



Galileo Positioning System™



Overview and System Basics for THA

Radlink History and Overview

Radlink is based in Southern California and has been in business since 1999 as a producer of digital radiography equipment. Our product line includes the Galileo Positioning System™ (GPS) for intra-operative imaging, direct radiography (DR) systems, computed radiography (CR) systems, film digitizers, and PACS solutions for the surgeons' private office.

Radlink products are known for advanced image processing capabilities and user-friendly software.

The GPS combined Radlink's direct radiography capabilities with a proprietary software program, Surgeon's Checklist™, that allows the surgeon to take intra-operative measurements. A second computer monitor was added to the system to allow the surgeon to view pre-operative images during the case as well as capturing and taking measurements on intra-operative images.

The software for direct posterior approach THA was co-developed with Dr. Brad Penenberg at Cedars Sinai Medical Center. The Surgeon's Checklist™ software for anterior approach THA was co-developed with Dr. Joel Matta at St. John's Health Center.

Galileo Positioning System (GPS)

Overview

The Radlink GPS consists of a computer system with two monitors – one to show pre-operative images and the other to show intra-operative images taken during the case. The system uses a proprietary software program called Surgeon's Checklist™ that allows the surgeon to take intra-operative measurements. Using information provided by the software, the surgeon can adjust cup position and/or component size before Leaving the Operating Room.

At this time, the GPS is primarily being used for THA surgeries, allowing the surgeon to measure abduction and anteversion angle of the acetabular cup as well as limb length and offset.

Both monitors have touchscreen capabilities so the surgeon can operate the software by using a sterile instrument.

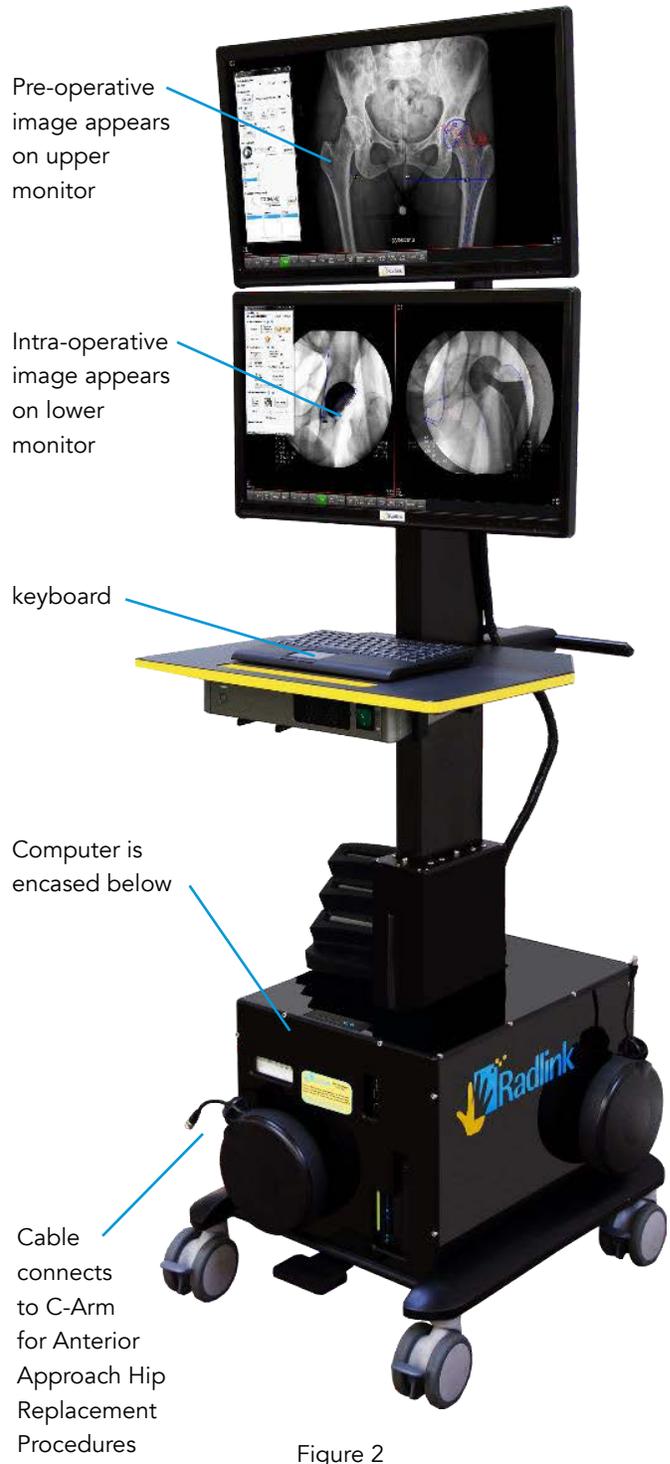


Figure 1

Figure 2

Using the Galileo Positioning System™ (GPS) in a Posterior Approach Total Hip Arthroplasty Case

A flat panel detector (DR panel) is used to obtain intra-operative images during posterior approach THA procedures. (Figure 3)

The DR panel is inserted into a grid for protection. The grid and panel are part of a height-adjustable mobile bucky, or cart, that is wheeled up next to the operating table to capture the image.

