Carestream

CS 7600



Safety, Regulatory and Technical Specifications

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.

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

This document is originally written in English.

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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

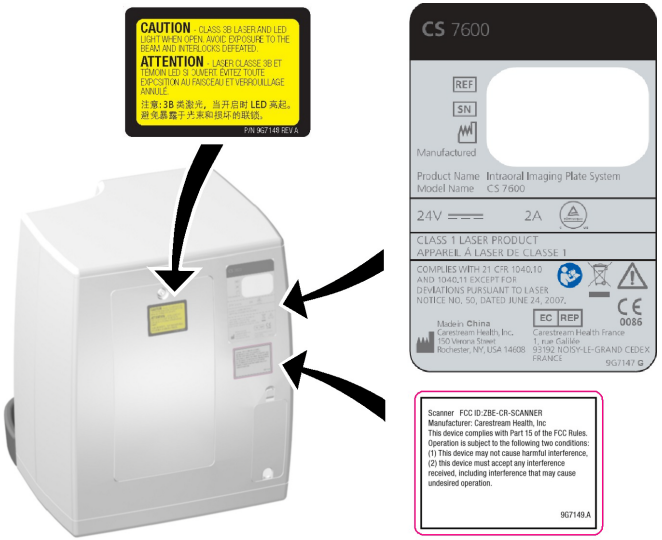
Label	Description
	Caution—consult accompanying documents
	Power On/Off
	Caution—Electrical shock hazard

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

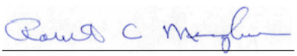
Carestream Health, Inc., hereby declares under its sole responsibility that the product(s) listed are made in conform Annex I, Essential Requirements, and ANNEX II, EC Declaration of Conformity (Full quality assurance system European Economic Community Medical Device Directive [Directive 93/42/EEC]; Article 4 of the Directive restriction of the use of certain hazardous substances in electrical and electronic equipment [Directive 2011/65/E Annex II of the Radio and Telecommunications Terminal Equipment Directive [Directive 1999/5/EC].

Manufacturer's Name and Address:	Carestream Health, Inc. 150 Verona Street Rochester, New York USA, 14608
Medical Device:	Storage Phosphor Reader System
Product List:	CS 7600 "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
Quality Management System Certificate:	TUV No. QS2 16 09 84685 005
European Notified Body:	British Standards Institute, BSI (0086)
Full Quality Assurance System Certificate:	BSI Certificate Number CE 01233
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Issuance date: September 23, 2016, Revision E, (CS 7600)
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Standards Applied

EN ISO 13485:2012	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	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: 2006/AC: 2010	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007/AC: 2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62304:2006/AC: 2008	Medical device software. Software life-cycle processes
EN 60825-1:2007	Safety of laser products - Part 1: Equipment classification and requirements
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN ISO 10993-1:2009/AC: 2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 300 330-2 v1.6.1: 2015	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
EN 50581: 2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN 62321: 2009	Electrotechnical products – Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)
EN 62474: 2012	Material Declarations for products of and for the electrotechnical industry



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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 V1.6.1/47CFRp15sb.C/RSS/210 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

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 8.1 64-bit • Windows 10 Professional	
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.

4 Contact Information

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