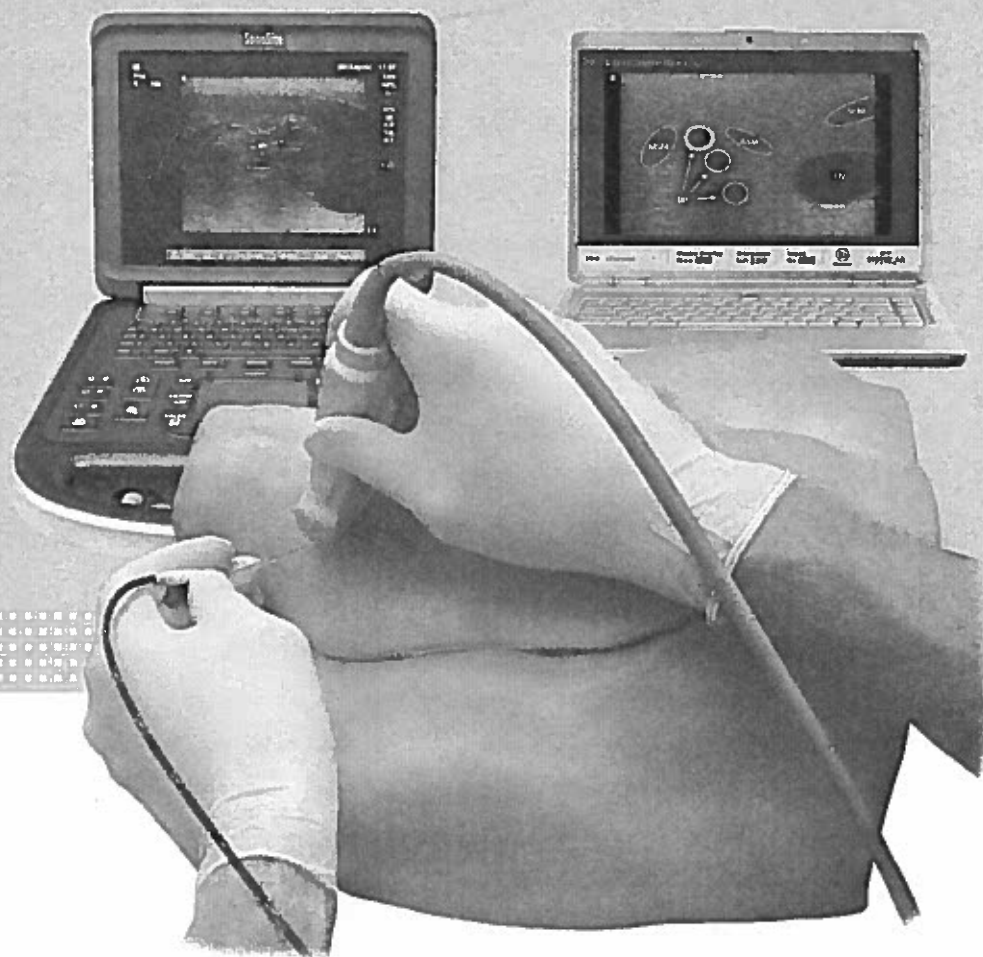




Interscalene/Supraclavicular Block Trainer with SmartTissue™



USER'S GUIDE v2.0

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Software included.

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SYSTEM OVERVIEW



The Interscalene/Supraclavicular Block with SmarTissue™ is the only nerve block training solution that provides instructors and users a feedback mechanism to gain procedural accuracy and enhance the training experience. It is both ultrasound compatible and offers visual and audio feedback when the needle position is proximal to the brachial plexus. If the needle tip either contacts

the nerve sheath or penetrates the brachial plexus this is indicated by the SmarTissue Software. The tissue is anatomically correct with realistic external and internal landmarks. It also includes a simulated arterial pulse and can be injected with simulated anesthesia, which is naturally expelled for repeated use.

This system has been designed to provide your training program with a realistic anatomical model complete with internal landmarks that allows users to practice administering nerve blocks using both the interscalene and supraclavicular approach.

This guide provides users with an overview of the Interscalene/Supraclavicular Block Trainer including how to install the software, prepare and use the system, and troubleshooting information.

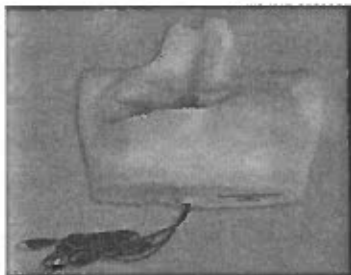
Anatomical Overview

The body form is oriented as if the head is turned to the left. Landmarks on the patient's right side include:

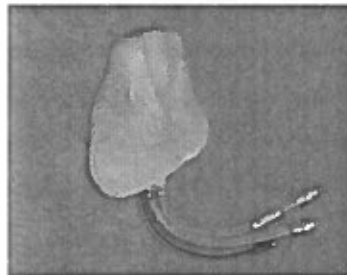
- » Sternocleidomastoid muscle
- » Clavicle
- » Interscalene groove
- » Anterior and middle scalene muscle
- » Pulse of the carotid artery

SYSTEM COMPONENTS

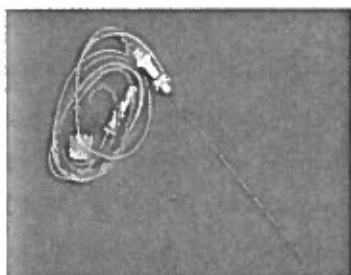
1. Body Form with Electronics



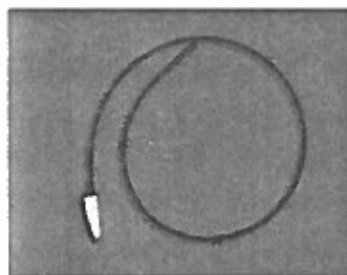
2. Interscalene/Supraclavicular SmarTissue



3. Pajunk Needle



4. Universal Needle Adapter



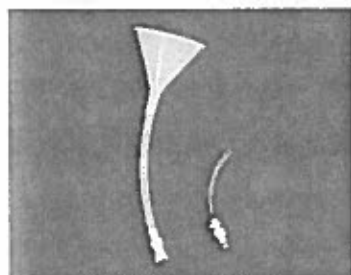
5. Software



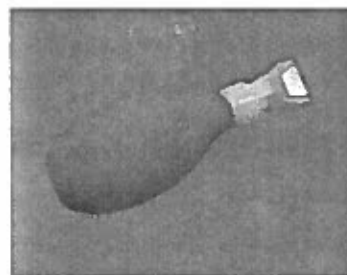
6. Red and Blue Fluid



7. Funnel with Fill Line and Fill Port



8. Pulse Bulb



SYSTEM COMPONENTS

9. Carrying Case



10. User's Guide



SOFTWARE INSTALLATION

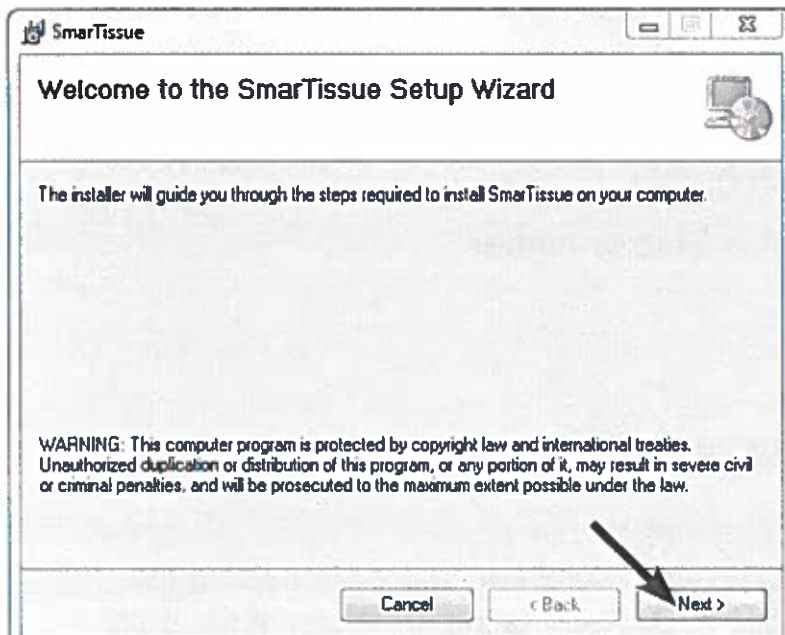
System Requirements:

- » Windows XP / Vista / 7 / 8
- » .Net Framework 4.0 or higher
- » Pentium Class CPU 1.0 GHz or higher
- » CD-ROM drive
- » USB 2.0 Port
- » RAM minimum requirement: 2GB

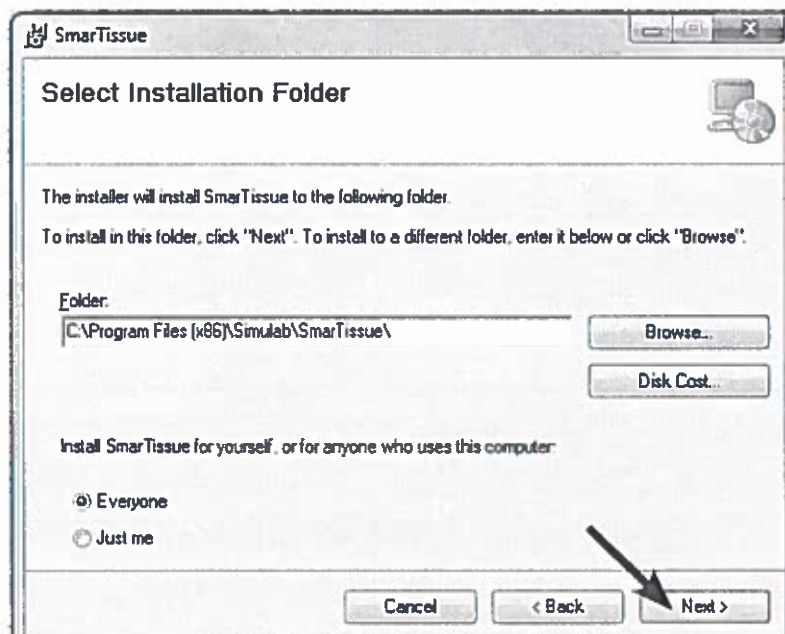
IMPORTANT:

Be sure to install the SmarTissue™ software before connecting the Interscalene/Supraclavicular Body Form to the computer. If the body form is connected prior to software install, you may need to follow the “Body Form Not Detected” troubleshooting steps on starting on page 24.

