Augmedics

xvision

xvision-Spine

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.

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.

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.
	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.

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 safety standards IEC 60601-1 and AAMI ES60601-1, 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.

The **XVISION-SPINE** Footswitch contains FCC-ID: 2AODW-NRF24L01SMD

The optional Tablet accessory contains FCC-ID: PD98265D2.

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 **XVS SOFTWARE** requires a wireless router configured as described in *xvision-Spine System Communication* (page 5-3).

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

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.

Only network ports (inbound) 24967, 24969 to 24975 (TCP), 104 (TCP) and the port configured for DICOM access (as defined by the installed scanner) should be opened for send/receive. All other ports should be disabled. See *Configuring the Scanner Imaging Protocol* on page 5-6 for information about DICOM access.

Hospital PC Security

It is the responsibility of the authorized user to ensure that the hospital PC on which the **XVISION-SPINE** application is installed is not left unattended, unlocked, or otherwise unsecured when not in use, to ensure that non-authorized medical, professional, or otherwise unapproved personnel are not exposed to, or gain access to, ePHI. The same applies to the pre-configured Augmedics PC.

Anti-Virus and Anti-Malware

Augmedics 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. A pre-configured Augmedics PC includes antivirus and antimalware utilities.

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 to the Windows Security Event log.

Caution: If XVS Software is installed by a third-party (the hospital) it is the responsibility of the third party to secure the network.

Note: No connection to the internet is possible since the firewall on the Augmedics-supplied PC is configured to block all network ports except 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.

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 their own unique username and password.

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

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 either on a hospital PC or 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 this and prevent running. This event is logged to the system log file.

Recovering from Compromised Accounts

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

When accounts are considered compromised, or unauthorized access is discovered or suspected, the healthcare organization's IT network administrators should suspend and modify the user login criteria and issue new login credentials for users to access their accounts securely. For a pre-configured Augmedics PC, a field-service personal shall be called.

Unavailable Service

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

Remaining Current on Cybersecurity Updates

Augmedics recommends that users configure their PC to update automatically, to ensure that cybersecurity and other security updates are applied to the PC as soon as they become available. For a pre-configured Augmedics PC, the updates will be part of the annual maintenance procedure.

Software Maintenance Support for the Software

Any software updates and patches are handled in a similar way to the basic installation. After the update is developed and verified and new software installation is created this is supplied to the service technician who will need to visit the customer and install the update. No customer-updates are allowed.

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)

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group1 Class A	The **XVS** system and the Tablet use 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.

Declaration: Electromagnetic Immunity (HEADSET)

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 wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
NOTE: UT is theAC 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) (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	

Optional TABLET and Router

Declaration: Electromagnetic Emissions (Optional Tablet and Router)

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group1 Class A	The **XVS** system and the Tablet use 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.
Harmonic emissions IEC 61000-3-2	Class A	The Tablet and Roll Stand are 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 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 Tablet and Roll Stand or shielding the location.
Voltage fluctuations and flicker IEC 61000-3-3:2013	Complies	

Declaration: Electromagnetic Immunity (Optional Tablet and 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 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 Tablet and Roll Stand requires continued operation during power mains interruptions, it is recommended that the Tablet and 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 theAC 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 (Optional Tablet and Router) (continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	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: 
Radiated RF IEC 61000-4-3	3V/m	3V/m	
	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	

Recommended Separation Distances (Headset and Optional Tablet)

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 Optional Tablet)

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 Optional Tablet) (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 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.

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 8-3) 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 **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.

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.

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 **HEADSET** of the **XVISION-SPINE** system displays two types of images: 2D stereotaxic screens 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 display 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 the **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, can be identified relative to CT imagery of the anatomy.

This can include the spinal implant procedures such as posterior pedicle screw placement in the thoracic and sacro-lumbar region.

