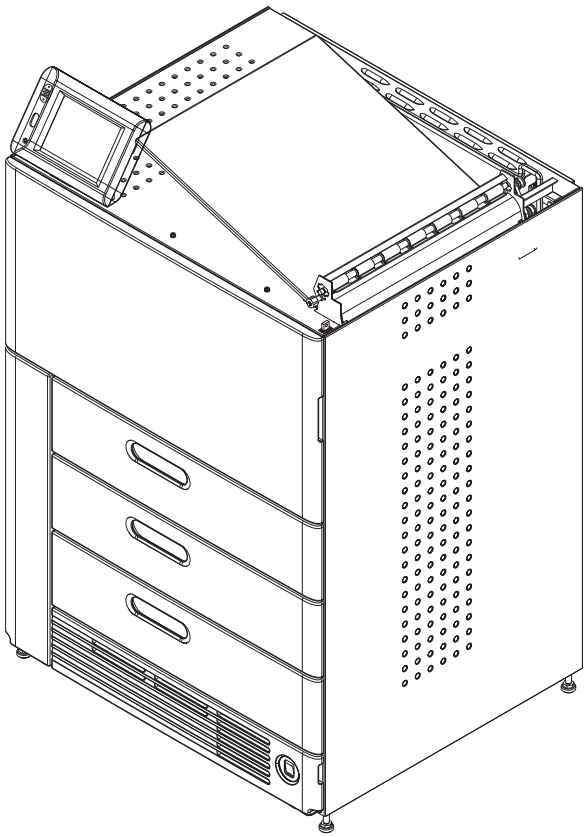
DRYVIEW 6850 Laser Imager



Safety Manual

Carestream HEALTH

150 Verona Street
Rochester, New York 14608

Pub No. 2G8646
Rev. A

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Safety and Related Information

Safety, Warnings, and Cautions

Please read and understand all instructions before using this product.

RISK OF ELECTRIC SHOCK:
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 of Carestream Health, Inc. products 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.
- Four power cord sets are provided with this equipment:
  - power cord with plug for use in North America
  - power cord with plug for use in China
  - power cord with plug for use in the United Kingdom
  - power cord with plug for use in Europe

  All other countries must use an Agency-approved power cord with plug type suitable for the country of use, or contact an authorized Carestream Health, Inc. dealer.

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.

- Do not operate equipment with the covers open.

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:
Do not use a cell phone within 2 meters 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 meters 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. It is not intended to be connected directly outside the building. Only an Authorized Service Provider of Carestream Health, Inc., products or customer's qualified service personnel may perform installation and service maintenance.

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 Gauss.

CAUTION:
Do not substitute or modify any part of this equipment without prior written approval of Carestream Health, Inc.

CAUTION:
Federal law prohibits dispensing without a prescription.

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.

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. Isopropyl alcohol can dissolve the exterior paint on 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. Go to the Carestream Health web site, search for the Environmental Technical Summary document, and refer to the End-of-Life-Management section.

CAUTION:

Lithium batteries should only be replaced by an Authorized Service Provider of Carestream Health, Inc., products. 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 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 of Carestream Health, Inc. products. 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.