SOFTWARE INSTALLATION

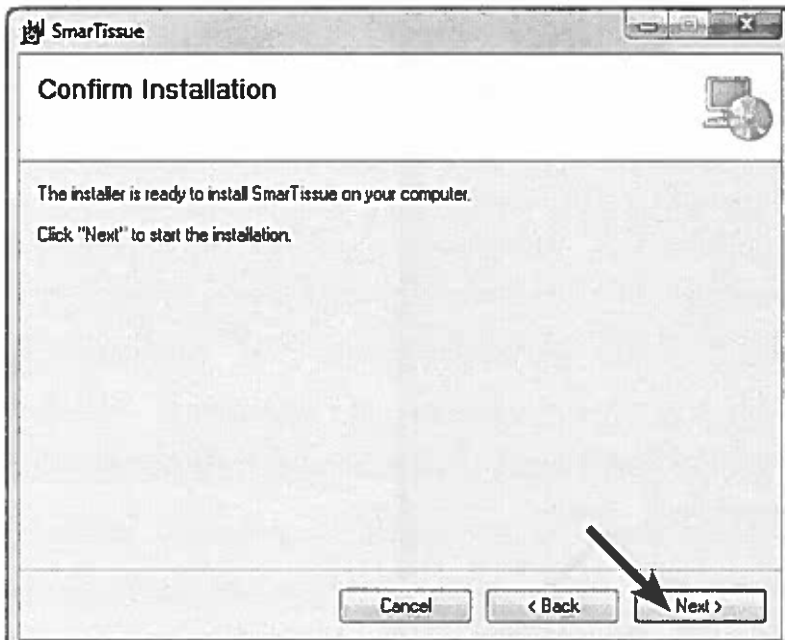


The "Welcome" screen will automatically appear on the screen. Click "Next" to begin installation.

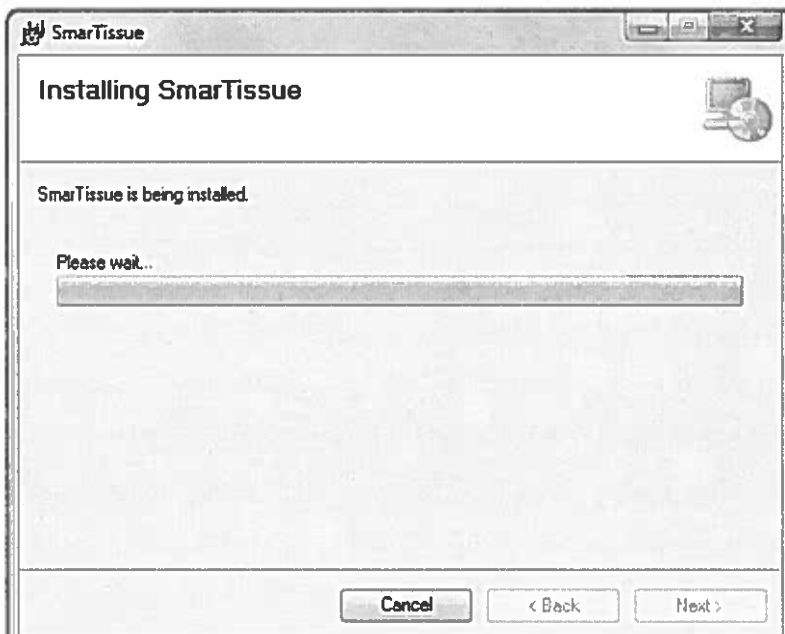


On the next screen, select the folder where the software should be saved. The default location is C:\Program Files\Simulab\SmarTissue. If that is an acceptable location, simply click "Next."

SOFTWARE INSTALLATION

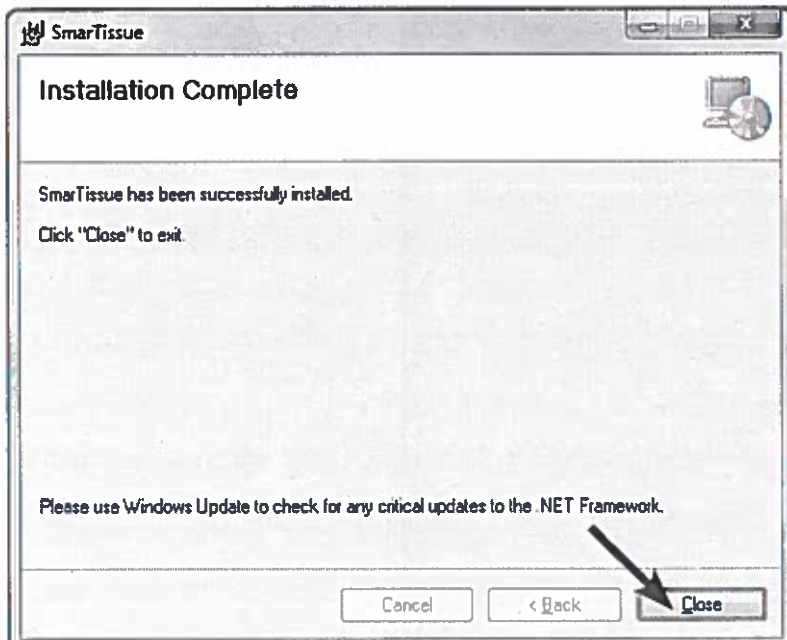


Clicking "Next" on the following screen will confirm that you wish to proceed with installation of the software.



Software installation will begin. Clicking "Cancel" on this screen will cause installation to cease.

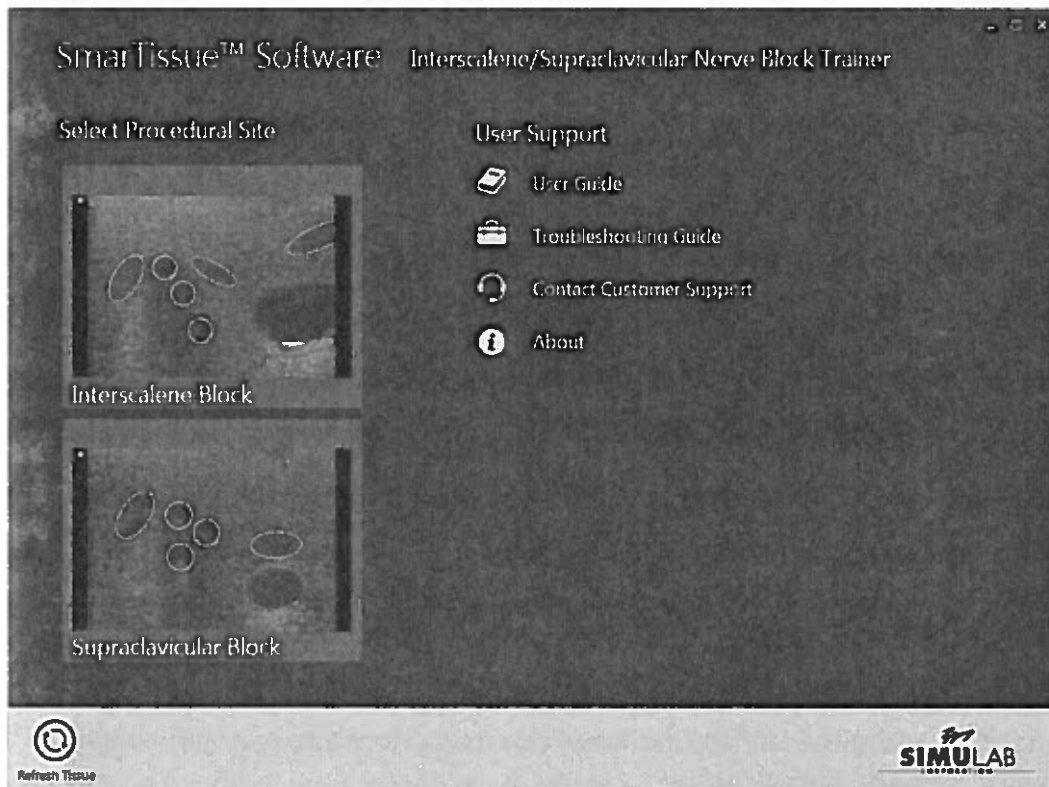
SOFTWARE INSTALLATION



Once the software is successfully installed, the "Installation Complete" screen will appear. Click "Close" and installation is complete. The SmarTissue Set-up CD can be removed from the disk drive. Restart the computer before proceeding.

SOFTWARE FUNCTIONALITY

HUB PAGE



When the software launches, the body form and tissue will be automatically identified. The hub page is oriented with the software and identified tissue name at the top while available procedural sites are shown as boxes below. Its primary function is to allow selection of the preferred procedural site and to provide options for user support.

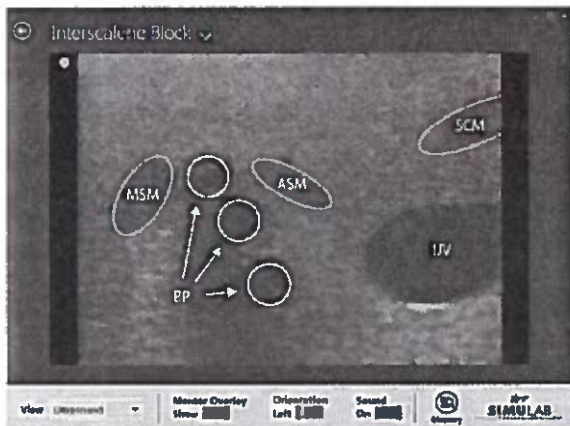
Procedural Sites: available procedural sites are automatically listed based on the attached body form and tissue. Selecting a procedural site will take you to the Interactive Page where you can interact with the tissue.

User Support: below User Support is a series of links providing help with troubleshooting, information to contact Simulab's Customer Care Team, and specifics about your SmarTissue™ Software version.

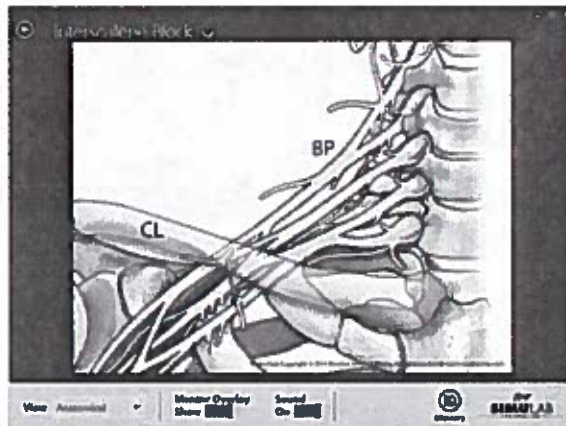
Refresh Tissue: if the incorrect tissue has been identified, the Refresh Tissue button will reset the tissue connection.

SOFTWARE FEATURES

Ultrasound View



Anatomical View



View: two view options are provided: Ultrasound and Anatomical. Both provide real-time feedback from either the Pajunk Needle or your needle connected via the Universal Needle Adapter.

Mentor Overlay: displays label abbreviations overlaid above anatomical features. Toggle this switch to "Hide" to turn off the labels.

