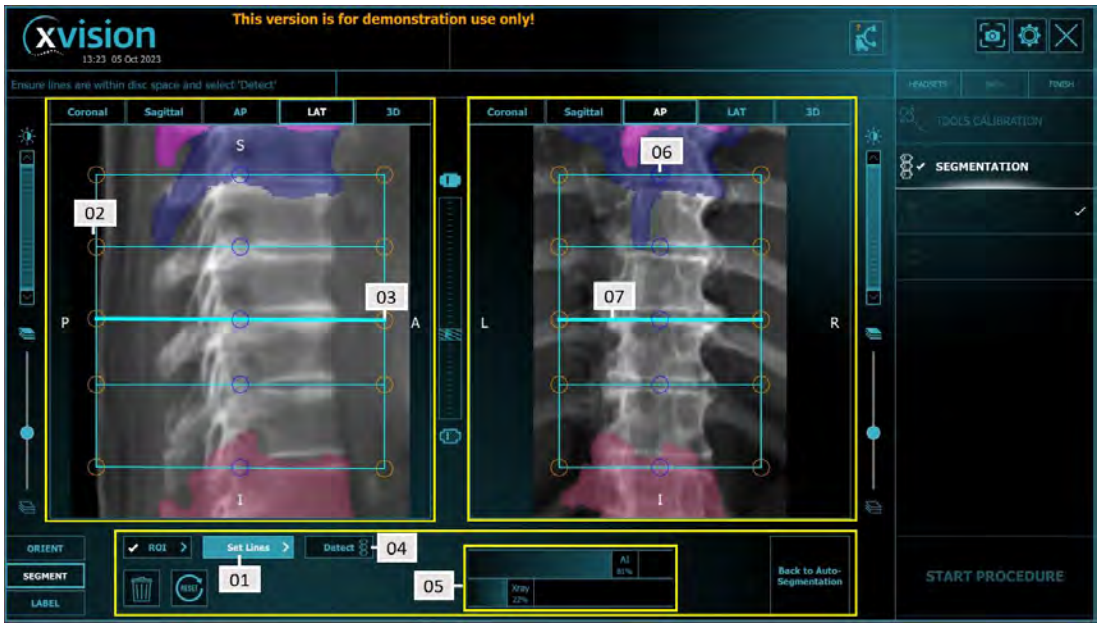
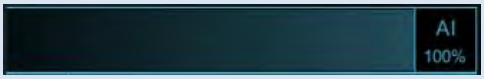


Figure 24: Manual Segmentation - Set Segmentation lines

Legend - Figure #28- Segment Tab - Set Lines		Description
01	Current Step/Operation control panel	Segment - Set segmentation Lines
02 03	Orange intersection dots (handle)	Drag the dots to set the segmentation lines over the DRR image
04	Detect Spine (Vertebrae)	Enable the spine detection algorithm to identify the vertebrae segmented by the lines.
05	AI Bone detection Sliders	AI algorithm levels for Bone detection levels Sliders to improve the visualization of detected segment
		**AI Slider:** Increases the discernment between Soft/Bony Anatomy, as well as included instrumentation + artifact
		Xray Slider: Increases the discernment between Soft/Bony Anatomy ONLY.
06	Blue (center) dots	When dragged right/left, this positions the correlating line (Over the AP) on the correct/adjusted height.
07	Segment Line	When selecting and dragging up/down, this translates the segment line position over the DRR. Left and right Border lines can also be translated when dragged.
		To delete line - select it with the Blue dot and then press the trash/bin
		Reset lines - restores the initial (auto-segmentation) lines following the ROI marking

		Needs to be selected after each AI slider adjustments to refresh Manual segmentation results
		When pressed - Auto Segmentation results are restored for the whole CT study

Set Lines & Detect Bone

During this step in the Manual Segmentation process, the user is requested to adjust the segmentation lines presented to his/her preference using the above described tools.

1. *Adjust the default segmentation lines in the disc space in both AP and LAT views using the Orange handles.*
   A segment line can also be selected and dragged to position while maintaining current line orientation.
2. *Drag the blue handles (Circles) from Right to Left in the LAT view to fine tune the Segmentation line vertical position in AP.*
3. *When lines are set in the disc space in both views, click Detect to see the segmentation results.*
   The AI bone detection slider can be adjusted to improve the segmentation results, and then click detect again to refresh.

Note: *Following a successful Manual segmentation the user can select ROI to Manually segment another Spine segment which requires attention.*

Note: *It is recommended to review the Manual segmentation results also in 3D view to verify that all spine features are well visualized. The 3D view visualizes the 3D volume that will be later appear in the Headset 3D view.*

Confirming Vertebral Segmentation

The following are guidelines for Successful Segmentation:

- No Segmentation line should intersect the end-plates of any vertebral body (This is mandatory).
- If applicable, each Segmentation line should be as parallel as possible to both the top and the bottom end-plate.
- If applicable, each Segmentation line should bisect the inter-vertebral disc space.
- If applicable, each colored circle (representing an orthogonal line through the opposing view) should be located centrally on the vertebral body.

An example of optimal Vertebral Segmentation is shown in the images provided in
The figure below.

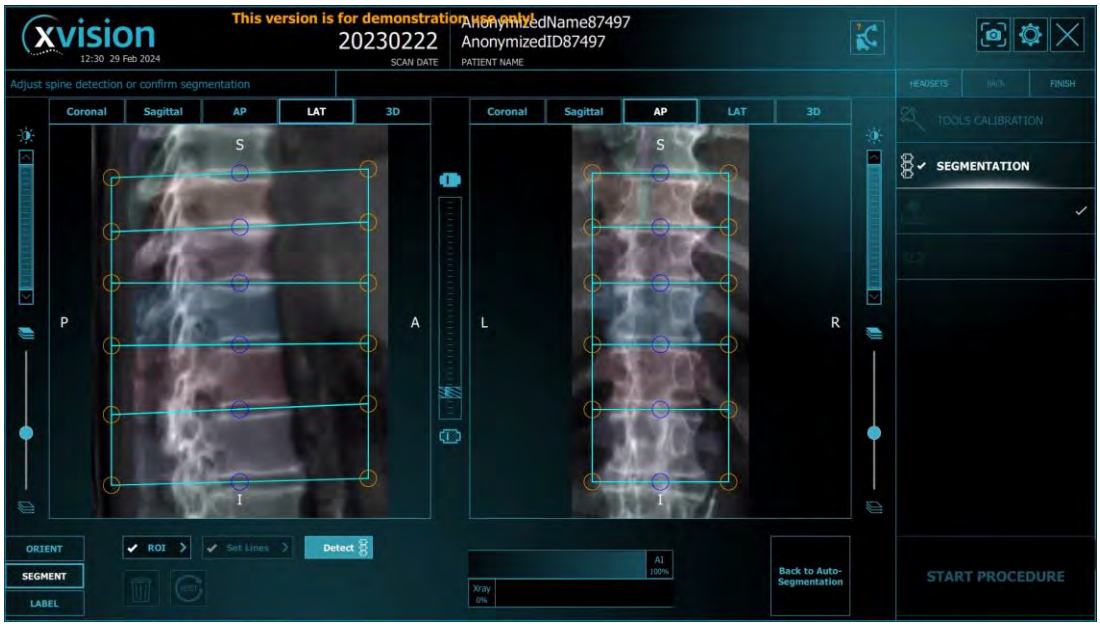


Figure 25: Optimal vertebral segmentation

It is recommended that the results of any segmentation be verified also in the 3D view. The 3D view will demonstrate 3D model visualization that will be used in the procedure. Segmentation might also affect the registration success, therefore it is ***Important*** *to make sure segmentation is satisfactory including all required Bony tissue, excluding instrumentation or objects not required for the registration process (e.g. Rods).*

Figure 26: Verifying Manual segmentation results - 3D view

During Set Lines, should the user create a segment which includes a body that still retains its highlighted coloration (from Automatic Segmentation), then the user selects the DETECT icon, the software will highlight the segment(s) ORANGE and provide the user with instructions for correction.

- *The ORANGE highlighted segments will be omitted from the manual registration process.*
- *To include, the user must adjust the previously generated ROI by either manually*

increasing/decreasing the ROI boundary lines, or by using the Select Segment icon in the ROI section.

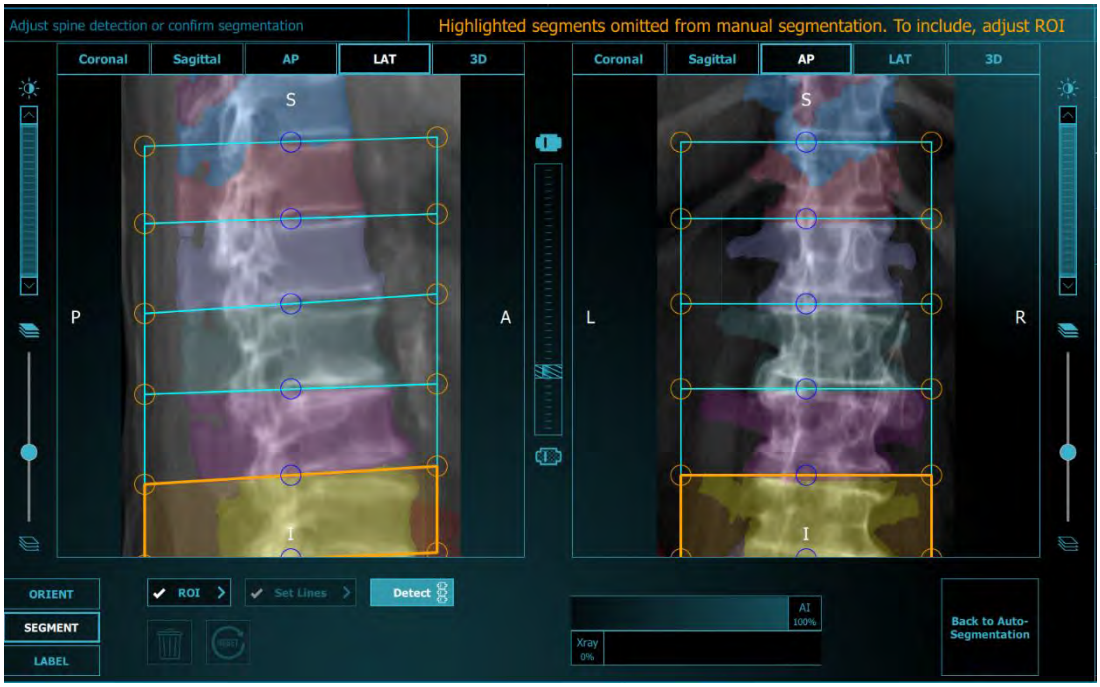


Figure 27: Highlighted segments included in ROI will be omitted from Manual Segmentation

*When all Manual segmentation adjustments are completed proceed to the Label Step, to label **all** vertebrae.*

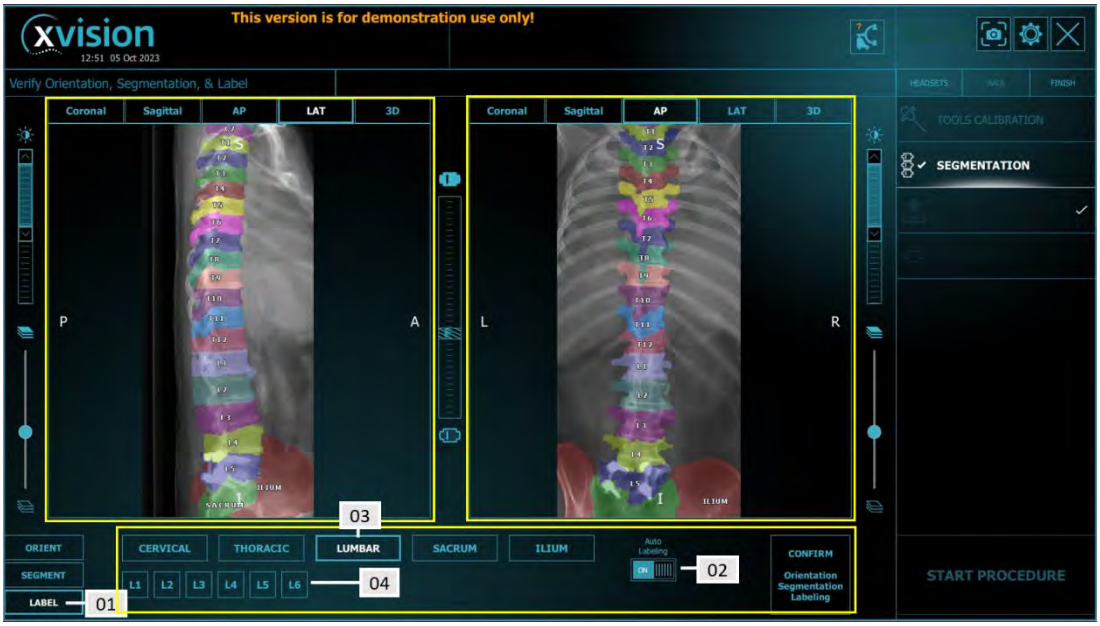
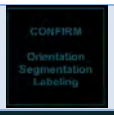


Figure 28: Manual Segmentation - Labeling the segments

Legend - Figure #32 - Labeling the segments	Description

01	Current Step/Operation control panel	Label – label the segmented vertebral bodies
02	Labeling Toggle	Toggles between Auto-labeling – which populates all labels in relation to the labeled body. Manual – will label only the selected body.
03	Spine region selection	Select the correct spine region from which the label will be selected. “Cervical” allows the user to label C3-C7, as C1-C2 are not available to navigate with the XVS system
04	The Labeling toolbar	Shows the available labels to select from the required body for labeling.
		Once segmentation is completed – this button confirms the Study orientation, segmentation and labeling.
		Next step following segmentation confirmation. The step is completed during a procedure.

To Label the Vertebral Segments

From the Segmentation Window, proceed as follows:

1. Click on the Label Tab in the left pane.
2. Select the correct spine region.
3. Select the required label.
4. Click one of the views with the identified body to label it.
   When Auto labeling is On, the rest of the bodies will be populated automatically.

Note: *When **Auto labeling is off**, each body can be labeled seperately, without affecting the adjacent vertebrae labels.*

Note: *To proceed to the next step, it is required that all segmented bodies will be labeled.*

5. *When labeling is completed Press **Confirm Orientation, Segmentation & Labeling**.*

Note: *Confirming the Orientation, Segmentation & Labeling is Mandatory to enable the next steps required for a navigated procedure.*

6. *Press the Load Image button on the Right pane.*

Setting up the XVISION Software to work with the C-Arrm

1. Connect the Xvision Workstation to the C-Arm composite output using the (BNC) video cable.
   The WS-Cart should have BNC to DVI adaptor installed on the PC's Back-Panel.

Note: *When composite (BNC) port isn't available any video output such as VGA/DVI to HDMI cable can be connected to the WS-Cart.*

Note: *When connecting the BNC cable to the C-arm, make sure to connect to the composite output, and not the "Low-res" (Usually located at the middle out of 3 ports)*

2. On the Home Screen Select Pre-Op

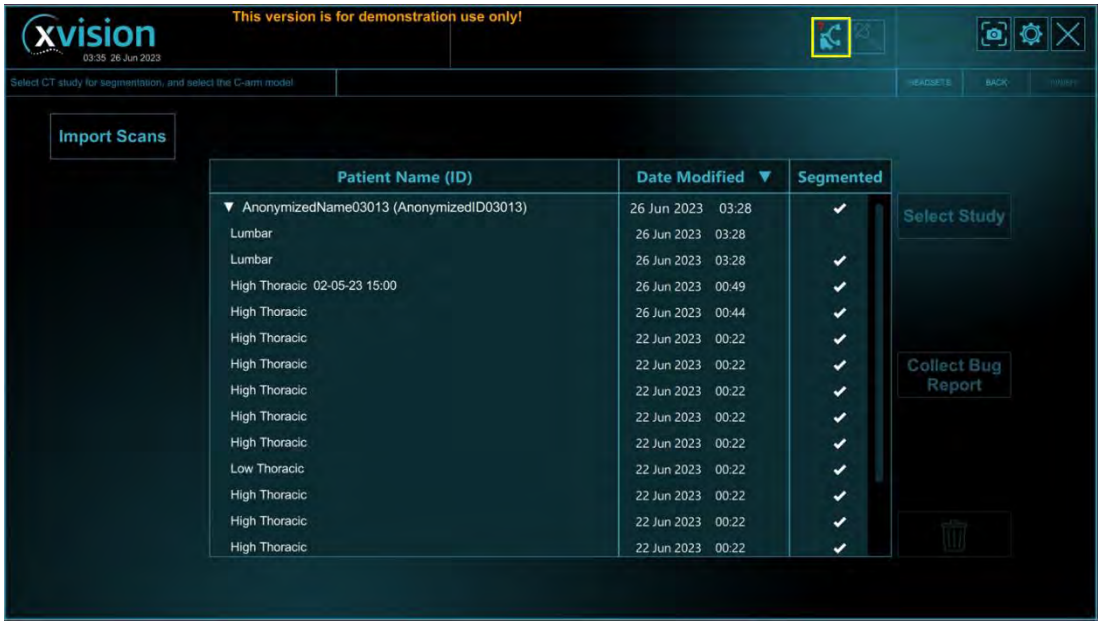


Figure 29:Patient Data Management - C-arm Setup

3. Tap the C-arm icon, to open the C-arm selection dialog box.

Figure 30: C-arm Selection dialog box

4. Select the correct C-arm from the list.

Note: *Selecting the wrong C-arm from the above list would result in incorrect image display during Load image step (Live Fluoro pane).*

Figure 31: C-arm dialog box - C-arm selected

5. Tap 'Confirm' to proceed with C-arm selection and close the window.
6. Following the confirmation the C-arm status icon should be refreshed as follows:

7. Once the checkmark indication appears proceed to Load image

7.4.1.4Load Image – Acquiring Registration images

Prior to proceeding to Load Image step the C-arm should be set.
If image is not displayed in the Live Fluoro screen, refer to troubleshooting section.

Warning: If a disconnection occurs between the C-arm and the XVISION system during the image acquisition the images will be deleted and the image acquisition should be restarted.

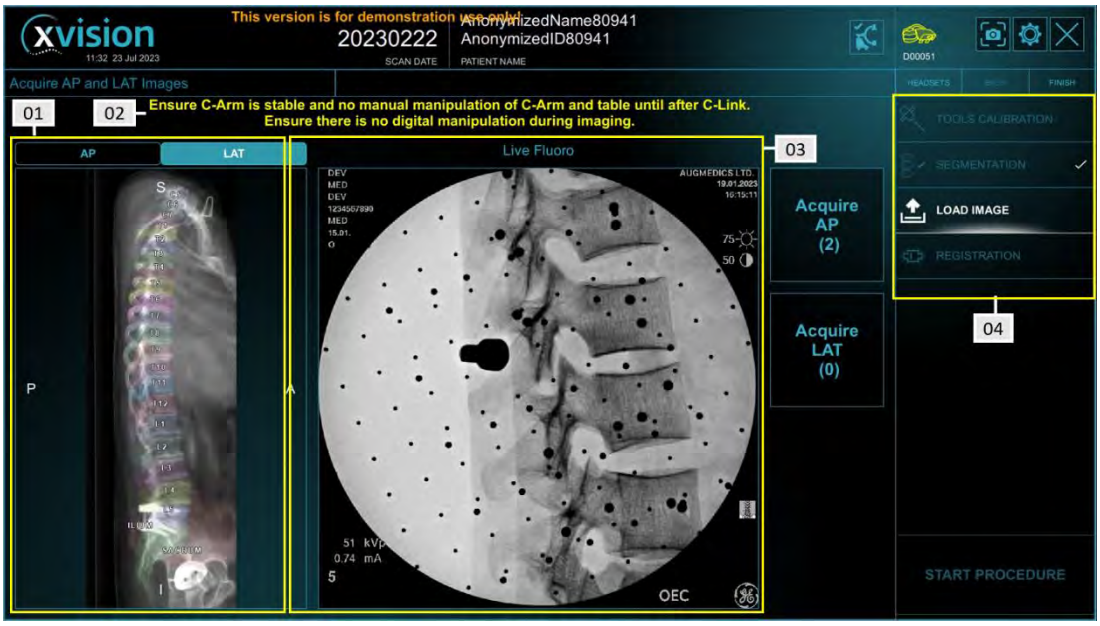
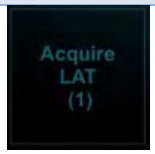


Figure 32:Load Image - Acquiring Fluoro images

Legend - Figure #36 - Acquiring Fluoro images		Description
01	CT reference image	AP & LAT projections from the CT to assist identifying the vertebral levels on the acquired image.
02	Warnings for Image acquisition step	Warning messages area It is mandatory to proceed while following these guidelines during image acquisition step.
03	Live Fluoro image	This frame will display the continuous live Fluoro from the connected C-arm
04	Procedure Progress bar	Shows the incomplete required steps for Navigating the tools.
		A button to acquire an AP image. User is directed to C-link step following each image acquired. The number in () represent the number of acquired AP images.
		A button to acquire an LAT image. User is directed to C-link step following each image acquired. The number in () represent the number of acquired LAT images
		Following image acquisition completion, Registration should be pressed to initiate Registration process.

Acquiring Fluoro Images

The xvision spine system requires the acquisition of two clear fluoroscopic images of the spine (AP and LAT). Following each image acquired, the system needs to record the patient position in relation to the C-arm. This process of the XVS System is called **C-link**.
The C-link requires a Patient marker to be mounted over the Patient (on the selected Platform e.g. Clamp/Perc-Pin), and the C-Marker to be fixated on the C-arm Ring Adapter.
During C-link acquisition both Markers should be visible to the selected Headset for the process while both are fixated rigidly in their designated location. The headlight should be ON during this process for detection of markers. The user should move the headlight all the way down and point to the area between the markers.

Following this image acquisition, the system software will match the two fluoroscopic images with the pre-operative CT Study of the current patient. Upon matching these images, the software will register each vertebral body position, in relation to the patient platform.

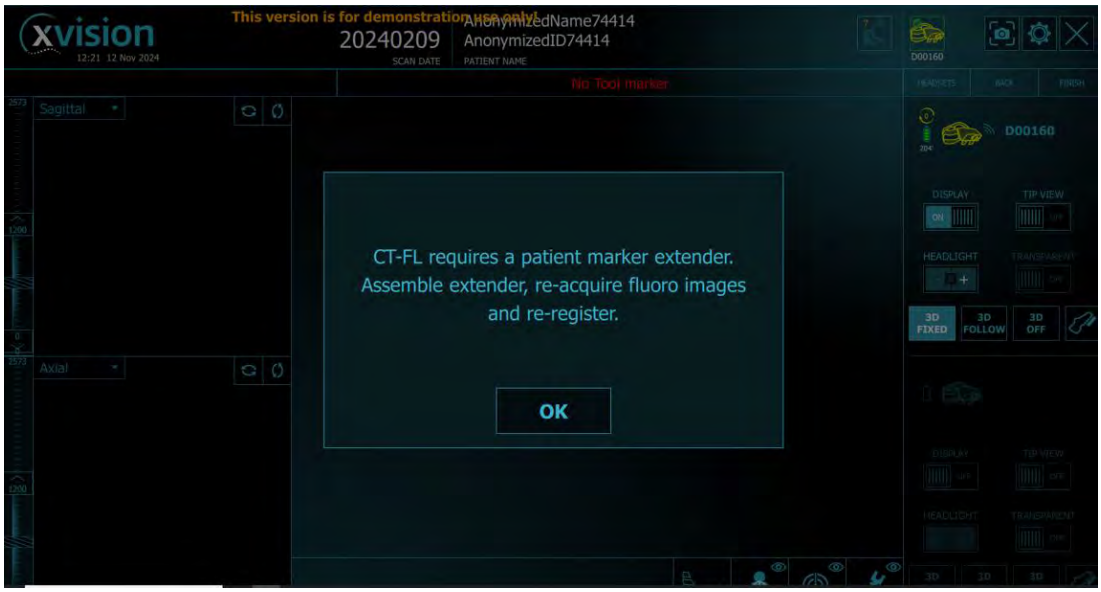
Warning: Placing the clamp over the vertebra to be registered might lead to the inability to register the specific vertebra.

C-Link registration method

Note: The c marker should be attached at 0 degrees and patient marker attached to patient midline.

