

# Ziehm Solo Ziehm Solo FD

Operating Instructions

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#### **Imprint**

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#### **Preface**

With Ziehm Solo and Ziehm Solo FD, Ziehm Imaging GmbH provides an active medical device connected to the mains power supply. The medical device is designed for contactless use. It does not require any contact with the patient to perform its intended use. It provides contactless energy in the form of X-rays.

Ziehm Imaging GmbH authorizes only trained and skilled personnel to operate this medical device. The system is intended for use by health care professionals such as physicians, orthopedic surgeons, vascular surgeons, neurovascular surgeons, cardiologists, radiologists and technologists in hospitals, outpatient clinics and other clinical environments.

Ziehm Imaging GmbH anticipates the system will be used on a nearly daily basis. Ziehm Imaging GmbH applications specialists and/or qualified site personnel provide on-site operator training in the proper use of the system.

#### Ziehm Solo Option Portable details

The Ziehm Solo Option Portable is a Ziehm Solo option allowing disassembly for transporting purposes. This system version is recommended in cases, in which the disassembly of the unit may be required due to transport requirements. The unit can be taken apart at the joints described by this document to allow disassembly into single components for transporting purposes. Further, there is a version type equipped with large transport wheels, which can be removed after transport.

#### Intended use

The system is a mobile C-arm providing image data by means of a non-invasive x-ray technique during medical procedures and stores them temporarily.

### Supplemental directives

The system can be used for all medical indications where fluoroscopy is required.

The system is intended for use with human beings of any age. It is the physician's responsibility to decide whether to use the system with infants, children and adipose patients.

The system is intended for use with human bodies covering structures such as but not limited to the following, e.g. organs, tissue, bones, implants depending on the medical indication.

This device is not intended for use in performing mammographic exposures.

#### Normal use

The system provides contactless fluoroscopy and according to this does not have applied parts.

The system may only be used in heights up to 6561.7 ft (2000 m) above sea level and must be used within the limits defined by the technical specification. The use of the system is only allowed in rooms used for medical purposes in accordance with EMC class A as well as with protective earth conductor. The system may only be used in an environment with an oxygen saturation of < 25%.

The system must be maintained regularly according to the maintenance procedures by qualified personnel authorized by Ziehm Imaging GmbH. The system may only be used in faultless condition and in accordance with the terms set forth by the Operating Instructions.

# Prescription use (USA)

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

#### Dose reduction disclaimer (USA)

In clinical practice, the use of SmartDose may reduce patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

#### Operation

Only trained and instructed qualified personnel are allowed to operate the system.

#### Operation (USA)

According to federal laws the system may only be operated by properly trained personnel under the direction of a physician.

#### Authorized personnel

Only authorized personnel are allowed to assemble the medical equipment described in this document, to put it into service, to install, to maintain and to repair it.

Authorized personnel are persons who have attended an appropriate training course provided by the manufacturer.

#### **Training**

Users and operators must have been instructed adequately in operating the system safely and efficiently, before attempting to operate the system described herein. Training requirements for this system may vary from country to country. Owners must ensure that users and operators receive adequate training in accordance with applicable laws or regulations.

# Contraindications to the use of X-rays

The exposure of humans to ionizing radiation must always be medically justified. Especially when used on pregnant women, adolescents, children, and pediatric patients, all procedures using ionizing radiation should be used with caution or be avoided altogether. However, the final decision lies with the attending physician or attending surgeon.

The monitors are suitable for fluoroscopic diagnostic imaging purposes but do not provide pre-evaluated diagnoses data.

#### Exclusion of liability

The manufacturer accepts responsibility for the safety, reliability and performance of the system only if

- any installation, modification or repair work is carried out exclusively by persons authorized by the manufacturer;
- the electrical installation of the site where the system is operated complies with the requirements of VDE 0107 or the corresponding national regulations of the country of installation;
- only original spare parts or components that comply with specifications determined by Ziehm Imaging GmbH are used;
- the system is used in accordance with the Operating Instructions.

The warranty becomes invalid in case that any repair, modification or installation work is carried out by unauthorized personnel, or any seals on components are broken. No consequential damages will be accepted either.

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The equipment conforms to Class IIb according to Council Directive 93/42/EEC.

This document has been written and reviewed originally in German and translated.

