

Table of Contents

EN - English	21
Documentation and Notice.....	21
Overview	21
Specifications	21
Product Information	24
Warnings and Limitations of Use	25
Location of Safety and Compliance Labels	25
Voltage Warning	25
Laser Warning	26
Temperature Warning	27
Compliance	27
Serial Number, Configuration, Date Code, and Modification Codes	27
ESD Caution.....	28
Potential for Radio Frequency Interference on Imager Operation.....	28
Potential for Radio and Television Interference	28
Guidance Regarding Electromagnetic Emissions and Immunity	29
Safety Precautions	31
Location Precautions.....	32
Cleaning Precautions.....	33
Media	33
Codonics Paper/White Film Media	34
File Transfer via FTP and LPR	34
Color Management	34
Image Scaling	34
Hardware Variations	34
Disposal Requirements	34
European Disposal Requirements.....	34
Indications for Use	35
User Manual Warnings and Cautions	36

Horizon® XL

Multi-media Imager

EN - English

Documentation and Notice

Codonics Products are Class I products intended for use by Healthcare Professionals.

Products 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 Appendix, Quick Start Guide & Setup IFU are available in simple translation Member State Languages; primary IFU are available in English.

Overview

The Horizon XL combines diagnostic film, color paper and grayscale paper printing in a versatile medical imager. Horizon XL features exclusive 36" and 51" dry long film ideal for long bone and scoliosis studies. A total CR/DR print solution, Horizon XL will reduce your costs, save you space, and completely eliminate your wet film processing needs. High speed image processing, networking and spooling are all standard.

Specifications

Print Technology: Dye-diffusion and direct thermal (dry, daylight safe operation)

Spatial Resolution: 320 DPI (12.6 pixels/mm)

Throughput: Up to 100 films per hour

Time To Operate: 5 minutes (ready to print from "off")

Grayscale Contrast Resolution: 12 bits (4096)

Color Resolution: 16.7 million colors

256 levels each of cyan, magenta, and yellow

Media Inputs: Three supply cassettes, 25-100 sheets each, one color ribbon

Media Outputs: Three receive trays, 50-sheet capacity each

Media Sizes: 8" x 10", 14" x 17" (blue and clear) DirectVista® Film

14" x 36", 14" x 51" (blue only) DirectVista® Film

A, A4, 14" x 17" DirectVista Grayscale Paper

A, A4 ChromaVista® Color Paper

Dmax: >3.0 with DirectVista Film

Archival: >20 years with DirectVista Film, under ANSI extended-term storage conditions

Media Supply: All media is pre-packaged and factory sealed

Interfaces: Standard: 10/100 Base-T Ethernet (RJ-45), Serial Diagnostic Port, Serial Console

Network Protocols: Standard: FTP, LPR

Optional: DICOM (up to 24 simultaneous connections), Windows network printing

Image Formats: Standard: TIFF, GIF, PCX, BMP, PGM, PNG, PPM, XWD, JPEG, SGI (RGB), Sun Raster, Targa

Optional: DICOM, PostScript™ compatibility

Image Quality: Automatic calibration using built-in densitometer

Image Control: Gamma, Contrast, Saturation, Medical Color Matching (MCM™), Polarity,

Rotation, Scaling, Antialiasing

Sheet Control: Density Adjustment (Dmax), Look-Up Tables (LUT), Image Warnings, Captions, Sheet Coverage, Border Color, Border Fill, Crop Anchor

Sheet Formatting: 1:1 - 1:81; Variable Multi-Formatting (VMF™), Fixed Multi-Formatting (FMF™)

Control Panel: Large, backlit LCD display, Status lights include Online, Alert, Fault, Active Power and Menu navigation buttons

Processor: Intel

Memory: 512MB RAM

Hard Disk: 80GB (60GB available for spooling)

Removable Disk: 100MB ZIP™ Disk for software upgrades

Smart Card: 72 KB for storing configuration data

Power: Universal Input: 100-120/230V~ 50/60 Hz, 600W printing, 150W idle

Heat Emission: Maximum 600W, 2,050 BTUs/hr. printing, 150W, 512 BTUs/hr. idle

Weight: 66 lbs. (30 kg.)

