

# Galileo Positioning System™

## User Guide



# Radlink Galileo Positioning System™

## Product Overview

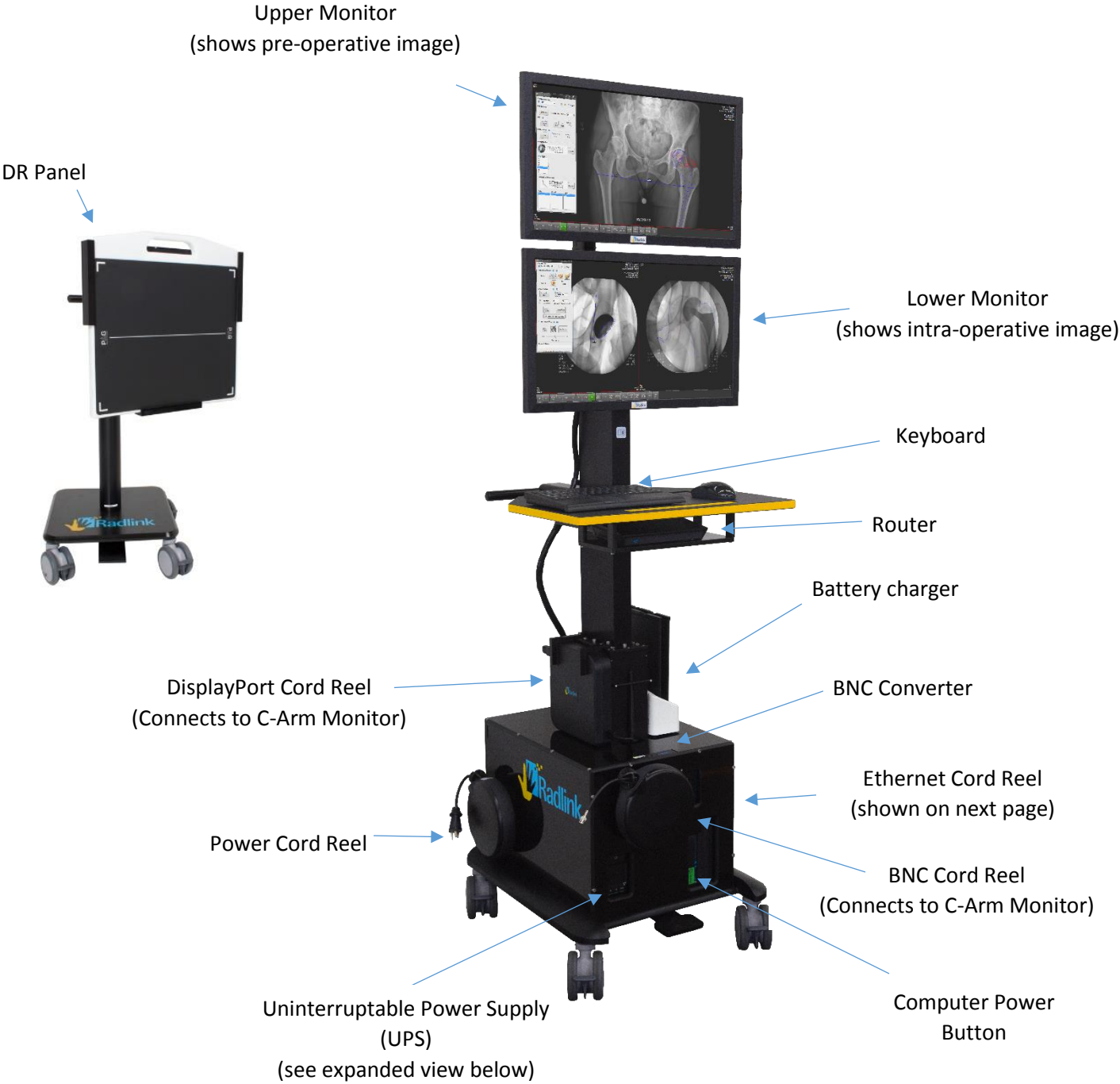
The Radlink Galileo Positioning System™ (GPS) provides surgeons with real-time feedback on orthopedic implant component positioning. Together, the GPS and its Surgeon's Checklist™ software offer easy-to-follow steps designed to address challenges such as component positioning, sizing, limb length and offset restoration. The Radlink GPS consists of a computer system that uses two monitors (see full diagram on pages 2-3). Pre-operative images can be viewed on the top monitor during surgery at the same time that intraoperative images are being viewed on the lower monitor.

