Carestream DENTAL

CS 8100 Family

CS 8100, CS 8100 Access, CS 8100SC and CS 8100SC Access

Safety, Regulatory and Technical Specifications User Guide

Notice

The Regulatory Information and Technical Specifications User Guide for CS 8100 Family includes information on the safety instructions, regulatory information and the technical specification of the devices. We recommend that you thoroughly familiarize yourself with this guide to make the most effective use of your system.

The CS 8100 Family includes:

CS 8100: the complete panoramic modality.

CS 8100 Access: the panoramic modality without the 2D+ radiological exam.

CS 8100SC: the complete panoramic and cephalometric modality.

CS 8100SC Access: the panoramic modality (without the 2D+ radiological exam feature) and the cephalometric modality (without the 26x24 FoV (Field of View)).

In this guide, the generic name CS 8100 Family is used when the information refer to all models. If not the specific name of each model is used.

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

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.

Manual Name: CS 8100 Family Safety, Regulatory and Technical Specification User Guide
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The CS 8100 Family complies with Directive 93/42/EEC relating to medical devices.

CE
0086

Contents

1 Safety Information

Indications for Use

The CS 8100 Family are intended to produce complete or segmented tomographic digital panoramic X-ray images to be used at the direction of health care professionals of the dento-maxillofacial region of the human anatomy as diagnostic support for pediatric and adult patient. In addition, the CS 8100SC and CS 8100SC Access are also intended to produce cephalometric images. This includes imaging the hand and wrist to obtain carpus image for growth and maturity assessment.

The CS 8100 Family includes:

- CS 8100: the complete panoramic modality.
- CS 8100 Access: the panoramic modality without the 2D+ radiological exam.
- CS 8100SC: the complete panoramic and cephalometric modality.
- CS 8100SC Access: the panoramic modality (without the 2D+ radiological exam feature) and the cephalometric modality (without the 26x24 FoV (Field of View)).

The CS 8100 and CS 8100 Access can be upgraded to Cephalometric modality, when the Scan Ceph module is provided as an upgrade kit.

This guide uses the generic name of CS 8100 Family when making reference to all models. If not, it uses the specific name of the concerned model.

CAUTION

Do NOT use on patients who are about 5 years old and below and who are less than about 21 kg (46 lb) in weight and 113 cm (44.5 in) in height.

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.

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 the unit you must follow the instructions contained in this guide.

Warning and Safety Instructions

When operating CS 8100 Family, 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.

WARNINGS

Unit

- **Read and understand this Safety Information before using the unit.**
- **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.**
- **Considering radiation safety of pediatric population, protocol for Acquisition on Pediatric patients must be followed. For more information on imaging pediatric patients more safely and effectively, refer to FDA Pediatric X-ray Imaging webpage: http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/ucm298899.htm**
- **Do NOT place objects within the field of operation of the unit.**
- **The patient should wear a protective lead-lined shoulder apron with a thyroid collar, 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.**
- **It is not recommended to use accessories other than those specified in this document and sold by Carestream Dental.**
- **If the installation of the Product is not carried out by qualified personnel or if the Product is installed incorrectly and as a result is not operating correctly or is damaged, it is the responsibility of the Distributor. The above will lead to an expiration of the warranty and the liability of Carestream Dental; Carestream Dental accepts no responsibility for failures caused by sub-standard or incorrect installations.**

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 1.83 m distance between the patient and the unit. The computer and the peripheral equipment must conform to the IEC 60950 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.**
- **Always use Microsoft Windows Update to make sure that the latest security patches are correctly installed.**

Hygiene and Disinfection

Cleaning the unit

To clean the unit, follow these steps:

1. Switch off the unit.

2. Remove all visible soil, if any, with disposable cloth or paper wipe.

Note: No disassembly shall be performed on the unit

3. Dampen (not soak) a lint-free cloth with soap and running water.

4. Thoroughly clean manually all accessible parts of the unit, including the temporal head clamps, with the dampened lint-free cloth.

5. Dry the unit with hygienic disposable cloth.

6. Dampen (not soak) a lint-free cloth with a low-level disinfectant that is U.S. Environmental Protection Agency (EPA)-registered or low-level disinfectant that is recognized by your Local Authority (for example, quaternary ammonium compounds and some phenolics). An EPA-registered hospital disinfectant or any other low-level disinfectant must have clear label claims for intended use.

7. Wipe thoroughly on all accessible parts of the unit with the dampened lint-free cloth. **You must follow the disinfectant's manufacturer instructions for use, especially with respect to contact time.**

8. Allow to dry in the open air for a minimum of 5 minutes.

9. Visually inspect the unit for signs of deterioration. If any damage is noted, do not use the unit and contact a service technician.

CAUTION
Avoid applying any cleaning liquid to the inside parts of the unit.

Cleaning and disinfecting the accessories

Cleaning and disinfecting the accessories that have contact with the mucous membranes

CAUTION:
You MUST cover the standard bite block and the bite block for edentulous patients with FDA-cleared or CE mark protective sheaths that are available from distributors to use them between each patient.
We recommend that you cover the TMJ nose rest with FDA-cleared or CE Mark protective sheaths that are available from distributors to use them between each patient.

The following accessories must first be cleaned and then steam-sterilized between each patient use:

- TMJ nose rest
- Standard bite block
- Frankfort guide bite block for panoramic
- Bite block for edentulous patient

Note: It is recommended that the accessory be reprocessed as soon as reasonably practical following use.

Cleaning

To clean the accessories that have contact with the mucous membranes, follow these steps:

1. Remove and discard the protective sheath from the accessory.

2. Remove all visible soil by with disposable cloth or paper wipe.

3. Rinse at least 1 minute under running water to thoroughly clean the accessory from any excess soil.

4. Using a soft brush, apply medical enzyme detergent solutions (basically with a multi-enzymatic formula) to all surfaces of the accessory. **Detergent manufacturer's directions must be strictly adhered to.**

5. Rinse thoroughly under running water for at least 1 minute to remove detergent residue.

6. Dry the accessory with compressed air or hygiene disposable cloth.

7. Visually inspect the accessory for residual soil. If soil is visible, either repeat steps 2 to 5, or safely dispose of the accessory.

Disinfecting with Steam Autoclave

To steam autoclave the accessory, once cleaning is complete, follow these steps:

CAUTION
You must use a medical autoclaving equipment cleared by the FDA in the USA or that is recognized by your Local Authority.
You must always follow the operating parameters recommended by the manufacturer of the autoclaving equipment.
Use FDA cleared or CE mark standard packaging material.

1. Wrap the cleaned accessory using a standard packaging material for autoclaving.

2. Steam autoclave at 132°C (270°F) for 4 minutes in the USA or depending on your local regulation you can steam autoclave at 134°C (273°F) for 18 minutes.

3. Visually inspect the accessory for signs of deterioration. If any damage is noted, do not use the accessory and contact your representative.

4. Once disinfected, the accessory can be used immediately or stored dry and dust-free in its sterilization wrapping under temperature specified in section “CS 8100 Family Environmental Requirements” of the present guide.

Cleaning and disinfecting Ear cones of CS 8100SC and CS 8100SC Access

CAUTION
Ear cones must be covered with a use FDA-cleared or CE mark protective sheaths that are available from distributors to use them between each patient. After use, remove and discard the protective sheath. You must clean and disinfect the ear cones between each patient use with an EPA-registered, or CE mark, intermediate-level disinfectant with label claims of tuberculocidal activity.