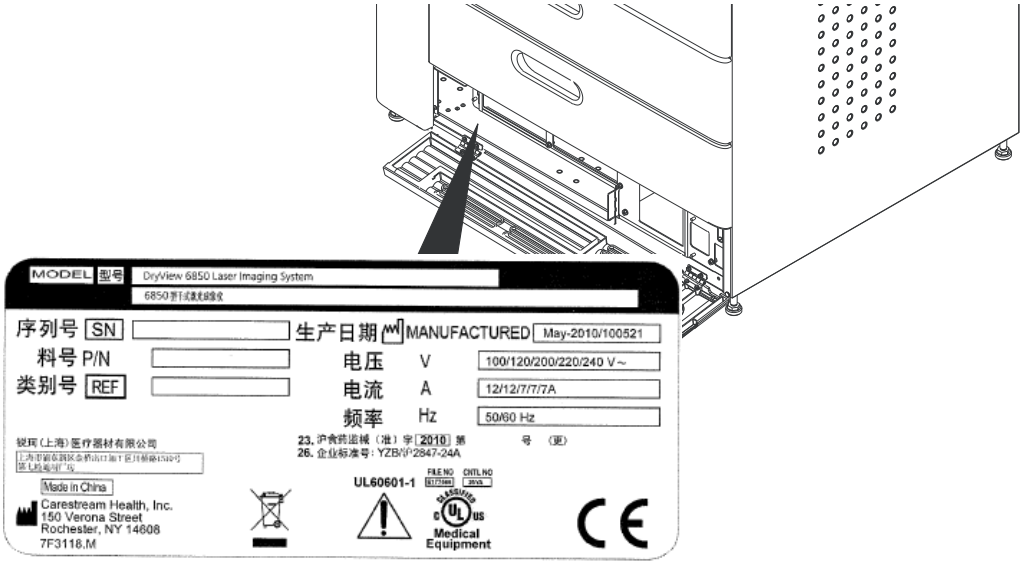
English Text on Labels

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 safety labels:

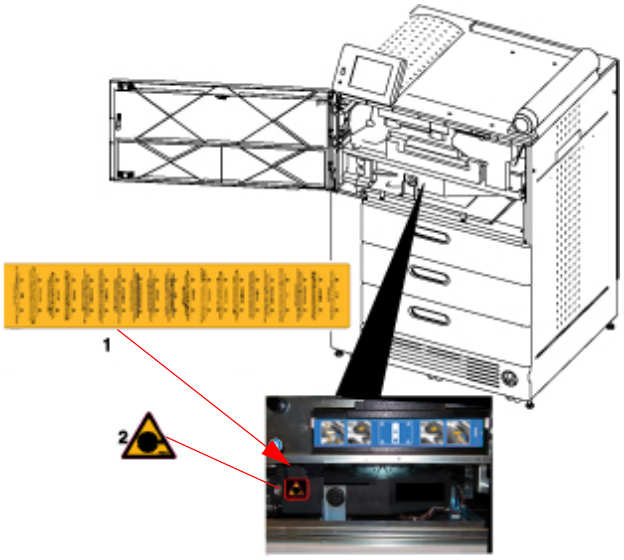
Symbol on label	Definition
	Belt Path
	Processor Drive Belt
	Turn Around Belt
	Transport Drive Belt
	Media Path
	Model Number
	Serial Number
	CAT Number
	Manufactured Date
	Manufactured By
	Sorter Belt Path
	Sorter Drive Belt

Symbol on label	Definition
	Tension Drive Belt
	Lower Drive-Roller Belt
	Main Drive Belt
	Cooling Roller Drive Belt
	Processor Belt Path
	Short Drive Belt
	Cooling Section Drive Belt
	Long Drive Belt
	Drum Drive Belt

Labels - Locations and Details



This label shows the serial number and model number of the Imager along with other important data items.



