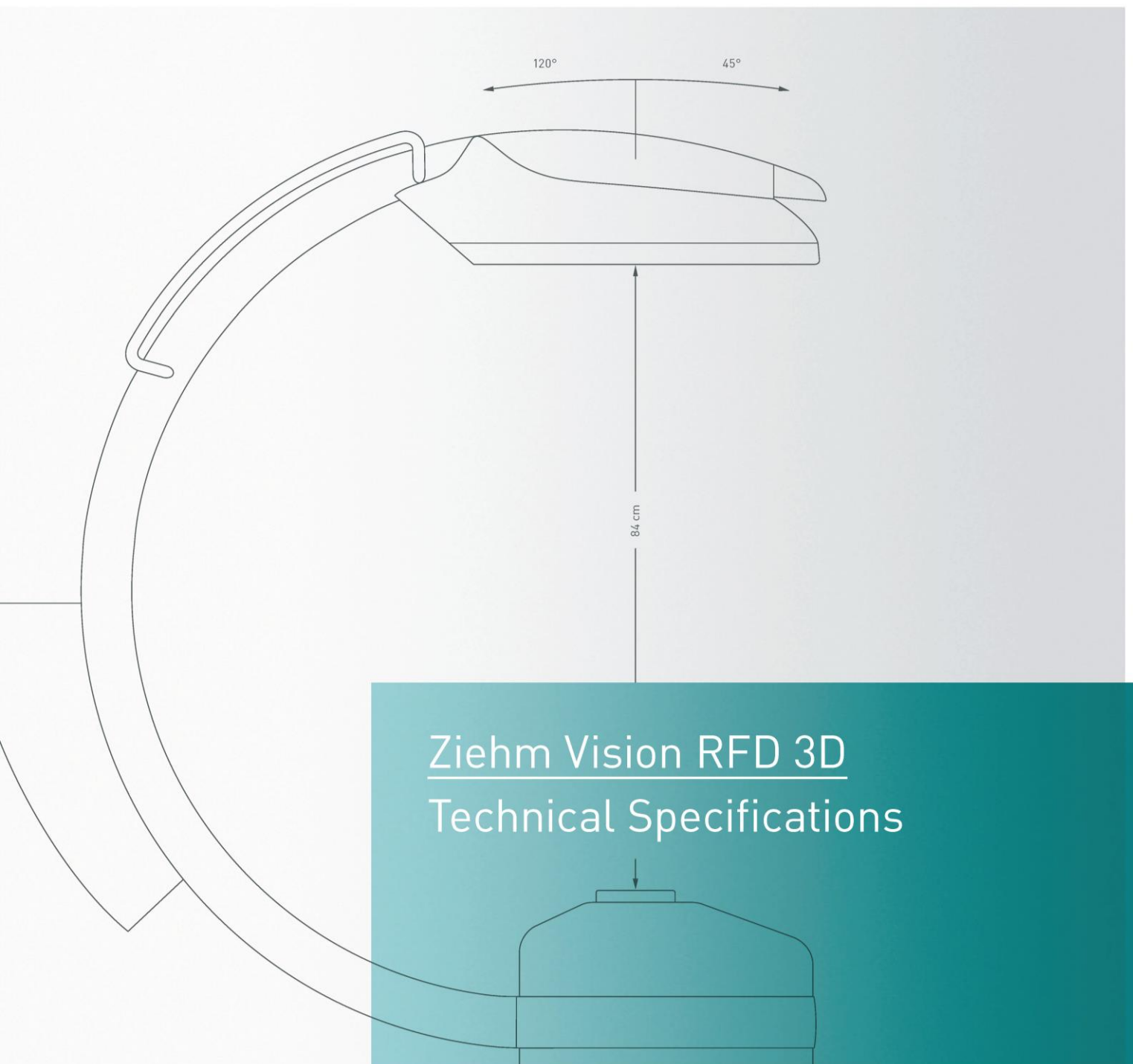




C-ARM MOBILE STAND

Dimensions and Mechanics

- Motor-driven vertical travel: 42 cm
- Horizontal travel: 28 cm
- Orbital rotation: -120° / $+45^{\circ}$
- Angulation: $\pm 225^{\circ}$
- **Swiveling (panning): $\pm 10^{\circ}$**
- **Source-image receptor distance: 105 cm**
- **C-arm vertical free space: 84 cm**
- C-arm depth: 68 cm
- Width: 80 cm
- Length: 191 cm / 219 cm
- Height: 160 cm / 202 cm
- Weight C-arm mobile stand (weight can vary depending on balancing and configuration): 415 kg $\pm$ 2 %
- Laser positioning device mounted in the middle of the C-arm

