



BUILDING HEALTHY COMMUNITIES FOR EVERYONE

**2011 DISABILITY and
HEALTH PARTNERS MEETING**

June 14 – 16, 2011





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Medical Diagnostic Equipment Accessibility

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Agenda

1. The Access Board
2. Accessibility
3. The Statute
4. Rulemaking Process
5. Selected comments from the public information meeting
6. HE75 Standard





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What is the Access Board?





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U.S. Access Board

- Independent Federal agency
- Promulgates guidelines and standards for accessible design
- Provides technical assistance and training
- The term “Access Board” is used to refer to the agency staff of the Board, as well as the official Board





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The Rulemaking Process

- Public Information Meeting (July 2010)
- Notice of Proposed Rulemaking (anticipated summer 2011)
- Public Hearing (during comment period)
- (Review public comments, regulatory assessment, OMB review)
- Final Rule (deadline: March 22, 2012)





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What is Accessibility?





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Accessible Design

- Design criteria which removes barriers that make it difficult or impossible for some people with disabilities to use MDE
- Rooted in civil rights with intention to provide an assurance of technological non-discrimination





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Disability Basics

- People with disabilities account for 20% of the U.S. population
- Many people will develop a temporary disability
- Accessibility helps improve usability for all





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The Statute





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Section 510

- Section 4203 of Patient Protection and Affordable Care Act
 - (Public Law 111-148, 124 Stat. L. 119)
- Added Section 510 to the Rehabilitation Act of 1973 on March 23, 2010
- Title: “ESTABLISHMENT OF STANDARDS FOR ACCESSIBLE MEDICAL DIAGNOSTIC EQUIPMENT”





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The Law (1)

Standards - ... [Access Board **in consultation with ... FDA**] ... setting forth minimum technical criteria for medical diagnostic equipment used in (or in conjunction with) physician's offices, clinics, emergency rooms, hospitals, and other **medical settings**. The standards shall ensure that such equipment is accessible to, and usable by, individuals with accessibility needs, and shall allow **independent entry to, use of, and exit from** the equipment by such individuals to the maximum extent possible.





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The Law (2)

- **Medical Diagnostic Equipment Covered - ...** shall apply to equipment that **includes** examination tables, examination chairs (... eye ... dental examinations or procedures), weight scales, mammography equipment, x-ray machines, and other radiological equipment commonly **used for diagnostic purposes by health professionals. ...”**





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Review of Parameters

Patient Access to Medical Diagnostic Equipment:

- by healthcare professionals (Who)
- in medical settings (Where)
- for diagnostic purposes (Why)





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From the Public Information Meeting (July 2010)

Barriers and Solutions





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Featured 6 Panels:

- Consumer perspective
- Legal
- Healthcare providers
- Standards
- Industry
- Research





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Chicago Site Visit with Presentations from staff of:

- Schwab Rehabilitation Hospital
- Rehabilitation Institute of Chicago
- Northwestern Memorial Hospital
- Rush University Medical Center
- Access Living (Independent Living Center)





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Key to Successful Integration of Accessible Medical Equipment

- Providers need training in the use of accessible medical equipment
- Vendors need to develop training modules to accompany their products
- Awareness of operational differences in medical offices and acute care hospitals





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Accessibility and Usability of Medical Equipment for People with Disabilities: A National Survey



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Survey Results: The Big 4

• Type of Equipment

• ≥ Moderate Difficulty

- | | |
|--------------------------------|-------|
| • Examination tables (n = 291) | 74.9% |
| • X-ray equipment (n = 258) | 68.2% |
| • Rehab/exercise eq. (n = 203) | 55.1% |
| • Weight scales (n = 222) | 53.6% |





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Examination Tables

- Height: too high
- Width: too narrow
- Comfort: hard surface, nothing to lean on
- Getting on: nothing to hold on to