Engine Dimensions: 14.5" (37 cm) H, 20.5" (52 cm) W, 24" (61 cm) L

Environment: Operating Temperature: 15-30°C, Storage: -22.2 - 50.6°C, Operating Humidity: 10-70% R.H. (non-condensing)

Regulatory: Full medical device compliance including Class 2 FDA and Class I

MDR 2017/745/EU (CE), GMP/QSR, ISO 13485:2016/NS-EN

ISO 13485:2016, Electrical Safety IEC 60601-1 Ed. 3.1 and EMC/EMI:

FCC Class A and IEC 60601-1-2: Ed. 4 for Professional Healthcare Facilities

Conventions Used in the User Manual

Bulleted Lists

Bullets are used to display a list of nonprocedural items. For example:

The control panel contains:

- A display panel
- Keys
- Indicators

Numbered Steps

The  icon indicates the beginning of a procedure. The steps in a procedure are numbered. For example:

1. Press the MENU key.

The Main Menu displays on the control panel. The selector arrow (►) automatically points to the first menu option.

2. To scroll through the menu options, press the up and down keys.

The selector arrow (►) moves up and down through the list. The bottom portion of the control panel display shows a message associated with the currently selected menu option.

Control Panel Navigation

Menu paths are used in some procedures instead of documenting every step needed to navigate to a specific menu option. For example:

From the Main Menu, select the following options:

Default Media
Grayscale
DV Film Blue

Control Panel Keys

Control panel keys are shown in small black ovals to resemble the actual keys, for example, "Press the **ENTER** key."

Control Panel Menu Options

Control panel menu options are shown in bold type, for example, "Select the **Gamma** menu option."

Notes and Tips

Notes contain additional information related to a topic or procedure. For example:

NOTE: If your network is managed by a network administrator or an information technology (IT) department, it would be considered a complex network. You should have the responsible person perform any network-related administrative tasks.

Tips provide additional insights about a topic or procedure (such as, why you may want to do something or a faster way to perform an operation). For example:

TIP: Specifying print settings in a multi-user environment

If the Horizon imager is accessed by multiple users, it is typically better for individual users to enter print values through the DICOM application interface rather than change the default settings through the control panel.

Cautions and Warnings

Cautions alert you to actions or situations that could cause harm to equipment or data. For example:

CAUTION Any changes you make to the imager default settings will also affect prints made by other users. Use caution when changing default settings.

Warnings alert you to actions or situations that could result in personal injury. For example:

WARNING With the imager cover open, touch only those internal components that are colored green.

Text Files and Displayed Text

Monospaced type is used for the contents of an ASCII file or machine text displayed in a terminal command window.

User Data

Bold monospaced type is used to indicate specific characters or words that you enter at a host workstation when performing advanced imager operations. *If the type is also italicized*, it indicates variable text. For example:

1. From your workstation, open a UNIX or MS-DOS command window.
2. Enter the command **telnet *hostname*** or **telnet *IP Address*** (using either the Horizon imager hostname or IP Address).
3. At the login prompt, enter the command status.

Important Information and Filenames

Bold type is used for emphasis, command names, and paths or filenames. For example:

- The Horizon imager default settings can be changed both at the control panel and using text files.
- The hostname and IP Address must be added to the ***/etc/hosts*** file.

New Terms

Italic type is used when a term is introduced and defined. For example:

- The Horizon imager has a complete set of *default settings* that contain preconfigured values for every aspect of a printed sheet.

Purpose and Scope

Refer to this user manual for procedures on how to perform the most common imager operations, including:

- Setting up the imager
- Loading media
- Sending print jobs from DICOM Print Service Classcompliant applications running on imaging devices or image viewing workstation
- Sending print jobs from workstations via PostScript
- Sending print jobs using FTP and LPR
- Changing the imager's default image and sheet settings
- Adjusting the appearance of printed images for user preference
- Performing preventive maintenance
- Performing film calibration
- Troubleshooting common problems

NOTE: Some features and functions described here may not apply to older versions of the software.

