

Eviva® Stereotactic Guided Breast Biopsy System

Addendum for Symbols

Introduction

This addendum modifies your Eviva® Stereotactic Guided Breast Biopsy System User Guides. The following content replaces the symbols tables. Place this addendum with your User Guides for future reference.







Affected Manuals










The following manuals are affected by this addendum:




- MAN-03329-4370 Manual, Eviva, Set-up Guide, Ge Senographe essential and GE Senographe DS (symbols)

Symbols

This section describes the Symbols on this system.

Symbol	Description	Standard
	Prescription use only	21 CFR 801.109
	Authorized Representative in the European Community	ISO 15223-1:2016, Reference 5.1.2
	Caution	ISO 15223-1:2016, Reference 5.4.4
	CE Mark with notified body reference number	MDR Regulation (EU) 2017/745
 www.hologic.com/package-inserts	Consult electronic instructions for use	ISO 15223-1:2016, Reference 5.4.3
	Translations in Box	Hologic

	Do not use if package is damaged	ISO 15223-1:2016, Reference 5.2.8
REF	Catalog number	ISO 15223-1:2016, Reference 5.1.6
LOT	Batch code	ISO 15223-1:2016, Reference 5.1.5
QTY	Quantity	Hologic
	Manufacturer	ISO 15223-1:2016, Reference 5.1.1
	Date of manufacture	ISO 15223-1:2016, Reference 5.1.3
	Keep dry	ISO 15223-1:2016, Reference 5.3.4
SN	Serial number	ISO 15223-1:2016, Reference 5.1.7
Patents	Patents	Hologic
	Non-sterile	ISO 15223-1:2016, Reference 5.2.7
	Do not re sterilize	ISO 15223-1:2016, Reference 5.2.6
	Do not re-use	ISO 15223-1:2016, Reference 5.4.2
	MR Conditional	ASTM F2503 Reference no. Table 2; 7.4.6.1; Fig 6,7
	MR Unsafe	ASTM F2503 Reference no. Table 2, Symbol 7.3.3;7.4.9.1; Fig. 9
STERILE R	Sterilized using irradiation	ISO 15223-1:2016, Reference 5.2.4

	Use-by Date	ISO 15223-1:2016, Reference 5.1.4
Made in Costa Rica	Made in Costa Rica	Hologic
YYYY-MM-DD	Expiration date is represented by the following: YYYY represents the year MM represents the month DD represents the day	Hologic
	Upper limit of temperature	ISO 15223-1:2016, Reference 5.3.6
	Do not cut this line	N/A



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