Warning: During C-Link capture the distance between C-Marker and the Patient Marker should not exceed 450mm. The distance is measured between the upper left centroid of each marker.

Warning: On Pre-Op workflow the Patient Marker Extender should be always fixated (Registration and Navigation). If not, the software will force the user to attach the extender and re-acquire images



Verify C-Marker is in line of sight together with the Patient Marker when C-arm is positioned in AP & Lateral (recommended 60 - 75 deg.).

Note: The Patient Marker position should be as close to the operated region and visible while the C-arm is positioned for AP or LAT image acquisition.

Warning: In case a platform movement (Perc-Pin or its Adaptor) is suspected after registration, perform additional Landmark Check before proceeding.

Acquiring the AP Image

1. On (Pre-op) **Load Image** – following acquire AP or LAT image press the software redirects the user to the C-link *screen*.
2. The OR team member acquires the AP image with the C-arm.

Note: The AP image should be taken in the true AP position. Before proceeding to the next steps (Acquire AP Image), make sure to take the best picture in this position.

3. When the required AP image (the best picture) is displayed in the Live Fluoro window, press the "Acquire AP" button to capture the image.

Warning: Do not cover the Patient marker with the C-arm detector to avoid the ability to complete C-link acquisition successfully.

Warning: Make sure that since the Acquire button press and the C-link capture the patient does not move, as well as C-arm wasn't touched or moved.

Warning: During C-Link capture the Headset on the physician head should be looking at the Markers as if they 'sit' on the same Vertical or Horizontal line. See example below

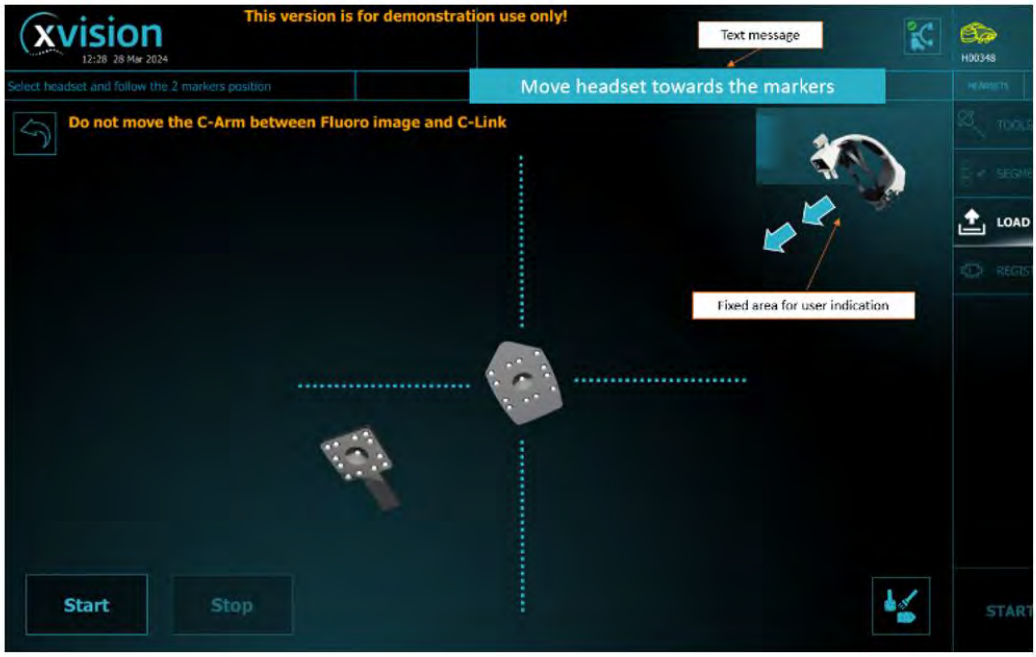


Figure 33: Patient Marker and C-Marker Horizontal positioning capture

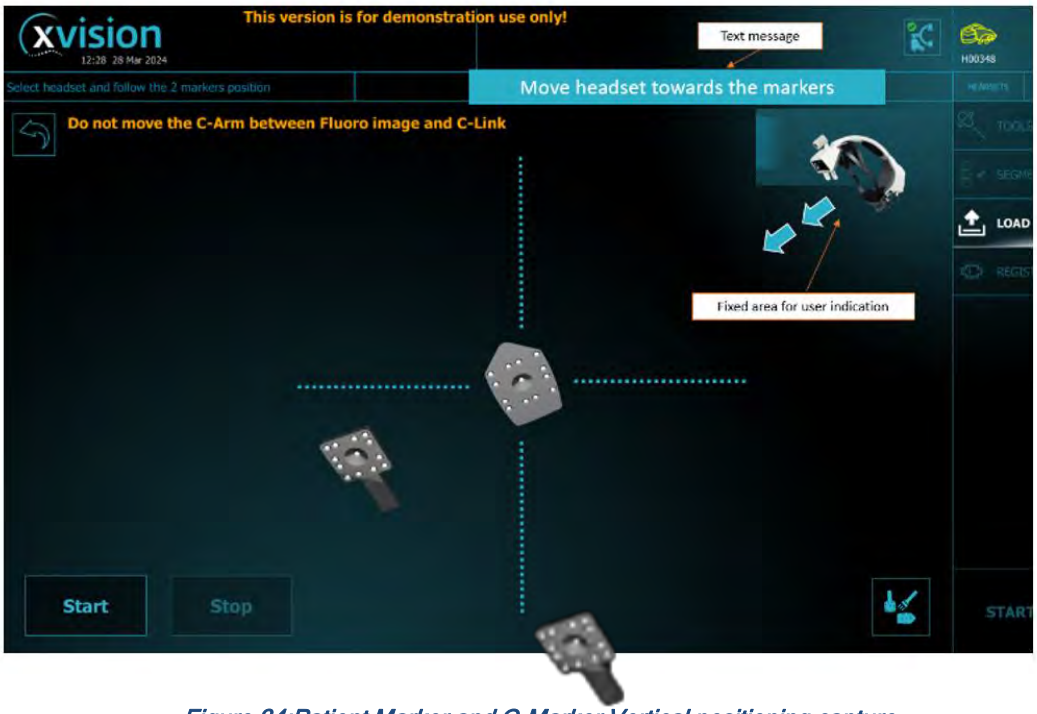


Figure 34:Patient Marker and C-Marker Vertical positioning capture

4. Use the HEADSET to capture an infrared image, making sure that both the C-Marker and the Patient Marker are included in the image and sitting on the same Horizontal/Vertical line,

Note: During C-Link acquisition the HEADSET should be in a range of 30 - 70cm from both Patient Marker and C-Marker.

5. As soon as all Marker positioning's criteria are met the SW will initiate Clink IR images acquisition of both markers.

During C-Link process a percentage progress will be presented in the notification area, both on the SW and on the HEADSET.

Note:	If C-Link process is not completed successfully the acquired image (AP/LAT) would not be saved and can't be used for registration.Take new images and redo the C-link process.

After the C-Marker infrared image and the Patient Marker is captured, a message saying "C-link succeeded" is displayed.

6. Only After C-link image capture succeeds, C-arm can be moved.

Warning:	Do not change the C-arm image orientation after the image is acquired until registration for each level is completed. If at any point in the fluoro image acquisition process the C-arm image is digitally modified (rotated, flipped, magnified, etc.), new images and C-links need to be acquired.

Acquiring the LAT Image

7. The OR team member moves the C-arm to the LAT position (recommended C-arm angle 60 - 75 deg).

Note:	LAT Images can be captured between 50°-90° C-arm position. It is important to position C-arm when C-Marker and Patient Marker are close, for easy C-Link capture.

8. When the required LAT image (the best picture) is displayed in the Live Fluoro window, press the "Acquire LAT" button to capture the image.

Warning: Make sure that since the Acquire button press and the C-link capture the patient does not move, as well as C-arm wasn't touched or moved.

Warning: During C-Link capture the Headset on the physician head should be looking at the Markers as if they 'sit' on the same Vertical or Horizontal line. See example above

9. As soon as the Patient Marker and C-Marker is sitting on the same Horizontal/Vertical line, Auto-**Start** is triggered and initiates acquiring Clink IR images of both markers.

   During C-Link process a percentage progress will be presented in the notification area, both on the SW and on the HEADSET.

Note: If C-Link process is not completed successfully the acquired image (AP/LAT) would not be saved and can't be used for registration.

After the C-Marker infrared image and the Patient Marker is captured, a message saying "C-link succeeded" is displayed.

10. Only after C-link image capture succeeds, C-arm can be moved.

Note: A minimum of 1 AP and 1 LAT images are required.
It is recommended to acquire each segment set of images and then instrument and not acquire multiple sets of images.A minimum of 50 degrees between AP and LAT images is mandatory

Note: For high BMI patients, adjust fluoro kV and mA as needed

11. Image Acquisition is complete when both AP and LAT images were acquired and the (Pre-Op workflow) Registration process is completed.

12. After acquisition of all required Fluoro images, tap the "Registration" button to complete the image acquisition process.

7.5. Pre-Op - Registration process

The XVISION-SPINE is designed to ease the registration process to the user. Therefore, the user is prompted to start with **Automatic Registration** process.
In case of improved registration results are required the user can use the **Manual Registration** feature as described in the Manual Registration section.

Following a successful Image acquisition (Load image) clicking Registration will lead the user to the Auto-Registration process.

Warning: **On Pre-Op workflow** - Do not flip or rotate the Patient marker after registration is complete. Flipping or rotation of the Patient marker is not allowed even if initial verification was performed. New Xray and C-link images are required to be re-taken If flipping / rotation of Patient marker occurred after registration is completed.

7.5.1.1Automatic Registration

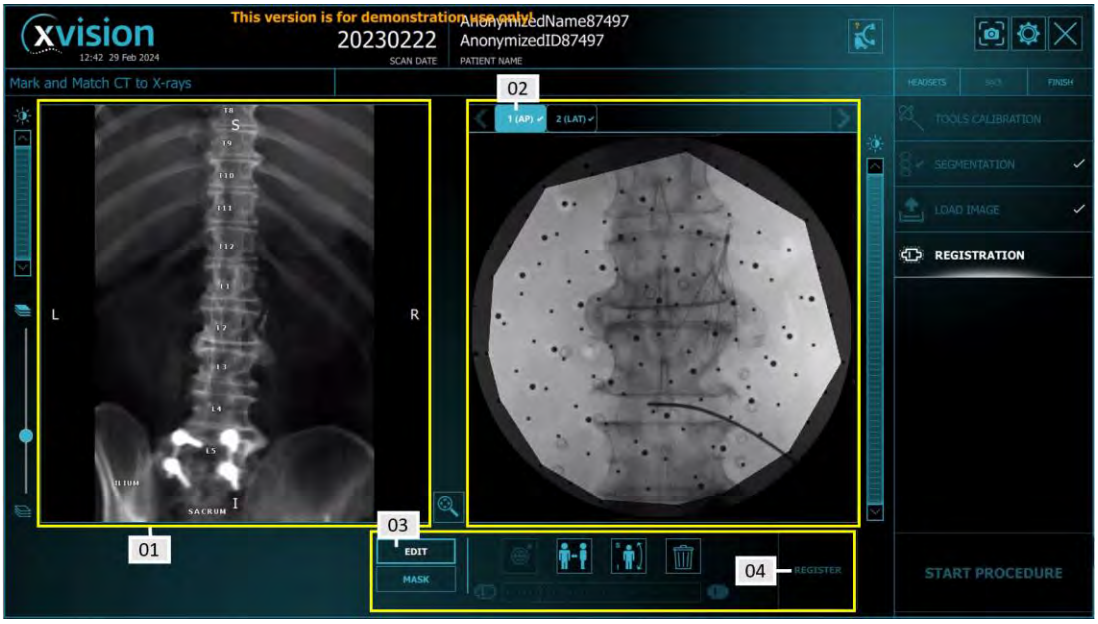


Figure 35: Auto Registration Screen

Legend - Figure #39 - Auto Registration Screen		Description
01	Left Pane - CT projection	The image displayed on the left pane matches the acquired image orientation that appears on the right pane
02	Right Pane - Acquired images Tabs	Toggle between the acquired images using the Tabs
03	Edit menu	During the Edit step the user can use the change acquired image orientation or remove current markings
04	REGISTER	Performs registration once the user placed a vertebra from the CT projection over AP and LAT fluoroscopic images.

To Perform Automatic Registration:

In the Fluoro Reference Window (Reference on image), the user will select the previously acquired AP and LAT images.

User should begin the Automatic Registration process by selecting either the desired AP or LAT corresponding to the appropriate surgical region of interest. It is recommended that the user select the Fluoro Reference Images that provide the clearest representation of the anatomy intended for registration (AP or LAT).

Note: The left pane corresponds the AP or LAT images selected for registration in the Fluoro Reference Window.

Figure 36:Registration Marker over AP

	Legend - Figure #40 - Registration Marker over AP	Description
01	Left Pane - CT projection	The image displayed on the left pane would match the acquired image orientation that appears on the right pane
02	Edit menu	During the Edit step the user can use the change acquired image orientation or remove current markings
03	Mask Menu	Used to toggle to Masking tools, in case elements in X-ray should be masked out to increase registration success. **Usually used in 2 Stage surgeries.**
04	Blue vertebra Shade - selection	Selected body for initial guess registration
05	Target marking	A target that marks the initial guess 1st identification spot
		Fluoro images Tabs - Toggle between available images for registration. 3 (LAT) - Available image for registration “Greyed” 2 (AP) - not available for registration do not apply to SW limitations. “V” 1 (AP) image - Already used image for current registration.
		Removes the Target mark placed over the acquired image.
		Change AP/LAT tag. Example: In case image was acquired in AP using the Acquire LAT button, this button will change the image ‘role’ to AP when pressed.
		Flips **all** acquired images orientation Superior ←→ Inferior
		Deletes the selected Tab’s acquired image.
		Vertebra opacity slider. Affects the **BLUE** Shade projected by vertebra selection.
		Tap Register to initiate registration once Initial Guess (Shade) is positioned on top of the X-ray AP & LAT images.

Once the Fluoro Reference Image and CT Reference images have been selected, perform the first steps in the automatic registration process. These steps can be completed regardless of which Fluoro Reference image (AP or LAT); however, these instructions will follow the user selecting an AP image first.

1. Identify a vertebral body that is clearly recognizable within the field-of-view of the Fluoro image displayed (AP).

2. Once identified, via the touchscreen, place "**INITIAL GUESS**" by touching the center (midline) of the identified vertebral body. This will place a BLUE, initial guess marker on the selected body.
3. Select the corresponding vertebral body on the CT Reference Window
    a. For example, if the user selects the patient's presumed L2 vertebral body in the Fluoro Reference Window, the user should mirror this by selecting in the L2 Body in the CT Reference Window.
4. This causes the corresponding body to be shaded **BLUE** as described in Figure #40 in the CT Reference Window. At this point, ensure that these selected bodies are in referencing the same vertebral body.
5. Once complete, select a second/corresponding Fluoro Reference Image (LAT) and **verify** the vertebral level crossed by the line is clearly visible. (users can acquire multiple images for use during registration).
    For example: if L3 is selected (in the AP view) in both Fluoro and CT Reference Windows, ensure that L3 is clearly identifiable (shaded in BLUE) in the LAT view, for both the Fluoro Reference and CT Reference Window.
6. Tap the selected body over the Fluoro image to show the **Reference Body** - Blue Shadow/Contour that represents the selected body from the CT.

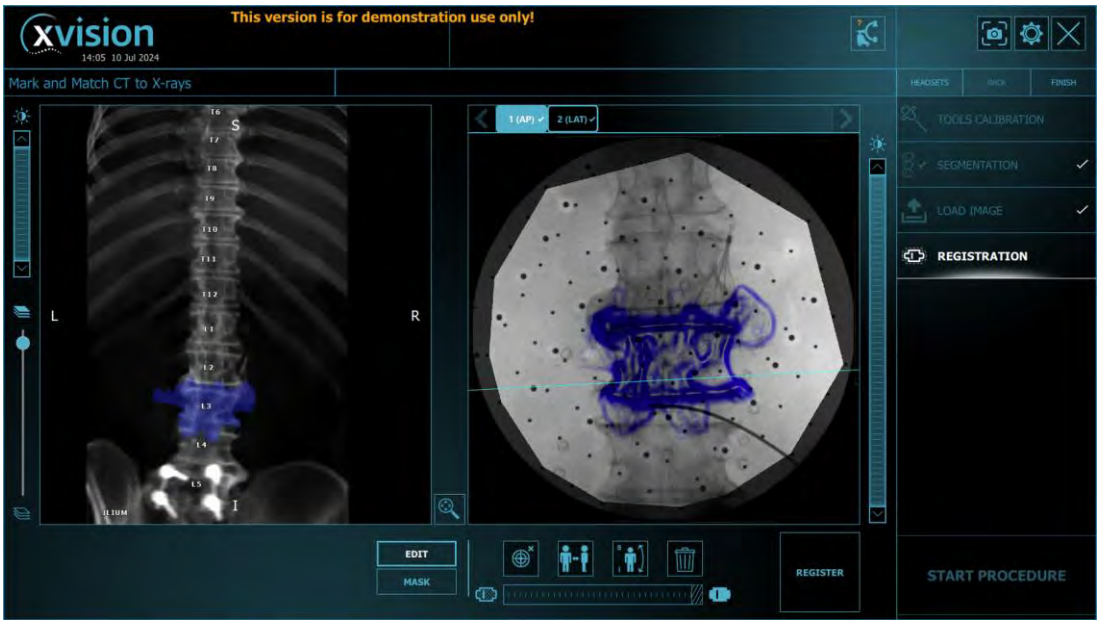


Figure 37:Registration - AP - Shade positioned

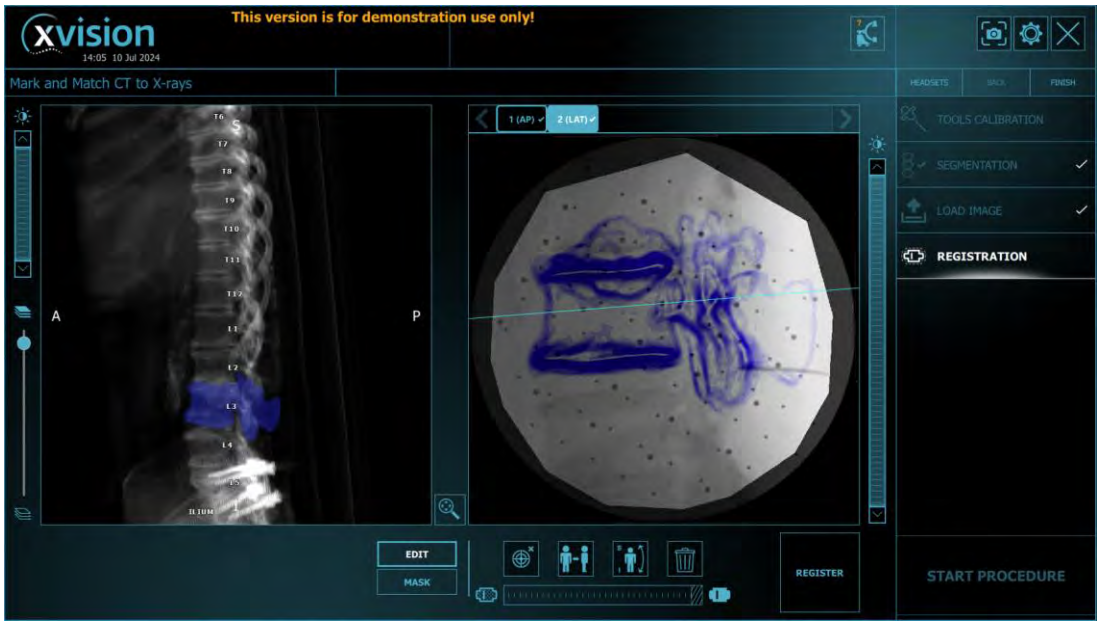


Figure 38:Registration - LAT image Marking line

Reference Body Positioning

1. Once the **INITIAL GUESS** was selected and successfully matched and the corresponding anatomy in both the Fluoro and CT Reference Windows, Now ALIGN the selected Reference Body over the desired body for registration.
2. The Reference Body will populate near the newly visible BLUE, Fluoro projection line the user established during INITIAL GUESS placement. The line represents the angle at which the Fluoro images used for registration were acquired.

   For example: In the AP images, the BLUE Fluoro projection plane illustrates the angle at which the lateral (LAT) image was captured. In the lateral (LAT) image, the plane illustrates the angle at which the AP image was captured.

Note: It is important that these angles are at least ≥ 50 degrees from one another to ensure an efficient registration process.

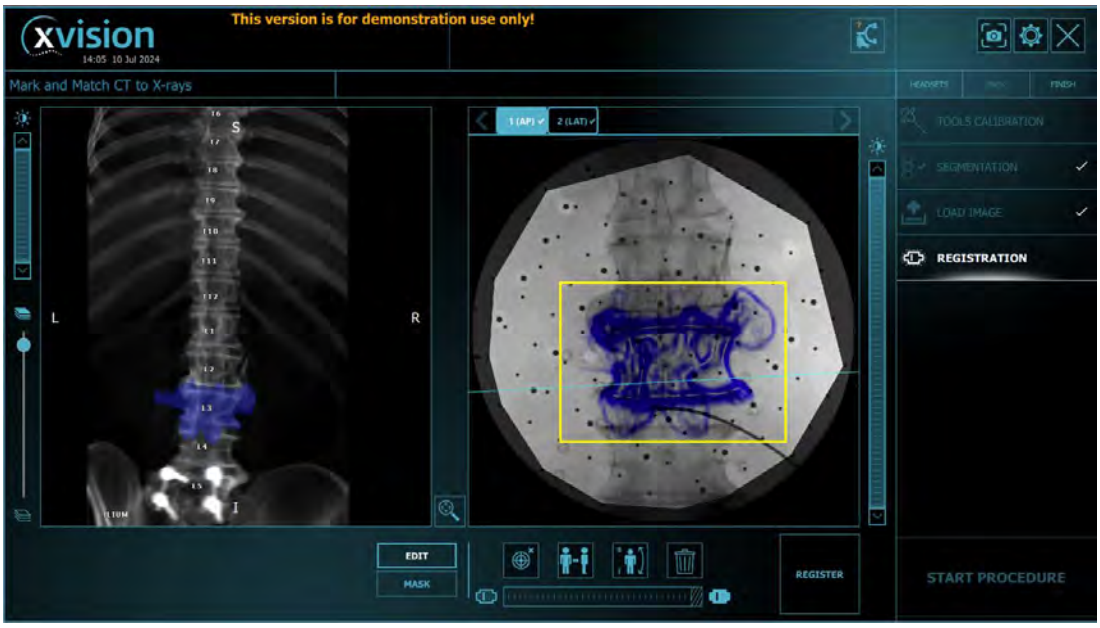


Figure 39:Registration - AP - Shade Positioned

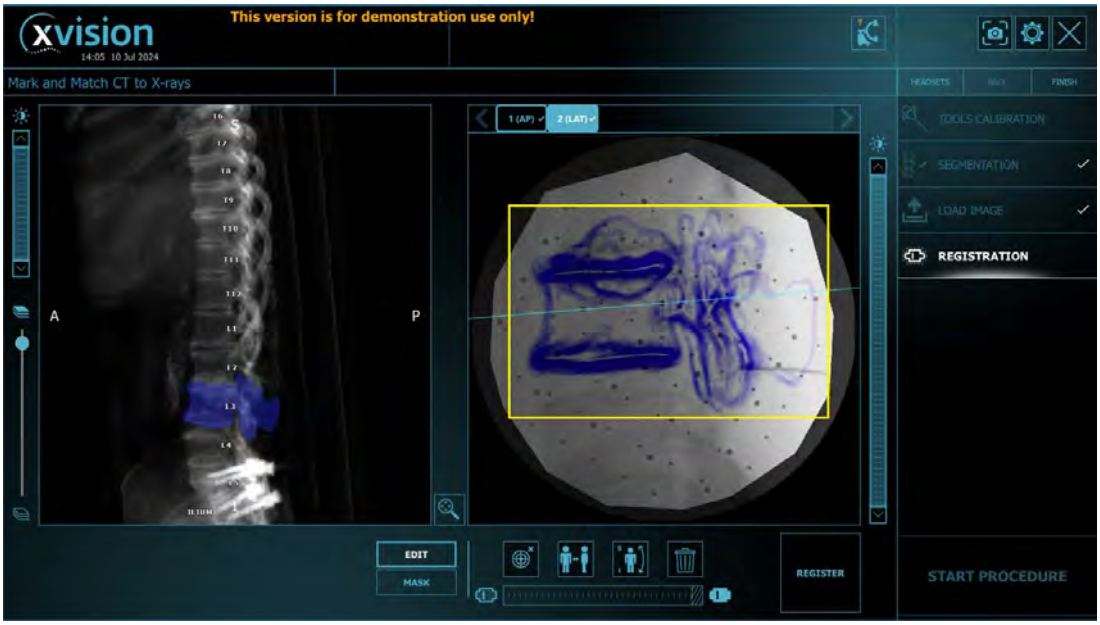


Figure 40:Registration LAT - L3

3. To adjust the Reference Body, use typical touchscreen maneuvers to superimpose the Reference Body image over the select vertebral body to be used for registration.
    a. To drag the image, touch the image (shade), hold for a moment, then the user will be able to move the Reference Body into position.
    b. To rotate the image, use 2 finger touch and hold for a moment, then rotate these fingers. The image will rotate until the finger's rotation is stopped, or when a finger is removed from the touchscreen.
4. After adjusting the Reference Body and confirming its accurate superimposition, select the "[REGISTER]" icon to begin Automatic Registration process.

