Carestream DENTAL

RVG 142, RVG 5200 & RVG 6200

Safety, Regulatory and Technical Specifications User Guide

Notice

The Regulatory Information & Technical Specification User Guide for RVG 142, RVG 5200 and RVG 6200 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 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.

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.

Manual Name: RVG 142, RVG 5200 and RVG 6200 Safety, Regulatory and Technical Specification User Guide
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RVG 142, RVG 5200 and RVG 6200 comply with Directive 93/42/EEC relating to medical equipment.

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Contents

1 Safety Information

Indications for Use

The RVG 142, RVG 5200 and RVG 6200 digital intra-oral X-ray sensors are 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.

RVG 142, RVG 5200 and RVG 6200 transmit an acquired image to a computer using a USB cable. To do so, they require additional components such as conventional extra-oral X-ray source and imaging software.

In addition, RVG 6200 can be used with an RVG Connect unit connected to the LAN (Local Area Network).

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.

Note: Emphasizes important information.

Tip: Provides extra information and hints.

Warning and Safety Instructions

WARNINGS:

Device

- **Read and understand this safety information before using RVG 142, RVG 5200 and RVG 6200.**
- **You are responsible for the operation and maintenance of this device. Only legally qualified persons can operate this device. They MUST have training to use the 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.**
- **To dispose of the device or its components, contact a service technician.**
- **No modification of this device 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.**
- **Single-use disposable protective hygienic sleeves must cover the RVG sensor before placing it in the patient's mouth.**
- **To prevent cross-contamination, use a new hygienic barrier for each new patient and disinfect the RVG sensor.**
- **To ensure the best quality images, you must connect the RVG sensor to a USB port on the BACK of the workstation.**
- **RVG Connect: the management and the allocation of the static IP address must be done by a network administrator.**
- **RVG Connect: For the smooth functioning of the image recovery mechanism, do NOT switch off the RVG Connect unit and do NOT disconnect the ethernet cable from the RVG Connect unit.**
- **Place the sensor in the patient mouth ONLY if the RVG icon is green on the imaging software.**
- **If you find that the RVG sensor is too hot, disconnect the RVG sensor and contact an authorized service technician.**

Computer

- **RVG 5200 or RVG 6200 or RVG 142 shall be supplied by Low Voltage-Low Power (<15W) source separated from the mains by DI/RI Isolation (Double isolation / Reinforced isolation). The USB port of a computer or the hub is separated from the mains by DI/RI Isolation.**
- **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.**
- **Always use Microsoft Windows Update to make sure that the latest security patches are correctly installed.**

Hygiene and Disinfection

Cleaning the Sensor Head

WARNINGS:

- **Disinfect the sensor head after each patient.**
- **Never place the sensor in an autoclave as this could result in serious damage to the sensor.**
- **Do not use UV disinfection nor ultrasound cleaning as this could result in serious damage to the sensor.**
- **Do not move the sensor using its cable when you remove the protective hygienic sleeves.**
- **You must first clean the RVG sensor before disinfecting it.**
- **You must use the disinfectant according to the manufacturer instructions.**

You must first clean the RVG sensor before disinfecting it. To do so, follow these steps:

1. Remove the protective hygienic sleeves.
2. Remove debris or organic matter from the sensor surfaces with a disposable wipe or surface brush.
3. Inspect the sensor for debris. Repeat cleaning if there is any debris left.
4. Disinfect the sensor head with disinfecting wipes or soak it in a disinfecting solution with intermediate-level hospital disinfectant with label claims of tuberculocidal activity (for example: a chlorine containing product, a quaternary ammonium compound with alcohol, a phenolics, an iodophors, an EPA-registered chlorine-base product). **You must follow the manufacturer instructions for use**.

Cleaning the Sensor Cable

The cable must be cleaned with disposable disinfecting wipes with intermediate-level hospital disinfectant with label claims of tuberculocidal activity.

Cleaning and Disinfecting Positioning Accessories

Positioning Accessories Daily Maintenance Tasks

Accessory	Maintenance Tasks
RVG Holder	**Cleaning the RVG Holder** You must clean the RVG sensor holder before you disinfect it. To clean the sensor holder, follow these steps: 1. Remove all debris and organic matter with a disposable wipe. 2. Rinse under running water. 3. Using a soft brush, scrub with warm taps water and soap or detergent. 4. Rinse under running water. 5. Dry with compressed air or hygienic disposable cloth. 6. Visually inspect the RVG sensor holder for residual debris. Repeat steps 1 to 5 if you see residual debris.

