NOVARAD®
ENTERPRISE HEALTHCARE SOLUTIONS

VisAR

System User Manual

VisAR User Manual —Version 3.0.67 – Part No. L-PL-IUV.001– Rev. 05–October 2025

Novarad Corporation USA • 3152 N University Ave, Suite 200 • Provo, UT 84604
Office 801-642-1001 • Fax 801-642-1030 • Toll Free 877-668-2723 • info@novarad.net
www.novarad.net • www.facebook.com/novaradcorp • www.twitter.com/novaradcorp

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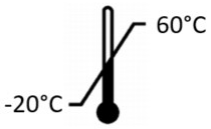
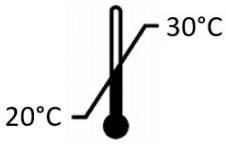
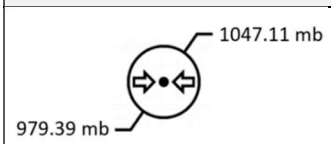
PART 1: WARNINGS AND CAUTIONS

LIST OF SYMBOLS

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

Symbol	Meaning
	Indicates the need for the user to consult the instructions for use.
	Indicates important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Denotes the manufacturer.
	Indicates the date when the medical device was manufactured.
	Denotes the manufacturer's European Community representative.
	Indicates DO NOT THROW IN TRASH.
	Denotes Class II power supply.
	Indicates equipment power on/off.
	Indicates the transport temperature: from -20°C to 60°C.
	Indicates the storage temperature: from 20°C to 30°C.
	Indicates the transport and storage humidity limits: from 35% to 65%.

Symbol	Meaning
	Indicates the transport and storage barometric pressure limits: from 979.39 mb to 1047.11 mb.
	Indicates radio frequency device. Interference may occur in the vicinity of the device.
REF	Indicates the part number.
LOT	Indicates the batch code. Example: 16/32 means the HoloLens headset was manufactured on week 32, Year 2016.
	Use by date: indicates the date after which the device shall not be used.
STERILE R	Sterilized using irradiation.
	Indicates a medical device that has not been subjected to a sterilization process.
	Do not reuse/single use only.
	Do not re-sterilize.
	Do not use if package is damaged or opened.
R_x ONLY	Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.
	Keep dry.
	Keep away from sunlight.
MD	Medical Device
UDI	Unique device identifier

⚠ Indications for Use:

The VisAR System is intended as an aid for precisely locating anatomical structures in either open or percutaneous spine procedures. VisAR is indicated for any medical condition in which the use of stereotaxic surgery may be appropriate, and where reference to at least one rigid anatomical structure, such as the spine or iliac crests, can be identified relative to CT imagery of the anatomy. This can include guidance for procedures, such as Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region.

VisAR displays a virtual screen for stereoscopic 3D images acquired from CT sources. It is intended to enable users to segment previously acquired 3D datasets, overlay, and register these 3D segmented datasets with the anatomy of the patient in order to support intraoperative analysis and guidance.

The virtual screen is indicated for displaying the virtual instrument location in relation to the virtual anatomy to assist in visualization and trajectory planning for both open and percutaneous surgeries.

⚠ Caution: Federal law restricts this device to sale by or on the order of a physician.

Serious Incidents:

Any serious incident that occurs in relation to VisAR medical device should be reported to Novarad and the competent authority of the Member State in which the user and/or patient is established.

Installation Instructions:

Software installation is the responsibility of Novarad Technical Services. If assistance is required, Novarad Technical Services will direct users accordingly.

The initial installation of the VisAR software on a HoloLens can only be done by Novarad Technical Services. We do allow customers to re-install and update the VisAR software as needed.

VisAR is only intended for use with specified hardware that meets or exceeds minimum performance requirements and satisfies current safety and applicable regulations.

Maintenance/Upgrade Procedures:

Maintenance, upgrades, and warranty replacements are the responsibility of Novarad Technical Services and the Original Equipment Manufacturer (OEM). If assistance is required, Novarad Technical Services will direct users accordingly.

Hardware Disposal/End of Expected Service Life:

Contact Novarad Technical Support regarding any hardware warranty replacement or disposal issues before taking action. Disposal of hardware and accessories should be authorized by technical support and done in accordance with the procedures specified in the original equipment manufacturer's manual (see Attachment A: Microsoft HoloLens Regulatory and Warranty Guide: Disposal of Waste Batteries and Electrical & Electronic Equipment).

VisAR single use devices should be disposed of according to best practices of the medical industry (e.g. hospitals, clinics, etc.).

Degree of Accuracy for measuring functions:
Measurements done on DICOM images that include pixel scaling data are precise within two pixel lengths. VisAR will not return a measurement with more precision than is appropriate for the DICOM data and resolution of the images.

Due to the imprecise nature of a computer monitor, a mouse and a person's hand, calibrating measurements by hand can result in inaccurate measurements. Measurement taken after calibration should be treated as rough estimates. Calibration is only valid for the current image.

⚠ **Warning:** Reuse of VisAR single-use devices may result in patient harm or injury.

Contraindications:

⚠ Warning: Emergency Medical Situations

In an emergency situation where the VisAR system is not able to function, doctors should immediately fall back to their existing protocols, standard modalities, and training. VisAR is intended to be used in planned surgery and not for medical emergencies.

⚠ Warning: Personal Medical Devices

Radio-frequency emissions from electronic equipment can negatively affect the operation of other electronic equipment, causing them to malfunction. Although the device is designed, tested, and manufactured to comply with regulations governing radio frequency emission in countries such as the United States and Canada, the wireless transmitters and electrical circuits in the device may cause interference in other electronic equipment. Therefore, please take the following precautions:

Pacemakers- The Health Industry Manufacturers Association recommends that a minimum separation of 15 cm (6 inches) be maintained between a wireless device and a pacemaker to avoid potential interference with the pacemaker.

Persons with pacemakers-

- Should always keep the device more than 15 cm (6 inches) from the pacemaker when the wireless device is turned on.
- If you have any reason to suspect that interference is taking place, turn the device off immediately.

⚠ Warning: Electrosurgical equipment

Use of VisAR is contraindicated while operating electrosurgical equipment or tools.

⚠Warning: Parts of this device are magnetic

Parts of your device are magnetic and may attract metallic items. To reduce the potential risk of sparks and resulting damage to your device, other objects, and/or possible personal injury, verify the electrical connection areas are free of metallic objects before interconnecting devices or charging connectors. Do not place magnetically sensitive devices, credit cards, other magnetic storage media within six inches your device to reduce the potential for magnetic interference between your device and other devices, possible disruption of medical device operation, or corruption of magnetically stored data.

Unique Device Identification (UDI) Label:

A unique device identification number is assigned to each imaging software version. The UDI label is implemented into the software and displayed through the HoloLens headset by selecting the About tab. The UDI label is provided in human readable code (below the barcode).
Example depicted here can be different from actual label:

Compliance with IEC 60601-1 Standard:

The VisAR system complies with safety standard IEC 60601-1.

Electromagnetic Compatibility Tables:

The VisAR system is designed and tested and complies with the electromagnetic compatibility (EMC) limits for medical devices to the IEC 60601-1-2 standard for EMC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

⚠ Warning: All medical electronic devices must conform to the requirements of IEC 60601-1-2. Precautions and adherences to the Electromagnetic Compatibility (EMC) guideline information provided in the manual and verification of all medical devices in simultaneous operation are required to ensure

the electromagnetic compatibility and co-existence of all other medical devices prior to a surgical procedure.

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

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

The following EMC tables are provided for reference: Electromagnetic Emissions, Electromagnetic Immunity, and Recommended Separation Distances.

> *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. Users may need to take mitigation measures, such as relocating or reorienting the equipment.*

Electromagnetic Emissions

Guidance and manufacturer's declaration—electromagnetic emissions		
The VisAR system is intended for use in the electromagnetic environment specified below. Users should ensure that it is used in such an environment.		
Emissions	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The VisAR system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The VisAR system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2		

Guidance and manufacturer's declaration—electromagnetic emissions		
The VisAR system is intended for use in the electromagnetic environment specified below. Users should ensure that it is used in such an environment.		
Emissions	Compliance	Electromagnetic environment - guidance
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	The following limits apply: •The value of Pst shall not be greater than 1.0. •The value of Plt shall not be greater than 0.65. •The relative steady-state voltage change, dc, shall not exceed 3.3%. •The value of d(t) during a voltage change shall not exceed 3.3% for more than 500 ms. •The maximum relative voltage change, dmax, shall not exceed the following: a) 4% without additional conditions. b) 6% for equipment which is • switched manually OR • switched automatically more frequently than twice per day and also has either a delayed restart (the delay being not less than a few tens of seconds) or manual restart after a power supply interruption. c) 7% for equipment which is • attended whilst in use (for example, hair dryers, vacuum cleaners, kitchen equipment such as mixers, garden equipment such as lawn mowers, portable tools such as electric drills) OR • switched on automatically, or is intended to be switched on manually, no more than twice per day and also has either a delayed restart (the delay being not less than a few tens of seconds) or manual restart after a power supply interruption.

Electromagnetic Immunity

Guidance and manufacturer's declaration—electromagnetic immunity		
The VisAR system is intended for use in the electromagnetic environment specified below. Users should ensure that it is used in such an environment.		
Immunity Test	Compliance Level	Electromagnetic environment: guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF field IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% Amplitude Modulated 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the VisAR system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: 1.2 150 kHz to 80 MHz 1.2 80 MHz to 800 MHz 2.3 800 MHz to 2.5 GHz where the maximum output power rating of the transmitter is in watts (W) according to the transmitter manufacturer and 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. Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity fields from wireless communication equipment IEC 61000-4-3	80 MHz to 2.7 GHz. 3 V/m Spot Tests: 385 MHz at 27 V/m; (710, 745, 780, 5240, 5500, 5785) MHz at 9 V/m; (450, 810, 870, 930, 1720, 1845, 1970, 2450) MHz at 28 V/m	
Conducted RF IEC 61000-4-6	3 V (0.15 - 80 MHz) 6 V ISM Bands (6.765-6.795; 13.553-13.567; 26.957-27.283; 40.66- 40.70 MHz) 80% Amplitude Modulated 1kHz	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration—electromagnetic immunity		
The VisAR system is intended for use in the electromagnetic environment specified below. Users should ensure that it is used in such an environment.		
Immunity Test	Compliance Level	Electromagnetic environment: guidance
Surge IEC 61000-4-5	0.5 kV line to neutral, 0°, 90°, 180°, 270° 1 kV line to neutral, 0°, 90°, 180°, 270°	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m – 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% dip, 0.5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° (60 Hz) 100% dip, 1 period, 0° (60 Hz) 30% dip, 30 periods, 0° (60 Hz) 100% dip, 300 periods, 0° (60 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If users of the VisAR system require continued operation during power mains interruptions, it is recommended that the VisAR system be powered from an uninterruptible power supply or a battery.

Note: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VisAR system is used exceeds the applicable RF compliance level above, the VisAR system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the VisAR system.

Note: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the VisAR System			
The VisAR system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of the VisAR system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VisAR system as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz d=1.2$\sqrt{P}$	80 MHz to 800 MHz d=1.2$\sqrt{P}$	800 MHz to 2.5 GHz d=2.3$\sqrt{P}$
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

⚠ 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 VisAR system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could occur.

Separation Distance Notes:

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Overview:

Technical Specifications	
Wireless Signal Type	802.11ac-capable, 2x2 Wi-Fi radio
Frequency Band	5.15 – 5.25 GHz
Network Security Protocol	256-bit AES Encryption TLS 1.1 or above
Network Communication Connectivity	TCPIP Network DHCP Client Support

Technical Specifications	
	TCP/443 outbound to Microsoft windows update servers TCP/443 outbound to the NovaPACS servers TCP/UDP53 outbound to DHCP assigned DNS server
Frame Rate / System Latency	60 fps with 1 frame latency
Maximum Range	The effective range may vary depending upon the environment in which the product is operating. See Performance section below for instructions to achieve optimum performance and range.
Operating Temperature	50°F to 80°F (10°C to 27°C)
Operating Humidity	35% to 65% RH
Operating Barometric Pressure	979.39 mb to 1047.11 mb (734.6 mmHg to 785.4 mmHg)
Storage Temperature	68°F to 86°F (20°C to 30°C)
Transport Temperature	-4°F to 140°F (-20°C to 60°C)
Transport and Storage Humidity	35% to 65% RH
Transport and Storage Barometric Pressure	979.39 mb to 1047.11 mb (734.6 mmHg to 785.4 mmHg)

Performance Tested Hardware:

VisAR supports the following third-party hardware specifications:

- Microsoft HoloLens version 2 and above

Feature	Microsoft HoloLens 2 Specification, Model Number 1855
Display	See-through holographic lenses (waveguides) 2x 3:2 light engines >2.5k radiant (light points per radian) Display optimization for 3D eye position Type of display: Scanning Laser Color Contrast ratio: 500:1 Optical combiner technology in HMD: The HoloLens 2 display is a combination of waveguides and light projectors. Users look through the waveguides—the lenses inside the visor—when wearing the headset. The light projectors are inside the enclosure above the brow. HoloLens 2 uses laser light to illuminate the display. Source: https://docs.microsoft.com/en-us/hololens/hololens2-display Transmittance of HMD - 35% minimum

Feature	Microsoft HoloLens 2 Specification, Model Number 1855
	Eye relief of HMD and use of prescription glasses - 12mm - 24mm inclusive Interpupillary Distance (IPD) and eye box size - 53mm to 71mm inclusive
Framerate	60 Hz Min Rate, up to 120 Hz using 2 fields
Sensors (Motion tracking technology for HMD)	Head tracking: 4 visible light cameras Eye tracking: 2 Infrared (IR) cameras Depth: 1-MP Time-of-Flight depth sensor Inertial measurement unit (IMU): Accelerometer, gyroscope, magnetometer Camera: 8-MP stills, 1080p30 video Source: https://www.microsoft.com/en-us/hololens/hardware
Location of virtual content	Novarad controls this in Novarad's app(s)
Field of view	43.5 degrees Horizontal x 28.3 degrees Vertical in each eye
Compute and connectivity	System on chip: Qualcomm Snapdragon 850 Compute Platform Holographic processing unit: Second generation custom built holographic processing unit Memory: 4-GB LPDDR4x system DRAM Storage: 64-GB UFS 2.1 Wi-Fi: 802.11ac 2x2 Bluetooth: 5.0 USB Type-C
Fit	Weight: 566 grams (1.2lbs) Sizing: Single size with adjustable band. Fits over eyeglasses
Audio	Microphone array: 5 channels Speakers: Built-in spatial sound
Power	Battery Life: 2–3 hours of active use. Up to 2 weeks standby time. Battery technology: Lithium batteries Charging behaviour: Fully functional when charging Cooling type: Passively cooled (no fans) Power draw: In order to maintain/advance Internal Battery Charge Percentage while the device is on, it must be connected minimum to a 15W charger.
Power Supply Unit	Microsoft model 1847

Feature	Microsoft HoloLens 2 Specification, Model Number 1855
Pre-installed software	Windows Holographic Operating System Microsoft Edge Dynamics 365 Remote Assist Dynamics 365 Layout Dynamics 365 Guides 3D Viewer OneDrive for Business HoloLens Tips Cortana

Intended Users:

VisAR is intended for use in hospitals, clinics, and procedure room environments. Trained health care professionals utilizing the VisAR product must be experienced in spine surgery and be trained on the hardware and system.

Patient Population:

VisAR is intended to be used with all patients, both male and female, requiring stereotactic spinal surgery from teenager and above as deemed necessary by a licensed physician.

Power Supply Unit:

Disconnect the power supply from the AC mains. The power supply is the only recognized disconnect device.

VisAR should be positioned so that its disconnect device is readily accessible.

Performance:

VisAR is intended for use in hospitals, clinics, and procedure room environments. Trained health care professionals including surgeons and interventional radiologists are the intended users in all operational environments.

The following steps will help you to achieve optimal performance of VisAR:

1. Access point range and signal strength maximization: Wireless performance depends on several factors, making a definitive range hard to predict. For example, the type and thickness of walls can impact the range of your network; fewer walls or floors are better, or uninsulated drywall is better than concrete. Deployments will also be affected by radio frequency interference. Cordless phones, microwave ovens, and neighboring wireless access points are common sources of interference.

2. To get the most from your equipment: Try moving access points to see if speed improves. Avoid placing access points near devices that emit radio interference.

Essential Performance:

VisAR is the combination of Microsoft HoloLens and Novarad's medical imaging software for medical image visualization. A hardware shutdown, power failure, or other hardware issue that makes the software inoperable may cause harm. Users can mitigate this risk by ensuring each system has fully redundant pre-operative workstations, Augmented Reality (AR) headsets, and servers to eliminate a single point of failure. Images are also cached on the AR headset, allowing a surgeon to proceed with a procedure even if there is failure of the hospital network or wireless systems.

The Microsoft HoloLens is not intended for use during High-Frequency (HF) surgery.

IT Network:

The purpose of the IT network connection is the initial download of image data from NovaPACS (via server) to VisAR and to receive updates to the VisAR software (OS, VisAR app). The intended information flow is as follows:

- Image data from the server to the device

> *Note: There is no streaming from the server to the HoloLens headset, just the initial transfer of image data. After that, there is no communication with the server.*

The Novarad PACS server is the backend technology that is used to work in an interoperable mannerwith modalities or hospital image archives. Users can upload images from any PACS server or upload images via cable connection from a PC to the headset before the surgical procedure takes place. It also accepts DICOM compatible annotations as well as standard STL files. Thus, images can be annotated or planned on a different system and viewed on VisAR.

IT Network Characteristics:

VisAR contains wireless technology using Wi-Fi 802.11ac networking standard. DHCP Server or services is required to assign an IP address to wireless clients. The network must be able to communicate with PACS server through the device. The network needs internet connectivity, app store availability, and the ability to receive windows updates.

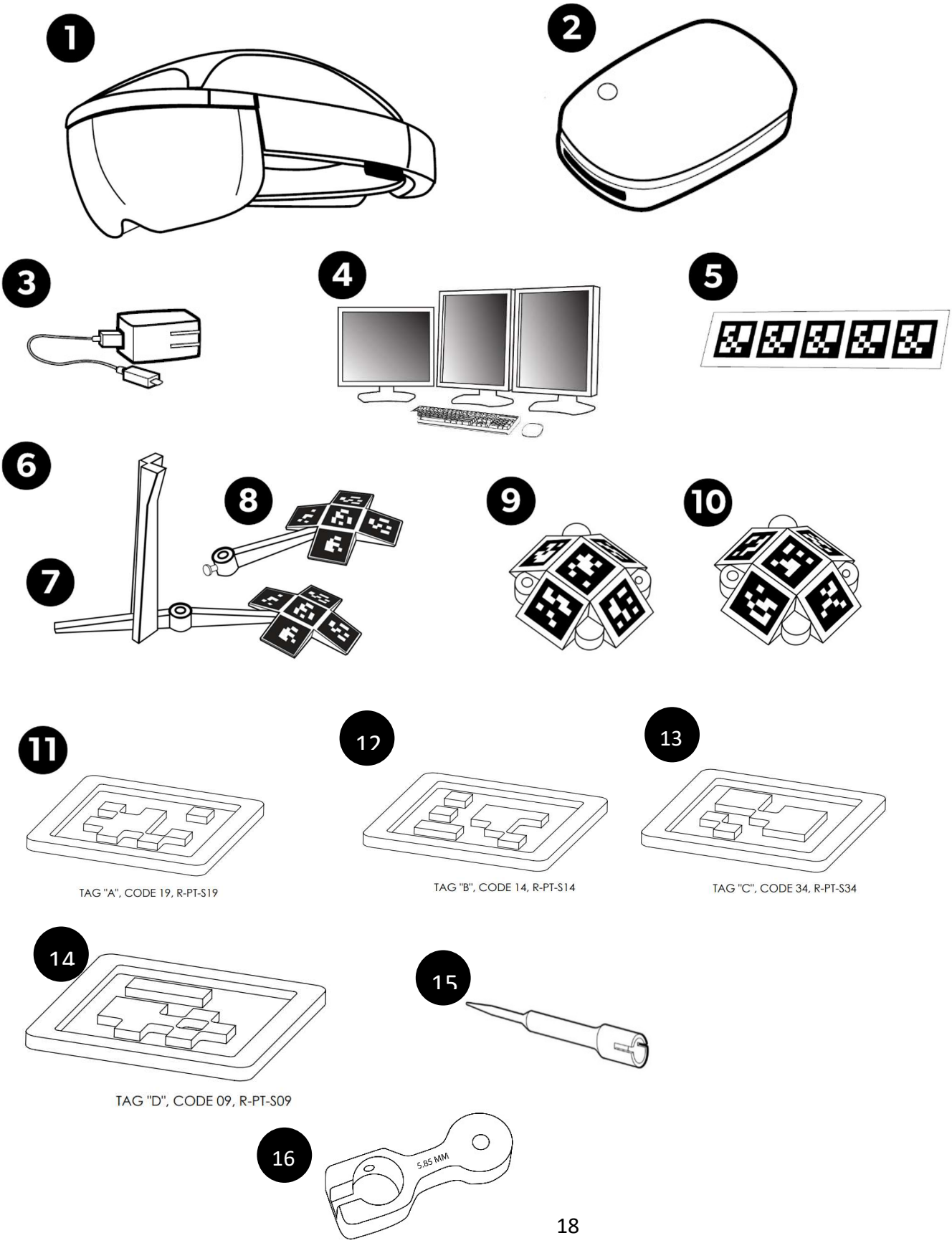
> *Note: No hazardous situations have been identified for the product due to loss of the IT network functionality.*

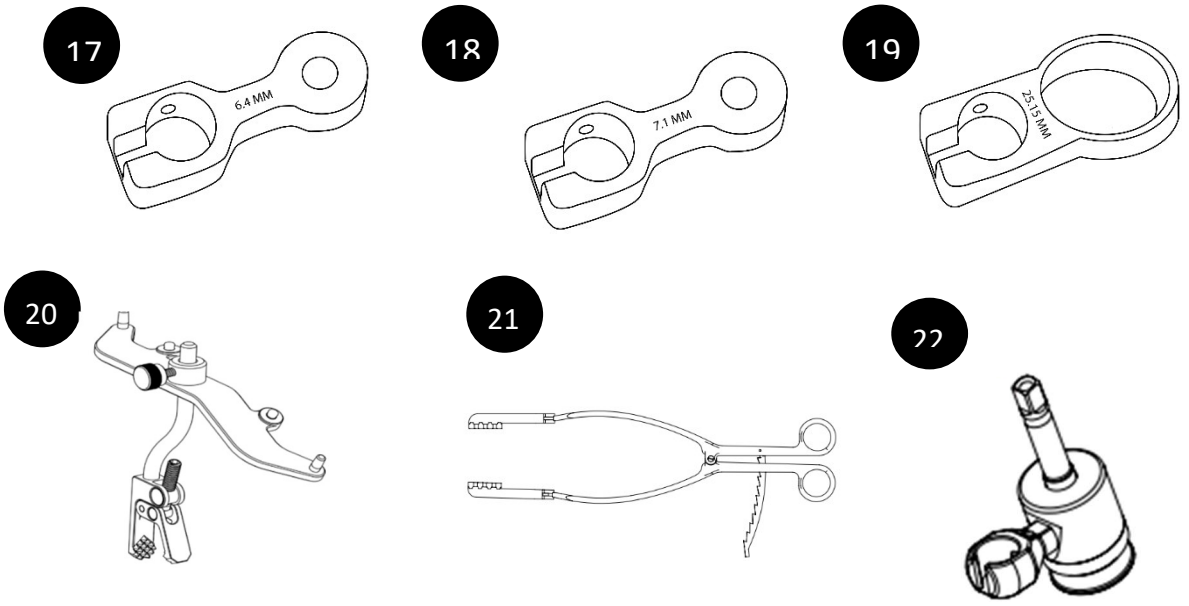
VisAR System Components:

The VisAR system consists of Novarad's immersive augmented reality software running on the Microsoft HoloLens 2 headset, image visible tags, a pre-operative planning workstation, and the Novarad PACS server. It uses optical tracking technology to co-localize the virtual 3D image datasets to the patient and displays to the surgeon the location of pre-operatively planned operative tracks and the tracked surgical instruments relative to the acquired preoperative or intraoperative patient's scan onto the surgical field. The NovaPACS viewer and 3D workstation software are used for surgical planning. In addition, limited

surgical planning can be performed on the headset. With the 3D datasets on the NovaPACS viewer, a healthcare professional can mark virtual trajectories, virtual landmarks, needles, incisions, saw cuts or instruments in the pre-operative planning system.

The VisAR system comprises the following main devices and components.





Sterile Items/Single Use Items (Used in Sterile Field)

Part Number(s)	Product Name	Description	Use
S-SK-GEN	Large Navigation Kit	Large patient trackers, calibration stand (base + tower), 2× instrument trackers, tags	Full navigation kit for larger patients
S-SK-S01	Small Navigation Kit	Small patient trackers, calibration stand (base + tower), 2× instrument trackers, tags	Kit optimized for smaller patients
S-SK-S02	Mixed Navigation Kit	Large + small trackers, calibration stand (base + tower), 2× instrument trackers, tags	Flexible kit for varied patient sizes
R-PT-CLT (5)	Adhesive Patient Tags	Sterile optical tags (set of 5)	Registers patient anatomy to imaging

Non-Sterile/Reusable Items

Part Number(s)	Product Name	Description	Use
R-PT-S09, S14, S19, S34 (11-14)	Metal Tracker Tags – Stainless Steel	Reusable stainless steel tags	Imaging alignment in fluoro, CT, x-ray
T-LI-STP (15)	Landmark Registration Tool	Stainless steel pointer with tracker mount	Selects anatomical landmarks for registration
T-AD-310, 585 (16-19)	Instrument Adapters	Aluminum adapters for surgical instruments ranging from 1.0 mm to 25.1 mm	Connects instruments to tracker for real-time navigation
R-TM-S01 (20)	Spine Clamp (L-S)	Titanium clamp for spinous process	Secures large or small trackers
R-TM-S02 (20)	Spine Clamp (S-S)	Titanium clamp for spinous process	Secures two small trackers
T-AD-S03 (21)	Retractor	Titanium Beckman-Eaton laminectomy retractor	Low-radiopacity retraction during spine surgery
T-AD-S01 (22)	Rotational Adapter	Stainless steel mount	Allows tracked rotation of instruments
VIS-1000 (1)	Microsoft HoloLens 2	AR headset with navigation software	Provides immersive surgical guidance

Typical Installation:

In most situations, the Server Room and access point locations are separate from the Procedure Room. One NovaPACS server is deployed per site. Restrictions on the number of HoloLens headsets a site can have are based on server sizing. Theoretically, there is no practical limit to the number of ORs a system can support.

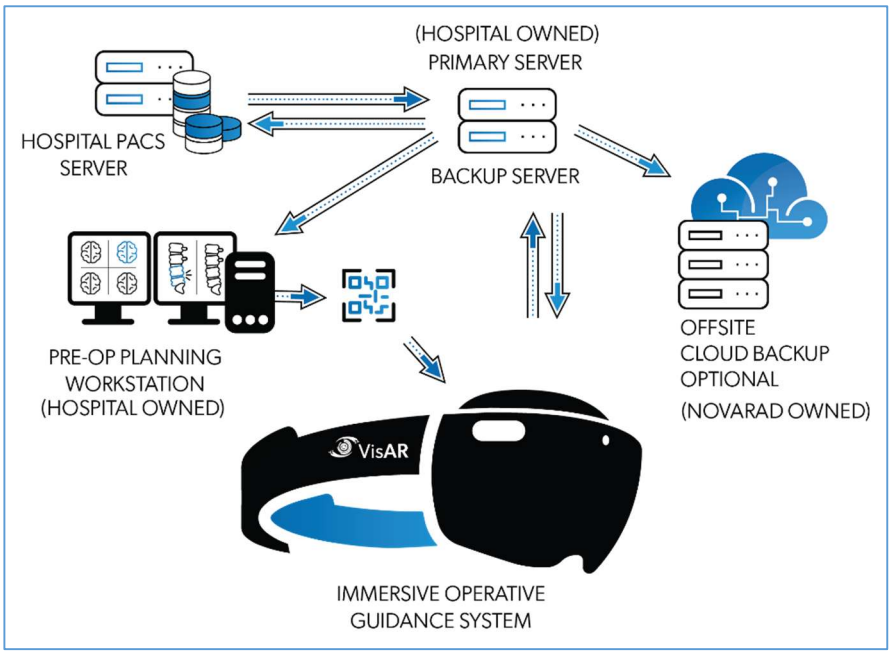
In instances where the Procedure Room does not have sufficient Wi-Fi, the images can be cached on the HoloLens headset.