Adjusting Fluoro Reference Window Image(s)

Attempting to acquire good images for registration may result in some constraints. In the required images for registration hardware might be visible on the acquired X-rays.
The hardware that will be present during image acquisition might add complexity to the registration success. Therefore, the hardware which exists in the X-ray and does not exist on the preoperative CT should be masked out to increase registration success.

Figure 41: Registration - AP - Retractor and Interbody (Cage)

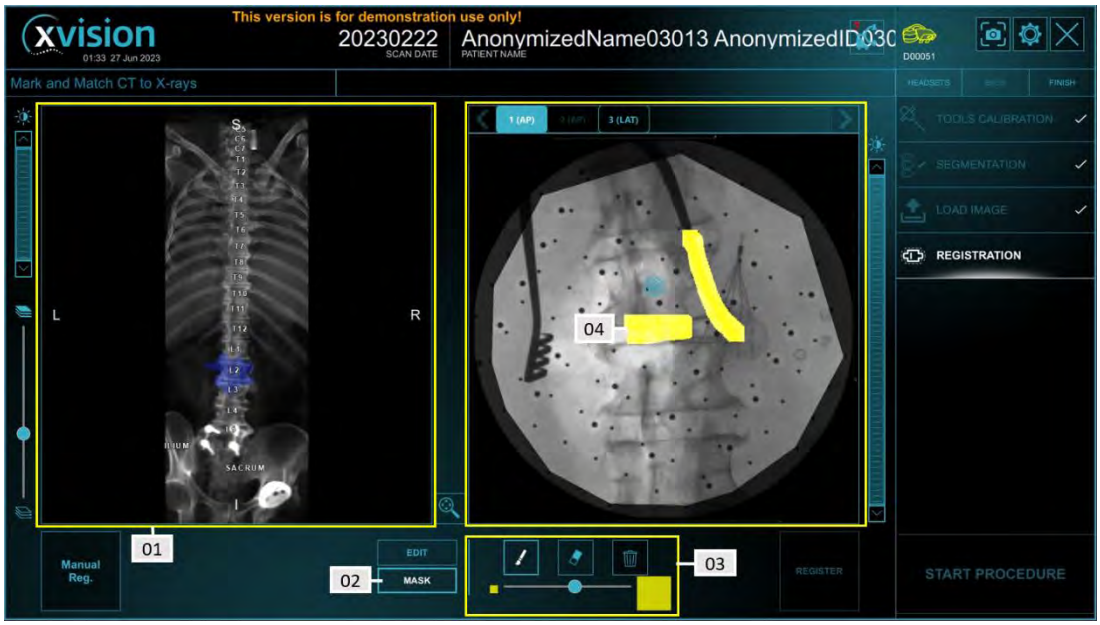
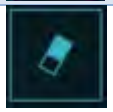
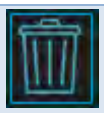


Figure 42: Registration - AP Mask

Legend - Figure #46- Registration - AP Mask		Description
01	Left Pane - CT projection	The image displayed on the left pane would match the acquired image orientation that appears on the right pane
02	Mask button	Toggles to Mask mode when X-ray image masking is required. Used to mask out existing Hardware on X-ray that doesn't exist on preoperative CT.
03	Mask Menu	Includes masking tools, to allow easy marking over the X-ray to mask out for registration.
04	Masked area - selection	The selected area over the X-ray that would be masked out for the registration process.
		Paintbrush - a tool to use for select/mark the X-ray of the (to be) excluded hardware.
		Eraser - To delete a previous mask while hovering over the (yellow) selected area.
		Deletes all masked area at once
		Paintbrush size slider. Affects the size of the paintbrush when marking the selected area for masking out.
		Tap Register to initiate registration once Initial Guess (Shade) is positioned on top of the X-ray AP & LAT images.

1. Upon selecting the Fluoro Reference Image (AP/LAT), the user can both edit the Fluoro image and mask included components of the Fluoro image.
    a. Masking radiopaque components of the Reference Fluoro Images can aid in both the Automatic and Manual registration process if not included in the Reference CT data.
2. The **MASK Tab** offers tools to assist "hiding" included radiopaque components of the Fluoro image.
    a. Using the paintbrush, trace any included radiopaque items within the reference Fluoro images (both the AP and LAT images to be used for registration).
    b. To ensure an accurate tracing, the paintbrush size slider icon can be used to adjust the relative size of the mask function.
    c. To delete a previous mask, utilize the eraser icon to select the desired mask and then select the delete icon (trashcan)

Figure 43: Performing Registration

Automatic Registration

Upon selecting the **"REGISTER"** button, the xvision software will begin running the CT to Fluoroscopic registration algorithm.
First, the software begins by attempting to register the body identified by the user during the **INITIAL GUESS** portion of the registration process. Once complete, the software will then attempt to register all previously segmented anatomy identified within the provided fluoroscopic images. As the software registers various anatomical structures and confirms this registration by validating adjacent levels, it will provide the user with messages throughout stating "Performing Registration" regarding a specific anatomical structure (included in the patient data and previously segmented).

Note:	A live update regarding registration success will be displayed for each successful body registered throughout the process. As described in **Figure #47** - Succeeded [Vertebra]

Registration Confirmation (User)

It is important that the surgeon verifies the registration of each vertebral body to be instrumented.

1. Wait until the Registration process has finished.
2. Upon completion, the verification icon tools become available.
3. If anatomic registration passes the predetermined scoring thresholds (level of accuracy set within the system), registration has been successful.

Note:	During the **INITIAL GUESS** validation process, the SW is looking for a better vertebral match with adjacent levels. Should the software identify the INITIAL GUESS as an anatomical level OTHER than the user's suggestion, the user will have the opportunity to accept or reject.

Figure 44: Registration Validation - Better Matching vertebra

Now the user can verify the registration by way of visual inspection and comparison of the CT and Fluoro images.

a. Anatomy that has been successfully registered with high matching between CT and Fluoro will be displayed at the bottom of the screen with a Green line below its label.
b. Yellow indication – the displayed body succeeded registration, but additional attention is required to verify matching is accurate to meet the user preference.

Figure 45: L3 - Failed to Register

Failed to Register

Figure 46: Failed Registration - Troubleshooting options

1. However, if registration scoring fails, the user may need to return to the previous screen and adjust the position of the INITIAL GUESS or Reference Body alignment or alternatively, re-acquire Fluoro images (with more clear anatomy/beads), followed by the Fluoro reference and approval process, may be required.
    a. Anatomy that has NOT been successfully registered will be displayed with an “X” and Red indication below. (See Figure #40)
    b. Select the “Back” button to adjust any portion of the previous registration steps. The previous screen in the workflow would be displayed.

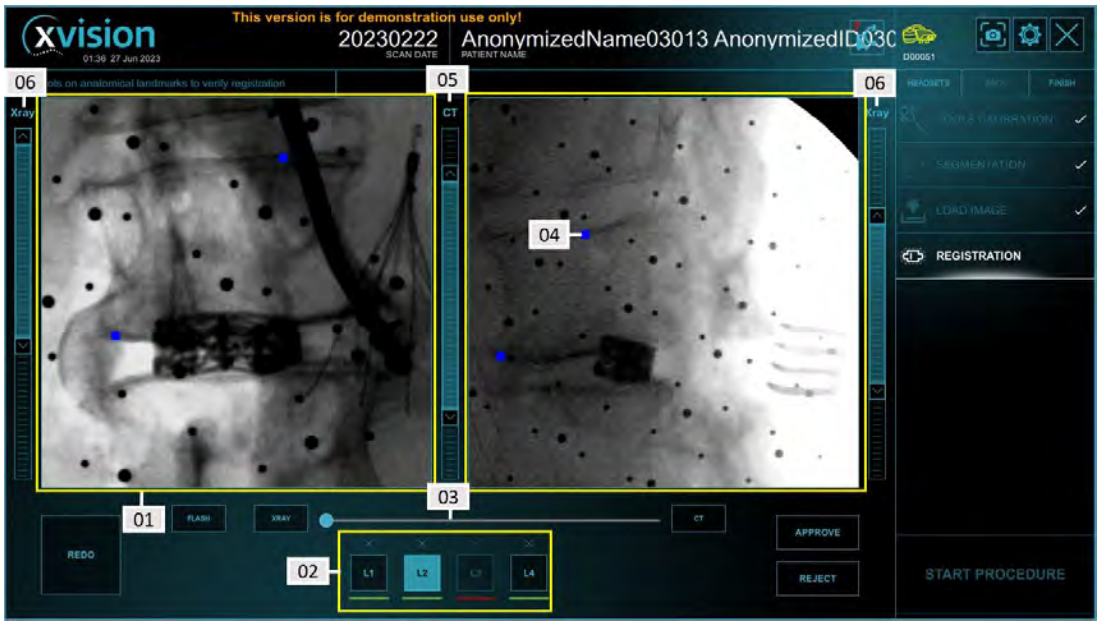
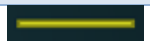
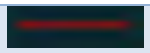


Figure 47: Registration - Blue Markers

Legend - Figure #51 - Registration	Description

01	Left Pane - X-ray & CT flashing images	The images displayed on the left & right panes displays X-ray images overlapping its matching CT projections following software registration
02	Registered Vertebrae list	Displays the vertebrae which were processed for registration and displays the registration result per each level.
		Successfully Registered Vertebra (pending approval)
		Matching requires user attention to approve upon his/her preference
		Unsuccessfully registered - consider manual registration tool.
03	X-ray to CT slider	Toggles between the CT projection and the X-ray overlapping to demonstrate the registration matching.
04	Blue Marker	Used to mark anatomical landmarks to assist analyzing the registration matching results. Use 2 markers on each image
05	CT Brightness/Contrast control	Affects both CT images' brightness & contrast
06	X-ray Brightness/Contrast control	Affects the adjacent X-ray image's brightness & contrast
		Start/Stop the flashing between the X-ray images and the CT projection
		To confirm that the matching is accurate. Confirmation or Rejection needs to be done per each vertebra.
		To reject the calculated matching. Confirmation or Rejection needs to be done per each vertebra. Once clicked the rejected vertebra would not appear in the visualization during the procedure.
		Back/Redo button - once clicked goes back one screen to allow the user adjusting the registration initial guess or enabling the Manual registration feature.

Confirmation Steps

1. Select the vertebral level to verify from the available successfully registered levels along the bottom of the screen (marked as either green or yellow).
2. Utilizing the X-RAY - CT slider, the user can "pause" the slow switching between X-Ray and CT so that the user can clearly identify at least 2 prominent boney landmarks of the anatomy.
3. Once these landmarks are identified, two (2) BLUE markers must be placed for use as reference indicators.
    a. Simply "touch" the identifiable boney landmarks on both the AP and LAT images for the anatomical level to be verified.
4. Once the BLUE markers are placed, "resume" or drag the slider functionality between X-Ray and CT to ensure that the software has accurately superimposed the vertebral level.

a. If no discernable “shift” or translation of the anatomy is visualized, select the “APPROVE” icon to confirm the registration for this level.
The vertebra will get a ‘V’ checkmark once approved.
b. If a noticeable “shift” is identified or non-alignment between X-RAY and CT images, this would indicate an inaccurate registration and user should select the “REJECT” icon.

Note: In case Manual Registrtaion is needed to include bodies that didn’t pass the Automatic registration click **‘Redo’,** and refer to ‘To Perform Manual Registration’ below.

5. The surgeon MUST complete the verification process for each level to be instrumented.

Note: All bodies that are marked with x will not be available for navigating tools after Start procedure is pressed.

To Perform Manual Registration

In some circumstances, it may be necessary for the user to perform manual registration on anatomical levels within a given region of interest (ROI). For instance, the user may prefer to manually register anatomical levels in addition to the levels provided by the automatic registration process.

Note: Manual Registration can only be accessed after the Automatic Registration suceeded for at least 1 body. From Registration verification screen hit **Redo**, and then **Manual Reg.** button.

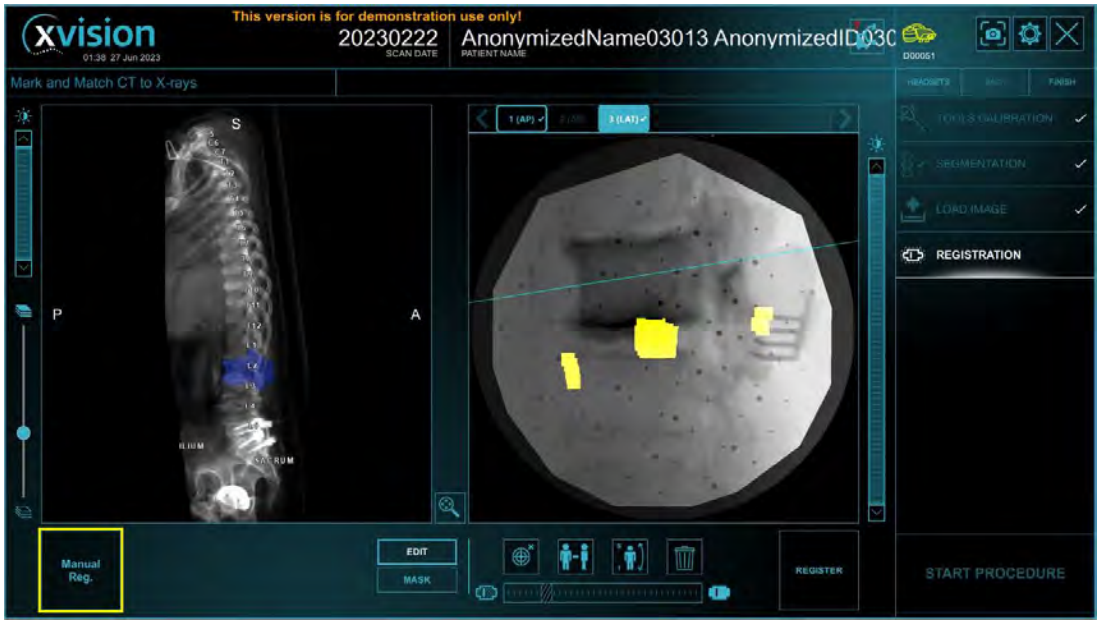


Figure 48: Registration - Go to Manual Registration

1. To begin Manual Registration, Tap **REDO** icon
2. Select **Manual Registration**

3. Once manual registration has begun, the registered vertebral bodies will be displayed in Green, both in left and right panes. Non-registered anatomy will be labeled on the left pane colored White.

Figure 49: Manual Registration Screen

4. Select the desired anatomical level for manual registration by clicking on the, non-registered, desired level on the CT Reference Window.
5. This will highlight the anatomical level BLUE (on the left Pane).

Figure 50: Manual Registration - User selects desired non-registered anatomical level in CT Reference Window (BLUE)

6. Position each Reference Body to superimpose it over the Fluoro image in **both AP and LAT views**, the same process used for Auto-registration.

a. This process would continue for each desired, previously non-registered, anatomical level the user elects to manually register within the imaged region of interest.
b. Each Reference body positioned over the Fluoro images will appear with its White Label over the Fluoro, once user picks the next body to superimpose.

Figure 51: Manual Registration - Confirm desired level on CT and FLUORO Reference Windows

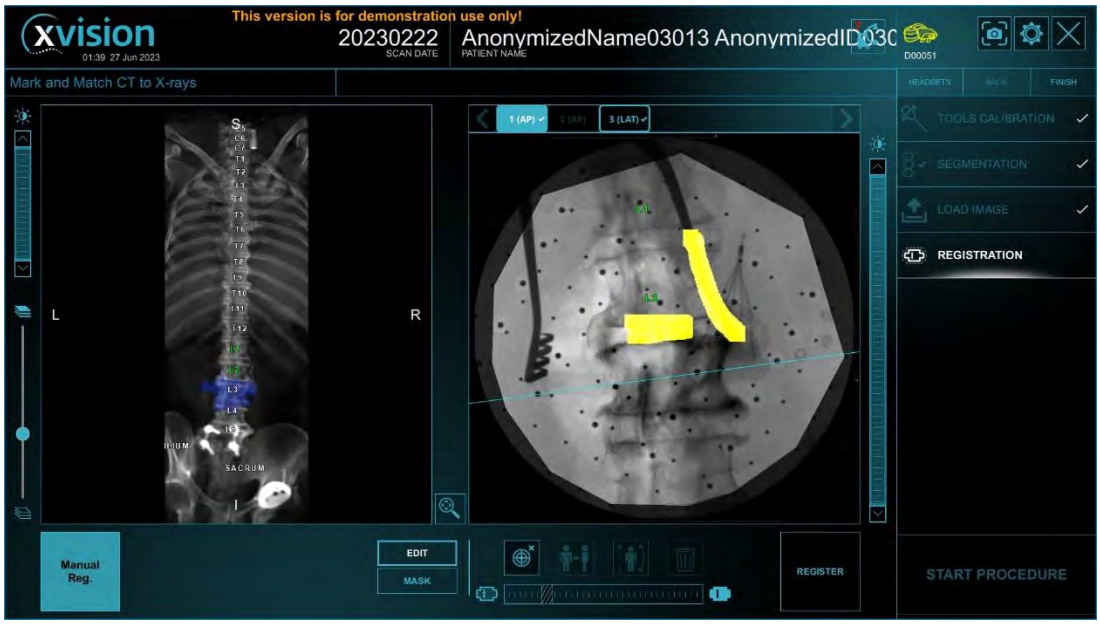


Figure 52: Manual Registration - User may use the same process for multiple anatomical levels within the ROI

Figure 53: Manual Registration - LAT view Reference body positioning

Note: Confirm the anatomical level in BOTH the AP and LAT views of the Fluoro Reference Window for each Reference body positioned

7. Once identification of all desired anatomical levels has been completed, and all reference levels have been set by the user in the CT Reference Window and Fluoro Reference Window (in both the AP and LAT images), click **'REGISTER'** to begin the Manual Registration process.
8. While performing Manual Registration, the xvision software will provide the user with progress updates via on-screen notifications.

Figure 54: Manual Registration - Performing Registration at L4 anatomical level

Figure 55: Manual Registration - Demonstrating multiple level manual registration results

9. Upon completion, select the “Start Procedure” to begin instrumenting the newly manually registered anatomical levels.

The 3D Volume presented for the Navigation is generated based on the matched and approved segmented Vertebrae. A non-segmented or not-approved vertebra will not be displayed on Navigation panes.

7.6. Tool Calibration

To complete Tool Calibration step, at least 1 instrument should be calibrated.
Each navigated surgical instrument must be calibrated before use: see *Calibration* (page 6-14).

Following tool calibration, a checkmark to show the default selected HEADSET for calibration will be displayed. To change the used HEADSET for tool calibration press the other MiniHMD icon.

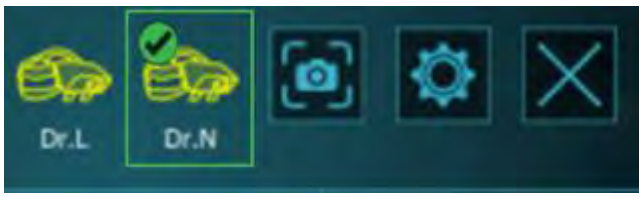


Figure 56: Default selected HEADSET for Calibration

7.7. Starting the Surgical Procedure

Warning: While wearing the HEADSET, if the user feels dizziness, headache or nausea remove the HEADSET and rest. Contact Augmedics service.

Warning: Do not use the XVISION-SPINE system if the image freezes, is blurry, disappears or keeps flickering for more than several seconds.

Warning: In case of observed delay in image, do not use the XVISION-SPINE system.

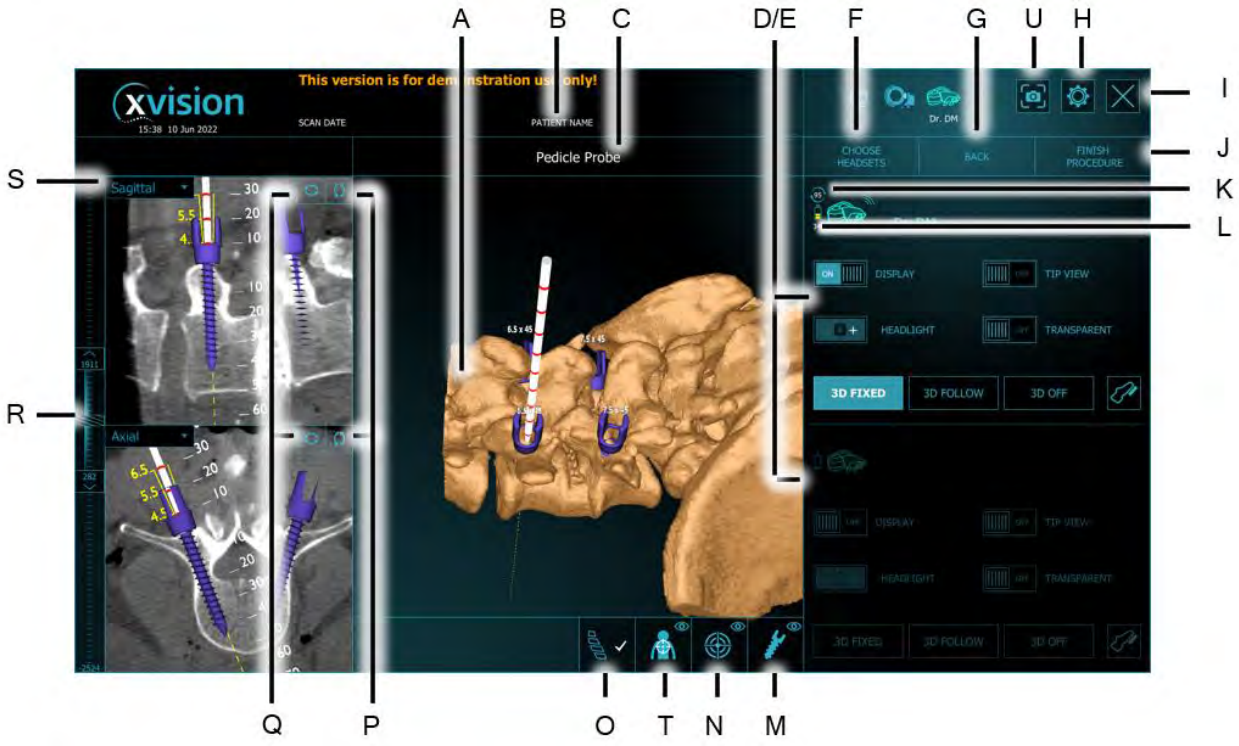
Warning: **On Pre-Op workflow** - any anatomical manipulation or instrumentation made intra-operatively or since the CT study was generated, will not be displayed in the 2D slices and virtual 3D model.

Note: Instrumentation of cervical vertebrae shall be performed not more than three levels beyond the Clamped vertebrae.

Note: During the surgical procedure, the HEADSET should remain between 30 cm and 70 cm above the tracked instruments. If the head moves outside this range, HEADSET image view will be lost. To return the image move the head within this range.