This User's Manual is intended to be as simple and straightforward as possible for the everyday user. If you need more detailed or more technical information on a feature or topic, or wish to perform more advanced operations, refer to the *Horizon Imager Technical Manual* (Catalog no. HORIZON MNL). The Technical Manual serves as a companion document to this manual

Product Information

For technical assistance with the Horizon, 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:

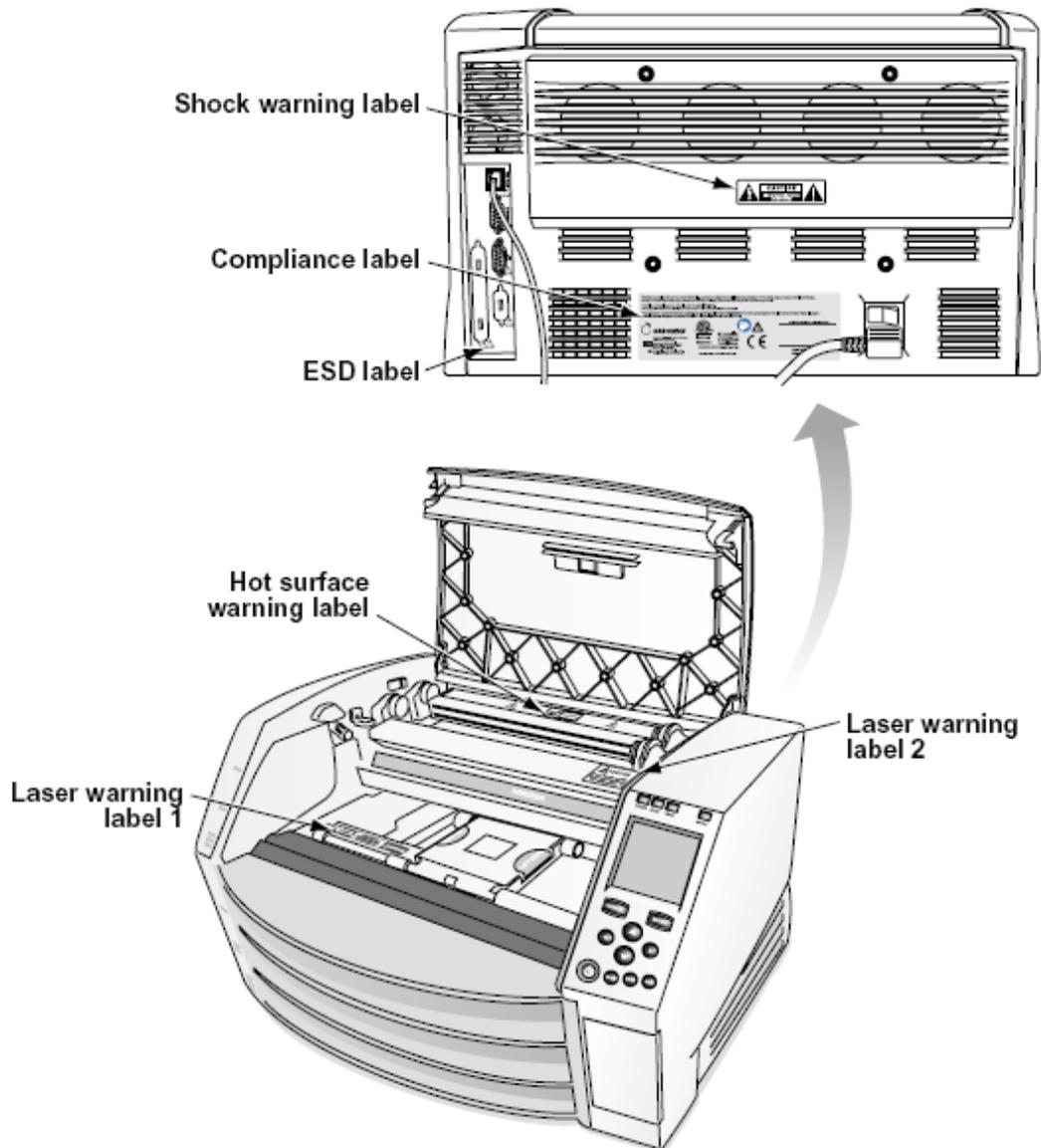
Email: info@codonics.com

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 figure shows the locations of the imager's safety and compliance labels.



Voltage Warning

The exclamation point 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 ENCASMENT FASTENERS VOIDS THE WARRANTY.

THIS APPARATUS MUST BE ELECTRICALLY GROUNDED.

TO PREVENT FIRE OR SHOCK HAZARD, DO NOT EXPOSE THIS IMAGER TO RAIN OR MOISTURE.

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.

WARNING Grounding reliability can be achieved only when the Horizon is connected to a receptacle marked "Hospital Only" (that is, "Hospital Grade").

WARNING The power cord connected to the Horizon is the main disconnect for the system.

