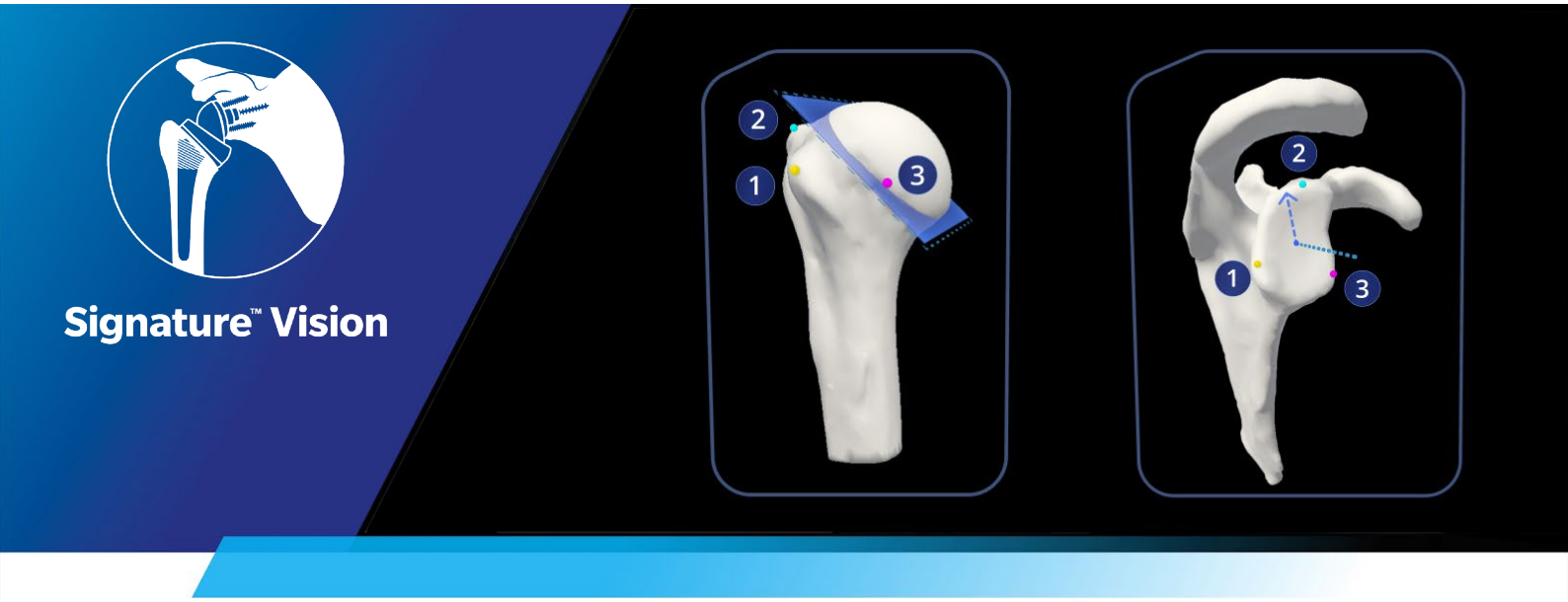


Signature™ Vision

Mixed Reality Shoulder Navigation

USER MANUAL

Version 06, 2026-07-02

Table of Contents

General Information

Abbreviations

3D	Three Dimensional
AR	Augmented Reality
HMD	Head-Mounted Device (OptiVu Tilt with HoloLens 2)
IPD	Interpupillary Distance
MR	Mixed Reality
OR	Operating Room
PIN	Personal Identification Number / PIN Code
PV	Photo Video
TSA	Total Shoulder Arthroplasty (anatomical)
RSA / TSA-R	Reverse Total Shoulder Arthroplasty
UI	User Interface

Conventions

This document employs the following conventions:

	**WARNING**: This symbol is present when a warning alerts a potential danger to health or life.
	**CAUTION**: This symbol is present to prevent a risk of damage to the equipment in the event of an error in handling.
	**REMARK**: This symbol is present to provide a general observation or information relating to procedures, events or practices that are recommended or essential for a successful operation.

Warnings, Cautions, and Remarks

Training, Use, and Maintenance

	Do not use or stop using the system if it is believed that the surgical procedure duration will increase significantly through its use. If it is believed that using the system will significantly increase the duration of the surgical procedure, do not use it or discontinue its use.

	Exposed glenoid and humerus bones must be cleaned of any soft tissue before performing registration.

	The HMD must be fully charged before each use.

	For the disposal of the OptiVu Tilt with HoloLens 2, please refer to the information in the respective user manual provided by Microsoft.

	Certain users might display increased photosensitivity when wearing HMDs like the OptiVu Tilt with HoloLens 2 and being exposed to bright moving holograms for longer periods of time. In rare cases, this can lead to dizziness, migraine, photo-sensitive epilepsy, or seizures. If any of these symptoms are experienced, immediately remove the OptiVu Tilt with HoloLens 2 (or have an assistant remove it), and, while maintaining the sterile field and ensuring patient safety at all times, resume the procedure without using the software

	and an HMD. Consult the product safety and warnings manual of the OptiVu Tilt with HoloLens 2 provided by Microsoft for further information.

	The HMD should be used and stored in a dry place with moderate temperature. Please refer to the information in the respective user manual provided by Microsoft.

	The cameras of the HMD must be unobstructed at all times and must not be covered by anything.

	The HMD must be charged using the supplied charger from the HMD manufacturer.

	The brightness of the HMD should be set for best visibility before beginning the procedure.

	Calibrate the user's interpupillary distance (IPD) for a better visualization of the holograms.

	Always consult the aiming cursors for central pin navigation, never just the mesh context alone.

	If the tracking is not stable or does not work, the user may need to adjust the lighting.

	Measurements during the reaming can be inaccurate. Stop reaming for accurate measurements.
	Always check if the tracker is properly attached to the tool and if it's not damaged.
	During the set-up, if the OptiVu Tilt with HoloLens 2 is unresponsive, the device may require a restart. To restart the device, press and hold down the power button for ten seconds.

Electrical Safety

	To avoid any risk of electric shock, the OptiVu Tilt with HoloLens 2 must only be connected to an electric power network equipped with grounding for charging. The device is Class II, type BF.
	Verify the integrity of the OptiVu Tilt with HoloLens 2 before each surgery. Visually inspect for any damage or malfunctions prior to use.
	Risks of laser beam exposure: The device uses a laser integrated into the navigation camera. This laser is of Class 1 (does not emit laser radiation).
	The battery of the OptiVu Tilt with HoloLens 2 is not replaceable or serviceable.
	IPX0 Protection: OptiVu Tilt with HoloLens 2 does not have special protection against the penetration of liquids. Do not pour any liquid over the device.
	The HMD must be charged using the supplied charger from the HMD manufacturer.
	Do not exceed the recommended input voltage for the device. Plugging the device into a higher voltage supply could damage the device when charging.
	Do not charge the OptiVu Tilt with HoloLens 2 during use.
	For the charging of the OptiVu Tilt with HoloLens 2, please refer to the information in the respective user manual provided by Microsoft.

Electromagnetic Compatibility and Radiation Safety

	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 MR Surgical Solutions LLC OptiVu™ Shoulder, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

	A risk of increased emissions or decreased immunity may result if any additional cables are attached.

	This device has not been tested for compatibility with all potential RF Emitters, or all variations of potential X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, NFC, WPT, or Electronic Article Surveillance (EAS) devices. Caution should be used if such emitters are present within the use environment.

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

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

Software

	A patient planning file must be uploaded to the HMD before being able to use the software.

	The user makes the final decision whether the suggested navigation information is followed or not.

	Quit all other applications running on the HMD before using the software.

	Do not use the HMD if holograms appear cut-off, double, offset, distorted, jittery, or blurry.
	Avoid any major movements while using the software.
	Voice commands must be spoken loudly and clearly.
	Always consult the Navigation Sphere parameters for the cut guide navigation, never just the mesh context alone.
	If the system or any patient data appears to have been accessed or altered by unauthorized personnel, the system and data should not be used and the system should be serviced by an authorized service technician.

Instruments

	The Adapter Handle instrument contains a magnet and is MR Unsafe. Keep away from Magnetic Resonance Imaging (MRI) Equipment. Keep this instrument 6 inches (15 cm) away from magnetically susceptible medical devices such as cochlear implants, neurostimulators, stents, and shunts.
	Take care to not damage the axillary nerve when affixing the Humeral Anchor.
	Take care to not drill the anchor pins too deeply when affixing the Scapular Anchor.
	Do not cover or touch the OptiVu Trackers once they are affixed to the humerus or coracoid.
	Do not overtighten the Humeral Anchor to the bone and the Reference Rod to the Humeral Anchor as this can lead to bone damage.

	Always make sure to push the handle of the reamer forward when reading the currently reamed depth value.

	Verify the integrity of all the instruments before each surgery. Visually inspect the instruments for damages.

	Refer to the respective IFU if the sterile barrier for Scapular Anchor Pins or OptiVu™ Tracker packaging is damaged.

	The Humeral Gauge is to be used as a visual aid only.

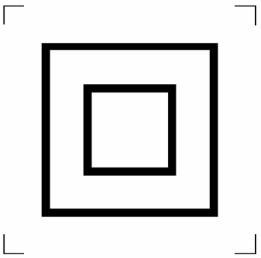
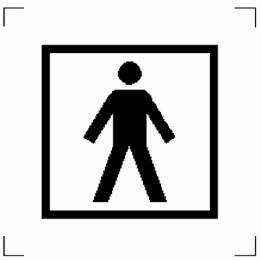
Contamination

	For the cleaning of the HMD please refer to the information in the respective user manual provided by Microsoft.

	Be careful not to touch nonsterile objects when interacting with the holograms.

	Do not touch the HMD during surgery to avoid the risk of contamination.

Signs and Symbols

Symbol	Standard title	Explanation / Symbol title and Reference number
	ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	Manufacturer (5.1.1)
	ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	Consult electronic instructions for use (5.4.3)
Rx Only	21 CFR 801.109	Prescription Only - Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	Unique device identifier (5.7.10)
	IEC 60417: Graphical symbols for use on equipment – Part 1: overview and application	Class II Equipment (IEC 60417-5172)
	IEC 60417: Graphical symbols for use on equipment – Part 1: overview and application	Type BF applied part (IEC 60417-5333)
	N/A	MR Unsafe: Keep away from Magnetic Resonance Imaging (MRI) equipment

	ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	Non-Sterile

For information on the Signs and Symbols on the OptiVu Tilt with HoloLens 2, please refer to the product safety and warnings manual of the OptiVu Tilt with HoloLens 2 provided by Microsoft.

Manufacturer:

MR Surgical Solutions, LLC
Bubenbergstrasse 1, 3rd Floor
8045 Zurich - CH

Distributed By:

Zimmer Biomet
1800 W. Center Street
Warsaw, Indiana 46580
USA

Purpose of the device

The Signature™ Vision is a stereotaxic surgical navigation system designed to aid surgeons in locating anatomical structures and aligning the endoprosthesis in total or reverse shoulder arthroplasty procedures. The system includes an augmented reality (AR) head-mounted display (HMD) (OptiVu Tilt with HoloLens 2) and mixed reality trackers to register and optically track anatomical landmarks and surgical instruments in real-time during the procedure.

The Signature™ Vision is intended to be used specifically with the Zimmer Biomet Alliance® Glenoid or Comprehensive® Reverse Shoulder system for total or reverse shoulder arthroplasty.

The Signature™ Vision is also indicated for pre-operative planning of the arthroplasty procedures using the Zimmer CAS Signature ONE™ System.

The intended users of the system are surgeons who are trained in performing shoulder arthroplasty procedures.

Intended Use

Signature™ Vision is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures (humerus and scapula), humerus resection, and aligning the endoprosthesis with the anatomical structures, provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan.

Limitations for Use

Refer to the labeling of the *Zimmer Biomet Alliance Glenoid* and *Comprehensive® Reverse Shoulder system* for the Limitations for Use of the implant systems that apply to the shoulder arthroplasty surgical procedure.

	The Adapter Handle instrument contains a magnet and is MR Unsafe. Keep away from Magnetic Resonance Imaging (MRI) Equipment. Keep this instrument 6 inches (15 cm) away from magnetically susceptible medical devices such as cochlear implants, neurostimulators, stents, and shunts.

	Certain users might display increased photosensitivity when wearing HMDs like the OptiVu Tilt with HoloLens 2 and being exposed to bright moving holograms for longer periods of time. In rare cases, this can lead to dizziness, migraine, photo-sensitive epilepsy, or seizures. If any of these symptoms are experienced, immediately remove the OptiVu Tilt with HoloLens 2 (or have an assistant remove it), and, while maintaining the sterile field and ensuring patient safety at all times, resume the procedure without using the software and an HMD. Consult the product safety and warnings manual of the OptiVu Tilt with HoloLens 2 provided by Microsoft for further information.

	If it is believed that using the system will significantly increase the duration of the surgical procedure, do not use it or discontinue its use.

Indications for Use / Intended Patient Population

Signature™ Vision is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures (humerus and scapula), humerus resection, and aligning the endoprosthesis with the anatomical structures, provided that the required anatomical landmarks can be identified on the patient's preoperative CT scan.

Signature™ Vision utilizes pre-operative planning files provided by the Zimmer CAS Signature ONE™ System. Signature™ Vision is compatible with any humeral implants that are supported by the Signature ONE™ System.

Signature™ Vision is specifically indicated for total shoulder arthroplasty using the Zimmer Biomet Alliance® Glenoid system or reverse shoulder arthroplasty using the Comprehensive® Reverse Shoulder system, to aid the surgeon in locating anatomical structures (humerus and scapula), humerus resection, and aligning the glenoid component with the anatomical structures.

Signature Vision includes an augmented reality (AR) head-mounted display (HMD) (OptiVu Tilt with HoloLens 2) and trackers to register and optically track anatomical landmarks and surgical instruments in real-time during the procedure. The HMD should not be relied upon solely and should always be used in conjunction with traditional methods.

Contraindications

Signature™ Vision is contraindicated for patients with implantable cardioverter-defibrillators (ICDs) or pacemakers.

Refer to the labeling of the *Zimmer Biomet Alliance® Glenoid* and *Comprehensive® Reverse Shoulder system* for the contraindications of the implant systems that apply to the shoulder arthroplasty surgical procedure.

Product Label / Software Version

The Product Label can be accessed within Signature™ Vision by opening the Hand Menu and tapping the "About" button. The software version is stated in the Product Label.

Signature Vision Application Description

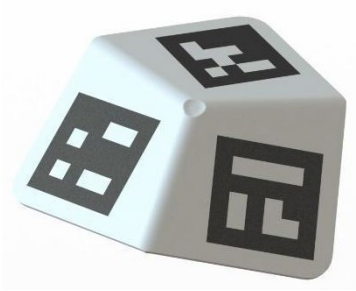
Application Overview

Signature Vision is an application for supporting surgeons in Anatomical and Reverse TSA procedures using Mixed Reality.

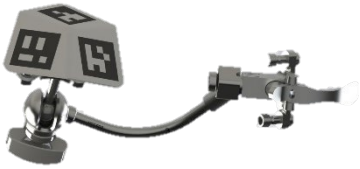
List of System Components

The following table shows all the system components to be used with the Signature Vision application:

Device	Rendering

OptiVu Tilt with HoloLens 2 Mixed Reality Headset (HMD)	
OptiVu Shoulder Tracker	
Zimmer CAS **Signature ONE™ System Software** (not part of the Signature Vision)	
Signature Vision Stylus	

Signature Vision Adapter Handle with **Pin Inserter**	
Signature Vision Adapter Handle with **Cut Guide**	
Signature Vision Reaming Guide	
Signature Vision Clocking Guide	
Hex Head Screwdriver	

Signature Vision Humeral Anchor (Shoulder Humeral Ref with **Humeral Ref Rod)**	
Signature Vision Scapular Anchor (Shoulder Scapula Ref with **Scapula Ref Rod)**	
Signature Vision Humeral Gauge with **version rods**	

Signature Vision Instruments

The following instruments are included in the system:

Component Part Number	Component Name
OVMR-HW-2-0201	OptiVu Tilt with HoloLens 2
OVMR-DS-2-0001	OptiVu Tracker, Stylus
OVMR-DS-2-0002	OptiVu Tracker, Adapter Handle
OVMR-DS-2-0003	OptiVu Tracker, Humeral Anchor
OVMR-DS-2-0004	OptiVu Tracker, Scapular Anchor
OVMR-DS-2-0005	OptiVu Tracker, Reaming Guide
OVMR-DS-2-0006	OptiVu Tracker, Clocking Guide
OVMR-HW-2-0324	OptiVu Shoulder Stylus
OVMR-HW-2-0312	OptiVu Shoulder Adapter Handle
OVMR-HW-2-0320	OptiVu Shoulder Pin Inserter
OVMR-HW-2-0321	OptiVu Shoulder Cut Guide
OVMR-HW-2-0328	OptiVu Shoulder Reaming Guide
OVMR-HW-2-0344	OptiVu Shoulder Clocking Guide
20-8087-400-00	Shoulder Humeral Ref
OVMR-HW-2-0334	OptiVu Shoulder Humeral Ref Rod
20-8087-300-00	Shoulder Scapula Ref, L
20-8087-301-00	Shoulder Scapula Ref, R

OVMR-HW-2-0331	OptiVu Shoulder Scapula Ref Rod
00-5120-087-00	Hex Head Screwdriver
OVMR-DS-2-0010	Pins, 2.5 mm, Scapular Anchor
SBHS107000	Pins, 2.7 mm, Identity Resection, 100mm
SBHS110000	Pins, 2.7 mm, Identity Resection, 70mm
OVMR-HW-2-0322	OptiVu Shoulder Humeral Gauge
SBHS01940	Threaded 30 Degree Version Rod
OVMR-TR-2-0001	OptiVu Shoulder Sterile Tray

Training

Signature Vision is intended to be used by healthcare professionals. Before using Signature Vision, healthcare professionals must receive training provided by Zimmer Biomet, or its authorized representative, on the proper use of the OptiVu Tilt with HoloLens 2 and the Signature Vision workflow. To request training, contact your local Zimmer Biomet representative.

Contact

MR Surgical Solutions, LLC
Bubenbergstrasse 1, 3rd Floor
8045 Zurich - CH

Complications

To date, no complications are known.

Visual Deficiencies

Signature Vision supports usage by mildly visually impaired users as it allows the wearing of glasses or prescription lenses without significantly altering the user experience. The OptiVu Tilt with HoloLens 2 has a laser integrated into the display of the HoloLens. Refer to Microsoft documentation for more details about visual impact here (http://docs.microsoft.com/en-us/hololens/).

	Certain users might display increased photosensitivity when wearing HMDs like the OptiVu Tilt with HoloLens 2 and being exposed to bright moving holograms for longer periods of time. In rare cases, this can lead to dizziness, migraine, photo- sensitive epilepsy, or seizures. If any of these symptoms are experienced, immediately remove the OptiVu Tilt with HoloLens 2 (or have an assistant remove it), and, while maintaining the sterile field and ensuring patient safety at all times, resume the procedure without using the software and an HMD. Consult the product safety and warnings manual of the OptiVu Tilt with HoloLens 2 provided by Microsoft for further information.

	Verify the integrity of the OptiVu Tilt with HoloLens 2 before each surgery. Visually inspect for any damage or malfunctions prior to use.

	The brightness of the HMD should be set to maximum for best visibility.

	Calibrate the user's interpupillary distance (IPD) for a better visualization of the holograms.

Storage

- The OptiVu Tilt with HoloLens 2 is made from precision electronic components. The functionality of the components depends on their careful handling.
- Protect the OptiVu Tilt with HoloLens 2 and the power supply from impact, humidity, liquid spills, dirt, marked temperature fluctuations, and direct sunlight. It is recommended to store the OptiVu Tilt with HoloLens 2 in its case whenever it is not being used.
- It is recommended to charge the OptiVu Tilt with HoloLens 2 in between usages to ensure that the device is charged for operation.

	The HMD should be used and stored in a dry place with moderate temperature. Please refer to the information in the respective user manual provided by Microsoft.

	The HMD must be fully charged before each use.

	The HMD must be charged using the supplied charger from the HMD manufacturer.

	For the disposal of the OptiVu Tilt with HoloLens 2, please refer to the information in the respective user manual provided by Microsoft.

Cleaning of the OptiVu Tilt with HoloLens 2

Before cleaning, turn off and disconnect the OptiVu Tilt with HoloLens 2 from the charger. For device cleaning, Microsoft documentation advises the use of the following cleaning materials:

List of Required Cleaning Materials

1. Non-bleach disinfectant wipes.
2. Solution of 70% Isopropyl alcohol and water to clean the hard surfaces of the device, including the visor.

Cleaning Procedure

1. Wipe all surfaces of the OptiVu Tilt with HoloLens 2 with a disinfectant wipe, until no visible contamination remains.
2. With a fresh disinfectant wipe, wipe all surfaces a second time.
3. For the individual exposure and drying time of the disinfectant, please consult the instructions of the wipe manufacturer and let dry accordingly
4. After disinfection, take a cloth slightly damp of deionized water to wipe the surfaces to prevent drying spots.

Find additional cleaning recommendations here (https://learn.microsoft.com/en-us/hololens/).

	For the cleaning of the HMD please refer to the information in the respective user manual provided by Microsoft.

	The cameras of the HMD must be unobstructed at all times and must not be covered by anything.

OptiVu Tilt with HoloLens 2 Life Expectancy

	Verify the integrity of the OptiVu Tilt with HoloLens 2 before each surgery. Visually inspect for any damage or malfunctions prior to use.

Handle the HMD with care. Avoid dropping HMD. Damage to HMD can significantly affect the function and accuracy of the device. The Signature Vision system's HMD and charging accessories have an estimated two-year lifespan under normal use. To determine whether the HMD is no longer suitable for use, please refer to the user manual provided by Microsoft. Contact Microsoft for any documents including circuit diagrams, component part lists, description, or calibration instructions to assist service personnel in repair of the device.

Installation, Set Up, and Maintenance

Carefully inspect the OptiVu Tilt with HoloLens 2 and its packaging visually for completeness, damage and/or excessive wear. If the package or device shows any signs of damage or significant wear that may compromise the function of the device, contact your MR Surgical Representative for a replacement.

For inspection of the Scapular Anchor Pins and OptiVu Tracker sterile packaging visually for completeness, damage and/or excessive wear, refer to the respective IFU.

	Refer to the respective IFU if the sterile barrier for Scapular Anchor Pins or OptiVu Tracker packaging is damaged.

	Refer to the Reusable Instructions for Use for more information on damaged instrumentation.

The OptiVu Tilt with HoloLens 2 is provided with the Signature Vision software installed on the device. Any maintenance of the OptiVu Tilt with HoloLens 2 must be performed by MR Surgical Solutions directly or by a Field Service Team Member authorized by MR Surgical Solutions.

	Do not open the device. In case of any issue or breakdown, do not intervene. Maintenance and service operations must only be carried out by MR Surgical Solutions Customer Service or any of its approved representatives.

	No modifications of the OptiVu Tilt with HoloLens 2 are allowed.

The OptiVu Tilt with HoloLens 2 is provided with a USB-C charging cord and Power Supply to charge the device. Charging may occur prior to or after the procedure, however, the HMD must not be charged when it is in use. For the charging of the OptiVu Tilt with HoloLens 2, please refer to the information in the respective user manual provided by Microsoft.

	For the charging of the OptiVu Tilt with HoloLens 2, please refer to the information in the respective user manual provided by Microsoft.

	The HMD must be charged using the supplied charger from the HMD manufacturer.

	Do not exceed the recommended input voltage for the device. Plugging the device into a higher voltage supply could damage the device when charging.

	Do not charge the OptiVu Tilt with HoloLens 2 during use.

The OptiVu Tilt with HoloLens 2 contains a battery that must not be tampered with. If the battery were to fail, do not remove or replace. For more information of the battery contained with the OptiVu Tilt with HoloLens 2, please refer to the information in the respective user manual provided by Microsoft.

	The battery of the OptiVu Tilt with HoloLens 2 is not replaceable or serviceable.

Lighting Conditions

Using Mixed Reality applications requires sufficient lighting.

The Operating Room lighting conditions are recommended to be at least 1,000 lux (measured in the patient's vicinity). The tracking requires enough contrast and lighting to work properly.

Recommended measures:

- OR lamps (luminaires) of higher luminescence (40,000-160,000 lux) may be used with Signature Vision and adjusted if needed to allow for stable tracking
- Turn up ambient room lights for more evenly distributed lighting

If tracking in the application is not working properly, consider improving the lighting in the environment. There may not be enough light for the camera to recognize the markers. The direct light shining on the markers may also be too bright, making the markers not visible for the camera.

Recommendations for optimal tracking

Do's	Don'ts
Make sure that the tracker always points at the HoloLens 2 Camera located above the visor.	Don't cover the tracker with your hand or other tools.
Make sure the room and your workplace is well-lit (between 1000 - 2000 lux).	Avoid operating room light beams pointing directly to the trackers.
Use as much diffuse light as possible.	Don't bend or damage the tracker.
Always check if trackers are correctly attached to the tools.	
Make sure the trackers are clean.	

	If the tracking is not stable or does not work, the user may need to adjust the lighting.

Using Gestures

Touch Gesture

The Touch Gesture is used to touch or press buttons in the Signature Vision Application. To use the Touch Gesture, the user should place their hand inside the frame with a finger out. The user can simply reach out and touch the area of the hologram they are targeting.

Grab Gesture

The Grab Gesture is used to grab holographic elements of the Signature Vision Application. To do so, the user should target the location by facing it with their palm, and then grab it by pinching together their thumb and index fingers.

Move Gesture

The Move Gesture is used to move holographic elements of the Signature Vision Application to any desired location in the user's MR environment. To do so, the user should maintain a grab of the holographic element, move it to the desired location, and release the grab.

Scale Gesture

The Scale Gesture is used to increase or decrease the size of holographic elements of the Signature Vision Application. To do so, the user should grab the 3D element or its bounds with two hands, pinch to hold, then drag it away to resize. When the desired size is reached, the user should place the element in place by releasing their fingers.

	Be careful not to touch nonsterile objects when interacting with the holograms.

Guide

Using the Signature Vision Application

Powering the OptiVu Tilt with HoloLens 2

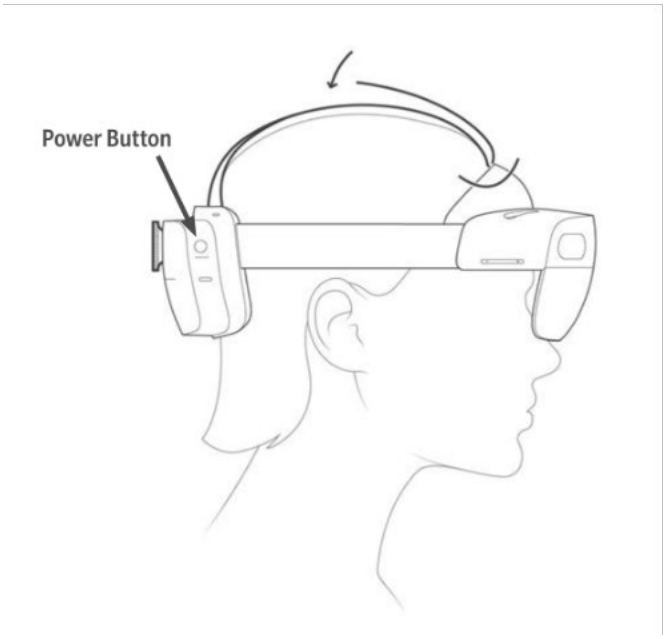
To launch the Signature Vision Application, power on the OptiVu Tilt with HoloLens 2 by pressing the power button to the right of the adjustment dial located behind the head.

	The HMD must be fully charged before each use.

	The HMD must be charged using the supplied charger from the HMD manufacturer.

	Do not touch the HMD during surgery to avoid the risk of contamination.

Figure 1: HMD Power Button Location

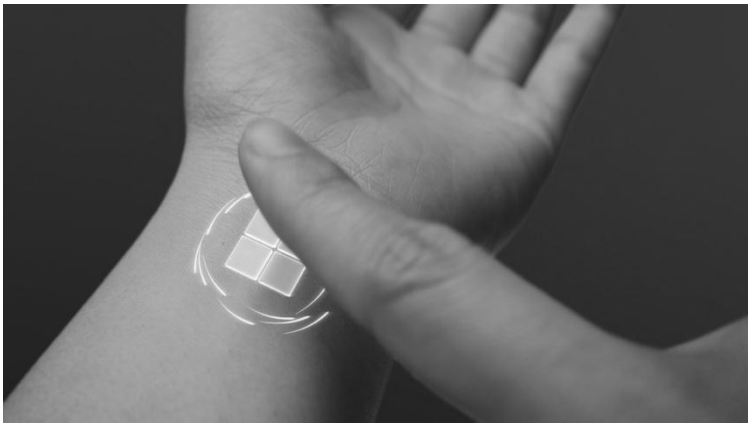


The device should be fully charged at the beginning of use for an optimal experience using the Signature Vision Application. The battery level is displayed at all times on the device's hand menu (see section 10.2.1. Hand Menu - Version for the Humerus Cut Step) and the OptiVu Tilt with HoloLens 2 headset (four solid lights illuminated underneath the power button).

Once the device is started, it will show the Start Menu of the Operating System. You

can always open and close the Start Menu by holding your finger on the wrist of your arm, as depicted below:

Figure 2: HMD Open and lose the Start Menu



In the Start Menu, tap the button All Apps, then tap the Signature Vision icon to start the Signature Vision Application.

The Signature Vision Application uses eye-tracking technology and can automatically launch a new eye calibration to adapt the mixed-reality environment to the user's head and face anthropometry if needed.

	During the set-up, if the OptiVu Tilt with HoloLens 2 is unresponsive, the device may require a restart. To restart the device, press and hold down the power button for ten seconds.

	Quit all other applications running on the HMD before using the software.

	Do not use the HMD if holograms appear cut-off, double, offset, distorted, jittery, or blurry.

	Avoid any major movements while using the software.

Signature Vision Application Flow and Surgical Technique

The user interface elements displayed at once at any given time of using the application will be called "screens".

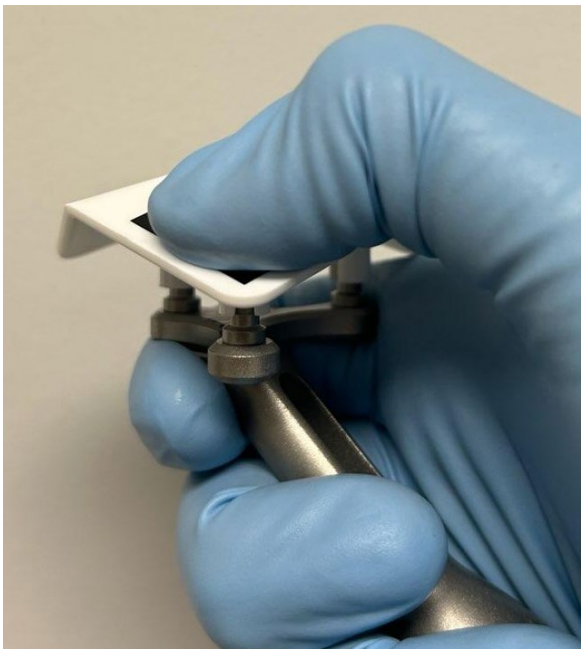
The surgical technique performed using mixed reality navigation with Signature Vision consists of the following steps:

1. Instrument and OptiVu Tracker Assembly
2. Patient Positioning and Incision
3. Humeral Preparation
4. Humerus Cut
5. Glenoid Preparation
6. Glenoid Central Pin
7. Glenoid Reaming
8. Glenoid Clocking
9. Navigation Finished
10. General UI/UX Elements

1. Instrument and OptiVu Tracker Assembly

General OptiVu Tracker Technical Information:
The OptiVu Trackers should be assembled only once on their dedicated instrument by applying pressure by hand to the center of the attachment posts (Figure 3). All three tracker posts should be firmly seated on the metal attachment studs. Verify that each post is fully engaged by visual inspection and confirmation that the tracker is stable and flush against the instrument. The indicator number and associated instrument name information directly marked on the reverse side of the trackers should align with indicator number and instrument name marked on the reusable instrument to which the tracker is attached. The user shall ensure that the OptiVu Trackers remain clean throughout the surgery. If they become soiled during use, use a dry gauze to gently wipe the faces clean. Minimize handling of the OptiVu Trackers to prevent damage or malposition. Disassemble the trackers by hand and follow instructions for disposal.

Figure 3: Assembling the Trackers by Hand

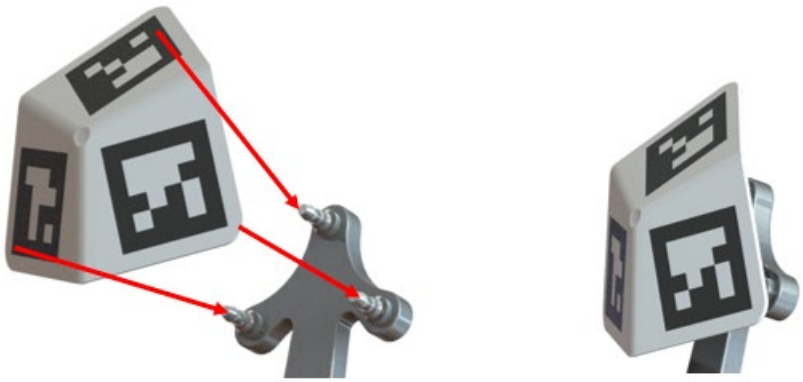


Assemble the following instruments:

Stylus Tracker

The tracker laser-marked with “1”, connects to the Stylus, also laser-marked with “1”. The tracker attaches in only one orientation (Figure 4). Press down on the center of each tracker post to snap it to the Stylus. Verify that each post is fully engaged by visual inspection and confirmation that the tracker is stable and flush against the instrument.

Figure 4: OptiVu Trackers Orientation onto the Instruments:



Adapter Handle Tracker

The tracker laser-marked with “2”, connects to the Adapter Handle, also laser-marked with “2”. The tracker attaches in only one orientation. Press down on the center of each tracker post to snap it to the Adapter Handle. Verify that each post is fully engaged by visual inspection and confirmation that the tracker is stable and flush against the instrument.

⚠	The Adapter Handle instrument contains a magnet and is MR Unsafe. Keep away from Magnetic Resonance Imaging (MRI) Equipment. Keep this instrument 6 inches (15 cm) away from magnetically susceptible medical devices such as cochlear implants, neurostimulators, stents, and shunts.

Humeral Anchor Tracker

The tracker laser-marked with “3”, connects to the Humeral Rod, also laser-marked with “3”. The tracker attaches in only one orientation. Press down on the center of each tracker post to snap it to the Humeral Rod. Verify that each post is fully engaged by visual inspection and confirmation that the tracker is stable and flush against the instrument.

Scapular Anchor Tracker

The tracker laser-marked with “4”, connects to the Scapular Rod, also laser-marked with “4”. The tracker attaches in only one orientation. Press down on the center of each tracker post to snap it to the Scapular Rod. Verify that each post is fully engaged by visual inspection and confirmation that the tracker is stable and flush against the instrument.

Reaming Guide Tracker

The tracker laser-marked with “5”, connects to the Reaming Guide, also laser-marked with “5”. The tracker attaches in only one orientation. Press down on the center of each tracker

post to snap it to the Reaming Guide. Verify that each post is fully engaged by visual inspection and confirmation that the tracker is stable and flush against the instrument.

