KODAK 9000 3D Extraoral Imaging System

User Guide

Notice

Congratulations on your purchase of the KODAK 9000 Extraoral Imaging System. Thank you for your confidence in our products and we will do all in our power to ensure your complete satisfaction.

The User Guide for the KODAK 9000 3D Extraoral Imaging System includes information both on the Panoramic features as well as the 3D features. If you have purchase only the KODAK 9000 Panoramic system, information relevant to 3D does not apply to your radiological system. We recommend that you thoroughly familiarize yourself with this Guide in order to make the most effective use of your system.

The information contained in this Guide may be subject to modification without notice, justification or notification to the persons concerned.

This document is originally written in English.

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KODAK 9000 3D Extraoral Imaging System, complies with Directive 93/42/CEE relating to medical equipment.

CE
0086

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About This Guide

Conventions in this Guide

The following special messages emphasize information or indicate potential risk to personnel or equipment:

WARNING
Warns you to avoid injury to yourself or others by following the safety instructions precisely.

CAUTION
Alerts you to a condition that might cause serious damage.

IMPORTANT
Alerts you to a condition that might cause problems.

NOTE
Emphasizes important information.

TIP
Provides extra information and hints.

Note to the User

WARNING
X-rays can be harmful and dangerous if not used properly. The instructions and warnings contained in this guide must be therefore carefully followed.

As a manufacturer of radiology units that conform to stringent radiological protection standards in force throughout the world, we guarantee a maximum degree of protection against radiation hazards. Nonetheless, you are handling a radiology unit specially designed to emit x-ray doses in order to carry out a medical diagnosis.

The room in which your radiology Unit is to be installed must comply with all official regulations applicable to protection against radiation. You must install your radiology unit in a room protected against x-ray emission. This room must reduce to at least 12db the frequency interferences of the 30MHz to 1GHz band.

Your local representative will assist you in the initial use of your radiology Unit and will supply any relevant information you may require.

To use and operate your panoramic unit and your digital imaging software you must follow the instructions contained in this guide.

Warning and Safety Instructions

When operating the Kodak 9000 3D unit, observe the following warning and safety instructions:

DANGER OF ELECTRIC SHOCK

This is an electrical Unit. DO NOT expose it to water spray. Such action may cause an electric shock or a malfunction of the Unit.

LASER WARNING

For maximum safety, advise the patient not to look at the beam. Before turning on the beams, lower the Frankfurt plane beam to the lowest level. While making adjustments, ensure that the beam is not directed into the patient's eyes.

WARNINGS:

- **You are responsible for the operation and maintenance of this unit. Only legally qualified persons can operate this unit. DO NOT open the cover of the unit.When necessary, have a trained authorized service technician carry out inspection and maintenance operations.**
- **Install this Unit in an x-ray room that complies with current installation standards. From this location, you must be able to maintain visual or audio communication with the patient and be able to access the Acquisition interface module during exposure. This Unit must be permanently connected to the ground with a fixed power supply cable.**
- **DO NOT place the PC and the peripheral equipment connected to it in the immediate vicinity of the patient in the Unit. Leave at least 1.5 m distance between the patient and the Unit. The PC and the peripheral equipment must conform to the IEC60950 standard.**
- **See your computer installation guide for details of the data processing system, PC and screen. Leave a sufficient amount of clear space around the CPU to ensure that it is properly ventilated.**
- **To obtain maximum image quality and visual comfort, position the screen to avoid direct light reflections from internal or external lighting.**
- **DO NOT operate the Unit if there is the threat of an earthquake. Following an earthquake, ensure that the Unit is operating satisfactorily before using it again. Failure to observe this precaution may expose patients to hazards.**
- **X-ray equipment is hazardous to patients and the operator if you do not observe the exposure safety factors and operating instructions.**
- **DO NOT place objects within the field of operation of the Unit.**
- **The patient should wear a protective lead-lined shoulder apron, unless other Radiation Protection Protocols apply locally.**
- **Disinfect any parts of the Unit that come into contact with the patient and the operator after each patient has been exposed to x-rays.**
- **While adjusting the height of the Unit, ensure that the patient is kept clear of the mechanism.**
- **When the Unit is not in use, ensure that the ON/OFF switch is set to OFF (O).**
- **If the Unit develops a fault, switch it to off (O), display an “Unserviceable” notice and contact a service technician.**
- **To dispose of the Unit or its components, contact a service technician.**
- **Ask the patient to refrain from moving during the entire period of exposure.**
- **Ask the patient to remain still until the Unit arm has stopped moving and the RESET movement has completed.**
- **DO NOT use this Unit in conjunction with oxygen-rich environments. This Unit is not intended for use with flammable anesthetics or flammable agents.**

Marking and Labeling Symbols

	Type B device symbol complying with the IEC 60601-1 standard
	In the EEC, this symbol indicates: DO NOT discard this product in a trash receptacle; use an appropriate recovery and recycling facility. Contact your local sales representative for additional information on the collection and recovery programs available for this product
	**WARNING** and **IONIZING RADIATION** symbols warn you about radiation dangers.
 	**LASER WARNING** Laser radiation. DO NOT stare into the beam. Class 2 laser product. Maximum output power: 1mW, 650 nm (IEC 60825-1 standard) This Unit emits laser radiation.

Chapter 2

KODAK 9000 3D DIGITAL IMAGING UNIT OVERVIEW

The KODAK 9000 3D digital imaging unit is compliant with the requirements of the EEC and international medical standards.

The KODAK 9000 3D Unit has been designed to carry out the following radiological examinations:

- Panoramic
- Maxillary Sinus
- Temporomandibular Joints (TMJ)
- 3D images

The KODAK 9000 3D Unit is composed of the following functional components:

- Control Panel
- Remote Control

Functional Overview

The following figures illustrate the components of the KODAK 9000 3D Unit.

Figure 2-1 illustrates the up and down movement of the Unit mobile component and the 180° rotation of the rotative arm.

Figure 2–1 KODAK 9000 3D Unit mobile components

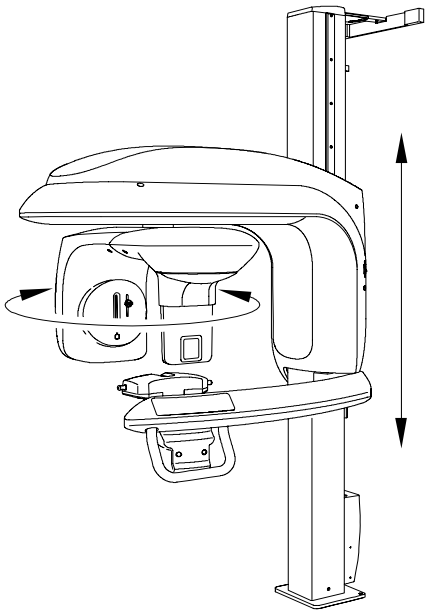
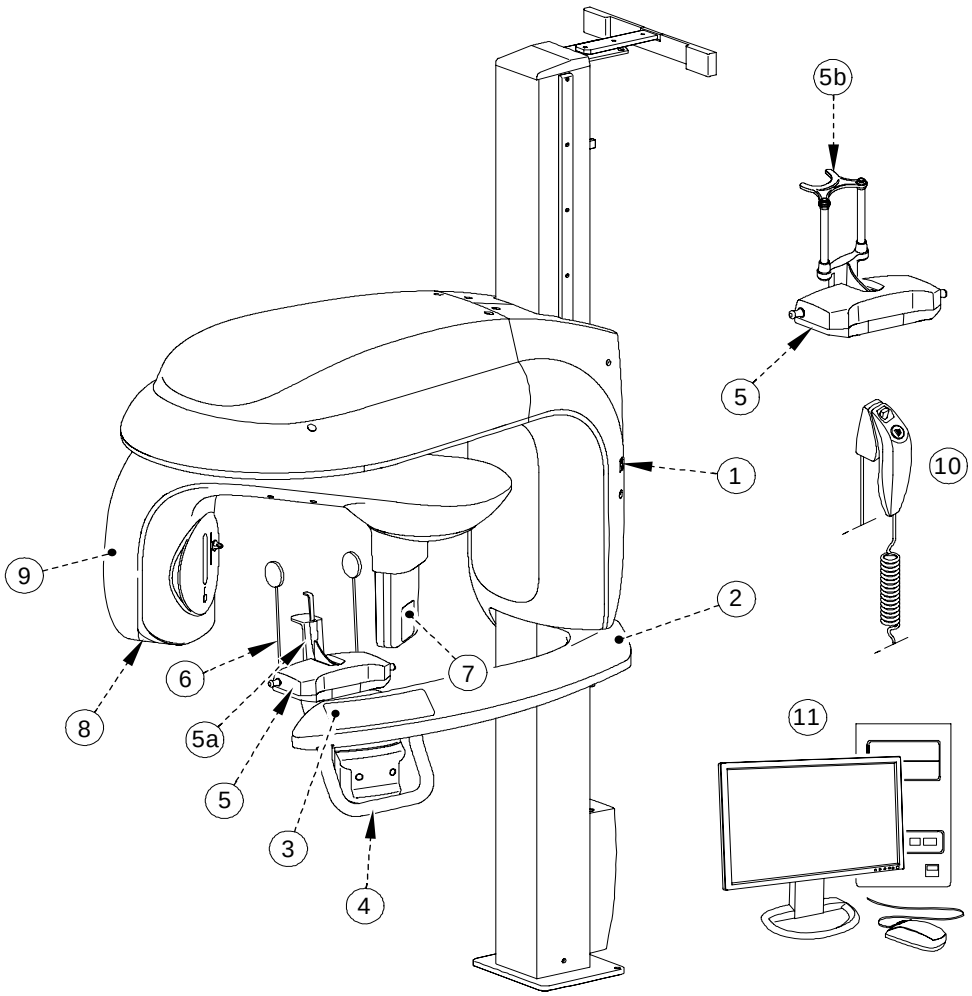
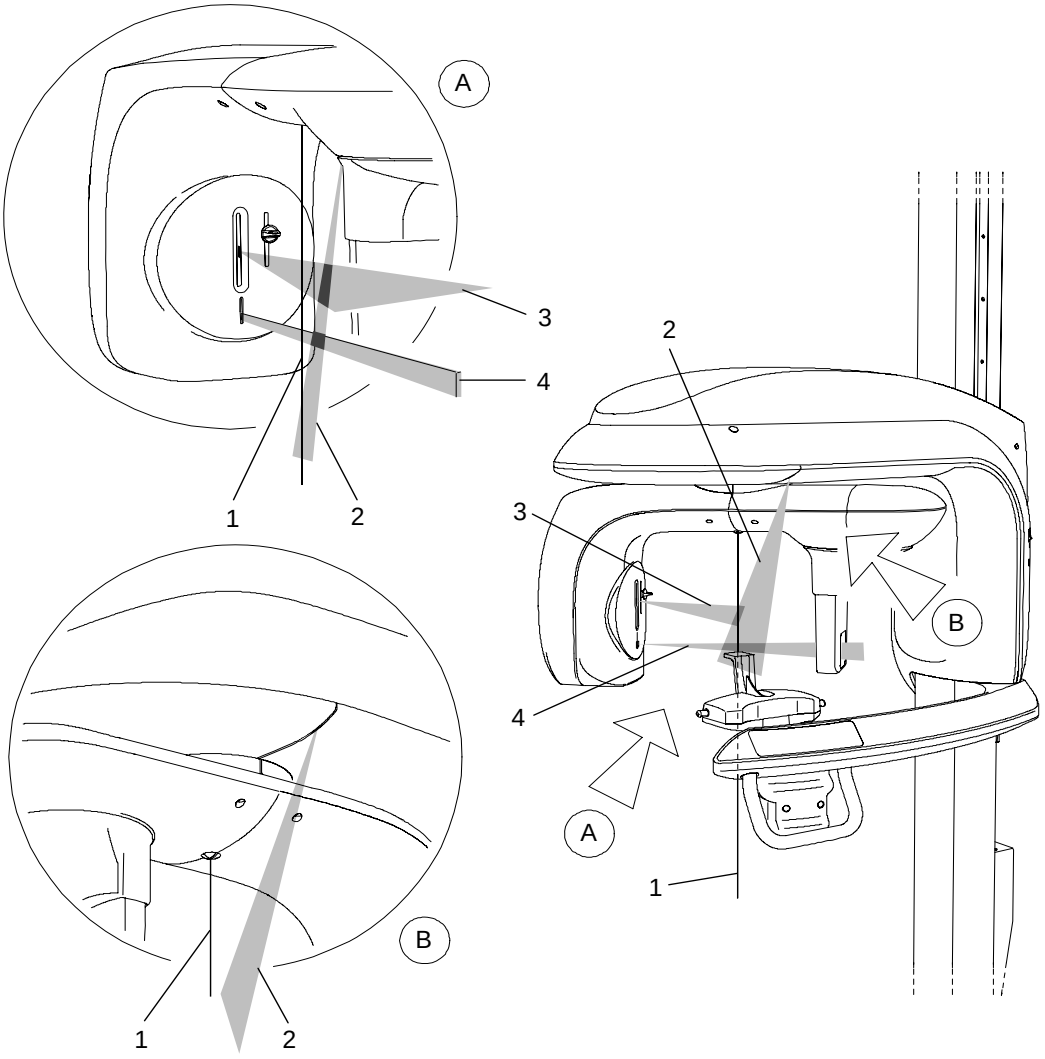


