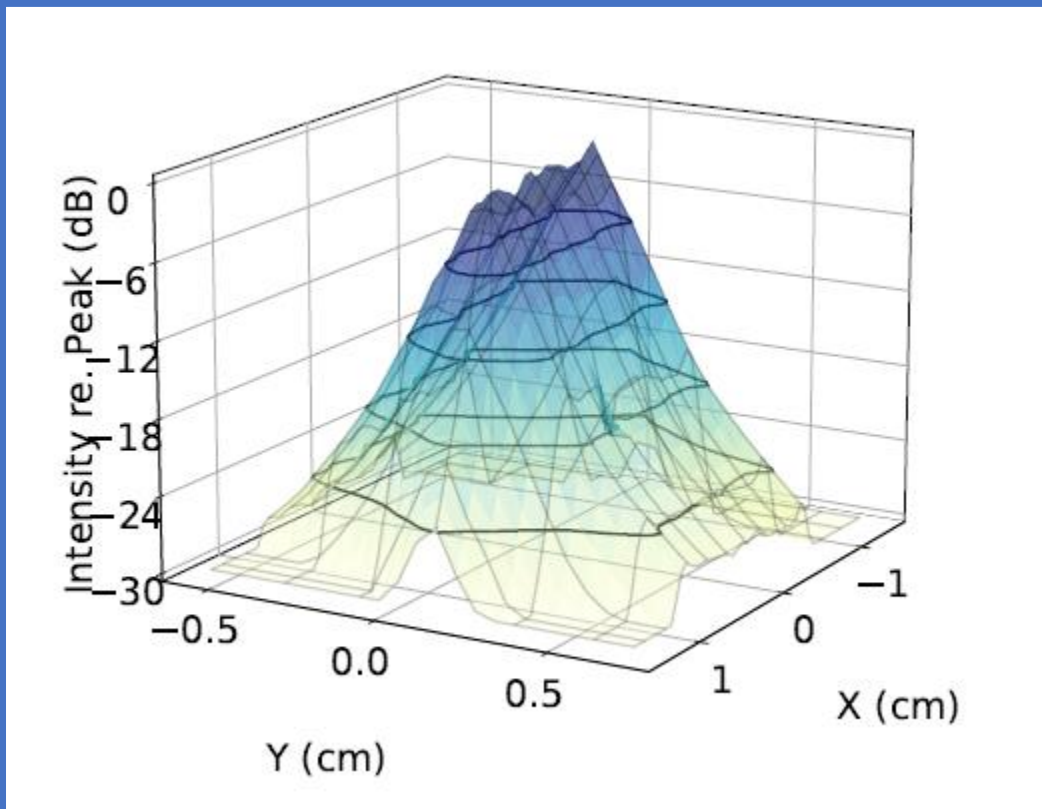


Acertara Technical Publications Series

Contemporary Acoustic Output Measurement Techniques for Diagnostic Ultrasound Systems



Wilder Iglesias, PhD, Anna Ursiny, BSBE, G. Wayne Moore, B.Sc., MA, FASE, FAIUM

Rev 1.0

GUIDEBOOK SERIES

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1950 Lefthand Creek Lane, Longmont, CO 80501

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Introduction and Scope

This Guidebook was designed and developed to provide physicists, acoustic engineers and others responsible for the testing and measurements of diagnostic ultrasound systems and transducers (also referred to in this text as probes), with the essential technical and consensus standards information necessary to perform, document and report USFDA (hereafter referred to as simply the FDA) the required premarket acoustic data, essential for FDA 510(k) market clearance of the device. While reading this document we recommend having the FDA Guidance Document open and follow along with FDA³. Pay special attention to Section 5.2.4.1 “Acoustic output test methodology”, and Appendix F & G.

Definitions of Several Key Terms Used in Text

- **Deconvolution:** *A process used to clean up or sharpen ultrasound signals by removing the effects of distortion from the system or tissue.*
- **Center Frequency:** *The main or average frequency of an ultrasound wave. It’s the “middle” pitch of the sound being used.*
- **Mechanical Index (MI):** *A number that indicates the chance that ultrasound might cause small gas bubbles (cavitation) in the body. A higher number means more potential for effects.*
- **Thermal Index (TI):** *A number that shows the potential for ultrasound to heat up body tissue. It helps keep the procedure safe by limiting heating.*
- **Conditional Increase Output (CIO):** *An option for the ultrasound system to temporarily increase its power if certain safety conditions are met, typically under user control.*
- **Raster Scan:** *A scanning method where the ultrasound beam moves in a grid-like pattern, line by line, to create an image.*
- **Peak Pulse Intensity Depth:** *The depth in the body where the ultrasound pulse is the strongest. This is important for measuring safety and performance.*
- **Acoustic Axis:** *An imaginary line straight out from the center of the ultrasound beam. It helps define the direction the beam travels.*

