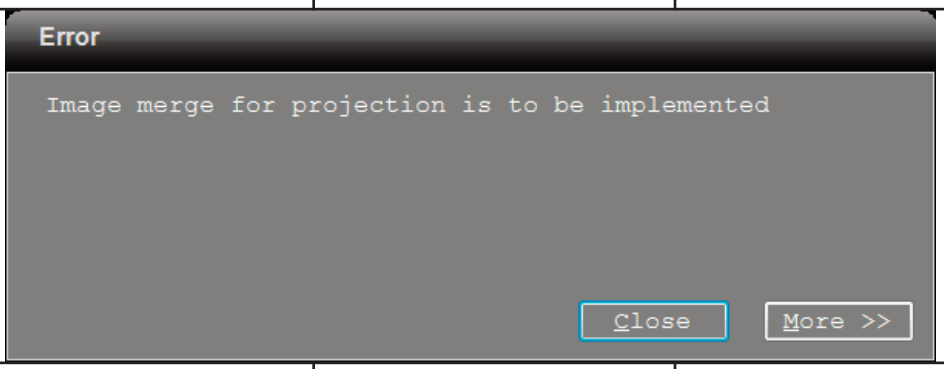
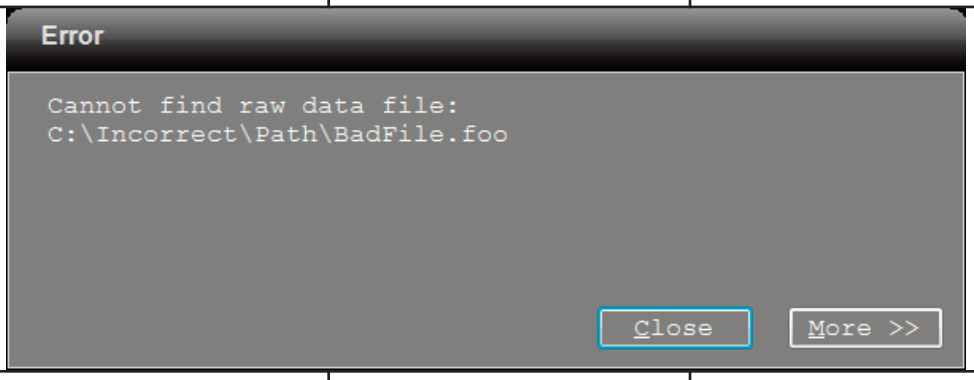
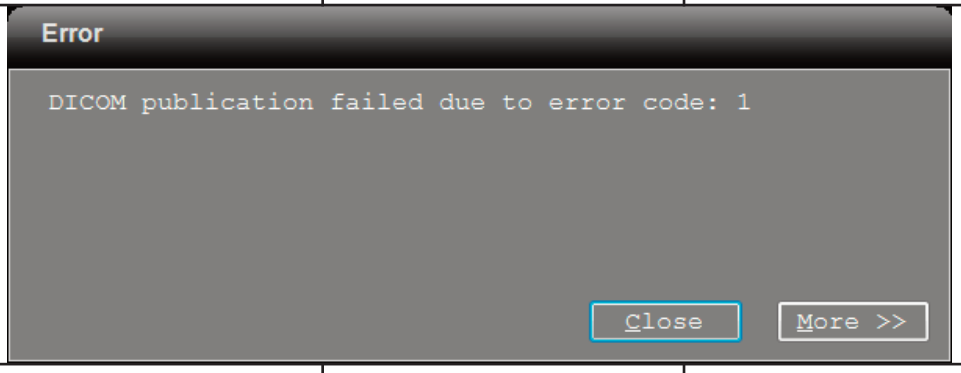
Message ID	Text	Explaination	Possible Resolution
IR-207-ER			
	Image merge for projection is to be implemented	This message may appear during reconstruction under rare circumstances and is indicative of configuration problems.	Contact Koning Corporation for assistance. Be aware that any unauthorized modification of the system files voids your service agreements.
IR-208-ER			
	Cannot find raw data file: x	This message may appear if the KBCT Console program is unable to locate one of the projections to be reconstructed.	Contact Koning Corporation for assistance.
IR-301-ER			
	DICOM publication failed due to error code: x	Shown if an attempt to publish images to the storage server fails. There are a variety of circumstances which may cause this error to appear.	Write down the error code and contact Koning for assistance.

Table Z.3-1: Error messages

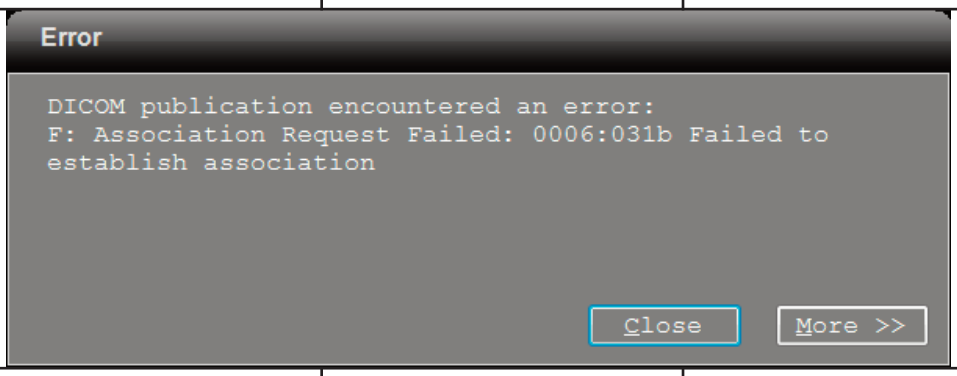
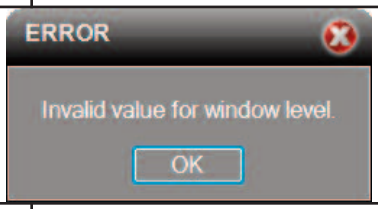
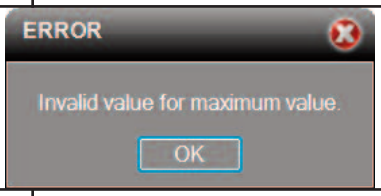
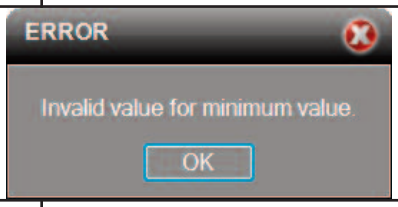
Message ID	Text	Explanation	Possible Resolution
IR-302-ER			
	DICOM publication encountered an error: (Additional text describing the error)	Shown if an attempt to publish images to the storage server encounters an error. There are a variety of circumstances which may cause this error to appear.	Have your system administrator verify that the 3D Visualization / DICOM Storage System settings are correct. Write down the error message. If the settings are correct, contact Koning for assistance.
IV-001-ER			
	Invalid value for window level.	May be seen when directly keying in a window level.	Verify the desired window level is a number.
IV-002-ER			
	Invalid value for maximum value.	May be seen when directly keying in a maximum display value.	Verify the desired maximum display value is a number.
IV-003-ER			
	Invalid value for minimum value.	May be seen when directly keying in a minimum display value.	Verify the desired minimum display value is a number.

