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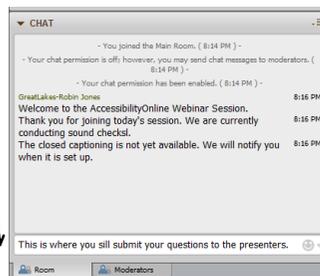
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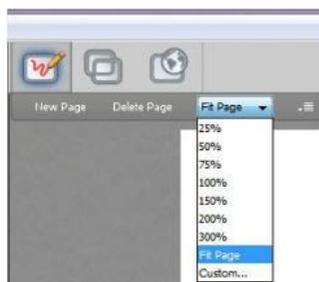
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GreatLakes-Robin Jones   8:15 PM
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Standards for Accessible Medical Diagnostic Equipment (MDE)

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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

14

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

17

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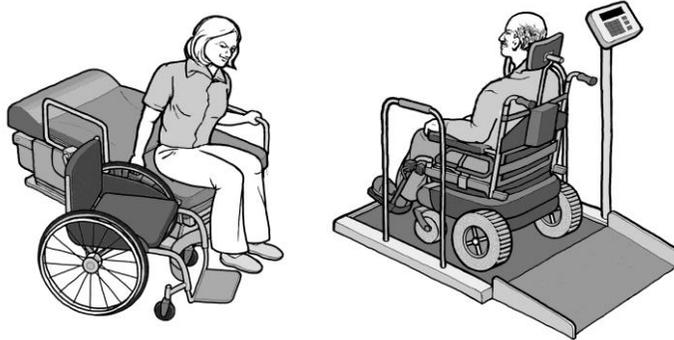
Technical criteria are based on adult dimensions and anthropometrics, use of medical equipment by children is not addressed in proposed rule.

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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

29

Application

30

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
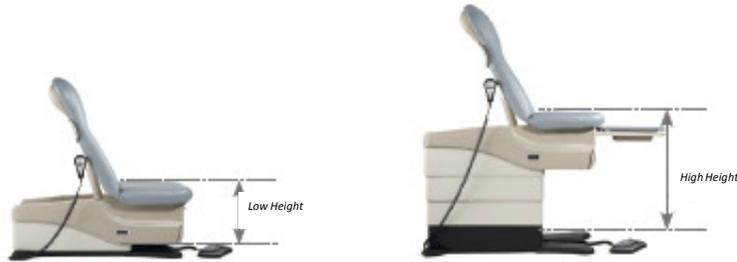
Advisory Committee Recommendations
- height adjustability for transfers:
- "high" height of 25"
- "low" height – no consensus
  options for 19", 18", and 17"
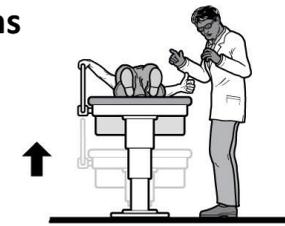
37

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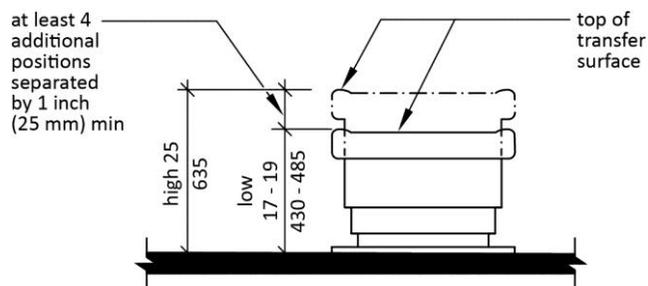
Sunset - low transfer position height ceases to have effect on January 9, 2022 (5 years after publication date in the Federal Register)

