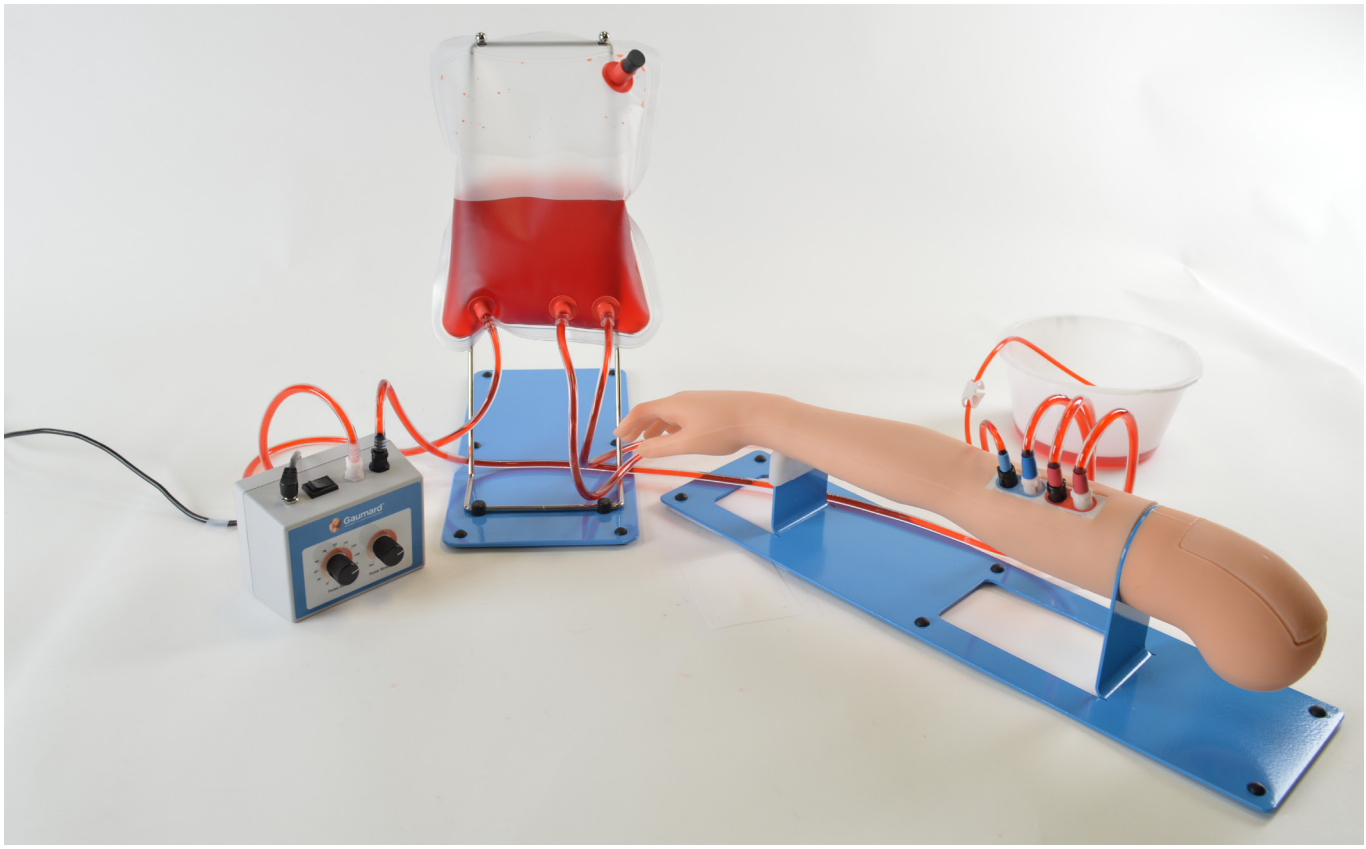
Gaumard®
Simulators for Health Care Education

# S405.100-S406.100

# PEDIATRIC IV AND ARTERIAL ACCESS TRAINING ARM

## USER GUIDE



The S405.100-S406.100 pediatric IV & arterial access training arm is an interactive educational system developed to assist a certified instructor. It is not a substitute for a comprehensive understanding of the subject matter and not intended for clinical decision making.

User Guide 20.10.02

www.gaumard.com

# 1. INTRODUCTION

## 1.1 SPECIFICATIONS OF S405.100

Weight: 2.4 lbs

Length of arm : 19.5″

Length with blue stand: 20.5″

The S405.100 Pediatric Patient Injection Training Arm accurately represents a pediatric 5 year old's arm and hand, complete with the Cephalic, Basilic, Antecubital, Radial, Median Cupital, and Ulnar veins. The simulators also feature the Radial artery, Brachial artery, subcutaneous injection site on the the lateral side of the upper arm, an intramuscular injection site in the deltoid area, and a section of the humerus.

## 1.2 SPECIFICATIONSOF S406.100

Weight: 1.4 lbs

Length of arm: 13″

Length with blue stand: 14.5″

The S406.100 Pediatric Patient Injection Training Arm accurately represents a pediatric 1 year old's arm and hand, complete with the Ulnar and Median Cubital veins. The simulators also feature the Radial artery, Brachial artery, an intramuscular injection site in the deltoid area, and a section of the humerus.

## 1.3 CARE AND MAINTENANCE

### General

- Do not wrap this or any other Gaumard product in newsprint.
- Marks made with ballpoint pens, ink, or marker cannot be removed.
- Replacement parts are available from Gaumard or from your distributor.
- Do not use povidone iodine or Betadine type antiseptic solutions as these may permanently stain the simulator.

**CAUTION: Damage caused by misuse is not covered by your warranty. It is critical to understand and comply with the following guidelines.**

### Cautions

- Use the injection training arm with the same precautions used with a real patient.
- Have providers wash their hands prior to use to prevent dirt and oils from clinging to the material.
- Do not palpate using fingernails as this may tear the skin; palpate using the pads of the fingers.

### Operating Temperatures

- Operating temperature: 50°- 95° F (10°- 35° C).
- Humidity: 5% - 95% (non-condensing).

### Storage

- Store the venous training arm in a cool, dry place.
- Humidity: 40% - 60% (non-condensing).
- Do not stack or store heavy materials on top of the bag. Please store and ship it in the bag provided.

### Cleaning

- The injection training arm is "splash-proof" but not water-proof. Do not submerge or allow water or other liquids to enter the interior of the simulator.
- The injection training arm should be cleaned with a cloth dampened with diluted liquid dishwashing soap.
- Dry thoroughly after every cleaning.
- A secondary cleaning with a cloth dampened with 70% isopropyl alcohol can be performed if required.
- Do not clean with harsh abrasives.
- Dry thoroughly after every cleaning.
- After drying, application of talcum powder can return the arm to its lifelike feel.

## IV Arm

- Only use Gaumard's simulated blood provided in the standard package. Any other simulated blood containing sugar or any additive may cause blockage and/or interruption of the vasculature in the IV arm.
- The use of needles larger than 22 to 23 gauge will reduce the lifetime of the arm skin and veins.
- Always purge with clean water, then drain the vein reservoirs at the end of each day of simulation. Doing so will retard the formation of mold and prevent clogging of the system.
- The skin of the training arm can be cleaned with a mild detergent, or soap and water. After drying the arm, lightly dust it with talcum powder. This will keep the training arm supple and easy to use.
- We recommend flushing veins with water after each use to prolong the life of the vasculature.
- For more information regarding the replacement of veins and other consumable items please contact technical support.

# 2. OVERVIEW

## 2.1 FEATURES OF 5 YEAR PEDIATRIC IV AND ARTERIAL PUNCTURE TRAINING ARM S405.100

- Realistic arterial and venous network
- Adjustable pulse strength and rate (12-180 BPM)
- Palpable radial and brachial pulse
- Simulated Cephalic, Basilic, Antecubital, Radial, Median Cupital, and Ulnar veins
- Ulnar and cubital venipuncture:
    - » Cannulation
    - » Infusion
    - » Bolus Injection
    - » Blood draw/collection
    - » Observe flashback
- Radial and brachial arterial puncture:
    - » Cannulation
    - » Blood sampling/collection
    - » Observe flashback
- IM injection
- Sub-Q injection
- Humeral IO access and continuous infusion
- External blood reservoir for continuous fluid supply and vessel pressurization
- Rotatable arm and shoulder
- Articulating wrist allowing palmar flexion
- Easily replaceable veins and arteries
- Lifelike skin
- Latex free
- Use as a stand-alone or attached to stand
- Option to attach to certain Gaumard pediatric manikins at time of purchase

## 2.2 FEATURES OF 1 YEAR PEDIATRIC IV AND ARTERIAL PUNCTURE TRAINING ARM S406.100

- Realistic arterial and venous network
- Adjustable pulse strength and rate (12-180 BPM)
- Palpable radial and brachial pulse
- Simulated Cephalic, Basilic, Antecubital, Radial, Median Cupital, and Ulnar veins
- Ulnar and cubital venipuncture:
    - » Cannulation
    - » Infusion
    - » Bolus Injection
    - » Blood draw/collection
    - » Observe flashback
- Radial and brachial arterial puncture:
    - » Cannulation
    - » Blood sampling/collection
    - » Observe flashback
- IM injection
- Humeral IO access and continuous infusion
- External blood reservoir for continuous fluid supply and vessel pressurization
- Rotatable arm and shoulder
- Articulating wrist allowing palmar flexion
- Easily replaceable veins and arteries
- Lifelike skin
- Latex free
- Use as a stand-alone or attached to stand
- Option to attach to certain Gaumard pediatric manikins at time of purchase

# 3. INITIAL SETUP

## 3.1 UNBOXING

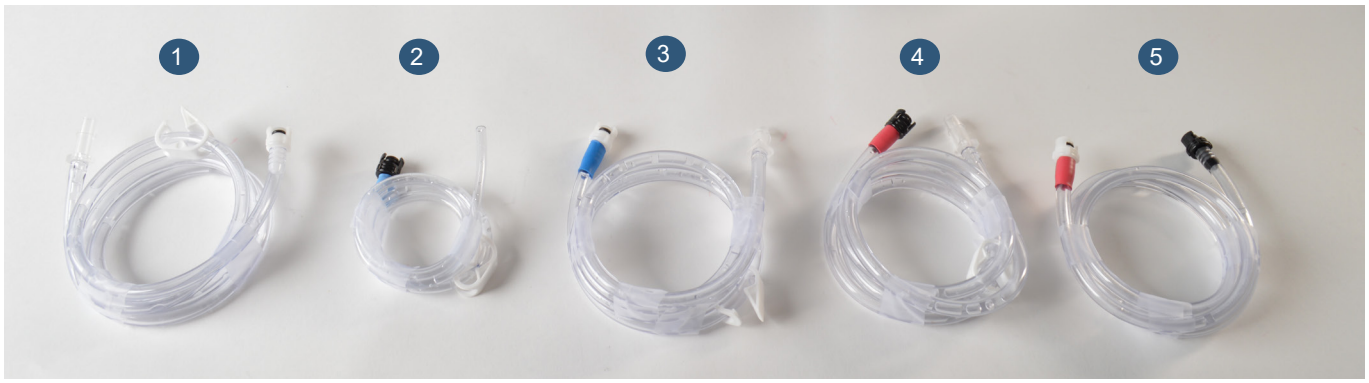
- Lift the arm from the box and remove the bag it is shipped in.
- Rest the arm on a bed or clean, flat surface.

## 3.2 PACKAGE CONTENTS

NOTE: Pictured above is the S405.100 (5Y Pediatric). The following package contents are the same for the S406.100 (1Y Pediatric) expect they will be of suitable size to represent a 1Y Pediatric.

1. Pediatric Patient Injection Training Arm
2. Arm Stand Assembly
3. Silicone Stand Cushion (installed on Arm Stand)
4. Blood dispensing bag
5. Blood Reservoir Stand Assembly
6. Filling and Drainage Kit
7. Blood Bag/Pump Accessories
8. Control box
9. Silicone Arm Shoulder Insert (1 installed, 1 spare)
10. Humeral I/O bone (1 installed, 6 spare)
11. Silicone arm skin (1 installed, 1 spare)
12. Replacement Vein Set
13. Artifical Blood Plus Additive Mix
14. Baby Powder
15. Funnel
16. Power supply with Power Cord

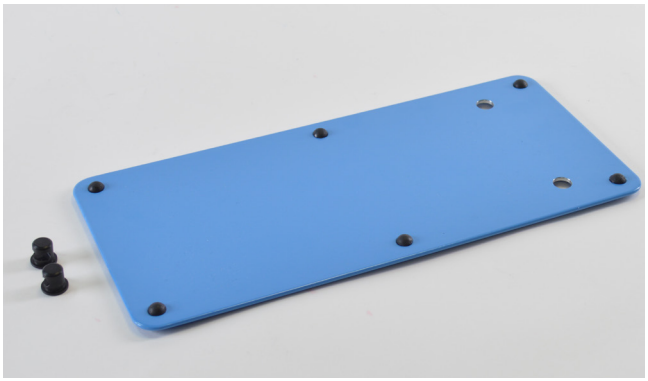
## 3.3 IDENTIFYING ARTERIAL AND VENOUS TUBING



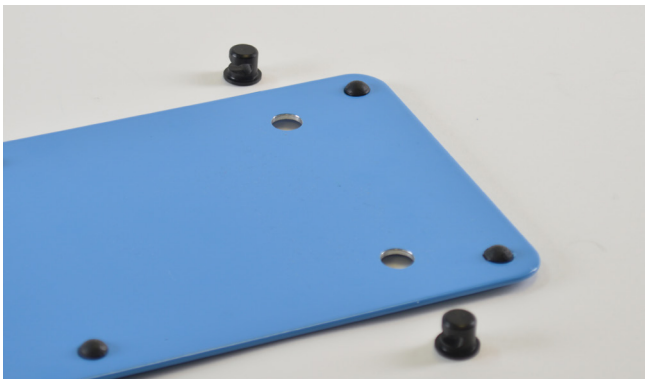

1. Pump Inlet Tubing
2. Venous Drain Tubing
3. Vein Inlet Tubing
4. Artery Oulet Tubing
5. Pump Outlet Tubing

## 3.4 BLOOD RESERVOIR STAND ASSEMBLY

1. Gather the blue metal base, blood stand wire frame, and 2 plastic blood stand brackets.

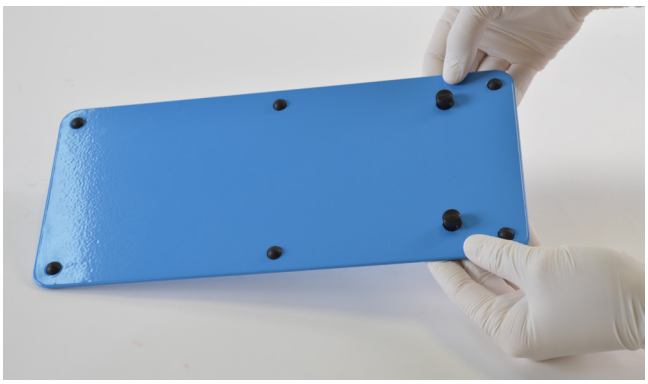


NOTE: The 2 plastic blood stand brackets have a hollowed out groove that will snap on to the wire frame. The plastic blood stand brackets will be inserted into the two larger punched out holes on the blue metal base..

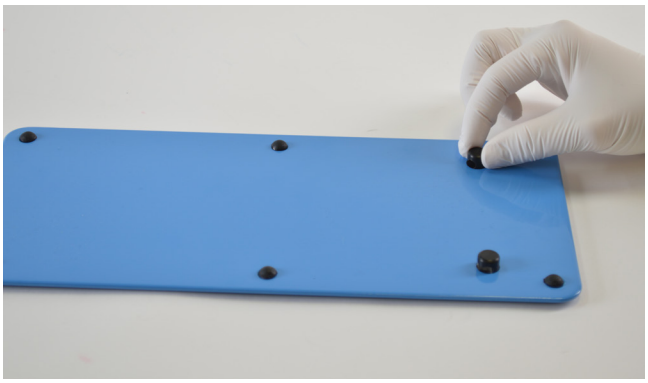


2. Insert both plastic blood stand brackets through the larger holes punched out on the blue metal base.

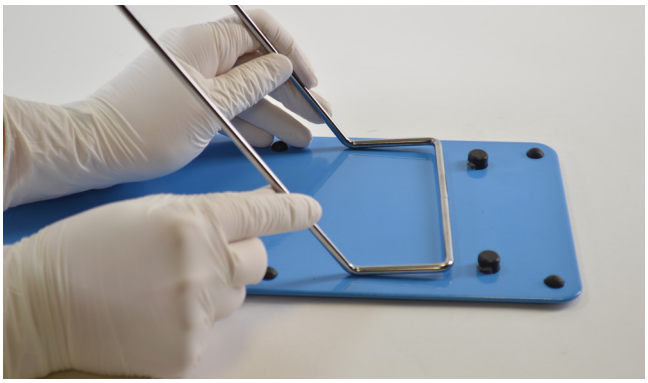
NOTE: It is easier to slip both of the plastic blood stand brackets into the large holes at once and then set the base on a flat surface.



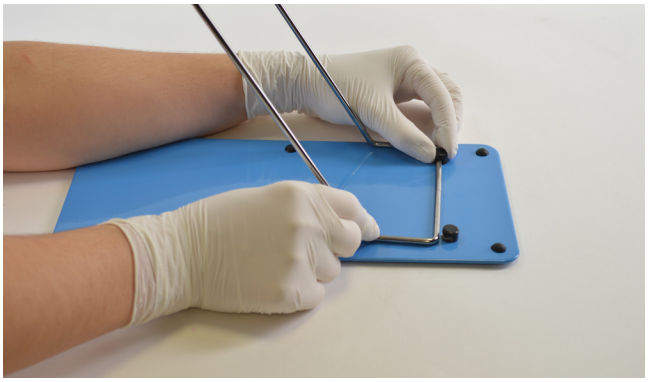
3. Rotate the plastic blood stand brackets so the hollowed out groove is pointing towards the longer length of the metal base.



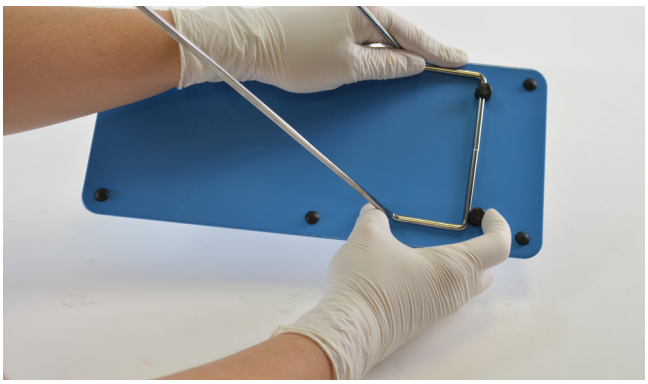
4. Align the blood stand wire frame to the plastic blood stand brackets.



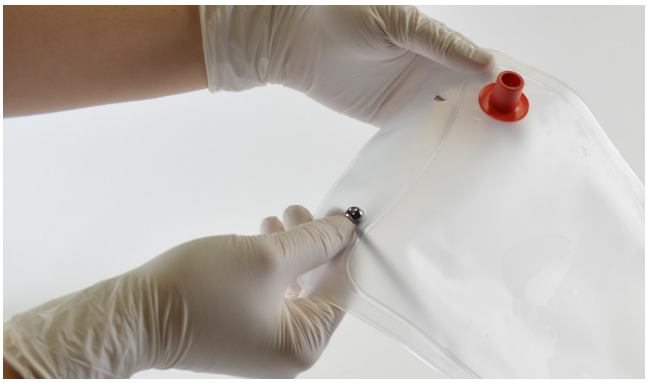
5. Use moderate force to snap the blood stand wire frame into the hollowed out grooves on the plastic blood stand brackets.



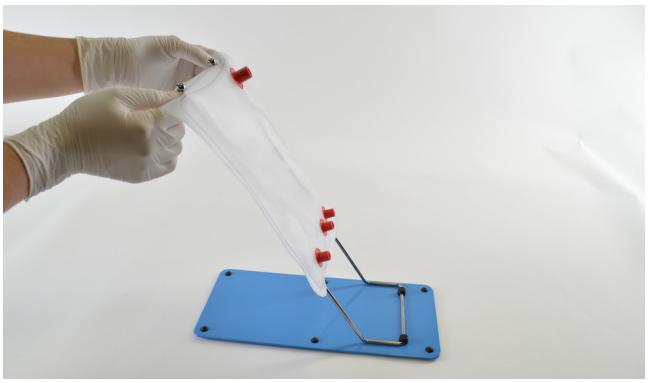
NOTE: It is helpful to brace your forefinger on the plastic blood stand brackets and use your thumb to push the blood stand wire frame into place.



