Augmedics

xvision

User Manual

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License Contract

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Table of Contents

1. Introduction

This manual is an accompanying document to the **XVISION-SPINE** (**XVS**) system, which is designed to enable accurate pedicle screw placement. 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.

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.

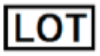
Caution: Alerts the user to a possible problem with the system concerning its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property. The caution statement includes the precaution that should be taken to avoid the hazard.

Notes provide tips, advice and other useful information.

Note: This is a note.

1.3. List of Symbols

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

Symbol	Meaning
	Consult operating instructions
	Manufacturer
	Date of manufacture
	Use by: the date after which the device shall not be used
	Do not reuse/single use only
	Serial Number
	Part number
	Batch code
	Sterilized using irradiation oxide
	Indicate that the component needs to be sterilized, but has not yet been through the sterilization process.
	Prescription only. U.S. federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.
	Dispose of used material as per the Waste Electrical and Electronic Equipment Directive (WEEE) requirements.

Symbol	Meaning
	Do not use if package is damaged or broken
	Temperature limit
	Radio frequency device. Interference may occur in the vicinity of the device.

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 your 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.

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

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: 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 safety standards IEC 60601-1 and AAMI ES60601-1, and is internally powered ME equipment.

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. At least four cm of separation distance between the **HEADSET** antennas and the user's body must be maintained at all times. This device must not be used with any other antenna or transmitter that has not been approved to operate in conjunction with this device.

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.

2.5. Cybersecurity Controls

Augmedics Ltd recommends that users install an anti-virus and an anti-malware application on the hospital PC and run regular scans on the PC to monitor, detect and prevent viruses or malware on their PC.

If the **XVISION-SPINE** cybersecurity has been compromised and any changes have been made to the **INTERFACE SOFTWARE**, the software will detect this and prevent running. This event is logged to the system log file.

If the **INTERFACE SOFTWARE** configuration has been compromised, an Augmedics service technician is required to restore the system.

The **INTERFACE SOFTWARE** requires a wireless router configured as described in *xvision-Spine System Communication* (page 5-2).

It is the responsibility of the authorized user to ensure that the hospital PC on which the **INTERFACE SOFTWARE** is installed is not left unattended, unlocked, or otherwise unsecured when not in use, in order to ensure that non-authorized medical, professional, or otherwise

unapproved personnel are not exposed to, or gain access to, electronic protected health information (ePHI).

Augmedics recommends that users enable a firewall on the hospital PC and configure the firewall so that only the **XVISION-SPINE** network is enabled.

Use of the **INTERFACE SOFTWARE** 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.

User names 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). Each user must have a unique username and password.

Only network ports 5550,5555,5560,5570 and the port configured for DICOM access (104) should be opened for send/receive. All other ports should be disabled.

All anomaly detection on the hospital PC is the responsibility of the end user. Augmedics uses industry-standard instructions to protect the **INTERFACE SOFTWARE** system that runs in a protected Windows 10 virtual machine. All events are logged to the Windows Security Event log.

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.

Warning: The **XVS** system tracks optical markers and displays tracking information on an augmented reality headset. The display of tracking information is critical for safe use of the **XVS** system and electromagnetic disturbances beyond limits specified in the tables below can cause degradation of tracking and display.

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.

Declaration: Electromagnetic Emissions

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, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

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Note

All of this text needs to be moved to be just above the first equation below

Declaration: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic En
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 w If floors are covere relative humidity sh
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency n levels characteristic typical commercial or hospital environment.
~~**NOTE**: UT is the a.c. mains voltage prior to application of the test level~~.			Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT or ME SYSTE including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3V/m	3V/m	$d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 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 metres (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	

StuartWolf
Note

Insert the following in bold just above the equations

Recommended separation distance

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 $d = [$	800 MHz to 2,5 GHz
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

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Note
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Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment

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
5240	5 100 – 5	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9	9
5500							

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Note
Not clear

should be 2400 - 2570 (one line) or
2400

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Note
Same comment as above

Test Specifications for Enclosure Port Immunity to RF Wireless Commun [illegible] (continued)

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distan [illegible] (m)	[illegible] Test Level (V/m)	[illegible] Level (V/m)
5785							

NOTE: If 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 worst case.

