

Cleaners & Disinfectants

Cleaner & Disinfectant Usage

The following table lists the cleaners and disinfectants compatible with your Viera™ Portable Breast Ultrasound and accessories. The products listed in the following table are chemically compatible and have been tested for efficacy.

Product	Qualified Use ^a	Viera™ Scanner	Clarius Fan	Clarius Cart	Viera™ Rechargeable Li-ion Battery	Viera™ Battery Charger	Clarius Battery Charger Hub
Accel® PREvention™ Wipes	LLD, ILD	✓	✓	✓	✓	✓	✓
Accel® TB Wipes	LLD, ILD	✓	✓	✓	✓	✓	✓
CaviWipes	LLD, ILD	✓	✓	✓	✓	✓	✓
CIDEX® OPA	HLD	✓			✓		
McKesson OPA/ 28 High-Level Disinfectant Solution	HLD	✓			✓		
Sani-Cloth® HB Germicidal Disposable Wipe	LLD, ILD	✓	✓	✓	✓	✓	✓
Sani-Cloth® Plus Germicidal Disposable Cloth	LLD, ILD	✓	✓	✓	✓	✓	✓
Tristel Trio Wipes System	HLD ^b	✓	✓		✓		
Virox™ AHP® 5 RTU Wipes	LLD, ILD	✓	✓	✓	✓	✓	✓

a. CL = Cleaner, HLD = High-level disinfectant, ILD = Intermediate-level disinfectant, LLD = Low-level disinfectant, S = Sterilant

b. EU only.

You may also use products not specifically listed in the compatibility table but with similar active ingredients, as indicated in this list, and marketed for medical use.

Cleaning & Disinfecting

It is important to clean and disinfect the Viera™ Portable Breast Ultrasound immediately after use. This document will guide you through the cleaning and disinfecting process.

The classification of cleaning and disinfecting you select will depend on the type of tissue the Viera™ Scanner comes into contact with. To find the correct classification, refer to *Spaulding Classification also attached*.

All compatible accessories may be cleaned using CaviWipes.

When cleaning and disinfecting: • Follow the procedures in the order they are described in this guide, without skipping steps. • Use only solutions approved by Clarius Mobile Health. Other solutions may be incompatible with the system and could damage the scanner. • Follow the manufacturer's instructions, recommendations, and guidelines for cleaners and disinfectants, as well as your regional regulations. • Check expiry dates, concentration, and efficacy of the chemicals used. • Wear the appropriate personal protective equipment (PPE), such as eyewear and gloves, as recommended by the chemical manufacturer.

Due to repeated use and cleaning, the cleanliness and sterility of the hardware deteriorates over its service life (five years for the scanner, fan, and Clarius Cart). • Using incompatible solutions to clean the scanner may damage its surface. • Cleaning or disinfecting the scanner while the battery is installed may cause the battery to short-circuit and overheat, causing an electric shock or burn. • Cleaning or disinfecting the scanner using IPA (isopropyl alcohol) may damage it. During an emergency where the scanner is used to examine multiple patients in a short period of time, the lack of proper cleaning and disinfecting between patients may spread infections to other patients and users.

Cleaning

Cleaning the Viera™ Portable Breast Ultrasound

Before cleaning, visually inspect the scanner to determine that it is free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use and contact Hologic Technical Support.

Cleaning the scanner requires that you select the proper cleaning level. Before you begin, determine the level of cleaning by referring to *Spaulding Classification* attached. Once you have determined the level, have the cleaning solution ready and follow the procedure below.

To clean the Viera™ Portable Breast Ultrasound: 1. Make sure the Viera™ Portable Breast Ultrasound is turned off. 2. Remove the battery and fan from the scanner. 3. To clean the scanner, dampen a soft cloth using a compatible cleaner. Alternatively, use a premoistened disinfectant wipe. For a list of compatible cleaners, see *Cleaners & Disinfectants* attached.