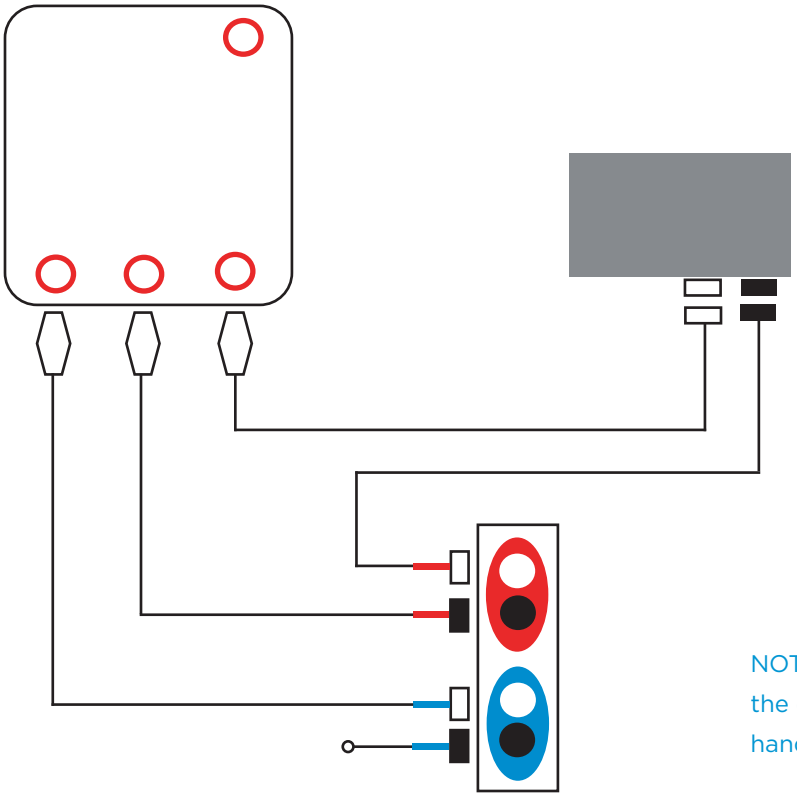
6. Align and push the small holes at the top of the blood dispensing bag on to the rounded metal knobs at the top of the blood stand wire frame.



NOTE: The blood bag will hang from the metal knobs at thetop of the wire frame.



## 3.5 SYSTEM CONNECTIONS QUICK GUIDE



| Legend | |
|---|---|
| | arterial connection |
| | venous connection |
| | fill/ inlet |
| | drain/ outlet |
| | waste container |

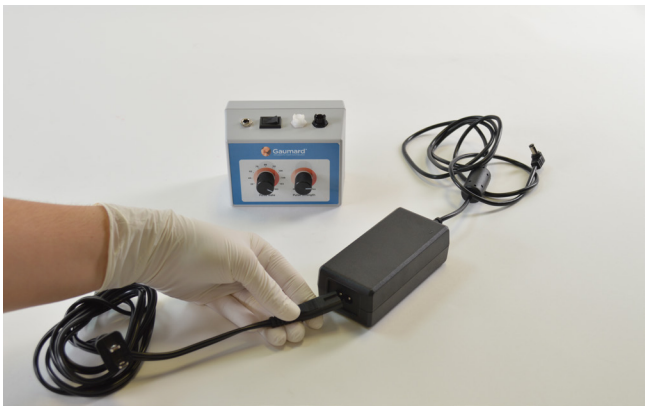
NOTE: This diagram is based upon having the orientation of the pediatric arm with the hand closest and pointing towards the user.

## 3.6 POWER SUPPLY FOR THE CONTROL BOX

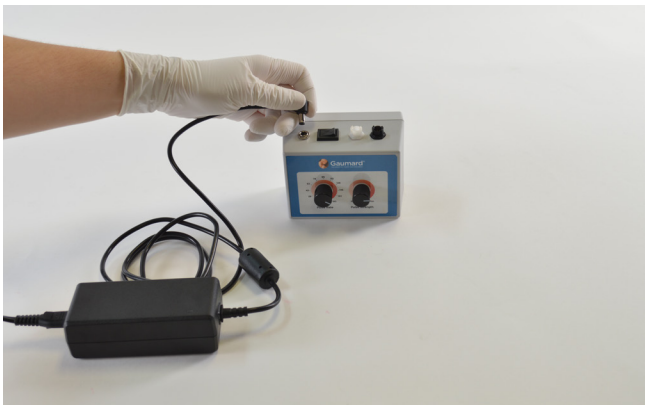
1. Gather the control box and the power supply with power cord.

   NOTE: Check that the power button is switch to OFF.

2. Connect the power cord to the power supply.



3. Plug the power cable into the control box and plug the other end into a wall outlet.



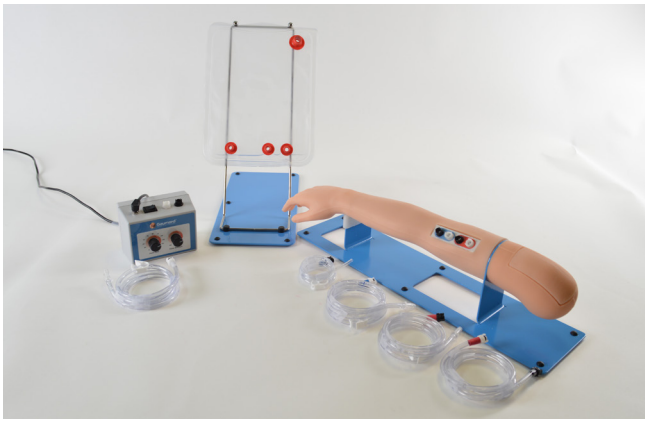
NOTE: If necessary, use one of the international adapters to plug the control box into a wall outlet.

# 4. WORKING WITH THE PEDIATRIC ARM

Please note the orientation of pediatric arm, control box, and blood dispensing bag in the following section. If you orient the items differently it is possible to connect the tubing into different ports on the blood dispensing bag.

## 4.1 CONNECTING THE PEDIATRIC ARM

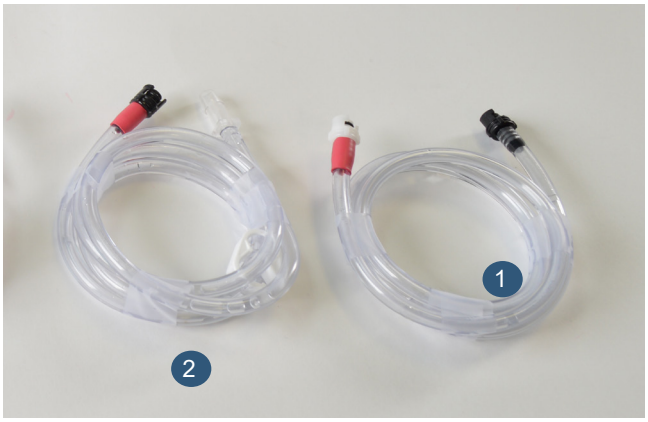
1. Gather the pediatric arm, tubing, blood dispensing bag assembly, and control box.



### Arterial Connections

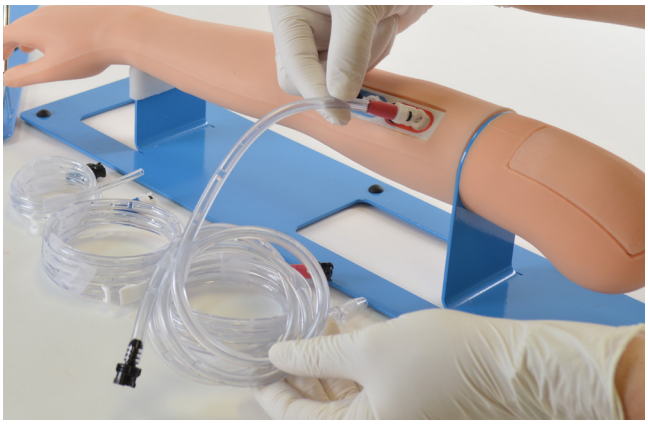
1. Gather the two tubes that are outlined in red.

   NOTE: The tubing for the pediatric arm is color coded. The tubes outlined in red represent the arterial network. They will be connected to corresponding ports on the pediatric arm that are also outlined in red. The first arterial tube is the pump outlet tubing. It has one end with a white luer lock outlined in red and the other end is a black luer lock. The second arterial tube is the artery outlet tubing. It has one end with a black luer lock outlined in red and the other end is a barb connector.

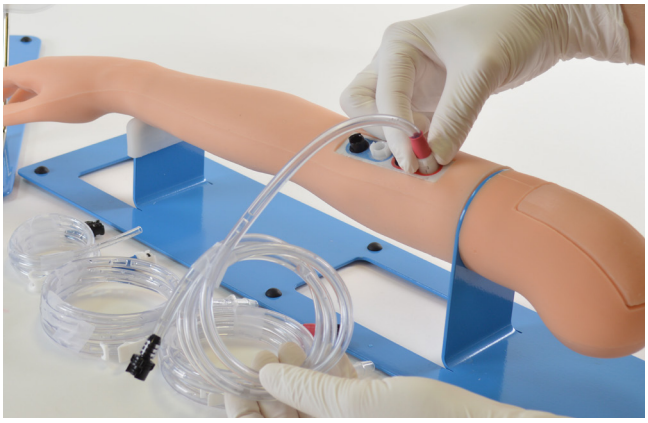



2. Using the first arterial (pump outlet) tube, connect the white luer lock outlined in red to the white port outlined in red on the pediatric arm.

   NOTE: Match the color of the connecting tube to the port it is being connected to.

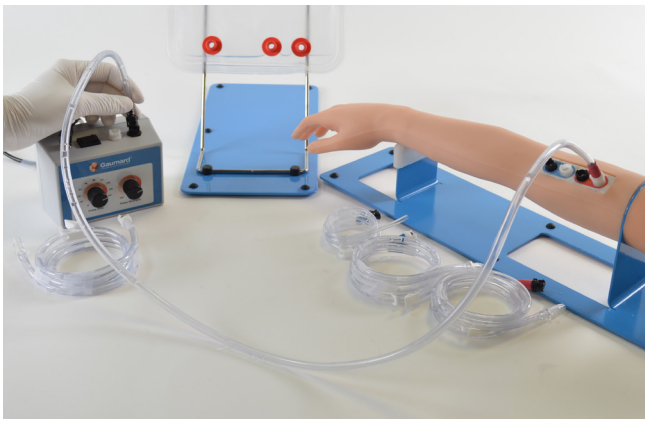


3. Secure the luer lock connection by twisting clockwise until you hear a click.



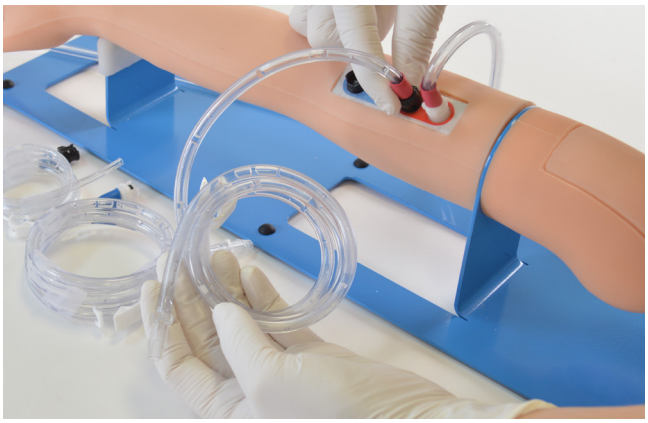
4. Connect and secure the black luer lock end of this tube to the black port on the control box.

   NOTE: Match the color of the connecting tube to the port it is being connected to.



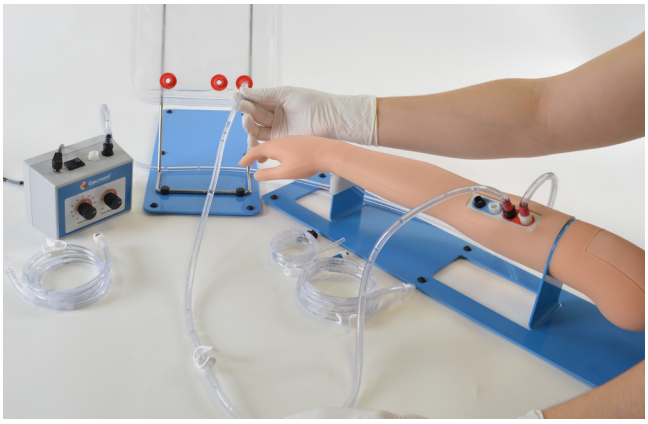
5. Using the second arterial (artery outlet) tube, connect and secure the black luer lock outlined in red to the black port outlined in red on the pediatric arm.

   NOTE: Match the color of the connecting tube to the port it is being connected to.

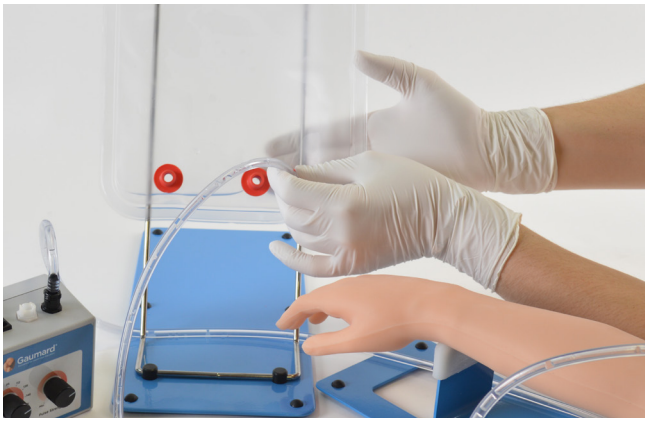


6. Connect the barb connector end of this tube to one of the bottom ports on the blood dispensing bag.

   NOTE: It is recommended to connect this end of the tube to the bottom right port of the blood dispensing bag.



NOTE: Push the barb connector past its barb so that the bag does not leak when filled with fluid. To facilitate this put your hand behind the bag to help when you are pushing the connector in.



## Venous Connections

1. Gather the two tubes outlined in blue.

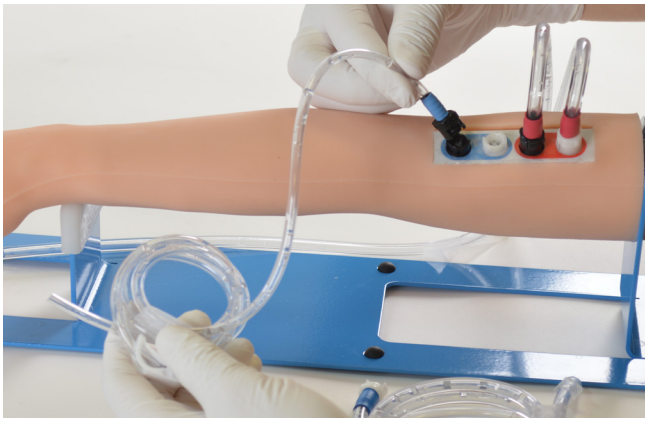
   NOTE: The tubing for the pediartic arm is color coded. The tubes outlined in blue represent the venous network. They will be connected to corresponding ports on the pediartic arm that are also outlined in blue. The first venous tube is the vein inlet tubing. It has one end with a white luer lock outlined in blue and the other end is a barb connector. The second venous tube is the venous drain tube. It has one end with a black luer lock outlined in blue and the other end is open.


2. Set aside the first venous (vein inlet) tube. It is the tube with the white luer lock outlined in blue on one end and a barb connector on the other end.

   NOTE: This tube will get connected after the system is primed for filling the system.

3. Using the second venous (venous drain) tube, connect and secure the black luer lock outlined in blue to the corresponding port on the pediatric arm.

   NOTE: Match the color of the connecting tube to the port it is being connected to.



4. Place the other end of this tube into a waste collection container.

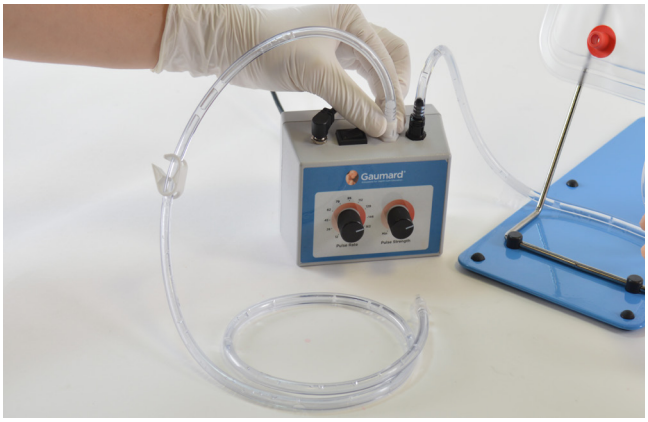
   NOTE: Leave the tube unclamped.

## Control Box Connection

1. Get the pump inlet tubing that has a white luer lock on one end and a barb connector on the other.

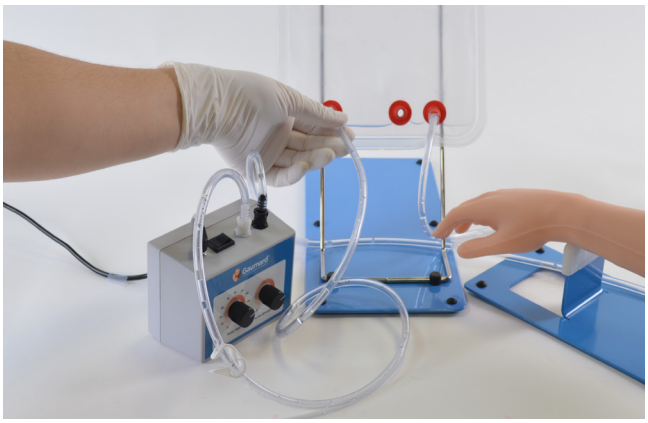
2. Connect and secure the white luer lock to the white port on the control box.

   NOTE: Match the color of the connecting tube to the port it is being connected to.

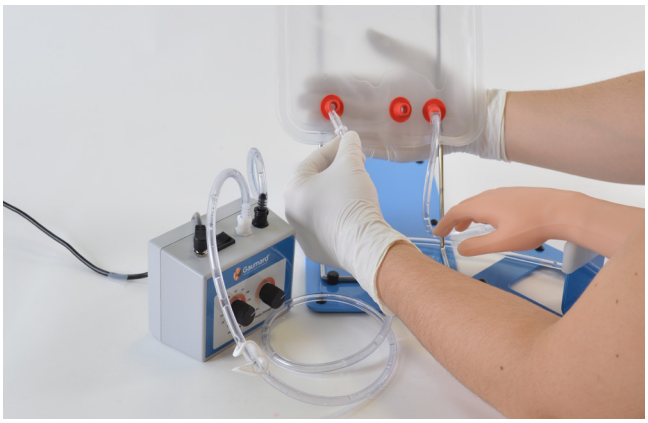


3. Connect the barb connector end to a port on the bottom of the blood dispensing bag.

   NOTE: It is recommended to connect this end to the bottom left port on the blood dispensing bag.



   NOTE: Push the barb connector past its barb so that the bag does not leak when filled with fluid. To facilitate this put your hand behind the bag to help when you are pushing the connector in.



## 4.2 PREPARING ARTIFICIAL BLOOD PLUS ADDITIVE MIX

**WARNING: The Artificial Blood Plus Additive Mix is ONLY for use in the S405.100, S406.100, and S408.100 Gaumard products. Using this Artifical Blood Plus Additive Mix with any other Gaumard product is not recommended and may cause vasculature blockage.**

1. Gather the bottle of Artificial Blood Plus Additive Mix, a gallon jug, and water to mix.

   NOTE: If you have available a magnetic plate and stirrer this is optional equipment that can assist in the mixing of this solution.

2. Alternate between adding the Artificial Blood Plus Additive MIx powder and water in the jug. Shake between each addition to aid dissolving of the powder.

   NOTE: If using a magnetic plate and stirrer, simply alternate between adding the Artifical Blood Pluss Additive Mix powder and water but allow time in between so the magnetic stirrer can mix the solution.

3. Add water to the jug, cap the jug, and shake to dissovle the Artificial Blood Plus Additive Mix.

   NOTE: It may take as long as 24 hours for any residual lumps in the mixture to completely dissovle if mixing the solution by hand. If using a magnetic plate and stirrer, leave the solution stirring for as long as 5 hours to completely dissolve.

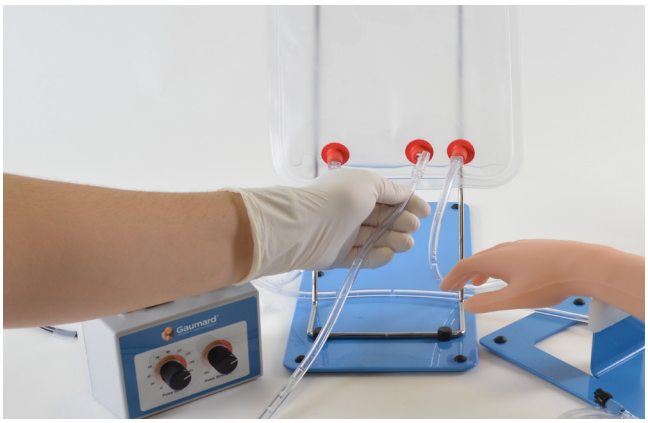
# 4.3 FILLING THE PEDIATRIC ARM

## Preparing the Blood Dispensing Bag

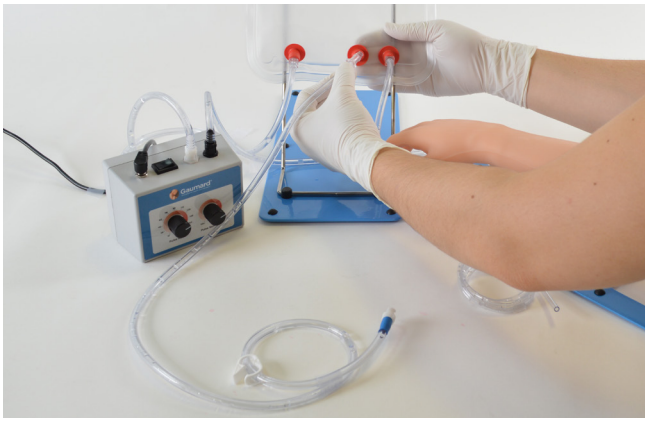
1. Gather the venous (vein inlet) tube that was set aside, funnel, black rubber stopper, and prepared artificial blood concentrate.

