Safety Manual

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Contents

Safety and Related Information

The information contained herein is based on the experience and knowledge relating to the subject matter gained by the manufacturer prior to publication.

No patent license is granted by this information.

The manufacturer reserves the right to change this information without notice and makes no warranty, express or implied, with respect to this information. The manufacturer shall not be liable for any loss or damage, including consequential or special damages, resulting from the use of this information, even if loss or damage is caused by the manufacturer's negligence or other fault.

For product specifications, see the *User Manual*.

Safety, Warnings, and Cautions

Please read and understand all instructions before using this product.

DANGER

This equipment is operated with hazardous voltage which can shock, burn, or cause death.

- Remove wall plug before servicing equipment. Never pull on cord to remove from outlet. Grasp plug and pull to disconnect. Do not attempt to service or repair the laser imager yourself to avoid exposure to dangerous voltage, laser beam, or other danger. Always call an authorized service provider for any service or repair.
- Do not operate equipment with a damaged power cord.
- Do not use an extension cord to power this equipment.
- Do not operate equipment with any of the safety interlocks overridden.
- Position the power cord so it will not be tripped over or pulled.
- Connect this equipment to a grounded wall outlet.
- A power cord is provided with this equipment. All countries must use an agency-approved power cord with plug type suitable for the country of use. Contact a qualified dealer for help.
- Do not operate equipment with the covers open.

DANGER

This equipment contains moving parts that may be accessible to the user. Loose clothing, jewelry or long hair may cause personal injury or damage to the equipment.

DANGER

This equipment is not contained in a sealed cabinet. Do not use this equipment in locations where it can come in contact with liquids, including body fluids.

Caution

The operator must not touch or have contact **simultaneously** with the patient **and** the laser imaging system.

Caution

Do not use a cell phone within 2.0 m (6.6 ft) of a laser imager. This proximity includes any imager behind a wall adjacent to your location.

Caution

Do not use a microwave oven within 4.0 m (13.1 ft) of a laser imager. Electromagnetic radiation from a microwave oven is only an issue if after the oven door is closed and latched, the seal does not maintain an electromagnetic tight fit between the oven door and oven main housing. Determining if the seal has an electromagnetic tight fit requires special detection equipment.

Caution

Do not use in the presence of flammable anesthetics, oxygen, or nitrous oxide. This equipment does not have a gas-sealed electronics enclosure and could ignite any flammable or explosive gases present in its environment.

Caution

This equipment uses a DICOM network port, and is intended to connect to other medical devices over the network. It is not intended to be connected directly to other medical devices. Only qualified personnel may provide installation and service.

Caution

This device should not be used in close contact with MRI devices, due to possible very high magnetic fields near an MRI unit. The magnetic field in the area where this equipment is installed must be less than 50 G.

Caution

Do not substitute or modify any part of this equipment.

Caution

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the User Guide and other User Documentation, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Caution

Do not use isopropyl alcohol to clean the exterior surfaces of the laser imager.

Caution

In the U.S., exhausted filters are considered to be non-hazardous waste according to the US Environmental Protection Agency Resource Conservation Recovery Act (RCRA). Municipality owned and licensed solid waste management facilities are an appropriate disposal option. Contact your local or state solid waste authorities to determine if additional disposal requirements apply. In other regions, contact local or regional solid waste authorities for proper disposal guidance.

Caution

Lithium batteries should only be replaced by an authorized service provider. The laser imager uses a lithium battery to power the clock and calendar circuitry. THERE IS A DANGER OF EXPLOSION IF THE BATTERY IS REPLACED INCORRECTLY. The battery must be replaced only with the same or equivalent type. The U.S. EPA's RCRA does not regulate disposal of this lithium battery. Users should discard spent batteries in municipal trash unless their community offers a battery collection program. In other regions, contact local or regional solid waste authorities for proper disposal guidance.

Laser Warning

The equipment uses an invisible laser beam with a maximum power of 120 milliwatts. Laser radiation may be present when the machine operates without the rear cover installed. Covers with this label may only be removed by an authorized service provider. USE OF CONTROLS OR ADJUSTMENTS, OR PERFORMANCE OF PROCEDURES OTHER THAN THOSE SPECIFIED HEREIN, MAY RESULT IN EYE DAMAGE.