Brakes

- **Steering & braking lever, with parallel movement of the mobile stand in all directions**
- Color-coded brake handles for all movements

Motorization

- Motor-driven vertical travel: 42 cm
- Motor-driven horizontal travel: 27 cm
- **Motor-driven orbital rotation: -119.5° / $+44.5^{\circ}$**
- **Motor-driven angulation: $\pm 225^{\circ}$**
- Speed:
 - $15^{\circ}/s$ for angulation and orbital rotation
 - 30 mm/s for vertical and horizontal movements
- Speed isocentric mode or without Distance Control:
 - $9.5^{\circ}/s$ for angulation and orbital rotation
 - 15 mm/s for vertical and horizontal movements

X-Ray Generator

- X-ray tube: rotating anode
- Dual focus: 0.3 / 0.6 (IEC 60336)
- Anode angle: 10°
- Anode speed:
 - Up to 3,000 RPM (50 Hz)
 - Up to 3,600 RPM (60 Hz)
- Max. anode heat content: 365 kHU / 260 kJ
- Max. anode heat dissipation: 1,000 W / 85 kHU/min
- **Powered by integrated Advanced Active Cooling and heat management system**
- 10 million HU system heat capacity
- 1,200 W / 102 kHU/min continuous heat dissipation in clinical performance
- Generator type:
 - monoblock
 - high-frequency generator
 - **frequency: 40 kHz**
 - **microprocessor-controlled**
- **Nominal output (100 kV): 25 kW** (IEC 60601-2-54)
- Maximum output: 25 kW

Filtration

- Total filtration: ≥ 4.3 mm Al + 0.1 mm Cu

Collimator System

- Dedicated pre-collimator for FPD
- Collimator rotation: $\pm 90^{\circ}$
- Iris collimator: 50-298 mm diameter
- Asymmetric slot collimator: 50-298 mm opening
- **Virtual collimation without radiation**

Operating Values

- **Continuous fluoroscopy:**
 - **kV range: 40-120 kV**
 - mA range: 1.7-17 mA (200-240 V)
- Pulsed fluoroscopy:
 - **kV range: 40-120 kV**
 - mA range: 1.5-250 mA (200-240 V)
 - pulse width: 7-40 ms
 - pulse rate: 1, 2, 4, 8, 12.5, 25 pulses/s
- **Digital radiography (snapshot):**
 - **kV range: 40-120 kV**
 - mA: up to 250 mA

Flat-Panel Detector System

- Type: amorphous silicon photodiode TFT technology
- Scintillator: cesium iodide
- Pixel size: 194 μ m
- **Grayscale: 65,536 gray scale values (16 bit)**
- System resolution: 2.6 lp/mm
- Anti-scatter grid:
 - 70 lines/cm; grid ratio 8:1
 - 70 lines/cm; grid ratio 10:1
- Laser positioning device integrated in detector housing
- Auto calibration
- Removable grid (option)
- DQE: 77% @ 0 lp/mm
- MTF: $> 50\%$ @ 1 lp/mm
- Dynamic range: 94 dB

Flat-Panel 3030

- Detector matrix:
 - overview format: **1,536 x 1,536 pixels**
 - o 1.4 lp/mm
 - Mag. mode 1: 1,024 x 1,024 pixels
 - o 2.5 lp/mm
 - Mag. mode 2: 768 x 768 pixels
 - o 2.5 lp/mm

MONITOR CART

User Interface

Vision Center - TFT Touchscreens on C-arm Stand and Monitor Cart

- Synchronized
- Intuitive icons for ease of use
- Resolution: 640 x 480 pixels
- Multi-lingual user interface
- Ziehm SmartEye live fluoro screen with SmartControl
- SmartArchive
- 4 axes movement control