For posterior approach THA procedures, a flat panel detector (DR panel) is used to capture intraoperative images, which take approximately four seconds to appear on the lower GPS monitor. For anterior approach THA procedures, C-Arm images are instantaneously transferred to the lower monitor of the GPS.

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# System Overview





# Radlink GPS Technical Specifications

## Basic Information

<b>Market name:</b>	Radlink GPS (Galileo Positioning System)
<b>Model:</b>	Radlink GPS 2200 (Available in 120V or 230V power)
<b>Revision Level:</b>	Rev. 4.0
<b>Software Revision Level:</b>	3.8
<b>Purpose:</b>	Picture Archival Communication System (PACS)
<b>Potential Wireless Acquisition types:</b>	Digital Flat Panel Digital Detector (FPD) <i>-Available in GadOx &amp; CsI Scintillator</i>
<b>Potential Wired Acquisition types:</b>	Video Input Signal (from BNC and DP cable connection)
<b>Detector Interface:</b>	Available in Wireless & Wired with tether cable
<b>Dimensions:</b>	20.3" (Width) X 23.5" (Length) X 67-78" (Height Range)
<b>Weight:</b>	206.6 lbs. (Image Console Cart), 84.6 lbs. (Bucky Cart)
<b>Safe Working Load:</b>	94 kg
<b>Body Type:</b>	Two Carts: Image Console Cart & Bucky Cart
<b>Operating System:</b>	Windows 10 Enterprise
<b>Integrated Software:</b>	Radlink Pro Imaging Software Suite & PACS Includes: ViewPro Application, Preview Images, Image Acquisition, Image Processing, Image Manipulation, Overlay Templating, Overlay Line/Angle Measurements
<b>Regulatory Certifications:</b>	Radlink FDA 510(k) #: K142718
<b>External Standards:</b>	IEC 60601-1 (Medical Electrical Equipment Safety) IEC 60601-1-2 (Medical Electrical Equipment EMC) IEC 60601-1-6 (Usability for Medical Devices)
<b>Radio Frequency Compliance:</b>	U.S.A. FCC Part 15 Subpart B & Subpart C
<b>Expected Device Lifetime (GPS):</b>	5-7 Years (Without Flat Panel Detector)
<b>Expected Device Lifetime (FPD):</b>	5 Years – Vieworks & Perkin Elmer
<b>Accuracy of measurements:</b>	0.2mm Note: Tolerance is dependent on position of patient relative to position of DR Panel and X-ray generator for posterior approach THA procedures and on C-arm resolution for anterior approach procedures.
<b>Device Classifications:</b>	<ul style="list-style-type: none"><li>- Class II ME Equipment</li><li>- No Sterile Parts, Applied Parts, Detachable Parts, Disposables</li><li>- Not intended for use in oxygen rich environment</li><li>- Suitable for continuous operation mode</li><li>- No High Voltage Terminals or multiple socket outlets</li><li>- GPS contains no PEMS required for basic safety or essential performance</li><li>- GPS contains no cooling liquids or oil lubrication systems</li></ul>

### **Overall Electrical Configuration:**

<b>Power Consumption:</b>	Average of 80-90 Watts
<b>Input Voltage:</b>	110/220 V (50-60 Hz)
<b>Fuse Type:</b>	110 V (5 Amps), 220 V (3 Amps)
<b>Input Current:</b>	0.3-1.2 Amps (AC)
<b>X-ray Energy Range:</b>	~40 kVp ~ 150 kVp
<b>Operating Temperature Range:</b>	50 – 95 degrees Fahrenheit (10 – 35 degrees Celsius)
<b>Humidity Range:</b>	30% ~ 70%
<b>Atmospheric Pressure Range:</b>	80 kPa – 106 kPa
<b>Maximum Altitude of Operation:</b>	2000 meters (or less)
<b>Ingress Water Protection Rating:</b>	IP20 – No Liquid Protection, Solids protection 12.5mm

