ARVIS® Surgical Navigation System

Instructions for Use

Model: ARV-01

CE
2797

⚠ WARNING: This document should always be used in conjunction with the ARVIS® Hip and Knee Surgical Technique Guide P/N IN-16000 which contains additional product instructions. Access the Surgical Technique Guide at www.insightmedsys.com/resources with password “ARVIS”.

Insight Medical Systems, Inc. www.insightmedsys.com

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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. It is the surgeon's responsibility to be familiar with this technique prior to 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.
- The eyepiece includes a headlight, infrared emitter and Class I laser. The surfaces near the IR emitter, as well as other surfaces, may become hot during use. Touch only parts of the eyepiece intended for adjustment.
- The system contains magnets. To avoid potential interference with pacemakers, do not place any system component near the patient's or user's chest.
- There is a 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, charger, 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 Insight Medical Systems.
  - Do not enable Wi-Fi or cellular communication except as directed by Insight Medical Systems.
  - Do not install or remove applications or store non-Insight data.
  - Insight recommends installing a password to restrict access to the computer module.
- 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.

System Description

The **ARVIS** Eyepiece contains 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** Application Software.

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 the 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 the 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 measures the following parameters with the stated accuracy with 95% confidence in simulated use on benchtop fixtures.

Total Hip Arthroplasty

- Anteversion and inclination of the acetabular cup inserter within ±3°
- Changes in leg length within ±2mm
- Sagittal plane pelvic tilt within ±3° for supine workflow Knee

Arthroplasty

- Coronal and sagittal plane resection angles within ±2°
- Tibial resection depth within ±2mm
- Axial rotation of a tool relative to the femur within ±2°

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

Total Hip Arthroplasty

- Anteversion and inclination of the acetabular cup angle within ±10°, with 90% confidence
- Changes in leg length within ±5.5mm, with 95% confidence Total

Knee Arthroplasty

- Tibial coronal plane resection angle within ±2°, with 90% confidence
- Tibial sagittal plane resection angle within ±3°, with 90% confidence
- Tibial resection depth within ±2.5mm, with 90% confidence
- Femoral coronal plane resection angle within ±3°, with 90% confidence
- Femoral sagittal plane resection angle within ±3°, with 90% confidence

Unicompartmental Knee Arthroplasty (Transverse Resection)

- Coronal plane resection angle within ±2°, with 90% confidence
- Sagittal plane resection angle within ±3°, with 90% confidence

Principle of Operation

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 user through a procedure-specific workflow to register the reference tracker to anatomic landmarks, the **ARVIS** 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 intra-operative measurements to the surgeon to aid in selection and positioning of orthopedic implant components.

Indications For Use

The **ARVIS** system 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 such as changes in leg length in Hip Arthroplasty. The system is compatible with straight acetabular impactors and with specific offset impactors, identified in the instructions for use, for which an adapter has been validated.

Example orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty
- Unicompartmental Knee Arthroplasty: Tibial Transverse Resection
- Hip Arthroplasty

Contraindications

Knee Arthroplasty

- Significant loss of bone affecting identification of the required landmarks
- Severe osteoporosis at fixation site(s)
- Hip ankylosis or any other hip condition limiting range of motion of the hip to less than 10° abduction/adduction or flexion/extension
- Severe hip arthritis or any other disease of the hip causing it to no longer approximate a ball joint
- The presence of infection
- Any contraindication associated with knee arthroplasty surgery

Hip Arthroplasty

- Excessive soft tissue interference affecting identification of the required landmarks
- Severe osteoporosis at the fixation site(s)
- The presence of infection
- Any contraindication associated with hip arthroplasty surgery

Adverse Effects

Possible adverse effects include premature implant failure, dislocation or instability, decreased range of motion, limp, 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

User Profile

The **ARVIS** system is to be used by orthopedic surgeons and operating room staff who perform hip arthroplasty and knee arthroplasty. Users should reference the ARVIS® Hip and Knee Surgical Technique Guide P/N IN-16000 for step-by-step product instructions. Training on product usage is available, and strongly recommended.

To arrange training, contact Insight Medical Systems, Inc.

