KODAK 8000 and KODAK 8000C Extraoral Imaging Systems

Safety, Regulatory & Technical Specification User Guide

Notice

The Regulatory Information & Technical Specifications User Guide for the KODAK 8000 and KODAK 8000C Extraoral Imaging Systems includes information on the safety instructions, regulatory information and the technical specifications of the devices. We recommend that you thoroughly familiarize yourself with this Guide in order to make the most effective use of your system.

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U.S. Federal law restricts this device to sale by or on the order of a dentist or physician.

This document is originally written in English.

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KODAK 8000 and KODAK 8000C Extraoral Imaging Systems, comply with Directive 93/42/CEE relating to medical equipment.

CE
0086

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Contents

1 Safety Information

Indications for Use

The KODAK 8000 and KODAK 8000C Extraoral Imaging Systems are intended to be used at the direction health care professionals for dental volumetric reconstruction of extra-oral dento- maxillo-facial region of the human anatomy.

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 followed carefully.

As a manufacturer of radiology units that conform to stringent radiological protection standards in force throughout the world, we guarantee as low as reasonably achievable 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 8000 and KODAK 8000C Extraoral Imaging Systems, 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 eyes of the patient.

Warning and Safety Instructions

WARNINGS

Unit:

- **Read and understand this Safety Information before using the KODAK 8000 and KODAK 8000C Extraoral Imaging Systems.**
- **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. To avoid the risk of electric shock, this equipment must ONLY be connected to a mains supply with protective earth.**
- **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.**
- **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.**
- **Using accessories other than those specified in this document with the exception of those sold by Carestream Health may result in a lower level of security for the entire system.**

Computer:

- **DO NOT place the computer 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 computer and the peripheral equipment must conform to the IEC60950 standard.**
- **See your computer installation guide for details of the data processing system 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.**

Hygiene and Disinfection

WARNINGS

- **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.**
- **To prevent cross-contamination, use a new hygienic sleeves for each new patient.**

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: General warning sign**
	**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.
	The ON/OFF button
	General mandatory action sign
	Follow operating instructions sign
	Non-ionizing radiation
	Manufactured Date
	Manufacturer's address

Label Locations

KODAK 8000 Labels

The following Figure illustrates the label locations of the KODAK 8000 System.

The patient entry can be positioned either on the right or the left side of the KODAK 8000 unit.

