ARVIS®

Shoulder Surgical Navigation System

Instructions for Use

⚠ WARNING: This document should always be used in conjunction with the ARVIS™ Shoulder Surgical Technique Guide P/N IN-23650 which contains additional product instructions.

A printable copy of the IFU for this device can be located at www.enovis.com/ifu

Table of Contents

System Information

Precaution

Federal (USA) law restricts this device to sale by or on the order of a physician.

General Warnings

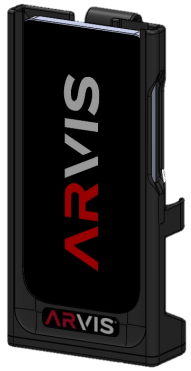
- Read all instructions prior to use.
- Do not operate the system without proper training. The surgeon must be familiar with the ARVIS™ Shoulder Navigation system and the respective compatible implant system's Instructions for Use (IFU) and surgical technique guidelines before proceeding with preoperative planning and surgery.
- Navigation output does not supersede the surgeon's clinical judgment.
- Use only accessories provided with the system. Do not substitute cables or any other components. Do not connect any accessories not provided by the manufacturer to the device's USB connectors, including the headlight output connector. Do not attempt to use a computing device other than the computer module provided with the system.
- Prior to use, check the instruments for wear or damage. Replace damaged or worn instruments before use.
- Prior to use, the coracoid process should be evaluated for suitability of mount fixation utilizing pins.
- The eyepiece includes a headlight, infrared emitter, and Class I laser. The surfaces near the headlight, as well as other surfaces, may become hot during use. Touch only parts of the eyepiece intended for adjustment.
- To avoid potential interference with pacemakers, do not place any system component near the patient's or user's chest. There is potential for electromagnetic interference. If the device interferes with other equipment, reposition or discontinue use of the device. If the device receives harmful interference affecting its function, discontinue use.
- Do not modify or service any system component.
- The ARVIS™ system includes the eyepiece, belt pack, battery, chargers, and instrument set. Instruments are provided NON-STERILE and must be cleaned and sterilized prior to each use. Electrical components are NON-STERILE and must not be sterilized.
- To avoid the risk or electric shock, this equipment must only be connected to a supply mains with protective earth.
- To maintain cybersecurity and correct operation, do not change settings on the provided computer module except as directed by Kico.
  - The computer module hosts a Mobile Device Management (MDM) tool that limits the function of the

device to only those essential for use. MDM protects the surgeon against potential cybersecurity risks. Do not attempt to remove or tamper with this capability.

- If the computer module alerts the surgeon that a security event has occurred, please discontinue use immediately and contact Kico.
- Do not attempt to enable Wi-Fi or cellular communication except as directed by Kico.
- Do not attempt to install or remove applications or store non-Kico data.
- Do not attach any devices to the USB port except as directed by Kico.
- Kico recommends installing a password to restrict access to the computer module.
- Kico recommends trusted users remember to control any removable drives used to transport encrypted plan files to the system and not use drives for any purposes other than storing and transferring plan data files.
- Confirm password and/or plan import in advance of patient being anesthetized
- Review and confirm patient and plan details before plan selection
- Stainless steel surgical instrumentation may contain nickel which is a known sensitizer. Sound medical judgement should be used if nickel sensitivity or allergy is suspected.

Gen 1

Gen 2



System Description

ARVIS™ Shoulder is a computer-controlled surgical navigation system for shoulder arthroplasty. It combines software, electronic hardware and surgical instruments to intraoperatively track tools and locate anatomical structures and display feedback to the user. The system aids the surgeon in executing an approved preoperative plan.

Both the Gen 1 and Gen 2 ARVIS™ Eyepieces contain stereo IR tracking cameras, a color camera, stereo display, IR illumination, and IR laser illuminator. A visible headlight is mounted to the Eyepiece and connected via a micro-USB cable. The Eyepiece communicates with the Belt Pack via a USB-C cable. All system instructions, prompts, alerts, and outputs are displayed to the surgeon on the Eyepiece display.

The Belt Pack includes the computer module, battery, and power management board. The Belt Pack supplies power to the Eyepiece and runs the ARVIS™ Shoulder Application Software. For Gen 2 systems, the Belt Pack also supplies power to the computer module.

The ARVIS™ electronics are worn on the surgeon's body during surgery. There is no interface to external equipment except for the ARVIS™ Battery Charger, which recharges the battery when not in use.

