OpenSight™

User Manual

OpenSight® User Manual – July 1, 2019—Version 1.8706
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Warnings and Cautions

This symbol indicates the need for the user to consult the instructions for use.

This symbol indicates important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

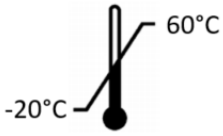
This symbol denotes the manufacturer.

This symbol denotes the manufacturer's European Community representative.

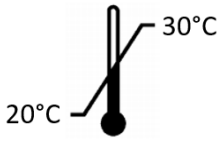
This symbol indicates DO NOT THROW IN TRASH.

This symbol denotes Class II power supply.

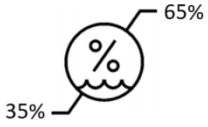
This symbol indicates equipment power on/off.



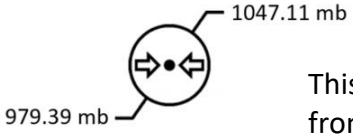
This symbol indicates the transport temperature: from -20°C to 60°C



This symbol indicates the storage temperature: from 20°C to 30°C



This symbol indicates the transport and storage humidity limits: from 35% to 65%



This symbol indicates the transport and storage barometric pressure limits: from 979.39 mb to 1047.11 mb

Medical Device

⚠ **Intended Use:**
OpenSight is intended to enable users to display, manipulate, and evaluate 2D, 3D, and 4D digital images acquired from CR, DX, CT, MR, and PT sources. It is intended to visualize 3D imaging holograms of the patient, on the patient, for pre-operative localization and pre-operative planning of surgical options. OpenSight is designed for use only with performance-tested hardware specified in the user documentation.

OpenSight is intended to enable users to segment previously acquired 3D datasets, overlay, and register these 3D segmented datasets with the same anatomy of the patient in order to support pre-operative analysis.

OpenSight is not intended for intraoperative use. It is not to be used for stereotactic procedures.

OpenSight is intended for use by trained healthcare professionals, including surgeons, radiologists, chiropractors, physicians, cardiologists, technologists, and medical educators. The device assists doctors to better understand anatomy and pathology of patient.

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

Serious Incidents:
Any serious incident that has occurred in relation to OpenSight medical device should be reported to Novarad and the competent authority of the Member State in which the user and/or patient is established.

Installation Instructions:
Software installation is the responsibility of Novarad Technical Services. The user will be directed by Novarad Technical Services if their assistance is required.
OpenSight is only intended for use with hardware that meets or exceeds minimum performance requirements and satisfies current safety and applicable regulations.

Maintenance/Upgrade Procedures:
Maintenance, upgrades, and warranty replacements are the responsibility of Novarad Technical Services and the Original Equipment Manufacturer (OEM). The user will be directed by Novarad Technical Services if their assistance is required.

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

Overview:

Technical Specifications	
Wireless Signal Type	802.11ac-capable, 2x2 Wi-Fi radio
Frequency Band	5.15 - 5.25 GHz
Network Security Protocol	256 bit AES Encryption TLS 1.1 or above
Network Communication Connectivity	TCPIP Network DHCP Client Support TCP/443 outbound to Microsoft windows update servers TCP/443 outbound to the NovaPACS servers TCP/UDP53 outbound to DHCP assigned DNS server
Frame Rate / System Latency	60 fps with 1 frame latency
Maximum Range	The effective range may vary depending upon the environment in which the product is operating. See Performance section below for instructions to achieve optimum performance and range.
Operating Temperature	50°F to 80°F (10°C to 27°C)
Operating Humidity	35% to 65% RH
Operating Barometric Pressure	979.39 mb to 1047.11 mb (734.6 mmHg to 785.4 mmHg)
Storage Temperature	68°F to 86°F (20°C to 30°C)
Transport Temperature	-4°F to 140°F (-20°C to 60°C)
Transport and Storage Humidity	35% to 65% RH
Transport and Storage Barometric Pressure	979.39 mb to 1047.11 mb (734.6 mmHg to 785.4 mmHg)

Performance Tested Hardware:

OpenSight supports the following third-party hardware specifications:

- Microsoft HoloLens version 1.0 and above

Feature	Microsoft HoloLens 1.0 Specification, Model Number 1688
Display	See-through holographic lenses (waveguides) 2x HD 16:9 light engines Automatic pupillary distance calibration

	2.3M total light points holographic resolution, 2.5k light points per radian
Sensors	Inertial Measurement Unit, 4x environment understanding cameras, mixed reality capture, 4x microphones, and ambient light sensor.
Processor	Custom Microsoft Holographic Processing Unit HPU 1.0, Intel 32-bit architecture
RAM	2GB
Storage	64GB
Weight	579g (1.2lbs)
Camera	2MP photos, HD video
Audio	External speakers, 3.5mm audio jack
Connectivity	Wi-Fi 802.11ac, Bluetooth 4.1 LE, Micro-USB 2.0
Power	2-3 hour active use battery life of continuous operation, 2 weeks standby, passive cooling
Power Supply Unit	Microsoft model 1751
OS	Windows 10 with Windows Store Human Understanding: spatial sound, gaze tracking, gesture input, voice support

Feature	Microsoft HoloLens 2 Specification, Model Number 1855
Display	See-through holographic lenses (waveguides) 2x 3:2 light engines >2.5k radiants (light points per radian) Display optimization for 3D eye position

Sensors	Head tracking – 4 visible light cameras Eye tracking – 2 Infrared (IR) cameras Depth – 1-MP Time-of-Flight depth sensor Inertial measurement unit (IMU) – Accelerometer, gyroscope, magnetometer Camera – 8-MP stills, 1080p30 video
Compute and connectivity	System on chip – Qualcomm Snapdragon 850 Compute Platform Holographic processing unit – Second generation custom built holographic processing unit Memory – 4-GB LPDDR4x system DRAM Storage – 64-GB UFS 2.1 WiFi – 802.11ac 2x2 Bluetooth – 5.0 USB Type-C
Fit	Weight – 566 grams (1.2lbs) Sizing – Single size with adjustable band. Fits over eyeglasses
Audio	Microphone array – 5 channels Speakers – Built-in spatial sound
Power	Battery Life - 2-3 hour of active use. Up to 2 weeks standby time. Battery technology – Lithium batteries Charging behavior – Fully functional when charging Cooling type – Passively cooled (no fans) Power draw – In order to maintain/advance Internal Battery Charge Percentage while the device is on, it must be connected minimum to a 15W charger.
Power Supply Unit	Microsoft model 1847
Pre-installed software	Windows Holographic Operating System Microsoft Edge Dynamics 365 Remote Assist Dynamics 365 Layout Dynamics 365 Guides 3D Viewer OneDrive for Business HoloLens Tips Cortana

Power Supply Unit:
Disconnect the power supply from the AC mains. The power supply is the only recognized disconnect device.

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

Performance:

OpenSight is intended for use in hospitals, clinics, procedure rooms, and classroom environments.

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

1. Access point range and signal strength maximization:
   Wireless performance depends on a number of factors, making a definitive range hard to predict. For example, the type and thickness of walls can impact the range of your network; fewer walls or floors are better, or uninsulated drywall is better than concrete. Deployments will also be affected by radio frequency interference. Cordless phones, microwave ovens, and neighboring wireless access points are common sources of interference.
   To get the most from your equipment:
   - Try moving access points to see if speed improves. Avoid placing access points near devices that emit radio interference.

IT-Network:

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

- Image data from the server to the device

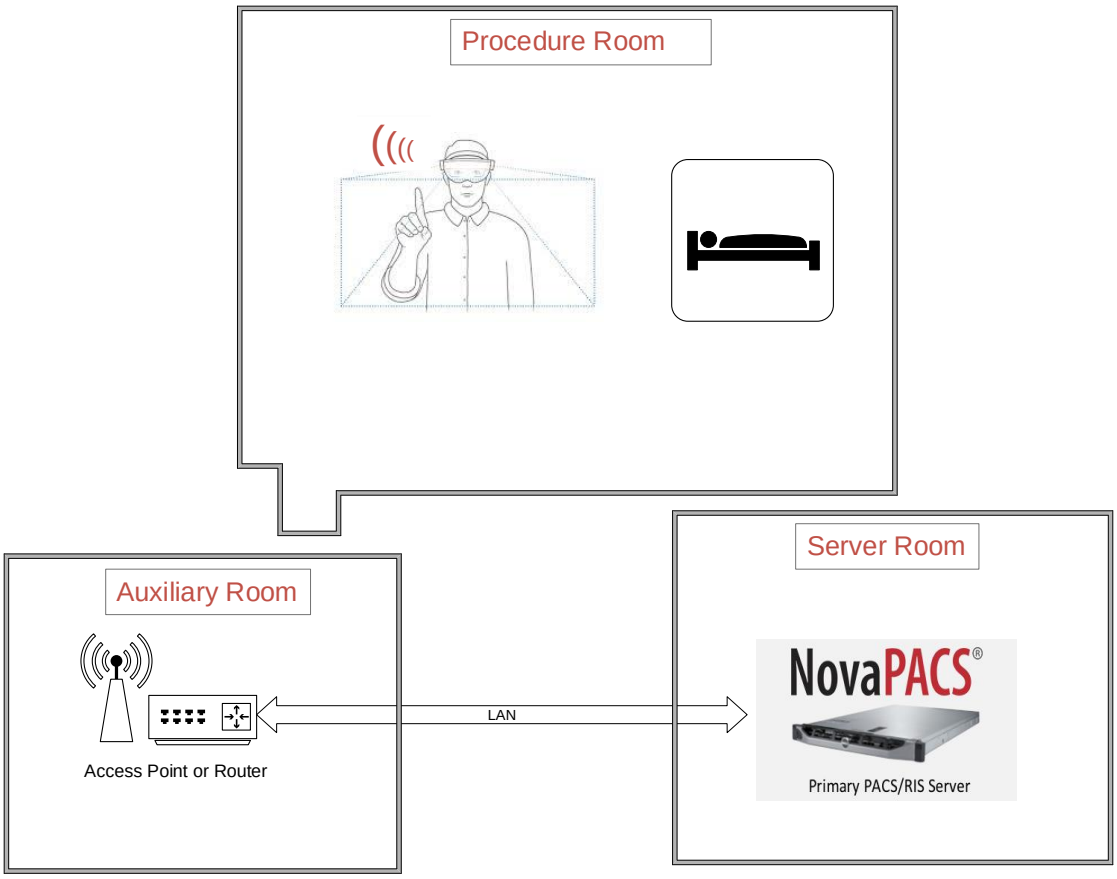
Note: There is no streaming from the server to the OpenSight headset, just the initial transfer of image data, after that there is no communication with the server.

IT-Network Characteristics:

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

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

Typical Installation



In most situations, the Server Room and access point locations are separate from the Procedure Room. One NovaPACS server is deployed per site. There are no restrictions on the number of OpenSight headsets a site can have.
In instances where there is not sufficient Wi-Fi to the Procedure Room, the images can be "cached" on the OpenSight headset.

Avoiding Co-Existence Interference
OpenSight deployment is a typically one server per site. There are no restrictions on number of OpenSight headsets.

Troubleshooting HoloLens and Holograms:

Problem	Possible Causes/Remedial Action
HoloLens if unresponsive, is not running well, or will not start.	Restart your HoloLens: Press the power button for 4 seconds, until all of the battery indicators fade out. Wait 1 minute, and then press the power button again to turn on the device. If that does not work, force restart the device. Hold down the power button for 10 seconds. Release it and wait 30 seconds, then press the power button again to turn on the device. If restarting your HoloLens does not help, another option is to reset or recover your HoloLens. Refer to Microsoft support for instructions.
My Holograms don't look right or are moving around (for example, they're jittery or shaky, or you see black patches on top of them)	• Clean your device visor and make sure nothing is blocking the sensors. • Try walking around and gazing at your surroundings so HoloLens can scan them more completely. • If you have placed a lot of holograms, try removing some. If you are still having problems, run the HoloLens device utility apps to make sure your device is properly adjusted. • **Calibration app.** Try this one first. It calibrates your HoloLens just for you, to help keep your holograms looking their best. Go to **Settings** > **System** > **Utilities**. Under Calibration, select **Open Calibration**. • **Sensor Tuning app**. If you have run the Calibration app and you are still having trouble, use the Sensor Tuning app to tune your device sensors. Go to **Settings** > **System** > **Utilities**. Under Sensor tuning, select **Open Sensor Tuning**.
I see messages that say Trying to map your surroundings and Use in limited mode.	When HoloLens is learning or loading a space, you might see a brief message that says Trying to map your surroundings. If this message continues for more than a few seconds, or you see a **Use in limited mode** button, it means HoloLens is having trouble mapping the space. If you use HoloLens in limited mode, you will be able to open apps but you will not be able to place holograms in your environment. Once HoloLens can map your space again, you will be able to return to normal mode. If you see these messages often, try the following: • Make sure your device visor is clean. • Make sure you have a strong Wi-Fi signal. If you enter a new environment that has no Wi-Fi or a weak signal, HoloLens will not be able to create a space for it. If you are in a space you have already

	saved and are having problems with Wi-Fi, load the space manually by going to **Settings > System** > **Spaces**. • If you move around too quickly, HoloLens might enter limited mode. Try moving more slowly. • If you have still having problems, run the Sensor Tuning app. Go to **Settings > System** > **Utilities**. Under Sensor tuning, select **Open Sensor Tuning**.
I am not seeing the holograms I expect to see in my space.	If you don't see holograms you placed, or you're seeing some you don't expect, try the following: • If your HoloLens is in limited mode, try turning on some lights. If that does not help, use the Sensor Tuning app to tune the device sensors. Go to **Settings > System** > **Utilities**. Under Sensor tuning, select **Open Sensor Tuning**. • Make sure the right space is loaded in **Settings > System** > **Spaces**. If it is not, select the correct space and then select **Load**. • If the correct space is loaded and you are still having problems, you might need to delete the space and recreate it. This will remove all holograms for the space. (Apps will not be removed, but their data for the space will be deleted.) Go to **Settings > System** >**Spaces** and select the space. Then select **Remove** > **Remove** and restart your HoloLens it will recreate the space. Note: If the layout or lighting in your space changes significantly, your device might have trouble identifying and loading the space.
My HoloLens cannot create a new space.	The most likely problem is that you are running low on storage space. Do one or more of the following to free up space, then try again: • Delete unused spaces. Go to **Settings** > **System** > **Spaces**, select a space you no longer need, and then select **Remove**. • Remove some of the holograms you have placed, or remove some saved data from within apps. • Delete some pictures and videos in the Photos app. This will also delete them from OneDrive. • Uninstall some apps from your HoloLens. In the All apps list, tap and hold the app you want to uninstall and then select **Uninstall**. (This will also delete any of that apps data from the device.)
I cannot place holograms where I want.	Here are some things to try if you're having trouble placing holograms: • Stand about 1 to 3 meters from where you are trying to place the hologram. • Do not place holograms on black or reflective surfaces. • Walk around the rooms so HoloLens can rescan your surroundings. To see what has already been scanned, air tap to reveal the mapping mesh graphic.

	• Use the Sensor Tuning app to tune your device sensors. Go to **Settings > System** > **Utilities**. Under Sensor tuning, select **Open Sensor Tuning**.
Apps move toward me when I am trying to place them.	Try walking around and looking at the area where you are placing the app so HoloLens will scan it from different angles. Cleaning your device visor may also help.
HoloLens does not respond to my gestures.	To make sure HoloLens can see your gestures, keep your hand in the gesture frame, which extends a couple of feet on either side of you. HoloLens can also best see your hand when you hold it about 18 inches in front of your body (though you do not have to be precise about this). When HoloLens can see your hand, the cursor will change from a dot to a ring.
I cannot connect to Wi-Fi.	Here are some things to try if you can't connect to Wi-Fi on HoloLens: • Make sure Wi-Fi is turned on. Use Bloom gesture to go to Start, then select **Settings > Network & Internet** > **Wi-Fi** to check. If Wi-Fi is on, try turning it off and on again. • Move closer to the router or access point. • Restart your Wi-Fi router, and then restart HoloLens. Try connecting again. • If none of these things work, check to make sure your router is using the latest firmware. You can find this information on the manufacturer's website.

Troubleshooting HoloLens fit and comfort:

Problem	Possible Causes/Remedial Action
I am experiencing discomfort when I use my device. What should I do?	If you experience discomfort, take a break until you feel better. Try sitting in a well-lit room and relaxing for a bit. The next time your use your HoloLens, try using it for a shorter period of time at first. (see Health and safety on HoloLens)
I cannot see the whole holographic frame, or my holograms are cut off.	To see the top edge of the holographic frame, move the device so it sits higher on your head, or angle the headband up slightly in front. To see the bottom edge, move the device to sit lower on your head, or angle the headband down slightly in front. If the left or right edge of the view frame is not visible, make sure the HoloLens visor is centered on your forehead.
I need to look up or down to see holograms.	Try adjusting the position of your device visor so the holographic frame matches your natural gaze. Here's how: • **If you need to look up to see holograms** – First, shift the back of the headband a bit higher on your head. Then use one hand to hold the headband in place and the other to gently rotate the visor so you have a good view of the holographic frame.

	• **If you need to look down to see holograms** – First, shift the back of the headband a bit lower on your head. Then place your thumbs under the device arms and your index fingers on top of the headband, and gently squeeze with your thumbs to rotate the visor so you have a good view of the holographic frame.
My arm gets tired when I use gestures. What can I do?	When using gestures, there is no need to extend your arm out far from your body. Keep it closer to your side, where it is more comfortable and will get less tired. In addition, be sure to try out voice commands.

Troubleshooting OpenSight Software:

Problem	Possible Causes/Remedial Action
Software malfunctions	1. Restart OpenSight 2. Restart OpenSight Headset
OpenSight application immediately closes	When using gestures, do not perform the bloom gesture while the OpenSight application is running.

CE 2797

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MD OpenSight is a Medical Device

OpenSight is the combination of Microsoft HoloLens and Novarad's medical imaging software to create three-dimensional holograms of scanned images from different modalities including CR, DX, CT, MR, and PT. This combination of augmented reality glasses and imaging software allows the user to see and manipulate hologram images with the swipe of a finger.

OpenSight uses the HoloLens technology to register scanned images over the patient when user has OpenSight headset on and in use. This allows the user to both see the patient and through them, with dynamic holograms of their internal anatomy. OpenSight tools/features include window level, segmentation and rendering, registration, motion correction, virtual tools, alignment, and the capability to measure distance and image intensity values, such as standardized uptake value. OpenSight displays measurement lines, annotations, and regions of interest.

3D Images include but are not limited to tumors, masses, appendices, heart, kidney, bladder, stomach, blood vessels, arteries, and nerves.

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

OpenSight integrates with NovaPACS software.

OpenSight contains wireless technology using Wi-Fi 802.11ac networking standard. The wireless technology is used to stream images in a 2D format from a Novarad server onto the OpenSight headset. Images are actual visible rendered of the object in the OpenSight device with reliable and accurate information. The wireless information transfer is encrypted with 256 encryption for data security.

Users are recommended to install and maintain a firewall configuration for protecting PHI data.

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

The following light level conditions are supported for intended use:

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

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

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

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Microsoft™ HoloLens Description

Novarad's OpenSight software utilizes both Microsoft HoloLens 1 and HoloLens 2 hardware, for more information about Microsoft HoloLens; please see the Microsoft HoloLens site.

Microsoft HoloLens 1

Microsoft HoloLens 2

Adjusting Head Straps:

Microsoft HoloLens 1: The overhead strap can help keep your OpenSight headset secure on your head, particularly if you are moving around a lot. The strap may also let you loosen the headband a bit.

You can also experiment with the positioning of the headband—depending on your head size and shape, you may need to slide it up or down to reposition it on your forehead.

If your OpenSight headset is adjusted correctly, the nose pad should rest lightly on your nose. If it feels heavy on your nose, try rotating the visor up or adjusting the angle of the headband. You can also slide the device visor out—grasp the device arms just behind the visor and pull forward gently.

The device visor can slide in and out to accommodate eyewear. Grasp the device arms just behind the visor and pull forward gently to adjust it.

See hololens.com/support/comfort for more information.

Microsoft HoloLens 2: To put the HoloLens on, use the adjustment wheel to expand the headband. With the HoloLens in place, tighten the adjustment wheel by turning to the right, until the headband is comfortable.

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

⚠ **Warning: Visor Cleaning for Fingerprints and other Marks:**

Keep your device free of dust and fingerprints. Use it with clean hands, and do not touch the visor. Visors that have been scratched, cracked, or contain marks that cannot become clean should not be used. Repeated cleaning could damage the visor, so try to keep your device clean.

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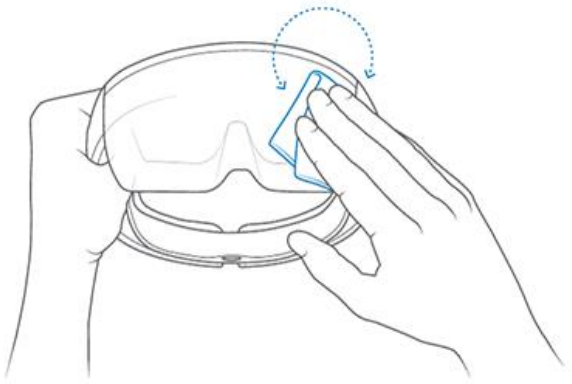
Cleaning the Device:

Handle your OpenSight headset carefully.
For HoloLens 1 use the device arms—not the overhead strap—to lift, carry, and adjust it.
For HoloLens 2 use the headband to lift and carry it.

To keep the visor free of dust and fingerprints, avoid touching it. Repeated cleaning could damage the visor, so try to keep your device clean.
Don't use any cleaners or solvents on your OpenSight headset, and don't submerge it in water or apply water directly to it.
To clean the visor, remove any dust using a camel or goat hair lens brush or a bulb-style lens blower. Lightly moisten the microfiber cloth with a small amount of distilled water, then use it to wipe the visor gently in a circular motion.
Clean the rest of the device, including the headband and device arms, with a lint-free cloth moistened with mild soap and water. Let your headset dry completely before using it again.
See www.hololens.com/support for additional details.



⚠ **Caution: Contamination:**

Cleaning the OpenSight headset as soon as possible after use can help to prevent contamination. Wrapping a disposable cover over the side edges of the outer ring of headset will minimize contamination from handling the device on/off of head.

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

Charging the Device:

OpenSight headset contains an internal rechargeable battery, with average life rated at 2–3 hours of active use or continuous operation, or 2 weeks of standby time. The battery indicator displays the charge level (5 illuminated dots indicates device is fully charged). When only one of the five lights is on, the battery level is below 20 percent.

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To charge the device, plug the power supply unit into the AC mains. Connect the power supply to the charging port using the included USB cable. Then plug the power supply into the AC mains. When the device is charging, the battery indicator will light up in a wave pattern.
After OpenSight headset charge is complete, remove the USB cable from the charging port and remove the power supply from the AC mains.

⚠ **Warning: AC adapter Safety:**
Do not operate the device while AC adapter is plugged into a power outlet. Do not charge the device inside a hospital operating room.
Use only the power supply unit model (see hardware specifications) and AC power cord from Microsoft when charging.
Refer to manufacturer (Attachment B: Microsoft HoloLens Health & Safety) warning regarding AC adapter Safety. It states:
Failure to take the following precautions can result in serious injury or death from electric shock, fire, or damage to the device. To select an appropriate power source for your device:

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

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

⚠ **Caution: Cable and Cord Safety:**
Refer to manufacturer (Attachment B: Microsoft HoloLens Health & Safety) caution regarding Cable and Cord Safety. It states:
Arrange all cables and cords so that people and pets are not likely to trip over or accidentally pull on them as they move around or walk through the area. Do not allow children to play with cables and cords.

