Carestream DENTAL

CS 8100 3D Family

CS 8100 3D, CS 8100 3D Access, CS 8100 3D Select, CS 8100SC 3D, CS 8100SC 3D Access and CS 8100SC 3D Select

Safety, Regulatory and Technical Specifications User Guide

Notice

The Regulatory Information and Technical Specifications User Guide for CS 8100 3D Family 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 to make the most effective use of your system.

The CS 8100 3D Family comprises:

- CS 8100 3D: panoramic modality and dental volumetric reconstruction modality (3D focused teeth acquisition and 3D full upper and lower jaw acquisition).
- CS 8100 3D Access: panoramic modality and dental volumetric reconstruction modality (limited to 3D focused teeth acquisition). The system has the capability to expand the field of view to the 3D full upper and lower jaw acquisition with license upgrade.
- CS 8100 3D Select: Panoramic modality and dental volumetric reconstruction modality, limited to 3D Single (lower or upper) jaw acquisition. The system has the capability to expand the field of view to the 3D full jaw acquisition with license upgrade.
- CS 8100SC 3D: panoramic modality, dental volumetric reconstruction modality (3D focused teeth acquisition and 3D full upper and lower jaw acquisition) and cephalometric modality.
- CS 8100SC 3D Access: panoramic modality, dental volumetric reconstruction modality (limited to 3D focused teeth application) and cephalometric modality (without the 26x24 Field of View (FoV)). The system has the capability to expand the field of view to the 3D full upper and lower jaw acquisition and to the cephalometric 26x24 FoV with licence upgrade.
- CS 8100SC 3D Select: Panoramic modality, dental volumetric reconstruction modality, limited to 3D Single (lower or upper) jaw acquisition, and cephalometric modality (without the 26x24 Field of View (FoV)). The system has the capability to expand the field of view to the 3D full jaw acquisition and to the cephalometric 26x24 FoV with license upgrade.

The CS 8100 3D, CS 8100 3D Access and CS 8100 3D Select can be upgraded to Cephalometric modality, when the Scan Ceph module is provided as an upgrade kit.
This document refers to all models as CS 8100 3D Family unless otherwise specified.

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 3D Family Safety, Regulatory and Technical Specifications User Guide
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CS 8100 3D Family comply with Directive 93/42/EEC relating to medical devices.

CE
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Contents

1 Safety Information

Indications for Use

The CS 8100 3D Family is intended to produce complete or segmented tomographic digital panoramic images and three-dimensional digital X-ray images of the dento-maxillofacial area to be used at the direction of healthcare professionals as diagnostic support for pediatric and adult patients. In addition, the CS 8100SC 3D, CS 8100SC 3D Access and CS 8100SC 3D Select are also intended to produce cephalometric images. This includes imaging the hand and wrist to obtain carpus image for growth and maturity assessment.

The following chart illustrates the different product configurations of the CS 8100 3D Family:
The CS 8100 3D, CS 8100 3D Access and CS 8100 3D Select can be upgraded to Cephalometric Modality,
when the Scan Ceph module is provided as an upgrade kit.

This document refers to all models as CS 8100 3D Family unless otherwise specified.

	CS 8100 3D	CS 8100 3D Access	CS 8100 3D Select	CS 8100SC 3D	CS 8100SC 3D Access	CS 8100SC 3D Select
2D	✓	✓	✓	✓	✓	✓
	✓	✓	✓	✓	✓	✓
BW	✓	✓	↻	✓	✓	↻
	↻	↻	↻	✓	✓	✓
	✓	✓	✓	✓	✓	✓
5x5	✓	✓	↻	✓	✓	↻
8x5	✓	↻	✓	✓	↻	✓
8x9	✓	↻	↻	✓	↻	↻
	✓	✓	↻	✓	✓	↻

✓ Available ↻ Upgradable

WARNING: Do not use cone beam imaging for routine or screening examinations. Consider using other diagnostic tools. You must justify that the imaging method that you use to examine each patient demonstrates that the benefit outweighs the risks.

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 3D 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.**
- **The Technician who installs the unit has the responsibility to warn Carestream Dental if the post installation produces a failed error message which, if ignored, can result in the improper installation of the unit.**

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 1.83m 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 and the 3D bite blocks 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
- 3D bite blocks

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 3D Family Environmental Requirements” of the present guide.

Cleaning and disinfecting Ear cones of CS 8100SC 3D, CS 8100SC 3D Access and CS 8100SC 3D Select

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 accessories and the components that have skin contact

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

- Panoramic chin rest
- Sinus chin rest
- Temple support cone

The following component and accessory of the CS 8100SC 3D, CS 8100SC 3D Access and CS 8100SC 3D Select 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 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 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 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 accessory with compressed air or hygiene disposable cloth.

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

Disinfecting

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

1. Disinfect the 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 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

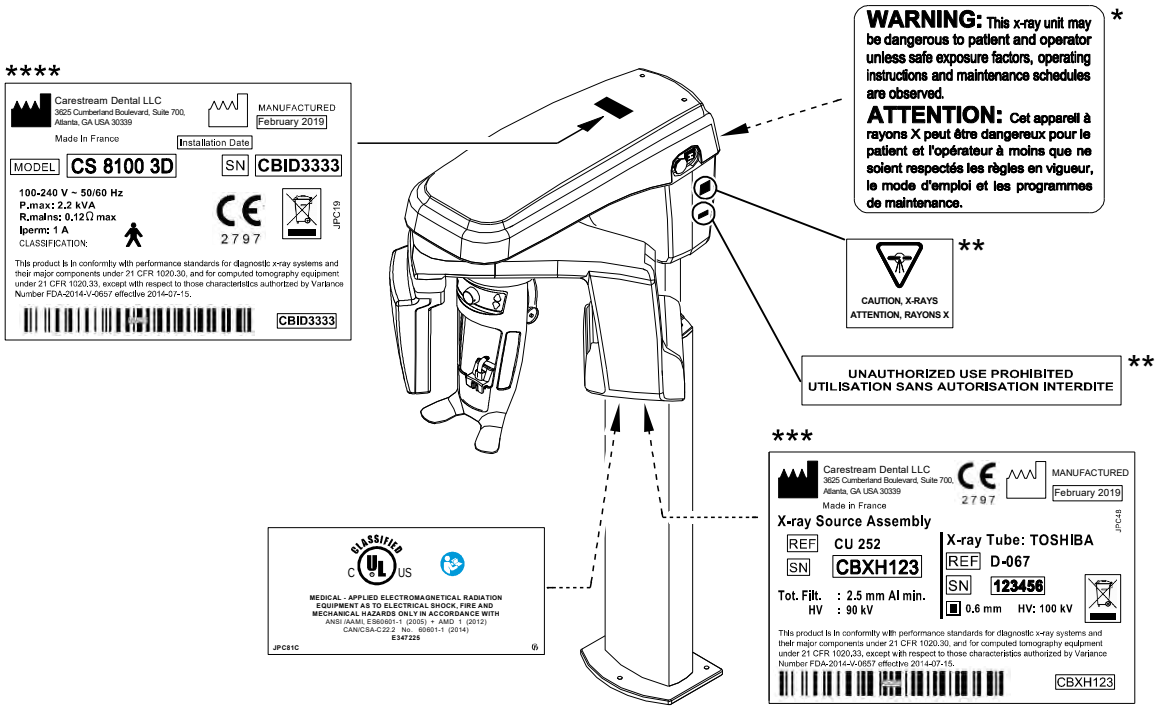
	Type B device symbol complying with the IEC 60601-1 standard.
	In the European Union, this symbol indicates: Do NOT discard this product in a trash receptacle; use an appropriate recovery and recycling facility. Contact your local sales representative for additional information on the collection and recovery programs available for this product.
	WARNING Attention, consult Accompanying document
	IONIZING RADIATION symbol 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 3D, CS 8100 3D Access and CS 8100 3D Select Labels

