

CLEANING INSTRUCTIONS FOR HOLOGIC IMAGING EQUIPMENT

3Dimensions[®] and Selenia[®] Dimensions[®] system

From User Guide MAN-20086_002_001_01 and MAN-20087_002_001_01

• General Cleaning Information

- Before each examination, clean and use an EPA approved disinfectant on any part of the system which touches a patient. Give the attention to the paddles and the image receptor.
- **Caution:** Do not use any hot source (like a heating pad) on the image receptor.
- Be careful with the compression paddles. Inspect the paddles. Replace the paddle when you see damage.
- Use a lint-free cloth or pad and apply a diluted dishwashing liquid.
- **Caution:** Use the least possible amount of cleaning fluids. The fluids must not flow or run.
- If more than soap and water is required, Hologic recommends any one of the following:
 - 10% chlorine bleach solution and water with one part commercially available chlorine bleach solution (normally 5.25% chlorine and 94.75% water) and nine parts water. Mix this solution daily for best results.
 - Commercially available isopropyl alcohol solution (70% isopropyl alcohol by volume, not diluted)
 - 3% maximum concentration of hydrogen peroxide solution
- After you apply any of the above solutions, use a pad and apply a diluted dishwashing liquid to clean any parts that touch the patient.
- **Warning:** If a paddle touches possible infectious materials, follow your established Infection Control protocol to remove any contamination from the paddle.
- **Caution:** To prevent damage to the electronic components, do not use disinfectant sprays on the system.

• To Prevent Possible Injury or Equipment Damage

- Do not use a corrosive solvent, abrasive detergent, or polish. Select a cleaning/disinfecting agent that does not damage the plastics, aluminum, or carbon fiber.
- Do not use strong detergents, abrasive cleaners, high alcohol concentration (above 70%), or methanol at any concentration.
- Do not expose equipment parts to steam or high temperature sterilization.
- Do not let liquids enter the internal parts of the equipment. Do not apply cleaning sprays or liquids to the equipment. Always use a clean cloth and apply the spray or liquid to the cloth. If liquid enters the system, disconnect the electrical supply and examine the system before returning it to use.
- **Caution:** Wrong cleaning methods can damage the equipment, decrease imaging performance, or increase the risk of electric shock.
- Always follow instructions from the manufacturer of the product you use for cleaning. The instructions include the directions and precautions for the application and contact time, storage, wash requirements, protective clothing, shelf life, and disposal. Follow the instructions and use the product in the most safe and effective method.

• Cleaning Acquisition Workstation

- Avoid touching the display screen of the Image Display monitor.
- Use care when cleaning the outer surface of the LCD screen. Always use a clean, soft, lint-free cloth to clean the display area. Microfiber cloths are recommended.
- **Caution:**
 - Never use a spray or flow a liquid on the display.
 - Never apply any pressure to the display area.
 - Never use a detergent with fluorides, ammonia, alcohol, or abrasives.
 - Never use any bleach.
 - Never use any steel wool.
 - Never use a sponge with abrasives.
- There are many commercially available products to clean LCD displays. Any of the products free of the ingredients described above and used according to the directions of the manufacturer can be used.

• Cleaning the Touchscreen Display

- Use a window or glass cleaning product to clean the Touchscreen display. Apply the cleaning product to a cloth, then clean the Touchscreen display. Do not apply the cleaning product to the display without the cloth.

• Cleaning the Keyboard

- Wipe the surfaces with a CRT wipe. If necessary, clean the keyboard with a vacuum. If liquids enter the keyboard, contact Technical Support for a replacement.

• Cleaning the Fingerprint Scanner

- To clean the Fingerprint Scanner window, do one of the following:
- Apply the adhesive side of cellophane tape, then remove the tape.
- Apply a product with ammonia base to a cloth and clean the Fingerprint Scanner window.
- **Caution:**
 - Do not apply any liquid product directly on the Fingerprint Scanner window.
 - Do not use products that contain alcohol.
 - Never put the Fingerprint Scanner under liquid.
 - Never apply any pressure to the Fingerprint Scanner window with abrasive material.
 - Do not push the Fingerprint Scanner window.

MammoPad Recycling Program

Hologic recognizes that some facilities may be uncertain about best practices for recycling of used MammoPads during this time. Your facility may elect to forego the recycling program. At your discretion, please dispose of any used MammoPads according to your facility's biohazardous material disposal policy and protocol.