To avoid damaging the power cords and power supply:

- *Protect the power cords from being walked on.*

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

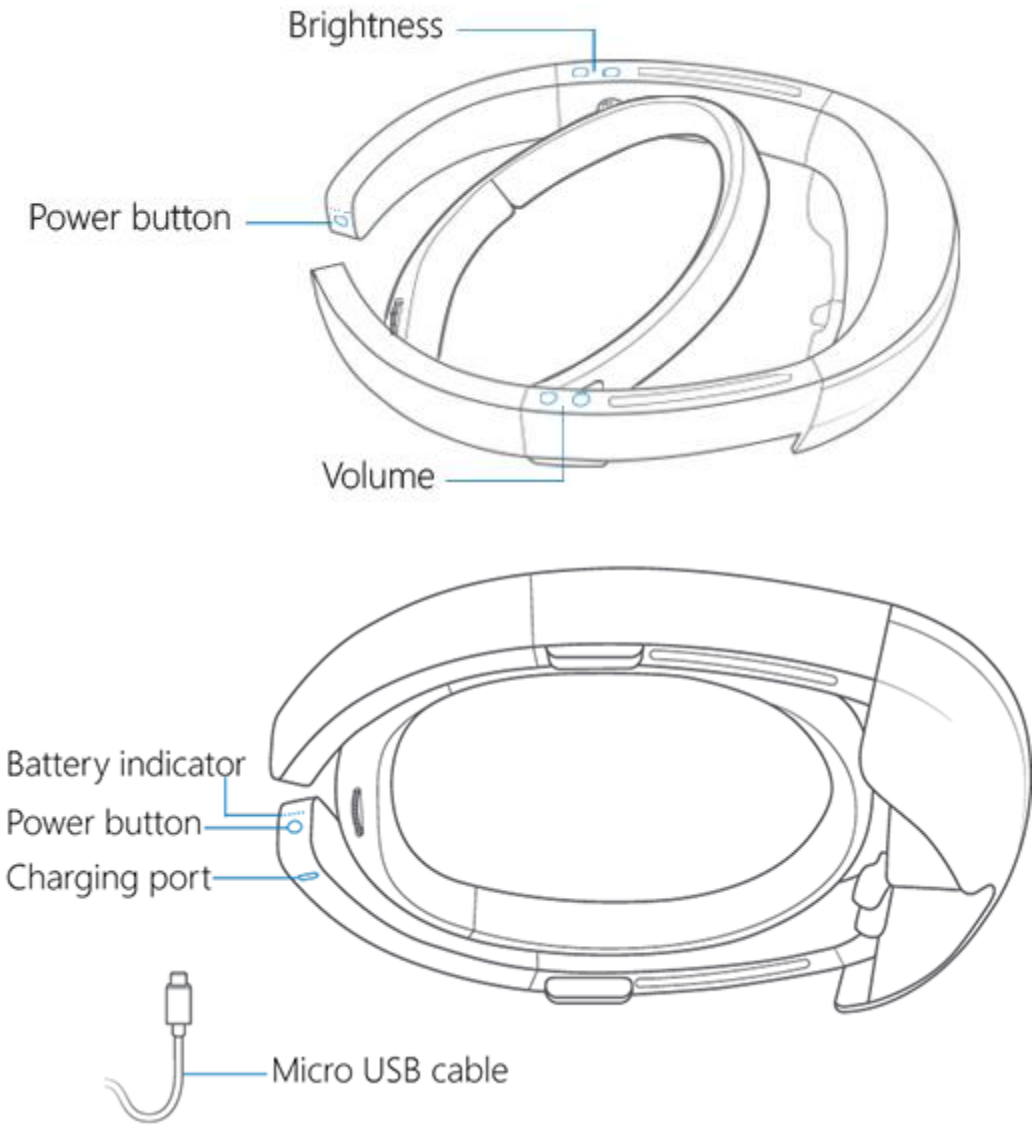
Wireless functions and technology:
The headset features IEEE 802.11ac Wi-Fi and Bluetooth wireless connectivity and a USB receptacle for charging its internal battery. It is an optical device, has 3d sensors, and cameras for detecting the environment. User input is done through hand gestures performed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

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

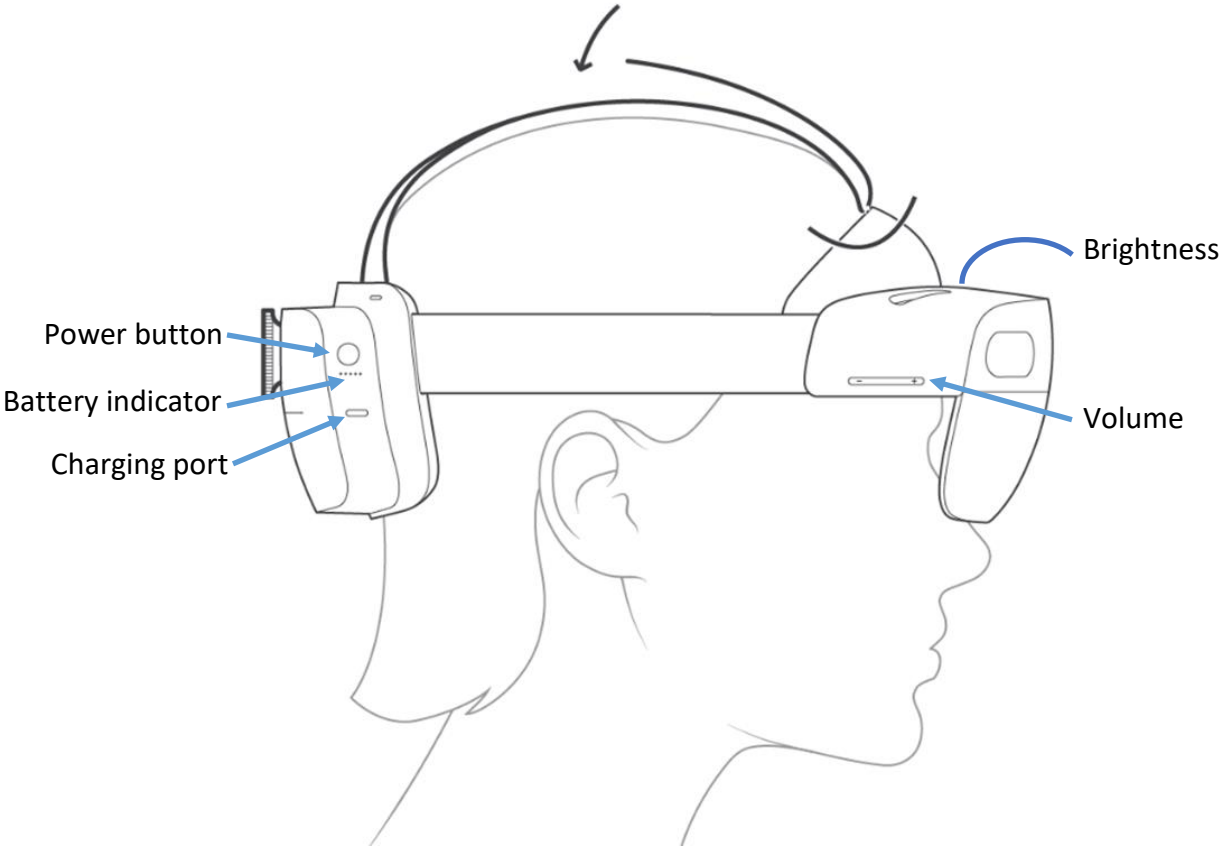
Using the Microsoft HoloLens for OpenSight

Use the power button to turn OpenSight headset on and off.

HoloLens 1:



HoloLens 2:

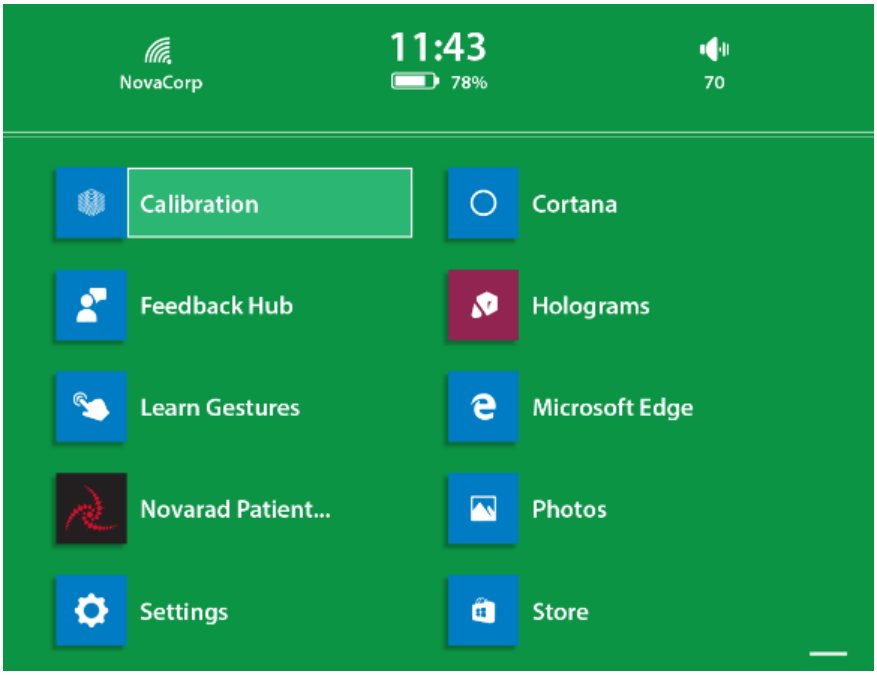

Brightness
Power button
Battery indicator
Charging port
Volume

Part 1: HoloLens 1 Instructions

Note: for HoloLens 2 Instructions see section Part 2: HoloLens 2 Instructions

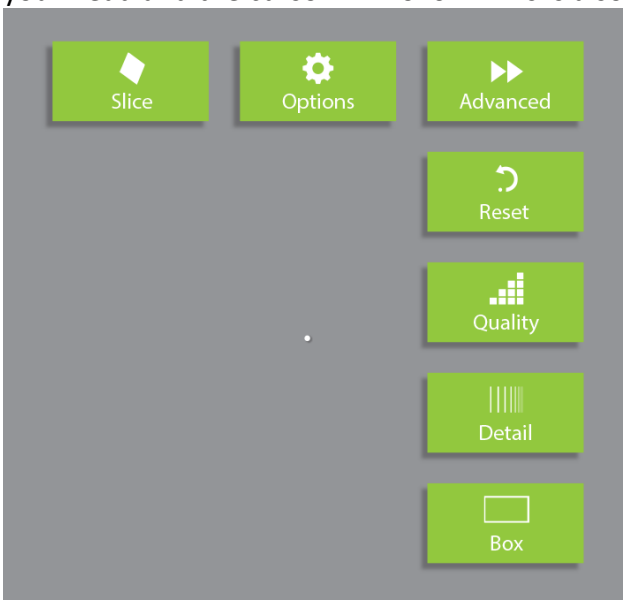
The OpenSight software utilizes functions on the OpenSight headset that will be explained in the subsequent section.

1. **Headset Calibration**
   The headset calibration application is built into HoloLens. For first time use, the user is required to perform calibration using the test pattern provided. The **Calibration** application is found in the **Start** menu of the OpenSight headset.



   Follow the instructions inside the **Calibration** application to properly calibrate the OpenSight headset for optimum viewing.

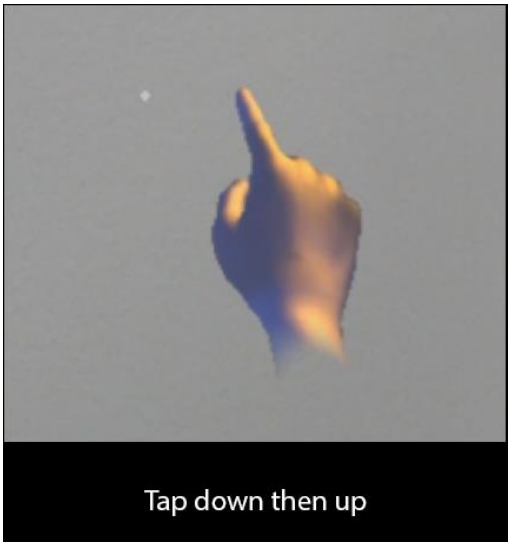
2. **Moving the cursor/Gaze**
   The cursor appears as a dot in the front of your field of vision. To move the cursor, move your head and the cursor will follow. This is also called the "**Gaze**" function.



3. **Ready gesture**

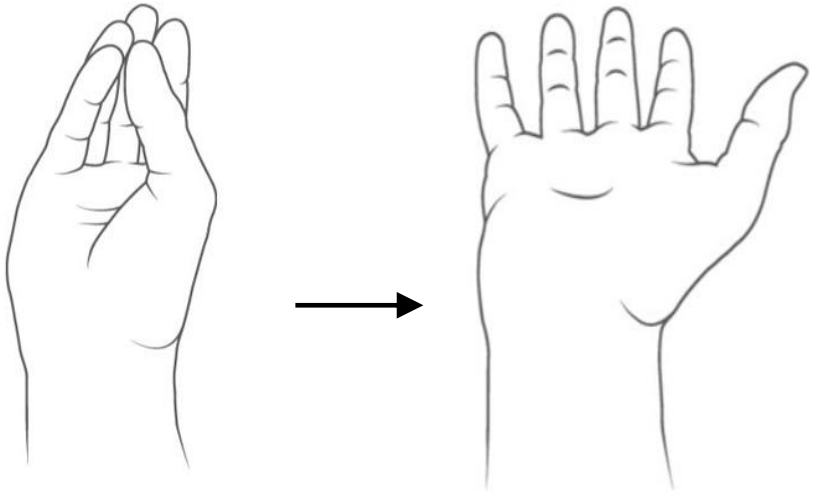
The **Ready** function is executed by raising the pointer finger as shown in the image below. This is visualized inside the OpenSight headset by the cursor turning from a dot to a ring.

4. **Air Tap (or click or select)**
   The **Air Tap** function the users will execute when selecting an option. To select an option from the **Ready** motion – tap down, then up.



5. **Tap-and-Drag**
   The **tap-and-drag** function is executed in a similar fashion as the **Air Tap** - first tap down, then hold the tap down action.

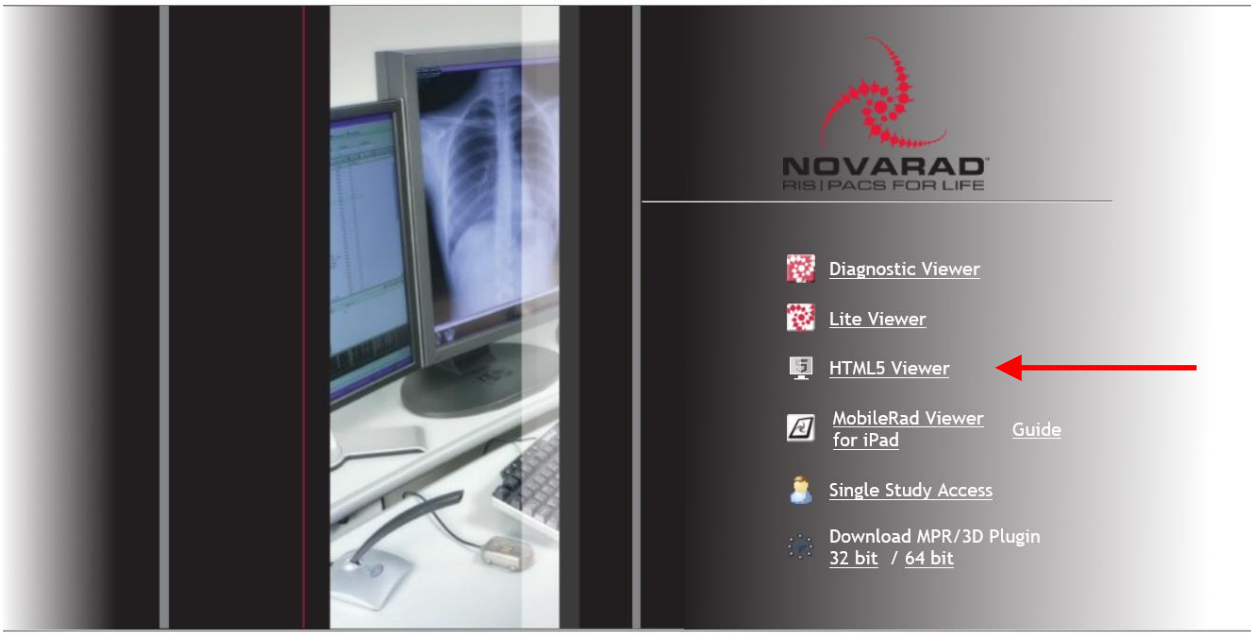
6. **Bloom**
   The **Bloom** function allows users to open or close the Start Menu. To execute the **Bloom** function, hold all five fingers together and release them at the same time in an opening motion.
   If this gesture is done while using the OpenSight application, the OpenSight application will immediately close.



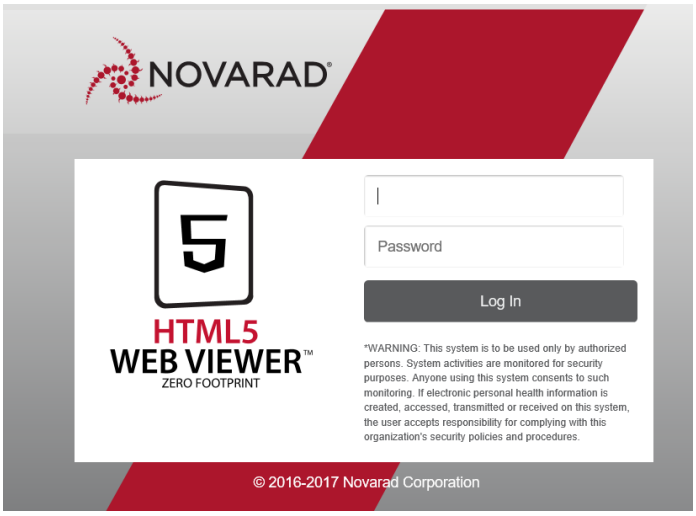
Downloading Studies

To access a patient's study inside the OpenSight:

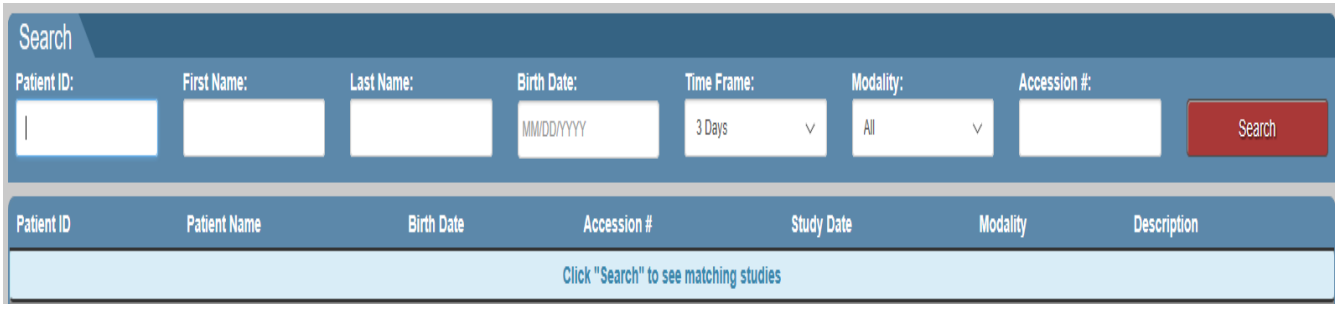
1. Users will need to launch a web browser inside of the OpenSight headset (Microsoft Edge).
2. Enter the URL for the NovaPACS web server in the address bar.
3. Tap on the "HTML 5 Viewer":



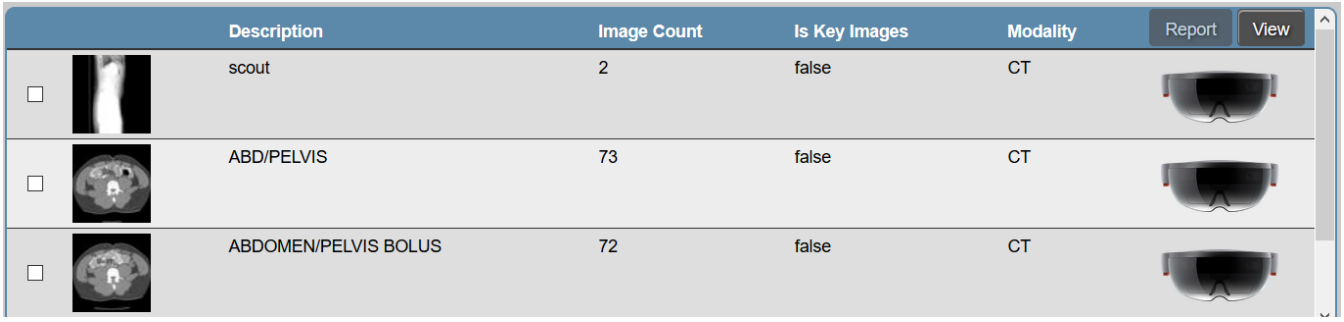
4. Login with a username and password:



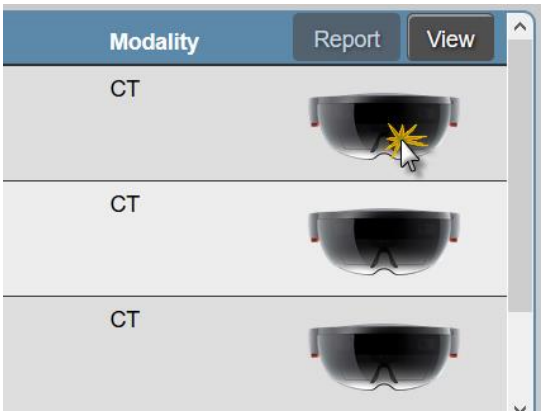
5. Use the “Search” interface to find the patient and study of interest.



6. The preview section will display all the series available for the study.



7. Tap on the headset icon on the right edge of the page to load the desired series in OpenSight.



8. Finally, tap the “Open” button at the bottom of the page. The image will download and OpenSight will launch automatically.

⚠ **Physical Changes between time of scan and OpenSight headset use:**
Conditions of physical changes such as swelling or anatomy that shifts or moves between time of scan and OpenSight headset use may cause inaccurate localization of anatomy. The following is recommended:

1. Patients be in the exact same position and they were in the scanner.
2. Time between scan and OpenSight headset use is under 24 hours.

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

OpenSight displays a warning label within the lenses indicating the elapse time. Elapse time always shows. The warning label will be colored red and bold and includes the words “May be inaccurate” if the time is greater than 24 hours.

Navigation Menu

The **navigational menu** is where users will be able to display, manipulate, and adjust the image or study they see. The subsequent sections will describe how each function works and how to access it.

Color

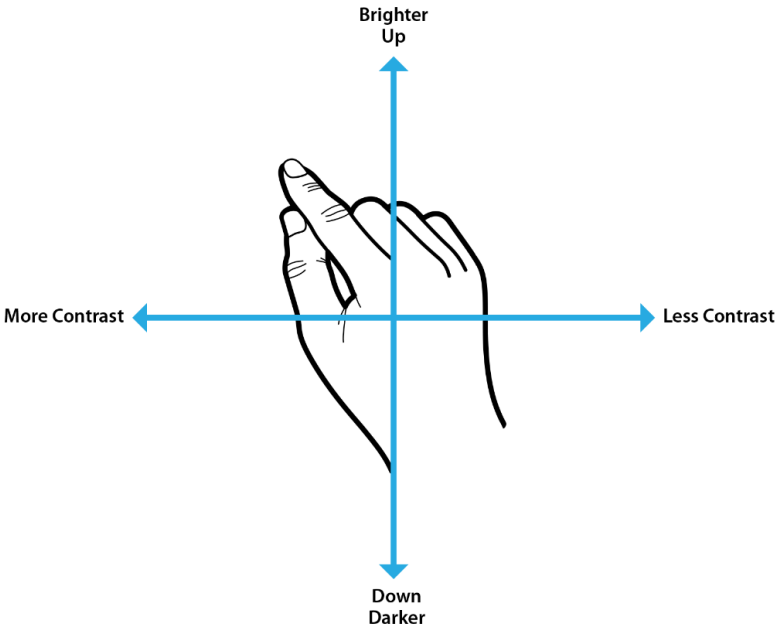
The **color** option inside OpenSight allows users to toggle the color of the image. To adjust the color of an image, Air Tap the Color icon to select it and Tap-and-Drag on the image from left to right to change the color of the image.

Window/Level

The **Window/Level** option allows users to adjust the window and level (brightness and contrast) of the images to their liking.

To adjust the window/level on the image, select the **Window/Level** option inside OpenSight.

Then using your fingers, tap and drag your hand up and down to adjust the level: up increases the brightness and down decreases it. Drag your hand left and right to adjust the window: left increases contrast and right decreases it.