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, 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 Software

The dedicated **XVS 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 **XVS 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. Router

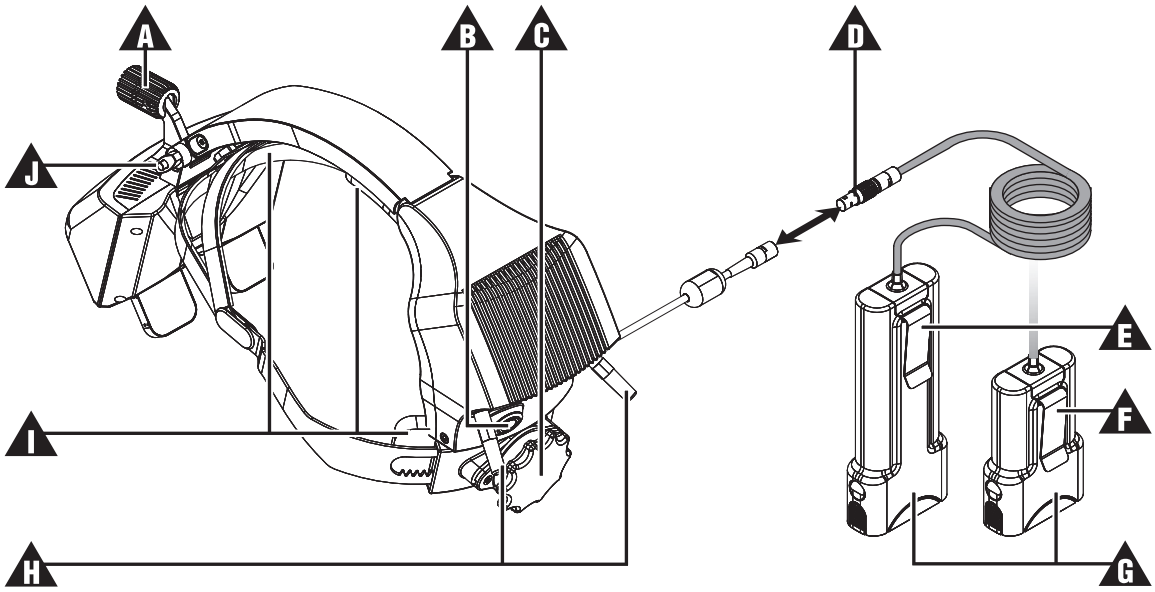
The router is used to support wireless communication between the computer on which the **XVS SOFTWARE** is installed.

4.3. 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** Head light
- **B** On/Off switch
- **C** Head strap adjustment knob
- **D** Battery connector
- **E** Large rechargeable battery
- **F** Small rechargeable battery (option)
- **G** Rechargeable battery holder
- **H** WiFi antennas
- **I** **HEADSET** pads
- **J** Folding lock mechanism

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

Note: The **HEADSET** can be powered by either a large- or small-size battery. See *System Specifications* on page A-1 for more information about the differences between these batteries.

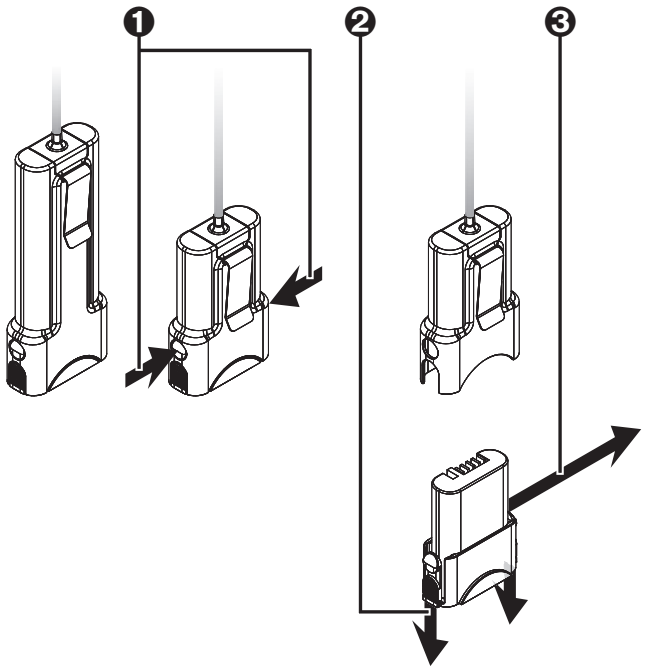
Recharge the **HEADSET** battery after every surgical procedure by placing it in its charger stand. The full charge cycle takes between one to two hours. See *Battery and Charger* on the facing page for more information.

