

Healthcare

CAE Blue Phantom User Guide

BP1610 Amniocentesis Ultrasound Training Model

BP1620 Percutaneous Umbilical Cord Blood Sampling (PUBS) Ultrasound
Training Model



CAE



Disclaimer

This product is a simulation device designed for training and demonstration purposes only.

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Cautions and Warnings

Read this user guide, including all cautions and warnings, before you use your CAE Blue Phantom™ ultrasound training model. Use this product only as described in this guide. If you use the product incorrectly, it may be unsafe and will void your warranty. Keep this information for future reference.

General Precautions

- Make sure the training model is set up on a stable, sturdy work surface such as a bed, stretcher, or table that will not collapse and cause injury to users.
- Heavier training models should be placed on a patient bed or stretcher rated to support such weight.
- Place the model on smooth surfaces only. Rough or uneven surfaces can leave impressions on the skin and damage the model.
- Do only the procedures supported by each product as described in this guide.
- Use only needles to access fluids.
- Do not use or store other sharp objects such as scissors, scalpels, or box-cutters with the training model.
- Do not pull on the training model skin. This can cause the skin to tear.
- Do not mark directly on the training model as this will permanently damage it.
- Do not insert any objects or tools into the model except for the equipment, accessories, or medical supplies intended for use with this model.
- Do not use chemical solvents on the models.
- Clean the training model with water and a light soap solution only. Do not immerse the model or use large amounts of liquid to wash it.

Latex-Free

- All CAE Blue Phantom training models, products, and accessories are manufactured only of materials that do not contain latex.

Needles and Catheters

- Use only new, sharp, unbent 18-21 gauge needles or 7F catheters. Smaller needles (higher than 22 gauge) can bend during use and damage the model.
- The self-healing feature of CAE Blue Phantom simulated tissue applies only to needle sticks from 18-21 gauge needles. Healing is not guaranteed if needles larger than 18 gauge, scalpels, or other sharp implements are used to cut into or pierce the model.
- Replace needles after ten uses. Dull needles can damage the model.
- Use extreme caution when using needles during training to avoid injury.



Fluids System

- Use only CAE Blue Phantom fluids. Other fluids can affect the imaging quality and promote fungal or bacterial growth, and may void your warranty. Use fluids only as directed.
- Do not substitute any other fluid unless indicated by this guide.
- Do not modify the fluid reservoirs or any assembly components.
- Protect your eyes, skin, and clothing against accidental fluid exposure. Refer to the Material Safety Data Sheet (MSDS) for guidance.
 - May irritate eyes or skin; flush well with water.
 - May contain pigments that stain clothing; wash immediately with cold soapy water.
- Fluid is not intended for human consumption. If accidental ingestion occurs, drink a glass of water and consult a physician.

Service and Repair

- The CAE Blue Phantom training models are not user-serviceable. Only a trained technician may open or disassemble the product.
- Unauthorized use or handling of the model may void the warranty.
- If you have a problem with your product, contact CAE Customer Support.

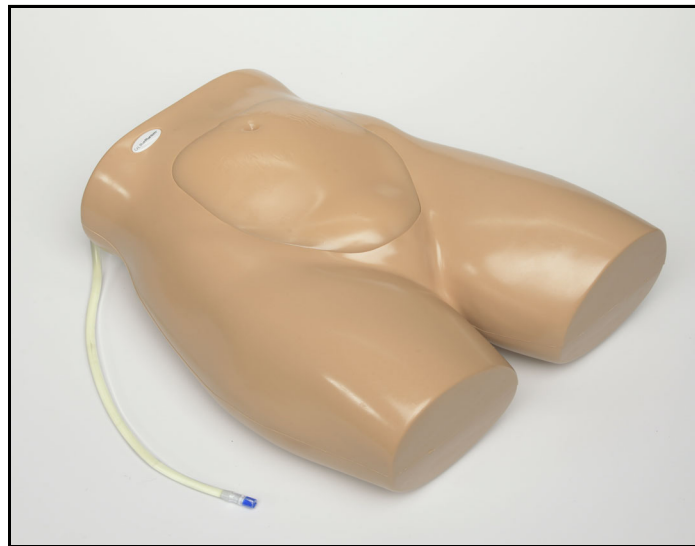


Introduction

This user guide describes the features, use, and care of the following training models:

- CAE Blue Phantom Amniocentesis Ultrasound Training Model (BP1610)
- CAE Blue Phantom Percutaneous Umbilical Cord Blood Sampling Ultrasound Training Model (BP1620)

These models are intended as platforms for the practice of ultrasound-guided amniocentesis and percutaneous umbilical-cord blood sampling (abbreviated PUBS, and also known as cordocentesis).



