Open-LIFU* User Manual
Openwater

*Disclaimer

The Open-LIFU platform is for research use only. Not for use in therapeutic procedures. All information contained herein, including but not limited to product features, specifications, and descriptions, is subject to change without notice.

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Contents

Device Description

Open-LIFU is a Research Use Only device designed to emit programmable sequences of steered, Low Intensity Focused Ultrasound (LIFU). The system is composed of a console, a transducer, and a software program, and uses an Android mobile application to assist with the treatment planning workflow. Through software configuration, users can use the system to generate sequences of LIFU pulses at chosen timings and amplitudes, steered using the 2D matrix array(s) in the transducer. A headset-style transducer housing allows the transducer to be securely and comfortably held in place. The photogrammetry-based mobile application is used to help localize and register the transducer position with a pre-procedural MRI.

Indications For Use

Open-LIFU is intended to generate low intensity focused ultrasound sequences and pulses for Research Use Only. The System is not intended to be used for the diagnosis or treatment of any disease or medical condition and is not cleared by the FDA for clinical use.

Contraindications

The following conditions are contraindicated when using the Open-LIFU platform; users or individuals displaying these signs or symptoms should not use Open-LIFU:

- Open cuts, sores, or wounds within the transducer contact area
- Head dressings, bandages, or gauze on or around the scan site that may interfere with the transducer coupling
- Subjects must be able to remain still for the duration of a procedure
- Prenatal and Obstetric applications
- Targets requiring a beam path that travels through eyes

Research Use

Use of the Open-LIFU to perform pre-clinical and/or clinical research may be subject to various domestic and international laws and regulations. It is the responsibility of the customer to be aware of and comply with all applicable laws and regulations pertaining to their particular use. While Openwater has endeavored to design Open-LIFU with

predictable performance and documented safety features, Open-LIFU is provided as-is without warranty. The safety and efficacy of Open-LIFU for any particular use is inherently subject to the specific requirements and risks of that application, and assessment and mitigation of such risks is the sole responsibility of the user.

Definitions

Android Application: A program for an Android phone to capture a Photocollection

Console: Electronics used to generate high voltage and connect to the PC

Coupling Pad: A deformable pad of acoustically transmissive material that provides an acoustic path for ultrasound from the Transmit Modules into the Subject

Focal Pattern: The spatial distribution of ultrasound foci around the Target

K-Wave: An open-source ultrasound simulation package

Meshroom: An open-source tool for photogrammetric reconstruction

PC Application: The executable software program for planning and controlling Sonications

Photocollection: A series of images captured of a subject. Used to reconstruct a Photoscan.

Photoscan: A reconstructed 3D mesh representing the scanned surface of a Subject

Protocol: The non-Target-and-Subject-specific configuration of a Sonication

Run: A recorded instance of a sonication solution

Sequence: The timing of ultrasound pulses for sonication

Session: An instance of sonication planning for a Subject

Solution: Subject-and-target-specific configuration of sonication to meet the requirements of a protocol

Sonication: Emission of a LIFU sequence

Subject: The person/animal/phantom being sonicated

System: The entire Open-LIFU System, including hardware and software

Target: A location within an MRI that provides a reference point for focusing

Transducer: The assembly containing one or more Transmit Modules in a durable housing

Transducer Tracking: The process of estimating actual Transducer position from a Photoscan and MRI data

Transmit Module: A module containing ultrasound beamforming electronics and an Ultrasound Array.

Ultrasound Array: A piezoelectric array of ultrasound elements

User: An account with access to the software

Veneer: The patterned outer face of the Transducer which is used during the photo collection step

Virtual Fitting: Prospective calculation of optimized transducer placement to focus on a Target

Symbols and Device Labels

Table 1: Open-LIFU Device Labels and Symbols

Symbol	Description
	Do not break or apply excessive bending forces to the cables.
	Caution. Use only as directed. Refer to specific details on the label itself and/or contained in the User Manual.
	Refer to User Manual or Instructions for Use for important safety information and contraindications.

Safety

Safety Standards

Openwater is committed to supplying high-quality, safe, and reliable products and services. The Open-LIFU device has been designed in accordance with the following quality standards:

- ISO 13485 Quality management systems
- ISO 14971 Application of risk management to medical devices
- IEC 62304 Software Lifecycle
- IEC 60601 Essential Performance (and related standards)
- IEC 62366 Usability Engineering

General Safety, Warnings, and Precautions

Please read this entire manual thoroughly before operating the device and always follow the instructions provided before attempting to operate it. Do not ignore warnings or precautions regarding safe operation and laser safety.

Position the device close to the wall with an electrical outlet or cover the electric cable with a cable mat to minimize tripping hazards.

This system is only intended to be used and operated by trained research personnel.

Ensure the device is mounted securely on a flat surface such that it will not move during general operation of the device.

The Open-LIFU device is intended to be used or serviced by suitably trained individuals. Untrained individuals must contact Openwater Support for assistance. Refer to the Service and Maintenance section of this manual for contact details.

Warnings

⚠️ *Warning: Creating or modifying protocols without properly validating them may result in unsafe ultrasound exposure to the body, leading to serious bodily harm. Use only approved and tested protocols.*

⚠️ *Warning: Damaged or compromised transducer housing may lead to high-voltage leakage, creating an electrical shock risk. Always inspect all enclosures to ensure they are damage-free and properly sealed prior to powering on the device.*

⚠️ *Warning: Prenatal and Obstetric applications have lower acoustic safety guidelines than adult applications. Open-LIFU is not designed for use in prenatal or obstetric applications.*

⚠️ *Warning: The console may lead to injury or electric shock if dropped. Ensure the console is placed on a stable, level surface and handle it with care.*

⚠️ *Warning: Dropping the transducer may lead to internal damage and system malfunction. Inspect transducers after impact and do not use them if damage is suspected.*

⚠️ *Warning: Delivering ultrasound energy to an incorrect subject or off-target location can cause unintended effects. Verify Subject identity and targeting parameters prior to each sonication session.*

⚠️ *Warning: Inputting incorrect sonication parameters may exceed safe exposure limits, resulting in tissue heating or damage. Confirm all parameters before initiating treatment.*

⚠️ *Warning: Selecting the wrong target may result in sonication of unintended tissues or under-treatment of the intended site. Always confirm treatment plan(s) and the respective target coordinates before sonication.*

⚠️ *Warning: This device was not designed for use in the eyes. Do not direct sonication through or toward a subject's eye(s).*

⚠️ *Warning: If the position of the transducer shifts on the subject during or after session planning, sonication may target unintended locations. Secure the transducer firmly during all procedures and avoid accidental bumps, then recapture the photogrammetry mesh and session planning.*

⚠️ *Warning: Inaccurate photogrammetry can result in poor image registration, leading to off-target sonication or under-treatment. Verify image registration accuracy before exposure.*

⚠️ *Warning: Using the incorrect session or sonication plan for a subject can lead to off-target sonication or under-treatment. Confirm the subject's name and treatment plan match prior to exposure.*

⚠️ *Warning: Identifying and using dissimilar landmarks between the photogrammetry mesh and input MRI will lead to poor image registration, resulting in off-target sonication or under-treatment. Verify image registration accuracy before exposure.*

⚠️ *Warning: Bad reconstructions may lead to off-target sonication or under-treatment; review photogrammetry mesh reconstruction prior to planning and repeat if necessary.*

⚠️ *Warning: Executing unverified or unreleased sonication protocols may cause excessive heating or bodily harm. Use only approved and tested protocols.*

⚠️ *Warning: Operation by untrained individuals may result in over-sonication, bodily harm, or unpredictable side effects. Only trained and qualified personnel should operate the system.*

⚠️ *Warning: Running additional or repeated sonications can cause overexposure and thermal damage to the target area. Avoid duplicative sonications unless medically justified.*

⚠️ *Warning: Storing the device in high-temperature environments may prematurely degrade the device enclosure, which may lead to electric shock. Store the system in a climate-controlled storage area and follow recommended environmental conditions.*

⚠️ *Warning: Unauthorized modification of firmware or device safety limits may result in serious bodily harm or loss of life. Never alter safety-critical settings or install unverified software/firmware. Use only approved and tested protocols.*

⚠️ *Warning: Always plug the device into a grounded outlet and only use an approved, undamaged power cord to avoid the risk of serious electric shock.*

⚠️ *Warning: Removing the device covers exposes individuals to a high-voltage power supply which carries high voltages and may cause serious electric shock. Only qualified personnel should service the device.*

⚠️ *Warning: Insufficient time between device usage may cause the device housing to exceed 43 °C. To avoid burns or injury, allow the device to sufficiently cool before continued use.*

⚠️ *Warning: Ensure the transducer housing is oriented on the subject correctly prior to sonication. Failure to do so may result in bodily harm, or unpredictable side effects.*

⚠️ *Warning: To reduce the risk of electrical shock, inspect any cables prior to use to ensure all cords are properly plugged in and free from damage.*

⚠️ *Warning: Creating or modifying protocols that exceed prescribed mechanical index (MI) limits may result in cavitation, bodily harm, or death. Confirm protocol adheres to safe MI parameters and use only approved protocols.*

⚠️ *Warning: Mismatched coupling media may alter focus and cause unintended sonication. Use only approved gels.*

⚠️ *Warning: Excess ambient temperature or humidity may cause device malfunction and/or electrical short. Always operate the device within recommended environmental conditions.*

Precautions

Position the Subject such that there is sufficient slack in the cables to avoid accidentally pulling on the device console.

Store user passwords securely according to institutional policies.

Restrict computer access to authorized users and only log in using assigned user credentials. Never share user IDs or passwords, or log in using another user's credentials. All users must follow their institutional cybersecurity protocols to protect PHI.

Only select targets that exist within the system's beam steering range. If a target exists beyond a safe range, then it is necessary to select a new target or reorient the transducer. Use onscreen imaging feedback to assist with repositioning the transducer.

Adjust strap to ensure the device is comfortably secured to the subject's head. If skin irritation occurs, then it may be necessary to remove the device from the subject.

Place the console on stable surfaces and handle it with care while transporting it to prevent it from falling.

Keep the transducer housing and straps clear of any hair, foreign objects, or debris.

Apply sufficient coupling gel on both sides of the coupling pad to minimize any air bubbles along the acoustic pathway prior to positioning the transducer on the subject.

When using coupling pads, open packaging carefully at marked areas to avoid tearing or damaging the pad.

Plan cable routing before capturing photogrammetry mesh and commencing sonication. Place cables so they do not pose a tripping hazard to anyone in the room.

Ensure all cables are securely connected to the console and do not present a tripping hazard to anyone in the room.

Do not remove or unplug the power cord once the console is powered on. Avoid accidental or unintentional power loss events by connecting the device to an external UPS (uninterruptible power supply).

Ensure every operator can easily identify and access the power shutoff switch before the start of each procedure.

Report all unintentional procedural interruptions to Openwater. Contact details are provided in the Service and Maintenance section.

Firmly grip the transducer while removing it from a subject to prevent recoil contact or bruising.

Clean Subject-contact components thoroughly per IFU between users to prevent the spread of bacterial and/or viral infection; verify no residue or visible debris remains.

Disconnect cables by firmly gripping connectors. Never pull the cables directly.

Store cables in wide loops without twisting or knotting; avoid sharp bends at connectors.

Store the system in a climate-controlled storage area and follow recommended environmental conditions.

Store sealed coupling pads according to recommended environmental conditions.

Discard used or compromised pads according to local medical waste standards.

Electrical Safety

In case of an emergency, flip the power switch on the back of the unit to the off position to turn off the device.

Always unplug the device from the wall outlet prior to performing any service or routine maintenance on the console.

Ensure the voltage for the AC mains supply is rated for 100-240V, 50-60Hz, 0.5 Amps before connecting the device. The supply must include a ground connection.

The Console is equipped with protection circuitry to protect the unit and users from unexpected power surges.

Clean the Open-LIFU Device after each use according to Device Cleaning and Storage.

System Specification

System Components

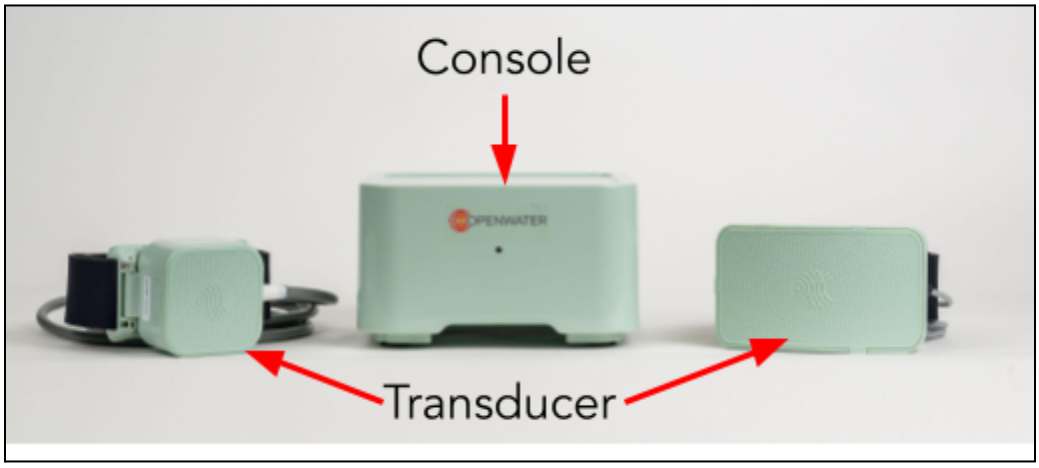


Figure 1: The Open-LIFU hardware consists of a console, a 1x or 2x transducer, and adjustable headband.

Console

The console connects to a PC via a USB-C cable and contains a bipolar high voltage supply, capable of producing up to +/- 60V or +/- 65V[1], with a maximum power output of 110W for driving the ultrasound elements, while also supplying low voltage power and USB communication to the transmit electronics.

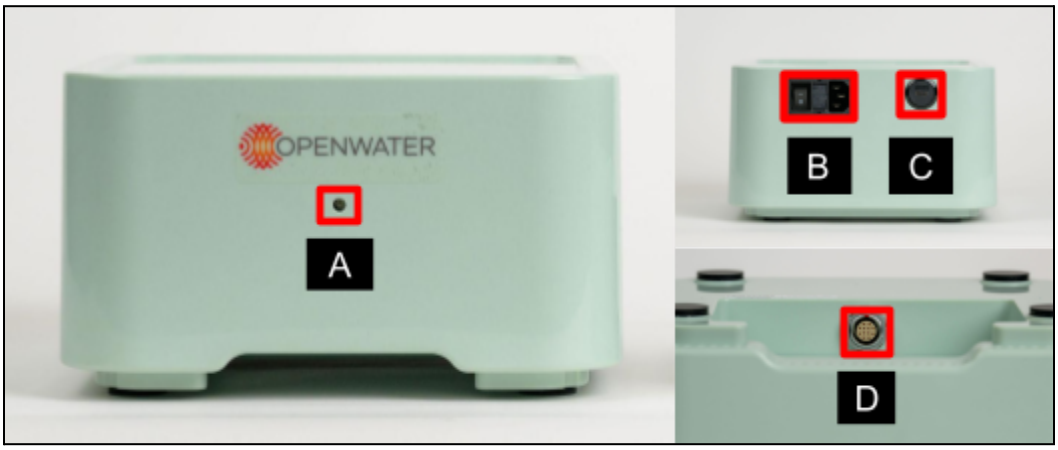


Figure 2: Parts of the Console: (A) Status LED on front face of console, (B) Power switch and receptacle for the device, (C) USB port to connect to computer, (D) Transducer cable port.

[1] Refer to the device serial number to determine which size power supply is installed in the console. 120 W power supply units are capable of +/- 60 V, whereas 180 W power supply units are capable of +/- 65 V.

Console Specifications

Table 2: Open-LIFU Console Specifications

Operating Voltage[2]	100-240 VAC, 50-60 Hz, 1.2 Amps (120 W) 100-240 VAC, 50-60 Hz, 3.5 Amps (180 W)
High Voltage Output[3]	+/- 10-60 V (120 W) +/- 10-65 V (180 W)
Connections	1x USB-C (USB3.0) 1x 12-pin socket
Device Status	LED indicator
Dimensions (w x h x d)	9.8 x 3.0 x 6.3 inches (250 x 75 x 160 mm)
Weight	3 lbs (1.36 kg)

Table 3: Console status LED indicator

Color	Pattern	Meaning
None	Off	System is Off
Green	Solid	System is On and ready
Blue	Solid	System is On and sonicating
Blue	Pulsing	Error

Transducer Configurations

Ultrasound pulses are produced from transmit modules located within the plastic housing; this assembly is collectively referred to as the Transducer. Integrated beamforming electronics take DC power from the console and generate the signals required for the piezoelectric arrays to emit the specified sequences of ultrasound pulses. There are a total of four (4) transducer variations available, representing two frequencies and two aperture sizes.

All transducer configurations are designed as wearable “headsets,” with a body containing the arrays and electronics, a soft strap to go around the head, a soft disposable coupling pad, and a

[2] Serial numbers 001 → 012 utilize the 120W power supply. Devices with a serial number starting at 013 and beyond use a 180W power supply. To determine which power supply is installed, refer to the serial number affixed to the bottom of the Open-LIFU console.

padded frame to prevent the body from slipping around on the subject's head. The outside face of the transducer also has a removable curved face plate with an embossed pattern used to aid with localizing the transducer. Do not remove or damage the textured faceplate.

NOTE: The transducer should always face up while being worn by a subject. There is an arrow on the side of the transducer body indicating the "up" direction. The cable exits the transducer towards the subject's left ear when the transducer is properly worn on the forehead.

NOTE: The transducer is not watertight. Never submerge the transducer in water. Doing so may lead to electric shock or damage the transducer.

NOTE: All Open-LIFU transducers have been factory calibrated. Reconfiguring or modifying any transducer immediately voids the factory calibration, requiring users to recharacterize the transducer to ensure it complies with all necessary application-specific requirements.

Depending on the application, users may need a Single (1x) or Double (2x) transmit module configuration (see Figure 3).

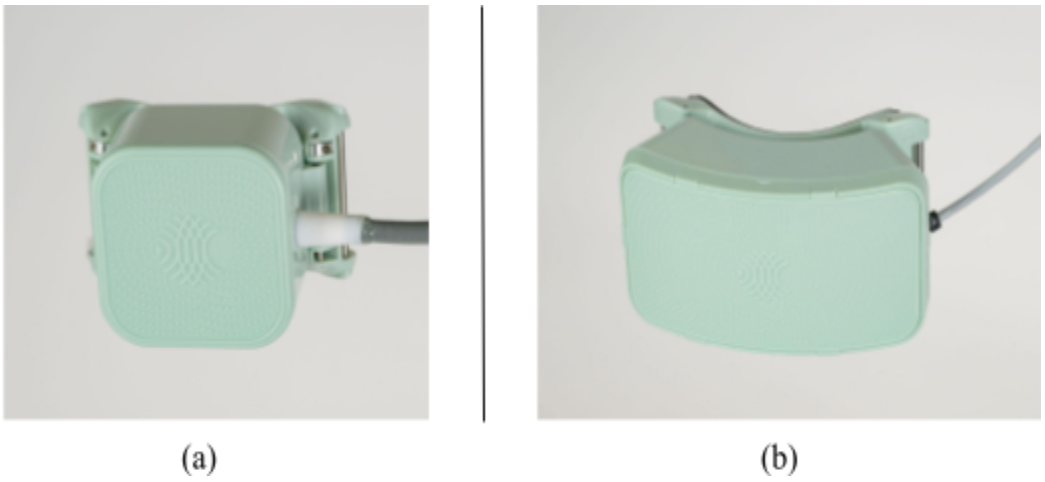


Figure 3: a) the single transmit module transducer configuration ("1x"); b) the dual transmit module transducer configuration ("2x"). Each configuration comes with either 155 kHz or 400 kHz transmit modules.

Table 4: Open-LIFU 1x and 2x configuration specifications. Note these are representative values only. Exact values will vary based on the serialized transducers.

