2 CS 7600 System Overview

Introduction

Note: The CS 7600 is intended for dental professionals. You are required to have training to use the CS 7600.

CS 7600 is a scanner system for intraoral X-ray exposed imaging plates.

The CS 7600 is intended for digital dental radiography using an imaging plate (storage phosphor plate) for radiographic diagnostic intraoral images. The CS 7600 system is used to scan and review intraoral dental X-ray images. When scanning the X-ray exposed imaging plate a digital image is previewed on the scanner's LCD and saved to the scanner's internal memory. After scanning, the scanner erases the imaging plate and ejects it. The imaging plate is ready for re-use.

The exam acquisition's scanned image is sent over the network to the workstation's image Acquisition interface. Using the image Acquisition interface the image is processed and reviewed.

The image Acquisition interface sends the images to the Kodak Dental Imaging Software, which archives the acquired images.

The scanner connects directly to the network, or is connected peer-to-peer to the workstation.

The scanner can be optionally placed on a desk/counter top or mounted on a wall, using a special shelf (adapter).

The system is composed of the following elements:

- CS 7600 scanning device (page 4)
- Smart imaging plates (page 6)
- CS 7600 image Acquisition interface (page 11)
- Scan & Go device (optional, page 9)

Note: The scanner is supplied with a separate viewing and archiving software package: *Kodak Dental Imaging Software*, approved by Carestream Health.

Note: The CS 7600 User Guide is also provided as a PDF file on the supplied CD-ROM.

CS 7600 Components Overview

Scanner Overview

The CS 7600 scanner performs the functions necessary for scanning and acquiring images from the imaging plates.

Figure 1 CS 7600 Front View

1 3.5" QVGA color LCD (320 X 240 pixels, landscape matrix)

2 Function buttons for scanner use and menu navigation

3 On/Off button + LED power indicator.
On/Off button functions:

- Turn scanner On: press for 1 second
- Turn scanner Off (close application and files and then turn off): press for 2 seconds.

4 Base

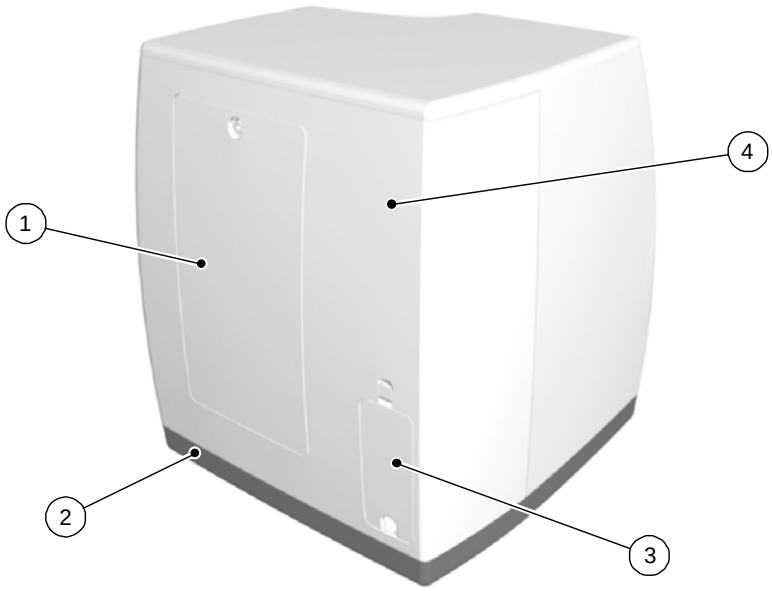
5 Intraoral imaging plates tray

6 Detachable insertion panel. The CS 7600 makes use of two insertion panel sizes according to the inserted imaging plates size (0–3 or 4).