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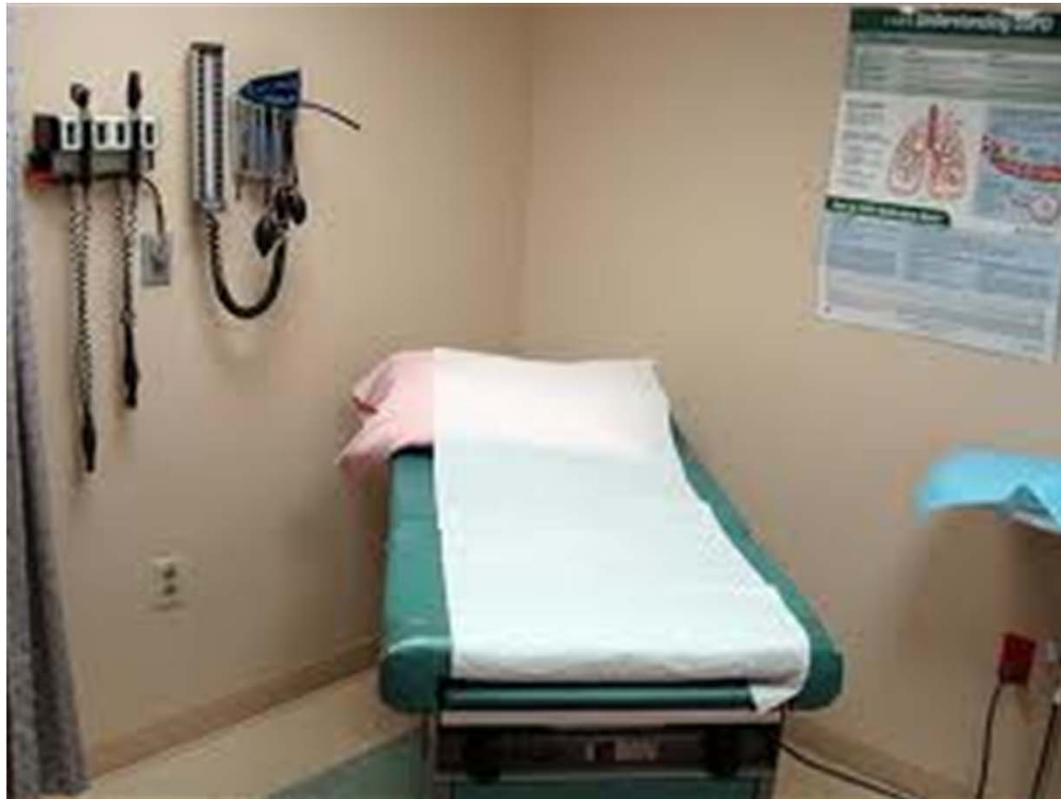
See the Difference





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Scoping: How many and where





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Paper Cover

- Paper on table is slippery
- However, people who are deaf like the paper for communicating by writing





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Stirrups



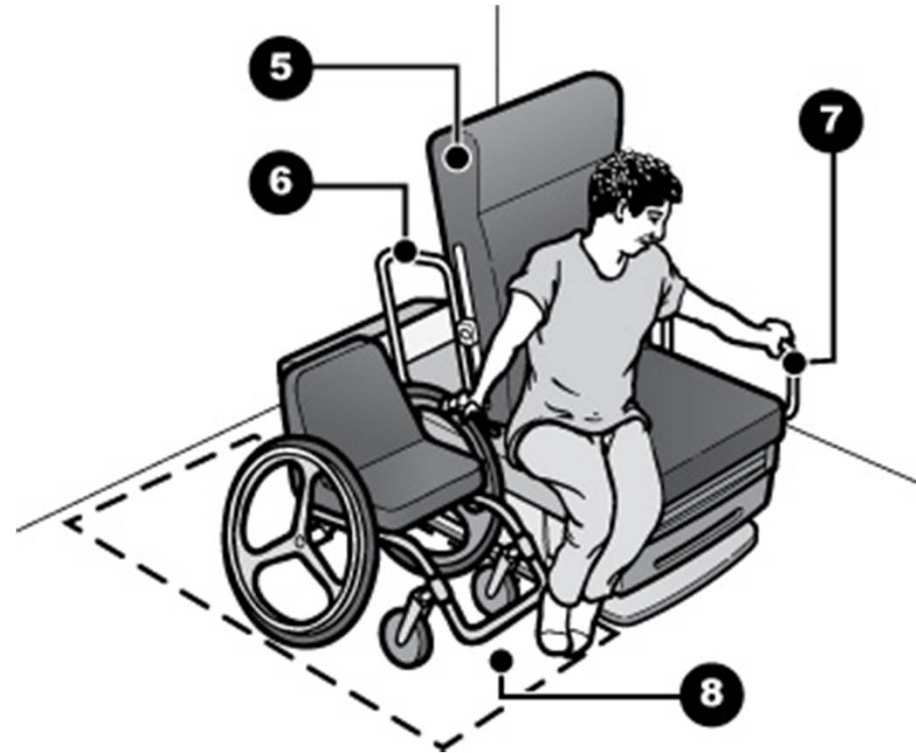
- Support leg
- Articulating
- Lock in position
- Velcro to help hold in place





