Acoustic Measurement System (AMS) Software Description

The Acoustic Measurement System (AMS) Software is based on 20 years of experience in making ultrasound measurements and reporting medical ultrasound data to government regulatory bodies. Specifically, Dr. Mark Schafer, the software's primary author, submitted his first Food and Drug Administration 510(k) acoustic output report in 1984 as a consultant to Interspec, Inc, in collaboration with Dr. Peter Lewin. These early measurements were done before the 1985 FDA Guidance document which provided a uniform reporting format and measurement approach. In fact, several aspects of the 1985 Guidance document were based on parts of Dr. Schafer's original reports.

Dr. Schafer has been continuously involved in regulatory ultrasound measurements since that time. The software has been described in refereed publications[1] since 1988, and has evolved to meet the increasingly sophisticated demands of the medical ultrasound industry. Over the years, specialized versions have been developed for IEC 1157 requirements (now obsolete but still available) and lithotripsy measurements. The software has now evolved to meet the needs of IEC 60601-2-37[2] (NEMA UD-3[3], or FDA Track III), otherwise known as the Output Display Standard.

The software has the following measurement and analysis features:

- Measurement and reporting of all relevant in-water acoustic parameters, such as the rarefactional pressure (p_r), pulse-intensity integral (PII), time average (I_{spta}) and pulse average (I_{spta}) intensities, and total power*
- Measurement and reporting of the corresponding derated parameters
- Calculation of the Mechanical and Thermal Indices (featuring an interactive "TI Calculator" which permits analysis of different scanning conditions based on the beam characteristics)
- Measurement of ancillary reporting parameters such as center frequency, pulse duration and beam widths in two dimensions. Additional information includes the axial plot of intensity (in-water or derated) and MI, cross-axis beam plots, and raster (full two-dimensional) scans of the field.

To support these measurement capabilities, the software has the following key features:

- Automatic loading of hydrophone sensitivity and effective aperture as a function of frequency. The data is entered once by the user with an ancillary program. After the program determines the effective center frequency of the probe under test, the appropriate hydrophone sensitivity is interpolated from the hydrophone datafile. The effective hydrophone aperture is used to account for spatial averaging, using the method described by Preston, Bacon et al.[4]
- Automatic beam alignment procedures, which involve operator adjustment to attain alignment to any degree desired (as a fraction of a wavelength).
- Automatic oscilloscope gain adjustment to maximize waveform SNR.

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* NOTE: Peak Intensity (I_{sptp}), Peak Compressional pressure, and Maximum Intensity (I_m) were abandoned by the U.S. FDA (in 1985 and 1993, respectively) as being too unstable for regulatory use. Any software which still calculates these values has clearly not kept up with current regulations!

- Automatic setting of optimal spatial step size for maximum scanning speed with exceptional accuracy
- Automatic setting of spatial scanning ranges, based on probe characteristics; full accounting for non-linear beam characteristics[5]
- Automatic beam scanning for peak location (selectable peak search algorithms based on probe data)
- Optimized waveform settling routines, which compensate for any hydrophone vibration after positioning movements and waveform averaging routines

The system also includes advanced features which make it especially suitable to more complex system testing and internal validation requirements;

- The software uses a "probe definition file" which contains all the necessary probe information such as nominal frequencies, apertures, focal locations, scanning conditions, etc. This file is generated by a separate program that guides the user through the data input process. Once loaded, the system software can then cycle automatically through the various probe conditions to generate a complete measurement set.
- A "script file" can be used to automate a specific sequence of tests.
- If the system under test can be interfaced to the host computer, the AMS software can be set up to control the system and run through a programmable set up test conditions. This allows the system to automatically run through all the focal zones, pulse types, etc, of a given probe, allowing for unattended operation.
- All measurement and reporting features can be independently verified using external data files. The system has been designed to allow for the input of test files, such as waveforms and beam plots, to validate the results of the calculation package. This is important when any software changes are made by the customer, allowing for traceable verification of the software results.

The software has been designed to be adaptable to various hardware configurations:

- The software makes generic calls to both oscilloscopes and motor controllers. For each installation, a config file determines the underlying drivers necessary for the specific tank setup in use. In this way, customization efforts for each system are minimized.
- The system has been optimized for the Tektronics TDS30xx series of oscilloscopes. With this series, additional features such as high resolution time waveform acquisition, automatic time window adjustment, and high speed data transfer are possible. Other oscilloscopes, such as the Tektronics 24xx series and HP 54xxx* scopes have been used as well.
- Motor controllers have ranged from GPIB, RS-232, and PCI bus to Ethernet-based controllers, both commercial and "home grown". As long as access to the proper drivers is available, the software can be rapidly customized to the particular setup. Note that travel limit switches have not been implemented, because not all systems have them - the software has other approaches to the

*NOTE: Many HP scopes are not well suited to these measurements, because of their waveform settling methods and times.

travel limit issue. In addition, backlash correction is not implemented, because it has been found that no software package can fully overcome inadequate hardware design (separate mechanical upgrade packages are available for certain systems).

- NOTE: A "drop-in" software upgrade package for NTR AIMS scanning systems is available, overcoming a number of it's software limitations and errors.
- The Acoustic Measurement System Software is implemented in LabView™, the standard for laboratory instrumentation control and analysis. Source code can be provided, allowing users to further customize their installation to suit their local requirements.

Additional features, which are not required for regulatory submissions, are available on a custom basis. These include:

- Round Trip Insertion Loss (RTIL) measurements against a flat plate or ball target
- Spectral Characterization of Pulse-Echo data, including bandwidth and center frequency
- Support for automated Pulser-Receiver test equipment (e.g Panametrics 5800PR), to allow for fully automated RTIL testing.
- Raster scanning in the X-Z plane, rather than the X-Y plane
- Customized reporting formats, to meet internal company requirements.
- Network-enabled control and feedback (under development as a release feature)

As part of an integrated system approach, the software builds on Dr. Schafer's 20 years experience in "what works and what doesn't work." He has worked and lectured on ultrasonic measurements for over 15 years, and has consulted in this area extensively in the United States, Europe and Japan[6]. He is considered a leading international authority in ultrasonic dosimetry and regulation, and has chaired the NEMA Technical Committee for many years. The Acoustic Measurement System Software embodies this measurement experience, providing the most accurate, reliable and useable diagnostic ultrasound software package available.

REFERENCES

[1] M.E. Schafer and P.A. Lewin, "A Computerized System for Measuring the Acoustic Output from Diagnostic Ultrasound Equipment," IEEE Trans. Ultrason. Ferroelec. Freq. Control **UFFC-35**, 102-109, 1988.

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[5] S.S. Corbett III, "The Influence of Non-Linear Fields on Miniature Hydrophone Calibrations Using the Planar Scanning Technique," IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. UFFC-35(2), pp. 162-167, 1988.

[6] Short Course Presentation at 1997 and 1998 IEEE Ultrasonics Symposia "Ultrasound Measurements in the Laboratory: Practice and Pitfalls"; consulting contracts with leading manufacturers worldwide.