Table Z.3-1: Error messages

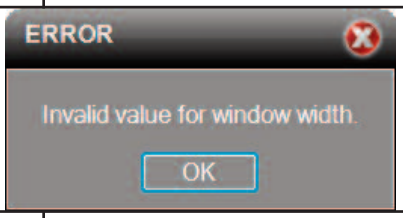
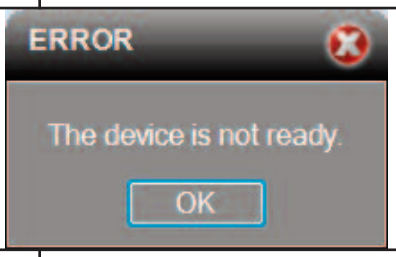
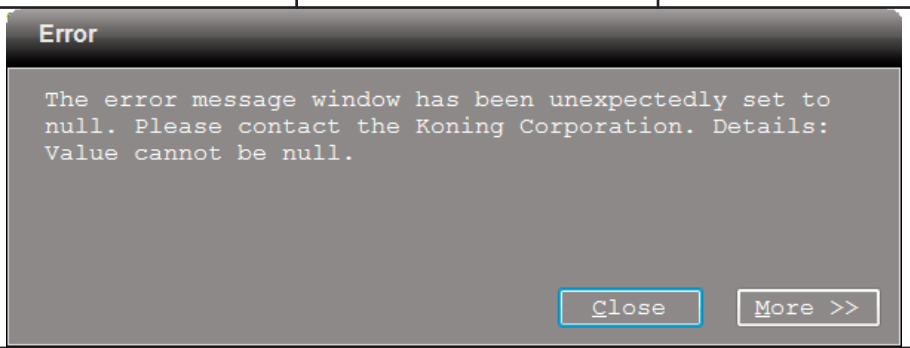
Message ID	Text	Explanation	Possible Resolution
IV-004-ER			
	Invalid value for window width.	May be seen when directly keying in a window width.	Verify the desired window width is a number.
LM-001-ER			
	Not ready	Shown when the System is in a non-ready state (for reasons other than an ongoing task). This message may appear under a variety of circumstances.	Verify that a connection has been successfully established. Verify that the Scanner doors are closed and that the patient safety cover is in place with all interlocks actuated. If the issue persists, contact Koning for assistance.
LM-002-ER			
	The device is not ready.	This message typically appears when unable to establish or maintain a connection to the Scanner.	Establish a connection and verify that the Scanner doors are closed. Contact Koning for assistance if the problem persists.
LM-401-ER			
	The error message window has unexpectedly set to null. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances.	Contact Koning Corporation for assistance.

Table Z.3-1: Error messages

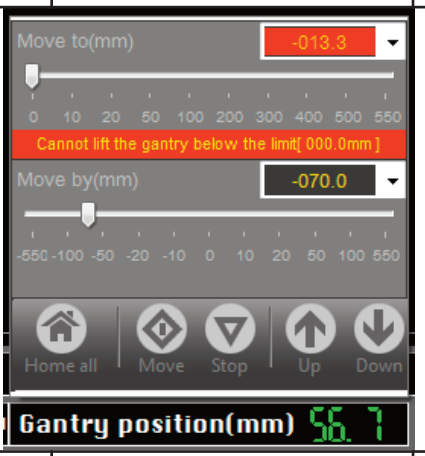
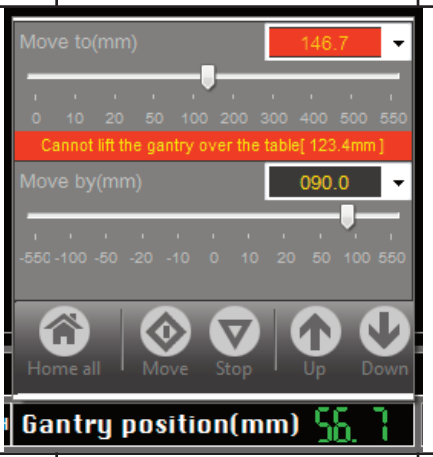
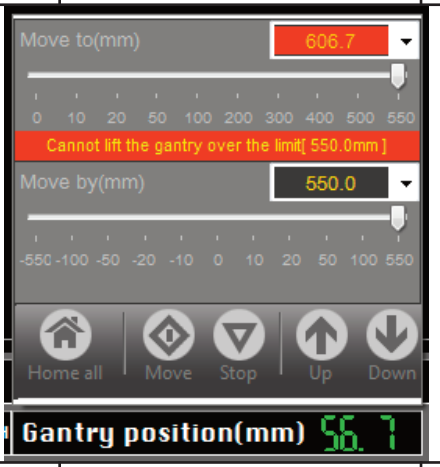
Message ID	Text	Explanation	Possible Resolution
MC-001-ER			
	Cannot lift the gantry below the limit [x mm]	Shown if attempting to move the gantry to a vertical position lower than 0 mm.	Verify the desired position or displacement is between 0 mm and the position of the patient table.
MC-002-ER			
	Cannot lift the gantry over the table [x mm]	Shown if attempting to move the gantry to a vertical position above the patient table.	Verify the desired position or displacement is between 0 mm and the position of the patient table.
MC-003-ER			
	Cannot lift the gantry over the limit [x mm]	May appear if attempting to move the gantry to a vertical position higher than 550 mm. Typically, MC-002-ER is seen instead.	Verify the desired position or displacement is between 0 mm and 550 mm.

