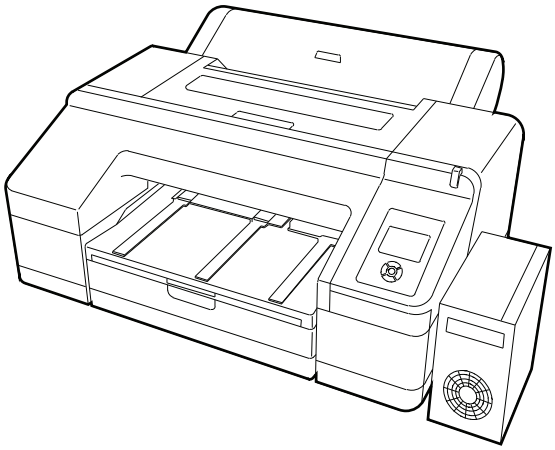
SHORT TERM CONFIDENTIAL

# DRYVIEW CHROMA Imaging System



# Safety Manual

Carestream

Carestream Health, Inc.
150 Verona Street
Rochester, New York 14608
United States


Printed in China.



Pub No. 9G4259_en
Rev. C

CE

# Table of Contents

Safety, Warnings, and Cautions ----------1
Safety Labels ----------4
Safety and Health Compliance ----------7
Safety ----------7
EMC ----------7
EU Directives ----------14
CE Marking ----------14
Please Note ----------15
Imager Specifications ----------15
Publication History ----------15

SHORT TERM CONFIDENTIAL

# Safety and Related Information

## Safety, Warnings, and Cautions

Please read and understand all instructions before using the DRYVIEW CHROMA Imaging System.

**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 imager yourself to avoid exposure to dangerous voltage or other danger. Always call a qualified 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.
- One power cord set is provided with this equipment.

  You must use an Agency-approved power cord with a plug type suitable for the country of use.

**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.**

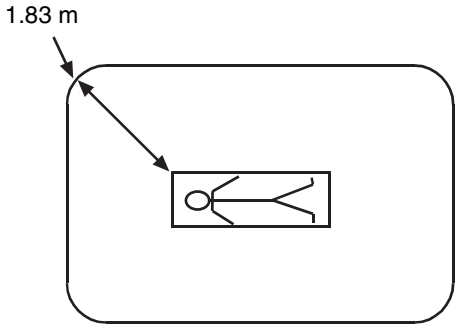
**CAUTION:**
**Double pole/neutral fusing.**

**CAUTION:**
**Do not use a cell phone within 2 m of this device. This proximity includes any imager behind a wall adjacent to your location.**

**CAUTION:**
**Do not use a microwave oven within 4 m of this device. 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 qualified personnel may perform installation and service.**




**CAUTION:**
**This device is NOT to be located within the patient environment. Therefore, the equipment must not be located closer than 1.83 m from a patient bed or chair.**

**CAUTION:**
**This device can affect implantable pacemaker or implantable cardioverter defibrillators at distances of less than 30.48 cm (1.00 ft).**

**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 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 device.**

**CAUTION:**
**Lithium batteries should only be replaced by a qualified service provider. The device 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.**

## Safety Labels

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

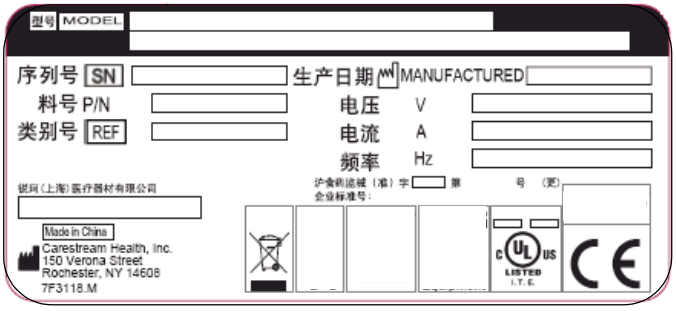
### English Text on Labels

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

| Symbol on label | Definition |
|---|---|
|   | Model Number |
|   | Serial Number |
|   | CAT Number |
|   | Manufactured Date |
|  | Manufactured By |