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 5-3 for more information.

4.4. Battery and Charger

The **HEADSET** is powered by a rechargeable battery that provides between two to four hours continuous work.

Figure 2: Removing **HEADSET** Battery for Charging



❶ Press the ribbed buttons on either side of the battery.

Note: Both large and small batteries are shown.

❷ Pull the battery out of the battery case.
❸ Set the battery into its charger stand.

Recharge the battery after every surgical procedure. The full charge cycle takes between one to two hours.

Note: When the battery reaches 30 life cycles, contact Augmedics Ltd.

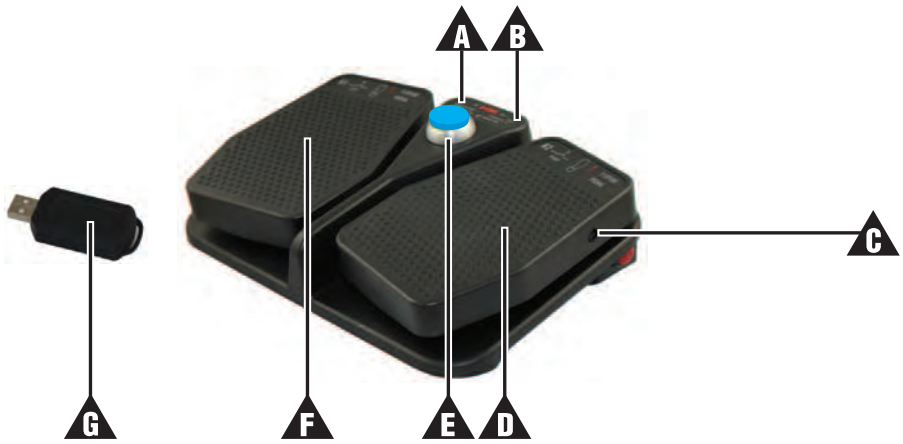
4.5. XVISION-SPINE Footswitch

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 7-9 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 3: 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