Once the implant has been placed, an X-ray generator is brought into the room and placed across the table from the bucky. The digital images captured by the DR panel are sent wirelessly to the GPS unit. The GPS unit works with any brand of X-ray generator. (Figure 4)



Figure 3

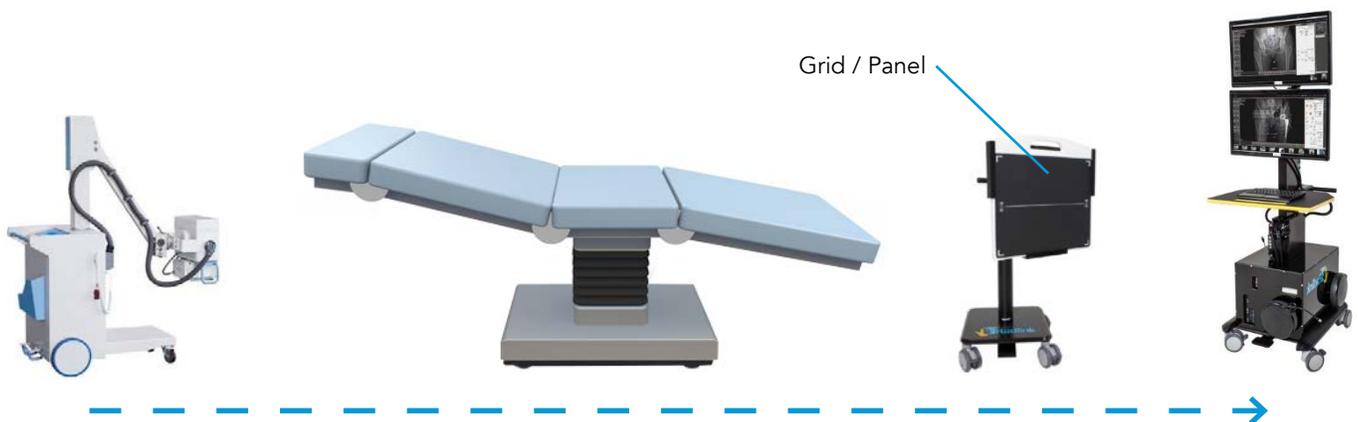


Figure 4

Using the Galileo Positioning System™ (GPS) in a Posterior Approach Total Hip Arthroplasty Case

Continued

Once the intra-operative image has been taken, measurements can be taken for cup abduction and anteversion angles, limb length and offset.

If the surgeon decides to make adjustments to cup position or component size, additional images and measurements can be taken to verify that final cup position and sizing are acceptable to the surgeon.

Pre-operative image is displayed on upper monitor

Intra-operative image is displayed on the lower monitor



Figure 5

Using the GPS in a Direct Anterior Approach Total Hip Arthroplasty Case

In direct anterior approach THA cases, the GPS pulls intra-operative images from the C-Arm. A cable connects the GPS to the C-Arm monitor for this purpose. The GPS works with any brand of C-Arm.

As C-Arm images are taken during the procedure, the person operating the GPS presses a button that transfers each image over to the GPS instantaneously. If the surgeon chooses to adjust the cup position or change component size based on information generated by the software, a new C-Arm image can be taken and imported. The surgeon can then take measurements on the additional images.



Figure 6



C-Arm images are instantly transferred to the GPS monitor by pressing the GRAB FRAME button

Figure 7

Pre-operative Images

During the demonstration phase, before the unit is sold, pre-operative images can be loaded into the GPS via flash drive or CD.

Once a GPS unit is sold and installed, Radlink personnel configure the system to tie into the hospital PACS. Pre-operative images can then be pulled from the PACS before each case.

Software

There are three software programs on the Radlink GPS unit.

The first is called Radlink Pro Imaging software and this allows the GPS unit to acquire, send, print and burn images as needed. Radlink also has the ability to "QC" images (change orientation and image appearance, calibrate for distance and make annotations on the screen).