Vision Center - TFT Touchscreen on C-arm Stand

- Emergency stop button
- X-ray button
- X-ray indication lamp

Remote Vision Center – Synchronized Touchscreen for Table Side Control (Option)

- 4 axes movement control
- Emergency stop button
- X-ray button
- X-ray indication lamp

Position Control Center - Dual Joystick Control for Motorized Movements (Option)

- 4 axes movement control
- Save and recall of up to 3 positions
- Home / 0 position button
- Isocentric mode
- Emergency stop button

Dimensions and Mechanics

- Width: 71 cm
- Depth: 70 cm
- Height: 175 cm
- Monitor Cart basic weight: 169 kg $\pm$ 10 %
(up to 65 kg additional weight depending on the configuration)

With Articulating Monitor Arm (Option):

- Monitor rotation: $\pm$ 40°
- Rotation of the arm: $\pm$ 115°
- Adjustment height: +23 cm, -16 cm
- Max. reach: 83 cm

Monitor

- **High-brightness and high-contrast 19" DUO monitor:**
 - screen size: 2 x 19" (48 cm)
 - native resolution: 1,280 x 1,024 pixels
 - viewing angle (horizontal and vertical): 178° (with contrast ratio:10:1)
 - tilt range: $\pm$ 10°
 - contrast ratio: typ. 1,000:1
 - brightness (panel): typ. 1,000 cd/m²
 - brightness (calibrated): $\geq$ 550 cd/m²
 - dimensions: 68 cm x 45 cm x 9 cm
- High-resolution and high-brightness 32" UHD monitor (option):
 - screen size: 31.5" (80 cm)
 - native resolution: 3,840 x 2,160 pixels
 - viewing angle (horizontal and vertical): typ. 178° (with contrast ratio $\geq$ 10:1)
 - tilt range: $\pm$ 10°
 - contrast ratio: typ. 1,700:1
 - brightness (panel): $\geq$ 700 cd/m²
 - brightness (calibrated): typ. 550 cd/m²
 - dimensions: 72 cm x 47 cm x 8 cm

3D Workstation

Hardware

- Intel Core I5-9500T
- 2 x 4 GB DDR4 RAM
- USB, CD / DVD (option)
- Mouse

Software

- Control software for variable isocentric movement
- 3D Visualization
 - **Multiplanar Reconstruction (MPR)**
 - Volume Rendering
 - Surface Rendering
- **Slice planes: axial, sagittal, coronal**
- Ziehm Iterative Reconstruction (ZIR) 3D reconstruction algorithm with intelligent auto-windowing
- 3D volume size:
 - **3D Volume size (standard): 16.0 cm x 16.0 cm x 16.0 cm**

- 3D Volume size (option Zoom in function):
10.0 cm x 10.0 cm x 10.0 cm
- 3D Volume size (option larger field of view):
19.8 cm x 19.6 cm x 18.0 cm

- Resolution: 320³ voxels
- Thick slice filter function
- Parallel slices function
- Iso loop
- Zoom function
- Measurement function: length, angle

3D image acquisition

- 180° motor-driven scan
 - 165° orbital rotation
 - 15° shift scan
- Standard scan
 - scan time: 48 s
 - up to 400 images

Note: For 3D-applications, a radiolucent, metal free OR table and accessories are required

Digital Image Processing

Real-Time Processing Functions

- Last Image Hold
- Recursive filter: 4 levels (out of 16)
- Edge enhancement filter: 5 levels
- Windowing and step windowing
- Digital image rotation and reversal without radiation
- Grayscale inversion
- Digital collimators
- Ziehm Adaptive Image Processing (ZAIP)

Application-Oriented Anatomical Programs

- Bone: Extremities, Trunk
- Heart, Abdomen, Soft
- Heart Coro, Heart EP (option)
- Vascular (option): Extremities, Trunk, Bolus
- Urology (option)
- 3D application specific programs:
head, shoulder, spine, pelvis, hand, knee, foot

Additional Functions

- Metal
- Reposition
- High Quality
- Pediatric
- Large Patient

Object Detected Dose Control (ODDC)