Cleaning

To clean the ear cones, follow these steps:

1. Remove and discard the protective sheath from the accessory.

2. Remove all visible soil with disposable cloth or paper wipe.

3. Dampen (not soak) a lint-free cloth with soap and running water.

4. Thoroughly clean manually the ear cones with the dampened lint-free cloth.

5. Rinse thoroughly with lint-free cloth with running water.

6. Dry the accessory with hygienic disposable cloth.

7. Visually inspect the accessory for residual soil. If soil is visible, either repeat steps 2 to 6, or safely dispose of the accessory.

Disinfecting

1. Use an intermediate-level disinfectant with tuberculocidal activity as identified above and as recommended by the manufacturer of the disinfectant.

2. Allow to dry in open air.

Cleaning and disinfecting the component and accessories that have skin contact

The following accessories must first be cleaned and then disinfected between each patient use:

- Frontal head rest
- Panoramic / Sinus chin rest

The following component and accessory of the CS 8100SC and CS 8100SC Access must first be cleaned and then disinfected between each patient use:

- Nasion support
- Frankfort tool
- Carpus support (available only with Carpus exam option)

Note: It is recommended that the accessory be reprocessed as soon as reasonably practical following use.

Cleaning

To manually clean the component and accessories that have skin contact, follow these steps:

1. Remove all visible soil by with disposable cloth or paper wipe.

2. Rinse at least 1 minute under running water to thoroughly clean the component and accessory from any excess soil.

3. Using a soft brush, apply medical enzyme detergent solutions (basically with a multi-enzymatic formula) to all surfaces of the component or accessory. **Detergent manufacturer's directions must be strictly adhered to.**

4. Rinse thoroughly under running water for at least 1 minute to remove detergent residue.

5. Dry the component and accessory with compressed air or hygiene disposable cloth.

6. Visually inspect the component and accessory for residual soil. If soil is visible, either repeat steps 1 to 4, or safely dispose of the accessory.

Disinfecting

To disinfect the component and accessory, once the cleaning is complete, follow these steps:

1. Disinfect the component and accessory by using an EPA-registered hospital disinfectant for low-level activity or low-level disinfectant that is recognized by your Local Authority (for example, quaternary ammonium compounds and some phenolics). **You must follow the disinfectant's manufacturer instructions for use, especially with respect to contact time.**

CAUTION
If there is a visible contamination with blood, you must clean the component and accessory with an EPA-registered hospital disinfectant for intermediate-level disinfectant or intermediate-level disinfectant that is recognized by your Local Authority that has claim for activity against hepatitis B after cleaning. The disinfectant's manufacturer instructions for use must always be followed, especially with respect to contact time.

Marking and Labeling Symbols

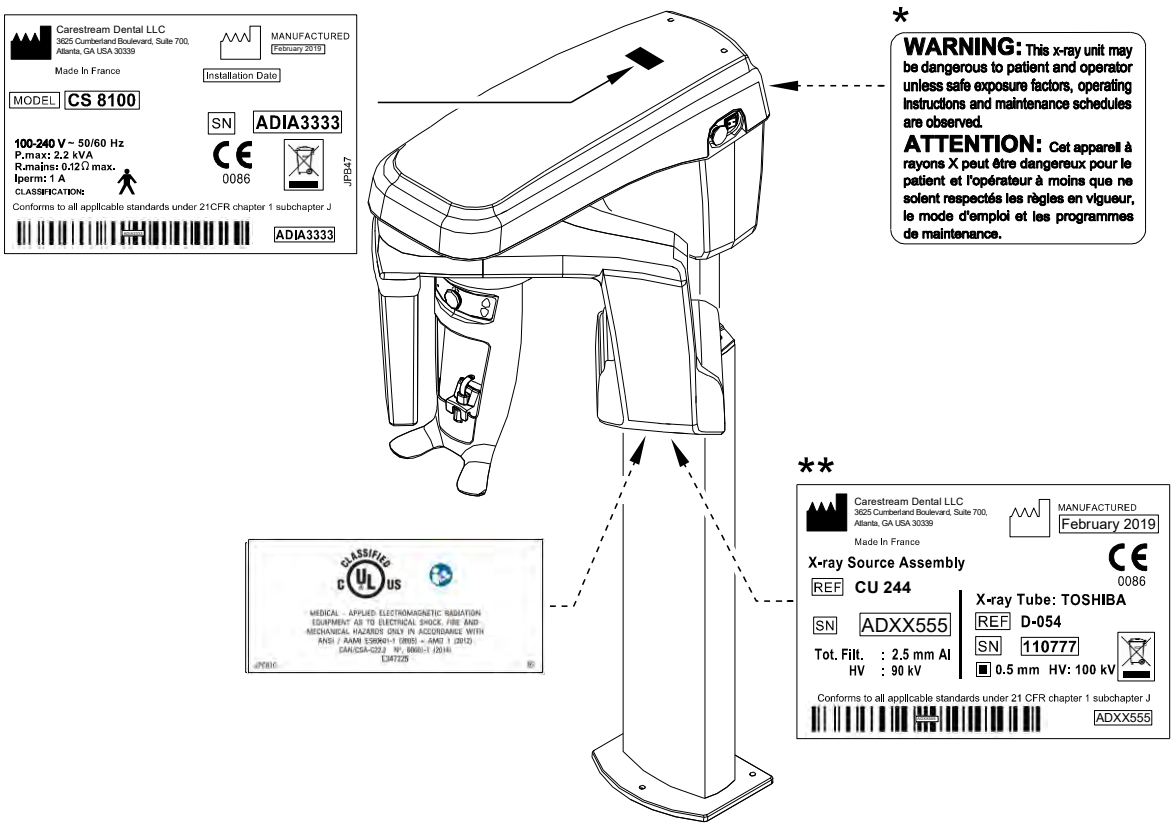
	Type B device symbol complying with the IEC 60601-1 standard
	In the European Union, this symbol indicates: Do NOT discard this product in a trash receptacle; use an appropriate recovery and recycling facility. Contact your local sales representative for additional information on the collection and recovery programs available for this product
	WARNING Attention, consult ACCOMPANYING DOCUMENTS
	IONIZING RADIATION symbols warn you about radiation dangers
	The ON/OFF button
	Refer to instruction manual/booklet
	Manufactured Date
	Manufacturer’s address
	Earth protection (ground)

Label Locations

CS 8100 Labels

The following figure illustrates the label locations of the CS 8100 and CS 8100 Access. This figure illustrates only the CS 8100 model but it also applies to the CS 8100 Access model.

Figure 1 CS 8100 Label Locations



Important:
*** Only for USA: This warning appears in the Parameter pane of the Acquisition interface.**