Clocking Guide Tracker

The tracker laser-marked with “6”, connects to the Clocking Guide, also laser-marked with “6”. The tracker attaches in only one orientation. Press down on the center of each tracker post to snap it to the Clocking Guide. Verify that each post is fully engaged by visual inspection and confirmation that the tracker is stable and flush against the instrument.

2. Patient Positioning and Incision

2.1. Surgical Planning

The surgical planning is done using the SignatureOne™ software. Once the planning has been done, it should be downloaded from the Personalized Medicine Portal to the USB-C drive. The files are protected with a PIN which is defined before the download.

Note: the USB-C drive is not part of or provided with the Signature Vision. The use of any USB-C drive is acceptable.

The USB-C drive is plugged into the USB-C slot on the OptiVu Tilt and the files on the USB-C drive can then be recognized and copied from the drive using the Signature Vision software. See “3.5 Planning File List”.

Both total shoulder arthroplasty (TSA) and reverse shoulder arthroplasty (RSA/TSA-R) can be contained in a single planning file for a specific case. The user can choose which technique to follow after opening the file in the Signature Vision software.

2.2. OR Setup

The patient placement is at the discretion of the surgeon as the HMD is placed on the surgeon’s head. A bone reference is installed on the humerus and another on the scapula during different parts of the workflow to serve as references during resection and reaming, respectively. Fiduciary markers are placed on each instrument for the HMD to register throughout the surgical procedure.

There are two possible OR setups:

- Operating on a right shoulder, with the surgeon on the same side as the operated shoulder.
- Operating on a left shoulder, with the surgeon on the same side as the operated shoulder.

2.3. Surgical Position

Software

None.

Hardware

Prepare the arm and shoulder in alignment with the Zimmer Biomet Alliance® Glenoid or Comprehensive® Reverse Shoulder system for total or reverse shoulder arthroplasty surgical technique.

2.4. Surgical Incision/Exposure

Software

None.

Hardware

Make an incision and expose the joint per the Zimmer Biomet Alliance® Glenoid or Comprehensive® Reverse Shoulder system for total or reverse shoulder arthroplasty surgical technique.

3. Humeral Preparation

3.1. Attach the Humeral Anchor

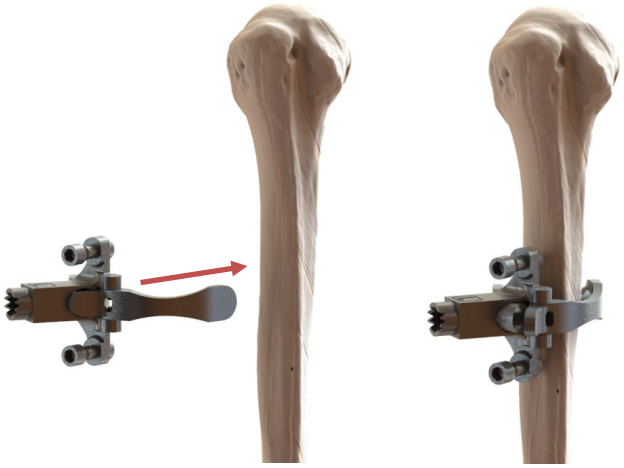
Software

None.

Hardware

Place the Humeral Anchor around the shaft of the humerus below the lesser tuberosity with the corresponding case laterality engraving facing distally to avoid interference with the registration region. Align the adjustable spikes of the Humeral Reference to be below the lesser tuberosity and the central screw facing medial to the patient (Figure 5).

Figure 5: Humeral Reference Rod Assembly attached to the Humerus



Tighten the screws with the Hex Head Screwdriver until connection is solid by starting with the main set screw and then proceeding with the adjustment spikes. Take care to avoid the axillary nerve when attaching the Humeral Anchor.

Attach the corresponding case laterality Humeral Reference Rod to the Humeral Anchor. Ensure that the Rod is fully seated within the grooves and visible before tightening (Figure 6). Ensure the tracker is facing the user and within the field of view. Adjust the Humeral Reference Rod and the tracker rod further during the Humerus - Anchor Placement step (Section 4.3).

Ensure entire assembly stability before proceeding.

Figure 6: Assembling the Humeral Reference Rod to the Shoulder Humeral Ref

⚠	Do not overtighten the Humeral Anchor to the bone and the Reference Rod to the Humeral Anchor as this can lead to bone damage.

⚠	Take care to not damage the axillary nerve when affixing the Humeral Anchor.

⚠	Do not cover or touch the Scapular Anchor Trackers once they are affixed to the humerus or coracoid.

3.2. Put OptiVu Tilt with HoloLens 2 on and prepare HMD

Hardware

Put the HMD on your head or have a surgical technician or assistant help you with putting it on your head. Make sure the device sits securely on your head. Adjust the straps and fitting if needed. The correct and secure placement minimises the risk of device accidentally falling. Ensure the sterile field is always maintained.

Software

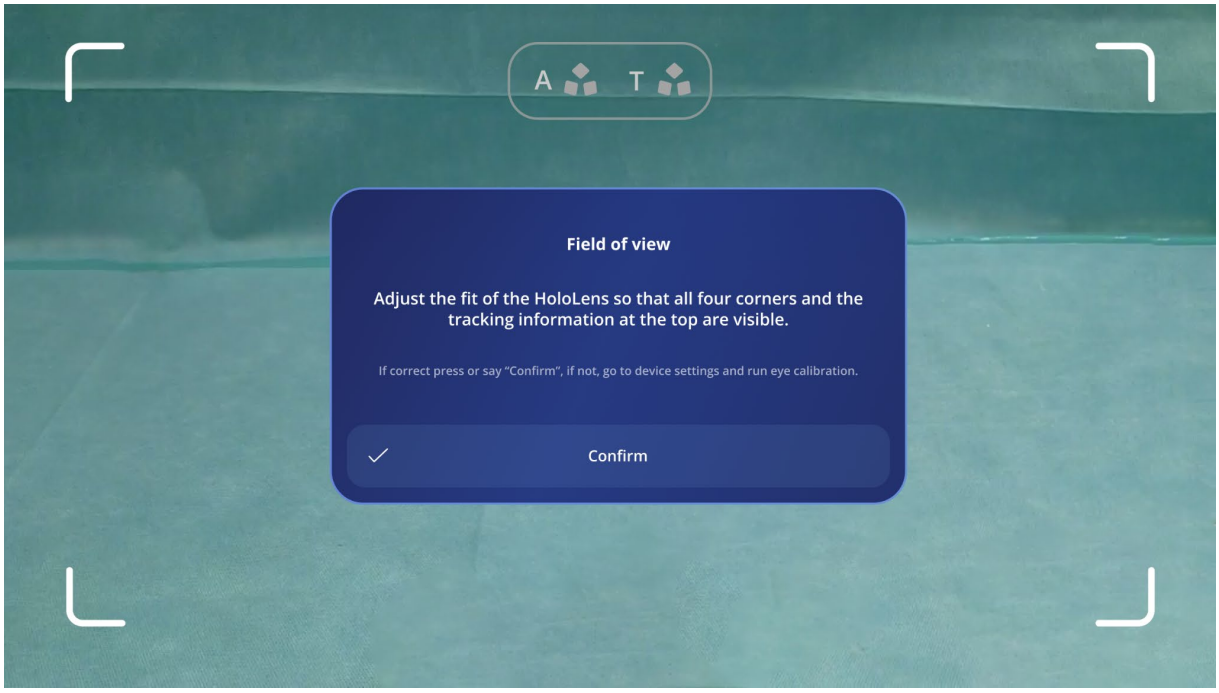
Start the Signature Vision Application if it is not running. If the application is running, reset the application by opening the Hand Menu and tapping the “Reset App” button. The Hand Menu can be accessed by looking at the palm of your hand.

⚠	Do not touch the HMD during surgery to avoid the risk of contamination.

3.3. FOV (Field of View) Check

Software

Figure 7: Signature Vision Application Field of View Screen



Voice Over

"Check your field of view. Make sure all four corners and the tracking information at the top are visible."

Buttons List

Button Name	Voice Command	Description
Confirm	Confirm	Activates the confirm button

Screen Description

The user is asked to confirm the visibility of the four white corners and the tracking panel. The user (or surgical tech or assistant) should adjust the HoloLens device's visor position to make sure that they can see all of the elements. The sterile field shall be maintained. Once these requirements are met the user should press the "Confirm" button to proceed.

Hardware

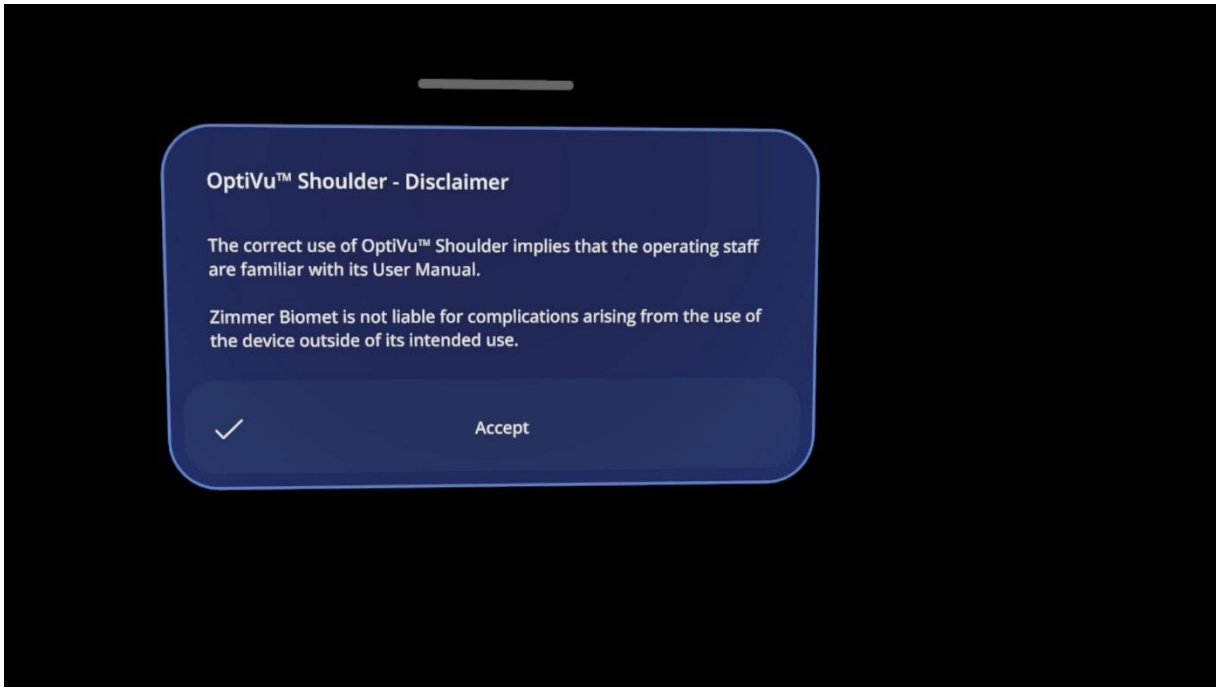
The user (or surgical tech or assistant) should adjust the HoloLens as needed to ensure the user can see all elements in the field of view. The sterile field shall be maintained.

⚠	Do not touch the HMD during surgery to avoid the risk of contamination.

3.4. Disclaimer Screen

Software

Figure 8: Signature Vision Application Disclaimer Screen



Voice Over

“Please read and accept the disclaimer.”

Buttons List

Button Name	Voice Command	Description
Accept	Accept	Goes to the next step
Pin	Select	Toggle button. Pins in place or unpins the UI Panel
Scroll Down	Scroll down	Scroll the file list down
Scroll Up	Scroll up	Scroll the file list up

Hardware

None.

3.5. Planning File List

Software

Figure 9: Signature Vision Application Selecting a Planning File

Voice Over

“Select a planning file.”

Buttons List

Button Name	Voice Command	Description
Check for the USB-C Drive	Check for the USB-C drive	The system checks if there’s a USB-C Flash Drive connected to the device. If yes, then the list of Planning Data files available on the device will be displayed here.
<Planning File name>	Select	Activates the selected planning file button.
Delete	Delete	Deletes specific planning file from the device.

Scroll down	Scroll down	Scroll the file list down.
Scroll up	Scroll up	Scroll the file list up.

Screen Description

This panel shows which planning data files are currently available to be used with the Signature Vision software. The panel shows a list of planning data files that are available on the device or on a USB-C Drive that's currently connected to the device. It might be that the lists are empty if there are no files on the device or the USB-C drive or the USB-C drive is not attached.

The above illustrations show these possibilities (Figure 9).

The user can scroll the file list using the buttons to the right of the file list. The user should select a planning file available on the device that they want to use. The files from the USB-C drive must be copied onto the device storage by tapping an entry before they can be used.

The user can also delete unwanted files from the device by using the "Delete" button.

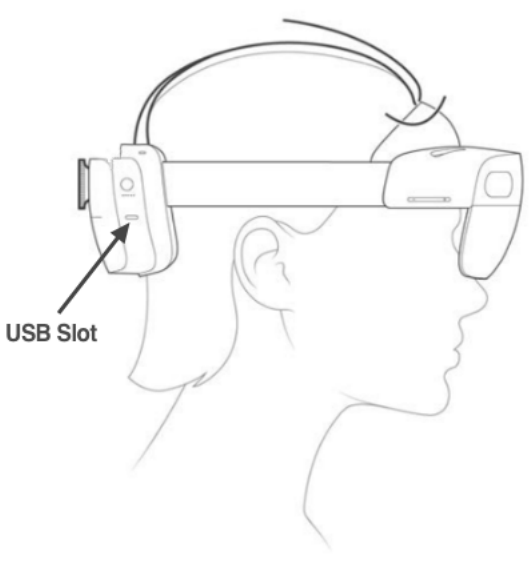
If the user activates the "Delete" button, a dialog "3.5.1. Confirmation Dialog - File Deletion" will be displayed asking for confirmation.

	A patient planning file must be uploaded to the HMD before being able to use the software.

Hardware

Insert the USB-C drive into the HMD as needed to copy or delete the planning file from the HMD.

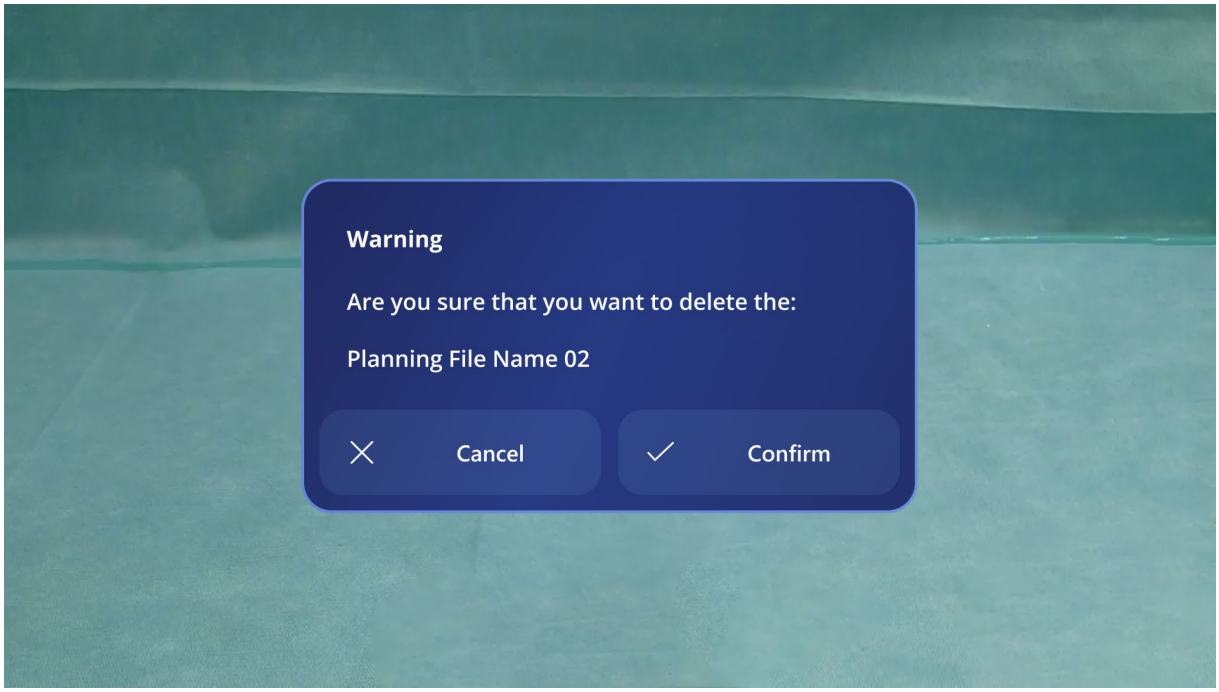
Figure 10: USB Slot Location on the HMD



3.5.1. Confirmation Dialog - File Deletion

Software

Figure 11: Signature Vision Application Delete File Warning



Voice Over

“Are you sure that you want to delete this file?”

Buttons List

Button Name	Voice Command	Description
Confirm	Confirm	Confirms the dialog. Deletes the file.
Cancel	Cancel	Closes the dialog. The file is not deleted.

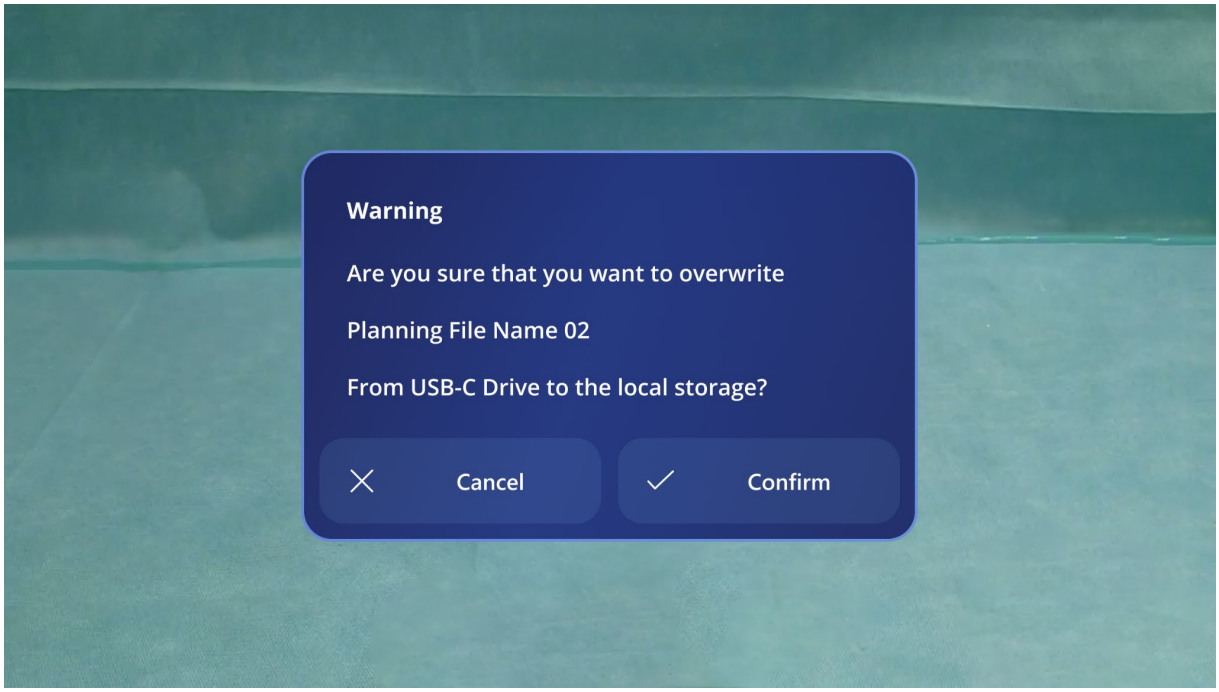
Screen Description

The user has to confirm deleting of the existing planning file.

3.5.2. Confirmation Dialog - Overwriting File

Software

Figure 12: Signature Vision Application Overwriting File Warning



Voice Over

“Are you sure that you want to overwrite this file?”

Buttons List

Button Name	Voice Command	Description
Confirm	Confirm	Confirms the dialog. Overwrites the file.
Cancel	Cancel	Closes the dialog. Does not overwrite the file.

Screen Description

If the user tries to copy a file from the USB-C drive that has the same name as a file present on the device, the file on the device will be overwritten.

Before overwriting, there will be a dialog displayed asking the user to confirm this action (Figure 12).

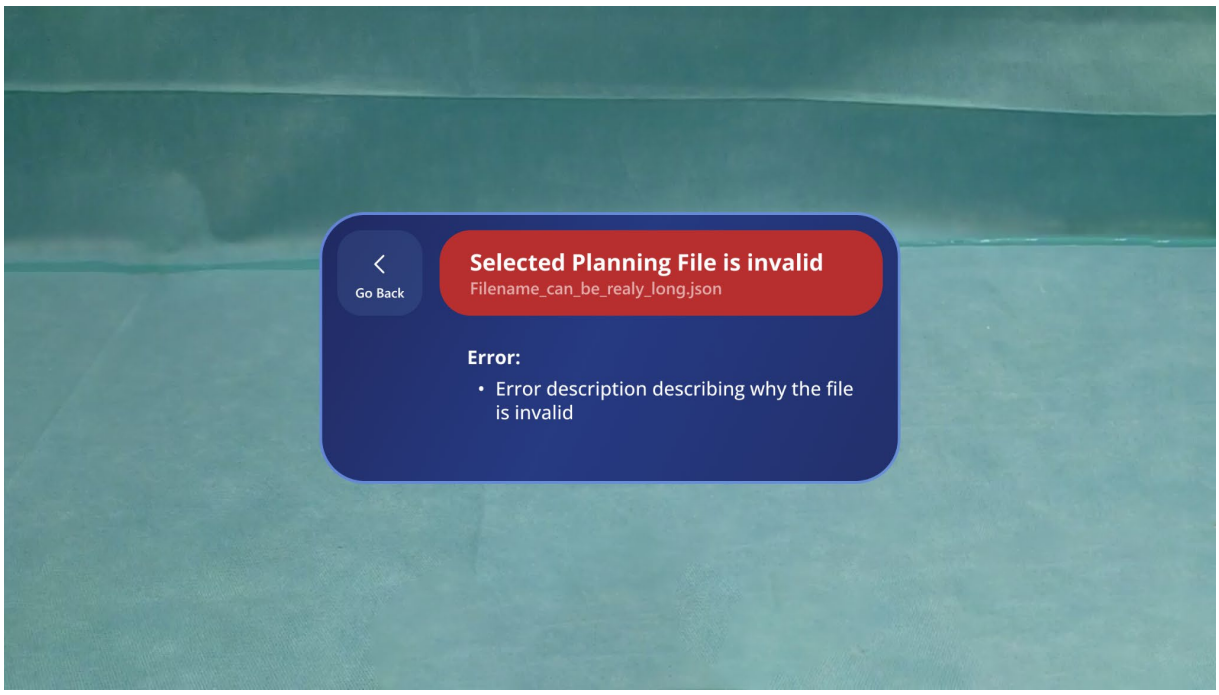
Hardware

The USB-C drive must be inserted into the HMD to overwrite a planning file to the HMD.

3.5.3. Information Error Dialog - Invalid Planning File

Software

Figure 13: Signature Vision Application Invalid Planning File Screen



Voice Over

“Selected planning data is invalid. Please go back and choose a different file.”

Button List

Button Name	Voice Command	Description
Go Back	Go back	Goes Back to the previous screen.

Screen Description

It might be that the file downloaded to the device is corrupt or invalid. In that case, a dialog will be opened with error information (Figure 13).

If the invalid planning file dialog is displayed, the user can check the error description and then go back to the planning file list screen.

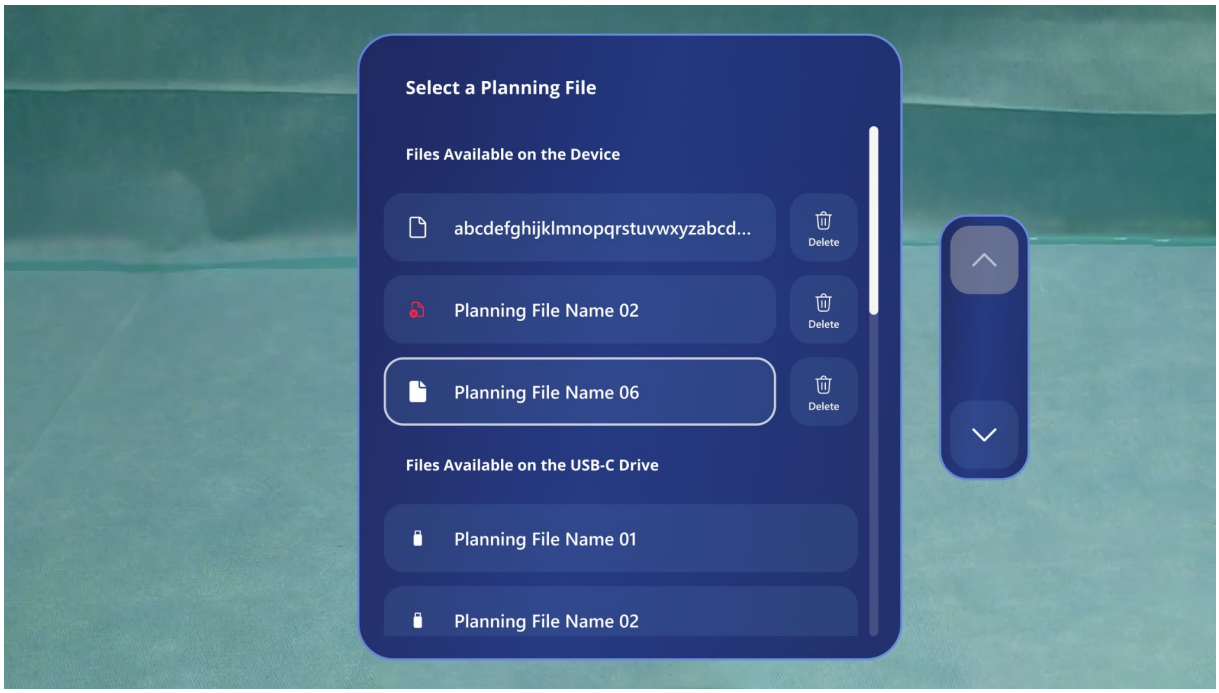
After going back to the planning file list, the invalid file will be marked with a different icon next to the file name.

Hardware

The USB-C drive may be inserted into the HMD to select a planning file. A planning file may also be selected from the files stored directly on the HMD.

3.5.4. Meaning of the Icons Next to File Names

Figure 14: Signature Vision Application Icon Description

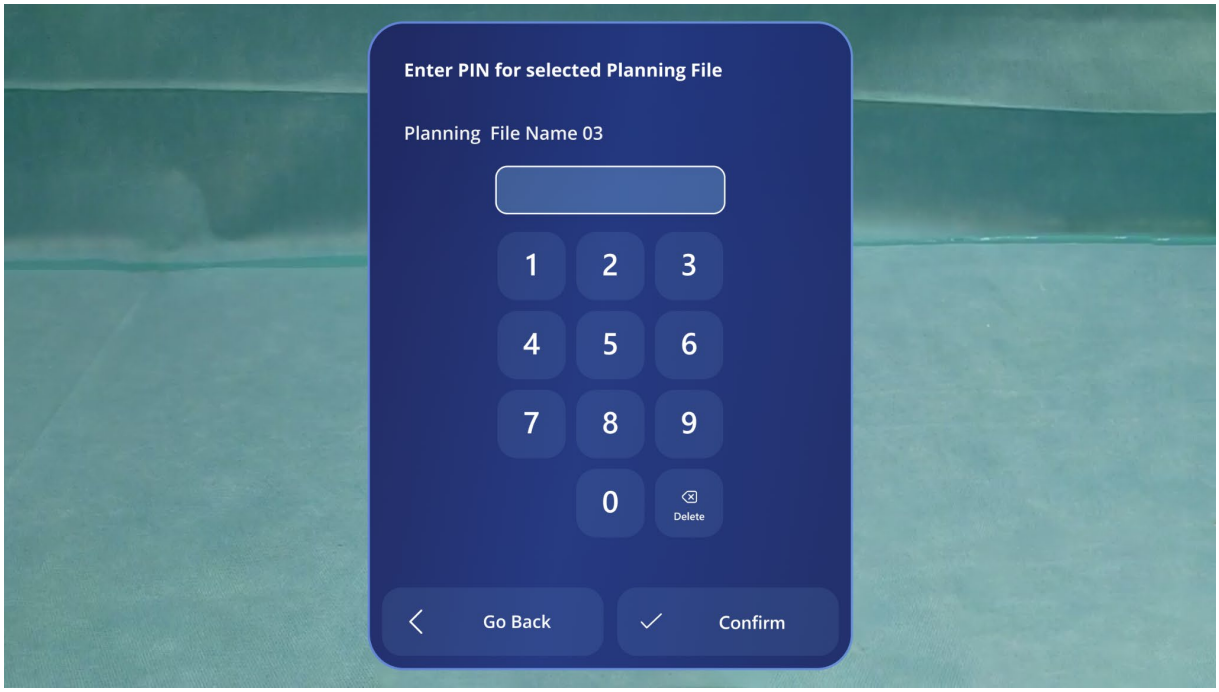


Icon	Description
	Invalid file
	File available on the USB-C drive
	File available on the device that was copied from the USB-C drive and was not opened in this application session yet.
	File available on the device that was already opened during this application session or was available before starting the application.

3.5.5. PIN Panel for the Planning File

Software

Figure 15: Signature Vision Application PIN for Planning File



Voice Over

“Enter PIN for selected planning file.”

Button List

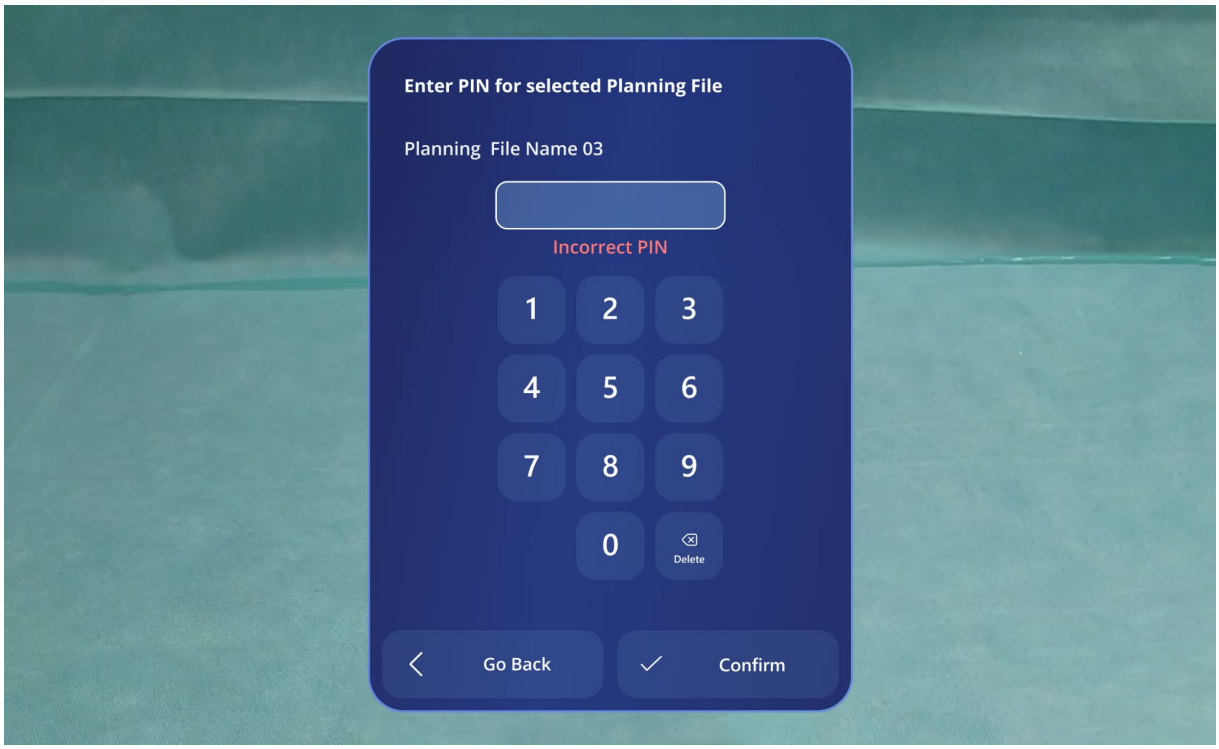
Button Name	Voice Command	Description
Go Back	Go back	Go back to the planning file list.
Confirm	Confirm	Checks if the PIN is correct and if it is, then it continues to the next step.
Delete	Delete	Deletes the last inputted number.
Buttons from 0 to 9	Select	The user can also use eye gaze (look at the number) and the voice command “Select” to enter the PIN code into the input field.

Screen Description

The patient file is encrypted with a PIN code to protect the patient's data contained in the file. The user must enter the correct PIN for the specific planning file to be able to open it. Once the correct PIN has been entered, the user can activate the "Confirm" button to proceed to the next screen.

If a wrong PIN was entered, the input field will be cleared and a message that the PIN was incorrect is shown.

Figure 16: Signature Vision Application Incorrect Pin Message



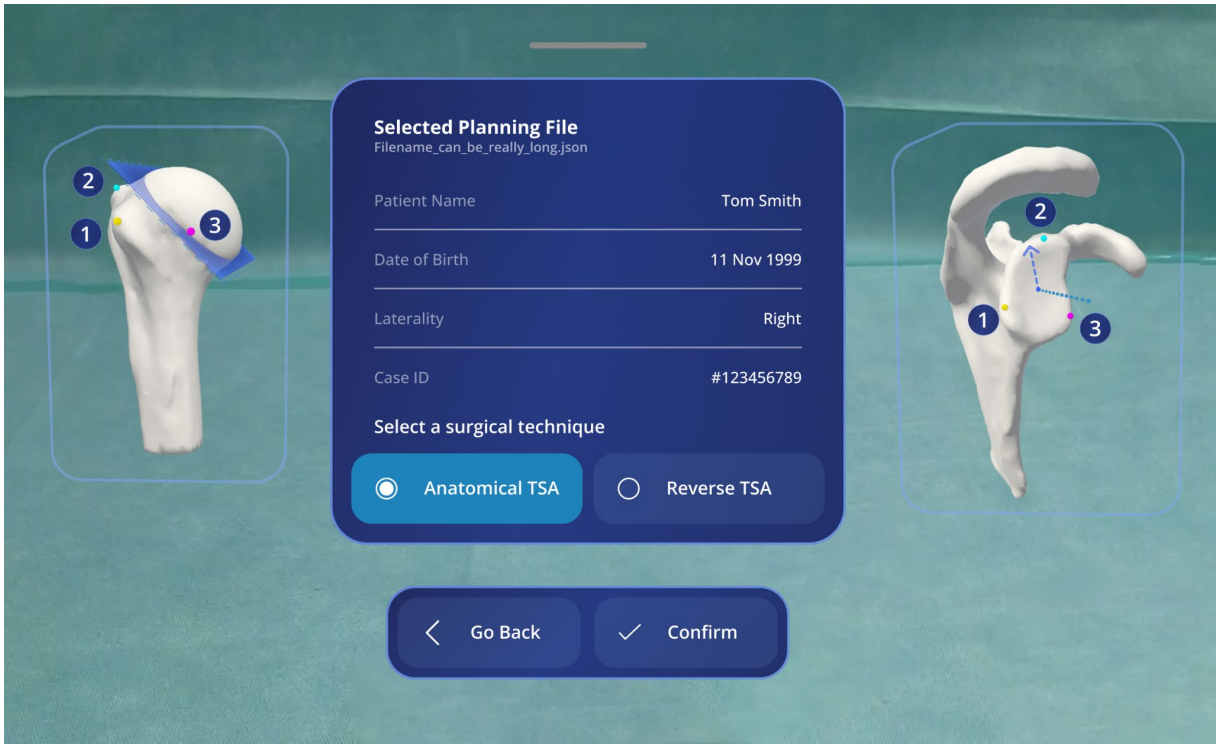
Hardware

None.

