

NEMA UD 3

**STANDARD FOR
REAL-TIME DISPLAY OF
THERMAL AND
MECHANICAL ACOUSTIC
OUTPUT INDICES ON
DIAGNOSTIC
ULTRASOUND
EQUIPMENT,
REVISION 2**

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Acoustic Output Indices on Diagnostic Ultrasound Equipment,
Revision 2*

Contains Errata

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ERRATA

NEMA UD 3-2004 *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment*, Revision 2, has the following errata.

Page 11, Subclause 4.1.3.1, second paragraph

Replace “,” with “.” after “for the real-time (B-mode) mode”.

Page 19, Equation 6.2.4.2-1. Replace with:

$$\text{spatial maximum } PII_{.3}(j, v_{mj}) = \max \text{ on } z \text{ of } \left(PII(j, v_{mj}, z) 10^{-0.03f_c(j)z} \right) \left(\frac{mJ}{cm^2} \right)$$

Page 19, Equation 6.2.4.2-2. Replace with:

$$\text{spatial maximum } PII_{.3}(j, v_{mj}) = PII(j, v_{mj}, z_{mjPII.3}) 10^{-0.03f_c(j)z_{mjPII.3}} \left(\frac{mJ}{cm^2} \right)$$

Page 21, Equation 6.2.5.2-2. Replace with:

$$\text{spatial maximum } PII_{B.3}(j, v_{mj}) = PII(j, v_{mj}, z_{mjPII B.3}) 10^{-2(0.03f_c(j)z_{mjPII B.3})} \left(\frac{mJ}{cm^2} \right)$$

Page 21, Equation 6.2.5.4-2. Replace with:

$$I_{SPTA B.3}(j, v_a) = I_{TA}(j, v_a, z_{mjPII B.3}) 10^{-2(0.03f_c(j)z_{mjPII B.3})} \left(\frac{mW}{cm^2} \right)$$

Page 22, Equation 6.2.5.5-2. Replace with:

$$TIB(j, v_a) = \min \left(\frac{\sqrt{W(j, v_a) I_{TA}(j, v_a, z_{mjPII B.3})}}{50} 10^{-0.03f_c(j)z_{mjPII B.3}} ; \frac{W_{.3}(j, v_a, z_{mjPII B.3})}{4.4} \right)$$

Page 22, Equation 6.2.6.2-1

Replace with:

$$A_{\text{aprt}}(j) \leq 1 \text{ cm}^2$$

Page 23, Subclause 6.2.6.20

Replace “ $A_{\text{aprt}}(j)=1\text{cm}^2$ ” with “ $A_{\text{aprt}}(j)\leq 1\text{cm}^2$ ”.

Page 23, Equation 6.2.6.20-1

Replace with:

$$A_{\text{aprt}}(j) \leq 1 \text{ cm}^2$$

Page 31, Equation A3.1-1. Replace with:

$$W_{.3}(z) = W_0 10^{-0.03f_c z}$$

Page 37, Equation A5.1.3-1

Replace " $(A_{prt} = 1 \text{ cm}^2)$ " with " $(A_{prt} \leq 1 \text{ cm}^2)$ ".

Page 39, Clause A7.1: Replace first two sentences of paragraph three with:

"To facilitate ALARA, display increments shall be in increments of no more than 0.2 for values of indices of 2.0 or less, and no more than 0.5 for values greater than 2.0."

Appendix A. Replace "Chart A-1" with "Table A-1" in the following places:

- Page 33, line 6
- Page 34, line 11
- Page 37, line 5
- Page 38, line 3
- Page 39, line 2

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Preface to Revision Two

This is the second significant revision of the 1992 *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment*, also known as the Output Display Standard, or ODS. The most noteworthy changes in this revision are contained in Sections 4.1.2.7, 4.2.1.1, 4.2.1.2, and 6.4. Under these new provisions, the equipment will display the best estimate of the mean index values, and a description of the display uncertainty will be included in the operator's instruction manual. Other changes were made to make the document compatible with the IEC 60601-2-37 standard, *Medical electrical equipment – Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment* (2001).

