KODAK 9000C AND KODAK 9000C 3D Extraoral Imaging System

User Guide

Notice

Congratulations on your purchase of the KODAK 9000C and KODAK 9000C 3D 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 9000C and KODAK 9000C 3D Extraoral Imaging System includes information on the cephalometric features. For the panoramic or the 3D features, see the KODAK 9000 and KODAK 9000 3D Extraoral Imaging System (SM710) User Guide. 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.

No part of this Guide may be reproduced without the express permission of Carestream Health, Inc.

The US Federal law restricts this device to sale by or on the order of a physician.

This document is originally written in English.

Manual Name: KODAK 9000C and KODAK 9000C 3D Extraoral Imaging System User Guide Part Number: SM713 Revision Number: 01 Print Date: 04/2008

The brand names and logos reproduced in this Guide are copyright. KODAK is a trademark of KODAK used under License. KODAK 9000C and KODAK 9000C 3D Extraoral Imaging System, complies with Directive 93/42/CEE relating to medical equipment.



Contents

1—About This Guide

Conventions in this Guide	. 1–1
Note to the User	. 1–2
Warning and Safety Instructions	. 1–2
Marking and Labeling Symbols	. 1–4

2—KODAK 9000C AND KODAK 9000C 3D UNIT OVERVIEW

General Overview	2–1
Mobile Components	2-2
General Functional Components	2–3
Digital Sensor Locations	2–4
Laser Locations	2–5
Label Locations	!-6
Control Panel Overview	2–7
X-Ray Remote Control Overview	2-8
Positioning Accessories and Replacement Parts	2–9

3—IMAGING SOFTWARE OVERVIEW

PC System Requirements	3–1
General Software Overview	
KODAK Dental Imaging Software	3–2
Cephalometric Acquisition Interface Module	3–2
Cephalometric Acquisition Interface Module	3–3
Cephalometric Acquisition Window Overview	3–3
Cephalometric Program Pane.	3–5
Cephalometric Patient Pane	
Cephalometric Parameter Pane	3–7

4—GETTING STARTED

Switching On the Unit	4–1
Starting the Imaging Software	4–2
Creating a Patient Record	4–2
Accessing the Cephalometric Acquisition Window	4–3

5—ACQUIRING CEPHALOMETRIC IMAGES

Acquiring a Lateral Image.	. 5–1
Preparing the Unit and Setting the Acquisition Parameters	. 5–1
Preparing and Positioning the Patient.	. 5–2
Acquiring a Frontal AP or PA Image	. 5–5
Preparing the Unit and Setting the Acquisition Parameters	. 5–5
Preparing and Positioning the Patient.	. 5–6
Acquiring an Oblique Image	.5–9

Preparing the Unit and Setting the Acquisition Parameters	
Preparing and Positioning the Patient	
Acquiring a Submento-Vertex Image	
Preparing the Unit and Setting the Acquisition Parameters	
Preparing and Positioning the Patient	
Acquiring a Carpus Image	
Preparing the Unit and Setting the Acquisition Parameters	
Preparing and Positioning the Patient	
X-Ray Dose Emission Information	

6-MAINTENANCE

Daily		 	 	 •	 • •	• •	 •••	 	•••	• •	•••	 	 • •	 • •	• •	• •	 	•••	 • • •	 	 	 	 • •	 	• •	 	 6–1
Monthly	·	 	 	 •	 		 •••	 				 	 	 			 		 • • •	 	 	 	 	 		 	 6–1
Annually	у	 	 	 •	 		 •••	 				 	 	 			 		 • • •	 	 	 	 	 		 	 6–1

7—TROUBLESHOOTING

Troubleshooting

8—TECHNICAL SPECIFICATIONS

Compliance with International Standards	
Manufactured by:	
Compliance with International Regulations	
Compliance with European and International Standards	
Classification in Accordance with EN/IEC 60601-1	
Classification in Accordance with EN/IEC 60601-1-2	
Ambient Operating Conditions	
Storage Conditions	
Transport Conditions	
Cephalometric Unit Technical Specifications	
Unit Electronic Specifications	
X-Ray Generator Technical Specifications	

Chapter 1 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 9000C and KODAK 9000C 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. They MUST have training to use the radiological equipment. 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.
- DO NOT hang from the cephalostat.

