

4.8.1. Roll Stand

The optional variable-height Roll Stand with a VESA mount can be used for the optional All-In-One Computer or optional Tablet Computer, described below.

Figure 7: Roll Stand



The roll stand is assembled when the system is set up for first time use.

4.8.2. All-In-One Computer

You can use the optional All-In-One Computer to run the **XVS SOFTWARE**, which is installed when your system is set up for first use.

Figure 8: All-In-One Computer



The All-In-One Computer is intended to serve as a medical monitor which is designed for general purpose for hospital environment and for diagnosis. It could be used for Surgical, Radiology, PACS (Picture Archiving Communication Systems), LIS (Lab Information Systems) and Electronic Medical Record purpose.

The All-In-One Computer can be attached to the VESA connector on the Roll Stand

See [All-In-One Computer User Manual](#) on page I-1 for more information.

4.8.3. Tablet Computer

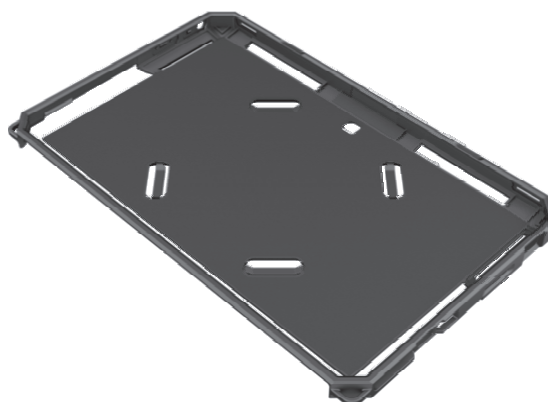
You can use the optional Tablet computer (FCC-ID: PD98265D2) to run the **XVS SOFTWARE**, which is installed when your system is set up for first use.

Figure 9: Tablet Computer



To mount the tablet portion of the Tablet computer to the optional Roll Stand first attach the optional HP ZBook x2 Protective Case to the VESA connector and then snap the tablet into place.

Figure 10: HP ZBook x2 Protective Case





Note:

Before snapping the detachable workstation to the optional HP ZBook x2 Protective Case attached to the Roll Stand remove the keyboard base from the tablet and set it aside. See [Tablet Computer User Guide](#) on page J-1 for more information.

See [Tablet Computer User Guide](#) on page J-1 for additional warnings.

5. XVISION-SPINE System Installation and First Use

When the system is delivered follow the procedures below.

- Remove the components of the **XVISION-SPINE (XVS)** system from its packaging and inspect for damage. Document any damage with photos and make notes. Inform your sales representative of any damage the unit incurred during shipping.
- Verify that all of the components are present.

**Note:**

If you have purchased any of the [Optional Accessories](#) (page 4-7), all required assembly or installation shall be done by authorized Augmedics personnel.

5.1. XVS Software Installation

**Note:**

On-site installation of **XVS SOFTWARE** is only required if the user has not purchased the optional All-in-one computer or the Tablet.

XVS SOFTWARE installation shall be done by authorized Augmedics personnel.

**Warning:**

Before installation make sure that all of the requirements specified in [Cybersecurity User Instructions](#) (page 2-3) have been fulfilled.

5.1.1. XVS Software Installation Procedure

Follow the procedure below to install **XVS SOFTWARE** on a hospital-supplied computer.

**Note:**

See [Hospital-Supplied Computer Requirements](#) on the next page to verify that the computer and monitor meet installation criteria.

1. Install the **XVS SOFTWARE** on the hospital computer.
2. Open the following ports on the hospital PC:
 - DICOM port as defined in the scanner (TCP)
 - 11112 (TCP), 21 (TCP), 22 (TCP) and 24969-24975 (TCP)
 - 5670 (UDP)
3. With the user, run **Refine Eye-Screen** from the **Setting** menu so the user will be familiar with the process. See DMR-XVS-SER-002.

5.1.2. Hospital-Supplied Computer Requirements

Install the **XVS SOFTWARE** on a hospital-supplied computer with the following minimal requirements:

- IEC 60601-1 compliant
- Operating System: Windows 10 Professional/Enterprise Version 1607+ (build 14393+)
- Processor: Intel I7
- Graphic Card: GeForce or Nvidia
- Graphics Memory: 1 GB
- RAM: 16 GB
- Hard Disk: 512 GB
- Available Hard Disk space: 130 GB
- Screen resolution: 1920X1280
- Touch screen (optional)
- Ethernet or WiFi connection
- 2 USB ports
- Anti-virus protection
- System firewall



Note: **XVS SOFTWARE** is preinstalled on the optional [All-In-One Computer](#) (page 4-8) or [Tablet Computer](#) (page 4-9).



Note: Using the **XVS SOFTWARE** interface can be done by touch screen or keyboard and mouse controls. “Tap” and “click” in this User Manual are used interchangeably.

The monitor used with the hospital-supplied computer must have the following minimal requirements:

- Monitor size: > 14” diagonal
- Resolution: 1920x1080 (Full HD)
- Aspect-Ratio: 16:9
- Pixel Pitch: ≤ 0.3 mm
- Viewing-Angle >170°
- Refresh-Rate ≥ 59 Hz
- Luminance>250 cd/m²
- Contrast-Ratio > 1:450
- Response Time< 25 ms
- Latency < 34 ms
- Number of Colors: 16.7 million (8-bit)
- Color Gamut: 70% sRGB; BT.709 or SMPTE-C
- Touch Screen: The **XVS SOFTWARE** supports multi-touch

- At least one of the following inputs:
 - HDMI
 - DVI-D
 - SDI

5.2. Accessory Assembly Instructions

Assemble and install accessories per DMR-XVS-SER-003.

5.3. XVISION-SPINE System Communication

Communication is done via any Wi-Fi router that supports the IEEE 802.11g standard and is configured to support the **XVS** network.

Configure communication as follows.

1. Turn on the computer. Make sure that **xvision** connects automatically.
2. Attach the router to the PC using either an Ethernet cable or wireless connection.
3. Connect to the router as an administrator.
4. Define **XVISION** as SSID in the wireless settings section of the router.
5. Configure wireless security to be WPA2 and set the wireless password.



Note: Steps **3** and **4** are performed only by authorized Augmedics personnel.

6. Restart the router.
7. Turn on the **HEADSET**.
8. Configure the unit DICOM address and application entity ID in coordination with the institution's IT department.



Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the the tablet and roll stand, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

5.4. Custom-Fit the Headset to the Surgeon

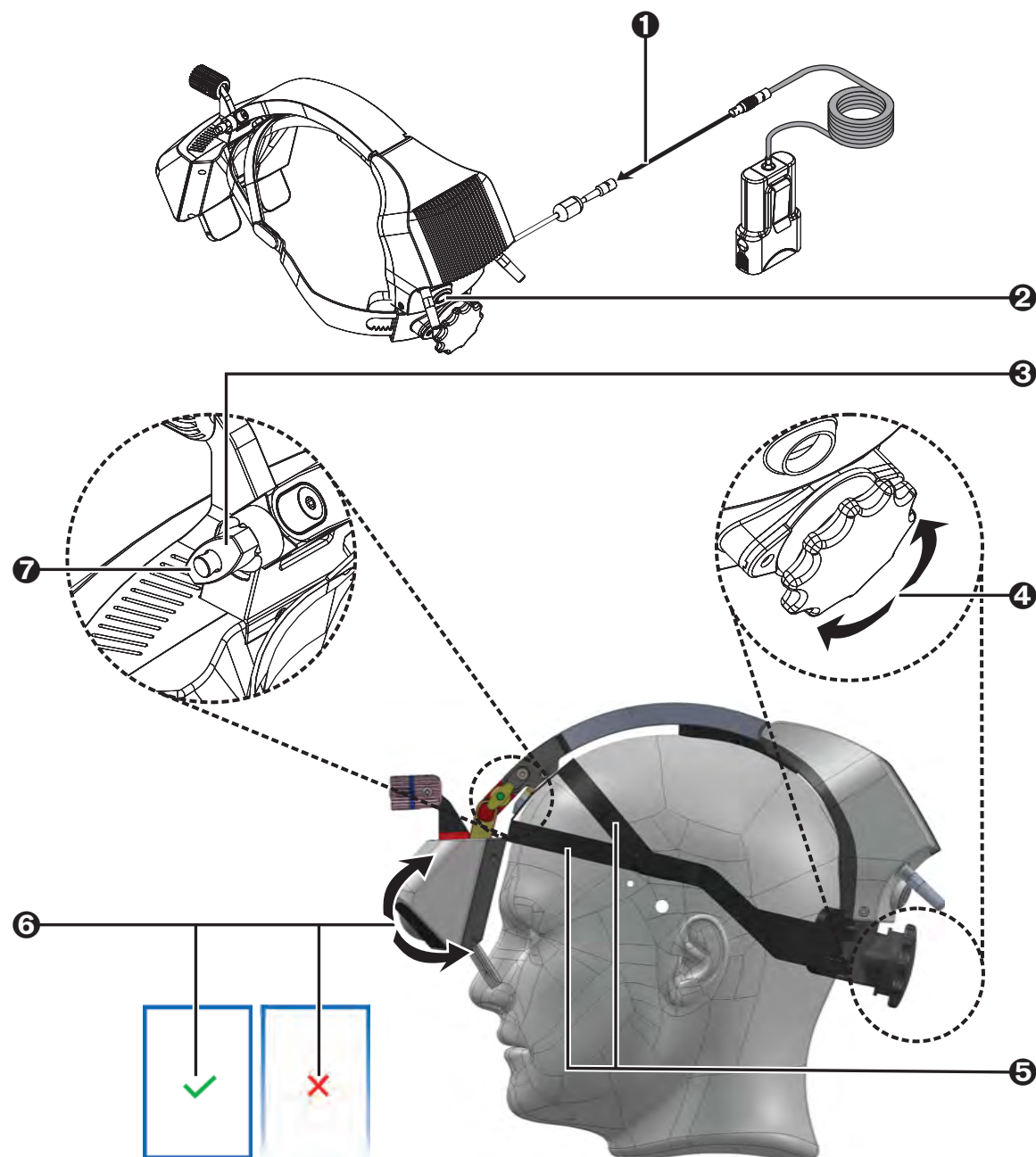
The **HEADSET** is factory customized, by Augmedics service personnel, for each user, taking into account inter-pupil distance (IPD).