Research project on Transfer to Medical Diagnostic Equipment

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Obstructions

Equipment components that extend beyond exam surface

39

Permitted Obstructions

no obstructions protrude above top of transfer surface

temporary obstruction repositioned

3 max
75
beyond transfer surface side
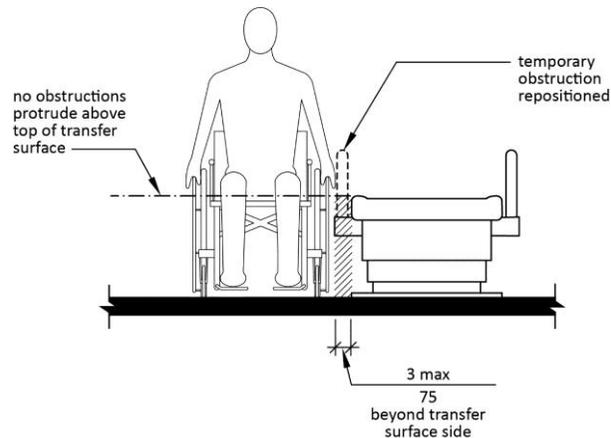
Permit up to 3-inch "gap" at/below transfer surface

40

Portable Lift Compatibility
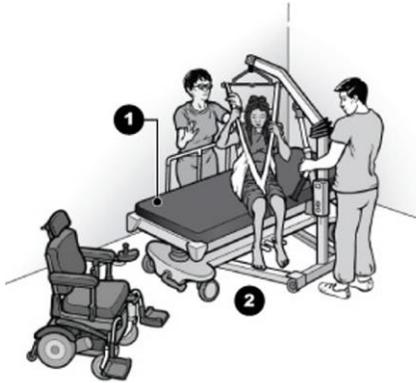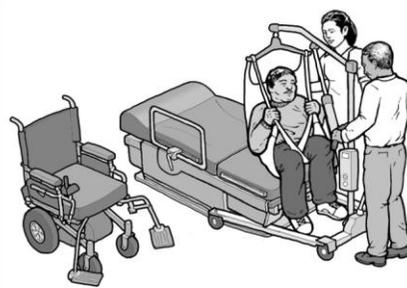
in base clearances

around base clearances

41

Portable Lift Compatibility
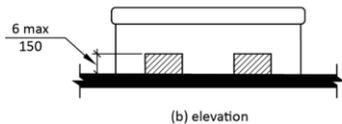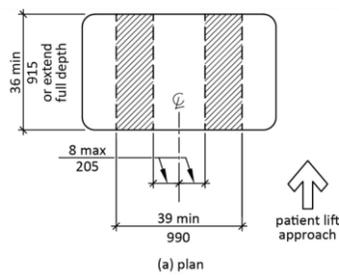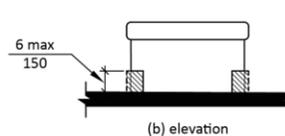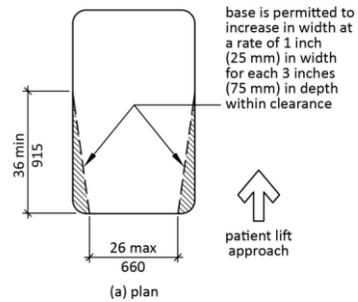
in base clearances

around base clearances

42

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

43

M305 Supports

Provisions for:

    transfer supports

    leg supports – stirrups

    head and back support – reclined positions

Positioning supports not addressed

44

Supine, Prone, or Side-lying Position - M301

45

Two Transfer Surface Locations in M301
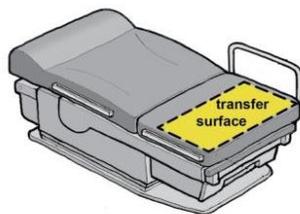
Equipment provides side and end transfer options

BUT

For some equipment side access is preferred or end is obstructed

46

Two Transfer Surface Locations in M301
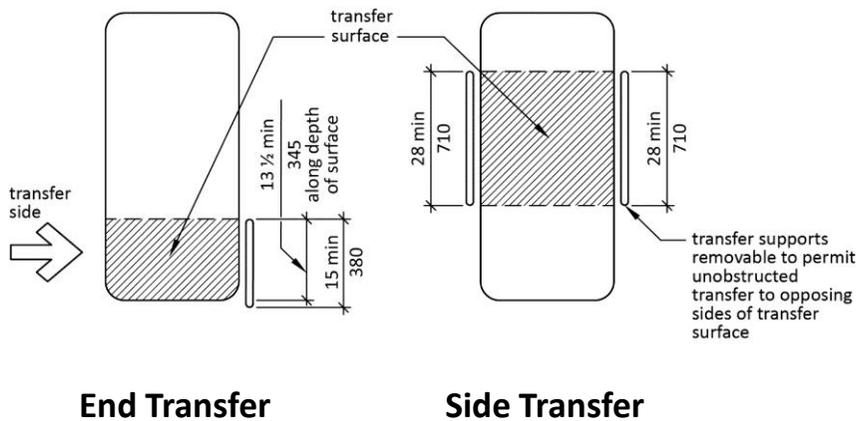
Surfaces types are defined terms

