

# CS 8200 3D Family



Safety, Regulatory and Technical Specifications User Guide

# Notice

The Regulatory Information and Technical Specifications User Guide for CS 8200 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 8200 3D Family comprises:

CS 8200 3D: Complete or segmented tomographic digital panoramic X-ray images and three-dimensional 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.

CS 8200 3D Access: Complete or segmented tomographic digital panoramic X-ray images and three-dimensional 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.

Both systems have the capability to expand the field of view with optional licenses upgrade.

The CS 8200 3D Family can be upgraded to cephalometric modality with the Scan Ceph module option

This document refers to all models as CS 8200 3D Family unless otherwise specified.

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

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

This document is originally written in English.

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The CS 8200 3D Family complies with the Medical Device Regulation (EU) 2017/745 and UK Medical Devices Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).



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# 1 Safety Information

## Indications for Use

The CS 8200 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 8200 3D Family can be upgraded to produce cephalometric digital X-ray images. This includes imaging the hand and wrist to obtain carpus image for growth and maturity assessment.

The CS 8200 3D Family can be upgraded to cephalometric modality with the Scan Ceph module option.

The following chart illustrates the different product configurations of the CS 8200 3D Family:

|                                                                                                                    | CS 8200 3D | CS 8200 3D Access                                    | Scan Ceph for CS 8200 3D Family |
|--------------------------------------------------------------------------------------------------------------------|------------|------------------------------------------------------|---------------------------------|
| <b>2D</b>                                                                                                          | ✓          | ✓                                                    |                                 |
|                                   | ✓          | ✓                                                    |                                 |
|                                 | ✓          | ✓                                                    |                                 |
|                                 | ✓          | ✓                                                    |                                 |
|                                 | ✓          | ✓                                                    |                                 |
|                                 |            |                                                      | ✓                               |
| <b>3D</b>                                                                                                          | ✓          | ✓                                                    |                                 |
| <br>4x4 - 5x5 - 5x8             | ✓          | ✓<br>• 4x4 - only for pediatric patients<br>• No 5x8 |                                 |
| <br>8x9 - 8x5                   | ✓          | ✓                                                    |                                 |
| <br>10x10 - 10x5 - 12x10 - 12x5 |            | Upgradable<br>Limited to 10x10 and 10x5              |                                 |
| ✓ Available                                                                                                        | Upgradable |                                                      |                                 |

This document refers to all models as CS 8200 3D unless otherwise specified.



**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.**

## Clinical benefits and performance characteristics

The CS 8200 3D Family benefits healthcare professionals by allowing them to acquire digital X-ray images (two-dimensional and three-dimensional) of the dento-maxillofacial regions. These outcomes allow the healthcare professional to support image diagnosis, establish relevant treatment plan and thus improve the clinical patient management. The clinical benefits of the CS 8200 3D Family are the positive impact that it has on patient management.

The clinical performances of the CS 8200 3D Family stem from the technical characteristics of the extraoral X-ray equipment defined in the IEC/EN 60601-2-63 standard. The characteristics are:

- Accuracy of loading factors (X-ray tube voltage, X-ray tube current, irradiation time and current time).
- Reproducibility of the radiation output.

## 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

There are no contra-indications identified for the CS 8200 3D Family. When operating the unit, observe the following warning and safety instructions:



Important: All known residual risks, contra-indications or undesirable side-effects are listed in this guide. If any serious incident occurs in relation to the device, you must report it to Carestream Dental and to the competent authority in your country.



### 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.
- 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 60950-1 or IEC 62368-1 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.**

## Disposal:



This equipment contains certain materials and chemical compounds incidental to the manufacture of electrical and electronic equipment, and improper “end-of-life” disposal of such equipment can result in environmental contamination. Therefore, this equipment should not be disposed of as ordinary household waste but should instead be delivered to a designated electrical and electronic waste disposal or recycling center. For further information on disposing of electrical and electronic waste, contact the cognizant authority within the local jurisdiction.

- **To dispose of the unit or its components, contact a service technician.**

## Precaution before use

Perform the following Cleaning and Disinfection activities on your product and accessories before use.

## Cleaning 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 be cleaned before use.

- Disposable Bite Block

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.**

**Disposable bite block (single use) need to be cleaned before use, but NOT disinfected by autoclave**

## 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 8200 3D Family Environmental Requirements" of the present guide.

## Cleaning and disinfecting Ear cones of Scan ceph module (optional)



### **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 Scan Ceph module (optional) 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:

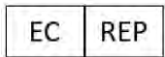
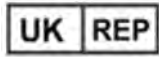
1. Disinfect the accessory by using an EPA-registered hospital disinfectant for low-level activity or low-level disinfectant that is recognized by your Local Authority (for example, quaternary ammonium compounds and some phenolics). **You must follow the disinfectant's manufacturer instructions for use, 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<br>Attention, consult accompanying document.                                                                                                                                                                                                                                        |
|    | IONIZING RADIATION symbol to warn you about radiation dangers.                                                                                                                                                                                                                              |
|    | The ON/OFF button.                                                                                                                                                                                                                                                                          |
|   | Refer to instruction manual/booklet.                                                                                                                                                                                                                                                        |
|  | Manufactured Date.                                                                                                                                                                                                                                                                          |
|  | Manufacturer's address.                                                                                                                                                                                                                                                                     |
|  | Earth protection (ground).                                                                                                                                                                                                                                                                  |
|  | Medical Device.                                                                                                                                                                                                                                                                             |
|  | Name of the European Authorized Representative and address of the registered place of business.                                                                                                                                                                                             |
|  | Name of the Responsible Person in the United Kingdom and address of the registered place of business.                                                                                                                                                                                       |
|  | Swiss Authorised Representative.                                                                                                                                                                                                                                                            |
|  | Catalogue number.                                                                                                                                                                                                                                                                           |

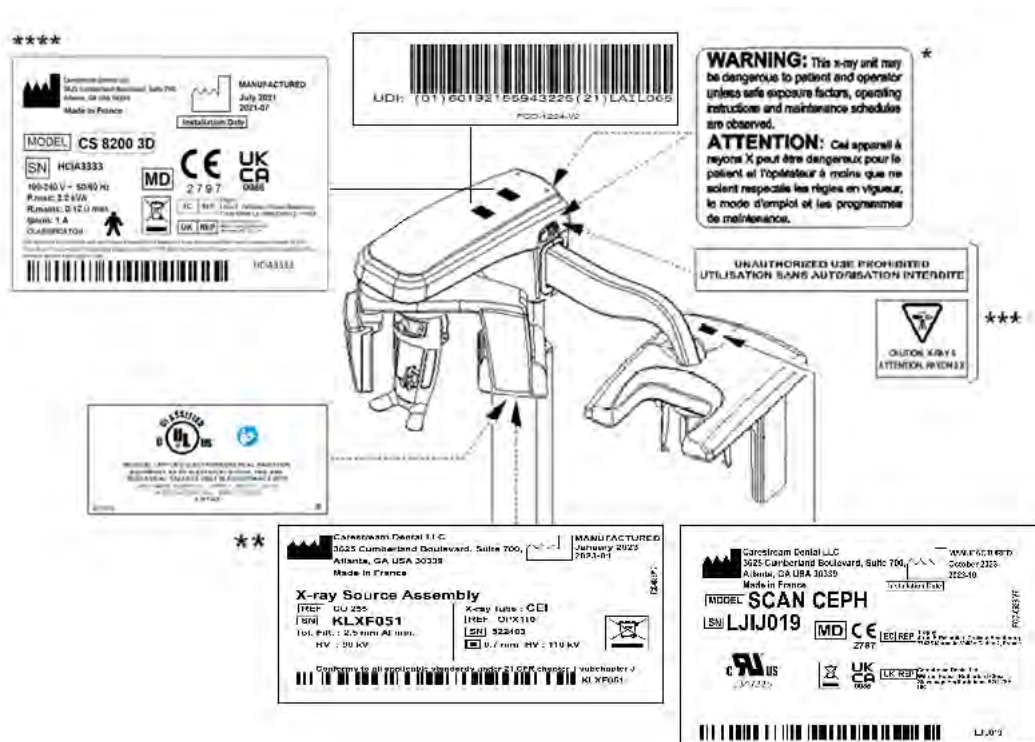
## CS 8200 3D Family Labels

### Figure 1 CS 8200 3D Family Label Locations



\* 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 8200 3D or C8200 3D Access.

**Figure 2 CS 8200 3D Family Label Locations (with Scan Ceph configuration)**



**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 8200 3D CS 8200SC 3D or C8200SC 3D Access.

**Table 1 Label Definition**

| Label                                                                                                                                                                                                                                                                                                                                                                   | Definition                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
|                                                                                                                                                                                                                                                                                      | Defines the unit's model                     |
|                                                                                                                                                                                                                                                                                      | Defines the date that the unit was installed |
| <p>This product is in conformity with performance Defines the unit's compliance with the US FDA standards for diagnostic X-ray systems and their radiation standards 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-2020-V-1568.</p> |                                              |

# 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 62366-1                                       | Medical devices – Part 1: 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 ISO 20417                                         | Medical devices - Information to be supplied by the manufacturer.                                                                                                                     |
| 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 8200 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 8200 3D Family must be installed and put into service according to the EMC information provided in this document.
- CS 8200 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 8200 3D Family System Components

Compliance to CS 8200 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 8200 3D Family.
- **Use limitation:** the use of CS 8200 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 8200 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 8200 3D Family including cables specified by Carestream. Otherwise, it could result in degradation of the performance of the CS 8200 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 8200 3D Family is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 8200 3D Family should assure that it is used in such an environment.

| Emissions Test                                              | Compliance | Electromagnetic Environment - Guidance                                                                                                                                                                                             |
|-------------------------------------------------------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RF emissions<br>CISPR 11                                    | Group 1    | The CS 8200 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<br>CISPR 11                                    | Class B    | The CS 8200 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<br>IEC 61000-3-2                         | Class A    |                                                                                                                                                                                                                                    |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | Complies   |                                                                                                                                                                                                                                    |

## Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The CS 8200 3D Family is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 8200 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)<br>IEC 61000-4-2                                                         | ±8 kV contact<br>±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<br>IEC 61000-4-4                                                       | ±2 kV for power supply lines<br>±1 kV for input/output lines                            | Mains power quality should be that of a typical commercial or hospital environment.                                                                                                                                                                                                                |
| Surge<br>IEC 61000-4-5                                                                                 | ±1 kV line(s) to line(s)<br>±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<br>IEC 61000-4-11 | 0 % UT for 0.5 cycle at 8 angles<br>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 8200 3D Family requires continued operation during power mains interruptions, it is recommended that the CS 8200 3D Family be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>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 8200 3D Family is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 8200 3D Family should assure that it is used in such an environment.

| Immunity Test                 | IEC 60601 Test Level                                                                                    | Electromagnetic Environment - Guidance                                                                                                                                                                                                                                                                                         |
|-------------------------------|---------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Conducted RF<br>IEC 61000-4-6 | 3 V<br>150 kHz to 80 MHz and 6V at ISM Frequencies                                                      | Environment of a care facility professional health.                                                                                                                                                                                                                                                                            |
| Radiated RF<br>IEC 61000-4-3  | 3 V/m<br>80 MHz to 2.7 GHz<br>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 8200 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 8200 3D Family is used exceeds the applicable RF compliance level above, the CS 8200 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 8200 3D Family.

