ADVANCED ULTRASOUND SOLUTIONS INC.—Technical Bulletin

Technical and Support Services — Bulletin #: INFO-120-A

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TO: Infection Control and Ultrasound Sonographers

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SUBJECT: Disinfecting, cleaning and the proper care of Ultrasound System Consoles and Transducers with compatibility information

PRODUCT: SONO Ultrasound Wipes and SONO Disinfecting Wipes

PROBLEM: Disinfecting of ultrasound equipment may not be done properly in certain areas of use

SOLUTION: Advanced Ultrasound Solutions (AUS), created a proprietary testing device that is automated and duplicates real world cleaning of medical devices and high touch surfaces. Our system allows us to document and verify results for compatibility. AUS also follows the Spaulding Classifications (non-critical, semi-critical) which determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection

PROCEDURE: The disinfection procedure in this document follows the Ultrasound OEMs cleaning guidelines as it relates to the Spaulding method of Disinfection and the FDA. Failure to follow these instructions may result in cross contamination and patient infection

Cleaning and Disinfecting of Ultrasound Transducers and Consoles

The level of cleaning and disinfecting required for the system is dictated by the type of tissue it contacts during use. Please follow one of the instructions below depending on the level your procedure falls under.

SPAULDING METHOD OF DISINFECTION	Spaulding classifications (non-critical, semi-critical) determine the approach for cleaning and disinfection of medical equipment based on the device, the way it has been used, and the risk of infection. The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses.
VERIFY EXPIRATION INFO FOR THE PACKAGE OF SONO WIPES	1. The bottom of each package or canister has the manufacture date stamped 2. SONO has a 2 year shelf life from the DOM (date of manufacture) 3. The product expires 1 year from the date the package is opened for use
VERIFY CHEMICAL COMPATIBILITY	See Compatibility list at the end of this document to make sure your OEM is listed. If you do not see your Medical Device Manufacturer listed, contact your local sales, applications or service team and ask them to verify SONO for your product. Most Manufacturers can qualify a product from the active ingredients but will likely reach out to us for testing data
YOUR SYSTEM *DID NOT* COME IN CONTACT WITH BROKEN SKIN, BLOOD, OR BODILY FLUIDS	Follow instructions on the following page for NON-CRITICAL MEDICAL DEVICE cleaning and disinfecting (LLD, Low Level Disinfection)
YOUR SYSTEM *CAME IN CONTACT* WITH BROKEN SKIN, BLOOD, OR BODILY FLUIDS	Follow instructions on the following page for SEMI-CRITICAL MEDICAL DEVICE cleaning and disinfecting (HLD, High-Level Disinfection)

Cleaning and Disinfecting of Ultrasound Transducers and Consoles

The level of cleaning and disinfecting required for the system is dictated by the type of tissue it contacts during use. Please follow one of the instructions below depending on the level your procedure falls under.

NON-CRITICAL MEDICAL DEVICE CLEANING AND DISINFECTING

(LOW-LEVEL DISINFECTING)

The system or transducer ***did not*** come in contact with broken skin, blood, mucosal membranes, or bodily fluids. See Instructions below:

1. Lightly wipe down outer areas of the system console with SONO that were touched during the procedure. Do not squeeze the towel over keys or areas where liquid can penetrate to the electronics. If you are going to wipe vigorously to remove gel or visible soil, it is recommended that you turn the unit off and unplug from the wall
2. Remove any gel from the surface of the transducer with a non-abrasive, lint free dry wipe
3. Take a wipe and lightly move around the transducer where contact with the patient was made
4. Wrap the wipe around the head of the transducer and leave in transducer holder as you prepare for your next patient (this process will guarantee that the contact time for proper disinfection was made)
5. Take the cloth and wipe down the head again and the cable of the transducer
6. This process should be done with each transducer used on the patient

SEMI-CRITICAL MEDICAL DEVICE CLEANING AND DISINFECTING

(HIGH-LEVEL DISINFECTING)

1. Turn off the system by pressing the power button
2. Unplug power cord
3. Unplug transducer from system and remove any sheathing and place transducer where it will not cross contaminate clean equipment
4. Wipe off any blood or bodily fluid that is visible on the system console and transducer using a fresh wipe for each
5. Take your time cleaning the system to insure a minimum 4 minute wet time is met
6. Pre-clean the transducer including the cable using a new SONO Wipe and let air dry prior to placing into your facilities HLD process (i.e. soaking station, Trophon, ASTRA, TD100)
7. Do not soak or wipe any electronic components like the inside of the connector housing

Medical device Compatibility Claims

Medical devices, panels and touch screens are taken apart and tested then put back on the systems and clinically tested. Other proprietary methods are used to evaluate for any cracking, or discoloration. SONO Wipes passed all compatibility tests for both system consoles and majority of the highly used probes and cables for the product lines below

ULTRASOUND OEM'S	GE (Voluson, Logiq, Vivid and portable lines)
	Philips (HDI, SONOS, iU, iE, HD series, Envisor, ClearVue, CX, Epiq and Affinity product lines)
	Siemens (Sequoia, Aspen, Antares, X, S and SC series product lines)
	Toshiba (Aplio, Nemio and Xario series product lines)
	SAMSUNG (Accuvix, SonoAce, W, H, HM and HS series product lines)
	Sonosite (SII, Edge, iViz, X-Porte, M-Turbo, Micro Maxx, Nano Maxx, S-Nerve series product lines)
	Mindray (DC, M, TE, DP and Z series product lines)
	Terason (uSmart and T series product lines)
	Esaote (MyLab series product lines)
	BD Site-Rite (Halycon, Prevue)
	Alpinion (E-CUBE series product lines)
	Whale Imaging (Lamda and Sigma series product lines)
OTHER NON-CRITICAL MEDICAL DEVICES TESTED	Fibroscan (630 Expert, 502 Touch, 530 compact, 430 mini)
	Nanosonics (Trophon EPR)
	PCI (GUS and Astra product lines)
	CS Medical (TD100)