Transducer Frequency	1x 155 kHz	1x 400 kHz	2x 400 kHz
Peak P- @ 60V and (0, 0, 50)mm	0.7 MPa	1.1 MPa	2.16 MPa
Derated P- ($P_{r.3}$) @ 60V	0.68 MPa	1.02 MPa	2.01 MPa
Voltage	+/- 10-65 Vmax	+/- 10-65 Vmax	+/- 10-65 Vmax
Mechanical Index (MI) in water[3] @ 60V and (0, 0, 50)mm	1.7	1.8	3.18
Axial FWHM @ (0, 0, 50)mm	34 mm	31 mm	15 mm
Transverse FWHM @ (0, 0, 50)mm	8 mm	4.5 mm	4.7 mm (elevation) 2.4 mm (azimuth)
Axial steering range	4 - 6 cm	4 - 7 cm	3 - 11 cm
Transverse steering range	+/- 1 cm	+/- 1.5 cm	+/- 2 cm
Pressure-voltage sensitivity @ (0, 0, 50) mm focus	6 kPa/Vpp @ 30 mm	9.9 kPa/Vpp @ 45 mm	18 kPa/Vpp @ 50 mm

[3] Limited to 1.9 by the Open-LIFU software.

Coupling Pad

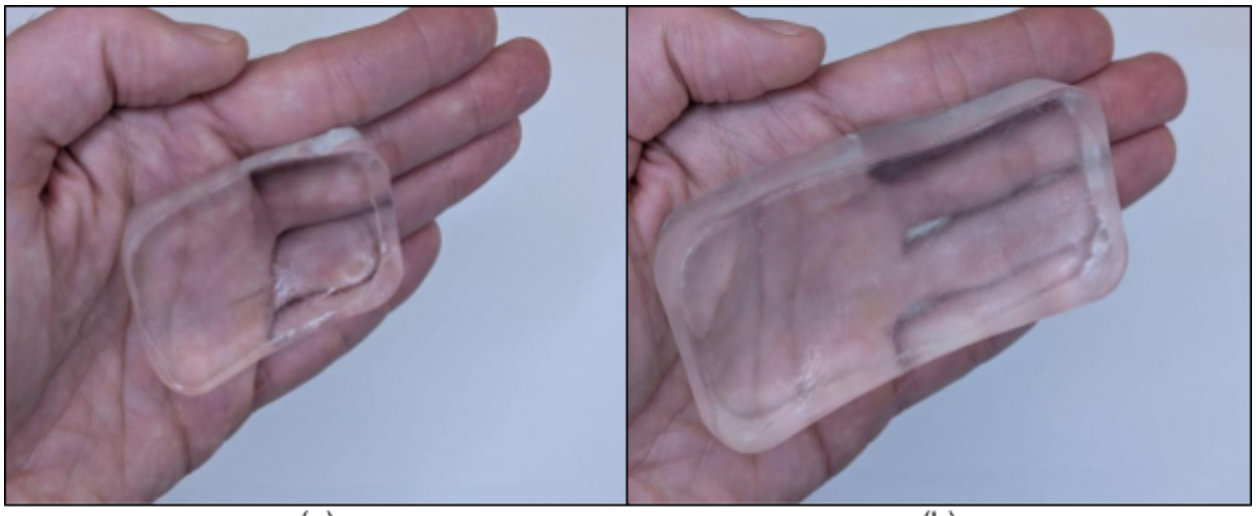


Figure 4: The coupling pad sits inside the transducer to help ensure good coupling is achieved between the transducer and subject. (a) the 1x coupling pad, (b) the 2x coupling pad.

Coupling pads are non-sterile and composed of a bio-compatible water-based polymer hydrogel shaped to fit the faceted transducer faces and conform to curved surfaces (e.g., the forehead). The coupling pad is needed to:

- Eliminate air interfaces between ultrasound probes and skin
- Reduce acoustic impedance mismatch
- Improve transmission of ultrasound energy

NOTE: When using coupling pads, open packaging carefully to avoid damaging the pad.

Software

The system is controlled by the Open-LIFU software, used to configure the steering and focusing of ultrasound emitted by the transducer to achieve a particular sequence of ultrasound pulses delivered to one or more positions in front of the transducer. The Open-LIFU software takes the position of a target defined within an MRI and the position of the transducer within MRI space and calculates the signals that need to be applied to each element, as well as the voltage setting for the console, to achieve the target dose. These calculations are configurable through user-defined Protocols.

Sonication Sequence Specifications

Table 5: Open-LIFU pulse sequence specifications

Category	Parameter	Description	Typical	Min	Max
Pulse	Frequency (kHz)	Pulse center frequency	155 Or 400	N/A	N/A
Pulse	Voltage (V)	Transmit voltage (±)	20	10	60
Pulse	Duration (ms)	Pulse duration	5	0.01	100
Sequence	PRI (ms)	Pulse repetition interval	100	10	1000
Sequence	Pulse count	Number of pulses per train	300	1	1000
Sequence	PTRI (s)	Pulse train repetition interval	30	0	120
Sequence	Train count	Number of pulse trains	20	1	Protocol Dependent
Beamforming	PNP (kPa)	Target pressure	820	100	1000
Simulation	Spacing (mm)	Voxel spacing	0.375	0.2	1

Table 6: Describes sonication protocol parameters

Category	Parameter	Description (Qualitative or Categorical)
Beamforming	Shape	Pattern shape and associated parameters
Beamforming	Target Pressure	Peak negative pressure at the focus (kPa)
Beamforming	Delays	Delay calculation method. Direct or raytraced
Beamforming	Apodization	Apodization calculation method (uniform, maximum angle, or piecewise linear)
Beamforming	Segmentation	Segmentation Method and associated parameters
Beamforming	Materials	Material properties (speed of sound, density, attenuation coefficient, thermal conductivity, and specific heat) for bone, tissue, air, water, coupling pad
Simulation	Grid extent	Lat-Ele-Ax extent (mm). Typical (−30, 30), (−30, 30), (−4, 80)
Constraints	Parameter constraints	Configurable constraints to throw warnings or errors that block ultrasound initiation when a computed parameter (such as MI or ISPTA) exceeds a set value
Constraints	Target constraints	Absolute limits on the spatial position of the target relative to the transducer. Target constraints can be used to identify invalid targets before beamforming and simulation.

Creating and Editing Sonication Protocols

Before starting a procedure, device administrators must ensure all protocols are well-defined, created, and available for the desired use case scenario(s) and device operators. The following sections describe how to create and modify existing sonication protocols.

NOTE: Only Admins can create or modify sonication protocols. Admins must ensure the proper protocol permissions are set before operators can access the protocols.

NOTE: The values used here are for illustration purposes only. Values used for creating a protocol are dependent on the individual transducer characteristics which are determined using the Acoustic Field Test during manufacturing. Output indices and safety constraints must be calculated to operate within safe operating limits of the region where the device is being used.

To begin, log in as an admin to access the Protocol Configuration wizard.

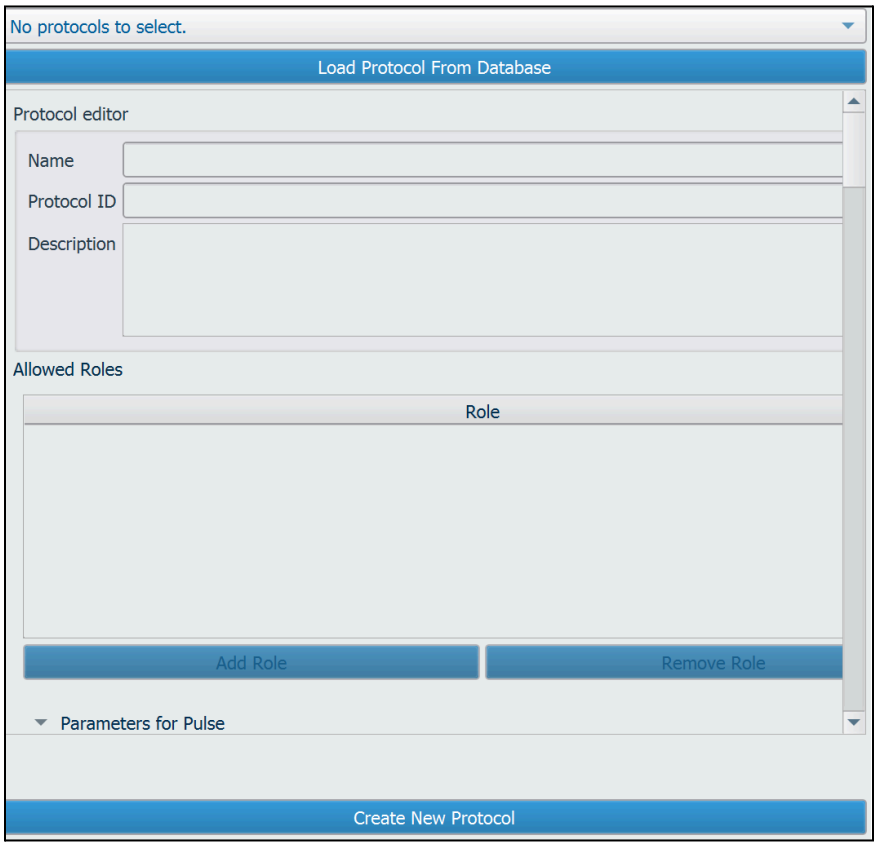


Figure 5: Use this dialogue box to either load or create a new protocol. Note that a user's permissions may prevent them from creating and/or editing a protocol.

Create a new protocol

To create a new protocol, click "Create New Protocol."

Load a protocol

To load a protocol, click "Load Protocol from Database," select a protocol, and click "OK."

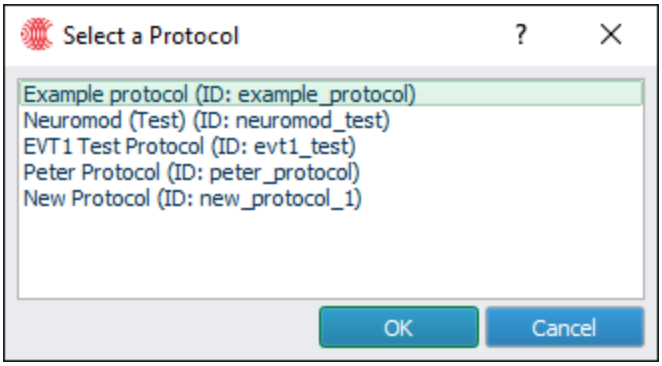


Figure 6: Saved protocols can be loaded from the database using the protocol selection window.

Once the Protocol is open, click “Edit Protocol” to make the attributes editable.

Edit Protocol Info

Figure 7: Editing the protocol allows users to assign it a name and unique ID.

In the Protocol Info section, the following can be set:

Table 7: Sonication protocol information

Protocol Info	Description
Name	Descriptive display name for the protocol
Protocol ID	unique identifier of the protocol (typically lowercase and underscores)
Description	Protocol Description

Protocol Roles

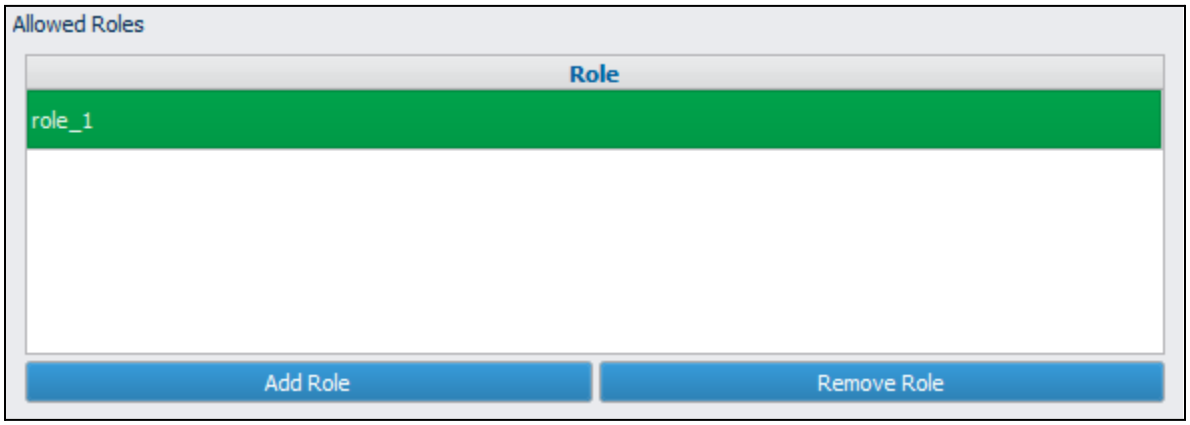


Figure 8: Admins can set user permissions which limit access to specific protocols.

The Protocol Roles table allows sessions with this protocol to be restricted in creation and loading to Users who have one or more of the listed roles. Admin Users can always create or load from any protocol. An empty list of roles means the protocol can only be loaded by admins.

Notably, the `operator` role is not assigned by default. Add the `operator` role to allow Users with the `operator` role to access this protocol.

Add Role

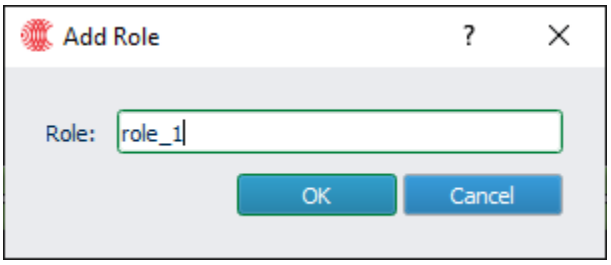


Figure 9: When creating a role, add in a name for the role.

To add a role, click “Add Role,” type the name of the role into the box, and click OK.

Delete Role

To delete a role, select it in the table and click “Remove Role.”

Sonication Protocol Parameters

The software allows for the configuration of various system attributes within a “Protocol.” A Protocol establishes the parameters for sonicating an intended target, encompassing the

targeted dose (amplitude and sequence timing) and the configuration for calculating the necessary steering delays and beam profile simulations. It also defines constraints for target locations and derived assessments of the simulated beam sequence. Protocols remain independent of any specific Subject or MRI target location; the combination of target-specific time delays and voltages is defined as a “Solution,” which is then used to configure the Open-LIFU hardware.

Pulse Parameters

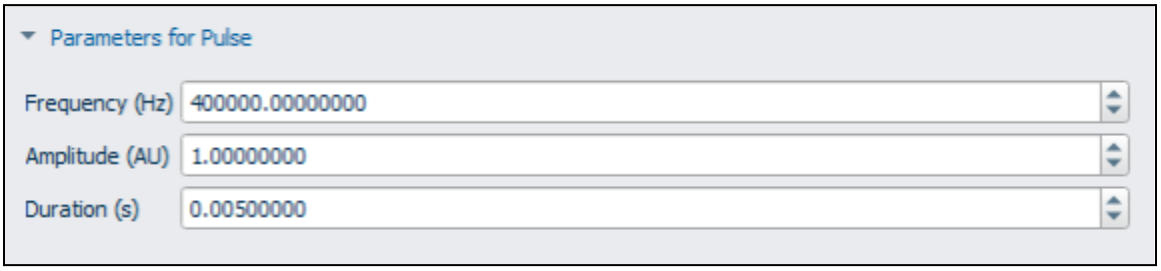


Figure 10: Example pulse parameters.

The Pulse Parameters section contains information about the pulse shape. Available parameters are:

Table 8: Sonication pulse parameters

Pulse Parameter	Description
Frequency (Hz)	Center Frequency of the pulse. Should match the hardware
Amplitude (AU)	Amplitude of the pulse (0-1). Can be used to lower the duty cycle at which pulses are generated by the transistors in the transmitter, making the output signal smaller. In general, it should be left at 1.00 and allow the beamformer to set amplitude via voltage settings.
Duration (s)	Duration of the pulse in seconds. Cannot be >100ms (0.1S)

Sequence Parameters

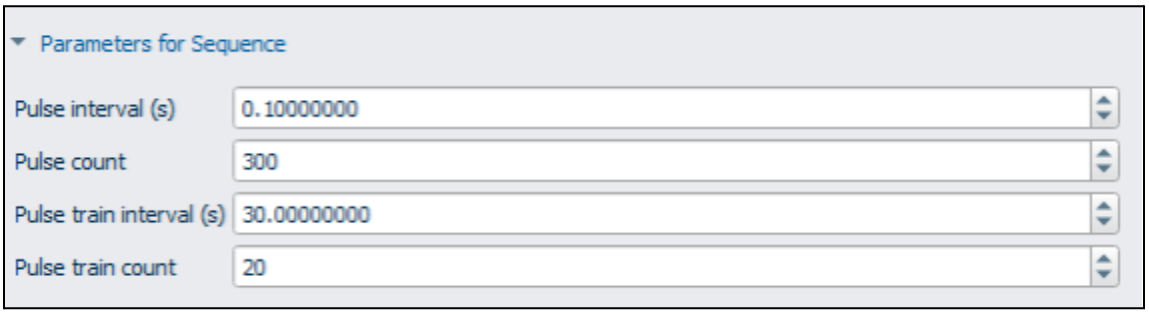


Figure 11: Sample sequence parameters.

Available sonication parameters are:

Table 9: Sonication sequence parameters

Sequence Parameters	Description
Pulse Interval (s)	Time between the onset of each pulse.
Pulse Count	Number of pulses within a single pulse train
Pulse Train Interval (s)	Time between the start of each pulse train. A special case of 0 sets the interval to the pulse train duration (pulse interval x pulse count)
Pulse Train Count	Number of pulse trains within a sequence

The Sequence Parameters section contains information about the sequence timing. A graphical representation of the sequence is displayed in Figure 8:

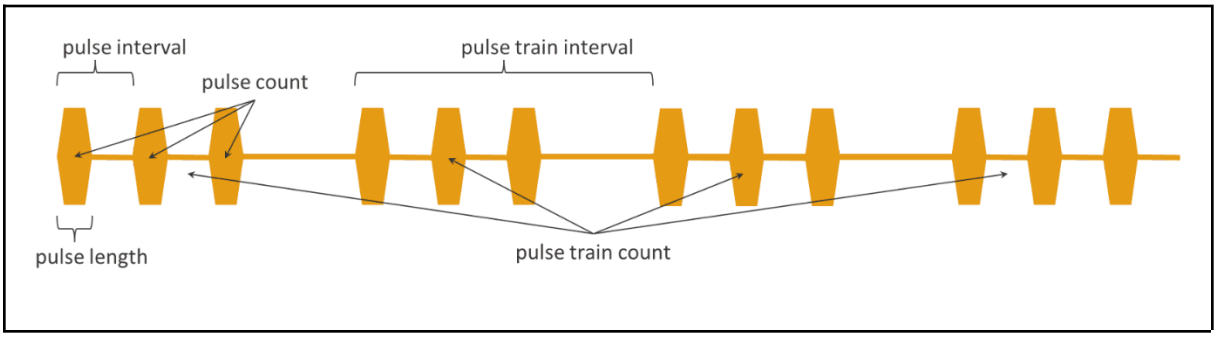


Figure 12: Sample pulse train.

Focal Pattern

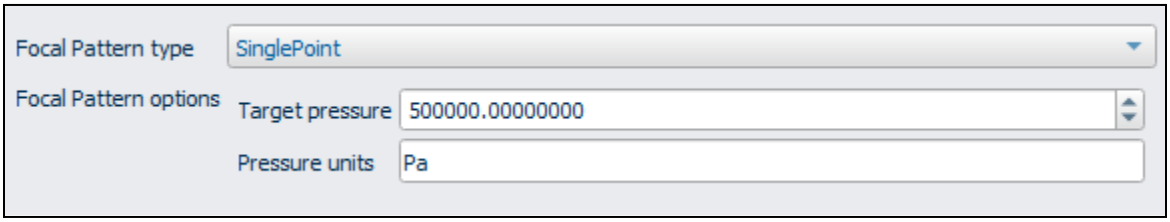


Figure 13: Sample target pressure value.

The Focal Pattern section configures the spatial distribution of pressure at the nominal target. The options available depend on which type of Focal Pattern is selected in the dropdown. As of June 2026, only the SinglePoint type is supported by device firmware. Available options are:

SinglePoint

A SinglePoint focal pattern is the default pattern, which uses a single focus onto the target location. A SinglePoint accepts the following inputs:

Table 10: SinglePoint focal pattern options

Focal Pattern Options	Description
Target Pressure	Targeted peak negative pressure at the focus
Pressure units	Units the pressure is provided in (Pa, MPa, kPa, etc)

Wheel / Beam Rastering (Future Implementation)

A Wheel Focal pattern rasters the focus in the x-y plane around a circular pattern. Because the length of the foci in the depth direction (z) are greater than they are wide, this allows for a more spherical region to be sonicated. The total number of foci (center + spokes) cannot exceed 16.

