

Open-LIFU*

Creating and Editing Sonication Protocols



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*The Open-LIFU platform is not yet cleared by the FDA and is intended for research purposes only. Not for commercial sale.

Creating and Editing Sonication Protocols

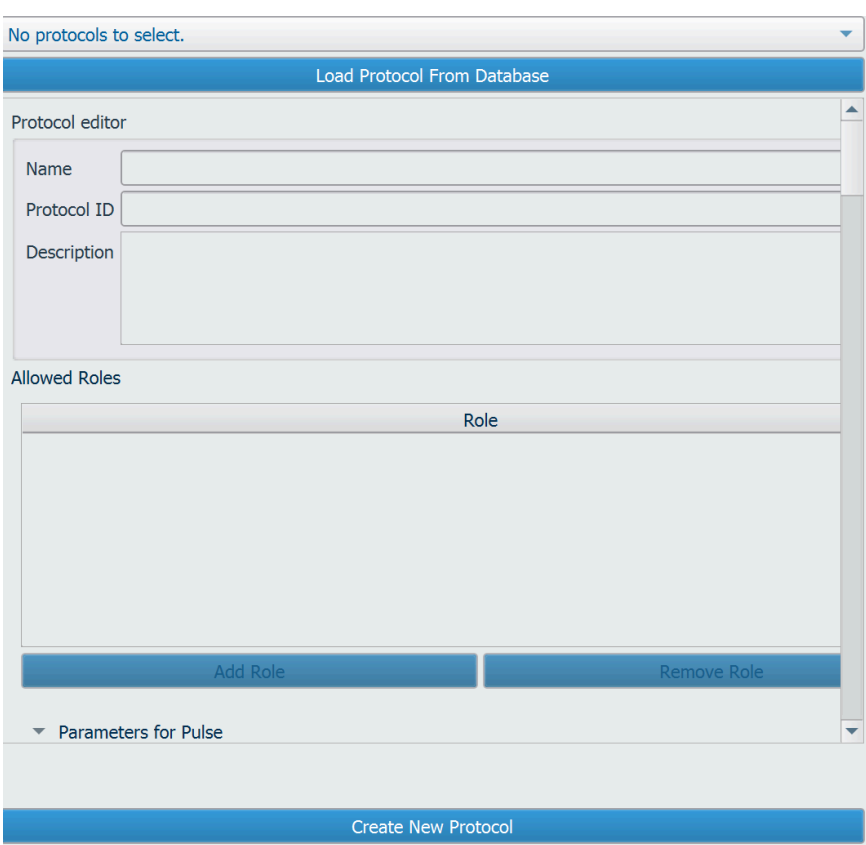
Before starting a procedure, device administrators must ensure all protocols are well-defined, created, and available for the desired use case scenario(s) and device operators. The following sections describe how to create and modify existing sonication protocols.

NOTE: Only Admins can create or modify sonication protocols. Admins must ensure the proper protocol permissions are set so 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 the U.S. FDA thresholds found in Section 5.2.4 of [Marketing Clearance of Diagnostic Ultrasound Systems and Transducers](#), issued on February 21, 2023.

Protocol Configuration

Log in as an admin to access the Protocol Configuration wizard.



No protocols to select.

Load Protocol From Database

Protocol editor

Name

Protocol ID

Description

Allowed Roles

Role

Add Role Remove Role

Parameters for Pulse

Create New Protocol

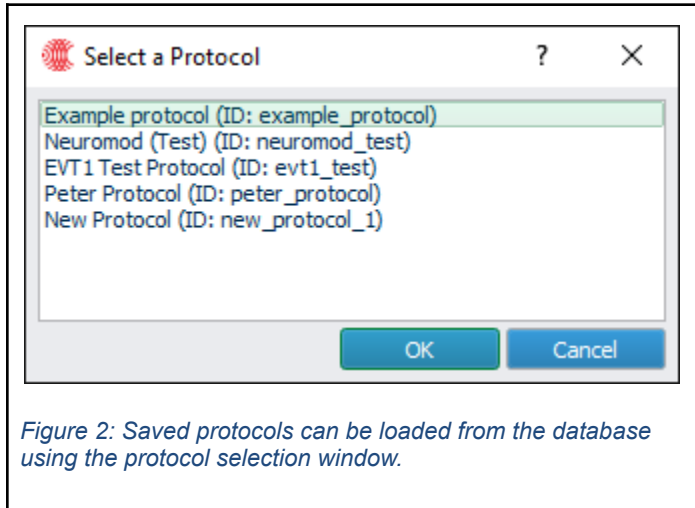
Figure 1: Use this dialogue box to either load or create a new protocol. Note that a user's permissions may prevent them from creating and/or editing a protocol.

