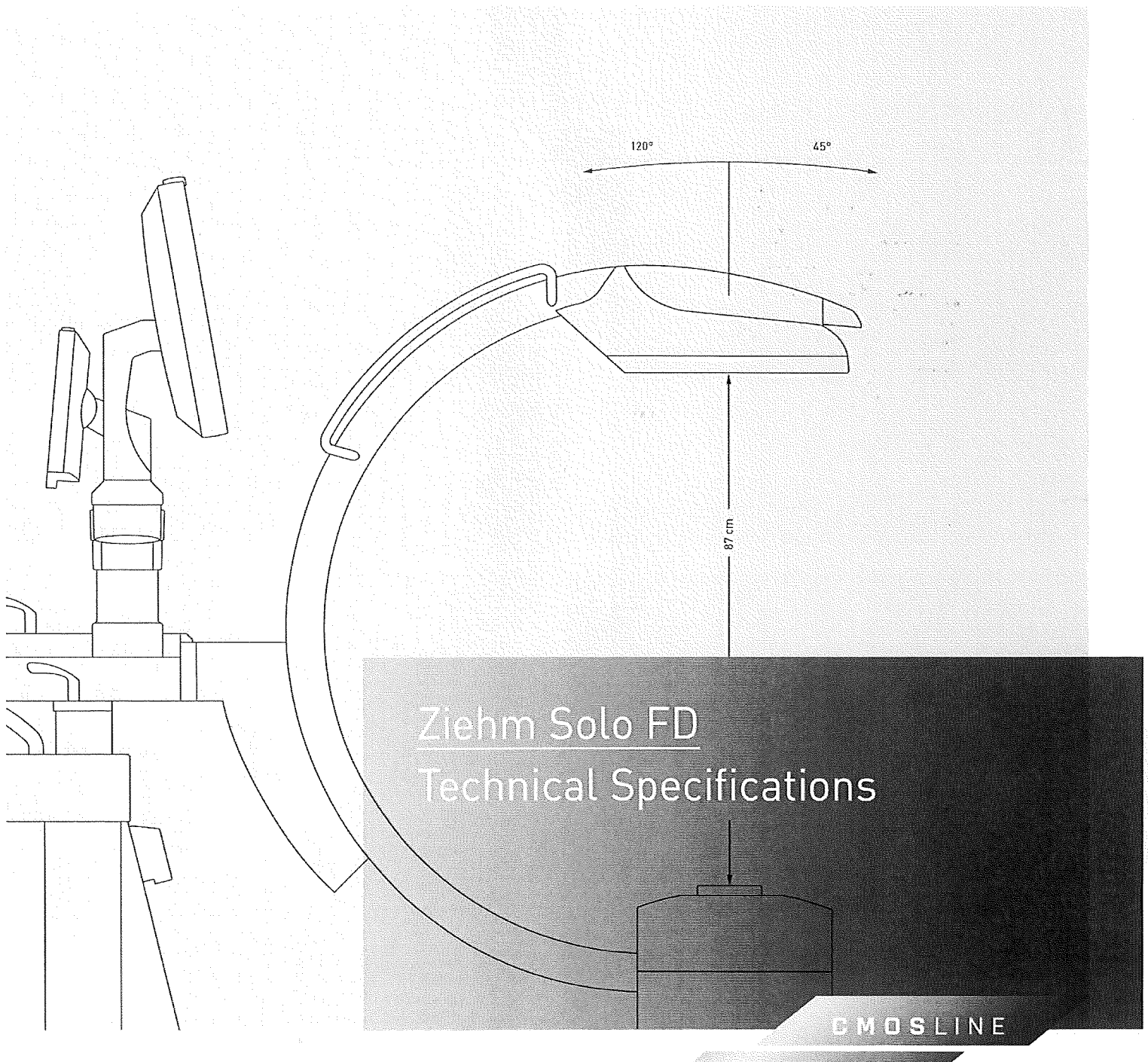


Anexo n.º 3



Ziehm Solo FD
Technical Specifications

CMOSLINE

C-ARM MOBILE STAND

Dimensions and Mechanics

- Motor-driven vertical travel: 42 cm
- Horizontal travel: 22 cm
- Orbital rotation: -120° / $+45^{\circ}$
- Angulation: $\pm 225^{\circ}$
- Swiveling (panning): $\pm 10^{\circ}$
- Source-image receptor distance: 109 cm
- C-arm vertical free space: 87 cm
- C-arm depth: 68 cm
- Width: 80 cm
- Length: 171 cm / 193 cm
- Height: 175 cm / 217 cm
- Weight C-arm mobile stand
(weight can vary depending on balancing
and configuration): 347 kg $\pm$ 3 %

