

CS 2100 and CS 2200

Safety, Regulatory, and Technical Specifications User Guide

Notice

The Regulatory Information and Technical Specifications User Guide for CS 2100 and CS 2200 includes information on the safety instructions, regulatory information and the technical specifications of the device. We recommend that you thoroughly familiarize yourself with this Guide in order 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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CS 2100 and CS 2200 systems comply with Directive 93/42/EEC relating to medical equipment.



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1 Safety Information

Indications for Use

CS 2100 and CS 2200 are intended for dental radiographic examination and diagnosis of teeth, jaw and oral structures.

Conventions in this Guide

The following mounting configurations are provided for CS 2100 and CS 2200:

Intraoral X-ray system	Configuration Type	Description
CS 2100 & CS 2200	Standard wall-mounting configuration	As an option, this configuration can be associated with the: • Mobile base to obtain the mobile unit • Floor mounting column to obtain the floor mounted unit
	Ceiling mounted configuration	
CS 2200	Irix-mounting configuration	Designed for replacing the previous Trophy Irix units

The CS 2100 and 2200 information applies to all configurations. If the information is only relevant to one specific configuration, this configuration will be clearly specified.



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.

Warning and Safety Instructions



WARNINGS

- 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 control timer unit or X-ray remote control during exposure. This unit must be permanently connected to the ground with a fixed power supply cable.
- There are no user serviceable parts in this system. The product must be installed, maintained, and serviced by qualified service personnel according to the procedures and preventive maintenance schedules in the product service manual. If your product does not operate as expected, contact your Service Representative.
- The assembly, extensions, adjustments, modifications, and repairs must be performed by an authorized Service Representative. Your radiology system must be installed in premises that comply with the applicable standards.
- If the unit develops a fault, switch it to off (O), display an “Unserviceable” notice and contact a service technician.
- If the unit does not operate properly or fails to respond to the controls as described in this manual:
 - 1 Follow the safety precautions as indicated in this manual.
 - 2 Stop using the equipment and do not make or authorize any changes.
 - 3 Contact your Service Representative immediately, report the problem, and wait for further instructions.
- To dispose of the unit or its components, contact a service technician.
- **Do not** operate the unit if there is the threat of an earthquake. Following an earthquake, ensure that the unit is operating satisfactorily before using it again. Failure to observe this precaution may expose patients to hazards.
- X-ray equipment is hazardous to patients and the operator if you do not observe the exposure safety factors and operating instructions.
- **Do not** place objects within the field of operation of the unit.
- The patient should wear a protective lead-lined apron, unless other Radiation Protection Protocols apply locally.
- Ask the patient to refrain from moving during the entire period of exposure.
- **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** operate the equipment in the presence of explosive liquids, vapors, or gases. Do not plug in or turn on the system if hazardous substances are detected in the environment. If these substances are detected after the system has been turned on, do not attempt to turn off the unit or unplug it. Evacuate and ventilate the area before turning off the system



DANGEROUS VOLTAGE

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.

- This product is designed and manufactured to ensure maximum safety of operation. Operate and maintain it in strict compliance with the safety precautions and operating instructions contained in this manual.
- This product meets all the safety requirements applicable to medical equipment. However, anyone attempting to operate the system must be fully aware of potential safety hazards.
- X-ray systems manufactured by Carestream Health, Inc. comply with safety standards throughout the world for optimum protection against radiation risks.
- No partial or total modification of the unit is allowed without prior written approval from Carestream Health, Inc.
- To ensure safety, read all user manuals carefully before using the system and observe all Caution, Important, and Note callouts located throughout the manual.
- Keep this manual with the equipment.
- Reading this manual does not qualify you to operate, test, or calibrate the unit.
- Be aware of the product specifications as well as system accuracy and stability limitations. Consider these limitations before making any decision related to quantitative values. If you have any doubt, consult your Sales Representative.



CAUTION: X-rays can be dangerous if used incorrectly. Take precautions even when following the instructions in this manual. Use conventional commercially available equipment to protect yourself and your patients against scattered radiation risks.

- If you fail to comply with these instructions, Carestream Health, Inc. will not be responsible for the safety reliability, and characteristics of the unit.

