Carestream DENTAL

CS 1200

Safety & Regulatory Guide

Notice

The CS 1200 is intended for professional use only.

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

Manual Name: *CS 1200 Intraoral Camera Safety, Regulatory, and Technical Specifications User Guide*
Part Number: 9H1808
Revision Number: 03
Print Date: 2017-04

CE

Contents

1 Safety Information

Conventions in This Guide

The following messages emphasize information or indicate potential risks to personnel or equipment.

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

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

Note: Emphasizes important information.

Tip: Provides extra information and hints.

Warnings and Safety Instructions

Warnings

Camera

- **You MUST read and understand this safety information before using the camera.**
- **The camera is not intended to be used with high frequency surgical equipment.**
- **Before using the camera, check the outer surfaces of the camera and any accessories to ensure there are no rough surfaces, sharp edges, or protrusions which may cause a safety hazard.**
- **The surface temperature of the LED window may rise to 40°C. Do not allow the window to come in contact with the patient's mouth for more than 10 minutes.**
- **You are responsible for the operation and maintenance of this camera. You MUST have training to use the camera.**
- **DO NOT place objects within the field of operation of the unit.**
- **When the unit is not in use, ensure that the camera is turned OFF.**
- **DO NOT use this camera in conjunction with oxygen-rich environments. This unit is not intended for use with flammable anesthetics or flammable agents.**
- **DO NOT pull or twist the cable.**
- **DO NOT drop the camera.**
- **DO NOT expose the camera to water spray or submerge it in water.**

- **DO NOT expose the camera to high vibrations.**
- **DO NOT expose the camera to ultraviolet radiation for a long period.**
- **DO NOT replace the cables provided with the camera with other cables. Doing so may damage the camera.**
- **Any other equipment not complying with IEC60601 shall be out of patient environment.**
- **DO NOT remove the cover of any camera components. For any repairs, contact a qualified Carestream service technician.**
- **DO NOT replace the power adapter provided with the camera with any other power adapter. Substitutes may not provide the required protection against electric shocks.**
- **If the equipment is faulty, turn it OFF, display an "Out of Service" notice, and contact a qualified service technician.**
- **Using components, accessories, and spare parts other than those specified, with the exception of those sold by the manufacturer of the equipment, may result in a lower level of security and may be hazardous.**
- **Do not stare at the LED emission window.**
- **No modification of this equipment is allowed.**
- **Additional multiple outlet strips or extension cords should not be connected to the system.**
- **To power off the device, push the power button for 3 seconds. To isolate the device from mains supply, unplug the USB/AV/S-Video cables and the adapter from the power outlet.**

Computer

- **DO NOT place the computer and the peripheral equipment connected to it in the immediate vicinity of the patient. Leave at least 1.83 m distance between the patient and the equipment.**
- **The camera is only intended to be connected to the computer or monitor which is at least IEC 60950 or equivalent standards certified. Connecting the camera to other equipment may be hazardous.**
- **See the installation guide for your computer for information about the data processing system, computer, and screen. Leave a sufficient amount of clear space around the computer to ensure that it is properly ventilated.**
- **Position the screen to avoid light reflections from internal or external lighting for maximum image quality and visual comfort.**

Hygiene and Disinfection

Perform the following maintenance activities on your CS 1200 and accessories regularly.

To ensure maximum hygienic safety for the patient, carefully follow the instructions to prepare the CS 1200 for use.

To minimize the risk for cross-contamination, after each patient, clean and disinfect the CS 1200. See "Cleaning and Disinfecting the Camera."

