Accessible Medical Diagnostic Equipment & Prescription Drug Container Labels

Pacific ADA Center webinar

3/26/2020

Agenda

• Medical Diagnostic Equipment
  • Background
  • Ch 1: Application
  • Ch 2: Scoping
  • Ch 3: Technical requirements
• Prescription drug containers
Medical Diagnostic Equipment

Background
Existing Standards

- ADA and ABA Accessibility Guidelines
- ANSI/AAMI HE75 – 2009 Human Factors Engineering – Design of Medical Devices
- RERC on Accessible Medical Instrumentation
- Research Data

Accessibility challenge

Accessible Medical Instrumentation RERC usability survey

- Survey reported usability of various medical diagnostic equipment
- Significant percent of respondents reported equipment was moderately difficult to impossible to use

Reports of:
Moderately difficult/impossible to use

- Examination tables – 75%
- X-ray equipment – 68%
- Weight scales – 53%
- Examination chairs – 50%
Rehabilitation Act §510

- Mandates the Access Board to issue minimum technical criteria for accessible medical diagnostic equipment in consultation with FDA

Affordable Care Act amends the Rehabilitation Act to address access to MDE (March 23, 2010)

Rehabilitation Act §510

- Specifically addresses equipment in:
  - Physicians offices, clinics, emergency rooms, hospitals, other medical settings. Includes optometrists and dentists
  - Scoping to be determined in appropriate regulatory or administrative context
  - Final Standards are voluntary until adopted by an enforcing Agency e.g., DOJ for the Americans with Disabilities Act
  - Could be used by FDA to verify labelling claims
  - Can be voluntarily adopted through policy
Federal Partners

• Health and Human Services
  • US Food and Drug Administration
• Department of Justice
  • Disability Rights Section
• Department of Veterans Affairs

Standards for Accessible Medical Diagnostic Equipment

Published in:
• Code of Federal Regulations, Title 36, §1195.1 Standards, Appendix to Part 1195
• Found on our website
  • www.access-board.gov

Chapter 1: Application and Administration
  M101 General
  M102 Definitions

Chapter 2: Scoping
  M201 General

Chapter 3: Technical Requirements
  M301 Diagnostic Equipment Used by Patients in Supine, Prone, or Side-Lying Position
  M302 Diagnostic Equipment Used by Patients in Seated Position
  M303 Diagnostic Equipment Used by Patients Seated in a Wheelchair
  M304 Diagnostic Equipment Used by Patients in Standing Position
  M305 Supports
  M306 Communication
  M307 Operable Parts
MDE Standards

- Do not address the accessibility of existing diagnostic equipment
- Do not require a percentage of new or replacement equipment to be accessible

Chapter 1: Application and Administration
Application

Purpose:

To ensure accessibility to, and usability of the diagnostic equipment by patients with disabilities.

- Provide for independent access and use of diagnostic equipment to the maximum extent possible
- Applies to new diagnostic equipment, based on the patient positions that the equipment supports, during patient transfer and diagnostic use
- Communication features or operable parts – where provided for patient use

“Diagnostic equipment” Includes:

- Examination tables
- Examination chairs (including those used for dental or optical exams)
- Weight scales
- Radiological equipment
  - X-ray machines
  - MRI, CT Scan
  - Mammography equipment
- Other MDE
“Diagnostic equipment”
Does not include:

- Personal devices
  - Blood glucose monitors
- Positioning aids
  - Wedges
- Surgical and medical instruments
  - Stethoscopes
  - Forceps, scalpels

Equivalent facilitation

- MDE language is different than 2010 ADA

The use of alternative designs or technologies that result in substantially equivalent or greater accessibility and usability than specified in the MDE Standards is permitted.
Measurements and Dimensions

- Based on Adult Dimensions and Anthropometrics
- Use of MDE by children is not addressed in these standards
- Dimensions not stated as maximum or minimum are absolute
- Subject to conventional industry tolerances
- Measured in US or metric units, independently

Definitions

Undefined terms:
- Not defined in M102.1 or in regulations or policies issued by an enforcing authority:
- Ordinarily accepted meaning in the sense that the context implies.