   NOTE: A plastic water bottle works really well for portioning smaller batches of the blood concentrate. The size and weight of the water bottle also makes it easy to pour into the blood dispensing bag.

2. Connect the barb connector end of the tube to the middle port on the bottom of the blood dispensing bag.

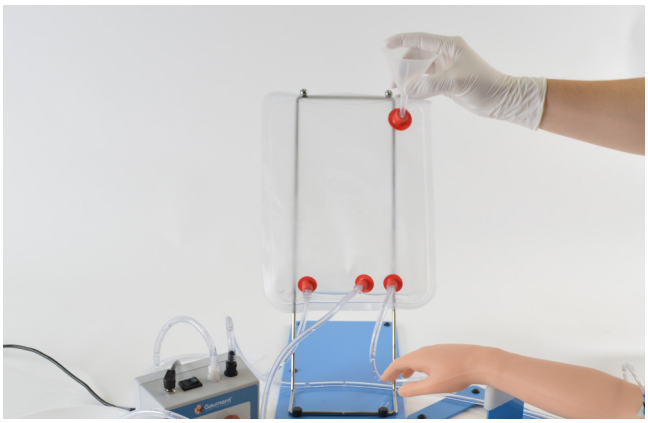


   NOTE: Push the barb connector past its barb so that the bag does not leak when filled with fluid. To facilitate this put your hand behind the bag to help when you are pushing the connector in.



3. Clamp this tube and place in a waste container.

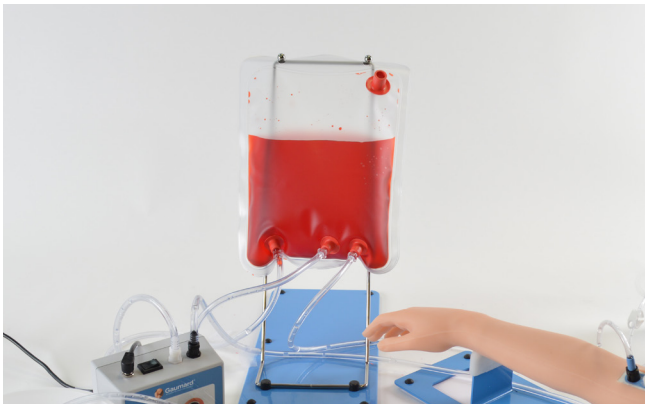
4. Place the funnel in the top right port of the blood dispensing bag.



5. Pour the prepared artificial blood concentrate into the blood dispensing bag.

NOTE: Follow the instructions on the artifical blood concetrate bottle to mix with water. It is easier to fill the blood dispensing bag when it is taken off the wire frame and filled.

NOTE:The blood dispensing bag can hold 1.5 Liters of fluid. Fill the blood dispensing bag with a minimum of 750 mL and place it back on to the wire frame. If there is not sufficient fluid in the blood dispensing bag there may not be noticeable flashback when performing procedures with the pediatric arm.



6. Place the black rubber stopper in the upper right port of the blood dispensing bag.

## Priming the Pediatric Arm

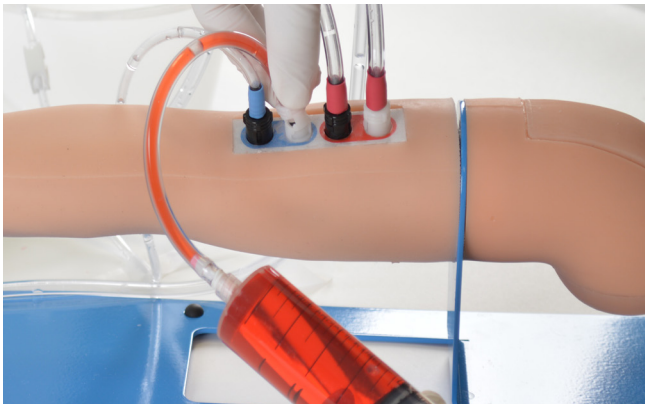
1. Gather the fill syringe kit and prepared artificial blood concentrate.

   NOTE: The artifical blood shown here is already mixed with water.

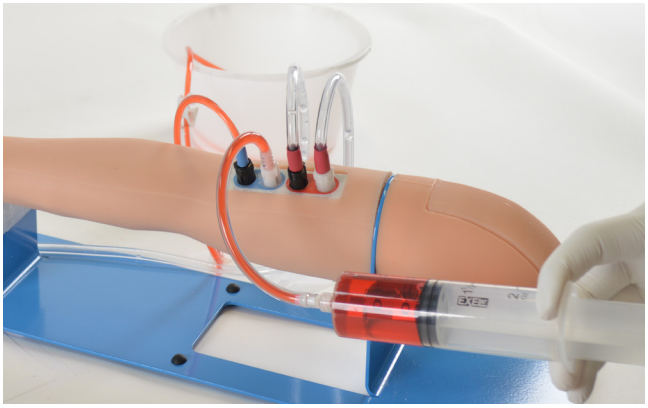
2. Assemble the fill syringe by screwing on the fill connector to the tip of the syringe.

3. FIll the syringe with artificial blood concentrate.

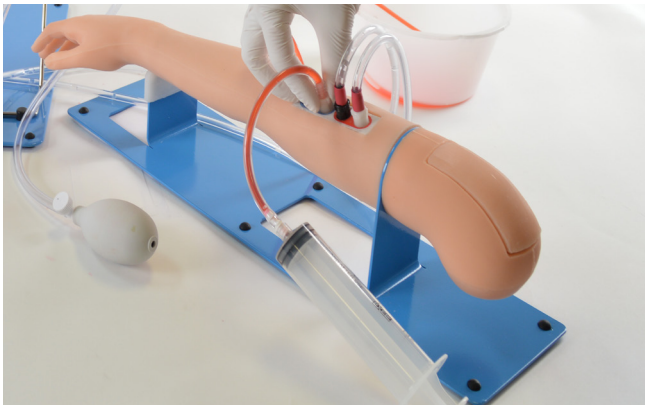
4. Connect and secure the syringe to the white venous port outlined in blue on the pediatric arm.



5. Push the syringe until the venous drain runs with blood and minimal air bubbles.



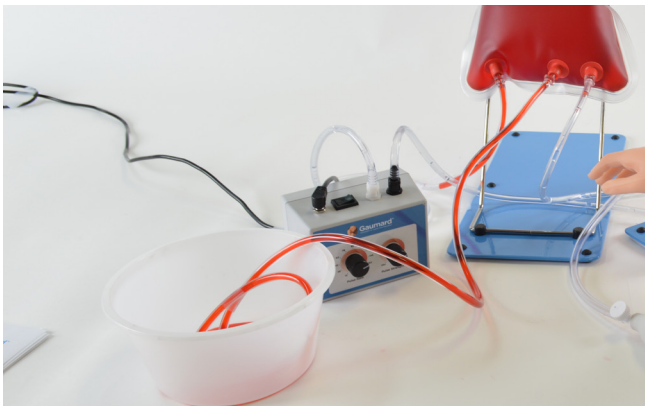
6. Disconnect the syringe from the venous port outlined in blue on the pediatric arm.



## Connecting the Venous (vein inlet) tube

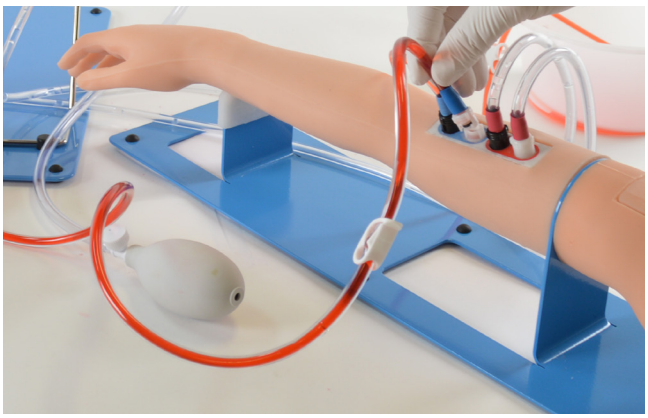
1. Unclamp the venous (vein inlet) tube that was previously set aside in the waste collection container.

2. Allow the artifical blood to run from the blood dispensing bag through this tube until the tube is completely filled and there are minimal air bubbles.

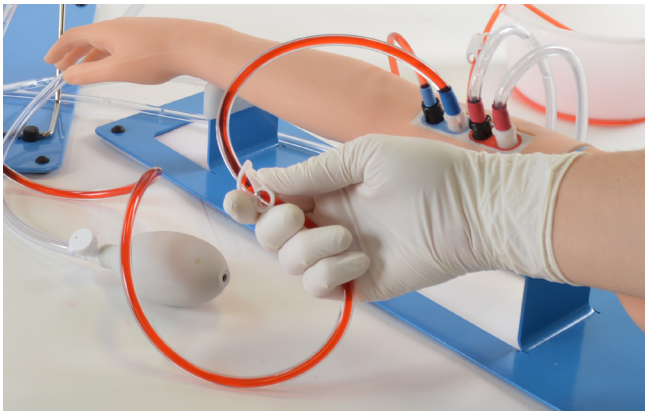


3. Clamp the tube so blood does not drip when you connect it to the pediatric arm.

4. Connect the venous (vein inlet) tube to the venous port outlined in blue on the pediatric arm.

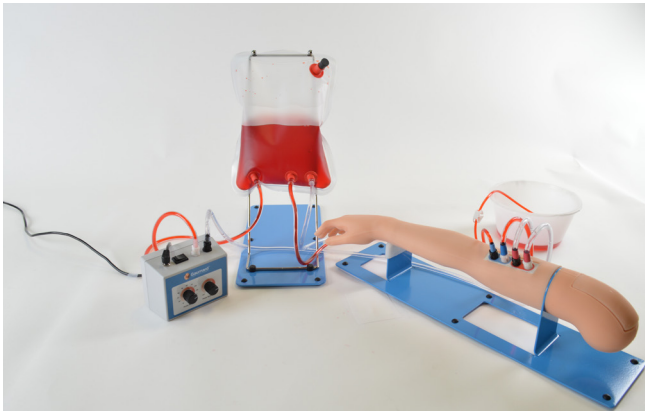


5. Unclamp the tube.

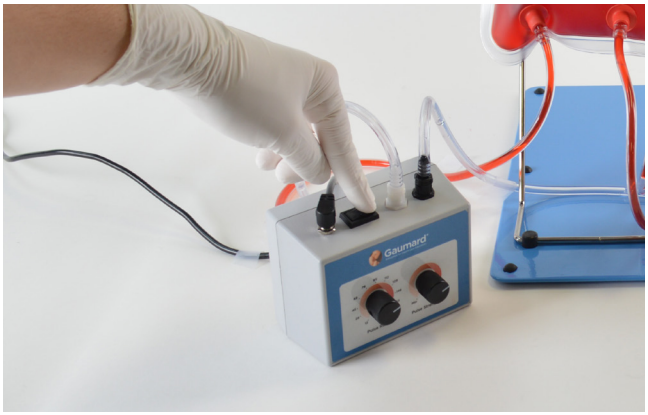


## Turning the system ON

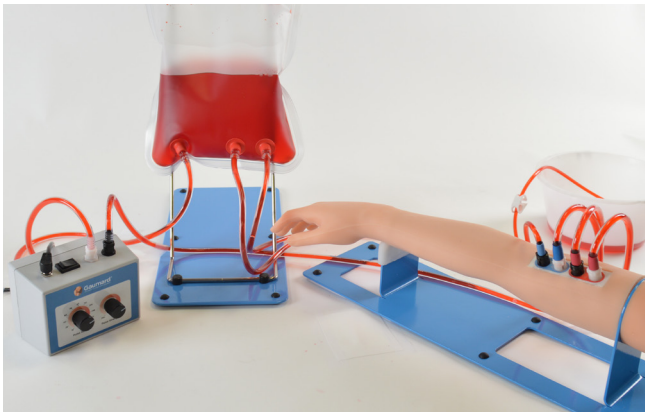
1. Unclamp all tubing that is connected to the system. Having any of the tubing clamped while turning the system ON to fill the system can increase pressure to the vasculature and potentially damage the control box if the pressure build up is too great.



2. Press the ON button on the control box.



3. Allow the system to fill with the artifiical blood from the blood dispensing bag until all tubing runs red.



## 4.4 DEVICE SIZE RECOMMENDATIONS

### S405.100

| Procedure | Device Size |
|---|---|
| Needle Stick | 22 G or smaller |
| Infusion of large amounts of fluid | 18-22 G |
| General infusion | 22 G |
| Subcutaneous injection | 25-27 G |
| Intradermal injection | 26 G |
| Intramuscular injection | 20-23 G |
| Humeral IO | 15 mm |

### S406.100

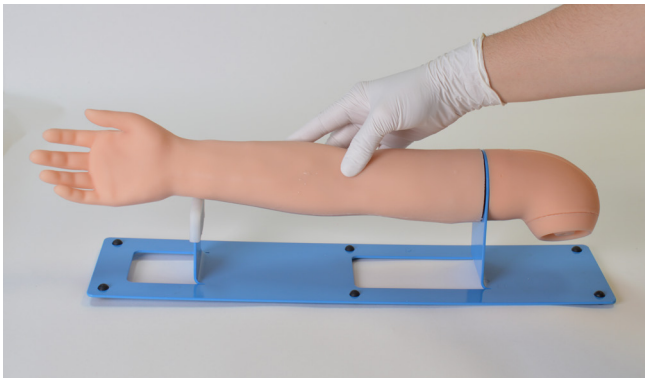
| Procedure | Device Size |
|---|---|
| Needle Stick | 22 G or smaller |
| Infusion of large amounts of fluid | 22-24 G |
| General infusion | 24 G |
| Intradermal injection | 26 G |
| Intramuscular injection | 20-23 G |
| Humeral IO | 15 mm |

# 4.5 POSSIBLE IV TRAINING PROCEDURES

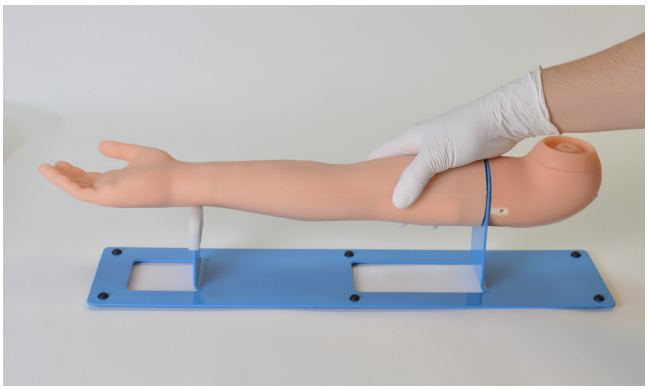
## Rotate the Arm to Locate Veins & Arteries

1. Grasp the pediatric arm and rotate to present the ventral side of the arm.

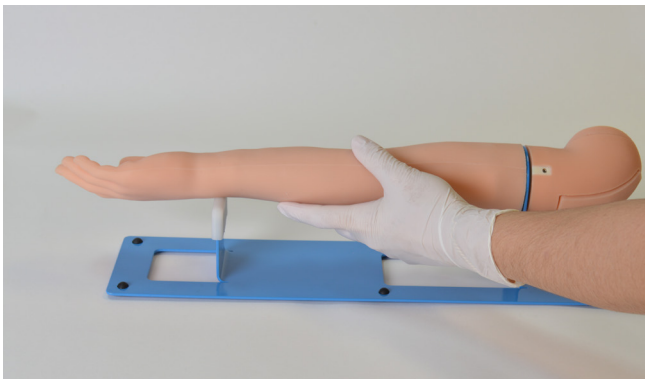
   NOTE: The ventral side of the S405.100 pediatric arm present the cephalic and basilic venous networks, the median cubital vein, and the radial artery (for arterial blood draw). The S406.100 only has ulnar and cubital venipuncture.



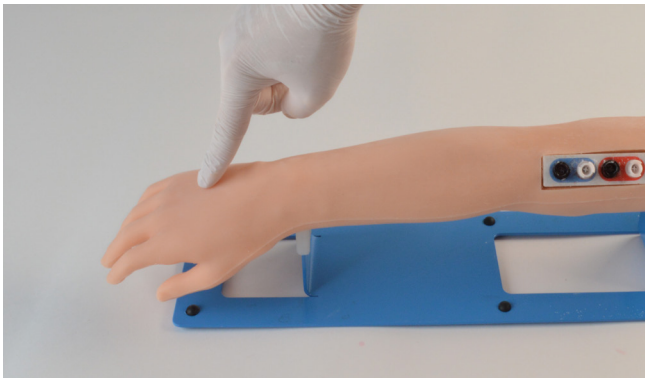
2. When finished rotating the pediatric arm allow it to rest on its stand.



3. Grasp the pediatric arm and rotate to present the dorsal side of the arm.



   NOTE: The dorsal side of the pediatric arm present the dorsal venous network, the cephalic vein, and the basilic vein.



## Simulate Bulging or Collasped Veins & Arteries

1. Remove the black rubber stopper from the upper right port on the blood dispensing bag.

2. Attach the blood bag pessurizing assembly to the blood dispensing bag.

3. Squeeze the bulb of the pressurizing assembly to increase pressure to the blood dispensing bag which in effect increases the pressure in the system's vasculature.

   NOTE: This will simulate bulging veins and/ or arteries for blood collection exercises.

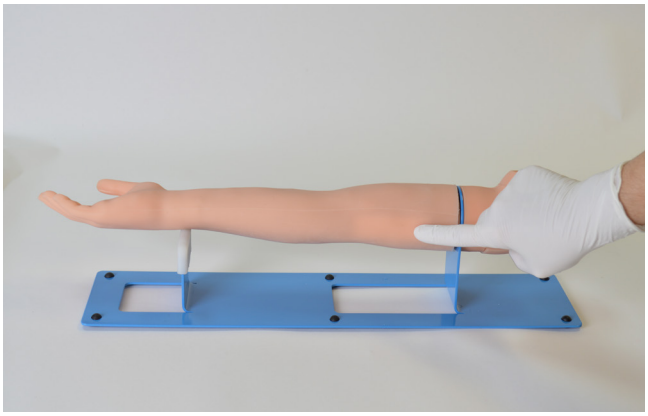
4. Twist the knob on the squeeze bulb of the pressurizing assembly to release the pressure in the blood dispensing bag which in effect decreases the pressure in the system's vasculature.

   NOTE: This will simulate collapsed veins and/ or arteries for blood collection exercises.

## Locate the Subcutaneous Injection Site

The S405.100 pediatric arm has one subcutaneous insert site on the lateral side of the upper arm.

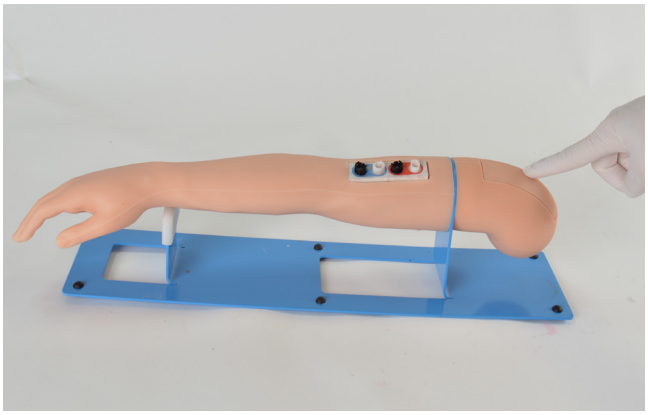
NOTE: The subcutaneous site is for placement only. It cannot hold or absorb large amounts of fluid. The S406.100 pediatric arm does not have a subcutaneous injection site.



## Locate the Intramuscular Injection Site

The pediatric arm has one arm insert assembly for intramuscular injection on the deltoid of the arm.

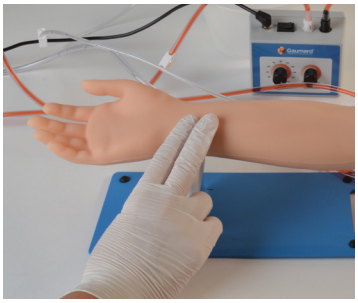
NOTE: The intramuscular site is for placement only. It cannot hold or absorb large amounts of fluid.



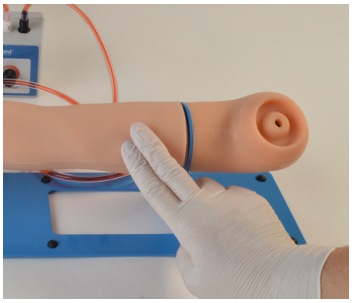
## 4.6 PULSE PALPATION

Radial and brachial pulse palpation is supported.