Create a new protocol

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

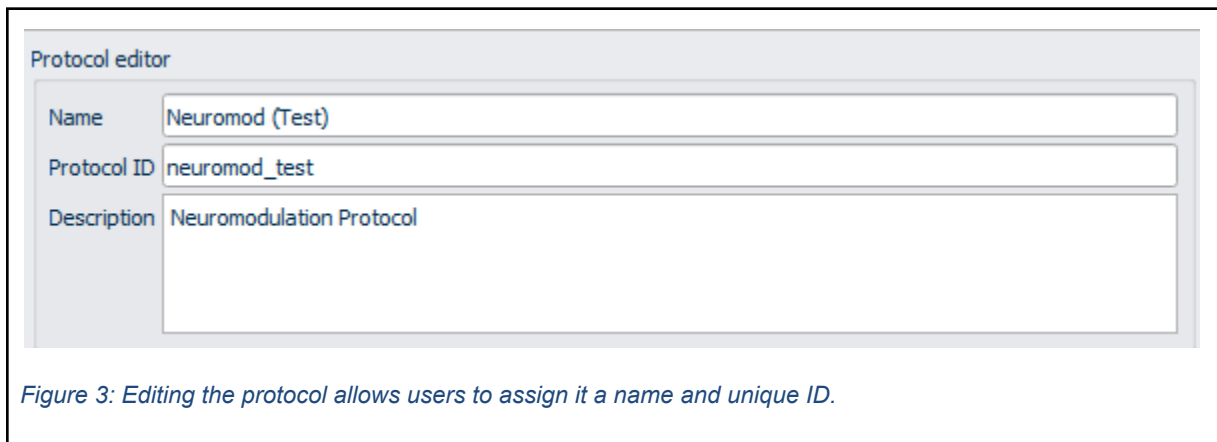
Load a protocol

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



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

Edit Protocol Info



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

Table 1: 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

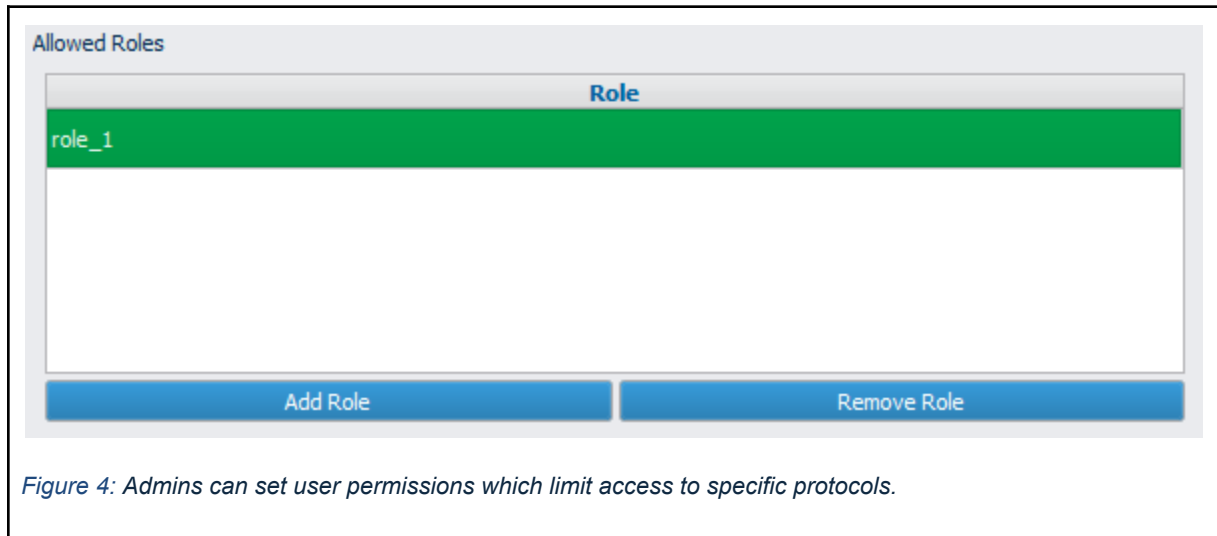


Figure 4: Admins can set user permissions which limit access to specific protocols.

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

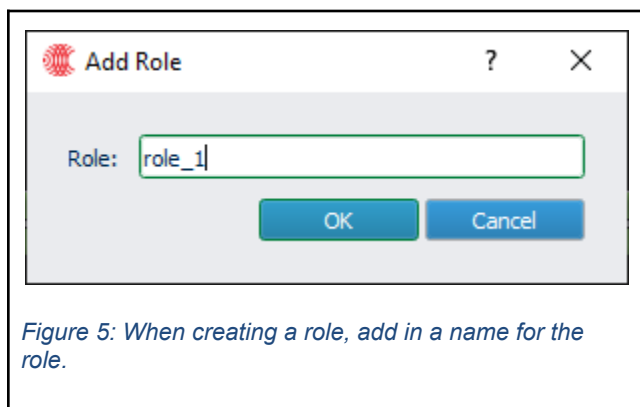


Figure 5: When creating a role, add in a name for the role.