Figure 2–2 KODAK 9000 3D Unit functional components



1	ON/OFF button	**6**	Temple supports
2	Unit fixed arm	**7**	Sensor
3	Control panel	**8**	Generator
4	Hand Grips	**9**	Unit rotative arm
5	Chin rest base	**10**	X-Ray remote control
5 a	Panoramic chin rest	**11**	PC hosting the imaging and the acquisition software
5 b	3D chin rest and bite block		

Figure 2–3 KODAK 9000 3D Unit Positioning Laser Beam components



1 3D central positioning laser beam

2 Mid-sagittal positioning laser beam

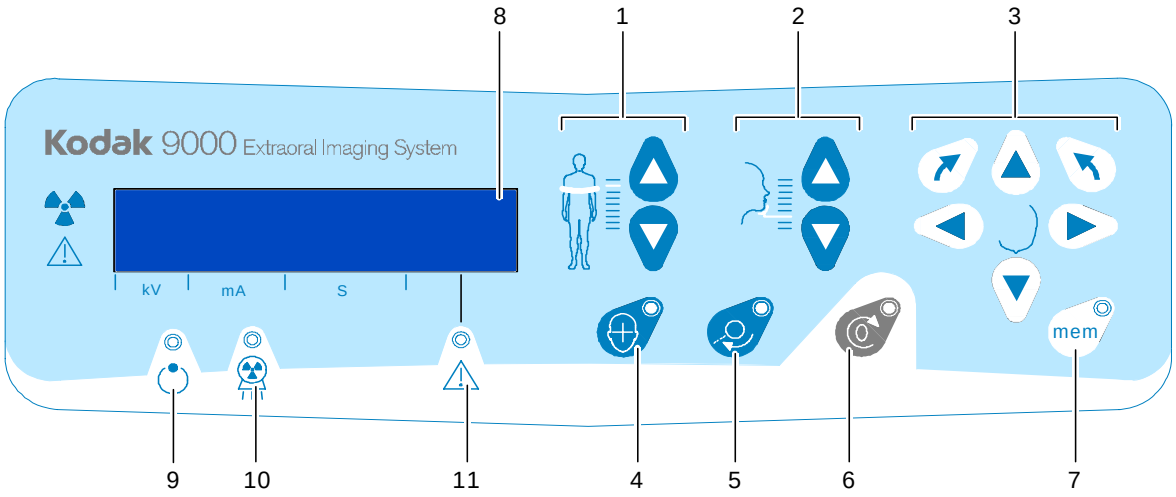
3 Horizontal positioning laser beam

4 3D Field of View (FoV) positioning laser beam

Control Panel Overview

The control panel is an alphanumeric, digital soft touch console. It allows the operator to control certain Unit functions. It also displays the operating parameters and error messages.

Figure 2–4 Unit Control Panel



1 **Height Adjustment button:** Adjusts the height of the unit to the height of the patient.

2 **3D Head Adjustment button:** Adjusts the patient head to the x-ray beams.

3 **3D Adjustment button:** Adjusts the Unit arm movements to correctly position the patient for 3D acquisition.

4 **Laser Beam button:** Activates the beams to correctly position the patient.

5 **3D Position Verification button:** Verifies the correct 3D positioning.

6 **Reset button:** Resets the Unit arm to the initial position to enable the patient to enter and exit the Unit.

7 **3D Memorization button:** Memorizes the 3D current positioning parameter settings that override the default parameters.

8 **Display Screen:** Displays the current acquisition parameters and the error messages.

9 **Ready Indicator LED:** Green indicates the Unit is ready for acquisition.

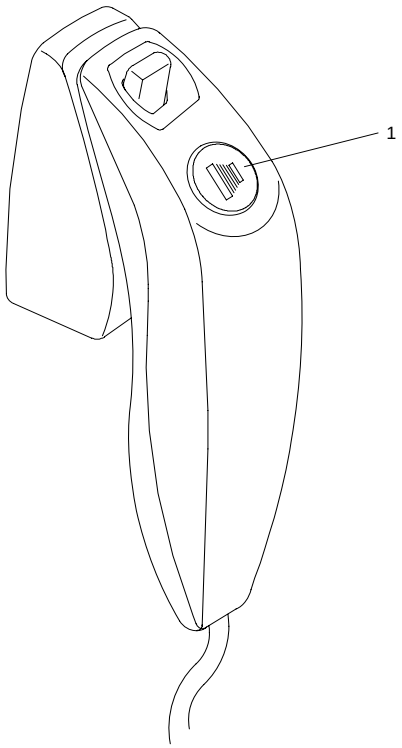
10 **X-Ray Emission LED:** Yellow indicates x-rays are being emitted.

11 **System Status LED:** Red indicates error alerts.

X-Ray Remote Control Overview

The x- ray remote control enables you to launch a radiological image acquisition via the exposure button from outside the x-ray room. You must press and hold the exposure button until the end of acquisition. Premature release of the exposure button interrupts the acquisition.

Figure 2–5 X-Ray Remote Control



1 Exposure button: launches image acquisition.

Positioning Accessories and Replacement Parts

The following accessories are used when positioning a patient. They are delivered with the KODAK 9000 3D digital imaging unit.

Table 2–1 Panoramic Positioning Accessories and Replacement Parts

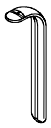
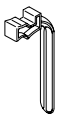
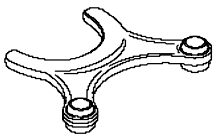
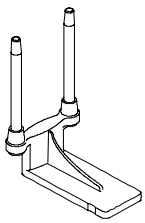
Accessory	Description
	• Panoramic chin rest • TMJ x2 • Sinus
	TMJ x4 nose rest
	Panoramic standard bite block
	Bite block for edentulous patients
	Single use sheaths for bite blocks (500 pcs box)

Table 2–2 3D Positioning Accessories and Replacement Parts

Accessory	Description
	3D bite block
	3D chin rest

Chapter 3
IMAGING SOFTWARE OVERVIEW

PC System Requirements

This section specifies the minimum PC system requirements for Kodak 9000 3D extraoral imaging system software.

IMPORTANT

It is MANDATORY to check that the PC system configuration is compatible with the PC system requirements for the Kodak 9000 3D software. If necessary you MUST update your PC system configuration. Kodak 9000 3D MUST be connected to the PC via a point-to-point Ethernet link and not via a LAN. DO NOT place the PC and the peripheral equipment connected to it in the immediate vicinity of the patient in the Unit. Leave at least 1.5 m distance from the Unit. The PC and the peripheral equipment must conform to the IEC 60950 standard.

Table 3–1 Minimum PC System Requirements

Item	Minimum Workstation Image Viewing Requirements	Minimum Workstation Acquisition Requirements	Comments
CPU	2 GHz Intel Duo Core	3 GHz Intel Pentium 4	
RAM	2 GB	2GB	RAM has a major impact on system performance.
Hard disk drive	• 1.2 GB for software installation • 80 GB free space to use the software	1.2 GB for software installation	
Graphic board	Nvidia / ATI based board supporting Open Glide 1.2 with 256 MB of video RAM on AGP x8 video bus (example: Nvidia GeForce 6800 GT)	Nvidia board on PCI Express video bus, minimum GeForce 8800 GTS 640 MB of video RAM, or Quadro FX 4600 768 MB of video RAM	The video RAM has major impact on system performance.
Monitor	• 1 monitor • 17" or larger • 1024 x 768 minimum screen resolution - 32 bits color mode	• 1 monitor • 17" • 1024 x 768 minimum screen resolution	Your monitor is a vital component in displaying quality images. Low-quality screens will prevent you from proper diagnoses and treatment.
Operating system	• Windows 2000 SP4 • Windows XP Home / Pro edition SP2 • Windows Vista 32 bits	• Windows 2000 SP4* • Windows XP Home / Pro edition SP2 • Windows Vista 32 bits*	
Ethernet interface	1 Ethernet interface	2 Ethernet interfaces (100Mbits)	
CD/DVD drive	A CD-ROM drive is required to install the product.	A CD-ROM drive is required to install the product.	

Table 3–1 Minimum PC System Requirements

Item	Minimum Workstation Image Viewing Requirements	Minimum Workstation Acquisition Requirements	Comments
Backup Media	Removable/portable, external hard disk drive	Removable/portable, external hard disk drive.	We strongly recommend a daily backup of x-ray images and patient records.
*** NOTE: The indicated operating systems considerably increase the 3D volume image reconstruction time. The normal duration of a few minutes is increased by more than an hour.**			

General Software Overview

The Kodak 9000 3D extraoral imaging system operates with the following software:

- Kodak dental imaging software
- Acquisition interface module

Kodak Dental Imaging Software

The Kodak dental imaging software is a user-friendly working interface that was designed and developed specifically for radiological diagnosis. It is the common imaging platform for all our digital systems for dentistry.

The Kodak dental imaging software has the following features:

- Patient record management via **Patient Window** features
- Extraoral and intraoral image management via **Imaging Window** features
- 3D image management via **3D Imaging Window** features

NOTE
If you access the **Imaging Window** directly from your own patient management software, you will not see the **Patient Window**.

