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CS 7600

Safety, Regulatory & Technical Specification User Guide

Notice

The Regulatory Information & Technical Specifications Guide for the CS 7600 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.

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

This document is originally written in English.

Manual Name: CS 7600 *System Safety, Regulatory and Technical Specifications User Guide*
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Manufacturer

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Authorized Representative in the European Community

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Contents

1 Safety Information

Indications for Use

The CS 7600 is intended for digital dental radiography using a storage phosphor screen for radiographic diagnostic intraoral images.

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.

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

Tip: Provides extra information and hints.

Note: Emphasizes important information.

Warning and Safety Instructions

WARNINGS

Device:

- Read and understand this Safety Information before using the CS 7600.
- To ensure safety, read all user manuals carefully before using the system and observe all Cautions, Important and Notes located throughout the manuals.
- Keep this manual with the equipment.
- You are responsible for the operation and maintenance of this device. Only legally qualified persons can operate this device. When necessary, have a trained authorized service technician carry out inspection and maintenance operations.
- The CS 7600 is Class I, continuous operated stationary equipment without applied parts and has one signal input/output part. Product is provided with ordinary protection against the harmful ingress of water.
- DO NOT use this device in the presence of a flammable anesthetics mixture with air or with oxygen or with nitrous oxide.
- DO NOT remove or open system covers or plugs. Internal circuits use high voltage capable of causing serious injury. Fuses blown within 36 hours of being replaced by a qualified technician may indicate malfunctioning electrical circuits within the system. Have the system checked by qualified service personnel. Do not attempt to replace any fuse. Fluids that seep into the active circuit components of the system may cause short circuits that can result in electrical fires. Therefore, do not place any liquid or food on any part of the system.
- DO NOT operate the device if there is the threat of an earthquake. Following an earthquake, ensure that the device is operating satisfactorily before using it again. Failure to observe this precaution may expose patients to hazards.
- DO NOT place objects within the field of operation of the device.
- Connect this equipment ONLY to a mains power supply with protective ground to avoid any risk of electric shock.

- The appliance coupler/inlet of the flexible power cord is used as a disconnecting device from the mains.
- To achieve grounding reliability in USA installations, the equipment must be connected to an equivalent receptacle marked “Hospital Only” or “Hospital Grade”.
- Disinfect the detachable panel of the CS 7600 scanner after TBD cycles.
- To dispose of the device or its components, contact a service technician.
- No modification of this equipment is allowed.
- DO NOT block air circulation around the unit. Always maintain at least 15 cm clearance around the unit to prevent overheating and damage to the system.

Plates:

- To prevent damage to the plates and the possibility of image artiacts, avoid contact between the plates and the following materials/solutions/solvents: Isopropyl alcohol, hydrogen peroxide and other peroxides, citrus-based cleaners, hand lotions and water-less hand sanitizers, as well as surfactants and lubricants.
- The plate contains Barium, and therefore may be considered hazardous or special waste at the end of its useful service life. For disposal or recycling information, contact your local authorities.
- Do not soak plate in any cleaning or disinfecting solutions. Do not autoclave; autoclaved plates must be discarded.
- Plates should be stored in their original packing or storage box when they are not in use. Always store plates in a dark and dry place.
- Do not expose the plates to light for long periods as this can have a degrading effect.
- Do not store plates in hot or moist conditions.
- Do not fold, crease, or bend the plates.
- Avoid touching the phosphor side of the plates. and be careful not to drag the phosphor side of the plate across any surface as this will damage the plate.
- Do not leave plates where they can become damaged by liquid or chemical spills.
- Read and follow the instructions in Material Safety Data Sheets (MSDS) for the CS Screen Cleaner.

- If a commercially prepared equivalent solution of diluted bleach is used, it should be used according to its manufacturer's instructions.

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 1.5 m distance between the patient and the unit. The computer and the peripheral equipment must conform to the IEC60950 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.
- In order to guarantee medical-grade leakage current, the computer connected to the system should be a medical-grade computer or connected to the mains through medical-grade power supply. This is not relevant if the system is connected to a laptop by USB through a USB isolator or network cable.