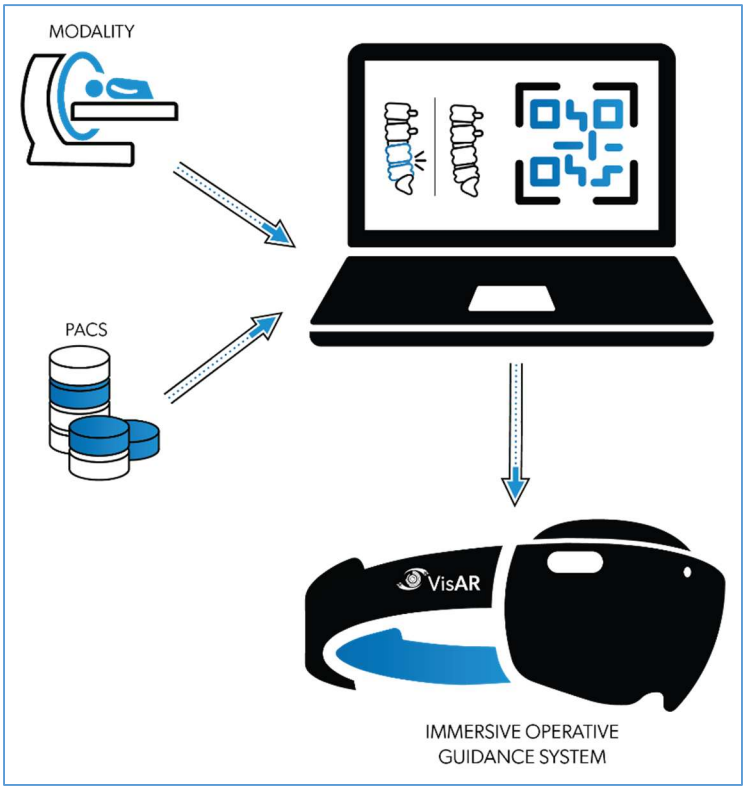
VisAR Interoperability Table

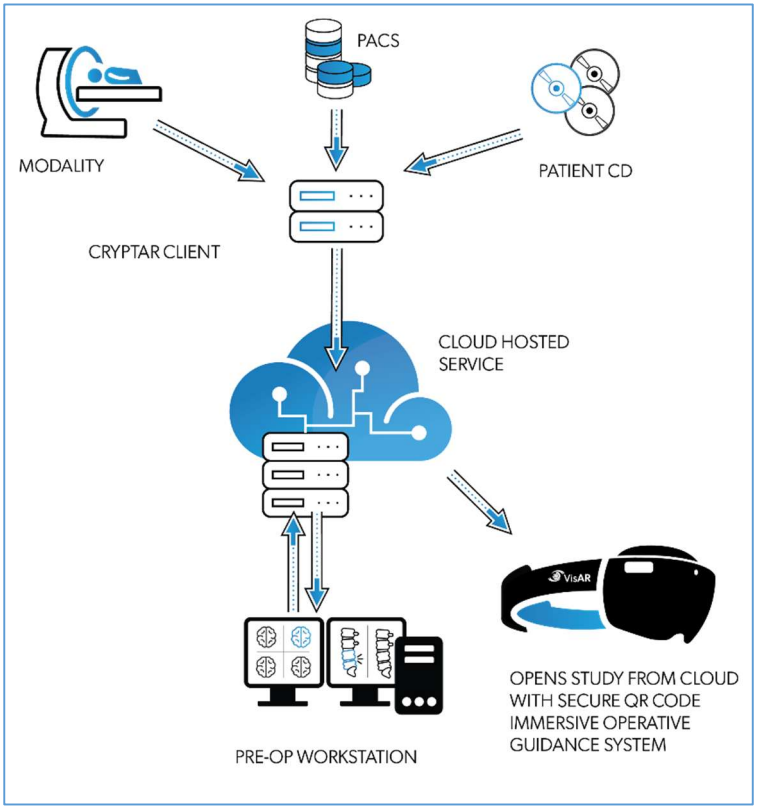
Interface Name	Interface Type	Standard / Protocol	Direction	Purpose / Functionality	Interoperability Dependencies	Risk Controls / Verification Methods
Hospital Network (LAN / WAN)	Communication Medium	TCP/IP (Ethernet/Wi-Fi), DICOM, HL7, HTTPS	Bidirectional	Provides communication between Novarad software and hospital systems (PACS, RIS, modalities, AI services).	Network connectivity,bandwidth, firewall rules, IP addressing, and VPN configuration.	Validate connectivity (C-ECHO, ping tests); confirm encryption (TLS 1.2+); assess under IEC 80001-1 for network risk management; document cybersecurity requirements in IFU.
NovaPACS Server	Novarad System	DICOM C-STORE, C-FIND, C-MOVE, Storage Commitment	Bidirectional	Central image repository and routing node for diagnostic images and structured reports.	Requires DICOM 3.0-compliant peers (modalities, viewers, AI nodes).	DICOM conformance verification; transaction integrity checks (UID match); image consistency and latency validation.

NovaPACS Viewer / Workstation	Novarad Application	DICOM Query/Retrieve, HTTPS REST API (internal)	Outbound	Displays patient studies, reports, and AI results; provides structured annotations.	Requires active network connection to NovaPACS Server and correct AE Title configuration.	Verify display consistency (window/level, overlays); confirm retrieval via C-FIND/C-MOVE; user acceptance test.
Hospital PACS Server	External Device	DICOM C-STORE, SCP	Inbound	Displays patient studies, reports, and AI results; provides structured annotations.	Requires active network connection to NovaPACS Server and correct AE Title configuration.	Verify display consistency (window/level, overlays); confirm retrieval via C-FIND/C-MOVE; user acceptance test.
VisAR Surgical Navigation Server	Novarad System	DICOM C-STORE, DICOM RT Structure Set	Inbound	Receives preoperative images and planning data from PACS; provides 3D AR navigation overlays intraoperatively.	Requires valid DICOM StudyUID mapping and consistent coordinate reference frame.	Confirm image registration accuracy; verify DICOM structure parsing; latency and frame rate testing; risk control per ISO 62304 and IEC 62366-1.
Hospital Modality (CT/MR/US/MG)	External Device	DICOM C-STORE, DICOM File Reader/Parser from Manual Transfer from Drive	Inbound	Sends diagnostic image data for archiving, AI analysis, or navigation use.	Modality must be configured with NovaPACS AE Title, IP, and port.	Verify C-STORE receipt; confirm metadata mapping (PatientID, StudyUID); test failure recovery

VisAR Interoperability







Avoiding Co-Existence Interference:

VisAR deployment is typically one server pair per site. There are no restrictions on the number of HoloLens headsets.

Troubleshooting VisAR Software:

Problem	Possible Causes/Remedial Action
Software malfunctions	• Restart VisAR App • Restart HoloLens Headset
VisAR application immediately closes	Do not use any start menu commands or perform the bloom gesture. Select Window icon on wrist, or say “Go to Start.”

Troubleshooting HoloLens and Stereoscopic 3D Images:

Problem	Possible Causes/Remedial Action
HoloLens is unresponsive, is not running well, or will not start.	• Restart the HoloLens: • Press the power button for 4 seconds until all the battery indicators fade out. Wait 30 seconds and press the power button again to turn on the device.

Problem	Possible Causes/Remedial Action
	• If that does not fix the problem, force restart the device. Hold down the power button for 10 seconds. Release it and wait 30 seconds. Press the power button again to turn on the device. • Run the "VisAR Reset" workflow utility apps to make sure the device is properly adjusted.
Stereoscopic 3D images do not look right or are moving around (for example, they're jittery or shaky or users see black patches on top of them).	• Turn on some lights. HoloLens works best in a well-lit space. • Clean the device visor and make sure nothing is blocking the sensors. • Run eye calibration or Room mapping: while in VisAR application "Run eye calibration" or "Start room calibration." • Try walking around and gazing at the surroundings so the HoloLens can scan them more completely to create stable room anchors. • Run the calibration app. This app calibrates the HoloLens to keep stereoscopic 3D images looking their best. Go to Settings → System → Calibration → Run Eye Calibration • Delete all Holograms: Settings -> System ->Holograms -> remove all holograms. Then look around at surroundings again. Make pinching gesture to set room mappings.
Messages say "Finding your space" or "positional tracking inhibited"	When HoloLens is learning or loading a space, a brief message says "Finding your space." If this message continues for more than a few seconds or if a Use in limited mode button appears, it means HoloLens is having trouble mapping the space. If the HoloLens is in limited mode, users are able to open apps, but cannot place stereoscopic 3D images in their environment. Once HoloLens can map the space again, users can return to normal mode. If these messages show often, try the following: • HoloLens works best in a well-lit space. • Make sure the device visor is clean. • Run the surgical workflow to enforce re-mapping of the room.
The expected stereoscopic 3D images are not showing.	If you do not see stereoscopic 3D images you placed or you're seeing some you don't expect, try the following:

Problem	Possible Causes/Remedial Action
	• Say “Where’s my image” an arrow will appear directing the user where the image is located. • If you saw the arrow but the user still can’t see the images, say “drag window level”: pinch and drag in a horizontal and vertical direction to change the brightness and contrast of the images. If a CT image is set the user can say “bone preset” for a quick brightness/contrast fix. • Say “Show/Hide Table” or “enable/disable sculpting” • Select and hold “VisAR” application in start menu. User will be prompted to “Pin,” “Close,” “Uninstall.” Select “Close” this will close all “VisAR” applications. Reopen the image from QR code or history. • If the correct space is loaded and users still have problems, users might need to delete the holograms and recreate it. This removes all stereoscopic 3D images for the space. (Apps are not removed, but their data for the space are deleted). Go to Settings → System → Holograms -> Remove all Holograms. The HoloLens will immediately start to remap the space around you. Look around to allow the HoloLens to see the space around you. • *Note: If the layout or lighting in the space changes significantly, the device might have trouble identifying and loading the space.*
HoloLens cannot create a new space.	The most likely problem is that users are running low on storage space. Do one or more of the following to free up space, then try again: • Run “Reset VisAR.”: Start Menu --> Settings --> Apps --> VisAR application --> Advanced Options --> Reset • Delete images stored in “History”: VisAR -> History -> User can then delete individual studies with the “trash” icon or the user can delete all studies cached on the headset by toggling to off. • Delete pictures and videos in the Photos app. This also deletes them from OneDrive. • Uninstall apps from the HoloLens. In the All Apps list, tap and hold the app and select Uninstall. This also deletes any of the app’s data from the device.
Stereoscopic 3D images do not place correctly.	Here are some things to try if you’re having trouble placing stereoscopic 3D images:

Problem	Possible Causes/Remedial Action
	• Change brightness/contrast of the image: Say “drag window level”: pinch and drag in a horizontal and vertical direction to change the brightness and contrast of the images. If a CT image set the user can say “bone preset” for a quick brightness/contrast fix. • Say “Show/Hide Table” or “enable/disable sculpting” • Select and hold “VisAR” application in start menu. User will be prompted to “Pin”, “Close”, “uninstall.” Select “Close” this will close all “VisAR” applications. Reopen the image from QR code or history. • Run “Reset VisAR.”: Start Menu --> Settings --> Apps --> VisAR application --> Advanced Options --> Reset • Stand about one to three meters from where the stereoscopic 3D image will be placed. • Do not place stereoscopic 3D images on reflective or clear surfaces such as a window. • Walk around the room so the HoloLens can rescan the surroundings. To see what has already been scanned, air tap to reveal the mapping mesh graphic.
Apps move toward the user when being placed.	Walk around and look at the area where the app is being placed so HoloLens scans it from different angles. Cleaning the device visor may also help. • Run the room calibration: use the voice command while in VisAR immersive view “Start Room Calibration”
HoloLens does not respond to gestures.	Keep the user’s hand in the gesture frame, which extends a couple of feet on either side of them. The HoloLens can also best detect the user’s hand when they hold it about 18 inches in front of their body (though users do not have to be precise about this). When HoloLens can detect the user’s hand, the cursor changes from a dot to a ring. It helps to use only one hand at a time.
Cannot connect to Wi-Fi.	• Make sure Wi-Fi is turned on. Say “go to Start” then select **Settings → Network & Internet → Wi-Fi** to check. If Wi-Fi is on, try turning it off and then on again. • Move closer to the router or access point. • Restart the Wi-Fi router, and then restart the HoloLens. Try connecting again. • Check to ensure the wireless router is using the latest firmware. Find this information on the manufacturer’s website.

Troubleshooting HoloLens fit and comfort:

Problem	Possible Causes/Remedial Action
The device causes discomfort.	If users experience discomfort, angle the headset up or take a break for a while, sit in a well-lit room, and relax for a bit. Use the HoloLens for a shorter period at first (see Health and Safety on HoloLens). Ensure the band is snug, but not so tight it causes a headache.
The stereoscopic 3D image frame or the stereoscopic 3D images are cut off.	To see the top edge of the stereoscopic 3D image frame, move the device so it sits higher on the head, or angle the headband up slightly in front. To see the bottom edge, move the device to sit lower on the head or angle the headband down slightly in front. If the left or right edge of the view frame is not visible, make sure the HoloLens visor is centered on the forehead.
Seeing stereoscopic 3D images requires looking up or down.	Adjust the position of the device visor so the stereoscopic 3D image frame matches the natural gaze. • If users need to look up to see stereoscopic 3D images, do the following: First, shift the back of the headband a bit higher on the head. Then use one hand to hold the headband in place and the other to gently rotate the visor until the user has a good view of the stereoscopic 3D image frame. • If users need to look down to see stereoscopic 3D images, do the following: First, shift the back of the headband a bit lower on the head. Then place thumbs under the device arms and index fingers on top of the headband. Gently squeeze with the thumbs to rotate the visor until user has a good view of the stereoscopic 3D image frame.

MD VisAR is a Medical Device

VisAR Basic UDI-DI: ++B109VISAR59

Manufacturing:

Novarad Corporation
3152 North University Avenue,
Suite 200
Provo, UT 84604
USA
Tel.: +1.801.642.1001
2022-05

Contact Information:
Technical Support & Regional Distributors
www.novarad.net/contact-us
info@novarad.net
support@novarad.net

Brazil Registration Holder:

Angel Care Solutions
Avenida Nova Independência
nº 87 – 12° andar conj. 124
Brooklin Paulista, São Paulo
Brazil
Tel: (11) 3044-2017
Registration #'s: 80770610006,
80770610005, 80770610007, 80770610008,
80770610009, 80770610010, 80770610011

PART 2: VISAR SYSTEM DESCRIPTION

SYSTEM DESCRIPTION

The VisAR system is an image-guided navigation system that is designed to assist surgeons or interventional radiologists in placing pedicle screws accurately, during open or percutaneous spinal surgery. The system consists of Novarad's immersive augmented reality software running on the Microsoft HoloLens 2 headset, image visible Patient Tags, a pre-operative planning workstation and the Novarad PACS server. It uses optical tracking technology to co-localize the virtual 3D image datasets to the patient and displays to the surgeon the location of pre-operatively planned operative tracks and the tracked surgical instruments relative to the acquired intraoperative patient's scan, onto the surgical field. The 3D scanned image, along with tracking information, are projected to the surgeons' retina using a transparent near-eye-display stereoscopic headset, allowing the surgeon to both look at the patient and the navigation data at the same time. The NovaPACS viewer and 3D workstation software is used for surgical planning. With the 3D datasets on the NovaPACS viewer, a health care professional can mark virtual trajectories, virtual landmarks, needles, incisions or instruments. Additional components available to the surgeon include an instrument tracker that attaches to any 11-gauge surgical instrument or needle system along with the instrument calibration stand. The optical Patient Tags for registration, the instrument tracker for tool guidance, and the instrument calibration stand are all disposable.

⚠ VisAR is not designed as a primary tool for disease detection or diagnosis.

VisAR integrates with NovaPACS software.

VisAR contains wireless technology using Wi-Fi 802.11ac networking standard. The wireless technology is used to stream encrypted images in a 2D format from a Novarad server onto the HoloLens headset. Images are renderings of the patient in the VisAR device. The wireless information transfer is encrypted with 256-bit encryption for data security.

Novarad recommends that users install and maintain a firewall configuration for protecting the device and PHI data.

Microsoft security software updates are automatically installed on the HoloLens to protect vulnerability. Refer to Microsoft website for recommendations for managing updates to the HoloLens.

The following light level conditions are supported for intended use:

- A typical office/procedure room setting (140-407 lux)
- An operating room setting with surgical lighting (3743 lux)

Note: Lighting environments outside the range of 140 to 3743 lux are not recommended for intended use.

⚠ To reduce needle deflection during insertion, a diamond-tip needle is recommended.

The user-friendly interface that VisAR® utilizes has easy navigation and makes for an easy workflow. This chapter will discuss how to access, edit, and view studies inside VisAR®.

INSTRUMENT AND DEVICE COMPATIBILITY

Novarad Products

Sterile Items/Single Use Items (Used in Sterile Field)

Part Number(s)	Product Name	Description	Use
S-SK-GEN	Large Navigation Kit	Large patient trackers, calibration stand (base + tower), 2× instrument trackers, tags	Full navigation kit for larger patients
S-SK-S01	Small Navigation Kit	Small patient trackers, calibration stand (base + tower), 2× instrument trackers, tags	Kit optimized for smaller patients
S-SK-S02	Mixed Navigation Kit	Large + small trackers, calibration stand (base + tower), 2× instrument trackers, tags	Flexible kit for varied patient sizes
R-PT-CLT	Adhesive Patient Tags	Sterile optical tags (set of 5)	Registers patient anatomy to imaging

Non-Sterile/Reusable Items

Part Number(s)	Product Name	Description	Use
R-PT-S09, S14, S19, S34	Metal Tracker Tags – Stainless Steel	Reusable stainless steel tags	Imaging alignment in fluoro, CT, x-ray
R-PT-TT5, TT6, TT7, TT8	Metal Tracker Tags	Reusable metal tags	MRI-compatible patient tracking

Part Number(s)	Product Name	Description	Use
T-LI-STP	Landmark Registration Tool	Stainless steel pointer with tracker mount	Selects anatomical landmarks for registration
T-AD-100, 102, 150, 180, 200, 240, 251, 310, 585, 640, 710, 805, 820, 910	Instrument Adapters	Aluminum adapters for surgical instruments ranging from 1.0 mm to 25.1 mm	Connects instruments to tracker for real-time navigation
R-TM-S01	Spine Clamp (L-S)	Titanium clamp for spinous process	Secures large or small trackers
R-TM-S02	Spine Clamp (S-S)	Titanium clamp for spinous process	Secures two small trackers
T-AD-S03	Retractor	Titanium Beckman-Eaton laminectomy retractor	Low-radiopacity retraction during spine surgery
T-AD-S01	Rotational Adapter	Stainless steel mount	Allows tracked rotation of instruments
VIS-1000	Microsoft HoloLens 2	AR headset with navigation software	Provides immersive surgical guidance

End-of-Life Statement for Reusable Metal Components

This device is designed for repeated use under normal operating and reprocessing conditions. The usable life of the reusable metal components is not limited to a fixed number of cycles but is dependent on their condition.

Prior to each use, the component must be inspected for signs of:

- Mechanical damage (e.g., bending, cracking, deformation, or fracture)
- Excessive wear (e.g., surface degradation, rounding of edges, or loss of function)
- Corrosion, pitting, or other material changes
- Loosened or compromised connections that may impact performance or patient safety

End of life is reached immediately when any such condition is identified. At that point, the component must be removed from service and replaced. Continued use of a damaged or worn device may result in patient or user harm.

Parts that work with VisAR

Part Name	How it works with VisAR
EKG pad	Place on patient and snap bottom of multi-tracker onto pad
2.7mm diameter bone pin/screw	Attach bone pin/screw to patient. Place corner of multi-tracker over bone pin and tighten using tightening screw.
Suture	Attach multi-tracker to patient using a set of sutures or a bone pin and suture.
Jamshidi needle	Slide Instrument Tracker to base of needle shaft and tighten using tightening screw.

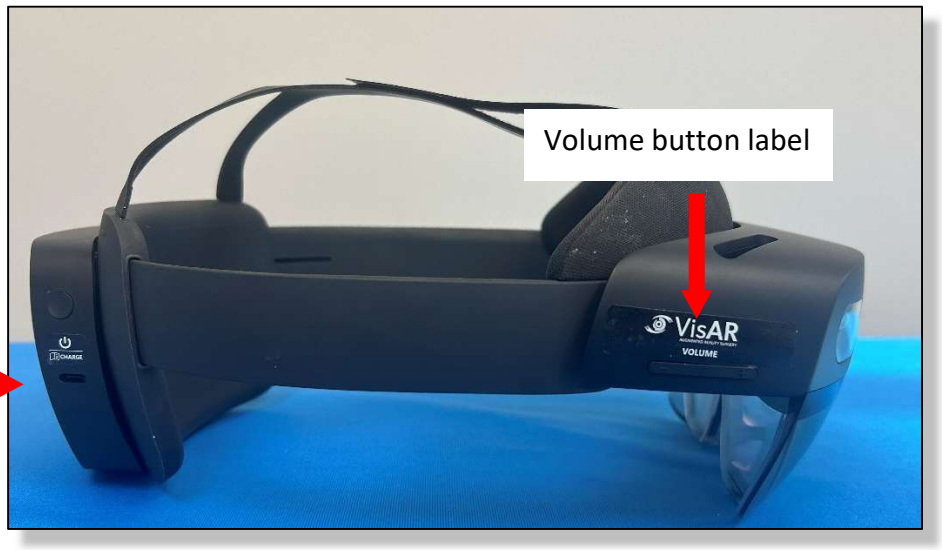
MICROSOFT HOLOLENS DESCRIPTION

Packaging Labels:

The HoloLens will arrive boxed with a VisAR Medical Device Label, shown below:

VisAR Labels:

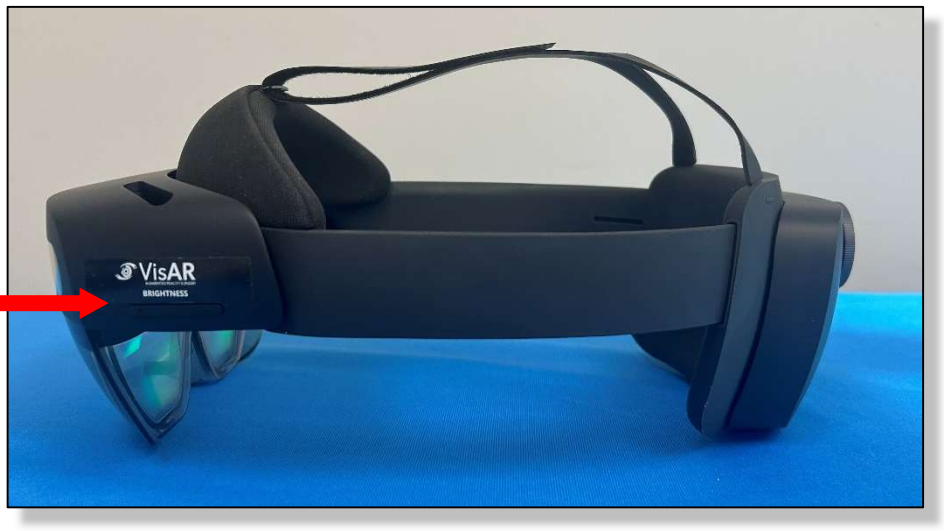
In addition, the actual headset will have labels on it identifying the different buttons/features.



Power button/Charging Port label

This label contains Novarad's Tech Support Number and VisAR's Patent numbers

Brightness button label



Adjustment

Microsoft HoloLens 2

Adjusting Head Straps:

To put the HoloLens on, use the adjustment wheel to expand the headband. With the HoloLens in place, tighten the adjustment wheel by turning it to the right until the headband is comfortable. The adjustment wheel can help keep the headset secure on the head, particularly if you are moving around a lot. The adjustment wheel may also let you loosen the headband a bit. Users can experiment with the positioning of the headband. Depending on their head size and shape, users may need to slide it up or down to reposition it on the forehead. Repeated cleaning could damage the visor, so try to keep your device clean.

⚠ *Warning: The headset is lightweight, but if the user does not adjust the head straps perfectly after putting it on, the weight can cause neck strain after extended use.*

Point of Use Care

The VisAR headset is a precision optical medical device and must be handled with care to ensure continued safe and effective performance. Users shall avoid damaging or scratching the lens or visor and must not expose the device to fluids or allow liquids to remain on its surfaces. The headset should be cleaned and disinfected between uses in accordance with validated cleaning procedures, using only microfiber or lens-safe cleaning cloths and approved agents. Do not use abrasive materials. The device should not be dropped or subjected to impact, and should always be held and positioned according to the Instructions for Use. The headset must not be exposed to excessive heat, direct sunlight, or other environmental extremes that may damage the optics or electronics. When not in use, the device should be stored in its protective case to prevent physical or environmental damage. Power should be supplied only through USB-C connections using commercial external battery packs that comply with applicable FDA and CE/UKCA regulatory requirements. Proper handling, storage, and cleaning help ensure the longevity of the device and maintain safety for clinical users and patients.

⚠ Warning: Visor Cleaning for Fingerprints and Other Marks:

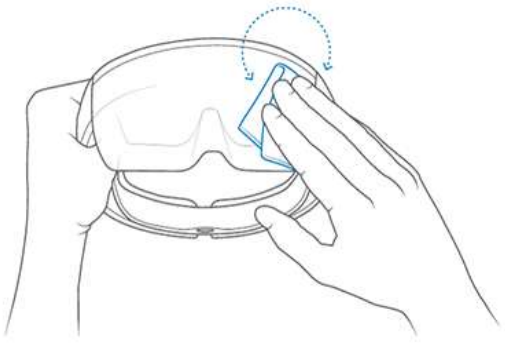
Keep the device free of dust and fingerprints. Use it with clean hands and do not touch the visor. Visors that have been scratched, cracked, or contain non-removable marks should not be used. Repeated cleaning could damage the visor.

Cleaning the Device:

Handle the HoloLens headset carefully. Use the headband to lift and carry it.

To keep the visor free of dust and fingerprints, avoid touching it. Don't use any lens cleaners on the HoloLens headset, and don't submerge in water or apply water directly to it.

1. Remove any dust by using a dry, lint-free microfiber cloth to gently wipe the surface of the device.
2. Lightly moisten the cloth with medical 70% alcohol, and then use the moistened cloth to gently wipe the surface of the device.
3. Let the device dry completely.



To Clean the Brow Pad

1. Use water and a mild, antibiotic soap to mois to wipe the brow pad.
2. Let the brow pad dry completely.

Users should use 70% Isopropyl Alcohol disinfecting wipes to clean the device. Make sure wipes do not contain corrosives (e.g. bleach and hydrogen peroxide).

⚠ Caution: Contamination:

Cleaning the HoloLens headset as soon as possible after use can prevent contamination. Wrapping a disposable cover over the side edges of the outer arms of the headset minimizes contamination from handling the device on and off the user's head.

To protect the headset from contamination, a disposable, clear plastic cap can be used to cover the outer arms of the HoloLens headset headband, creating a clean handle.

Storing and transporting the completely dry headset in its carrying case prevents exposure to contamination as well as protection from possible damage.

⚠ Caution: Autoclave sterilization and ultraviolet irradiation damages the HoloLens headset.

HOLOLENS COMPATIBILITY

The HoloLens 1 has reached end of life and will no longer be supported by VisAR. For more information, call VisAR Technical support at 801-642-1001.

MAINTENANCE, REPROCESSING, REUSE, STERILIZATION OF PEDICLE SCREW INSTRUMENTS

⚠ **Warning:** Manufactures may provide instruments in a sterile or non-sterile condition. For non-sterile instruments, clean and sterilize prior to each use per manufacturer instructions.

Follow the maintenance, reprocessing, reuse, and sterilization of instruments per manufacturer instructions.

For manufacturers that provide non-sterile instruments there is no shelf life or expiration date. Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use as determined by inspection and functional testing per manufacturer instructions.

For sterile instruments provided by the manufacturer, refer to the manufacturer's instructions for shelf life or expiration date.

IMPLANTS / PEDICLE SCREWS

⚠ Warning: Manufacturers may provide implants/pedicle screws in a sterile or non-sterile condition. Non-sterile implants/pedicle screws MUST be sterilized by the hospital prior to use per manufacturer instructions.

Follow the sterilization of implants/pedicle screws per manufacturer instructions.

For manufacturers that provide non-sterile implants/pedicle screws there is no shelf life or expiration date.

For sterile implants/pedicle screws provided by the manufacturer, refer to the manufacturer's instructions for shelf life or expiration date.

COMPATIBLE IMPLANTS AND INSTRUMENTS

The table below shows a list of instruments and pedicle screws that are compatible with the VisAR system.