Orientation: when using the Ultrasound view, you may choose to orient the image in either the Left or Right orientation.

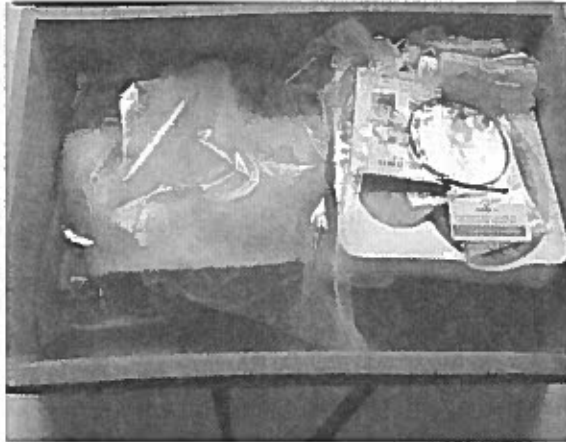
Sound: when on, a sound alarm will be triggered when the needle is proximal to a nerve or in direct contact with a nerve. Toggle this switch to "Off" to disable the sound.

Glossary: opens a pop-up box providing a glossary of terms for each Mentor Overlay abbreviation.

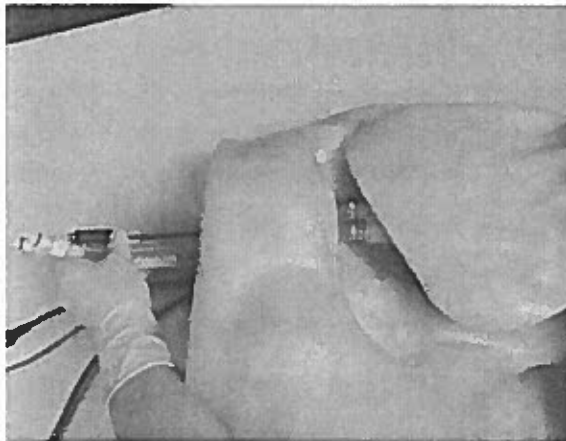
Procedural Site Quick Switch: to quickly switch between available procedural sites, click the down carat (arrow) next to the procedural site name.

SYSTEM SET-UP

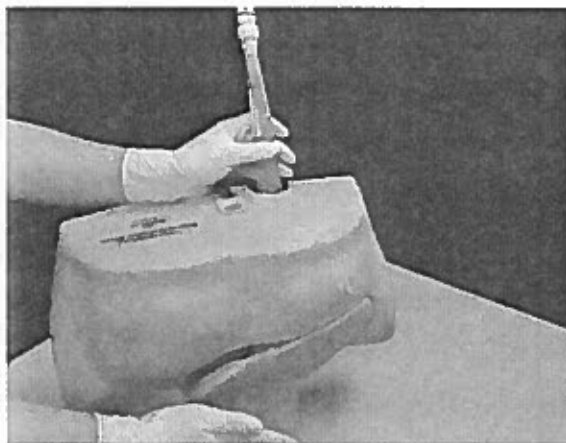
1. Check that all system components are in the carrying case (additional replaceable tissues ordered will also be included). Contact Simulab for assistance if any system component is damaged or missing.



2. Before attaching the arterial pulse bulb or the data cable, insert the replaceable tissue into the body form. For more detailed instructions go to the "Replacing a Tissue" section.

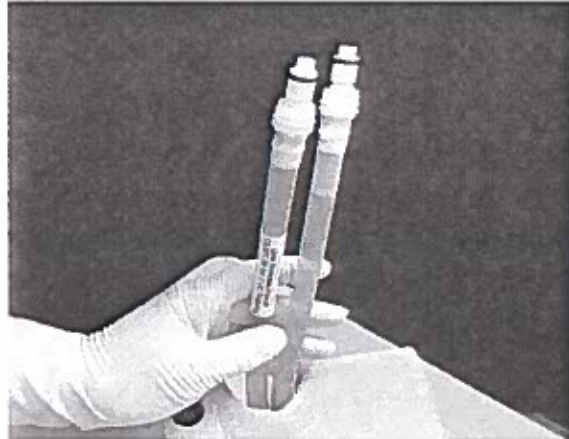


3. Next, check for excess air in the tubes. To do this, stand the simulator up and hold the vessels up. This will allow any trapped air to rise to the top.

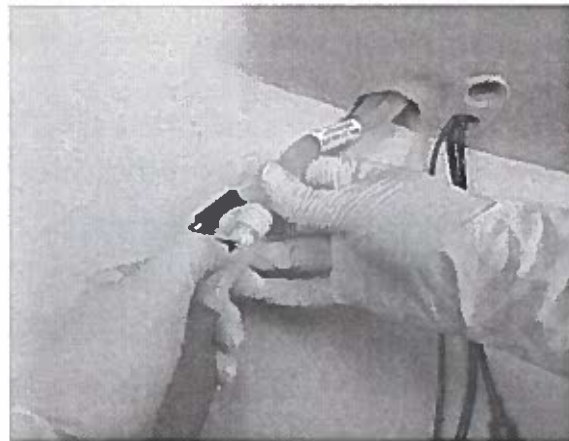


SYSTEM SET-UP

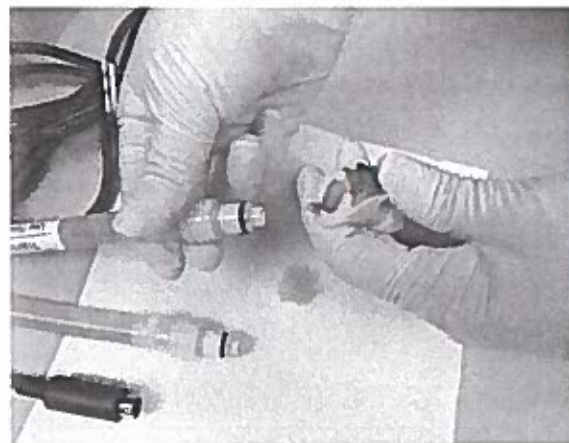
4. If there is any air in the vessels, go to the "Refilling Fluid Reservoirs" section for further instructions.



5. To create an arterial pulse, attach the pulse bulb to the artery (red line). It is pre-filled with red simulated blood. Should any air get into the pulse bulb, go to "Refilling Fluid Reservoirs."

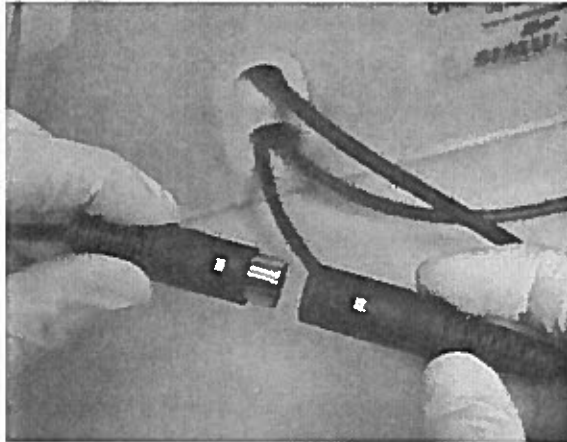


6. When removing the bulb, do so over a paper towel – there will be a small release of fluid.

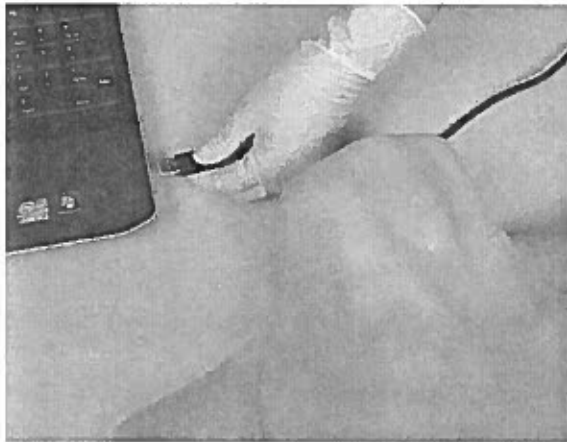


SYSTEM SET-UP

7. Connect the body form and tissue data cables. Each connector has a silver indication square and a raised alignment indicator line. Ensure the lines and squares are aligned between connectors. If the connectors have been forced together incorrectly, disconnect the cables and connect with the correct orientation.

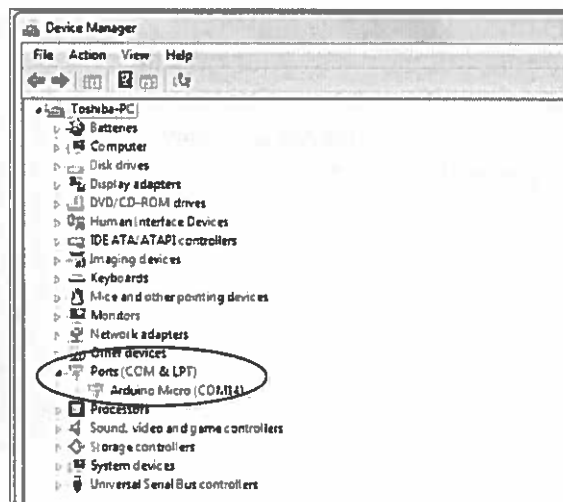


8. Plug the body form's USB cable into the PC.



9. Verify that the driver for the body form is installed via the Control Panel. For Windows 7 and Windows 8, go to System and Security > System > Device Manager. For Windows XP, go to System > Hardware > Device Manager. Look for Arduino Micro or Arduino UNO under "Ports." If it is not there, go to the Troubleshooting section for detailed instructions.

Note: the body form's initialization process only happens the first time you plug the body form into the PC.