ARVIS™ uses tracking cameras to measure the positions of trackers on the patient or instruments. ARVIS™ displays measurements as described in Performance Claims. Measurements are not displayed when a required tracker is not detected and in range of tracking cameras. Valid camera operating range extends at least from 40cm to 70cm from the Eyepiece, but ARVIS™ may be able to provide accurate measurements at shorter or longer ranges.

Performance Claims

ARVIS™ Shoulder measures the following parameters with the stated accuracy in simulated use on benchtop fixtures.

- Humeral resection inclination and version with an average absolute error of ≤ 2.0 °
- Humeral resection depth with an average absolute error of ≤ 2.0mm
- Drill inclination and version with an average absolute error of ≤ 1.5 °
- Superior/Inferior and Anterior/Posterior location of drill entry point with an average absolute error of ≤ 1.5mm on each axis
- Glenoid implant inclination and version with an average absolute error of ≤ 1.5 °
- Reaming Implant depth with an average absolute error of ≤ 2mm.
- Rotation of the glenoid implant about its central axis with an average absolute error of ≤ 2.0 °
- Length range of a virtual screw (up to 50mm) extending from a theoretical glenoid baseplate with an average absolute error of ≤ 1.5mm

Clinical accuracy depends on accurate registration and inputs to the ARVIS™ Shoulder Application Software. The system has been validated in simulated clinical use (cadaver) to achieve the following accuracy:

- Humeral resection inclination and version with an average absolute error of ≤ 3.0 °
- Humeral resection depth with an average absolute error of ≤ 2.0mm
- Superior/Inferior, Anterior/Posterior, and Medial/Lateral location of glenoid implant with an average absolute error of ≤ 2.0mm on each axis
- Glenoid implant inclination and version with an average absolute error of ≤ 3.0 °
- Rotation of the glenoid implant about its central axis with an average absolute error of ≤ 3.0 °
- Length range of a virtual screw (up to 50mm) extending from a theoretical glenoid baseplate with an average absolute error of ≤ 2.0mm

Principle of Operation

ARVIS™ Shoulder is an image-based surgical navigation system. A CT scan of the patient's shoulder joint is required to create a preoperative surgical plan including a landmarked digital bone model which is matched to intraoperative landmarks registered by the surgeon.

ARVIS™ uses cameras in the Eyepiece to measure locations and angles between trackers mounted on the patient and trackers mounted on instruments. By prompting the surgeon through a procedure-specific workflow to register the reference tracker to anatomic landmarks, the ARVIS™ Shoulder Application Software running on the belt pack calculates and displays positions of the instruments relative to the patient's anatomy.

Intended Use

The ARVIS™ system is a computer-controlled navigation system intended to provide intraoperative measurements to the surgeon to aid in selection and positioning of orthopedic implant components.

Indications For Use

ARVIS™ Shoulder is indicated for assisting the surgeon in the positioning and alignment of implants relative to reference alignment axes and landmarks in stereotactic orthopedic surgery.

The system aids the surgeon in making intraoperative measurements and locating anatomical structures of the shoulder joint based on the patient's preoperative imaging.

The system is intended to be used with the head mounted ARVIS™ Eyepiece display for augmented reality visualization of information, such as visualization of the preoperative plan and display of instrument and implant alignment information. The augmented/virtually displayed information should not be relied upon solely for absolute positional/alignment information and should always be used in conjunction with the displayed stereotaxic information.

ARVIS™ Shoulder is indicated for total shoulder arthroplasty using the Enovis AltiVate®, LimaCorporate PRIMA™, and LimaCorporate SMR™ implant systems.

Contraindications

- Significant loss of bone affecting identification of the required landmarks
- Excessive soft tissue interference affecting identification of the required landmarks
- Severe osteoporosis at fixation site(s), including but not limited to weakness of the coracoid process which could lead to adverse effects
- The presence of infection
- Any contraindication associated with shoulder arthroplasty surgery

Adverse Effects

Possible adverse effects include premature implant failure, dislocation or instability, decreased range of motion, infection, tissue injury, nerve injury and weakness, fracture, foreign body reaction, increased anesthesia time, heart attack, vascular injury, neck injury, burns, electrical shock, and cardiovascular injury.