Exam Chair Accessible Transfer

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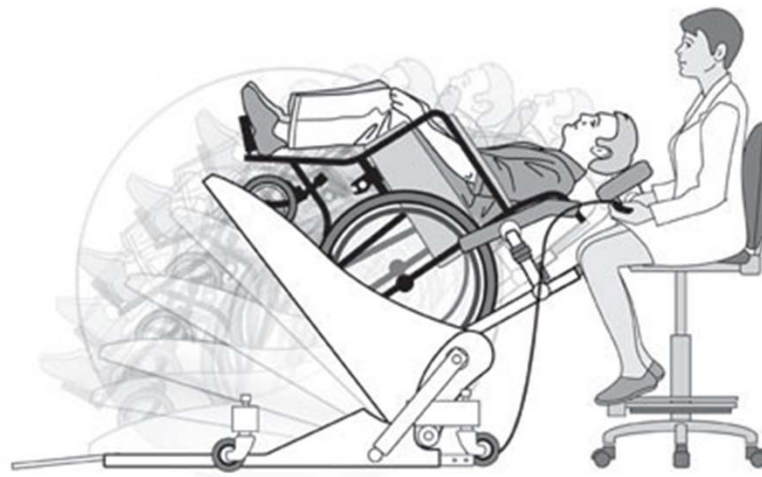
Floor Glide Moves Chair Out of the Way





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Dental – Back-tilt System





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Ophthalmology Equipment on Adjustable Height Table





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Accessible Scales

Stand or Wheel onto it



Sit on it or Stand





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Imaging Equipment

- **General x-ray**
- **MRI**
- **Mammogram**
- **CT**
- **PET**
- **Bone density**





Compatibility with Ceiling Lift

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Mammography Machine





Pedestals can be a Problem

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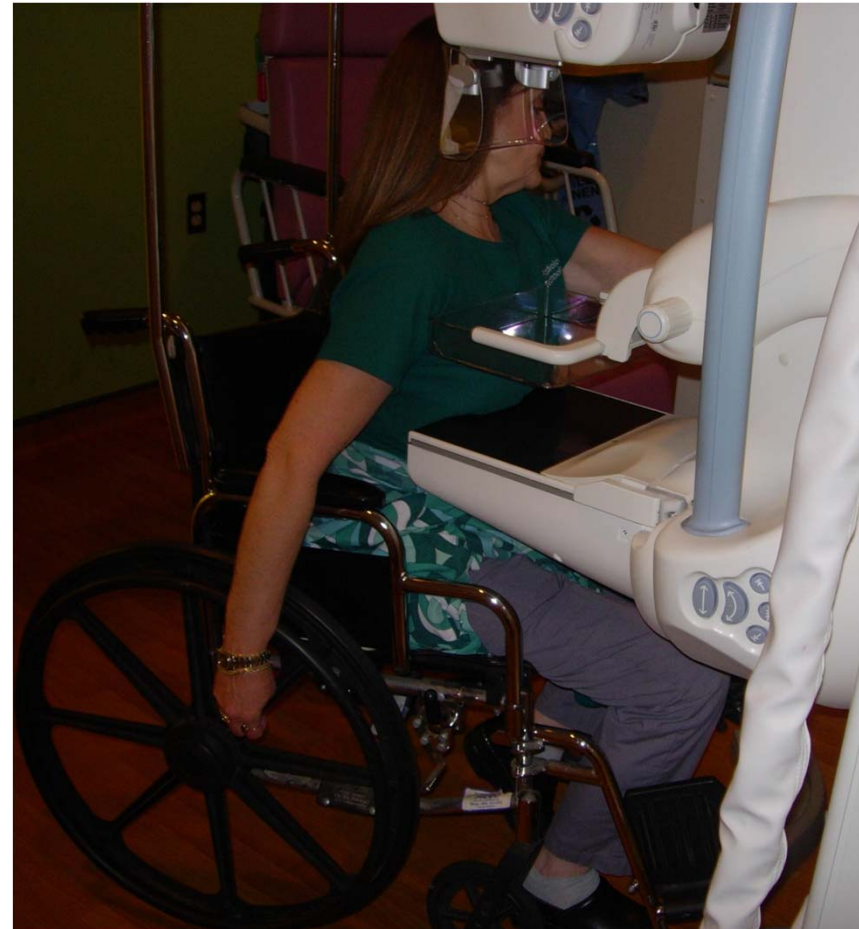




