

Radlink Wireless C-Arm Kit User Manual

*An accessory of the Radlink GPS
& Radlink GPS Tablet*



Radlink Wireless C-Arm Kit

Product Overview

The Radlink Wireless C-Arm (WCA) Kit is an accessory device of the Radlink GPS (Galileo Positioning System™) & GPS Tablet that is used to wirelessly send images from a video source such as a C-Arm to the Radlink GPS or GPS Tablet. The Radlink Wireless C-Arm Kit is a computer system that accepts video signals from BNC, VGA, or DVI connections and converts these signals into an image file, which is then sent wirelessly to a Radlink GPS or GPS Tablet.

- GPS or GPS Tablet can connect to the WCA Kit network & grab video-signal frames in real time
- Radlink WCA Kit uses software integrated with software on GPS/Tablet (Radlink Pro Imaging)
- Device consists of an on-board CPU, image capture software, a converter that accepts various video signals, and a USB-mounted wireless router that connects with the GPS/Tablet.

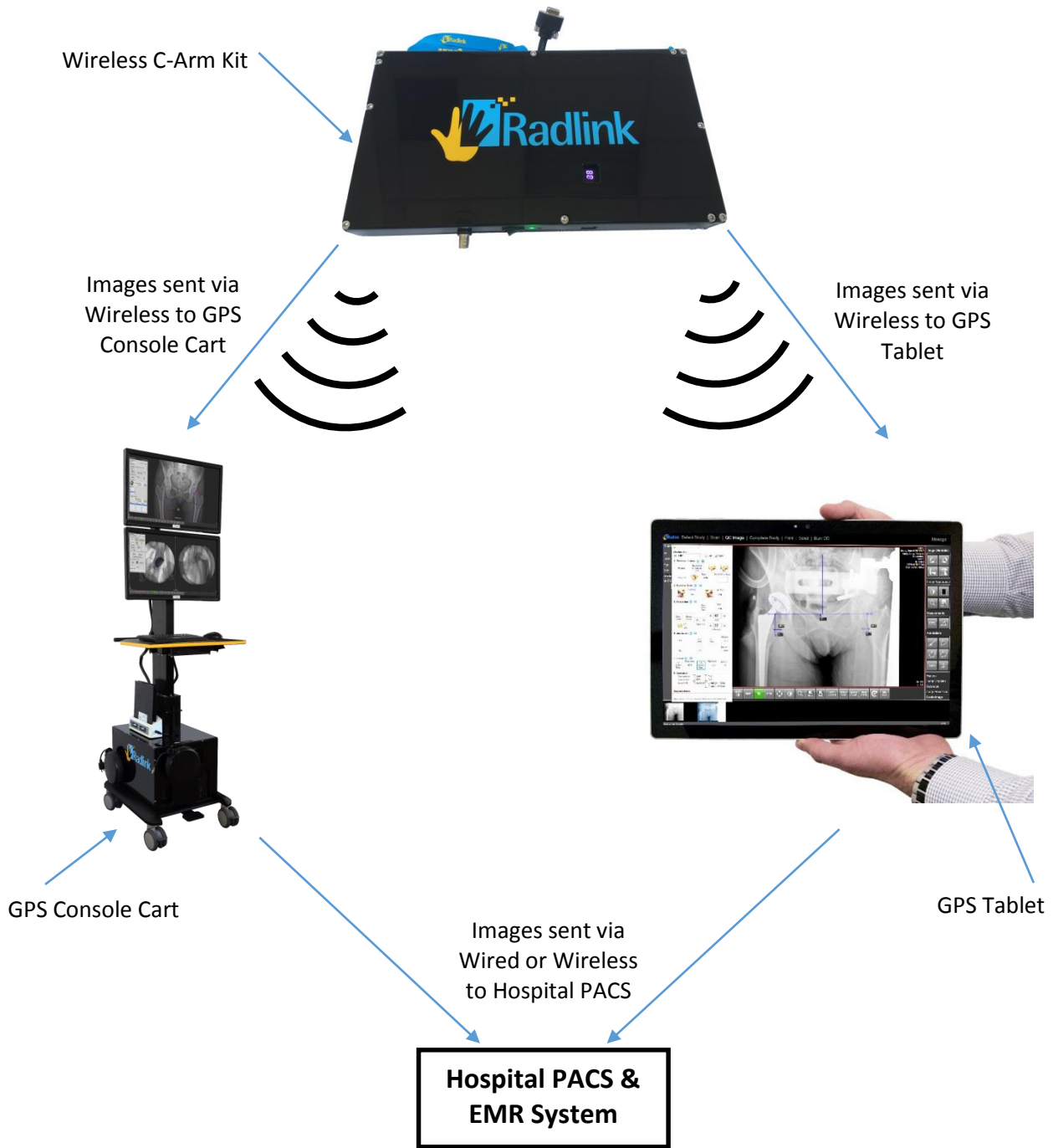
The Radlink GPS & GPS Tablet provides surgeons with real-time feedback on orthopedic implant component positioning. Together, the GPS product family and its Surgeon's Checklist™ software offer easy-to-follow steps designed to address challenges such as component positioning, sizing, limb length and offset restoration. The Radlink GPS product family consists of computer systems that use touchscreen monitors & other image display accessories. Pre-operative images can be viewed on the GPS products during surgery, which surgeons can use to reference against the intraoperative images captured during the procedure using the GPS products.