Warning: The **HEADSET** is a personalized device which is calibrated to the user's eyes and shall be used only by a user who performed screen-eye calibration by Augmedics authorized personnel.

The **HEADSET** includes an adjustable head strap for self-adjusted optimal positioning. There are several user specific **HEADSET** designs (IPD, forehead-eye distance).

Figure 11: Adjusting the **HEADSET**



- ❶ Attach the battery.
- ❷ Power on the **HEADSET** by pressing the on/off button.
- ❸ Rotate the lock knob in a counterclockwise direction to unlock the hinges.
- ❹ Mount the **HEADSET** and adjust the head strap by rotating the rear knob.
- ❺ Make sure the front straps are positioned as indicated in the figure.
- ❻ Adjust the front part of the **HEADSET** to position the lenses in the correct distance and angle relative to your eyes. Optimal **HEADSET** position is achieved when you can clearly see a blue rectangle in the right and left lenses.



Note: In order to see the blue rectangle, make sure that the **HEADSET** is not paired to the XVS Software. If pairing has already been done, unpair the **HEADSET**. See [Headset Pairing](#) on the next page for more information.

- ❼ Rotate the lock knob in a clockwise direction to lock the hinges and prevent unwanted movements of the front part of the **HEADSET**.



Warning: While wearing the **HEADSET**, if you feel dizziness, headache or nausea remove the **HEADSET** and rest. Contact Augmedics service.



Note: During the surgical procedure the **HEADSET** should remain between 30 cm and 70 cm above the tracked instruments.

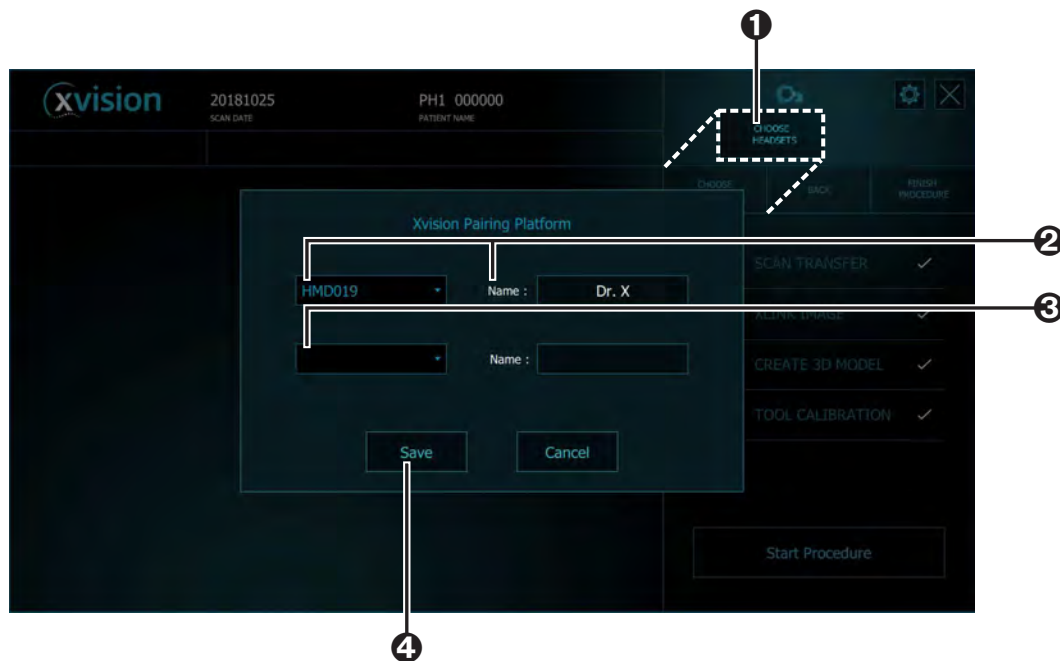


Note: While working with the **HEADSET**, if background seems too bright, it is recommended to adjust the OR lamp angle to reduce background light.

5.5. Headset Pairing

During installation of the **XVS** system the Augmedics technician pairs each **HEADSET**. Optionally, each **HEADSET** can be given a pairing name so that it can be more easily identified during **XVS** procedures.

Figure 12: **HEADSET** Pairing Screen



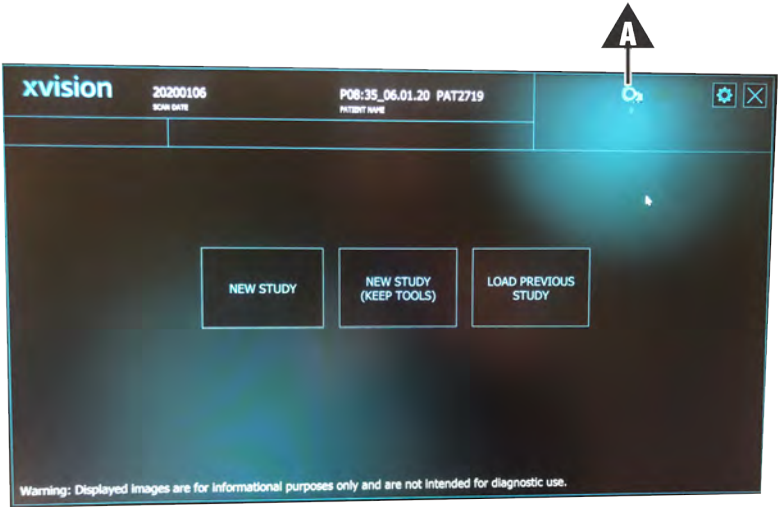
1. In the **XVS SOFTWARE** click **Choose Headset**
2. In the **HEADSET Pairing Screen** note the serial number for the **HEADSET** and key in an optional pairing name, such as the name of the surgeon, for the **XVS SOFTWARE** to use as the device name when the device is paired.
3. For procedures using two **HEADSETS** select the second headset and key in an optional pairing name, as before.
4. Click **Save**.

5.6. Configuring the Scanner Imaging Protocol

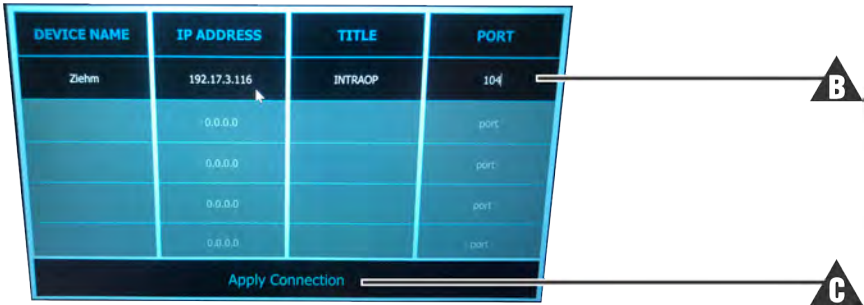


Note: **XVISION-SPINE** supports CT Image Storage (SOP CLASS 1.2.840.10008.5.1.4.1.1.2) only and specifically does not support Enhanced CT Image Storage (1.2.840.10008.5.1.4.1.1.2.1).


Before setting up the scanner used in your institution follow the procedure below to set scanners in **XVISION-SPINE** from the main **XVS SOFTWARE** screen.



1. Click the imaging icon (A).



2. Enter the following information (B) given from the scanner in the popup screen:
- Name of Scanner (title to name the connection)
 - IP Address
 - AE Title
 - Port
3. Press **Apply Connection** (C).

The scanner name appears above the scanner icon .



Caution: Ensure that the firewall on the **xVISION-SPINE** computer is disabled.

Continue with one of the supported scanners below:

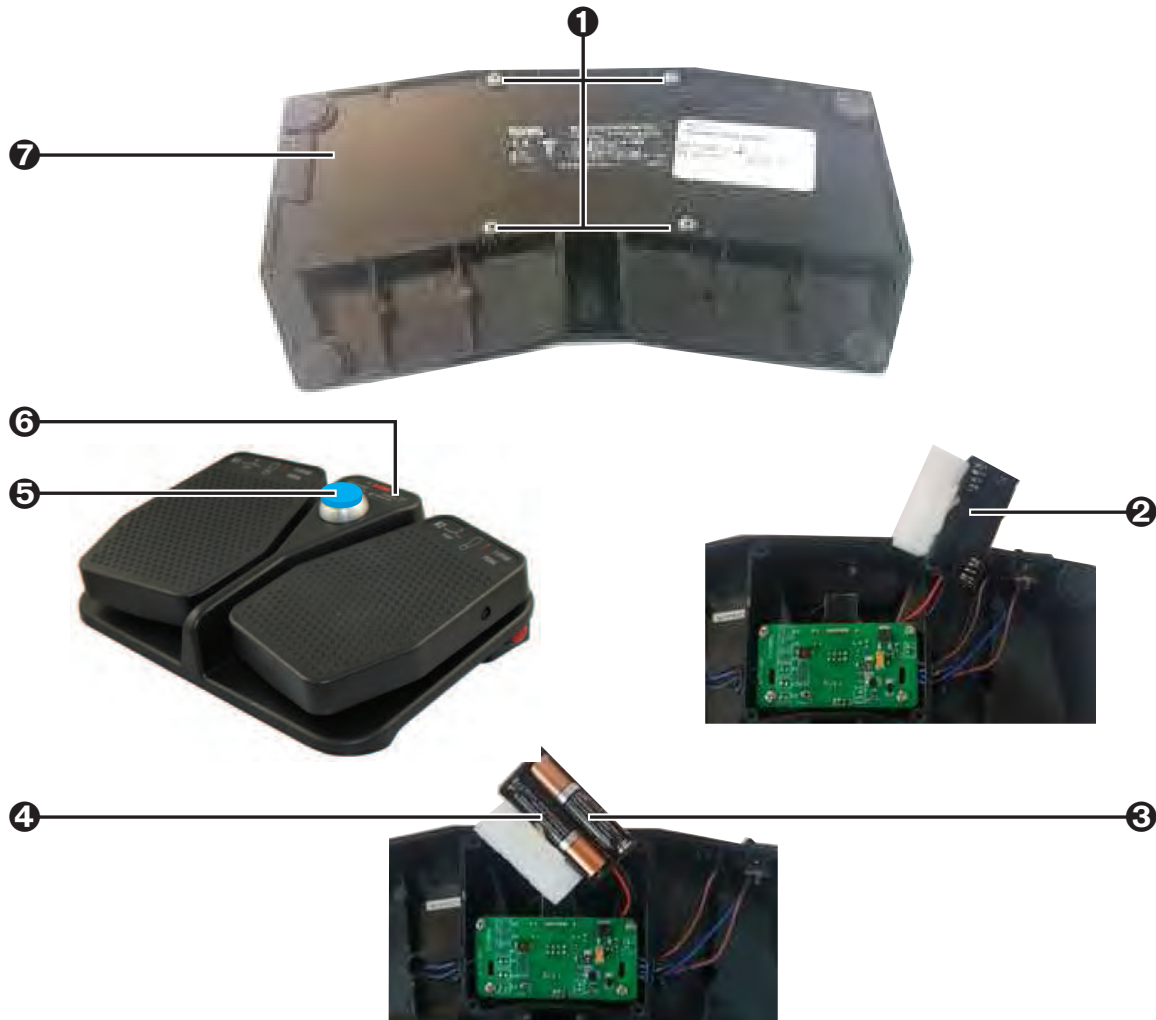
- [Setting up the Medtronic O-arm 2 Scanner](#) (page D-1)
- [Setting up the Medtronic O-arm 1 Scanner](#) (page E-1)
- [Setting up the Brainlab Airo Scanner](#) (page F-1)

- [Setting up the Ziehm RFD 3D Scanner](#) (page G-1)
- [Setting up the Siemens Cios Spin Scanner](#) (page H-1)

5.7. XVISION-SPINE Footswitch Battery Installation

The **XVISION-SPINE** Footswitch is powered by four AAA batteries. Follow the procedure below to install them.