Table Z.3-1: Error messages

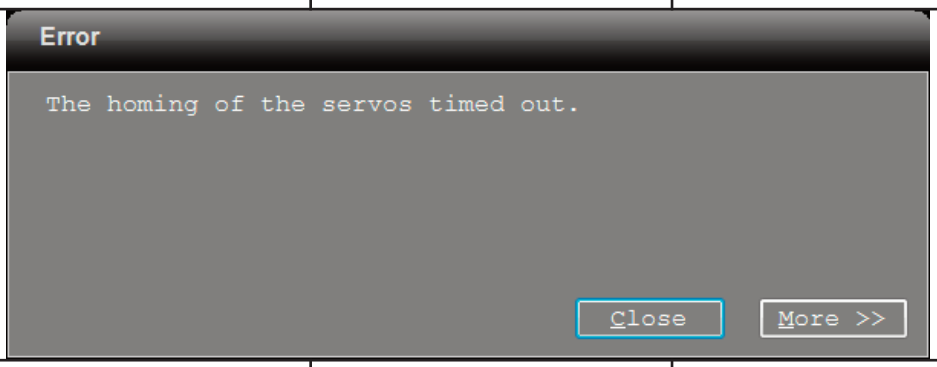
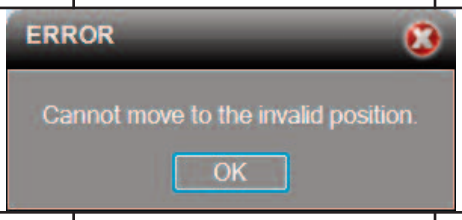
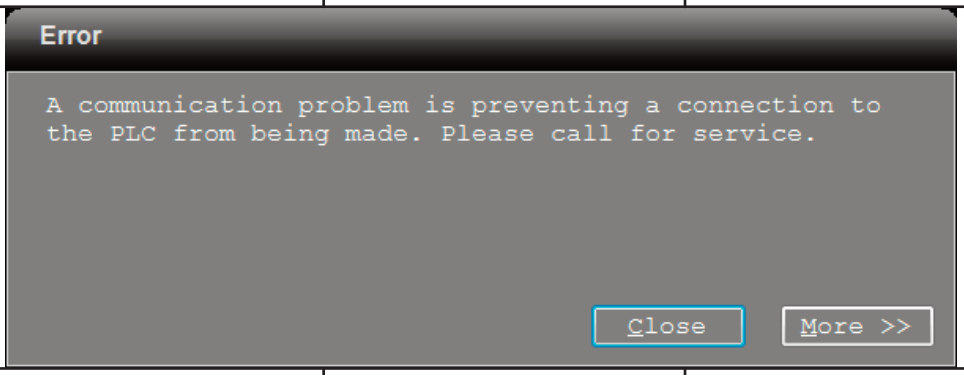
Message ID	Text	Explaination	Possible Resolution
MC-004-ER			
	The homing of the servos timed out.	May appear if the initial homing of the servos takes significantly longer than expected.	Verify that the servos are moving during the homing process. If motion is observed, try connecting again. Contact Koning for assistance.
MC-005-ER			
	Cannot move to the invalid position.	May appear when attempting to move the patient table or gantry lift to an invalid position.	Check the desired position. Keep in mind that the patient table and gantry lift may not pass each other.
MC-006-ER			
	A communication problem is preventing a connection to the PLC from being made. Please call for service.	May appear when attempting to establish a connection to the Scanner if the KBCT Console program encounteres problems communicating with the PLC.	Have your system administrator verify the configuration settings for connecting to the PLC. Have facility IT staff verify that the PLC is on and that all physical cable connections are not loose. Contact Koning if the issue persists.

Table Z.3-1: Error messages

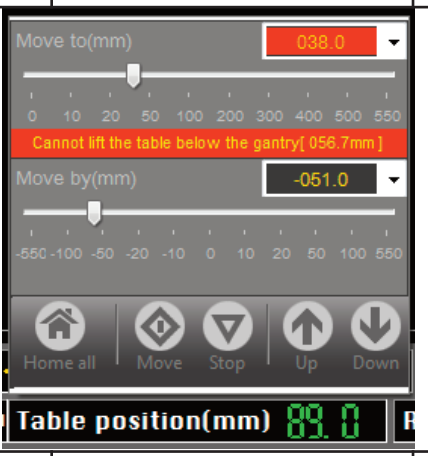
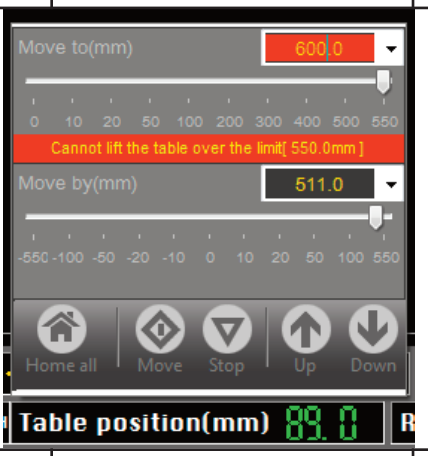
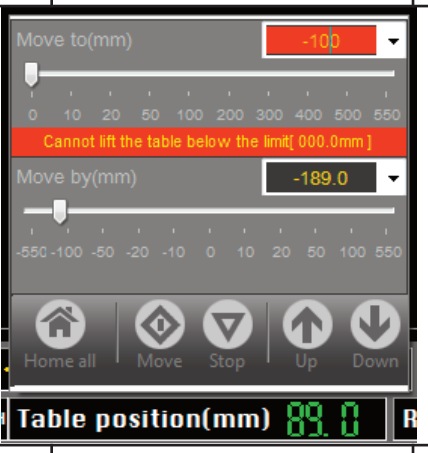
Message ID	Text	Explanation	Possible Resolution
MC-007-ER			
	Cannot lift the table below the gantry [x mm]	Shown if attempting to move the patient table to a position below the gantry.	Verify the desired position or displacement is between the position of the gantry and 550 mm.
MC-008-ER			
	Cannot lift the table over the limit [x mm]	Shown if attempting to move the patient table to a position above 550 mm.	Verify the desired position or displacement is between the position of the gantry and 550 mm.
MC-009-ER			
	Cannot lift the table below the limit [x mm]	May appear if attempting to move the patient table to a position lower than 0 mm. Typically, MC-007-ER is seen instead.	Verify the desired position or displacement is between 0 mm and 550 mm.