StuartWolf
Note

Because of the page split in the middle of the table the band for 5785 is not clear.

Can you keep this row together with the two above?

2.7. Method of Sterilization or Disinfection

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

See *Cleaning Reusable Components* on page 8-1 and *Steam Sterilization* (page 8-5) 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 personnel authorized by Augmedics
- 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.

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.

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.

3. Overview

The **XVISION-SPINE** (**XVS**) system is a stereotactic image-guided navigation system designed to assist surgeons in placing pedicle screws 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 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 **XVS** system, with the **INTERFACE SOFTWARE**, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic 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 images of the anatomy.

This can include the following spinal implant procedures, such as:

- Pedicle screw placement
- Iliosacral screw placement

3.2. Intended User and Environment

The system is to be used by trained professionals only. These include surgeons, nurses and technicians. 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 Interface Software

The dedicated **XVS INTERFACE SOFTWARE** receives the intraoperative 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 virtual images are of a 3D model and axial and sagittal 2D views.

The **HEADSET** displays the same virtual images with the 3D model aligned with the patient.

The computer running the **INTERFACE SOFTWARE** is connected to the **HEADSET** by WiFi.

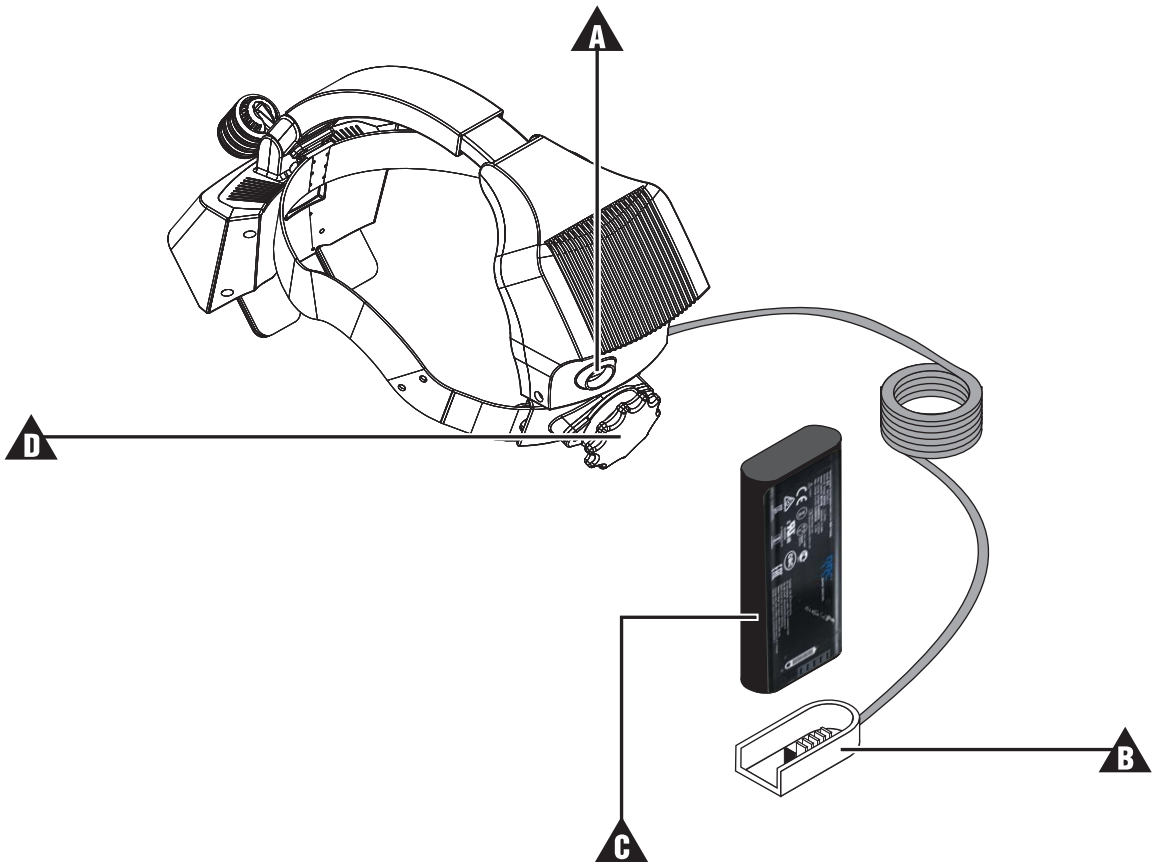
Dedicated menus of the user interface are accessed either with a touch screen or a mouse and keyboard.

