Augmedics

xvision

XVISION-SPINE
User Manual

Augmedics Ltd.
2 Ha-Otsma St., Yokneam Illit 2069205, Israel
1-888-814-4988
Version 1
https://augmedics.com/

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	Manufactured by Augmedics Ltd
Augmedics Ltd.	*2 Ha-Otsma St., Yokneam Illit 2069205, Israel*
	1-888-814-4988
	customerservice@augmedics.com

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1. Introduction

This manual is an accompanying document to the XVISION-SPINE (XVS) system, which is designed to enable accurate pedicle screws and angular trajectories execution. It provides the information necessary to operate and maintain the XVS system.

1.1. Scope of this Manual

The scope of this User Manual is to provide the safety information of the product, and to explain the basic operating instructions that are performed by the system user. All personnel must read this manual prior to operating this system.

Note: This product and/or the use of this product in a method may be covered by one or more patents or patent applications, available at https://augmedics.com/patents/.

1.2. Conventions Used in this Manual

Throughout this manual, cautions and warnings are used to provide critical information needed before the device is used.

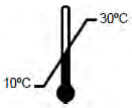
Warning: Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the system.

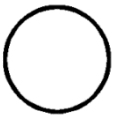
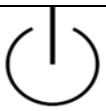
Caution: Alerts the user to a possible problem with the system concerning its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property. The caution statement includes the precaution that should be taken to avoid the hazard.

Note: Notes provide tips, advice and other useful information.

1.3. List of Symbols

The following symbols may appear on system equipment, system packaging or in this manual:

Symbol	Description	Standard	Reference
	Manufacturer	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.1
 YYYY-MM	Date of manufacture	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.3
 YYYY-MM	Use-by date	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.4
	Batch code	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.5
	Catalogue number	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.6
	Sterilized using irradiation + Double sterile barrier system	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.4 + 5.2.12
	Do not use if package is damaged and consult instructions for use	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.8
	Operating temperature limits	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.7
	Do not re-use	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.4.2
	Consult instructions for use or consult electronic instructions for use	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.3
	Unique device identifier	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.7.10
	Importer	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.8

	Follow instructions for use	ISO 7010:2019 Graphical symbols Safety colors and safety signs Registered safety signs	M002
	No sitting	ISO 7010:2019 Graphical symbols Safety colors and safety signs Registered safety signs	P018
	No stepping on surface	ISO 7010:2019 Graphical symbols Safety colors and safety signs Registered safety signs	P019
	Do not stack	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	2402
	“OFF” (power)	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5008
	Stand-By	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5009
	Protective earth (ground)	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5019
	Non-ionizing electromagnetic radiation	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5140
	Class II equipment	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5172
	FCC symbol	Federal Communications Commission	FCC part 15
	Waste Electrical and Electronic Equipment (WEEE)	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)	L 197/66
	Prescription Only	21 CFR 801.15 21 CFR 801.109	(c) (1) (i) (F) (b) (1)

For a full list of requirements of symbols and labels *refer to DHF-VER-000016 (XVS Labeling Verification Report).*

2. Safety Information

This chapter contains important information regarding the safety and performance of the XVISION-SPINE (XVS) system.

Setup and training of the XVS system is provided by Augmedics Ltd.

Do not operate the XVS system before reading this manual and gaining a clear understanding of the operation of the system. If any part of this manual is not clear, contact local Augmedics representative for clarification.

This manual should always accompany the XVS system, and its location must be known to all personnel operating the system. Additional copies of this manual are available from your manufacturer.

Warning: Failure to follow the guidelines and instructions provided in this chapter could result in faulty function of the XVS system and cause personal injury or death.

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

Caution: Operation of the XVS system shall be performed by qualified personnel only.

2.1. Compliance with IEC 60601-1 Standard

The XVS system complies with IEC 60601-1 and AAMI ES60601-1 safety standards, and is internally powered ME equipment.

Warning: Use only batteries provided by the manufacturer.

Warning: Avoid spilling any liquids on the device. In any case of liquid spill, shut off the device and notify the manufacturer before using it again.

2.2. Electromagnetic Compatibility

The XVS system complies with electromagnetic compatibility standard IEC/EN 60601-1-2. The system is Class A compliant.

2.3. Protection against EMC Interference

Caution: Changes or modifications to this equipment not expressly approved by the party responsible for compliance [Augmedics Ltd] could void the user's authority to operate the equipment.

2.4. RF Exposure

This product contains FCC ID: 2AR2O-VOB-P3310.

RF Exposure: This device has been tested for compliance with FCC RF exposure limits in a portable configuration. This device must not be used with any other antenna or transmitter that has not been approved to operate in conjunction with this device.

This product contains FCC ID: 2AR2O-VOB-P3310 for the Gen1 headset and 2AR2O-R68OQ865S for the Gen2 headset

The All-in-One Computer contains FCC-ID: PPD QCNFA364AH.

The Roll Stand – AIO Router contains FCC ID: Q87-03431.

The Workstation (WS-Cart PC) contains FCC ID: SEFD1812039.

The WS-Cart Router contains FCC ID: 2AXJ4AX23

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 **XVISION-SPINE** system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Caution: Any changes or modifications not expressly approved by Augmedics Ltd could void the user's authority to operate the equipment.

2.4.1. FCC Class A

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference than may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This

equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

2.5. Cybersecurity User Instructions

The **XVISION-SPINE** system consists of XVS Software (runs on workstation PC), Headset, router and footswitch (described in detail in **XVISION-SPINE Components** section). The **XVISION-SPINE** system includes security controls such as:

- Firewall - blocks all network ports except those required by **XVS SOFTWARE.**
- Anti-virus – Windows Defender.
- PC operation system hardening – e.g., allow running only **XVS SOFTWARE**.
- Encrypted wireless communication between headset and workstation PC.
- De-identification of patient data.

Augmedics Ltd. uses industry-standard instructions to protect the **XVISION-SPINE** system. All events are logged to the Windows Security Event log.

In addition, Augmedics maintains regular security patches for operating systems, applications, and modules used.

2.5.1. Network Connectivity

The system interconnections are shown in the figure below.

Note: No connection to the internet is possible since the firewall on the workstation PC is configured to block all network ports except for those required by **XVS SOFTWARE**. The system connects to CT scanner only and does not permit connection to any IT network. All ports are blocked by a PC firewall except for some dedicated ports for **XVISION-SPINE** communication.

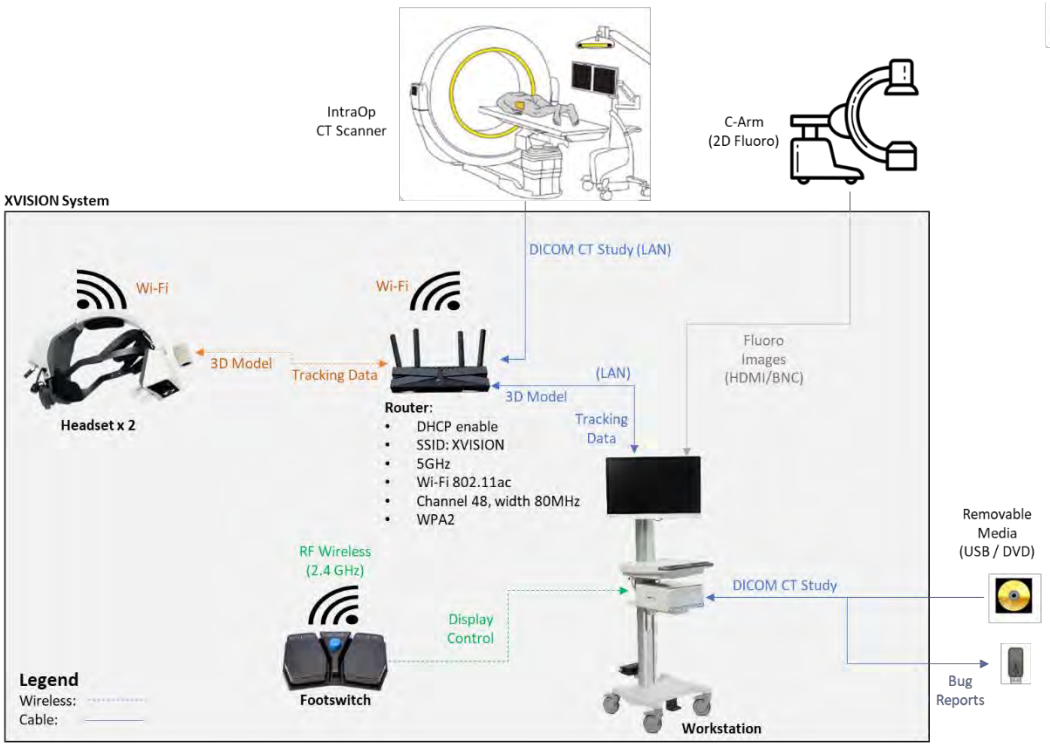


Figure - System Network Diagram

(Note: Router is enclosed within WS-Cart workstation drawer)

Table 1- Ports required for communication through firewall.

Port	Description	Protocol Type	Traffic Direction
24969 to 24975	Used for headset – workstation Communication	TCP	Inbound
104	Used for receiving DICOM CT study file from DICOM server on IntraOp CT scanner	TCP	Inbound
67,68	Used for DHCP server and client communication	UDP	Inbound and Outbound
62000, 62001	Used for screen sharing with Siemens IntraOp CT scanner monitors	TCP	Inbound and Outbound
22, 21	SSH and SFTP headset ports used for SW update (of the headset)	TCP	Inbound

2.5.2. User Responsibility

Use of the XVISION-SPINE application and the PC on which it runs is the responsibility of the end user. To prevent potential unauthorized access, the user should not leave the PC unattended or in the possession of a non-authorized user. Augmedics uses industry-standard instructions to protect the XVS SOFTWARE system. All events are logged on to the Windows Security Event log. The anti-virus and firewall are pre-configured and does not require any additional action by the end user.

Usernames or passwords must not be shared with colleagues or others, even if they are permitted by law and provider policy to view the same type of information (e.g., two users reviewing the same

patient case).

Users have access to patients' info, and they must not take snapshots, screen shots or pictures (e.g., using another device) of any information viewed through the PC.

2.5.3. Security Controls

The XVISION-SPINE system allow access only to XVS SOFTWARE UI and does not allow running any other application. Access to workstation PC operation system is available only to authorized service technician (protected by separate credentials).

The XVISION-SPINE system was designed to protect information even in situations where cybersecurity may have been compromised. For example:

- Patient info is encrypted when stored on workstation PC.
- Patient info is not transferred outside the workstation PC –
    - Not sent to the headset.
    - Bug reports are de-identified.
- Previous 'IntraOp' patient studies are automatically deleted when starting new 'IntraOp' study.
- 'PreOp' patient studies are stored on encrypted hard drive in the workstation PC.

Communication between the headset and workstation PC is encrypted using WPA2.

2.5.4. Reporting Device Security or Privacy Breaches

Users must contact their local IT department and disclose any suspected or confirmed compromised devices or user accounts, and any other privacy or security breaches on a pre-configured Augmedics PC.

If the XVISION-SPINE cybersecurity has been compromised and any changes have been made to the XVS SOFTWARE, the software will detect it upon startup (using checksum code integrity check), prevent running and notify the user. This event is logged to the system log file.

In addition, the PC Windows operation system is configured to audit security events such as login attempts in the Windows Security Event log. When needed, the operation system also notifies the user, for example in case of too many failed login attempts were made.

2.5.5. Recovering from Compromised Accounts

When accounts are considered compromised, or unauthorized access is discovered or suspected, the healthcare organization's IT network administrators should contact Augmedics Local Service.

2.5.6. Unavailable Service

Users should report unavailable service or prohibited access to information to their local healthcare organization's IT department.

2.5.7. Software Maintenance Support for the Software

Any software updates and patches are handled in a similar way to the basic installation. Each update or patch is supplied to an authorized service technician who will arrive to the customer and install it on-site. Software updates or patches are not available to end users.

2.5.8. Software Bill of Materials (SBOM)

The software bill of materials (SBOM) of **XVISION-SPINE** system can be provided upon request from Augmedics Local Service.

2.5.9. Decommissioning of Devices

The company will notify users in writing for end of life of the device. End of life device that is intended for decommissioning, Augmedics will sanitize all media within it, prior to sending it to the company to avoid potential risk of customer data compromise.

2.6. Electromagnetic Immunity Declaration

The **XVS** system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile communication equipment (transmitter) and the **XVS** system, as recommended in the tables below.

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Headset

Declaration: Electromagnetic Emissions (HEADSET and Roll Stand - AIO Router)

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group1 Class A	The XVS system uses RF energy only for internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Declaration: Electromagnetic Immunity (HEADSET and Roll Stand - AIO Router)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
NOTE: UT is the AC mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Declaration: Electromagnetic Immunity (HEADSET and Roll Stand - AIO Router) (continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Radiated RF IEC 61000-4-3	3V/m	3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **XVS**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol: 
	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	
	10V/m from 80MHz to 2.7GHz	10V/m from 80MHz to 2.7GHz	

WS-Cart

Declaration: Electromagnetic Emissions (WS-Cart, Roll Stand AIO Router)

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group1 Class A	The **XVS** system uses RF energy only for its internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	Both the Roll Stand and the WS-Cart is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided that the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Roll Stand or shielding the location.
Voltage fluctuations and flicker IEC 61000-3-3:2013	Complies	

Declaration: Electromagnetic Immunity (WS-Cart, Roll Stand AIO Router)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines	2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	1 kV for input/output lines	1 kV for input/output lines	
Surge IEC 61000-4-5	1 kV line(s) to line(s)	1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
	2 kV line(s) to earth	2 kV line(s) to earth	
	2 kV Signal input/output) to earth	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315°	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Roll Stand requires continued operation during power mains interruptions, it is recommended that the Roll Stand be powered from an uninterruptible power supply or a battery.
	0% UT; 1cycle and 70% UT; 25/30 cycles	0% UT; 1cycle and 70% UT; 25/30 cycles	
	Single phase at 0° 0% UT; 250/300 cycle	Single phase at 0° 0% UT; 250/300 cycle	
NOTE: UT is the AC mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Declaration: Electromagnetic Immunity (WS-Cart, Roll Stand AIO Router) (continued)

<table>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment – Guidance</th></tr>
<tr><td>Conducted RF IEC 61000-4-6</td><td>3V, 6V</td><td>3Vrms, 6V</td><td rowspan="4">Portable and mobile RF communications equipment should be used no closer to any part of the XVS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended Separation Distance
$d = [\frac{3,5}{V_1}]\sqrt{P}$
$d = [\frac{12}{V_2}]\sqrt{P}$
$d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
$d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>3V/m</td><td>3V/m</td></tr>
<tr><td></td><td>3V from 0.15 to 80MHz;
6V from 0.15 to 80MHz and 80% AM at 1kHz</td><td>3V from 0.15 to 80MHz;
6V from 0.15 to 80MHz and 80% AM at 1kHz</td></tr>
<tr><td></td><td>10V/m from 80MHz to 2.7GHz</td><td>10V/m from 80MHz to 2.7GHz</td></tr>
</table>

Recommended Separation Distances (Headset and Roll Stand - AIO Router)

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the XVS System

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment (Headset and Roll Stand – AIO router Router)

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation[b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level (V/m)
385	380 -390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 - 787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9	9
745							
780							
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28	28
870							
930							
1720	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28	28
1845							
1970							
2450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28	28

Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment (Headset and Roll Stand - AIO Router) (continued)

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation[b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compliance Level (V/m)
5240	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9	9
5500							
5785							

Note: If it is necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50% duty cycle square wave signal.

[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because, while it does not represent actual modulation, it would be the worst case.

IMMUNITY to proximity magnetic fields

IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz shall be evaluated according to steps a) through d) below. MANUFACTURERS may proceed directly to step d). The result of the evaluation for each applicable step shall be documented in the test report or RISK MANAGEMENT FILE, as applicable.

While communication might not be possible when ME EQUIPMENT that includes radio equipment is tested in its passband, the ME EQUIPMENT or ME SYSTEM shall still be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE.

a) ME EQUIPMENT and ME SYSTEMS that do not contain magnetically sensitive components or circuitry within the ENCLOSURE or as part of an attached ACCESSORY need not be evaluated further for IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz; otherwise,
b) ME EQUIPMENT and ME SYSTEMS containing magnetically sensitive components or circuitry where a separation distance of those components or circuitry of at least 0,15 m from the field sources specified in Table 11 is ensured by the ENCLOSURE or by the physical design of an attached ACCESSORY during INTENDED USE need not be evaluated further for IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz;

2.7. Method of Sterilization or Disinfection

The sterile components of the **XVS** system are supplied sterile (sterilized by gamma radiation) and are intended for single use only.

See *Cleaning Reusable Components* on page 8-133 and *Steam Sterilization* on page 8-3 for information on cleaning and sterilization of reusable components of the **XVS** system.

The other parts of the **XVS** system should not be sterilized.

2.8. Manufacturer Responsibility

Augmedics Ltd. is responsible for the safety, reliability and performance of the **XVS** system only if:

- Assembly, operations, extensions, modifications, service and repairs are carried out by authorized Augmedics personnel
- The electrical supply complies with local requirements and the product's specifications
- The **XVS** system is used in accordance with this User Manual and all applicable safety regulations

2.9. General Notes, Cautions, and Warnings

Warning: The system is not suitable for use in the presence of an anesthetic flammable mixture with air or oxygen or nitrous oxide.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Do not use the HEADSET if inspection before use reveals any damage, such as case damage or loose connectors. Contact service.

Warning: The XVISION-SPINE system is not intended for diagnostic purposes.

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 XVISION-SPINE system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Caution: For continued protection against the risk of fire, use only system cables and accessories approved or supplied by Augmedics. Other cables and accessories may damage the system or interfere with its safe operation.

Caution: Do not touch the HEADSET with sterile gloves, as the HEADSET is not provided sterile.

Note: It is important that all the warnings, cautions and instructions in this manual be followed. Current medical practices regarding patient care and safety should also be considered.

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

3. Overview

The XVISION-SPINE (XVS) system is a stereotactic image-guided navigation system designed to assist surgeons in placing pedicle screws and angular trajectories accurately, during open or percutaneous computer- assisted spinal surgery. The system is designed to provide surgeons with an immersive 3D and 2D visualization of patient's anatomy through skin and tissue. The XVS system uses optical tracking technology to display to the surgeon the real-time intraoperative location of navigated surgical instruments relative to computed tomography acquired 2D images and 3D reconstruction.

The HEADSET of the XVISION-SPINE system displays three types of images: 2D stereotaxic, composite anatomic, and a virtual screen displaying the 3D reconstructed model. The stereotaxic screens are indicated for correlating the tracked instrument location to the registered patient imagery, and the virtual screen is indicated for displaying the virtual tracked instrument location in relation to virtual anatomy to assist in percutaneous visualization and trajectory planning.

The virtual and composite anatomic displays should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed stereotaxic information.

The system should be used only as an adjunct for surgical guidance. It is not a replacement for the surgeon's knowledge, expertise, or judgment.

3.1. Intended Use

The XVISION-SPINE System, with XVISION-SPINE System Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous spine procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to a patient's fluoroscopic or CT imagery of the anatomy. This can include the following spinal procedures:

- Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region.
- Posterior Screw Placement in C3-C7 vertebrae
- Iliosacral Screw Placement
- Angular procedures requiring access to the disc space
- Lateral trajectories required to access the Sacro-Iliac joint

The HEADSET of the XVISION-SPINE System displays 2D stereotaxic screens and a virtual anatomy screen. The stereotaxic screen is indicated for correlating the tracked instrument location to the registered patient imagery. The virtual screen is indicated for displaying the virtual instrument location in relation to the virtual anatomy to assist in percutaneous visualization and trajectory planning.
The virtual display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed stereotaxic information.

3.2. Intended User and Environment

The system is to be used by trained professionals only. These include surgeons, OR staff and trained Augmedics' representatives. The system is to be used only in an operating room.

3.3. Contraindications

Medical conditions which contraindicate the use of the XVS system include any medical conditions which may contraindicate the medical procedure itself.

4. XVISION-SPINE Components

The XVISION-SPINE (XVS) system is comprised of the following main components.

4.1. XVS Software

The dedicated XVS SOFTWARE receives the 3D scanner images and calculates the registration between the patient's anatomy and the acquired intraoperative images. It also creates a 3D scanned spine model and initializes the HEADSET.

It then receives tracking information calculated by the infrared (IR) HEADSET camera and displays tracked virtual images of the surgical instrument aligned with the patient on the computer monitor. These images are of a virtual 3D model, 2D stereotactic, and 2D composite anatomic views.

The HEADSET displays the same virtual images with the 3D model aligned with the patient. The computer running the XVS SOFTWARE is connected to the HEADSET by Wi-Fi.
Dedicated menus of the user interface are accessed either via a touch screen or a mouse and keyboard.

4.2. Router

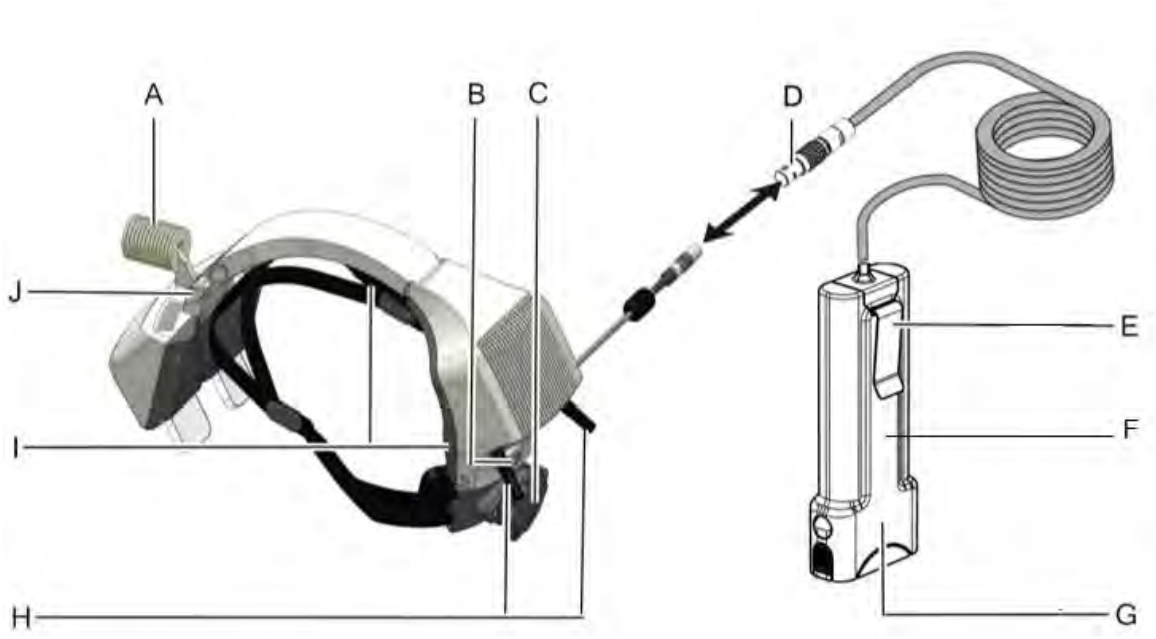
The router is used for supporting wireless communication between the computer on which the XVS SOFTWARE is installed.

4.3. Gen-1 Headset

The **HEADSET** is comprised of an infrared tracking camera, infrared illumination, optical transparent near eye displays and two optional LCDs for partial occlusion of the scene.

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

Figure: HEADSET ID of Parts



A Head light
B On/Off switch
C Head strap adjustment knob
D Battery connector
E Belt Clip
F Large rechargeable battery
G Rechargeable battery holder
H Wi-Fi antennas
I HEADSET pads
J Folding lock mechanism

The **HEADSET** is powered by a rechargeable battery (F) that is clipped to the surgeon's pocket during the procedure.

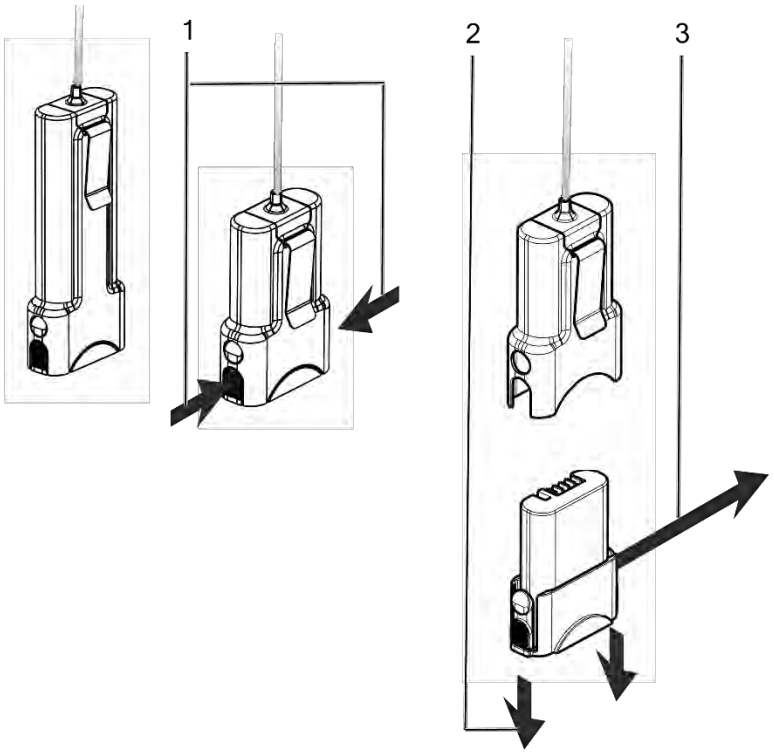
Recharge the **HEADSET** battery after every surgical procedure by placing it in its charger stand. The full charge cycle takes approx. 1 to 2 hours. See *Battery and Charger* on page 4-3 for more information.

The projected display of the 3D spine model and 2D images can be toggled on or off during the procedure upon the surgeon's request. The **HEADSET** is fitted to the surgeon's head with an adjustable strap. See *Custom-Fit the Headset to the Surgeon* on page 5-27 for more information.

4.4. Battery and Charger

The **HEADSET** is powered by a rechargeable battery that provides approx. 4 hours of continuous work.

Figure: Removing HEADSET Battery for Charging



1 Press the ribbed buttons on either side of the battery.
2 Pull the battery out of the battery case.
3 Set the battery into its charger stand.

Recharge the battery after every surgical procedure. The full charge cycle takes approx. 1 to 2 hours.

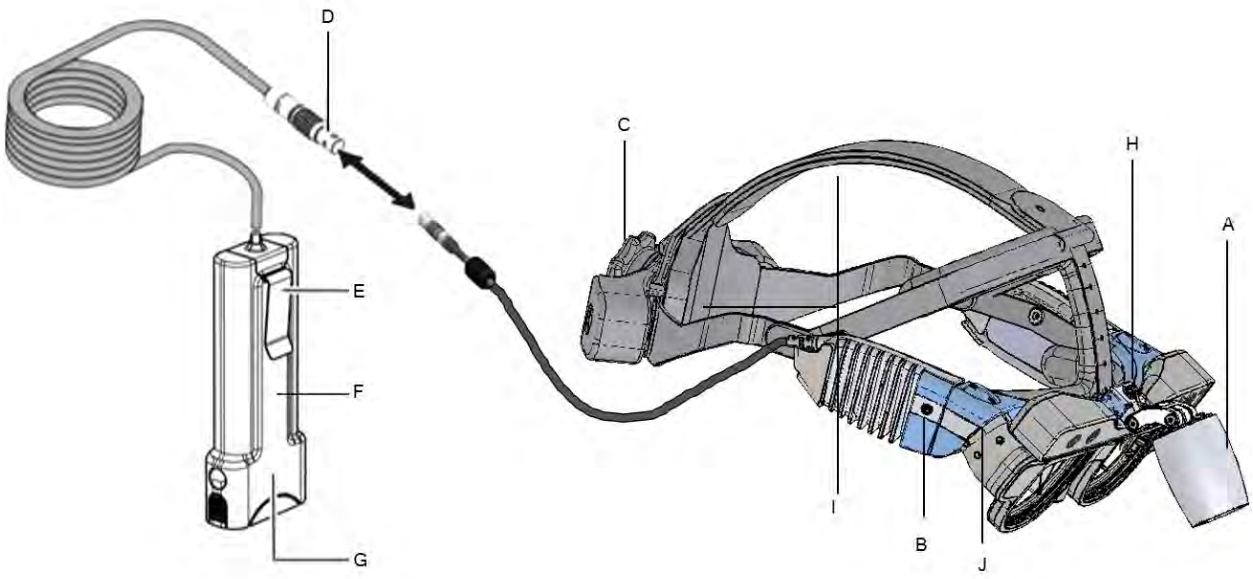
Note: When the battery reaches 99 life cycles, contact Augmedics Ltd.

4.5. Gen-2 Headset

The **HEADSET** is comprised of an infrared tracking camera, infrared illumination, optical transparent near eye displays and two clip-on options. The inner part of the **HEADSET** around the lenses can be disassembled and reading/prescriptive lenses can be assembled in place.

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

Figure: HEADSET ID of Parts



A Head light
B On/Off switch
C Head strap adjustment knob
D Battery connector
E Belt Clip
F Large rechargeable battery
G Rechargeable battery holder
H Button to remove optional Headlight
I HEADSET pads
J Tilting mechanism

The **HEADSET** is powered by a rechargeable battery (F) that is clipped to the surgeon's pocket during the procedure.

