

Signature™ ONE

Scanning Protocol



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*DICOM is a registered trademark of the National Electrical Manufacturers Association

Signature™ ONE Scanning Protocol

CT scans acquisitions made for Signature™ ONE must be performed using the settings provided in this protocol. The shoulder CT scanning protocol consists of an axial high resolution scan of the patient's scapula and humerus. CT scan quality can directly affect guide manufacturing and accuracy of the glenoid guide. These protocol steps were determined for optimum scan quality.

The CT scanner parameters must be set before the first Zimmer Biomet patient scan. An initial sample scan is required to qualify your specific equipment and help you become accustomed to the protocol. Details on how to qualify your equipment is provided in section 4.

The goal of this protocol is to provide guidelines to help you with:

- Patient preparation
- Producing consistent images with adequate image quality

This protocol must be followed closely. If deviations must be made to uphold the radiological standard of care, the imaging center must confirm the deviation with Zimmer Biomet and notify the prescribing surgeon before submitting the data to Zimmer Biomet. Unconfirmed deviations to this protocol may result in unusable images.

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 patient's shoulder joint is in a neutral resting/relaxed position
- Arms are resting straight alongside the body and touching the chest wall with the palms facing the sagittal plane on both sides of the body
- The patient must not move during the acquisition
- Verify that there are no metallic objects near the region to be scanned as this could generate artifacts on the images

2. Scan Specification

The scan is executed as a single acquisition scan. Only axial images are required and no image reformatting is needed. The cortical bone structure of the glenoid should be clearly visible and the resulting images should be homogeneous (smooth) without patient movement, distortion or artifact. Please adjust the technique to maximize the visibility (contrast) of the cortical bone, while keeping patient radiation dose as low as reasonably achievable. 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 proximal third of humerus, at a minimum, including the entire humeral head.

Slice Thickness and Spacing (Collimation)

- The pixel spacing must be less than 1 mm x 1 mm
- The slice thickness must not exceed 1 mm and be constant throughout the acquisition
- The scan spacing should be equal to slice thickness
- Slices should be contiguous with no overlap

Field of View (FOV)

- Use a 250 mm FOV or smallest to include all bony anatomy of the scapula and adjacent humerus anatomy
- Limit the FOV to the operative shoulder
- Do NOT use gantry tilt during the acquisition (Tilt of 0° / No tilt)
- No oblique images
- 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.
- The pitch[†] should be set to 1:1

Table Position

- Do not raise or lower the table position between slices as this will not create a unified volume
- Do not alter the X and Y centering between slices

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 (no edge enhancement).
- Only the axial series is necessary; there is no need to include sagittal or coronal slices, SCOUTS (localizers, study plannings), nor 3D reconstructions.
- Provide the complete image series of primary DICOM images
- Lossy compression is not acceptable

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
- 120 kVp
- If possible, set DICOM tag “Study Description” to **“ZBSHOULDER”**

[†]Table distance traveled in one 360° rotation/total collimated width of the X-ray beam

3. Zimmer Biomet Signature™ ONE Shoulder CT Protocol Summary Table

Acquisition (Scan Type)	Helical or Volume	
Patient position	Head First Supine (HFS) or Feet First Supine (FFS) Patient's shoulder joint is in a neutral resting/relaxed position Patient's arm is resting straight alongside their body and touching the chest wall with the palm facing parallel to the native sagittal plane.	
Field of view		Set Field of View to include the entire scapula and the proximal third of humerus at a minimum. Ensure that the inferior and medial parts of the scapula are fully included in the FOV.
Slice thickness	1 mm or less (equal to scan spacing)	
Scan spacing	1 mm or less (equal to slice thickness)	
Pixel Spacing	Less than 1 mm x 1 mm	
Pitch	1:1	
Gantry angle (tilt)	0° (no tilt)	
Image Orientation	No Oblique Images	
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	512 x 512 (DICOM)	



The CT Scan quality can directly affect guide manufacturing and accuracy of the glenoid guide. Please ensure that all protocol steps are closely followed unless a deviation is required to uphold normal standard of radiological care. If a deviation is needed please notify the Zimmer Biomet representative at the time of submitting the images.

4. Imaging Center Qualification

A CT scan of a Phantom Scapula is required to be submitted in order to qualify an imaging center for use with Signature™ ONE. 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 Biomet 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 Biomet using the instructions described in the following section, or provide to the Zimmer Biomet representative for transmission.



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

5. CT Scan transfer from Imaging Center to Zimmer Biomet

Imaging centers are required to transfer images to Zimmer Biomet via a secure direct method. There are multiple ways Zimmer Biomet receives DICOM images:

1. VPN connection through the combined efforts of your Network/Infrastructure team and ours creating a secure one-way connection from your site to ours and allows a DICOM push from PACS (Picture Archiving and Communication Systems) and/or any modality to us.
2. Laurel Bridge is a client service that routes DICOMs through a secure TLS V1.2 connection (port 443) to our DICOM router at dicom.zimmerbiomet.com. It can be set up to accept from any modalities as well (as long as the PC it is installed on has a constant IP address). If the PC to be used does not have a constant IP address, then it can also accept upload from a disk by simply dragging the images from the disk to a folder created on the PC and set up as a “Hot Folder”. This folder ingests the images then removes them when uploaded.
3. If the site has an account with Nuance® Powershare, Ambra Health® or LifelImage®, a direct share can be arranged with the aid of their respective support and ours. This will also allow a direct push through any existing relays with the respective service. If the site has another option similar to these methods that can be automated, Zimmer Biomet is willing to research the possibility of using their method as long as it fits within the workflow and is secure.

Please contact Zimmer Biomet PACS team to assist with getting the imaging center set up to send images directly by contacting:

Personalized Solutions

Email: PACS@zimmerbiomet.com

Tel: 1 (574) 371-3710

FOR ZIMMER BIOMET SALES REPRESENTATIVES only.

Imaging Centers must upload images directly to Zimmer Biomet.

6. CT Scan transfer through ZSMS (Surgical Management System)

Zimmer Biomet SMS (SMS) is a platform that Zimmer Biomet uses to manage surgical scheduling and transmission of information surrounding surgical cases including PSI images and preoperative plans. This option of uploading images to Zimmer Biomet is only available to **Zimmer Biomet Representatives**. The CT scan site is required to send the images directly.

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.
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.
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 the “PERSONALIZED SOLUTIONS” TAB. Then click on “Upload Scans” under the Upload Files section next to the corresponding Product.



Figure 2: Upload Scans option

6.2 ZSMS Transfer of Phantom CT

Create a “TEST SCAN” Patient in ZimmerSMS and enable the case with the Personalized Solutions product. To transfer the test images, click on the “PERSONALIZED SOLUTIONS” TAB and then click on “Upload Scans” under the “Upload Files” section next to the corresponding Product.

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CE mark is not valid unless there is a CE mark on the product label.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

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