- Automatic object detection
- Automatic motion detection
- Automatic dose reduction
- Automatic metal correction

Image Acquisition

- Autosave
- Cine loop with auto-playback:
 - sequential image storage and display:
1-8 frames/s

- 1-12.5 frames/s (option)
- 1-25 frames/s (option)

- start, stop and replay rate controls

Postprocessing Functions

- Edge enhancement: 5 levels
- Zoom: 3 levels
- Image rotation
- Windowing and step windowing
- Grayscale inversion
- Image cropping (digital collimators)
- Digital measurement functions: distance/angle

SmartVascular Plus Package (Option)

- Smart Vascular workflow
 - DSA real-time subtraction with re-masking capability
 - MSA max. opacification sequence
 - Single frame, Multiframe RSA (roadmapping)
- Pixel shift / landmarking
- Wireless Dual Plus footswitch
- Cine Loop 1-12.5 frames/s
- 2 video connectors for external DVI display, for left and right monitor in landscape mode
- Anatomical Marking Tool

SmartVascular Advance Package (Option)

- Smart Vascular workflow
 - DSA real-time subtraction with re-masking capability
 - MSA max. opacification sequence
 - Single frame, Multiframe RSA (roadmapping)
- Pixel shift / landmarking
- Wireless Dual Plus footswitch
- Cine Loop 1-25 frames/s
- 2 video connectors for external DVI display, for left and right monitor in landscape mode
- Measurement functions
- Anatomical Marking Tool
- CO₂ Package

Vascular Color Package (Option)

- Enhanced Vessel Visualization: Automatic display of colored vessel overlay
- Color on live monitor for Anatomical Marking Tool and Measurement functions
- High-resolution and high brightness 32" UHD monitor

Anatomical Marking Tool - AMT (Option)

- Mark anatomical structures
- Indicate side of body
- Line and connected line

Measurement Function (Option)

- For precise measurement of distances, angles and vessel lumen

Brachytherapy (Option)

- SAD value and orbital rotation are stored in DICOM Tag
- DICOM Standard: RT modality
- Supporting treatment planning software of Varian (BrachyVision) and Elekta (Oncentra)

CO₂ Package (Option)

- Automatic image optimization when using negative contrast medium in vascular modes

Digital Memory

- Storage capacity:
 - 100,000 images
 - 220 scans (320³ voxels)
- Digital image processing: up to 32 bit

Data Organization

- Patient-based data management with 16-image mosaic display
- Pre-registration via DICOM Worklist
- Manual input or emergency registration
- Calculated Dose Area Product (DAP)
- DAP value tagged to stored image
- Air Kerma dose display
- Air Kerma value tagged to stored image
- HIPAA security package (option)
- Radiation Dose Structured Report (RDSR)

Video Output

- Full HD SDI (split display), 1,920 x 1,080 pixels, 60Hz

Archiving

- Paper printer (option)
- USB port:
 - storage capacity depends on storage medium
 - formats: DICOM, TIFF, Multimedia (AVI)
 - downsized formats: DICOM, JPG
- DVD-RW drive (option):
 - 4.7 GB storage capacity
 - formats: DICOM, TIFF, Multimedia (AVI)
 - downsized formats: DICOM, JPG
- DICOM viewer software for DVD and USB 3.0 device (option)

Networking

- Ziehm NetPort (option): DICOM 3.0 interface (LAN interface or WLAN connection) for digital network integration
- 'Primary Capture' mode
- Available DICOM Classes:
 - Storage Class incl. multiframe capability and Storage Commitment
 - Print Class
 - Media Class
 - Worklist Class incl. Modality Performed Procedure Step (MPPS)
 - Query Class
 - Retrieve Class
 - Verification Class
- WLAN interface for wireless data transfer (option)
- DICOM interface for connecting to NaviPort 3D navigation

Electrical Requirements

- Power supply: 100-240 V_{AC} (± 10 %), 50/60 Hz
- Current consumption:
 - 20 A continuous (100-120 V)
 - 16 A continuous (200-240 V)
- Max. impedance:
 - ≤ 0.3 Ω (100-200 V)
 - ≤ 0.6 Ω (220-240 V)
- Installation fuse (release characteristic compliant to VDE 0641, Part 11; EN 60898 & IEC 60898):
 - 100-200 V: C 20 A or C 32 A
 - 220-240 V: C 16 A

