

Radlink DR Retrofit User Manual

A Radlink GPS product-family device



Radlink DR Tablet Retrofit System

Product Overview

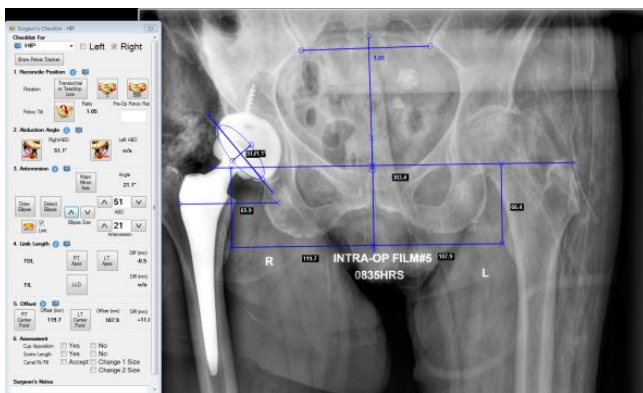
The Radlink DR Retrofit provides medical facilities the ability to upgrade their portable x-ray generator into a mobile DR x-ray generator system instantly. This is accomplished by retrofitting a tablet PC onto the facility's existing portable x-ray generator that will be wirelessly connected to a Digital Radiography Flat Panel Detector (FPD) with automatic energy detection (AED). The DR system does not need to communicate directly with the portable x-ray generator as long as the steps to acquiring an image are completed in the proper order. Images are wireless transmitted from the FPD to the DR Retrofit tablet PC in approximately 4 seconds.

The touchscreen tablet PC used in the DR Retrofit solution will be mounted onto the portable x-ray generator on the opposite side as the x-ray emitting column (see image below). The DR Retrofit tablet PC has wireless (and wired) network connectivity and also has a local PACS used for temporary image storage prior to transmission to your healthcare networks PACS. The Radlink Pro Imaging software in the DR Retrofit solution is compatible with all brands of x-ray generator, PACS, and modality worklists.

The DR Retrofit comes with optional software features such as imaging-stitching for (multiple x-rays) and Surgeon's Checklist™ software that provides surgeons with real-time feedback on orthopedic implant component positioning. The Surgeon's Checklist™ software offers easy-to-follow steps designed to address challenges such as component positioning, sizing, limb length and offset restoration. Pre-operative images can be viewed on the DR Retrofit during surgery, which surgeons can use to reference against the intraoperative images captured during the procedure.

The DR Retrofit solution can also be paired with the Radlink Wireless C-Arm Kit to acquire images from your C-Arm unit for processing, manipulation, evaluation using Surgeon's Checklist™ software and storage to your healthcare facility's PACS. Radlink also offers a mobile cassette holding cart (the Radlink Bucky Cart) that will safely store your FPD against accidental dropping, and a collimating x-ray grid that can improve image quality with large patients and when metal objects are in the imaging field.

Surgeon's Checklist™ Software



Wireless C-Arm Kit (WCA Kit)



