

Please Read Prior to Performing Procedure

This setup guide is designed to be used in conjunction with, not replace, the Eviva breast biopsy device instructions for use and/or the Siemens MAMMOMAT Inspiration. Prior to performing the procedure, the physician must review and be familiar with the full operating instructions for the Eviva breast biopsy device and Siemens system(s). Consult the Eviva breast biopsy device instructions for use and the Siemens system(s) operator manual for full operational instructions, as well as any contraindications and safety information. Verification testing was conducted to ensure accuracy of the Eviva biopsy device on the Siemens system(s). However, the setup numbers provided herein are for guidance purposes only. The setup numbers must be verified onsite with the corresponding Eviva biopsy device prior to performing any procedure.

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 Therefore some of the information in this guide may be out of date.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

Eviva Biopsy Device Setup for Siemens MAMMOMAT INSPIRATION

Program the Siemens system(s) for Eviva biopsy device according to the needle setup instructions provided in the Instructions for Use Mammomat Inspiration manual. Specific parameters are listed below.

LATERAL APPROACH NEEDLE HOLDER CONFIGURATION (mm)	
Mat. Number	10655844
X	72,0
Y	0,0
Z	114,5
Safety Distance	15,0

LATERAL APPROACH					
Biopsy Device	Gauge	Needle Guide	L1 Horizontal (mm)	L2 (mm)	L3 (mm)
Eviva 0910-20	9	Eviva NG09R	92	17	19
Eviva 1210-20	12	Eviva NG12R	92	17	19
Eviva 0910-12T	9	Eviva NG09R	92	14	11

VERTICAL APPROACH NEEDLE HOLDER CONFIGURATION (mm)	
Mat. Number	10847076
X	0,0
Y	4,0
Z	38,0
Safety Distance	5

VERTICAL APPROACH					
Biopsy Device	Gauge	Needle Guide	L1 Vertical (mm)	L2 (mm)	L3 (mm)
Eviva 0910-12	9	Eviva NG09R	63	11	12
Eviva 0910-12T	9	Eviva NG09R	65	14	11
Eviva 0913-20	9	Eviva NG09R	90	17	19
Eviva 1213-20	12	Eviva NG12R	90	17	19
Eviva 0913-12	9	Eviva NG09R	90	11	12
Eviva 0913-12T	9	Eviva NG09R	90	14	11

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Performing a Stereotactic Biopsy using the Eviva biopsy device on the Siemens MAMMOMAT INSPIRATION

1. Attach the appropriate Siemens Inspiration needle holder to the *Eviva Adapter*
2. Install the *Eviva Adapter* with Siemens Inspiration needle holder onto the Siemens system(s).
3. Install the appropriate disposable needle guide, *Eviva_NG09R* or *Eviva_NG12R*, onto the Siemens system(s).
4. Ensure the proper Eviva biopsy device is selected in the Siemens system(s) software prior to sending the target to the stereotactic system.

NOTE: The selected Eviva biopsy device should match the biopsy device that is being used in the procedure.

5. Perform the biopsy procedure per the Eviva breast biopsy device instructions for use and per the Supplement to the Instructions for Use Mammomat Inspiration Manual.

Cleaning Instructions for Eviva Adapter

1. Upon completion of the biopsy procedure, immediately rinse the *Eviva Adapter* with warm water.
2. Spray all components with a cleaner

NOTE: The following cleaning products are NOT RECOMMENDED as they may damage exposed components:

- **Bleach based cleaning agents**
- **Hydrogen Peroxide**
- **Any cleaners/disinfectants with a pH of less than 4 or greater than 10**

3. Allow the necessary time for the chosen cleaner to disinfect the components.
4. Rinse with warm water.
5. Wipe dry with cloth or paper towel.