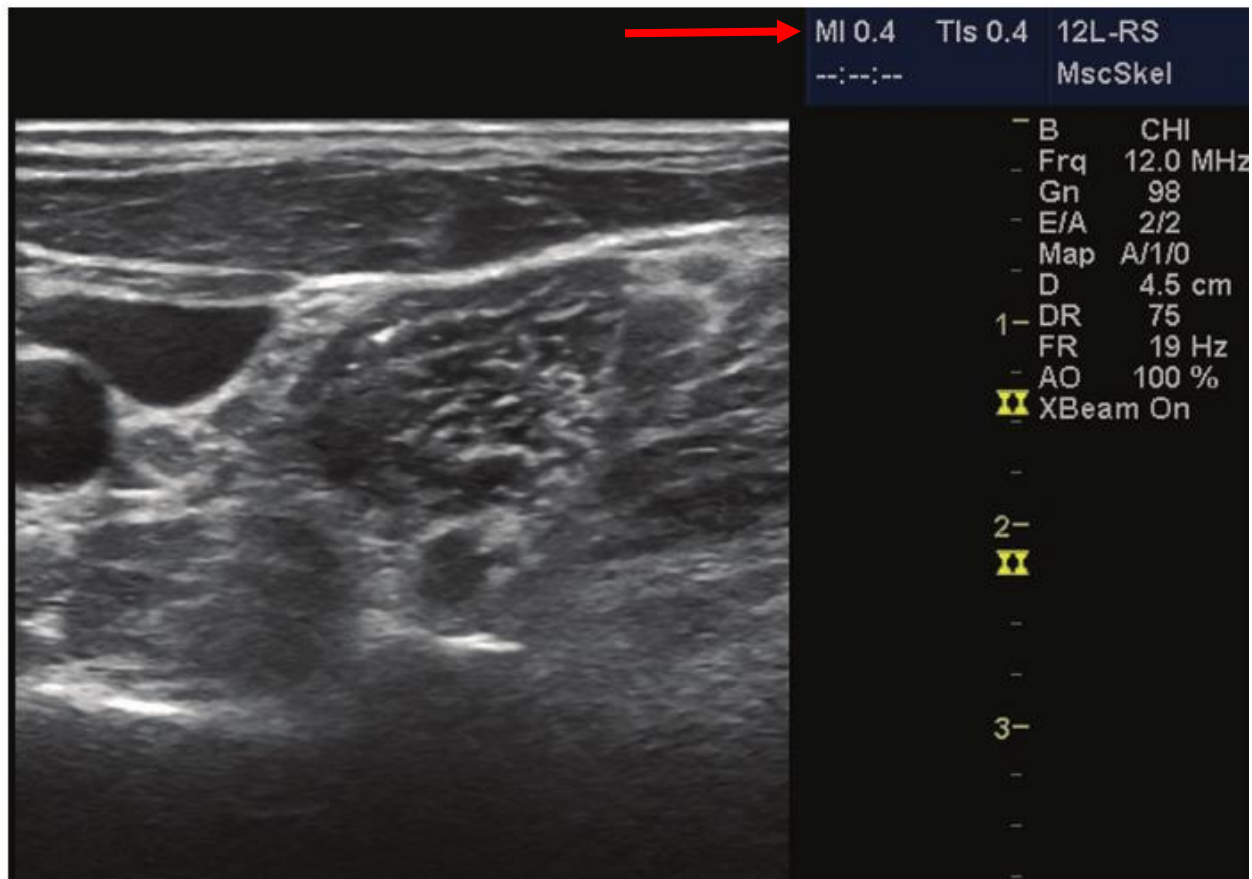
- **Output Display Standard (ODS):** A set of rules that tells ultrasound systems how to display important safety information like MI and TI on the screen.
- **Rarefactional Pressure:** The part of the ultrasound wave where pressure is negative. It's closely related to the potential for bubble formation.
- **Peak Negative Pressure:** The most negative (pulling) pressure during an ultrasound wave. This is important for understanding the potential to create bubbles (cavitation).
- **Pulse Intensity Integral (Derated):** The total energy in a pulse of ultrasound, adjusted to account for how tissue weakens (attenuates) the sound.
- **Measurement Uncertainty:** A way to describe how confident we are in a measurement. It shows the possible range of error in the result.
- **Cavitation:** The forming and collapsing of tiny gas bubbles in the body due to ultrasound. It can be helpful or harmful depending on how it's used.
- **SPTA – Spatial Peak Temporal Average:** A way of measuring ultrasound intensity by looking at the strongest spot in the beam and averaging it over time.
- **API – Acoustic Power and Intensity:** Measures of how strong or energetic the ultrasound waves are. Power is the total energy sent out, and intensity is how concentrated it is.
- **Transmit Profiles (TPs) and Reportable Modes (RMs):** TPs describe how the ultrasound is sent into the body (e.g., settings or styles of scanning). RMs are the specific modes the system must report safety data for.

Measurement Standards

The acoustic measurement consensus standards for diagnostic ultrasound devices that are currently recognized by the United States Food and Drug Administration (FDA) for acoustic power and intensity (API) testing are:

- IEC60601-2-37
- IEC62359
- IEC62127-1,2,3

These standards are well developed and supply adequate guidance for measuring diagnostic ultrasound imaging systems and their attendant probes (aka, transducers, scan heads, etc.). These standards define measurement equipment requirements and measurement methods, which ultimately apply to the Output Display Standard (ODS) indices of Mechanical Index (MI) and Thermal Index (TI) as shown in the example below. Potential bioeffects related to MI and TI are described on the following page.




Measurement Objectives

The objective of measuring ultrasonic acoustic output levels is to ensure that certain relevant performance parameters fall within published guidelines relative to potential bioeffects associated with a clinical diagnostic ultrasound examination. Specifically these parameters are referred to as Mechanical Index and Thermal Index. MI is a measure of the risk of a mechanically induced bioeffect primarily related to cavitation. TIs is the measure of risk of a thermal bioeffect from localized tissue heating. The FDA currently limits the maximum MI value for diagnostic ultrasound at 1.9, although certain clinical applications such as ophthalmic

exams, are limited to far less³ and others (Conditionally Increased Output or CIO) may have temporarily higher MI values, such as shear wave elastography applications⁴. In an ultrasound system the TI value is slaved to the selected MI value and cannot be individually changed by the system operator.

Mechanical Index is defined as the derated peak negative pressure divided by the square root of the acoustic working frequency measured at the depth of the maximum derated pulse intensity integral (see Figure below). MI is a “pulse parameter” that is, it can be determined from a single pulse pressure waveform. The rationale for this measurement is that it provides a measure of the likelihood of mechanical effects caused by high rarefactional pressures, which is commonly cavitation.



$$MI = \frac{p_{r,3}(\text{MPa})}{\sqrt{f(\text{MHz})} \cdot 1 \frac{\text{MPa}}{\sqrt{\text{MHz}}}}$$

$$p_{r,\alpha}(z) = p_r(z) \cdot 10^{-\alpha z f_{awf}/20 \text{ dB}}$$

where α is the acoustic attenuation coefficient and is equal to $0.3 \text{ dB cm}^{-1} \text{ MHz}^{-1}$ for soft tissue. Hence, the derated rarefactional pressure denoted as $p_{r,3}$.

Thermal Index is a parameter that, based on theoretical models, estimates tissue temperature rise resulting from ultrasonic heating. For example a TI of 1 estimates a tissue temperature rise of 1° C . Depending on the clinical application there are three different TI types labeled, TIS, TIB, and TIC. TIS is used for a soft tissue interface, TIB is used for a bone interface, and TIC is used

for a skull interface (also known as transcranial). The equations used to calculate each are shown below.

