Appendix 1: Acoustic Output Reporting Table for Track 3

Transducer Model: Acessa Transducer
Operating Mode: B-Mode

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Nonscan	
					Aaprt≤1 cm2	Aaprt>1 cm2		
Maximum index value			0.786	0.068	-	-	-	(a)
Associated acoustic parameter	pr.3 (MPa)		1.797					
	W_0 (mW)			10.06	-		-	(a)
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$] (mW)					-		
	z1 (cm)					-		
	zbp (cm)					-		
	zsp (cm)		1.60				-	
	deq(zsp) (cm)						-	
	fc (MHz)		5.23	5.23	-	-	-	(a)
	Dim of A_{aprt}	X (cm)		0.78	-	-	-	(a)
		Y (cm)		0.40	-	-	-	(a)
Other Information	PD (µsec)		0.227					
	PRF (Hz)		7936					
	p_r @ PII_{max} (MPa)		2.40					
	d_{eq} @ PII_{max} (cm)						-	
	Focal Length	FL_x (cm)		1.8	-	-		
		Fl_y (cm)		2.2	-	-		
	IPA.3 @ MImax (W/cm^2)		246.6					
Operating Control Conditions	19 mm focus, 5 MHz		✓	✓				

Note 1: Information need not be provided for any formulation of *TIS* not yielding the maximum value of *TIS* for that mode.
Note 2: Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).
(a) Intended use does not include cephalic so TIC is not computed

Acessa Transducer with Sensor (Model Number 7700)

Instructions for Use

CAUTION: Federal Law (U.S) restricts this device to sale by or on the order of a physician.

This brochure provides basic information on the Acessa Transducer with Sensor. For complete information on how to use this device with the Acessa Procedure see the Acessa System User's Guide (PL-01-0040).

Product description:
The Acessa Transducer with Sensor is an ultrasound transducer designed specifically for use with the Acessa procedure to display the image in B-Mode only. The operator has access to operating controls for frequency, focus, depth, and gain.

Acessa Procedure Indications for use:
The Acessa Transducer with Sensor is an accessory to the Acessa System Console (Model 7100) for use during the Acessa procedure.

Contraindication:
The Acessa Transducer with Sensor is contraindicated for use any time use of Acessa procedure is contraindicated.

Warnings:
- This Transducer may injure the human body. Do not use it in continuous contact with the human body for more than 60 minutes. This Transducer is designed for temporary use during surgery.
- This Transducer must not be used in direct contact with the heart. Use the probe only for the purposes described above.

Precautions:
- Prior to use, refer to the Acessa System User's Guide (PL-01-0040) for complete information.
- The Acessa Transducer with Sensor is designed for use with the Acessa procedure.
- The Acessa Transducer with Sensor should be used only by physicians and medical staff who have been trained and have a thorough understanding of the system.
- The Acessa Transducer with Sensor is a precision instrument that is fragile and vulnerable to damage by shock.
- Care must be taken when handling the Acessa Transducer with Sensor not to drop it or strike it against hard surfaces. When dropped or struck against a hard surface, the Transducer may develop an abnormal state that cannot be located visually. If this occurs, contact Hologic, Inc. for replacement.
- Always use the Transducer in a dried state. Condensation or waterdrops may appear by being moved from cold to warm place. Use without proper care, can cause short-circuiting.
- The Acessa Transducer has not been validated for more than 100 uses.
- Perform the ultrasound procedure prudently using the principle of ALARA (As Low As Reasonably Achievable)

Potential Complications:
Potential complications of RF ablations may include, but are not limited to:
- Unintended Burns
- Bleeding
- Pain
- Local and/or Systemic Infections
- Hematoma at entry side
- Tissue Nerve Damage

Limitations of Reprocessing
The Acessa Transducer with Sensor has been designed and tested to perform effectively for a minimum of 100 cycles of cleaning and sterilization. Therefore, replacement is recommended to ensure safe and effective performance. See the inspection section for additional guidance on evaluating device functionality.
Note: Use life is dependent upon many factors, including the number or reprocessing cycles, compliance with device instructions, as well as precautions taken in handling cleaning, and storage. Proper care must be taken of the transducer to ensure the transducer remains in good working order.