### **Transport & Storage Atmospheric Conditions:**

<b>Temperature Range:</b>	14 – 113 degrees Fahrenheit (-10 – 45 degrees Celsius)
<b>Humidity Range:</b>	30% ~ 70%
<b>Atmospheric Pressure Range:</b>	80 kPa – 106 kPa

## **Intended Use**

### **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, 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

### The Uninterruptible Power Supply (UPS)

UPS



UPS Control Panel



#### 1 Power Switch

Used as the master on/off switch for equipment connected to the battery power supplied outlets. Press & hold to turn the unit on or off.

#### 2 Power On Indicator

This LED is illuminated when the utility power is normal and the UPS outlets are providing power, free of surges and spikes

#### 3 LCD Module Display

Intelligent LCD display shows all the UPS information using icons and messages.

#### 4 Down/Display Button

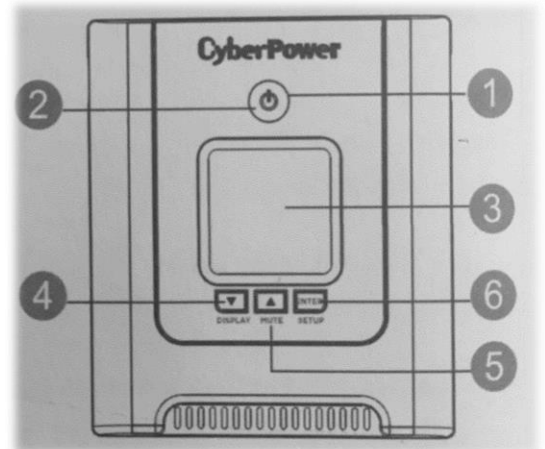
The button can be used to select the LCD display contents including Input Voltage, Output Voltage, and Estimated Run Time. Short Press the button to scroll down the function menu. Pressing the button for 2 seconds will keep the LCD display always on or turn the LCD display off while in AC/Utility power mode.

#### 5 Up/Mute Button

Short press the button to scroll up the function menu. Holding the button for more than 2 seconds will silence the alarm.

#### 6 Enter/Setup Button

Press the button for 2 seconds to enter the setup menu and then select the functions for configuration.



## System Start-up

1. Plug the power cord of the unit into an AC power outlet.
2. Press & hold the **Power Button** for the UPS to turn it on. The UPS Power indicator light should now be illuminated.



*When the UPS is on, this light will be illuminated.*

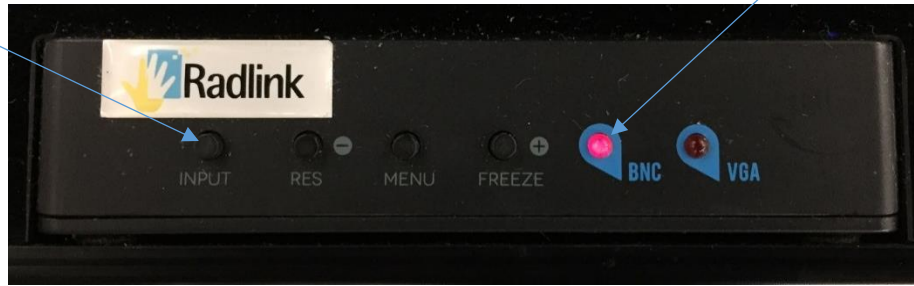
3. If the GPS is unplugged, the system will go to battery mode and the UPS will begin to beep. To silence the beeping sound, press the MUTE button on the UPS control panel for two seconds.

## Using the Radlink GPS in an Anterior Approach THA Procedure

1. Pull the BNC cable or DisplayPort cable from its cord reel and plug the cable into the Video Output Port on the back of the C-Arm monitor cart. For the BNC cable push and twist clockwise when plugging it in.
  - a. When using the BNC cable, make sure the BNC Converter is set to BNC. If it is not, press the Input button on the Converter.