The Gen-2 **HEADSET** also allows the user 5 optional tinting lenses to improve the display during navigation.

Figure: Gen-2 HEADSET Tinting lenses assembly

To assemble the tinting lenses selected follow the Blue arrow in the above figure.

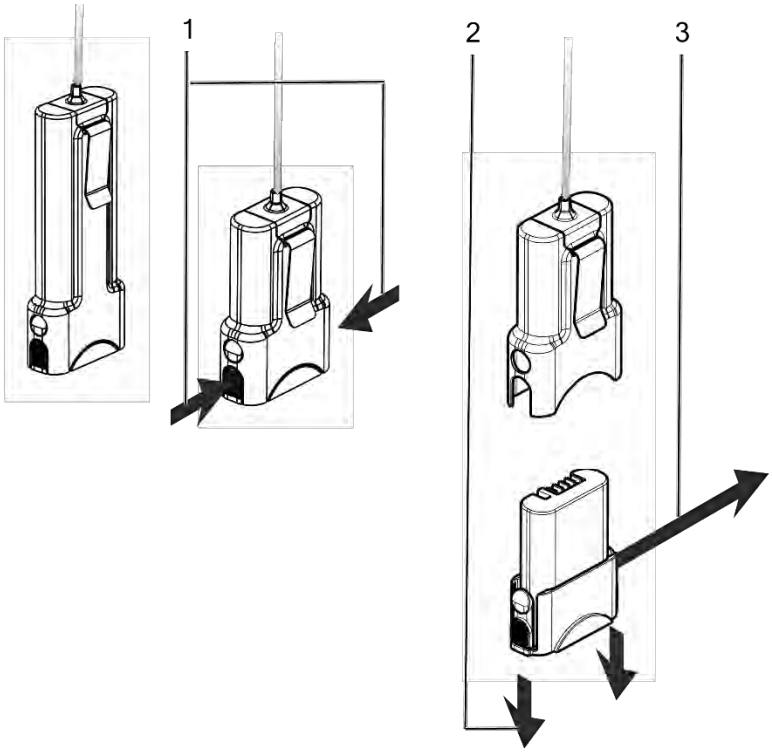
Recharge the **HEADSET** battery after every surgical procedure by placing it in its charger stand. The full charge cycle takes approx. 1 to 2 hours. See *Battery and Charger* on page 4-3 for more information.

The projected display of the 3D spine model and 2D images can be toggled on or off during the procedure upon the surgeon's request.
The **HEADSET** is fitted to the surgeon's head with an adjustable straps. See *Custom-Fit the Headset to the Surgeon* on page 5-27 for more information.

4.5.1. Battery and Charger

The **HEADSET** is powered by a rechargeable battery that provides approx. 4 hours of continuous work.

Figure: Removing HEADSET Battery for Charging



4 Press the ribbed buttons on either side of the battery.
5 Pull the battery out of the battery case.
6 Set the battery into its charger stand.

Recharge the battery after every surgical procedure. The full charge cycle takes approx. 1 to 2 hours.

Note: When the battery reaches 99 life cycles, contact Augmedics Ltd.

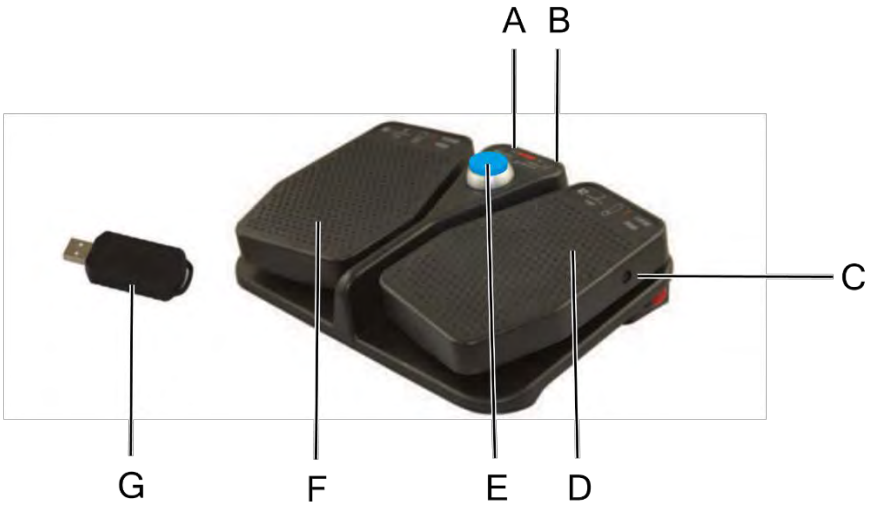
4.6. XVISION-SPINE Footswitch

The **XVISION-SPINE** Footswitch (FCC-ID: 2AODW-NRF24L01SMD) enables wireless control of the **XVISION-SPINE** by the surgeon **XVS SOFTWARE** functions. See *Footswitch Controls* on page 7-105 for more information.

Note: The **XVISION-SPINE** Footswitch is powered by four AAA batteries. See *xvision-Spine Footswitch Battery Installation* on page 5.8 for more information.

Always dispose of spent batteries according to local codes.

Figure: Footswitch



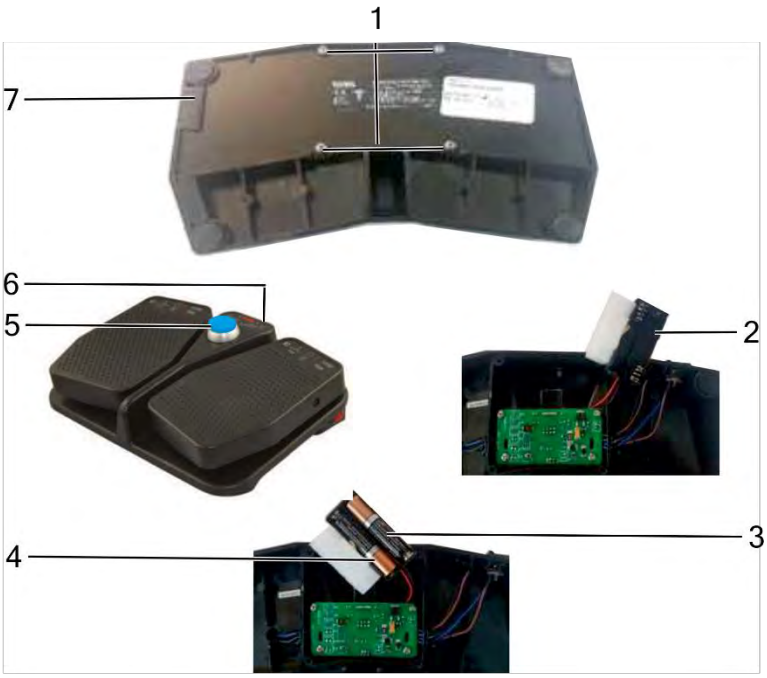
A Power indicator
B Connection indicator
C Power input
D Right pedal: Add/Remove virtual screw
E Center switch: Toggle display off and on
F Left pedal: Toggle 3D Fixed/3D Off
G USB receiver module

When using a WS-Cart, the Footswitch is located at the main column's back in its designated place.

4.6.1. The Footswitch Battery Installation

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

Figure: Insert Batteries into XVISION-SPINE Footswitch



1 Turn the footswitch over and use a Phillips screwdriver to remove the four screws holding the rear panel in place. Set the screws aside.
2 Gently remove the rear panel and rubber pad and set it aside. Lift out the battery holder.
3 Insert four AAA alkaline batteries, making sure that the correct polarity of the batteries (+ and -) is maintained according to the indications in the battery holder.
4 Re-place the battery holder.
5 Carefully turn the footswitch over and press the center switch to verify functionality.
6 If the blue LED illuminates on the footswitch, it means that the batteries have been correctly installed and that connection has been achieved.
7 Install the rubber pad and rear panel.
8 Lock the rear panel in place with the four screws removed at the beginning of the procedure.

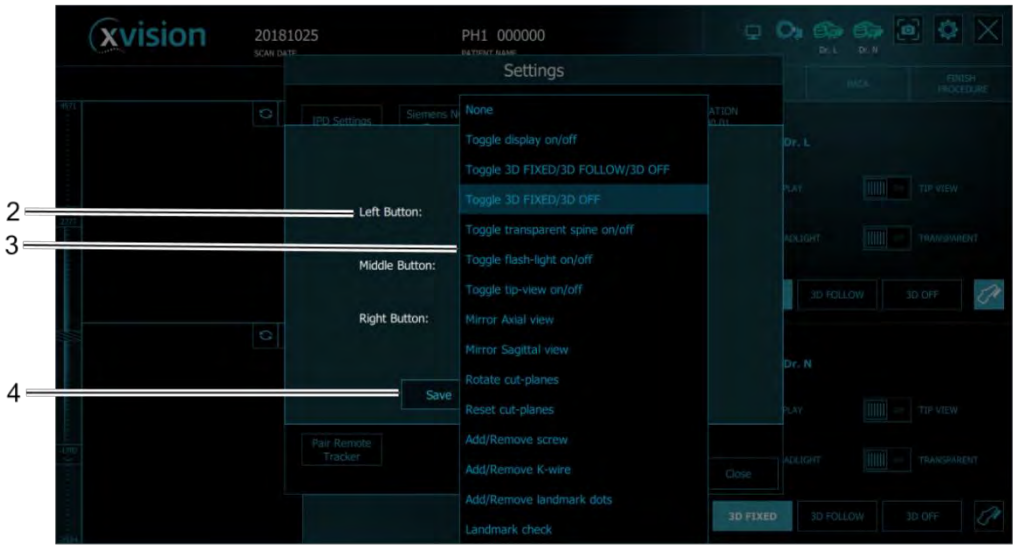
4.6.2. Configuring the Footswitch for other features

The user can configure the Footswitch left and Right buttons to make and remove other features by following the procedure below.

Figure: Footswitch Settings (1st step)

1 Open the **Footswitch Settings** window)password-protected via Service user and password(.

Figure: Footswitch Settings (2nd step)



2 In the **Left** Button menu, select **Add/Remove any feature.**
3 In the **Right** Button menu, select Add/Remove any feature.

Press Save.

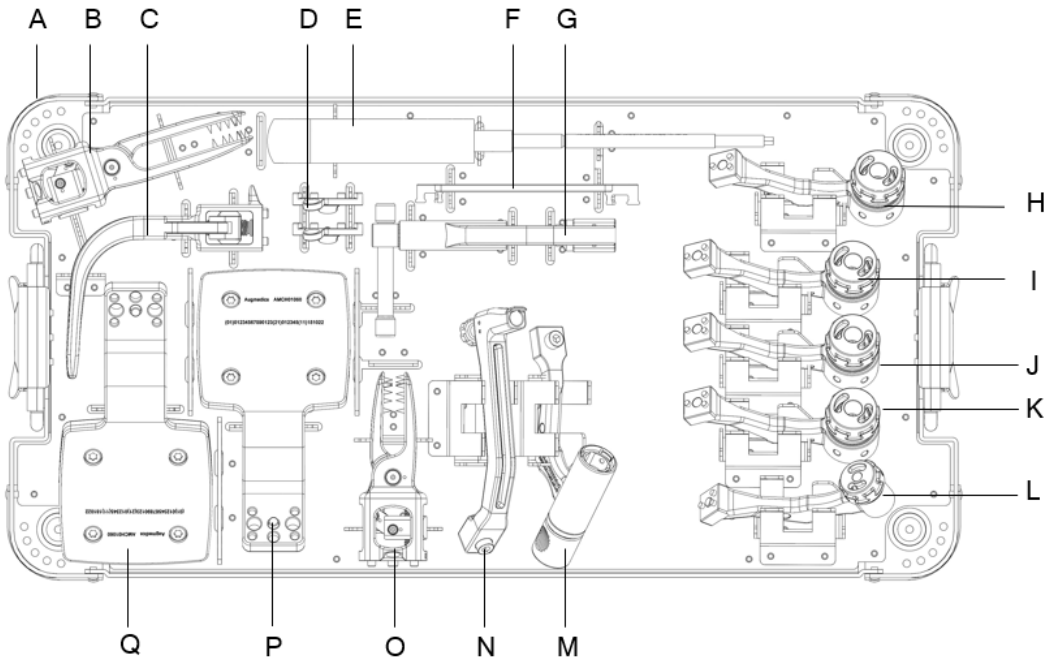
4.7. Reusable Components

XVISION-SPINE is provided with reusable components that can be sterilized and stored after use.

Warning: Do not use the reusable components if they are not sterile. See *Cleaning Reusable Components* on 8-133 for more information.

Figure illustrates the XVISION-SPINE instrumentation tray.

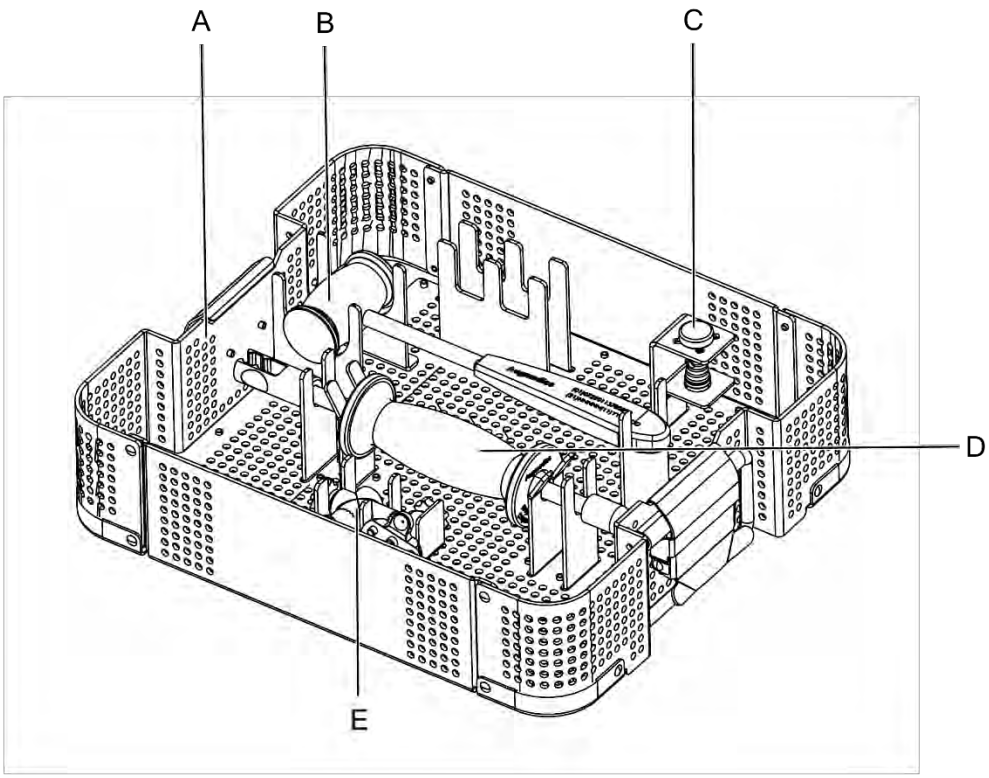
Figure: XVISION-SPINE Instrument Tray



A XVS Instrument Tray	K Swivel 3-4 mm Universal Tool Adaptor Leg Up
B XVS Tall Straight Clamp (82 mm)	L Fixed 3-4 mm Universal Tool Adaptor Leg Up
C XVS Arc Clamp	M Ergonomic Navigated Tool Adaptor
D Rotating Marker Adaptor	N XVS VP Tool Adaptor
E Allen Screwdriver 4 mm	O XVS Short Straight Clamp (62 mm)
F XVS Wrench	P Z-Marker-40
G Clamp Removal Tool	Q Z-Marker-60
H Swivel 6-7.5mm Universal Tool Adaptor Leg Up	
I Swivel 5-6 mm Universal Tool Adaptor Leg Up	* Patient Marker Extender
J Swivel 4-5 mm Universal Tool Adaptor Leg Up	

Figure shows the surgical kit used when a Perc Pin is used for patient registration instead of a clamp attached to the spinous process.

Figure: Perc Pin Surgical Kit



A Perc Pin Tray (AMCH07100)
B Perc Pin Mallet 250 gr. (AMCH07700)
C Perc Pin Insertion Cap (AMCH07320)
D Perc Pin Slap Hammer (AMCH073700)
E Perc Pin Adaptor (AMCH07200)

4.8. Single Use Sterile Kit

There are 3 types of single use sterile kit:
(1) XVS Markers with XLINK Kit
(2) XVS MARKERS WITH C-LINK KIT
(3) XVS MARKERS FOR ASC KIT

Kits 1&2 described above include the following:

- Two (2) Patient Markers with double-sided stickers at the back
- Six (6) Tool Markers: there are no two identical Tool Markers in a single sterile kit. Tool Markers ensure unique identification of the instrument during the procedure.

The XVS Markers with XLINK Kitincludes the following:

- One (1) X-Marker Registration Marker
- Three (3) double-sided stickers for fixing the X-Marker to the patient

Kits 2 &3 described above includes the following:

- One (1) C-Marker (Can't be used with Intra-op workflow)

The ASC Sterile Kit has **only** 4 Tool Markers.

One kit is provided for each surgical procedure.
All Markers in each kit are sterile and are intended for single use.

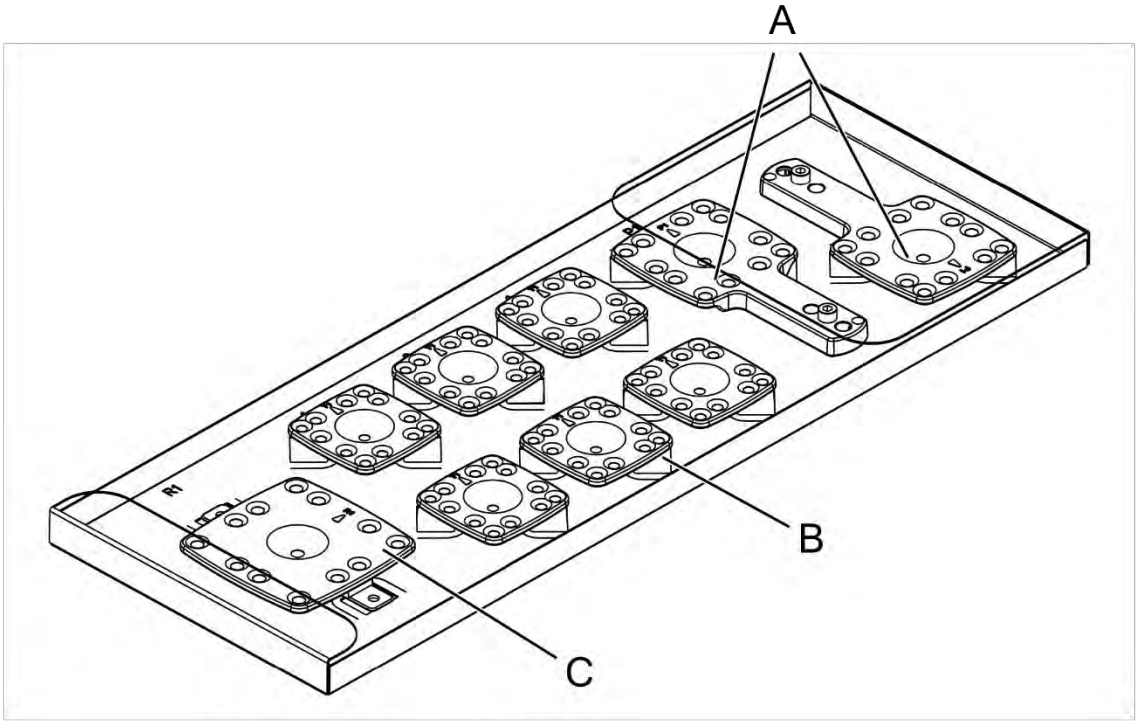
Warning: Do not use the sterile components if the expiration date has passed.

Warning: The sterile components are intended for use during a single procedure only.

Discard after use. Do not re-sterilize. If the package is found opened or damaged, discard these components and use components from a new package.

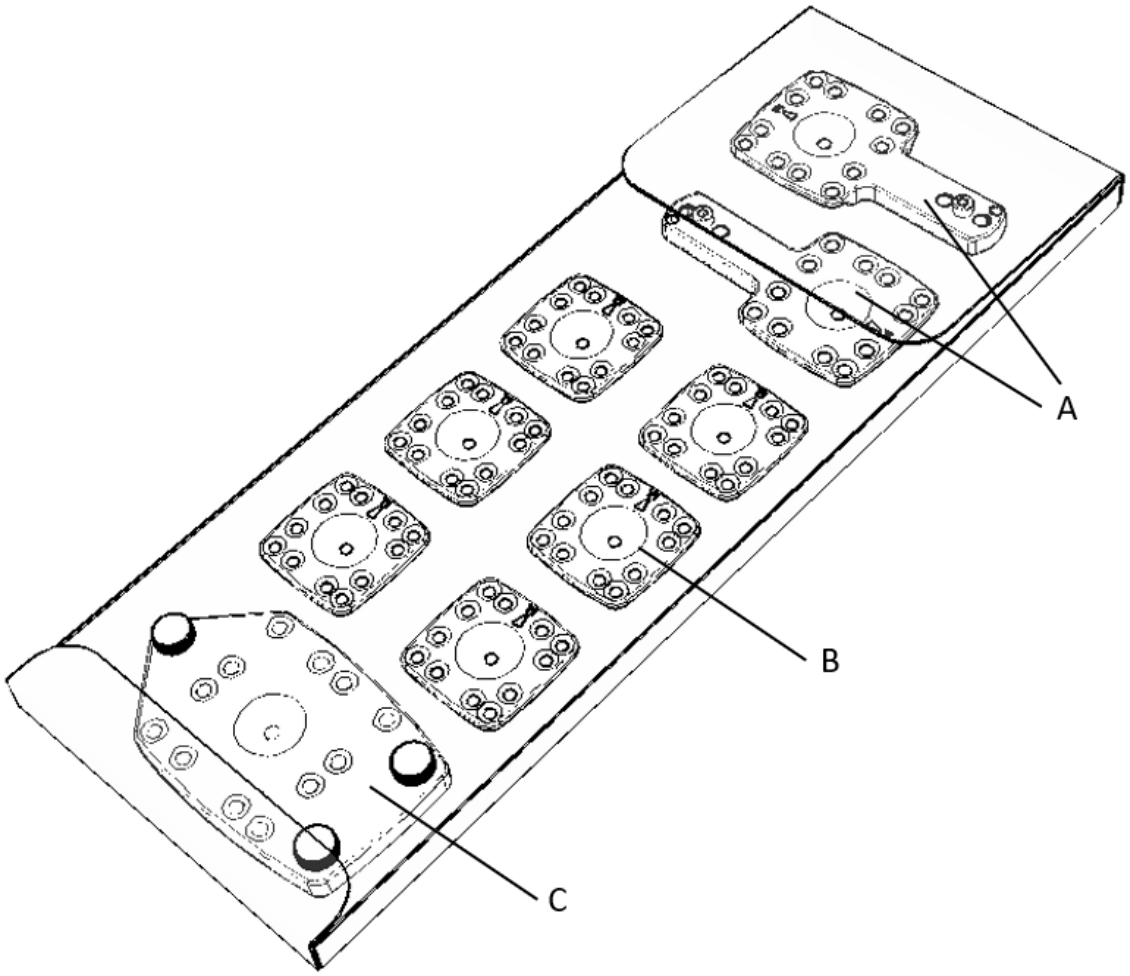
Warning: Do not use the contents of more than one Single Use Sterile Kit in a single procedure. Markers with the same ID from different kits may confuse the **XVISION-SPINE** system.

Figure: XVS Markers with XLINK Kit



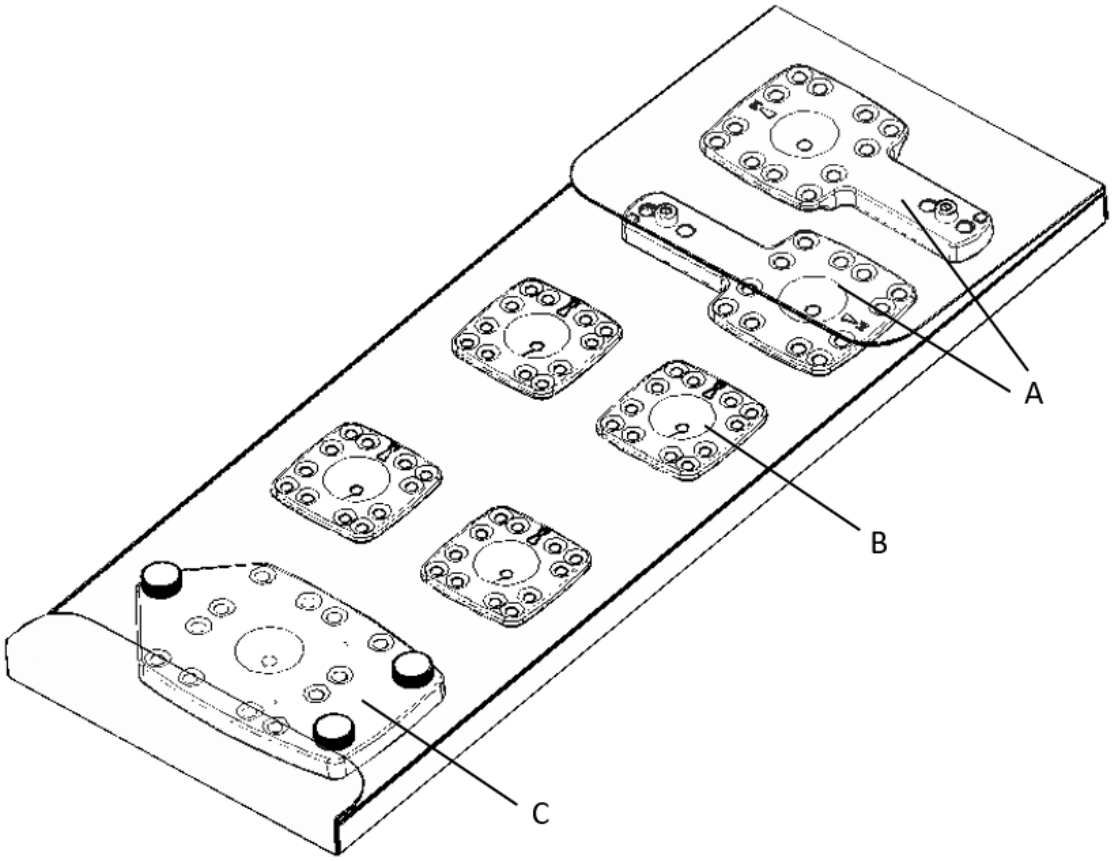
A Patient Markers (2)
B Tool Markers (6)
C X-Marker Registration Marker
D X-Marker double-sided stickers (3)

Figure: XVS MARKERS WITH C-LINK KIT



A Patient Markers (2)
B Tool Markers (6)
C C-Marker (Registration Marker)

Figure: XVS MARKERS FOR ASC KIT



1. Patient Markers (2)
2. Tool Markers (4)
3. C-Marker (Registration Marker)

4.9. Sterile Perc Pin (100/125/150 mm)

The **XVISION-SPINE** sterile Perc Pin is intended to be inserted into the posterior superior iliac spine (PSIS) for the attachment of a patient reference during image-guided surgery using the **XVISION-SPINE** system. It is intended for single use only.

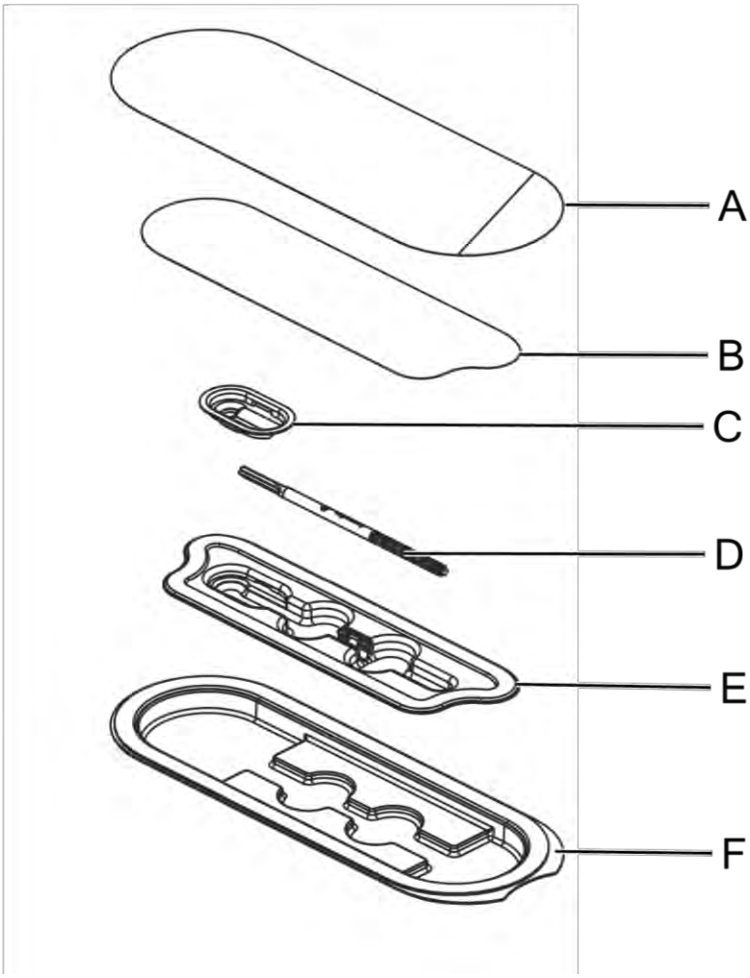
The Perc Pin is inserted percutaneously into the PSIS (and extracted after the surgical procedure) using a mallet and a slap hammer provided separately as part of the **XVISION-SPINE** reusable components. See *The Sterile Perc Pin Platform* on Page 6-32 and *Perc-Pin Removal* on Page 7-116 for more information.