Safety Features

- Electrical Protection Class I equipment, Type B (IEC 60601-1)
- Emergency stop button on user interface, Monitor Cart, Remote Vision Center, Mobile Stand, Position Control Center
- Joystick control with two-point contact
- Security key switch (X-ray)

Options

- Laser positioning device integrated in generator housing
- Remote Service
- Measured dose area product (DAP) with digital display
- Video connectors for external monitors:
 - DVI
 - analog
- Connector for external radiation lamp
- Wireless Video Package: wireless transmission of the left /right image from the Monitor Cart to external monitors
- Distance Control (option) in FD housing to control distance, speed, and braking within proximity of an object

Accessories

- Disposable sterile covers
- Remote Vision Center TFT touchscreen
- Dual Plus footswitch (also available with protection bar)
- Wireless multifunctional Dual Plus footswitch with programmable configuration (also available with protection bar)
- Skin Cone for the generator: A removable mechanical extension of the generator cap in order to avoid a focal spot to skin distance smaller than 30 cm.
- Mobile Cart for Remote Vision Center (stand accommodates both the Position Control Center and Remote Vision Center)

Regulatory Compliance

Device Classification

- MDD 93/42 EEC, Annex IX: IIb
- U.S. 21CFR: II

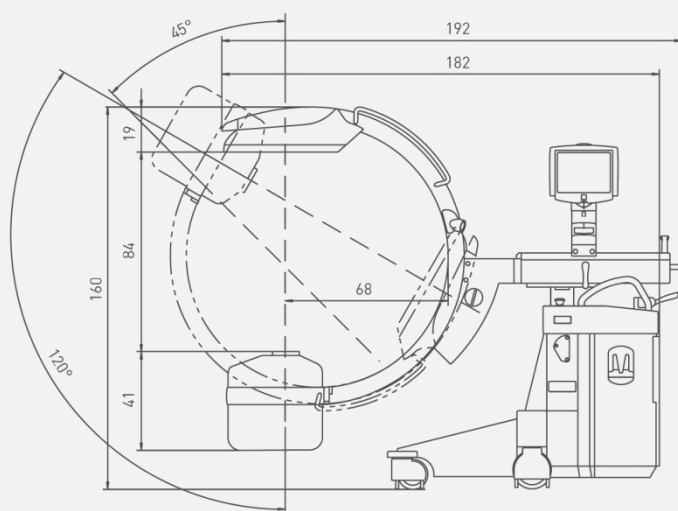
Compliance to QM Requirements

- EN ISO 13485 certified
- MDD 93/42/EEC, Annex II certified
- MDSAP certified
 - Australian Therapeutic Good Regulation
 - Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2013, RDC ANVISA n. 67/2009
 - Canada Medical Device Regulations Part 1 – SOR 98/282
 - Japan MHLW Ministerial Ordinance 169
 - United States 21 CFR 820
- ISO 14971
- IEC 62304
- IEC 62366

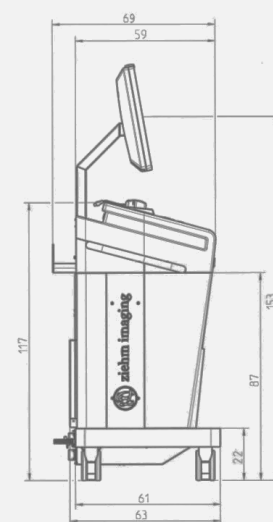
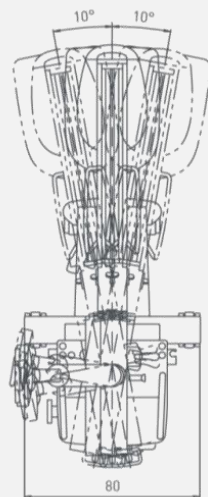
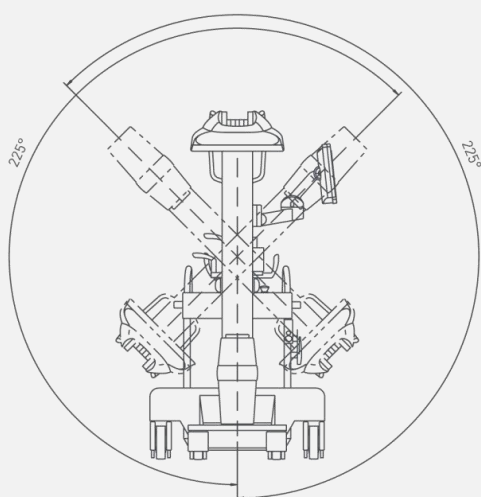
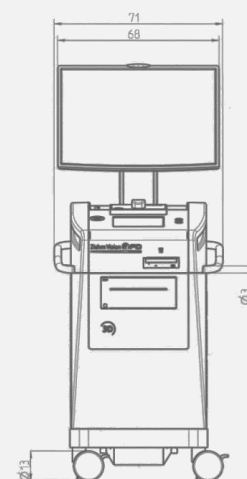
Product Compliance