The following figure illustrates the label locations of the CS 8100 3D, CS 8100 3D Access and CS 8100 3D Select.

Figure 1 CS 8100 3D, CS 8100 3D Access and CS 8100 3D Select Label Locations



Important:

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

**** Canada specific labels.**

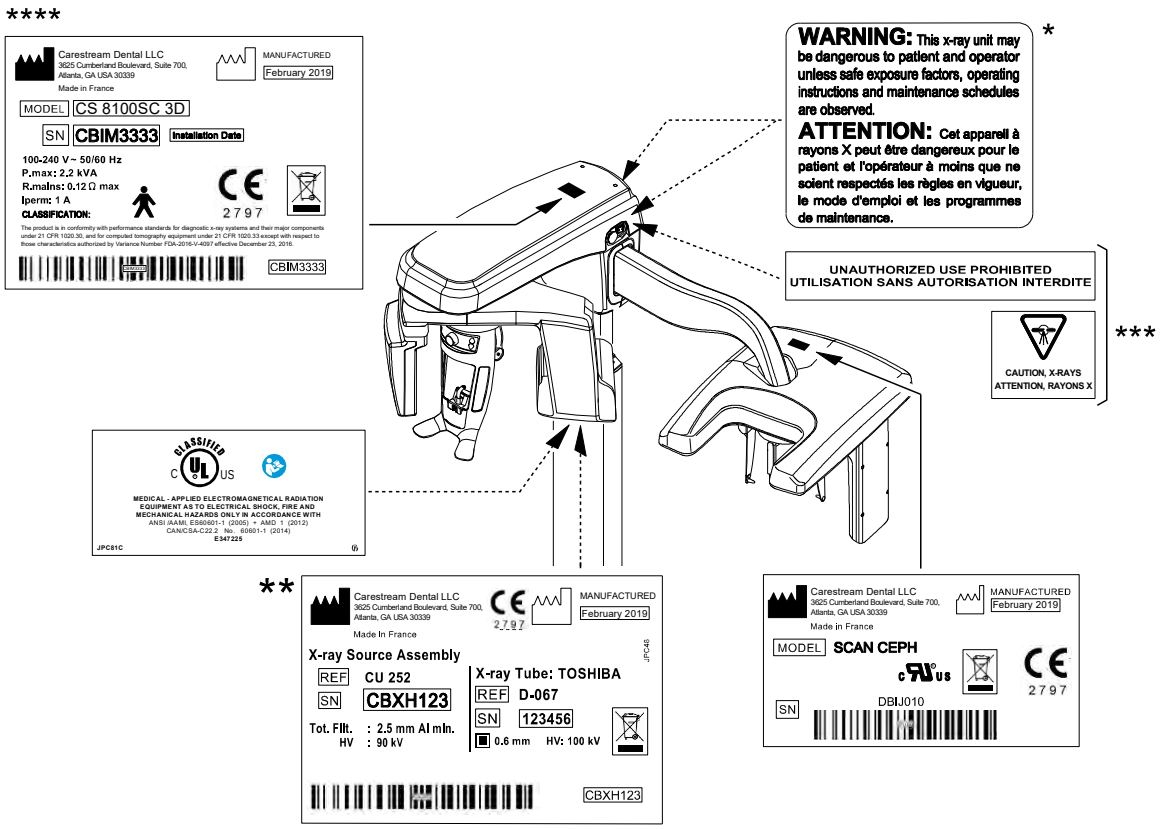
***** X-ray tube can be Toshiba/Canon D-067 or CEI OPX110.**

****** Product label can be CS 8100 3D, CS 8100 3D Access or CS 8100 3D Select.**

CS 8100SC 3D, CS 8100SC 3D Access and CS 8100SC 3D Select Labels

The following figure illustrates the label locations of the CS 8100SC 3D, CS 8100SC 3D Access and CS 8100SC 3D Select

Figure 2 CS 8100SC 3D, CS 8100SC 3D Access and CS 8100SC 3D Select Label Locations



Important:

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

**** X-ray tube can be Toshiba/Canon D-067 or CEI OPX110**

***** Canada specific labels**

****** Product label can be CS 8100SC 3D, CS 8100SC 3D Access or CS 8100SC 3D Select.**

Table 1 **Label Definition**

Label	Definition
MODEL	Defines the unit's model
Installation Date	Defines the date that the unit was installed
This product is in conformity with performance standards for diagnostic X-ray systems and their major components under 21 CFR 1020.30, and for computed tomography equipment under 21 CFR 1020.33, except with respect to those characteristics authorized by Variance Number FDA-2014-V-0657 effective 2014-07-15.	Defines the unit's compliance with the US FDA radiation standards Only applicable for CS 8100 3D
This product is in conformity with performance standards for diagnostic X-ray systems and their major components under 21 CFR 1020.30, and for computed tomography equipment under 21 CFR 1020.33, except with respect to those characteristics authorized by Variance Number FDA-2015-V-0980 effective 2015-05-28.	Defines the unit's compliance with the US FDA radiation standards Only applicable for CS 8100 3D Access
This product is in conformity with performance standards for diagnostic x-ray systems and their major components under 21 CFR 1020.30, and for computed tomography equipment under 21 CFR 1020.33, except with respect to those characteristics authorized by Variance Number FDA-2016-V-4097 effective December 23, 2016.	Defines the unit's compliance with the US FDA radiation standards Only applicable for CS 8100SC 3D and CS 8100SC 3D Access
This product is in conformity with performance standards for diagnostic x-ray systems and their major components under 21 CFR 1020.30, and for computed tomography equipment under 21 CFR 1020.33, except with respect to those characteristics authorized by Variance Number 2019-V-1916 effective May 28, 2019.	Defines the unit's compliance with the US FDA radiation standards Only applicable for CS 8100 3D Select and CS 8100SC 3D Select

2 Regulatory Information

General Regulatory Information

Compliance with European and International Standards	
EN/IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements For 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.
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing.
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 3D Family is intended to be used in a professional healthcare facility environment.