Special thanks for this revision go to the Output Standards Subcommittee, a joint AIUM/NEMA task group formed by the AIUM Technical Standards Committee. The current co-chairs are Paul Carson and Mark Schafer. The previous co-chairs were Gerald Harris and Charles Hottinger. Past and current subcommittee members 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

Preface to Revision One

This is the first significant revision of the 1992 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, also known as the Output Display Standard, or ODS. The 1996 "Second Printing" of the ODS included typographical and editorial corrections.

The most significant change in this revision is in Section 4.1.1. Here, the display resolution for the Mechanical Index has been changed to increments of no more than 0.2 over the entire range of display. Other changes were made to make the document compatible with the revised *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*, designated AIUM AOMS-1998 and NEMA Standard UD 2-1998.

Special thanks for this revision go to the Output Standards Subcommittee, a joint AIUM/NEMA task group formed by the AIUM Technical Standards Committee. The current co-chairs are Gerald Harris and Charles Hottinger. The previous chair was Peter Lewin, and subcommittee members are John Abbott, Paul Carson, Peter Edmonds, Charles Grossman, Peter Lewin, Michael MacDonald, Ernest Madsen, Kurt Sandstrom, Mark Schafer, Kai Thomenius, Doug Worth, Junru Wu, James Zagzebski, and Marvin Ziskin.

Peter Lewin
Chair, AIUM Technical Standards Committee

Foreword

Since June 1976, the American Institute of Ultrasound in Medicine (AIUM) and the National Electrical Manufacturers Association (NEMA) have worked cooperatively on regulatory issues of mutual interest. One category of cooperative activities has included the development of the voluntary standards, including *Safety Standard for Diagnostic Ultrasound Equipment*, *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*, and *Standard Methods for Measuring Performance of Pulse-Echo Ultrasound Imaging Equipment*.

The *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* continues this productive cooperation. But more importantly, this standard came about from the broad-based efforts of professional societies, manufacturers' organizations, manufacturers, governments, and consumer groups. User input has been considered in the development of this standards publication. The organizations involved in the standard's development are listed as follows, and all had a vital role in its development:

PROFESSIONAL ORGANIZATIONS

American Academy of Neurology
American Academy of Ophthalmology
American Association of Physicists in Medicine
American College of Cardiology
American College of Obstetricians & Gynecologists
American Medical Association
American College of Osteopathic Obstetrics & Gynecology
American College of Radiology
American Institute of Ultrasound in Medicine
American Registry of Diagnostic Medical Sonographers
American Society of Echocardiography
International Perinatal Doppler Society
National Council on Radiation Protection and Measurements
Society of Diagnostic Medical Sonographers
Society of Pediatric Echocardiography
Society of Perinatal Obstetricians
Society of Radiologists in Ultrasound
Society of Vascular Surgeons
Society of Vascular Technologists
World Federation for Ultrasound in Medicine & Biology

MANUFACTURERS' ORGANIZATIONS

Electronic Industries Association Japan
National Electrical Manufacturers Association

MANUFACTURERS' GROUPS

Acoustic Imaging Corporation
Acuson
Advanced Technology Laboratories, Inc.
Diasonics, Inc.
Elscint, Ltd.
General Electric Medical Systems
Hewlett Packard Company
Hitachi Medical Systems America, Inc.
Interspec Incorporated
Medasonics, Inc.
Philips Ultrasound
Siemens Quantum, Inc.
Sonic Technologies
Toshiba America Medical Systems
Yokogawa Medical Systems

GOVERNMENTS

Bureau of Radiation and Medical Devices
Health and Welfare, Canada

Center for Devices and Radiological Health
Food and Drug Administration, USA

CONSUMER GROUPS

International Childbirth Education Association
National Women's Health Network

Scope

This voluntary standard applies to diagnostic ultrasound **equipment** that is intended for use on humans, and is capable of exceeding a **thermal index** of 1.0, or a **mechanical index** of 1.0.