### Radial



### Brachial

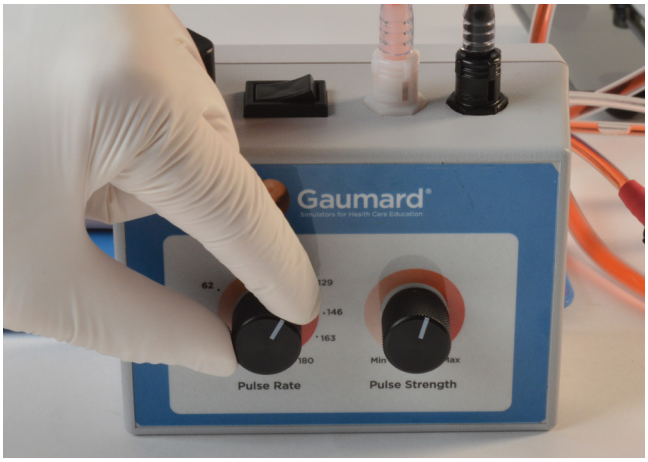


## 4.7 CHANGING PULSE RATE AND PULSE STRENGTH

### Pulse Rate

1. On the control box, turn the "Pulse Rate" knob clockwise to increase or counter-clockwise to decrease the pulse rate.

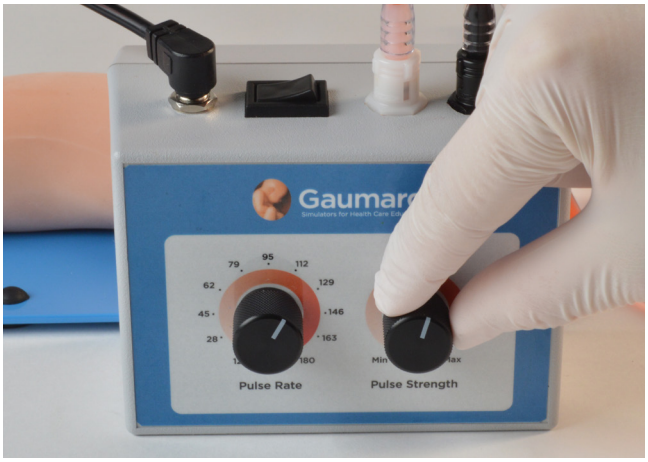
   NOTE: The pulse rate can be set bewteen 12-180 bpm. If a pulse rate of zero is desired, turn off the control box.




### Pulse Strength

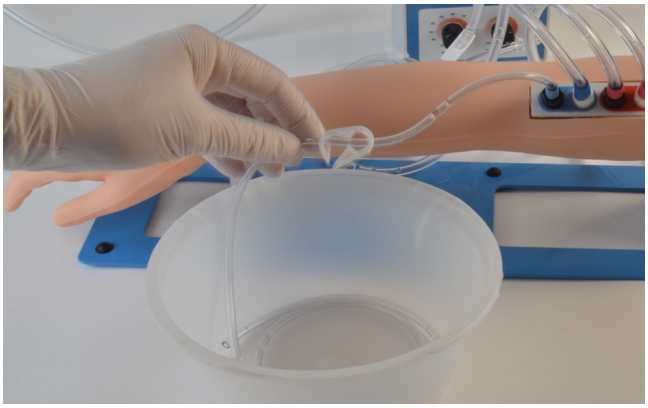
1. On the control box, turn the "Pulse Strength" knob clockwise to increase or counter-clockwise to decrease the pulse strength.

   NOTE: The pulse strength varies on a scale between 'Min' and 'Max'.



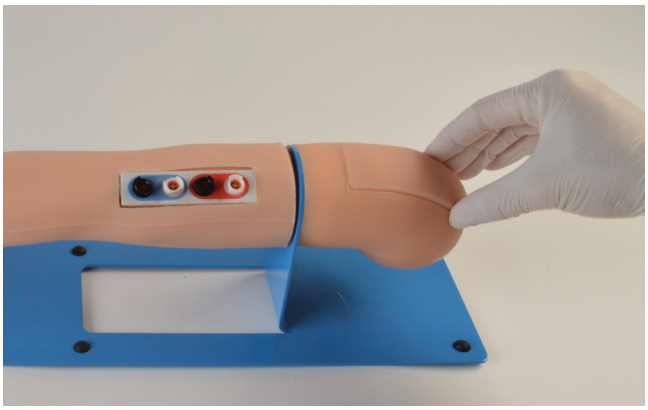
## 4.8 HUMERAL IO ACCESS AND INFUSIONS

1. Unclamp the venous drainage tube. Leaving the venous drainage tube clamped while the system is ON can cause damage if too much pressure is built up.



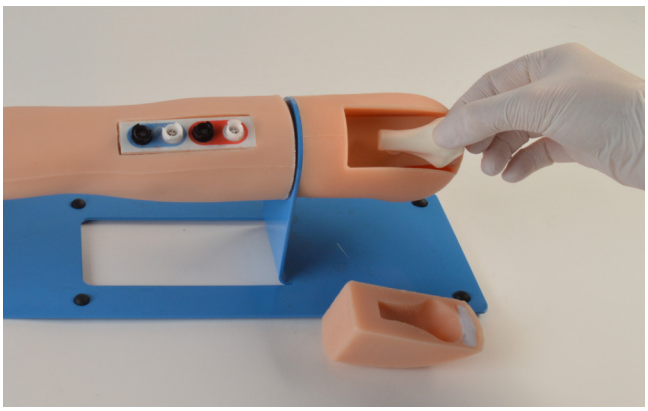
2. Perform the IO procedure on the humerus of the pediatric arm using the appropriate medical equipment.

   NOTE: Recommended humeral IO needle is 15 mm for both the S405.100 and S406.100.



3. Refer to section "5. Routine Maintenance" on page 38 for instructions on how to replace the humerous bone after an IO procedure.

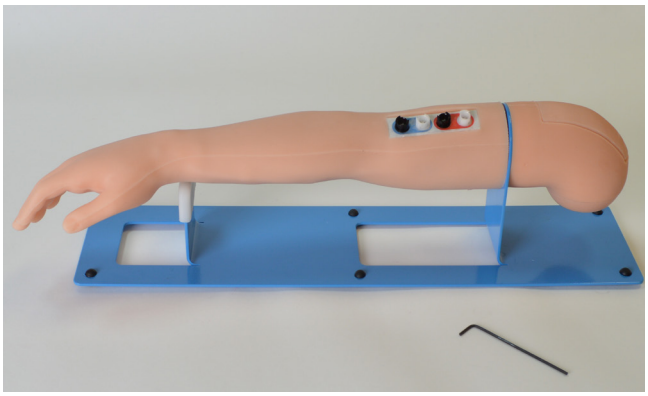
   NOTE: It is recommended to replace the humerus bone after it has been punctured. If the humerus is not replaced and the pediatric arm is in use the pediatric arm may leak from the puncture on the bone.



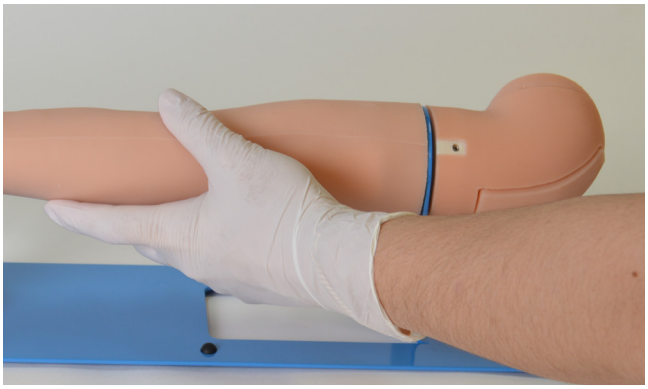
# 4.9 STAND ALONE CONFIGURATION

## Disconnecting the Pediatric Arm

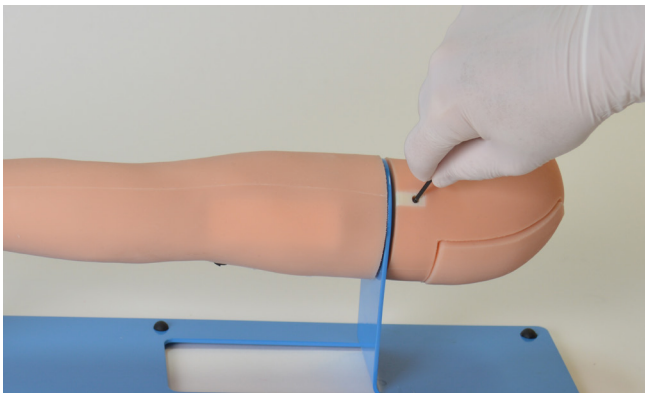
1. Gather the pediatric arm and the allen key hex.



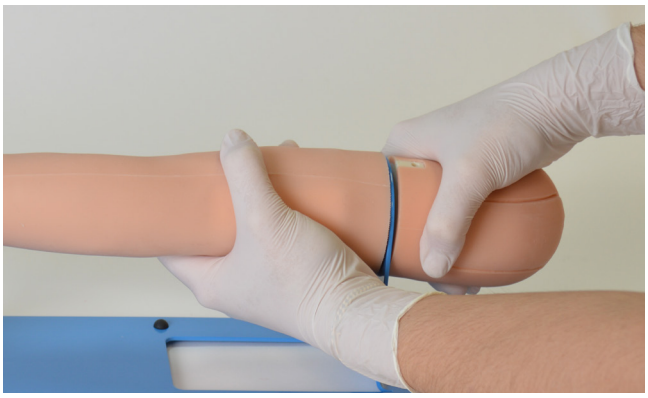
2. Rotate the pediatric arm to see the screw in the upper shoulder.



3. Use the allen key hex to loosen the screw in the upper shoulder.

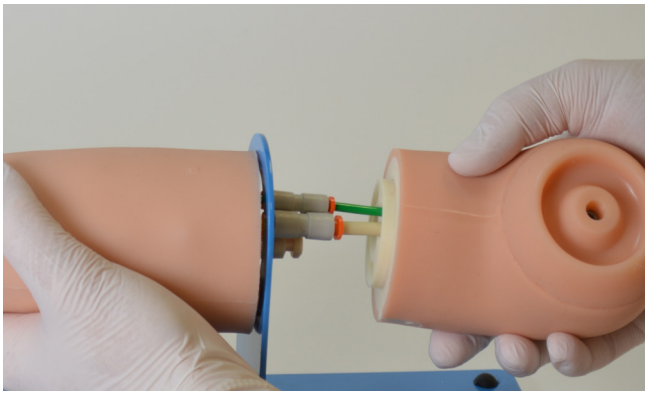


4. Brace the arm using two hands to twist the two halves.

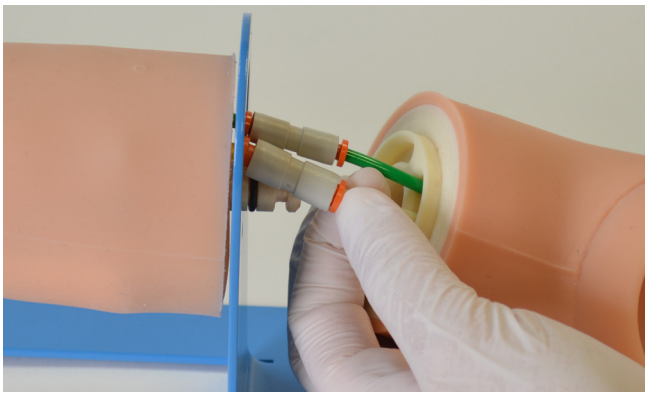


5. Gently pull apart.

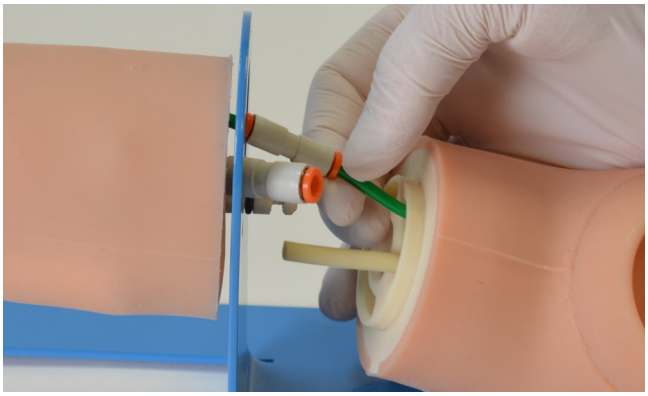
   NOTE: Do not pull too hard. If you do it may rip out the connections.



6. Disconnect the tubing by pressing the orange part of the quick connector inward like a button and pulling the tube outward.



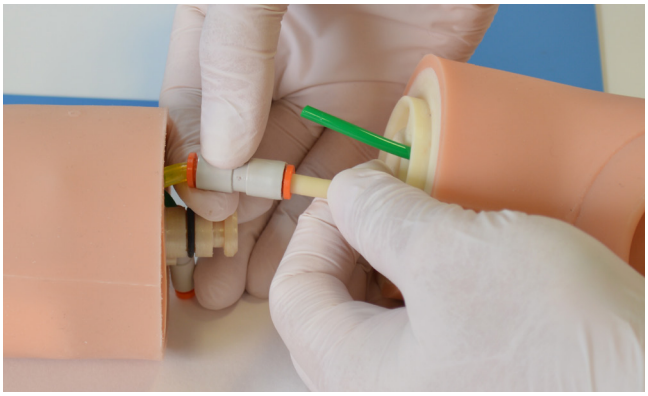
   NOTE: Do the same thing to disconnect the other tube.



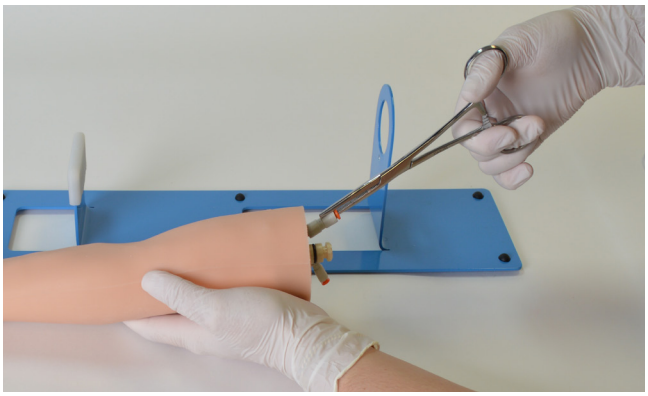
7. Remove the arm from the stand.

## Reconnecting the Pediatric Arm

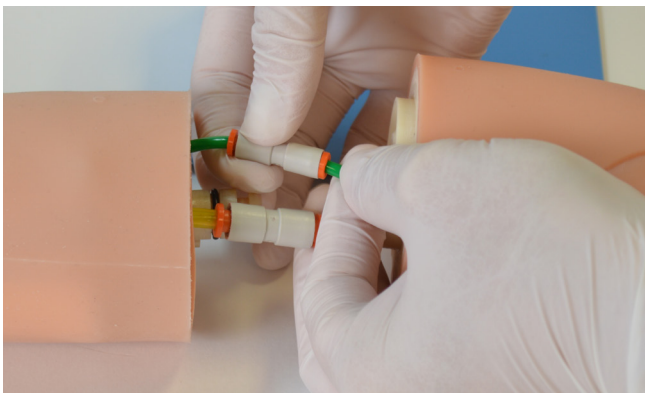
1. Reconnect the off-white tube from the shoulder to the quick connector in the arm that is attached to a yellow hose. Reconnect by simply pushing the hose into the quick connector.



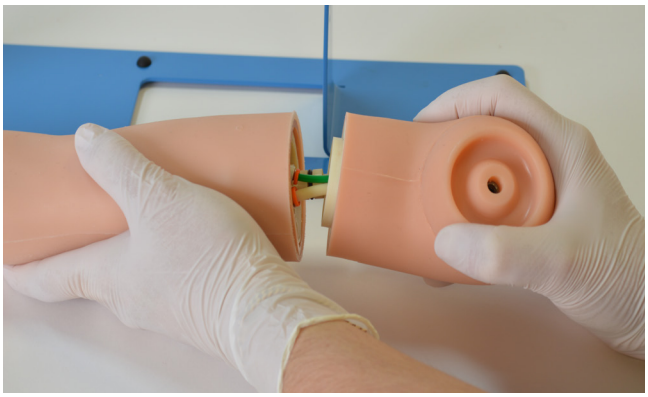
NOTE: If any of the quick connectors are lost inside the pediatric arm use a pair of hemostats or long nosed pliers to fish them out.



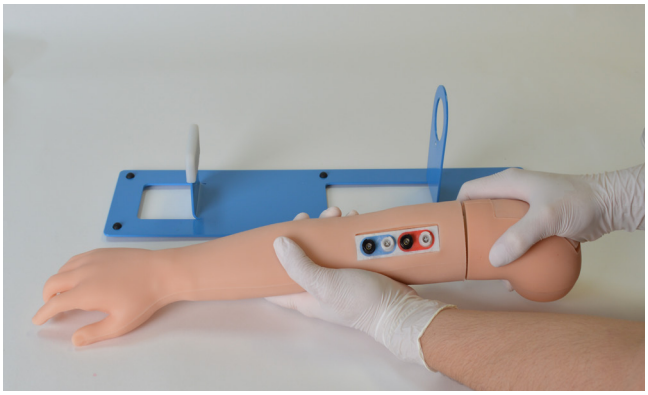
2. Reconnect the green tube from the shoulder to the quick connector in the arm that is attached to a green tube. Reconnect by simply pushing the hose into the quick connector.



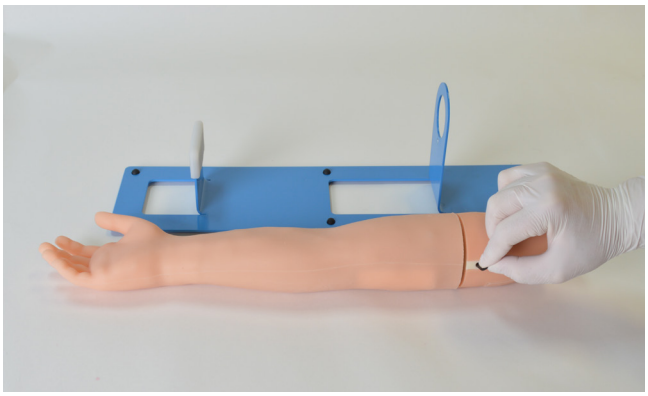
3. Aligh the shoulder and arm back together.



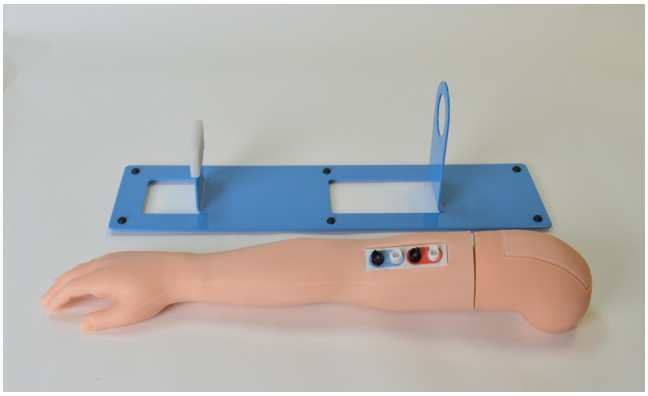
4. Twist the shoulder and arm halves so that they are secure.



5. Tighten the screw in the shoulder with the allen hex wrench.



NOTE:The arm is now ready for stand alone use.



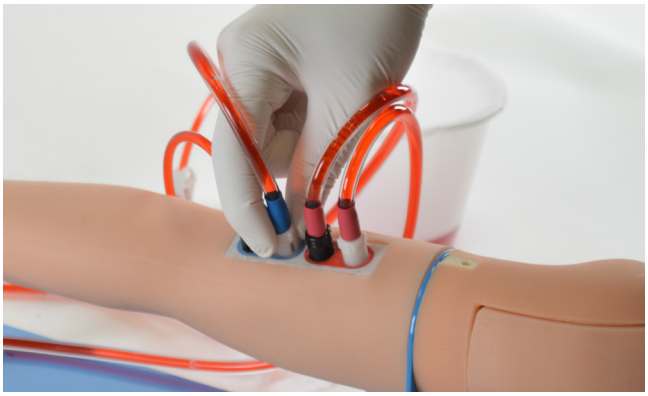
# 5. ROUTINE MAINTENANCE

## 5.1 CLEANING THE SYSTEM

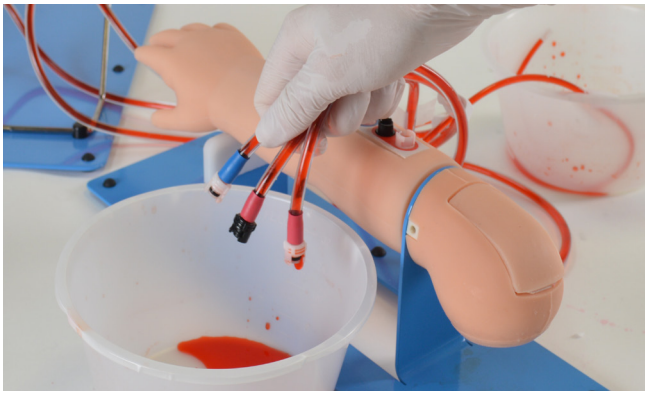
It is recommended to clean the vasculature system at the end of the simulation day to prevent clogging of the system.

### Flushing the Pediatric Arm - Venous Network

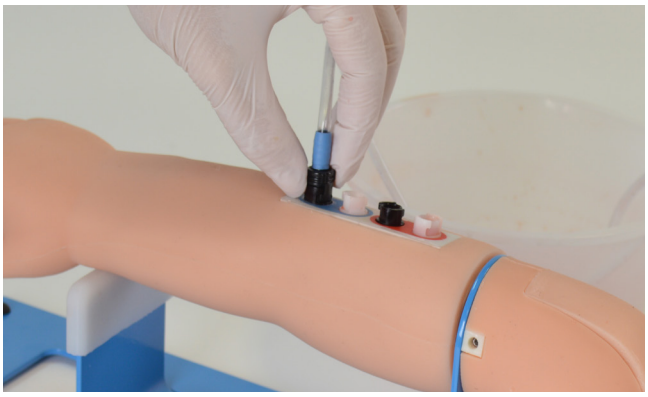
1. Disconnect all tubing from the pediatric arm except the venous drain that has the black luer lock connection outlined in blue.



NOTE: Clamp the disconnected tubes to keep the blood from spilling and place them into a waste colletion container.