Input



- b. When using the DisplayPort cable, make sure the BNC Converter is set to VGA. If it is not, press the Input button on the Converter.



2. If images need to be pulled from PACS and WiFi access is not available, pull the Ethernet cable from its cord reel and plug into an Ethernet port.
3. Double-click the **Radlink Pro Imaging** icon on the lower monitor.
4. Double-click the **Pre-op Viewer** icon on the upper monitor to access the PACS. Select the pre-operative image to be used as a reference during the case.
5. On the lower monitor, click on the row for the study if the order is displayed in the modality worklist. Otherwise, click **New Patient** and enter the study information.
6. Once you are in **QC Image** page, click the **Grab Frame** tab.



7. C-Arm images will appear at the bottom of the lower monitor screen.

8. **Refer to the Surgeon's Checklist™ user manual for instructions on how to take measurements with the software.**
9. If images need to be sent to PACS and WiFi access is not available, pull the Ethernet cable from its cord reel and plug into an Ethernet port.
10. Once cases have been completed for the day, unplug the video cable from the back of the C-Arm monitor. For the BNC cable, pull and twist counter-clockwise and then gently pull on the BNC cable until it retracts. For the DisplayPort cable, hold down the tab on the cable head and unplug it.

### Using the Radlink GPS in a Posterior Approach THA Procedure

**Important: Do not position the X-ray generator between the GPS and the DR Panel. Lead inside the mobile X-ray generator can interfere with the wireless communication, resulting in a lost connection or the inability of the panel to acquire images.**

1. Turn on the DR Panel

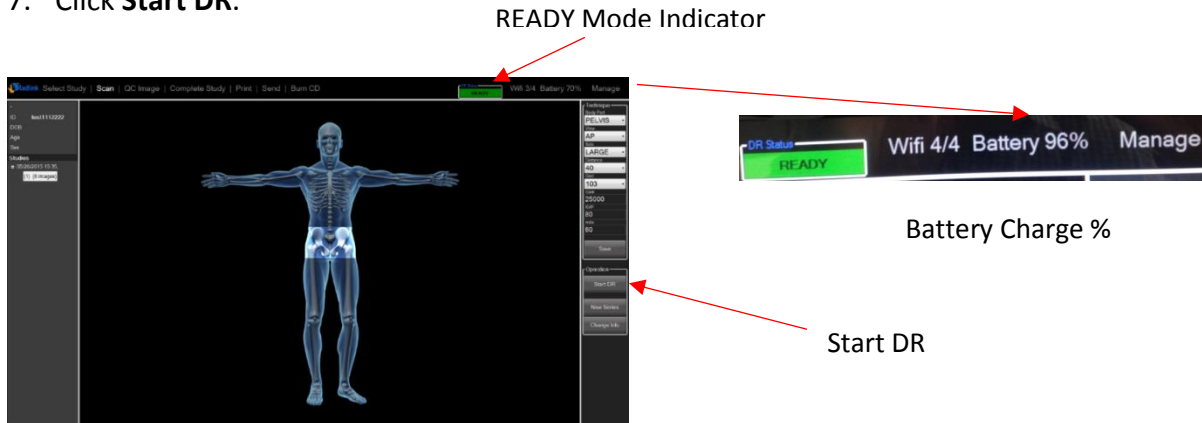
To turn on the DR panel, press and hold the power button until the panel turns on.



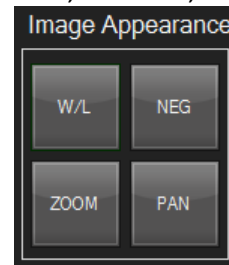
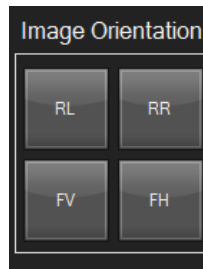
**Once the DR panel has been turned on, follow Steps 2-12 to complete the THA procedure:**

2. Double-click the **Radlink Pro Imaging icon** on the lower monitor.
3. Double-click the **Pre-op Viewer** icon on the upper monitor to access the PACS. Select the patient ID with the pre-operative image to be used as a reference during the case.
4. On the lower monitor, 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.