Laser Safety Instructions

WARNINGS

The CS 7600 is a CLASS 1 Laser product.

- During normal operation, always keep the unit enclosed in its protective cover to prevent the outside area from being exposed to laser radiation.
- During normal operation, do not remove the cover. Only authorized service personnel may remove the cover.
- Do not operate the system while the access door is open.

WARNING

Laser radiation when cover is removed. Avoid direct exposure to beam. Class 3B laser inside.

Hygiene and Disinfection

WARNINGS

- Do not use chemical autoclave for disinfecting the detachable panel.
- To prevent cross-contamination, use a new envelope for each new patient.

WARNING

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.

General Notice

WARNING

If the product does not operate properly or fails to respond to the controls as described in the product accompanying documentation:

- Follow the safety precautions as specified in this guide.
- Stop using the unit and prevent any changes to it.
- Immediately contact the service office, report the problem, and await further instructions

Marking and Labeling Symbols TBD

	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** Using accessories other than those specified in this document with the exception of those sold by Carestream Health may result in a lower level of security for the entire system.
	The ON/OFF button
	General mandatory action sign
	Follow operating instructions sign
	Manufactured Date
	Manufacturer’s address

IEC Symbols Used

The system may have labels with one or more of the following symbols.

	Caution—consult accompanying documents
	Power ON
	Caution—Electrical shock hazard

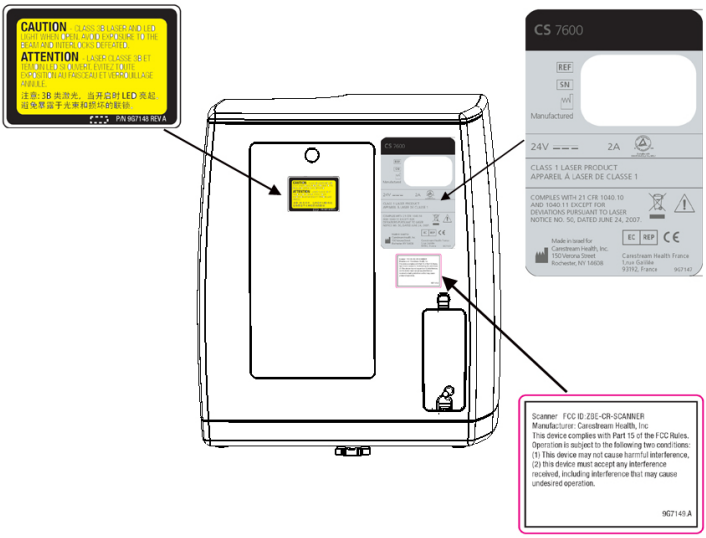
Safety Labels

Label	Description	Location
	Caution—Electrical shock hazard	PM board
	Laser-emitting product	Optical head
	Class 3B laser product inside scanner	Optical head

Label Locations

The following figures illustrate the label locations of the CS 7600 components.

Figure 1 CS 7600 Labels



2 Regulatory Information

General Regulatory Information

Compliance with European and International Standards	
EN 60601-1 / IEC 60601-1	Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-1-2 / IEC 60601-1-2	Medical Electrical Equipment, Part 1-2: Electromagnetic Compatibility
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 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 62304/IEC 62304	Medical device software - Software life cycle processes
EN 300 328	Electromagnetic Compatibility and Radio Spectrum Matters
EN 301 489-17	ElectroMagnetic Compatibility and Radio Spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 17 : Specific Conditions for 2.4 GHz Wideband Transmission Systems and 5 GHz High Performance RLAN Equipment
EN 50371	Generic Standard to demonstrate the compliance of low power electronic and electrical apparatus with the basic restrictions related to human exposure to electromagnetic fields (10 MHz - 300 MHz). General Public

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 – No Applied Parts
Protection against harmful ingress of water	Ordinary equipment, IPX0
Operation mode	Continuous operation

Conformity with EN/IEC 60601-1-2

Electromagnetic Compatibility Precautions

- Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC).
- CS 7600 must be installed and put into service according to the EMC information provided in this document.
- Communication Equipment: Portable and mobile Radio Frequency (RF) communications equipment can affect the Electromagnetic Compatibility of CS 7600s.
- CS 7600 may be interfered with other equipment even if that other equipment complies with CISPR emission requirements.