**** X-ray tube can be Canon D-054 or CEI OPX105 or Siemens SR 90/15 FN**

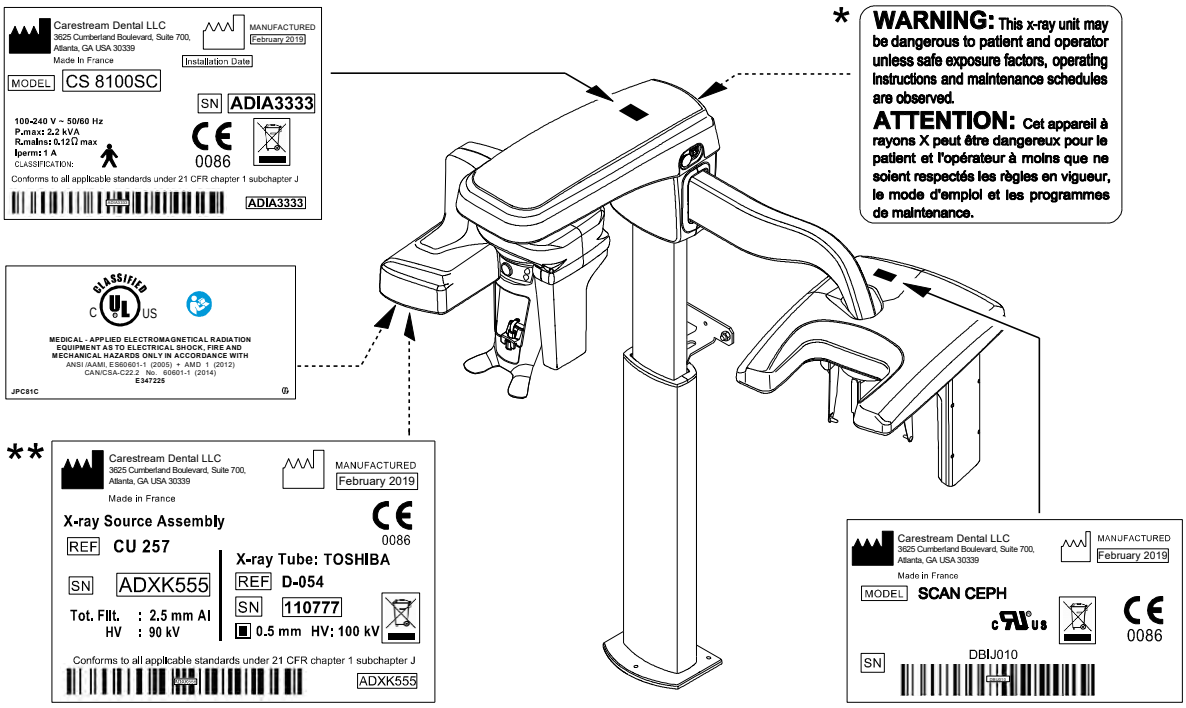
Table 1 Label Definition

Label	Definition
MODEL	Defines the unit's model
Installation Date	Defines the date that the unit was installed
Conforms to all applicable standards under 21 CFR chapter 1 subchapter J	Defines the unit's compliance with the US FDA radiation standards

CS 8100SC Labels

The following figure illustrates the label locations of the CS 8100SC and CS 8100SC Access. This figure illustrates only the CS 8100SC model but it also applies to the CS 8100SC Access model.

Figure 2 CS 8100SC Label Locations



Important:
*** Only for USA: This warning appears in the Parameter pane of the Acquisition interface.**
**** X-ray tube can be Canon D-054 or CEI OPX105 or Siemens SR 90/15 FN**

Table 2 Label Definition

Label	Definition
MODEL	Defines the unit's model
Installation Date	Defines the date that the unit was installed
Conforms to all applicable standards under 21 CFR chapter 1 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/IEC 60601-1	Medical Electrical Equipment, Part 1: General Requirements for basic safety and essential performance.
EN/IEC 60601-1-2	Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Disturbances - Requirements and tests.
EN/IEC 60601-1-3	Medical Electrical Equipment, Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.
EN/IEC 60601-1-6	Medical Electrical Equipment, Part 1-6: General requirements for basic Safety and essential performance - Collateral Standard: Usability.
EN/IEC 62366	Medical devices - Application of usability engineering to medical device.
EN/IEC 60601-2-63	Medical Electrical Equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment.
EN/IEC 62304	Medical device software - Software life cycle processes.
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.
EN 1041	Information supplied by the manufacturer of medical devices.
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing.
EN ISO 14971	Medical devices - Application of risk management to medical devices.
CAN/CSA C22.2 N°60601-1	Medical Electrical Equipment - Part 1: General Requirements For basic Safety and essential performance.
ANSI/AAMI ES60601-1	Medical Electrical Equipment - Part 1: General Requirements For basic Safety and essential performance.

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

CS 8100 Family is intended to be used in a professional healthcare facility environment.

Compliance of the CS 8100 Family was achieved using the following cables:
- 1 main power supply cable (maximum length of 3 m)
- 1 Ethernet cable (maximum length of 10 m)
- 1 X-ray switch cable (maximum length of 10 m)

Conformity with EN/IEC 60601-1-2
Electromagnetic Compatibility Precautions

- Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC).
- CS 8100 Family must be installed and put into service according to the EMC information provided in this document.
- CS 8100 Family may interfere with other equipment even if that other equipment complies with CISPR emission requirements.
- Portable and Mobile RF communications equipment can affect medical electrical equipment.

CS 8100 Components
▪ CS 8100

CS 8100 Access Components
▪ CS 8100 Access

CS 8100SC Components
▪ CS 8100SC

CS 8100SC Access Components
▪ CS 8100SC Access

- **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 Dental LLC as replacement parts of internal components, may result in increased emissions or decreased immunity of CS 8100 Family.**
- **CS 8100 Family should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the CS 8100 Family 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.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions (IEC 60601-1-2)		
CS 8100 Family is intended for use in the electromagnetic environment specified below. The customer or the user of CS 8100 Family should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	CS 8100 Family uses RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	CS 8100 Family is 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		
CS 8100 Family is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 8100 Family should assure that it is used in such an environment. The essential performance concerns accuracy of loading factors (mA, kV), if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES, the system stops the examination and the user is notified of the error.		
Immunity Test	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 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	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	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	0 % UT for 0.5 cycle at 8 angles At 0°, 0 % UT for 1 cycle and 70 % UT for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CS 8100 Family system requires continued operation during power mains interruptions, it is recommended that the CS 8100 Family systems be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 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)		
CS 8100 Family is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 8100 Family should assure that it is used in such an environment.		
Immunity Test	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz and 6V at ISM Frequencies and amateur radio frequencies	Environment of a care facility professional health
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2.7 GHz Test levels and frequencies according to table 9 from IEC 60601-1-2: 2014	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CS 8100 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
NOTE: 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 CS 8100 Family is used exceeds the applicable RF compliance level above, the CS 8100 Family should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CS 8100 Family.		

Compliance with International Regulations

- Medical Device Directives 93/42/ European Economic Community (EEC), Class IIb as amended by 2007/47/EEC
- Directive 2011/65/EU on the Restriction Of the use of certain Hazardous Substances in electrical and electronic equipment (ROHS).
- FDA Center for Devices & Radiological Health (CDRH-CFR title 21 chapter 1 subchapter J) (USA)
- Radiation Emitting Devices Act - C34 (Canada).
- Medical Devices Regulations (Canada).

3 Technical Specification

Factory

TROPHY

4, rue F. Pelloutier, Croissy-Beaubourg

77435 Marne la Vallée Cedex 2, France

Manufacturer

Carestream Dental LLC
3625 Cumberland Boulevard, Suite 700,
Atlanta, GA USA 30339

Model

CS 8100

CS 8100 Access

CS 8100SC

CS 8100SC Access

CS 8100 Family Technical Specification

Table 3 CS 8100 Family Technical Specification

Components	X-ray Generator
Tube voltage	60-90 kV
Tube current	2-15 mA
Frequency	140 kHz
Tube focal spot (IEC 60336)	0.5 mm
Total filtration	> 2.5 mm eq. Al
Anode voltage	90 kV
Cathode current	15 mA