Acquisition Interface Module

The Acquisition interface module is a user-friendly working interface that was designed and developed specifically for Kodak 9000 3D extraoral imaging system.

The Acquisition interface module has the following features:

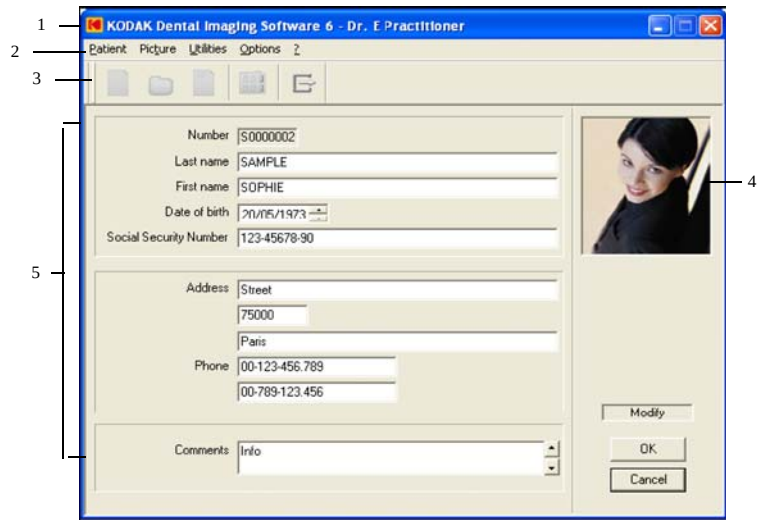
- Panoramic acquisition interface via **Panoramic Acquisition Window**
- 3D acquisition interface via **3D Acquisition Window**

Kodak Dental Imaging Software Overview

Patient Window Overview

The **Patient Window** is the first window that appears when you launch the Kodak dental imaging software. This window is the main patient record management interface that provides you with all the patient record functions.

Figure 3–1 Patient Window



1 Title Bar: Displays:

- Software name
- Software version
- Practitioner name

2 Menu Bar: Provides access to the following functions:

Menu	Submenu	Description
Patient	New	Creates a new patient record
	Find	Finds a patient file
	Modify	Modifies a patient record
	Delete	Deletes a patient file
	Imaging	Leads to the **Imaging window**

3 Toolbar: Provides quick access to the following menu functions:

	Exit	Exits the **Patient window** 
Picture	Insert picture	Inserts the patient picture
	Remove picture	Removes the patient picture
Utilities	Reindex	Regenerates all the index table
	Archival...	Archives images before the given date
Options	Preferences...	Configures the language and the database location
	Toolbar	Hides or shows the toolbar
?	Help topics	Displays the online contextual help
	About...	Lists the following information: • Software version • Copyright

4 Patient photograph if available.

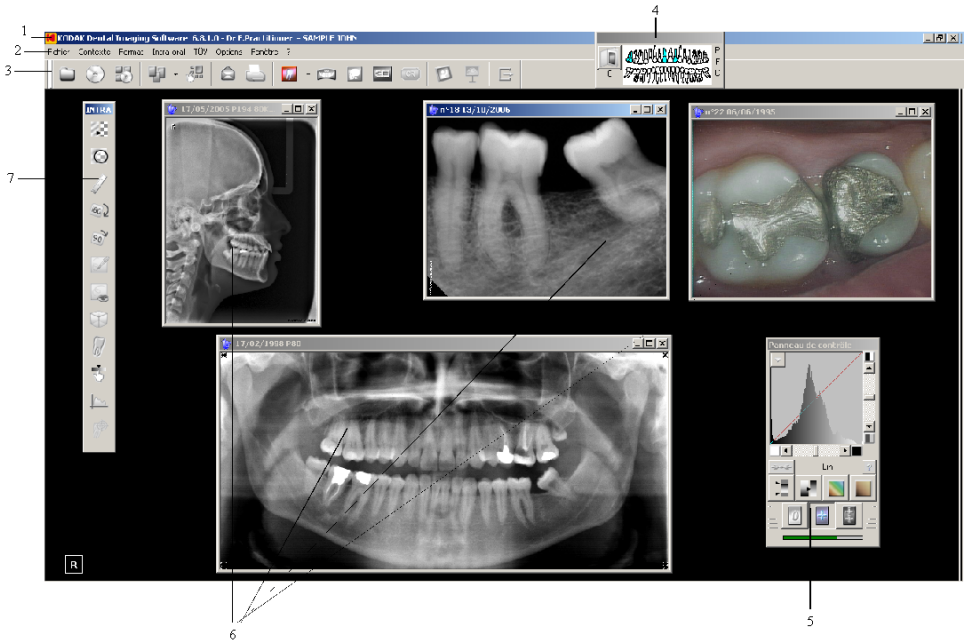
5 **Patient Record Pane:** Patient information that you must enter in each field.

NOTE
For information and procedures on how to use these functions, from the menu bar click **?** to access the online help.

Imaging Window Overview

The **Imaging Window** is the main imaging interface that provides you with the panoramic imaging functions.

Figure 3–2 Imaging Window



1 **Title Bar:** Displays:

- Software name
- Software version
- Practitioner name
- Patient name

2 **Menu Bar:** Provides access to the following functions:

3 Toolbar: Provides quick access to the following menu functions:

Menu	Submenu	Description
File	New panoramic image	Accesses the **Panoramic Acquisition Window** for a panoramic image
	New 3D image	Accesses the **3D Acquisition Window** for a 3D image
	History Open	Opens the patient history record with image files
	Save	Saves the acquired image
	Close	Closes the patient image

	Delete	Deletes selected image	
	Print	Prints the patient image	
	Print Setup	Sets up the printing parameters	
	Slide Show	Displays a set of images in a particular sequence	
	Report	Creates customized letters	
	Word Report	Creates a report template	
	Import image file	Imports images from a selected folder	
	Import digital camera	Imports images acquired with a digital camera	
	DICOMDIR	Imports/Exports DICOM images	
	TWAIN	Scans images	
	Copy	Copies selected image to clipboard	
	Paste	Pastes selected image	
	Send to	Sends the selected image either via e-mail or to a selected folder	
	Exit	Exits the Imaging Window	
Context	Save context	Saves the current images and screen display	
	Open context	Opens the saved images and screen display	
	Print context	Prints the selected images	
TUV	Panoramic certification	Creates one series of quality reference images at installation (by installer)	
	Panoramic constancy test	Generates monthly images to compare with reference images	
Options	Preferences	Customizes specific preferences, such as, interface and online help languages, practitioner name, image preferences and so on.	
	Advanced options	Enters acquisition location data information	
	Customized	Customizes contextual toolbars	

Window	Clear screen	Clears the screen
	Rearrange screen	Rearranges by default the displayed content of the screen
	Iconize all	Reduces images to icons
	Tools default position	Positions the imaging toolbar, control panel and dental arch in the default position
	Main toolbar	Displays the main toolbar if checked
?	Help topics... F1	Displays the online contextual help
	Tooltips	Displays, if checked, the name of the icon when the cursor points at it
	Install masking files	Installs the masking files in case the files were not installed initially
	License...	Displays License information
	About...	Displays Kodak dental imaging software version information

4 **Dental Arch Pane:** Displays the existing teeth images of the patient dental arch. To open different history types to access patient images:

- Click **P** for a display of all Panoramic images.
- Click **F** for a reduced history with the FMS displayed.
- Click **C** for a reduced history with the Cephalometric images displayed.
- Click  to access the Patient History dialog box.

5 **Control Panel:** Adjusts and enhances certain zones of the image for a clearer display.

6 **Image Windows:** Depending on the image type, the title bar displays different information.

7 **Contextual Toolbar:** The toolbar type depends on the image type context. You can reposition the toolbar.

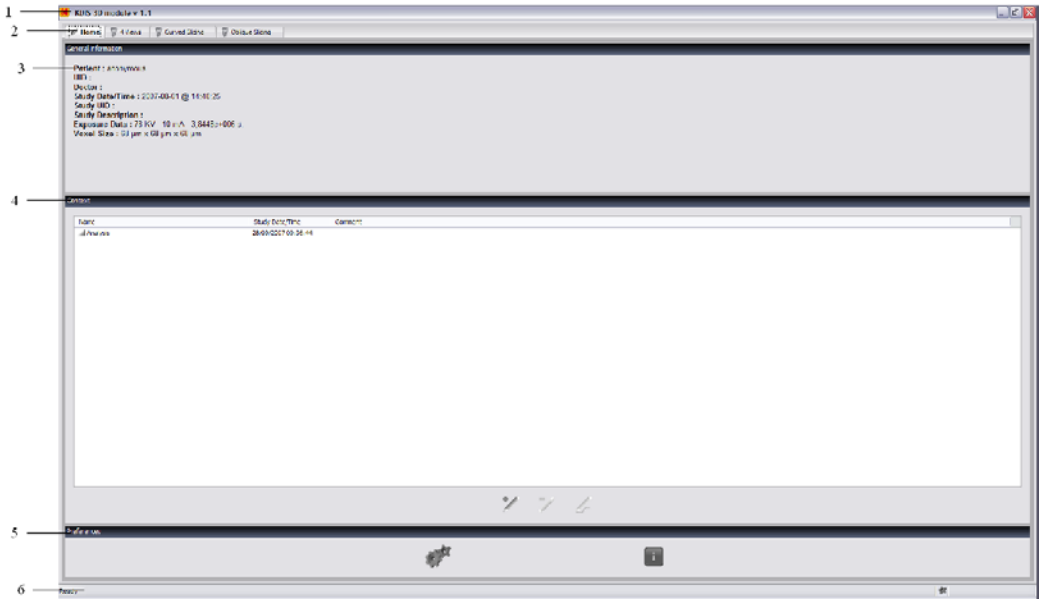
NOTE

For information and procedures on how to use these functions, from the menu bar click **?** to access the online help.

3D Imaging Windows Overview

The **3D Imaging Windows** are the main imaging interfaces that provide you with the 3D imaging functions.

Figure 3–3 3D Home Page Window



1 Title Bar: Displays Software name and version.

2 Window Tabs: Provide access to the indicated Windows.

3 General Information: Displays the 3D image acquisition information.

4 Context: Enables you to manage the patient 3D image analyses files.

- Click  to create a new analyses file.
- Click  to delete an analyses file.
- Click  to edit an analyses file.

