OMEGA®

by WillowWood®

New Features Guide
Version 1.6.1

Published By
The Ohio Willow Wood Company
Mt. Sterling, Ohio
USA

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INTRODUCTION

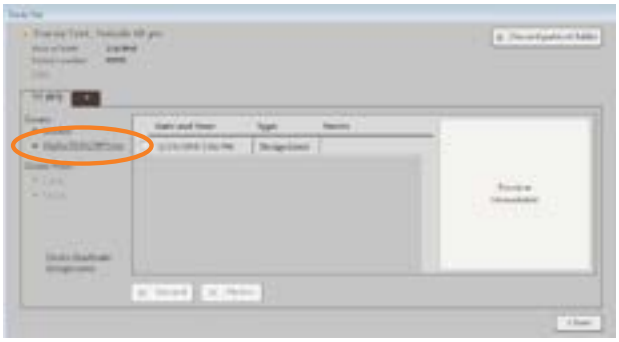
This guide describes how to use the new features in OMEGA Version 1.6.1. This guide is written as a supplement to your existing OMEGA documentation. Refer to your existing OMEGA documentation for information not covered here.

CREATING AN ALPHA DESIGN LINER

OMEGA now allows you to create custom Alpha DESIGN Liners for your transtibial (TT) and transfemoral (TF) patients. You will acquire and edit the limb shape in the Capture Stack, then create the liner in the Design Stack.

CAPTURE STACK

- After selecting or creating a patient folder, select **+ Alpha DESIGN Liner**.



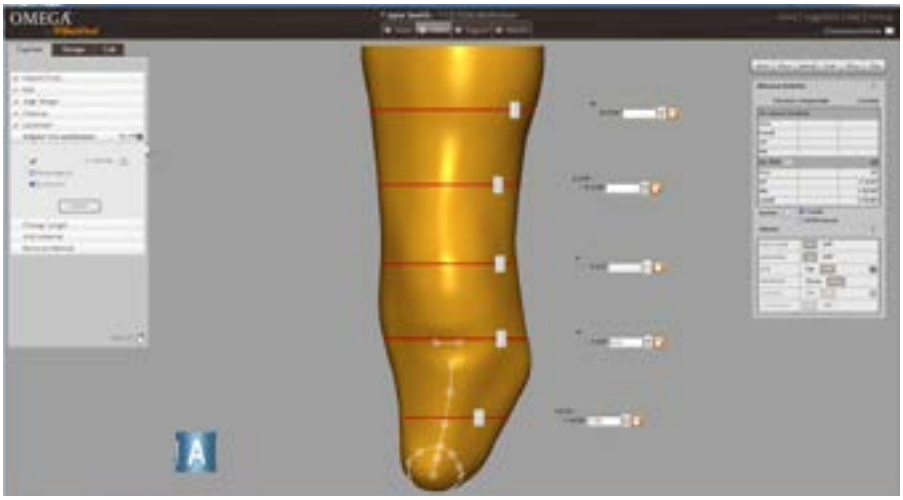
- The Capture Stack appears.
  a. To import a scan, click the **Search for file** icon to browse for an STL or OBJ file.
  b. To scan, click the **Scan with VXelements** icon. A window for the VXelements software will open. Begin scanning when the colored arrows appear in the middle of the screen. The indicator on the left side of the screen will be green when the scanner is at the correct distance, yellow when the scanner is too close, and blue when the scanner is too far away.

     When scanning is complete, press the pause button on the VXelements menu, then rotate the model to confirm that the entire shape was captured. After clicking **Accept Scan** to finish the scanning process, click the **Import completed scan** button on the Capture Stack to bring the completed scan into OMEGA.

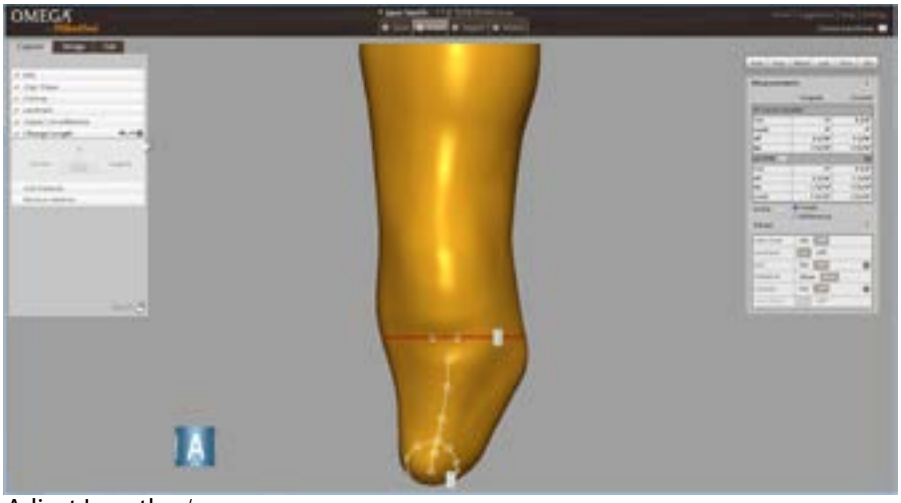
  c. If you have enabled a Tracer Pen for use with the software, you may click the **Trace with Tracer Pen** icon to scan a cast. Refer to the Internal Tracing section of this document for details.