Warning: Do not use the sterile component if the expiration date has passed.

Warning: The sterile Perc Pin is intended for use during a single procedure only. Discard after use. Do not re-sterilize. If the package is found opened or damaged, or the Perc Pin is found outside of its snap and groove holder, discard this component, and use a component from a new package.

Warning: Do not use the Perc Pin for more than a single procedure.

Figure: Sterile Perc Pin Kit



A Outer Tyvek cover
B Inner Tyvek cover
C Protecting cap
D Sterile Perc Pin
E Inner blister tray
F Outer blister tray

4.10. System configurations

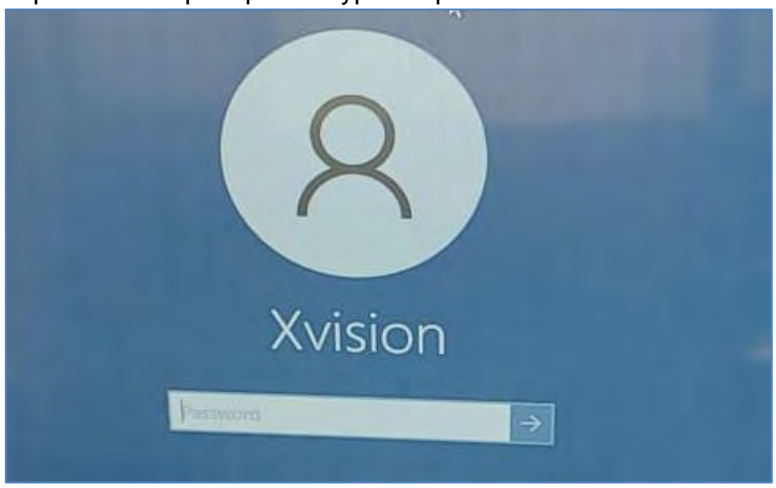
The XVS system supports the following Workstation configuration:

1. To power-up the system connect the power cord to main power outlet.

2. To power up the system:

    a. Connect the main power cord to main power-outlet.
    b. Press the power button on the PC.
    (The power button should be lit blue when turned on)

On system's startup the user is prompted to type the password:



Type the password provided for a certified XVS personnel.
If the system remains unattended more than 60 minutes (set by default) the user is logged off automatically.

Warning: Do not use an extension cord with the **XVISION SPINE** system.

For detailed information regarding each assembly main parts, see the below section.

Figure:

4.10.1. WS-Cart (USM-500)

The WS-Cart is provided as an alternative option for a computer, monitor and a cart.
It is comprised of 3 main components:

(1) Workstation (Computer)
(2) 27” Touch Screen
(3) WS-Cart

Caution: Make sure to dock the WS-Cart using the casters’ brakes for storage.

Caution: Make sure the WS-Cart casters are locked while being used in the OR.

Caution: When maneuvering the WS-Cart from place to place make sure to use the handles to push or pull. See the WS-Cart’s handles in the Figure below.

Figure: WS-Cart

The WS Cart includes a drawer in which the MSO, router and cables are stored. Blue arrows on the drawer, as shown in the Figure above are intended to be used for easy maneuvering of the WS cart from place to place.

4.10.1.1 Workstation

The Workstation-Computer (FCC ID: SEFD1812039) is a computer on which the **xvision SW** is

installed.

Figure: Workstation

Once the Main system's power-cord is connected, press the Power-On button  at the bottom left of the PC front-panel to turn the system ON.

Note: The front panel USB ports on the Workstation are to be used for data import/export using a Flash-drive.

Caution: Do not use Workstation back-panel USB ports for USB Flash-drive.

Warning: Only the integral multiple socket outlet that is provided with the system is to be used for connecting system's components only.

The Workstation Back-panel includes the following connectors:

Figure: Workstation Back-panel

1. LAN cable
2. Touch I/O USB cable
3. Monitor back-panel USB-Hub cable
4. Monitor MiniDP to HDMI cable
5. MiniDP to multiple video-out adaptor
6. Power cable
7. Footswitch dongle

See *Workstation User Manual* on page N-1 for more information.

4.10.1.2 Touchscreen

The 27" Touchscreen provided with the WS-Cart is intended to serve as the main controlling unit of the XVS WS, based on touch inputs on the display itself.

The Touchscreen shall be attached to the VESA mount on the WS-Cart.

Figure: Touchscreen Monitor

Figure: Touchscreen Monitor Back-panel

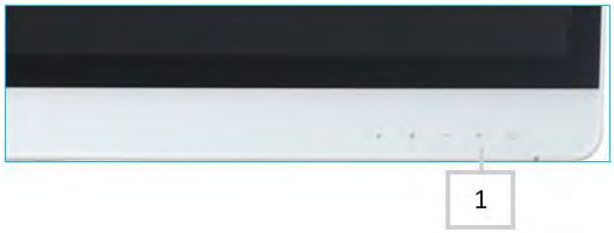
The Monitor is connected to the system using the following cords:

1. Power cable
2. USB ports extension cable
3. HDMI input cable
4. USB Touch-input cable

Note: The free USB ports on the Monitor's Back panel may be used for Flash-drive to import or export data.

Once the Main system's power-cord is connected the Monitor should be ON (standby).

Figure: Touchscreen Monitor – Touch-buttons



If the Monitor's LED doesn't light up or display is off, press the Power-ON button below the power symbol.

4.10.1.3 WS-Cart

The WS-Cart is intended to serve as an assembly platform for the computer and monitor of the xvision spine system. On the WS-Cart the 3 components of the workstation are assembled and connected.

Figure: WS-Cart assembly

The WS-Cart is assembled on its first time installation on site.

To complete all the WS-Cart assembly on 1st time installation the following cables are required:

P/N	Description
ACC00407	Network Extension Cable for Easy 45 Module S/FTP RJ45 plug to RJ45 jack Cat.6A 50 cm black
ACC00411	mini-DP to HDMI cable
ACC00412	LAN cable 1m from PC to router Cat.6A
YACC00414	Adapter mini DisplayPort 1.1 male > DisplayPort / HDMI / DVI with Label

For First time installation instructions *refer to: DMR-SER-000011.*

The WS-Cart following first time installation shall include the following components in the main storage drawer:

1. Router + PSU.
2. Monitor's PSU
3. MSO (Multi-socket Outlet)
4. Workstation Power cable
5. Monitor's Power cable
6. Router to WS LAN cable
7. LAN Input extension cable

Figure: WS-Cart storage drawer (assembled)

In case of suspected disconnection, to lift the main storage pull with a finger from each side.

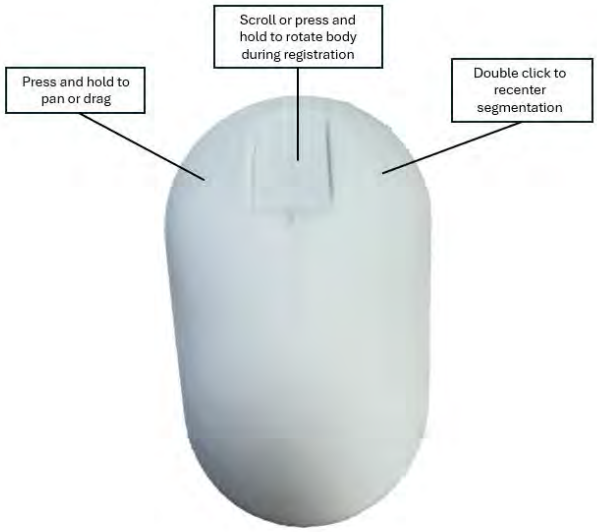
4.10.1.4 Mouse

Using the provided screwdriver, unscrew the battery case and insert the two provided AA batteries

4.10.1.5 Place the USB into a monitor USB port.

4.10.1.6 Mouse

Using the provided screwdriver, unscrew the battery case and insert the two provided AA batteries.
Place the USB into a monitor USB port.



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 local sales representative of any damage that the unit has incurred during shipping.
- Verify that all of the components are present.

5.1. System Assembly Instructions

Each System configuration is assembled during 1st time installation.
1st time installation is performed by designated Augmedics' trained personnel.
For 1st time installation instructions of the Roll Stand AIO refer to DMR-XVS-SER-003.
For 1st time installation instructions of the WS-Cart assembly refer to DMR-SER-0000011.

5.2. XVISION-SPINE System Communication

Communication is performed via a Wi-Fi router that supports the IEEE 802.11g/802.11n/802.11ac standard and is configured by the manufacturer.

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 **XVISION-SPINE** system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

5.3. Custom-Fit the Headset to the Surgeon

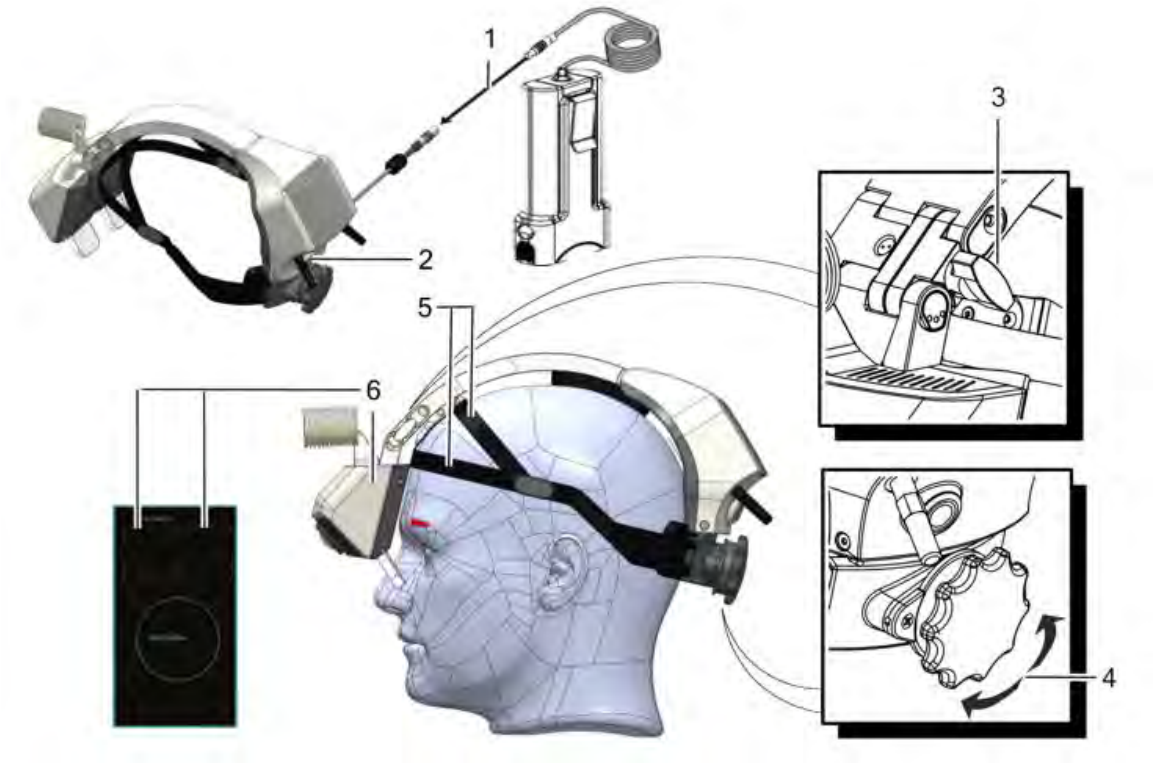
The **HEADSET** is factory customized, by Augmedics service personnel, for each user, taking into account inter-pupil distance (IPD)

Warning: The **HEADSET** is a personalized device which is calibrated to the user's eyes.

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

5.3.1. Adjusting the Gen-1 Headset to the Surgeon

Figure: Adjusting the HEADSET



1 Attach the battery.
2 Power on the HEADSET by pressing the on/off button.
3 Rotate the lock knob counterclockwise to unlock the hinges.
4 Mount the HEADSET and adjust the head strap by rotating the rear knob.
5 Tighten the straps to optimize the position of the headset.

6 Adjust the front part of the **HEADSET** to position the lenses in the correct distance and angle relative to the user's eyes. Optimal **HEADSET** position is achieved when two rectangles and a circle can be seen.

Note: In order to see the two rectangles and the circle, make sure that the **HEADSET** is not paired to the **XVS SOFTWARE**. If pairing has already been performed, unpair the **HEADSET**. See *Headset Pairing* on page 5-33 for more information.

7 Rotate the lock knob clockwise to lock the hinges and prevent undesired movements of the front part of the **HEADSET**.

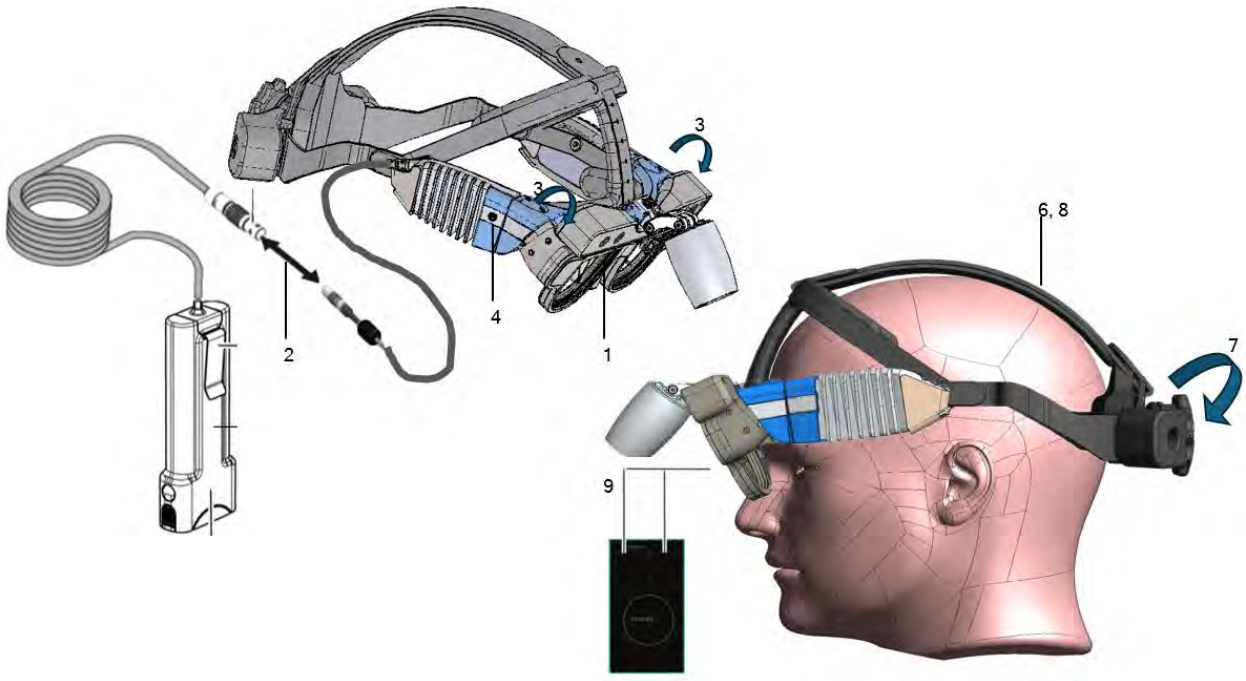
Warning: While wearing the **HEADSET**, if the user feels dizziness, headache or nausea remove the **HEADSET** and rest. Contact Augmedics service.

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.

5.3.2. Adjusting the Gen-2 Headset to the Surgeon

Figure: Adjusting the HEADSET



1 Connect the nose bridge from the supplied kit to the **HEADSET**.

Note: Headset is provided with a kit of 3 nose bridge types. The user can select the most comfortable nose bridge to his preference.

2 Attach the battery.
3 Adjust the front part of the **HEADSET** to fully open (Prone position) or fully closed (Lateral decubitus position) as preferred.
4 Power on the **HEADSET** by pressing the ON/OFF button.
5 Rotate the rear knob counterclockwise to loosen the head circumference strap.
6 Make sure the upper/top (Velcro) strap is sticked, and the nose bridge is in place.
7 Mount the **HEADSET** and adjust the head strap by rotating the rear knob clockwise (half way closed).
8 Detach the upper/top (Velcro) strap to allow the **HEADSET** to rest on the nose bridge.
9 Tighten the straps to optimize the position of the **HEADSET**.
Optimal **HEADSET** position is achieved when full blue frame around the two rectangles and circle can be seen.

Warning: Tighten the straps to optimize the position of the headset to optimized position on the head and to get full field of view

10 In case the optimal **HEADSET** position can not be achieved, perform the following actions:

- Replace Nose bridge and retry.
- Adjust the front part of the **HEADSET** 1-2 levels up/down
- Open, adjust and close the upper/top (Velcro) strap.
- Open, adjust and close the head circumference strap.

Note: In order to see the two rectangles and the circle, make sure that the **HEADSET** is not paired to the **XVS SOFTWARE**. If pairing has already been performed, unpair the **HEADSET**. See *Headset Pairing* on page 5-33 for more information.

11 Attempt to assemble the tinting Snap-on lenses to test AR image quality.

Figure: Assemble the optional tinting lenses on Gen-2 HEADSET

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

Warning: In case of headset overheating, If a malfunction is detected or the user feels discomfort when the reality and projected display are not properly aligned, discontinue use immediately and switch to another headset.

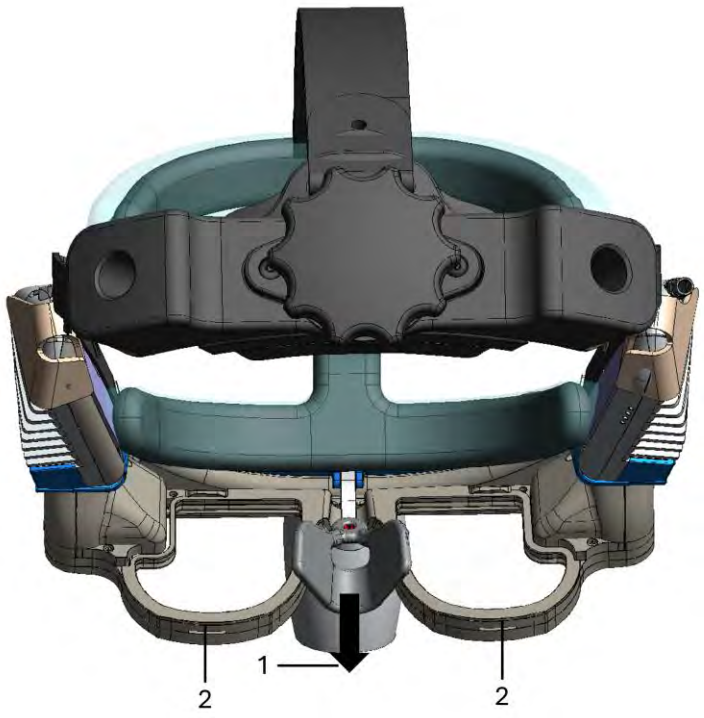
Warning: To prevent damage, avoid allowing water or blood to spill on the headset.

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.

5.3.3. Prescription Lenses assembly - Gen-2 Headset

The Gen-2 HEADSET is comprised of optical transparent near eye displays and 2 clip-on options. The inner part of the HEADSET around the lenses can be disassembled and reading/prescriptive lenses can be assembled instead.
To replace the inner default Lenses, to readings/prescriptive lenses:



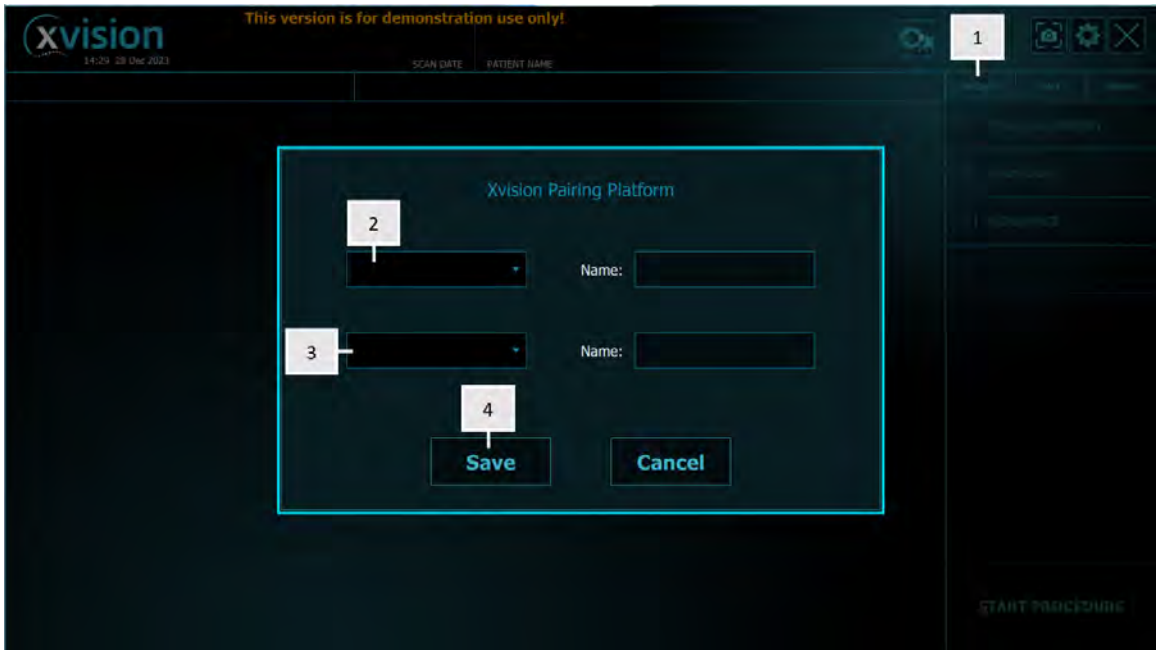
1 Pull the nose pad out, while wiggling the pad.
2 Use your fingers/nails to lift the inner Snap-on lenses frame.
3 Verify the supplied Prescription lenses is correct.
4 Clean the supplied Lenses from both sides with a cloth prior to assembly.
5 Snap the Readers/Prescription lenses on the frame.
6 Turn the HEADSET ON.
7 Use a demo image to verify the optical lenses improve the AR experience.
In case a double-vision occurs, or image is blur, contact local representative.

Note: Make sure to store the replacement lenses in the Gen-2 Headset's case, on its designated slot to prevent scratches and breakage.

5.4. 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.
To perform **HEADSET** pairing once the Home Screen launched, select **IntraOp** or **PreOp** according to the registration method selected for the procedure and then proceed to the instructions below:

Figure: HEADSET Pairing Screen



1 In the **XVS SOFTWARE**, click Headsets.
The HEADSET Pairing window opens.

2 In the HEADSET Pairing window, select the HEADSET serial number 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.

Note: The 1st paired **HEADSET** is selected as default for Tools Calibration. This can be changed later by pressing the MiniHMD icon.

3 For procedures using two HEADSETs, select the second HEADSET and key in an optional

pairing name, as before.

4 Click Save.
Once 'Save' is clicked the window will close and the XVS SOFTWARE begins to sync the HEADSET.

5.5. Configuring the Scanner Imaging Protocol

Note: XVISION-SPINE supports CT Image Storage (SOP CLASS 1.2.840.10008.5.1.4.1.1.2) and Enhanced CT Image Storage (1.2.840.10008.5.1.4.1.1.2.1).

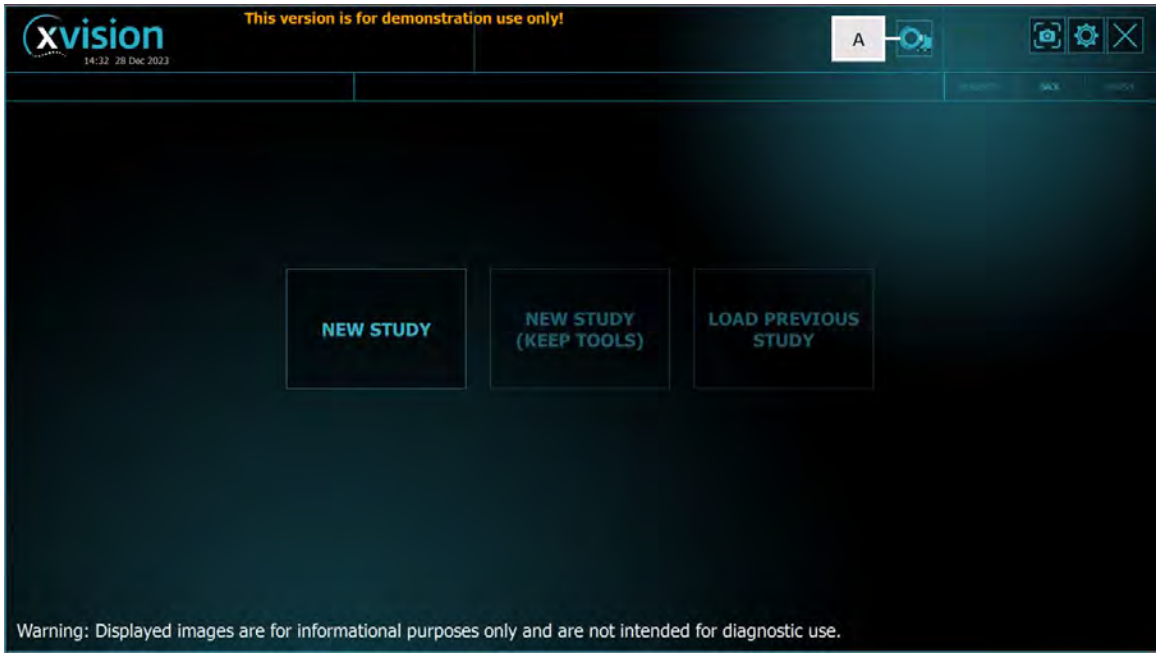
XVISION-SPINE System supports the following 3D (intra-op/portable) imaging devices:

- *Medtronic O-arm 2 Scanner* (page F-1)
- *Medtronic O-arm 1 Scanner* (page G-1)
- *Brainlab Airo Scanner* (page H-1)
- *Ziehm RFD 3D Scanner* (page I-1)
- *Healthineers Cios Spin Scanner* (page J-1)
- *GE OEC 3D Scanner* (page L-1).
- *Globus Excelsius3D Scanner*

Note: Globus Excelsius3D imaging data can be transferred only via USB drive.

Before setting up the scanner, follow the procedure below to set scanners in XVISION-SPINE. From the XVS SOFTWARE Home screen Select IntraOp and then proceed with the instructions below:

Figure: Imaging Icon



1 Click the imaging icon (A).

Figure: Scanner Information

2 In the popup window (B), enter the following information from the scanner:

- 3D Imaging Device name
- IP Address
- AE Title
- Port.

3 Press Apply Connection.

Continue with one of the supported scanners below:

- *Setting up the Medtronic O-arm 2 Scanner* (page F-1)
- *Setting up the Medtronic O-arm 1 Scanner* (page G-1)
- *Setting up the Brainlab Airo Scanner* (page H-1)
- *Setting up the Ziehm RFD 3D Scanner* (page I-1)
- *Setting up the Siemens Healthineers Cios Spin Scanner* (page J-1)
- *Setting Up the GE OEC 3D Scanner* (page L-1).

5.6. Siemens Healthineers InstantLink™

Siemens Healthineers InstantLink™ can be used to stream XVISION-SPINE GUI content to the Siemens Healthineers Cios system and provide a return channel for mouse/touch input to control the XVISION-SPINE GUI from the Cios integrated display. A license for InstantLink™ can be obtained from Siemens Healthineers.

For details of Setting Up Siemens Healthineers InstantLink™, see page K-1.

5.7. Sound Feedback and Date Settings

XVISION-SPINE can be set to provide sound feedback for calibration and verification, by following the procedure below.

Figure: Settings

1 Click the Settings icon to open the Settings window.
2 Set Calibration Sound to ON.
3 Set Verification Sound to ON.
4 Set Xlink Sound to ON.
5 Date and Time - set to ON to display on the xvision user interface.

6. XVISION-SPINE System Preprocess Workflow

Follow the procedures below prior to a surgical procedure.