RVG Holder (continued)	**Disinfecting the RVG Holder** **WARNINGS:** • **You must use medical autoclaving equipment cleared by the FDA in the USA or one that is recognized by your Local Authority.** • **DO NOT use a chemical autoclave to disinfect the RGV sensor holder.** • **You must always follow the operating parameters recommended by the manufacturer of the autoclaving equipment.** • **Use FDA-cleared or CE-marked standard packaging material.** To disinfect the RVG sensor holder after cleaning it, follow these steps: 1. Steam autoclave at 134° C (273° F) for 3 minutes using distilled water. 2. Leave to dry before use. **WARNING: Avoid direct contact with the metallic part of the autoclave.**
Arm and Ring	**Disinfecting the Arm and Ring** To disinfect the arm and ring, follow these steps: 1. Disassemble the metal arm and the plastic ring. 2. Remove any residue from components with hot water and soap. 3. Put components in disinfection pouches, and place in the middle tray of the autoclave, away from autoclave walls and heating element. Plastic parts must be in a separate pouch than metal arms, to avoid melting or warping. 4. Steam autoclave at 132°C (270°F) for 10 minutes before the next patient. • Do not exceed 134°C (273°F). • Do NOT use phenol-based glutaraldehyde. • Do NOT use special application or ultrasonic cleaners. • Do NOT CHEMICLAVE or DRY-HEAT STERILIZE. • Do NOT cold sterilize **Note: Plastic parts have a limited life and should be replaced periodically. Any method of sterilization will shorten the life of plastic parts.**

Cleaning the RVG Connect Unit

The RVG Connect unit must be cleaned with disposable disinfecting wipes with intermediate-level hospital disinfectant with label claims of tuberculocidal activity.

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
	Refer to instruction manual/booklet
	Date of Manufacture.
	Manufacturer’s address.

Label Locations

The following figures illustrate the label locations of RVG 5200, RVG 6200, and RVG Connect

Figure 1: RVG 142, RVG 5200 & RVG 6200 sensor box label

Figure 2: RVG 142, RVG 5200 and RVG 6200 USB cable label

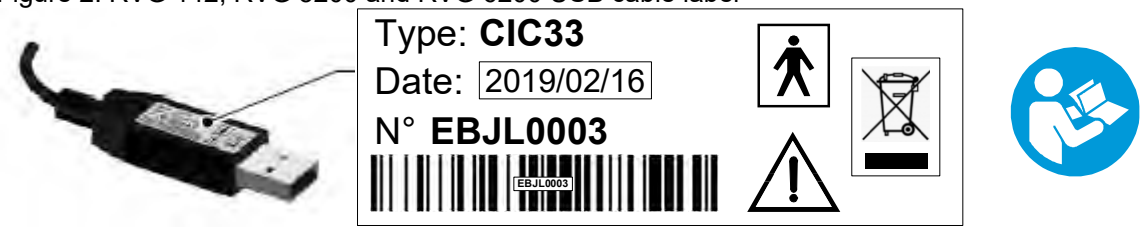


Figure 3: RVG 142 product label

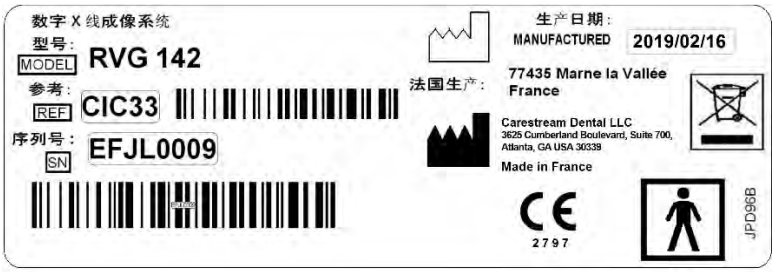
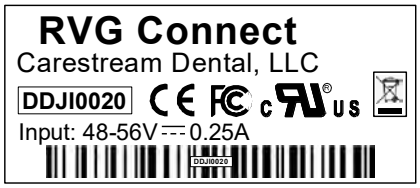


Figure 4 RVG Connect unit label



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 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 62366/IEC 62366	Medical devices - Application of usability engineering to medical devices
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 ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
CAN/CSA C22.2 N°60601-1	Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance
ANSI/AAMI ES60601-1	Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance

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 60601-1-2

Electromagnetic Compatibility Precautions

WARNINGS:

- **Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC).**
- **RVG 142, RVG 5200 and RVG 6200 are intended to be used in a professional healthcare facility environment.**
- **RVG 142, RVG 5200 and RVG 6200 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 142, RVG 5200 and RVG 6200.**
- **RVG 142, RVG 5200 and RVG 6200 may be interfered with other equipment even if that other equipment complies with CISPR emission requirements.**

RVG 142, RVG 5200 and RVG 6200 Components

Sensor	
USB cable	Length ≤ 3 m
RVG Connect	Used only with RVG 6200

WARNINGS:

- **Use limitation: The use of accessories, cables, or transducers other than those specified in the user guide with the exception of cables, accessories or transducers sold by Carestream Dental LLC as replacement parts of internal components may result in increased emissions or decreased immunity of RVG 142, RVG 5200 and RVG 6200.**
- **RVG 142, RVG 5200 and RVG 6200 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, RVG 142, RVG 5200 and RVG 6200 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)**
RVG_5200_RVG_6200_RVG_142_S&R_Ed04.docx