# **Supplemental directives**

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### 1 General Information

#### **Target group**

This document addresses to trained and skilled personnel. The aim is to enable owners and operators to operate the system described herein safely and efficiently.

# Scope of validity of this document

This document applies to Ziehm Solo and Ziehm Solo FD, software version 7.06 or higher.

All illustrations in this manual are exemplary only, and may differ from the actual situation.

This document describes a system with maximum configuration. Due to customer-specific system configuration or country-dependent approval restrictions the system may not contain all options and functions described here. In this case, concerned descriptions do not apply to the system. Consequently, please ignore those contents.

# Separate operating instructions

For several system options, separate operating instructions may be available. You will find a corresponding reference to those operating instructions in the relevant sections of this document.

# Environmental compatibility

The system does not produce any waste during operation.

When the system has reached the end of its useful service life, the relevant waste disposal regulations of the country of installation must be observed.

Ziehm Imaging GmbH takes back your devices and undertakes to dispose of them appropriately in accordance with national regulations. If you want to return a device, contact the Service department of Ziehm Imaging GmbH.

# Life cycle / Spare parts supply

The useful service life defined for this medical device is seven years. For this period and beyond, up to a time frame of 10 years, Ziehm Imaging GmbH ensures that spare parts can be supplied after product discontinuation. Due to technical progress, Ziehm Imaging GmbH reserves the right to check whether the technology used is appropriate, and if applicable, ensures to provide compatible alternative solutions.

### 1.1 Typographical conventions

In this document, the following notations and formats are used to highlight certain elements of the Solo Center control panel or the documentation itself: Conventions for safety instructions

Element	Format	Example
Solo Center elements (buttons, tabs and boxes), operating modes, functions	Bold	Fluoro
Cross-references	Italic, preceded by an arrow	→ Chapter 19 "Configuration" on page 301
Procedure steps	Numbered Intermediate results are preceded by an arrow icon	→ Chapter 19.2.1 "Autotransfer" on page 302
Text input	Courier, bold	Administrator

Table 1: Notations and formats used in this document

### 1.2 Conventions for safety instructions

The present document does not constitute a complete catalog of all safety measures necessary for the operation of the respective medical equipment, since special operating conditions may require further measures. However, it does contain instructions which must be observed in order to ensure the personal safety of operating staff and patients as well as to avoid damage to property. These instructions are highlighted as follows:

#### A DANGER DANGER



DANGER indicates a hazardous situation which, if not avoided, will result in death or serious injury.

#### WARNING WARNING

CAUTION



WARNING indicates a hazardous situation which, if not avoided, may result in death or serious injury.

#### **▲** CAUTION



CAUTION indicates a hazardous situation which, if not avoided, may result in minor or moderate injury.

Conventions for norm naming

#### NOTICE NOTICE

NOTICE indicates a property damage message.



#### NOTE

Notes are merely informative. Additional useful information and hints are provided for the operator here.

# Conventions for norm naming



#### NOTE

This document uses the term IEC 60601 to identify all relevant national norms based on IEC 60601.

# Conventions for labeling of figures

This document contains figures labeled by numbers. The numbers are explained in the adjacent text or by means of a caption visualized as a table. The numbers are indicated as (X).

If a caption refers to multiple figures you find a special note.

# **1 General Information**

Conventions for labeling of figures

# 2 System Information

### 2.1 System configuration

### 2.1.1 System versions

Depending on the system version, your system contains the following features:

#### Ziehm Solo

	Generator in kW	Flatscreen type
With monitor support arm	2.0	27" High-Brightness Full HD
With Viewing Station	2.0	27" High-Brightness Full HD
With externally mounted monitors	2.0	27" High-Brightness Full HD

#### Ziehm Solo FD

	Generator in kW	Flatscreen type
With monitor support arm	2.4	19" DUO
With Viewing Station	2.4	19" DUO
With externally mounted monitors	2.4	27" High-Brightness Full HD

#### Ziehm Solo Option Portable (M2)

	Generator in kW	Flatscreen type
With monitor support arm	2.0	19" DUO

The Ziehm Solo Option Portable and Ziehm Solo Option Portable M2 (USA only) are the versions allowing disassembly. It is equipped with 19" DUO flat-screen monitor and additional C-arm handles.