Hygiene and Disinfection



WARNINGS

- Ensure that any parts of the unit that may come into contact with the patient and the operator have been disinfected with an intermediate disinfectant or a low-level disinfectant after each patient has been exposed to X-rays.
- Do not allow liquids to drip into the system.
- Do not spray cleaner or disinfectant directly onto the machine
- Follow the manufacturer's safety recommendations when using the cleaner or disinfectant.

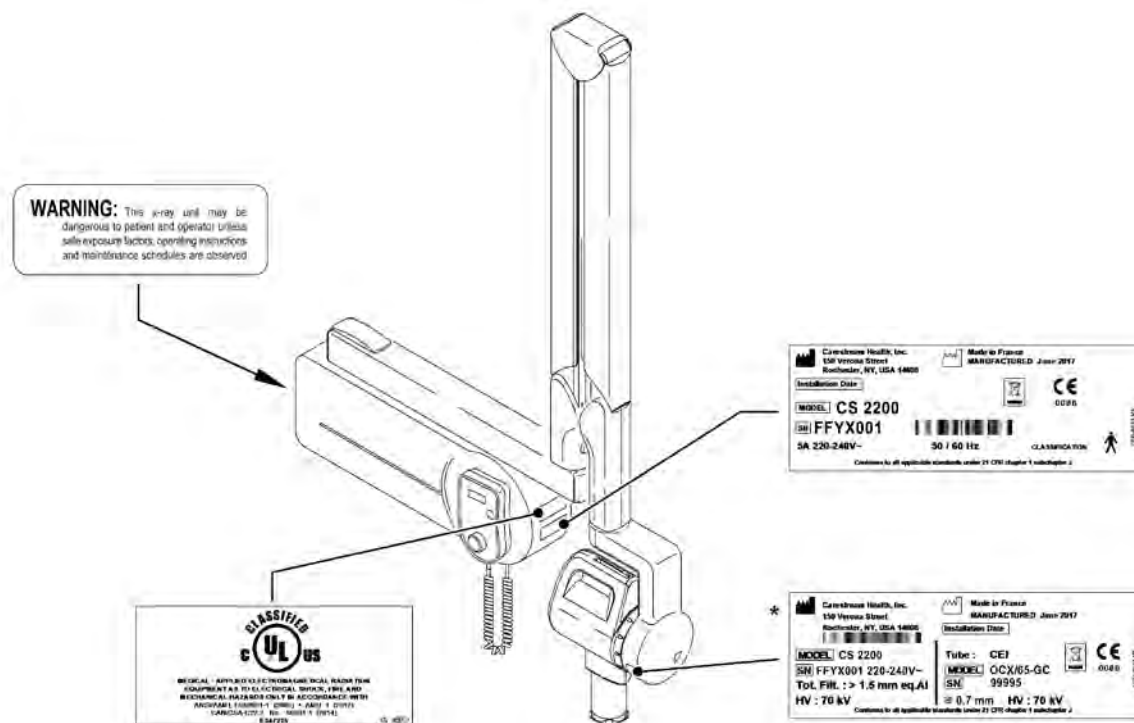
Marking and Labeling Symbols

	TYPE B Applied Part
	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: General warning sign
	Ionizing radiation
	Protective earth (ground)
	Earth (ground)
	ON/OFF button
	Refer to instruction manual/booklet
	Manufactured Date
	Manufacturer's Address and Name