Marking and Labeling Symbols

Ŕ	Type B device symbol complying with the IEC 60601-1 standard
X	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.
LASER RADIATION DO NOT STARE INTO BEAM CLASS 2 LASER PRODUCT Maximuliaer output InW,660m IEC60825-1:1993+A1:1997+A2:2001	Class 2 laser product. Maximum output power: 1mW, 650 nm (IEC 60825-1 standard) This unit emits laser radiation.

Chapter 2 KODAK 9000C AND KODAK 9000C 3D UNIT OVERVIEW

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

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

- Lateral
- Frontal (PA or AP)
- Oblique
- Submento-vertex
- Carpus

General Overview

The KODAK 9000C unit is composed of the following functional components:

- The rotative arm
- The fixed arm with a control panel
- The panoramic digital sensor
- The x-ray source assembly
- The x-ray remote control
- The chin rest base
- The panoramic chin rest and bite block
- The temple supports
- The hand grips
- The cephalostat arm
- The cephalostat head
- The head clamps and ear cones
- The nasion support
- The acquisition software (see "Imaging Software Overview")

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

- The rotative arm
- The fixed arm with a control panel
- The panoramic digital sensor
- The 3D digital sensor

- The x-ray source assembly
- The x-ray remote control
- The chin rest base
- The panoramic chin rest and bite block
- The 3D chin rest and bite block
- The temple supports
- The hand grips
- The cephalostat arm
- The cephalostat head
- The head clamps and ear cones
- The nasion support
- The acquisition software (see "Imaging Software Overview")

The following figures illustrate the general overview of the KODAK 9000C and KODAK 9000C 3D unit.

Mobile Components

Figure 2-1 illustrates the up and down movement of the KODAK 9000C and KODAK 9000C 3D mobile component and the 180° rotation of the rotative arm.

Figure 2–1 KODAK 9000C and KODAK 9000C 3D Unit Mobile Components



General Functional Components

Figure 2-2 illustrates the general functional components of the KODAK 9000C and KODAK 9000C 3D.

Figure 2–2 KODAK 9000C and KODAK 9000C 3D Unit Functional Components



- 1 ON/OFF button
- 2 Unit fixed arm
- 3 Control panel
- 4 Hand Grips
- 5 Chin rest base
- 5 a Panoramic chin rest
- **5 b** 3D chin rest and bite block
- 6 Temple supports

- 7 Sensor
- **8** X-ray source assembly
- 9 Unit rotative arm
- 10 X-Ray remote control
- 11 Chephalostat arm
- 12 Cephalostat head
- 13 Head clamps and ear cones
- 14 Nasion support
- 15 PC hosting the imaging and the acquisition software

Digital Sensor Locations

Figure 2-3 illustrates the locations of the panoramic, 3D and cephalometric digital sensors of the KODAK 9000C and KODAK 9000C 3D.

IMPORTANT

* When the unit is ONLY panoramic, the 3D option is not available. Therefore, the location of the digital sensor indicates that it is ready for the 3D option.

Figure 2–3 KODAK 9000C and KODAK 9000C 3D Unit Panoramic, 3D and Cephalometric Digital Sensor Locations



Laser Locations

Figure 2-4 illustrates the location of the lasers of the KODAK 9000C and KODAK 9000C 3D.



Figure 2–4 KODAK 9000C and KODAK 9000C 3D Unit Laser Positions

- 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
- 5 Cephalometric Frankfurt positioning laser beam

Label Locations

Figure 2-5 illustrates the location of all the labels of the KODAK 9000C and KODAK 9000C 3D. The label locations of the KODAK 9000C are represented with *.

IMPORTANT The labels presented are ONLY for the KODAK 9000C 3D option. The "*Panoramic" presents the labels and their locations for the KODAK 9000C.

Figure 2–5 KODAK 9000C and KODAK 9000C 3D Unit Label Locations



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.





- **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 rotative 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:** Positions the unit rotative arm at the selected or memorized 3D position.
- 6 **Reset button:** Resets the unit arm to the initial position to enable the patient to enter and exit the Unit.
- **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 the x-rays are being emitted.
- 11 System Status LED: Red, indicates the 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 2–7 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 9000C and KODAK 9000C 3D digital imaging unit.