WARNING To disconnect overall power to the Horizon prior to servicing it, power of the system.

WARNING Do not modify this equipment without authorization of the manufacturer

WARNING External equipment intended for connection to signal input, signal output, or other connectors, shall comply with relevant IEC standard (e.g., IEC 60950 for IT equipment and the IEC 60601 series for medical equipment). In addition, all such combinations - systems - shall comply with the IEC 60601-1 standard for Medical Electrical Equipment Systems. Equipment not complying to IEC 60601 shall be kept outside the patient environment, as defined in the standard. Any person who connects external equipment to signal input, signal output, or other connectors has formed a system and is therefore responsible for the system to comply with the requirements of IEC 60601-1-1. If in doubt, contact a qualified technician or Codonics Technical Support for approved configurations.

WARNING Do not touch a patient while also accessing the internal components that are under the top cover or receive trays.

Laser Warning

The Horizon imager uses a laser to read barcode information on the media cassettes. The laser module is a 650 – 670nm device of 1.26 mW or less. As such it has been found to comply with the 21 CFR 1040.10 and 1040.11 and IEC 60825 laser standards as a low power Class 1 device.

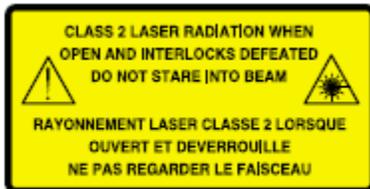
For safety reasons, the laser is turned on only for a short time when a cassette is inserted. Still, one should use caution and never stare at the laser beam, should avoid exposure to the laser, and should never override any of the interlocks and safety mechanisms. These measures are taken for your protection.

WARNING Use of controls or adjustments to the performance of procedures other than those specified in this manual may result in hazardous radiation exposure.

The laser apertures are marked with a single label, shown below. There are three apertures that correspond to the three cassette locations, one for each, on the same side of the Horizon imager as this label.



Safety interlocks are marked by the following label. They are located on the same side of the Horizon imager as this label.



Temperature Warning

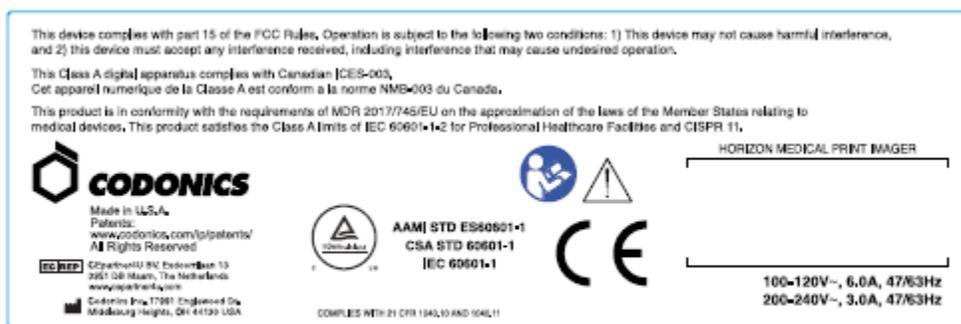
Because the Horizon imager is a thermal print device, the surface of the thermal print head heat sink gets hot. Avoid directly touching any components not colored green when accessing the interior of the imager if the imager has been printing. (During some preventative maintenance tasks, you will be touching internal components with cleaning pads or swabs.)

The temperature warning label is shown below.

Compliance

Codonics is in compliance with various regulations.

The Compliance label, which is affixed at the back of the imager, is shown below.



Compliance label

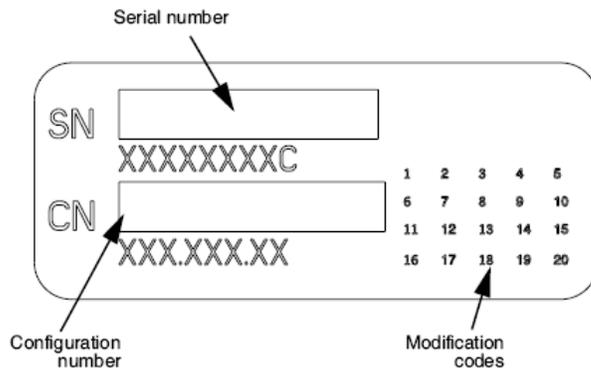
Serial Number, Configuration, Date Code, and Modification Codes

The Serial number label is placed onto the Compliance label. It includes the following information.