Table Z.3-1: Error messages

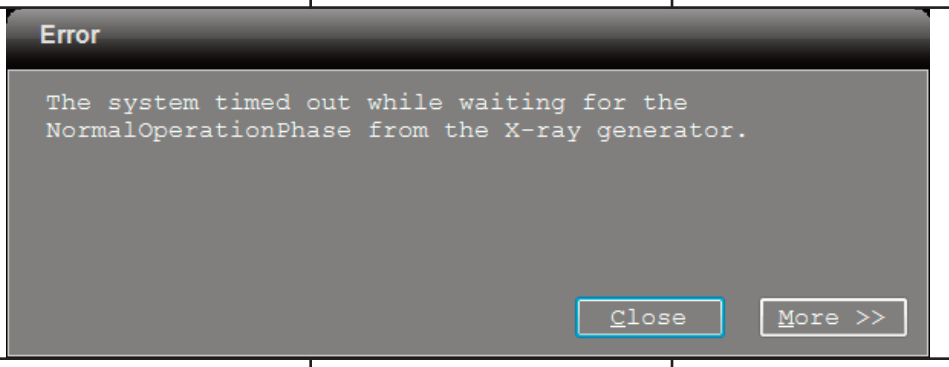
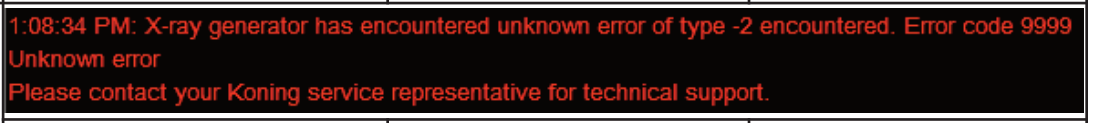
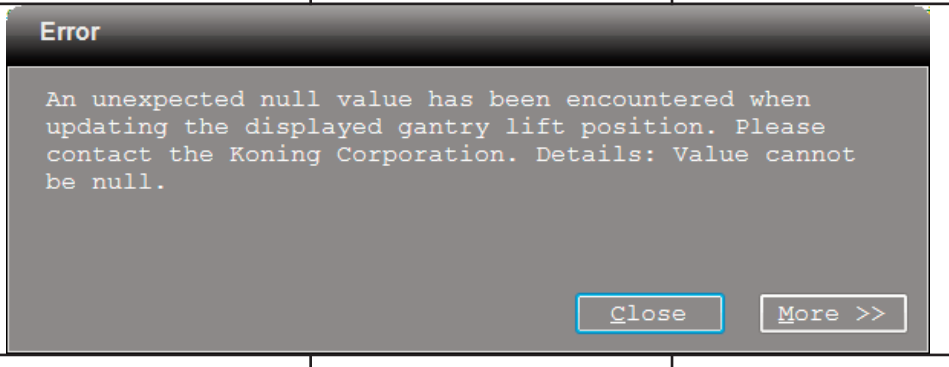
Message ID	Text	Explanation	Possible Resolution
MC-010-ER			
	hh:mm:ss (AM/PM): Unknown error.	This message is logged if the KBCT Console program receives an unknown error code from the PLC.	Contact Koning for assistance.
MC-011-ER			
	The system timed out while waiting for the NormalOperationPhase from the X-ray generator.	May appear when establishing a connection if the X-ray generator takes too long to indicate that it is in the normal operation phase.	Have facility IT staff verify that no physical cable connections are loose. Contact Koning if the issue persists.
MC-012-ER			
	hh:mm:ss (AM/PM): X-ray generator has encountered unknown error of type x encountered. Error code y (Additional information may be provided, if available.) Please contact your Koning service representative for technical support.	This message is logged if the X-ray generator gives an unknown error code.	Contact Koning for assistance.
MC-013-ER			
	An unexpected null value has been encountered when updating the displayed gantry lift position. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.

Table Z.3-1: Error messages

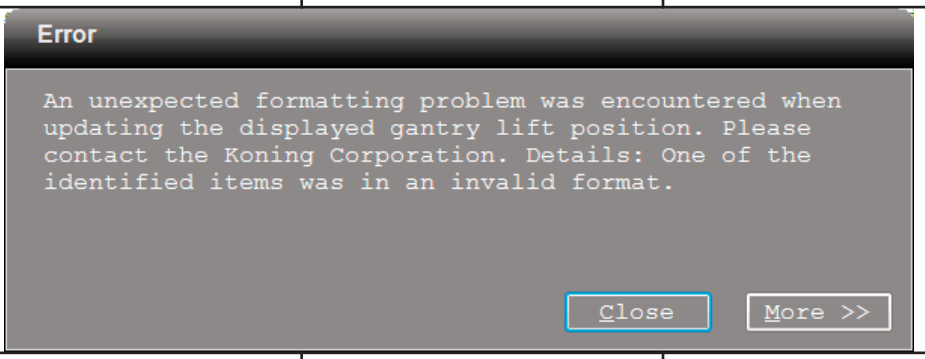
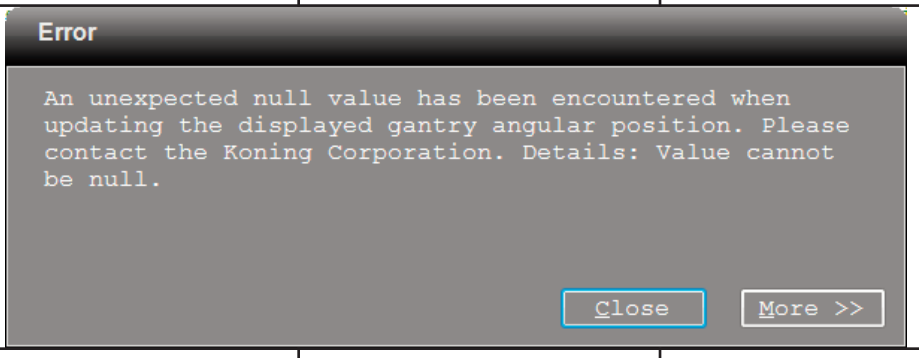
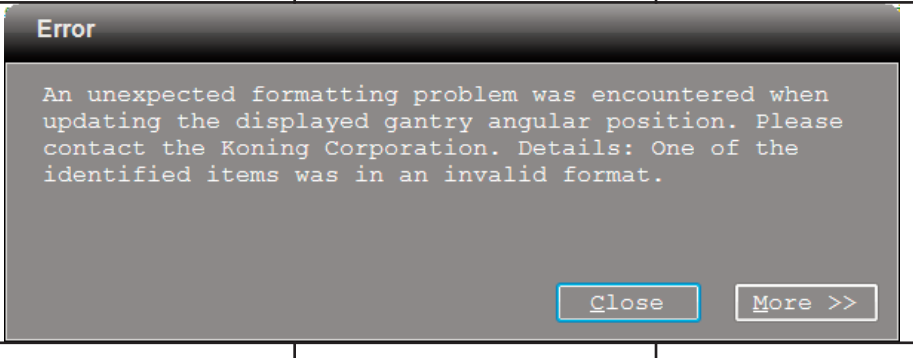
Message ID	Text	Explanation	Possible Resolution
MC-014-ER			
	An unexpected formatting problem was encountered when updating the displayed gantry lift position. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.
MC-015-ER			
	An unexpected null value has been encountered when updating the displayed gantry angular position. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.
MC-016-ER			
	An unexpected formatting problem was encountered when updating the displayed gantry angular position. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.

