

# Radlink GPS Tablet User Manual

## *Galileo Positioning System™*



# Radlink Galileo Positioning System™ Tablet

## Product Overview

The Radlink GPS Tablet (Galileo Positioning System™) provides surgeons with real-time feedback on orthopedic implant component positioning. Together, the GPS Tablet 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 Tablet consists of a Tablet PC computer system that uses a touchscreen monitor & other image display accessories. Pre-operative images can be viewed on the GPS Tablet during surgery, which surgeons can use to reference against the intraoperative images captured during the procedure.

For posterior approach THA procedures, a flat panel detector (DR panel) is used to capture intraoperative images, which takes approximately four seconds to appear on the GPS Tablet. For anterior approach THA procedures, C-Arm images are instantaneously transferred to the GPS Tablet using the Radlink Wireless C-Arm Kit.

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# GPS TABLET SYSTEM OVERVIEW



# Radlink GPS Tablet Technical Specifications

## Basic Information

<b>Market name:</b>	Radlink GPS Tablet (Galileo Positioning System)
<b>Model:</b>	Radlink GPS Tablet 2200 (Available in 120V & 230V)
<b>Revision Level:</b>	Rev. 2.0
<b>Software Revision Level:</b>	3.8
<b>Purpose:</b>	Picture Archival Communication System (PACS)
<b>Potential Wireless Acquisition types:</b>	1.) Digital Flat Panel Digital Detector (FPD) <i>-Available in GadOx &amp; CsI Scintillator</i> 2.) Wireless C-Arm Kit (WCA)
<b>Potential Wired Acquisition types:</b>	None
<b>Detector Interface:</b>	Wireless only
<b>Dimensions of GPS Tablet:</b>	9.1" (Width) X 12.3" (Length) X 0.9" (Height Range)
<b>Weight:</b>	3.3 lbs. (GPS Tablet), 84.6 lbs. (Bucky Cart)
<b>Safe Working Load:</b>	1.5 kg
<b>Body Type:</b>	Tablet PC
<b>Operating System:</b>	Windows 10 Professional
<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 – (Perkin Elmer FPD)
<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 Tablet contains no PEMS required for basic safety or essential performance</li><li>- GPS Tablet contains no cooling liquids or oil lubrication systems</li></ul>

### **Overall Electrical Configuration:**

<b>Power Consumption:</b>	Average of 36 Watts
<b>Input Voltage:</b>	100-240 V (50/60 Hz)
<b>Input Current:</b>	1.0 Amps (AC) [No Fuses]
<b>Output Current:</b>	12V at 2.58 Amps, 5V at 1.0 Amps (AC)
<b>X-ray Energy Range:</b>	~40 kVp ~ 150 kVp
<b>Operating Temperature Range:</b>	41 – 104 °F (5 – 40 °C)
<b>Humidity Range:</b>	8-85% non-condensing
<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>	-104 – 140 °F (-76 – 60 °C)
<b>Humidity Range:</b>	8-95% non-condensing
<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

### SYSTEM START-UP

1. The GPS Tablet 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 GPS Tablet screen for 5 seconds to turn it on. The screen will illuminate within 5 seconds as the computer starts to boot.



3. Enter the password for the GPS User account if your facility has one, otherwise press enter to continue
4. Open the Radlink Pre-Op Viewer Software by double-clicking the desktop icon "Radlink Pre-Op" or open the Radlink Pro Imaging Acquisition Software by double-clicking the desktop icon "Radlink Pro Imaging"

### SYSTEM SHUT-DOWN

1. Shut-down the GPS Tablet 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 GPS Tablet has shut-down via Windows, close the lid and place it back in the carrying case with all of the accessories for display and power charging cables.

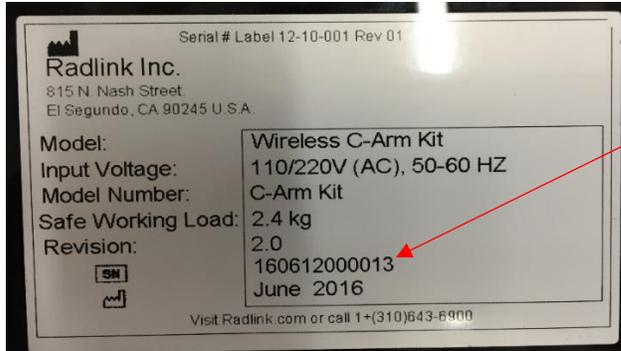
### CHARGING THE RADLINK GPS TABLET

1. Plug the power cable from the wall power source into the power port on the side of the GPS Tablet unit. Charge the Radlink GPS Tablet using the below provided charging cable (Radlink Part #: 13-14-001-C).