See Appendix A (page 10) for an overview of the Radlink Pro Imaging Main Menu, QC Image Functions and Hot Buttons.

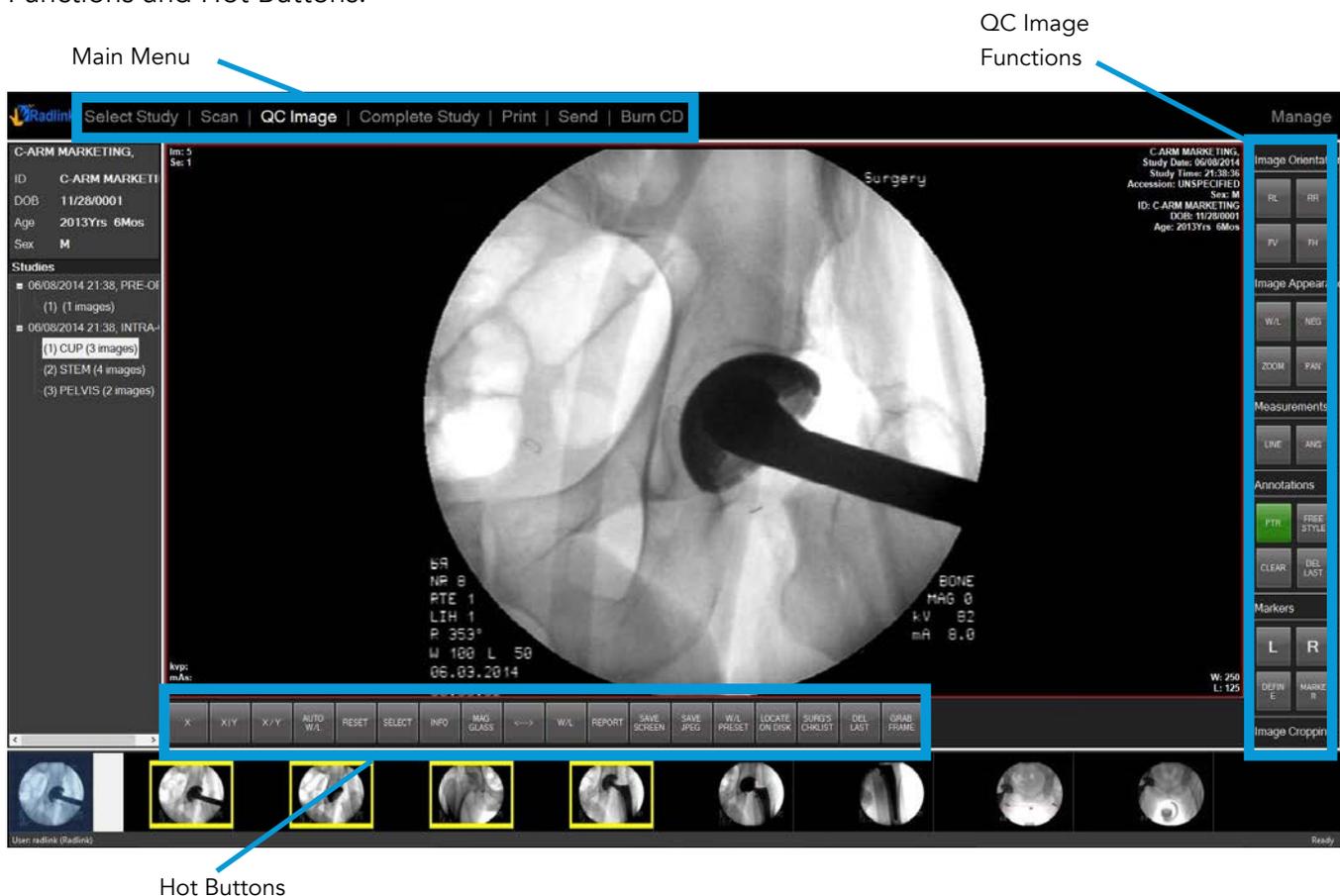


Figure 8

Software

Continued

The second software program used by the GPS is the Surgeon's Checklist™ software that allows the surgeon to measure acetabular cup angles, limb length and femoral offset. There are three software modules pertaining to hip procedures: Anterior Hip, Posterior Hip (simply called "HIP"), and Pre-Operative Hip.

