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Listening to the Webinar, *continued*



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Listening to the Webinar, *continued*



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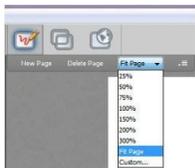
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Customize Your View *continued*



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Standards for Accessible Medical Diagnostic Equipment (MDE)

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Presenters

U.S. Access Board



Rex Pace



Earlene Sesker

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Agenda

- Overview
- Application & Administration
- Scoping
- Technical Requirements

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Overview of Standards

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Barriers Affecting Accessibility and Usability of Medical Diagnostic Equipment

- 75% - examination tables moderately difficult to impossible to use
- 68% - radiology equipment moderately difficult to impossible to use
- 53% - weight scales moderately difficult to impossible to use
- 50% - examination chairs moderately difficult to impossible to use

Rehabilitation Engineering Research Center on Accessible Medical Instrumentation 2004 national Survey

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MDE - Examples

- Examination tables and chairs
- Weight scales, x-ray machines
- Radiological and mammography equipment



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MDE - Examples



Rule does not cover personal devices or positioning aids – “diagnostic equipment” only

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Federal Partners

- U.S. Food and Drug Administration, Department of Health and Human Services
- Disability Rights Section, Department of Justice
- Department of Veterans Affairs



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MDE - Background



- ANSI/AAMI HE75 – 2009 Human Factors Engineering – Design of Medical Devices - Chapter 16
- RERC on Accessible Medical Instrumentation
- ADA and ABA Accessibility Guidelines
- Research Data

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MDE - Background

- Responses to NPRM
- Advisory Committee Recommendations
<http://www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/advisory-committee-final-report>



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MDE - Overview

- Mandate is to establish technical criteria
- Scope (who must comply, when, and minimum number) is to be determined in appropriate regulatory or administrative context
- Final Standards will be voluntary unless adopted by an enforcing Agency e.g., DOJ for the Americans with Disabilities Act
- Could be used by FDA to verify labelling claims

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Organization of Standards

- M1 Application and Administration
- M2 Scoping Requirements
- M3 Technical Criteria

By patient position supported
Supine, Prone, or Side Lying
Seated
In Wheelchair
Standing

Across equipment types
Supports
Communication
Operable Parts

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Chapter 1: Application & Administration

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Application and Administration

- Purpose
- Application
- Existing Diagnostic Equipment
- Equivalent Facilitation
- Dimensions
- Dimensional Tolerances
- Units of Measurement
- Definitions

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Existing Diagnostic Equipment

The Standards **do not**:

- address the accessibility of existing diagnostic equipment; or,
- require a percentage of new or replaced equipment to be accessible.

Once adopted by an enforcing authority, the Standards will be enforced only to the extent required by such authority e.g., the Department of Justice under the ADA.

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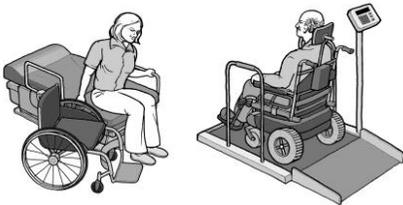
Equivalent Facilitation

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.

- The Access Board does not certify or otherwise approve equipment designs or alternatives.

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Adult Dimensions



Technical criteria are based on adult dimensions and anthropometrics, use of medical equipment by children is not addressed in proposed rule.

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Definitions

- 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

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Application

- Based on the patient positions that the equipment supports, during patient transfer and diagnostic use
- Applied to diagnostic equipment where communication features or operable parts are provided for patient use

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Application



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Application



M301 Exception
Examination chairs complying with M302 that recline to facilitate diagnosis after patients transfer onto the chair are not required to comply with M301.

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Chapter 2: Scoping

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Scope Applied by Enforcing Authority

What equipment needs to comply?

Upon adoption of the Standard the enforcing agency will determine the number and type of equipment required to comply.