Cleaning and Disinfecting the Camera

General Warnings

WARNINGS:

- **Read and follow the warnings and personal protection instructions provided in the Safety Data Sheet (SDS) of the disinfectant before use.**
- **The disinfectant should be approved by the applicable competent authority for use on a dental medical device.**
- **You must wear gloves while handling and using the camera.**
- **Always protect the camera with a hygienic barrier sheath before use.**
- **The camera should be disinfected with a U.S. Environmental Protection Agency (EPA)-registered or CE-marked intermediate-level disinfectant solution with tuberculocidal activity between patients.**
- **DO NOT use a disinfectant containing phenolics or iodophors; doing so will damage the surface coating of the camera.**
- **Never put the camera in a sterilizing device or immerse it in water or the disinfectant solution.**
- **Excessive fluids can damage the camera.**
- **Not protected against water spray.**

Cleaning the Camera

If the camera is visibly contaminated with blood and/or body fluids, you must clean the camera before disinfecting it.

To clean the camera, follow these steps:

1 Dampen (**do not soak**) a lint-free cloth with lukewarm water.

2 Remove the blood and/or body fluids with the dampened lint-free cloth.

Disinfecting the Camera

After each patient, the camera must be thoroughly disinfected.

To adequately disinfect the camera, follow the disinfectant manufacturer's instructions for the appropriate contact time.

Important: If the camera is visibly soiled, it must be thoroughly cleaned prior to disinfecting. See "Cleaning the Camera."

To disinfect the camera, follow these steps:

1 Remove the protective sheath.

2 Remove all visible soil (see **"Cleaning the Camera"**).

3 Dampen (**do not soak**) a lint-free cloth with 0.525% sodium hypochlorite (1:10 dilution of household bleach), or use a commercially prepared disinfectant wipe. For example: Clorox Healthcare Bleach Germicidal Wipes, if in the USA.

4 Thoroughly wet the surface of the camera with the disinfectant solution. Allow the surfaces to remain wet for the time specified by the disinfectant manufacturer.

WARNING: Do not rinse.

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

Visually Inspecting the Camera for Damage

Visually inspect the camera for signs of deterioration, especially around the buttons and the cable. If damage is noted, do not use the camera and contact your representative.

2 Regulatory Information

Marking and Labeling Symbols

	Type BF applied part symbol classification in accordance with IEC 60601standards.
	Class II equipment
	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.
	Manufacturer's address
	**Attention:** Consult accompanying documentation.
	Refer to instruction manual/booklet.
	Direct current

Label Locations

Figure 1 CS 1200 Camera Box Label

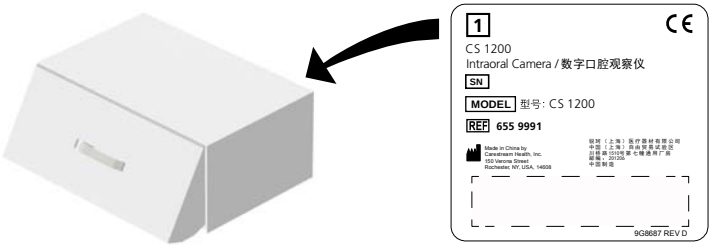


Figure 2 CS 1200 Camera Label

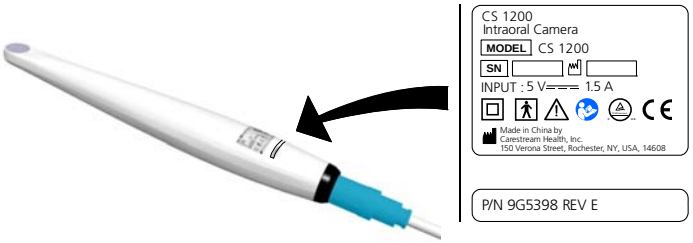
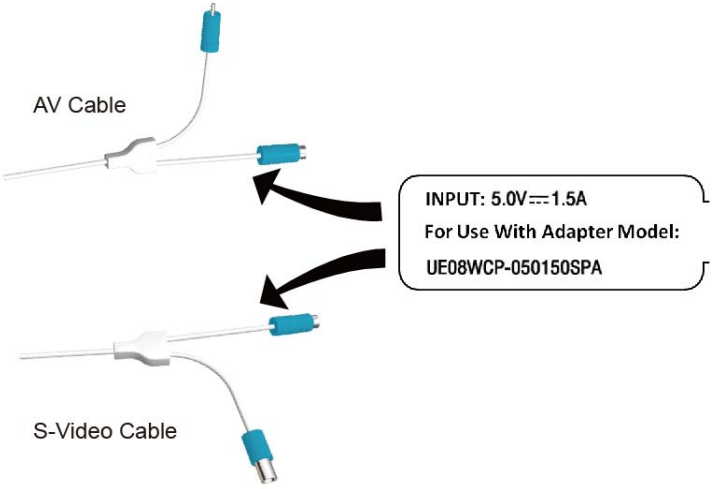