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 to 25°C)
- Humidity (20-80% non-condensing)
- Pressure (70-106 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 orthopaedic surgery where rigid anatomic structures, such as the pelvis, femur, or tibia; 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:

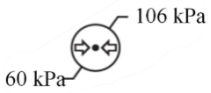
Follow Instructions for use

Do not dispose in trash

Non-Sterile

Humidity

Storage Temperature



Pressure

Manufacturer

Catalog Number

Authorized Representative in the EU

Importer

Hardware Information

ARVIS 2.0 Instrument Set Components (P/N IN-21200)

Catalog Number	Description
IN-20000	Instrument Tray Base
IN-11000	Instrument Tray Lid
IN-17200	Pin Caddy
IN-17300	Pin Caddy Lid
IN-18600	Registration Stylus
IN-10200	Reference Mount
IN-10400	Tracker D
IN-10500	Impactor V-Block Assembly
IN-10600	Tracker B
IN-15900	Impactor Adapter, DJO
IN-10800	3.5mm Hex Driver
IN-16300	Tibial Slot Adapter
IN-20100	Adjustable Mount, 1
IN-20200	Adjustable Mount, 2
IN-20300	Tibial Reference Mount, Left
IN-20400	Tibial Reference Mount, Right
IN-21000	Flex Jack
IN-15600	Femoral Cutting Block
IN-19100	Precision Adjustable Distal Guide
IN-16400	Tracker A
IN-16100	Tracker C
IN-15700	Femoral Reference Mount, Left
IN-15800	Femoral Reference Mount, Right
IN-14700	Landmark Punch
IN-16200	Femoral Slot Adapter
IN-19900	Resection Check Tool
IN-18900	Femoral AP Sizer Adapter
IN-20500	Pin Driver

ARVIS Electronic Hardware Components and Accessories (P/N IN-50000[1])

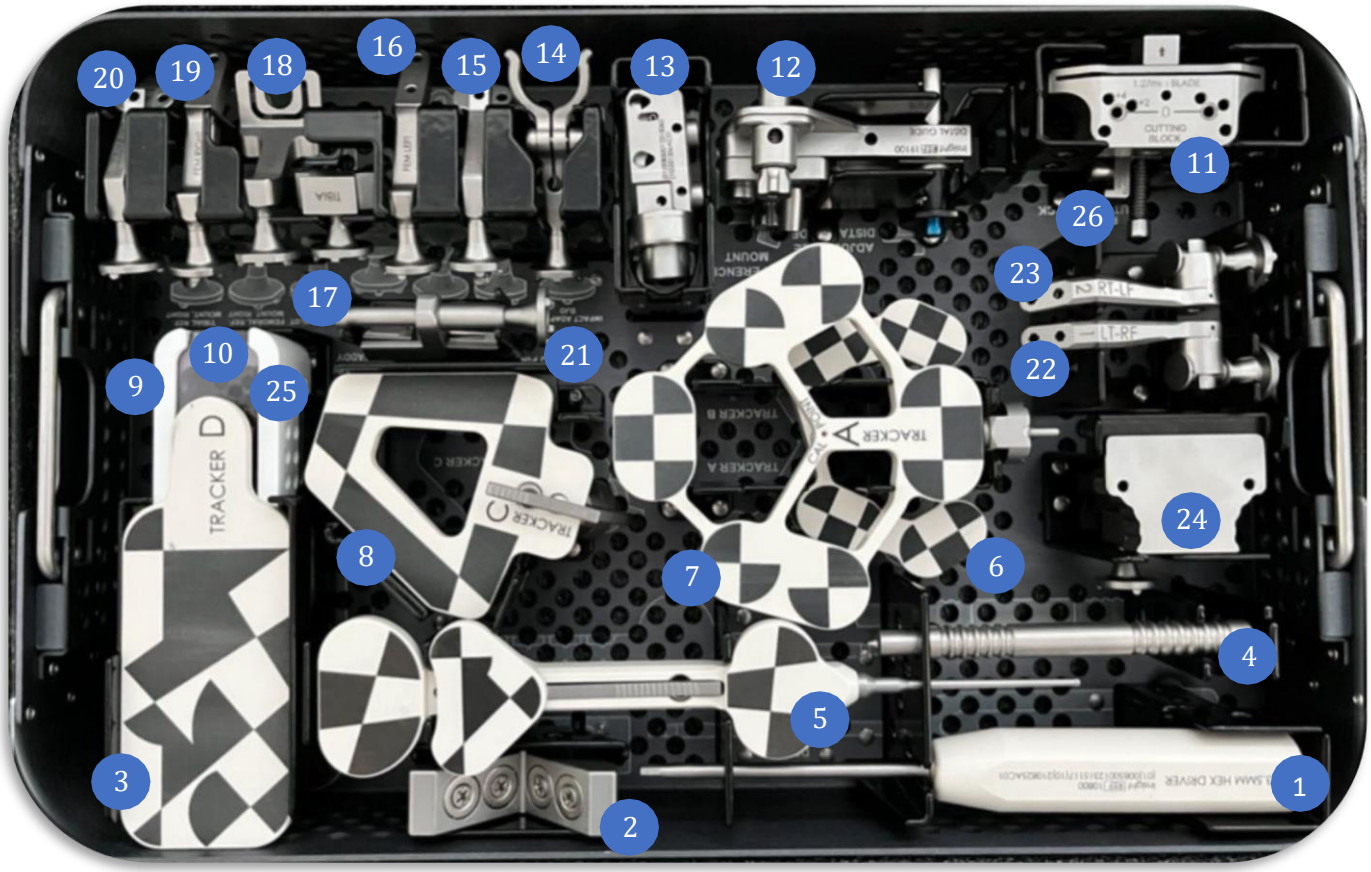
Catalog Number	Description
IN-12400	ARVIS Eyepiece Assembly
IN-12500	ARVIS Belt Pack
IN-12700	ARVIS Computer Module
IN-12800	ARVIS Battery
IN-13200	ARVIS Eyepiece Cable
IN-13000	ARVIS Battery Charger
IN-13800	ARVIS Charger Power Supply
IN-15202	Cable, USB-C, 1m
IN-14103	Cable Hook
IN-17700	ARVIS Installation Kit