- Comple the **Edit**, **Align Shape, Cleanup**, and **Landmark** steps as described in your existing OMEGA documentation.

- Use the **Adjust Circumference** and **Change Length** steps to verify and make any edits to the scanned shape before designing the liner in the Design Stack.

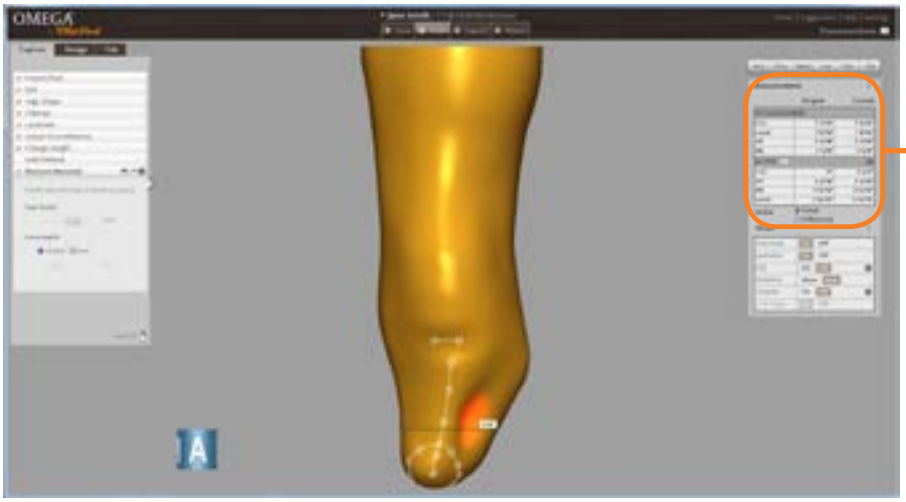


Adjust Circumference *step*

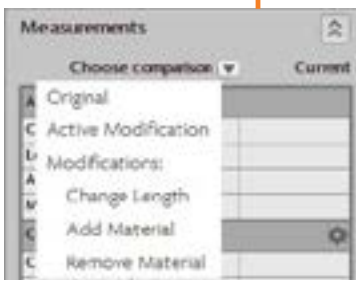


Adjust Length *step*

- If needed, use the **Add Material** and **Remove Material** steps to edit the shape prior to designing the liner in the Design Stack. As an example, the **Remove Material** tool could be used to enhance an invaginated area of a patient scan in cases where the area is not sufficiently defined or represented.



You may use the **Measurements** pane to compare the current measurements to the measurements of an earlier version of the model. Use the drop-down arrow to select from the available comparison options.



DESIGN STACK

- When you have completed the Capture Stack, click the Design Tab to create the liner in the Design Stack. The **Patient Details** step appears.

  Enter the following measurements:

  - The highest obtainable proximal circumference of the limb.
  - The distance from the distal end at which that circumference was taken, unless the length of the scan is 16″ or longer, in which case this field will be auto-populated with 16″.

  Indicate whether the patient has sufficient hand strength to don a thick liner, and whether the limb has redundant fleshy tissue.

  When you are done, click the **Select Liner Options** step.

- Click the drop-down arrow next to **Choose a liner style** and select whether you want a Cushion Liner or a Locking Liner.

- Click the drop-down arrow next to **Choose a gel type** and select whether you want Classic gel or Hybrid gel.

- Click the drop-down arrow next to **Choose a fabric type** and select whether you would like Original, Spirit, MAX, or Select fabric.

- Click the drop-down arrow next to **Choose a color** and select from the list of fabric colors that are available for the type of fabric that you selected.

- Click the drop-down arrow next to **Choose a designer** and select one of the following options:
  - Select **Customer will design liner** if you would like to design the gel profile yourself. If you select this option, you will proceed through a series of steps to set the gel thickness at various locations on the liner.
  - Select **WillowWood will design liner** if you would like an Alpha DESIGN Technician to create the gel profile for you. If you select this option, you will be able to provide some notes for the designer in the next step.

- The next step(s) in the stack will depend on which option you chose in the previous step:
  - If you selected **WillowWood will design liner**:
    - <u>For TT liners</u>

      The **Notes** step will appear. Click on **Notes** and enter any information that will be helpful to the designer who creates your liner.