Label Locations

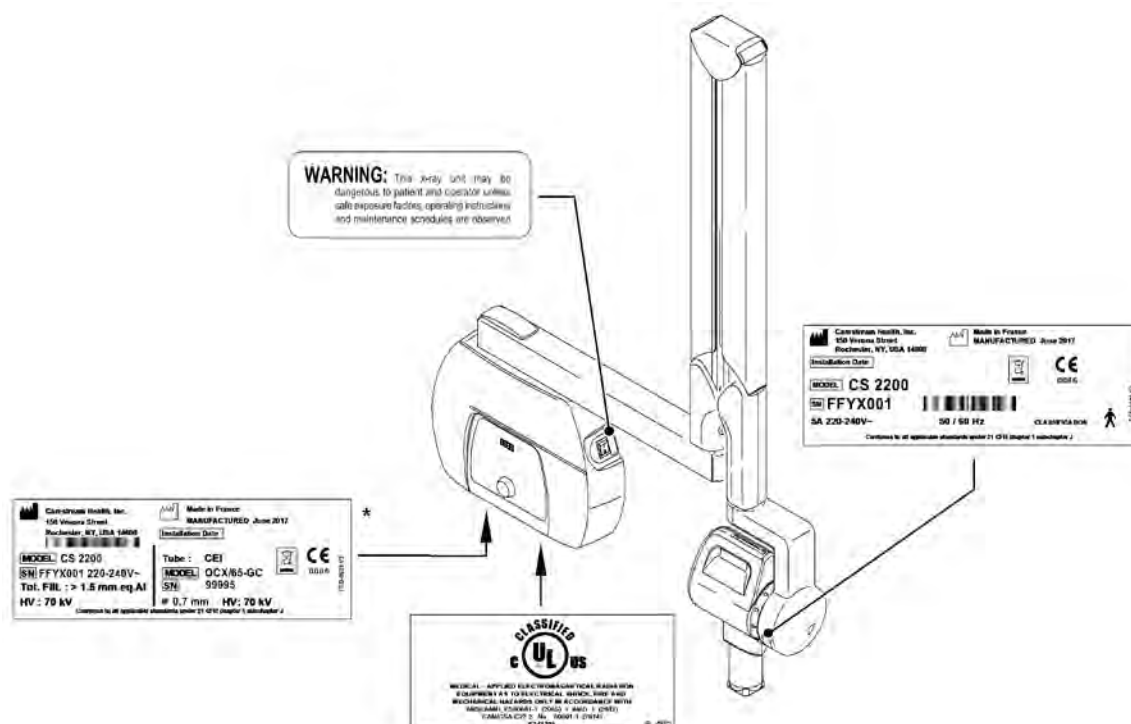
The following figures illustrate the label locations of the CS 2200 and CS 2100 systems.

Figure 1 Identification labels on the CS 2200 Standard mounting system



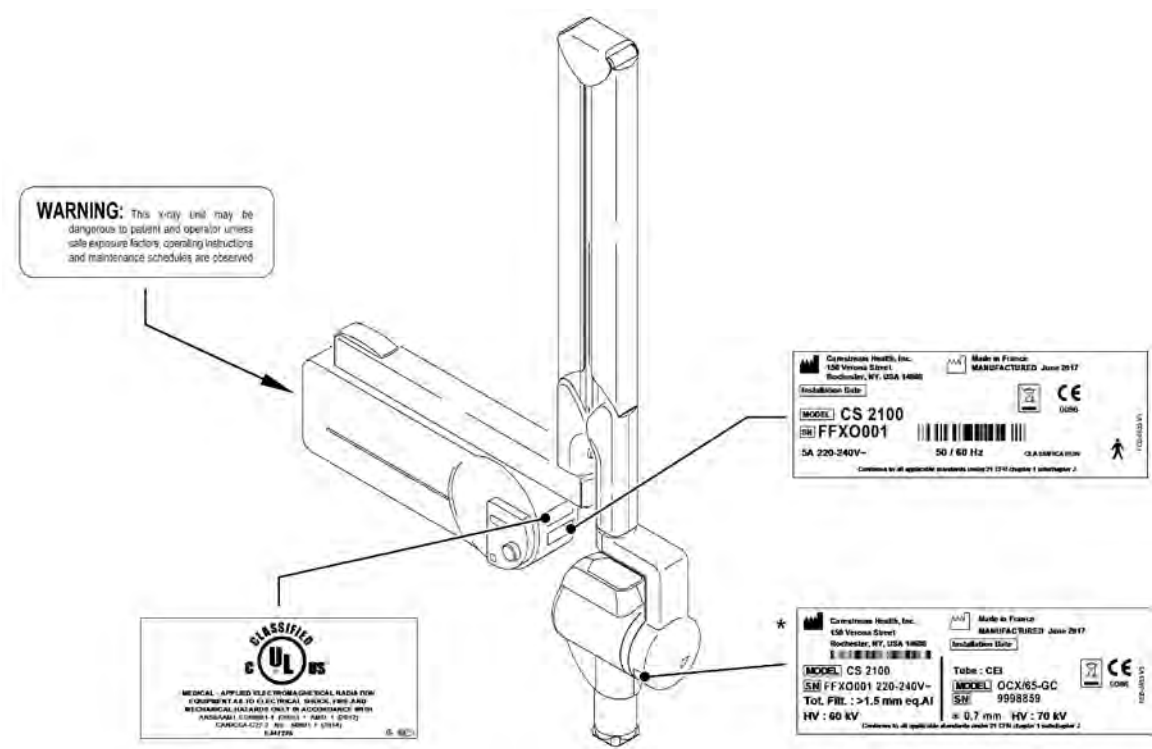
* Product may also be fitted with X-ray generator model TROPHY type TRX 708.