Use only accessories supplied by the manufacturer.

Surgeon/Case-Specific ARVIS Accessories

Catalog Number	Description
Select one per surgeon preference	
IN-17100	ARVIS Headband[2]
IN-17500	FLYTE Mounting Kit[2]
IN-21700	T7 Adapter Kit[2]
IN-13900	ARVIS Charger Cord, USA
IN-13910	ARVIS Charger Cord, AU
IN-13920	ARVIS Charger Cord, EU
IN-15201	Wall Adapter, 25W, USA
IN-15221	ARVIS Wall Adapter, AU
IN-15211	ARVIS Wall Adapter, EU
Select one or more per surgery (TKA, THA, UKA)	
150-00-001	Tech Knee Pack
150-00-002	Tech Ancillary Pack
160-00-001	Tech Hip Pack

1. Alternative versions of Electronic Hardware are available with ARVIS accessories included, including but not limited to IN-14100
2. See IN-14001 for mounting instructions.



P/N IN-21200 Rev A ARVIS Hip & Knee Instrument 2.0 Set (*Cover Removed*)

1. 3.5mm Hex Driver
2. Impactor V-Block Assembly
3. Tracker D
4. Landmark Punch
5. Registration Stylus
6. Tracker B
7. Tracker A
8. Tracker C
9. Pin Caddy
10. Pin, 4mm X 115mm (in caddy)
11. Femoral Cutting Block
12. Precision Adjustable Distal Guide
13. Reference Mount
14. Impactor Adapter, DJO
15. Tibial Reference Mount, Left
16. Femoral Reference Mount, Left
17. Tibial Slot Adapter
18. Femoral Slot Adapter
19. Femoral Reference Mount, Right
20. Tibial Reference Mount, Right
21. Femoral AP Sizer Adapter
22. Adjustable Mount, 1
23. Adjustable Mount, 2
24. Resection Check Tool
25. Pin Driver (in caddy)
26. Flex Jack