Table Z.3-1: Error messages

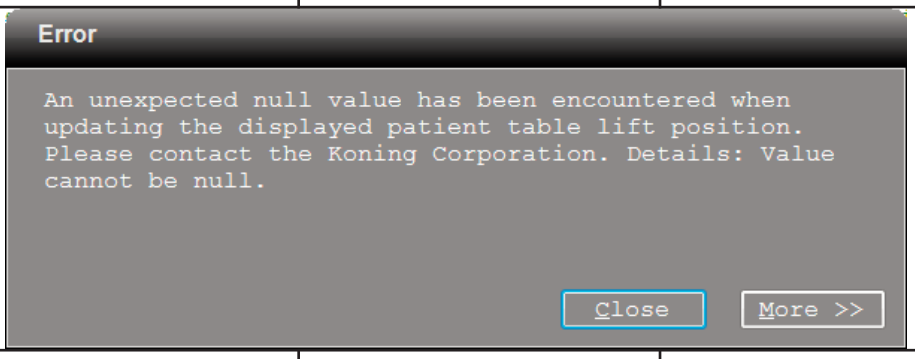
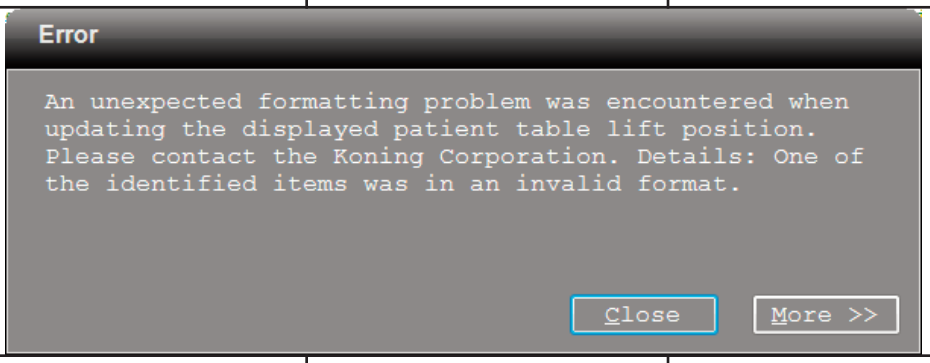
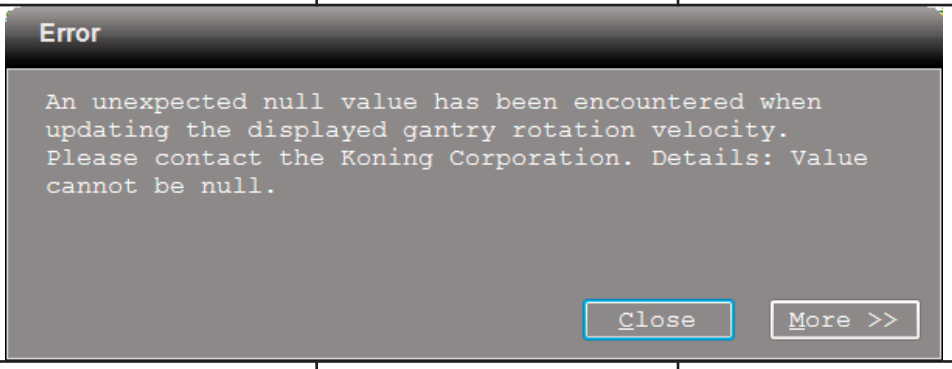
Message ID	Text	Explaination	Possible Resolution
MC-017-ER			
	An unexpected null value has been encountered when updating the displayed patient table lift position. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.
MC-018-ER			
	An unexpected formatting problem was encountered when updating the displayed patient table lift position. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.
MC-201-ER			
	An unexpected null value has been encountered when updating the displayed gantry rotation velocity. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.

Table Z.3-1: Error messages

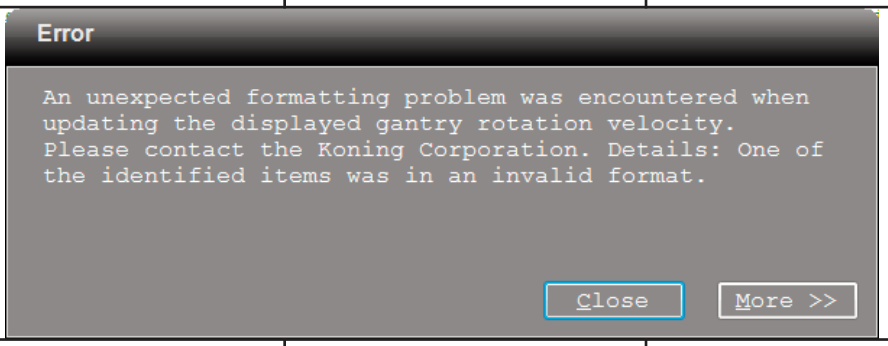
Message ID	Text	Explanation	Possible Resolution
MC-202-ER			
	An unexpected formatting problem was encountered when updating the displayed gantry rotation velocity. Please contact Koning Corporation. Details: (Details)	May be seen under rare circumstances once a connection has been established.	Contact Koning Corporation for assistance.
MC-801-ER			
	Failed to connect to PLC.	May be seen when running the KBCT Console program's built in connection checks. Indicates that the test for PLC connectivity failed.	Have your system administrator verify the configuration settings for connecting to the PLC. Have facility IT staff verify that the PLC is on and that all physical cable connections are not loose. Contact Koning if the issue persists.
MC-802-ER			
	Failed to connect to the X-ray generator. Unable to open COM port.	May be seen when running the KBCT Console program's built in connection checks. Indicates that the test for X-ray generator connectivity has failed, due to an inability to open the COM port.	Have your system administrator verify the configuration settings for connecting to the X-ray generator. Contact Koning if the issue persists.
MC-803-ER			
	Unable to connect to the frame grabber card because (additional information)	May be seen when running the KBCT Console program's built in connection checks. Indicates that the test for frame grabber connectivity failed, for the reason given in the additional information.	Write down the additional information word for word and contact Koning for assistance.

