THE **PARAMETER® 3D**

Tomosynthesis System



INSTRUCTIONS FOR USE

KUBTEC®
SCIENTIFIC

The PARAMETER® 3D Tomosynthesis System

Instructions for Use IFU-23 Rev C July 2026

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KUBTEC is the owner and sole manufacturer of The PARAMETER® 3D Tomosynthesis System.

Read this manual thoroughly before using this device. Follow all safety procedures and guidelines when operating radiographic systems.

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PREFACE

Intended Use

The PARAMETER® 3D Tomosynthesis System provides 2D and 3D tomographic digital X-ray images for multiple applications, including bone mineral density/body composition, organic and inorganic samples, and 3D tomosynthesis. This system has been proven to provide more anatomical information than single-planar 2D imaging alone.

Tomosynthesis is an advanced radiographic application that produces individual coronal “slice” images through an anatomical region of interest (ROI). To produce these slices, multiple projection radiographic images are acquired in rapid succession as the X-ray tube sweeps and rotates across the sample. Once acquired, these projection images are subject to image processing that registers and reconstructs them into individual tomographic slices.

Tomosynthesis provides visualization of anatomy by doing the following:

- Visually removing overlying anatomical structures, which could otherwise obscure a structure of interest by superimposition in a 2D presentation, and
- Producing a number of slice images throughout the entire volume of the anatomy.

The exceptionally high magnification capability (up to 2.0x) with optimized cabinet geometry and the superior contrast available from the low kV capability provide enhanced digital imaging performance. This device is configured to acquire high-resolution, DICOM-compliant, digital X-ray images through the use of KUBTEC® The DIGICOM® Radiography Software and an integrated camera for optical images.

Sale of this System



CAUTION:

The sale of this item may be subject to regulation by the U.S. Food and Drug Administration and state and local regulatory agencies.

Instructions for Use

The purpose of the Instructions for Use manual is to provide guidance for the proper use and care of the system. Keep this manual with the system for easy reference.

The most extensive system configuration is described in this manual and may not be representative of the system in your facility. Not every function, option, or accessory described in the manual may have been purchased or licensed on your system.

The Instructions for Use do not cover detailed electronic functions or major system troubleshooting and repair. For assistance in these areas, contact the KUBTEC® Customer Care Center.

KUBTEC Customer Care Center

KUBTEC offers customer support through the KUBTEC Customer Care Center at any time for problems not resolved through online help or product documentation. If the Customer Care Center is closed, leave a voicemail message. Make sure to have the following information available when calling:

- Site name
- Hardware system type
- System serial number
- Software version number

Phone: USA: +1.203.364.8544, option 3
International: +1.203.364.8544, option 3

Email: service@kubtec.com

Web: www.kubtecscientific.com

Mail: KUBTEC®
111 Research Drive,
Stratford, CT 06615 USA

NOTE: Any serious incident that occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

User Responsibility

When the system is assembled, operated, maintained, and repaired in accordance with the instructions provided, the system conforms with the description in the Instructions for Use and with accompanying labels and/or inserts.

- It is the responsibility of the user to ensure that this product is checked periodically.
- Do NOT use a defective product.
- Replace broken, missing, plainly worn, distorted, or contaminated parts immediately.
- If repair or replacement is needed, request service by calling 203-364-8544, extension #3, or emailing service@kubtec.com.
- Do NOT use this product or any of its parts other than in accordance with the written instructions provided by KUBTEC and KUBTEC-trained personnel.
- Do NOT alter this product without the prior written approval from KUBTEC.
- The user of this product has the sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than KUBTEC.

NOTE: As part of the system installation, the Windows operating system is configured to prevent automatic execution of Windows updates. If your facility's IT department requires changes to this configuration, the site assumes full responsibility for ensuring that updates are scheduled in a manner that does not impact system use.

Training

Users must receive adequate training on the safe and effective use of the system before operating it. Training requirements may vary by country. It is the user's responsibility to ensure that training is completed in accordance with applicable local laws or regulations. Information regarding training is available from your local KUBTEC representative.

Safety Information

Observe and heed all warnings, cautions, and notes in the manual and on the system.



WARNING:

Warnings are directions that, if not followed, can cause fatal or serious injury, and/or lead to damage to the system. Warnings in this manual are emphasized with a yellow triangle safety icon.

Safety Information (continued)



CAUTION: Cautions are directions that, if not followed, can cause damage to the system and/or cause environmental pollution. Cautions in this manual are indicated with a blue circle surrounding an exclamation point.

NOTE: Notes provide tips and important information to guide the use of the system. Notes in this manual are emphasized with the word "**NOTE**" in capital and bold letters.

Receiving and Inspection

The system is carefully inspected mechanically and electrically before shipment and should be free from damage. As a normal part of receiving, make sure to do the following:

- When the system is delivered by commercial carrier, check it for damage in the presence of the carrier. If any damage is found, contact the carrier's office and KUBTEC Customer Care Center.
- Compare the packing list with the order invoice. If any discrepancies are found, contact KUBTEC office.
- Retain packing material in case the system needs to be moved or shipped again.

Terms and Definitions

Click - Throughout the manual, the instruction for "click" means to left-click the mouse. When a right-click is needed, it will be stated as such.

A qualified engineer/technician is a person who has completed training conducted by KUBTEC and has been certified by KUBTEC on this system.

Tomosynthesis creates a 3D image utilizing multiple X-ray images taken at multiple angles.

CE Mark

This product carries the CE Mark and the Intertek Mark.

CE

Class 1

The CE Declaration of Conformity becomes invalid if the product is changed without the explicit consent of the manufacturer. This applies to all parts, not only to safety elements

ETL Mark

Conforms to UL 61010-1, UL 61010-2-091

Certified to CSA C22.2#61010-1,

C22.2#61010-2-091

Name of Product

The PARAMETER® 3D Tomosynthesis System

Manufacturer

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Gotthardstrasse 28,
6302 Zug Switzerland

CHAPTER 1: GENERAL INFORMATION

Introduction

The PARAMETER® 3D Tomosynthesis System is used to provide 2D and 3D tomographic digital X-ray images.



Figure 1-1: The PARAMETER® 3D System

Safety Information: Warnings

The following warnings appear at appropriate places in this manual and on the system. Contact KUBTEC® Customer Care Center if any of these statements are unclear.



WARNING: Do not remove covers. Potentially lethal voltages are present inside the system.



WARNING: For cybersecurity, ensure your network is secure.



WARNING: This system utilizes a class 2 laser.
DO NOT STARE INTO THE BEAM.



WARNING: Never operate this system with the grounding conductor disconnected.



WARNING: This is a heavy system. If the system needs to be moved, use assistance. If access underneath is required, make sure it is securely supported first.

Safety Information: Cautions

The following cautions appear at appropriate places in this manual and on the system. Contact KUBTEC® Customer Care Center if any of these statements are unclear.



CAUTION: The sale of this item may be subject to regulation by the U.S. Food and Drug Administration and state and local regulatory agencies.



CAUTION: This system is sensitive and needs to be handled with care. Dropping it from a height or banging it against a hard surface can damage interior components.



CAUTION: No operator serviceable parts are inside. Refer all servicing to qualified personnel.



CAUTION: When transporting this system, do not drag the cables along the floor.

System Handling

Transporting

- Transport or relocation of the system is prohibited unless performed or approved by KUBTEC or its authorized representative.
- Use the utmost care when transporting this system. Any drop or bump can lead to extensive damage and the inability to produce images.
- Disconnect cables using the cable connector.
- Do not pull on the electric or data cable line as this can result in an electric shock or fire.
- Do not drag the cables along the floor. Either hold them or drape them over the transport handle while moving the system.
- When the system reaches its final destination, ensure that it rests on a flat surface. Then, lock the casters.

Environmental conditions

- To ensure consistent imaging, operate the system at normal room temperature within the guided operating levels stated in Table 1-3: Performance Specifications.
- Drastic and sudden changes in temperature will cause condensation to form on the surfaces. It is strongly recommended to wait until the condensation dissipates and the system acclimates to the surrounding environment conditions before operating the system.

System storage

Store this system in a safe, dry location with particular caution to minimize any chances of damage due to falling objects or tipping.

System Maintenance

The Maintenance Chapter contains specific instructions for the care of the system. To ensure safe and consistent use of the system, make sure to read, understand, and follow the stated instructions.



CAUTION: For safety reasons, be sure to inspect the system before using it. In addition, carry out a regular inspection at least once a year.



CAUTION: Changes, additions, or maintenance to the equipment performed by persons without appropriate qualifications and training and/or using unapproved spare parts can lead to serious risk of injury and damage to the system as well as voiding the warranty.

System Maintenance (continued)



CAUTION:

Use ONLY a soft cloth, neutral detergents, or cleaning liquids to wipe system parts and accessories that come into contact with samples during use. Harsh liquids or rough surface cleaners will damage the system surfaces.



CAUTION:

All KUBTEC systems come with Windows updates disabled and Windows Defender enabled. Both Windows Defender and Windows updates are the responsibility of the customer and/or facilities Security/IT department to manage and support. KUBTEC is not responsible for any mismanagement leading to unintended consequences.

System Inspection

Inspect the system daily before use by following the daily inspection checklist in the Maintenance Chapter. Perform annual inspection by a KUBTEC engineer or a KUBTEC-trained engineer.



WARNING:

The system must be repaired by a qualified engineer only. If it is not repaired properly, it can cause a fire, electric shock, or an accident.

Inspection procedures

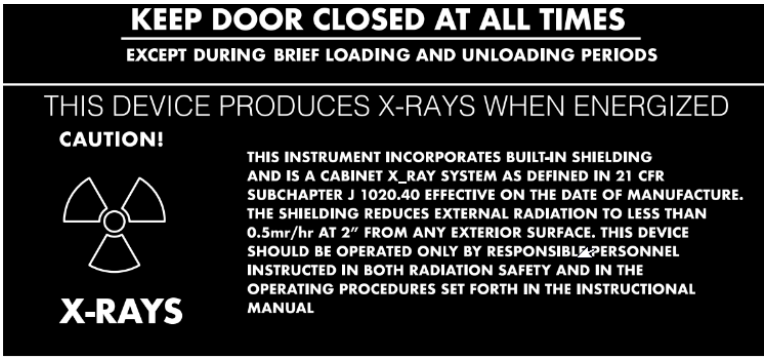
Instructions to perform each inspection are found in the Maintenance Chapter. If any problem is found during the inspection, take the measures indicated. If the problem still cannot be corrected, contact the KUBTEC representative or the distributor.