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Considerations: Imaging Equipment

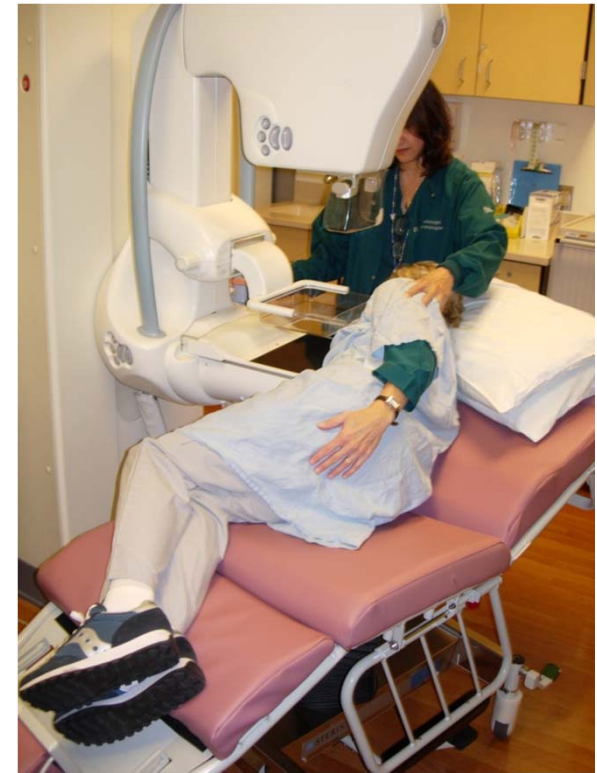
- Mammography Units
 - Requires dedicated mammography unit with gantry which lowers to permit imaging of the patient in a sitting position. Currently FDA approved units now meet this requirement. Some older units may not meet this criteria.





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Positioning with Hausted Mammography Chair





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Stereotactic Biopsy: Use of a Stryker cart to transfer

1



3



2



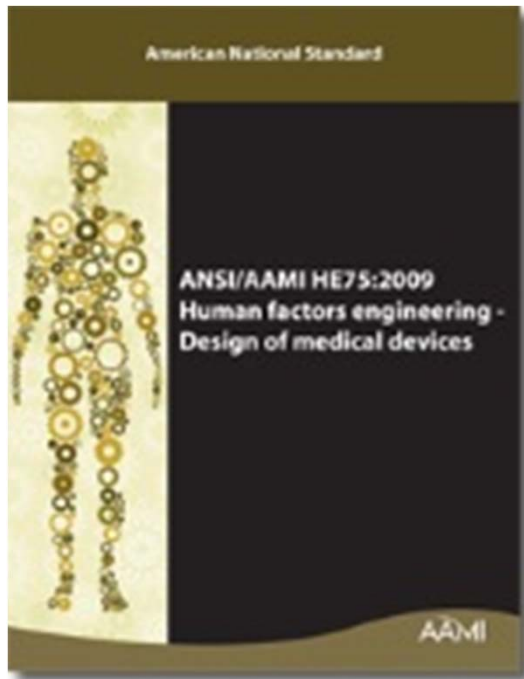
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HE 75