## CONNECT TO RADLINK WIRELESS C-ARM KIT

1. First, identify the last 4 digits of the Serial Number of the Radlink Wireless C-Arm Kit that you are trying to connect to. Make sure the device is powered on, and the green power light is illuminated



2. Once the GPS Tablet is powered-on and Windows has booted, prior to opening the Radlink Pro Imaging Software, click on the “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 “RadlinkWCAXXX”, where the XXXX represents the last 4 digits of the Wireless C-Arm Kit’s serial number.
4. The password for the network will be “radlinkwca”
5. Confirm the network shows “No Internet, Secured” under the wireless network name
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 “Wireless Frame Grabber” for the System Mode inside the software. Click the “Test” button and verify it is “Ready”.
7. Click “Save Settings” in the bottom right corner, and go to “Select Study” to begin

## CONNECT TO 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 GPS Tablet is on and Windows has booted, prior to opening the Radlink Pro Imaging Software, click on the “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”
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 GPS TABLET IN AN ANTERIOR APPROACH THA PROCEDURE

1. Make sure that your Radlink Wireless C-Arm Kit is on and connected to the wireless internet network “RadlinkWCAXXXX” where XXXX is the last 4 digits of the Wireless C-Arm Kit serial number
2. If images need to be pulled from PACS and WiFi access is not available, use the USB Ethernet LAN adapter with an Ethernet cable to plug into an Ethernet port.
3. Double-click the **Radlink Pre-op** icon on to access the PACS. Select the pre-operative image to be used as a reference during the case (if one is available)
4. Double-click the **Radlink Pro Imaging** to open the acquisition software
5. 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.
6. Once you are in **QC Image** page, click the **Grab Frame** tab.



7. C-Arm images will appear in the viewing window for review and measurement
8. If needed, click **Pano/Pano Static** tab for panoramic function.



9. Refer to the Surgeon's Checklist™ user manual for instructions on how to take measurements with the software.
10. If images need to be sent to PACS and WiFi access is not available, use the USB to Ethernet accessory cable provided with the GPS Tablet and plug into an Ethernet port.
11. Once cases have been completed for the day, turn off the Wireless C-Arm Kit, shut-down the GPS Tablet and plug both devices in to charge until their next use

## USING THE RADLINK GPS TABLET 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.

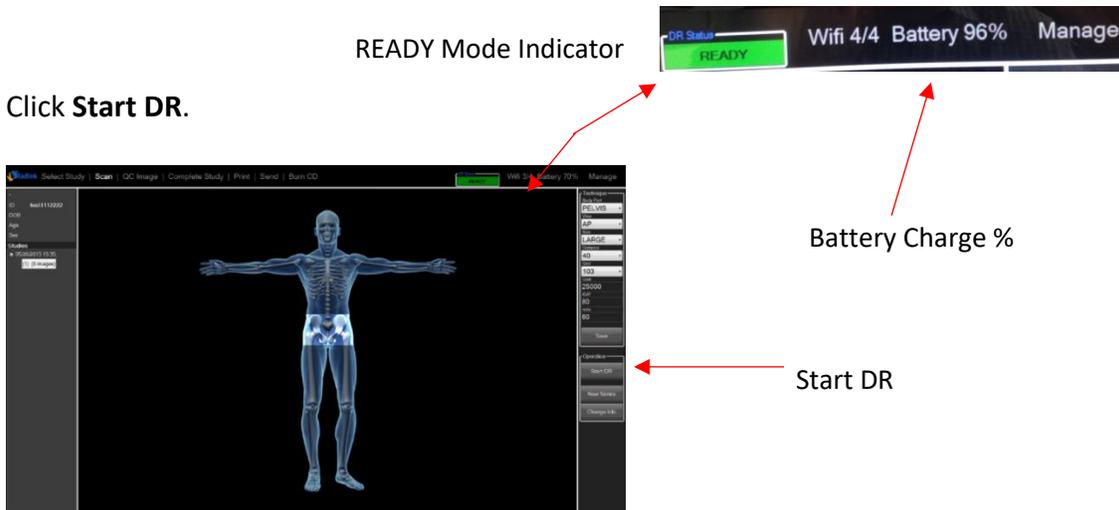


**Once the DR panel has been turned on, follow Steps 2-12 to complete the THA procedure:**

2. Double-click the **Radlink Pre-op** icon on to access the PACS. Select the pre-operative image to be used as a reference during the case (if one is available)
3. Double-click the **Radlink Pro Imaging** to open the acquisition software
4. 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, 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.

- Click **Start DR**.



- Take the intraoperative X-ray. The image will appear in the viewing window.
- 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 7-10.

