



SIRAMEDICAL

Instructions For Use

Sira Medical

Augmented

Reality Application

www.siramedical.com

@2023

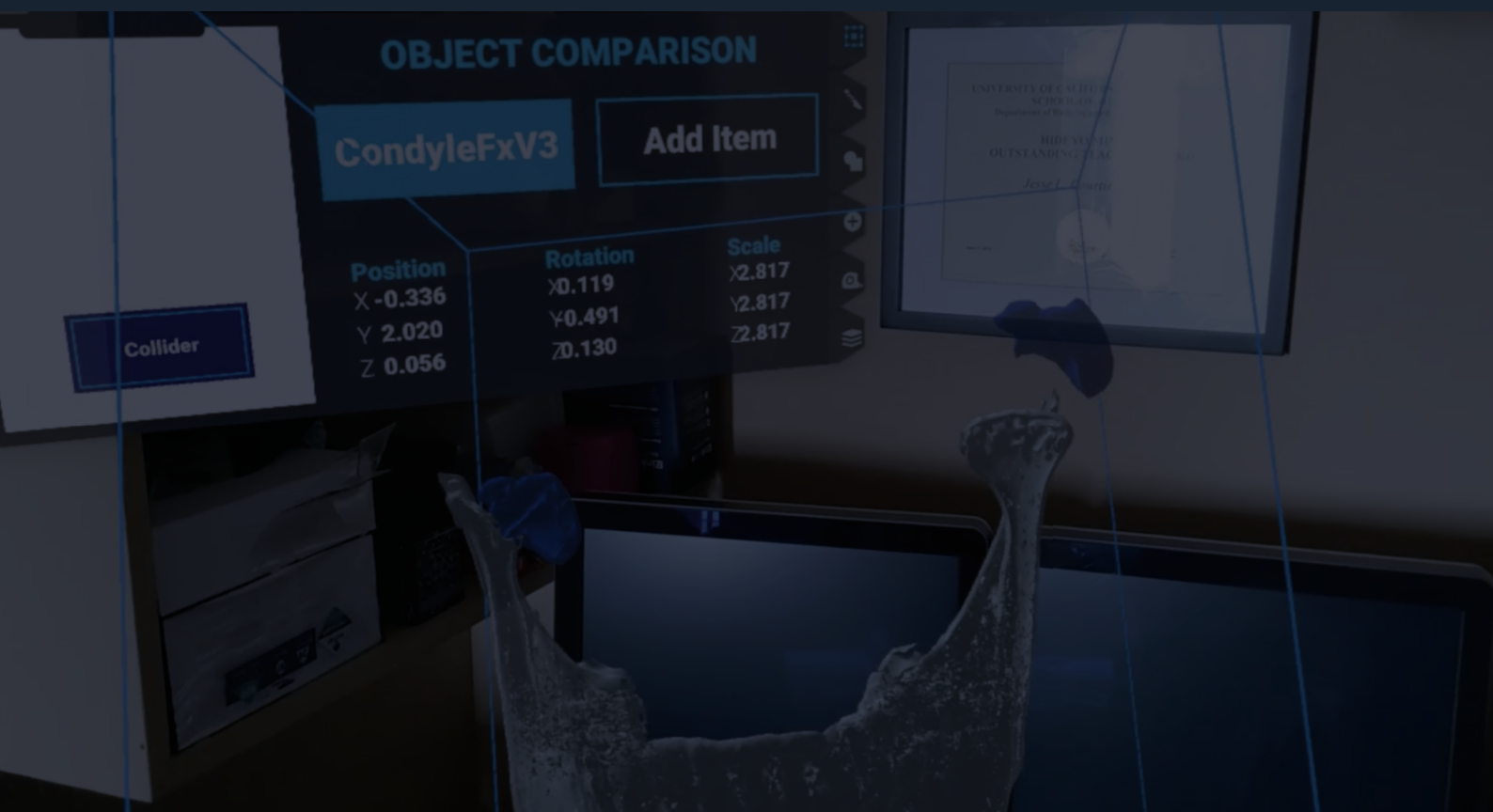


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1. Sira Medical

1 Product Description

The Sira Medical Augmented Reality Application and 3D Image Preparation Service provide access to patient-specific images which allow greater anatomical clarity and fidelity than conventional CT scans and MRIs. The application permits manipulation of the images to help clinicians preoperatively plan for surgery and allows capture of video and still images for use in preoperative surgical planning outside the application.

2 Intended Use

Sira Medical develops patient-specific images derived from the same data used to generate conventional imaging such as CT scans, MRIs and other images to help with preoperative surgical planning. The Sira Medical Augmented Reality Application is designed to help users view and manipulate these images.

Within preoperative surgical planning, the Sira Medical Augmented Reality Application and the images viewed through the application are used by clinicians to review patient anatomy and evaluate surgical paths, among other activities, and are intended for use across a range of medical specialties.

3 Indications for Use

Sira Medical Augmented Reality Application is intended as a medical imaging system that allows the processing, review, analysis, and communication of augmented reality images acquired from the same data used to generate conventional CT scans and MRIs. Sira Medical software is designed for preoperative surgical planning and intended to be used by trained and qualified clinicians who are responsible for making patient management decisions.

4 Contraindications

The Sira Medical Augmented Reality Application is not a diagnostic tool. The application is not to be used for stereotactic or intraoperative procedures.

5 Essential Functions

The Sira Medical Augmented Reality Application is used in conjunction with the Sira 3D Image Preparation Service. The Sira 3D Image Preparation Service prepares image files for viewing within the Sira Medical application. The 3D Image Preparation Service is operated by Sira Medical personnel, under control of Sira Medical, using specified inputs, tools, and processes, to create 3D outputs from the user's radiological study images. The image files are delivered in .fbx format.

The Sira Medical Augmented Reality Application is used for viewing and manipulating 3D models created by the Sira 3D Image Preparation Service. The application allows the user to manipulate one or more 3D models in real time in an Augmented Reality (AR) environment. The user can view the model, adjust the orientation, scale, rotate, and position the models within the AR visual space. Models can be sliced to create separate objects or merged together to create a single object. Screenshots and video files can be captured using the HoloLens 2 platform and exported for use outside the application.



Note: The environment for the Sira Medical Augmented Reality Application is limited to the Microsoft HoloLens 2 platform.

Models are accessed from a OneDrive location configured by the Sira 3D Image Preparation Service. The Sira Medical Augmented Reality Application does not update the 3D model as stored; all manipulations are local to the HoloLens 2 environment and are not preserved after the session is closed. Still shots and video files created during manipulation of the model are stored local to the HoloLens or on network locations to which the HoloLens has access.

