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Virtua® and Virtua® XR

Medical Disc Publisher

EN - English

Documentation Notice

This document is part of the EU MDR requirements. The Codonics Virtua® Product(s) are Class I medical devices intended for use by Healthcare Professionals. Product packaging and labeling, including Graphic User Interface (GUI) for operation are offered in English and meet MDR, Annex I, Chapter III, 23.4, taking account the training and the knowledge of the potential user.

Web information, Key Specifications, Intended Use, User Manual Appendices, Quick Start Guide and Setup IFU (Instructions for use) are available in basic translation for Member State Languages. Primary IFU are available in English.

Overview

The Codonics Virtua Medical Disc Publisher offers exceptional speed, efficiency and ease of use in an automatic disc recorder. This innovative medical device is a DICOM-compliant network appliance that can concurrently record and label multiple medical studies onto CD and DVD media. Virtua's compact design features an advanced embedded processor, robotic disc handling and a user-friendly touch screen interface that optimizes workflow and productivity. The built-in printer produces brilliant, full-color disc labels that include patient demographics and the facility's address and logo for marketing. Customers can create their own custom labels or use Codonics disc label design service offered exclusively to our customers.

Specifications

Media Inputs: Two 50-disc input bins

Media Output: One 25-disc output bin

Optical Drives: Two CD/ DVD drives

Recordable Formats: CD-R, DVD-R

Label Print Technology: Inkjet

Print Resolution: Up to 4800 dpi

Ink Cartridge: One tri-color cartridge

User Interface: Integrated/detachable 15" LCD touch screen and remote web browser access

Performance:

Virtua: Up to 30 CDs per hour, 15 DVDs per hour (based on a typical clinical study and network configuration)

Virtua XR: Up to 62 CDs per hour, 31 DVDs per hour (based on a typical clinical study and network configuration)

Processor: Intel® Celeron® G3900

Memory: 4 GB

Data Storage: 120 GB

Interface: 10/100Base-T/Gigabit Ethernet (RJ-45)

Network Protocols:

DICOM Store SCP (up to 24 simultaneous connections)

DICOM query/retrieve (optional)

HTTP Web Server (for remote control and configuration)

Smart Drive: USB flash drive for storing configuration data

Power: Universal Input: 100-240VAC, 50/60 Hz, 300VA (rated power)

Dimensions: 26.7“ (67.8 cm) H, 19.2“ (48.6 cm) W, 26.7“ (67.8 cm) L

Weight: 60 lbs. (28 kg.)

Regulatory: Full medical device compliance including Class 2 FDA and Class 1 MDR 2017/745/EU (CE), GMP/QSR, ISO13485:2016/NS-EN ISO13485:2016, Electrical Safety IEC 60601-1 Ed. 3.1 and EMC/EMI: FCC Class B and IEC 60601-1-2: Ed. 4 for Professional Healthcare Facilities.

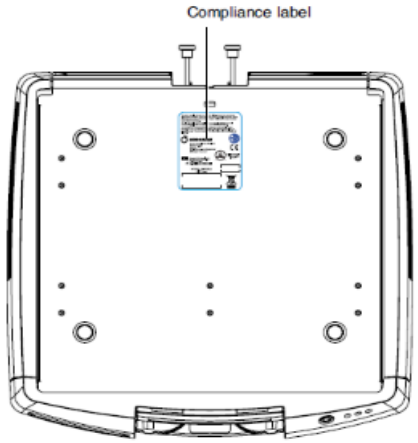
Product Information

For technical assistance with the Virtua, call Codonics Technical Support at the following number:
Phone: +1.440.243.1198
Toll Free: 800.444.1198 (USA only)
Technical Support is available anytime. Technical Support is also available online via email and the Codonics web site:
Email: support@codonics.com
Web Site: www.codonics.com
General product information can also be requested by sending email to:
Email: info@codonics.com
Please include your postal mailing address and telephone number in the email message. Basic product information is returned via email unless otherwise requested.