Figure 2 Identification labels on the CS 2200 Irix mounting system



* Product may also be fitted with X-ray generator model TROPHY type TRX 708.

Figure 3 Identification labels on the CS 2100 system



* Product may also be fitted with X-ray generator model TROPHY type TRX 708.

Table 1 Label Definitions

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

2 Regulatory Information

General Regulatory Information

Compliance with European and International Standards	
EN/IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance.
EN/IEC 60601-1-2	Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Disturbances - Requirements and tests.
EN/IEC 60601-1-3	Medical Electrical Equipment, Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
EN/IEC 60601-1-6	Medical Electrical Equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN/IEC 60601-2-65	Medical Electrical Equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN 980	Symbols for use in the labeling of medical devices
EN 1041	Information supplied by the manufacturer of medical devices
EN/IEC 62304	Medical device software - Software life cycle processes
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

Electromagnetic Compatibility Precautions



- Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC).
- CS 2100 and CS 2200 must be installed and put into service according to the EMC information provided in this document.
- CS 2100 and CS 2200 may be interfered 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 2100 and 2200 intraoral X-Ray components

Control timer unit

X-ray source assembly

Power board



- Use limitation: the use of accessories, cables, or transducers other than those specified in this document with the exception of cables, accessories or transducers sold by Carestream Health as replacement parts of internal components, may result in increased emissions or decreased immunity of the CS 2100 and 2200.
- CS 2100 and CS 2200 must not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the CS 2100 and 2200 should be observed to verify normal operation in the configuration in which it will be used.



The room in which your radiology unit is to be installed must comply with all official regulations applicable to protection against radiation.

Table 2 Electromagnetic emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The CS 2100 and CS 2200 are intended for use in the electromagnetic environment specified below. The customer or the user of the CS 2100 and CS 2200 should ensure that they are used in such an environment.		
Emission test	Compliance	Electromagnetic environment - Guidance
RF emissions CISPR 11	Group 1	The CS 2100 and CS 2200 use RF energy only for their internal function. Therefore, their RF emissions are very low and not likely to cause any interference in nearby electronic equipment. The CS 2100 and CS 2200 are suitable for use in all establishments, including domestic ones and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 3 Electromagnetic immunity**Guidance and Manufacturer's Declaration - Electromagnetic Immunity**

The CS 2100 and CS 2200 are intended for use in the electromagnetic environment specified below. The customer or the user of the CS 2100 and CS 2200 should ensure that they are 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	Compliance level	Electromagnetic environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 2 kV, 4 kV, 8 kV air	INTENDED USE for X-ray imaging: during the exposure time, no one is close to the ME EQUIPMENT except the PATIENT
Electrostatic fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth	1 kV line(s) to line(s) 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	<5% U_r (>95% dip in U_r) for 0.5 cycle 40% U_r (60% dip in U_r) for 5 cycles 70% U_r (30% dip in U_r) for 25 cycles <5% U_r (>95% dip in U_r) for 5 sec	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 2100 or CS 2200 requires continued operation during power mains interruptions, it is recommended that the CS 2100 or CS 2200 system be powered from an interruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_r is the A.C. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The CS 2100 and CS 2200 are intended for use in the electromagnetic environment specified below. The customer or the user of the CS 2100 and CS 2200 should ensure that they are used in such an environment.

Immunity test	IEC 60601 test level	Electromagnetic environment - Guidance
Conducted RF IEC 6100-4-6	3 Vms 150 kHz to 80 MHz and 6V at ISM Frequencies	Portable and mobile communications equipment should be used no closer to any part of the CS 2100 and CS 2200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vms 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 2100 or CS 2200 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

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

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

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CS 2100 and CS 2200 are used exceeds the applicable RF compliance level above, the CS 2100 and CS 2200 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 2100 and CS 2200.