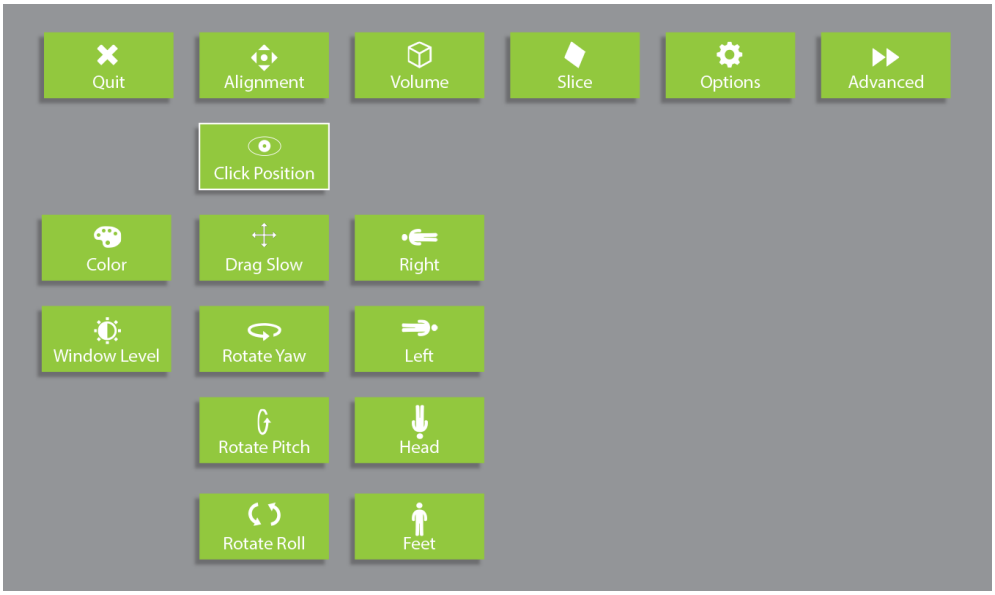


Alignment

The **alignment** option is where users have the ability to move the study 360 degrees around your viewing area along with several other options in order to get the desired angle, yaw, pitch, and roll for optimum viewing.

Tap Position

Tap Position places the image in the center of the users gaze. The images will try to "snap" or "fit" to a surface in front of the user. While looking at the patient, the user then taps his finger to place the images over the patient.



Drag Slow

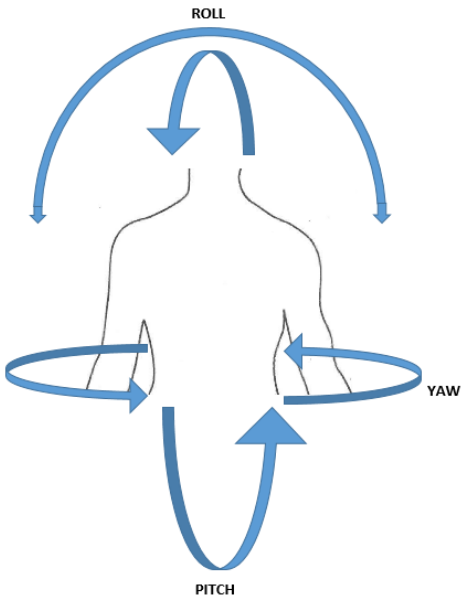
The **Drag Slow** option allows users to tap-and-drag the image up/down and left/right.

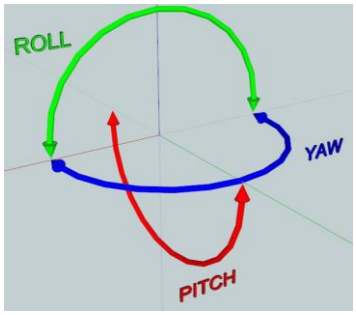
When Automatic Registration is not properly aligned, carefully, manually adjust until proper alignment is achieved.

Rotation

Select one of the rotation commands and use the drag gesture to complete the rotation.

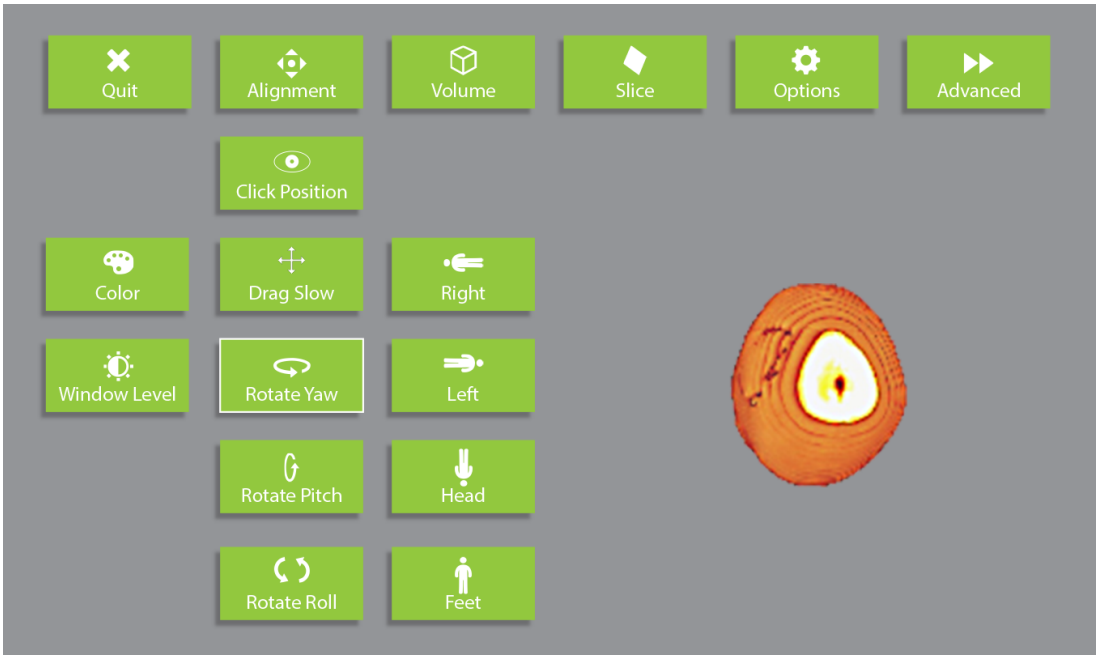
1. Rotate Pitch – rotates the image forwards and backwards from the user's perspective.
2. Rotate Yaw – rotates the images around it's vertical axis (like a top)
3. Rotate Roll – rotates the image around the user's view direction (like a clock)





Rotate Yaw

Rotate Yaw will rotate the image or study along the horizontal (X) axis by tapping and dragging the image with their finger in the direction they wish the image to rotate. Example: If an image of a skull is facing the user and they wish to view the right ear, if the user tap and drags the image to the right, the skull would rotate to the right to reveal the right ear.



Rotate Pitch

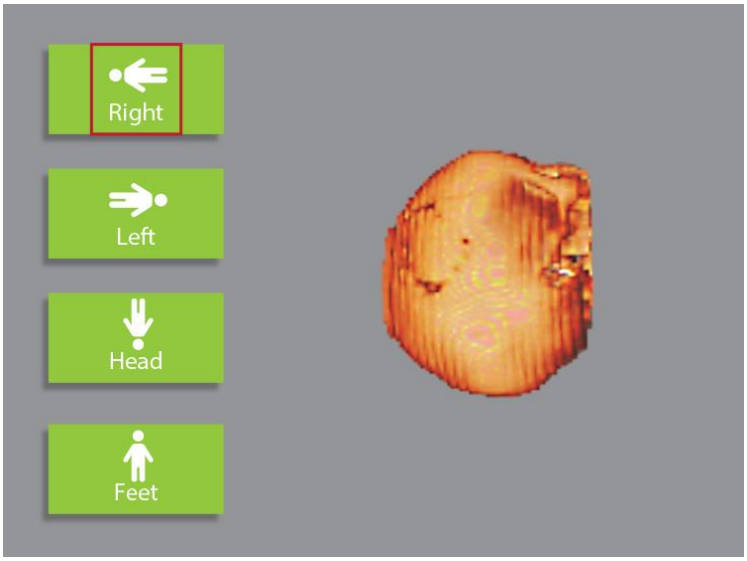
Rotate Pitch will rotate the image on the vertical (Y) axis by tapping and dragging the image with their finger up or down in the direction they wish the image to rotate. Example: If a skull is facing the user, and the user wishes to view the top of the skull, they would select Rotate Pitch, tap and hold the image and drag downwards to reveal the top of the skull.

Rotate Roll

Rotate Roll will rotate the image clockwise or counter-clockwise by having the user tap and drag the image to the left or right depending on which way the user wishes to rotate the image. Example: If a skull is facing the user and the user wishes to view the skull with the jaw facing to the left, the user would tap the skull and drag their finger to the right until the jaw was facing the left.

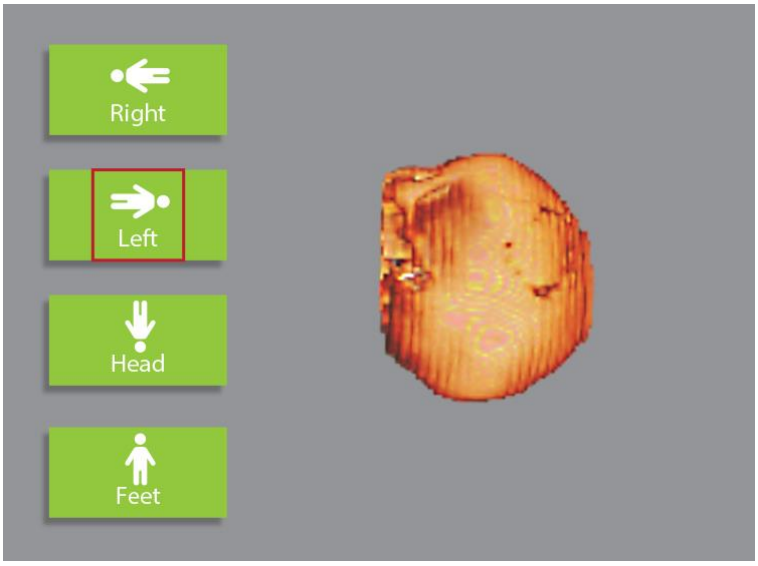
Right

The **Right** function will automatically set the image so that the top of the image is facing up (supine position) patients right is facing toward the user and starting with left moving to the right. Example: If the image is of an entire body, the head will be facing upwards with the body extending to the right.



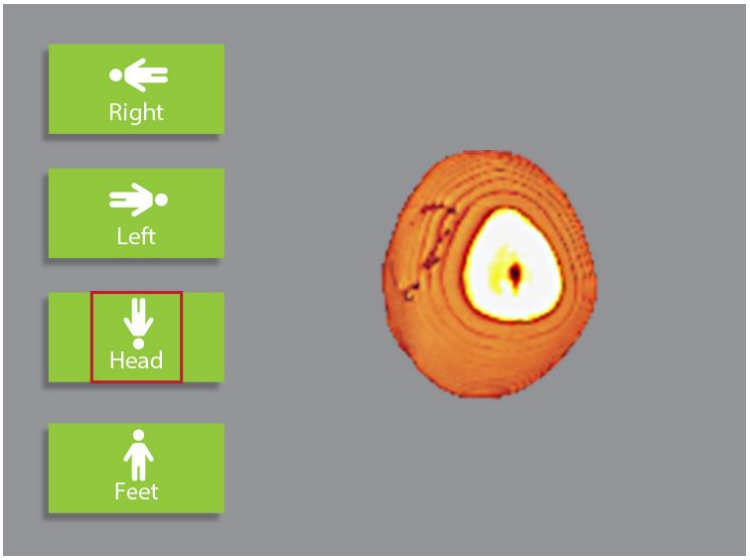
Left

The **Left** function will automatically set the image so that the top of the image is facing up and moving to the left. Example: If the image is of an entire body, the head will be facing upwards with the body extending to the left.



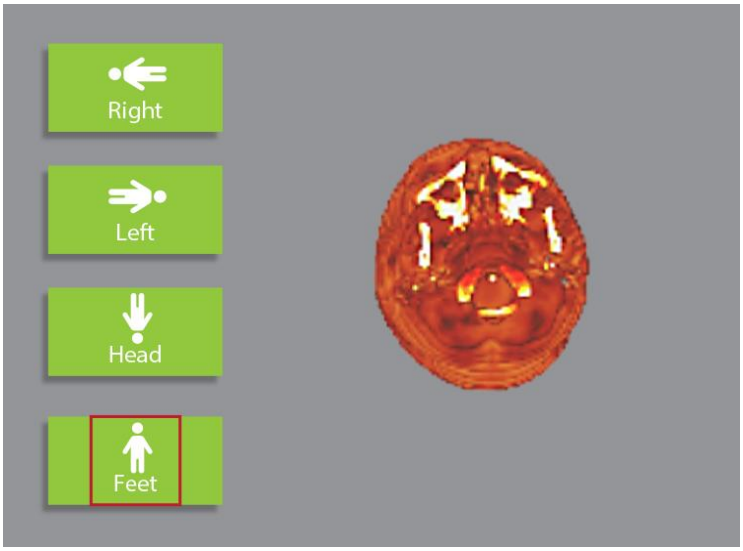
Head

The **Head** function will automatically set the image so that the top of the image facing the user extending away from the users. Example: If the image is of an entire body, the top of the head will be facing the user with the body extending away from the user.



Feet

The **Feet** function will automatically set the image so that the bottom of the image facing the user extending away from the users. Example: If the image is of an entire body, the feet will be facing the user with the body extending away from the user.

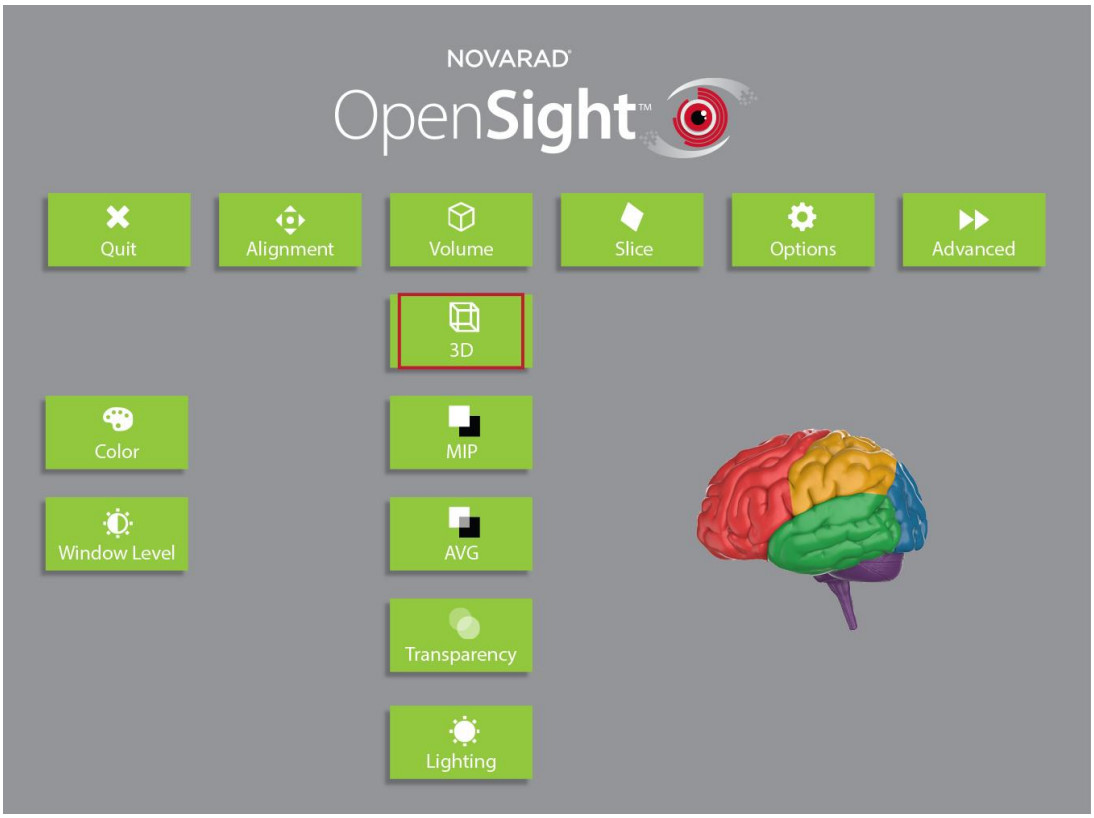


Volume

The **Volume** option allows the user to view the image or study in a full rendered 3D format. The options to adjust the lighting and transparency are also found in the Volume section.

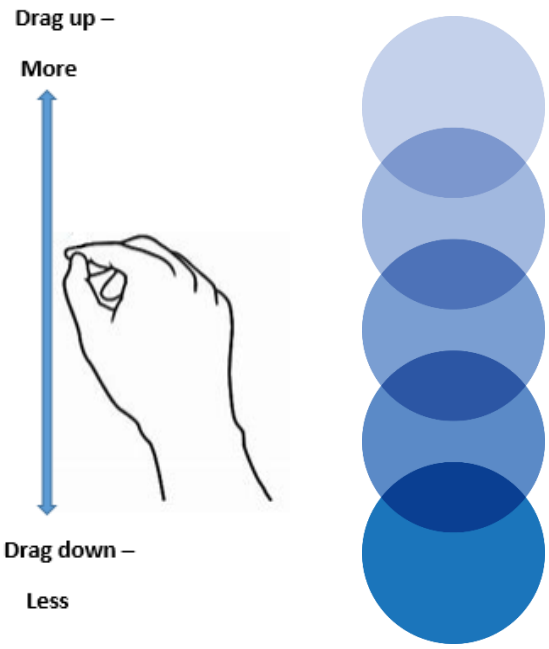
3D

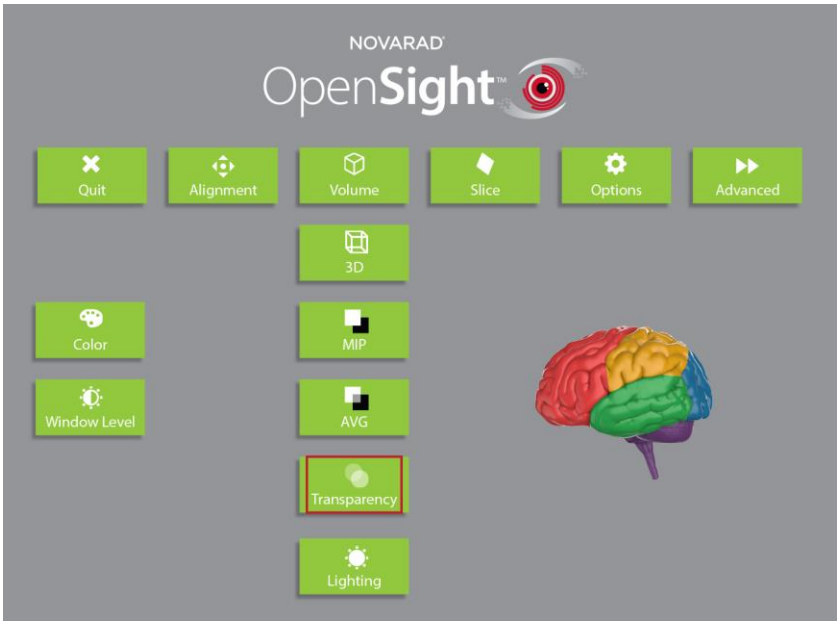
The **3D** option allows users to view the image or study in the full rendered 3D form. The Transparency and Lighting options will only populate while the 3D option is highlighted.



Transparency

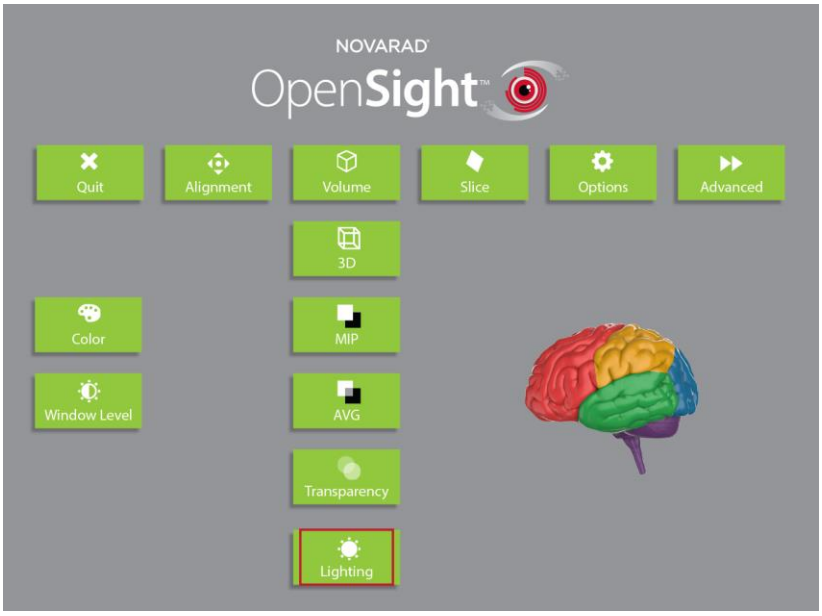
The **Transparency** option allows users to adjust the level of transparency of the image or study by tapping on the image, and while holding the tap, dragging your finger up and down until the image or study is at the lighting level that the user finds ideal. Dragging up makes the image more transparent and down makes it less.





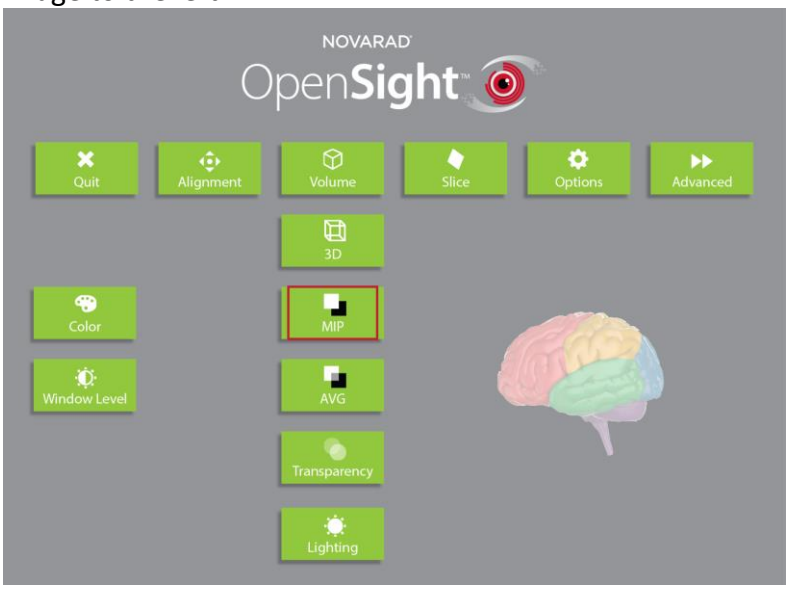
Lighting

The **Lighting** option allows users to obtain lighting for the image. This is a toggle to turn lighting on and off. Lighting looks more realistic, but runs slower.



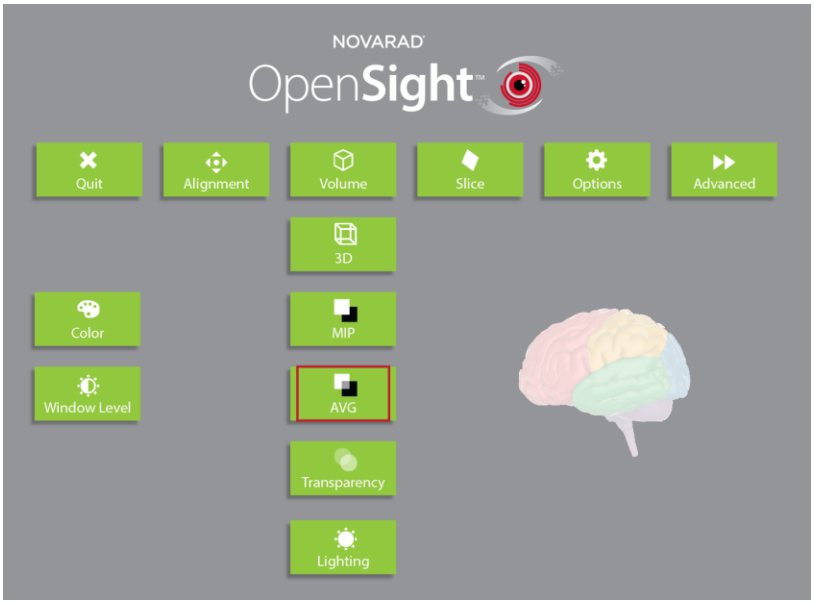
MIP/AVG/3D

MIP/AVG/3D are exclusive modes of volume rendering (only one of these is active). The **MIP** function (Maximum Intensity Projection) allows the user to adjust the MIP settings of the image or study. To increase the MIP, tap-and-drag your finger on the image and drag your finger to the right. To decrease the MIP, tap-and-drag your finger on the image to the left.