3.6. Confirm Patient Data and Select Surgical Technique

Software

Figure 17: Signature Vision Application Patient Data and Selecting Surgical Technique



Voice Over

"Confirm the chosen planning file and make sure the chosen surgical technique is correct."

Button List

Button Name	Voice Command	Description
Go Back	Go back	Go back to the planning file list.
Confirm	Confirm	Go to the next screen.
Anatomical TSA	Anatomical	Activate the Anatomical TSA toggle button.
Reverse TSA	Reverse	Activate the Reverse TSA toggle button.

Screen Description

The user is presented with the selected planning file details:

- File name
- Patient Name
- Laterality

- Case ID

There are two 3D models shown:

1. The patient's Humerus bone scan with marked landmark points and planned cut plane.
2. The patient's Scapula bone scan with marked landmark points and planned central pin trajectory.

The 3D models and the panel can be easily repositioned by using the grabbing gesture. The user can select the desired surgical technique used for the selected planning data. If the surgical technique is changed, the 3D models will be reloaded to reflect this change (e.g. the planned cut plane and central pin trajectory will change according to the plan).

The user must activate the "Confirm" button to proceed.

The user can also use the "Go Back" button if they would like to go to the previous screen and choose a different file.

Hardware

None.

3.7. Humerus – Remove Cartilage

Software

None.

Hardware

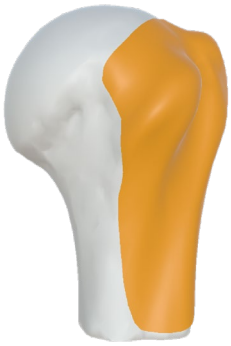
Use a Scraper to thoroughly remove all cartilage and soft tissue from the surface of the bone. This step is critical to ensure unobstructed access to key anatomical landmarks of the upper Humerus, including the Anatomical Neck, Lesser and Greater Tuberosity, and the upper Humeral Shaft. The Humeral Head can be excluded since this part will not get sampled. The objective is to remove all structures not visible on a CT scan, complete removal of non-bony material is essential for accurate registration. Do not remove osteophytes and other bony structures, as they are visible on the CT scan and essential for accurate registration.

Note: The Scraper is not part of or provided with the Signature Vision.

	Complete removal of all cartilage and soft tissue from the prepared bone surface is imperative, as even minimal residual material can compromise registration accuracy

The following image depicts the area where the tip of the Stylus needs to reach the bone surface.

Figure 18: Sampling area on the Humerus



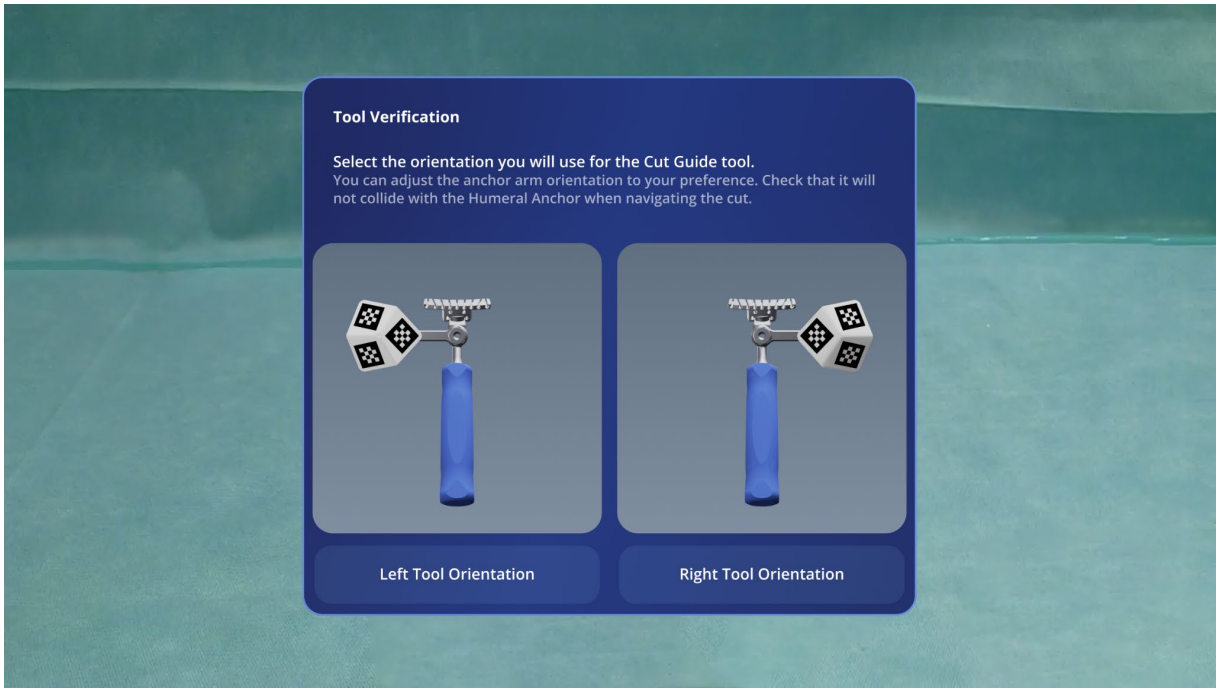
⚠	Exposed glenoid and humerus bones must be cleaned of any soft tissue before performing registration.

4. Humerus Cut

4.1. Tool Verification - Cut Guide Orientation Selection

Software

Figure 19: Signature Vision Application Cut Guide Orientation Selection



Voice Over

“Tool Verification. Select the orientation you will use for the Cut guide tool.”

Button List

Button Name	Voice Command	Description
Left Tool Orientation	Left tool orientation	Selects the left tool orientation.
Right Tool Orientation	Right tool orientation	Selects the right tool orientation.

Screen Description

Before registering the Adapter Handle with Cut Guide, the user must select the chosen tool configuration from the dialog. The user can choose either the left or right tool configuration.

Once the user activates the “Left Tool Orientation” or “Right Tool Orientation” button, the correct tool hologram will be displayed in the next step (Figure 19).

Hardware

Slide the Cut Guide onto the Adapter Handle slot in the direction shown below (Figure 20). A magnet in the Adapter Handle retains the Cut Guide. Loosen the knob by hand on the front of the Adapter Handle, pull the tracker arm out, and rotate the Adapter Handle arm to the left or right, based on the shoulder orientation and laterality. Place the tracker arm into its slot by aligning the laser marked arrows on the knob and with the body of the Adapter Handle and tighten the knob to lock it in place (Figure 21). Ensure the tracker is facing the user and within the field of view.

Figure 20: Attaching the Cut Guide to the Adapter Handle

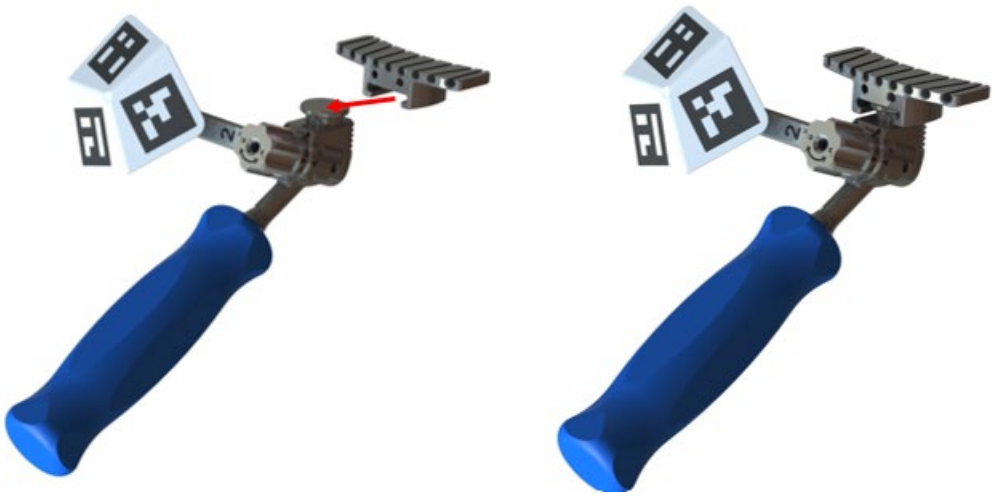
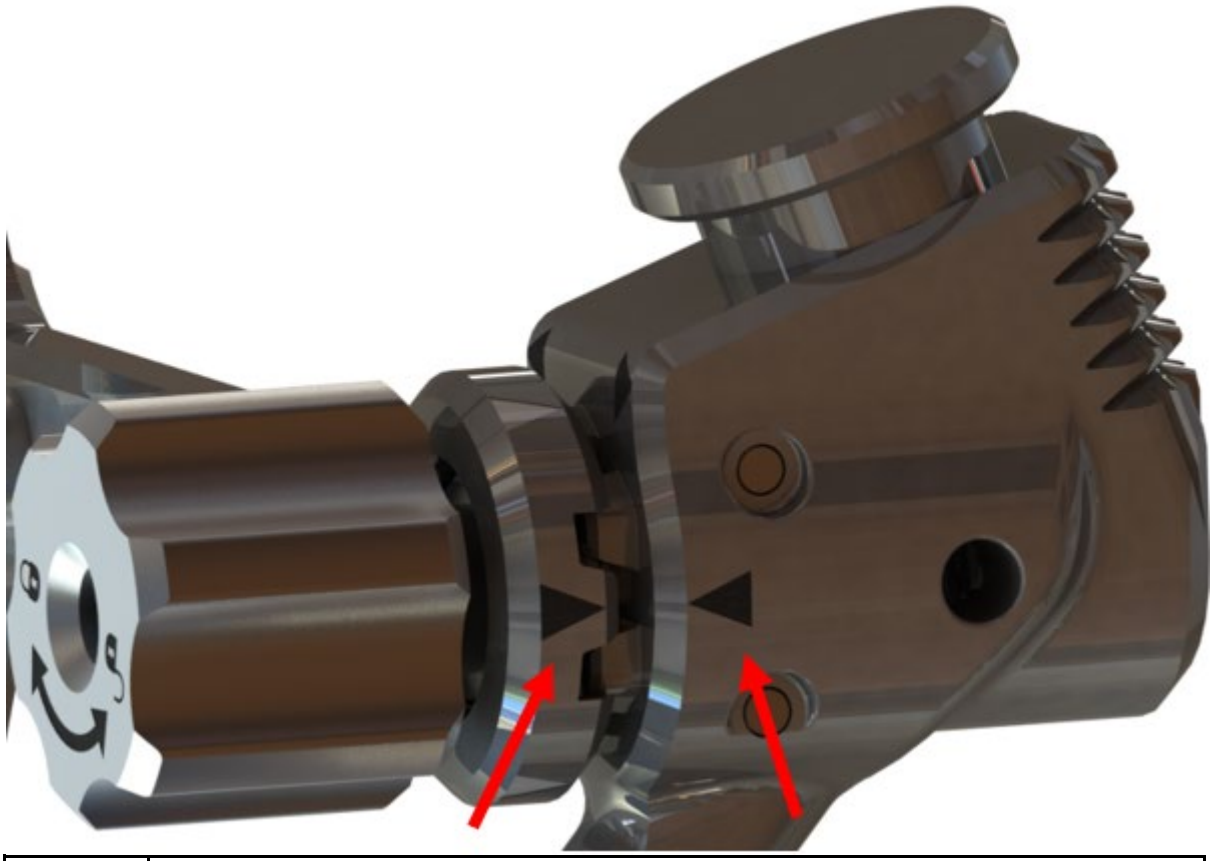


Figure 21: Adapter Handle Arrow Alignment



⚠	The Adapter Handle instrument contains a magnet and is MR Unsafe. Keep away from Magnetic Resonance Imaging (MRI) Equipment. Keep this instrument 6 inches (15 cm) away from magnetically susceptible medical devices such as cochlear implants, neurostimulators, stents, and shunts.

4.2. Tool Verification Screens

Software

Figure 22: Signature Vision Application Tool Verification Screen

Screen Description

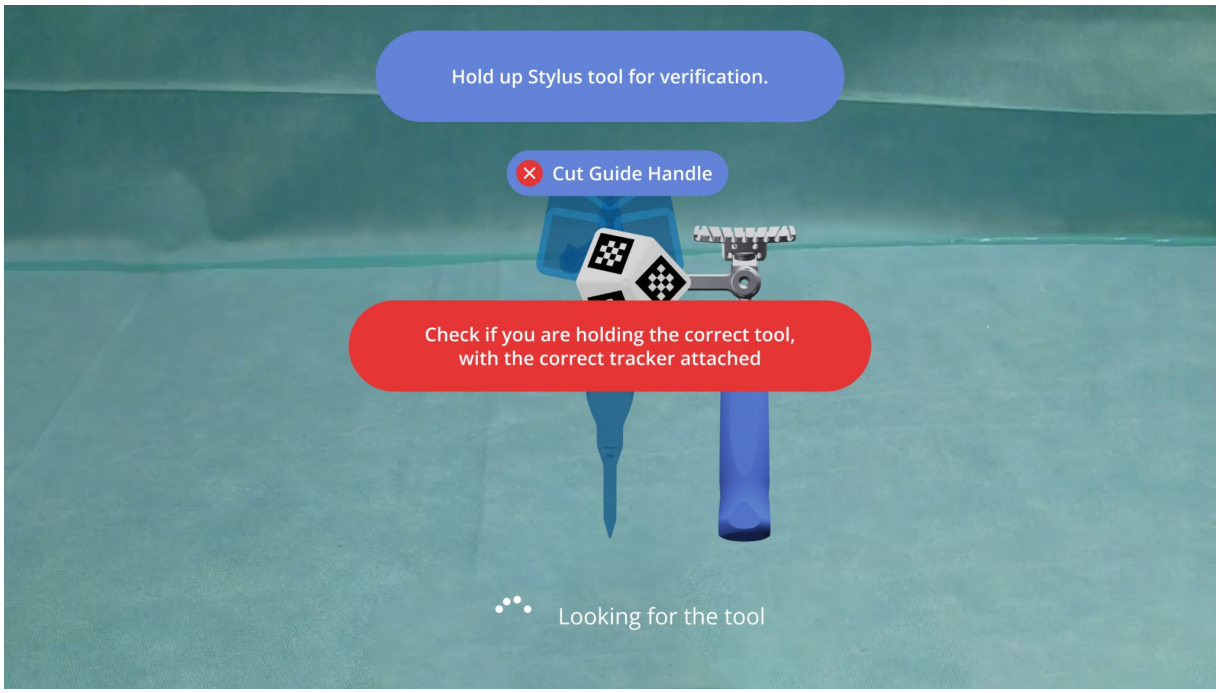
The user must show the different tools in front of the OptiVu Tilt with HoloLens 2 PV (Photo Video) camera. The user should direct the marker attached to the tool, so it is visible to the PV camera. The tool and tracker should overlap with the presented hologram.

Other tools present in the field of view of the camera will also be recognized.

The user should make sure that the ambient lighting recommendations are met when trying to register or use the tools with the OptiVu Tilt with HoloLens 2 device. The software should automatically recognize the shown marker and proceed to the next step.

If the user holds a wrong tracker in front of the camera, a warning will be displayed:

Figure 23: Signature Vision Application Incorrect Tool Warning



	Always check if the tracker is properly attached to the tool and if it's not damaged.

Hardware

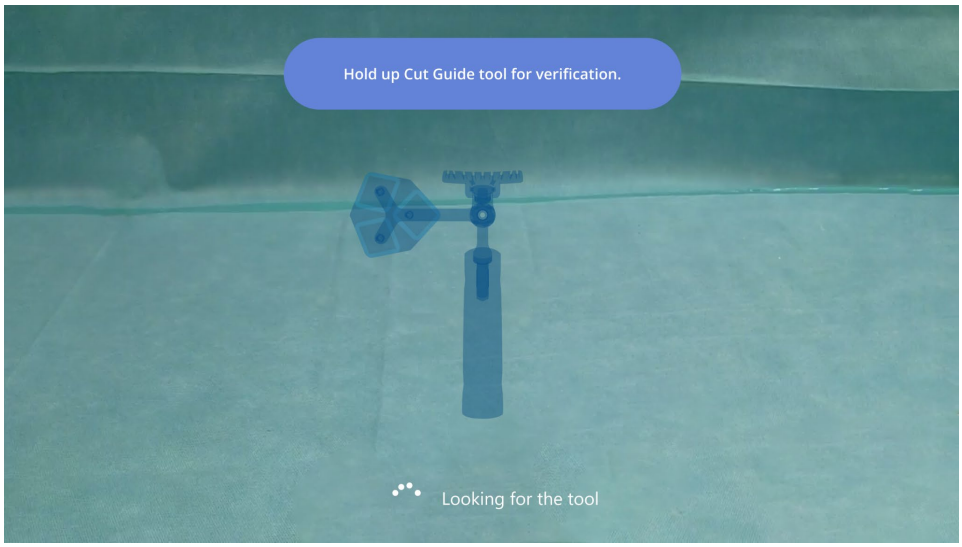
Ensure the instruments are properly assembled for tool verification.

4.2.1. Tool Verification - Cut Guide

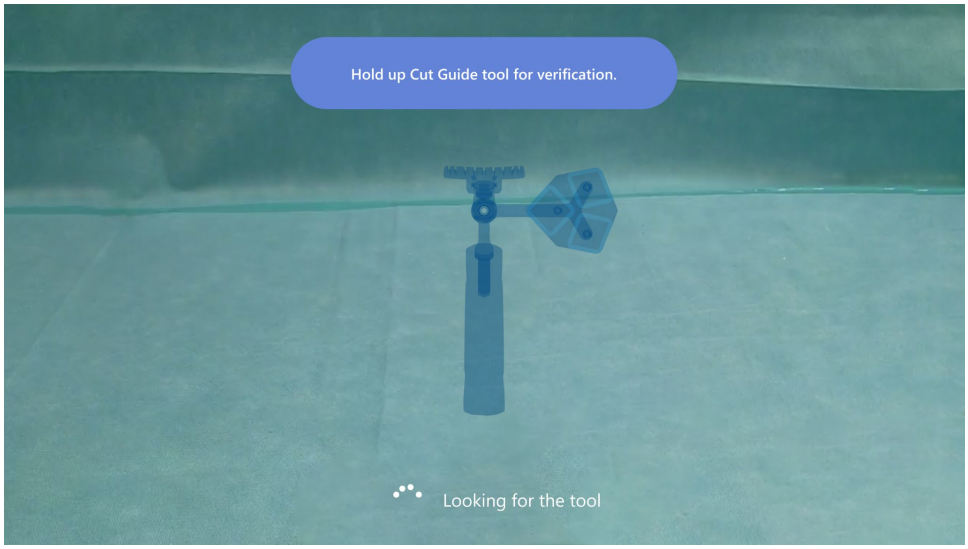
Software

Figure 24: Signature Vision Application Tool Verification - Cut Guide

Variant – Left



Variant - Right



Voice Over

“Hold up Cut Guide tool for verification.”

Screen Description

The hologram will have the orientation selected in the Cut Guide orientation selection screen.

Hardware

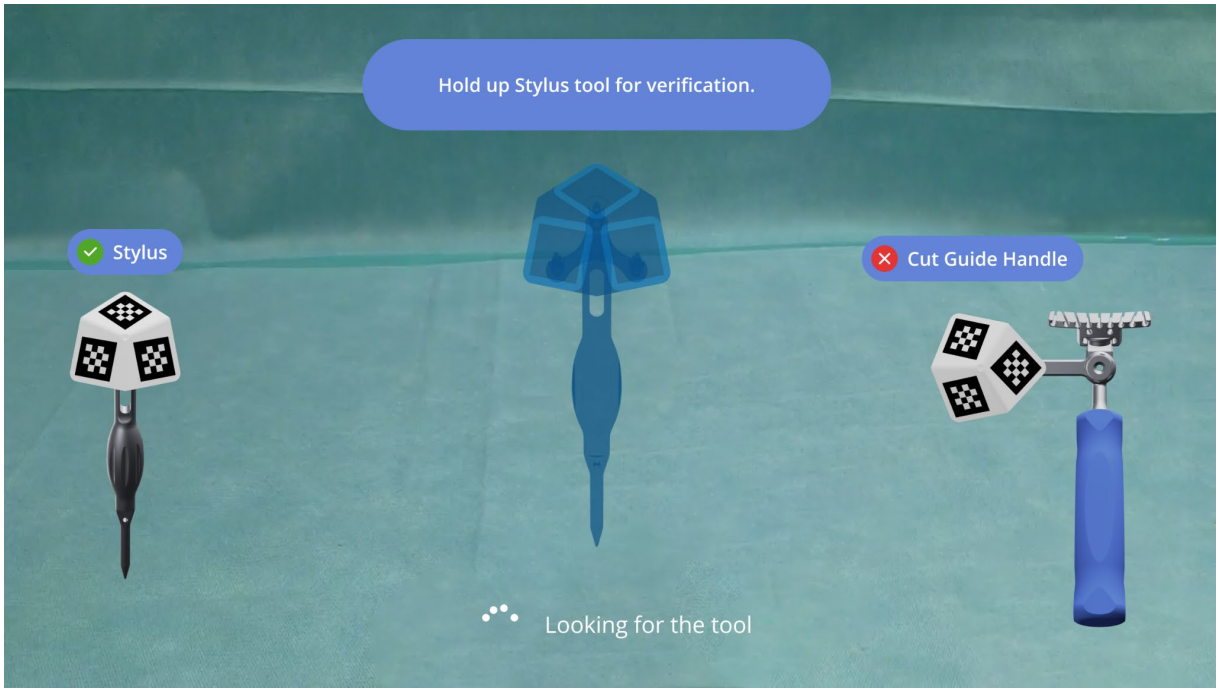
Ensure the tracker is facing the user and within the field of view.

	Always check if the tracker is properly attached to the tool and if it's not damaged.

4.2.2. Tool Verification - Stylus

Software

Figure 25: Signature Vision Application Tool Verification - Stylus



Voice Over

"Hold up your Stylus tool for configuration."

Hardware

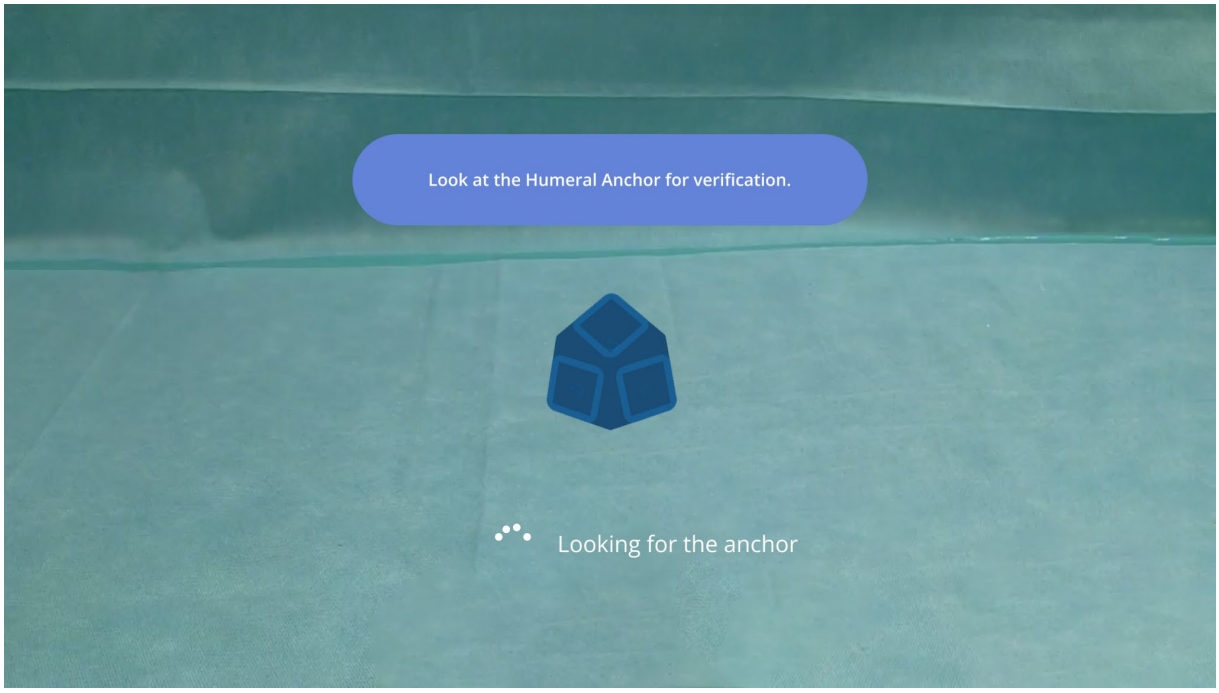
Ensure the tracker is facing the user and within the field of view.

	Always check if the tracker is properly attached to the tool and if it's not damaged.

4.2.3. Tool Verification - Humeral Anchor

Software

Figure 26: Signature Vision Application Tool Verification - Humeral Anchor



Voice Over

“Look at the Humeral Anchor for verification.”

Hardware

Ensure the tracker is facing the user and within the field of view.

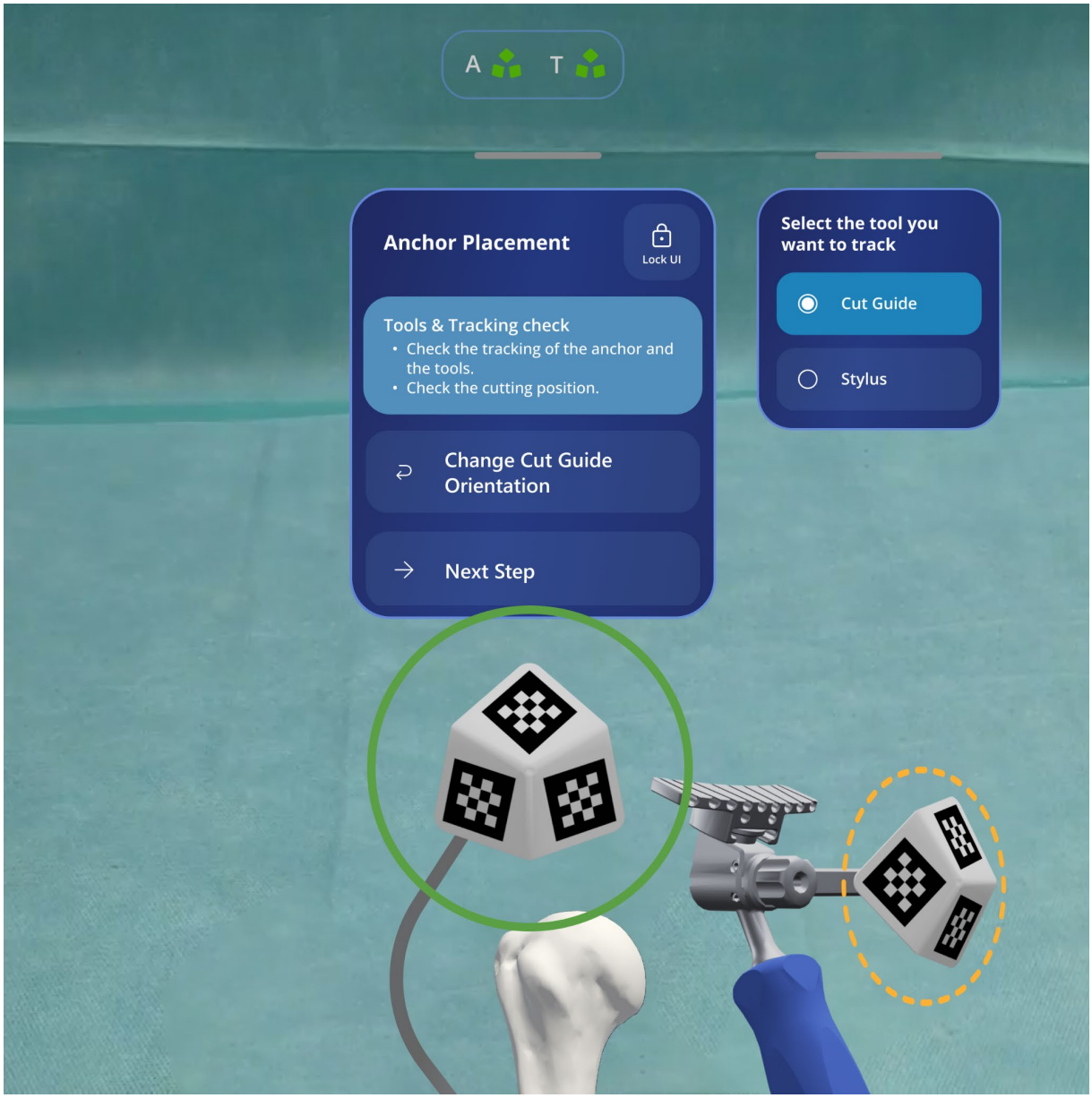
Once the Humeral Anchor is registered, do not touch or reposition the Humeral Anchor. The Humeral Anchor is a static reference point that the software uses to oversee the surgical steps.

	Always check if the tracker is properly attached to the tool and if it’s not damaged.

4.3. Humerus - Anchor Placement

Software

Figure 27: Signature Vision Application Humerus - Anchor Placement



Voice Over

“Tools & Tracking check. Check the tracking of the anchor and the tools. Focus specifically that you can track well the anchor and the Cut Guide at the cutting position.”

Button List

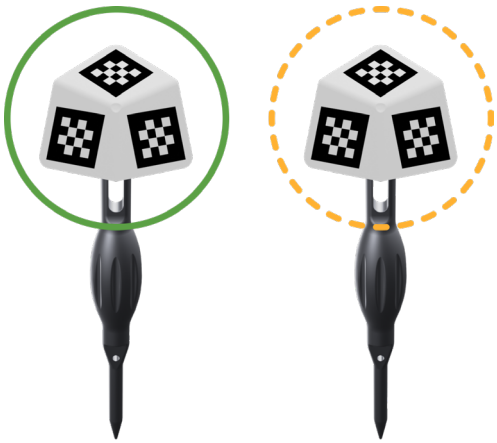
Button Name	Voice Command	Description
Change Cut Guide Orientation	Change cut guide orientation	Open the menu to choose the desired orientation of the cut guide tool (L/R).

Next Step	Next step	Go to the next screen.
Cut Guide	Cut guide	Set Cut Guide as an actively tracked tool.
Stylus	Stylus	Set Stylus as an actively tracked tool.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

This step is used to check if both the Humeral Anchor and the Stylus and Cut Guide tools can be correctly tracked in the chosen setup. The user should check that the tools are not colliding with each other. The user can choose which tool should be tracked (Stylus or Cut Guide). The anchor is always tracked by the system.

Figure 28: Visual Display of the OptiVu Tracker angle greater than 30 degrees



The color-coded circles around the trackers provide additional information about the tracking. If the camera is looking at the tracker at an angle greater than 30 degrees, it will turn dashed and orange. The circle will turn solid and green when the tracker is oriented towards the camera (Figure 28).

This step has 3 UI Elements.

1. **The Context Panel** - A UI Panel spawned above the Humeral Anchor which informs in which step the user currently is in and what they have to do. It contains a “Lock UI” button. The user can reposition the panel by grabbing the grabbable indicator (a horizontal line above the blue backplate).

2. **The Side Menu** - A UI Panel with additional options. The user can reposition the panel by grabbing the grabbable indicator (a horizontal line above the blue backplate). In this step, the user can choose which tool should be tracked by the system in

addition to the anchor that is being tracked all the time.

3. **Tracking Panel** - Shows the current status of the anchor and Stylus/Cut Guide tracking. See details in chapter “10.2.4 Tracking Panel”.

Recommendations for optimal tracking

Do’s	Don'ts
Make sure that the trackers always point at the HoloLens 2 Camera located above the visor.	Do not cover the trackers with your hand or other tools.
Make sure the room and your workplace are well lit (between 1000 - 2000 lux).	Avoid operating room light beams pointing directly to the trackers.
Use as much diffuse light as possible.	Do not bend or damage the trackers.
Always check if trackers are correctly attached to the tools.	
Make sure the trackers are clean.	

Hardware

Hold the Stylus or Adapter Handle within the field of view. Ensure the tracker is facing HMD camera and within the field of view. If either instrument is incorrectly tracked, return to the verification step.

After verifying the tools (Stylus, Cut Guide, Humeral Anchor), adjust the Humeral Anchor rod and tracker as needed, per user preference, ensuring the rod and tracker will not collide with the Adapter Handle, Cut Guide, Stylus, or trackers during humeral registration, positioning the Cut Gude, or humeral resection. The tracker arm on the Adapter Handle may be adjusted as needed to ensure it will not collide with the Humeral Anchor rod or tracker, changing the Cut Guide orientation in the software if adjusted. Ensure all trackers are facing the user and within the field of view. The trackers in the field of view should be relatively parallel with each other for best tracking performance.

	Do not cover or touch the OptiVu Trackers once they are affixed to the humerus or coracoid.
	Always check if the tracker is properly attached to the tool and if it’s not damaged.

4.4. Humerus Registration Step

In this step, the user is asked to register 3 marked landmark points on the humerus using the stylus tool.

The user will be asked to save points one after the other. After saving the third point, the software checks if the registered landmarks are at the correct distance from each other. If this is not the case, a voice-over is played: “Landmarks are not at a correct distance from each

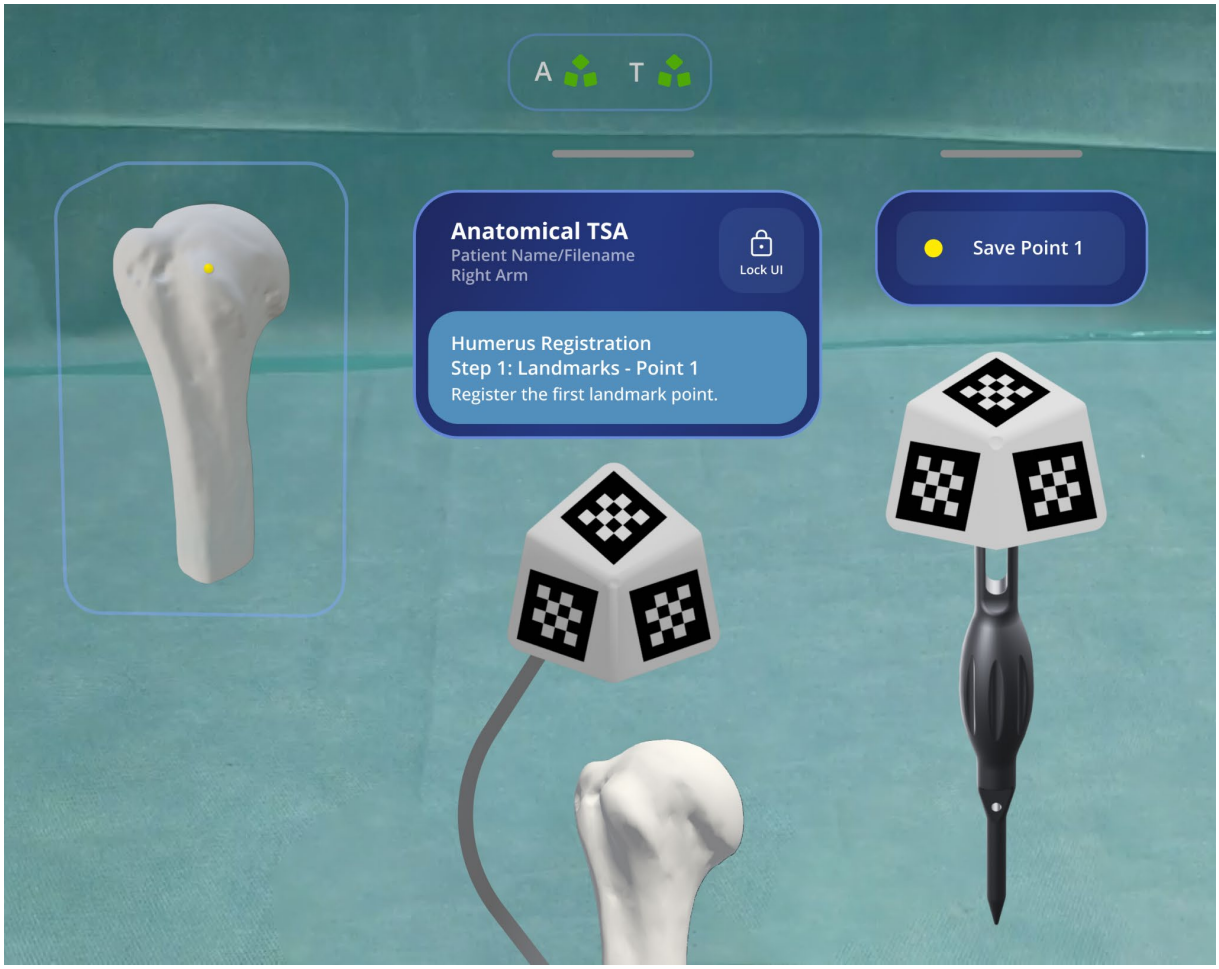
other. Please save the landmarks very precisely.”

