



Customer Technical Bulletin

CTB-00262

Date: 01/19/2017
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Product: Breast Imaging & Biopsy **Subsystem:** All
Subject: Recommended Cleaning and Disinfecting of Products

Scope:

Inform all (customer) safety control officers and/or representatives of important information pertaining to the cleaning and disinfecting of all Hologic Breast Imaging and Biopsy Products.

Purpose:

Provide the facility safety control officer/representative with the flexibility to utilize our recommended cleaning solution as is publicized in our product manual, or the option to select an alternate commercially available cleaner/disinfectant in compliance with the FDA Citation: 900.122(e)13(i),(ii),(iii) – Infection Control

Hologic Guidance:

In response to recent inquiries regarding approved cleaning solutions please refer to your product operator manual for Hologic’s care and cleaning recommendations. Hologic recommends you follow the cleaning and disinfecting guidance outlined in our product manual.

Should you voluntarily elect to choose an alternate commercially available cleaning/disinfecting product that meets our recommendations noted on Page 2, please be advised of the potential for adverse effects that will be experienced to your Hologic product as a result of the active ingredients used in many of the commercially available cleaners/disinfectants in the market today.

Active Ingredients – (Adverse Effects)

The active ingredients listed on Page 2 of this document are used by cleaner manufacturers in a variety of forms, and are contained in many of the most common and commercially available cleaning/disinfectant products. These active ingredients, alone or in combination with others not specifically listed, have been observed to degrade, dry, or discolor various parts of the product over a period of time including impact to plastics, fabrics, stitching, paints, silkscreening, labels, lubricated components, adhesives, and chemically treated metals.

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List of Active Ingredients:

Before selecting an (alternate) cleaner/disinfectant Hologic advises you to review its Material Safety Data Sheet (MSDS) to identify the active ingredients. Questions regarding the active ingredients are easily researched on the Internet, or by consulting the product manufacturer of the cleaner. Be advised that all cleaners and disinfectants will have an impact on the product over time, and Hologic recommends you make every effort to remain at, or below the percentages noted in the list. Doing so will not prevent the adverse effect from occurring, but will assist to delay or minimize its effect on many components,*excluding the plastics and polycarbonates.

- Ammonia, or Ammonium $\leq 10\%$
- Chlorine and Chlorides (Alkyl, Ethyl, Methyl) in concentrations $\leq 10\%$
- Sodium (Hypoxides or Hydroxides) in concentrations $\leq 10\%$
- Propanol/Isopropanol (Alcohol) in concentrations $\leq 70\%$
- Hydrogen Peroxide (antiseptic) solution in concentrations $\leq 3\%$

**Certain plastics and polycarbonates that are routinely exposed to the active ingredients in most commercially available cleaners/disinfectant's, and are repetitively cycled under compression pressure, or force have experienced accelerated wear as is observed by crazing, cracking, peeling and/or yellowing of the plastics and/or polycarbonates. (Example: Compression Paddles, Face Shields). Following frequent cleanings plastics may retain residual compounds from the cleaner and may experience yellowing or cloudiness upon changing to a different cleaner.*

Hologic Cleaning Recommendations:

Unless stated otherwise, or under the direction of the manufacturer of the cleaner/disinfectant Hologic recommends all cleaners be;

- a). Rinsed/Wiped (using only non-chlorinated or distilled water applied to a damp, lint free cloth),
- b). DO NOT use Anti-bacterial soaps as part of the cleaning process.
- c) DO NOT soak or immerse any part or component.
- d) DO NOT use undiluted Ammonia to clean plastics
- e). Completely dry the component paying particular attention to all corners and crevices.

Cleaning procedures for the stainless steel Stereotactic Biopsy paddles used on Hologic's upright and prone Stereotactic products may vary from one facility to another. Please consult the product operator manual and/or your safety control representative for cleaning instructions as it may apply to your facility.

Disclaimer:

All cleaners and disinfectants should be selected based on their specific and intended use for cleaning and disinfecting medical equipment and associated components. Hologic Inc, its employees, subsidiaries and assignees accept no responsibility for the use or disposal of any cleaning product, nor any negative impact that could result from use including, but not limited to; physical or material damage that may result to the product, the user, patient, facility, or personal property as part of the cleaning and disinfecting process resulting from use, change in product or in the product's formulation, education and training, or safety practices of the manufacturer or facility. Responsibility for training and the safe use of any cleaning product resides with the manufacturer of the product, and the facility including the responsible safety control representative. As such, the final determination for use of these products for any purpose, particularly where human contact, and/or through skin absorption, or inhalation is possible due to improper application and/or practices, resides solely with the facility and the responsible safety control representative.