AVG

The **AVG** (Average) function allows the user to adjust the AVG value.



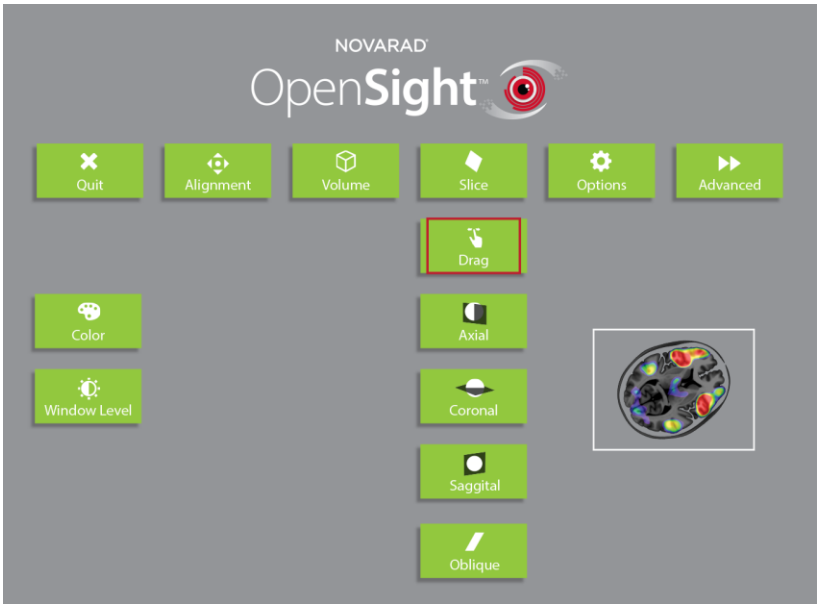
Slice

Slice

The **Slice** functionality allows users to view the study by slice and can be viewed from multiple views including axial, sagittal, coronal, and oblique. After the view is selected, users are able to tap-and-drag along the cube where the slices populate to view the different slices within the image or study.

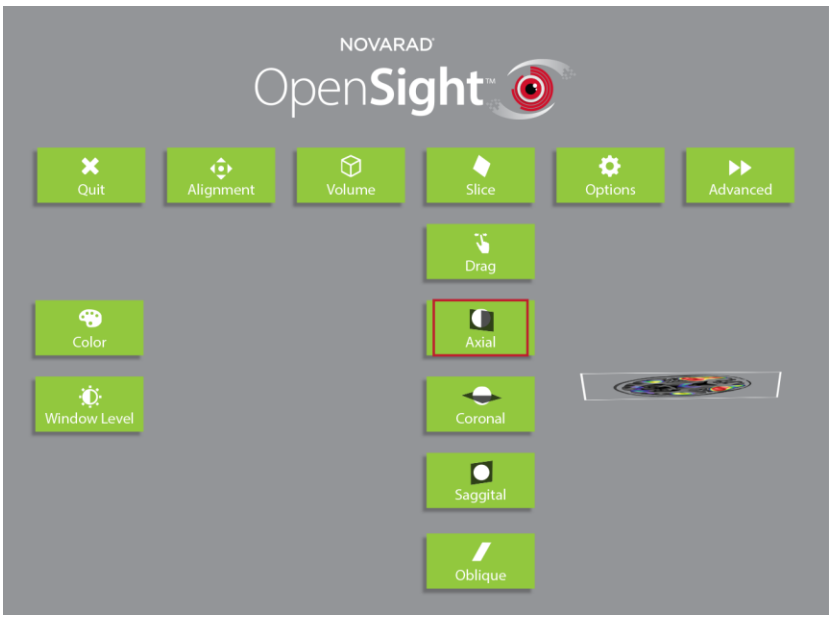
Drag

The **Drag** function allows the users to drag the slice cube to a different area by executing a tap-and-drag function and placing the slice cube in the desired area.



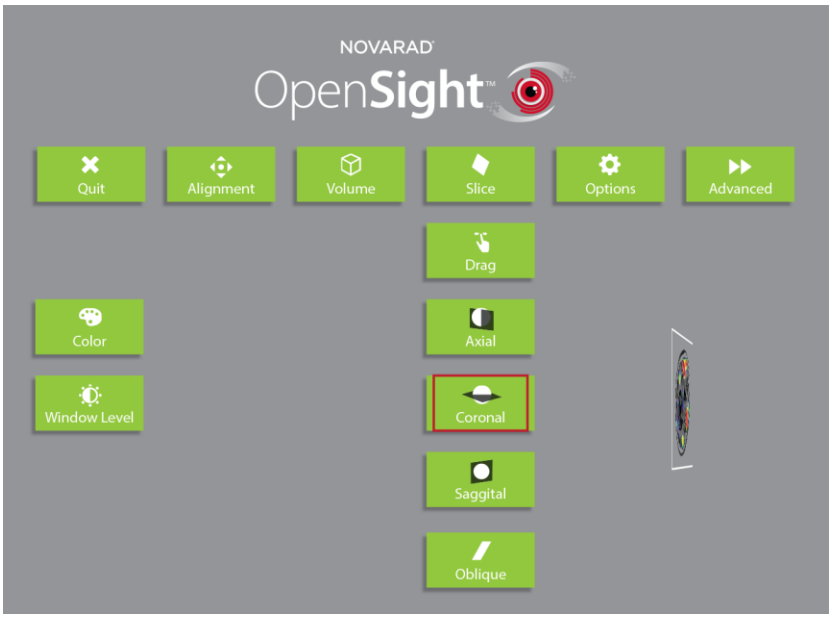
Axial

The **Axial** function allows users to view the study or image by slice location from the axial point of view.



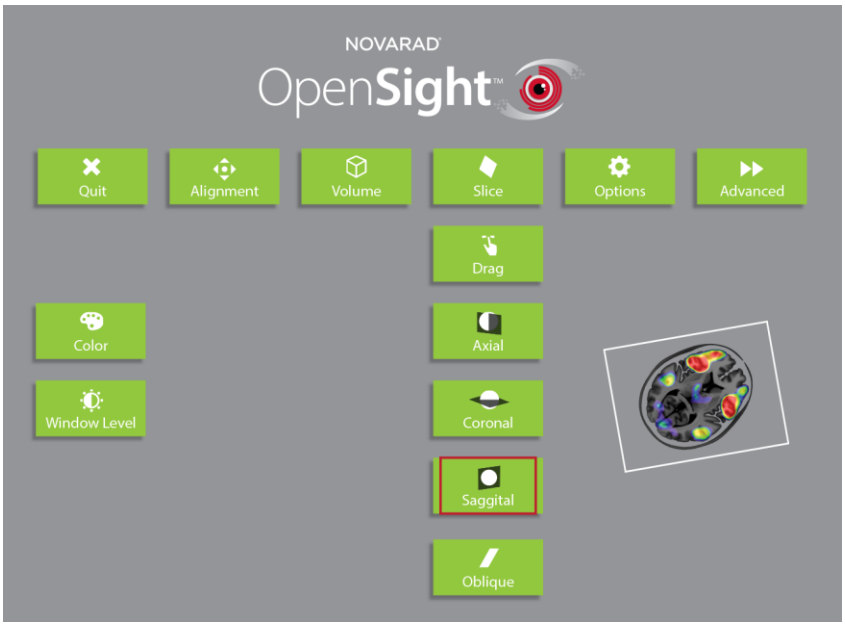
Coronal

The **Coronal** function allows users to view the study or image by slice location from the coronal point of view.



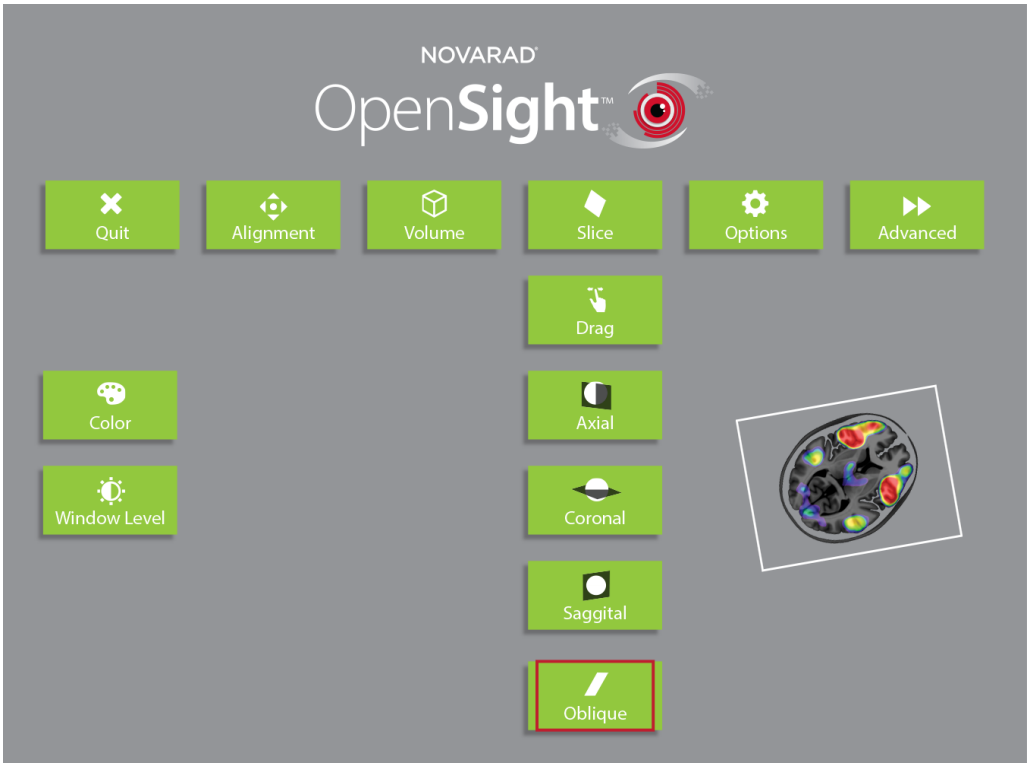
Sagittal

The **Sagittal** function allows users to view the study or image by slice location from the sagittal point of view.



Oblique

The **Oblique** function allows users to view the study or image by slice location from the oblique point of view. The slice auto-rotates to be perpendicular to the viewpoint of the user.



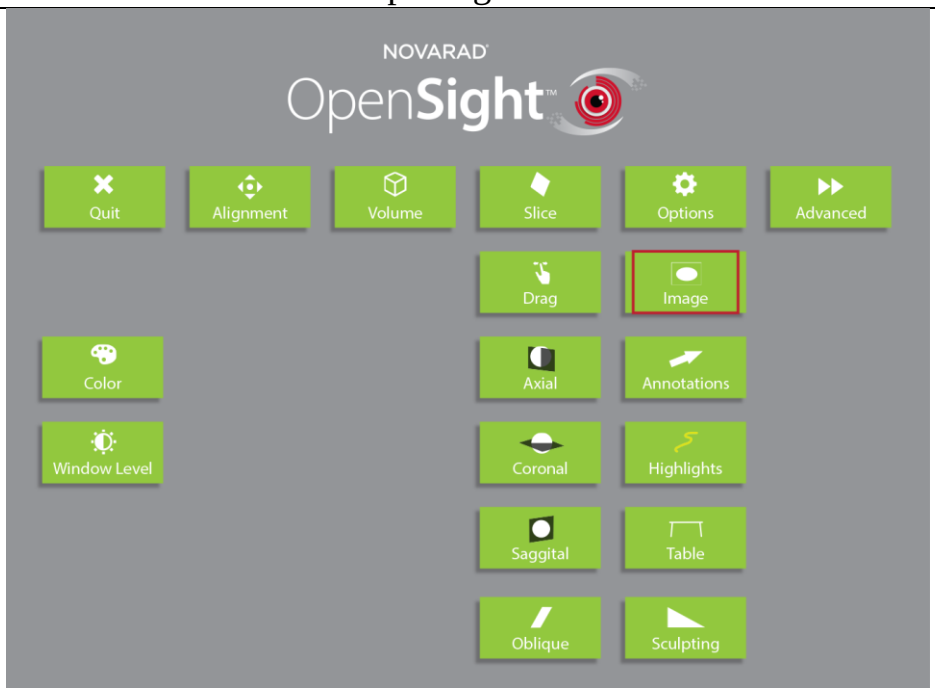
Options

Options

The Options menu allows users to adjust settings to better optimize viewing in the OpenSight software.

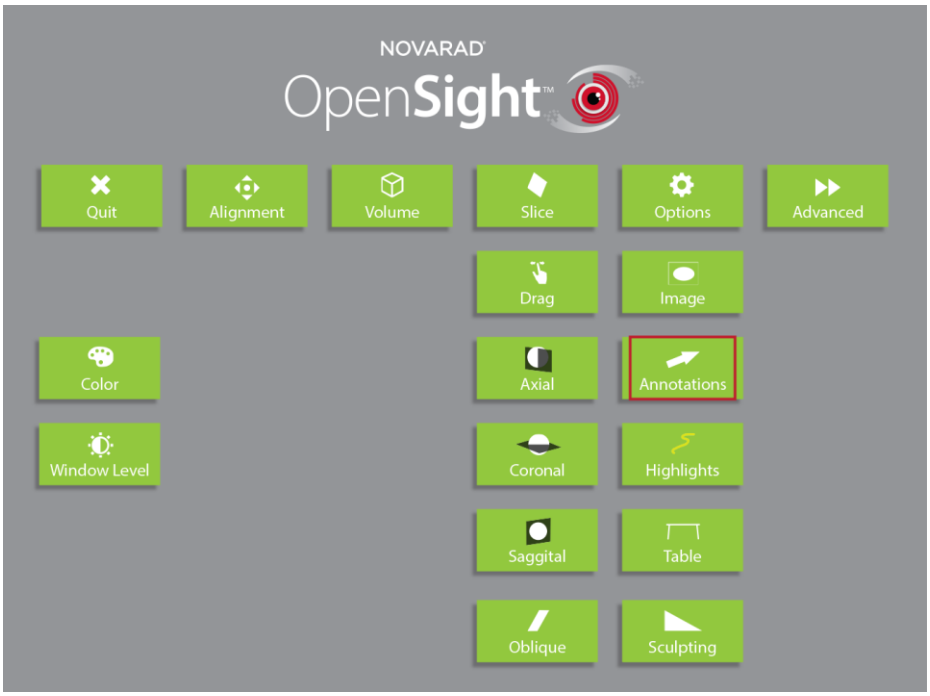
Image

The **Image** function allows users to toggle the image or study showing inside OpenSight. Turning the image off allows the user to see the real-life patient without the virtual image distracting the view.



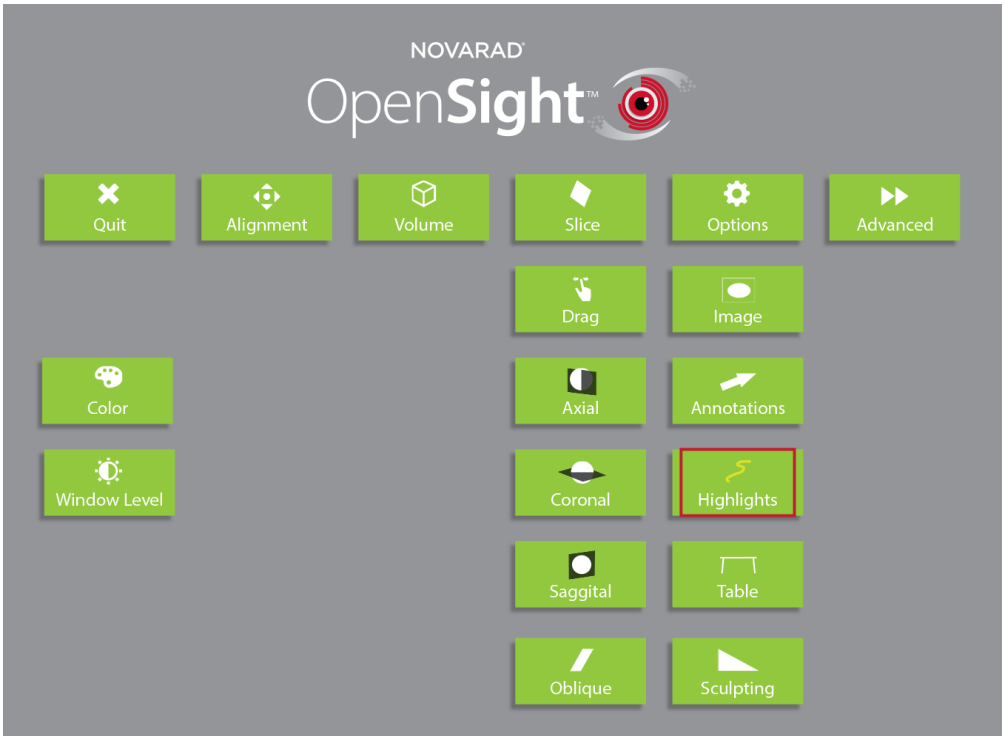
Annotations

The **Annotations** button is present if annotations were created in the study with the PACS viewer.



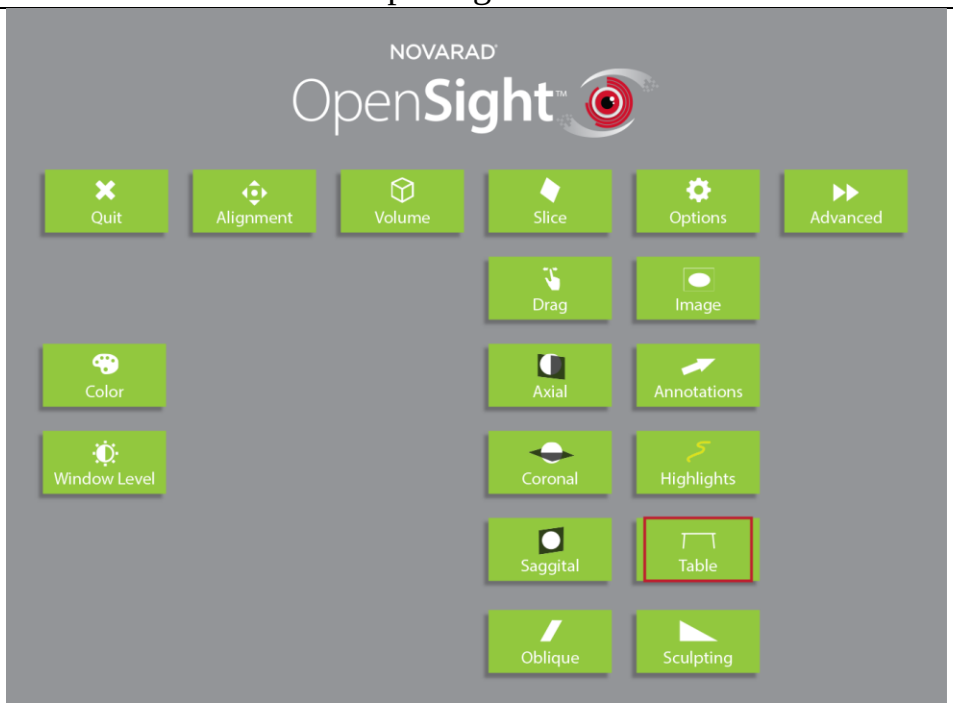
Highlights

The **Highlights** options turns on or off highlights that were created in the study with the PACS viewer.



Table

The Table options shows or hides the virtual table that was present in the medical images period. By hiding the virtual table, it allows the medical image to align to the patient in a new area. In order to have the table option, it must be created in the study with the PACS viewer. If part of the virtual patient is missing, the table algorithm may have removed it. In that case, the “Table” can be toggled back on if an essential part of the image is removed. Performing the toggle will restore the table to the medical image being viewed.



Sculpting

Sculpting must be added to the series with the PACS viewer prior to opening the image. Sculpting is used to cut away any data or layers of the patient. The **Sculpting** function in OpenSight allows users to toggle the previous sculpting of the image or study. Example: If the user were viewing an image of a head, and the skull was sculpted away previously with the PACS viewer, OpenSight will enable the sculpting button allowing the user to toggle the skull on/off.

Sculpting of images is performed within the PACS and can be toggled on/off within the OpenSight headset. Parts of the image sculpted previously with the PACS can be toggled back on if desired. Sculpting is removed away after the alignment process within OpenSight headset and will allow the user to toggle on/off the corresponding anatomy. When sculpting is on, the corresponding anatomy disappears. The toggle button is lit on the user interface that would indicate sculpting is on.

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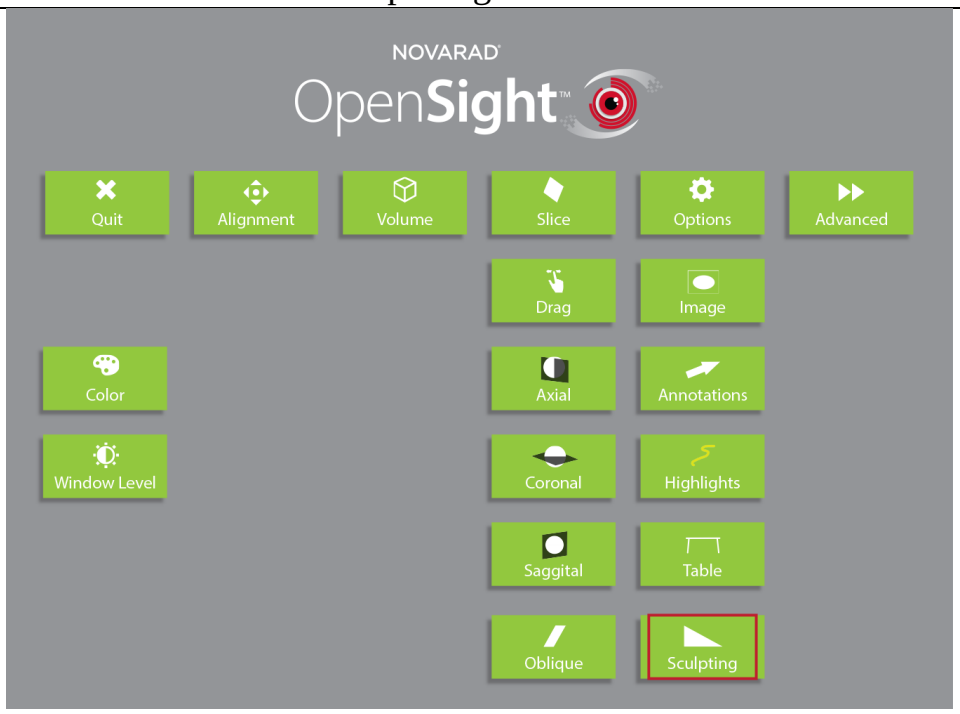


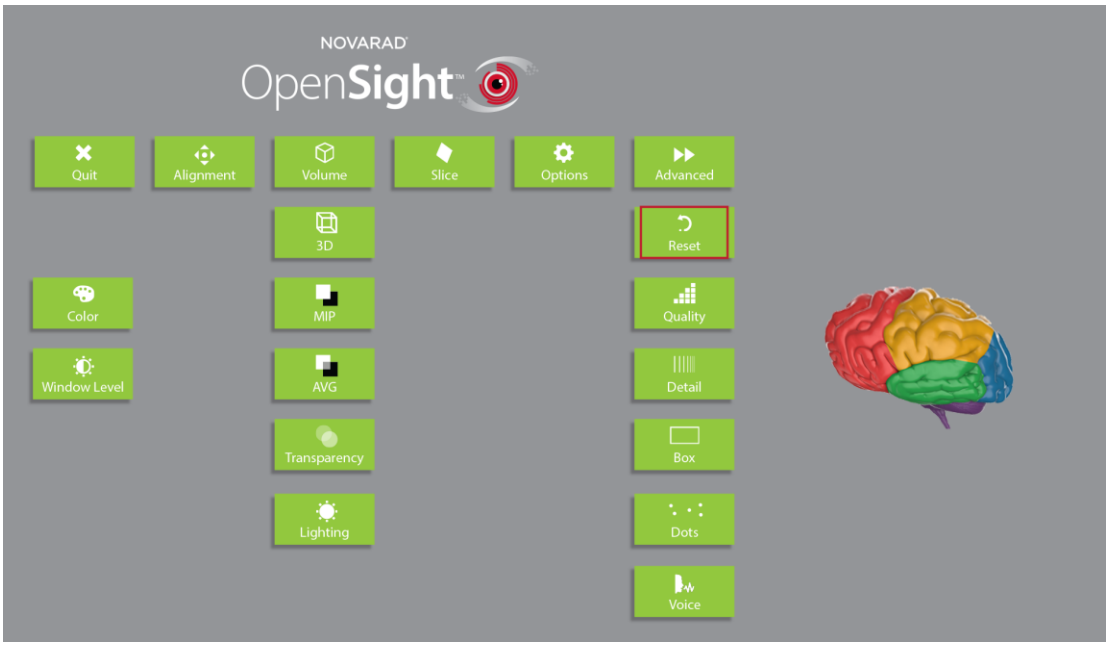
Advanced

Advanced

The Advanced menu is where users will find additional options that are not in the regular Options menu.