5 Preferences: Enables you to configure your settings.

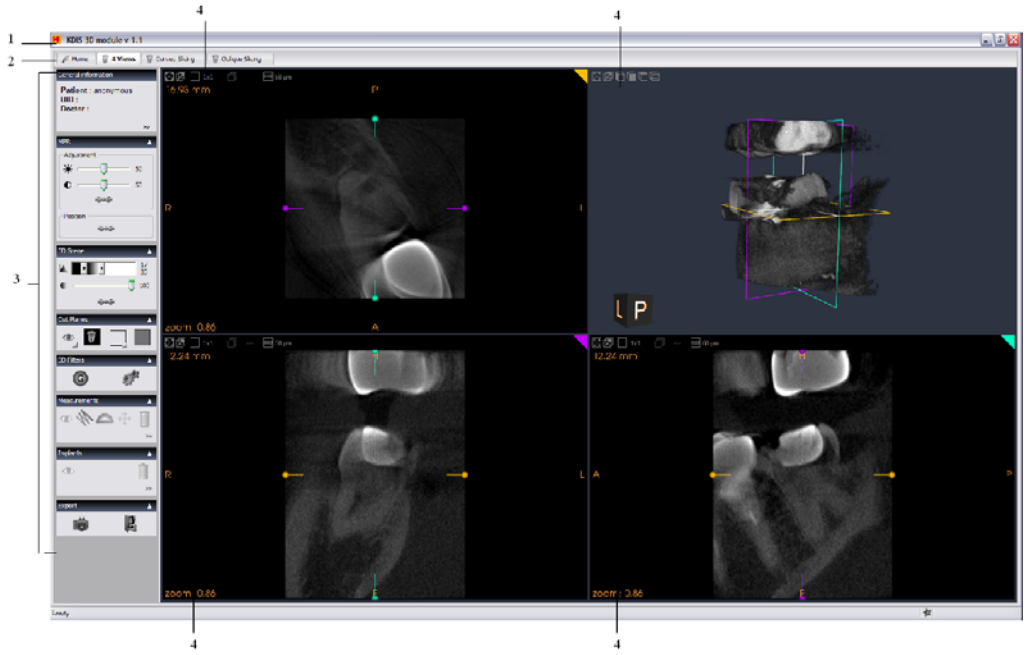
- Click  to configure the functional settings.
- Click  to display the software version information.

6 Status bar: Informs the user about the status of the 3D Windows.

- Click  to configure the functional settings.

To access the **4 View Window**, from the **Home Page** click the **4 View Window** tab.

Figure 3–4 4 View Window



1 **Title Bar:** Displays software name and version.

2 **Window Tabs:** Provides access to the indicated windows.

3 **Menu bar:** provides access to the following functions:

Menu	Submenu	Description
General Information		Displays the 3D image acquisition information
MPR (MultiPlanar Reformat)	Adjustment	Adjusts the slices contrast and brightness
	Position	Resets the cut planes position
3D Scene		Adjusts the 3D view
Cut Planes	Click  to show or hide the cut planes.	
	Click  to display the cut plane as images.	
	Click  to display the cut plane as wireframe.	
	Click  to display the cut plane as colored planes.	
3D Filters	Click  to apply the smooth filter.	
	Click  to configure the smooth filter settings.	

Measurements

Click  to show or hide measurements.

Click  to measure the length.

Click  to measure the angle.

Click  to edit the measurements.

Click  to delete the measurements.

Implant

Click  to show or hide all implants.

Click  to delete all implants.

Export

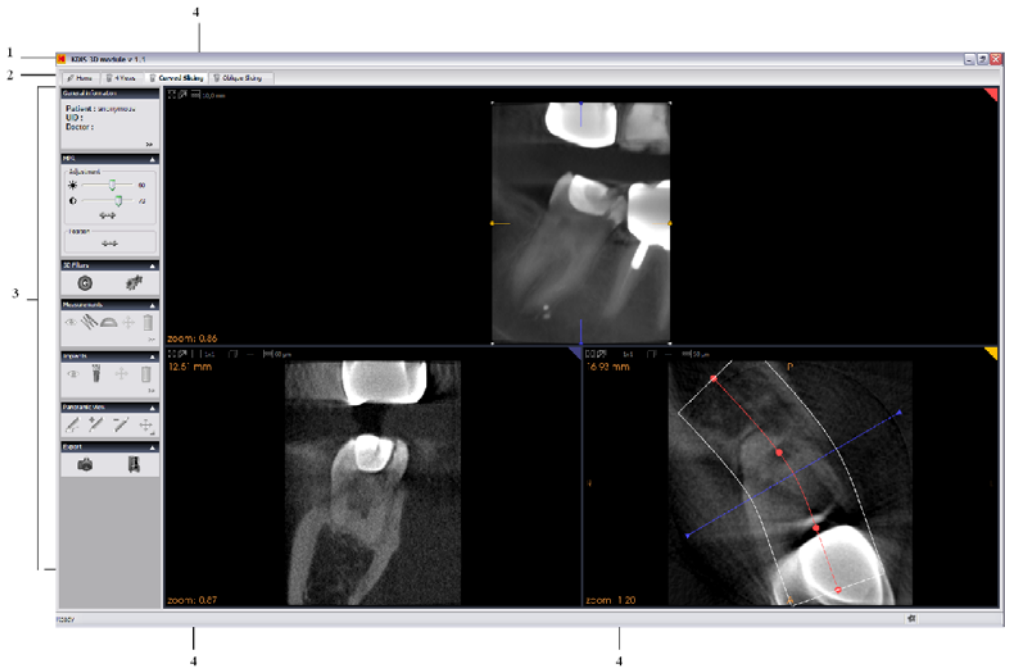
Click  to create a screen capture file.

Click  to access the screen capture file in the directory.

4 **Display options:** Display the specific screen in different formats.

To access the **Curved Slicing Window**, from the **Home Page** click the **Curved Slicing Window** tab.

Figure 3–5 Curved Slicing Window



1 **Title Bar:** Displays software name and version.

2 **Window Tabs:** Provides access to the indicated windows.

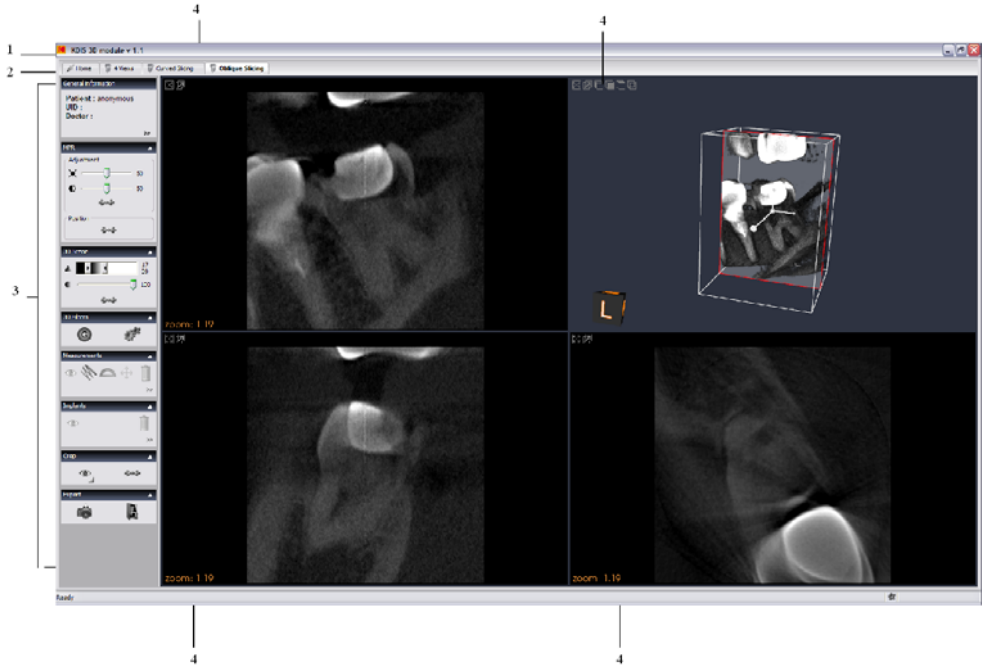
3 **Menu bar:** provides access to the following functions:

Menu	Submenu	Description
General Information		Displays the 3D image acquisition information.
MPR (MultiPlanar Reformat)	Adjustment	Adjusts the slices contrast and brightness.
	Position	Resets the cut planes position.
3D Filters		Click  to apply the smooth filter.
		Click  to configure the smooth filter settings.
Measurements		Click  to show or hide measurements.
		Click  to measure the length.
		Click  to measure the angle.
		Click  to edit the measurements.
		Click  to delete the measurements.
Implant		Click  to show or hide all implants.
		Click  to add an implant.
		Click  to edit all implants.
		Click  to delete all implants.
Panoramic View		Click  to create a curved line.
		Click  to add control points to the curved line.
		Click  to remove control points from the curved line.
		Click  to edit the curved line.
Export		Click  to create a screen capture file.
		Click  to access the screen capture file in the directory.

4 **Display options:** Display the specific screen in different formats.

To access the **Oblique Slicing Window**, from the **Home Page** click the **Oblique Slicing Window** tab.

Figure 3–6 Oblique Slicing Window



1 **Title Bar:** Displays software name and version.

2 **Window Tabs:** Provides access to the indicated windows.

3 **Menu bar:** Provides access to the following functions:

Menu	Submenu	Description
General Information		Displays the 3D image acquisition information.
MPR (MultiPlanar Reformat)	Adjustment	Adjusts the slices contrast and brightness.
	Position	Resets the cut planes position.
3D Scene		Adjusts the 3D view.
3D Filters	Click  to apply smooth filter.	
	Click  to configure the smooth filter settings.	
Measurements	Click  to show or hide measurements.	
	Click  to measure the length.	
	Click  to measure the angle.	

Click  to edit the measurements.

Click  to delete the measurements.

Implant

Click  to show or hide all implants.

Click  to delete all implants.

Crop

Click  to show or hide the crop tool.

Export

Click  to create a screen capture file.

Click  to access the screen capture file in the directory.

4 **Display options:** Display the specific screen in different formats.

NOTE

Click  to use the default value.

Acquisition Interface Module

Panoramic Acquisition Window Overview

The **Panoramic Acquisition Window** is the main panoramic interface with the Kodak 9000 3D extraoral imaging system that provides you with imaging acquisition functions.

Figure 3–7 Panoramic Acquisition Window

1 **Information button:** identifies:

- Unit serial number
- Software version
- The default parameters set by the manufacturer

2 **Preview Screen:** Displays the acquired image in real time.

3 **Selected Parameter Display:** Displays the current acquisition parameter settings.

4 **System Status Screen:** Displays various alert or warning messages originating from the Unit.

5 **X-Rays ON / OFF button:** Turns off the x-ray emissions to demonstrate the acquisition process for the patient.

6 **Generator Cooling indicator:** Indicates the automatic cooling time (mm:ss) required for the generator to reach 0 for a new acquisition.

7 **Stop button:** Stops the Unit rotative arm movement

8 **Ready Indicator LED**

- Green indicates the Unit is ready to start acquisition.
- Black indicates the Unit is not ready to start acquisition.

9 **Exit button:** Closes the Acquisition Window.

10 **X-Ray Emission indicator:** Yellow, it indicates the x-ray emission status.

11 **Selector Button:** Selects different acquisition setting options.

- Click **Program** to select examination type options.
- Click **Patient** to select patient type parameters.
- Click **Parameters** to select exposure parameter options.

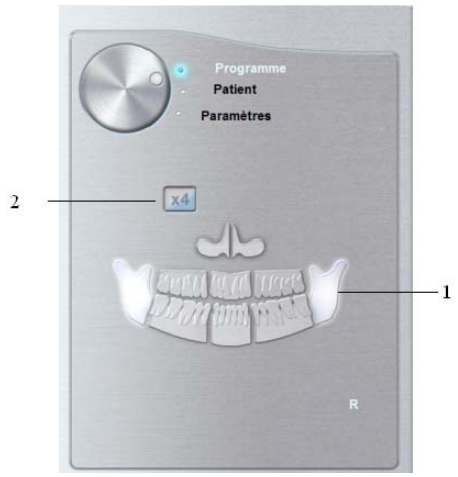
The **Selector button** enables you to access the following 3 panes:

- **Program pane:** Examination type options
- **Patient pane:** Patient type parameter options
- **Parameters pane:** Exposure parameter options

Panoramic Program Pane

The Panoramic **Program pane** enables you to choose different radiological exams. The diagram in the **Panoramic Program pane** represents a jaw, with the right side of the diagram corresponding to the right side of the patient. Click on a section of the jaw to select an anatomical zone for radiological exam. The selected segment is highlighted.

