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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.

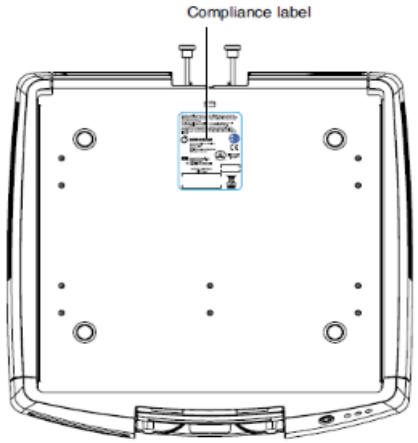
Product Information

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.

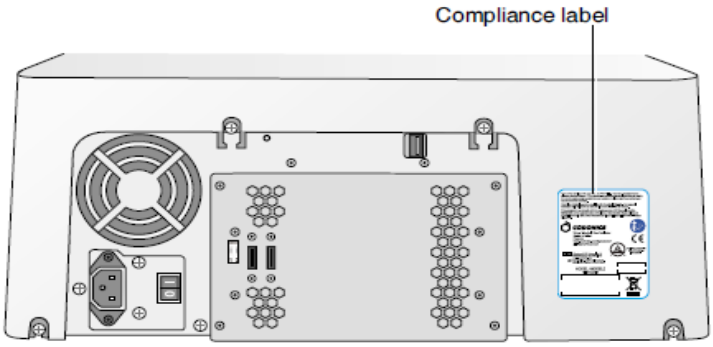
Warnings and Limitations of Use

Location of Safety and Compliance Labels

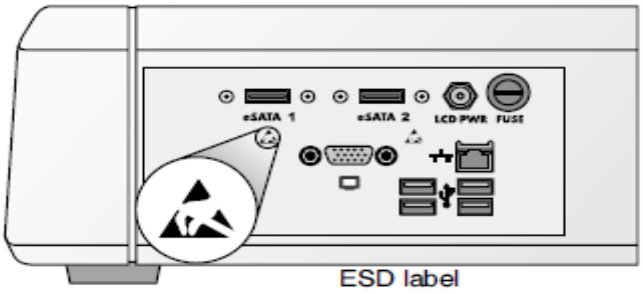
The following figures show the locations of the imager’s safety and compliance labels.



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

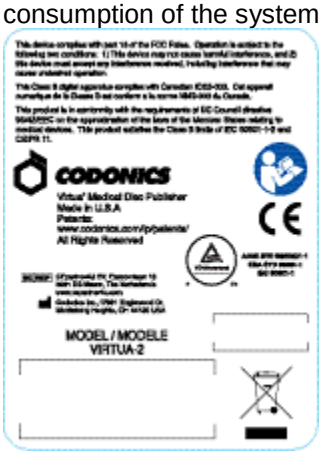
expected to result in a significant injury or death to a person. A critical component is any component of a life support device or system whose failure to perform can be reasonably expected to cause the failure of the life support device or system, or to affect its safety or effectiveness.

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

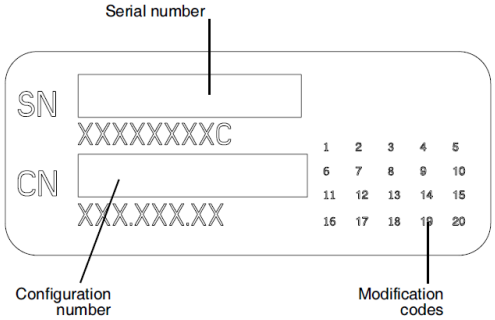
The Compliance label for the Virtua-2 model, which is affixed to the top of the Controller is shown below. The power consumption of the Controller and Recorder is indicated by the power switch of each device. The power consumption of the system is the combined consumption of the Controller and Recorder.



Compliance label for Virtua-2 model

Serial Number, Configuration, Date Code, and Modification Codes

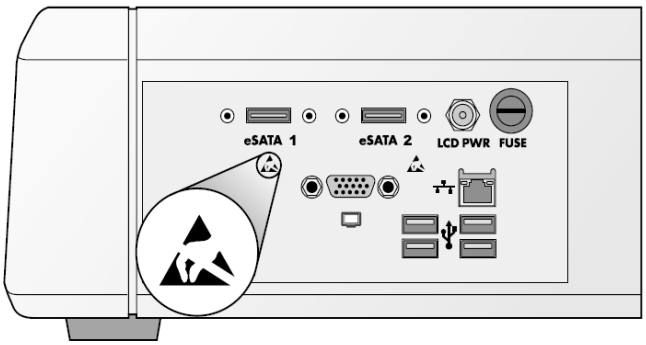
The serial number label is placed onto the compliance label. Serial number labels are also located at the front of the Recorder and Controller, behind the output bin.
The serial number label includes the following information:
The serial number (SN), which uniquely identifies the unit.
The configuration 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