Defined in section M102.1:
- End Transfer Surface
- Enforcing Authority
- Examination Chair
- Imaging Bed
- Imaging Equipment with Bores
- Medical Diagnostic Equipment (Diagnostic Equipment)
- Operable Parts
- Side Transfer Surface
- Transfer Surface

Defined in regulations or policies issued by enforcing authority
Chapter 2: Scoping

M201 General

- Scoping to be determined by enforcing authority
  - Potential enforcing authorities could include DOJ, HHS, or adoption through policy (like select VAs)

- General exception:
  - “rare circumstances where compliance would alter diagnostically required structural or operational characteristics of the equipment and would prevent the use of the equipment for its intended diagnostic purpose”
  - Diagnostic equipment shall comply to the maximum extent practicable
Chapter 3: Technical Requirements

• Supine, prone, or side-lying positions (M301)
• Seated position (M302)
• Seated in a wheelchair (M303)
• Standing position (M304)
• Supports (M305)
• Communication (M306)
• Operable parts (M307)
Chapter 3

• **Supine, prone, or side-lying positions (M301)**
  • Seated position (M302)
  • Seated in a wheelchair (M303)
  • Standing position (M304)
  • Supports (M305)
  • Communication (M306)
  • Operable parts (M307)

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Supine, Prone, or Side-Lying Position (M301)

Includes:

- MRI, CT scan
- Examination tables
- Hospital stretcher

Does not include:

- Examination chairs that recline (covered in M302)
Supine, Prone, or Side-Lying Position (M301)

Transfer surface
- Height adjustable
- Size
  - End transfer surface
  - Side transfer surface
  - Unobstructed transfer

Supports
- Transfer supports
- Leg supports, where provided
- Head and back support

Lift compatibility
- Clearance in base
- Clearance around base
- Exception: overhead lifts

Transfer surface

Height adjustable
- Measured from floor to top of uncompressed transfer surface
- High transfer position at 25 inches minimum
- Low transfer position of (17-19 inches) maximum
- At least 4 additional transfer positions located between the low and high, separated by 1 inch minimum
Transfer surface

Low position sunset clause

• Low transfer position height (17” – 19”) expires in 5 years (January 9, 2022)
• Research to be done on transfer heights

Transfer surface

End Transfer Surface

• Located at one end of an examination surface that allows transfer at the end and one adjoining side

Side Transfer Surface

• Located within the length of the examination surface that allows transfer on two opposing sides
Transfer surface

Size
• Comply with either:
  • End Transfer
    • 17” x 28” min
  • Side Transfer
    • 28” x 28” min
• Measured from center points of their opposing sides

Transfer surface

Size: Exception
• Imaging equipment with bores
  • Width: 21” min
• Not less than the full width of the examination surface provided
Transfer surface

Unobstructed transfer
• Each transfer surface shall provide two unobstructed sides for patient transfer
  • Side transfer = L side + R side
  • End transfer = end + (L/R) side

Permitted obstructions
• Obstructions less than 3” deep
• Extend beyond transfer sides of transfer surfaces
• Do not protrude above the tops of transfer surfaces
• Temporary obstructions provided they can be repositioned during transfer
Supports

- **Transfer support**
  - Required at transfer surfaces
  - (covered in M305.2)
- **Leg supports**
  - Where stirrups are provided, leg supports shall also be provided
  - (covered in M305.4)
- **Head and back support**
  - Where diagnostic equipment is used in a reclined position
  - (covered in M305.5)

Transfer supports

**Location**

- **End Transfer:**
  - Short side of transfer surface, opposite transfer side
- **Side Transfer:**
  - Opposite sides of transfer surface, removable supports
- **Gap**
  - 1 ½” maximum gap
  - Measured horizontally from nearest edge
Transfer supports

Length
• End Transfer:
  • Short side of transfer surface, opposite transfer side
  • 15” minimum
  • At least 13 ½” along depth of the transfer surface
• Side Transfer:
  • Opposite sides of transfer surface, removable supports
  • 28” minimum

Transfer supports

Height
• During use, tops of Gripping surfaces must be between 6” minimum and 19” maximum
• Supports do not need to be horizontal

Horizontal supports not required – gripping surface must be within min and max height
Transfer supports

Location: Exception
• Where the support folds, collapses, or articulates, the transfer support shall be permitted to be located 3” maximum from the edge of the transfer surface

Transfer supports

Length: Exception
• Where side transfer surfaces are part of an articulating surface, the support is permitted to be 15” long min.
Transfer supports

Exception: Wide Imaging Exam Surfaces

• Where width of imaging bed is greater than 24”
• Transfer supports can be 12” long min.
• During use, tops of gripping surfaces can be 3” min. and 6” max. higher than the top of the transfer surface.