It is recommended that inspection records be maintained. Inspection documentation may consist of completed checklists from this manual or equivalent records provided by the facility or administrator.

Labels

Warning labels, safety labels, and a certification label are attached at various locations on the unit. These labels must remain permanently attached and in good condition. Tampering with labels is against federal law. Under NO circumstances should the labels be removed or re-affixed.



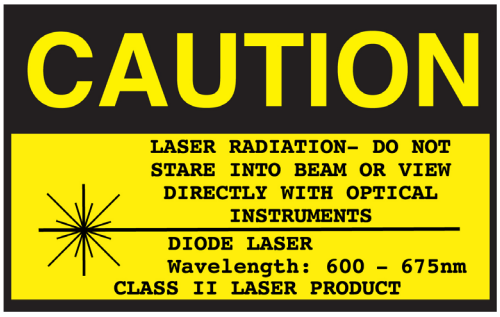


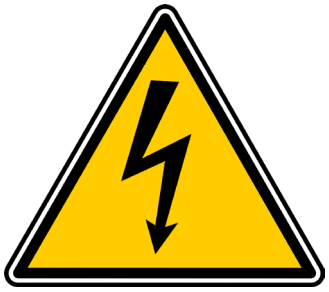
Fuse Rating:

250V, 5A, SB

This label is on the back of the cabinet.

Labels (continued)





Shock hazard.

Disconnect power before servicing.



X-rays are produced when energized.

CAUTION - THIS DEVICE IS POWERED BY SEVERAL SOURCES. THE MAIN DISCONNECT IS IN THE BACK OF THE CABINET. THIS WILL DISCONNECT ALL POWER EXCEPT POWER TO THE INTERNAL UPS.



CAUTION: To ensure safe system operation, read the Instructions for Use before operating this system.

Separation Distances

The PARAMETER® 3D System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of this system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this system as recommended below, according to the maximum output power of the communications equipment.

Table 1-1: Recommended separation distances between portable and mobile RF communications equipment and this system

Rated maximum output power (W) of the transmitter	**Separation distance (m) according to the frequency of the transmitter**		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Compliance

The PARAMETER® 3D System complies with US federal guidelines that require radiation leakage of not more than 0.5 mR/hr (0.005 mSv/hr) at a distance of 5 cm from the external machine surface.

The PARAMETER® 3D System is designed, manufactured, and registered in accordance with strict criteria established by the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), Department of Health and Human Services (DHHS). This system meets or exceeds all certification requirements for a cabinet X-ray system used in an industrial/laboratory environment.

This system is manufactured, tested, and certified to comply with the US Federal Performance Standards for cabinet X-ray systems, Title 21, Sub-chapter J of the Code of Federal Regulations, Section 1020.40. Modification or damage to the equipment could result in an X-ray exposure hazard.

KUBTEC recommends reviewing and complying with work-site radiation safety requirements.

This system has been designed and tested for compliance when used in all its modes. KUBTEC products comply with IEC Safety Standards.

This system is intended for use in the electromagnetic environment specified in the next table. The customer or user of this system shall ensure that it is used in a Guidance and Manufacturer Declaration environment.

Table 1-2: Guidance and Manufacturer Declaration for electromagnetic immunity

Immunity test	IEC 61010-1 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) and neutral	±1 kV line(s) and neutral	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If a dip or an interruption of mains power occurs, the current of the system may drop off from the normal level, and it may be necessary to use an uninterrupted power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Table 1-2: Guidance and Manufacturer Declaration for electromagnetic immunity (continued)

Immunity test	IEC 61010-1 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of this system, including cables, then the recommended separation distance is calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2.5 GHz • P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation. • Distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, and should be below the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, consider an electromagnetic site survey. If the measured field strength at the location where this system is used exceeds the applicable RF compliance level, observe the system to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 1-3: Performance specifications

Degree of protection against penetration of water	No protection provided
Classification in accordance with 61010-1 degree of protection against electric shock	This system has no applied parts
Methods of sterilization or disinfection	See Cleaning & Disinfection section in the Maintenance Chapter
Where the equipment is not suitable for use	In the presence of flammable mixtures
Mode of operation	Suitable for continuous operation
Pollution degree rating	Pollution degree 2 (normal atmosphere)
Electromagnetic compatibility (EMC) in accordance with 61010-1 • Noise suppression • Immunity to interference	This system conforms to the requirements of IEC 61010-1 (EMC)
Variants	Software programmable variants from third-party
Product life	Service life of the product is seven years

Table 1-4: Wireless adapter specifications

Interface	M.2:PCIe
Dimensions (W x D x H)	M.2 2230: 22 mm x 30 mm x 2.4 mm [1.5 mm max (top side)/0.1 mm max (bottom side)]
Antenna type	Internal
Wireless	
IEEE WLAN standards	IEEE 802.11-2016 and select amendments (selected feature coverage) IEEE 802.11a, b, c, e, g,h, i, k, n, r, u, v, w, ac, ax; Fine timing measurement based on 802.11-2016
Bluetooth®	Bluetooth® 5.1
Frequency	5 GHz 2.4 GHz
Security methods	WAP2* Personal and Enterprise; WPA3*
Authentication protocols	802.1X EAP-TLS, EAP-TTLS/MSCHAPv2, PEAPVO-MSCHAPv2 (EAP-SIM, EAP-AKA, EAP-AKA')
Encryption	64-bit and 128-bit WEP, TKIP, 128-bit AES-CCMP, 256-bit AES-GCMP
Product safety	UL, C-UL, CB (IEC 60950-1)

* Other names and brands may be claimed as the property of others.



For cybersecurity, ensure your network is secure.

WARNING:

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CHAPTER 2: COMPONENTS AND CONTROLS

System Overview

The PARAMETER® 3D System consists of the following major components:

- Two vertically attached cabinets mounted on a movable cart.
- A user interface that is attached to a height-adjustable extension arm.



Figure 2-1: System Components

Figure Legend

1	Cabinet control panel	**5**	Cart with locking casters
2	Monitor	**6**	Lower cabinet
3	Keyboard tray	**7**	Upper cabinet
4	Articulating extension arm		

User Interface

The user interface is mounted on an articulated arm that extends off the upper cabinet. Interface components consist of a monitor and a keyboard tray that supports a keyboard and a mouse.

The keyboard tray has a slide-out work surface that can be extended to either side. The keyboard is attached with Velcro to keep it stationary. Both the keyboard and mouse have waterproof coverings to prevent potential damage from contact with fluids.

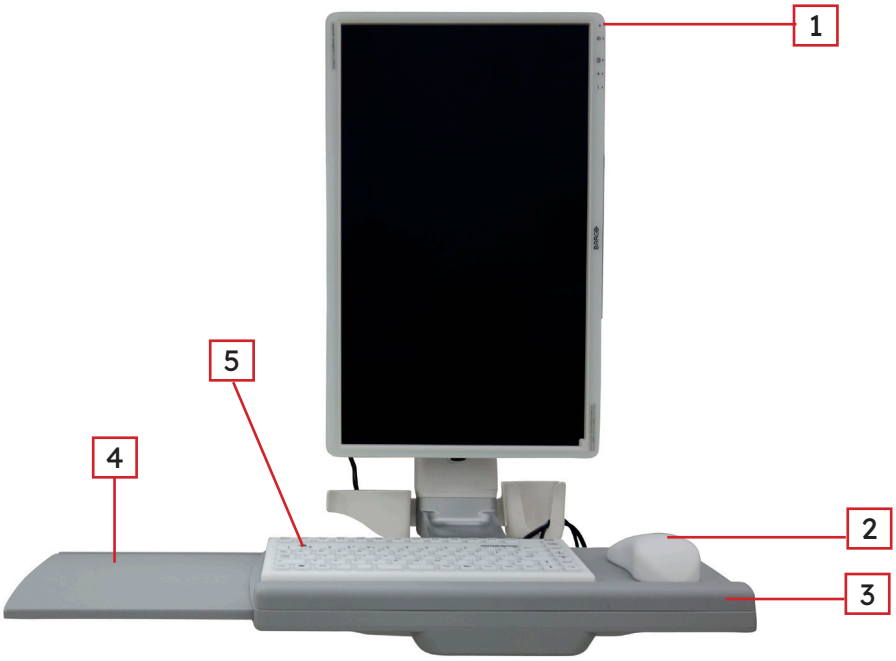


Figure 2-2: Monitor

Figure Legend

1 Monitor ON/OFF switch

2 Mouse

3 Keyboard tray

4 Left extended work surface

5 Keyboard

User Interface (continued)

The keyboard has the functionality of a standard Windows PC keyboard with the following exceptions as indicated in the next figure.



Figure 2-3: Keyboard

Figure Legend

1 "F" keys are not mapped to specific functions.

2 Used to display dropdown menus.

3 Control keys

NOTE: There is no numeric keypad.

Clean Mode functionality locks the keys so that cleaning of the keyboard can be done without input from any key. To use the Clean Mode, follow these steps:

1. To clean your keyboard while it's plugged into PC, press the left and right control (Ctrl) keys at the same time for 3 seconds to lock the keyboard.
2. When the keyboard is locked, the caps lock icon will blink.
3. After cleaning the keyboard, press both control (Ctrl) keys again for 3 seconds to unlock the keyboard.

Cabinet Components: Control Panel

The control panel has a key switch, power button, and the KUBTEC® light. The function of these components is described in the Figure Legend.

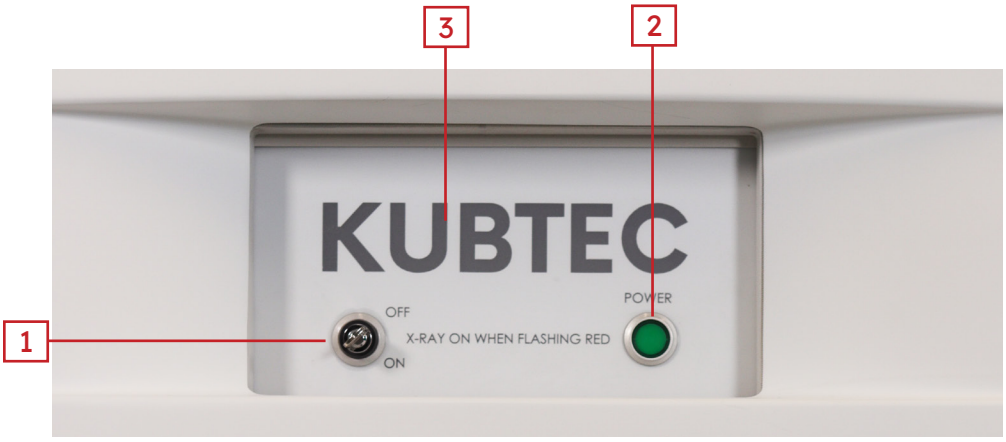


Figure 2-4: Cabinet Control Panel

Figure Legend

1	**Key switch**	OFF position: The system is locked. X-rays cannot be generated. ON position: The system is unlocked and ready to be powered up. X-rays can be generated. **NOTE:** The key is removable when it is in the OFF position. To prevent unauthorized use of the system, KUBTEC® recommends the removal of the key when the system is not in use.
2	**Power button**	Power ON: LED is green. Power OFF: LED is clear.
3	**KUBTEC light**	Turns **amber** when the system is ready to capture an image. Flashes **red** when X-rays are being generated.

