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RVG 5100 and RVG 6100

Safety, Regulatory & Technical Specifications User Guide

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Notice

The Regulatory Information & Technical Specifications User Guide for the RVG 5100 and RVG 6100 includes information on the safety instructions, regulatory information and the technical specifications of the device. We recommend that you thoroughly familiarize yourself with this Guide in order to make the most effective use of your system.

The information contained in this Guide may be subject to modification without notice, justification or notification to the persons concerned.

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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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RVG 5100 and RVG 6100 comply with Directive 93/42/EEC relating to medical equipment.

CE
2797

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1 Safety Information

Indications for Use

The RVG 5100 and RVG 6100 digital intra-oral X-ray sensor is intended to produce an image of the dental area at the direction of dentists, oral surgeons and orthodontists for X-ray imaging of the dento-maxillofacial area.

The RVG 5100 and RVG 6100 transmit an acquired image to a computer using a USB cable. To do so, they require additional components such as conventional extraoral X-ray source and imaging software.

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.

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Warning and Safety Instructions



WARNINGS

Device:

- Read and understand this Safety Information before using the RVG 5100 and RVG 6100.
- You are responsible for the operation and maintenance of this device. Only legally qualified persons can operate this device. When necessary, have a trained authorized service technician carry out inspection and maintenance operations.
- Install this device in an X-ray room that complies with current installation standards. From this location, you must be able to maintain visual or audio communication with the patient and be able to access the Acquisition interface module during exposure.
- 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.
- X-ray equipment is hazardous to patients and the operator if you do not observe the exposure safety factors and operating instructions.
- 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.
- To dispose of the device or its components, contact a service technician.
- No modification of this equipment is allowed.
- DO NOT use this device in conjunction with oxygen-rich environments. This device is not intended for use with flammable anesthetics or flammable agents.
- It is not recommended to use accessories other than those specified in this document and sold by Carestream Dental LLC.

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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.
- Always use Microsoft Windows Update to make sure that the latest security patches are correctly installed.

Hygiene and Disinfection



WARNINGS

- Never place the sensor in an autocalve as this could result in serious damage to the sensor.
- Never immerse the RVG sensor in any solution.
- Disinfect the sensor head after each patient.
- Do not use chemical autoclave for the toothbrush holders and avoid direct contact with the metallic part of the autoclave.
- To prevent cross-contamination, use a new hygienic barrier for each new patient.

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Marking and Labeling Symbols

	Type BF device symbol complying with the IEC 60601-1 standard
	In the European Union, this symbol indicates: DO NOT discard this product in a trash receptacle; use an appropriate recovery and recycling facility. Contact your local sales representative for additional information on the collection and recovery programs available for this product
	Warning: Consult the accompanied documents.
	The ON/OFF button
	General mandatory action sign
	Follow operating instructions sign
	Non-ionizing radiation
	Manufactured Date
	Manufacturer's address

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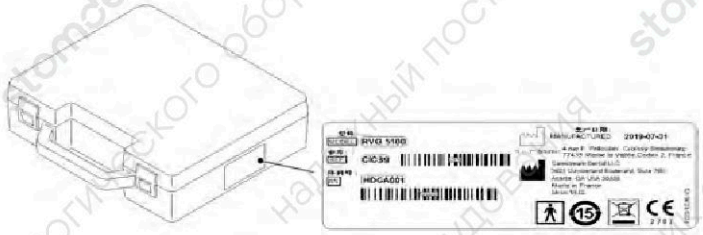
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Label Locations

The following figures illustrate the label locations of the RVG 5100 and RVG 6100.

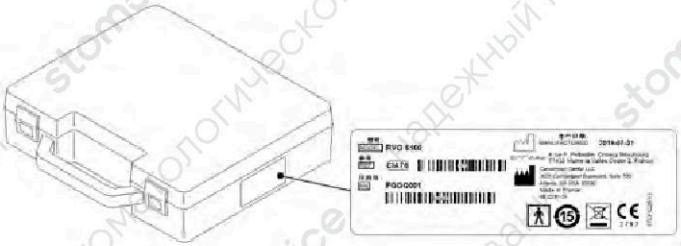
RVG 5100 Label Locations

Figure 1 RVG 5100



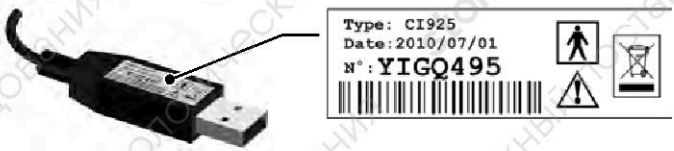
RVG 6100 Label Locations

Figure 2 RVG 6100



RVG 5100 & 6100 USB Cable Label

Figure 3 RVG 5100 & 6100 USB Cabel



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2 Regulatory Information

General Regulatory Information

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 Compatibility
EN 60601-1-3/IEC 60601-1-3	Medical Electrical Equipment, Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
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 ISO 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 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing

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Classification in Accordance with EN/IEC 60601-1	
Type of protection against electric shock	Class 1 equipment
Degree of protection against electric shock	Type BF
Protection against harmful ingress of water	Ordinary equipment
Operation mode	Continuous operation
Flammable anesthetics	Not suitable for use in presence of flammable anesthetics or a mixture of flammable anesthetics with air or oxygen or nitrous oxide

Conformity with EN/IEC 60601-1-3	
Attenuation equivalent for the enclosure of the image receiver unit (at 100 kV)	0.2 mm eq. Al

Conformity with EN/IEC 60601-1-2

Electromagnetic Compatibility Precautions



- Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC).
- RVG 5100 and RVG 6100 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 RVG 5100 and RVG 6100.
- RVG 5100 and RVG 6100 may be interfered with other equipment even if that other equipment complies with CISPR emission requirements.

