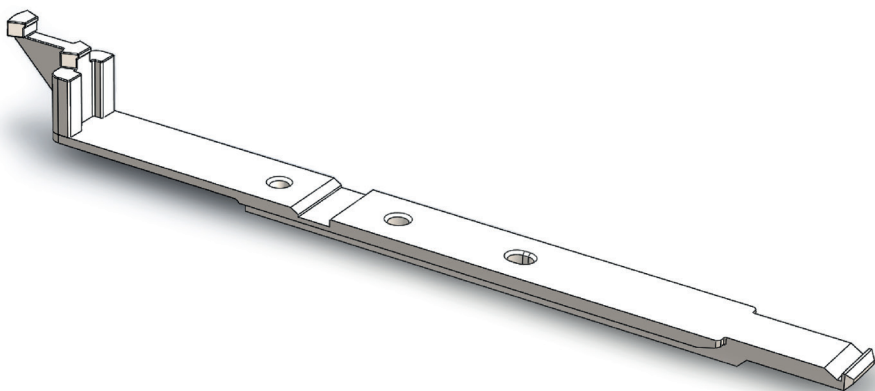


Brevera®

Breast Biopsy System



Hologic Biopsy Guidance System
Setup Guide

HOLOGIC®

Brevera® System

Setup Guide for Hologic Affirm® and Multicare® Platinum Products

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 Therefore some of the information in this guide may be out of date.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.

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.

Hologic Affirm and Multicare Platinum Products are Compatible with the following Brevera Components and Biopsy Accessories:

Catalog Number	Description
BREVDRV	Brevera Driver
BREVDPTR	Brevera Adapter
BREV09	Standard Stereotactic Biopsy Needle
EVIVA_NG09L	Needle Guide

Setup of Hologic Affirm Biopsy Guidance System with or without the Lateral Arm Upright Biopsy Accessory and Affirm Prone Biopsy System for Use with Brevera Biopsy

To Install the Brevera Adapter:

1. Align the outer holes in the adapter with the guide pins on the mount.
2. Align the center hole with the mount screw.
Check the Brevera Adapter components (reference Figure 1) to ensure they are secure . If the components are not secure call technical support.
3. Turn the knob clockwise on the mount to attach the adapter.
4. Place needle guide in needle guide holder.
Check to make sure the cable, tubing, and other parts of the Brevera biopsy device are clear of the x-ray tube during rotation.

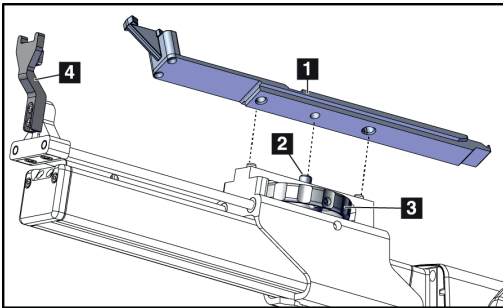


Figure 1: How to Install the Brevera Adapter

Figure Legend

1. Adapter
2. Mount Screw
3. Mount Knob
4. Needle Guide Holder

To Remove the Brevera Adapter:

1. Turn the knob counterclockwise on the mount to release the adapter.
2. Pull the adapter away from the mount.

Parameter Setup for use of Brevera Biopsy Device on the Affirm Upright Biopsy Guidance System

Parameters	Safety Margin Parameters (mm)	
	BREV09	
	20mm (Standard)	12mm (Petite)
Aperture	19.81	13.56
Dead Space	7.87	7.87
Diameter	4.17	4.17
Length	202.74	202.74
Offset	37.34	37.34
Prefire Pullback	-5.23	-0.35
Stroke	23.00	15.00
Front Edge	86.36	86.36
Body Size	16.00	16.00

Parameter Setup for use of Brevera Biopsy Device on the Affirm Prone Biopsy System

Parameters	Safety Margin Parameters (mm)	
	BREV09	
	20mm (Standard)	12mm (Petite)
Aperture	19.81	13.56
Dead Space	7.87	7.87
Diameter	4.17	4.17
Length	202.74	202.74
Offset	37.34	37.34
Prefire Pullback	-5.23	-0.35
Stroke	23.00	15.00
Needle Front	86.36	86.36
Needle Width	55.88	55.88

Setup of Hologic Multicare Platinum Prone Biopsy System for Use with Brevera Biopsy

Contact Technical Support to confirm compatibility of your biopsy device. Install the biopsy adapter as shown below, then install the biopsy device. (Refer to the user manual provided by the biopsy device manufacturer for installation and operating instructions.)

To Install the Brevera Adapter:

1. Align the adapter with the pins on the Stage platform, and put the adapter on the platform.
2. Turn the knob clockwise to tighten the adapter.
Check the Brevera Adapter components (reference Figure 2) to ensure they are secure . If the components are not secure call technical support.
3. Place needle guide in needle guide holder.

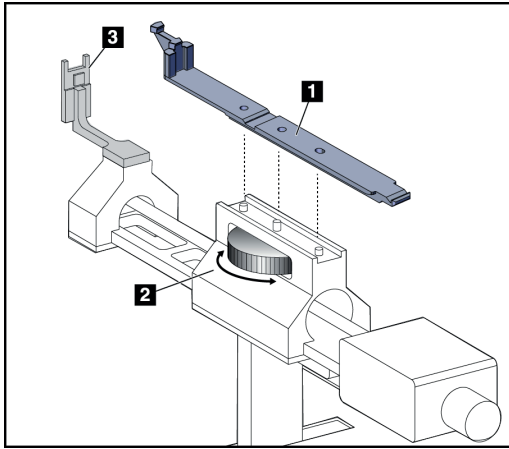


Figure 2: How to Install the Brevera Adapter on the Stage

Figure Legend

1. Adapter
2. Mount Knob
3. Needle Guide Holder

To Remove the Brevera Adapter:

1. Turn the knob counterclockwise on the mount to release the adapter.
2. Pull the adapter away from the mount.

Parameter Setup for use of Brevera Biopsy Device on the Multicare Platinum Biopsy System (PRONE)

Parameters	Safety Margin Parameters (mm)	
	BREV09	
	20mm (Standard)	12mm (Petite)
Mode	Needle Core Biopsy	Needle Core Biopsy
Stroke	23	15
Differential	-5.2	-0.4
Safety Equation	$Z + 6 \leq \text{compression}$	$Z + 3 \leq \text{compression}$
Minimum Compression	28	22

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:



Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
Phone: 1-877-371-4372
www.hologic.com

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




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Tel: +32 2 711 46 80


Symbols:

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

 Authorized representative in the European Community

 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

 Quantity

 Serial number

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

 CE marking of conformity with notified body identification number

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