 Table 2–1
 Cephalometric Positioning Accessories and Replacement Parts

Accessory	Description							
×2	Head clamps with ear cones							
	Nasion support							

Chapter 3 IMAGING SOFTWARE OVERVIEW

PC System Requirements

This section specifies the minimum PC system requirements for KODAK 9000C and KODAK 9000C 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 9000C and KODAK 9000C 3D software. If necessary you MUST update your PC system configuration. KODAK 9000C and KODAK 9000C 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.



IMPORTANT

For KODAK 9000C, you can use the "Viewing" graphic board configuration for acquisition.

Table 3–1	Minimum	PC	System	Rec	uirements
		· ·			

Item	Viewing	Acquisition *	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 GT 512 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" 1280 x 880 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 XP Home / Pro edition SP2	

Item	Viewing	Acquisition *	Comments
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.	
Backup MediaRemovable/portable, external hard disk driveRemovable/portable, external hard disk drive.We strongly recommend a daily backup of x-ray images and patient records.			
* For the KODAK 9000C, panoramic and cephalometric acquisition, you need only the "Viewing" graphic board configuration.			

Table 3–1 Minimum PC System Requirements (Continued)

General Software Overview

The KODAK 9000C and KODAK 9000C 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 using Patient Window features •
- Extraoral and intraoral image management using Imaging Window features •
- 3D image management using 3D Imaging Window features •



NOTE

For a complete information on the KODAK Dental Imaging Software, see the "KODAK Dental Imaging Software, Quick Start Guide".

Cephalometric Acquisition Interface Module

The cephalometric acquisition interface module is a user-friendly working interface that was designed and developed specifically for KODAK 9000C and KODAK 9000C 3D extraoral imaging system.

Cephalometric Acquisition Interface Module

Cephalometric Acquisition Window Overview

The **Cephalometric Acquisition Window** is the main cephalometric interface with the KODAK 9000C and KODAK 9000C 3D extraoral imaging system that provides you with imaging acquisition functions.



Figure 3–1 Cephalometric Acquisition Window

1 Information button:

- About: Identifies the Software and the Firmware versions
- Reset of the Values: Resets to the manufacturing parameter settings
- Memorize settings: Memorizes the user preference settings for each patient type (kV, mA and seconds)
- 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, 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

Cephalometric Program Pane

The cephalometric **Program pane** enables you to choose different radiological exams as well as different acquisition formats.

Figure 3–2 Cephalometric Program Pane



1 Radiological exam options:





NOTE

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

Cephalometric Patient Pane

The cephalometric **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.





1 Patient type parameters:



Cephalometric Parameter Pane

The cephalometric **Parameter pane** enables you to choose exposure parameters for the radiological image acquisition. If the default parameter setting is not adapted to your patient type, you can manually adapt the parameter settings to the patient type and save this setting as the default setting.

Figure 3–4 Cephalometric Parameter Pane



1 Radiation dose options:







2 Fine-tuning buttons:



to fine-tune the kV, mA and the second.

Chapter 4 GETTING STARTED

Switching On the Unit

Before switching on the unit, check that:

- The installation of the unit is complete.
- The PC is switched ON.



IMPORTANT

You must switch On the PC and wait for it to be ready for connection before switching ON the unit.

To switch on the unit, follow these steps:

- 1. On the unit column, press the **ON** button.
- 2. Switch on the unit and wait for a minute for the connection between the unit and the PC to

be established. In the status bar, where the status bar, the status bar, become

3. If you start the imaging software before the connection is established an error message is displayed. Click **OK**, close the imaging software and wait for the connection to be established.

Error #3	316 🛛 🔀
1	Unable to connect to the acquisition unit. Please check the Ethernet link and check the acquisition unit is turned on.
	ОК

4. You can now proceed to start the imaging software.



IMPORTANT

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

1. In the Panoramic Acquisition Window, select the Parameter pane.

- 2. Select the following series of parameter settings:
 - 70 kV 6.3 mA
 - 80 kV 10 mA
 - 85 kV 10 mA
- 3. leave the x-ray room and close the door. For each parameter setting, from the x-ray remote control, press and hold the button to launch the x-ray

The unit is now ready to be used for acquisition.