Safety Labels

Safety labels are attached to the laser imager in compliance with international standards.

English Text on Labels

Some names on the labels are shortened and left in English. Below is a key to understand the meanings of the shortened words on the labels:

Symbol on label	Definition
	Model Number
	Serial Number
	CAT Number
P/N	Part Number
	Manufactured Date
	Manufactured By
	Operator must read the user documentation
	Consult instructions for use
	Attention! Consult accompanying documents

System Labels

Laser Radiation Warning

1

2

1	**Class 3B invisible laser radiation.** This label states: "When open and interlocks defeated, avoid exposure to the beam."
2	**Hazard symbol**

Table 1: Laser specifications

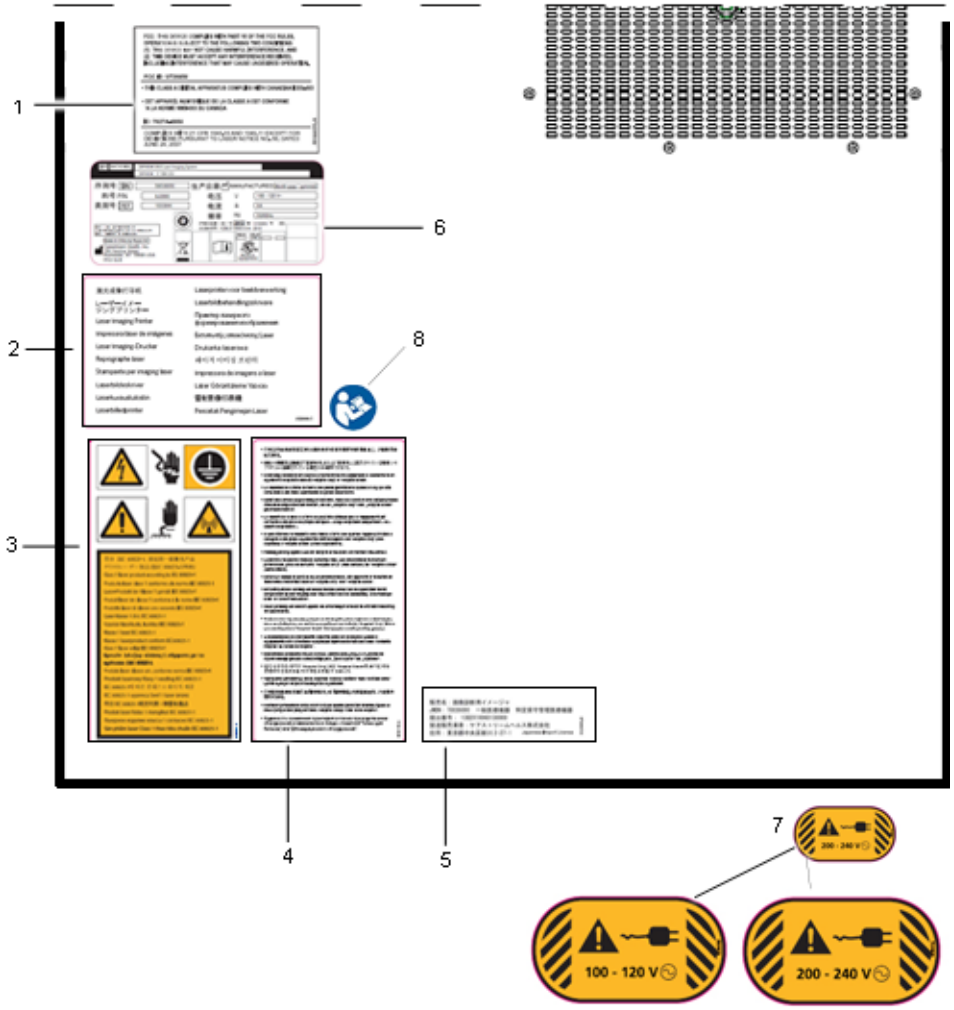
Type	Scanning (moving) laser beam emitting from a diode
Wavelength	810 ±10 nanometers
Maximum power	120 mW
Beam divergence from Laser Diode	Minimum: 5 °, maximum: 32 °

High Voltage Warning

This warning label indicates that high voltage is present under panels or enclosures where labels are attached. These panels may only be removed by an authorized service provider.