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General Exception



- If compliance would alter **diagnostically required** structural or operational characteristics so as to prevent use for the intended purpose
- Comply to the “maximum extent practicable”

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Chapter 3: Technical Requirements

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**Supine, Prone, or
Side-lying
Position - M301**



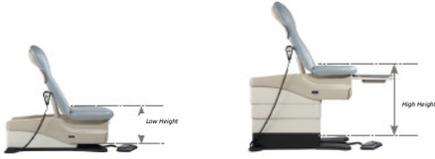
**Seated
Position -
M302**



**Key Issues:
transfers, obstructions
supports, and lift use**

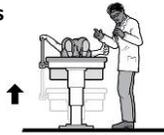
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Transfer Surface Height



Advisory Committee Recommendations

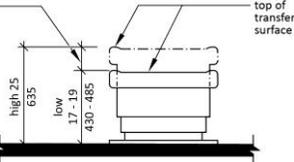
- height adjustability for transfers:
- “high” height of 25”
- “low” height – no consensus options for 19”, 18”, and 17”



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Transfer Surface Height

at least 4 additional positions separated by 1 inch (25 mm) min



Sunset - low transfer position height ceases to have effect on January 9, 2022 (5 years after publication date in the Federal Register)

Research project on Transfer to Medical Diagnostic Equipment

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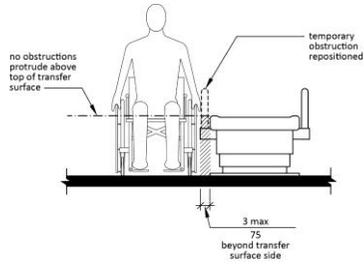
Obstructions



Equipment components that extend beyond exam surface

39

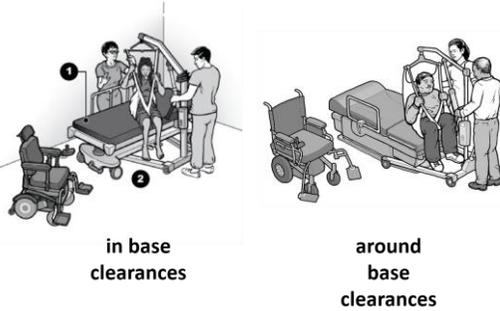
Permitted Obstructions



Permit up to 3-inch "gap" at/below transfer surface

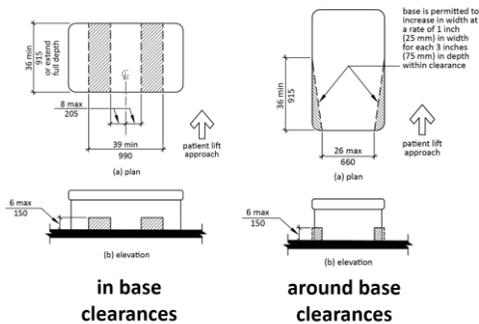
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Portable Lift Compatibility



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Portable Lift Compatibility



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Overhead Lifts



Exception - fixed overhead patient lift permitted in lieu of base clearances when:

- permitted by an enforcing authority
- equipment is clearly labeled as not compatible with portable floor lifts

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M305 Supports

Provisions for:

transfer supports

leg supports – stirrups

head and back support – reclined positions

Positioning supports not addressed



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Supine, Prone, or Side-lying Position - M301



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Two Transfer Surface Locations in M301



Equipment provides side and end transfer options

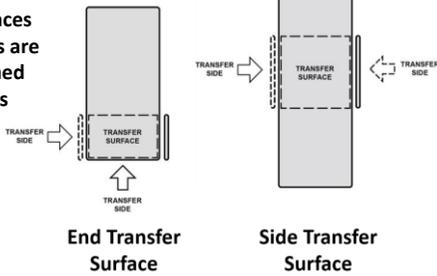
BUT

For some equipment side access is preferred or end is obstructed

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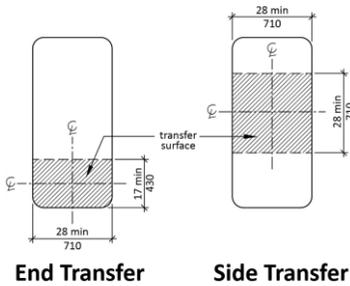
Two Transfer Surface Locations in M301

Surfaces types are defined terms



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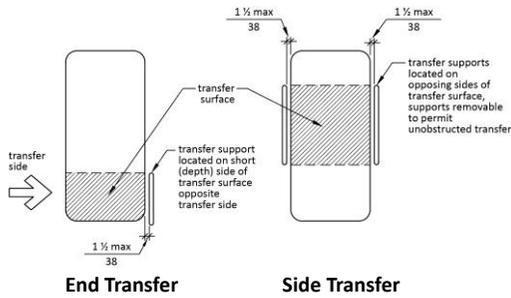
Transfer Surface Size