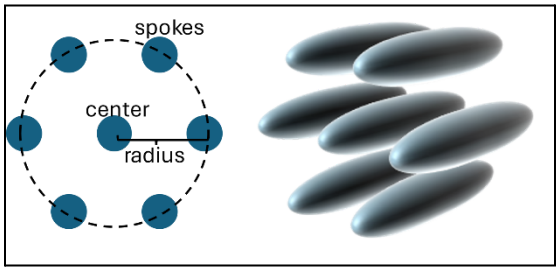


Figure 14: The Wheel Focal pattern.

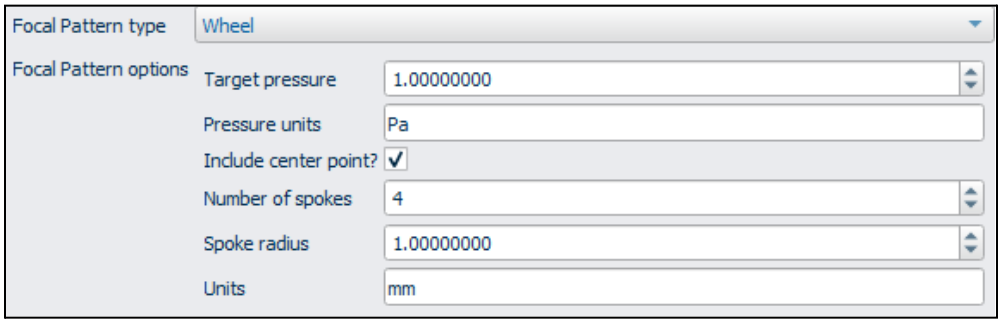


Figure 15: Focal Pattern Editor showing adjustable geometric and spacing parameters.

Available focal pattern options include:

Table 11: Wheel focal pattern options

Focal Pattern Options	Description
Target Pressure	Targeted peak negative pressure at the focus
Pressure units	Units the pressure is provided in (Pa, MPa, kPa, etc)
Include Center Point	Includes the center of the circle if selected
Number of Spokes	Number of points along the circle to use
Spoke Radius	Radius of the circle
Units	Spatial units of the spoke radius (default mm)

Simulation Setup

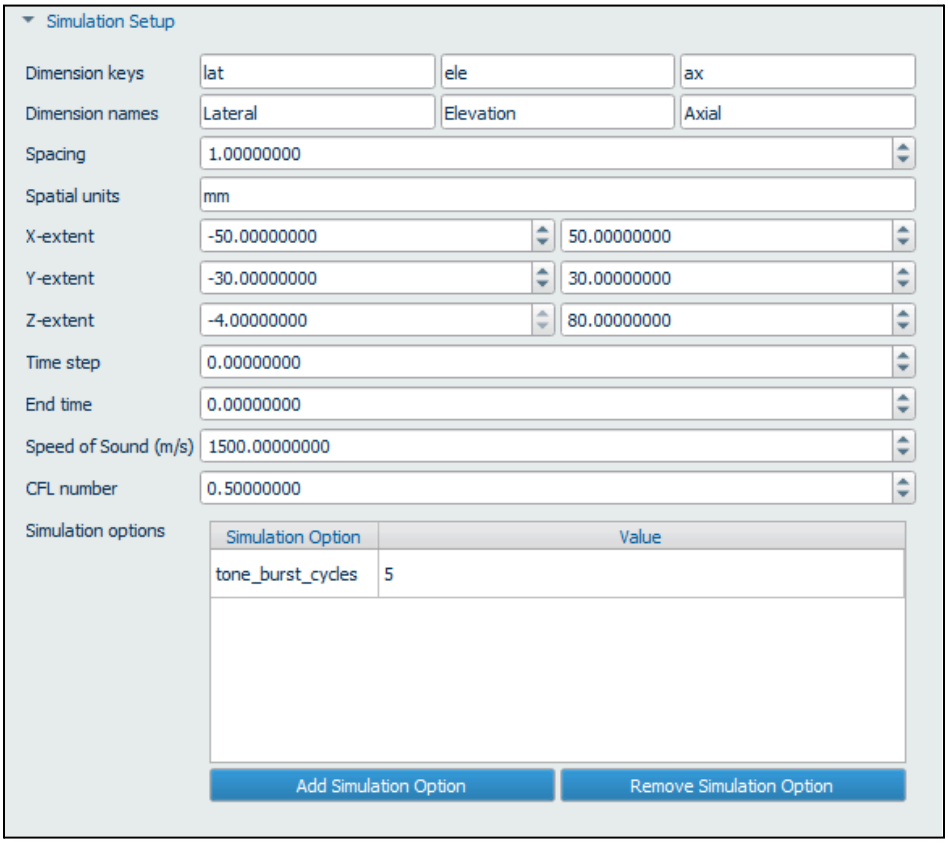


Figure 16: Sample values used to define the simulation setup.

The simulation setup section provides parameters for configuring k-Wave simulations. For most applications, users will only need to verify and/or adjust the X-, Y-, and Z- extents to ensure that the expected depth and position of the treatment target is within the simulation grid. The available options include:

Table 12: K-wave configuration parameters

Simulation Setup	Description
Dimension Keys	ids of the x,y, and z dimensions (please leave as “lat,” “ele,” and “ax”)
Dimension Names	Display names for the dimensions
Spacing	Voxel spacing
Spatial Units	Units of the Voxel spacing (mm or m)
X-extent, Y-extent, Z-extent	Upper and lower simulation bounds
Time step	Time step of the simulation (s). Leave at 0 for automatic calculation of the time step
End time	Duration of the simulation (s). Leave at 0 for automatic calculation of the end time
Speed of Sound	Nominal speed of sound for auto-calculating simulation duration

Simulation Setup	Description
CFL	Courant–Friedrichs–Lewy Number for numerical convergence. This is set to 0.5 by default.
Simulation Options	Additional options that can be passed to the simulation code (dictionary)

Beamforming Delay Options

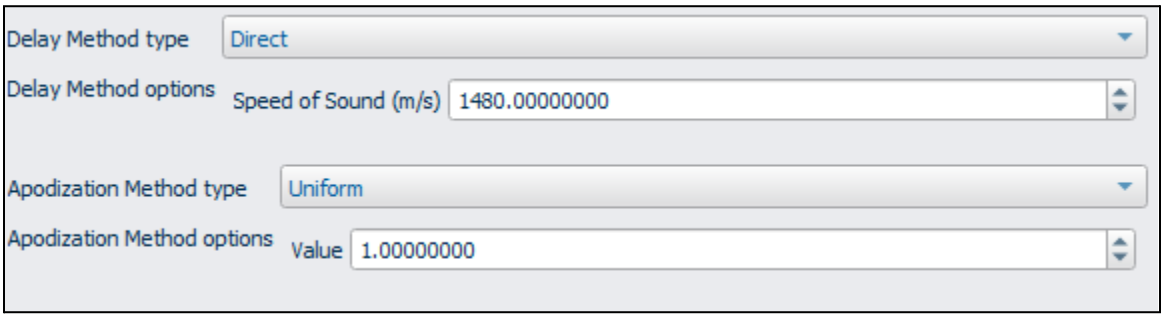


Figure 17: Sample beamforming delay options.

This section allows configuration of time-delay calculations. Delay Method Type chooses the type of beamforming used for calculating time delays. Subsequent options depend on the chosen method. If custom beamformers have been added to the code, they will be available in this section.

Beamforming Options

Direct

Direct Beamforming uses distance and uniform time-of-flight calculations to determine transmit delays. Options:

Table 13: Direct beamforming transmit delay

Delay Method	Description
Speed of Sound (m/s)	The speed of sound used for beamforming in the absence of a volume

Beamforming Apodization Options

“Apodization” in Open-LIFU refers to which elements are active or not – partial apodization of each element is not currently supported.

The options for Apodization are determined by the selection of Apodization Method type (Figure 17). Options include:

Uniform

Uniform apodization sets all apodization values the same.

Value: Apodization scaling (0-1). Will scale all element signals down if <1.0. Leave at 1.0.

Max Angle

Maximum angle apodization. Determines whether an element is active based on the angle between its normal vector and the target. Max Angle apodization

- Max Angle: Maximum angle beyond which an element turns off.
- Angle Units: The units in which the maximum angle is specified (rad or deg. Default deg.)

Segmentation Options

Segmentation is the process by which voxels of the MRI image are converted into material properties used for beamforming. For beamforming methods like Direct, the voxel-values are not used, so simple segmentations are acceptable.

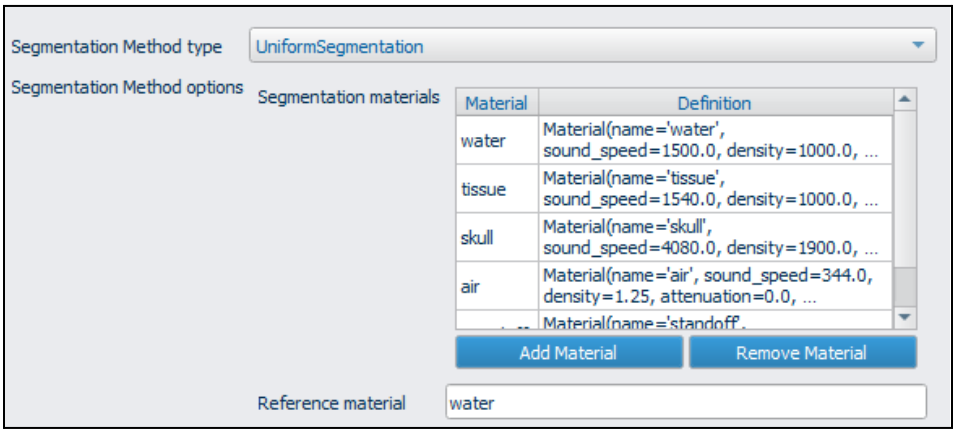


Figure 18: Use this window to select segmentation options.

All segmentation methods include a dictionary of “Materials,” which specify a speed of sound, density, attenuation coefficient, specific heat, and thermal conductivity, which can be modified.

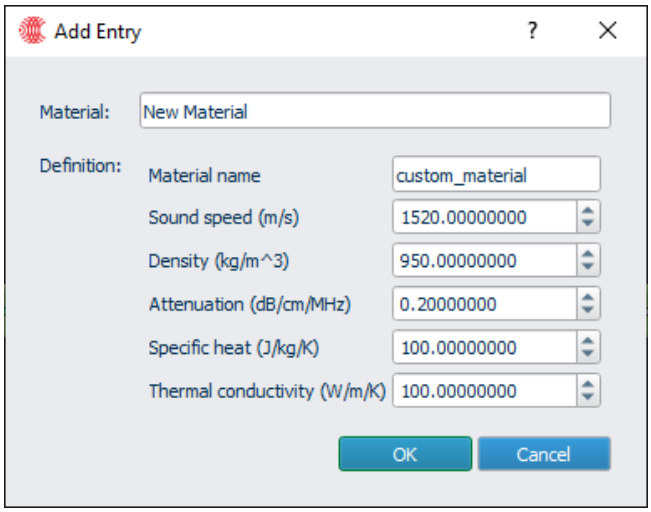


Figure 19: Users can create new material definitions by inputting values into this window and giving it a material name.

Uniform Water

The Uniform Water segmentation method assigns all parameters to be the “water” material.

Uniform Tissue

The Uniform Tissue segmentation method assigns all parameters to be the “tissue” material.

Uniform Segmentation (Custom)

The generic Uniform Segmentation method assigns all parameters to be the material specified.

Parameter Constraints

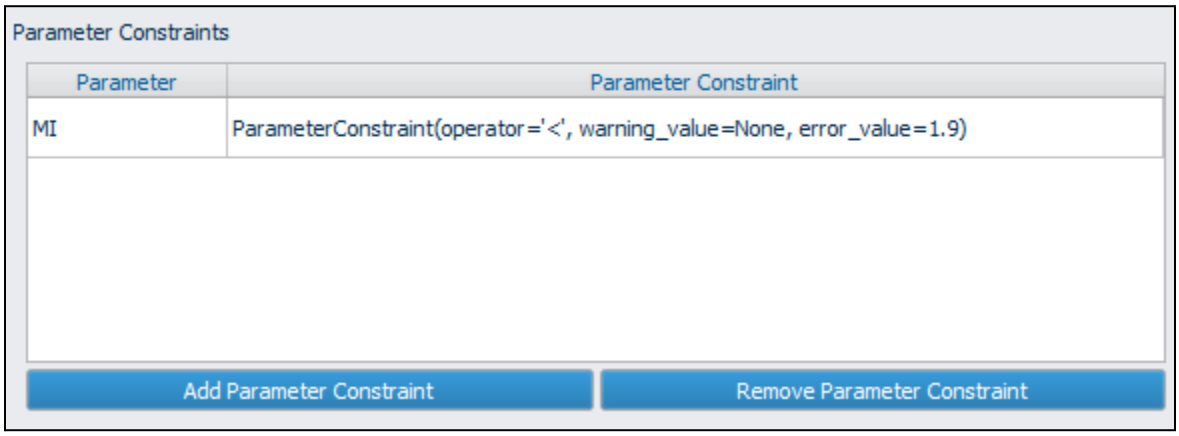


Figure 20: Procedure guardrails can be put into effect by setting the appropriate parameter constraints.

Parameter Constraints set requirements on the results of a Solution Analysis, which can provide safety guardrails or warn the user if certain parameters are outside of the expected range. If a warning is flagged, the user will be prompted to revise the protocol or proceed to sonication. If an error is flagged, the user cannot proceed to sonication with this solution.

Click “Add Parameter Constraint” to define a new constraint:

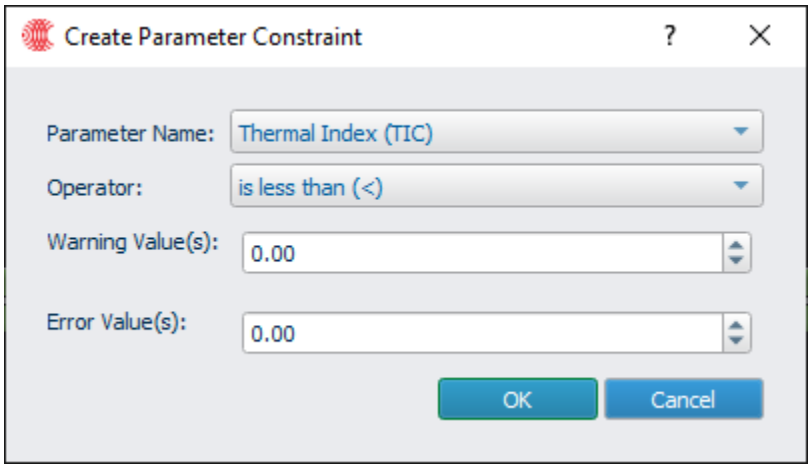


Figure 21: A popup window is displayed when creating a parameter constraint.

Parameter Constraint Options

- Parameter Name: Which parameter to constrain.
- Operator: What direction to apply the constraint. The constraint defines the condition for which the *parameter is acceptable*. A “Less than” operator means that the parameter is OK if it is less than the Warning or Error Value.
- Warning Value: The threshold for throwing a warning.
- Error Value: The threshold for throwing an error. If an error is thrown, it takes precedence over a warning.

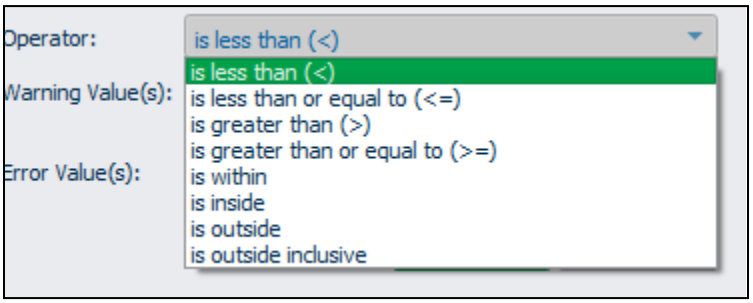


Figure 22: Users can select the appropriate operator using the dropdown menu.

Target Constraints

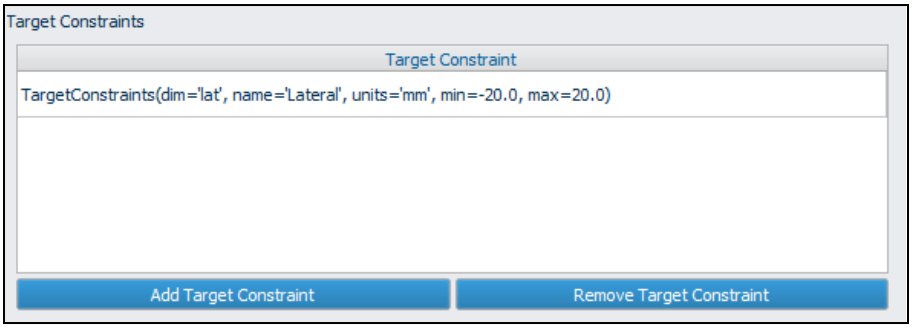


Figure 23: Users may also create target constraints.

The Target Constraints section allows configuration of nominal limits on the placement of targets relative to the transducer. This can be used to exclude poor transducer positions prior to any beamforming or simulation. To add a Target Constraint, click “Add Target Constraint.” To remove a Target Constraint, select a row, and click “Remove Target Constraint.” When adding a constraint, the following window appears:

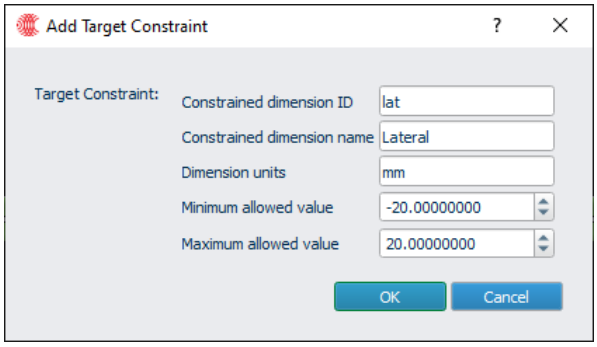


Figure 24: Users can select the appropriate target constraints by adjusting these values.

Parameters are:

Table 14: Sonication target constraints

Target Constraint	Description
Constrained dimension ID	Must match a dimension in the sim setup
Constrained dimension Name	Name from the sim setup
Dimension units	units in which the constraint is specified
Minimum Allowed Value	lower bound for that dimension
Maximum Allowed Value	upper bound for that dimension

Solution Analysis Options

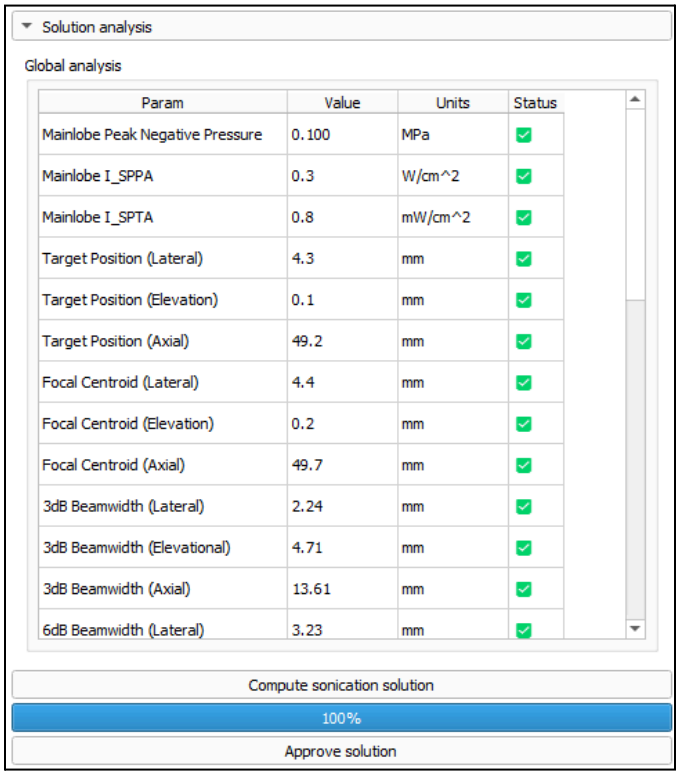


Figure 25: Sample solution analysis options.