6 Intended User

The intended user for the Sira Medical Augmented Reality Application are trained and qualified clinicians. User should be trained in the medical aspects of using and assessing radiology studies for preoperative surgical planning. User should be familiar with the use of the HoloLens in an Augmented Reality (AR) environment, AR manipulation of objects, and Sira Medical application.

7 Technical Specifications

Technical specifications for the Sira Medical application below with the latest at: siramedical.com/holo-lens-technical-specifications/

Item	Minimum Requirement
Headset	HoloLens 2 Mixed Reality Headset
HoloLens 2 Free Memory for Sira Medical Application	1 GB
Operating system	Windows Holographic 22H1
Network connection	WiFi 5 or later including performance supporting real time data synchronization, remote content streaming and updating.
Cloud storage	OneDrive account

The Sira Medical Augmented Reality Application uses relative spacing information and does not provide measurement information for the models. Relative distance positioning information is displayed in meters and relative angles are displayed in degrees.

2. Safety Advisory

Warnings and Cautions indicate conditions or consequences that you should pay particular attention to when working with Sira Medical applications and formulating a preoperative surgical plan.

1 Verify Information on Request Form



Warning!

Submitting incorrect data can lead to a poor preoperative surgical plan. Double check to make sure the information that is being submitted is correct. Always maintain conventional imaging as a backup.



Caution!

Make sure the information being submitted is anonymized. Always use the field in the Sira Medical Request Form to enter the anonymized Package ID and Source Image ID(s).

2 Select the Appropriate Model and Manipulate Properly



Warning!

Selecting the wrong model will lead to an incorrect preoperative surgical plan. Cross check the model package ID on the screen to make sure you are selecting the correct model file.



Warning!
No Package ID

If the Sira Medical Image Preparation Service did not include a package ID or labeled it incorrectly, the Label will show "No Package ID". Do not use a model without a package ID as this could result in a preoperative surgical plan for the wrong patient. Contact Sira Medical Customer Service for model correction.



Warning!

The Sira Medical application permits transparency of models to be adjusted from completely transparent to completely opaque. Inadvertently making a model completely transparent can lead to an incorrect preoperative surgical plan. If the model is completely transparent use the transparency slider to adjust the transparency setting.



Warning!

Failure to properly manipulate an image can lead to an ineffective preoperative surgical plan. Users must be trained and qualified clinicians who are familiar with the use of the HoloLens 2 in an AR environment, AR manipulation of objects, and the Sira Medical Augmented Reality Application.



Warning!

Merging models with scales mismatched can result in an incorrect preoperative surgical plan. The software automatically resets the scale of item 2 to match item 1. Please confirm position and try again.

3 Logging Off



Warning!

Double check to make sure you have logged out of the Sira Medical application when done. Failure to logout can lead to model manipulation by others and ultimately an incorrect preoperative surgical plan.

4 Image Display



Warning!

As with any imaging modality, models may hide clinically relevant data leading to an incorrect preoperative surgical plan.

5 Critical Anatomy



Warning!

Reviewing a model while using the wrong orientation can lead to an incorrect preoperative surgical plan. Double check to make sure the orientation is appropriate for proper preoperative surgical planning.



Warning!

This application is designed for HoloLens 2 manufactured by Microsoft. Use of these models with other head mounted devices can lead to poor model display and an incorrect preoperative surgical plan.

6 Other Issues



Warning!

Unauthorized access to the HoloLens 2 captured sessions could lead to an incorrect preoperative surgical plan. Users should take action to prevent unauthorized access to the HoloLens 2 files and always have a trained and qualified clinician review output screenshots or video prior to clinical use.



Warning!

Cybersecurity breach could result in unauthorized access to the Sira Medical Augmented Reality Application and the Microsoft OneDrive account which could lead to lost or modified 3D Models and ultimately an incorrect preoperative surgical plan. Always inspect 3D models prior to use. If any anomalies such as unexpected labels or colors in the model are noted, contact Sira Medical Customer Service for model correction. Always check the Microsoft Store for the latest security patch updates to the Sira Medical Augmented Reality Application.

7 Hazardous Situations Associated with Use of Applications

As with all network-connected applications, some hazards may be introduced by installing and running the Sira Medical Augmented Reality Application. While cybersecurity has been carefully considered during the design and testing of the Sira Medical Augmented Reality Application, the user is advised to work with their IT department to ensure that network connection hazards have been considered and appropriate measures and policies are in place. The following information is a guide in assessing potential risks from use of a network-connected application and includes general advice on use of applications in a network-connected environment.

- Maintain physical control of HoloLens 2 with the Sira Medical AR app at all times. Add a physical lock to the USB-C port to prevent unwanted connections. Disable Bluetooth while using the app to improve security.
- Failure of the network or network access will limit the application's ability to access and download 3D model files but does not present any additional risks.
- The network should be configured for appropriate security including firewalls, user authentication, and other standard methods of access control. The application does not require any special network configuration other than access to a OneDrive location and Microsoft voice transcription services.
- Normal network security practices should be applied. Medical devices and medical databases should be segregated on a network separate from business functions. All data transfers should be configured to use encrypted protocols like HTTPS where possible. Always change default access credentials upon receiving new medical devices or networking equipment.
- The HoloLens 2 platform should be configured for controlled user authentication to control unintended access to model files in accordance with the user's security policies. Enforce use of complex passwords coupled with multifactor authentication. A password manager can automatically generate complex passwords, verify sites you visit and insert usernames and passwords in web forms. Always follow manufacturer recommendations for any identity and access management solutions used in your networks and edge devices (including HoloLens 2).
- Reduce your attack surface by assigning role-based access controls and administering access based on least privilege required to accomplish a task. Establish a system access control list for the local storage folders on HoloLens 2 to enable file system auditing for 3D model and log files.
- Set a group policy for USB devices to disable all but charging functionality (./Device/Vendor/MSFT/Policy/Config/Connectivity/AllowUSBConnection = 0).
- The HoloLens 2 platform should be configured for minimum inactivity lock timeouts to control unintended access to model files in accordance with the user's security policies.
- Enable automatic updates to Windows, networking software and applications to maintain a high level of security.
- Routinely scan your networks and edge devices for malware. If you use a Bluetooth or USB-C keyboard and/or mouse with your HoloLens 2, screen for malware before attaching to HoloLens 2.