Reset

The **Reset** option allows users to set the image back to default, as if they had just opened the image for the first time. The image will populate directly in the user's field of vision.



HoloLens App Voice Commands

The **Voice** option may be OFF by default, but if you turn it ON, you can control the app through your voice. Below are some basic voice commands:

Quit App

Alignment Mode
Rotate At Right
Rotate At Left
Rotate At Head
Rotate At Feet
Rotate Facing (no button for this, but rotates the images upright and facing the observer)
Tap Position
Rotate Yaw (Pitch, Roll)
Drag Position (no button for this, but drags quickly around)
Drag Slow

Volume Mode
Turn Lighting On (Off)
Render 3D (MIP, Average)

Drag Transparency

Slice Mode
Axial Slice
Coronal Slice
Sagittal Slice
Oblique slice
Drag Slice

(In Any Mode)
Drag Window Level
Drag Time (if the series has 4-D this is great!)
Turn Color On (Off)
Turn Box On (Off)
Turn Dots On (Off)
Turn Image On (Off)
Turn Annotations On (Off)
Turn Table On (Off)
Turn Sculpting On (Off)
Turn Highlights On (Off)
Turn Voice Off (turning voice on with your voice will not work)
Turn Menu On (Off)
Drag Quality
Drag Detail
Drag Zoom (Careful, this breaks any usefulness with a real patient)
Reset Zoom

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Part 2: HoloLens 2 Instructions

Note: for HoloLens 1 Instructions see section Part 1: HoloLens 1 Instructions

2-1 Downloading OpenSight

1. Download from the App store

Users can download OpenSight from the Microsoft™ App store. To download OpenSight, complete the following steps.

a. Open the Microsoft™ Store from the HoloLens main menu.

b. Using the search field, locate “OpenSight” in the app store.

c. Once OpenSight is found, select the OpenSight icon.

d. Click Download.

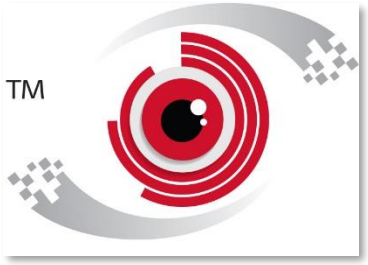
e. The app will be downloaded to the HoloLens headset.

2-2 Opening OpenSight

1. To launch the OpenSight software, find the OpenSight icon on your HoloLens main menu.

   Please note: *OpenSight may not appear on the first page, select the* ***All Apps*** *option to populate all the downloaded apps on your HoloLens device.*

2. Hover the cursor over the OpenSight icon and select it.



The software will open.

2-3 Calibration

Users should use the calibration feature for OpenSight each time OpenSight is used. This will ensure an optimal viewing experience and accuracy.

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

To calibrate inside OpenSight complete the following steps:

1. Open OpenSight.
2. Say “Turn Calibration On”
   The left-eye calibration will commence first.
3. Look at the Calibration QR code through the HoloLens.
4. Use the pinch-and-drag hand motion to align the calibration QR code with the calibration QR code.
5. Click to advance to the right-eye calibration.
6. Use the pinch-and-drag hand motion to align the calibration QR code with the calibration QR code.
7. Click to exit calibration.
8. The HoloLens is now calibrated for OpenSight

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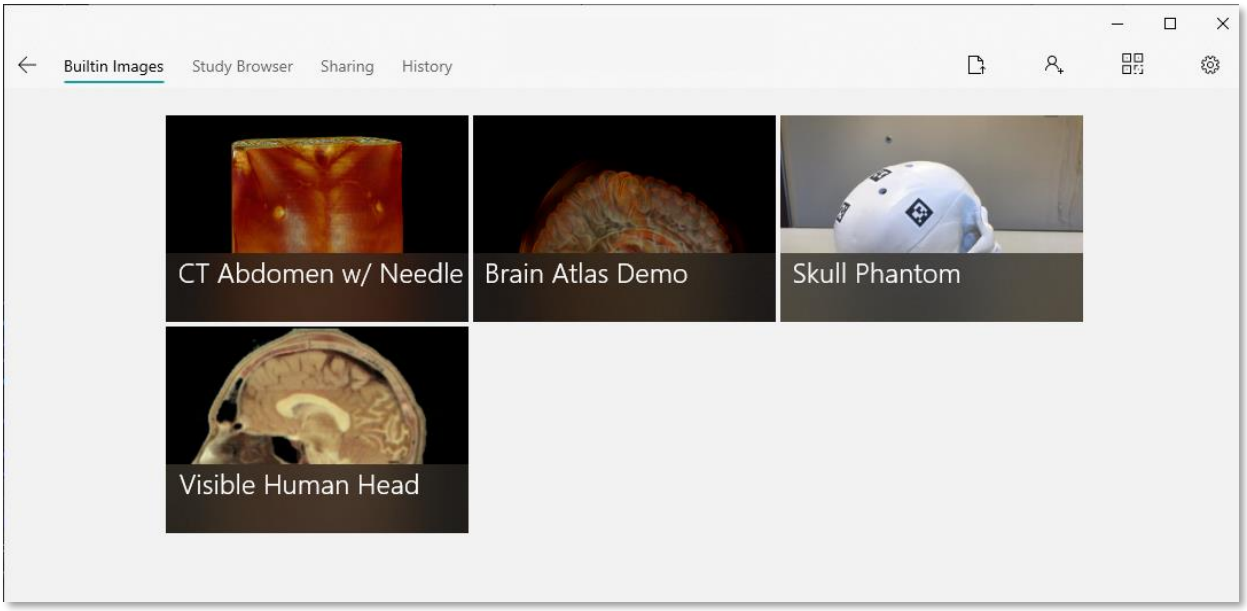
2-4 Builtin Images

OpenSight has a **Builtn images** function that allows users to see a demo of a few studies as well as the Gibby-Cvetko Brain Atlas.

To access Built-In Images, after opening OpenSight, select the **Builtin Images** option.



From this screen, select the option you wish to view.

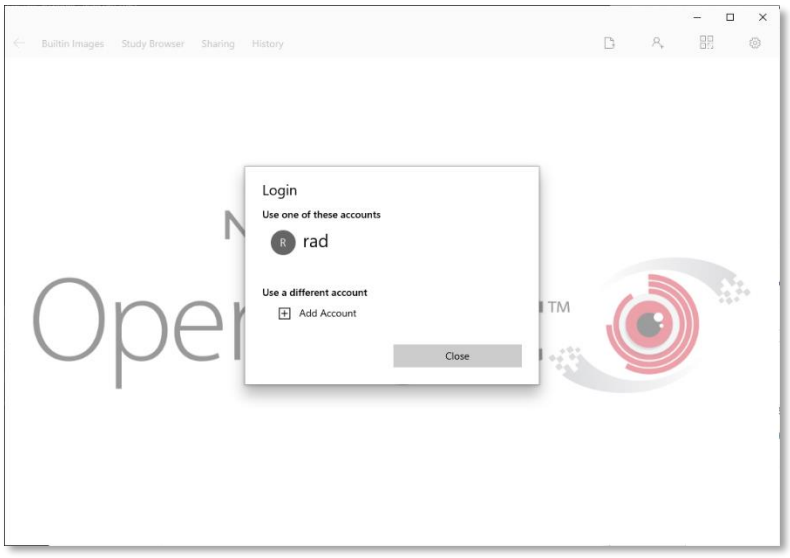
2-5 Login

Users are able to log into a different account by using the Login icon.

To log in, complete the following steps.

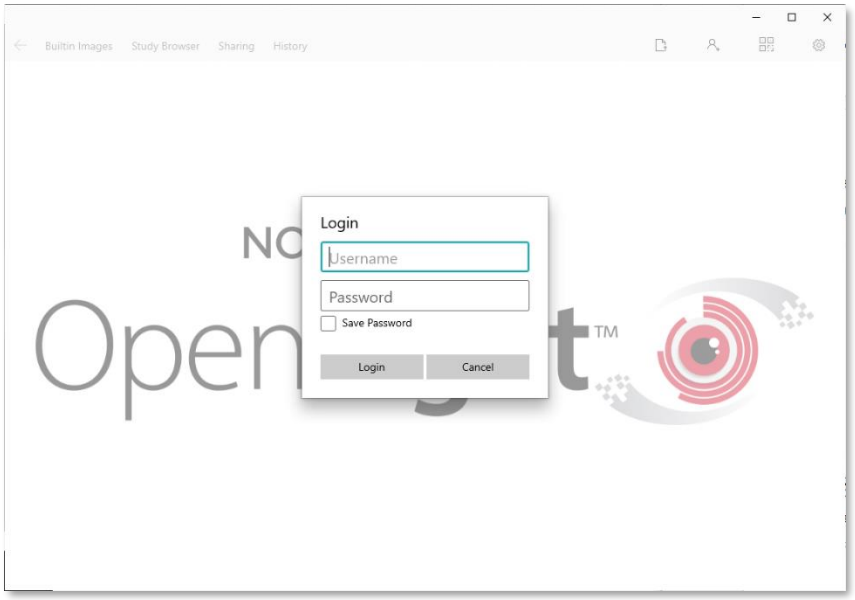
1. Select the Login icon.

A Login window will populate.



2. Select the user account to log in.

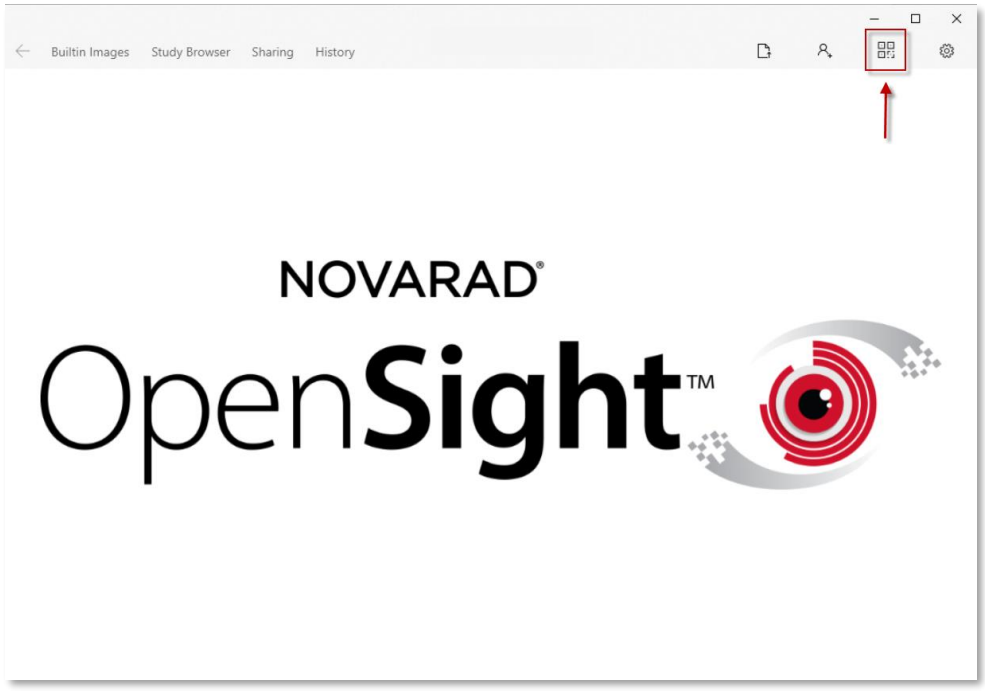
3. If the user account does not populate, users will be asked to add a new account.



2-6 Scan Code

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

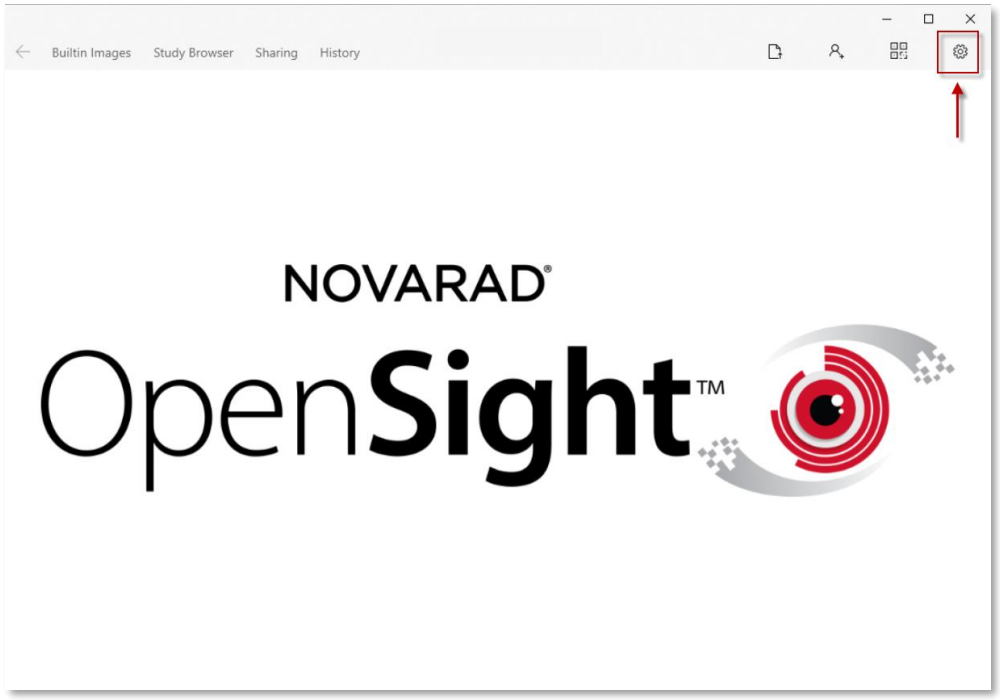
To use this feature, select the Scan Code option and position the viewer to see the QR code.



The code will be scanned and users will be prompted to navigate to the QR code's destination.

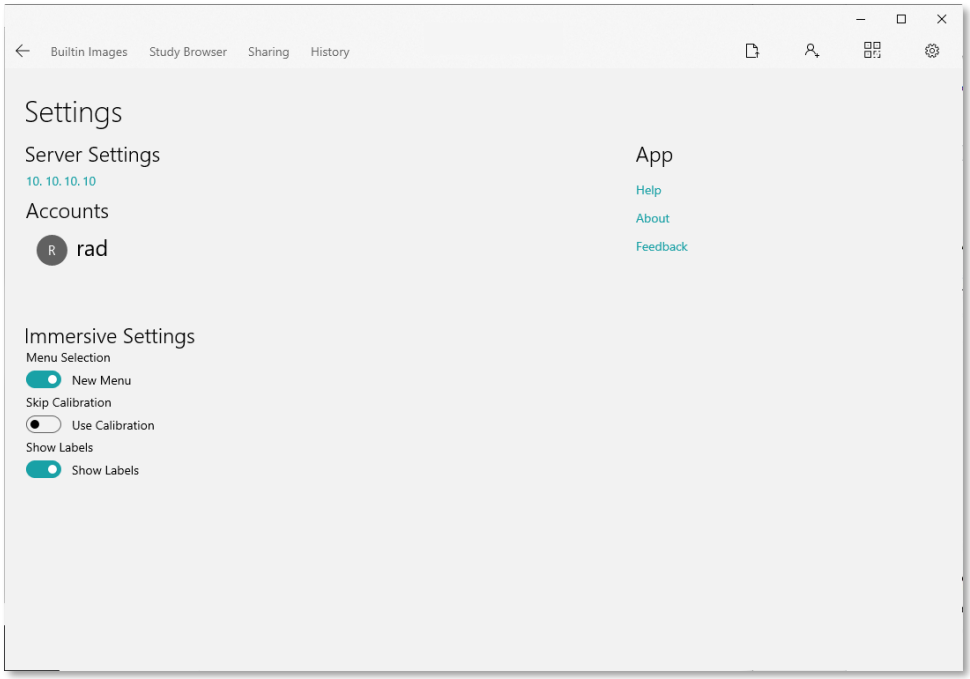
2-7 Settings

Users are able to select the Gear Icon to populate the settings page.



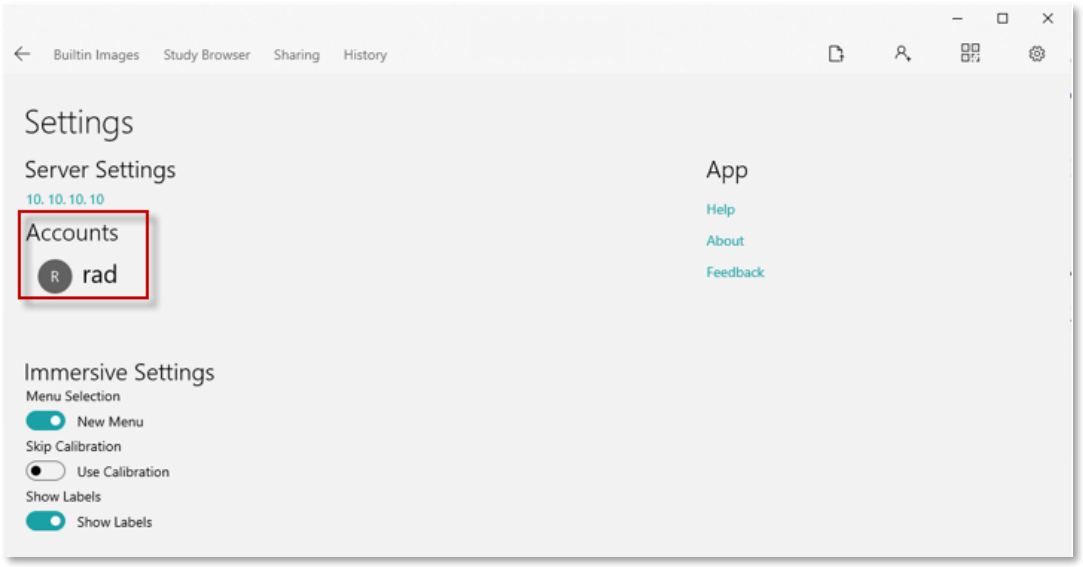
1. Server Settings

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



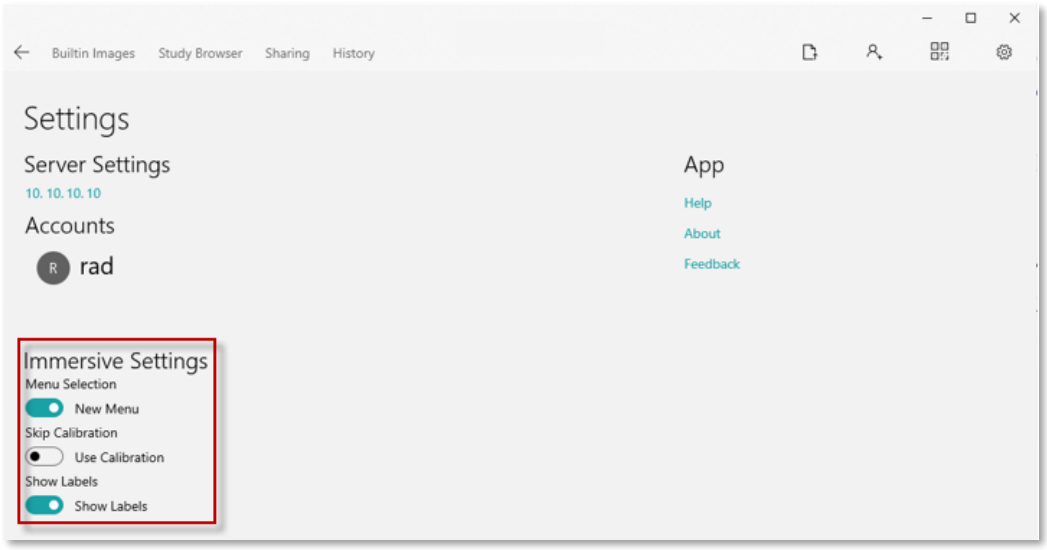
2. Accounts

Users are able to log into a different account from this page.



3. Immersive Settings

Users can enable settings within the Immersive settings section.



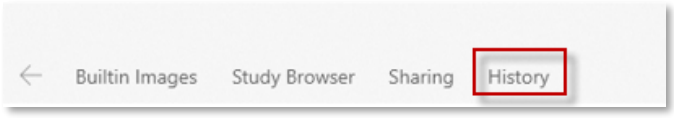
1. New Menu
   The New Menu toggle will tell OpenSight to use the newest version of the menu.

2. Skip Calibration
   The Skip Calibration option will allow users to skip the calibration step when first opening OpenSight (This is not recommended)

3. Show Labels
   The Show Labels option will populate the labels in the Immersive Viewer so the user is always able to see what the title of each option is. If Show Labels is disabled, the title of the option will only populate when it is hovered over with the cursor.

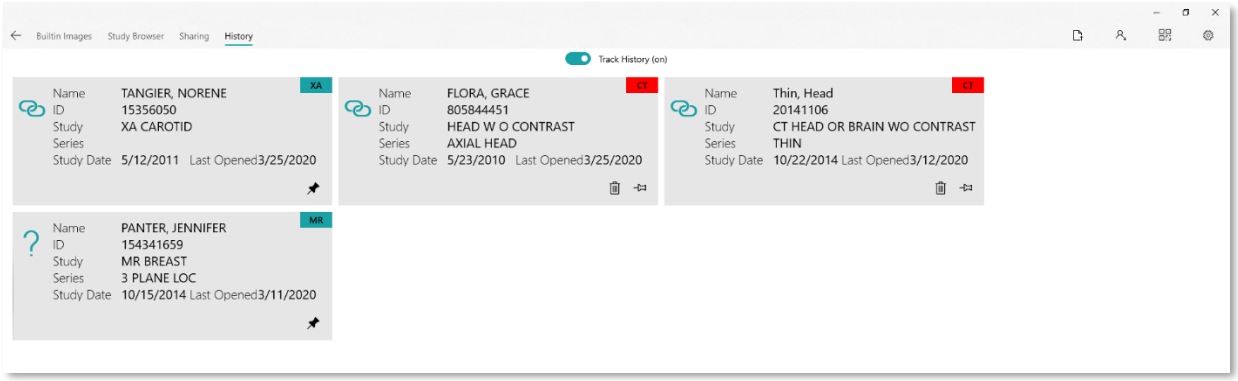
2-8 History Tab

The History tab allows users to view and load previously viewed studies in OpenSight. A typical use case is if a surgeon if going to a situation where there is not reliable Wi-Fi and wants to pre-load the study on to the HoloLens headset.



After selecting the History tab, a list of the ten most recently opened studies with the pertinent information will populate. Users are able to open any of those studies shown by selecting the study.

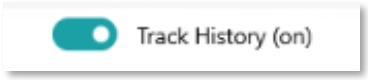
***Please note**: All patient health information that is saved to the HoloLens is encrypted. If any PHI is not desired on the device, the user can disable the History option.*



Users are able to delete individual history items by selecting the trash icon on the individual history information box.

Users are also able to pin individual history items by selecting the pin icon on the history information box. This will make it so any pinned studies will not have the trash icon so they cannot be deleted until they are unpinned.

Users are able to enable/disable the history tracking by using the toggle switch at the top-center of the History tab. The user will also be prompted to delete all history items when disabling the History.