Ultrasound Training Model

Anatomy

CAE Blue Phantom training models are constructed using our patented Simulex™ ultrasound tissue which has imaging characteristics that mimic human tissue. The models contain skeletal components so the user will encounter the same imaging landmarks as in a human patient.

These training models have one or more tubes that exit through the top of the pelvis. One tube is to fill the amniotic sac within the model. The PUBS model has additional tubes for the umbilical cord. The tubes have a female Luer lock connector that is designed to work with syringes that have a male Luer lock connector.

Models are delivered with minimal fluid. Users must infuse additional fluid to prepare the model for use. More information can be found in the *Using the Training Model* section of this guide.



The Amniocentesis Model (BP1610)

This anatomy of this model includes:

- 18-week male fetus
- Anterior/anterolateral placenta
- Cervix
- Variety of fluid pockets
- Adjustable amniotic fluid volumes

The Percutaneous Umbilical Cord Blood Sampling Model (BP1620)

This anatomy of this model includes:

- 18-week male fetus
- Anterior/anterolateral placenta
- Cervix
- Variety of fluid pockets
- Adjustable amniotic fluid volumes
- Three-vessel umbilical cord with fetal and placental cord insertions

The umbilical cord is filled with red ultrasound refill fluid to simulate blood and offers a pulsatility feature. More information is available in the *Using the Training Model* section of this guide.

Equipment Overview

The following items are included with your shipment:

- Ultrasound training model
- Clear ultrasound refill fluid
- Red ultrasound refill fluid (BP1620 only)

The following additional items are required for training but not included with shipment:

- Ultrasound system with appropriate transducer
- Ultrasound gel
- Amniocentesis equipment per local protocol
- Percutaneous umbilical-cord blood sampling equipment per local protocol (BP1620 only)

CAE Blue Phantom training models are compatible with any diagnostic ultrasound system. General frequency ranges for diagnostic ultrasound imaging are 2-20MHz.



Optional accessories and consumables for your model are available on the CAE website for purchase:

- BP1612 Amniocentesis replacement insert
- BP1614 Percutaneous umbilical-cord blood sampling replacement insert (BP1620 only)
- BRS182-CLEAR Clear ultrasound refill fluid
- BRS180-RED Red ultrasound refill fluid (BP1620 only)
- BPH602-B Soft storage case



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Using the Training Model

This section has information and instructions about the setup and use of the training model and any specific training procedures.

Setup

Follow the guidelines below to unpack and set up your CAE Blue Phantom training model.

1. Open the shipping carton:
 - Use extreme caution with sharp tools, such as a box cutter, to avoid damage to the training model.
2. Unpack the equipment:
 - Remove the training model from its shipping container. For heavier models, use proper lifting techniques to prevent bodily injury.
 - Review the equipment, accessories, and supplies to make sure all necessary pieces are present. See the *Equipment Overview* section of this guide for a list of items included with this model.
3. Set up for training:
 - Put the model on a stable patient bed, stretcher, or table.
 - Prepare your ultrasound system and equipment.
 - Gather any procedural equipment and supplies.

Fluid Setup

The training model is shipped with minimal fluid in any vessels or fluid spaces. During periods of non-use, fluid may also evaporate from inside the model. Before first use, you must add fluid and remove any air.

Amniotic Fluid

The amniocentesis model has one tube to fill the amniotic sac. To fill with fluid, use one of these methods:

Method A: Syringe Fill (also to remove air)

1. Stand the model upright.
2. Remove the cap of the amniotic tube.
3. Fill a syringe half-full with clear ultrasound fluid and connect it to the tube.
4. Hold the tube up and tap it to move any air bubbles upwards.
5. Aspirate the air before filling for optimal imaging.
6. Inject 10 ml of fluid.



Using the Training Model

7. Remove 5 ml of fluid along with any air.
8. Repeat steps 4 through 7 until all the air is removed.
9. Remove the syringe and replace the cap.

Method B: Quick-Fill port for high volume use

1. Connect an IV bag containing CAE Blue Phantom fluid to the amniotic tube.
2. Hang the IV bag no more than 12 inches (30 cm) above the training model to avoid overfilling.