TRANSFER SIDE → TRANSFER SURFACE ↑ TRANSFER SIDE

TRANSFER SIDE → TRANSFER SURFACE ← TRANSFER SIDE

End Transfer Surface **Side Transfer Surface**

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Transfer Surface Size

28 min / 710

28 min / 710

transfer surface

17 min / 430

28 min / 710

End Transfer **Side Transfer**
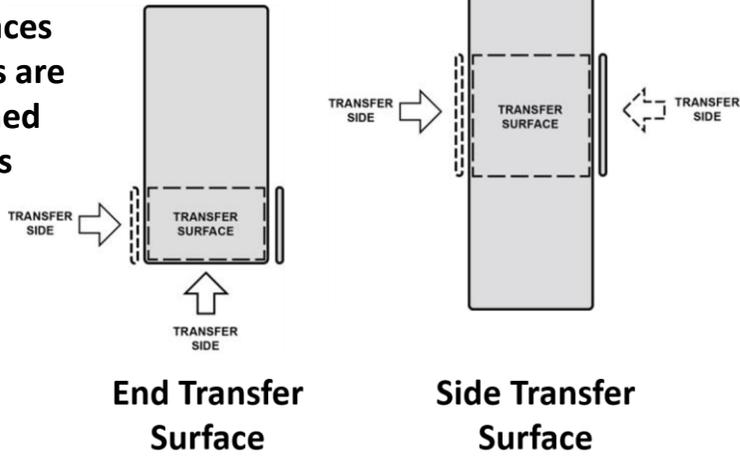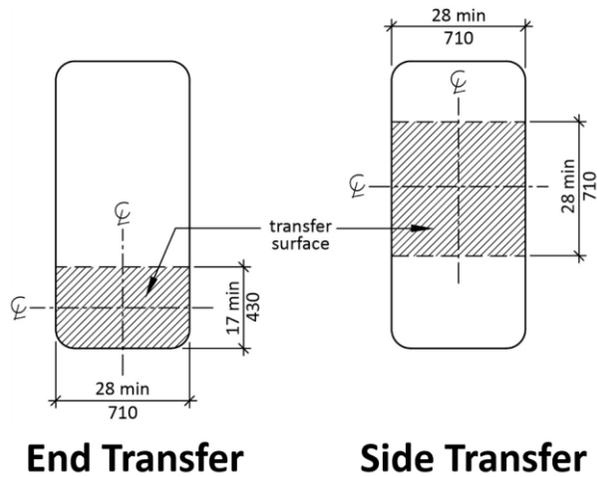
M301.2.2 Size