Figure 13: Insert Batteries into **XVISION-SPINE** Footswitch



1. Turn the footswitch over and use a Philips screwdriver to remove the four screws holding the back panel in place. Set the screws aside.
2. Gently remove the back panel and rubber pad and set it aside. Lift out the battery holder.
3. Insert four AAA alkaline batteries, making sure to maintain the correct polarity of the batteries (+ and -) according the indications in the battery holder.
4. Replace the battery holder.
5. Carefully turn the footswitch over and press the center switch to verify functionality.

6. If the blue LED illuminates the footswitch it means that the batteries have been correctly installed and that connection has been achieved.
7. Replace the rubber pad and back panel.
8. Lock the back panel in place with the four screws removed at the beginning of the procedure.

6. XVISION-SPINE System Preprocess Workflow

Follow the procedures below prior to the surgical procedure.

6.1. Starting up the XVISION-SPINE System

In the operating room launch the **XVS SOFTWARE** and power up the router and the **HEADSET** that is to be used in the procedure to automatically connect all of the devices.

Before scrubbing in, mount the **HEADSET** when you are not sterile.



Caution: The **HEADSET** is a non-sterile device and cannot be sterilized.

Continue with **HEADSET** pairing as follows:

Figure 14: **HEADSET** Pairing Screen



1. In the **XVS SOFTWARE** click **Choose Headset**
2. In the **HEADSET Pairing Screen** note the serial number for the **HEADSET** and key in an optional pairing name, such as the name of the surgeon, for the **XVS SOFTWARE** to use as the device name when the device is paired.

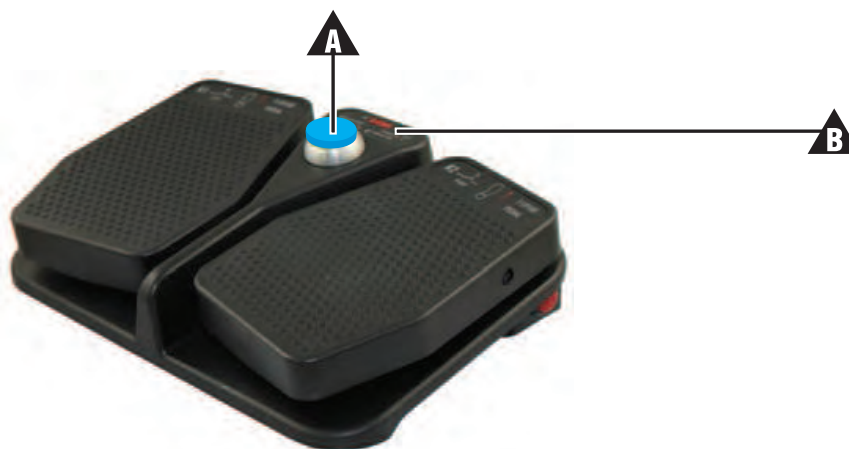
3. For procedures using two **HEADSETS** select the second headset and key in an optional pairing name, as before.
4. Click **Save**.



Note: The **HEADSET** should be powered up at least ten minutes before the surgical procedure to enable it to reach its operating temperature.

Continue with footswitch connection.

Figure 15: Check Footswitch Connection



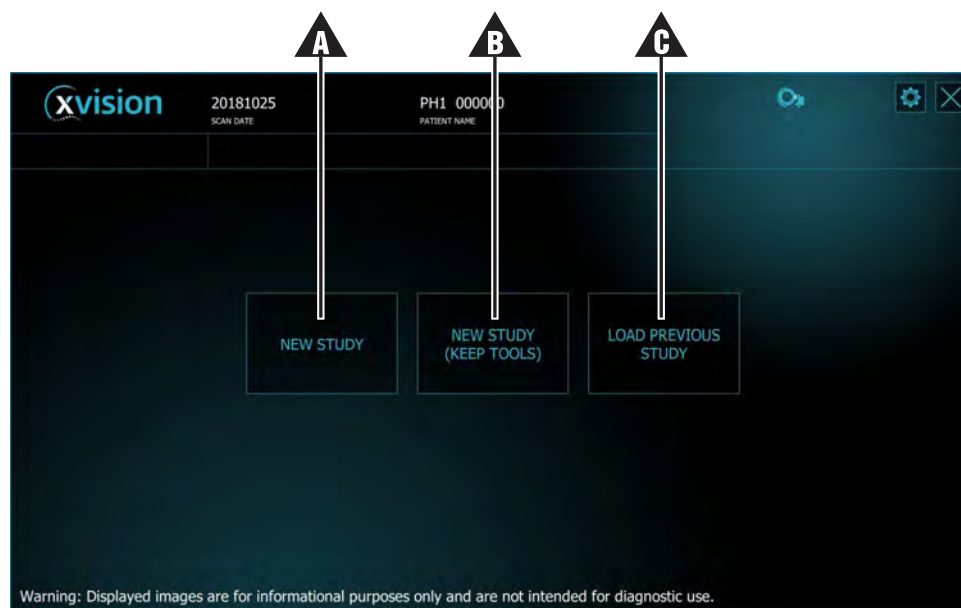
Press the center switch (A) to test connectivity.



Note: If the blue LED (B) does not illuminate the battery may require replacement. See [xvision-Spine Footswitch Battery Installation](#) on page 5-8 for more information.

The **XVS SOFTWARE** displays the main screen.

Figure 16: New Study Screen



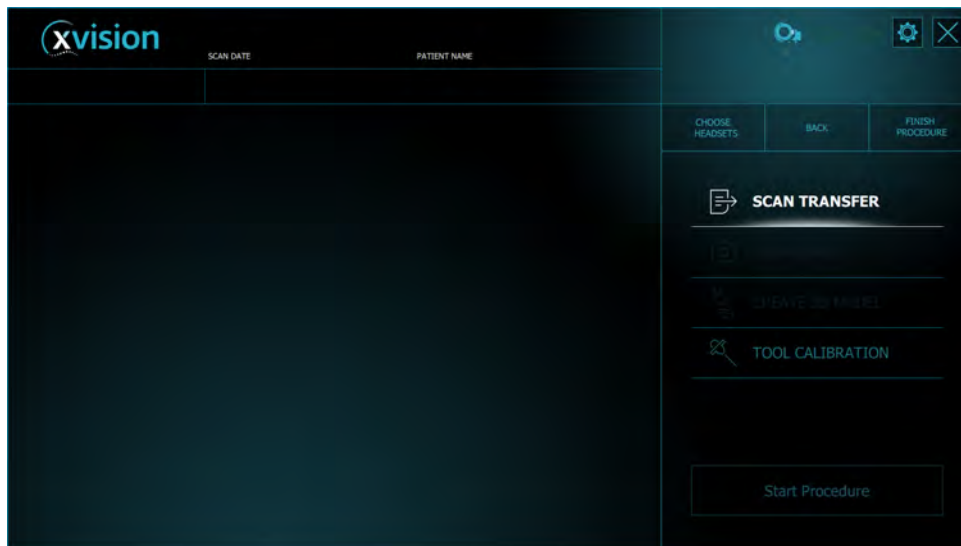
- A New Study (A):** use this when this is the first surgical procedure for a new patient.
- B New Study (Keep Tools):** discard patient data but use the calibrations of the selected tools from the previous study. Useful if you need to do several scans on the same patient for different areas of the back.
- C Load Previous Study:** usually used in the event of a system problem; after rebooting it uses the information previously stored.



Note: If no selection is made, the **XVS SOFTWARE** defaults to **New Study (Keep Tools) (B)** when the scan arrives. This is the recommended option.

When you have made your choice the **xVISION-SPINE** system is now ready to receive data from the patient scan, as seen in the following screen.

Figure 17: New Study Menu



Note: In rare cases the monitor display may not be seen while wearing the **HEADSET**. In this case tilt your head by a few degrees to the left or right to restore visibility of monitor display.

See [New Study](#) on page 7-1 for more information.

6.2. Prepare Surgical Tools

The system supports up to six navigated instruments per a single procedure. Contact Augmedics Ltd regarding supported tools.

Augmedics provides universal tool adaptors for a variety of surgical instruments and a set of single-use markers for each tool. See [XVS Tool Adaptors](#) on page C-1 and [Single Use Sterile Kit](#) (page 4-6) for more information.



Note: The swivel Universal Tool Adaptor allows the tool to rotate while the marker stays stationary.