Table Z.3-1: Error messages

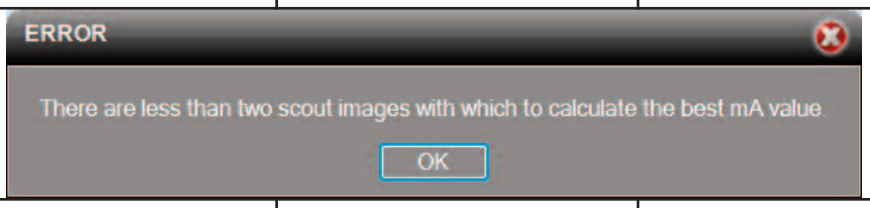
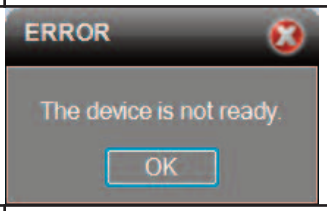
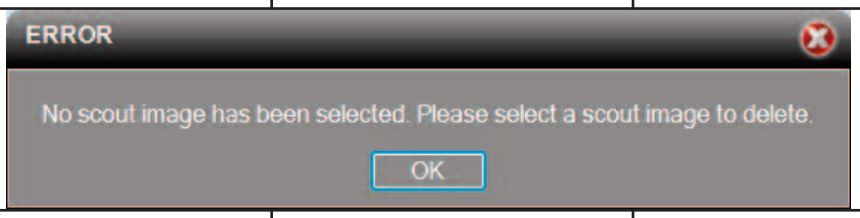
Message ID	Text	Explaination	Possible Resolution
MC-804-ER	Unable to connect to the frame grabber card due to an unknown error. Return code: 999		
	Unable to connect to the frame grabber card due to an unknown error. Return code: x	May be seen when running the KBCT Console program's built in connection checks. Indicates that the test for frame grabber connectivity failed due to an unknown error.	Write down the error code and contact Koning for assistance.
SC-101-ER			
	There are less than two scout images with which to calculate the best mA value.	May appear when attempting to calculate the best mA. Indicates that an insufficient number of scout images have been acquired.	Always acquire at least 2 scout images prior to performing the best mA calculation.
SC-102-ER			
	The device is not ready.	Seen if attempting a best mA calculation while no connection has been established.	Re-establish a connection and try again.
SC-201-ER			
	No scout image has been selected. Please select a scout image to delete.	Seen when attempting to delete a scout image without having selected an image to be deleted.	Select the scout image you wish to remove prior to pressing the "Delete" button.

Table Z.3-1: Error messages

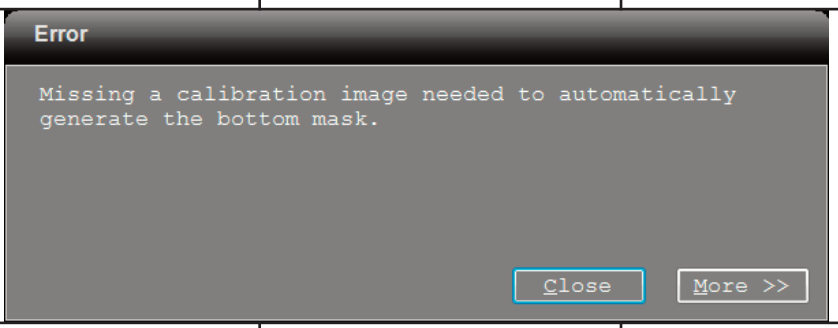
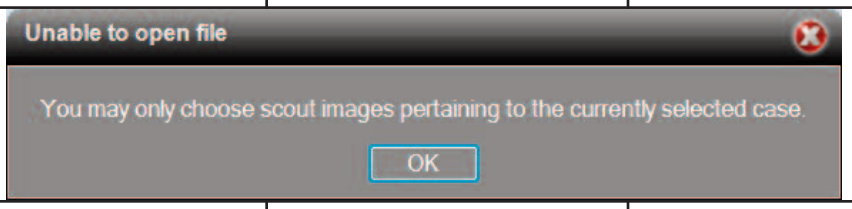
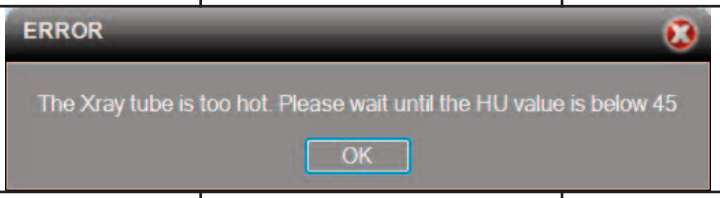
Message ID	Text	Explanation	Possible Resolution
SC-601-ER			
	Missing a calibration image needed to automatically generate the bottom mask.	Depending on the system configuration, may appear during gain calibration if the KBCT Console program is unable to locate the calibration files needed to calculate a new bottom mask.	Contact Koning for assistance.
SC-801-ER			
	You may only choose scout images pertaining to the currently selected case.	May be seen when reviewing old scout images. Caused by attempting to load a file which is not a scout image associated with the current case.	Do not explore when prompted for the archived scout image you wish to review; the dialog automatically opens to the correct location.
SF-001-ER			
	The system is in e-stop mode. Please release the e-stop button, power on the device and click ‘Connect to device’ button.	May be seen when an emergency stop button is pressed.	Release the emergency stop button and restore power to the device. Wait a few minutes, then click “Connect to device.” If no emergency stop button has been pressed, contact Koning for assistance.
SF-002-ER			
	The X-ray tube is too hot. Please wait until the HU value is below x.	May be seen when attempting to perform a scout image, scan, or gain calibration. Appears when the operation would cause the HU used to rise above the limit set in the configuration.	Wait 5 minutes while the X-ray tube cools down. Observe the maximum duty cycle.