48

Transfer Supports – Location

End Transfer   **Side Transfer**
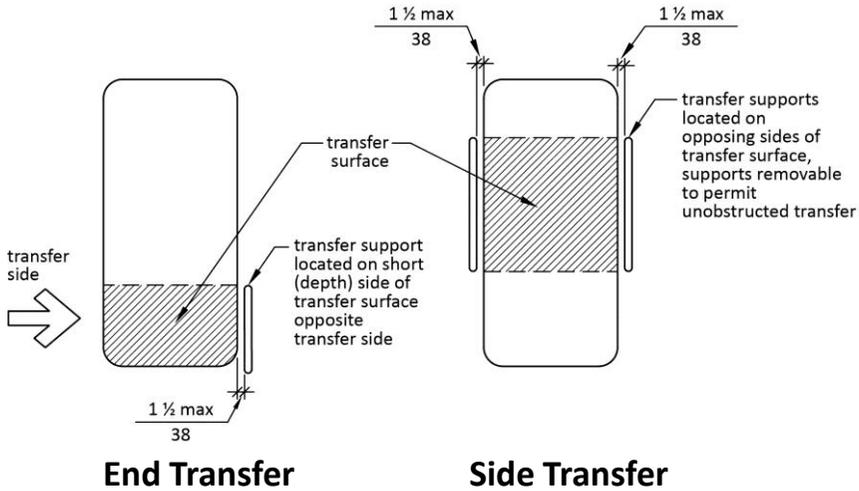
49

Transfer Supports – Length

End Transfer   **Side Transfer**

50

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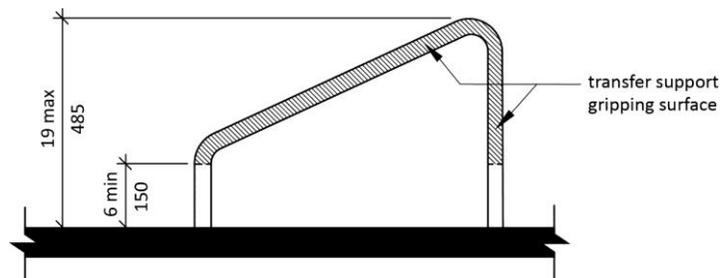
**Horizontal supports not required –
gripping surface must be within min and
max height**

51

Transfer Supports – Exceptions
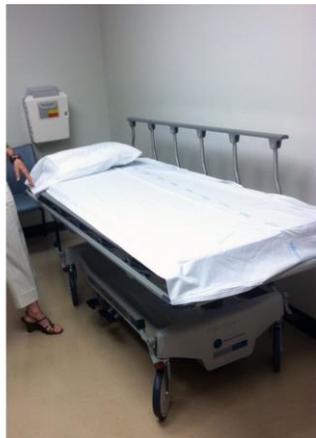
**Folding Transfer
Supports**

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.
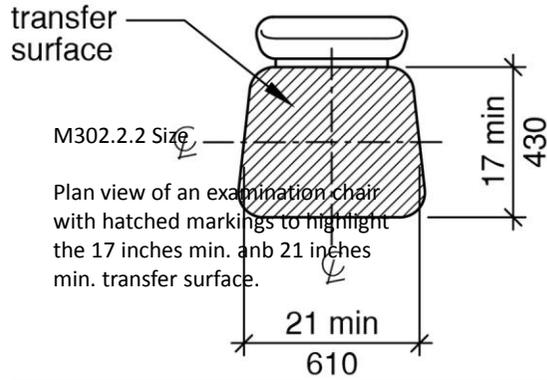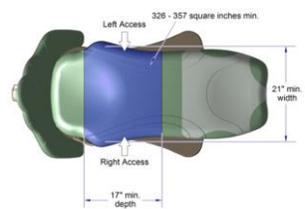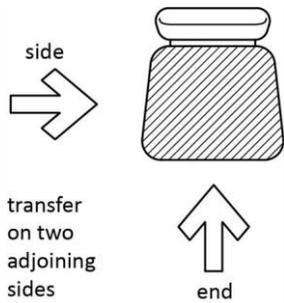
53

Seated Position - M302

54

Transfer Surface Size

transfer surface

M302.2.2 Size

Plan view of an examination chair with hatched markings to highlight the 17 inches min. anb 21 inches min. transfer surface.

17 min
430

21 min
610

M302.2.2 Size

Examination Chairs - M302

side

transfer on two adjoining sides

end

17" min. depth

low height

326 - 357 square inches min.

Left Access

21" min. width

Right Access

17" min. depth

Transfer Sides - exception for chairs with fixed footrest

Transfer Support Length

transfer side

13 ½ min
345
along depth of surface

15 min
380
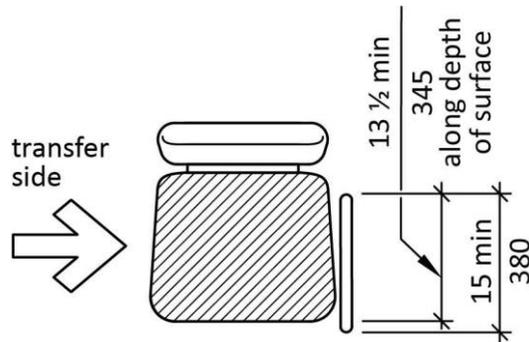
M302.3.1 Transfer Supports

57

Additional Requirements of M305 Supports Applicable to both M301 and M302
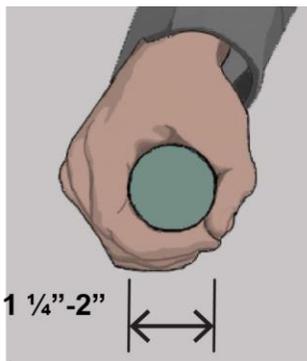
58