The system can be disassembled into the following individual components:

Ziehm Solo Option Portable	Ziehm Solo Option Portable M2
C-arm	Mobile stand
Mobile stand	Monitor head with 19" flatscreen monitors
Detachable C-arm stand foot	
Monitor head	

System configuration > Basic configuration

Ziehm Solo Option Portable	Ziehm Solo Option Portable M2
Monitor support arm with Solo Center	
Horizontal carriage	

### 2.1.2 Basic configuration

By default, your system contains the following features and functions:

#### Hardware

- Mobile stand
- Hand switch
- Two-pedal foot switch
- Control panel
- · Advanced Heat Management
- Hand rail at the image receptor
- Laser positioning device in the flat-panel detector
- · Color-coded brake handles and scales
- EMERGENCY STOP push button on the mobile stand
- · Memory capacity for 100,000 images
- X-ray key switch
- · USB 3.0 interface
- Full HD SDI video connection (split display)

#### **Software**

- SmartEye with SmartControl
- Electronic image magnification PreMag
- Object Detected Dose Control (ODDC)
- Low Dose function for pediatric applications
- Application-specific anatomical programs
- Calculation of dose area product and air kerma
- · Virtual collimator
- ZAIP-Filter (for systems with flat-panel detector only)
- Patient annotation function
- Mosaic view
- Post-processing
- SmartArchive function (Ziehm Solo FD only)
- · Real-time image-processing
- Ziehm NetPort DICOM Package Plus (incl. DICOM 3.0 interface)
   (Ziehm Solo FD only)
  - Storage Class including multiframe capability
  - Storage Commitment Class
  - Media Class
  - Worklist Class
  - MPPS Class
  - Query Class
  - Verification Class

- DICOM Viewer (MicroDicom) (Ziehm Solo FD only)
- Application Plus Package (Ziehm Solo FD only)

### 2.1.3 Options

This document describes a system with maximum configuration. The system configuration you have chosen may not contain all options and functions described here.

#### **Hardware options**

- Option Portable
- Option Portable M2
- 120 kV option
- Viewing Station (see corresponding operating instructions)
- Dose meter for measuring the dose area product (n/a for USA)
- Laser positioning device on the generator and/or image receptor
- Key switch Power on/off (replaces key switch X-ray on/off)
- Connection for external separate radiation indication lamp (including software)
- DVD writer
- Removable anti-scatter grid
- Video printer for printout on paper
- Video printer for printout on paper or transparent film (only available with Viewing Station)
- External 60 Hz video connection
- Additional video connections for external flatscreen monitors (right and left monitor), optionally with
  - analog signal (BNC sockets)
  - digital signal (DVI sockets)
- 19" DUO flatscreen monitor (default for Ziehm Solo Option Portable / Ziehm Solo Option Portable M2)
- External 19" DUO flatscreen monitor
- External 27" flatscreen monitor (single screen)
- NaviPort 2D (only with DICOM 3.0 interface)
- Additional handles for orbital rotation at the C-arm (default for USA)
- Wheels with 90 mm floor clearance (USA only) (default for Ziehm Solo Option Portable M2)
- Customer-specific foot switch configuration
- Dual Plus foot switch
- · Wireless Dual Plus foot switch
- · Wireless Dual Plus foot switch (with protective bracket)
- · Wireless Video
- WLAN

#### Software options

- Application Plus Package (Ziehm Solo only)
- Vascular Package
- Subtraction mode: DSA

System configuration > Ziehm Solo Option Portable M2 options

- · Cine loop with up to
  - 8 frames per second (at 50 Hz)
  - 10 frames per second (at 60 Hz)
  - 25 frames per second (Ziehm Solo FD only)
- · Measuring functions
- Ziehm NetPort DICOM Package Plus (incl. DICOM 3.0 interface) (for systems with image intensifier only)
  - Storage Class including multiframe capability
  - Storage Commitment Class
  - Media Class
  - Worklist Class
  - MPPS Class
  - Query Class
  - Verification Class
- Ziehm NetPort DICOM Package Advance (incl. DICOM 3.0 interface)

Corresponds to Ziehm NetPort DICOM Package Plus. Additionally, the following DICOM classes are supported:

- Print Class
- Query/Retrieve Class
- DICOM Viewer (MicroDicom) (Ziehm Solo only)
- SmartArchive function (Ziehm Solo only)
- Radiography operating mode (for systems with image intensifier only)
- User administration (HIPAA)
- Anatomical Marking Tool (AMT)

### 2.1.4 Ziehm Solo Option Portable options

The system can be equipped with options described in  $\rightarrow$  Chapter 2.1.3 "Options" on page 21 (Exception: additional handles for orbital rotation at the C-arm).