- Use OneDrive for Business instead of a personal OneDrive account for transferring Sira Medical 3D model files.
- Operate HoloLens 2 in a secure area free of potentially interfering equipment (radio frequency generators).
- Use of the Sira Medical Augmented Reality Application on a network could result in previously unidentified risks to patients, users, or third parties as a result of unauthorized access to the network or cybersecurity breach. Employ appropriate security policies and methods. The user is advised to identify, analyze, evaluate and control these risks as appropriate to their environment.
- Subsequent changes to the network could introduce new risks and require additional analysis, including:
 - changes in network configuration
 - addition of items (hardware and/or software platforms or software applications) to the network
 - removal of items from the network
 - update of hardware and/or software platforms or software applications on the network
 - upgrade of hardware and/or software platforms or software applications on the network

3. Installation

This section includes information on installing the Sira Medical Augmented Reality Application.

1 Installation

The Sira Medical Augmented Reality Application is installed through the Microsoft Store once your account with Sira Medical has been established. Installation instructions are below as well as on the Sira Medical webpage: siramedical.com/hololens-installation/

- 1. Access the Application Link:** Open the specific link shared with you. This can be done on any device including a computer, tablet, or the HoloLens itself.
- 2. Authorize the Account:** Ensure the Microsoft account you are using is authorized for installation. If you are not signed in already, the Microsoft Store will prompt you to sign in. Use your authorized account credentials.
- 3. Click on 'Get':** Once you've accessed the link and confirmed your account, you will see a "Get" button. Click this to authorize your account to install the application on a HoloLens.
 - If you are doing this on the HoloLens, the application will automatically start installing.
 - If you are doing this on another device, the application will not automatically install on the HoloLens, but it will be made available to install later.
- 4. Install the Application on HoloLens (if you used another device for previous steps):**
 - Open the Microsoft Store on your HoloLens device.
 - Click on the 'Library' icon, usually found on the upper-right of the screen.
 - Set the filter to show 'Apps not installed on this device'. This should show a list of apps associated with your account that are not currently installed on the HoloLens.
 - Look for your application in the list and click on the 'cloud' icon next to it. This will start installing the application on your HoloLens.

To assure a secure environment we recommend the following HoloLens 2 set up:

- Follow the HoloLens 2 instructions for Multi-Factor Authentication.
- Follow HoloLens 2 instructions to enable iris authentication for individual log in to your HoloLens 2.
- Setting inactivity lockout time configuration can be managed in the system settings and is suggested to be set at the minimum time possible.
- Follow the Microsoft instructions to assure each user is set up with their own Microsoft account for OneDrive access to 3D Model files.


Contact your IT department or Sira Medical Customer Service for assistance in installing the application and configuring your HoloLens 2 for use with the Sira Medical Augmented Reality Application if further support is needed.

2 Application Updates

The Sira Medical Augmented Reality Application is updated through the Microsoft Store. Contact your IT department or Sira Medical Customer Service for assistance in updating the application.

3 HoloLens 2 Environment

The Sira Medical Augmented Reality Application is intended to run on the HoloLens 2 platform with version 22H1, Build 20348.1501 or later. Reference Technical Specifications for hardware and network requirements.

 Note: Reference the Sira Medical Augment Reality Application release notes or the Sira Medical website for latest version(s) of the Microsoft HoloLens 2 System with which the application has been optimized.

The Sira Medical Augmented Reality Application requires internet access to operate. The HoloLens 2 may be configured to use WiFi 5 protocols for faster internet access.

For use of HoloLens-native features in an AR environment, refer to your HoloLens 2 user instructions - <https://learn.microsoft.com/en-us/hololens/hololens2-basic-usage>

The Sira Medical start menu includes a quality control image intended to ensure appropriate brightness settings given ambient lighting conditions. The quality control image, a white, gray, and black vertical number board up to number 9 is situated next to the start menu icons. A picture of the quality control image is on the right. For best viewing, adjust the brightness settings on the left hand side of the HoloLens 2 visor until you can see the numbers contained in the quality control image clearly.



In low level light all numbers 1-9 on the quality control image should be visible. In medium level light, if you cannot see the number 6 on the quality control image, consider reducing the ambient light or moving to a darker environment. In bright light all numbers on the quality control image will be difficult to see. Reduce ambient light or move to a darker environment.

For additional information regarding appropriate brightness settings, review Microsoft's environment considerations here: <https://learn.microsoft.com/en-us/hololens/hololens-environment-considerations>.

4 OneDrive Access

The Sira Medical Augmented Reality Application requires OneDrive to access 3D model files. Secured access to OneDrive with appropriate user authentication should be configured to provide appropriate network security. Reference the Technical Specifications section for OneDrive and network requirements.


4. Submitting Images for 3D Modeling

1 Establish Client Services

Before requesting a Sira 3D Model, the following must be completed:

- Obtain a HoloLens 2 and set it up as defined above,
- Order and install the Sira Medical Augmented Reality Application as defined above,
- Establish a contract with Sira Medical for 3D Model Image Preparation services.
- Have your Sira Medical Augmented Reality Application Sales Order Number which will be required on the 3D Model Request Form,
- Establish your OneDrive account for receipt of requested 3D Models,

Sira Medical Customer Service will provide a 3D Model Request Form once client services have been set up as given above.

 Note: Each model requested requires an individual request form.

2 Requesting a 3D Model

After receiving the 3D Model Request Form, complete all sections and include any special instructions for what you would like included within your model.

3D Models are identified with a Package ID you specify. This identification should be an anonymized ID which traces to the patient as well as the package of images which you are supplying to create this model. In addition, each DICOM image file supplied should be identified using an anonymized identification number which traces to the image and the patient. The Package ID and source Image ID's will appear on the 3D Model with the Package ID appearing first.

Upload your completed order form and DICOM images to the Sira share drive link which was provided to you by Sira on the 3D Model Request form.



Warning!

Submitting incorrect data can lead to a poor preoperative surgical plan. Double check to make sure the information that is being submitted is correct. Always maintain conventional imaging as a backup.



Caution!


Make sure the information being submitted is anonymized. Always use the field in the Sira Medical Request Form to enter the anonymized Package ID and Source Image IDs.

3 Receiving a completed 3D Model

Completed 3D model files will be delivered to your OneDrive directory. Sira Medical radiologist staff use commercial and open-source software according to a Standard Operating Procedure to prepare output files and return ready-to-view 3D files to Sira customers after a quality assurance check performed by a board-certified radiologist. The QA check includes verification that package IDs and image IDs have been added, manually assigned colors match assigned colors or colors requested in customer request form, anatomy included matches customer request form, and any special labeling

required by customer is included. The QA check also includes a model file and memory check, confirmation that all artifacts from the original DICOM remain, there are no artificial artifacts, and model image orientation is correct.