The Solution Analysis Options section dictates the post-processing and scoring of a calculated Solution following beam simulation. These configurations establish the acoustic reference environment, geometric masking for mainlobe and sidelobe differentiation, and specific parameter constraints for identifying out-of-range Solutions. The mainlobe is represented as an ellipsoidal model focused at the target, with dimensions governed by the aspect ratio and mask radius. Conversely, the sidelobe region includes everything exterior to an outer ellipsoid, constrained by a minimum axial depth to filter out near-field transducer artifacts. Beamwidth evaluations are performed along lateral and elevation axes relative to the focus, extending to the defined search radius.

Solution Options

Table 15: Solution analysis options

Solution Analysis Option	Description
Standoff sound speed (m/s)	Acoustic velocity within the coupling medium, required for calculating initial impedance at the transducer interface.
Standoff density (kg/m³)	The mass density of the standoff material used for initial impedance calculations.
Reference sound speed (m/s)	The baseline speed of sound in the propagation medium used for deriving metrics.
Reference density (kg/m³)	The baseline density of the propagation medium used for deriving metrics.
Mainlobe aspect ratio (lat, ele, ax)	Proportional dimensions of the mainlobe mask; for example, (1, 1, 5) indicates an axial length five times its width.
Mainlobe mask radius	The radial size of the mainlobe ellipsoid, scaled by the aspect ratio and expressed in "Distance units."
Beamwidth search radius	The maximum lateral and elevation distance from the focal center used for beamwidth detection.
Sidelobe radius	Defines the boundary of the outer ellipsoid; acoustic energy beyond this point is categorized as sidelobe.
Sidelobe minimum z	An axial depth threshold that excludes near-field signal noise from sidelobe calculations.
Distance units	Specifies the linear units (mm, cm, or m) for all spatial parameters in this section.
Parameter constraints	A list of requirements used to evaluate the Solution, managed via the standard constraint interface.

Virtual Fit Options

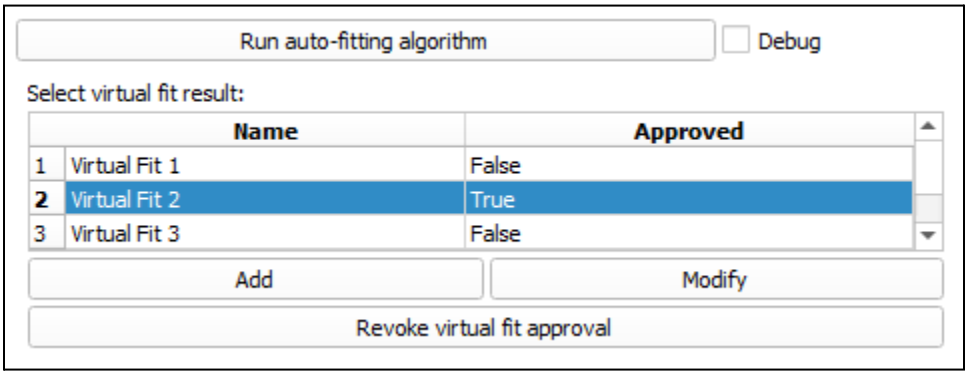


Figure 26: Sample virtual fit options.

The Virtual Fit Options section defines the automated algorithm for identifying optimal transducer positioning on the subject's anatomy for a specific target. The process involves sweeping a grid of candidate orientations—defined by target-centric pitch and yaw—and refining these candidates by aligning the transducer face with a localized grid of skin surface points. Target reach is validated against steering constraints. The system generates a list of top-tier placement options for operator selection.

Pitch and yaw coordinates are centered on the target within the subject's ASL (anterior-superior-left) coordinate system:

Pitch: The angle formed between the anterior axis and the ray pointing to the candidate's projection on the anterior-superior plane.

Yaw: The angle formed between the anterior-superior plane and the direct ray to the candidate location.

Available configurations include:

Table 16: Virtual fit options

Virtual Fit Option	Description
Length units	The units (mm, cm, or m) applied to all distance-based fields in this configuration.
Steering center distance	The “optimum” axial distance from the transducer to the center of the steering volume. Candidate poses will be ranked by how close to (0,0,steering center distance) the target is.
Steering limits	The per-axis spatial boundaries (min/max pairs) define the transducer's reachable steering area. Order is X(lateral), Y(elevation), Z(axial), and steering limits are defined relative to (0,0,steering center distance).
Pitch range	The angular span (in degrees) used for the pitch sweep during the fitting search.
Pitch step size	The angular increment for the pitch sweep; finer steps increase precision but extend processing time.

Virtual Fit Option	Description
Yaw range	The angular span (in degrees) used for the yaw sweep during the fitting search.
Yaw step size	The angular increment between yaw values in the fitting search grid.
Plane fit yaw extent	The half-width of the localized skin-sampling grid along the yaw axis for surface fitting.
Plane fit yaw step	The angular distance between consecutive sample points along the yaw axis for plane fitting.
Plane fit pitch extent	The half-width of the localized skin-sampling grid along the pitch axis for surface fitting.
Plane fit pitch step	The angular distance between consecutive sample points along the pitch axis for plane fitting.
No. of candidates returned	The limit on the number of high-scoring placement recommendations presented to the operator.

Save a Protocol

After completing configuration of a protocol for editing, click “Save Protocol to Database” to save changes.

Delete a Protocol

To delete a protocol, while editing, click “Delete Protocol from Database.”

Additional Hardware Requirements

PC

A PC is required to download and run the Open-LIFU application. While computers meeting the recommended specifications will be capable of running the software, some computer configurations may introduce compatibility issues beyond Openwater’s control. For incompatibility issues with a particular computer configuration, users are encouraged to engage with Openwater’s open source community.

Recommended PC specifications:

1. Graphics Card[4, 5]: NVIDIA CUDA 11+
2. Operating System: Windows 11 with all recommended updates installed.
3. Network card
    a. Recommended, but not required for installation

[4] While Openwater strives to make the Open-LIFU software releases compatible with CUDA-enabled graphics cards, certain computer and GPU configurations may require additional support measures to work with the software. Users are encouraged to refer to the Open-LIFU Community or to contact support for any questions related to GPU compatibility.
[5] A GPU is only needed for local (offline) image reconstruction. Users using Openwater’s Online Cloud Services for image reconstruction do not require a high-end GPU.

    b. Required for Openwater's Cloud Services
4. Storage: At least 5GB of free disk space

Android Phone

To capture the photocollections, a mobile device with a camera is required for transducer localization. Official support is provided for Google Pixel phones, and the photogrammetry app has been tested on the Pixel 5, 7, 9, and 10. Additional phones that meet the minimum specifications should also work, e.g. Samsung Galaxy A16 or Motorola moto g, however full compatibility cannot be guaranteed. Developers are encouraged to visit Openwater's Discord for help with non-supported phones.

Minimum phone specifications:

1. Android phone running Android 14 or newer.
2. Dual Camera: 12.2 MP, f/1.7, 27mm (wide), 1/2.55", 1.4µm, dual pixel PDAF, OIS 16 MP, f/2.2, 117˚ (ultrawide), 1.0µm
3. Accelerometer, gyro

Open-LIFU Software Operation

Overview

The application is divided into two parts – the software controls are shown on the left within the Active Module, while the display viewports are shown on the right within the Volume Area.

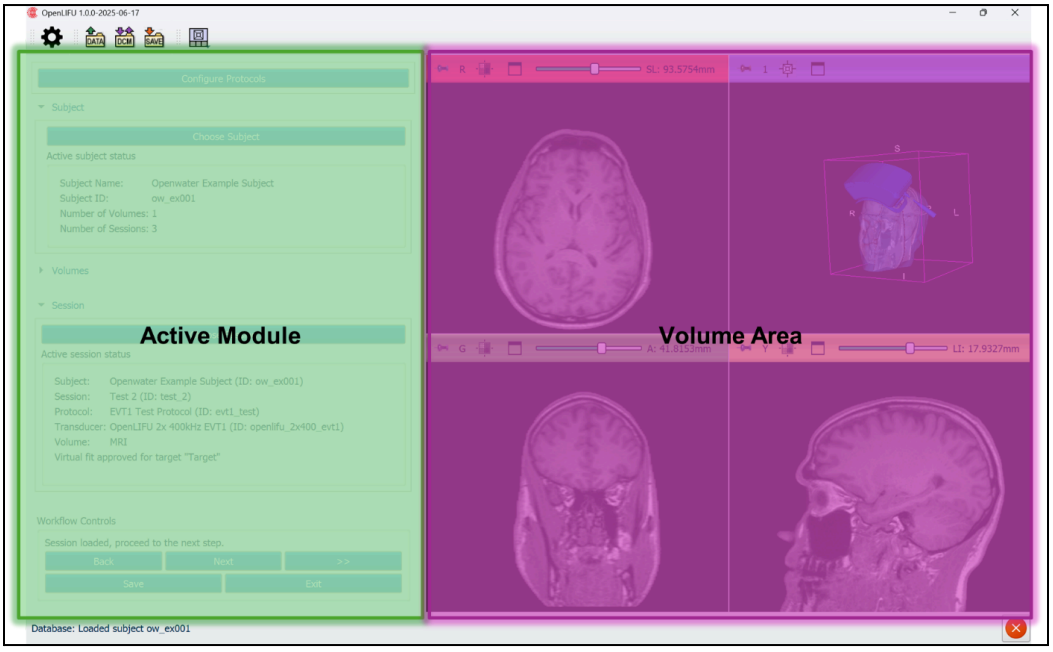


Figure 27: Displays how the graphical user interface (GUI) is rendered.

The viewports display the selected MRI planes, as well as interactive 3D volumes and segmented models. For full details on interacting with the viewports, refer to the 3DSlicer documentation.

Selecting the view icon allows the User to configure the viewport layout (Figure 28):

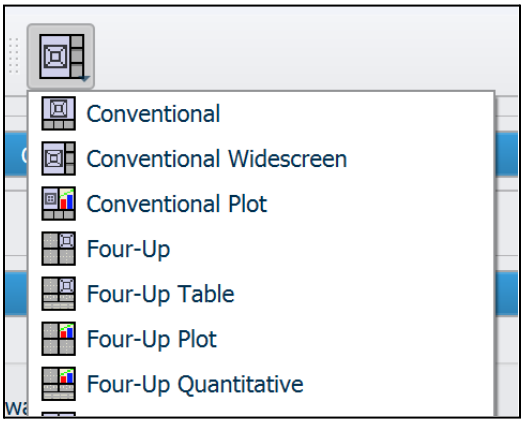


Figure 28: Use this screen to select the desired image viewer layout.

General Workflow Navigation

Navigate the procedure workflow using the “Active Module,” see Figure 29. The workflow is split into a series of sequential Modules:

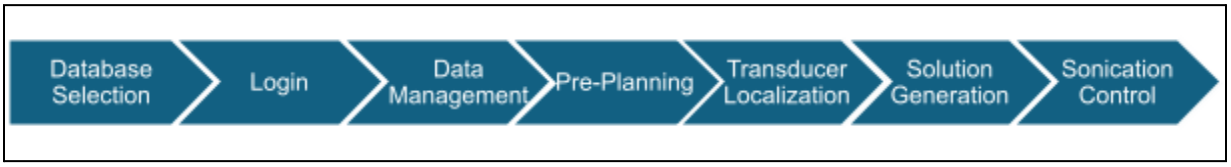


Figure 29: This is a summary of the general workflow navigation and modules contained within the Open-LIFU application.

At the bottom of each Module is a set of workflow controls (Figure 30) used to navigate between the different modules.

NOTE: When using the Open-LIFU Desktop Application, users must complete all steps within a module before advancing on.

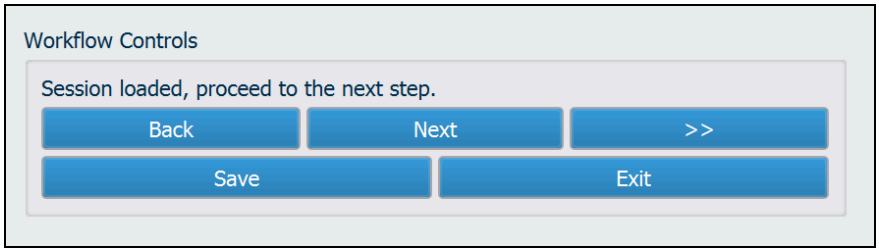


Figure 30: The standard controls used to navigate the Open-LIFU workflow.

- Selecting “Save” will save the current session state to the Database (only available when a session is loaded)
- Selecting “Exit” will exit the current session (and prompt the user to save) (only available when a session is loaded)

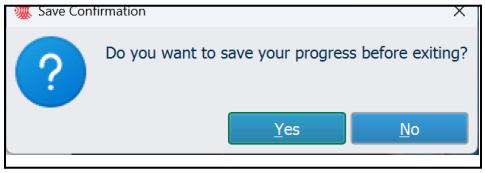


Figure 31: Exiting a session without saving will result in a user’s progress being lost.

Database Selection

Database selection only needs to be completed on the initial system setup. After initial setup, the selected location will be automatically loaded, and the user will be directed to the log-in page.

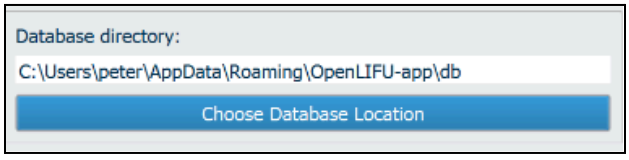


Figure 32: Select a database directory that is easily identifiable.

Use the “Database Directory” to manually type the desired file path or select one using the file system navigator by clicking “Choose Database Location.” Invalid directories will be outlined in red (see Figure 33). When a valid database is identified, the field will become outlined in green, Figure 34.

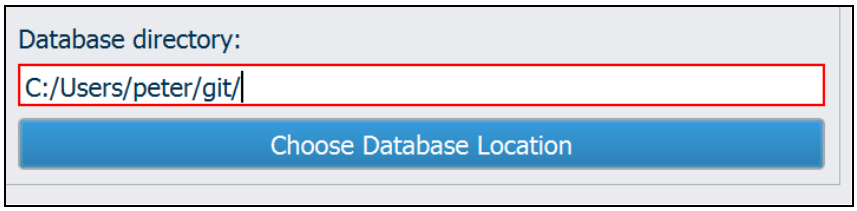


Figure 33: Invalid directories will be outlined in red.

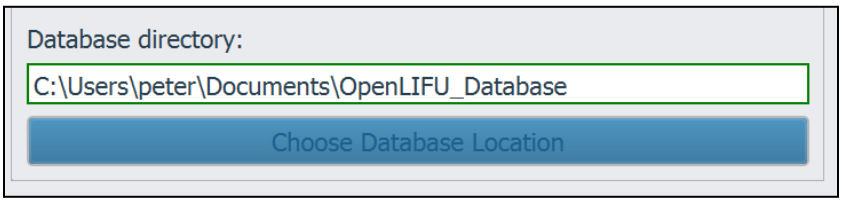


Figure 34: Valid directories will be outlined in green.

If a database is not found, the application will prompt users to create a new database.

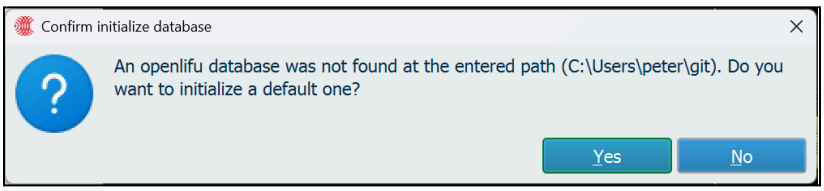


Figure 35: If a database does not exist then users will be prompted to create one.

NOTE: Only Admins can create and edit database directories. Standard Operators can only select database directories for which they have access to.

Log In

Open the Open-LIFU application and click “Login” on the login module. Enter a valid Username and Password and click OK.

NOTE: The “Manage Accounts” button is only available to admin users.

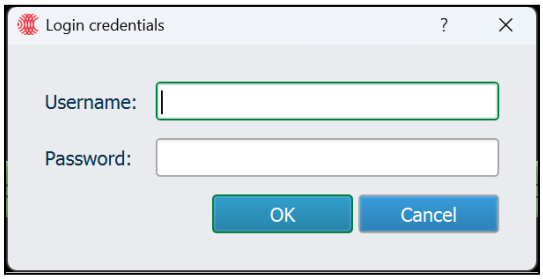


Figure 36: A user’s login credentials are related to a set of permissions within the application and allows the user to perform a specific set of tasks.

System Configuration

Choosing a Sonication Protocol

Before starting a procedure, it is recommended that users ensure all protocols are well-defined, created, and available for the desired use case scenario(s). The following sections describe how to create, load, and modify existing sonication protocols.

NOTE: Only Admins can create or modify sonication protocols. Admins must ensure the proper protocol permissions are set so operators can access the protocols.

Protocol Configuration

Users wishing to create or edit an existing protocol must log in as an admin to access the Protocol Configuration wizard. Detailed instructions for creating and editing protocols can be found on page 21.

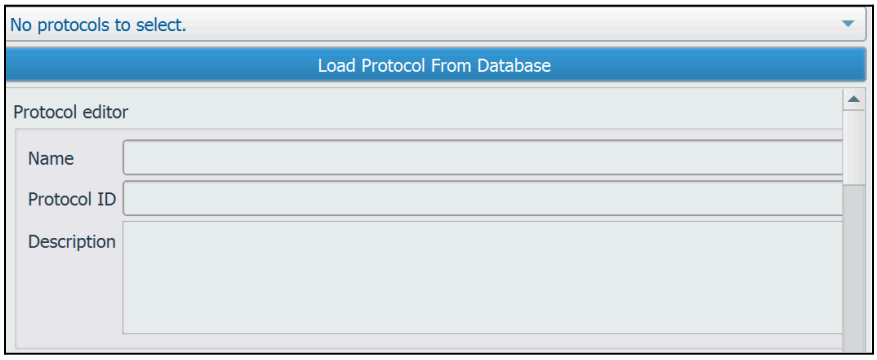


Figure 37: Use this dialogue box to either load or create a new protocol. Note that a user's permissions may prevent them from creating and/or editing a protocol.

Loading a protocol

To load a protocol, click "Load Protocol from Database," choose a protocol, and click "OK."

NOTE: Protocol permissions must be adequately set in order for them to be available to each user within the system. Contact a device administrator if a needed protocol is not available during a session.

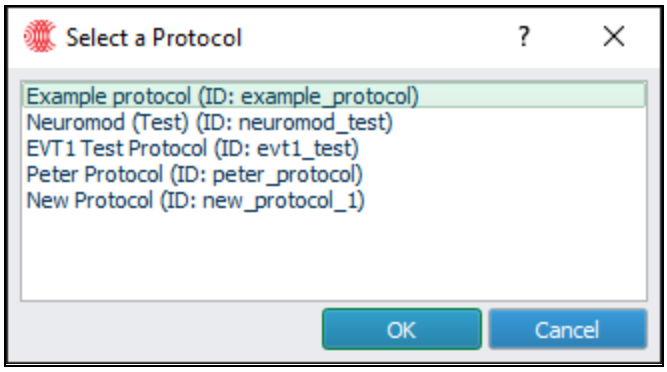


Figure 38: Saved protocols will be available in the protocol selection window.

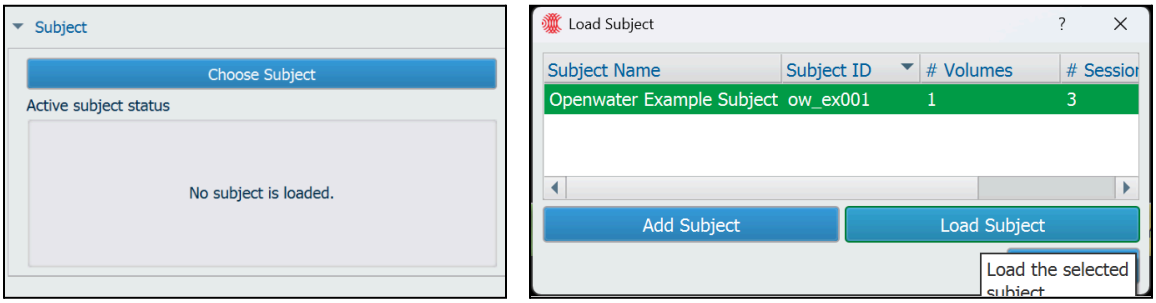
Planning Workflow

In the Planning stage, the user will configure the system, load information about the subject, and plan how the sonication will be conducted.