The calculated value of TI depends on the target tissue, the transducer aperture size, location of the focal point, i.e., at surface versus at depth, and the transmit pattern, i.e., scanning versus non-scanning (stationary). TI determination for the multiple TI model equations requires acoustic power (P), intensity (I_{spta}), derating factors (DER), spatial distribution (including equivalent diameter, D_{eq}) and acoustic frequency (f). Power can be measured directly with an acoustic force balance or determined by hydrophone measurements. Acoustic working frequency and intensity values are determined from hydrophone measurements.

$$TIS = \begin{cases} \frac{P \times DER \times f}{210 \text{ MHz} \cdot \text{mW}}, & \text{for } A \geq 1 \text{ cm}^2 \\ \frac{P \times f}{210 \text{ MHz} \cdot \text{mW}}, & \text{for } A < 1 \text{ cm}^2 \end{cases}$$

$$TIB = \min \left[\frac{\sqrt{P \times DER_{Z_{b.3}} \times I_{SPTA_{b.3}}}}{50 \text{ mW} \cdot \text{cm}^{-1}}, \frac{P \times DER_{Z_{b.3}}}{4.4 \text{ mW}} \right]$$

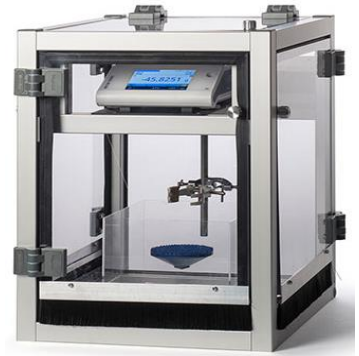
$$TIC = \frac{P / D_{eq}}{40 \text{ mW} \cdot \text{cm}^{-1}}$$

Sensors

There are two common types of sensors used in measuring ultrasonic acoustic energy, the Radiation Force Balance (RFB) and the Hydrophone of which there are two basic types, the needle hydrophone and the P_vDF (polyvinylidene fluoride) membrane hydrophone.

Radiation Force Balance:

Radiation Force Balances (RFB) are designed to measure the very small forces exerted by acoustic waves, particularly in the context of ultrasound. When ultrasound waves travel through a medium, such as tissue or a fluid, they generate a radiation force, which is the result of the interaction between the sound waves and the particles in the medium. The device works by detecting the minute displacement or deflection of a small, sensitive target placed in the acoustic field. This testing method is critical for compliance with international standards such as IEC 60601-2-5, which defines procedures for measuring ultrasonic power output for measuring ultrasonic power output in medical diagnostic and therapeutic devices. RFBs are widely used in laboratories performing regulatory compliance testing, transducer characterization, and system validation for applications ranging from medical imaging and physiotherapy to high-intensity therapeutic ultrasound (HIFU) and industrial non-destructive testing (NDT).



Needle Hydrophone:

A needle hydrophone is a miniature device with a high-frequency piezoelectric sensor at the tip. It's designed to measure acoustic pressure in ultrasonic fields with minimal perturbation. The small sensing element, often on the order of tens to hundreds of micrometers, allows for precise spatial resolution when mapping ultrasound fields. Their small size enables detailed scanning of ultrasound beams, which is crucial for applications like medical imaging transducers, therapeutic ultrasound, and device quality control. It also allows for getting measurements up close due to their slim profile without geometrical restrictions, causing major reflections, or standing waves.



The hydrophone tip contains a thin piezoelectric film that converts acoustic pressure into an electrical signal. This signal is then amplified and analyzed using an oscilloscope or a dedicated ultrasound measurement system.

Membrane Hydrophone:

Membrane hydrophones measure and characterize acoustic pressure fields in a broad range of ultrasound applications. Measuring key parameters such as acoustic pressure, frequency response, intensity distribution, and spatial-temporal variations, a membrane hydrophone ensures compliance with IEC 60601-2-37 and FDA regulations for diagnostic and therapeutic ultrasound devices. Also used in HIFU research, non-destructive testing (NDT), and other biomedical studies, this style of sensor provides essential data for transducer performance optimization. Membrane hydrophone calibrations tend to be more consistent than their needle counterparts.

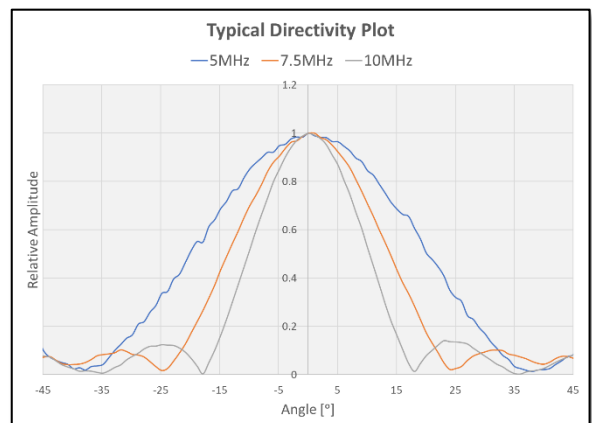
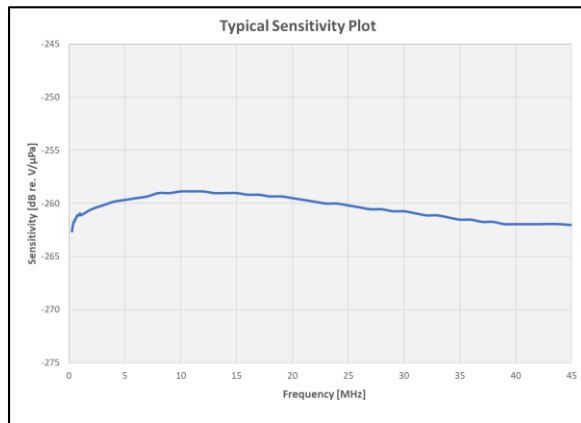


Sensor Calibration:

Routine calibration is critical for ensuring accurate and reliable measurements in acoustic power testing, particularly for sensors such as hydrophones and RFBs. Both membrane and needle hydrophones require calibrations to maintain measurement integrity. Without a routine calibration, there is potential for sensitivity, frequency response, and spatial accuracy to drift over time. Hydrophones must be calibrated to traceable standards such as IEC 62127 to ensure consistency and compliance in diagnostic and therapeutic ultrasound applications.

Radiation force balances also require regular calibration to maintain accuracy. RFBs should be calibrated in compliance with standards like IEC 61161, to prevent drift in measurements that could lead to incorrect power output estimations.

Without proper calibration practices in place, measurement errors can occur and result in noncompliance with regulatory standards, inaccurate device characterizations, and potential safety risk in ultrasound applications in the clinical setting.