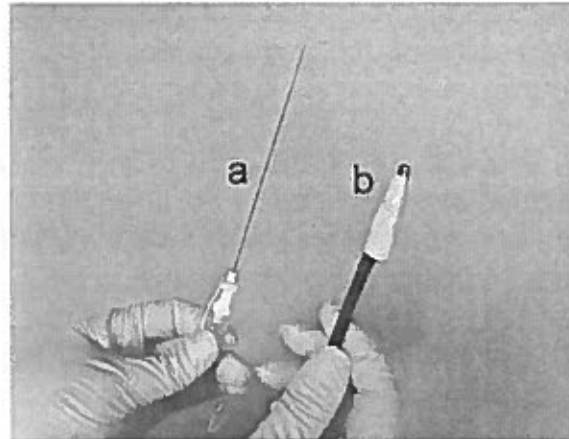


SYSTEM SET-UP

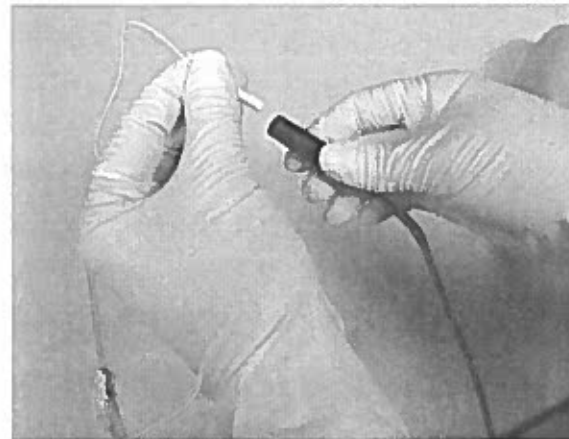
10. The system includes:

- a. Pajunk Needle
- b. Universal Needle Adapter

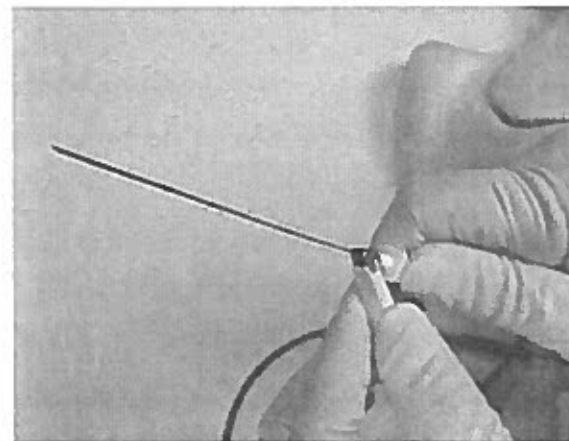
The universal needle adapter can be used with your own needle.



11. Attach the Pajunk needle to the nerve power supply cable.



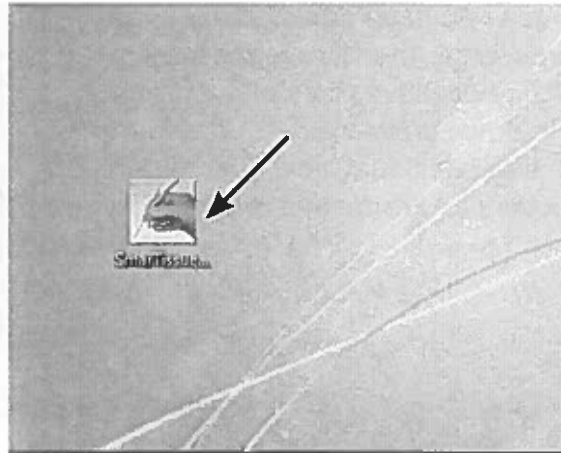
12. If you are using the universal needle adapter, clip your needle securely at the base. Ensure the needle is uninsulated and remove any needle sheaths.



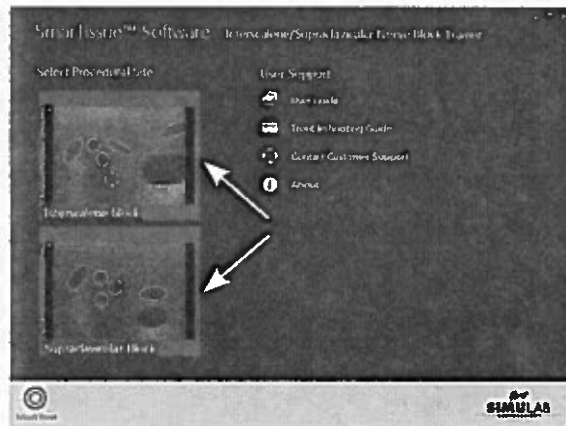
USING THE SYSTEM

1. Once you have verified that the body form has been initialized, you are ready to launch the SmarTissue software.

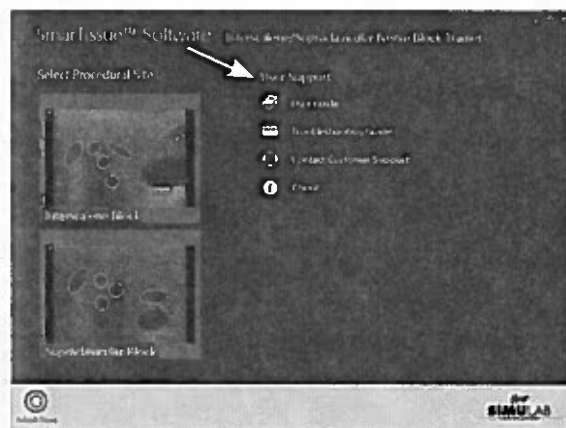
Launch the SmarTissue software by clicking on the application icon on your desktop, via the Start menu, or via the directory in which you chose to install the software.



2. The software will open and display available procedural sites. Select either the Interscalene or Supraclavicular Block procedure by clicking anywhere on the respective frame.

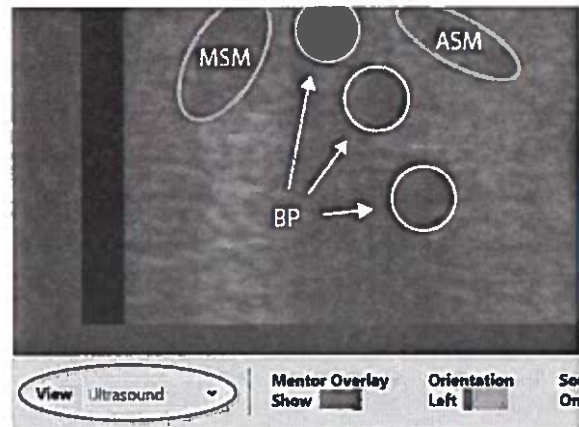


3. A version of this User's Guide and Troubleshooting Guide are available to view locally by clicking on the "User's Guide" and "Troubleshooting Guide" links. To contact Simulab's Customer Care Team, call (206) 297-1260, email info@simulab, or select the "Contact Customer Support" button for assistance.

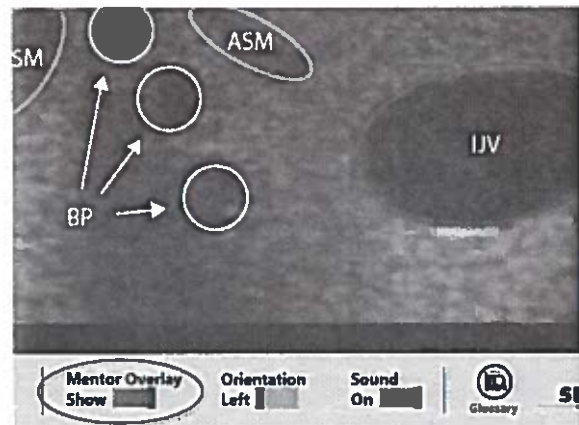


USING THE SYSTEM

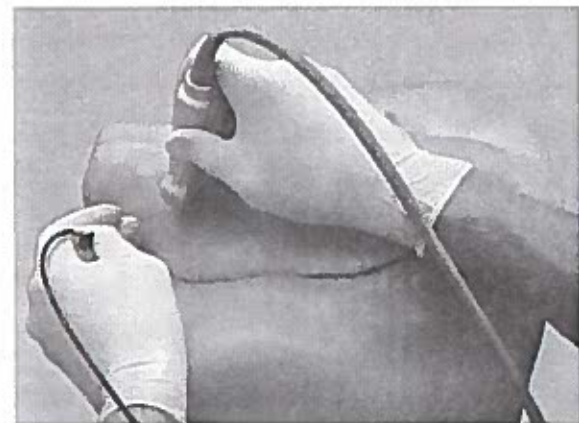
4. Once you have selected a procedure, the Ultrasound view will be displayed by default. Click the down arrow next to Ultrasound to see additional view options. All views provide real-time feedback.



5. The Mentor Overlay provides labels for each tissue component. Click the "Glossary" button on the bottom bar to view a full glossary of terms for each abbreviated label.

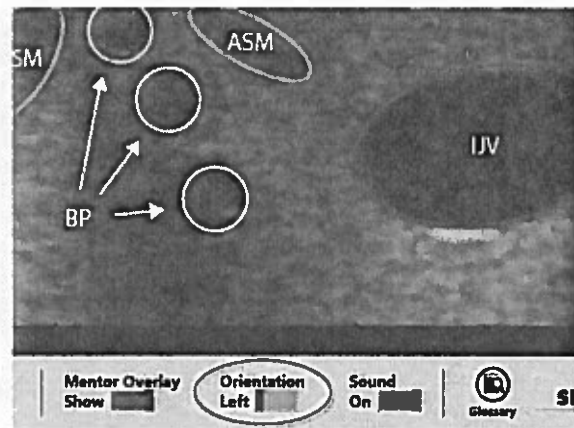


6. Ultrasound can be used with this trainer to guide needle insertion. Either the included needle or your needle attached to the universal adapter should be used to receive feedback from the SmarTissue software.

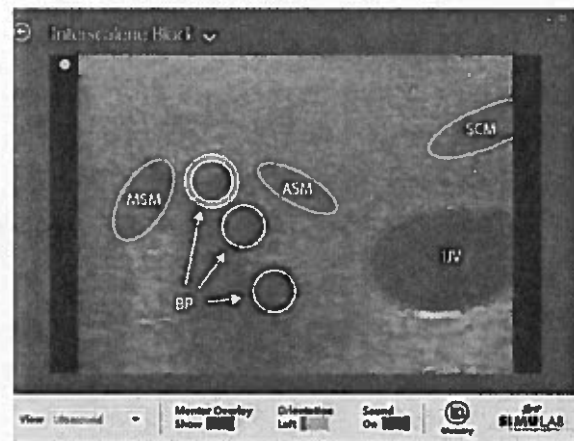


USING THE SYSTEM

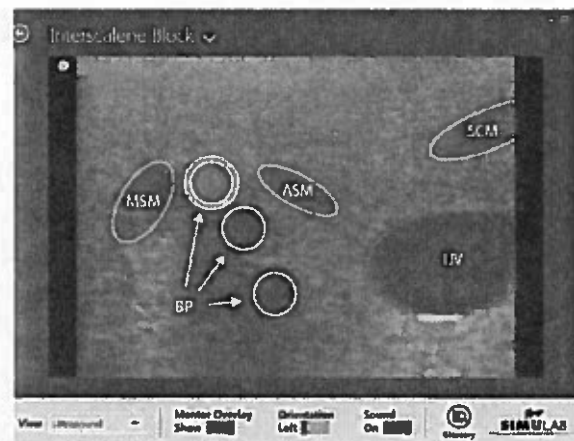
7. If you are using the Ultrasound view and would like to see the image reversed, toggle the "Orientation" toggle switch from Left to Right. Orientation is not available in the Anatomical view.



8. Upon entering the proximal region of each nerve, the SmarTissue software will outline the associated nerve in orange. If the "Sound" toggle is turned on, an intermittent alarm will sound to indicate nerve proximity.



9. If the nerve is penetrated, the associated nerve will be highlighted in red to indicate the nerve has been hit. If the "Sound" toggle is turned on, an alarm will sound to indicate nerve penetration.