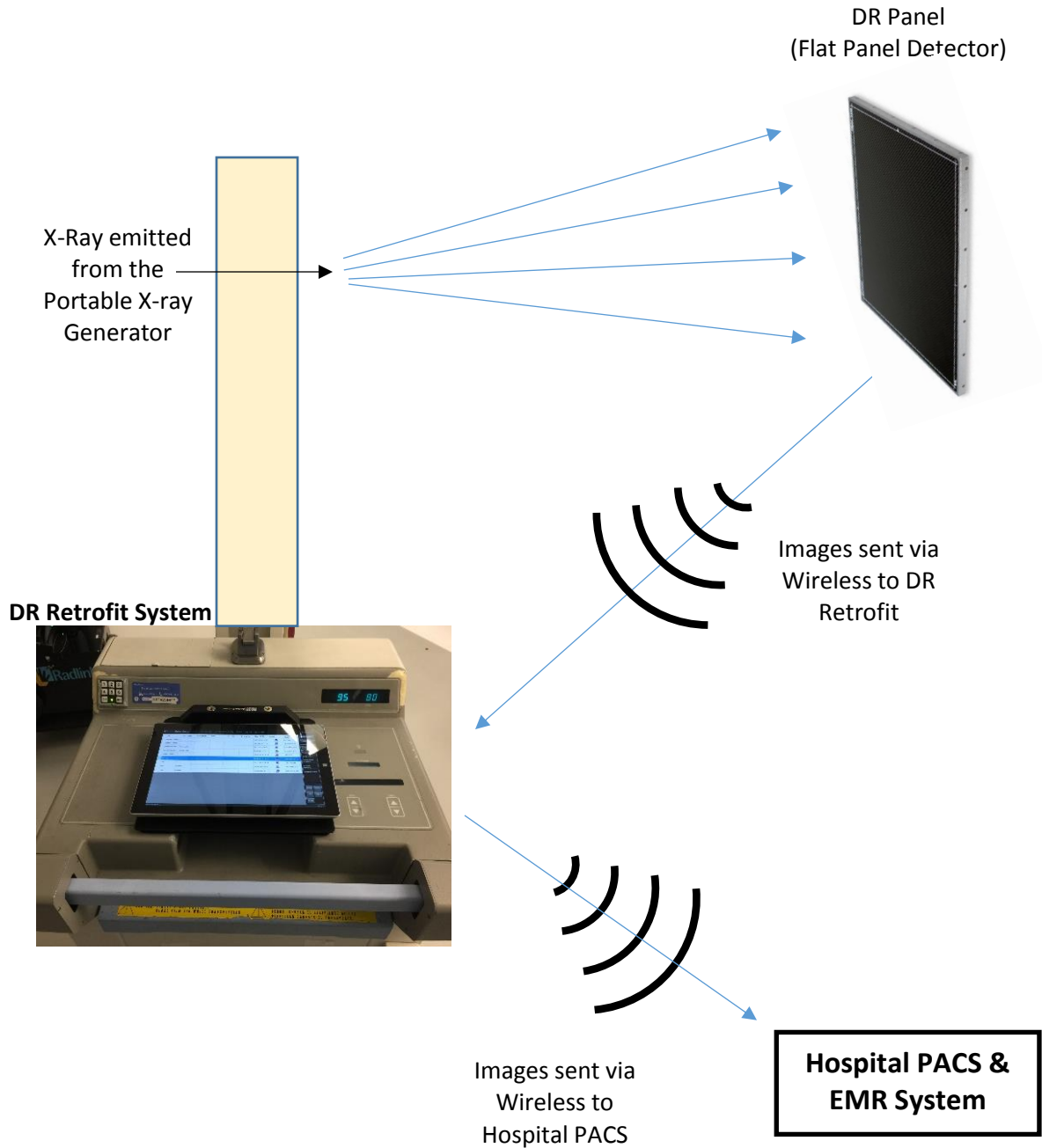
Bucky Cart & Grid



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DR RETROFIT SYSTEM OVERVIEW






















Radlink DR Retrofit Technical Specifications

Basic Information

Market name:	Radlink DR Retrofit (DR Tablet Retrofit)
Model:	Radlink DR Retrofit (Available in 120V & 230V)
Revision Level:	Rev. 1.0
Software Revision Level:	3.8
Purpose:	Picture Archival Communication System (PACS)
Potential Wireless Acquisition types:	1.) Digital Flat Panel Digital Detector (FPD) -Available in Cesium Iodide (CsI) Scintillator
Potential Wired Acquisition types:	None
Detector Interface:	Wireless FPD or Wireless C-Arm Kit only
Dimensions of DR Retrofit:	12.0" (Width) X 11.0" (Length) X 1.5" (Height Range)
Weight:	6.6 lbs. (Tablet PC + Mount), 8.4 lbs. (FPD)
Safe Working Load:	3.0 kg
Body Type:	Tablet PC & Flat Panel Detector (FPD)
Operating System:	Windows 10 Professional
Integrated Software:	Radlink Pro Imaging Software Suite & PACS Includes: ViewPro Application, Preview Images, Image Acquisition, Image Processing, Image Manipulation, Overlay Templating, Overlay Line/Angle Measurements
Regulatory Certifications:	Radlink FDA 510(k) #: K142718
Radio Frequency Compliance:	U.S.A. FCC Part 15 Subpart B & Subpart C
Expected Device Lifetime (DR):	5-7 Years (Without Flat Panel Detector)
Expected Device Lifetime (FPD):	5 Years – (Perkin Elmer FPD)
Accuracy of measurements:	0.2mm (<i>Dependent on image-capture precision</i>)
Device Classifications:	<ul style="list-style-type: none">- Class II ME Equipment. Suitable for continuous operation mode- No Sterile Parts, Applied Parts, Detachable Parts, Disposables- Not intended for use in oxygen rich environment. No oil lubrication systems- No High Voltage Terminals, multiple socket outlets, cooling liquids- DR Retrofit contains no PEMS required for basic safety or essential performance
<u>Overall Electrical Configuration:</u>	
Power Consumption:	Average of 39 Watts
Input Voltage & Current:	100-240 V (50/60 Hz), 1.0 Amps (AC) [No Fuses]
Output Current:	12V at 2.58 Amps, 5V at 1.0 Amps (AC)
X-ray Energy Range:	~40 kVp ~ 150 kVp
Operating Temperature Range:	41 – 104 °F (5 – 40 °C)
Humidity Range:	8-85% non-condensing
Atmospheric Pressure Range:	80 kPa – 106 kPa
Maximum Altitude of Operation:	2000 meters (or less)
Ingress Water Protection Rating:	IP20 – No Liquid Protection, Solids protection 12.5mm
<u>Transport & Storage Atmospheric Conditions:</u>	
Temperature Range:	-104 – 140 °F (-76 – 60 °C)