M301.2.2 Size

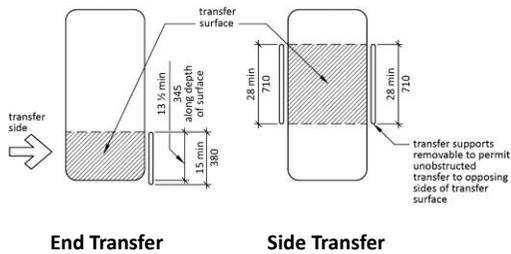
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Transfer Supports – Location



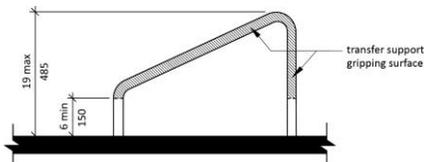
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Transfer Supports – Length



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Transfer Supports Height



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

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Transfer Supports – Exceptions



Folding Transfer Supports

Where support folds, collapses, or articulates - permitted to be located 3 inches max. from edge of the transfer surface

Where transfer surfaces are part of an articulating surface, the support permitted to be 15 inches long min.

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Transfer Supports – Exceptions



Wide Imaging Exam Surfaces

Where width of imaging bed is > 24 inches - transfer supports can be 12 inches long min.

Where width of the transfer surface for imaging beds > 24 inches - the tops of the gripping surfaces can be 3 inches min. and 6 inches max. higher than the top of the transfer surface.

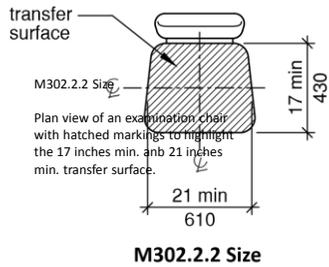
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Seated Position - M302



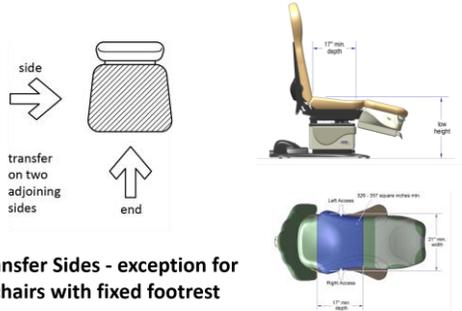
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Transfer Surface Size



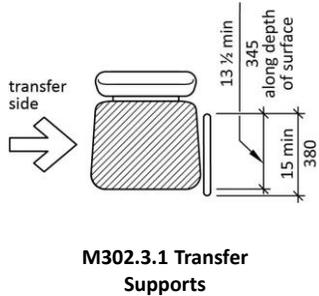
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Examination Chairs - M302



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Transfer Support Length



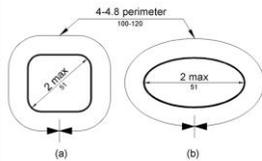
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Additional Requirements of M305 Supports Applicable to both M301 and M302

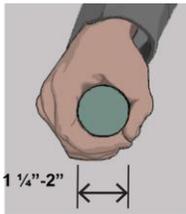
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Example of relevant ADA-ABA 2004 Guidelines provisions

Section 609 Grab Bars cross section specifications



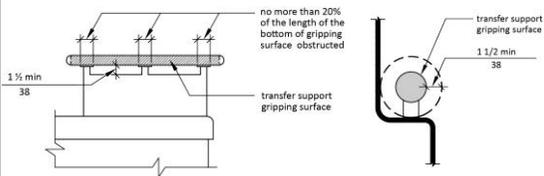
Non-circular Cross Section



Circular Cross Section

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Gripping Surface



Gripping surface - minimum unobstructed surface and clearance around

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M305 Supports

Surface Hazards - Transfer supports and surfaces adjacent to transfer supports shall be free of sharp or abrasive components and shall have eased edges

Fittings - supports shall not rotate within their fittings when in place for transfer

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M305 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.