Figure 3 CS 1200 Adapter Reference Label



Indications for Use

The CS 1200 intraoral camera is indicated for use by health professionals in viewing and capturing intraoral or extraoral color video images for the purposes of:

- Allowing practitioners to view regions of the oral cavity.
- Assisting communications with the patient by providing a view of treatment areas before and after a procedure.
- Providing images for documentation in patient records.

Regulatory Information

The CS 1200 intraoral camera complies with the following regulations:

- Medical Device directives 93/42/European Economic Community (EEC), Class I following the rule 5 as amended by 2007/47/EEC
- FDA Center for Devices & Radiological Health CDRH - Title 21 CFR 872.3661 (USA)
- Medical Devices Regulations (Canada)

Electromagnetic Compatibility Precautions

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

Other equipment can interfere with communications with the intraoral camera, even if the equipment complies with CISPR emissions requirements.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance and Manufacturer's Declarations

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The CS 1200 intraoral camera is intended for use in the electromagnetic environment specified below. The customer or user of the intraoral camera should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1 Class B	The intraoral camera uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
Harmonics Emissions IEC 61000-3-2	Complies	The intraoral camera is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3		

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The CS 1200 intraoral camera is intended for use in the electromagnetic environment specified below. The customer or the user of the intraoral camera should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the CS 1200 intraoral camera, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.17 $\sqrt{P}$ d = 1.17 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.33 $\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Conducted RF IEC 61000-4-6	3 V(rms) 150 kHz to 80 MHz	3 V(rms)	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

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 radios, AM and FM radio broadcasts, and TV broadcasts 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 intraoral camera system is used exceeds the applicable RF compliance level above, the intraoral camera should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CS 1200 intraoral camera.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

EMC Standards Information

Electromagnetic Immunity for Equipment and Systems Fully Compliant with IEC 60601-1-2: 2007			
The CS 1200 intraoral camera is intended for use in the electromagnetic environment specified below. The customer or the user of the intraoral camera should assure that it is used in such an environment.			
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 +/- 8 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	+/- 1kV for input/output lines +/-2kV for power supply lines	+/- 1kV for input/output lines +/-2kV for power supply lines	Mains power quality should be that of a typical commercial or clinical environment.
Surge IEC 61000-4-5	+/- 1 kV line to line	+/- 1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T(60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70%U_T (30% dip in U_T) for25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. Note: Most components in the intraoral camera are powered from an uninterruptible power supply. IEC 61000-4-11 is applicable only to the intraoral camera.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Recommended Separation Distances

Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the Intraoral Camera System

The CS 1200 intraoral camera is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the intraoral camera can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the CS 1200 intraoral camera as recommended below, according to the maximum output of the communications equipment.

Rated Maximum Output Power of Transmitter Watts	Separation Distance According to Frequency of Transmitter Meters		
	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.37	0.37	0.737
1	1.17	1.17	2.33
10	3.7	3.7	7.36
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note 1: At 80 MHz and 800 MHz, the separation distance for 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.

EMC Standards for Intraoral Camera

IEC 60601-1-2: 2007 EMC requirements and tests, Medical Electrical Equipment including CISPR11:2003 +A1: 2004 + A2:2006 Group 1, Class B.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his own expense.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Electromagnetic Interference and Electrostatic Discharge

According to CISPR11:2003 + A1:2004 + A2:2006 Group 1, Class B.