Compatible Pedicle Screws and Instruments:

Company	Products	Part Number
Aesculap Implant Systems	ENNOVATE Spinal System	For ordering parts refer to the manufacturer's product guide
	ENNOVATE	
Alphatec Spine (αtec)	Atec Lateral Interbody System	For ordering parts refer to the manufacturer's product guide
	Atec Lateral Interbody System	
	Identiti Porous Ti Interbody System	
	Atec Alif And Llif Spacer System	
	Atec Alif Spacer System	
	Atec Universal Spacer System	
	Xycor® Expandable Spinal Spacer System	
	Battalion Universal Spacer System	
	Epicage Interbody Fusion Device	
	Guided Lateral Interbody Fusion (Glif) System	
	Novel Alif Spinal Spacer System	
	Novel Spinal Spacer System	
Auxein Medical	Osteobone Dual Thread Screw	For ordering parts refer to the manufacturer's product guide
	Vertaux Occipital System (Polyaxial Pedicle)	
	Apex-3.5mm cancellous screws, self tapping	
Camber Spine Med Tech	Orthos Posterior Stabilization System; Orthros MIS Posterior Stabilization System	For ordering parts refer to the manufacturer's product guide
	FORTICO Anterior Cervical Fixation System	
CTL Medical	Preference Elite Pedicle Screw System	For ordering parts refer to the manufacturer's product guide

	Taurus Pedicle Screw System	
	Raphael Pedicle Screw System	
	Renior Posterior C-Y Fixation System (Accel Spine, Dallas, TX)	
	Picasso II Percutaneoud Screws	
DePuy Synthes Spine	Expedium Verse Spine System	For ordering parts refer to the manufacturer's product guide
	Viper Prime System	
Globus Medical	CREO S2AI Stabilization System	For ordering parts refer to the manufacturer's product guide
	Creo Stabilization System	
	CREO Threaded Stabilization System	
	CREO CoCr Stabilization System	
	CREO Side Loading Stabilization System	
	CREO NXT Stabilization System	
	CREO DLX Stabilization System	
Innovasis	Excella Iii-D Spinal Deformity System	For ordering parts refer to the manufacturer's product guide
	Excella Ii Spinal System Model Ec2-00	
	Excella MIS	
	Excella Spinal System, Excella-M (Monoaxial Screws), Excella-P (Polyaxial Screws)	
Kyocera	S100 Pedicle Screw System	For ordering parts refer to the manufacturer's product guide
Medtronic	CD Solera Spinal System	For ordering parts refer to the manufacturer's product guide
	Infinity Oct System	
	Vertx Select Reconstruction System	
	T2 Stratosphere	
	CD Horizon Longitude II	
	CD Horizon Spinal System	
	CD Horizon Legacy 5.5 (Alternative)	

Precision Spine	Reform Pedicle Screw System	For ordering parts refer to the manufacturer's product guide
	Reform HA Coated	
	Reform Modular	
	SureLok pedicle screw system	
SeaSpine	Daytona® Small Stature Spinal System	For ordering parts refer to the manufacturer's product guide
	Mariner Mis Pedicle Screw System; Seaspine Navigation System	
	Mariner Outrigger Revision System	
	Seaspine Daytona Small Stature Spinal System	
	Seaspine Newport Spinal System	
	Seaspine Mariner Pedicle Screw System	
	Seaspine® Daytona® Small Stature Spinal System	
	Seaspine® Newport™ Spinal System	
	Mariner Pedicle Screw System	
	Malibu Spinal System With The Daytona Deformity System	
	Newport Spinal System	
	Malibu Spinal System	
	Malibu Spinal System	
	Malibu Spinal System	
	Malibu Spinal System	
	Ucr Spinal System	
Stryker	Xia 3 spinal system	

	Serrato pedicle screw	For ordering parts refer to the manufacturer's product guide
	ES2 MIS Pedicle Screw System	
	Mesa 2 Deformity Spinal System	
	Everest Deformity	
	Rail 4D Technology	
	Everest MI XT (Recalled 07/12/2020)	
	Xia 4.5	
	Yukon OCT	
Zavation	Thoracolumbosacral Pedicle Screw System	For ordering parts refer to the manufacturer's product guide
	Z-Span	
	Z-Link Lumbar	
Zimmer Biomet	Vitality Spinal Fixation System	For ordering parts refer to the manufacturer's product guide

⚠ Caution: Package labels and instructions for use for navigated instruments and implantable pedicle screws are provided by the manufacturer. Follow the manufacturer instructions, warnings, precautions, and contraindications when using these accessories.

MAINTENANCE, REPROCESSING, REUSE, STERILIZATION OF BONE PINS & BONE PIN DRIVER

⚠ Warning: Manufactures may provide bone pins & bone pin driver in a sterile or non-sterile condition. For non-sterile bone pins & bone pin driver, clean and sterilize prior to each use per manufacturer instructions.

Follow the maintenance, reprocessing, reuse, and sterilization of bone pins & bone pin driver per manufacturer instructions. The bone pin is a single use component.

For manufacturers that provide non-sterile bone pins & bone pin driver there is no shelf life or expiration date. Repeated processing has minimal effect on the bone pin driver. End of life is normally determined by wear and damage due to use as determined by inspection and functional testing per manufacturer instructions.

For sterile bone pins & bone pin driver provided by the manufacturer, refer to the manufacturer’s instructions for shelf life or expiration date.

COMPATIBLE BONE PINS & BONE PIN DRIVER

The table below shows an example of FDA cleared bone pin driver instruments and bone pins that are compatible with the VisAR system. Bone pin diameter is 3.1mm +/-.1mm and material is custom 17-4 stainless steel per ASTM A564.

Compatible Bone Pins & Bone Pin Driver:

Company	Products	Part Number
Innovasis	Pedicle Subtraction Osteotomy Set; SpineWorks ALIF Instruments	For ordering parts refer to the manufacturer's product guide

⚠ Caution: Package labels and instructions for use for bone pin driver instruments and bone pins are provided by the manufacturer. Follow the manufacturer instructions, warnings, precautions, and contraindications when using these accessories

BIOCOMPATIBILITY

The VisAR software has no direct or indirect contact with the human body. For navigated instruments and implantable pedicle screws, which do contact the body, the VisAR system does not control the process. Follow the manufacturer instructions for instruments and pedicle screws that address biocompatibility issues including tissue-contacting components, the contact classification and duration, and the associated materials for each implant and instrument used.

For bone pin driver instruments and bone pins which do contact the body, the VisAR system does not control the process. Follow the manufacturer instructions for instruments and bone pins that address biocompatibility issues including tissue-contacting components, the contact classification and duration, and the associated materials for each bone pin and instrument used.

For VisAR single use devices, the biocompatibility of patient contact materials was verified according to applicable standards and FDA guidance documents. All tests were successfully completed.

Charging the Device:

The Microsoft HoloLens contains an internal rechargeable battery, with average life rated at two to three hours of active use or continuous operation or two weeks of standby time. The battery indicator displays the charge level. Five illuminated dots indicate the device is fully charged. When only one of the five lights is on, the battery level is below 20 percent.

To charge the device, plug the power supply unit into the AC mains. Connect the power supply to the charging port using the included USB cable. Then plug the power supply into the AC mains. When the device is charging, the battery indicator lights up in a wave pattern.

After the HoloLens headset charge is complete, remove the USB cable from the charging port and remove the power supply from the AC mains.

⚠ Warning: AC adapter Safety:

Do not operate the device while AC adapter is plugged into a power outlet. Do not charge the device inside a hospital operating room.

Use only Microsoft's power supply unit model (see hardware specifications) and AC power cord when charging.

Refer to manufacturer (Attachment B: Microsoft HoloLens Health & Safety) warning regarding AC adapter Safety. It states,

> *Failure to take the following precautions can result in serious injury or death from electric shock, fire, or damage to the device. To select an appropriate power source for your device:*
>
> - *Use only the power supply unit and AC power cord that came with your device or that you received from an authorized Microsoft retailer.*
> - *Do not use non-standard power sources, such as generators or inverters, even if the voltage and frequency appear acceptable. Only use AC power provided by a standard wall outlet.*
> - *Do not overload your wall outlet, extension cord, power strip, or other electrical receptacle. Confirm that they are rated to handle the total current (in amps [A]) drawn by the device (indicated on the power supply unit) and any other devices that are on the same circuit.*
> - *On devices where the AC prongs may be folded for storage, before plugging the AC adapter into a power outlet, make sure its prongs are fully extended.*
>
> *On devices where the AC prongs are removable and where the power supply uses a universal adapter, before plugging the AC adapter into a power outlet, make sure the prong assembly is of the proper configuration for the power outlet and fully seated into the adapter.*

⚠ Caution: Cable and Cord Safety:

Refer to manufacturer's caution (Attachment B: Microsoft HoloLens Health & Safety) regarding Cable and Cord Safety. It states:

> *Arrange all cables and cords so that people and pets are not likely to trip over or accidentally pull on them as they move around or walk through the area. Do not allow children to play with cables and cords.*
>
> *To avoid damaging the power cords and power supply:*
>
> - *Protect the power cords from being walked on.*
> - *Protect cords from being pinched or sharply bent, particularly where they connect to the power outlet, the power supply unit, and the device.*
> - *Do not jerk, knot, sharply bend, or otherwise abuse the power cords.*
> - *Do not expose the power cords to sources of heat.*
> - *Keep children and pets away from the power cords. Do not allow them to bite or chew on them.*

- *When disconnecting the power cords, pull on the plug—do not pull on the cord.*
- *If a power cord or power supply becomes damaged in any way, stop using it immediately.*
- *Unplug your device during lightning storms or when unused for long periods of time.*

Wireless functions and headset technology:

The headset features IEEE 802.11ac Wi-Fi and Bluetooth wireless connectivity and a USB receptacle for charging its internal battery. It is an optical device, has 3D sensors, and cameras for detecting the environment. User input is done through hand gestures performed in front of the device or voice input. The device also provides auditory feedback.

⚠Warning: When connecting the system in an IT network:

Simultaneous connection of other equipment to the same wireless connection may result in previously unidentified risks to patients, operators or third parties. Risks to a wireless network must be identified, analyzed, evaluated, and controlled. Subsequent changes to the wireless connection can introduce new risks that require additional analysis. Changes to the IT-network include changes to its configuration, connecting additional items, disconnecting items, and updates and upgrades of connected equipment.

VISAR END USER SECURITY— DIRECTIONS FOR USE

SYSTEM OVERVIEW

The VisAR system consists of two main components:

1. The Microsoft HoloLens AR headset which is used during surgical procedures.
2. The preoperative planning system includes a workstation and some PACS services, optionally running on a separate server.

Both of these run Novarad software to accomplish their functions. Each device runs the Microsoft Windows operating system.

An abbreviated workflow looks like this:

1. Images are sent to the PACS services via DICOM either locally over a LAN or uploaded to Novarad's cloud. (The images are used in preoperative planning and visualization during surgical procedures.)
2. The physician opens the images on the Novarad pre-operative workstation to perform the preoperative planning and saves the data. Alternatively, the headset can be used to both receive images and perform preoperative planning.
3. When the surgical procedure is ready to begin, a user employs the headset to open the data previously saved on the workstation or headset.

4. The physician uses the headset during the surgical procedure to visualize internal anatomical structures and to receive guidance, incorporating the real-time visualization of the patient and the data from the preoperative plan.

NETWORK

VisAR is designed to be run on a LAN protected by firewall from threats both internal and external. Customers are responsible for the security of the network on which VisAR operates.

MEDIA

The headset is a wireless, battery-powered device. It connects to the network over Wi-Fi to download the images used during surgery, to download Novarad and Operating System software updates, and optionally, to share its visualization with others.

The workstation and optional server are designed to be connected to a LAN.

FIREWALL

As an added measure of protection, the HoloLens Headset is shipped with the Windows firewall active. This allows no external inbound connections to be made to the HoloLens device.

INTERNAL (LAN) ACCESS

DICOM image transmissions are accepted by the PACS services on port 104 (by default.) These transmissions may come from a PACS system, or optionally, from modalities themselves. This is the preferred method for providing the images with which the surgical plan will be developed on the workstation, and which will be used for the image visualization on the headset during surgical procedures.

The headset needs to be able to access the Novarad PACS services over HTTPS. The workstation needs to be able to access the same PACS services.

EXTERNAL INTERNET ACCESS

No inbound Internet access should be given to the headset. However, Network Administrators need to give access to the VisAR system to allow it (all components) to communicate on the Internet with:

1. Novarad for product updates and licensing. (https://ncc.novarad.net)
2. The Microsoft Store to get important Novarad product updates.
3. Microsoft Windows Update to retrieve important Operating System updates.

PHYSICAL ACCESS

The headset is a portable device. Care should be taken to restrict physical access only to appropriate personnel.

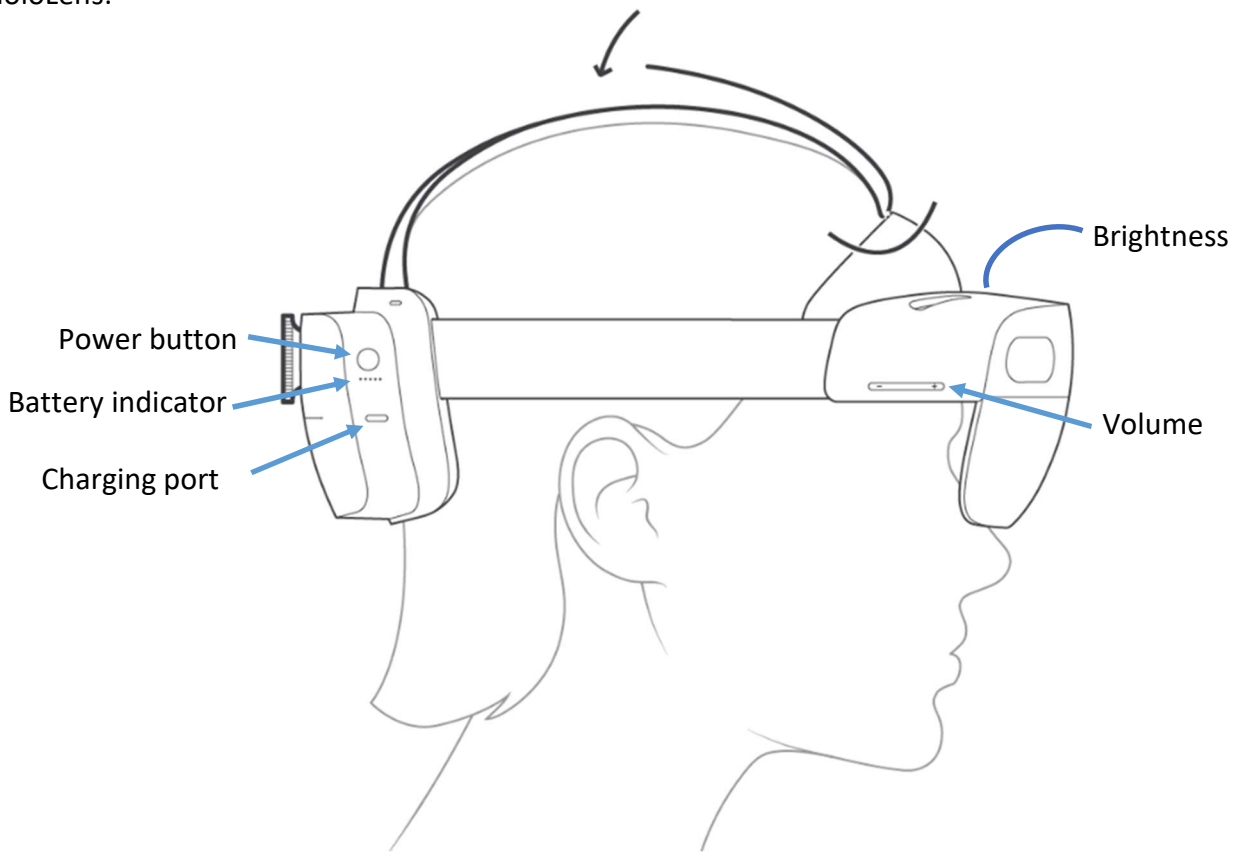
STORAGE

The headset may optionally maintain a history of the radiological exams it has accessed recently. (Alternatively, the system can be configured such that no history of exams is left on the device.)

This information is considered to be ePHI and therefore the headset should be stored in an appropriately secured area that is capable of charging. It is also recommended that during storage, the device be powered on and provided with Internet access to allow for automatic updates to occur as needed.

USING THE MICROSOFT HOLOLENS FOR VISAR

HoloLens:



CLINICAL BENEFITS OF VISAR

1. Reduces Learning Curve of a surgery and improves accuracy as a function of a surgeon's surgical experience.
   Increases accuracy over current state of the art care which is free hand placement of screws using fluoroscopy or a spin CT to confirm (96% success for augmented reality vs 84% success freehand)

SANITATION TECHNIQUES

Before either sanitation technique, the patient's skin must be prepped for surgery according to standard surgical procedures prior to attaching either Tegaderm Film, Allevyn Classic, or the Patient Tags.

Patient Tags are a single-use and sterile tag.

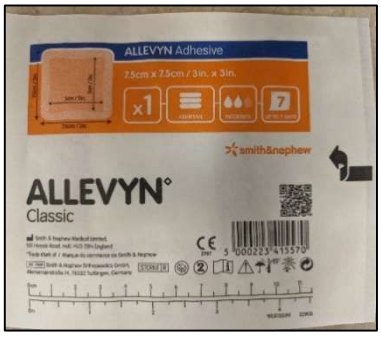
TECHNIQUE 1 –

If the patient has an allergy to the Patient Tags, this technique should be utilized.

Patient Tags were placed on underlying bandages so that it can act as a protective layer to the skin if the patient has any allergy to the Patient Tag code.

1. The patient's skin must be prepped for surgery according to standard surgical procedures prior to continuing the subsequent steps.

2. Place a sterile "Tegaderm Film" or "Allevyn Classic" film on the patient where the Patient Tags will be placed. (Placement of Patient Tags will vary from procedure to procedure. Consult with the operating surgeon if you are unsure where Patient Tags should be placed.)



3. Place the Patient Tags on **top** of the sterile film dressing. Ensure that the Patient Tags are smoothed out and no wrinkles are present.

4. Obtain a CT scan of the patient.

   After the CT scan is completed successfully, apply the following sterilization techniques on top of the Patient Tags:

   a. Apply "Ioban 2" antimicrobial incise drape over each Patient Tag.

TECHNIQUE 2

If the patient does **not** have an allergy to the Patient Tag, technique 2 may be used.

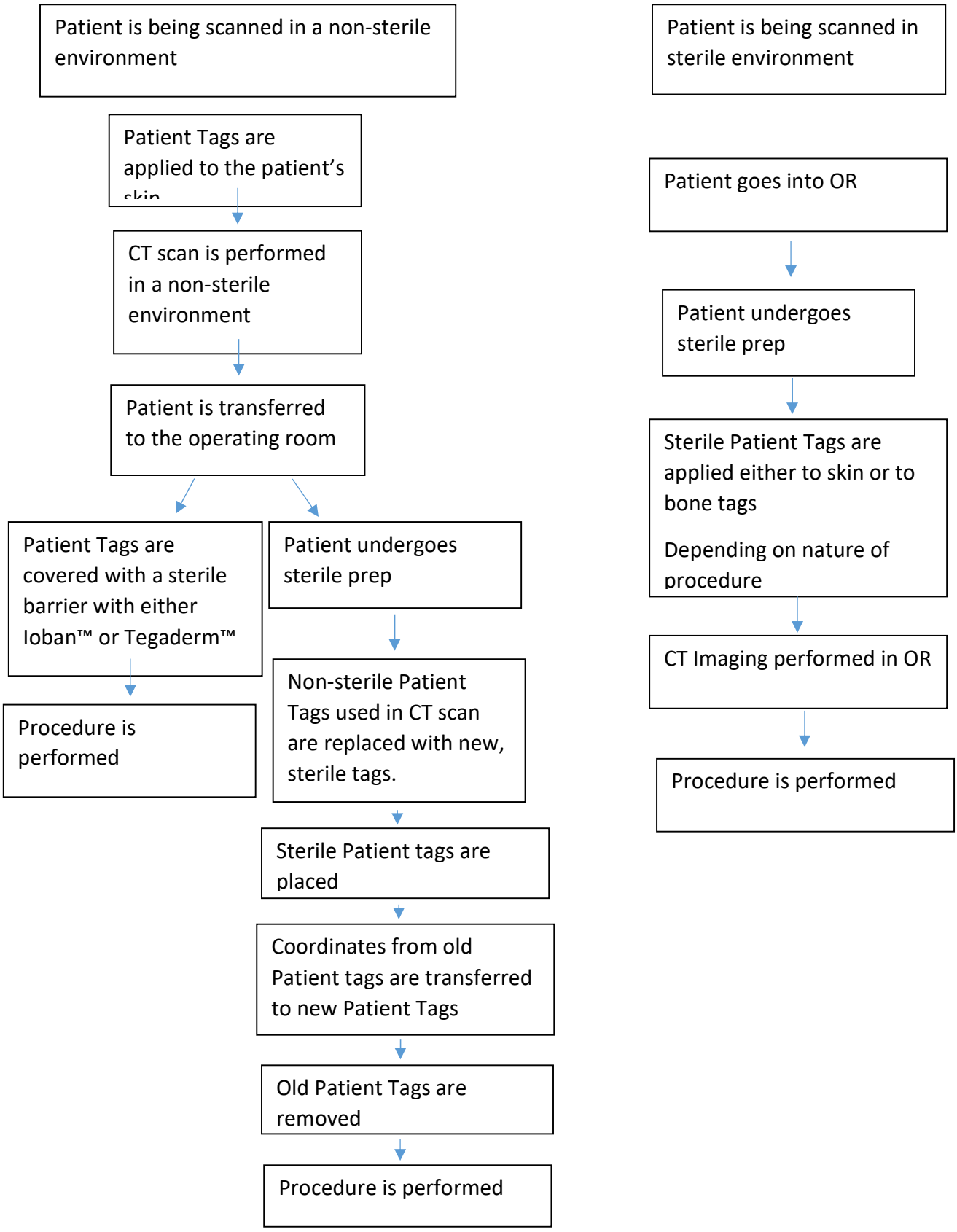
1. The patient's skin must be prepped for surgery according to standard surgical procedures prior to continuing the subsequent steps.

2. Properly sterilize patient's skin where Patient Tags will be placed. (Placement of Patient Tags will vary from procedure to procedure. Consult with the operating surgeon if you are unsure where Patient Tags should be placed.)

3. Place Patient Tags directly on sterilized portion of patient's skin. Ensure that the Patient Tags are smoothed out and no wrinkles are present.

4. Obtain a CT scan of the patient.

5. Place sterile "Tegaderm Film" or "Allevyn Classic" film over top of the Patient Tags after the CT scan is finished. Ensure that the sterile film strips are smoothed out and no wrinkles are over the Patient Tags.


Patient is being scanned in a non-sterile environment
Patient Tags are applied to the patient's skin
CT scan is performed in a non-sterile environment
Patient is transferred to the operating room
Patient Tags are covered with a sterile barrier with either Ioban™ or Tegaderm™
Procedure is performed
Patient undergoes sterile prep
Non-sterile Patient Tags used in CT scan are replaced with new, sterile tags.
Sterile Patient tags are placed
Coordinates from old Patient tags are transferred to new Patient Tags
Old Patient Tags are removed
Procedure is performed
Patient is being scanned in sterile environment
Patient goes into OR
Patient undergoes sterile prep
Sterile Patient Tags are applied either to skin or to bone tags
Depending on nature of procedure
CT Imaging performed in OR
Procedure is performed

PART 3: HOLOLENS INSTRUCTIONS

3-1 DOWNLOADING VISAR

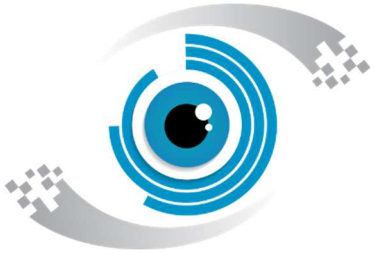
DOWNLOAD FROM THE APP STORE

You can download VisAR from the Microsoft App store by scanning the below QR code or following the numbered steps.

1. Open the Microsoft Store from the HoloLens main menu.
2. Using the search field, locate “VisAR” in the app store.
3. Once VisAR is found, select the VisAR icon.
4. Click **Download**. The app downloads to the HoloLens headset.
5. Users can access a demo mode until licensed with Novarad.

3-2 OPENING VISAR

Find the VisAR icon (see below) on the HoloLens main menu. Hover the cursor over the VisAR icon and select it. The software opens.



Note: VisAR may not appear on the first page. Select All Apps to populate all the downloaded apps on the HoloLens device.

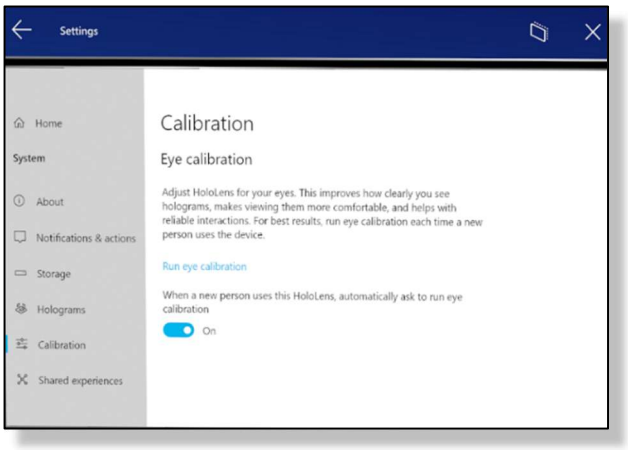
3-3 CALIBRATION

Calibration is required prior to using the headset. This consists of a Microsoft HoloLens Headset calibration, a Novarad interpupillary distance (IPD) calibration, and a room mapping calibration.

MICROSOFT HOLOLENS HEADSET BUILT-IN CALIBRATION

The Microsoft HoloLens Headset built-in calibration is required for each user. Calibrating the HoloLens ensures that it can accurately track your eyes and that the hologram appears accurate to you. It also helps with comfort, stereoscopic 3D image alignment, and hand tracking. You should calibrate the HoloLens when you wear it for the first time, if the headset is changed to a new user, or if the calibration failed the last time the user used the HoloLens.

Note: The user's previous calibration is retrieved by the VisAR system upon use. An audible signal is given to the user indicating whether calibration has been performed. The Microsoft data is retrieved by Novarad and if that user has not calibrated with the Novarad calibration, an audible signal is also given.



To calibrate the HoloLens, open the wrist menu and navigate to Settings → System → Calibration → Run Eye Calibration.

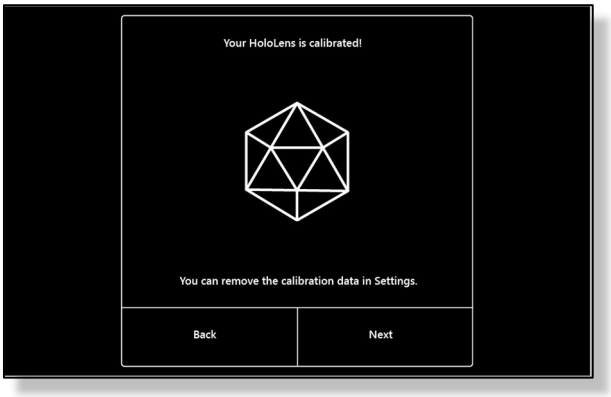
Once the calibration program launches, you will see and hear a message from the HoloLens about how the calibration is run.

You must adjust the headset to see the outline of the Eye Calibration window.

The HoloLens prompts you to hold your head still and follow image-guided navigation system gems with your eyes.

The HoloLens populates six gems, one at a time, in various areas in the field of vision. After you have looked at all the gems, the HoloLens displays a message telling you it is adjusting the device.

Upon successful calibration, a message populates telling you the HoloLens is calibrated. If the calibration was unsuccessful, run the calibration program again.



NOVARAD INTERPUPILLARY DISTANCE (IPD) CALIBRATION

The interpupillary distance (IPD) measures the distance between your eyes (pupils).

The IPD calibration procedure is intended to be used after the Microsoft HoloLens Headset built-in calibration. For the IPD calibration, a VisAR Calibration Tool with a large, printed QR code is placed on the wall in the Operating Room. Stand between 2 and 4 feet away, facing the card. The voice command “Start eye calibration" initiates the procedure. Alternatively, viewing the QR code and pressing the HoloLens start button will initiate the calibration.

The HoloLens will project yellow plus signs onto the plus signs printed around the Calibration Tool. The following slide controls will also appear:

- Left Eye Horizontal
- Left Eye Vertical
- Right Eye Horizontal
- Right Eye Vertical

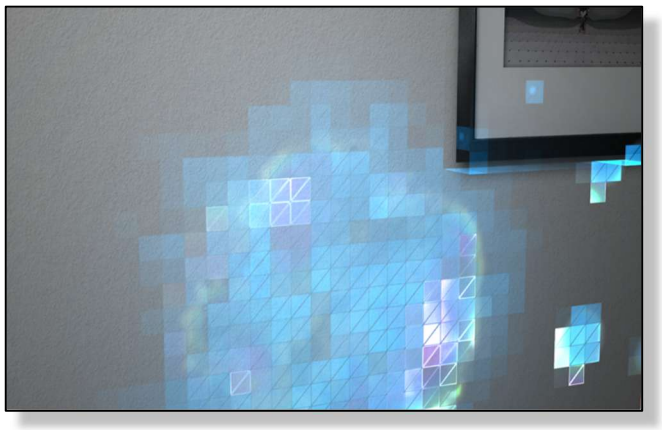
These controls can be used to align the virtual plus signs with the printed ones. To move the slide controls, pinch and drag the slider until the plus signs are lined up.