7 Front cover

8 Back covers

Figure 2 CS 7600 Rear View



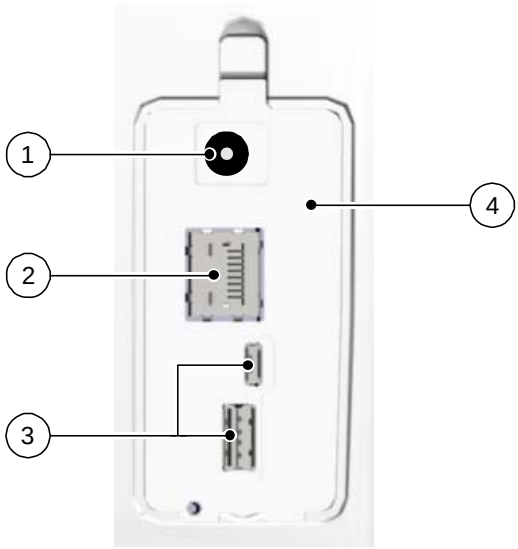
1 Service door

2 Base

3 Cables compartment for power supply connection and interface ports (RJ-45 Ethernet port)

4 Back cover

Figure 3 Cables Compartment in Detail



1 Power supply inlet

2 RJ-45 Ethernet port (Ethernet activity LEDs: yellow indicates speed, green indicates link status)

3 Service ONLY ports

4 Compartment cover

Smart Imaging Plates Overview

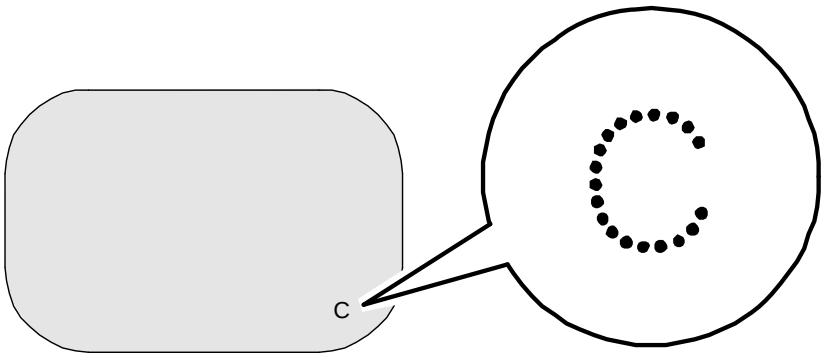
The CS 7600 works with five imaging plate sizes: 0 to 4. The scanned image file size depends on the imaging plate size and the scanning resolution set by the user.

The smart function of the imaging plates is utilized when using the Scan & Go device.

Table 1 Intraoral Imaging Plate Sizes

Size	Illustration	Application
0		Periapical exam (Pediatric dentistry)
1		Bitewing exam (Pediatric dentistry)
2		Periapical exam (Adult)
3		Bitewing exam (Adult)
4		Occlusal exam

The imaging plate has two sides: the active side for capturing the X-ray image and the inactive side. The active side of the imaging plate includes an orientation mark ‘c’ to facilitate accurate positioning within the patient’s mouth. The inactive side has a printed dot that corresponds to the location of the orientation mark on the active side. This dot is visible through the transparent hygienic sheath and is also helpful for positioning the imaging plate correctly in the patient’s mouth.



Active side

Inactive side

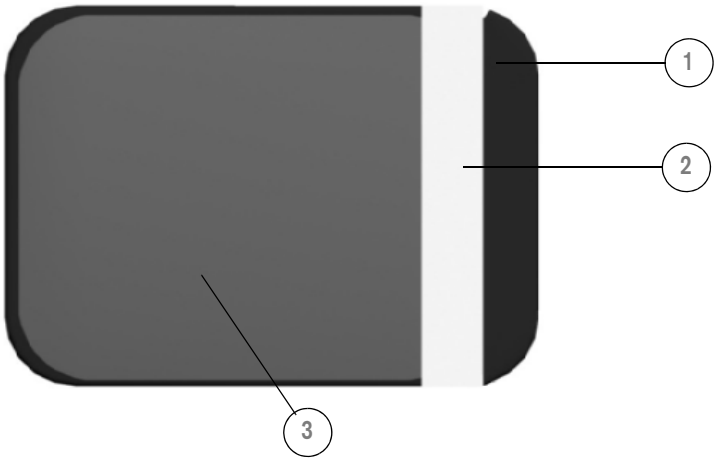
Important: Use only Carestream imaging plates and hygienic sheaths!