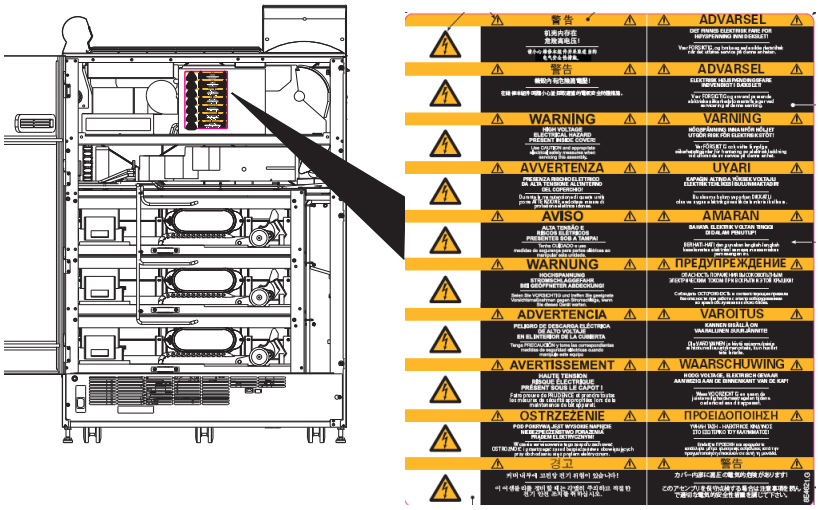
Laser Radiation Warning Labels

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

2 **Hazard symbol.**

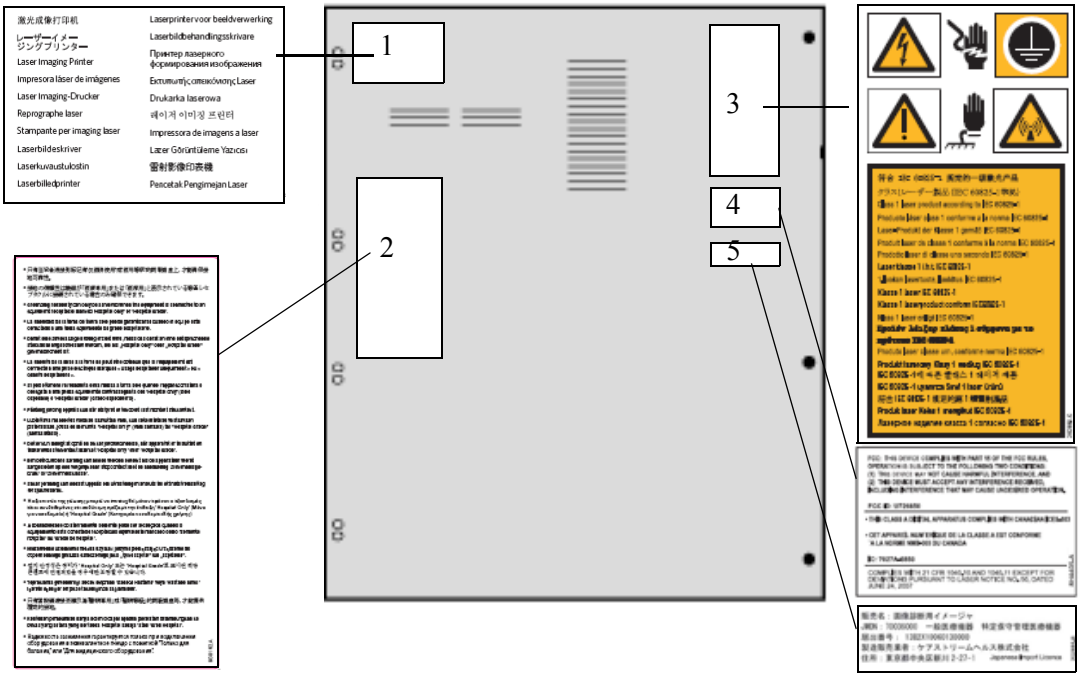
Laser Specifications

Type	Scanning (moving) laser beam emitting from a diode
Wavelength	810 +/- 10 nanometers
Maximum power	120 milliwatts
Beam divergence from Laser Diode	Minimum: 6.8 degrees, maximum: 32 degrees



High Voltage Warning Label

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 of Carestream Health, Inc. products.



Agency Statements

1 **Product Label.** This label states that the imager is a Laser Imaging Printer.

2 **Grounding Reliability.** This label states that grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade."

3 **Agency Symbols 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 of Carestream Health, Inc. products should attempt access.