Note: The user is recommended to work towards the rigid reference frame (Clamp or Perc Pin) and not away from it.

Figure: Screenshot of Main Screen during Surgical Procedure Example



Area	Name	Notes
A	3D Mesh display	Use this area to manipulate the image
B	Current patient information	
C	Notification area	
D	HEADSET 1 Controls	For procedures when two HEADSETs are used
E	HEADSET 2 Controls	*Headset Controls* (page 7-102)
F	Choose HEADSET	
G	Back	Can be used to access tool calibration and other functions
H	Setup menu	
I	Exit	
J	Finish procedure	
K	Battery life cycle indication	
L	Battery energy indication	
M	Virtual screw on/off	*Virtual Target, Virtual Screw and Trajectory Guide* (Page 7-117). Pressing the eye icon toggles between hiding and displaying all virtual screws

Area	Name	Notes
N	Target on/off	*Virtual Target, Virtual Screw and Trajectory Guide* (Page 7-117). Pressing the eye icon toggles between hiding and displaying all virtual targets.
O	Anatomical landmark check	*Anatomical Landmark Check* (page 7-107)
P	2D flip	
Q	Axial mirror view / Sagittal mirror view	
R	Window level threshold controls	
S	2D Navigation (slice) and Visualization Menu	This area is visible only after *Tool Verification* (page 7-106). 2D Slice views must be utilized during instrumentation.
T	Skin landmark dots	
U	Screenshot	USB must be inserted

7.7.1. Headset Controls

The technician in the operating room uses the controls below according to the verbal instructions of the surgeon during the procedure.

Caution: If the HEADSET fails, a message appears on the HEADSET and the system monitor. Stop using the HEADSET and call service.

Caution: In case of loss of image in either or both eyes, stop using the HEADSET and call service.

Warning: In case of detected failure or an insecure feeling, or when reality and projected display are not aligned, stop using the HEADSET and call service.

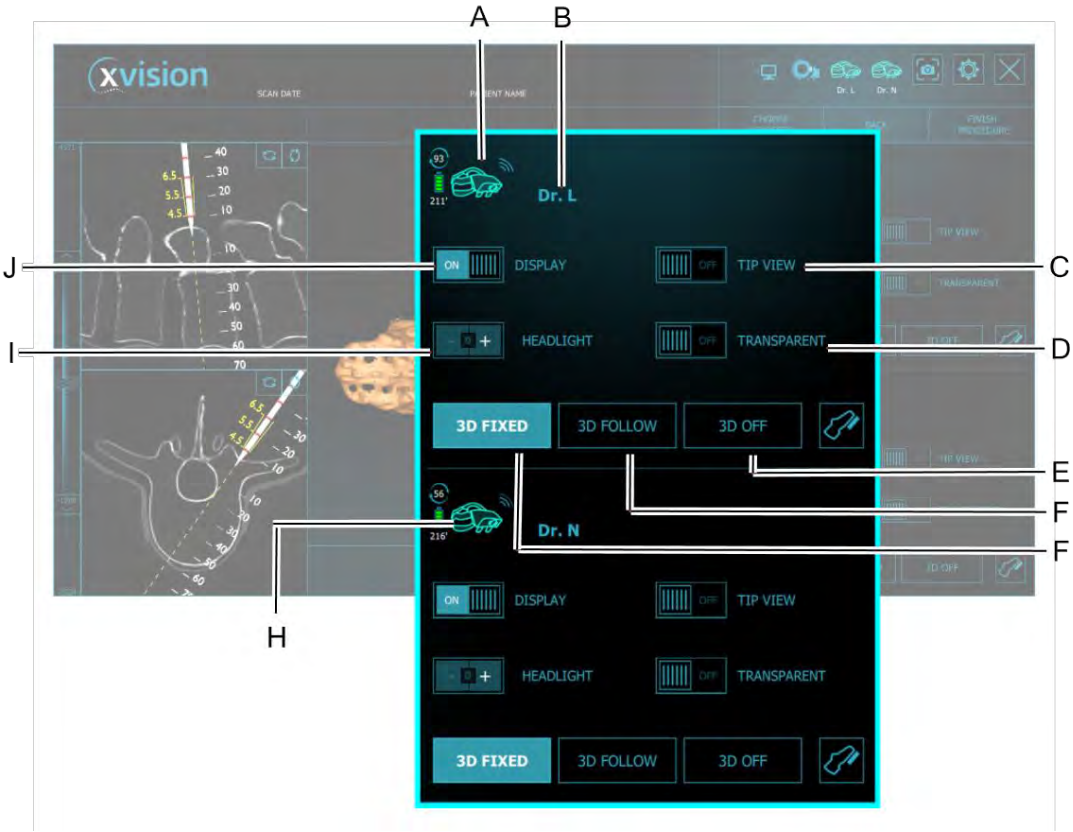
Warning: If the image freezes, disappears or flickers for more than several seconds stop using the HEADSET and call service.

Warning: The 3D Fixed and 3D Follow modes are not intended for use in open surgeries and shall only be used in less or minimally invasive surgeries. Do not rely solely on the information displayed in these modes. Always use it in conjunction with the displayed 2D stereotaxic information.

Note: Check lenses and (optional) LCD before starting the procedure. If the lenses are dirty or the image is blurry use a different HEADSET and call service.

See *Footswitch Controls* on page 7-105 for controls available to the surgeon using the Footswitch.

Figure: Headset Controls



Area	Name	Notes
A	HEADSET status	• Blue: Located and initiated • Yellow: Waiting for data or initiating data
B	HEADSET device name	See *Headset Pairing* on page 5-33 for more information
C	Tip View	Available only on HEADSET
D	Transparent Model	Available only on HEADSET
E	3D Off	2D view only
F	3D Follow	Region interest follows the tool. **Warning:** The 3D Follow mode is not intended for use in open surgeries and shall only be used in minimally invasive surgeries.

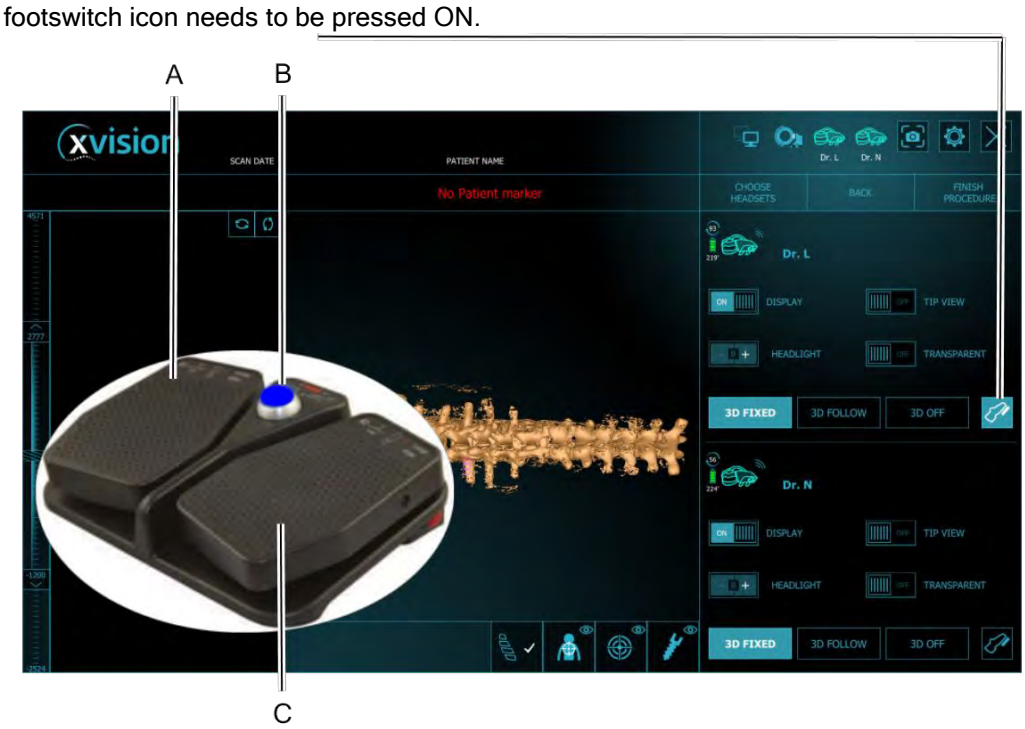
Area	Name	Notes
G	3D Fixed	Show fixed 3D and 2D (slice) displays (according to HEADSET movement) **Warning:** The 3D Fixed mode is not intended for use in open surgeries and shall only be used in minimally invasive surgeries.
H	Second HEADSET	Up to two HEADSETs can be used during a single procedure
I	Head Light	Increases/decreases HEADSET light intensity. Five levels of intensity are available.
J	Display	Toggle HEADSET display off and on

7.7.2. Footswitch Controls

The surgeon can control the following XVISION-SPINE software functions using the Footswitch.

Figure: Footswitch Controls

The footswitch icon needs to be pressed ON.



Area	Name	Notes
A	Left switch	Toggle 3D Fixed/3D Off (unless custom set to make/ *Configuring the Footswitch for other features* (on Page 4-6)
B	Central switch	Activate footswitch and toggle Headset display on and off
C	Right switch	Add/Remove virtual screw unless custom set to make/remove other features: See *Configuring the Footswitch for other features* (on Page 4-6)

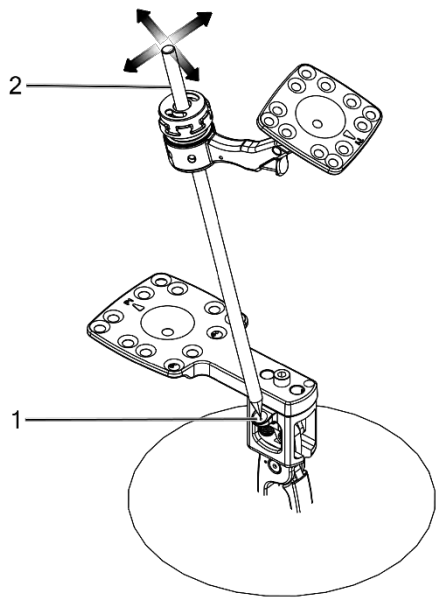
7.8. Tool Verification

When a new tool (surgical instrument) enters the area, the system requests tool verification. The surgeon sees a red notice on the HEADSET.

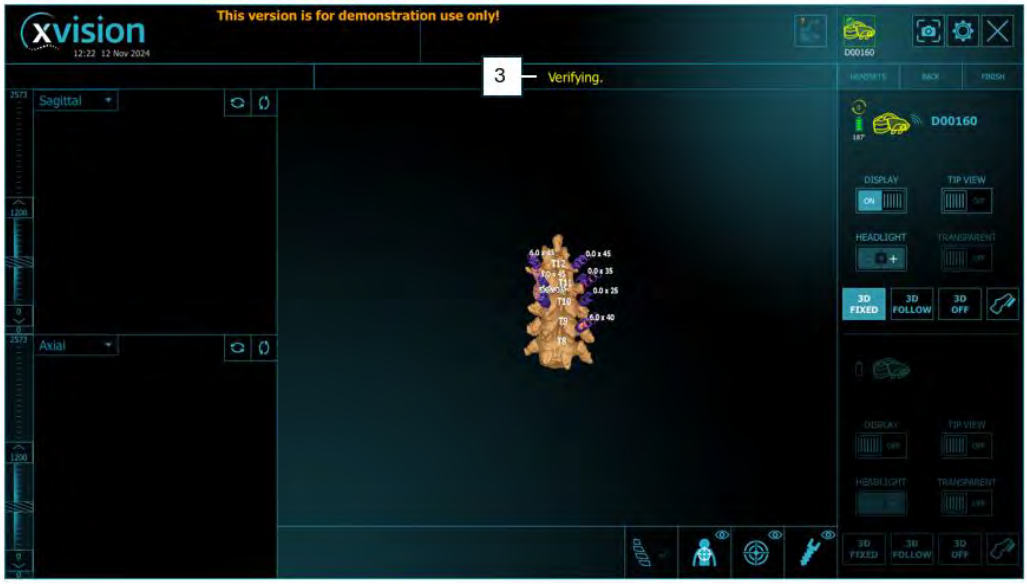
Note: Tool verification is required for the screwdriver every time a new screw is attached to the tool.

Note: XVISION-SPINE can be set to provide sound feedback for verification. See *Sound Feedback Settings* on page 5-37.

Figure: Tool Verification



1 Touch the tip of the surgical instrument to the divot on the body clamp.
2 Swivel the surgical instrument, keeping the tip on the divot.
3 When message ‘veryifying…’ appears in headset and on screen, it means verification is in progress and user should keep the tool as is.



When verification has been completed, the HEADSET and the computer where the XVS SOFTWARE is installed indicate **Tool OK**.

	Warning:	When the Patient Marker is being rotated to a different rotating angle (0, 90,180, 270), the user must verify the tool on the verification divot before continuing with surgery.

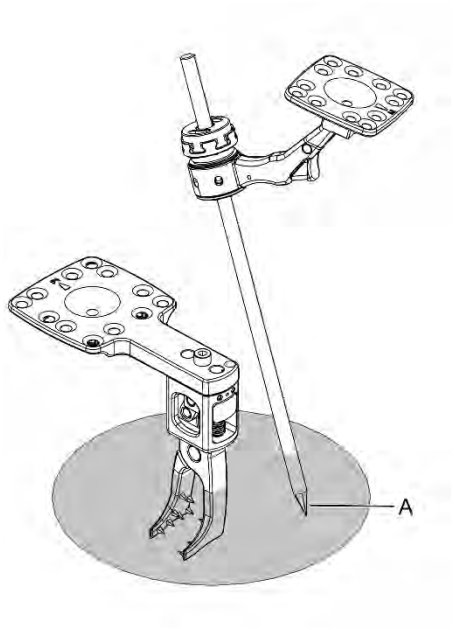
	Note:	When the user switches instruments, every instrument shall be verified before navigating.

	Note:	When verifying Cervical screwdriver, make sure that the identified screw length is correct. If it doesn't, screw size can be manually adjusted to improve screw visualization.

7.9. Anatomical Landmark Check

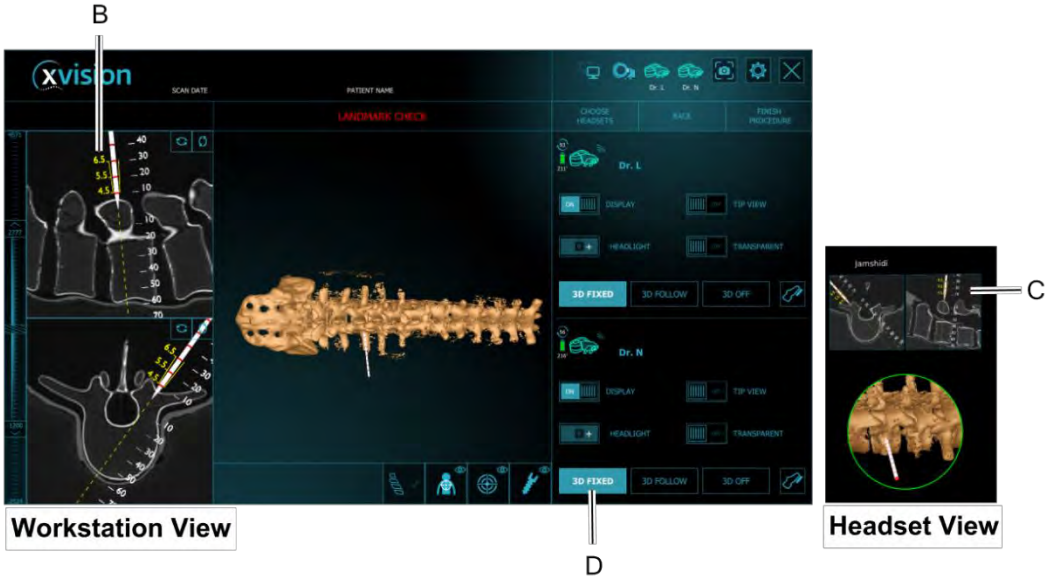
After verification of the first tool, perform an anatomical landmark check as detailed below. The landmark check verifies that the XVISION-SPINE system is correctly interpreting the location of the tool's tip.

Figure: Anatomical Landmark Check (A)



1 Touch the tool tip **(A)** to a known anatomical spot, such as a particular vertebra, or a part of the vertebra.

Figure: Anatomical Landmark Check (B-D)

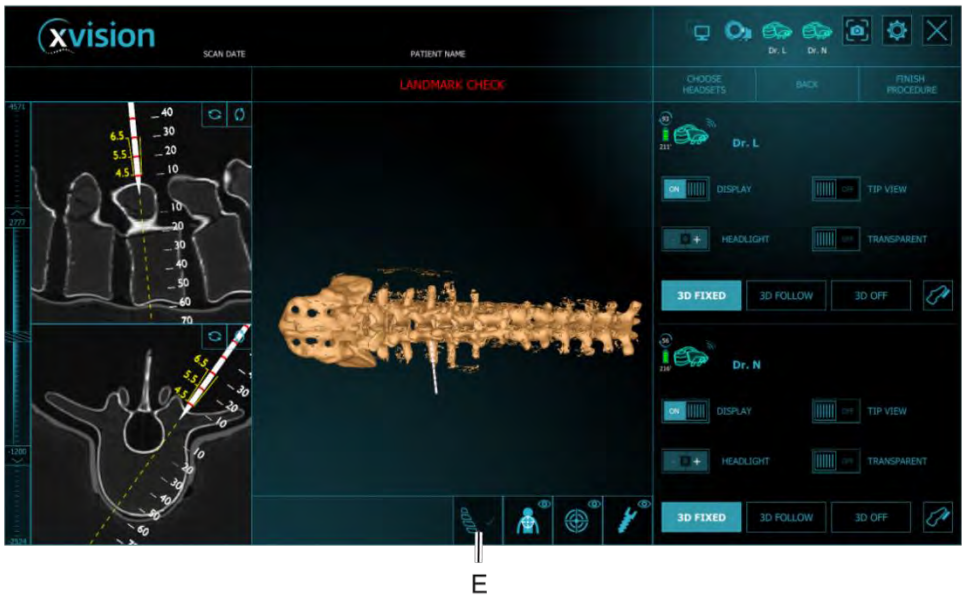


2 If the physical location of the tool tip and its displayed location on the XVISION-SPINE monitor (B) and the HEADSET (C) match, the surgeon instructs the technician to tap the **Anatomical Landmark Check** icon (D) to confirm the match.

Note: During Pre-Op workflow it is required to complete at least 2 Anatomical Landmark Checks prior to navigating the tools for instrumentation.

Figure: Anatomical Landmark Check - On HEADSET

Figure: Anatomical Landmark Check (E)



3 The check mark in the **Anatomical Landmark Check** icon turns from blue to white (E), indicating that the anatomical landmark check has been completed.

Warning: In case of suspicion of movement of the Perc Pin, clamp, or Patient Marker at any time during the surgical procedure, the recommendation is to repeat the anatomical landmark check.

Warning: For Pre-Op workflow with planned S2AI instrumentation and Perc-Pin platform, following the Anatomical Landmark Check, place a calibrated tool and mark the Perc-Pin trajectory as a Target to prevent collisions during S2AI instrumentation.

7.9.1. Navigation on 2D views

The Headset of the XVISION-SPINE system displays both 2D stereotaxic and composite anatomic views.

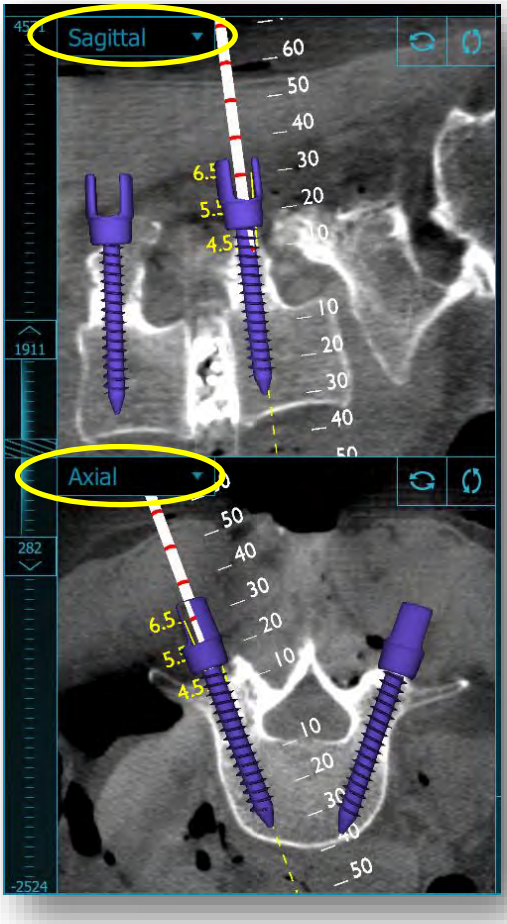
- The stereotaxic views (Axial and Sagittal) are indicated for correlating the tracked instrument location to the registered patient imagery.
- The composite anatomic views (in dual square views) are indicated for displaying the virtual instrumentation location in relation to the composite anatomic view to assist in visualization and trajectory planning.

Warning: Composite anatomic views should not be used for stereotaxic navigation during the procedure. The Axial and Sagittal (slice) views provide tracked instrument location correlating to the registered patient imagery

7.9.2. Stereotaxic Views

- The stereotaxic views (Axial and Sagittal) are indicated for correlating the tracked instrument location to the registered patient imagery.
- Access these views by selecting Axial/Sagittal in the Navigation and Visualization drop down menu within the square viewing window. Highlighted in yellow in Figure:

Figure: Stereotaxic Views. Axial and Sagittal 2D windows.



7.9.3. Composite Anatomic Views

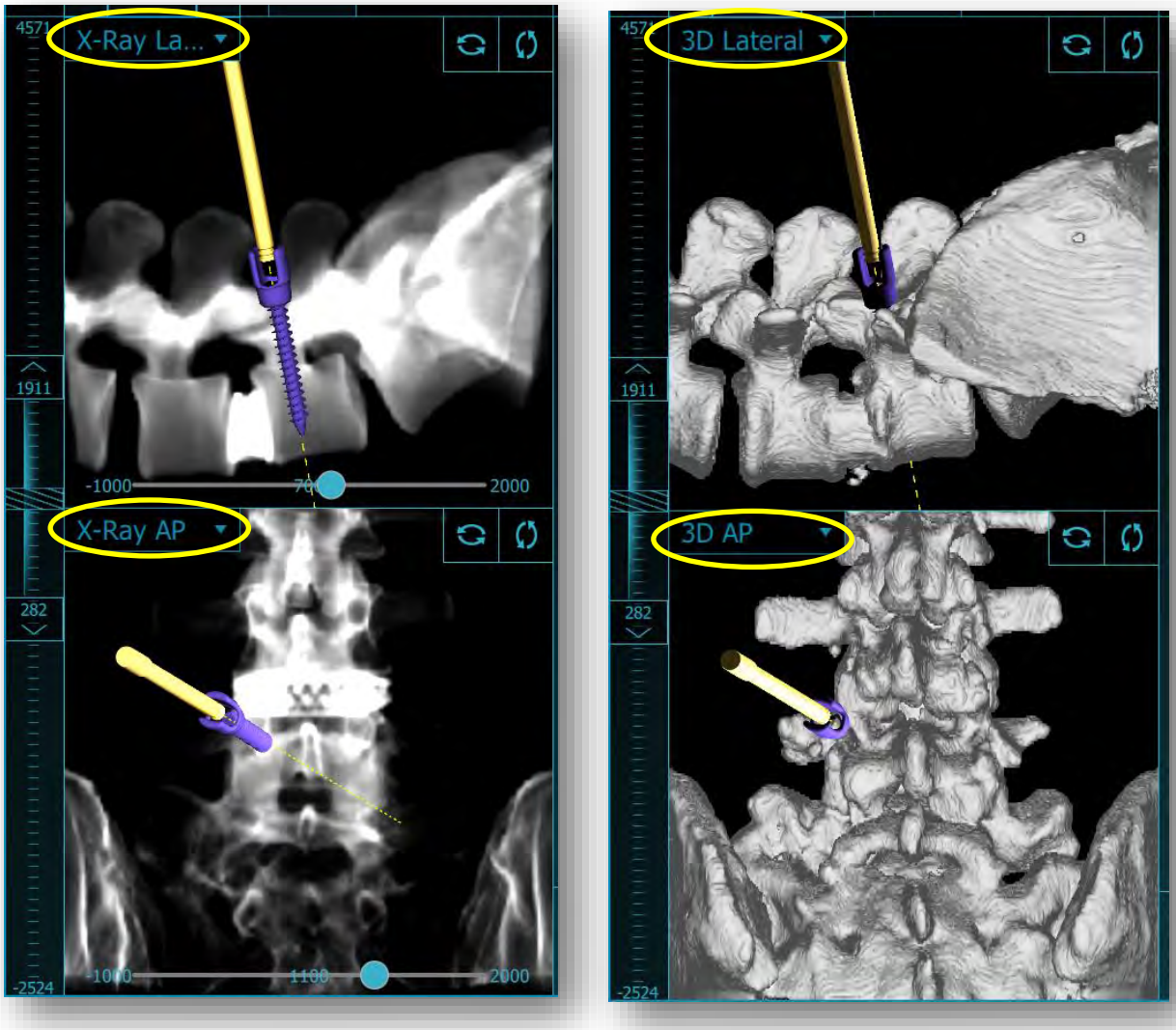
- The composite anatomic views (dual square viewing windows) are indicated for displaying the virtual instrumentation location in relation to the virtual anatomy to assist in percutaneous visualization and trajectory planning.