Cabinet Components (continued)

Upper Cabinet: Front

The shielded upper cabinet accommodates the following imaging:

- Contact imaging in 2D and 3D
- Two levels of magnified imaging in 2D

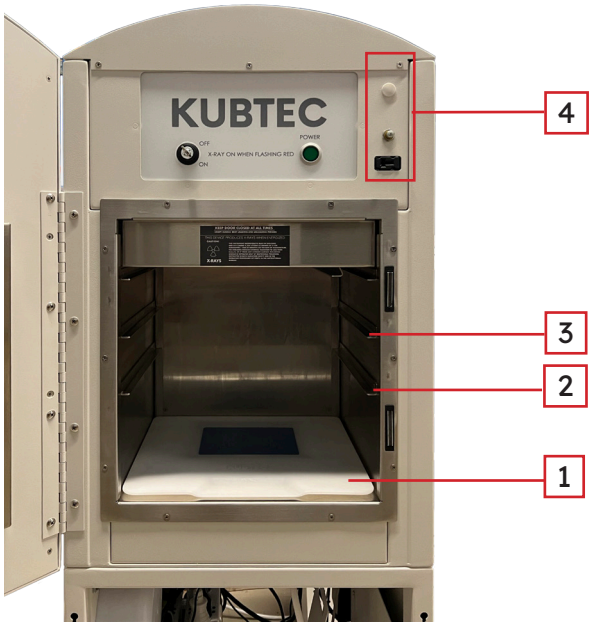


Figure Legend

1 Magnification tray

2 Level 2 magnification rail (1.2x)

3 Level 3 magnification rail (2x)

4 Interlocks*

Figure 2-5: Upper Cabinet

*X-rays cannot be generated unless the upper cabinet door is fully closed and the interlocks are engaged.

NOTE: The upper cabinet also houses an optical (RGB) camera, which is not visible in Figure 2-5. This camera acquires high-resolution RGB images of the sample and displays them along with the X-ray image. Images acquired with the camera are used with the The Image Blender™ tool in the Image Viewer.

Cabinet Components (continued)

Lower Cabinet

The lower cabinet houses the system's computer and the battery backup called the Uninterruptible Power Supply or UPS.

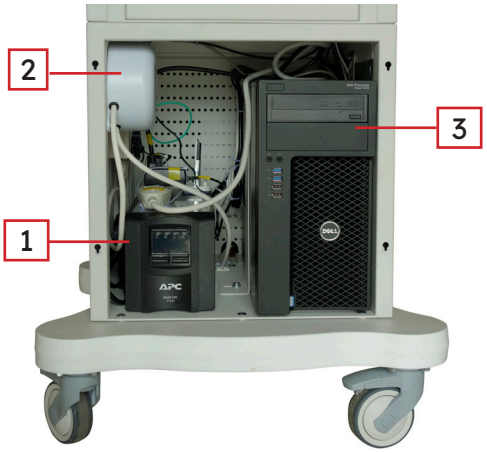


Figure Legend

1 UPS

2 Isolation transformer

3 Computer

Figure 2-6: Lower Cabinet

The user typically does not need to open the lower cabinet. When access to the cabinet components is needed, follow these steps:

1. Grab both sides of the lower cabinet door.
2. Pull up, and then gently lift the door out of the slots.

To replace the door:

1. Align the door with the slots.
2. Push down to lock the door.

Upper Cabinet: Back

On the back of the upper cabinet is a power entry module, which provides an emergency disconnect from power for all critical components in the cabinet, except an internal UPS.



Figure 2-7: Power Entry Module

Moving the System

Before moving the system, be sure to disconnect the power cord from the wall outlet and unlock the cart casters.

CAUTION:

This system is sensitive and needs to be handled with care. Dropping it from a height or banging it against a hard surface can damage interior components.

CAUTION:

When transporting this system, do not drag the cables along the floor.

How to lock/unlock the casters

To lock a caster, use your foot to press down on the locking lever until it snaps into the locked position.



Figure 2-8: Locked Position

To unlock a caster, use your foot to push up on the locking lever until it snaps into the unlocked position.



Figure 2-9: Unlocked Position

How to move the cabinet

1. Make sure that all cables are off the floor and that all components are in a secure position.
2. Unlock the casters.
3. Use the handle on the back of the upper cabinet to assist in pushing/pulling the unit.
4. When the desired location is reached, ensure the unit is on a flat surface, then lock the casters.

Cable Connections

Follow these steps to connect the cables:

1. Insert the power cord fully into the wall receptacle.
2. If a wireless connection is not available, insert the Ethernet cable into the Ethernet jack.



CAUTION: Before using this system, make sure it is on a flat surface.



CAUTION: To prevent electromagnetic interference, be sure to maintain at least the minimum distance between portable and mobile RF communications equipment (transmitters). Table 1-1 in this manual shows the recommended separation distances.

CHAPTER 3: SYSTEM START UP AND SHUT DOWN

Introduction

Before the system is turned on for the first time each day, perform the daily inspection as stated in the checklist in the Maintenance Chapter.

NOTE: To obtain consistent results, the system should be operated at normal room temperature within the guided operating levels stated in the Specifications Chapter. Drastic and sudden changes in temperature may cause condensation to form on the surface. If this happens, it is strongly recommended to wait until the condensation dissipates and the system acclimates to the surrounding environmental conditions before resuming operation.

Pre-Startup Checks

Make sure of the following:

- The system is on a flat surface.
- The cart casters are in the locked position.
- The power cord is fully inserted into the wall outlet.

How to Start the System

1. Press the monitor power button.
2. Turn the key switch to the ON position.
3. Press the power button. The computer automatically starts.
4. Double-click the  icon on the desktop. Make sure the cabinet door is tightly closed. If an initialization screen displays, wait for the initialization process to finish. When the software finishes loading, the Main Screen will display. A message will flash on the screen says **Checking if Calibration is Required, Please Wait...**
5. Make sure that there is nothing in the X-ray field inside the cabinet.
6. Close the cabinet door gently and tightly. The **X-Ray Ready** light at the bottom left of the screen illuminates.
7. Select **NEXT**. The Calibration Wizard automatically performs the calibrations for the detector.
8. When the calibration process is complete, click **Back to Main Window**. The system is now ready to start the image acquisition process. Follow the instructions in the next chapter for acquiring images.

Main Screen

The Main Screen provides access to all software functions of the system. Each component of the screen is explained in the legend on the opposite page.

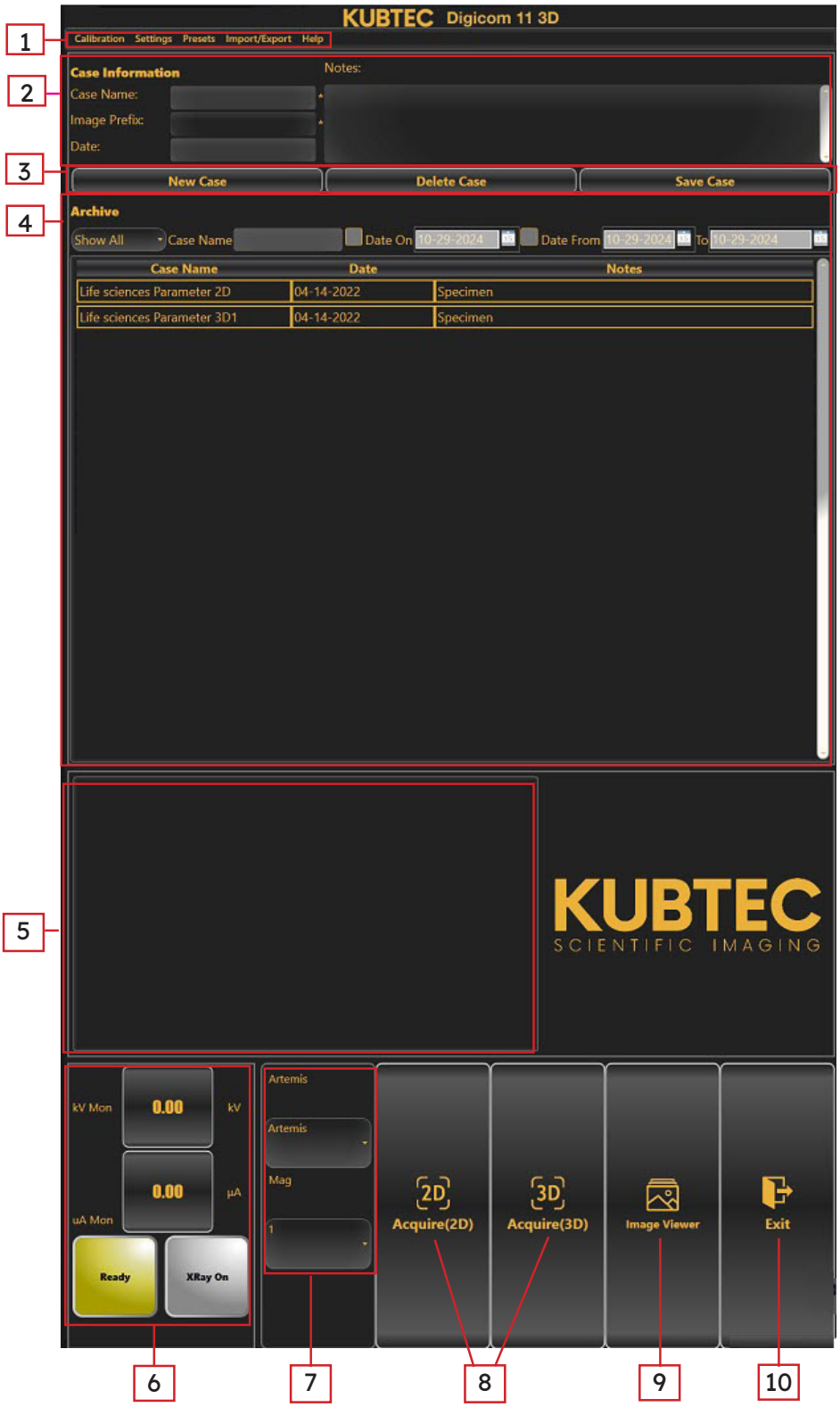


Figure 3-1: Main Screen

Main Screen Legend

Screen Legend

No.	Function
1	**Menu bar functions** • **Calibration** access the Calibration Wizard. • **Settings** has options to return to factory settings and to create Master settings. • **Presets** displays the Presets Manager screen. • **Import/Export** **Import** has the option for importing a series or importing an image contained in a series. **Export** provides the means to send patient studies to a removable storage device, such as USB flash drive. • **Help** provides user access to the Instructions for Use and KUBTEC® contact information. The **Registration** option is for service personnel to register the software for use.
2	**Case information** displays image data that is retrieved from stored files or manually entered as a new case.
3	Options to create a **New Case**, **Delete the current case**, and **Save the current case**.
4	**Archive** allows searching for stored cases by case Name or by the date.
5	Icons of acquired images are displayed in this area.
6	**Ready Light and XRay On Light** • **Ready** light illuminates when the system is prepared to generate X-rays. • **XRay On** light illuminates when the system is generating X-rays.
7	**Image Filter** and **Magnification** options.
8	**Acquire** initiates the X-ray exposure process.
9	**Image Viewer** provides full screen display of the last acquired image (or one selected thereafter by the user) along with a toolbar for image processing.
10	**Exit** closes the system software program.