Components	CS 8100 CS 8100 Access	CS 8100SC CS 8100SC Access
Panoramic Modality		
Sensor technology	CMOS	
Image field	6.4 x 131.2 mm	6.4 x 131.2 mm (adult) 6.4 x 120 mm (pediatric)
Gray scale	4096 - 12 bits	
Magnification	1.2 (±10 %)	
Radiological exams	Full panoramic Segmented panoramic Maxillary sinus Lateral TMJ x 2 Lateral TMJ x 4 2D+ (not available for CS 8100 Access and CS 8100SC Access)	
Exposure mode	4 patient sizes (child, small adult, medium adult, large adult) 3 dental arch morphology (normal, square, sharp)	
Exposure time	2 to 12.5 seconds	
Cephalometric Modality		
Sensor technology	N/A	CMOS
Image field	N/A	6.4 x 263.3 mm
Gray scale	N/A	16384 - 14 bits
Magnification	N/A	1.13 (±10 %)
Radiological exams	N/A	Lateral Frontal AP or PA Oblique Submento-vertex Carpus (optional)
Exposure time	N/A	3 to 10 seconds

Components	CS 8100 CS 8100 Access	CS 8100SC CS 8100SC Access
Input voltage (AC)	100 - 240 V 50/60 Hz	
Unit dimensions	330 (L) x 834 (D) x 1596 (H) mm	1842 (L) x 936 (D) x 1596 (H) mm
Minimum required space	1200 (L) x 1400 (D) x 2400 (H) mm	2000 (L) x 1400 (D) x 2400 (H) mm
Weight without the cephalostat component	72 kg (158 lb 12 oz)	N/A
Weight of only the cephalostat component	N/A	35 kg (77 lb)
Total weight	N/A	107 kg (236 lb)

Minimum Computer System Requirement

The computer and the peripheral equipment must conform to the IEC 60950 standard.

Item	Viewing	Acquisition
CPU	2 GHz Intel Duo Core	2 GHz Intel Duo Core
RAM	4 GB	4 GB for CS 8100 and CS 8100 Access 8 GB for CS 8100SC and CS 8100SC Access
Hard disk drive	▪ 1.2 GB for software installation ▪ 80 GB free space to use the software	▪ 4 GB for software installation ▪ 250 GB free space to use the software
Graphic board	Graphic-based board supporting Open GL 1.2 with 256 MB of video RAM on AGP x8 video bus	Graphic-based board on PCI Express video bus with minimum 512 MB of video RAM
Display	1024 x 800 minimum screen resolution 32 bits color mode	1280 x 1024 minimum screen resolution
Operating system	Windows 7 Windows 8* Windows 10*	Windows 7 (64 bits) Windows 8* (64 bits) only for CS 8100 & CS 8100 Access Windows 8.1* (64 bits) Windows 10* (64 bits)
Ethernet interface	N/A	2 Ethernet interfaces: ▪ 1 Gbits Ethernet board for the connection with the unit** ▪ Another optional Ethernet board for a LAN connection
CD/DVD drive	A DVD-BURNER drive is required.	A DVD-BURNER drive is required.
Backup Media	Removable/portable, external hard disk drive	Removable/portable, external hard disk drive.
Mouse	A mouse with 2 buttons and a scroll wheel is required	A mouse with 2 buttons

* not compatible with touch-screen desktops.

** This must be the Ethernet board of the motherboard if the computer has several gigabit Ethernet boards.

Note: Always use Microsoft Windows Update to make sure that the latest security patches are correctly installed.

X-Ray Dose Emission Information

Radiation protection

CAUTION
This device is NOT intended for use on patients who are less than 21 kg (46 lb) (approximately) in weight and 113 cm (44.5 in) in height. These measurements correspond approximately to that of an average 5 year old US child. The use of equipment and exposure settings designed for adults of average size can result in excessive radiation exposure for a smaller patient.
Studies have shown that pediatric patients may be more radiosensitive than adults (i.e. the cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for pediatric patients.

The relevant radiation protection regulation and measures must be observed. Use only approved radiation protection equipment. To reduce patient radiation exposure, the user instructions require that the patient wear a lead apron with a thyroid collar.
With the exception of the patient, no other persons without radiation protection should stay in the room during an exposure.
During an exposure, the operator is prompted to leave the X-ray room and close the door while keeping visual contact with the patient during acquisition.
If problems arise and requires you to stop the acquisition, release the exposure button of the remote control or press the red emergency stop button.

Recommendation for pediatric population

Compared to middle-aged adults, children and adolescents are three times more at risk from radiation. You must state and establish that the health benefits of using the X-ray method outweighs the risk posed by radiation. Consider using other methods with similar health benefits but does not involve any, or only low-level exposure to radiation when weighing up the situation.
Medical radiation exposure as part of dental care for children and adolescents must produce sufficient benefits, whereby radiation exposure resulting from X-ray examination is to be limited as much as is acceptable within the requirements of medical science (as defined by the ALARA principle).
The CS 8100 Family offers many options that can reduce radiation exposure for adults, and especially for children and adolescents, to a necessary minimum.

Table 4 Dose reduction options

Selecting the appropriate patient size for children/adolescent	
The two smallest patient size icons represent the exposure values for children and adolescent patients. Both patient sizes are associated to reduced kV / mA values which reduces the dose related to these exposure parameters.	
Child Patient size	Recommended for the children population of between 5 to 12 years old [~ 21 kg (46 lb); 113 cm (44.5 in) to ~ 52 kg (115 lb); 156 cm (61.5 in).
Adult Small Patient size	Recommended for the adolescent population of approximately ~ 52 kg (115 lb); 156 cm (61.5 in).
Selecting the fast scan option for a quick exam	
The fast scan option reduces the dose by doing a quick exam.	
Selecting the appropriate Field of View (FoV) for Cephalometric Exam	
Three Field of Views (FoV) are available for cephalometric exams: 18x18, 18x24 and 26x24. We	

recommend that you select the appropriate FoV size according to the size of your patient's head. Especially for children and adolescent patients, use the two smallest FoV sizes instead of the 26x24 FoV. Particularly for interceptive treatment made for children below 12 years old, we strongly recommend that you limit the FoV to 18x18. For adolescent treatment, we recommend that you limit the FoV to 18x18 or a maximum of 18x24. By minimizing the FoV, you will also reduce the dose associated with the cephalo-metric exam.

The CS 8100 Family provides additional options that help to simplify X-ray acquisitions of children and adolescents:

- Children and adolescents can be more still and stable in the seated position. The CS 8100 Family can be brought down for an exposure in the seated position to a bite block height of 104 cm.
- If you want to do some preliminary explanations to assure the patient, you can use the radiation free test cycle (called X-ray off mode) at any time from the acquisition interface by clicking 

- Face to face positioning and U-shape design of the cephalostat head helps to minimize the fear of confined space in the unit for children and adolescent patients.
- There are no distressing noises when the unit is in operation.
- The CS 8100 Family does not require any pre-shoot exposure to check the correct patient positioning. This prevents unnecessary radiation.

Panoramic mode for CS 8100 and CS 8100 Access

Table 5 Patient Dose information for Panoramic modality

	kV	83	80	80	68
	mA	8	8	6,3	10
		Patient size			
Radiological exam	Area of interest	Large	Medium	Small	Child
		DAP* in mGy.cm.cm			
Full Panoramic	Incisors, molars and TMJ	101	89	65	67
Segmented Panoramic Anterior	Incisor	46	41	27	26
Segmented Panoramic Anterior and Posterior	Incisors, one molar block and TMJ	74	65	46	47
Segmented Panoramic Anterior and Posterior	Incisors and one molar block	68	60	42	42
Segmented Panoramic Posterior	One molar block and TMJ	33	28	22	24
Segmented Panoramic Posterior	Two molar blocks and TMJ	66	57	44	48
Segmented Panoramic Posterior	One molar block	27	23	18	19
Segmented Panoramic Posterior	Two molar blocks	54	47	36	38
Segmented Panoramic Bitewing	Two molar blocks	54	47	36	38
Segmented Panoramic Anterior and Posterior	Incisors and molars	90	79	57	58
TMJ x2	TMJ	21	19	15	17
TMJ x4	TMJ mouth open and mouth closed	42	38	30	35
Maxillary Sinus	Maxillary sinus	69	54	38	49
2D+ Anterior or posterior	Incisors or one molar block	111	92	67	63

*DAP: Dose Area Product. The accuracy of DAP in the table above is +/-30 % when compared with the values that could be measured.