Table Z.3-1: Error messages

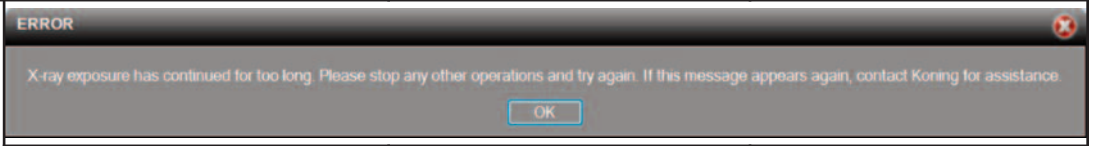
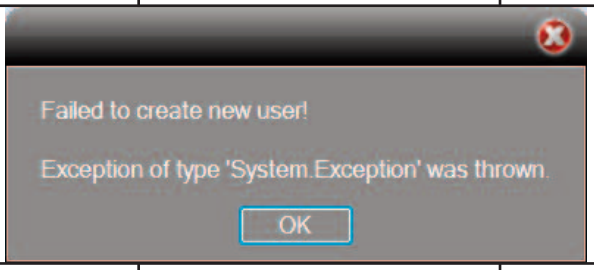
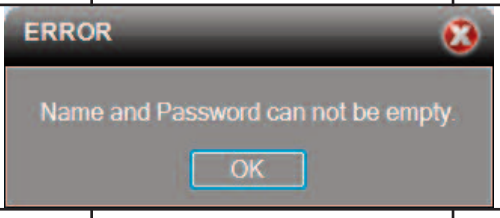
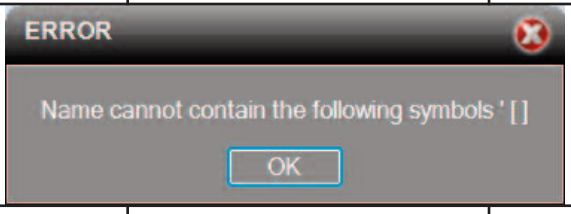
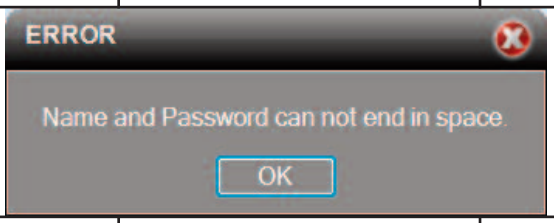
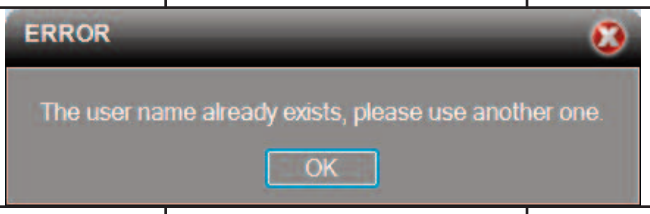
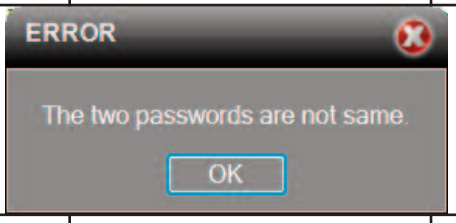
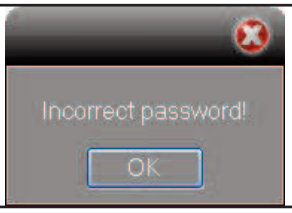
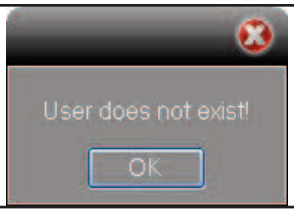
Message ID	Text	Explaination	Possible Resolution
SF-003-ER			
	X-ray exposure has continued for too long. Please stop any other operations and try again. If this message appears again, contact Koning for assistance.	This message may appear during X-ray exposure if duration of the exposure is abnormally long.	Notify Koning that this message appeared.
SF-004-ER			
	hh:mm:ss (AM/PM): Error: X-ray exposure has continued for too long.	Message logged if duration of the X-ray exposure is abnormally long.	Notify Koning that this message appeared.
UM-101-ER			
	Failed to create new user! (Detailed information follows.)	Seen if creation of a new user fails.	Verify that the user does not already exist. Contact Koning for assistance.
UM-102-ER			
	Name and password can not be empty.	Seen when attempting to create a new user without providing a user name and password.	Obtain credentials for the new user prior to creation.
UM-103-ER			
	Name cannot contain the following symbols ‘ [ ]	May be seen when attempting to create a new user. Appears if the user name includes those characters.	Verify that user credentials do not contain any of the symbols ‘ [ ]

Table Z.3-1: Error messages

Message ID	Text	Explanation	Possible Resolution
UM-104-ER			
	Name and Password cannot end in space.	May be seen when creating a new user, or changing a password. Appears when a new user name or new password ends in a space.	Choose credentials which do not end in a space.
UM-105-ER			
	The user name already exists, please use another one.	May be seen when creating a new user, if a user with the new user's name already exists.	Ensure each user name is unique.
UM-301-ER			
	The two passwords are not the same.	May appear when changing a password. Indicates the contents of the 2 password fields do not match.	Retype the desired new password into each field, slowly. Verify that Caps Lock is off.
UM-501-ER			
	Incorrect password!	Shown when attempting to log in with an invalid password.	Try typing your password in again, slowly. Have your system administrator reset your password.
UM-502-ER			
	User does not exist!	Shown when attempting to log in with an invalid user name.	Double-check the credentials you've typed in. Verify with your system administrator that they are correct.

Glossary

3D Reconstruction – Refers to the process of taking the projection images retrieved from a CT scan and using them to recreate a 3D model of the object which was scanned.

Administrator – A system role which has access to functionality for user management and the system configuration.

adu – Analog-to-digital unit, a unit for measuring the brightness of a pixel based on the data received by the X-ray detector.

Error – A type of message indicating that something has gone wrong which caused undesirable behavior (such as being unable to perform a task).

Experiment – A system role used by for carrying out experiments. An Experiment user has access to all functionality except user management, including full control of the X-ray parameters used.

Gain Calibration – A type of calibration in which an offset calibration is performed and then X-ray exposure occurs with nothing in the beam. The purpose of this is to ensure an image of uniform brightness where no object is present.

Gantry – Refers to the structure in the KBCT System Scanner which holds the X-ray generator, X-ray tube and image detector. It may be moved vertically to a desired position and can also be rotated around the tissue to be scanned.

Gy – Gray, the absorption of one joule of ionizing radiation energy (such as X-rays or gamma particles) by one kilogram of matter.

Home Position – The position used as a zero point by a moving part.

Koning Client/Server – Refers to the application used to view reconstructed DICOM images stored on the server.

KBCT Console Program – Refers to the software program which comes pre-installed on the KBCT System workstation.

KBCT System – Refers to both the hardware and software components of the KBCT System device.

KBCT System Scanner – Refers to the Koning CT's Scanner.

kVp – Peak voltage in kilovolts, a unit for measuring the difference (or the peak difference in this case) in electrical potential.

mA – Milliamps, a unit for measuring electric current.

mAs – Milliamp seconds, a unit for measuring current multiplied by time.

mGy – Milligrays, a derived metric (SI) measurement unit of absorbed radiation dose of ionizing radiation.

ms – Milliseconds, a unit for measuring time.

Offset Calibration – A calibration during which the data is acquired while no X-rays are emitted. It compensates for some of the irregularities in pixel brightness in the detector.

Patient Table – The portion of the KBCT System which the patient lies on top of, which may be moved vertically to a desired position.

Patient Case – Contains information on patients and their treatments. Part of the DICOM standard.

PLC – Programmable Logic Controller, a device and associated software controlling the KBCT System Scanner.

Projection – Refers to the raw data acquired by the KBCT System during a scan. If you were to look at a projection image, you would see what the X-ray detector sees.

RIS – Radiology Information System, refers to the standard database system used by radiology departments.

Scan – The type of scan typically performed by the KBCT System. Refers to scans in which X-rays are emitted in a full 360 degrees around the scanned object.

Scout Image – A type of scan in which a single projection is taken. Scout images are typically used to confirm that the desired region is being scanned and to determine ideal X-ray parameters before proceeding to an "actual" scan.

Series – A series of medical images. In the KBCT Console program, a series contains the projections obtained during a scan, slices of the reconstructed object (if a reconstruction has occurred), and information about the scan and resulting images. Part of the DICOM standard.