Wide Imaging Exam Surfaces

Portable Lift Compatibility
**Lift compatibility**

**Clearance in Base**
- 6 inches high minimum
- 36 inches deep minimum
- Measured from edge of examination surface
- Or extend full depth if less than 36 inches deep
- 39 inches wide minimum
- Equipment permitted within 8 inches maximum of the centerline

**Clearance around Base**
- 6 inches high minimum
- 36 inches deep minimum
- Measured from edge of examination surface
- 26 inches wide minimum
- Permitted to increase at a rate of 1 inch in width for each 3 inches in depth
Lift compatibility

Exception: Overhead lifts
- Where fixed overhead patient lifts are provided and:
  - Use is permitted by enforcing authority
  - Equipment clearly labeled as not compatible with portable floor lifts

Chapter 3
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- Seated position (M302)
  - Seated in a wheelchair (M303)
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  - Supports (M305)
  - Communication (M306)
  - Operable parts (M307)
Seated Position (M302)

- Transfer surface
  - Height adjustable
  - Size
  - 2 adjoining sides
  - Unobstructed transfer

- Supports
  - Transfer supports
  - Leg supports, where provided
  - Head and back support

- Lift compatibility
  - Exception: overhead lifts
  - Clearance in base
  - Clearance around the base

Transfer surface

Height adjustable (same)
- Measured from floor to top of uncompressed transfer surface
- High transfer position at 25 inches minimum
- Low transfer position of (17-19 inches) maximum
- At least 4 additional transfer positions located between the low and high, separated by 1 inch minimum
Transfer Surface

Two Adjoining Sides

Exception: Chairs with Fixed Footrest

Transfer Surface

Minimum size

How to measure

M302.2.2 Size
Supports

• (same as M301)

• Transfer supports
  • Required at transfer surfaces
  • (covered in M305.2)

• Leg supports
  • Where stirrups are provided, leg supports shall also be provided
  • (covered in M305.4)

• Head and back support
  • Where diagnostic equipment is used in a reclined position
  • (covered in M305.5)

Lift compatibility

(same as M301)

• Clearance under base
• Clearance around the base
• Overhead lift exception
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Seated in a Wheelchair (M303)

• Wheelchair spaces
  • Orientation
  • Width
  • Depth
  • Front or rear entry
  • Pass-through entry
  • Side entry
  • Equipment clearance
    • Breast platforms
    • Other equipment
  • Surfaces
  • Edge protection
• Entry
  • Beveled
  • Ramped
• Components
  • Breast platform adjustability
Wheelchair spaces

Orientation

• Designed so that a patient seated in a wheelchair orients in the same direction that a patient not seated in a wheelchair orients when the MDE is in use.

Wheelchair spaces

Width:

• 36” wide minimum

Depth:

• Front or rear entry: 36” min
• Side entry: 60” min
• Pass-through: 40” min
  • (weight scales)
Wheelchair spaces

- Width and depth based on ADA maneuvering clearances where spaces are confined on 3 sides (ADA - 305.7)

Wheelchair spaces

- The MDE Standard does NOT address clear floor space for transfers
Wheelchair Weight Scales

- Width exception for Raised Platform (M303.2.2x)
- Pass-through entry wheelchair space (M303.2.3.2)
- May require edge protection (M303.2.6)
- Change in level at entry, may require bevels or ramps (M303.3)

Wheelchair Spaces on Weight Scales - M303

Pass through entry depth and width exception address
Ramps Entries

Combination of height and steep slope a barrier

Beveled change in level

Running slope Exception:
consentient with ADA Standards exception for rises of 3” or less in alterations, except max height is 2 ½”

Clearances beneath Components (M303)

Most MDE knee and toe clearance will be the same as ADA
Breast platforms

Height adjustable platform (M303.4.1)
- continuously adjustable
- low height of 26 inches
- high height of 42 inches

Clearances beneath Components (M303)
- Knee clearance 17” deep min to allow user to bring chest in contact with platform
- Knee and toe clearance allows additional obstruction under foot plates
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Standing Position (M304)

• Slip resistant standing surface
• Supports provided on two sides
• Exception: Equipment with pass-through entry/exit can provide one horizontal support
Standing Supports – M305.3

Horizontal Supports:
- On most equipment 4” min long
- 34” min. – 38” max.
- Above standing surface to top

Vertical Supports:
- 18” min. long
- 34” min. - 37” max.
- Above standing surface to lowest end of the gripping surface

Standing Supports (M305.3)

Horizontal Supports on weight scales with wheelchair spaces:
- One entry – gripping surface along 80% of platform length
- Pass- through:
  - Gripping surface equal to length of platform length
  - On one side only (M304.2.2 exception)
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Transfer and Standing Supports

Structural strength
• Not addressed like in ADA and ABA standards for grab bars
• More variables
• Industry standards address
Supports

Leg supports – must provide a method of supporting, positioning, and securing the patient’s legs

Head and back support – Where equipment is used in a reclined position, head and back support shall be provided. Where the incline of the back support can be modified while in use, it must be provided throughout the entire range of the incline.
Transfer supports

- Similar to ADA grab bars in section 609
- Free of sharp or abrasive components
- Eased edges
- Shall not rotate within their fittings

Circular Cross Section
Outside diameter 1 ¼” min and 2” max

Non-circular Cross Section
Cross-section 2” max
Perimeter 4” min to 4.8” max

Transfer supports

Gripping surfaces
- Continuous along their length and not obstructed on top or sides
- No more than 20% of the length of the bottom of gripping services can be obstructed
- 1 ½” minimum clearance
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  - Operable parts (M307)