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

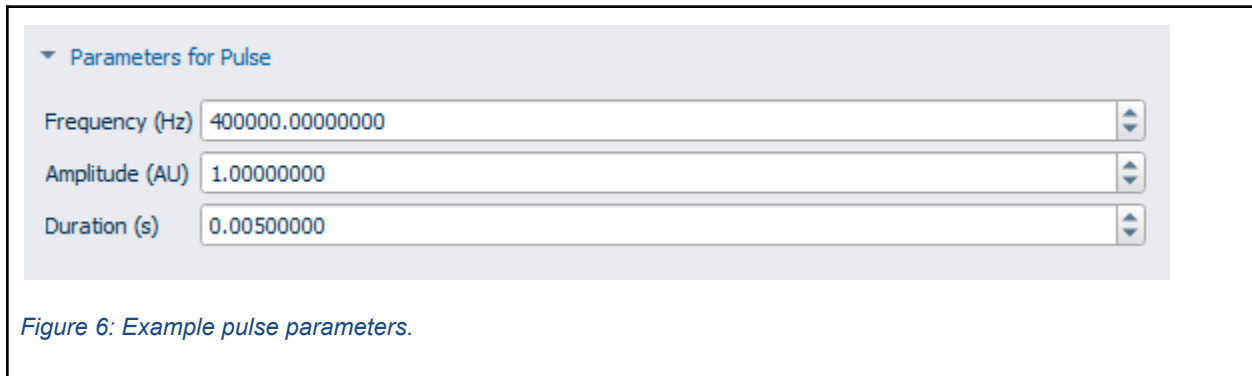
Delete Role

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



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

Table 2: 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

▼ Parameters for Sequence

Pulse interval (s)

Pulse count

Pulse train interval (s)

Pulse train count

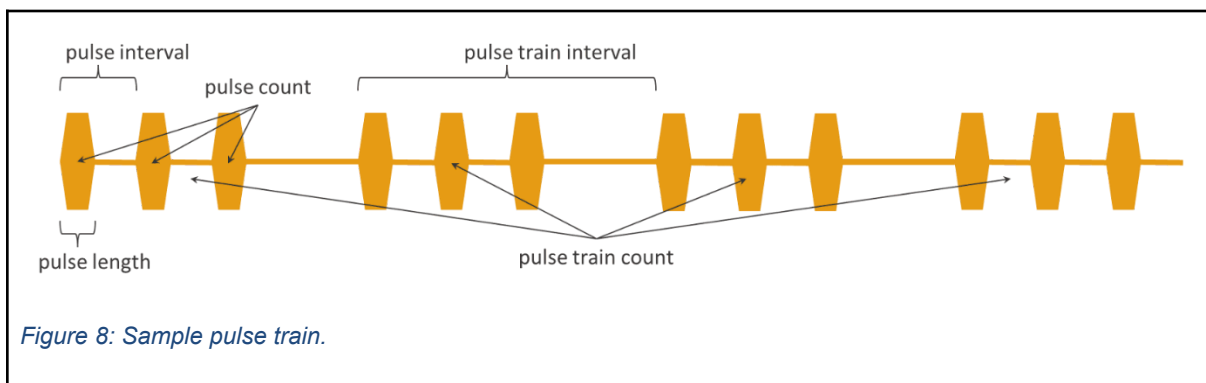
Figure 7: Sample sequence parameters.

Available sonication parameters are:

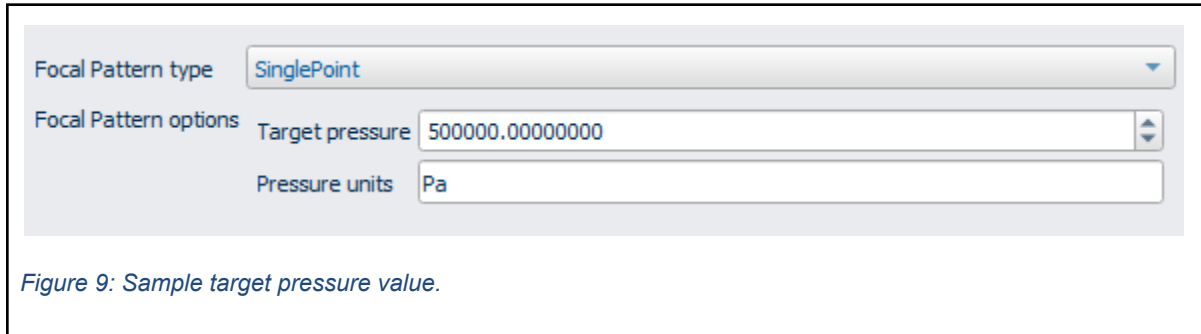
Table 3: Sonication sequence parameters

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:



Focal Pattern



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

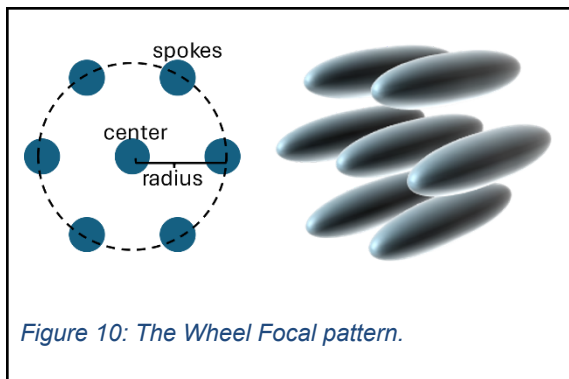
A SinglePoint focal pattern is the default pattern, which uses a single focus onto the target location. A SinglePoint accepts the following inputs:

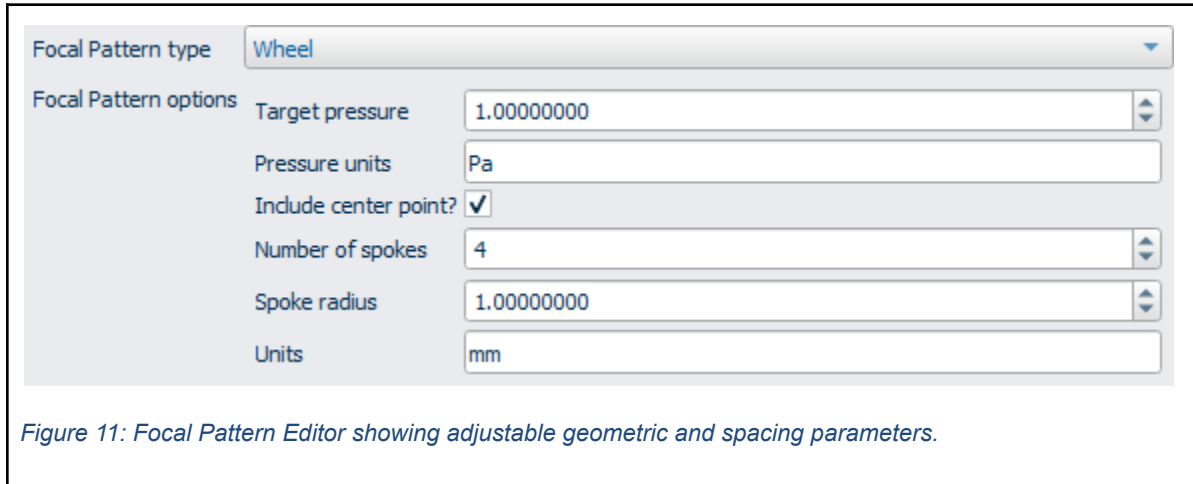
Table 4: SinglePoint focal pattern options

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 (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.



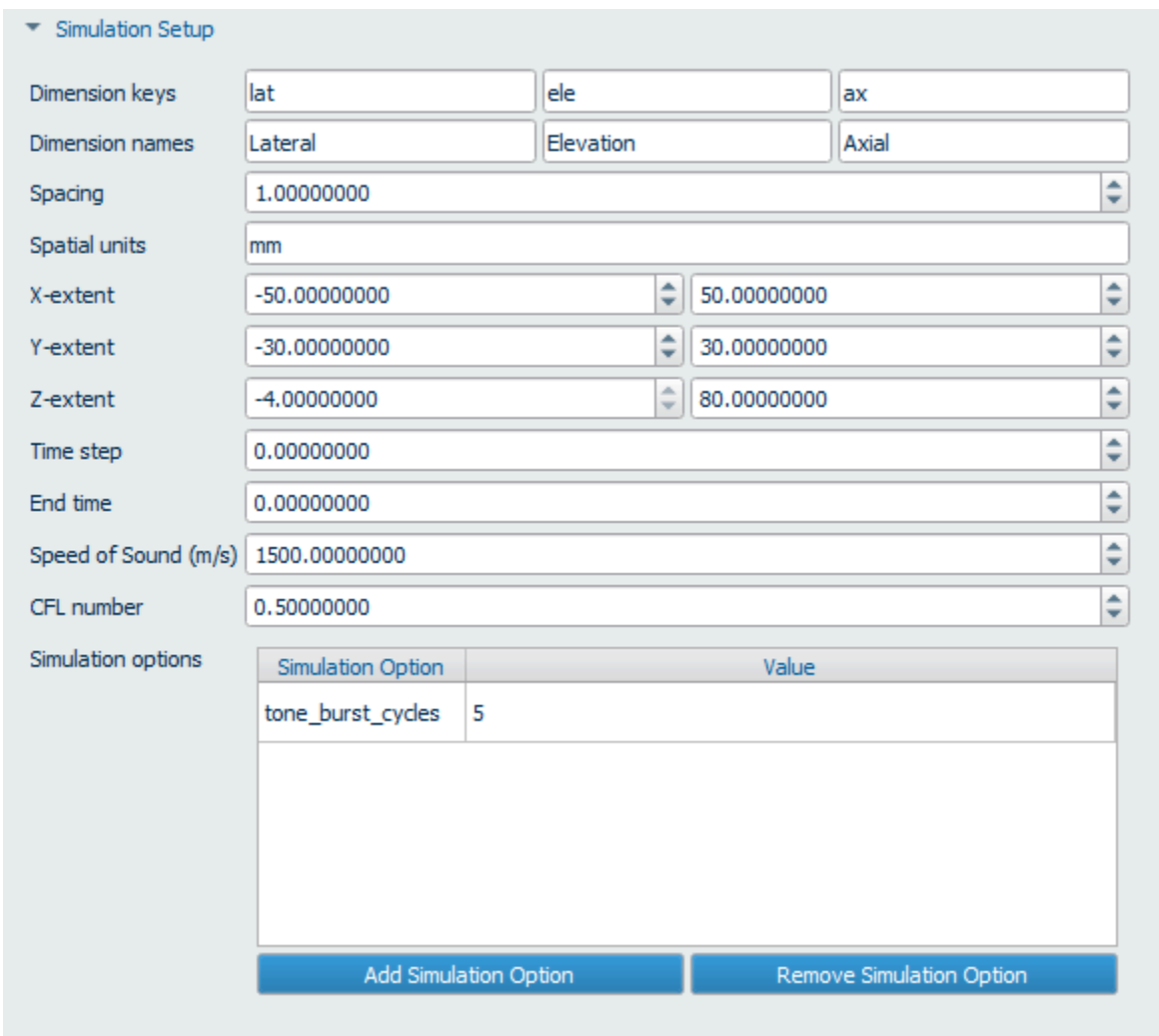


Available focal pattern options include:

Table 5: 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



The screenshot shows a 'Simulation Setup' panel with the following fields and values:

- Dimension keys: lat, ele, ax
- Dimension names: Lateral, Elevation, Axial
- Spacing: 1.00000000
- Spatial units: mm
- X-extent: -50.00000000 to 50.00000000
- Y-extent: -30.00000000 to 30.00000000
- Z-extent: -4.00000000 to 80.00000000
- Time step: 0.00000000
- End time: 0.00000000
- Speed of Sound (m/s): 1500.00000000
- CFL number: 0.50000000
- Simulation options table:

Simulation Option	Value
tone_burst_cycles	5

Buttons at the bottom: 'Add Simulation Option' and 'Remove Simulation Option'.

Figure 12: Sample values used to define the simulation setup.

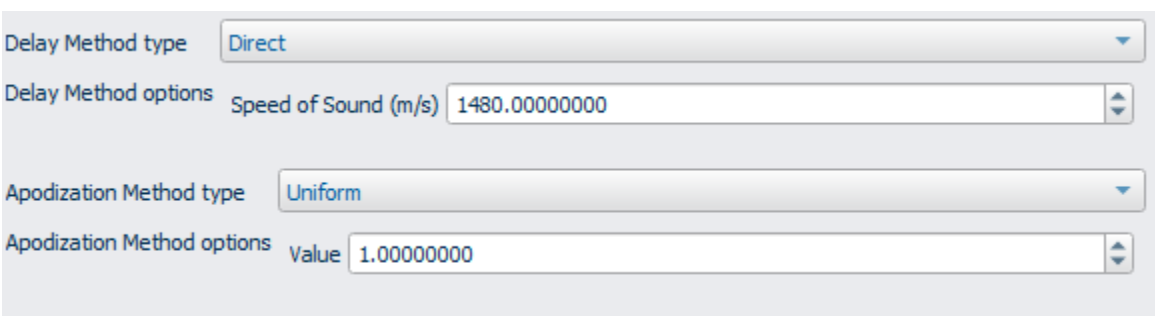
The simulation setup section provides parameters for configuring k-Wave simulations. For most applications, users will only need to verify and/or adjust the X-, Y-, and Z- extents to ensure that the expected depth and position of the treatment target is within the simulation grid. The available options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

Table 6: 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

Simulation Setup	Description
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
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



Delay Method type: Direct

Delay Method options: Speed of Sound (m/s) 1480.00000000

Apodization Method type: Uniform

Apodization Method options: Value 1.00000000

Figure 13: Sample beamforming delay options.

This section allows configuration of time-delay calculation. 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.

Options include:

Direct

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

Table 7: 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 13). 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.

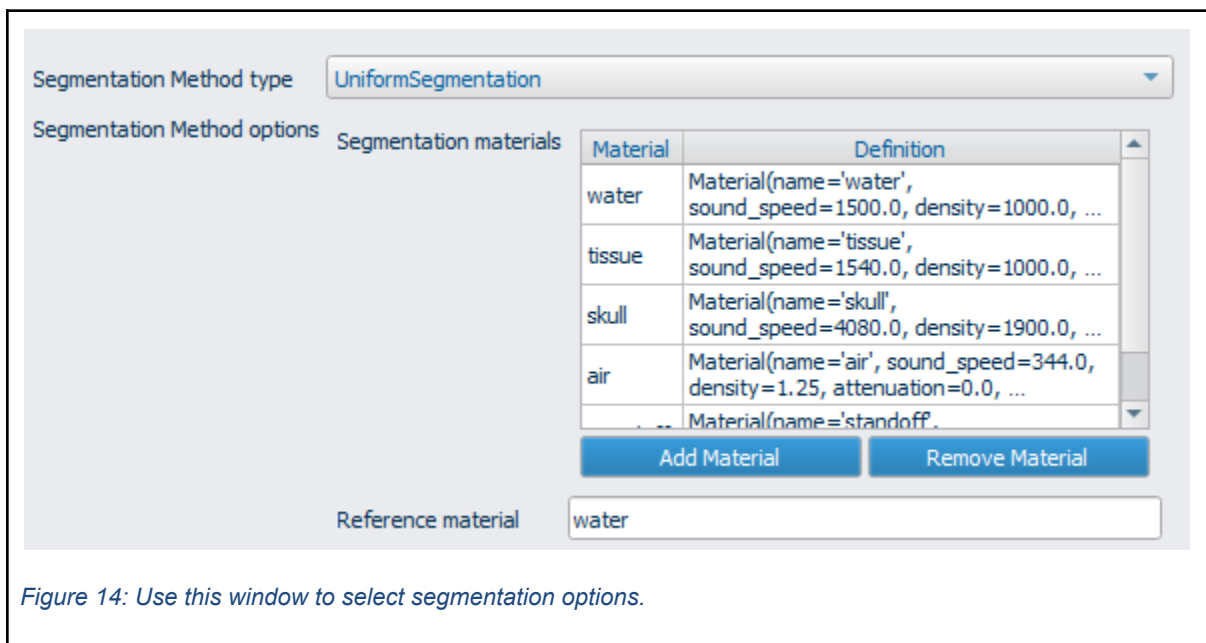


Figure 14: Use this window to select segmentation options.