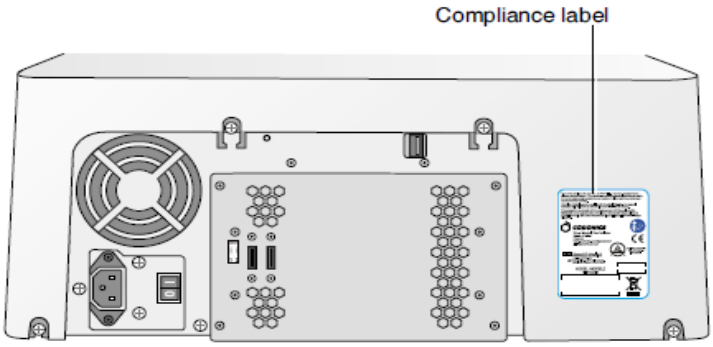
Warnings and Limitations of Use

Location of Safety and Compliance Labels

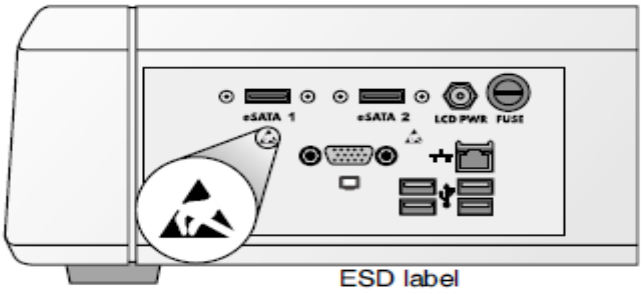
The following figures show the locations of the imager’s safety and compliance labels.



Location of compliance label at top of Controller



Location of compliance label at rear of Recorder



Location of ESD labels at rear of Controller (Display arm not attached)

Voltage Warning

The exclamation points within an equilateral triangle and person reading a manual symbol are intended to alert the user to the presence of important operating and maintenance (servicing) instructions in the literature accompanying this device.

NO USER-SERVICEABLE PARTS INSIDE. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.
REMOVAL OF LABELS, COVERS, OR ENCASEMENT FASTENERS VOIDS THE WARRANTY.
WARNING Do not modify this equipment without authorization of the manufacturer
THIS APPARATUS MUST BE ELECTRICALLY GROUNDED.
TO PREVENT FIRE OR SHOCK HAZARD, DO NOT EXPOSE THIS IMAGER TO RAIN OR MOISTURE.
WARNING The power cord plug is the main disconnect for the device. The power outlet should be near the device and be easily accessible.
WARNING Remove the power cord plug from the power outlet to disconnect overall power to the device.
WARNING Grounding reliability can be achieved only when this equipment is connected to an equivalent receptacle marked “Hospital Only” (that is, “Hospital Grade”).
WARNING To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
WARNING Do not touch a patient while also accessing Virtua internal components that are under the front cover.
EQUIPMENT IS NOT TO BE USED AS A COMPONENT OF A LIFE SUPPORT SYSTEM. Life support devices or systems are devices or systems that support or sustain life, and whose failure to perform can be reasonably

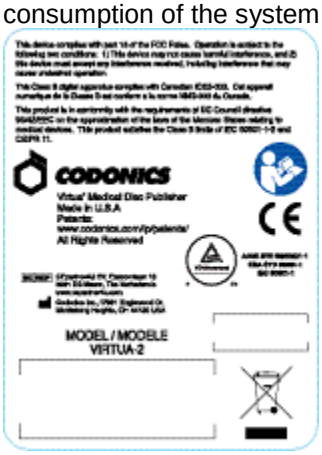
expected to result in a significant injury or death to a person. A critical component is any component of a life support device or system whose failure to perform can be reasonably expected to cause the failure of the life support device or system, or to affect its safety or effectiveness.