All model files use a proprietary .fbx file format. Sira Medical will contact the phone number provided on the Request Form to obtain access information for uploading the 3D Model to your OneDrive directory which is used within the Sira App.

 **Note:** The One Drive directory you provided to Sira Medical Customer service should be the same One Drive Account which is signed into within the Sira Medical Augmented Reality Application.

5. Getting Started with the Sira Medical Augmented Reality Application

1 Network Configuration

The Sira Medical Augmented Reality Application requires internet connection and OneDrive download capability as defined in the Installation Section above.

2 Sira Medical Augmented Reality Application

1. Turn power on by pressing the circular power button on the rear right side of the HoloLens 2.



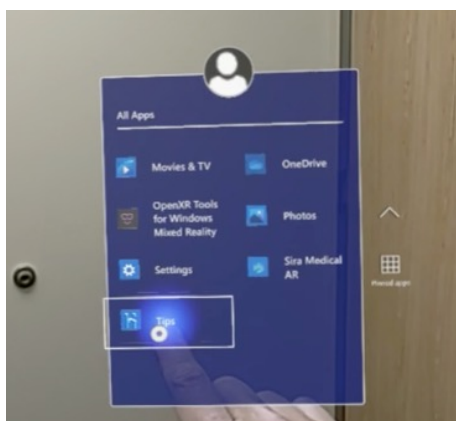
Warning!

This application is designed for HoloLens 2 manufactured by Microsoft. Use of these models with other head mounted devices can lead to poor model display and an incorrect preoperative surgical plan.




Note: Proper model display is subject to fully functioning head-mounted devices not manufactured by Sira Medical. This hardware is subject to hazards typical for these types of devices and should be maintained in accordance with the manufacturers' instructions.

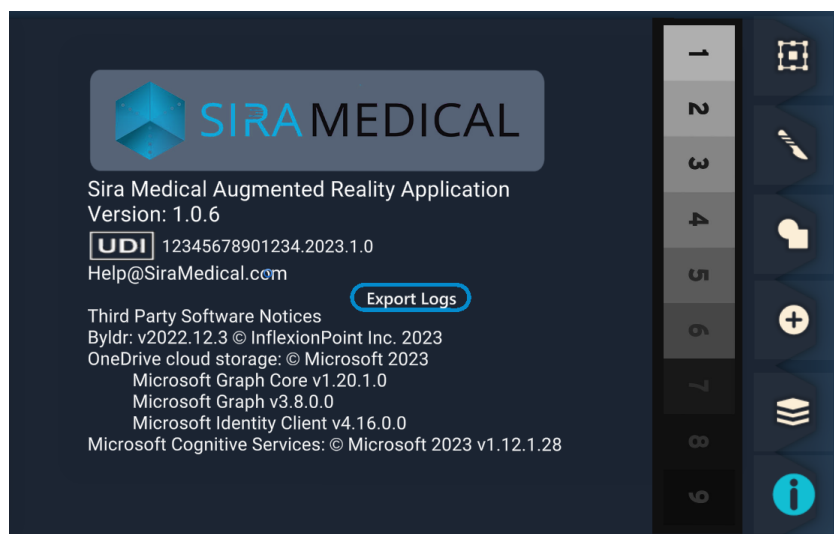
2. For instructions on using HoloLens 2 press the Tips button on the home menu and follow the instructions. Setting inactivity lockout time configuration can be managed in the system settings and is suggested to be set at the minimum time possible.



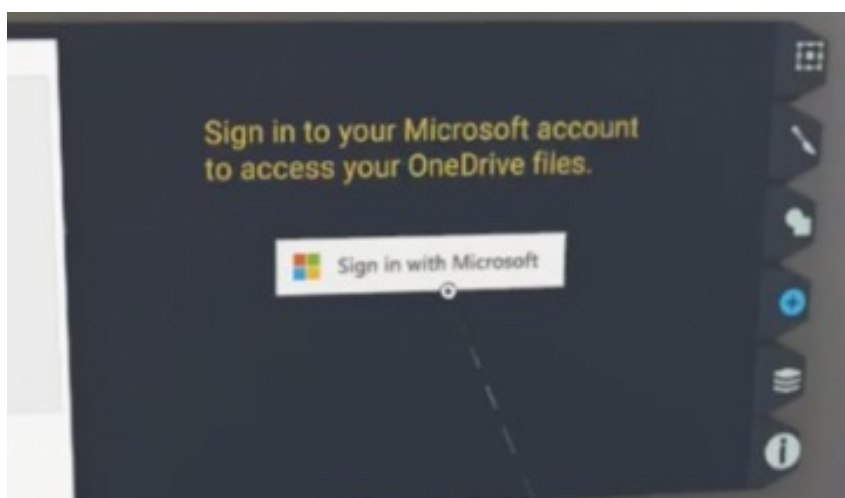
Note: Use of or opening other applications at the same time as the Sira Medical Augmented Reality Application could result in interference or unexpected closure of the Sira Medical application. User is advised to close other applications prior to starting the Sira Medical Augmented Reality Application.

3. Once finished reviewing the tips, download the application as directed in the installation section above. Open the Sira Medical Augmented Reality Application.

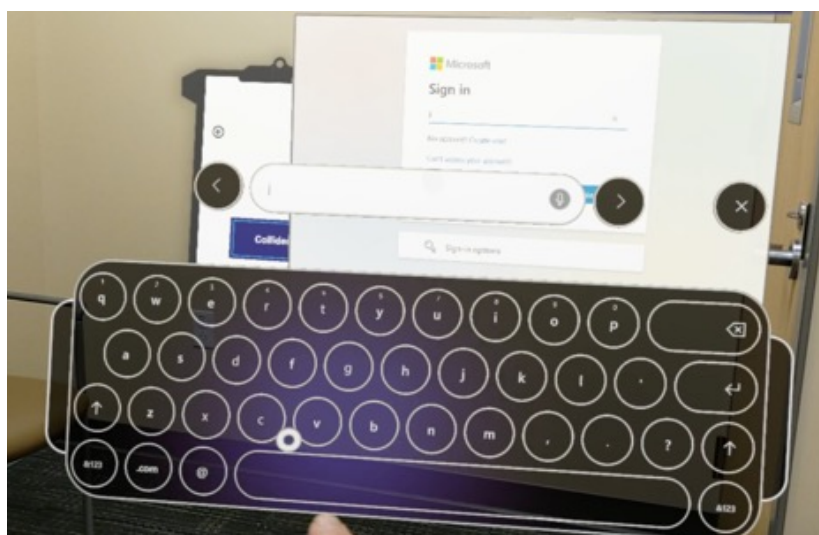
4. Once the application is open the tool palette will be visible.
Select  by touching or air tapping the icon on the right-hand side of the screen if not already signed in.