Additionally the following options can be selected as desired:

- · Transport wheels
- Field transport set
- Field transport boxes

#### 2.1.5 Ziehm Solo Option Portable M2 options

The system can be equipped with options described in  $\rightarrow$  Chapter 2.1.3 "Options" on page 21 (Exception: additional handles for orbital rotation at the C-arm).

Additionally the following options can be selected as desired:

· Transport wheels

System configuration > X-ray protective equipment

### 2.1.6 Optional accessories

The following accessories are optionally available for the system:

- Sterile disposable drapes (see corresponding operating instructions)
- Universal film cassette holder (n/a for Germany)
- · Interface for Remote Solo Center
- Remote Solo Center (accessorial control panel) (see corresponding operating instructions)
- · Skin protection

### 2.1.7 X-ray protective equipment

We recommend that you use the following X-ray protective equipment:

- X-ray protective apron
- X-ray protective eyewear
- · Thyroid collar
- · X-ray protective gloves

# 2.2 Parts of the system

#### 2.2.1 Mobile stand

Mobile stand, side view (right)

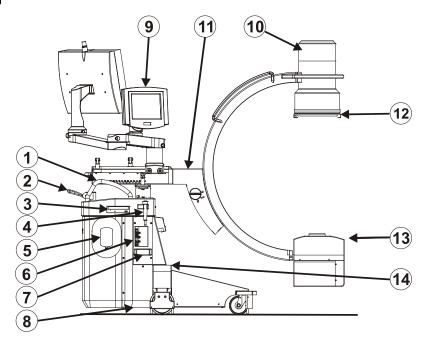


Fig. 1: Mobile stand with monitor support arm, side view (right)

- 1 Handle
- 2 Steering & braking lever
- 3 DVD writer
- 4 Hand switch
- 5 Support for foot switch
- 6 Interface panel
- 7 Coupling cable connection (Viewing Station / Remote Solo Center)
- a if required by norm

- 8 Cable guards
- 9 Solo Center control panel
- 10 Image intensifier with integrated CCD camera
- 11 Horizontal carriage
- 12 Cassette holder
- 13 Generator
- 14 Skin protection resting position<sup>a</sup>

#### Mobile stand side view (left)

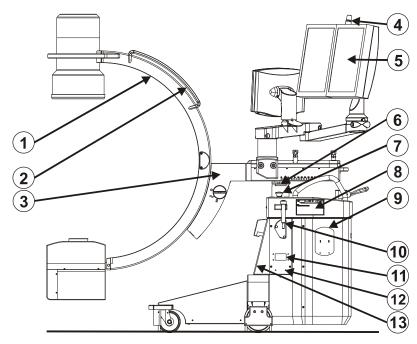


Fig. 2: Mobile stand with monitor support arm, side view (left)

- C-arm
- 2 C-arm handles
- 3 Swivel arm
- Radiation indication lamp
- 5 Flatscreen monitors
- Lifting column
  EMERGENCY STOP push button
- Video printer
- Cable support
- 10 Hand switch
- 11 Power supply connection
- 12 Equipotential grounding
- 13 Circuit breaker

Ziehm Solo with Solo Center support arm, side view (right)

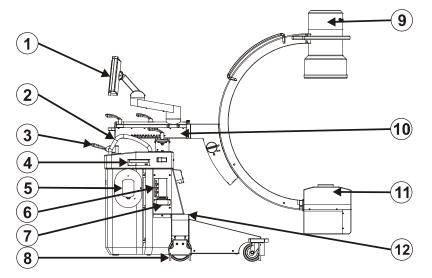


Fig. 3: Mobile stand with Solo Center support arm, side view (right)