6.1. Starting up the XVISION-SPINE System

The **XVS SOFTWARE** is designed to work with 2 OR workflows:

1. Pre-Op
2. Intra-Op

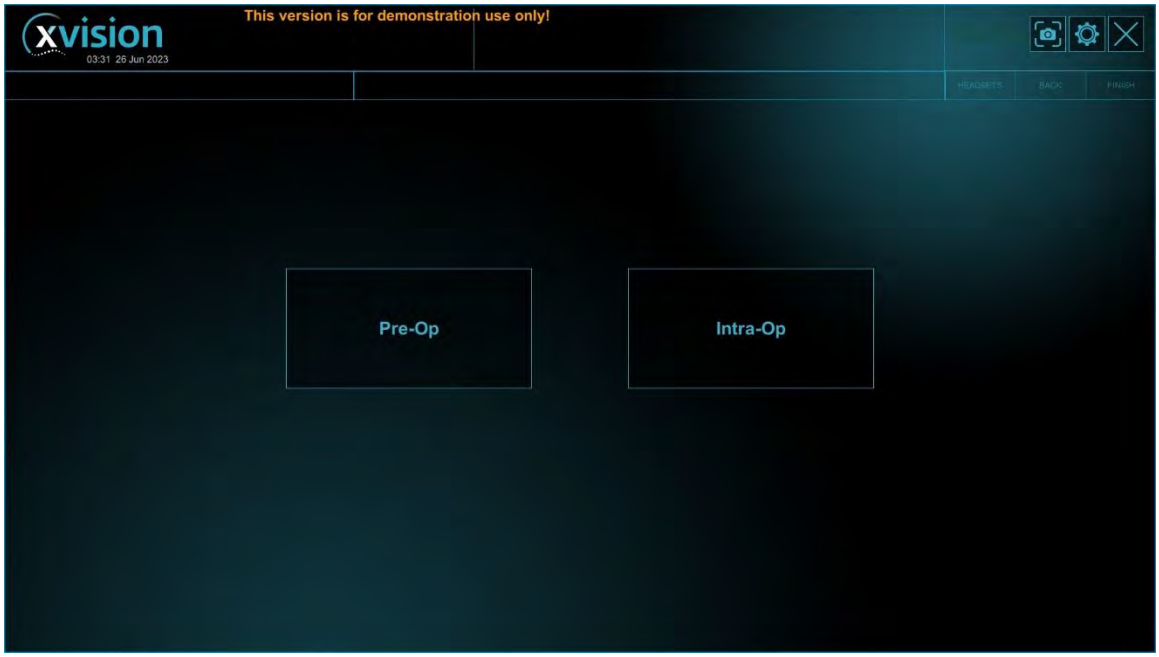
The **Pre-Op** option allows the user to manage the current CT data stored in the system and prepare it for CT to Fluoro image matching workflow. The user is then directed to the Data Management screen in-order to Import new data or handle the current stored data with required segmentation for the CT to Fluoro procedure.

The **Intra-Op** is a workflow that provide the user the ability to start directly from intra-operatively scanning the patient with 3D imaging device and operating over the scanned data. This process will not be handled via Data management screen.

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

When the xvision Software is launched the Home screen is then displayed:

Figure: XVS SOFTWARE Main Screen



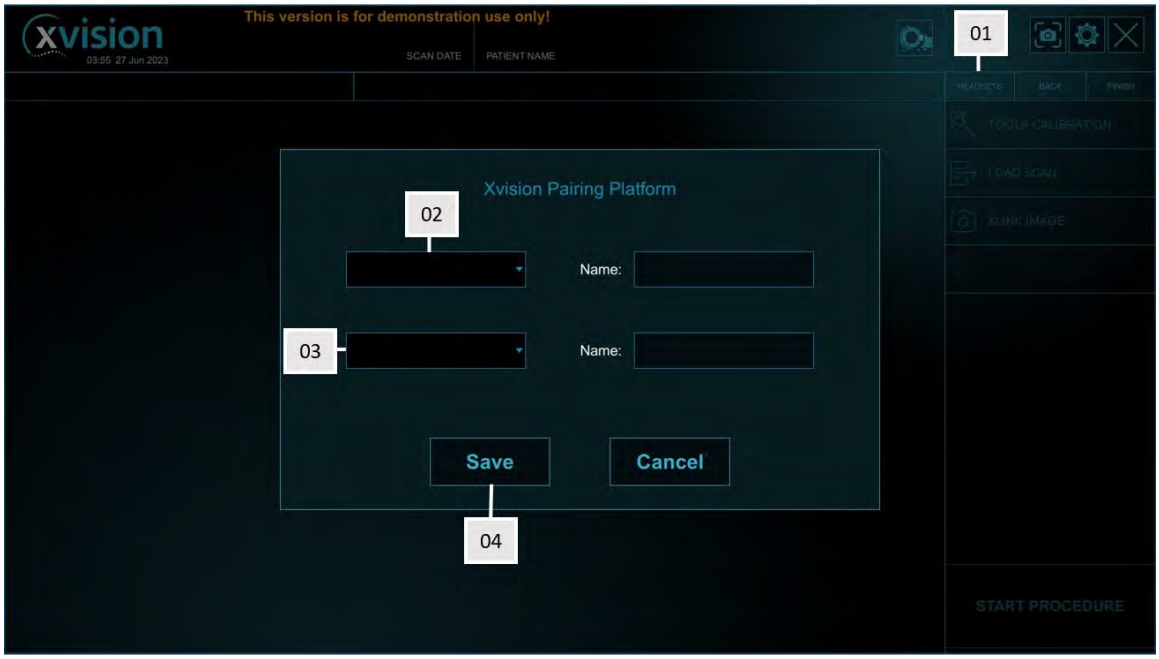
In the **XVS SOFTWARE** Main Screen, select the desired workflow for operation.

It is recommended to mount the **HEADSET** when not sterile.

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

Continue with **HEADSET** pairing as follows:

Figure: HEADSET Pairing Screen

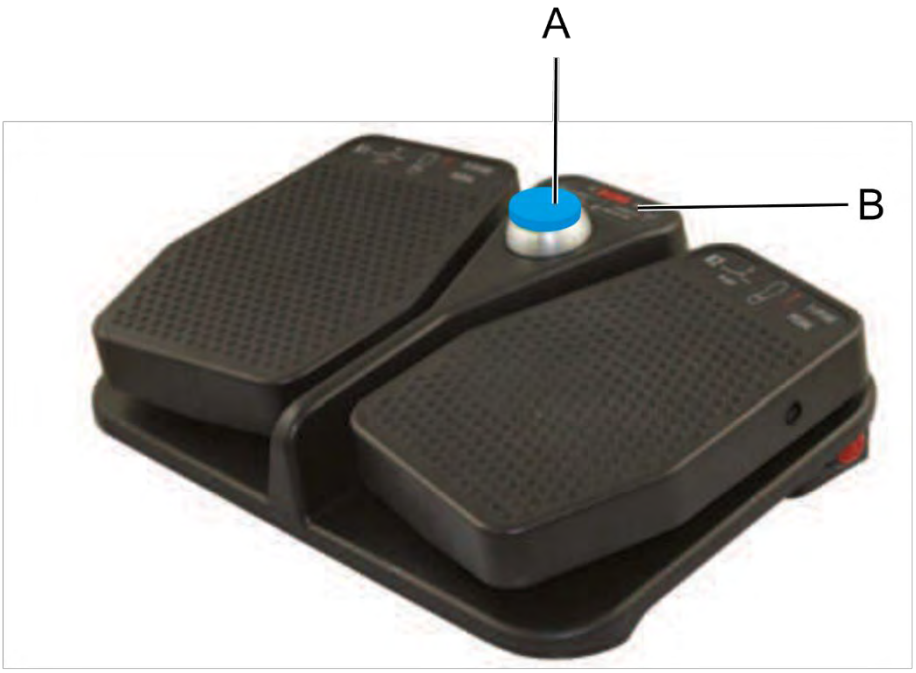


1 Click **HEADSETS**. (For Intra-Op workflow New Study should be selected)
2 In the HEADSET Pairing Screen, note the HEADSET serial number and key in an optional pairing name, such as the name of the surgeon, for the **XVS SOFTWARE** to use as the device name when the device is paired.

Note: The 1st paired **HEADSET** is selected as default for Tools Calibration. This can be changed later by pressing the MiniHMD icon.

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

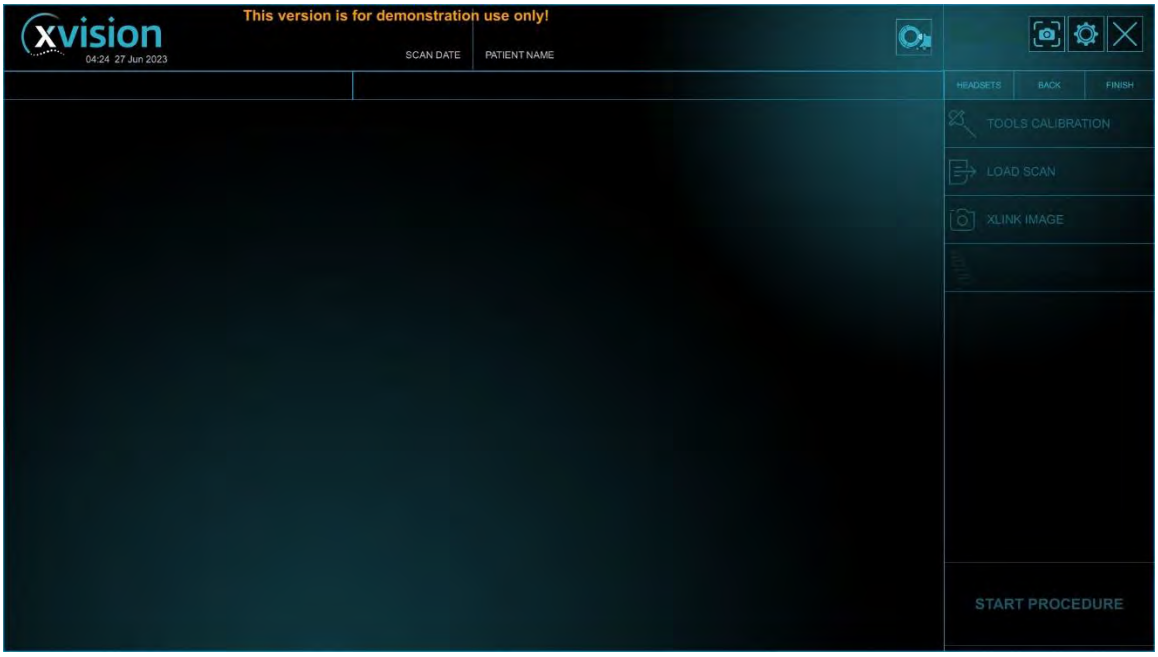
Figure: Check Footswitch Connection



Press the center switch (A) to test connectivity.

Note: If the blue LED (B) does not illuminate, the battery may require replacement. See *The Footswitch Battery Installation* on page 4-5 for more information.

Figure: Setup Phase Options



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

See *New Study* on page 7-2 for more information.

For Pre-Op workflow procedure the C-arm Ring adapter should be assembled over the designated C-arm for the procedure.

6.1.1. C-arm Ring Adaptor assembly Procedure

Prior to using C-arm for CT-Fluoro workflow, it is required to fixate the C-arm Ring Adaptor over the C-arm.
The C-arm Ring adaptor was designed to be assembled only on the below list of devices:

- GE OEC 9900 Elite 9”/12”
- GE OEC 9800 9”/12”
- GE OEC 9800 Plus 9”/12”

Attaching the Ring Adapter to the C-Arm

Note: The Ring Adaptor must be attached to the C-Arm's X-ray Image Intensifier (XRII) prior the image acquisition and registration

Warning: Inspect the Ring Adaptor for any damage or residue before use. Do not use a ring adaptor if it has any visual cracks, missing beads, squeaking of the closing knob or any other signs of wear

Figure 1: C-arm Ring Adaptor Assembly

1. Remove the Ring Adaptor from the its storage compartment and set it close to the C-arm.

Figure 2: C-arm 9" to 12" bracket (9" settings)

2. Confirm if the C-arm is a 12 inch or 9 inch.
    a. Adjust the 3 brackets of the ring adapter by pushing in the pin and sliding the feet to the appropriate size.

Figure 3: C-arm Ring Adaptor - Locking screw release

3. Fully open the ring adaptor by rotating the locking screw manually, counter-clockwise.

Figure 1: C-arm Ring Adaptor assembly on C-arm - Screw alignment

4. Align Screw perpendicular to C-arm.

Caution: Do not let go of the Ring Adaptor. Continue to support it until Step 6 is completed.

5. Gently press the upper Ring Adaptor plate against the surface of the C-Arm's image intensifier, ensuring that the Ring Adaptor plate is positioned parallel to the surface of the C-Arm's intensifier and that there is absolutely no space between them.
    a. All 3 brackets should be over the lip of the C-arm's intensifier

Warning: The Ring Adaptor should be used with a strap when assembled on a non-lip C-arm

Figure 2: C-arm Ring Adaptor - Tightening the locking screw

6. Firmly tighten the screw by rotating manually, clockwise.

Note: The C-arm Ring Adaptor's tightening screw has a torque limiter, therefore tighten until you hear/feel the click

Figure 3: C-arm Ring Adaptor - C-Marker attachment to the Ring Adaptor

7. Cover the C-arm with designated drape.
8. After the C-arm is draped, attach the C-Marker to the Ring Adaptor by placing it firmly in the designated slot, while tightening the 3 Screws.

Note: *It is recommended to strech the drape along the C-marker docking spot prior to placing the C-marker to ease tightening the screws.*

6.2. Prepare Surgical Tools

The system supports up to six navigated instruments for 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 D-1 and *Markers* on page 4-13 for more information.

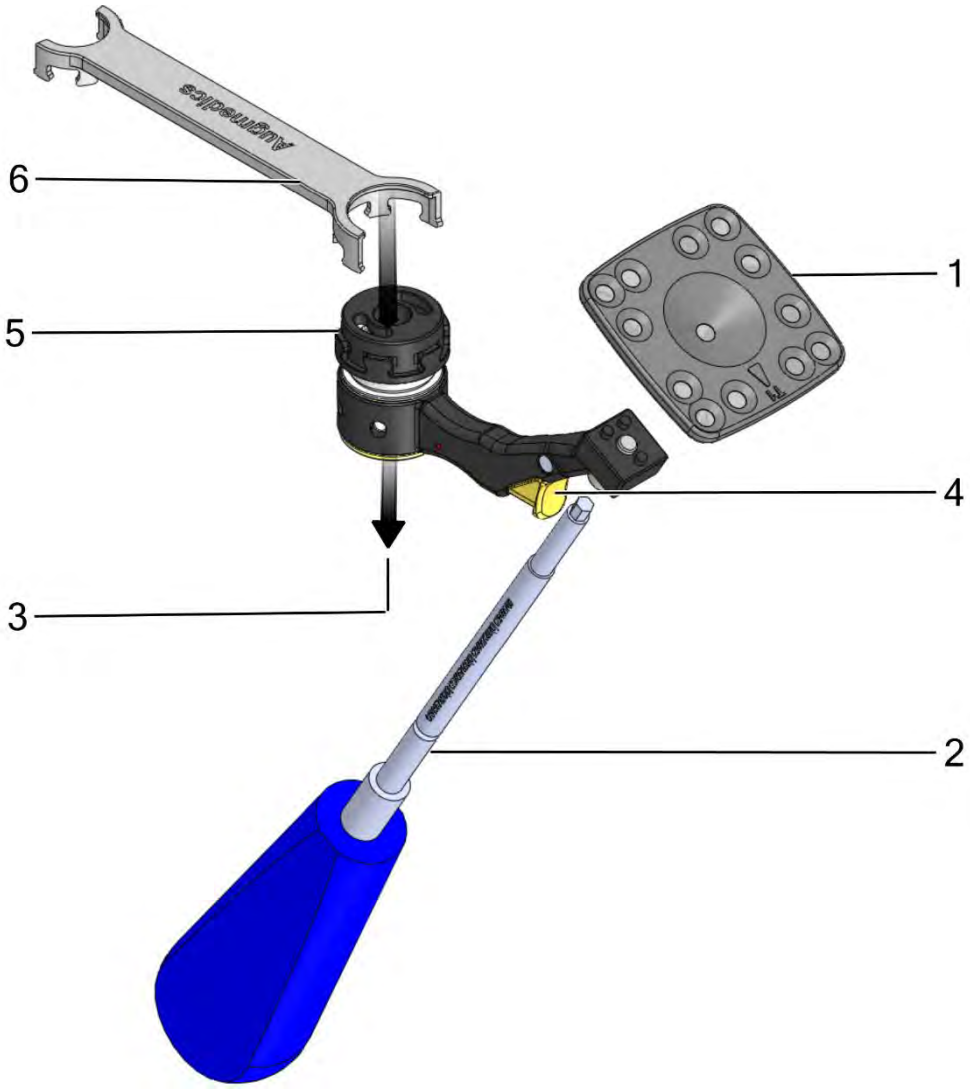
Note: The swivel Universal Tool Adaptor allows the tool to rotate while the Marker stays stationary.

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, flexible, or damaged instruments. Using bent, flexible, or damaged instruments may affect system accuracy. Verify that the instrument is not bent or damaged in any way.

6.2.1. Universal Tool Adaptors

Figure: Prepare Surgical Tool for Universal Tool Adaptor



Note: Universal Swivel Tool Adaptors are provided in the following diameter sizes and colors in the locking button.

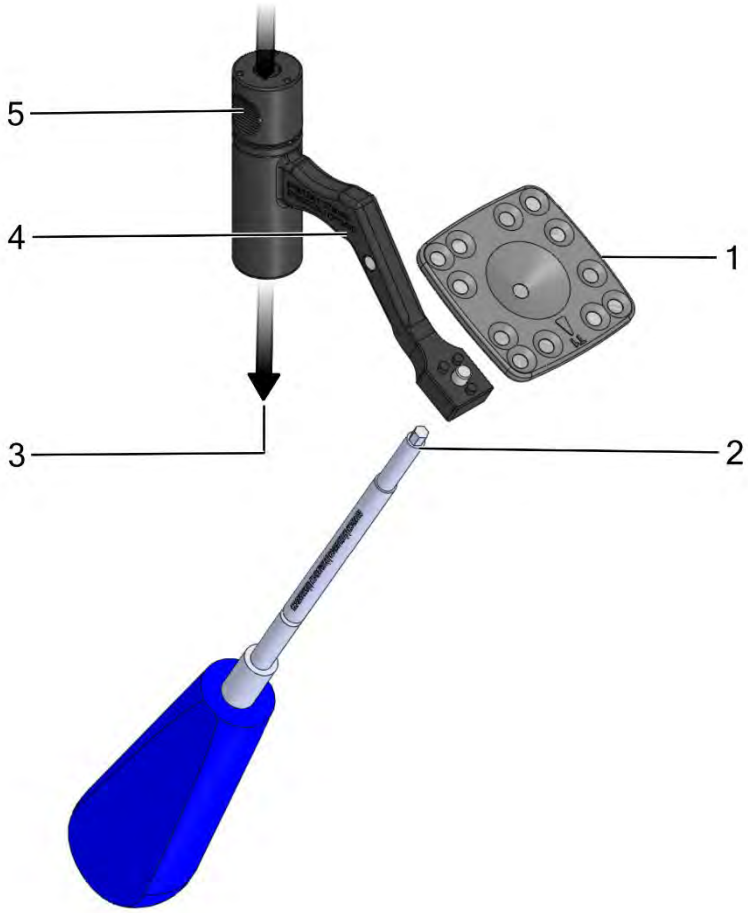
- 3÷4mm – locking button Mint Turquoise
- 4÷5mm – locking button Purple
- 5÷6mm – locking button Orange
- 6÷7.5mm - locking button Green
- 7.5÷9mm - locking button Blue

1 Remove the appropriate Tool Marker from the sterile packaging and set it on the Universal Tool Adaptor.
2 Use Allen screwdriver to tighten the Tool Marker to the Universal Tool Adaptor.
3 Insert the surgical instrument.

4 For swivel tools, press the locking button.
5 Manually tighten the Universal Tool Adaptor to the instrument.
6 Use the XVS Wrench to complete tightening the Universal Tool Adaptor to the instrument.

6.2.2. Ergonomic Navigated Tool Adaptors

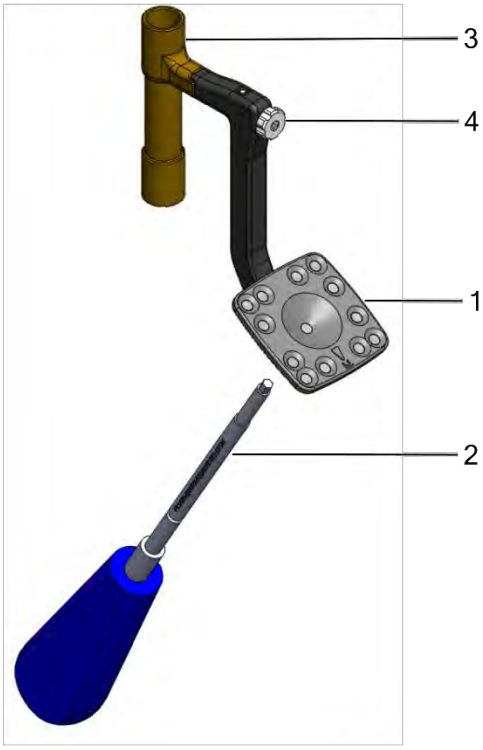
Figure: Prepare Surgical Tool for Navigated Tool Adaptors



6 Remove the appropriate Tool Marker from the sterile packaging and set it on the Navigated Tool Adaptor.
7 Use Allen screwdriver to tighten the Tool Marker to the Navigated Tool Adaptor.
8 Insert the surgical instrument.
9 Hold the Navigated Tool Adaptor where indicated.
10 Grasp the Navigated Tool Adaptor with a thumb and forefinger and pull up to fix the tool in place.

6.2.3. VP Tool Adaptors

Figure: Prepare Surgical Tool for VP Tool Adaptors



1 Remove the appropriate Tool Marker from the sterile packaging and set it on the VP Tool Adaptor.
2 Use Allen screwdriver to tighten the Tool Marker to the VP Tool Adaptor.
3 Align the surgical instrument.
4 Secure the VP Tool Adaptor to the instrument by manually spinning the knob clockwise until the arm is tight.

For all tool adaptors:

Warning: Make sure that the adaptor is firmly attached to the surgical instrument and cannot move up or down. A change in the height of the adaptor on the tool 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. Tool Calibration

Each navigated surgical instrument must be calibrated before use.

The procedures in this section are recommended because they can be performed while the patient is being prepared for surgery.

Before starting calibration, secure a Patient Marker to the sterile table using double-sided tape. It is recommended to avoid 2 Patient markers in the HEADSET FOV while performing Tool Calibration.

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

6.3.1. Surgical Instrument Calibration (Excluding Screwdrivers)

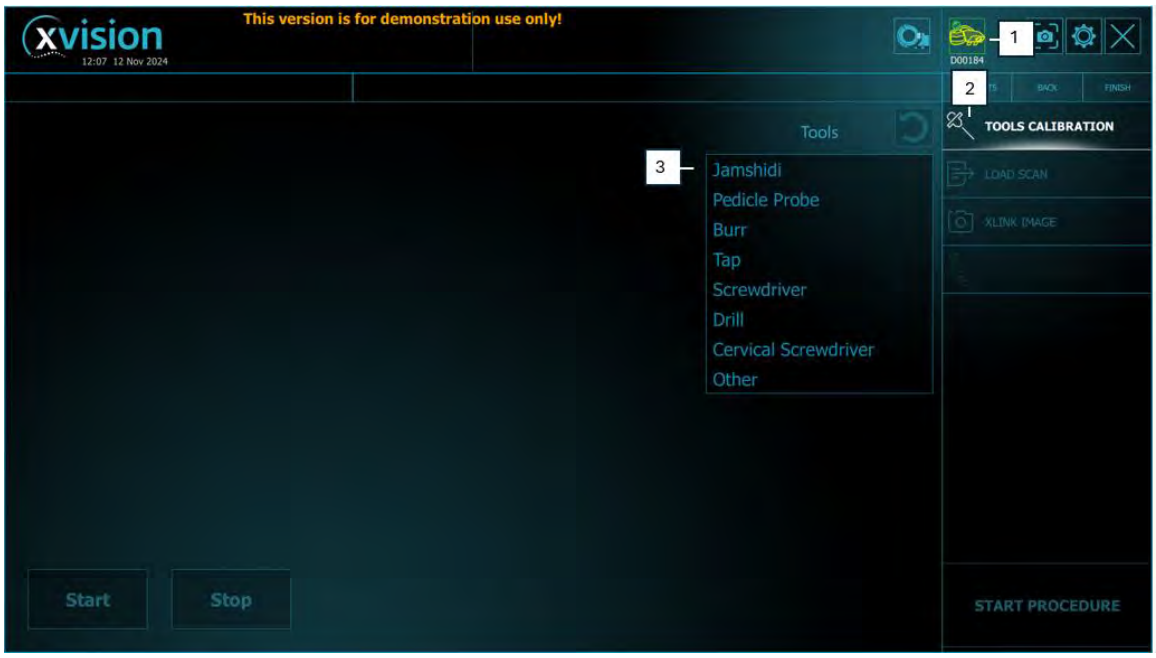
Note: Screwdrivers require a different calibration procedure. See *Screwdriver Calibration* on page 6-20 for information.

Figure: Default HEADSET selected for Tools Calibration

1 The XVS SOFTWARE selects the 1st paired HEADSET by default for TOOLS CALIBRATION. In case the other HEADSET needs to be selected for the calibration **Tap** the MiniHMD icon.

Note: The HEADSET is listed by its serial number or its pairing name. See *Headset Pairing* on page 5-33 for more information.

Figure: Calibrate Tools (1st step)



2 Select TOOL CALIBRATION from the **XVS SOFTWARE**.

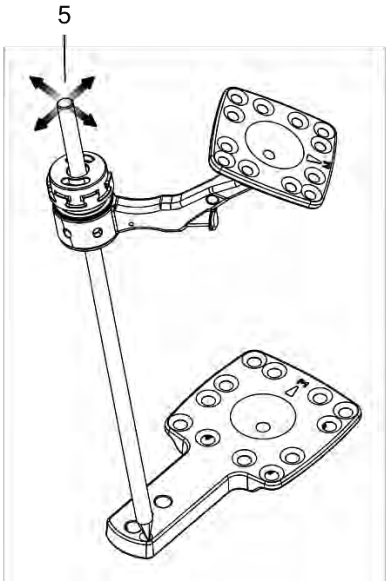
3 Select a surgical instrument to be calibrated.

Note: None of the names are specific, except for the **Screwdriver**and **Cervical Screwdriver**. If the generic name is not appropriate, select **Other** and then type in the appropriate name for the instrument: See *Non-Generic Instrument Name Entry* on page 6-28.

Figure: Calibrate Tools (2nd step)

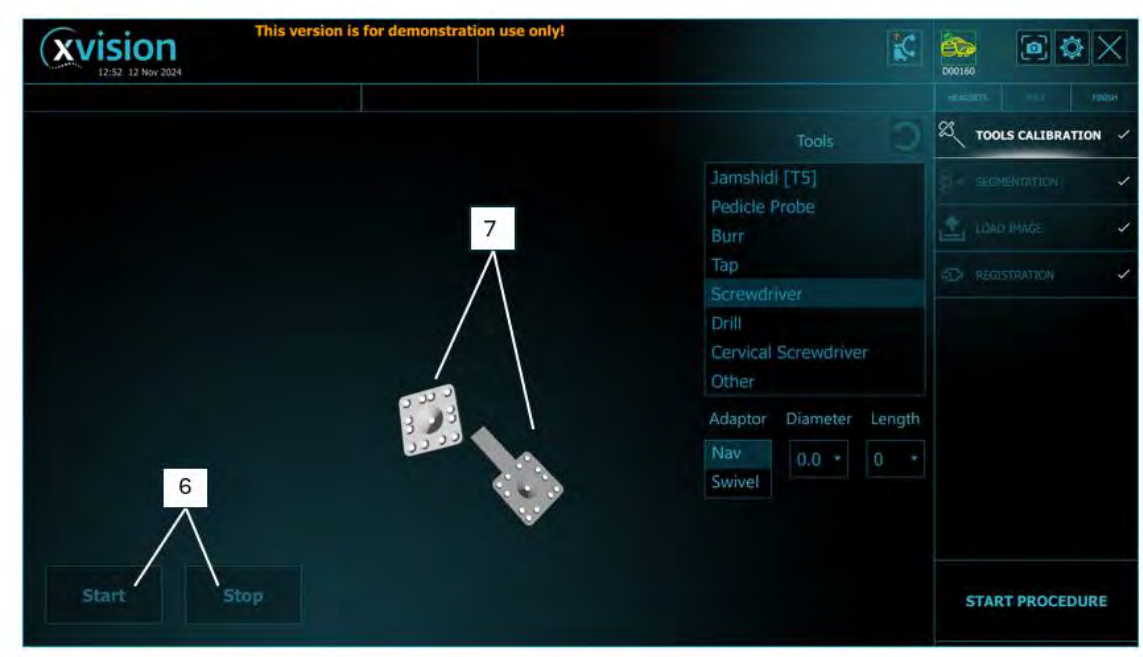
4 The Select Tool Adaptor window appears.
Select the appropriate type of tool adaptor: Swivel, Nav (navigated), or Fixed.

Figure: Calibrate Tools (3rd step)



5 Take one of the prepared surgical instruments and touch its tip to the calibration point on the Patient Marker.

Figure: Calibrate Tools (4th step)



6 The XVS will Start tool calibration automatically as soon as the adaptor is selected. (If you would like to stop/start the calibration process use the buttons on the bottom left).

7 Make sure that the Tool Marker and Patient Marker are both within the HEADSET field of view and displayed on the **XVS SOFTWARE**. Move the tool in a circle while the tool tip is inside the Patient Marker divot.

8 Continue as follows:

- For a swivel or navigated tool, make sure that the Patient Marker is facing the HEADSET. Then perform a swivel test by rotating the tool (with its tip to the calibration point on the Patient Marker) until the system finishes the calibration attempt (which takes 10 seconds).
- Fixed Tool Adaptor does not require a swivel test.

Note: If the swivel test is not performed correctly, a bent tool might pass calibration but will later fail tool verification.

Note: If the tool tip does not fit in calibration divot, calibration, verification, and visualization of tool length may be impacted.