RVG 5100 and RVG 6100 Components	
RVG sensor and the remote control	
Cable between sensor and remote control	70 cm
USB cable	2 meters

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- Use limitation: the use of accessories, cables, or transducers other than those specified in this document with the exception of cables, accessories or transducers sold by Carestream Dental as replacement parts of internal components, may result in increased emissions or decreased immunity of the RVG 5100 and RVG 6100.
- The RVG 5100 and RVG 6100 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the RVG 5100 and RVG 6100 should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions (IEC 60601-1-2)

The RVG 5100 and RVG 6100 is intended for use in the electromagnetic environment specified below. The customer or the user of the RVG 5100 and RVG 6100 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The RVG 5100 and RVG 6100 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 B	The RVG 5100 and RVG 6100 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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Guidance and Manufacturer's Declaration - Electromagnetic Immunity

RVG 5100 and RVG 6100 are intended for use in the electromagnetic environment specified below. The customer or the user of RVG 5100 and RVG 6100 should assure that they are used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of RVG 5100 and RVG 6100 requires continued operation during power mains interruptions, it is recommended that RVG 5100 and RVG 6100 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

NOTE: UT is the A.C. mains voltage prior to application of the test level.

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Guidance and Manufacturer's Declaration - Electromagnetic Immunity (IEC 60601-1-2)

RVG 5100 and RVG 6100are intended for use in the electromagnetic environment specified below. The customer or the user of RVG 5100 and RVG 6100 should assure that they are used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[V1]= 3 V	Portable and mobile RF communications equipment should be used no closer to any part of RVG 5100 and RVG 6100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E1]= 3 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which RVG 5100 and RVG 6100 are used exceeds the applicable RF compliance level above, RVG 5100 and RVG 6100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating RVG 5100 and RVG 6100.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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Recommended Separation Distances between Portable and Mobile RF Communications Equipment and RVG 5100 and RVG 6100 (IEC 60601-1-2)

RVG 5100 and RVG 6100 are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of RVG 5100 and RVG 6100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and RVG 5100 and RVG 6100 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter		
	150 kHz to 80 MHz $d=[\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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



Note: Uninterrupted communication is essential for electromagnetic compatibility.

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Compliance with International Regulations

Medical Device directives 93/42/European Economic Community (EEC), Class IIa follow the rule 16 as amended by 2007/47/EEC. RVG 5100 and RVG 6100 are active devices specifically intended for the recording of X-ray diagnostic images.

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3 Technical Specifications

Factory

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4, Rue F. Pelloutier, Croissy-Beaubourg
77435 Marne la Vallée Cedex 2, France

Manufacturer

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Model

RVG 5100
RVG 6100

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RVG 5100 and RVG 6100 Technical Specifications

Components	RVG 5100	RVG 6100
RVG Sensor		
Sensor Technology	• CMOS • Scintillator • Optical fiber	• CMOS • Scintillator • Optical fiber
Sensor matrix	• Size 1:1200 x 1600 pixels • Size 2: 1440 x 1920 pixels	• Size 0: 900 x 1200 pixels • Size 1: 1200 x 1600 pixels • Size 2: 1440 x 1920 pixels
Sensor active surface dimensions	• Size 1: 22.2 x 29.6 mm • Size 2: 26.6 x 35.5 mm	• Size 0: 16.6 x 22.2 mm • Size 1: 22.2 x 29.6 mm • Size 2: 26.6 x 35.5 mm
Gray scale	4096 bits	4096 bits
Sensor and Remote Control		
Dimension	102 mm (H) x 23 mm (W) x 14 mm (D)	145 mm (H) x 35 mm (W) x 18.5 mm (D)
Weight with RVG sensor	• Size 1: 120 g • Size 2: 140 g	• Size 0: 110 g • Size 1: 120 g • Size 2: 130 g

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Minimum Computer System Requirements

The computer and the peripheral equipment must conform to the IEC60950 standard.

Item	Display and Aquisition
CPU	2 GHz Intel Duo Core
RAM	2 GB
Hard disk drive	• 1.2 GB for software installation • 80 GB free space to use the software
Graphic board	Nvidia/ATI based board with 256 MB of RAM
Display	1024 x 768 minimum screen resolution 32 bits color mode
Operating system	• Windows XP Home/Pro edition SP3 (32 bits) • Windows Vista SP1 • Windows 7 (32/64 bits)
USB 2.0	2 ports available
CD/DVD drive	DVD-ROM drive is required to install the product.
Backup media	Removable/portable, external hard disk drive.

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Environmental Requirements

Ambient Operating Conditions	
Temperatures	0–45 °C
Relative humidity	45–85%
Atmospheric pressure	700–1060 hpa

Storage Conditions	
Temperatures	-20–60 °C
Relative humidity	45–85%
Atmospheric pressure	700–1060 hpa

Transport Conditions	
Temperatures	-20–60 °C
Relative humidity	45–85%
Atmospheric pressure	700–1060 hpa

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