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

- Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC).
- CS 8100 3D Family must be installed and put into service according to the EMC information provided in this document.
- CS 8100 3D 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 3D Family System Components
Compliance to CS 8100 3D 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)

WARNINGS

- **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 the CS 8100 3D Family.**
- **Use limitation: the use of CS 8100 3D Family adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the CS 8100 3D Family equipment and the other equipment should be observed to verify that they are operating normally.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 1 m (39 in) to any part of the CS 8100 3D Family including cables specified by Carestream. Otherwise, it could result in degradation of the performance of the CS 8100 3D Family equipment.**

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)		
The CS 8100 3D Family is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 8100 3D Family should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The CS 8100 3D Family 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	The CS 8100 3D 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

The CS 8100 3D Family is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 8100 3D 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	**IEC 60601 Test 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 3D Family requires continued operation during power mains interruptions, it is recommended that the CS 8100 3D Family 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)		
The CS 8100 3D Family is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 8100 3D Family should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz and 6V at ISM 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 1 m (39 inches) to any part of the CS 8100 3D Family 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 CS 8100 3D Family is used exceeds the applicable RF compliance level above, the CS 8100 3D 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 3D Family.

Compliance with International Regulations

- Medical Device Directives 93/42/EEC, Class IIb as amended by 2007/47/EC.
- Directive 2011/65/EU on the Restriction Of the use of certain Hazardous Substances in electrical and electronic equipment (RoHS), as amended by Directive 2017/2102.
- FDA Center for Devices & Radiological Health:

  CS 8100 3D: This product is in conformity with performance standards for diagnostic X-ray systems and their major components under 21 CFR 1020.30, and for computed tomography equipment under 21 CFR 1020.33, except with respect to those characteristics authorized by Variance Number FDA-2014-V-0657 effective 2014-07-15 (USA).

  CS 8100 3D Access: This product is in conformity with performance standards for diagnostic X-ray systems and their major components under 21 CFR 1020.30, and for computed tomography equipment under 21 CFR 1020.33, except with respect to those characteristics authorized by Variance Number FDA-2015-V-0980 effective 2015-05-28 (USA).

  CS 8100SC 3D and CS 8100SC 3D Access: This product is in conformity with performance standards for diagnostic X-ray systems and their major components under 21 CFR 1020.30, and for the computed tomography equipment under 21 CFR 1020.33, except with respect to those characteristics authorized by Variance Number FDA-2016-V-4097 effective 2016-12-23 (USA).

  CS 8100 3D Select and CS 8100SC 3D Select: This product is in conformity with performance standards for diagnostic X-ray systems and their major components under 21 CFR 1020.30, and for computed tomography equipment under 21 CFR 1020.33, except with respect to those characteristics authorized by Variance Number 2019-V-1916 effective May 28, 2019.
- Radiation Emitting Devices Act - C34 (Canada).
- Medical Devices Regulations (Canada).

3 Technical Specifications

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 3D

CS 8100 3D Access

CS 8100SC 3D

CS 8100SC 3D Access

CS 8100 3D Select

CS 8100SC 3D Select

CS 8100 3D Family Technical Specifications

Table 2 **CS 8100 3D Family Technical Specifications**

Components	CS 8100 3D Family
X-ray Generator	
Tube voltage	60-90 kV
Tube current	2-15 mA
Frequency	140 kHz
Tube focal spot (IEC 60336)	0.7 mm with X-ray tube OPX110 0.6 mm with X-ray tube D-067
Total filtration	> 2.5 mm eq. Al
Anode voltage	90 kV
Cathode current	15 mA

Components	CS 8100 3D Family
Panoramic Modality	
Sensor technology	CMOS
Image field	6.4 x 140 mm (Adult) 6.4 x 120 mm (Pediatric)
Gray scale	16384 - 14 bits
Magnification	1.2
Radiological exams	Full panoramic Segmented panoramic Maxillary sinus Lateral TMJ x 2 Lateral TMJ x 4
Exposure mode	4 patient sizes (child, small adult, medium adult, large adult) 3 dental arch morphology (normal, square, sharp)
Exposure time	2 to 14 s
3D Modality	
Technology	Dental Volumetric Reconstruction (DVR)
Sensor technology	CMOS
Volume Field Of View (FOV) diameter x height (cm)	5 x 5 (Child 4 x 4) Optional for CS 8100 3D Select and CS 8100SC 3D Select 8 x 5 Optional for CS 8100 3D Access and CS 8100SC 3D Access 8 x 9* (Ontario 8 x8) Optional for CS 8100 3D Access, CS 8100 3D Select, CS 8100SC 3D Access and CS 8100SC 3D Select
Radiological exams	Full, upper or lower jaw Full, upper or lower molar Maxillary sinus Occlusion Focused teeth
Gray scale	16384 - 14 bits
Magnification	1.4
Voxel Size	75 µm minimum
Scan mode	Continuous
Exposure time	3 to 15 s
Reconstruction time	Less than 2 minutes based on the recommended computer system configuration requirements

* In Ontario (Canada), the use by dentists, of FOVs that are over 8 x 8, is subject to conditions

Components	CS 8100 3D CS 8100 3D Access CS 8100 3D Select	CS 8100SC 3D CS 8100SC 3D Access CS 8100SC 3D Select
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
Radiological exams	N/A	Lateral Frontal AP or PA Oblique Submento-vertex Carpus (optional)
Exposure time	N/A	2.9 to 11 s
Input voltage (AC)	100-240 V - 50/60 Hz	
Unit dimensions	330 (L) x 894 (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	92 kg (202 lb)	
Weight of only the cephalostat components	N/A	30 kg (77 lb)
Total weight	95 kg (202 lb)	125 kg (280 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	9th Generation Intel Core i5-9500 6 cores (3 GHZ base frequency, up to 4,4 GHz with Intel® Turbo Boost Technology)
RAM	4 GB	16 GB
Hard disk drive	▪ 1.2 GB for software installation ▪ 250 GB free space to use the software	▪ 4 GB for software installation ▪ 500 GB free space to use the software
Graphic board	Nvidia/ATI based board supporting Open GL 1.2 with 512 MB of dedicated video RAM on AGP x8 video bus	▪ Cuda version 10.1 or higher ▪ Compute capability 3 or higher ▪ Nvidia based board on PCI Express video bus with minimum 4 GB of video RAM
Display	1024 x 768 minimum screen resolution 32 bits color mode	1280 x 1024 minimum screen resolution 1/1000
Operating system	▪ Windows 7 (64 bits) ▪ Windows 8/8.1** (64 bits) ▪ Windows 10** (64 bits)	▪ Windows 10**
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

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

** CS 8100 3D Family is not compatible with touch screen desktop

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

X-ray Dose Emission Information

Panoramic mode for CS 8100 3D, CS 8100 3D Access and CS 8100 3D Select

Table 3 **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	133	116	86	59
Segmented Panoramic Anterior	Incisor	78	57	33	17
Segmented Panoramic Anterior and Posterior	Incisors, one molar block and TMJ	105	87	59	38
Segmented Panoramic Anterior and Posterior	Incisors and one molar block	100	82	55	34
Segmented Panoramic Posterior	One molar block and TMJ	44	36	26	18
Segmented Panoramic Posterior	Two molar blocks and TMJ	88	73	53	37
Segmented Panoramic Posterior	One molar block	38	31	23	15
Segmented Panoramic Posterior	Two molar blocks	78	62	46	31
Segmented Panoramic Bitewing	One molar blocks	71	60	42	22
Segmented Panoramic Bitewing	Two molar blocks	142	119	84	44
Segmented Panoramic Anterior and Posterior	Incisors and molars	123	107	78	53
TMJ x2	TMJ	27	22	16	11
TMJ x4	TMJ mouth open and mouth closed	54	44	32	22
Maxillary Sinus	Maxillary sinus	95	81	55	34

*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.