- IEC 60601-1 and relevant collateral and particular standards
- U.S. 21CFR subchapter J

**Ziehm Vision RFD 3D
(C-Arm Mobile Stand)**

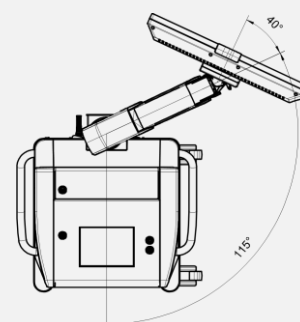
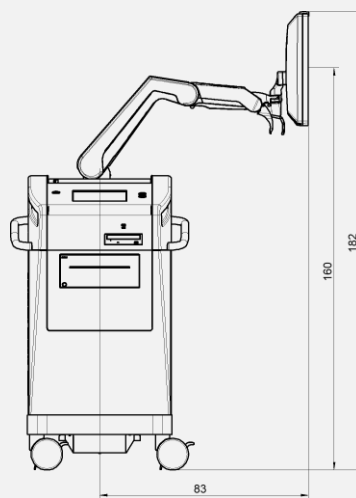
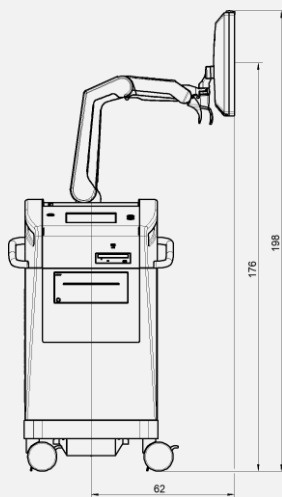
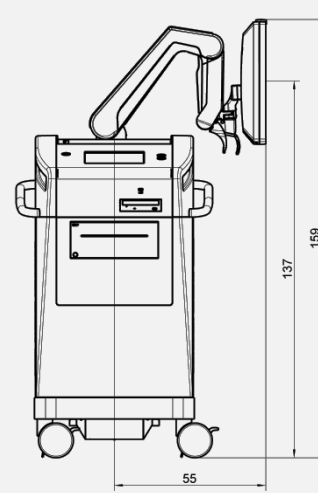
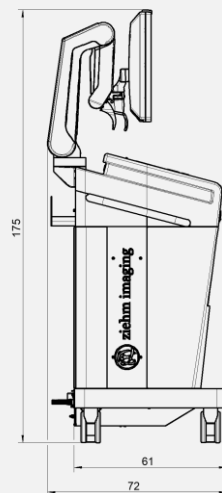
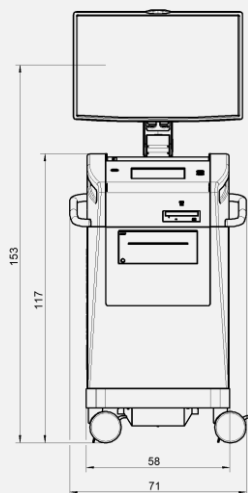


**Ziehm Vision RFD 3D
(Monitor Cart)**



All dimensions in cm.

Ziehm Vision RFD 3D
(Monitor Cart with Articulating Monitor Arm)



All dimensions in cm.

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