## Compliance with International Regulations

- Medical Device Regulation (EU) 2017/745, Class IIb.
- Directive 2011/65/EU on the Restriction Of the use of certain Hazardous Substances in electrical and electronic equipment (RoHS), as amended by Directive (EU) 2015/863.
- UK Medical Devices Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478), Class IIb.
- FDA Center for Devices & Radiological Health: 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-2020-V-1568 (USA).
- Radiation Emitting Devices Act - C34 (Canada).
- Medical Devices Regulations (Canada).

# 3 Technical Specifications

## Model

CS 8200 3D Family

## CS 8200 3D Family Technical Specifications

Table 2 CS 8200 3D Family Technical Specifications

| Components                  | CS 8200 3D Family                                             |
|-----------------------------|---------------------------------------------------------------|
| <b>X-ray Generator</b>      |                                                               |
| 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<br>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 8200 3D Family                                                                              |
|---------------------------|------------------------------------------------------------------------------------------------|
| <b>Panoramic Modality</b> |                                                                                                |
| Sensor technology         | CMOS                                                                                           |
| Image field               | 6.4 x 140 mm (Adult)<br>6.4 x 120 mm (Pediatric)                                               |
| Gray scale                | 16384 - 14 bits                                                                                |
| Magnification             | 1.2                                                                                            |
| Radiological exams        | Full panoramic<br>Segmented panoramic<br>Maxillary sinus<br>Lateral TMJ x 2<br>Lateral TMJ x 4 |

| Components                                        | CS 8200 3D Family                                                                                                                                                                                    |
|---------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Exposure mode                                     | 4 patient sizes (child, small adult, medium adult, large adult)<br>3 dental arch morphology (normal, square, sharp)                                                                                  |
| Exposure time                                     | 2 to 14 s                                                                                                                                                                                            |
| <b>3D Modality</b>                                |                                                                                                                                                                                                      |
| Technology                                        | Dental Volumetric Reconstruction (DVR)                                                                                                                                                               |
| Sensor technology                                 | CMOS                                                                                                                                                                                                 |
| Volume Field Of View (FOV) diameter x height (cm) | 4 x 4<br>5 x 5<br>5 x 8 (not available for access version)<br>8 x 5<br>8 x 9 (Ontario 8 x 8) *<br>10 x 5 - 10 x 10** (optional)<br>12 x 5 and 12 x 10** (optional, not available for access version) |
| Radiological exams                                | Full, upper or lower jaw<br>Full, upper or lower molar<br>Maxillary sinus<br>Occlusion<br>Focused teeth                                                                                              |
| Gray scale                                        | 16384 - 14 bits                                                                                                                                                                                      |
| Magnification                                     | 1.4                                                                                                                                                                                                  |
| Voxel Size                                        | 75 µm minimum                                                                                                                                                                                        |
| Scan mode                                         | Continuous                                                                                                                                                                                           |
| Exposure time                                     | 3 to 15 s for FOV < 10 cm (Ø) / to 20 s for FOV ≥ 10 cm (Ø)                                                                                                                                          |

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

\*\* With tip

| Components                                                                       | CS 8200 3D Family                                                              |
|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| <b>Cephalometric Modality (optional, available with Scan Ceph configuration)</b> |                                                                                |
| Sensor technology                                                                | CMOS                                                                           |
| Image field                                                                      | 6.4 x 263.3 mm                                                                 |
| Gray scale                                                                       | 16384 – 14 bits                                                                |
| Magnification                                                                    | 1.13                                                                           |
| Radiological exams                                                               | Lateral<br>Frontal AP or PA<br>Oblique<br>Submento-vertex<br>Carpus (optional) |
| Exposure time                                                                    | 2.9 to 11 s                                                                    |

| Components                          | CS 8200 3D Family                                                                                     |
|-------------------------------------|-------------------------------------------------------------------------------------------------------|
| <b>Input voltage (AC)</b>           | 100-240 V - 50/60 Hz                                                                                  |
| <b>Unit dimensions</b>              | 330 (L) x 894 (D) x 1596 (H) mm<br>1842 (L) x 936 (D) x 1596 (H) mm (with Scan Ceph configuration)    |
| <b>Minimum required Space</b>       | 1200 (L) x 1400 (D) x 2400 (H) mm<br>2000 (L) x 1400 (D) x 2400 (H) mm (with Scan Ceph configuration) |
| <b>Weight without the Scan Ceph</b> | 92 kg (202 lb)                                                                                        |
| <b>Weight with Scan Ceph</b>        | 125 kg (280 lb)                                                                                       |

## Minimum Computer System Requirement

The computer and the peripheral equipment must conform to the IEC 60950-1 or IEC 62368-1 standard.

| Item                      | Viewing                                                                                              | Acquisition                                                                                                                                                                                     |
|---------------------------|------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>CPU</b>                | 2 GHz Intel Duo Core                                                                                 | 2,4 Ghz Intel Duo Core                                                                                                                                                                          |
| <b>RAM</b>                | 4 GB (16 GB for CS MAR)                                                                              | 16 GB                                                                                                                                                                                           |
| <b>Hard disk drive</b>    | 1.2 GB for software installation<br>250 GB free space to use the software                            | 250 GB free space on a local disk for software installation<br>Minimum 20 GB free space for one acquisition                                                                                     |
| <b>Graphic board</b>      | Nvidia/ATI based board supporting Open GL 1.2 with 512 MB of dedicated video RAM on AGP x8 video bus | Cuda compatible with 4 Gb of dedicated video RAM                                                                                                                                                |
| <b>Display</b>            | 1024 x 768 minimum screen resolution<br>32 bits color mode                                           | 1600 x 900<br>(landscape mode only)                                                                                                                                                             |
| <b>Operating system</b>   | Windows 10** (64 bits) or higher                                                                     | Windows 10** or higher                                                                                                                                                                          |
| <b>Ethernet interface</b> | N/A                                                                                                  | 2 Ethernet interfaces: <ul style="list-style-type: none"> <li>1 Gbits Ethernet board for the connection with the unit*</li> <li>Another optional Ethernet board for a LAN connection</li> </ul> |
| <b>CD/DVD drive</b>       | A DVD-BURNER drive is required.                                                                      | A DVD-BURNER drive is required.                                                                                                                                                                 |
| <b>Backup Media</b>       | Removable/portable, external hard disk drive                                                         | Removable/portable, external hard disk drive.                                                                                                                                                   |
| <b>Mouse</b>              | 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 8200 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

### 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 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 problem arise and required you to stop the acquisition, release the exposure button of the remote control or press the red emergency stop button.

### Recommendations 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 acceptable within the requirements of medical science (as defined by the ALARA principle).

CS 8200 3D Family offers many options that can reduce radiation exposure for adults, and especially for children and adolescents, to a necessary minimum.

### Recommendations for women of childbearing age

Prior to imaging, women of childbearing age should be asked if they are pregnant or possibly pregnant. If pregnant or possibly pregnant, the patient should not undergo the exam unless an accredited radiologist from a hospital setting has been consulted to discuss with the patient and operator, the benefits and risks associated with this type of procedure along with other possible exam types.

Table 3 **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 may reduces the dose related to these exposure parameters. |                                                                                                                                                |
| Child Patient size<br>                                                                                                                              | Recommended for the children population of between 5 to 12 year old [~ 21 kg (46 lb); 113 cm (44.5 in) to ~52 kg (115 lb) ; 156 cm (61.5 in)]. |
| Adult Small Patient size<br>                                                                                                                        | Recommended for the adolescent population of approximately ~ 52 kg (115 lb); 156 cm (61.5 in).                                                 |

| Selecting the low dose or fast mode for a quick exam                                                                                                                                                                                                                                                                                         |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| The low dose imaging mode  (for panoramic and 3D modality) and the fast imaging mode  (for cephalometric modality) reduces the dose by minimizing the exposure parameters. |  |

| Selecting the appropriate 3D Modality Field of View for children/adolescent                                                                                                                                                                                |                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| By reducing the Field of View (FoV) for 3D X-ray imaging on children or adolescent, you are reducing the exposed area and this reduces the dose received by the patient. Recommended Field of View to be used for children/adolescent are indicated below. |                                                   |
| Standard Field of View                                                                                                                                                                                                                                     | Recommended Field of View for children/adolescent |
| 5x5                                                                                                                                                                                                                                                        | 4x4                                               |
| 10x5                                                                                                                                                                                                                                                       | 8x5                                               |
| 10x10                                                                                                                                                                                                                                                      | 8x9                                               |
| 12x5                                                                                                                                                                                                                                                       | 10x5                                              |
| 12x10                                                                                                                                                                                                                                                      | 10x10                                             |

| Selecting the appropriate Cephalometric Modality Field of View for children/adolescent                                                                                                                                                                                                                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| By reducing the Field of View (FoV) for cephalometric X-ray imaging on children or adolescent, you are reducing the exposed area and this reduces the dose received by the patient. Recommended Field of View to be used for children/adolescent are indicated below.                                                                                                                                                                                                |
| We strongly recommend that you select the appropriate FoV size according to the size of your patient head: <ul style="list-style-type: none"> <li>- Especially for children and adolescent patients, use the two smallest FoV sizes instead of the 26x24.</li> <li>- Particularly limit the FoV for interceptive treatments made for children below 12 years old to 18x18.</li> <li>- To treat adolescents, limit the FoV to 18x18 or a maximum of 18x24.</li> </ul> |

The CS 8200 3D 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 8200 3D Family can be brought down for an exposure in the seated position.
- To allow proper positioning of a pediatric patient, and where relevant, depending on the patient size, you can use the 3D child bite block accessory instead of the standard 3D bite block.
- You can use  on the acquisition interface to launch a radiation free test cycle at any time to do some preliminary demonstrations and explanations to assure the patient.
- Face to face positioning helps to minimize the fear of confined space in the unit for children and adolescent patients.