Back Panel and Agency Statements

Figure 1: Laser Imager Back Panel



Item	Label	Description
1	FCC compliance	Describes compliance, if applicable for the country of installation.
2	Product	States that the imager is a Laser Imaging Printer.

Item	Label	Description
3	Agency labels and Class 1 Laser Safety	• **High voltage.** Indicates that high voltage is present under panels where the label is attached. Only an authorized service provider should attempt access. • **Static Sensitive Equipment.** Identifies static-sensitive components. Connect a personal grounding strap to the appropriate ground before servicing this laser imager. These panels may only be removed by an authorized service provider. • **Radio Frequency Energy.** Indicates that the laser imager can radiate radio frequency energy. If not installed and used in accordance with the instructions, the laser imager may cause harmful interference to radio communications. • **Class 1 Laser.** Indicates that the laser imager complies with IEC requirements for Class 1 Laser systems.
4	Grounding reliability	States that grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked “Hospital Only” or “Hospital Grade.”
5	Japanese import license	Allows importation into Japan.
6	Serial plate	Shows the serial number and model number of the imager along with other important data items.
7	Power cord inlet	Covers the power cord inlet when shipped from manufacturing. Shows the voltage at which the laser imager must be operated. The label is removed or moved during installation.
8	Safety sign ISO 7010–M002	Indicates that the operator must read the user documentation.

Hot and Sensitive Surface Labels

Figure 2: Drum labels: Hot Surface and Sensitive Surface (No Sharp Objects in this Vicinity)

This label indicates that you must use care where the label is installed:

- Hot surface! Take care to avoid possible burns.
- Sensitive coating! Do not use abrasive or sharp objects around the drums.

Safety and Health Compliance

This equipment has been tested for and complies with the following Safety and Emissions Standards. Certificates of Compliance and Declarations of Conformity have been issued as shown below.

Safety Standards

United States

- 21 CFR 1040.10 Class I
  Code of Federal Regulations Title 21 Food and Drugs
  Chapter I Food and Drug Administration, Department of Health and Human Services
  Volume 8 - Parts 800 to 1299
  Subchapter J - Radiology Health
  Part 1040 - Performance Standards for Light Emitting Products
  Section 10 - Laser Products
- UL 60601-1:2003 - Medical Electrical Equipment. General Requirement for Safety.
- ANSI/AAMI ES60601-1:2005 - Medical Electrical Equipment. Part 1: General requirements for basic safety and essential performance.

Canada

CSA C22.2 NO 60601-1 CAN/CSA:2008 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

Europe

EN 60601-1:2006 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

International

- IEC 60601-1:1988 - Medical Electrical Equipment. General Requirement for Safety.
- IEC 60601-1:2005 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60825-1:2007 - Safety of laser products - Part 1: Equipment classification and requirements.

EMC Standards

United States

- FCC Rules and Regulations, Title 47, Part 15, Subpart B, Class A: Radio Frequency Devices: Unintentional Radiators.
- This equipment has been tested and been found to comply with the limits for a Class A digital device pursuant to part 15 of the FCC rules. Those limits are designed to

provide reasonable protection against harmful interference in a commercial or light industrial installation.

- FCC Rules and Regulations, Title 47, Part 15, Subpart C, Radio Frequency Devices: Intentional Radiators. “FCC ID: U726950”
- RF Exposure Guidance: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter, except in accordance with FCC multi-transmitter product procedures.

Canada

- CAN/CSA-C22.2 NO. 60601-1-2-08 Medical Electric Equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and Tests.
- Intentional Radiation “IC: 7027A-6950”
- This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.
- Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.
- Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.
- Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada.
- This Class A digital apparatus complies with Canadian ICES-003 (A).
- CET APPAREIL NUM ENRIQUE DE CLASSE A EST CONFORME A LA NORME NMB-003 (A) DU CANADA.
- This Class A digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Europe

EN60601-1-2: Medical Electrical Equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and Tests.

Rest of World

IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and Tests.