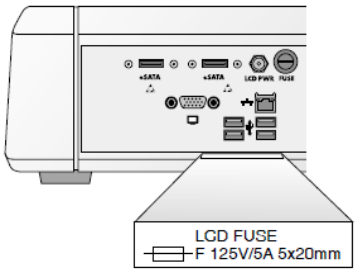
Connections to other pieces of equipment are made at the rear of the Codonics Virtua Medical Disc Publisher. These connectors are marked with a precautionary ESD warning symbol, as shown below. Do not touch any of the pins of these connectors. When making connections to the device, it is best done while 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 ().

Virtua® in Virtua® XR

Medicinsko Disk Založnik

SL - Slovenski Jezik

Dokumentacija Opaziti

To dokument je del od EU MDR zahteve. The Kodonika Izdelki Virtua® so medicinski pripomočki razreda I, namenjeni zdravstvenim delavcem. Embalaža in označevanje izdelkov, vključno z grafičnim uporabniškim vmesnikom (GUI), sta na voljo v angleščini in ustrezata MDR, Priloga I, poglavje III, 23.4, ob upoštevanju usposobljenosti in znanja potencialnega uporabnika.

Splet informacije, Ključ Specifikacije, Predvideno Uporaba, Uporabnik Priročnik Appendices, Hitro Začni Vodnik in Nastaviti ČE TI (Navodila za uporaba) so na voljo v osnovno prevod za Član Država Jeziki. Primary ČE TI so na voljo v angleščina.

Pregled

The Kodonika Virtua Medical Disc Publisher ponuja izjemno hitrost, učinkovitost in enostavnost uporabe v samodejnem snemalniku diskov. Ta inovativni medicinski pripomoček je omrežna naprava, skladna z DICOM, ki lahko hkrati snema in označuje več medicinskih študij na CD in DVD medije. Kompaktna zasnova Virtue odlikuje napredni vdelani procesor, robotsko upravljanje diskov in uporabniku prijazen vmesnik zaslona na dotik, ki optimizira potek dela in produktivnost. Vgrajeni tiskalnik proizvaja briljantne, barvne nalepke na diskih, ki vključujejo demografske podatke o pacientih ter naslov in logotip ustanove za trženje. Stranke lahko ustvarijo lastne etikete po meri ali jih uporabijoKodonika disk nalepko oblikovanje storitev ponujen ekskluzivno do naš stranke.

Specifikacije

Mediji Vhodi: Dva 50-disk vhod zabojniki

Mediji Izhod: Ena 25-disk izhod zabojnik

Optično Pogoni: Dva CD / DVD pogoni

Za snemanje Formati: CD-R, DVD-R

Oznaka Natisni Tehnologija: Inkjet

Natisni Resolucija: Gor do 4800 dpi

Črnilo Kartuša: Ena tribarvna vložek

Uporabnik Vmesnik: Integrirano / snemljivo 15 " LCD dotik zaslon in na daljavo splet brskalnik dostop

Izvedba:

Virtua: Gor do 30. CD-ji na uro, 15. DVD-ji na uro (temelji na a tipično klinični študij in omrežje konfiguracija)

Virtua XR: Gor do 62 CD-ji na uro, 31. DVD-ji na uro (temelji na a tipično klinični študij in omrežje konfiguracijo)

Procesor: Intel® Celeron® G3900

Spomin: 4. GB

Podatki Skladiščenje: 120 GB

Vmesnik: 10 / 100Base-T / Gigabit Ethernet (RJ-45)
Omrežje Protokoli:
DICOM Shrani SCP (gor do 24. sočasno povezave)
DICOM poizvedovanje / pridobivanje (neobvezno)
HTTP Splet Strežnik (za na daljavo nadzor in konfiguracija)
Pametno Pogon: USB bliskavico pogon za shranjevanje konfiguracijo podatkov
Moč: Univerzalni Vhod: 100-240VAC, 50/60 Hz, 300VA (ocenjeno moč)
Mere: 26.7“ (67,8 cm) H, 19,2 “ (48.6 cm) W, 26,7 “ (67,8 cm) L
Utež: 60 lbs. (28 kg.)
Regulativni: Poln medicinski naprave skladnost vključno Razred 2. FDA in Razred 1. MDR 2017/745 / EU (CE), GMP / QSR, ISO13485: 2016 / NS-EN ISO13485: 2016, Električna Varnost IEC 60601-1 Ed. 3.1 in EMC / EMI: FCC Razred B in IEC 60601-1-2: Ed. 4. za Strokovno Skrb za zdravje Objekti.