**WARNING: The Field of View (FoV) must be selected to irradiate the minimum area necessary for the examination in order to minimize the radiation exposure to the patient.**

## Panoramic mode for CS 8200 3D Family

Table 4 Dose information for panoramic modality

| Program                                            | ADULT LARGE |    |    |                |
|----------------------------------------------------|-------------|----|----|----------------|
|                                                    | T(s)        | kV | mA | DAP* mGy.cm.cm |
| MAXILLARY SINUS                                    | 8.8         | 76 | 10 | 91.1           |
| FULL PANORAMIC                                     | 12.3        | 76 | 10 | 128            |
| FULL PANORAMIC LOW DOSE                            | 8.5         | 73 | 8  | 64.7           |
| FULL PANORAMIC REDUCED                             | 11.4        | 76 | 10 | 118.3          |
| FULL PANORAMIC REDUCED LOW DOSE                    | 7.6         | 73 | 8  | 58.1           |
| SEGMENTED PANORAMIC MOLARS R and L                 | 8.2         | 76 | 10 | 85.3           |
| SEGMENTED PANORAMIC MOLARS R or L                  | 4.1         | 76 | 10 | 42.6           |
| SEGMENTED PANORAMIC REDUCED MOLARS R and L         | 7.3         | 76 | 10 | 75.6           |
| BITEWING R and L                                   | 13.1        | 76 | 10 | 136.3          |
| BITEWING R or L                                    | 6.6         | 76 | 10 | 68.2           |
| SEGMENTED PANORAMIC REDUCED MOLARS R or L          | 3.6         | 76 | 10 | 37.8           |
| SEGMENTED PANORAMIC INCISIVE                       | 7.2         | 76 | 10 | 74.9           |
| SEGMENTED PANORAMIC INCISIVE MOLARS R or L         | 9.8         | 76 | 10 | 101.4          |
| SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L | 9.3         | 76 | 10 | 96.6           |
| LATERAL TMJx2                                      | 2.5         | 76 | 10 | 25.9           |
| LATERAL TMJx4                                      | 5           | 76 | 10 | 51.8           |

\* 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 table above may be subject to modification. Without notice or justification to those concerned.**

| Program                                            | ADULT MEDIUM |    |     |                |
|----------------------------------------------------|--------------|----|-----|----------------|
|                                                    | T(s)         | kV | mA  | DAP* mGy.cm.cm |
| MAXILLARY SINUS                                    | 8.3          | 76 | 8   | 69.3           |
| FULL PANORAMIC                                     | 11.9         | 76 | 8   | 98.9           |
| FULL PANORAMIC LOW DOSE                            | 8.1          | 73 | 6.3 | 48.8           |
| FULL PANORAMIC REDUCED                             | 10.9         | 76 | 8   | 90.8           |
| FULL PANORAMIC REDUCED LOW DOSE                    | 7.2          | 76 | 8   | 43.4           |
| SEGMENTED PANORAMIC MOLARS R and L                 | 7.4          | 76 | 8   | 61.7           |
| SEGMENTED PANORAMIC MOLARS R or L                  | 3.7          | 76 | 8   | 30.9           |
| SEGMENTED PANORAMIC REDUCED MOLARS R and L         | 6.4          | 76 | 8   | 53.5           |
| BITEWING R and L                                   | 12.2         | 76 | 8   | 101            |
| BITEWING R or L                                    | 6.1          | 76 | 8   | 50.5           |
| SEGMENTED PANORAMIC REDUCED MOLARS R or L          | 3.2          | 76 | 8   | 26.8           |
| SEGMENTED PANORAMIC INCISIVE                       | 5.8          | 76 | 8   | 48.6           |
| SEGMENTED PANORAMIC INCISIVE MOLARS R or L         | 8.9          | 76 | 8   | 73.8           |
| SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L | 8.4          | 76 | 8   | 69.7           |
| LATERAL TMJx2                                      | 2.2          | 76 | 8   | 18.6           |
| LATERAL TMJx4                                      | 4.4          | 76 | 8   | 37.2           |

\* 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.**

| Program                                            | ADULT SMALL |    |     |                |
|----------------------------------------------------|-------------|----|-----|----------------|
|                                                    | T(s)        | kV | mA  | DAP* mGy.cm.cm |
| MAXILLARY SINUS                                    | 7.3         | 75 | 8   | 59.2           |
| FULL PANORAMIC                                     | 11.3        | 75 | 8   | 91.8           |
| FULL PANORAMIC LOW DOSE                            | 7.7         | 72 | 6.3 | 45.3           |
| FULL PANORAMIC REDUCED                             | 10.3        | 75 | 8   | 83.6           |
| FULL PANORAMIC REDUCED LOW DOSE                    | 6.8         | 72 | 6.3 | 39.9           |
| SEGMENTED PANORAMIC MOLARS R and L                 | 7.1         | 75 | 8   | 57.3           |
| SEGMENTED PANORAMIC MOLARS R or L                  | 3.5         | 75 | 8   | 28.6           |
| SEGMENTED PANORAMIC REDUCED MOLARS R and L         | 6.1         | 75 | 8   | 49.1           |
| BITEWING R and L                                   | 11          | 75 | 8   | 89.3           |
| BITEWING R or L                                    | 5.5         | 75 | 8   | 44.6           |
| SEGMENTED PANORAMIC REDUCED MOLARS R or L          | 3           | 75 | 8   | 24.6           |
| SEGMENTED PANORAMIC INCISIVE                       | 4.4         | 75 | 8   | 35.7           |
| SEGMENTED PANORAMIC INCISIVE MOLARS R or L         | 7.9         | 75 | 8   | 63.7           |
| SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L | 7.4         | 75 | 8   | 59.7           |
| LATERAL TMJx2                                      | 2.1         | 75 | 8   | 17             |
| LATERAL TMJx4                                      | 4.2         | 75 | 8   | 29             |

\* 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.**

| Program                                            | CHILD |    |     |                |
|----------------------------------------------------|-------|----|-----|----------------|
|                                                    | T(s)  | kV | mA  | DAP* mGy.cm.cm |
| MAXILLARY SINUS                                    | 6.4   | 70 | 8   | 36.9           |
| FULL PANORAMIC                                     | 10.8  | 70 | 8   | 62.5           |
| FULL PANORAMIC LOW DOSE                            | 7.2   | 68 | 6.3 | 30.8           |
| FULL PANORAMIC REDUCED                             | 9.7   | 70 | 8   | 56.3           |
| FULL PANORAMIC REDUCED LOW DOSE                    | 6.3   | 68 | 6.3 | 26.8           |
| SEGMENTED PANORAMIC MOLARS R and L                 | 6.8   | 70 | 8   | 39.5           |
| SEGMENTED PANORAMIC MOLARS R or L                  | 3.4   | 70 | 8   | 19.7           |
| SEGMENTED PANORAMIC REDUCED MOLARS R and L         | 5.7   | 70 | 8   | 33.2           |
| BITEWING R and L                                   | 8     | 70 | 8   | 46.4           |
| BITEWING R or L                                    | 4     | 70 | 8   | 23.2           |
| SEGMENTED PANORAMIC REDUCED MOLARS R or L          | 2.9   | 70 | 8   | 16.6           |
| SEGMENTED PANORAMIC INCISIVE                       | 3.3   | 70 | 8   | 19.3           |
| SEGMENTED PANORAMIC INCISIVE MOLARS R or L         | 7.1   | 70 | 8   | 40.9           |
| SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L | 6.5   | 70 | 8   | 37.8           |
| LATERAL TMJx2                                      | 2     | 70 | 8   | 11.6           |
| LATERAL TMJx4                                      | 4     | 70 | 8   | 23.2           |