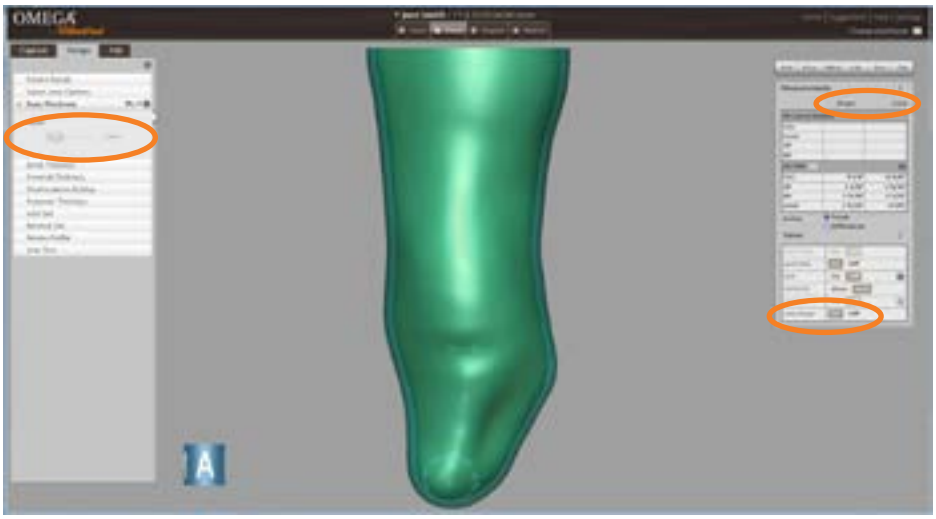
    - <u>For TF liners</u>

      The **Comfort Cuff** step will appear. Refer to page 10 for information on completing this step.

      When you are done with the **Comfort Cuff** step, click on **Notes** and enter any information that will be helpful to the designer who creates your liner.

  - If you selected **Customer will design liner**, a series of steps will appear that will allow you to create the desired gel pattern. These steps are described on the following pages.

- Click on the **Base Thickness** step. You will see a 3 mm layer of gel applied to the shape. If desired, use the slider to adjust the base thickness to a maximum of 15 mm as a starting point for the DESIGN Liner. In later steps, you will be able to add or remove material from this starting thickness.

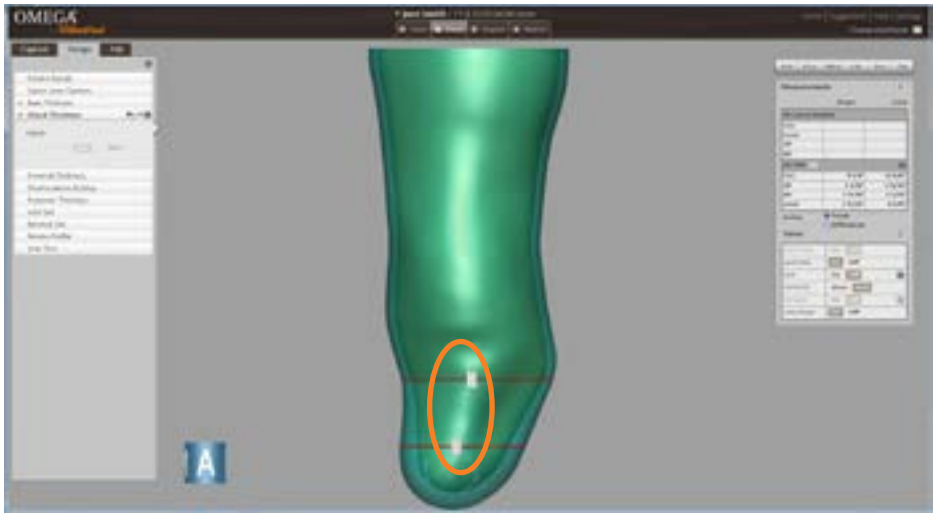


Notice that, when a liner is present, the **Measurements** pane will have a column for **Liner** measurements in addition to the column for **Model** measurements, and the **Views** pane will have an option to turn the liner off and on.

- Click on the **Distal Thickness** step, which allows you to change the thickness of the gel at the distal end of the liner. The range that is allowed is 3 mm to 15 mm.

  The thickness of the gel below the bottom red ring will be changed to the distal end thickness that you select. The area between the two red rings is where the transition from the base thickness to the distal end thickness will occur. The area above the proximal ring will remain unchanged.

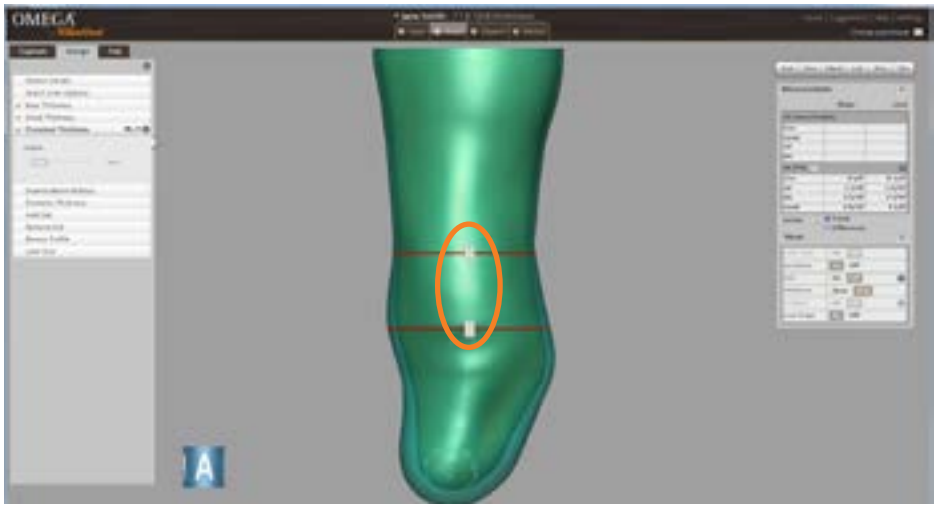
  Click and drag the handles of the red rings to reposition the rings as desired.