Note: The information in the table above may be subject to modification. Without notice or justification to those concerned.

Panoramic mode for CS 8100SC and CS 8100SC Access

Table 6 Patient Dose information for Panoramic modality

	kV	76	73	72	68
	mA	10	10	8	8
		Patient size			
Radiological exam	Area of interest	Large	Medium	Small	Child
		DAP* in mGy.cm.cm			
Full Panoramic	Incisors, molars and TMJ	120	102	75	42
Segmented Panoramic Anterior	Incisor	55	47	32	16
Segmented Panoramic Anterior and Posterior	Incisors, one molar block and TMJ	87	74	53	29
Segmented Panoramic Anterior and Posterior	Incisors and one molar block	80	68	49	26
Segmented Panoramic Posterior	One molar block and TMJ	39	33	25	15
Segmented Panoramic Posterior	Two molar blocks and TMJ	78	66	51	30
Segmented Panoramic Posterior	One molar block	32	27	21	12
Segmented Panoramic Posterior	Two molar blocks	64	54	41	24
Segmented Panoramic Bitewing	Two molar blocks	64	54	41	24
Segmented Panoramic Bitewing	One molar block	32	27	21	12
Segmented Panoramic Anterior and Posterior	Incisors and molars	106	90	66	36
TMJ x2	TMJ	25	22	17	11
TMJ x4	TMJ mouth open and mouth closed	50	44	34	22
Maxillary Sinus	Maxillary sinus	82	62	44	23
2D+ Anterior or posterior	Incisors or one molar block	131	105	76	39

*DAP: Dose Area Product. The accuracy of DAP in the table above is +/-30 % when compared with the values that could be measured.

Note: The information in the table above may be subject to modification. Without notice or justification to those concerned.

Cephalometric mode

Table 7 Patient Dose information for Cephalometric modality for Lateral exam

kV	82	80	78	74
mA	12	10	8	8
	Patient size			
Program	Large	Medium	Small	Child
	DAP* in mGy.cm.cm			
18x18 High resolution	24	19	14	13
18x18 Fast	10	8	6	6
18x24 High resolution	32	26	20	18
18x24 Fast	14	11	8	8
26x24 High resolution	46	37	28	26
26x24 Fast	20	16	12	11

*DAP: Dose Area Product. The accuracy of DAP in the table above is +/-30 % when compared with the values that could be measured.

Note: The information in the table above may be subject to modification. Without notice or justification to those concerned.

Table 8 Patient Dose information for Cephalometric modality for Carpus exam

kV	66	64	64	60
mA	15	15	15	15
	Patient size			
Program	Large	Medium	Small	Child
	DAP* in mGy.cm.cm			
18x18 High resolution	19	18	18	15
18x18 Fast	8	8	8	6
18x24 High resolution	27	26	26	22
18x24 Fast	12	11	11	10
26x24 High resolution	39	37	37	32
26x24 Fast	17	16	12	11

*DAP: Dose Area Product. The accuracy of DAP in the table above is +/-30 % when compared with the values that could be measured.

Note: The information in the table above may be subject to modification. Without notice or justification to those concerned.

Table 9 Patient Dose information for Cephalometric modality for Frontal AP / PA, Oblique and Submento-vertex exam

kV	90	90	88	84
mA	10	10	10	10
	Patient size			
Program	Large	Medium	Small	Child
	DAP* in mGy.cm.cm			
18x18 High resolution	23	23	22	21
18x18 Fast	10	10	10	9
18x24 High resolution	31	31	30	28
18x24 Fast	13	13	13	12
26x24 High resolution	45	45	43	40
26x24 Fast	19	19	18	17

*DAP: Dose Area Product. The accuracy of DAP in the table above is +/-30 % when compared with the values that could be measured.

Note: The information in the table above may be subject to modification. Without notice or justification to those concerned.

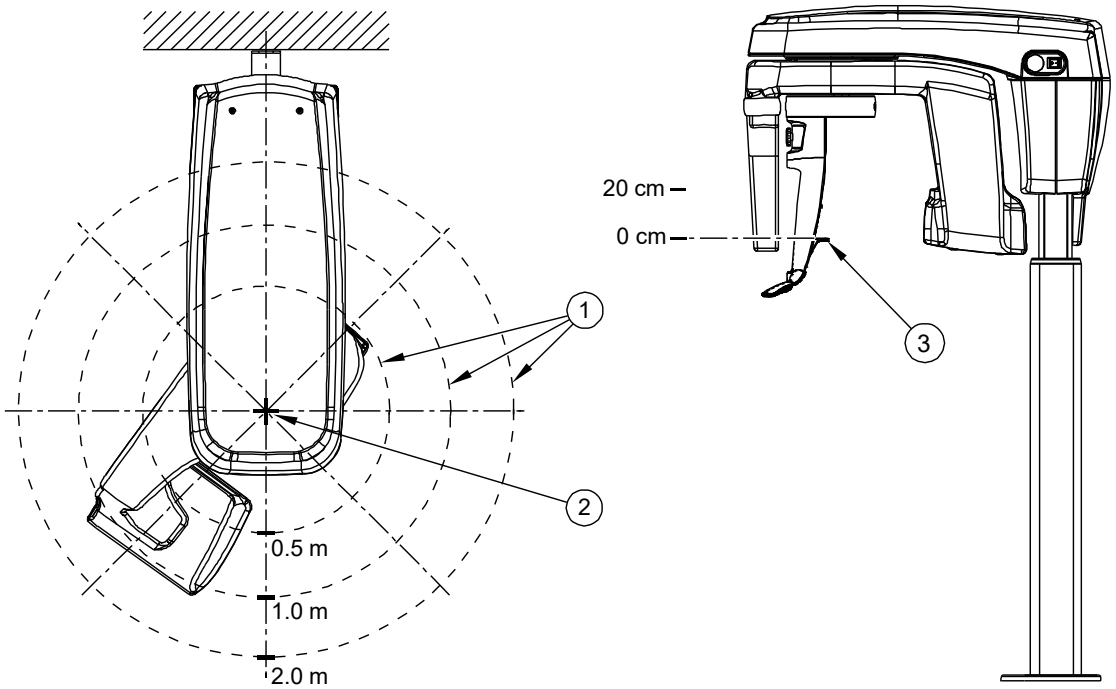
User Dose information

Stray radiation

Stray radiation measures are highly dependent on environmental conditions, such as the composition of walls and their locations, therefore in certain circumstances the values may be significantly different.
The points of measurement used are at 0.5 m, 1.0 m and 2.0 m respectively from the central rotation axis.

Figure 3 Circular Points of Measurement

Points of measurement	
1	Circular Points of Measurement
2	Chin Rest Axis
3	Chin Rest



Stray radiation is measured in full panoramic mode, for a large sized patient selected with a PMMA phantom cylinder (Φ 16 cm, h 15 cm) to simulate a patient head.

