

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

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

The system should be used in the hospital environment except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CS 7600, including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.



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.
- Connection of the PEMS to an IT-NETWORK that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties.
- The RESPONSIBLE ORGANIZATION should identify, analyze, evaluate and control these RISKS.
- Subsequent changes to the IT-NETWORK could introduce new RISKS and require additional analysis and changes to the IT-NETWORK that include:
 - Changes in the IT-network configuration.
 - Connection of additional items to the IT-NETWORK.

- Disconnecting items from the IT-NETWORK.
- Update of equipment connected to the IT-NETWORK.
- Upgrade of equipment connected to the IT-NET.

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.

| Cable Description | From | To | Cable Type (or Detail model name and manufacturer for this cable) | Cable Length |
|-------------------|---------------------------|-----------------|---|--------------|
| USB cable | Scan & Go Device USB Port | PC USB Port | Shield | 2 m |
| Network cable | CS 7600 Network Port | PC Network Port | Unshielded | 3 m |
| Power cord | Adapter AC inlet | Mains | Unshielded | 1.5 m |

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 |
|---|---|
|  | <p>In the European Union, this symbol indicates: DO NOT discard this product in a trash receptacle; use an appropriate recovery and recycling facility.</p> <p>Contact your local sales representative for additional information on the collection and recovery programs available for this product.</p> |
|  | <p>Warning: General warning sign</p> <p>Using accessories other than those specified in this document with the exception of those sold by Carestream Dental LLC may result in a lower level of security for the entire system.</p> |
|  | <p>General mandatory action sign.</p> |
|  | <p>Refer to instruction manual / booklet.</p> |
|  | <p>Manufactured Date.</p> |
|  | <p>Manufacturer's address.</p> |

IEC Symbols Used

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

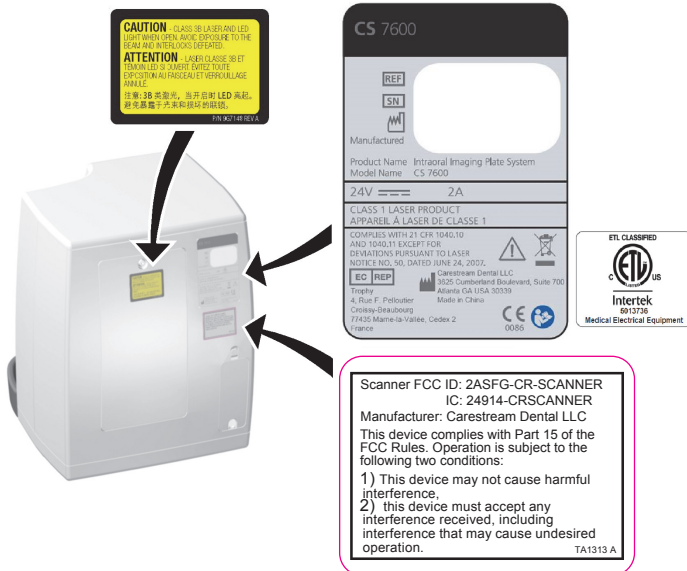
| Label | Description |
|---|--|
|  | Caution—consult accompanying documents |
|  | Power On/Off |
|  | Caution—Electrical shock hazard |

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.



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

The CS 7600 is an active device specifically intended for scanning of X-ray diagnostic images. This device complies with the following regulations:

- 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.
- Electro-magnetic Compatibility (EMC) directive 89/336/EEC, Group 1, Class A
- Radio Equipment directives 2014/53/EU
- FCC rules part 15/EN 300 330 V2.1.1/47CFR15sb.C/RSS/210 Issue 7
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).
- 21 CFR 1040.10
- FDA Center for Devices & Radiological Health CDRH - Title 21 CFR 872.1800 (USA)
- Medical Devices Regulations (Canada)