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

Note: U_r is the AC mains voltage prior to application of the test level.

Compliance with International Regulations

Medical Device directives 93/42/ European Economic Community (EEC), amendment with 07/47 directive, Class IIb following the rule 10

FDA Center for Devices & Radiological Health (21CFR chapter 1 subchapter J)

Radiation Emitting Devices Act - C34 (Canada)

Medical Devices Regulations (Canada)

Directive 2011/65/EU on the Restriction Of the use of certain Hazardous Substances in electrical and electronic equipment (ROHS).



CAUTION: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

3 Technical Specifications

Factory

TROPHY

4, Rue F. Pelloutier, Croissy-Beaubourg

77435 Marne la Vallée Cedex 2, France

Manufacturer

Carestream Health, Inc.

150 Verona Street

Rochester, New York USA 14608

Model

CS 2100

CS 2200

Electrical Specifications

	CS 2100		CS 2200	
Type of electrical power supply	220-240 V ~ ($\pm 10\%$), 50/60 Hz	100-130 V ~ ($\pm 10\%$), 50/60 Hz	220-240 V ~ ($\pm 10\%$), 50/60 Hz	100-130 V ~ ($\pm 10\%$), 50/60 Hz
Apparent resistance of the power supply circuit	0.5 Ω (max).	0.2 Ω (max)	0.5 Ω (max).	0.2 Ω (max).
Permanent absorbed current	220 mA			
Current absorbed during the X-ray emission	5 A	12 A	5 A	12 A
Nominal high voltage	60 kV		70 kV	
Maximum corresponding tube current	7 mA		7 mA	
Nominal tube current	7 mA		7 mA	
Maximum corresponding high voltage	60 kV		70 kV	
Tube current/voltage combination for maximum output power	60 kV, 7 mA		70 kV, 7 mA	
Nominal power for an exposure time of 0.1 s	420 W at 60 kV, 7 mA		490 W at 70 kV, 7 mA	
Minimum value of the current/time in the range of conformity	0.07 mAs at 7 mA		0.07 mAs at 7 mA	
Maximum Use Rate	at 60 kV, 7 mA, 0.1 s and at the maximum X-ray source assembly : approximately one exposure every 6 s		at 70 kV, 7 mA, 0.1 s and at the maximum X-ray source assembly : one exposure every 7 s	
Selection of the Load Parameters	Fixed parameters : 60 kV, 7 mA		70 kV, 7 mA and 60 kV, 7 mA	

Measurement Conditions	
kV	Indirect measurement with the peak kilovolt meter
mAs	Direct in the circuit with a mAs-meter
Exposure time	Indirect measurement on the kV signal at 75 % of the peak value

Accuracy of the Load Parameters	
High voltage	kV $\pm 10\%$
Current in the tube	mA $\pm 20\%$
Exposure time seconds	Seconds $\pm(10\% + 1\text{ms})$ or $\pm(5\% + 50\text{ms})$

Environmental Specifications

Ambient Operating Conditions	
Temperatures	5 - 35 °C (41 °F to 140 °F)
Relative humidity	30 - 85 %
Atmospheric pressure	700 - 1060 hpa
Altitude	Up to 3000 m

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

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

Dimensional Specifications

	Dimensions			Weight		
	CS 2100	CS 2200 (Standard)	CS 2200 (Irix Mounting)	CS 2100	CS 2200 (Standard)	CS 2200 (Irix Mounting)
Control unit	13 x 9 x 4 cm (5.1 x 3.5 x 1.6 in.)	16 x 9 x 4 cm (6.3 x 3.5 x 1.6 in.)	NA	0.15 kg (0.33 lb)	0.4 kg (0.9 lb)	NA
Wall framework	51.4 x 18.9 x 10.8 cm (20.2 x 7.4 x 4.3 in.)		42.0 x 30.9 x 9.8 cm (16.5 x 12.2 x 3.9 in.)	4.3 kg (9.5 lb)		4.1 kg (9.0 lb)
X-ray emitting unit	43.8 x 22.6 x 12 cm (17.2 x 8.9 x 4.7 in.)			4.3 kg (9.5 lb)		
Scissor arm	87.3 x 13.3 x 6.3 cm (34.4 x 5.2 x 2.5 in.)			10 kg (19.8 lb)		
Mobile stand (optional)	90 x 60 x 110 cm (35.4 x 23.6 x 43.3 in.)		NA	40 kg (88.2 lb)		NA
Floor column (optional)	24 x 23 x 90 cm (9.4 x 9.1 x 35.4 in.)		NA	20 kg (44.2 lb)		NA
Ceiling column	50 x 50 x 154 cm (19.7 x 19.7 x 60.6 in.)		NA	12.8 kg (28.2 lb)		NA

