Healthcare

CAE Blue Phantom User Guide

BPH700 Cardiac Ultrasound Training Block, opaque BPH700-C Cardiac Ultrasound Training Block, transparent



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.
 - ^o 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.



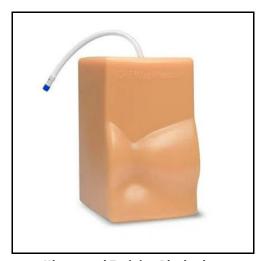
Introduction

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

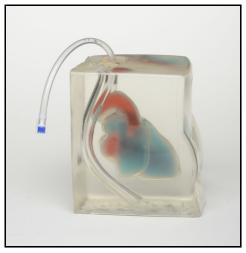
- CAE Blue Phantom Cardiac Ultrasound Training Block, opaque (BPH700)
- CAE Blue Phantom Cardiac Ultrasound Training Block, transparent (BPH700-C)

These models are intended as platforms for the practice of transthoracic and transesophageal (TEE/TOE) echocardiography and pericardiocentesis. The opaque model supports blind transducer manipulation and ultrasound-guided pericardiocentesis. The transparent model allows for visibility of transducer insertion/manipulation and insertion of the needle into the pericardium.

NOTE: Transesophageal echocardiogram has two common abbreviations, TEE and TOE (from the alternate spelling: trans-oesophageal).



Ultrasound Training Block, clear



Ultrasound Training Block, transparent

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Anatomy

CAE Blue Phantom training models are constructed using our patented Simulex™ ultrasound tissue which has imaging characteristics that mimic human tissue. These models have one tube to the pericardial space. The tube has 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 Cardiac Ultrasound Training Block has the following internal anatomy:

- Left and right ventricles
- · Left and right atria
- · Mitral, tricuspid, aortic, and pulmonic valves
- · Left atrial appendage
- Pulmonary arteries and veins
- Pericardium (with adjustable fluid level)
- Ascending aorta
- Superior and inferior vena cava

Equipment Overview

The following items are included with your shipment:

- Ultrasound training block
- · Clear ultrasound refill fluid

The following additional items may be required for training but are not included in your purchase:

- · Ultrasound system with appropriate transducer
- Ultrasound gel
- Pericardiocentesis equipment as per local protocol

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:

BRS182-CLEAR Clear ultrasound refill fluid



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. Use either of the methods below.

Note: The maximum fill volume of the Cardiac Block Ultrasound Training Model pericardial space is 500 ml.

Method A: Syringe Fill

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

- 7. Repeat steps 3 through 6 until all the air is removed and the vessels are filled.
- 8. Replace the cap.

Method B: Quick-Fill port for high volume use

- 1. Connect an IV bag containing CAE Blue Phantom fluid to the fill 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, it is refilled continuously from the IV bag.

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.

Transesophageal Echocardiogram (TEE/TOE)

To do a TEE/TOE simulation, you will need a transesophageal transducer probe. To use a TEE/TOE probe in simulation on a training model, you must lubricate both the transducer and the esophagus of the training model with ultrasound gel. This additional step is necessary because unlike live patients, the training model does not have a naturally-lubricated esophagus. Ensure the length of the transducer is well-lubricated prior to inserting into the esophagus of the training model.



Transducer covers are often used in exams with real patients. Transducer covers are not necessary when using a training model, but you may use them for realism if desired. If you use a transducer cover, follow these steps:

- 1. First, cover the tip of the transducer with gel.
- 2. Next, place the transducer cover over the transesophageal transducer.
- 3. Then apply gel to the sheathed transducer in adequate quantities so that the probe slides easily into the model. Add more gel as needed.

Buildup of dried ultrasound gel should not impair echocardiographic imaging and can easily be cleaned from the model. For instructions, see the *Care and Maintenance* section of this user guide.

A CAUTION

You must lubricate the transesophageal transducer and the esophagus of the training model with ultrasound gel, or damage to the model will occur.

In addition, follow these guidelines when using the transesophageal transducer:

- If you use the transducer rotary controls per the manufacturer's user guide to put a slight forward flex in the probe tip to help with introduction, do not lock the rotary controls in this position. If the flexed tip is locked, it can perforate the esophagus.
- Do not force the transducer if you encounter resistance moving it through the esophagus. If there is resistance, end the procedure immediately.
- Do not flex the transducer excessively while the probe is in the model's esophagus. This can damage the esophagus.

During imaging, the cardiac structures will come into view as you first pass the great vessels, and then the cardiac chambers. All standard TEE/TOE views are obtainable.