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.

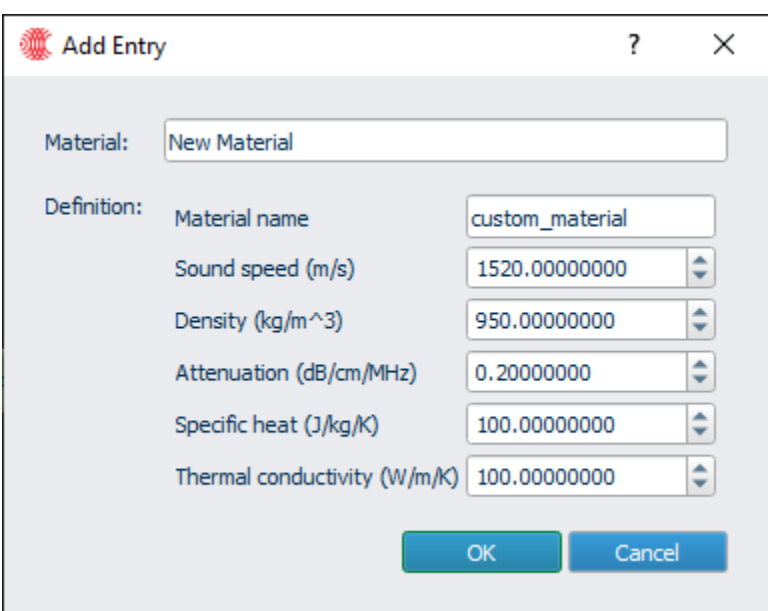


Figure 15: Users can create new material definitions by inputting values into this window and giving it a material name.

Uniform Water

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

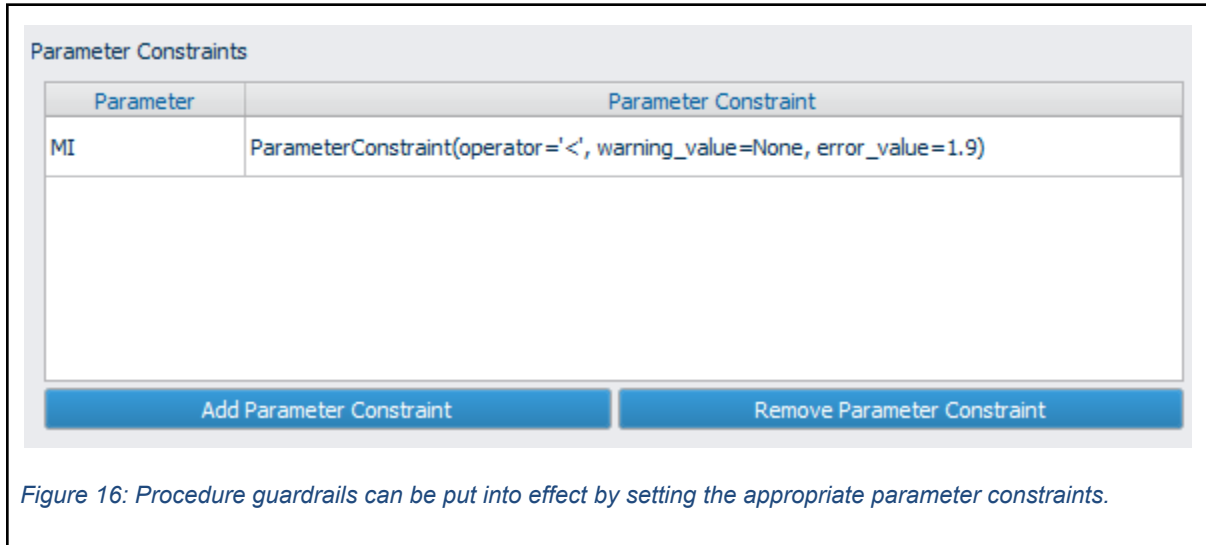
Uniform Tissue

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

Uniform Segmentation (Custom)