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

Figure 1: **HEADSET** ID of Parts



A On/Off switch
B Battery socket
C Rechargeable battery
D Adjustment dial

The **HEADSET** is powered by a rechargeable battery (C) that provides between two and a half to three hours continuous work. During the surgical procedure the battery is plugged into the battery socket (B) and placed in the surgeon's pocket.

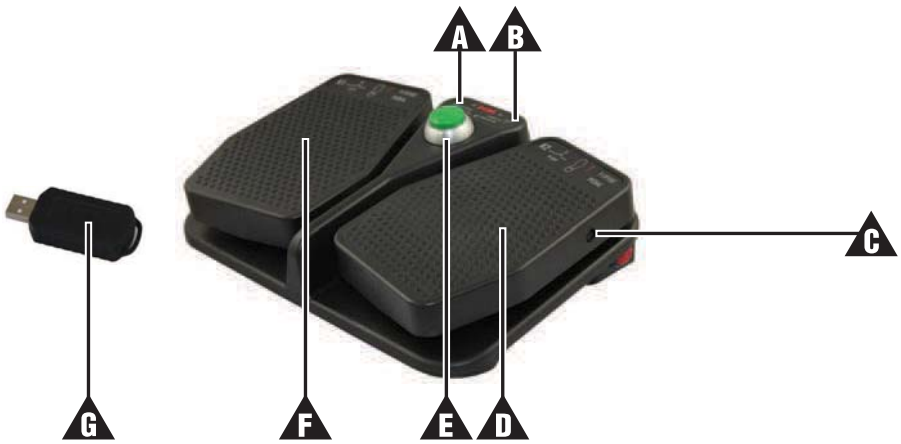
Recharge the **HEADSET** battery after every surgical procedure by placing it in its charger stand. The full charge cycle takes between one to two hours.

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 5-2 for more information.

4.3. XVISION-SPINE Footswitch

The **XVISION-SPINE** Footswitch is an optional WiFi accessory that provides the surgeon **INTERFACE SOFTWARE** functions. See *Footswitch Controls* on page 7-9 for more information.

Figure 2: Footswitch



- **A** Power indicator
- **B** Connection indicator
- **C** Power input
- **D** Right pedal: Place virtual trajectory guide or screw
- **E** Center switch: Cycle between 3D modes (**3D Fixed > 3D Follow > 3D Off**)
- **F** Left pedal: Toggle display on/off
- **G** USB receiver module

