Appendix 1: Acoustic Output Reporting Table for Track 3

Transducer Model: Acessa ProVu
Operating Mode: B-Mode

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Nonscan	
					*A*aprt≤1 cm2	*A*aprt>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

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Acessa ProVu Transducer with Sensor (Model Number 7700)

Instructions for Use

℞ only

CAUTION: Federal Law (U.S) restricts this device to sale by or on the order of a physician trained in the use of the Acessa ProVu System for ablation of symptomatic uterine fibroids

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

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

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

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 ProVu System User's Guide (PL-01-0040) for complete information.
- The Acessa ProVu Transducer with Sensor is designed for use with the Acessa ProVu System.
- The Acessa ProVu 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 ProVu Transducer with Sensor is a precision instrument that is fragile and vulnerable to damage by shock.
- Care must be taken when handling the Acessa ProVu 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 Acessa Health 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 ProVu 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 ProVu 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@MImax
Acessa ProVu	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 Acessa Health for service or a replacement device.

Device Preparation and Operation

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

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

Recommended Cleaning and Sterilization

Clean and sterilize the transducer before first and every use. Acessa Health 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 40°C (104°F), making sure all foreign matter, blood, mucus, etc. are removed with a debris removal tool (ex. soft bristle brush, lint free cloth, sponge, etc.).

Immerse device (shaft and cables only) in an Enzymatic Cleaner with water at approximately 43°C (110°F) for three (3) minutes, while wiping and scrubbing shaft and cables with a debris removal tool.

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

Rinse with water for four (4) minutes at 40°C (104°F).

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 40°C (104°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	Water 40°C (104°F)

Sterilization

The Acessa ProVu 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 ProVu Transducer with Sensor should be run in a STERRAD® NX, 100S, or V-PRO® load at a time and No more than two (2) Acessa ProVu Transducers with Sensor should be run in a 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 Double wrap with H400 Sterilization Wrap, Halyard Health, PC:68248	STERRAD® Model NX Standard Cycle.
		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.aspji.com/,
Or STERIS Corporation at: http://www.steris.com/.

WARRANTY: Every Model Number 7700 Acessa ProVu Transducer with Sensor sold by Acessa Health Inc. carries a 1-year manufacturer's warranty from the date of sale. Acessa Health Inc. hereby guarantees that the product is free from any defect in material and workmanship. Acessa Health's obligation under this warranty is expressly limited to repairing or replacing any unit that fails, the repair or replacing is at the sole discretion of Acessa Health. This warranty excludes damage or failure due to abuse, usage beyond intended use, and/or improper installation. Acessa Health Inc. reserves the right to perform warranty service in its factory or at the customer's site based on the nature of the repair and/or the type of service. Acessa Health does not allow service training for any non-authorized service group. Acessa Health Inc. must complete all service; any tampering or unauthorized servicing may void any manufacturer's warranties.

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Glossary of Symbols

Symbol	Standard Reference	Symbol Title/Description
	US 21 CFR 801.109	**Prescription Only** / Device restricted to use by or on the order of a physician.
	ISO 15223-1:2016 5.1.5	**Lot Identification** / Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1:2016 5.1.1	**Manufacturer** / Indicates the medical device manufacturer.
	ISO 15223-1:2016 5.1.6	**Catalogue or Model Number** / Indicates the manufacturer's catalogue number so that the medical device can be identified.
	IEC 60601-1:2012 Table D.2, Symbol 10	**Follow Instructions for Use** / Refer to instruction manual/booklet.
	ISO 15223-1:2016 5.3.4	**Keep dry** / Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1:2016 5.2.7	**Non-sterile** / Sterilize Prior to Use (manufacturer does not provide this device sterile)
	ISO 15223-1:2016 5.4.4	**Attention, see Instructions For Use /** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions.
	IEC 60601-1:2012 Table D.1, Symbol 20	**BF Type Applied Part** / To identify a type BF applied part complying with IEC 60601-1
	ISO 7000 No. 659	**Biohazard/** Dispose of biohazardous materials according to local safety regulations
IPX7	IEC 60529	**IPX7/** Protection against immersion up to 1 meter