Zimmer® PSI Shoulder

CT Protocol

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Zimmer PSI Shoulder CT Protocol

CT scans to be used in conjunction with ***Zimmer Patient-Specific Instruments (PSI) Shoulder*** must be performed following the settings provided in this protocol at a Zimmer pre-qualified medical imaging center. The goal of this protocol is to provide guidelines to help with:

- Patient positioning
- Producing consistent images with adequate image quality
- Comply with the ALARA principle

With the goal of maximizing the accuracy and utility of the images for surgical planning and intraoperative instrument guidance.

The product delivered to Zimmer by the imaging center is a series of DICOM axial images of the patient's scapula. The Zimmer team will use this axial series to generate a 3D model of the anatomy and enable the surgeon to visualize and plan the implant placement, as well as to generate patient-specific instrument guides for intraoperative use.

The Zimmer CT Scan Protocol defines the parameters required to get a proper scapula's reconstruction and maximize the performance of the PSI instrument guides. It is critical that this protocol is followed precisely. If deviations to this protocol must be made to uphold the radiological standard of care, the medical imaging center must notify Zimmer (Contact information in the last section) and the prescribing surgeon of this deviation before submitting the data to Zimmer.

1. Patient Preparation and Positioning

The patient should be positioned within the gantry according to the following criteria:

- The patient lies Supine, Head First (HFS) or Feet First (FFS)
- The arms are extended and relaxed on both sides of the body

2. General Scan Specification

An axial image series of the patient's scapula is to be produced. The cortical bone structure of the glenoid should be clearly visible and the resulting images should be homogeneous (smooth) without distortion or artifact. The final DICOM output should be a set of axial slices that contain the entire scapula including the complete medial border down to the inferior angle and the humeral head.

3. Specific Parameters

3.1. Acquisition Parameters

- The slice thickness should not exceed 1mm.
- The scan spacing should be equal to slice thickness (contiguous slices = no overlap)
- The pitch* should be set to 1:1
- The gantry should not be angled (Tilt of 0° / No tilt)
- Close the Supero-Inferior (SI) Field of View (FOV) tightly around the scapula and open the Medio-Lateral (ML) FOV just enough to include the full scapula and proximal humerus.

3.2. Post-Processing Parameters

- The filter/algorithm settings should moderately smooth the image. Use a standard or medium smoothing kernel and do not apply a "Bone/Sharpening" filter.
- Only the axial series is necessary; there is no need to include sagittal or coronal slices, SCOUTS (localizers, study plannings), nor 3D reconstructions.

3.3. DICOM Export Settings

- Includes the axial series only.
- The DICOM images should have matrix dimensions of 512 by 512 pixels and a spatial resolution of 1 mm or less.

3.4. Important notes

- A primary function of this scan is to get a good view of the cortical surface of the glenoid. Please adjust the technique to maximize the visibility (contrast) of the cortical bone, while keeping patient radiation dose as low as reasonably achievable, consistent with your radiological training and the ALARA principle.
- Image artifact caused by metallic implants can obscure anatomy of interest. Please take any available steps to minimize metal artifact including positioning any metal out of the beam and/or application of metal artifact reduction corrections if available.
- Image distortion from patient motion can severely compromise the accuracy of PSI Shoulder. Please ensure that scans are free from motion artifact. If patient motion occurs, the scan must be restarted.

* *"Table distance traveled in one 360° rotation/total collimated width of the X-ray beam"*

4. Zimmer PSI Shoulder CT Protocol Summary Table

Patient position	Head First Supine (HFS) or Feet First Supine (FFS) Arms resting along the body.
Slice thickness	1mm or less. Slice Thickness should be equal to slice spacing.
Topogram Direction	Craniocaudal Start above Acromial-Clavicular (AC) joint and scan through the bottom of the scapula
Acquisition (Scan Type)	Helical or Volume
Field of view	 Set Field of View to include the entire scapula and proximal third of humerus. Ensure that the inferior and medial parts of the scapula are fully included in the FOV.
Slice spacing (scan spacing)	1mm or less. Slice Spacing should be equal to Slice Thickness. (E.g. Slices should be contiguous with no overlap.)
Pitch	1:1
Gantry angle (tilt)	0° (no tilt)
Slice reconstruction	Axial slices only
Reconstruction filter / algorithm / Kernel	Standard or Medium Smoothing Kernel. For example: GE: Standard Siemens: Medium Kernel Toshiba: Medium Kernel
Reconstruction matrix	512x512 (DICOM)

The CT Scan Protocol defines the most important parameters that will influence the performance of the system.
It is therefore critical that the protocol be followed correctly unless a deviation is required to uphold normal standard of radiological care. If a deviation is needed please notify the Zimmer representative at the time of submitting the images.