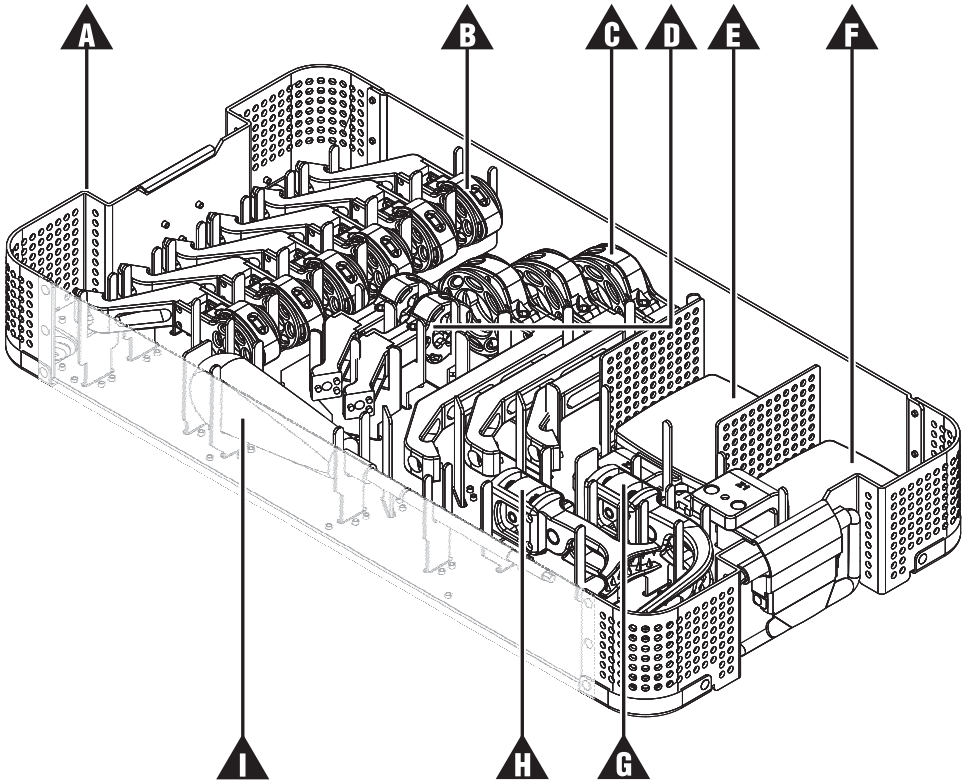
4.4. Reusable Components

Reusable components are provided in a tray that can be used for sterilization and storage.

Warning: Do not use the reusable components if they are not sterile. See *Cleaning Reusable Components* on page 8-1 for more information.

The figure below shows a maximal selection of components.

Figure 3: Reusable Component Tray (Maximal Configuration)



A Reusable Component Tray
B Short swivel universal tool adaptor (six pieces)
C Long swivel universal tool adaptor (three pieces)
D Small universal tool adaptor (two pieces)
E Z-Marker-10
F Z-Marker-40
G Patient Clamp—Arc
H Patient Clamp—Straight
I Allen screwdriver

Note: The front left panel of the tray is shown transparent for illustration purposes only.

4.5. Single Use Sterile Kit

A single use sterile kit containing two Patient Markers, one X-Marker registration marker and six Tool Markers is provided for each surgical procedure. All markers within the set are sterile and are intended for single use.

Each patient marker includes double-sided stickers on the back. Additional double sided stickers in the kit are used for the registration marker.

There are no two identical tool markers in a single sterile kit.