For anterior approach THA procedures, C-Arm images are instantaneously transferred to the GPS product family via wireless connection using the Radlink Wireless C-Arm Kit.

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Radlink Wireless C-Arm Kit System Overview



Radlink Wireless C-Arm Kit Technical Specifications

Basic Information:

| | |
|---------------------------------------|--|
| Market name: | Radlink Wireless C-Arm Kit |
| Model: | Wireless C-Arm Kit (WCA Kit) |
| Revision Level: | Rev. 3.0 |
| Software Revision Level: | 3.8 |
| Purpose: | Wireless Image Transfer Device |
| Input Types Accepted: | DVI-D, DVI-I/A, VGA, BNC |
| Image Transmission Method: | Wireless |
| Wireless C-Arm Kit Dimensions: | 16.0" (Width) X 7.7" (Length) X 1.7" (Thickness) |
| Weight: | 6.6 lbs. |
| Body Type: | Mobile & Mountable |
| Operating System: | Raspbian (Debian, optimized for Raspberry Pi) |
| Integrated Software: | Radlink Pro Imaging Wireless C-Arm Kit Software |
| External Standards: | IEC 60601-1 (Medical Electrical Equipment Safety) IEC 60601-1-2 (Medical Electrical Equipment EMC) IEC 60601-1-6 (Usability for Medical Devices) |
| Radio Frequency Compliance: | U.S.A. FCC Part 15 Subpart C & Subpart E |
| Expected Device Lifetime: | 5 Years |
| Battery Lifetime: | 10 Hours |
| Battery Recharge Time: | 2 Hours |

Overall Electrical Configuration:

| | |
|---|--|
| Power Consumption: | Average of 60-70 Watts |
| Input Voltage: | 100-240 V |
| Input Current: | 1.7 A |
| Temperature Range: | 32 – 104 degrees Fahrenheit (0 – 40 degrees Celsius) |
| Humidity Range: | 10% ~ 85% |
| Ingress Water Protection Rating: | IP20 – No Liquid Protection, Solids protection >12.5mm |

Transport & Storage Atmospheric Conditions:

| | |
|---------------------------|--|
| Temperature Range: | 32 – 104 degrees Fahrenheit (0 – 40 degrees Celsius) |
| Humidity Range: | 10% ~ 85% |

Device Classifications:

- Class I ME Equipment
- No Sterile Parts, Applied Parts, Detachable Parts, Disposables
- Not intended for use in oxygen rich environment
- Suitable for continuous operation mode
- No High Voltage Terminals or multiple socket outlets
- GPS Tablet contains no PEMS required for basic safety or essential performance
- GPS Tablet contains no cooling liquids or oil lubrication systems

