





Safety, Regulatory and Technical Specifications User Guide

Notice

The Regulatory Information and Technical Specifications User Guide for the CS 9600 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 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 9600 complies with Directive 93/42/EEC relating to medical devices.



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1 Safety Information

Indications for Use

CS 9600 is extraoral system intended to produce two-dimensional and three-dimensional digital Xray images of the dento-maxillofacial, ENT (Ear, Nose and Throat), cervical spine and wrist regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.

The CS 9600 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.



CAUTION

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



CAUTION

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.



CAUTION

Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, the appropriate imaging should be conventional medical CT or MR, rather than 3D imaging using Cone Beam technology.

Conventions in this Guide

The following special messages emphasize information or indicate potential risk to personnel or equipment:



WARNING: Warns you to avoid injury to yourself or others by following the safety instructions precisely.



CAUTION: Alerts you to a condition that might cause serious damage.



Important: Alerts you to a condition that might cause problems.



Note: Emphasizes important information.



Tip: Provides extra information and hints.

Note to the User



WARNING: X-rays can be harmful and dangerous if not used properly. The instructions and warnings contained in this guide must be followed carefully.

As a manufacturer of radiology units that conform to stringent radiological protection standards in force throughout the world, we guarantee as low as reasonably achievable degree of protection against radiation hazards. Nonetheless, you are handling a radiology unit specially designed to emit X-ray doses in order to carry out a medical diagnosis.

The room in which your radiology unit is to be installed must comply with all official regulations applicable to protection against radiation. You must install your radiology unit in a room protected against X-ray emission.

Your local representative will assist you in the initial use of your radiology unit and will supply any relevant information you may require.

To use and operate the unit you must follow the instructions contained in this guide.

Warning and Safety Instructions

When operating the unit, observe the following warning and safety instructions:



DANGER OF ELECTRIC SHOCK

This is an electrical unit. Do NOT expose it to water spray. Such action may cause an electric shock or a malfunction of the unit.



- 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: <u>http://www.fda.gov/radiation-</u> <u>emittingproducts/radiationemittingproductsandprocedures/medicalimaging/ucm2</u> 98899.htm
- Do NOT place objects within the field of operation of the unit.
- The patient should wear a protective lead-lined shoulder apron, unless other Radiation Protection Protocols apply locally.
- While adjusting the height of the unit, ensure that the patient is kept clear of the mechanism.
- When the unit is not in use, ensure that the ON/OFF switch is set to OFF (O).
- If the unit develops a fault, switch it to off (O), display an "Unserviceable" notice and contact a service technician.
- To dispose of the unit or its components, contact a service technician.
- Ask the patient to refrain from moving during the entire period of exposure.
- Ask the patient to remain still until the unit arm has stopped moving and the RESET movement has completed.
- Do NOT use this unit in conjunction with oxygen-rich environments. This unit is not intended for use with flammable anesthetics or flammable agents.
- It is not recommended to use accessories other than those specified in this document and sold by Carestream Dental.
- If the touchscreen does not work, do NOT operate the unit and contact a service technician.
- If the installation of the Product is not carried out by qualified personnel or if the Product is installed incorrectly and as a result is not operating correctly or is damaged, it is the responsibility of the Distributor. The above will lead to an expiration of the warranty and the liability of Carestream Dental; Carestream Dental accepts no responsibility for failures caused by sub-standard or incorrect installations.

Computer:

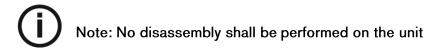
- Do NOT place the computer and the peripheral equipment connected to it in the immediate vicinity of the patient in the unit. Leave at least 1.50 m distance from the unit. The computer and the peripheral equipment must conform to the IEC 60950 standard.
- See your computer installation guide for details of the data processing system and screen. Leave a sufficient amount of clear space around the CPU to ensure that it is properly ventilated.
- To obtain maximum image quality and visual comfort, position the screen to avoid direct light reflections from internal or external lighting.
- Always use Microsoft Windows Update to make sure that the latest security patches are correctly installed.

Cleaning and Disinfection

Cleaning the CS 9600 Unit and Accessory with no patient contact

To clean the unit and accessory with no patient contact such as the 3D bite block support, follow these steps:

- 1. Switch off the unit.
- 2. Remove all visible soil, if any, with disposable cloth or paper wipe.



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, and if applicable the 3D bite block support with the dampened lint-free cloth.

5. Dry 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 panoramic bite blocks 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 block with FDA-cleared or CE mark protective sheaths that are available from distributors to use them between each patient.

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

- TMJ nose rest
- Panoramic standard bite block
- Bite block for edentulous patient
- Frankfort guide bite block for panoramic
- 3D bite blocks



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

Cleaning

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

- 1. Remove and discard the protective sheath from the accessory.
- 2. Remove all visible soil by with disposable cloth or paper wipe.
- 3. Rinse at least 1 minute under running water to thoroughly clean the accessory from any excess soil.
- 4. Using a soft brush, apply medical enzyme detergent solutions (basically with a multi-enzymatic formula) to all surfaces of the accessory. **Detergent manufacturer's directions must be strictly adhered to.**
- 5. Rinse thoroughly under running water for at least 1 minute to remove detergent residue.

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

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

Disinfecting with Steam Autoclave

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



CAUTION

You must use a medical autoclaving equipment cleared by the FDA in the USA or that is recognized by your Local Authority.

You must always follow the operating parameters recommended by the manufacturer of the autoclaving equipment.

Use FDA cleared or CE mark standard packaging material.

- 1. Wrap the cleaned accessory using a standard packaging material for autoclaving.
- 2. Steam autoclave at 132°C (270°F) for 4 minutes in the USA or depending on your local regulation you can steam autoclave at 134°C (273°F) for 18 minutes.
- 3. Visually inspect the accessory for signs of deterioration. If any damage is noted, do not use the accessory and contact your representative.
- 4. Once sterilized, the accessory can be used immediately or stored dry and dust-free in its sterilization wrapping under temperature specified in section "CS 9600 Environmental Requirements" of the present guide.

Cleaning and disinfecting the ear cones of the Scan Ceph (applicable only with cephalometric modality configuration)



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 labels 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 components and accessories that have skin contact

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

- Panoramic and sinus chin rest
- 3D frontal head rest
- Wrist support (optional accessory)
- Facial scanner support (optional accessory)



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

Cleaning

To manually clean the component or accessory that have skin contact, follow these steps:

- 1. Remove all visible soil by with disposable cloth or paper wipe.
- 2. Rinse at least 1 minute under running water to thoroughly clean the component/accessory from any excess soil.
- 3. Using a soft brush, apply medical enzyme detergent solutions (basically with a multi-enzymatic formula) to all surfaces of the component/accessory. **Detergent manufacturer's directions must be strictly adhered to.**
- 4. Rinse thoroughly under running water for at least 1 minute to remove detergent residue.
- 5. Dry the component/accessory with compressed air or hygiene disposable cloth.
- 6. Visually inspect the component/accessory for residual soil. If soil is visible, either repeat steps 1 to 4, or safely dispose of the accessory.

Disinfecting

To disinfect the component or 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 lowlevel 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