The serial number (SN), which uniquely identifies the unit.

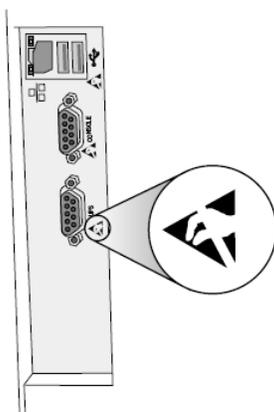
The Configuration number (CNFG), which details the build configuration.

The modification codes, which are to the right of the CNFG 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.



ESD Caution

Connections to other pieces of equipment are made at the rear of the Horizon imager. 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 imager, it is best done while the imager is plugged in but not powered on. ESD may cause erratic behavior of the imager when powered on. Should this occur, power to the imager may have to be cycled. It is recommended that all staff involved in making connections to the imager be aware of these ESD precautions.



Rear panel

Potential for Radio Frequency Interference on Imager Operation

Both portable and mobile RF communications equipment can affect medical electrical equipment, including the Horizon imager. Keep such RF communications equipment out of the immediate area.

Potential for Radio and Television Interference

The Horizon imager 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. It 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 imager 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:

- Reorient the receiving antenna
- Relocate the imager 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 requirements of EC Council directive MDR 2017/745/EU (CE) on the approximation of the laws of the Member States relating to medical devices. This product satisfies the Class A limits of IEC60601-1-2 and CISPR 11. A declaration of conformity with the requirements of the Directive has been signed by the Director of Operations. Horizon is approved for export via FDA Certificates to Foreign Government and registered as a medical device for import. A current list of countries is available on request.

Guidance Regarding Electromagnetic Emissions and Immunity

Suitable Environments:

- Horizon is intended for use in professional healthcare facility environments, including hospitals and medical clinics.
- Horizon 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 Horizon. If Horizon does not perform correctly in this environment, move the Horizon farther from the source of the electromagnetic disturbance.
- Horizon has not been evaluated for use in emergency medical vehicles.

As a support device, Horizon 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 Horizon, 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 A
RF Emissions FCC Part 15	Class A
Conducted Emissions CISPR 11	Group 1, Class A
Harmonic Distortion IEC 61000-3-2	Class A
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

Electromagnetic Immunity Standards and Test Levels: (Continued)

Test / Standard	Compliance Level
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	

Safety Precautions

- Never connect this imager to any outlet or power supply that has a voltage or frequency different than that specified on the rear of the imager.
- When servicing the imager, always power it off using the (power) key at the control panel, then turn the rocker switch in the back to the 0 (off) position, then unplug the imager.

- 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 imager's power configuration.
- If the imager is smoking or making unusual sounds, power off and unplug the imager immediately.
- Do not insert foreign objects of any kind into the imager; doing so can constitute a safety hazard and cause extensive damage.
- Do not place any liquid containers on the imager. If, for some reason, liquid seeps into the imager, power off the imager and unplug the power cord from the source outlet. If used without corrective measures, the imager may be damaged.
- Do not use the imager near flammable gases.
- With the imager top cover open or the receive trays removed, touch only those internal components that are colored green (shown in the following figure). Remove rings, ties, jewelry, and other items, and tie back hair, so that they do not fall into or get caught in the imager.



Internal Components That Are Colored Green (called out in the illustration) Are Safe to Touch

Location Precautions

- The imager's operating ambient temperature range is 15–30°C (59–86°F), with a relative humidity of 10%–80%.
- If the imager is moved quickly from an extremely cold place to a warmer one, condensation is likely to form. Do not use the imager if condensation has formed. Wait until the condensation has evaporated. You can speed up the evaporation time by moving the imager to a dryer location.
- Ventilation slots and holes are provided on the sides and rear of the imager. Place the imager on a hard level surface and locate it at least 10 cm (4 in.) from walls to ensure proper ventilation

CAUTION Adequate ventilation is required for proper operation of the imager

CAUTION When positioning the Horizon Imager, ensure there is adequate space to access the rear power switch.