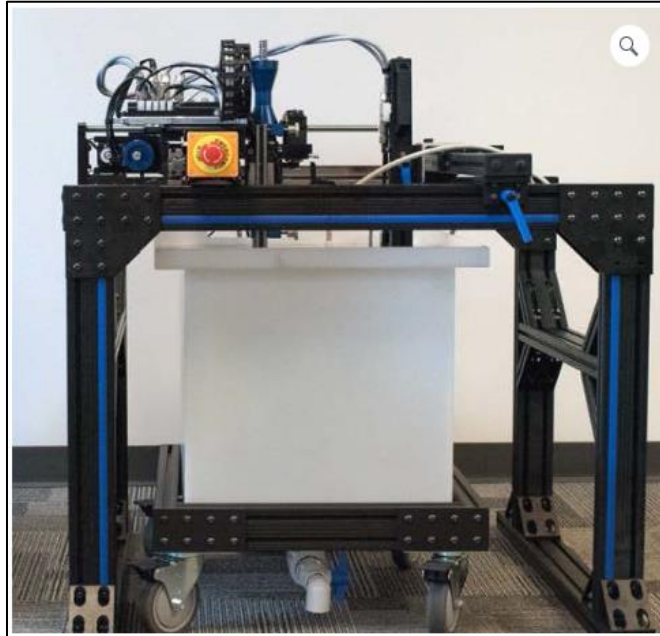


Measurement System

Because hydrophones measure at a single point in space, a mechanical positioning system is necessary to precisely locate the hydrophone relative to the transducer being measured. Hydrophone data is collected by a data acquisition system with software that usually automates specific measurements. It is important that the limitations of measurement sensors and systems are well understood and characterized. The limitations are usually quantified as “measurement uncertainty” which must be reported as part of a FDA 510(k) submission. The photo on the following page shows a complete acoustic testing tank (Acertara).

All measurements are performed in water. Water should be:

- 1) De-ionized
 - Allow consistent measurements across sites and over time
- 2) De-gassed
 - Removal of dissolved gas prevents cavitation which could damage the hydrophone and prevents the formation of gas bubbles that will scatter the ultrasound and distort measurements
- 3) Monitored for temperature
 - Speed of sound changes with temperature (directly affects radiation force measurement and the conversion of pressure to intensity)



Hydrophone Selection

It is essential to select the appropriate hydrophone for the device under test (DUT) to obtain accurate and reliable acoustic measurements in ultrasound testing. The choice of hydrophone directly impacts the precision of data collected, the efficiency of testing and the ability to meet regulatory standards. Based on the application, there are unique requirements to consider.

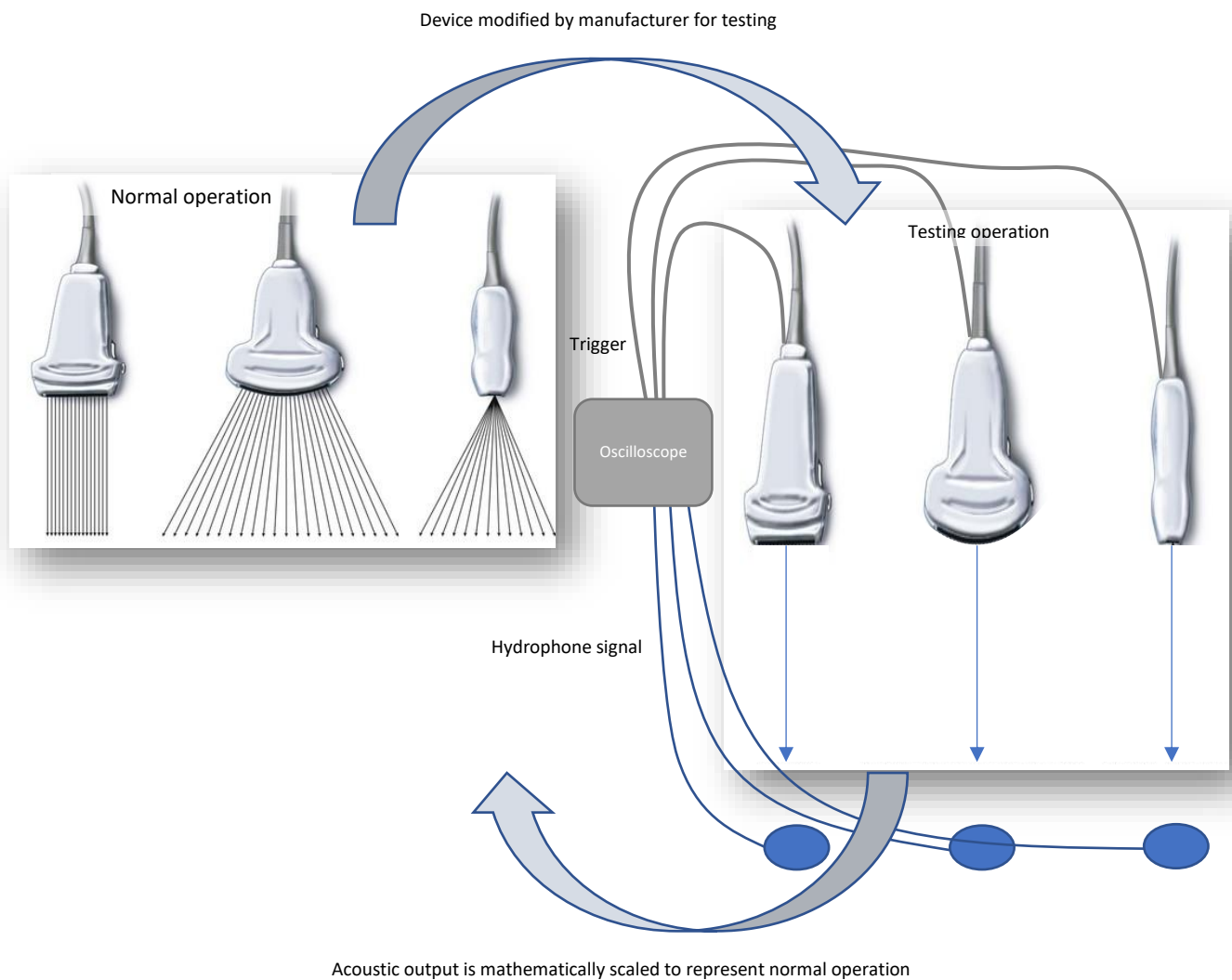
Key factors to consider:

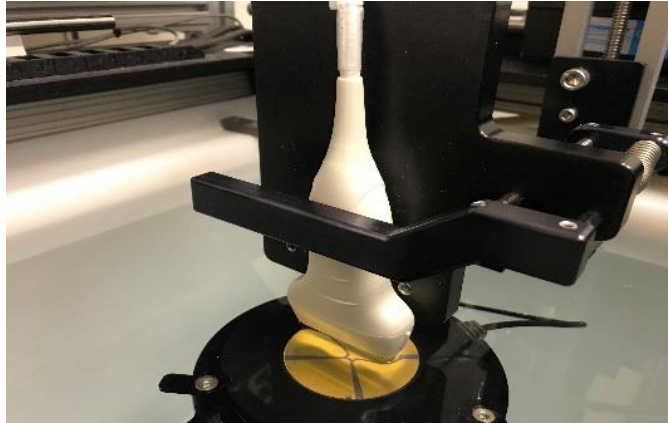
When selecting a hydrophone, key factors to consider include frequency response, sensitivity, active element size, calibration accuracy, voltage gain, and system compatibility.

- Frequency range should correspond with the intended ultrasound application.
- Sensitivity should be selected based on expected signal amplitude.
- Active element size impacts the indirect relationship between spatial resolution and sensitivity.
- Calibration accuracy must adhere to IEC 62127 standards, establishing confidence in data.
- Voltage gain will impact signal amplification whereas verifying system compatibility with existing acoustic measurement setups will ensure seamless integration.

- For pulsed measurements, bilaminar membrane hydrophones are preferred in our laboratory due to a flat frequency response and good long-term stability.
- If the waveforms to be measured are continuous wave (CW) or a very long pulse, a needle hydrophone is often used to avoid acoustic reverberation issues.
- For diagnostic CW signals, frequency response flatness is less critical because non-linear propagation is minimal.

Device Under Test (DUT)





Photograph of device under test

Essential Measurements

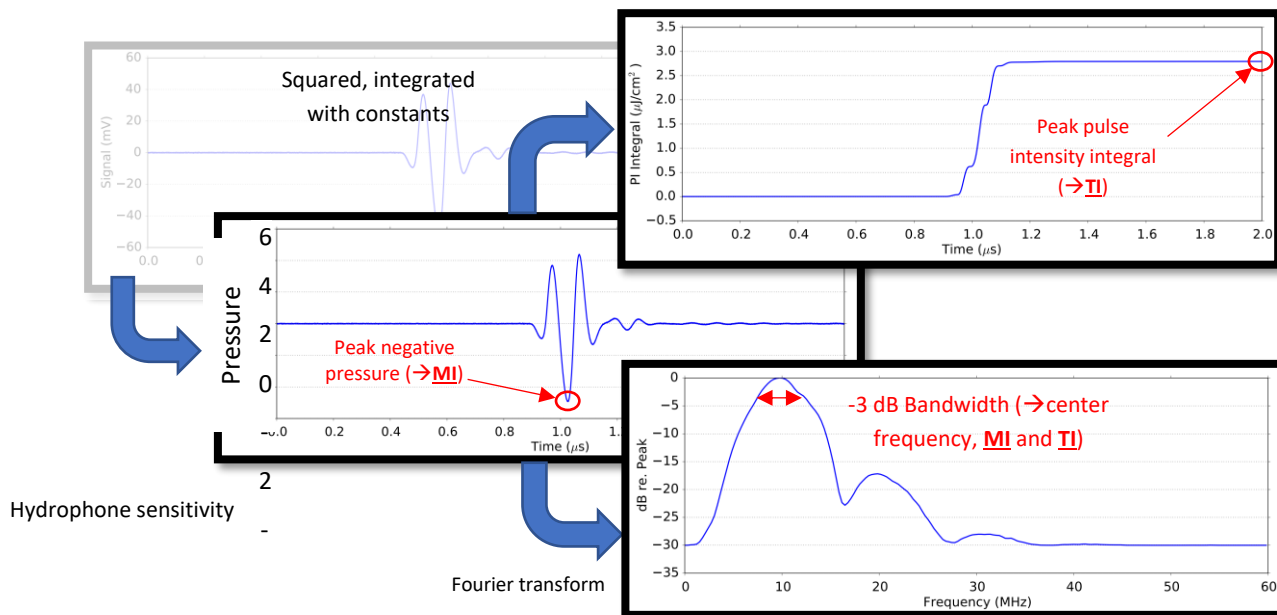
Characterizing the acoustic output of a diagnostic ultrasound probe primarily involves measuring the pressure and energy output of the transducer. These measurements are crucial for assessing the probe's performance and ensuring compliance with safety and regulatory standards.

Specifically, as previously mentioned, the displayed values of the **Mechanical Index (MI)** and **Thermal Index (TI)** are key indicators of the potential bioeffects of ultrasound exposure. The MI quantifies the potential for cavitation, while the TI estimates localized in vivo tissue heating due to ultrasound energy absorption.

Pressure values obtained from hydrophone measurements serve as the foundation for calculating intensity. By squaring the pressure, intensity values can be derived, which provide insight into the power distribution within the acoustic field. Further, integrating these intensity values over time and space allows for the computation of energy per unit area, a critical parameter in quantifying the total acoustic energy delivered by the transducer.

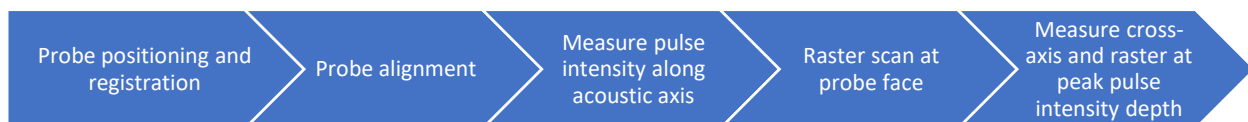
Beyond pressure and energy measurements, the characterization of a transducer's output also requires an analysis of its frequency properties. The **central (aka center) frequency** and **frequency distribution** are essential parameters that describe the spectral content of the emitted ultrasound wave. These values are typically obtained through a Fourier transform of the acquired waveform, providing information on the bandwidth and harmonic components of the ultrasound signal. Understanding these frequency characteristics is important for optimizing image resolution and ensuring diagnostic effectiveness.