Compliance with European and International Standards

| Compliance with European and International Standards | |
|--|---|
| 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 Disturbances – Requirements and tests. |
| 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 15223-1 | Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements. |
| EN 1041 | Information supplied by the manufacturer of medical devices |
| EN 62304/IEC 62304 | Medical device software - Software life cycle processes |
| EN 300 330 | 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 |
| EN 60825-1 / IEC 60825-1 | Safety of laser products - Part 1: Equipment classification and requirements |
| EN 62366 / IEC 62366 | Medical devices - Application of usability engineering to medical devices |
| EN ISO 10993-1 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| ANSI AAMI ES60601-1 | Medical Electrical Equipment - Part 1: General Requirements for Safety |
| CAN/CSA-C22.2 No. 60601-1 | Medical Electrical Equipment - Part 1: General Requirements for Safety |

Classification in Accordance with EN/IEC 60601-1

| | |
|---|--------------------------|
| Type of protection against electric shock | Class 1 equipment |
| Degree of protection against electric shock | 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 7600.
- 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, other than 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 | Not applicable | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not applicable | |

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 Level | Electromagnetic Environment - Guidance |
|--|--|--|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact ±15 kV air | ±8 kV contact ±15 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) ±2 kV line(s) to earth | 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 | 0 % U_T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 ^a) cycle Single phase: at 0° 0 % U_T ; 250/300 ^a) cycle | 0 % U_T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 ^a) cycle Single phase: at 0° 0 % U_T ; 250/300 ^a) cycle | 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. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment |

a) e.g 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

NOTE: U_T is the AC mains voltage prior to the application of the test level.

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 6 Vrms in ISM bands between 150 kHz and 80 MHz ^{a)} | 3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz ^{a)} | Environment of a care facility professional health. WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CS 7600 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.7 GHz | 3 V/m 80 MHz to 2.7 GHz | |

a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz to 6.795 MHz; 13.533 MHz to 13.567 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 1: 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.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

For the immunity to proximity fields from RF wireless communications equipment, the CS 7600 is compliant with the test levels specified below according to IEC60601-1-2 standard. The customer or the user of the CS 7600 should assure that it is used in such an environment.

| Test frequency (MHz) | Band (MHz) | Immunity test levels |
|-----------------------------|-------------------|--|
| 385 | 380-390 | Pulse modulation 18Hz, 27V/m |
| 450 | 430-470 | FM, ± 5 kHz deviation, 1 kHz sine, 28V/m |
| 710 | | |
| 745 | 704-787 | Pulse modulation 217Hz, 9V/m |
| 780 | | |
| 810 | | |
| 870 | 800-960 | Pulse modulation 18Hz, 28V/m |
| 930 | | |
| 1720 | | |
| 1845 | 1700-1990 | Pulse modulation 217Hz, 28V/m |
| 1970 | | |
| 2450 | 2400-2570 | Pulse modulation 217Hz, 28V/m |
| 5240 | | |
| 5500 | 5100-5800 | Pulse modulation 217Hz, 9V/m |
| 5785 | | |



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

Compliance with FCC Rules

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.

3 Technical Specifications

Model

CS 7600

Factory Address

Rayco (Shanghai) Medical Products Company Limited
Building 7, No. 1510 Chuanqiao Road,
China (Shanghai) Pilot Free Trade Zone
201206 Shanghai China
PEOPLE'S REPUBLIC OF CHINA

Manufacturer's Address

U



Carestream Dental LLC
3625 Cumberland Boulevard, Suite 700
Atlanta, GA USA 30339

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 Or Mean Well Model #: GSM60A24 100-240V(ac), 50/60 Hz, 1.4-0.7A |
| Laser wavelength | 635 – 660 nm (Class 3B) |
| Laser power | Up to 12 mW |

* For external AC/DC power supply medical grade, complies with IEC 60601-1

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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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

Manufacturer's Address

1



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Authorized Representatives

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EC REP

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