Figure: Message Displayed When Tool Passes Calibration (A)

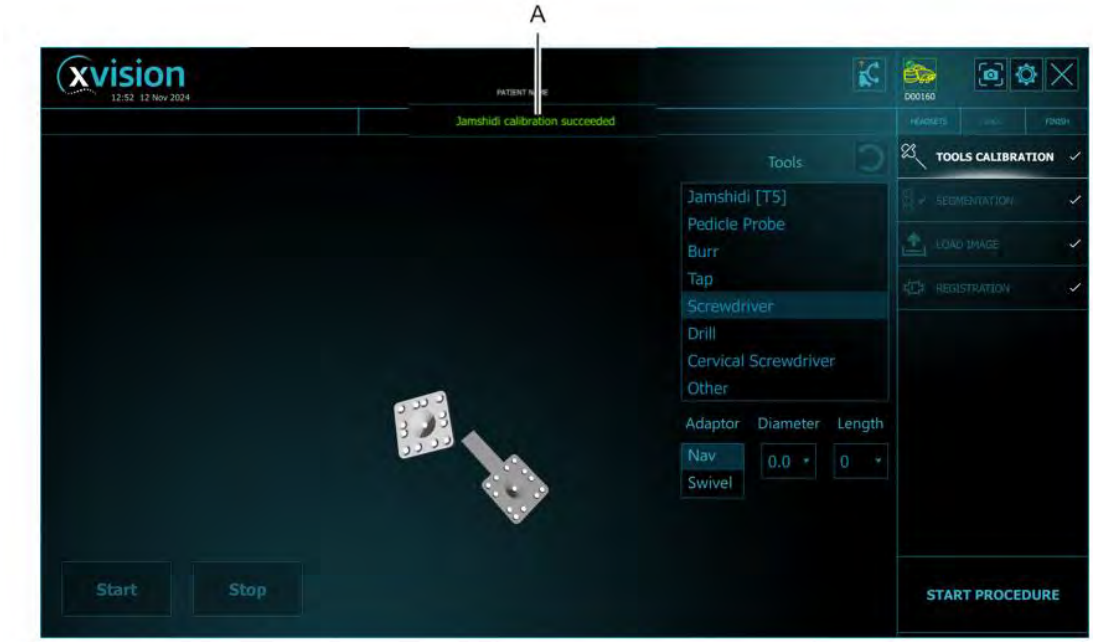
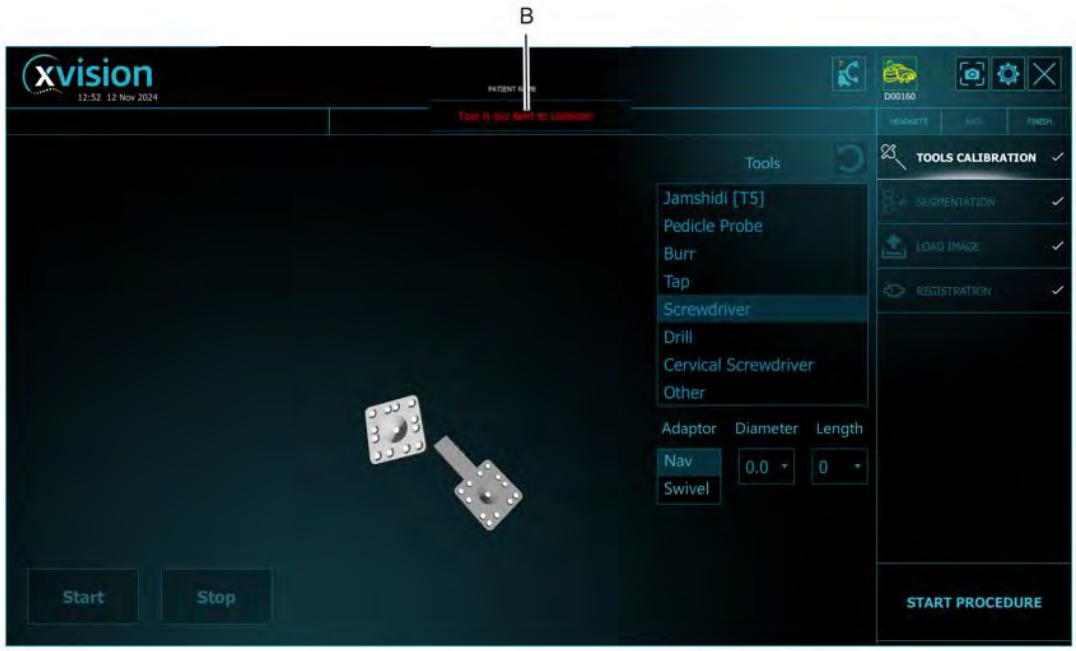

A
xvision
12:52 12 Nov 2024
Jamshidi calibration succeeded
D00160
TOOLS CALIBRATION
SEGMENTATION
LOAD IMAGE
REGISTRATION
Tools
Jamshidi [T5]
Pedicle Probe
Burr
Tap
Screwdriver
Drill
Cervical Screwdriver
Other
Adaptor
Diameter
Length
Nav
Swivel
0.0
0
Start
Stop
START PROCEDURE

Figure: Message Displayed When Tool Fails Calibration (B)



9 The system displays the result of the calibration attempt:

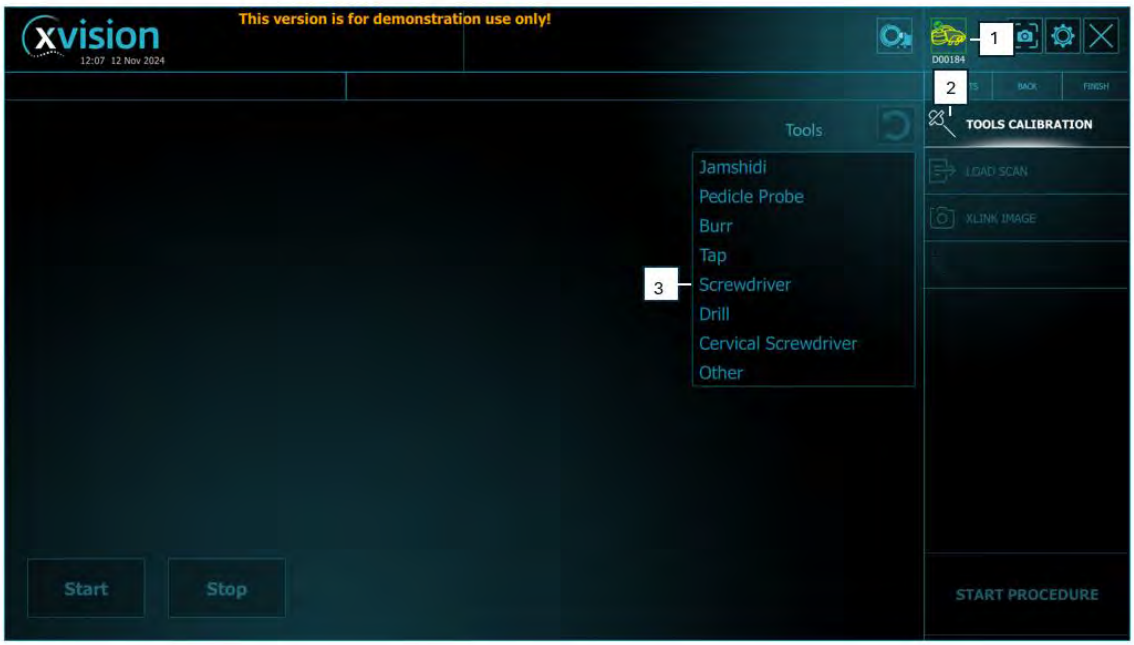
- If the tool tip is straight, the tool passes calibration, and the system details its accuracy (**A**).
- If the tool tip is bent, the tool fails calibration, and the system displays the following message: **Tool is too bent to calibrate** (**B**).

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

6.3.2. Screwdriver Calibration

Note: See *Surgical Instrument Calibration (Excluding Screwdrivers)* on page 6-14 for information about calibrating tools other than screwdrivers.

Figure: Calibrate Screwdriver (1st step)



1 Select the HEADSET to be used for calibration.
2 Select **TOOL CALIBRATION** from the **XVS SOFTWARE**.

Note: The **HEADSET** is listed by its serial number or its pairing name. See *Headset Pairing* on page 5-33 for more information.

3 Select **Screwdriver**.

Note: For a VP adaptor, select **Swivel**.

Figure: Calibrate Screwdriver (2nd step)

4 Select the appropriate type of tool adaptor: **Swivel** or **Nav** (navigated).

Figure: Calibrate Screwdriver (3rd step)

5 Select screw diameter and length.
To restore the last selected screw dimensions, click the reset arrow.

Note: The system supports cervical screw lengths from 8 mm to 50 mm in increments of 2 mm and cervical screw diameter from 3 mm to 5mm in increments of 0.5 mm.

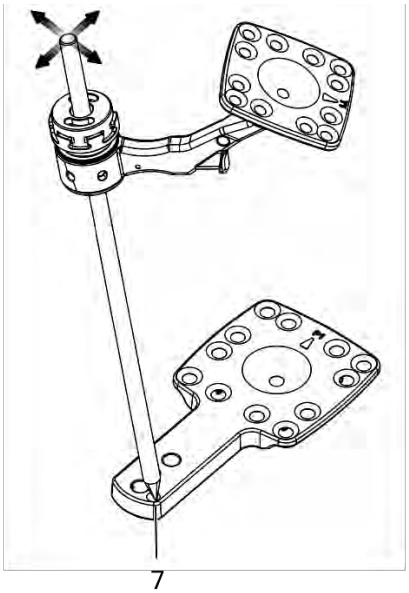
The system supports screw lengths (excluding cervical) from 25 mm to 120 mm in increments of 5 mm and screw diameter from 4 mm to 10mm in increments of 0.5 mm.

The system supports drill widths from 2 mm to 3.5mm in increments of 0.1mm.

Figure: Step 1 in Screwdriver Calibration - screenshot

6 The XVS will Start tool calibration automatically as soon as the adaptor is selected. (If you would like to stop/start the calibration process use the buttons on the bottom left).

Figure: Step 1 in Screwdriver Calibration - illustration



7

7 Take the prepared screwdriver and touch its tip to the calibration point on the Patient Marker. Move the tool in a circle while the tool tip is inside the Patient Marker divot.

Figure: Step 2 in screwdriver calibration – Swivel Test- screenshot

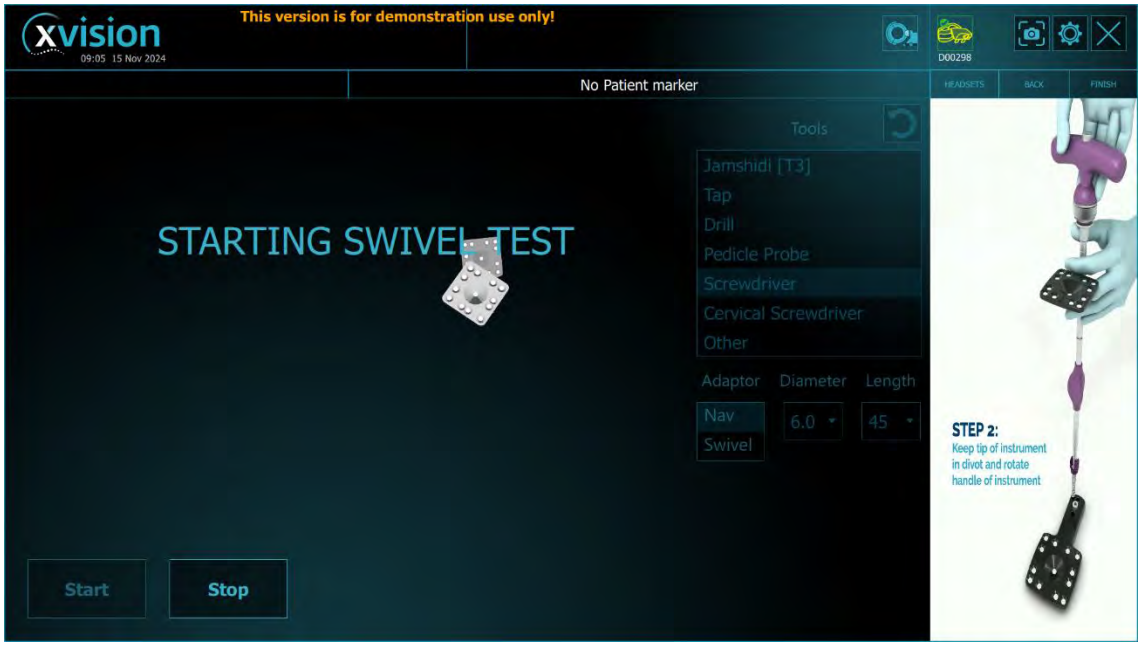
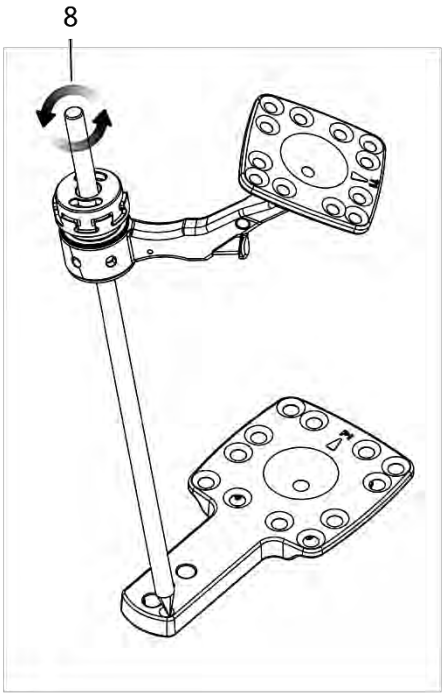


Figure: Step 2 in screwdriver calibration- Swivel Test- illustration



8 Perform a swivel test as follows:

- Verify that the Patient Marker is facing the HEADSET.
- Rotate the tool (with its tip to the calibration point on the Patient Marker) until calibration reaches 100% (which takes 10 seconds).

Note: If the swivel test is not performed correctly, a bent tool might pass calibration but will later fail tool verification.

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

Figure: "Starting Swivel Test" Message

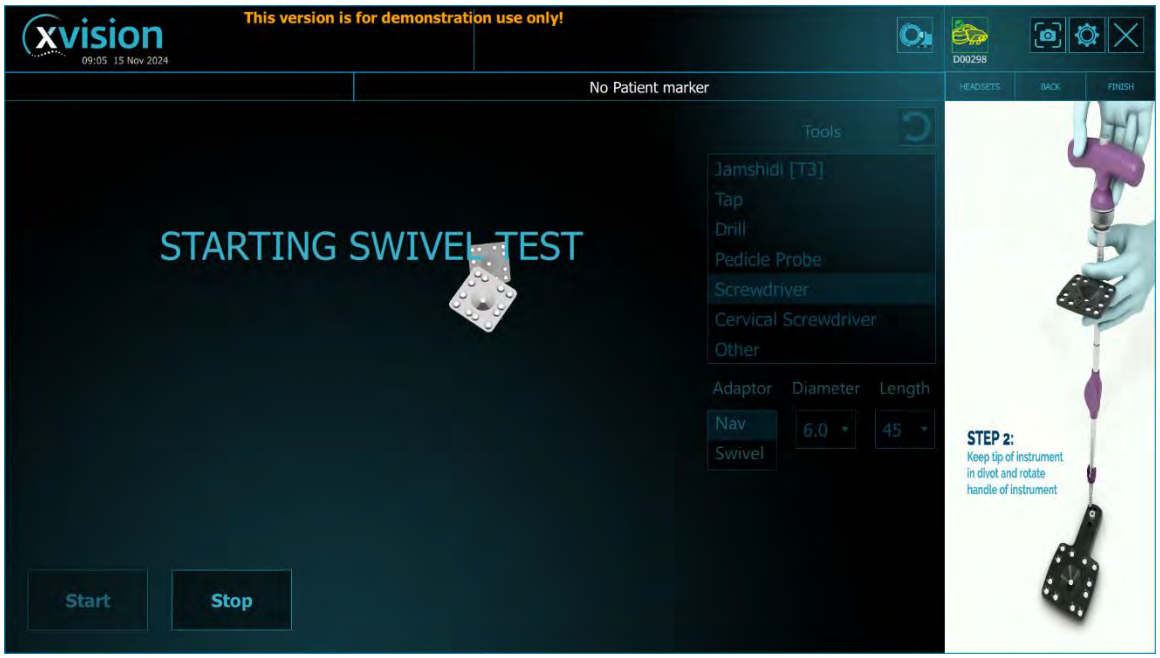
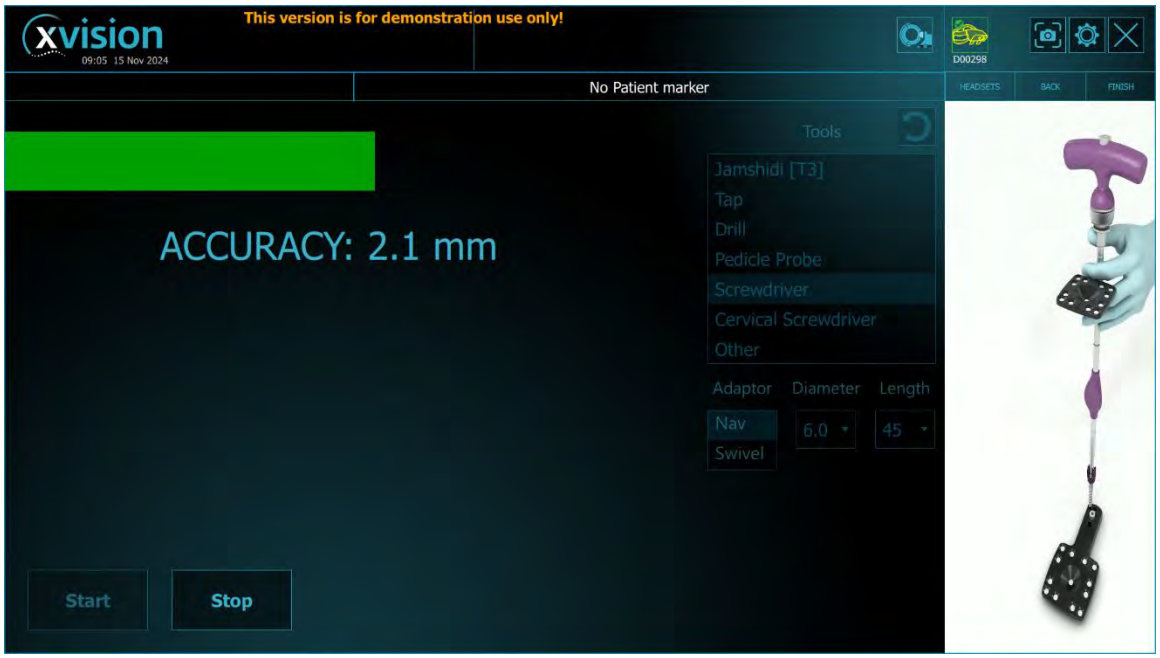


Figure: Swivel Test Progress



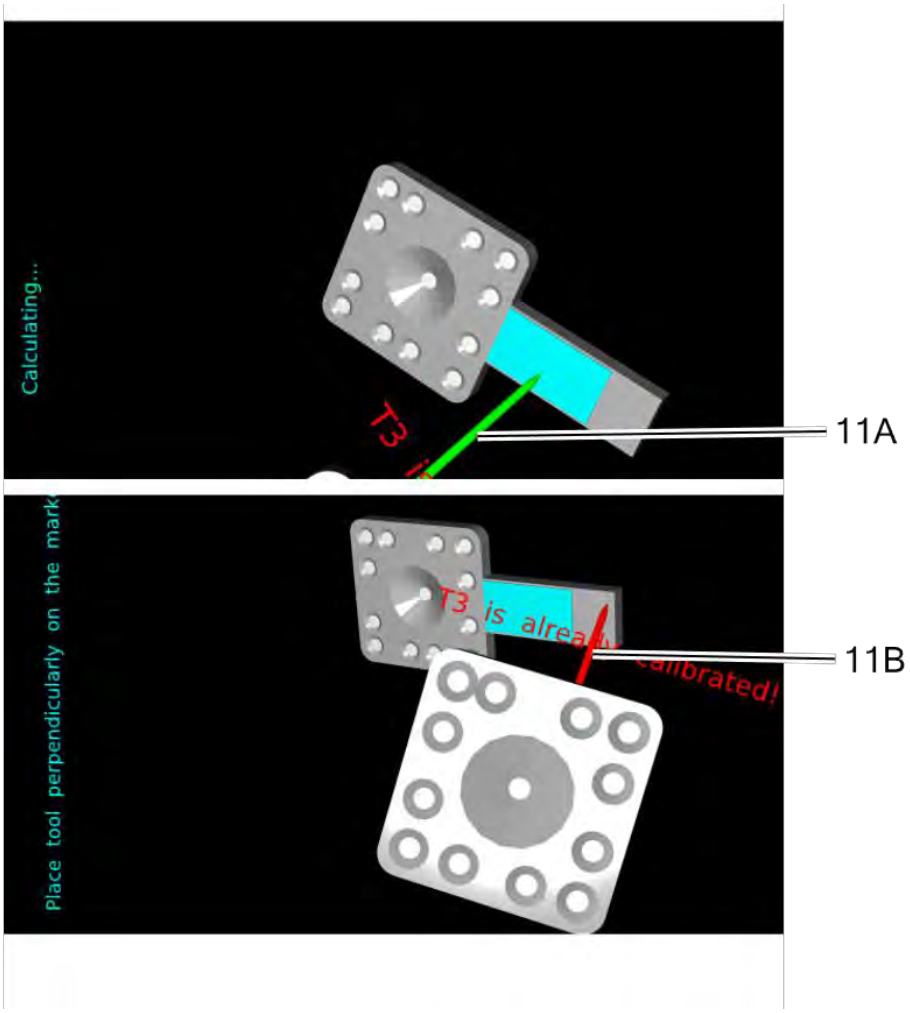
9 The system displays the result of the swivel test attempt:

- If the tool is straight, the tool passes the swivel test and continues to the next step.
- If the tool tip is bent, the tool fails calibration, and the system displays the following message: **Tool is too bent to calibrate**.

Figure: Step 3 in Screwdriver Calibration

10 If the tool passes swivel test, the system prompts the user to **place the screwdriver perpendicularly on the Patient Marker, outside the divot**. In the prompt window, tap **OK**; and perform as prompted.

Figure: Screwdriver Incorrect/Correct Place



11 Check on the **HEADSET** display to verify that the screwdriver has been correctly placed, and change its position as necessary:

- When the screwdriver is correctly placed (perpendicular to the Patient Marker) it is colored green (**A**) in the **HEADSET** display.
- When the screwdriver is incorrectly placed (not perpendicular to the Patient Marker) it is colored red (**B**) in the **HEADSET** display.

12 Wait for **Calibration Succeeded** message before continuing.

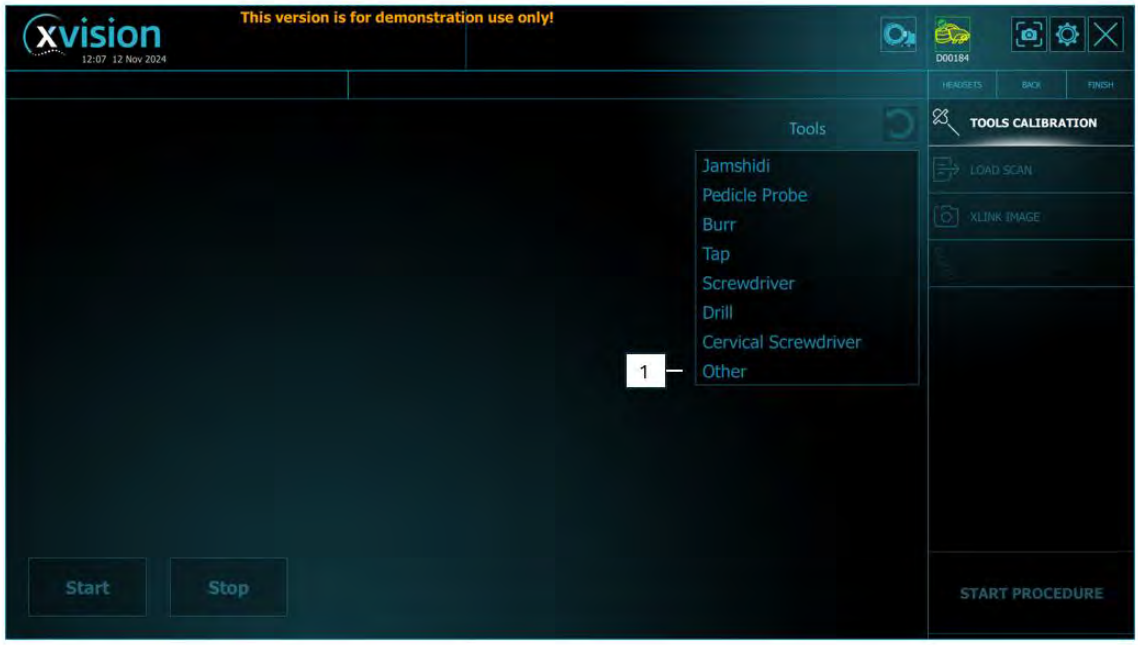
Note: During the screwdriver calibration process, animation will display on the System's monitor and will progress with every step.

Note: For cervical procedure, the user shall calibrate "cervical screwdriver".

6.3.3. Non-Generic Instrument Name Entry

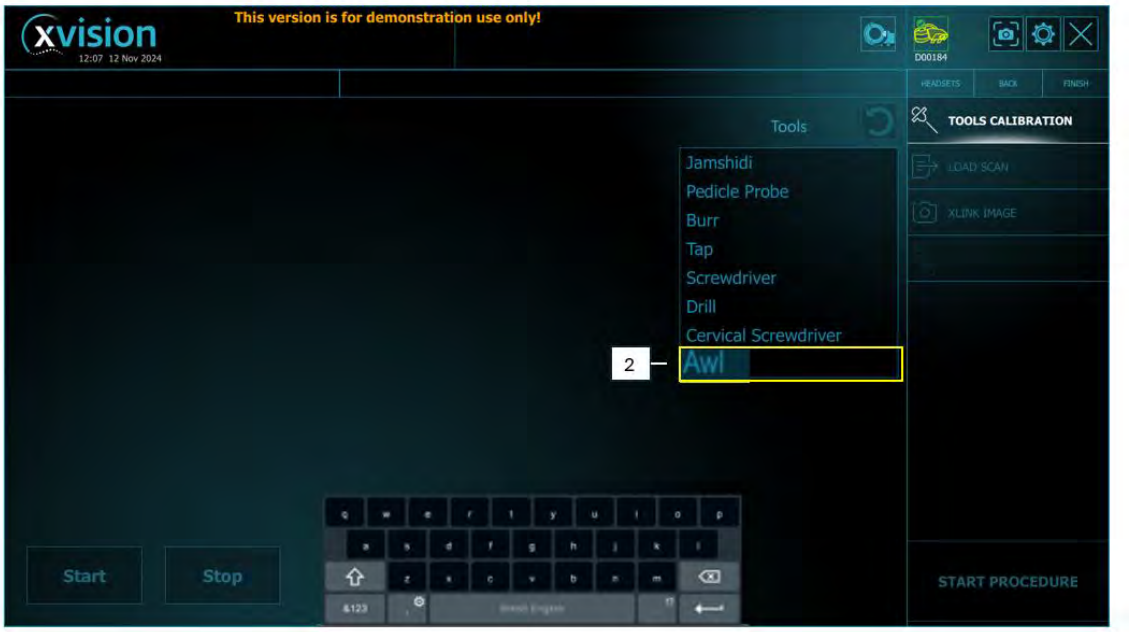
The **Tool Calibration** window lists various generic surgical instrument names, any of which can be selected when calibrating an instrument. If none of these names are appropriate, a new name to the list can be added by following the procedure below (up to four new names can be added)

Figure: Tool Calibration - Adding a New Name (1st step)



1 In the **Tool Calibration** window, select **Other** (tool list).

Figure: Tool Calibration - Adding a New Name (2nd step)



2 In the "**New Tool"** box, type the appropriate name for the tool.

6.4. Patient Marker Platform Selection

Patient registration is the process whereby the XVISION-SPINE system orients the transformation between the patient scan and the Patient Marker.
In both Pre-Op and Intra-Op workflows the Platform serves as affixation point to the patient for the Patient Marker.

The following (Linking) Markers are available:

- Z-Marker - this method is used for Intra-Op registration. To understand Z-Marker assembly instructions, refer to Z-Marker Registration method. (See section 6.4.3)
- X-Marker - this method can be used when a Z-Marker is not suitable, either because of the patient's anatomy or because the intraoperative 3D scan cannot include both the Z-Marker and the area of the spine intended for the procedure (due to its limited field of view).
- C-Marker – this method is unique for the Pre-Op workflow and is positioned over the C-arm Ring Adapter. See Attaching C-Marker to the Ring Adaptor

Note: In cases of high BMI patients, where the scanner field of view may be insufficient, it is recommended to use X-Marker registration.

To perform patient registration, select one of the following four anchor points for the Marker, and follow the instructions in the referenced section:

- XVS Straight clamp (62 mm or 82 mm long). See *XVS Straight Clamp Attachment* on page 6-31
- XVS Arc Clamp. See *XVS Arc Clamp Attachment* on page 6-33
- Sterile Percutaneous Iliac Pin (Perc Pin). The Sterile Perc Pin Platform on Page 6-32

Note: For thoracic procedures, it is recommended to use a clamp.