- Do not place imager in a high humidity or high dust area. Airborne dirt particles can cause image quality problems. Avoid placing the imager in areas where ventilation ducts, open doors, or frequent passers-by might expose the imager and media to high levels of debris.
- Do not locate the imager in hot-springs areas where hydrogen sulfide and acidic ions are likely to be generated.
- Do not locate the imager where there are oily fumes and vapors.
- Do not locate the imager in direct sunlight.
- Do not locate imager near sources of high RF energy.
- Do not locate the imager where it might be subject to jarring or vibrations, such as a table or desk in a hightraffic area. Jarring and vibrations can affect the print quality of images.
- Horizon satisfies the electrical safety limits of IEC60601-1 and CISPR 11 and is suitable for patient care area location. Check with local ordinances and installation guidelines to confirm approved location requirements.

Cleaning Precautions

- Many plastic components are used in the imager's construction. Coat flecking and deformation is likely to occur if the imager is wiped with chemical dusters, benzene, thinners, insecticides, or other solvents. Rubber and PVC materials left in contact with the imager for extended times will cause damage. Never use petroleumbased solutions or abrasive cleaners.
- To clean the imager cover, first power off the imager using the (power) key at the control panel, then turn the rocker switch in the back to the 0 (off) position, then unplug the imager. 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 imager again.

Media

For **ChromaVista**[®] color prints, the consumed ribbon contains facsimiles of any patient images printed to **ChromaVista** color sheets. Therefore, you must properly dispose of or destroy consumed ribbon to ensure the confidentiality of patient images.

The optical density of reflective and transmissive prints have a nominal range of: Dmin = 0.10 OD (reflective), 0.11 OD (transmissive) to Dmax = 2.10 OD (reflective), 3.1 OD (transmissive). Actual optical densities may vary based on media variations and on the instrument being used to measure density. For example, **DirectVista**[®] Clear film may have a lower Dmin and Dmax than **DirectVista** Blue film.

- The Horizon imager includes a built-in densitometer. The built-in densitometer is designed to produce consistent prints by compensating for variation from one film cassette to another and one imager to another. For applications that require absolute control of the maximum density, the results should be checked against a bench-top commercial densitometer. The internal densitometer can be calibrated to a desktop unit. See the *Horizon Imager Technical Manual* for more information.
- **DirectVista** media is optimized for grayscale prints, while **ChromaVista** is optimized for color prints. If **ChromaVista** is not giving you satisfactory results with grayscale images, you may want to consider using **DirectVista** media for those applications.
- Media variations between different production lots may produce subtle differences in image quality and color. These variations most often occur in color ribbons and are characterized as a slight color hue in grayscale images.
- Codonics film media is designed to be viewed using a light box suitable for viewing medical diagnostic images.
- Codonics paper/white film media is designed to be viewed under coolwhite, fluorescent light. Spectral differences and intensity variations in the viewing light sources can change the apparent color of images printed on paper/white film.

- Printed images that are subject to prolonged exposure to sunlight, ultraviolet light, or extreme heat may degrade in image quality. (For example, printed sheets should not be stored in an automobile on a sunny day.) Precautions should be used to avoid prolonged direct exposure.

Codronics Paper/White Film Media

The terms “white paper” and “white film” are synonymous references and used interchangeably in this manual.

File Transfer via FTP and LPR

- Different users who share a user name when transferring files to the imager may cause unpredictable and erroneous printed output. The imager associates information with the user name. Each user should have a unique user name when connecting to the imager via FTP and LPR.

Color Management

- Image settings—including gamma, contrast, Dmax, saturation, and MCM™ (Medical Color Matching™)—are intended to compensate for differences that may occur between image acquisition and image printing. These filters allow you to accurately render the final printed image. You should use care when applying these filters to avoid over compensation.
- The Default User Settings set at the control panel will potentially affect prints made by all users. Use caution when changing the default settings.

Image Scaling

- Scaling an image will filter the original image data and add or remove information, which may affect the accuracy of the final printed image. The amount of information added or removed will also vary with the magnitude of the scale factor applied. This can also affect the accuracy of the final printed image. You should be aware of the properties and limitations of each scaling algorithm and select the appropriate algorithm for the task.

Hardware Variations

- Components used in the imager may vary, causing differences in image quality. The thermal process of producing a print utilizes many components that are calibrated to provide consistency between imagers. There are subtle differences between imagers that can cause print variations. These differences usually apply to thermal print head calibration. Other factors such as age, usage, heat, mechanical wear, and shipping can affect image color and quality.
- The type of media used to install software updates and to backup imager configuration settings depends on hardware variations. If the imager has a built-in Zip drive, installations and backups are performed using 100-MB Zip disks. If the imager does not have a built-in Zip drive, USB flash drives are used with the USB ports on the rear panel. Throughout this manual, Zip disks and USB flash drives are referred to as *installation media* or *backup media*, depending on the operation being performed.