Humidity Range:	8-95% non-condensing
Atmospheric Pressure Range:	80 kPa – 106 kPa

WARNINGS FOR RADLINK DR RETROFIT SYSTEM

-  Radlink Technical Support is the only approved Service Personnel
-  Recommended that the user reads Radlink DR Retrofit user manual prior to operating unit
-  Do not touch the Radlink DR Retrofit and the patient at the same time
-  The Radlink DR Retrofit has no “Applied Parts”, or parts meant for direct patient contact
-  WARNING - No modification of the Radlink DR Retrofit is allowed
-  WARNING - Do not modify the Radlink DR Retrofit without authorization of the manufacturer
-  WARNING - If the equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment
-  Other equipment or network/data couplings shall not be attached to any signal input/output port except for those which form the Radlink DR Retrofit system
-  Contraindications: Do not use the Radlink DR Retrofit for mammography
-  No parts of the Radlink DR Retrofit shall be serviced or maintained while in use with a patient
-  No parts of the Radlink DR Retrofit are suitable for use within the patient environment
-  Do not use near water/liquid - unit does not have Ingress Protection Rating for liquid
-  To maintain wireless signal strength, do not use near source of EMC or RF interference
-  The full list of notices and warnings for the DR Retrofit tablet PC (13-14-005) can be found at www.surface.com/support for the Microsoft SurfacePro 4
-  Tablet Wireless LAN Adapter (13-14-001) full list of notices and warnings can be found at www.asus.com/support/ for the ASUS USB-AC51
-  WARNING - There is potential for electromagnetic or other reciprocal interference between the Radlink DR Retrofit and other medical electrical devices together. To minimize the possibility of such interference, keep other medical electrical equipment away from the Radlink DR Retrofit
-  Installation is not required by the user for the Radlink DR Retrofit
-  Position the Radlink DR Retrofit so the mains plug is readily accessible for quick disconnection from the power supply
-  The Radlink DR Retrofit does not create any “waste products” during standard use. The device owner should properly dispose of the DR Retrofit tablet PC hardware in accordance with government regulations at the end of the device life

WARNINGS FOR RADLINK DR RETROFIT SYSTEM (CONT'D)



The Radlink DR Retrofit uses batteries. The device owner should properly dispose of the DR Retrofit's batteries in accordance with government regulations at the end of the device life.