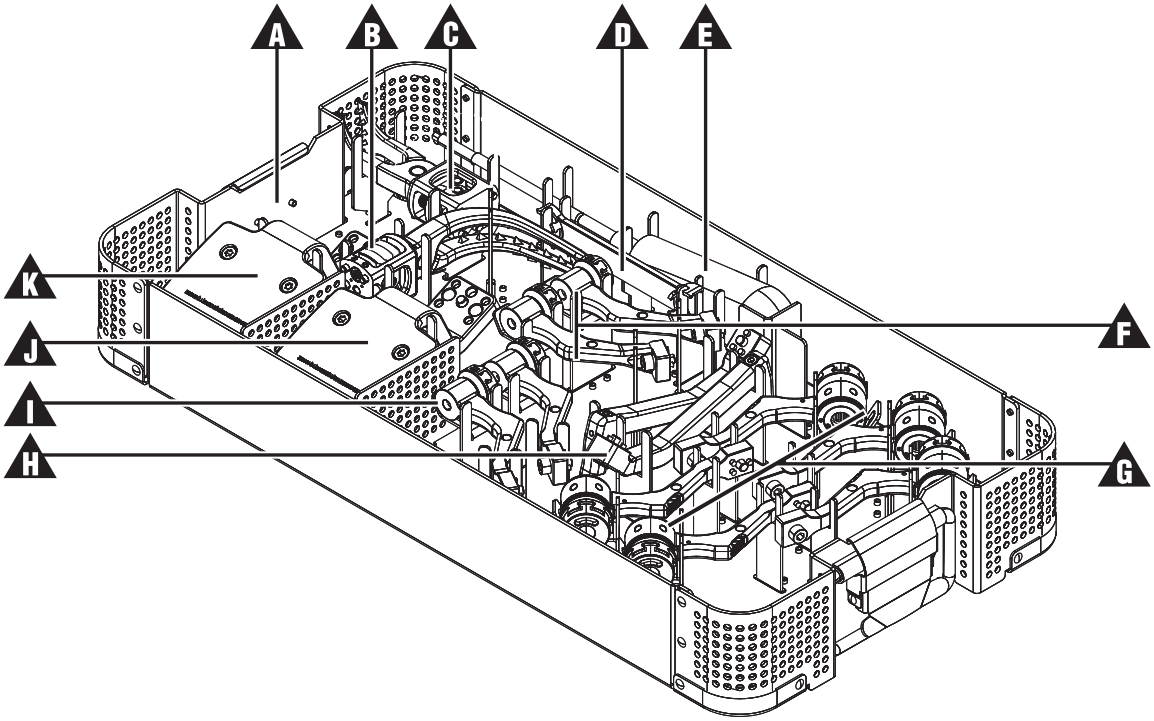
4.6. Reusable Components

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.

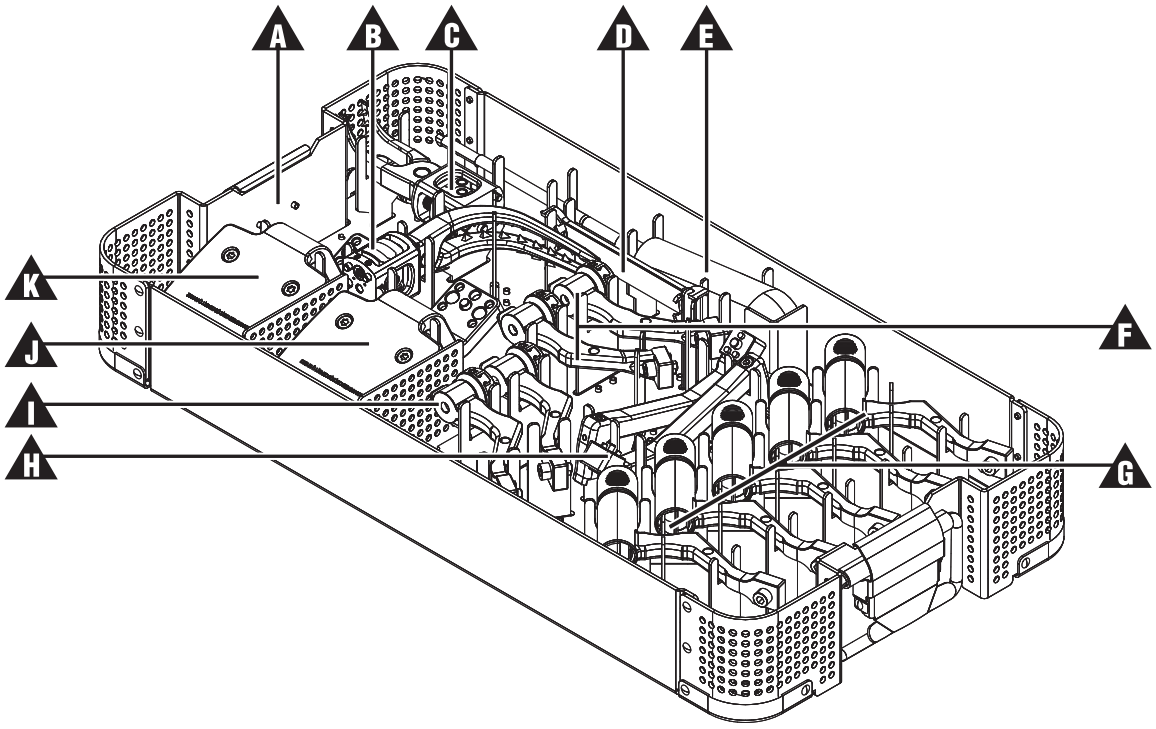
The figure below shows a maximal selection of components.