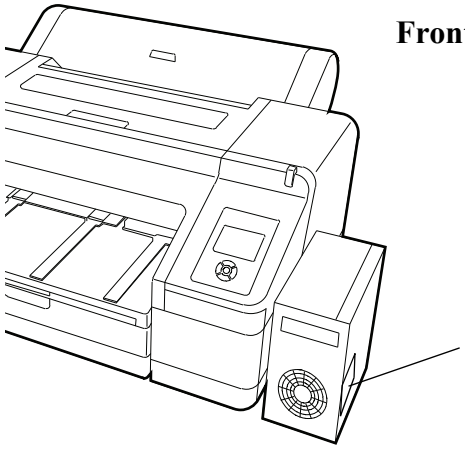
## Labels—Locations and Details

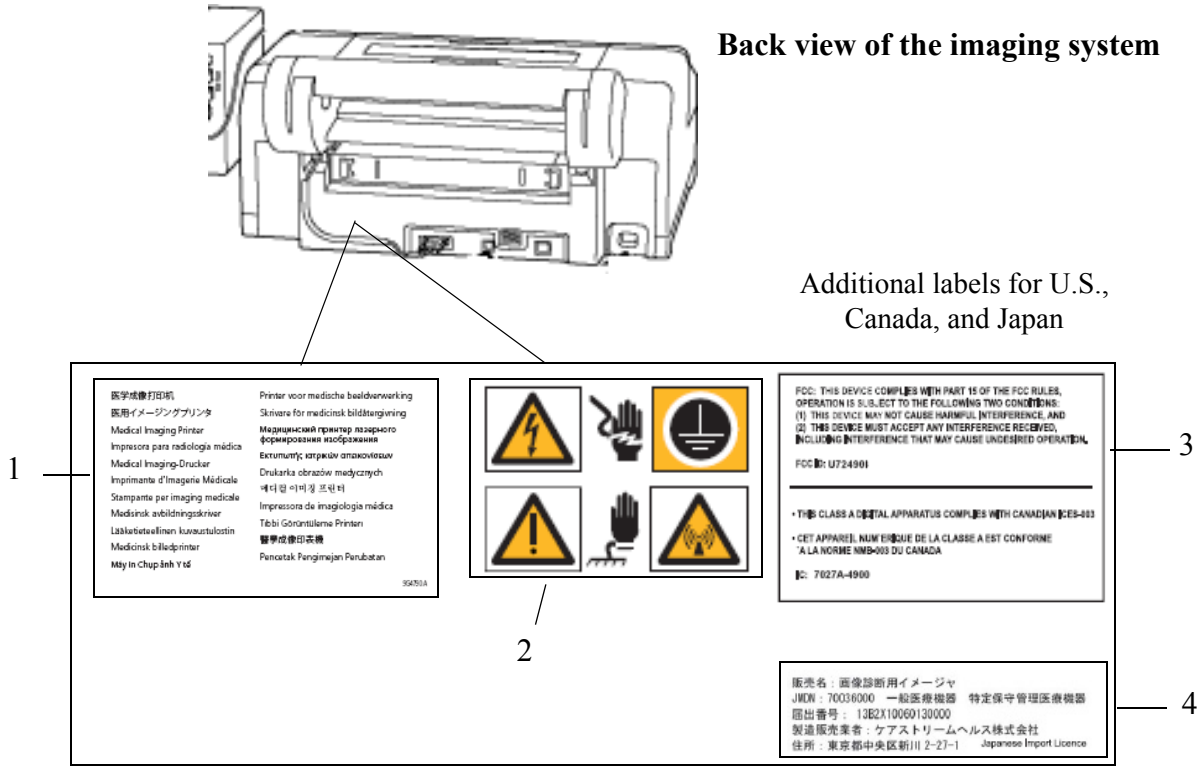
See “Safety and Health Compliance” on page 7 for the specific details of the safety and health compliance.




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

**Front view of the imaging system**






## Agency Statements

1 **Product Label.** This label states that the imager is a medical imaging printer.

2 **Static Sensitive Equipment.** This label identifies static-sensitive components. Connect a personal grounding strap to the appropriate ground before servicing this device. These panels may only be removed by a qualified service provider.