Stray radiation measured at the maximum use rate permitted by the X-Ray generator, (this corresponds to a continuous average anodic power of 33 W), or 13 exams per hour.	
Distance between the rotation axis and measurement point (Circular Points of Measurement)	Stray radiation*
0.5 m	60 µGy /h
1.0 m	15 µGy /h
2.0 m	4 µGy /h
Stray radiation at mean use rate in practice, or 2 exams per hour.	
Distance between the chin rest axis and measurement point Circular Points of Measurement)	Stray radiation*
0.5 m	8 µGy /h
1.0 m	2 µGy /h
2.0 m	< 1 µGy /h

*This is the maximum value measured 20 cm above the horizontal cross sectional plane with a chin rest. Other values in the vertical axis are lower than these values.

Imaging performance information

Line Pair Resolution*: 3.1 lp/mm
Low Contrast Resolution*: a minimum of 2 low contrast steps for panoramic and a minimum of 1 low contrast step for cephalometric

* Using a dental phantom for digital image acquisition that complies with the IEC 61223-3-4:2000 standard.

Controlling the Image Quality

For optimum results, perform a control test of the image quality. To do this, see ***"Controlling the Image Quality"*** chapter in the User Guide (SM784)***.***

CS 8100 Family Environmental Requirements

Ambient Operating Conditions	
Temperatures	10 - 35 °C (50 - 95 °F)
Relative humidity	30 - 80 %
Atmospheric pressure	700 - 1060 hpa
Altitude	Up to 3000 m

Storage Conditions	
Temperatures	-10 - 60 °C (14 - 140 °F)
Relative humidity	10 - 90 %
Atmospheric pressure	700 - 1060 hpa

Transport Conditions	
Temperatures	-10 - 60 °C (14 - 140 °F)
Relative humidity	10 - 90 %
Atmospheric pressure	700 - 1060 hpa

CS 8100 Family Electrical Specifications

Type of Electrical Power Supply	100 - 240 V ~ (± 10%) 50/60 Hz, Single-Phase
Acceptable fluctuation	± 10%
Apparent resistance of the power supply circuit	0.12 Ω max
Permanent absorbed current	1.0 A
Current absorbed during the X-ray emission	20 A
Maximum absorbed power	2.2 kVA
Protection for the power supply system	By shutter release at a maximum current of 20 A and a differential current of 30 mA
Nominal high voltage	90 kV
Maximum corresponding tube current	10 mA
Nominal tube current	15 mA
Maximum corresponding high voltage	80 kV
Tube current/voltage combination for maximum output power	80 kV, 15 mA, 1200 W
Nominal power for an exposure time nearest to 100 kV and to 0.1 s.	at 90 kV, 10 mA: 900 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

Accuracy of the Load Parameters	
High voltage	kV ± 10 %
Current in the tube	mA ± 20 %
Exposure time seconds	Seconds ± (10 % + 1ms) or ±(5% + 50 ms)

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 10 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	>1.7 mm (0.06") eq. Al
Nominal value of the supplementary filtration at 70 kV	1.5 mm (0.05") Al
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)	>0.5 mm (0.019") eq. Al
Filtration value for the enclosure of the image receiver unit (at 100 kV)	0.5 mm (0.019") eq. Al
Filtration value for the sensor case	0.5 mm (0.019") eq. Al

The X-ray generator comprises the following:

- Transformers 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 4 Location of the Reference Axis for Panoramic Imaging

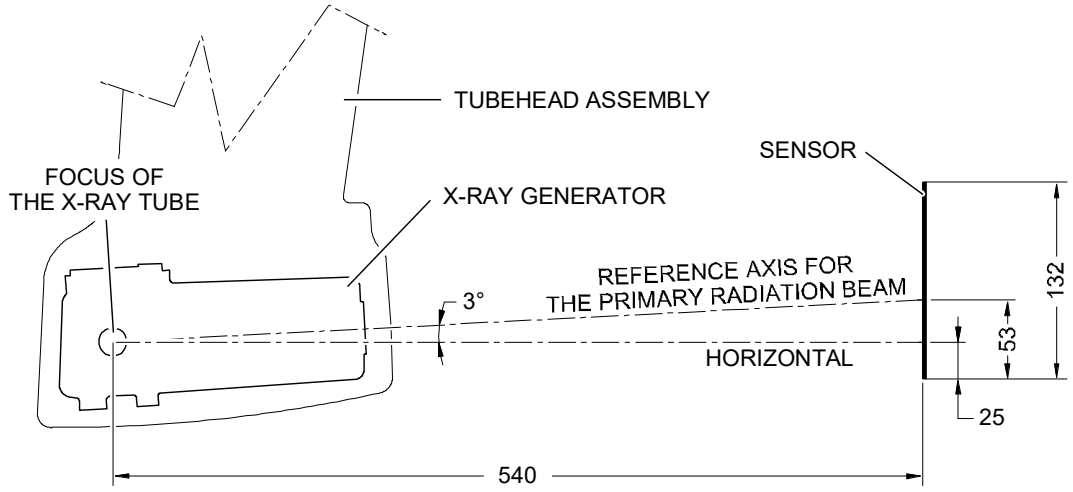


Figure 5 Location of the Reference Axis for Cephalometric Imaging

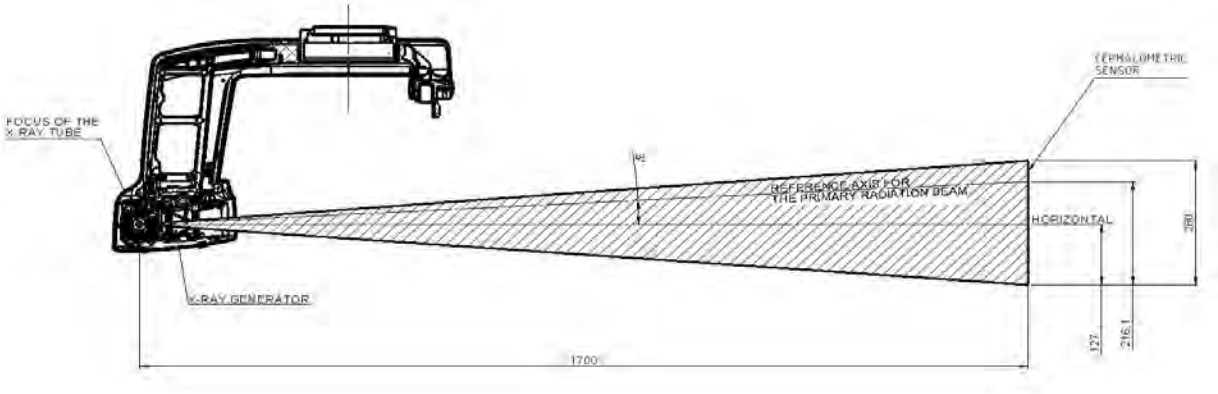


Table 11 Technical Specifications of the X-ray tube Assembly

Standard	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
Continuous Anode Input Power that corresponds to the maximum specified energy input to the Anode (110kJ)	33W at 90kV
Radiation leakage after one hour's operation (maximum utilization rate of 33W)	< 1 mGy
Weight	7 kg
Dimensions	270 x 200 x 100 mm