Figure 1–1 KODAK 8000 Unit Label Locations

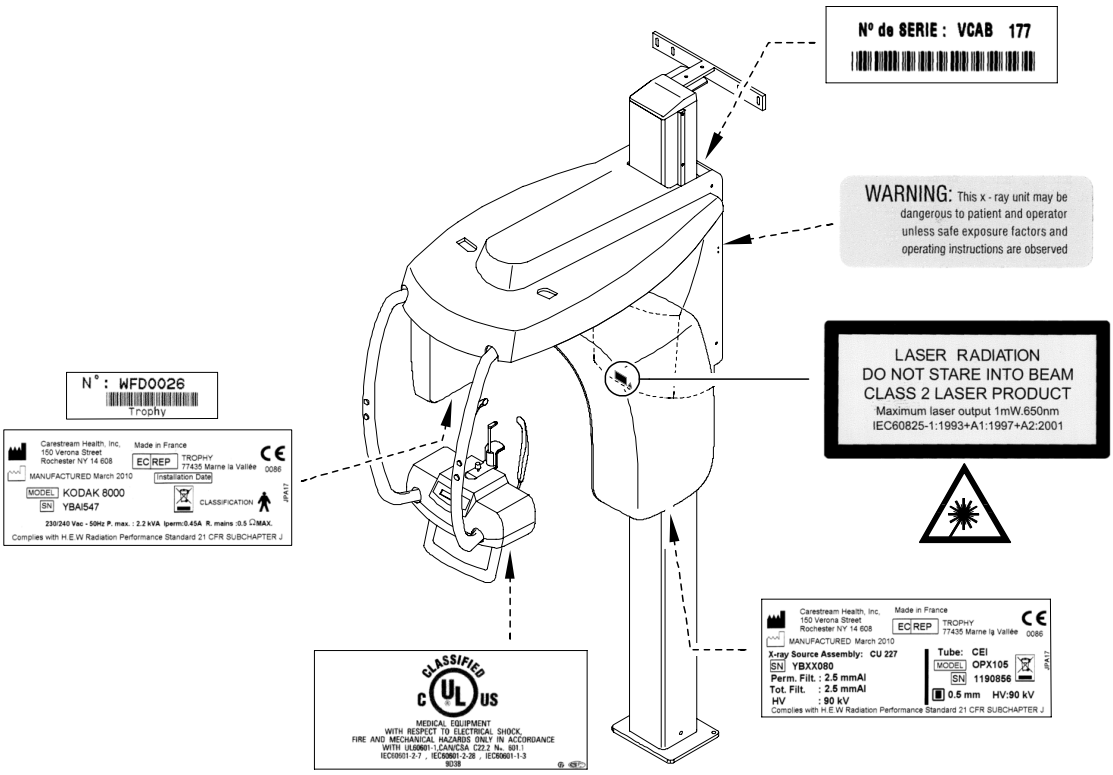

Table 1 Label Definition

Label	Definition
MODEL	Defines the unit's model
Installation Date	Defines the date that the unit was installed
Complies with H.E.W Radiation Performance Standard 21 CFR SUBCHAPTER J	Defines the unit's compliance with the US FDA radiation standards

KODAK 8000C Labels

The following Figure illustrates the label locations of the KODAK 8000C System.

The cephalostat can be positioned on the right or the left side of the KODAK 8000 unit.