**Radio Frequency Energy.** This label indicates that the device can radiate radio frequency energy. If not installed and used in accordance with the instructions, the imager may cause harmful interference to radio communications.

3 **FCC ID and Intentional Radiation IC.**

4 **Japanese Import License.**

# 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**

FDA 21CFR 807 Premarket Notification 510(K): Regulatory Requirements For Medical Devices.

UL 60950-1, 2nd Ed.: Safety of Information Technology Equipment, including Electrical Business Equipment (Bi-National Standard).

**Canada**

CAN/CSA - C22.2 NO 60950-1-07 Information Technology Equipment - Safety - Part 1: General Requirements (Bi-National Standard, with UL 60950-1, 2nd Ed.).

**Europe**

EN60950-1: Safety of Information Technology Equipment, including Electrical Business Equipment (IEC 60950-1, 2nd Ed.).

**Rest of World**

IEC 60950-1, 2nd Ed.: Safety of information technology equipment.

## 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 for CHROMA Imager: U724901.

### Canada

CAN/CSA-C108.6-M91, Class A: Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment.

Intentional Radiation IC for CHROMA Imager: 7027A-4900.

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 and the Rest of World

Under 60601-1-2, there are four tests for 61000-4-11. Three of the tests were passed normally at the declared test voltages.

Compliance with one of the tests, a 60 % dip in voltage for 5 cycles (which is approximately one tenth of a second) was not met due to a technological limitation. The imager portion of the CHROMA Imaging System will not function at the minimum nominal voltage of 100 V, when it dips to 40 V. At 40 V, the imager stops and requires operator intervention to be restored to full operation (Test Performance Criteria “C”. However, the imager must meet Test Performance Criteria “B” or “A”). Although the imager stops and intervention is required, no images are lost by the imaging system.

The imager passes the 60 % dip test at 115 V nominal, dipping to 46 V. No operator intervention is required, and there are no performance degradation results due to the voltage dip (Test Performance Criteria “A”).

The DICOM interface passes the 60 % dip test at 100 V nominal, dipping to 40 V (Test Performance Criteria “A”). Therefore, the DICOM interface may be plugged directly into a 100 V system, wall outlet, and meets all the requirements of 61000-4-11 under 60601-1-2.

| Guidance and Manufacturer's Declaration for Electromagnetic Emissions | | |
|---|---|---|
| The imager is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic Environment—Guidance** |
| RF emissions:<br>• EN55011<br>• CISPR 11 | Group 1 | The 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:<br>• EN55011<br>• CISPR 11 | Class A | The 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:<br>• EN61000-3-2<br>• IEC 61000-3-2 | Class A | The 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:<br>• EN61000-3-3<br>• IEC 61000-3-3 | Complies | The 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 imager is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment—Guidance** |
| Electrostatic discharge (ESD):<br>• EN61000-4-2<br>• IEC 61000-4-2 | ± 6 kV contact<br>± 8 kV air | ± 6 kV contact<br>± 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:<br>• EN61000-4-4<br>• IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge:<br>• EN61000-4-5<br>• IEC 61000-4-5 | ± 1 kV differential mode<br>± 2 kV common mode | ± 1 kV differential mode<br>± 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|---|---|---|---|
| Voltage dips, short interruptions, and voltage variations on power supply lines:<br>• EN61000-4-11<br>• IEC 61000-4-11 | <5 % Ut* (>95 % dip in Ut*) for 0.5 cycle<br>40 % Ut* (60 % dip in Ut*) for 5 cycles<br>70 % Ut* (30 % dip in Ut*) for 25 cycles<br><5 % Ut* (>95 % dip in Ut*) for 5 sec. | <5 % Ut* (>95 % dip in Ut*) for 0.5 cycle<br>70 % Ut* (30 % dip in Ut*) for 25 cycles<br><5 % Ut* (>95% dip in Ut*) for 5 sec.<br>115 V (ac) 40 % Ut* (60 % dip in Ut*) for 5 cycles<br>40 % Ut* (60 % dip in Ut*) for 5 cycles | Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the imager is powered from an uninterruptible power supply or a battery.<br>Under 60601-1-2, there are four tests for 61000-4-11. Three of the tests were passed normally.<br>One of the tests is a 60 % dip in voltage for 5 cycles, which is approximately one tenth of a second dip, to 40 % of the nominal voltage. The imager portion of the CHROMA Imaging System did not pass that test, at the planned nominal voltage of 100 V, dipping to 40 V. At that voltage, operator intervention was required to restore the system to full operation (Performance Criteria “C”. The system must meet Performance Criteria “B” or greater). No images were lost by the imaging system.<br>The imager passes the 115 V nominal test, dipping to 46 V. No operator intervention is required, and there is no performance degradation (Test Performance Criteria “A”).<br>The DICOM interface passes the test at 100 V nominal, dipping to 40 V (Performance Criteria “A”).<br>If the imager is to be powered by a 100 V system, an uninterruptible power supply (UPS) must be placed in the power circuit, between the wall outlet and the imager, to ensure the imager will meet the minimum requirements of this test (Performance Criteria “B”).<br>The DICOM interface may be plugged directly into a 100 V system wall outlet and meets the requirements of 61000-4-11. |
| Power frequency (50/60 Hz) magnetic field:<br>• EN61000-4-8<br>• IEC 61000-4-8 | 3 A/m | 3 A/m | Mains power quality should be that of a typical commercial or hospital environment. |
| NOTE: * Ut is the a.c. mains voltage prior to application of the test level. | | | |