- Click on the **Proximal Thickness** step, which allows you to change the thickness of the gel at the proximal end of the liner. The range that is allowed is 3 mm to 15 mm.

  The thickness of the gel above the top red ring will be changed to the proximal end thickness that you select. The area between the two red rings is where the transition from the base thickness to the proximal end thickness will occur. The area above the proximal ring will remain unchanged.

  Click and drag the handles of the red rings to reposition the rings as desired.

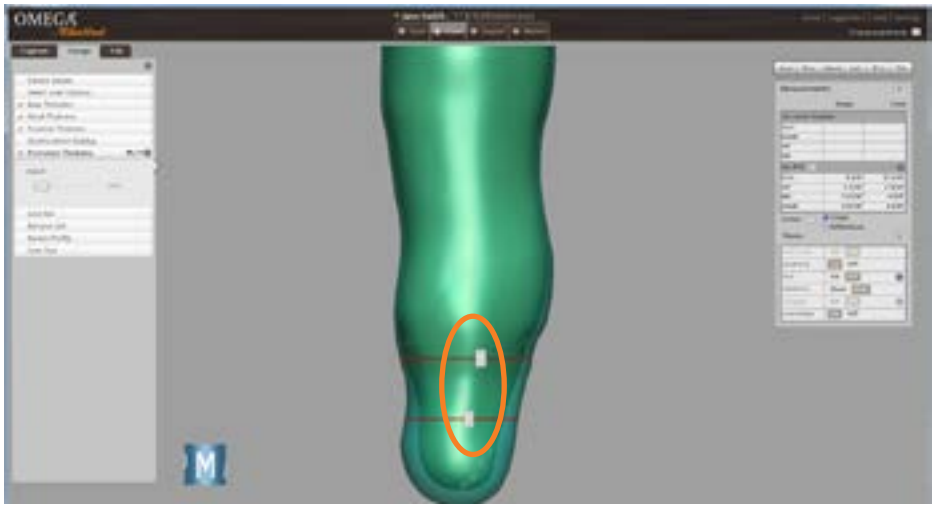


- For shape types with a bulbous distal end, such as Symes or knee disarticulation (KD), you may click the **Disarticulation Buildup** step to apply gel to the narrowed area between the bulbous end and the widest proximal point. *Note: because the example used elsewhere in this section does not have a bulbous distal end, a different shape is being used as an example for this step).*

  To apply the gel buildup, begin by clicking **Apply Gel**. Two red rings will appear. Click and drag the handles of the red rings to position them at the widest distal point and the widest proximal point. The area between these two lines will be filled with gel, up to a maximum thickness allowed of 25 mm. Reposition the red rings as appropriate.

- Click on the next step to adjust the **Posterior Thickness** (for TT liners) or the **Medial Thickness** (for TF liners). This is especially helpful for decreasing the thickness in TT liners to facilitate joint flexion.

  The range that is allowed is 3 mm to 15 mm. The chosen thickness is applied between the two red rings. The top ring controls the location of the of the thickness selected with the slider. Click and drag the handles of the red rings to reposition the rings as desired.



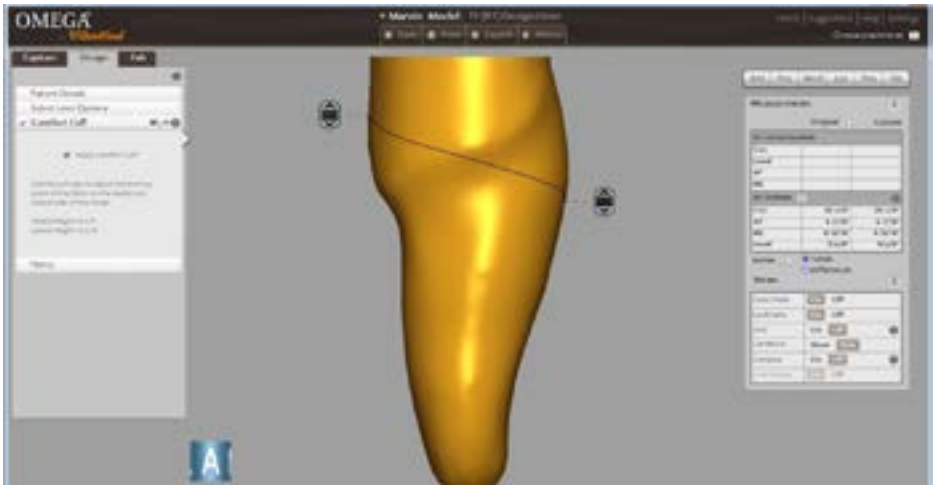
- The next step, **Comfort Cuff,** appears only for TF liners. Click on this step to add a fabric cuff, for an additional fee, to the interior of the liner that extends above the proximal end. The Comfort Cuff can be reflected down over the socket brim to protect the gel from wear and tear.

  Note: the Comfort Cuff is not compatible with Select fabric.