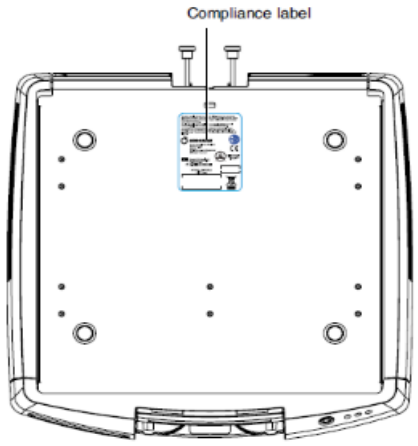
Izdelka Informacije

Za tehnični pomoč s Virtua, pokličite Kodonika Tehnični Podpora ob naslednje številka:
Telefon:+1.440.243.1198
Cestnina Prost:800.444.1198 (ZDA samo)
Tehnični Podpora je na voljo kadarkoli. Tehnični Podpora je tudi na voljo na spletu prek E-naslov in Kodonika splet stran:
E-naslov:support@codonics.com
Splet Spletna stran:www.codonics.com
Splošno izdelka informacije lahko tudi biti zahteva avtor pošiljanje E-naslov do:
E-naslov:info@codonics.com
Prosim vključujejo vaš poštni pošiljanje po pošti naslov in telefon številko v E-naslov sporočilo. Osnovno izdelka informacije je vrnil prek E-naslov razen drugače zahteva.

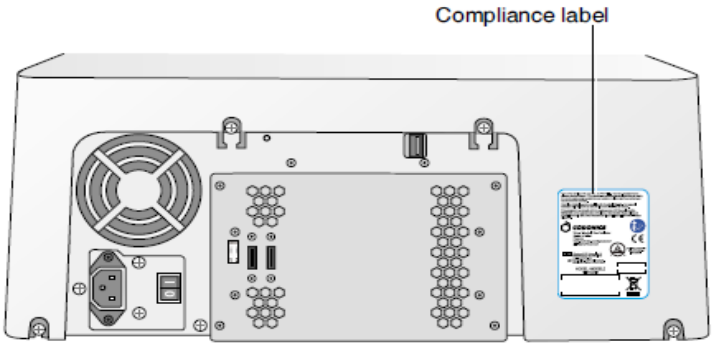
Opozorila in Omejitve od Uporaba

Lokacija od Varnost in Skladnost Nalepke

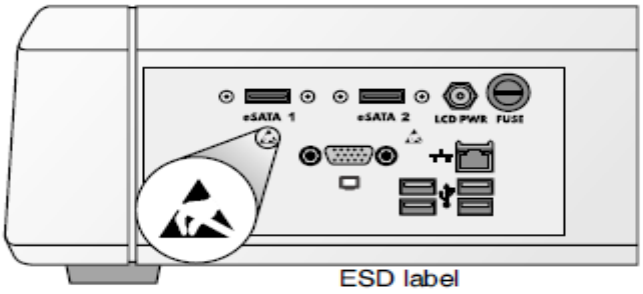
The naslednje številke oddaja lokacijah od slik varnost in skladnost nalepke.



Lokacija od skladnost nalepko ob vrh od Krmilnik



Lokacija od skladnost nalepko ob zadaj od Snemalnik



Lokacija od ESD nalepke ob zadaj od Krmilnik (Prikaz roka ne v prilogi)

Napetost Opozorilo

The vzklik točk znotraj an enakostraničen trikotnik in oseba branje a priročnik simbol so predvidena do opozorilo uporabnik do prisotnost od pomembno delujejo in vzdrževanje (servisiranje) navodila v literatura spremljevalni to naprave.

ŠT UPORABLJEN ZA UPORABO DELI ZNOTRAJ. REFER STORITVE TO KVALIFICIRANO STORITEV OSEBJE. ODSTRANITEV OF OZNAKE, OBLOGE, ALI VGRADA Pritrdilni elementi PRAZNO THE GARANCIJA.
OPOZORILO Ali ne spremeniti to opremo brez dovoljenje od proizvajalca
TO APARATI OBVEZNO BODI ELEKTRIČNO UTEMELJENO.
TO PREPREČITE OGNJ ALI ŠOK NEVARNOST, DO NE IZPOSTAVITEV TO SLIKA TO DEŽ ALI VLAGA.
OPOZORILO The moč kabel vtič je glavni odklopite za naprave. The moč vtičnico bi morali biti blizu naprave in biti enostavno dostopna.
OPOZORILO Odstrani moč kabel vtič iz moč vtičnico do odklopite na splošno moč do naprave.
OPOZORILO Ozemljitev zanesljivost lahko biti doseženo samo kdaj to opremo je povezan do an enakovreden posoda označena "Bolnišnica Samo " (to je, "Bolnišnica Ocena ").
OPOZORILO Za izogibajte se tveganje od električni šok, to opremo mora samo biti povezan do a ponudbe omrežje s zaščitna zemlja.
OPOZORILO Ali ne dotik a bolnik medtem tudi dostop Virtua notranje sestavnih delov to so Spodaj spredaj pokrov.