3D mode for CS 8100 3D, CS 8100 3D Access and CS 8100 3D Select

Table 4 **Dose information for 3D modality**

	kV	90	90	90	87
	mA	4	3,2	2,5	2
		Patient size			
Radiological exam	**FoV**	**Large**	**Medium**	**Small**	**Child**
		DAP* in mGy.cm.cm			
Jaw	8x 9**	1372	1097	857	NA
Jaw	8x9** Fast	640	512	400	NA
One arch (Lower or Upper Jaw)	8x5	856	685	535	396
One arch (Lower or Upper Jaw)	8x5 Fast	399	319	249	184
Jaw	8x8	1247	997	779	576
Jaw	8x8 Fast	581	465	363	269
Focused teeth	5x5 Fast	248	198	155	NA
Focused teeth	4x4 Fast	NA	NA	NA	78

	kV	90	90	90	90
	mA	6,3	5	4	2,5
		Patient size			
Radiological exam	**FoV**	**Large**	**Medium**	**Small**	**Child**
		DAP* in mGy.cm.cm			
Focused teeth	5x5	838	665	532	NA
Focused teeth	4x4	NA	NA	NA	228

*DAP: Dose Area Product. The accuracy of DAP in the table above is +/-30 % when compared with the values that could be measured.
** 8 x 9 FoV: In Ontario (Canada), the use by dentists, of FOVs that are over 8 x 8, is subject to conditions.

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

	kV	90	90	85	80
	mA	2,5	2	2	2
		Patient size			
Radiological exam	**FoV**	**Large**	**Medium**	**Small**	**Child**
		DAP* in mGy.cm.cm			
Jaw	8x9** Low dose	177	142	124	NA
Jaw	8x8 Low dose	161	129	113	98
One arch (Lower or Upper Jaw)	8x5 Low dose	111	88	78	67
Focused teeth	5x5 Low dose	69	55	48	NA
Focused teeth	4x4 Low dose	NA	NA	NA	29

*DAP: Dose Area Product. The accuracy of DAP in the table above is +/-30 % when compared with the values that could be measured.
** 8 x 9 FoV: In Ontario (Canada), the use by dentists, of FOVs that are over 8 x 8, is subject to conditions.

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

Panoramic mode for CS 8100SC 3D, CS 8100SC 3D Access and CS 8100SC 3D Select

Table 5 **Dose information for Panoramic modality**

	kV	76	73	72	68
	mA	8	8	6.3	6.3
		Patient size			
Radiological exam	**Area of interest**	**Large**	**Medium**	**Small**	**Child**
		DAP* in mGy.cm.cm			
Full Panoramic	Incisors, molars and TMJ	102	91	66	46
Segmented Panoramic Anterior	Incisor	60	44	26	14
Segmented Panoramic Anterior and Posterior	Incisors, one molar block and TMJ	81	68	46	30
Segmented Panoramic Anterior and Posterior	Incisors and one molar block	78	64	43	28
Segmented Panoramic Posterior	One molar block and TMJ	34	28	20	14
Segmented Panoramic Posterior	Two molar blocks and TMJ	68	57	42	29
Segmented Panoramic Posterior	One molar block	30	25	18	12
Segmented Panoramic Posterior	Two molar blocks	61	49	35	25
Segmented Panoramic Bitewing	One molar block	54	47	32	17
Segmented Panoramic Bitewing	Two molar blocks	109	93	65	34
Segmented Panoramic Anterior and Posterior	Incisors and molars	94	83	61	41
TMJ x2	TMJ	20	17	12	9
TMJ x4	TMJ mouth open and mouth closed	42	35	25	17
Maxillary Sinus	Maxillary sinus	73	63	43	27

*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.

3D mode for CS 8100SC 3D, CS 8100SC 3D Access and CS 8100SC 3D Select

Table 6 **Dose information for 3D modality**

	kV	90	90	90	80
	mA	3.2	2.5	2	2
		Patient size			
Radiological exam	**FoV**	**Large**	**Medium**	**Small**	**Child**
		DAP* in mGy.cm.cm			
Jaw	8x9**	1509	1179	943	NA
Jaw	8x9** Fast	704	550	440	NA
One arch (Lower or Upper Jaw)	8x5	916	715	572	453
One arch (Lower or Upper Jaw)	8x5 Fast	427	334	267	211
Jaw	8x8	1347	1052	842	665
Jaw	8x8 Fast	628	491	393	310
Focused teeth	5x5 Fast	273	214	171	NA
Focused teeth	4x4 Fast	NA	NA	NA	92

	kV	90	90	90	90
	mA	5	4	3.2	2
		Patient size			
Radiological exam	**FoV**	**Large**	**Medium**	**Small**	**Child**
		DAP* in mGy.cm.cm			
Focused teeth	5x5	916	732	586	NA
Focused teeth	4x4	NA	NA	NA	249

*DAP: Dose Area Product. The accuracy of DAP in the table above is +/-30 % when compared with the values that could be measured.
** 8 x 9 FoV: In Ontario (Canada), the use by dentists, of FOVs that are over 8 x 8, is subject to conditions.

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

	kV	85	80	75	70
	mA	2	2	2	2
		Patient size			
Radiological exam	**FoV**	**Large**	**Medium**	**Small**	**Child**
		DAP* in mGy.cm.cm			
Jaw	8x9** Low dose	174	154	134	NA
Jaw	8x8 Low dose	156	137	119	101
One arch (Lower or Upper Jaw)	8x5 Low dose	106	94	81	69
Focused teeth	5x5 Low dose	68	60	52	NA
Focused teeth	4x4 Low dose	NA	NA	NA	30

*DAP: Dose Area Product. The accuracy of DAP in the table above is +/-30 % when compared with the values that could be measured.
** 8 x 9 FoV: In Ontario (Canada), the use by dentists, of FOVs that are over 8 x 8, is subject to conditions.