  If you wish to include a Comfort Cuff, click **Apply Comfort Cuff**. A blue line will appear across the model, indicating the starting point of the fabric. User the pull tabs to adjust starting point of the fabric on the medial and lateral sides of the model as follows:

  - For limbs of average length, the starting point should be about 2" below the ischium.
  - For shorter limbs, the starting point should be about 1.5-2" below the ischium.
  - For longer limbs, the starting point should be more than 2" below the ischium.

  If you decide that you do not want the Comfort Cuff, uncheck the **Apply Comfort Cuff** box.

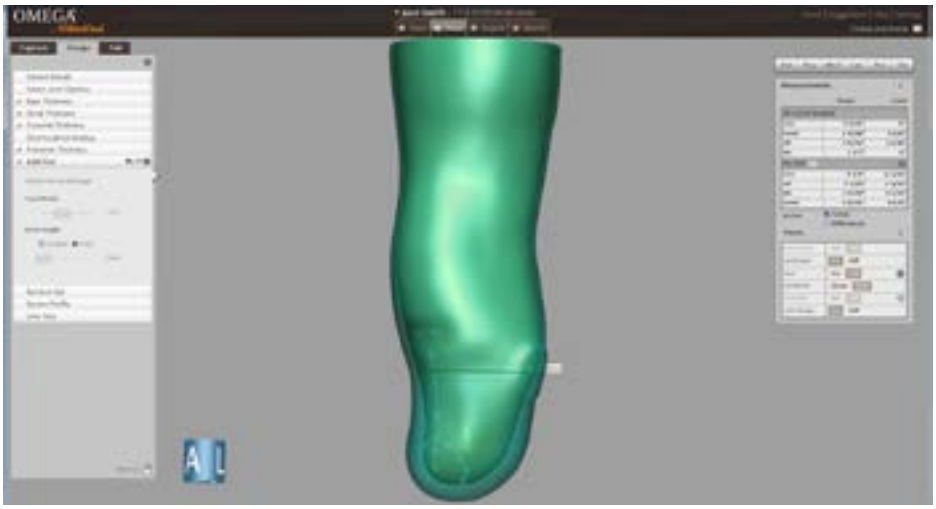


- Click on the **Add Gel** screen to build up the gel in specific areas if desired. Use the **Tool Width** slider bar to adjust the diameter of the buildup. To build up the gel by a fixed amount, click the **Fixed** button and use the slider bar to set the height.

  To apply the buildup, move the mouse cursor over the model while holding down the left mouse button.

  If you exceed the maximum allowed thickness of 25 mm, you will receive a pop-up notification, and OMEGA will automatically adjust the buildup to the maximum allowed thickness.

  Use the right mouse button to smooth the gel in any area if desired.

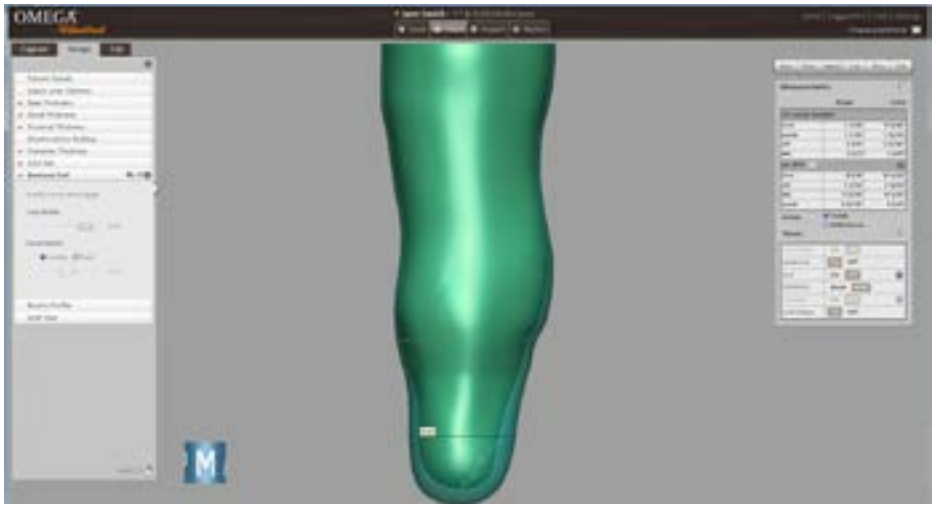


- Click on the **Remove Gel** screen to carve away the gel in specific areas if desired. Use the **Tool Width** slider bar to adjust the diameter of the reduction. To carve the gel by a fixed amount, click the **Fixed** button and use the slider bar to set the depth.

  To apply the reduction, move the mouse cursor over the model while holding down the left mouse button.