To end the procedure, verify that all rotary controls are in a neutral and unlocked position, then slowly withdraw the transducer.

Ultrasound-Guided Procedures

Your CAE Blue Phantom training model is a realistic platform for pericardiocentesis procedural training. Use your normal protocol and equipment for these procedures, and follow the policies and guidelines of your institution.

A CAUTION

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

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

Using the Training Model

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.

Different color fluids are used to assist you as you practice the procedure:

- Pericardial fluid is clear (or light red if red fluid was added to the clear fluid to simulate blood in the pericardial fluid).
- Intracardiac fluid has two colors: Blue in the right heart and red in the left heart.

As you practice pericardiocentesis, you should see clear fluid when you are in the pericardium. If you see blue or dark red fluid, you have inadvertantly entered the heart. Do not withdraw the needle. To make a correction, follow these steps:

- 1. Re-inject the fluid removed from the heart (make sure you do not inject any air).
- 2. Withdraw the needle until you are in the pericardium.
- 3. Continue the simulated pericardiocentesis.

NOTE: Never inject fluid withdrawn from the heart into the pericardium, or from the pericardium into the heart. Do not inject air into the heart or the pericardium because air will obstruct imaging. If air enters the system, it must be removed. To do this, see the *Troubleshooting* section of this user guide.



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 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:

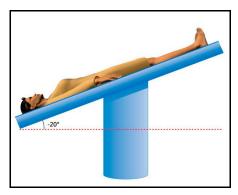
- 1. Mix one cup of tap water with ¼ teaspoon of mild liquid soap (such as dish soap).
- 2. Gently clean the model's exterior with the soap mixture and a soft, non-abrasive sponge or cloth.
- 3. Rinse lightly with clean water.
- 4. Dab or pat with a clean, soft, lint-free cloth to dry the product after 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.

Cleaning the Esophagus

If you encounter reduced quality of the echocardiographic image after extensive use, it may be necessary to clean the esophagus with the liquid soap/water mixture.

To clean the esophagus:

1. Place the training model in a moderate Trendelenburg position. This puts the superior opening to the esophagus lower than the torso to help with the draining of fluid.



Moderate Trendelenburg Position

- 2. Fill the 1:1 water and soap mixture into a syringe with tubing attached.
- 3. Put the tubing into the esophagus and infuse the soap mixture through the tube.
- 4. Flush the esophagus with the soap mixture and allow the fluid to flow back out.
- 5. Repeat steps 4-5. You will have flushed the esophagus two times.
- 6. Leave the model in the Trendelenburg position and let it dry. Drying time is approximately three (3) hours at room temperature.

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. Push 500cc of fluid into the heart line labeled "Effusion."
- 2. Massage the area on the surface of the model around the heart to help circulate the fluid.
- 3. Let the model sit for at least one hour to allow any air to rise to the top. You can leave it overnight for this step, if preferred.
- 4. Use the included syringe to slowly pull the fluid out of the model.
- 5. Watch for air bubbles and let them rise to the top of the syringe.
- 6. Slowly push the fluid back in without pushing the air back in.
- 7. Repeat Steps 4 to 6 three to four times, as needed.
- 8. Dispense any remaining fluid back into the container and use the syringe to remove any additional fluid. When the effusion is empty, the syringe will be under vacuum. Do not put excessive force on the syringe or the tissue may rupture.
- 9. If the procedure is not successful, fill the model again with 500cc of fluid and let it sit overnight. Then repeat the procedure.

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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.

Tel +1 941-377-5562 or 866-233-6384

For customer support, please contact CAE.

Customer Support Headquarters - United States Monday - Friday from 7:00 a.m. to 6:00 p.m. ET Phone 1-866-462-7920 Email: srqcustomerservice@cae.com

Customer Support - Canada Monday - Friday from 8:00 a.m. to 5:00 p.m. ET Phone 1-877-223-6273 Email: can.service@cae.com

Customer Support - Europe, Middle East, and Africa Monday - Friday from 8:00 a.m. to 5:00 p.m. CET Phone +49 (0) 6131 4950354 Email: international.service@cae.com

Customer Support - United Kingdom and Ireland Monday - Friday from 9:00 a.m. to 5:00 p.m. GMT Phone +44 (0) 800-917-1851 Email: uk.service@cae.com

Customer Support - Latin America Monday - Friday from 9:00 a.m. to 5:00 p.m. BRT/BRST Phone +55 11 5069–1510 Email: la.service@cae.com

Customer Support - Asia Pacific Monday - Friday from 8:00 a.m. to 5:00 p.m. CET Phone +49 (0) 6131 4950354 Email: ap.service@cae.com