Figure 6 Heating and Cooling Curves of the X-ray Tube Assembly

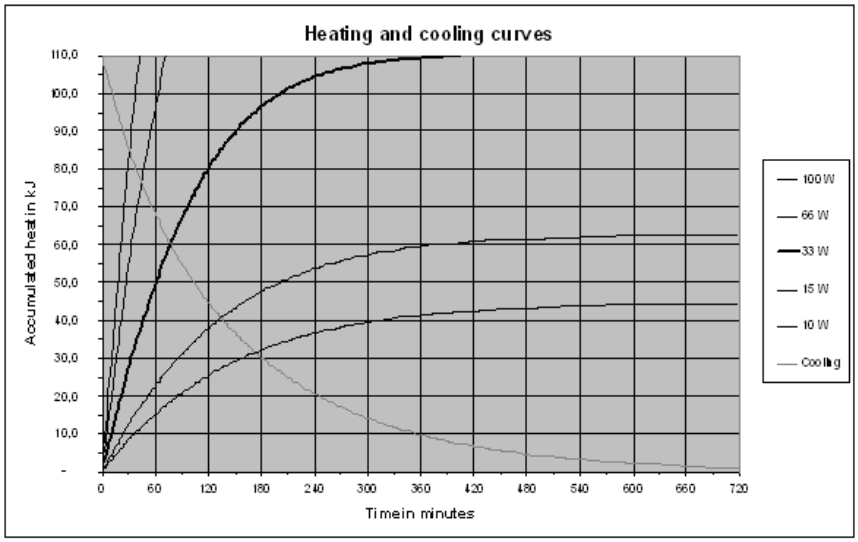


Table 12 Beam Limitations of the X-ray Tube Assembly

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 540 mm from the focal point	5 mm x 132 mm At the detector reference plane
Maximum symmetrical field of radiation in cephalometric mode at a distance of 1700 mm from the focal point	5 mm x 260 mm At the detector reference plane
Location of the reference axis	See Figure 4 and Figure 5

Table 13 Characteristics of the X-ray Tube

Manufacturer's name	CEI	Toshiba or Canon	Siemens
Type	**OPX105**	**D-054**	**SR 90/15 FN**
Nominal high voltage	105 kV	100 kV	90 kV
Nominal anode input power	2000 W (at 0.1 s)	1755 W (at 1.0 s)	1395 W (at 1.0 s)
Anode heat storage capacity	30 kJ	35 kJ	19.5 kJ
Nominal focal spot size (EN 60336)	0.5 mm (0.020")	0.5 mm (0.020")	0.5 mm (0.020")
Anode materials	Tungsten	Tungsten	Tungsten
Target angle	5°	5°	5°
Inherent filtration	0.5 mm (0.020 ") eq. Al	0.8 mm (0.032") eq. Al	1,0 mm (0.04") eq. Al