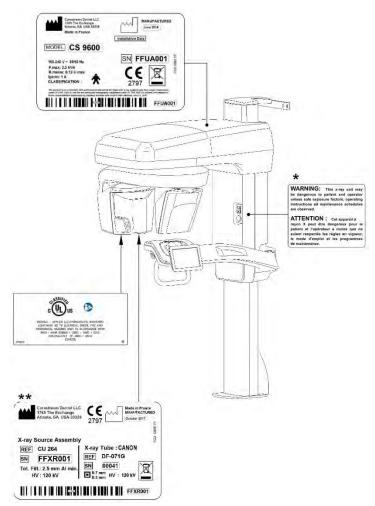
†	Type B device symbol complying with the IEC 60601-1 standard
	In the European Union, this symbol indicates: Do NOT discard this product in a trash receptacle; use an appropriate recovery and recycling facility. Contact your local sales representative for additional information on the collection and recovery programs available for this product
\bigwedge	WARNING Attention, consult accompanying document
A . A	IONIZING RADIATION symbol warn you about radiation dangers.
$ \bigcirc$	The ON/OFF button
(Refer to instruction manual/booklet
~~~	Manufactured Date
***	Manufacturer's address

# **Label Locations**

#### CS 9600 Labels

The following figure illustrates the label locations.

#### Figure 1 CS 9600 Label Locations

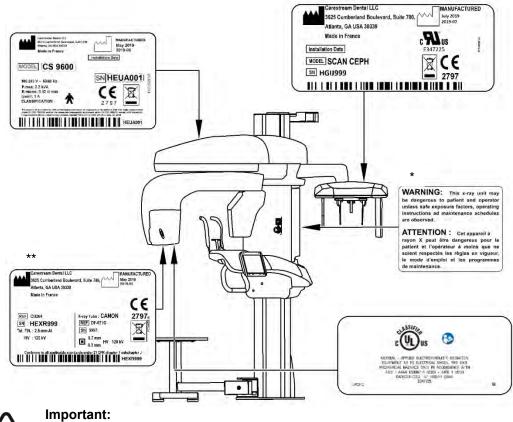




#### Important:

* Only for USA this warning appears in the Parameter pane of the Acquisition interface. ** X-ray tube can be CEI OX/120-0307 or Toshiba/Canon DF-071G

#### Figure 2 CS 9600 Label Locations (with Scan Ceph configuration)



* Only for USA this warning appears in the Parameter pane of the Acquisition interface. ** X-ray tube can be CEI OX/120-0307 or Toshiba/Canon DF-071G

#### **Table 1 Label Definition**

Label	Definition
MODEL	Defines the unit's model
Installation Date	Defines the date that the unit was installed
This product is in conformity with performance standards for diagnostic x-ray systems and their major components under 21 CFR 1020.30, and for computed tomography equipment under 21 CFR 1020.33, except with respect to those characteristics authorized by Variance Number FDA-2018-V-1901 effective June 15, 2018	Defines the unit's compliance with the US FDA radiation standards

# **General Regulatory Information**

Compliance with European and International Standards		
EN/IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance.	
EN/IEC 60601-1-2	Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Disturbances – Requirements and tests.	
EN/IEC 60601-1-3	Medical Electrical Equipment, Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.	
EN/IEC 60601-1-6	Medical Electrical Equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability.	
EN/IEC 62366	Medical devices - Application of usability engineering to medical device.	
EN/IEC 62304	Medical device software - Software life cycle processes.	
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 ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	
EN 1041	Information supplied by the manufacturer of medical devices.	
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing.	
EN ISO 14971	Medical devices - Application of risk management to medical devices.	
CAN/CSA C22.2 N°60601-1	Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance.	
ANSI/AAMI ES60601-1	Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance.	

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

#### Conformity with EN/IEC 60601-1-2

Group I, class B

CS 9600 is intended to be used in a professional healthcare facility environment.

Compliance of the CS 9600 has been achieved using the following cables:

One main supply cable (maximum length 3 m)

One Ethernet cable (maximum length 10 m)

One X-ray switch cable (maximum length 10 m)

#### Conformity with EN/IEC 60601-1-2

**Electromagnetic Compatibility Precautions** 



- Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC).
- The CS 9600 must be installed and put into service according to the EMC information provided in this document.
- The CS 9600 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.



- 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 9600 system.
- The CS 9600 system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the CS 9600 system should be observed to verify normal operation in the configuration in which it will be used.
- 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 9600 including cables specified by Carestream. Otherwise, it could result in degradation of the performance of the CS 9600 equipment.



WARNING: The room in which your radiology unit is to be installed must comply with all official regulations applicable to protection against radiation. You must install your radiology unit in a room protected against X-ray emission.

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

The CS 9600 system is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 9600 system should assure that it is used in such an environment.

Emissions Test Compliance		Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The CS 9600 system uses RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 Class B The CS 9600 system is s	The CS 9600 system is suitable for use in	
Harmonic emissions IEC 61000-3-2	Class A	all establishments, including domestic establishments and those directly connected to the public low-voltage power
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	supply network that supplies buildings used for domestic purposes.

#### Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The CS 9600 system is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 9600 system should assure that it is used in such an environment.

The essential performance concerns accuracy of loading factors (mA, kV), if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES, the system stops the examination and the user is notified of the error.

-		
Immunity Test	IEC 60601 Test Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT for 0.5 cycle at 8 angles At 0°, 0 % UT for 1 cycle and 70 % UT for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CS 9600 system requires continued operation during power mains interruptions, it is recommended that the CS 9600 system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

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

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

The CS 9600 system is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 9600 system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz and 6V at ISM Frequencies	Environment of a care facility professional health
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz Test levels and frequencies according to table 9 from IEC 60601-1- 2: 2014	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CS 9600 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CS 9600 system is used exceeds the applicable RF compliance level above, the CS 9600 system 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 9600.

## **Compliance with International Regulations**

- Medical Device Directives 93/42/EEC, Class IIb as amended by 2007/47/EC.