\* 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 8200 3D

Table 5 Dose information for 3D modality

Imaging Mode: HR = High resolution – STD = Standard – LD = Low Dose – FAST = Fast

|          | T(s) |      | ADULT LARGE<br>DAP* in<br>mGy.cm.cm |     |      | ADULT MEDIUM<br>DAP* in<br>mGy.cm.cm |     |      | ADULT SMALL<br>DAP* in<br>mGy.cm.cm |     |      | CHILD<br>DAP* in<br>mGy.cm.cm |    |     |
|----------|------|------|-------------------------------------|-----|------|--------------------------------------|-----|------|-------------------------------------|-----|------|-------------------------------|----|-----|
|          |      |      | kV                                  | mA  |      | kV                                   | mA  |      | kV                                  | mA  |      | kV                            | mA |     |
| 4 x 4    | HR   | 15.0 | 90                                  | 5   | 624  | 90                                   | 4   | 499  | 90                                  | 3.2 | 399  | 90                            | 2  | 249 |
|          | STD  | 15.0 | 90                                  | 3.2 | 399  | 90                                   | 2.5 | 312  | 90                                  | 2   | 249  | 80                            | 2  | 197 |
|          | FAST | 7.0  | 90                                  | 3.2 | 186  | 90                                   | 2.5 | 145  | 90                                  | 2   | 116  | 80                            | 2  | 92  |
|          | LD   | 3.1  | 90                                  | 3.2 | 82   | 90                                   | 2.5 | 64   | 85                                  | 2   | 46   | 70                            | 2  | 30  |
| 5 x 5    | HR   | 15.0 | 90                                  | 5   | 916  | 90                                   | 4   | 732  | 90                                  | 3.2 | 586  | 90                            | 2  | 366 |
|          | STD  | 15.0 | 90                                  | 3.2 | 586  | 90                                   | 2.5 | 458  | 90                                  | 2   | 366  | 80                            | 2  | 290 |
|          | FAST | 7.0  | 90                                  | 3.2 | 273  | 90                                   | 2.5 | 214  | 90                                  | 2   | 171  | 80                            | 2  | 135 |
|          | LD   | 3.1  | 90                                  | 3.2 | 121  | 90                                   | 2.5 | 95   | 85                                  | 2   | 68   | 70                            | 2  | 44  |
| 5 x 8    | HR   | 15.0 | 90                                  | 5   | 1282 | 90                                   | 4   | 1025 | 90                                  | 3.2 | 820  | 90                            | 2  | 513 |
|          | STD  | 15.0 | 90                                  | 3.2 | 820  | 90                                   | 2.5 | 641  | 90                                  | 2   | 513  | 80                            | 2  | 405 |
|          | FAST | 7.0  | 90                                  | 3.2 | 383  | 90                                   | 2.5 | 299  | 90                                  | 2   | 239  | 80                            | 2  | 189 |
|          | LD   | 3.1  | 90                                  | 3.2 | 170  | 90                                   | 2.5 | 132  | 85                                  | 2   | 95   | 70                            | 2  | 62  |
| 8 x 5    | HR   | 15.0 | 90                                  | 5   | 1431 | 90                                   | 4   | 1145 | 90                                  | 3.2 | 916  | 90                            | 2  | 572 |
|          | STD  | 15.0 | 90                                  | 3.2 | 916  | 90                                   | 2.5 | 715  | 90                                  | 2   | 572  | 80                            | 2  | 453 |
|          | FAST | 7.0  | 90                                  | 3.2 | 427  | 90                                   | 2.5 | 334  | 90                                  | 2   | 267  | 80                            | 2  | 211 |
|          | LD   | 3.1  | 90                                  | 3.2 | 189  | 90                                   | 2.5 | 148  | 85                                  | 2   | 106  | 70                            | 2  | 69  |
| 8 x 8 ** | HR   | 15.0 | 90                                  | 5   | 2104 | 90                                   | 4   | 1683 | 90                                  | 3.2 | 1347 | 90                            | 2  | 842 |
|          | STD  | 15.0 | 90                                  | 3.2 | 1347 | 90                                   | 2.5 | 1052 | 90                                  | 2   | 842  | 80                            | 2  | 665 |
|          | FAST | 7.0  | 90                                  | 3.2 | 628  | 90                                   | 2.5 | 491  | 90                                  | 2   | 393  | 80                            | 2  | 310 |
|          | LD   | 3.1  | 90                                  | 3.2 | 278  | 90                                   | 2.5 | 217  | 85                                  | 2   | 156  | 70                            | 2  | 101 |
| 8 x 9    | HR   | 15.0 | 90                                  | 5   | 2357 | 90                                   | 4   | 1886 | 90                                  | 3.2 | 1509 | 90                            | 2  | 943 |
|          | STD  | 15.0 | 90                                  | 3.2 | 1509 | 90                                   | 2.5 | 1179 | 90                                  | 2   | 943  | 80                            | 2  | 746 |
|          | FAST | 7.0  | 90                                  | 3.2 | 704  | 90                                   | 2.5 | 550  | 90                                  | 2   | 440  | 80                            | 2  | 348 |
|          | LD   | 3.1  | 90                                  | 3.2 | 312  | 90                                   | 2.5 | 244  | 85                                  | 2   | 174  | 70                            | 2  | 113 |
| 10 x 5   | STD  | 20   | 90                                  | 5   | 1229 | 90                                   | 4   | 983  | 90                                  | 3.2 | 787  | 90                            | 2  | 492 |
|          | FAST | 14.0 | 90                                  | 3.2 | 551  | 90                                   | 2.5 | 430  | 90                                  | 2   | 344  | 80                            | 2  | 269 |
|          | LD   | 6.2  | 90                                  | 3.2 | 244  | 90                                   | 2.5 | 190  | 85                                  | 2   | 136  | 70                            | 2  | 86  |
| 10 x 10  | STD  | 20.0 | 90                                  | 5   | 2007 | 90                                   | 4   | 1606 | 90                                  | 3.2 | 1284 | 90                            | 2  | 803 |
|          | FAST | 14.0 | 90                                  | 3.2 | 899  | 90                                   | 2.5 | 702  | 90                                  | 2   | 562  | 80                            | 2  | 438 |
|          | LD   | 6.2  | 90                                  | 3.2 | 398  | 90                                   | 2.5 | 311  | 85                                  | 2   | 222  | 70                            | 2  | 140 |
| 12 x 5   | STD  | 20.0 | 90                                  | 5   | 1426 | 90                                   | 4   | 1140 | 90                                  | 3.2 | 912  | 90                            | 2  | 570 |
|          | FAST | 14.0 | 90                                  | 3.2 | 639  | 90                                   | 2.5 | 499  | 90                                  | 2   | 399  | 80                            | 2  | 312 |
|          | LD   | 6.2  | 90                                  | 3.2 | 283  | 90                                   | 2.5 | 221  | 85                                  | 2   | 157  | 70                            | 2  | 99  |
| 12 x 10  | STD  | 20.0 | 90                                  | 5   | 2328 | 90                                   | 4   | 1862 | 90                                  | 3.2 | 1490 | 90                            | 2  | 931 |
|          | FAST | 14.0 | 90                                  | 3.2 | 1043 | 90                                   | 2.5 | 815  | 90                                  | 2   | 652  | 80                            | 2  | 509 |
|          | LD   | 6.2  | 90                                  | 3.2 | 462  | 90                                   | 2.5 | 361  | 85                                  | 2   | 257  | 70                            | 2  | 162 |

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

\*\* 8x8 FoV is only available in Ontario (Canada) by licensing protection.



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

### 3D mode for CS 8200 3D ACCESS

Table 6 Dose information for 3D modality

Imaging Mode: HR = High resolution – STD = Standard – LD = Low Dose

|         | T(s) |     | ADULT LARGE<br>DAP* in |     |           | ADULT MEDIUM<br>DAP* in |     |           | ADULT SMALL<br>DAP* in |     |           | CHILD<br>DAP* in |     |           |
|---------|------|-----|------------------------|-----|-----------|-------------------------|-----|-----------|------------------------|-----|-----------|------------------|-----|-----------|
|         |      |     | kV                     | mA  | mGy.cm.cm | kV                      | mA  | mGy.cm.cm | kV                     | mA  | mGy.cm.cm | kV               | mA  | mGy.cm.cm |
| 4 x 4   | HR   | 15  | -                      | -   | -         | -                       | -   | -         | -                      | -   | -         | 90               | 4   | 249       |
|         | STD  | 10  | -                      | -   | -         | -                       | -   | -         | -                      | -   | -         | 90               | 2.5 | 104       |
|         | LD   | 6.2 | -                      | -   | -         | -                       | -   | -         | -                      | -   | -         | 70               | 2   | 30        |
| 5 x 5   | HR   | 15  | 90                     | 10  | 916       | 90                      | 8   | 732       | 90                     | 6.3 | 577       | 90               | 4   | 366       |
|         | STD  | 10  | 90                     | 6.3 | 385       | 90                      | 5   | 305       | 90                     | 4   | 244       | 90               | 2.5 | 153       |
|         | LD   | 6.2 | 90                     | 3.2 | 121       | 90                      | 2.5 | 95        | 85                     | 2   | 68        | 70               | 2   | 44        |
| 8 x 5   | STD  | 10  | 90                     | 10  | 954       | 90                      | 8   | 763       | 90                     | 6.3 | 601       | 90               | 4   | 382       |
|         | LD   | 6.2 | 90                     | 3.2 | 189       | 90                      | 2.5 | 148       | 85                     | 2   | 106       | 70               | 2   | 69        |
| 8 x 8** | STD  | 10  | 90                     | 10  | 1403      | 90                      | 8   | 1122      | 90                     | 6.3 | 884       | 90               | 4   | 561       |
|         | LD   | 6.2 | 90                     | 3.2 | 278       | 90                      | 2.5 | 217       | 85                     | 2   | 156       | 70               | 2   | 101       |
| 8 x 9   | STD  | 10  | 90                     | 10  | 1572      | 90                      | 8   | 1257      | 90                     | 6.3 | 990       | 90               | 4   | 629       |
|         | LD   | 6.2 | 90                     | 3.2 | 312       | 90                      | 2.5 | 244       | 85                     | 2   | 174       | 70               | 2   | 113       |
| 10 x 5  | STD  | 15  | 90                     | 10  | 1229      | 90                      | 8   | 983       | 90                     | 6.3 | 774       | 90               | 4   | 492       |
|         | LD   | 9.3 | 90                     | 3.2 | 244       | 90                      | 2.5 | 190       | 85                     | 2   | 136       | 70               | 2   | 86        |
| 10 x 10 | STD  | 15  | 90                     | 10  | 2007      | 90                      | 8   | 1606      | 90                     | 6.3 | 1264      | 90               | 4   | 803       |
|         | LD   | 9.3 | 90                     | 3.2 | 398       | 90                      | 2.5 | 311       | 85                     | 2   | 222       | 70               | 2   | 140       |

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

\*\* 8x8 FoV is only available in Ontario (Canada) by licensing protection.