The **center frequency** in ultrasound is generally defined as the midpoint between the -3 dB points of the spectral distribution because it provides a standardized way to define the frequency content of the transducer's output while accounting for the effective bandwidth. The -3 dB points correspond to the frequencies where the power of the signal drops to half of its peak value. By defining the central frequency as the midpoint between these points, we ensure that it represents the most significant portion of the transducer's emitted frequency spectrum.

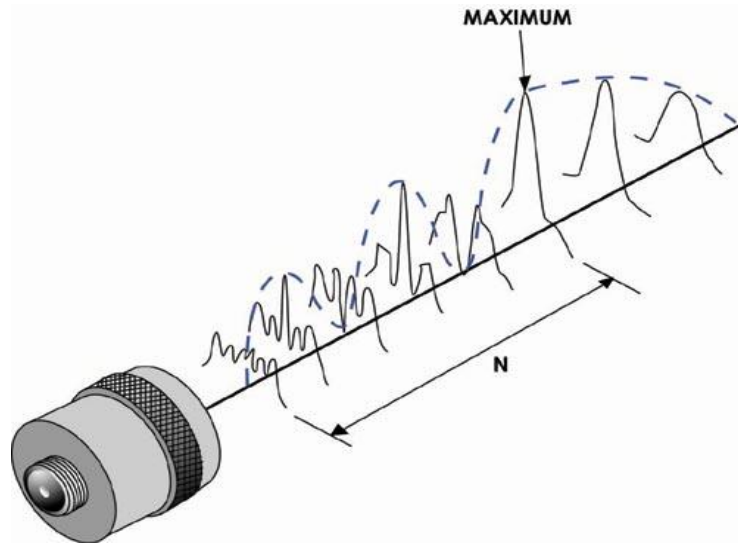


Measurement Process

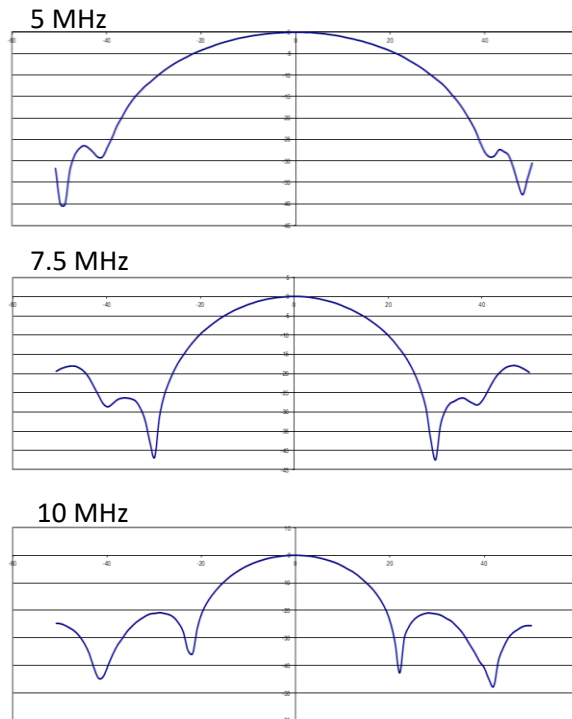
The measurement of acoustic power output for a diagnostic ultrasound transducer, as specified by **IEC 60601-2-37**, involves standardized procedures to ensure accuracy, repeatability, and safety compliance. The process primarily focuses on determining the total acoustic power emitted by the transducer under defined conditions.



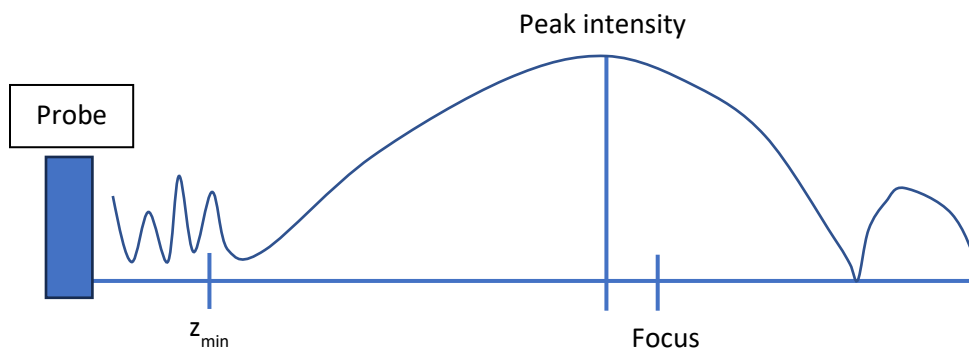
1. **Transducer Setup and Alignment:** The ultrasound transducer is placed in a tank filled with degassed, deionized water to prevent acoustic reflections and losses. A precision positioning system ensures the probe and measurement instruments are correctly aligned. Initial spacing between the transducer and hydrophone is set using micrometers or gauge blocks. High-precision goniometers are used to align the transducer (DUT) and hydrophone along the acoustic axis, critical for accurate measurement.



2. **Radiation Force Balance (RFB) Method:** To determine total acoustic power, we use the RFB technique: the ultrasound beam exerts a force on an absorbing or reflective target. This force is proportional to the acoustic power output, providing a direct and traceable measurement.
3. **Hydrophone-Based Pressure Mapping:** We use calibrated hydrophones to measure pressure waveforms at various points within the ultrasound field. Squaring and integrating these values over time and space provides intensity and energy density information, enabling detailed analysis of the beam's focus and peak intensity characteristics (e.g., ISPTA.3).
4. **Alignment Refinement:** Proper alignment is essential—misalignment can significantly affect pressure readings. For example, a 5° angular error at 10 MHz can result in a 12% pressure error. We refine alignment by locating intensity maxima at two axial planes and adjusting until both lie on a common axis.

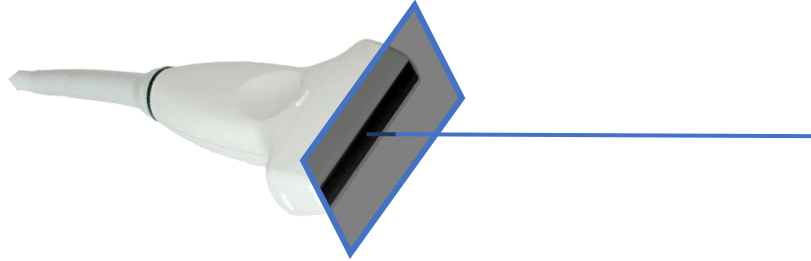


5. **Peak Intensity and Bioeffect Indexes:** Measurements are made along the beam axis from the transducer face through the focus. The maximum derated negative pressure defines the Mechanical Index (MI), while Thermal Index (TI) and ISPTA.3 are calculated at the depth of peak intensity integral beyond the focus.