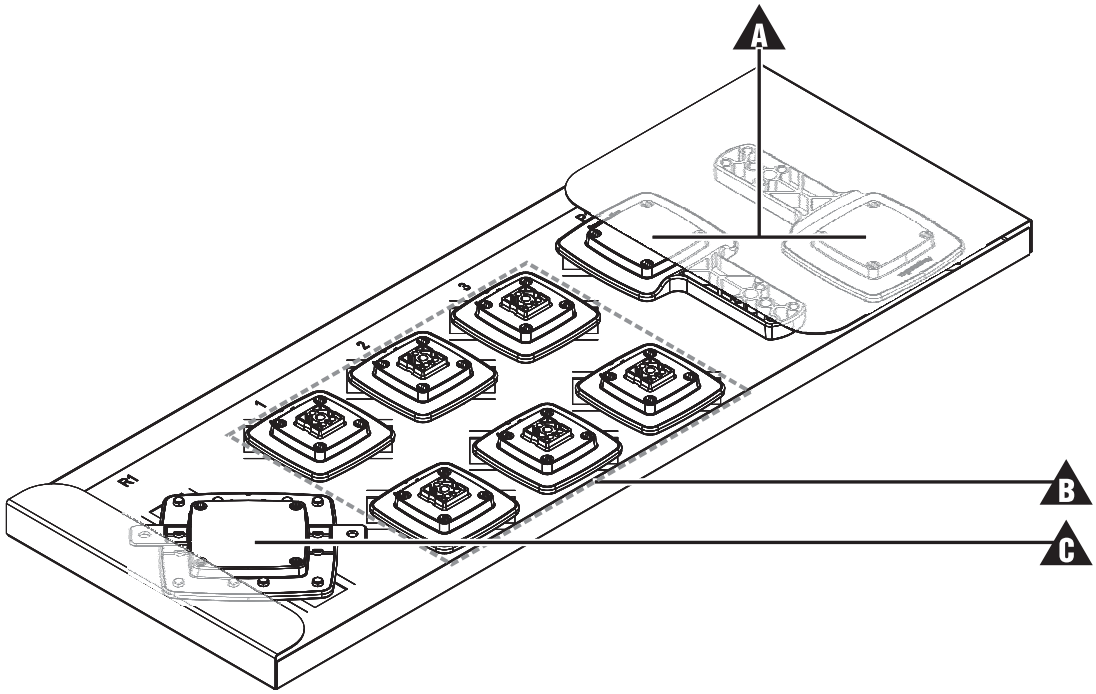
Tool markers ensure unique identification of the instrument during the procedure.

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 Sterile Use Kit in a single procedure. Markers with the same ID from different kits may confuse the **XVISION-SPINE** system.

Figure 4: Single Use Sterile Kit



A Patient markers (2)
B Tool markers (6)
C X-Marker registration marker

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 on the bill of lading. This will qualify any damage for possible insurance claim with the freight company and reduce liability for further incurred cost of any damage to the equipment during shipping. Inform your sales representative of any damage the unit incurred during shipping.
- Verify that all of the components are present.

5.1. XVS Interface Software Installation

XVS INTERFACE SOFTWARE installation is done by an authorized technician from Augmedics Ltd.

Warning: Before installation make sure that all of the requirements specified in *Cybersecurity Controls* (page 2-2) have been fulfilled.

Install the **INTERFACE SOFTWARE** on a computer with the following minimal requirements:

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

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

5.2. XVISION-SPINE System Communication

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

Configure communication as follows.

1. Attach the router to the hospital PC using either an ethernet cable or wireless connection.
2. Connect to the router as an administrator.
3. Define `XVISION` as SSID in the wireless settings section of the router.
4. Configure wireless security to be WPA2 and set the wireless password.

Note: Steps **3** and **4** are performed only by an Augmedics service technician.

5. Restart the router.
6. Configure the unit DICOM address and application entity ID in coordination with the institution's IT department.
7. Configure the WiFi connection between the computer and the **HEADSET**s.

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).

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

Tighten and adjust the head-straps in the proper manner.

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

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

5.4. Headset Pairing

The serial number that appears on each **HEADSET** is used by the **INTERFACE SOFTWARE** as the device name when the device is paired.

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.

In the **INTERFACE SOFTWARE** the technician first clicks **Choose Headset** to open the **HEADSET** Pairing Screen.

Figure 5: **HEADSET** Pairing Screen

During the pairing process, the **HEADSET** device name (A) is identical to the device's serial number. The **HEADSET** can be given a pairing name (B), such as the name of the surgeon, and the change is then saved (C).

6. XVISION-SPINE System Preprocess Workflow

Follow the procedures below prior to the surgical procedure.

6.1. Starting up the XVISION-SPINE System

In the operating room launch the **INTERFACE SOFTWARE**, power up the **HEADSET** that is to be used in the procedure.