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

Cephalometric mode for CS 8100SC 3D, CS 8100SC 3D Access and CS 8100SC 3D Select

Table 7 **Patient Dose information for Cephalometric modality for Lateral exam**

kV	90	87	86	82
mA	10	10	8	8

	Patient size			
Program	**Large**	**Medium**	**Small**	**Child**
	DAP* in mGy.cm.cm			
18x18 High resolution	16	15	12	11
18x18 Fast	7	6	5	5
18x24 High resolution	19	18	14	13
18x24 Fast	8	8	6	5
26x24 High resolution	28	26	20	18
26x24 Fast	12	11	9	8

*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 tables 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	74	72	72	68
mA	15	15	15	15

	Patient size			
Program	**Large**	**Medium**	**Small**	**Child**
	DAP* in mGy.cm.cm			
18x18 High resolution	16	15	15	13
18x18 Fast	7	6	6	6
18x24 High resolution	19	18	18	15
18x24 Fast	8	8	8	7
26x24 High resolution	27	25	25	22
26x24 Fast	12	11	11	9

*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 tables 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	87	86	82
mA	10	10	8	8

	Patient size			
Program	**Large**	**Medium**	**Small**	**Child**
	DAP* in mGy.cm.cm			
18x18 High resolution	18	16	13	12
18x18 Fast	8	7	6	5
18x24 High resolution	21	20	15	14
18x24 Fast	10	9	7	6
26x24 High resolution	30	28	22	20
26x24 Fast	14	13	10	9

*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.

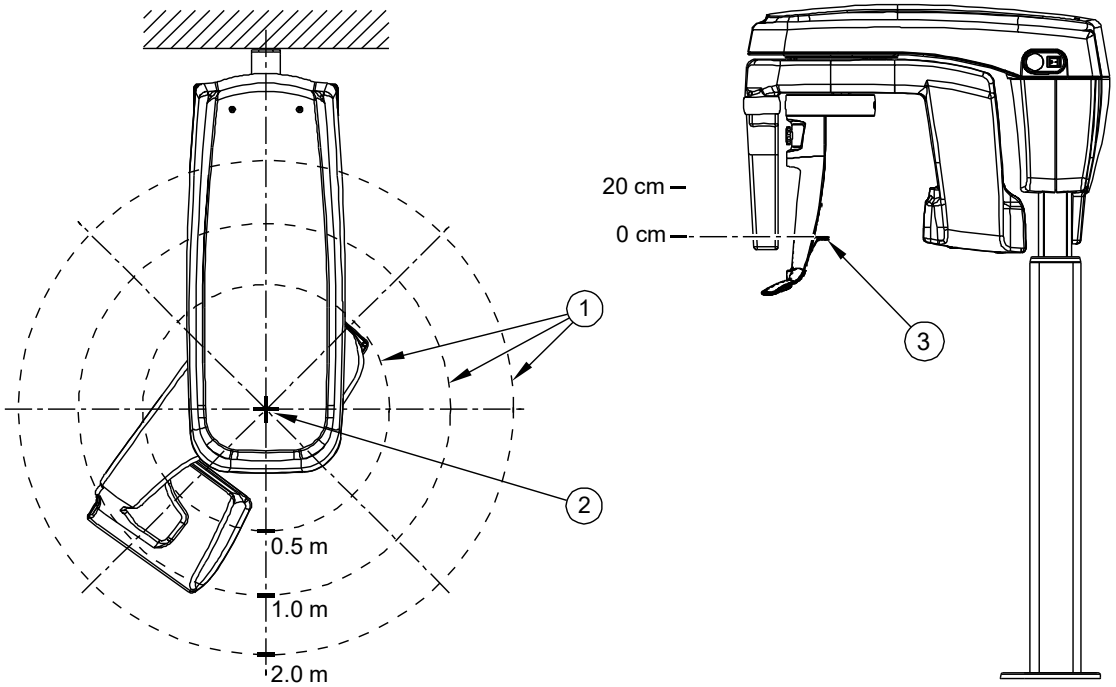
User Dose information

Stray radiation in Panoramic Mode

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

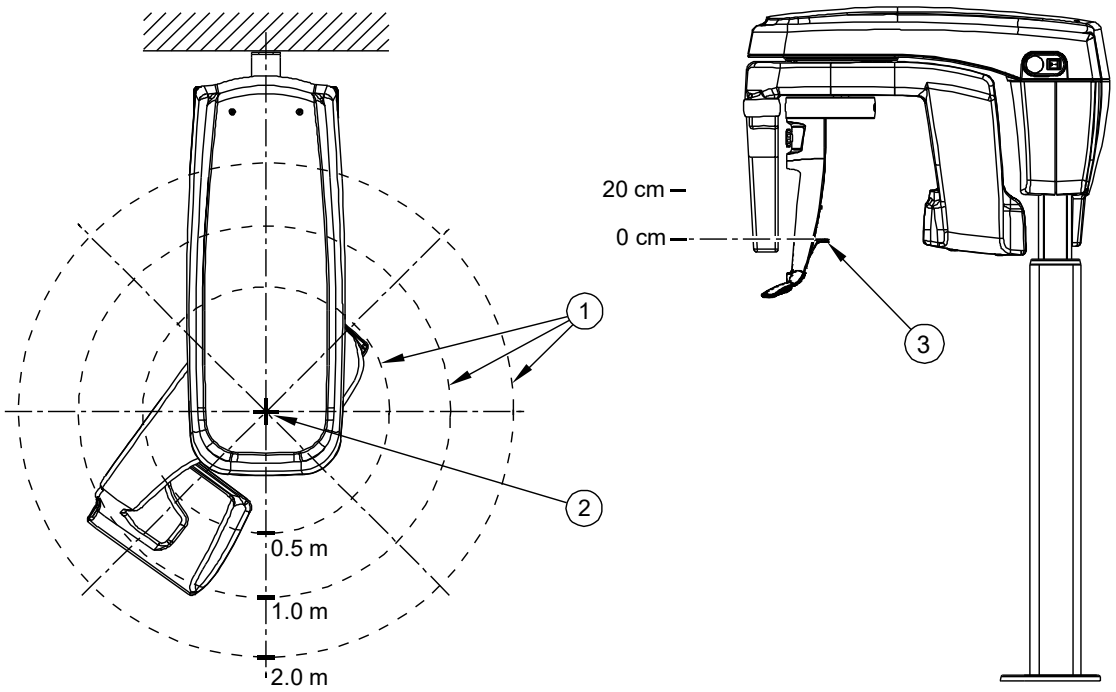
*****This is the maximum value measured 20 cm above the horizontal cross sectional plane with a chin rest. Other values in the vertical axis are lower than these values.

Stray radiation in 3D Mode

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 4 Circular Points of Measurement

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



Stray radiation is measured in largest 3D mode available, ie 8x9 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 8 exams per hour.	
Distance between the rotation axis and measurement point (Circular Points of Measurement)	Stray radiation*
0.5 m	420 µGy /h
1.0 m	105 µGy /h
2.0 m	26 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	108 µGy /h
1.0 m	27 µGy /h
2.0 m	7 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

Panoramic and Cephalometric

Line Pair Resolution*: 3.1 lp/mm minimum.
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.