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

## Cephalometric mode for CS 8200 3D Family with Scan Ceph configuration

Table 7 Patient Dose information in Cephalometric mode

| Lateral exam<br>(W x H) |      | T(s) | ADULT LARGE<br>DAP*<br>mGy.cm |    |    | ADULT MEDIUM<br>DAP*<br>mGy.c |    |    | ADULT SMALL<br>DAP*<br>mGy.cm |    |    | CHILD<br>DAP*<br>mGy.cm.cm |    |    |
|-------------------------|------|------|-------------------------------|----|----|-------------------------------|----|----|-------------------------------|----|----|----------------------------|----|----|
|                         |      |      | kV                            | mA |    | kV                            | mA |    | kV                            | mA |    | kV                         | mA |    |
| 18 x 18                 | HR   | 6.92 | 90                            | 10 | 16 | 87                            | 10 | 15 | 86                            | 8  | 12 | 82                         | 8  | 11 |
|                         | Fast | 2.96 | 90                            | 10 | 7  | 87                            | 10 | 6  | 86                            | 8  | 5  | 82                         | 8  | 5  |
| 18 x 24                 | HR   | 6.92 | 90                            | 10 | 19 | 87                            | 10 | 18 | 86                            | 8  | 14 | 82                         | 8  | 13 |
|                         | Fast | 2.96 | 90                            | 10 | 8  | 87                            | 10 | 8  | 86                            | 8  | 6  | 82                         | 8  | 5  |
| 26 x 24                 | HR   | 10   | 90                            | 10 | 28 | 87                            | 10 | 26 | 86                            | 8  | 20 | 82                         | 8  | 18 |
|                         | Fast | 4.28 | 90                            | 10 | 12 | 87                            | 10 | 11 | 86                            | 8  | 9  | 82                         | 8  | 8  |

| Oblique or Submentovertex or Frontal AP/PA exams<br>(W x H) |      | T(s)  | ADULT LARGE<br>DAP*<br>mGy.cm.c |    |    | ADULT MEDIUM<br>DAP*<br>mGy.c |    |    | ADULT SMALL<br>DAP*<br>mGy.c |    |    | CHILD<br>DAP*<br>mGy.cm.cm |    |    |
|-------------------------------------------------------------|------|-------|---------------------------------|----|----|-------------------------------|----|----|------------------------------|----|----|----------------------------|----|----|
|                                                             |      |       | kV                              | mA |    | kV                            | mA |    | kV                           | mA |    | kV                         | mA |    |
| 18 x 18                                                     | HR   | 7.6   | 90                              | 10 | 18 | 87                            | 10 | 16 | 86                           | 8  | 13 | 82                         | 8  | 12 |
|                                                             | Fast | 3.46  | 90                              | 10 | 8  | 87                            | 10 | 7  | 86                           | 8  | 6  | 82                         | 8  | 5  |
| 18 x 24                                                     | HR   | 7.6   | 90                              | 10 | 21 | 87                            | 10 | 20 | 86                           | 8  | 15 | 82                         | 8  | 14 |
|                                                             | Fast | 3.46  | 90                              | 10 | 10 | 87                            | 10 | 9  | 86                           | 8  | 7  | 82                         | 8  | 6  |
| 26 x 24                                                     | HR   | 10.99 | 90                              | 10 | 30 | 87                            | 10 | 28 | 86                           | 8  | 22 | 82                         | 8  | 20 |
|                                                             | Fast | 5     | 90                              | 10 | 14 | 87                            | 10 | 13 | 86                           | 8  | 10 | 82                         | 8  | 9  |

| Carpus exam<br>(W x H) |      | T(s) | ADULT LARGE<br>DAP*<br>mGy.cm.cm |    |    | ADULT MEDIUM<br>DAP*<br>mGy.cm.cm |    |    | ADULT SMALL<br>DAP*<br>mGy.cm.cm |    |    | CHILD<br>DAP*<br>mGy.cm.cm |    |    |
|------------------------|------|------|----------------------------------|----|----|-----------------------------------|----|----|----------------------------------|----|----|----------------------------|----|----|
|                        |      |      | kV                               | mA |    | kV                                | mA |    | kV                               | mA |    | kV                         | mA |    |
| 18 x 18                | HR   | 6.92 | 74                               | 15 | 16 | 72                                | 15 | 15 | 72                               | 15 | 15 | 68                         | 15 | 13 |
|                        | Fast | 2.97 | 74                               | 15 | 7  | 72                                | 15 | 6  | 72                               | 15 | 6  | 68                         | 15 | 6  |
| 18 x 24                | HR   | 6.92 | 74                               | 15 | 19 | 72                                | 15 | 18 | 72                               | 15 | 18 | 68                         | 15 | 15 |
|                        | Fast | 2.97 | 74                               | 15 | 8  | 72                                | 15 | 8  | 72                               | 15 | 8  | 68                         | 15 | 7  |

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



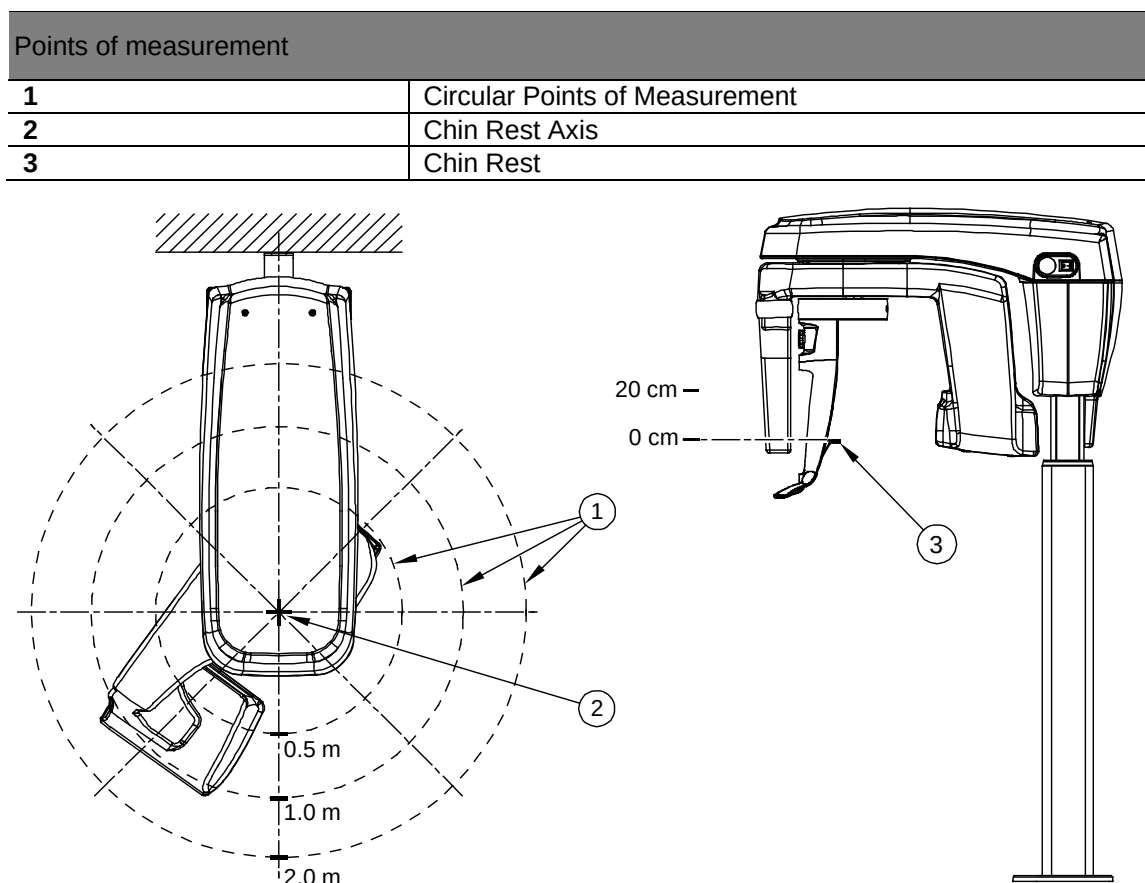
**Note:** The information in the table above may be subject to modification. Without notice or justification to those concerned.

## 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**



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

| Stray radiation for one large adult full panoramic exam                                    |                  |
|--------------------------------------------------------------------------------------------|------------------|
| Distance between the chin rest axis and measurement point (Circular Points of Measurement) | Stray radiation* |
| 0.5 m                                                                                      | < 4 $\mu$ Gy     |
| 1.0 m                                                                                      | < 1 $\mu$ Gy     |
| 2.0 m                                                                                      | < 0.25 $\mu$ Gy  |

\* Maximum use rate permitted by the CS 8200 3D Family X-ray generator is 14 large adult full panoramic exam per hour, this corresponds to a continuous average anodic power of 33 W