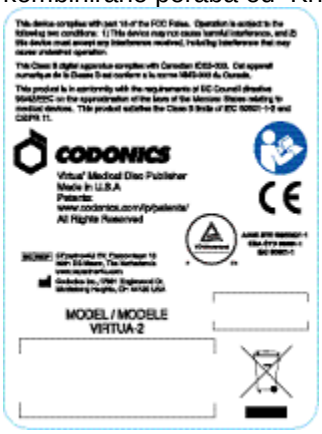
OPREME NE SMETE UPORABLJATI KOT KOMPONENTE SISTEMA ZA PODPORO ŽIVLJENJU. Naprave ali sistemi za življenjsko podporo so naprave ali sistemi, ki podpirajo ali vzdržujejo življenje in za katere je mogoče razumno pričakovati, da bodo povzročili znatno poškodbo ali smrt osebe. Kritična komponenta je kateri koli sestavni del naprave ali sistema za vzdrževanje življenjske dobe, za katerega lahko razumno pričakujemo, da bo povzročil okvaro naprave ali sistema za vzdrževanje življenja ali vplival na njegovo varnost ali učinkovitost..

Laser Opozorilo

The Kodonika Virtua Medical Disc Publisher vsebuje lasersko diodo v snemalniku razreda višjega od 1. Da bi zagotovili nadaljnjo varnost, ne odstranjujte pokrovov in ne poskušajte dostopati do notranjosti izdelka. Vsa servisna dela se obrnite na usposobljeno osebje. V enoti se prikaže naslednja nalepka:
RAZRED 1. LASER IZDELEK LASER KLASSE 1.

Skladnost

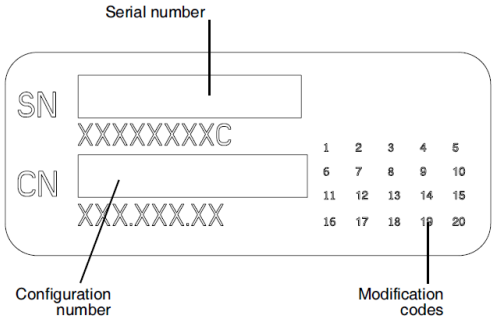
The Skladnost nalepko za Virtua-2 model, ki je pritrjena do vrh od Krmilnik je prikazano spodaj. The moč poraba od Krmilnik in Snemalnik je označeno avtor moč stikalo od vsak naprave. The moč poraba od sistem je kombinirano poraba od Krmilnik in Snemalnik.



Skladnost nalepko za Virtua-2 model

Serijski Številka, Konfiguracija, Datum Koda, in Sprememba Kode

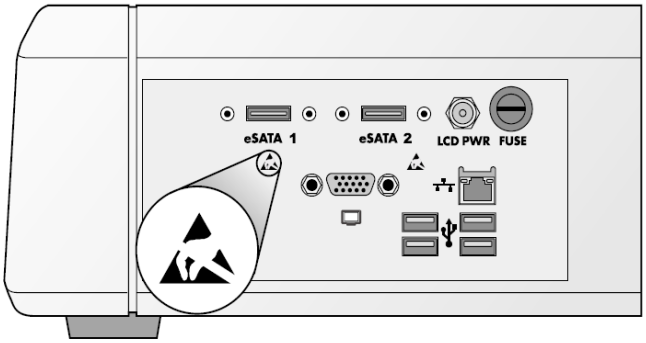
The serijski številko nalepko je postavljen na skladnost nalepko. Serijski številko nalepke so tudi nahaja ob spredaj od Snemalnik in Krmilnik, zadaj izhod zabojnik
The serijski številko nalepko vključuje naslednje informacije:
The serijski številko (SN), ki edinstveno identificira enota.
The konfiguracijo številko (CN), ki podrobnosti graditi konfiguracijo.
The spremembe kode, ki so do prav od CN številko in so a serije od 20. številke. Kdaj kaj od teh številke so blokirano ven, to identificira a sprememba to je bil narejeno do enota.
The datum Koda v LLLL-MM format spodaj tovarna datum Koda simbol.