Brakes

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

X-Ray Generator

- X-ray tube: stationary anode
- Single focus: 0.6 (IEC 60336)
- Max. anode heat content: 85 kHU / 60 kJ
- Max. anode heat dissipation: 600 W / 51 kHU/min
- Powered by integrated advanced heat management system
- 1.14 million HU system heat capacity
- 200 W / 17 kHU/min continuous heat dissipation in clinical performance
- Generator type:
 - monoblock
 - high-frequency generator
 - frequency: 40 kHz
 - microprocessor-controlled
- Nominal output (100 kV): 2.0 kW
- Maximum output: 2.4 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: 50-198 mm diameter
- Asymmetric slot collimator: 50-198 mm diameter
- Virtual collimation without radiation

Operating Values

- Continuous fluoroscopy:
 - kV range: 40-120 kV
 - mA range: 1.7-11 mA (200-240 V)
- Pulsed fluoroscopy:
 - kV range: 40-120 kV
 - mA range: 0.2-20 mA (200-240 V)
 - pulse width: 10-40 ms
 - pulse rate: 1, 2, 4, 8, 12.5, 25 pulses/s
- Digital radiography (snapshot):
 - kV range: 40-120 kV
 - mA: up to 24 mA

Output

- Pulsed fluoroscopy: 1.7 kW
- Digital radiography (snapshot): 2.0 kW

Flat-Panel Detector System

- Type: CMOS technology
- Scintillator: cesium iodide
- Pixel size: 100 μ m
- Grayscale: 65,536 gray scale values (16 bit)
- System resolution (Nyquist): 5 lp/mm
- Anti-scatter grid: 70 lines/cm; grid ratio 8:1
- Laser positioning device integrated in detector housing
- Auto calibration
- Removable grid (option)
- DQE: @ 0 lp/mm: 75 %
- MTF:
 - 1 lp/mm: 55 %
 - 2 lp/mm: 23 %
 - 3 lp/mm: 10 %
 - 4 lp/mm: 5 %
- Dynamic range:
 - 1x1 binning: 84 dB
 - 2x2 binning: 95 dB
- Frame rate: max. 30 frames/s

20.5 cm x 20.5 cm Flat-Panel

- Detector matrix:
 - overview format: 2,048 x 2,048 pixels
 - Mag. mode 1: 1,536 x 1,536 pixels
 - Mag. mode 2: 1,024 x 1,024 pixels

User Interface

Solo Center - TFT Touchscreen on Monitor Support Arm

- Intuitive icons for ease of use
- Resolution: 640 x 480 pixels
- Multi-lingual user interface
- Ziehm SmartEye live fluoro screen with SmartControl
- Emergency stop button
- X-ray button
- X-ray indication lamp
- SmartArchive

Remote Solo Center - Synchronized Touchscreen for Table Side Control (option)

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

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): 160° (with contrast ratio $\geq 20:1$)
 - tilt range: $\pm 10^\circ$
 - contrast ratio: typ. 1,000:1
 - brightness (panel): typ. 1,000 cd/m²
 - brightness (calibrated): ≥ 550 cd/m²
 - dimensions: 68 cm x 45 cm x 9 cm

Digital Image Processing

Real-Time Processing Functions

- Recursive filter: 4 levels (out of 16)
- Stack filter ('Last Image Hold'): 5 levels
- 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
- Vascular (option): Extremities
- Urology (option)

Additional Functions

- Metal
- Reposition
- Pediatric

Object Detected Dose Control (ODDC)

- Object detection
- Motion detection
- Automatic dose reduction
- Automatic metal correction

Image Acquisition

- Resolution: (max.) 4 lp/mm
- Autosave
- Cine loop with auto-playback (option):
 - sequential image storage and display:
 - 1 - 8 frames/s (option)
 - 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 (option)

Vascular Package (Option)

- DSA real-time subtraction with re-masking capability
- MSA max. opacification sequence
- Single frame, multiframe RSA (roadmapping)
- Pixel shift / landmarking