Subject Selection / Creation

Existing Subjects

1. Get started by clicking Choose Subject
2. Select the subject from the list and click Load Subject.



(a) (b)

Figure 39: a) Once selected, a subject's information will be displayed here. b) Use this window to add a new subject or select an existing one.

Creating a New Subject

Click "Add Subject" to create a new Subject:

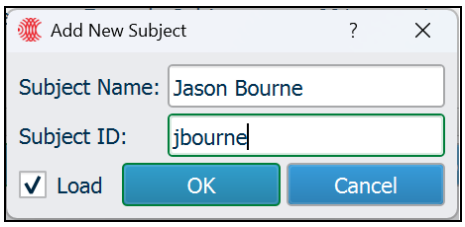


Figure 40: When creating a new subject, the Subject ID should be unique to that individual.

"Subject Name" is the display name of the subject, while "Subject ID" is the alphanumeric string used to represent the subject in the database.

Check the "Load" checkbox to load the subject upon creation.

Subject Information

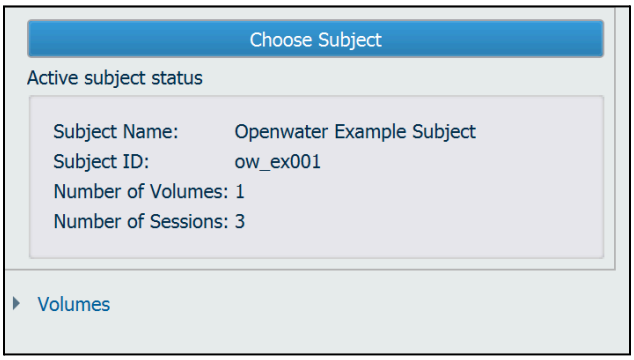


Figure 41: Displays the subject's case-specific information.

Once a subject is loaded, their information is displayed on screen.

Viewing/Adding Volumes

Expanding the "Volumes" section will show all Volumes associated with the currently loaded Subject.

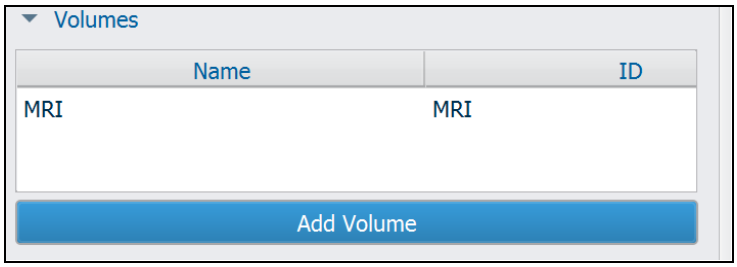


Figure 42: Users will see which volume(s) is loaded during a session in this window.

Select “Add Volume” to choose a volume, specify its display Name and its ID, and add it to the database, attached to the subject.

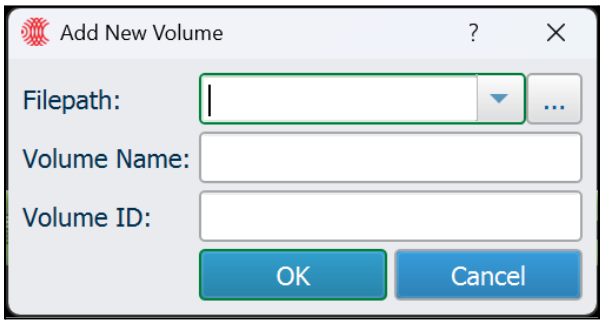


Figure 43: When adding a new volume, provide it with an easy to identify volume name and unique volume ID.

NOTE: Volumes loaded in as a DICOM will automatically be converted to the NIFTI format.

Start A Session

Loading Sessions

Select “Choose Session” to open the Sessions Dialog

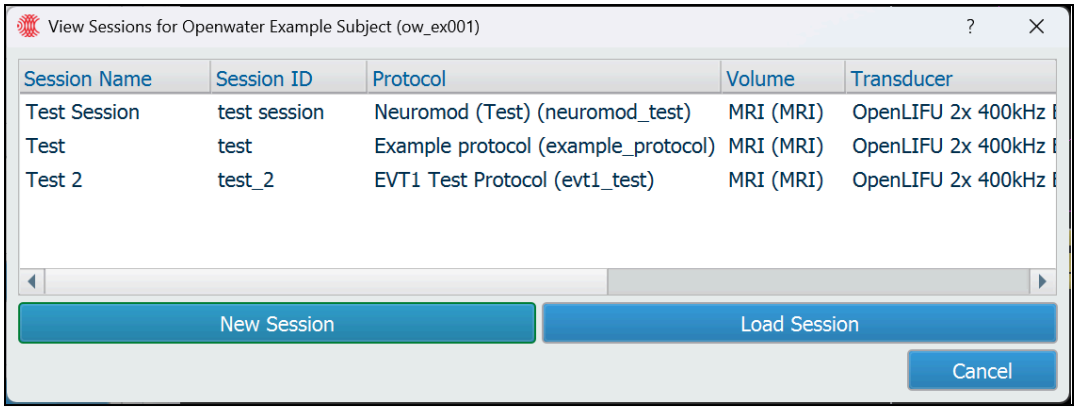


Figure 44: Sessions are displayed in a table where users can create new sessions or select existing ones.

To load a saved session, double click or select a row and click “Load Session”

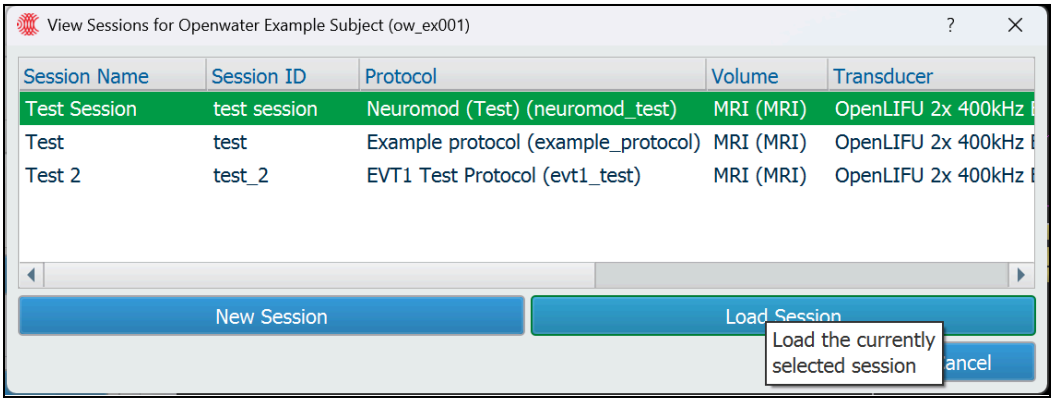


Figure 45: When choosing an existing session, it will become highlighted.

If the user does not have access to the protocol associated with the session, they will receive an error. Users must contact their administrator to gain access to a protocol that is unavailable.

Figure 46: This error message is displayed when a user does not have access to the protocol needed.

Creating a New Session

To create a new session, click “New Session”

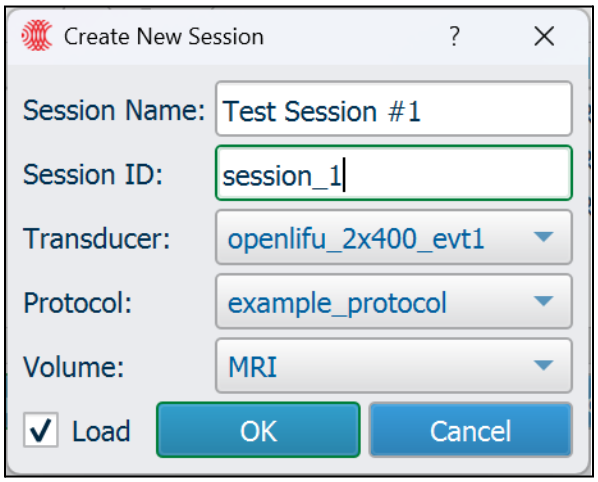


Figure 47: When creating a new session, input a session name and unique ID.

Users are prompted to enter a Session Name (for display) and a Session ID for the new session.

- The “Transducer” dropdown will show all available transducer definitions.
- The “Protocol” Dropdown will show all available protocols.

Once the session has been loaded, select “Next” in the Workflow Controls.

Pre-Planning

The Pre-Planning module contains information about the focal target and allows for running “Virtual Fitting,” which will analyze the subject’s MRI and recommend the placement of the ultrasound transducer to optimally focus on the Target.

Select Target(s)

Target Management

The Target dialog provides users with a list of all placed targets.

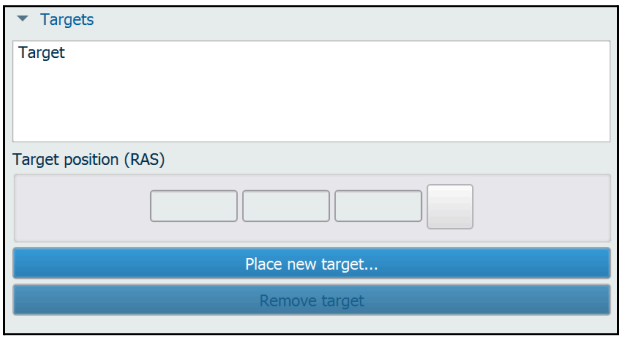


Figure 48: Targets that have been placed are shown here.

Select “Place New Target,” to identify and place a target in one of the viewports.

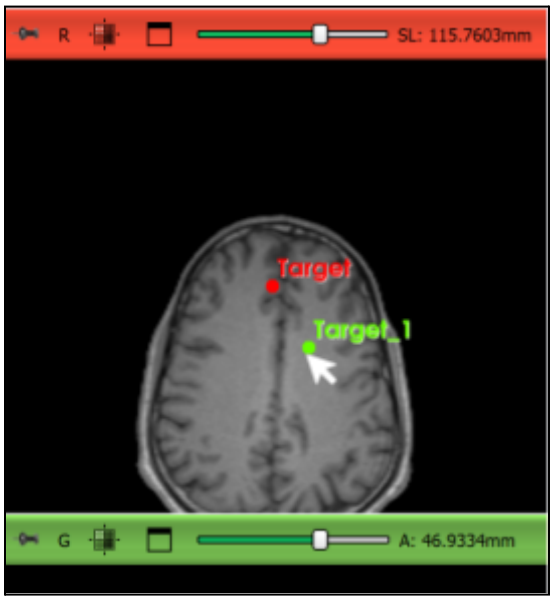


Figure 49: Targets can be placed using any of the three viewports.

- Users can drag the target around or edit its coordinates directly.
- When finished editing the target, click the lock icon.

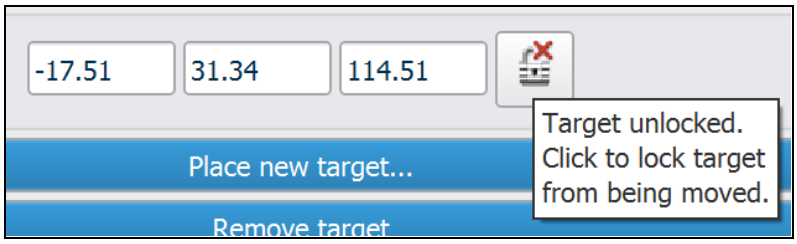


Figure 50: Users must lock the target(s) before advancing to the next step.

Once a target is created, users may view corresponding RAS coordinates by selecting the desired target(s), as shown in Figure 51.

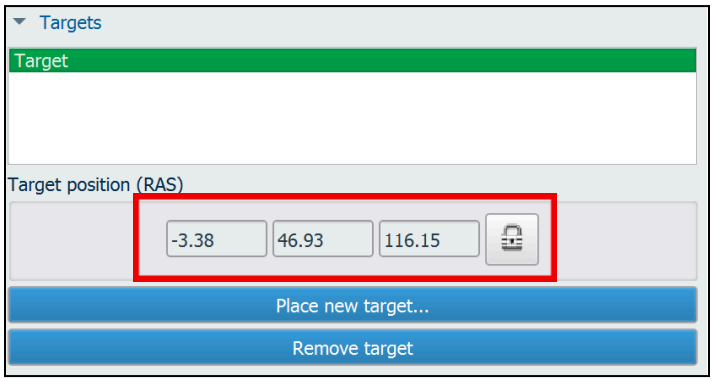


Figure 51: selecting a target displays the RAS coordinates in the boxes.

Virtual Fitting

Select the desired target from the list and click “Run auto-fitting algorithm” to run the virtual fitting. Virtual fitting may take 2 minutes or longer to complete.

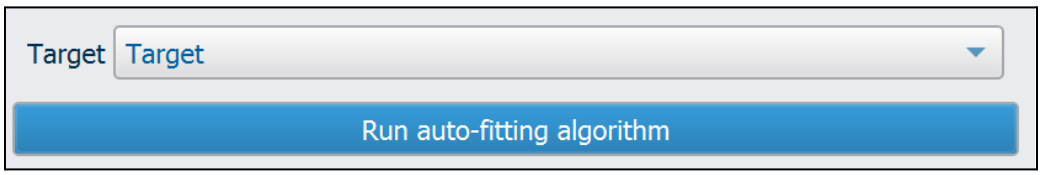


Figure 52: Running the auto-fitting algorithm is done on the target selected in the dropdown menu.

Once completed, users are shown transducer positions in the Virtual Fit Results table that have been optimized based on the target location. Selecting a row will cause the transducer to turn blue and appear in that location.

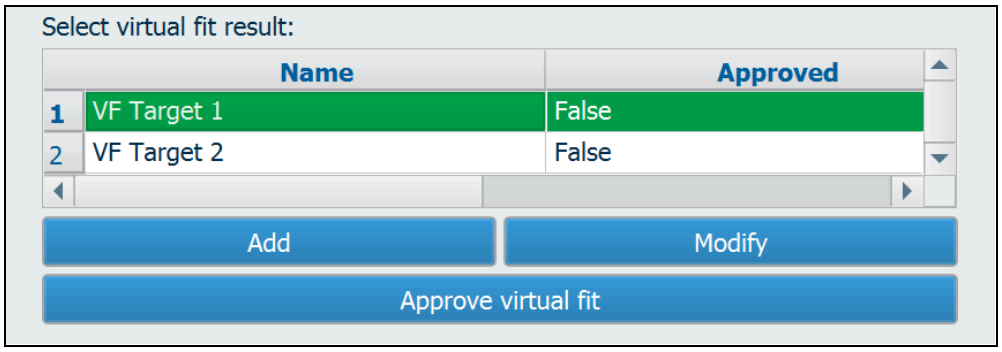


Figure 53: Confirm the desired virtual fit option by selecting it in the table and approving it.

Modifying a Virtual Fit

Click “Modify” to show interaction handles on the transducer and allow the User to manually reposition the Virtual fit location. Select “Finish” when done editing the position.

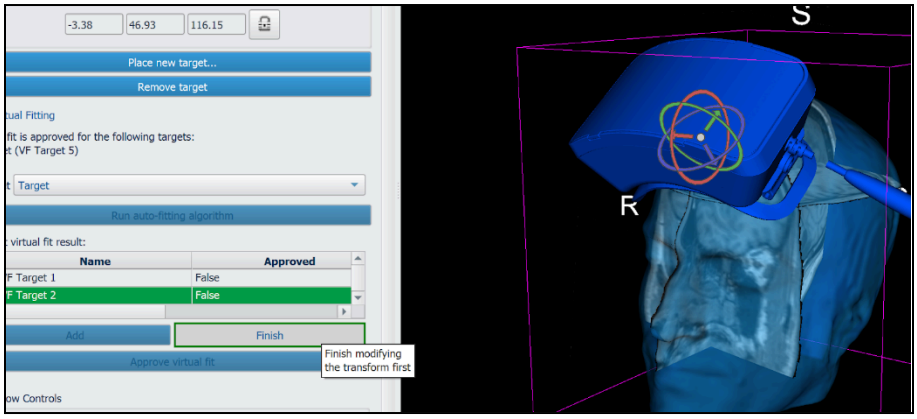


Figure 54: Modifying the virtual fit can be done using the XYZ widget. Users can move the transducer linearly along the X, Y, or Z axes. Users can also rotate the transducer about each of the axes.

Adding a manual Virtual Fit Location

Click “Add” to copy the current virtual fit position to a new row and enable interaction. This allows customized virtual fit locations to be defined.

Approving a Virtual Fit

Once the user has chosen their desired Virtual Fit location, select “approve” to mark the location as reviewed and approved. Users cannot proceed until at least one location is Approved.

Saving A Session Plan

Once the Virtual Fit is completed, the session can be saved, and returned to later, once the subject is present, to complete the final planning stages and begin sonication.

Sonication Workflow

Once the subject is present, a session can be loaded and the user can proceed to fit the transducer to the subject, complete the final beamforming and analysis steps, and proceed to sonication of the subject.

Transducer Localization

Subject Preparation

Coupling pads (Figure 4) are non-sterile, single-use pads made of a biocompatible water-based polymer hydrogel, having a curved face to conform to curved surfaces (e.g. forehead).

> *NOTE: When using coupling pads, open packaging carefully at marked areas to avoid tearing or damaging the pad.*

Prepare the Open-LIFU transducer by:

1. Thoroughly wash hands before handling the coupling pad.
2. Do not set an opened pad directly on dirty surfaces.
3. Carefully open the peel-pack.
4. Apply a small amount of coupling gel to both sides of the coupling pad. Place the pad inside the transducer cavity, ensuring there is good contact between the coupling gel and transducer array.
5. Inspect the gel pad to ensure that no air bubbles are visible underneath the coupling pad. If air bubbles are present, physically press the coupling pad with a soft tool to knead away the bubbles.
6. Secure the transducer to the Subject using the adjustable strap.

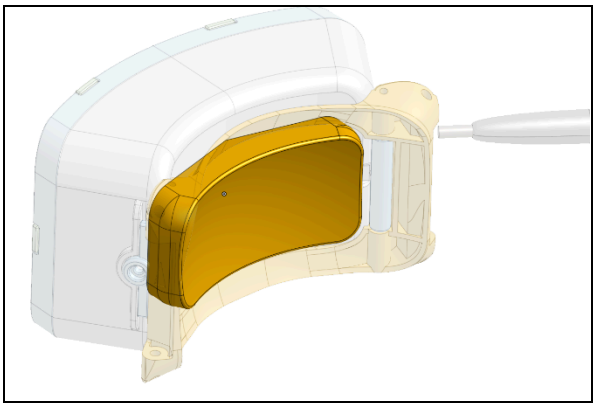


Figure 55: This shows how the coupling pad should be placed in the transducer.

Next, use the Photogrammetry application to localize the transducer on the subject and process a Photoscan to help guide sonication.