Hygienic Sheaths

For each imaging plate size there is a corresponding one-time use, disposable, hygienic sheath for preventing cross contamination. The transparent side allows you to see the orientation mark for positioning the imaging plate correctly in the patient’s mouth while the opaque side protects the active

side of the inserted imaging plate from light damaging effects. The foam strip is a stopper which prevents inserting the hygienic sheath by mistake into the scanner (as long as the insertion direction is correct).

Figure 4 Hygienic Sheath (front view)



1 Adhesive strip (for sealing the hygienic sheath)

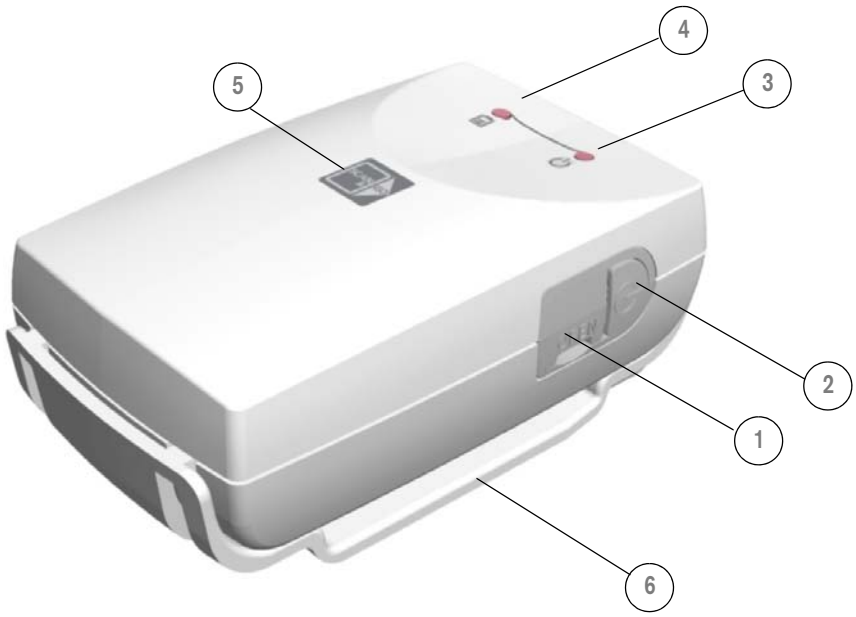
2 Foam stopper

3 Sheath, transparent on one side and with a light protection barrier on the other side

Scan & Go Overview

Scan & Go is an optional device that enables you to link the imaging plate to a specific exam acquisition (for example, patient) prior to acquisition. This information is retrieved by the scanner and the imaging plate is scanned automatically according to this information (resolution, target workstation, etc.). Scanned images are then routed automatically to the correct workstation, associated to the correct exam acquisition and placed in the correct frame in the CS 7600 image Acquisition interface.

