Supersonic™ MACH™ Series Cleaning Instruction Guide

PM.LAB.178-A

SUPERSONIC MACH30™

This document refers to the following Supersonic™ MACH™ 30 User Guide:

- PM.LAB.145-A
- PM.LAB.146-A

SUPERSONIC MACH20™

This document refers to the following Supersonic™ MACH™ 20 User Guide:

- PM.LAB.143-A
- PM.LAB.144-A

SUPERSONIC MACH40™

This document refers to the following Supersonic™ MACH™ 40 User Guide:

- PM.LAB.142-A

Changing Printer Paper and Toner

Refer to the user's manual of your specific printer for guidance on how to properly change printer paper and toner.

Cleaning the System

Cleaning Frequency

You can perform the maintenance operations as described in this chapter. Cleaning of the SuperSonic MACH series ultrasound systems should occur at regular intervals, or more frequently as needed.

Hologic provides the following recommended cleaning intervals as guidelines:

Part		Recommended Cleaning Frequency
	System Display Monitor	Weekly, or as needed
	System Control Panel	Daily, or between patients
	Touchscreen Display	Daily, or between patients
	System Exterior: chassis and Handles	Weekly, or as needed
	Air Filter	Clean monthly
	Transducers: cleaning and disinfection	Between patients

It is prudent to continually survey the system for maintenance needs.
Contact your Hologic Sales or Service authorized representative for further details.

CAUTION

If you have any questions regarding basic maintenance, or prefer to have maintenance service performed, contact your authorized Hologic Service representative.

Always press the On/Off switch, turn off the power switch at the back of the machine, and disconnect the system from the wall outlet before performing maintenance or cleaning the system.

It is recommended that gloves and protective eyewear are used when cleaning the system.

Do not spray any cleaning agents directly onto the system. They may leak into the system, damaging the system and voiding the warranty.

Do not allow standing liquid to collect around the control panel keys.

Do not allow liquid to drip inside the system chassis.

Cleaning the Exterior of the Machine

The exterior of the system should be periodically cleaned with a soft cloth, lightly moistened with water and a gentle soap. This includes the system chassis, control panel and handles. Be sure to clean any unused gel from the surface of the control panel after system use.

The products below have been tested and found to be compatible with the SuperSonic™ MACH™ series systems.

Solution	Manufacturer	Cleaner/ Disinfectant	Active ingredient
Sani-Cloth Active	PDI	Cleaner Disinfectant	Quat. Ammonia

Cleaning the Monitor

A clean, soft cotton cloth dampened with an ammonia-based window cleaner should be used to clean the Monitor display. Do not use paper towels, as these may scratch the display monitor. The cleaning agent should be sprayed onto the cloth, not directly onto the display surface. Take care not to get any cleaning agent into the housing of the system. This may lead to system damage.

Cleaning the Touch Screen Display

A clean, soft cotton cloth dampened with an ammonia-based window cleaner should be used to clean the Touch Screen display. Do not use paper towels, as these may scratch the display monitor. The cleaning agent should be sprayed onto the cloth, not directly onto the display surface. Take care not to get any cleaning agent into the housing of the system. This may lead to system damage.

Cleaning the Air Filter

The SuperSonic MACH series ultrasound systems are equipped with an air filter. It should be inspected every month and cleaned as needed. At first switch on of the system after the first day of the month, the system displays an icon as a reminder to check the air filter. Please refer to the following air filter cleaning procedure, and click OK on the popup window.

The air filter is located below the system on the left side.

To remove it, pull it towards you using the handle. It is recommended that the air filter be cleaned monthly or more frequently if a significant accumulation of dust or debris is noted.

The air filter may be removed, cleaned with slightly compressed air, vacuumed, and/or rinsed with clean water. Allow the filter to air dry before re-installing in the system. Spare the air filter is provided for immediate use. Additional air filters can be ordered from Hologic Customer Service.

TO MAINTAIN THE AIR FILTER

1. Remove the air filter by pulling the handle towards you
2. Inspect the filter, and if it is dirty, clean it following the cleaning instructions

   If it the air filter is damaged, replace it with a spare
3. Depending on the condition of the air filter, use either a vacuum cleaner or water to clean the dirty filter
4. Thoroughly dry the cleaned filter before re-installing

WARNING

Before performing maintenance or cleaning, always press the On/Off switch, turn off the power switch at the back of the machine, and then disconnect the system from the wall outlet.

Increased internal temperature can be caused by dirty air filter.