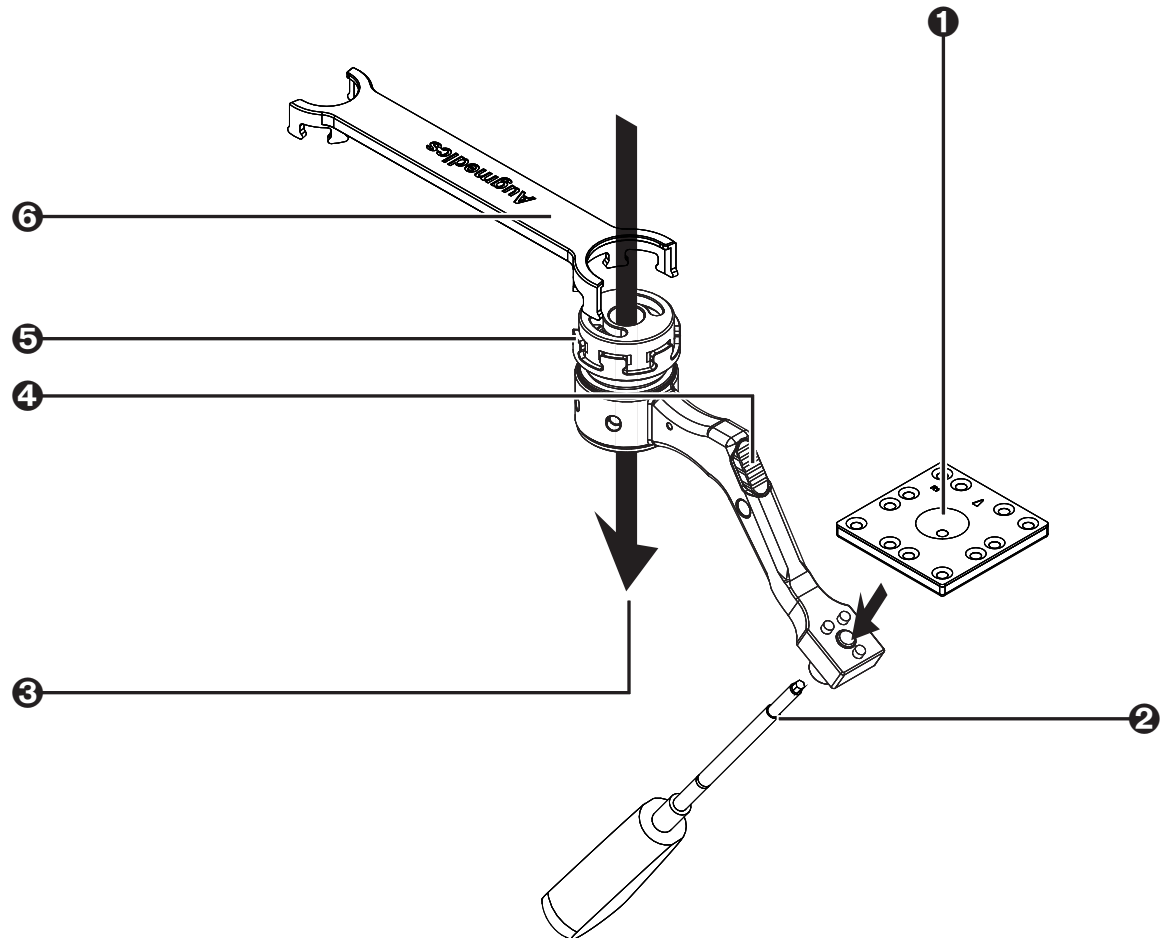
Caution: Before using the Universal Tool Adaptor verify that it is free of rust. If the Universal Tool Adaptor has signs of rust set it aside and use a different Universal Tool Adaptor for the surgical procedure.



Warning: The **xVISION-SPINE** system is not compatible with bent instruments. Using bent or damaged instruments may affect system accuracy. Verify that the instrument is not bent or otherwise damaged.

Universal Tool Adaptors

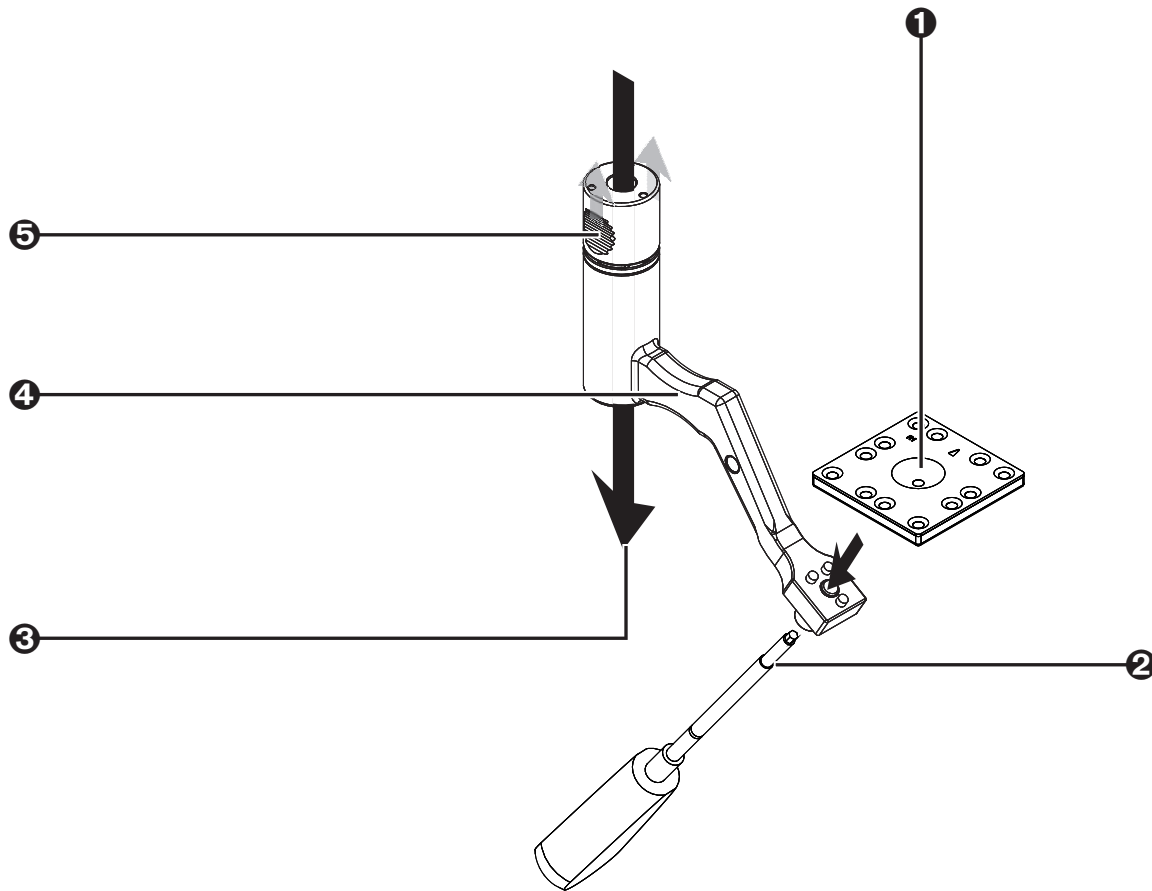
Figure 18: Prepare Surgical Tool for Universal Tool Adaptor



- ❶ Remove the appropriate instrument marker from the sterile packaging and set it on the universal tool adaptor.
- ❷ Use the hex screwdriver to tighten the instrument marker to the universal tool adaptor.
- ❸ Insert the surgical instrument.
- ❹ For swivel tools, press the locking button.
- ❺ Manually tighten the universal tool adaptor to the instrument.
- ❻ Then use the XVS wrench to complete tightening the universal tool adaptor to the instrument.

Navigated Tool Adaptors

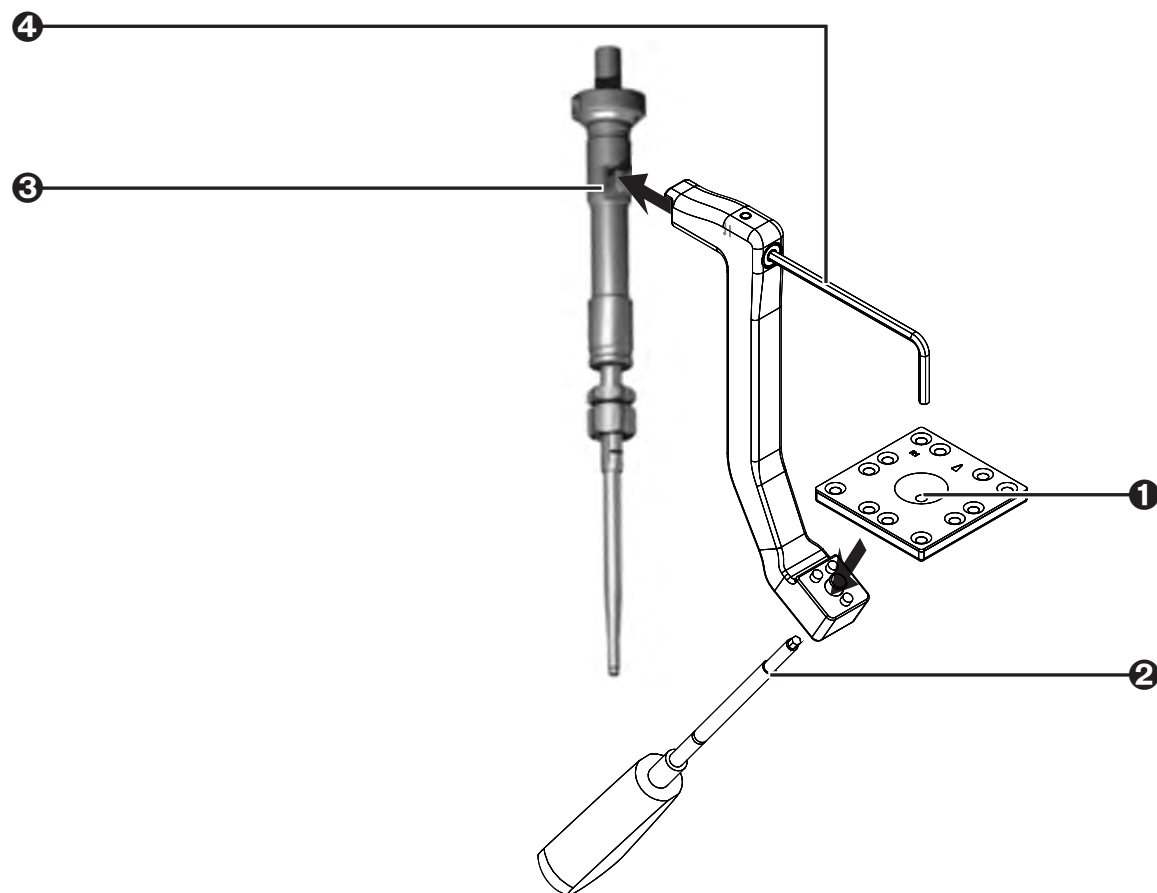
Figure 19: Prepare Surgical Tool for Navigated Tool Adaptors



- ❶ Remove the appropriate instrument marker from the sterile packaging and set it on the navigated tool adaptor.
- ❷ Use the hex screwdriver to tighten the instrument marker to the navigated tool adaptor.
- ❸ Insert the surgical instrument.
- ❹ Hold the navigated tool adaptor where indicated.
- ❺ Grasp the navigated tool adaptor with your thumb and forefinger and pull up to fix the tool in place.