NOTE: If the imager has both a Zip drive and a USB port, always use the Zip disk to install software and save configuration settings.

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.

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 Inc.

17991 Englewood Drive

Middleburg Heights, OH 44130 USA

Phone: +1.440.243.1198

Fax: +1.440.243.1334

E-mail: WEEE@codonics.com

www.codonics.com

Codonics electronic products and accessories 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

CAUTION Approved FDA Class 2 device - Federal law restricts this device to be sold for use by or on the order of a physician.

The intended use of the Horizon Series Imagers is high-resolution hardcopy imaging of digital image source material and through the conversion of electronic signals from a wide variety of direct/indirect medical imaging modality outputs. The hardcopy output includes, however is not limited to, digital radiography, nuclear medicine, ultrasound, CT, MRI, CR, and Radiation Therapy planning. Images are suitable for medical image diagnosis use and referral. The system is intended for use by medical radiologists, imaging modality specialists, and communications to referring physicians.

The Horizon Series Imagers are dry, thermal, grayscale (G, GS,GSs,GS-Rad, G1, and G2 models) and grayscale/color (Ci, Ci-s, CiRAD, and SF models) direct thermal printer/imagers.

The Horizon XL is a special model adding 14 x 36in. and 14 x 51in. true size "long" media that permits digital direct orthopedic application hardcopy, including diagnosis and analysis of scoliosis, weight bearing spine/hip/knee, and long bone/hip prosthetic and orthopedic appliances work-up and surgical planning. Horizon XL is applicable to true-size hardcopy of whole body CT, MRI, and Angiographic and Venous flow imaging procedures.

Horizon Imagers are 510(k) cleared to market as FDA Class 2 devices, Regulation number 892.2040, Classification Product Code LMC: Horizon Series Medical Multimedia Dry Imagers K021054 and Horizon XL Medical Long Film Imager Hardcopy Multimedia K060440.

CAUTION Approved FDA Class 2 device - Federal law restricts this device to be sold for use by or on the order of a physician.

CAUTION Make sure that the table can support the weight of the imager [approximately 66.7 kg (147 lbs) with receive trays and three full supply cassettes installed].

WARNING The imager is heavy. To avoid injury, use two people to unpack and position the imager.

CAUTION Do not scratch or nick the sheet metal. Scratches and nicks in the basement will damage the printed side of ChromaVista sheets.

CAUTION Make sure that the imager is powered off before connecting the Ethernet cable. For information about powering the imager on and off, refer to "Powering the Imager On and Off".

CAUTION Do not touch any of the connector pins.

CAUTION If the thermal print head is not parked, power on the imager, then repeat steps 2 and 3 to properly power off the imager so that it does park.

CAUTION Push the ribbon carriage down slowly. Forcing it down too quickly may damage the carriage.

CAUTION If the imager is powered off using the POWER key, unprinted queued jobs are saved and will finish printing once the imager is powered on again (you can purge all jobs). However, if the imager is powered off using the rocker switch in the back or power is interrupted (for example, an unexpected power failure), queued jobs may be lost.

WARNING When servicing the imager, always power it off using the POWER key, turn the rocker switch in the back to the 0 (off) position, then unplug the imager.

CAUTION Use only Codonics media. Do not use plain paper, office transparencies, or other unapproved media as damage, improper operation, or malfunction may result. For information about the approved Codonics media types and sizes, and how to order cassettes, refer to "Ordering Media".

CAUTION Do not refill a cassette. Do not tamper with or remove the barcode label. The cassette's barcode information is essential for ensuring diagnostic image quality. Compromising the cassette in any way jeopardizes the quality and reliability of the imager.

CAUTION Do not remove or insert a cassette while a sheet is being printed, or you could affect the image quality of the printed sheet or cause a jam. Always pause the imager first.

CAUTION Do not remove the printed cassette cover; it protects the media from dust and other contaminants. Always hold and store the cassette with the open side up to prevent the sheets from falling out.

WARNING With the imager cover open, touch only those internal components that are colored green. Remove rings, ties, jewelry, and other items, and tie back hair, so that they do not fall into or get caught in the imager.