Failure to keep the air filter clean can result in the system becoming unavailable during critical use.

Never install an air filter that is not completely dry.

CAUTION

Turn off power before you remove the air filter.

Do not turn power on without the air filter installed.

Cleaning and Disinfecting the Barcode Scanner

Maintenance

Cleaning the Scanning Window

Reading performance may degrade if the scanner's window is not clean. If the window is visibly dirty, or if the scanner isn't operating well, clean the window with a soft cloth or lens tissue dampened with water (or a mild detergent - water solution). If a detergent solution is used, rinse with a clean lens tissue dampened with water only.

Cleaning the Scanning Housing

The HS-1M is IP54 rated when the cable is attached. This means that liquids and dusts will not penetrate into the housing. However, the scanner should not be submerged in water or other liquids. It is also good practice to dampen the cleansing cloth vs. spraying the scanner directly.

The HS-1M housing is compatible with the following medical grade cleaners:

- Sani-Cloth® HB
- Sani-Cloth® Plus
- Hydrogen Peroxide
- CaviWipes™
- 409® Glass and Surface Cleaner
- Windex® Blue
- Clorox® Bleach (100%)
- Isopropyl Alcohol
- Gentle dish soap and water

CAUTION

Do not submerge the HS-1M in water.

Do not use abrasive wipes or tissues on the HS-1M's window - abrasive wipes may scratch the window.

Never use solvents (e.g., acetone, benzene, ether, or phenol-based agents) on the housing or window - solvents may damage the finish or the window.

Cleaning and Disinfecting Transducers

Transducer Cleaning Safety

WARNING

Use care when handling and cleaning ultrasound transducers.

Do not use a damaged or defective transducer.

Do not immerse or allow liquid to penetrate a transducer which has had its face or cable sheath compromised.

Failure to follow these precautions can result in serious injury and equipment damage.

Follow these precautions to avoid injury and equipment damage.

Inspect the transducer prior to cleaning for damage or degeneration to the lens, housing, cable and connector.

Do not use or apply liquid cleaning agents to a damaged or defective transducer.

Do not immerse the transducer into any liquid beyond the level specified for that transducer.

Never immerse the transducer connector or transducer adapters into any liquid.

Transducer damage can result from contact with inappropriate coupling or cleaning agents.

Use only cleaning agents which have been approved for the specified transducer.

Do not soak, immerse, or maintain prolonged contact with solutions containing alcohol, bleach, ammonium chloride compounds or hydrogen peroxide.

The level of disinfection required for a device is dictated by the type of tissue it will contact during use. Ensure the solution strength and duration of contact are appropriate for the intended clinical use of the transducer.

Always use protective eyewear and gloves when cleaning, disinfecting or sterilizing any equipment.

Be sure to observe the expiration date of the solution.

Avoid disinfectant contact with the connector label.

CAUTION

Biological hazards may exist if ultrasound transducers are not properly cleaned, disinfected or sterilized.

This is especially true if the transducer comes in contact with mucous membranes or bodily fluids.

Proper cleaning and disinfection are necessary to prevent disease transmission and infection control.

It is the responsibility of the equipment user to verify and maintain the effectiveness of the infection control procedures in use.

For any procedures where the transducer may come in contact with bodily fluids or mucous membranes, the use of a legally marketed, sterile, nonpyrogenic transducer sheath is recommended.

Only use disposable sheaths. Sheaths are never to be reused.

Use caution when using disinfectant products.

Wear rubber gloves and protective eyewear.

Always follow the manufacturer’s instructions.

In order for liquid chemical disinfectants to be effective, all visible residues must be removed during the cleaning process.

For effective cleaning, follow the instructions accompanying the cleaner or disinfectant product.

Care should be taken to avoid applying disinfectant agents to the cablehousing junction.

Do not allow any fluids to enter the cable-housing junction.

Do not use any alcohol or alcohol-based products on the transducer cable.

If the transducer shows signs of damage such as cracks, splitting, delamination of the face or cable damage, discontinue use of the transducer and contact your authorized Hologic Service representative for assistance.

Transducer Cleaning and Disinfection Guidance

Cleaning and disinfection is a two step process: a cleaning step followed by a disinfection step.

CLEANING

Cleaning is intended to remove all foreign matter (blood, tissue, protein, scanning gel, etc.) from the device.

DISINFECTION

The level of disinfection required for a device is dictated by the type of tissue it will contact during use. There are three classifications: noncritical, semi-critical, and critical. These are based on the degree of risk of infection involved in the use of the device.

