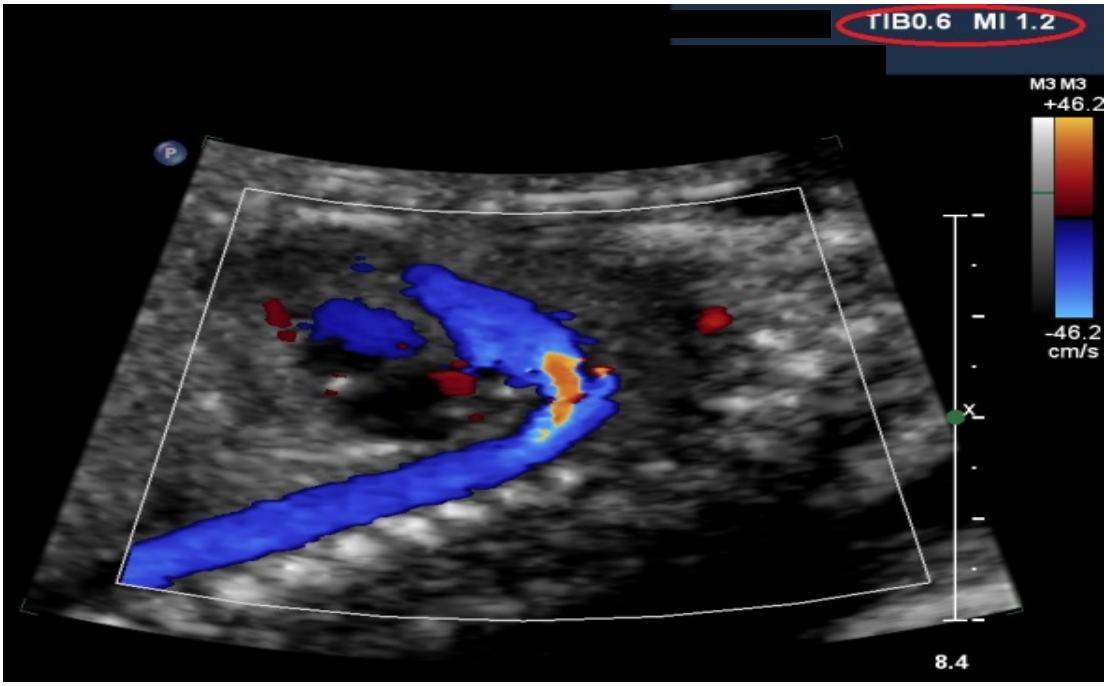
ACERTARA
acoustic laboratories

Ultrasound Output Display – What do the numbers mean?

G. Wayne Moore, B.Sc., MA, FASE

July 13, 2015

The ultrasound Output Display Standard* (ODS) has a specific technical definition but that definition is generally found standing in contextual isolation. Specifically, how do these dimensionless MI and TI numbers, displayed on the ultrasound system monitor (see photo below), relate to: (1) the laws of ultrasound physics, (2) FDA prescribed regulatory constraints placed on the limits of the transmitted acoustic energy, (3) the other user controls on the ultrasound system, and (4) the ALARA principle. Related to the potential for bio-effects occurring at certain levels of ultrasound acoustic intensity, the MI and TI indices displayed serve as a guide, and a reminder to the clinical end-user that although ultrasound is generally regarded as a safe imaging modality, one must always use the minimal amount of energy necessary to obtain a diagnostic quality image (including Doppler). MI, or mechanical index, relates to the potential of non-thermal effects from ultrasound occurring within tissue (e.g., cavitation). TI, or thermal index, relates to the potential for tissue temperature increases within the acoustic beam. There are three types of TI that may be displayed on the monitor, depending on the clinical application selected: (1) TIS, for soft tissues, (2) TIB, for bone tissue (shown in the photo below), and (3) TIC, for transcranial.



When designing an ultrasound system there is a classical macro-level engineering trade-off that must be dealt with and resolved; balancing image resolution and depth of penetration. Both of these parameters are related to the ultrasonic frequency being used and are in opposition. Specifically, the higher the frequency being used the better the resolution, but at the expense of the depth of penetration. That's the physics of it. Although a tad more complicated an easy math example will explain; ultrasound energy is lost in soft tissue at the rate of approximately 0.7dB/cm/MHz, where MHz is the ultrasonic frequency. So at 3MHz the attenuation would be 2.1dB/cm, while at 8MHz the attenuation would be at 5.6dB/cm. This relationship means that

***** The official title of the ODS is: "*Standard for Real-Time Display of Thermal and Mechanical Output Indices on Diagnostic Ultrasound Equipment*"

as the frequency (let's relate this to the probe frequency) is increased and image resolution improved, the depth of penetration will decrease, unless we increase the ultrasound system's output power, which the FDA says is a no-no beyond an estimated *in-situ* intensity of 720mW/cm^2. So ultrasound systems and their attendant probes are designed with the intended clinical application clearly in mind; striking the optimal balance between resolution and required depth of penetration within the FDA acoustic output power constraints. So within each clinical application there is a range of MI and TI numbers. The MI and TI "values" change as the clinical user changes various parameters of the image or modes of operation (e.g., B-mode, M-mode, spectral Doppler, or color flow Doppler), but especially the "power" knob. Enter the ALARA principle; As Low as Reasonably Achievable. Even though through regulation there is a maximum upper limit on acoustic output, user groups have developed the ALARA principle with the guiding premise that the clinical user should only use (that is, only expose the patient to) as much acoustic power required to obtain a diagnostically acceptable image; hence the range of MI and TI values adjustable by the acoustic output knob. Original Equipment Manufacturers (OEMs) are required by the FDA to submit testing results in the form of acoustic output power tables for each probe and mode of operation for which they seek 510(k) market clearance. This testing is an on-going requirement throughout the product life-cycle of any given probe on the cleared system to ensure that no significant changes have occurred in the manufacturing process, or if new acoustic materials

are being substituted**. This ensures that the output power of any given probe is still within the statistical range of the reported MI and TI values displayed on the monitor, and, therefore, still a valid indicator to the clinical user relative to how much power they are inputting into the patient.

Safe and efficacious are the by-words for an FDA cleared ultrasound system and probe sold in the United States. Unfortunately there are some probe "repair" companies in the United States that replace the acoustic stack of a probe with an array manufactured by someone other than the OEM without performing acoustic power testing. This practice has the potential for rendering the MI and TI values displayed as unreliable indicators for the clinical user, and may lead to higher than necessary acoustic exposure to the patient, and/or producing sub-diagnostic images. Replacing OEM arrays with un-tested and un-validated arrays manufactured by non-OEM companies also renders the probe as an "adulterated" product as defined by the FDA**. Before giving permission to any probe repair company to replace an acoustic array, the user should first demand to see the acoustic power testing results for that array, the name of the manufacturer of that array, and the comparison chart of the OEM array test results with those from the non-OEM array. To do less would be a disservice to the patient.

**Guidance for Industry and FDA Staff "*Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*" Document Issued on - 09/09/2008