Note: In cases where there is concern about spine movement, such as deformity correction, it is recommended to use a clamp.

Warning: In case of any suspected movement of selected fixation method during or after registration, regardless of registration mode, re-spin and re-register to maintain navigation accuracy.

6.4.1. The Clamp platform

Note: In MIS procedures (or when direct anatomic visualization is limited) involving unstable spine segments and/or high respiratory variability, users should ensure close proximity between the operative region and the patient fiducial. To address challenges from anatomical instability or motion, secure all patient platforms to stable anatomy, perform meticulous anatomical landmark verification, and use fluoroscopy as needed to maintain navigation accuracy and procedural

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

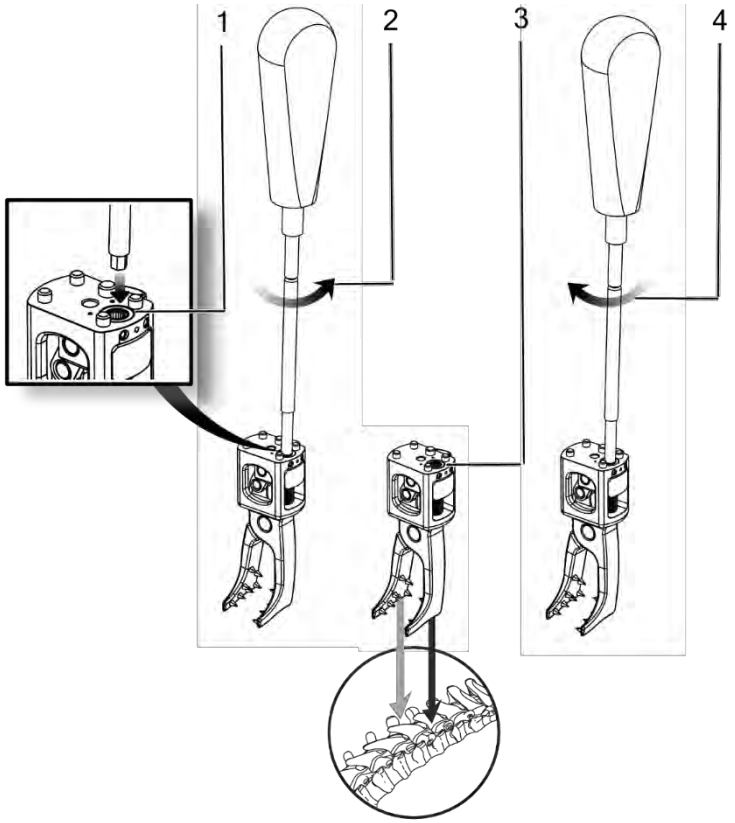
XVS Straight Clamp Attachment

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

Once the patient is positioned on the OR table and anesthetized, the surgeon attaches the desired size of XVS Straight Clamp as detailed below.

Warning: Inspect the clamp for damage before use. Do not use a clamp if it is scratched, its anodized surface is compromised, or if its teeth are bent or broken.

Figure: 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 counterclockwise to open the clamp jaws.

Warning: If the screw is difficult to untighten, discard the clamp and use another one.

3 Attach the clamp to the Spinous Processes in the operated area.

4 Use the Allen screwdriver to close the XVS Straight Clamp on the spinous processes as follows:

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 to prevent it from moving during the surgical procedure.

If performing Intra-Op workflow continue with one of the following:

- *Z-Marker Registration* (page 6-35)
- *X-Marker Registration* (page 6-41)

For the Pre-Op workflow Continue with:

- *C-Marker Registration* (Pre-Op Workflow Section 7.3)

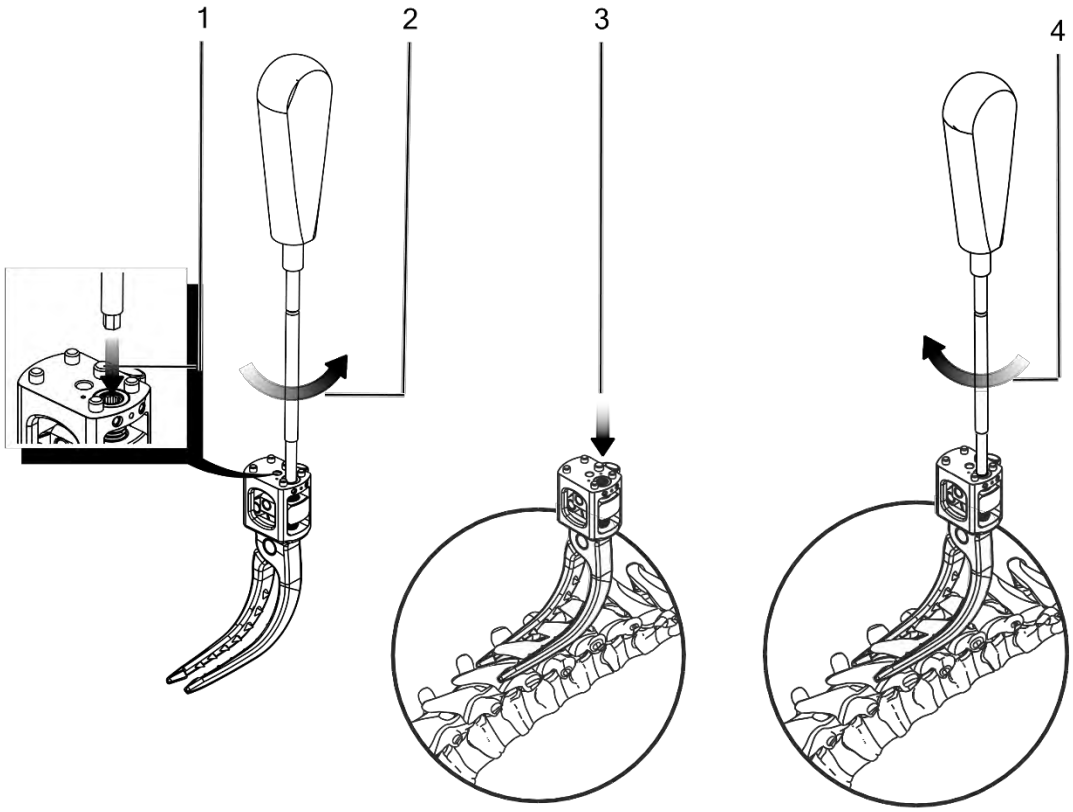
XVS Arc Clamp Attachment

Once the patient is positioned on the OR table and anesthetized, the surgeon attaches the XVS Arc Clamp as detailed below.

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

Warning: Inspect the clamp for damage before use. Do not use a clamp if it is scratched, or if its anodized surface is compromised, or if its teeth are bent or broken.

The recommended direction is to place the clamp in the cranial-to-caudal direction with the pointed end pointing caudally for Thoraco-Lumbar procedure. For Cervical procedures its recommended to fixate the Arc Clamp in the caudal-to-cranial direction with the curved ends pointing cranially.



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 counterclockwise to open the clamp jaws.

Warning: If the screw is difficult to untighten, discard the clamp and use another one.

3 Attach the clamp to the spinous processes in the operated area.

4 Use the Allen screwdriver to close the XVS Arc Clamp on the spinous processes as follows:

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 to prevent it from moving during the surgical procedure.

If performing Intra-Op workflow continue with one of the following:

- *Z-Marker Registration* (Section 6.4.3)
- *X-Marker Registration* (Section 6.4.4)

If performing Pre-Op workflow continue with one of the following:

- *C-Marker Registration* (Pre-Op Workflow Section 7.5)

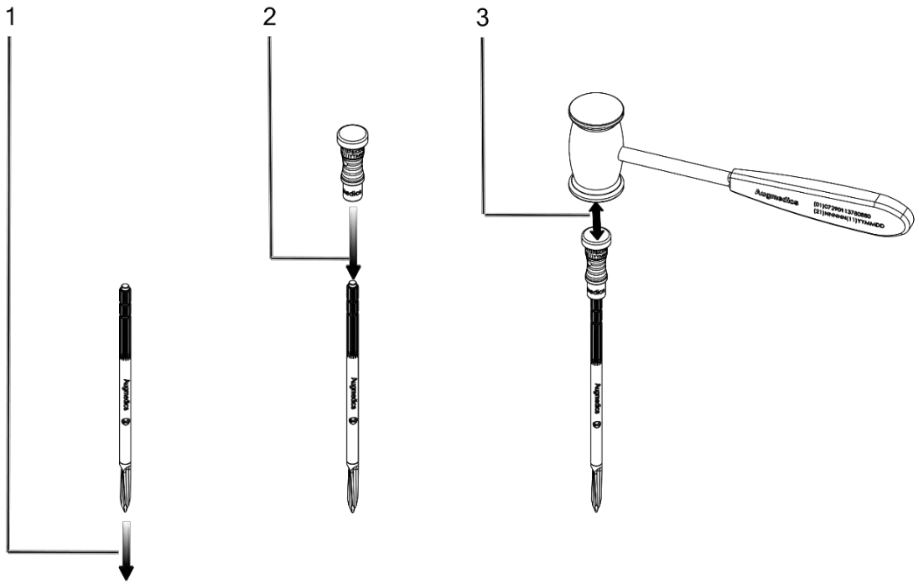
6.4.2. The Sterile Perc Pin platform

Once the patient is positioned on the OR table and anesthetized, the surgeon palpates the PSIS, makes a small incision in the appropriate area over the pelvis, and performs the procedure below.

To perform Paramedian trajectories such as **'Lateral Approach'** or **TLIF trajectories** the sterile Perc-Pin is recommended to be used. The Patient marker positioning with Perc-Pin assembly for such exection is unique, for guidelines refer to Paramedian Trajectories.

Warning: Make sure that the skin incision causes the minimum tissue damage possible.

Figure: Securing the Sterile Perc Pin



1 Insert the Perc Pin into the incision and push it through the tissue until it touches bone.
2 Place the Perc Pin insertion cap on the proximal end of the pin.
3 Apply the Perc Pin mallet to the insertion cap to insert the sharp tip of the Pin into the PSIS. The wider part of the Pin should protrude from the PSIS.
4 Remove the insertion cap.

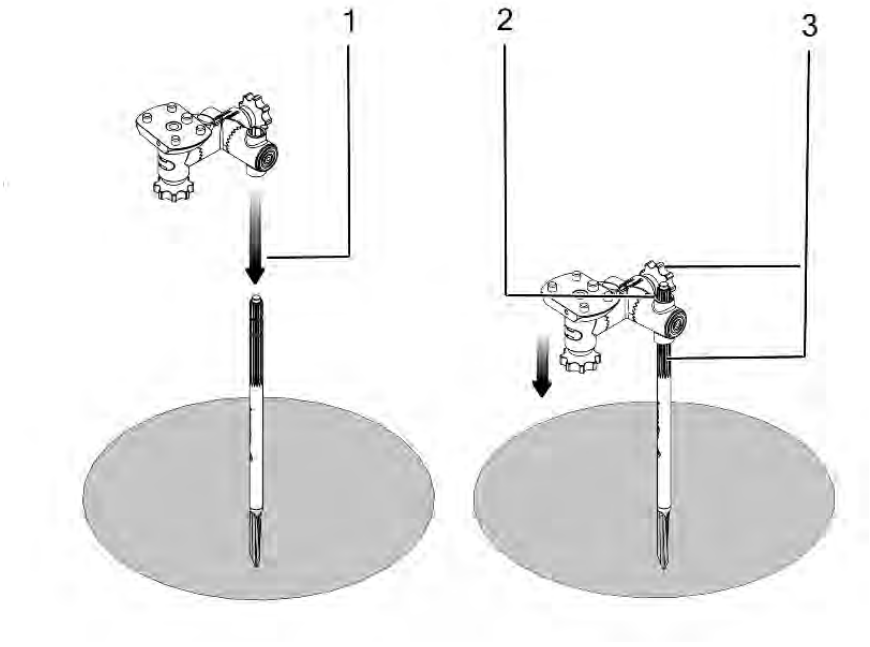
Note: X-ray the patient to make sure that only the sharp tip of the Perc Pin is inside the PSIS.

	Note:	In MIS procedures (or when direct anatomic visualization is limited) involving unstable spine segments and/or high respiratory variability, users should ensure close proximity between the operative region and the patient fiducial. To address challenges from anatomical instability or motion, secure all patient platforms to stable anatomy, perform meticulous anatomical landmark verification, and use fluoroscopy as needed to maintain navigation accuracy and procedural reliability.

	Note:	Consider surgical approach when placing the Perc Pin. An axial plane of 0° to 10° mediolaterally (distal tip medial) and Sagittal plane of 30° to 40° caudally (distal tip cranial) will direct patient reference frame and Perc Pin away from the surgical field and trajectories.

Perc Pin Adaptor assembly

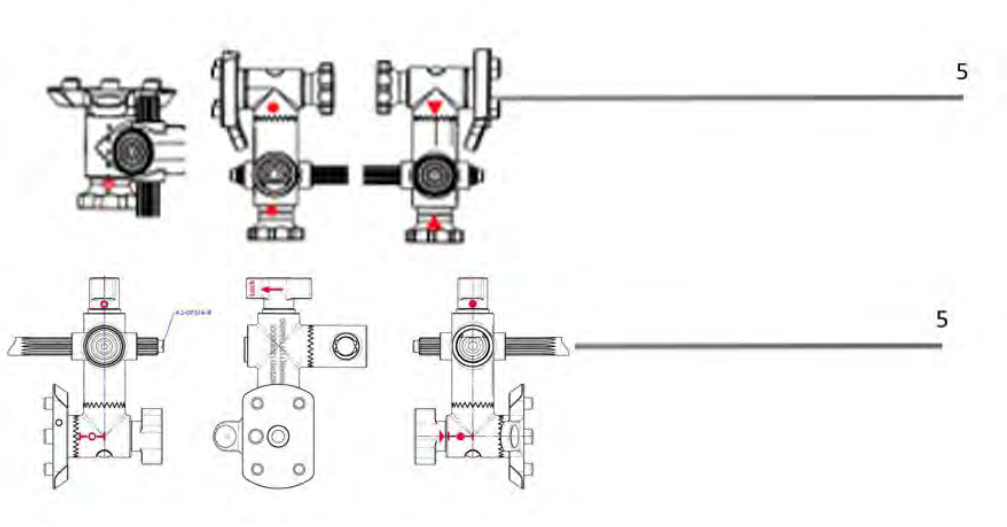
Figure: Sterile Perc Pin assembly



1 Slide the Perc Pin Adaptor over the pin.
2 Adjust the two knobs of the adaptor.
3 Align it with the correct height for the procedure:
    - When using a Z-Marker for patient registration, mock mount the Z-Marker on the adaptor, to make sure it doesn't touch the Skin.

4 Turn the two knobs to lock it in place.

Figure: Perc Pin Adaptor tightening



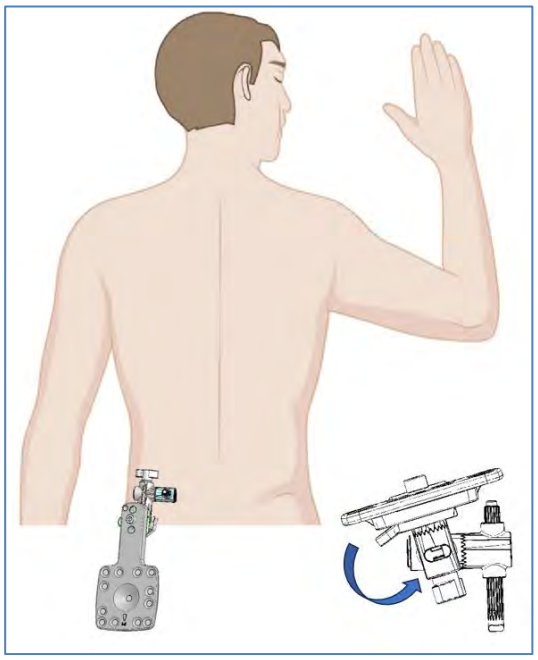
5 Verify that the adaptor is correctly aligned: (2 types of Perc Pin Adaptor, relate the correct indication as described above)

- The triangle on one side of the adaptor should be aligned with the triangle on the opposite side of the adaptor; (type A)
  The circle on one side of the adaptor should be aligned with the related circle range on the opposite side of the adaptor (Type B)
- The circle on one side of the adaptor should be aligned with the circle on the opposite side of the adaptor; (type A)
  The circle on one side of the adaptor should be aligned with the related circle range on the opposite side of the adaptor (Type B)
- The verification divot at the top of the adaptor should be over the identical verification mark underneath the adaptor. (Type A)
  The Lock direction is indicated on the knob, follow this direction to lock it. (Type B)

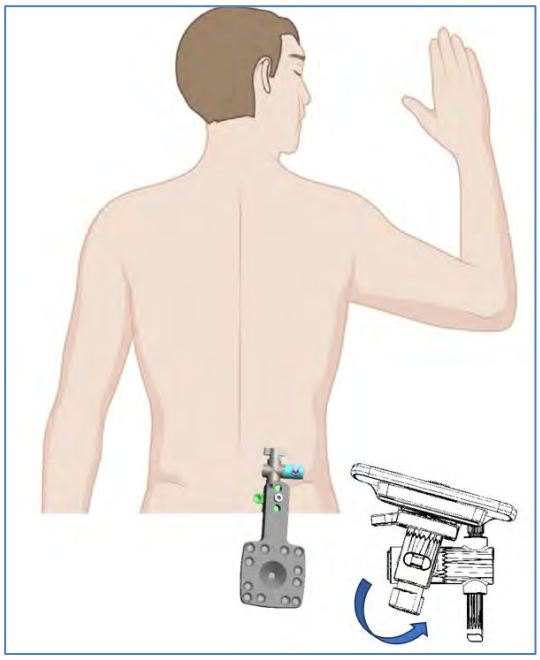
6.4.2.1Paramedian Trajectories (Lateral approach and TLIF)

When using the Perc-Pin for paramedian trajectories – it is recommended to fixate the Perc-Pin adaptor over the Perc-Pin in a tilt where the patient marker, facing the HEADSET during these trajectories' instrumentation. See the figure below to demonstrate correct assembly.

Figure: Perc Pin Adaptor assembly for Paramedian trajectories

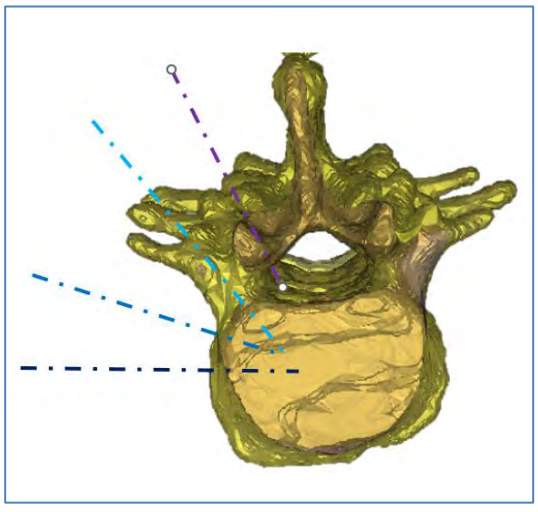


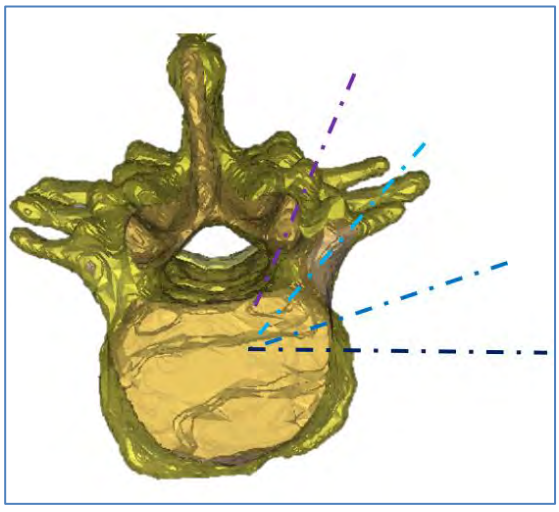
Left side Perc-Pin assembly



Right side Perc-Pin assembly

The example below shows the recommended tilt direction when instrumenting "Lateral approach" trajectories on the left side of the patient – **Left Figure**, and for the Right side of the patient – **Right Figure.**





To support Bilateral instrumentation keep the patient marker centered and facing straight to the Feet.

6.4.3. Z-Marker Registration

Z-Marker Registration is performed only for the Intra-Op workflow.

Figure: Z-Marker Registration on Clamp

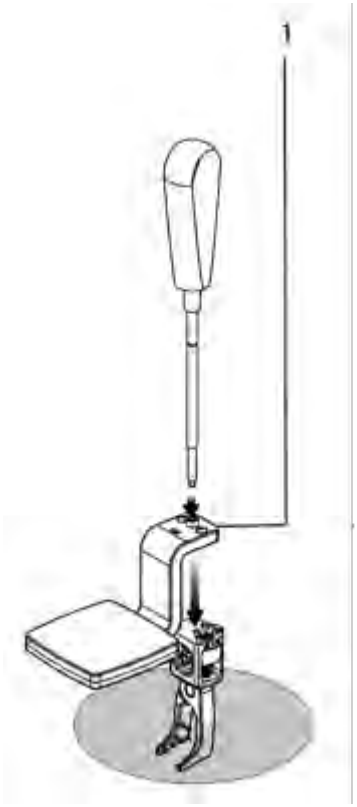
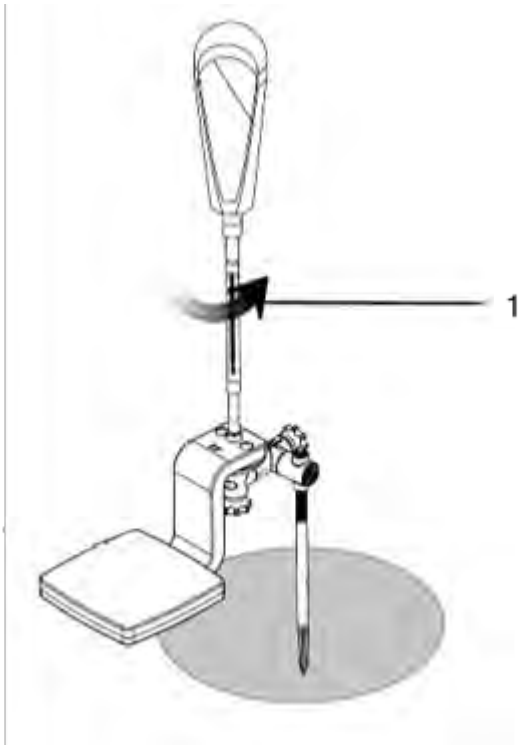


Figure: Z-Marker Registration on Perc Pin



1 Attach the Z-Marker to the Patient Clamp/Perc Pin Adaptor using the Allen screwdriver. Select 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.

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

Check the A-P and lateral view.

Note: Make sure that the Z-Marker is seen in the A-P and lateral view.

Make sure that only one Registration Marker appears in the scan.

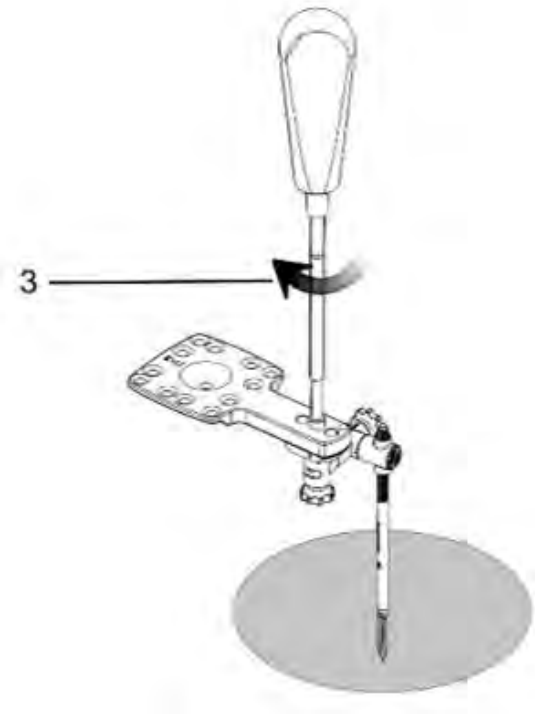
After checking the A-P and lateral view, perform an intraoperative 3D scan of the area, making sure that the desired spine anatomy and the Z-Marker are included in the scan.

Warning: Make sure that, during the scan, the patient does not move and the patient's breath is held.

2 Remove the Z-Marker and set it aside.
At the end of the procedure it will be sent for cleaning and sterilization. See *Cleaning Reusable Components* on page 8-133 for more information.

Figure: Patient Marker on Clamp

Figure: Patient Marker on Perc Pin



3 Attach the Patient Marker to the Patient Clamp/Perc Pin Adaptor using the Allen screwdriver.
The Patient Marker can be attached at one of the following angles:

- 0° (**A**) - directly to the clamp (or Perc Pin Adaptor)
- 90° (**B**) - with the Rotating Marker Adaptor
- 180° (**C**) - directly to the clamp (or Perc Pin Adaptor)
- 270° (**D**) - with the Rotating Marker Adaptor

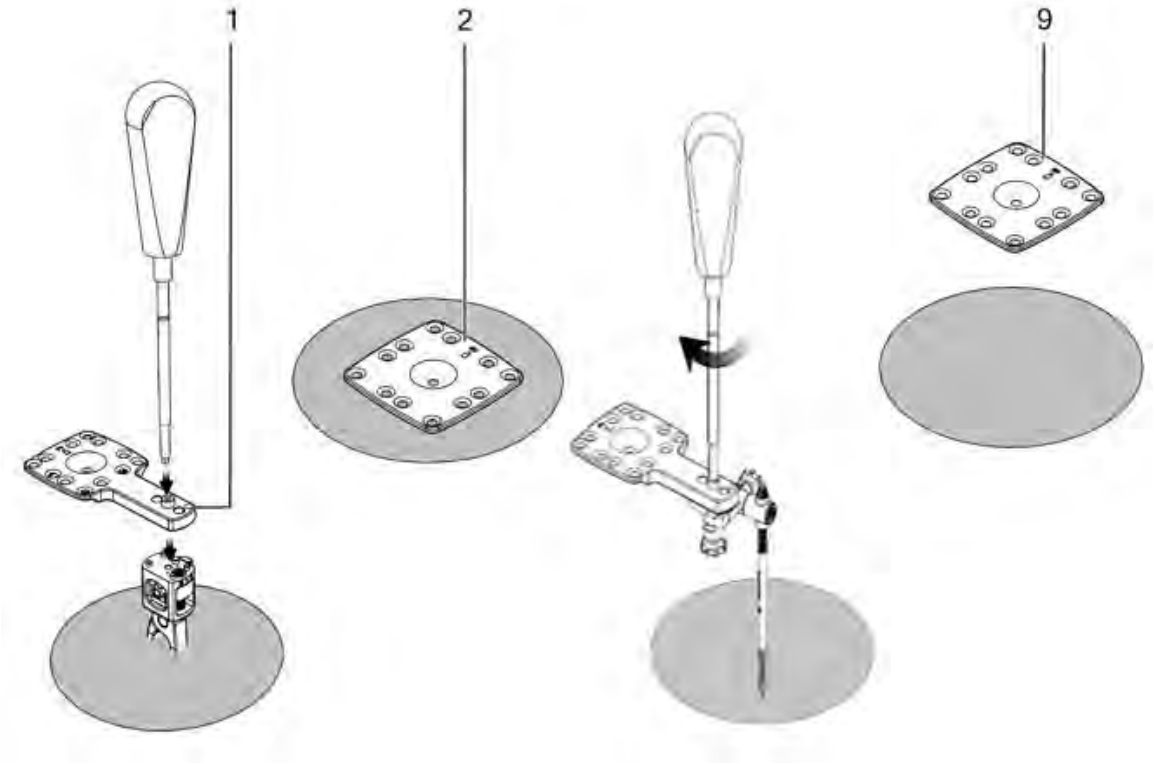
For details of the Rotating Marker Adaptor see *Patient Marker Attachment* on Section 6.4.7
After attaching the Patient Marker, continue with *Spine Surgery with the xvision-Spine System* Section 7

6.4.4. X-Marker Registration

Two Markers are used for X-Marker registration. They are placed as follows:

- The X-Marker is placed on the patient in the area that will be operated on and scanned.
- The Patient Marker is placed on the patient clamp/Perc Pin Adaptor.

Figure: X-Marker Registration with Clamp/Perc Pin Adaptor



1 Attach the Patient Marker to the Patient Clamp/Perc Pin Adaptor using the Allen screwdriver. The Patient Marker should point away from the area to be operated on, and can be attached at one of the following angles:

- 0° (**A**) - directly to the clamp (or Perc Pin Adaptor)
- 90° (**B**) - with the Rotating Marker Adaptor
- 180° (**C**) - directly to the clamp (or Perc Pin Adaptor)
- 270° (**D**) - with the Rotating Marker Adaptor

For details of the Rotating Marker Adaptor See *Patient Marker Attachment* on Section 6.4.6.