Please inform the manufacturer and the national authority if you believe a product-related incident has occurred while using this device

Compatibility

- ARVIS™ Shoulder is indicated for use with the Enovis AltiVate®, LimaCorporate PRIMA™, and LimaCorporate SMR™ implant systems.
- Steinmann Pins (x2), 2.5mm x 100mm, are required for the Mechanical Mount. The system was validated using 170-00-002 Tech Shoulder Pack.
- Precision AI Surgical Planning Software must be used for preoperative planning before navigation.
- Stryker® Flyte®or T7® helmet together with provided compatible adaptors can be used to wear the ARVIS™ Eyepiece.

User Profile

The ARVIS™ system is to be used by orthopedic surgeons and operating room staff who perform shoulder arthroplasty. Users should reference the ARVIS™ Shoulder Surgical Technique Guide P/N IN-23650 for step-by-step product instructions. Training on product usage is available, and strongly recommended.

To arrange training, contact Kico.

Usage Environment

The ARVIS™ system is designed for use within hospital operating room environments. Infrared Radiation (IR) sources, including operating room lights and windows, may interfere with the cameras that are part of the ARVIS™ system. Avoid environments with excessive IR sources.

The ARVIS™ system is designed for use in a hospital operating room within the following conditions:

- Temperature (15°C to 25°C)
- Humidity (20% to 80% non-condensing)
- Pressure (70kPa to 106 kPa)

The ARVIS™ Eyepiece is worn on the surgeon's head. The ARVIS™ Belt Pack is worn on the surgeon's belt or waistband. No electronic hardware is applied to the patient. The surgeon stands adjacent to the patient to operate.

The ARVIS™ Battery Charger is intended to be used outside the operating room.

Patient Population

ARVIS™ is intended for patients undergoing orthopedic surgery where rigid anatomic structures, such as the scapula and humerus, can be identified and referenced.

Clinical Benefit

Surgical and navigation instruments assist in the implantation of prostheses and do not have a direct therapeutic or diagnostic function.

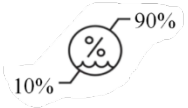
Definition of Symbols

The following symbols are used in the ARVIS™ system labeling:

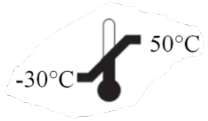
Follow Instructions for use

Do not dispose in trash

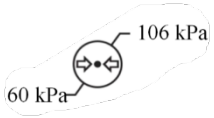
Non-Sterile



Humidity



Storage Temperature



Pressure

Manufacturer

Serial Number

Catalog Number

Caution

Hardware Information

ARVIS™ Shoulder Instrument Set Components (P/N IN-23600)

Catalog Number	Description
IN-20010	ARVIS Outer Case
IN-23500	ARVIS Shoulder Tray Insert
IN-23400	ARVIS Shoulder Tray Lid
IN-22100	In-Line Trigger Stylus
IN-23000	Mechanical Mount
IN-24000	Mechanical Tracker A
IN-26000	Cobb Elevator, 1 in
IN-10800	3.5mm Hex Driver
IN-18300	Glenoid Drill Guide
IN-22200	Reverse Registration Tool
IN-18500	Reference Pin Guide
IN-22400	Straight Reamer Adapter
IN-22500	Adjustable Humeral Guide
IN-22600	Tracker B, Mechanical
IN-22800	Stem Adapter
IN-22900	Wedge Reamer Adapter
IN-23100	Anatomic Guide Tip, Small
IN-23200	Anatomic Guide Tip, Large
IN-26100	Anatomical Rotation Guide

ARVIS™ Gen 2 Electronic Hardware Components and Accessories – US (P/N IN-29200)

Catalog Number	Description
IN-29001	ARVIS Eyepiece Assembly, Gen 2
IN-29002	ARVIS Belt Pack, Gen 2
IN-29003	ARVIS Computer Module, Gen 2
IN-29030	Screencast Tablet, Gen 2
IN-21904	ARVIS Screen Cast Router
IN-12800	ARVIS Battery
IN-13000	ARVIS Battery Charger
IN-13800	ARVIS Charger Power Supply
IN-29018	ARVIS Cables Kit, Gen 2, Global
IN-29019	ARVS Wall Adapters Kit, US
IN-17700	ARVIS Installation Kit

Use only accessories supplied by the manufacturer.