- 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.
- Note: if you have images in the study, it goes to “QC Image”, not “Scan”.
- Click **Start DR**.



- Take the intraoperative X-ray. The image will appear on the lower monitor.
- Use Image Orientation buttons to rotate the image.
- Use the Image Appearance buttons to Window Level, Zoom in, etc.



- Refer to the Surgeon’s Checklist™ user manual to take measurements with the software.
- If it is necessary to shoot another image, click **SCAN** and **Start DR** and repeat steps 8-11.

## The 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 sticker 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 sticker on the battery should be on the opposite side of the sticker of the panel. Insert the battery all the way until it clicks.



2. To remove the battery, push the knobs inward until the battery ejects.



## Radlink GPS System Shut-Down Instructions

1. Click the **Windows icon** in the lower left-hand corner of the lower monitor screen. Click **Shut down**.
2. Press the power button on the UPS. When the UPS is off, the power button will no longer be illuminated.
3. For a Posterior case, press and hold the power button of the DR panel in order to turn it off.

## Preventative Maintenance

The Radlink GPS 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 isopropyl alcohol. (Other cleaning methods should be confirmed with the manufacturer.)*  
To mitigate the potential spread of infectious diseases, the surfaces of the Radlink GPS should be thoroughly cleaned as they are taken in and out of high-risk environments (e.g. the operating room), especially if surfaces come into contact with any equipment or materials from these environments.
  - Never spray or pour any liquid directly onto the unit.
  - To clean the monitor screen use a clean, soft, lint-free cloth and a small amount of non-ammonia, non-alcohol based glass cleaner
2. *Visual inspection of dust on equipment cooling fans. Recommended monthly. Clean as needed from visual inspection. Different environments will cause different rates of dust buildup.*
3. *Verify that the Uninterruptable Power Supply (UPS) is holding a charge. Recommended monthly.*
  - Turn on the UPS.
  - Turn on the rest of the electronic components of the GPS unit (including booting the computer to the home-screen).
  - Look at the UPS power-level indicator on the desktop of the computer.
4. *Check Windows Defender scan history periodically and look for signs of malware detection. Recommended monthly.*  
*Full system scans can be done manually in addition to automatic daily scans.*
5. *Updates for Windows OS operating system are tested and approved by Radlink. A list of the most current approved updates can be found at Radlink.com. Recommended monthly.*  
**Note:** Installation of additional software requires administrative privileges provided by Radlink.

## TROUBLESHOOTING




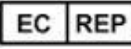












Problem	Reason	Solution
Frame Grabber is not pulling images from the C-Arm	The video output at the back of the C-Arm monitor may be damaged or broken	Adjust/repair the video output port or try using a different C-Arm port.
	The signal mode on the Converter is not set to BNC when using the BNC cable	Press the Input button on the BNC Converter to switch to BNC mode.
	The signal mode on the Converter is not set to VGA when using the DP cable	Press the Input button on the BNC Converter to switch to VGA mode.
	Frame Grabber is not selected in the software	<ol style="list-style-type: none"> <li>1. Open the Radlink Pro Imaging software and click "Manage".</li> <li>2. Make sure the Frame Grabber is checked under Hot Buttons.</li> <li>3. Click Save Settings.</li> </ol>
Touch screen is not responding	The user may be touching the inside of the monitor frame, blocking the sensors	Press edges of the monitor frame to reconnect the touch screen sensors.
	The USB cable for the touch screen may be loose	Check the USB cable and make sure it is firmly connected. If it is connected, unplug the cable and plug it back in.
Computer response time is slow	The computer may have been shut down by loss of power rather than via Windows	Turn the computer on and let the computer reconfigure itself. This process may take several hours, and the unit may run slowly during this time.
	Too many images from previous use are being stored on the computer	Call Radlink Technical Support.
DR Status light reads "Initializing" instead of "Ready", or DR Panel will not connect	The wireless communication between the panel and the router on the GPS is blocked by a lead shield, or slow	Make sure there is no lead (in the X-ray generator, lead gown, or lead shield) between the bucky and the GPS.
	DR Panel battery may be low	Replace the battery with a fully charged battery.
	Unstable connection between DR panel and GPS	<ol style="list-style-type: none"> <li>1. Close Radlink Pro Imaging software by clicking Manage → Logout.</li> <li>2. Turn off the DR Panel.</li> <li>3. Turn on the DR Panel and wait until the LEDs stop flashing.</li> </ol> Launch Radlink Pro Imaging software.
The GPS will not turn on	The battery has been depleted because the GPS was not properly shut down	Call Radlink Technical Support.