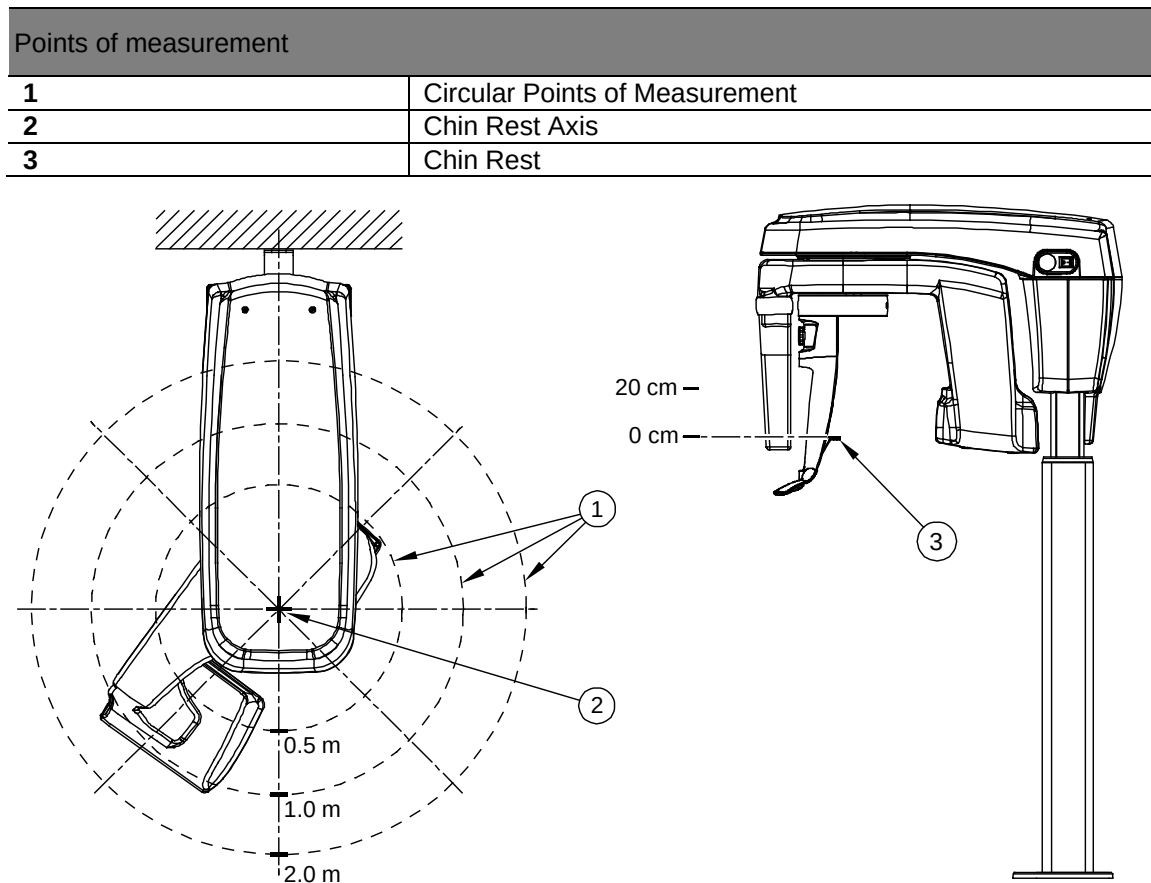
This is the maximum value measured 10 cm above the horizontal cross-sectional plane with a chin rest. Other values in the vertical axis are lower than these values.

## 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**



Stray radiation is measured in largest 3D mode available, ie 12x10 mode, for a large sized patient selected with a PMMA phantom cylinder ( $\Phi$  16 cm, h 15 cm) to simulate a patient head.

| Stray radiation for one large adult 12x10 3D exam                                          |                  |
|--------------------------------------------------------------------------------------------|------------------|
| Distance between the chin rest axis and measurement point (Circular Points of Measurement) | Stray radiation* |
| 0.5 m                                                                                      | < 80 $\mu$ Gy    |
| 1.0 m                                                                                      | < 20 $\mu$ Gy    |
| 2.0 m                                                                                      | < 5 $\mu$ Gy     |

\* Maximum use rate permitted by the CS 8200 3D Family X-ray generator is 13 large adult 12x10 3D exam per hour, this corresponds to a continuous average anodic power of 33 W

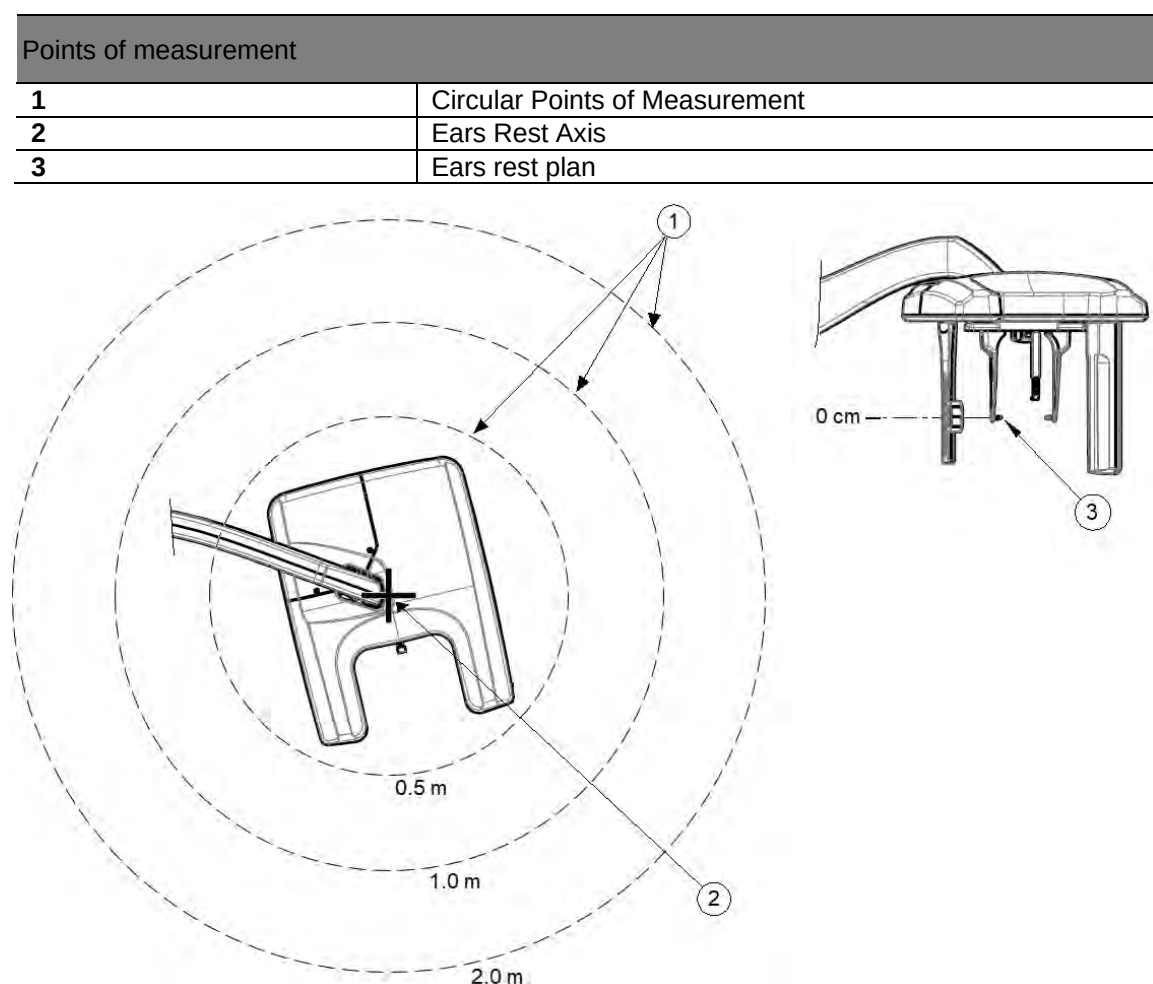
This is the maximum value measured 10 cm above the horizontal cross-sectional plane with a chin rest. Other values in the vertical axis are lower than these values.

## Stray radiation in cephalometric 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 point of the ears rest.

**Figure 1 Circular Points of Measurement**



Stray radiation is measured in largest cephalometric mode available, ie AP 26x24 HR mode, for a large sized patient selected with a PMMA phantom cylinder ( $\Phi$  16 cm, h 15 cm) to simulate a patient head.

| Stray radiation for one large adult AP 26x24 HR cephalometric exam                                    |                  |
|-------------------------------------------------------------------------------------------------------|------------------|
| Distance between the central ears rest axis and measurement point<br>(Circular Points of Measurement) | Stray radiation* |
| 0.5 m                                                                                                 | < 12 $\mu$ Gy    |
| 1.0 m                                                                                                 | < 3 $\mu$ Gy     |
| 2.0 m                                                                                                 | < 0.75 $\mu$ Gy  |

\* Maximum use rate permitted by the CS 8200 3D Family X-ray generator is 12 large adult AP 26x24 HR cephalometric exam per hour, this corresponds to a continuous average anodic power of 33 W

This is the maximum value measured at the horizontal cross-sectional plane with the ears rest.

Other values in the vertical axis are lower than these values.

## Imaging performance information

### Panoramic and Cephalometric

Line Pair Resolution\*: 2.5 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 8200 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 8200 3D Family (SMA65)***.