| **Guidance and Manufacturer's Declaration for Electromagnetic Immunity** | | | |
|---|---|---|---|
| The imager is intended for use in the electromagnetic environment specified below. The customer or user 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 imager, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Conducted RF | 3 Vrms | 3 Vrms | $d = 1.17\sqrt{P}$ |
| IEC 61000-4-6 | 150 kHz–80 MHz | | |
| Radiated RF | 3 v/m | 3 v/m | $d = 1.17\sqrt{P}$ 80 MHz–800 MHz |
| IEC 61000-4-3 | 80 MHz–2.5 GHz | | $d = 2.33\sqrt{P}$ 800 MHz–2.5 GHz |
| | | | d is the recommended separation distance in meters (m).<br>P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer.<br>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].<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| NOTE:<br>At 80 MHz and 800 MHz, the higher frequency range applies.<br>These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.<br>[a]See NOTE 1 on the top of the next page.<br>[b]See NOTE 2 on the top of the 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 imager is used exceeds the applicable RF compliance level above, the imager should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the imager. |
| NOTE 2 | Over the frequency range 150 kHz–80 MHz, field strengths should be less than 3 v/m. |

**Recommended separation distance between portable and mobile RF communications equipment and the imager**

The imager is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the 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–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 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.17 | 1.17 | 2.33 |
| 10 | 3.70 | 3.70 | 7.37 |
| 100 | 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 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

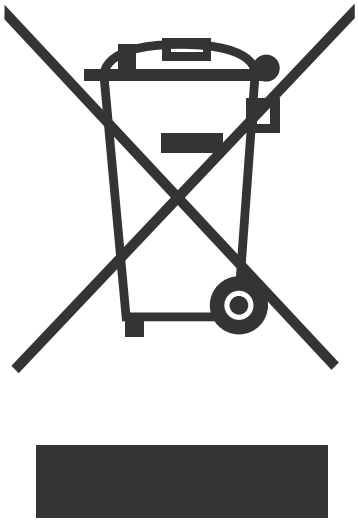
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

## EU Directives

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

1999/05/EC Title: Council Directive Concerning Radio and Telecommunications Terminal Equipment.

2006/95/EC Title: Council Directive on the Harmonization of the Laws of Member States Relating to Electrical Equipment Designed for Use within Certain Voltage Limits.



**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

1, rue Galilée

93192 NOISY-LE-GRAND CEDEX

FRANCE

## Please Note

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 negligence of the manufacturer or other fault.

# Imager Specifications

See the User's Guide, 9G4260.

# Publication History

| Revision | Date | Reason for Change |
|---|---|---|
| A | 2011-05-05 | First release |
| B | 2011-08-19 | Page 13 - Added values to the table. |
| C | 2012-02-24 | Added Caution about implantable pacemakers/implantable cardioverter defibrillators, updated the FCC ID. |

SHORT TERM CONFIDENTIAL