Scissor Arm

Equipped with springs specially designed for this application.

X-ray Generator Technical Specifications

Characteristics of the X-ray tubes:

	TROPHY type TRX 708	CEI type OCX/65-GC
Rated high voltage	70 kV	70 kV
Rated anodic power	490 W	490 W
Maximum heat accumulated in the anode	8,700 J	7,000 J
Rated value of focal spot (IEC 60336)	0.7 mm (0.027 in.)	0.7 mm (0.027 in.)
Target materials	Tungsten	Tungsten
Target slope	19°	19°
Filtration due to fixed materials	0.6 mm (0.023 in.) eq Al	0.5 mm (0.020 in.) eq Al

Figure 4 Heating and cooling curves for the Trophy TRX 708 tube

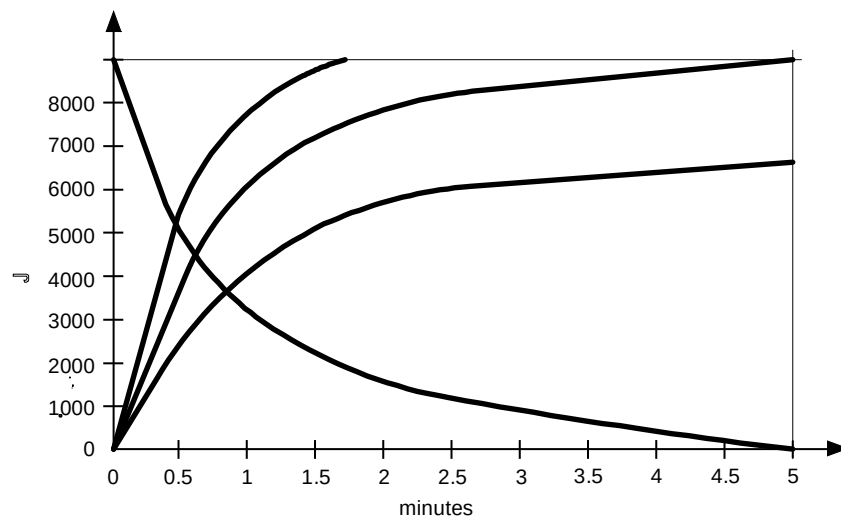
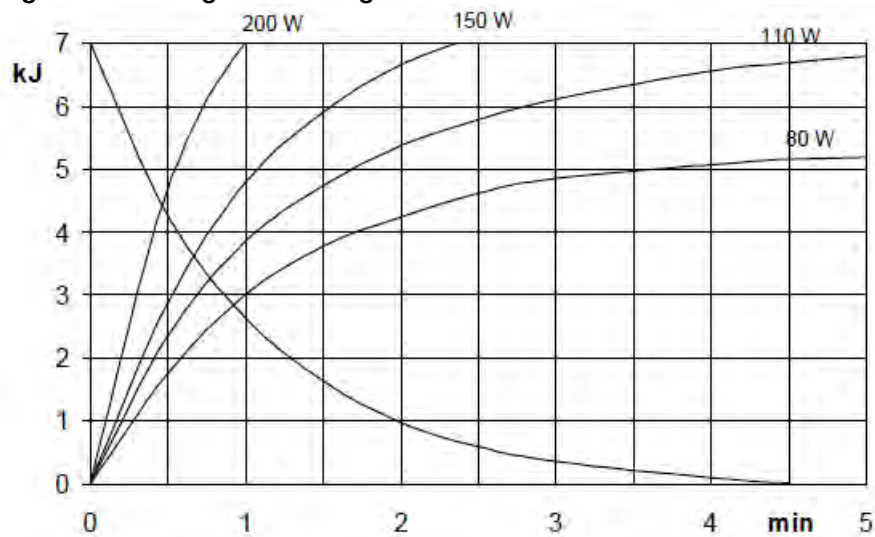