- Access these views by selecting Axial/Sagittal in the Navigation and Visualization drop down menu within the square viewing window. Highlighted in yellow in Figure.

Square Viewing Window Options

- X-Ray Lateral
- X-Ray AP
- 3D Lateral
- 3D AP

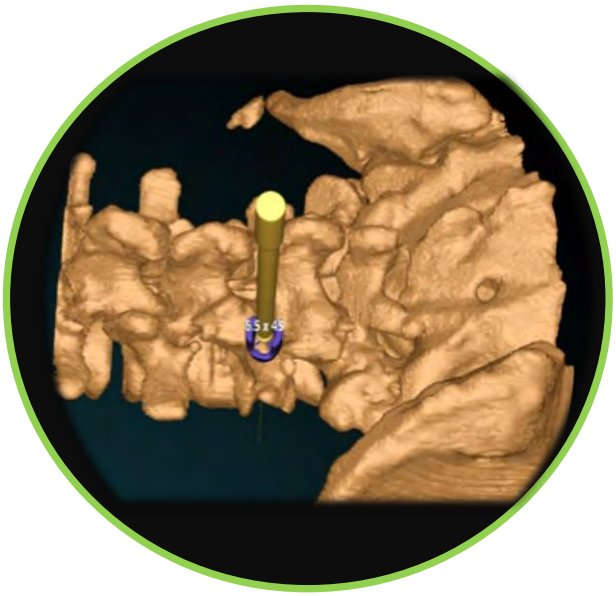
Figure: Composite Anatomic Views.



Circle Viewing Window Option

- 3D *Virtual* Anatomy of registered imagery.
    - This viewing pane can be toggled ON/OFF by the user at any point and is displayed in the central circle viewing window on the XVISION headset.
    - This view should be toggled OFF during open instrumentation as surgeon has direct visualization of anatomy.

Figure: Headset View – 3D Virtual Anatomy



7.10. Skin Landmark Check

Warning: A skin landmark check is not an alternative to an anatomical landmark check. Always perform an anatomical landmark check as and when one is prescribed by this manual.

However, if any suspicion that the Perc Pin, clamp, or Patient Marker has moved, it may be helpful to perform a skin landmark check in addition to an anatomical landmark check.

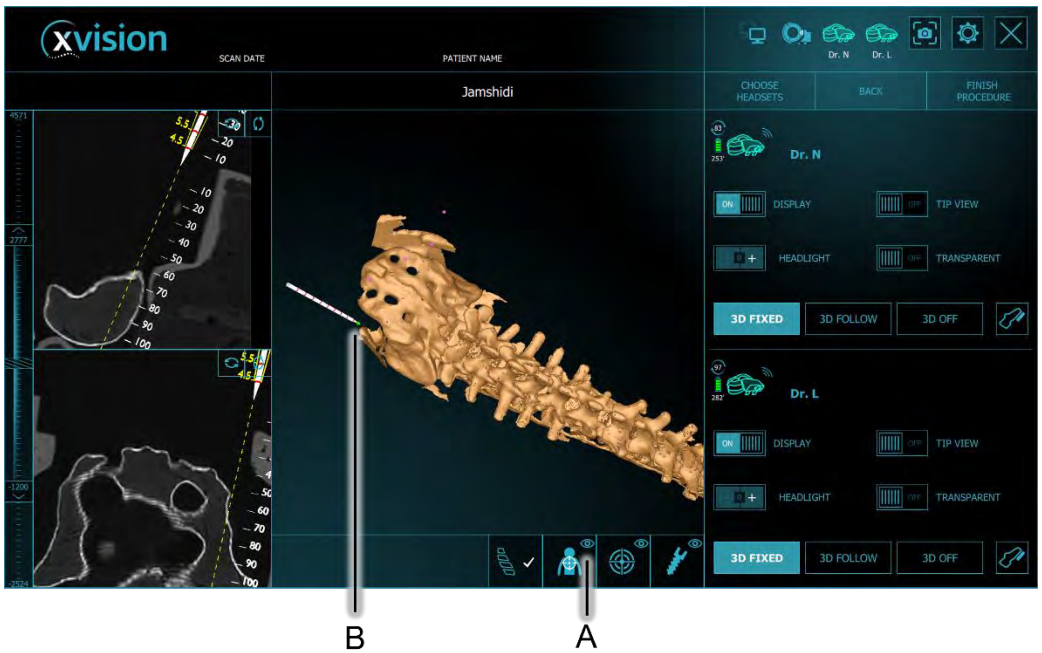
A skin landmark is the mapping of an ink dot on the patient's skin to a virtual dot in XVISION-SPINE.

Up to 10 skin landmarks can be performed. If there are already 10 skin landmarks and a new one is made, then the oldest skin landmark will be deleted.

7.10.1. Making a Skin Landmark

1 Make an ink dot on the patient's skin with a pen.
2 Place the tool tip on the dot.

Figure: Making a Skin Landmark

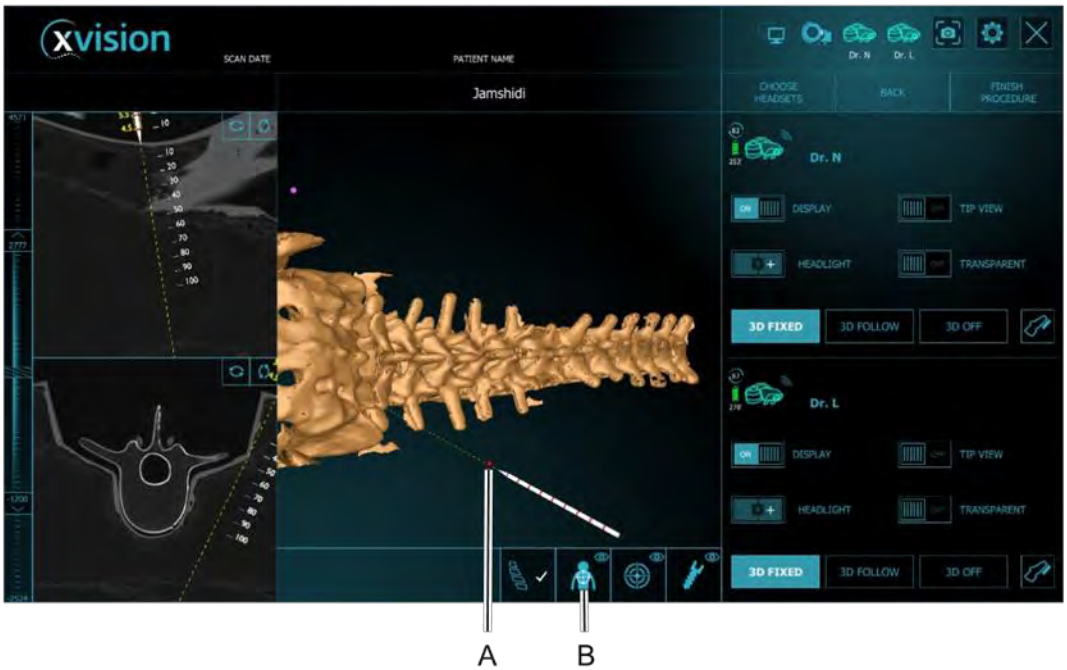


3 Press the skin landmark icon (A).
4 A virtual dot (**B**) appears on the display.
- When the tool tip is touching the ink dot, the virtual dot is highlighted green (**B**).
- When the tool tip is not touching the ink dot, the virtual dot is pink.

7.10.2. Removing a Specified Skin Landmark

1 On the workstation, select the landmark (virtual dot) to be removed.

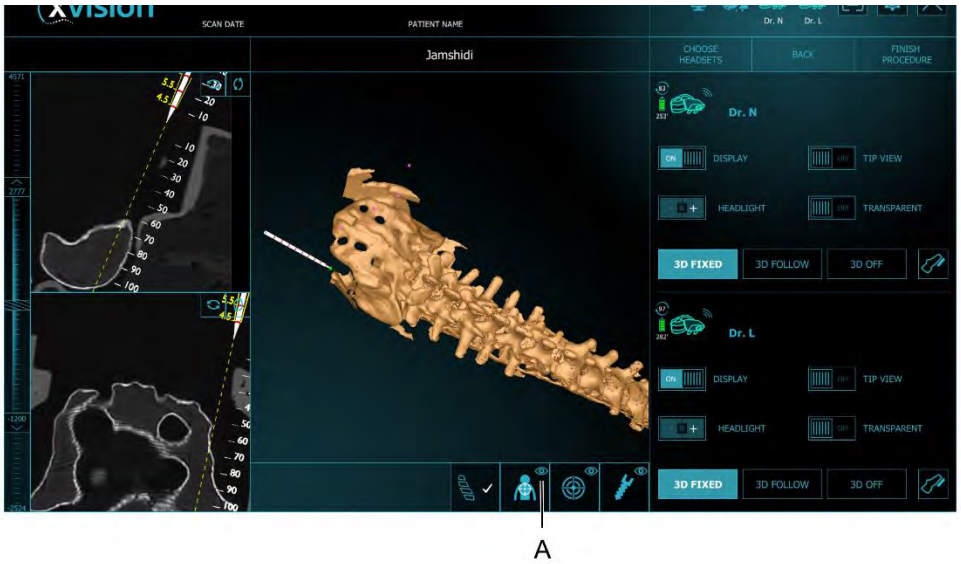
Figure: Removing a Specified Skin Landmark



2 The virtual dot turns red (A) when selected.
3 Press the skin landmark icon (B).
4 The skin landmark is now removed.

7.10.3. Hiding and Displaying Skin Landmarks

Figure: Hiding and Displaying Skin Landmarks



To toggle between displaying and hiding all the skin landmarks, press the eye icon (**A**) next to the landmark icon.

5

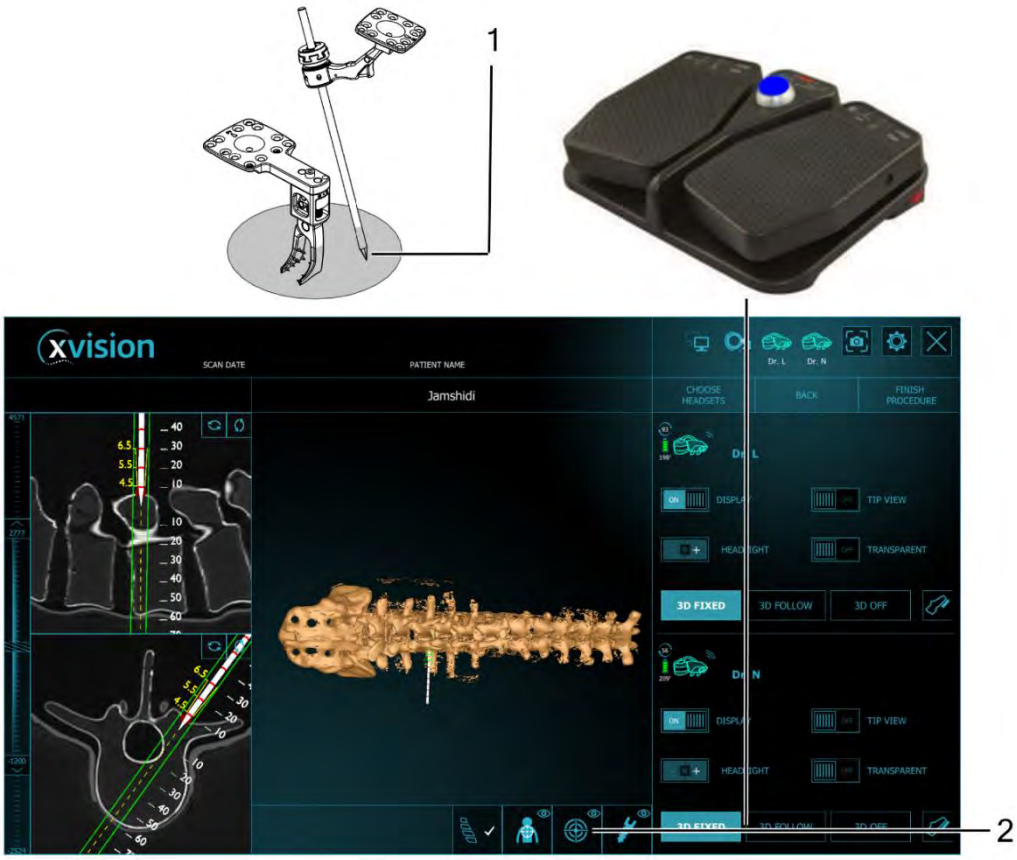
7.11. Virtual Target, Virtual Screw and Trajectory Guide

During the procedure, the surgeon may want to prepare and use a virtual target for a tool, a virtual guide for the tool's trajectory to the target and a virtual screw. This section details how to perform this.

7.11.1. Preparing a Virtual Target and Trajectory Guide

To prepare a virtual target and trajectory guide, the surgeon first marks them and then sets them. Both these procedures are described in this section.

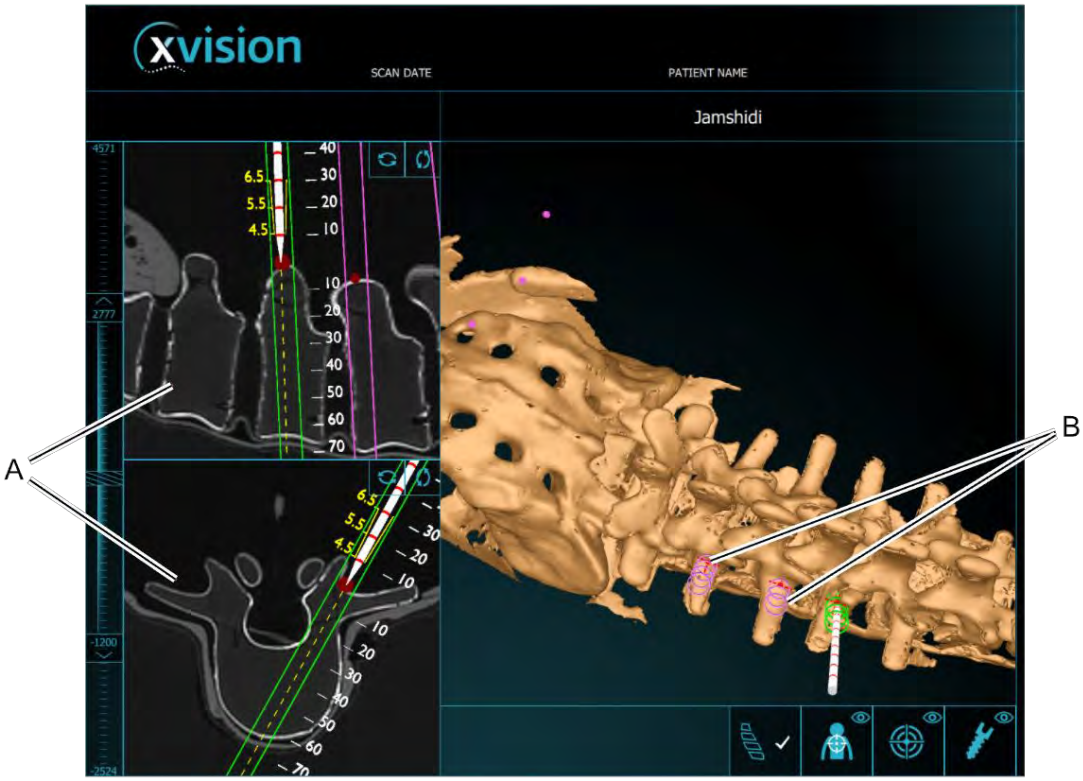
Figure: Marking a Virtual Target and Trajectory Guide (1st step)



1 Using the navigated tool, the surgeon touches the tip of the surgical instrument to the relevant part of the patient's anatomy (that is, the actual target).

2 The surgeon presses the right pedal or instructs the technician to tap the **Target** button.

Figure: Marking a Virtual Target and Trajectory Guide (2nd step)



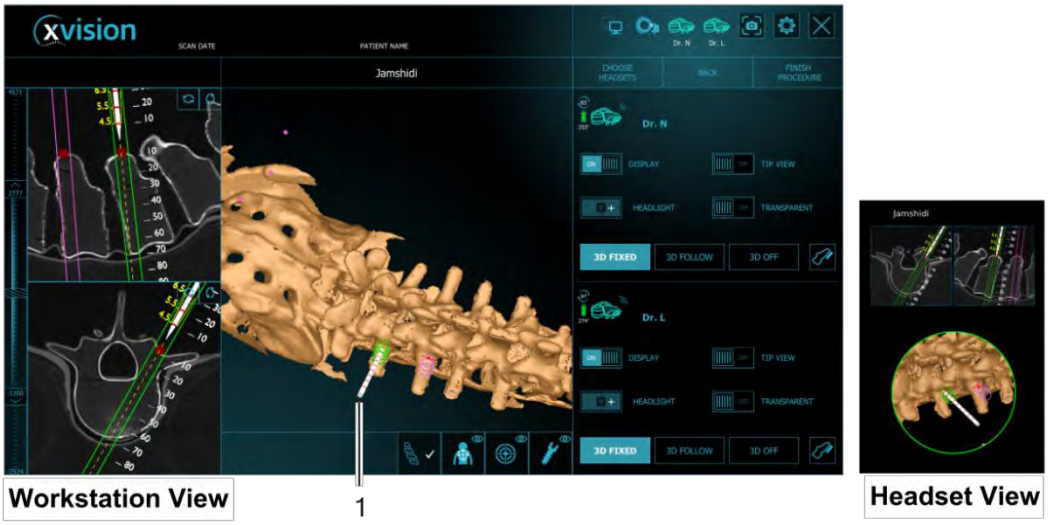
3 The following appear:

- A new virtual target. In 2D view this is displayed as a red sphere (**A**) and two parallel green lines on the patient's anatomy bone. In 3D view this is displayed as red cross hairs (**B**) and a set of rings in the same diameter.

Note: When eleven (11) rings are highlighted, it also highlights the lines of the target in 2D views.

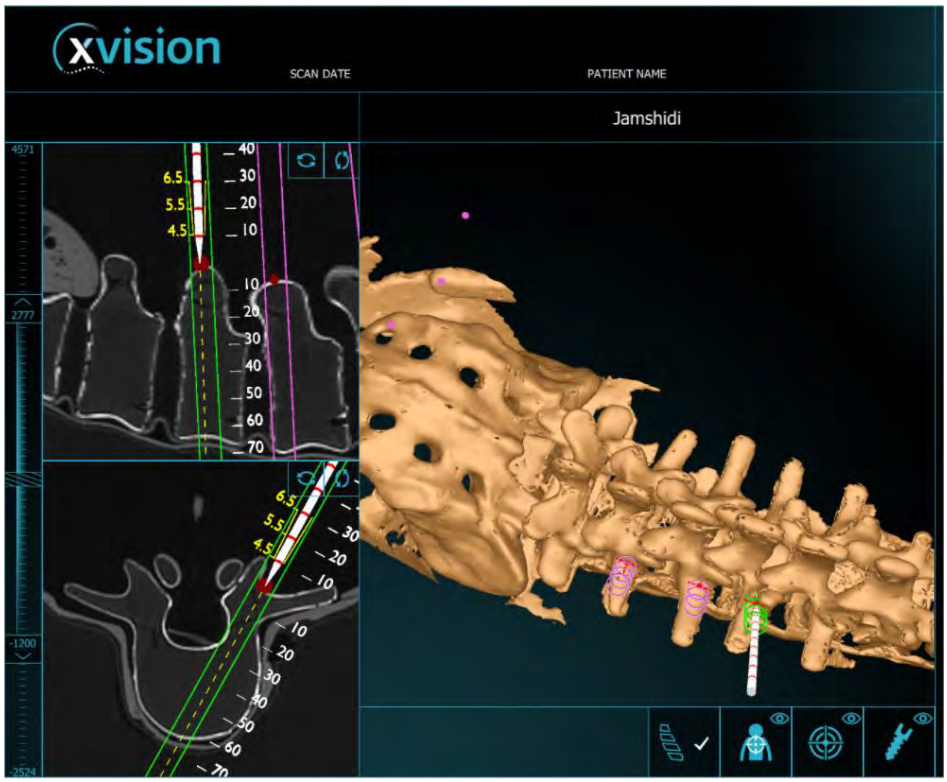
When two rings are highlighted, the target can be removed by footswitch or UI button.

Figure: Setting the Virtual Trajectory Guide (1st step)



1 When the tool is placed within the field of view it appears on the visual display.

Figure: Setting the Virtual Trajectory Guide (2nd step)



2 To start navigating the virtual trajectory, bring the tool tip to the pink rings furthest from the target. The ring will turn green to indicate that this part of the virtual trajectory guide has been set successfully.

Note: Ring diameters are:

- 2D ring = 7.5 mm diameter
- 3D ring = 9 mm diameter

Tolerances for rings turning green are:

- 2D tolerance = Green < 2 degrees
- 3D tolerance = Green < 2 degrees

Note: Pressing the **Target** button when fewer than three rings are colored green results in adding another target.

Note: Of the rings above the tool tip, only the three immediately above the bullseye are displayed at any time.

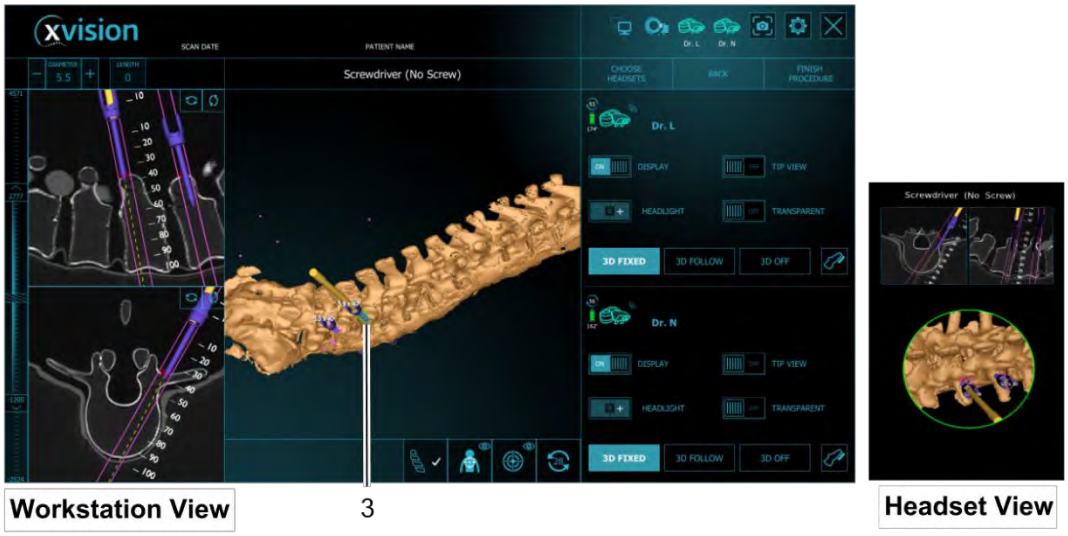
The surgeon now has a virtual trajectory guide that can be used to insert another surgical tool at the same location.