**For questions, call Radlink Technical Support:**

**310-643-6900, ext. 2**

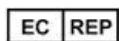
**Mon-Fri, 6:00 a.m. – 5:00 p.m. PST**

## 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 the instruction manual before using this product
	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
	This way up

Refer to Radlink GPS 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.


### European Representative Information





MDSS GmbH  
Schiffgraben 41  
30175 Hannover, Germany





## Warnings for Radlink GPS Unit

 The Radlink GPS has a non-detachable power supply cord. If broken, call Radlink Technical Support and service personnel will replace it


 Radlink Technical Support is the only approved Service Personnel


 Recommended that the user reads Radlink GPS user manual prior to operating unit


 Do not touch the Radlink GPS Console Cart and the patient at the same time


 The Radlink GPS has no “Applied Parts”, or parts meant for direct patient contact


 **WARNING** - No modification of the Radlink GPS is allowed


 **WARNING** - Do not modify the Radlink GPS 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 GPS unit


 **WARNING** - To avoid the risk of electric shock, the Radlink GPS must only be connected to a supply mains with protective earth


 No parts of the Radlink GPS shall be serviced or maintained while in use with a patient


 No parts of the Radlink GPS 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


 Antennas for the Wireless Router (08-14-017) must be 20cm from all persons & must not be co-located or operating in conjunction with any other antenna or transmitter


 Wireless LAN Adapter (08-14-007) should be installed & operated with minimum distance 0.5cm between radiator and human body


 **Contraindications:** Do not use the Radlink GPS for mammography


 **WARNING** - There is potential for electromagnetic or other reciprocal interference between the Radlink GPS and other medical electrical devices together. To minimize the possibility of such interference, keep other medical electrical equipment away from the Radlink GPS unit


 Installation is not required for the Radlink GPS


 Radlink GPS does not create any “waste products” during standard use. The device owner should properly dispose of the GPS unit in accordance with government regulations at the end of the device life


 The Radlink GPS uses batteries. The device owner should properly dispose of the GPS unit’s batteries in accordance with government regulations at the end of the device life.

 An additional multiple socket-outlet or extension cord shall not be connected to the Radlink GPS.


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


 Multiple socket-outlets provided with the Radlink GPS shall only be used for supplying power to equipment that is intended to form part of the device.

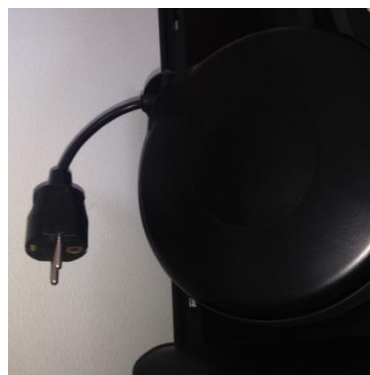
 Components are housed within their own individual enclosures and additionally placed inside the PACS cart enclosure. Liquid entering PACS cart enclosure and component enclosure is not likely to occur.


 If the pneumatic piston (for height adjustment) loses pressure, the table top may drop quickly once the user depresses the foot pedal.

 **WARNING** - The Radlink GPS is not configurable (or reconfigurable)

 The power plug and socket provide suitable means for isolation from the supply mains. Do not position the Radlink GPS so that it is difficult to operate the disconnection device (power plug to the wall)

 The disconnect device for the Radlink GPS is the power cable cord reel (on the left side) shown below:



 The assembly of the Radlink GPS and modifications during the actual service life require evaluation to the requirements of IEC 60601-1.



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