> *NOTE: Online and Offline users may wish to scan the QR code with the photogrammetry app to eliminate the need to manually type Subject or Session ID numbers into the app.*

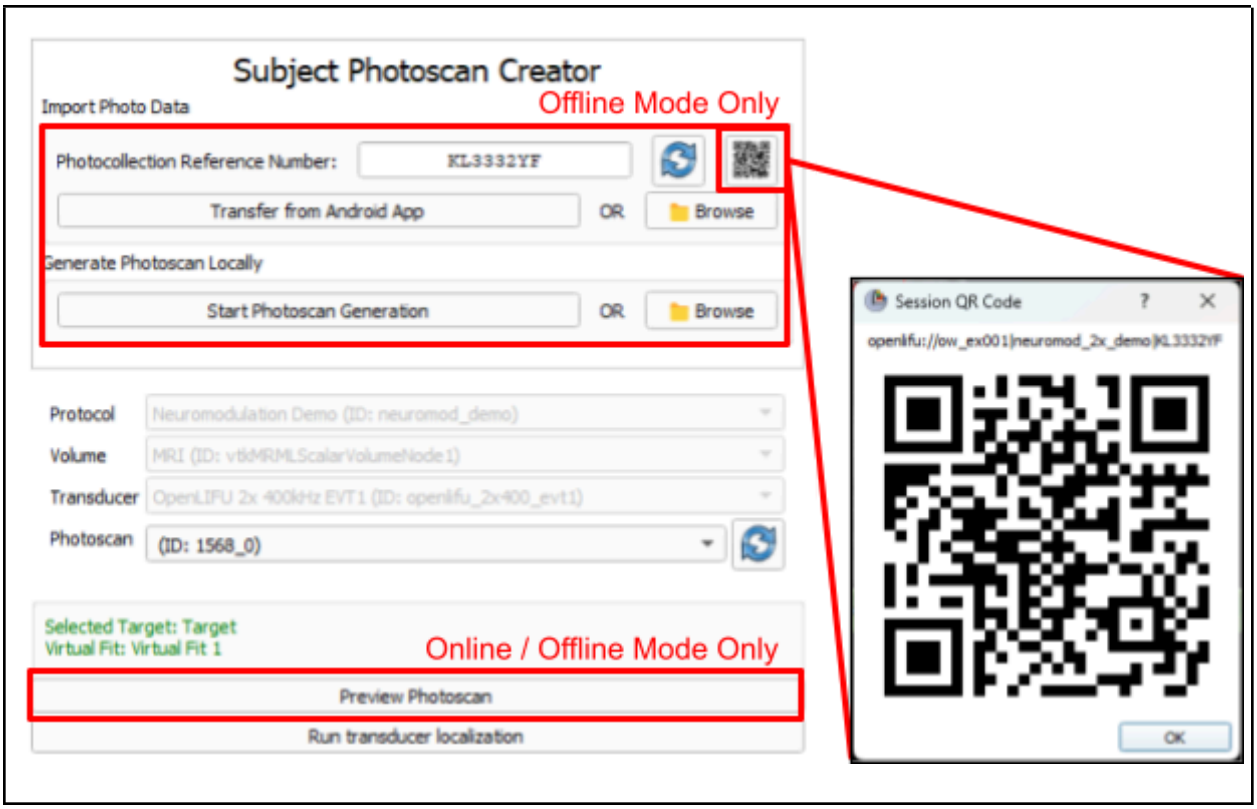


Figure 56: This identifies where the offline and online image reconstruction workflows exist in the Subject Photoscan Creator section. Use these controls for importing a photocollection, generating a photoscan, and viewing the photoscan.

Photocollections and Photoscans

Environment Setup

The Subject should be comfortably reclined in a chair such that the user can circle all the way around them to capture images at eye level. The area should be well lit and clear of any tripping hazards. It is helpful to have the background free of distractions too. The Subject should have their eyes closed and their face in a neutral position.

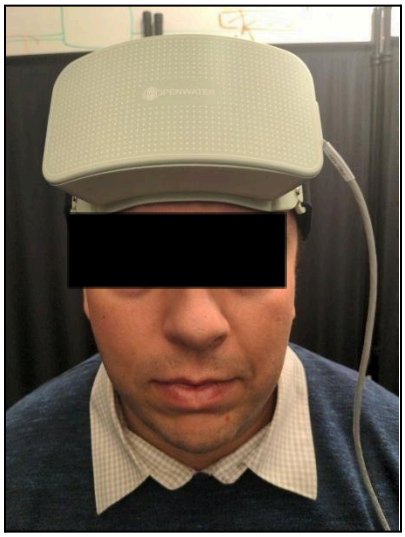


Figure 57: Ensure the transducer is snug when placed on the subject such that it will not slide or fall off.

Initiating a New Capture

Click “Start Photocollection Capture.” A popup will appear with a reference number. This reference number must be used in the Android application and must match what is used in the desktop application to synchronize the data between the phone (for offline users) and cloud (for online users), and the PC.

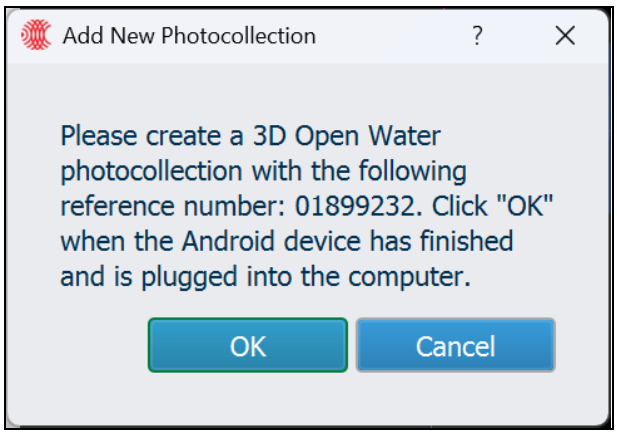


Figure 58: Users must enter their reference number into the phone app to ensure the photocollection synchronizes properly with the desired subject/session.

Capturing a Photocollection

Using a mobile phone with the Photogrammetry App installed (Google Play), capture the photo collection of the subject. First time users are encouraged to review the Open-LIFU Photogrammetry App Instructions For Use to learn how to transfer a photocollection from the phone via USB cable (Offline Mode) or the cloud (Online Mode). They may also review how to capture a photocollection by watching this instructional video.

NOTE: Users with a Cloud Services account must log into the phone app prior to beginning their photogrammetry scan to ensure the online syncing works properly.

Generate Photoscan (Offline Mode)

Start by connecting the phone to the computer via USB cable and then clicking “Transfer from Android App.”

Once the photocollection has been transferred to the computer, click “Start Photoscan Generation.” If more than one photocollection is available, users will be prompted to select which photocollection to use. Reference numbers will be uploaded chronologically from Oldest to Newest in order, so the newest is always at the bottom of the list.

The app will create a popup with the default photoscan generation values. Click “OK” to proceed to photoscan generation.

NOTE: Advanced users may wish to configure the default photoscan values to further optimize MRI-to-photoscan image registration.

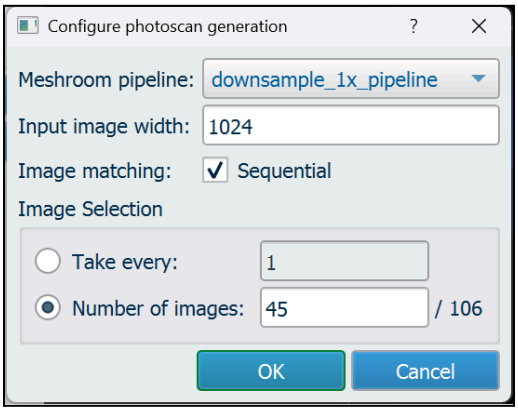


Figure 59: Advanced features that (advanced) users can manually adjust to enhance the 3D mesh reconstruction.

Advanced Photoscan Features (Offline Mode)

NOTE: These steps are only recommended for advanced users.

1. "Meshroom Pipeline" selects from preset collections of options for reconstruction. The default pipeline has been chosen for a balance of mesh detail and processing time.
2. Input image width downsamples input images to improve processing time (may be necessary for phones with especially high resolution).
3. The Image Matching Sequential text box indicates that the application will order the photographs in acquisition order, and only match features within their sequential neighbors, as opposed to an exhaustive matching between all images, which will take much longer, but may produce more accurate results.
4. The final box selects between different image downsampling methods to only use a subset of the images in the photocollection. "Take Every" will downsample by that many images (1 = use every image, 2 = use every other image, etc.), which number of images will set a total target number of images and downsample to that number.

NOTE: Depending on the CPU and GPU used, desktop processing times can vary dramatically when adjusting Photoscan Reconstruction parameters: ~3 minutes - ~60+ minutes. Faster reconstruction times can be achieved by using Openwater's Cloud Services.

NOTE: During reconstruction, it is normal for the app to become unresponsive during certain steps. Do not attempt to complete other steps in the workflow or exit out of the app while photoscan reconstruction is in process.

Generate Photoscan (Online Mode)

NOTE: If a user doesn't have an online account then skip this step.

Users with an online account must first sign into their Cloud Services account on the phone application and in the Open-LIFU application. Next, scan the QR code using the phone application and proceed with capturing the photocollection of the subject. When done, the photocollection will be sent to the cloud for reconstruction and synchronized to the corresponding subject on the desktop application.

Preview Photoscan

Select the correct photoscan ID from the dropdown menu and click "Preview Photoscan" to view the reconstructed Photogrammetry Mesh.

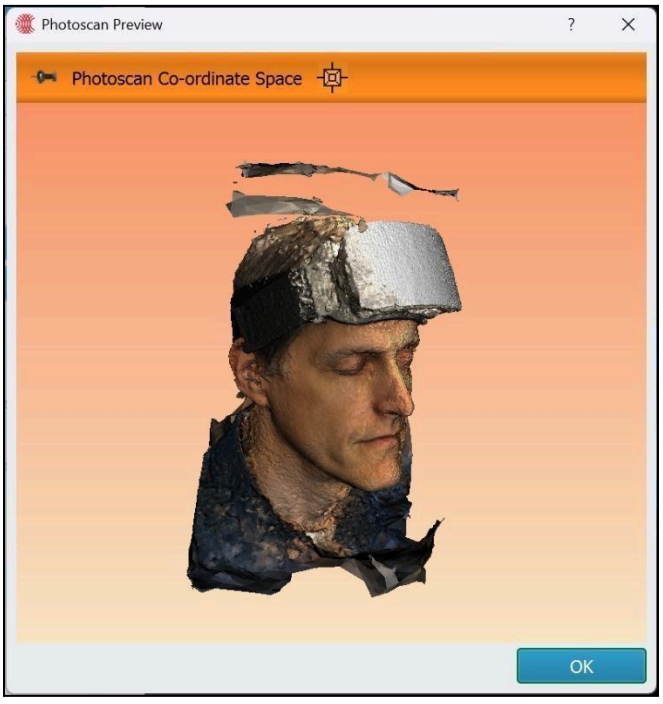


Figure 60: Preview window of the 3D reconstructed photoscan.

Table 17: Transducer localization mouse controls

Mouse Button	Description
Left mouse button: click and drag	Rotate

Mouse Button	Description
Mouse wheel or right mouse button: click and drag	Zoom in / out
Middle mouse button: click and drag	Pan

Transducer Localization Wizard

Select “Run Transducer Localization” to open the Transducer Localization Wizard.

Navigate forward and back using the “Next” and “Back” buttons.

Each page has a “Lock” icon that will set the input values of that page as Approved. Clicking the lock button will unlock the values on that page for editing.

Place Facial Landmarks on Photoscan

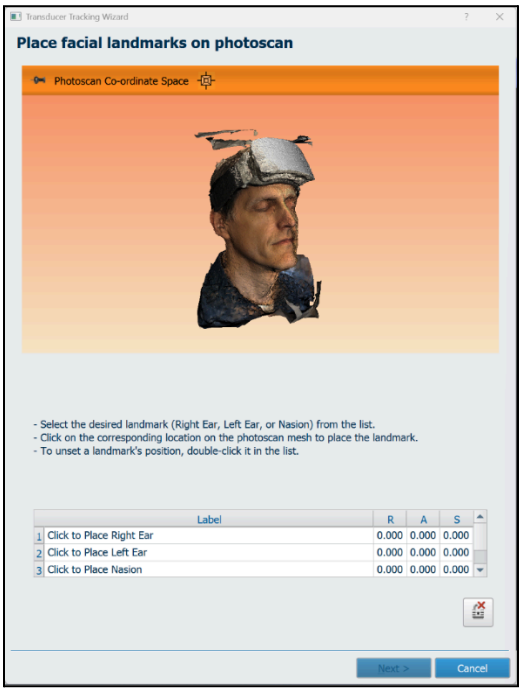


Figure 61: Identify and place three landmarks as described in the popup window.

Click the Lock/Unlock button to modify the landmarks.

Select each row in the table and then position the marker over the photoscan. Right click to place it. Points will snap to the mesh surface.

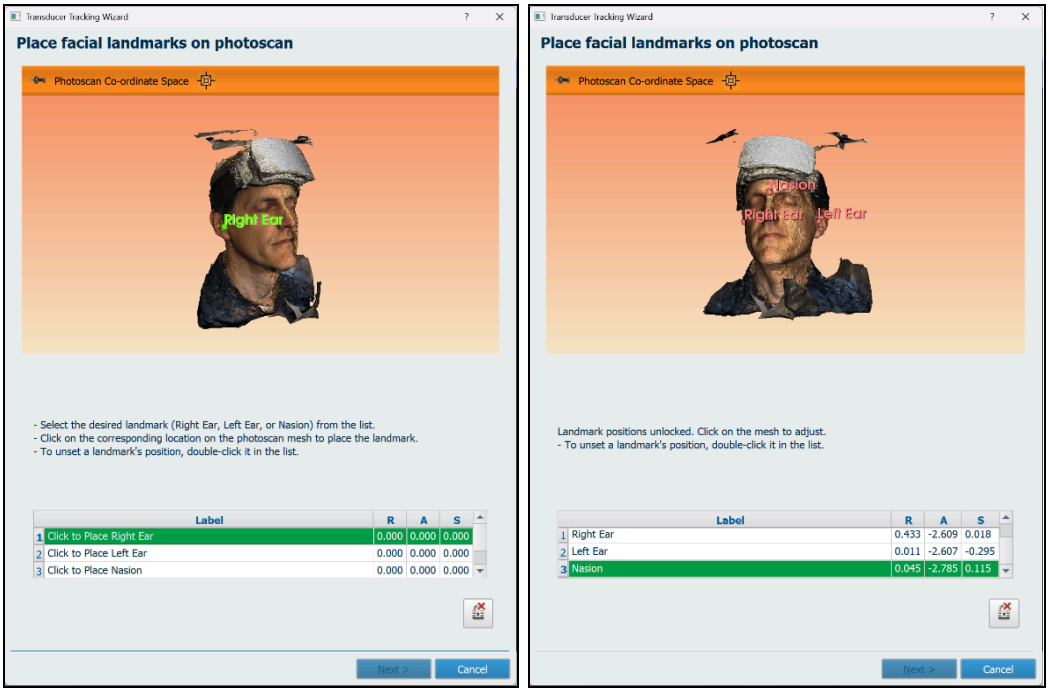


Figure 62: Users must select on the desired landmark prior to placing the marker on the 3D photoscan.

A mouse can be used to drag points around, and the R,A,S values can be manually edited in the table. The ear markers should be placed on the Tragus, while the Nasion should be placed in the concavity of the nose bridge.

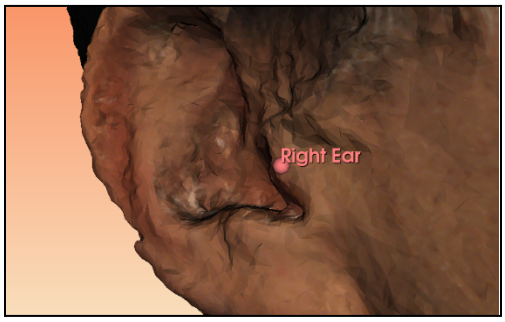


Figure 63: Accurately place the landmark on the photoscan by zooming into the desired location.

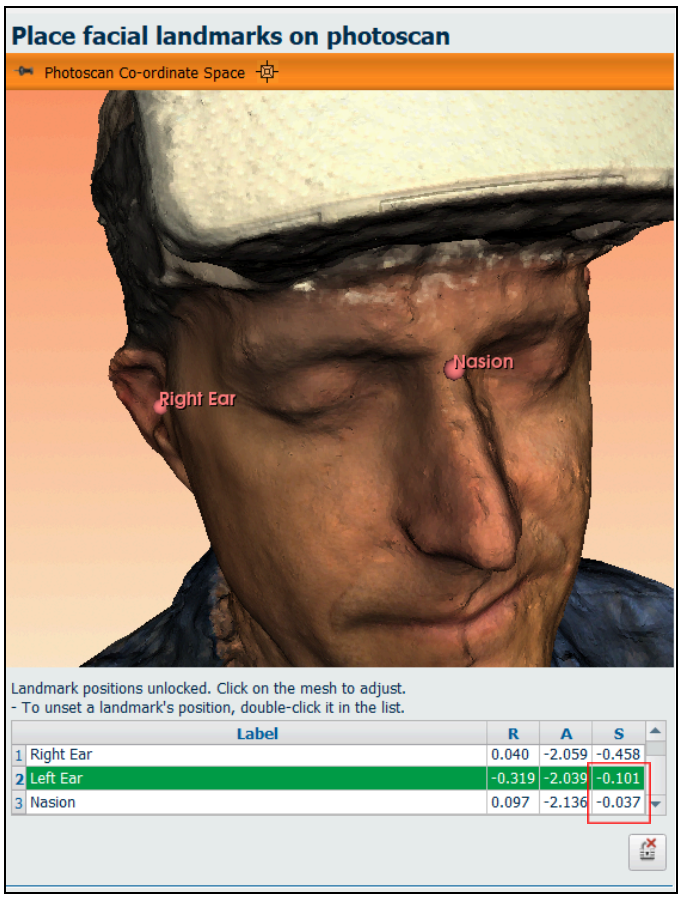


Figure 64: Once all landmarks have been placed, click the lock button.

Click the Lock button to lock in the values when satisfied. These markers are used for an initial registration of the scan to the MRI.

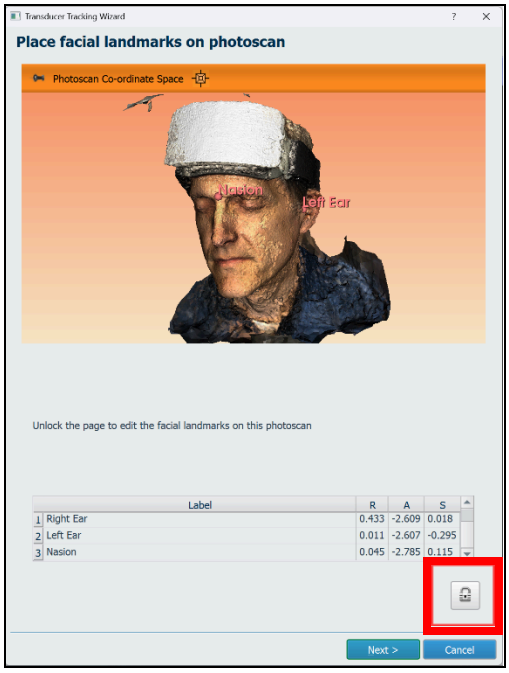


Figure 65: Once the landmarks are locked, advance to the next step.

Click Next.

Place Facial Landmarks on MRI Skin Surface

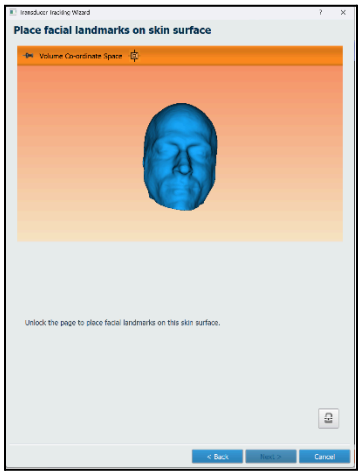


Figure 66: Landmarks can now be selected on the segmented MRI volume.

Repeat the same procedure shown in Figure 62 to place markers on the detected surface of the MRI.

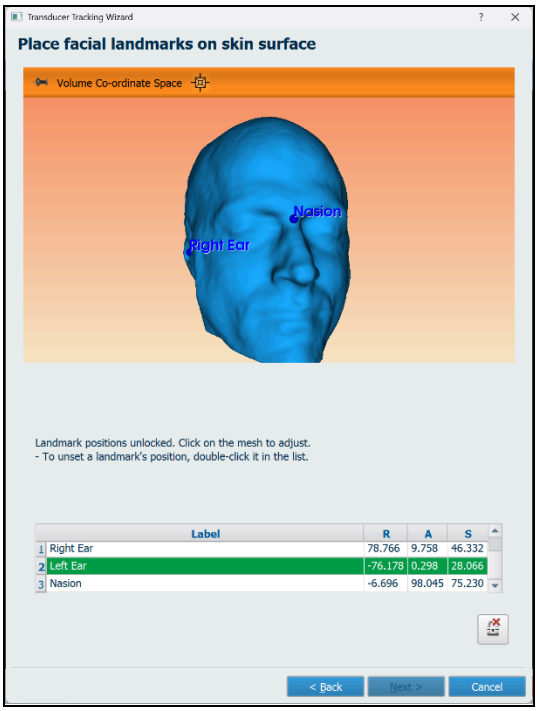


Figure 67: Users must select similar landmarks on the segmented volume as were selected on the 3D mesh.

