Carestream

CS 7200

Safety, Regulatory and Technical Specifications

Notice

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

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Contents

1 Safety Information

Conventions in This Guide

The following 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.

Note: Emphasizes important information.

Tip: Provides extra information and hints.

Warnings and Safety Instructions

Warnings

Scanner

- **Read and understand this safety information before using the CS 7200.**
- **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 7200. When necessary, have a trained authorized service technician carry out inspection and maintenance operations.**
- **The CS 7200 is Class II following the IEC 60601-1 standard, 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. 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.

- **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 operate the equipment in the presence of explosive liquids, vapors, or gasses. 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.**
- **The scanner should be positioned so that there is always easy access to the mains power supply socket.**

Imaging Plate

- **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 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 when they are not in use. Always store imaging plates in a dark and dry place.**
- **Avoid exposing the imaging plates to light 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.**
- **Do not autoclave.**
- **Read and follow the instructions in Material Safety Data Sheets (MSDS) for the CS Screen Cleaner.**
- **The commercially prepared desinfectant must be used according to manufactrer's instructions.**

Computer

- **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 leakage current level, when connecting the computer to the CR scanner, the system shall comply with the requirements of the IEC 60601-1-1 standard; If in doubt, please contact the CSH service.**
- **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 IEC 60950 standard.**

Laser Warnings

WARNINGS:

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.

WARNINGS:

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

- **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.

Power Supply

The power supply, supplied with the system is a part of the system, and the scanner shall be connected to the mains using only the supplied AC/DC adapter P/N TR30RAM240.

Hygiene and Disinfection

Imaging Plate Care

If used with care, Carestream Health imaging plates can be used repeatedly. However, the imaging plates will show wear over time due to continuous use. Inspect the imaging plates regularly and replace them if they are scratched and/or show signs of excessive wear.

WARNINGS:

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.

Cleaning and Disinfecting the Imaging Plate

Disinfecting the Hygienic Sheath and the Imaging Plates

After removing from the patient's mouth and before extracting the imaging plate from within it, the hygienic sheath must be thoroughly disinfected.

WARNING: Do not soak the hygienic sheath in any cleaning or disinfecting solutions. Hygienic sheath must be discarded after use (single use component).

WARNING: To prevent cross-contaminaiton, use a new hygienic sheath for each new patient.

Cleaning the Imaging Plate

If the imaging plate is visibly contaminated with dirt, dust particles or finger prints, you must clean the imaging plate with the following cleaning materials, before disinfecting it.

- Clean, dry non-abarsive, lint-free wipes or cloths
- Carestream X-OMAT Screen Cleaner (ask your Carestream Health representative).

To clean the imaging plate, follow these steps:

1 Fold a non-abrasive, lint-free wipe or cloth and dampen with a small amount of the solution. Be careful not to pour the solution directly on the imaging plate. Excessive amounts of the screen cleaner may damage the imaging plate.

2 Wipe the imaging plate thoroughly dry with a clean, dry, non-abrasive, lint-free cloth to remove residual cleaner. DO NOT LEAVE THE imaging plate TO AIR-DRY. Apply pressure to remove persistent dirt, if necessary.

The imaging plate must be disinfected after each scan.

To disinfect use a commercially prepared product that adheres to the following specifications and restrictions:

- A commercially prepared equivalent solution of diluted bleach that does not contain any ingredients (Isopropyl alcohol, hydrogen peroxide and other peroxides, citrus-based cleaners, hand lotions and water-less hand sanitizers, as well as surfactants and lubricants) that can cause damage to the hygienic sheaths and imaging plates

Follow the desinfectant manufacturer's instructions for disinfecting the sheaths and imaging plates:

1 The sheaths and plate should be kept visibly wet for the full contact time specified on the desinfectant label.

Note: Do not soak the sheath or imaging plate in disinfectant solution.

2 Wipe with a non-abrasive, lint free cloth after keeping it wet for a specified period of time.

Disposing of the Image Plate

WARNING: The imaging plate contains Barium and should be considered hazardous or special waste in specific conditions at its useful service life. For disposal or recycling information, contact local authorities.

Scanner Care

Cleaning the Scanner Body

Use disinfection wipes for medical equipment to clean the scanner body thoroughly from all sides.