CAUTION Used ribbon retains the negative of the color images that were printed using that ribbon. If you are required to ensure patient confidentiality and privacy, the ribbon should be destroyed.

CAUTION Use caution when changing the imager default settings. Changes could affect prints made by other users.

CAUTION Changing the default settings will affect prints made by other users. Use caution when changing default settings. Typically, it is better to specify sheet and image parameter settings from the DICOM application or a PostScript printer's settings, or use a Job Settings file that contains the values you need. For information about Job Settings files, refer to the *Horizon Imager Technical Manual*.

CAUTION If the imager's settings were changed from the factory defaults prior to being shipped (for example, to accommodate a special OEM configuration), resetting to the factory defaults will not restore the "as shipped" settings. Instead, they will be reset to the standard factory default values.

CAUTION Resetting to the factory defaults will affect prints made by other users. Use caution when changing default settings. Typically, it is better to specify sheet and image parameter settings from the

DICOM application or a PostScript printer's settings, or use a Job Settings file that contains the values you need. For information about Job Settings files, refer to the *Horizon Imager Technical Manual*.

CAUTION Changing the imager's Default Media and Default User Settings could affect subsequent prints made by other users. Use caution when changing default settings.

CAUTION Changing the imager's Default Media and Default User Settings could affect subsequent prints made by other users. Use caution when changing default settings.

WARNING With the imager cover open, touch only those internal components that are colored green. Remove rings, ties, jewelry, and other items, and tie back hair, so that they do not fall into or get caught in the imager.

WARNING The thermal print head may be hot.

WARNING When cleaning the print head, avoid the extreme ends of the print head, which are sharp.

CAUTION Use only the print head cleaning wipe when cleaning the thermal print head. Also, do not touch the glass surface of the thermal print head with your fingers; it could damage the print head. To avoid touching the glass surface, you may want to wear gloves when cleaning the thermal print head.

CAUTION The thermal print head must be completely dry before attempting to use the imager.

Allowing the thermal print head to heat up again while still wet will damage the thermal print head.

WARNING With the imager cover open, touch only those internal components that are colored green. Remove rings, ties, jewelry, and other items, and tie back hair, so that they do not fall into or get caught in the imager.

CAUTION Use only the platen roller cleaning wipe when cleaning the platen. The platen roller could be damaged if you use the print head cleaning wipe.

WARNING With the receive trays removed, touch only those internal components that are colored green. Remove rings, ties, jewelry, and other items, and tie back hair, so that they do not fall into or get caught in the imager.

CAUTION Use only the platen roller cleaning wipe when cleaning the pick tires. The tires could be damaged if you use the print head cleaning wipe.

CAUTION Do not touch the pick tires (which may be white or green); body oils from your fingers are hard to remove and could eventually damage the tires.

WARNING With the receive trays removed, touch only those internal components that are colored green. Remove rings, ties, jewelry, and other items, and tie back hair, so that they do not fall into or get caught in the imager.

CAUTION Use only cleaning swabs from a Barcode Reader Cleaning Kit.

CAUTION Do not scratch or nick the sheet metal. Scratches and nicks in the basement will damage the printed side of ChromaVista sheets.

CAUTION Federal law restricts this device to be sold for use by or on the order of a physician.

WARNING With the top cover open, touch only those internal components that are colored green. Remove rings, ties, jewelry, and other items, and tie back hair, so that they do not fall into or get caught in the imager.

CAUTION Do not touch the pick tires (which may be white or green); body oils from your fingers are hard to remove and could eventually damage the tires.

CAUTION To avoid damaging internal components, use care when removing a sheet from the media path in the upper part of the imager.

CAUTION Never put a sheet back in the cassette. Dust or oil from your finger will affect the image quality.

WARNING With the top cover open, touch only those internal components that are colored green. Remove rings, ties, jewelry, and other items, and tie back hair, so that they do not fall into or get caught in the imager.

CAUTION Be careful not to scratch the polished sheet metal or damage the sensor near the upper guide notch.

CAUTION Make sure you do not overrotate the media guide, as shown below.

CAUTION Federal law restricts this device to be sold for use by or on the order of a physician.

CAUTION Use care when running the Purge Print Jobs function. This function will purge other users' print jobs as well as yours.

CAUTION All files uploaded using anonymous FTP are readable by other FTP users. DO NOT upload sensitive or classified information.