Figure 4: **XVS** Instrument Tray for Universal Tools (Maximal Configuration)



A XVS Instrument Tray for Universal Tools (ASP00027)
B XVS Arc Clamp (AMCH00006)
C XVS Short Straight Clamp (62 mm) (AMCH00005)
D XVS Wrench (AMCH00030)
E Screwdriver 4 mm (SCDH00004)
F Fixed 3-4 mm universal tool adaptor Leg Up (AMCFSU03)
G Swivel 7.5-9 mm universal tool adaptor Leg Down (AMCRMD75)
H XVS VP Adaptor (AMC00001)
I Fixed 3-4 mm universal tool adaptor Leg Down (AMCFSD03)
J Z-Marker-40 (AMCH01040)
K Z-Marker-60 (AMCH01060)

Figure 5: **XVS** Instrument Tray for Navigated Tools (Maximal Configuration)



A XVS Instrument Tray for Navigated Tools (ASP00011)
B XVS Arc Clamp (AMCH00006)
C XVS Short Straight Clamp (62 mm) (AMCH00005)
D XVS Wrench (AMCH00030)
E Screwdriver 4 mm (SCDH00004)
F Fixed 3-4 mm universal tool adaptor Leg Up (AMCFSU03)
G Navigated Tool Adaptor (AMC04180)
H XVS VP Adaptor (AMC00001)
I Fixed 3-4 mm universal tool adaptor Leg Down (AMCFSD03)
J Z-Marker-40 (AMCH01040)
K Z-Marker-60 (AMCH01060)

4.7. Single Use Sterile Kit

A single use sterile kit containing two Patient Markers 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.

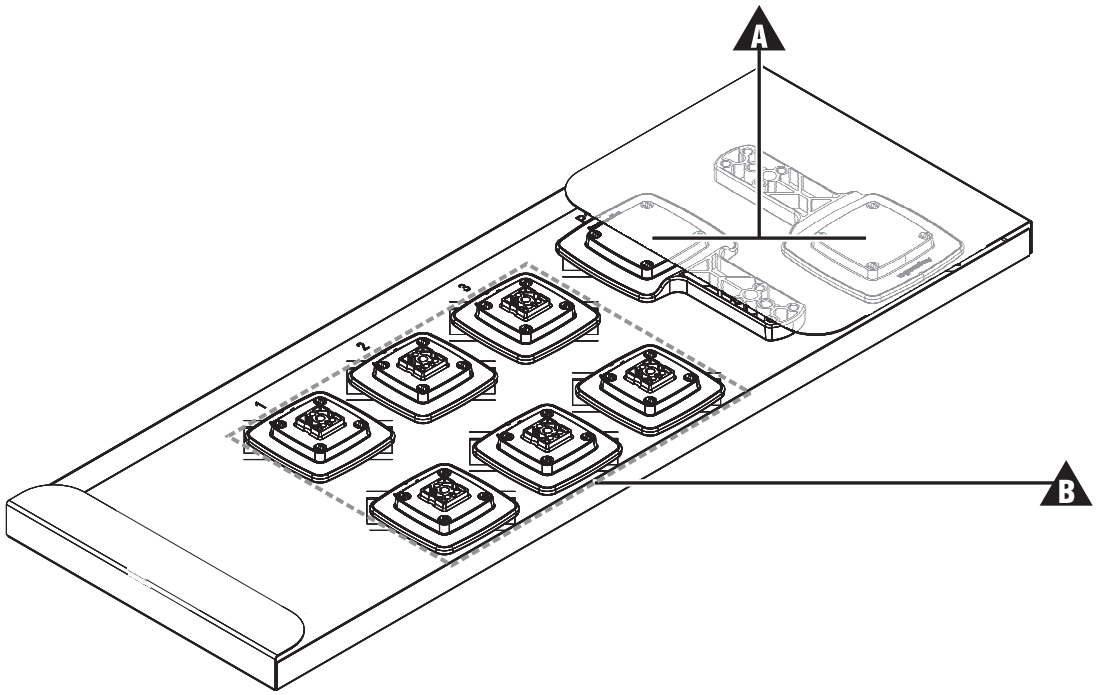
There are no two identical tool markers in a single sterile kit. Tool markers ensure unique identification of the instrument during the procedure.

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 6: Single Use Sterile Kit



A Patient markers (2)
B Tool markers (6)

4.8. Optional Accessories

The following optional accessories are available for the **XVISION-SPINE**.