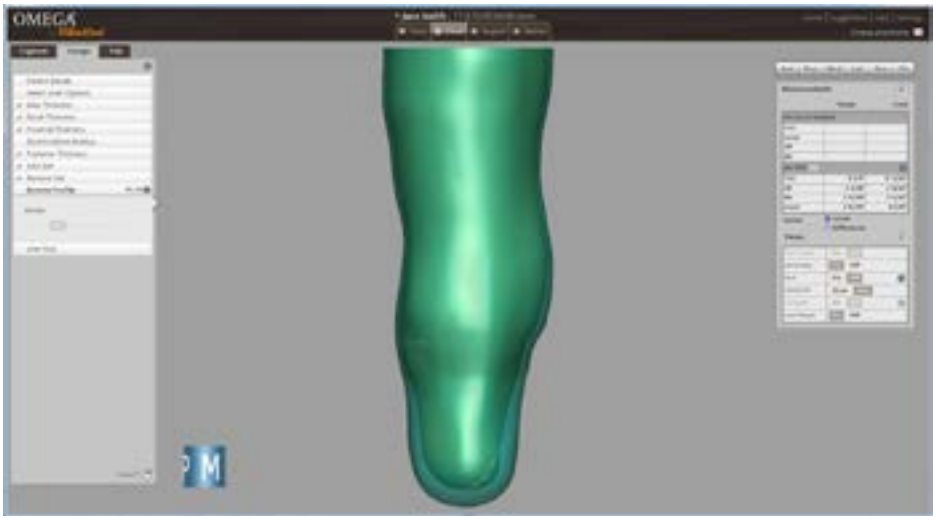
  If you exceed the minimum allowed thickness, you will receive a pop-up notification, and OMEGA will automatically adjust the reduction to the minimum allowed thickness.

  Use the right mouse button to smooth the gel in any area if desired.



- After making your adjustments to the gel pattern, click the **Review Profile** step. Use the slider bar to rotate the shape and examine the gel profile.

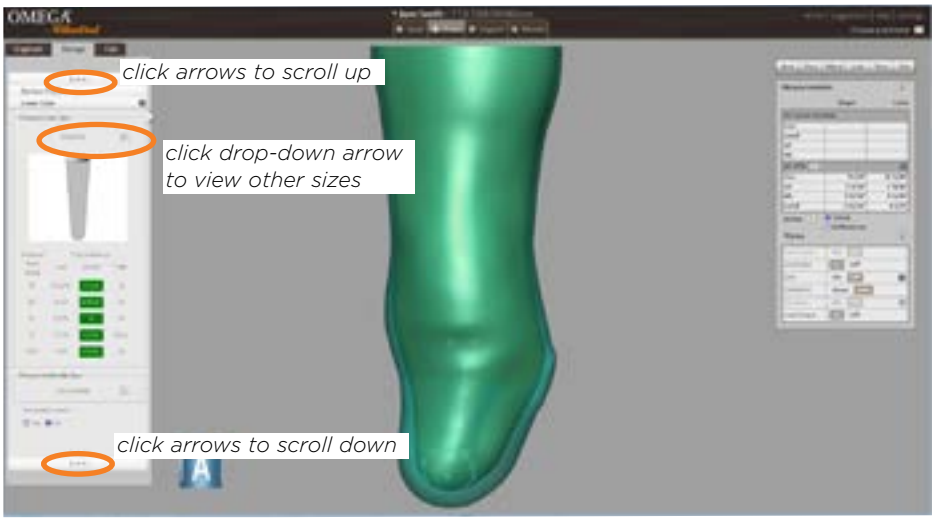
  You may return to any of the previous steps if desired to make additional changes the thickness and placement of the gel.



- Click the **Liner Size** step. A liner size option will be displayed; however, you may use the drop-down menu to choose a different available size if desired.

  Displayed in the **Low** and **High** columns for each size are the minimum and maximum circumferences that are allowed for the outer gel profile of the liner.

  A green box in the **Actual** column indicates a circumference that is within the range for that particular level; a red box indicates a circumference that is outside the range for that level. If the circumference is too large or too small, you may consider removing or adding gel so that the profile will fit within the size range.



- For locking liners, scroll down and make a selection from the **Choose Umbrella Size** drop-down menu.

- If the patient's circumference measurements fall in the upper half of a particular size range, you may wish to have WillowWood stretch the liner to promote a more comfortable fit. If so, select the **Yes** button under **Pre-stretch Liner?**

- Make sure the desired liner size is displayed in the window before proceeding.

FAB STACK

After completing the steps in the Design Stack, click the **Fab** tab to send the file to WillowWood for production. OMEGA will automatically save the file.

- Fill in all the required fields in the **Order Information** step.

  Note: the screen shown below is for orders placed by customers in the United States. Some of the options on this screen will be different for international customers.

- Click on the **Additional Information** step.

  - For TF liners, select the **Amputation Level** from the drop-down menu.
  - Enter any desired instructions in the **Notes** field.
  - For orders placed by customers in the United States:
    - Select the **Yes** button if you would like a WillowWood technician to contact you before proceeding with your order.
    - Check the **Yes, I understand** box to indicate that you are aware of the $75 fee that will be assessed if you cancel a DESIGN Liner order that is already in progress.
  - Click the **Send** button when you are ready to transmit your order to WillowWood.

INTERNAL TRACING

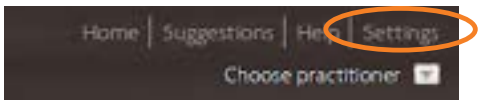
OMEGA now allows you to use a Tracer Pen with the WandXtension to trace the inside of a cast. The tracing process takes place outside of OMEGA in a separate window.