- ANSI/AAMI HE75-2009 Human Factors Engineering – Design of Medical Devices
- Chapter 16 posted on AAMI website for complimentary download





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**Selected Overview of HE 75
(445 Pages; Key Relevant Sections):**

Introduction; (1-3) ... 3: Definitions

General Considerations and Principles (4-16)

4: General Principles

5: Managing the Risk of Use Error

6: Basic Human Skills and Abilities

7: Anthropometry & Biomechanics

8: Environmental Considerations

9: Usability Testing ...

16: Accessibility Considerations (pp. 230-243)

Design Elements (18-21) 18: Controls; 19: Visual Displays ...

Integrated Solutions (22-25) ... **25: Home Health Care**





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Research-based design guidelines for patient support surfaces (HE75 16.4)

- Width of device base
- Clearance for lift equipment
- Adjustability of surface height
- Transfer path
- Hand-holds
- Contact surfaces
- Controls





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Possible Uses of HE 75 Sec 16 Guidance

- Two Classic Approaches:
 - Design Production Requirements
 - Requirements on Products
 - Ex: Sec 255 of Telecom Act
 - Ex: FDA Device Evaluation Process
 - Purchasing/Procurement Requirements
 - Equitable Access to Services by Entities
 - Ex: Sec 508 (Federal facilities/services)
 - Ex: “Accessible” fraction [parking spaces, hotel rooms]
 - Critical need: Specifications for certification
 - Possible bodies: Joint Commission; CARF





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Coordinated Effort

From “*Safe and Effective Access to Medical Devices for All Americans*”: The challenge of maximizing safe access to medical products by all patients and practitioners who qualify for use requires an evolutionary process on 3 levels:

- a) good science aimed at understanding how human-technology interfaces affect performance and safe use for a diversity of both devices and people;
- b) generation of design guidelines that can help train current and future product designers and engineers in integrating risk analysis with accessible design considerations, and can lead to advances such as certification programs;
- c) a vision of social policy change that makes access to medical technology a priority.





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Advocacy

- **Survey of 379 Massachusetts health care providers found they made access changes based on:**
 - 60% ADA compliance
 - 49% State requirements
 - 25% JCAHO and other certifying agencies
 - **33% PATIENT RECOMMENDATIONS FOR IMPROVEMENT**





Benefits of Accessible Design

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- Improve “bottom line” via expanded customer base
- Congruency with non-discrimination policies in existence
- Risk management
- Strategic planning to prepare for potential regulations





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THE GOAL

EQUAL access to and inclusion of *all people* regardless of type or level of disabilities!

- Prevention
- **Diagnoses**
- Monitoring and treatment





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How to Reach the U.S. Access Board

- **Telephone (voice):**
 - **202-272-0013** (direct to David Baquis)
 - **800-872-2253** (toll-free in U.S.)
- **E-mail: baquis@access-board.gov**
- **Internet: <http://www.access-board.gov>**





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Other Resources

- <http://thebarrierfreehealthcareinitiative.org/>
- [It Takes More than Ramps to Solve the Healthcare Crisis for People with Disabilities](#) (2004)
J. Panko Reis, M.L. Breslin, L. I. Iezzoni, K. Kirscher
- The **Alliance for Disability in Health Care Education**, an organization of health care educators and administrators at American medical schools and nursing schools who are working to promote the inclusion of disability-related content in health care curricula. <http://www.disabilityhealth.org/>





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“Access to Medical Care for Persons with Mobility Disabilities”

- Joint DOJ (www.ada.gov) & HHS (www.hhs.gov/ocr) technical assistance document, targeting providers (related to ADA, Section 504)
- p. 8-19 on *Part 4: Accessible Medical Equipment*
 - *Fully consistent with Section HE75 16.4. Complementary!*





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Questions