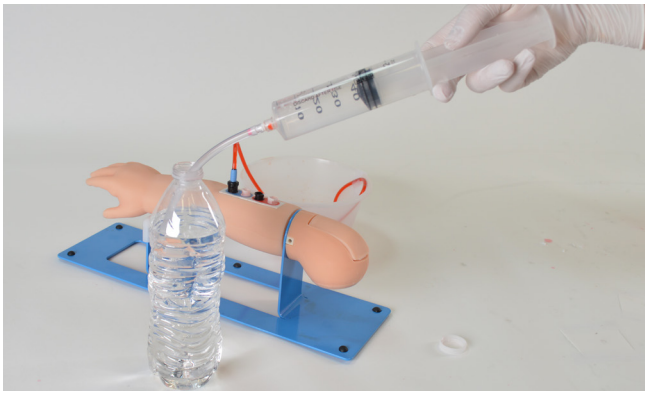


NOTE: Leave the venous drain (black luer lock connection outlined in blue) connected to the newborn arm. We will use this to flush the system of its artificial blood.

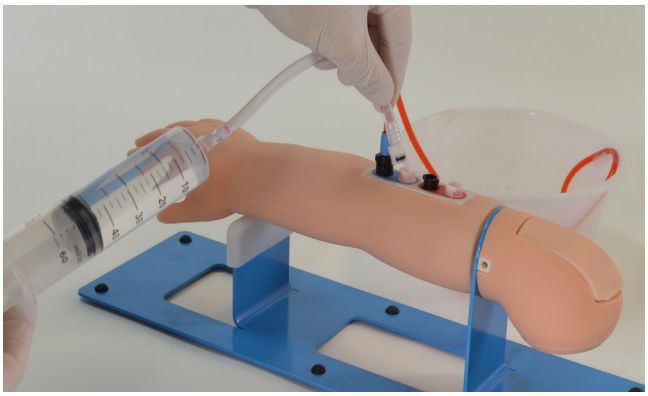


2. Use clean distilled water and fill the syringe.

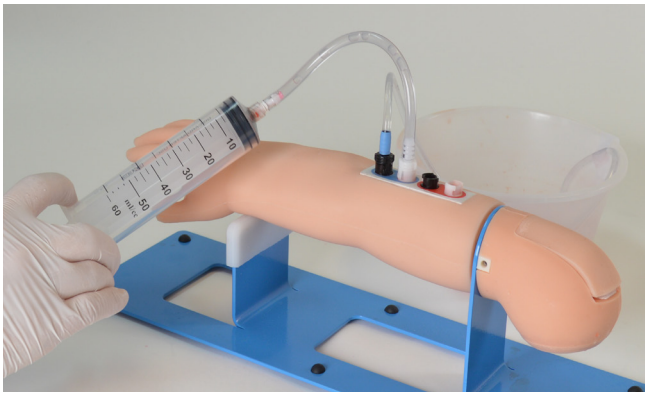
   NOTE: Do not mix alcohol into the distilled water. Flush the veins with pure distilled water.



3. Connect and secure the syringe to the white luer lock venous connection outlined in blue on the pediatric arm.

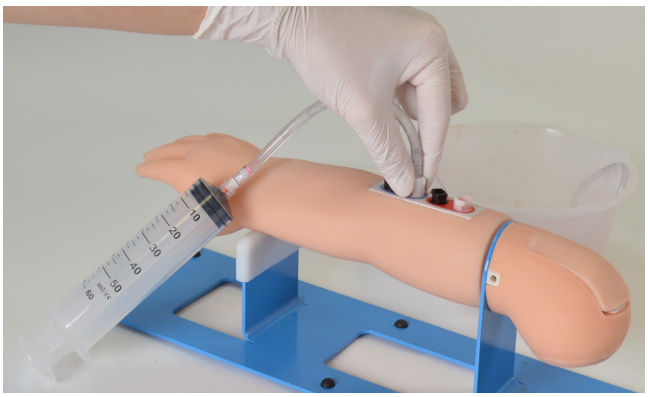


4. Push the distilled water through the pediatric arm until the drain runs clear.

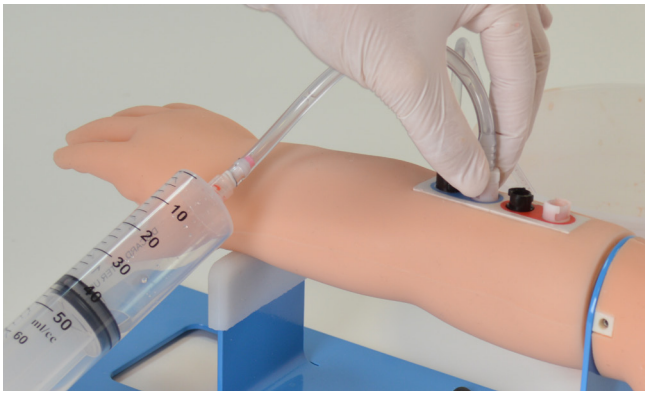


5. Disconnect the syringe from the white luer lock venous connection outlined in blue and fill the syringe with air.

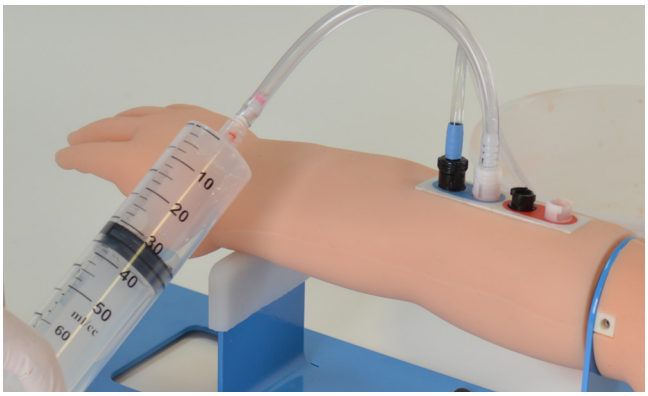
   NOTE: If there is left over distilled water in the syringe empty the syringe and then fill it with air.



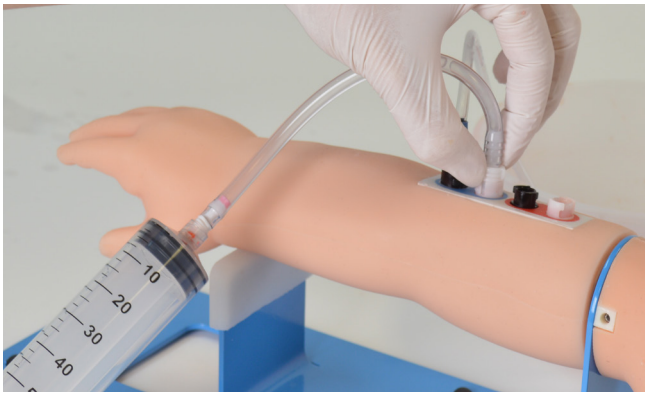
6. Connect and secure the syringe back to the white luer lock venous connection outlined in blue on the pediatric arm.

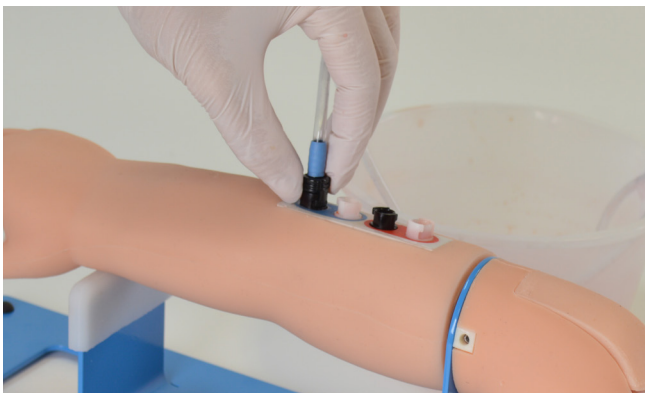


7. Push the air through the venous network to purge any remaining fluid out through the drain.



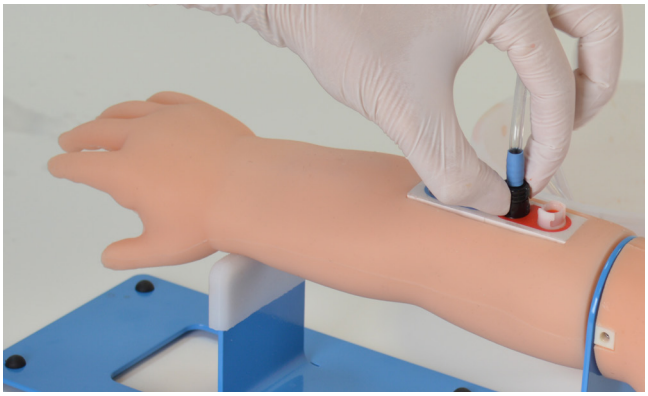
8. Diconnect the syringe and drain from the venous ports on the pediatric arm.





## Flushing the Pediatric Arm - Arterial Network

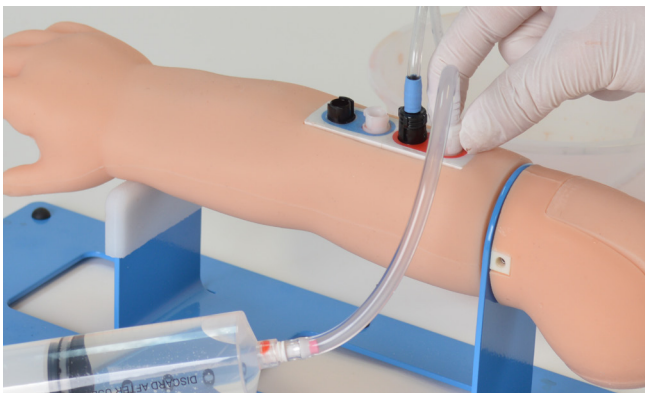
1. Connect and secure the drain to the black luer lock arterial port outlined in red on the pediatric arm.



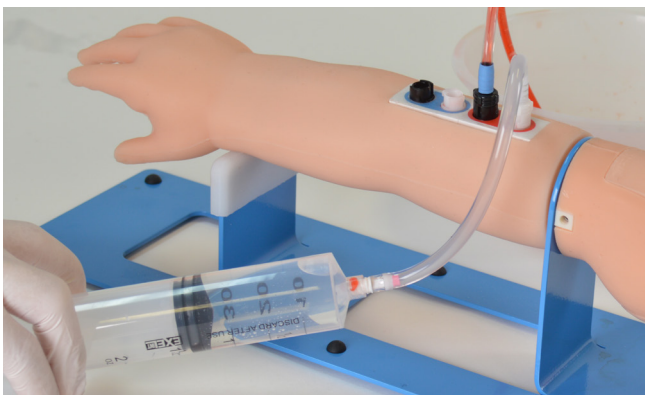
2. Fill the syringe with distilled water.

   NOTE: Do not mix alcohol into the distilled water. Flush the veins with pure distilled water.

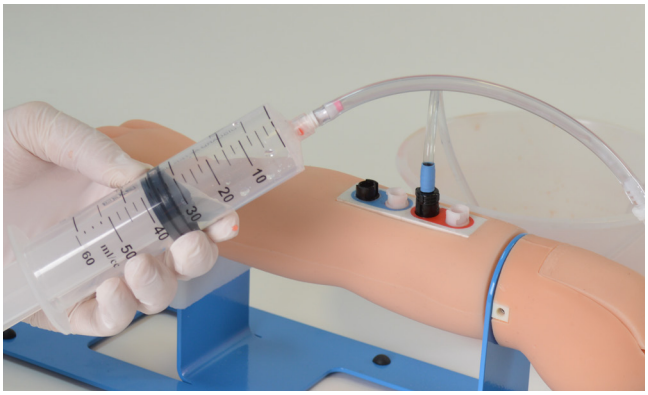
3. Connect and secure the syringe to the white luer lock arterial port outlined in red on the pediatric arm.



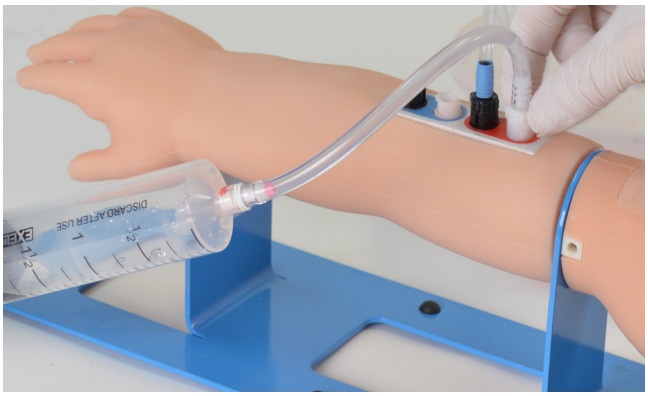
4. Push the distilled water through the newborn arm until the drain runs clear.



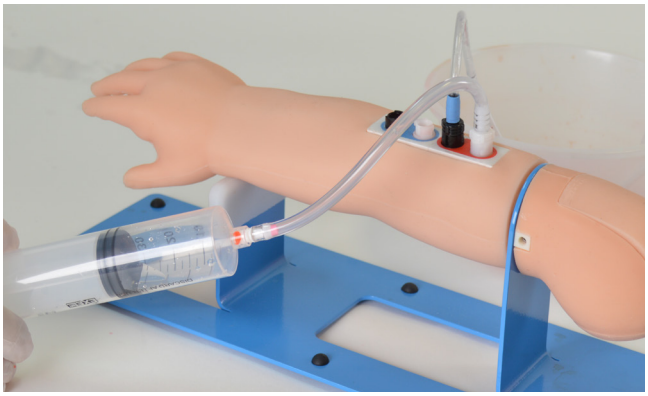
5. Disconnect the syringe from the white luer lock arterial port outlined in red and fill the syringe with air.



6. Reconnect and secure the syringe to the white luer lock arterial port oulined in red on the pediatric arm.

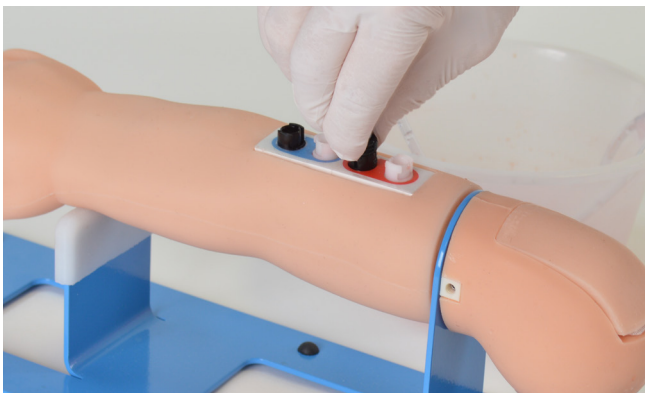


7. Push the air through the arterial network to purge any remaining fluid out through the drain.



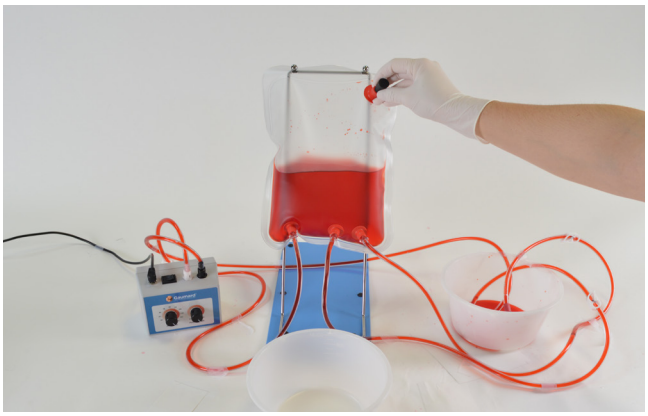
8. Disconnect the syringe and drain from the pediatric arm and store the arm in appropriate conditions.

NOTE: Refer to "Storage" on page 5

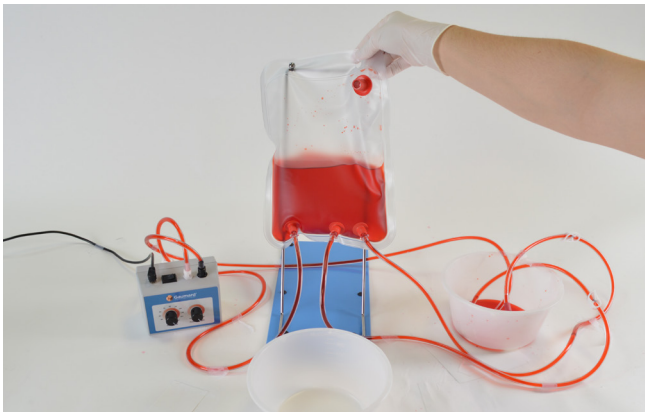


## Flushing the Blood Dispensing Bag and Control Box

1. Remove the black rubber stopper from the upper right port on the blood dispensing bag.

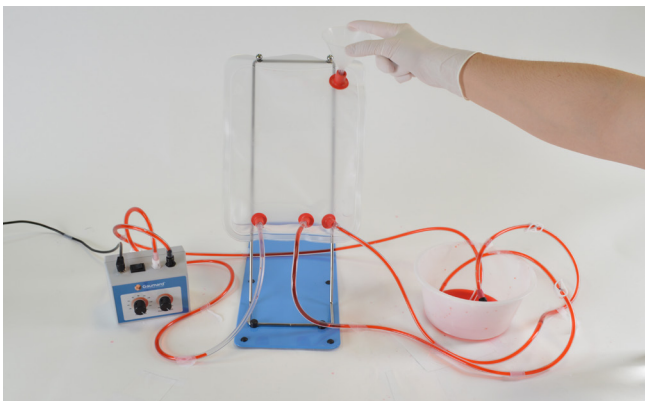


2. Remove the blood dispensing bag from the wire frame.

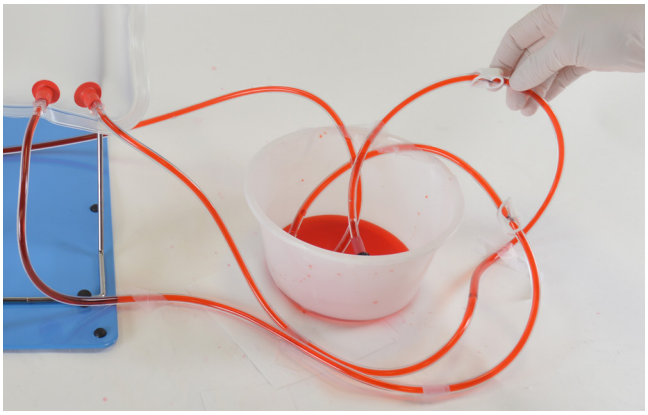


3. Empty the remaining contents of the blood dispensing bag through the top right port on the bag into a waste collection container.

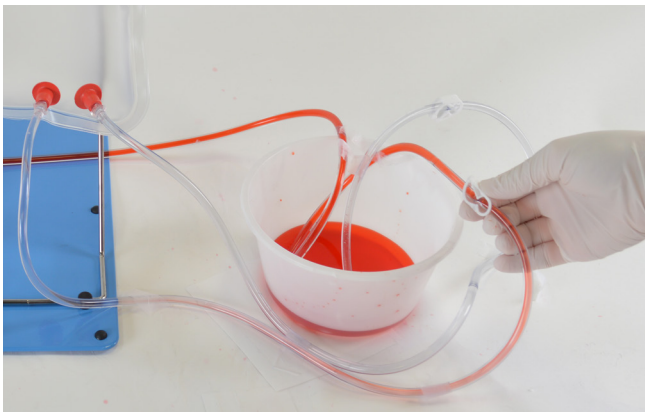
4. Hang the blood dispensing bag back on the wire frame and place the funnel in the upper right port on the bag to fill it with distilled water.



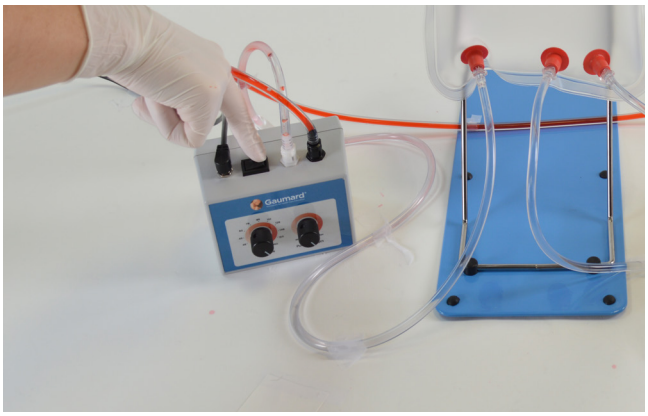
5. Unclamp all tubes.



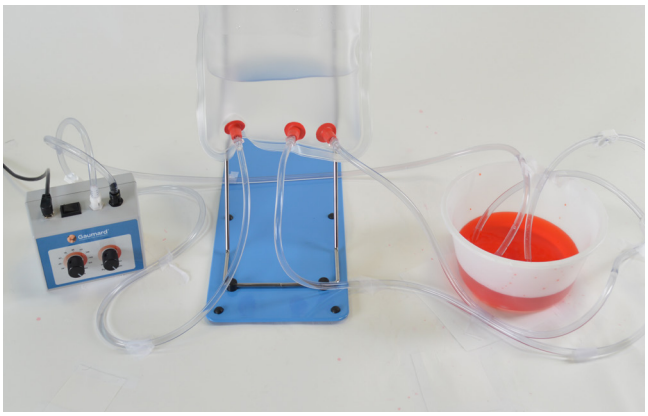
NOTE: As you unclamp the tubes the cleaning solution may already run through the tubes by itself.