ARVIS™ Gen 1 Electronic Hardware Components and Accessories (P/N IN-23620[1])

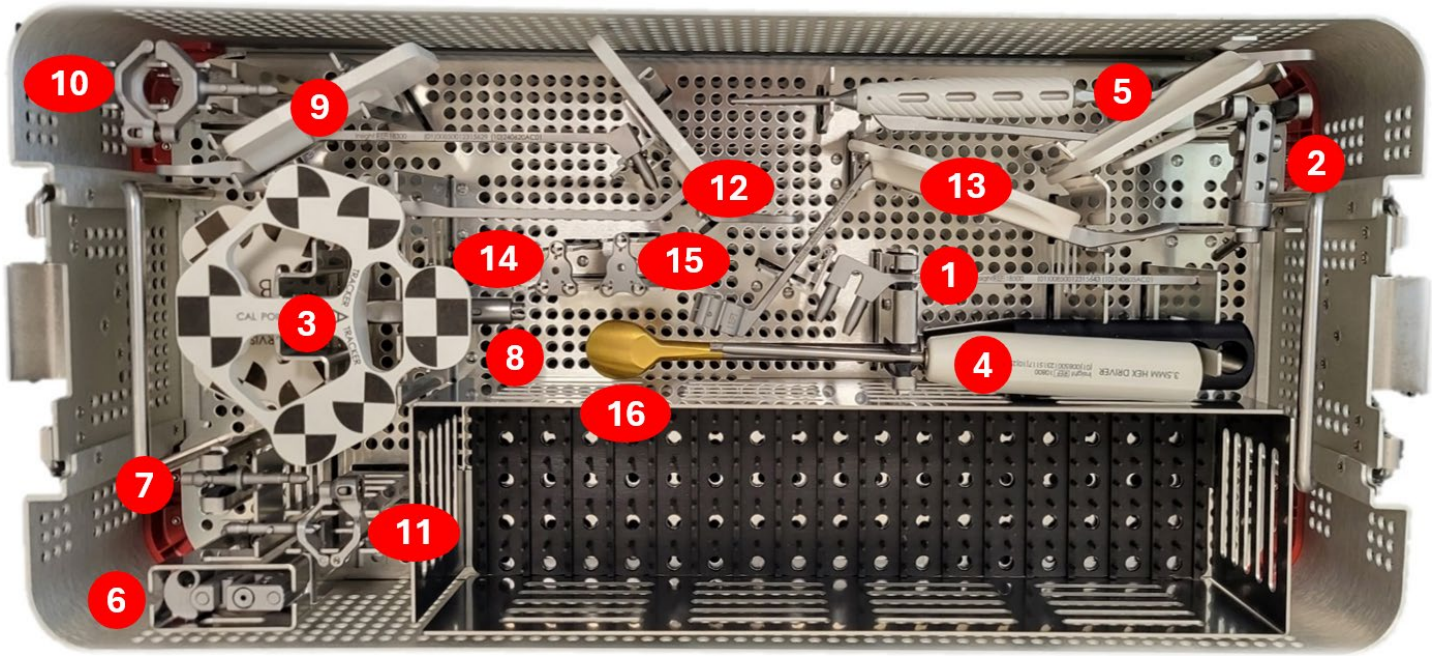
Catalog Number	Description
IN-12400	ARVIS Eyepiece Assembly
IN-12500	ARVIS Belt Pack
IN-12700	ARVIS Computer Module
IN-12800	ARVIS Battery
IN-13200	ARVIS Eyepiece Cable
IN-13000	ARVIS Battery Charger
IN-13800	ARVIS Charger Power Supply
IN-15202	Cable, USB-C, 1m
IN-17700	ARVIS Installation Kit

Use only accessories supplied by the manufacturer.

Surgeon/Case-Specific ARVIS™ Accessories

Catalog Number	Description
Gen 1 Compatible[2]	
IN-17100	ARVIS Headband
IN-17500	FLYTE Mounting Kit
IN-21700	T7 Adapter Kit
Gen 2 Compatible	
IN-29100	ARVIS Headband, Gen 2
IN-29101	Flyte Mount Kit, Gen 2
IN-29102	T7 Mount Kit, Gen 2
Other	
170-00-002	Tech Shoulder Pack
IN-21900	ARVIS Screen Casting Kit
IN-13900	ARVIS Charger Cord, USA
IN-15201	Wall Adapter, 25W, USA

1. Alternative versions of Electronic Hardware are available with ARVIS accessories included, including but not limited to IN-23610
2. See IN-14001 for mounting instructions.