5. Imaging center pre-qualification

A CT scan of a Phantom Scapula is required to be submitted in order to pre-qualify an imaging center for use with Zimmer PSI Shoulder. Please complete the following steps:

1. Obtain a Sawbone™ scapula model (p/n 1021-1 or 1021) either from www.sawbones.com or from your Zimmer representative to be used as the imaging Phantom.
2. Scan the Phantom using the protocol requirements described in this document. Be sure to scan the entire scapula.
3. Transfer the DICOM axial image data to Zimmer using the instructions described in the following section, or provide to the Zimmer representative for transmission.

Figure 1: Sawbones Scapula Phantom to generate sample scan for site pre-qualification

6. CT Scan transfer through Zimmer SMS (Surgical Management System)

Zimmer SMS (ZSMS) is a platform that Zimmer uses to manage surgical scheduling and transmission of information surrounding surgical cases including PSI images and preoperative plans. To access ZSMS please work with your Zimmer representative to set up an External User account. The URL is www.zimmersms.com.

Once your account has been set up, you may access a user instruction document entitled "*HT-CTS-009- Adding & Qualifying Scan Equipment for a PSI Scan Center*". This document can be downloaded or viewed from the Help Section of ZSMS.

Follow the steps below for the transfer of images through ZSMS. Note that removal of Patient-Identifying information is NOT required for CT Scan upload on ZSMS.

1. Acquire the images according to the technique described in this document.
2. Save the scans in the DICOM file format.
3. ZIP the DICOM image files all together into a single .zip (compressed) file. (See Section 8)
4. Rename the ZIP (compressed) file:
   a. For a Phantom Scan for Site Qualification: rename the file to ABC1234L.zip
   b. For a patient case: rename it with the PSI Case ID provided corresponding to the case. (This Case ID can be obtained either from ZSMS or from the Zimmer Representative.)
5. Upload the ZIP file on SMS using the applicable scenario described below.
   a. For Patient Scans: follow section 6.1.
   b. For Phantom Scans for site qualification: follow section 6.2.

6.1. ZSMS Transfer of Patient CT

Once logged on ZimmerSMS, transfer the images by clicking on “UPLOAD SCANS” in the corresponding case which will bring you to the upload page.

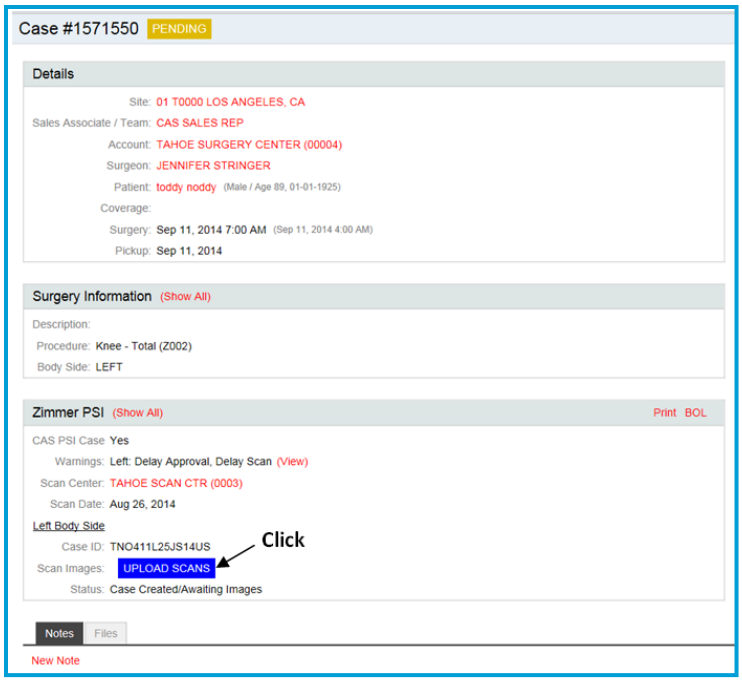


Figure 2: Transfer of Patient CT scan on ZSMS

6.2. ZSMS Transfer of Phantom CT

Phantom scans for site qualification are handled a little differently. Once logged on ZimmerSMS, in the “Cases” tab, click on “Manage Scanners” and then on the link under the “Files” column to bring you to the upload page.