7.11.2. Inserting a Screw Using the Virtual Trajectory Guide

Figure: Inserting a screw using Virtual Trajectory Guide (1st step)

1 Align the screw along the virtual trajectory guide and insert it.

Figure: Inserting a Screw Using Virtual Trajectory Guide (2nd step)

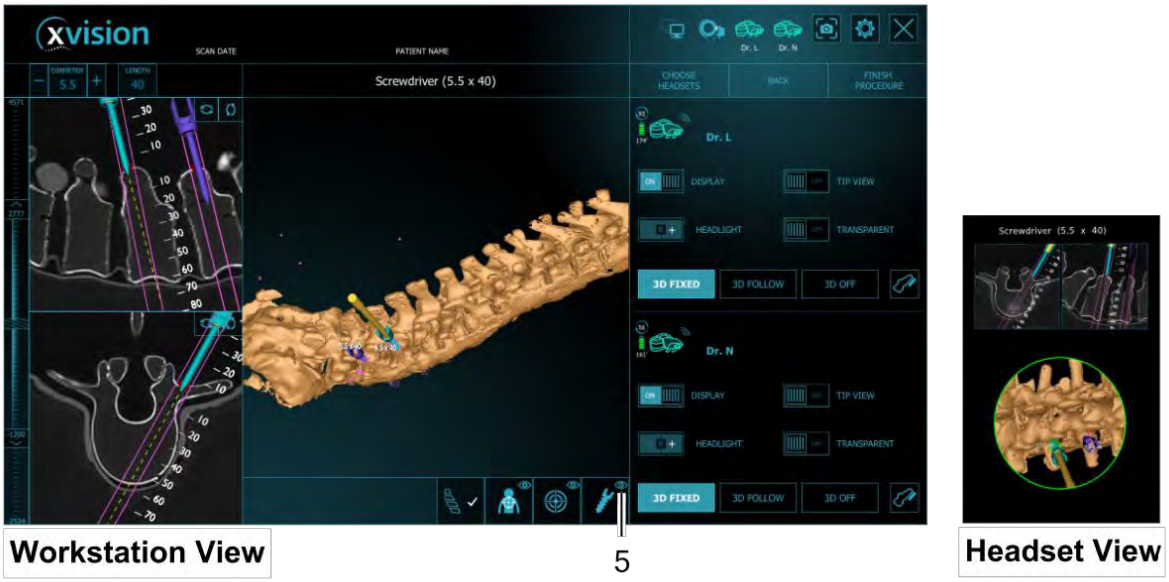


2 When the screw has been inserted the technician taps the screw icon to release the virtual screw from the virtual tool.

3 The screw turns purple.

Note: If a virtual screw is accidentally released, it is no longer navigated. From the moment of release, there is a 30 second period in which the virtual screw can be reconnected (returned) to the virtual tool: See *Reconnecting a Screw* on page 7-122. After reconnection, navigation may be proceeded.

Figure: Inserting a Screw Using Virtual Trajectory Guide (3rd step)



4 As screws are inserted and released, they appear purple in the workstation view and headset view.
When placing a new screw on the screwdriver, screw length is automatically detected during verification.

Note: Screw diameter is not automatically detected. The screw diameter value is kept as that of the last screw placed. The user must verify and adjust screw diameter manually (when applicable) whenever placing a new screw.

5 Tap the eye on the screw icon to hide (or view) the virtual screws.

7.11.3. Reconnecting a Screw

If a screw was accidentally released from the screwdriver, it can be reconnectd (returned) to the screwdriver within 30 seconds of release, by following the procedure in this section.

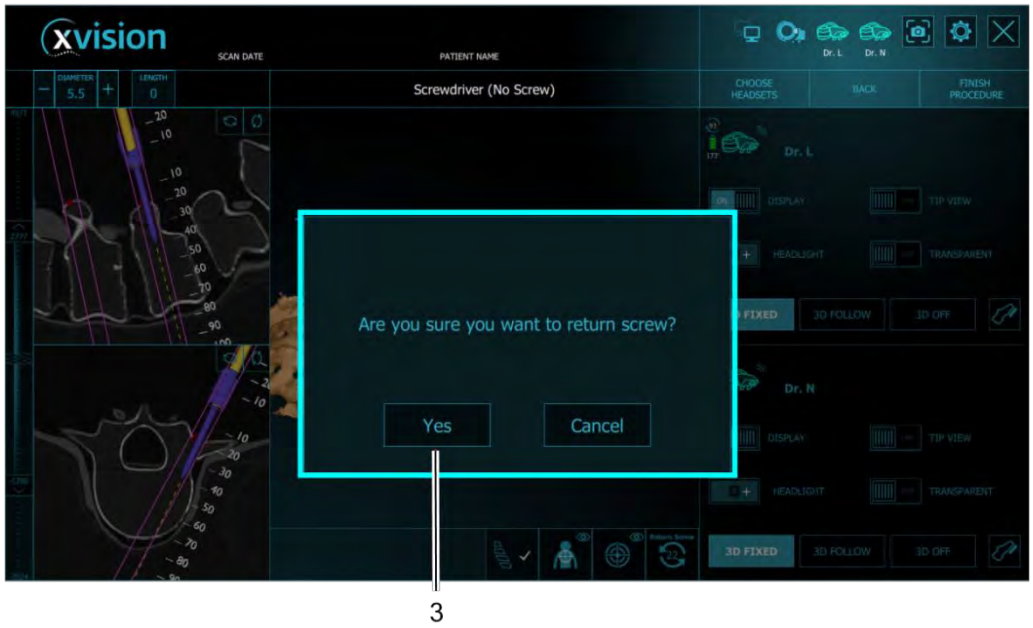
Figure: Reconnecting a Screw (1st step)

1 Tap the screw icon.

Figure: Reconnecting a Screw (2nd step)

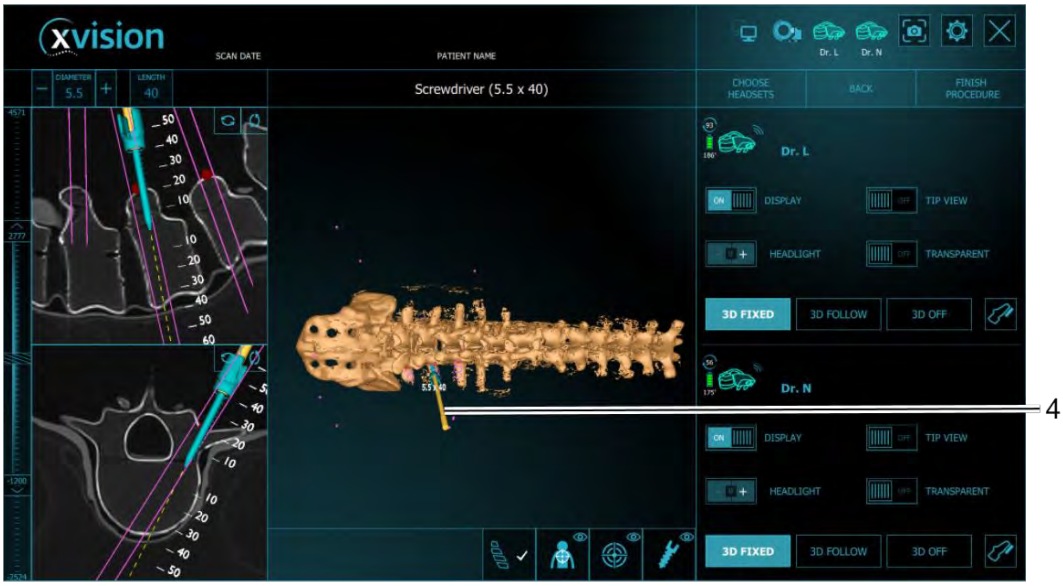
2 A timer (2) appears in place of the screw icon. It counts down the time available to reconnect the screw. Tap the timer.

Figure: Reconnecting a Screw (3rd step)



3 In the confirmation pop-up window, tap **Yes**.

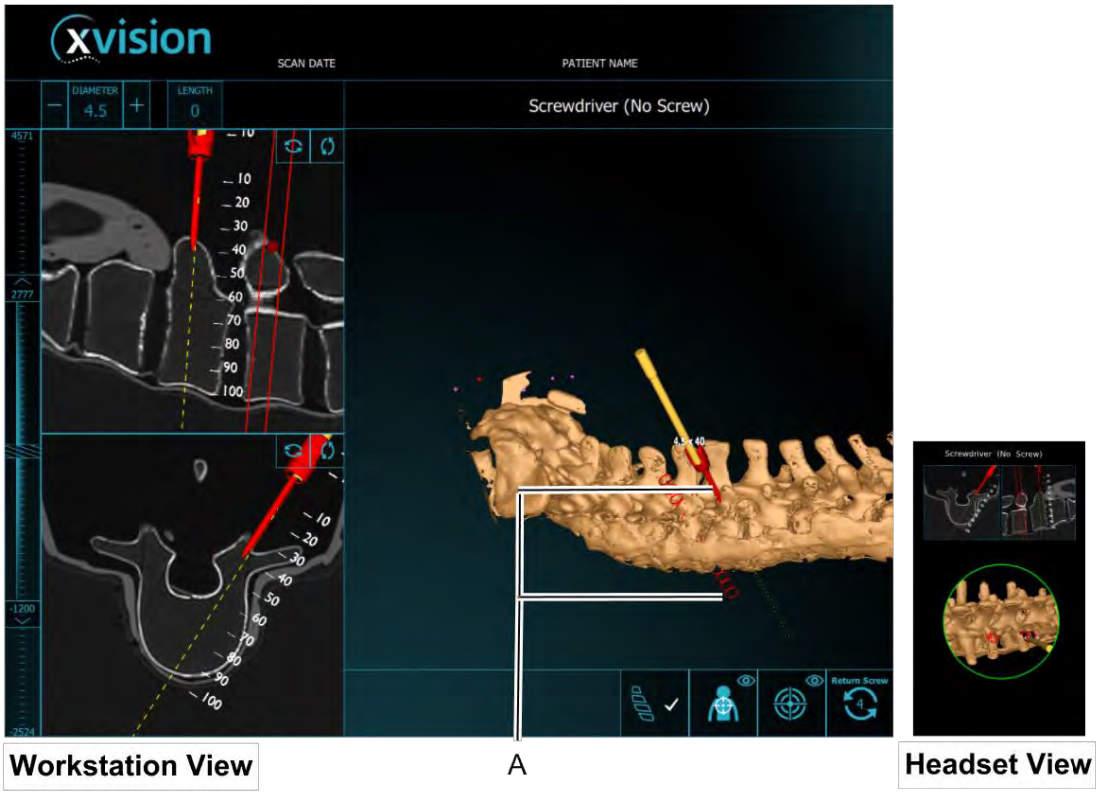
Figure: Reconnecting a screw (4th step)



4 The screw reconnects to the screwdriver.

7.11.4. Removing a Virtual Target or a Virtual Screw

Figure: Removing a Virtual Target or a Virtual Screw



1. Click the virtual target or the virtual screw. When it turns red (A) click it again, or
2. Move the tool inside the green funnel and click the target button on the display or click on the footswitch pedal.

Note: If the virtual target is accidentally deleted, create a new one by repeating the first procedure in this section.

7.12. Ending an xvision-Spine Procedure

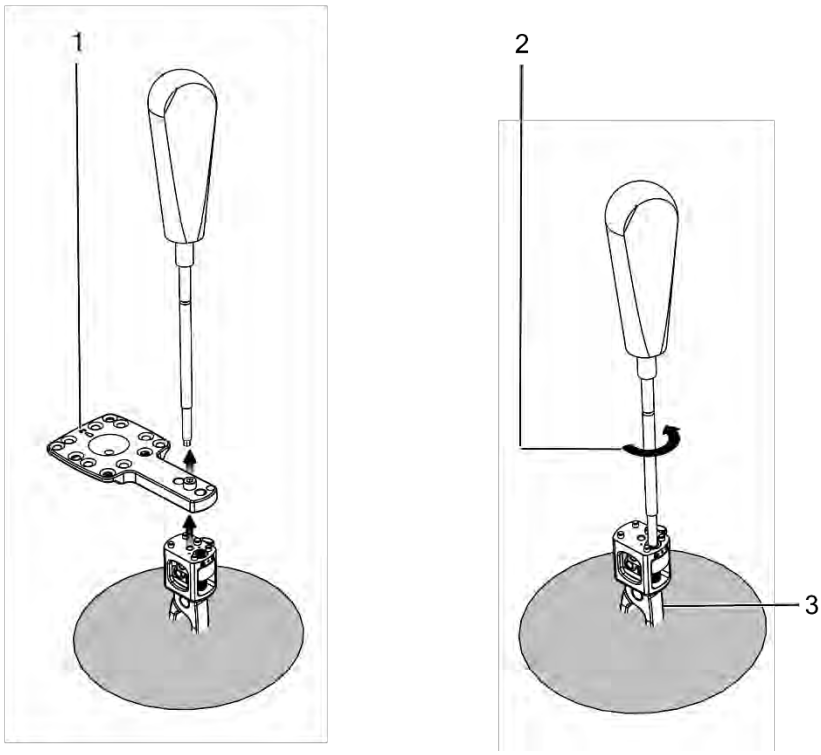
Warning: Do not plug-out the power-cord prior to shutting down the PC properly, as described in Final Steps on section 7.10.3.

At the end of the **XVS** portion of the surgical procedure follow the steps in the relevant subsection below:

- See *XVS Spine Clamp Removal* on page 7-126.
- For procedures using a sterile Perc Pin, See *Perc Pin Removal* on page 7-128.

7.12.1. XVS Spine Clamp Removal

Figure: Removing the XVS Spine Clamp



1 Remove the Patient Marker (with or without the PM Extender) from the Patient Clamp using the Allen screwdriver.
Disconnect the Patient Marker from the Patient Marker Extender and discard **only the Patient Marker.** (Patient Marker Extender should be returned to the Standard tray).

2 Loosen the Patient Clamp using the Allen screwdriver and set it aside for cleaning and sterilization.

Note: In some cases, the Patient Clamp cannot be loosened using the Allen screwdriver. In this case continue with *Clamp Removal Tool* (page 7-126).

3 Remove the Patient Clamp and set it aside for cleaning and sterilization.

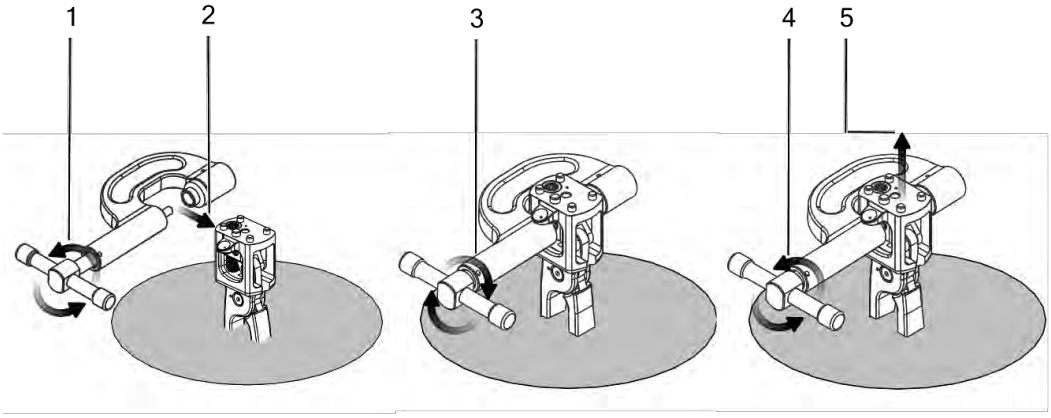
Continue with *Final Steps* (page 7-129).

Clamp Removal Tool

Follow the procedure below when the Patient Clamp cannot be loosened using the Allen screwdriver.

Note: The Clamp Removal Tool releases a screw in the Patient Clamp and renders it obsolete. The Patient Clamp cannot be reused.

Figure: Clamp Removal Tool

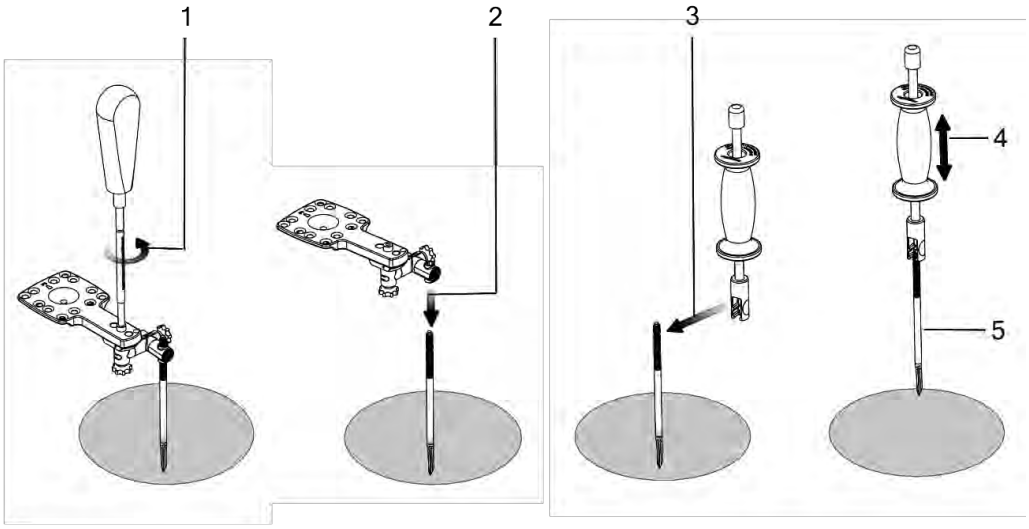


1 Rotate the Clamp Removal Tool handle counterclockwise.
2 When the jaws are open sufficiently, place the clamp removal tool over the Patient Clamp.
3 Rotate the handle (of the removal tool) clockwise until the clamp is fully closed.
4 Rotate the handle counterclockwise until the Patient Clamp opens completely.
5 Remove the Patient Clamp and Clamp Removal Tool.
6 Set the clamp removal tool aside for cleaning and sterilization.
7 Discard the Patient Clamp.

Continue with *Final Steps* (page 7-129)

7.12.2. Perc Pin Removal

Figure: Removing the Perc Pin



1 Remove the Patient Marker (with or without the PM Extender) using the Allen screwdriver. Disconnect the Patient Marker from the Patient Marker Extender and discard **only the Patient Marker.** (Patient Marker Extender should be returned to the Standard tray)
2 Remove the Perc Pin adaptor and set it aside for cleaning and sterilization.
3 Slide the slap hammer over the Perc Pin so that it is held by the Perc Pin's indentations.
4 Grasp the slap hammer handle and move it up and down to remove the Perc Pin from the bone. Set the slap hammer aside for cleaning and sterilization.
5 When the Perc Pin has been removed, dispose of it according to local regulations for disposition of contaminated material.

Continue with *Final Steps* (page 7-129).

7.12.3. Final Steps

When the spine Clamp or Perc Pin have been removed, continue as follows:

1. Remove surgical tools from their tool adaptors.
2. Inspect any XVS Straight Clamp or XVS Arc Clamp for damage:

Warning: Discard clamps when they are scratched, or the anodized surface is compromised, or the clamp teeth are bent or broken.

Warning: Discard clamps with screws that are difficult to tighten or untighten.

3. Send undamaged clamps and other surgical tools for cleaning and sterilization. See *Cleaning Reusable Components* on page 8-133 for more information.
4. Inspect any Universal Tool Adaptor for damage:

Warning: Discard Universal Tool Adaptors with screws that are difficult to tighten or untighten.

5. For **Pre-Op procedure** make sure that:
   a. Ensure C-arm Ring adaptor is disassembled, **cleaned** and stored in its enclosure.

Warning: The C-arm Ring Adaptor **must be cleaned** according to the C-arm Ring Adaptor Cleaning instructions.

   b. Ensure connecting cable to C-arm is disconnected from both C-arm system and the **XVS SYSTEM**

   For **Intra-Op procedure** disconnect LAN cable from 3D imaging device and the **XVS SYSTEM**.

6. Tap Finish Procedure in the **XVS SOFTWARE**.
   a. For Intra-op procedure data will be deleted once confirmed.
   b. For Pre-Op procedure the following prompt appears:

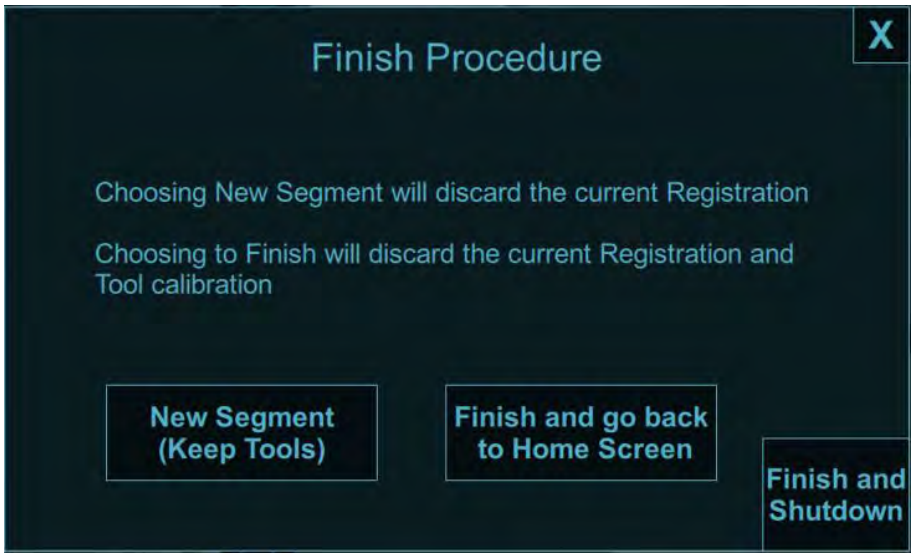


Figure: Finish Procedure prompt

7. Tap 'X' in the XVS SOFTWARE.
8. Select one of the three options following software pop-up prompt (Figures below).
    a. **Restart**: Selecting this option will restart the XVISION application and the XVISION home screen will be displayed.
    b. **Shut Down**: Selecting this option will fully Shut Down the XVISION workstation (i.e. between procedures, of for storage after completion of procedure).
    c. **Log Off**: Utilized by Augmedics representative or technician.
9. Follow confirmation prompts based on user selection.

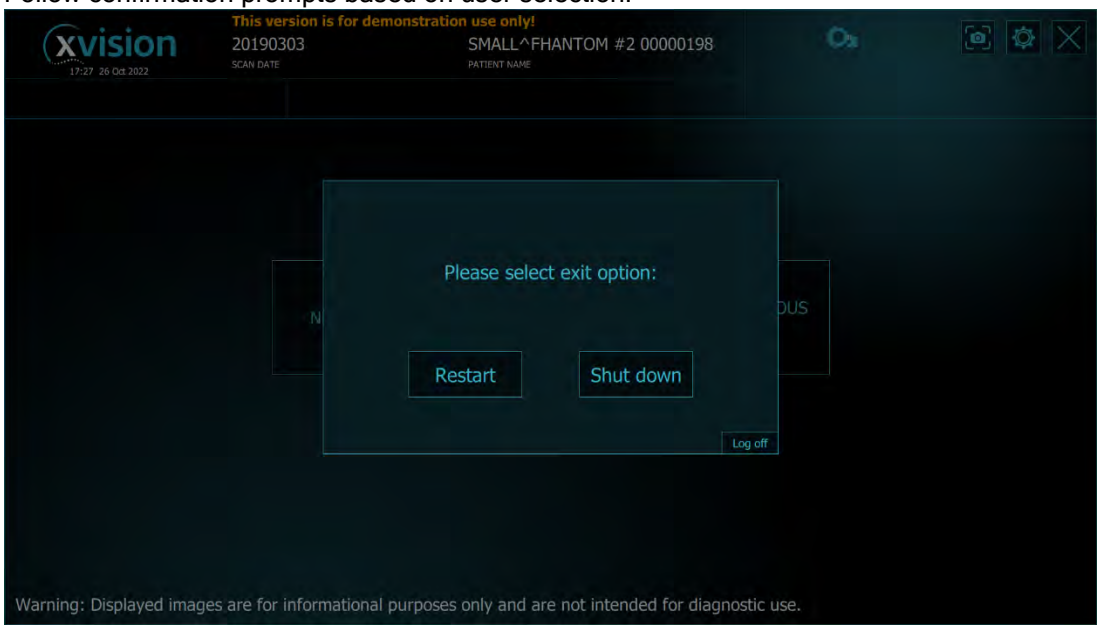


Figure: Exit prompt. Select Restart, Shut Down, or Log Off.