Figure 5 Scan & Go device (Before June 2012)



1 USB 2.0 port

2 On/Off button

3 On/Off/Recording LED status indicator (blue)

Turning On/Off, 3 short flashes

Standby (intermittent flashing)

Recording data to the imaging plate (successive short flashes)

4 Battery LED status indicator (amber):

Charging (static light)

Low battery (successive short flashes)

(light Off) battery charged

5 Recording surface for imaging plate

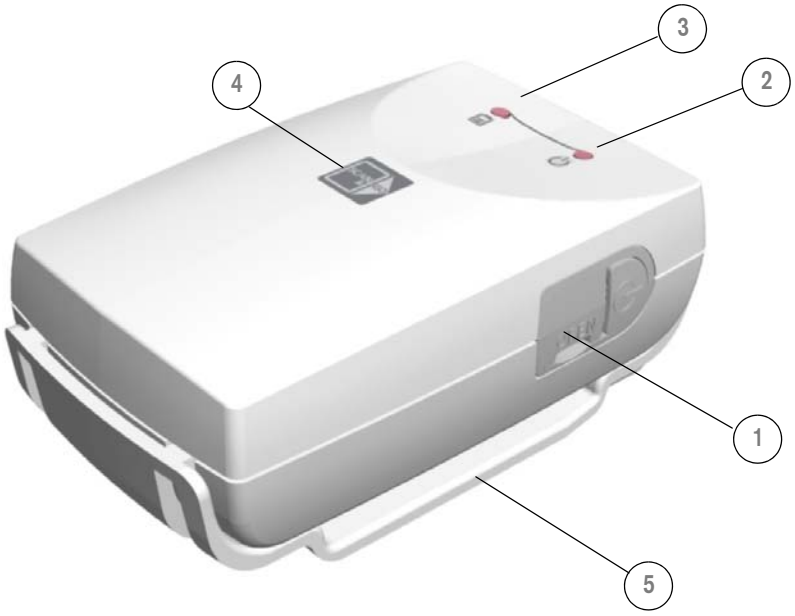
6 Mounting adapter

Scan & Go Overview (for Scan & Go models released from June 2012)

A new Scan & Go device is available from June 2012. The following improvements have been made to the new Scan & Go device:

- Faster scanning - Approximately 1/4 sec instead of 1 sec
- No battery - Therefore no need for charging.
- No on off switch - Turns on automatically when the USB is connected.

Figure 6 Scan & Go device (After June 2012)



1 USB 2.0 port

2 On/Off/Recording LED status indicator (blue)


Power Up: One Flash & Beep (Internal FW)


Beacon: Flashes blue every few seconds in idle mode (Not during Tagging)


Tagging OK: One flash (long) & 1 bleep (long)R


Tagging Fail: One Red flash (long) & 1 bleep (long)R

3 Connected to USB: LED status indicator (green):

4 Recording surface for imaging plate

5 Mounting adapter

Carestream DENTAL

CS 7600 - Intraoral Imaging Plate System

Scan & Go Installation

Carestream

Carestream Health, Inc.
150 Verona Street
Rochester, NY 14 608, USA

CE 0086

Reference:
HT022_20120424_EN
ATHT0296_20120424_EN

Package Content:

- Carestream genuine Scan & Go device
- USB interface cable
- Scan &Go clip
- Double sided tape
- Image acquisition interface Installation CD

Note: *To use this Scan & Go, you need to install Acquisition Interface V1.0 Rev 3 (or higher).*
Unlike previous versions, this Scan & Go does not use batteries.

Installing the Scan & Go device

(For Scan & Go released from June 2012)

1. Connect the USB cable to the computer and to the USB port on the Scan & Go device.
   The right LED flashes green once, the left LED lights green continuously and the device bleeps twice to indicate that it is ready for use.

2. Launch the image Acquisition interface. Verify that the USB icon located in the upper right corner of the main window is white.