VP Tool Adaptors

Figure 20: Prepare Surgical Tool for VP Tool Adaptors



- ❶ Remove the appropriate instrument marker from the sterile packaging and set it on the vp tool adaptor.
- ❷ Use the hex screwdriver to tighten the instrument marker to the vp tool adaptor.
- ❸ Align the surgical instrument.
- ❹ Tighten the vp tool adaptor to the instrument using a 3 mm Allen key (not supplied).

For all tool adaptors:



Warning: Make sure that the adaptor is firmly attached to the surgical instrument and cannot be moved up or down. A change in the height of the after completing calibration may affect the accurate display of the instrument's tip.



Caution: Do not overtighten.

Continue with the other adaptors that will be used in the procedure (up to six).

6.3. Surgical Instrument Calibration

Each navigated surgical instrument must be calibrated before use.



Note: It is recommended to calibrate tools 20 minutes after the **HEADSET** has been powered up and paired. After the tool calibration, the **HEADSET** will remain powered up and paired.

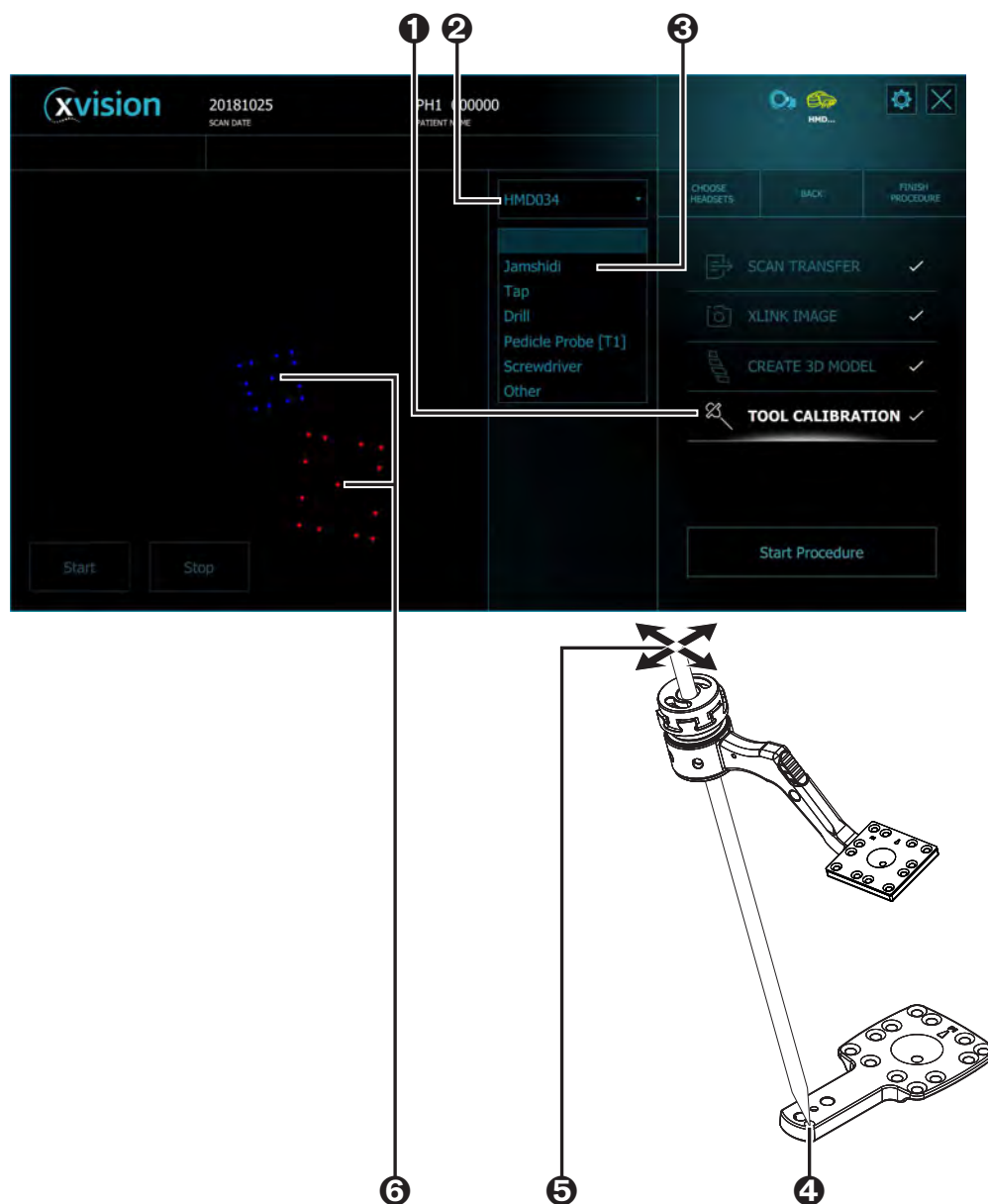
The procedure below is recommended because it can be done while the patient is being prepared for surgery.

Before beginning calibration secure a patient marker to the sterile table with a double-sided tape. It should be at least 50 cm from the location on the patient's spine where the patient marker on the patient clamp will be located.



Note: Screwdrivers require a difference calibration procedure. See [Screwdriver Calibration](#) on page 6-10 for more information.

Figure 21: Calibrate Tools



- ❶ Select **TOOL CALIBRATION** from the **XVS SOFTWARE**.
- ❷ Select the **HEADSET** to be used for calibration.



Note: The **HEADSET** is listed by its serial number or its pairing name. See [Headset Pairing](#) on page 5-6 for more information.

- ❸ Select a surgical instrument to be calibrated.



Note: None of the names is specific, except for the Screwdriver. If the generic name is not appropriate, choose **Other**.

- ④ Take one of the prepared surgical instruments and touch the tip of the tool to the calibration point on the patient marker.
- ⑤ Press the **Start** button (located on the bottom left of the screen) and swivel the tool, keeping the tip on the point.
- ⑥ Make sure that the tool marker and patient marker are both within the field of view of the Headset and displayed on the **XVS SOFTWARE**.

After the message **Calibration Succeed** continue with as many tools as required for the surgical procedure.

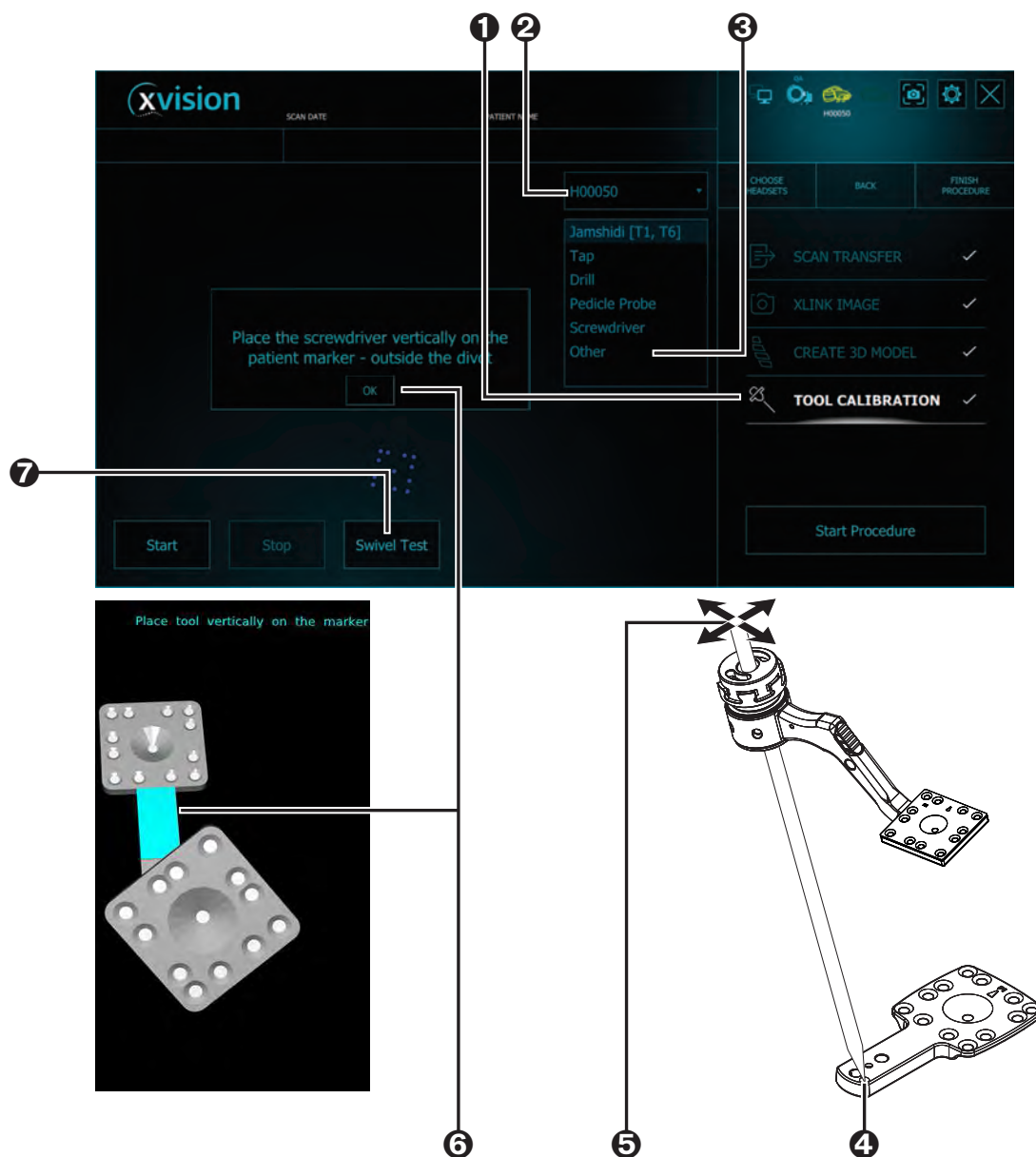
6.4. Screwdriver Calibration

Each navigated surgical instrument must be calibrated before use. Follow the procedure below to calibrate screwdrivers.