1. Reference Pin Guide
2. Mechanical Mount
3. Tracker A, Mechanical
4. 3.5mm Hex Driver
5. In-Line Trigger Stylus
6. Adjustable Humeral Guide
7. Stem Adapter
8. Mechanical Tracker B
9. Glenoid Drill Guide
10. Straight Reamer Adapter
11. Wedge Reamer Adapter
12. Reverse Registration Tool
13. Anatomical Rotation Tool
14. Anatomic Guide Tip, Small
15. Anatomic Guide Tip, Large
16. Cobb Elevator, 1 in

Electronics Cleaning Instructions

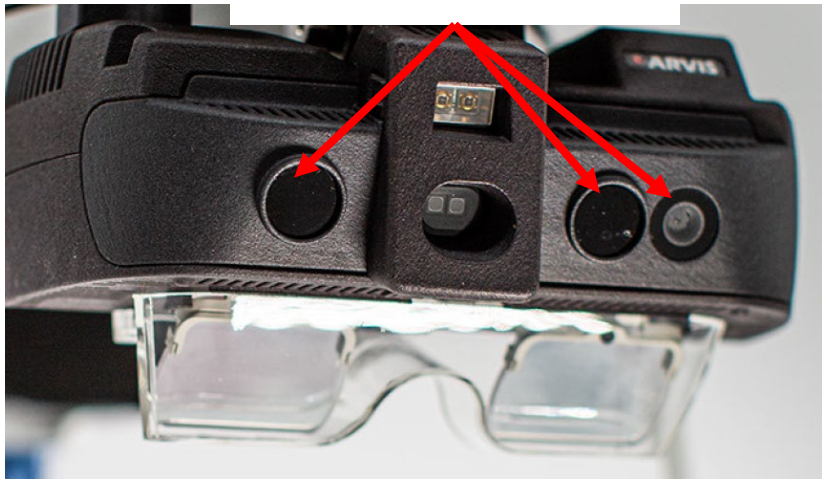
The electronic hardware components comprising the ARVIS™ system are the Eyepiece, Belt Pack, Battery, and Chargers. The electronic hardware components are re-usable.

- The Chargers are not intended for use in the operating room.
- The Eyepiece does not provide eye protection. If there is a likelihood of airborne blood or other soil, the user is advised to wear a legally marketed face shield for protection. The user is further advised to wear a legally marketed surgical gown or toga when a likelihood of soiling exists.

With appropriate attire, the electronic components of the ARVIS™ system should not need frequent cleaning, but they may be cleaned as described below as needed.

- Remove the ARVIS™ Battery and shut down the ARVIS™ Computer Module.
- Wipe with isopropyl alcohol solution (70-99%) using a lint-free cloth for one minute. Follow all label instructions for isopropyl alcohol.
- Do not use abrasive brushes or cloths.
- Take care not to scratch the camera covers. Visually inspect each camera cover after cleaning to verify that there are no scratches or residue.
- Take care not to introduce excess liquids into the Eyepiece via the cooling vents.
- Do not immerse. Do not sterilize. Allow to dry fully prior to use.
- Do not use phenolic disinfectants, as they may damage the Eyepiece or Belt Pack enclosures.

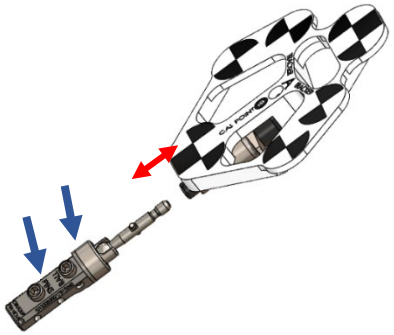
Camera Covers
(Gen 1 eyepiece shown)



Instrument Cleaning Instructions

The ARVIS™ Instruments are re-usable. Clean and sterilize all instruments prior to first use and after every use.

1. Clean the instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse, or use moist towels or sponges soaked with distilled or de-ionized water to keep moist prior to cleaning.
2. Disassemble instruments into the component parts listed in the "ARVIS™ Shoulder Instrument Set Components" table.
    a. Separate tracker from mount.
    b. Loosen all screws in Mechanical Mount IN-23000, IN-22900 Wedge Reamer Adapter, IN-22400 Straight Reamer Adapter, and IN-22500 Adjustable Humeral Guide