2-9 Using the OpenSight Study Browser

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

1. Accessing Study Browser

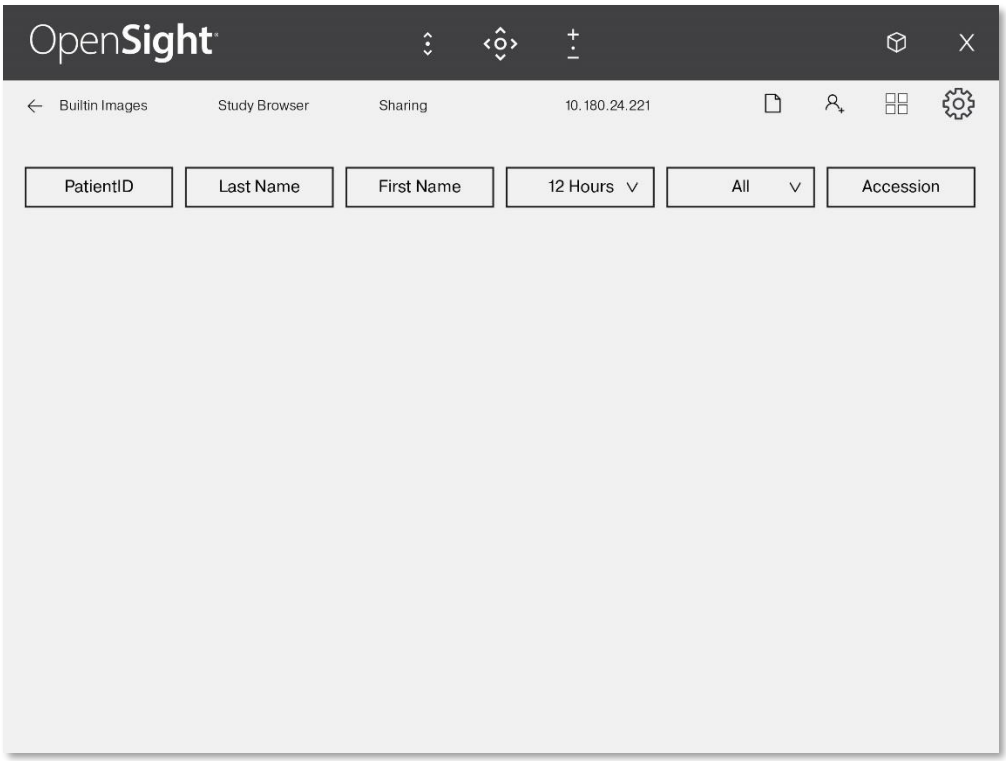
To access the Study Browser, complete the following steps.

a. Open OpenSight from the HoloLens main menu.

b. Log into OpenSight.

c. Select the **Study Browser** option.

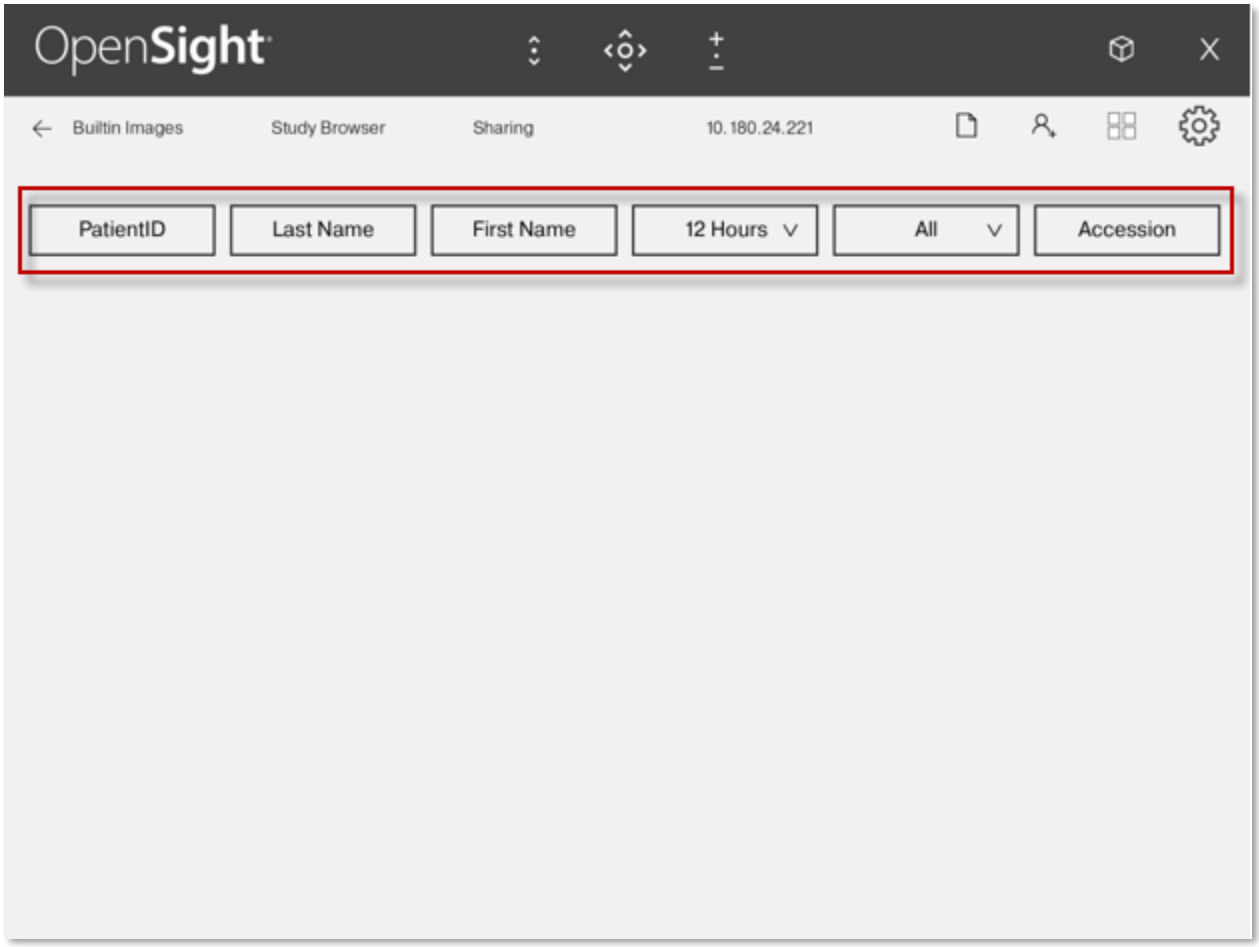
The Study Browser will open.



Please note: If the user is not connected to a server, OpenSight will prompt the user to log into a server's IP address and then to log in with a username and password. Contact your IT department for support if you are not connected to a server.

2. Searching for Studies

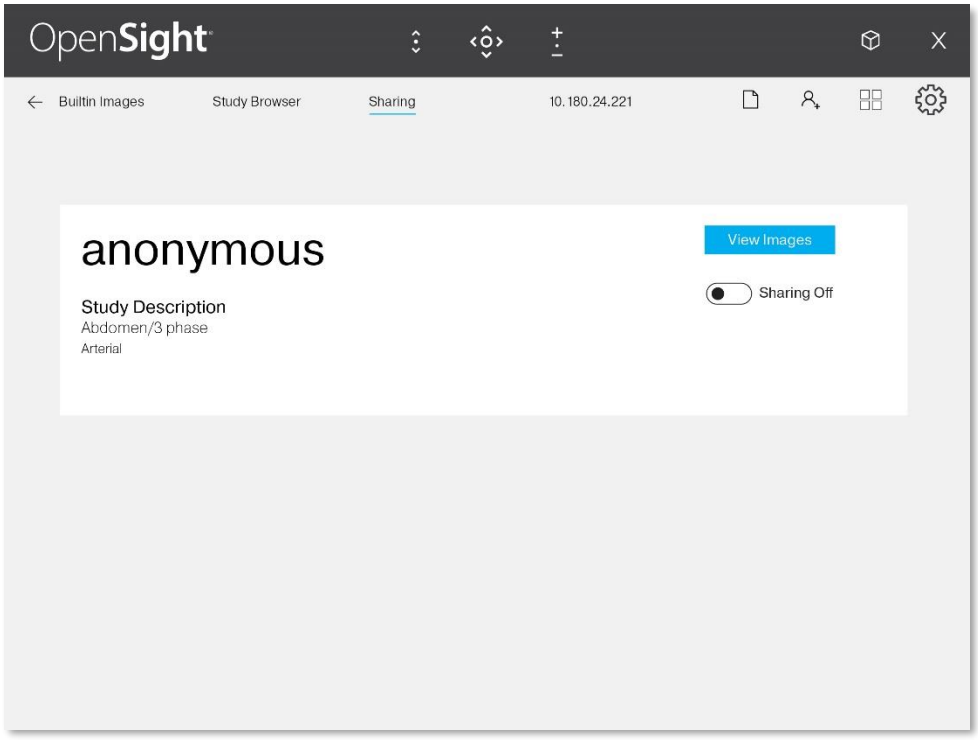
Users can search for studies by using the search filters. Patient ID, first name, last name, time, modality type, and accession number.



Once the study has populated from the search, use your cursor to select it.

Users will be brought to the study page.

Select **View Images**.



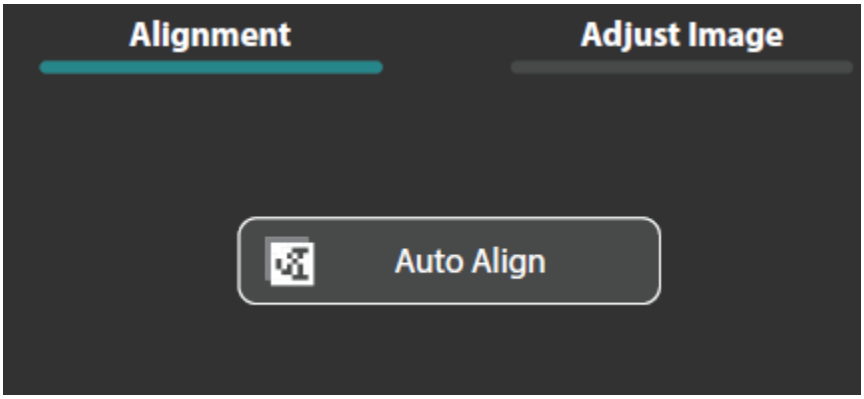
The Study will open in the Immersive Viewer.

2-10 Alignment Menu in the OpenSight Immersive Viewer

The Alignment menu is where users can manipulate and adjust the image in the immersive viewer. The following sections will describe how each function works and how to access it.

2-11 Auto Align

The Automatically Align option will use April Tags that have been placed on the patient to orient the image in the immersive viewer over the patient.

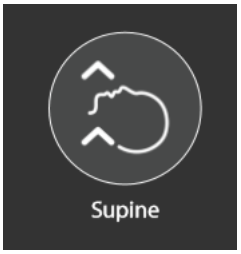


April Tags are the QR codes that are placed on the patient. For more information about April Tags, please see the April Tags section.

2-12 Positioning Presets

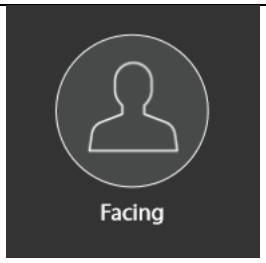
3. Supine

This function will place the image in a supine position. (Image facing up towards the ceiling.) Users are able to use the voice command “Rotate Supine _____” depending on the orientation the user wishes the hologram to face the options are: Head, Feet, Right, or Left.

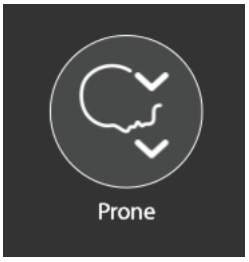


4. Facing

This function will place the image in a facing position. (Image facing towards the OpenSight user.) Users are able to use the voice command “rotate facing” to activate this feature.



Prone
This function will place the image in a prone position. (Image facing down towards the floor.) Users are able to use the voice command “Rotate Prone _____” depending on the orientation the user wishes the hologram to face the options are: Head, Feet, Right, or Left.



2-13 Drag Commands

5. Drag Slow

The Drag Slow command allows users to fine tune the position of the hologram. Users are also able to activate this feature by using the voice command “Drag Slow.”

6. Drag Position

The Drag Position command allows the user to move the image quickly. Users are also able to activate this feature by using the voice command “Drag Position.” .

7. Pitch (HoloLens 1 only)

The Pitch option allows users to rotate the hologram along the Y-Axis. Users can also activate this feature by using the voice command “Rotate Pitch.”

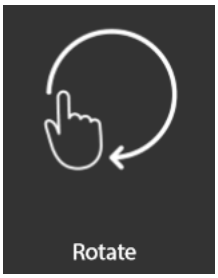
8. 360 Drag (HoloLens 2 only)

The 360-Drag feature allows users to manipulate the image in a 360-degree motion. This feature is currently only available on HoloLens 2.

2-14 Image Rotation

9. Rotate

The rotate option allows users to rotate the holograms along the Z-axis. Users can also activate this option by using the voice command “Rotate Roll.” .



10. Spin

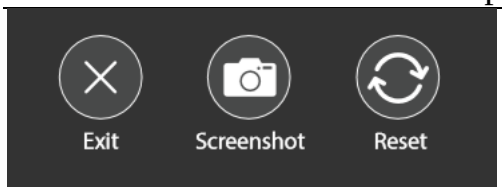
The Spin option allows users to rotate to holograms along the X-axis. Users can also activate this option by using the voice command “Rotate Yaw.”

2-15 Window/Level

The Window/Level option will allow users to adjust the window/level value of the hologram by using the drag function, which can be likened to contrast and brightness. Users are also able to activate this option by using the voice command “Adjust Window/Level.”

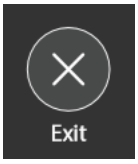
2-16 Footer Options

The footer options will be available in every menu in OpenSight. The following section details those functions.



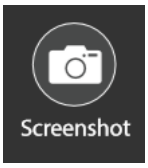
11. Exit

The Exit feature will exit out of the Immersive Viewer and bring the user back to the OpenSight Landing page.



Screenshot

The Screenshot function will take a picture of the user's current view with any holograms included. If OpenSight is connected to a server, it will first try to save the picture to that server, and if that is not successful, the screenshot will be saved locally on the HoloLens in the Pictures folder.



Reset

The Reset option will reset the image as it was when the user initially opened the study in the Immersive Viewer, with any changes made in the Immersive Viewer removed.

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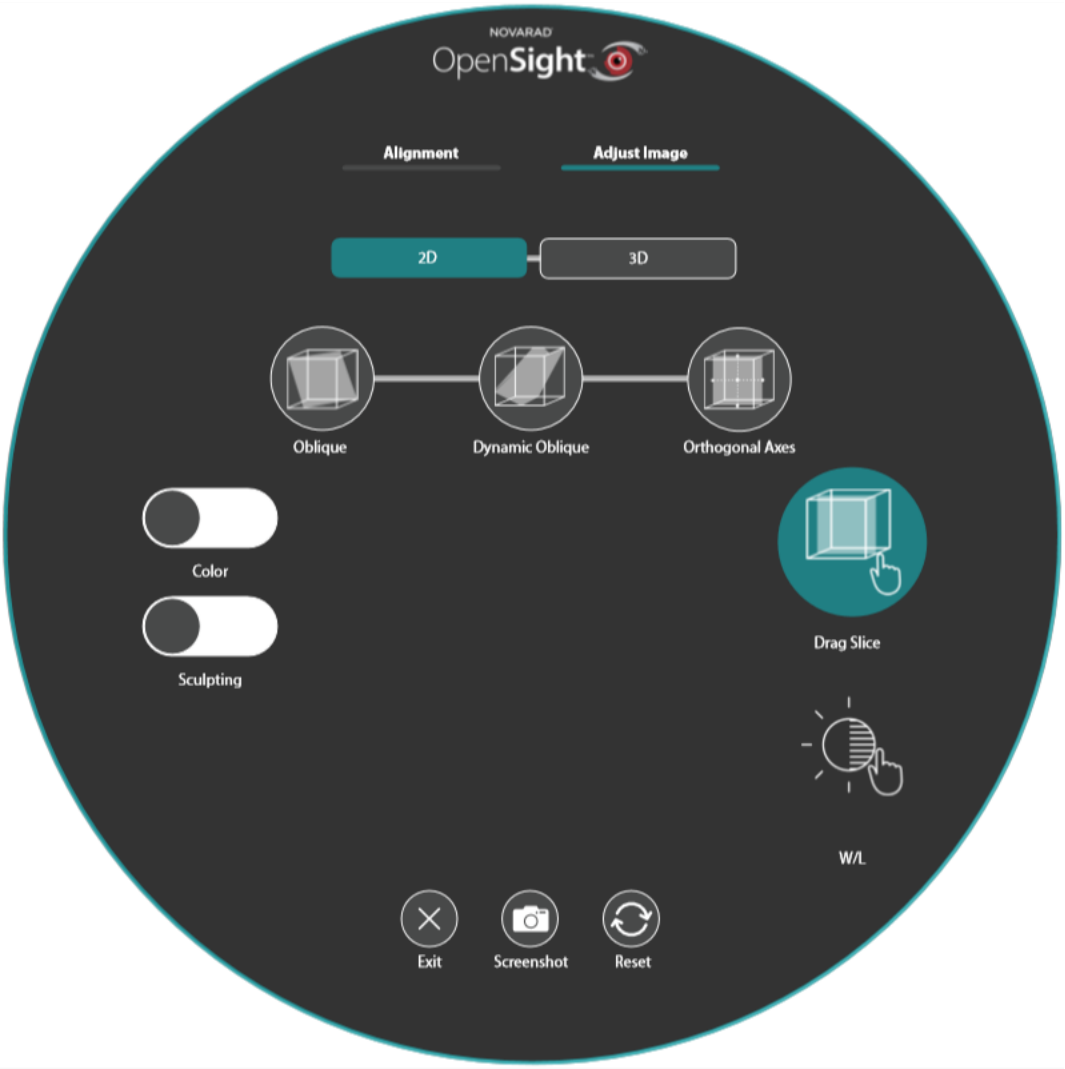
2-17 Surgeon Workflow

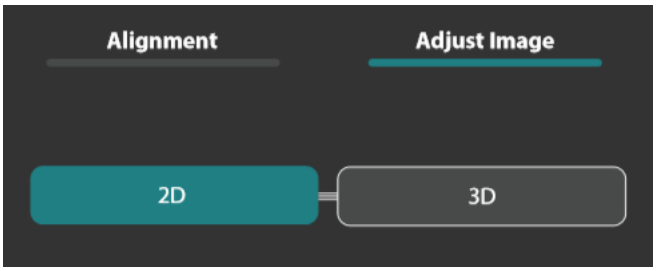
OpenSight features two separate workflows: Surgeon workflow and atlas workflow.

The Surgeon workflow is the menu that populates when a patient's study is opened in the Immersive Viewer. The atlas workflow is the menu that populates when one of OpenSight's builtin images (such as the brain atlas) is opened in the Immersive Viewer.



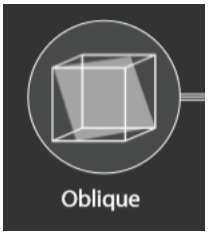
2-18 Adjust Image – 2D View

The 2D view in the Immersive Viewer shows the user the different options to manipulate the 2D view, also known as Slice View.



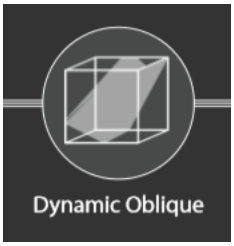
12. Oblique

Selecting the Oblique option locks the oblique slice shown in the immersive viewer. Users can use the "Un/Lock Oblique" voice command to change the oblique slice.



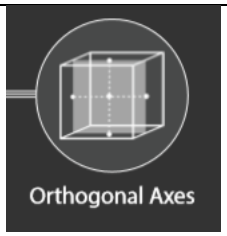
13. Dynamic Oblique

Dynamic Oblique enables the dynamic view and the slice will always face the user, regardless of where they move.



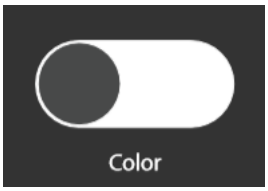
14. Orthagonal Axes

The Orthogonal Axes option populates the axial, sagittal, or coronal slice view. The type of view will depend on the orientation of the user regarding the hologram.



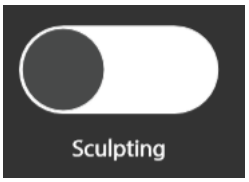
15. Color

The Color option will enable/disable the color on the hologram in the Immersive Viewer. Users can also use the voice command “Turn Color on/off.”



16. Sculpting

The Sculpting option will enable/disable any sculpting annotations made in the NovaPACS® Image Viewer. Users are also able to use the voice command “Turn Sculpting on/off”



17. Drag Slice

The Drag Slice enables the user to pinch-and-drag through the various slice images of the hologram. Users can also use the voice command “Drag Slice”

18. Window/Level

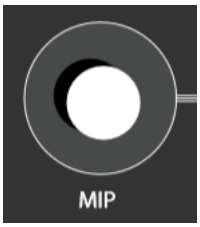
The Window/Level option allows users to adjust the window/level value of the hologram by using the drag function. Users can activate this option by using the voice command “Adjust Window/Level.”

2-19 Adjust Image – 3D View

The Adjust Image – 3D view will populate when the user is viewing the hologram in OpenSight.

19. MIP

Maximum Intensity Projection (MIP) changes the way the hologram is rendered. When MIP is activated, the HoloLens shows the brightest pixels in the volume. Users can also activate this feature using the voice command “render MIP.”

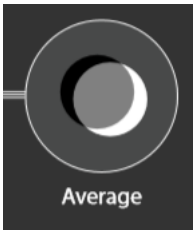


20. Standard

When Standard is activated, the HoloLens gives the 3D effect with the pixels in front obscuring the pixels behind. Users can also activate this feature by use the voice command “render 3D.”

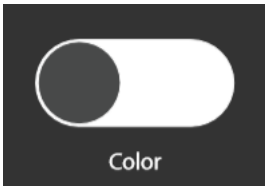
21. Average

When Average is activated, the render averages the pixels in the volume. Users can also activate this feature by using the voice command “render Average.”



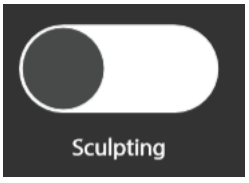
22. Color

The Color option will enable/disable the color on the hologram in the Immersive Viewer. Users can also use the voice command “Turn Color on/off”



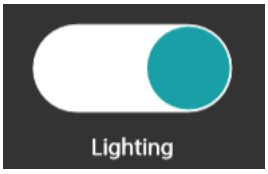
23. Sculpting

The Sculpting option will enable/disable any sculpting annotations made in the NovaPACS® Image Viewer. Users can also use the voice command “Turn Sculpting on/off”



24. Lighting

The Lighting option adjusts where the source of the light is shining on the image. Users can also enable this feature by using the voice command “Adjust Lighting” to enable this feature.



25. Transparency

The Transparency option adjusts the transparency of the holograms. After selecting the option, use the pinch-and-drag option to adjust the transparency to the users liking.