Note: See [Surgical Instrument Calibration](#) on page 6-8 for more information about calibrating other tools.

Figure 22: Calibrate Screwdriver



- ❶ Select **TOOL CALIBRATION** from the **XVS SOFTWARE**.
- ❷ Select the **HEADSET** to be used for calibration.



Note: The **HEADSET** is listed by its serial number or its pairing name. See [Headset Pairing](#) on page 5-6 for more information.

- ❸ Select Screwdriver and screw length.
- ❹ Take the prepared screwdriver and touch its tip to the calibration divot of the patient marker.

- ⑤ Swivel the tool, keeping the tip on the point, until calibration reaches 100%.



Note: The surgeon can monitor progress on the **HEADSET** display.

- ⑥ When calibration is 100% place the screwdriver perpendicular on the patient marker as marked in the **HEADSET** display. Wait for the **Calibration Succeed** message Calibration Succeed before continuing.

- ⑦ Press **Swivel Test** to verify that the tool is not bent and follow the procedure below.

1. Rotate the tool while the marker faces the **HEADSET**.
2. The monitor displays the deviation number
3. A deviation less than 2 mm is colored green.
4. A deviation more than 2 mm is colored yellow.



Note: Consider replacing instruments with a deviation greater than 2 mm.

This step can be performed at any time and for any swivel tool.

6.5. Patient Registration Using Spine Clamp

Once the patient is positioned on the OR table and anesthetized, the surgeon performs the following:

1. Selects one of two clamp types to attach to the spinous processes to serve as the anchoring point.
2. Registers the patient using the Z-Marker method. See [Z-Marker Registration](#) on page 6-16 for more information.
3. Performs an intraoperative 3D scan



Note: It is recommend to make a preview 2D scan to ensure that both the registration marker and patient spine are in the field of view.

6.5.1. Patient Clamp

The surgeon selects one of following patient clamps to be connected to the spinous process of the patient during the procedure according to the requirements of the procedure.

- The XVS Short Straight Clamp (62 mm)
- The XVS Tall Straight Clamp (82 mm)
- The XVS Arc Clamp

Once connected to the spinous process, ensure that the clamp is firmly attached to the patient spinous processes.



Warning: Do not over-tighten the patient clamp, as this may damage the spinous processes.



Warning: Verify that the clamp is closed tightly enough on the spinous processes so that it does not move during the surgical procedure.



Note: The available working area is five levels beyond the base of the clamp.

Patient clamps are reusable components of the **XVS** system. Once disconnected from the spinous process at the end of the procedure they must be cleaned and autoclaved prior to the next procedure. See [Cleaning Reusable Components](#) on page 8-1 for more information.



Warning: Discard clamps that become scratched, or when the anodized surface is compromised.

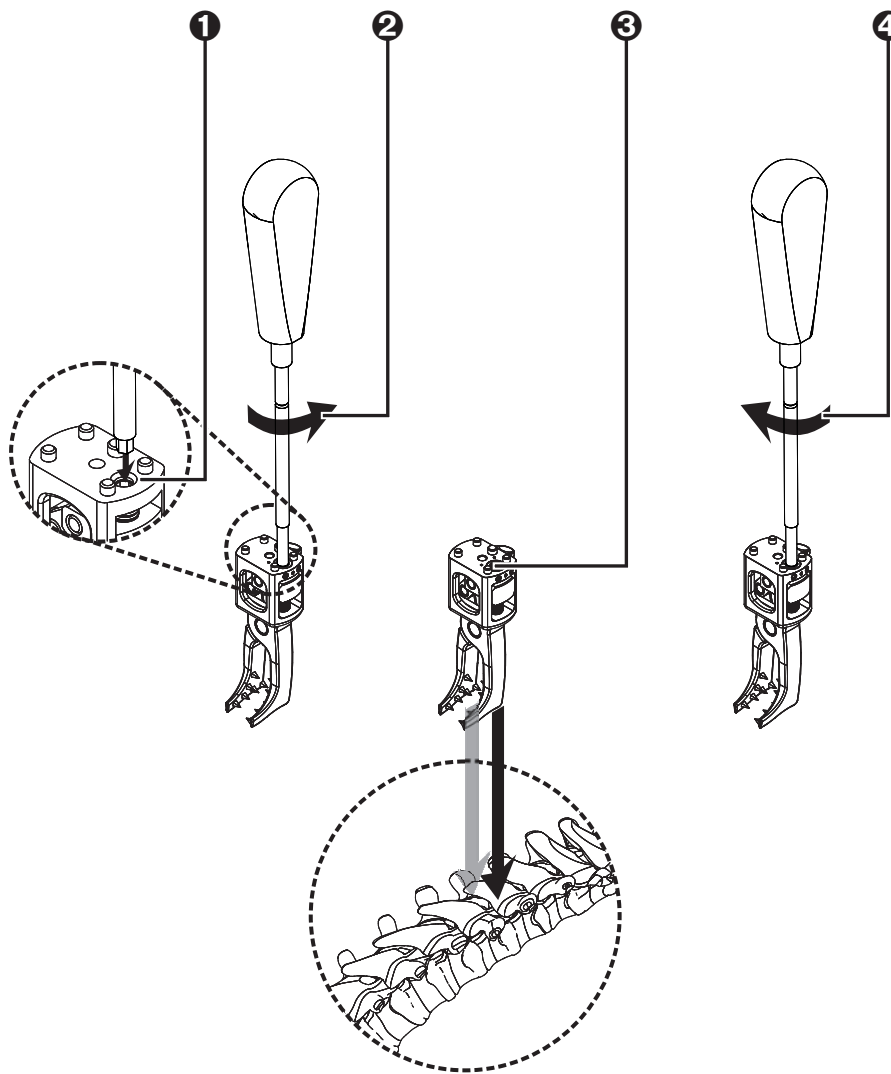


Warning: Discard any clamps or Universal Tool Adaptors with screws that are difficult to tighten or untighten.

XVS Straight Clamp

The XVS Short Straight Clamp (62 mm) and XVS Tall Straight Clamp (82 mm) can be used for open and minimally invasive back surgery.

Figure 23: XVS Straight Clamp



- 1 Insert the allen screwdriver into the adjustment screw of the XVS Straight Clamp.



Caution: Take care to use the aperture located to the side of the clamp. Attempting to tighten the central aperture, used for the patient marker, may damage the XVS Straight Clamp.

- 2 Turn the allen screwdriver in a counter-clockwise direction to open the clamp jaws.
- 3 Making sure that the verification point is opposite the area to be scanned, attach the clamp to the spinous processes in the operated area.
- 4 Use the allen screwdriver to close the XVS Straight Clamp tightly on the spinous processes.

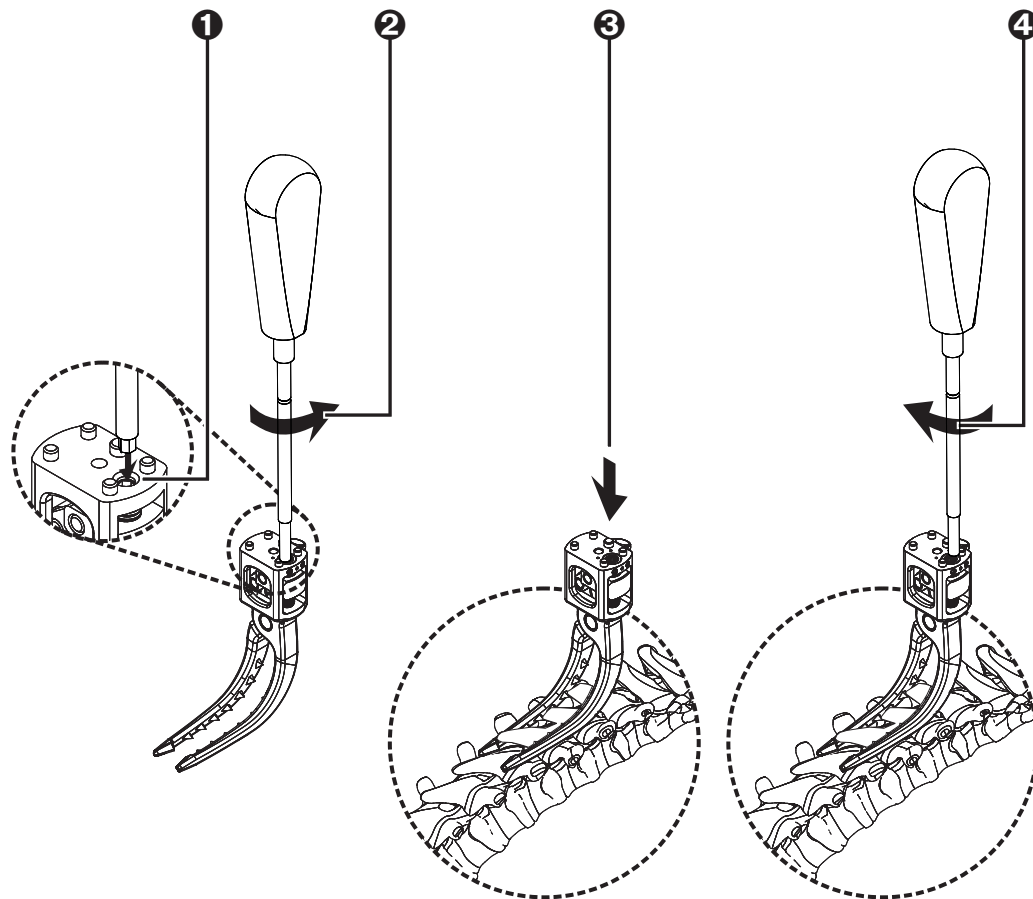
XVS Arc Clamp



Warning: The XVS Arc Clamp configuration is to be used only during open spine procedures.

The recommended direction is to place the clamp in the cranial to caudal direction with the pointed end pointing caudally.

Figure 24: XVS Arc Clamp Attachment



- 1 Insert the allen screwdriver into the adjustment screw of the XVS Arc Clamp.



Caution: Take care to use the aperture located to the side of the clamp. Attempting to tighten the central aperture, used for the patient marker, may damage the XVS Arc Clamp.