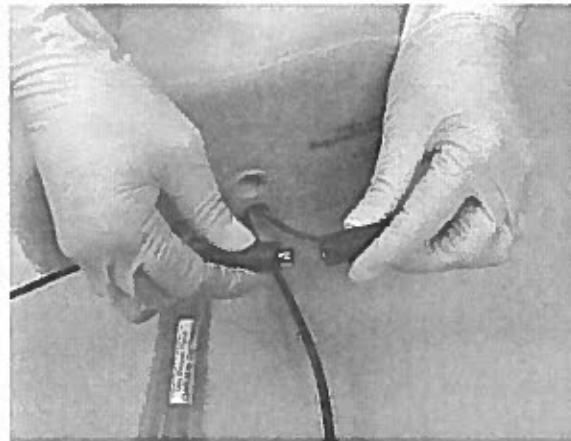


REPLACING A TISSUE

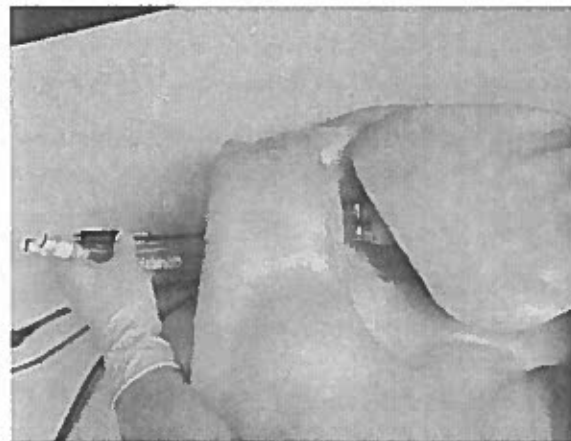
1. To replace a used tissue, remove the bulb over a paper towel – there will be some leakage.



2. Unplug the tissue's data cable from the body form. Then pull the tissue out of the body form.



3. Next, insert the extending lines and electronics cord of the new tissue through the opening on the lower portion of the torso's base.

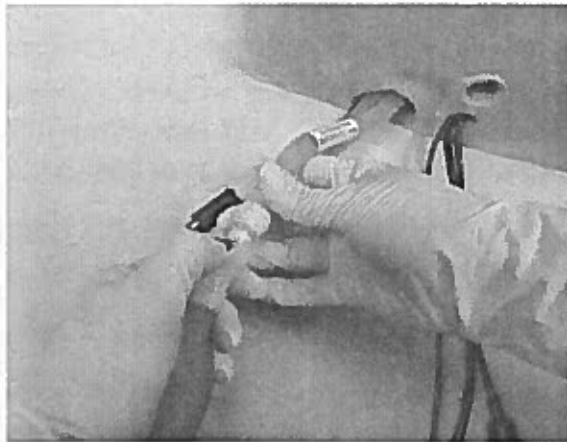


REPLACING A TISSUE

4. Gently pull the vessels away from the body form to make sure there are no kinks.

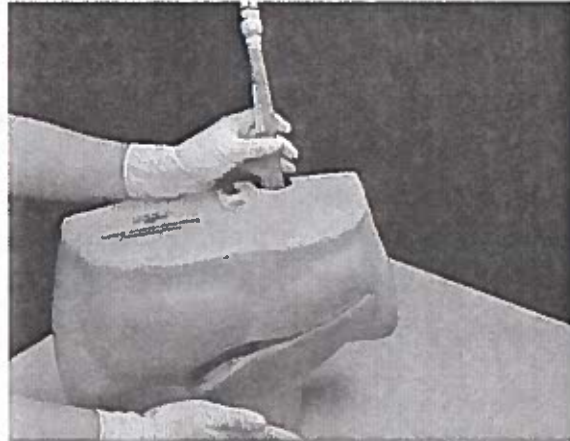


5. Attach the pulse bulb to the arterial (red) line and the tissue's data cable to the body form and the system is ready for use.



REFILLING FLUID RESERVOIRS

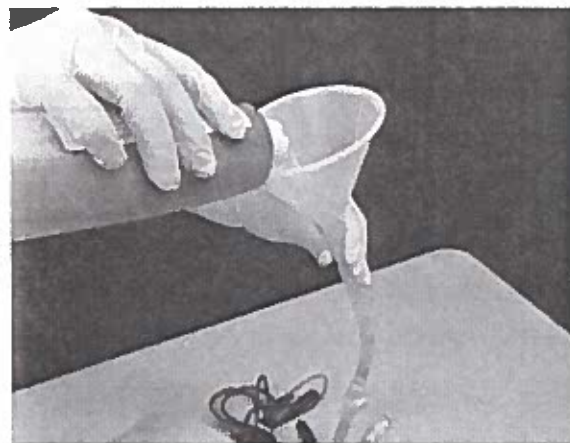
1. To begin, stand the simulator up and gently pat the tissue – this allows any trapped air to rise to the top of the tubing.



2. If the arterial line needs to be refilled, remove the bulb. The vein can be refilled with no prior preparation. Attach the fill port with the funnel to the vessel that needs refilling.

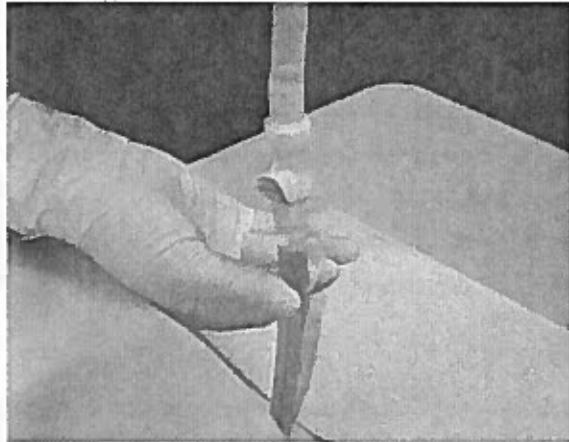


3. Slowly add the fluid using the funnel. Make sure to use the proper color of fluid for each vessel.

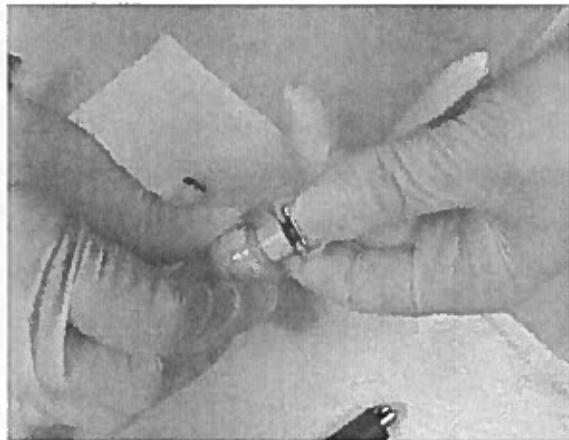


REFILLING FLUID RESERVOIRS

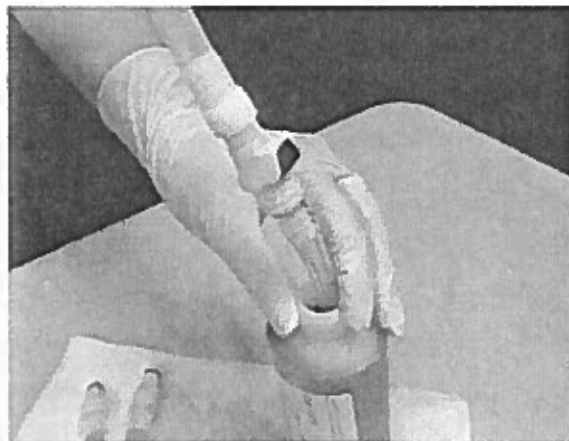
4. To fill the vessel and release all the air, gently squeeze the fill port's tubing to allow the air to rise up and the fluid to enter into the vessel.



5. Once filled, release the port from the simulator. Use paper towels to absorb any leakage.

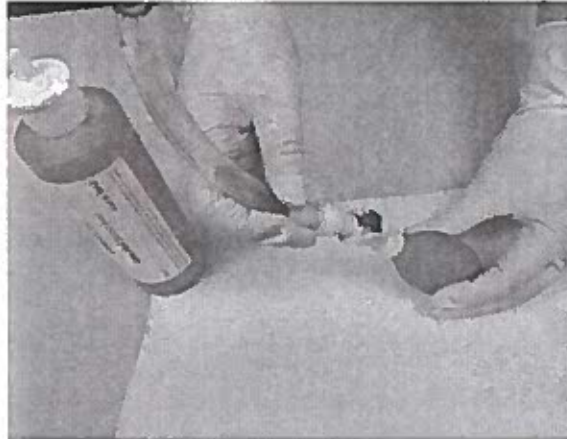


6. To empty excess fluid, start by placing the fill line into the appropriate bottle of fluid. Then attach the funnel to the fill line and the fluid will drain.

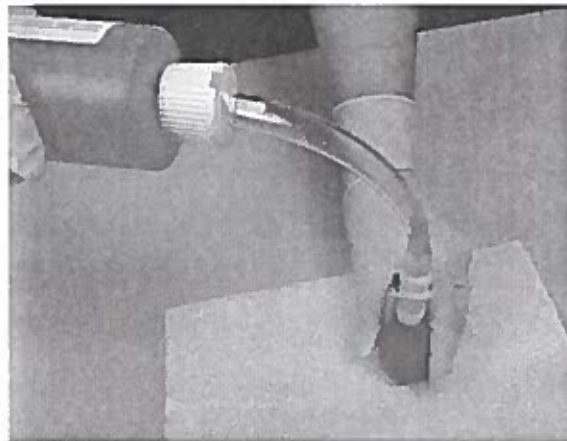


REFILLING FLUID RESERVOIRS

7. To refill the bulb, attach the fill line to the bulb and slowly add more red fluid.



8. Gently squeeze the bulb to add fluid. When the bulb will not take any more fluid and all air bubbles have risen, disconnect the fill line and drain back into the fluid bottle.



9. The bulb can then be reconnected to the vessel and the body form is ready for use.

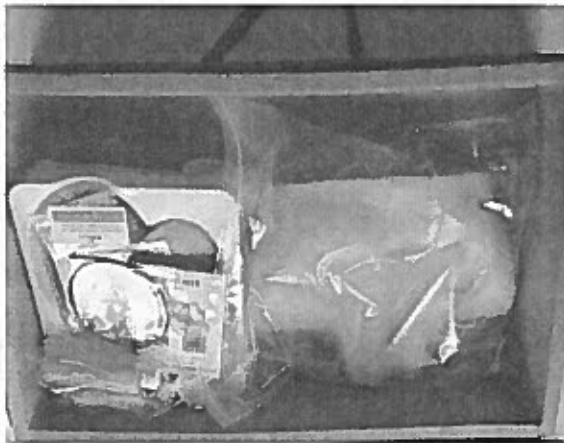


MAINTENANCE AND STORAGE

1. Check that all system components are in the carrying case (additional replaceable tissues ordered will also be included). Contact Simulab for assistance if any system component is damaged or missing.