3. Rinse instruments under running cold utility (tap) water to remove gross soil.
    a. While rinsing, actuate all moving parts of the instruments and use a soft bristled brush to aid in removal of gross soil.
4. Flush utility (tap) water through lumens and other hard-to-reach areas of instruments.
5. An ultrasonic cleaner may be optionally used.
6. Load the instruments into automated parts washer for processing.
7. Run the automated washer with the following parameters:
    a. Pre-wash for 2 minutes with cold tap water.
    b. Enzyme wash for 2 minutes with hot tap water and enzymatic detergent prepared per the manufacturer's directions for use.
    c. Rinse for 5 minutes with 43°C (nominal) de-ionized or reverse-osmosis water.
    d. Dry for 7 minutes at 90°C (nominal).
8. After cleaning, instruments (disassembled, if applicable) should be visually inspected. All steps of the cleaning process should be repeated for incompletely cleaned instruments.

Note: Use of water-soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively to another instrument.

Autoclave Sterilization of Re-Usable Instruments

- Wrapped pre-vacuum, 4 minutes at 270°F (132°C). Dry time is 45 minutes*. Use an FDA-cleared wrap or sterile barrier. (Validation is based on use of Halyard Health H400.)
- Unwrapped pre-vacuum ("Flash"), 4 minutes at 270°F (132°C).
  *In addition to the prescribed dry time, an additional 30-minute cool down after removal from the sterilization chamber is recommended to ensure the devices are free from condensation and other moisture.

The recommended sterilization process has been validated to produce a sterility assurance level of (10^{-6}) when parts have been cleaned to the instructions above. Other steam cycles and cleaning procedures have not been evaluated and must be qualified by the user.

Effective sterilization is predicated on thorough cleaning and drying processes. Failure to do so will compromise the sterilization process and render the processed instrument unsuitable for clinical use.

Disposal

Do not throw any part of this system in the trash. Dispose of components in accordance with local regulations and the standard waste procedures of the healthcare institution.

Storage and Transportation

Temperature: -30 to 50 °C; Humidity: 10 to 90% RH; (non-condensing); Pressure: 60 kPa to 106 kPa.

Handle with care.

Maintenance

Prior to each use, check the instruments for wear or damage. Note especially the condition of tracker markings and fit of interfaces between trackers and tracker mounts. Although the system's instruments do not have a usage limit and are expected to last for extended use, damaged or worn instruments should be replaced. Use of damaged instruments may lead to errors in navigation.

Follow instructions for the proper inspection, cleaning, and sterilization (as applicable) of system components. No further maintenance is required. Do not service or modify any system component.

Any part failing to perform as intended should be reported to the manufacturer for resolution.

Warranty

The product is warranted to be free from defects in material and workmanship.

Electrical Safety

This equipment has been tested and found to comply with EMC limits per IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interface with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult Kico or authorized representative for help.

FCC ID: SH6MDBT42Q This device compiles 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 that may cause undesired operation.

Operating Conditions: Temperature: 15-25 °C; Humidity: 20-80% (RH) non-condensing; Pressure: 70-106kPa.

Warning: This device is designed for very specific tasks. Use in an environment containing EM disturbances outside the capability of this device may compromise the surgical outcome.

Warning: This device is not designed for use next to or stacked with other equipment. Use next to or stacked with other equipment should be avoided due to improper operation.

Warning: Use of batteries, computing modules or cables other than those provided by Kico could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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 ARVIS™ system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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 reorienting the equipment.

Note: This device has been tested for electromagnetic immunity and shown to maintain essential performance (tracking error ≤5mm) when exposed to expected levels of electromagnetic disturbances (further defined in the subsequent tables). The system has internal software quality controls, which stop progression through the workflow. If a user repeatedly fails to progress beyond a step in the workflow, the user should first ensure they are properly following the surgical technique and that there are no obstructions blocking the eyepiece. If still unable to proceed, the user should discontinue use of the device.

Disturbances to the ARVIS™ System when in use may result in:

- Loss of Tracker visibility
- Loss of ARVIS™ Eyepiece functionality
- Unexpected shut down of the system