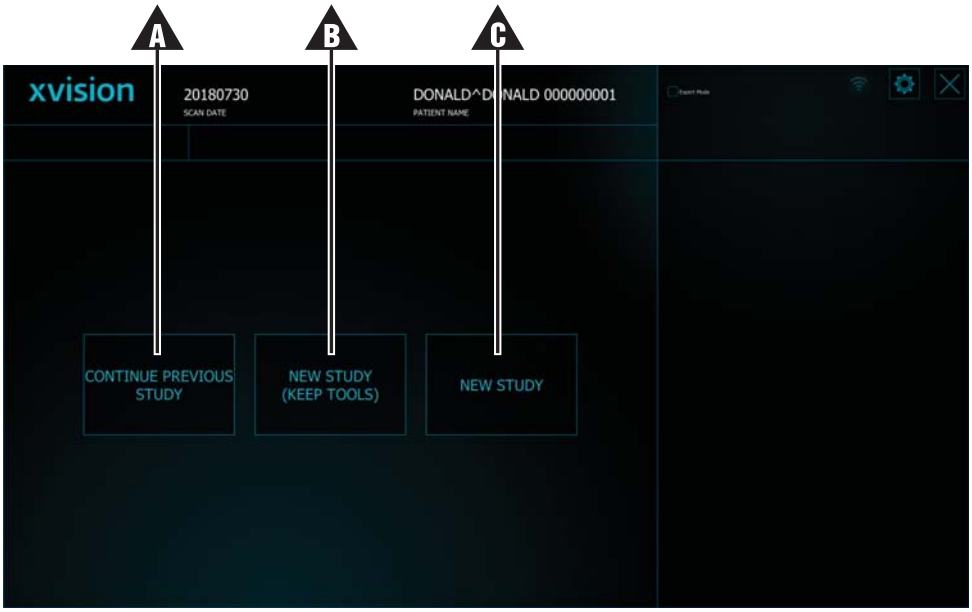
The **INTERFACE SOFTWARE** supports the use of two **HEADSET**s during the procedure, typically for the surgeon and an assistant.

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

When using a footswitch, insert its USB receiver module into the computer USB port where the **INTERFACE SOFTWARE** is running.

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

Figure 6: New Study Screen



Tap **New Study** (A) when this is the first surgical procedure for a new patient.

The other two options are for the following cases:

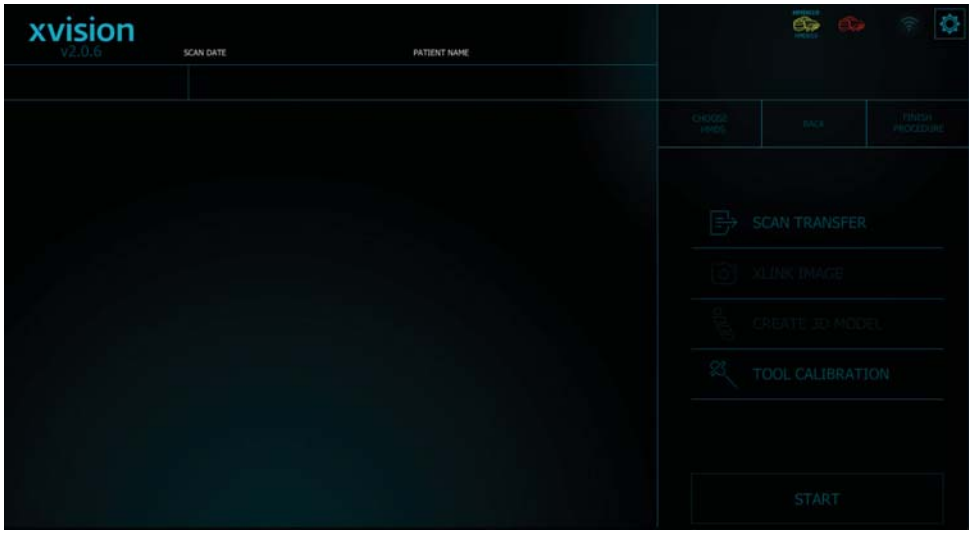
A **Continue Previous Study**: usually used in the event of a system problem; after rebooting it uses the information previously stored.