6. Turn ON the control box to clean the remaining tube.



7. Allow the system to run until the tubing runs clear with distilled water.



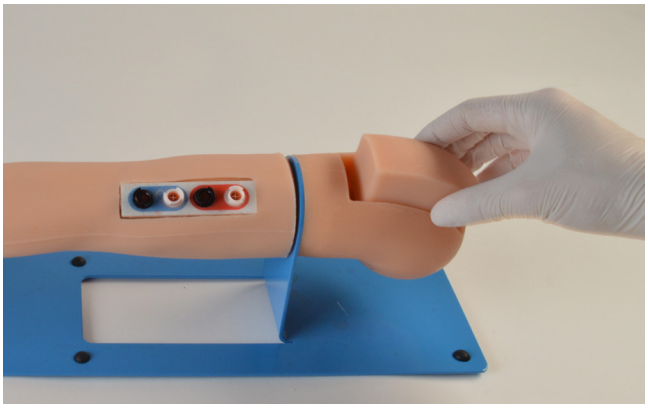
8. Disconnect the system and dry everything thoroughly. Store in appropriate conditions.

NOTE: Refer to "Storage" on page 5

## 5.2 REPLACING THE HUMERUS

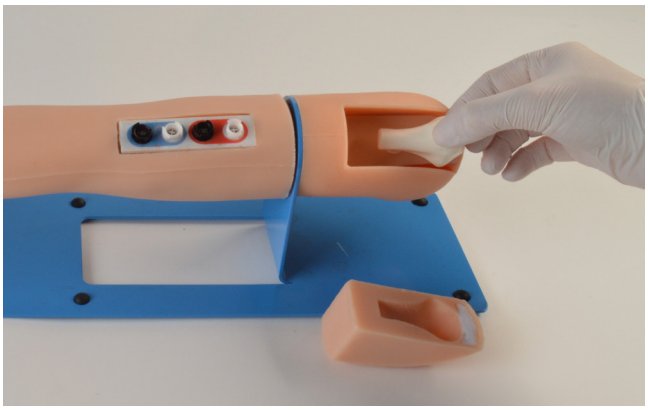
1. Remove the intramuscular insert at the deltoid area of the pediatric arm.

   NOTE: Use the pads of your fingers to remove the intramuscular site. Do not dig into the insert with fingernails because it will leave marks and potentially tear the material.

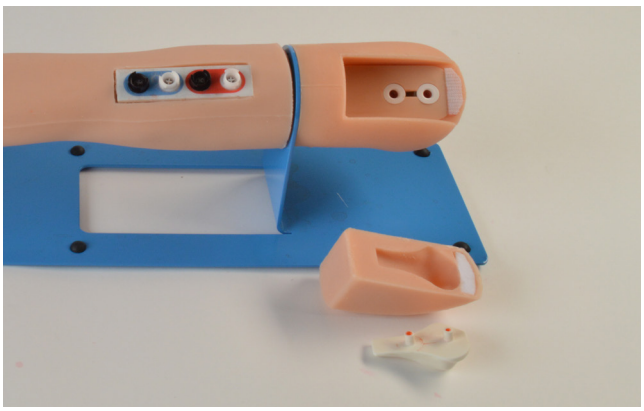


2. Grip on to the grooves of the humerus bone and pull outwards to disconnect it from the pediatric arm.

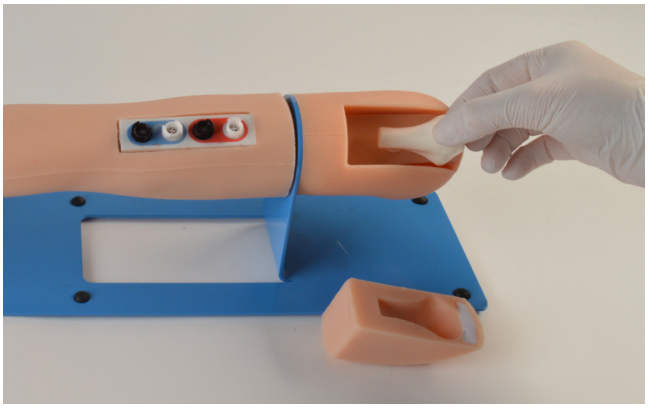
   NOTE: The humerus will have to be replaced after each puncture to prevent leaking when pressure is added to the venous network.



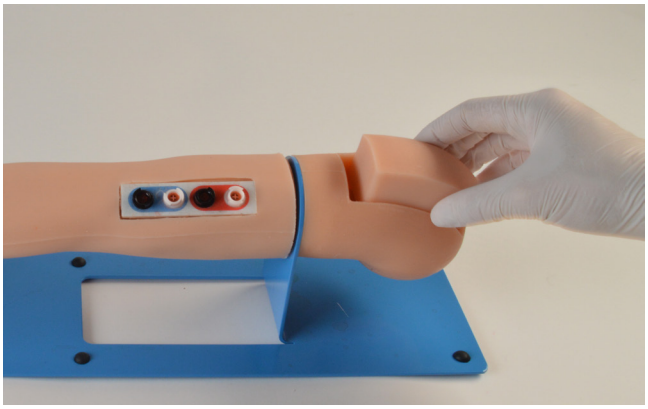
   NOTE: Once the humeral bone is removed the two ports that the bone snaps into will be visible.



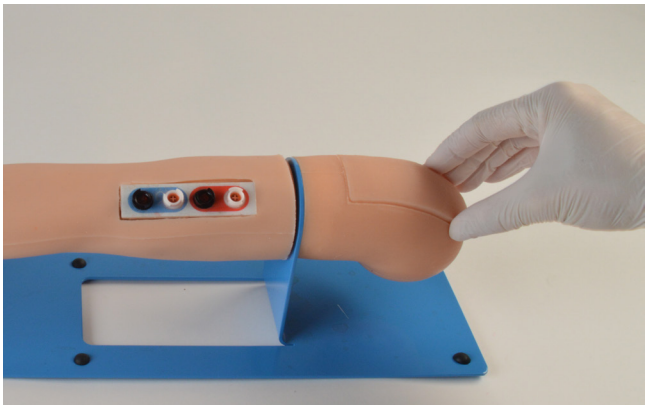
3. Replace with a new, unpunctured humerus by inserting the new humeral bone into the ports that were revealed.



4. Replace the intramuscular insert by sliding the insert into the recess.

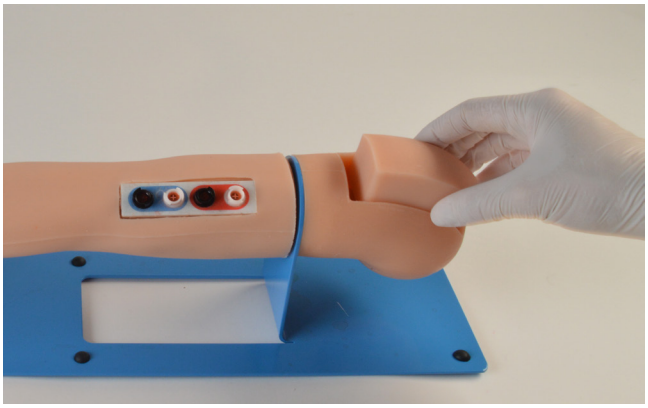


NOTE: Push the intramuscular insert into its recess until it is completely flush with the deltoid of the pediatric arm.

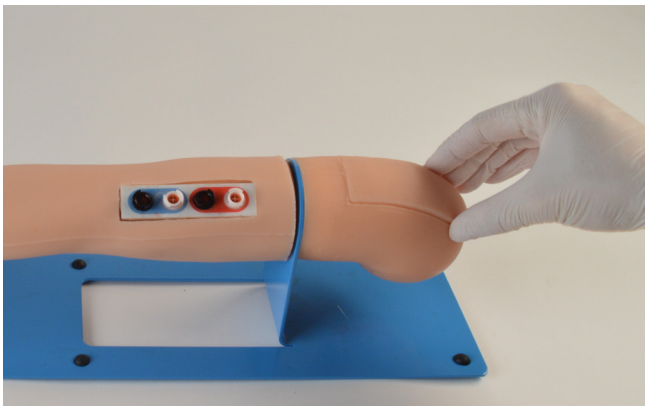


## 5.3 REPLACING THE INTRAMUSCULAR INJECTION INSERT

1. Remove the intramuscular insert at the deltoid area of the pediatric arm.

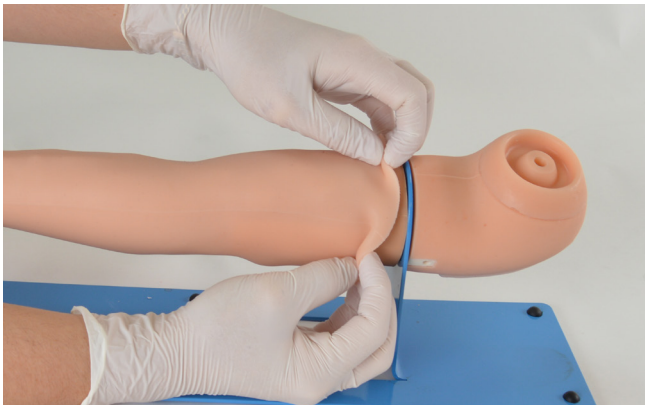


2. Replace with a new, unpunctured intramuscular insert.

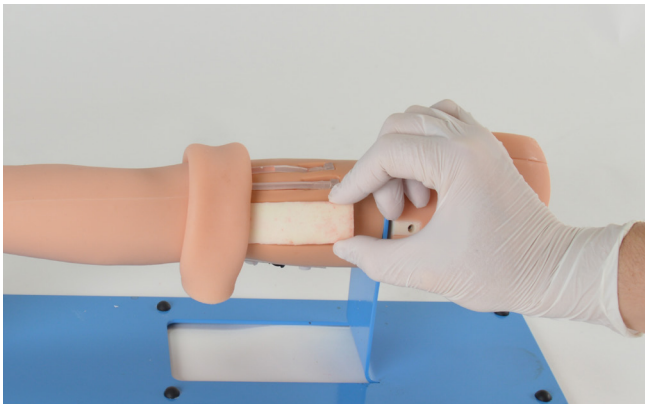


## 5.4 REPLACING THE SUBCUTANEOUS INJECTION INSERT

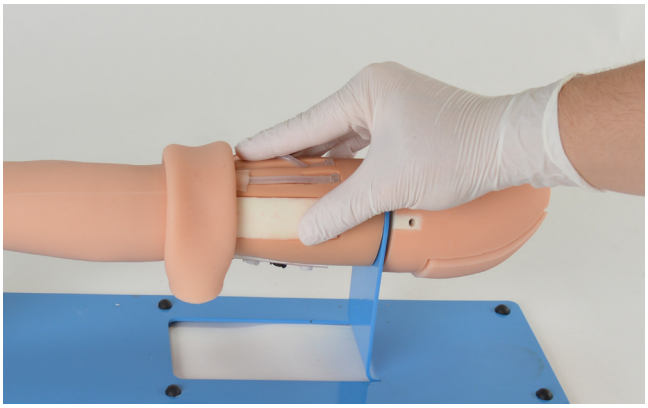
1. Carefully roll down the skin on the pediatric arm about a quarter of the way to reveal the upper lateral subcutaneous injection insert.



2. Lift out the used subcutaneous injection insert and replace it with a new one.

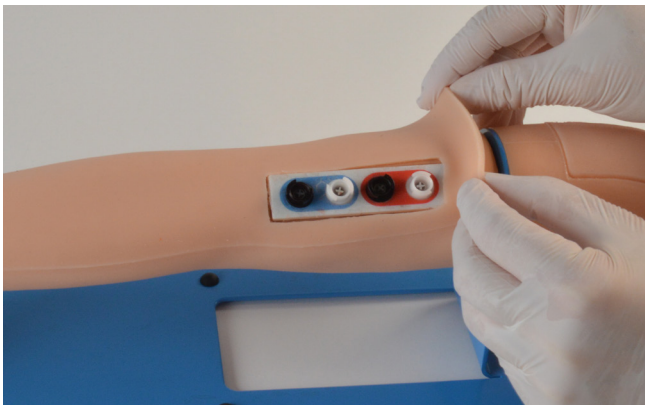


3. Hold the subcutaneous injection insert in place while you roll the skin back into place.



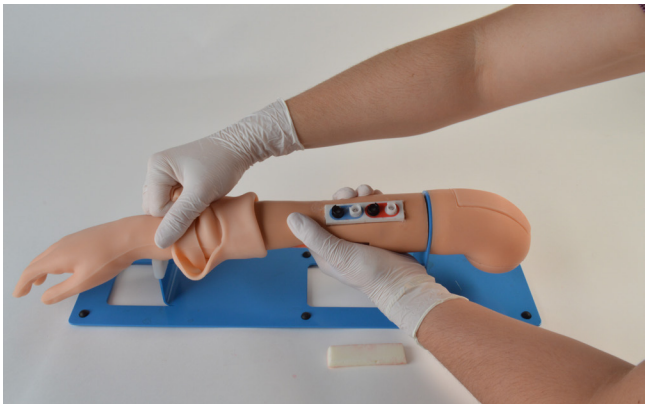
## 5.5 REPLACING THE ARM SKIN

1. Roll the arm skin down starting at the end closest to the shoulder.

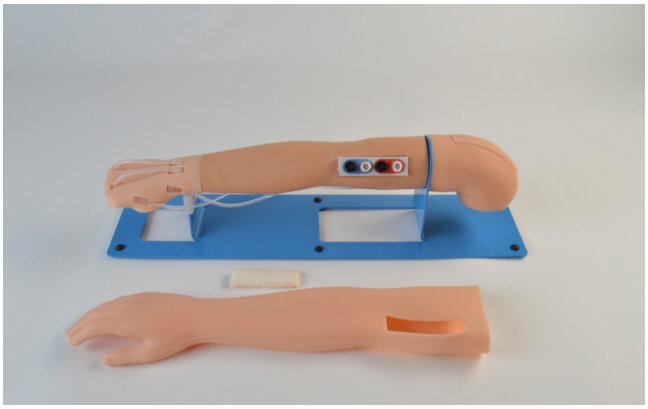


2. Fold the skin over itself and brace the injection arm to slide the arm skin off.

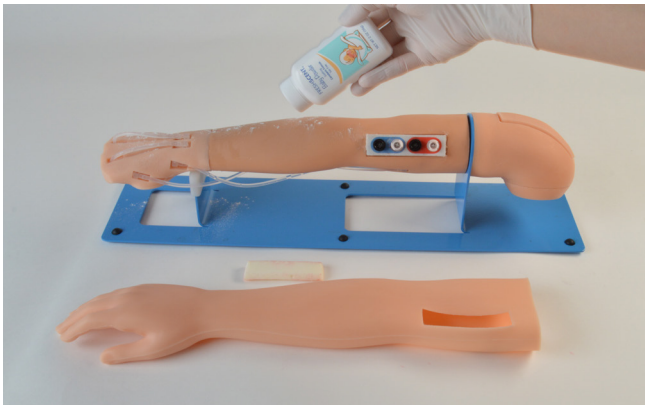
   NOTE: Due to the friction between the skin and the arm, the skin will slide off slowly. Just have patience and work the skin off the arm.



3. Remove the arm skin completely.

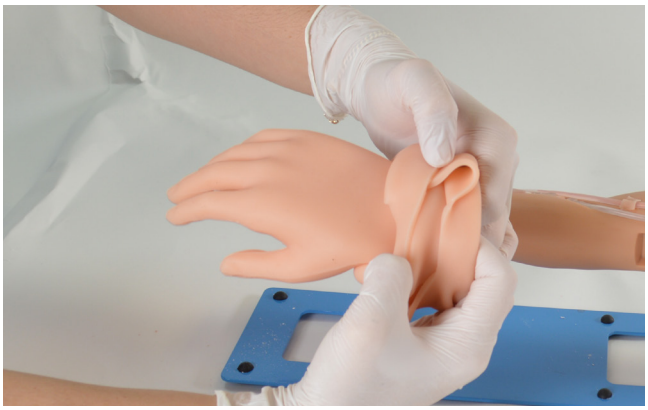


4. Liberally sprinkle talcum powder on the arm base to aid in rolling on the new skin.

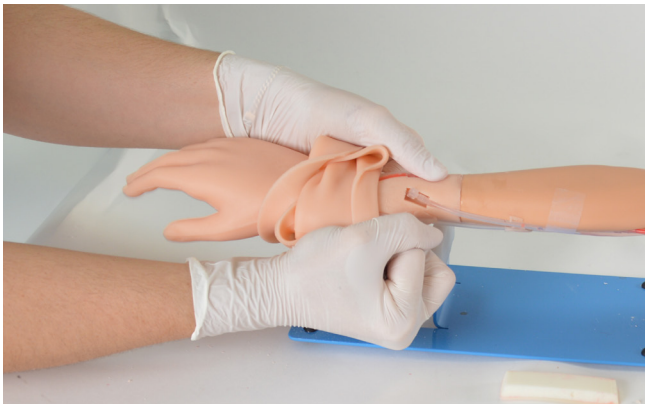


5. Fold the arm skin on itself to put over the hand of the arm.

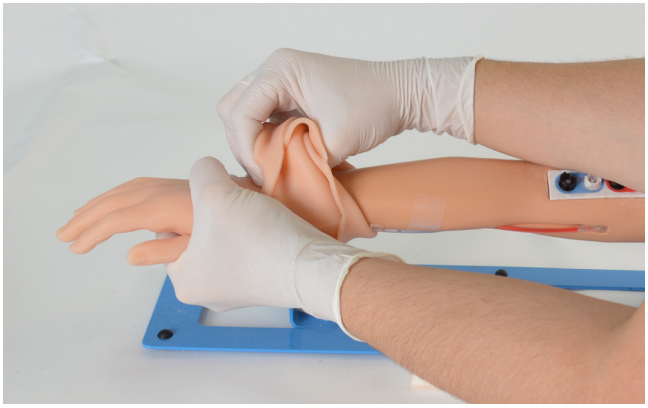
   NOTE: Be careful not to grip the skin with fingernails as this may leave marks or tear the material. Place the subcutaneous inserts back in place before completely rolling up the arm skin.



6. Work the skin of the hand onto the palm of the hand.

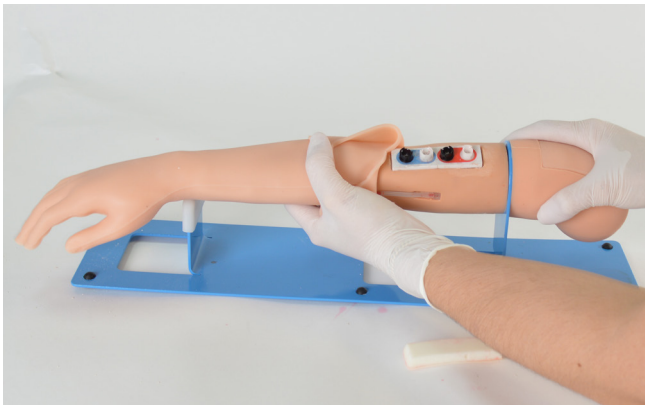


NOTE: Use the pads of your fingers to pinch and pull the skin into place over the palm of the hand. Be careful to not use your finger nails. Nails can leave imprints on the skin and potentially tear the skin.



7. After getting the skin over the hand, slide the rest of the skin up the arm.

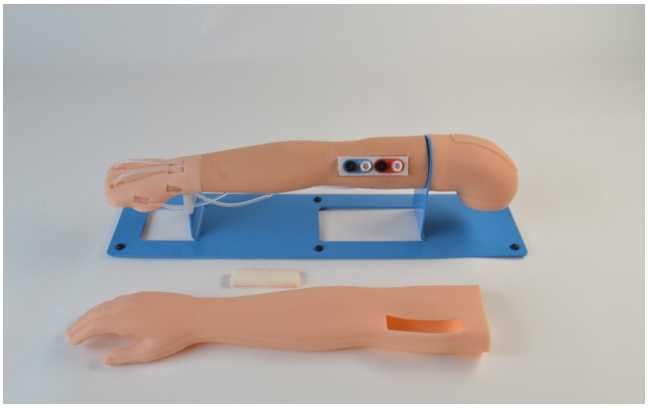
NOTE: This is the easy part!



NOTE: Line up the the skin opening to fit over the ports on the pediatric arm.