The user should improve the position of the registered points by setting them again. When the checked distances are correct, the user will be allowed to continue to the next step.

4.4.1. Humerus Registration Step 1: Landmarks - Point 1

Software

Figure 29: Signature Vision Application Humerus Registration Step - Landmarks Point 1



Voice Over

“Humerus registration - Step 1: Landmarks. Point 1. Register the first landmark point.”

Button List

Button Name	Voice Command	Description
Save Point 1	Save point one	Registers the position of the stylus tip and adds a visual to mark the 1st landmark point.

Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

In this step, the user is asked to register 3 marked landmark points using the stylus tool.

This step has four UI Elements.

1. **The Context Panel** - A UI Panel spawned above the Humeral Anchor which informs in which step the user currently is in and what they have to do. It contains a “Lock UI” button. The user can reposition the panel by grabbing the grabbable indicator (a horizontal line above the blue backplate).

2. **Virtual Bone Model** - A 3D model in a bounding box. In this step, a 3D model of the patient's bone with marked landmark points is shown. The user can reposition, rotate, and scale the 3D model by grabbing the bounding box.

3. **The Side Menu** - A UI Panel with the “Save Point 1” button. The user can reposition the panel by grabbing the grabbable indicator (a horizontal line above the blue backplate).

4. **Tracking Panel** - Shows the current status of the anchor and stylus tracking. See details in chapter “10.2.4 Tracking Panel”

The user must place the Stylus tip on the anatomy at the position of the landmark point. When the Stylus tip is in the correct position, the user should press the corresponding “Save Point 1” button or use the corresponding voice command to register the selected landmark.

The “Save Point 1” button and its voice commands are disabled when the tracking of the tools is lost.

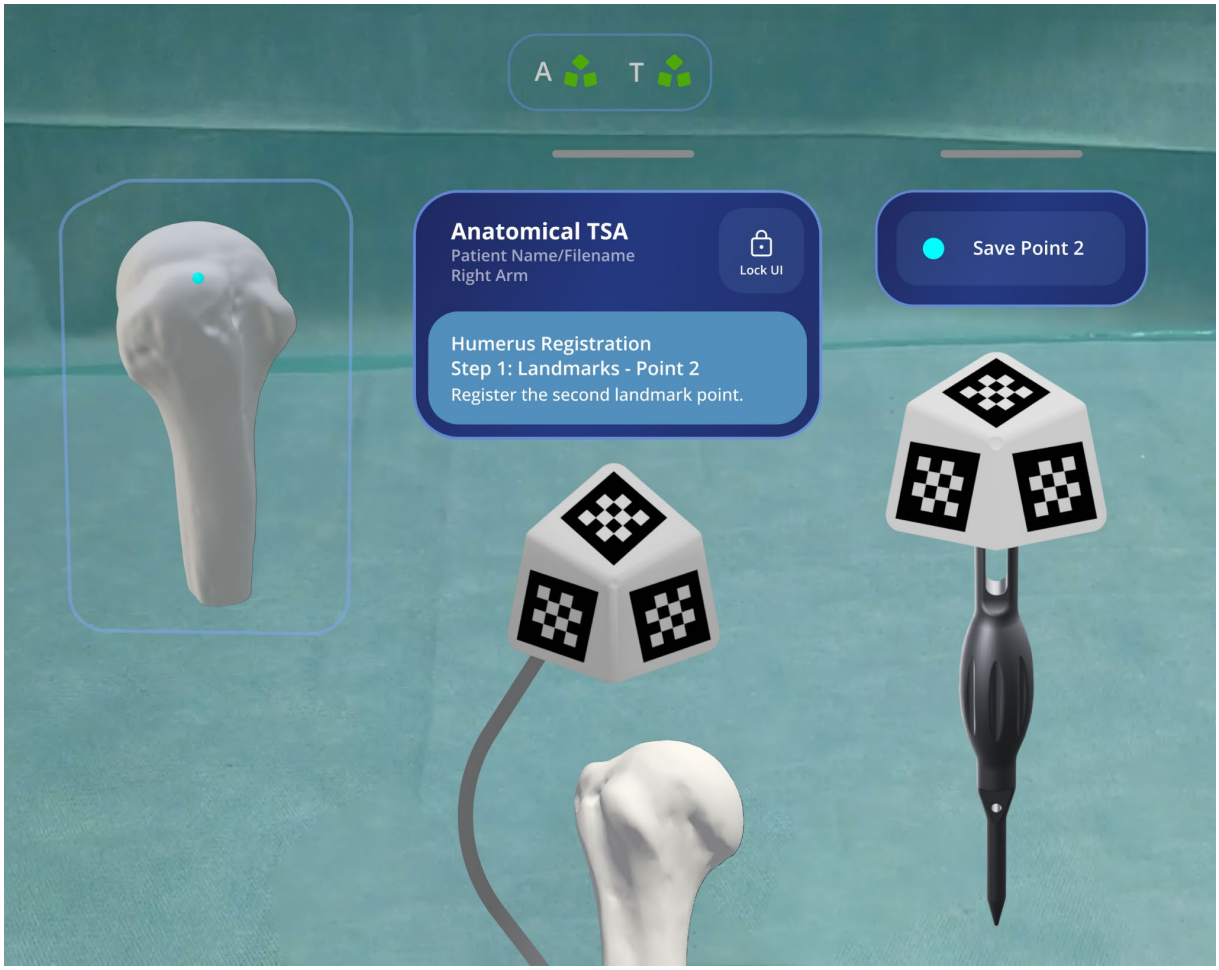
Hardware

Place the Stylus tip on the humerus at the location of the first landmark as defined in the Pre-Op planning. Ensure the Humeral Anchor and Stylus Trackers are visible in the field of view.

4.4.2. Humerus Registration Step 1: Landmarks - Point 2

Software

Figure 30: Signature Vision Application Humerus Registration Step - Landmarks Point 2



Voice Over

"Register the second landmark point."

Button List

Button Name	Voice Command	Description
Save Point 2	Save point two	Registers the position of the stylus tip and adds a visual to mark the 2nd landmark point.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to "Unlock UI" when activated.

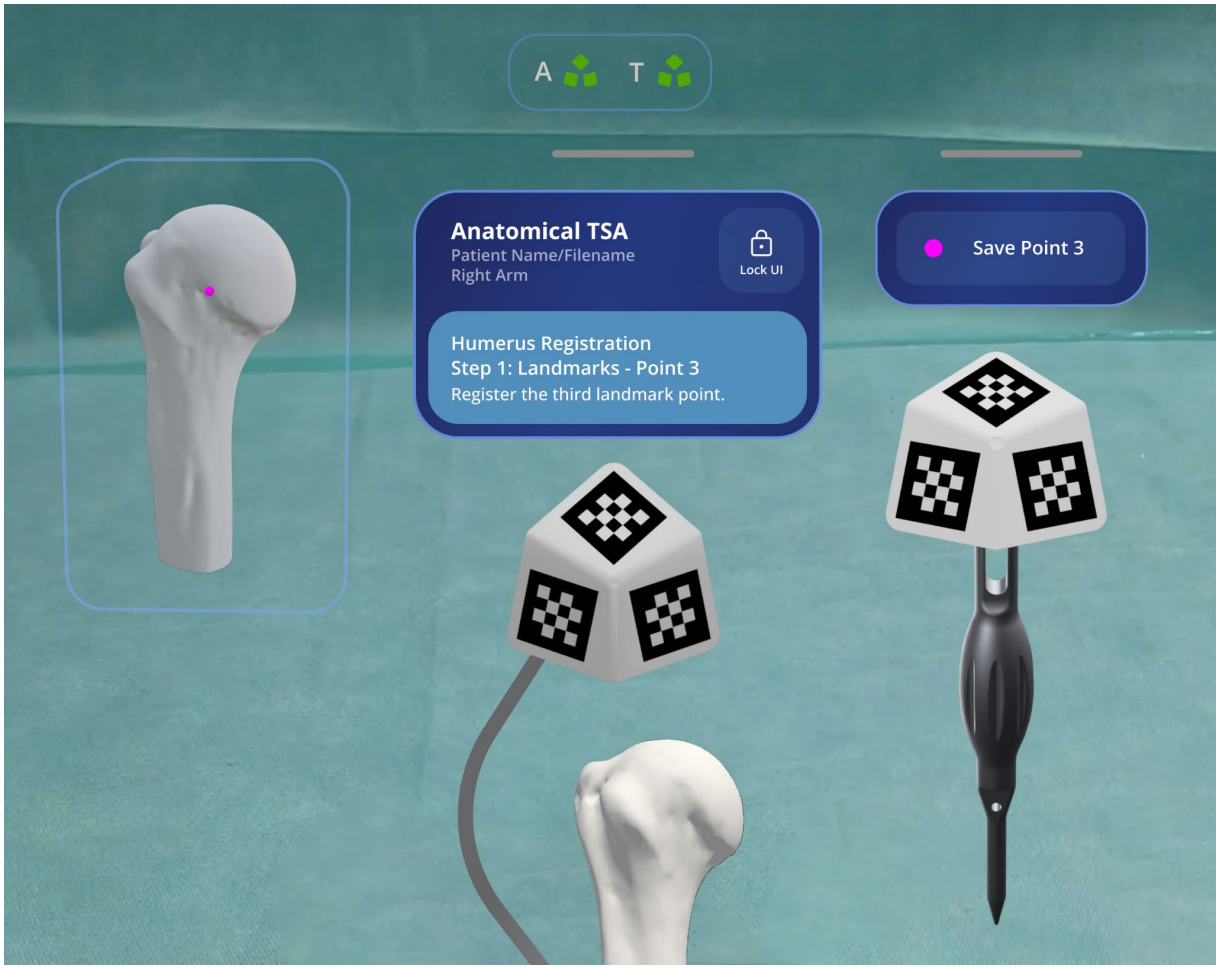
Hardware

Place the Stylus tip on the humerus at the location of the second landmark as defined in the Pre-Op planning. Ensure the Humeral Anchor and Stylus Trackers are visible in the field of view.

4.4.3. Humerus Registration Step 1: Landmarks - Point 3

Software

Figure 31: Signature Vision Application Humerus Registration Step - Landmarks Point 3



Voice Over

“Register the third landmark point.”

Button List

Button Name	Voice Command	Description
Save Point 3	Save point three	Registers the position of the stylus tip and adds a visual to mark the 3rd landmark point.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface

		elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

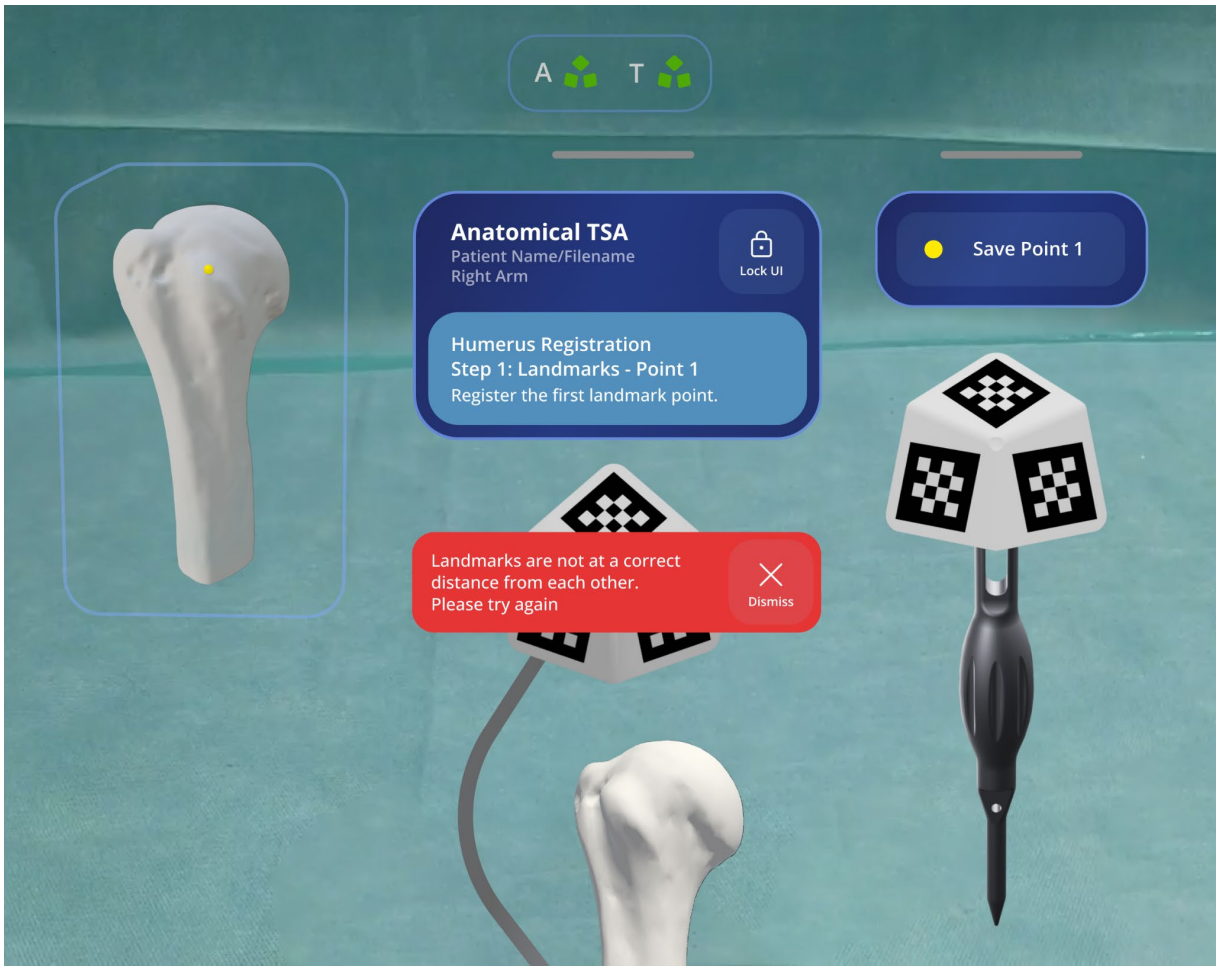
Hardware

Place the Stylus tip on the humerus at the location of the third landmark as defined in the Pre-Op planning. Ensure the Humeral Anchor and Stylus Trackers are visible in the field of view.

4.4.4. Landmarks Registration – Failed

Software

Figure 32: Signature Vision Application Humerus Registration Step - Landmark Registration Failed



Voice Over

“Landmarks are not at a correct distance from each other. Please try again. Register the first landmark point.”

Button List

Button Name	Voice Command	Description

Save Point 1	Save point one	Registers the position of the stylus tip and adds a visual to mark the 1st landmark point.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.
Dismiss	Dismiss	Hides the red warning panel.

Screen Description

If the landmarks have been registered wrongly or not precise enough, the user will be asked to repeat the process and register all 3 points again.

The red label will disappear automatically after registering the first point again (Figure 32).

Hardware

Repeat the registration process by placing the Stylus on the humerus at each landmark.

4.5. Humerus Registration Step 2: Sampling

Software

Figure 33: Signature Vision Application Humerus Registration Step - Sampling

Voice Over

"Step 2: Sampling. Scan the bone area as marked on the illustration."

Button List

Button Name	Voice Command	Description
Start Scan / Stop Scan	Start scan / Stop scan	Toggle button. Starts recording the points at the position of the stylus tip. When activated, the title will change to "Stop Scan" which then would stop recording of the points if activated.

Next Step	Next step	By default, this button is disabled. It only gets enabled if the required coverage has been reached.
Reject Scan	Reject scan	Deletes the registered sampling points. There's a confirmation dialog before doing so.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to "Unlock UI" when activated.

Screen Description

In this step, the user is asked to sample the bone surface as marked on the illustration.

The user must place the Stylus tip on the bone surface and start the scan by pressing the "Start Scan" button or using the corresponding voice command.

After starting the scanning process, the user should hear a sound cue, "Started collecting" and the "Start Scan" button changes to a "Stop Scan" button.

During the scan process, the system will register the points at the Stylus tip only if both the Humeral Anchor markers and Stylus markers are being successfully tracked. Registered points will show on the Virtual Bone model. Whenever the system successfully registers a point, a sound is played, and visual feedback is given to the user. There will be a circle showing and fading away around the Stylus tip. If tracking is lost, the Tracking panel will show which tool is not properly tracked (Anchor or Instrument / Stylus), and the visual and audio feedback will stop. Correct the Stylus orientation towards the camera to continue scanning (Figure 33).

A progress indicator informs the user if enough points have been collected.

During sampling, the user must not lift the Stylus tip from the bone surface as this risks registering points that are not on the bone surface. This might result in an inaccurate registration.

Once the user has sampled enough points, while still holding the Stylus on the bone, they can press the "Stop Scan" button or use the corresponding voice command. The scanned points will be saved. The user can start and stop scans multiple times. If the user would like to reject points (e.g. scanned points not on the bone), press the "Reject Scan" button or use the corresponding voice command to restart the scanning.

Once enough points have been successfully registered, the "Next Step" button is enabled and the user can activate it by pressing or using a voice command to go to the next step.

If sampling is not done precisely enough, the system will inform the user that the registration failed and to restart the sampling process. A dialog presented will be displayed (Figure 35, Section 4.6.1, Registration Failed Dialog).

If at any moment tracking is lost, a "Tracking Lost" information will be displayed. For details about the tracking see "10. General UI/UX Elements - Tracking Panel".

Recommendations for optimal sampling

Do’s	Don'ts
Hold your head still.	Avoid rotating your head and focus on the sampling area.
Sample slowly and steadily. The illustration shows the recommended sampling pace.	Don’t lift the pointer tip from the bone surface while sampling.
If you lose tracking while sampling, try to find a position in which it will work again.	Avoid sampling cartilage and tissues.
Make sure the pointer is always on the bone.	Avoid sampling only in one small spot.
Try to sample as broad an area as possible.	

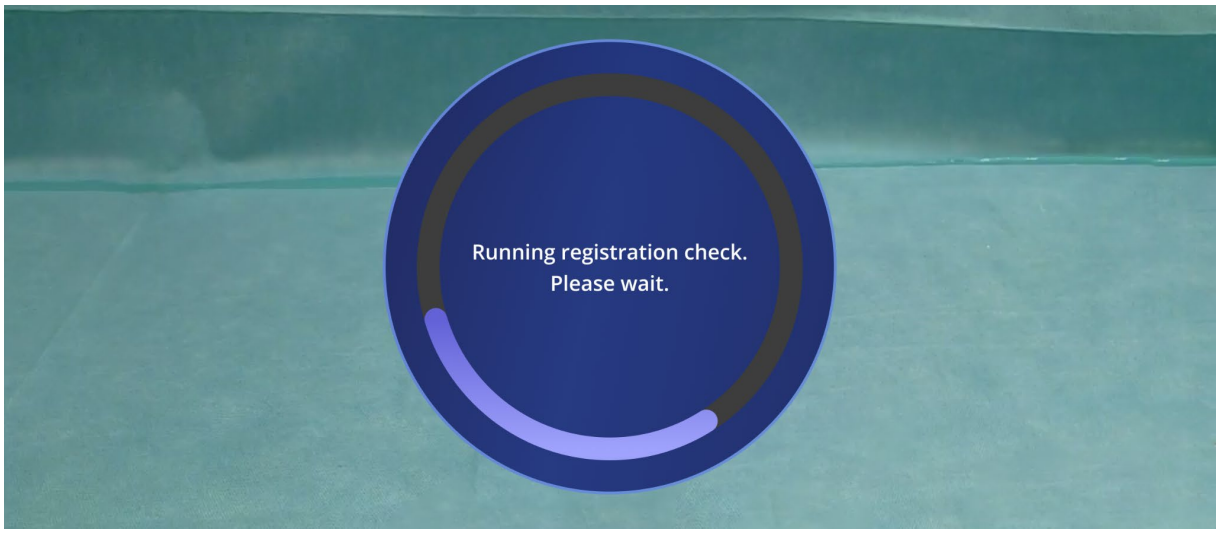
Hardware

Drag the Stylus tip over the humerus as shown in the Virtual Bone Model to sample the bone surface. Ensure the Stylus tip is in contact with the bone during sampling.

4.6. Registration Check

Software

Figure 34: Signature Vision Application Humerus Registration - Registration Check



Screen Description

After sampling, an additional check will be run. If the check is successful, the user will proceed to the validation. Otherwise, a “registration failed” dialog will be displayed and the user must restart the sampling process (Figure 34).

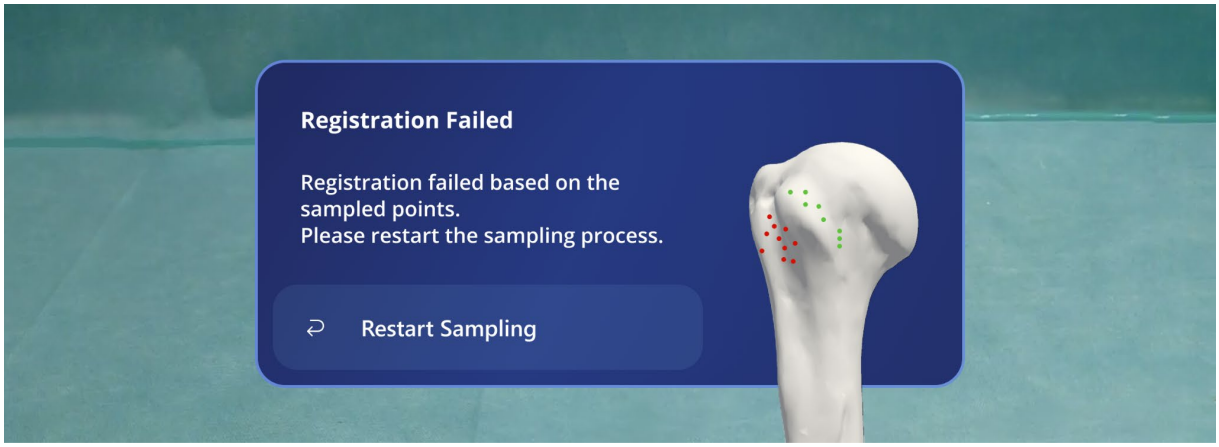
Hardware

None.

4.6.1. Registration Failed Dialog

Software

Figure 35: Signature Vision Application Humerus Registration Step - Registration Failed



Voice Over

“Registration failed based on the sampled points. Please restart the sampling process.”

Button List

Button Name	Voice Command	Description
Restart Sampling	Restart sampling	Restarts the sampling process.

Screen Description

The screen shows a visualization of the patient's humerus and registered points. The points considered “good” are marked green. The points considered “bad” are marked red (Figure 35).

The user is asked to restart the sampling process.

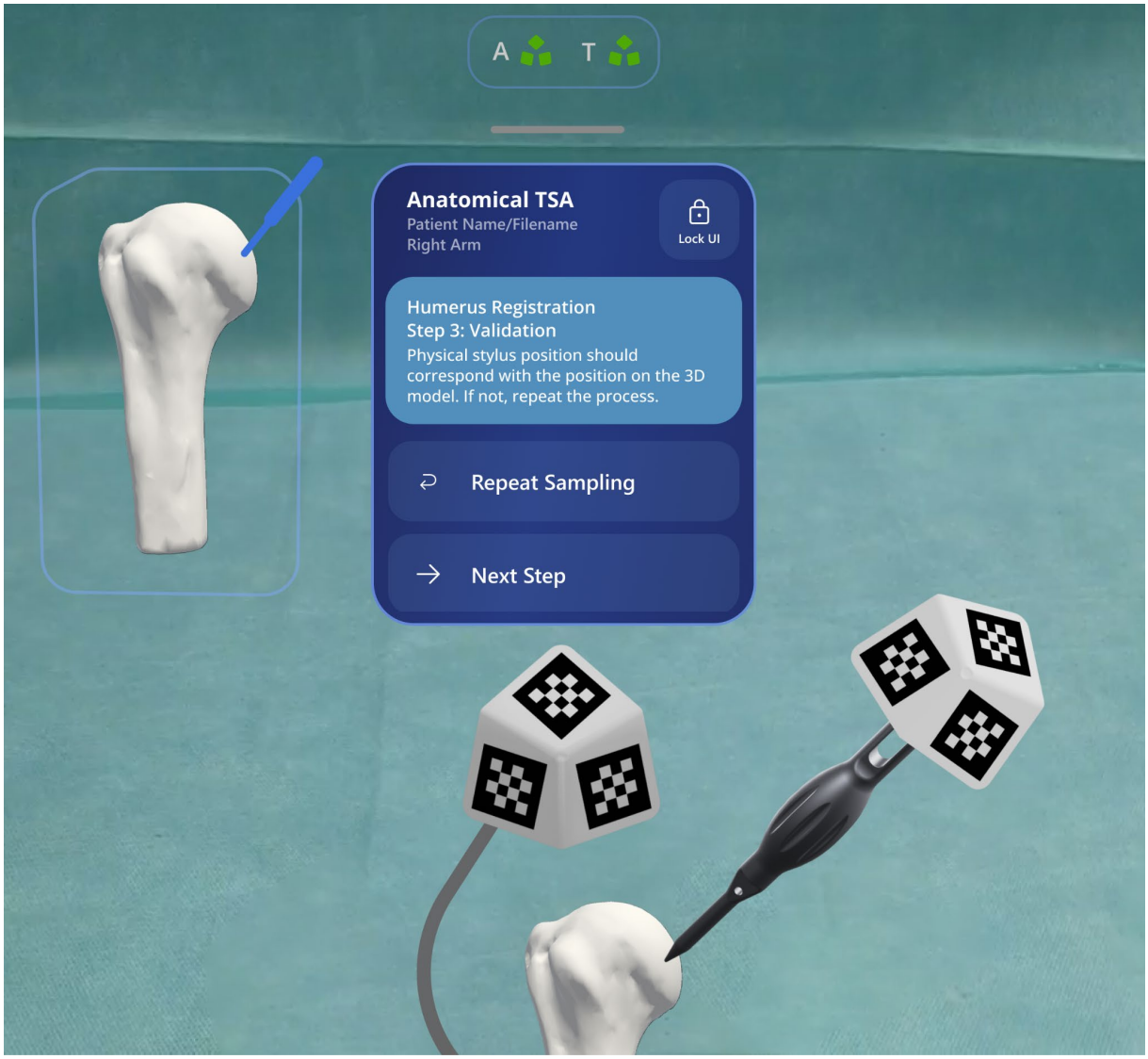
Hardware

None.

4.7. Humerus - Validation Step

Software

Figure 36: Signature Vision Application Humerus Registration Step - Humerus Validation Step



Voice Over

“Registration successfully completed. Step 3: Validation. Physical stylus position should correspond with the position on the 3D model. If not, repeat the process.”

Button List

Button Name	Voice Command	Description
Repeat Sampling	Repeat sampling	A warning dialog will be displayed. If it’s confirmed, then the app will be reset and will go back to the

		Sampling step. Discards current registration.
Next Step	Next step	Goes to the next step.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

In this step, the user is asked to confirm the correct registration of the anatomy. To do so, the user can check if the tracked Stylus tip corresponds to the visualization of the tip presented in the Virtual Bone Model.

The 3D model shows the patient’s humerus with registered points on it.

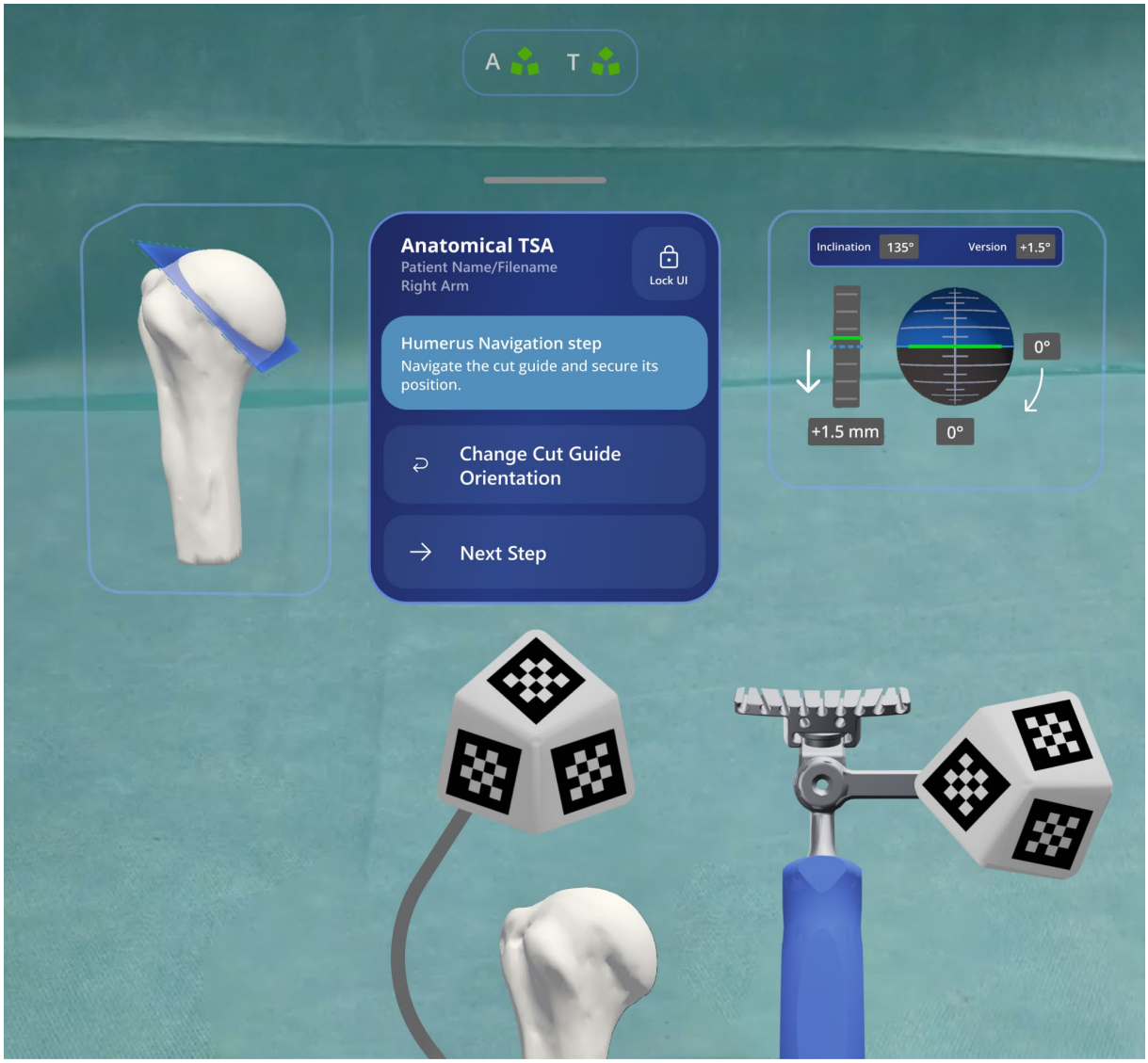
Hardware

Move the Stylus tip near the humerus to confirm that the tracked Stylus corresponds to the visualization of the tip in the Virtual Bone Model. If necessary, re-sample the humerus.

4.8. Humerus - Navigation Step

Software

Figure 37: Signature Vision Application Humerus Registration Step - Humerus Navigation Step



Voice Over

“Navigation step. Navigate the cut guide and secure its position.”

Button List

Button Name	Voice Command	Description
Next Step	Next step	Goes to the next step.
Change Cut Guide Orientation	Change cut guide orientation	A menu will be displayed where the user can choose a different orientation for the Cut Guide tool.

Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

In this step, the user is asked to navigate the Cut Guide to a planned position to perform a precise cut of the humeral head.

The system will track both the Humeral Anchor and the Adapter Handle with the Cut Guide tool and will show the visualization of the Cut Guide to the planned cut plane.

The visualization will be shown on the Virtual Bone Model. The Virtual Bone Model will show a blue plane that is the planned cut plane. It will also show a color-coded plane position which represents the position of the tracked Cut Guide.

The colors will change from red through yellow to green as the tracked cut plane will be close to the planned cut plane.

This step contains an additional UI element that will help with the precise navigation: The Navigation Sphere. It consists of:

1. A bar chart that shows the distance between the planned and tracked cut plane. The dashed blue line on the bar represents the planned cut plane. The color-coded solid line represents the tracked cut plane.

2. A sphere that shows the angles between the planned and tracked cut plane. The color-coded 3D element in front of the sphere represents the tracked cut plane while the blue disc inside of the sphere represents the planned cut plane. The label to the right of the sphere shows the roll angle in real-time. The label below the sphere shows the pitch angle.

3. The information about the version and inclination parameters of the tracked Cut Guide.

The white arrows show in which direction the user should move or rotate the Cut Guide to reach the planned position (Figure 37).

	Always consult the Navigation Sphere parameters for the cut guide navigation, never just the mesh context alone.

	Do not rely on suggested surgical navigation information if it is believed to be incorrect.

	If it is believed that using the system will significantly increase the duration of the surgical procedure, do not use it or discontinue its use.

Once the user finishes using the Cut Guide navigation, they can press “Next Step” or use the

corresponding voice command to go to the next step.