2 Secure the X-Marker on the patient's back in the area of the 3D scan using the provided double- sided adhesive.

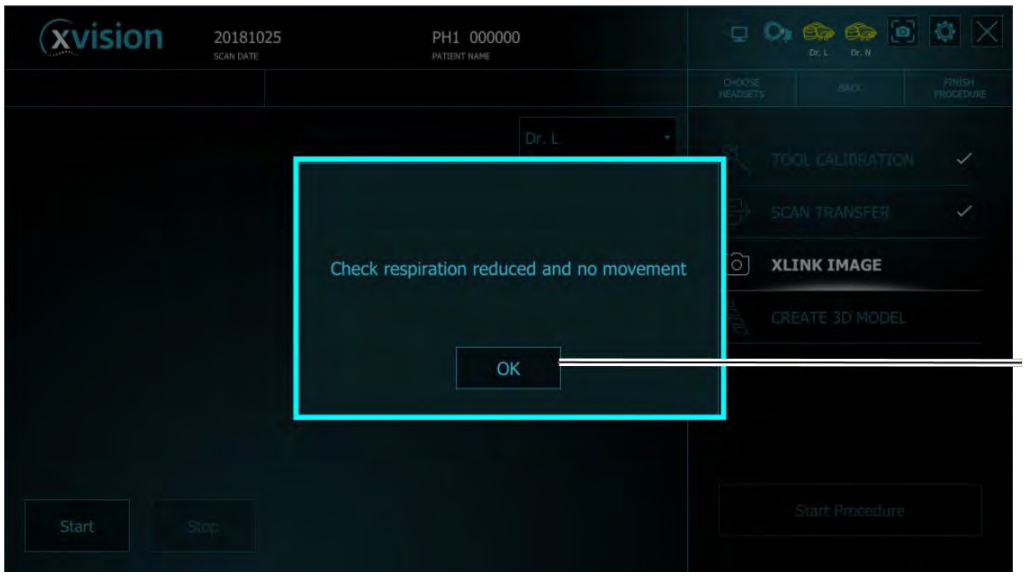
Note: The X-Marker should be attached on a Ioban drape to ensure non-direct contact between the Marker and the patient's skin.

3 Check the A-P and lateral views.

Note: Make sure that the X-Marker is seen in the A-P and lateral views.
Make sure that only one Registration Marker appears in the scan.

4 The system prompts the user to check respiration reduced and no movement.

Figure: Respiration and no movement check



Warning: Make sure that, during the scan and infrared image capture, the patient does not move, and the patient's breath is held.

5 In the prompt window, press **OK**.
6 Press **Start** to initiate an X-Marker to Patient Marker Pairing (registration) while exploring the operated region.
7 Use the HEADSET to capture an infrared image, making sure that both the X-Marker and the Patient Marker are included in the image.
8 After the X-Marker infrared image and the Patient Marker is captured, a message pops up, saying "x link succeeded".
9 After X link image capture succeeds, remove X Marker from patient.

X-Marker registration is complete when the infrared image is captured by the XVS software.
Continue with *New Study* on Page 7-2.

6.4.5. C-Marker Registration

C-Marker Registration is performed only for the **Pre-Op** workflow.

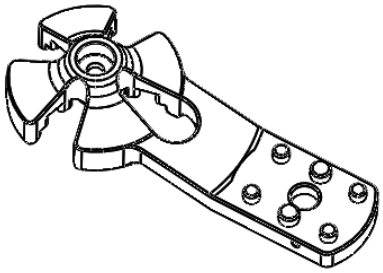
To attach the Patient Marker to the selected platform, See **Patient Marker Extender** section below.

C-Marker Registration is performed only when the Patient Marker extender is assembled.

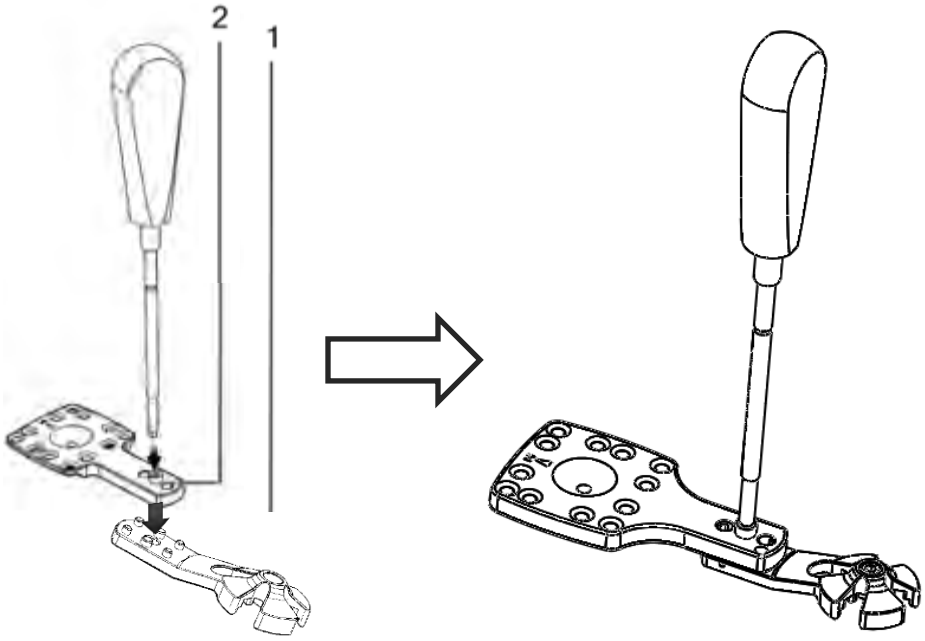
6.4.5.1Patient Marker Extender

The Patient Marker Extender is a mandatory tool designated to support the user on a Pre-op Workflow
The Patient Marker Extender is provided with the CT-Fluoro upgrade kit. The Patient Marker Extender is in the reusables Standard tray.

Figure: Patient Marker Extender



To complete intra-op X-ray image acquisition on the Pre-Op workflow, the user is requested to assemble the Patient Marker Extender to the selected platform, while the Patient Marker is fixated to it.
Figure: Patient Marker Extender + Patient Marker



To fixate the Patient Marker to the selected platform, follow the below steps:

1. Place the Patient Marker Extender on a table.
2. Secure the Patient Marker to the Patient Marker Extender using the Allen screwdriver.

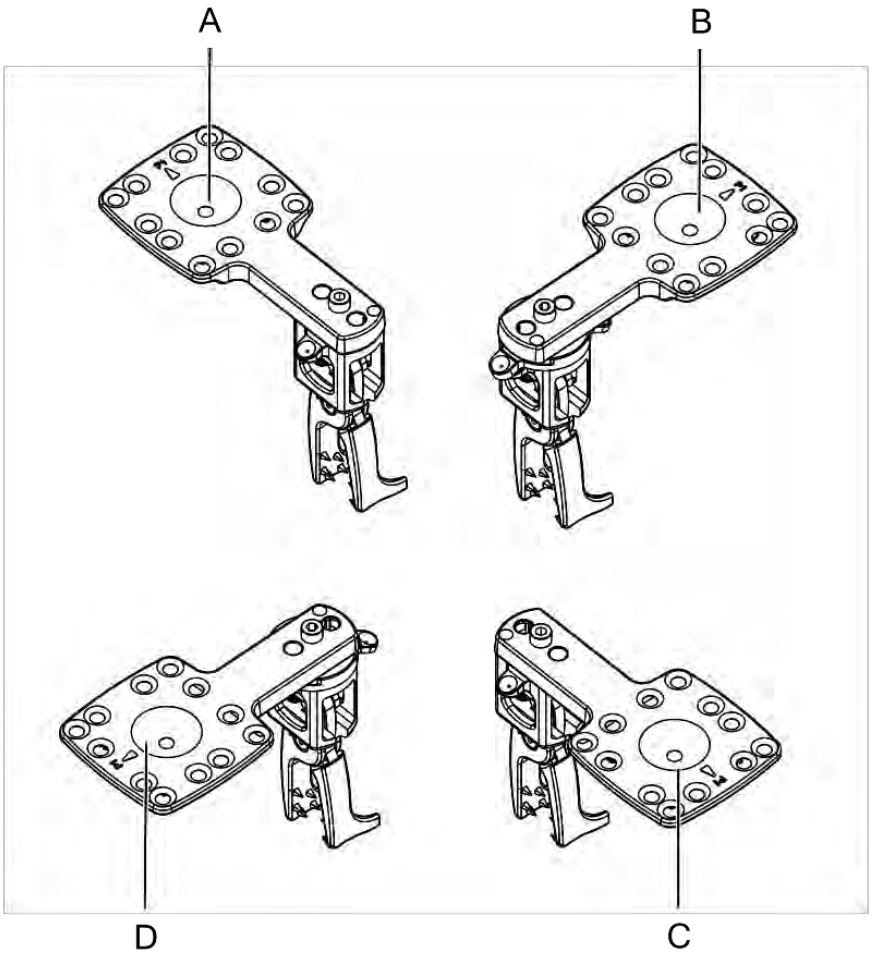
Two Markers are used for C-Marker registration. They are placed as follows:

- The C-Marker is placed on a C-arm over the C-arm Ring Adapter in its designated place. (C-arm with its Ring Adaptor should be draped prior to C-Marker placement)
- The Patient Marker with its extender is placed on the spine clamp (or the Perc Pin Adaptor when a Perc Pin is utilized).

To fixate the Patient Marker with its extender, proceed to Patient Marker Attachment - Pre-op workflow.

6.4.6. Patient Marker Attachment – Intra-op workflow

Figure: Possible Patient Marker Positions



The Patient Marker may be attached to the clamp (or Perc Pin adaptor) at any one of the following angles:

- 0° (**A**) - directly to the clamp (or Perc Pin Adaptor)
- 90° (**B**) - with the Rotating Marker Adaptor: see in Figure
- 180° (**C**) - directly to the clamp (or Perc Pin Adaptor)
- 270° (**D**) - with the Rotating Marker Adaptor: see in Figure

Figure: The Rotating Marker Adaptor

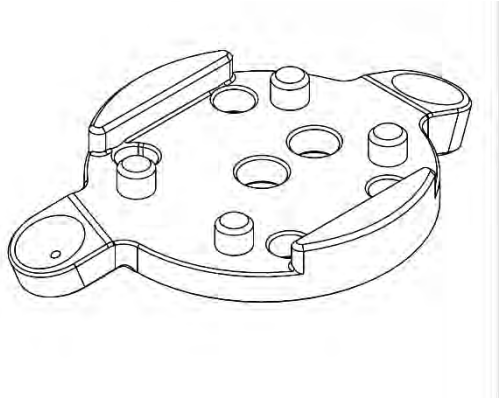
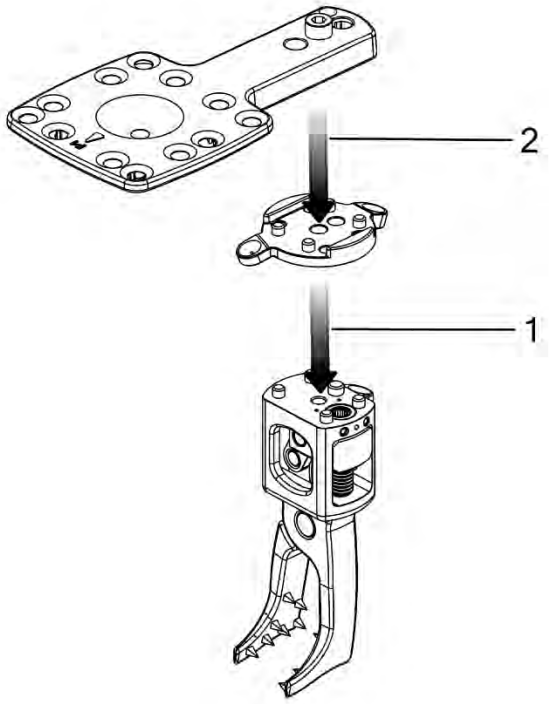


Figure: Attaching the Patient Marker and Rotating Marker Adaptor

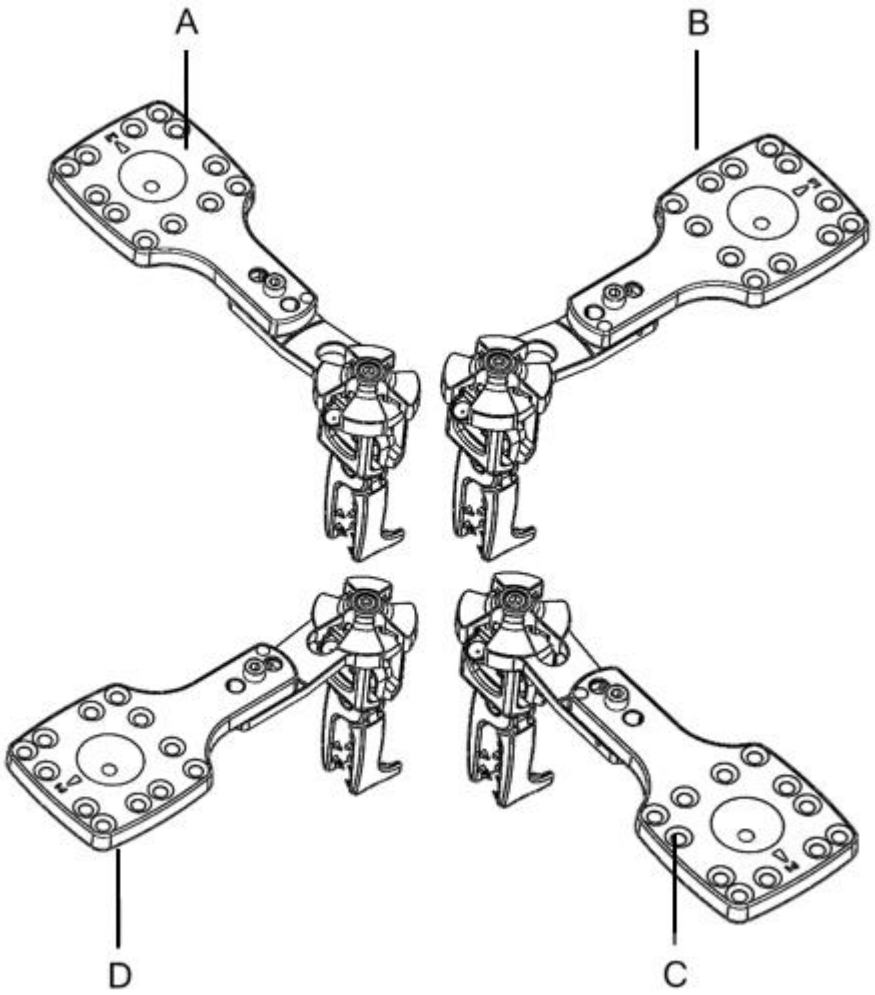


1 Place the Rotating Marker Adaptor on the clamp (or Perc Pin Adaptor).
2 Secure the Patient Marker to its adaptor and the Patient Clamp (or Perc Pin Adaptor) using the Allen screwdriver.

The Patient Marker is positioned.
To Proceed with Intra-op Workflow refer to Intra-Op Workflow.

6.4.7. Patient Marker Attachment – Pre-op workflow

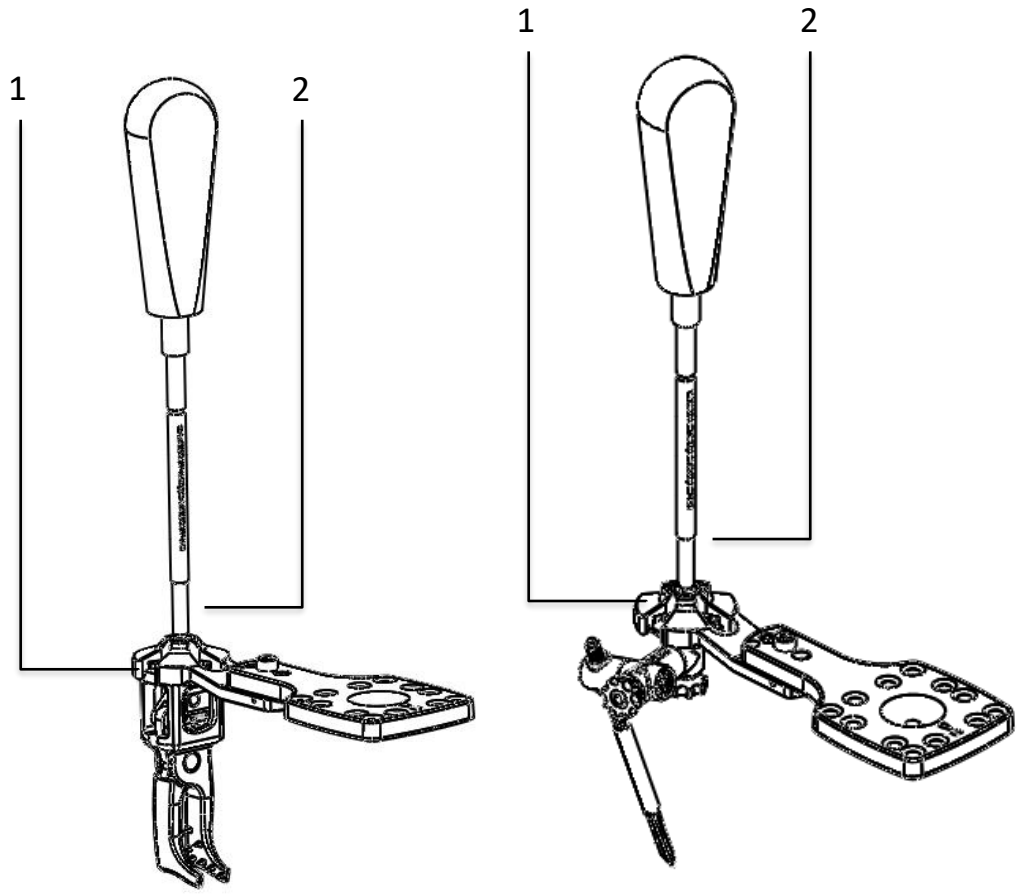
Figure: Possible Patient Marker Extender Positions



The Patient Marker Extender may be attached to the clamp (or Perc Pin adaptor) at any one of the following angles:

- 0° (**A**) - directly to the clamp (or Perc Pin Adaptor)
- 90° (**B**) – Rotated 90° - see in Figure
- 180° (**C**) - Rotated 180° - see in Figure
- 270° (**D**) - Rotated 270° - see in Figure

Figure: Patient Marker Extender assembly on selected platform

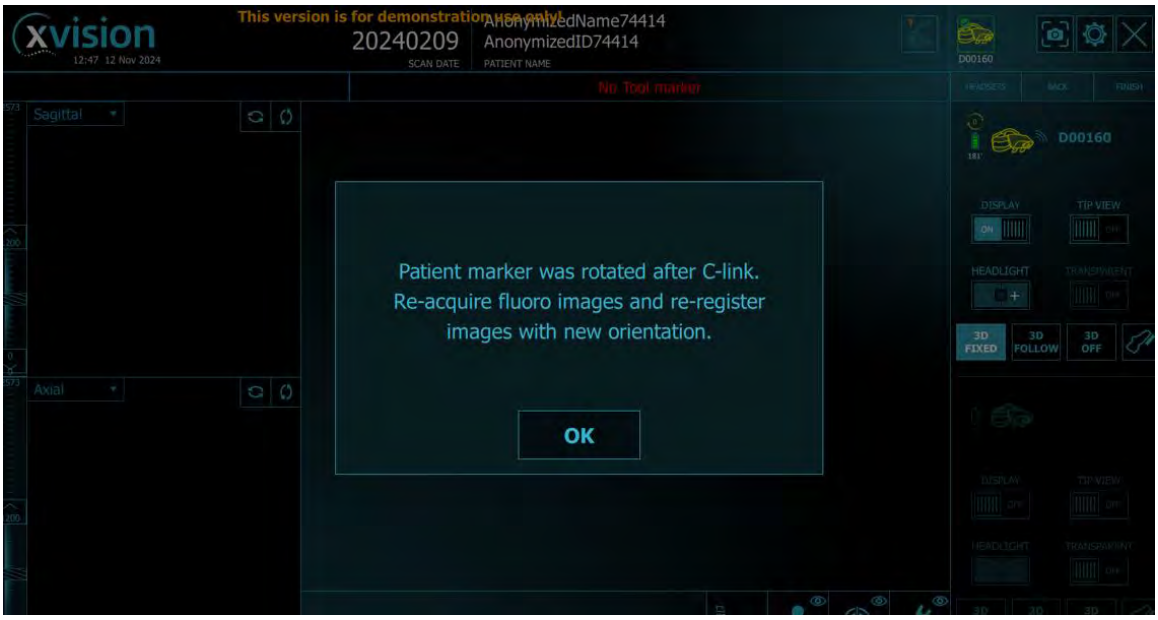


3 Place the Patient Marker Extender on the clamp (or Perc Pin Adaptor).
4 Secure the Patient Marker Extender to the Patient Clamp (or Perc Pin Adaptor) using the Allen screwdriver.

The Patient Marker with its extender is positioned.

To Proceed with C-Link process – Patient Marker and C-Marker registration refer to Pre-Op chapter - Load Image.

Warning: The patient marker extender cannot change positions during registration or operation once placed on the patient attachment.



7. Spine Surgery with the XVISION-SPINE System

When all preprocess tasks have been completed, continue preparing the surgical procedure on the computer where the **XVS SOFTWARE** is installed.
If the XVS system remains unattended 60 minutes since last input (button press), the user is prompted as follows: (the prompt appears for 60 seconds)

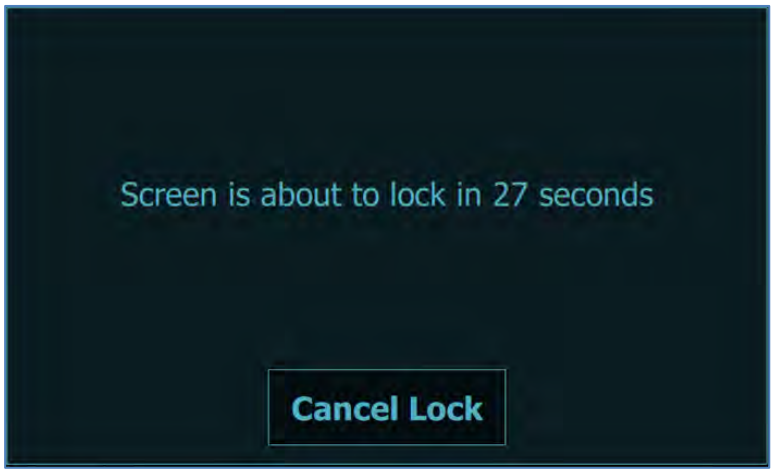


Figure 4: User Lock prompt

To proceed with operation, tap **Cancel Lock**.
When the prompt times out, the user is locked. The Xvision user password needs to be retyped to log-in again to return to the XVS software.

Figure 5:Xvision user Windows welcome screen

7.2. Xvision Home Screen

When the xvision Software is launched the Home screen is then displayed:

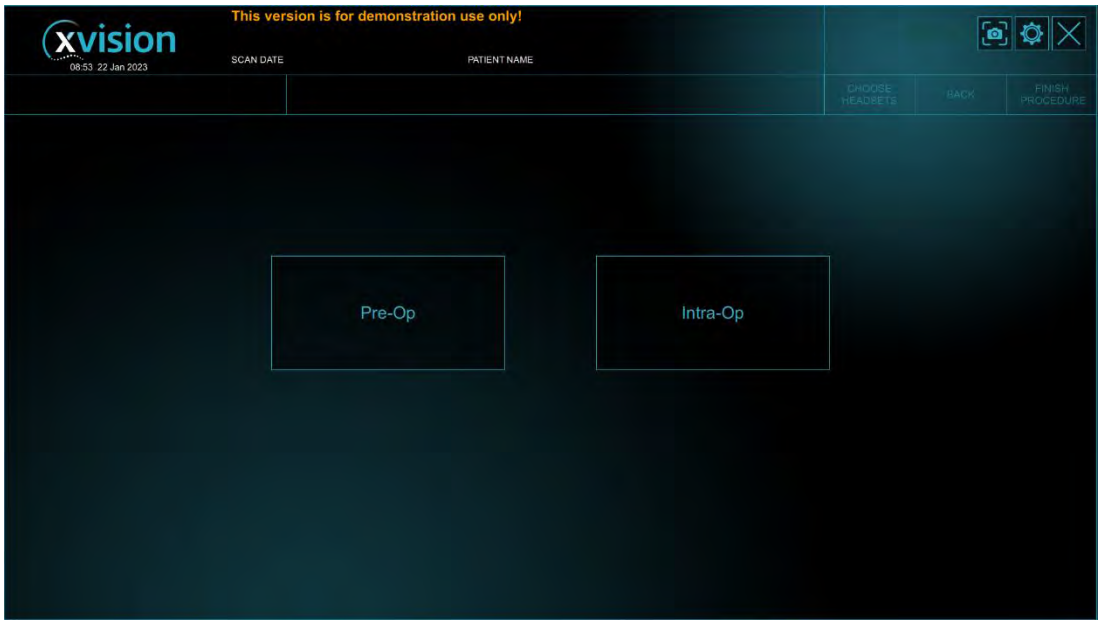


Figure 6: Xvision Home screen

7.2.1. Intra-Op

The intra-Op is a workflow that provide the user the ability to start directly from intra-operatively scanning the patient with 3D imaging device and operating over the scanned data. This process will not be handled via Data management screen.

7.2.2. Pre-Op

The Pre-Op option allows the user to manage the current CT data stored in the system and prepare it for CT to Fluoro image matching workflow. The user is then directed to the Data Management screen in-order to Import new data or handle the current stored data with required segmentation for the CT to Fluoro procedure.

Once the user has selected the **Intra-Op** method, he/she is directed to the Intra-Op workflow screen as describe below:

7.3. Intra-Op –

The **XVS SOFTWARE** displays the Intra-op study selection Screen.

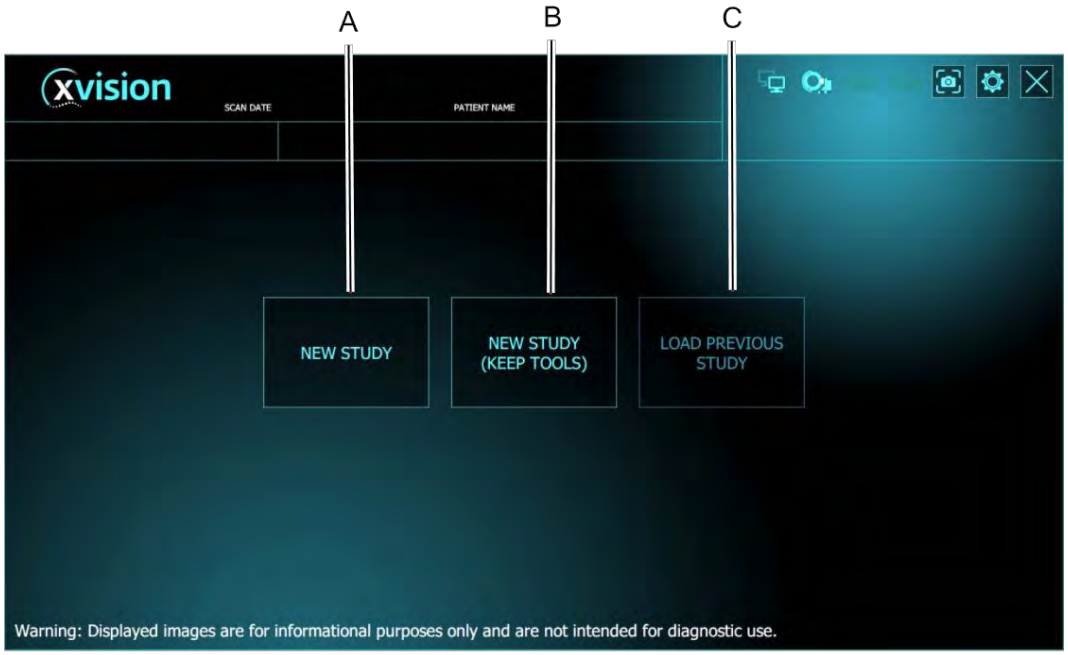


Figure 7: Study Selection Screen

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 when performing several scans on the same patient for different segments of the spine.

C **Load Previous Study**: usually used in the event of a system fault; after rebooting, it uses the information previously stored.

Note: Verify 3D scan orientation on the scanner prior to sending the data over to the **XVS SOFTWARE**.

Caution: When a new scan is sent to the **XVS** (**New Study** or **New Study (Keep Tools)**), a prompt appears to confirm that the new scan needs to be uploaded. Selecting reject will stop the scan transfer.

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

After choosing, **XVISION-SPINE** system is ready to receive data from the patient scan, and the following screen appears.

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 5-34 for more information.

Note: During Intra-Op workflow previous patient data is never saved.

The intraoperative scan transferred over LAN or selected from a portable USB drive starts loading. The progress can be seen in the number of slices shown as completed in the top right corner of the screen.