Example of relevant ADA-ABA 2004 Guidelines provisions
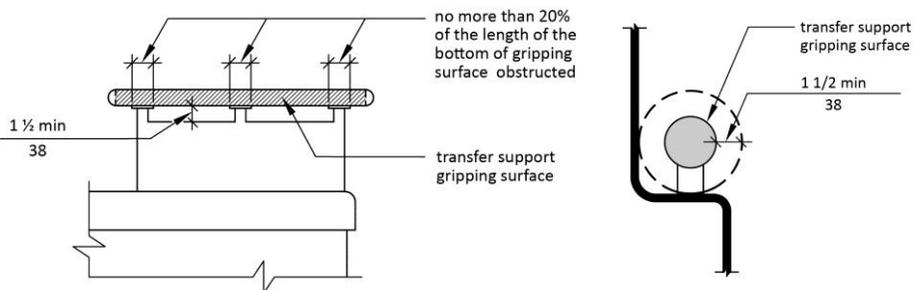
Section 609 Grab Bars cross section specifications
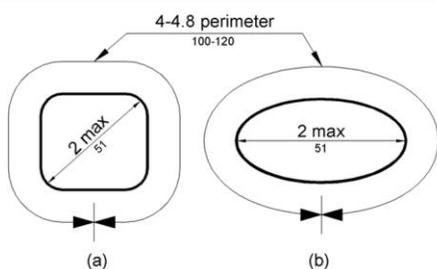
Non-circular Cross Section

Circular Cross Section

59

Gripping Surface

no more than 20% of the length of the bottom of gripping surface obstructed

transfer support gripping surface

1 ½ min 38

transfer support gripping surface

1 1/2 min 38

transfer support gripping surface

Gripping surface - minimum unobstructed surface and clearance around

60

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

61

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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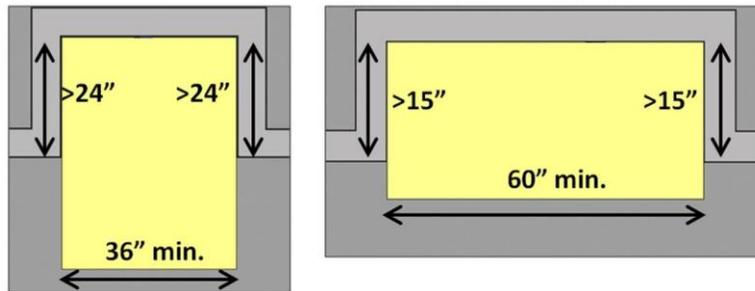# Seated in a Wheelchair - M303

63

Wheelchair Spaces
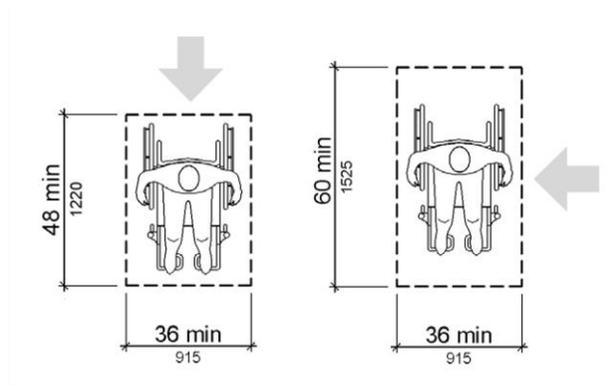
Width and Depth

64

Wheelchair Spaces

>24"   >24"

>15"   >15"

60" min.

36" min.