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

The CS 7600 is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 7600 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The CS 7600 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The CS 7600 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The CS 7600 is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 7600 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance	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	±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.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (Continued)			
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) Not applicable	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 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	< 5 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CS 7600 requires continued operation during power mains interruptions, it is recommended that the CS 7600 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) 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

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

The CS 7600 is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 7600 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[V1]= 3 V	Portable and mobile RF communications equipment should be used no closer to any part of the CS 7600, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = (\frac{3.5}{V_1})\sqrt{P}$ $d = (\frac{3.5}{E_1})\sqrt{P}$ 80 MHz to 800 MHz $d = (\frac{7}{E_1})\sqrt{P}$ 800 MHz to 2.5 GHz 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E1]= 3 V/m	

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

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 7600 is used exceeds the applicable RF compliance level above, the CS 7600 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 7600.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the CS 7600 (IEC 60601-1-2)

The CS 7600 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CS 7600 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CS 7600 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance (m) According to Frequency of Transmitter		
	150 kHz to 80 MHz $d = (\frac{3.5}{V_1})\sqrt{P}$	80 MHz to 800 MHz $d = (\frac{3.5}{E_1})\sqrt{P}$	800 MHz to 2.5 GHz $d = (\frac{7}{E_1})\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

Note: The communication without breaking has been determined to be essential performance with regard to electromagnetic compatibility.

Compliance with International Regulations

The product conforms to the following safety standards: EN 60601-1:90 + A1(93) + A2(95) + A13(96)/IEC 60601-1:88 + A1(91) + A2(95)/EN/IEC 60601-1-1, EN/IEC 60825-1:94 + a1(97) + a2(01) + Cor1(02), EN 60601-1:06/IEC 60601-1:05, UL 60601-1:03, rev.06, IEC 60825-1:93+A1:97+A2:2001 (Foe LED module), IEC 60825-1:2007 (For Laser module CAN\CSA-C22.2 No. 601.1-M90, JIS T 0601-1:1999.

This device complies with 21CFR 1040.10.

- Medical Device directives 93/42/ European Economic Community (EEC), Class IIa follow the rule 16 as amended by 2007/47/EEC.
- The CS 7600 is an active device specifically intended for scanning of X-ray diagnostic images.
- ElectroMagnetic Compatibility (EMC) directive 89/336/EEC, Group 1, Class A
- Radio and Telecommunications Terminal Equipment directives 1999/5/EEC
- FCC rules part 15/EN 300 330-2 V1.3.1/47CFRp15sb.C/RSS/210:07 Issue 7

Compliance with FCC Rules

This equipment has been tested and found compliant 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 in a residential installation. This equipment generates, uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that the interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

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

Declaration of Conformity with the R-TTE Directives

TBD -- WILL NEED THE DECLARATION OF CONFORMITY FOR THE CS 7600 TO REPLACE THIS.

Carestream HEALTH

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

EC Declaration of Conformity
to R&TTE Directive 1999/5/EC

Manufacturer: **Carestream Health Inc.**
150 Verona Street
Rochester, New York
USA

EU Representative: **Trophy**
4, rue F. Pelloutier
Croissy-Beaubourg
77437 Marne la Vallée cedex 2

Products: **Kodak RVG 6500 System**
Kodak RVG 6500 IPS System

Declaration:

We Carestream Health, Inc. declare under our own responsibility that this equipment is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. These devices are also declared by Carestream Health, Inc. within a separate Declaration of Conformity to comply with the European Economic Community Medical Device Directive, [Directive 93/42/EEC].