- Directive 2011/65/EU on the Restriction Of use of certain Hazardous Substances in electrical and electronic equipment (RoHS), as amended by Directive 2017/2102.
- FDA Center for Device & Radiological Health: This product is in conformity with performance standards for diagnostic x-ray systems and their major computed tomography equipment 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-2018-V-1901 effective June 15, 2018 (USA).
- Radiation Emitting Devices Act C34 (Canada).
- Medical Devices Regulations (Canada).



# Factory

TROPHY

4, rue F. Pelloutier, Croissy-Beaubourg

77435 Marne la Vallée Cedex 2, France

# Manufacturer



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

## Model

CS 9600

# **CS 9600 Technical Specifications**

#### Table 2 CS 9600 Technical Specifications

Components	X-ray Generator
Tube voltage	60 – 90 kV 60 – 120 kV (optional)
Tube current	2 - 15 mA
Frequency	140 kHz
Tube focal spot0.3 or 0.7 mm(IEC 60336)	
Total filtration	> 2.5 mm eq. Al

#### **Panoramic Modality**

Sensor technology	CMOS
Image field	6.4 x 140 mm (for adult patient size) 6.4 x 120 mm (for child patient size) 120 x 140 mm (for sinus one-shot exam)
Gray scale	16384 - 14 bits
Magnification	1.28

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Panoramic Modality		
Radiological exams	Full panoramic Segmented panoramic Bitewing Maxillary sinus Lateral TMJ x 2 Lateral TMJ x 4 Sinus AP / PA / Lateral Orthogonal panoramic	
Exposure time	0.5 to 13 s	
Exposure mode	4 patient sizes (child, small adult, medium adult, large adult) 3 dental arch morphology (normal, square, sharp)	

Panoramic modality is not available in Australia when the device is installed only with the 3D modality.

3D Modality				
Technology	Dental Volumetric Reconstruction (DVR)			
Sensor technology	CMOS			
Volume Field Of View (FOV) diameter x height (cm)	$\begin{array}{c} 4 \times 4 \\ 5 \times 5 \\ 5 \times 8 \\ 6 \times 6 \\ 8 \times 5 \\ 8 \times 8 \\ 10 \times 5^{1} \\ 10 \times 10^{*1} \\ 12 \times 5^{1} \\ 12 \times 10^{*1} \\ 16 \times 6^{1} \\ 16 \times 10^{*1} \\ 16 \times 12^{1} \\ 16 \times 17 \\ ^{*} \text{with tip of the volume} \end{array}$			
Radiological exams	Tooth / Teeth Full, upper or lower jaw TMJ Face ENT Upper cervical spine Wrist			
Gray scale	16384 - 14 bits			
Magnification	1.4			
Voxel Size	75 µm minimum			
Exposure time	5.5 to 40 s (2 x 20 s)			
Scan mode	Continuous			

¹ In Ontario (Canada), the use by dentists, of FOVs that are over 8x8 is subject to conditions.

Cephalometric modality (available with Scan Ceph configuration)					
Sensor technology	CMOS				
Image field	6.4 x 263.3 mm				
Grey scale	16384 – 14 bits				
Magnification	1.13				
Radiological exams	Lateral Frontal AP or PA Oblique Submento-vertex Carpus (optional)				
Exposure time	2.96 to 10s				

Cephalometric modality is not available in Australia when the device is installed only with the 3D modality.

Components	CS 9600
Input voltage (AC)	100-240 V – 50/60 Hz
Unit dimensions	1284 (L) x 1669 (D) x 2526 mm (H)
Required space	1500 (L) x 2000 (D) x 2200 (H) mm (without optional Stool or when Stool installed on the left) 1900 (L) x 2000 (D) x 2200 (H) mm (with optional Stool installed on the right)
Weight without the Scan ceph	210 kg
Weight with Scan Ceph	240 kg

# **Minimum Computer System Requirement**

The computer and the peripheral equipment must conform to the IEC 60950 standard. The computer for acquisition is delivered with CS 9600.

The following table provides the minimum computer system requirement for the computer intended to be used to review acquired images.

ltem	Viewing			
CPU	Intel Core i7-2600 (2 nd generation)			
RAM	8 GB 16 GB (PDIP option) 32 GB (for CS MAR option)			
Graphic board	Any GPU with 1Go RAM that is compatible with Open GL 3.2.			
Display	1024 x 768 minimum screen resolution 32 bits color mode			
Operating system	Windows 10 (64 bits)			
Ethernet interface	1 Gbps			
CD/DVD drive	A DVD-BURNER drive is required.			
Backup Media	Removable/portable, external hard disk drive			
Mouse	A mouse with 2 buttons and a scroll wheel is required			



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 9600 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 Ĩ	Recommended for the children population of between 5 to 12 year old [ $\sim$ 21 kg (46 lb); 113 cm (44.5 in) to $\sim$ 52 kg (115 lb) ; 156 cm (61.5 in)].
Adult Small Patient	Recommended for the adolescent population of approximately
size	~ 52 kg (115 lb); 156 cm (61.5 in).

Selecting the low do	
The low dose imagi	ng mode 🖤 (for panoramic and 3D modality) and the fast
imaging mode	(for cephalometric modality) reduces the dose by minimizing the rs.

#### 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
6x6	5x5
10x5	8x5
10x10	8x8
12x5	10x5
12x10	10x10
16x17	16x12

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:

- Especially for children and adolescent patients, use the two smallest FoV sizes instead of the 26x24.
- Particularly limit the FoV for interceptive treatments made for children below 12 years old to 18x18.
- To treat adolescents, limit the FoV to 18x18 or a maximum of 18x24.

CS 9600 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 9600 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.

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- 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

#### Table 4 Patient Dose information for panoramic modality

Jaw arch	Program			ADUL	T LARGE
		T(s)	kV	mA	DAP* mGy.cm.cm
all	MAXILLARY SINUS	7	76	10	93.7
	SINUS PA WATERS	1	90	10	331.9
	SINUS AP / PA <i>FRONTAL</i>	1	90	10	331.9
	SINUS LATERAL SPHENOID	1	90	5	166
	FULL PANORAMIC	13	76	10	174.3
	FULL ORTHOGONAL PANORAMIC	13	76	10	174.3
	FULL PANORAMIC LOW DOSE	9.7	76	10	130.0
	FULL ORTHOGONAL PANORAMIC LOW DOSE	9.8	76	10	131.4
	FULL PANORAMIC REDUCED	10.2	76	10	136.7
	FULL ORTHOGONAL PANORAMIC REDUCED	10.6	76	10	142.1
	FULL PANORAMIC REDUCED LOW DOSE	7.9	76	10	105.9
	FULL ORTHOGONAL PANORAMIC REDUCED LOW DOSE	7.9	76	10	105.9
	SEGMENTED PANORAMIC MOLARS R and L	11.6	76	10	155.5
	ORTHOGONAL PANORAMIC MOLARS R and L	10.6	76	10	142.1
	SEGMENTED PANORAMIC MOLARS R or L	5.8	76	10	77.7
	ORTHOGONAL PANORAMIC MOLARS R or L	5.3	76	10	71.0
Filling - 1-1	SEGMENTED PANORAMIC REDUCED MOLARS R and L	8.8	76	10	118.0
Ellipsoid	ORTHOGONAL PANORAMIC REDUCED MOLARS R and L	8.4	76	10	112.6
	BITEWING R and L	8.4	76	10	112.6
	BITEWING R or L	4.2	76	10	56.3
	SEGMENTED PANORAMIC REDUCED MOLARS R or L	4.4	76	10	59.0
	ORTHOGONAL PANORAMIC REDUCED MOLARS R or L	4.2	76	10	56.3