## CS 8200 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 8200 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 $\pm$ 10 %                                   |
| Current in the tube             | mA $\pm$ 20 %                                   |
| Exposure time seconds           | Seconds $\pm$ (10 % + 1ms) or $\pm$ (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 8      **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 + Aluminum filter (for CS 8200 3D Family), which enhances the quality of the beam and reduces the dose received by the patient
- A lead collimator, which limits the size of the beam at the image receiver unit
- A thermal cutout, which trips at an operating temperature between 63 to 70 °C ( $\pm 5^{\circ}\text{C}$ )

**Figure 2      Location of the Reference Axis for Panoramic and 3D Imaging**

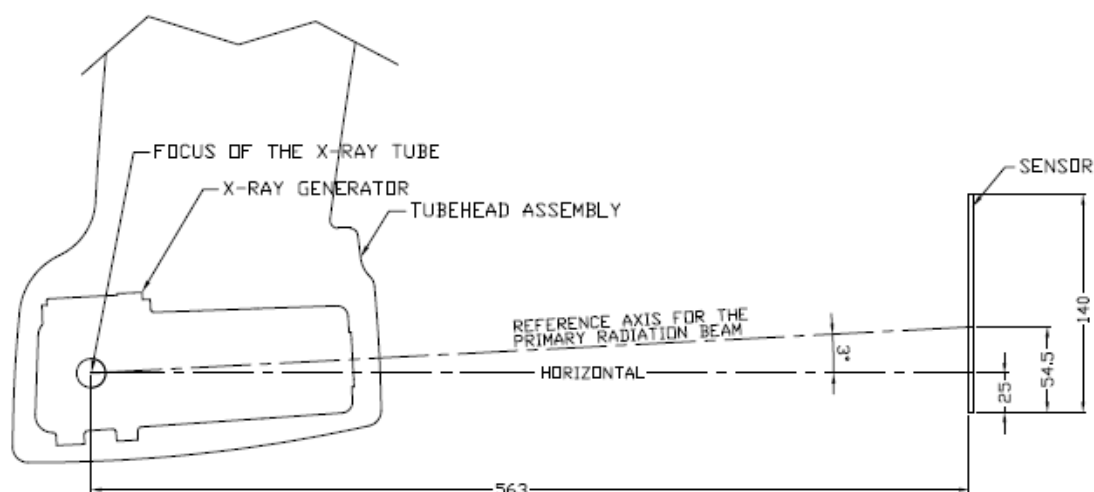


**Figure 3 Location of the Reference Axis for Cephalometric Imaging**

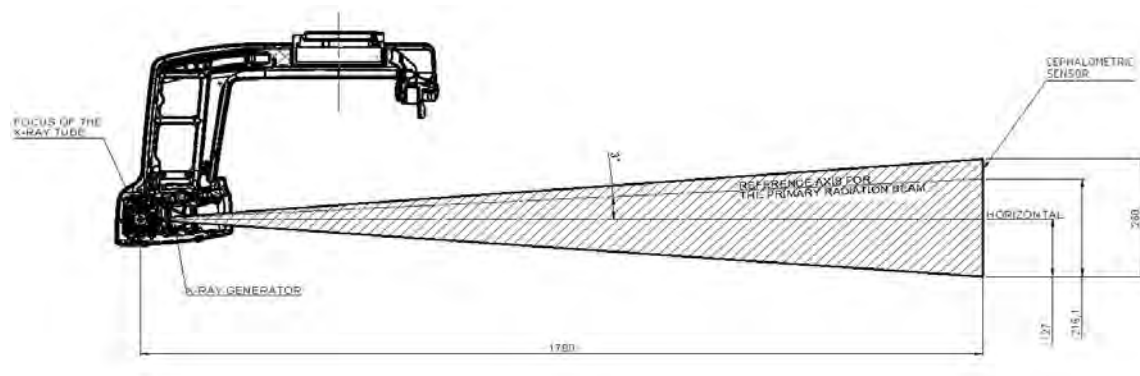


**Table 9 Technical Specifications of the X-ray tube Assembly**

| 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<br>0.6 mm with X-ray tube D-067 |
| Tolerances on the position of the focal spot                                                              | $\pm 2.5$ mm                                                   |
| Total filtration                                                                                          | >2.5 mm eq. Al                                                 |
| 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 4 Heating and Cooling Curves of the X-ray Tube Assembly**

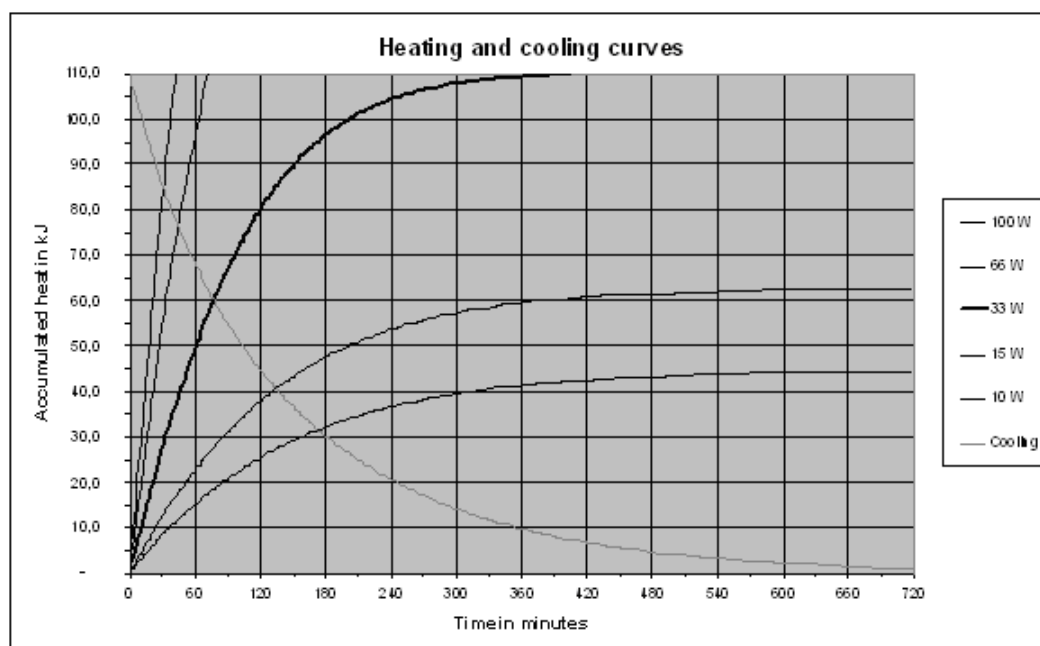


**Table 10 Beam Limitations of the X-ray Tube Assembly**

|                                                                                                          |                                                                                                  |
|----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| 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<br>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 (60 x 140 mm for access version)<br>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<br>At the detector reference plane                                                 |
| Location of the reference axis                                                                           | See Figure 5 and Figure 6 Location of the Reference Axis for Panoramic and 3D Imaging            |