Please use the Calibration Tool found at the end of this document.

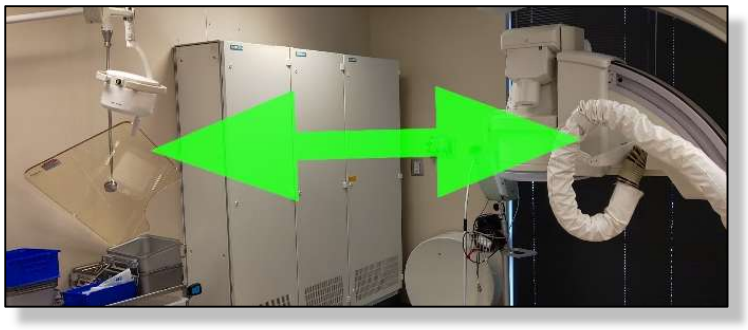
ROOM MAPPING CALIBRATION

In addition to calibrating the Microsoft HoloLens, you should also utilize the spatial mapping features of the HoloLens when using VisAR. This helps create an accurate hologram anchoring and assists during tag registration. Spatial mapping provides a detailed representation of real-world surfaces in the environment around the HoloLens and makes it possible to place objects on real surfaces. This helps anchor objects in the user's world and takes advantage of real-world depth cues, such as an operating room table.

Spatial mapping happens automatically and continuously when you start the HoloLens and again when you open a study in VisAR. You can recognize when spatial mapping is happening by hearing an audio cue as well as seeing blue polygons map over your surroundings.



After hearing the audio cue and seeing the polygons, you should rotate 360° to look at the surfaces in the room. For example, in an operating room you should turn your head and look 360° around the operating table and theater to make sure that it is properly mapped.



⚠ Physical Changes between time of scan and HoloLens headset use:

Conditions of physical changes such as swelling or anatomy that shifts or moves between time of scan and headset use may cause inaccurate localization of anatomy.

1. Patients should be in the same position as they were in the MR or CT scanner, whether pre- or intraoperative.

2. Scans should be obtained as close to the time of surgery as possible.
3. A surgeon can look at the visible anatomy and correlate with the virtual anatomy seen through the headset. If the images do not align, registration or patient anatomy may have changed.

VisAR displays a warning label within the lenses if the patient is not lying in the same orientation as the medical scan. The warning label is colored red and bold and includes the words “May be inaccurate.”

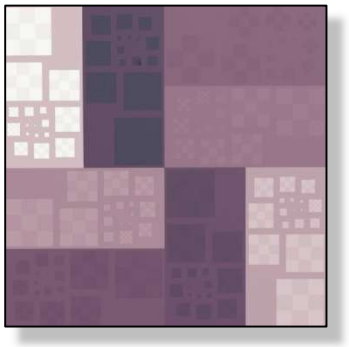
3-4 TEST PATTERNS

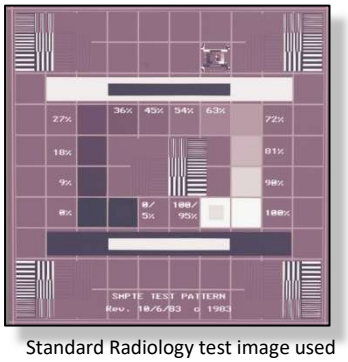
VisAR comes equipped with test patterns that help users ensure the image quality is adequate for the safe guidance and navigation of surgical instruments during surgery.

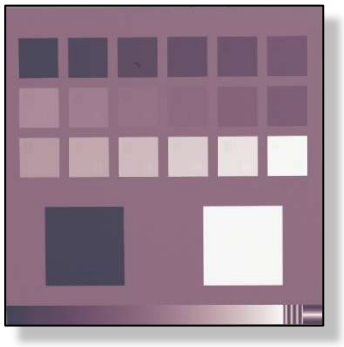
Use the voice command “Show Test Patterns.”

A series of five test patterns will appear. Click your fingers to progress from one to the next. After the fifth, the process ends, and the user can continue other activities in VisAR.

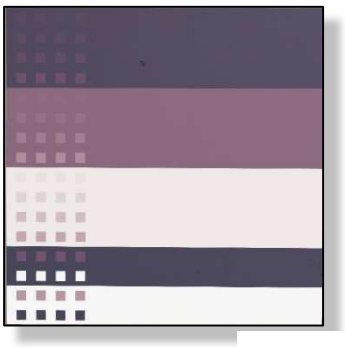
Below are the test images shown in the order they appear in VisAR.

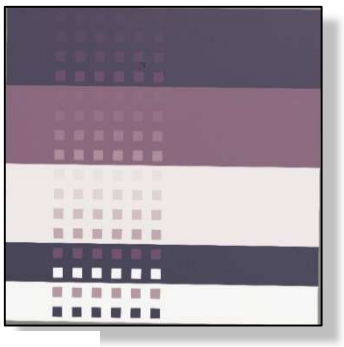






Standard Radiology test image used to evaluate displays





These are used to evaluate the dynamic performance of the display

If you are having trouble seeing the images, that is an indicator that it is not safe to proceed with surgery until the display has been fixed.

PART 4: SURGICAL PLANNING

This section details how to use the Augmented Reality/VisAR features in the Surgical Planning App. All features require a VisAR license.

4-1 IMAGE VISIBLE TAGS

Tags are optical codes that assist VisAR in aligning the stereoscopic 3D image study onto the patient in the operating room.

Tags are placed on the patient before the pre-op scan and are included in the same scan. When placing tags on the patient, the areas must first be sanitized. The tags should then be placed on the patient. After the tags are placed on the patient, Tegaderm film (or another transparent, sterile film) may be placed over the tags to ensure that they stay in one place following the scan if a significant time lapse between imaging and surgery is expected.

⚠ Warning: Take the following precautions to ensure registration functions properly when placing transparent film dressing over the tags.

- A white border must be present on each tag.
- Tag should not be wrinkled.
- Dressing needs to be clear.

After the pre-op scan takes place, you must align the tags in the Surgical Planning Workstation.

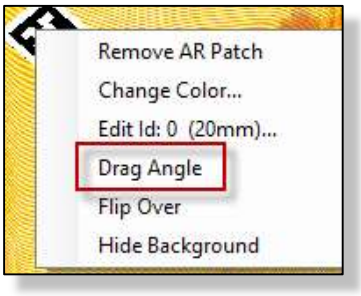
For the alignment to be successful, virtual tags need to be populated along with the physical tags on the patient. This section details how to populate tags for viewing in a virtual three-dimensional space.

> *Note: This step takes place after the patient has been scanned and the study has been routed to the pre-operative Advanced 3D Workstation. Users may also choose to send DICOM images directly to surgical planning from the modality.*

1. Find the study in the Study Browser.
2. Select the desired series and double-click to populate it in the Image Viewer.
3. Select the 3D icon. 
4. Allow the image to render in the Surgical Planning App.
5. After the image is completely loaded, right-click to populate the menu.
6. Select **Surgical Planning.** The tags should automatically populate over the scanned tags on the 3D image overview in the bottom right-hand quadrant.

   Note: Images are visible behind tags during surgical planning.

If the tags are not automatically detected, users may need to manually place the virtual tags on the 3D model following the steps below:



1. Select Add Tag in the Surgical Planning window.
2. A tag populates on the cursor and users can place the virtual tag on the 3D image over the tags that were previously scanned by the modality.
3. Users can adjust the angle of the virtual tag to match the scanned tags. Right-click the virtual tag and select Drag Angle.
4. Users also need to set the ID for each tag. Right-click the tag and select Edit ID.
5. A window populates and users are asked to select an ID (numbered from 0-10). If there are 5 tags on the patient, they should be numbered 0–4. Each tag should have a different ID.

   Note: When tags aren't automatically identified during surgical planning, the system allows you to identify which tag ID matches the unidentified tags by displaying a list with thumbnails of each tag in surgical planning, under Tags.

6. Repeat for each tag that is populated on the 3D image.

   Note: If the system is unable to automatically detect tags after manual placement, users can force the system to recognize a tag by clicking it directly.

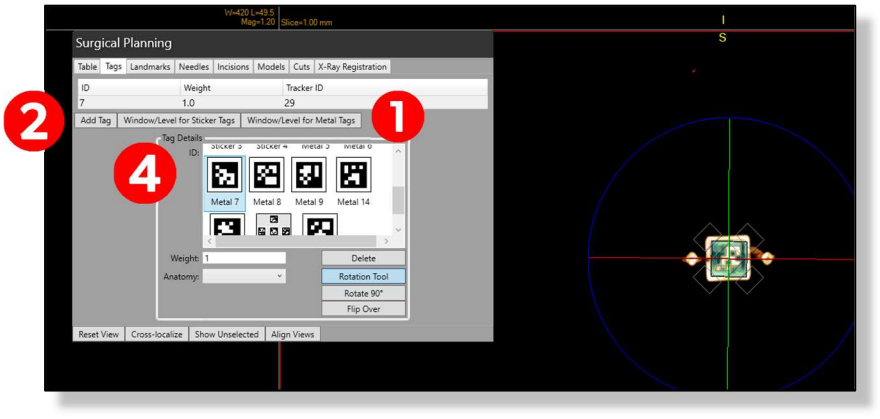
METAL TAGS

The metal tags function similar to the Patient Tags. The Metal Tags contain an optical code that assists in aligning the stereoscopic 3D image study onto the patient in the operating room.

Metal tags are inserted into the patient tracker before the scan, and it's important to ensure that each tracker contains the correct tag and that it is properly oriented (see section 7-4 Patient Trackers for more information on placing metal tags in patient trackers). The metal tags are detectable by radiographic imaging.

Once the scan is obtained, surgical planning must be performed on the metal tag:

1. In the tags tab, click Window/Level for Metal Tags. This will make the metal tag visible.
2. Click Add Tag.
3. Left click to place a virtual tag on the metal tag.
4. Select the corresponding metal tag from the tag details box.
5. Rotate the virtual tag using the rotation tool that automatically appears around the tag. Rotate the virtual tag until the virtual tag pattern aligns with the physical tag pattern.



Note: *As of VisAR 3.0.67, titanium tags have reached end of life. They will continue to be supported by VisAR however. All metal tags going forward will be made of stainless steel.*

EDITING TAGS

Surgical Planning allows you to manipulate tags for your convenience.

You can change the Window/Level preset to make metal tags more visible:

- Under the *Tags* tab in Surgical Planning, there is a button that lets you set the Window/Level to a value that increases the visibility of tags.

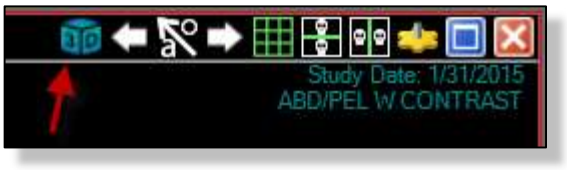
You can rotate tags in surgical planning as well:

- After you place a tag, right-click on the tag and select "Rotation Tool." A rotation icon will appear, allowing you to rotate the tag.

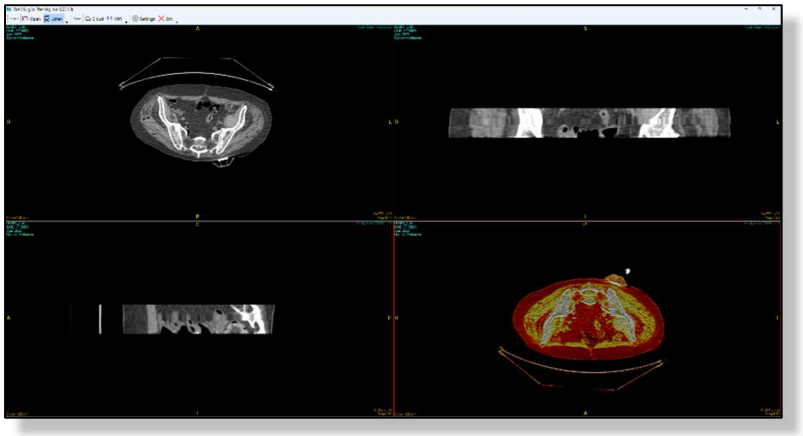
4-2 ADDING A VIRTUAL NEEDLE: TWO METHODS

METHOD 1: ADD NEEDLE

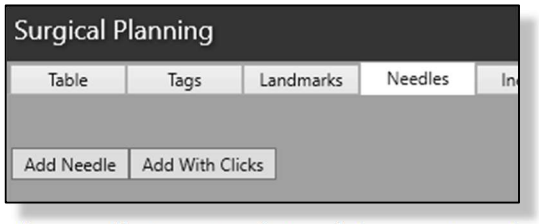
1. Search for the study in the Surgical Planning App and open it in the PACS Viewer.
2. After the study has completely loaded in the Image Viewer, select the **3D icon** to render the study into 3D.



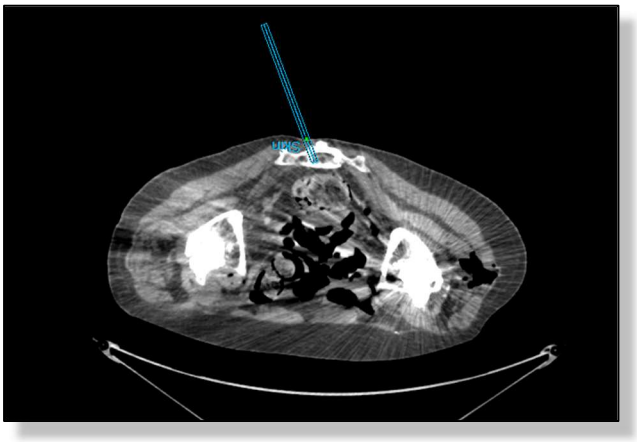
3. This populates three orthogonal multi-planar images along with a 3D model.



4. Once the image is completely rendered, right-click to populate the menu and select Surgical Planning.
5. To create a virtual needle, select the Needles tab on the Surgical Planning window and select Add Needle.



6. Right-click and drag to create the annotation. Start with the needle target point and draw outwards towards the insertion point.



7. The annotation populates on all 2D and 3D images.

Note: Use the undo/redo commands to fix mistakes made in surgical planning:

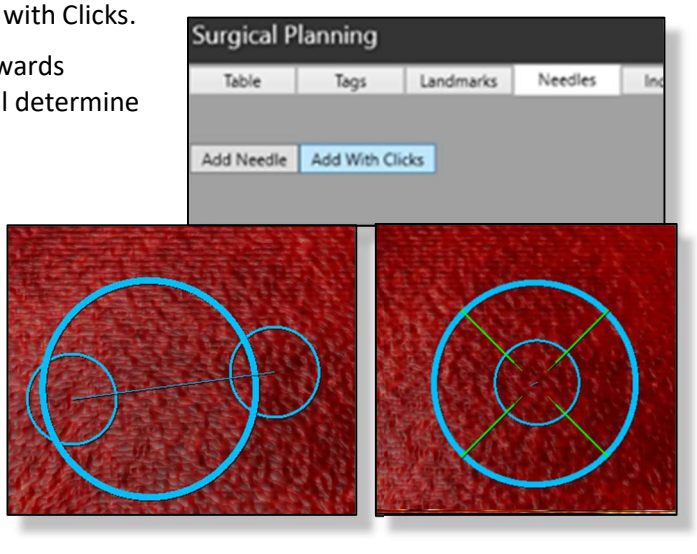
Undo: Ctrl-Z

Redo: Ctrl-Y

8. Save the changes in the Surgical Planning App.

METHOD 2: ADD NEEDLE WITH CLICKS

1. To create a virtual needle with clicks, select the Needles tab on the Surgical Planning window and select Add with Clicks.
2. Start with the needle target point and draw outwards towards the insertion point. The second click will determine the end of the needle.
3. When you rotate the 3D image,
   The user sees the length of the needle populated in the 3D model window.
   Once you have lined up directly with the virtual needle on the 3D model, the circle

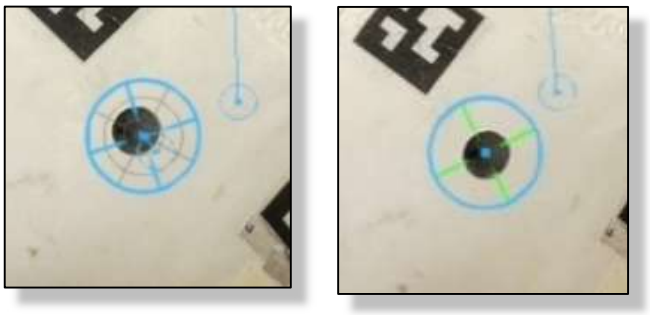


crosshairs disappear, and you are left with a crosshair that indicates you are directly lined up with the virtual needle.

Not lined up over needle

Lined up over needle

4. When viewing the virtual needle in VisAR, the endpoint of the needle target point is the bottom circle, and the crosshair is the upper circle. The extended line is used for aligning the physical needle. See figures for examples.

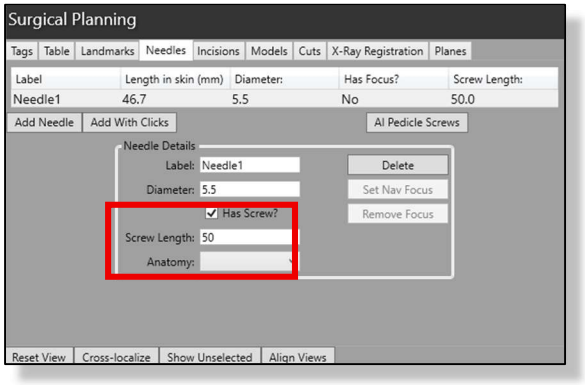


First-person view aligning target point and crosshair circle.

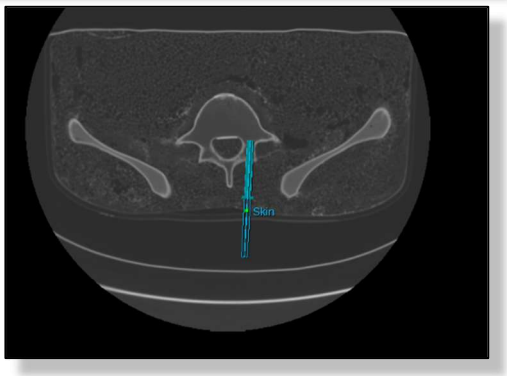
PEDICLE SCREWS

Users can create a path in surgical planning specifically for Pedicle Screws. To do this:

1. Go to the needles tab.
2. Click Add Needle.
3. Draw the needle in the desired pedicle
4. Check the Has Screw? option.
5. Specify screw length.
6. Make sure the virtual instrument draws in-front of the virtual screw so it is visible for presice navigation.



Once the study is saved and the QR code is printed out, the pedicle screw will appear in the immersive view.

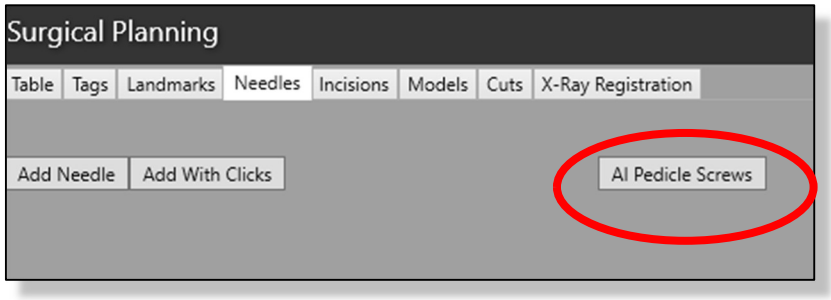


Pedicle Screw Planned in Surgical Planning

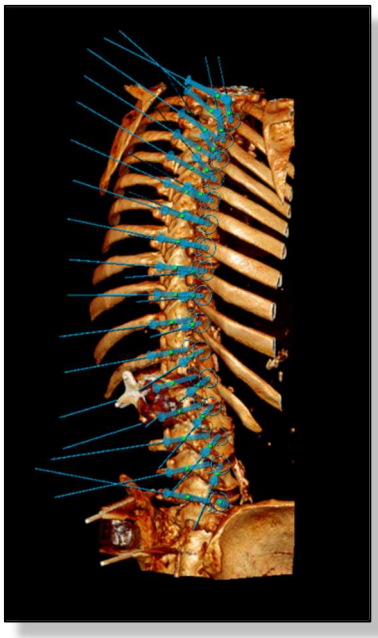
ASSISTIVE INTELLIGENCE PEDICLE SCREW PLACEMENT

Users have the ability to plan pedicle screws using VisAR's Assistive Intelligence (AI).

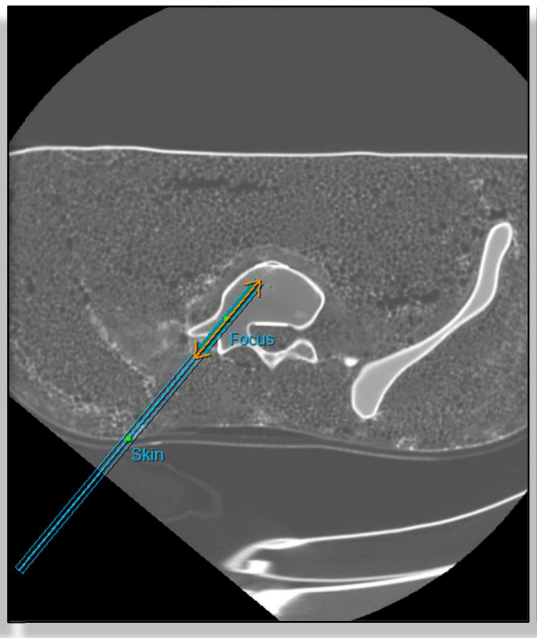
1. In the Needles tab, click the AI Pedicle Screws button.



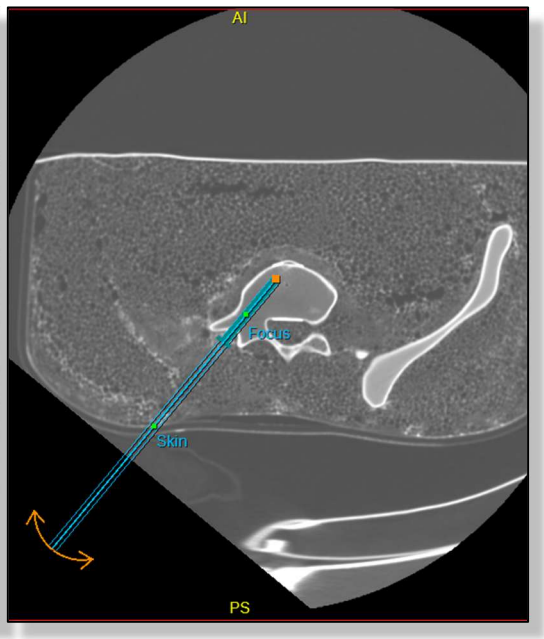
2. The system will automatically plan screws in the patient's pedicles.
3. Once the screws appear, click on the list of screws to adjust the screw trajectory, focus point, and skin point accordingly.



AI Planned Pedicle Screws



Adjusting the focus point



Adjusting the Trajectory

IN THE IMMERSIVE VIEWER

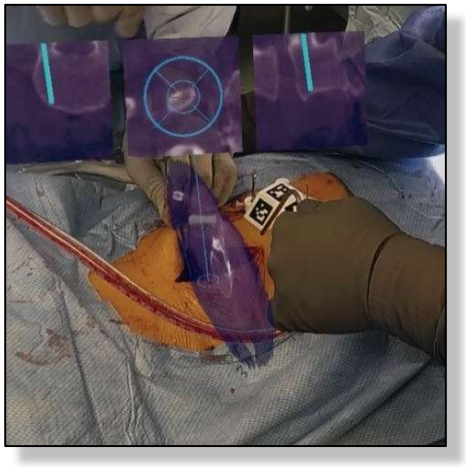
The virtual needle is annotated in the Immersive Viewer and uses a guidance feature that allows you to know exactly where and how deep the needle should be inserted.

When viewing the virtual needle, the annotation changes colors depending on how close your eye is to the annotation as well as how on-target you are. The virtual needle annotation turns green when you are aligned with the annotation.

When you move physically close enough to the virtual needle annotation, VisAR alerts you to close an eye (VisAR specifies which eye to close).

USING NAVIGATION VIEWS

The Navigation Views feature allows you to see three orthogonal views displayed above the center of your view. These views show perpendicular slices along a virtual needle that was created in the pre-operative planning stage or tracked instrument.

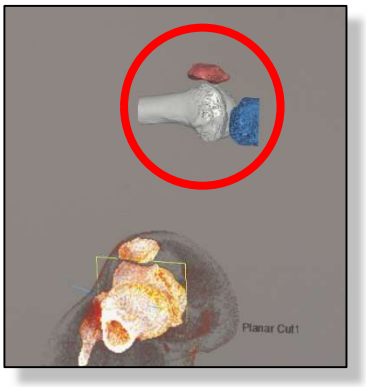


Use the voice command “Show Nav Views.” The views are centered and rotate around the current needle. If there are no needles placed than it will center around the instrument.

You can Show/Hide Navigation views and drag the navigation views to a different placement within 3D space. This allows you to place the navigation views in a location that does not interfere with the patient, surgery, or image viewing. The views will also tell you when instrument tracking is synced with the Nav Views. The Center Nav View will be highlighted in green when tracking is active, and the HoloLens can see the tracker. If the Center Nav View becomes highlighted in red, that means the HoloLens can’t see the tracker and is no longer tracking your instrument.

3D NAV VIEWS

You can also view 3D Nav Views on studies that contain models. Use the voice command “Show 3D Nav Views” to make them appear. You can move the views by clicking and dragging the title bar.



Point at the Nav View to get the Rotation and Exit Buttons to appear. The rotation button in the title bar will let you rotate the view. Click ‘X’ to exit from the view.

Use the voice command “Drag 3D Nav View Zoom” and click and drag in the air to change the size of the viewed area.

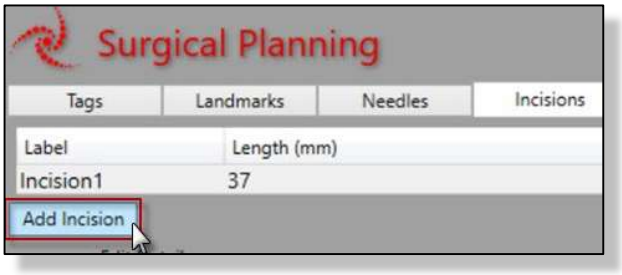
4-3 VIRTUAL INCISION

1. Find and open the study in the Study Browser.
2. Select the series you wish to annotate.
3. Select the 3D icon in the Image Viewer.

   Allow the image to render.

   Note: You can also open the Radius Menu to populate in 3D.

4. Right-click to populate the menu and select Surgical Planning.
5. To create a virtual incision, select the Incisions tab on the Surgical Planning window and select Add Incision.
6. Right-click and drag to create the incision.
7. Save changes in the Surgical Planning App.



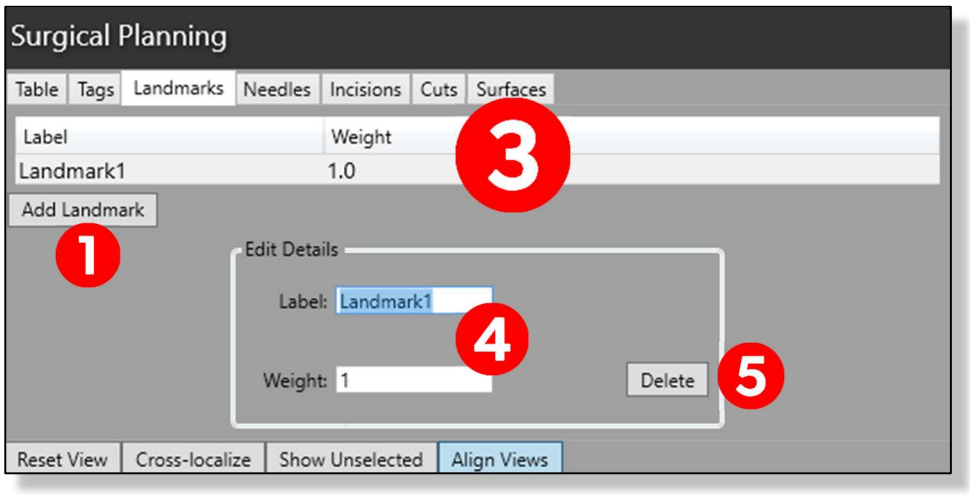
4-4 LANDMARKS

The Landmarks Tab is where you can place and edit landmarks which are used in place of skin tags. Landmarks are points on a patient's anatomy that you identify in surgical planning which VisAR will then use to accurately place the holograms.

