

**NEMA UD 2**

**ACOUSTIC OUTPUT  
MEASUREMENT  
STANDARD FOR  
DIAGNOSTIC  
ULTRASOUND  
EQUIPMENT,  
REVISION 3**



**NEMA Standards Publication UD 2-2004 (R2009)**

*Acoustic Output Measurement Standard  
For Diagnostic Ultrasound Equipment,  
Revision 3*

*Published by:*

**National Electrical Manufacturers Association**

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## **Foreword to *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3***

This is the initial revision of the 1998 *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*. The most noteworthy change in this document is the revision of Appendix A, Statistical Considerations. Included in this revised appendix are discussions of the one-sided tolerance limit for normal distributions, Type A and Type B uncertainty specifications, and multiple console/transducer combinations for a particular model, all topics that were not addressed in the previous version. In addition, minor notational and typographical corrections were made to the standard.

Special thanks for this revision go to the Output Standards Subcommittee (OSS), a joint AIUM/NEMA task group formed by the AIUM Technical Standards Committee. In particular, Marvin Ziskin is thanked for his spearheading the revision of Appendix A. The current co-chairs of the OSS are Paul Carson and Mark Schafer. The previous co-chairs were Gerald Harris and Charles Hottinger. Past and current subcommittee members, in addition to the past and current co-chairs, are John Abbott, Paul Biggins, Chris Bohl, Barbara Campbell, Anupam Dattamajumdar, David Dea, Richard Eaton, Peter Edmonds, Jim Gessert, Peng Jiang, Peter Lewin, Michael Macdonald, Ernest Madsen, Dennis Mendoza, Kathy Meschisen, Kurt Sandstrom, Paul Smolenski, Terry Sweeney, Jinxing Tan, Tat-Jin Teo, Kai Thomenius, Junru Wu, Jim Zagzebski, Qian Zhang, and Marvin Ziskin.

Karen Ophir  
Chair, AIUM Technical Standards Committee

## **Foreword to the *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*, May 1998**

In 1996, the decision was made to break the measurement and labeling parts of the *Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment* (AIUM, 1993) into two separate documents. The resulting measurements standard, the *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*, is now fully harmonized with and identical to its sister NEMA document, the *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (UD 2), Revision 2*. The new labeling document, the *Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment* (AIUM 1998), has been substantially changed, with the original labeling requirements being replaced by the labeling specified in the FDA's 510(k) Guideline (FDA 1997) and, optionally, the labeling specified in IEC 1157 (IEC 1992a). As of this writing, the International Electrotechnical Commission, Technical Committee 87, is developing additional standards for ultrasonic output measurement, calibration, and labeling. Their efforts have been helpful in the development of this document. Relevant IEC standards should be consulted for further technical information as they become available.

User needs have been considered throughout the development of this publication. Proposed or recommended revisions should be submitted to:

Chairman, AIUM Technical Standards Committee  
American Institute of Ultrasound in Medicine  
14750 Sweitzer Lane, suite 100  
Laurel MD 20707-5906

Revisions have been included which make the standard consistent with the NEMA UD-2 (as noted above) and *The AIUM/NEMA Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment*, (AIUM/NEMA, 1998).

A few improvements are reflected here which represent changes in all three of the documents. Members of the AIUM/NEMA Harmonization Task Group performing this revision were:

### AIUM

Paul L. Carson, Ph.D.  
John G. Abbott, Ph.D.  
Gerald R. Harris, Ph.D.  
Peter Lewin, Ph.D., Chairman

### NEMA

Charles Hottinger, Ph.D.  
Douglas Worth  
Kurt Sandstrom

The amended requirements supersede those of all previous revisions of the standard.

## **Foreword to the *Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment*, 1993, Revision 1**

In July 1993, the *Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment* was amended. The primary purposes of the amendments are to (1) introduce harmonized requirements into both the AIUM publication *Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment* and the National Electrical Manufacturers Association's (NEMA) *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment* (UD 2), so that they are technically equivalent with regard to measurement procedures; (2) introduce those improved measurement practices developed for the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (UD 3) (Output Display Standard) into this standard, so that it represents the latest thoughts on measurement practices; and (3) expand the coverage of the standard to the extent that generic measurement procedures necessary to support the Output Display Standard are included.

The amended requirements supersede those of the original edition.

The amendments were developed by a joint AIUM/NEMA Task Group, whose members were:

Peter Lewin, Ph.D., Chairperson  
Charles Grossman  
Charles Hottinger, Ph.D.  
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Marvin Ziskin, M.D.

The encouragement of the past chairperson of the AIUM Standards Committee, Peter Edmonds, Ph.D., is acknowledged.

## **Foreword to the Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment, 1992 Version**

This document has been prepared by a Task Force composed of members of the American Institute of Ultrasound in Medicine (AIUM) and members of the National Electronic Manufacturer's Association (NEMA). Initially the aim of this Task Force was to revise the 1981 document entitled, *The AIUM/NEMA Safety Standard for Diagnostic Ultrasound Equipment*. However, considerable progress has occurred in this field recently necessitating major rewriting to the point where the result is a truly new document. Furthermore, the discussion of safety considerations has been deleted because this is being pursued elsewhere by AIUM and the National Council on Radiation Protection and Measurements (NCRP).

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Appendices A, B, C, D, E, F, G, H, I, J, and K are for informational purposes only.

In this standard, the following print types are used:

- requirements and definitions: arial type
- NOTES: in 8 arial type
- terms used in this standard as defined in Section 1: **bold arial type**

## **Purpose**

The objective of this Standards Publication is to describe a set of measurement procedures for ultrasonic output parameters. This document implements this by setting forth precise definitions of quantities, primarily those relating to acoustic output levels, and specifying standard procedures for measuring the pertinent acoustic output parameters.

It is hoped that this standard will be found useful to individuals performing the indicated measurements.

## Scope

This standard covers all active ultrasound apparatus designed for medical diagnostic use, including ultrasonic echo ranging devices (both manual and automatically **scanned**), through-transmission devices, Doppler echo equipment, and combinations thereof.

This document establishes measurement standards for acoustic output quantities of ultrasonic diagnostic equipment.

Measurements of acoustic output quantities are to be performed in water. However, in order to provide values more typical of what might occur within tissue, derated values of output quantities will be required in addition to the in-water values. To provide an example, detailed derating procedures and requirements are discussed in this standard for a specific model; this is a 0.3 dB/cm-MHz uniform attenuation model, and will be notationally designated by the subscript “.3,” i.e.,  $I_{SPPA.3}$ .

It is anticipated that in the future, different **derating factors** will be necessary to better represent different applications. The standard provides for the implementation of different derating schemes by the manufacturer, provided that the implementation of that scheme is described.