- 2 Turn the allen screwdriver in a counter-clockwise direction to open the clamp jaws.
- 3 Attach the clamp to the spinous processes in the operated area.
- 4 Use the allen screwdriver to close the XVS Arc Clamp tightly on the spinous processes.

6.5.2. Patient Registration

Patient registration is the process whereby the **XVISION-SPINE** system orients the transformation between the patient scan and the patient marker.

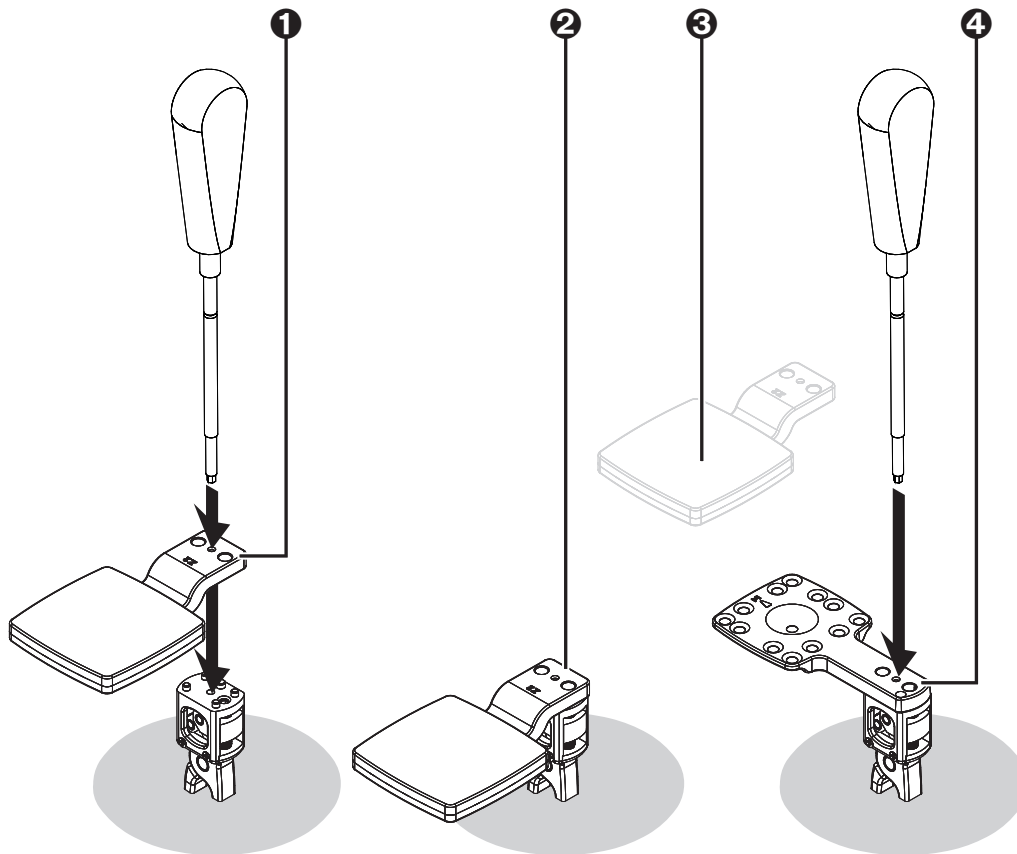


Note: The recommendation of manufacturers of intraoperative scanners is to take care that, during a scan, the patient does not move, the patient is not moved, and that the patient's breath be held. Otherwise the 3D image reconstruction may contain errors. It is recommended to follow this recommendation of your scanner manufacturer

Z-Marker Registration

Patient registration is performed using the Z-Marker.

Figure 25: Z-Marker Registration



- ❶ Attach the Z-Marker to the patient clamp with the allen screwdriver. Choose either the Z-Marker-60 or Z-Marker-40 so it will be as close as possible to the surface of the patient's body.



Note: Make sure that the Z-Marker does not touch the patient's skin.

- ❷ Initiate an intraoperative 3D scan of the area, verifying that the desired spine anatomy and the Z-Marker are included in the scan. The Z marker needs to be seen in the A-P and lateral view before initiating a scan.
- ❸ Remove the Z-Marker and set it aside for cleaning and sterilization. See [Cleaning Reusable Components](#) on page 8-1 for more information.
- ❹ Attach the patient marker to the patient clamp with the allen screwdriver.

Continue with [Spine Surgery with the xvision-Spine System](#) (page 7-1).

7. Spine Surgery with the XVISION-SPINE System

When all preprocess tasks have been completed continue with preparing the surgical procedure at the computer where the **XVS SOFTWARE** is installed.

7.1. New Study

Use the **New Study** screen to finalize all procedures for the surgical procedure.

Typically, at the end of the intraoperative scan, 3D data is sent directly to the computer where the **XVS SOFTWARE** is installed. Whenever a network connection between the scanner and **XVS SOFTWARE** is not available, data can be loaded via a portable USB drive.

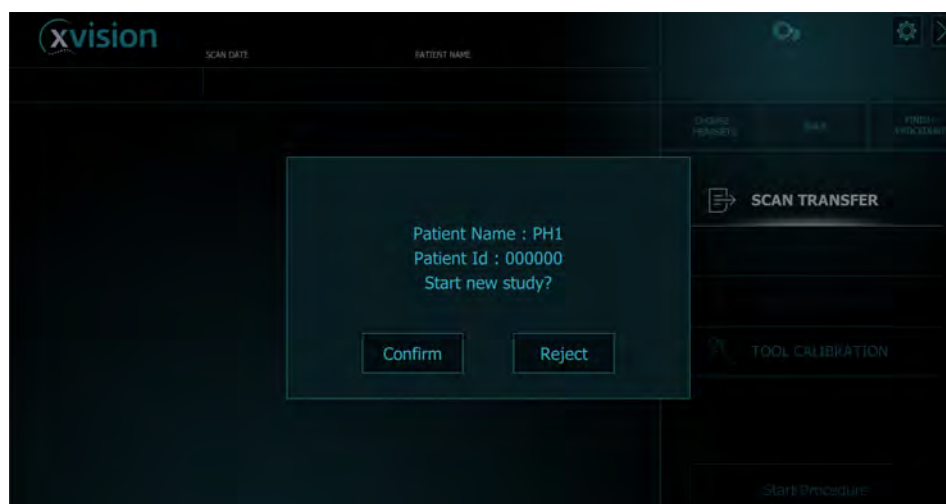
See [Configuring the Scanner Imaging Protocol](#) on page 5-6 for more information.



Note: Old data is never saved.

The intraoperative scan that is waiting in the queue, or that you have selected from a portable USB drive, begins to load. The progress can be seen in the number of slices shown as completed in the top right corner of the screen.

Figure 26: Confirm New Study

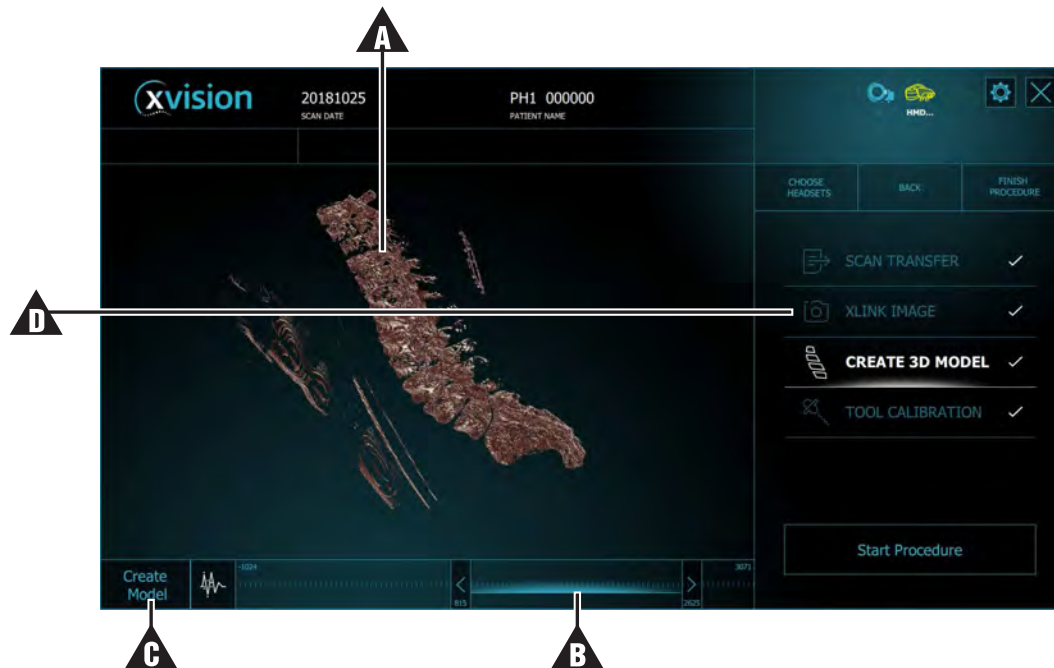


When the scan has been loaded confirm that this is the correct scan for the patient.

7.2. Create 3D Model

With a completed registration tap **Create 3D Model**.

Figure 27: Create 3D Model



Note: For touch screens, the technician uses standard pinch and swipe gestures to manipulate the model (A), including pan, zoom in/out, and rotate rendered data.

The window level (B) is used to set thresholds for the image to eliminate everything but bone tissue.

When the image is satisfactory tap **Create Model** (C).



Note: **XLINK IMAGE** (D) is used for demonstration purposes only.

Figure 28: Create Mesh



- A** Thresholds
- B** Amoeba button to erase scan artifacts
- C** Save the model
- D** Back to previous screen

The bounding box around the mesh can be adjusted to remove artifacts by rotating it and then pressing one of the orange handles to crop out unneeded data.

When the mesh shows the spinous process as clearly as possible tap **Save**. The save process may take several minutes. Then press **Start Procedure**.

7.3. Beginning the Surgical Procedure



Warning: While wearing the **HEADSET**, if you feel dizziness, headache or nausea remove the **HEADSET** and rest. Contact Augmedics service.