WARNING - The Radlink DR Retrofit is not configurable (or reconfigurable)



An additional multiple socket-outlet or extension cord shall not be connected to the Radlink DR Retrofit while plugged in and charging



Only connect items that have been specified as part of the Radlink DR Retrofit or have been specified as being compatible with the unit.



To disconnect the Radlink DR Retrofit from power, remove the quick-connect power cable on the right side of the keyboard.



WARNING – To prevent falling hazards and potential damage, hold the Radlink DR Retrofit tablet PC firmly or place securely on tabletops and desks (when not mounted to the x-ray generator)

INTENDED USE(S) OF THE RADLINK GPS PRODUCT FAMILY (DR RETROFIT)

FDA 510(k) Indications for use

The Radlink GPS is intended for digital image capture use in general radiographic examinations, whenever conventional screen-film systems may be used. The Radlink GPS allows imaging of the pelvis, knee, skull, chest, shoulder, spine, abdomen and extremities. The digital images are transmitted from the panel or from a connection to PACS via computer networks or from a video input port to a personal computer (PC) where they may be displayed, processed, altered, overlaid with templates, and compressed for archiving or transmission via computer networks to other medical facility sites. The Radlink GPS is not for mammography.

CE Mark (European Union) Intended Use

The Radlink GPS is a computer-based Picture Archival Communication System (PACS) that receives digital images (processed or raw/unprocessed) from various sources and displays them to the user for preliminary review. These sources include, but are not limited to, video signal inputs, wired or wireless transfer of image files from other acquisition systems (e.g. X-Ray Flat Panel Detector Systems), or images transmitted to the Radlink GPS from other PACS systems. Using the Radlink GPS, you can manipulate/post-process images, overlay lines/measurements/templates, store images, and transmit images to other PACS destinations.

FREQUENTLY USED FUNCTIONS

SYSTEM START-UP

1. The DR Retrofit runs on battery power, so it may not be necessary to plug the unit into power in order to start the system
2. Press & hold the **Power Button** on the upper left side of the DR Retrofit tablet PC for 5 seconds to turn it on. The screen will illuminate within 5 seconds as the computer starts-up

**DR Retrofit
Power Button**



3. Enter the password for the “DR SNxxxx” user account if your facility has one, otherwise press enter to continue
4. Open the Radlink Pro Imaging Acquisition Software by double-clicking the desktop icon “Radlink Pro Imaging”

SYSTEM SHUT-DOWN

1. Shut-down the DR Retrofit tablet PC using standard Windows shut-down procedure
 - a. Click the Windows icon (‘Start Button’) in the bottom left corner of the desktop
 - b. Click “Power”
 - c. Click “Shut Down”
2. Once the DR Retrofit has shut-down via Windows, make sure the FPD is powered off as-well by holding the blue power button down for 5 seconds.