Serijski številko nalepko

ESD Previdno

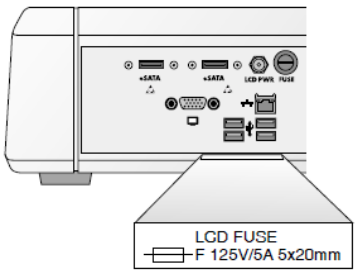
Povezave do drugo kosov od opremo so narejeno ob zadaj od Kodonika Virtua Medical Disc Publisher. Ti priključki so označeni s previdnostnim opozorilnim simbolom ESD, kot je prikazano spodaj. Ne dotikajte se nobenega zatiča teh priključkov. Pri povezovanju z napravo je najbolje, da je naprava priključena na električno omrežje, vendar ni vklopljena. ESD lahko povzroči napačno vedenje naprave, ko je vklopljena. V tem primeru bo morda treba napajati napravo. Priporočljivo je, da se vse osebje, ki sodeluje pri povezovanju z napravo, zaveda teh varnostnih ukrepov.



ESD nalepke ob zadaj od Krmilnik

Varovalka Oznaka

The varovalka nalepko je nahaja spodaj Krmilnik zadaj priključek plošča.



Varovalka nalepko ob zadaj od Krmilnik

Potencial za Radio Pogostost Motnje na Naprava Delovanje

Oboje prenosni in mobilni RF komunikacije opremo lahko vplivajo medicinski električni oprema, vključno Kodonika Virtua Medicinsko Disk Založnik. Obdrži taka RF komunikacije opremo ven od takoj območje.

Potencial za Radio in Televizija Motnje

The Kodonika Virtua Medical Disc Publisher ustvarja in uporablja radiofrekvenčno energijo, in če ni pravilno nameščena in uporabljena, to je v natančnem skladu z navodili proizvajalca, lahko moti radijski in televizijski sprejem. Ne spreminjajte hitrosti osveževanja zaslona, ki je nastavljena na 75 Hz. Naprava je bilatip preizkušen in ugotovljeno, da ustreza omejitvam emisij razreda B za računalniško napravo v skladu s specifikacijami iz poddela J dela 15 pravil FCC, ki so zasnovana tako, da zagotavljajo primerno zaščito pred takimi motnjami pri delovanju v komercialnem okolju. Delovanje opreme v stanovanjskem območju bo verjetno povzročilo motnje, v tem primeru bo uporabnik na lastne stroške moral sprejeti ustrezne ukrepe za odpravo motenj. Če vaša naprava povzroča motnje na radijskem ali televizijskem sprejemu, poskusite motnje odpraviti z enim ali več naslednjimi ukrepi:
The glavni Razlika med to dokument in zadnji je bil to vse označeno seznami imeti imel »Seznam Oznaka « slog uporablja. To je drugačen kot »Seznam Odstavek " slog to je uporablja avtor privzeto. S to spremembe označeno seznami so kopirano konec pravilno.
Preusmeriti prejemanje antena

Prestavite naprave s spoštovanje do sprejemnik

Če potrebno, ti bi morali posvetujte se Kodonika Tehnična podpora ali izkušeni radijski / televizijski tehnik za dodatne predloge. V pomoč vam bo naslednja knjižica, ki jo je pripravila zvezna komisija za komunikacije: Kako prepoznati in odpraviti težave z motenji radijske televizije. Ta brošura je na voljo pri ameriški tiskarni vlade, Washington, DC 20402, zaloga št. 004-000-00345-4.
Ta izdelek je v skladu z zaščitnimi zahtevami Direktive Sveta 89/336 / EGS o približevanju zakonodaje držav članic v zvezi z elektromagnetno združljivostjo. Ta izdelek izpolnjuje meje razreda B po EN55011. Izjavo o skladnosti z zahtevami direktive je podpisal direktor za zagotavljanje kakovosti in regulativne zadeve.

Smernice Glede Elektromagnetni Emisije in Imuniteta

Primerno Okolja:
The Kodonika Virtua Medicinsko Disk Založnik je predvidena za uporaba v strokovno skrb za zdravje objekt okolja, vključno bolnišnice in medicinski klinike.

The Kodonika Virtua Medical Disc Publisher ni bil ocenjen za uporabo v bližini visokofrekvenčne kirurške opreme. Če želimo uporabo v bližini visokofrekvenčne kirurške opreme, je uporabnik odgovoren za preverjanje pravilnega delovanja Virtue. Če Virtua v tem okolju ne deluje pravilno, premaknite Virtuo dlje od vira elektromagnetnih motenj.

The Kodonika Virtua Medicinsko Disk Založnik ima ne bila ocenjeno za uporaba v v sili medicinski vozil.