The ARVIS™ system is battery powered, which modifies the applicable EMC immunity tests. Shown here are the emissions and immunity tests applicable to the ARVIS™ system comprised of the eyepiece, belt pack, battery and USB cable assembly that is worn by the user during surgery.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The ARVIS™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS™ system should assure that it is used in such an environment.		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF Emissions CISPR 11	Group 1	The ARVIS™ product uses RF energy only for internal function (except for intentional communication). RF emissions are very low and not likely to cause interference with nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ARVIS™ product is suitable for use in all non-domestic establishments.
RF emissions IEC 61000-3-2	N/A	
RF emissions IEC 61000-3-3	N/A	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The ARVIS™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS™ system should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/-15 kV air	+/- 8 kV contact +/-15 kV air	Normal ESD preventions should be taken, including use in the absence of floors covered with synthetic material. Relative humidity should be at least 20%.
Electrical fast transient / burst IEC 61000-4-4	Not Applicable to Battery Powered ARVIS™		
Surge IEC 61000-4-5	Not Applicable to Battery Powered ARVIS™		
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable to Battery Powered ARVIS™		
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.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The ARVIS™ system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS™ system should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Conducted RF IEC 61000-4-6	Not Applicable to Battery Powered ARVIS™		
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ARVIS™ product (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 2.3*(P)^{1/2}$ $d = 2.3*(P)^{1/2}$ 800 MHz to 2.7 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.

RECOMMENDED SEPARATION DISTANCES TO NEARBY TRANSMITTERS	
The ARVIS™ system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the ARVIS™ system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ARVIS™ system as recommended below, according to the maximum output power of the communications equipment.	
Nearby Transmitter's EIRP (W)	**Minimum Separation Distance (m)**
10	1.33
1	0.42
0.1	0.13
0.01	0.04

In addition to the battery powered ARVIS™ system, support equipment is provided to charge the ARVIS™ battery as needed. This support equipment is not part of the operating environment and is not required during surgery. The support equipment has been tested to the standards shown in this table.

Safety & EMC	**In combination with included external AC/DC power supply**	
Regulatory Approvals	Europe	CE
	International	CB
Electromagnetic Emissions	Europe	EN55011, EN55032, level B
	USA	FCC15 class B
Electromagnetic Immunity	ESD Immunity	EN/IEC61000-4-2
	Electromagnetic field immunity	EN/IEC61000-4-3
	EFT / Burt	EN/IEC61000-4-4
	Surge	EN/IEC61000-4-5
	Conducted Immunity	EN/IEC61000-4-6
	Magnetic Fields	EN/IEC61000-4-8
	Voltage dips, short instrumentations & voltage variations	EN/IEC61000-4-11
	Immunity characteristics	EN55024

Preoperative Planning

The goal of preoperative planning for ARVIS™ Shoulder is to define CT-based anatomical models and references, and desired implant positions for use during stereotactic surgery to assist the surgeon in the positioning of orthopedic implants.

Operating Instruction

The planning software is web based and does not require installation.
To log into the platform the user first needs to enter their username and password. To obtain access to the website, please send a request to support@precisionai.com.au.
The planning software consists of several pages for various stages of the surgical planning process.
The surgeries overview page provides an overview of all the surgical cases that are available for that account.
To commence planning and for more detailed instructions, please refer to the ARVIS™ Shoulder Surgical Technique Guide P/N IN-23650.

Privacy Statement

All personal patient information stored within the software will be deidentified before being stored. No personal patient information will be shared with third parties. All information sent to third parties will be deidentified before sending.

Warnings and Precautions

- This software must only be used by trained, qualified persons, aware of the directions for use.
- Ensure that the minimum system requirements are used as outlined in this document.

Packaging and Labelling

The software is web-based, therefore, there is no packaging requirement applicable for this software. However, a copy of these Instructions for Use will be made available to each user prior to use of the software.

Cybersecurity

The software operates within a secure operating platform which includes systems to monitor and identify vulnerabilities and reduce any risks of cyber-attacks.

System Requirements

Minimum and recommended system requirements for using the planning software are as follows:

Minimum system requirements

Web browser:
Google Chrome (v.107 or later)
Apple Safari (v.16 or later)

Operating system:
Microsoft Windows 8 or newer
MacOS 10.x or newer

Screen resolution:
1280 x 800

Internet:
Internet connection required.
Internet connection 10Mbps or higher

Recommended system requirements

Web browser:
Google Chrome (v.107 or later)

Operating system:
Microsoft Windows 10 or 11
MacOS 12.x

Screen resolution:
1920 x 1080

Symbol Legend (Planning software)

LOT	Software version number		Warning
	Software release date	UDI	Unique device identifier
Rx Only	Prescription only	MD	Medical device

Further Information

If further information on this product is needed or you wish to obtain a return product authorization, please contact Customer Service at 1-800-456-8696 (Central Time 8:00 AM - 5:00 PM) in the USA.

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This document is intended for the US market only.