3D

The value of the Modulation Transfer Function** (MTF) at 10 % is superior to 1 lp/mm.
The Signal-to-Noise Ratio (SNR) measured in an homogeneous 1 mm thick slice of PMMA*** material is greater than 10.
** Using a dental phantom for digital image acquisition that complies with the DIN 6868-161 standard.
*** Polymethyl methacrylate (PMMA) is a transparent thermoplastic material.
The CS 8100 3D Family do not provide Computed Tomography (CT) numbers, therefore, conventional analyses using CT numbers cannot be made.

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 ***Panoramic and 3D Modality User Guide for CS 8100 3D Family, (SM842)***.

CS 8100 3D 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 3D 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

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

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

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

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 (0.07") eq. Al
Nominal value of the supplementary filtration at 70 kV	2.5 mm (0.10'') eq. Al min
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 (0.020") eq. Al
Filtration value for the sensor case (at 100 kV)	1 mm (0.039") eq. Al

The X-ray generator comprises the following:

- Transformers and an X-ray tube and their associated electronic components immersed in oil
- Copper filter (for CS 8100 3D, CS 8100 3D Access and CS 8100 3D Select) or Copper + Aluminum filter (for CS 8100SC 3D, CS 8100SC 3D Access and CS 8100SC 3D Select), 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 5 Location of the Reference Axis for Panoramic and 3D Imaging

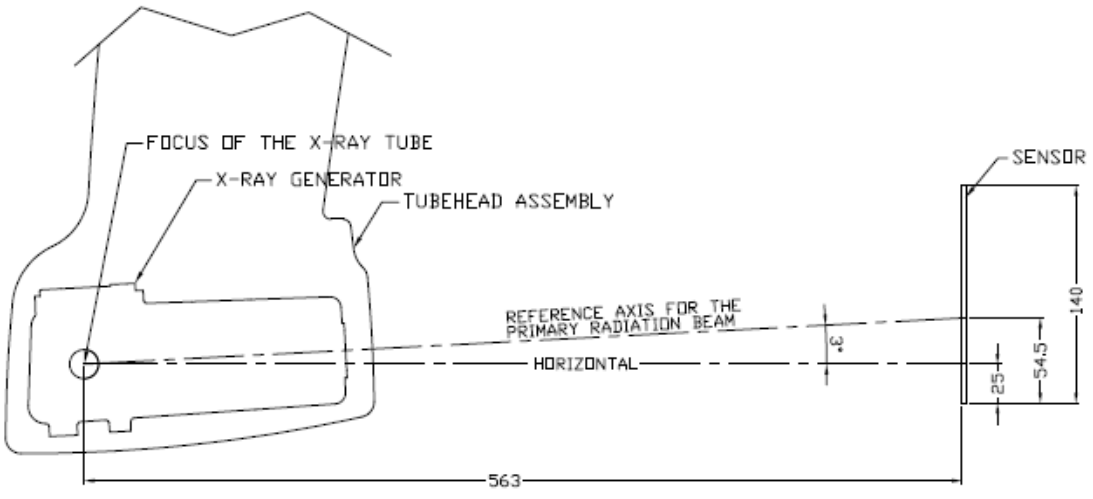


Figure 6 Location of the Reference Axis for Cephalometric Imaging

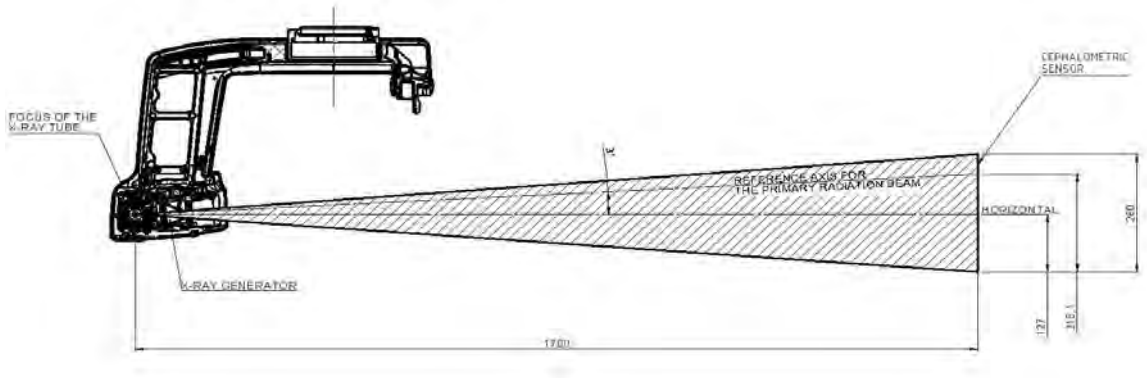


Table 11**Technical Specifications of the X-ray tube Assembly**

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	0.7 mm with X-ray tube OPX 110 0.6 mm with X-ray tube D-067
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 (110 kJ)	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 7 Heating and Cooling Curves of the X-ray Tube Assembly

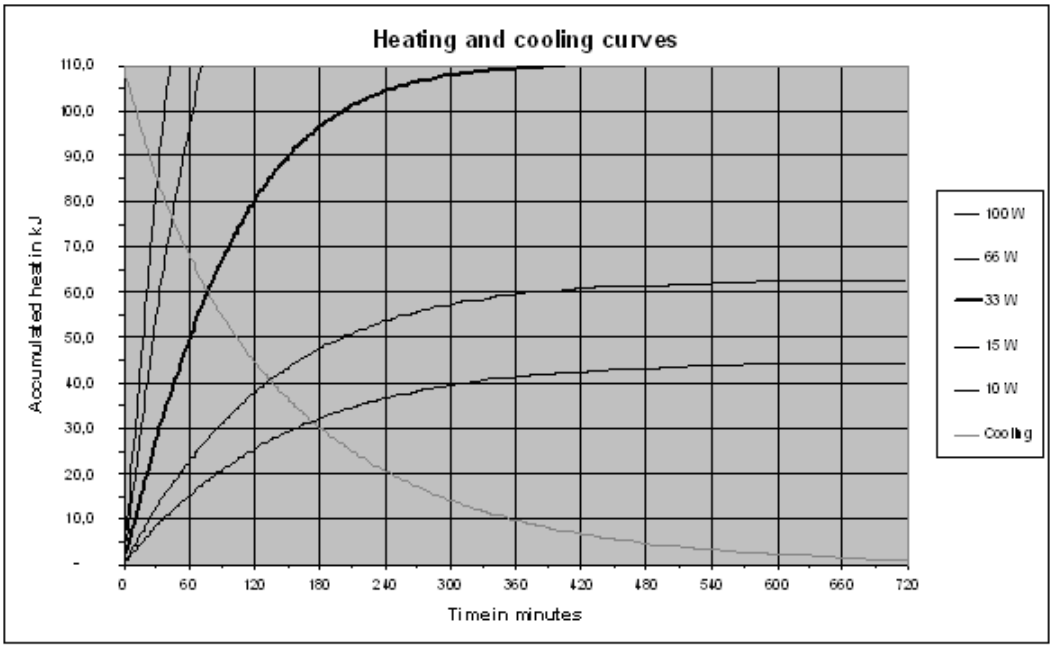


Table 12 **Beam Limitations of the X-ray Tube Assembly**

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 563 mm from the focal point	5 mm x 140 mm At the detector reference plane
Maximum symmetrical field of radiation in 3D mode at a distance of 563 mm from the focal point	120mm x 140mm At the detector reference plane
Maximum symmetrical field of radiation in cephalometric mode at 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 5 and Figure 6Location of the Reference Axis for Panoramic and 3D Imaging