Starting the Imaging Software

To start the imaging software, follow these steps:

1. On your desktop, double-click

OR





A 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 Cephalometric Acquisition Window

To access the Acquisition Windows, follow these steps:

- 1. In the **Imaging Window**, from the toolbar, click **Imaging Window**. to access the **Cephalometric Acquisition Window**.
- 2. Prepare the acquisition parameters and launch an acquisition.

Chapter 5 ACQUIRING CEPHALOMETRIC IMAGES

Acquiring a Lateral Image

Before acquiring a lateral image, check that you have:

- Reset the unit rotative arm to the start position for patient to enter the unit.
- Selected the patient record.
- Accessed the Imaging Window.
- Accessed the Cephalometric Acquisition Window.

Preparing the Unit and Setting the Acquisition Parameters

To set the acquisition parameters, follow these steps:

1. Position the head clamps manually for the lateral exam.



IMPORTANT

You must position the head clamps manually because they are not positioned automatically from the Program pane exam type selection. In this case, the relevant exam type selection icon becomes active.

- 2. In the **Cephalometric Acquisition Window**, click the **Program** button to access the **Program pane**. In the **Program pane**:

 - The for a lateral exam is active.
 - Select the appropriate acquisition format option.
- 3. Click the **Patient** button to access the **Patient pane**. Select the patient type.
- 4. If the default parameter setting is not adapted to your patient type, click the **Parameter** button and select the appropriate parameters. To save the new parameter settings as the

default settings, click *u* and select **Memorize settings**.

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's shoulders.
- 3. Open the head clamps and ask the patient to stand up straight, in front of the cephalometric unit, in the appropriate position.
- 4. On the control panel, press and hold **v** to level the ear cones to the patient's auditory canals.
- 5. Insert gently one cone in the auditory canal of the patient. Turn gently the button to close the arms. Insert gently the second cone in the auditory canal of the patient.
- 6. On the control panel, click to turn ON the Frankfort laser positioning beam. Align the patient with the Frankfort laser beam.



7. Lower the nasion support to a vertical position.



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 visual 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 **Cephalometric Acquisition Window**. When the acquisition ends, the **Cephalometric Acquisition Window** disappears and the acquired image is transferred automatically to the **Imaging Window**.

3. Check the image quality, if satisfactory, remove the ear cones and the nasion support and release the patient.

Acquiring a Frontal AP or PA Image

Before acquiring a frontal AP or PA image, check that you have:

- Reset the unit rotative arm to the start position for patient to enter the unit.
- Selected the patient record.
- Accessed the **Imaging Window**.
- Accessed the Cephalometric Acquisition Window.

Preparing the Unit and Setting the Acquisition Parameters

To acquire a frontal AP or PA image, follow these steps:

1. Position the head clamps manually for the frontal AP or PA exam.



You must position the head clamps manually because they are not positioned automatically from the Program pane exam type selection. In this case, the relevant exam type selection icon becomes active.

- 2. In the **Cephalometric Acquisition Window**, click the **Program** button to access the **Program pane**. In the **Program pane**:
 - The is for a frontal AP exam is active.
 - Click for a frontal PA exam.
 - Select the appropriate acquisition format option.
- 3. Click the **Patient** button to access the **Patient pane**. Select the patient type.
- 4. If the default parameter setting is not adapted to your patient type, click the **Parameter** button and select the appropriate parameters. To save the new parameter settings as the

default settings, click **1** and select **Memorize settings**.

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's shoulders.
- 3. Open and position the head clamps parallel to the cephalometric sensor. Ask the patient to stand up straight in front of the cephalometric unit in the following positions:
 - For a frontal AP, facing the generator
 - For a frontal PA, facing the cephalometric sensor
- 4. On the control panel, press and hold **v** to level the ear cones to the patient's auditory canals.
- 5. Insert gently one cone in the auditory canal of the patient. Turn gently the button to close the arms. Insert gently the second cone in the auditory canal of the patient.
- 6. On the control panel, click to turn ON the Frankfort laser positioning beam. Align the patient with the Frankfort laser beam for the frontal AP only.