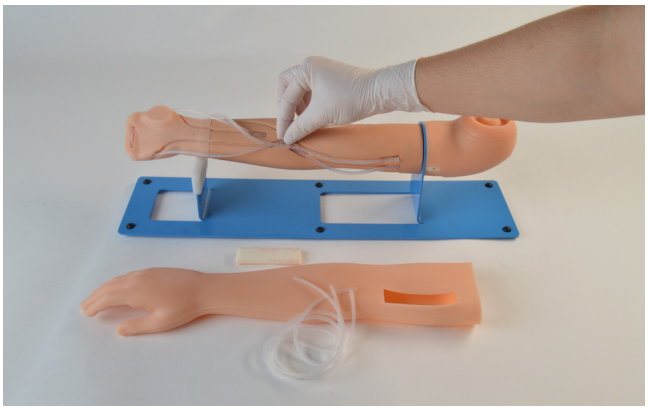
## 5.6 REPLACING THE VEINS

1. Remove the arm skin as described in "5.5 Replacing the Arm Skin" on page 48.

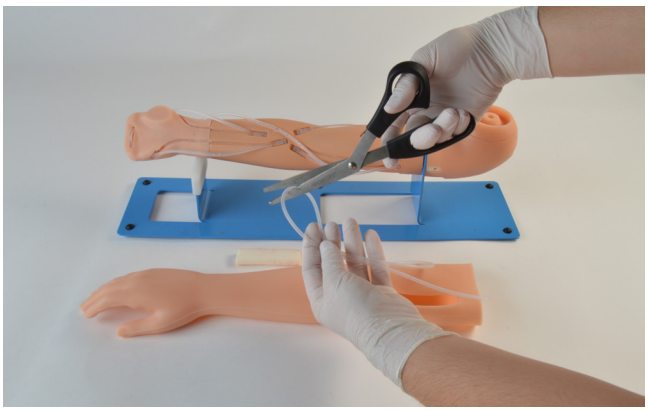


2. Remove the veins by pulling upwards and popping it off its white connector.

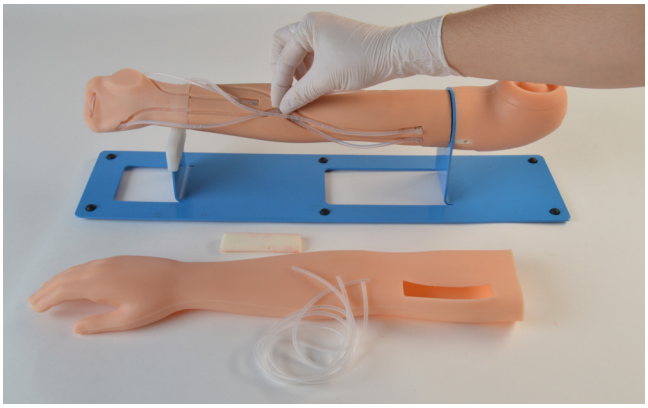
   NOTE: Do not pull too hard on the veins. A minimal amount of force is required to get the veins off the white connector. You may use a finger to keep the white connector in place and use your other hand to pull the vein off.



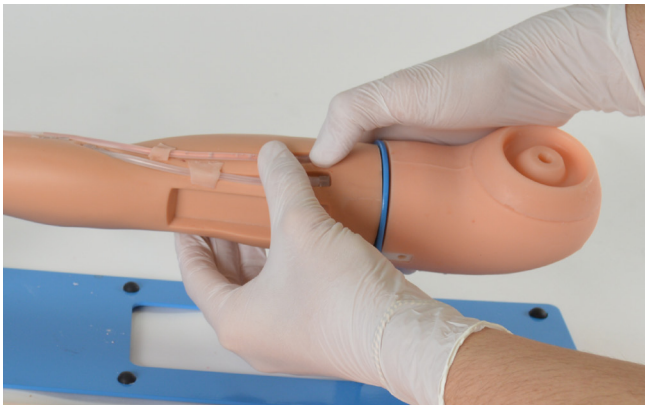
3. Use the removed vein to measure out a length of new vein tubing and cut with a pair of scissors.



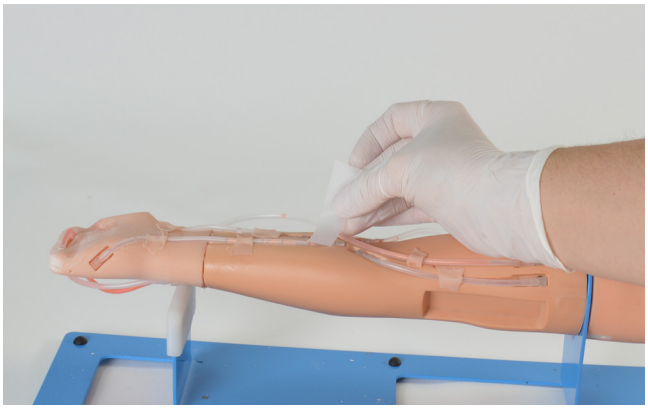
4. Replace the removed vein with the newly cut vein tubing by sliding the vein back onto the white connector.



NOTE: Slide the new vein past the barb on the white connector until it is fully seated. Secure all veins this way so that the system doesn't leak when filled.



5. For veins that slip out of their designated spots use a piece of tape to keep them in place.



6. After replacing the veins roll the arm skin back on. Refer to section "5.5 Replacing the Arm Skin" on page 48

# 6. TROUBLESHOOTING

## 6.1 GENERAL TROUBLESHOOTING

| Symptom | Possible Cause | Solution |
|---|---|---|
| Control box not circulating blood dispensing bag fluid | Power is not being delivered to the control box | Check that the port on the control box that the power cable plugs into is not damaged. Remove the power cable from the control box and inspect the port. The metal pin inside the port should not be damaged or bent in any way. |
| | | Disconnect and firmly reconnect the power cable that plugs into the port on the control box. It may be that the power cable was not properly connected. |
| | | Check that the outlet the power cable is plugged into is a working one. |
| There is no fluid flowing through the vasculature of the arm when the system is turned ON; no fluid is exiting the drainage tubings. | The fluid flow is restricted | Ensure that all of the tubing is unclamped. |
| | | Disconnect and clean the system. It is possible that leftover artificial blood concentrate in the system clogged the vasculature. Reconnect the system and try again. |
| | | Roll down the arm skin and inspect the veins. Ensure that the veins are not kinked. Tape down veins to keep them in place if necessary. Replace veins as needed. |
| The arm is leaking from the puncture marks on the arm skin | The arm skin and/or veins have been punctured with too large a needle or too many times | Replace the arm skin and veins as needed. Refer to section "5. Routine Maintenance" on page 38 |

# 7. APPENDIX

## 7.1 REPLACEMENT PARTS LIST

### S405.100 5Y Pediatric Arm Parts List

| Part Number | Description | Type |
|---|---|---|
| 13081807B | S405.100 5YO AIV Arm Skin, Light | Consumable |
| 13081808B | S405.100 5YO AIV Arm Skin, Medium | Consumable |
| 13081809B | S405.100 5YO AIV Arm Skin, Dark | Consumable |
| 30081009B | Pediatric AIV Arms Blood Bag/Pump Accessories | Replacement Part |
| 30081010A | Pediatric AIV Arms Vein Filling & Drainage Kit | Replacement Part |
| 30081022A | S405.100 Humeral I/O Bone Kit | Consumable |
| 30080279A | Artificial Blood Concentrate Kit | Consumable |
| 30081176A | CMC Additive | Consumable |
| 11090012 | Baby Powder | Consumable |
| 13082005A | S405.100 IV Arm Shoulder Insert, Light | Consumable |
| 13082032A | S405.100 IV Arm Shoulder Insert, Medium | Consumable |
| 13082033A | S405.100 IV Arm Shoulder Insert, Dark | Consumable |
| 30081021B | Pediatric IV Arms Replacement Veins | Consumable |
| 30022220A | Pediatric AIV Arms Blood Reservoir Stand Assembly | Replacement Part |
| 30022195B | S405.100 AIV Arm Stand Assembly | Replacement Part |
| 13050354A | 5YO I/V Arm Subcutaneous Insert Lateral | Consumable |
| 14060059 | Power Supply Desktop, AC/DC, 12V, 5A, 60W | Replacement Part |
| 30070925B | Pediatric AIV Arm Control Box Assembly | Replacement Part |
| 13090034D | Blood Dispensing Bag | Replacement Part |

## S406.100 1Y Pediatric Arm Parts List

| Part Number | Description | Type |
|---|---|---|
| 30081009B | Pediatric AIV Arms Blood Bag/Pump Accessories | Replacement Part |
| 30081010A | Pediatric AIV Arms Vein Filling & Drainage Kit | Replacement Part |
| 30080279A | Artificial Blood Concentrate Kit | Consumable |
| 30081176A | CMC Additive | Consumable |
| 11090012 | Baby Powder | Consumable |
| 30081021B | Pediatric IV Arms Replacement Veins | Consumable |
| 30022220A | Pediatric AIV Arms Blood Reservoir Stand Assembly | Replacement Part |
| 14060059 | Power Supply Desktop, AC/DC, 12V, 5A, 60W | Replacement Part |
| 30070925B | Pediatric AIV Arm Control Box Assembly | Replacement Part |
| 13090034D | Sealed Bags, New ITA Tank (3 Outlets), 11.50" L, 8.00" W, 4 Ports, Flange, Plastic, Clear | Replacement Part |
| 13081815B | S406.100 1YO AIV Arm Skin, Light | Consumable |
| 13081816B | S406.100 1YO AIV Arm Skin, Medium | Consumable |
| 13081817B | S406.100 1YO AIV Arm Skin, Dark | Consumable |
| 30081016A | S406.100 Humeral I/O Bone Kit | Consumable |
| 13082031A | S406.100 IV Arm Shoulder Insert, Light | Consumable |
| 13082040A | S406.100 IV Arm Shoulder Insert, Medium | Consumable |
| 13082041A | S406.100 IV Arm Shoulder Insert, Dark | Consumable |

## 7.2 GAUMARD SALES TERMS AND CONDITIONS

These Gaumard Scientific Company, Inc. (“Gaumard”) Sales Terms and Conditions (“Terms”) apply to the sale or use of Gaumard equipment (“Equipment”), Software (“Software” as defined in paragraph 13), and supplies (“Supplies”), collectively referred to as “Product” or “Products” between Gaumard and the entity named on the applicable Gaumard Purchase Order (“Customer”) (collectively, “Party” or “Parties”). The Parties, intending to be legally bound, agree as follows.

1. Agreement. Customer agrees to purchase from Gaumard the Products set forth in quotes and purchase orders accepted by both Customer and Gaumard from time-to-time. These Terms, along with any Exhibits, any applicable Gaumard Purchase Order documents, Gaumard Warranty documents, Gaumard Cares Service Plan documents, and any other purchasing or service documents executed by the Parties constitute the complete and entire agreement between Gaumard and Customer (collectively referred to herein as the “Agreement”). This Agreement will supersede all other quotations, agreements, understandings, warranties, and representations (whether written or oral) between the Parties with respect to the subject matter set forth in the Agreement. Any Customer documentation (including Customer’s purchase order terms and conditions) that conflicts with or attempts to modify the Agreement in any way is hereby rejected and of no effect unless specifically agreed to in writing and signed by the Parties. No provision of this Agreement sHAL®l be waived, amended, modified, superseded, canceled, terminated, renewed, or extended except in a written document signed by both Parties or signed by the Party against whom the modification is sought to be enforced. This agreement can be terminated by Gaumard without cause by giving thirty (30) days prior written notice to Customer.

2. Prices. Prices, fees, and charges for Products and services (including maintenance, installation, and training as described in the applicable Gaumard Purchase Order documents, Gaumard Warranty documents, Gaumard Cares Service Plan documents) (“Service” or “Services”) are payable in United States (U.S.) Dollars only, and do not include any applicable taxes or shipping charges. If Customer claims any tax exemption, it must furnish a valid tax exemption certificate before shipment of Products. Unless such certificate is furnished, Customer agrees to pay at its sole expense all applicable taxes, assessments, fees, penalties, import duties, and merchandise processing fees that may be levied or assessed upon Customer or Gaumard with respect to this Agreement, the Products, or any interest thereon. Gaumard reserves the right to increase prices on thirty (30) days written notice to Customer.

3. Payment. Unless otherwise agreed to in writing by Gaumard, Customer sHAL®l pay invoices net twenty (20) days from the invoice date. A late charge will be due on any unpaid balance at a rate of 1.0% per month or the maximum rate otherwise permitted by law, whichever is lower. Gaumard may charge interest at the maximum rate permitted by law on all amounts not paid by the invoice due date. Gaumard retains a purchase money security interest in all Products sold to Customer to secure payment of the total purchase price thereof. Customer hereby grants Gaumard the right to file a copy of this Agreement with any appropriate authorities to evidence this security interest. Customer agrees to execute and deliver such other documents as Gaumard may request in connection therewith. Gaumard sHAL®l not be obligated to deliver any Product or perform any Service during any period when Customer payment is past due. Customer will be responsible for all costs (including reasonable attorneys’ fees) incurred by Gaumard to collect overdue payments and/or to take possession or otherwise dispose of Products for which payment is overdue.

4. Product Shipment and Risk of Loss. Unless otherwise agreed to in writing by Gaumard, all Products will be shipped F.O.B. Origin, regardless of any provisions for payments of freight, insurance, the form of shipping documents, or selection of carrier by Gaumard. F.O.B. Origin means title to the Products passes to the Customer at the shipping dock of Gaumard or Gaumard’s supplier or authorized agent. Customer is responsible for shipping charges and for the cost of insurance paid to cover any losses from Gaumard’s shipment point to Customer’s receipt. Gaumard will assist Customer in processing any loss claims. Gaumard sHAL®l use reasonable efforts to meet the specified delivery dates. If Gaumard fails to make delivery within a reasonable time for reasons other than Customer’s fault or circumstances beyond Gaumard’s reasonable control, then Customer’s only remedy is the right to terminate the applicable Purchase Order, whereupon Gaumard will refund any prepayments received from Customer relating to such Purchase Order.

5. Installation and Acceptance. Product orders are subject to 1) written acceptance by Gaumard, 2) receipt of specified deposits, as applicable and 3) continuing credit approval. If applicable, Gaumard will install Equipment at an agreed upon location ("Installation"). Installation sHAL®l be complete upon Gaumard's demonstration that the Equipment meets Gaumard's then-current operating specifications ("Installation"). Installation is subject to Customer cooperating in preparing and maintaining the site in compliance with Gaumard specifications, including but not limited to, applicable electrical and other connection regulations and all environmental conditions. If Customer fails to accept shipment of Products other than for breach of warranty, Customer sHAL®l immediately pay the full purchase price as if shipment and Installation had occurred. If Customer fails to accept Products and if Gaumard decides to store ordered Products, Customer sHAL®l be responsible for Gaumard's reasonable insurance, handling, and storage charges. If Gaumard elects not to store ordered Products, Gaumard may arrange shipment and storage in a bonded warehouse at Customer's sole risk and expense.

6. Delay of Performance. The Parties’ obligations under this Agreement are subject to force majeure, including but not limited to, civil insurrection, terrorism, fire, flood, labor disputes, shortages, delays of suppliers or contractors, or government priority systems, actions taken or threatened by any governmental agencies, acts of God or other contingencies or acts not within the sole control of the Parties. Gaumard reserves the right during any shortage period to (a) make Supplies available to Customer (as it sees fit) without any liability to Customer, and (b) to make substitutions and modifications in the specification of any Products, provided such substitutions or modifications do not materially affect the performance of Products.

7. WARRANTIES. Gaumard warrants that if a Product proves to be defective in material or workmanship within one year from the date on which title to the Product passes to the Customer (“Warranty Period”), Gaumard will, at Gaumard's option, repair or replace the Gaumard product. This limited warranty covers all defects in material and workmanship in the Gaumard product, except: (a) Damage resulting from accident, misuse, abuse, neglect, or unintended use of the Gaumard product; (b) Damage resulting from failure to properly maintain the Gaumard product in accordance with Gaumard product instructions, including failure to properly clean the Gaumard product; and (c) Damage resulting from a repair or attempted repair of the Gaumard product by anyone other than Gaumard or a Gaumard representative. Replacement parts are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer. Services are warranted to be supplied in a workman-like manner. Gaumard

does not warrant that use of the Products will be uninterrupted or error-free, or that the Products will operate with non-Gaumard authorized third-party products. THE FOREGOING WARRANTIES ARE IN LIEU OF AND EXCLUDE ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT. SUCH LIMITED WARRANTY IS GIVEN SOLELY TO THE ORIGINAL CUSTOMER AND IS NOT GIVEN TO ANY THIRD PARTY INCLUDING, WITHOUT LIMITATION, SUBSEQUENT PURCHASERS OR USERS OF THE PRODUCTS OR CUSTOMERS OF THE CUSTOMER. THIS WARRANTY IS VOID UPON TRANSFER OF PRODUCT BY CUSTOMER TO ANY OTHER ENTITY. SOME STATES DO NOT ALLOW THE EXCLUSION OF IMPLIED WARRANTIES SO THE ABOVE EXCLUSIONS MAY NOT APPLY TO CUSTOMER. These warranties do not apply to any Products that are supplied on a pre- release or "as-is" basis.

8. Warranty Claims and Remedies. In the event of any warranty claim, Gaumard will replace with new or repaired items any Product part or component that is in breach of the above limited warranties. Alternatively, Gaumard may elect to repay or credit to Customer an amount equal to the purchase price of the defective Product. Items replaced sHAL®l become Gaumard property. All claims sHAL®l be initiated by contacting Gaumard within the applicable Warranty Period and within thirty (30) days after discovery of the non- conformity. If Customer has failed to notify Gaumard within the Warranty Period, then Customer sHAL®l be barred from instituting any action thereafter. Customer sHAL®l not return the Product to Gaumard without prior authorization from Gaumard. If the necessary repairs to the Product are covered by this limited warranty, then Customer will pay only the incidental expenses associated with the repair, including any shipping, handling, and related costs for sending the product to Gaumard and for sending the product back to the first purchaser. However, if the repairs are not covered by this limited warranty, then Customer will be liable for all repair costs in addition to costs of shipping and handling. Upon request, Gaumard must be given access to and an opportunity to inspect the Product and any working areas and storage areas. These remedies sHAL®l comprise Gaumard's entire liability and Customer's exclusive remedy for breach of warranty and are in lieu of any other remedies at law or equity.

9. LIMIT OF LIABILITY. GAUMARD SHAL®L NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, EXEMPLARY, OR CONSEQUENTIAL LOSSES, DAMAGES, OR EXPENSES (INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS, DATA, OR USE), DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, HANDLING, SERVICE, OR USE OF PRODUCT OR SERVICES ORDERED OR FURNISHED, OR FROM ANY CAUSE RELATING THERETO. EXCEPT FOR PERSONAL INJURY OR DEATH TO THE EXTENT RESULTING FROM GAUMARD'S NEGLIGENT OR INTENTIONALLY WRONGFUL ACTS OR OMISSIONS, IN NO EVENT SHAL®L GAUMARD BE LIABLE UNDER ANY LEGAL THEORY OR FOR ANY CAUSE RELATED TO A PRODUCT OR SERVICE, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, NEGLIGENCE, OR OTHER THEORY, EVEN IF ADVISED OF THE POSSIBILITY THEREOF, FOR ANY AMOUNT IN EXCESS OF THE PRICE, FEE, OR CHARGE RECEIVED BY GAUMARD FOR SUCH PRODUCT OR SERVICE.

10. Governmental Authorizations. Customer is responsible for compliance and costs associated with all required licenses, permits, or other governmental authorizations, including but not limited to, any license or certification needed for Customer to use the Product, and any export or import license, exchange permit, or the like ("Licenses"), even if applied for by Gaumard on Customer's beHAL®f. If any authorization is delayed, denied, revoked, restricted, or not renewed, Gaumard sHAL®l not be liable, and Customer is not relieved of its obligations. Customer represents and agrees that it will handle all Product and technical data related to the Licenses so that it conforms to all applicable U.S. laws and regulations, including U.S. export licensing laws and the U.S. Foreign Corrupt Practices Act. Customer sHAL®l not trans-ship, divert, re-export or otherwise dispose of any U.S. origin goods or technology obtained from Gaumard except as U.S. laws and regulations expressly permit.

11. Indemnity.

a. Gaumard agrees to indemnify, defend and hold Customer, its officers, directors, employees, agents and contractors harmless from and against all loss, damage, liability, cost and expense (including reasonable attorneys' fees and expenses) by reason of any claims or actions by third parties against Customer for (1) bodily injury or death, and damage, loss or destruction of any real or tangible personal property, which third party claims arise out of or relate to Gaumard's gross negligence or willful misconduct or (2) infringement or misappropriation by Gaumard of any intellectual property rights under this Agreement.

b. Customer agrees to indemnify, defend and hold Gaumard, its officers, directors, employees, agents and contractors harmless from and against all loss, damage, liability, cost and expense (including reasonable attorneys' fees and expenses) by reason of any claims or actions by third parties against Gaumard for (1) bodily injury or death or damage, loss or destruction of any real or tangible personal property, which third party claims arise out of or relate to Customer's gross negligence or willful misconduct; (2) infringement or misappropriation by Customer of any intellectual property rights; or

(3) Customer's or its customer's use of the Products or Services, including without limitation, defamation, libel, slander, obscenity, pornography, or violation of the rights of privacy or publicity, or spamming or any other tortious or illegal conduct.

12. Software License. For purposes of these Terms, the term "Software" includes all Gaumard computer software, firmware, and associated documentation, whether in printed or machine-readable form, supplied by reason of this Agreement or for use in connection with Equipment or Services. To the extent the Product includes Software, Customer's use of the Software is governed by the Gaumard End User License Agreement attached as Exhibit A to these Terms.

13. Confidential Information. Customer sHAL®l maintain the confidentiality of any information provided or disclosed by Gaumard relating to the Software (as defined above), business or customers of Gaumard, as well as this Agreement and its terms (including the pricing and other financial terms under which the Customer will be obtaining the Services hereunder). Customer sHAL®l use reasonable care to protect the confidentiality of Gaumard's information disclosed, but no less than the degree of care it would use to protect its own confidential information, and sHAL®l only disclose Gaumard's confidential information to its employees and agents having a need to know this information and who are subject to confidentiality agreements having terms at least as restrictive as those contained herein. The obligations of confidentiality set forth herein sHAL®l not apply to any information in the public domain at the time of disclosure.

14. Intended Uses. Products are only intended for the uses described in the applicable user's manual or instructions for use. Customer assumes all risks associated with non-listed uses of Products and hereby indemnifies and holds Gaumard harmless from any claim associated with such non-listed uses.

15. Compliance with Laws. Gaumard and Customer agree to comply with all federal and state laws that govern the enforceability and performance of this Agreement.