Table 13 **Characteristics of the X-ray Tube**

Manufacturer’s name	CEI	Toshiba or Canon
Type	OPX110	D-067
Nominal high voltage	110 kV	100 kV
Nominal anode input power at 0.1 s (AC)	1755 W	1260 W
Anode heat storage capacity	30kJ	35 kJ
Nominal focal spot size (IEC 60336)	0.7 mm	0.6 mm
Anode materials	Tungsten	Tungsten
Target angle	12°	12°
Inherent filtration	0.5 mm (0.020 ") eq. Al	0.8 mm (0.032’’) eq. Al

Figure 8.1 X-ray tube drawing OPX110

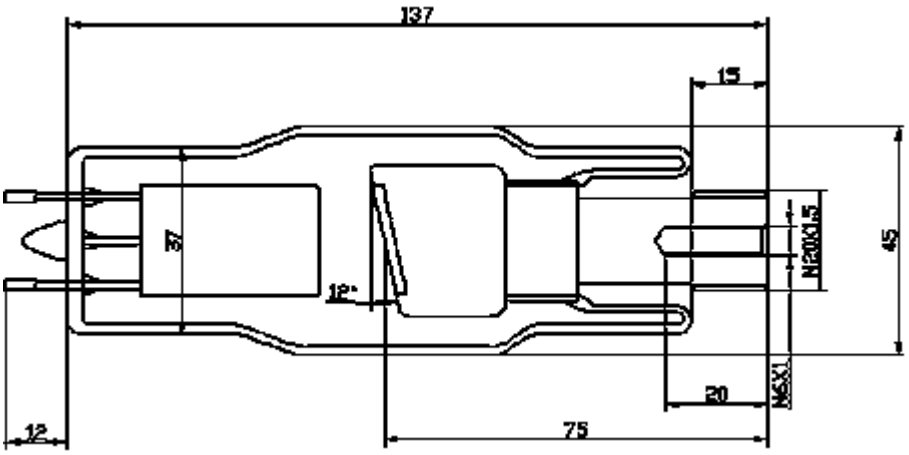


Figure 8.2 X-ray tube drawing D-067

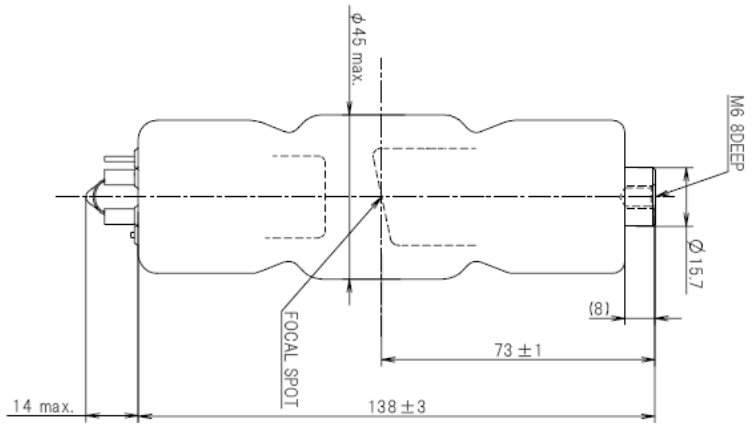


Figure 9.1 Heating and Cooling Curves of the X-ray Tube OPX110