5. Select login. A login screen will appear for MS OneDrive



6. Enter your OneDrive credentials to login.



 Note: The keyboard can be repositioned by pinching one or both of the handles on the right and left side of the virtual keyboard.

7. All models on OneDrive will be visible.

 **Note:** UI may freeze temporarily while loading large image files.



8. Select a model to download. Package ID will be included in file name.
9. Once the file has been downloaded to the HoloLens 2, close the Add tab and view the model. The Package ID will be displayed with the model. To ensure the model being displayed is the intended image for the patient, confirm the package ID is as expected.





Warning!

Selecting the wrong model will lead to an incorrect preoperative surgical plan. Cross check the model package ID on the screen to make sure you are selecting the correct model file.



Warning!
No Package ID

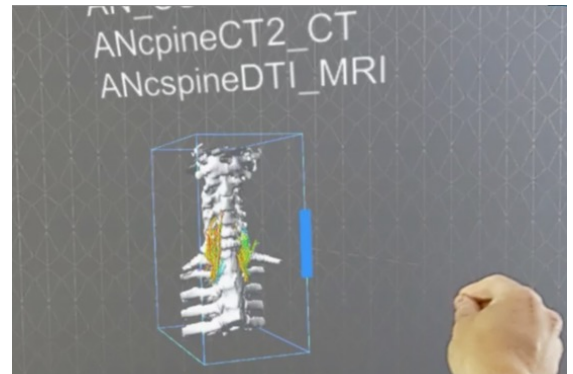
If the Sira Medical Image Preparation Service did not include a package ID or labeled it incorrectly, the Label will show "No Package ID". Do not use a model without a package ID as this could result in a preoperative surgical plan for the wrong patient. Contact Sira Medical Customer Service for model correction.

-  **Note:** Sira Medical's applications and images are delivered via cloud services and speed of the application and image delivery is dependent on the speed of the network you are using to access the applications and images.
-  **Note:** Sira Medical's applications and images are delivered via cloud services and are subject to cybersecurity risks typical for these types of services.

3 Model Manipulation/360 Degree Tour

The HoloLens2 uses finger tracking. The model can be moved by holding directly to rotate, reposition and resize. Pinching the borders allows for rotation, reposition, and resizing will allow the user to manipulate the model.

▶ Video example here:
[vimeo.com/user203243304/
modelmanipulation?share=copy](https://vimeo.com/user203243304/modelmanipulation?share=copy)



Warning!

Failure to properly manipulate an image can lead to an ineffective preoperative surgical plan. Users must be trained and qualified clinicians who are familiar with the use of the HoloLens 2 in an AR environment, AR manipulation of objects, and the Sira Medical Augmented Reality Application.

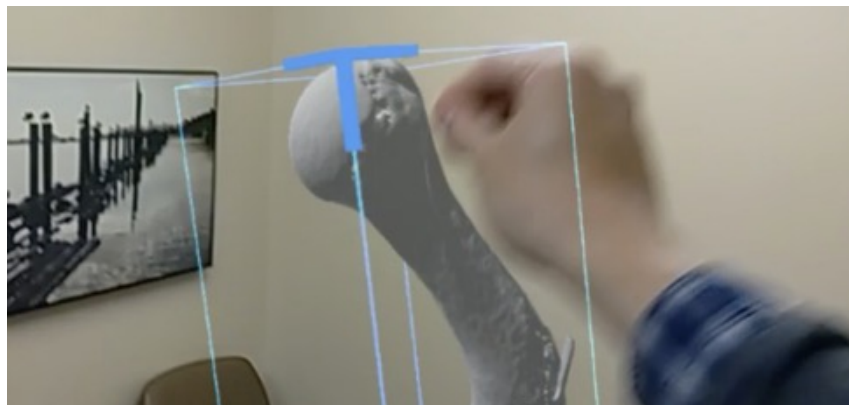


Warning!

Reviewing a model while using the wrong orientation can lead to an incorrect preoperative surgical plan. Double check to make sure the orientation is appropriate for proper preoperative surgical planning.

4 Sizing and Resizing

Pinching the blue lines at the corners of the model will allow the user to increase or decrease the size of the model.



Warning!

Failure to properly manipulate an image can lead to an ineffective preoperative surgical plan. Users must be trained and qualified clinicians who are familiar with the use of the HoloLens 2 in an AR environment, AR manipulation of objects, and the Sira Medical Augmented Reality Application.



Warning!

As with any imaging modality, models may hide clinically relevant data leading to an incorrect preoperative surgical plan.

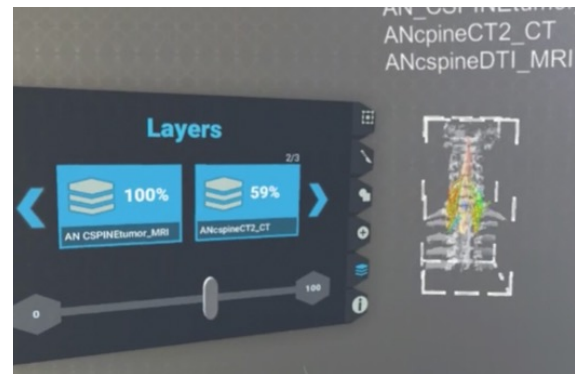
5 Layer Visibility

Select  on the right.

This can be adjusted via a slider bar positioned at the bottom of the tool palette. Visibility can be adjusted for each sublayer between completely invisible (0%) to completely solid (100%) and anywhere in between.

▶ Video example here:

[vimeo.com/user203243304/
adjustinglayervisibility?share=copy](https://vimeo.com/user203243304/adjustinglayervisibility?share=copy)



Warning!

The Sira Medical Augmented Reality Application permits transparency of models to be adjusted from completely transparent to completely opaque. Inadvertently making a model completely transparent can lead to an incorrect preoperative surgical plan. If the model is completely transparent use the transparency slider to adjust the transparency setting.