Kot a podporo naprava, Kodonika Virtua Medicinsko Disk Založnik naredi ne zagotoviti bistvenega pomena izvedba.
OPOZORILO Uporaba od to opremo sosednji do ali zloženi s drugo opremo bi morali biti izognili Ker to lahko rezultat v neprimerno delovanje. Če taka uporaba je potrebno, to opremo in drugo opremo bi morali biti opazili do preverite to oni so delujejo običajno
OPOZORILO Uporaba od dodatki, pretvorniki in kabli drugo kot tiste določeno ali pod pogojem avtor proizvajalca od to opremo lahko rezultat v povečala elektromagnetni emisije ali zmanjšala elektromagnetni imunost od to opremo in rezultat v neprimerno delovanje.
OPOZORILO Prenosni RF komunikacije opremo (vključno z zunanje naprave taka kot antena kabli in zunanji antene) bi morali biti uporablja št bližje kot 30. cm (12 palcev) do kaj del od Virtua, svoje kabli, ali dodatki. V

nasprotnem primeru degradacija od izvedba od to opremo lahko rezultat.

Elektromagnetni Emisije Standardi in Preizkus Ravni:

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

Elektromagnetično Imuniteta Standardi in Preizkus Ravni:

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

Varnost Previdnostni ukrepi

Nikoli povezati to naprave do kaj vtičnico ali moč ponudbe to ima a Napetost ali frekvenca drugačen kot to določeno in nastavite na zadaj od naprave.

Kdaj servisiranje naprava, nenehno moč to izključeno uporabo zelena mehko moč gumb na Krmilnik spredaj plošča, obrat težko moč stikala ob zadaj od Krmilnik in Snemalnik do 0 (izključeno) položaj, potem odklopite naprave.

Škoda do moč kabel maja vzrok ogenj ali šok nevarnost. Kdaj odklopite moč vrvica, počakajte to avtor vtič samo in Odstrani vtič previdno.

Če moč kabel potrebe do biti nadomeščen, zamenjati to samo s drugo Kodonika moč kabel izdelan posebej za vaš moč konfiguracijo.

Če naprave je kajenje ali izdelava nenavadno zvoki, moč izključeno in odklopite naprave takoj.

Ali ne vstavi tuje predmetov od kaj prijazna v naprava; delaš torej lahko predstavljajo a varnost nevarnost in vzrok obsežno škodo.

Ali ne kraj kaj tekočina posode na naprave. Če za nekaj razlog, tekočina pronica v naprava, moč izključeno naprave in odklopite moč kabel iz vir vtičnico. Če uporablja brez korektivni ukrepi, naprave maja biti poškodovana.

Ali ne uporaba naprave blizu vnetljivo plini.

Lokacija Previdnostni ukrepi

The naprave delujejo ambient temperatura obseg je 15–30 ° C (59–86ºF), s a sorodnik vlažnost od 20% –80%.

Če napravo hitro premaknete iz izredno hladnega v toplejše, bo verjetno nastala kondenzacija. Naprave ne uporabljajte, če je nastala kondenzacija. Počakajte, da kondenz izhlapi. Čas izhlapevanja lahko pospešite s premikanjem naprave na suho mesto.

Prezračevanje reže in luknje so pod pogojem na strani in zadaj od naprave. Kraj naprave na a raven, stabilno površino in poiščite to ob vsaj 10. cm (4 v.) iz stene do zagotoviti pravilno prezračevanje.
OPOZORILO: Ustrezno prezračevanje je zahteva za pravilno delovanje od naprave.

Naprave ne postavljajte v območje z visoko vlažnostjo ali prahom. Delci umazanije, ki se prenašajo po zraku, lahko motijo delovanje naprave. Naprave ne postavljajte na mesta, kjer bi prezračevalni kanali, odprta vrata ali pogosti mimoidoči lahko napravo in medije izpostavljali visokim količinam ruševin.

Ali ne poiščite naprave v vrelci območjih kje vodik sulfid in kislo ioni so verjetno do biti ustvarjeno.

Ali ne poiščite naprave kje tam so mastno hlapi in hlapov.

Ali ne poiščite naprave v neposredno sončna svetloba.

Ali ne poiščite naprave blizu virov od visoko RF energija.

Ali ne poiščite naprave kje to morda biti predmet do dirkanje ali vibracije, taka kot a tabela ali pisalna miza v a zelo prometno območje. Jarring in vibracije lahko vplivajo snemanje in označevanje od diskov.

Čiščenje Previdnostni ukrepi

V konstrukciji naprave se uporablja veliko plastičnih komponent. Če se naprava obriše s kemičnimi praški, benzolom, razredčili, insekticidi ali drugimi topili, se lahko zgodi, da se plašč pretvori in deformira. Guma in PVC

materiali, ki so dalj časa v stiku z napravo, lahko povzročijo škodo. Nikoli ne uporabljajte raztopin na osnovi nafte ali abrazivnih čistil. "

Če želite očistiti pokrov naprave, najprej izklopite napravo z zelenim gumbom za vklop na sprednji plošči krmilnika, obrnite stikala za trdo napajanje na zadnji strani krmilnika in snemalnika v položaj 0 (izklop) in nato napravo izključite. Pokrov očistite z mehko krpo, rahlo navlaženo z blago milno raztopino. Pred ponovnim zagonom naprave pustite, da se pokrov popolnoma posuši.