NOTE: A clear sign of overfill is the appearance of small dimples of simulated blood on the surface of the model at the sites of previous cannulations. To correct overfill, see the *Troubleshooting* section.

3. As users withdraw fluid from the amniotic sac, it is refilled continuously from the IV bag.

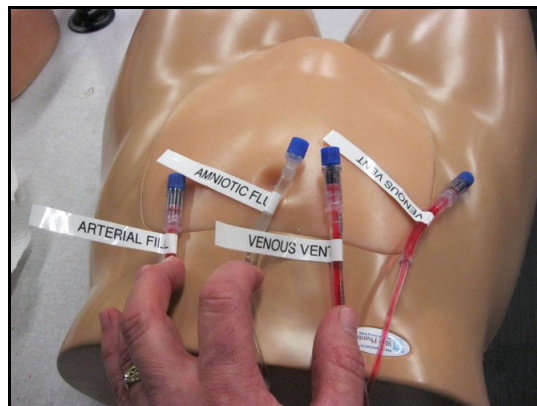
Umbilical Cord Blood Fluid (BP1620 only)

The BP1620 model also has a simulated umbilical cord. Before your first use of this model, you must also add fluid to the umbilical cord.

There are four tubes attached to model:

- One (1) amniotic fill tube (clear fluid)
- One (1) arterial fill tube (red fluid)
- Two (2) venous vent tubes (red fluid)

The three red lines are attached to the terminus of the umbilical cord.



BP1620 Model Tubes

To fill the umbilical cord:

1. Remove blue caps from one (1) venous vent tube and from the arterial fill tube (leave the check valves in place).
2. Fill a syringe with red ultrasound refill fluid and attach it to the arterial fill tube.



3. Attach the body of a second empty syringe (without the plunger) to the venous vent tube.
4. Slowly inject fluid into the arterial fill tube. Any air will be pushed up into the venous vent tube along with some fluid.
5. When the cord is full, remove the arterial syringe, then remove the venous vent syringe and replace the caps. The maximum fill volume of the cord is 10 ml.
6. If any air bubbles remain, repeat steps 1-5 with the other venous line.

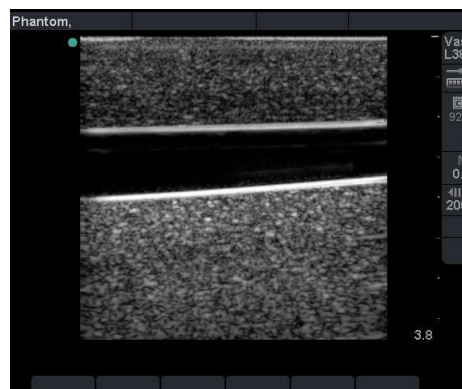


Removing Air and Filling the Cord

⚠ CAUTION

Filling the umbilical cord without venting may overpressure the cord and cause it to burst.

An optimally-filled umbilical cord can be identified using ultrasound by the presence of a black echo-free lumen.



Normal Fluid Level - Good Imaging



Using the Training Model

A low fluid environment is identified by the inability to see the cord during normal ultrasound imaging. This is due to the presence of air, which reflects all sound energy.



Low Fluid Level - Poor Imaging

Umbilical Cord Pulsatility Feature

To set up pulsatility for the umbilical cord:

1. Connect an empty syringe to the Quick Fill™ tube.
2. Quickly push and pull the plunger to simulate umbilical arterial pulsation.

Training

This section provides information about using your model for training and practice.

Ultrasound Scanning

Note: CAE Blue Phantom products do not teach ultrasound procedures or techniques. Refer to your institution or training program for more information.

To scan with your training model and conduct a simulated ultrasound-guided procedure:

1. Place the model in the appropriate position for scanning.
2. Place ultrasound gel on the transducer or on the training model in an adequate quantity so that the transducer slides effortlessly on the model. Add more gel as needed.
3. Adjust the ultrasound system controls per your training protocol and the manufacturer's instructions. Optimize the image with the ultrasound controls as needed.

Ultrasound-guided Procedures

Your CAE Blue Phantom training model is a realistic platform for complete amniocentesis and cordocentesis (BPI620 only) procedural training. For amniocentesis or cordocentesis, use your normal protocol and equipment, and follow your institution's policies and guidelines.



⚠ CAUTION

Do not use antiseptics, such as iodine, on your training model. This can cause permanent damage to the model.

During amniocentesis and cordocentesis training, users may withdraw fluid from the model. To maintain the fluid level, any fluid that is withdrawn must be refilled.