	SEGMENTED PANORAMIC INCISIVE	3.3	76	10	44.2
	ORTHOGONAL PANORAMIC INCISIVE	4.5	76	10	60.3
	SEGMENTED PANORAMIC INCISIVE MOLARS R or L	8.1	76	10	108.6
	ORTHOGONAL PANORAMIC INCISIVE MOLARS R or L	8.5	76	10	113.9
	SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L	6.7	76	10	89.8
	ORTHOGONAL PANORAMIC INCISIVE REDUCED MOLARS R or L	7.3	76	10	97.9
		4.6	76	10	61.7
	LATERAL TMJx4	4.6	76	10	61.7
	FULL PANORAMIC	13	76	10	174.3
	FULL ORTHOGONAL PANORAMIC	13	76	10	174.3
	FULL PANORAMIC LOW DOSE	9.7	76	10	130.0
	FULL ORTHOGONAL PANORAMIC LOW DOSE	9.7	-	10	130.0
	FULL PANORAMIC REDUCED		76 76	10	130.0
	FULL ORTHOGONAL PANORAMIC REDUCED	10.3	-	10	
	FULL PANORAMIC REDUCED	10.6 7.7	76 76	-	142.1
				10	103.2
	FULL ORTHOGONAL PANORAMIC REDUCED LOW DOSE	7.8	76	10	104.6
	SEGMENTED PANORAMIC MOLARS R and L	11.5	76	10	154.2
		10.5	76	10	140.7
Upsiloid	SEGMENTED PANORAMIC MOLARS R or L	5.7	76	10	76.4
	ORTHOGONAL PANORAMIC MOLARS R or L	5.3	76	10	71.0
	SEGMENTED PANORAMIC REDUCED MOLARS R and L	8.7	76	10	116.6
	ORTHOGONAL PANORAMIC REDUCED MOLARS R and L	8.4	76	10	112.6
	BITEWING R and L	8.4	76	10	112.6
	BITEWING R or L	4.2	76	10	56.3
	SEGMENTED PANORAMIC REDUCED MOLARS R or L	4.4	76	10	59.0
	ORTHOGONAL PANORAMIC REDUCED MOLARS R or L	4.2	76	10	56.3
	SEGMENTED PANORAMIC INCISIVE	3.6	76	10	48.3
	ORTHOGONAL PANORAMIC INCISIVE	4.5	76	10	60.3
	SEGMENTED PANORAMIC INCISIVE MOLARS R or L	8.3	76	10	111.3
	ORTHOGONAL PANORAMIC INCISIVE MOLARS R or L	8.6	76	10	115.3

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Jaw arch	Drogram		ADULT LARGE			
	Program	T(s)	kV	mA	DAP* mGy.cm.cm	
	SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L	6.9	76	10	92.5	
	ORTHOGONAL PANORAMIC INCISIVE REDUCED MOLARS R or L	7.4	76	10	99.2	
	LATERAL TMJx2	4.6	76	10	61.7	
	LATERAL TMJx4	4.6	76	10	61.7	
	FULL PANORAMIC	13	76	10	174.3	
	FULL ORTHOGONAL PANORAMIC	13	76	10	174.3	
	FULL PANORAMIC LOW DOSE	9.7	76	10	130.0	
	FULL ORTHOGONAL PANORAMIC LOW DOSE	9.7	76	10	130.0	
	FULL PANORAMIC REDUCED	10.3	76	10	138.1	
	FULL ORTHOGONAL PANORAMIC REDUCED	10.6	76	10	142.1	
	FULL PANORAMIC REDUCED LOW DOSE	7.8	76	10	104.6	
	FULL ORTHOGONAL PANORAMIC REDUCED LOW DOSE	7.7	76	10	103.2	
	SEGMENTED PANORAMIC MOLARS R and L	11.6	76	10	155.5	
	ORTHOGONAL PANORAMIC MOLARS R and L	10.8	76	10	144.8	
	SEGMENTED PANORAMIC MOLARS R or L	5.8	76	10	77.7	
	ORTHOGONAL PANORAMIC MOLARS R or L	5.4	76	10	72.4	
Davahalaid	SEGMENTED PANORAMIC REDUCED MOLARS R and L	8.9	76	10	119.3	
Paraboloid	ORTHOGONAL PANORAMIC REDUCED MOLARS R and L	8.2	76	10	109.9	
	BITEWING R and L	8.2	76	10	109.9	
	BITEWING R or L	4.1	76	10	55.0	
	SEGMENTED PANORAMIC REDUCED MOLARS R or L	4.5	76	10	60.3	
	ORTHOGONAL PANORAMIC REDUCED MOLARS R or L	4.1	76	10	55.0	
	SEGMENTED PANORAMIC INCISIVE	3.1	76	10	41.6	
	ORTHOGONAL PANORAMIC INCISIVE	4.5	76	10	60.3	
	SEGMENTED PANORAMIC INCISIVE MOLARS R or L	8.1	76	10	108.6	
	ORTHOGONAL PANORAMIC INCISIVE MOLARS R or L	8.5	76	10	113.9	
	SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L	6.7	76	10	89.8	
	ORTHOGONAL PANORAMIC INCISIVE REDUCED MOLARS R or L	7.3	76	10	97.9	
	LATERAL TMJx2	4.8	76	10	64.3	
	LATERAL TMJx4	4.8	76	10	64.3	



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

Jaw arch	Program			ADULT	MEDIUM
Jaw arch	Program	T(s)	kV	mA	DAP* mGy.cm.cm
	MAXILLARY SINUS	7	73	8	69.3
all	SINUS PA WATERS	0.9	90	10	298.6
dli	SINUS AP / PA <i>FRONTAL</i>	0.9	90	10	298.6
	SINUS LATERAL SPHENOID	0.9	90	5	149.3
	FULL PANORAMIC	12.3	73	8	121.7
	FULL ORTHOGONAL PANORAMIC	12.3	73	8	121.7
	FULL PANORAMIC LOW DOSE	9.2	73	8	91.1
	FULL ORTHOGONAL PANORAMIC LOW DOSE	9.8	73	8	97.0
	FULL PANORAMIC REDUCED	10.2	73	8	101.0
	FULL ORTHOGONAL PANORAMIC REDUCED	10.1	73	8	100.0
	FULL PANORAMIC REDUCED LOW DOSE	7.5	73	8	74.2
	FULL ORTHOGONAL PANORAMIC REDUCED LOW DOSE	8.1	73	8	80.2
	SEGMENTED PANORAMIC MOLARS R and L	11.2	73	8	110.9
	ORTHOGONAL PANORAMIC MOLARS R and L	9.7	73	8	96.0
	SEGMENTED PANORAMIC MOLARS R or L	5.6	73	8	55.4
	ORTHOGONAL PANORAMIC MOLARS R or L	4.9	73	8	48.5
Ellipsoid	SEGMENTED PANORAMIC REDUCED MOLARS R and L	9.1	73	8	90.1
Linpsolu	ORTHOGONAL PANORAMIC REDUCED MOLARS R and L	8	73	8	79.2
	BITEWING R and L	8	73	8	79.2
	BITEWING R or L	4	73	8	39.6
	SEGMENTED PANORAMIC REDUCED MOLARS R or L	4.5	73	8	44.5
	ORTHOGONAL PANORAMIC REDUCED MOLARS R or L	4	73	8	39.6
	SEGMENTED PANORAMIC INCISIVE	3.5	73	8	34.6
	ORTHOGONAL PANORAMIC INCISIVE	4.3	73	8	42.6
	SEGMENTED PANORAMIC INCISIVE MOLARS R or L	7.9	73	8	78.2
	ORTHOGONAL PANORAMIC INCISIVE MOLARS R or L	8.4	73	8	83.1
	SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L	6.8	73	8	67.3
	ORTHOGONAL PANORAMIC INCISIVE REDUCED MOLARS R or L	7.3	73	8	72.3
	LATERAL TMJx2	3.7	73	8	36.6
	LATERAL TMJx4	3.7	73	8	36.6
	FULL PANORAMIC	12.3	73	8	121.7
	FULL ORTHOGONAL PANORAMIC	12.3	73	8	121.7
	FULL PANORAMIC LOW DOSE	9.2	73	8	91.1
	FULL ORTHOGONAL PANORAMIC LOW DOSE	9.4	73	8	93.0
	FULL PANORAMIC REDUCED	10.1	73	8	100.0
	FULL ORTHOGONAL PANORAMIC REDUCED	10.2	73	8	101.0
	FULL PANORAMIC REDUCED LOW DOSE	7.5	73	8	74.2
	FULL ORTHOGONAL PANORAMIC REDUCED LOW DOSE	7.8	73	8	77.2
	SEGMENTED PANORAMIC MOLARS R and L	11.2	73	8	110.9
	ORTHOGONAL PANORAMIC MOLARS R and L	9.6	73	8	95.0
	SEGMENTED PANORAMIC MOLARS R or L	5.6	73	8	55.4
Upsiloid	ORTHOGONAL PANORAMIC MOLARS R or L	4.8	73	8	47.5
50511010	SEGMENTED PANORAMIC REDUCED MOLARS R and L	9	73	8	89.1
	ORTHOGONAL PANORAMIC REDUCED MOLARS R and L	8	73	8	79.2
	BITEWING R and L	8	73	8	79.2
	BITEWING R or L	4	73	8	39.6
	SEGMENTED PANORAMIC REDUCED MOLARS R or L	4.5	73	8	44.5
	ORTHOGONAL PANORAMIC REDUCED MOLARS R or L	4	73	8	39.6
	SEGMENTED PANORAMIC INCISIVE	4.4	73	8	43.6
	ORTHOGONAL PANORAMIC INCISIVE	4.3	73	8	42.6
	SEGMENTED PANORAMIC INCISIVE MOLARS R or L	8.3	73	8	82.2
	ORTHOGONAL PANORAMIC INCISIVE MOLARS R or L	8.5	73	8	84.1
	SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L	7.2	73	8	71.3
	ORTHOGONAL PANORAMIC INCISIVE REDUCED MOLARS R or L	7.4	73	8	73.2

Jaw arch	Program	ADULT MEDIUM			
Jaw arch		T(s)	kV	mA	DAP* mGy.cm.cm
	LATERAL TMJx2	3.5	73	8	34.6
	LATERAL TMJx4	3.5	73	8	34.6
	FULL PANORAMIC	12.3	73	8	121.7
	FULL ORTHOGONAL PANORAMIC	12.3	73	8	121.7
	FULL PANORAMIC LOW DOSE	9.2	73	8	91.1
	FULL ORTHOGONAL PANORAMIC LOW DOSE	9.2	73	8	91.1
	FULL PANORAMIC REDUCED	9.6	73	8	95.0
	FULL ORTHOGONAL PANORAMIC REDUCED	10	73	8	99.0
	FULL PANORAMIC REDUCED LOW DOSE	7.5	73	8	74.2
	FULL ORTHOGONAL PANORAMIC REDUCED LOW DOSE	7.4	73	8	73.2
	SEGMENTED PANORAMIC MOLARS R and L	10.8	73	8	106.9
	ORTHOGONAL PANORAMIC MOLARS R and L	10	73	8	99.0
	SEGMENTED PANORAMIC MOLARS R or L	5.4	73	8	53.4