## CHARGING 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 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.



## PREVENTATIVE MAINTENANCE

The Radlink GPS Tablet 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. 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 GPS Tablet 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 GPS Tablet. Don't use window cleaner or other chemical cleaners on your GPS Tablet.
  - **Keep it covered.** Close the cover while you're in transit or not using your GPS Tablet.
  - **Keep it out of the sun.** Don't leave your GPS Tablet 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 GPS Tablet. 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 GPS Tablet charger's cords, stop using the cord and contact Radlink Technical support.
- 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 Wireless C-Arm Kit	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 on the Wireless C-Arm Kit is not set to BNC or VGA mode (depending on your connection)	Press the Input button on the BNC Converter to switch to BNC mode.
	Wireless Frame Grabber is not selected as the System Mode 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 Wireless Frame Grabber is checked under System Mode</li> <li>3. Click Save Settings</li> </ol>
Touch screen is not responding	The user may be touching the inside of the monitor already in one place, blocking the sensors, and preventing it from registering another touch simultaneously	Only press on one location of the screen at a time to ensure consistent registering of every touch
Computer response time is slow	The computer may have been shut down by loss of power rather than via Windows	Restart your computer and allow it to reconfigure itself
	Automatic Windows Updates	Wait for the automatic updates to complete if the system is too slow
	Computer may be out of disk space – storing too many images	Call Radlink Technical Support.
DR Status light reads "Initializing" instead of "Ready", or DR Panel (Flat Panel Detector) will not connect	The wireless communication between the panel and the GPS Tablet is blocked by a lead shield, or slowed by obstructions in the path	Make sure there is no lead (in the X-ray generator, lead gown, or lead shield) between the Flat Panel Detector and the GPS Tablet
	Flat Panel Detector battery may be low	Replace the battery with a fully charged battery.
	Unstable connection between Flat Panel Detector and GPS Tablet	<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> <li>4. Launch Radlink Pro Imaging software.</li> </ol>
The GPS will not turn on or will not respond (or is stuck on a screen, and will not respond)	The battery has been depleted because the GPS was not properly shut down	Plug the GPS Tablet in to charge, and use it while plugged in if necessary
	The Windows Operating System on the Microsoft Surface Book encountered an error, and is locked in a nonresponsive state	<p>If the GPS Tablet will not respond, press and hold the power button for 35 seconds to hard reboot the Surface Book</p> <p>If your device is still not responding, please call Radlink Technical Support</p>

**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 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 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 TABLET UNIT

-  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 Tablet and the patient at the same time
-  The Radlink GPS Tablet has no “Applied Parts”, or parts meant for direct patient contact
-  WARNING - No modification of the Radlink GPS Tablet is allowed
-  WARNING - Do not modify the Radlink GPS Tablet 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 Tablet unit
-  Contraindications: Do not use the Radlink GPS Tablet for mammography
-  No parts of the Radlink GPS Tablet shall be serviced or maintained while in use with a patient
-  No parts of the Radlink GPS Tablet 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 GPS Tablet (13-14-001) full list of notices and warnings can be found at [www.surface.com/support](http://www.surface.com/support) for the Microsoft Surface Book
-  The Wireless Display Adapter (13-14-002) full list of notices and warnings can be found at [www.surface.com/support](http://www.surface.com/support) for the Microsoft Wireless Display Adapter
-  Tablet Wireless LAN Adapter (13-14-004) full list of notices and warnings can be found at [www.asus.com/support/](http://www.asus.com/support/) for the ASUS USB-AC51
-  WARNING - There is potential for electromagnetic or other reciprocal interference between the Radlink GPS Tablet and other medical electrical devices together. To minimize the possibility of such interference, keep other medical electrical equipment away from the Radlink GPS Tablet unit
-  Installation is not required for the Radlink GPS Tablet
-  The Radlink GPS Tablet does not create any “waste products” during standard use. The device owner should properly dispose of the GPS Tablet hardware in accordance with government regulations at the end of the device life
-  Position the Radlink GPS Tablet so the mains plug is readily accessible for quick disconnection from the power supply
-  The Radlink GPS Tablet uses batteries. The device owner should properly dispose of the GPS Tablet’s batteries in accordance with government regulations at the end of the device life.
-  WARNING - The Radlink GPS Tablet is not configurable (or reconfigurable)
-  An additional multiple socket-outlet or extension cord shall not be connected to the Radlink GPS Tablet while plugged in and charging
-  Only connect items that have been specified as part of the Radlink GPS Tablet or have been specified as being compatible with the unit.
-  To disconnect the Radlink GPS Tablet from power, remove the quick-connect power cable on the right side of the keyboard.
-  The accessories of the Radlink GPS Tablet and modifications during the actual service life require evaluation to the requirements of IEC 60601-1.
-  WARNING – To prevent falling hazards and potential damage, hold the Radlink GPS Tablet firmly or place securely on tabletops and desks

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