Guidance and Manufacturer's Declaration for Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment— Guidance
RF emissions: • EN55011 • CISPR 11	Group 1	The system 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: • EN55011 • CISPR 11	Class A	The system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics emissions: • EN61000-3-2 • IEC 61000-3-2	Class A	The system is suitable for use everywhere, including those establishments directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations and flicker emissions: • EN61000-3-3 • IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration for Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or user of the laser imager should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment— Guidance
Electrostatic discharge (ESD): • EN61000-4-2 • 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: • EN61000-4-4 • 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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment— Guidance
Surge: • EN61000-4-5 • IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines: • EN61000-4-11 • IEC 61000-4-11	<5 % UT*(>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec.	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the laser imager requires continued operation during power mains interruptions, it is recommended that the laser imager be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field: • EN61000-4-8 • IEC 61000-4-8	3 A/m	3 A/m	Mains power quality should be that of a typical commercial or hospital environment.

* UT is the a.c. mains voltage prior to application of the test level

Guidance and Manufacturer's Declaration for Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or user of the laser imager should ensure that it is used in such an environment.

Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment— Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz–80 MHz	3 Vrms	$d = 1.17 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 v/m 80 MHz–2.5 GHz	3 v/m	$d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ 800 MHz to 2.5 GHz where *d* is the recommended separation distance in meters (m) *P* is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range†. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note

At 80 MHz and 800 MHz, the higher frequency range applies.

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

* Field strengths from fixed transmitters, such as base station 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 laser imager is used exceeds the applicable RF compliance level above, the laser imager should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the laser imager.

† Over the frequency range 150 kHz–80 MHz, field strengths should be less than 3 v/m.

Additional Guidance and Manufacturer's Declaration–Electromagnetic Emissions/Immunity

Electromagnetic Compatibility Precautions

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Medical equipment must be installed and put into service according to the EMC information provided in this document.

Communications Equipment

Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment EMC performance.

Replacement of Cables, Accessories, or Transducers

The use of cables, accessories or transducers other than those specified in this document with the exception of transducers or cables sold by the manufacturer of the equipment as replacement parts for internal components, may result in increased emissions or decreased immunity of the medical equipment.

Other Equipment

The System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.

Shielded Locations

The System is fully compliant with the requirements of IEC 60601-1-2 without being located in a shielded room.

External Cables Listing

Description	Length	Shielded?
Cable, Category 5E, Shielded RJ45 to RJ45, Patch Cord, 4 Pair	2.1 m (7.0 ft)	Yes
Cord Assembly, Power, China	2.5 m (8.2 ft)	No
Cord Assembly, Power, Continental Europe Schuko	2.5 m (8.2 ft)	No
Cord Assembly, Power, India/South Africa	2.5 m (8.2 ft)	No
Cord Assembly, Power, North American	3.0 m (10.0 ft)	No
Cord Assembly. Power, UK, Fused	2.5 m (8.2 ft)	No

Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the System

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

Rated Maximum Output Power of Transmitter (P)	**Separation Distance (d) According to Frequency of Transmitter**		
Watts	**Meters**		
	150 kHz–80 MHz $d = 1.17 \sqrt{P}$	80 MHz–800 MHz $d = 1.17 \sqrt{P}$	800 MHz–2.5 GHz $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.24
0.10	0.37	0.37	0.74
1.00	1.17	1.17	2.33
10.00	3.70	3.70	7.37
100.00	11.70	11.70	23.30

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

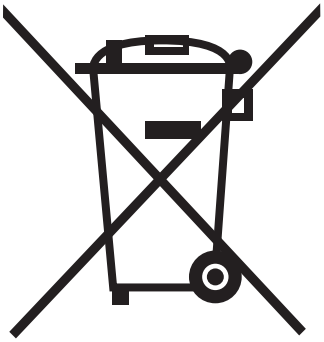
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

EU Directives

- 93/42/EEC Title: Council Directive Concerning Medical Devices.
- 1999/5/CE Title: Council Directive Concerning Radio Equipment and Telecommunications Terminal Equipment.

Figure 3: Recycling Label



In the European Union, this symbol indicates that when the last user wishes to discard this product, it must be sent to the appropriate facilities for recovery and recycling. Contact your local authorized representative for additional information.

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