Warnings for Radlink Wireless C-Arm Kit unit



Radlink Technical Support is the only approved Service Personnel



Recommended that the user reads Radlink Wireless C-Arm Kit User Manual prior to operating unit



Do not touch the Radlink Wireless C-Arm Kit and the patient at the same time



The Radlink Wireless C-Arm Kit has no “Applied Parts”, or parts meant for direct patient contact



WARNING - No modification of the Radlink Wireless C-Arm Kit is allowed



WARNING - Do not modify the Radlink Wireless C-Arm Kit 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



WARNING - To avoid the risk of electric shock, the Radlink Wireless C-Arm Kit must only be connected to a supply main with protective earth.



No parts of the Radlink Wireless C-Arm Kit shall be serviced or maintained while in use with a patient



No parts of the Radlink Wireless C-Arm Kit are suitable for use within the patient environment



Do not use near water/liquid – Radlink Wireless C-Arm Kit does not have Ingress Protection Rating for liquid



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



To maintain wireless signal strength, do not use near source of EMC or RF interference



Installation is not required for the Radlink Wireless C-Arm Kit

Warnings for Radlink Wireless C-Arm Kit unit (Continued)



Position the Radlink Wireless C-Arm Kit so the mains plug is readily accessible for quick disconnection from the power supply



Antennas for the Wireless Router (12-14-003) inside of the Wireless C-Arm Kit must be 20cm from all persons & must not be co-located or operating in conjunction with any other antenna or transmitter



The on-board wireless LAN Adapter in the Raspberry Pi 3 (12-14-005) should be installed & operated with minimum distance of at least 20cm between radiator and human body and must not be co-located or operating in conjunction with any other antenna or transmitter, except in accordance with FCC multi-transmitter product guidelines



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



The Radlink Wireless C-Arm Kit 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 Wireless C-Arm Kit is not configurable (or reconfigurable)



An additional multiple socket-outlet or extension cord shall not be connected to the Radlink Wireless C-Arm Kit while plugged in and charging



Only connect items that have been specified as part of the Radlink Wireless C-Arm Kit or have been specified as being compatible with the unit



To disconnect the Radlink Wireless C-Arm Kit from power, unplug the charging cable from the side of the device



The accessories of the Radlink Wireless C-Arm Kit and modifications during the actual service life require evaluation to the requirements of IEC 60601-1

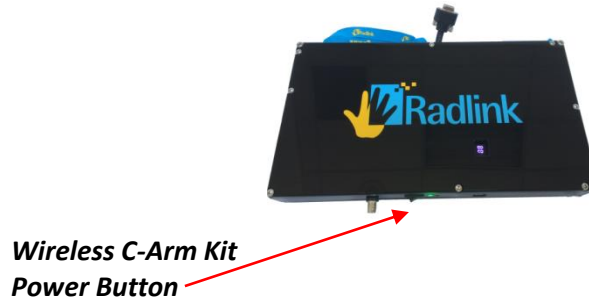


WARNING – To prevent falling hazards and potential damage, place the Radlink Wireless C-Arm Kit securely on tables or hanging locations using the support lanyard

FREQUENTLY USED FUNCTIONS

System Start-up

1. The Radlink Wireless C-Arm Kit runs on battery power, so it may not be necessary to plug the unit into power in order to start the system
2. Press the **Power Switch** on the bottom side of the Wireless C-Arm Kit to turn it on. The blue lights will illuminate within 5 seconds as the system powers on. If not, plug in the unit



System Shut-down

1. Shut-down the Wireless C-Arm Kit by pressing the **Power Switch** on the bottom side
2. The blue light will turn-off, to indicate that the Wireless C-Arm Kit has been powered-off

Charging the Radlink Wireless C-Arm Kit

1. Plug the Radlink Wireless C-Arm Kit Charging Cable from the wall power source into the power port on the side of the Wireless C-Arm Kit unit. Charge the Radlink Wireless C-Arm Kit using the below provided charging cable (Radlink Part #: 12-30-017).