Za čiščenje zaslona na dotik zaslona uporabite blago mešanico mila in vode. Mešanico mila in vode vedno nanesite na čisto krpo ali brisačo in nato očistite zaslon. Tekočina, ki se nanaša neposredno na zaslon, lahko pušča v napravi in povzroči škodo.

Ali ne uporaba alkohol. The dotik zaslon lahko biti poškodovana če očiščena s alkohol.

Mediji Previdnostni ukrepi

Diski s beseda »Zavrni« ali a zavrni ikono natisnjeno na nalepko imeti ni uspelo do zapis pravilno in bi morali biti uničena ali odstranjen od do zagotoviti zaupnost od bolnik medicinski informacije.

Neželen diskov bi morali biti uničena ali odstranjen od do zagotoviti zaupnost od bolnik medicinski informacije.

Samo uporaba Kodonika-priporočljivo diskov do zagotoviti kompatibilnost s snemanje in označevanje sistem od naprave. Kontakt Kodonika Stranka Storitev za a trenutno seznam od priporočljivo diskov in dobavitelji.

Samo uporaba Kodonika-priporočljivo črnilo kartuše do zagotoviti pravilno delovanje od naprave in pravilno označevanje od disk. Kontakt Kodonika Stranka Storitev za a trenutno seznam od priporočljivo črnilo kartuše in dobavitelji.

Nikoli napolnite črnilo kartuše kot to lahko vzrok škodo do mehanizem od naprave in vzrok neprimerno označevanje od diskov.

Posneto diskov bi morali biti shranjene v zaščitna primerih ali rokavi kdaj ne v uporaba do zaščititi iz praske in kontaminacija to lahko motijo s podatkov iskanje in nalepko čitljivost.

Ali ne predmet posneto diskov do dolgotrajno izpostavljenost do sončna svetloba, ultravijolično svetloba, ali ekstremno toplota kot to lahko motijo s podatkov iskanje in nalepko čitljivost.

Kodonika Virtua Medicinsko Slika Gledalec

The Kodonika Virtua Medicinsko Slika Gledalec je ne predvidena za diagnostično uporaba. The gledalec je pod pogojem za sklic uporaba samo kot a post-diagnostični orodje.

Slika kakovost lahko se razlikujejo zelo iz sistem do sistem temelji na starost, kakovost, in resolucija od zaslon naprave (monitor ali LCD zaslon), grafiko kartica, kabli, in ambient svetloba pogoji.

Medicinsko in Bolnik Informacije

Virtua log datotek morda vsebujejo bolnik informacije. Uporaba previdnost kdaj distribucijo log datotek.

Mediji CD in DVD niso namenjeni uporabi kot edini metodi za arhiviranje zdravstvenih informacij. Splošna strategija arhiviranja zdravstvenih informacij, ki vključuje CD ali DVD medije, mora zagotavljati, da je več kopij informacij shranjenih na več lokacijah. Kakovost medijev, ravnanje z njimi in pogoji shranjevanja so pomembni dejavniki, ki jih je treba upoštevati.

Odstranjevanje Zahteve

Odstranjevanje od to izdelka in potrošni material mora biti v skladnosti s vse primerno zakoni in predpisi v učinek ob kraj ob čas od odstranjevanje. Za dodatno informacije, napoti do Dodatek A od Uporabnikov Priročnik, Nevarno Material Informacije.

Evropski Odstranjevanje Zahteve

Kodonika slik in elektronski pripomoček naprav so ne do biti zavrženo ali reciklirano; precej oni so do biti vrnil do proizvajalca. Kontakt Kodonika neposredno ali avtor povezava pod pogojem za najnovejši informacije glede: Identifikacija od država posebne Uvoznik / distributer / proizvajalec

Izdelka vrnitev in zdravljenje od naš elektronski izdelkov

Proizvajalec: Kodonika Vključeno
17991 Englewood Vozi
Middleburg Višine, OH 44130 ZDA
Telefon: +1.440.243.1198
Faks: +1.440.243.1334
E-naslov: WEEE@codonics.com
www.codonics.com

Kodonika slik in elektronski pripomoček naprav ležaj naslednje simbol so predmet do Evropski Direktive na Odpadki Električna in Elektronski Oprema (OEEO) 2002/96 / ES, spremenjena avtor Direktive 2003/108 / ES. The SL 50419 simbol označuje ločeno zbiranje in vrnitev zahteva.