Cleaning the Detachable Insertion Panel

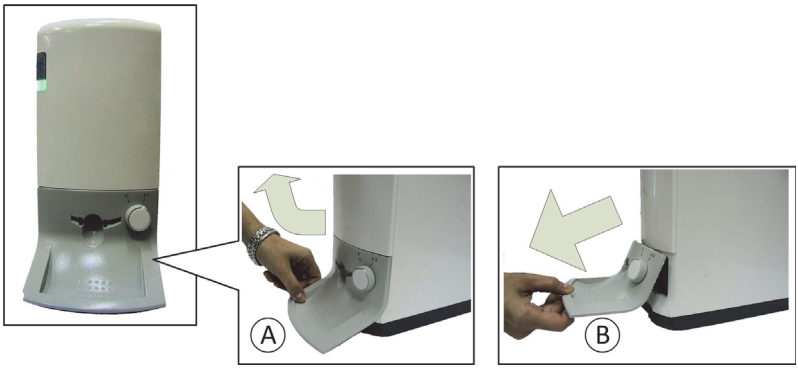
WARNING: It is the user's responsibility to disinfect the detachable insertion panel daily to prevent cross contamination.

WARNING: Do not autoclave; autoclaved detachable insertion panel must be discarded.

WARNING: Do not use chemical autoclave for disinfecting the detachable insertion slot panel.

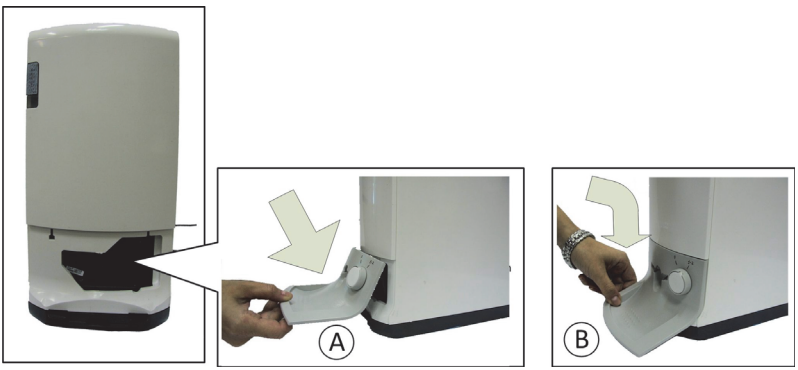
To clean and disinfect the insertion panel, follow these steps:

1 Remove the installed insertion panel by inserting a finger in the designated removal depression at the bottom of the insertion panel (A) and lifting out the insertion panel (B).



2 Use disinfection wipes for medical equipment to clean the detachable insertion panel thoroughly from all sides including the slot.

3 Install the cleaned and disinfected insertion panel by inserting the location pins into the designated slots in the scanner (A) and pressing the insertion slot panel in (B) until it's completely inserted.



2 Regulatory Information

Marking and Labeling Symbols

	Power On/Off
	Manufacturer’s address
	Date of manufacture
	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
	**Caution:** Consult accompanying documentation.
	Laser-emitting product (located on the laser head).
	Warning, electricity (located on the PM board).
	Class 3B laser product inside scanner (located on the optical head and scanner back cover)
	General mandatory action sign.
	Refer to instruction manual/booklet.

Label Locations

The following figure illustrates the label locations of the CS7200 components.

Indications for Use

The CS 7200 is intended for use in dental digital radiography using imaging plates (phosphor storage screens) for dental intra-oral X-ray imaging.

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.

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 7200 is an active device specifically intended for scanning of imaging plate (storage phosphor screen) for radiographic diagnostic intraoral images.
- ElectroMagnetic Compatibility (EMC) directive 89/336/EEC, Group 1, Class B.
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Electromagnetic Compatibility Precautions

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC).

CS 7200 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 7200.

CS 7200 may be interfered with other equipment even if that other equipment complies with CISPR emission requirements.

Plug in the AC/DC adapter TR30RAM240 used as a means of electrical isolation from the supply mains.

Guidance and Manufacturer's Declarations

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

The CS 7200 is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 7200 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The CS 7200 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 7200 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 7200 is intended for use in the electromagnetic environment specified below. The customer or the user of the CS 7200 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			
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 7200 requires continued operation during power mains interruptions, it is recommended that the CS 7200 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

EMC Standards Information

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (IEC 60601-1-2)			
The CS 7200 is intended for use in the electromagnetic environment specified below. The customer or the user of the CS7200 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	[V1]= 3 V [E1]= 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CS 7200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = (\frac{3.5}{V_1})\sqrt{P}$ $= (\frac{3.5}{E_1})\sqrt{P}$ 80 MHz to 800 MH $d = (\frac{7}{E_1})\sqrt{P}$ 800 MHz to 2.5 GH 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: 

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 7200 is used exceeds the applicable RF compliance level above, the CS 7200 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 7200.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the CS 7200 (IEC 60601-1-2)

The CS 7200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CS 7200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CS 7200 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 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.