Figure 3–8 Panoramic Program Pane



1 Radiological exam options:

Click  for a Maxillary Sinus exam.

Click  for an anterior exam.

Click  for a Panoramic exam.

2 TMJ exam options:

Select  for a TMJ x2.

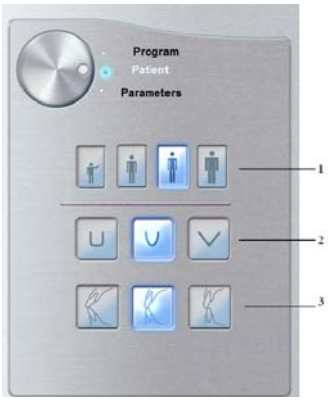
Select  for a TMJ x4 exam and click  .

NOTE
The above list of exam types are only a sample of exam options of the **Program pane**.

Panoramic Patient Pane

The Panoramic **Patient pane** enables you to choose different patient parameters. The selection of the patient parameters influences the quality of the image. The selected parameters must be based on the patient age and morphology.

Figure 3–9 Panoramic Patient Pane



1 Patient corpulence parameters:

Click  if the patient is a child.

Click  if the patient is small.

Click  if the patient is medium.

Click  if the patient is large.

2 Patient dental arch morphology:

Click  for a **square** dental arch.

Click  for a **normal** dental arch.

Click  for a **sharp** dental arch.

3 Incisors orientation:

Click  for a vestibular orientation.

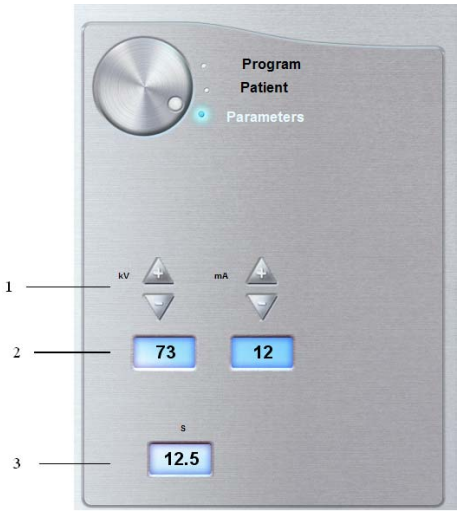
Click  for an axial orientation.

Click  for a lingual orientation.

Panoramic Parameter Pane

The Panoramic **Parameter pane** enables you to choose exposure parameters for the radiological image acquisition. You must adapt the parameter settings to the patient type.

Figure 3–10 Panoramic Parameter Pan



1 Fine-tuning buttons:

Click  to fine-tune the kV and click  to fine-tune the mA.

2 Radiation dose options:

 Kilovolt

 milliampere

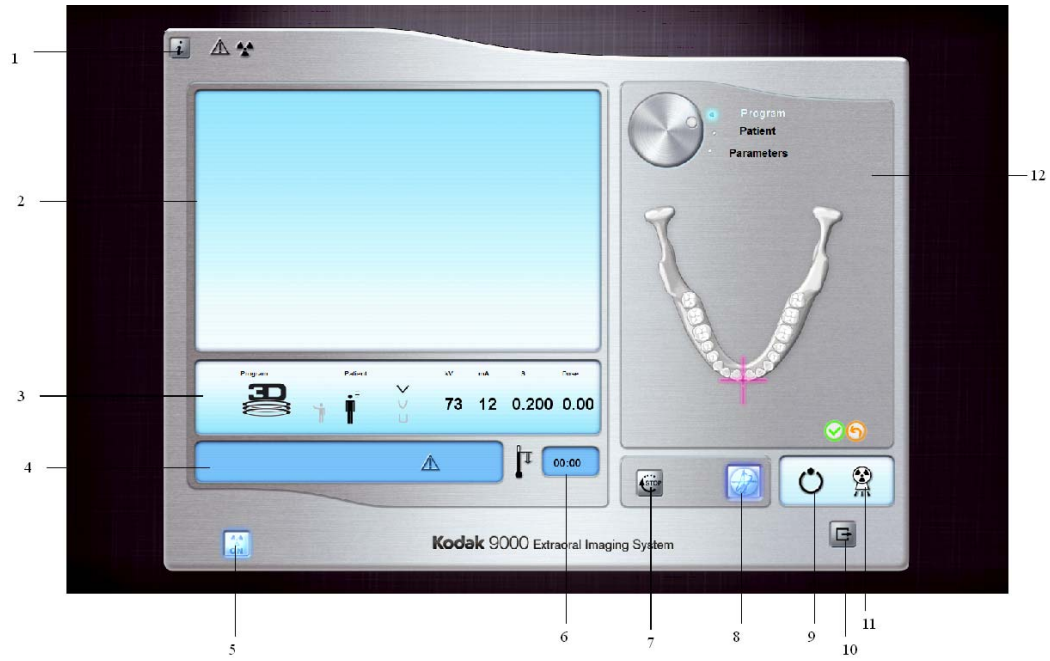
3 Exposure time:

 seconds

3D Acquisition Window Overview

The **3D Acquisition Window** is the main 3D interface with the Kodak 9000 3D extraoral imaging system that provides you with imaging acquisition functions.

Figure 3–11 3D Acquisition Window



1 **Information button:** identifies:

- Unit serial number
- Software version
- Default parameters set by the manufacturer

2 **Preview Screen:** Displays the acquired image in real time.

3 **Selected Parameter Display:** Displays the current acquisition parameter settings.

4 **System Status Screen:** Displays various alert or warning messages originating from the Unit.

5 **X-Rays ON / OFF button:** Turns off the x-ray emissions to demonstrate the acquisition process for the patient.

6 **Generator Cooling indicator:** Indicates the automatic cooling time (mm:ss) required for the generator to reach 0 for a new acquisition.

7 **Stop button:** Stops the Unit rotative arm movement.

8 **Pre-shoot button:** Pre-acquires test images for correct selection of region of interest.

9 **Ready Indicator LED:**

- Green indicates the Unit is ready to start acquisition
- Black indicates the Unit is not ready to start acquisition

10 **Exit button:** Closes the Acquisition Window.

11 **X-Ray Emission Indicator:** Yellow indicates the x-ray emission status.

12 **Selector button:** Selects different acquisition setting options.

- Click **Program** to select examination type options
- Click **Patient** to select patient type parameters
- Click **Parameters** to select exposure parameter options

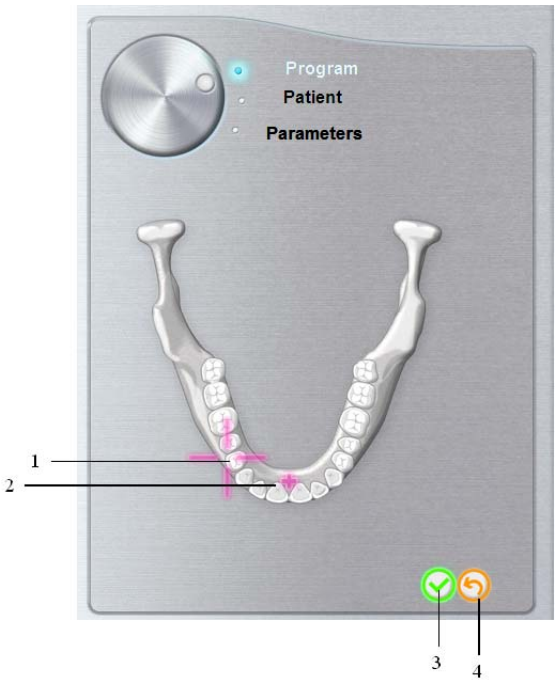
The **Selector button** enables you to access the following 3 panes:

- **Program pane:** Examination type options
- **Patient pane:** Patient type parameter options
- **Parameters pane:** Exposure parameter options

3D Program Pane

The 3D **Program pane** enables you to choose different radiological exams. The diagram in the **Program pane** represents the jaw.

Figure 3–12 3D Program Pane



1 **Manual Selection Indicator:** Enables you to select the region of interest manually.

2 **Rotative Arm Position Indicator:** Indicates the rotative arm position, using the 3D central positioning laser beam.

3 Click  to validate the region of interest selection.

4 Click  to cancel the region of interest selection.

3D Patient Pane

The 3D **Patient pane** enables you to choose different patient parameters. The selection of the patient parameters influences the quality of the image. The selected parameters must be based on the patient age and morphology.

Figure 3–13 Panoramic Patient Pane

1 Patient corpulence parameters:

Click  if the patient is a child.

Click  if the patient is small.

Click  if the patient is medium.

Click  if the patient is large.

2 Patient dental arch morphology:

Click  for a **square** dental arch.

Click  for a **normal** shape dental arch.

Click  for a **sharp** dental arch.

3 Incisors orientation:

Click  for a vestibular orientation.

Click  for an axial orientation.

Click  for a lingual orientation.

3D Parameter Pane

The 3D **Parameter pane** enables you to choose exposure parameters for the radiological image acquisition. You must adapt the parameter settings to the patient type.

Figure 3–14 3D Parameter Pane.

1 Fine-tuning buttons:

Click  to fine-tune the kV and click  to fine-tune the mA.

2 Radiation dose options:

 Kilovolt

 milliampere

Chapter 4
GETTING STARTED

Starting the Imaging Software

Before starting your imaging software, check that:

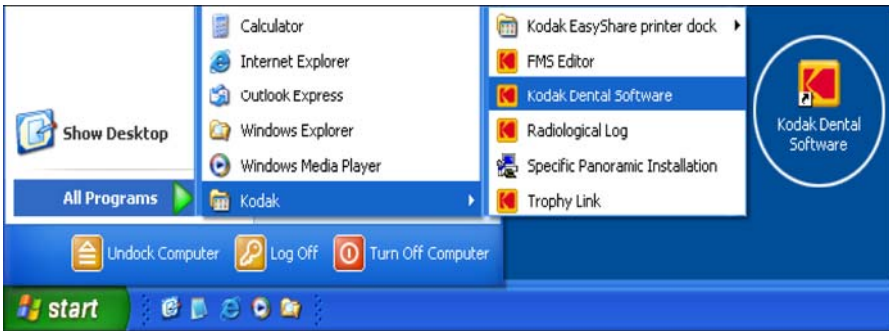
- All the connections between the Unit and the PC are properly connected.
- The PC is turned ON.

To start your imaging software, follow these steps:

1. On your desktop, double-click 

   OR

   From your PC, click **Start > All Programs > Kodak > Kodak Dental Software.**



Blank **Patient Window** is displayed.

2. Create or open an existing patient record.

Creating a Patient Record

To create a patient record, follow these steps:

1. In the **Patient Window,** from the toolbar, click 

   OR

   From the menu bar, select **Patient > New**.