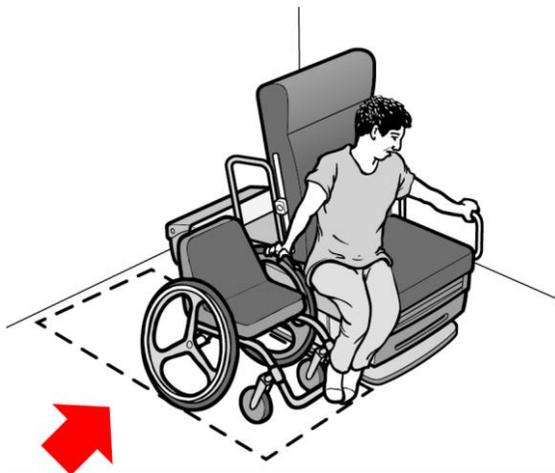**Based on 305.7 Maneuvering Clearances where space confined on 3 sides (and more than half of space depth confined)**

65

Wheelchair Spaces

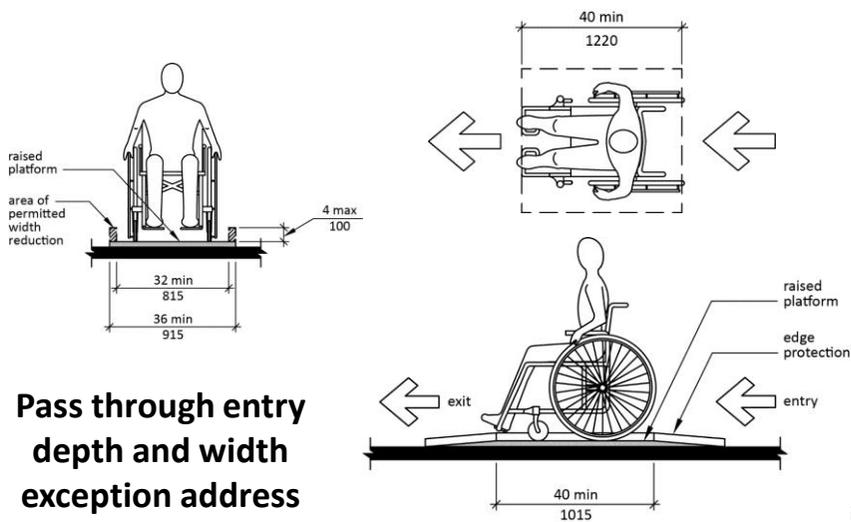**The Standard does NOT address clear floor space for transfers**
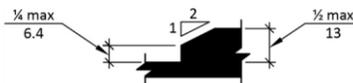
66

Portable Scales

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Wheelchair Spaces on Weight Scales - M303

40 min
1220

raised platform

area of permitted width reduction

4 max
100

32 min
815

36 min
915

raised platform

edge protection

exit

entry

40 min
1015

Pass through entry depth and width exception address

Ramped Entries

¼ max
6.4

2
1

½ max
13

Beveled change in level

Combination of height and steep slope a barrier

1
8

2 1/2 max
64

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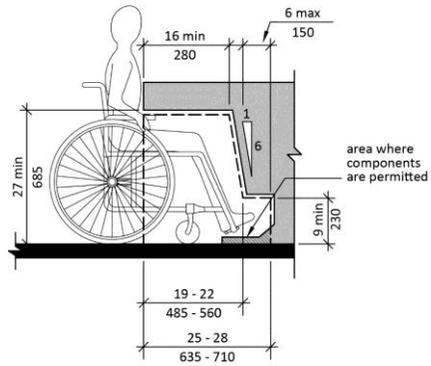consentient with ADA Standards exception
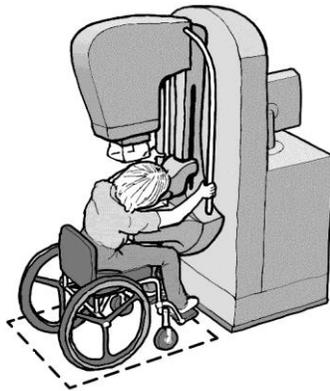for rises of 3" or less in alterations**

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Clearances beneath Components - M303