NOTE: The screen layout will appear different in portrait and landscape orientations; however, all functionality remains the same.

Menu Bar

The menu bar provides options for setting up the system and customizing it for client use. The use of each menu bar option is described next.



Figure 3-2: Main Screen Menu Bar

Menu Bar: Settings



Figure 3-3: Calibration Screen

Click **Calibration** in the menu bar to access the **Calibration Wizard**. To calibrate the system, follow these steps:

1. Remove any object that is in the X-ray field.
2. Close the cabinet door gently and tightly.
3. Click **Next** to start the calibration.
4. When the calibration finishes, click **Back to Main Window**.

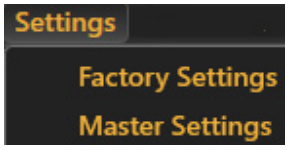


Figure 3-4: Settings Options

Click **Settings** to access the Factory and Master Setting options.

Factory Settings are those that are in place when the system is delivered. The use of this option requires password access.

Master Settings include those for the online image filter, window/level, and preset technologists and radiologists. The use of this option requires password access.

Menu Bar: Presets

Click the **Presets** option in the Main Screen menu bar to access the **Presets Manager** screen, where exposure parameter combinations (Presets) can be added. Each created setting is displayed as a selectable option on the Presets screen, when the manual mode is selected for image acquisition.

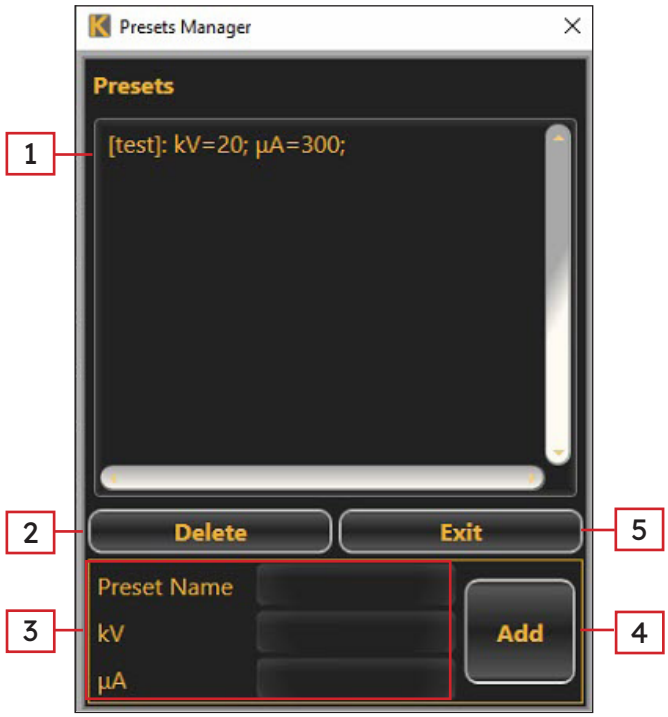


Figure 3-5: Preset Manager Screen

Screen Legend

1 List of Presets.

2 Delete a selected Preset.

3 Enter data for a new Preset.

4 Add a new Preset.

5 Exit the Preset Manager screen.

To add a Preset to the list:

1. In the **Preset Name** field, enter a name for the new Preset.
2. In the kV and µA fields, enter the desired values for this Preset.
3. Click **Add**.
4. Click **Exit**.

To delete a Preset from the list:

1. The preset to be deleted is clicked.
2. Click **Delete**.

Menu Bar: Import/ Export

The Import option in the **Import/Export** menu allows users to import images from a different location within the current series. The Export option allows users to send images that are saved in the system to an external device.

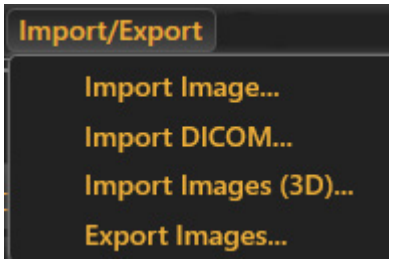


Figure 3-6: Import/Export Options

The use of each option in the **Import/Export** menu is explained in the following sections.

Menu Bar: Import Image

To import an image (or images) into the current case:

1. Click **Import Image** in the Import/Export menu bar option list.
2. Click the **Browse** button and navigate to the image(s) to import.
3. Select the files to be imported.
4. Click **Import**.
5. When the files finish importing, click **Exit** to close the screen.

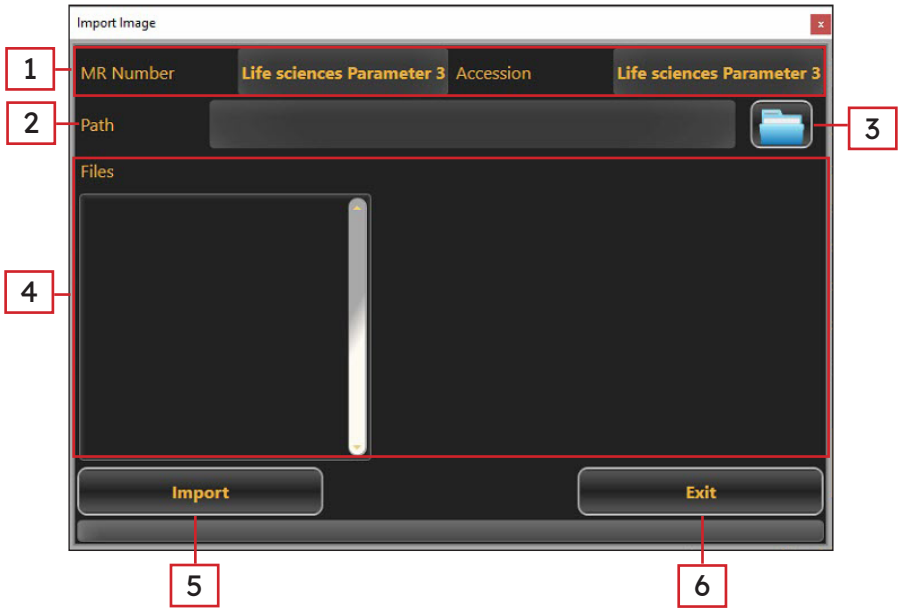


Figure 3-7: Import Image Screen

Screen Legend

1 Current case identification.

2 Location of the files to be imported.

3 Browse to the image to be imported.

4 List of files for preview.

5 Import the selected image(s) into the current case.

6 Close the Import screen.

Menu Bar: Import DICOM

To import DICOM images into the current case:

1. Click **Import Dicom** in the Import/Export menu bar option list.
2. Click the **Browse** button, then navigate to the DICOM image(s).
3. Select the image(s) to import.
4. Click **Import**.
5. When the files finish importing, click **Exit** to close the screen.

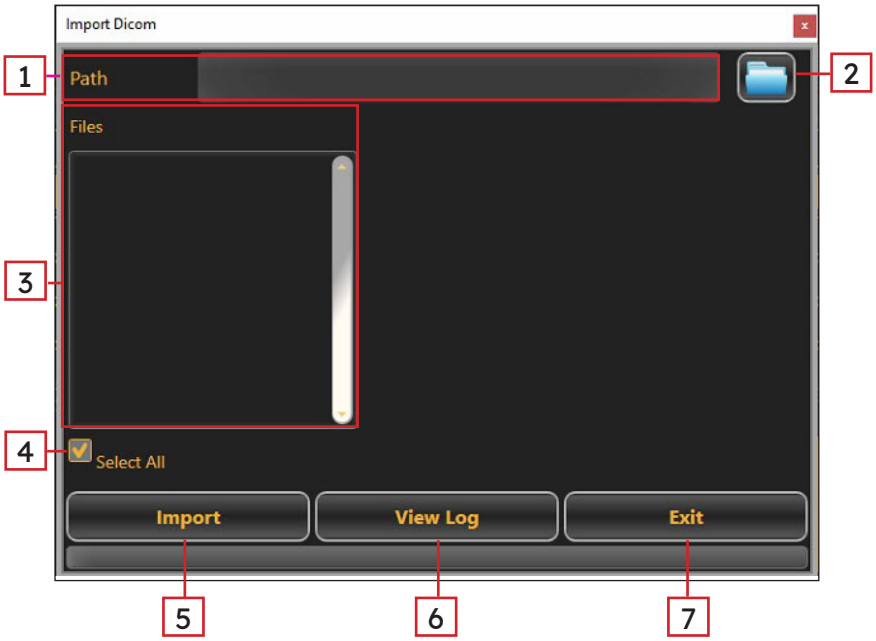


Figure 3-8: Import DICOM Screen

Screen Legend

1 Location of the images to be imported.

2 Browse to the image(s) to be imported.

3 List of files for preview.

4 Selects all files displayed in the list.

5 Import the selected image(s) into the current case.

6 Displays the path of the file to be imported and the status of the import.

7 Close the Import screen.

Menu Bar: Import Images (3D)

To Import Images (3D) into the current case:

1. Click **Import Images** in the Import/Export menu bar option list.
2. Click the **Browse** button, then navigate to the 3D image(s).
   NOTE: Only the TIFF file format is accepted for 3D images.
3. Select the image(s) to import.
4. Click **Import**.
5. When the files finish importing, click **Exit** to close the screen.