B **New Study (Keep Tools)**: discard patient data but use the calibrations of the selected tools from the previous study. Useful if you need to do several scans on the same patient for different areas of the back.

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

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

Figure 7: New Study Menu



6.2. Prepare Surgical Tools

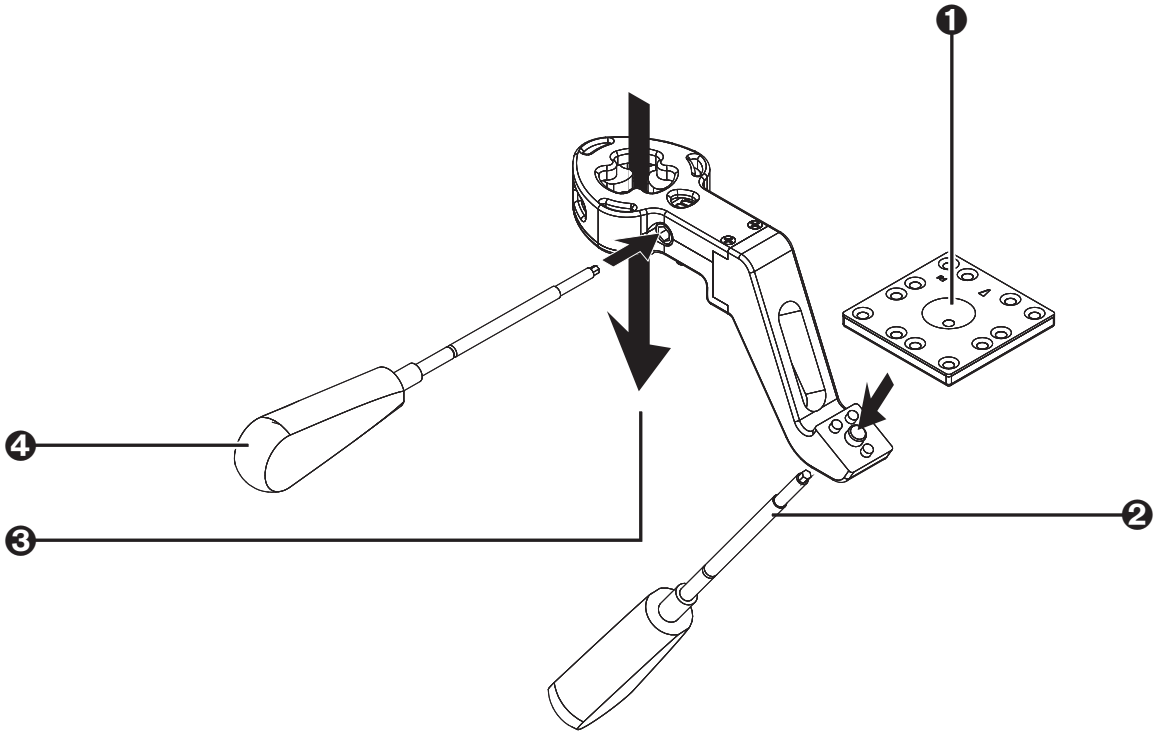
The system supports up to six navigated instruments per a single procedure. Contact Augmedics Ltd regarding supported tools.

Augmedics provides universal tool adaptors for a variety of surgical instruments and a set of single-use markers for each tool. See *Universal Tool Adaptors* on page A-3 and *Single Use Sterile Kit* (page 4-4) for more information.

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

Warning: 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 a different Universal Tool Adaptor for the surgical procedure.