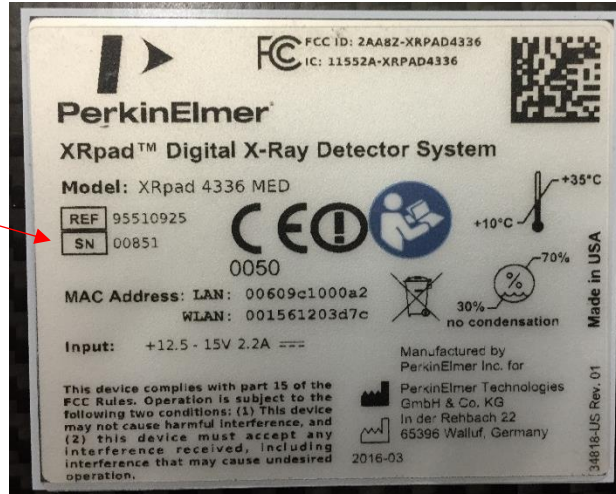
CHARGING THE RADLINK DR RETROFIT

1. Plug the power cable from the wall power source into the power port on the side of the DR Retrofit Tablet unit. Charge the Radlink DR Retrofit tablet PC using the below provided charging cable (Radlink Part #: 13-14-005-A).



CONNECTING TO A RADLINK FLAT PANEL DETECTOR

1. First, identify the 5 digits of the Serial Number of the Radlink Flat Panel Detector that you are trying to connect to. Make sure the FPD is powered on, and the blue power light is illuminated on the power button



2. Once the DR Retrofit is powered-on and Windows has booted to the desktop, prior to opening the Radlink Pro Imaging Software, click on the “Wireless Internet Access” icon in the bottom right corner of the desktop
3. Scroll through the list of available wireless networks and select the network titled “RadlinkDRxxxx”, where the “xxxx” represents the last 4 digits of the Flat Panel Detector’s serial number.
4. The password for the network will be “PerkinElmer” (*Note: Case-sensitive*)
5. Confirm the network shows “No Internet, Secured” under the wireless network name and is at the top of the list of networks available
6. Open the Radlink Pro Imaging software and ensure the system-mode is properly set by clicking “Manage” in the upper right, and then selecting “Perkin Elmer” for the System Mode inside the software. Click “Save Settings” in the bottom right corner.

USING THE RADLINK DR RETROFIT FOR X-RAY IMAGE CAPTURE

Important: Do not position the X-ray generator between the DR Retrofit tablet PC and the DR Panel. Lead inside the mobile X-ray generator and lead shields can interfere with the wireless communication, resulting in a lost connection or inability of the FPD to acquire images.

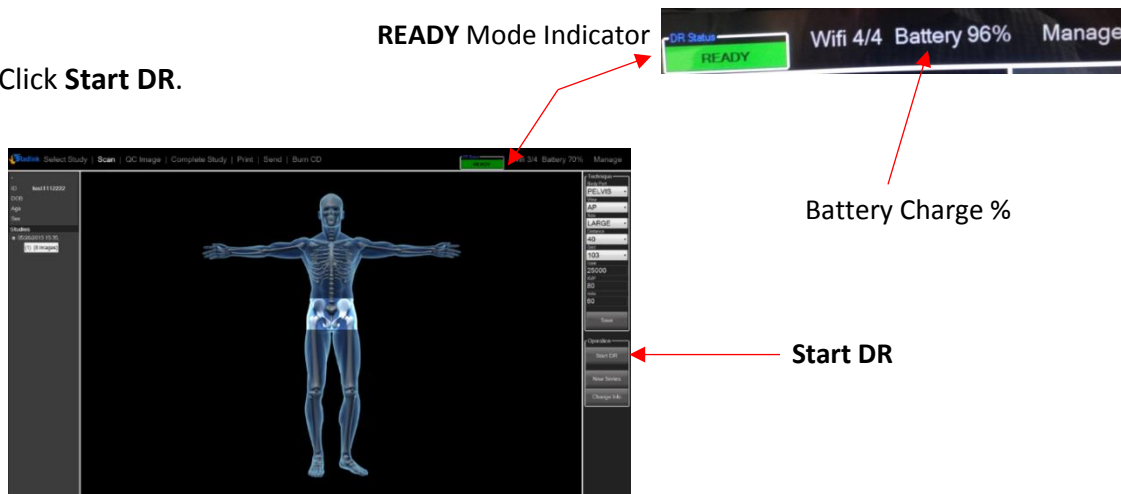
1. Turn on the DR Panel (press and hold the power button until the panel turns on.)