Laser Warning

The Codonics Virtua Medical Disc Publisher contains a laser diode in the Recorder unit of a class higher than 1. To ensure continued safety, do not remove any covers or attempt to gain access to the inside of the product. Refer all servicing to qualified personnel. The following label appears inside your unit:
CLASS 1 LASER PRODUCT LASER KLASSE 1

Compliance

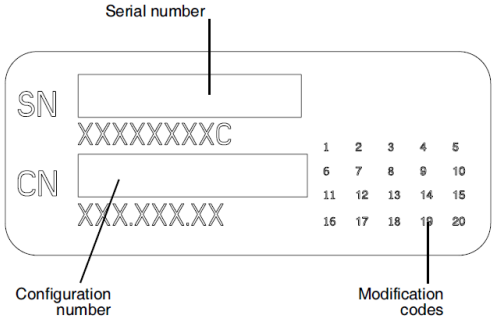
The Compliance label for the Virtua-2 model, which is affixed to the top of the Controller is shown below. The power consumption of the Controller and Recorder is indicated by the power switch of each device. The power consumption of the system is the combined consumption of the Controller and Recorder.



Compliance label for Virtua-2 model

Serial Number, Configuration, Date Code, and Modification Codes

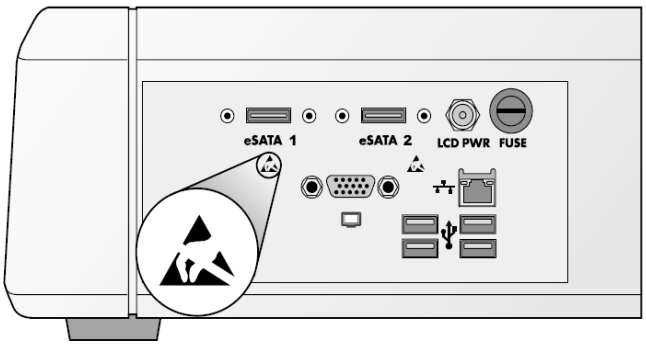
The serial number label is placed onto the compliance label. Serial number labels are also located at the front of the Recorder and Controller, behind the output bin.
The serial number label includes the following information:
The serial number (SN), which uniquely identifies the unit.
The configuration number (CN), which details the build configuration.
The modifications codes, which are to the right of the CN number and are a series of 20 numbers. When any of these numbers are blocked out, that identifies a modification that was made to the unit.
The date code in YYYY-MM format below the factory date code symbol.



Serial number label

ESD Caution

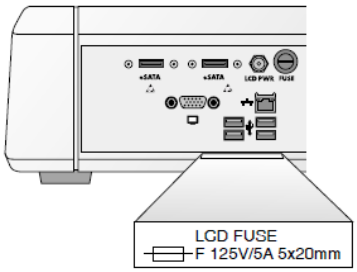
Connections to other pieces of equipment are made at the rear of the Codonics Virtua Medical Disc Publisher. These connectors are marked with a precautionary ESD warning symbol, as shown below. Do not touch any of the pins of these connectors. When making connections to the device, it is best done while the device is plugged in but not powered on. ESD may cause erratic behavior of the device when powered on. Should this occur, power to the device may have to be cycled. It is recommended that all staff involved in making connections to the device be aware of these ESD precautions.



ESD labels at rear of Controller

Fuse Label

The fuse label is located beneath the Controller rear connector panel.



Fuse label at rear of Controller

Potential for Radio Frequency Interference on Device Operation

Both portable and mobile RF communications equipment can affect medical electrical equipment, including the Codonics Virtua Medical Disc Publisher. Keep such RF communications equipment out of the immediate area.