2. Enter the required patient information. The **Last name**, the **First name** and the **Date of birth** fields are required.
3. From the menu bar, select **Picture > Insert Picture** to add a ***.tif** or ***.bmp** picture of the patient to the record. Select the picture from your directory and click **Open**.
4. Click **OK** to save. The patient record is automatically assigned a 7-digit number starting with a letter (for example, M0000001).
5. Click  to access the **Imaging Window**.
6. Select an image acquisition.

Accessing the Acquisition Windows

To access the **Acquisition Windows**, follow these steps:

1. In the **Imaging Window,** from the toolbar, click  to access the **Panoramic Acquisition Window**, or, click  to access the **3D Acquisition Window**.
2. Prepare the acquisition parameters and launch an acquisition.

Switching On the Unit

Before switching on the Unit, check that the installation of the Unit is complete.

To switch on the Unit, follow these steps:

1. On the Unit column, press the **ON** button. The name of the patient appears in the **Display Screen** of the **Control Panel.**

   IMPORTANT

   To increase the operating life of the x-ray tube, if the Unit has not been used for a month, you must follow these following procedures before use.

2. In the **Panoramic Acquisition Window**, select the **Parameter pane.**
3. Select the following parameter settings; then, for each setting, from the **Remote Control**, press and hold the button to launch the x-ray:

   - 70 kV - 6.3 mA
   - 80 kV - 10 mA
   - 85 kV - 10 mA

   The Unit is now ready to be used for acquisition.

Chapter 5
ACQUIRING IMAGES

Acquiring a Panoramic, TMJ x2 or Sinus Image

Before acquiring an image, check that you have:

- Reset the Unit rotative arm to start position for patient entry
- Selected the patient record
- Accessed the **Imaging Window**
- Accessed the **Panoramic Acquisition Window**

Preparing the Unit and Setting the Acquisition Parameters

To set the acquisition parameters, follow these steps:

1. In the **Panoramic Acquisition Window,** click the **Program** button to access the **Program pane**. Click on the section of the jaw to select the anatomical zone for the x-ray image, such as panoramic, TMJ x2 or sinus.

2. Click the **Patient** button to access the **Patient pane**.

   Select the patient:

   - Corpulence
   - Dental arch morphology
   - Incisors orientation

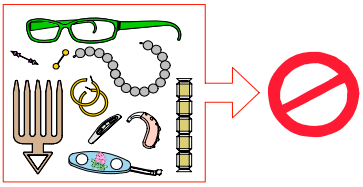
3. If needed, click the **Parameter** button to access the **Parameter pane** and select the appropriate parameters.

4. Position the appropriate chin rest on the chin rest support and cover the bite block with a hygienic barrier. If needed, use the edentulous bite block. Press and hold  to raise the chin rest to the maximum height.

Preparing and Positioning the Patient

To prepare and position the patient, follow these steps:

1. Ask the patient to remove all metal objects.



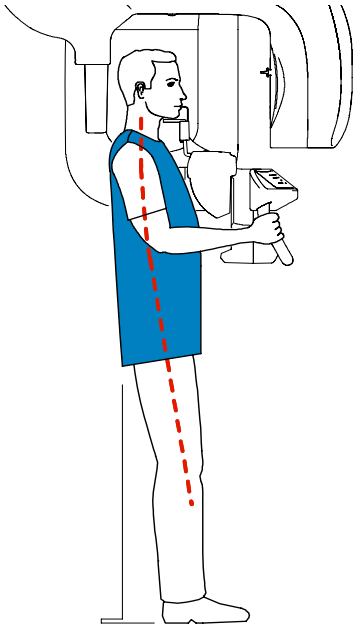
2. Ask the patient to wear a lead apron. Ensure that the apron lays flat across the patient shoulders.

3. Ask the patient to enter the Unit. On the **Control Panel**, press and hold  to adjust the Unit to the patient height.

> ***NOTE***
> If the patient is too tall, ask the patient to sit on a stool.

4. Ask the patient to do the following:

- Stand up straight.
- Grip the lower handle on each side.
- Rest the chin on the chin rest support and bite into the bite block.
- Position the feet slightly forward.
- Relax the shoulders for full motion of the Unit rotative arm.

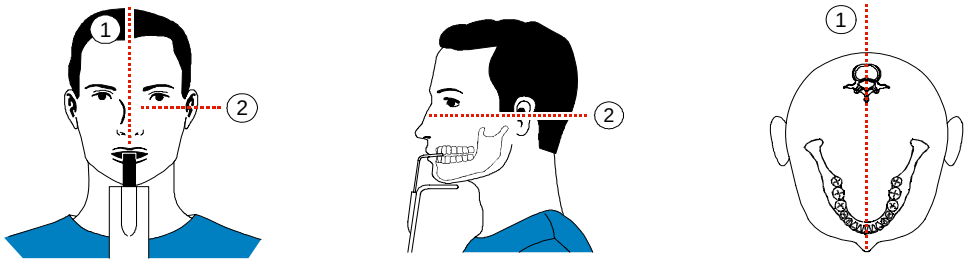


> ***NOTE***
> Correct posture reduces the shadow of the spinal column transferred to the image.

5. On the **Control Panel** click  to turn ON the positioning laser beams. Press and hold  to correctly position the patient using the 2 positioning laser beams:

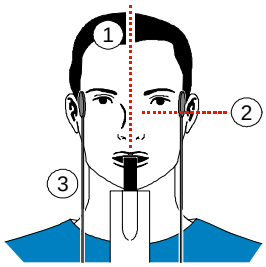
   - The mid-sagittal (1) positioning laser beam for a vertical alignment.
   - The horizontal (2) positioning laser beam for a Frankfurt plane alignment.

> ***NOTE***
> You can re-activate the laser positioning beams as needed. You can press the same button to turn OFF the laser beams, or wait 60 seconds for the beams to turn OFF automatically.

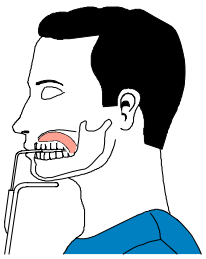


> ***IMPORTANT***
> **The spinal column and the nose of the patient must be aligned in a straight line (1).**

6. Immobilize the patient head with the temple supports (3).



7. Ask the patient to close the eyes, to remain still, to swallow, to place the tongue in contact with the palate and to breath through the nose.



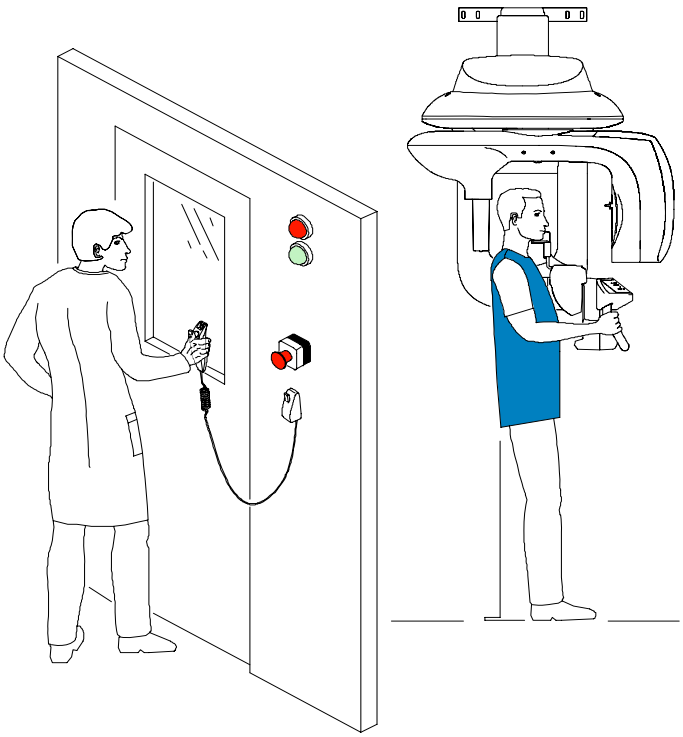
Launching the X-ray

To launch the x-ray, follow these steps:

1. Leave the x-ray room and close the door. You must keep eye contact with the patient during acquisition.

IMPORTANT

To stop the acquisition, if any problem, release the exposure button of the remote control or press the red emergency stop button.



2. Launch the x-ray with the remote control**.** Press and hold the exposure button until the end of acquisition. The  turns yellow indicating x-ray emission. The image appears on the **Preview Screen** of the **Panoramic Acquisition Window**. When the acquisition ends, the **Panoramic Acquisition Window** disappears and the acquired image is automatically transferred to the **Imaging Window**.
3. Check the image quality.
4. Do the following when the acquisition is finished:
   - Open the temple supports and release the patient.
   - Remove the hygiene barrier of the bite block.
   - Reset the Unit rotative arm for the next acquisition.

Acquiring a TMJ x4 Image

Before acquiring a TMJ x4 image, check that you have:

- Reset the Unit rotative arm to start position for patient entry
- Selected the patient record
- Accessed the **Imaging Window**
- Accessed the **Panoramic Acquisition Window**

To acquire a TMJ x4 image, follow these steps:

1. From the **Panoramic Acquisition Window**, in the **Program pane**, select the TMJ and click 

.

2. Remove  , place  on the chin rest support and cover it with a hygienic barrier.

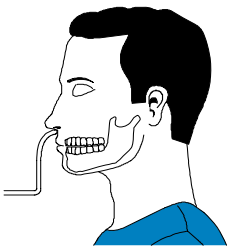
3. Press and hold  to raise the chin rest to the maximum height.

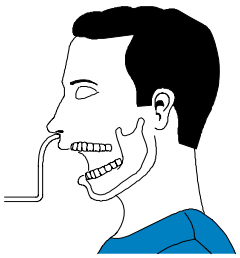
4. Correctly position the patient using the 2 positioning laser beams.

5. Ask the patient to remain still and close the eyes. Acquire an image with the mouth closed.

6. To acquire an image with open mouth, on the **Control Panel** click  to reset the Unit rotative arm.

7. Ask the patient to stay in the same position and open the mouth. Acquire an image with the mouth open.





8. Do the following when the acquisition is finished:

   - Open the temple supports and release the patient.
   - Remove the hygiene barrier of the bite block.
   - Reset the Unit rotative arm for the next acquisition.

Acquiring a 3D Image

Before acquiring a 3D image, check that you have:

- Reset the Unit rotative arm in start position for patient entry
- Selected the patient record
- Accessed the **Imaging Window**
- Accessed the **3D Acquisition Window**

Preparing the Unit and Setting the Acquisition Parameters

To set the acquisition parameters, follow these steps:

1. In the **3D Acquisition Window,** click the **Program** button to access the **Program pane**.

   Select the region of interest and click  to validate the selection, or click  to cancel the modifications.

2. Click the **Patient** button to access the **Patient pane**.

   Select the patient:

   - Corpulence
   - Dental arch morphology (optional)
   - Incisors orientation (optional)

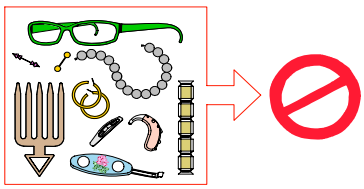
3. Click the **Parameter** button to access the **Parameter pane**. Select the appropriate parameters.