Wireless Standards : ETSI EN 300 328
ETSI EN 301 489-17

EMC Standards : EN 60601-1-2
EN 50371

Product Safety Standard : EN 60601-1

Signature: *Dale B. Parks*

Name: Dale B. Parks

Title: Manager – International EHS

3 Technical Specifications

TBD Factory/Country of Origin

SANMINA TBC

Manufacturer

Carestream health, Inc.

150 Verona Street

Rochester,

New York - USA 14608

Model

CS 7600

CS 7600 Technical Specifications

System specifications

Components	CS 7600
Gray scale	4096 bits
Dimensions (without bracket)	266.5 mm (H), 236.6 mm (W), 259.4 mm (D)
Weight	Approximately 6 kg
Power supply	100–240 V AC, 50/60 Hz, 1.5 A
Laser Wavelength	635 nm– 650 nm (Class 3B)
Output Power	Up to 12 mW

Plate Specifications

Plate Dimensions

	Plate Size	0	1	2	3	4
	Height (mm)	22	24	31	27	54
	Width (mm)	31	40	41	54	76
SHR	Height (pixels)	1552	2003	2053	2704	3805
	Width (pixels)	1101	1202	1552	1352	2704
HR	Height (pixels)	884	1141	1169	1540	2167
	Width (pixels)	627	684	884	770	1540
HS	Height (pixels)	499	643	659	868	1222
	Width (pixels)	354	386	499	434	868

Plate Scanning Resolution

Resolution Level	Laser Spot Size	Practical Resolution	Pixel Size
Super high resolution (SHR)	20.0 micron	20 LP/mm*	0.019 mm
High resolution (HR)	35.0 micron	14 LP/mm*	0.035 mm
High speed (HS)	62.5 micron	8 LP/mm*	0.062 mm

*LP/mm: Line pairs per millimeter (when scanning Resolution Phantom)

RF Information.

RF Information	
RFID	ISO15693
Frequency	13.56 MHz
Output Power	20 mW

CR Environmental Requirements

Ambient Operating Conditions

Ambient Operating Conditions	
Temperatures	5 °C ~35 °C
Relative humidity	30 % ~ 85 % Non-condensing
Atmospheric pressure	700 hPa ~ 1060 hPa

Storage Conditions

Storage Conditions (in packaging)	
Temperatures	-10 °C ~ 60 °C
Relative humidity	10 % ~ 95 % Non-condensing
Atmospheric pressure	700 hPa ~ 1060 hPa

Transport Conditions

Transport Conditions	
Temperatures	-20 °C ~ 60 °C
Relative humidity	45 %~ 85 %
Atmospheric pressure	700 hPa ~ 1060 hPa

Minimum Computer System Requirements

The computer and the peripheral equipment must conform to the IEC60950 standard.

Item	Viewing and Acquisition	Comments
CPU	2 GHz Intel Duo Core	
RAM	1 GB (2 GB recommended)	RAM has a major impact on system performance.
Hard disk drive	• 1.2 GB for software installation • 80 GB free space to use the software	
Graphic board	Nvidia/ATI based board supporting Open Glide 1.2 with 256 MB of video RAM on AGP x8 video bus (example: Nvidia GeForce 6800 GT)	The video RAM has major impact on system performance.
Monitor	• 1 monitor • 17" or larger • 1024 x 768 minimum screen resolution, 32-bit color mode	Your monitor is a vital component in displaying quality images. Low-quality screens will prevent you from proper diagnoses and treatment.
Operating system	• Windows XP Pro edition SP3 • Windows Vista Ultimate 32-bit SP2 • Windows 7 Professional 32-bit • Windows 7 Ultimate 32-bit	
Ethernet interface	10/100 LAN card	Second Ethernet interface is recommended for Internet\PACS\ Server connection option
USB 2.0	3 ports (4 ports recommended)	
Wireless adapter	Wireless 802.11g Adapter (USB, PCMCIA or PCI)	

Item	Viewing and Acquisition	Comments
CD/DVD drive	DVD-ROM drive is required to install the product software	
Audio speakers		To enable hearing audible alarms initiated by the system
Blue Tooth interface on board (Optional)	Recommended for RFID option.	External USB dongle for BT can be used also.