The third conductor (circular)
is a functional earth
connection (ground)



Connect Radlink Wireless C-Arm Kit to a GPS Tablet

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 blue power light is illuminated. The illuminated green light will indicate that the router is ready to connect
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 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 “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 Radlink Wireless C-Arm Kit to a GPS Console Cart

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 blue power light is illuminated. The illuminated green light will indicate that the router is ready to connect
2. Once the GPS Cart 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 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 “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

Using a 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 WCA Kit serial number
2. If images need to be pulled from PACS and WiFi access is not available:
 - For GPS Cart - pull the Ethernet cable from its cord reel and plug into an Ethernet port,
 - For GPS Tablet – connect the USB to LAN Adapter accessory cable and plug into network
3. Double-click the **Radlink Pre-op** icon on the computer desktop 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. **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, use the hard-wire ethernet network-connection steps listed in #2 of this section
10. 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

TROUBLESHOOTING
















| Issue Experienced | Description of Problem | Solution |
|--|--|---|
| <p style="text-align: center;">Your GPS or GPS Tablet Unit is not pulling images from the Radlink Wireless C-Arm Kit</p> | <ul style="list-style-type: none"> - The Wireless C-Arm Kit may be powered off - The Wireless C-Arm Kit may be out of battery power - The Wireless C-Arm Kit is on, but not connecting to my GPS unit - The video output at the back of the C-Arm monitor may be damaged or broken - The signal mode on the Converter on the Wireless C-Arm Kit is not set to BNC or VGA mode (depending on your connection) - “Wireless Frame Grabber” is not selected as the System Mode in the software | <p>Verify that the power switch on the bottom side of the unit is on, and the green light is illuminated</p> <p>Plug in the Wireless C-Arm Kit into wall-power to charge while in use</p> <p>Verify in Windows on the GPS unit that the wireless network shows “Connected” to the WiFi network “RadlinkWCAXXXX”, where the XXXX represents the last 4 digits of the WCA Kit’s serial number</p> <p>Adjust/repair the video output port or try using a different C-Arm port</p> <p>Press the Input button on the BNC Converter on the Wireless C-Arm Kit to switch to BNC or VGA mode</p> <ol style="list-style-type: none"> 1. Open the Radlink Pro Imaging software and click “Manage”. 2. Make sure the Wireless Frame Grabber is checked under System Mode 3. Click Save Settings |

For questions, call Radlink Technical Support:

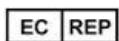
310-643-6900, ext. 2

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 |

European Representative Information



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



Preventative Maintenance

The Radlink Wireless C-Arm Kit 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 Wireless C-Arm Kit. 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 mitigate potential spread of infectious disease by thoroughly cleaning the surfaces of the Radlink Wireless C-Arm Kit which have come into contact with any equipment from those environments.

2. Periodic re-charging of system batteries:

- **Charge Battery Fully:** The best method to get the maximum lifetime from your lithium ion battery pack is to charge the battery for a full 4 hours prior to disconnecting it from power
- **Turn battery off while not in use:** The best method to get the maximum lifetime from your lithium ion battery pack is to turn the WCA Kit off while not in use, or in preparation for use
- **Keep system within temperature & humidity ranges:** The best method to get the maximum lifetime from your lithium ion battery pack is to keep it within proper atmospheric conditions

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 run over the Radlink Wireless C-Arm Kit power cable with other equipment, carts, or place heavy/sharp objects on top of it
- Don't wrap your power cord too tightly, especially around the power brick. Instead, wrap it using loose coils rather than creating tight angles or tension in the cord.
- Inspect your power cord regularly, especially where it joins the power brick, to make sure the connections are clean and tightly secured.
- Avoid pulling on the power cord when unplugging your Wireless C-Arm Kit. Gently removing the connectors from the charging connector can help prevent damage to your power cord.
- If you find any damage on any part of your Radlink Wireless C-Arm Kit charger cable, stop using the cable and contact Radlink Technical support for a replacement.

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