Figure 7 X-ray tube drawing: OPX105

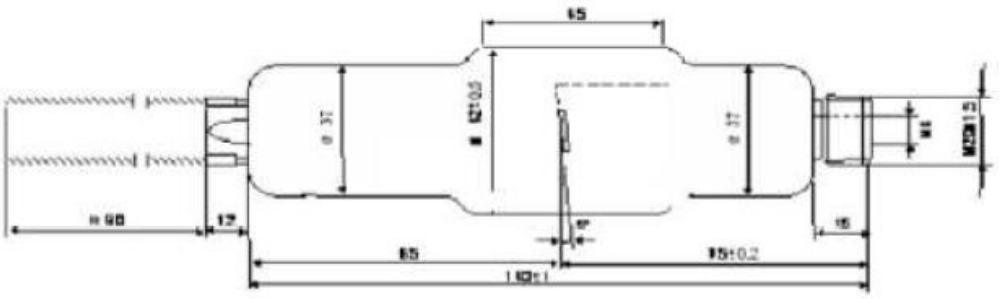


Figure 8 X-ray tube drawing: D-054

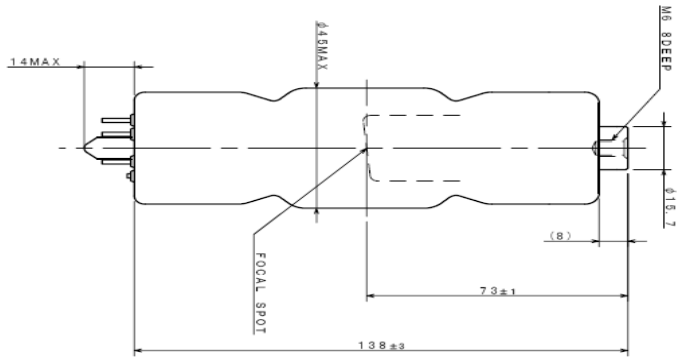


Figure 9 X-ray tube drawing: SR 90/15 FN

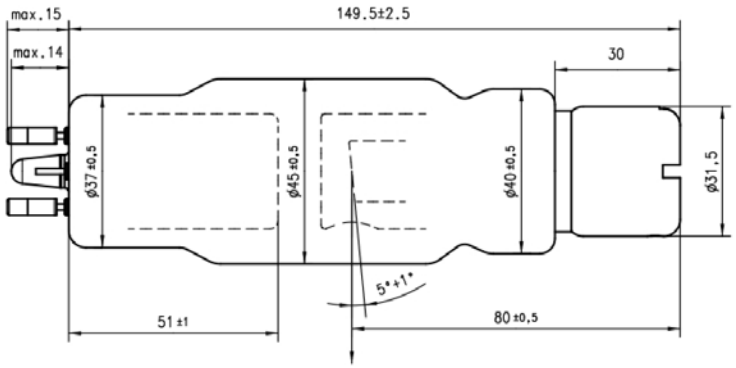


Figure 10 Heating and Cooling Curves of the X-ray Tube: OPX 105

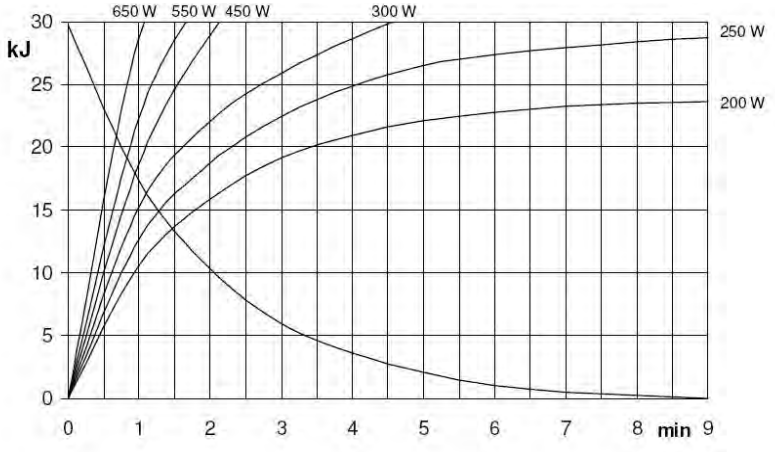


Figure 11 Single Load Chart of the X-ray Tube: OPX 105

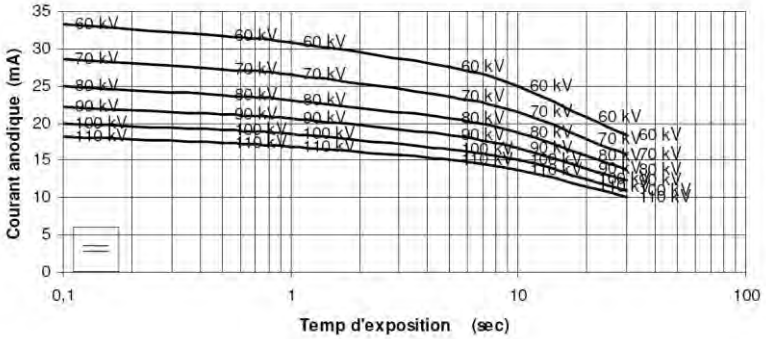


Figure 12 Filament Emissions of the X-ray Tube: OPX 105

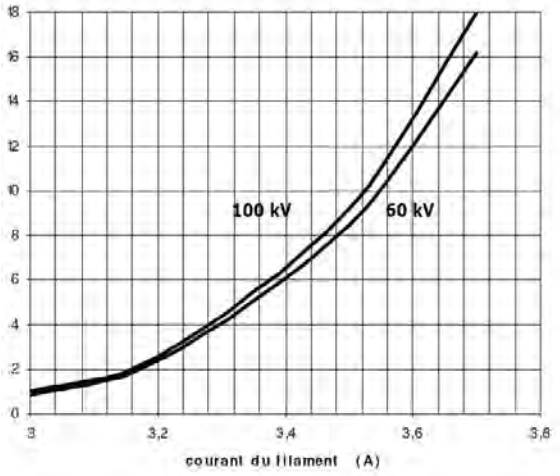


Figure 13 Heating and Cooling Curves of the X-ray Tube: D-054

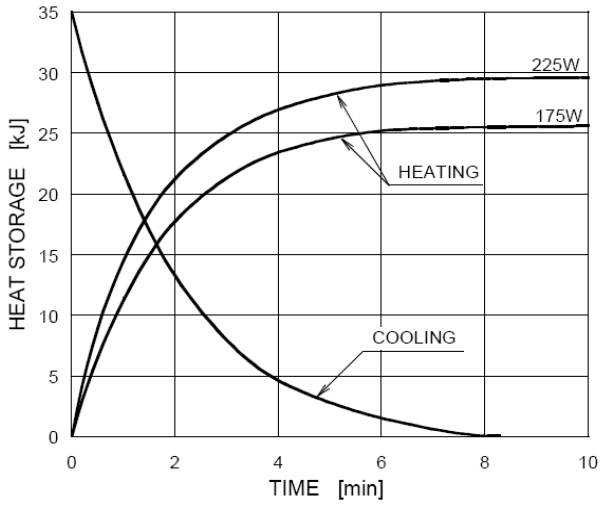


Figure 14 Single Load Chart of the X-ray Tube: D-054

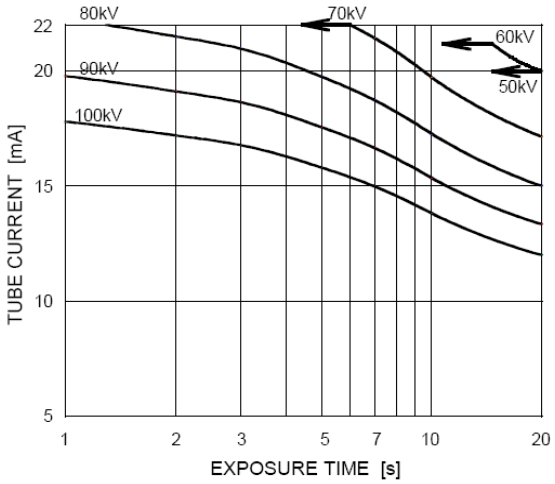
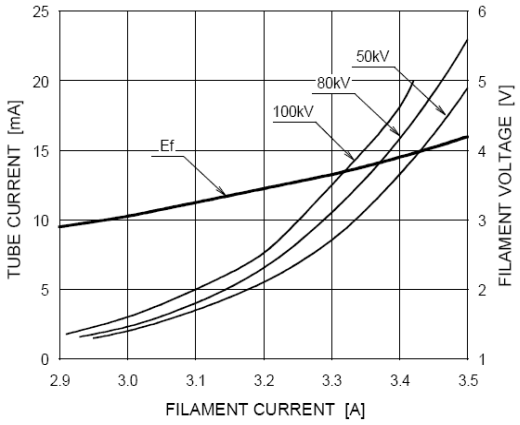


Figure 15 Filament Emissions of the X-ray Tube: D-054



Note: This graph indicates typical characteristics.

Figure 16 Heating and Cooling Curves of the X-ray Tube: SR 90/15 FN

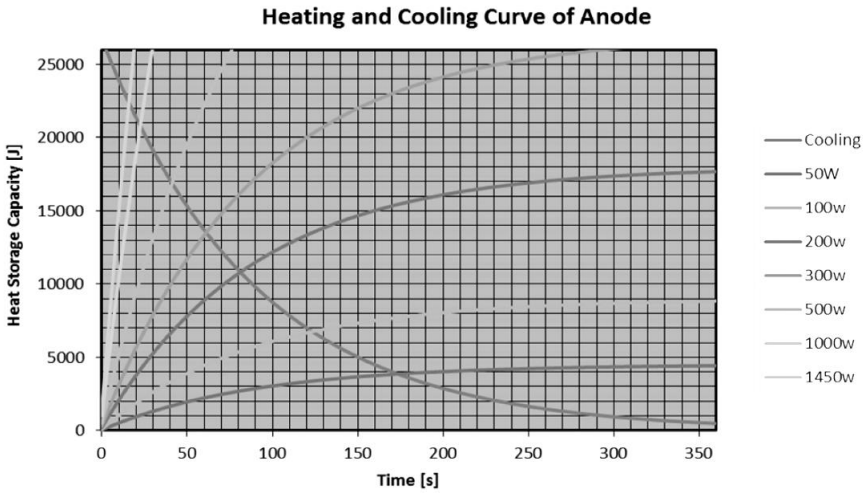


Figure 17 Single Load Chart of the X-ray Tube: SR 90/15 FN

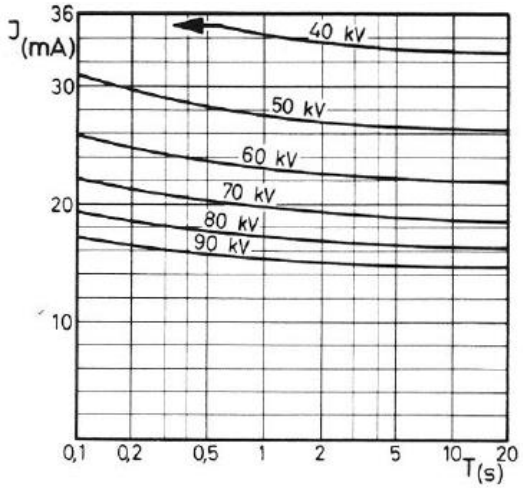
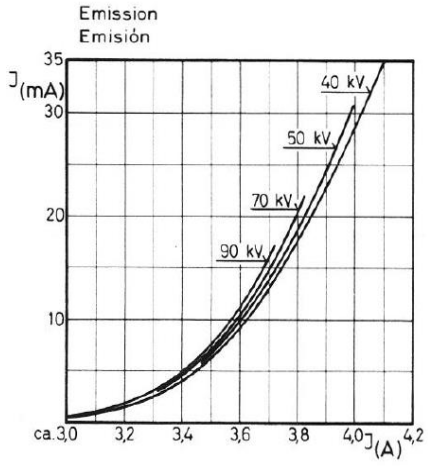


Figure 18 Filament Emissions of the X-ray Tube: SR 90/15 FN



4 Contact Information

Manufacturer's Address

Carestream Dental LLC
3625 Cumberland Boulevard, Suite 700,
Atlanta, GA USA 30339

Authorized Representatives

European Authorized Representative

Trophy

4, rue F. Pelloutier, Croissy-Beaubourg

77435 Marne La Vallée Cedex 2, France

Authorized Representative in Brazil

CARESTREAM DENTAL BRASIL EIRELI
Rua Romualdo Davoli, 65
1º Andar, Sala 01 - São José dos Campos
São Paulo - Brazil
Cep (Zip Code): 12238-577

For more information, visit: **www.carestreamdental.com**

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