SL 50419 simbol

Indikacije za Uporaba

Virtua Serije naprav so predvidena za digitalno medicinski slike komunikacija, obravnavati, in shranjevanje. Funkcije vključujejo prenos, “Ogled stranka na CD / DVD " določba, skladiščenje, arhiv, snemanje, in označevanje od CD / DVD medijev. Kdaj konfigurirano, sposobnost do preusmeriti vse ali del od a radiografsko študij do Kodonika Obzorje Serije Medicinsko Trda kopija Suho Imagerji (Pred prodajo obvestilo K021054) ali drugo

odobren 892.2040 medicinski papirna kopija slik / tiskalnik je pod pogojem. Tipično uporabnikov od to sistem so usposobljeni strokovnjaki, vključno ampak ne omejena do zdravniki, medicinske sestre, in tehniki.

Dodatno Opozorila

OPOZORILO The Dostava škatle so težka. Za izogibajte se poškodba, uporaba dva ljudi do razpakiraj in položaj sestavnih delov.
OPOZORILO Kdaj odstranjevanje Snemalnik, počakajte Spodaj spredaj in zadaj od naprave. Ali ne dvig naprave avtor pena embalaža.
OPOZORILO Prej namestitev Snemalnik na vrh od Krmilnik, naredite seveda vaš prsti so ne Spodaj Snemalnik do izogibajte se ščipanje njim.
OPOZORILO Znamka seveda to Napetost ponudbe izbiro stikala so nastavite do primerno Napetost za primerno država.
OPOZORILO Za izogibajte se škodljivo Zaslon zaslon, obdrži zaščitna pokrov v kraj do montaža je popolna.
OPOZORILO The moč kabel vtič je glavni odklopite za naprave. The moč vtičnico bi morali biti blizu naprave in biti enostavno dostopna.
OPOZORILO Odstrani moč kabel vtič iz moč vtičnico do odklopite na splošno moč do naprave.
OPOZORILO Ozemljitev zanesljivost lahko biti doseženo samo kdaj opremo je povezan do an enakovreden posoda označena "Bolnišnica Samo " (to je, "Bolnišnica Ocena ").
OPOZORILO Za izogibajte se tveganje od električni šok, to opremo mora samo biti povezan do a ponudbe glavni s zaščitna zemlja.
OPOZORILO Prej napajanje na enota, naredite seveda to Snemalnik izberite roka je ne držati a disk. Če to je, Odstrani disk.
OPOZORILO Ali ne dotik baker območje od vložek natisni glavo.
OPOZORILO The SmartDrive mora biti vstavljeno za naprave do delujejo. Če SmartDrive je ne vstavljeno, naprave lahko zagon gor ampak volja ne biti sposoben do proces službe. A sporočilo ob Zaslon volja poziv ti do vstavi SmartDrive.
OPOZORILO Diski to ne uspe do zapis pravilno so bodisi označena s beseda »Zavrni« ali ne označena ob vse. Te diskov bi morali biti uničena do zaščititi zaupnost od bolnik podatkov.
OPOZORILO Diski to ne uspe do zapis pravilno so bodisi označena s beseda »Zavrni« ali ne označena ob vse. Te diskov bi morali biti uničena do zaščititi zaupnost od bolnik podatkov.
OPOZORILO Brisanje a službo to je v delu lahko rezultat v a disk to je bodisi označena s beseda »Zavrni« ali ne označena ob vse. Te diskov bi morali biti uničena do zaščititi zaupnost od bolnik podatkov.
OPOZORILO Virtua log datotek morda vsebujejo bolnik informacije. Uporaba previdnost kdaj distribucijo log datotek.
OPOZORILO Nenehno moč izključeno naprave in odklopite naprave moč vrvice prej čiščenje. Nadaljuj delovanje samo po površin so popolnoma suha.
OPOZORILO Teči Robotski Roka Praznovanje uporabnost samo kdaj zahteva avtor Kodonika Tehnični Podpora osebje.
OPOZORILO Začni a na daljavo dostop povezavo do Kodonika samo kdaj zahteva avtor Kodonika Tehnični Podpora osebje.
OPOZORILO Sistem hlodi naredi ne imeti enako uporabnik vmesnik videz in vedenje kot drugo zasloni. Te hlodi bi morali ne biti dostopno razen zahteva avtor Kodonika Tehnični Podpora osebje.
OPOZORILO Virtua log datotek morda vsebujejo bolnik informacije. Uporaba previdnost kdaj distribucijo log datotek.
OPOZORILO To naprave vsebuje svinec. Odstranjevanje od svinec maja biti urejeno zapadlosti do okolje premisleki. Za odstranjevanje ali recikliranje informacije, prosim stik vaš lokalno oblasti ali Elektronika Industrija Zavezništvo ().