1. To add a landmark, click Add Landmark.
2. You will then be prompted to left-click on the 3D image to place your landmark.
3. Once you left-click, the landmark will appear both on the 3D image and in the Surgical Planning Window.
4. In the Surgical Planning Window you can change the name and weight of the landmark.

   Note: Weight is the same for Landmarks as it is for tags.

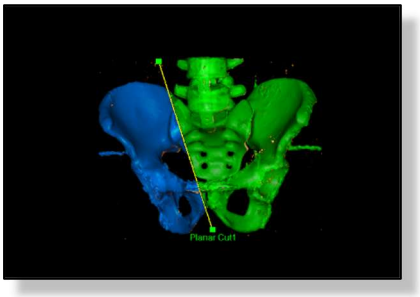
5. To delete a landmark, select the specific landmark you want to delete and then click Delete.
6. Add multiple Landmarks by clicking Add Landmarks again.



4-5 MODELS

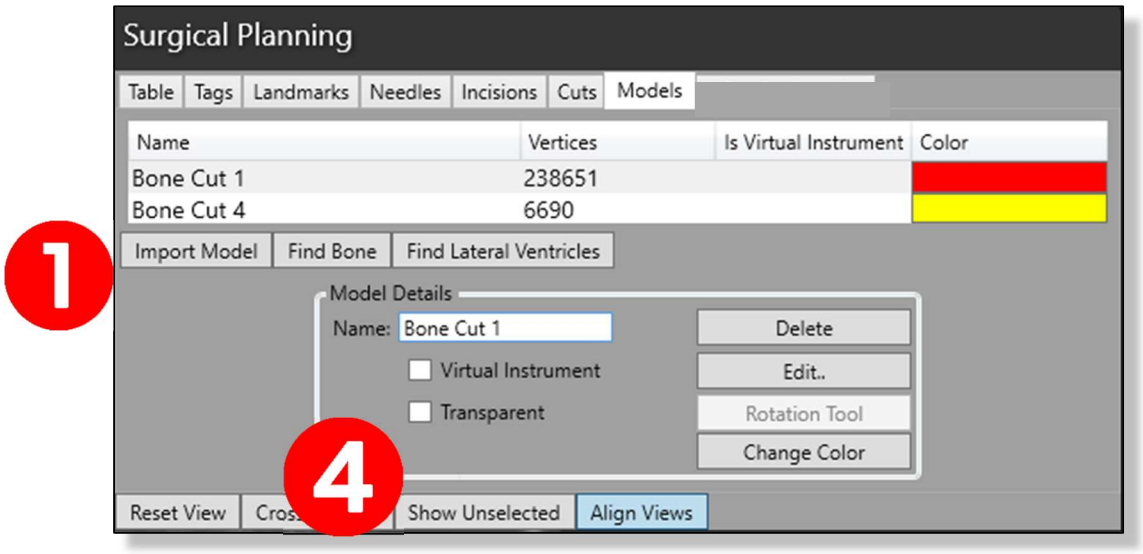
The Models tab lets you plan for surfaces/anatomy that is going to move during surgery.

1. Click Find Bone to identify the bones in the image. You will be prompted to right click and drag to find the threshold of the bone. This can help clean up messy surfaces.
    a. Users can also import a virtual instrument model. This is helpful for surgeons who will have to use multiple different kinds of instruments in surgery. To import a virtual instrument model, click Import Model and import the STL file of your instrument.
        i. For some surgeries, surgeons will want to flip their instrument. To flip your virtual instrument with your physical instrument, use the voice command "Flip Virtual Instrument."



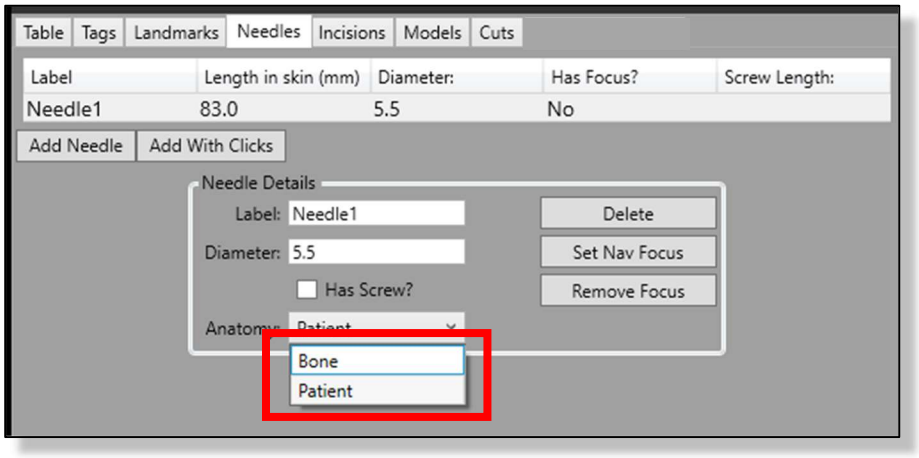
2. Once the surfaces have been identified, click and move them independently of the other surfaces. The surfaces will be distinguished by different colors.
3. Find Lateral Ventricles only works on images of the brain. It allows you to window/level to find the threshold of the lateral ventricles.

   Checking the Transparent Check box turns the 3D image transparent.
4. Once you have created models, you can then use the anatomy drop-downs in the other tabs (Tags, Landmarks, Needles, Cuts…). This will associate the annotation with the model. Once the model is registered to a patient tracker in surgery, then the annotation will move with the model.



Once the model has been created and named, users can then associate annotations with the model. Annotations that have been associated with a model will then move with that model during surgery.

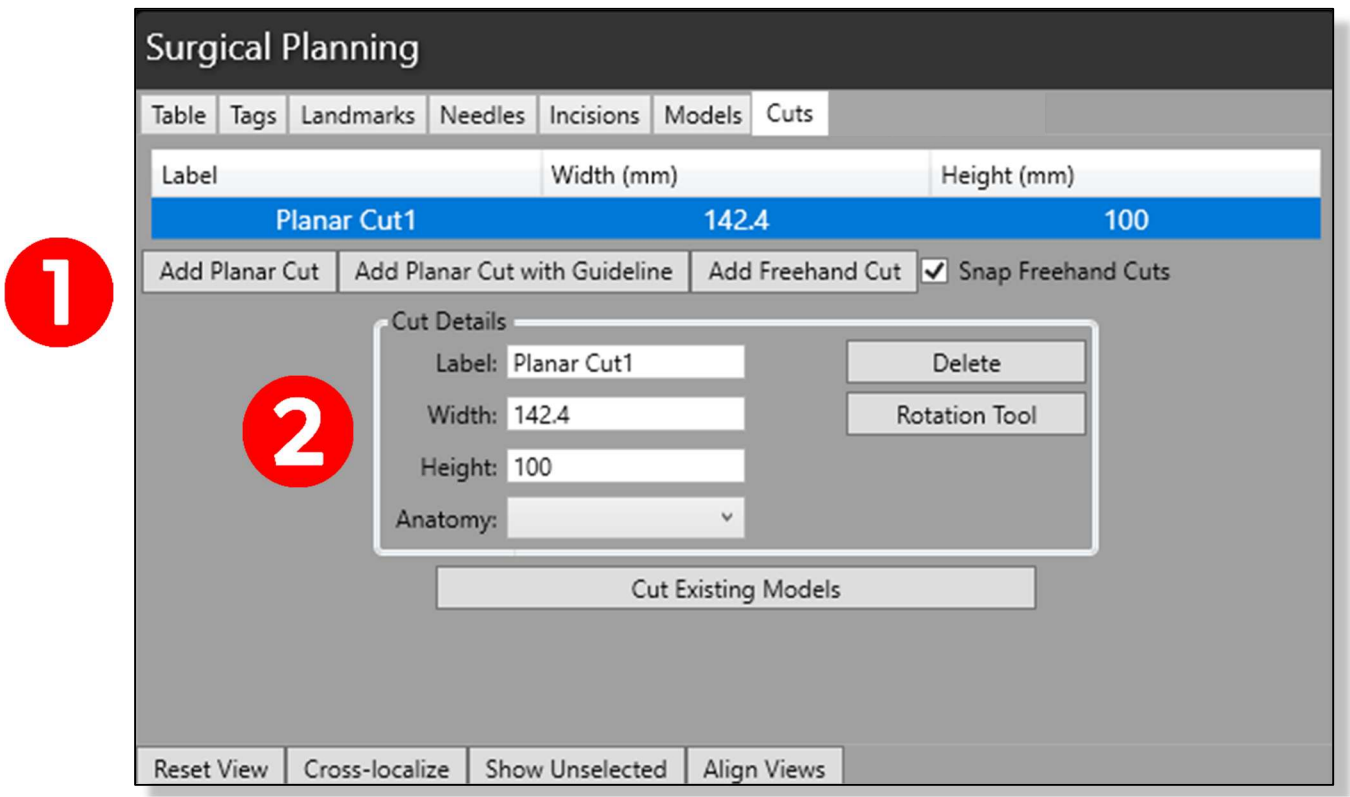
To associiate an annotation with a model, navigate to the desired annotation's tab in surgical planning, and select the model's name from the dropdown:



4-6 CUTS

The Cuts tab is useful when planning bone cuts. Users must have a model in place in order for cuts to be effective.

1. To add a cut, click Add Planar Cut, Add Planar Cut with Guideline, or Add Freehand Cut.
   - Add Planar Cut: Allows you to create a regular planar cut.
   - Add Planar Cut with Guideline: Allows you to create a planar cut with guidelines and measurements that show you how much you've rotated a cut.
   - Add Freehand Cut: Allows you to draw your own planar cut. This option is most useful for very specific and refined cuts.
2. Once you add a cut, you will be able to edit the details such as the label, width, and height.



Click Delete to delete a planar cut. The Rotation Tool button will allow you to rotate the cut after you've made it.

The Cut existing models button will cut an existing model along the plane of a cut. This is helpful for users who want to separate a single bone model into multiple.

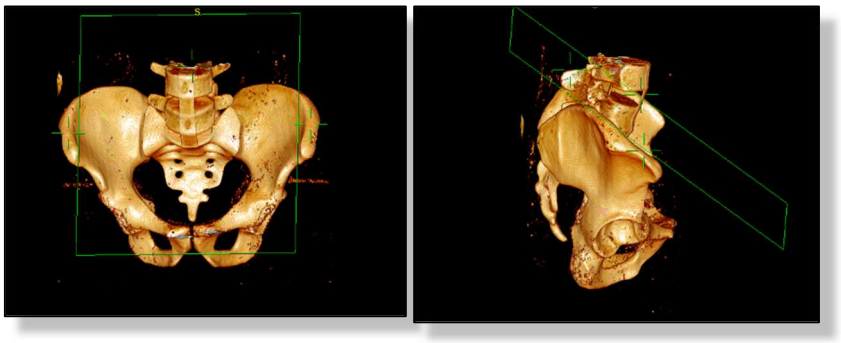
4-7 X-RAY REGISTRATION

See section 9-10 X-Ray/CT Registration for more information on how to conduct Surgical Planning for X-ray registration.

4-8 PLANES

Users can also create reference planes in Surgical Planning based on the anatomy of the patient. These planes can be used for measuring angles and distances of other annotations.

1. To add a reference plane, click on the **Planes** tab.
2. Click **Add with 3 points.**
3. Click the 3 points of desired anatomy in the 3D view to construct the plane.
    a. Users can also add a perpendicular plane to the first plane by clicking **Add Perpendicular.**
    b. Then, click two points of anatomy to construct the perpendicular plane.



When users edit needles/screws in the needles tab, users will be able to see the angle the needle makes with the reference planes.

4-7 UPLOADING 3D MODELS

You can upload .stl files during surgical planning to insert a 3D model instead of a two-dimensional image. Select "Import a 3D Model" and choose the desired .stl file.

In addition to uploading, you can also edit 3D models. In Surgical Planning, under the Models Tab, click Edit…

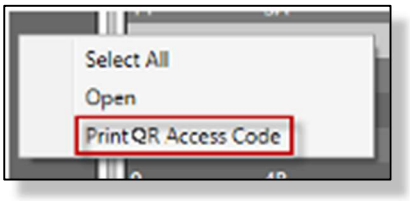
A window will appear that lets you change the model's properties.

4-8 CREATE QR ACCESS CODE

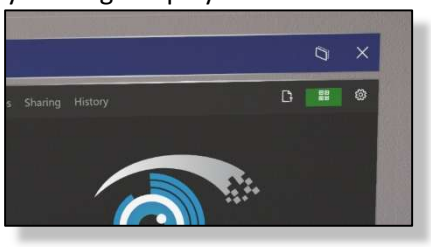
The VisAR QR Access Code allows users to print a QR code that automatically retrieves and populates a study in the VisAR system.

1. Manipulate the series in the Immersive Viewer, save changes, and close the study.
2. Navigate to that same series in the NovaPACS Study Browser.
3. Right-click the series.
4. Select Print QR Access Code.

   The print option populates, and you can print the QR Access code the same way you would print any other kind of document.



5. To populate the Study in the VisAR Immersive Viewer, simply look at the QR Access Code with the HoloLens headset turned on. You will be prompted to open the study by clicking the play button that appears on the QR code.
   a. If you are already in the immersive app, click the QR code button in the top-right corner of the 2D View. The button will turn green to show it's looking for a QR code; look at the QR code from a couple of feet away. The study will then open.



OPENING IMAGES WITHOUT WIFI

In order to open images without WiFi:

1. Save the images/surgical plan as an NRTX file on a PC.
2. Transfer the NRTX file to a local folder on the headset using a USB drive or an app that allows remote access to the headset's storage folders (like Microsoft's Device Portal).
3. Use VisAR's "Open From File" feature to open the NRTX file from the headsets local folder.

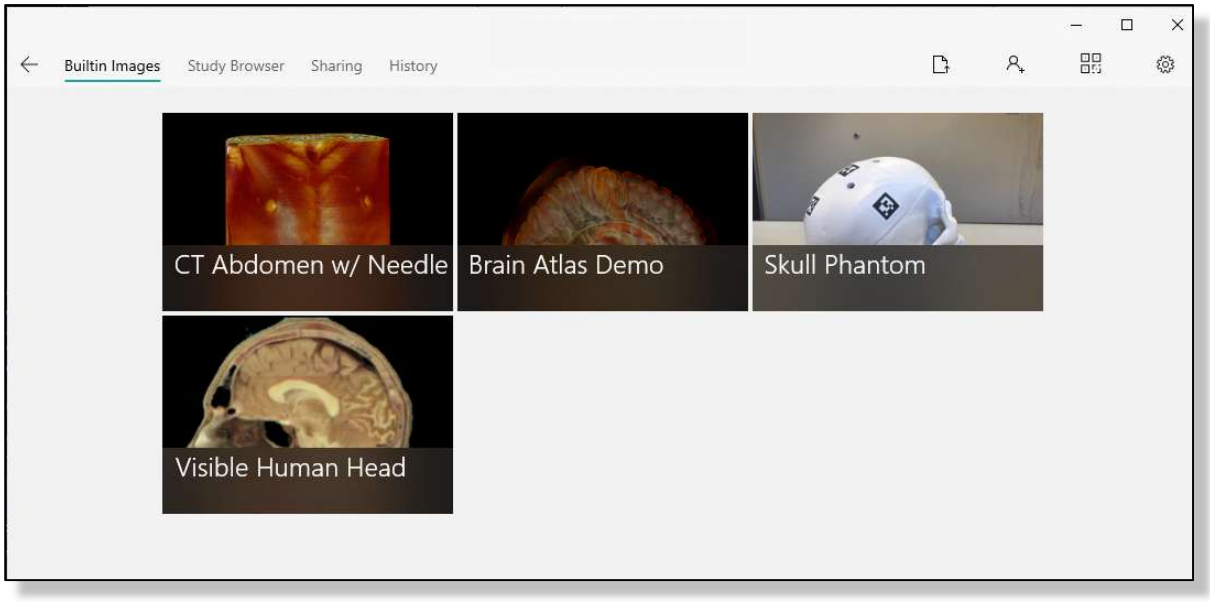
PART 5: VISAR LANDING PAGE

5-1 BUILT-IN IMAGES

VisAR has a Built-in Images function that allows you to try several types of studies as well as the Gibby-Cvetko Brain Atlas.

After opening VisAR, select Built-in Images. From this screen, select the desired option to view. Built-in images are also accessible directly from the immersive viewer using the voice commands “Show Built-In Images.”

Warning: The Built-in Images are to be used for educational purposes only!



CT Abdomen w/Needle – A demo image of a CT Abdomen with a virtual needle. This image series shows how a virtual needle looks when combined with a CT Abdomen study and should be used for demonstrating and training purposes. Trainees can view the capacity of the VisAR system and how a needle appears in the image series after it has been planned in the pre-operative planning application. Trainees can also use the image series to change views and drag slices to locate specific anatomical features and learn how to create other needle placements on the fly.

These images help users understand the targeting system by letting them line up the crosshairs and practice hitting their target with a needle. This means surgeons can practice using the HoloLens in a safe virtual environment to improve their experience and skill set, which will help them avoid patient harm during device use in future surgeries.

Brain Atlas Demo – Sample image of a brain scan for demonstrating purposes only to illustrate what an MRI of the brain looks like using the VisAR system. Users can view the different slices of the brain through different views. In addition, the Brain Atlas allows the user to identify key areas of the brain.

Skull Phantom – Sample image series that can be used in conjunction with a plastic skull phantom for training purposes. The training done with such a phantom will teach registration and general use of the VisAR system during cranial surgery. It provides a safe environment for practice using the key elements of the VisAR system (Registration, Navigation, and Calibration). This provides practice in a safe virtual environment to improve experience and skillset for surgeons to avoid patient harm during device use in future surgeries.

Visible Human Head – Sample image for training biopsy, ventriculostomy, external ventricular drain placement, or deep brain stimulation and for demonstrating the capacity of the VisAR system for cranial procedures. Trainees can use this image to learn how to change image views and drag slices to locate certain anatomical features for surgery. Trainees can also use the image series to learn how to create needle placements on the fly. This provides practice in a safe virtual environment to improve experience and skillset for surgeons to avoid patient harm during device use for future surgeries.

5-2 LOGIN

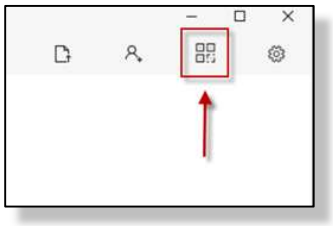
Users can log into a different account.

1. Select the Login icon.

   The Login window populates.
2. Select the user account to log in.
3. If your account does not populate, you will be asked to add a new account.

5-3 SCAN CODE

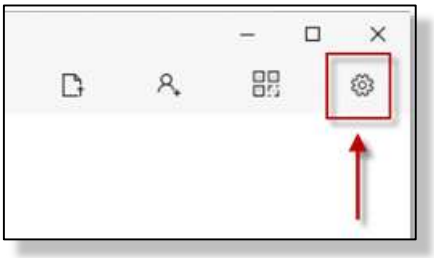
VisAR also uses a Scan Code function for use with QR codes.



Select the Scan Code icon and position the viewer to see the QR code. The code is scanned, and you are prompted to navigate to the QR code's destination.

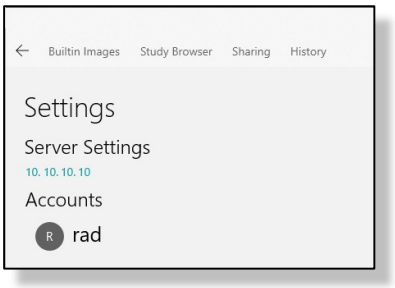
5-4 SETTINGS

You can select the Gear icon to populate the settings page.



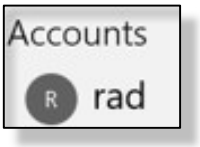
SERVER SETTINGS

This section displays the IP address for the server to which the user is currently connected.



ACCOUNTS

You can log into a different account from this page.



IMMERSIVE SETTINGS

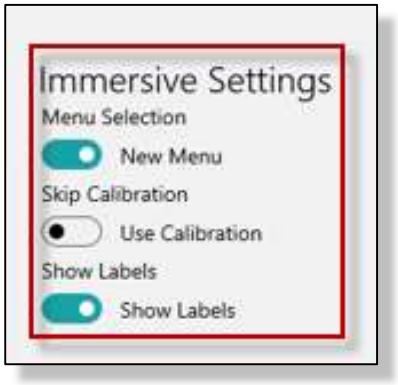
You can enable and disable settings within the Immersive Settings section.

New Menu

The New Menu toggle tells VisAR to use the newest version of the menu.

Skip Calibration

The Skip Calibration option allows you to skip the calibration step when first opening VisAR. This is not recommended**.** In operative workflow, this setting is ignored, and calibration is enforced.



Show Labels

The Show Labels option populates the labels in the Immersive Viewer, so you are always able to see the title of each option. If Show Labels is disabled, the option's title only populates when your cursor hovers over the option.

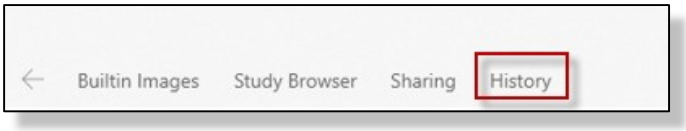
ABOUT

About contains the software version number and VisAR's UDI.

To get to the About page, click About in settings. The About page is also directly accessible from the immersive viewer; there is an About button next to the Exit button in the immersive main menu. See section 7-1 Surgical Menu for more details.

5-5 HISTORY TAB

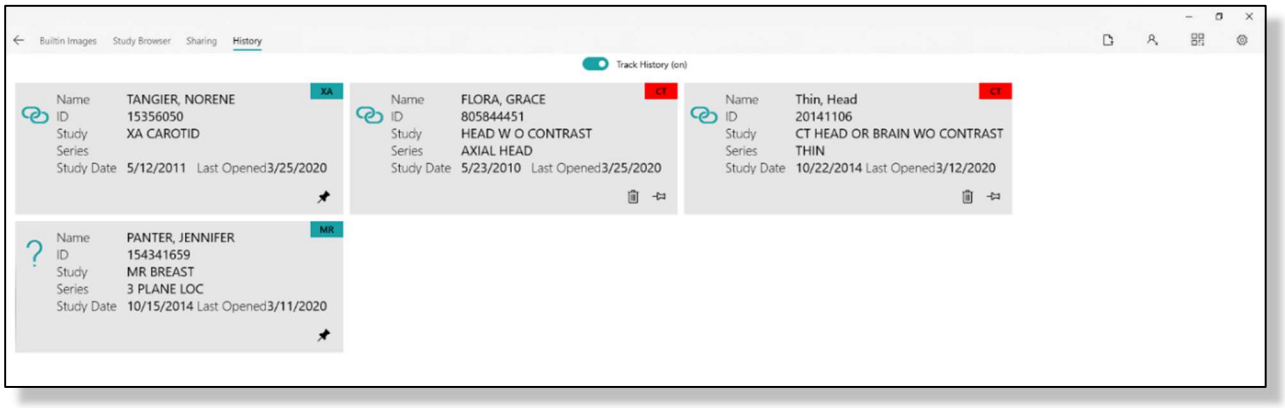
The History tab allows you to view and load previously viewed studies in VisAR. A typical use case is if a surgeon is going to a location without reliable Wi-Fi and wants to pre-load the study onto the HoloLens headset.



After selecting the History tab, a list of the ten most recently opened studies with the pertinent information populates. You can open any of those studies shown by selecting the study.

The History Feature is also accessible directly from the immersive viewer using the voice command "Show History."

> *Note: All patient health information that is saved to the HoloLens is encrypted. If you don't want any PHI on the device, you can disable the History option.*



You can delete individual history items by selecting the Trash icon in the individual history information box.

You can pin individual history items by selecting the pin icon in the history information box. This removes the trash icon from any pinned studies, so they cannot be deleted until they are unpinned.

You can enable/disable Track History using the toggle switch at the top-center of the History tab. You will be prompted to delete all history items when disabling Track History.

5-6 SHARING TAB

The sharing tab allows you to connect your HoloLens to another user's. All users connected to the same session share a mirrored virtual experience; users will be able to see the same study and any tracked instruments, imported instrument models, instrument adapters, and notifications.The host user must perform room calibration to ensure the virtual images are aligned correctly when sharing.

The Sharing Tab can be accessed from the top of the VisAR landing page or from the immersive viewer. To do this, enable Lobby Sharing in the VisAR settings on all devices that are going to be using the feature. Then, when in the immersive view, each headset will actively try to join with each other and share anchors in order to understand the shared space.

Users can also start a sharing session directly from the immersive view, so users don't have to close a study to access the Sharing tab.

1. The host user must use the voice command "Start Remote Sharing."
2. A 6-digit password will be generated on the host's headset, which the guest will need to join the session.
3. The guest headset will then use the "Connect Remote Sharing" voice command.
4. A number pad will appear on the guest headset. Enter the 6-digit password that appeared on the host's headset.

Then users will be connected to the sharing session.

When sharing is enabled, the computer names of each headset display above each user in the sharing session.

Both the user controlling the session, as well as any connected users, can interact with the immersive system, using the following voice commands:

"Sharing from owner" forces virtual components like needles and nav views to display oriented to the host user.

"Sharing from self" forces virtual components like needles and nav views to display oriented to the speaking user.

"Take ownership of sharing" changes the host of the current sharing session to the speaking user.

"Disconnect sharing" disconnects all other headsets from the session.

"Enable/Disable voice sharing" allows users to toggle whether the host headset receives voice commands from all users in the vicinity or just the voice of the host user.

FOCUS POINT

Once Sharing, users can create a focus point which will call attention to an area of interest for others in the shared session to look at. Users can create and manipulate focus points with the commands below:

- “Create Focus Point”
- “Drag Focus Point”
- “Next/Previous Focus Point”
- “Select Focus Point”
- “Show/Hide All Focus Points”
- “Delete Focus Point”
- “Where is the Focus Point”

5-7 DICOM COMMUNICATION

Users can send DICOM X-ray images directly to the VisAR system directly from the modalities. When the VisAR headset is Sharing from the Surgical Planning PC, and the PC receives a DICOM X-ray, it will send to VisAR through the sharing interface. The exact steps of sending a DICOM X-ray will vary depending on the modality.

To send images through DICOM communication, VisAR needs to be connected to the Surgical Planning PC through the Wi-Fi save option. This starts and maintains sharing between the two. Once this happens, any X-ray images sent through the DICOM protocol to the PC are sent directly to the headset.

PART 6: VISAR STUDY BROWSER

6-1 USING THE VISAR STUDY BROWSER

The Study Browser displays information including study information, patient information, patient history, the number of series in a study, the number of images in a series, and applicable reports for studies. In addition to these details, the viewable columns can be set to show information such as studies with existing reports and the name of the reviewing radiologist. The Study Browser is where you search for and open your studies into the Image Viewer.

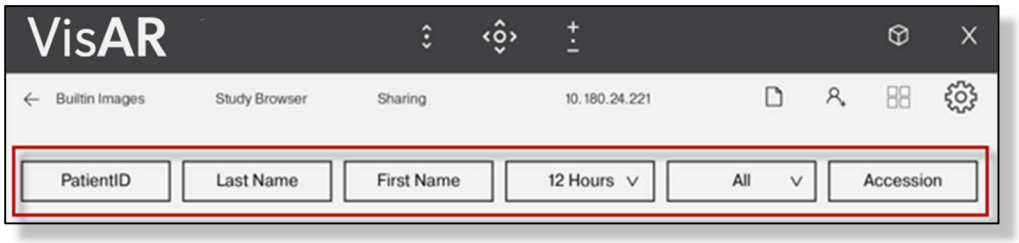
ACCESSING STUDY BROWSER

1. Open VisAR from the HoloLens main menu.
2. Log into VisAR.
3. Select Study Browser.
4. The Study Browser opens.

Note: If you are not connected to a server, VisAR prompts you to log into a server's IP address and then log in with a username and password. Contact the IT department for support.

SEARCHING FOR STUDIES

You can search for specific studies using the search filters. The filter options are Patient ID, last name, first name, time, modality type, and accession number.

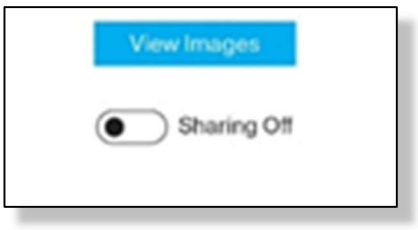


Once the study populates from the search, use the cursor to select it.

You are brought to the study page.

Select View Images.

The study opens in the Immersive Viewer.