Hardware

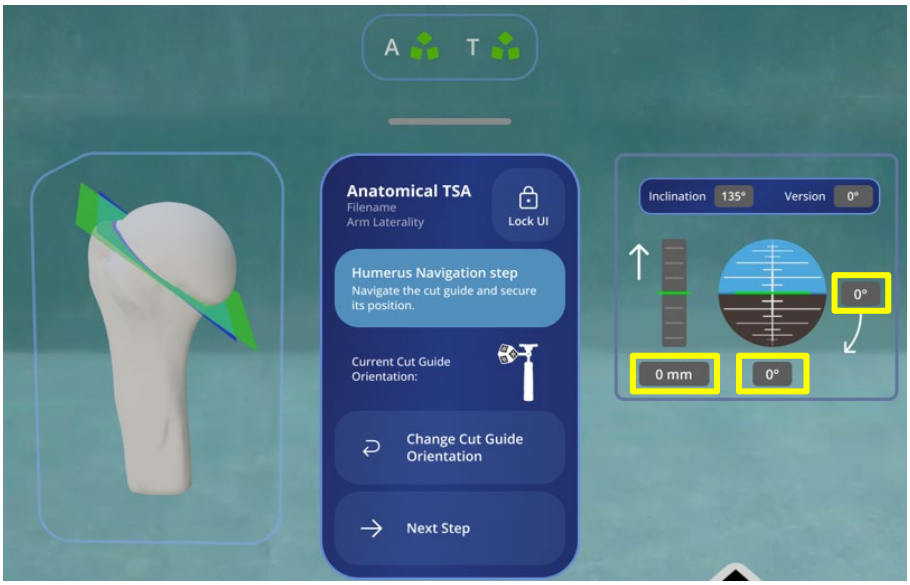
Align the Cut Guide with the angle shown in the Virtual Bone Model. Place the 70mm Identity Resection Pin, PN SBHS107000, through one of the diverging angled holes in the Cut Guide and into the humerus. Then, place the 100mm Identity Resection Pin, PN SBHS110000, through another diverging angled hole of Cut Guide and into the Humerus to secure the Cut Guide to the bone. Once the Cut Guide is secure, slide the Adapter Handle off of the Cut Guide; keep the Cut Guide in place.

After removing the Adapter Handle, a surgical tech or assistant can remove the HMD or adjust the HMD out of the field of view, if desired. The sterile field must be maintained.

Note: the pins are not part of or provided with the Signature Vision. Pins are part of or provided with the Zimmer Biomet Identity® Shoulder System.

	When navigating instruments, ensure alignment as closely as possible with the parameters indicated in the graphical user interface, aiming to minimize error to exactly 0 mm and 0 ° (see also highlighted values in Figure 38).

Figure 38: GUI Display of Accurate Humeral Resection Navigation



	Do not make any adjustments to navigated instrumentation after navigation has been performed, as this can compromise the accuracy and reliability of the system

Figure 39: Adapter Handle with the Cut Guide with the Humeral Anchor on the Humerus

⚠	Do not touch the HMD during surgery to avoid the risk of contamination.

4.9. Humerus – Optional Humeral Version Check

Software

None.

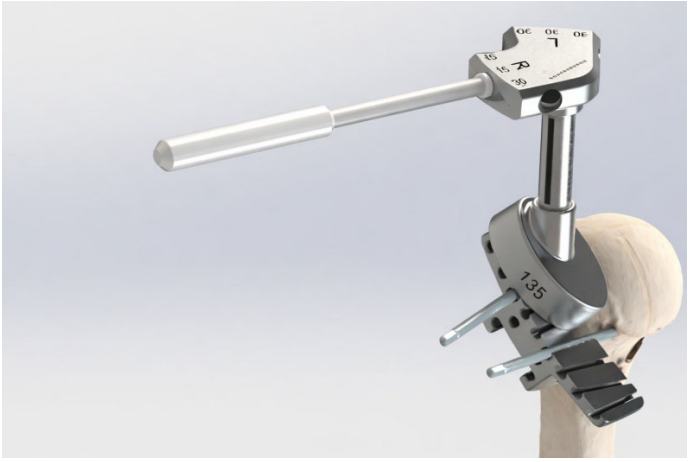
Hardware

The Humeral Gauge is an optional visual aid designed to assist in approximating the humeral version of the resection plane for a 135° inclination angle. Prior to humeral head resection, magnetically attach the Humeral Gauge to the superior surface of the pinned Cut Guide. The device is universal for left or right shoulders, with lateral prientation indicated by “L” (left) or “R” (right) markings on the top surface. Ensure the laser-marked longitudinal axis of the Humeral Gauge is vertically aligned with the anatomical axis of the humeral shaft.

For improved visualization, a threaded 30° version rod may be screwed into the central port. When using the version rod, flex the forearm to 90° and align the rod parallel to the forearm to confirm the desired version prior to resection. Adjustments can be made at the surgeon’s discretion before proceeding.

Remove the Humeral Gauge from the Cut Guide before performing the humeral head resection, taking care not to disturb the Cut Guide or fixation pins.

Figure 40: Humeral Gauge magnetically attached to the Cut Guide on a Right Humerus



⚠	The Humeral Gauge is to be used as a visual aid only.

4.10. Humerus – Resect Humeral Head

Software

None.

Hardware

Remove the Humeral Anchor from the humerus before proceeding with humeral resection. Use an oscillating saw to remove the humeral head. Remove the pins and Cut Guide when resection is complete.

❗	Ensure the oscillating saw remains flush with the surface of the Cut Guide and resection pins throughout the cut. After resection, the top of the resection pins must remain visible.

Note: The oscillating saw is not part of or provided with the Signature Vision.

⚠	During this section, position the retractors such that there is appropriate exposure of the proximal humerus and no interference with the instrumentation.

⚠	Ensure the Humerus remains stable during all steps of Humeral Resection.

5. Glenoid Preparation

5.1. Assemble Adapter Handle and Pin Inserter

Software

None.

Hardware

Attach the Pin Inserter to the Adapter Handle by screwing the components together (Figure 41). Ensure the tracker is facing the user and in the appropriate orientation for the laterality.

Figure 41: Assembling the Pin Inserter to the Adapter Handle

5.2. Glenoid – Remove Cartilage

Software

None.

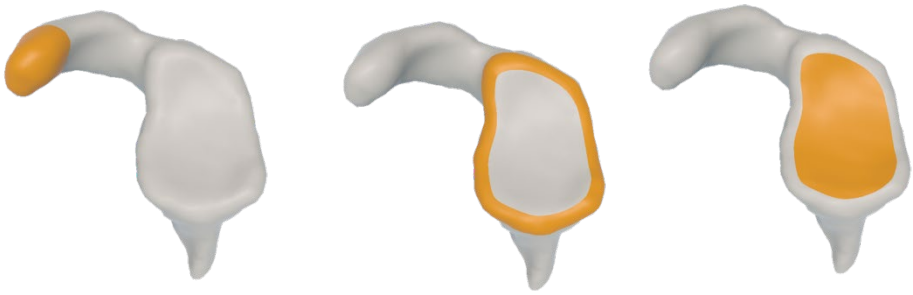
Hardware

Use a Scraper to thoroughly remove all cartilage and soft tissue from the surface of the bone. This step is critical to ensure unobstructed access to key anatomical landmarks of the Glenoid Fossa and Coracoid. Particular attention must be paid to completely removing all cartilage and soft tissue form the rim of the Glenoid Fossa, as even residual material can compromise registration accuracy. The objective is to remove anything that is not visible on a CT scan, complete removal of non-bony material is essential for accurate registration. Do not remove osteophytes and other bony structures, as they are visible on the CT scan and essential for accurate registration.

	Complete removal of all cartilage and soft tissue from the prepared bone surface is imperative, as even minimal residual material can compromise registration accuracy

The following image depicts the area where the tip of the Stylus needs to reach the bone surface.

Figure 42: Sampling area on the Scapula



Note: The Scraper is not part of or provided with the Signature Vision. The scraper is part of or provided with the Zimmer Biomet Alliance® Glenoid or Comprehensive® Reverse Shoulder system.

⚠	Exposed glenoid and humerus bones must be cleaned of any soft tissue before performing registration.

5.3. Attach the Scapular Anchor

Software

None.

Hardware

Attach the appropriate Scapula Reference for the laterality (left/right) to the scapula by drilling 2 (two) of the 2.5mm threaded pins (100 mm length) into the Scapula Reference to the depth marker.

⚠	Take care to not drill the anchor pins too deeply when affixing the Scapular Anchor.

Attach the Scapula Reference Rod to the Scapula Reference by sliding the rod under the set screw in the center of the Scapular Anchor. Tighten the center screw with the Hex Head Driver to secure the anchor. Loosen the knob by hand to adjust the location of the tracker. Ensure the tracker is visible to the user. Adjust the Scapula Reference Rod and the tracker rod further during the Glenoid – Anchor Placement step (Section 6.2).

Figure 43: Securing the Scapula Clamp to the Scapula

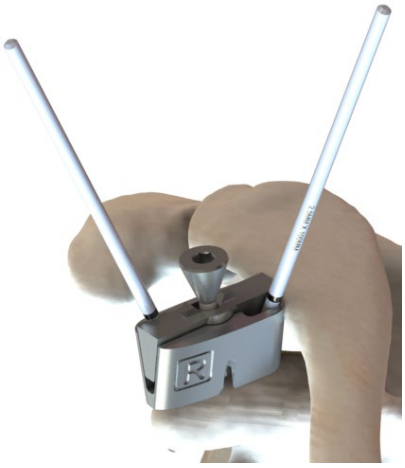
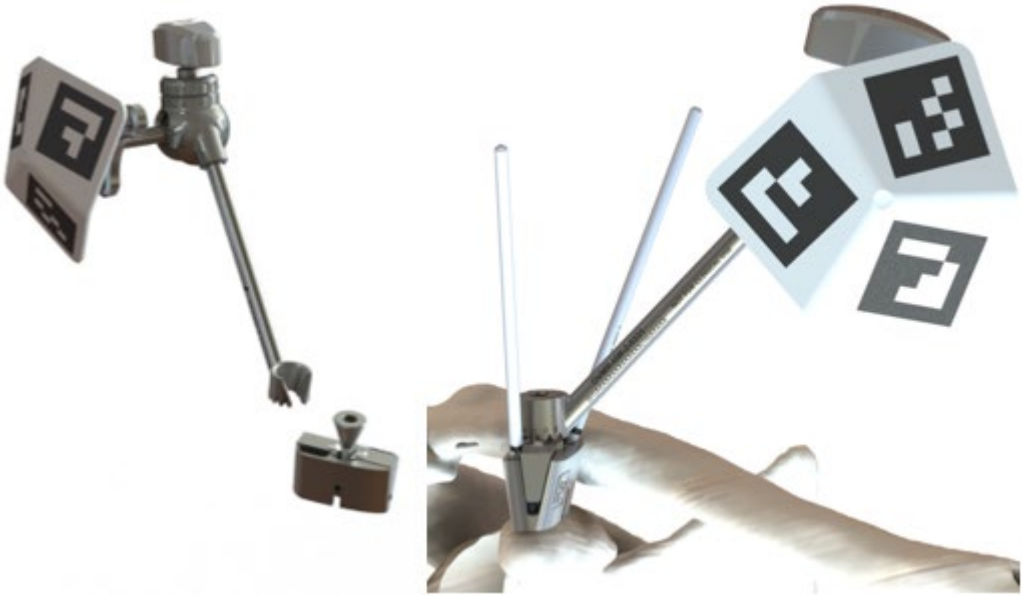


Figure 44: Attaching the Scapula Anchor to Scapula Clamp

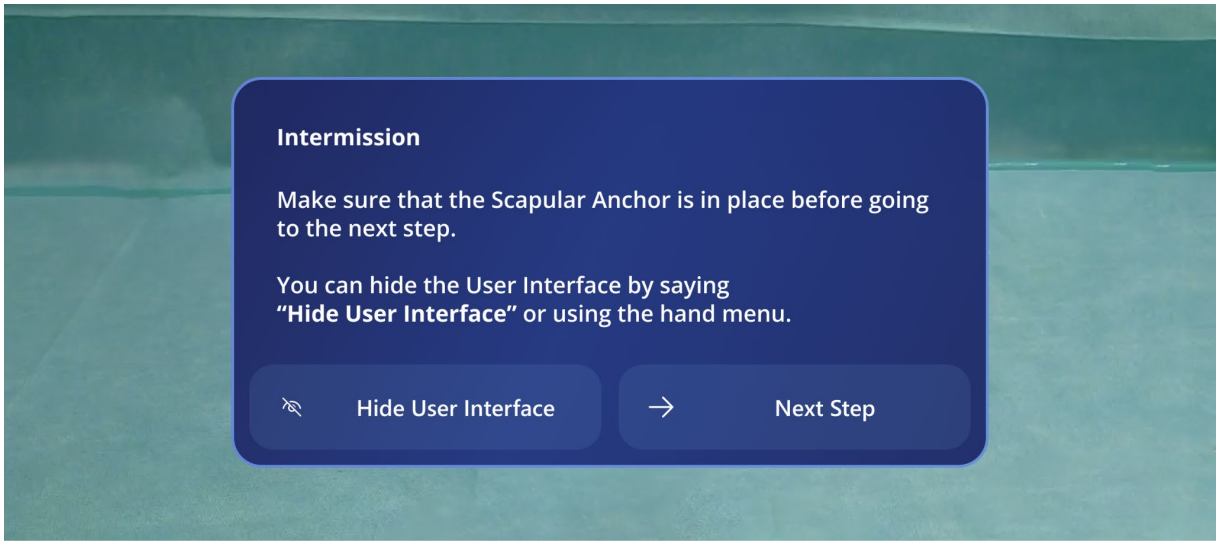


⚠	Do not cover or touch the OptiVu Trackers once they are affixed to the humerus or coracoid.

5.4. Intermission Screen

Software

Figure 45: Signature Vision Application Intermission Screen



Voice Over

"Make sure that the Scapular Anchor is in place before going to the next step. You can hide the User Interface by saying "Hide User Interface" or using the hand menu."

Button List

Button Name	Voice Command	Description
Next Step	Next step	Goes to the next step.
Hide User Interface	Hide user interface	Hides the user interface.

Screen Description

This dialog is displayed before the user can proceed to the Glenoid part of the application (Figure 45). The user should confirm that the Scapular Anchor is correctly attached before going to the next step.

The user can press the "Next Step" button or use the corresponding voice command to proceed to the next step.

If the user hides the User Interface, they can reenable it by using the "Show User Interface" voice command or by using the "Show UI" button in the Hand Menu.

Hardware

A surgical tech or assistant can put the HMD on the user or adjust the HMD into the field of view. The sterile field shall be maintained.

⚠	Do not touch the HMD during surgery to avoid the risk of contamination.

6. Glenoid Central Pin

6.1. Tool Verification Screens

Software

Figure 46: Signature Vision Application Tool Verification Screen

Screen Description

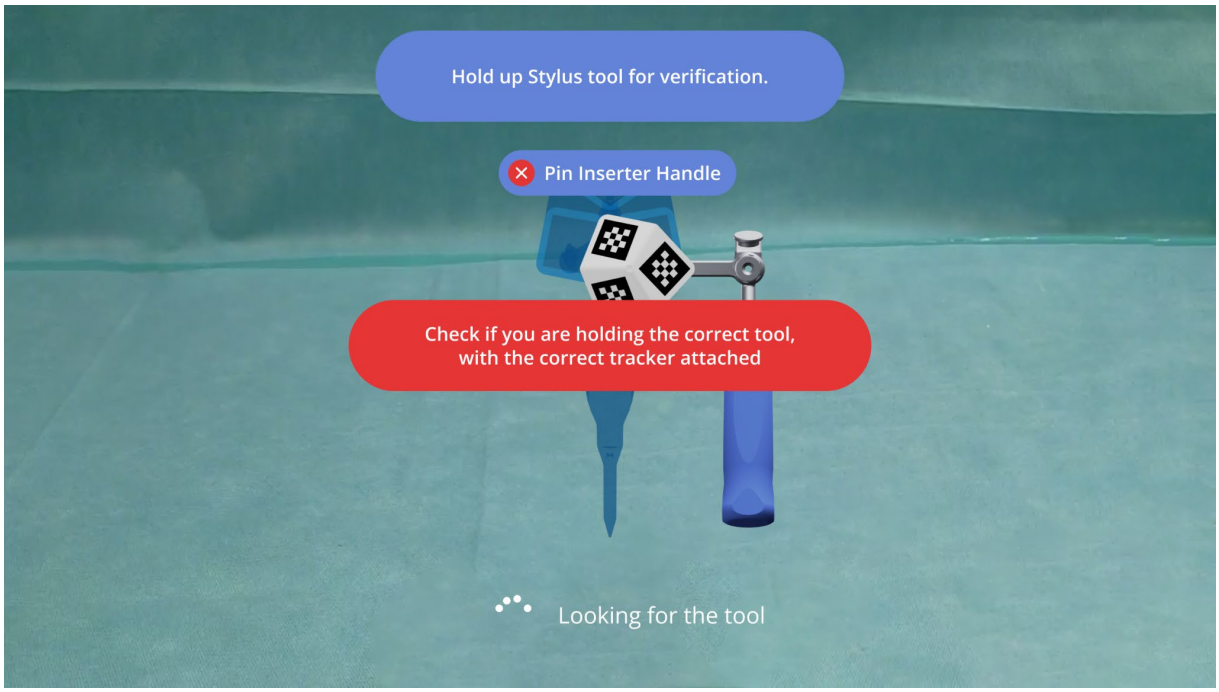
The user must show the different tools in front of the OptiVu Tilt with HoloLens 2 PV (Photo Video) camera. The user should direct the marker attached to the tool so it is visible to the PV camera. The tool and tracker should overlap with the presented hologram.

Other tools present in the field of view of the camera will also be recognized.

The user should make sure that the ambient lighting recommendations are met when trying to register or use the tools with the OptiVu Tilt with HoloLens 2 device. The software should automatically recognize the shown marker and proceed to the next step.

If the user holds a wrong tracker in front of the camera, a warning label will be displayed:

Figure 47: Signature Vision Application Tool Verification Error Screen



	Always check if the tracker is properly attached to the tool and if it's not damaged.

Hardware

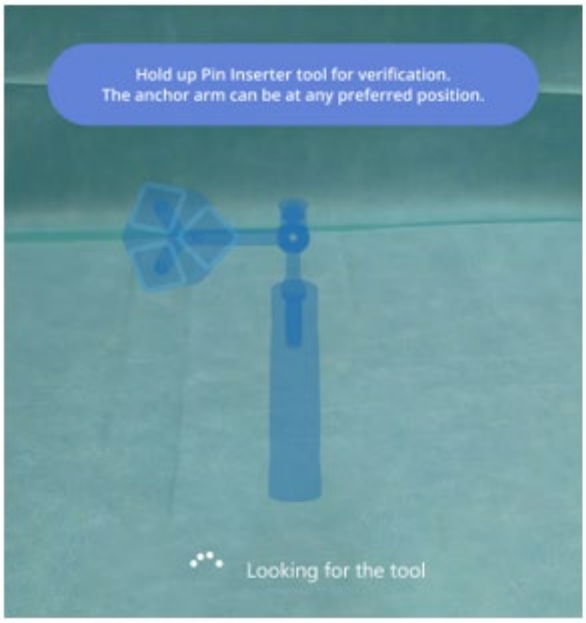
Ensure the instruments are properly assembled for tool verification.

6.1.1. Tool Verification - Pin Inserter

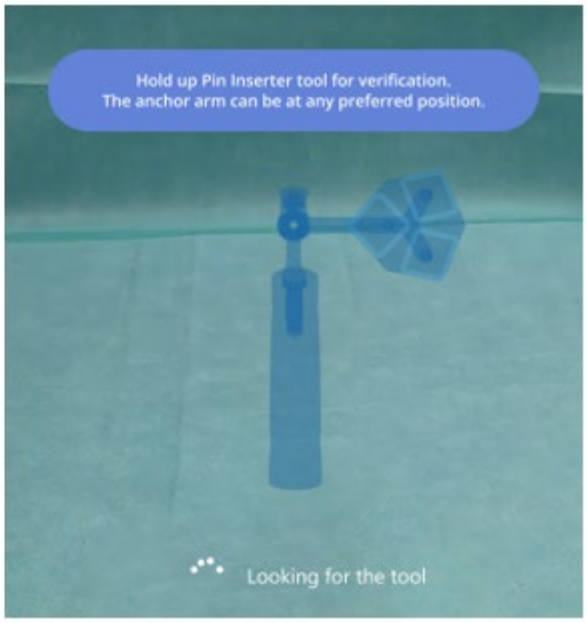
Software

Figure 48: Signature Vision Application Tool Verification - Pin Inserter

Variant - Left



Variant - Right



Voice Over

"Hold up Pin Inserter tool for verification. The anchor arm can be at any preferred position."

Screen Description

Based on the choice of the Cut Guide orientation this screen will present the hologram with similar orientation. The Signature Vision software accepts any position of the Pin Inserter arm.

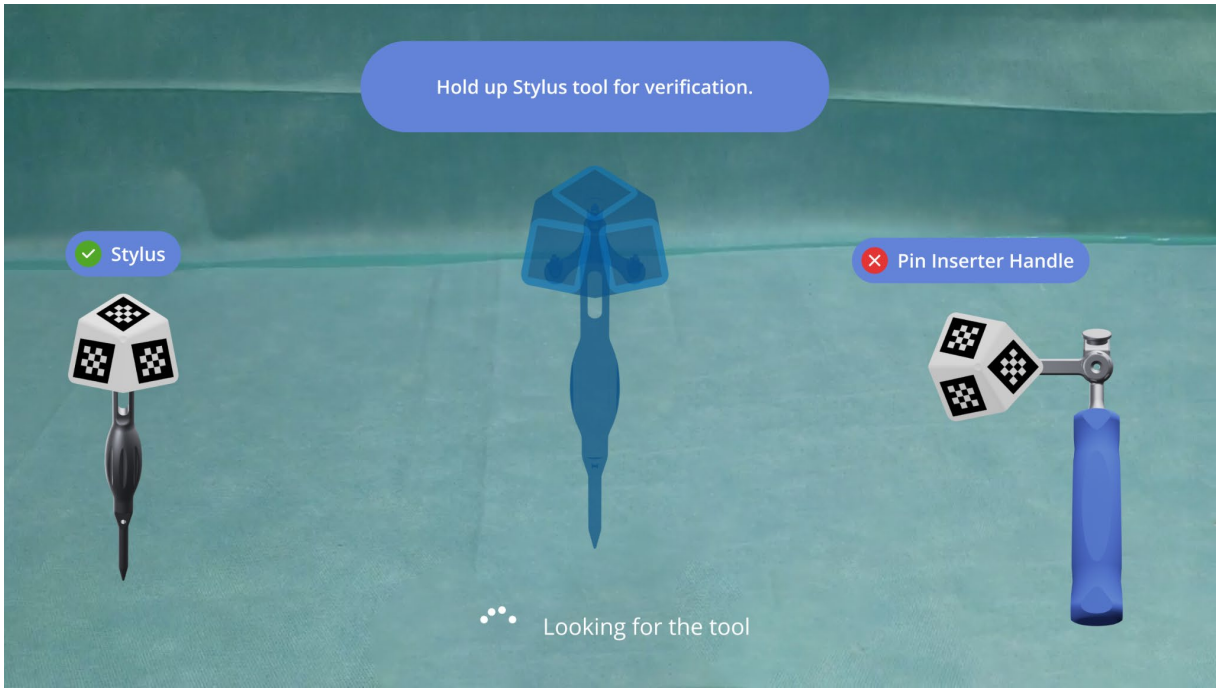
Hardware

Ensure the tracker is facing the user and within the field of view.

6.1.2. Tool Verification - Stylus

Software

Figure 49: Signature Vision Application Tool Verification - Stylus



Voice Over

“Hold up Stylus tool for verification.”

Hardware

Ensure the tracker is facing the user and within the field of view.

	Always check if the tracker is properly attached to the tool and if it’s not damaged.

6.1.3. Tool Verification - Scapular Anchor

Software

Figure 50: Signature Vision Tool Verification - Scapular Anchor

Voice Over

“Look at the Scapular Anchor for verification.”

Hardware

Ensure the tracker is facing the user and within the field of view.

Once the Scapular Anchor is registered, do not touch or reposition the Scapular Anchor. The Scapular Anchor is a static reference point that the software uses to oversee the surgical steps.

	Always check if the tracker is properly attached to the tool and if it’s not damaged.

6.2. Glenoid - Anchor Placement

Software

Figure 51: Signature Vision Glenoid - Anchor Placement

Voice Over

“Tools & Tracking check. Check the tracking of the anchor and the tools. Focus specifically that you can track well the anchor and the Pin Inserter at the glenoid.”

Button List

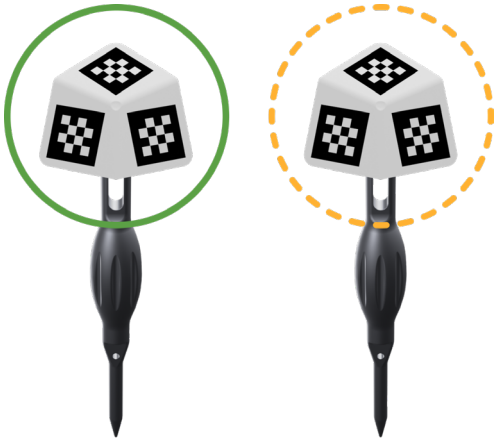
Button Name	Voice Command	Description
Next Step	Next step	Go to the next screen.
Pin Inserter	Pin inserter	Set Pin Inserter as an actively tracked tool.

Stylus	Stylus	Set Stylus as an actively tracked tool.
Reaming Guide	Reaming guide	Set the Reaming Guide as an actively tracked tool.
Clocking Guide	Clocking guide	Set the Clocking Guide as an actively tracked tool.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

This step is used to check if both the anchor and the tools can be correctly tracked in the chosen setup. The user should check that the tools are not colliding with each other. The user can choose which tool should be tracked (Stylus, Pin Inserter, Reaming Guide or Clocking Guide). The anchor is always tracked by the system.

Figure 52: Visual Display of the OptiVu Tracker angle greater than 30 degrees



The color-coded circles around the trackers provide additional information about the tracking. If the camera is looking at the tracker at an angle greater than 30 deg then it will turn dashed orange (Figure 52). The circle will turn solid and green when the tracker is oriented towards the camera.

This step has 3 UI Elements.

1. **The Context Panel** - A UI Panel spawned above the Scapular Anchor which informs in which step the user currently is in and what they have to do. It contains a “Lock UI” button. The user can reposition the panel by grabbing the grabbable indicator (a horizontal line above the blue backplate).

2. **The Side Menu** - A UI Panel with additional options. The user can reposition the panel by grabbing the grabbable indicator (a horizontal line above the blue backplate). In this step, the user can choose which tool should be tracked by the system in

addition to the anchor that's being tracked all the time.

3. **Tracking Panel** - shows the current status of the anchor and stylus tracking. See details in chapter "10.2.4 Tracking Panel".

Recommendations for optimal tracking

Do's	Don'ts
Make sure that the trackers always point at the HoloLens 2 Camera located above the visor.	Don't cover the trackers with your hand or other tools.
Make sure the room and your workplace are well-lit (between 1000 - 2000 lux).	Avoid operating room light beams pointing directly to the trackers.
Use as much diffuse light as possible.	Don't bend or damage the trackers.
Always check if trackers are correctly attached to the tools.	
Make sure the trackers are clean.	

Hardware

Hold the tool (Stylus, Pin Inserter, Reaming Guide, Clocking Guide) within the field of view. Ensure the tracker is facing the HMD camera and within the field of view. If either instrument is incorrectly tracked, return to the verification step.

After verifying the tools, adjust the Scapular Anchor rod and tracker as needed, per user preference, ensuring the rod and tracker will not collide with the Stylus, Adapter Handle, Pin Inserter, Reaming Guide, Clocking Guide, or trackers during glenoid/coracoid registration or positioning of the Pin Inserter, Reaming Guide, or Clocking Guide. The tracker arm of the Adapter Handle may be adjusted as needed to ensure it will not collide with the Scapular Anchor rod or tracker. Ensure all trackers are facing the user and within the field of view. The trackers should be relatively parallel with each other for best tracking performance.

	Do not cover or touch the OptiVu Trackers once they are affixed to the humerus or coracoid.

6.3. Glenoid Registration

In this step, the user is asked to register 3 marked landmark points using the Stylus tool.

The user will be asked to save points one after the other. After saving the third point, the software checks if the registered landmarks are at the correct distance from each other. If that's not the case, a voice-over is played: "Landmarks are not at a correct distance from each other. Please save the landmarks very precisely."

The user should improve the position of the registered points by setting them again. When the checked distances are correct, the user will be allowed to continue to the next step.

6.3.1. Glenoid Registration Step 1: Landmarks - Point 1

Software

Figure 53: Signature Vision Application Glenoid Registration Step - Landmarks Point 1

Voice Over

“Glenoid Registration Step 1: Landmarks. Point 1. Register the first landmark point.”

Button List

Button Name	Voice Command	Description
Save point 1	Save point one	Registers the position of the Stylus tip and adds a visual to mark the 1st landmark point.

Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

In this step, the user is asked to register the marked landmark points using the Stylus tool.

This step has 4 UI Elements.

1. **The Context Panel** - A UI Panel spawned above the Scapular Anchor which informs in which step the user currently is in and what they have to do. It contains a “Lock UI” button. The user can reposition the panel by grabbing the grabbable indicator (a horizontal line above the blue backplate).

2. **Virtual Bone Model** - A 3D model in a bounding box. In this step, a 3D model of the patient's bone with marked landmark points is shown. The user can reposition, rotate, and scale the 3D model by grabbing the bounding box.

3. **The Side Menu** - A UI Panel with the “Save Point 1” button. The user can reposition the panel by grabbing the grabbable indicator (a horizontal line above the blue backplate).

4. **Tracking Panel** - shows the current status of the anchor and stylus tracking. See details in chapter “10.2.4 Tracking Panel”.

The user must place the Stylus tip on the anatomy at the position of the landmark point. When the Stylus tip is in the correct position, the user should press the corresponding “Save Point 1” button or use the corresponding voice command to register the selected landmark.

The “Save Point 1” button and its voice commands are disabled when the tracking of the tools is lost.

Recommendations for optimal sampling

Do’s	Don'ts
Hold your head still.	Avoid rotating your head and focus on the sampling area.
Sample slowly and steadily. The illustration shows the recommended sampling pace.	Don’t lift the pointer tip from the bone surface while sampling.
If you lose tracking while sampling, try to find a position in which it will work again.	Avoid sampling cartilage and tissues.
Make sure the pointer is always on the bone.	Avoid sampling only in one small spot.
Try to sample as broad an area as possible.	

Hardware

Place the Stylus tip on the glenoid at the location of the first landmark as defined in the Pre-Op planning. Ensure the Scapular Anchor and Stylus Trackers are visible in the field of view.

6.3.2. Glenoid Registration Step 1: Landmarks - Point 2

Software

Figure 54: Signature Vision Application Glenoid Registration Step - Landmarks Point 2

Voice Over

“Register the second landmark point.”

Button List

Button Name	Voice Command	Description
Save Point 2	Save point two	Registers the position of the stylus tip and adds a visual to mark the 2nd landmark point.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a

		toggle button which changes to “Unlock UI” when activated.

Hardware

Place the Stylus tip on the glenoid at the location of the second landmark as defined in the Pre-Op planning. Ensure the Scapular Anchor and Stylus Trackers are visible in the field of view.

6.3.3. Glenoid Registration Step 1: Landmarks - Point 3

Software

Figure 55: Signature Vision Application Glenoid Registration Step - Landmarks Point 3

Voice Over

“Register the third landmark point.”

Button List

Button Name	Voice Command	Description
Save Point 3	Save point three	Registers the position of the stylus tip and adds a visual to mark the 3rd landmark point.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

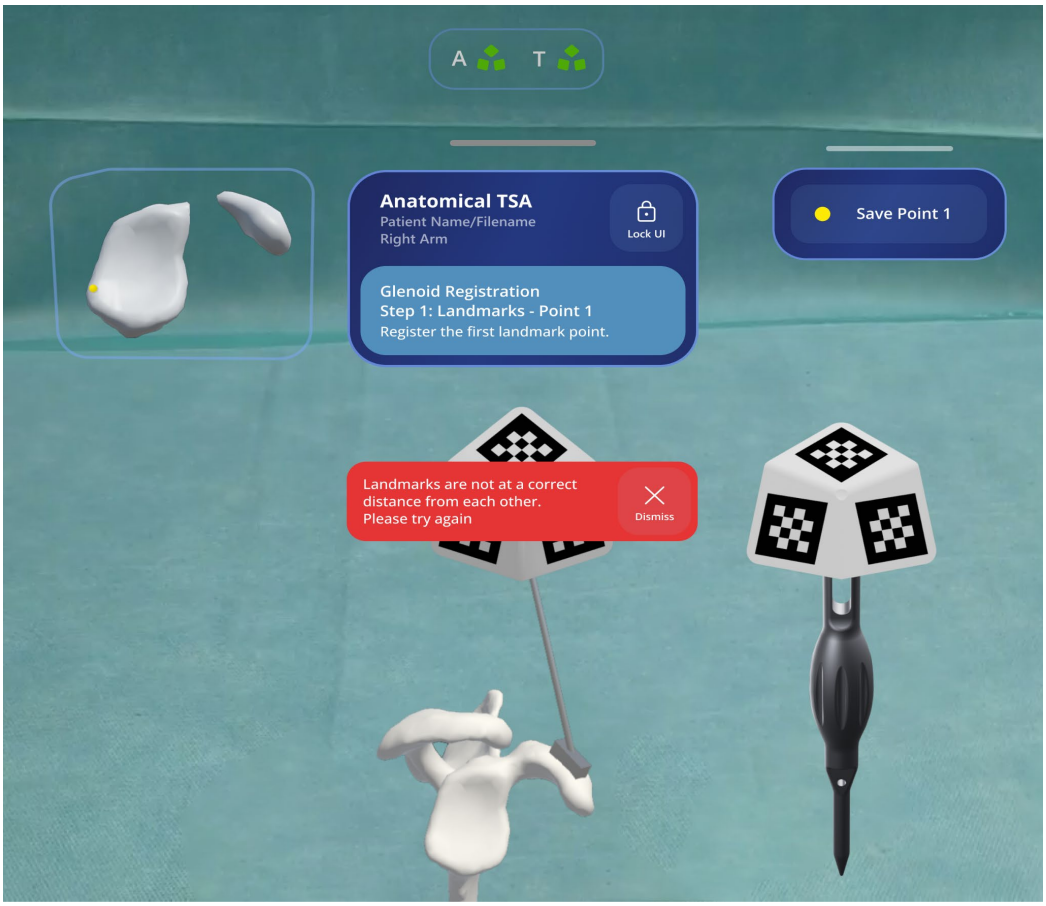
Hardware

Place the Stylus tip on the glenoid at the location of the third landmark as defined in the Pre-Op planning. Ensure the Scapular Anchor and Stylus Trackers are visible in the field of view.

6.3.4. Landmarks Registration – Failed

Software

Figure 56: Signature Vision Application Registration Step - Landmark Registration Failed



Voice Over

“Landmarks are not at a correct distance from each other. Please try again. Register the first landmark point.”

Button List

Button Name	Voice Command	Description
Save Point 1	Save point one	Registers the position of the stylus tip and adds a visual to mark the 1st landmark point.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.
Dismiss	Dismiss	Hides the red warning panel.

Screen Description

If the landmarks have been registered wrongly or not precise enough, the user will be asked to repeat the process and register all 3 points again.

The red label will disappear automatically after registering the first point.

Hardware

Repeat the registration process as needed by placing the Stylus on the glenoid at each landmark.