This Class A ISM device complies with Canadian ICES-001.

Compliance with European and International Standards

Europe and Other Countries:

EN 60601-1 / IEC 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance

EN 60601-1-2 / IEC 60601-1-2: Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic Compatibility

IEC 60601-2-18: Medical Electrical Equipment, Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

EN 62471 / IEC 62471: Photobiological safety of lamps and lamp systems: Equipment classification, requirements, and User's Guide

EN 60601-1-6 / IEC 60601-1-6: Medical Electrical Equipment, Part 1-6: General requirements for basic safety and essential performance –Collateral Standard: Usability

EN 62366 / IEC 62366: Medical devices - Application of usability engineering to medical devices

EN 62304/IEC 62304: Medical device software - Software life cycle Processes

EN ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

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

CAN/CSA-C22.2 No. 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

CAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment, Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Condition	Classification
Type of protection against electric shock	Class II equipment
Degree of protection against electric shock	Type BF Applied Part
Degree of protection against ingress of water	IPX0 Note: When it is covered by the protective sheath, the camera head is IPX1.
Flammable anesthetics	Not suitable for use in the presence of flammable anesthetics or a mixture of flammable anesthetics with air or oxygen or nitrous oxide.
Mode of operation	Continuous operation

Accessories

The use of cables or accessories other than those specified, with the exception of those sold by the manufacturer of the equipment, as replacement parts for internal components may result in increased emissions or decreased immunity of the medical equipment.

Other Equipment

The CS 1200 intraoral camera should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the CS 1200 intraoral camera should be observed to verify normal operation in the configuration in which it will be used.

3 Technical Specifications

Manufacturer

Carestream Health, Inc.
150 Verona Street
Rochester, New York - USA 14608

Model

CS 1200

Technical Specifications

Components	Technical Specifications
Camera	
Sensor technology	• 1/2.5 inch CMOS • Effective pixels: 5 M
Resolution	• Image: 1024 x 768 pixels Video: 640 x 480 pixels
Lighting	White LEDs
FOV	80°
Focus range	3 mm - 25 mm
Connecting cable length	3 m
Connection: Computer	USB 2.0 high speed
Connection: Monitor	S-Video; AV

(Continued)

Components	Technical Specifications
Output impedance of S-Video and AV cable	75 ohm
Dimension	207 x 29x 22 mm
Weight of camera without cable	60 g
Adapter	
Adapter	• Input: 100-240V ~ 50/60Hz, 400mA • Output: 5V ⎓ 1.5A
Environmental Requirements	
Operating temperature	+5 ~ +30 °C
Transportation and storage temperature	-10–60 °C
Operating relative humidity	10 ~ 85% RH
Transportation and storage relative humidity	10 ~ 95% RH
Operating atmospheric pressure	700-1060 hPa
Transportation and storage atmospheric pressure	600-1060 hPa

Minimum Computer System Requirements

If necessary, you must update your computer system configuration.

Item	Minimum System Requirement
CPU	1.8 GHz Intel Pentium IV
RAM	2 GB
Monitor	1024 x 768 minimum screen resolution - 32 bits color mode
Operating system	• Windows 7 (32 or 64 bits) • Windows 8 or 8.1 (32 or 64 bits) • Windows 10 (64 bits)
USB port	USB 2.0 high speed port
CD/DVD drive	DVD-ROM drive is required to install the product.
Video memory	128M (integrated or dedicated)
Video card driver	Support OpenGL version 1.4 or higher

The computer should be situated in or close to the operating area, in the visual field of the practitioner when using the camera.

Note: The quality of images is affected by the quality of the monitor and monitor settings. See your monitor user's guide for information.

4 Contact Information

Manufacturer's Address

Carestream Health, Inc.
150 Verona Street
Rochester, NY USA 14608

Authorized Representatives

Authorized Representative in the European Community

EC REP

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9H1808 Ed03 2017-04