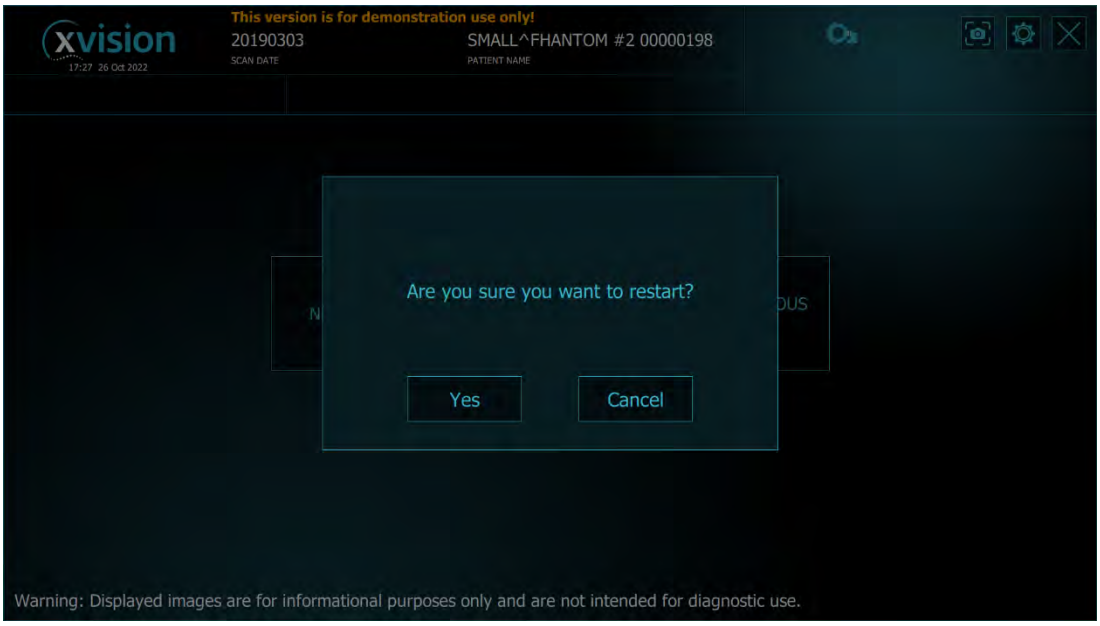


Figure: Restart pop-up prompt.

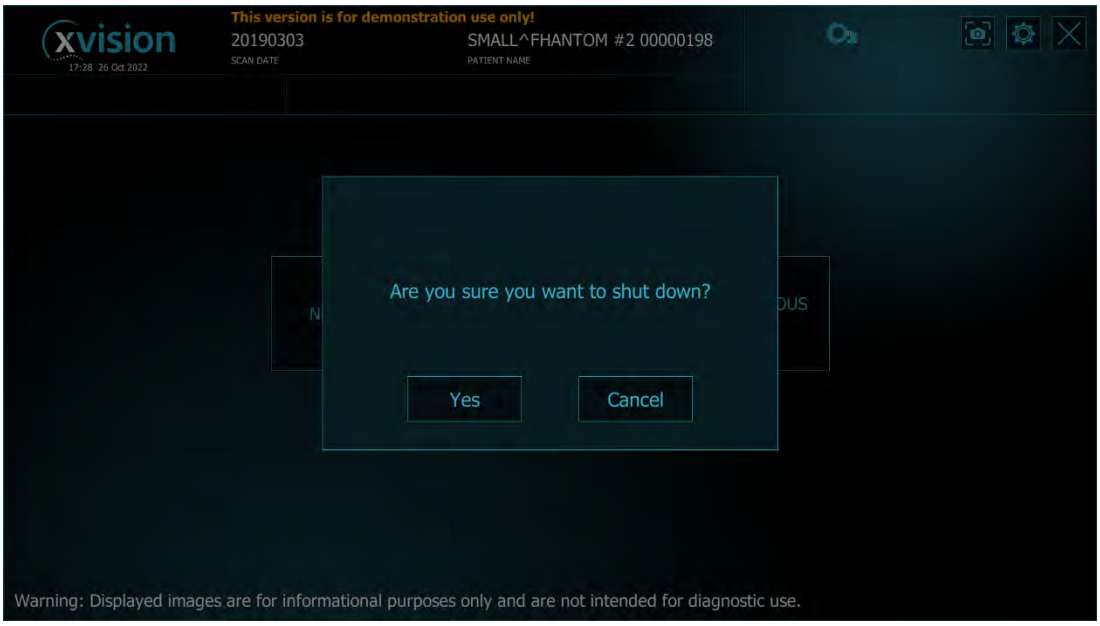


Figure: Shut Down pop-up prompt.

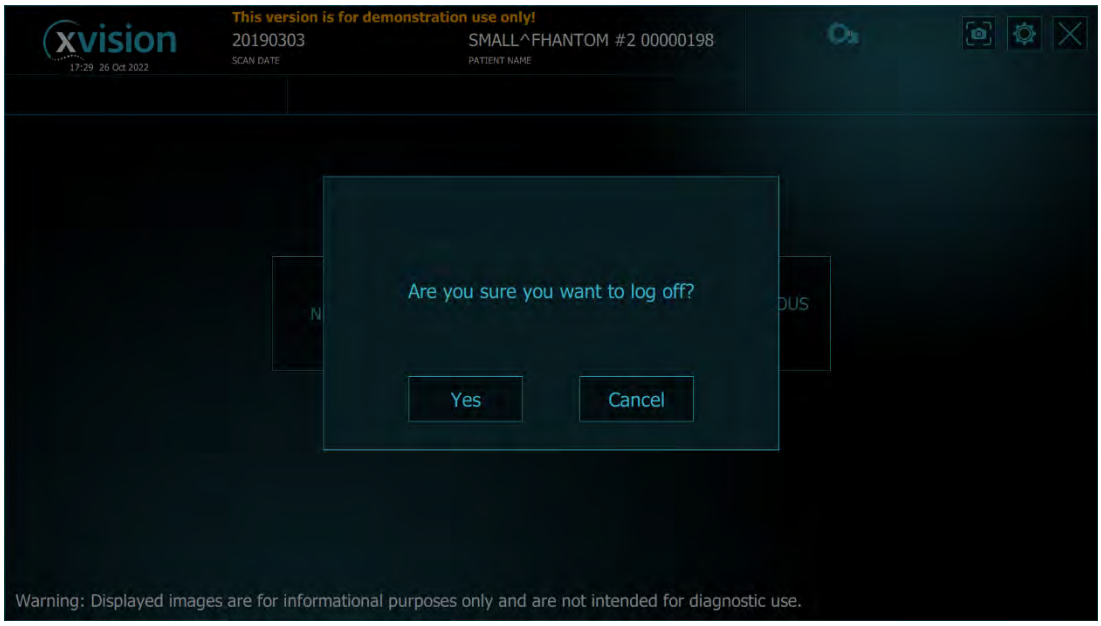


Figure: Log Off pop-up prompt.

10. If **Shutdown** is selected:
    a. Wait for the Power button LED to be off (Not Blue)
    b. Unplugthe white power cord from (Wall) power outlet.
11. Power down the HEADSET by pressing the ON/Off button.
12. Disconnect the battery cable.
13. Remove the HEADSET.

Warning: When removing the headset, take care to touch only the plastic parts.

14. Place the **HEADSET** battery in the charging station.
15. Clean and disinfect the **HEADSET** according to the instructions in *Cleaning and Disinfection of the Headset* (page 8-136).
16. Dispose of all components from the Single Use Sterile Kit (Patient Markers, Tool Markers, and X-Marker Registration Marker) according to local regulations for disposition of contaminated material.
17. Dispose of any Sterile Perc Pin according to local regulations for disposition of contaminated material.

8. Cleaning Reusable Components

Follow the procedure below to clean the reusable components of the XVISION-SPINE system:

- Patient Clamps (XVS Straight Clamp Short/Tall, XVS Arc Clamp)
- Universal Tool Adaptors
- Patient Marker Extender
- Allen screwdriver
- Z-Markers
- Navigated Tool Adaptors
- XVS Adaptors
- Rotating Marker Adaptor
- XVS wrench
- Clamp Removal Tool
- VP Tool Adaptor
- Perc Pin kit (if used)
    - Perc Pin mallet
    - Perc Pin insertion cap
    - Perc Pin slap hammer
    - Perc Pin adaptor

All reusable components must be thoroughly cleaned and sterilized before initial use and after each subsequent use.

None of the reusable components in the system require disassembly prior to cleaning.

Caution: Do not use solvents, lubricants, or other chemicals unless otherwise specified.

Note: Whenever possible, do not allow blood, debris, or body fluids to dry on instruments. For best results, and to prolong the life of the reusable components, process immediately after use.

8.1. Automatic Cleaning

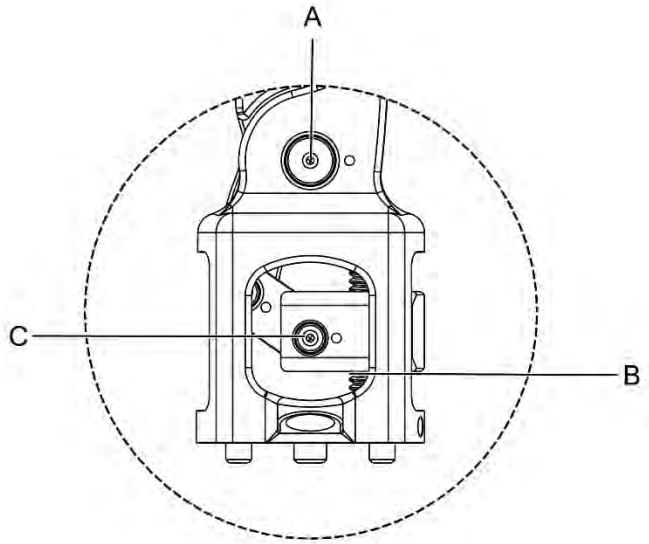
Follow the pre-cleaning procedure below:

1. Rinse the devices under cold running utility water to remove gross soiling.

Note: Water quality is specified in AAMI TIR34: 2014.

2. While rinsing, use a soft-bristled brush to aid in the removal of soiling, focusing on all hard-to-reach places. See the following figures for more information.
3. Prepare a detergent bath of Valsure® Enzymatic Cleaner at 8 mL per liter (1 oz per gallon) or Neodisher® Mediclean Forte Detergent at 5 mL per liter of lukewarm utility water in an ultrasonic unit.
4. Immerse the devices in the detergent bath and sonicate for a minimum of 2 minutes.
5. Transfer the devices onto a rack accessory contained inside the washer for processing.

Figure: Cleaning Patient Clamp



A Clamp pin
B Set screw
C Hinge pin

Figure: Cleaning Tool Adaptor Apertures

Take care to clean all surfaces.
Perform visual inspection after cleaning for any debris or residues, if such are found, repeat the cleaning process.
Use the following washer cycle.

Phase	Recirculation Time (minutes)	Temperature	Detergent Type and Concentration (if applicable)
Pre-rinse 1	02:00	Cold utility water	N/A
Wash 1	02:00	43 °C utility water	Valsure® Neutral Detergent (US) at 2.0 mL/L or Neodisher® Mediclean Forte (EU) at 2.0 mL/L
Rinse 1	1:00	Cold utility water	N/A
Pure Water Rinse	1:00	43 °C criticall water	N/A
Dry Time	07:00	s °C	N/A

8.2. Steam Sterilization

Sterilize the devices per the parameters below. Two cycles are possible.

Prior to the sterilization cycle, the tray of devices should be individually wrapped in two layers of 1-ply polypropylene wrap (Halyard Health H600 or equivalent).

Note: The hospital is responsible for cleaning and autoclave sterilization of all reusable components.

Steam Sterilization Parameter	Cycle # 1	Cycle # 2
Cycle Type	Pre-vacuum	Pre-vacuum
Preconditioning Pulses	4	4
Temperature	132 °C	134 °C
Exposure time	4 minutes	3 minutes
Dry time	30 minutes	30 minutes

8.3. Cleaning and Disinfection of the (Gen-1 & Gen-2) HEADSET

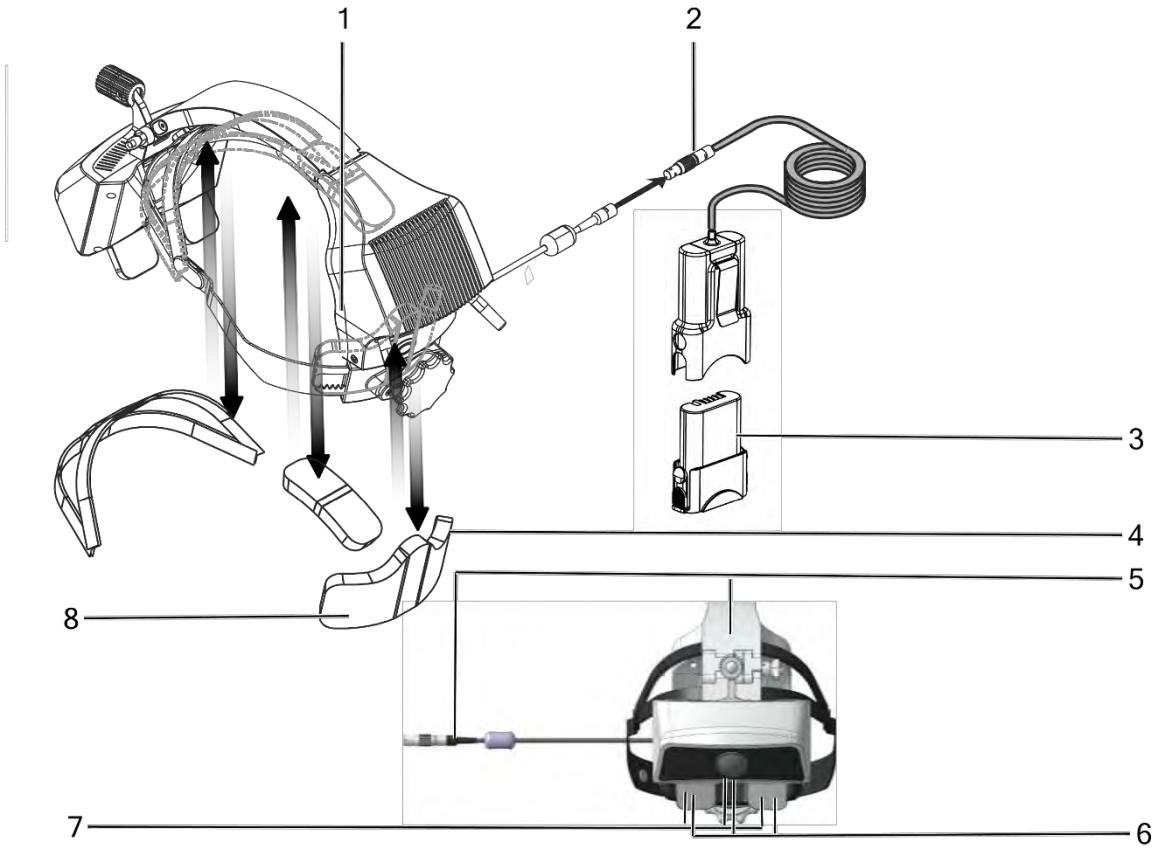
Follow the procedure below to clean and disinfect the HEADSET. All components must be thoroughly cleaned before initial use and after each subsequent use. None of the HEADSET's components require disassembly prior to cleaning, except for the detachable pads and the battery socket.

There is a risk of HEADSET damage if the HEADSET is subjected to cleaning methods not approved by the manufacturer. To reduce the risk of loss of function and/or damage to the HEADSET use only the approved cleaning methods described below.

Caution: Do not attempt to sterilize any part of the HEADSET. Any attempt is likely to cause damage to the HEADSET and its components.

Note: Whenever possible, do not allow blood, debris, or any body fluids to dry on instruments. For best results, and to prolong the life of the HEADSET, process immediately after use.

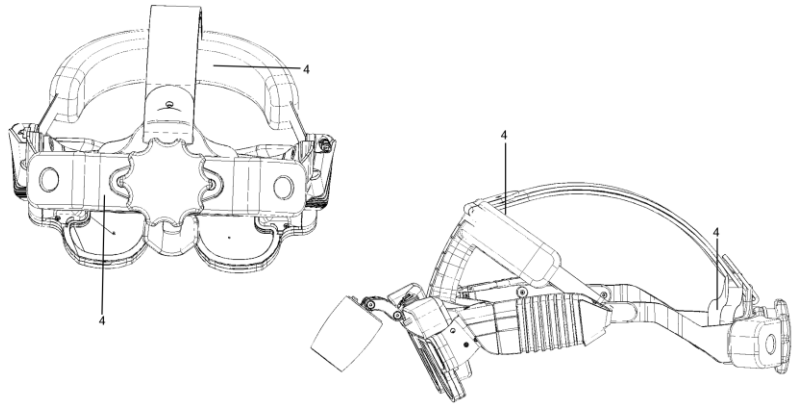
Figure: Cleaning and Disinfection of the HEADSET Gen 1



Follow the cleaning procedure below:

1 Wearing disposable gloves, turn off the HEADSET's power switch.
2 Disconnect the battery socket from the HEADSET.
3 Remove the battery. For more information see *Battery and Charger* on page 4-3 for more information.
4 Remove the three pads attached to the inner portion of the HEADSET (Gen-2 Headset has two Pads) and clean them with CaviWipes METREX™ to remove blood stains or other contaminants. Allow the pads to air dry.

Figure: Dettaching the inner pads of the HEADSET Gen 2



5 Hold the HEADSET in a way that the optical elements are vertical and facing down as shown and clean all the surfaces of the HEADSET and the battery socket with CaviWipes METREX™.
6 Carefully wipe the optical elements of the HEADSET (lenses and camera), as shown, with CaviWipes METREX™ to avoid smears or scratches. Leave the HEADSET to air dry for at least 3 minutes.
7 Visually inspect the HEADSET after cleaning for any debris, or residues, in case such are found, repeat the cleaning process (steps 5-6).
8 Gently wipe the optical elements with a disposable lens cloth.
9 Reattach the pads to the cleaned HEADSET.

Warning: Dispose the used wipes in accordance with Federal, State, and local regulations for infectious materials disposal.

Caution: Do not operate the system until the HEADSET is thoroughly dry.

When the cleaning and disinfection procedure is completed, return the HEADSET to its case.

8.4. C-arm Ring Adaptor Cleaning

Follow the procedure below to clean and disinfect the RING ADAPTOR. All components must be thoroughly cleaned before initial use and after each subsequent use. None of the RING ADAPTOR's components require disassembly prior to cleaning.

There is a risk of RING ADAPTOR damage if the RING ADAPTOR is subjected to cleaning methods not approved by the manufacturer. To reduce the risk of loss of function and/or damage to the RING ADAPTOR use only the approved cleaning methods described below.

Caution: Do not attempt to sterilize any part of the RING ADAPTOR. Any attempt is likely to cause damage to the RING ADAPTOR and its components.

Note: Whenever possible, do not allow blood, debris, or body fluids to dry on instruments. For best results, and to prolong the life of the reusable components, process immediately after use.

Figure: Cleaning and Disinfection of the RING ADAPTOR

Follow the cleaning procedure below:

Wearing disposable gloves, clean all the surfaces of the **RING ADAPTOR** with CaviWipes METREX™ to remove blood stains or other contaminants. Leave to dry for 3 minutes.

Warning: Dispose the used wipes in accordance with Federal, State, and local regulations for infectious materials disposal.

Caution: Do not operate the system until the **RING ADAPTOR** is thoroughly dry.

When the cleaning procedure is completed, return the **RING ADAPTOR** to its enclosure.

Note: If the visual inspection does not pass and you find blood stains or other contaminants, repeat the cleaning and inspection process until the RING ADAPTOR meets the required standards.

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9. Maintenance and Service

The XVISION-SPINE (XVS) system requires annual maintenance. System calibration and updates are provided as required by service personnel. Service should only be provided by authorized Augmedics personnel.

9.1. Periodic (Gen1 & Gen2) Headset Optical Maintenance

The luminance of the HEADSET lens assembly may decrease due to aging. The purpose of this periodic maintenance test is to verify that the luminance of the display is within predefined specifications.

This test shall be performed when the SLT value in the **Settings** menu is higher than 1500H (hours). Perform it according to DMR-XVS-SER-001, and document it accordingly.

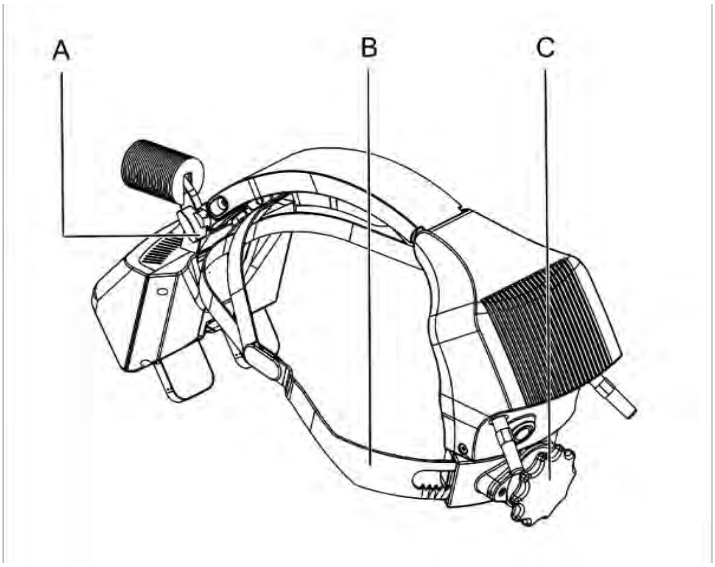
Note: The test shall be performed by qualified personnel.

9.2. Annual Headset Mechanical Maintenance

On an annual basis verify the mechanical functionality of the HEADSET, paying special attention to the following elements.

9.2.1. Gen-1 Headset

Figure: HEADSET Mechanical Maintenance

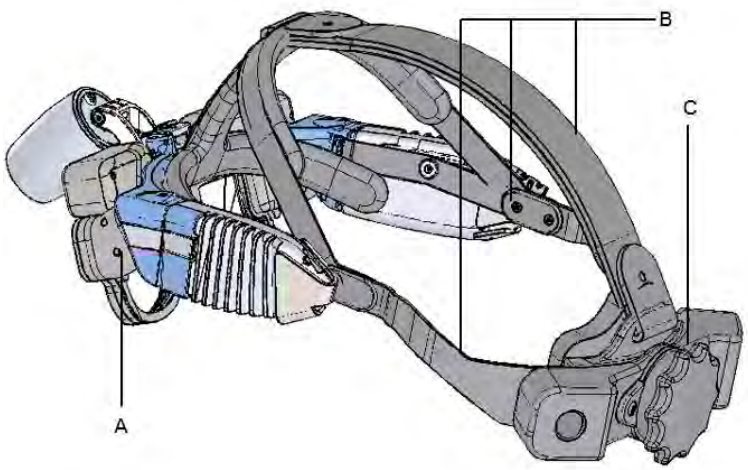


A Folding lock mechanism
B Head strap
C Head strap adjustment knob

1. Perform a thorough visual inspection of the HEADSET and check the following:
   - All enclosures are complete
   - No cracks have developed
   - All screws are in place
   - Pads do not need to be replaced
2. Check the folding lock mechanism (A) in all three states:
   - Float
   - Lock
   - Stow.
3. Verify the functionality of the head strap mechanism (B), including the adjustment knob (C). If there are any problems with the mechanical functionality of the HEADSET contact Augmedics' technical support.

9.2.2. Gen-2 Headset

Figure: HEADSET Mechanical Maintenance



D Lenses Tilting mechanism
E Head straps
F Head strap adjustment knob

4. Perform a thorough visual inspection of the HEADSET and check the following:
   - All enclosures are complete
   - No cracks have developed
   - All screws are in place
   - Pads do not need to be replaced
5. Check the Lenses tilting mechanism (A) in all five states:

- All the way up
- 1st Station
- 2nd Station
- 3rd Station
- All the Way down (45 dg)

Verify that the tilting mechanism slides easily but not freely.