Non-critical applications are those where the device contacts only intact skin; semi-critical applications are those where the device contacts mucus membranes or minor

skin breach; critical applications are those where the device enters a normally sterile environment, sterile tissue or vasculature.
Ultrasound transducers used for non-critical applications generally need only to be cleaned and low-level disinfected between patient uses.

Transducer used in semi-critical application should be cleaned and high level disinfected after use even if a sheath was used.

Transducers used in critical applications should be sterilized and the use of a sterile sheath is recommended. Transducer used in critical application should be cleaned and sterilized after use even if a sheath was used.

General Cleaning and Disinfection Procedures for the SuperSonic MACH series Transducers

The SuperSonic MACH series transducers are intended for use in non-critical and semi-critical imaging applications. The transducer must be thoroughly cleaned and disinfected after each use. In general, only low-level disinfection is required for non-critical applications of the SuperSonic MACH series transducer.

For semi-critical applications, high-level disinfection is required and only one of the high-level disinfectants chosen from the list below should be used.

High-level disinfection for semi-critical is recommended, carefully following the manufacturer's instructions with regard to application and contact time as indicated on the product label.

PROCEDURE TO PREPARE TRANSDUCER FOR DISINFECTION

1. After every patient exam, carefully wipe the face and housing of the ultrasound transducer to remove any traces of ultrasound coupling gel.
2. Inspect the transducer for any signs of damage such as cracks, splitting, delamination of the face or cable damage. If any damage is noted, do not proceed with the cleaning or disinfecting procedures and call your authorized Hologic Service representative for assistance.
3. Wipe the transducer face, housing and cable with a water-moistened soft cloth. The use of a mild soap, low-level cleaner or enzymatic cleaner (from the table below) is acceptable.

4. If stubborn material has dried on the face or housing of the transducer, carefully scrub the transducer using water moistened gauze, sponge or surgeon's soft bristle brush. Wipe away any material with a watermoistened soft cloth.
5. Rinse the transducer thoroughly with water. Do not allow water to access the cable-housing junction.
6. Air dry or dry using a soft dry cloth.

DISINFECTION PROCEDURE

1. Always clean the transducer prior to disinfection. (See steps above.)
2. When using an FDA or CE -cleared (as appropriate) disinfecting agent, carefully follow the instructions provided by the manufacturer of the product.
3. For low-level disinfection, the lens and housing of the transducer may be wiped with any of the **cleaners/low level disinfectants** listed in the associated transducer table.
4. For high-level disinfection, the transducer may be wiped or soaked using one of the **disinfectants** listed in the associated transducer table.
5. Air dry or dry using a soft dry cloth.
6. Re-inspect the transducer for any signs of damage such as cracks, splitting, delamination of the face or cable damage before putting the transducer back into use.

Cleaning and Disinfection Products

LIST OF COMPATIBLE PRODUCTS

The table below lists the product compatibility ("YES") with the SuperSonic MACH series probes.

Only use compatible products with the SuperSonic MACH series probes.

Solution/ system	Manufacturer	Cleaner/ Disinfectant	Active ingredient	L18-5 L10-2 MC12-3	E12-3	LV16-5	C6-1X C9-2X P5-1X LH20-6
Alkaspray GSA (Cidalkan)	Alkapharm	Cleaner Disinfectant	Isopropyl alcohol Alkylamine	YES			

Solution/ system	Manufacturer	Cleaner/ Disinfectant	Active ingredient	L18-5 L10-2 MC12-3	E12-3	LV16-5	C6-1X C9-2X P5-1X LH20-6
Alkazyme	Alkapharm	Cleaner Disinfectant	Quat. Ammonia	YES			
Anioxyde 1000	Anios	Disinfectant	Peracetic acid	YES	YES		
Antigermix S1	Germitec	High-level disinfectant	UV-C		YES		
Cidex OPA (DISOPA in Japan)	Advanced Sterilization Products	Disinfectant	Orthophtalaldehyde	YES	YES	YES	YES
Cidex Plus	Advanced Sterilization Products	Disinfectant	Orthophtalaldehyde				YES
Cidezyme	Johnson and Johnson	Cleaner	Proteolytic enzymes	YES	YES	YES	
Enzol	Advanced Sterilization Products	Cleaner	Proteolytic enzymes				YES
Gigasept FF	Schuller&May	Disinfectant	Succindialdehyde, dimethoxytetrahydro-furan	YES	YES		YES
Hypernova Chronos	Germitec	High-level disinfectant	UV-C		YES		
KlenZyme	Steris	Cleaner	Proteolytic enzymes				YES
Linget'Anios	Anios	Cleaner Disinfectant	Ethanol Digluconate de chlorhexidine Alkylaminoalkylgly-cine	YES		YES	YES
MetriZyme	Metrex	Cleaner	Proteolytic enzymes				YES
Mikrobac Tissues	Bode	Disinfectant	Benzyl-C12-18-alkyldimethylammoni-um chlorides didecyl- dimethylam-monium chloride	YES		YES	
Milton	Milton	Disinfectant	Sodium Hypochlorite				YES
Sani-Cloth Active	PDI	Cleaner Disinfectant	Quat. Ammonia	YES			
Sani-Cloth HB	PDI	Disinfectant	Quat. Ammonia				YES