**Communication (M306)**

- Information Communicated through the equipment
- Information provided in at least two methods:
  - audible
  - visible
  - tactile
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Operable Parts (M307)

Only controls operated by the patient

Features addressed:

- Tactilely Discernible
- Operation
- Operating Force
DOJ Guidance is Available

www.ada.gov

Final Standards

The final Standards for Accessible Medical Diagnostic Equipment can be found on www.access-board.gov under Healthcare, Medical Diagnostic Equipment
Guidance on Prescription Drug Container Labels

What Is a Prescription Drug Container Label

LEGAL DOCUMENT

UNIVERSAL STANDARD

U.S. PHARMACOPEIAL CONVENTION
Section 904 Of the Food and Drug Administration Safety and Innovation Act

§904. ACCESSIBILITY OF INFORMATION ON PRESCRIPTION DRUG CONTAINER LABELS BY VISUALLY-IMPAIRED AND BLIND CONSUMERS.

• Establishment of Working Group
• Develop “best practices” on access to information on prescription drug container labels for individuals who are blind or visually impaired.

Guidance on Prescription Drug Container Labels

(Advisory non-mandatory guidance)

Advisory guidance developed by a stakeholder working group provides best practices on providing access to prescription drug container labels for people who have vision impairments or who are elderly.
Section 904 of the Food and Drug Administration Safety and Innovation Act

The law directed the National Council on Disability (NCD) to conduct an informational and educational campaign in cooperation with the stakeholder working group to inform the public, including people with disabilities and pharmacists, of the best practices. [https://ncd.gov/publications/2016/best-practices-accessible-prescription-drug-labeling](https://ncd.gov/publications/2016/best-practices-accessible-prescription-drug-labeling)

The law also called upon the Comptroller General to conduct a review to assess the extent to which pharmacies are implementing the best practices and to determine whether barriers to prescription drug labels remain. [https://www.gao.gov/products/GAO-17-115](https://www.gao.gov/products/GAO-17-115)

Delivery Methods

- Hard Copy Braille and Large Print
- Digital Voice or Text to Speech Recorder
- Radio Frequency Identification Device
- Smart Devices and Computers
Questions?
Contact info

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(800) 872-2253
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Additional Resources

- https://adata.org/factsheet/accessible-medical-diagnostic-equipment
- https://www.ada.gov/medcare_mobility_ta/medcare_ta.htm
Summary: Supine, prone, or side-lying position (examination tables)

1. When adjustable, head and back support provided throughout the entire range of the incline (M301.3.3)
2. Transfer support resists vertical and horizontal forces of 250 lbs. at all points and does not rotate within its fittings (M305.2.2 and M305.2.3)
3. Rail serves as transfer support within reach of transfer surface (M301.3.1 and M305.2.1)
4. When provided, stirrups provide a method of supporting, positioning, and securing the patient’s leg (M301.3.2)
5. Support rail removable / repositioned to permit unobstructed transfer (M301.2.3 EXCEPTION)
6. Rail serves as transfer support within reach of transfer surface (M301.3.1 and M305.2.1)
7. Head and back support provided throughout the entire range of the incline (M301.3.3)
8. Transfer support resists vertical and horizontal forces of 250 lbs. at all points and does not rotate within its fittings (M305.2.2 and M305.2.3)
9. Rail serves as transfer support within reach of transfer surface (M301.3.1 and M305.2.1)
10. When provided, stirrups provide a method of supporting, positioning, and securing the patient’s leg (M301.3.2)
11. Support rail removable / repositioned to permit unobstructed transfer (M301.2.3 EXCEPTION)

Summary: Seated position (examination chairs)

1. When adjustable, head and back support provided throughout the entire range of the incline (M302.3.3)
2. Transfer surface 21 inches wide minimum and 15 inches deep minimum (M302.2.2)
3. Armrest folds up to permit unobstructed transfer (M302.2.3 EXCEPTION)
4. Transfer surface 17 inches minimum and 19 inches maximum above floor level (M302.2.1), when not needed to facilitate transfer, the transfer surface may be positioned above or below the height range (Advisory M302.2.1)
5. Required armrest serves as transfer support within reach of transfer surface (M302.3.1, M302.3.2, and M305.2.1)
6. Transfer support resists vertical and horizontal forces of 250 lbs. at all points and does not rotate within its fittings (M305.2.2 and M305.2.3)
7. One short side (depth) and one long side (width) of the transfer surface permit unobstructed transfer from a mobility device (M302.2.3)
8. Base permits clearance around base for a patient portable floor lift (M302.4 and M302.4.2)