6. Verify the functionality of the head strap mechanism (B), including the adjustment knob (C).

If there are any problems with the mechanical functionality of the HEADSET contact Augmedics' technical support.

9.3. C-arm Ring Adaptor Maintenance

The provided C-arm Ring Adaptor should be inspected prior to each case usage as described in C-arm Ring Adaptor Assembly section (Section 6.1.1).
Once the C-arm Ring Adaptor reaches 240 cases it should be sent back to manufacturer for maintenance.

9.4. Annual Software Maintenance

If Augmedics is the supplier of the computer, perform the following annual maintenance on the computer.

1. Open the Windows Event Viewer and look for intrusion events or cybersecurity events.
2. Run a cybercheck and verify that it complies with the hardening as defined by Augmedics.

Update virus definition tables.

10. Troubleshooting

1. Clinical troubleshooting:

Problem	Result/Reason	Solution
• Tool is not verifying • Wrong screw length detected	• Message appears: “verify tool” and user cannot proceed to navigation • Screw length detected is different than that of the screw attached to the screwdriver.	• Verify that the Headset tracker sees both tool and Patient Marker (green and red dots) • Verify that instrument tip is inside the center verifications divot. • Adjust the instrument’s angle • Verify that Tool Adaptor hasn’t moved • Verify that Tool Marker isn’t loose • Verify instrument isn’t bent • Recalibrate tool- if all the above do not resolve the problem

2. Message Area Notifications

Problem or Message	Result/Reason	Solution	Notes
No Navigation Display on Headset: MULTIPLE TOOLS	The system has detected more than one tool in the operating area (field of view)	Remove the tool that is not in use	No image displayed on HEADSET
No Navigation Display on Headset: MULTIPLE MARKERS	The system has detected more than one Patient Marker in the operating area (field of view)	Remove the Patient Marker that is not in use	No image displayed on HEADSET
No Navigation Display on Headset: NO TOOL	The system cannot detect Tool Marker	Ensure that the Tool Marker is attached to tool/ Ensure that the Tool Marker is not obstructed and is clean	
No Navigation Display on Headset: NO MARKER	The system cannot detect Patient Marker	Ensure that the Patient Marker is attached to clamp/Ensure that the Patient Marker is clean	
No Navigation Display on Headset: XVISION Logo displayed	The Headset is not paired with the Interface software	Perform Headset pairing	
No Navigation Display on Headset: WAITING FOR START PROCEDURE	“Start Procedure” has not been selected in Interface software/Software version mismatch detected	Contact Service	
No Navigation Display on Headset: SYNCING	Headset is Initializing		
No Navigation Display on Headset: Hardware Problem Detected OR Hardware failure detected in…”	There is a problem with the Headset electronics.	Power off the Headset and then on. If the problem persists, replace the battery. If the problem persists after that- contact service.	

Problem or Message	Result/Reason	Solution	Notes
No Navigation Display on Headset: DISPLAY OFF	“Display Off” option was selected in the Interface software or footswitch.	Press again for Display ON	
No Navigation Display on Headset: DISPLAY OFF	The Display button was pressed, turning the display OFF	Press the Display button again to turn the display ON	
Scan Transfer Error: Less than 30 images	The scan transferred contains too few slices	Resend the scan	
Scan Transfer Error: Wrong UID	Scan transferred is corrupt	Resend the scan	
Scan Transfer Error: Image File is Not CT:	The scanner has been incorrectly configured and is transferring an unsupported modality.	Configure the scanner for CT_STORAGE	
Scan Transfer Error: Can't find a supported DICOM file	Folder that does not contain support images has been selected on USB stick		
"Low resources in … "	System problem	Power off the Headset and then on. If the problem persists, contact service.	
"Application is low on resources"	System problem	Contact service.	
Versions mismatch detected in …"	Software version mismatch detected	Contact Service	
"Pairing failed”	Communication problem	Try again or Power off and on the Headset. If the problem persists, contact service.	
"There are no network adaptors with IPv4 enabled on the local system"	PC is not correctly configured	Contact Service	
"Registration Failed…”	Registration Marker not detected	Make sure that the Registration Marker is correctly placed on the patient and in the scanner field of view and rescan. If the problem persists, contact service.	
“Error: Missing eye-screen calibration.”	System problem	Contact Service	
"Xvision application is already running."	Previous instance was not closed correctly.	Reboot PC	
Calibration failed	Tool calibration failed for one of the reasons indicated	Follow instructions and repeat the process	If this problem persists with multiple tools, contact service

Problem or Message	Result/Reason	Solution	Notes
"<Tool Marker number> is already calibrated" For example, "T2 is already calibrated"	Same Tool Marker has been used to calibrate two different tools Or, User is recalibrating a tool that has already been calibrated	Recalibrate the tool(s)	
Blue screen on computer monitor	Make sure all cables are properly connected.	If all cables are properly connected, shut down the system and contact service.	
Blurry or no image display	Lens and LCD are not clean	Gently wipe them using a lint-free soft cloth	If problem persists, contact service
Lens and/or LCD are scratched	Use another HEADSET.		
Projected display is not aligned with reality	Insecure feeling due to projected display's lack of alignment with reality	Use another HEADSET or consider re-registering.	If problem persists, contact service

3. HEADSET Troubleshooting

Problem or Message	Result/Reason	Solution
HEADSET not turning on	No power supply	• Make sure that the battery cord is properly attached. • Make sure that the battery is fully inserted, and that the indicator is full.
HEADSET LED flashes light blue	HEADSET is initializing	Wait for flashing green.
HEADSET LED flashes slow green	HEADSET is connected to the XVISION-SPINE network (router) but not paired to the Workstation	Pair the HEADSET.
HEADSET LED solid green	HEADSET paired to the Workstation	NA
HEADSET flashes fast green.	HEADSET is trying to connect to the router.	Make sure that only one router is on and that it is configured according to the manufacturer's recommendations.
HEADSET LED red	Hardware problem	Try to restart the HEADSET several times. If this does not resolve the problem, replace the HEADSET and contact service.
HEADSET LED purple	The user pressed the restart button for more than five seconds, putting the HEADSET into technician mode.	Turn off the HEADSET and restart it (pressing the restart button for one to two seconds only).

Technical troubleshooting

Problem or Message	Result/Reason	Solution	Notes
No signal is displayed on Main monitor	Disconnected cables	Verify all cables at the back of the Main screen are connected	WS doesn't display xvision
WS doesn't load XVISION software	Disconnected cables	Verify all cables are connected, including the drawer with Multiple socket outlets	PC doesn't turn-ON
Touch-Screen doesn't respond to any tap	Disconnected USB cable	Verify the USB cable is connected at the back of the Main Monitor. If already connected disconnect for 2 sec. and reconnect	If problem persists, contact service
BitLocker Recovery prompt	Hardware disconnection	Contact local Service provide	Recovery Keys should be provided by service

5 CT-F troubleshooting

Problem or Message	Result/Reason	Solution	Notes
Failed Registration	No vertebra registered	Improve initial guess positioning on both AP & LAT views	
Failed Registration	No vertebra registered	Select a different vertebra for initial guess.	
Failed Registration	No vertebra registered	Attempt to use manual registration to populate multiple initial guesses.	
Failed Registration	No vertebra registered	Select new AP & lateral images.	

Appendix A: System Specifications

The specifications listed apply to system operation under typical conditions:

Environmental Conditions	
Operating Temperature	Between 18 °C and 24 °C
Electrical Safety	
Battery Specification	Battery operated 9-12 V
HEADSET Large Battery Pack	
Normal voltage	11.25V
Battery capacity	6400 mAh
Maximum charge current	4340 mA
Discharge current	1200 mA

System Classifications	
Electrical Safety Classification (IEC 60601-1:2005+A1:2012)	Battery operated
Electromagnetic Emissions Compatibility, IEC 60601-1-2	Class A
HEADSET Water Ingress Classification	IPX0 (not protected)
HEADSET Rx/Tx	802.11g/802.11n/802.11ac
HEADSET Frequency Range	2.4 GHz or 5.0 GHz
HEADSET Bandwidth	20MHz (802.11g & 802.11n) and 40MHz(802.11n) or 80MHz(802.11ac)
Footswitch Ingress Classification	IP68
All-In-One Computer dimensions	WxHxD: 606x398x65.6 mm
WS-Cart dimensions:	WxHxD :640x1800x680 mm
General	
Reusable Components	
Patient Clamp	Biocompatible (compliant with ISO 10993-1); Steam sterilized
Tool Marker Holder	Steam sterilized
Z-Marker	Steam sterilized
Sterile, Single Use Components	
Patient Marker	Dimensions: 64 mm X 64 mm X 8 mm, gamma sterilized
Tool Marker	Dimensions: 48 mm X 48 mm X 18 mm, gamma sterilized
X-Marker	Dimensions: 82mm X 110mm X 10mm, gamma sterilized

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Appendix B: Waste Electrical and Electronic Equipment

In accordance with Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE), any item which is marked with the crossed-out wheelie bin symbol must not be disposed of as unsorted municipal waste, but segregated from other waste types for eventual procedure and recovery at an approved recycling facility.

By returning waste electrical and electronic equipment via the correct segregated disposal channel, users can ensure the environmentally sound procedure and disposal of the waste equipment, thereby reducing the potential for any environmental or health risks that could arise as a result of incorrect disposal.

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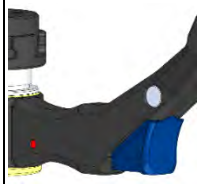
Appendix C: XVS Tool Adaptors

The XVISION-SPINE system includes XVS adaptors that are suitable for most surgical instruments.

Tool Name	Diameter
Swivel 7.5-9.0 mm Universal Tool Adapter Leg Up	7.5 mm to 9.0 mm
Swivel 6-7.5mm Universal Tool Adapter Leg Up	6.0 mm to 7.5 mm
Swivel 5-6 mm Universal Tool Adapter Leg Up	5.0 mm to 6.0 mm
Swivel 4-5 mm Universal Tool Adapter Leg Up	4.0 mm to 5.0 mm
Swivel 3-4 mm Universal Tool Adapter Leg Up	3.0 mm to 4.0 mm
Fixed 3-4 mm Universal Tool Adapter Leg Up	3.0 mm to 4.2 mm
Ergonomic Navigated tool adaptor	NA
XVS VP adaptor	NA

Color coded Swivel Universal Adaptor table:

Tool Name	Diameter	Tool button color
Swivel 7.5-9.0 mm Universal Tool Adapter Leg Up	7.5 mm to 9.0 mm	 Blue
Swivel 6-7.5mm Universal Tool Adapter Leg Up	6.0 mm to 7.5 mm	Green
Swivel 5-6 mm Universal Tool Adapter Leg Up	5.0 mm to 6.0 mm	Orange
Swivel 4-5 mm Universal Tool Adapter Leg Up	4.0 mm to 5.0 mm	Purple
Swivel 3-4 mm Universal Tool Adapter Leg Up	3.0 mm to 4.0 mm	Mint Turquoise

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Appendix D: XVS Patient Clamps

The XVISION-SPINE system includes XVS Patient Clamps.

Tool Name
XVS Short Straight Clamp (62 mm)
XVS Tall Straight Clamp (82 mm)
XVS Arc Clamp

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Appendix E: C-arm Ring Adaptor

The XVISION-SPINE system includes C-arm Ring Adaptor.
This is provided only per request to CT-Fluoro users.
The C-arm Ring Adaptor is a component of the XVS system that is required for CT to Fluoro registration method.
The C-arm Ring Adaptor is intended to be used only during Pre-Op registration method.
The C-arm Ring Adaptor is attached to the C-arm during the image acquisition process of the procedure.
The C-arm Ring Adaptor should be draped using a standard/designated C-arm cover prior to entering the sterile field.

Tool Name
C-arm Ring Adapter

Figure: C-arm Ring Adaptor

The C-arm Ring Adapter is stored in its designated enclosure on the WS-Cart.
The C-arm Ring Adapter is designed to support the following C-arm Models:

C-arm Model
GE OEC 9900 Elite - 12"
GE OEC 9900 Elite - 9"
GE OEC 9800 - 12"
GE OEC 9800 - 9"
GE OEC 9800 Plus - 12"
GE OEC 9800 Plus - 9"

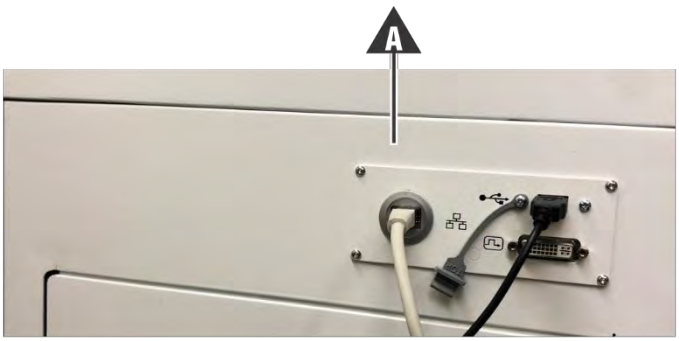
Appendix F: Setting up the Medtronic O-arm 2 Scanner

Use the procedures below to set up the Medtronic O-arm 2 scanner.

F.1: Connecting Ethernet Cable to XVISION-SPINE

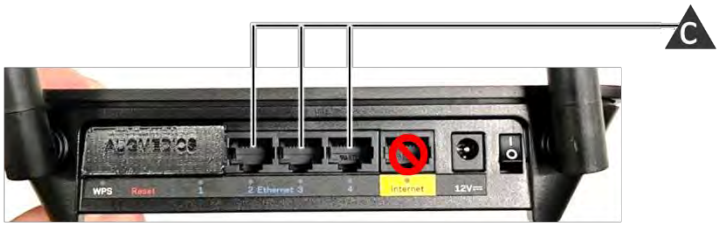
Note: The ethernet cable must be a CAT6a cable (10,000 Mbit/s, 500MHz) or higher.

Figure: Plugging Ethernet Cable to O-Arm 2 Workstation (A)



1. Plug one end of the ethernet cable into the rear of the O-arm 2 workstation (A).
2. In case the system's configuration is Roll Stand AIO, proceed to step #3.
   If the system's configuration is WS-Cart **Skip Step #3**

   Figure: Plugging Ethernet Cable to Router (C) - Roll Stand configuration



3. Plug the other end of the ethernet cable into the rear of the XVISION-SPINE router as follows:
   - In the XVISION-SPINE router, plug the cable into any of LAN ports 2-4 (C).
   - Skip Step #4

Note: Do not plug the ethernet cable into the WAN port.

Figure: Plugging Ethernet (D) - WS-Cart configuration

Located at the left side below the storage drawer.

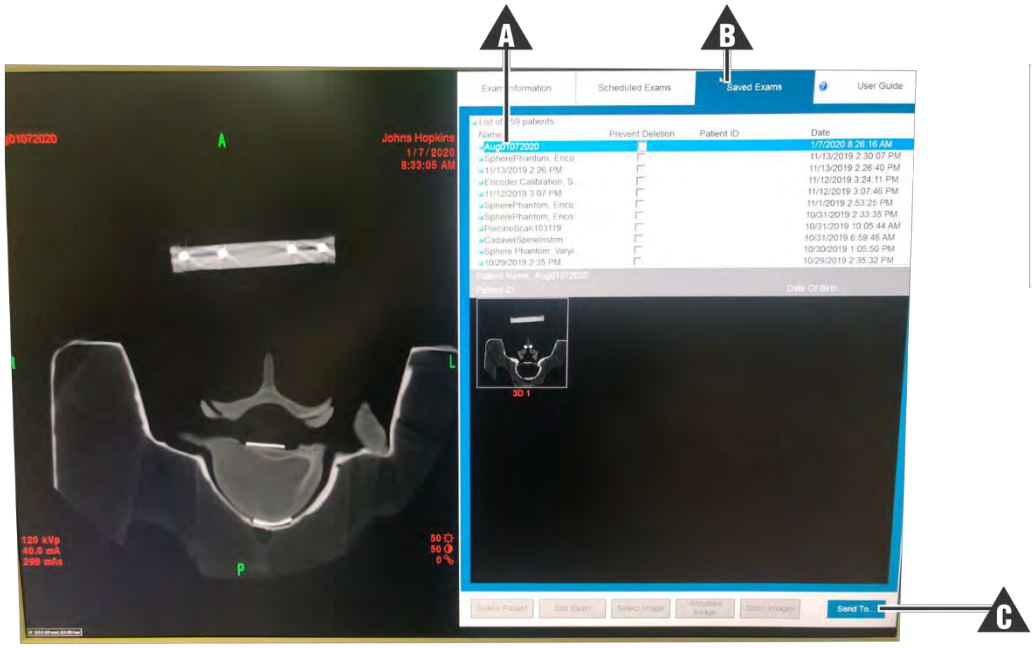
4. Plug the other end of the ethernet cable into the left side external LAN port of the WS-Cart as described in the figure above **(D)**.

Note: Do not plug the ethernet cable directly to the router.

F.2: Setting IP Address

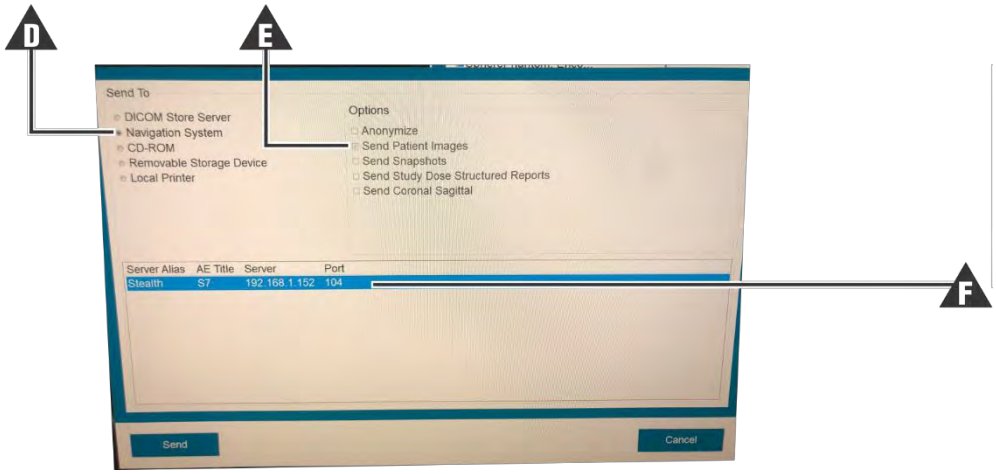
Use the procedure below to set the IP address.

Figure: Setting IP Address (1st step)



1. Select an existing study (A), select **Saved Exams** (B) and press **Send To...** (C).

Figure: Setting IP address (2nd step)

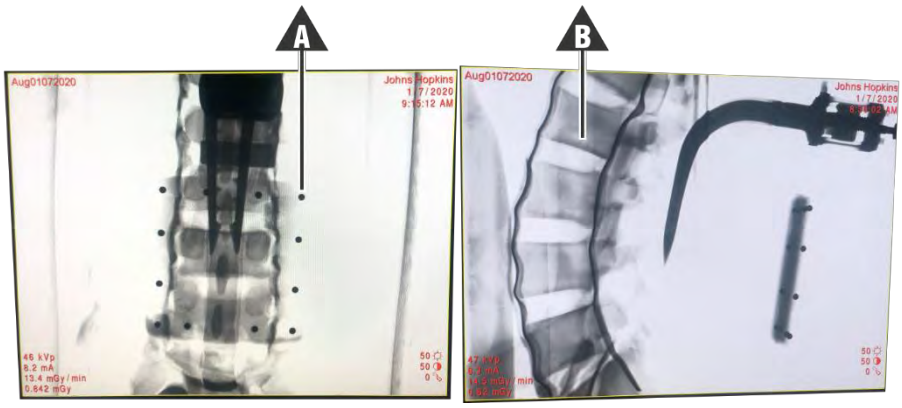


2. Press Navigation System (D) and Send Patient Images (E).
3. Copy Stealth IP information (F) into the **XVS SOFTWARE**. See *Configuring the Scanner Imaging Protocol* on page 5-34 for more information.

F.3: Imaging Settings

Configure imaging setting as follows:

Figure: Configure Imaging Setting (1st step)



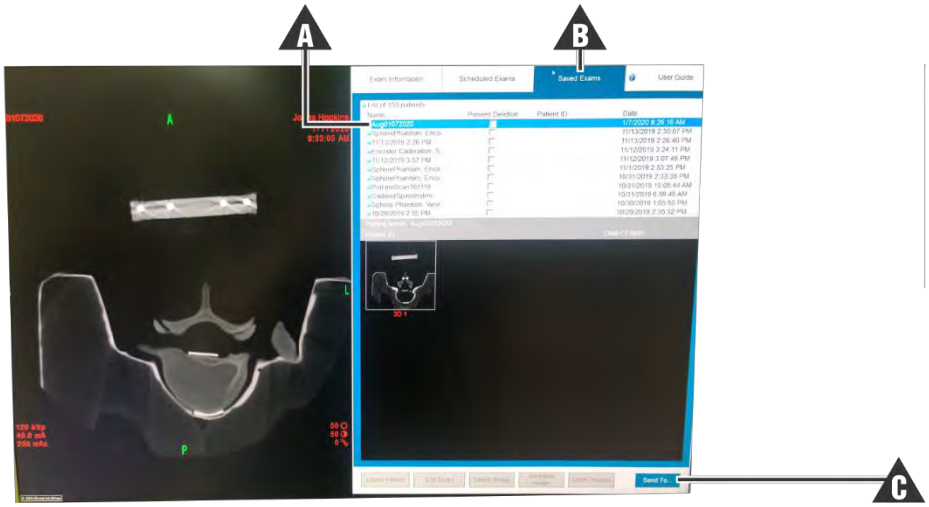
1. Make sure all Z-Marker beads (A) and anatomy (B) are in both axial and lateral scout shots.
2. Have the radiology technician set the following 3D settings prior to the 3D spin:
   - Always select **HD**
   - Select anatomy location
   - Select patient size (only use Medium, Large or XL)
   - Select patient positioning
   - Select side O-arm in coming in from
   - Patient's breath must be held before scan.
3. Scroll through 3D axial image and make sure all 12 Z-Marker beads are visible, as in Figure.

Figure: Configure Imaging Setting (2nd step)

F.4: Sending Image to XVISION-SPINE

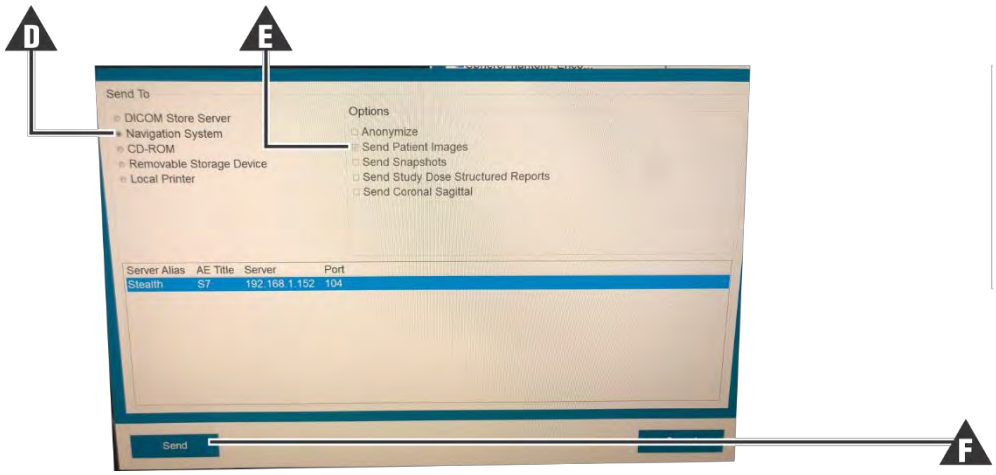
When the scan is complete, press **ESC** to return to the menu.

Figure: Sending Image to XVISION-SPINE (1st step)



1. Select the current patient (A), press **Saved Exams** (B) and then press **Send To…** (C).

Figure: Sending Image to XVISION-SPINE (2nd step)



2. Press Navigation System (D), Send Patient Images (E) and then press Send (F).

   Information is automatically sent to **XVS SOFTWARE**.