	ORTHOGONAL PANORAMIC MOLARS R or L	5	73	8	49.5
Paraboloid	SEGMENTED PANORAMIC REDUCED MOLARS R and L	8.1	73	8	80.2
Parapoloiu	ORTHOGONAL PANORAMIC REDUCED MOLARS R and L	7.9	73	8	78.2
	BITEWING R and L	7.9	73	8	78.2
	BITEWING R or L	4	73	8	39.6
	SEGMENTED PANORAMIC REDUCED MOLARS R or L	4.1	73	8	40.6
	ORTHOGONAL PANORAMIC REDUCED MOLARS R or L	4	73	8	39.6
	SEGMENTED PANORAMIC INCISIVE	3.4	73	8	33.7
	ORTHOGONAL PANORAMIC INCISIVE	4.3	73	8	42.6
	SEGMENTED PANORAMIC INCISIVE MOLARS R or L	7.9	73	8	78.2
	ORTHOGONAL PANORAMIC INCISIVE MOLARS R or L	8.2	73	8	81.2
	SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L	6.5	73	8	64.3
	ORTHOGONAL PANORAMIC INCISIVE REDUCED MOLARS R or L	7	73	8	69.3
	LATERAL TMJx2	4.4	73	8	43.6
	LATERAL TMJx4	4.4	73	8	43.6

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

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Jaw arch	Ducator			ADULT SMALL			
Jaw arch	Program	T(s)	kV	mA	DAP* mGy.cm.cm		
	MAXILLARY SINUS	7	72	6.3	53		
- 11	SINUS PA WATERS	0.8	90	10	265.3		
all	SINUS AP / PA <i>FRONTAL</i>	0.8	90	10	265.3		
	SINUS LATERAL SPHENOID	0.8	90	5	132.6		
	FULL PANORAMIC	11.6	72	6.3	87.9		
	FULL ORTHOGONAL PANORAMIC	11.6	72	6.3	87.9		
	FULL PANORAMIC LOW DOSE	8.7	72	6.3	65.9		
	FULL ORTHOGONAL PANORAMIC LOW DOSE	9.5	72	6.3	72.0		
	FULL PANORAMIC REDUCED	9.9	72	6.3	75.0		
	FULL ORTHOGONAL PANORAMIC REDUCED	9.9	72	6.3	75.0		
	FULL PANORAMIC REDUCED LOW DOSE	7.2	72	6.3	54.5		
	FULL ORTHOGONAL PANORAMIC REDUCED LOW DOSE	8	72	6.3	60.6		
	SEGMENTED PANORAMIC MOLARS R and L	9.3	72	6.3	70.4		
	ORTHOGONAL PANORAMIC MOLARS R and L	8.2	72	6.3	62.1		
	SEGMENTED PANORAMIC MOLARS R or L	4.6	72	6.3	34.8		
	ORTHOGONAL PANORAMIC MOLARS R or L	4.1	72	6.3	31.1		
	SEGMENTED PANORAMIC REDUCED MOLARS R and L	7.6	72	6.3	57.6		
Ellipsoid	ORTHOGONAL PANORAMIC REDUCED MOLARS R and L	6.6	72	6.3	50.0		
	BITEWING R and L	6.6	72	6.3	50.0		
	BITEWING R or L			6.3	25.0		
	SEGMENTED PANORAMIC REDUCED MOLARS R or L	3.3	72 72	6.3	28.8		
		3.8		6.3	25.0		
	ORTHOGONAL PANORAMIC REDUCED MOLARS R or L	3.3	72	6.3	35.6		
	SEGMENTED PANORAMIC INCISIVE	4.7	72				
		4.1	72	6.3	31.1		
	SEGMENTED PANORAMIC INCISIVE MOLARS R or L	8.2	72	6.3	62.1		
	ORTHOGONAL PANORAMIC INCISIVE MOLARS R or L	8.6	72	6.3	65.1		
	SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L	7.3	72	6.3	55.3		
	ORTHOGONAL PANORAMIC INCISIVE REDUCED MOLARS R or L	7.7	72	6.3	58.3		
	LATERAL TMJx2	2.8	72	6.3	21.2		
	LATERAL TMJx4	2.8	72	6.3	21.2		
	FULL PANORAMIC	11.6	72	6.3	87.9		
	FULL ORTHOGONAL PANORAMIC	11.6	72	6.3	87.9		
	FULL PANORAMIC LOW DOSE	8.7	72	6.3	65.9		
	FULL ORTHOGONAL PANORAMIC LOW DOSE	8.9	72	6.3	67.4		
	FULL PANORAMIC REDUCED	8	72	6.3	60.6		
	FULL ORTHOGONAL PANORAMIC REDUCED	10	72	6.3	75.7		
	FULL PANORAMIC REDUCED LOW DOSE	7.2	72	6.3	54.5		
	FULL ORTHOGONAL PANORAMIC REDUCED LOW DOSE	7.4	72	6.3	56.1		
	SEGMENTED PANORAMIC MOLARS R and L	9.6	72	6.3	72.7		
	ORTHOGONAL PANORAMIC MOLARS R and L	8	72	6.3	60.6		
	SEGMENTED PANORAMIC MOLARS R or L	4.8	72	6.3	36.4		
Upsiloid	ORTHOGONAL PANORAMIC MOLARS R or L	4	72	6.3	30.3		
0,000	SEGMENTED PANORAMIC REDUCED MOLARS R and L	7.9	72	6.3	59.8		
	ORTHOGONAL PANORAMIC REDUCED MOLARS R and L	6.3	72	6.3	47.7		
	BITEWING R and L	6.3	72	6.3	47.7		
	BITEWING R or L	3.1	72	6.3	23.5		
	SEGMENTED PANORAMIC REDUCED MOLARS R or L	3.9	72	6.3	29.5		
	ORTHOGONAL PANORAMIC REDUCED MOLARS R or L	3.1	72	6.3	23.5		
	SEGMENTED PANORAMIC INCISIVE	4.3	72	6.3	32.6		
	ORTHOGONAL PANORAMIC INCISIVE	4.1	72	6.3	31.1		
	SEGMENTED PANORAMIC INCISIVE MOLARS R or L	8	72	6.3	60.6		
	ORTHOGONAL PANORAMIC INCISIVE MOLARS R or L	8.8	72	6.3	66.7		
	SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L	7.1	72	6.3	53.8		
ŀ	ORTHOGONAL PANORAMIC INCISIVE REDUCED MOLARS R or L	7.9	72	6.3	59.8		

low arch	Drogrom	ADULT SMALL							
Jaw arch	Program	T(s)	kV	mA	DAP* mGy.cm.cm				
	LATERAL TMJx2	2.9	72	6.3	22.0				
	LATERAL TMJx4	2.9	72	6.3	22.0				
	FULL PANORAMIC	11.6	72	6.3	87.9				
	FULL ORTHOGONAL PANORAMIC	11.6	72	6.3	87.9				
	FULL PANORAMIC LOW DOSE	8.7	72	6.3	65.9				
	FULL ORTHOGONAL PANORAMIC LOW DOSE	8.7	72	6.3	65.9				
	FULL PANORAMIC REDUCED	10.2	72	6.3	77.3				
	FULL ORTHOGONAL PANORAMIC REDUCED	9.9	72	6.3	75.0				
	FULL PANORAMIC REDUCED LOW DOSE	7.4	72	6.3	56.1				
	FULL ORTHOGONAL PANORAMIC REDUCED LOW DOSE	7.2	72	6.3	54.5				
	SEGMENTED PANORAMIC MOLARS R and L	9	72	6.3	68.2				
	ORTHOGONAL PANORAMIC MOLARS R and L	7.3	72	6.3	55.3				
	SEGMENTED PANORAMIC MOLARS R or L	4.5	72	6.3	34.1				
	ORTHOGONAL PANORAMIC MOLARS R or L	3.7	72	6.3	28.0				
Paraboloid	SEGMENTED PANORAMIC REDUCED MOLARS R and L	7.6	72	6.3	57.6				
Parabololu	ORTHOGONAL PANORAMIC REDUCED MOLARS R and L	6	72	6.3	45.4				
	BITEWING R and L	6	72	6.3	45.4				
	BITEWING R or L	3	72	6.3	22.7				
	SEGMENTED PANORAMIC REDUCED MOLARS R or L	3.8	72	6.3	28.8				
	ORTHOGONAL PANORAMIC REDUCED MOLARS R or L	3	72	6.3	22.7				
	SEGMENTED PANORAMIC INCISIVE	4.7	72	6.3	35.6				
	ORTHOGONAL PANORAMIC INCISIVE	4.1	72	6.3	31.1				
	SEGMENTED PANORAMIC INCISIVE MOLARS R or L	8.1	72	6.3	61.4				
	ORTHOGONAL PANORAMIC INCISIVE MOLARS R or L	8.2	72	6.3	62.1				
	SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L	7.4	72	6.3	56.1				
	ORTHOGONAL PANORAMIC INCISIVE REDUCED MOLARS R or L	7.4	72	6.3	56.1				
	LATERAL TMJx2	2.5	72	6.3	18.9				
	LATERAL TMJx4	2.5	72	6.3	18.9				

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

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	_		CHILD						
Jaw arch	Program	T(s)	kV	mA	DAP* mGy.cm.cm				
	MAXILLARY SINUS	7	68	6.3	37.6				
all	SINUS PA WATERS	0.5	90	10	165.2				
an	SINUS AP / PA <i>FRONTAL</i>	0.5	90	10	165.2				
	SINUS LATERAL SPHENOID	0.5	90	5	82.6				
	FULL PANORAMIC	10.9	68	6.3	58.5				
	FULL ORTHOGONAL PANORAMIC	10.9	68	6.3	58.5				
	FULL PANORAMIC LOW DOSE	8.2	68	6.3	44.0				
	FULL ORTHOGONAL PANORAMIC LOW DOSE	8.2	68	6.3	44.0				
	FULL PANORAMIC REDUCED	9.3	68	6.3	49.9				
	FULL ORTHOGONAL PANORAMIC REDUCED	9.7	68	6.3	52.1				
	FULL PANORAMIC REDUCED LOW DOSE	6.7	68	6.3	36.0				
	FULL ORTHOGONAL PANORAMIC REDUCED LOW DOSE	7.1	68	6.3	38.1				
	SEGMENTED PANORAMIC MOLARS R and L	8.3	68	6.3	44.6				
	ORTHOGONAL PANORAMIC MOLARS R and L	6.7	68	6.3	36.0				
	SEGMENTED PANORAMIC MOLARS R or L	4.2	68	6.3	22.6				
	ORTHOGONAL PANORAMIC MOLARS R or L	3.4	68	6.3	18.3				
Ellipsoid	SEGMENTED PANORAMIC REDUCED MOLARS R and L	6.7	68	6.3	36.0				
Empsolu	ORTHOGONAL PANORAMIC REDUCED MOLARS R and L	5.4	68	6.3	29.0				
	BITEWING R and L	5.4	68	6.3	29.0				
	BITEWING R or L	2.7	68	6.3	14.5				
	SEGMENTED PANORAMIC REDUCED MOLARS R or L	3.3	68	6.3	17.7				