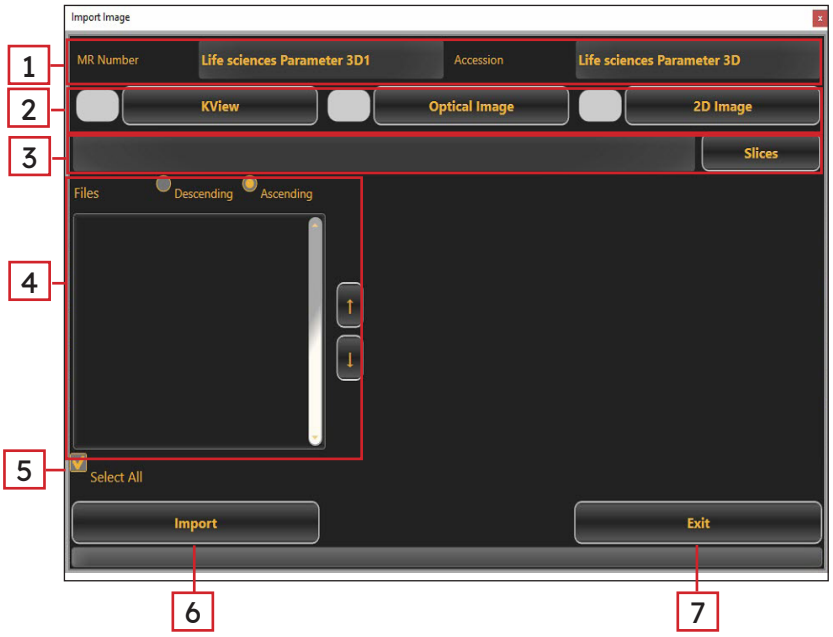


Figure 3-9: Import Image Screen

Screen Legend

1 Current case identification.

2 View options.

3 Browse and select the folder that contains all 3D slices.

4 List of files for preview.

5 Selects all files displayed in the list.

6 Import the selected image(s) into the current case.

7 Close the Import screen.

Menu Bar: Export Images

To export images from the system:

1. Click **Export Images** in the Import/Export menu bar option list.
2. Click the **Browse** button and navigate to the image(s) to be exported.
3. Select the image(s) to be exported, then assign a format.
4. Identify the destination for the exported image(s).
5. Click **Export**.
6. Click **Exit** to close the screen.

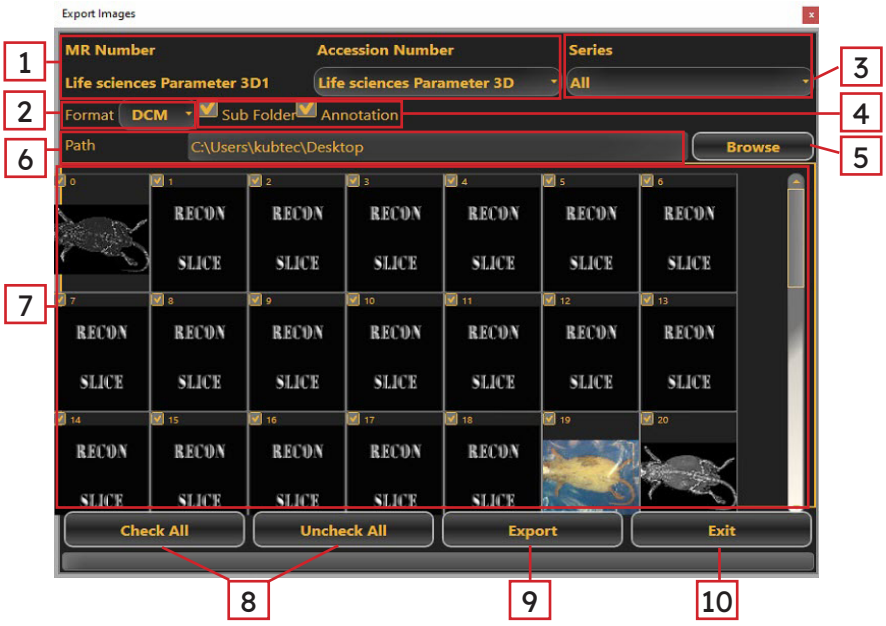


Figure 3-10: Export Images Screen

Menu Bar: Export Images (continued)

Screen Legend

1 Current case identification.

2 The dropdown menu options for the format of images to be exported:

- DCM is DICOM. This is the default and recommended format for systems that have a DICOM viewer.
- JPEG minimizes image size, making the image more compact.
- TIFF provides a full-resolution image, and is recommended for systems that do not have a DICOM viewer.

3 The dropdown menu allows the selection of all images in the series or individual images.

4 **Subfolder**: Option to have all selected images contained in a separate folder when they are exported to the location in the Path field.

Annotation: Option to keep existing annotations with the images to be exported.

5 Navigate to the location of the image(s) to be exported.

6 Location of the images to be exported.

7 Image preview.

8 Select or unselect all images in the display area.

9 Export selected images to a designated location.

10 Close the Export screen.

Menu Bar: Help

The **Help** option provides access to information about the system.

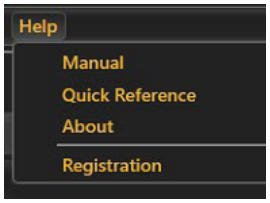


Figure 3-11: Help Menu

- **Manual** is to access the PDF of the Instructions for Use.
- **About** shows KUBTEC® contact information and the version of the software currently running on the system.



Figure 3-12: About Screen

- **Registration** is required to access the screen which contains information that must be communicated to KUBTEC personnel in the event of a software reset. After providing KUBTEC with the alphanumeric Machine Code, the registered Product Key will be provided to unlock the software.

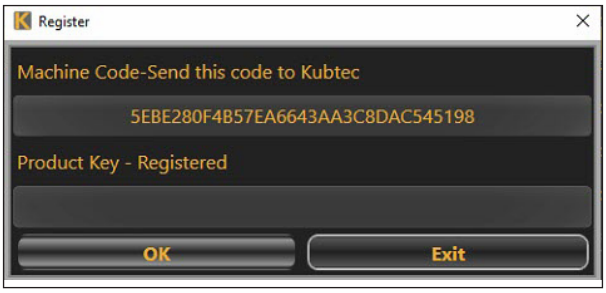


Figure 3-13: Registration Screen

How to Shut Down the System

To shut down the system:

1. Click  on the Main Screen, then click **OK** in the exit program prompt.
2. Click  in the lower left area of the screen.
3. Click the power icon, and then click **Shut down** to turn off the computer.
4. Leave the monitor ON.
5. On the control panel of the shielded cabinet, push the **power** button. The power button light extinguishes.
   - If the system is to remain in its current location, leave the Key Switch in the **ON** position, and the power cord connected to the wall.
   - If the system is planned to be moved, turn the key switch to the **OFF** position, disconnect the power cord from the wall receptacle, and prepare the unit for transport.

Uninterruptible Power Supply (UPS)

The following information applies to systems that are equipped with UPS.

The UPS beeps when the system is running on battery backup. This occurs when the system power cord is unplugged from the wall outlet and the system is in operation. The UPS will continue to beep until one of the following happens:

- The system is connected to another power source.
- The battery reserve in the UPS runs out.
- The UPS is shut down.

To manually shut down the UPS:

1. Remove the lower cabinet cover.
2. Press and hold down the power button for five seconds.
3. Click **YES**, then select **Shutdown without delay.**
4. Replace the lower cabinet cover.

To check the remaining battery reserve:

1. Click the CONSOLE icon on the monitor desktop. The software for the UPS automatically logs in the user name.
2. Enter the password: kubtec, all in lowercase. The screen displays the remaining runtime.

   NOTE: The remaining runtime depends on available charge, how long the X-rays are on, and idle power demand.

   NOTE: The UPS battery backup is intended for room-to-room placement of the system, and should then be plugged into an outlet. Using the UPS to take images or leaving the system unplugged and running on UPS battery power for an extended period will result in damage to the UPS battery.

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CHAPTER 4: IMAGE ACQUISITION

Introduction

After the system is properly set up, it is ready to start the image acquisition process. The first step is to identify the sample to be X-rayed. The system software offers two options to do this:

- Creating a new case.
- Recall an existing case from the system Archive.

The use of each option is explained next.

Create a New Case

The **New Case** screen requires the entry of a unique name for the case along with an image prefix. To create a new case, follow these steps:

1. On the Main Screen, click **New Case**.
2. In the **New Case** screen, type in the required information.
3. Click **Save Case**. The new case information is displayed at the top of the Main Screen and in the Archive section.

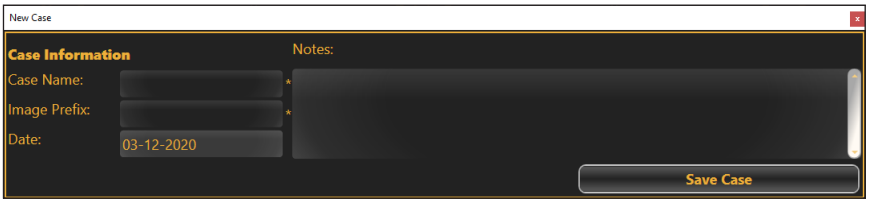


Figure 4-1: New Case Screen

Recall a Case from the Archive

To recall a case from the system archive, follow these steps:

1. From the dropdown menu in the Archive section of the screen, select **Show All** to display a list of cases that are loaded into the system. OR, select **Show by Case Name**, then enter the **Case Name**.

   NOTE: Additional filtering options allow searching the archived cases by a date or a date range.

2. Click on the desired case. Information about that case is displayed in the **Case Information** section of the screen. Images from the case study are displayed below the list of cases.

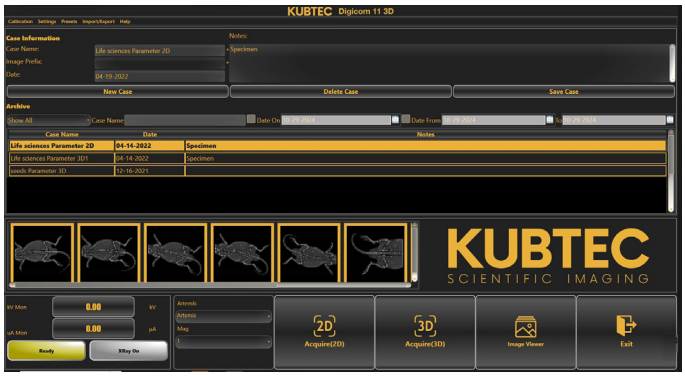


Figure 4-2: Case Selection from Archive

Acquire Images

This system offers two modes for acquiring images:

1. Automatic Exposure Control (AEC) mode, which selects the optimal kV and µA for image acquisition.
2. Presets and Manual mode, which require user interaction for the selection of exposure factors.