Solution/ system	Manufacturer	Cleaner/ Disinfectant	Active ingredient	L18-5 L10-2 MC12-3	E12-3	LV16-5	C6-1X C9-2X P5-1X LH20-6
Sani-Cloth Plus	PDI	Disinfectant	Quat. Ammonia				YES
Sporox	Reckitt & Colman	Disinfectant	Hydrogen Peroxide				YES
Sporox II	Reckitt & Colman	Disinfectant	Hydrogen Peroxide				YES
Steranios	Anios	Disinfectant	Glutaraldehyde	YES	YES		
Steranios OPA	Anios	Disinfectant	Orthophtalaldehyde				YES
Super Sani Cloth	PDI	Disinfectant	Quat. Ammonia				YES
T-Spray	Pharmaceutical Innovations Inc.	Disinfectant	Quat. Ammonia	YES	YES		
Transeptic spray	Parker laboratories	Cleaner	Chlorhexidine Gluconate, Isopropyl Alcohol				YES
Tristel Duo	Tristel Solutions Limited	Disinfectant	Chlorine dioxide	YES	YES		
Tristel Solo	Tristel Solutions Limited	Disinfectant	Hexamethylenebigu-anide	YES			
Trophon	Nanosonics	High-level disinfectant	Hydrogen peroxide mist generated in a disinfection chamber				YES
Trophon 2	Nanosonics	High-level disinfectant	Hydrogen peroxide mist generated in a disinfection chamber				YES
Wavicide 01	MCC	Disinfectant	Glutaraldehyde				YES

WARNING

For endocavity probes, make sure the cleaner/disinfectant is compatible with mucosa.

NOTE

Some cleaner/disinfectant products may cause coloration or discoloration of the probe housing. This coloration/discoloration does not affect the image quality of the probe.

GENERAL RECOMMENDATIONS FOR ALL PROBES

The above cleaner and disinfectant products have been tested and found to be compatible with SuperSonic MACH series transducers material solely. Questions regarding efficacy, instructions for use, and proper handling should be directed to the manufacturer. Please check whether the recommended products are approved for use in your country. The use of a non-approved cleaner or disinfectant which results in damage to the probe will void the warranty. The use of products outside of those on this list is to be done at the user's and patient's own risk.

