Healthcare

CAE Blue Phantom User Guide

BPPARA-FEM1301-NFN-NFV Paracentesis Ultrasound Training Model
BPPARA-FEM1301-FN-FV Paracentesis Ultrasound Training Model with Femoral Vessels and Nerves

Disclaimer

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

Proprietary Notice

Trademark Information

Contents

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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

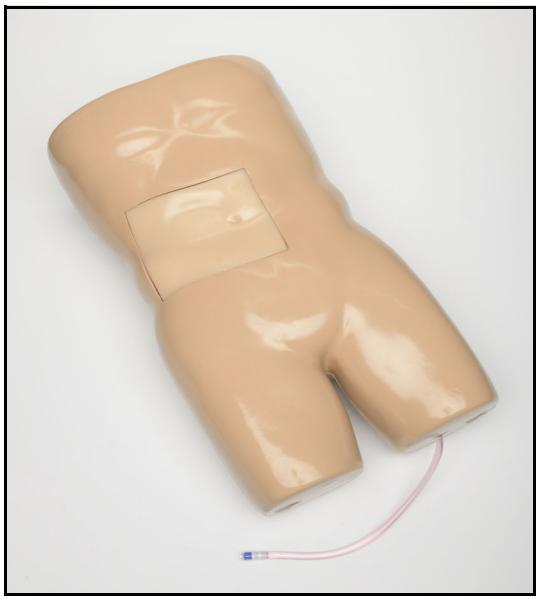
- The CAE Blue Phantom training models are not user-serviceable. Only a trained technician may open or disassemble the product.
- Unauthorized use or handling of the model may void the warranty.
- If you have a problem with your product, contact CAE Customer Support.

Introduction

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

- CAE Blue Phantom Paracentesis Ultrasound Training Model (BPPARA-FEM1301-NFN-NFV)
- CAE Blue Phantom Paracentesis Ultrasound Training Model with Femoral Vessels and Nerves (BPPARA-FEM1301-FN-FV)

These models are intended as platforms for the practice of ultrasound-guided paracentesis.



Ultrasound Training Model

Ultrasound Training Model with Femoral Vessels and Nerves

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.

The internal anatomy includes:

- Right lobe of the liver
- Small bowel
- Transverse colon
- Peritoneal fluid collections
- Several fluid pockets
- Femoral vessels and nerves (BPPARA-FEM1301-FN-FV only)

Both models have one tube to fill or drain the fluid space. The tube has a female Luer lock connector that is designed to work with syringes that have a male Luer lock connector.

Model BPPARA-FEM1301-FN-FV has two additional tubes to fill the femoral vessels. One tube has a hand bulb to manually simulate arterial pulsation. For more information, see the *Using the Training Model* section of this guide.

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.

Equipment Overview

The following items are included with your shipment:

- Ultrasound training model

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

- Ultrasound system with appropriate transducer
- Ultrasound gel
- Paracentesis and vascular access 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 or consumables for your model are available to purchase on the CAE website:

- BPPARA1302 Paracentesis replacement insert
- BPF1412-HP Gen I Femoral Vascular Access replacement insert with hand pump
- BPF1415-HPGen I Femoral Vascular Access and Regional Anesthesia replacement insert with hand pump
- BRS182-CLEAR Clear Ultrasound refill fluid
- BPPARA1304 -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. Use one of these methods:

Method A: Syringe Fill (also to remove air)

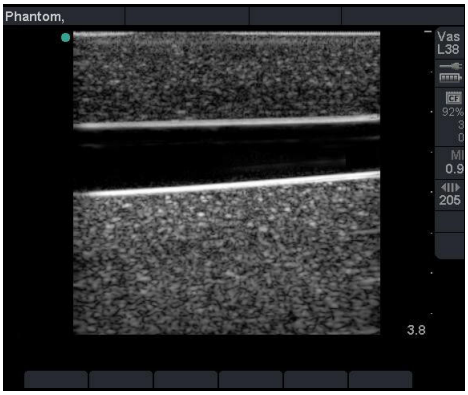
1. Remove the cap of the fill tube.
2. Fill a syringe half-full and connect it to the tube.
3. Hold the tube up and tap it to move any air bubbles upwards.
4. Aspirate the air before before filling for optimal imaging.
5. Inject 10 ml of fluid.
6. Remove 5 ml of fluid along with any air.
7. Repeat steps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

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



Normal Fluid Level - Good Imaging

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

Low Fluid Level - Poor Imaging

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 paracentesis, femoral vascular access (BPPARA-FEM1301-FN-FV only), and nerve block (BPPARA-FEM1301-FN-FV only) training. 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 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.

  NOTE: This method cannot be used with full catheter placements.

Using the Hand Bulb

Applies to BPPARA-FEM1301-FN-FV only

This model is equipped with a hand bulb. You can create a pulse in the arteries by lightly squeezing the hand bulb. The pulse is not physically palpable, but is visible via ultrasound.

The veins do not pulsate, and are collapsible with light pressure from the transducer.

⚠ CAUTION

Excess pressure on the hand bulb may cause a fistula between arteries and veins.

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 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

Follow these steps:

1. Position your training model in the upright position.
2. Gently lift up and pull the insert out completely.
3. Place the new insert into the base.
4. Adjust the insert as needed so it aligns with the surface of the model.

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.

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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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