Potential for Radio and Television Interference

The Codonics Virtua Medical Disc Publisher generates and uses radio frequency energy, and if not installed and used properly, that is, in strict accordance with the manufacturer's instructions, may cause interference to radio and television reception. Do not change the Display refresh rate, which is set for 75 Hz. The device has been type tested and found to comply with Class B emission limits for a computing device in accordance with the specifications in Subpart J of Part 15 of FCC Rules, which are designed to provide reasonable protection against such interference when operating in a commercial environment. Operation of the equipment in a residential area

is likely to cause interference, in which case the user, at his own expense, will be required to take whatever measures may be appropriate to correct the interference. If your device does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:
The main difference between this document and the last was that all bulleted lists have had the "List Bullet" style applied. This is different than the "List Paragraph" style that is applied by default. With this change bulleted lists are copied over properly.
Reorient the receiving antenna

Relocate the device with respect to the receiver

If necessary, you should consult Codonics Technical Support or an experienced radio/television technician for additional suggestions. You may find the following booklet prepared by the Federal Communications Commission helpful: How to Identify and Resolve Radio-TV Interference Problems. This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402, Stock No. 004-000-00345-4.
This product is in conformity with the protection requirements of EC Council directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility. This product satisfies the Class B limits of EN55011. A declaration of conformity with the requirements of the Directive has been signed by the Director of Quality Assurance and Regulatory Affairs.

Guidance Regarding Electromagnetic Emissions and Immunity

Suitable Environments:
The Codonics Virtua Medical Disc Publisher is intended for use in professional healthcare facility environments, including hospitals and medical clinics.

The Codonics Virtua Medical Disc Publisher has not been evaluated for use near HF surgical equipment. If use near HF surgical equipment is desired, the user is responsible for verifying proper operation of the Virtua. If Virtua does not perform correctly in this environment, move the Virtua farther from the source of the electromagnetic disturbance.

The Codonics Virtua Medical Disc Publisher has not been evaluated for use in emergency medical vehicles.

As a support device, the Codonics Virtua Medical Disc Publisher does not provide essential performance.
WARNING Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally
WARNING Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
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 Virtua, its cables, or accessories. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Emissions Standards and Test Levels:

Test / Standard	Compliance Level
RF Emissions CISPR 11	Group 1, Class B
RF Emissions FCC Part 15	Class B
Conducted Emissions CISPR 11	Group 1, Class B
Harmonic Distortion IEC 61000-3-2	Class B
Voltage Fluctuations and Flicker IEC 61000-3-3	Complies

Electromagnetic Immunity Standards and Test Levels:

Test / Standard	Compliance Level
Electrostatic Discharge IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF Immunity IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless equipment IEC 61000-4-3	Complies
Electrical Fast Transient / Burst IEC 61000-4-4	AC Port: ± 2 kV, 100 kHz repetition frequency SIP/SOP Ports: ± 1 kV, 100 kHz repetition frequency
Surge IEC 61000-4-5	Line-to-Line: ± 0.5 kV, ± 1.0 kV Line-to-Ground: ± 0.5 kV, ± 1.0 kV, ± 2.0 kV
Conducted Immunity IEC 61000-4-6	AC Port and SIP/SOPs: 3V, 0.15 MHz - 80 MHz 6V, in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Magnetic Field Immunity IEC 61000-4-8	30 A/m, 50 Hz or 60 Hz
Voltage Dips IEC 61000-4-11	0% U_T, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T, 1 cycle AND 70% U_T, 25/30 cycles, Single phase: at 0°
Voltage Interruptions IEC 61000-4-11	0% U_T, 250/300 cycle

Safety Precautions

Never connect this device to any outlet or power supply that has a voltage or frequency different than that specified and set on the rear of the device.

When servicing the device, always power it off using the green soft power button on the Controller front panel, turn the hard power switches at the rear of the Controller and Recorder to the 0 (off) position, then unplug the device.

Damage to the power cord may cause fire or shock hazard. When unplugging the power cord, hold it by the plug only and remove the plug carefully.

If the power cord needs to be replaced, replace it only with another Codonics power cord manufactured specifically for your power configuration.

If the device is smoking or making unusual sounds, power off and unplug the device immediately.

Do not insert foreign objects of any kind into the device; doing so can constitute a safety hazard and cause extensive damage.