Surgeon's Checklist™ for
Posterior Approach Hip
Replacement Procedures

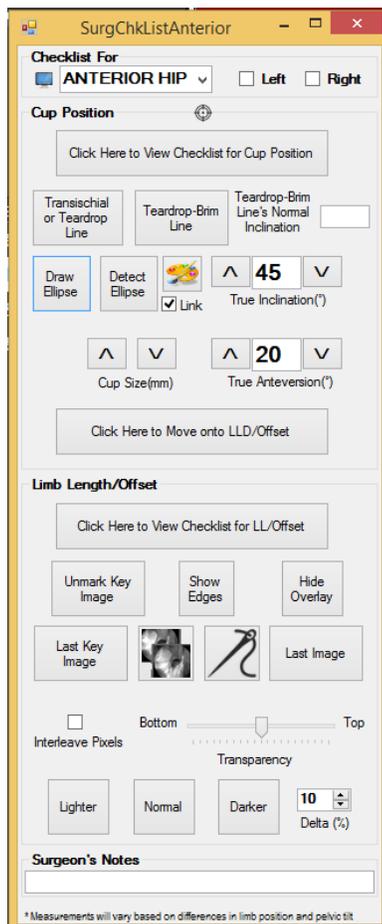


Figure 9

Surgeon's Checklist™ for
Anterior Approach Hip
Replacement Procedures

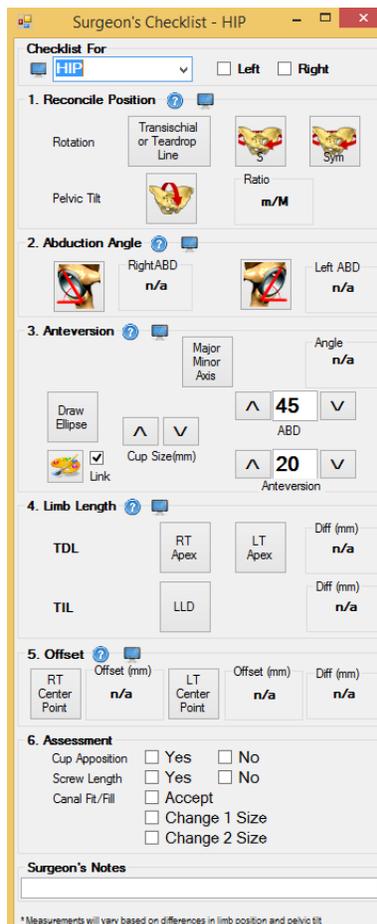


Figure 10

Surgeon's Checklist™ for
Pre-Operative Hip
Replacement Procedures

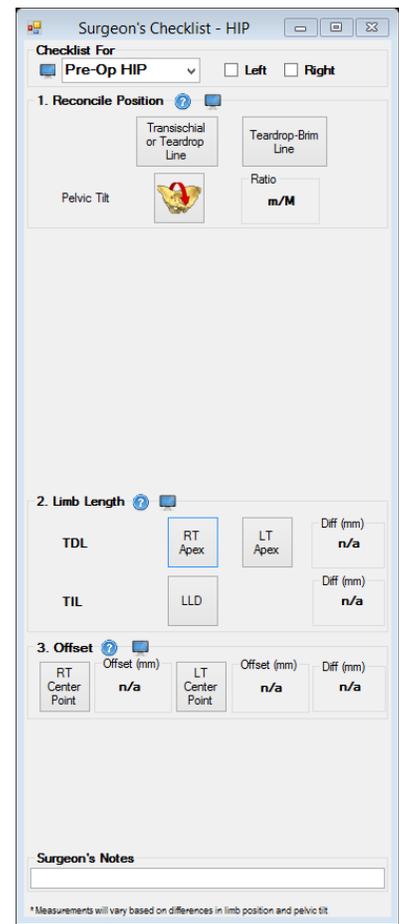


Figure 11

Software

Continued

The Surgeon's Checklist™ software is launched by clicking the SURG'S CHKLIST Hot Button once the Radlink Pro Imaging software is open.

Surgeon's Checklist™ can be launched on either monitor to take measurements on pre-operative or intra-operative images.

Please see the Surgeon's Checklist™ Anterior Software User Guide and the Surgeon's Checklist™ Posterior Software User Guide for details on how to use the software.

The third software program on the GPS is called the Pre-op Viewer. This software is normally launched on the upper monitor and allows viewing of the pre-operative image.