Refill the fluid using one of the filling methods described in the *Fluid Setup* section of this guide. A third way is for users to refill fluid by simply re-injecting it:

- During use, the user immediately injects any withdrawn fluid back into the model at the injection site.
- Take care not to inject any air into the model when using this method.



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Care and Maintenance

With proper care, your training model will remain in optimal condition and ready for use.

Storage and Transport

Follow these guidelines to properly store or transport your model:

- Storage temperature degree range: 45 to 85 °F (7 to 29 °C)
- Store the model as is, or in a CAE Blue Phantom storage case (if available for your model).
- Do not store in contact with other models or hard objects as the pressure can damage the Simulex tissue. Do not stack multiple training models on top of each other.
- Ensure any tubes are not pinched or compressed under the model. This will damage the tubes and void the warranty.
- When models with inserts are stored standing up for long periods of time, gravity may cause the insert to deform slightly. Remove the insert and let it sit for a few days to regain its shape.
- Store the model with some fluid in any vessels and fluid spaces. If these become dry, it will damage the model and cause poor ultrasound imaging.
- If fluid was infused into the model during training, remove excess fluid after each training session. If you store the model with too much fluid inside, it can cause damage.
- Transport the model securely so it does not fall.
- Do not carry by the tubes or use them as handles as this will damage the model.

Cleaning

To maintain the product skin for the lifespan of the product, clean the exterior of the model after each use. Follow these steps:

1. Mix one cup of tap water with ¼ teaspoon of mild liquid soap (such as dish soap).
2. Gently clean the model's exterior with the soap mixture and a soft, non-abrasive sponge or cloth.
3. Rinse lightly with clean water.
4. Dab or pat with a clean, soft, lint-free cloth to dry the product after cleaning. Do not wipe or rub the skin, which can damage it.
5. After the model has dried completely, lightly coat the external surface of the model with baby powder and dust off any excess.



Replacing the Tissue Insert

To replace the insert, you will need:

- Replacement insert
- 1:4 soap and distilled water mixture
- Clean, lint-free cloth

Follow these steps:

1. Position your training model in the upright position.
2. Lubricate the opening(s) around the tube(s) with the soap and distilled water mixture. Apply enough lubrication so the tube slides out easily. Do not inject the soap and distilled water mixture directly into the tubing.
3. Gently lift up and pull the insert and tube(s) out completely.

⚠ CAUTION

The attachment point of the tube to the Simulex tissue is delicate. Do not apply stress to the connection or it can tear. Do not pull hard on tubes or use them to carry the insert.

4. Place the tube(s) of the new insert into the correct openings.
5. Set the tissue insert into the space.
6. Adjust the insert as needed so it aligns with the surface of the model.
7. Dry with the clean, lint free cloth as needed.

Troubleshooting

This section provides information to identify and fix problems that may occur with the product.

Fluid Overfill

You can overfill fluid spaces and vessels if you inject too much fluid. Overfill does not usually result in permanent damage, but you should correct it as soon as possible.

Withdraw excess fluid to alleviate overfill, or, with the Quick Fill method, make sure the IV bag is not hanging any higher than 12 inches (30 cm) above the training model.

Removing Air

Fluid can evaporate from the model during shipment or during extended periods of non-use. Air may also enter through accidental injection during fluid filling or training use. This may cause the Simulex tissue to



stick together in some areas, preventing fluid from circulating. Remove any air from the model for optimal performance.

To remove air:

1. Fill a syringe with fluid and connect it to the tube.
2. Infuse fluid, and tilt the model up at least 6-10" so any air rises to the top.
3. Let the model sit for at least one hour to allow any air to rise.
4. Use the syringe to slowly pull the fluid out of the model.
5. Watch for air bubbles and let them rise to the top (back) of the syringe.
6. Slowly push fluid back in without pushing the air in.
7. Repeat steps 4-6 three to four times.
8. Empty the syringe into a container and use it to remove any additional fluid, then disconnect it.

NOTE: When all the fluid is removed, the syringe will be under vacuum. Do not put excessive force on the syringe or the tissue may rupture.

9. If there is still air, fill any fluid spaces or vessels with fluid and let the model sit overnight, then repeat the procedure.

Air in the Umbilical Cord (BP1620 only)

To remove air from the umbilical cord, follow the procedure in the *Fluid Setup* section of this guide.



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For more information about CAE products, contact your regional sales manager or the CAE distributor in your country, or visit caehealthcare.com.

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