Do not place any liquid containers on the device. If, for some reason, liquid seeps into the device, power off the device and unplug the power cord from the source outlet. If used without corrective measures, the device may be damaged.

Do not use the device near flammable gases.

Location Precautions

The device's operating ambient temperature range is 15–30ºC (59–86ºF), with a relative humidity of 20%–80%.

If the device is moved quickly from an extremely cold place to a warmer one, condensation is likely to form. Do not use the device if condensation has formed. Wait until the condensation has evaporated. You can speed up the evaporation time by moving the device to a drier location.

Ventilation slots and holes are provided on the sides and rear of the device. Place the device on a level, stable surface and locate it at least 10 cm (4 in.) from walls to ensure proper ventilation.
WARNING: Adequate ventilation is required for proper operation of the device.

Do not place device in a high humidity or high dust area. Airborne dirt particles can cause interference with the operation of the device. Avoid placing the device in areas where ventilation ducts, open doors, or frequent passers-by might expose the device and media to high levels of debris.

Do not locate the device in hot-springs areas where hydrogen sulfide and acidic ions are likely to be generated.

Do not locate the device where there are oily fumes and vapors.

Do not locate the device in direct sunlight.

Do not locate device near sources of high RF energy.

Do not locate the device where it might be subject to jarring or vibrations, such as a table or desk in a high-traffic area. Jarring and vibrations can affect the recording and labeling of discs.

Cleaning Precautions

Many plastic components are used in the device's construction. Coat flecking and deformation is likely to occur if the device is wiped with chemical dusters, benzene, thinners, insecticides, or other solvents. Rubber and PVC

materials left in contact with the device for extended times will cause damage. Never use petroleum-based solutions or abrasive cleaners."

To clean the device cover, first power off the device using the green soft power button on the Controller front panel, turn the hard power switches at the rear of the Controller and Recorder to the 0 (off) position, then unplug the device. Clean the cover with a soft cloth slightly moistened with a mild soap and water solution. Allow the cover to completely dry before operating the device again.

To clean the Display's touch screen, use a mild soap and water mixture. Always apply the soap and water mixture to a clean cloth or towel first and then clean the screen. Liquid applied directly to the Display could possibly leak inside the device and cause damage.

Do not use alcohol. The touch screen can be damaged if cleaned with alcohol.

Media Precautions

Discs with the word "reject" or a reject icon printed on the label have failed to record properly and should be destroyed or disposed of to ensure the confidentiality of patient medical information.

Unwanted discs should be destroyed or disposed of to ensure the confidentiality of patient medical information.

Only use Codonics-recommended discs to ensure compatibility with the recording and labeling system of the device. Contact Codonics Customer Service for a current list of recommended discs and suppliers.

Only use Codonics-recommended ink cartridges to ensure proper operation of the device and proper labeling of the disc. Contact Codonics Customer Service for a current list of recommended ink cartridges and suppliers.

Never refill ink cartridges as this can cause damage to the mechanism of the device and cause improper labeling of discs.

Recorded discs should be stored in protective cases or sleeves when not in use to protect from scratches and contamination that can interfere with data retrieval and label legibility.

Do not subject recorded discs to prolonged exposure to sunlight, ultraviolet light, or extreme heat as this can interfere with data retrieval and label legibility.

Codonics Virtua Medical Image Viewer

The Codonics Virtua Medical Image Viewer is not intended for diagnostic use. The viewer is provided for reference use only as a post-diagnostic tool.

Image quality can vary greatly from system to system based on the age, quality, and resolution of the display device (monitor or LCD display), graphics card, cabling, and ambient light conditions.

Medical and Patient Information

Virtua log files might contain patient information. Use caution when distributing log files.

CD and DVD media are not intended to be used as the only method for archiving medical information. An overall strategy for archiving medical information that includes CD or DVD media must ensure that multiple copies of the information be stored at multiple locations. Media quality, handling, and storage conditions are important factors that must be considered.