Figure 1–2 KODAK 8000C Unit Label Locations

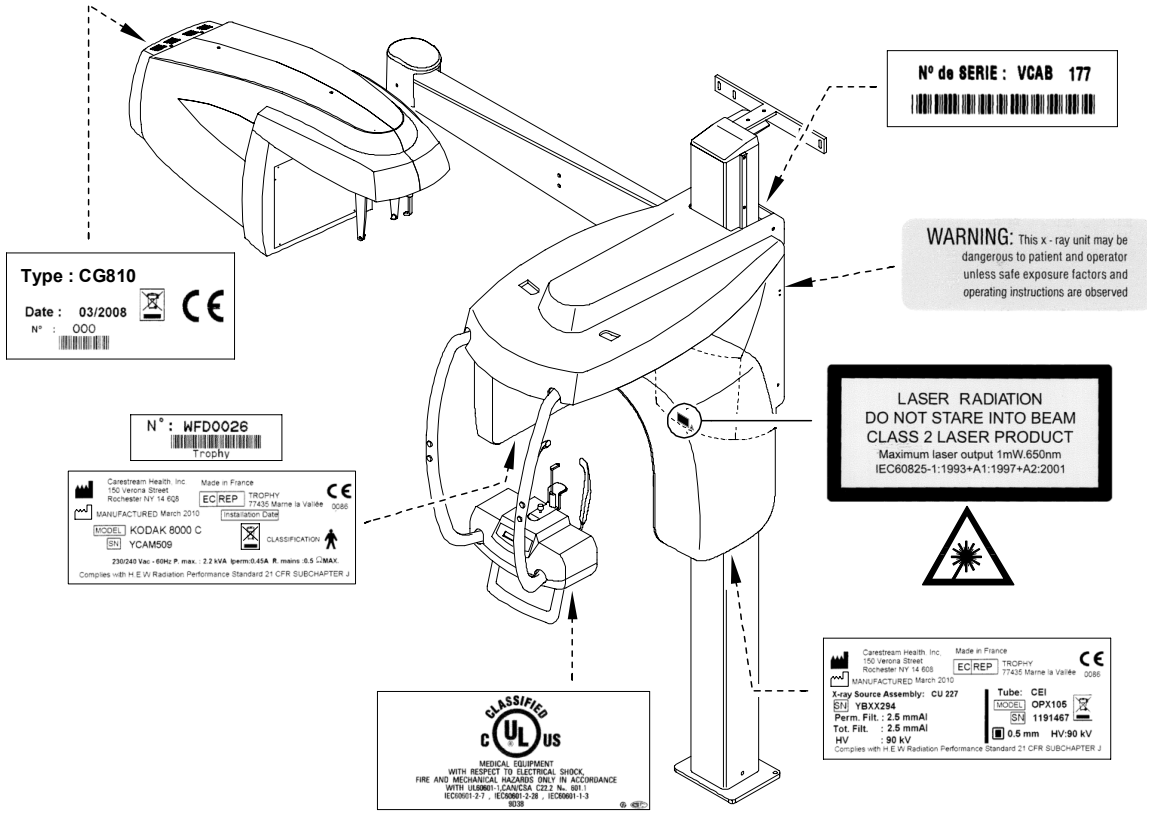

Table 2 Label Definition

Label	Definition
MODEL	Defines the unit's model
Installation Date	Defines the date that the unit was installed
Complies with H.E.W Radiation Performance Standard 21 CFR SUBCHAPTER J	Defines the unit's compliance with the US FDA radiation standards

2 Regulatory Information

General Regulatory Information

Compliance with European and International Standards	
EN 60601-1 / IEC 60601-1	Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-1-2 / IEC 60601-1-2	Medical Electrical Equipment, Part 1-2: General requirements for Safety - Collateral Standard: Electromagnetic Compatibility
EN 60601-1-3 / IEC 60601-1-3	Medical Electrical Equipment, Part 1-3: General requirements for safety - Collateral Standard: Radiation protection in diagnostic X-ray equipment
EN 60601-1-4 / IEC 60601-1-4	Medical Electrical Equipment, Part 1-4: General requirements for collateral standard: Programmable Electrical Medical Systems
EN 60601-1-6 / IEC 60601-1-6	Medical Electrical Equipment, Part 1-6: General requirements for safety - Collateral Standard: Usability
EN 60601-2-7 / IEC 60601-2-7	Medical Electrical Equipment - Part 2-7: Particular Requirements for the Safety of high voltage generators of diagnostic X-ray generators.
EN 60601-2-28 / IEC 60601-2-28	Medical Electrical Equipment - Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis.
EN 62304 / IEC 62304	Medical device software - Software life cycle processes.
EN 980	Symbols for use in the labeling of medical devices.
EN 1041	Information supplied by the manufacturer of medical devices.
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing
ISO 14971	Medical devices - Application of risk management to medical devices
CSA 22.2 N° 601-1	Medical Electrical Equipment - Part 1: General Requirements For Safety.
UL 60601-1	Medical Electrical Equipment - Part 1: General Requirements For Safety.

Classification in Accordance with EN/IEC 60601-1	
Type of protection against electric shock	Class 1 equipment
Degree of protection against electric shock	Type B
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

Conformity with EN/IEC 60601-1-2
Group I, class B +12db

Conformity with EN/IEC 60601-1-2

Electromagnetic Compatibility Precautions

- Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC).
- KODAK 8000 and KODAK 8000C Extraoral Imaging Systems must be installed and put into service according to the EMC information provided in this document.
- KODAK 8000 and KODAK 8000C Extraoral Imaging Systems may interfer with other equipment even if that other equipment complies with CISPR emission requirements.
- Portable and Mobile RF communications equipment can affect medical electrical equipment.

KODAK 8000 System Components
KODAK 8000 System

KODAK 8000C System Components
KODAK 8000C System

- Use limitation: the use of accessories, cables, or transducers other than those specified in the user's guide with the exception of cables, accessories or transducers sold by Carestream Health, Inc. as replacement parts of internal components, may result in increased emissions or decreased immunity of the KODAK 8000 and KODAK 8000C Extraoral Imaging Systems.
- The KODAK 8000 and KODAK 8000C Extraoral Imaging Systems should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the KODAK 8000 and KODAK 8000C Extraoral Imaging Systems should be observed to verify normal operation in the configuration in which it will be used.

Warning:

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 1 GHz band (CISPR 11: 2003 + A1 2004).