Principles of Operation
This Transducer and the diagnostic equipment enable B-mode imaging using ultrasonic waves. These instruments operate under the principles described below.
(1) When an electric pulse signal is applied from the main equipment to the probe, the transducer in the probe makes vibrations while converting electric vibration to mechanical vibration energy. This enables ultrasonic waves to be emitted into media such as an organism or liquid that is in contact with the irradiation area of the transducer.
(2) The Transducer is also used to receive ultrasonic reflected waves. The Transducer mechanically vibrates as a result of the vibration of the received ultrasonic waves and receives a signal through an electro-mechanical conversion operation that converts that mechanical vibration into electric energy.
(3) Since multiple transducers are arranged in the probe, the electric scan operation of the ultrasonic pulse signal can be repeated many times, and the reflected signal received can be observed in real time.
(4) The time required between transmission and reception is converted into a distance, and images are displayed on the screen.

Device Description

Indications for Use	Laparoscopic surgery
Type of array	Linear
Number of elements	128
Center frequency	7.5MHz
Bandwidth	≥75%
Focus adjustment	.2-8
Environmental conditions	Ambient temperature 10°C~40°C 50°F~104°F Relative humidity 30%~85% Atmospheric pressure 700 hPa~1060 hPa
Diameter	Diameter 10 mm
Cable length	2.5m

Track 3 Summary

Transducer	ISPTA.3	TI Type	TI Value	MI	IPA.3@M Imax
Acessa Transducer	17.0 mW/cm^2	TIS	0.068	0.79	246.6 W/cm^2

See Appendix 1 for Acoustic Output Reporting Table for Track 3.

Storage Conditions

Ambient temperature:	10°C~50°C 14°F~122°F
Relative humidity:	10%~90%
Atmospheric pressure	700 hPa~1060 hPa

Device Inspection
Conduct the following Inspections before each use and before cleaning and sterilization. Verify the following:
1. Insertion area of Transducer is free from holes, dents, scratches, cracks, deformations and color changes on the surface.
2. There are no flaws, fissure, delamination or any other nonconformities on the connector and cable.
3. There are no loose or missing components

Do not use the device if it does not pass inspection. Contact Hologic, Inc. for service or a replacement device.

Device Preparation and Operation

1. Store in a dry place.
2. Clean and sterilize the Acessa Transducer with Sensor. Refer to the recommended cleaning and sterilization instruction.
3. Place the Acessa Transducer with Sensor in the sterile field.
4. Conduct a Visual Safety Check. Refer to section 'Device Inspection'.
5. Attach the Acessa Transducer with Sensor to the Acessa Console.
6. Ensure that the Ultrasound function displays on the Acessa Console.

Note: For detailed instructions and illustrations on connectors and configuration see the Acessa System User's Guide (PL-01-0040).

Recommended Cleaning and Sterilization

Clean and sterilize the transducer before first and every use. Hologic, Inc recommends the following cleaning and sterilization steps as outlined below. Prior to cleaning and sterilization conduct an inspection according to the 'Device Inspection' section of this document. All Transducers must be thoroughly cleaned, rinsed and dried according to the process described in this section before proceeding with sterilization of the device. Thorough cleaning and rinsing are the first and most important steps in reprocessing of any reusable medical device. Without thorough cleaning and rinsing, it is not possible to achieve effective sterilization of the device.

Cleaning

Rinse contact or insertion area of probe thoroughly with running water for two (2) minutes at approximately 43°C (110°F), making sure all foreign matter, blood, mucus, etc. are removed with a soft bristle brush.

Immerse device (shaft and cables only) in Prolystica Enzymatic Cleaner, at a concentration of ½ ounce cleaner to 1 gallon water, at approximately 43°C (110°F) for three (3) minutes, while wiping and scrubbing shaft and cables with an Endozime Sponge.

Follow the detergent manufacturer's instructions for concentration and other conditions.

Rinse with deionizied water for one minute.

Dry with a lint free cloth.

Thoroughly examine all surfaces that have been cleaned and visually inspect the entire device to make sure it is clean.

Table 1. Recommended Manual Cleaning Durations

TREATMENT	TIME(MM:SS)	CLEANING SOLUTION
Rinse under running water with a with a debris removal tool ensuring all soil has been removed.	02:00	Water 43°C (110°F)
Immerse device while wiping and scrubbing Shaft and Wires with a debris removal tool.	03:00	Enzymatic Cleaner 43°C (110°F)
Rinse	04:00	Deionized Water

Sterilization

The Acessa Transducer with Sensor is provided non-sterile. The transducer is sterilized using low-temperature hydrogen peroxide gas plasma technology, selected for its ability to process heat- and moisture-sensitive medical devices quickly, without producing toxic residues or emissions. The Acessa transducer has been designed to be compatible with ASP STERRAD® 100NX, NX, and 100S systems, as well as STERIS V-PRO® systems.