	ORTHOGONAL PANORAMIC REDUCED MOLARS R or L	2.7	68	6.3	14.5				
	SEGMENTED PANORAMIC INCISIVE	4.7	68	6.3	25.2				
	ORTHOGONAL PANORAMIC INCISIVE	3.8	68	6.3	20.4				
	SEGMENTED PANORAMIC INCISIVE MOLARS R or L	7.8	68	6.3	41.9				
	ORTHOGONAL PANORAMIC INCISIVE MOLARS R or L	8.8	68	6.3	47.3				
	SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L	7	68	6.3	37.6				
	ORTHOGONAL PANORAMIC INCISIVE REDUCED MOLARS R or L	8.2	68	6.3	44.0				
	LATERAL TMJx2	2.6	68	6.3	14.0				
	LATERAL TMJx4	2.6	68	6.3	14.0				
	FULL PANORAMIC	10.9	68	6.3	58.5				
	FULL ORTHOGONAL PANORAMIC	10.9	68	6.3	58.5				
	FULL PANORAMIC LOW DOSE	8.2	68	6.3	44.0				
	FULL ORTHOGONAL PANORAMIC LOW DOSE	8.2	68	6.3	44.0				
	FULL PANORAMIC REDUCED	9.9	68	6.3	53.2				
	FULL ORTHOGONAL PANORAMIC REDUCED	9.7	68	6.3	52.1				
	FULL PANORAMIC REDUCED LOW DOSE	6.8	68	6.3	36.5				
	FULL ORTHOGONAL PANORAMIC REDUCED LOW DOSE	7.1	68	6.3	38.1				
	SEGMENTED PANORAMIC MOLARS R and L	9.1	68	6.3	48.9				
	ORTHOGONAL PANORAMIC MOLARS R and L	6.7	68	6.3	36.0				
	SEGMENTED PANORAMIC MOLARS R or L	4.5	68	6.3	24.2				
	ORTHOGONAL PANORAMIC MOLARS R or L	3.3	68	6.3	17.7				
Upsiloid	SEGMENTED PANORAMIC REDUCED MOLARS R and L	7.4	68	6.3	39.7				
	ORTHOGONAL PANORAMIC REDUCED MOLARS R and L	5.3	68	6.3	28.5				
	BITEWING R and L	5.3	68	6.3	28.5				
	BITEWING R or L	2.6	68	6.3	14.0				
	SEGMENTED PANORAMIC REDUCED MOLARS R or L	3.7	68	6.3	19.9				
	ORTHOGONAL PANORAMIC REDUCED MOLARS R or L	2.6	68	6.3	19.9				
	SEGMENTED PANORAMIC INCISIVE	4	68	6.3	21.5				
	ORTHOGONAL PANORAMIC INCISIVE	3.8	68	6.3	20.4				
	SEGMENTED PANORAMIC INCISIVE SEGMENTED PANORAMIC INCISIVE MOLARS R or L	6.3	68	6.3	33.8				
	ORTHOGONAL PANORAMIC INCISIVE MOLARS R OF L								
		8.6	68 68	6.3	46.2				
	SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L	6.7 °	68	6.3	36.0				
	ORTHOGONAL PANORAMIC INCISIVE REDUCED MOLARS R or L	8	68	6.3	43.0				

low arch	Drogrom	CHILD							
Jaw arch	Program	T(s)	kV	mA	DAP* mGy.cm.cm				
	LATERAL TMJx2	2.6	68	6.3	14.0				
	LATERAL TMJx4	2.6	68	6.3	14.0				
	FULL PANORAMIC	10.9	68	6.3	58.5				
	FULL ORTHOGONAL PANORAMIC	10.9	68	6.3	58.5				
	FULL PANORAMIC LOW DOSE	8.2	68	6.3	44.0				
	FULL ORTHOGONAL PANORAMIC LOW DOSE	8.2	68	6.3	44.0				
	FULL PANORAMIC REDUCED	9.4	68	6.3	50.5				
	FULL ORTHOGONAL PANORAMIC REDUCED	9.7	68	6.3	52.1				
	FULL PANORAMIC REDUCED LOW DOSE	6.8	68	6.3	36.5				
	FULL ORTHOGONAL PANORAMIC REDUCED LOW DOSE	7.1	68	6.3	38.1				
	SEGMENTED PANORAMIC MOLARS R and L	7.8	68	6.3	41.9				
	ORTHOGONAL PANORAMIC MOLARS R and L	6.3	68	6.3	33.8				
	SEGMENTED PANORAMIC MOLARS R or L	3.9	68	6.3	20.9				
	ORTHOGONAL PANORAMIC MOLARS R or L	3.6	68	6.3	19.3				
Paraboloid	SEGMENTED PANORAMIC REDUCED MOLARS R and L	6.3	68	6.3	33.8				
Parabololu	ORTHOGONAL PANORAMIC REDUCED MOLARS R and L	6	68	6.3	32.2				
	BITEWING R and L	6	68	6.3	32.2				
	BITEWING R or L	3	68	6.3	16.1				
	SEGMENTED PANORAMIC REDUCED MOLARS R or L	3.2	68	6.3	17.2				
	ORTHOGONAL PANORAMIC REDUCED MOLARS R or L	3	68	6.3	16.1				
	SEGMENTED PANORAMIC INCISIVE	4.9	68	6.3	26.3				
	ORTHOGONAL PANORAMIC INCISIVE	3.8	68	6.3	20.4				
	SEGMENTED PANORAMIC INCISIVE MOLARS R or L	7.9	68	6.3	42.4				
	<b>ORTHOGONAL PANORAMIC INCISIVE MOLARS R or L</b>	8.3	68	6.3	44.6				
	SEGMENTED PANORAMIC INCISIVE REDUCED MOLARS R or L	7.1	68	6.3	38.1				
	ORTHOGONAL PANORAMIC INCISIVE REDUCED MOLARS R or L	7.6	68	6.3	40.8				
	LATERAL TMJx2	2.5	68	6.3	13.4				
	LATERAL TMJx4	2.5	68	6.3	13.4				

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

#### 3D mode



#### CAUTION:

High Resolution Mode results in higher radiation doses than Standard Mode and Low Dose Mode for the same FOV. Each exam must be justified by demonstrating that the benefits outweigh the risks. Do NOT use high resolution mode unless the benefits associated with higher resolution images outweigh the radiation risks.

# Table 5Patient Dose information in 3D Mode120kV is optional

FILTRATION				ADUL	T LARGE DAP*	A	DULT	MEDIUM DAP*		ADUL	r SMALL DAP*		С	HILD DAP*
0.7mm Cu		T(s)	kV	mA	mGy.cm.cm	kV	1	mGy.cm.cm	kV	mA	mGy.cm.cm	kV	mA	
	HR	19.0	120	8	539	120	6.3	424	120	3.2	215	100	4	154
4 x 4	STD	10.0	120	8	283	120	6.3	223	120	3.2	113	100	4	81
	LD	5.5	105	2	26	100	2	22	95	2	19	91	2	16
	HR	19.0	120	8	803	120	6.3	632	120	3.2	321	100	4	229
5 x 5	STD	10.0	120	8	424	120	6.3	334	120	3.2	169	100	4	121
	LD	5.5	105	2	39	100	2	33	95	2	28	91	2	24
	HR	19.0	120	8	1136	120	6.3	894	120	3.2	454	100	4	324
6 x 6	STD	10.0	120	8	598	120	6.3	471	120	3.2	239	100	4	171
	LD	5.5	105	2	55	100	2	47	95	2	40	91	2	34
	HR	19.0	120	8	1282	120	6.3	1009	120	3.2	513	100	4	366
5 x 8	STD	10.0	120	8	676	120	6.3	532	120	3.2	270	100	4	193
	LD	5.5	105	2	62	100	2	53	95	2	45	91	2	38
	HR	18.8	120	8	1245	120	6.3	981	120	3.2	498	100	4	356
8 x 5	STD	15.0	120	5	620	120	4	496	120	2	248	100	2.5	177
	LD	5.5	105	2	61	100	2	52	95	2	44	91	2	38
	HR	18.8	120	8	1998	120	6.3	1573	120	3.2	799	100	4	591
8 x 8	STD	15.0	120	5	995	120	4	796	120	2	398	100	2.5	294
	LD	5.5	105	2	100	100	2	86	95	2	73	91	2	63
	HR	20.0	120	8	854	120	8	854	120	6.3	673	100	8	506
10 x 5	STD	20.0	120	8	854	120	6.3	673	120	3.2	342	100	4	253
	LD	12.0	105	2	88	100	2	76	95	2	64	91	2	56
	HR	20.0	120	8	1457	120	8	1457	120	6.3	1147	100	8	862
10 x 10	STD	20.0	120	8	1457	120	6.3	1147	120	3.2	583	100	4	431
	LD	12.0	105	2	150	100	2	129	95	2	110	91	2	95
	HR	20.0	120	8	1034	120	6.3	814	120	3.2	414	100	4	306
12 x 5	STD	12.0	120	6.3	489	120	5	388	120	2.5	194	100	3.2	147
	LD	12.0	105	2	107	100	2	92	95	2	78	91	2	67
	HR	20.0	120	8	1713	120	6.3	1349	120	3.2	685	100	4	507
12 x 10	STD	12.0	120	6.3	810	120	5	643	120	2.5	321	100	3.2	243
	LD	12.0	105	2	177	100	2	152	95	2	129	91	2	111
16 6	HR	20.0	120	8	1610	120	6.3	1268	120	3.2	644	100	4	476
16 x 6	STD	12.0	120	6.3	761	120	5	604	120	2.5	302	100	3.2	229

HR = High resolution – STD = Standard – LD = Low Dose

CS 9600 Safety, Regulatory & Technical Specifications (SMA17) Ed05

FILTRATION			ADULT LARGE			ADULT MEDIUM			ADULT SMALL				CHILD		
0.7mm Cu		T(s)	kV	mA	DAP* mGy.cm.cm	kV	mA	DAP* mGy.cm.cm	kV	mA	DAP* mGy.cm.cm	kV	mA	DAP* mGy.cm.cm	
	LD	12.0	105	2	166	100	2	143	95	2	121	91	2	105	
	HR	20.0	120	8	2124	120	6.3	1673	120	3.2	850	100	4	629	
16 x 10	STD	12.0	120	6.3	1004	120	5	797	120	2.5	398	100	3.2	302	
	LD	12.0	105	2	219	100	2	189	95	2	160	91	2	138	
	HR	40.0	120	5	2182	120	5	2182	120	3.2	1397	100	4	1033	
16 x 12	STD	24.0	120	6.3	1650	120	5	1309	120	2.5	655	100	3.2	496	
	LD	24.0	105	2	360	100	2	310	95	2	263	91	2	227	
	HR	40.0	120	5	2646	120	5	2646	120	3.2	1693	100	4	1253	