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 visual 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 image appears on the **Preview Screen** of the **Cephalometric Acquisition Window**. When the acquisition ends, the **Cephalometric Acquisition Window** disappears and the acquired image is automatically transferred to the **Imaging Window**.

3. Check the image quality. If satisfactory, remove the ear cones and release the patient.

Acquiring an Oblique Image

Before acquiring an oblique image, check that you have:

- Reset the unit rotative arm to the start position for patient to enter the unit.
- Selected the patient record.
- Accessed the **Imaging Window**.
- Accessed the Cephalometric Acquisition Window.

Preparing the Unit and Setting the Acquisition Parameters

To acquire an oblique image, follow these steps:

1. Position the head clamps manually for the oblique exam with the desired angle.



You must position the head clamps manually because they are not positioned automatically from the Program pane exam type selection. In this case, the relevant exam type selection icon becomes active.

- 2. In the **Cephalometric Acquisition Window**, click the **Program** button to access the **Program pane**. In the **Program pane**:
 - The for an oblique exam is active.
 - Click
 - Select the appropriate acquisition format option.
- 3. Click the **Patient** button to access the **Patient pane**. Select the patient type.
- 4. If the default parameter setting is not adapted to your patient type, click the **Parameter** button and select the appropriate parameters. To save the new parameter settings as the

default settings, click *u* and select **Memorize settings**.

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's shoulders.
- 3. Open the head clamps and ask the patient to stand up straight in front of the cephalometric unit, in the appropriate position.
- 4. On the control panel, press and hold to level the ear cones to the patient's auditory canals.
- 5. Insert gently one cone in the auditory canal of the patient. Turn gently the button to close the arms. Insert gently the second cone in the auditory canal of the patient.
- 6. Lower the nasion support to a vertical position.



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 visual contact with the patient during acquisition.



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 image appears on the **Preview Screen** of the **Cephalometric Acquisition Window**. When the acquisition ends, the **Cephalometric Acquisition Window** disappears and the acquired image is automatically transferred to the **Imaging Window**.

3. Check the image quality. If satisfactory, remove the ear cones and the nasion support. Release the patient.

Acquiring a Submento-Vertex Image

Before acquiring a submento-vertex image, check that you have:

- Reset the unit rotative arm to the start position for patient to enter the unit.
- Selected the patient record. •
- Accessed the **Imaging Window**. •
- Accessed the Cephalometric Acquisition Window. •

Preparing the Unit and Setting the Acquisition **Parameters**

To acquire a submento-vertex image, follow these steps:

1. Position the head clamps manually for a frontal AP exam.



IMPORTANT

You must position the head clamps manually because they are not positioned automatically from the Program pane exam type selection. In this case, the relevant exam type selection icon becomes active.

- 1. In the Cephalometric Acquisition Window, click the Program button to access the Program pane. In the Program pane:
 - for a frontal AP exam is active. The
 - for a submento-vertex exam. Click
 - Select the appropriate acquisition format option. •
- 2. Click the **Patient** button to access the **Patient pane**. Select the patient type.
- 3. If the default parameter setting is not adapted to your patient type, click the Parameter button and select the appropriate parameters. To save the new parameter settings as the

default settings, click *u* and select **Memorize settings**.

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's shoulders.
- 3. Open the head clamps and ask the patient to sit, for a more comfortable position, or stand up straight in front of the cephalometric unit, in the appropriate position.
- 4. On the control panel, press and hold to level the ear cones to the patient's auditory canals.
- 5. Insert gently one cone in the auditory canal of the patient. Turn gently the button to close the arms. Insert gently the second cone in the auditory canal of the patient.



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 visual contact with the patient during acquisition.

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 x-ray emission. The image appears on the **Preview Screen** of the **Cephalometric Acquisition Window**. When the acquisition ends, the **Cephalometric Acquisition Window** disappears and the acquired image is
- 3. Check the image quality. If satisfactory, remove the ear cones and release the patient.

automatically transferred to the Imaging Window.

Acquiring a Carpus Image

Before acquiring a carpus image, check that you have:

- Reset the unit rotative arm to the start position for patient to enter the unit.
- Selected the patient record.
- Accessed the Imaging Window.
- Accessed the Cephalometric Acquisition Window.