2. When repacking the body form, make sure the base is positioned towards the case's handle. This ensures that the body form's electronics are not damaged.



3. When not in use, store replaceable tissues in a plastic zip lock bag. This will contain any leakage and prevent evaporation of fluid.

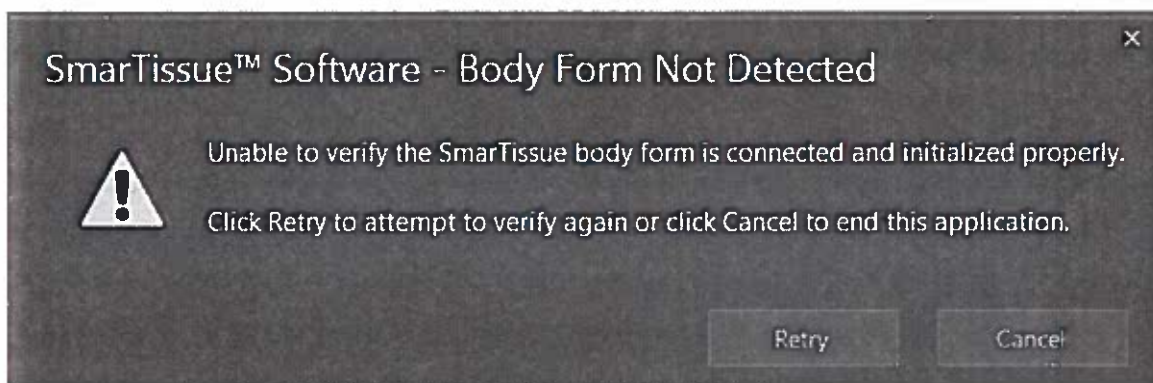


TROUBLESHOOTING

Issue:

» Body Form Not Detected.....	24
» TissueNotDetected.....	30
» Windows produces an "Add New Hardware Wizard" pop-up box (Windows XP)....	31
» Nerves contacted with the needle are not indicated on the software.....	33
» No sound is heard when proximal to or in contact with the nerves.....	35
» The Tissue Produces an Unrealistic Ultrasound Image.....	36
» Other Issues with Software Functionality.....	38

Unable to Verify the Body Form

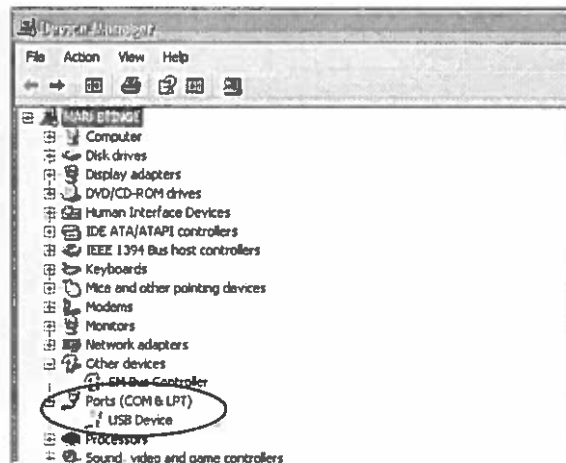


1. Double check that the body form USB cable is connected to the PC running the SmarTissue software. If it is not connected, do so and select "Retry."
2. If the body form is connected and you see the pop-up box, disconnect the USB cord from the PC and wait several seconds. Reconnect the cord and select "Retry".
3. If you still experience issues, take the following steps specific to your Windows Operating System.

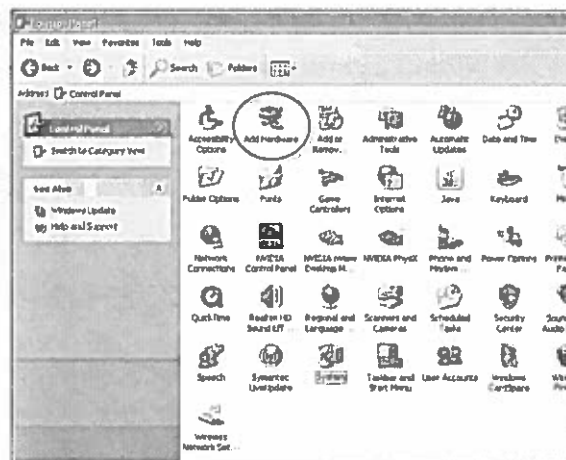
TROUBLESHOOTING

Body Form Not Detected (Windows XP)

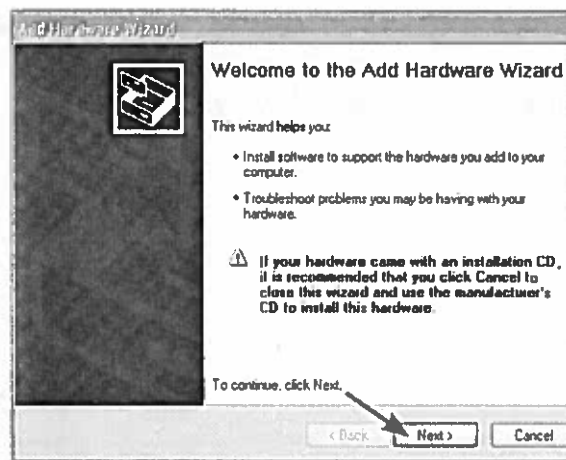
1. If the "New Hardware Found Wizard" doesn't automatically launch and/or if the driver is not shown under "Ports," open the Device Manager. Go to Control Panel > System and click on the "Hardware" tab.



2. Go to Control Panel and click on "Add Hardware." This will launch the "Add Hardware Wizard."

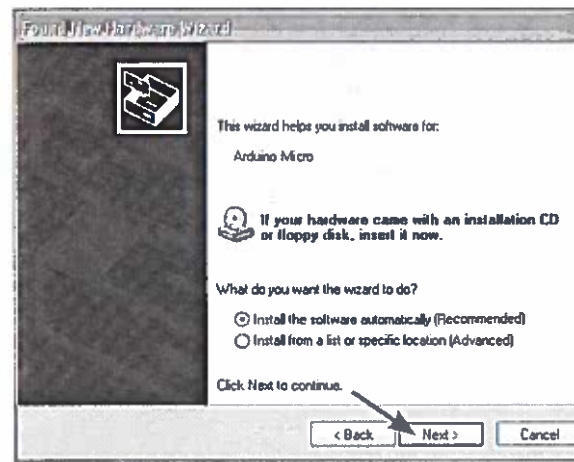


3. Click on "Next."

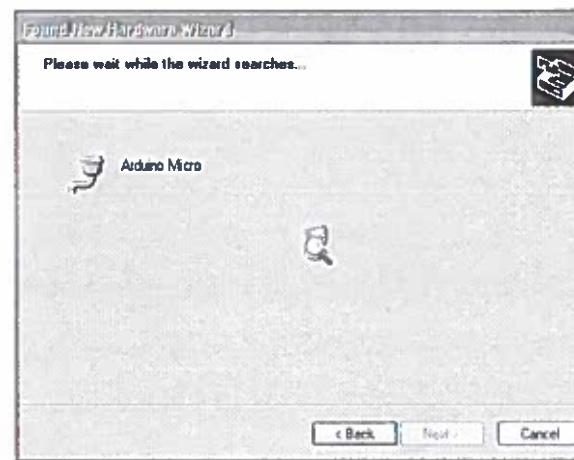


TROUBLESHOOTING

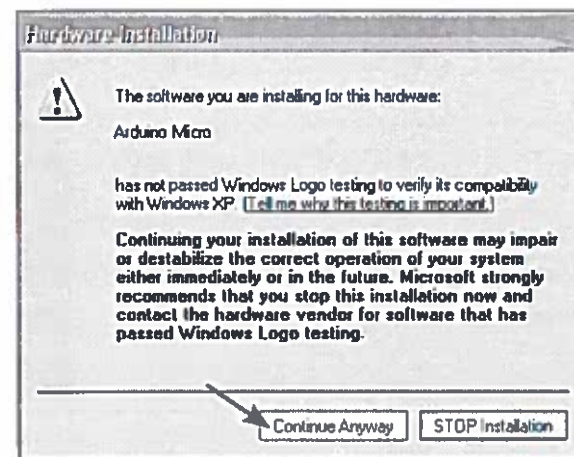
4. Select "Install the software automatically" and click on "Next."



5. Do not click on "Back" or "Cancel" as the wizard searches.



6. When asked if you want to continue installing the software, click on "Continue Anyway."



TROUBLESHOOTING

7. The wizard is now complete – click on “Finish.”

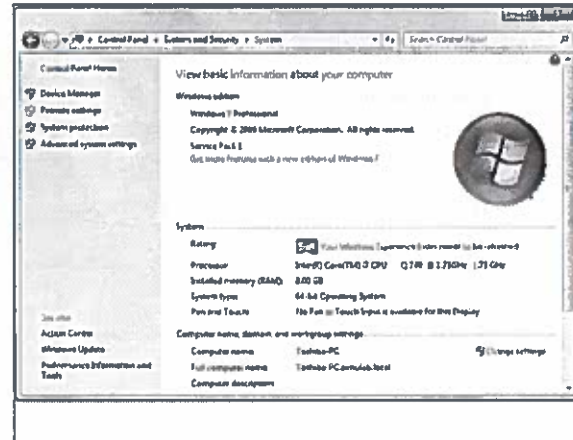
You are now ready to launch your SmarTissue software. Go to your desktop and double-click on the SmarTissue icon to begin.



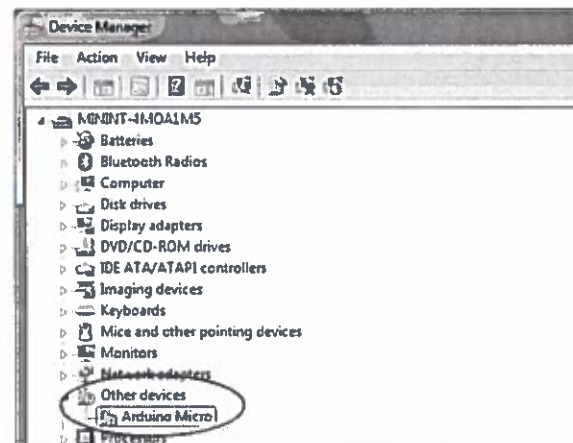
TROUBLESHOOTING

Body Form Not Detected (Windows 7, Windows 8)

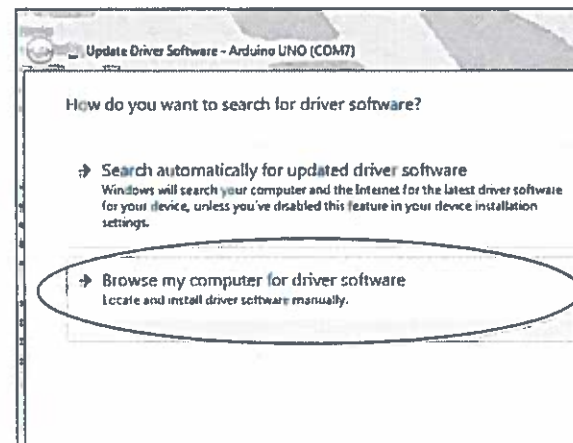
1. Open the Device Manager by going to Control Panel > System and Security > System and clicking on "Device Manager" at the top left.