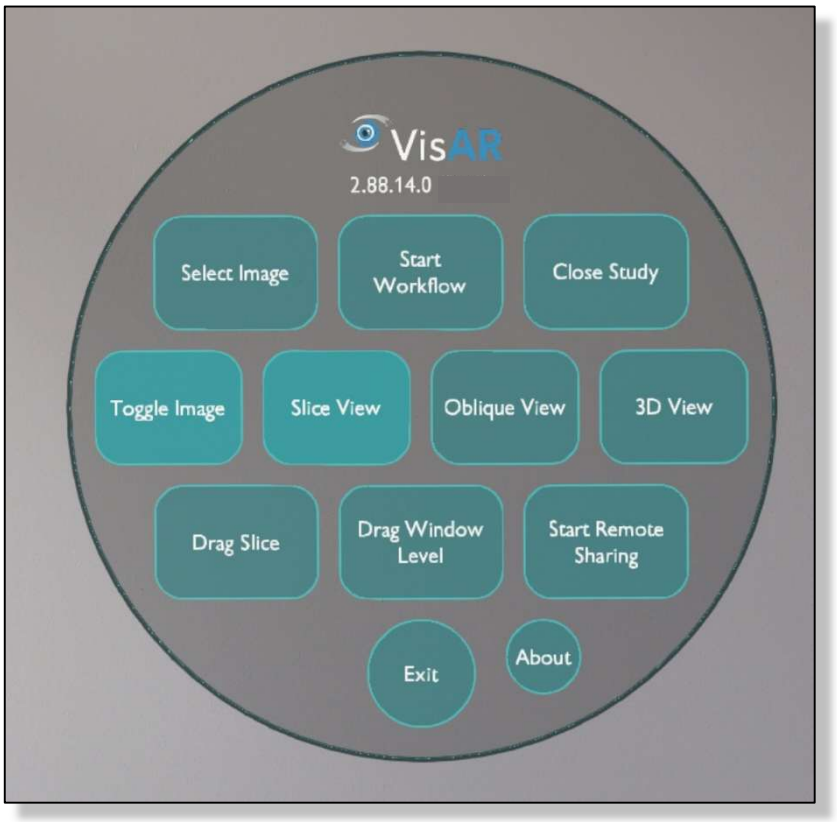


PART 7: VISAR USER VIRTUAL INTERFACE IN THE IMMERSIVE VIEWER.

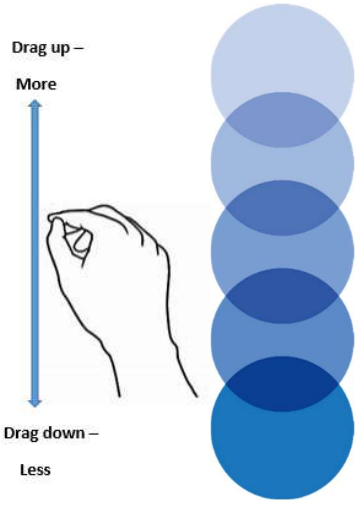
Use the voice command “Show Menu” to make the surgical menu appear. When you’re done, use the command “Hide Menu.”

7-1 SURGICAL MENU

The Alignment menu is an option that populates in the Patient Case. This is where you can manipulate and adjust the image in the Immersive Viewer.



Gesture	Description
Start Room Calibration	Starts Room Calibration.
Start Instrument Tracking	Starts Instrument Tracking.
Start Patient Tracking	Starts Patient Tracking.
Drag Window/Level	Window/Level allows users to adjust the window/level value of the image using the drag function, which can be likened to contrast and brightness. Users can also activate

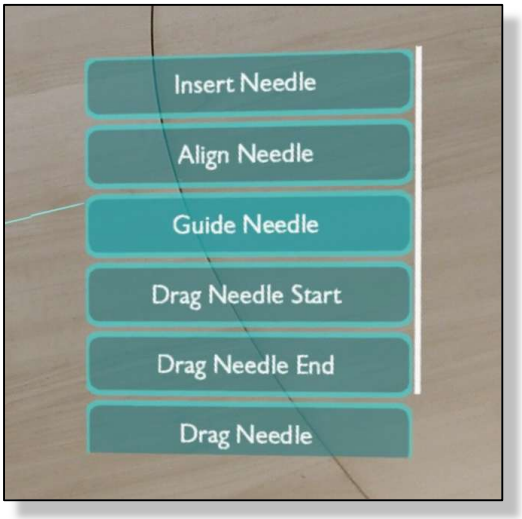
Gesture	Description
	this feature with the voice command “Adjust window/level.” 
Drag Slice	Drag Slice enables the user to pinch-and-drag through the various slices of the images. Users can also activate this feature with the voice command “Drag Slice.”
Slice View/3D View	Transitions you from 3D View to Slice View and vice versa.
Show/Hide Image	Shows/Hides the image.
Next needle	Moves to next annotated needle that was added during preoperative planning.
Show Nav Views	Shows the Nav Views.
Drag Nav Views	Allows you to move the Nav Views.

CONTEXT MENUS

If users forget relevant voice commands, or would like to learn more about the specific commands they can use on an item, they can pull up the context menu for help. Context menus exist for patient trackers, registration tags, instrument trackers, models, and images.

To get the context menu for an object to appear select the object using the “Select X” voice command (X=the name of the desired object).

Then, a menu will appear containing the different voice commands that can be used on that object.

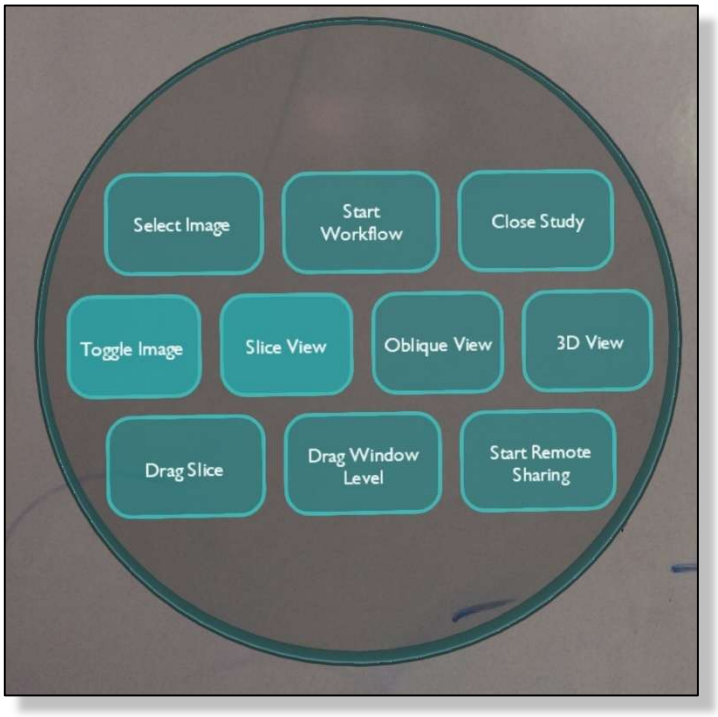


HAND MENU

VisAR also contains the Hand Menu. The Hand Menu is similar to the context menu; it provides some basic buttons/commands that can be used in a study.

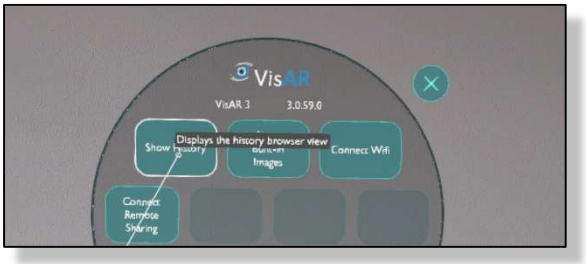
To see the Hand Menu, users can simply look at the palm of their hand and the menu will appear above it.

> Note: The user's gaze must be away from the image. The Hand Menu will not open if the user is looking in the same direction as the image.



TOOLTIPS AND HINTS

If users are unsure what a specific button does, hover the hand pointer over the button for a couple seconds and a tooltip will appear. This will provide more information about the button's action.



7-2 AUTO ALIGN

When using the workflows, the images automatically align during registration. No manual alignment should be needed.

7-3 WORKFLOWS

VisAR's workflows are a single voice command that can be used to walk through a series of steps in the immersive viewer.

INSTRUMENT NAVIGATION WORKFLOW

The instrument navigation workflow starts immediately after the image is opened. It can also be started with the voice command "Navigation Workflow." It will move through the following steps:

1. Show the image.
2. Start Patient Tracking
3. If there are needles, it will select the first needle
    a. If there are needles, but no surfaces, needle slice will enable
    b. If there are needles and surfaces, it will enable the closest slice and set the slice location to the selected needle
    c. In any other case it will enable the closest slice
4. Show Nav Views
5. Start Instrument Tracking
6. Enable Instrument adapter
7. Show Instrument Path

REGISTRATION WORKFLOW

Use the voice command Registration Workflow to register the patient:

1. Stop any tracking that might be using the camera.
2. Hide holograms that might cause confusion or distraction (medical image, nav views, annotations).
3. If registration fiducials exist in the plan, perform automatic patient registration, including verifying tag placement.
4. If there are no fiducials, perform manual registration.
5. Start patient tracking.

CREATE NEEDLE WORKFLOW

The "Create Needle Workflow will help you create a needle in VisAR with the following steps:

1. Start Instrument Tracking
2. Closest Slice

3. Drag Slice
4. Say “Pinch and drag the image to____”
5. Wait 1 second
6. Say “Stop Dragging” when done
7. Wait 10 seconds
8. Say “Create Needle.” This will create the needle.
9. Drag Needle End
10. Say “Drag needle end, allow the____”
11. Wait 15 seconds
12. Drag Needle Start
13. Say “Drag needle start, allow the____”
14. Wait 15 seconds
15. Show Nav Views

TAGS WORKFLOW

There is also a workflow designed to help you learn how to use patient tags for registration. Using the voice command “Tags Workflow” will walk you through the steps below:

1. Delete all landmarks
2. Delete all patient trackers
3. Room calibration
4. Patient tag registration
5. Start patient tracking
6. Show first needle
7. Show needle slice view (unless there are no needles, in which case, it shows the oblique slice.)
8. Show nav views
9. Start instrument tracking

PART 8: VOICE COMMANDS

Workflows	"Begin/Start Nav"	"Create Needle Workflow"	"X-ray"
	"Start/Stop Tracking"	"Pedicle Workflow"	"Custom Workflow"
	"Manual Registration"	"Calibration Workflow"	
Image/View	"Closest Slice"	"Drag Slice"	"Change Nav Views"
	"Coronal View"	"Drag Rotation"	"Drag Nav Views"
	"Sagittal View"	"Drag/Reset Window Level"	"Drag Nav View Size"
	"Axial View"	"Show/Hide Image"	"Enable/Disable Clipping Plane"
	"Oblique Slice"	"Zoom In/Out"	"3D View"
	"Needle Slice"	"Show/Hide Table"	"Click Position"
	"Rotate Prone/Supine"	"High/Medium/Low Brightness"	"Drag/Reset Transparency"
	"Skin/Bone/Soft-Tissue Preset"		
Instruments/ Models	"Set Instrument Length"	"Insert/Guide/Align Needle"	"Start Tracking"
	"Drag Length/Tip/End"	"Start Measurement"	"Start Instrument Calibration"
	"Drag Instrument Tip"	"Flip Instrument"	"Calibrate Instrument"
	"Drag Instrument Length"	"Register Model"	"Enable/Disable Adapter"
	"Create Needle"	"Reset Model"	"Check Tip"
	"Drag Screw"	"Drag Screw Length"	
Annotations	"Select (X*)"	"Show/Hide all (X's*)"	"Verify Registration"
	"Where is the (X*)?"	"Next/Previous (X*)"	"Stop Dragging"
Study Management	"Close Study"	"Help With (X*)"	"Delete All Trackers"
	"Show/Hide Menu"	"Save Demo Settings"	"Document This"

*X="Needle", "Model", "Cut", "Instrument", "Tag", "X-Ray"

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PART 9: VISAR HARDWARE

This section of the VisAR User Manual details the hardware that is used with the software (patient trackers, instrument trackers, calibration stands, and patient tags.)

9-1— PARTS OVERVIEW

The hardware is packaged in Novarad's Surgical Kit. The kit contains:

- Patient Trackers
    - Customers can select a Surgical Kit with two large trackers or a kit with one large tracker and one small tracker.
- Instrument Trackers
- Calibration Stand (made up of Calibration Base and Calibration Tower)
- Patient Tags
- Metal Tags
    - The metal tags are not included in the kits because they are not sterile product. They are stored in their own separate bag and must be purchased separately.

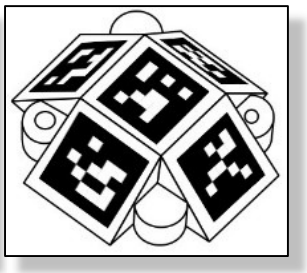
Note: *As of VisAR 3.0 metal tags have reached end of life. They will continue to be supported by VisAR however. All metal tags going forward will be made of stainless steel.*

- Instrument Adapters
    - The instrument adapters are not included in the kits because they are not a sterile product. They are stored in their own separate bag and must be purchased separately.

Large Patient Trackers (#28 and #31)

- Height: 19.8 mm
- Top Tag Plate: 28.0 mm
- Each Tag Plate: 20.0 mm^2
- Patient Tags 15-19 for tracker #28 and 10-14 for tracker #31

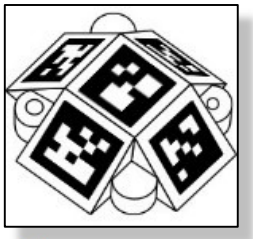
Large Tracker #28

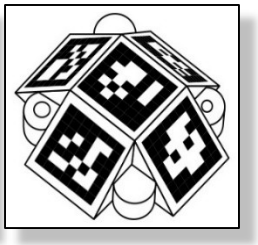


Larger Tracker #31

Small Patient Tracker (#29 and #32)

- Height: 14.14 mm
- Top tag plate: 20.0 mm



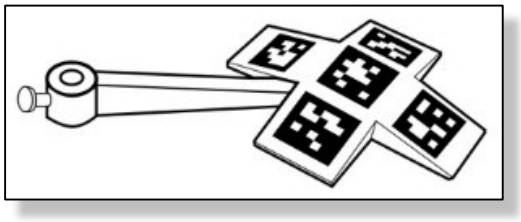


- Each tag is 13 mm square
- Patient Tags 30-34 for tracker #29 and 20-24 for tracker #32

Small Tracker #29 Small Tracker #32

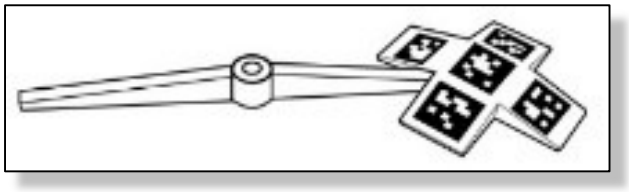
Instrument Tracker

- Tag Cluster Height: 6.14 mm
- Top tag plate: 20.0 mm square
- Width of each tag plate: 20.0 mm
- Tag Plates show 13.0 mm tags #25-29
- 3.11 mm hole is drilled in the base.



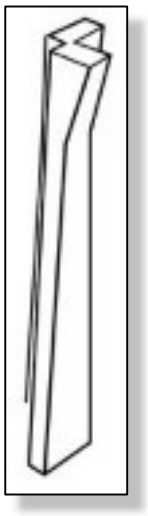
Calibration Base

- Height of tag cluster: 6.14mm
- Top Tag Plate: 20.0 mm
- Width of each tag plate: 20.0 mm
- Tag plates show 13.0 mm Patient Tags #20-24

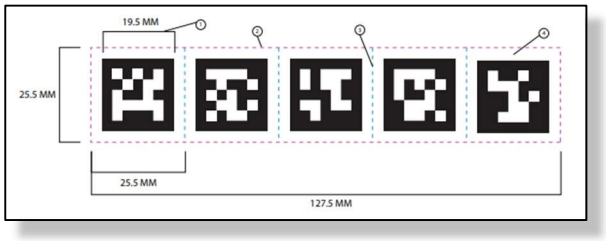


Calibration Tower

- Tower Height: 3.822 mm
- Support Structures: 1.014 mm x 0.213 mm

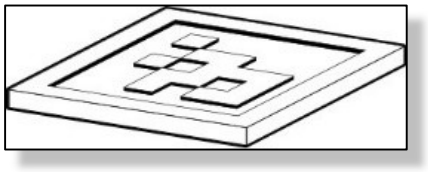


Patient Tags



- 26mm x 26mm
- 19.5 mm square
- All five tags are printed as a single unit.

Metal Tags



- Each Metal Patient Tag is 25.0 X 25.0 mm and 1.0 mm in height.
- Imprinted design has a depth of 0.5 mm (half the depth of the tag height).
- Metal Tags have a 2.0 mm wide border.
- An additional 2.0 mm wide imprinted inner border around the entire tag will be on every tag.
- One of four Patient Tags Tag designs will be imprinted on each tag.

End-of-Life Statement for Reusable Metal Components

This device is designed for repeated use under normal operating and reprocessing conditions. The usable life of the reusable metal components is not limited to a fixed number of cycles but is dependent on their condition.

Prior to each use, the component must be inspected for signs of:

- Mechanical damage (e.g., bending, cracking, deformation, or fracture)
- Excessive wear (e.g., surface degradation, rounding of edges, or loss of function)
- Corrosion, pitting, or other material changes
- Loosened or compromised connections that may impact performance or patient safety

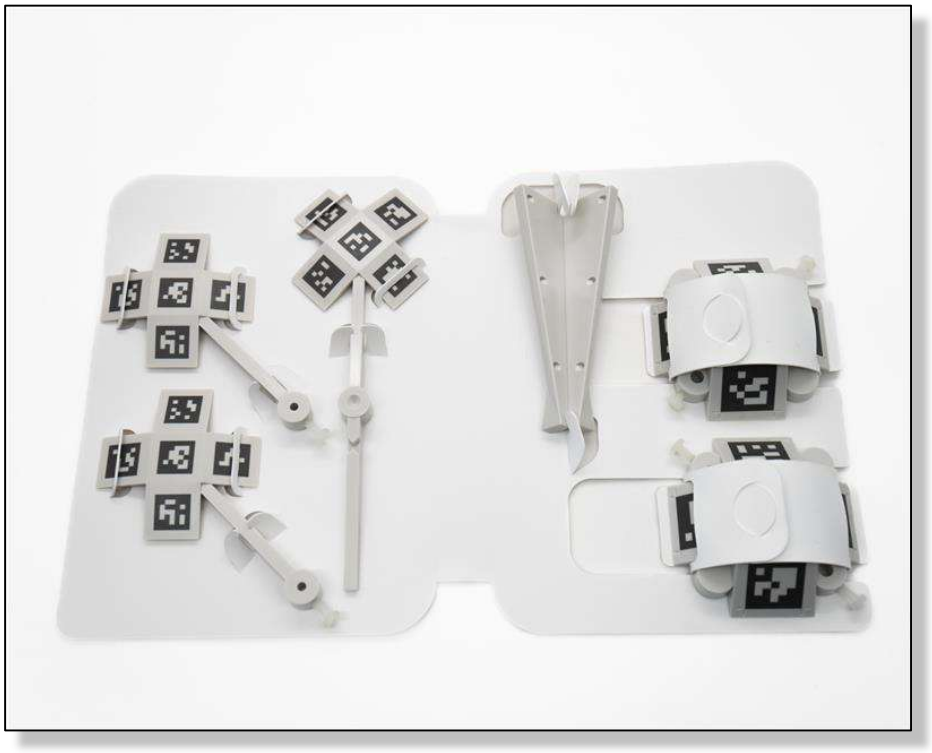
End of life is reached immediately when any such condition is identified. At that point, the component must be removed from service and replaced. Continued use of a damaged or worn device may result in patient or user harm.

When used and maintained according to the Instructions for Use, and provided no damage or wear is observed, the reusable metal component may be used until end-of-life criteria are met.

9-2— SURGICAL KITS

The surgical kits contain all the hardware listed above (Patient Trackers, Patient Tags, Instrument Tracker, Instrument Calibration Stand). To ensure sterility, keep the Surgical Kit sealed in the pouch until time of use. Only open the kits in an aseptic environment. The metal tags are packaged and shipped separately. They must also be purchased separately.

All the hardware is attached to a backing card and comes packaged as shown below.



STERILIZING REUSABLE METAL PARTS INCLUDING THE METAL TAG, LANDMARK INDICATOR, INSTRUMENT/ROTATIONAL ADAPTERS, SPINE CLAMPS, AND RETRACTORS

Sterilization Cycle: Thoroughly clean, Sterilization temperature 132 C, Sterilization Time 15, Min Dry Cycle 30 Min

Sterilization Parameters:

- Sterilizer Type: Autoclave
- Sterilization Method: Steam
- Sterilization Temperature: 132 C

- Sterilization Pressure: NA
- Exposure Time: 15 Min
- Dry Cycle: 30 Min

Sterilization Process:

a. Pre-sterilization Preparation:
    - Rinse with distilled water.
    - Verify that the equipment/instrument is thoroughly clean and free from any visible contamination.
    - Check the packaging integrity, ensuring it is intact and suitable for steam sterilization.
    - Load the equipment/instrument into the sterilization chamber according to the manufacturer's instructions.

b. Sterilization Cycle:
    - Start the sterilization cycle following the appropriate settings for the equipment/instrument and the type of load.
    - Monitor and record the sterilization temperature, pressure, and exposure time throughout the cycle.
    - Ensure the sterilization conditions remain within the specified parameters.

c. Cooling and Drying:
    - Once the sterilization cycle is complete, allow the equipment/instrument to cool down before handling.
    - If applicable, dry the equipment/instrument according to the manufacturer's instructions or allow it to air dry.

Sterilization Monitoring:

- Monitor the sterilization process using biological indicators, chemical indicators, or other suitable methods.
- Record the results of sterilization monitoring, including indicator type, lot number, and results (e.g., pass/fail).

Documentation and Record Keeping:

- Maintain a logbook or electronic record of all sterilization cycles performed, including equipment/instrument details, sterilization parameters, monitoring results, and any deviations or incidents encountered.

Quality Control:

- Regularly review and validate the sterilization process to ensure its effectiveness and compliance with applicable standards.
- Perform periodic maintenance and calibration of the sterilization equipment according to the manufacturer's recommendations.

*This process has been validated

REUSABLE PRODUCT

Other items, such as the instrument adapters, landmark registration tool, retractors, and metal tags can be reused if the following conditions are met:

- The optical HBICC code printed on the components is currently readable.
- Prior to each use, the component must be inspected for signs of:
  - Mechanical damage (e.g., bending, cracking, deformation, or fracture)
  - Excessive wear (e.g., surface degradation, rounding of edges, or loss of function)
  - Corrosion, pitting, or other material changes
  - Loosened or compromised connections that may impact performance or patient safety

End of life is reached immediately when any such condition is identified. At that point, the component must be removed from service and replaced. Continued use of a damaged or worn device may result in patient or user harm.

If the above conditions are not met, do not reuse the component.

SINGLE USE PRODUCT

The items in the surgical kit cannot be reused. The following symbol appears on product labelling and indicates single use product:

9-3— PATIENT TAGS

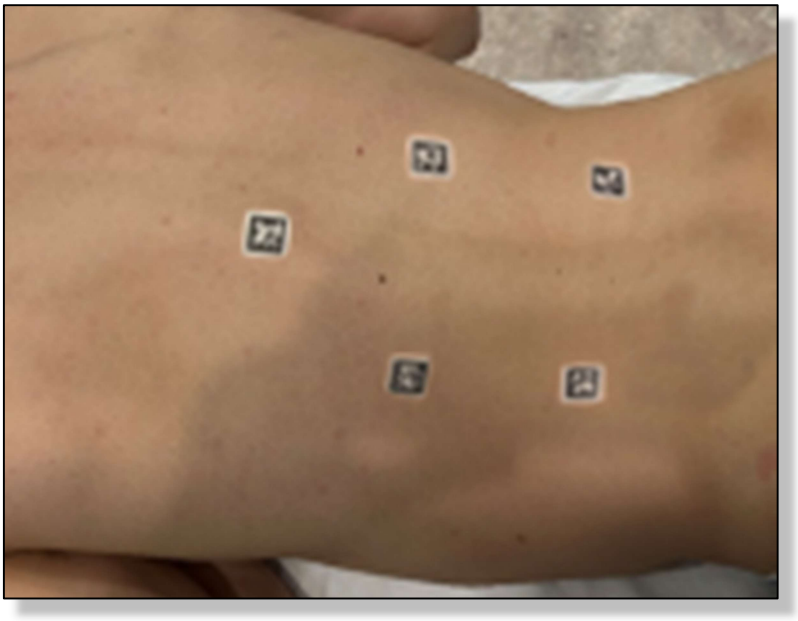
The patient tags are used to help populate the patient imagery and align it with the patient's anatomy during surgery.

TAG PLACEMENT

Below are instructions on how to correctly place Patient Tags on a patient:

Note: The patient must be scanned in the precise position prior to surgery as they will be in surgery.

1. Make sure the patient's skin is clean and dry. Otherwise, the Patient Tags may move or fall off.
2. Make sure the Patient Tags have not been stretched, folded, wrinkled, or discolored.
3. Place the Patient Tags around the operating site at least 10 cm apart from each other. Make sure that they are not more than 20 cm from the operating site.
4. Make sure all Patient Tags are visible in the scan.
5. Use at least 5 Patient Tags.

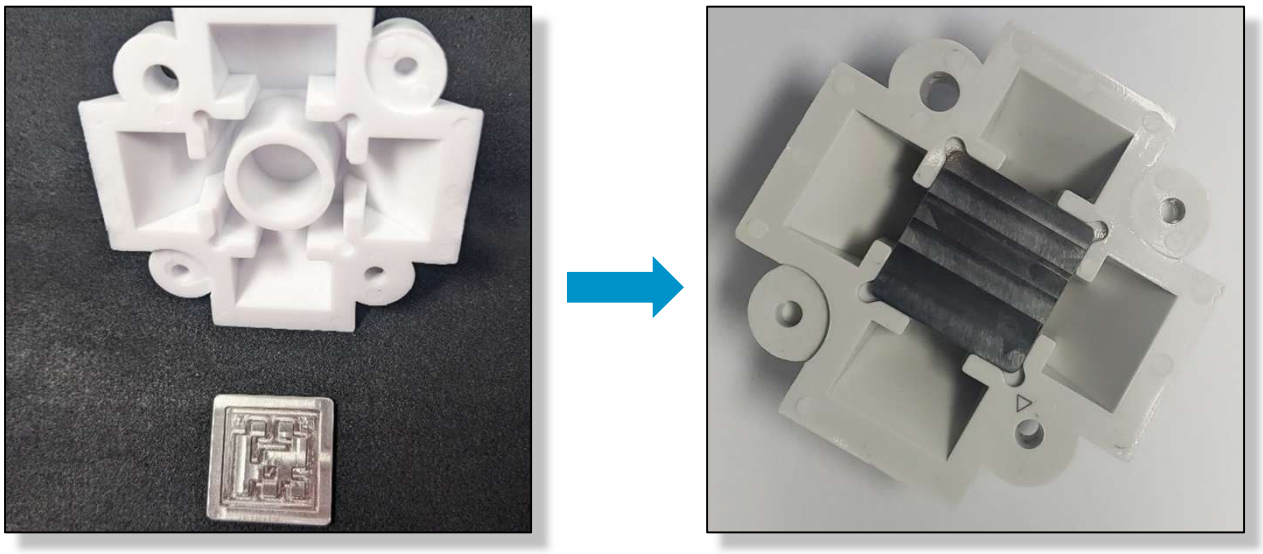


9-4— PATIENT TRACKERS

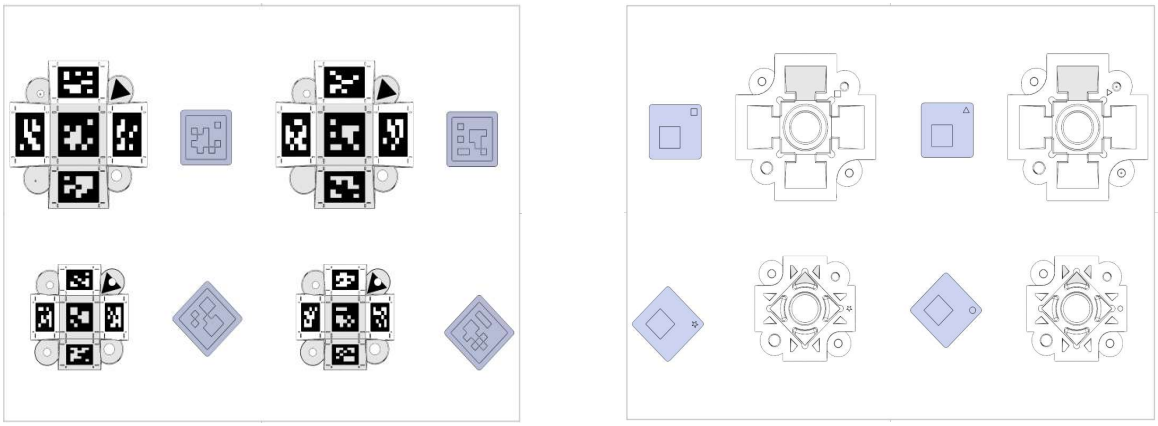
Patient trackers are used to track any patient's movement and ensure that the images follow the patient's anatomy. The following section explains how to attach a patient tracker to a patient.