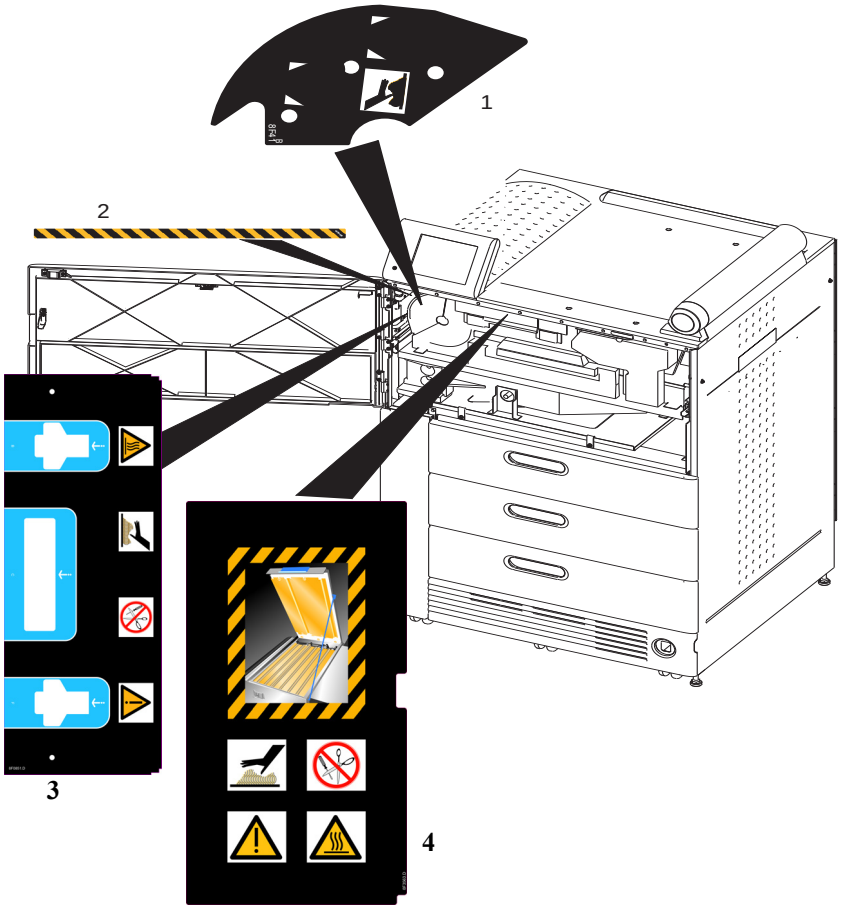
Static Sensitive Equipment: Identifies static-sensitive components. Connect a personal grounding strap to appropriate ground before servicing this laser imager. These panels may only be removed by an Authorized Service Provider of Carestream Health, Inc. products.

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. This label indicates that the laser imager complies with IEC requirements for Class 1 systems.

4 **FCC Compliance.** Provides FCC ID and describes compliance.

5 **Japanese Import License.**



Hot Surface Labels

1 **Drum end cap hot surface.** This label indicates to use care near the processor drum end cap to avoid possible burns.

2 **Drum hinge hot surface.** This label indicates to use care near the processor drum hinge to avoid possible burns.

3 **Drum hot surface.** This label advises to use care near the processor drum to avoid possible burns.

4 **Processor flatbed hot surface.** This warning label advises to use care near the processor flatbed to avoid possible burns.

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

United States

21 CFR 900.12(e) Mammography Quality Standards Act; Quality Standards; Quality Assurance for Equipment.

FDA 21CFR 807 Subpart E - Premarket Notification Procedures.

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: Medical electrical equipment - Part 1: General requirements for safety.

IEC 60825-1 Ed. 2 (2007): Safety of laser products - Part 1: Equipment classification, requirements and user's guide.

Canada

CAN/CSA - C22.2 NO 60601-1 Ed. 2 - Medical electrical equipment - Part 1: General requirements for safety.

IEC 60825-1 Ed. 2 (2007): Safety of laser products - Part 1: Equipment classification, requirements and user's guide.