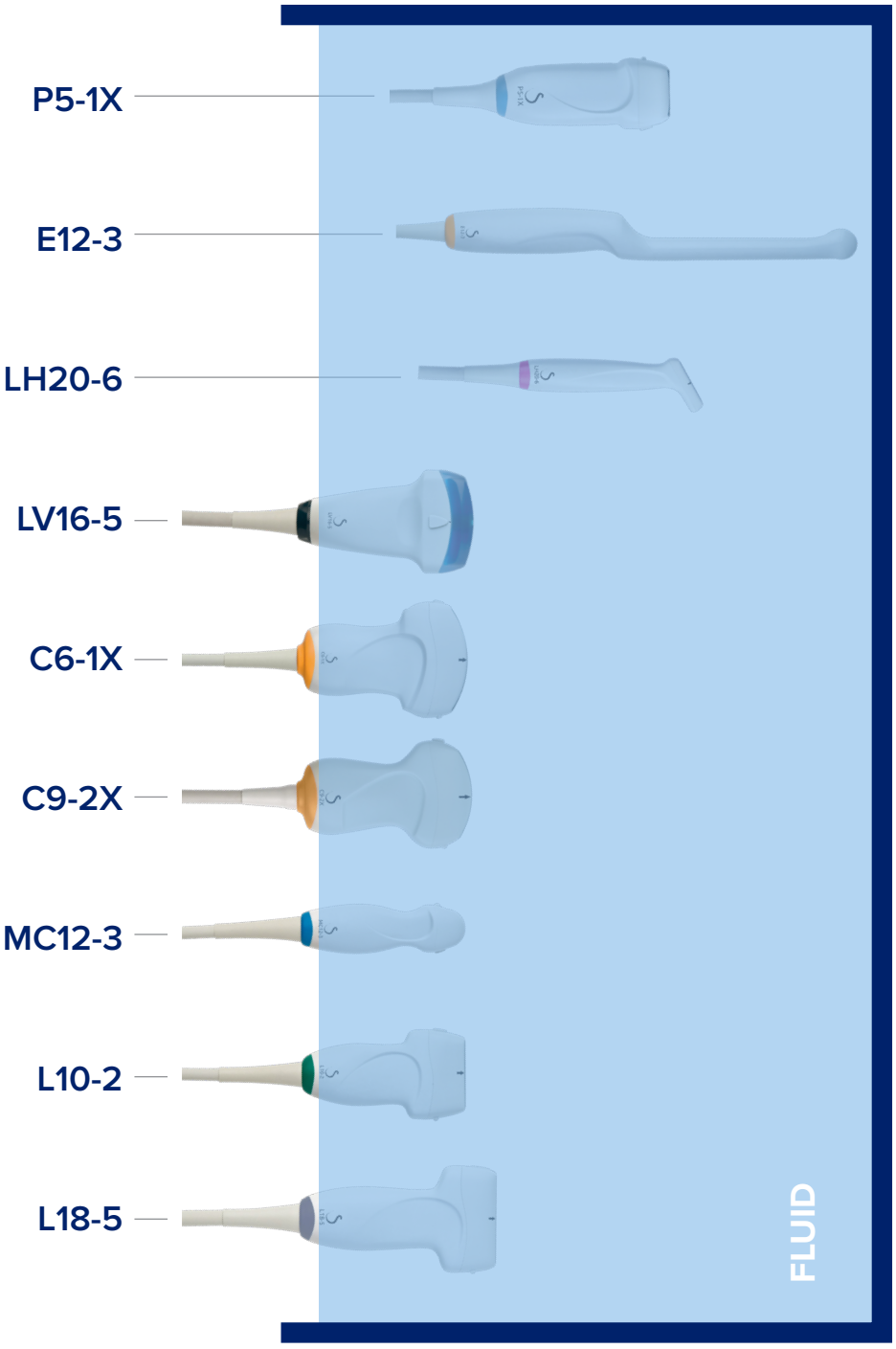
Soaking Limits

If soaking a transducer is required, the L18-5, L10-2, MC12-3, LV16-5, C6-1X and C9-2X transducers may only be immersed in liquid to a level of 3cm (1.18 in.) above the cable-strain relief junction. The P5-1X, LH20-6 and E12-3 transducers may be immersed in liquid to a level of 1m (39.37in.) above the cable-strain relief junction.

According to the IEC 60529 standard:

- SuperSonic MACH 30, SUPERSONIC MACH 20 and SuperSonic MACH 40 are IPX0
- The footswitch pedal and the L10-2, L18-5, MC12-3, C6-1X, C9-2X, and LV16-5 transducers are IPX1
- The E12-3, P5-1X and LH20-6 transducers are IPX7

Never immerse the probe connector. Never immerse the cable-connector junction. Do not leave the transducer immersed longer than required for disinfection. See figure below.


P5-1X
E12-3
LH20-6
LV16-5
C6-1X
C9-2X
MC12-3
L10-2
L18-5
FLUID

The following figure displays the part of each transducer to be in contact with patients.

Face in contact with patient

P5-1X

E12-3

LH20-6

LV16-5

C6-1X

C9-2X

MC12-3

L10-2

L18-5

Additional Information Regarding Cleaning and Disinfection of Ultrasound Transducers

Additional information regarding cleaning and disinfection of ultrasound transducers can be found in the following references:

Chemical Sterilization and high-level disinfection in health care facilities. ANSI/AAMI ST58:2005 Sterilization and Disinfection of Medical Devices: General Principles. Centers for Disease Control, Division of Healthcare Quality Promotion.

http://www.cdc.gov/ncidod/hip/sterile/sterilgp.htm (5-2003) [http://www.cdc.gov/ncidod/hip/sterile/sterilgp.htm%20(5-2003)]

ODE Device Evaluation Information—FDA Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices.

http://www.fda.gov