Note: *If the Scan & Go LED lights up green and the USB icon appears red, there is a possibility that the image acquisition version needs updating to V1.0.Rev 3*

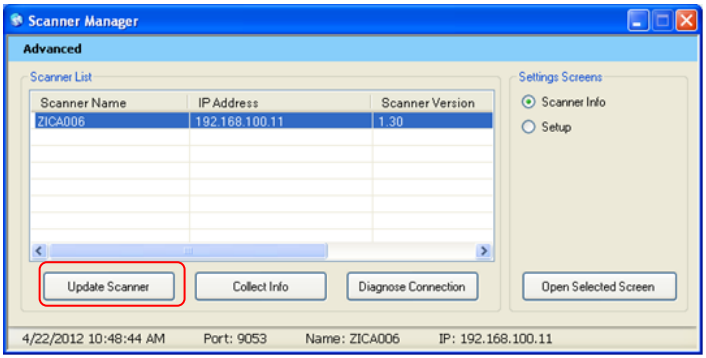
---

3. Place the mouse in the bottom right corner of the image Acquisition interface, on the gray frame.
The Acquisition Version number appears.

4. Ensure that the Acquisition version number is 1.0.3.2 or higher.

5. If the Acquisition version number is lower than 1.0.3.2, update the Scanner Version to 1.30, by performing the following steps:

   a) Open the Scanner Manager by clicking Start > Programs > IP Image Acquisition > Scanner Manager or click the Scanner Manager icon.
   The Scanner Manager opens



Note: This picture is for demonstration only and the Scanner version may vary.

   b) After the Scanner Version appears in the Scanner List, select the relevant scanner.

   c) Click **Update Scanner**
   The process takes a few minutes until the reboot window appears.

   d) Click **OK** and restart the scanner.
   The scanner update process takes a few minutes to be completed.

*Note: If the scanner is already updated with Version 1.30, and you have clicked Update Scanner, a message appears **The scanner is already updated** then, click **OK**, close the Scanner Manager window.*

*Note: In the rare case that the **Update Failed** message appears, restart the scanner, press*  *and verify that the scanner version is 1.30.*

e) When a message appears **Press any button to continue**, press any button on the scanner.
The scanner reboots and is now ready for use.

6. To secure the Scan & Go to a desired location, apply the double sided tape to the back side of Scan & Go clip and then attach it to the Scan & Go device.

The Scan & Go is ready for use.

Note: For more information, see the CS 7600 User Guide provided in the original CD delivered with the system.

Intraoral Imaging Plate System

CS 7600

Safety, Regulatory & Technical Specifications User Guide

Notice

The Regulatory Information & Technical Specifications User Guide for the CS 7600 includes information on the safety instructions, regulatory information and the technical specifications of the device. Please read and observe all warnings and instructions in this Guide and those marked on the unit.

The information contained in this Guide may be subject to modification without notice, justification or notification to the persons concerned. Make sure you have the most current version.

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.

Guide Name: Intraoral Imaging Plate System CS 7600 *System Safety, Regulatory and Technical Specifications User Guide*
Part Number: 8J4070
Revision Number: 02
Print Date: *2012-06*

CE
0086

Manufacturer

Carestream Health, Inc.
150 Verona Street
Rochester, NY 14 608, USA

Authorized Representative in the European Community

EC REP

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1, rue Galilée
93192 NOISY-LE-GRAND CEDEX
FRANCE

Contents

1 Safety Information

Indications for Use

The CS 7600 is intended for digital dental radiography using an imaging plate (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

Scanner

- **Read and understand this safety information before using the CS 7600.**
- **To ensure safety, read all user guides carefully before using the system and observe all Warnings, Important and Notes located throughout the guides.**
- **Keep this guide with the equipment.**
- **You are responsible for the operation and maintenance of this device. You are required to have training to use the CS 7600. 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. Access to the rear inspection cover is allowed, as an exception, according to the instructions for Retrieval of the imaging plate in the Troubleshooting section of the user guide.**
- **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 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.**
- **The scanner should be positioned so that there is always easy access to the mains power supply socket.**

Imaging Plates:

- **To prevent damage to the imaging plates and the possibility of image artifacts, avoid contact between the imaging 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 imaging plate contains Barium and should be considered hazardous or special waste in specific conditions at the end of its useful service life. For disposal or recycling information, contact your local authorities.**
- **Do not soak the imaging plate in any cleaning or disinfecting solutions. Do not autoclave; autoclaved imaging plates must be discarded.**
- **Imaging plates should be stored in their original packing or storage box when they are not in use. Always store imaging plates in a dark and dry place.**
- **Do not expose the imaging plates to light for long periods as this can have a degrading effect.**
- **Do not store imaging plates in hot or moist conditions.**
- **Do not fold, crease, or bend the imaging plates.**
- **Avoid touching the imaging side of the imaging plates and be careful not to drag the imaging side of the imaging plate across any surface as this will damage the imaging plate.**
- **Do not leave imaging 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 1.83 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 an isolator or network cable.**

General Notice

WARNINGS

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.**

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 service door is open**
- **Access to the rear inspection cover is allowed, as an exception, according to the instructions for Retrieval of the imaging plate in the troubleshooting section of the user guide.**

WARNING

Laser radiation when cover is removed. Avoid direct exposure to beam.
Class 3B laser inside. Do not operate the system while the service door is open.

Hygiene and Disinfection

WARNINGS

- **Do not use chemical autoclave for disinfecting the detachable insertion slot panel.**
- **To prevent cross-contamination, use a new hygienic sheath 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.

Marking and Labeling Symbols

Label	Description
	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.
	General mandatory action sign.
	Refer to instruction manual / booklet.
	Manufactured Date.
	Manufacturer’s address.

IEC Symbols Used

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

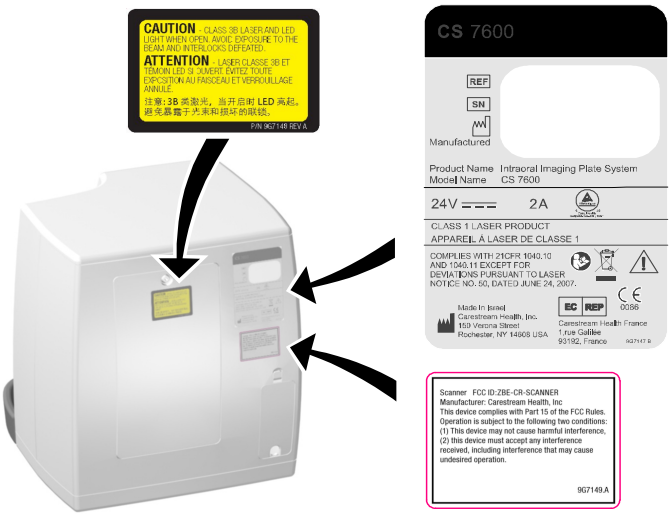
Label	Description
	Caution—consult accompanying documents
	Power On/Off
	Caution—Electrical shock hazard

Safety Labels

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

Label Locations

The following figure illustrates the label locations of the CS 7600 components.



Declaration of Conformity

Carestream

DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares under its sole responsibility that the product(s) listed are made in conformity with Annex I, Essential Requirements, and ANNEX II, EC Declaration of Conformity (Full quality assurance system), of the European Economic Community Medical Device Directive, [Directive 93/42/EEC], and the Radio and Telecommunications Terminal Equipment Directive [Directive 1999/5/EC], Annex II.

Manufacturer's Name and Address:	Carestream Health, Inc. 150 Verona Street Rochester, New York, USA 14608
Medical Device:	Imaging Plate System
Product List:	CS 7600 System "End of List"
Device Classification:	Class IIa, Rule 16 (Council Directive 93/42 EEC, ANNEX IX)
GMDN Code and Term:	17904, Computed Radiography System
Scope of Application:	All Declared Products
Full Quality Management System Certificate:	LNE/G-MED N 19949 rev 0
Design Examination Certificate:	BSI Certificate Number CE 01233
European Authorized Representative:	Carestream Health France 1, rue Galilée 93192 NOISY-LE-GRAND CEDEX FRANCE

May 19, 2011 (CS 7600)
Carestream Health, Inc.