Servos – Moving parts. In the case of the KBCT System, this refers to the patient table and gantry.

Slice – Refers to a slice of a three dimensional model reconstructed from projections acquired during a scan. The plane of a slice is perpendicular to the plane of a projection, so if you were to look at a slice you would see the top of one of these horizontally made slices.

SPS – Scheduled Procedure Step, a step of a medical procedure which has been scheduled to be performed. Part of the DICOM standard.

System Log – A log of all the messages generated by the KBCT Console program.

System Role – Concepts used to define a type of user, for example an administrator.

Technician – A system role which has access to calibration and maintenance functionality.

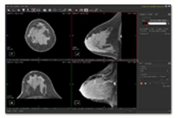
User – Anyone who uses the KBCT Console program.

Warning – A type of message indicating something which may cause undesirable behavior.

Notes

Seamless Integration

RIS/HIS Compatibility
- Scheduling
- Case feedback



MPR and Volume Display
- Multi-planar viewers
- 3D volume rendering
- Side-by-Side hanging protocols
- Volume measurement

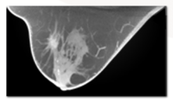
DICOM Printer

Archive

High Volume Storage

Koning CT Scanner
- Easy access
- Fast acquisition

Fast Image Processing and Reconstruction



Quick Image Review

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KONING

Accurate Diagnosis

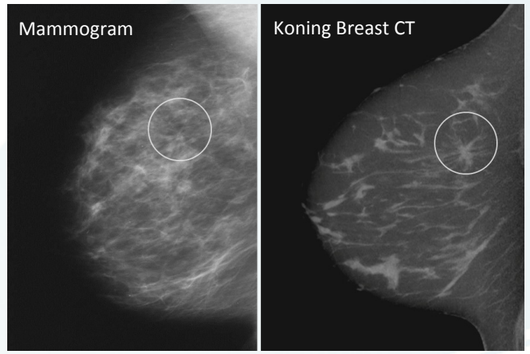
True, Isotropic 3D Imaging

KONING BREAST CT

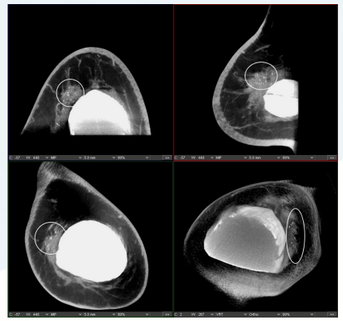
the *future* of breast imaging is here

Excellent image quality

Breast Imaging Experts agree that image quality is the key to accurate diagnosis of Breast Cancer. Koning Breast CT (KBCT) achieves both high contrast and high spatial resolutions sufficient to allow differentiation of small structures from background tissue which is often described as structure and tissue overlap.

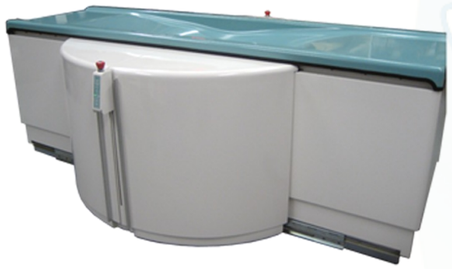


Integrated visualization tools



Hundreds of images are captured in a single 10 second rotation of the gantry and processed within seconds. Images are presented in both thin multislice multiplanar projections and true isotropic 3D format, eliminating tissue overlap and superimposition of structures common to 2D mammography. KBCT comes with a complete set of visualization tools including side by side hanging protocols for comparison to previous mammograms. KBCT is DICOM compliant for RIS/PACS connectivity and allows remote viewing from up to 3 simultaneous locations (expandable if needed).

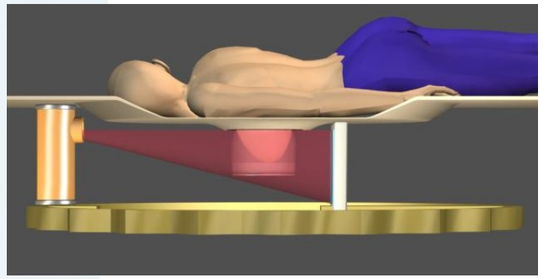
Designed specifically for breast imaging



With its unique exam table and pendulous positioning of the breast, KBCT is able to acquire a true 3D image of the entire breast. Prone positioning on the ergonomic table ensures patient comfort. The self shielded design and the dedicated operator's console eliminate the need for a separate control room. Access to the patient is available from wide interlocking safety covers on both sides, and the table can be elevated to up to 1.5 meters this makes it possible to perform other operations such as biopsy.

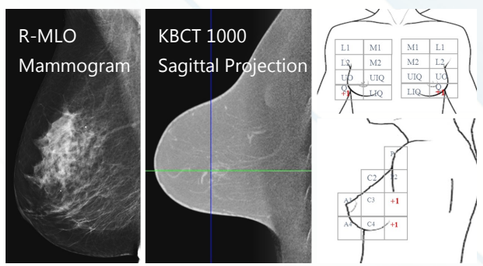
No breast compression, low radiation

Diagnostic mammography requires breast compression, which is painful to many women. Breast scanning with KBCT is easier on women because it allows scanning the breast in its natural state without having to pull, flatten and compress the tissue, eliminating the pain due to compression. Radiation doses are within range of diagnostic mammography.

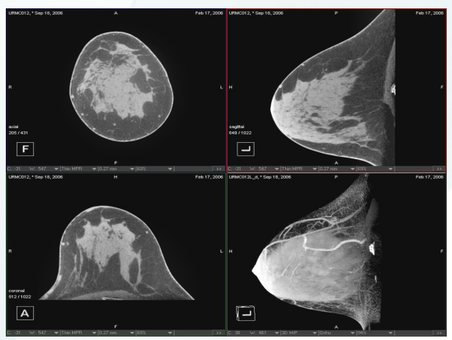


3D image of the entire breast

Unlike whole body CT scanners, KBCT is the first fully integrated, dedicated CT scanner designed specifically to image the entire breast, from the chest wall to the nipple, with high spatial and contrast resolution. Traditional mammography is a two-dimensional (2D) projection acquisition permitting structure and tissue overlap which can obscure a breast lesion. KBCT images are displayed in both 3D and thin multislice format to improve performance on structure and tissue overlap.



Diagnostic information



True isotropic 3D imaging and thin multislice formats are available with KBCT that aid in collecting diagnostic information. In a subjective assessment of breast tissue coverage conducted at the University of Rochester Medical Center, KBCT was perceived to have better coverage than mammography in the inferior, posterior, medial, and lateral aspects and equivalent coverage in the superior aspect.