Europe

EN60601-1 Ed. 2 - Medical electrical equipment - Part 1: General requirements for safety.

EN60825-1: Safety of laser products - Part 1: Equipment classification, requirements and user's guide.

Rest of World

IEC 60601-1 Ed. 2 - Medical electrical equipment - Part 1: General requirements for safety.

IEC 60825-1: Safety of laser products - Part 1: Equipment classification, requirements and user's guide.

EMC

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 residential installation.

FCC Rules and Regulations, Title 47, Part 15, Subpart C, Radio Frequency Devices: Intentional Radiators. “FCC ID: U726850”

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-6850”

This Class A digital apparatus complies with Canadian ICES-003.

CET APPAREIL NUM ENRIQUE DE CLASSE A EST CONFORME A LA NORME NMB-003 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.

Europe and the Rest of World

Guidance and Manufacturer's Declaration for Electromagnetic Emissions		
The DRYVIEW 6850 Laser Imaging System is intended for use in the electromagnetic environment specified below. The customer or user of the 6850 Laser Imager should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions: • EN55011 • CISPR 11	Group 1	The 6850 Laser Imager 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 6850 Laser Imager 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 6850 Laser Imager 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	The 6850 Laser Imager 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.

Guidance and Manufacturer's Declaration for Electromagnetic Immunity			
The 6850 Laser Imager 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.
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% Uτ * (>95% dip in Ut*) for 0.5 cycle 40% Uτ * (60% dip in Uτ *) for 5 cycles 70% Uτ * (30% dip in Uτ *) for 25 cycles <5% Uτ * (>95% dip in Uτ *) for 5 sec.	<5% Uτ * (>95% dip in Uτ *) for 0.5 cycle 40% Uτ * (60% dip in Uτ *) for 5 cycles 70% Uτ * (30% dip in Uτ *) for 25 cycles <5% Uτ * (>95% dip in Uτ *) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 6850 Laser Imager requires continued operation during power mains interruptions, it is recommended that the 6850 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.
NOTE: * Uτ is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration for Electromagnetic Immunity			
The 6850 Laser Imager is intended for use in the electromagnetic environment specified below. The customer or user of the 6850 Laser Imager should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the 6850 Laser Imager, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 v/m 80 MHz to 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 *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[a], 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: • 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. [a]See Note 1 on next page. [b]See Note 2 on next page.			

Guidance and Manufacturer's Declaration for Electromagnetic Immunity	
Note 1	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 6850 Laser Imager is used exceeds the applicable RF compliance level above, the 6850 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 6850 Laser Imager.
Note 2	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 v/m.

Recommended separation distance between portable and mobile RF communications equipment and the 6850 Laser Imager

The 6850 Laser Imager is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 6850 Laser Imager can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the 6850 Laser Imager as recommended below, according to the maximum output of the communications equipment.

Rated maximum output power of transmitter (*P*) in Watts (W)	**Separation distance (*d*) according to frequency of transmitter in meters (m)**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01			
0.1			
1			
10			
100			

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.

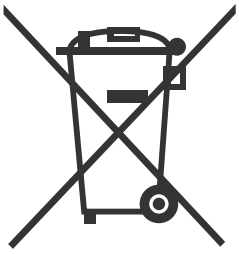
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

EU Directives

93/42/EEC Title: Council Directive Concerning Medical Devices.

1999/5/CE Title: Council Directive Concerning Radio Equipment and Telecommunications Terminal Equipment.



Recycling Label

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

CE Marking

Documents concerning the conformance of this product to Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices can be obtained from the Carestream Health, Inc. European Representative at:

EC REP

Carestream Health France
LES MERCURIALES
40, rue Jean Jaures
93176 BAGNOLET CEDEX
France

Please Note

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Imager Specifications

See the Site Readiness guide for the 6850 Laser Imager, 8H5321.

Publication History

Revision	Date	Reason for Change
A	2010-11-04	First release

Carestream HEALTH

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CE