Once the DR panel has been turned on, follow Steps 2-12 to complete the THA procedure:

2. Double-click the **Radlink Pro Imaging** to open the acquisition software
3. Click on the row with the patient ID for the study if the order is displayed in the modality worklist. Otherwise, click **New Patient** and enter the study information.
4. The **SCAN** page will appear. On the body avatar, click the body part to be scanned. The DR Status on the upper right corner of screen must be in the **READY** mode. If the **DR Status** is not in the READY mode, refer to Troubleshooting on page 15.
5. Note: if you have images in the study, the software goes to “**QC Image**”, not “**Scan**”. In this case, just click the “Scan” button on the top bar to proceed to the acquisition page.

6. Click **Start DR**.



7. Take the intraoperative X-ray. The image will appear in the viewing window.
8. Use Image Orientation & Image Appearance buttons to rotate the image right/left, flip the image horizontal/vertical, window level, make negative, zoom and pan.



9. Refer to the Surgeon’s Checklist™ user manual to take measurements with the software.
10. If it is necessary to shoot another image, click **SCAN** and **Start DR** and repeat steps 7-10.

CHARGING THE FPD (DR PANEL) BATTERY

The DR Panel comes with two battery packs and one battery charger. When fully charged, each battery lasts 2-3 hours. For best results, start each surgical procedure with a fully charged battery.

To charge the DR Panel battery:

1. With the label at the bottom facing front and downward, insert the battery into the charger.

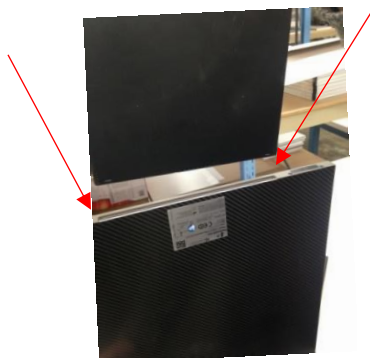


2. When the battery is fully charged, the four solid green lights will be illuminated. If the battery is not fully charged the lights will blink.



To insert the battery into the DR panel:
















1. Place the battery in the slot on the DR panel. The label on the battery should be on the opposite side of the label of the panel. Insert the battery all the way until it clicks.
2. To remove the battery, push the tabs inward until the battery ejects.



TROUBLESHOOTING

Problem	Reason	Solution
<p>DR Status light reads “Initializing” instead of “Ready”, or DR Panel (Flat Panel Detector) will not connect</p>	<p>The wireless communication between the panel and the DR Retrofit PC is blocked by lead shield, or slowed by obstructions in the path</p> <p>Flat Panel Detector (FPD) battery may be low</p> <p>Unstable connection between Flat Panel Detector and DR Retrofit</p>	<p>Make sure there is no lead (in the X-ray generator, lead gown, or lead shield) between the Flat Panel Detector and the DR Retrofit PC</p> <p>Replace the battery with a fully charged battery</p> <ol style="list-style-type: none"> 1. Close Radlink Pro Imaging software by clicking Manage → Logout 2. Turn off the DR Panel (FPD) 3. Turn on the DR Panel (FPD) and wait until the LEDs stop flashing 4. Launch Radlink Pro Imaging software, wait for reconnection
<p>Touch screen is not responding</p>	<p>The user may be touching the inside of the screen already in one place, blocking the sensors, and preventing it from registering another touch simultaneously</p>	<p>Only press on one location of the screen at a time to ensure consistent registering of every touch, do not use plastic or metal utensil unless approved compatible</p>
<p>Tablet PC response time is slow</p>	<p>The Tablet PC may have been shut down by loss of power rather than via Windows</p> <p>Automatic Windows Updates going</p> <p>Computer may be out of disk space – (e.g. from storing too many images)</p>	<p>Restart your Tablet PC and allow it to reconfigure itself via Windows</p> <p>Wait for the automatic updates to complete if the system is too slow</p> <p style="text-align: center;"><i>Call Radlink Technical Support</i></p>
<p>The DR Retrofit will not turn on or will not respond (or is stuck on a screen, and will not respond)</p>	<p>The battery has been depleted because the DR Retrofit tablet PC was not properly shut down</p> <p>The Windows Operating System on the Microsoft SurfacePro encountered an error, and is locked in a nonresponsive state</p>	<p>Plug the DR Retrofit tablet PC in to charge, and use it while plugged in if necessary until a charge is held</p> <p>If the DR Retrofit will not respond, press and hold the power button for 35 seconds to hard reboot the SurfacePro device</p> <p style="text-align: center;"><i>If your device is still not responding, please call Radlink Technical Support</i></p>