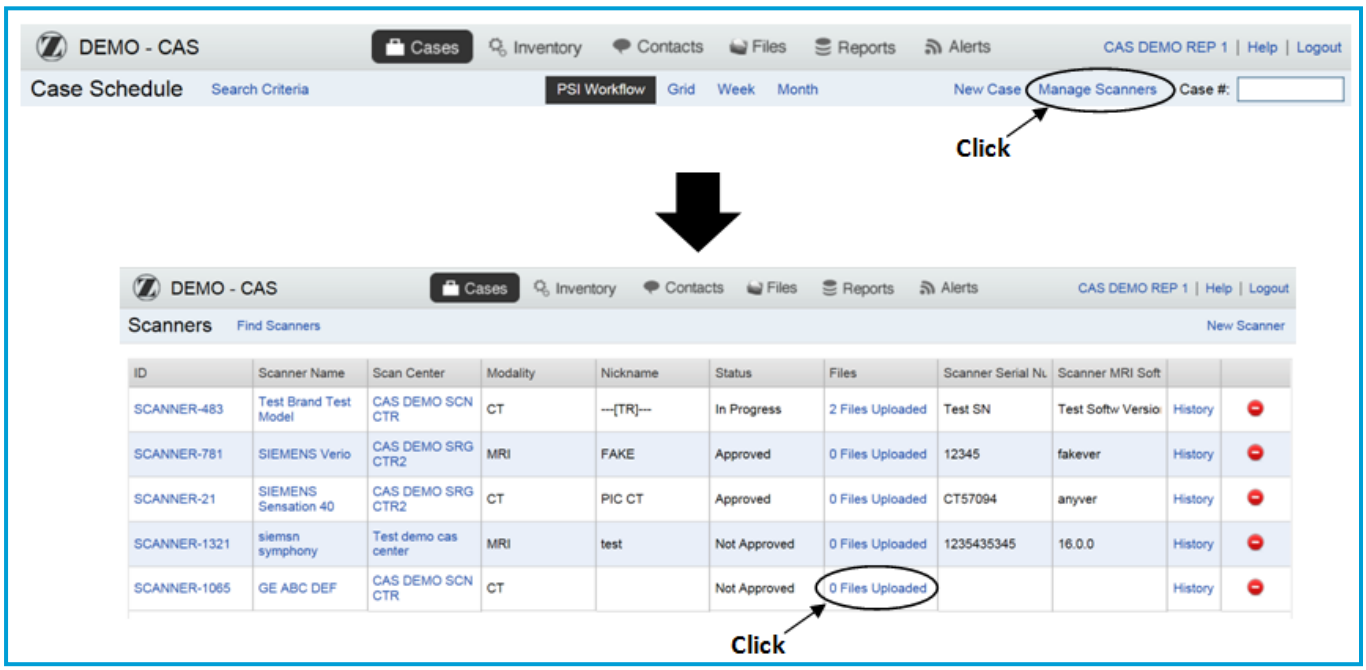


Figure 3: Transfer of Phantom Scan on ZSMS, for site pre-qualification

7. CT Scan Transfer through other transfer methods (non–ZSMS)

(CD, DVD, USB, FTP, other transfer methods such as www.wetransfer.com, www.hightail.com[‡])

Note that removal of patient identifying information is ALWAYS required for CT data transfer outside of the ZSMS system.

When transmitting images outside of ZSMS, the imaging center is responsible to reduce the patient identification of the DICOM images set to appropriately maintain patient privacy. The reduced identification shall remove any element which could allow patient identification, including but not limited to Patient Name, Date Of Birth, Social Insurance Number, Phone Number, etc.

Follow the steps below for the transfer of images:

1. Acquire the images according to the protocol and save axial series in DICOM file format
2. Reduce the patient information contained in the DICOM images as shown in Table 1. (Note that this differs if the CT Scan is a patient case or a phantom for site qualification)
3. Zip / Compress the DICOM image files all together into a single .zip (compressed) file. (See Section 8)
4. Rename the ZIP file (compressed) file according to Table 1 first row:
5. Transfer the ZIP file to Zimmer using the desired method. (See last page for Contact information.)

Table 1 | Reduced Identification Parameters

DICOM Field	Phantom Scan for Site Qualification	PATIENT Case
	Value	**Value**
Patient Name (0010,0010)	**ABC1234L** (Put this actual value)	**XXXYYYYR** (Zimmer PSI Case ID) (8 or 15 characters)
Patient ID (optional) (0010,0020)	**HOSP12345** (Put this actual value)	**XXXXYYYYYY** (Hospital Patient ID)
Patient Birth Date (0010,0030)	**1900/01/01** (If date can't be deleted, put this actual value)	**1900/01/01** (If date can't be deleted, put this actual value)