2. Ensure SmarTissue software is closed. Under "Other Devices" right click Arduino Micro or Arduino UNO and select "Update Driver Software". If Arduino is not displayed, right click "Unknown Device" and select "Update Driver Software".

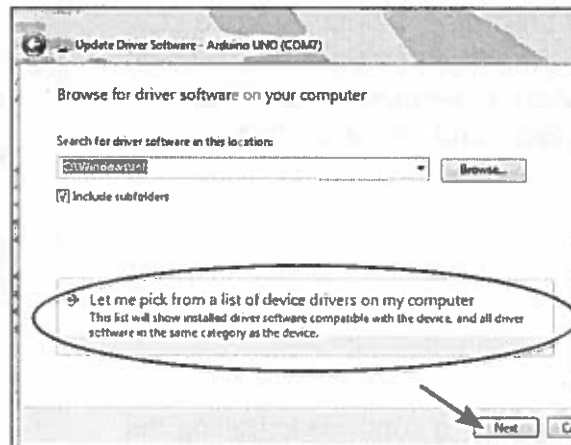


3. Click on "Browse my computer for driver software."

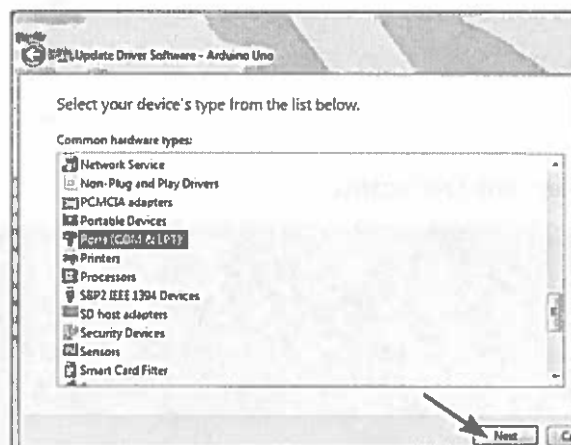


TROUBLESHOOTING

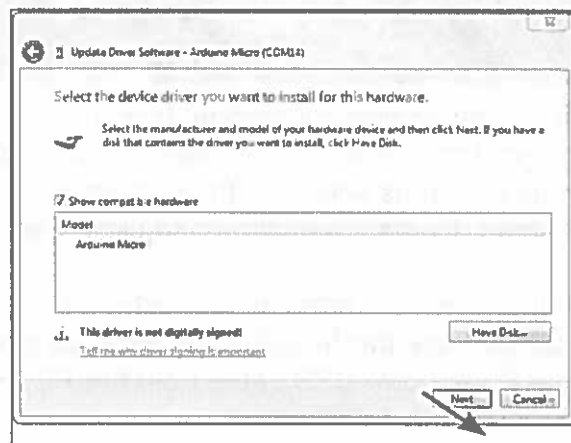
- Click on "Let me pick from a list of device drivers on my computer" and click on "Next."



- Next select "Ports (COM & LPT)" and click on "Next."

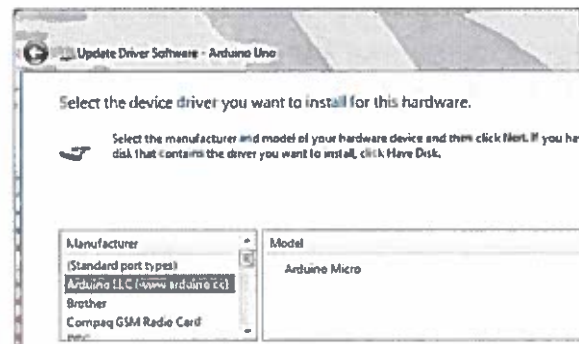


- Select Arduino Micro or Arduino UNO and click on "Next."

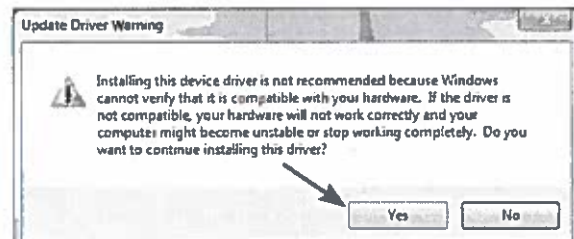


TROUBLESHOOTING

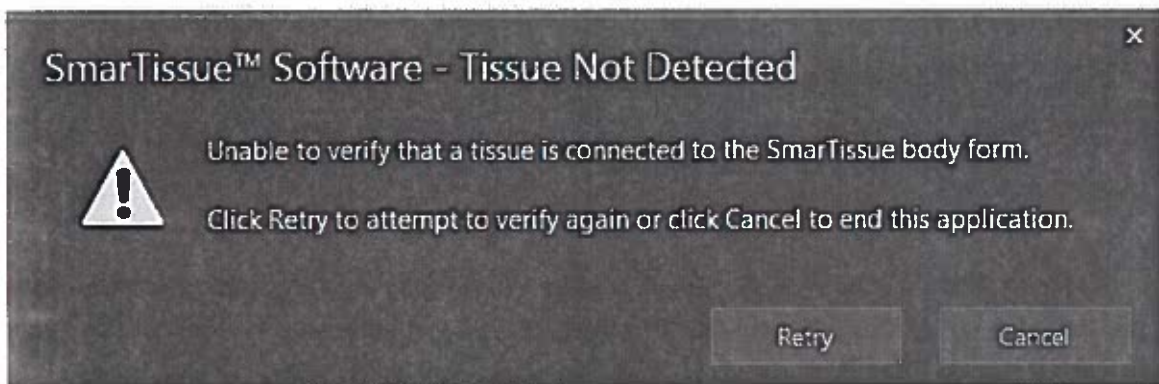
7. If prompted, select "Arduino LLC" as the Manufacturer and Arduino Micro or Arduino UNO R3 as the Model and click on "Next."



8. If asked to continue installing the driver, click on "Yes."



Tissue Not Detected



1. If you encounter this pop-up box, your SmarTissue Body Form is operational but cannot detect an attached tissue. Double check the tissue data cable connection as shown in the system set up. If the tissue was improperly connected, fix the connection and click "Retry."
2. If the tissue is correctly connected and you still see this pop-up, select "Cancel" to close the SmarTissue software and wait several seconds. Disconnect the Body Form USB cable from the PC. Reconnect the cord and reopen the SmarTissue software.
3. If you still experience issues, follow the steps specific to your operating system under "Body Form Not Detected".

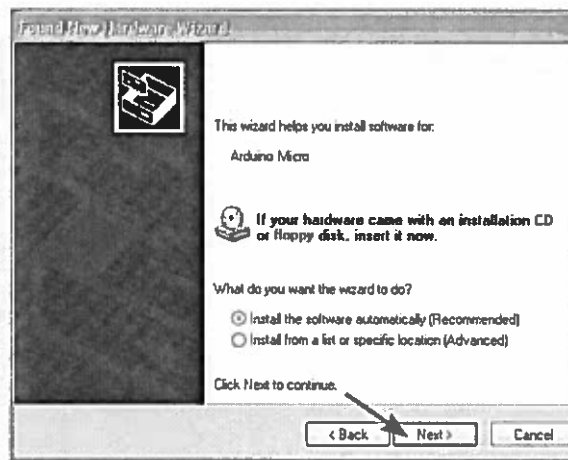
TROUBLESHOOTING

Windows Produces an “Add New Hardware Wizard” pop-up box on Windows XP

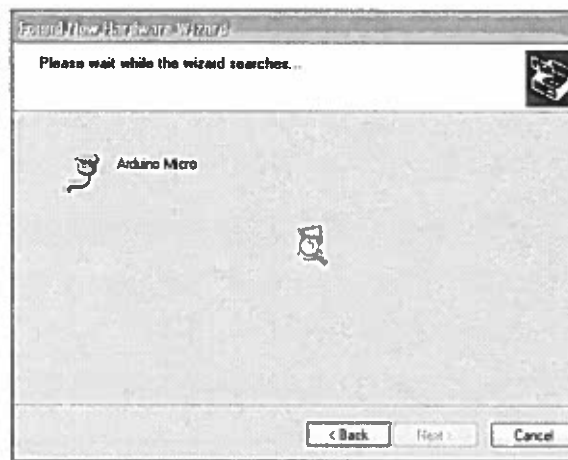
1. When asked “Can Windows connect to Windows Update to search for software?” select “Yes, this time only” and click on “Next.”



2. On the next screen, select “Install the software automatically” and click on “Next.”

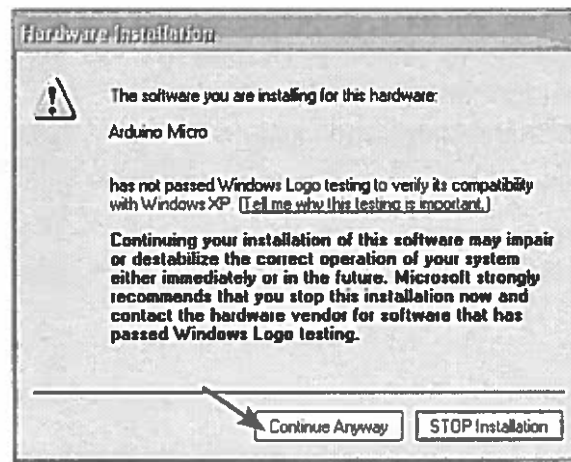


3. Do not click on “Back” or “Cancel” as the wizard searches.



TROUBLESHOOTING

4. When asked if you want to continue installing the software, click on "Continue Anyway."



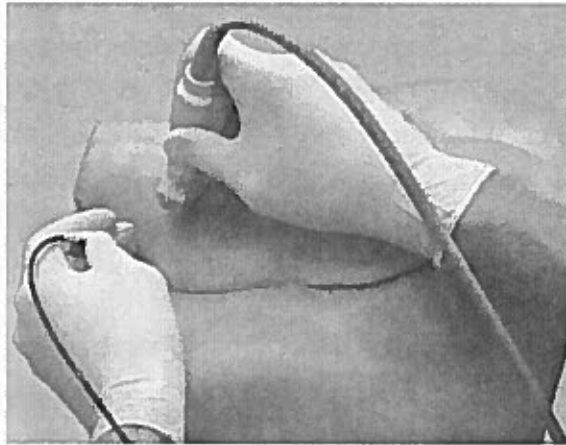
5. The wizard is now complete – click on "Finish."