RVG 142, RVG 5200 and RVG 6200 are intended for use in the electromagnetic environment specified below. The customer or the user of RVG 142, RVG 5200 and RVG 6200 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	RVG 142, RVG 5200 and RVG 6200 use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	RVG 142, RVG 5200 and RVG 6200 are 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	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity		
RVG 142, RVG 5200 and RVG 6200 are intended for use in the electromagnetic environment specified below. The customer or the user of RVG 142, RVG 5200 and RVG 6200 should assure that they are used in such an environment. The essential performance of the RVG 142; RVG 5200 and RVG 6200 sensors is Image Quality. The Image quality is specified in term of Contrast and Resolution.		
Immunity Test	**IEC 60601 Test Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Not Applicable	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 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.		

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (IEC 60601-1-2)		
RVG 142, RVG 5200 and RVG 6200 are intended for use in the electromagnetic environment specified below. The customer or the user of RVG 142, RVG 5200 and RVG 6200 should assure that it is used in such an environment.		
Immunity Test	IEC 60601 Test Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz and 6V at ISM Frequencies and amateur radio frequencies	Environment of a care facility professional health.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz Test levels and frequencies according to table 9 from IEC 60601-1-2: 2014	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 RVG including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

NOTE: 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 the RVG systems are used exceeds the applicable RF compliance level above, the RVG systems should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RVG.

Note: Uninterrupted communication is essential for electromagnetic compatibility.

Compliance With International Regulations

Medical Device directives 93/42/European Economic Community (EEC), Class IIa following the rule 16 as amended by 2007/47/EEC. RVG 142, RVG 5200 and RVG 6200 are active devices specifically intended for the recording of X-ray diagnostic images.

Medical Device directives 93/42/European Economic Community (EEC), Class I following the rule 12 as amended by 2007/47/EEC. The RVG Connect unit is an active device.

FDA Center for Devices & Radiological Health (CDRH-CFR title 21 chapter 1) (USA)
Medical Devices Regulations (Canada).
Federal Communications Commission (FCC Part 15) for the RVG Connect (USA)

Directive 2011/65/EU on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (RoHS)

3 Technical Specification

Factory

TROPHY

4, rue F. Pelloutier, Croissy-Beaubourg

77435 Marne la Vallée Cedex 2, France

Manufacturer

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

Model

RVG 5200

RVG 6200

RVG 142

RVG 142, RVG 5200 and RVG 6200 Technical Specifications

Components	Specification
RVG Sensor	
Sensor Technology	CMOS Scintillator Optical fiber*
Sensor matrix	Size 1 : 1168 x 1562 pixels Size 2 : 1402 x 1874 pixels
Sensor active surface dimensions	Size 1 : 22.2 x 29.6 mm Size 2 : 26.6 x 35.5 mm
Gray scale	4096 grey levels (12 bits)
Dimension	Size 1 : 27,6 mm(W) x 37,7 mm (H) x 7,3 mm (D) Size 2 : 32,2 mm(W) x 44,2 mm (H) x 7,3 mm (D)
Weight	Size 1 : 65 g Size 2 : 75 g
Input voltage	5V DC (USB interface)
USB Interface	USB 2.0 high Speed
USB Connector	Plug Type A

*Optical fiber: Only use with RVG 5200 and RVG 6200

RVG Connect Technical Specification

Components	Specification
RVG Connect	
Ethernet interface	100 BaseT
USB connector	Receptacle Type A
USB Interface	USB 2.0 high Speed
Power supply interface	Power Over Ethernet (POE) 802.3af
Dimension	60 mm (W) x 115 mm (H) x 30 mm (D)
Weight	120 g
Input voltage	48 - 56 V DC

Minimum Computer System Requirements

The computer and the peripheral equipment must conform to the IEC 60950 standard.

Item	Display and Acquisition
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 10 (64 bits)
USB 2.0	2 ports available
Ethernet	100 BaseT
CD/DVD drive	DVD-ROM drive is required to install the product.
Backup media	Removable/portable, external hard disk drive.

Imaging Performance Information

Imaging performance of RVG 142, RVG 5200 and RVG 6200 complies with the IEC 61223-3-4: 2000 standard.

Controlling the Image Quality

For optimum results, perform a control test of the image quality. To do this, see the ***User & Installation Guide***.

Environmental Requirements

Ambient Operating Conditions	
Temperatures	10 – 40 °C
Relative humidity	30 – 85%
Atmospheric pressure	700 – 1060 hpa
Altitude	Up to 3000 m

Storage Conditions	
Temperatures	-10 – 60 °C
Relative humidity	10 – 90%
Atmospheric pressure	700 – 1060 hpa

Transport Conditions	
Temperatures	-10 – 60 °C
Relative humidity	10 – 90%
Atmospheric pressure	700 – 1060 hpa

4 Contact Information

Manufacturer's Address

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

Factory

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For more information, visit: **www.carestreamdental.com**

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