Once all landmarks are placed, lock the values and click Next.

Register Photoscan to Skin Surface

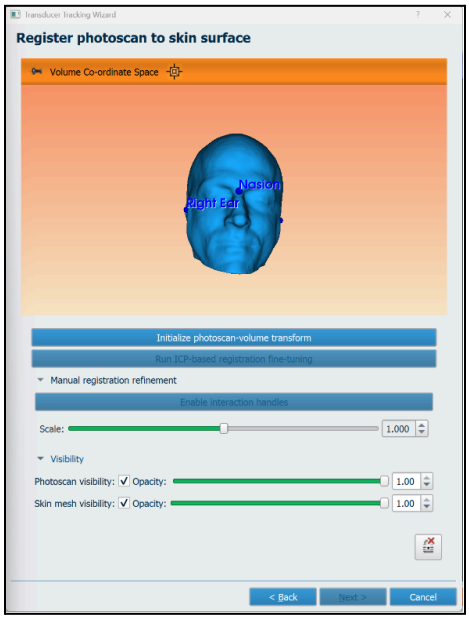


Figure 68: Once landmarks are placed, register the 3D mesh with the MRI volume.

Click “Initialize photoscan-volume transform” to perform the initial fiducial registration based on the landmarks placed in the prior steps.

Figure 69: Displays the (two) co-registered volumes.

The Photoscan Visibility and Skin Mesh Visibility checkboxes and sliders can be used to adjust the opacity of each object.

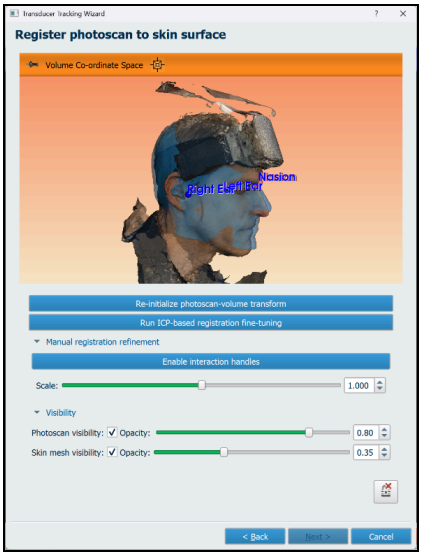


Figure 70: Users can adjust the opacity of the photoscan and MRI volume by adjusting the corresponding sliders.

Select “Run ICP-based registration fine-tuning” to register the surfaces together. A band of the face including the eyes, nose, and ears is used to scale and register the two meshes.

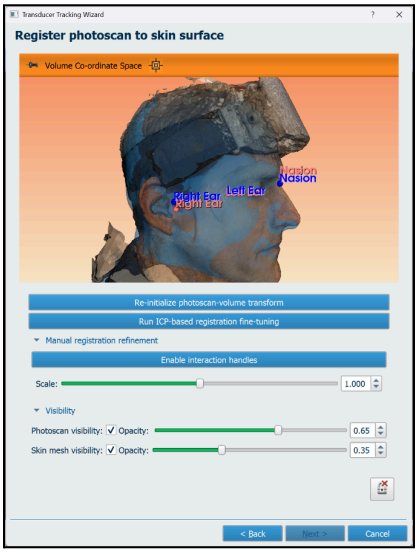


Figure 71: Display of how the two images are co-registered after ICP is run.

To adjust the positioning, rotation or scaling of the registration, select “Enable Interaction Handles” to edit the registration. Click “Disable Manual Transform Interaction” when finished.

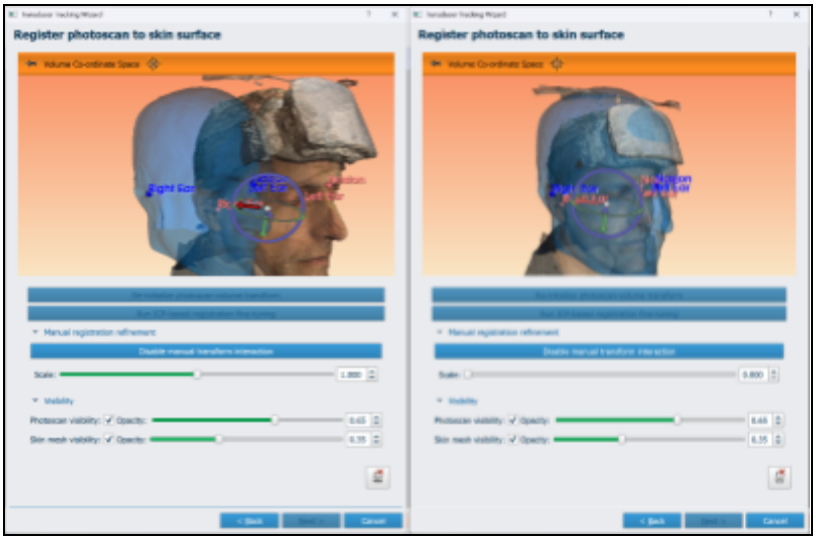


Figure 72: Use the Interaction Handles to manually adjust the position of the 3D mesh.

When satisfied with the registration, click the Lock to approve the registration and then click Next.

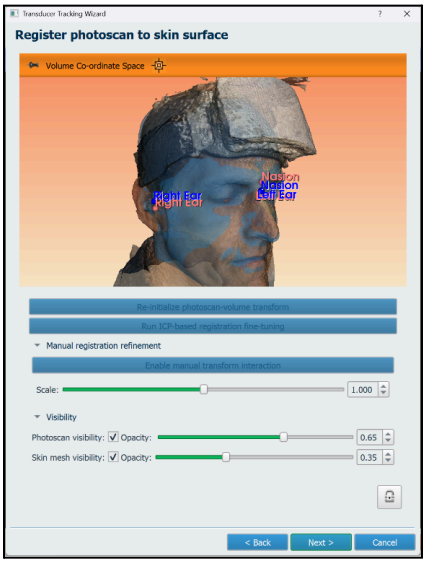


Figure 73: Lock the registration prior to advancing.

Register Transducer to Photoscan

Figure 74: Displays the 3D transducer overlaid on the 3D mesh.

Click “Initialize transducer-photoscan transform” to set the position of the Transducer to the Virtual Fit location. If the transducer is not aligned with the scan, Enable Interaction handles can be used to adjust the position of the transducer prior to running ICP fine-tuning.

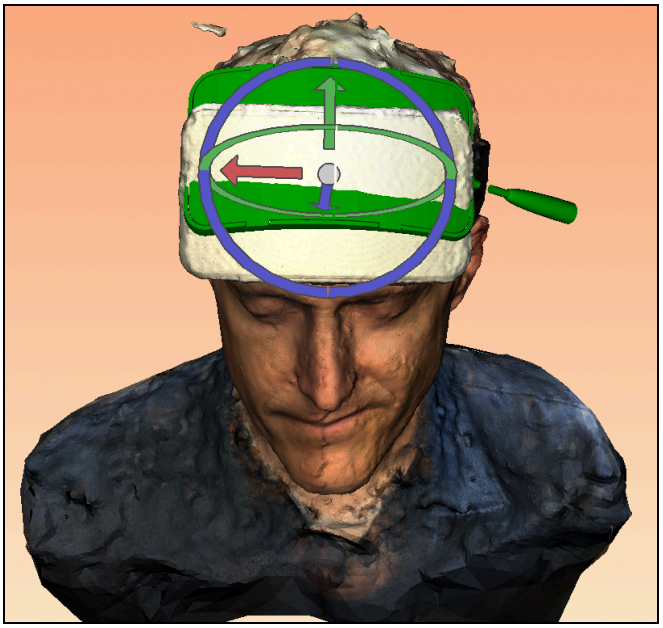


Figure 75: Once the interaction handles are enabled, users can manually adjust the transducer placement.

When aligning the transducer to the mesh, zoom in as close as possible to better align the transducer model to the mesh.

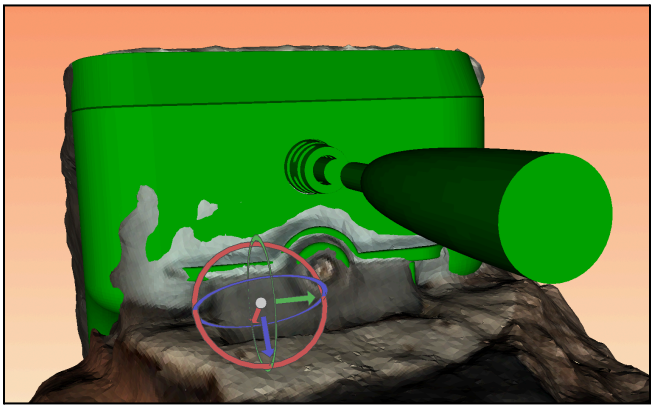


Figure 76: Zoom in to assist with aligning the transducer to the photoscan volume.

When zoomed in, rotate and move the transducer model so that the ridged edge above the screw hole on the side is aligned with that of the mesh.

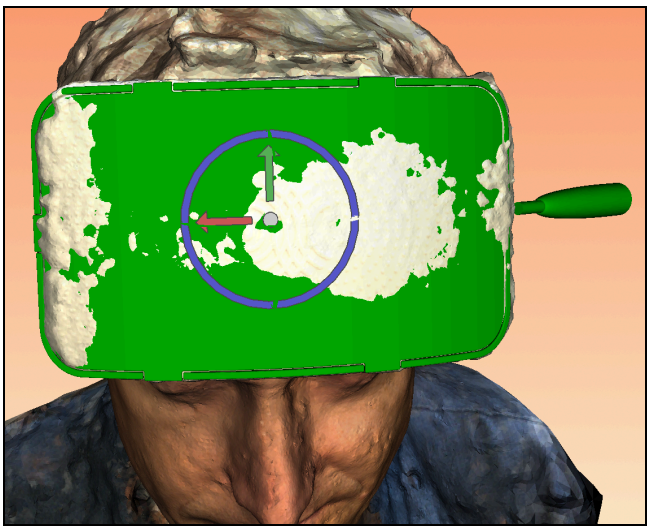


Figure 77: Once the transducer is properly aligned, it should fit within 3D photoscan.

Once the side of the transducer is aligned, navigate to the front of the transducer. Enable the “transducer registration surface.” Once the surface is aligned with that of the mesh, it is normal to see “splotches.” These indicate the interference between the transducer model and the mesh transducer surface. The four extrudes on the top and bottom edge of the transducer are also a good reference for alignment.

Click “Run ICP-based registration fine-tuning,” which will register the transducer surfaces between the stored transducer geometry and the photoscan.

Enable Interaction Handles can also be used to further adjust the position and rotation of the transducer if the ICP registration is unsatisfactory.

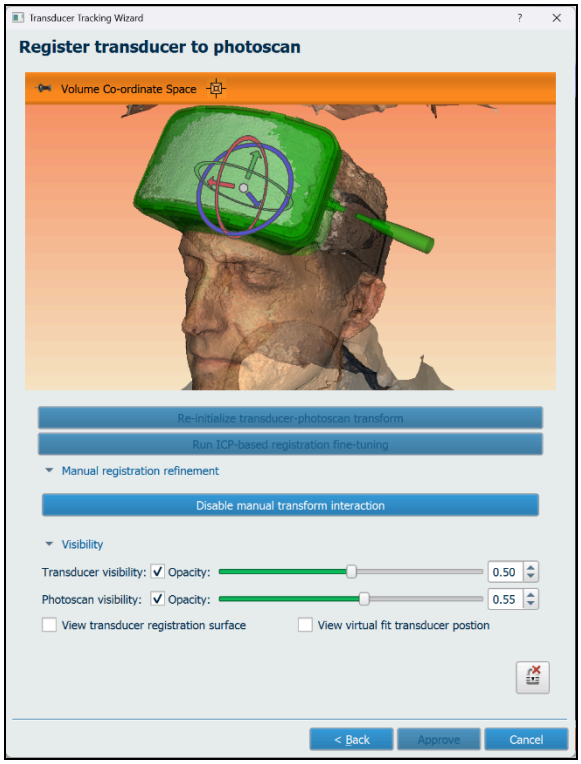


Figure 78: Refine the transducer position, if necessary, and lock the position of the transducer prior to advancing on.

Click the Lock and then click Approve to finish.

Review Localization Results

Once localization is complete, the “Photoscan Visibility” checkbox can be used to view the registered photoscan in the main window. The View Virtual Fit Transducer Position checkbox will also allow comparison of the localized position (Green) to the Virtual Fit position (Blue).

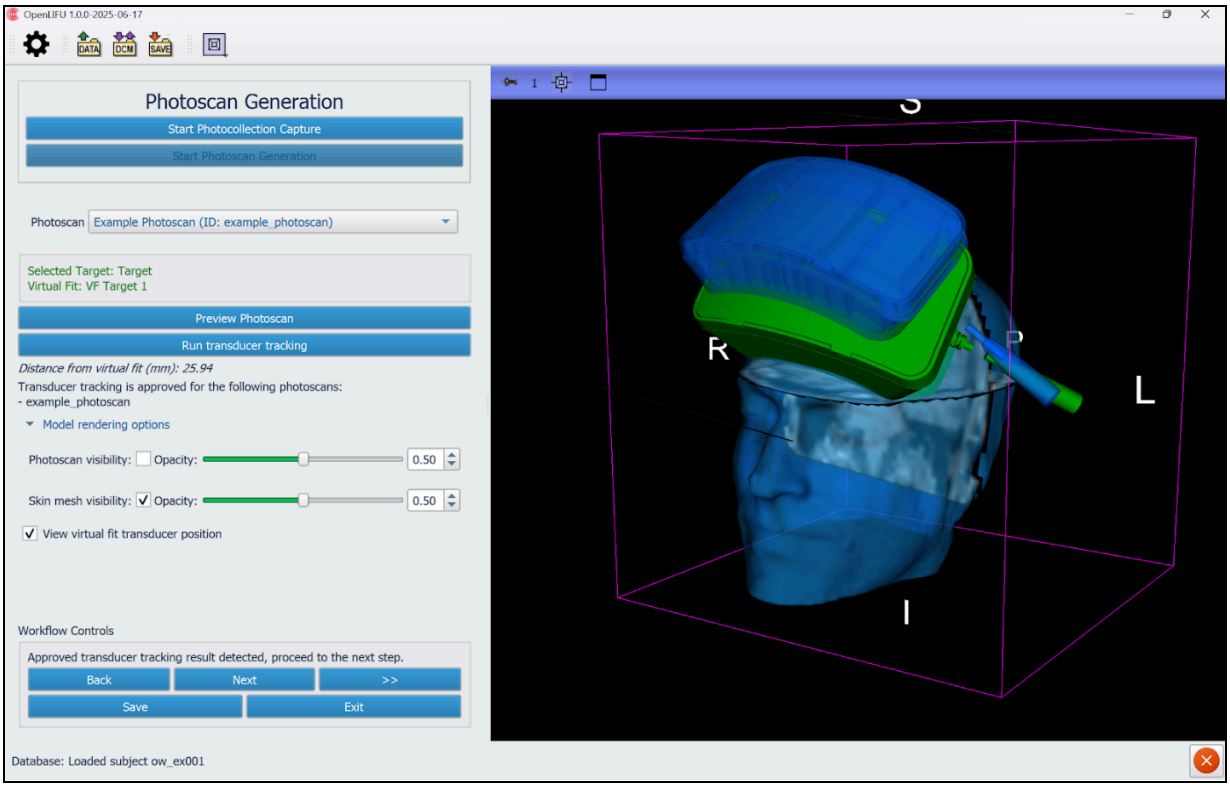


Figure 79: Display of the localized transducer position (green) and virtual transducer position (blue).

Click “Next” to proceed.

Solution Generation

A Solution is a set of pulses, delays, and the voltage required to complete the sonication protocol for a particular relative location of the transducer and target within a subject. The Solution contains all the information needed to instruct the hardware on what signals to generate and must be calculated while the transducer is secured to the subject. Because of pulser electronics’ limited ability to dissipate heat, certain combinations of voltage and duty cycle are disallowed. The formula for determining if a combination is safe is:

$$V + DC(\%) < 70$$

where V is the positive and negative voltage setting and DC is the Duty cycle, expressed in percent. It follows that voltages of <=20 can be used at the maximum duty cycle of 50%, and Voltages > 65 should not be used. See Figure 80 for details.

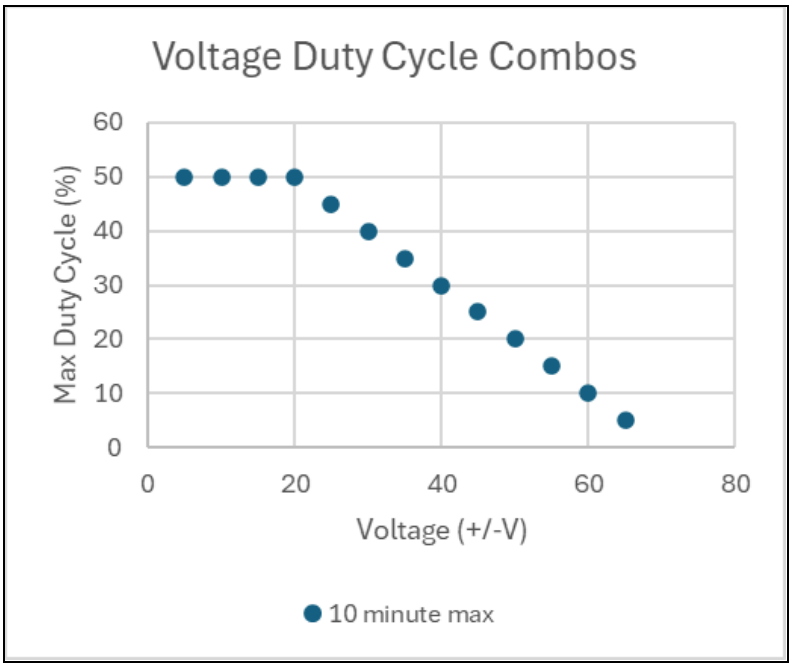


Figure 80: Users may refer to this table to assist with determining the maximum sonication parameters for delivering energy to the annotated target(s).

⚠️ *WARNING: If the transducer moves relative to the Subject, the Solution will be invalid, and it will be necessary to re-capture the photoscan.*

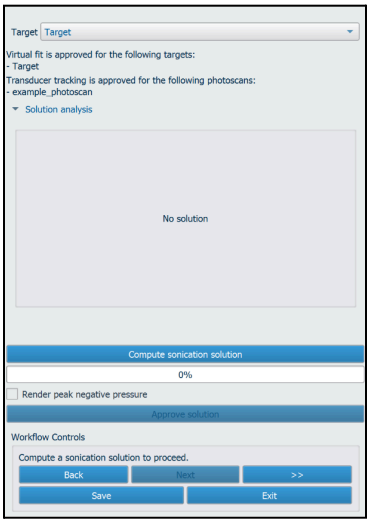


Figure 81: Users can click on the Computer Sonication Solution to generate

the solution associated with the session plan.

Run Solution Generation

Click “Compute Sonication Solution” to compute the solution. When complete, the Solution Analysis Table appears:

Figure 82: Summary table of the computed sonication solution.

The “Status” column evaluates the value of the parameters against any Parameter Constraints defined in the protocol.

Checking “Render Peak Negative Pressure” will create a Maximum Intensity Projection in the 3D View. The volume slice controls (see the Slicer documentation) and “Mesh Visibility” checkbox on the Tracking Module can be used to adjust which objects are visible in this view.