The use of each mode is described in the next sections.



This system utilizes a class 2 laser.

DO NOT STARE INTO THE BEAM.

WARNING:

Acquire 3D Using AEC

To acquire 3D images using the AEC mode:

1. Ensure that the case selected on the Main Screen is the desired case.
2. Place the sample at the bottom of the cabinet (contact level).

   NOTE: Center the highest area of the sample under the red laser light.
3. Close the cabinet door tightly.
4. Left-click the **Acquire(3D)** button at the bottom of the screen. A measurement of the height of the sample is displayed.
5. If necessary, reposition the sample.
   - If the sample is small enough to fit within the borders of the detector, center it within the imaging area.
   - If the sample is larger than the imaging area, make sure one corner of the imaging area is exposed.
6. Click the **Continue** button.
   - If an optical (RGB) camera is enabled, the KUBTEC® logo on the cabinet control panel flashes red as X-rays turn on and expose a scout X-ray image from which the system determines optimal kV and µA settings. The system displays **Acquiring images, please wait....** Shortly thereafter, a preview of the 2D X-ray image is displayed along with an RBG image. The system continues with 3D acquisition, during which time a green progress bar displays below the 2D image.
   - If an optical (RGB) camera is disabled, the KUBTEC logo on the cabinet control panel flashes red as X-rays turn on and expose a scout image from which the system determines optimal kV and µA settings. The system displays **Acquiring images, please wait...** until X-ray image acquisition is complete.

Acquire 3D Using AEC (continued)

NOTE: For 3D image acquisition, both modes (AEC mode and Presets and Manual mode) require the sample to be placed at the bottom of the cabinet (contact level) without using the magnification tray. If a magnification tray is in place, the system displays **Invalid Specimen Height** and will not acquire images.

NOTE: For 3D imaging, samples should have a minimum height of 1 cm and maximum height of 10 cm.

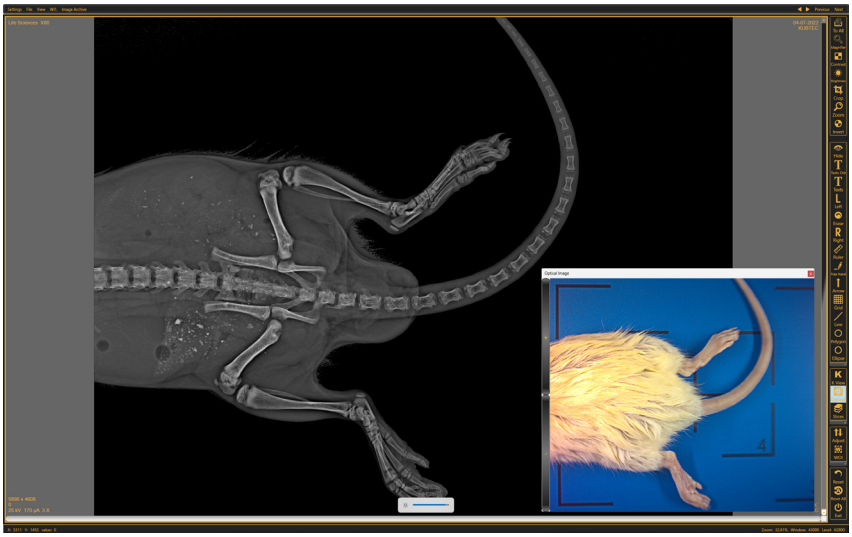


Figure 4-3: 3D Image Acquisition

Acquire 3D Using Presets and Manual

To acquire 3D images using a Preset of exposure factors or by entering exposure factors manually, follow these steps:

1. Ensure that the case selected on the Main Screen is the desired case.
2. Place the sample at the bottom of the cabinet (contact level).

   NOTES: Center the highest area of the sample under the red laser light.
3. Close the cabinet door tightly.
4. Right-click **Acquire(3D)** at the bottom of the screen. The Presets screen is displayed.



Figure 4-4: Preset Screen

5. Acquire the image:
   - To acquire an image using a Preset, double-click the desired Preset or select the Preset and click **Acquire**.
   - To acquire an image using the manual entry of settings, type in the desired kV (between 20 and 50) and µA (between 300 and 1000), then click **Acquire**.

   A measurement of the height of the sample is displayed.
6. If necessary, reposition the sample:
   - If the sample is small enough to fit within the border of the imaging area, center it on the detector.
   - If the sample is larger than the imaging area, make sure one corner of the detector is exposed.

Acquire 3D Using Presets and Manual (continued)

7. Click the **Continue** button.
   - If an optical (RGB) camera is enabled, the KUBTEC logo on the cabinet control panel flashes red as X-rays turn on and expose a scout X-ray image from which the system determines optimal kV and µA settings. The system displays **Acquiring images, please wait...** Shortly thereafter, a preview of the 2D image is displayed along with an RGB image. The system continues with 3D acquisition during which time a green progress bar displays below the 2D image.
   - If an optical (RGB) camera is disabled, the KUBTEC logo on the cabinet control panel flashes red as X-rays turn on and expose a scout image from which the system determines optimal kV and µA settings. The system displays **Acquiring images, please wait...** until 2D X-ray image acquisition is complete.

Acquire 2D Using AEC

To acquire 2D images using the AEC mode, follow these steps:

NOTE: The following instructions do not apply to BMD image acquisition. Refer to the DIGIMUS for PARAMETER Systems Instructions for Use for detailed steps on acquiring 2D BMD images.

1. Ensure that the case selected on the Main Screen is the desired case
2. Center the sample within the black lines and under the red laser light.
3. Close the cabinet door tightly.
4. Left-click the **Acquire(2D)** button at the bottom of the screen.

When the X-rays are turned on, the KUBTEC logo on the control panel flashes red, and the message "**Acquiring images, please wait...**" displays. Shortly thereafter, the 2D image displays.

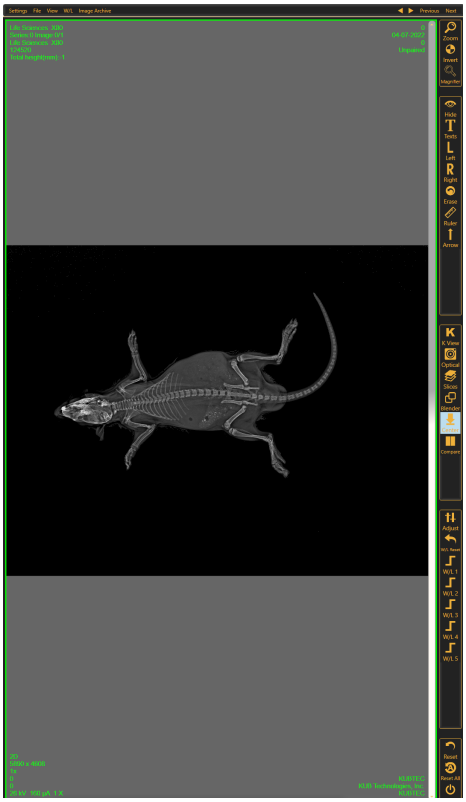


Figure 4-5: Acquired 2D image in Image Viewer

Acquire 2D Using Presets and Manual

To acquire 2D images using a Preset of exposure factors or by entering exposure factors manually, follow these steps:

1. Ensure that the case selected on the Main Screen is the desired case.
2. Center the sample within the black lines and under the red laser light.
3. Close the cabinet door tightly.
4. Right-click the **Acquire(2D)** at the bottom of the screen. The Presets screen displays.



Figure 4-6: Presets Screen

5. Acquire the image:
   - To acquire an image using a preset, double-click the desired Preset, or select the Preset and click **Acquire**.
   - To acquire an image using manual settings, type in the desired kV (between 20 and 50) and µA (between 300 and 1000), then click **Acquire**.

   When the X-rays are turned on, the KUBTEC logo on the control panel flashes red, and the message "**Acquiring images, please wait**" displays. Shortly thereafter, the 2D image displays.

Magnification

To acquire 1.5x or 2x magnification images, follow these steps:

NOTE: Magnification is available only in the 2D imaging modes.

1. Place the magnification tray in the 1.5x or 2x magnification tray rails.
2. Place the sample on the magnification tray, making sure that the sample is behind the red laser light.
3. Close the door gently and tightly.
4. At the bottom of the Main Screen, the magnification mode (1.5x or 2x) automatically selected from the dropdown menu.



Figure 4-7: Filter and Mag Menu

5. Artemis filters enhance contrast and detail in imaging. The filter can be selected from the **Artemis Filter** dropdown menu based on the imaging requirements. To capture a raw (unprocessed) X-ray image, select **None** in the Artemis Filter dropdown menu.
6. Acquire the image:
   - To use AEC, left-click the **Acquire(2D)** button. Shortly thereafter the 2D image displays.
   - To use a Preset, right-click the **Acquire(2D)** button, then double-click the option from the list.

     OR, click the desired Preset, then click **Acquire** on the Preset screen.
   - To use manual settings, right-click the **Acquire(2D)** button, type in the desired kV and µA settings, then click **Acquire** on the Preset screen.

   When the X-rays are turned on, the KUBTEC logo on the control panel flashes red, and the message "A**cquiring images, please wait...**" displays. Shortly thereafter, the 2D image displays.

CHAPTER 5: IMAGE VIEWER

Introduction

The PARAMETER® 3D System has tools for processing acquired images and options for viewing acquired images.

