

1.1 Introduction

This addendum modifies your Affirm® breast biopsy guidance system User Guide and Service Manual. The following content replaces the Symbols table and Label Locations diagram. Place this addendum with your User Guide and Service Manual for future reference.








1.2 Affected Manuals

The following manuals are affected by this addendum:

- MAN-10548-002 Affirm Breast Biopsy Guidance System User Guide Versions 1.11 and 2.2, Revision 001, section 1.10 (Symbols) and section 2.6 (Label Locations)
- MAN-10378 Affirm Breast Biopsy Guidance System Service Manual, Version 1.11 and 2.2, Revision 001, section 1.10 (Symbols) and section 2.6 (Label Locations)










1.3 Symbols

This section describes the Symbols on this system.

Symbol	Description	Standard
	Prescription use only	FDA 21 CFR 801.109
	Caution	ISO 7010, Reference 5.1.6
	Remote station standby ("On" and "Off" for the computer and display)	IEC 60417-5009
	Discard electrical and electronic equipment separately from standard waste. Send decommissioned material to Hologic or contact your service representative.	WEEE Directive 2002/96/EC
	Potential equalization terminal	IEC 60417, Reference 5021
	Protective earth terminal	IEC 60417, Reference 5019
 www.hologic.com/package-inserts	Follow operating instructions	ISO 15223-1, Reference 5.4.3

Affirm Breast Biopsy Guidance System

Addendum for Symbols and Label Locations

Symbol	Description	Standard
	Catalog number	ISO 15223-1, Reference 5.1.6
	Serial number	ISO 15223-1, Reference 5.1.7
	Manufacturer	ISO 15223-1, Reference 5.1.1
	Date of manufacture	ISO 15223-1, Reference 5.1.3
	Lateral Arm Use Only	Hologic
	Patents	Hologic
	Made in USA	Hologic
	Authorized Representative in the European Community	ISO 15223-1, Reference 5.1.2
	CE Mark with notified body reference number	MDR Regulation (EU) 2017/745

1.4 Label Locations Diagram

The Label Locations diagram in section 2.6 in each of the following manuals is no longer applicable:

- MAN-10548-002 Revision 001
- MAN-10378 Revision 001