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# Customer Technical Bulletin

## CTB-00262 Rev 006

**Date:** *February 24,2022*

**Author:** Service Engineering

**Product:** Breast and Skeltal Health Products **Subsystem:** All

**Subject:** Recommended Cleaning and Disinfecting of Products

## Revision History:

Rev 006 – Added "*Hologic Cleaning & Disinfecting Recommendations for Selenia Dimensions/3Dimensions Fingerprint Scanners*" section

Rev 005 – On Page 3, added to statement to the removal of cleaner/disinfectant: "after the manufacturer's recommended cleaning/disinfection period."

Rev 004 – a) Added a recommendation to fully power down the systems during any site wide disinfection/decontamination procedure to the Hologic Guidance Section. b) Added instructions to the Cleaning Recommendations to not apply spray or liquid directly on the equipment.

Rev 003 – a) Added Skeletal Division references; b) Added "No Idophor" and "No Iodine containing disinfectants" to List of Active Ingredients section.

Rev 002 - Contents were not changed. Internal processes assign training to document through Hologic Learning Edge.

## Scope:

Inform all (customer) safety control officers and/or representatives of important information pertaining to the cleaning and disinfecting of all Hologic Breast and Skeletal Health 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

# Customer Technical Bulletin (cont.)

## 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 3, 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.

If you perform a disinfection/decontamination method that uses a foam, spray, aerosol, or fog (mist) designed to treat an entire room or all system surfaces; all Hologic equipment in that area should be should be fully shut down including the circuit breaker(s) on the system. Refer to the appropriate user's manual for the location of the circuit breaker(s) and instructions on how to completely remove power from the system. This is required because many systems have fans that will run to keep components at optimal temperatures even if they are "shut down" by the user. Fully removing power including turning off the circuit breaker will help prevent infiltration of contaminants via foam, spray, aerosol, or fog (mist) into the system which can have an adverse effect on system performance. Secondly, using aerosols that atomize or create a vapor/mist should not be sprayed directly onto or within a 3 foot range of the gantry (including room air fresheners) when powered on.

If these types of products are intended to be used, they should be compared with the active ingredients mentioned in this Customer Technical Bulletin on page 3 and applied or sprayed on to a cloth at least 3 feet from the system for a wipe down as the means to clean the system. Spraying cleaners directly on or at the system may cause adverse conditions that are unpredictable in nature and in the form of contaminants introduced through atomization or vapor.

Once the area is safe for human occupation without specialized respiratory protection then it is also safe to re-energize the systems following the appropriate user's manual for specific instructions. Note that some systems require additional time to warm up prior to clinical or QC use after being powered on, specific details are contained in each user's manual.

## Active Ingredients – (Adverse Effects)

The active ingredients listed on Page 3 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.

# Customer Technical Bulletin (cont.)

**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 ≤ 10%
- Chlorine and Chlorides (Alkyl, Ethyl, Methyl) in concentrations ≤10%
- Sodium (Hypoxides or Hydroxides) in concentrations ≤ 10%
- Propanol/Isopropanol (Alcohol) in concentrations ≤70%
- Hydrogen Peroxide (antiseptic) solution in concentrations ≤3%
- No Idophor
- No Iodine containing disinfectants

**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 off using only non-chlorinated or distilled water applied to a damp, lint free cloth after the manufacturer's recommended cleaning/disinfection period.
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) DO NOT apply cleaning sprays or liquids to the equipment. Always use a clean cloth and apply the spray or liquid to the cloth. Spray any aerosols onto cleaning cloths at least three feet from the gantry.

f) 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.

**Hologic Cleaning & Disinfecting Recommendations for Selenia Dimensions/3Dimensions Fingerprint Scanners:**

Use Ethanol or Isopropanol in concentrations of less than 50%.

1. Apply the liquid to a soft lint-free material (same as used to clean camera lenses) and gently dab the fingerprint reader window.

2. DO NOT pour any liquid directly on the reader window.

3. DO NOT submerge the scanner in liquid.

4. DO NOT rub the window with an abrasive material, including paper.

**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.*