PATIENT TRACKER PLACEMENT

1. Place the metal tag in the tracker prior to scanning.



Note: Using the pictures below, make sure the metal tag is oriented correctly inside the patient tracker.



This diagram shows two side-by-side setups: on the left, patient trackers are placed face-up

next to their metal tags, and on the right, the trackers are placed face-down beside the same type of metal tags.

2. Attach the tracker to the iliac crest or to a spinous process clamp (see Figure 1 and Figure 2). There are multiple ways to do this:

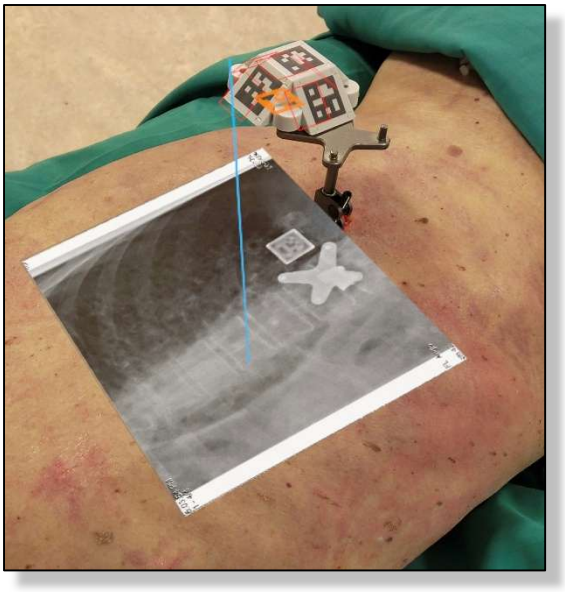


Figure 1: Patient Tracker Attached to a Spinous Process Clamp

   a. Attach via a thumbscrew to a bone pin, frame, or other fixed object.

⚠ Note: DO NOT over-tighten the thumbscrew. Otherwise, breakage of the screw or tracker may occur.

   b. Attach to an ECG/EKG pad.

   c. Suture the tracker onto the patient.

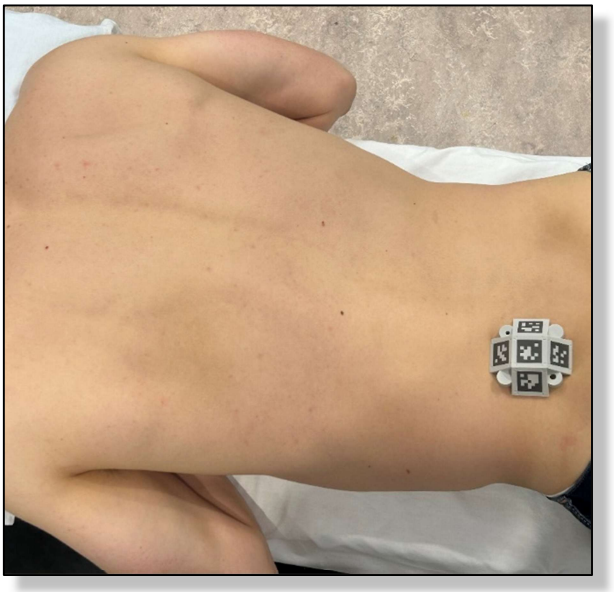


Figure 2: Patient Tracker Attached to Iliac Crest

TAKING THE CT SCAN

After the metal tag has been correctly inserted in the tracker and the tracker has been secured to the patient, it is time to take the CT scan:

1. For a spin CT, make sure the tracker is visible on the lateral view. It is better to err on the side of seeing the tracker and not necessarily all the vertebral body. It is important to get a complete image of the patient tracker to ensure accurate patient tracking.
2. The tracker should be in the same position as the patient will be during surgery.
3. It is recommended that scanning be done at 1.5 to 2.5 mm thickness (See VisAR User Manual for details).

SENDING IMAGES

After the Patient Tags and patient tracker have been placed and the images have been taken, users can send those images.

Images can be sent directly through DICOM Send with the VisAR system if an Enterprise System is being used, with a port 104 and AE title NovaPACS with the IP address of the computer.

The images can also be copied from a jump drive or CD onto the machine that will preoperatively plan and provide pedicle screw planning.

9-5— INSTRUMENT CALIBRATION STAND

The instrument calibration stand consists of the Calibration Base and Calibration Tower. The tower fits in the base, and together, they are used for instrument calibration. This way, VisAR can track your instrument during surgery.

ASSEMBLING THE INSTRUMENT CALIBRATION STAND

1. Place the notch on the bottom of the tower in the notch on the base.
2. The spine of the tower should face toward the tracker on the base (shown in the picture).
3. Place the instrument with the tracker in the instrument calibration stand (see Chapter 6 for more information on instrument trackers).

4. VisAR will use the tracker on the instrument stand and on the instrument tracker to register the instrument.

Once the instrument has been registered, VisAR will be able to track its movements in surgery and project the instrument's path.

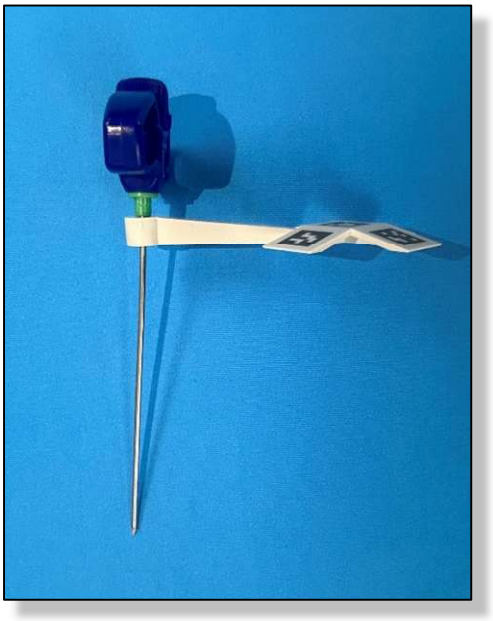
Assembled Calibration Stand with Instrument

9-6— INSTRUMENT TRACKER

The instrument tracker is used by VisAR to track the instrument during surgery.

ATTACHING THE INSTRUMENT TRACKER

1. Put the needle through the hole of the instrument tracker.
2. Tighten the thumbscrew so the instrument is secure in the tracker.



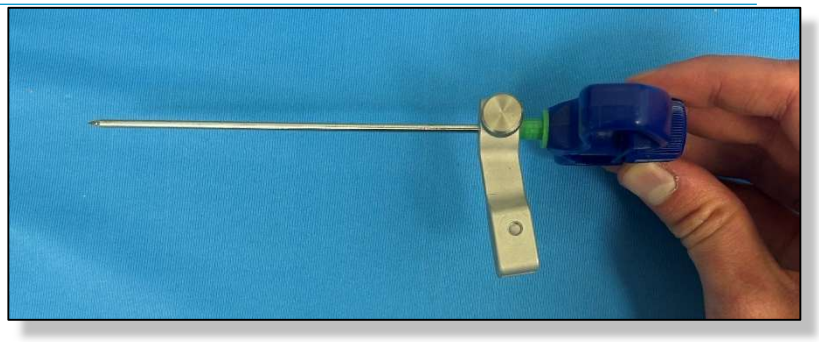
Note: DO NOT over-tighten the thumbscrew. Otherwise, breakage of the screw or tracker may occur.

9-11— INSTRUMENT ADAPTERS

Surgeons can use an instrument adapter to attach a tracker to an instrument.

PLACING AN INSTRUMENT IN THE INSTRUMENT ADAPTER

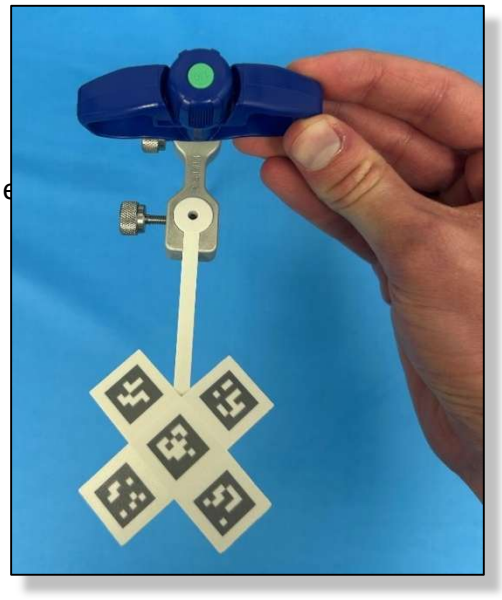
1. Place the instrument in the instrument opening on the sterile adapter. The instrument end of the adapter will contain an opening that goes all the way through the adapter and the diameter will vary depending on the size of the instrument.



2. Screw the thumbscrew in place to secure the instrument.

   Note: DO NOT over-tighten the thumbscrew. Otherwise, breakage of the screw or tracker may occur.

3. Place the instrument tracker on the other end of the adapter. This end will stay the same on every adapter.
4. Screw the other thumbscrew in place to secure the instrume



REGISTERING AN INSTRUMENT ADAPTER

There are two ways to register an instrument adapter:

1. During the Navigation Workflow, VisAR will ask users if they are using an adapter. If they respond with a “yes” VisAR will enable the adapter.

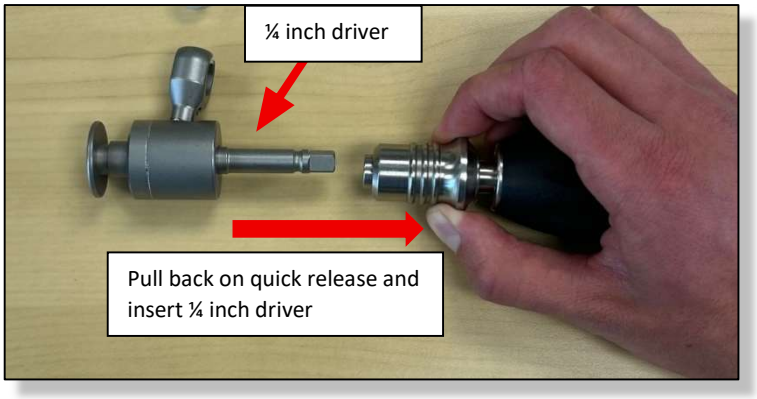
2. If users register their instrument outside of the Navigation Workflow, they must first calibrate it (see 9-5—Instrument Calibration Stand for more info). Then, to enable the instrument tracker, they should use the voice command “Enable Adapter.”

   Note: Instrument adapters can be disabled with the voice command “Disable Adapter.

¼ INCH ADAPTER

To assemble:

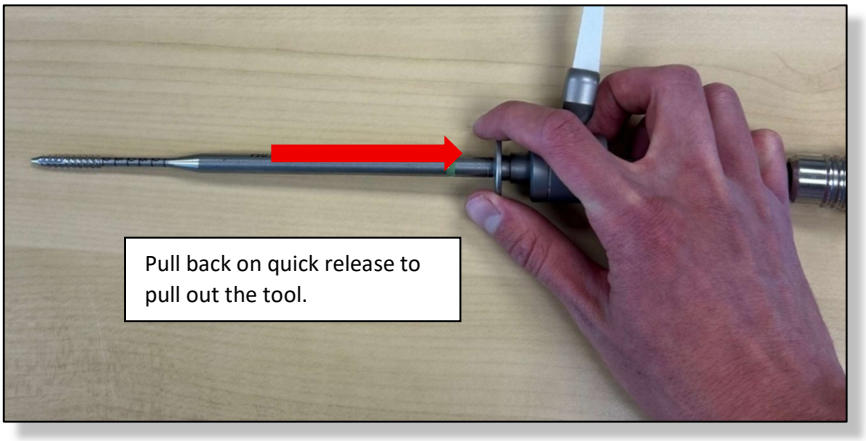
1. Pull back on the handle quick release and insert the ¼ inch driver into the handle.
2. Let go of the quick release to secure the driver in place.



3. Insert the tool end of into the driver.
4. Place patient tracker in the adapter so the tracker tags are facing towards the handle.

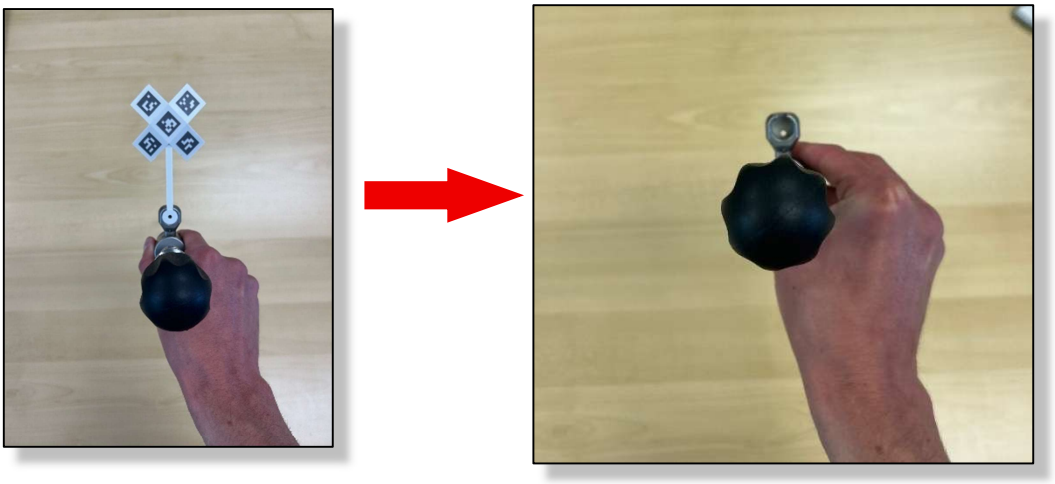
To disassemble:

1. Pull back on the ¼ inch driver's quick release to release the tool end.
2. Pull the end of the tool out of the adapter.



3. Pull back on the collar on the handle to remove the middle piece.

4. Take patient tracker out of adapter.



9-12— SPINE CLAMP

1. Place spine clamp on spinous process.
2. Insert the allen wrench into the socket.
3. Twist the allen wrench to tighten clamp around the process.
4. Place the patient tracker on two of the pegs on the clamp. Small patient trackers fit on the smaller pegs, while large patient trackers fit on the larger pegs (See figure 1).
5. To remove the spinal clamp, re-insert the allen wrench and twist counter-clockwise.

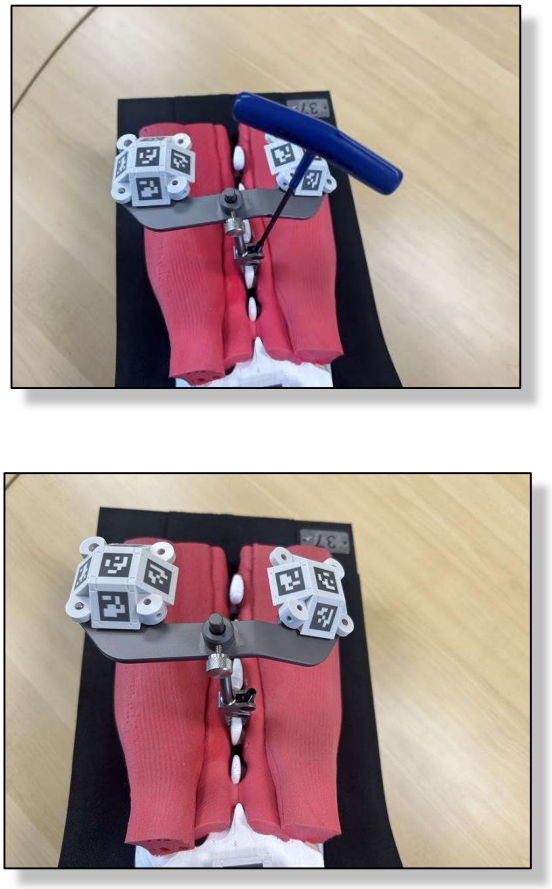


Figure 1 Spine Clamp (S-S) with small patient trackers

9-13— SPINOUS PROCESS CLAMP

INTENDED USE

The Spinous Process Clamp is intended to provide temporary fixation to a vertebral spinous process for attachment of a patient tracker during spinal surgery. It is designed for use by trained and qualified surgeons familiar with open spinal surgical techniques.

USER QUALIFICATONS

This device must be used only by surgeons trained in:

- Open surgical technique.
- Spinal anatomy and spinal surgical procedures.
- Proper application and removal of spinal clamps.
- Navigation workflow and tracker handling.

Note: Untrained personnel must not use this device.

INDICATIONS

The Spinous Process Clamp is indicated for temporary fixation of an intact spinous process during procedures requiring a patient tracker or reference array.

CONTRAIN**DICATIONS**

AVOID USING THE CLAMP IN THESE SITUATIONS:

- Severe osteoporosis or poor bone quality.
- Compromised or fractured spinous processes.
- Previous Laminectomy at the intended clamp level.
- Gross anatomical variation preventing secure seating.
- Active infection at the surgical site.
- Known sensitivity or allergy to titanium.

Note: If secure fixation cannot be achieved, do not proceed.

WARNINGS

- Do not overtighten the clamp. Excessive tightening may fracture the spinous process.
- Verify clamp stability before attaching a patient tracker.
- Do not use the clamp if it shows any signs of wear, bending, cracking or damage.
- Reconfirm registration if the clamp or tracker is bumped or subject to high force.
- Ensure the tracker plate does not rotate after placement.

- Maintain sterile technique throughout use.

CAUTIONS

- Use only the correct peg size for the selected patient tracker.
- Confirm full seating of both jaws before tightening.
- Avoid applying torsional or lateral force to the clamp after tightening.
- Remove the clamp slowly to avoid soft-tissue irritation.

PRECAUTION

- Inspect the clamp for mechanical integrity before each use.
- Do not use the clamp if dropped or subjected to excessive force.
- Do not modify, bend, or alter any component.
- Reusable clamps must be cleaned and sterilized exactly as described in Section 10.

INSTRUCTIONS FOR USE

Preparation:

- Ensure the clamp has been cleaned and steam sterilized.
- Inspect for damage or wear.
- Confirm the appropriate patient tracker size is available.

Clamp Application:

1. Position the jaws of the clamp around the selected spinous process.
2. Insert the provided Allen wrench into the tightening screw.
3. Rotate clockwise until the clamp is secure. Do not overtighten.
4. Verify clamp stability with a gentle shake test.

Tracker Attachment:

5. Place the patient tracker onto the appropriate pegs:

- Small trackers -> small pegs
- Large trackers -> large pegs

Note: Ensure full seating and verify the tracker is not obstructed.

Removal:

6. To remove the clamp, insert the Allen wrench and rotate counterclockwise. Remove the clamp slowly and with care.

Verification During Use

- Reconfirm clamp stability after retractor placement or if any movement is suspected.
- Re-verify navigation registration after any high-force event.

Cleaning, Disinfection, and Sterilization:

Reusable clamps must be processed using validated cleaning and steam sterilization procedures.

- Clean with enzymatic detergent and mechanical scrubbing.
- Rinse thoroughly and inspect for debris.
- Sterilize using validated steam cycles per institutional practice.

Note: Incomplete cleaning or sterilization may result in contamination or infection.

Inspection Before and After Use:

Inspect the clamp for:

- Cracks, deformation, or structural wear
- Damage to jaws, screw mechanism, or pegs
- Restricted mechanical movement

Note: Do not use the clamp if abnormalities are identified.

Adverse Events:

Potential complications include:

- Spinous process fracture.
- Local bleeding or soft-tissue trauma
- Loss of fixation
- Tracker movement or inaccurate navigation
- Infection
- Allergic response

9-14— BECKMAN-EATON LAMINECTOMY RETRACTOR

INTENDED USE

The Beckman-Eaton Laminectomy Retractor provides controlled, self-retaining soft-tissue retraction during spinal procedures. The device is reusable and must be cleaned and sterilized before each use.

USER QUALIFICATIONS

This device must be used only by surgeons and operating room staff trained in:

- Open surgical technique
- Spinal anatomy and laminectomy procedures
- Safe operation of retraction systems

Note: Untrained personnel must not use this device.

CONTRAINDICATIONS

Do not use the retractor in the following situations:

- When adequate visualization cannot be achieved.
- When tissues are fragile or compromised due to prior surgery, trauma, or pathology
- In patients with known metal hypersensitivity
- When blades cannot be placed under direct visualization
- When the device shows signs of damage, corrosion, bending, or wear

Note: Do not proceed if a secure and stable placement cannot be achieved.

WARNINGS

- Avoid over-retraction. Excessive force or prolonged spreading may cause muscle injury.
- Do not use the retractor as a lever or pry tool.
- Ensure full visualization when placing blades.
- Do not insert blades blindly or into delicate tissue planes.
- Do not use the device if any component is damaged.
- Always maintain visualization of nearby structures.
- Failure to properly clean and sterilize may increase infection risk.

CAUTIONS

- Open the ratchet gradually.
- Use the minimum retraction needed for visualization.
- Confirm stable blade placement before locking the ratchet.

- Ensure the retractor does not interfere with nearby instruments.
- Monitor the field periodically for bleeding or excessive tension.
- Use care when releasing the ratchet to avoid pinching soft tissue or gloves.

INSTRUCTIONS FOR USE

Preparation:

- Ensure the retractor has been cleaned and steam sterilized.
- Inspect for wear, corrosion, bent blades, or ratchet/hinge issues.
- Remove from service if defects are found.

Placement:

- Insert blades gently under direct visualization.
- Seat each blade in the paraspinal muscle.
- Ensure blades are not placed under thin bones or on spinous processes.

Retraction:

- Slowly open the ratchet using small, incremental clicks.
- Stop if resistance exceeds normal expectation.
- Once exposure is adequate, lock the retractor in place.
- Periodically reassess tissues for tension, discoloration, bleeding, or loss of exposure
- Reduce or release retraction when appropriate.

Adjustment During Surgery:

- Reposition blades as needed under visualization.
- Ensure the retractor does not obstruct other instruments.
- After any high-force event, confirm proper placement.

Removal

- Release the ratchet gradually.
- Remove blades slowly to avoid tissue pinching.
- Inspect for debris before sending for reprocessing.

Cleaning and Sterilization

Cleaning:

- Rinse immediately after use to prevent drying of debris.
- Clean with an enzymatic detergent and a brush, focusing on hinges and the ratchet.
- Rinse thoroughly and inspect for residue.

Note: Incomplete cleaning may result in contamination.

Sterilization:

- Sterilize using validated steam cycles per institutional requirements.
- Typical parameters: 132–135°C (270–275°F) for 3–4 minutes with appropriate dry time.
- Confirm compatibility with facility sterilization equipment.

Inspection Before and After Use

Inspect the retractor for:

- Corrosion or pitting
- Mechanical resistance in hinge or ratchet
- Bent or misaligned blades
- Loose or worn component
- Remove from service if any defects are present.

Adverse Events

Potential complications may include:

- Muscle injury from excessive retraction
- Spinous process or lamina fracture
- Blade slippage and tissue tearing
- Bleeding or hematoma
- Surgical-site infection
- Allergic response (rare)

Storage and Handling:

- Store in a clean, dry environment.
- Keep in an instrument tray to protect blades and hinges.
- Do not place heavy instruments on top of the retractor.

PART 10: REGISTRATION

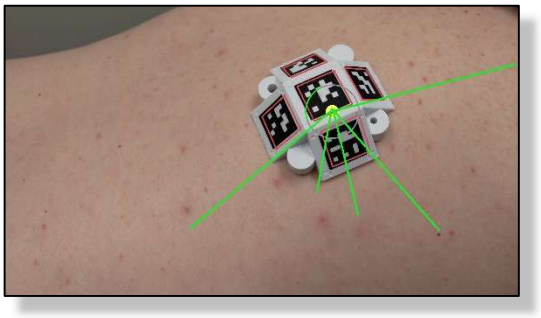
This section explains how to complete registration in VisAR.

9-7— REGISTRATION

There are multiple ways to complete registration using fiducials, depending on the scenario:

Scenario 1: No patient tracker is present in the image.

1. Use the voice command “Registration Workflow.”
2. VisAR will look for any fiducials or landmarks and prompt the user to register them.
    a. If fiducials are found, users will have to look at them from multiple angles.



Look at the fiducial from multiple angles until the green circle is complete

    b. If landmarks are found, VisAR will prompt users to register them with the landmark registration tool (See section 9-8 Landmark Registration for more information).
    c. If no fiducials or landmarks are found, VisAR will initiate Manual Registration (See section 9-9 Manual Registration for more information).

Scenario 2: The patient tracker is present in the image.

1. If a tracker is present in the image, VisAR will automatically complete registration when the study is opened.

9-8— LANDMARK REGISTRATION

Landmark Registration is a registration method that can be used if there are no fiducials in the image.

First, users must add Landmarks to the study in Surgical Planning. (See section 4-4 for more details).

1. In VisAR, use the voice command “Landmark Registration” or “Registration Workflow.”
2. When VisAR doesn’t detect any fiducials, it will automatically start Landmark Registration.
3. To register the landmarks, touch the landmark registration tool to the landmark.
4. Say “Next” to move to the next landmark. Users will then be prompted to touch the next landmark.

   Note: Users will be prompted to try again if the landmark fails to register.
5. Users will be prompted to touch all of the landmarks with the tool again. This time, the landmarks will be identified with green circles.

Note: *When touching the landmarks a second time, make sure the Landmark Registration tool is angled differently than it was the first time. The landmarks will fail to register properly if they are held in the same position.*

9-9— MANUAL REGISTRATION

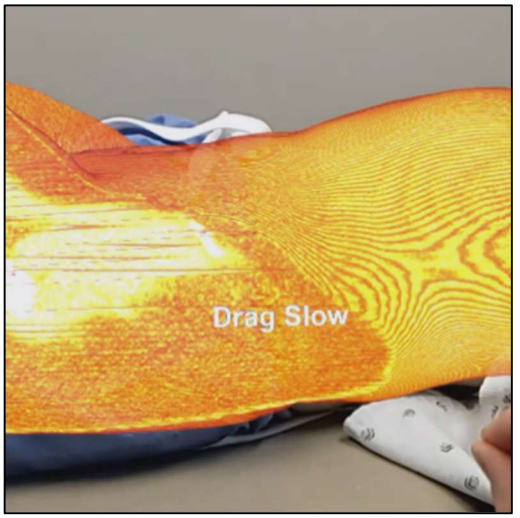
With manual registration, the user can manually align images to the patient. This may be required if surgical planning was not possible. To complete manual registration:

1. Use the voice command “Manual Registration” or “Registration Workflow.”

VisAR will prompt the user through the following steps;

2. Drag the image onto the patient.
3. Drag the slices (axial, sagittal, coronal) to find identifiable anatomy.
4. Rotate/adjust each slice until the image is aligned with the anatomy.
5. VisAR will then show the 3D image and ask if the image is aligned; reply with “yes” or “no.”
    a. If the response is “no,” VisAR will prompt the user to try manual registration again.
    b. If the response is “yes,” users will then be prompted to register the patient tracker.
6. Look at the patient tracker from several angles. VisAR will inform the user when registration is complete.

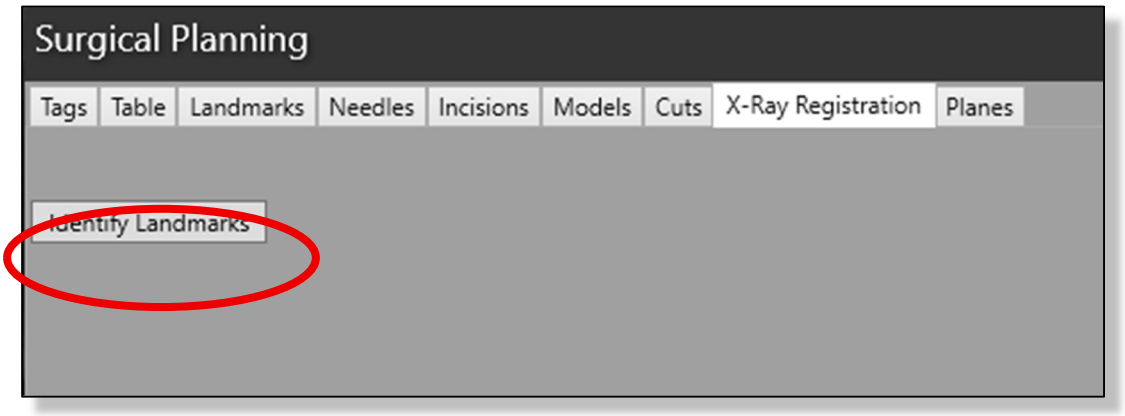
Picture of slice aligned with anatomy



9-10— X-RAY/CT REGISTRATION

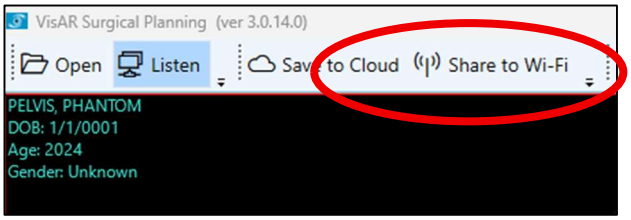
Users can automate X-Ray registration using the Assistive Intelligence X-Ray CT Registration:

1. Open the Pre-op CT in Surgical Planning.
2. Navigate to the X-Ray Registration Tab.
3. Click “Identify Landmarks.”

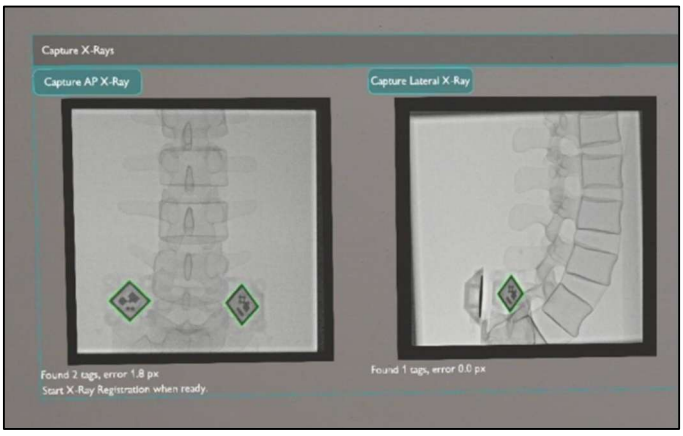


This will automatically identify landmarks that can be used to register the images to the patient.