6 Object Comparison

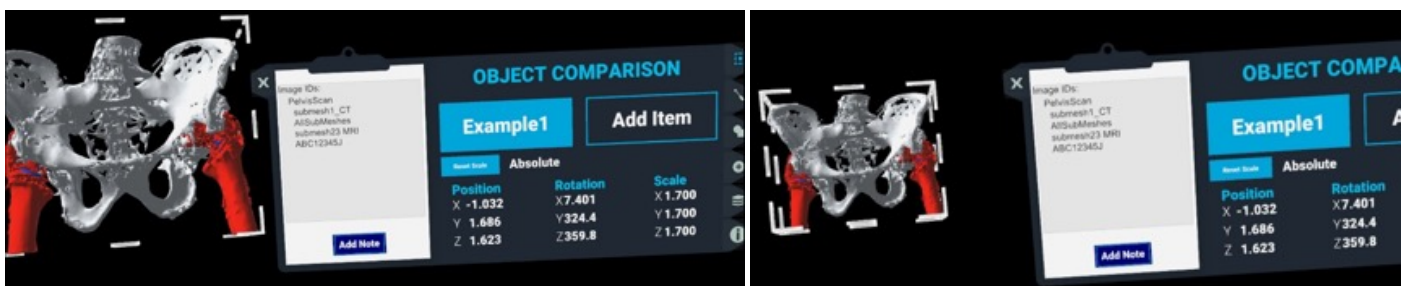
When comparing two 3D objects the tool palette will allow the user to compare the positions of two objects in space relative to one another. If only one object is selected, it will show position in space relative to the origin point.

If two objects are selected, it will show relative to the first object comparisons. To return to one object inspection double click on either of the object buttons. Select **Add Item** and select another model in the scene to make **Match Scale** and **Match Position** icons visible.

Scale is relative: 1.000 is normal scale, 2.00 is twice normal scale.

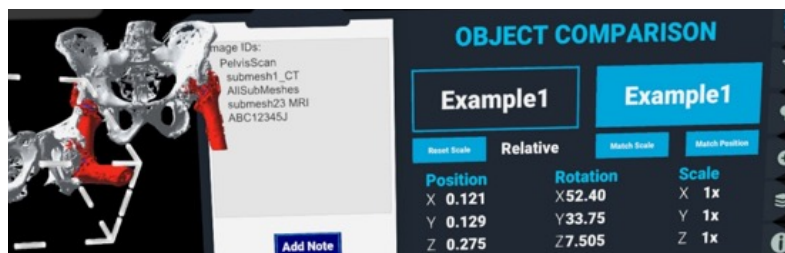
- Reset Scale**

Pressing **Reset Scale** will revert the left selected model back to its original scale of 1x.



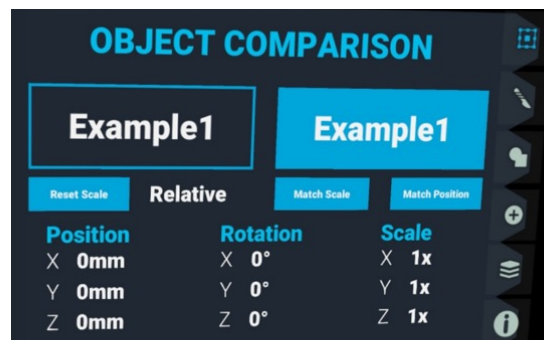
- **Match Scale**

When viewing two objects, selecting **Match Scale** will set the right selected model at the same scale of the left selected model.



- **Match Position**



When viewing two objects, selecting **Match Position** will set the right selected model at the same position, rotation, and scale of the left selected model.



- **Reset to Single Item Analysis**

To remove the second item to view just a single item analysis, double click one of the item name boxes

7 Virtual Cut


Select  on the right. Select blue cutting plane below the model. Reposition to desired cutting angle. Select .



 **Note: Application will temporarily go blank for 5-10 seconds**

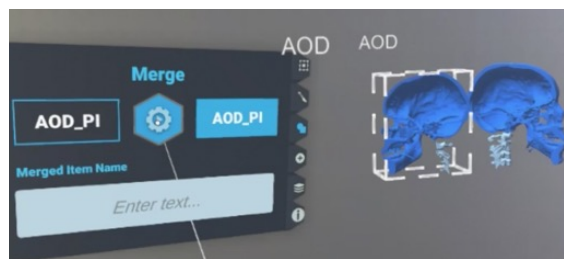
Model will reappear with cutting plane no longer present. Model pieces can now be moved separately.



 Video example: vimeo.com/user203243304/virtualcut?share=copy

 Note: While segmenting a model double check to make sure the appropriate layer is being selected for review.

Merging of two 3D models can be performed by clicking on the  on the left of the palette. Selecting a name for the object, then selecting one object > clicking add > then selecting the other object. Finally click the  in the center.



Video example: vimeo.com/user203243304/merginganaugmentedrealitymodel?share=copy

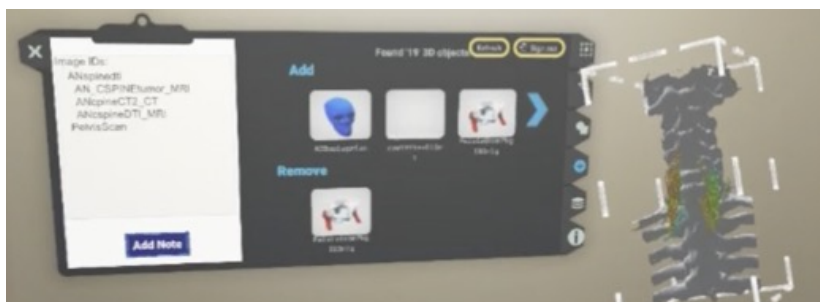


Warning!

Merging models with scales mismatched can result in an incorrect preoperative surgical plan. The software automatically resets the scale of item 2 to match item 1. Please confirm position and try again.

8 Adding Notes, Annotations, and Labels

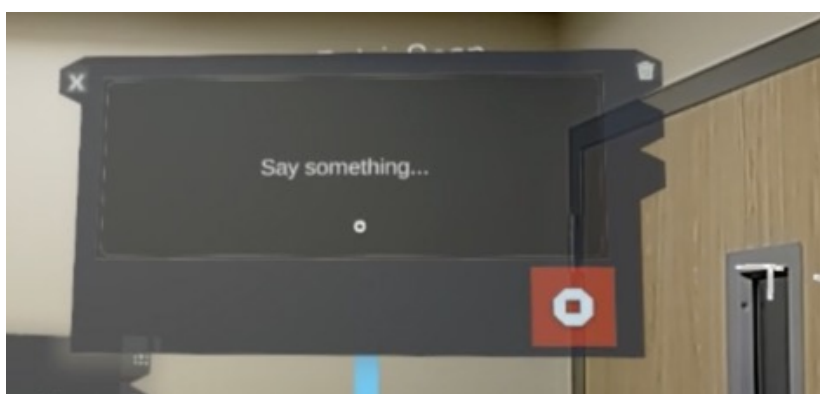
1. To add a note, click on **Add Note** on the clipboard, or say the voice command "New Note".