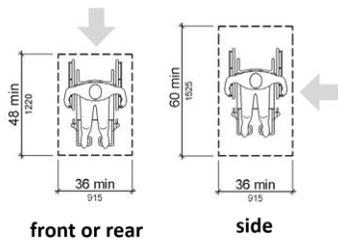
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Seated in a Wheelchair - M303



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Wheelchair Spaces



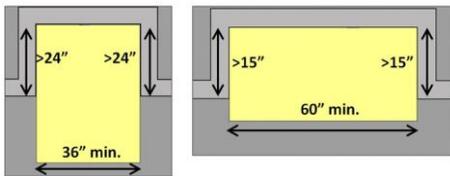
front or rear

side

Width and Depth

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Wheelchair Spaces



Based on 305.7 Maneuvering Clearances where space confined on 3 sides (and more than half of space depth confined)

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Wheelchair Spaces



The Standard does **NOT** address clear floor space for transfers

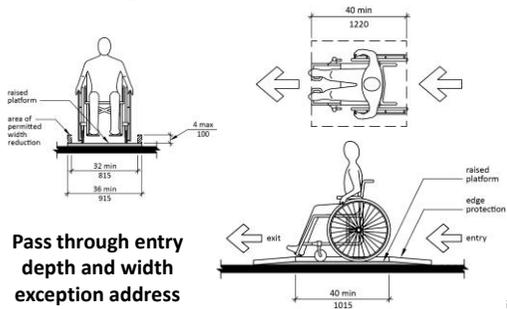
66

Portable Scales



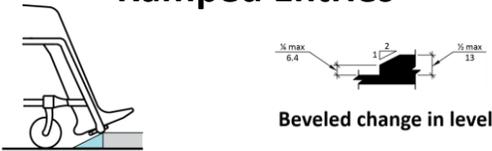
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Wheelchair Spaces on Weight Scales - M303



i8

Ramped Entries



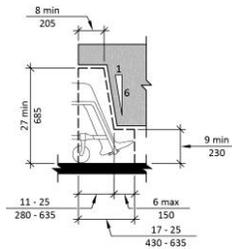
Combination of height and steep slope a barrier



Running slope Exception – consentient with ADA Standards exception for rises of 3” or less in alterations

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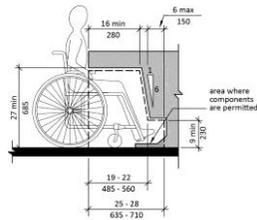
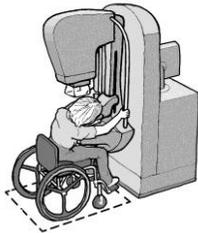
Clearances beneath Components - M303



Most equipment knee and toes space will be essentially same as Standards.

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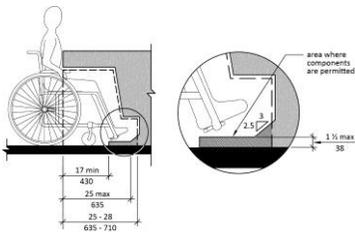
Knee and Toe Clearance Under Breast Platform



Deeper Knee and Toe Clearance Required

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Knee and Toe Clearance Under Breast Platform



Exception permits an area where equipment parts may extend

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Standing Position – M304

Provisions for:

- standing surface - slip resistant
- standing supports – horizontal or vertical



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Standing Supports – M305.3

Vertical Supports:

- 18" min. long
- 34" min. - 37" max. above standing surface to lowest end of the gripping surface



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Standing Supports – M305.3

Horizontal Supports:

- on most equipment 4" min long
- 34" min. - 38" max. above standing surface to top



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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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Standing Supports – M304.3

Exception for breast platforms – mammography equipment



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Transfer and Standing Supports

Structural strength not addressed as in ADA and ABA Standards for grab bars

More variables, Industry Standards address



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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

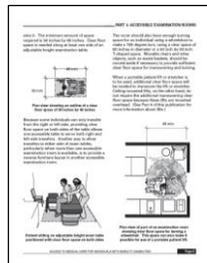
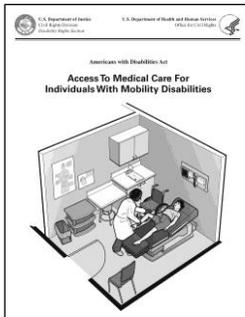
Features addressed:

- Tactilely Discernible
- Operation
- Operating Force



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DOJ Guidance is Available



www.ada.gov

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The Final for Accessible Medical Diagnostic Equipment available at

www.access-board.gov/guidelines-and-standards/health-care/about-this-rulemaking/final-standards

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