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



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

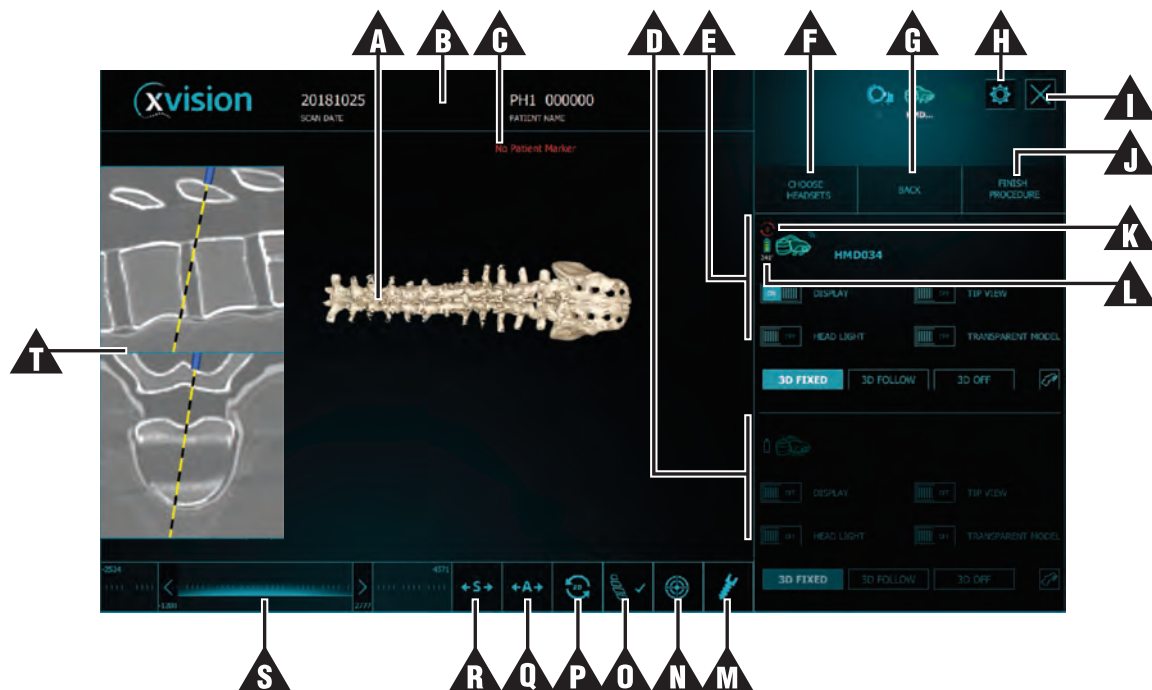


Note: During the surgical procedure the **HEADSET** should remain between 30 cm and 70 cm above the tracked instruments.














Note: Return the **HEADSET** image view by moving the head when you are out of working limits.

Figure 29: Main Screen



Area	Name	Notes
A	3D Mesh display	Use this area to manipulate the image
B	Current patient information	
C	Notification area	
D	HEADSET 2 Controls	For procedures when two HEADSET s are used
E	HEADSET 1 Controls	Headset Controls (page 7-6)
F	Choose HEADSET	
G	Back	
H	Setup menu	
I	Exit	

Area	Name	Notes
	Finish procedure	
	Battery life cycle indication	
	Battery energy indication	
	Virtual screw on/off	Virtual Target Guide (page 7-12)
	Target on/off	
	Landmark check	Landmark Check (page 7-11)
	2D flip	
	Axial mirror view	
	Sagittal mirror view	
	Window level threshold controls	
	2D Slice display	This area is visible only after Tool Verification (page 7-10)

7.3.1. 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. In this case use a different **HEADSET**.



Caution: In case of loss of image in either or both eyes use a different **HEADSET**.



Warning: In case of detected failure or an insecure feeling, or when reality and projected display are not aligned, use a different **HEADSET**.



Warning: If the image freezes, disappears or flickers for more than several seconds use a different **HEADSET**.



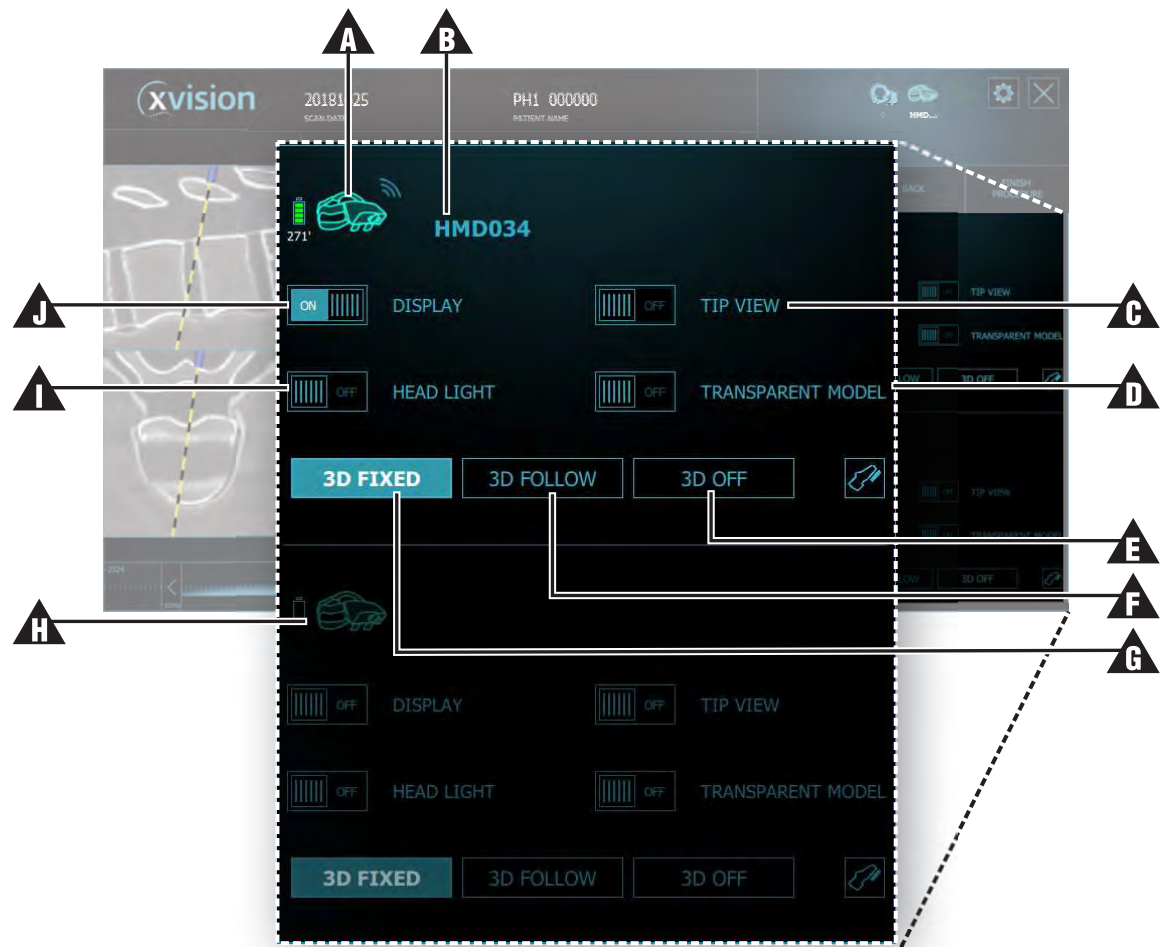
Warning: The 3D Fixed and 3D Follow modes are not intended for use in open surgeries and shall only be used in less or minimally invasive surgeries. Do not rely solely on the information displayed in these modes. Always use it in conjunction with the displayed 2D stereotaxic information.







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

See [Footswitch Controls](#) on page 7-9 for controls available to the surgeon using the Footswitch.

Figure 30: Headset Controls



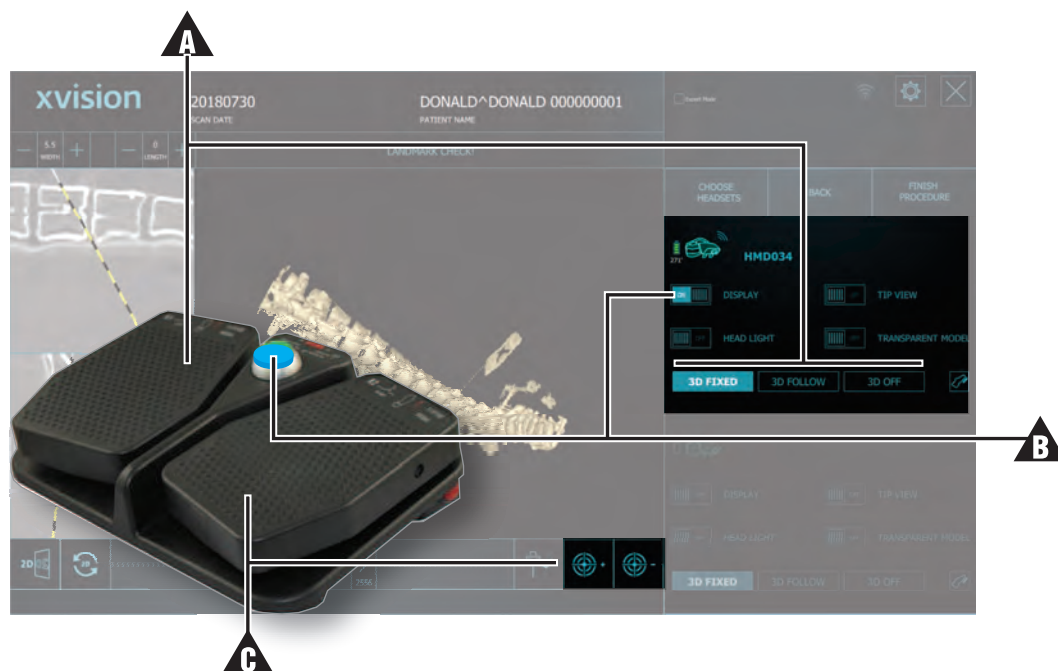
Area	Name	Notes
A	HEADSET status	<ul style="list-style-type: none"> Blue: Located and initiated Yellow: Waiting for data or initiating data
B	HEADSET device name	See Headset Pairing on page 5-6 for more information
C	Tip View	Cuts/removes layers according to where the tip of the surgical instrument is located
D	Transparent Model	Available only on HEADSET
E	3D Off	Slice 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
	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.
	Inactive HEADSET	Up to two HEADSET s can be used during a single procedure
	Head Light	Toggle HEADSET light off and on
	Display	Toggle HEADSET display off and on

7.3.2. Footswitch Controls

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

Figure 31: Footswitch Controls



Area	Name	Notes
A	Left switch	Toggle 3D Fixed/3D Off
B	Central switch	Toggle Headset display off and on
C	Right switch	Add/Remove virtual screw