26. Window/Level

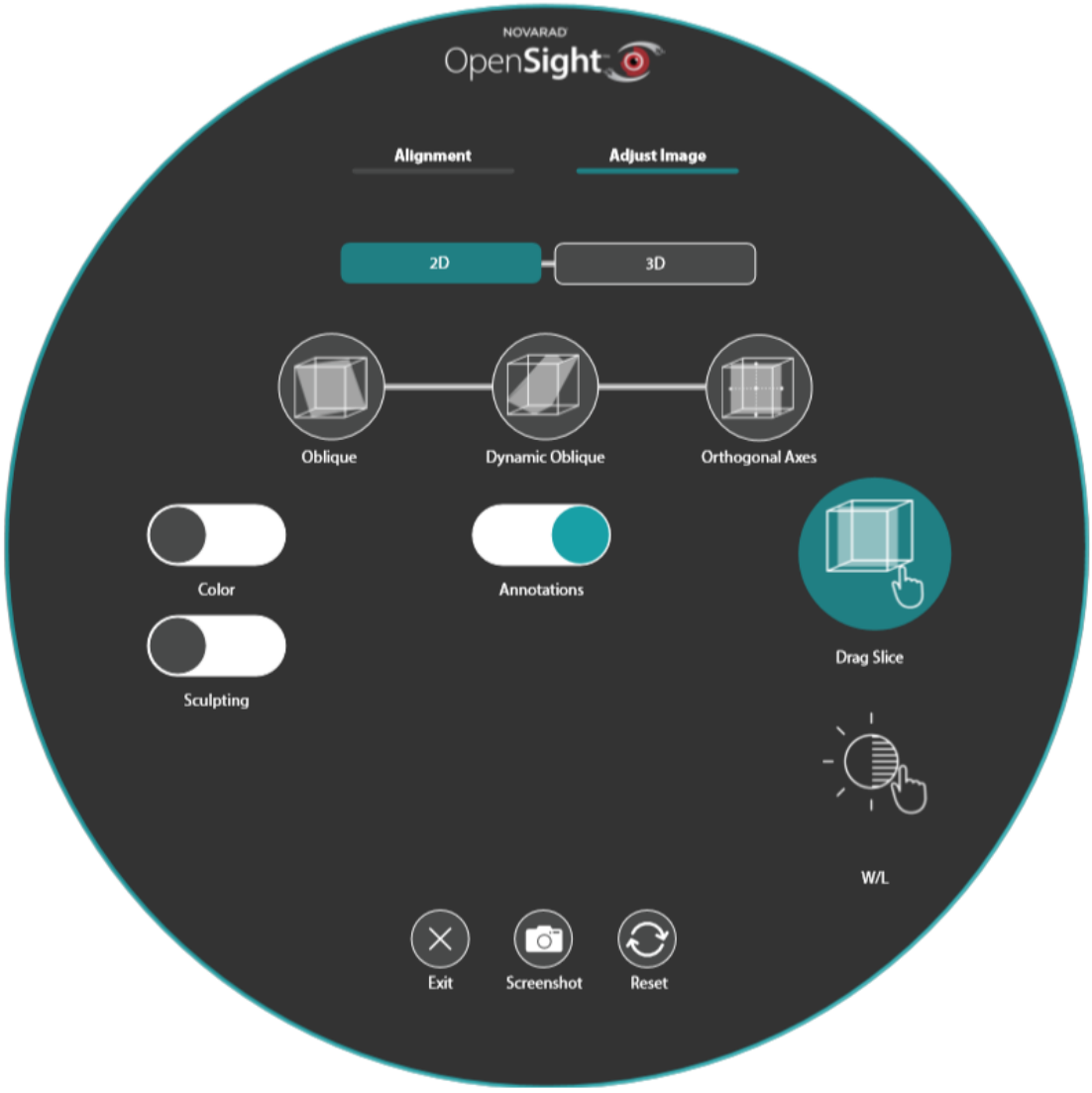
The Window/Level option allows users to adjust the window/level value of the hologram with the drag function. Users are also able to activate this option by using the voice command “Adjust Window/Level.”

2-20 Atlas Workflow

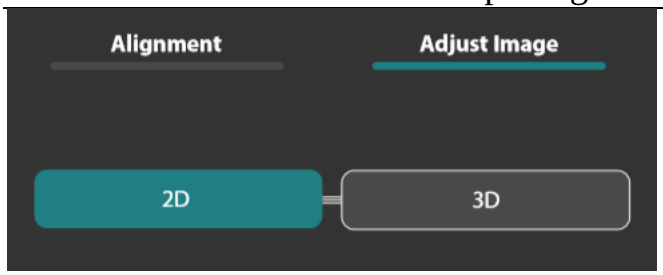
OpenSight features two separate workflows: Atlas workflow and surgery workflow.

The atlas workflow is the menu that populates when one of OpenSight's built-in images (such as the brain atlas) is opened in the Immersive Viewer. The Surgeon workflow is the menu that populates when a patient's study is opened in the Immersive Viewer.

2-21 Adjust Image – 2D View

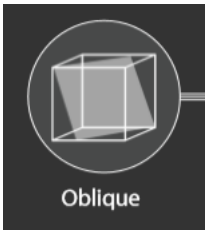


The 2D view in the Immersive Viewer shows the user different options to manipulate the 2D view, also known as Slice View.



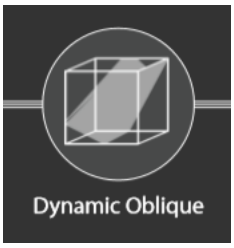
27. Oblique

Selecting the Oblique option locks the oblique slice shown in the immersive viewer. Users can use the Drag Slice option or “Drag Slice” voice command to change the oblique slice.



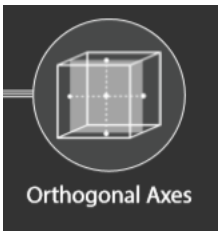
28. Dynamic Oblique

Dynamic Oblique enables the dynamic view and the slice will always face the user, regardless of where they move.



29. Orthagonal Axes

The Orthogonal Axes option populates the axial, sagittal, or coronal slice view. The type of view will depend on the orientation of the user regarding the hologram.



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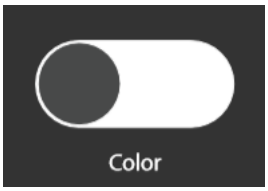
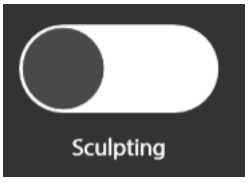
30. Color

The Color option will enable/disable the color on the hologram in the Immersive Viewer. Users can also use the voice command “Turn Color on/off”



31. Sculpting

The Sculpting option will enable/disable any sculpting annotations made in the NovaPACS® Image Viewer. Users can also use the voice command “Turn Sculpting on/off”

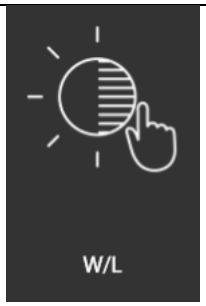


32. Drag Slice

The Drag Slice enables the user to pinch-and-drag through the various slice images of the hologram. Users can also use the voice command “Drag Slice”

33. Window/Level

The Window/Level option will allow users to adjust the window/level value of the hologram by using the drag function. Users can also activate this option using the voice command “Adjust Window/Level.”



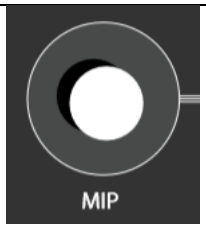
34. Annotations

The Annotations option will enable/disable any annotations that were created in the NovaPACS® system prior to opening in the OpenSight Immersive Viewer. Users can also use the voice command “Turn Annotations on/off”

2-22 Adjust Image – 3D View

35. MIP

Maximum Intensity Projection (MIP) changes the way the hologram is rendered. When MIP is activated the HoloLens shows the brightest pixels in the volume. Users can also activate this feature using the voice command “render MIP.”

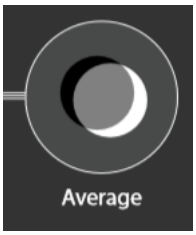


36. Standard

When Standard is activated, it gives the 3D effect with the pixels in front obscuring the pixels behind. Users can also activate this feature by using the voice command “render 3D” to activate this feature.

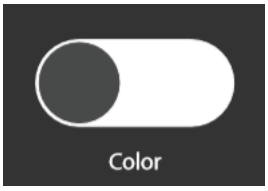
37. Average

When Average is activated, the render averages the pixels in the volume. Users can also activate this feature by using the voice command “render average” to activate this feature.



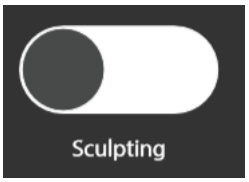
38. Color

The Color option will enable/disable the color on the hologram in the Immersive Viewer. Users can also use the voice command “Turn Color on/off”



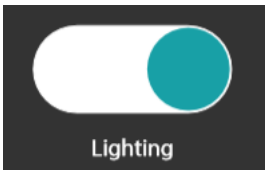
39. Sculpting

The Sculpting option will enable/disable any sculpting annotations made in the NovaPACS® Image Viewer. Users are also able to use the voice command “Turn Sculpting on/off”



40. Lighting

The Lighting option adjusts where the source of the light is shining on the image. Users can also enable this feature by using the voice command “Adjust Lighting.”



41. Transparency

The Transparency option adjusts the transparency of the holograms. After selecting the option, use the pinch-and-drag option to adjust the transparency to the users liking.

42. Window/Level

The Window/Level option allows users to utilize the drag function to adjust the window/level value of the hologram. Users are also able to activate this option by using the voice command “Adjust Window/Level.”

43. Annotations

The Annotations option will enable/disable any annotations that were created in the NovaPACS® system prior to opening in the OpenSight Immersive Viewer. Users can also use the voice command “Turn Annotations on/off”

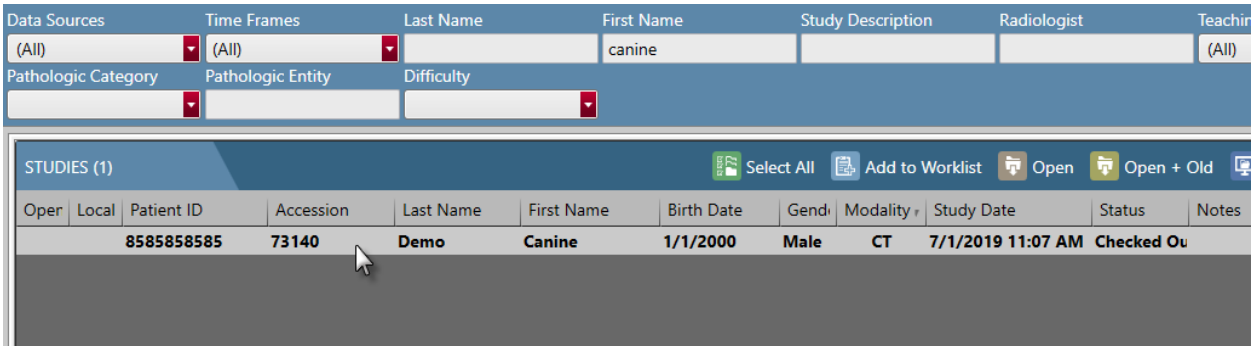
2-23 Augmented Reality Features in NovaPACS®

This section will detail how to use the Augmented Reality/OpenSight features in NovaPACS®. All these features require an augmented reality/OpenSight license.

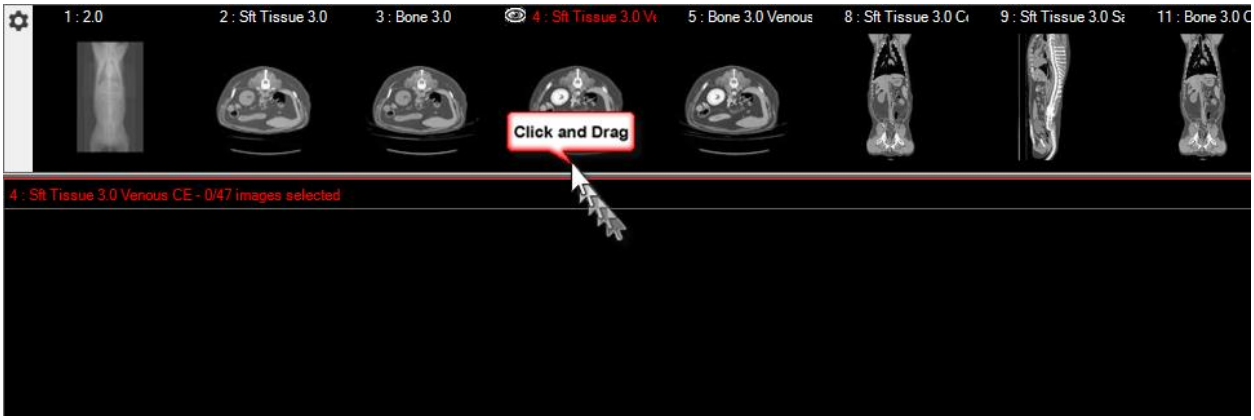
2-24 Virtual Needle

1. In NovaPACS®
   To add a virtual needle annotation, complete the following steps:

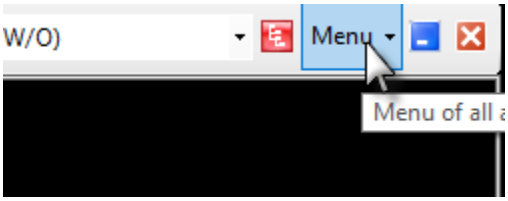
   1. Find and open the study in the Study Browser.



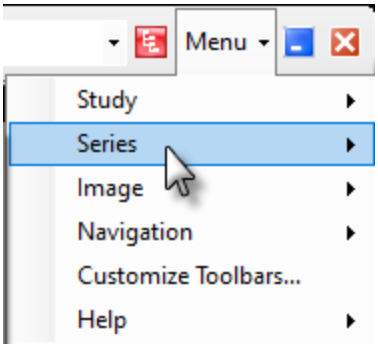
   2. After the study has completely loaded, select the series you wish to annotate.



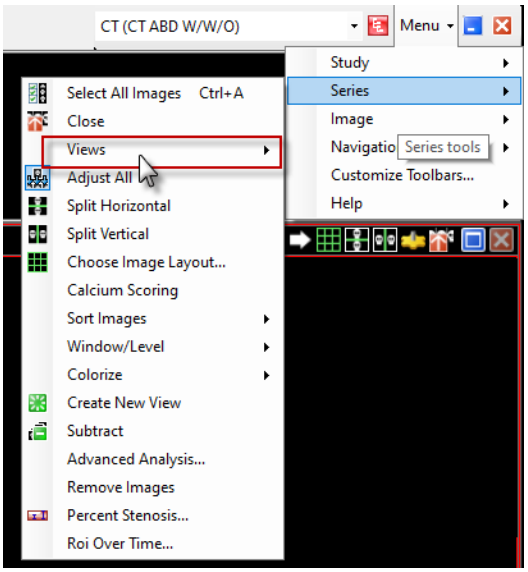
3. Select the Image Viewer **Menu**.



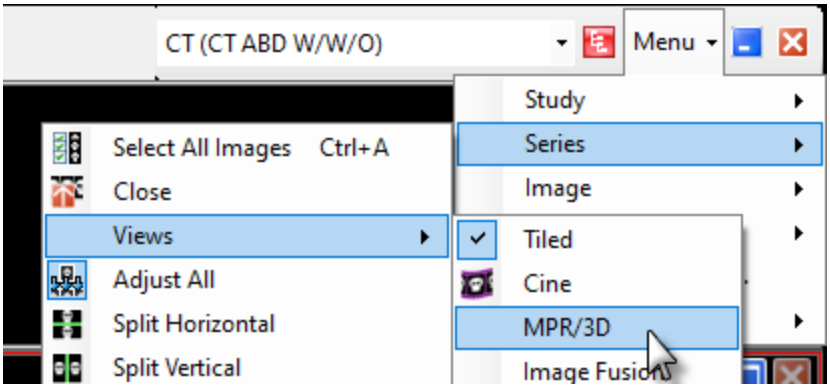
4. Select the **Series** menu in the Image Viewer.



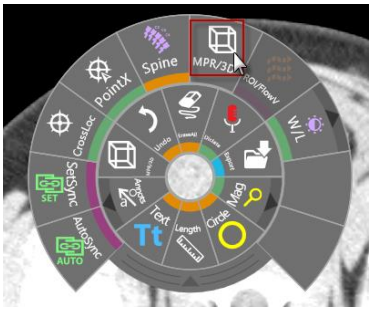
5. Hover your mouse over the **Views** option under the Series menu.



6. Select MPR/3D.



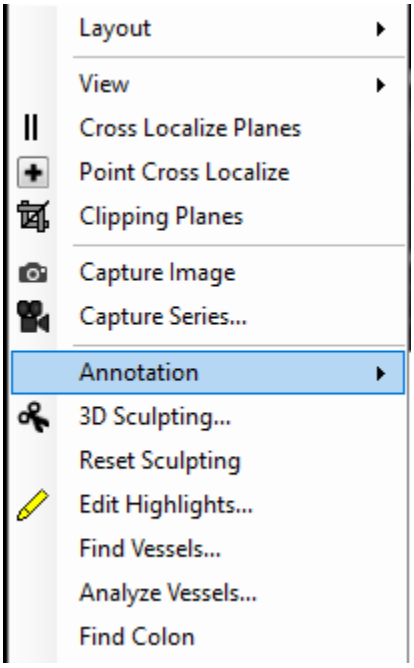
Please note: *Users can make the* ***MPR/3D*** *option a shortcut on the Image Viewer or Radius Menu.*



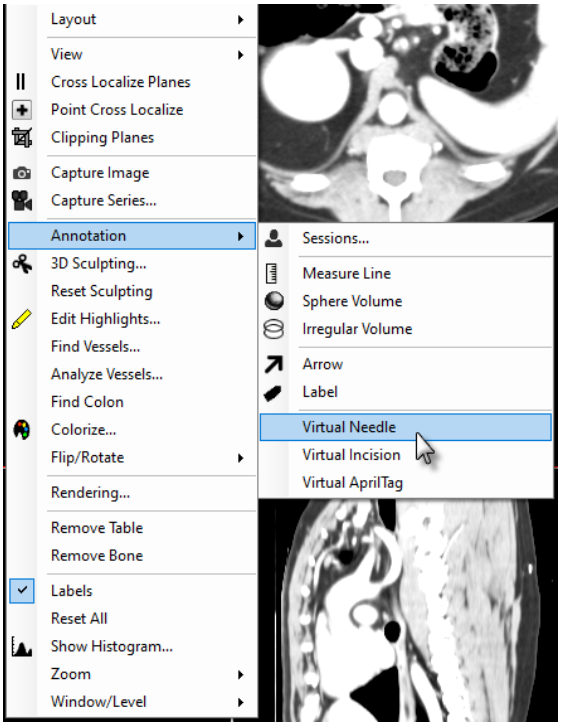
The image will render in the 3D Viewer.

7. For the **Virtual Needle** annotation, the user should create the annotation in a series within the 3D viewer with an axial, coronal, or sagittal view.

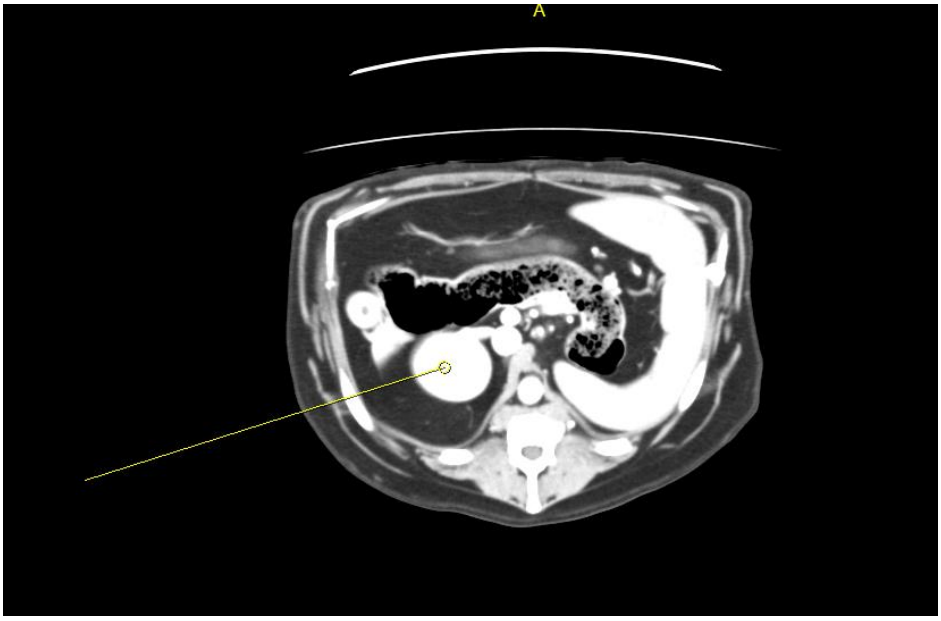
8. Select the Annotation option from the right-click menu.



9. Select the Virtual Needle option.



10. Create the annotation.



The virtual needle should be created by first clicking on the user's target (inside the body), and then dragged out of the body.

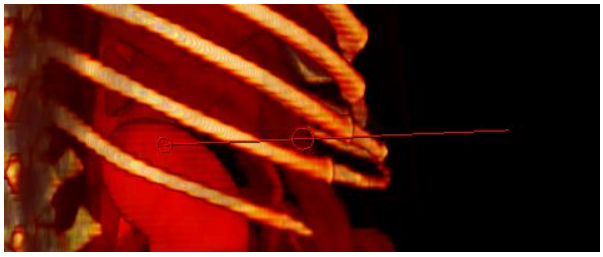
> ***Please note**: For the Virtual Needle, ensure that the annotation goes beyond the insertion point (as shown above) to ensure easy visibility in the OpenSight Immersive Viewer.*

The annotation will populate on the 3D image as well.

11. Save the changes in NovaPACS®.

When the user rotates the 3D image:

If the annotation is red, the user is not lined up with the insertion point of the virtual needle.



If the annotation is yellow, the user is closer to lining up with the insertion point of the virtual needle.

If the annotation is green, the user will see the insertion point of the needle, and how far the needle will need to be inserted according to the annotation.

2. In the Immersive Viewer

   To view the virtual needle, open the study that includes the virtual needle annotation in the Immersive Viewer.

   The virtual needle uses a guidance feature that allows the user to know exactly where the needle should be inserted, and how deep.

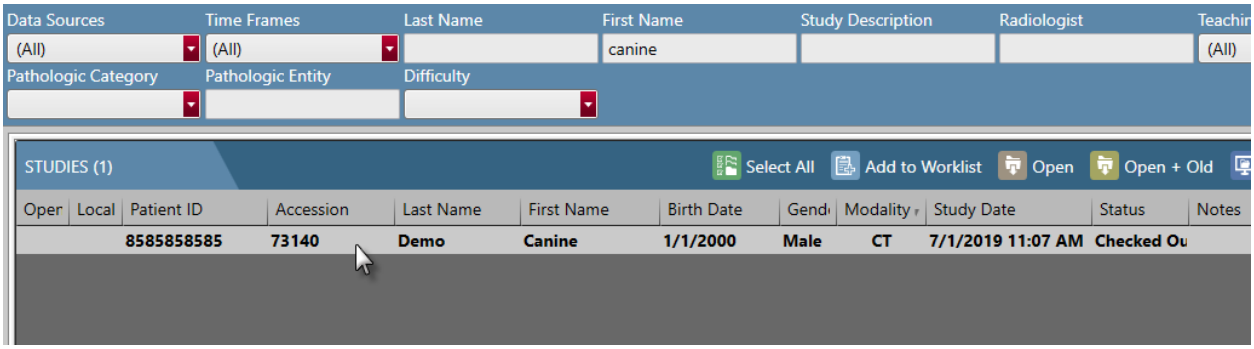
   When users are viewing the virtual needle, the annotation will change colors, depending on how close the user's eye is to the annotation, as well as how "on target" the user is. The virtual needle annotation will turn green when the user is aligned with the annotation.

   When the user gets physically close enough to the virtual needle annotation, OpenSight will also alert the user to close an eye (OpenSight will tell the user which eye to close).

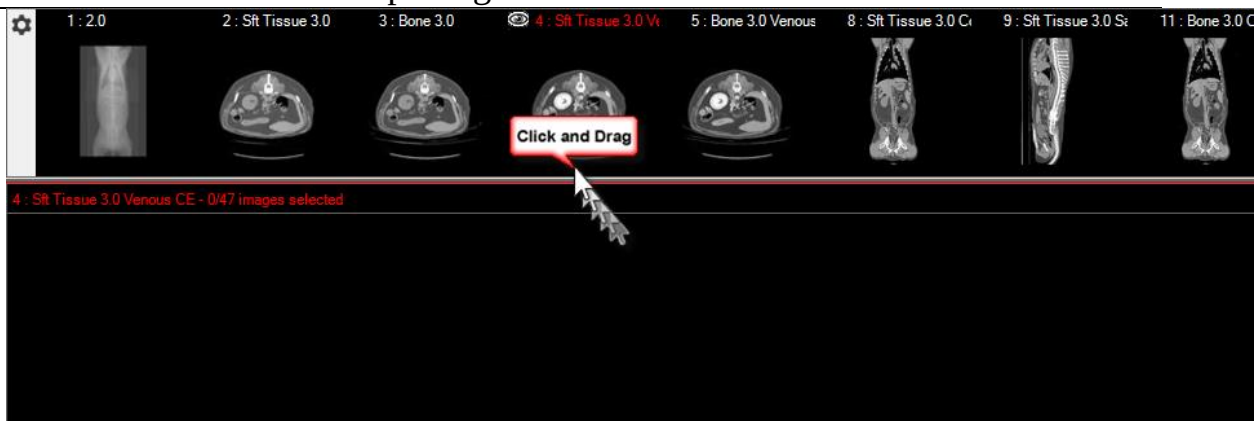
2-25 Virtual Incision

To create an annotation in the NovaPACS® Image Viewer, complete the following steps.