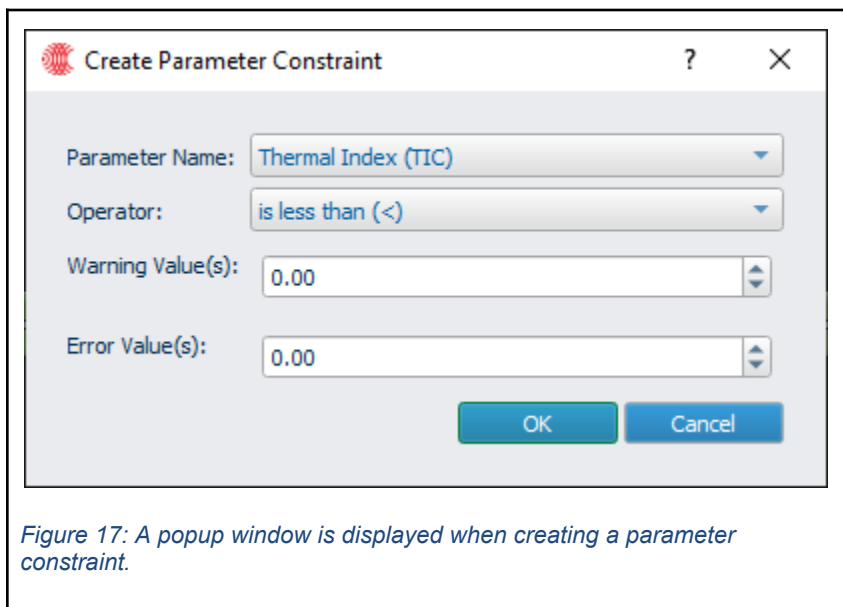
The generic Uniform Segmentation method assigns all parameters to be the material specified.

Parameter Constraints



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.

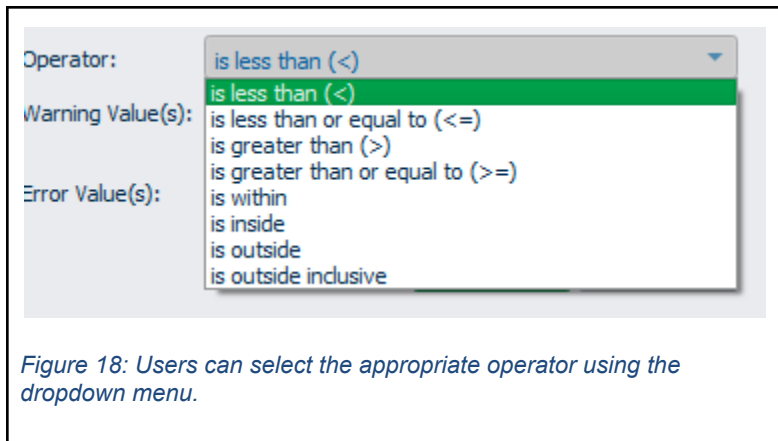
Click “Add Parameter Constraint” to define a new constraint:



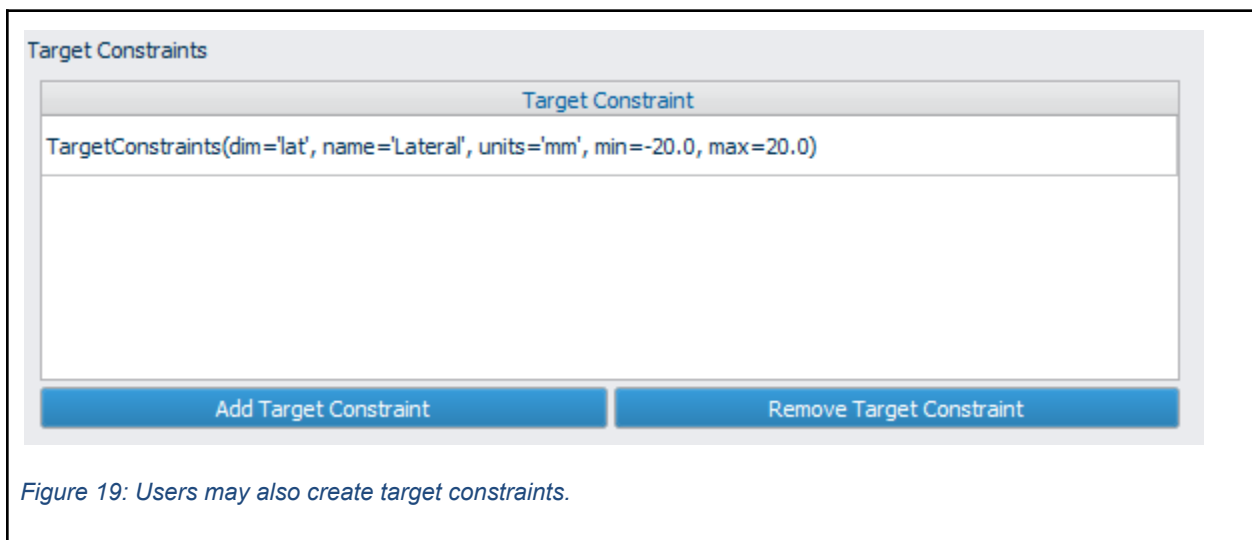
Options Include:

- Parameter Name: Which parameter to constrain.