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

EN 60825-1: Safety of laser products-Part 1: Equipment classification and requirements

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

CAN/CSA-C22.2 No. 6060-1: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.

ANSI/AAMI E60601-1: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.

Condition	Classification
Type of protection against electric shock	Class II equipment
Degree of protection against electric shock	No Applied Parts
Degree of protection against ingress of water	Ordinary equipment, IPX0
Mode of operation	Continuous operation

3 Technical Specifications

Manufacturer

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

Model

CS 7200

CS 7200 Technical Specifications

Components	Technical Specifications
CS 7200	
Laser power	Up to 12 mW
Laser wavelength	635 - 660 nm (Class 3B)
Power supply	100 - 240 V (AC), 47 - 63 Hz, 0.8 - 0.4 A
Dimension (without bracket)	130 x 270 x 300 mm (5.1 x 10.6 x 11.8 in.)
Weight	3.5 kg (7.71 lb)
Noise Levels:	
Stand-by	0 db (A)
During scanning	50 db (A)

Components	Technical Specifications
CS 7200 Environmental Requirements	
Operating temperature	+15 ~ +35 °C
Transportation and storage temperature	-10–60 °C
Operating relative humidity	30 ~ 85% RH (Non-condensing)
Transportation and storage relative humidity	10 ~ 95% RH (Non-condensing)
Operating atmospheric pressure	700-1060 hPa
Transportation and storage atmospheric pressure	600-1060 hPa

Mode	TTFI	Cycle Time	Resolution
HS	< 8 [Sec]	< 14 [Sec]	8 [LP/mm]
HR	< 16 [Sec]	< 24 [Sec]	14 [LP/mm]
SHR	< 36 [Sec]	< 44 [Sec]	17 [LP/mm]
UHR	60[Sec]	< 66 [Sec]	19 [LP/mm]

Imaging Plate Technical Specifications

Components	Technical Specifications
Imaging Plates	
Imaging Plate Environmental Requirements	
Operating temperature	+15 ~ +35 °C
Transportation and storage temperature	-10–60 °C
Operating relative humidity	30 ~ 85% RH (Non-condensing)
Transportation and storage relative humidity	10 ~ 85% RH (Non-condensing)
Operating atmospheric pressure	700-1060 hPa
Transportation and storage atmospheric pressure	700-1060 hPa

Scanning Resolution	Theoretical	True
Super high resolution (SHR)	25 LP/mm	17 LP/mm
High resolution (HR)	15.6 LP/mm	14 LP/mm
High speed (HS)	8 LP/mm	8 LP/mm
Ultra High Resolution (UHR)	34 LP/mm	19 LP/mm

Imaging Plate Dimensions

Imaging Plate Size	0	1	2
Height (mm)	22	24	31
Width (mm)	35	40	41

Minimum Computer System Requirements

If necessary, you must update your computer system configuration.

Item	Minimum System Requirement	Comments
CPU	2 GHz Intel® Dual Core™ or AMD Athlon or higher	For best performance it is recommended to use an ***Intel***® Core™ i7 processor
RAM	2 GB (4 GB recommended)	RAM has a major impact on system performance
Hard disk drive	• 80 GB minimum (250 GB recommended) free space to use the software • At least 4 GB free for software installation	
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	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 8.1 64-bit • Windows 10 Professional	Recommended 64 bit.
USB port	3 USB 2.0 ports	4 ports recommended
CD/DVD drive	DVD-ROM drive is required to install the product.	
Audio speakers	1 speaker	To enable hearing audible alarms initiated by the system

4 Contact Information

Factory Address

Building 7, No. 1510, Chuanqiao Road,
China (Shanghai) Pilot Free Trade Zone
Shanghai China 201206

Manufacturer's Address

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

Authorized Representatives

Authorized Representative in the European Community

EC REP

Carestream Health France
COPERNIC II
Immeuble Le Neptune
1, rue Galilée
93192 Noisy-Le-Grand
France

Importer for European Union

Carestream Health Netherlands B.V.
Bramenberg 12
3755 BZ Eemnes
The Netherlands

Representante no Brasil Carestream do Brasil Comércio e Serviços de Produtos MédicosLtda.

Rua Pequetita, 215 cjs.
31 E 32 Edifício Atrium VII - Vila Olímpia
São Paulo - Brazil
CEP (Zip code): 04552-060

Carestream Dental
A Division of Carestream Health, Inc.
150 Verona St.
Rochester, NY 14608
USA

For more information, visit: **www.carestreamdental.com**
To give documentation feedback, visit:
www.carestreamdental.com/documentationfeedback

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