2. Blue circle will appear. Place this blue circle where you would like to annotate on the model



3. Tap to place the annotation. A screen will appear where text can be added via voice command or selected to bring up a keyboard.



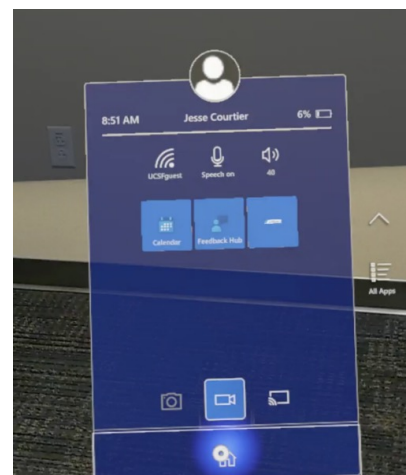
4. Add desired text.




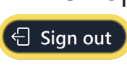
9 Session Recording

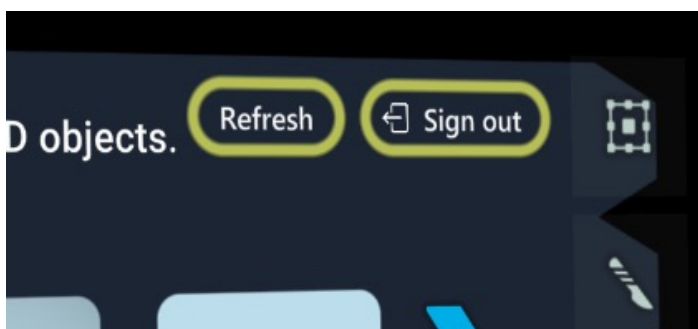
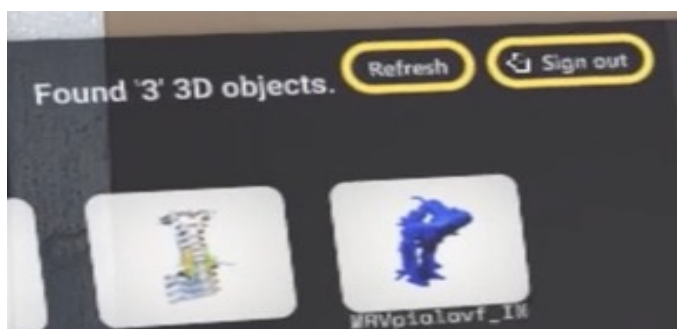
Sound and video capture can be done via HoloLens 2's built in recording capabilities. Saying "Start recording" to turn on recording and "Stop recording" to turn off recording or accessing the start menu and clicking on and off the recording icon can allow the user to record their model review session.

- ❗ Failure to properly store captured images and recordings of the preoperative surgical plan can result in difficulty in retrieval or loss of these files.



10 Logging Off

Click Sign out on the tool palette to remove access to the signed in OneDrive account. Closing the application or logging out of the headset will clear the current session models but will continue to allow access to OneDrive for the same user when opening the application again. In order to sign out of OneDrive, go to Add Tab  and click .



Warning!

Double check to make sure you have logged out of the Sira Medical application when done. Failure to logout can lead to model manipulation by others and ultimately an incorrect preoperative surgical plan.



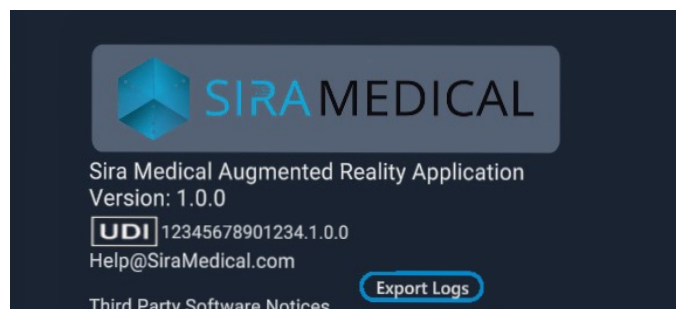
Warning!

Unauthorized access to the HoloLens 2 captured sessions could lead to an incorrect preoperative surgical plan. Users should take action to prevent unauthorized access to the HoloLens 2 files and always have a trained and a qualified individual review output screenshots or video prior to clinical use.

6. Troubleshooting

Before attempting any of the below troubleshooting measures, first export the log file via **Export Logs** on the About tab, then restart the application or reinstall the application, confirm your application compatibility with the current software, and confirm your application license.

If issues persist, please contact Sira Customer Service. Log files can be exported from the application by clicking **Export Logs**. This will place a copy of the log file in the Pictures folder that can be downloaded and forwarded to the support team. Be aware that reinstalling the application will clear out the local log file, so export a copy before reinstalling to help identify problems.



1 Common Errors

The following errors may be encountered when using the application.



Error Code	Error	Details
Error 10	Not enough memory to import the model. Aborting download	The model is too large to download. The model file may be too large or there may be too many model files in cache. Try restarting the HoloLens 2 to clear cache. Contact Sira Medical Customer Service if further support is needed.
Error 11	Not enough memory to slice the model. Aborting slice.	This can happen if the model is or has become too large to slice, the model has become too complex with multiple slices, or too many models have been added to the application. Try restarting the HoloLens 2 to clear cache. Contact Sira Medical Customer Service if further support is needed.
Error 12	Internet connection lost, please check internet connection and try again	Model could not be downloaded due to connection loss. Check your internet connection and try again.
Error 30	File cannot be Loaded	The model may not appear or displays as a cube object with a question mark if the file could not be loaded. If the file is corrupted this this may happen. The model will likely need to be re-saved by the Sira Medical 3D Image Preparation service and tried again.

Error Code	Error	Details
Error 31	An update is available. Please update it from the Microsoft store.	A new application update has been released. To ensure the latest version of the application is being used with up-to-date security features go to the Microsoft Store and update to the latest release.
Error 32	A mandatory update is available. Please update the app in the Microsoft store to continue.	A new mandatory application update has been released. To ensure the latest version of the application is being used with up-to-date security features, it is mandatory to go to the Microsoft Store and update to the latest release to continue.
Error 40	Warning! No Package ID Do Not Use	If the Model creation team did not include a package ID or labeled it incorrectly, the Label will show "No Package ID". Do not use a model without a package ID as this could result in a preoperative surgical plan for the wrong patient. Contact Sira Medical Customer service for model correction.
Error 41	Warning! Merge Not Completed Scales have been set to match. Please confirm position and try again	Scales of merged objects were not the same. Merging models with scales mismatched can result in an incorrect preoperative surgical plan. The software automatically resets the scale of item 2 to match item 1. Please confirm position and try again.