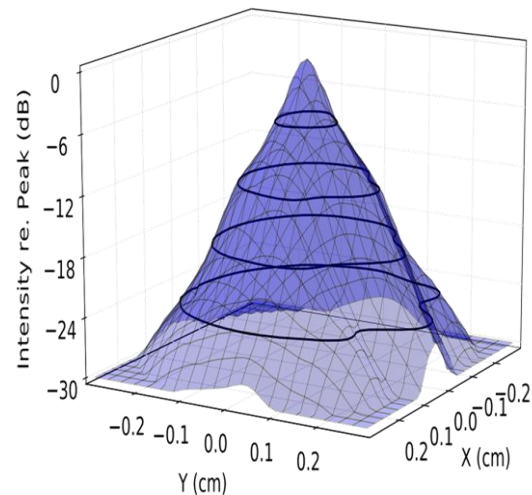
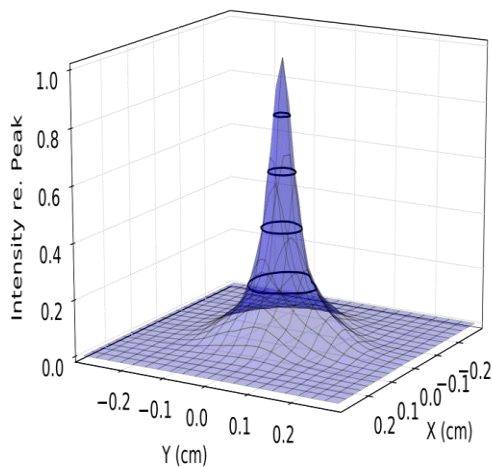


6. **Raster and Cross-Axis Scans:** We perform 2D raster scans in the focal region to measure pressure-squared integrals and identify output beam area and energy fluence. These are

essential for calculating scanning-mode TI and bounded output power (P_{1x1}). Cross-axis scans further define the beam width and focus area.



7. **Frequency and Beam Characterization:** A Fourier transform of the waveform reveals the center frequency and bandwidth. This frequency guides derating and scan resolution and is used to apply hydrophone calibration data. Beam symmetry and directivity are assessed from scan data.



8. **Data Processing and Compliance:** All data are processed and compared to IEC 60601-2-37 safety limits for various imaging modes. Reports are generated to demonstrate compliance and provide traceable documentation for customers and regulatory bodies.

Measurement and Consideration

Even with careful alignment, it may be necessary to search for the spatial peak at each successive depth, particularly at higher operational frequencies. The spatial averaging due to the physical size of the hydrophone should be evaluated and if necessary, compensated for. Be aware that measurements made close to the spatial peak can give a measure of the underestimation due to finite-sized hydrophones. The Fourier-transformed waveform is used to find the center frequency of the probe. This frequency defines both the derating factor with depth, and the acoustic wavelength which in turn determines an appropriate step-size for raster and cross-axis scans. The center frequency is also used to apply the appropriate hydrophone calibration coefficient to determine pressure from the voltage value. Deconvolution is also permitted to account for non-uniform sensitivity over a range of frequencies. Cross-checking measurements with a second hydrophone serve as a rapid means of confirming measured data.

Calculations and Reporting

Calculate and report the following for a 510(k) FDA submission:

- MI
- TI
- $I_{spta.3}$
- Effects of uncertainty
- Sampling statistics

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.20	3.03E-02		3.03E-02		6.86E-03
Index component value			3.03E-02	3.03E-02	3.03E-02	3.03E-02	
Acoustic Parameters	$P_{r,\alpha}$ at z_{MI} (MPa)	0.30					
	P (mW)		2.93		2.93		2.93
	$P_{1 \times 1}$ (mW)		2.93		2.93		
	z_s (cm)			N/A			
	z_b (cm)					N/A	
	z_{MI} (cm)	0.70					
	$z_{pii,\alpha}$ (cm)	0.70					
	f_{awf} (MHz)	2.17	2.17		2.17		2.17
Other Information	prf (Hz)	2160.0					
	srf (Hz)	45.0					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	2.6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	0.75					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	0.83					
	p_r at z_{pii} (MPa)	0.31					
Operating control conditions	2.25MHz-3.0mm-1 element Ping, 1.5 cycle WF						

Sample of Report Table

Uncertainty

Understanding measurement uncertainty is critical to ensuring the accuracy and validity of acoustic output assessments. In the context of ultrasound testing, uncertainties are typically divided into two categories: Type A and Type B. These represent different sources of variation and are treated separately before being combined to estimate overall uncertainty.

It is assumed that the sources of uncertainty are uncorrelated so that they can be combined using the root-sum-of-squares method. The FDA bases its output display limits on calculations using only Type A uncertainty, under the assumption that Type B uncertainty remains below 15% for pressure and 30% for intensity. IEC 60601-2-37, on the other hand, incorporates both Type A and Type B uncertainty into its final reported values.

Type A (Random Uncertainty): This category includes uncertainties that arise from random fluctuations in repeated measurements, such as variability between probe samples or experimental runs. These variations are typically modeled using a normal (Gaussian) distribution and are quantified statistically from repeated observations.

Type B (Systematic Uncertainty): Type B uncertainties stem from systematic sources, such as calibration errors, instrument drift, or environmental influences. These sources are not evaluated through repeated measurements but are instead estimated based on equipment

specifications, prior data, or expert judgment. Type B uncertainties are usually modeled with a rectangular (uniform) distribution and adjusted accordingly when combined with normally distributed Type A values.