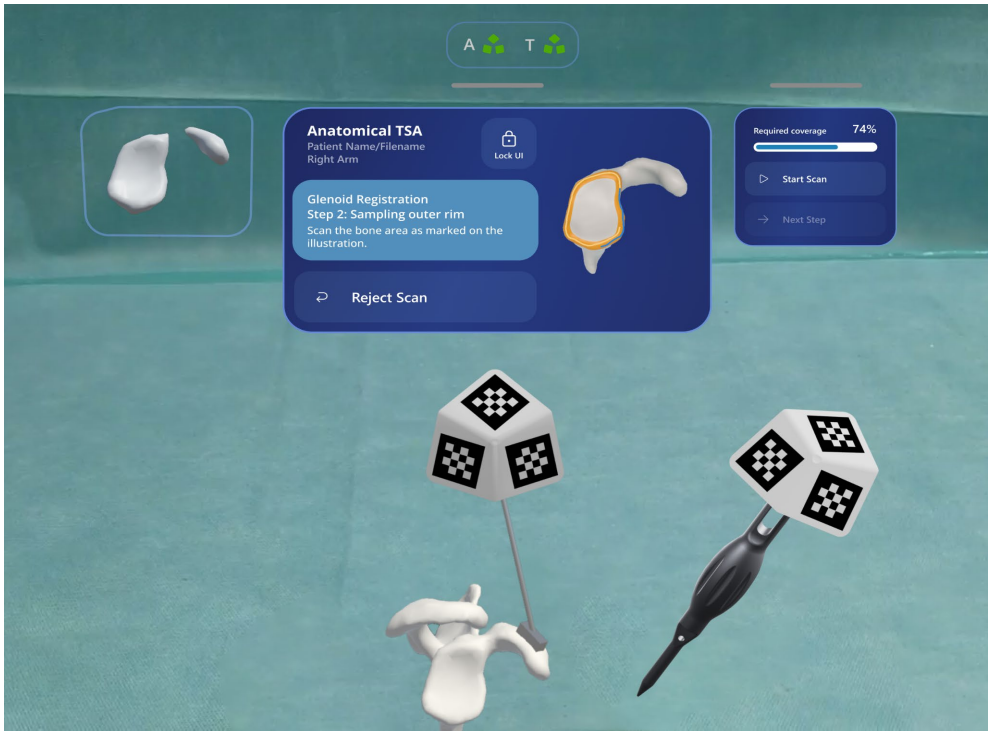
6.4. Glenoid Registration

In this step, the user is asked to sample the bone surface as marked on the Virtual Bone Model.

6.4.1. Glenoid Registration Step 2: Sampling Outer Rim

Software

Figure 57: Signature Vision Application Glenoid Registration - Sampling Outer Rim



Voice Over

“Step 2: Sampling. Outer rim. Scan the bone area as marked on the illustration.”

Button List

Button Name	Voice Command	Description
Start Scan / Stop Scan	Start scan / Stop scan	Toggle button. Starts recording the points at the position of the Stylus tip. When activated, the title will change to “Stop Scan” which then would stop recording of the points if activated.
Next Step	Next step	By default, this button is disabled. It only gets enabled if required coverage has been reached.
Reject Scan	Reject scan	Deletes the registered sampling points. There’s a confirmation dialog before doing so.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

In this step, the user is asked to sample the bone surface as marked on the Virtual Bone

Model.

The user must place the Stylus tip on the bone surface and then start the scan by pressing the “Start Scan” button or using the corresponding voice command.

After starting the scanning process, the user should hear a sound cue, “Started collecting” and the “Start Scan” button changes to a “Stop Scan” button.

During the scan process, the system will register the points at the Stylus tip only if both the Scapular Anchor markers and tool markers are successfully tracked. Registered points will show on the Virtual Bone model. Whenever the system successfully registers a point, there will be sound and visual feedback for the user. There will be a circle showing and fading away around the Stylus tip.

A progress indicator informs the user if enough points have been collected.

During the sampling, the user must not lift the Stylus tip from the bone surface as this risks registering points that are not on the bone surface. This might result in an inaccurate registration.

Once the user has sampled enough points, they can press the “Stop Scan” button or use the corresponding voice command to do so. The scanned points will be saved. The user can start and stop scans multiple times. If the user would like to reject points registered from the last scan, they can press the “Reject Scan” button or use the corresponding voice command.

Once enough points have been successfully registered, the “Next Step” Button will be enabled and the user can activate it by pressing or using a voice command to go to the next step.

	Exposed glenoid and humerus bones must be cleaned of any soft tissue before performing registration.

If at any moment tracking is lost, a “Tracking Lost” information will be displayed. For details about the tracking see “10.2.4 Tracking Panel”.

Hardware

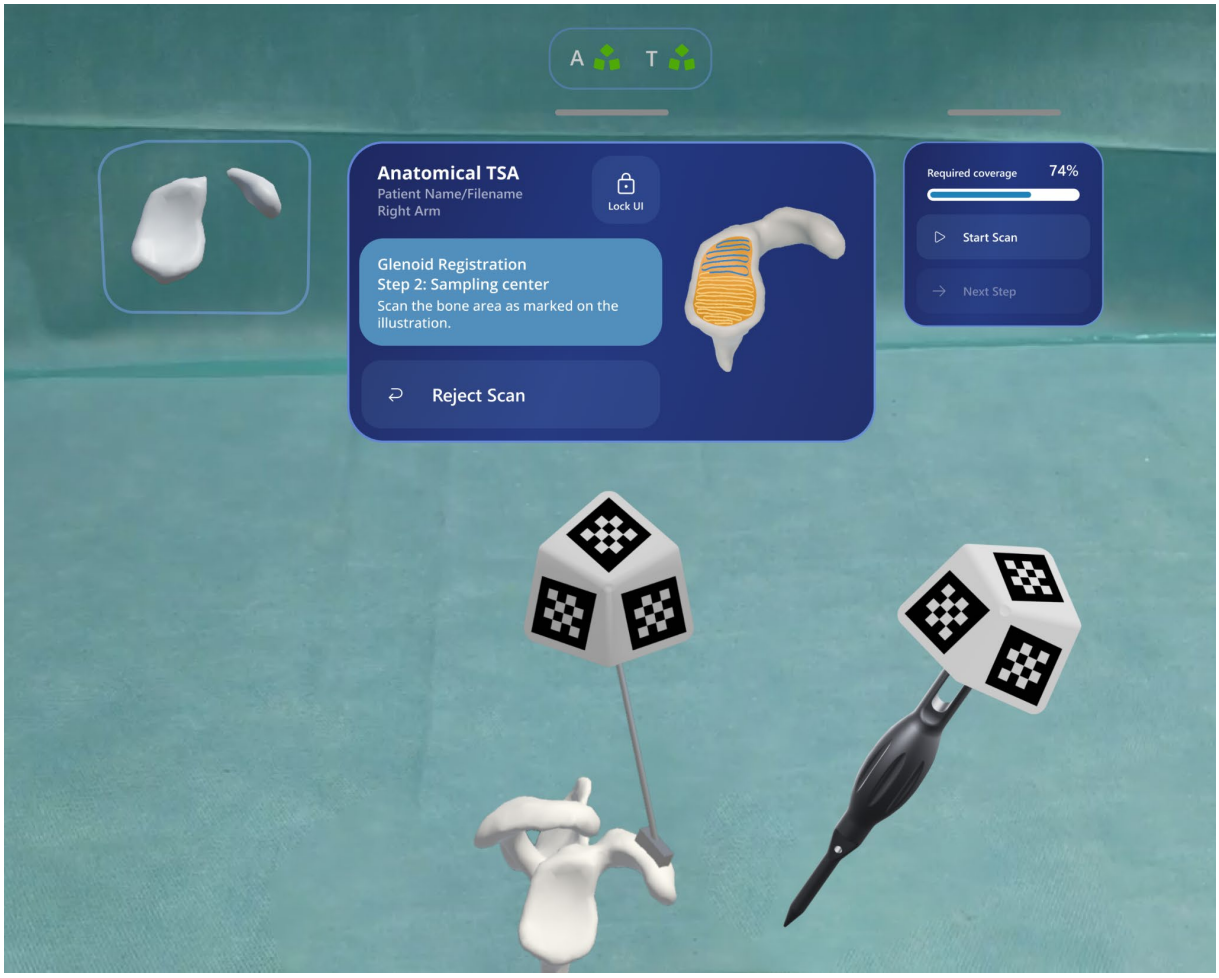
Drag the Stylus tip over the glenoid as shown in the Virtual Bone Model to sample the bone surface. Ensure the Stylus tip is in contact with the bone during sampling.

	Be sure to adequately sample the full glenoid rim as this anatomical landmark is imperative for accurate registration

6.4.2. Glenoid Registration Step 2: Sampling Center

Software

Figure 58: Signature Vision Application Glenoid Registration - Sampling Center



Voice Over

"Points saved. Sampling center. Scan the bone area as marked on the illustration."

Button List

Button Name	Voice Command	Description
Start Scan / Stop Scan	Start scan / Stop scan	Toggle button. Starts recording the points at the position of the Stylus tip. When activated, the title will change to "Stop Scan" which then would stop recording of the points if activated.
Next Step	Next step	By default, this button is disabled. It only gets enabled if required coverage has been reached.
Reject Scan	Reject scan	Deletes the registered sampling points. There's a confirmation dialog before doing so.

Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

Sampling glenoid is divided into 3 steps. This is the second step.

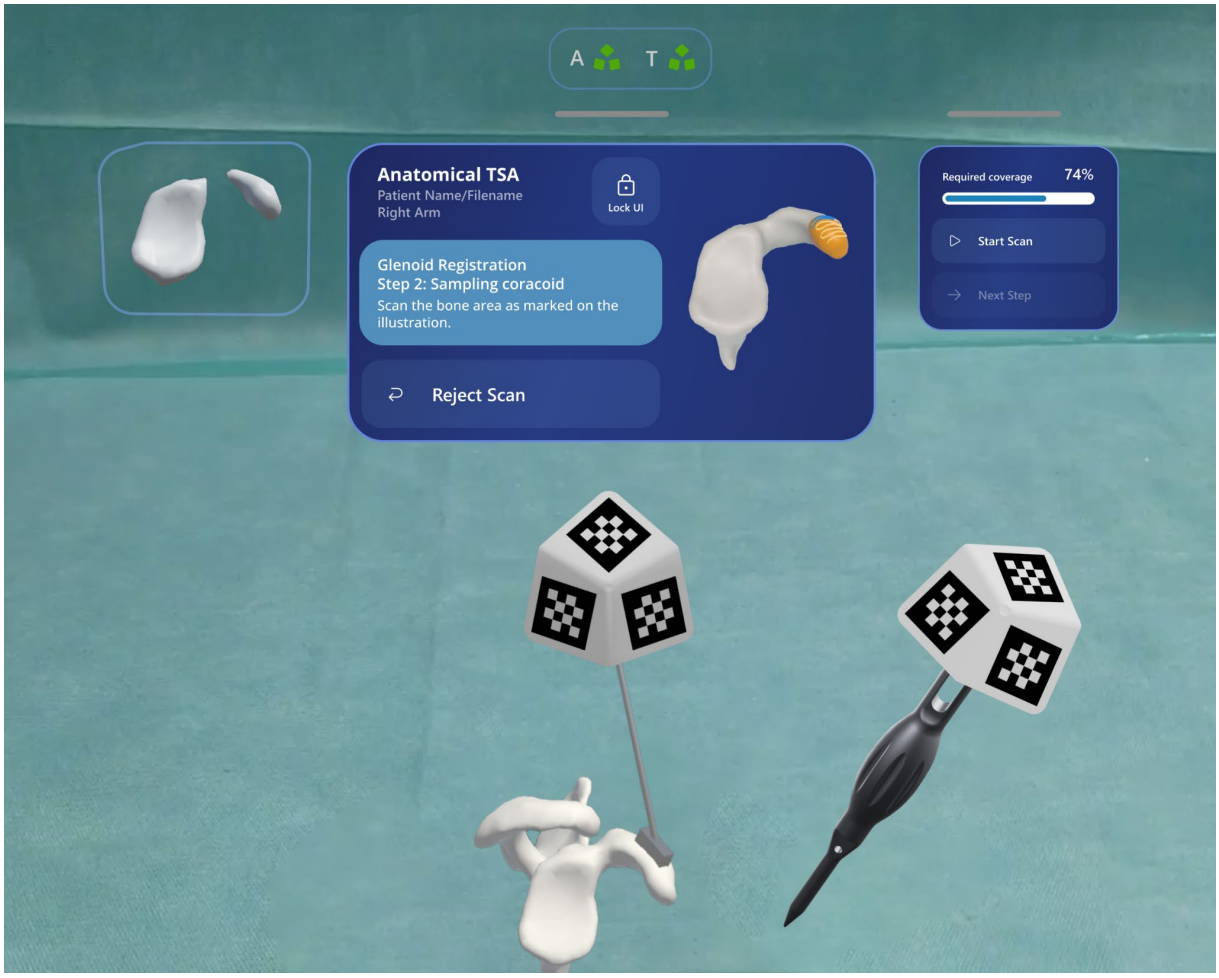
Hardware

Drag the Stylus tip over the glenoid as shown in the Virtual Bone Model to sample the bone surface. Ensure the Stylus tip is in contact with the bone during sampling.

6.4.3. Glenoid - Sampling Coracoid

Software

Figure 59: Signature Vision Application - Sampling Coracoid



Voice Over

“Points saved. Now scan the coracoid area.”

Button List

Button	Voice	Description

Name	Command	
Start Scan / Stop Scan	Start scan / Stop scan	Toggle button. Starts recording the points at the position of the Stylus tip. When activated, the title will change to “Stop Scan” which then would stop recording of the points if activated.
Next Step	Next step	By default, this button is disabled. It only gets enabled if required coverage has been reached.
Reject Scan	Reject scan	Deletes the registered sampling points. There’s a confirmation dialog before doing so.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

Sampling glenoid is divided into 3 steps. This is the third step.

If sampling is not done precisely enough, then the system will inform the user that the registration failed and that they need to restart the sampling process. A dialog presented will be displayed (Figure 61, Section 6.5.1, *Registration Failed Dialog*).

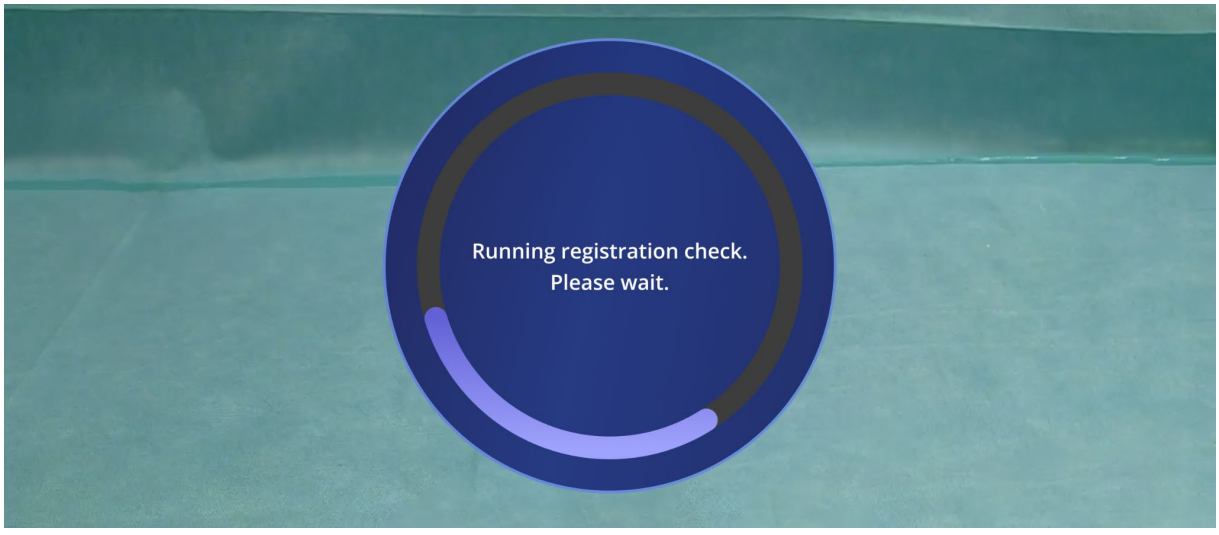
Hardware

Drag the Stylus tip over the coracoid as shown in the Virtual Bone Model to sample the bone surface. Ensure the Stylus tip is in contact with the bone during sampling.

6.5. Registration Check

Software

Figure 60: Signature Vision Application – Registration Check



Screen Description

After proceeding to the next step from the sampling an additional check will be run. If the

check is successful, the user will proceed to the validation. Otherwise, a registration failed dialog will be displayed.

Hardware

None.

6.5.1. Registration Failed Dialog

Software

Figure 61: Signature Vision Glenoid Sampling Registration Failed Dialog

Voice Over

“Registration failed based on the sampled points. Please restart the sampling process.”

Button List

Button Name	Voice Command	Description
Restart Sampling	Restart sampling	Restarts the sampling process.

Screen Description

The screen shows a visualization of the patient's glenoid and registered points. The points considered “good” are marked green. The points considered “bad” are marked red (Figure 61).

The user is asked to restart the sampling process.

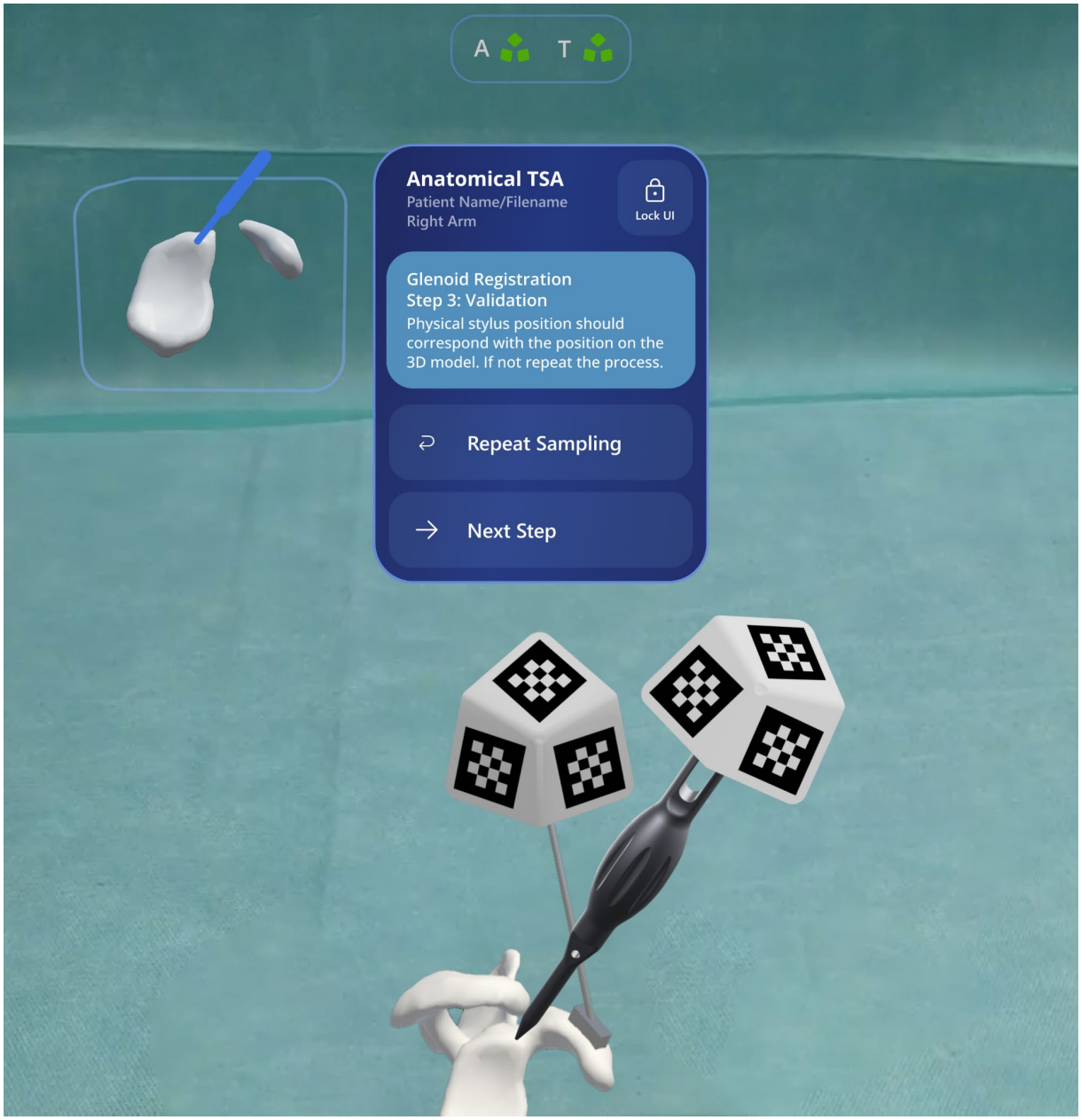
Hardware

None.

6.6. Glenoid - Validation Step

Software

Figure 62: Opti Vu Shoulder Application – Glenoid Validation Step



Voice Over

“Registration successfully completed. Step 3: Validation Physical stylus position should correspond with the position on the 3D model. If not, repeat the process."

Button List

Button Name	Voice Command	Description
Restart Sampling	Restart sampling	Goes back to the Sampling step. Discards current registration.

Next Step	Next step	Goes to the next step.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

In this step, the user is asked to confirm the correct registration of the anatomy. To do so, the user can check if the Stylus tip of the tracked Stylus corresponds to the visualization of the tip presented in the Virtual Bone Model.

The 3D model shows the patient’s humerus with registered points on it.

Hardware

Move the Stylus tip near the glenoid to confirm that the tracked Stylus corresponds to the visualization of the tip in the Virtual Bone Model. If necessary, re-sample the glenoid and coracoid.

6.7. Glenoid - Navigation Step

Software

Figure 63: Signature Vision Application Glenoid Navigation Step

Voice Over

"Glenoid Navigation step. Navigate the Central Pin."

Button List

Button Name	Voice Command	Description
Next Step	Next step	Goes to the next step.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to "Unlock UI" when activated.

Screen Description

In this step, the user is asked to navigate the Adapter Handle with Pin Inserter to a planned position to perform a precise placement of the central pin.

The system will track both the Scapular Anchor and the Adapter Handle with the Pin Inserter tool and will show the visualization of the tracked trajectory (color-coded solid line) to the planned trajectory (blue dashed line).

The visualization will be shown on the Virtual Bone Model. The Virtual Bone Model will show:

- Patient bone 3D model
- The planned trajectory of the Central Pin - as a blue dashed line
- Tracked trajectory of the Pin Inserter - as a color-coded solid line

This step contains an additional UI element that will help with the precise navigation: The aiming cursors.

The top aiming cursor visualizes the Pin Inserter tip distance to the planned entry point of the central pin. The red dot will turn green if the Pin Inserter tip is placed in the correct position.

The top aiming cursor also shows the distance numerical value from the Pin Inserter tip to the planned entry point.

The bottom aiming cursor visualizes the angle between the Pin Inserter and the planned central pin trajectory. The cursor will turn green when the Pin Inserter angle aligns with the central pin trajectory.

The bottom aiming cursor also shows the angle numerical value between the Pin Inserter and the planned central pin trajectory.

Below the aiming cursors, there is information about the version and inclination parameters of the tracked central pin trajectory.

The color coding for the above elements changes from red through yellow to green as a desired position is reached.

	Always consult the aiming cursors for central pin navigation, never just the mesh context alone.

	Do not rely on suggested surgical navigation information if it is believed to be incorrect.

	If it is believed that using the system will significantly increase the duration of the surgical procedure, do not use it or discontinue its use.

Once the user finishes using the Central Pin Navigation, press the “Next Step” button or use the corresponding voice command to go to the next step (Figure 61).

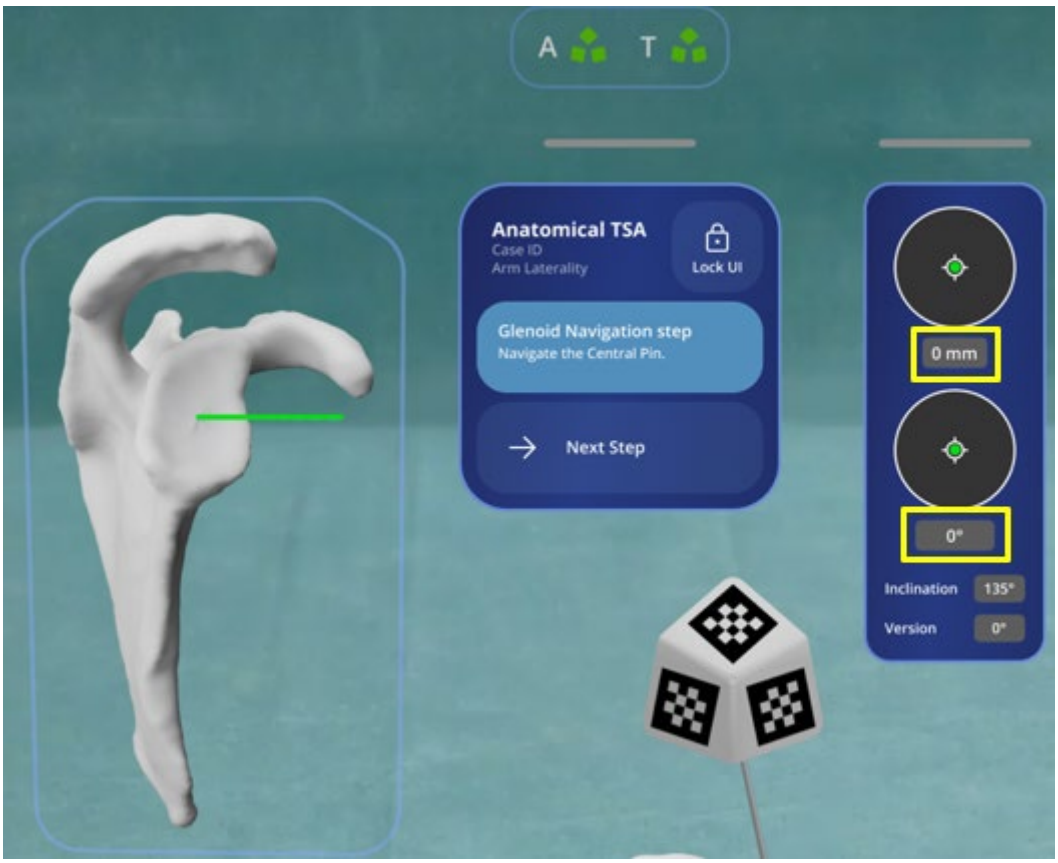
Hardware

Align the Adapter Handle position and orientation with the Virtual Bone model. Insert the threaded Steinmann Pin through the Adapter Handle and carefully drill under power to the appropriate depth marking until the pin has engaged the medial cortex of the glenoid vault. Once the Steinmann Pin is placed, back the Adapter Handle out over the pin and remove from the joint.

Note: The Steinmann Pin is not part of or provided with the Signature Vision. The pin is part of or provided with the Zimmer Biomet Alliance® Glenoid or Comprehensive® Reverse Shoulder system

	When navigating instruments, ensure alignment as closely as possible with the parameters indicated in the graphical user interface aiming to minimize error to exactly 0 mm and 0 ° (see also highlighted values in Figure 643).

Figure 64: GUI Display of Accurate Glenoid Central Pin Navigation



	Do not make any adjustments to navigated instrumentation after navigation has been performed, as this can compromise the accuracy and reliability of the system

7. Glenoid Reaming

7.1. Assemble Reamer

Software

None.

Hardware

A. Alliance Glenoid

Remove the reamer body from the reamer sleeve. Insert the reamer sleeve into the Reaming Guide until the sleeve bottoms out on the split bushing. Insert the reamer body through the reamer sleeve. Attach the drive shaft to the reamer sleeve by screwing the components together (Figures 65).

Note: the reamer sleeve, reamer body, and drive shaft are not part of or provided with the Signature Vision. These components are part of or provided with the Zimmer Biomet Alliance® Glenoid.

Figure 65: Reamer Guide Assembly over the Alliance® Glenoid Reamer

B. Comprehensive Reverse

Remove the retainer ring from the reamer. Insert the reamer into the Reaming Guide until it bottoms out. Slide the ring over the reamer from the proximal end to secure the reamer in the Reaming Guide (Figure 65).

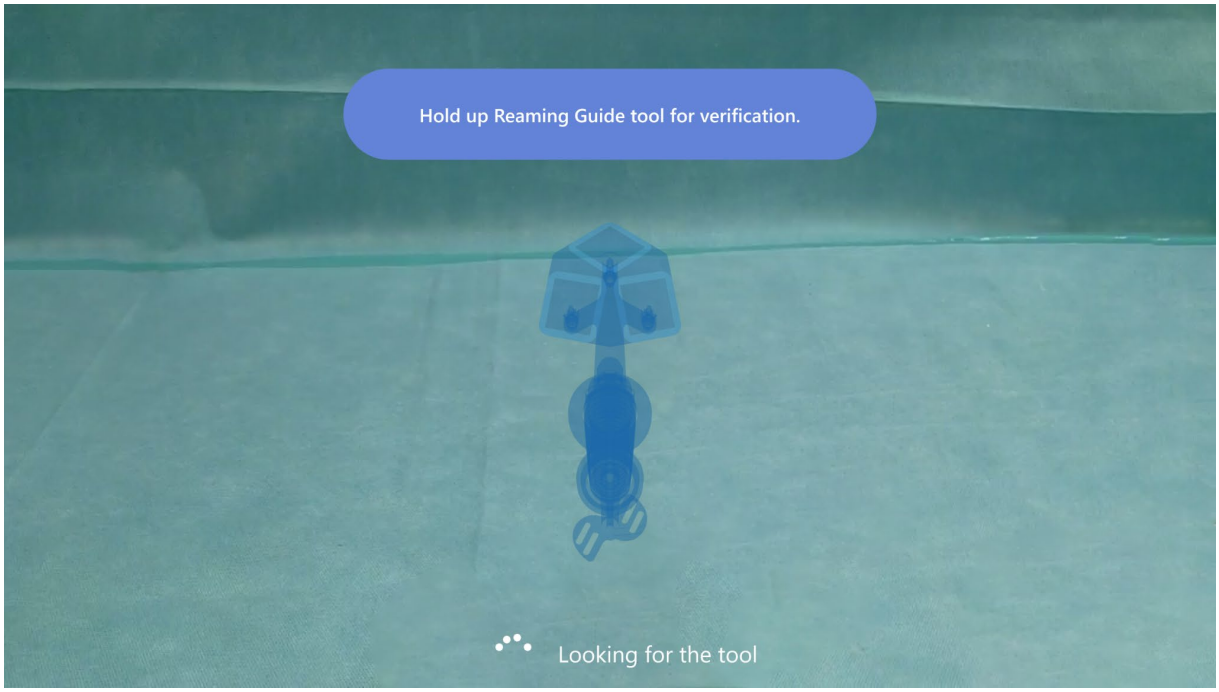
Note: the reamer is not part of or provided with the Signature Vision. This component is part of or provided with the Comprehensive® Reverse Shoulder system.

Figure 66: Reamer Guide Assembly over the Comprehensive® Shoulder System

7.2. Tool Verification - Reaming Guide

Software

Figure 67: Signature Vision Application Tool Verification – Reaming Guide



Voice Over

“Hold up Reaming Guide tool for verification.”

Screen Description

The user must show the Reaming Guide tool in front of the OptiVu Tilt with HoloLens 2 PV (Photo Video) camera. The user should direct the marker attached to the tool so it’s visible to the PV camera. The user should make sure that the ambient lighting recommendations are met when trying to register or use the tools with the OptiVu Tilt with HoloLens 2 device. The software should automatically recognize the shown marker and proceed to the next step.

Hardware

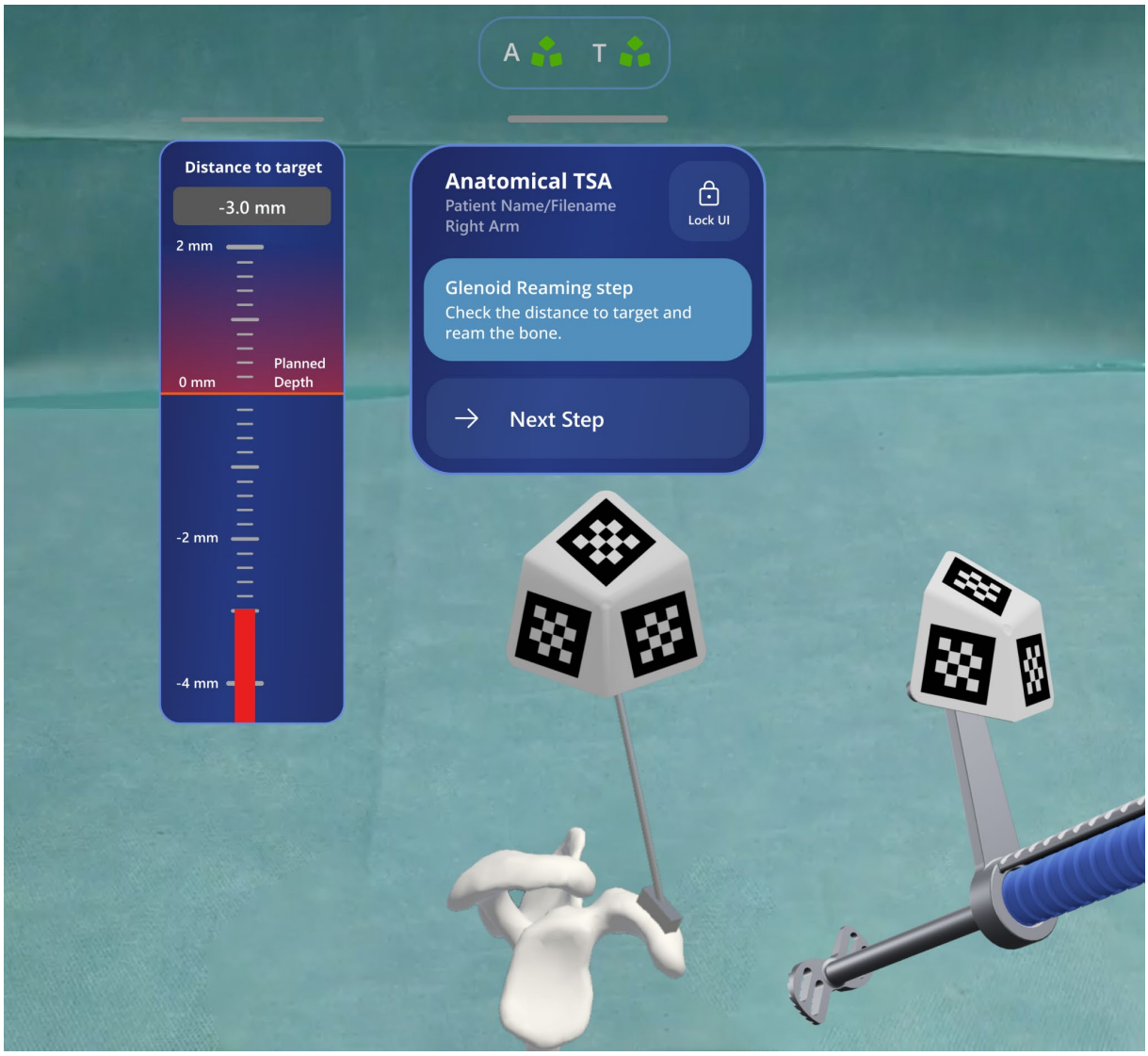
Ensure the tracker is facing the user and within the field of view.

	Always check if the tracker is properly attached to the tool and if it's not damaged.

7.3. Glenoid - Reaming Step

Software

Figure 68: Signature Vision Application Glenoid – Reaming Step



Voice Over

"Glenoid Reaming step. Check the distance to target and ream the bone."

Button List

Button Name	Voice Command	Description
Next Step	Next step	Goes to the next step.

Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

In the reaming navigation step, the user first slides the reamer tool over the central pin. The SW shows the reaming distance between the reamer surface and the final reaming endpoint according to the planning data. The software provides both a numerical value in millimeters, as well as a visual component showing the distance to the endpoint (Figure 69).

In the event the central pin falls out of the patient before reaming is completed, the user must re-navigate the central pin placement.

Special attention should be given to always pushing the handle with the tracker forward when reading the values.

Also, stop reaming for accurate measurements. The vibrations during reaming can cause inaccurate measurements.

	Always make sure to push the handle of the reamer forward when reading the currently reamed depth value.

	Measurements during the reaming can be inaccurate. Stop reaming for accurate measurements.

	During this section, position the retractors such that there is appropriate exposure of the glenoid and no interference with the instrumentation.

This step has two UI elements.

1. **The Context Panel** - A UI Panel spawned above the Scapular Anchor which informs in which step the user currently is and what they have to do. It contains a “Lock UI” button. The user can reposition the panel by grabbing the grabbable indicator (a horizontal line above the blue backplate).

   In this screen, the panel contains the “Next Step” button.

2. **The Side Menu** - A UI Panel titled “Reamer distance to target” with a label showing a numerical value in millimeters of the distance between the Reamer tip and a planned reaming depth. The value is only shown when both the Scapular Anchor and the Reaming Guide are being successfully tracked.

The user can reposition the panel by grabbing the grabbable indicator (a horizontal line above the blue backplate).

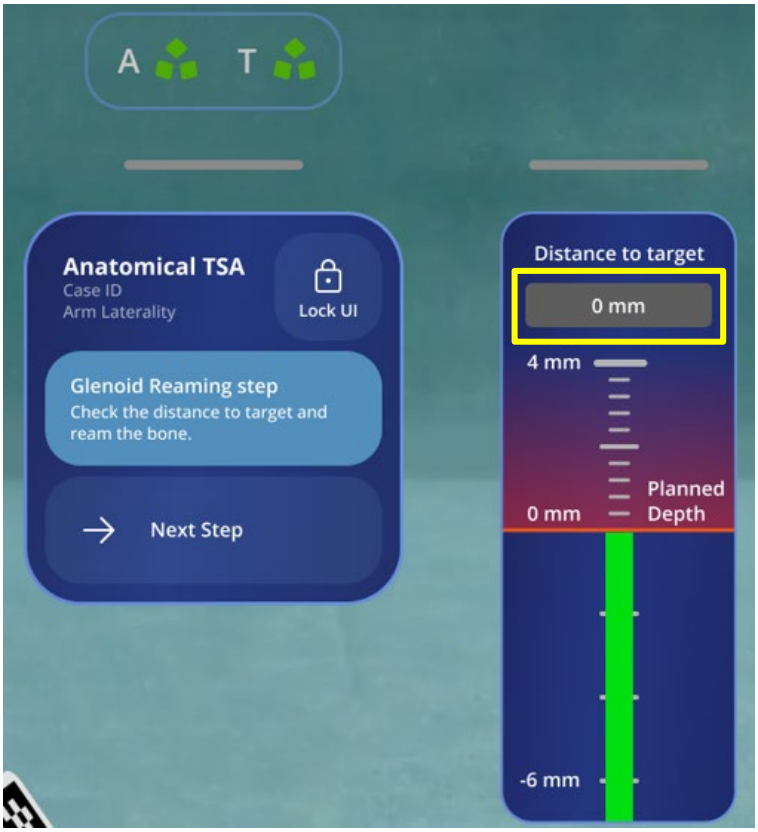
⚠	Do not rely on suggested surgical navigation information if it is believed to be incorrect.

Hardware

Slide the Reaming Guide over the Central Pin. Ream the glenoid to the planned depth.

❗	When navigating instruments, ensure alignment as closely as possible with the parameters indicated in the graphical user interface, aiming to minimize distance to target to exactly 0 mm (see also highlighted value in Figure 68).

Figure 69: GUI Display of Accurate Reaming Depth Navigation



❗	Do not make any adjustments to navigated instrumentation after navigation has been performed, as this can compromise the accuracy and reliability of the system

8. Glenoid Clocking

If the user does not wish to use the clocking feature, skip to step 8.

There are two clocking options: navigated clocking and guided clocking. The clocking step in

Signature Vision can be navigated or guided depending on the planning and chosen surgical technique. This information is defined in the planning file.

If the user is using Comprehensive® Reverse Shoulder Augment implants, select “navigated clocking”.

If the user is using Zimmer Biomet Alliance® Glenoid or non-augmented Comprehensive® Reverse Shoulder implants, select “guided clocking”.

8.1. Assemble Clocking Guide

Software

None.

Hardware

Thread the augment drill guide onto the Clocking Guide until the Clocking Guide is secure.

Figure 70: Assembly of the Clocking Guide

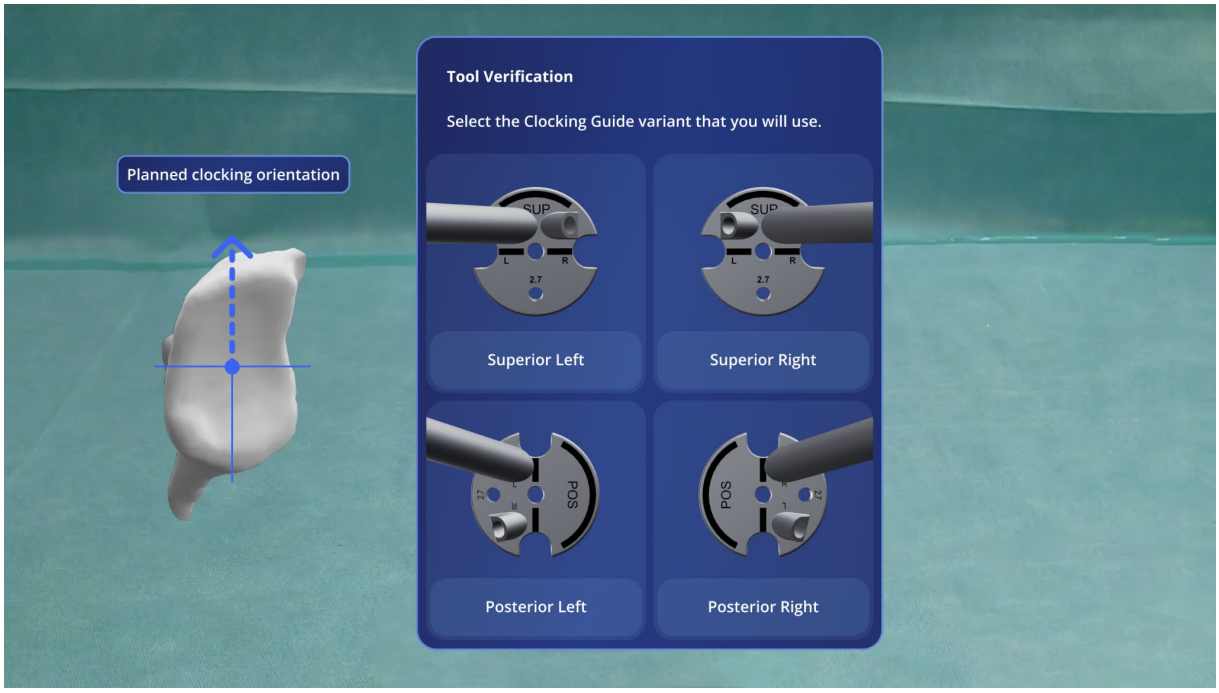
Note: the augment drill guide is not part of or provided with the Signature Vision. The drill guides are part of or provided with the Comprehensive® Reverse Shoulder system, Augment tray.

	Always check if the tracker is properly attached to the tool and if it’s not damaged.

8.2. Glenoid - Clocking Step - Navigated Version

Software

Figure 71: Signature Vision Application Glenoid – Clocking Step – Navigated Version



Voice Over

“Select the Clocking Guide variant that you will use.”

Button List

Button Name	Voice Command	Description
Superior Left	Superior left	Selects the superior left tool variant.
Superior Right	Superior right	Selects the superior right tool variant.
Posterior Left	Posterior left	Selects the posterior left tool variant.
Posterior Right	Posterior right	Selects the posterior right tool variant.

Screen Description

The clocking step in Signature Vision can be navigated or guided depending on the planning and chosen surgical technique. This information is defined in the planning file.

For the navigated clocking, the user is asked to select the tool variant that they will use.

This step consists of the selection panel and a virtual bone model where the clocking orientation is displayed (Figure 71).

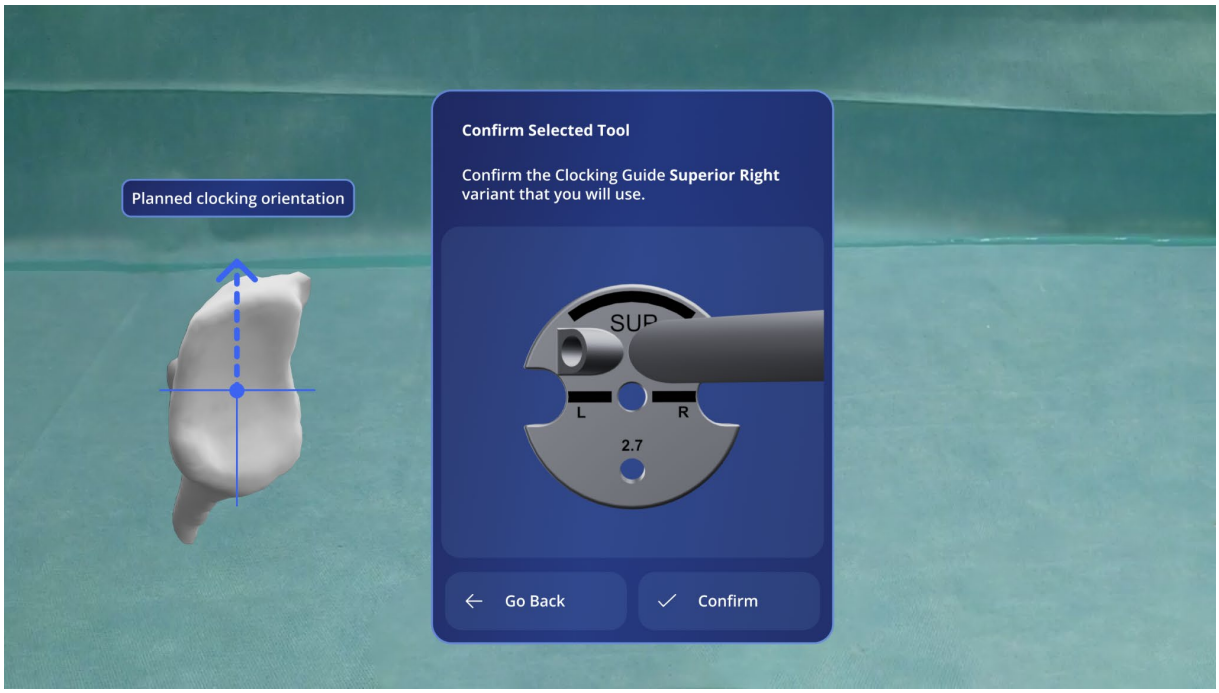
Hardware

Ensure the selected Clocking Guide variant is assembled.

8.2.1. Glenoid - Clocking Step - Navigated Version - Selection Confirmation

Software

Figure 72: Signature Vision Application - Glenoid Clocking Step - Navigated Version - Selection Confirmation



Voice Over

"Confirm the Clocking Guide variant that you will use."

Button List

Button Name	Voice Command	Description
Go Back	Go back	Goes back to the tool variant selection.
Confirm	Confirm	Confirm the selected tool and go to the next step.

Screen Description

The user is asked to confirm the chosen tool variant.

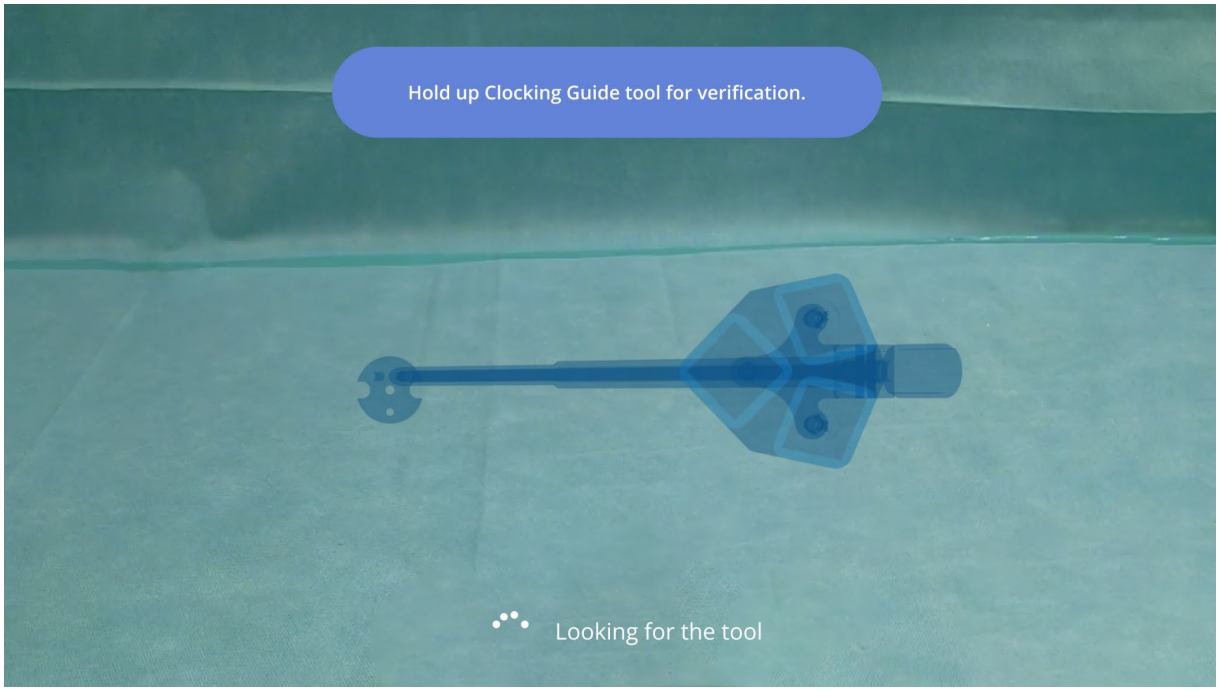
Hardware

None.

8.2.2. Glenoid - Clocking step - Navigated Version - Tool Verification

Software

Figure 73: Signature Vision Application - Glenoid Clocking Step - Navigated Version - Tool Verification



Voice Over

“Hold up Clocking Guide tool for verification.”

Screen Description

The user must show the Clocking Guide tool in front of the OptiVu Tilt with HoloLens 2 PV (Photo Video) camera. The user should direct the marker attached to the tool so it’s visible to the PV camera. The user should make sure that the ambient lighting recommendations are met when trying to register or use the tools with the OptiVu Tilt with HoloLens 2 device. The software should automatically recognize the shown marker and proceed to the next step.

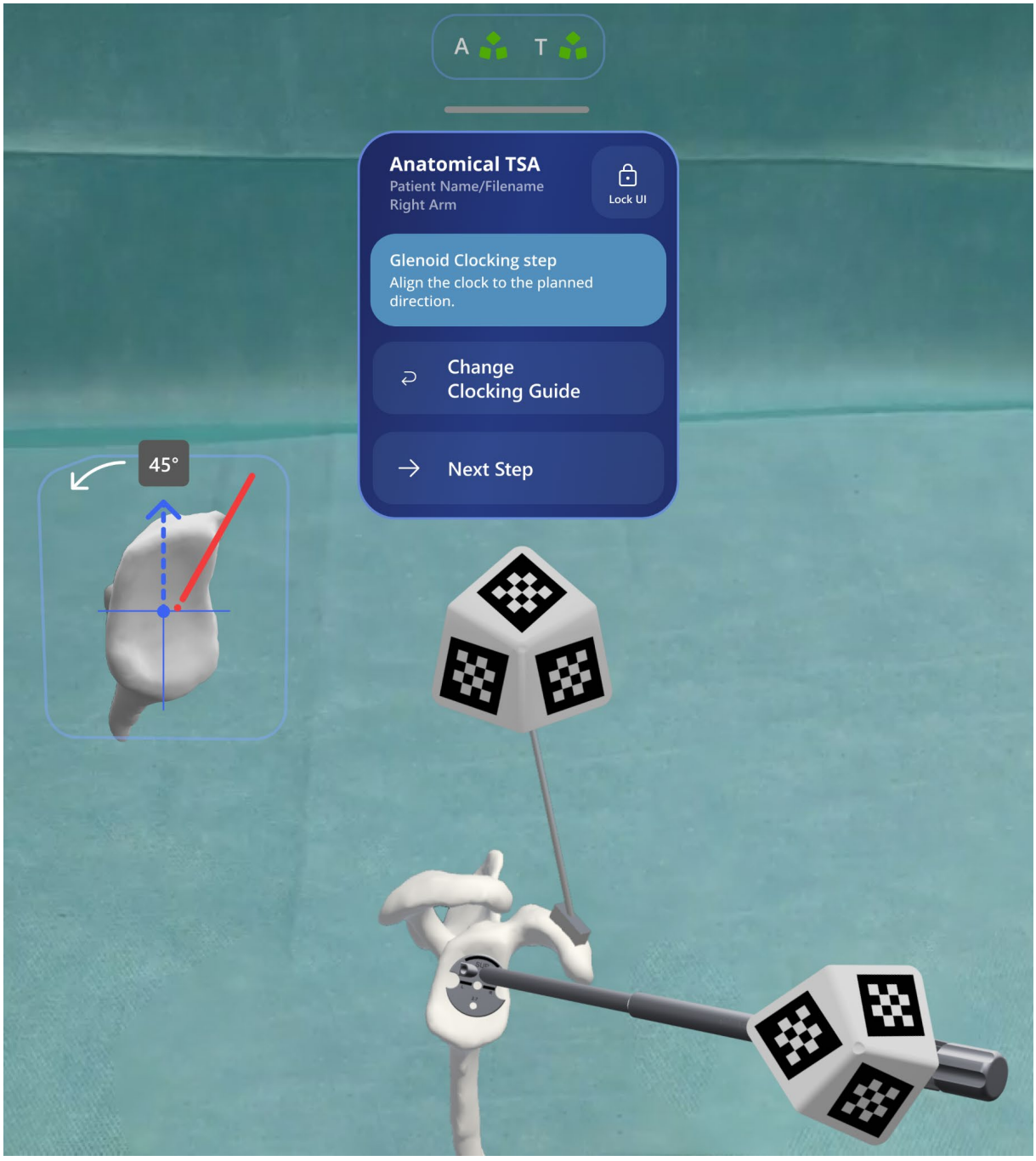
Hardware

Ensure the tracker is facing the user and within the field of view.

8.2.3. Glenoid - Clocking Step - Navigated Version – Navigation

Software

Figure 74: Signature Vision Application - Glenoid Clocking Step - Navigated Version - Navigation



Voice Over

“Glenoid Clocking step. Align the clock to the planned direction.”

Button List

Button Name	Voice Command	Description

Change Clocking Guide	Change clocking guide	Goes back to the tool variant selection.
Next Step	Next step	Goes to the next step.
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

In this step, the user is asked to navigate the Clocking Guide tool to a planned clocking orientation.

The step has 3 UI Elements.

1. **The Context Panel** - A UI Panel spawned above the Scapular Anchor which informs in which step the user currently is and what they have to do. It contains a “Lock UI” button. The user can reposition the panel by grabbing the grabbable indicator (a horizontal line above the blue backplate).

   On this screen, the panel contains the “Next Step” button and “Change Clocking Orientation” button.

2. **Virtual Bone Model** - A 3D model in a bounding box. In this step, a 3D model of the patient's bone with a dashed blue arrow showing the planned Clocking Guide direction. The user can reposition and rotate the 3D model by grabbing the bounding box.

3. **Tracking Panel** - shows the current status of the anchor and stylus tracking. See details in chapter “10.2.4 Tracking Panel”.

The system will track both the Scapular Anchor and the Clocking Guide tool and will show the visualization of the current clocking orientation (color-coded solid line) to the planned clocking orientation (blue dashed line) (Figure 74).

The visualization will be shown on the Virtual Bone Model. The Virtual Bone Model will show:

- Patient bone 3D model
- The planned clocking orientation - as a blue dashed line
- Tracked clocking orientation of the clocking guide - as a color-coded solid line

The color coding for the above element changes from red through yellow to green as a desired position is reached.

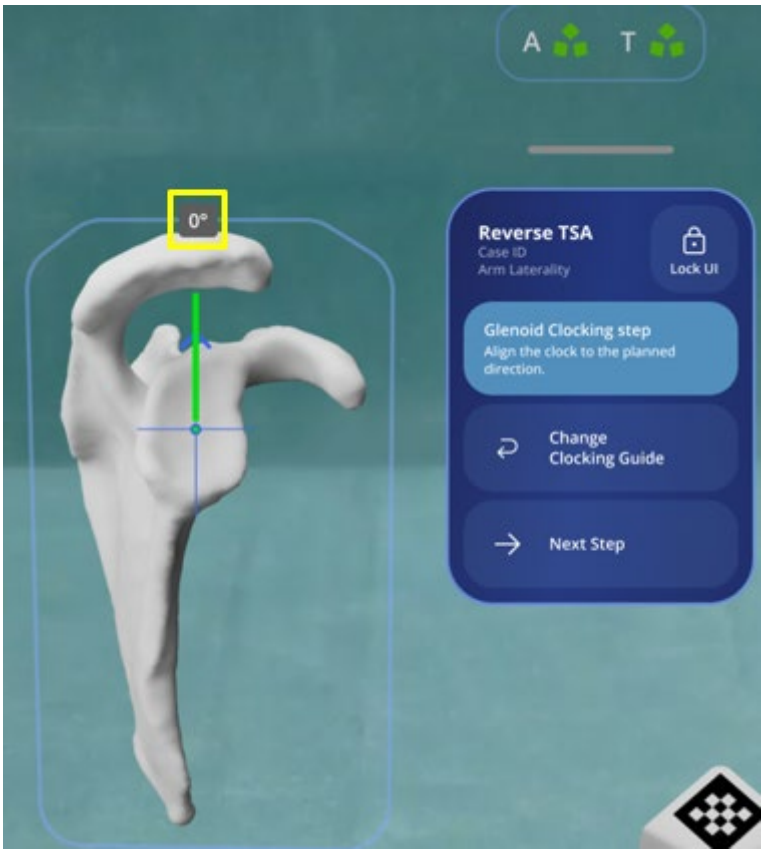
	Do not rely on suggested surgical navigation information if it is believed to be incorrect.

Hardware

Slide the Clocking Guide over the Steinmann Pin. Rotate the Clocking Guide sleeve until the drill guide is aligned with the Virtual Bone model. Use the 2.7 mm drill and drill a pilot hole through the drill guide. Advance to step 8.
GUI Display of Accurate Glenoid Clocking Navigation

	When navigating instruments, ensure alignment as closely as possible with the parameters indicated in the graphical user interface aiming to minimize error to exactly 0 ° (see also highlighted value in Figure 74).

Figure 75: GUI Display of Accurate Glenoid Clocking Navigation



	Do not make any adjustments to navigated instrumentation after navigation has been performed, as this can compromise the accuracy and reliability of the system

8.3. Glenoid - Clocking Step - Guided Version

Software

Figure 76: Signature Vision Application Glenoid – Clocking Step – Guided Version

Voice Over

"Glenoid Clocking step. Align the clock to the planned direction."

Button List

Button Name	Voice Command	Description
Confirm Position	Confirm position	Goes to the next step.

Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

In this version of the clocking step, the user is asked to align the clock to the planned direction. No navigation is offered.

The step has 3 UI Elements.

1. **The Context Panel** - A UI Panel spawned above the Scapular Anchor which informs in which step the user currently is and what they have to do. It contains a “Lock UI” button. The user can reposition the panel by grabbing the grabbable indicator (a horizontal line above the blue backplate).

   In this screen, the panel contains the “Next Step” button.

2. **Virtual Bone Model** - A 3D model in a bounding box. In this step, a 3D model of the patient's bone with a dashed blue arrow showing the planned Clocking Guide direction. The user can reposition and rotate the 3D model by grabbing the bounding box.

3. **Tracking Panel** - shows the current status of the anchor and stylus tracking. See details in chapter “10.2.4 Tracking Panel”.

No tool tracking is required in this step. The user must match the guided clocking direction as closely as possible to the direction shown on the Virtual Bone Model (Figure 76).

Once the user is ready, they can activate the “Next Step” button by pressing or using the corresponding voice command to continue.

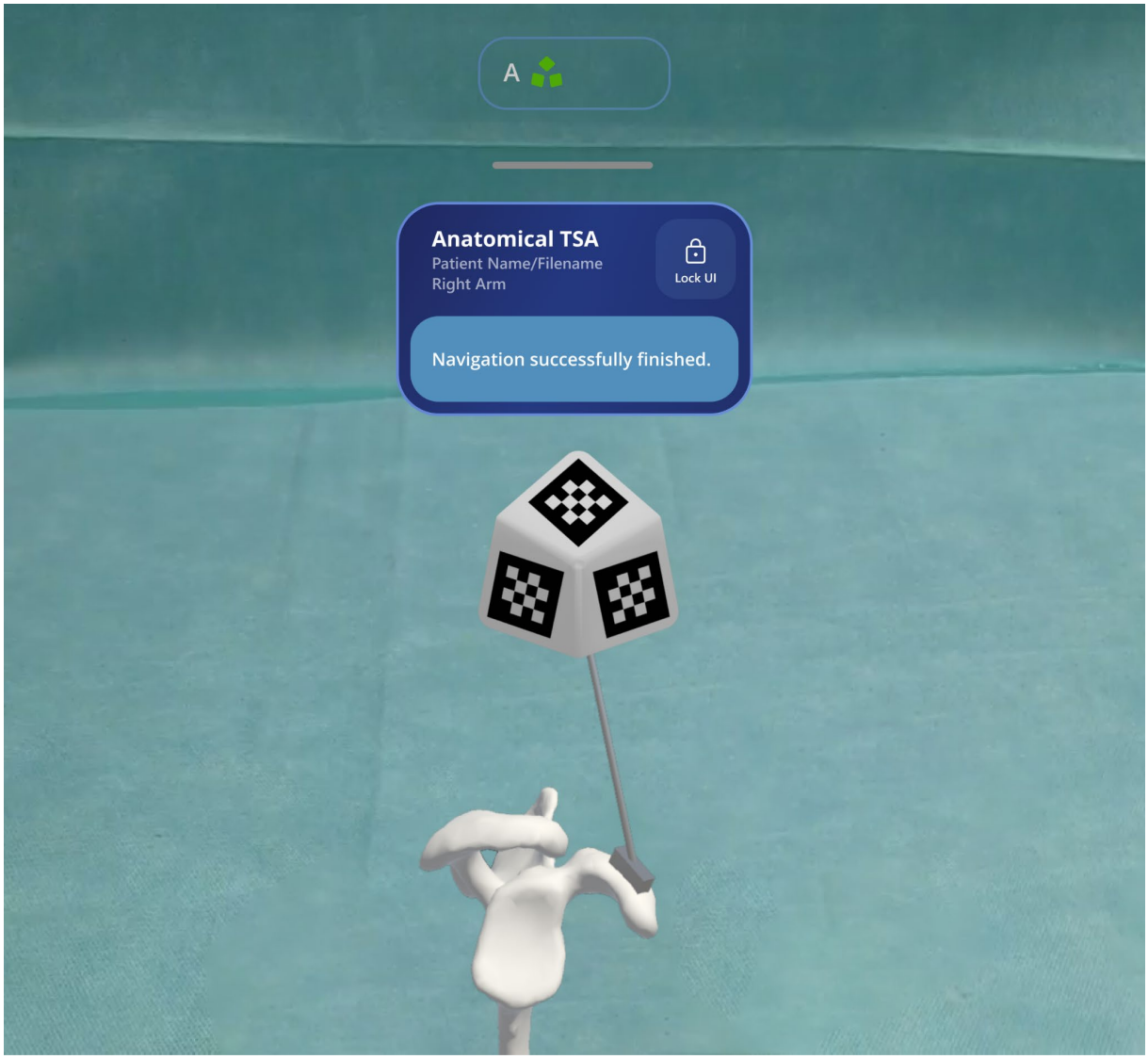
Hardware

Slide the Clocking Guide over the Central Pin. Rotate the Clocking Guide sleeve, using the Virtual Bone Model as a guide. The Clocking Guide is not tracked in this step. Use the 2.7 mm drill and drill a pilot hole through the drill guide. Advance to step 9.

9. Navigation finished

Software

Figure 77: Signature Vision Application – Navigation Finished



Voice Over

“Navigation successfully finished.”

Button List

Button Name	Voice Command	Description
Lock UI	Lock UI	Locks the ability to drag all of the User Interface elements in a scene. This is a toggle button which changes to “Unlock UI” when activated.

Screen Description

In this step, the user is informed that they’ve successfully finished the navigation (Figure 76).

This is the last screen in the application flow. The application can be now safely closed.

The hand menu is still active and accessible.

Hardware

Remove the Central Pin from the glenoid. A surgical tech or assistant can take off the HMD or adjust the HMD out of the field of view. The sterile field shall be maintained.

Proceed with the Zimmer Biomet Alliance® Glenoid or Comprehensive® Reverse Shoulder system for total or reverse shoulder arthroplasty surgical technique.

	Do not touch the HMD during surgery to avoid the risk of contamination.

Remove and dispose of all trackers.

10. General UI/UX Elements

10.1. General Voice Commands

	Voice commands must be spoken loudly and clearly.

Most of the voice commands are context-specific and connected to specific buttons. There are four global voice commands listed below which would work at any time in the application.

The general rule is that the voice command matches the text on the button. Voice command for clicking the buttons with numbers (e.g. Pin screen) or Planning File names (e.g. Planning file selection screen) are activated using the “Select” voice command.

Only the “Lock UI” button in the hand menu requires the user’s eye gaze to be activated.

If the user focuses their eye gaze at any button, a small label with the corresponding voice command will appear.

Be aware that voice commands might be triggered by other speakers in the environment.

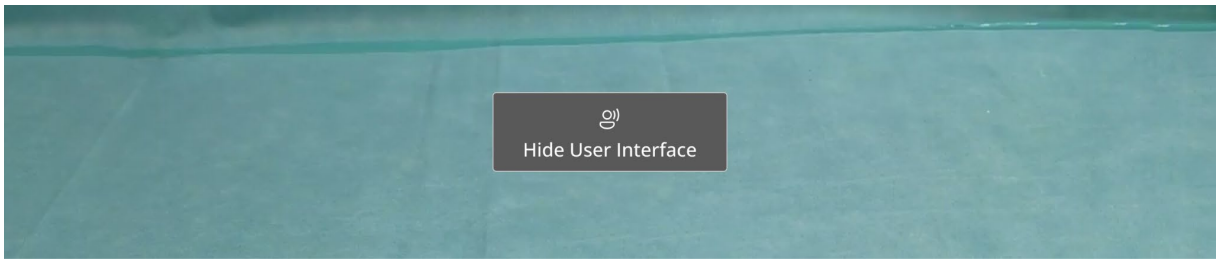
There are four global voice commands that can be activated at any time of using the application.

Global Voice Commands

Voice Command	Description
Hide User Interface	Hides all user interface elements. The interface can be re-enabled by using the hand menu or using “Show User Interface” voice command.
Show User Interface	Shows the user interface if it is hidden.

Lock User Interface	Locks the user interface so that it is not possible to grab the UI elements anymore.
Unlock User Interface	Unlocks the user interface so that the grabbable UI elements can be grabbed and repositioned.

Figure 78: Signature Vision Application - Hide User Interface Graphic

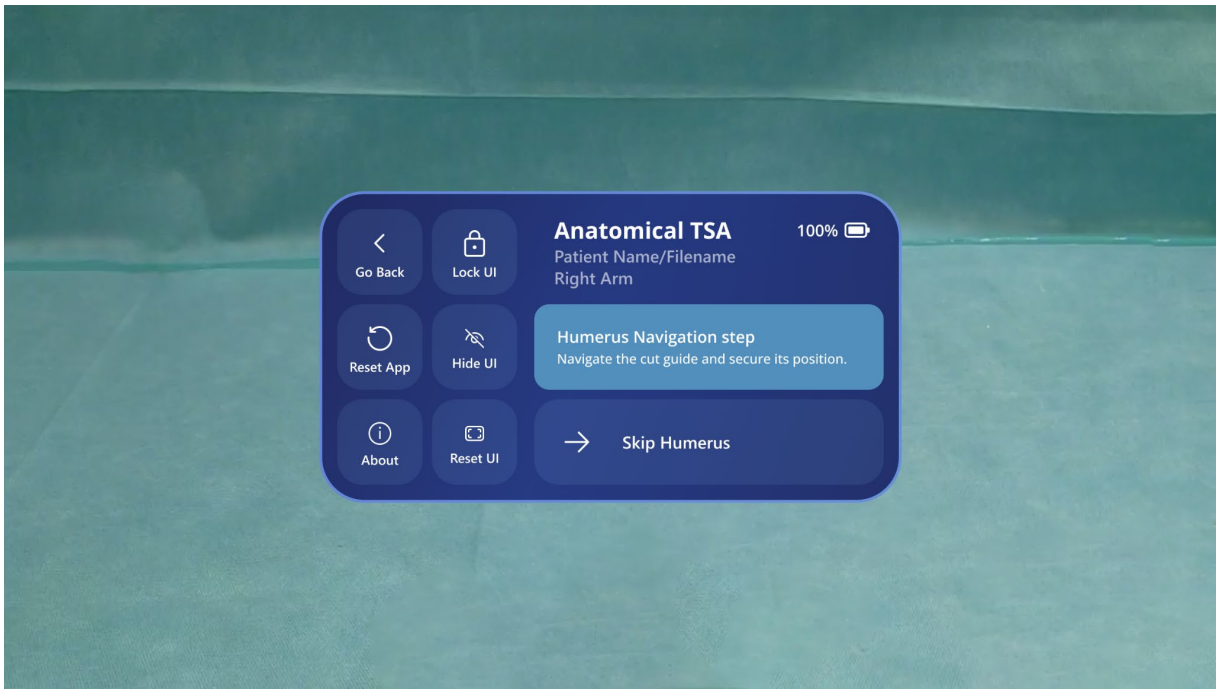


Example of the confirmation pop-up that appears when a global voice command has been successfully recognized.

10.2. General UI Elements

10.2.1. Hand Menu - Version for the Humerus Cut Step

Figure 79: Signature Vision Application - Hand Menu - Version for the Humerus Cut Step Graphic



Element Description

The hand menu can be activated any time the user looks at the palm of their hand. To hide it, the user should stop looking at the palm and move the hand away.

The Hand Menu panel is composed of six buttons and two text areas that describe the current screen context in which the user is. In specific screens, the Hand Menu can have

additional context-specific buttons below the text areas. In the above example, the “Skip Humerus” button is only present during the Humerus part of the application (Figure 79).