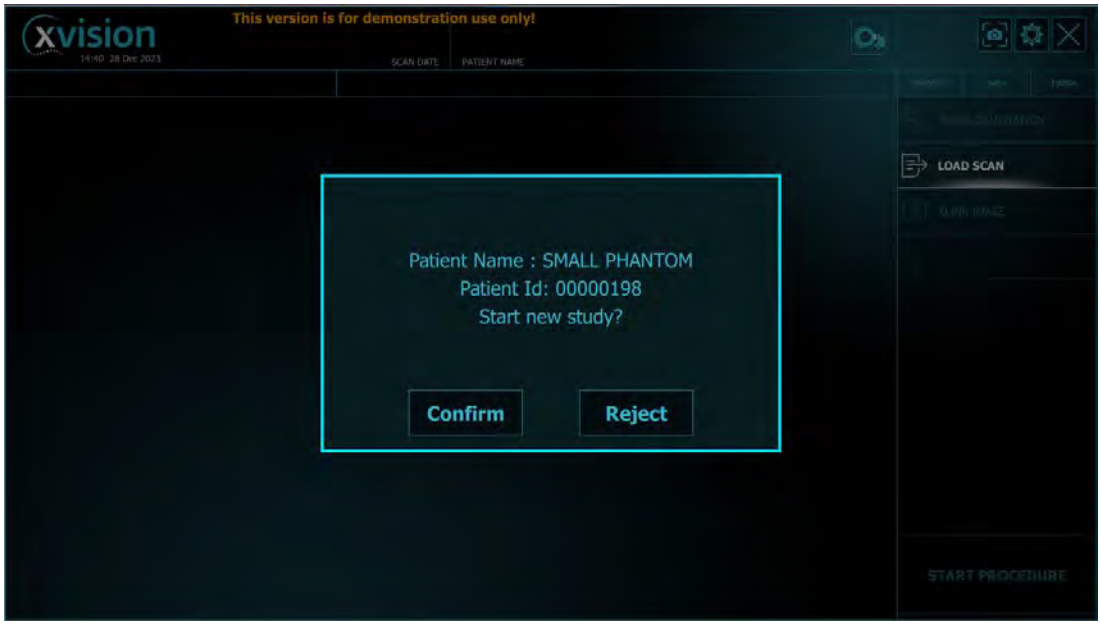


Figure 8: Confirm New Study

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

Warning: Make sure that the transferred scan is correct by verifying Patient Name and/or Patient ID with the physician in-charge.

When the X-Marker is used for registration, continue with *Completing X-Marker Registration*. on Page 7-4 Otherwise go to *Create 3D Model* (page 7-57).

7.3.1. Completing X-Marker Registration

When the Scan Transfer in *New Study* (page 7-50) is completed, continue as follows:

Figure 9: Completing X-Marker Registration

1 Transfer the captured images from the scanner to **XVS** (using DICOM or USB).
2 The first paired headset will be selected. If the user would like to change headsets, tap the miniHMD icon.

The **XVS SOFTWARE** prompts the user to capture an X-Marker image using the **HEADSET**.

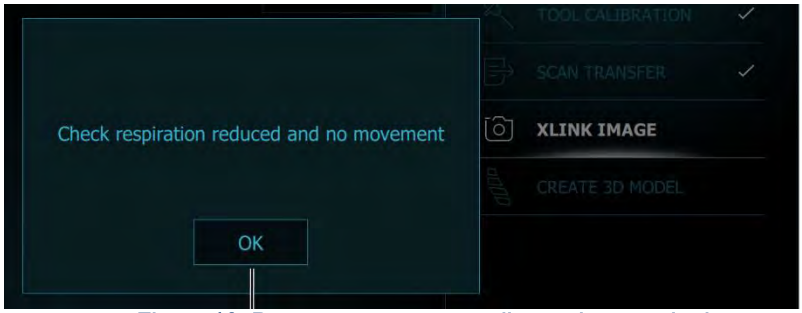


Figure 10: Pop up message regarding patient respiration

3 The system prompts the user to check respiration reduced and no movement. Press **OK**.

Warning: During X-Marker image capture make sure that respiration is reduced, and that no movement occurs.

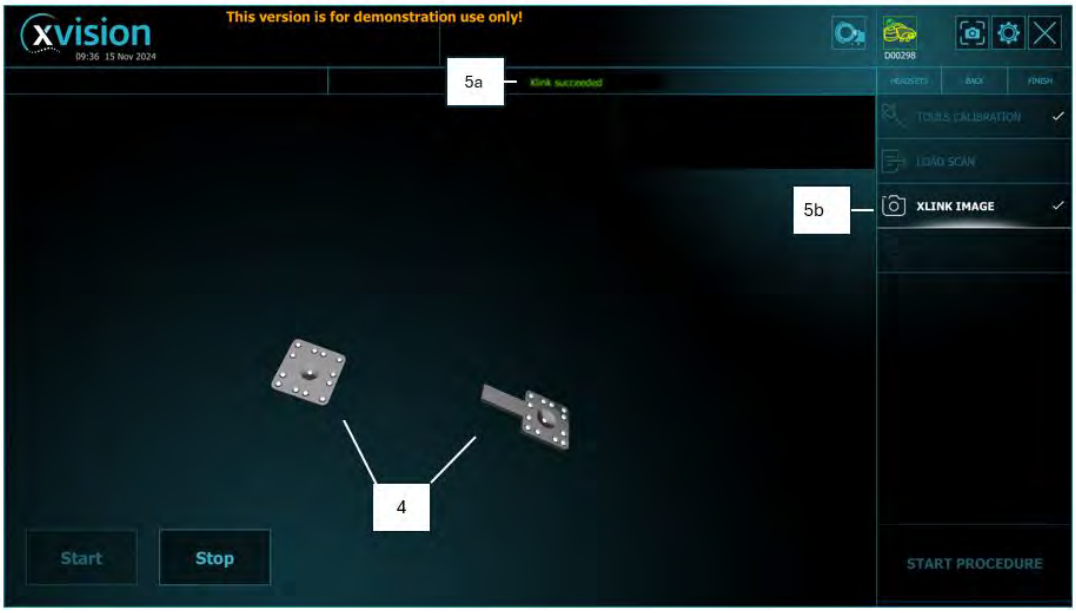


Figure 11: Completing X-Marker Registration

4 Using the **HEADSET**, the surgeon looks at both Markers until they appear on the the **HEADSET**'s display or on the Workstation Monitor.

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

5 Once registration is completed successfully, X-Link succeeded message appears (A), and X-Link image will be checked in the menu (B).

6 Remove the X-Marker from the surgical field.

Note: The X link image can only be captured once. If the user attempts to capture a different image for the same scan during procedure, previous data will be deleted, and a new study will start.

7 Continue with *Create 3D Model* (page 7-57).

7.3.2. Create 3D Model

After registration is completed, tap **Create 3D Model**.

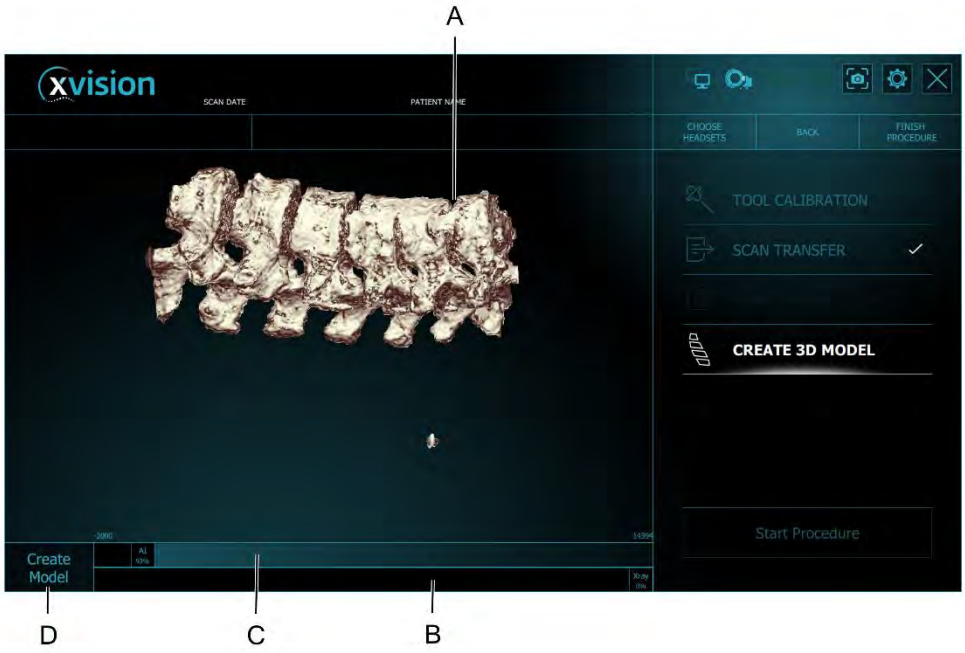


Figure 12: Create 3D Model

Note: When using large FOV scans as Brainnlab Airo or O-arm 2 extended FOV the AI (C) slider will not be displayed.
The AI visualization enhancement supports up to 250*250*250 (mm) scan size.

1 Use the touch screen to rotate the model (**A**).

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.

2 The **Xray** level (**B**) is used to set thresholds for the image to distinguish bone from surrounding tissue.
3 The **AI** level (**C**) is used to set threshold only on the parts that were segmented: the vertebrae bone and previously implanted screws and cages.
4 When the image is satisfactory tap **Create Model** (**D**).

Note: AI level threshold activates the segmentation for vertebrae bone and previously implanted screws and cages. AI threshold default to 100% segmentation. To inactivate segmentation the user should slide the AI slider to the 0 and X ray slider should be moved towards 100%

Warning: Use the AI level threshold only for scans that were taken under the following imaging conditions:

- kVp: 100-120
- Minimal resolution of 1mm
- BMI < 31

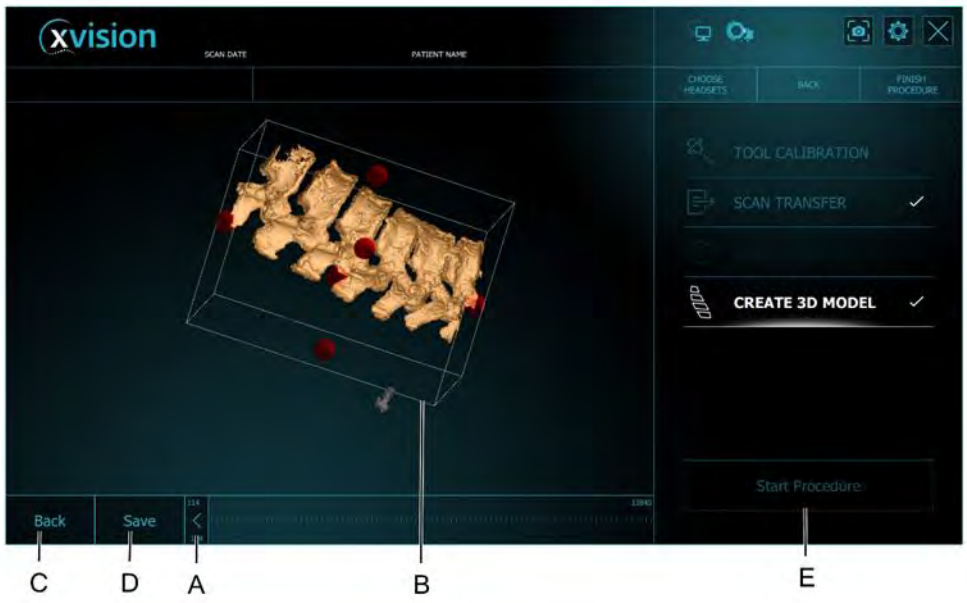


Figure 13: Create Mesh

A Thresholds
B 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.
C Back to previous screen
D Save the model
E Start Procedure.

1. When the mesh shows the bony anatomy as clearly as possible, tap **Save** (D). The save process may take several minutes. When all checks on the XVS menu (Right on the display) are done, press **Start Procedure** (E).

Warning: Make sure that, during the scan and infrared image capture, the patient does not move, and the patient's breath is held.

7.4. Pre-Op Workflow

Once pre-op workflow has been selected, the Patient Data Management screen will be displayed on the **XVS** monitor.

The Patient Data Management screen is where all (Pre-Op workflow) imported studies are located and can be selected for Segmentation and/or Registration.

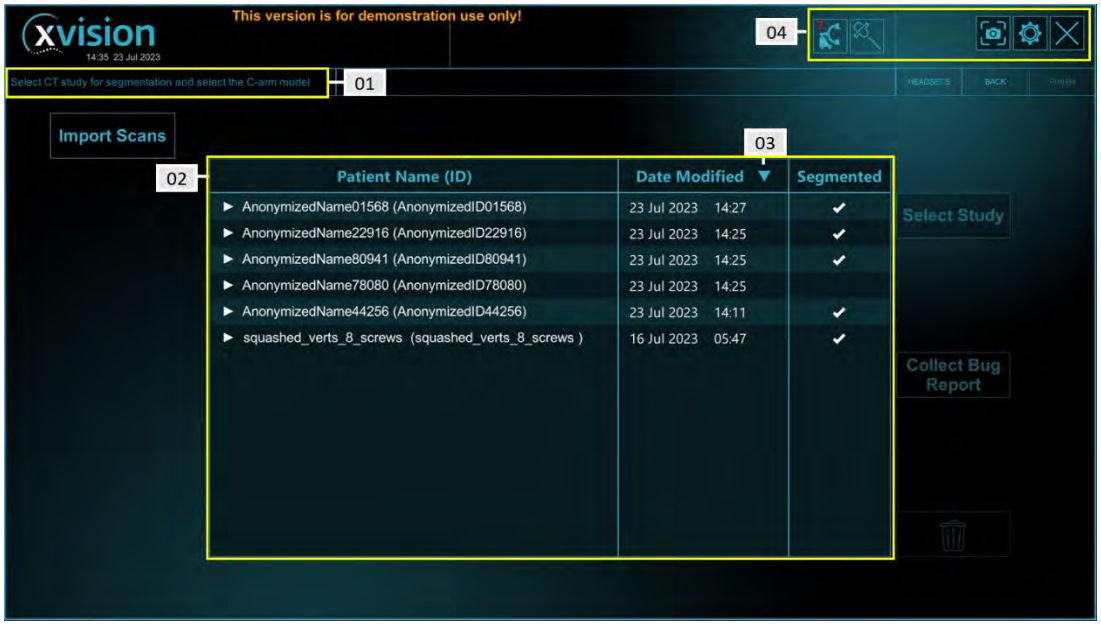
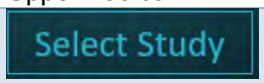
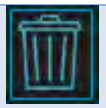
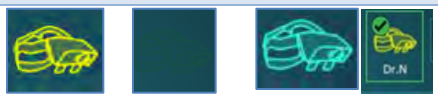
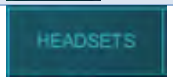


Figure 14:Pre-Op - Patient Data Management Screen

Legend - Figure #18 - Patient Data Management		Description
01	User Instructions bar	Current Step - user instructions
02	Main Patient Data Table	Patient Management Table
03		Sorted by (Column) Date - default Can be sorted by Patient Name or Date
04	Upper Toolbar	Controls and indications toolbar
		Following study selection from the table, Select study will proceed to Segmentation step
		When a study is selected on the table, The log files are packed and archived. ***Requires connected USB media driveWill save to first connected USB**
		Deletes the selected study in the table
		C-arm selection Icon ? - Currently undefined X - Not Connected V - Connected

		Tool Calibration Icon Redirects the user to Tool Calibration screen
		Mini HMD icon Shows the Headset Status Yellow HMD – Syncing Data Greyed out - Unpaired Cyan – Connected and SyncedTemperature -Warming up Box around headset with check – selected headset
		Screen capture - Grabs current display screen capture from the main XVS Monitor – Requires connected USB media
		Settings button
		Software Shutdown/Restart/Log off Mainly for restarting the system or complete system shutdown.
		Headset pairing selection Opens a pop-up to select the identified headsets 2 headsets can be paired simultaneously
		Back button – goes back 1 step backwards
		Finish procedure button - Used after procedure is completed, or a new segment for registration is needed

If the study was already imported to the system earlier, it will be displayed in the List.
The User can select the study and perform the required actions (i.e., segmentation and labeling) to prepare the CT data for CT to Fluoro procedure.

	**Note**:	The Segmented column indicates if the Study segmentation was completed and confirmed for procedure. Only 'Segmented' (Confirmed) studies can proceed to the C-Marker Registration (Load Image Step)

Load a New Study

To import new CT Study – Click **Import Scans**
Overlapping window is then displayed:

Figure 15: Path selection and Study Import

The available drives to be displayed on the Top Left of the screen would be a DVD-RW drive and a USB Flash drive if Media is inserted.

To select the appropriate study from a Media drive it is recommended to go to the 'lowest' Sub-folder in the tree to minimize the system's processing time.

1. Once the required folder is selected on the left pan hit the **Scan** button. A cogwheel is then displayed while the software is processing the data in the selected path.

	Note:	In-order to see the required study on the media, wait for the software to populate the right window with the correct patient's name with the supported CT protocol – colored BLUE.

The software analyzes which of the DICOM files within the selected folder complies with XVS system's requirements.
Each DICOM study in the folder that was identified by the xvision software will show a description of the Study and the Scan protocol parameters on the right window.
RED Study details – **unable to import** this study to the XVS Software.
BLUE Study details - **can be imported** to the XVS Software.

The Augmedics CT Protocol is documented in this user manual Appendix M.

2. Select the required eligible study from the right pane.
3. Click **Import** to proceed with study data import.

Figure 16: Verify Patient Name and ID

4. If importing Patient Study in OR – verify with Physician the correct Patient name as prompted in the XVS Software.

Warning: Make sure that the imported scan is the correct by verifying Patient Name and/or Patient ID with the physician in-charge.

5. Once patient name is verified, confirm with 'Yes' to proceed with the import.

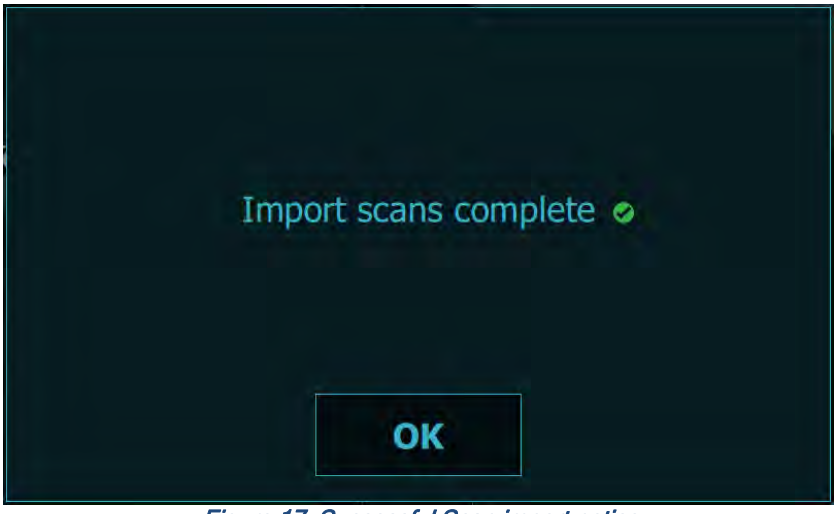


Figure 17: Successful Scan import notice

6. Wait for the study to be imported and confirm with OK when completed.
7. Click the 'X' button to close the Import Scans dialog.

To Proceed to the '**Segmentation**' a study must be selected for the procedure.

7.4.1. Segmentation

To select the study for the operation, navigate to the Patient Data Management Screen in the Pre-Op workflow.

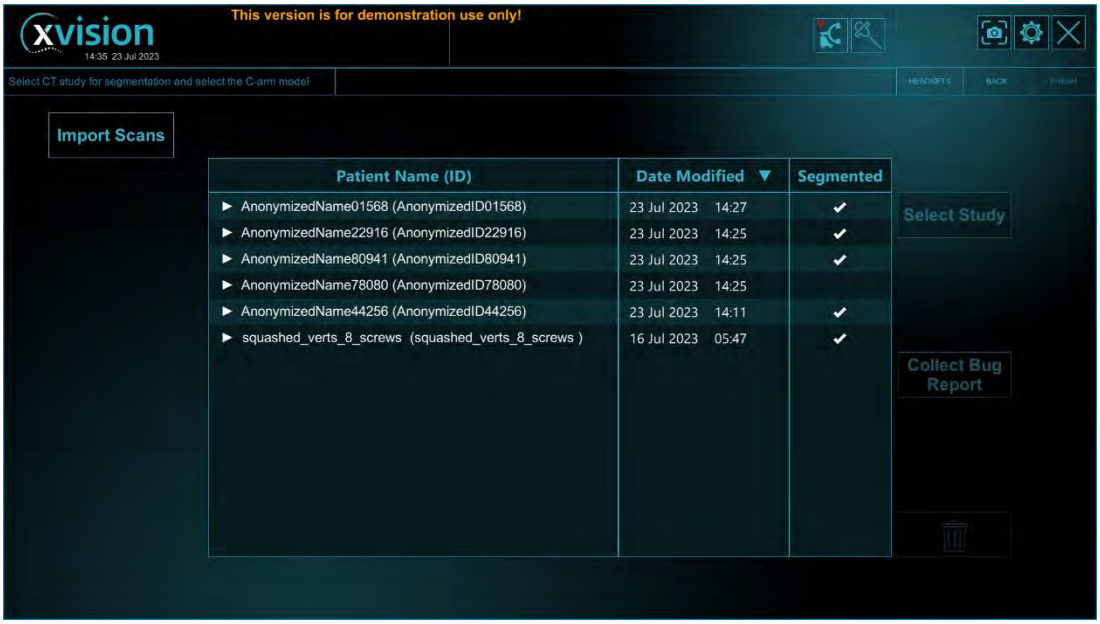


Figure 18: Patient Data Management Screen

1. Select the study from the list, by selecting the Patient Name & ID.
   In case multiple studies under the same patient name appears, select the relevant study based on date modified indication.

Note: To avoid confusion, it is recommended to keep only the studies to be used and delete the irrelevant ones from the Patient Data Management.

2. Tap 'Select Study' icon.
   A prompt to verify Patient Name & ID is displayed.

Figure 19: Verify Patient details with OR staff

Warning: Make sure that the selected scan is correct by verifying Patient Name and/or Patient ID with the physician in-charge.

After the study is selected, the XVS Software performs Auto-Segmentation on the CT study. On the 1st attempt the XVS Software automatically segments each vertebra according to its anatomical order.

At the end of the segmentation process the user is required to **confirm** Orientation, Segmentation and Labeling.

Note: To confirm Orientation, Segmentation & Labeling the user is required to identify and label 1 vertebra, and then the software will auto populate the rest of the labels in the correct anatomical order.

Typically, the **auto-segmentation** feature should segment all the vertebrae in the imported CT study. In case changes are needed, the user can adjust the study manually to his/her preference to improve segmentation results.

7.4.1.1Pre-Op Views

At the end of automatic segmentation, the user can review the Auto-segmentation results. The XVISION Software offers the user 5 different views.

Figure 20: Pre-Op views during Segmentation process

Views

Each pane allows the user to select the desired view.
The Available views are as follows:

- Sagittal – CT Slices sagittal view
- Coronal – CT Slices coronal view
- LAT – Lateral (DRR) Stacked view
- AP - AP (DRR) Stacked view
- 3D – Rendered Segmented 3-dimensional Volume

Each view introduces different sliders to control the image display quality.
Sagittal and **Coronal** Views allow the user to scroll the CT slice by slice, reviewing and verifying the auto segmentation results as well as scrolling to identify and review the Patient CT study.
The views described above are available throughout the Segmentation Process. Each view utilizes the required sliders to control the displayed image quality.

7.4.1.2 Orient

In case the scan is not oriented as the software expects (e.g., posterior spine is displayed near the notation “A” (anterior) or superior spine is displayed near the notation “I” (inferior)), segmentation may be affected.

Figure 21: Orient - Adjust the study orientation

The orient Tab allows the user to adjust current ‘default’ orientation. Each orientation change will cause the Auto-Segmentation algorithm to run again (up to 30 Sec.)

	Note:	Default view would present right in the display as right in the reality. **Left – Right switch** (mirroring) button will be available on the next (**Segment**) Tab.

Figure 22: Segmentation Screen - Coronal & Sagittal Controls

Legend - Figure #26 - Orient Tab		Description
01	Current Step/Operation control panel	Orient -adjust Orientation if required
02	Left pane Slider	Windowing control - Left (Pane) Image
03	Scroll bar	Scroll slice by slice over the CT study
04	Center slider	Vertebra/Segment (color) Opacity control
05	Main Workflow - Right Pane	Main procedure - milestones controls
06	User Instructions bar	Current Step - user instructions
07	System controls bar - upper toolbar	System Controls
		Anterior ←→ Posterior orientation flip Flips/Changes the CT study orientation Causes Auto-segmentation restart
		Superior ←→ Inferior orientation flip Flips/Changes the CT study orientation Causes Auto-segmentation restart
		Confirm - Confirms orientation, segmentation & Labeling. **Disabled** until labeling is completed
		Proceed to Manual segmentation Step
		Proceed to Labeling Step **Mandatory step** for confirming segmentation results

1. Adjust the orientation only if required. Any flip will cause the auto-segmentation to re-run.

If adjustments to the Auto-Segmentation results are required proceed to the **'Segment'** tab to perform it manually.
If no Orientation/Segmentation changes are required on the orientation screen, proceed directly to '**Label**' tab.

7.4.1.3 Segment – Manual Segmentation

During this step the default Views are changed from 'Coronal/Sagittal views' to 'AP/LAT views.
The Region of Interest Selection is performed (only) over AP & LAT views.
Other views are available **only** for reviewing the study in Slices view and 3D view.
To complete the **Manual segmentation** process it is required to perform all 3 Steps:

1. *ROI (Selection) - Slide a finger along the foramen over the required vertebrae to be manually segmented.*
2. *Set Lines - Set the segmentation lines in each vertebra disc space.*
3. *Detect - Operates the AI algorithm to perform segmentation in each segmented vertebra separately.*

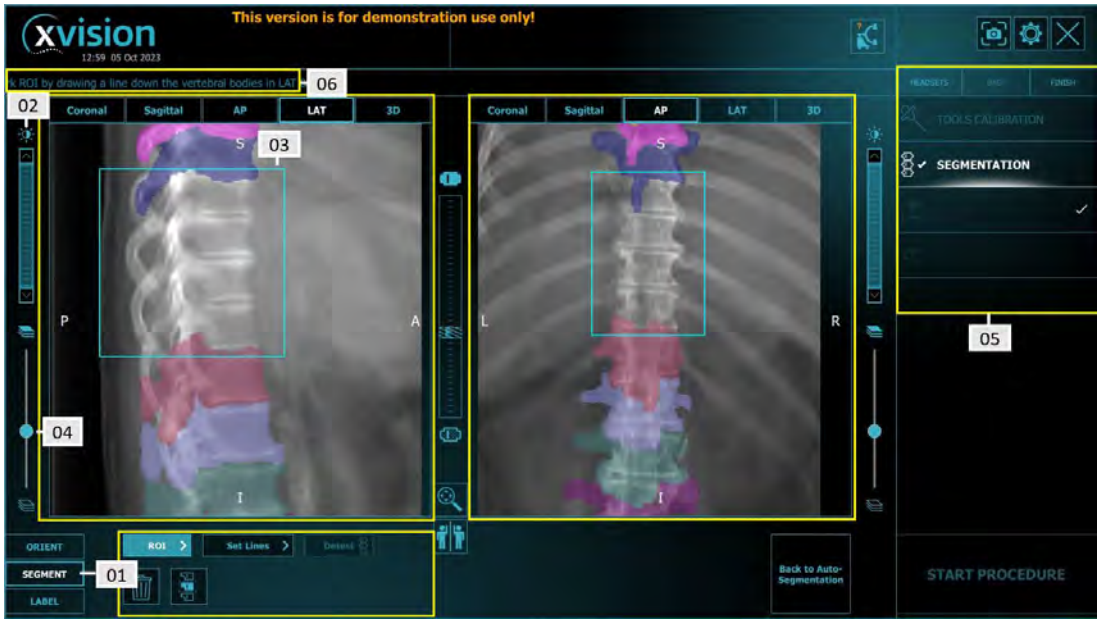


Figure 23: Manual Segmentation - ROI selection

Note: Zoom & Pan are enabled by default prior to ROI button press.
It is recommended to zoom over the required segment for Manual Segmentation.
Upon ROI selection over the LAT and AP projections, Zoom & Pan can be enabled by its designated button.

Legend - Figure #27 - Segment Tab		Description
01	Current Step/Operation control panel	Segment – Manual adjustment to segmentation
02	Left Slider	Windowing control – Left (Pane) Image
03	ROI volume selection	Region of Interest selection for Manual segmentation adjustments
04	CT Threshold	Set the CT Threshold detection values Used to improve the image display on AP/LAT views
05	Main Workflow – Right Pane	Main procedure - milestones controls

06	User Instructions bar	Current Step – user instructions
		Select/Unselect vertebra to exclude/include in the Manual segmentation detection
		Zoom/Pan – select to enable touch gestures **#Note:** other actions are disabled while pressed.
		Image Mirror – Switch patients Right/Left display (Doesn't affect the CT orientation)
		Current Step – ROI selection When selected user may 'draw' a line to set the ROI for Manual segmentation
		Deletes the current ROI selection
		Next Step following the ROI selection is setting the segmentation lines manually.
		Following Lines setting Detect step is required to complete the manual segmentation phase
		When pressed – Auto Segmentation results are restored for the whole CT study

ROI Selection –

1. Slide a finger along the foramen over the required vertebrae to be manually segmented. (also applies over unsegmented vertebrae)
   The bodies that are at least 50% contained within the newly generated ROI will change from the highlighted and multicolored bodies, to unselected "grey." This indicates to the user that these selected bodies will be available for the Manual Segmentation process.

Note: It is recommended to include up to 5 vertebrae to ease the lines setup for manual segmentation.

2. Adjust the square borders to include all required levels for manual segmentation.
   Recommended – to include more of the above/below segments in the ROI box.
3. Set the Best Brightness & Contrast view and then click **Set Lines**.