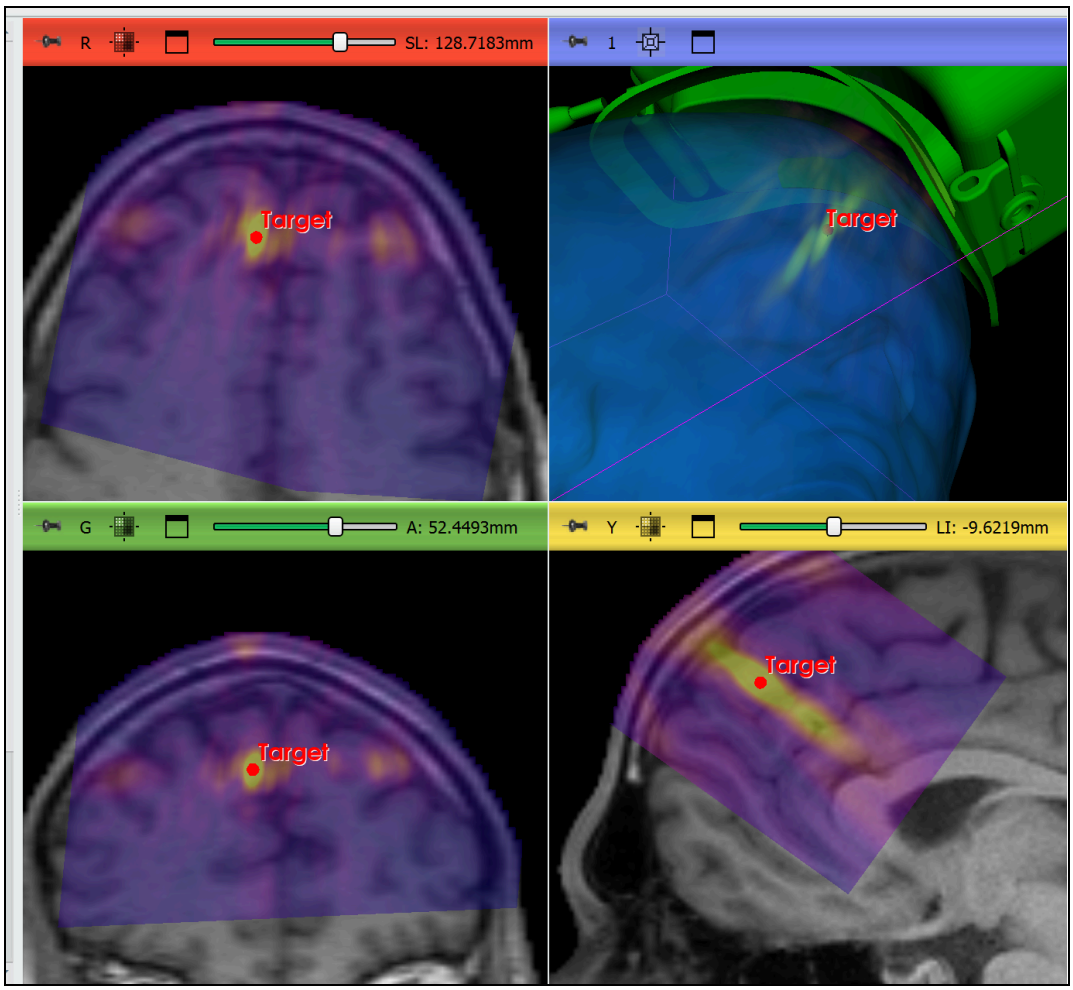


Figure 83: Users may view the simulated LIFU energy deposition to assist with sonication planning.

Solution Approval

If any of the parameter values are outside of their constraints and in an “error” state (“X”), it will not allow the user to Approve the solution:

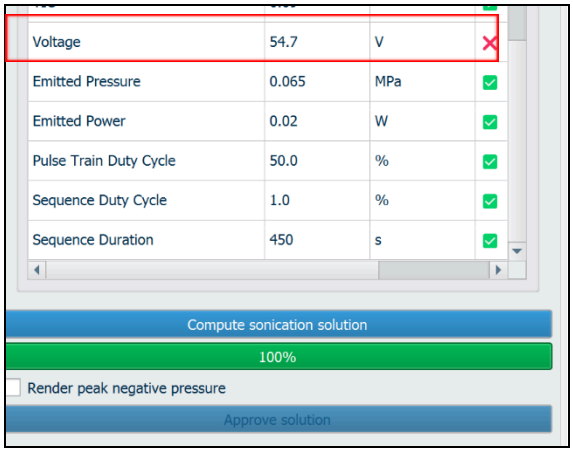


Figure 84: Example of an error state within the solution.

When finished, click “Approve Solution.”

If the solution contains a warning on one or more parameters, it will prompt the user to acknowledge and approve:

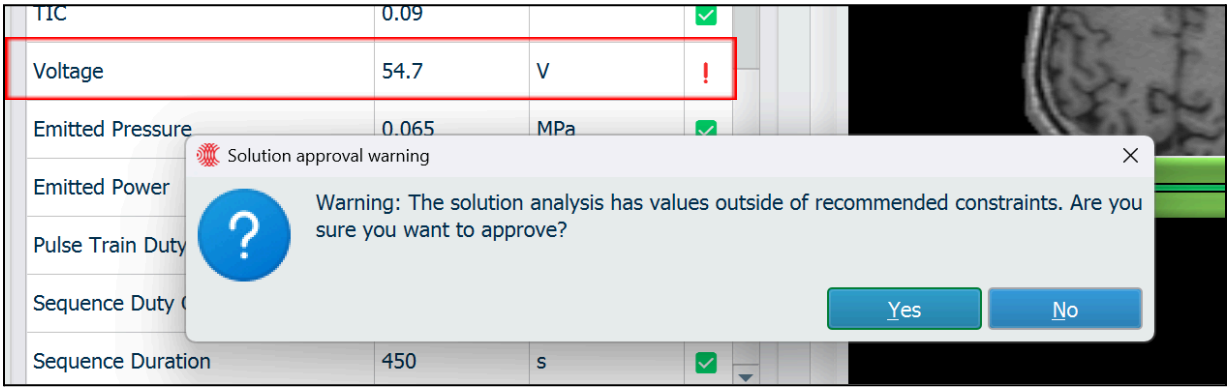


Figure 85: Users must approve any warnings prior to sonicating a subject.

Once the solution has been approved, click “Next.”

Sonication

Start Sonication

The Sonication Control module allows Approved Solutions to be sent to the hardware.

When the device is connected, Connection Status turns Green

Click “Send Sonication Solution to Device” to program the transmitter. This will take a few seconds.

Once Programmed, ensure that the physical transducer has not moved with respect to the subject since Transducer Localization and is ready to complete the Sonication Sequence. Click “Run” to begin sonication. The progress bar will update in real time as the sonication completes.

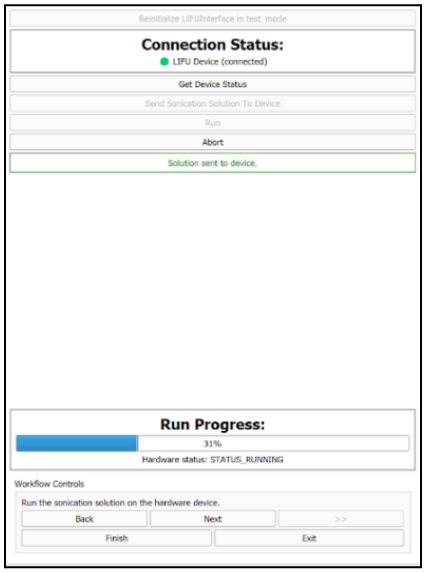


Figure 86: Connection status of the hardware and progress of sonicating is displayed in the progress bar.

Monitoring The Procedure

The user can click “Abort” at any time to halt sonication. When aborted, the sonication run is automatically marked as unsuccessful, and the user is prompted to enter notes about the aborted sonication run.

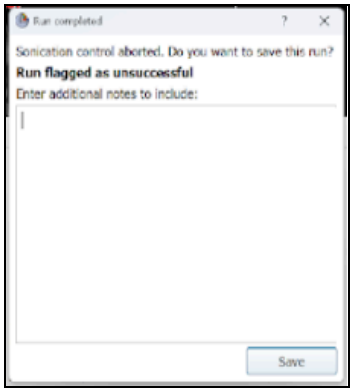


Figure 87: Notes can be manually added if sonication was completed successfully or had to be aborted.

Once a sonication run is completed, the user will be prompted to check whether the run was successful. The user should not check this box if the transducer was moved during sonication or a run failure occurred that was not automatically caught by the software. The user may also optionally enter additional notes about the run.

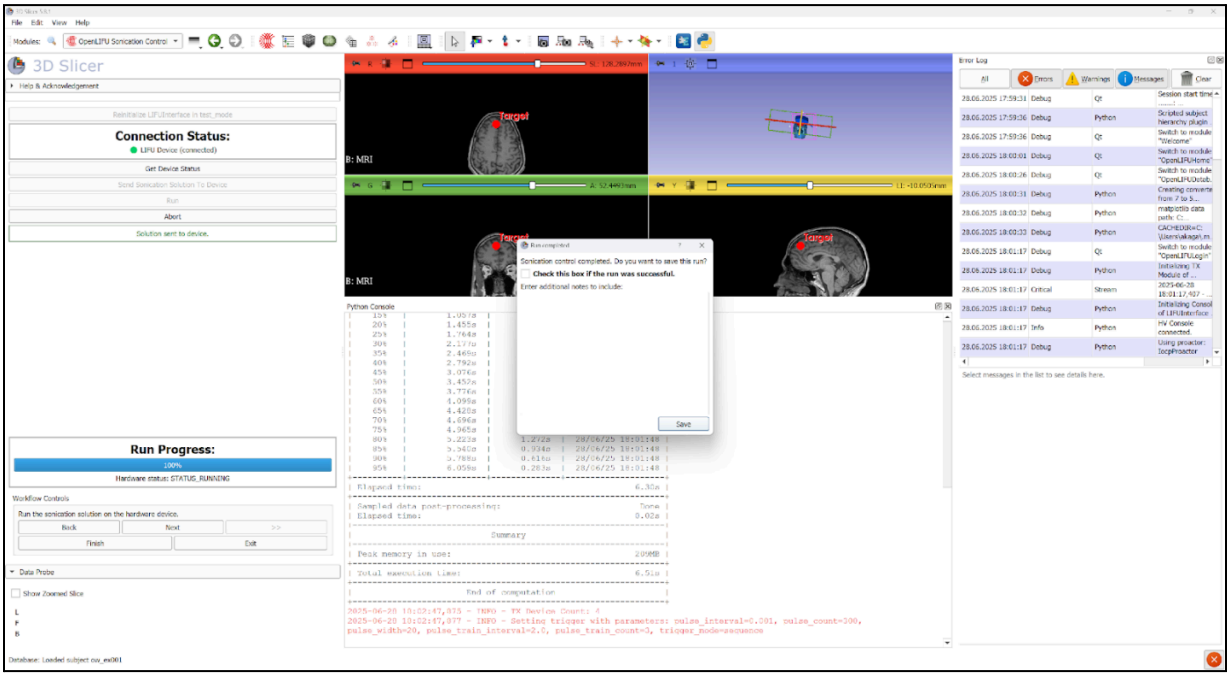


Figure 88: If the run was successful then ensure to check the box in the popup window.

In either case, click Save to save a record of the run into the Session data.

After saving the run, the session is complete and the application can be closed.

Logging Out

Once a session is completed and all data saved, it is safe to log out. Navigate back to the login screen and click “Logout.”

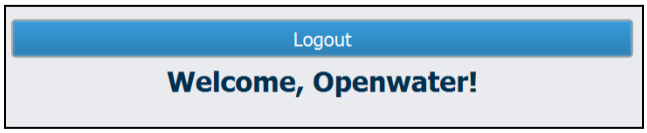


Figure 89: Logout of the application when done with the procedure.

Device Cleaning and Storage

1. Remove the coupling pad from the transducer and dispose of it according to the necessary hospital protocols.
2. Clean the exposed transducer faces of gel residue with CaviWipes or damp cloth.

NOTE: Do not press directly on or apply excessive force to the transmit module array. Doing so may damage the device.

NOTE: The transducer is not watertight. Never clean the transducer by submerging it in water. Doing so may lead to electric shock or damage the device.

NOTE: Do not use isopropyl alcohol to clean the transducer as it can damage the photogrammetry patterned veneer.

Administration and User Management

From the Login page, if the user has admin rights, the “Manage Accounts” button can be selected to open the Account Management table.

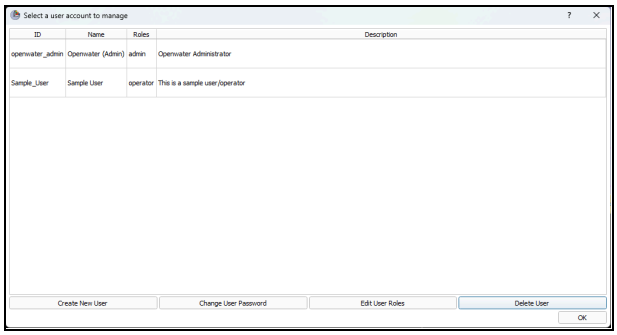


Figure 90: Displays the Account Management table.

Each entry in the table corresponds to a different user.

To create a new user, click “Create New User” to open the New User Dialog.

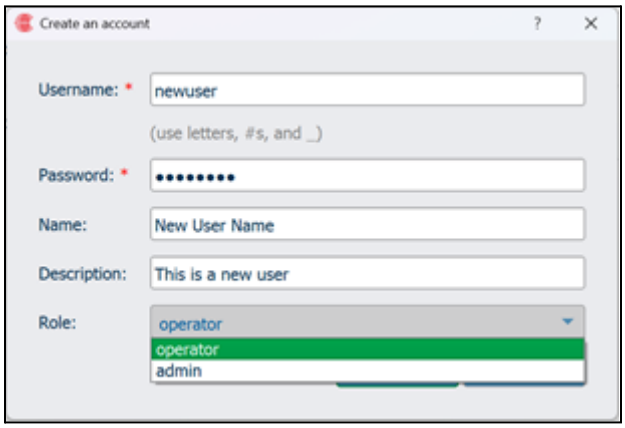


Figure 91: Complete each entry to create a new user.

For each user, enter a Username, Password, Name (for display), and optional Description. In addition, select a Role as either “operator” or “admin.”

There are three types of user roles:

Admin role

The “admin” role is a special role detected by the PC application, which grants access to the following functions:

1. Open Account Management
    1.1. Create Users
    1.2. Change User Passwords
    1.3. Assign User Roles

    1.4. Delete Users
2. Open Protocol Configuration
    2.1. Create New Protocols
    2.2. Edit Protocols
    2.3. Save Protocols
3. Change Database Location
4. Load all protocols, regardless of protections

Operator role

The “operator” role allows access to all app functions except those that require the admin role.

Custom Roles

Admins can define additional custom roles for users by selecting “Edit User Roles.” These roles can be used to restrict which protocols non-admin users have the rights to generate sessions with. If a protocol has one or more roles defined, the user must have one of those roles to access it.

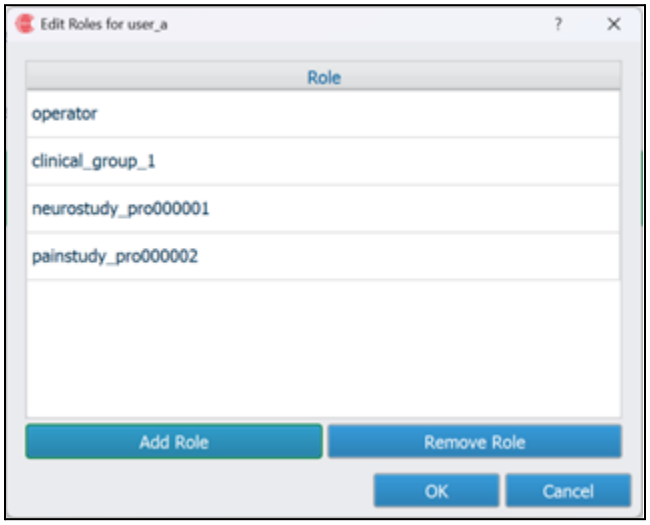


Figure 92: Identifies the user types that have been created for the local installation of the Open-LIFU Desktop Application.

Service and Maintenance

Service and maintenance on the Open-LIFU device should only be performed by suitably trained individuals. Contact Openwater's Support Team using the provided contact information below or using the details provided in your Service Agreement.

✉️: support@openwater.cc
📞: (415) 484-3776
🌎: www.openwater.health

Troubleshooting

Table 18: Common troubleshooting issues, potential causes, and recommended steps.

Issue	*Potential Cause*	*Recommended Steps*
Slow Photogrammetric Reconstruction	• Too many images are acquired for reconstruction • PC is underpowered	• Limit captured images to the recommended quantity and run on a device meeting required performance specifications
		• Use the online mode to generate the photoscan
	• The photogrammetry app is outdated	• Visit the Google Play store and update to the latest phone application
Cannot connect to Photogrammetry Application (Offline)	• Cable not properly connected • Faulty Cable • Incompatible Drivers • Computer antivirus blocks access	• Inspect connection cables, verify drivers, and allow application access through network and security settings

Issue	*Potential Cause*	*Recommended Steps*
	• ADB not installed • Environment variables are not set properly	• Refer to the “Install Android Tools” section of Open-LIFU Quickstart Guide for step-by-step instructions on how to install ADB manually and set up the environment variables on a Windows PC
Cannot connect to Photogrammetry Application (Online)	• Not signed into Openwater’s Cloud Services on both devices	• Ensure you are signed into both devices with the same cloud user account
	• Not signed into Openwater’s Cloud Services on both devices with the same Cloud Services account	
	• Cloud account does not exist	• Ensure you have an active Cloud Services account
	• The photogrammetry app is outdated	• Visit the Google Play store and update to the latest phone application

Issue	*Potential Cause*	*Recommended Steps*
	• Unstable or no network connection	• Check network connection • Connect to a different network • Contact your IT department or network provider if the problem persists
The Open-LIFU application is not synchronizing with the Photogrammetry Application (Online)	• Not signed into Openwater's Cloud Services on both devices	• Ensure you are signed into both devices with the same cloud user account
	• Not signed into Openwater's Cloud Services on both devices with the same Cloud Services account	
	• Cloud account does not exist	• Ensure you have an active Cloud Services account

Issue	*Potential Cause*	*Recommended Steps*
	• Unstable or no network connection	• Check network connection • Connect to a different network • Contact your IT department or network provider if the problem persists
Photocollections are not synchronizing from the phone application to the cloud	• Not signed into Openwater's Cloud Services on the phone application	• Ensure you are signed into both devices with the same cloud user account
	• Cloud account does not exist	• Ensure you have an active Cloud Services account
	• Cloud reconstruction credits have been exhausted	• Contact Openwater Support
	• The photogrammetry app is outdated	• Visit the Google Play store and update to the latest phone application

Issue	*Potential Cause*	*Recommended Steps*
	• Unstable or no network connection	• Check network connection • Connect to a different network • Contact your IT department or network provider if the problem persists
Slow system performance	• No/incompatible graphics card • Graphics card not functioning • Too many programs, apps, or background processes running simultaneously	• Use the recommended GPU and ensure drivers are up to date • Close all other programs and apps before running Open-LIFU
Poor image reconstruction	• Low quality photo collection • The background in the photos may be too “busy”	• Ensure the photogrammetry app is up to date • Adjust/optimize photogrammetry app settings • Minimize any furniture or objects that may be in the captured images

Issue	*Potential Cause*	*Recommended Steps*
	• Phone held too far away from the subject's head/face	• Adjust closeness/camera position relative to subject • Adjust/optimize photogrammetry app settings
Poor photogrammetry registration with the MRI	• Low quality image reconstruction (photo scan)	• Ensure the photogrammetry app is up to date • Adjust/optimize photogrammetry app settings
	• Selected anatomical landmarks or features between the 3D mesh and MRI do not match	• Accurately select corresponding anatomical landmarks or features on both the 3D mesh and MRI

Issue	*Potential Cause*	*Recommended Steps*
Open-LIFU transducer shifts on the subject's body after the photogrammetry mesh has been acquired	• The transducer was not properly secured to the subject • The transducer was accidentally bumped	• Adjust the transducer straps to firmly hold it in place on the subject and recapture the photogrammetry mesh • If necessary, adjust the transducer, then recapture the photogrammetry mesh • Ensure subject is sitting in a comfortable position where their movement is minimal
Missing sonication protocol	• The protocol has not been created • The desired protocol has incorrect permission settings	• Contact the device administrator to create the appropriate sonication protocol • Contact the device administrator to update the necessary protocol permissions

Issue	*Potential Cause*	*Recommended Steps*
Device Not Connecting	• Cable is unplugged or faulty • Another program is connected to the device	• Shut down any other applications using the device • Restart both the device and application • Use the Test App to examine connectivity. If console is connected and transmit modules are not, toggle *12V enable* off and on • Check Device manager - two COM ports should appear when the device is connected. If not, contact support