Anatomical Marking Tool - AMT (Option)

- Mark anatomical structures
- Indicate side of body

Digital Memory

- Storage capacity: 100,000 images
- Digital image processing: up to 32 bit

Data Organization

- Patient-based data management with 16-image mosaic display
- Pre-registration via DICOM Worklist (option)
- 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

- Printer (option): paper
- 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

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)

Electrical Requirements

- Power supply: 100-240 V_{AC} ($\pm 10\%$), 50/60 Hz
- Current consumption: 8 A continuous (200-240 V)
- Max. impedance: $\leq 0.6 \Omega$ (200-240 V)
- Class I equipment, Type B
- Security key switch (X-ray)
- Emergency stop button on the C-arm

Options

- Laser positioning device integrated in generator housing
- 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.
- Measured dose area product (DAP) with digital display
- Video connectors for external monitors:
 - DVI
 - analog
- Connector for external radiation lamp
- Additional handrails on the C for orbital rotation support
- Remote Solo Center TFT touchscreen
- Wireless Video Package: wireless transmission of the left /right image from the C-arm to external monitors
- Wireless multifunctional footswitch with programmable configuration
 - Also available with protection bar
- Power-on key switch

Accessories

- Disposable sterile covers

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 VIEWING STATION (Option)

Dimensions and Mechanics

- Width: 68 cm
- Depth: 64 cm
- Height: 175 cm
- Weight (weight can vary depending on configuration): 122 kg $\pm$ 8 %

Monitors

- High-brightness FullHD 27" split monitor (option):
 - screen size: 27" (69 cm)
 - native resolution: 1,920 x 1,080 pixels
 - viewing angle (horizontal and vertical): 178° (with contrast ratio $\geq$ 10:1)
 - contrast ratio : typ. 1,000:1
 - brightness (panel): $\geq$ 725 cd/m²
 - brightness (calibrated): $\geq$ 550 cd/m²
 - dimensions: 65 cm x 39 cm x 6 cm
- High-brightness and high-contrast 19" DUO monitor (option):
 - screen size: 2 x 19" (48 cm)
 - native resolution: 1,280 x 1,024 pixels
 - viewing angle (horizontal and vertical): 160° (with contrast ratio $\geq$ 20:1)
 - 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

Archiving

- Printer, mounted on viewing station (option):
 - paper and film
 - paper

MONITORS MOUNTED ON CEILING SUPPORT (Option)

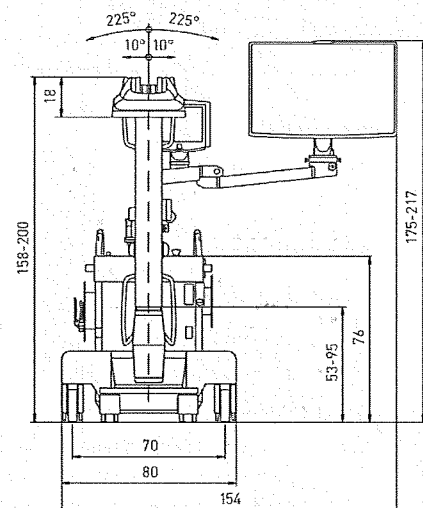
Mechanics

- Mounting: VESA 100 (for 19" DUO monitor)
- Mounting on existing ceiling support systems (verifiable calculations to be done by the customer)

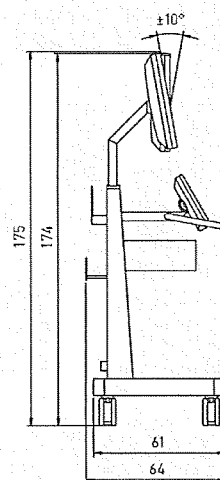
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Technical drawing of the mobile stand showing dimensions in mm. The drawing includes a side view and a front view. Dimensions are: 111, 109, 87, 35, 68, 16, 40-63, 171-193, 219-241, 92-134.



Technical drawing of the 'Lectura de Datos' (Data Reading) station. The drawing shows a vertical stand with a monitor at the top, a control panel in the middle, and a base with two wheels. Dimensions are indicated: 68 cm for the monitor width, 152 cm for the total height, 94 cm for the height to the control panel, and 58 cm for the base width.



All dimensions in cm.

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