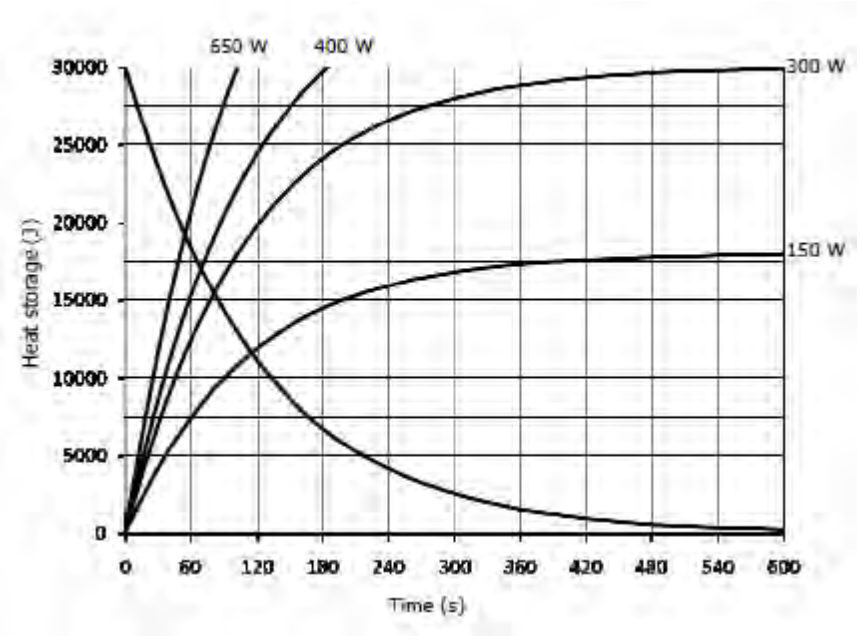


Figure 9.2 Heating and Cooling Curves of the X-ray Tube D-067

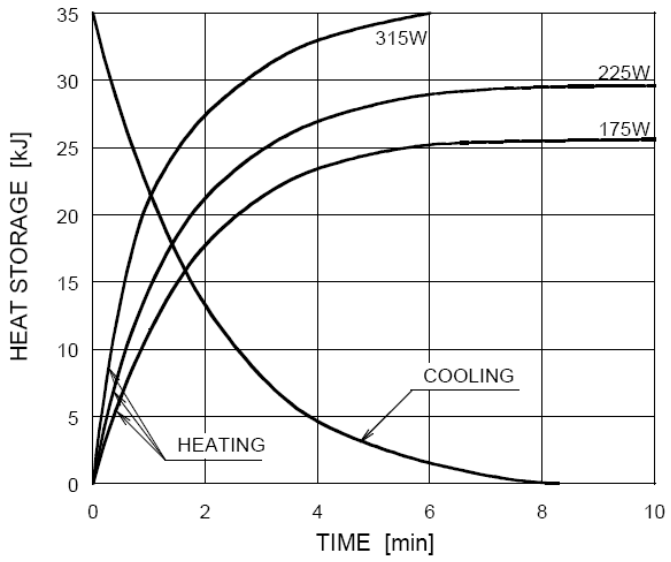


Figure 10.1 Single Load Chart of the X-ray Tube OPX110

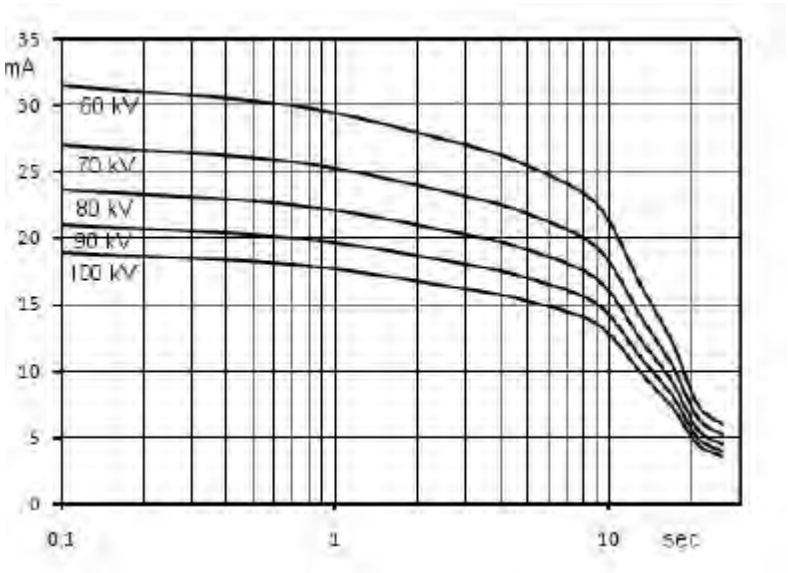


Figure 10.2 Single Load Chart of the X-ray Tube D-067

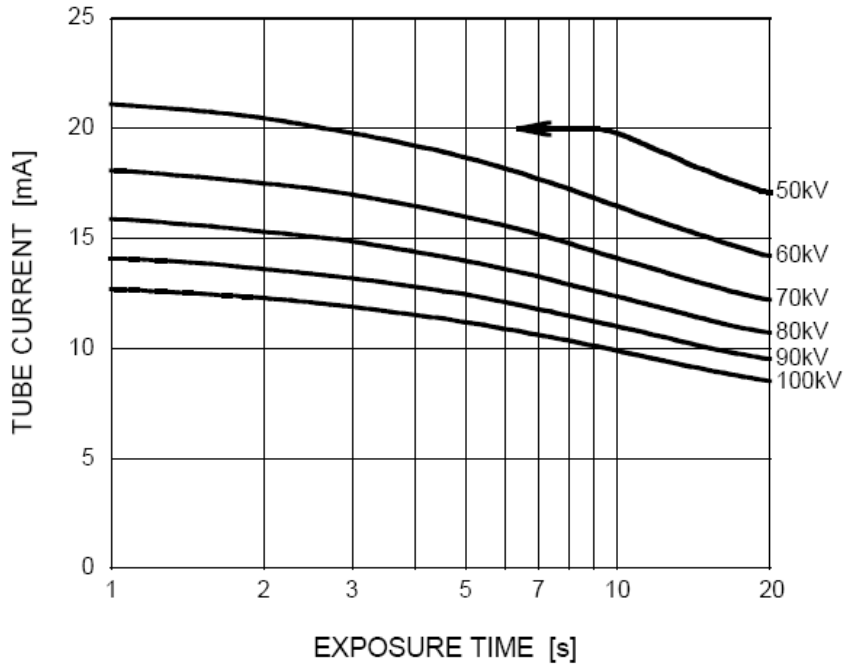


Figure 11.1 Filament Emissions of the X-ray Tube OPX110

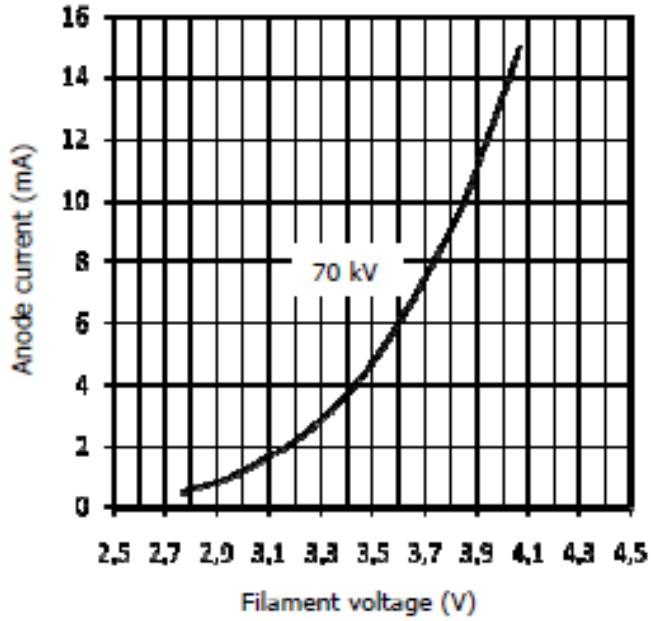
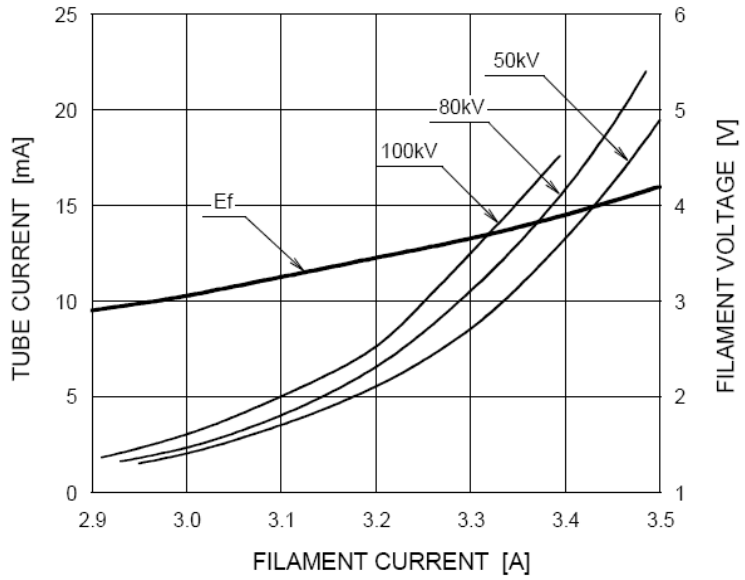


Figure 11.2 Filament Emissions of the X-ray Tube D-067



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