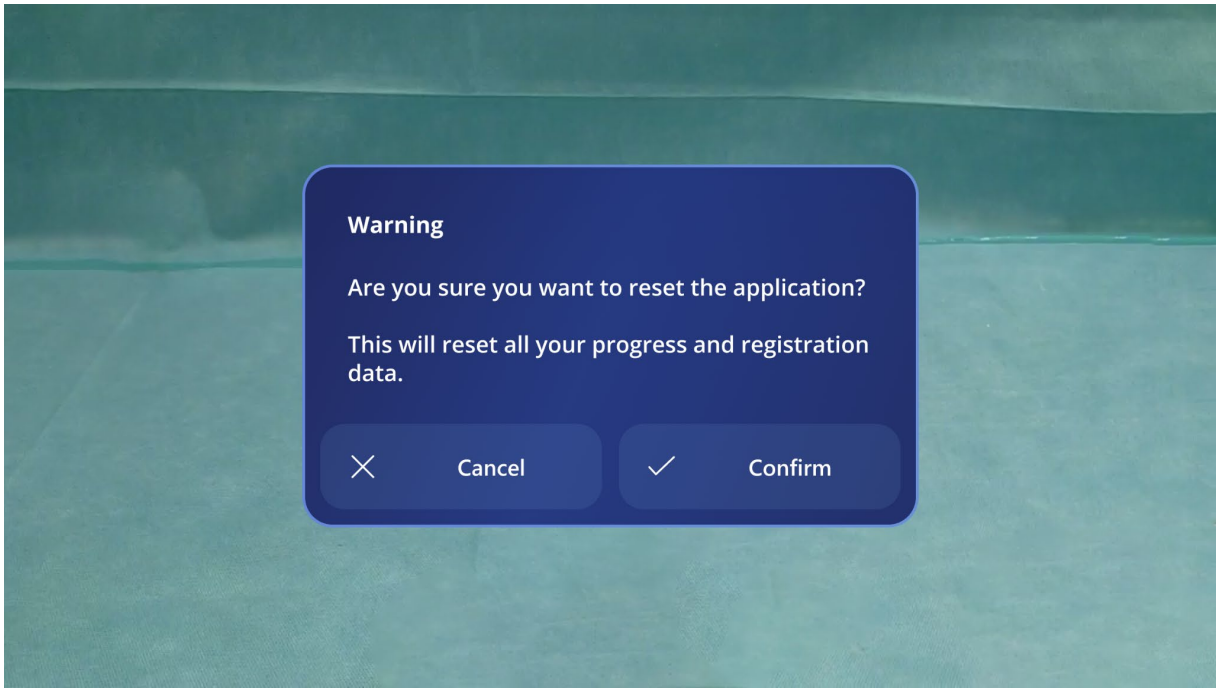
Buttons List

Button Name	Voice Command	Description
Go Back	Go back	Goes back to the previous screen.
Lock UI	Lock UI	Toggle button. Locks all of the movable user interface.
Reset App	Reset app	A warning dialog will be displayed. If it’s confirmed, then the app will be reset and will go back to the first screen.
Hide UI	Hide UI	Required to properly adjust the display of the HMD to the user’s IPD.
About	About	Goes to the Product Label panel.
Reset UI	Reset UI	Resets the position of all currently visible User Interface elements to their default positions.
Skip Humerus	Skip humerus	Skips the Humerus part of the application and goes to the Intermission screen.

When pressing the “Reset App” button, the following Warning dialog will be displayed:

10.2.2. Warning - Application Reset Dialog

Figure 80: Signature Vision Application - Warning - Application Reset Dialog Graphic



Voice Over

“Are you sure you want to reset the application?”

Element Description

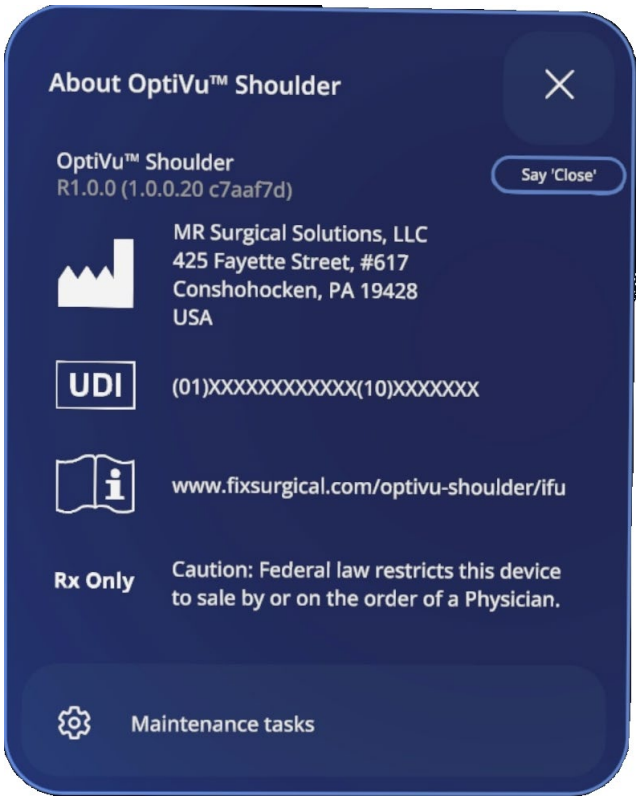
The user is asked for confirmation when they want to reset the application. Resetting the application goes back to the Field of View screen and resets any registration or sampling progress (Figure 80).

Buttons List

Button Name	Voice Command	Description
Confirm	Confirm	Confirms the dialog and resets the application.
Cancel	Cancel	Closes the dialog.

10.2.3. Product Label Screen

Figure 81: Signature Vision Application Product Label Screen



Element Description

The product label screen is a UI Panel that floats in front of the user and follows their head movement. It contains the information about:

- The application version
- The manufacturer

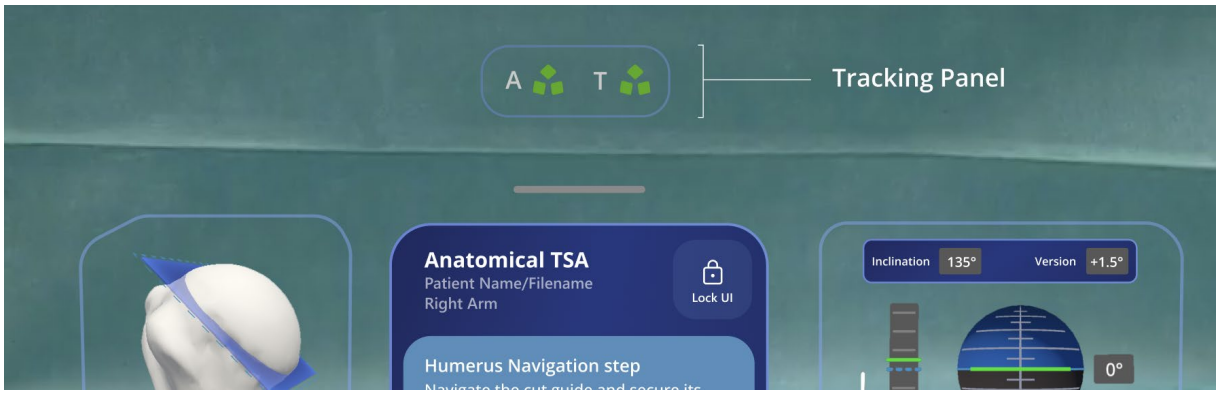
- The UDI number
- Link to the User Manual

Buttons List

Button Name	Voice Command	Description
Close	Close	Closes the Product Label screen and goes back to the previous screen where the user was.

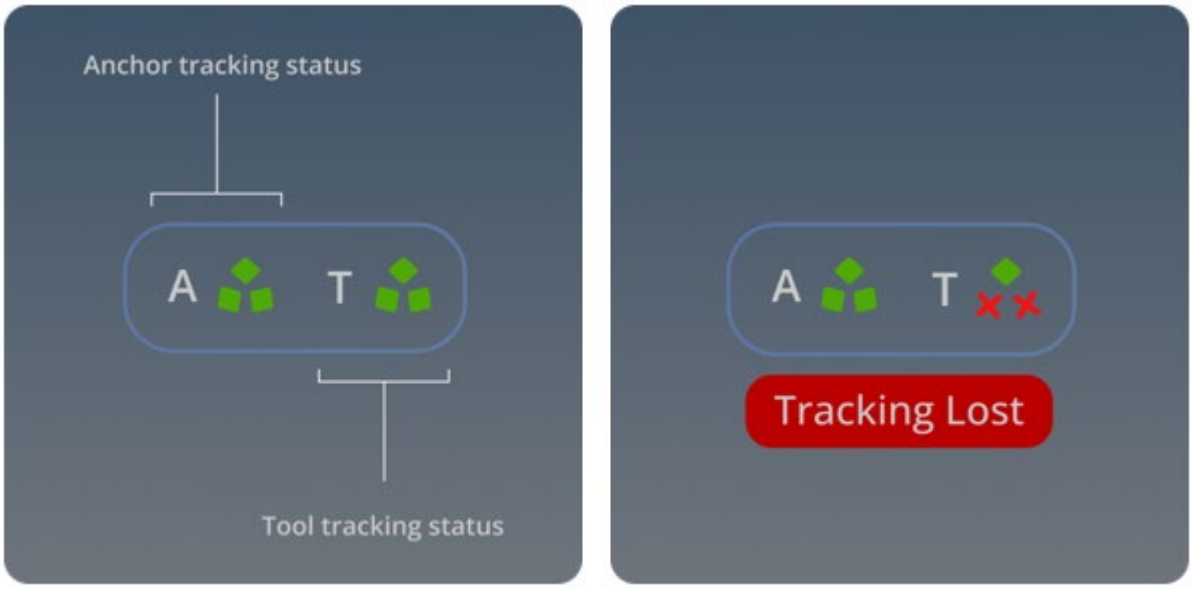
10.2.4. Tracking Panel

Figure 82: Signature Vision Application - Tracking Panel



Tracking Panel's default position is at the top of the user's field of view (Figure 82).

Figure 83: Signature Vision Application - Tracker Status Graphic



Element Description

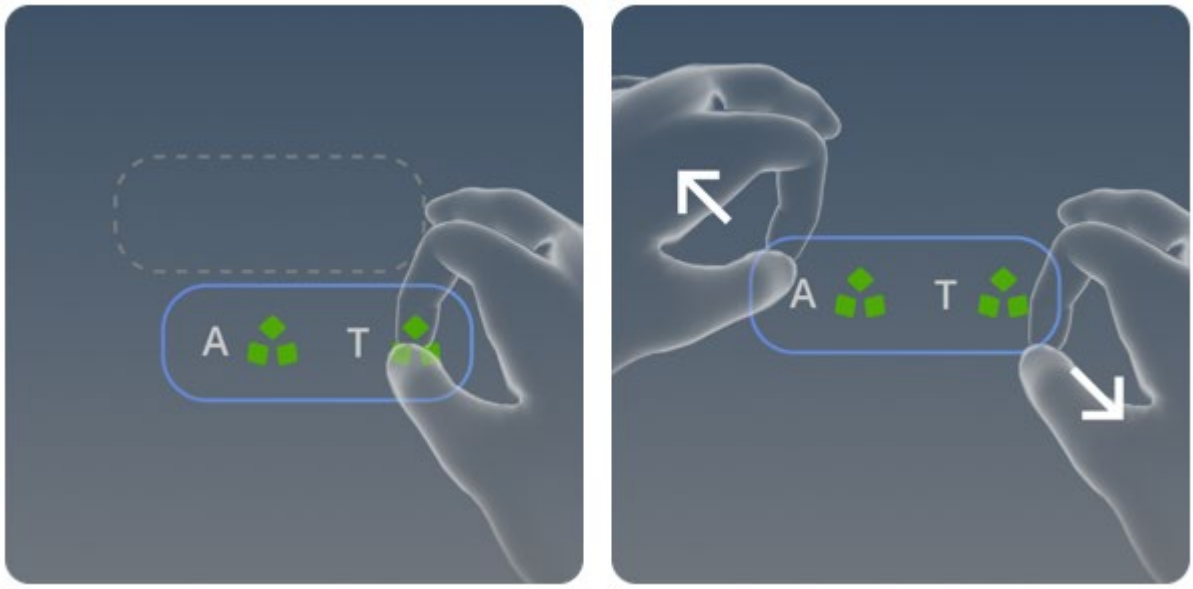
The tracking panel displays the tracking status for the anchor and the tool being tracked in the current step. The icons next to the letters indicate the tracking status of each marker on

the tracker. If the icon is green the marker is tracked. If the system is unable to track the marker it will be marked with the red cross (Figure 83).

If not enough markers are tracked for using the system, a “Tracking Lost” label will be displayed. The label will disappear if the markers are found and tracked again.
By default, the tracking panel is “docked” in the user’s field of view. The user can grab it and position it anywhere in space. The tracking panel can also be reattached to the user’s field of view by moving the panel inside the dotted line area.

The tracking panel can also be rescaled by using both hands and pinching gestures.

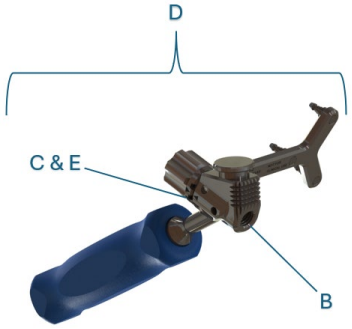
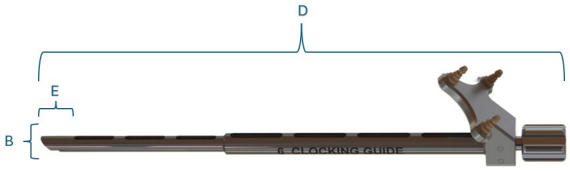
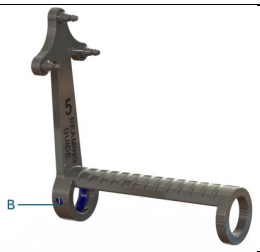
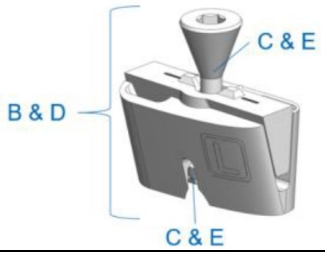
Figure 84: Signature Vision Application Rescaling Trackers

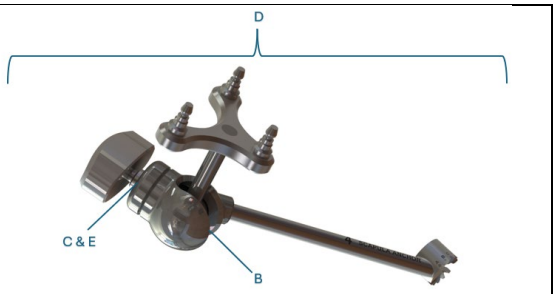
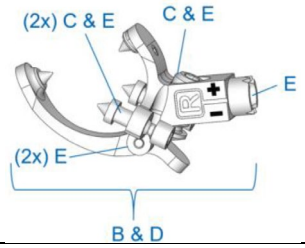
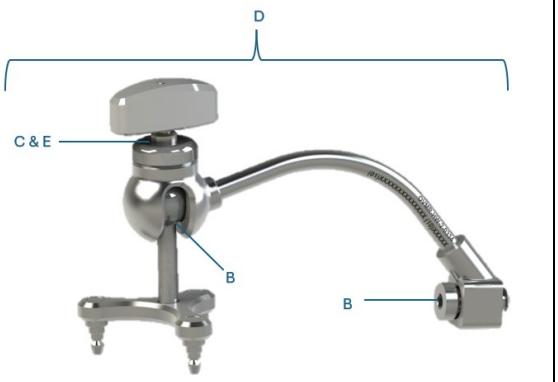
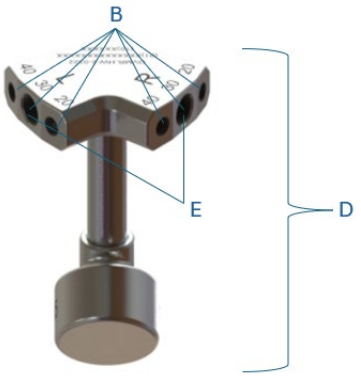


11. Cleaning, Disinfection, and Sterilization

In addition to the surgical Instrument Package Insert cleaning and sterilization requirements, the instruments listed in the table below require additional cleaning instructions from the following list:

A. Requires disassembly
B. Requires water jet to flush difficult to access areas
C. Screw/unscrew components while flushing the area
D. Requires a minimum of 10 minutes ultrasonic cleaning cycle in an enzymatic solution
E. Screws/mechanisms should be checked and lubricated with a medical surgical lubricant after each cleaning as determined upon inspection

Part Number	Description	Additional Cleaning Instructions	Instrument
OVMR-HW-2-0312	Adapter Handle Asm	B, C, D, E	
OVMR-HW-2-0344	Clocking Guide Asm	B, D, E	
OVMR-HW-2-0328	Reaming Guide Asm	B	
20-8087-300-00	Shoulder Scapula Ref, L/R	B, C, D, E	

OVMR-HW-2-0331	Scapular Ref Rod Asm	B, C, D, E	
20-8087-400-00	Shoulder Humeral Ref	B, C, D, E	
OVMR-HW-2-0334	Humeral Ref Rod Asm	B, C, D, E	
OVMR-HW-2-0322	Humeral Gauge 135	B, D	

11.1. Signature Vision Instrument Lifetime Expectancy

⚠	Verify the integrity of all the instruments before each surgery. Visually inspect the instruments for damages.

Handle instruments with care. Avoid dropping instruments. Damage to an instrument can significantly affect the function and accuracy of the procedure and, consequently, the postoperative surgical outcome. The Signature Vision's reusable instruments have a five-year lifespan under normal use, corresponding to 180 surgeries. To determine whether a reusable instrument has worn to the extent that it is no longer suitable for use, please refer to the Reusable Instrument Lifespan Manual.

11.2. Storage

11.2.1. Device Storage and Protection

At the end of the procedure, the device should be stored in an area fulfilling the storage conditions defined by the manufacturer. The HMD should be stored in its case provided by the manufacturer and in a dry area with moderate temperature. The HMD and USB used for the system should be stored in a secure location with access restricted to authorized personnel only. The device should be stored in an area where it will not be exposed to fluids. The device must not be placed on sloping ground without the assurance of its stability.

11.2.2. Instrument Storage and Protection

The instruments shall remain protected from all impacts during handling and storage. Special care shall be taken for all the instruments because any damage whatsoever may directly affect the registration accuracy and the positioning accuracy of instruments.

11.3. Single-Use OptiVu Trackers

The trackers are single-use devices, provided sterile. After use, dispose of the trackers per the OptiVu Tracker – Package Insert. Trackers in their sterile packaging have a 2-year shelf-life.

11.4. Safe Disposal

The instruments and their components are subject to wear and therefore have to be considered as non-durable material. The integrity of the instruments has to be checked before use and if necessary, instruments must be returned to the responsible local representative for repair or disposal. After use, all wastes and residues must follow the hospital recycling guidelines. Especially, attention must be paid to instruments which could be potential biohazards, since they may be contaminated with blood or other body fluids, bone or other tissue. Handle and dispose this product in accordance with accepted medical practice and with applicable local, state and national laws and regulations.

For the disposal of the OptiVu Tilt with HoloLens 2, please refer to the information in the respective user manual provided by Microsoft.

Troubleshooting

OptiVu Tilt with HoloLens 2 Device

Problem	Possible Cause	Possible Solution
The HMD does not start	Battery too low	Please charge your HMD.
The HMD is making me feel dizzy and/or I get a headache	Wrong IPD	Please adjust your IPD in *Settings/System/Calibration/Run eye calibration.*
	Headband too tight	Try to loosen the head band a bit. Too tight head bands can cause headaches.

	Using the HMD might cause temporary feelings of nausea, motion sickness, dizziness, disorientation, headache, fatigue, eye strain, or dry eyes.	Keep your first few sessions with HMD brief and be sure to take breaks. If you experience discomfort, stop and rest until you feel better.
The HMD getting very hot	Intense usage over a longer period.	Take a break, turn off the HMD until it cools down. Use a separate device to continue the surgery.
The HMD is not charging	Unsupported charger	Please use the charger that was bundled with the HMD.
I cannot open the start menu	Usually, the start menu opens by tapping your wrist with the index finger. Depending on your device's configuration, the start menu opens only after holding your index finger on the wrist for 5 seconds.	Keep your index finger on the wrist for 5 seconds.
The HMD seems frozen, how can I reset the device?	HMD crashed.	Hold the power button on the back of the device for 5 seconds until the device reboots.
The HMD asks me to calibrate my Interpupillary Distance (IPD)	First time wearing this specific device	Run the eye calibration wizard found in *Settings/System/Calibration/Run eye calibration*.
	Someone else calibrated the device before you	Re-do the eye calibration found in *Settings/System/Calibration/Run eye calibration*.

	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 MR Surgical Solutions LLC OptiVu™ Shoulder, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

	A risk of increased emissions or decreased immunity may result if any additional cables are attached.

	This device has not been tested for compatibility with all potential RF Emitters, or all variations of potential X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, NFC, WPT, or Electronic Article Surveillance (EAS) devices. Caution should be used if such emitters are present within the use environment.

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

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

Holograms

Problem	Possible Cause	Possible Solution
The HMD does not show any holograms	HMD not started	Make sure the HMD is started by checking the indicators at the back of the device next to the power button.
	Hide UI enabled	Within the Signature Vision app, open the Hand Menu and tap the “Show UI” button
I cannot see all the holograms or only parts of them	The visor is not placed correctly	Check the HMD fitting and the visor's position. Try different settings.
The holograms have an orange tint where they should be white		
All holograms have disappeared suddenly	The device or app crashed	Restart the device.
	UI elements are placed somewhere else in space	Look around you and check if you find some misplaced panels. Use the Hand Menu and Reset UI to bring all UI elements back to their default location (in front of you).
	Accidentally triggered the Hide UI button or used the corresponding voice command	Show the Hand Menu and tap “Show UI” button.
	The battery is too low, and the device has shut down	Charge the device and/or use another, fully charged HMD.
The holograms are too bright or too dimmed	Brightness wrongly adjusted	Adjust the hologram brightness using the buttons on the left side of the visor.
The holograms are occluding the patient's anatomy	Suboptimal hologram positions	Most UI elements can be repositioned. Try grabbing the handlebar above the panels and move it to a better position. Make sure that Lock UI is not enabled.
I cannot move the holograms or UI panels anymore	Lock UI enabled	Use the Hand Menu and tap the “Unlock UI” button.
I cannot find some UI elements anymore	UI elements are positioned somewhere else	Look around you to find misplaced UI elements. Use the Hand Menu and tap the “Reset UI” button to reset all UI element positions.
I frequently move UI elements without intention	Misinterpreted hand gestures	Use the “Lock UI” button in the Context Menu or the Hand Menu

		to lock the position of the UI elements.

Voice Commands / Sounds

Problem	Possible Cause	Possible Solution
The voice commands and sounds are very silent	Volume too low	Turn up the volume using the volume buttons located on the right side of the visor.
Sometimes the voice commands don't work	The environment is too loud	Make sure that not too many people are talking while using voice commands.
	Device Error	Restart the device.
A voice command triggered an action I did not intend to	Wrongly recognized voice command	Use the Hand Menu and then the Go Back button to go back to a previous screen if needed.

Patient Planning File

Problem	Possible Cause	Possible Solution
The Signature Vision SW does not find the planning files on the attached USB-C drive	Patient Planning file format	Make sure the Patient Planning file has the correct format and file ending.
	USB drive format	Make sure the attached USB drive has a compatible storage format. Check if the USB drive is working on a Windows PC.
The Signature Vision SW shows me an error when loading the Patient Planning file	Corrupt file or unsupported version.	Redownload the file from SignatureOne portal. Make sure the version of the file format is supported by Signature Vision.
I selected the wrong Patient Planning file but only noticed it after the patient verification screen	Use error	Use the Hand Menu and tap the “Reset App” button to load the correct Patient Planning file.
I don't remember the PIN to open the planning file in Signature Vision	Forgotten PIN	Redownload the file from SignatureOne portal and import it to Signature Vision again. Remember the PIN you defined during the download process.
I cannot delete the Patient Planning files from the USB-C drive	Not supported.	Within the Signature Vision software, you can only remove locally stored Patient Planning files. To remove the files from the USB drive, attach it to another computer to do so.
The Patient Planning file shows a wrong patient, wrong drill	Wrong Patient Planning file	Redownload the correct file from SignatureOne portal.

trajectory, and/or a wrong cut pane	Selected the wrong file	Use the Hand Menu and tap the “Reset App” button to load the correct Patient Planning file.

Instrument Tracking

Problem	Possible Cause	Possible Solution
Signature Vision does not recognize my tools	Suboptimal lighting conditions	Improve the lighting, see Section Lighting Conditions.
	Wrong tool or wrongly assembled tracker	Make sure you are using the correct tool for the specific step and that you assembled the correct tracker on the instrument.
Tracking only works sporadically. I see the tracking lost warning a lot	Suboptimal lighting conditions	Improve the lighting, see Section Lighting Conditions.
	Tracker positions	Make sure both trackers are facing toward you with all three markers.
I have accidentally moved the anchor	Accidental use error	Re-registration of the anatomy is needed. Use the Hand Menu to Go Back to the registration step or Reset the app.
The holograms close to the instruments are offset	Some offsets of the holograms to the expected location are acceptable within 1 to 2 millimeters.	Consider running the eye calibration again, found in *Settings/System/Calibration/Run eye calibration.*
	Incorrect eye calibration	Please run the eye calibration again, found in *Settings/System/Calibration/Run eye calibration.*
	Tracker not attached properly	Check the assembly of the tracker on the instrument.

Landmark Registration

Problem	Possible Cause	Possible Solution
The Signature Vision SW tells me that the landmarks are not at the correct distance from each other.	Not accurately placed landmarks	Check the landmarks on the Virtual Bone model and re-register the landmarks.
	Suboptimal lighting conditions	Improve the lighting, see Section Lighting Conditions.
I'm having difficulty tapping the buttons while keeping the instrument in place	UI Placement sub-optimal	Use voice commands to activate the “Save Point” or any other buttons. Look at the button you

		want to trigger and wait for the label that tells you what to say. Try to place the panels in a more convenient position.
I cannot see exactly where to place the landmarks on the anatomy	Suboptimal placement of the Virtual Bone Model	Use your fingers to move, rotate, and/or scale the mesh context to better see the landmarks.
I cannot tap the Save Point buttons or use the voice commands to activate them	The “Save Point” buttons are only active when tracking both trackers	Make sure both the anchor and the instrument are tracked.
I accidentally placed a landmark in the wrong position	User error	Continue as normal, after the third landmark point, the software will go back automatically if the landmarks were not placed correctly. Or use the Hand Menu and “Go-Back” button.
I cannot tap the Confirm button in the landmark registration step	The “Confirm” button is only active after saving all three landmarks	Save all three landmarks first.

Sampling Step

Problem	Possible Cause	Possible Solution
I accidentally collected some sampling points that are not on the anatomy	Lifted the instrument by accident or too early during the sampling	Tap the “Reject Scan” button and re-sample the points.

Validation Step

Problem	Possible Cause	Possible Solution
The virtual stylus is not shown at the expected position or is constantly offset	Bad registration	Re-do the registration by tapping the “Restart Sampling” button.

Navigation Step

Problem	Possible Cause	Possible Solution
The angle indicator shows me an angle of around 180° although the cut planes look correct	Wrongly configured tool	You probably have registered the wrong configuration (left/right tracker position) of the tool. Either switch the tracker on the

The virtual cut plane behaves strangely, not according to my movement of the instrument		instrument to the opposite direction, use the Hand Menu to Reset the app, or Go Back step by step to the tool configuration step and select the correct tool configuration.
Everything seems to be shifted. It looked correct before (e.g. on the Patient Planning confirmation screen or during the validation step)	Possibly moved the anchor	If you accidentally moved the anchor, you need to re-register the anatomy. Use the Hand Menu to Reset the app and start over, or the “Go Back” button to go back step by step until you reach the registration step again.

Central Pin

Problem	Possible Cause	Possible Solution
The Central Pin falls out before, during, or after reaming.	Incorrect depth placement, bone quality, etc.	Re-navigate the central pin following the steps within section 6, Glenoid Central Pin.

Reaming

Problem	Possible Cause	Possible Solution
The reaming distance is not accurate or stable during the reaming	Tracking during reaming is not stable	To get accurate measures, stop the reamer to check for the value.

Clocking

Problem	Possible Cause	Possible Solution
The position of the implant is not shown on the virtual bone model.	Clocking is not navigated using tracked instruments	Use the clocking position on the Virtual Bone Model to find the end position of the implant.

Technical Information

Technical Specifications

Environmental Specifications

Below is a summary table of the Environmental specifications. Please refer to the provided environmental specifications supplied by Microsoft for more information.

OptiVu Tilt with HoloLens 2, Environmental Specifications	
Operating Temperature	50°F to 80°F (10°C to 27°C)
Transportation/Storage Temperature	-4°F to 140°F (-20°C to 60°C)
Operating/Storage Humidity	8% to 90% RH (Relative Humidity)
Operating/Storage Atmospheric Pressure	70 to 106 kPa

FCC Manual Statements and EMC Information

This equipment has been tested and found to comply with the applicable limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

For electromagnetic compatibility information, warnings, and recommended separation distances, refer to the Electromagnetic Compatibility and Radiation Safety section of this manual.

Safety Classification & Standards

The below table is the electrical classification of the OptiVu Tilt with HoloLens 2.

Classification Per IEC 60601-1	**Level**
Protection of electrical shock	Class II Patient Protection, Type BF applied part.
IP Level	IPX0

The OptiVu Tilt with HoloLens 2 is an off-the-shelf device used within the system. The device is to be considered as a non-defibrillation proof device. Additionally, the OptiVu Tilt with HoloLens 2 is not intended for use in an oxygen rich environment.

The standards followed by the Signature Vision are provided in the table below.

Standard	Description
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performances
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performances – Collateral Standard: Electromagnetic Compatibility
IEC TR 60601-4-2	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
AIM 7351731	Medical Electrical Equipment & System Electromagnetic Immunity Test for RFID Readers
IEEE/ANSI C63.27	American National Standard for Evaluation of Wireless Coexistence
IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices
ISO 17665-1	Sterilization of healthcare products-Moist heat-Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
AAMI TIR12	Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
ANSI/AAMI ST98	Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices
ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ASTM F1980	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F2096	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F88	Standard Test Method for Seal Strength of Flexible Barrier Materials
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
IEC 62304	Medical device software – Software life cycle process
ASTM F2554	Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems

Electromagnetic (EM) Emissions

The device has been designed for use in an electromagnetic environment such as specified below. The user must ensure that it operates in this type of environment.

Guidance and manufacturer's declaration – electromagnetic emissions

The MR Surgical Solutions LLC OptiVu™ Shoulder is intended for use in the electromagnetic environment specified below. The customer or the user of the MR Surgical Solutions LLC OptiVu™ Shoulder should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The MR Surgical Solutions LLC OptiVu™ Shoulder 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 MR Surgical Solutions LLC OptiVu™ Shoulder is suit-able for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power sup-ply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the opera-tion of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the MR Surgical Solutions LLC OptiVu™ Shoulder or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations IEC 61000-3-3	Complies	

Reference	Performance Specification	If Lost or Degraded due to EM Disturbances
Essential Performance 1	Indication of Tool Tracking	Tracking is Lost
Essential Performance 2	Sequential Tracker Identification	Software Does Not Proceed

Using Signature Vision with other products or components unless such other products or components are expressly recognized as compatible with Signature Vision could affect basic safety and essential performance in terms of EM disturbances.

Electromagnetic and Magnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The MR Surgical Solutions LLC OptiVu™ Shoulder is intended for use in the electromagnetic environment specified below. The customer or the user of the MR Surgical Solutions LLC OptiVu™ Shoulder should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1kV live to neutral	±1kV live to neutral	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % *U*T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0° 0 % *U*T; 250/300 cycle	0 % *U*T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0° 0 % *U*T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MR Surgical Solutions LLC OptiVu™ Shoulder requires continued operation during power mains interruptions, it is recommended that the MR Surgical Solutions LLC OptiVu™ Shoulder be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The MR Surgical Solutions LLC OptiVu™ Shoulder is intended for use in the electromagnetic environment specified below. The customer or the user of the MR Surgical Solutions LLC OptiVu™ Shoulder should ensure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 Vrms
0,15 MHz – 80 MHz

6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80.0 MHz
80 % AM at 1 kHz

3 V/m
80 MHz to 2.7 GHz</td><td>3 Vrms
0,15 MHz – 80 MHz

6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80.0 MHz
80 % AM at 1 kHz

3 V/m
80 MHz to 2.7 GHz</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the MR Surgical Solutions LLC OptiVu™ Shoulder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance:

$d = [3.5/10] \sqrt{P}$ 80 MHz to 800 MHz
$d = [7/10] \sqrt{P}$ 800 MHz to 2.7 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, 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.</td></tr>
<tr><td colspan="4">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 MR Surgical Solutions LLC OptiVu™ Shoulder is used exceeds the applicable RF compliance level above, the MR Surgical Solutions LLC OptiVu™ Shoulder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MR Surgical Solutions LLC OptiVu™ Shoulder.</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity							
The MR Surgical Solutions LLC OptiVu™ Shoulder is intended for use in the electromagnetic environment specified below. The customer or the user of the MR Surgical Solutions LLC OptiVu™ Shoulder should ensure that it is used in such an environment.							
Immunity test	IEC 60601 test level			Compliance level			Electromagnetic environment - guidance
IMMUNITY to proximity fields from RF wireless communications equipment IMMUNITY to proximity magnetic fields IEC 61000-4-39	MHz 385 450 710 745 780 810 870 930 1720 1845 1970 2450 5240 5500 5785 0.1342 13.56 0.030	Modulation 18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 18 Hz 18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 2.1kHz 50kHz CW	Field Strength 27 V/m 28 V/m 9 V/m 9 V/m 9 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 9 V/m 9 V/m 9 V/m 65 A/m 7.5 A/m 8 A/m	MHz 385 450 710 745 780 810 870 930 1720 1845 1970 2450 5240 5500 5785 0.1342 13.56 0.030	Modulation 18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 18 Hz 18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 2.1kHz 50kHz CW	Field Strength 27 V/m 28 V/m 9 V/m 9 V/m 9 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 9 V/m 9 V/m 9 V/m 65 A/m 7.5 A/m 8 A/m	Portable and mobile RF communi-cations equipment should be used no closer to any part of the MR Surgical Solutions LLC OptiVu™ Shoulder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $E = [6/d] \sqrt{P}$ $d = [6/E] \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manu-facturer, d is the recommended separation distance in meters (m), and E is the field strength in V/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: 
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.							

Portable and Mobile Radiofrequency (RF) and RF Wireless Communication Equipment

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the MR Surgical Solutions LLC OptiVu™ Shoulder.

The MR Surgical Solutions LLC OptiVu™ Shoulder is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MR Surgical Solutions LLC OptiVu™ Shoulder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MR Surgical Solutions LLC OptiVu™ Shoulder 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)			
	80 to 800 MHz $d = [3.5/3] \sqrt{P}$	800 MHz to 2.7 GHz $d = [7/3] \sqrt{P}$	710, 745, 780, 5240, 5500, 5785 MHz $d = [6/9] \sqrt{P}$	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 MHz $d = [6/28] \sqrt{P}$
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143

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 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.

Complaint Handling and Customer Support

Any healthcare professional (e.g., customer or user) who has a complaint or who has experienced any dissatisfaction in the product quality, durability, reliability, safety, effectiveness, and/or performance should notify MR Surgical Solutions:

MR Surgical Solutions, LLC
Bubenbergstrasse 1, 3rd Floor
8045 Zurich - CH

When reporting a complaint, please provide the unique identification number (UDI) or the lot number, your name and phone number, and the nature of the problem.

Copyrights and Trademarks

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Regulatory Device Name

The FDA-cleared medical device officially designated as OptiVu™ Shoulder is commercially distributed under the marketing name Signature™ Vision by Zimmer Biomet.