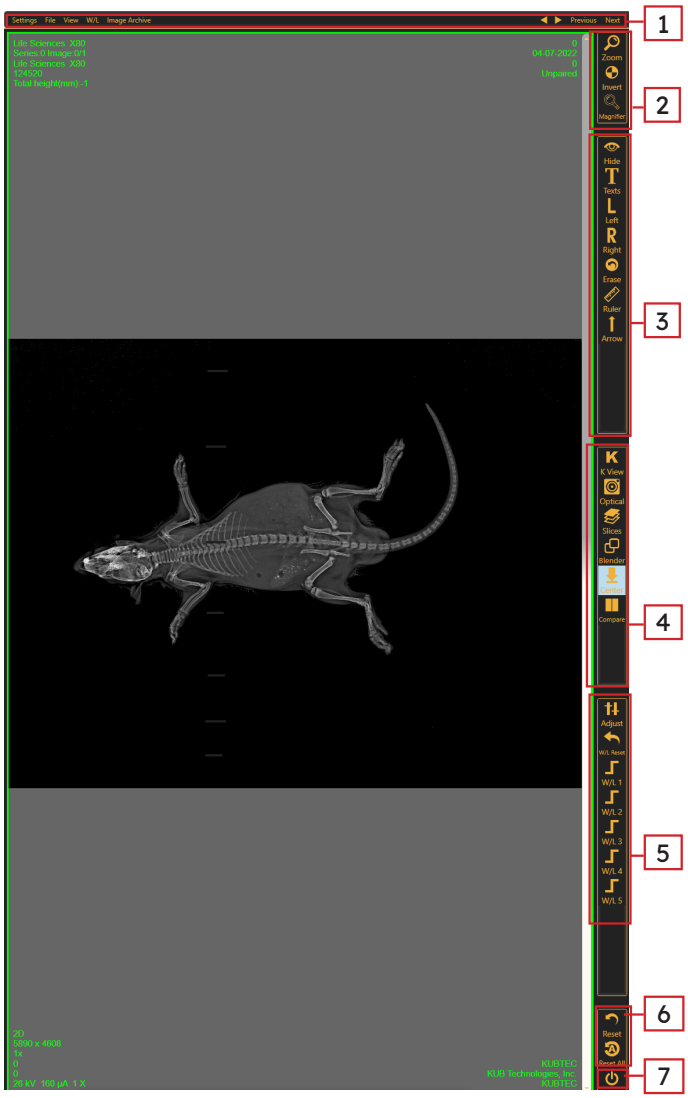


Figure 5-1: Image Viewer

Figure Legend

1 Image Viewer toolbar
2 Image processing tools
3 Annotation tools
4 Viewing options
5 Window/Level tools
6 Reset options
7 Close the Image Viewer

NOTE: Tools seen on the toolbar in this image may show on your screen in a submenu and/or in a different order.

Image Viewer Tools

The next tables describe the use of each tool available in the Image Viewer.

How to Use Image Viewer Tools

1. Use the arrows at the top of the Image Viewer to scroll through images within a series, or click **Previous** or **Next** to go to another series.
2. Click a tool to activate it, then click on the image to use the tool.

NOTE: To pan the image, left-click and hold while moving the mouse.

Image Processing Tools

The following table describes tools that enhance the visualization of specific areas within an acquired image.

Table 5-1: Image Processing Tools

Icon	Name	Function
	**Zoom**	• Click the **Zoom** icon. The cursor changes to a hand. • Use the mouse to move the hand over the image, then left-click to zoom in and right-click to zoom out. • To stop the tool, click the Zoom icon.

	**Magnifier**	• Click the **Magnifier** icon. The cursor changes to a Magnifier.
		• Move the Magnifier onto the image. The arrow at the corner of the Magnifier points to the area in the image shown in the magnified area.
		• To change the Magnifier settings:
		  • Right-click the Magnifier icon.
		  • In the Magnifier window, select the desired Magnifier shape, size, and ratio, and then close the window. The new Magnifier settings are visible when the Magnifier icon is clicked.
		• To stop the tool, click the highlighted Magnifier icon.

	**Invert**	Click the **Invert** icon to change the black pixels to white pixels. Click again to reverse the pixels.

Image Annotation Tools

The following table provides information on tools that provide means to annotate acquired images.

Table 5-2: Annotation Tools

Icon	Name	Function
	**Texts**	• Click the **Texts** icon, then click on the image. The Text Input box appears, allowing the user to add and format text on the image, as well as add and delete text presets. • Make the selections, and then click OK. **NOTE:** Options in the box allow the user to make any text into a preset for use on other images. Multiple presets can also be added to an image. • To stop the tool, click the highlighted Texts icon or right double-click on the image.
	**Left Tag**	• Click the **Left** icon, then click on the image. • To access the Text Input box, which offers options for text entry and formatting, and options for presets, double-click the L tag in the image. • To access options for the L tag for all slices, right-click the L tag in the image. • To delete an L tag, close the Text Input box (if opened), left-click the green box above the L tag in the image, then press Delete on the keyboard. • To stop the Left Tag tool, click the highlighted L icon in the toolbar.
	**Right Tag**	• Click the **Right** icon, then click on the image. • To access the Text Input box, which offers options for text entry and formatting, and options for presets, double-click the R tag in the image. • To access options for the R tag for all slices, right-click the R tag in the image. • To delete an R tag, close the Text Input box (if opened), left-click the green box above the R tag in the image, then press Delete on the keyboard. • To stop the Right Tag tool, click the highlighted R icon in the toolbar.

Image Annotation Tools (continued)

Table 5-2: Annotation Tools

Icon	Name	Function
	**Ruler**	• Click the **Ruler** icon. • Click on one end of the area to be measured. • Move the mouse to the other end of the area to be measured, then click. The distance between the two points is displayed. • To delete the measurement, select the distance marker in the image, then select Delete on the keyboard. • To stop the Ruler tool, click the highlighted Ruler icon. **NOTE:** The unit of measurement can be set (in the **Annotations Settings** screen) to display in mm, cm, inches, or microns.
	**Arrow**	• Click the **Arrow** icon, then click on the image. • Move the mouse to draw an arrow to a region in the image, then click to end the creation of the arrow. • To stop the creation of additional arrows, double right-click on the image. • To change the direction or length of the arrow, click and hold one end of the arrow while dragging it. • To stop the Arrow tool, click the highlighted Arrow icon.
	**Erase**	Click the **Erase** icon, then click Yes to the prompt to erase all annotations in the image.
	**Show/ Hide**	Click the Show/Hide icon to toggle between showing and hiding annotations on the image.

Image Viewing Options

The following table describes the options available for viewing acquired 3D images.

NOTE: Image viewing options are available only with 3D images.

How to use image viewing options

1. Ensure that the desired image is displayed in the Image Viewer. If it is not, click **Previous** or **Next** at the top of the Viewer to scroll to the desired image.
2. Click a view icon on the toolbar to activate that view option.

Table 5-3: Viewing Options

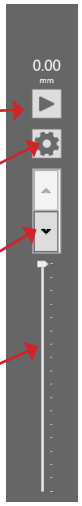
Icon	Mode	Function
	**K-View**	K-View is a composite image of all the slices.
	**Slices**	Click the Slices icon to access the slices toolbar, which provides three options for viewing the slices in the acquired image: • The play button scrolls automatically through all slices. • Thlices option allows the user to adjust the speed and behavior of the slice animation. • Up/Down arrows step through the slices in 1 mm increments. • Slide allows manual scrolling through the slices. 

Image Viewing Options (continued)

Table 5-3: Viewing Options

Icon	Mode	Function

	**Blender**	The Blender overlays the optical image on the X-ray image.
		To enable Blender, click the **Blender** icon.
		A window opens and offers following options:
		• Slider changes the opacity of the optical image:
		  • Fully to the right shows only the optical image.
		  • Fully to the left shows only the X-ray image.
		• Save to Series saves the blended image as a new DICOM image and makes it part of the series.
		• Open Blended Viewer allows blended images to be displayed in the main viewer. If there are many blended images, a selection window opens for the user to choose the image to display.
		• Export saves the image as a .jpg or .tiff to a selected destination.

	**Optical (RGB)**	• Click the **Optical** (RGB) icon to view the RGB image from the 3D acquisition. • Click in the RGB window to switch between images in the smaller optical window and the larger main Image Viewer window.
	**Compare**	• Click the **Compare** icon to enable the comparison of two images. The displayed screen provides options to select the accession number, series, view, image ID, and blended images. • To stop the tool, click another view icon.

Window/Level Options

The information in the following table describes Window/Leveling Adjusts. The Window/Level can be adjusted by holding down the right mouse button and dragging the cursor on the image.

Table 5-4: Window/Leveling Options

Icon	Name	Function
	**W/L Adjusts**	• Click the Window/Level **Adjust** icon to display the vertical slides that allows to adjust W/L in the displayed image. • On either slide, click and hold the button, then drag up or down the slide.
	**W/L Presets**	• Click one of the Window Level (W/L) Preset icons to have the image displayed in a pre-defined W/L value. • To change a preset, adjust the Window/Level of the image, then right-click on the desired preset to change. Click Yes to the prompt about overwriting the existing preset. • Select YES to confirm the new value.
	**W/L Reset**	Click this icon to reset the W/L of the current image to its recommended values that are calculated upon acquisition.

Other Image Viewer Options

The information in the following table describes other Image Viewer capabilities.

Table 5-5: Reset Options

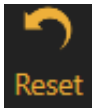
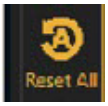
Icon	Name	Function
	**Reset**	• Applies to the displayed image. • Click the **Reset** icon to erase all annotations, reset the W/L to the recommended settings, and remove all other image processing that was applied.
	**Reset All**	• Applies to all images contained in the series. • Click the **Reset All** icon to erase all annotations, reset W/L to recommended settings, and remove all other image processing applied to all images contained in the study of the image in the preview screen.
 **CAUTION:**		**To prevent a software error:** Once the PACS screen or your preferred network drive is open, do not minimize it until the Send process is complete.
	**Exit**	Click the **Exit** icon to return to the Main Screen.

Image Viewer Menu

The Image Viewer menu is located at the top of the screen. This menu has options for handling acquired images. Information in the following table describes these options.

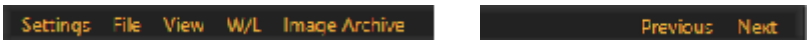


Figure 5-2: Image Viewer Menu Bar

Table 5-6: Image Viewer menu

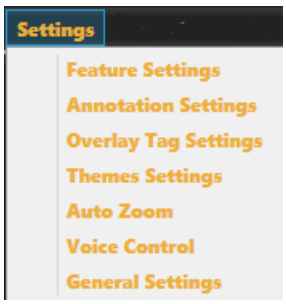
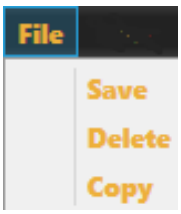
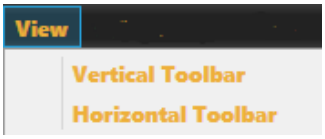
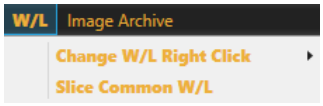
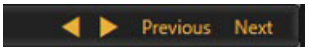
Menu Item	Function
	**Feature Settings** allows the setup of the Image Viewer Tool buttons. The user can select to have a button visible and to have it placed higher or lower in the toolbar. **NOTE:** To move a tool to a different position on the toolbar, left-click the button to be moved and drag/drop it to the new location.
	Annotation Settings offers options for the appearance of annotations on the image, such as changing the color and size of the overlay as well as the annotations.
	Overlay Tag Settings offers options for the location of various tags on the image.
	Themes Settings provides options for changing the color scheme of the image viewer.
	Auto Zoom - When enabled, uses image processing to locate the sample, then zooms in until the whole sample is visible and fills as much of the screen as is possible.
	Voice Control allows users to enable or disable the voice activation feature of the software. When Voice Control is enabled, the system can perform functions that are indicated by voice commands. See “Page 5-11: Voice Control Use and Commands for 3D Images”.
	General Settings allows various system options to be enabled or disabled.