Preparing the Unit and Setting the Acquisition Parameters

To acquire a carpus image, follow these steps:

1. Position the head clamps manually for a frontal AP exam.



IMPORTANT

You must position the head clamps manually because they are not positioned automatically from the Program pane exam type selection. In this case, the relevant exam type selection icon becomes active.

- 2. In the **Cephalometric Acquisition Window**, click the **Program** button to access the **Program pane**. In the **Program pane**:
 - The for a frontal AP exam is active.
 - Click for a carpus exam.
 - Select the appropriate acquisition format option.
- 3. Click the Patient button to access the Patient pane. Select the patient type.
- 4. If the default parameter setting is not adapted to your patient type, click the **Parameter** button and select the appropriate parameters. To save the new parameter settings as the

default settings, click *u* and select **Memorize settings**.

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's shoulders.
- 3. Ask the patient to stand on the side of the cephalometric unit, open the hand fully and place it on the sensor.





WARNING Make sure that the patient is not positioned in front of the x-ray emission.

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 visual 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 image appears on the **Preview Screen** of the **Cephalometric Acquisition Window**. When the acquisition ends, the **Cephalometric Acquisition Window** disappears and the acquired image is automatically transferred to the **Imaging Window**.

3. Check the image quality, if satisfactory, then release the patient.

X-Ray Dose Emission Information

Compliance with EURATOM 97/43 Directive

You can right-click on each image to display the estimated emitted dose received by the patient. You can use this information to calculate the effective dose received by the patient for the image.

The radiation emission dose is expressed in mGy.cm2. This dose is measured at the primary collimator outlet. The dose is accurate to $\pm -30\%$. The primary slot is 17.6 mm wide and 17.6 mm high.



Chapter 6 MAINTENANCE

This section describes the maintenance tasks that you need to perform regularly for your KODAK 9000C and KODAK 9000C 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
Head clamps and ear cones	Clean with medical-grade 76% alcohol disinfectant before the next
Nasion support	patient is x-rayed.
All components that come into contact with the patient and the operator	Clean 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. <i>WARNING</i> 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.

Annually

Chapter 7 TROUBLESHOOTING

Quick Troubleshooting

Occasionally, malfunctions can occur during use in the event of an incorrect action. An information (I) error code is displayed on the **Display Screen** of the unit **Control Panel** and the message is displayed on the popup on the **Acquisition Window System Status Screen**. In some cases, an audible warning is also issued.

The following table lists the information messages, their description and the action to take:



IMPORTANT

If an "E" message is displayed, the malfunction persists or more serious conditions occur, contact a qualified technician. When you call the qualified technician have the following information ready:

- Model Number: KODAK 9000C or KODAK 9000C 3D
- Error Code Number: E xx
- Message displayed on the popup on the Acquisition Window.

Information Error Code	Information Message	Description	Action
I 1	X-ray tube cooling	Cooling in progress.	Wait until the Generator Cooling Indicator on the Acquisition Window reaches zero.
I 2	Thermal security	Cooling in progress.	Wait until the Generator Cooling Indicator on the Acquisition Window reaches zero.
I 3	Release handswitch	The acquisition has ended.	Release the exposure button of the x-ray remote control.
15	Head clamps position	The head clamps position does not match the selected exam program.	Position manually the head clamps for the selected exam.
19	Cooling Ceph sensor	The Cephalometric sensor is in the cooling process.	Wait until the Ready Indicator LED is green.
I 15	Interface inactive	The Acquisition Window cannot be accessed.	 Check that the unit is switched ON. Wait for the connection between the unit and the PC. Check that the Acquisition Window is not masked by another application, in this case close the masking application.
I 17	Sensor in movement	The sensor is in the positioning process for either panoramic, 3D or Ceph mode.	Wait for the end of the positioning process.

Table 7–1 Quick	Troubleshooting
-----------------	-----------------

Quick Troubleshooting

Chapter 8 TECHNICAL SPECIFICATIONS

Compliance with International Standards

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

Manufactured by:

TROPHY

4, Rue F. Pelloutier, Croissy-Beaubourg 77435 Marne la Vallée Cedex 2, France

For: Carestream Health, Inc.