Guidance and Manufacturer's Declaration - Electromagnetic Emissions (IEC 60601-1-2)

The KODAK 8000 and KODAK 8000C Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the KODAK 8000 and KODAK 8000C Systems should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The KODAK 8000 and KODAK 8000C Systems uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B + 12db	The KODAK 8000 and KODAK 8000C Systems are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The KODAK 8000 and KODAK 8000C Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the KODAK 8000 and KODAK 8000C Systems should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the KODAK 8000 and KODAK 8000C Systems requires continued operation during power mains interruptions, it is recommended that the KODAK 8000 and KODAK 8000C Systems be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (IEC 60601-1-2)

The KODAK 8000 and KODAK 8000C Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the KODAK 8000 and KODAK 8000C Systems should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[V1]= 3 V	Portable and mobile RF communications equipment should be used no closer to any part of the KODAK 8000 and KODAK 8000C Systems, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	[E1]= 3 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the KODAK 8000 and KODAK 8000C Systems are used exceeds the applicable RF compliance level above, the KODAK 8000 and KODAK 8000C Systems should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the KODAK 8000 and KODAK 8000C Systems.

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the KODAK 8000 and KODAK 8000C System s

The KODAK 8000 and KODAK 8000C Systems are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KODAK 8000 and KODAK 8000C Systems can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KODAK 8000 and KODAK 8000C Systems as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Compliance with International Regulations

- Medical Device directives 93/42/ European Economic Community (EEC), Class II b as amended by 2007/47/EEC
- FDA Center for Devices & Radiological Health (CDRH-CFR title 21 sub chapter J) (USA)
- Radiation Emitting Devices Act - C34 (Canada)
- Medical Devices Regulations (Canada)

3 Technical Specifications

Factory

TROPHY

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Manufacturer

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Model

KODAK 8000 and KODAK 8000C

KODAK 8000 and KODAK 8000C Systems Technical Specifications

Table 3 KODAK 8000 and KODAK 8000C Systems Technical Specifications

Components	KODAK 8000 System	KODAK 8000C System
X-Ray Generator		
Tube voltage	60 - 90 kV (max)	
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	
Anode voltage	90 kV max.	
Cathode current	15 mA max.	
Digital Sensor		
Sensor technology	CCD and optical fiber	CCD
Sensor matrix	64 x 1348 pixels	1360 x 1840 pixels
Image field	6.1 x 129.4 mm	195 x 263 mm
Gray scale	16.384 - 14 bits	16.384 - 14 bits
Magnification	1.27 (± 10%)	1.14

Table 3 KODAK 8000 and KODAK 8000C Systems Technical Specifications (Continued)

Components	KODAK 8000 System	KODAK 8000C System
Radiological exam options	• Full panoramic • Segmented panoramic • Maxillary sinus • Lateral TMJ x2 • Lateral TMJ x4	• Lateral • AP/PA • Oblique • Submento-vertex • Carpus
Exposure mode	• 2 patient types (adult and child). • 3 patient sizes (small, medium, large).	• 2 patient types (adult and child). • 3 patient sizes (small, medium, large).
Exposure Time	4 to 14 seconds depending on the program	0.1 to 3.2 secs
Input voltage	• 230 / 240 V - 50/60 Hz • 100/110/130 V - 50/60 Hz	
Unit dimensions	888mm (L) x 180mm (D) x 2315mm (H)	2250mm (L) x 1261mm (D) x 2315mm (H)
Required space	1500 (L) x 1950 (D) x 2400 (H) mm	2350 (L) x 1950 (D) x 2400 (H) mm
Weight	120 kg (265 lb.)	145 kg (320 lb.)

KODAK 8000 and KODAK 8000C Systems Environmental Requirements

Ambient Operating Conditions	
Temperatures	5 ~ 35 °C
Relative humidity	30% ~ 80%
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

KODAK 8000 and KODAK 8000C Systems Electrical 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	1.0 A	1.0 A
Current absorbed during the X-ray emission	10 A	20 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, 5mA - 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 Tube Assembly Technical Specifications

Table 4 Filtration of the Material in the X-ray Field

Standard	Compliant
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") eq. Al
Filtration value for the enclosure of the image receiver unit (at 100 kV)	0.2 mm (0.008") eq. Al
Filtration value for the sensor case	0.8 mm (0.031") eq. Al
Value for the arms of the temple supports ((at 100 kV)	1.0 mm (0.039") 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)