16. HIPAA Compliance. As of the Effective date, the Parties are not planning to transfer any personal patient information between them. However, the Parties understand and agree that this Agreement may become subject to the Health Insurance Portability and Accountability Act of 1996 as amended ("HIPAA"), the privacy and security regulations promulgated thereunder, including 45 C.F.R. 160, 162 and 164, as amended (the "HIPAA Regulations"), and Title XIII of Division A and Title IV of Division B (the "Health Information Technology for Economic and Clinical Health Act ("HITECH"), part of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) ("ARRA"). The Parties agree to strictly comply with HIPAA and to execute any documents that may be required by HIPAA, HITECH, and any other applicable federal or state privacy laws and regulations. The Parties agree that if they directly or indirectly gain access to Protected Health Information ("PHI") held by the other Party during any interaction, the receiving Party will keep the PHI confidential under the terms of this Agreement

17. State Reporting and Disclosure Laws. Unless otherwise noted in this Agreement, the cost of any Product training provided by Gaumard sHAL®l be included in the purchase price of the Product where applicable. Customer acknowledges and agrees that state reporting laws may require Gaumard to disclose certain aspects of this arrangement.

18. Fraud and Abuse. Gaumard hereby certifies that it is not currently a listed vendor in the: (a) Federal General Services Administration's "List of Parties Excluded from Federal Procurement or Nonprocurement Programs" in accordance with Presidential Executive Orders 12549 and 12689 "Debarment and Suspension;" and (b) in the Office of the Inspector General of the Department of Health and Human Services' "List of Excluded Individuals/Entities." Any discounted pricing terms offered under this Agreement may be a "discount or other reduction in price" under the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). Customer sHAL®l take all actions necessary to comply with the Anti-Kickback Statute discount safe harbor regulations, 42 C.F.R. § 1001.952(h), including but not limited to, (1) maintaining accurate records reflecting the pricing terms of items and Services purchased under this Agreement, (2) fully and accurately report any discount received under this Agreement if applicable, and (3) make available information provided to Customer by Gaumard concerning cost reports and other filings with the government, including but not limited to, the Secretary of the U.S. Department of Health and Human Services or other state agencies.

19. Bankruptcy. Except as may be prohibited by applicable bankruptcy laws, a Party to this Agreement may elect to terminate this Agreement (including any Purchase Orders ) if any of the following situations arise: (1) the other Party becomes insolvent or is unable to pay debts as they become due; (2) a voluntary or involuntary bankruptcy proceeding is instituted by or against a Party hereto; or (3) an appointment of a receiver or assignee for the benefit of creditors occurs on beHAL®f of a Party hereto.

20. Waiver and Severability. If either Party fails to perform obligations under this Agreement, such nonperformance sHAL®l not affect the other Party's right to enforce performance at any time. Waiver of any remedy or material breach of any subject matter contained in this Agreement sHAL®l not be viewed as a waiver unless agreed to by the Parties in writing. Each provision of this Agreement is separate and independent of one another, and the unenforceability of any provision will not affect the enforceability of any other provision. If any provision is held to be excessively broad or unenforceable, such provision sHAL®l be modified so that it is enforceable to the fullest extent possible by law.

21. Assignment. Customer sHAL®l not assign this Agreement without the prior written consent of Gaumard, which consent sHAL®l not be unreasonably withheld or delayed. Subject to the foregoing, the rights and obligations herein will be binding upon the successors and assigns of Customer.

22. Notices. Any required notices will be given in writing to Gaumard as set forth in the applicable Gaumard Purchase Order or other purchasing document.

23. Governing Law. Upon execution, this Agreement sHAL®l be governed and viewed under the laws of the State of Florida without reference to its conflict of laws provisions. Customer and Gaumard specifically agree that any action relating to the relationship between the Parties, the Agreement, or Products provided, purchased or licensed hereunder, sHAL®l be brought and tried in the Courts of Dade County, Florida. Customer waives all objections to, and consents to the jurisdiction of such Courts.

24. Miscellaneous. See applicable Gaumard Purchase Order documents, Gaumard Warranty documents, and Gaumard Cares Service Plan documents for other terms and conditions, which may include, but are not limited to: Term, Termination, Customer Training and Support, and Product Repairs and Tune Ups.

## 7.3 END USER LICENSE AGREEMENT

GAUMARD END USER LICENSE AGREEMENT

This End User License Agreement ("EULA") sets forth the respective rights and responsibilities between the entity named in the Purchase Order associated with this EULA ("End User") and Gaumard Scientific Company, Inc., a Florida corporation ("Gaumard"), relative to the Gaumard Software (as defined below). This EULA is effective as of the date Gaumard accepts and confirms the Purchase Order (the "Effective Date"). BY USING THE GAUMARD SOFTWARE, END USER IS AGREEING TO BE BOUND BY THE TERMS OF THIS EULA. IF END USER DOES NOT AGREE, END USER MAY NOT USE THE GAUMARD SOFTWARE.

1. Definitions.

1.1 "Gaumard Documentation" means the Gaumard user and operations manuals, guides, and related materials provided by Gaumard to End User to facilitate use of the Gaumard Products.

1.2 "Gaumard Equipment" means Gaumard hardware components for medical simulation and training, including manikins and associated instrumentation, and other hardware and tangible products sold by Gaumard to End User.

1.3 "Gaumard Products" means Gaumard Software licensed and Gaumard Equipment sold or otherwise made available by Gaumard to End User currently or in the future.

1.4 “Gaumard Software” means the object code form of computer programs and Gaumard Documentation owned by Gaumard or its licensors and licensed to End User in accordance with this EULA. Gaumard Software includes (a) computer programs embedded in firmware in the Gaumard Equipment; (b) computer programs embedded in a separate medium (such as CD or flash drive) for use in conjunction with the Gaumard Equipment; (c) computer programs downloaded or received via mail from Gaumard; (d) computer programs used on servers storing or processing data related to the Gaumard Products; and (e) computer programs used to create and manage a network for the Gaumard Equipment, interface with the components of the Gaumard Equipment, manage and compute location information related to the Gaumard Equipment, and monitor health of the Gaumard Equipment.

2. Software License and Restrictions.

2.1 License. Subject to End User’s compliance with the terms and conditions of this EULA, the Gaumard Sales Terms and Conditions, the Purchase Order, and the Gaumard Cares Service Plan Agreement, Gaumard grants End User a non-exclusive, non-transferable (except as otherwise set forth herein), personal license to execute and use the Gaumard Software for End User’s internal purposes, but only so long as the Gaumard Software is installed on the Gaumard Product on which it was originally installed. End User may not, directly or indirectly, sell, sublicense, display, timeshare, loan, lease, distribute, or create derivative works of the Gaumard Software.

2.2 Ownership. All rights, title, and interest in and to the Gaumard Software, and any derivative works thereof, whether created by Gaumard, End User, or a third party, will remain at all times solely and exclusively owned by Gaumard. Nothing in this EULA or the Purchase Order will be construed to grant End User any rights of any kind with respect to the Gaumard Software, except as expressly set forth in this EULA.

2.3 Reverse Engineering and Other Restrictions. End User will not, and will not allow any third party to, tamper with, modify, decompile, disassemble, derive the source code of, reverse engineer, or attempt to obtain the internal design of the Gaumard Software or Gaumard Products for any purpose whatsoever (collectively, “Restricted Acts”). If applicable law permits End User to take any of the Restricted Acts notwithstanding the previous prohibition, and End User wishes to take any Restricted Act notwithstanding the previous prohibition, End User will first provide Gaumard with thirty (30) days prior written notice. Gaumard may terminate this EULA at any time during such notice period without liability arising from such termination. The parties agree that all information needed for interoperability is available from Gaumard in accordance with applicable government directives.

2.4 Updates. From time to time Gaumard may develop new versions or updates for the Gaumard Software that may be made available to the End User as agreed under the terms of the Gaumard Sales Terms and Conditions, Gaumard Purchase Order documents, Gaumard Warranty documents, or Gaumard Cares Service Plan documents. Unless otherwise agreed to by Gaumard, End User sHAL®l be responsible for installing the provided new versions or updates for the Gaumard Software.

2.5 Proprietary Notices. End User agrees to maintain and reproduce on all copies of the Gaumard Software, any names, logos, copyright notices, trademarks, other proprietary markings, and legends that appear on the Gaumard Software.

2.6 Control of Duplication. End User will not, nor will it allow any third party to, circumvent the protection controlling the duplication or use of the Gaumard Software, for example and without limitation, any software lock controlling the number of copies End User may make of the Gaumard Software.

2.7 No Source Code. End User acknowledges and agrees that its rights under this EULA do not include rights to source code. In its exercise of the rights granted under this EULA, End User agrees not to take any action that would result in any requirement to disclose or make available to other parties the Gaumard Software in source code format.

2.8 Certification. Upon thirty (30) days written notice to End User from Gaumard, End User sHAL®l certify End User’s compliance with the restrictions and obligations in this EULA. Such requests will not occur more frequently than once per calendar year. If End User has used the Gaumard Software in violation of this EULA, End User sHAL®l, in addition to any other remedies Gaumard may have, pay Gaumard additional fees for the excess use according to Gaumard’s then-current price list and policies, plus a late payment charge of one percent (1.0%) per month (or the highest amount allowed by applicable law, if lower) for each month of excess use from the date of initial excess use.

2.9 Privacy and Recordings. End User will comply with all applicable laws, rules and regulations related to privacy, publicity and data protection related to use of the Gaumard Products. End User sHAL®l not use the Gaumard Software to record or collect personal data from any person in violation of End User’s policies or privacy statements. End User sHAL®l receive express consent from all persons recorded by the Gaumard Software sufficient for End User’s use, storage, and distribution of such recordings.

3. Term and Termination

3.1 Term. This EULA commences on the Effective Date and continues perpetually, unless terminated earlier in accordance with the terms hereof.

3.2 Termination for Cause. This EULA is automatically terminated by Gaumard if the other party materially breaches this EULA, the Gaumard Sales Terms and Conditions, the Purchase Order, or the Gaumard Cares Service Plan Agreement. In addition, Gaumard may terminate this EULA if (a) End User becomes insolvent or makes an assignment for the benefit of End User’s creditors; or (b) a receiver is appointed or a petition in bankruptcy is filed with respect to End User and such petition is not dismissed within thirty (30) days.

3.3 Effect of Termination. Upon the termination of this EULA for any reason, all licenses granted in Section 2 above will immediately cease and terminate. Upon termination, End User will immediately cease using the Gaumard Software.

3.4 Survival. Sections 3 through 6 will survive the termination of this EULA.

4. Confidential Information; Trademarks.

4.1 Confidential Information. End User acknowledges and agrees that the Gaumard Software is confidential information and contains trade secrets of Gaumard. End User agrees to (i) hold the Gaumard Software in the strictest confidence, (ii) not disclose the Gaumard Software to any third party for any purpose, and (iii) use at least the same security measures as End User to protect its own confidential and trade secret information but no less than reasonable measures to protect the confidentiality of the Gaumard Software. End User agrees and acknowledges that any breach of the provisions regarding ownership or confidentiality contained in this Agreement sHAL®l cause Gaumard irreparable harm and Gaumard may obtain injunctive relief without the requirement to post a bond as well as seek all other remedies available to Gaumard in law and in equity in the event of breach or threatened breach of such provisions.

4.2 Trademarks. End User may not use Gaumard’s trademarks, logos, service marks, or names in press releases, web sites, marketing, or other forms of public materials without the prior written consent of Gaumard. All use of the Gaumard trademarks and all goodwill associated with them will inure solely to the benefit of Gaumard.

5. Disclaimer; Limitation of Liability; Infringement Indemnification

5.1 Warranty and Disclaimer. For a period of twelve (12) months from the Effective Date, Gaumard will (a) provide all updates to the Software that are made available generally, and (2) use reasonable efforts to fix or provide a workaround for any Gaumard Software defect or bug which prevents operation in substantial conformity with the Gaumard Documentation. Other than the above, the Gaumard Software is provided “as- is,” with no express or implied warranties of any kind, including the warranties of merchantability, fitness for a particular purpose, or non-infringement.

5.2 Limitation of Liability. THE TOTAL LIABILITY, IF ANY, OF GAUMARD TO END USER OR ANY THIRD PARTY FOR ALL DAMAGES BASED ON ALL

CLAIMS, WHETHER ARISING FROM BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY, TORT, OR OTHERWISE, ARISING FROM THE GAUMARD PRODUCTS IS LIMITED TO ONE HUNDRED DOLLARS. IN NO EVENT WILL GAUMARD BE LIABLE TO END USER OR ANY THIRD PARTY FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, OR PUNITIVE DAMAGES, INCLUDING BUT NOT LIMITED TO, LOSS OF REVENUES, LOSS OF PROFITS, OR LOSS OF DATA, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

5.3Infringement Indemnification. Gaumard will, as further described below, indemnify, defend, and hold End User harmless, at its expense, against any claim or suit brought by a third party against End User alleging that any Gaumard Software furnished under this EULA infringes the United States patent, trademark, copyright or other intellectual property right of a third party. Gaumard will pay all settlements entered into or damages finally awarded, including attorneys' fees and costs, based on any such claim or suit; provided that End User gives Gaumard prompt written notice of such claim and gives Gaumard information, reasonable assistance ,and sole authority to defend or settle the claim. In defense or settlement of the claim, Gaumard may obtain for End User the right to continue using the Gaumard Software, replace or modify the Gaumard Software so that it becomes non-infringing, or, if such remedies are not reasonably available, grant End User a refund for the associated Gaumard Products (depreciated over three years) and accept their return. Gaumard will not have any liability if the alleged infringement is based upon (a) the use or sale of the Gaumard Software in combination with other products or devices not furnished by or approved by Gaumard; (b) the use of the Gaumard Software in a manner for which they were not designed as described by the Gaumard Documentation; (c) any modification of the Gaumard Software not performed by or authorized by Gaumard;

(d) any use of Gaumard Software by End User after End User learns of such allegation of infringement; or (e) any failure by End User to utilize a non-infringing version of the Gaumard Software made available by Gaumard along with notice that such update is non-infringing. The obligations set forth in this Section 5.3 are Gaumard's sole obligations, and End User's sole and exclusive remedy, for the Gaumard Software infringing third party intellectual property rights.

6. Miscellaneous.

6.1Binding Effect; Assignment. This EULA will be binding upon, and inure to the benefit of, End User's and Gaumard's respective permitted successors and permitted assigns. Neither party may assign or transfer this EULA or any of the rights, privileges, duties or obligations under this EULA without the prior written consent of the other party, except that either party may assign this Agreement to any entity controlled by, controlling, or under common control with such party at such time, as well as in connection with the sale, transfer, merger, or acquisition, whether by operation of law or otherwise, of substantially all of the assets of such party. In addition, if End User transfers the Gaumard Product on which the Gaumard Software is installed to a third party, End User may assign this EULA to such third party, provided that the third party agrees in writing with Gaumard to be bound by this EULA.

6.2Notices. Any written notice required by this EULA will be deemed made (a) when delivered by personal service, (b) one (1) business day after being sent by recognized international overnight courier service (such as FedEx), or (c) when received, if sent by certified or registered mail, postage prepaid, return receipt requested. Any such notice given to a party sHAL®l be sent to the addresses on the attached Purchase Order. By giving to the other party written notice thereof, the parties hereto and their respective permitted successors and assigns will have the right from time to time to change by written notice their respective addressee or address for notices.

6.3Applicable Law. The validity of this EULA and the rights, obligations and relations of the parties hereunder sHAL®l be construed and determined under and in accordance with the substantive laws of the State of Florida. All disputes arising under or related to this EULA sHAL®l be resolved exclusively in the State or Federal Courts located in Dade County, Florida. The parties consent to the jurisdiction and venue of such courts and waive any claims as to inconvenient forum. The judgments of such courts may be enforced in any court of competent jurisdiction.

6.4 Export Control. End User will not export or re-export the Gaumard Software, including any technical data, except as authorized and permitted by, and in compliance with, the laws and regulations, including but not limited to all export and re-export laws and regulations, of the United States.

6.5Severability. If any provision of this EULA is invalid or unenforceable in any circumstances, it will be interpreted as much as possible to reflect the intent of the parties, and its application in any other circumstances and the remaining provisions of this EULA will not be affected thereby.

6.6 Entire Agreement. This EULA constitutes the entire agreement and understanding of the parties relating to the subject matter thereof. This EULA supersedes all prior written and oral agreements and all other communications between End User and Gaumard (or a Gaumard distributor) regarding the subject matter hereof. No contradictory terms and conditions of any purchase order, invoice, or other document issued by End User relating to the subject matter of this EULA sHAL®l be binding, unless agreed by the parties.

6.7Waiver of Breach. No waiver by a party of any breach of this EULA will constitute a waiver of any other breach of the same or other provisions of this EULA. No waiver by a party will be effective unless made in a record signed or otherwise authenticated by an authorized representative of such party.

6.8Relationship of the Parties. The parties are independent contractors. Nothing in this EULA or in the activities contemplated by the parties will be deemed to create an agency, partnership, employment or joint venture relationship between the parties. Neither party will have any responsibility nor liability for the actions of the other party except as expressly provided in this EULA. Neither party will have any right or authority to bind or obligate the other party in any manner or make any representation or warranty on beHAL®f of the other party. This EULA is made and entered into for the sole protection and benefit of Gaumard, its licensors and suppliers, and End User, and no other person or entity sHAL®l be a direct or indirect beneficiary of or sHAL®l have any direct or indirect cause of action or claim arising from this EULA.



**ACKNOWLEDGMENT**

**By installation of this software, you acknowledge that you have read and understand the foregoing and that you agree to be bound by its terms and conditions. You also agree that this agreement is the complete and exclusive statement of agreement between the parties and supersedes all proposed or prior agreements, oral or written, and any other communications between the parties relating to the license described herein.**

## 7.4 EXCLUSIVE ONE-YEAR LIMITED WARRANTY

Gaumard warrants that if the accompanying Gaumard product proves to be defective in material or workmanship within one year from the date on which the product is shipped from Gaumard to the customer, Gaumard will, at Gaumard's option, repair or replace the Gaumard product.

This limited warranty covers all defects in material and workmanship in the Gaumard product, except:

- Damage resulting from accident, misuse, abuse, neglect, or unintended use of the Gaumard product;
- Damage resulting from failure to properly maintain the Gaumard product in accordance with Gaumard product instructions, including failure to properly clean the Gaumard product;
- Damage resulting from a repair or attempted repair of the Gaumard product by anyone other than Gaumard or a Gaumard representative.

This one-year limited warranty is the sole and exclusive warranty provided by Gaumard for the accompanying Gaumard product, and Gaumard hereby explicitly disclaims the implied warranties of merchantability, satisfactory quality, and fitness for a particular purpose. Except for the limited obligations specifically set forth in this one-year limited warranty, Gaumard will not be liable for any direct, indirect, special, incidental, or consequential damages, whether based on contract, tort, or any other legal theory regardless of whether Gaumard has been advised of the possibilities of such damages. Some jurisdictions do not allow disclaimers of implied warranties or the exclusion or limitation of consequential damages, so the above disclaimers and exclusions may not apply and the first purchaser may have other legal rights.

This limited warranty applies only to the first purchaser of the product and is not transferable. Any subsequent purchasers or users of the product acquire the product "as is" and this limited warranty does not apply.

This limited warranty applies only to the products manufactured and produced by Gaumard. This limited warranty does not apply to any products provided along with the Gaumard product that are manufactured by third parties. For example, third-party products such as computers (desktop, laptop, tablet, or handheld) and monitors (standard or touch-screen) are not covered by this limited warranty. However, third-party products are covered by the warranties provided by the respective third-party manufacturers and such warranties are transferred from Gaumard to purchaser upon purchase of the Gaumard product. Defects in third-party products are covered exclusively by the warranties provided by the third-parties. Gaumard does not provide any warranty, express or implied, with respect to any third-party products. Please contact the third-party manufacturer for information regarding the availability of extended warranties for third-party products.

Any waiver or amendment of this warranty must be in writing and signed by an officer of Gaumard.

- In the event of a perceived defect in material or workmanship of the Gaumard product, the first purchaser must:
- Contact Gaumard and request authorization to return the Gaumard product. Do NOT return the
- Gaumard product to Gaumard without prior authorization.
- Upon receiving authorization from Gaumard, send the Gaumard product along with copies of (1) the original bill of sale or receipt and (2) this limited warranty document to Gaumard at 14700 SW 136 Street, Miami, FL, 33196-5691 USA.

If the necessary repairs to the Gaumard product are covered by this limited warranty, then the first purchaser will pay only the incidental expenses associated with the repair, including any shipping, handling, and related costs for sending the product to Gaumard and for sending the product back to the first purchaser. However, if the repairs are not covered by this limited warranty, then the first purchaser will be liable for all repair costs in addition to costs of shipping and handling.

### Extended Warranty

In addition to the standard one year of coverage we offer a range of service plans through our Gaumard Cares program. For more information about Gaumard Cares service planes please contact customer service.

## 7.5 CONTACT TECHNICAL SUPPORT

Before contacting Technical Support, please make sure to have the following:

1. Your simulator's serial number
2. Access to the simulator for possible troubleshooting as needed

### Technical Support

Email: support@gaumard.com
USA: 800-882-6655
INT: 01-305-971-3790

## 7.6 GENERAL INFORMATION

### Sales and Customer Service

E-mail: sales@gaumard.com
USA: 800-882-6655
INT: 01-305-971-3790
Fax: 305-252-0755

### Post

Gaumard Scientific
14700 SW 136 Street
Miami, FL 33196-5691
USA

### Office Hours

Monday-Friday, 8:30am - 7:30pm EST (GMT-5)