4. Position the 3D head rest and 3D standard bite block and cover the bite block with a hygienic barrier.

Preparing and Positioning the Patient

To prepare and position the patient, follow these steps:

1. Ask the patient to remove all metal objects.



2. Ask the patient to wear a lead apron. Ensure that the apron lays flat across the patient shoulders.

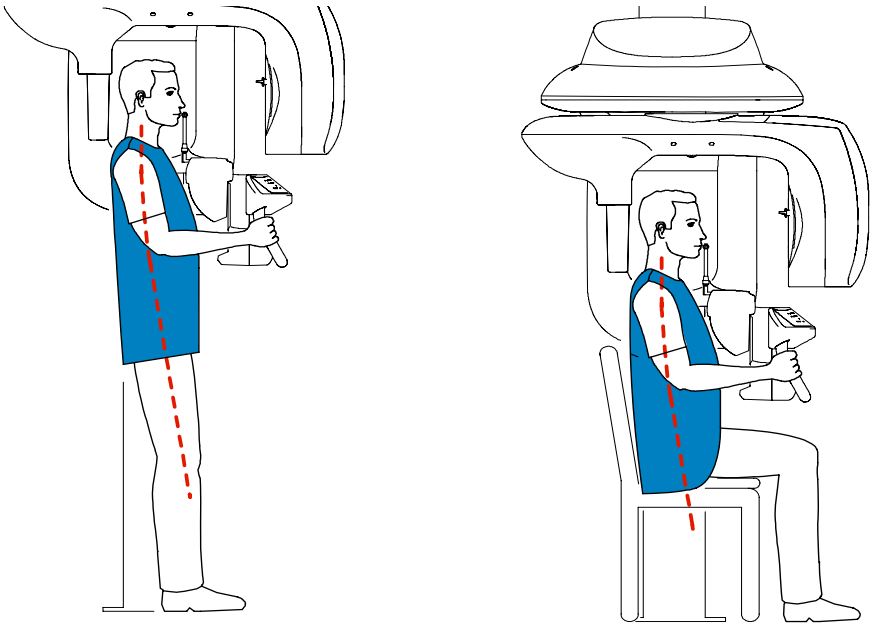
3. Ask the patient to enter the Unit. On the **Control Panel**, press and hold  to adjust the Unit to the patient height.

4. Ask the patient to do the following:

   - Stand up straight or sit on a stool.
   - Grip the lower handle on each side.
   - Position the feet slightly forward.
   - Relax the shoulders for full motion of the Unit rotating Arm.

   NOTE
   If the patient is too tall, ask the patient to sit on a stool.

:



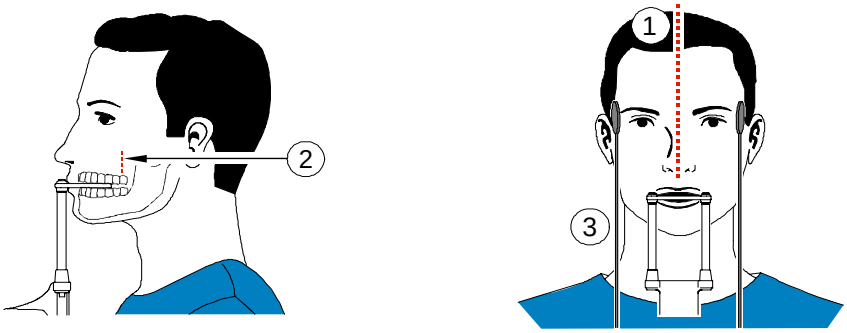
5. Position the patient head in the 3D head support.

   - Ask the patient to open the mouth.
   - Ask the patient to bite gently and naturally into the bite block without joining the incisors.
   - Center the upper incisors with the bite block.

6. Click  on the **Control Panel** to turn ON the positioning laser beams. Adjust the patient using the following 2 positioning laser beams:

   - The mid-sagittal (1) positioning laser beam
   - The 3D FoV (2) positioning laser beam

> ***NOTE***
> You can re-activate the laser positioning beams as needed. You can press the same button to turn OFF the laser beams, or wait 60 seconds for the beams to turn OFF automatically.



7. Press and hold  to align the upper or lower jaw with the 3D FoV (2) positioning laser beam. Tighten the temple supports (3).

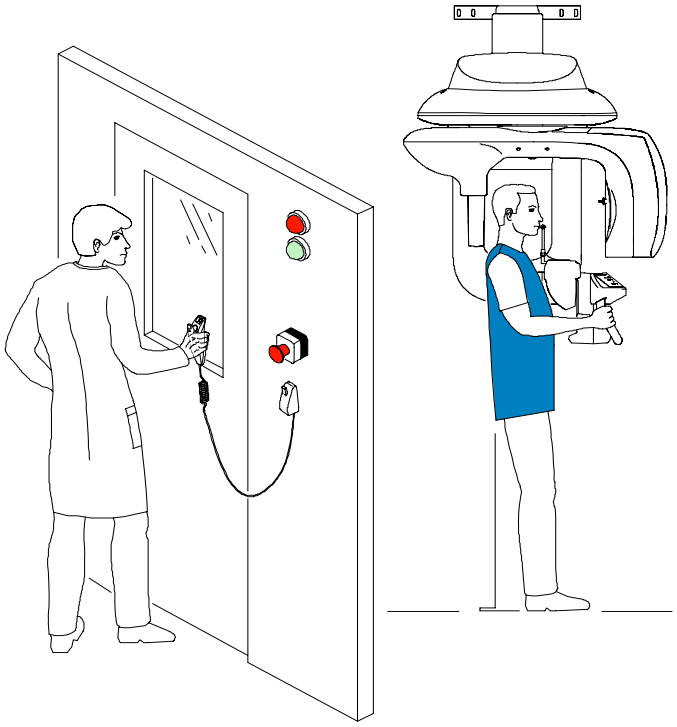
8. Ask the patient to close the eyes, to remains still and to breath through the nose.

Launching the x-ray

To launch the x-ray, follow these steps:

1. Leave the x-ray room and close the door. You must keep eye contact with the patient during acquisition.

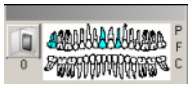
IMPORTANT
To stop the acquisition, if any problem, release the exposure button of the remote control or press the red emergency stop button.



2. Trigger the x-ray with the remote control**.** Press and hold the exposure button until the end of acquisition. The  turns yellow indicating x-ray emission. The image appears in the **Preview Screen**. When the acquisition ends, the **3D Acquisition Window** disappears.

3. Open the 3D head support and release the patient while waiting for the 3D image reconstruction. Remove the hygiene barrier of the bite block.

4. Wait for the 3D image reconstruction. Open the **Imaging Window** and

in the  pane, click  to access the patient record and open the acquired 3D image.

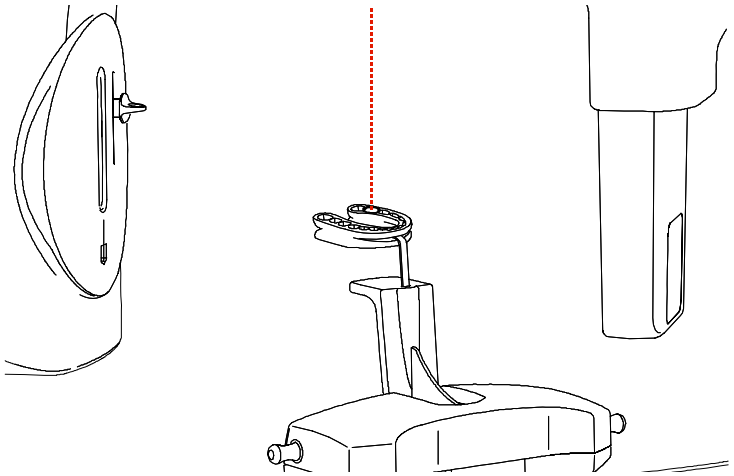
Manually Pre-Setting the Patient Positioning

> ***TIP***
> You can pre-set the acquisition parameters of the region of interest manually using dental plaster imprint.

To pre-set the acquisition parameters, follow these steps:

1. Select the appropriate settings in:
   - The **Program pane**
   - The **Patient pane**
   - The **Parameter pane** if needed
2. To pre-set the patient positioning, ask the patient to bite into a plate of dental plaster and wait for the plaster imprint to harden.
3. Place the dental imprint on the bite block location. Press and hold  to align the Unit rotative arm to the region of interest using the 3D central positioning laser beam.

   Press  to save the manually selected parameter settings of the Unit rotative arm.



4. Remove the plaster imprint and position the patient in the Unit and follow the appropriate steps to acquire the 3D image of the region of interest.

Chapter 6
MAINTENANCE

This section describes the maintenance tasks that you need to perform regularly for your KODAK 9000 3D Unit and the accessories.

WARNING

Switch off the Unit, then, clean all accessible parts of the machine with an alcohol-based non-corrosive product. Avoid using liquids inside the Unit. Follow the alcohol-based product manufacturer recommendations for safety precautions.

CAUTION

You can use the usual disinfectant products, but we recommend that you protect the Unit from contamination by using barriers available from dental distributors. Follow the disinfectant product manufacturer recommendations for safety precautions.

Daily

Carry out the following maintenance tasks:

Table 6–1 Daily Maintenance Tasks

Accessories	Maintenance Tasks
3D and Panoramic bite block	Sterilize with cold sterilization or autoclave up to 134°C before the next patient is x-rayed.
Edentulous bite block	Sterilize with cold sterilization or autoclave up to 134°C before the next patient is x-rayed.
Temple support	Sterilize the head support and chin rest with medical-grade 76% alcohol disinfectant before the next patient is x-rayed.
Chin rest (panoramic, sinus and TMJ)	
All components that come into contact with the patient and the operator	Sterilize all components with medical-grade 76% alcohol disinfectant before the next patient is x-rayed.
Outer covers of the Unit	Wipe the Unit with a dry cloth at the end of each day's operation.  ***WARNING*** **Do not use detergents or solvents to clean the outer covers of the Unit.**

Monthly

Wipe the outer covers of the unit with a soft, dry cloth.

Annually

We recommend a general inspection of the Unit carried out by an authorized service technician.

Chapter 7
TECHNICAL SPECIFICATIONS

Compliance with International Standards

The KODAK 9000 3D digital imaging Unit is compliant with the International and EEC standards.

Manufacturer

TROPHY

A subsidiary of Carestream Health, Inc.

4, Rue F. Pelloutier, Croissy-Beaubourg

77435 Marne la Vallée Cedex 2, France

Model

KODAK 9000 3D Unit, KODAK 9000 Unit.

Compliance with International Regulations

- Medical Device directives 93/42/ European Economic Community (EEC), Class II b
- ElectroMagnetic Compatibility (EMC) directive 89/336/EEC

Compliance with International Standards

- International Electrotechnical Commission (IEC) 60601-1 Class I Type B
- IEC 60601-1-2, Group I, Class B +12db
- IEC 60601-1-3
- IEC 60601-2-7
- IEC 60601-1-28

Ambient Operating Conditions

- **Temperatures:** 5 ~35 °C
- **Relative humidity:** 30 ~ 85%
- **Atmospheric pressure:** 700 ~ 1060 hpa

Storage Conditions

- **Temperatures:** -10 ~ 60 °C
- **Relative humidity:** 10 ~ 95%
- **Atmospheric pressure:** 700 ~ 1060 hpa

Transport Conditions

- **Temperatures:** -10 ~ 60 °C
- **Relative humidity:** 10 ~ 95%
- **Atmospheric pressure:** 700 ~ 1060 hpa

Unit Technical Specifications

Table 8-1 describes the technical specifications for the KODAK 9000 3D digital imaging unit and Kodak 9000 digital imaging unit.