Affirm® Breast Biopsy Guidance System (Upright Add-On To Mammo) and Affirm® Prone Biopsy System

From User Guide MAN-04068_002 and MAN-04480_004

• General Cleaning Information

- Before each examination, clean and use an EPA approved disinfectant on any part of the system and any accessory that touches a patient. Give the attention to the paddles and the image receptor.
- All previously mentioned directions for general cleaning and preventative injury and equipment damage applies here.

• Cleaning the Biopsy Control Module Screen

- There are many commercially available products to clean LCD screens. Make sure the product that you select is free of strong chemicals, abrasives, bleach, and detergents that contain fluorides, ammonia, and alcohol. Follow the directions of the manufacturer of the product.

• Equipment Drapes

- To reduce potential for contamination and equipment damage, protect the equipment with drapes during biopsy procedures.

Cleaning and Disinfecting Recommendations

- Do NOT spray liquid or solutions directly onto equipment components
 - Always spray liquids directly onto lint-free cloth.
 - If liquid enters the system, disconnect the electrical supply and examine before returning it to use.
- Do NOT use Anti-bacterial soaps as part of cleaning process
- Do NOT soak or immerse equipment part or component
- Do NOT use abrasive cleaners
- Completely dry equipment components, paying particular attention to corners and crevices.

ALTERNATIVE CLEANING AND DISINFECTING SOLUTIONS FOR IMAGING EQUIPMENT

Hologic understands that due to the COVID-19 outbreak, cleaning and disinfecting products may be in short supply. When commercially prepared disinfectant products are no longer available, prepare the following pre-cleaning and alternative disinfecting solutions for imaging equipment and other contaminated surfaces.

When Mixing or Diluting A Solution:

- Follow the 'manufacturer recommendations' when mixing and using cleaning and disinfecting products to avoid getting them in your eyes, on your skin, inhaling aerosolized (sprayed) particulates, or ingesting them.
- Wear the appropriate PPE recommended on the product label, which may include:
 - Surgical mask and splash goggles, or facial shield, gloves, fluid resistant smock or apron
- Dilute solutions using purified or distilled water. Tap water may be used if you do not have purified or distilled water during a shortage. Tap water will not harm equipment.
- The use of funnels is recommended when transferring liquids from container to container.

For Pre-Cleaning Visible Contamination of Blood or Other Body Fluids:

- Mild Dishwashing Soap Diluted with Water
 - Note: do not use antibacterial soap
 - Mix well in a spray bottle:
 - 1 bottle of dish liquid (more specific measurement?) to 1 gallon of water
 - 2 teaspoons of dish liquid to 1 quart of water
 - 1 teaspoon of dish liquid to 1 pint of water
 - Apply the diluted dishwashing liquid solution to clean any surfaces that have visible blood or other body fluids.
 - Note: Use the least possible amount of cleaning fluid. The fluid must not flow or run into openings in the equipment. When necessary, spray the cloth instead of the equipment.
 - Use a lint-free cloth or pad to wipe away visible contamination and follow with a disinfectant solution.

Alternative Disinfecting Solutions

- Use a lint-free cloth or pad to disinfect medical equipment. A paper towel may be used to disinfect other surfaces. After disinfection, use of water or a dishwashing soap and water solution to clean any germicidal residue that remains.
- 10% Bleach
 - 10% Chlorine Bleach & Water Solution consisting of 9 parts water and 1 part commercially available chlorine bleach solution (usually 5.25% chlorine and 94.75% water)
 - Mix well in a spray bottle:
 - 5 tablespoons (1/3 cup) bleach per gallon of water
 - 4 teaspoons bleach per quart of water
 - Important: Bleach solutions do not last longer than 24 hours and must be made fresh daily
- 70% Isopropyl Alcohol Undiluted
 - If 70% Isopropyl Alcohol, no need to dilute.
 - If Isopropyl Alcohol is 100%, dilute to 70% by mixing 7 parts alcohol with 3 parts water
- 3% Hydrogen Peroxide
 - If 3% Hydrogen Peroxide, no need to dilute.
 - If over 3% Hydrogen Peroxide, dilute to 3% Hydrogen Peroxide and 97% water
- 10% or less Ammonia, or Ammonium
 - Do NOT use undiluted Ammonia to clean plastics
- 10% or less Sodium Hypoxides or Hydroxides

Any infectious materials, including blood, should be handled according to the infection control protocols of the site. Hologic does not recommend any specific brand of dishwashing detergent, that is customer preference and availability. The dilution of the dishwashing detergent depends on the concentration of the detergent and the wiping down residue after cleaning.