150 Veronal Street Rochester, New York - USA 14608

Model

KODAK 9000C 3D and KODAK 9000C

Compliance with International Regulations

- Medical Device directives 93/42/ European Economic Community (EEC), Class II b
- ElectroMagnetic Compatibility (EMC) directive 89/336/EEC
- FDA Center for Devices & Radiological Health (CDRH-21CFR title 21 sub chapter J) (USA)
- Radiation Emitting Devices Act C34 (Canada)
- Medical Devices Regulations (Canada)

Compliance with European and International Standards

- EN 60601-1 / IEC 60601-1
- EN 60601-1-3 / IEC 60601-1-3
- EN 60601-2-7 / IEC 60601-2-7
- EN 60601-2-28 / IEC 60601-2-28
- EN 60601-1-4 / IEC 60601-1-4
- CSA 601.1
- UL 60601.1
- EN ISO 14971

Classification in Accordance with EN/IEC 60601-1

Type of protection against electric shock	Class 1 equipment
Degree of protection against electric shock	Туре В
Protection against harmful ingress of water	Ordinary equipment
Operation mode	Continuous operation with intermittent loading
Flammable anesthetics	Not suitable for use in presence of flammable anesthetics or a mixture of flammable anesthetics with air or oxygen or nitrous oxide

Classification in Accordance with EN/IEC 60601-1-2

Group I, class B +12db

Ambient Operating Conditions

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

Storage Conditions

- **Temperatures:** $-10 \sim 60 \,^{\circ}\text{C}$
- **Relative humidity:** 10 ~ 95%
- Atmospheric pressure: 700 ~ 1060 hpa

Transport Conditions

- **Temperatures:** $-10 \sim 60 \,^{\circ}\text{C}$
- **Relative humidity:** 10 ~ 95%
- Atmospheric pressure: 700 ~ 1060 hpa

Cephalometric Unit Technical Specifications

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

•	KODAK 9000C	
	KODAK 9000C	KODAK 9000C 3D
Sensor Technology	CCD	
Sensor matrix	2100 x 2092 pixels	
Image field	300 x 300 mm	
Gray scale	16.384 - 14 bits	
Magnification	1.14	
Exposure time	0.1 to 3.2 sec.	
Radiological exam options	 Lateral Frontal AP or PA Oblique Submento-vertex Carpus 	
Acquisition format size	 18 x 18 18 x 24 24 x 24 24 x 30 30 x 30 	
Input voltage	 230 / 240 V - 50/60 Hz 100/110/130 V - 50/60 Hz 	
Unit dimensions	2137mm (L) x 1595mm (D) x 2378mm (H)* *Unit with 2225 mm (H) is also possible	
Required space	2230 (L) x 2000 (D) x 2400 (H) mm	
Weight of only the cephalostat component	39 kg (85.8 lb.)	
Total weight with K9000 or K9000 3D	199 kg (437.8 lb.)	

Table 8–1 Cephalometric Unit Technical Specification

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	0.9 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	$kV \pm 10\%$
Current in the tube	mA ± 20%
Exposure time seconds	Seconds $\pm (10\% + 1ms)$

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 8–2 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 (\pm 5° C)

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	Туре В
Operation mode	Continuous operation with intermittent loading
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

Table 8–3 Technical Specifications of the X-ray Generator





Table 8–4	Beam Limitations of the X-ray Generator
-----------	---

Manufacturer	Trophy
Туре	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
Maximum symmetrical field of radiation at a distance of 1720 mm from the focal point (cephalometric mode)	 205 (± 15) x 205 (± 15) mm 205 (± 15) x 274 (± 15) mm 274 (± 15) x 274 (± 15) mm 274 (± 15) x 300 (± 15) mm 300 (± 15) x 300 (± 15) mm At the detector reference plane

Table 8–4 Beam Limitations of the X-ray Generator (Continued)

Table 8–5Characteristics of the X-ray Tube

Manufacturer's name	CEI
Туре	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 8–2

Heating and Cooling Curves of the X-ray Tube





Figure 8–3Single Load Chart of the X-ray Tube

Figure 8–4 Filament Emissions of the X-ray Tube