SAFETY SIGNS AND SYMBOLS

	General Warning Sign
	Conformité Européenne (CE Mark Clearance)
	Radlink's CE Mark Clearance from Notified Body 0123 Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65. 80339, Munich, Germany
	Radlink European Union Representative
	Name and Address of Manufacturer
	Date of Manufacture
	Serial Number
	Refer to instruction manual
	Input voltage is alternating current (AC)
	Earth (ground)
	Temperature limit to which this equipment can be safely exposed
	Indicates the range of humidity to which this equipment can be safely exposed
	Indicates the range of atmospheric pressure to which this equipment can be safely exposed
	Fragile, handle with care
	Keep this equipment dry

Refer to Radlink GPS and DR Software User Guide (00.09-007) for detailed software instructions, including system, error, and fault messages that are generated, unless these messages are self-explanatory.

For questions, call Radlink Technical Support:

310-643-6900, ext. 2

Mon-Fri, 6:00 a.m. – 5:00 p.m. PST

Preventative Maintenance

The Radlink DR Retrofit is designed to require little preventative maintenance over an extended period of use. The main features that will require attention over time and extended use are as follows:

1. Disinfection & Decontamination periodically with cleaning wipes.

This is the most important and regularly required service to the Radlink DR Retrofit. As the equipment is frequently taken in and out of high-exposure environments inside of hospitals (e.g. the operating room), it is critical to control the potential spread of infectious disease by thoroughly cleaning the surfaces of the DR Retrofit which have come into contact with any equipment from those environments.

2. Scratches, finger grease, dust, chemicals, and ultraviolet light can affect the performance of your touchscreen. Here are a few things you can do to help protect the screen:

- **Clean frequently.** The DR Retrofit touchscreen has been coated to make it easier to clean. You don't need to rub hard to remove fingerprints or oily spots. To avoid scratches, use a soft, lint-free cloth to gently wipe the screen. You can dampen the cloth with water or an eyeglass cleaner, but don't apply liquids directly to your DR Retrofit. Don't use window cleaner or other chemical cleaners on your DR Retrofit.
- **Keep it protected.** Protect the tablet PC screen while in transit or not using your DR Retrofit.
- **Keep it out of the sun.** Don't leave your DR Retrofit in direct sunlight for a long time. Ultraviolet light and excessive heat can damage the display.

3. Power cords, like any other metal wire or cable, can be weakened or damaged if repeatedly twisted or bent in the same spot. Here are a few things you can do to keep your power cord from being damaged:

- Avoid twisting or pinching your power cord.
- Don't wrap your power cord too tightly, especially around the power brick. Instead, wrap it using loose coils rather than tight angles.
- Inspect your power cord regularly, especially where it joins the power brick.
- Avoid pulling on the power cord when unplugging your DR Retrofit. Gently removing the connector from the charging connector can help prevent damage to your power cord.
- If you find any damage on any part of your DR Retrofit charger's cords, stop using the cord and contact Radlink Technical support.

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