Figure 3–3 Location of the Reference Axis for Panoramic Imaging

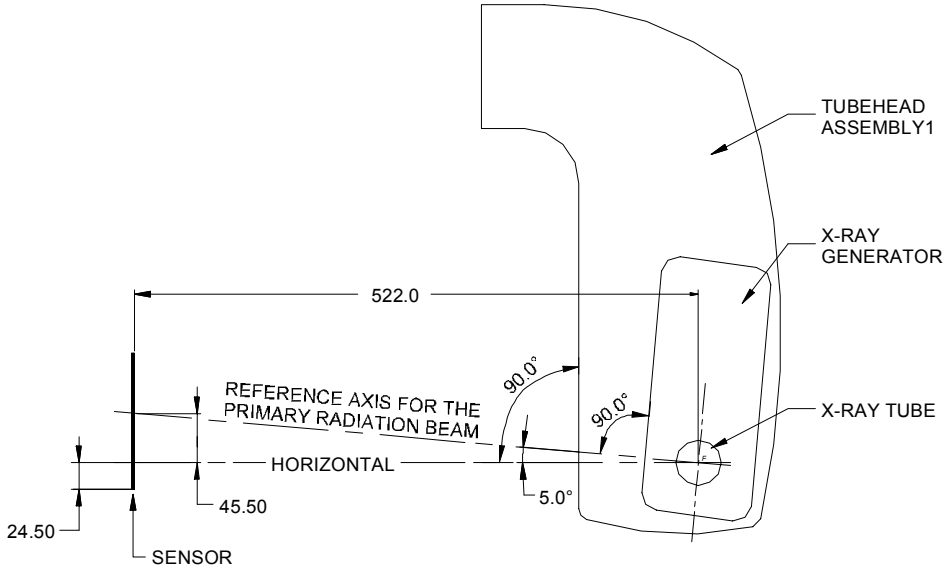

Figure 3–4 Location of the Reference Axis for Cephalometric Imaging

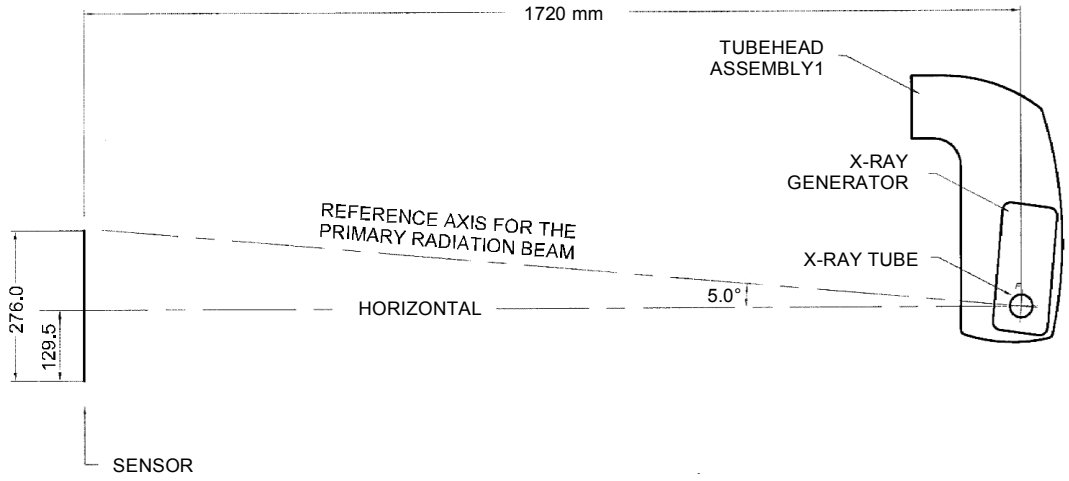

Table 3–5 Technical Specifications of the X-ray tube Assembly

Standard	Compliant
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
Operation mode	Continuous operation with intermittent loading
Maximum accumulated heat	110 kJ
Maximum continuous heat dissipation	33 W
Nominal value of the focal spot	0.5 mm
Tolerances on the position of the focal spot	-/- 2.5 mm
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 4 Heating and Cooling Curves of the X-ray Tube Assembly