Disposal Requirements

Disposal of this product and consumables shall be in accordance with all applicable laws and regulations in effect at the locality at the time of disposal. For additional information, refer to Appendix A of the User's Manual, Hazardous Material Information.

European Disposal Requirements

Codonics imagers and electronic accessory devices are not to be discarded or recycled; rather they are to be returned to the manufacturer. Contact Codonics directly or by the link provided for the latest information concerning:
Identification of the country specific Importer/Distributor/Producer

Product return and treatment of our electronic products

Manufacturer: Codonics Incorporated
17991 Englewood Drive
Middleburg Heights, OH 44130 USA
Phone: +1.440.243.1198
Fax: +1.440.243.1334
Email: WEEE@codonics.com
www.codonics.com

Codonics imagers and electronic accessory devices bearing the following symbol are subject to European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, amended by Directive 2003/108/EC. The EN 50419 symbol indicates separate collection and return required.

EN 50419 symbol

Indications for Use

Virtua Series devices are intended for digital medical image communication, processing, and storage. Functions include transfer, "viewing client on CD/DVD" provision, storage, archive, recording, and labeling of CD/DVD media. When configured, the ability to re-direct all or part of a radiographic study to Codonics Horizon Series

Medical Hardcopy Dry Imagers (Pre-market notification K021054) or other approved 892.2040 medical hardcopy imager/printer is provided. Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians.

Additional Warnings

WARNING The shipping cartons are heavy. To avoid injury, use two people to unpack and position the components.
WARNING When removing the Recorder, hold under the front and rear of the device. Do not lift device by the foam packaging.
WARNING Before placing the Recorder on top of the Controller, make sure your fingers are not under the Recorder to avoid pinching them.
WARNING Make sure that the voltage supply selection switches are set to the appropriate voltage for the applicable country.
WARNING To avoid damaging the Display screen, keep the protective cover in place until assembly is complete.
WARNING The power cord plug is the main disconnect for the device. The power outlet should be near the device and be easily accessible.
WARNING Remove the power cord plug from the power outlet to disconnect overall power to the device.
WARNING Grounding reliability can be achieved only when the equipment is connected to an equivalent receptacle marked “Hospital Only” (that is, “Hospital Grade”).
WARNING To avoid risk of electrical shock, this equipment must only be connected to a supply main with protective earth.
WARNING Before powering on the unit, make sure that the Recorder’s pick arm is not holding a disc. If it is, remove the disc.
WARNING Do not touch the copper area of the cartridge print head.
WARNING The SmartDrive must be inserted for the device to operate. If the SmartDrive is not inserted, the device can boot up but will not be able to process jobs. A message at the Display will prompt you to insert the SmartDrive.
WARNING Discs that fail to record properly are either labeled with the word “Reject” or not labeled at all. These discs should be destroyed to protect the confidentiality of patient data.
WARNING Discs that fail to record properly are either labeled with the word “Reject” or not labeled at all. These discs should be destroyed to protect the confidentiality of patient data.
WARNING Deleting a job that is in-progress can result in a disc that is either labeled with the word “Reject” or not labeled at all. These discs should be destroyed to protect the confidentiality of patient data.
WARNING Virtua log files might contain patient information. Use caution when distributing log files.
WARNING Always power off the device and disconnect the device’s power cords before cleaning. Resume operation only after the surfaces are completely dry.
WARNING Run the Robotic Arm Calibration utility only when requested by Codonics Technical Support personnel.
WARNING Initiate a remote access connection to Codonics only when requested by Codonics Technical Support personnel.
WARNING System logs do not have the same user interface appearance and behavior as other screens. These logs should not be accessed unless requested by Codonics Technical Support personnel.
WARNING Virtua log files might contain patient information. Use caution when distributing log files.
WARNING This device contains lead. Disposal of lead may be regulated due to environmental considerations. For disposal or recycling information, please contact your local authorities or the Electronics Industry Alliance ().