8 min
205

1
6

27 min
685

9 min
230

11 - 25
280 - 635

6 max
150

17 - 25
430 - 635
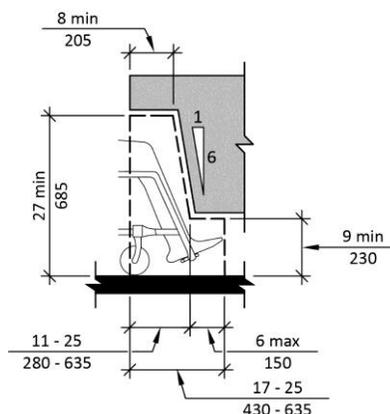
**Most equipment knee and toes space
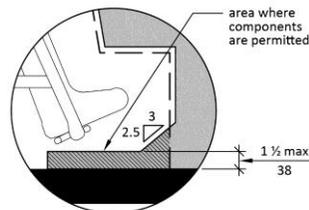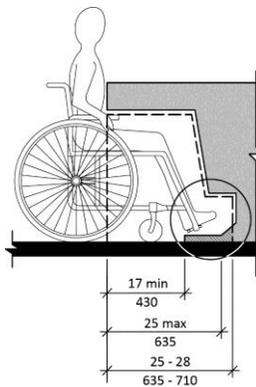will be essentially same as Standards.**

70

Knee and Toe Clearance Under Breast Platform

Deeper Knee and Toe Clearance Required

71

Knee and Toe Clearance Under Breast Platform

Exception permits an area where equipment parts may extend

72

Standing Position – M304

Provisions for:

- **standing surface - slip resistant**

- **standing supports – horizontal or vertical**

73

Standing Supports – M305.3

Vertical Supports:

- **18" min. long**

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

74

Standing Supports – M305.3

Horizontal Supports:

- **on most equipment 4" min long**

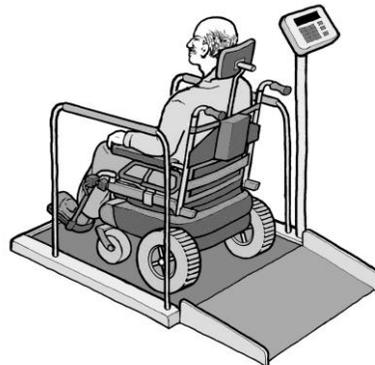- **34" min. - 38" max. above standing surface to top**

75

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

Transfer and Standing Supports

Structural strength not addressed as in ADA and ABA Standards for grab bars
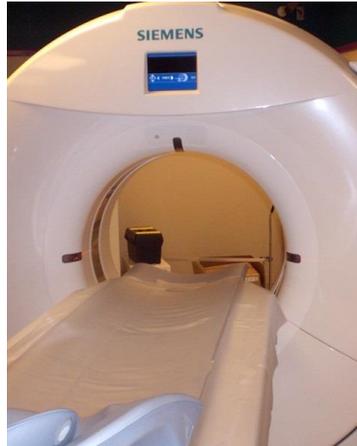
More variables, Industry Standards address

Communication - M306

Information communicated through the equipment

Information provided in at least two methods:

- **audible**
- **visible**
- **tactile**

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Operable Parts - M307

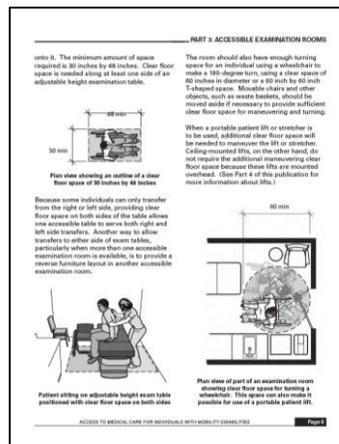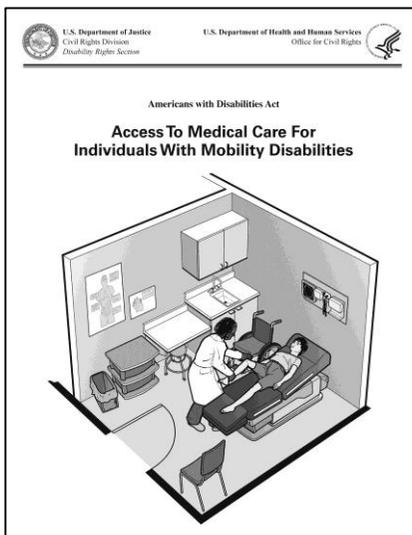**Only controls operated by the patient**

Features addressed:

- **Tactilely Discernible**
- **Operation**
- **Operating Force**

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DOJ Guidance is Available

www.ada.gov

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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