16 x 17	STD	24.0	120	6.3	2000	120	5	1587	120	2.5	794	100	3.2	601	
	LD	24.0	105	2	437	100	2	376	95	2	318	91	2	275	



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

#### HR = High resolution – STD = Standard – LD = Low Dose

FILTRATION			ADULT LARGE DAP*			ADULT MEDIUM DAP*			ADULT SMALL DAP* in				CHILD DAP*			
0.15mm Cu		T(s)	kV	mA	mGy.cm.cm	kV	mA	mGy.cm.cm	kV	mA	mGy.cm.cm	kV	mA			
	HR	19.0	90	8	843	90	6.3	664	90	3.2	337	80	4	323		
4 x 4	STD	10.0	90	8	444	90	6.3	350	90	3.2	178	80	4	170		
	LD	5.5	90	3.2	98	90	2.5	76	90	2	61	80	2.5	58		
	HR	19.0	90	8	1291	90	6.3	1017	90	3.2	516	80	4	495		
5 x 5	STD	10.0	90	8	681	90	6.3	536	90	3.2	272	80	4	261		
	LD	5.5	90	3.2	150	90	2.5	117	90	2	94	80	2.5	90		
	HR	19.0	90	8	1808	90	6.3	1424	90	3.2	723	80	4	693		
6 x 6	STD	10.0	90	8	952	90	6.3	750	90	3.2	381	80	4	365		
	LD	5.5	90	3.2	209	90	2.5	164	90	2	131	80	2.5	125		
	HR	19.0	90	8	1989	90	6.3	1567	90	3.2	796	80	4	762		
5 x 8	STD	10.0	90	8	1049	90	6.3	826	90	3.2	420	80	4	402		
	LD	5.5	90	3.2	231	90	2.5	180	90	2	144	80	2.5	138		
	HR	18.8	90	8	1990	90	6.3	1567	90	3.2	796	80	4	763		
8 x 5	STD	15.0	90	5	991	90	4	793	90	2	396	80	2.5	380		
	LD	5.5	90	3.2	233	90	2.5	182	90	2	145	80	2.5	139		
	HR	18.8	90	8	3198	90	6.3	2518	90	3.2	1279	80	4	1229		
8 x 8	STD	15.0	90	5	1593	90	4	1274	90	2	637	80	2.5	612		
	LD	5.5	90	3.2	374	90	2.5	292	90	2	234	80	2.5	224		
	HR	20.0	90	10	1774	90	10	1774	90	6.3	1118	80	8	1091		
10 x 5	STD	20.0	90	8	1419	90	6.3	1118	90	3.2	568	80	4	545		
	LD	12.0	90	3.2	341	90	2.5	266	90	2	213	80	2.5	204		
	HR	20.0	90	10	2911	90	10	2911	90	6.3	1834	80	8	1789		
10 x 10	STD	20.0	90	8	2328	90	6.3	1834	90	3.2	931	80	4	895		
	LD	12.0	90	3.2	559	90	2.5	437	90	2	349	80	2.5	335		
12 x 5	HR	20.0	90	8	1701	90	6.3	1340	90	3.2	680	80	4	654		
12 X 2	STD	12.0	90	6.3	804	90	5	638	90	2.5	319	80	3.2	314		

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FILTRATION				ADU	LT LARGE DAP*		ADULT	MEDIUM DAP*		ADU	LT SMALL DAP* in		С	HILD DAP*
0.15mm Cu		T(s)	kV	mA	mGy.cm.cm	kV	mA	mGy.cm.cm	kV	mA	mGy.cm.cm	kV	mA	mGy.cm.cm
	LD	12.0	90	3.2	408	90	2.5	319	90	2	255	80	2.5	245
	HR	20.0	90	8	2722	90	6.3	2144	90	3.2	1089	80	4	1046
12 x 10	STD	12.0	90	6.3	1286	90	5	1021	90	2.5	510	80	3.2	502
	LD	12.0	90	3.2	653	90	2.5	510	90	2	408	80	2.5	392
	HR	20.0	90	8	2632	90	6.3	2073	90	3.2	1053	80	4	1011
16 x 6	STD	12.0	90	6.3	1244	90	5	987	90	2.5	494	80	3.2	485
	LD	12.0	90	3.2	632	90	2.5	494	90	2	395	80	2.5	379
	HR	20.0	90	8	3398	90	6.3	2676	90	3.2	1359	80	4	1306
16 x 10	STD	12.0	90	6.3	1606	90	5	1274	90	2.5	637	80	3.2	627
	LD	12.0	90	3.2	816	90	2.5	637	90	2	510	80	2.5	490
	HR	40.0	90	6.3	4449	90	6.3	4449	90	3.2	2260	80	4	2170
16 x 12	STD	24.0	90	6.3	2669	90	5	2118	90	2.5	1059	80	3.2	1042
	LD	24.0	90	3.2	1356	90	2.5	1059	90	2	847	80	2.5	814
	HR	40.0	90	6.3	5352	90	6.3	5352	90	3.2	2718	80	4	2611
16 x 17	STD	24.0	90	6.3	3211	90	5	2549	90	2.5	1274	80	3.2	1253
	LD	24.0	90	3.2	1631	90	2.5	1274	90	2	1019	80	2.5	979

#### EARS ONLY

FILTRATION				ADUL	T LARGE DAP*	AD	DULT	/IEDIUM DAP*		ADU	LT SMALL DAP*		СН	IILD DAP*
0.15mm Cu		T(s)	kV ı	mA	mGy.cm.cm	kV n	nA	mGy.cm.cm	kV	mA	mGy.cm.cm	kV	mA	mGy.cm.cm
6 x 6	HR	19.0	120	6.3	2493	120	5	1979	120	2.5	989	100	3.2	901
	STD	10.0	120	6.3	1312	120	5	1041	120	2.5	521	100	3.2	474
	LD	5.5	105	2	179	100	2	163	95	2	147	91	2	134
16 x 6	HR	20.0	120	6.3	3627	120	5	2878	120	2.5	1439	100	3.2	1310
	STD	12.0	120	5	1727	120	4	1382	120	2	691	100	2.5	614
	LD	12.0	105	2	540	100	2	491	95	2	442	91	2	404
6 x 6	HR	19.0	90	10	2261	90	8	1808	90	4	904	80	5	866
	STD	10.0	90	10	1190	90	8	952	90	4	476	80	5	456
	LD	5.5	90	4	262	90	3.2	209	90	2.5	164	80	3.2	160
16 x 6	HR	20.0	90	10	3290	90	8	2632	90	4	1316	80	5	1264
	STD	12.0	90	8	1579	90	6.3	1244	90	3.2	632	80	4	607
	LD	12.0	90	4	790	90	3.2	632	90	2.5	494	80	3.2	485

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



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

## **Cephalometric mode**

## Table 6 Patient Dose information in Cephalometric Mode

Lateral														
exam				ADU		4	ADULT	MEDIUM		ADUL	SMALL		С	HILD
(W x H)		T(s)	kV	mA	DAP* mGy.cm.cm	kV	mA	DAP* mGy.cm.cm	kV	mA	DAP* mGy.cm.cm	kV	mA	DAP* mGy.cm.cm
10 10	HR	6,92	82	12	20	80	10	15,9	78	8	12,1	74	8	10,8
18 x 18	Fast	2,96	82	12	8,6	80	10	6,8	78	8	5,2	74	8	4,6
40	HR	6,92	82	12	23,1	80	10	18,3	78	8	13,9	74	8	12,5
18 x 24	Fast	2,96	82	12	9,9	80	10	7,9	78	8	6	74	8	5,3
26 × 24	HR	10	82	12	33,4	80	10	26,5	78	8	20,1	74	8	18
26 x 24	Fast	4,28	82	12	14,3	80	10	11,3	78	8	8,6	74	8	7,7

HR = High resolution – Fast = Fast Acquisition Speed

Oblique or Submento- vertex or Frontal AP/PA exams				ADU	LT LARGE	Δ	DULT	MEDIUM		ADUL	ΓSMALL		с	HILD
					DAP*			DAP*			DAP*			DAP*
(W x H)		T(s)	kV	mA	mGy.cm.cm	kV	mA	mGy.cm.cm	kV	mA	mGy.cm.cm	kV	mA	mGy.cm.cm
18 x 18	HR	6,92	90	10	19,7	90	10	19,7	88	10	18,9	84	10	17,4
19 X 19	Fast	2,97	90	10	8,4	90	10	8,4	88	10	8,1	84	10	7,5
10	HR	6,92	90	10	22,7	90	10	22,7	88	10	21,9	84	10	20,2
18 x 24	Fast	2,97	90	10	9,8	90	10	9,8	88	10	9,4	84	10	8,6
26 x 24	HR	10	90	10	32,9	90	10	32,9	88	10	31,7	84	10	29,1
20 X 24	Fast	4,28	90	10	14,1	90	10	14,1	88	10	13,6	84	10	12,5

Carpus														
exam				ADU	LT LARGE DAP*	4	ADULT	MEDIUM DAP*		ADUL	SMALL DAP*		С	HILD DAP*
(W x H)		T(s)	kV	mA	mGy.cm.cm	kV	mA	mGy.cm.cm	kV	mA	mGy.cm.cm	kV	mA	mGy.cm.cm
18 x 18	HR	6,92	66	15	15,8	64	15	14,8	64	15	14,8	60	15	13
19 X 19	Fast	2,97	66	15	6,8	64	15	6,3	64	15	6,3	60	15	5,6
10 24	HR	6,92	66	15	18,2	64	15	17	64	15	17	60	15	15
18 x 24	Fast	2,97	66	15	7,8	64	15	7,3	64	15	7,3	60	15	6,4
26 x 24	HR	10	66	15	26,3	64	15	24,6	64	15	24,6	60	15	21,6
20 X 24	Fast	4,28	66	15	11,3	64	15	10,6	64	15	10,6	60	15	9,3

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



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

# **User Dose information**

## **Stray radiation**

Stray radiation measures are highly dependent on environmental conditions, such as the composition of walls and their locations, therefore in certain circumstances the values may be significantly different.

Measured with a PMMA phantom cylinder ( $\Phi$  16 cm x h 16 cm) at 1.0 m from the central phantom axis.

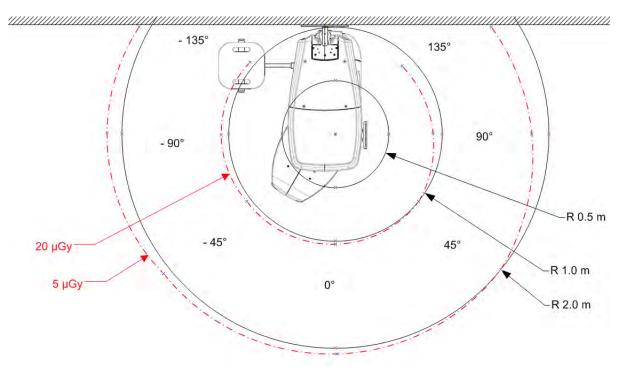
## 3D Mode

Stray radiati	on for o			@ 120 kV or 0.15 m		- 6.3 mAs -	- 20 s	
ANGLE	Deg.	-135	-90	-45	0	45	90	135
Stray radiation*	μGy	22	23	21	21	20	17	16

Stray radiation 16 x 10	HR @ 12			num outpu ı or 0.15 m		60W – 14 x	c exams pe	r hour)
ANGLE	Deg.	-135	-90	-45	0	45	90	135
Stray radiation*	μGy	314	329	300	300	286	243	229

*Maximum values measured 20 cm below the horizontal cross sectional plane with chin rest. Other values in the vertical axis are lower than these values.

