

Brevera® System

Setup Guide for MammoTest®

PLEASE READ PRIOR TO PERFORMING PROCEDURE:

This setup guide is designed to be used in conjunction with, not replace, the Brevera breast biopsy device instructions for use. Prior to performing the procedure, the physician must review and be familiar with the full operating instructions for the Brevera breast biopsy device and biopsy image guidance system. Consult the Brevera breast biopsy device instructions for use for full operational instructions, as well as any contraindications and safety information.

Please retain this setup guide. Note that while Hologic frequently updates the contents of this guide, medical information and technology can change rapidly. Therefore some of the information in this guide may be out of date. Use of these instructions with any product other than those specifically noted may result in injury to the patient and/or damage to the equipment.

Note: Applies to MammoTest systems made by Fischer, Siemens, or Mammotome.

Program the breast biopsy image guidance system for the Brevera breast biopsy device according to the needle setup instructions provided in the appropriate breast biopsy guidance system user manual. Specific parameters are listed below.

MammoTest is Compatible with the following Brevera Components and Biopsy Accessories:

| Catalog Number | Description |
|----------------------|-------------------------------------|
| BREVDRV | Brevera Driver |
| BREVADPTRM | Brevera Adapter for MammoTest |
| BREV09 | Standard Stereotactic Biopsy Needle |
| BREVSTYLBRKT | Stylet Bracket |
| EVIVA_NG09L | Needle Guide |
| EVIVA_NG HOLDER | Needle Guide Holder for MammoTest |
| EVIVA_CALIBRATE_13CM | Calibration Handpiece 13cm |

Setup of MammoTest for Use with Brevera Biopsy (Frontal and Lateral Approaches)

To Install the Brevera Adapter:

NOTE: The following is a general setup guide. Refer to the MammoTest Operator Manual for more details.

1. Slide the needle guide holder into place on the rail of the AutoGuide.
2. Slide the Brevera adapter into place on the rail of the AutoGuide until it stops at the Depth Stop.
Check the Brevera Adapter components (reference Figure 1) to ensure they are secure . If the components are not secure call technical support.
3. Place needle guide in needle guide holder.

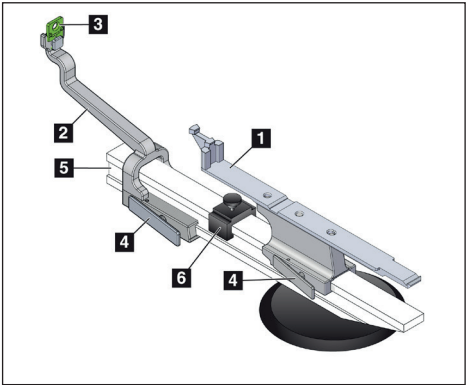


Figure Legend

- 1. Adapter
- 2. Needle Guide Holder
- 3. Needle Guide
- 4. Levers (2)
- 5. Rail
- 6. Depth Stop

Figure 1: How to Install the Brevera Adapter

To Remove the Brevera Adapter:

1. Press the lever on the side of the adapter to release and slide off the rail.
Repeat process to remove needle guide holder.

Parameter Setup for use of Brevera Biopsy Device on the MammoTest (Frontal and Lateral Approach)

Entering the Holder

NOTE: The following is a general setup guide. Refer to the MammoTest Operator Manual for more details.

NOTE: Log in as Administrator to enter Holder settings.

- At the MammoVision® screen, click **UTILITIES**
- At the Utilities Control Panel, click **SETUP**
- At the Password screen, type password (such as **siemens**)
- At the Install Control Panel, click **DESCRIBE HOLDERS**
- Click on the number to be assigned to this holder
- Enter title to be assigned to this holder: **BRH09-20**
- Enter holder length: **-86.6**
- Click on **DONE**
- At the Install Control Panel, click **DESCRIBE HOLDERS**
- Click on the number to be assigned to this holder
- Enter title to be assigned to this holder: **BRH09-12**
- Enter holder length: **-94.6**
- Click on **DONE**

Entering the Needle

- At MammoVision screen, click **UTILITIES**
- At Utilities Control Panel, click **SET-UP**
- At Set-up Control Panel, click **DESCRIBE NEEDLES**
- Click on the number to be assigned to this needle
- Click on the title of the holder: **BRH09-20**
- Enter the Needle Name, Length, Needle Gauge, Stroke, and BackUp information for each needle per the table
- Click on **DONE**

| Parameters | BREV09 | |
|-------------------------|-----------------|---------------|
| | 20mm (Standard) | 12mm (Petite) |
| Recommended Needle Name | BREV0920 | BREV0912 |
| Holder Name | BRH09-20 | BRH09-12 |
| Length (mm) | 103.5 | 103.5 |
| Needle Gauge | 9.0 | 9.0 |
| Stroke (mm) | 23.0 | 15.0 |
| BackUp (mm) | 5.23 | 0.35 |