2 Memory Overload Prevention

For importing models and slicing, the application evaluates the estimated memory use to execute that task compared to the available memory remaining. If errors are encountered, the import aborts and displays an error message. Reference Error 10 and 11 above for further details if these errors are encountered.

3 Sira Medical Augmented Reality Application Troubleshooting

The following troubleshooting guide provides solutions for unexpected conditions. If the actions listed do not resolve the issue, contact Sira Medical customer service.

Issue	Details
Modeling is unsuccessful	If the model cannot be loaded or manipulated as needed, request a new model from the Sira Medical Image Preparation Service or use conventional planning methods.
Motion tracking is not working as expected, or objects are not following in visual field as expected	In an exceptionally sparse visual environment such as an empty or overly dark room, the HoloLens 2 may have difficulty in tracking the user's movement and view. Increasing light or adding some physical objects to the visual field may improve the HoloLens' ability to track movement in space.
Model trimming by proximity to the user is not working as expected	Models should be trimmed as the viewer moves into the virtual space they occupy. If trimming is not occurring as expected, moving the object closer to or further away from the headset or moving the headset closer or further away from the object will adjust where trimming occurs.
Scaling is not working as expected	Adjusting the viewing distance to the object will impact the visual scaling result. If objects are not scaling as expected, adjust the object's distance to be closer or further away from the headset.
Object is not responding to manipulation as expected.	Viewing distance and scale will affect the visual result of manipulating an object. Adjusting the viewing distance to the object or adjusting the object's scale may make manipulation of the object easier to control and observe. An object may be downloaded again if needed.
Memory usage error is preventing new file download	When an object is downloaded, it is cached locally until the application session is logged out. If many large files have been downloaded during the session, even if they have been removed from the active view, they will remain in the memory cache. Closing the application and reopening it clears the memory cache. If you are getting an unexpected memory usage error, closing the application, and reopening it will clear the cache and free up memory, allowing you to load the files.
OneDrive login is disabled	If you cancel during the OneDrive login process, you will need to close the application using the X on the clipboard and restart the application.

Issue	Details
Cannot import models after logging out and logging back into OneDrive	If the models will not import after logging out and back in, you will need to restart the application to access the new account models.

4 OneDrive and Network Access Troubleshooting

The following troubleshooting guide provides solutions for unexpected conditions. If the actions listed do not resolve the issue, contact your IT department or Sira Medical customer support.

Issue	Details
Unable to access OneDrive	<ul style="list-style-type: none"> • Verify that your network access is available and the HoloLens 2 is connected to the internet. • Verify that you are logged in to your OneDrive account on the HoloLens 2. • Contact your IT department for issues related to network and OneDrive connectivity.
Unable to access OneDrive	<ul style="list-style-type: none"> • Rebooting the headset and reconnecting to the internet and OneDrive account may clear issues with connectivity. • While insufficient memory is unlikely to be a cause, closing the Sira Augmented Reality Application and restarting will clear models from memory cache and should resolve the issue if insufficient memory is the cause.
<p>“No 3D objects found”</p> <p>No model files displayed for download from OneDrive</p>	<ul style="list-style-type: none"> • This may occur if there are no .fbx files available in the OneDrive folder currently being accessed. Verify the correct OneDrive account is active on the HoloLens 2 and you are currently logged in to the correct OneDrive account. • If the 3D model is not showing up in your OneDrive account from within the Sira Medical Augmented Reality Application try accessing your OneDrive Account via a computer browser, refresh your OneDrive account and confirm 3D model file is present. Return to the Sira Medical Augmented Reality Application and try again. If 3D Model file is missing, contact Sira Medical Customer Service for further support.

7. Maintenance

1 Regular Maintenance

Patches or updates may be periodically available through the Microsoft Store. Always check the Microsoft Store for Sira Medical Augmented Reality Application updates.



Warning!

Cybersecurity breach could result in unauthorized access to the Sira Medical Augmented Reality Application and the Microsoft OneDrive account which could lead to lost or modified 3D Models and ultimately an incorrect preoperative surgical plan. Always inspect 3D models prior to use. If any anomalies such as unexpected labels or colors in the model are noted, contact Sira Medical Customer Service for model correction. Always check the Microsoft Store for the latest security patch updates to the Sira Medical Augmented Reality Application.

Refer to your HoloLens 2 user instructions for maintenance of your HoloLens 2.

Always check to assure your HoloLens 2 software is updated to address security patches -

<https://learn.microsoft.com/en-us/hololens/hololens-update-hololens>



Warning!

Unauthorized access to the HoloLens 2 captured sessions could lead to an incorrect preoperative surgical plan. Users should take action to prevent unauthorized access to the HoloLens 2 files and always have a trained and qualified clinician review output screenshots or video prior to clinical use.

2 Sufficient Memory

Maintain adequate storage space on HoloLens 2 to provide adequate image storage memory and close other applications before using the Sira Medical Augmented Reality Application to provide adequate working memory.


The application performs cleanup of locally cached files at startup and shutdown, however if an issue is suspected with local memory, locally cached files can be deleted using native HoloLens 2 features.

3 Cybersecurity End-of-Support


Cybersecurity support for the Sira Medical Augmented Reality Application will end concurrently with Microsoft's end of cybersecurity support for Windows 10 Holographic. At that time a Sira Medical Augmented Reality Application update to address vulnerabilities may not be possible.

4 Product End-of-Life

The Sira Medical Augmented Reality Application will be decommissioned through the Microsoft Store. When the application reaches end-of-life, users will be informed through the Sira Medical support web page. The application may be safely deleted from HoloLens 2 without risk of personal or health related data disclosure because all health data is anonymized. In addition, the Sira Medical Augmented Reality Application does not have a save feature and any data in cache is cleared when the application is closed. Models available for use in the application will remain in the OneDrive account and remain unaffected by deletion of the application.

 Note: Management and maintenance of the 3D Models users store in their OneDrive accounts and video session recordings/image captures stored in the user’s HoloLens 2 is outside of the Sira Medical Augmented Reality Application and is the responsibility of the user.

5 Export Logs

The  button in the “About” tab allows you to save a record of the application’s activities. When clicked, a detailed log file named “SiraLogs.txt” is created in your HoloLens’ Pictures folder. This feature is valuable for troubleshooting and reporting issues for support.

8. Symbols



Warning or Caution,
Consult Accompanying
Documentation



Unique device identifier



Consult Instructions for Use



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

Safety in MRI Not Evaluated as the Sira Medical Augmented Reality Application is software and is not intended to be used in the MR environment.

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