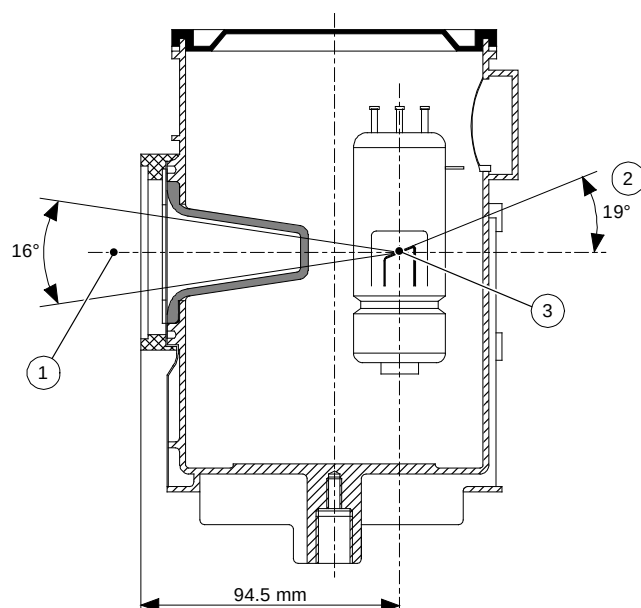
Figure 5 Heating and cooling curves for the CEI OCX/65-GC tube



X-ray Source Assembly Technical Specifications

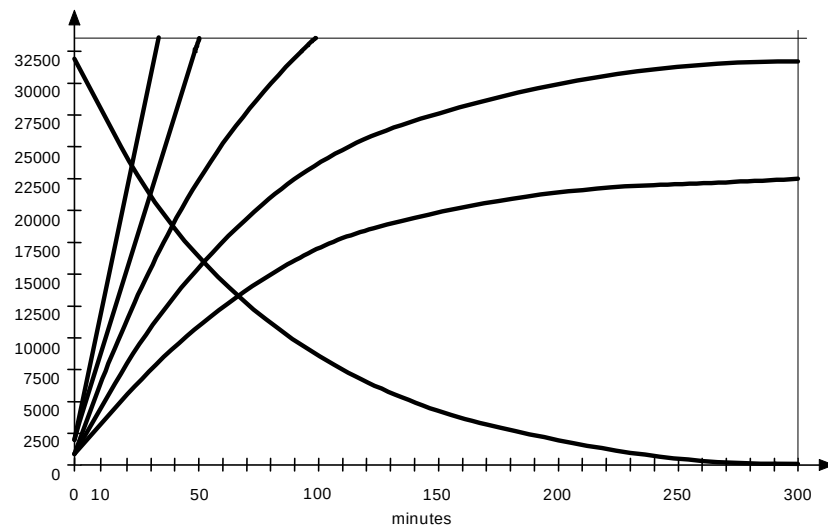
Parameters	
IEC standard 60601-2-65	Conform
Type of protection against electric shocks	Class 1
Degree of protection against electric shock	Type B
Rated value of inherent filtration	1.0 mm (0.039 in.) eq. Al
Rated value of total filtration	At least 1.5 mm (0.059 in.) eq. Al
Beam-limiting cone, focal spot/skin distance	20 cm (8 in.)
Maximum accumulated heat	32.500 J
Maximum continuous thermal dissipation	7 W at 70 kV
Leaking radiation at maximum rate during one hour's use	< 0.25 mGy
Maximum field of symmetrical radiation	6 cm (2.375 in.) diameter
Position and tolerance of the focal point on the reference axis	0 mm +/- 0.5 mm (0.020 in.)

Figure 6 X-ray Source Assembly



1. Reference axis
2. Target angle
3. Focal point

Figure 7 Heating and cooling curves of CS 2100 and CS 2200 X-ray source assembly



4 Contact Information

Manufacturer



Carestream Health, Inc.
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Rochester, NY USA 14608

Authorized Representatives

Authorized Representative in the European Community

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