NOTE: Only one (1) Acessa Transducer with Sensor should be run in a STERRAD® NX, 100S, V-PRO® , or STERRAD® 100NX load at a time. All sterilization should be performed with the black connector cap off.

The following low-temperature hydrogen peroxide gas plasma sterilization cycles have been validated to result in a SAL of 10^{-6} in accordance with applicable standards, including AAMI TIR12:

Table 2. Recommended Sterilization Cycles (STERRAD®)

STERILIZATION METHOD	PREPARATION*	STERRAD® STERILIZATION SYSTEM & CYCLE TYPE
Low-temperature Hydrogen Peroxide Gas Plasma Technology	Double wrap utilizing (inner wrap 500 grade, outer wrap 600 grade) FDA cleared Sterilization Wrap	STERRAD® Model 100NX Standard Cycle.
	Place into APTIMAX® Instrument Tray, PC:13837	STERRAD® Model NX Standard Cycle.
	Double wrap with H400 Sterilization Wrap, Halyard Health, PC:68248	STERRAD® Model 100S Short and Long Cycles.

**Device preparation is based on the Acessa validated process. Reference appropriate STERRAD® model instructions for additional information or guidance.*

Table 3. Recommended Sterilization Cycles (V-PRO®)

STERILIZATION METHOD	PREPARATION*	STERIS V-PRO® STERILIZER & CYCLE TYPE
Low-temperature Hydrogen Peroxide Gas Plasma Technology	Place into STERIS Sterilization Tray and wrap with H600 OneStep wrap	V-PRO® 1 – Standard Cycle.
		V-PRO® 1 Plus – Lumen and Non-Lumen Cycles
		V-PRO® maX – Lumen, Non-Lumen & Flexible Cycles
		V-PRO® maX 2 – Lumen, Non-Lumen, Flexible and Fast Non-Lumen Cycles
		V-PRO® 60 – Lumen, Non-Lumen and Flexible Cycles
		V-PRO® s2 – Lumen, Non-Lumen, Flexible and Fast Cycles

**Device preparation is based on the Acessa validated process. Reference appropriate V-PRO® model instructions for additional information or guidance.*

No toxic residues are left after STERRAD® or V-PRO® sterilization. No aeration is needed for devices sterilized using the STERRAD® or V-PRO® Systems.

Specific sterilization questions should be made directly either to Advanced Sterilization Products at: http://www.aspjj.com/,
Or STERIS Corporation at: http://www.steris.com/.

Warranty: Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ("Warranty Period"); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products. These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

Contact Hologic Technical Support if the Tranducer fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and a biohazard kit if applicable. Return the *Transducer* according to the instructions provided by Technical Support. Be sure to clean and sterilize the product before returning it.

Return used or opened product according to the instruction provided with the Hologic-supplied biohazard kit.

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Symbols Glossary

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
LOT	EN ISO 15223-1, 5.1.5 ISO 7000, 2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
6	ISO 7000 No. 659	Biohazard	Dispose of biohazardous materials according to local safety regulations
REF	EN ISO 15223-1, 5.1.6 ISO 7000, 2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	EN ISO 15223-1, 5.4.4 ISO 7000, 0434A IEC 60601-1, Table D.1, 10	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	EN ISO 15223-1, 5.4.3 ISO 7000, 1641 IEC 60601-1, Table D.1, 11	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	EN ISO 15223-1, 5.2.8 ISO 7000, 2606	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	EN ISO 15223-1, 5.1.1 ISO 7000, 3082	Manufacturer	Indicates the medical device manufacturer.
NON STERILE	EN ISO 15223-1, 5.2.7 ISO 7000, 2609	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 7000, 2794	Packaging unit	To indicate the number of pieces in the package.
Rx ONLY	FDA 21 CFR 801.109	Prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician.
	IEC 60601-1, Table D.1, 20 IEC 60417, 5333	Type BF applied part	To identify a Type BF applied part complying with IEC 60601-1.
	EN ISO 15223-1, 5.1.4 ISO 7000, 2607	Use-by date	Indicates the date after which the medical device is not to be used.