Electronics Cleaning Instructions

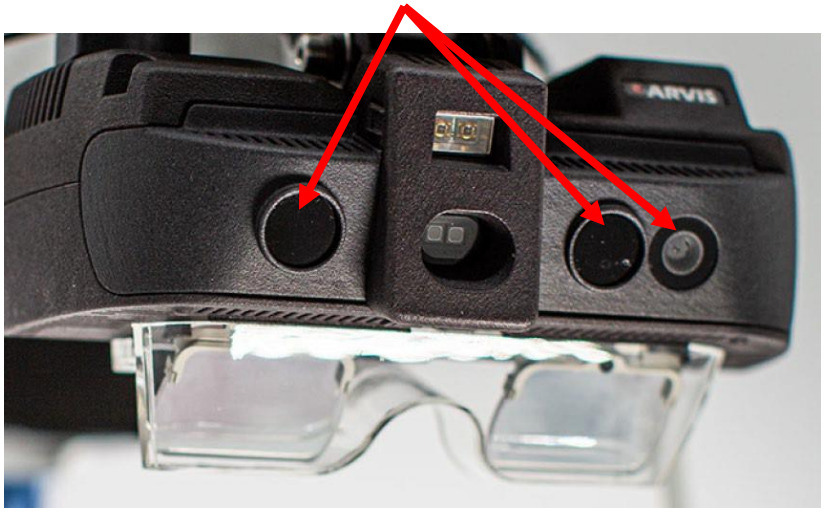
The electronic hardware components comprising the **ARVIS** system are the Eyepiece, Belt Pack, Battery, and Charger. The electronic hardware components are re-usable.

- The Charger is 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

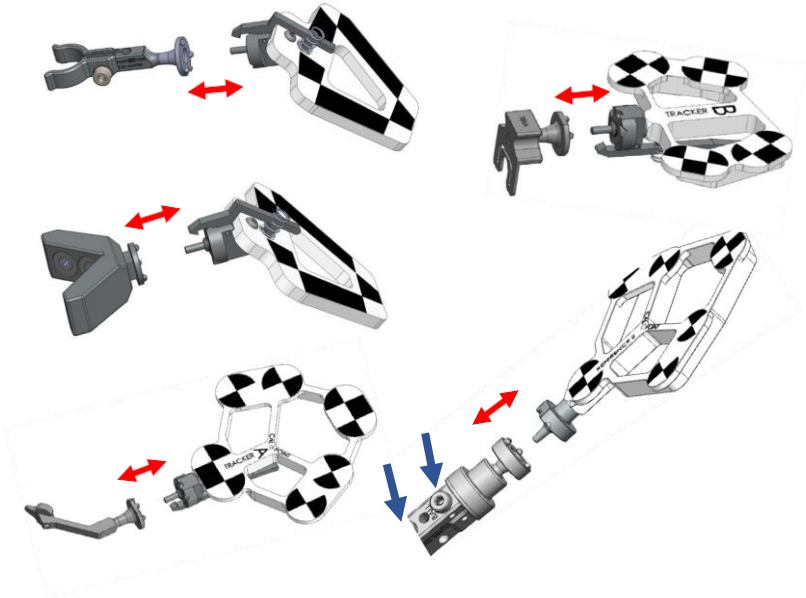


Instrument Cleaning Instructions

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** Instrument Set Components" table.
    a. Separate all trackers from reference mounts or adapters to which they may be coupled.
    b. Separate slot adapters from cutting blocks.

c. Loosen both clamping screws in Reference Mount IN-10200.



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. 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 75 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, cutting guides, and tracker adapters. 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 Insight Medical Systems 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 Insight Medical Systems 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 re- orienting 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 ustomer 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		

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**
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.
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.

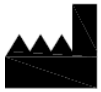
RECOMMENDED SEPARATION DISTANCES TO NEARBY TRANSMITTERS	
The ARVIS system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARVIS system can help prevent electromagnetic interference by maintaining a minimum distance 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 International	CE 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

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.



Kico Knee Innovation Company Pty Limited Unit 1,
25 Frenchs Forest Rd E,
Frenchs Forest, NSW 2086 AUSTRALIA
Email: compliance@360med.care

EC REP

MedEnvoy Global B.V.
Prinses Margrietplantsoen 33 – Suite 123
2595 AM The Hague
THE NETHERLANDS