- Examples
 - Hydrophone calibration
 - Oscilloscope
 - Temperature adjustment
 - Spatial averaging
 - Effects of non-linearity
 - Motor position accuracy

Quantity (x)	K	\bar{x}	σ_x	L_1 upper bound	γ_x	L_2 upper bound
MI	4.26	1.34	8.36E-02	1.70	0.11	1.80
$I_{spta,\alpha}$ (mW/cm ²)	4.26	157.27	29.43	282.58	33.17	298.51
TIS	4.26	0.91	0.11	1.40	0.15	1.54
TIB	4.26	0.91	0.11	1.40	0.15	1.54
TIC	4.26	2.16	0.28	3.37	0.36	3.67

Statistical output example table for n=3

Output Display Standard (ODS)

The ODS requires that for any diagnostic ultrasound system that can exceed an MI or TI of 1.0 they must display these values whenever they exceed 0.4. The display of these values informs the sonographer of the acoustic output power being used and facilitates the ALARA principle (As Low As Reasonably Achievable). For a general-purpose diagnostic ultrasound device, the measurements required to generate the data to fulfill the ODS typically involves several days/weeks of lab testing. Regulatory (e.g., 510(k) submission) reports require the worst-case settings only³. A large percentage of the lab test time is to determine the values displayed for all system settings. If you follow the ODS the FDA considers your device as a Track 3 submission, as explained on the following page.³

FDA Track 1 and Track 3

There are two paths that can be followed in submitting a 510(k) to the FDA for diagnostic ultrasound devices known as Track 1 and Track 3. For reference there was never a Track 2 path. The details in deciding from a technical and acoustic output power level standpoint which Track you should test to please see the FDA Guidance document ³. See Track 1 Recommendations on Page 24, section 5.2.7 and Track 3 Recommendations on Page 28, section 5.2.8 of said document.

Frequently Asked Questions on API Testing

What engineering operating mode needs to be provided to successfully perform acoustic testing of an ultrasound transducer and system?

The following are required to make testing more efficient and accurate:

- Means for obtaining a signal synchronous with the main transmit signal, including CW modes, if applicable
- Means that the unit operates in a stationary beam mode for all pulser firing conditions. If this is not possible, then a triggering signal, which can be used to isolate a unique firing direction, is required.
- Means of disabling any automatic freeze mode capabilities to ensure capabilities of continuous, unchanging, unattended operation or periods of at least 20 minutes
- Technical data to calculate output levels in scanning modes such as frame rate, lines per frame, line averages, scan dimension, sector angle and sector offset from center of rotation if applicable
- Technical data to calculate output levels in non-scanning modes such as pulse repetition frequency or duty cycle for long pulses

How to fill out the TPs and RMs form?

TP sheet:

ACERTARA acoustic laboratories		Acertara API Lab Testing Questionnaire 23004, Rev. E; Appendix A			Copyright 2021	
#	Mode description	Focal depth (mm)	Frequency (MHz)	Other identifier	Single transmit aperture area (mm ²)	Special instructions for selecting mode or other useful information
1	B-mode/M-mode	30	9.0		1.73	Each element of 3.46mm height and 0.5mm width, 1 element per transmit
2	Color-mode	20	5.0		6.92	4 elements per transmit

- Add each individual mode to each row and describe any special instructions for selecting the mode or any other useful information in the corresponding field of the TPs sheet. Adding dimensional information of the element(s) used in the transmit is useful for precise calculation of the convolution of the signal. Any variation in focal depth, frequency or aperture area must be added in a different row as a different transmit.

RM Sheet:

#	Reportable Mode Name	Constituent TP(s)	Scanning or non-scanning?	PRF (Hz)	Duty cycle for long pulses	Frame rate (Hz)	Lines per frame	Line averages	Scan dimension (mm)	Sector angle (°)	Sector offset from center of rotation (mm)	Resulting TP-specific PRF (Hz)
1	Peripheral Vessel (B-only)	1: B-mode/M-mode-D30-F9	Scanning			60	128	1	30			7680
2	Peripheral Vessel (B+C)	1: B-mode/M-mode-D30-F9, 2: Color-mode-D20-F5										
	Peripheral Vessel (B)	1: B-mode/M-mode-D30-F9	Scanning			45	128	1	30			5760
	Peripheral Vessel (C)	2: Color-mode-D20-F5	Non-scanning	2000								2000

- Add each reportable mode in the order and the name that is desired to appear as in the report.
- For combined modes, add the mode in a numbered row including all the constituent TPs. Overall properties of the combined mode are not necessary to be included. Individual TPs to be added subsequently without a numbered row and filling out the necessary properties of the firing sequence. Add all potential TPs in the Constituent field that can be used for that mode (e.g., add all B-mode TPs and we will choose the highest output option as the B-mode to report).
- Every TP listed on the TP sheet should be included in the RMs sheet.

How many samples should we test?

- The minimum number of samples is 3 to include the statistical table at the end of the report containing the L1 and L2 limits
- The k-factor used in the uncertainty calculation, coming from the variance in manufacturing of the device, depends on the number of samples utilized. The L1 limit is calculated as:

$$L_1 = \bar{x} + K \cdot \sigma_x$$

where \bar{x} is the average value, K is the k-factor and σ_x is the standard deviation of the measured value.

- If the variance of the power output of the device is large or unknown, it is recommended to include more samples. We typically observe an average standard deviation of 10% - 20% of the average output. For example, if the mean MI of a device is

1.0, the average deviation can be as high as 0.2. Thus, for $n=3$, that would make $L1 = 1.0 + 4.258 \cdot 0.20 = 1.85$

Table 1: K-factor for one-sided statistical bounds for 90% confidence that 90% of the population does not exceed L1

Number of Samples	K-factor
3	4.258
4	3.187
5	2.742

Conclusion:

This document provides a comprehensive overview of acoustic output measurement procedures for ultrasound systems and transducers, with a focus on compliance with recognized standards and regulatory expectations. Key concepts such as acoustic intensity, sensor types, calibration requirements, and uncertainty have been clearly defined to support consistent and accurate testing.

The measurement process outlined here—including sensor selection, data acquisition, and calculation methods—ensures reproducible results that align with international guidance and the FDA's Track 1 and Track 3 pathways. The document also addresses common questions related to engineering modes, test sample sizes, and reporting protocols to aid manufacturers in preparing compliant and technically sound submissions.

Ultimately, by following the methodologies and considerations described, users can reliably characterize the acoustic performance of their devices, meet safety and regulatory requirements, and support informed clinical use of ultrasound technology.

Useful References for the Adventurous Reader

- 1) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-clearance-diagnostic-ultrasound-systems-and-transducers>

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Acertara Acoustic Laboratories
1950 Lefthand Creek Lane
Longmont, CO 80501
www.acertaralabs.com