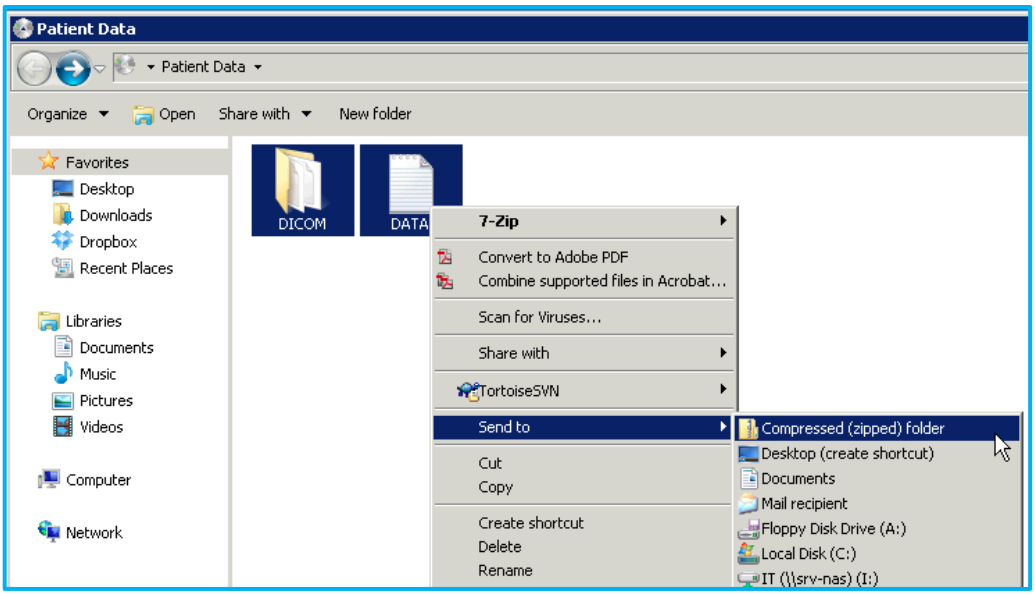
[†] Zimmer does not endorse or recommend any particular transfer method. It is the responsibility of the transferring party to ensure that the transfer method complies with applicable privacy and security laws and regulations.

[‡] Do NOT use "ALTE" (DICOM export via PACS) to save the images. "AGFA" or preferably CD should be used. If you are located in EMEA, refer to *806 001 - PSI Logistics Guide EMEA.*

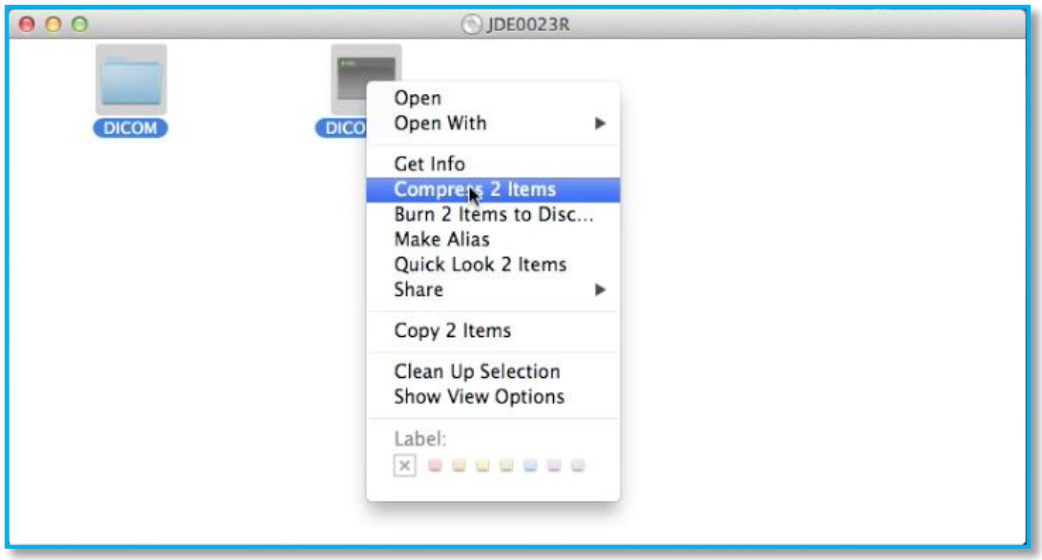
8. How to Zip a DICOM Image Series

When transmitting images to Zimmer, the data must be compressed or "zipped" into a single file. To accomplish this: First, copy the folder containing all DICOM images to the computer desktop. Then, right click on this folder and select Compress. The following images show how this is done on a computer with a PC or Mac operating system:

8.1. Compressing files on a PC:



8.2. Compressing files on a Mac:



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