4. Click Share to WiFi.
5. Open the series in VisAR and look at the QR code.



6. Use the “X-Ray Registration” voice command or click on the X-Ray Registration option on the hand menu.
7. Users will be prompted to register the patient trackers from multiple angles.
8. Connect X-Ray images to VisAR either through video or DICOM.
9. Click “Capture AP X-Ray” or “Capture Lateral X-Ray.”



Note: *DICOM is more reliable for accuracy. X-rays sent via DICOM will appear in VisAR the "X-Ray History." This window will appear automatically but can also be accessed by clicking the "X-Ray History" button.*

Important: *Some X-ray modalities do not provide certain parameters such as focal length, size, and pixel spacing. If this is this case, users must know and input these parameters in the X-Ray History window using sliders. These parameters must be set independently for each X-Ray.*

10. After the X-Rays are captured, the following results will display:
    a. Tags will be highlighted green if they are matched with the patient trackers.
    b. Tags will be yellow if they are found in the image but not matched with 3D trackers.
    c. If nothing is highlighted, then the tags are not found in the image.
    d. Below the X-ray, an error will appear, such as "0.4 px."
        i. A lower number is better. If the value is greater than 10, the result will be rejected, and users will be unable to proceed.

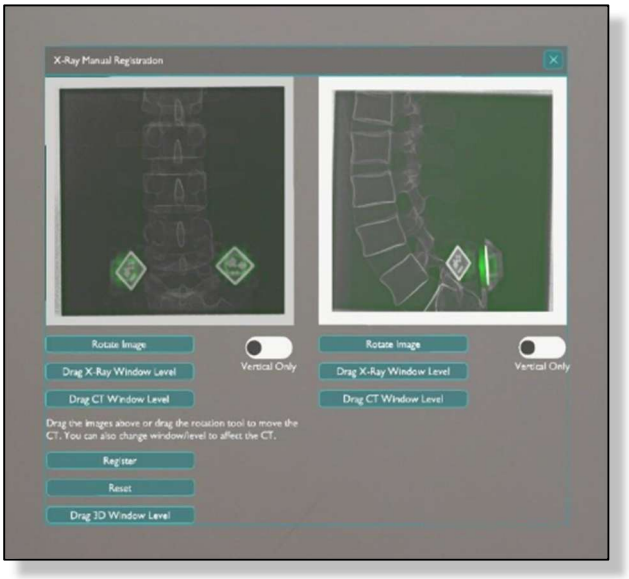
11. There is an optional "Constrain Angles" toggle on the X-Ray window. When enabled, the system will use angles reported by the modality through the X-ray if available. VisAR will use these angles to increase accuracy.
12. Click the "AI Alignment" button.

13. Click “Register.” This will bind the trackers to the image and start tracking.

AI Registration will align the CT with the X-ray.

The Manual Registration Window allows users to register the X-Rays ManuallyAfter the images have been aligned, users can adjust the registration using the manual registration window.

a. Drag the slices so they all line up with identifiable anatomy.
b. Fine tune the image placement by rotating each slice into position.
c. Adjust the window/level for the AP X-ray
d. Adjust the window/level for the Lateral X-ray
e. Move the X-ray projection onto the patient by either dragging the X-ray or using the rotational tool.



ATTACHMENT A: MICROSOFT HOLOLENS REGULATORY AND WARRANTY GUIDE

Taken from Microsoft.com website.

REGULATORY INFORMATION

DISPOSAL OF WASTE BATTERIES AND ELECTRICAL & ELECTRONIC EQUIPMENT

This symbol on the product or its batteries or its packaging means that this product and any batteries it contains must not be disposed of with your household waste. Instead, it is your responsibility to hand this over to an applicable collection point for the recycling of batteries and electrical and electronic equipment. This separate collection and recycling will help to conserve natural resources and prevent potential negative consequences for human health and the environment due to the possible presence of hazardous substances in batteries and electrical and electronic equipment, which could be caused by inappropriate disposal. For more information about where to drop off your batteries and electrical and electronic waste, please contact your local city/municipality office, your household waste disposal service, or the shop where you purchased this product. Contact erecycle@microsoft.com for additional information on WEEE and waste batteries. This product contains multiple Lithium-ion battery packs. This device is not intended for use in machinery, medical or industrial applications. Any changes or modifications not expressly approved by Microsoft could void the user's authority to operate this device. This product is for use with NRTL Listed (UL, CSA, ETL, etc.), and/or IEC/EN 60950-1 compliant (CE marked) Information Technology equipment. No serviceable parts included.

This device is rated as a commercial product for operation at +50ºF (+10ºC) to +80ºF (+27ºC).

FOR CUSTOMERS IN THE UNITED STATES AND CANADA

This Class B digital apparatus complies with, as applicable, Part 15 of the U.S. Federal Communications Commission (FCC) rules, Canadian ICES-003, and applicable RSS standards. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications made to this equipment not expressly approved by the manufacturer may void the FCC authorization to operate this equipment.

This product is restricted to indoor use only to reduce any potential for harmful interference with licensed operation in the 5.15-5.25 GHz frequency range.

Additional information about RF safety can be found on the FCC website at https://www.fcc.gov/general/radio-frequency-safety-0 and the Industry Canada website at www.ic.gc.ca/eic/site/smt-gst.nsf/eng/sf01904.html.

RADIO AND TV INTERFERENCE REGULATIONS

The Microsoft hardware device(s) can radiate radio frequency (RF) energy. If not installed and used in strict accordance with the instructions given in the printed documentation and/or online help files, the device may cause harmful interference with other radio communications devices (for example AM/FM radios, televisions, baby monitors, cordless phones, etc.). There is, however, no guarantee that RF interference will not occur in a particular installation. To determine if your hardware device is causing interference to other radio-communications devices, turn off and unplug the device from any external power source. If the interference stops, it was probably caused by the device. If this hardware device does cause interference, try the following measures to correct it:

- Relocate the antenna of the other radio-communications device (for example AM/FM Radios, televisions, baby monitors, cordless phones, etc.) until the interference stops.
- Move the hardware device farther away from the radio or TV or move it to one side or the other of the radio or TV.
- Plug the device into a different power outlet so that the hardware device and radio or TV are on different circuits controlled by different circuit breakers or fuses.
- If necessary, ask your device dealer or an experienced radio-TV technician for more suggestions. For more information about interference issues, go to the FCC Web site at https://www.fcc.gov/cgb/consumerfacts/interference.html. You can also call the FCC at 1-888-CALL FCC to request Interference and Telephone Interference fact sheets.

EXPOSURE TO RADIO FREQUENCY (RF) ENERGY

This device contains radio transmitters and has been designed, manufactured, and tested to meet the Federal Communications Commission (FCC), Industry Canada, and European guidelines for RF exposure and Specific Absorption Rate.

To ensure that your exposure to RF energy generated by the Wi-Fi and Bluetooth radios does not exceed the exposure limits set forth by these guidelines, orient the device according to the instructions given in the printed documentation and/or onscreen help files.

EU ENERGY CONSUMPTION

This device complies with COMMISSION REGULATION (EC) No 1275/2008 of 17 December 2008 implementing Directive 2009/125/EC of the European Parliament and of the Council with regards to eco-design requirements for standby and off mode, and networked standby, electric power consumption of electrical and electronic household and office equipment.

Model	First Year of Manufacture	Off-Mode Power Demand (watts)	Power Supply Efficiency
HoloLens 1688	2016	0.28	80.8%

To place the HoloLens in the lowest power state (“Off” mode); use one of the following methods:

- Say “Hey Cortana" to bring up the digital assistant and ask to turn off the device.
- Press and hold the power button for 4 seconds.

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MANUFACTURER’S WARRANTY

See hololens.com/support/warranty for latest information on product warranty.

ATTACHMENT B: MICROSOFT HOLOLENS HEALTH AND SAFETY

Taken from Microsoft.com website.

USE REQUIREMENTS

An interpupillary distance (an eye measurement of the distance between your two pupils) between 51 and 74 is needed to correctly and comfortably view stereoscopic 3D images with the HoloLens. This range accommodates most adults and children aged 13 and older. HoloLens is not intended for use by children under age 13. Good binocular vision is required to view stereoscopic 3D content. The HoloLens can be worn over most glasses and used with contacts. If you have a binocular vision disorder, such as strabismus (eye misalignment, crossed or wandering eye), you may not be able to view 3D images comfortably. A small percentage of people have a pre-existing binocular vision disorder that they might not be aware of until they try viewing 3-D images. Consider consulting an eye doctor if you are not able to view the 3D effect clearly and comfortably.

SAFETY AND COMFORT

⚠ This symbol identifies safety and health messages in this Device Guide

⚠ WARNING

Surgeons should get fluoroscopic confirmation before placing a screw in the early phases of use.

Failure to properly set up, use, and care for the HoloLens can increase the risk of serious injury, death, property damage, or damage to the product or related accessories. If you let anyone borrow your HoloLens, make sure that they understand the health and safety information in this guide and complete the Calibration application.

⚠ Warning: Use in safe surroundings

Using the HoloLens can distract you and make it hard to see your surroundings. Stereoscopic 3D images may appear to be at a distance but still block your view of nearby real objects.

Use only in a safe place that is appropriate for your activities. Avoid trip hazards, stairs, low ceilings, fragile or valuable items that could be damaged, etc. Do not use the HoloLens when a full field of view and attention are needed for safety, such as while operating a vehicle or doing other potentially hazardous activities.

⚠ Caution: Discomfort

You may experience discomfort when using HoloLens. Keep your first few sessions with HoloLens brief and be sure to take breaks. If you experience discomfort, stop and rest until you feel better. This discomfort might include temporary feelings of nausea, motion sickness, dizziness, disorientation, headache, fatigue, eyestrain, or dry eyes. See hololens.com/support/comfort for more information.

⚠ Caution: Using Mixed Reality Comfortably

Some people may experience discomfort such as nausea, motion sickness, dizziness, disorientation, headache, fatigue, eyestrain, or dry eyes when using mixed or virtual reality, particularly as they adjust to using it. Typically, motion sickness and related symptoms occur when there is a mismatch between what you see and what your body perceives. If you are prone to motion sickness in other situations, are afraid of heights, get migraine headaches, have an inner ear disorder or other health conditions, you may be at increased risk of discomfort.

Certain situations can increase your risk of discomfort.

For example,

- Being a new user: symptoms tend to decrease as your vision system adapts.
- The display is not calibrated or the headset is not oriented correctly on your head. Make sure the HoloLens is properly calibrated and that it is properly aligned by using the Calibration application.
- If certain types of content cause discomfort, particularly games or movies that make you feel as if you are moving through space or looking down from high or interactions that involve tracking moving objects.
- Using the HoloLens for extended periods without a break.
- Using the HoloLens in a completely dark environment that keeps you from seeing visual cues with your peripheral vision.

Consider keeping your first sessions brief. Start slowly and look around to get a feel for how the virtual objects and the outside world interact. For most people, discomfort should decrease as you get more practice over your first few sessions.

Take breaks periodically. Stop and rest if you experience any discomfort. The timing and length of breaks may depend on the individual user and what you are doing with the HoloLens.

If you experience discomfort, stop using HoloLens and rest until you feel better. Sitting still in a well-lit environment can help speed recovery from disorientation. If you feel disoriented, avoid activities that require balance, coordination, or other capabilities until you recover. Be sure the display is properly calibrated. Take note of the type of content you were viewing and other aspects of the situation in which the discomfort occurred so you can adjust or ease into the situation next time. People differ in the time they take to adapt. Consider taking more frequent or longer breaks.

If symptoms are severe or persist, consult your doctor. Viewing 3D or Mixed Reality is not known to harm vision development or cause binocular vision disorders. If you are not able to view the 3-D effect clearly and comfortably, consider consulting an eye doctor, as you may have an undiagnosed binocular vision disorder.

⚠ Warning: Be physically capable of your intended use

Make sure the balance and physical abilities are sufficient for any movements while using the HoloLens. Take breaks periodically and stop and rest if you get tired, sore, or experience any discomfort.

⚠ Warning: Hearing Safety

Set the volume loud enough to hear clearly in quiet surroundings and no louder.

- Do not increase the volume after you start listening. Your ears can adapt over time so that high volume sounds normal, but the high volume may still damage your hearing.
- Do not increase the volume to block out outside noise. The combination of outside noise and sound from your headphones can damage your hearing. Sealed or noise-canceling headphones can reduce outside noise so that you do not have to turn up the volume.
- If you cannot understand someone nearby speaking normally, turn down the volume. Sound that drowns out normal speech can damage your hearing. Even with sealed or noise-canceling headphones, you should be able to hear nearby people speak.

⚠ Warning: Minimize your time listening to loud Sound

The more time you spend exposed to loud sound, the more likely you are to damage your hearing. The louder the sound, the less time it takes to damage hearing.

- At maximum volume, listening to music on the device with headphones can permanently damage your hearing in 15 minutes.
- Even lower volumes can damage hearing if you are exposed for many hours.
- All the sound that you are exposed to during a day adds up. If you are exposed to other loud sounds, it takes less time listening at high volumes to cause hearing damage.
- To safely use the device with no time limit, keep the volume low enough that you can carry on a conversation with people nearby.

⚠ Warning: Be Aware of Hearing Loss Symptoms

Stop using this device and have your hearing checked if

- You experience any hearing loss.
- You hear ringing in your ears.
- Your speech sounds muffled.
- Sound seems dull or flat.

It is a good idea to have your hearing checked regularly by an audiologist.

⚠ Warning: Do not attempt repairs

⚠ Warning: Do not attempt to take apart, open, service, or modify the product, accessories, or power supply.

Doing so could present the risk of electric shock or other hazards.

⚠ Warning: AC Adapter Safety

Failure to take the following precautions can result in serious injury or death from electric shock or fire or in damage to the device. To select an appropriate power source for your device, do as follows:

- Use only the power supply unit and AC power cord that came with your device or that you received from an authorized Microsoft retailer.
- Do not use non-standard power sources, such as generators or inverters, even if the voltage and frequency appear acceptable. Only use AC power provided by a standard wall outlet.
- Do not overload your wall outlet, extension cord, power strip, or other electrical receptacle. Confirm that they are rated to handle the total current (in amps [A]) drawn by the device (indicated on the power supply unit) and any other devices that are on the same circuit.
- On devices where the AC prongs may be folded for storage, before plugging the AC adapter into a power outlet, make sure its prongs are fully extended.

On devices where the AC prongs are removable and where the power supply uses a universal adapter, before plugging the AC adapter into a power outlet, make sure the prong assembly is of the proper configuration for the power outlet and fully seated into the adapter.

⚠ Caution: Cable and cord safety

Arrange all cables and cords so that people and pets are not likely to trip over or accidentally pull on them as they move around or walk through the area. Do not allow children to play with cables and cords. Take care not to pull on the power cord when wearing the device.

To avoid damaging the power cords and power supply,

- Protect the power cords from being walked on.
- Protect cords from being pinched or sharply bent, particularly where they connect to the power outlet, the power supply unit, and the device.
- Do not jerk, knot, sharply bend, or otherwise abuse the power cords.
- Do not expose the power cords to sources of heat.
- Keep children and pets away from the power cords. Do not allow them to bite or chew on them.
- When disconnecting the power cords, pull on the plug—do not pull on the cord.
- If a power cord or power supply becomes damaged in any way, stop using it immediately.
- Unplug your device during lightning storms or when unused for long periods of time.

⚠ Warning: Battery Safety

This device contains a built-in battery, improper use of which may result in explosion. Do not heat, open, puncture, mutilate, or dispose of the product in fire. Do not leave the device in direct sunlight for an extended periods of time, which could cause melting or battery damage. The battery in this device is not user replaceable and should only be replaced by Microsoft or a Microsoft Authorized Service Provider. See www.hololens.com/support additional details.

⚠ Warning: Use Near Water

To reduce the risk of fire or shock, do not use this device near water and do not expose it to rain or moisture. Do not attempt to dry the device with a hair dryer or a microwave oven.

⚠ Warning: follow instructions to avoid interference Problems

Turn off your HoloLens in any location where posted notices instruct you to do so. In an aircraft, turn off your device whenever instructed to do so by airline staff, or prior to packing a wireless device in luggage.

⚠ Warning: Potentially explosive atmospheres

Areas with potentially explosive atmospheres are often, but not always, posted and can include fueling areas, such as below decks on boats, fuel or chemical transfer or storage facilities, or areas where the air contains chemicals or particles, such as grain dust, or metal powders. When you are in such an area, turn off your HoloLens and do not remove or install battery chargers, AC adapters, or any other accessory. In such areas, sparks can occur and cause an explosion or fire.

⚠ Warning: Personal Medical Devices

Radio-frequency emissions from electronic equipment can negatively affect the operation of other electronic equipment, causing them to malfunction. Although the device is designed, tested, and manufactured to comply with regulations governing radio frequency emission in countries such as the United States and Canada, the wireless transmitters and electrical circuits in the device may cause interference in other electronic equipment. Therefore, please take the following precautions:

Pacemakers: The Health Industry Manufacturers Association recommends that a minimum separation of 15 cm (6 inches) be maintained between a wireless device and a pacemaker to avoid potential interference with the pacemaker.

Persons with pacemakers:

- Should always keep the device more than 15 cm (6 inches) from the pacemaker when the wireless device is turned on.
- If you have any reason to suspect that interference is taking place, turn the device off immediately.

⚠ Caution: Heat-Related Concerns

The device may become very warm during normal use. The device complies with the user-accessible surface temperature limits defined by the International Standard for Safety of Information Technology Equipment (IEC 60950-1). To reduce heat related concerns, follow these guidelines:

- Allow for adequate air circulation under and around the device.
- Use caution when operating your device with a pillow, blanket, hat or other soft material contacting the device, because the material can block the airflow, which may result in the device overheating.
- If your device gets uncomfortably warm, remove it and take a break.

⚠ Warning: Photosensitive Seizures

A very small percentage of people may experience a seizure when exposed to certain visual images, including flashing lights or patterns that may appear in video games. Even people who have no history of seizures or epilepsy may have an undiagnosed condition that can cause these “photosensitive epileptic seizures” while watching video games.

These seizures may have a variety of symptoms, including lightheadedness, altered vision, eye or face twitching, jerking or shaking of arms or legs, disorientation, confusion, or momentary loss of awareness. Seizures may also cause loss of consciousness or convulsions that can lead to injury from falling down or striking nearby objects.

Immediately stop using the HoloLens and consult a doctor if you experience any of these symptoms. Parents should watch for or ask their children about the above symptoms. Children and teenagers are more likely than adults to experience these seizures. The risk of photosensitive epileptic seizures may be reduced by taking the following precautions:

- Using the HoloLens in a well-lit room.
- Do not use the HoloLens when you are drowsy or fatigued.

If you or any of your relatives have a history of seizures or epilepsy, consult a doctor before using the HoloLens.

⚠ Warning: Choking Hazard

This device may contain small parts, which may be a choking hazard to children under 3. Keep small parts away from children.

⚠ Caution: Skin Irritation

This device is made of materials commonly used in wearable consumer electronic devices. However, certain people may develop skin irritation due to allergies or sensitivities.

To reduce the risk of skin irritation:

- Wipe your device dry with a cloth if it gets wet.

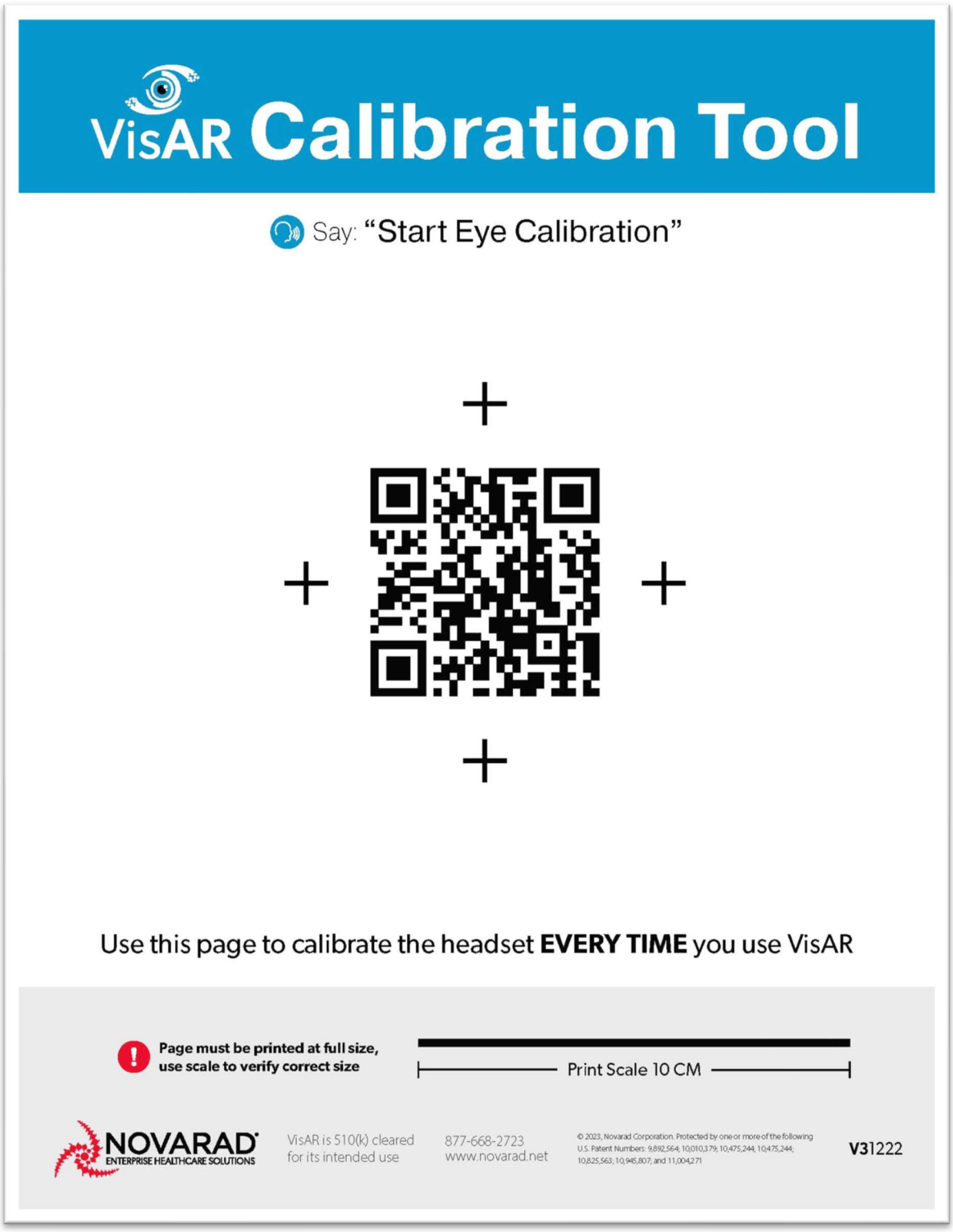
- Avoid using lotions or other products under the portions of the HoloLens that contact your head.
- Do not wear over injured skin.
- Adjust the headband only until snug—avoid tightening the headband uncomfortably.

If your skin becomes irritated, stop using HoloLens. If symptoms are severe or persist, consult your physician.

⚠ Warning: Evaluate eye protection needs for your environment

The HoloLens is not intended to provide eye protection against high impacts (Z87.1+), debris, chemicals, UV light, etc. The HoloLens has been tested and found to conform to the basic impact protection requirements of ANSI Z87.1, CSA Z94.3 and EN 166.

CALIBRATION TOOL



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APPENDIX A: USING THE DIFFERENT REGISTRATION TYPES

There are multiple ways users can register patient tags and trackers. Depending on the procedure, some registration types may be more accurate than others. Below are the different registration methods and the procedures they are best suited for:

ANATOMIC LANDMARKS

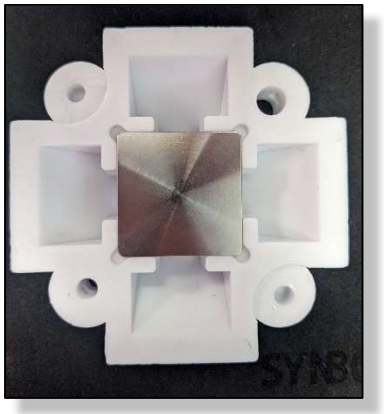
Using Anatomic Landmarks to register a patient involves identifying landmarks in a patient's anatomy during presurgical planning that can be used to anchor the patient's images. Users will need the Landmark Registration tool, to touch the landmarks specified in surgical planning. This is how VisAR will complete Landmark Registration.

PATIENT SKIN TAGS

Using Patient Skin Tags to register a patient involves placing the skin tags on a patient for their CT scan. You will then print the study from pre-surgical planning in the form of a QR code. If the tags come off in between the CT scan and when the patient goes in for surgery, you will need to place the patient skin tags in the same spots that you placed them for the CT scan. Then, VisAR will have you look at each patient tag and tracker from several different angles until they are registered, and the image appears. This method of registration is best to use with a procedure that requires a CT scan.

METAL TAGS

Using a metal tag to register a patient involves placing a metal tag in the bottom of a patient tracker. Place the tracker and tag on the patient prior to their CT scan. The orientation of the metal tag in the patient tracker is very important.; whichever way the tag is oriented in relation to the tracker for the CT scan is how it needs to be oriented in the actual surgery. VisAR will have you register the tag by looking at the tracker. VisAR will register both the tag and the tracker. This method is best suited to be used with a procedure that requires an OR Spin CT scan right before the surgery.



APPENDIX B: VISAR WITH MULTIPLE CLINICIANS

VisAR can be used by multiple clinicians at a time on the same procedure. Each HoloLens can use the VisAR product to download and cache the images containing the planned surgery or procedure for a patient and project 2D or 3D overlays onto that patient independent of any other VisAR system. This allows each clinician to see the images along with the virtual tools and landmarks added without interrupting another surgeon or user. These steps can be done at the same time as other users or at any time.

1. Each user independently calibrates their HoloLens device
2. Each user independently calibrates their VisAR application
3. Each user independently verifies the patient information on the Access Code against the patient armband or other based on hospital procedures and views the QR code with the HoloLens. This downloads the images to that device and opens the images in the VisAR application for that patient.
4. Each user independently registers the images on the patient and uses the VisAR application as needed during the procedure. The images are projected from the view of each user individually. As they move around the patient, the perspectives change accordingly.

By allowing clinicians to independently view 2D or 3D projections on the patient as well as the pre-operative planning, they can work on different areas during a surgery, or they can provide an extra set of eyes for the same area.

⚠ Caution : Patient Motion Concern

VisAR should not be used for surgical assistance where fiducial structures on the patients cannot be accurately defined to corresponding locations on the image of the same patient. Surgeons should always use appropriate clinical judgement and consider conventional guidance techniques if patient motion or technical factors make use of this system impractical.

In order to mitigate patient motion and check if the patient has moved, the user can compare three factors to ensure that registration is correct. After VisAR tag tracking has been performed, the user looks at the alignment of the white outline tag (DICOM image data), the image-guided navigation system tag (where VisAR draws the coordinate location of the stereoscopic 3D image), and the physical tag (on the patient). If all three tags align, then correct registration of the patient, DICOM data, and stereoscopic 3D image is present. If the image-guided navigation system tags and the physical tags superimpose, the registration is as good as possible with the physical tags. If the user observes an offset of the image-guided navigation system tag from the physical tag and white outline tag, then it represents a movement of the physical tags. The physical tags could have moved in their relation to each other.

A physical tag is placed on the patient before the scan, which is the ground base frame of reference.

A white outline of the tag represents where the DICOM Tag has been placed in the PACS.

Stereoscopic 3D image representation of the tag is where VisAR triangulates where the physical/real world tag is.