Refer to the documentation you received with your Tracing Hardware for details on attaching the WandXtension, preparing the cast, and positioning the patient sensor and transmitter cube. **Remember that there should not be any large pieces of metal within two feet of the transmitter or cast.**

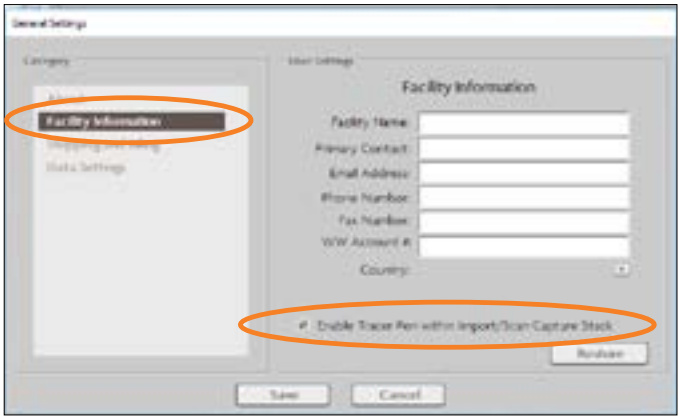
GETTING STARTED

Before attempting to use the Tracer Pen with this software for the first time:

- Select **Settings** from the Main Menu Bar.

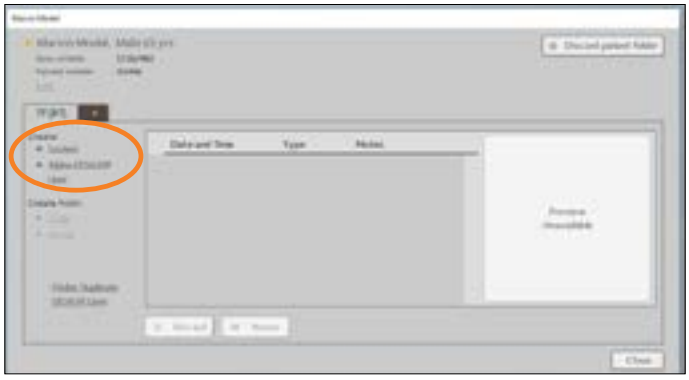


- Select the **Facility Information** category.
- In the **Facility Information** window, check the the **Enable Tracer Pen within Import/Capture Stack** box.

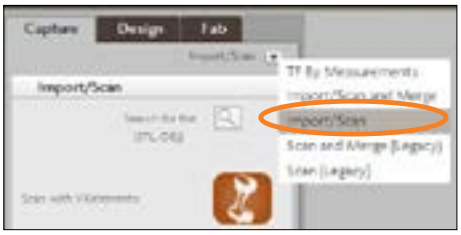


LAUNCHING THE TRACING APP

- After selecting an existing patient or creating a new patient folder, the patient's folder window appears.
  - Select **+ Socket** to capture a shape for the fabrication of socket.
  - Select **+ Alpha DESIGN® Liner** to capture a shape for the creation of an Alpha DESIGN Liner.

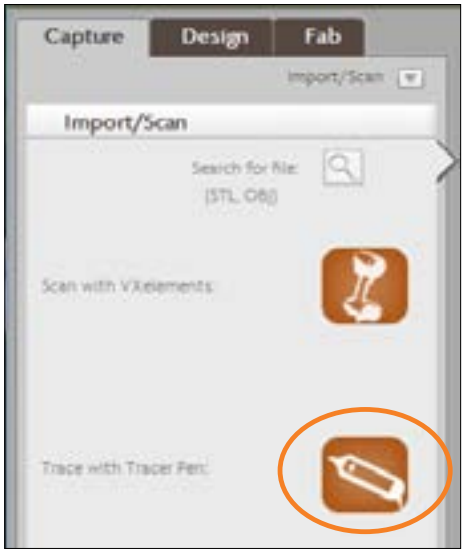


- The Capture Stack opens.
  - If you are creating a socket, select **Import/Scan** from the drop-down menu at the top of the Capture Stack.



  - If you are creating a DESIGN Liner, there is no drop-down menu because there is only one Capture Stack option for DESIGN Liners.

- Click the **Trace with Tracer Pen** icon.



  - The Tracing App will open in a new window.

CALIBRATING THE WANDXTENSION

- Before doing your first internal tracing with this software, we recommend calibrating the WandXtension.

  Click the **Calibration** tab at the bottom of the window.

  Select one of the calibration options, then click **Start Calibrating**:

  - Select **Short pipe** if your transmitter is mounted on a base with extension pipes (original Tracer case design).
  - Select **Calibration Attachment** if your transmitter is mounted on a tripod (newer Tracer case design).

  Set up the pipe or calibration attachment according to the instructions provided with your Tracing Hardware.