4. Start at the top of the scanner and wipe toward the scan head. Be sure to remove any gels or particulate matter. 5. Clean the heat sink (the grooves along the body of the scanner) using a thin, disposable instrument, such as a swab, to push a soft cloth lightly dampened with a cleaning solution (or use a premoistened wipe) across the slot. Move the cloth back and forth from one side of the heat sink to the other. 6. Dispose the cloth and the instrument used to insert the cloth. 7. Verify that all gel, particulate matter, and bodily fluids have been removed. 8. Repeat with new cleaning material if necessary. 9. To clean the battery, dampen another soft cloth using a compatible cleaner or disinfectant. Alternatively, use a premoistened disinfectant wipe. 10. Remove all gel, particulate matter, and bodily fluids from the battery. 11. Repeat with new cleaning material if necessary. When you are done, keep the two parts separate. You will be disinfecting them individually. For disinfecting instructions, see *Disinfecting the Viera™ Portable Breast Ultrasound* attached.

Due to particulate matter (for example, biological agents, ultrasound gel, and dirt) in the scanner crevasses, openings, and/or cavities, there is the possibility that the scanner is not cleaned easily or correctly.

Cleaning the Fan

To clean the Clarius Fan: 1. Remove the fan from the Viera™ Portable Breast Ultrasound. 2. Wipe down all surfaces using a premoistened disinfectant wipe. For a list of compatible cleaners, see *Cleaners & Disinfectants* on page 79. 3. Repeat with new cleaning material if necessary. 4. Air-dry the fan. Alternatively, towel-dry with a clean, non-linting cloth. When you are done, keep the two parts separate. You will be disinfecting them individually.

Disinfecting

Disinfecting the Viera™ Portable Breast Ultrasound

Before you begin disinfecting, make sure you have cleaned the scanner.

Disinfecting requires that you choose the proper disinfecting level. Determine the necessary disinfection level by referring to *Spaulding Classification* attached. Once you have determined the required disinfecting level, have the disinfectant ready and follow one of the appropriate procedures below. Note that different levels of disinfection require different steps, not just different solutions.

Intermediate Disinfection

Refer to *Cleaners & Disinfectants* attached for a list of disinfectants recommended for intermediate disinfection of the scanner.

If the scanner has come into contact with broken skin, mucosal membranes, or blood, it is classified as semi-critical, and you must perform a high-level disinfection.

High-Level Disinfection

Refer to *Cleaners & Disinfectants* attached for a list of disinfectants recommended for high-level disinfection of the scanner. 1. Make sure the battery and fan are still detached from the scanner. 2. Disinfect the scanner by wiping with a cloth moistened with a compatible disinfectant. Alternatively, use a premoistened disinfectant wipe. 3. Disinfect the heat sink (the grooves along the body of the scanner) using a thin, disposable instrument, such as a swab, to push a soft cloth lightly dampened with a disinfectant (or use a premoistened wipe) across the slot. Move the cloth back and forth from one side of the slot to the other. 4. Remove the disinfecting wipe from the slot. 5. Air-dry.

Alternatively, towel-dry with a clean, non-linting cloth. 6. Examine the scanner for damage, such as cracks or splitting where fluid can enter. If damage is evident, do not use the scanner and contact Hologic Technical Support. 7. Disinfect the battery and the battery connector by wiping with a cloth moistened with a compatible disinfectant. Alternatively, use a premoistened disinfectant wipe. 8. Air-dry. Alternatively, towel-dry with a clean, non-linting cloth. 9. Examine the battery for damage, such as cracks or splitting where fluid can enter. If damage is evident, do not use the battery and contact Hologic Technical Support.