Perform target verification with 13cm Calibration Handpiece

The tip of the 13cm Calibration Handpiece (EVIVA_CALIBRATE_13CM) represents the location of the tip of the Standard Brevera handpiece (BREV09, 20mm) in the pre-fire position. Therefore, the Depth, and not the Adjusted Depth, must be used when positioning the Calibration Handpiece for verification.

Verify Correct Parameters

- At the MammoVision screen, click **UTILITIES**
- Click **TARGET VERIFY**
- Click **PHANTOM**
- Click **SELECT NEEDLE**
- Select **entered name for 20mm (Standard)**
- Verify that information in the lower left of the MammoVision screen matches that in the Parameters Table for the 20mm (Standard) needle (BackUp value will be rounded and display 5.2 mm)
- At the MammoVision screen, click **UTILITIES**
- Click **TARGET VERIFY**
- Click **PHANTOM**
- Click **SELECT NEEDLE**
- Select **entered name for 12mm (Petite)**
- Verify that information in the lower left of the MammoVision screen matches that in the Parameters Table for the 12mm (Petite) needle (backup will be rounded and display 0.4)

Cleaning Instructions for Adapter Components

Remove adapter from biopsy guidance system before cleaning.

Use a lint-free cloth and apply a diluted, mild detergent to clean components and surfaces. To remove more difficult soils, use a soft bristle brush as needed.

Caution: Use the least possible amount of cleaning fluids. The fluids must not flow or run.

Disinfecting the Adapter

To disinfect the system's components and surfaces, Hologic recommends the following disinfecting solutions:

- 10% chlorine bleach and water with one part commercially available chlorine bleach (normally 5.25% chlorine and 94.75% water) and nine parts water. Mix this solution daily for best results
- Commercially available isopropyl alcohol solution (70% isopropyl alcohol by volume, not diluted)
- Commercially available wipes containing less than or equal to 2% quaternary ammonium compounds by weight in water

Apply disinfecting solutions to the system using a clean, lint-free cloth or wipe. Wipe the system with the wet cloth, observing appropriate contact (wet) times. Do not spray cleaning solutions directly on the console or other parts of the Brevera breast biopsy system.

Caution: To prevent damage to the electronic components, do not use disinfectant sprays on the system.

To Prevent Possible Injury or Equipment Damage

Do not use a corrosive solvent, abrasive detergent, or polish. Select a cleaning/disinfecting agent that does not damage the plastics, aluminum, or carbon fiber.

Do not use strong detergents, abrasive cleaners, high alcohol concentration, or methanol at any concentration.

Do not expose equipment parts to steam or high temperature sterilization.

Do not let liquids enter the internal parts of the equipment. Do not directly apply cleaning sprays or liquids to the equipment. Always use a clean, lint-free cloth and apply the spray or liquid to the cloth. If liquid enters the system, disconnect the electrical supply and examine the system before returning it to use.

Caution: Wrong cleaning methods can damage the equipment, decrease imaging performance, or increase the risk of electrical shock.

Always follow instructions from the manufacturer of the product you use for cleaning and disinfection. The instructions include the directions and precautions for the application and contact time, storage, wash requirements, protective clothing, shelf life, and disposal. Follow the instructions and use the product in the most safe and effective method.

Warranty

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ("Warranty Period"); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products. These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

How Supplied

The Brevera adapter is supplied as a separately packaged accessory.

For More Information

For technical support or reorder information in the United States, please contact:



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International customers, contact your distributor or local Hologic Sales Representative:



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Symbols:


The following symbols may be found on the product labeling for the Brevera adapter:

- EC


REP


Authorized representative in the European Community
- REF


Catalog number
- 


Consult instructions for use
- 

Date of manufacture
- YYYY-MM-DD

Expiration date is represented by the following:
YYYY represents the year
MM represents the month
DD represents the day
- 


Keep dry
- 


Manufacturer
- 

MR Unsafe
- 

Non-sterile
- QTY

Quantity
- SN

Serial number
-  ONLY

Caution: Federal law restricts this device to sale by or on the order of a physician
-  2797

CE marking of conformity with notified body identification number