**Table 11 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

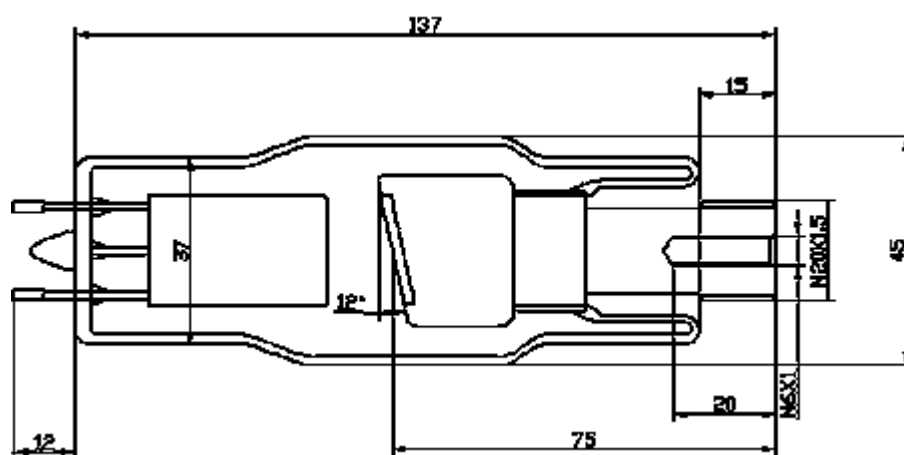


Figure 8.2 X-ray tube drawing D-067

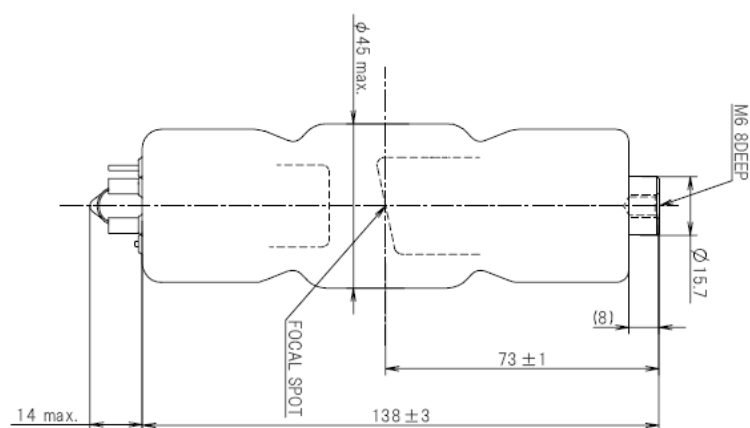


Figure 9.1 Heating and Cooling Curves of the X-ray Tube OPX110

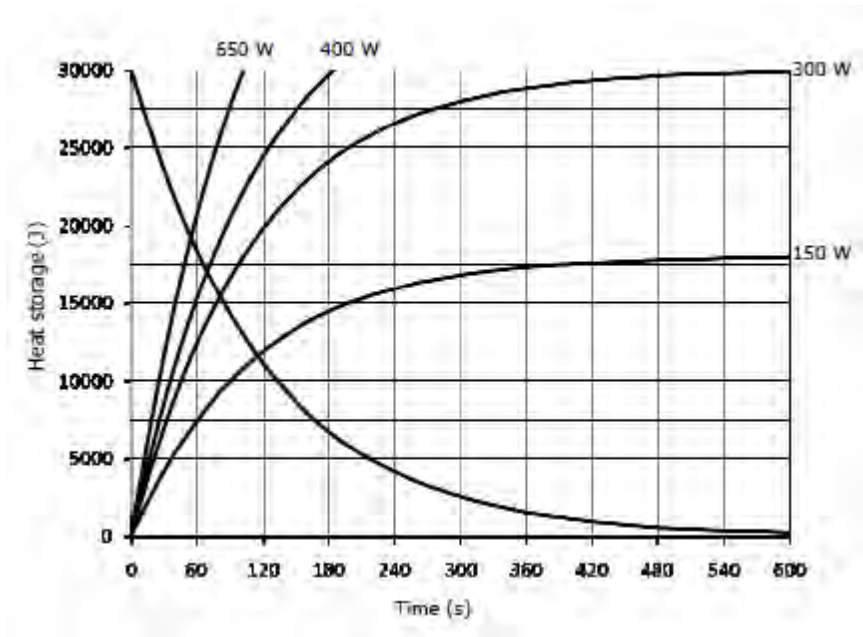


Figure 9.2 Heating and Cooling Curves of the X-ray Tube D-067

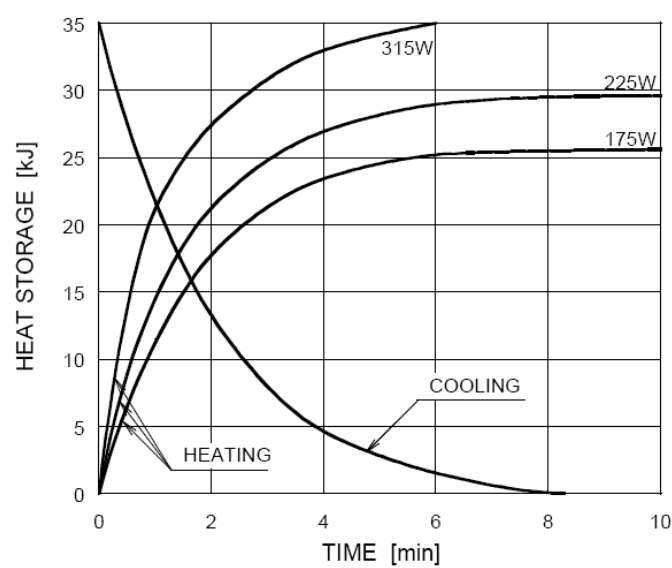


**Figure 10.1 Single Load Chart of the X-ray Tube OPX110**

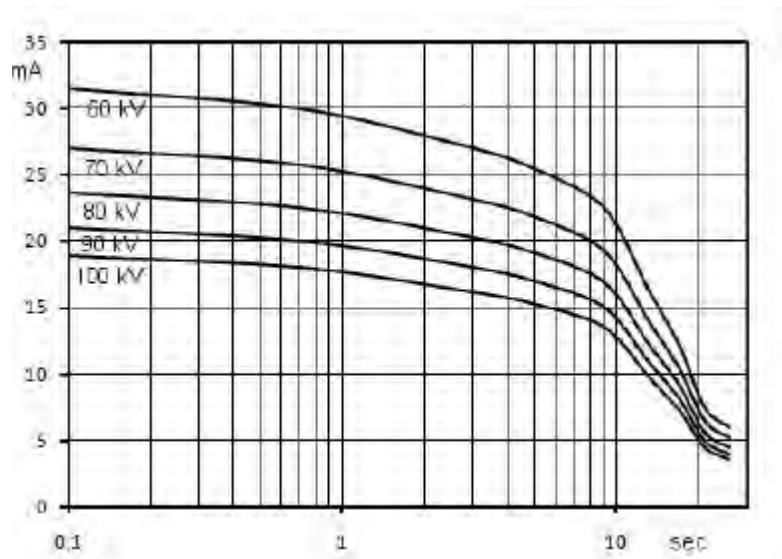


**Figure 10.2 Single Load Chart of the X-ray Tube D-067**

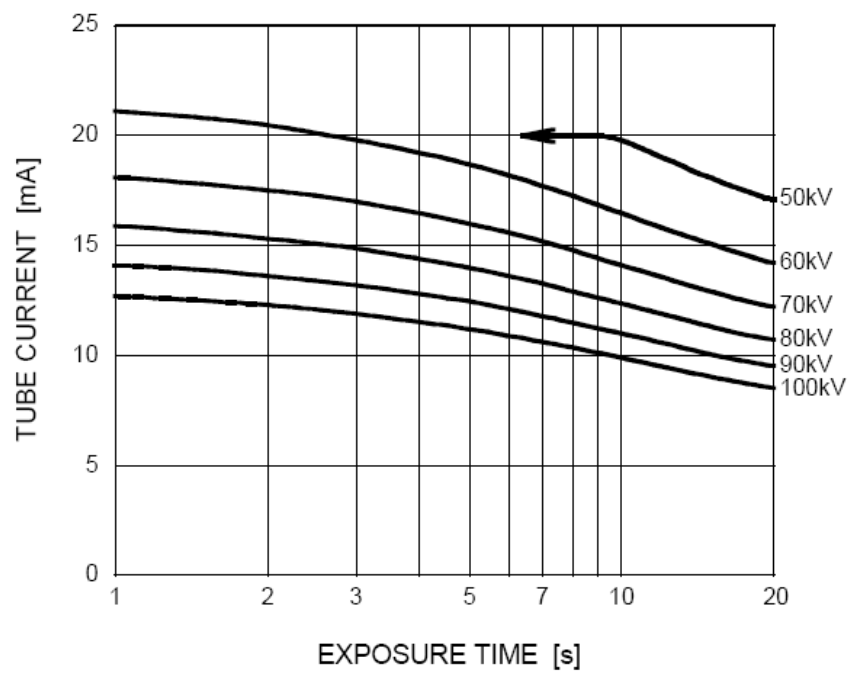


**Figure 11.1 Filament Emissions of the X-ray Tube OPX110**

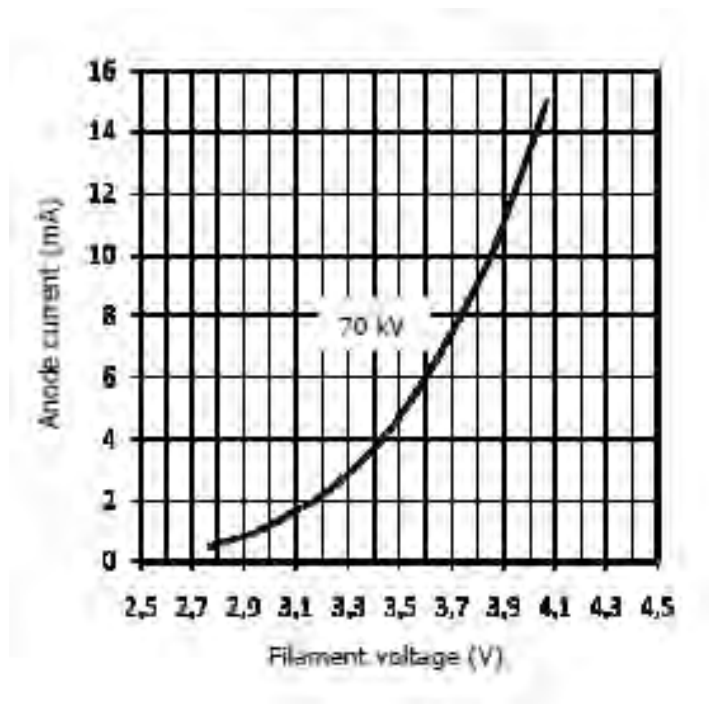
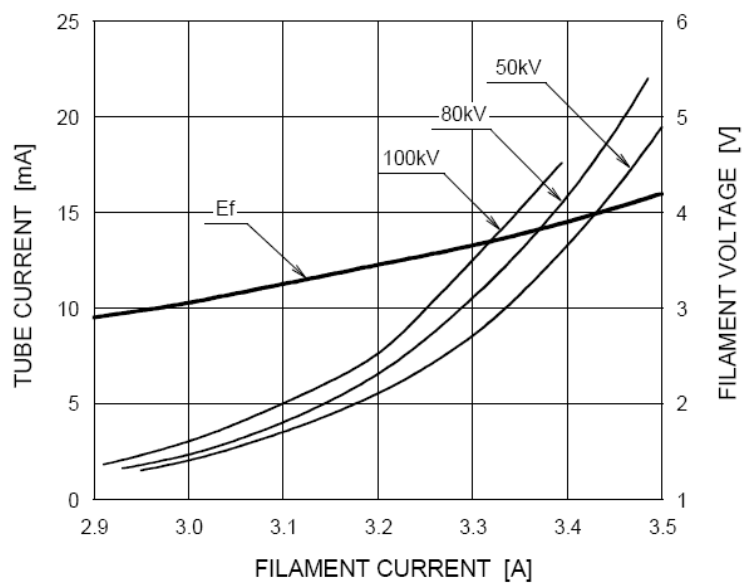


**Figure 11.2 Filament Emissions of the X-ray Tube D-067**



# 4 Contact Information

## Manufacturer's Address



### **Carestream Dental LLC**

3625 Cumberland Boulevard, Suite 700,  
Atlanta, GA USA 30339

## Factory

### **TROPHY**

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

## Authorized Representatives

### Authorized Representative in the European Community

#### **TROPHY**

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

### Responsible Person in the United Kingdom

#### **CARESTREAM DENTAL LTD**

Jessica Igies-Mikaelson  
Wiltron House, Rutherford Close Stevenage, Hertfordshire  
SG1 2EF  
England, United Kingdom

### Authorized Representative in Brazil

#### **CARESTREAM DENTAL BRASIL LTDA**

Rua Romualdo Davoli, 65  
1º Andar, Sala 01 - São José dos Campos ; São Paulo - Brazil  
Cep (Zip Code): 12238-577  
- CNPJ: 27.462.540/0001-43  
- Responsável Técnico: Joyce Miliati - CRF-SP N°85.482  
- ANVISA registration n°: 81522400001

## List of Importers for European Union according MDR 2017/745

#### **CARESTEAM DENTAL FRANCE SAS**

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

CARESTEAM DENTAL GERMANY GmbH  
Hedelfinger Str. 60, 70327 Stuttgart, Germany

CARESTEAM DENTAL SPAIN

S.L.U. Paseo de la Castellana, 79 Madrid 28046, España

CARESTEAM DENTAL Italy S.r.l.  
Via Mario Idiojmi 3/3, Assago 20090 (MI), Italia

## List of Importers for Switzerland

### **CURADEN AG**

Riedstrasse 12  
CH-8953 Dietikon  
Switzerland

### **Dema dent AG**

Furtbachstrasse 16  
CH-8107 Buchs  
Switzerland

### **Jordi Röntgentechnik AG**

Dammstrasse 70  
CH-4142 Münchenstein  
Switzerland

### **E. Schweizer AG**

Bernerstrasse Nord 182  
CH-8064 Zürich  
Switzerland



For more information visit: [www.carestreamdental.com](http://www.carestreamdental.com)