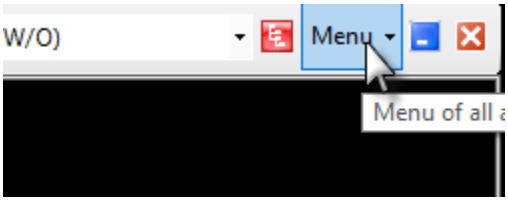
1. Find and open the study in the Study Browser.



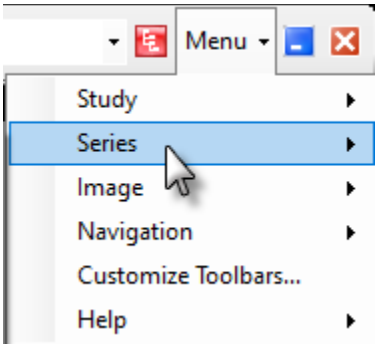
2. After the study has completely loaded, select the series you wish to annotate.



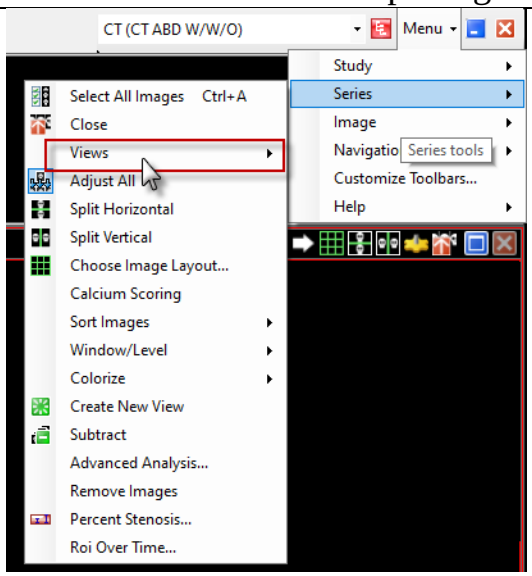
3. Select the Image Viewer **Menu**.



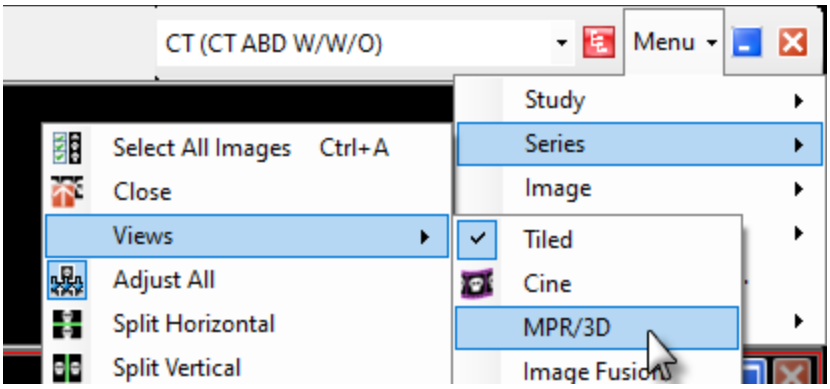
4. Select the **Series** menu in the Image Viewer.



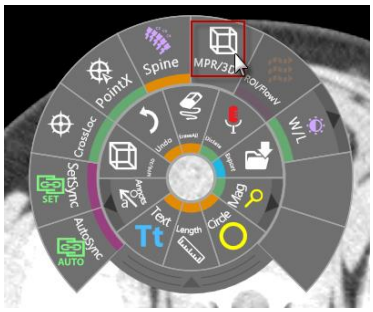
5. Hover your mouse over the **Views** option under the Series menu.



6. Select **MPR/3D** option.

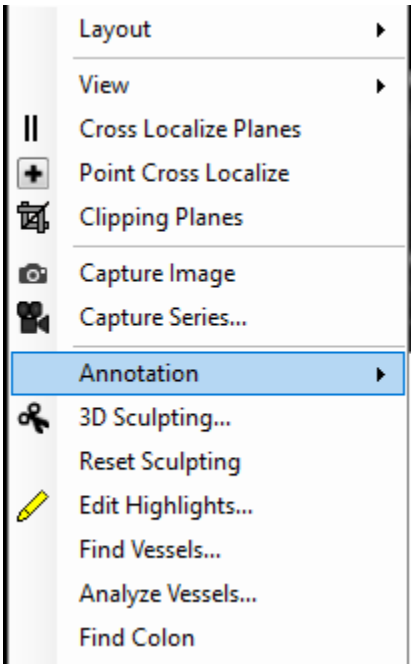


Please note: *Users can make the* ***MPR/3D*** *option a shortcut on the Image Viewer or Radius Menu.*

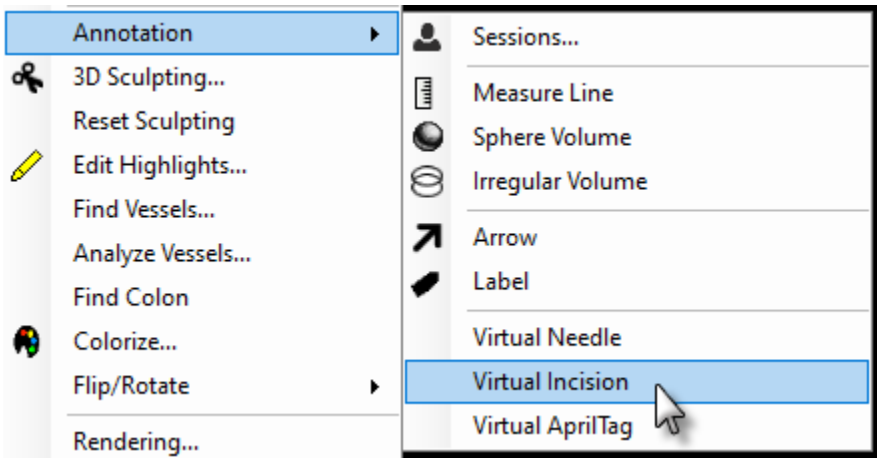


Allow the 3D image to completely render in the Image Viewer.

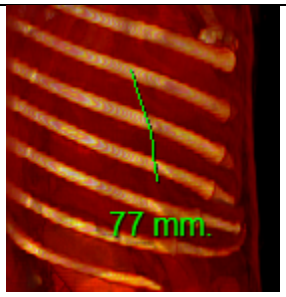
7. After the image has rendered in Nova3D+, right-click to populate the menu and select the **Annotation** option.



8. Select **Virtual Incision.**



9. Create the annotation on the 3D Image in the Image Viewer by right-clicking and dragging the mouse along where you want the incision to be. The length of the incision will also populate.

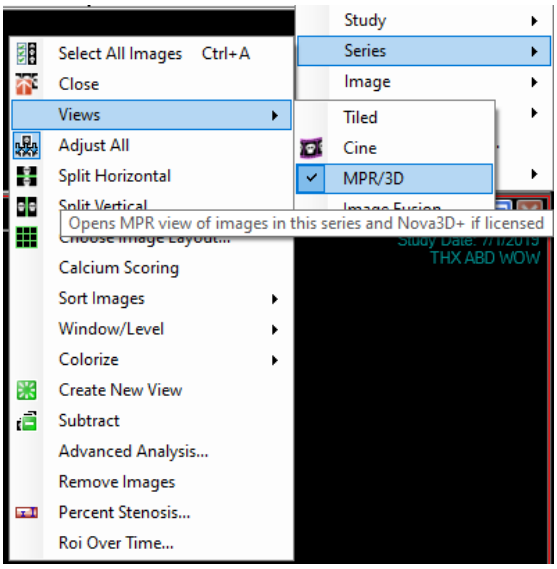


10. Save the changes in NovaPACS®.

2-26 Sphere Annotation

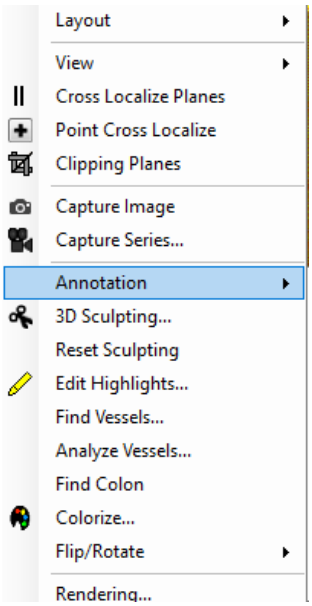
To create an annotation in the NovaPACS® Image Viewer, complete the following steps.

1. Launch NovaPACS®.
2. Find and open the study in the Study Browser.
3. After the study has completely loaded, select the series you wish to annotate.
4. Click the Image Viewer **Menu**.
5. Navigate to **Series → Views → MPR/3D**

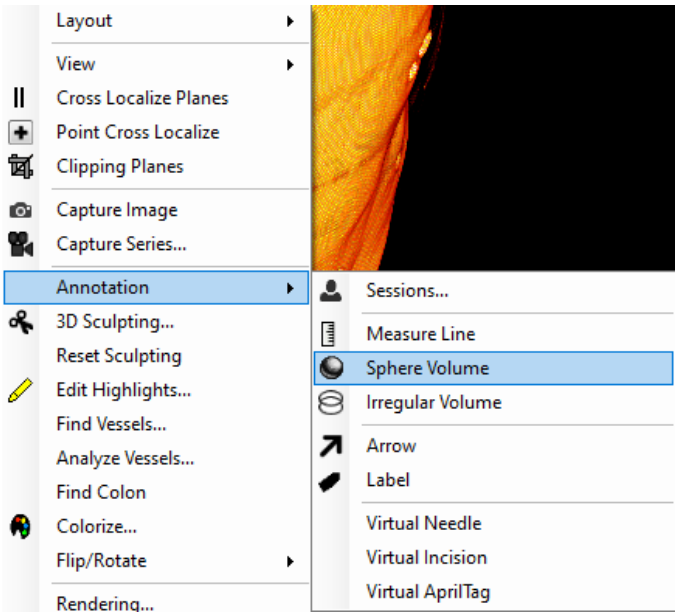


6. Allow the image to completely render in the Image Viewer.

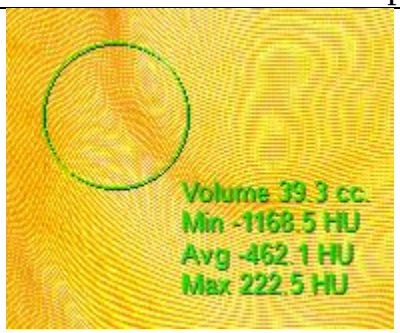
7. After the image has rendered in Nova3D+, right-click to populate the menu and select the **Annotation** option.



8. Select the **Sphere Volume** option.



9. Create the annotation on the 3D Image Viewer.



Please note: *The sphere annotation will show a circle all the way around the annotation, regardless of which orientation the OpenSight user is viewing from.*

10. Save the changes made in NovaPACS®.

2-27 April Tags

April tags are optical codes that assist OpenSight in aligning the hologram study onto the patient in the operating room. April Tags are placed on the patient before the pre-op scan and are included in the same scan. When placing the April Tags on the patient, the areas must first be sanitized with whatever kind of sanitizing method you wish. The April Tags should then be placed on the patient. After the April Tags are placed on the patient, place Tegaderm film (or another transparent, sterile film) over the April Tags to ensure that the tags stay in one place during the scan.

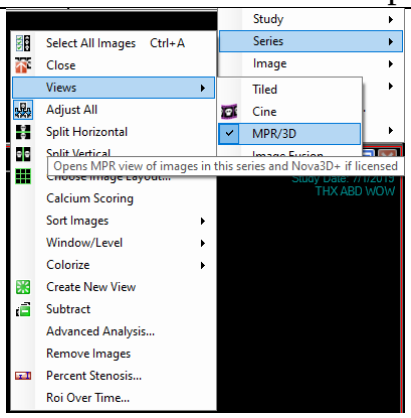
After the pre-op scan takes place, users will need to align the April Tags in NovaPACS®.

Manually Align

1. Open the study in the NovaPACS® Image Viewer.

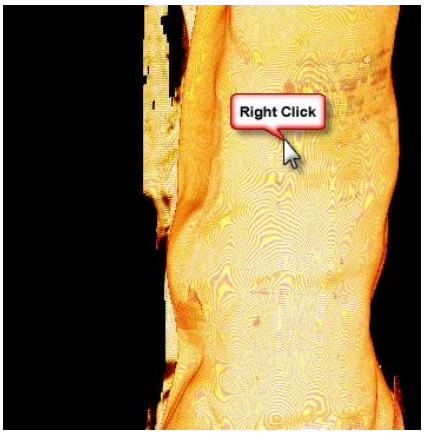
2. Select the series you wish to view.

3. Navigate to **Menu → Series → Views → MPR/3D**

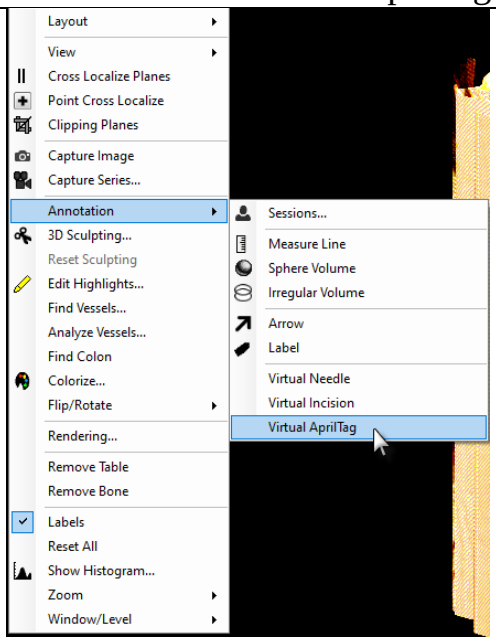


Allow the image to render in the 3D+ Viewer.

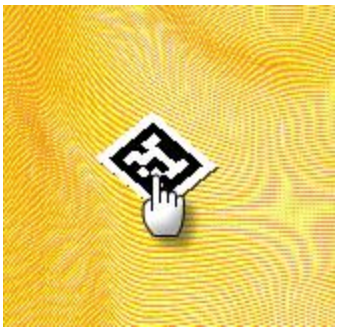
4. Right-click to populate the menu.



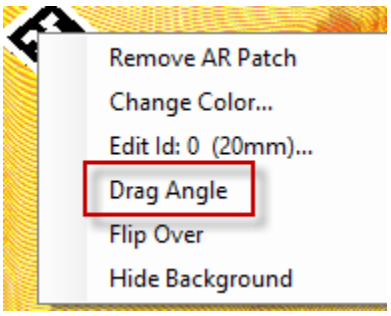
5. Select **Annotation → Virtual AprilTag.**



6. An April Tag will populate on the mouse cursor and users are able to place the virtual April Tag on the 3D image over where the previously scanned April Tags that were scanned by the modality.



7. Users can adjust the angle of the virtual April Tag to match the scanned April Tags by right-clicking on the virtual April Tag and selecting **Drag Angle**.



8. Repeat for each April Tag that is populated on the 3D image.

2-28 Voice Commands

This section details all the available voice commands in OpenSight.

Action in Immersive Viewer	**Voice Command(s)**
Enter calibration mode	Calibration mode, turn calibration on (**Please note:** Users will need to have the OpenSight calibration sheet in the field of view.)
Rotates the image to the prone position with the left side oriented towards the viewer	Rotate prone left
Rotates the image to the prone position with the right side oriented towards the viewer	Rotate prone right
Rotates the image to the prone position with head oriented towards the viewer	Rotate prone head
Rotates the image to the prone position with the feet oriented towards the viewer	Rotate prone feet
Rotates the image to the supine position with the left side oriented towards the viewer	Rotate supine left
Rotates the image to the supine position with the right side oriented towards the viewer	Rotate supine right
Rotates the image to the supine position with head oriented towards the viewer	Rotate supine head
Rotates the image to the supine position with the feet oriented towards the viewer	Rotate supine feet
Orients the image to be as though the patient is facing you.	Rotate facing
Turns lighting on/off	Turn lighting on/off, lighting Toggle
Changes from the slice color map (blue) to the volume color map (orange) and vice versa	Turn color on/off

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Turns on/off rendering of the image bounding box when in slice mode	Turn box on/off
Turns the hologram on/off	Turn image on/off
Turns on/off annotations if annotations have been made	Annotations on/off, annotation toggle
Populates/removes the table from the rendered image	Turn table on/off
Turns on/off all highlights associated with the image	Turn highlights on/off
Places the menu in the scene	Place menu
Shows/hides the menu	Turn menu on/off
Auto Detects April Tags in the image	Find April Tags, Detect April Tags
Displays the image orientation compass	Turn compass on, show compass
Turns on/off the Warning Text	Show Warnings, turn warnings on/off
Displays an arrow to assist in finding an image when it's not rendered within the view frame	Find image, find the image, where's the image?
Hides the image-location-assist-arrow if displayed	Hide image indicator
Takes a screenshot	Document this, capture this, save this
Enter/Exits slice mode	Slice on/off
Displays slices along the axial plane	Axial slice, axial plane
Displays slices along the coronal plane	Coronal slice, coronal plane
Displays slices along the sagittal plane	Sagittal slice, sagittal plane
Displays slices along the oblique plane	Oblique slice, oblique plane
Displays slices along the closest plane	Closest slice, closest plane
Locks/unlocks oblique slice	Lock/unlock oblique slice

Anchors the image to the point indicated by the cursor at the time of the click	Click position
Adjusts the contrast of the image	Adjust brightness
Sets the drag command to adjust the window level	Drag window level, adjust window level
Returns the window level to its default settings	Reset window level
Sets the drag command to adjust the transparency	Drag transparency
Adjusts the speed of the Cine in loops per minute	Drag speed, drag cine speed, adjust speed
Turns on/off the Automatic Cine of the 4D images	Turn cine on/off, start/stop cine
Sets the drag command to rotate the image about the x-axis	Rotate horizontal, rotate yaw
Sets the drag command to rotate the image about the y-axis	Rotate vertical, rotate pitch
Sets the drag command to rotate the image about the z-axis	Rotate circular, rotate roll
Sets the drag command to the 360 Drag (HoloLens 2 only)	Drag fast rotation
Sets the drag command to drag the position of the image	Drag position
Sets the drag command to slowly drag the position of the image	Drag slow, drag slow position
Sets the drag command to adjust the scale of the image	Drag slice
Adjusts the scale of the image	Drag zoom
Restores the scale of the image to its actual size	Reset zoom

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Adjusts the thickness of the slice	Drag thickness
Creates a sphere annotation	Create sphere
Deletes the sphere annotation	Delete sphere
Causes the image to spin	Auto spin, auto spin on
Causes the image to stop spinning	Stop auto spin, auto spin off
Adjust Auto Spin Speed	Auto Spin Speed

⚠ **Physical Changes between time of scan and OpenSight headset use:**

Conditions of physical changes such as swelling or anatomy that shifts or moves between time of scan and OpenSight headset use may cause inaccurate localization of anatomy. The following is recommended:

1. Patients be in the exact same position and they were in the scanner.
2. Time between scan and OpenSight headset use is under 24 hours.

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

OpenSight displays a warning label within the lenses indicating the elapse time. Elapse time always shows. The warning label will be colored red and bold and includes the words “May be inaccurate” if the time is greater than 24 hours.

Attachment A: Microsoft HoloLens Regulatory and Warranty Guide

Taken from Microsoft.com website

REGULATORY INFORMATION

Disposal of Waste Batteries and Electrical & Electronic Equipment

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

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

For Customers in the United States and Canada

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

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

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

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

Radio and TV Interference Regulations

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

- Relocate the antenna of the other radio-communications device (for example AM/FM Radios, televisions, baby monitors, cordless phones, etc.) until the interference stops.
- Move the hardware device farther away from the radio or TV, or move it to one side or the other of the radio or TV.
- Plug the device into a different power outlet so that the hardware device and radio or TV are on different circuits controlled by different circuit breakers or fuses.

- If necessary, ask your device dealer or an experienced radio-TV technician for more suggestions. For more information about interference issues, go to the FCC Web site at: https://www.fcc.gov/cgb/consumerfacts/interference.html. You can also call the FCC at 1-888-CALL FCC to request Interference and Telephone Interference fact sheets.

Exposure to Radio Frequency (RF) Energy

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

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

EU Energy Consumption

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

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

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

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

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MANUFACTURER'S WARRANTY

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

Attachment B: Microsoft HoloLens Health & Safety

Taken from Microsoft.com website

Use requirements

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

Safety and comfort

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

⚠ **WARNING**

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

⚠ **Warning: Use in safe surroundings**

Using HoloLens can distract you and make it hard to see your surroundings. Holograms may appear to be at a distance but still block your view of nearby real objects.
Use only in a safe place that is appropriate for your activities. Avoid trip hazards, stairs, low ceilings, fragile or valuable items that could be damaged, etc. Do not use HoloLens when a full field of view and attention are needed for safety, such as while operating a vehicle or doing other potentially hazardous activities.

⚠ **Caution: Discomfort**

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

⚠ **Caution: Using Mixed Reality Comfortably**

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

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

Consider keeping your first sessions brief. Start slowly and look around to get a feel for how the virtual objects and the outside world interact. For most people discomfort should decrease as you get more practice over your first few sessions.
Take breaks periodically, stop, and rest if you experience any discomfort. The timing and length of breaks may depend on the individual user and what you are doing with HoloLens.
If you experience discomfort, stop using HoloLens and rest until you feel better. Sitting still in a well-lit environment can help speed recovery from disorientation. If you feel disoriented, avoid activities that require balance, coordination, or other capabilities until you recover. Be sure the display is properly calibrated. Take note of the type of content you were viewing and other aspects of the situation in which the discomfort occurred so you can adjust or ease into the situation next time. People differ in the time they take to adapt. Consider taking more frequent or longer breaks.

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

⚠ **Warning: Be physically capable of your intended use**

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

⚠ **Warning: Hearing Safety**

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

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

⚠ **Warning: Minimize your time listening to loud Sound**

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

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

⚠ **Warning: Be aware of Hearing Loss Symptoms**

Stop using this device and have your hearing checked if:

- You experience any hearing loss.

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

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

⚠ **Warning: Do not attempt repairs**

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

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

⚠ **Warning: AC adapter Safety**

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

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

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

⚠ **Caution: Cable and cord safety**

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

- Protect the power cords from being walked on.
- Protect cords from being pinched or sharply bent, particularly where they connect to the power outlet, the power supply unit, and the device.

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

⚠ **Warning: Battery Safety**

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

⚠ **Warning: Use near Water**

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

⚠ **Warning: follow instructions to avoid interference Problems**

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

⚠ **Warning: Potentially explosive atmospheres**

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

⚠ **Warning: Personal Medical Devices**

Radio-frequency emissions from electronic equipment can negatively affect the operation of other electronic equipment, causing them to malfunction. Although the device is designed, tested, and manufactured to comply with regulations governing radio frequency emission in countries such as the United States and Canada, the wireless transmitters and electrical circuits in the device may cause interference in other electronic equipment. Therefore, please take the following precautions: Pacemakers: The Health Industry Manufacturers Association recommends that a minimum separation of 15 cm (6 inches) be maintained between a wireless device and a pacemaker to avoid potential interference with the pacemaker.

Persons with pacemakers:

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

⚠ **Caution: Heat related Concerns**

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

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

⚠ **Warning: Photosensitive Seizures**

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

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

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

- Using HoloLens in a well-lit room.

- Do not use HoloLens when you are drowsy or fatigued.

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

⚠ **Warning: Choking Hazard**

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

⚠ **Caution: Skin irritation**

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

- Wipe your device dry with a cloth if it gets wet.
- Avoid using lotions or other products under the portions of HoloLens that contact your head.
- Do not wear over injured skin.
- Adjust the headband only until snug – avoid tightening the headband uncomfortably.

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

⚠ **Warning: Evaluate eye protection needs for your environment**

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

OpenSight®

Calibration Tool

Use this page to calibrate the headset **every time** you use OpenSight

Say:
"Turn Calibration On"

and follow the prompts

To calibrate inside OpenSight complete the following steps:

1. **Open** OpenSight
2. **Say** "Turn Calibration On"
   The left-eye calibration will commence first.
3. **Look at the Calibration QR code** through the HoloLens.
4. **Use the pinch-and-drag hand motion** to align the calibration QR code with the green virtual box
5. **Click to advance** to the right-eye calibration
6. **Use the pinch-and-drag hand motion** to align the calibration QR code with the green virtual box
7. **Click to exit** calibration
8. **The HoloLens will be calibrated for OpenSight**

OpenSight is 510(k) cleared for its intended use

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OpenSight AUGMENTED REALITY SURGERY