It is important that you disinfect the two pieces individually. Make sure the battery is still detached from the scanner. 2. Mix the disinfectant solution by following the disinfectant label instructions for solution strength and disinfectant contact duration. 3. Using a compatible disinfectant at a temperature of 23°C (73°F), immerse the scanner and the battery in the disinfectant solution for 45 minutes. 4. Using the instructions on the disinfectant label, rinse both the scanner and the battery. 5. Air-dry both pieces. Alternatively, towel-dry with a clean, non-linting cloth. 6. Examine the parts for damage, such as cracks or splitting where fluid can enter. If damage is evident, discontinue use of the scanner and/or battery, and contact Hologic Technical Support.

Disinfecting the Fan

Before you begin disinfecting, make sure you have cleaned the fan.

Because the fan cannot be submerged in liquid, you must always use intermediate-level disinfection.

1. Make sure that the fan is detached from the scanner. 2. Disinfect the fan by wiping with a cloth moistened with a compatible disinfectant. Alternatively, use a premoistened disinfectant wipe. 3. Air-dry. Alternatively, towel-dry with a clean, non-linting cloth. 4. Examine the fan for damage, such as cracks or splitting. If damage is evident, do not use the fan and contact Hologic Technical Support. It is important that you disinfect the two pieces individually. If the battery has been recently used or charged, wait 30 seconds before submersing it in any liquid. It is important that you immerse the two pieces individually, detached from each other.

Because of the large number of available cleaners and disinfectants, it is impossible to have an all-inclusive list. If you are unsure of the suitability of a particular product, please contact Hologic Technical Support for more information.

Cleaner & Disinfectant Details

Solution	Origin ^a	Usage	Active Ingredients
Accel® PREvention™ Wipes	CA	Wipe	Hydrogen Peroxide
Accel® TB Wipes	CA	Wipe	Hydrogen Peroxide
CaviWipes	US	Wipe	Alcohol, Quaternary Ammonia
CIDEX® OPA	US	Soak	Ortho-phthalaldehyde
McKesson OPA/28 High-Level Disinfectant Solution	US	Soak	Ortho-phthalaldehyde
Sani-Cloth® HB Germicidal Disposable Wipe	US	Wipe	Alcohol, Quaternary Ammonia
Sani-Cloth® Plus Germicidal Disposable Cloth	US	Wipe	Alcohol, Quaternary Ammonia
Tristel Trio Wipes System	UK	Pre-clean wipe, Sporicidal wipe, Rinse wipe	Enzymes, Chlorine Dioxide
Virox™ AHP® 5 RTU Wipes	CA	Wipe	Hydrogen Peroxide

a. AU = Australia, CA = Canada, US = United States, UK = United Kingdom

Sterilization Systems

The following sterilization systems are approved for use with the Viera™ Portable Breast Ultrasound and its batteries:

Sterilization System	For general reprocessing instructions, including proper cleaning, and drying, and packaging information prior to reprocessing any medical device using this system, refer to:	For specific sterilization efficacy questions, contact:
STERRAD® 100S (Short Cycle)	STERRAD® System User's Guides	STERRAD® Advanced Sterilization Products 1-888-STERRAD

Spaulding Classification

The level of cleaning and disinfecting required for your Viera™ Portable Breast Ultrasound is based on the Spaulding classification system. Following the correct classification will help reduce cross-contamination and infection.

Each Spaulding classification mandates a specific level of cleaning and disinfecting of the equipment before it can be used in the next exam. Determine the Spaulding classification based on your scanner's usage.

SPAULDING CLASSIFICATION

Class	Use	Method
Non-Critical Class	Touches intact skin	Cleaning followed by intermediate disinfection
Semi-Critical Class	Touches mucous membranes and non-intact skin	Cleaning followed by high-level disinfection (HLD)

Probe Covers

Brand	Product Name	Product Number
CIVCO	Standard Width - Latex-Free Ultrasound Covers for Wireless Probes	610-1212
Safersonic	Modified Single - Sterile Sonography Cover with Adhesive Area without fixation tape	DAN-33803-NT
Safersonic	Single Plus - Sterile Sonography Cover with Adhesive & Gel	DAN-33803-WG