Image Viewer Menu (continued)

Table 5-6: Image Viewer menu

Menu Item	Function
	**Save** overwrites the original image with the current image that is displayed in the viewer. **Delete** deletes the current image displayed in the viewer. **IMPORTANT!** Deleted images cannot be recovered. **Copy** makes a copy of the displayed image.
	**Vertical Toolbar** and **Horizontal Toolbar** options for displaying the Toolbar along the side of the screen or across the bottom of the screen.

	The W/L submenu offers two options for viewing:
	• **Change W/L Right Click:** This option allows the user to adjust W/L by AXIS or by ROI.
	  • AXIS: Right-click and hold, then move left/right to adjust window and up/down to adjust level.
	  • ROI: Right-click and hold while creating a region of interest. The W/L of the entire image adjusts to W/L selected in the region of interest.
	• **Slice common W/L** - keep one window level for all slices. This option is enabled by default.

	Provides DICOM information in **Tree View** and **Header View**.
	Provides the means to scroll through acquired images.

Voice Commands

Voice Control Use

To **enable** Voice Control, open the Image Viewer, select Settings, then select Voice Control.

To **start** Voice Control, clearly state the Wake-Up command, “Hello MOZART”.

The light (KUBTEC®) in the Control Panel turns from amber to blue, indicating that the system is ready to accept commands. After 30 seconds, if no voice command is issued, voice control shuts off automatically. The Wake-Up command is required to restart voice control.

To **stop** voice control, state the Shut Off command, “Bye MOZART”.

Voice Commands for 3D Images

The following commands are available only after Voice Control is started with the “Hello MOZART” command.

NOTE: Some commands do not apply to 2D images.

Main Commands

- Hello MOZART
- Bye MOZART
- Zoom In
- Zoom Out
- Show Slice View
- Run Animation
- Stop Animation
- Up One
- Down One
- Show K View
- Show Blender
- Show Optical View
- Hide Optical View
- Show Slice (1–100)

Blender Commands

- Show Optical
- Show X-ray
- More Optical/Less X-ray
- More X-ray/Less Optical
- Close Blender

Blender + Slice View Commands

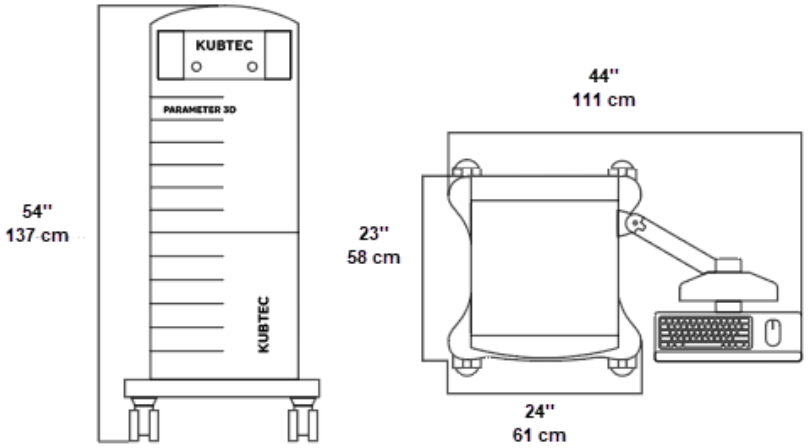
- Run Animation
- Stop Animation
- Up One
- Down One

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CHAPTER 6: SYSTEM SPECIFICATIONS

Specifications

The following tables list specifications for the PARAMETER® 3D System components.



Electrical Requirements

Table 6-1: Electrical requirements

Input line voltage	90–250 VAC, 50/60 Hz, 500 VA
Peak input power	500 W
Frequency	50/60 Hz

Physical Construction

Table 6-2: Physical specifications

Construction	Fully Integrated Mobile System
Dimensions	23" L x 24" W x 54" H (58 cm x 61 cm x 137 cm)
Weight	300 lbs (136 kg)

Digital Image Receptor

Table 6-3: Digital image receptor

Imaging area	5" x 6" (12 cm x 15 cm)
Output image	16-bit

X-ray Source

Table 6-4: X-ray source specifications

Energy range	20–50 kV
Anode type	Tungsten
Tube current	1 mA
Focal spot size	50 µm nominal
Filtration	0.127 mm Beryllium

CHAPTER 7: SYSTEM MAINTENANCE

Introduction

This chapter provides information on actions that users need to perform to maintain the safe and consistent performance of the system.

The first section of this chapter provides information about cleaning and disinfection. There are recommendations for products to use and procedures to follow.

The second section in this chapter contains checklists for the routine system inspections.

NOTE: To avoid damage to the system and unnecessary cleaning, protect the equipment from dust, dirt, and any other environmental hazards that damage surfaces or impair operation.

Cleaning and Disinfecting

Cleaning

At the completion of each sample case, clean and disinfect interior components of the upper cabinet and all system controls and components that the user touched during the examination. This practice is both for user protection and to avoid cross-contamination of samples.

For purposes of this manual, cleaning means wiping off dust, fingerprints, and other substances that do not contain biological or contaminating fluids. Solutions to use for this purpose are over-the-counter, neutral detergents and/or liquids. Be sure to use a soft cloth with these cleaners.



CAUTION: Harsh liquids or rough surfaces will damage the system surfaces.



CAUTION: Use only a glass cleaner and a soft cloth on any leaded glass, if present. The leaded glass is designed especially for protection against X-ray radiation exposure. Abrasives may damage its protective capabilities.

- Clean controls and stainless steel surfaces with a no-rinse liquid cleaner.
- Clean glass and machine surfaces with a glass cleaner and a soft cloth.
- Regularly clean the top and bottom of the acrylic tray with an acrylic plastic cleaner and a soft cloth.
- Regularly clean the top of the carbon fiber detector with a mild, non-abrasive cleanser such as isopropyl alcohol.

Cleaning and Disinfecting (continued)

Disinfecting

For purposes of this manual, disinfecting means using approved solutions to wipe areas that have come in contact with biological or contaminating fluids.

The following list shows cleaning solutions (and their main ingredients) that KUBTEC® approves for use in cleaning and disinfecting this system.

KUBTEC approved item	Ingredients
CaviWipes-XL	Quaternary ammonium + alcohol disinfectant
Accel-TB wipes	Stabilized hydrogen peroxide wipe
PDI and Clorox disinfectant bleach wipes	1:10 hypochlorite:water
PDI SaniCloth-HB wipes	Quaternary ammonium and isopropyl alcohol (IPA) disinfectant

Areas to clean/disinfect



WARNING: To disinfect trays, use a soft cloth that is dampened with an approved solution to wipe the tray surface. DO NOT spray or spill solutions directly onto the detector surface.

In addition to cleaning/disinfecting surfaces that contact the samples, surfaces touched by the user(s) also need to be cleaned/disinfected at the end of each session. These surfaces include:

- Interior and exterior walls of the sample cabinet
- Inside cover on the cabinet door
- Mag tray rails
- Cabinet control panel buttons and indicators
- Monitor
- Keyboard and keyboard tray

NOTE: It is also recommended to clean and disinfect the power cord and all exterior surfaces of the unit before removing the system from the facility.

Recycling and Disposal



At the end of the service life, KUBTEC® requests that the system be returned for proper disposal and recycling. Responsible recycling helps reduce waste and ensures that hazardous materials do not pose a risk to public health.
The hazardous materials present in the system include:

- Lead is used to line the cabinet.
- Oil is contained in the X-ray components.
- Beryllium (Be) is in the X-ray tube.

Additionally, the system contains electronic components that must be recycled appropriately.

Daily Inspection Checklist

Perform the following inspection daily, before using the system. Contact a KUBTEC representative or distributor if there is any problem.

Inspection	Review	Remedy
Visual	Are there any anomalies with the system?	If any visual anomalies are observed during this procedure, contact KUBTEC or your distributor.
Test image	Was a test exposure completed?	If there are any issues completing a test exposure or with image quality, contact KUBTEC or your distributor.

Yearly Inspection

Preventive Maintenance services are to be performed annually by a KUBTEC engineer or a KUBTEC-trained engineer. This ensures your system is kept compliant with performance and regulatory guidelines.

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FREQUENTLY ASKED QUESTIONS

This section provides answers to questions that users typically ask about the system.

Q: How is the computer turned on?

The computer initiates automatically when the power switch of the system cabinet is turned on.

Q: How long does the UPS last when AC power is interrupted?

The standard UPS maintains usability of the system for about 24–30 minutes. The exact number of minutes will vary depending on the activity.

Q: Does the unit need to be kept plugged in?

KUBTEC® recommends leaving the system plugged in so that the UPS is always charged.

Q: Should the key be removed at night?

Follow institutional policy regarding X-ray equipment. To prevent unauthorized use of the system, KUBTEC® recommends the removal of the key when the system is not in use.

Q: Is the unit equipped with Wi-Fi?

Yes, the unit has a Wi-Fi adapter.

Q: Does it matter where the sample is placed under the laser in the chamber?

Yes, it matters. Place the highest point of the sample under the laser to ascertain maximum height, then click **Acquire**. After the height is verified, center the sample. Make sure the area of interest is fully within the detector boundaries, then click **Continue**.

Q: Is the user exposed to radiation during operation? Is a lead apron required for shielding?

X-rays are controlled and sealed inside the unit. A lead apron is not required.

Q: How can the unit be cleaned?

Wipe the tray of the sample chamber with a soft cloth dampened with an ethanol or glutaraldehyde solution to disinfect and prevent contamination. Do not spray or spill solutions directly onto surfaces. Refer to the Maintenance Chapter in the Instruction for Use for more details about cleaning and disinfection.

Q: How often does the system need to be serviced?

Manufacturer's recommendation is that the system get serviced once a year by a KUBTEC-trained/certified technician.

Q: How are the image slices of the sample displayed when 3D imaging is performed?

The software displays 1 mm image slices through the sample from top to bottom. Slice 0 is the uppermost image slice.

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