Figure 12

Appendix A

Radlink Pro Imaging Software – Main Menu

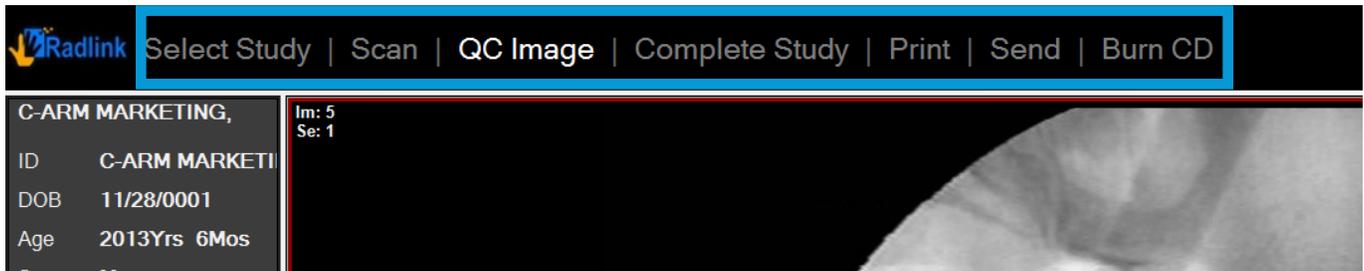


Figure 13

- Select** Study Allows a study to be pulled from the PACS
- Scan** Used to acquire image from DR panel during a posterior case
- QC Image** Allows appearance and orientation of images to be manipulated
- Complete Study** Pushes study to hospital PACS
- Print** Prints study to a DICOM printer
- Send** Allows user to sends an individual image, series of images, or a complete study to a specific, designated destination
- Burn CD** Burns study to a CD

Radlink Pro Imaging Software

QC Image Functions

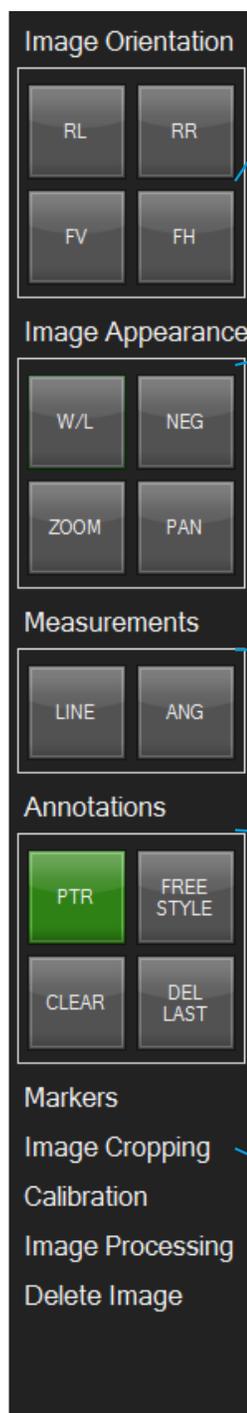


Image Orientation

RL = Rotates image 90 degrees to the left

RR = Rotates image 90 degrees to the right

FV = Flip Vertical – flips image over and vertical 180 degrees.

FH = Flip Horizontal – flips image over and horizontal 180 degrees.

Image Appearance

W/L = Window Level – allows user to adjust contrast and brightness

NEG = Image appears as negative

Zoom = Zoom in

Pan = Move the image

Measurements

Allows measurements and angles beyond those provided by Surgeon's Checklist™

Annotations

PTR = Insert pointer (arrow) on the screen

FREESTYLE = draw freestyle

Clear = Clears screen of all prior inputs

Del Last = deletes last input

Markers = Insert R or L marker

Cropping = Crop image

Calibration = Calibrate distance

Image Processing = Converts "raw image" into viewable image

Radlink Pro Imaging Software

Hot Buttons



Hot Button	Description
X	Displays on image on the screen
XIY	Displays two images side by side
X/Y	Displays two images one on top of another
Auto W/L	Restores origina Window Level (W/L) setting
Reset	Restores all image orientation, image appearance, measurements, and annotations to their original values
Select	Resets to previous mode
Info	Overlays patient information on the image
Mag Glass	Inserts a magnifying glass onto the image to magnify an area of interest
<- ->	Expands the image to full screen
W/L	Window Leveling Click and drag mouse (or use touch screen) horizontally to change brightness Click and drag mouse (or use touch screen) vertically to change contrastv Click W/L twice to access ROI (Region of Interest) Window Leveling
Report	Create a report – attach notes to a study and save to PACS with the images
Save Screen	Saves the current screen
Save JPEG	Saves image as a compressed JPEG file
W/L Preset	Pre-set window-level setting for designated areas of the body
Locate on Disk	Locates Dicom image in computer folder
SURG's CHKLIST	Launch Surgeon's Checklist™ software
DEL LAST	Grab image from C-Arm

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