Table 7–1 Unit Technical Specification

	Kodak 9000 3D	Kodak 9000
X-Ray Generator		
Tube voltage	60 - 90 kV (max), pulsed mode for 3D modality	
Tube current	2 - 15 mA (max)	
Frequency	140 kHz (max)	
Tube focal spot	0.5 mm (IEC 60336)	
Total filtration	> 2.5 mm eq. Al	
3D Modality		
Technology	Digital Volumetric Tomography (DVT)	NA
Sensor technology	• CMOS • Optical fiber sensor with Csi coating	NA
Gray scale	16384 - 14 bits	NA
Volume size	50 x 37 mm	NA
Voxel size	76.5 x 76.5 x 76.5 µm	NA
Reconstruction time	Depends on the PC	NA
X-ray pulse time	30 ms	
Panoramic Modality		
Sensor technology	• CCD • Optical fiber sensor with Csi coating	
Sensor matrix	61 x 1244 pixels	
Image field	6.3 x 129.4 mm	
Gray scale	16384 - 14 bits	
Magnification	1.27	
Exposure time	• Adult panoramic 13.9 sec. • Pediatric panoramic 13.2 sec.	
Programs	12 anatomical settings	
Radiological exam options	• Panoramic • Segmented panoramic • Maxillary sinus • LA TMJ x2 • LA TMJ x4	

Table 7–1 Unit Technical Specification

	Kodak 9000 3D	Kodak 9000
Input voltage	• 230 / 240 V - 50/60 Hz • 100/110/130 V - 50/60 Hz	
Unit dimensions	1158mm (L) x 1595mm (D) x 2378mm (H)* * Unit with shorter column is available on special order	
Required space	1500 (L) x 2000 (D) x 2400 (H) mm	
Weight	160 kg (353 lb)	

Unit Electronic Specifications

Type of Electrical Power Supply	230/240 V (± 10%) 50/60 Hz, Single-Phase	100/110/130V (± 10%) 50/60 Hz, Single-Phase
Acceptable fluctuation	± 10%	± 10%
Apparent resistance of the power supply circuit	0.5 Ω (max.)	0.12 Ω (max.)
Permanent absorbed current	0.45 A	0.9 A
Current absorbed during the x-ray emission	9.5 A	22 A
Maximum absorbed power	2.2 kVA	2.2 kVA
Protection for the power supply system	By shutter release at a maximum current of 16A and a differential current of 30 mA	By shutter release at a maximum current of 20A and a differential current of 30 mA
Nominal high voltage	90 kV	90 kV
Maximum corresponding tube current	10 mA	10 mA
Nominal tube current	15 mA	15 mA
Maximum corresponding high voltage	80 kV	68 kV
Tube current/voltage combination for maximum output power	80 kV, 15 mA	85 kV, 12 mA
Nominal power for an exposure time of 0.1 s.	at 80 kV, 15 mA: 1200 W	at 85 kV, 12 mA: 1020 W

Utilization Rate in Continuous Mode (for example: one exposure - 85 kV, 5 mA - 13.9 second, every 3 minutes)	Utilization Rate in Intermittent Mode (for example: one exposure - 80 kV, 15 mA - 13.9 second, every 3 minutes)
33 W	93 W

Selection of the Load Parameters:	
kV (in increments of 1 kV)	From 60 to 90 kV
mA (in increments of 25%)	From 2 to 15 mA

Cooling Conditions	
Maximum dissipation of heat from the x-ray radiogenic assembly into the ambient air (for utilization rate in continuous mode)	33 W

Accuracy of the Load Parameters	
High voltage	kV ± 10%
Current in the tube	mA ± 20%
Exposure time seconds	Seconds ± (10% + 1ms)

Measurement Conditions	
kV	Indirect on the peak kilovolt meter
mA	Direct measurement in the circuit using an oscilloscope
Exposure time	Measurement at 75% of the kV values with peak kilovolt meter

X-Ray Generator Technical Specifications

Table 7–2 Filtration of the Material in the X-ray Field

Standard	Compliance
IEC 60601.1.3	Compliant
Nominal value of the inherent filtration at 70 kV	2.5 mm (0.10") eq. Al
Nominal value of the supplementary filtration at 70 kV	NA
Nominal value of the total filtration at 70 kV	2.5 mm (0.10") eq. Al
Filtration value for the enclosure of the x-ray tube (at 100 kV)	0.2 mm (0.008")
Filtration value for the enclosure of the image receiver unit (at 100 kV)	0.2 mm (0.008")
Filtration value for the sensor case	0.8 mm (0.031") eq. Al

The x-ray generator comprises the following:

- A transformer and an x-ray tube and their associated electronic components immersed in oil
- An aluminum filter, which enhances the quality of the beam and reduces the dose received by the patient
- A lead collimator, which limits the size of the beam at the image receiver unit
- A thermal cutout, which trips at an operating temperature between 63 to 70° C (± 5° C)

Table 7–3 Technical Specifications of the X-ray Generator

Standard	Compliance
IEC Standard 60601.2.28	Compliant
Manufacturer	Trophy
Degree of protection against electric shock	Class I
Degree of patient protection from the parts applied to the leakage current	Type B
Maximum accumulated heat	110 kJ
Maximum continuous heat dissipation	33 W
Tolerances on the position of the focal spot	+/- 2.5mm
Radiation leakage after one hour's operation (maximum utilization rate of 93W, i.e. 90 kV, 10 mA, 13.9 sec. every 2 minutes 15 sec.)	< 1 mGy
Weight	8.2 kg
Dimensions	235 x 245 x 120 mm

Figure 7–1 Heating and Cooling Curves of the X-ray Generator.

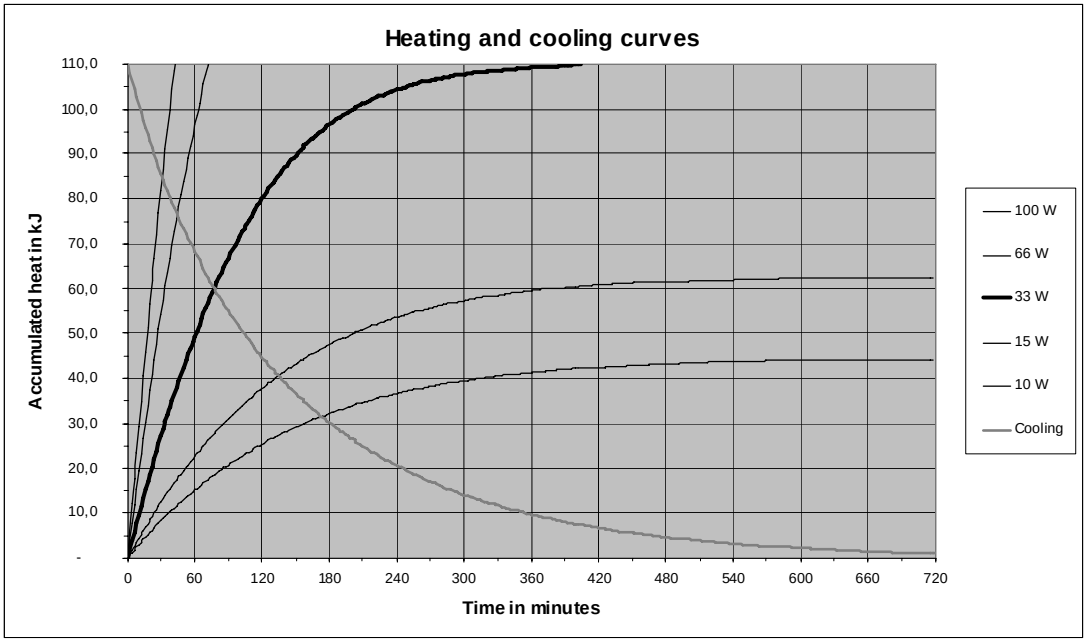


Table 7–4 Beam Limitations of the X-ray Generator

Manufacturer	Trophy
Type	Rigidly mounted unit with fixed window dimensions, not removable, and integrated x-ray generator
Maximum symmetrical field of radiation at a distance of 613 mm from the focal point (Panoramic mode)	4 (-0.5/+1) x 128 (± 2) mm
Maximum symmetrical field of radiation at a distance of 690 mm from the focal point (3D mode)	47 (± 1) x 59 (± 1) mm

Table 7–5 Characteristics of the X-ray Tube

Manufacturer's name	CEI
Type	OPX 105
Nominal high voltage	90 kV
Nominal anode power	810 W
Maximum amount of heat accumulated in the anode	30 kJ
Nominal focal spot diameter (IEC 60336)	0.5 mm (0.020")
Anode materials	Tungsten
Target angle	5°
Inherent filtration	0.5 mm (0.20 ") eq. Al

Figure 7–2 Heating and Cooling Curves of the X-ray Tube

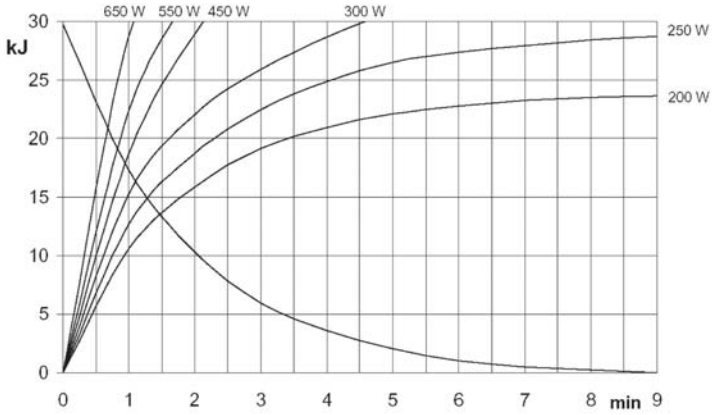


Figure 7–3 Single Load Chart of the X-ray Tube

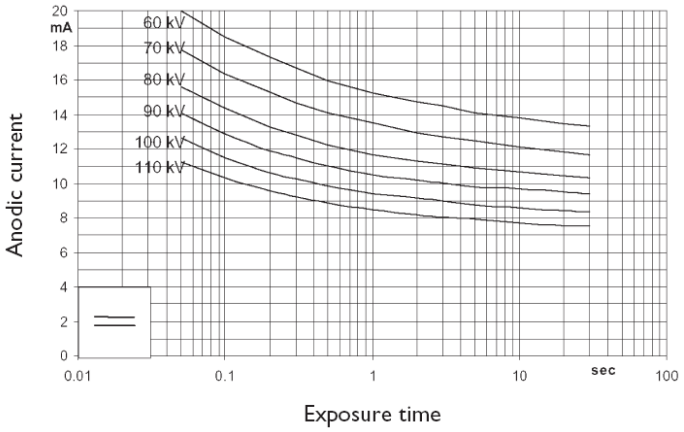


Figure 7–4 Filament Emissions of the X-ray Tube