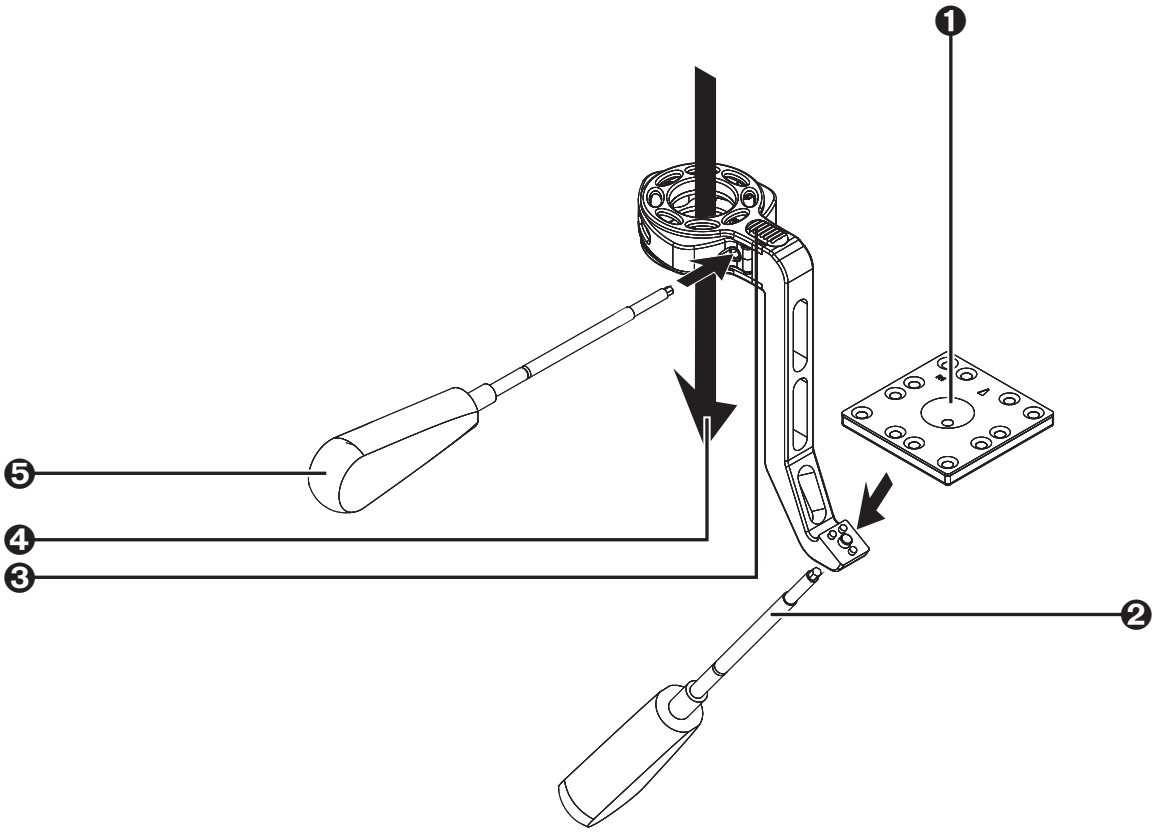
Figure 8: Prepare Surgical Tool for Fixed Universal Tool Adaptor



1. Remove the appropriate instrument marker from the sterile packaging and set it on the universal tool adaptor.
2. Use the hex screwdriver to tighten the instrument marker to the universal tool adaptor.
3. Insert the surgical instrument.
4. Use the hex screwdriver to tighten the universal tool adaptor to the instrument.

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

Figure 9: Prepare Surgical Tool for Swivel Universal Tool Adaptor



1. Remove the appropriate instrument marker from the sterile packaging and set it on the universal tool adaptor.
2. Use the hex screwdriver to tighten the instrument marker to the universal tool adaptor.
3. Set the swivel lock.
4. Insert the surgical instrument.
5. Use the hex screwdriver to tighten the universal tool adaptor to the instrument.

For all Universal Tool Adaptors:

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

Caution: Do not overtighten.

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

6.3. Surgical Instrument Calibration

Each navigated surgical instrument must be calibrated before use.

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

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

Figure 10: Calibrate Tools