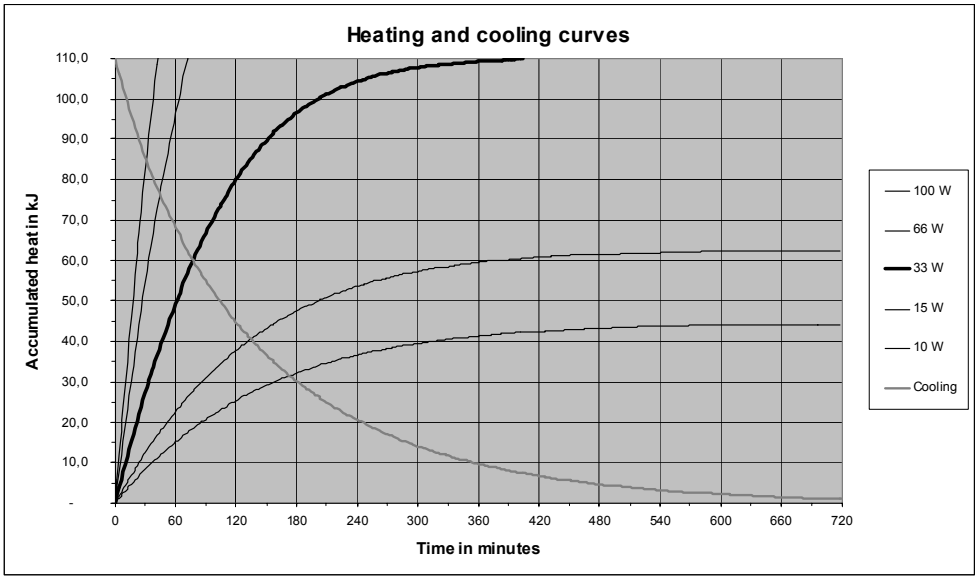

Table 6 Beam Limitations of the X-ray Tube Assembly

Manufacturer	Trophy
Type	Rigidly mounted unit with fixed window dimensions, not removable, and integrated x-ray generator
Maximum symmetrical field of radiation in panoramic mode at a distance of 522 mm from the focal point	4 mm (- 0.5 / + 1 mm) x 128 mm (± 2 mm)
Maximum symmetrical field of radiation in cephalometric mode at a distance of 1720 mm from the focus	190 mm (± 8mm) x 258 mm (± 8 mm)
Location of the reference axis	See Figures 3-3 and 3-4

Table 7 Characteristics of the X-ray Tube

Manufacturer's name	CEI
Type	OPX 105
Nominal high voltage	90 kV
Nominal anode input power at 0.1 s (AC)	810 W
Anode heat storage capacity	30 kJ
Nominal focal spot size (EN 60336)	0.5 mm (0.020")
Anode materials	Tungsten
Target angle	5°
Inherent filtration	0.5 mm (0.020 ") eq. Al

Figure 3–5 Heating and Cooling Curves of the X-ray Tube

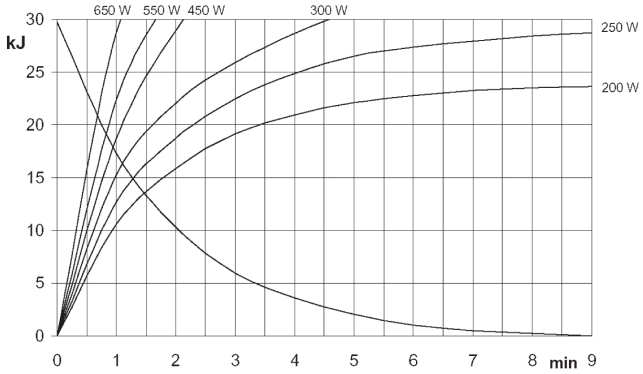

Figure 3–6 Single Load Chart of the X-ray Tube

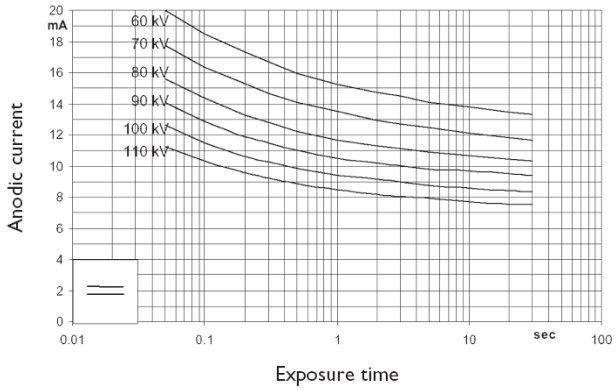

Figure 3–7 Filament Emissions of the X-ray Tube