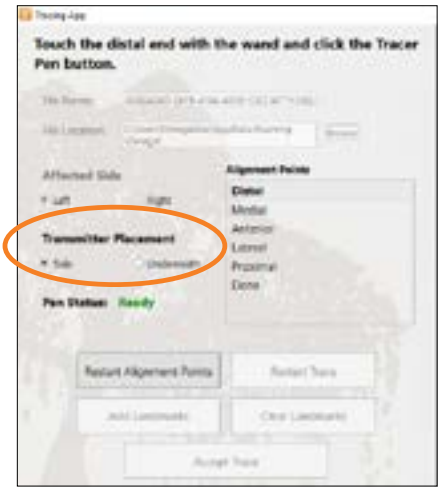
  Hold the wand straight up and down, rotate the wand in one direction until you hear a "ding," then rotate the wand in the other direction until you hear another "ding."

- If you have question about this procedure or any other aspect of internal tracing, click the **Help** tab for the technical support phone number.

- Click the **Diagnostics** tab to view Pen Status and Sensor Status.

USING THE TRACING APP

- The **File Name** and **File Location** fields will be auto-populated. The patient's **Affected Side** is indicated according to the selection that was made in the patient folder.
- The default selection for the **Transmitter Position** is **Side**. If the transmitter is positioned under the cast, select **Underneath.**

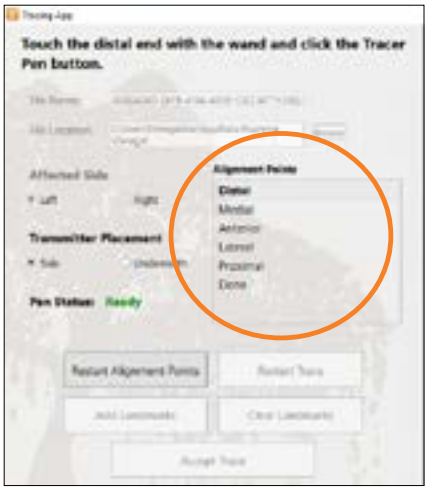


- The next step is to indicate the alignment points required for the model you are tracing.

  Indicate **Distal** by touching the distal end of the inside of the cast with the ball tip of the wand, then pressing and releasing the switch on the Tracer Pen.

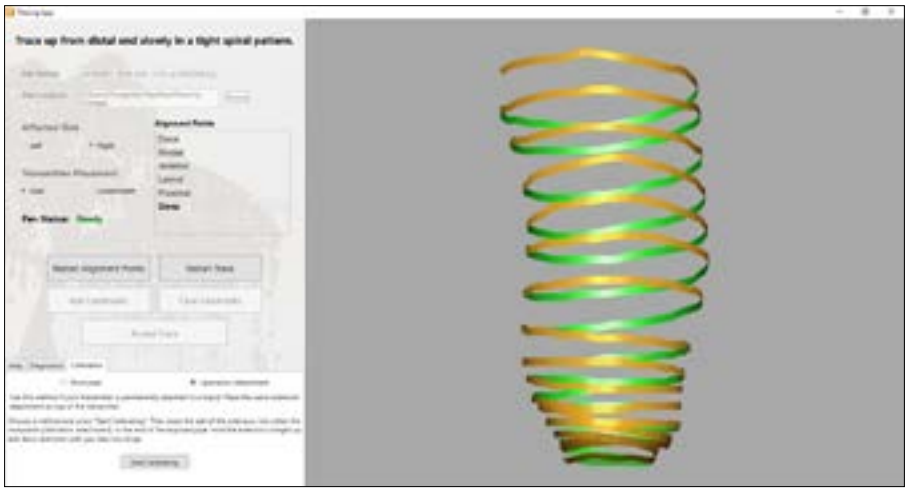
  Repeat for the **Medial, Anterior**, **Lateral**, and **Proximal** points. (For **Proximal**, indicate the most proximal point of interest.)

  Some very narrow shapes may require you to indicate the point on the exterior of the cast instead of the interior.



- After you have finished indicating the alignment points, move the wand at least 12" away from the cast and press the pen switch.
- You will hear the "Begin trace" audio prompt. Without pressing the switch on the Tracer Pen, place the ball end of the wand inside the cast surface at the proximal end. Slide the ball down the inside wall of the cast, maintaining contact with the surface, until you reach the distal end. (If you place the wand straight down into the socket instead of sliding it down the side, the tracing process will begin too soon.).

- Slowly trace up from the distal end in a tight spiral pattern, keeping the wand in contact with the surface, until you reach the most proximal level. A ribbon is displayed on the screen showing you the path of the ball.



- When you are done tracing, pull the wand at least 5″ out of the cast. The software will construct the shape on screen.

  If you are not satisfied with the shape, you may click **Restart Alignment Points** or **Restart Trace**.

  If you are satisfied with the shape, you may add landmarks by clicking **Add Landmarks** and using either of these methods:

  - Touch the landmark with the ball tip of the wand, then press and release the switch on the pen.
  - Use the mouse to indicate the landmark on the screen.

- When you are done adding landmarks, click **Stop Adding Landmarks**. If you decide not to use these landmarks, click **Clear Landmarks**.

  Click **Accept Trace** to close the Tracing App window.

- Click the **Import from Tracer Pen** icon.

  The traced shape appears in OMEGA. The initial view has a very low resolution, but will be sharper when you reach the **Cleanup** step.

  Proceed with the Capture Stack as usual.

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PN-1730-K 25 MAY 2018