#### 3D isodose curves for one exam.



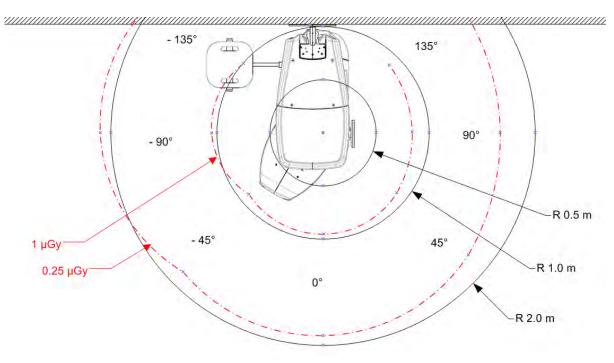
## **Panoramic Mode**

		(6	add. filt. 1.	5 mm Al)				1
ANGLE	Deg.	-135	-90	-45	0	45	90	135
Stray radiation*	μGy	1	1.1	0.8	0.9	0.8	0.7	0.8

Stray radiation PANOR	AIVIIC 5	0	add. filt. 1.		power (o	UVV – 30 X (	exams per	nour)
ANGLE	Deg.	-135	-90	-45	0	45	90	135
Stray radiation*	μGy	30	33	24	27	24	21	24

*Maximum values measured 20 cm below the horizontal cross sectional plane with chin rest. Other values in the vertical axis are lower than these values.

#### Panoramic isodoses curves for one exam.



# **Imaging Performance Information**

## Panoramic and Cephalometric modality

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 (with Scan Ceph configuration).

*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.

CS 9600 does 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 the User Guide, Chapter "**Controlling the Image Quality**".

## **CS 9600 Environmental Requirements**

Ambient Operatin	ng Conditions
Temperatures	10 – 35 °C
Relative humidity	30 – 80 %
Atmospheric pressure	700 – 1060 hpa
Altitude	Up to 3000 m

Storage Co	nditions
Temperatures	-10 – 60 °C
Relative humidity	10 – 90 %
Atmospheric pressure	700 – 1060 hpa

Transport Co	onditions
Temperatures	-10 – 60 °C
Relative humidity	10 – 90 %
Atmospheric pressure	700 – 1060 hpa

# CS 9600 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	10 A	
Maximum absorbed power	2.2 kVA	
Protection for the power supply system	By shutter release at a maximum current of 16 A and a differential current of 30 mA	
Nominal high voltage	120 kV	
Maximum corresponding tube current	8 mA	
Nominal tube current	15 mA	
Maximum corresponding high voltage	80 kV	
Tube current/voltage combination for maximum output power	80 kV, 15 mA	

Selection of the Load Parameters:		
kV (in increments of 1 kV)	From 60 to 120 kV	
mA (in increments of 25 %)	From 2 to 15 mA	

Accuracy of the Load Parameters		
High voltage	kV ± 10 %	
Current in the tube	mA ± 20 %	
Exposure time seconds	± (5% + 50 ms)	
Measurement Conditions		
kV	Indirect on the peak kilovolt meter	
mA	Direct measurement in the circuit using an oscilloscope	
Exposure time	Measurement at 75 % of the kV values with peak kilovolt meter	

# X-ray Tube Assembly Technical Specifications

## Table 7 Filtration of the Material in the X-ray Field

Standard	Compliance
IEC 60601-1-3	Compliant
Nominal value of the inherent filtration at 70 kV	2.5 mm (0.10") eq. Al
Nominal value of the supplementary filtration at 70 kV	1.5 mm Al or 2.0 mm Al or 0.15 mm Cu or 0.7 mm Cu
Nominal value of the total filtration at 70 kV	>2.5 mm (0.10") eq. Al
Filtration value for the enclosure of the X-ray tube (at 100 kV)	0.2 mm (0.008")
Filtration value for the enclosure of the image receiver unit (at 100 kV)	0.2 mm (0.008")
Filtration value for the sensor case	0.3 mm (0.012") eq. Al

The X-ray generator comprises the following:

- A transformer and an X-ray tube and their associated electronic components immersed in oil.
- An aluminum filter, which enhances the quality of the beam and reduces the dose received by the patient.
- A lead collimator, which limits the size of the beam at the image receiver unit.
- A thermal cutout, which trips at an operating temperature between 63 to 70 °C (±5 °C).
- Copper filter.

Figure 3 Location of the Reference Axis for panoramic and 3D modality

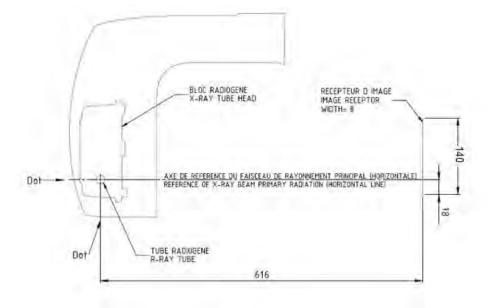
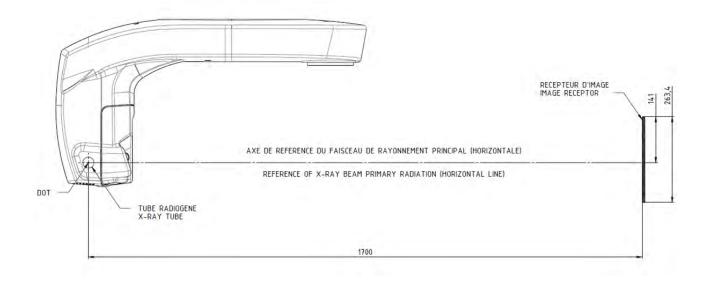


Figure 4 Location of the Reference Axis for cephalometric modality (with Scan Ceph configuration)



#### Table 8 Technical Specifications of the X-ray tube Assembly

Standard	Compliance
Manufacturer	Trophy
Degree of protection against electric shock	Class I
Degree of patient protection from the parts applied to the leakage current	Туре В
Operation mode	Continuous operation with intermittent loading
Maximum accumulated heat	33 kJ
Maximum continuous heat dissipation	60 W
Tolerances on the position of the focal spot	± 1.5 mm
Continuous Anode Input Power that corresponds to the maximum specified energy input to the Anode	60 W
Radiation leakage after one hour's operation (maximum utilization rate of 60W)	< 1 mGy
Weight	8.2 kg
Dimensions	235 x 245 x 120 mm



To increase the operating life of the X-ray tube, at the first loading or if the unit has not been used for a month, you must follow the following procedures before use:

1. In the **3D Acquisition** interface.

2. Select the following series of parameter settings:

- 70 kV 6.3 mA
- 80 kV 10 mA
- 85 kV 10 mA
- 100kV 8 mA
- 120 kV 8 mA
- 3. Leave the X-ray room and close the door. For each parameter setting, from the X-ray remote control, press and hold the button to launch the X-ray

The unit is now ready to be used for acquisition.

Figure 5 Heating and Cooling Curves of the X-ray Tube DF-071G

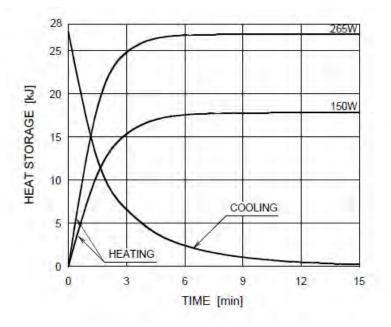
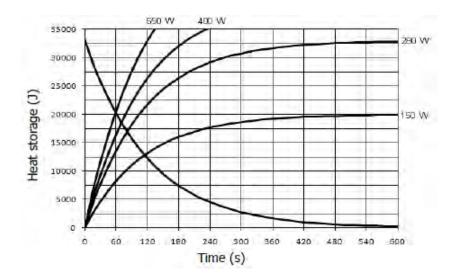


Figure 6 Heating and Cooling Curves of the X-ray Tube OX/120-0307

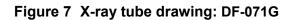


## Table 9 Beam Limitations of the X-ray Tube Assembly

Manufacturer	Trophy
Туре	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 616 mm from the focal point	6.4 mm x 140 mm
Maximum symmetrical field of radiation in panoramic mode (sinus exam) and in 3D mode at a distance of 616 mm from the focal point	120 mm x 140 mm
Maximum symmetrical field radiation in cephalometric mode (with Scan Ceph configuration only) at a distance of 1700 mm from the focal point	5 mm x 260 mm
Location of the reference axis	See Figure 3 and Figure 4

# Table 10 Characteristics of the X-ray Tube

Manufacturer's name	Toshiba or Canon	CEI
Туре	DF-071G	OX/120-0307
Nominal high voltage	120 kV	120 kV
Nominal anode input power (at 1.0 s)	1360 W for Large Focus 440 W for Small Focus	1900 W for Large Focus 500 W for Small Focus
Anode heat storage capacity	28 kJ	33 kJ
Nominal focal spot size (EN 60336)	0.7 mm for Large Focus 0.3 mm for Small Focus	0.7 mm for Large Focus 0.3 mm for Small Focus
Anode materials	Tungsten	Tungsten
Target angle	12°	12°
Inherent filtration	0.8 mm (0.032") eq. Al	0.5 mm (0.028") eq. Al



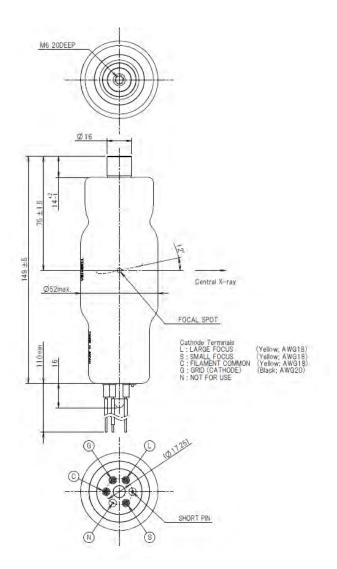
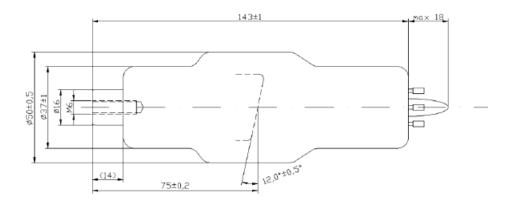


Figure 8 X-ray tube drawing: OX/120-0307





# Manufacturer's Address



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## Authorized Representative in the European Community



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## Authorized Representative in Brazil

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