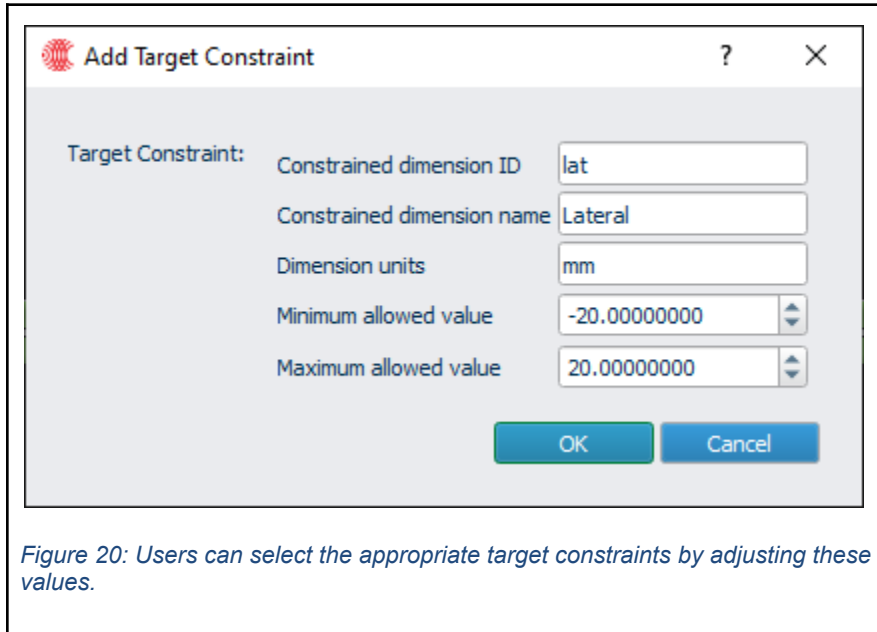
- Operator: What direction to apply the constraint. The constraint defines the condition for which the *parameter is acceptable*. A “Less than” operator means that the parameter is OK if it is less than the Warning or Error Value.
- Warning Value: The threshold for throwing a warning.
- Error Value: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



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:



Parameters are:

Table 8: 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

▼ Solution analysis

Global analysis

Param	Value	Units	Status
Mainlobe Peak Negative Pressure	0.100	MPa	✓
Mainlobe I_SPPA	0.3	W/cm ²	✓
Mainlobe I_SPTA	0.8	mW/cm ²	✓
Target Position (Lateral)	4.3	mm	✓
Target Position (Elevation)	0.1	mm	✓
Target Position (Axial)	49.2	mm	✓
Focal Centroid (Lateral)	4.4	mm	✓
Focal Centroid (Elevation)	0.2	mm	✓
Focal Centroid (Axial)	49.7	mm	✓
3dB Beamwidth (Lateral)	2.24	mm	✓
3dB Beamwidth (Elevational)	4.71	mm	✓
3dB Beamwidth (Axial)	13.61	mm	✓
6dB Beamwidth (Lateral)	3.23	mm	✓

Compute sonication solution

100%

Approve solution

Figure 21: 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

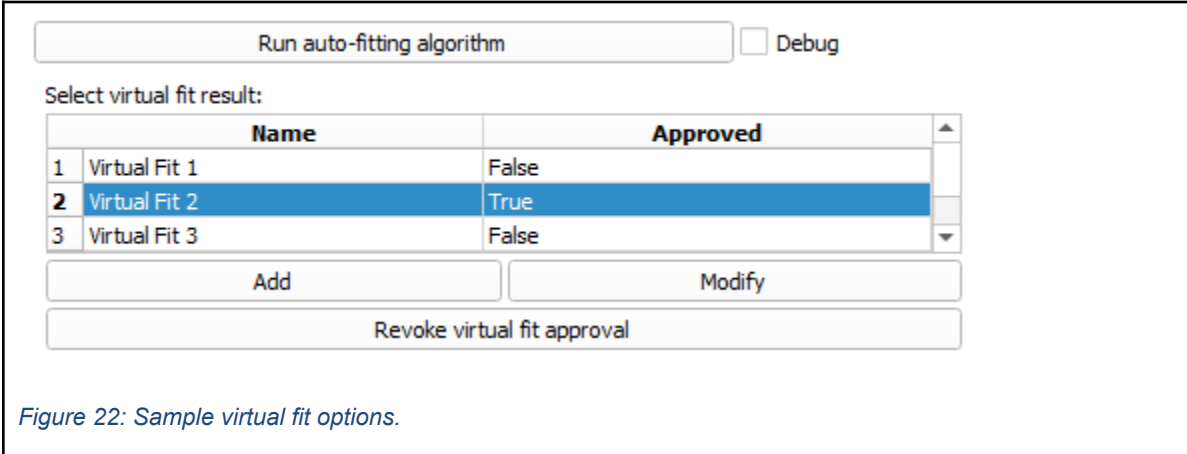
evaluations are performed along lateral and elevation axes relative to the focus, extending to the defined search radius.

The following options are available:

Table 9: 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/m ³)	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/m ³)	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



Run auto-fitting algorithm Debug

Select virtual fit result:

	Name	Approved
1	Virtual Fit 1	False
2	Virtual Fit 2	True
3	Virtual Fit 3	False

Add Modify

Revoke virtual fit approval

Figure 22: Sample virtual fit options.

The Virtual Fit Options section defines the automated algorithm for identifying optimal transducer positioning on the patient'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 patient'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 10: 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.
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.”