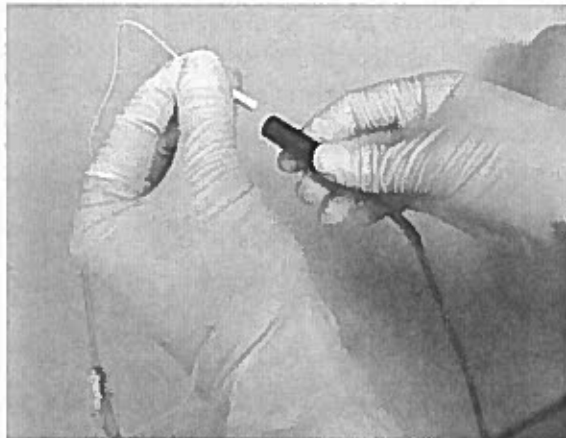
TROUBLESHOOTING

Nerves contacted with the needle are not indicated on the software

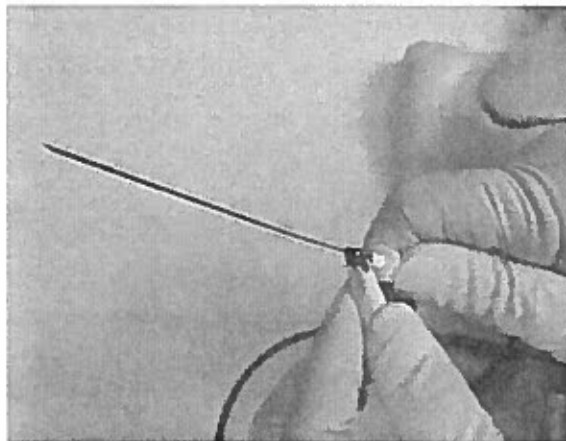
1. It can be difficult to accurately and repeatedly achieve proximity or contact with a nerve. A slight “pop” should be palpated and nerve proximity should be visualized under ultrasound to confirm nerve proximity or contact.



2. Make sure that your Pajunk Needle is properly connected to the Needle Power Supply.

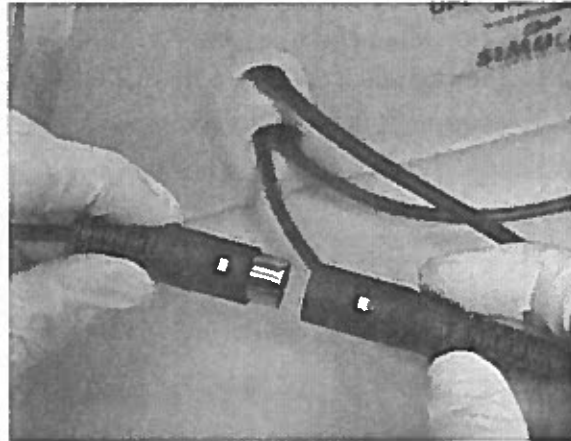


3. If you are using a non-Pajunk needle, ensure that the Universal Needle Adapter is properly clipped to a metallic portion of the needle.

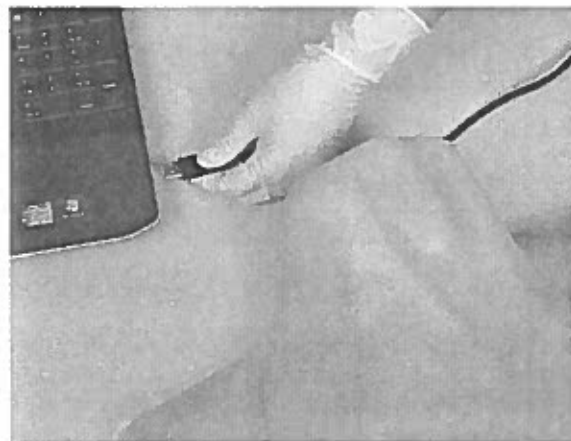


TROUBLESHOOTING

4. Ensure the black Tissue Data Cable is connected to the Body Form Data Cable.



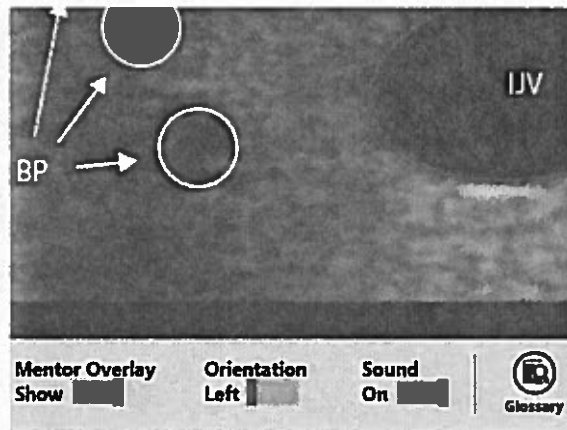
5. If you still experience issues, follow the instructions to check the Body Form connection under Troubleshooting - "Body Form Not Detected".



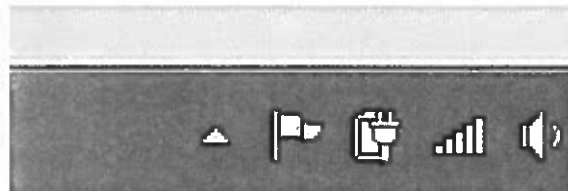
TROUBLESHOOTING

No sound is heard when proximal to or in contact with the nerves.

1. The SmarTissue software utilizes your PC speakers to provide audio feedback. Make sure the "Sound" toggle on the SmarTissue software is turned "On".



2. Also check your PC system volume by clicking on the speaker icon in the system tray or adjusting the volume manually on your speaker system.



TROUBLESHOOTING

The Tissue Produces an Unrealistic Ultrasound Image

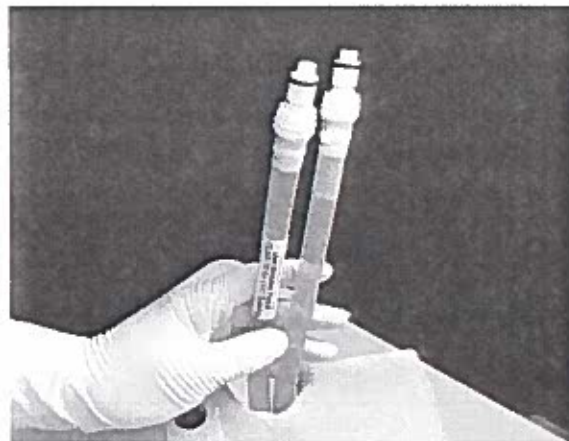
1. If you experience difficulty getting a realistic ultrasound image, there may be air in the vein or artery. To check for air, stand body up on its end and raise fluid lines all the way above the body form.



2. Gently pull the vessels away from the body form to make sure there are no kinks. Gently pat the tissue to make sure all trapped air has escaped.



3. If an air bubble rises, squeeze the vessel near the tip to release the air. Use the pulse bulb or syringe, depending on the vessel to replace the air with fluid. If air remains, refer to the "Refilling Fluid Reservoirs" section.



TROUBLESHOOTING

4. If the ultrasound image you are seeing is not optimal, reset to vascular settings or default settings by turning your machine "off" and then "on."



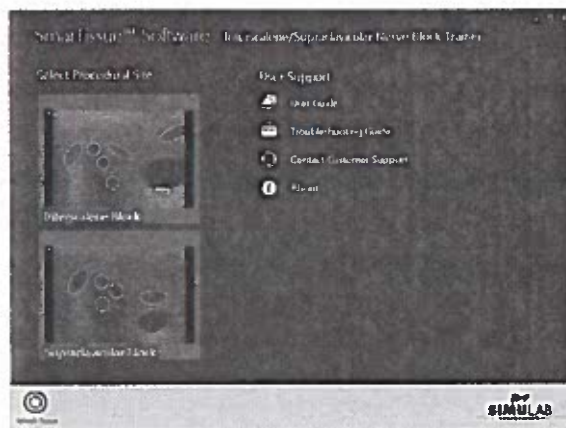
5. It may be necessary to adjust the gain, depth, penetration, and exam settings on the ultrasound machine to achieve a very realistic image.



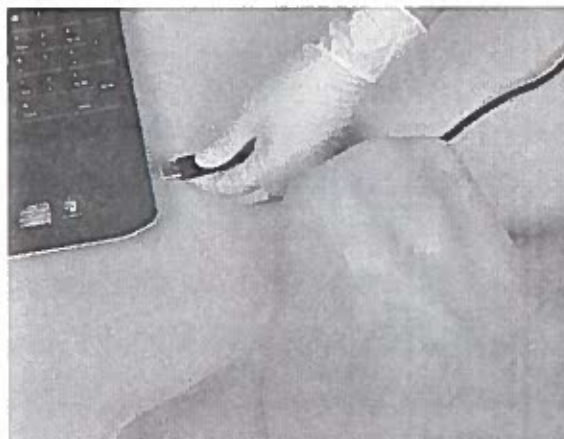
TROUBLESHOOTING

Other Issues with Software Functionality

1. If you experience any issues with the software launching or any other unexpected behaviors, close the application and restart the software.



2. If you still experience issues, disconnect the USB cord from the PC and wait several seconds. Reconnect the cord.



3. If you still experience difficulty, restart your computer. Make sure the body form USB cable is plugged into the computer and that the tissue's data cable is plugged into the body form.

TROUBLESHOOTING

4. Finally, like during System Setup, verify that the driver for the body form is installed via the Control Panel.

For Windows 7 and 8, go to the Control Panel > System and Security > System > Device Manager.

For Windows XP, go to Control Panel > System > Hardware > Device Manager. Look for Arduino Micro or Arduino Uno under "Ports".

If it is not there, go to "Body Form Not Detected" on page 24 for detailed instructions.



5. Once you have verified that the body form is re-initialized, launch the SmarTissue software. If you continue to experience issues, contact Customer Support.



REPLACEMENT PARTS PRICE LIST

Part #	Product	Price
ISBST-20	SmarTissue Replaceable Tissue	\$1,568.00
STUBF-10	Body Form for SmarTissue	\$1,980.00
ISBS-1004	Replacement Software	\$75.00
ISBS-1005	User's Guide	\$27.00
ISBS-1003	Universal Needle Adapter	\$187.00
CLP-1008	Pulse Bulb	\$25.00
CLP-1003	Funnel with Fill Port	\$20.00
CLP-1004	Fill Line	\$16.00
MV-16	Blue Fluid	\$17.00
MA-16	Red Fluid	\$17.00
NBT-1001	Carrying Case	\$286.00
001185-77	Pajunk SonoPlex Stim Canula	Contact manufacturer



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