Standards Applied:

EN ISO 13485:2003	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2009	Medical devices – Application of risk management to medical devices
EN 980:2008	Symbols for use in the labeling of medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 60601-1:1990+A1:1993+A2:1995	Medical electrical equipment -- Part 1: General requirements for safety
EN 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performances - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 62304:2006	Medical device software. Software life-cycle processes
EN 300 330-2 v1.5.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Part 2: Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive

Robert C. Meagher
Director
International Regulatory Affairs
Carestream Health, Inc.
150 Verona Street
Rochester, New York 14608
Telephone 585-627-6528

May 18, 2011 (CS 7600)
Carestream Health, Inc

2 Regulatory Information

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

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 300 330-2	Electromagnetic Compatibility and Radio Spectrum Matters

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 s	< 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 s	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 disruption has been determined to be essential performance with regard to electromagnetic compatibility.

Compliance with International Regulations

The product conforms to the following safety standards: IEC 60601-1:2005 - Medical Electrical Equipment - Part 1: General requirements for safety and essential performance, 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 (for 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.

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3 Technical Specifications

Manufacturer

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

Model

CS 7600

CS 7600 Technical Specifications

System Specifications

Components	CS 7600
Dimensions (without bracket)	267 mm (H), 237 mm (W), 260 mm (D)
Weight	Approximately 6 kg
Power supply*	SL Power Model #: MW174KB2403F01 100 – 240 V (ac), 50/60 Hz, 1.5 A
Laser wavelength	635 – 660 nm (Class 3B)
Laser power	Up to 12 mW

* For external AC/DC power supply medical grade, complies with IEC 601-1

Imaging Plate Specifications

Imaging Plate Dimensions

	Imaging Plate Size	0	1	2	3	4
	Height (mm)	22	24	31	27	57
	Width (mm)	35	40	41	54	76
Super high resolution (SHR)	Height (pixels)	1356	1476	1500	1802	2800
	Width (pixels)	2052	2298	2000	3009	3750
High resolution (HR)	Height (pixels)	772	841	860	1026	1580
	Width (pixels)	1169	1308	1150	1713	2122
High speed (HS)	Height (pixels)	435	474	480	578	900
	Width (pixels)	659	738	640	966	1200

Imaging Plate Scanning Resolution

Resolution Level	Practical Resolution (LP/mm*)
Super high resolution (SHR)	17
High resolution (HR)	14
High speed (HS)	8

*LP/mm: Line pairs per millimeter (measured on grid resolution target, in scan direction)

RF Information.

RF Information	
Scan & Go standard	ISO15693
Frequency	13.56 MHz

CS 7600 Environmental Requirements

Ambient Operating Conditions

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

Storage and Transport Conditions

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

Imaging Plates Environmental Requirements

Ambient Operating Conditions

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

Storage and Transport Conditions

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

Minimum Computer System Requirements

Item	Viewing and Acquisition	Comments
CPU	2 GHz Intel® Dual Core™ or AMD Athlon or higher	For best performance it is recommended to use an ***Intel***® Dual Core™ processor.
RAM	1 GB (2 GB recommended)	RAM has a major impact on system performance.
Hard disk drive	• 4 GB for software installation • 80 GB minimum (250 GB recommended) free space to use the software	
Graphic board	Nvidia/ATI based board supporting Open Glide 1.2 with 256 MB of video RAM	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 monitors will impede proper diagnoses and treatment.
Operating system	• Windows 7 Ultimate/Professional with SP1, 32/64-bit • Windows XP Professional with SP3 • Windows Vista Ultimate with SP2, 32-bit	
Ethernet interface	100/1Gb LAN card	
USB 2.0	3 ports	4 ports recommended
CD/DVD drive	DVD-ROM drive	Required to install the product software
Audio speakers	1 speaker	To enable hearing audible alarms initiated by the system and the Scan & Go option.