- 1 Solo Center control panel
- 2 Handle
- 3 Steering & braking lever
- 4 DVD writer
- 5 Support for foot switch
- 6 Interface panel
- 7 Coupling cable connection (Viewing Station / Remote Solo Center)
- <sup>a</sup> if required by norm

- 8 Cable guards
- 9 Image intensifier with integrated CCD camera
- 10 Horizontal carriage
- 11 Generator
- 12 Skin protection resting position<sup>a</sup>

Ziehm Solo with Solo Center support arm, side view (left)

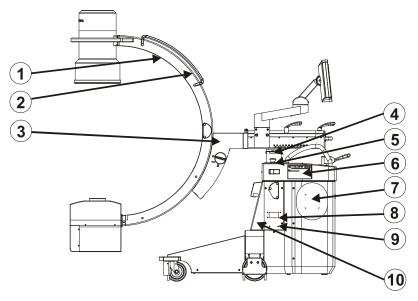


Fig. 4: Mobile stand with Solo Center support arm, side view (left)

- 1 C-arm
- 2 C-arm handles
- 3 Swivel arm
- 4 Lifting column
- 5 EMERGENCY STOP push button
- 6 Video printer
- 7 Cable support
- 8 Power supply connection
- 9 Equipotential grounding
- 10 Circuit breaker

#### Mobile stand Ziehm Solo FD, side view (right)

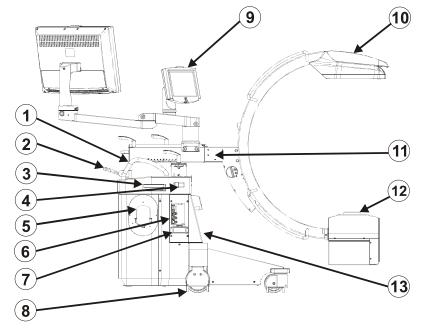


Fig. 5: Mobile stand with monitor support arm, side view (right)

- 1 Handle
- 2 Steering & braking lever
- 3 DVD writer
- 4 Hand switch
- 5 Support for foot switch
- 6 Interface panel
- Coupling cable connection (Vision Center / Remote Solo Center)
- a if required by norm

- 8 Cable guards
- 9 Solo Center control panel
- 10 Flat-panel detector
- 11 Horizontal carriage
- 12 Generator
- 13 Skin protection resting position<sup>a</sup>

**Mobile stand Ziehm** Solo FD, side view (left)

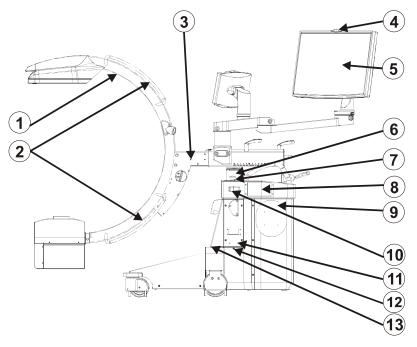


Fig. 6: Mobile stand with monitor support arm, side view (left)

- 1 C-arm
- C-arm handles 2
- Swivel arm
- Radiation indication lamp
- 5 Flatscreen monitors
- Lifting column
- EMERGENCY STOP push button
- 8 Video printer
- Cable support
- 10 Hand switch
- 11 Power supply connection12 Equipotential grounding
- 13 Circuit breaker

Ziehm Solo FD with Solo Center support arm, side view (right)

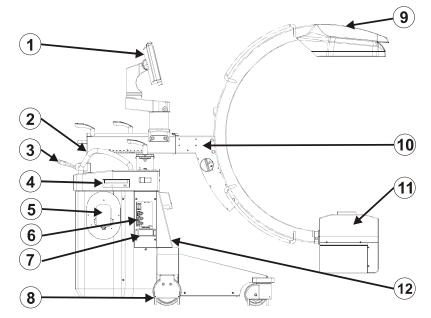


Fig. 7: Mobile stand with Solo Center support arm, side view (right)

- Solo Center control panel
- Handle
- 2 Steering & braking lever
- DVD writer
- Support for foot switch
- Interface panel
- Coupling cable connection (Viewing Station / Remote Solo Center)
- <sup>a</sup> if required by norm

- Cable guards
- Flat-panel detector
- 10 Horizontal carriage
- 11 Generator
- 12 Skin protection resting positiona

Ziehm Solo FD with Solo Center support arm, side view (left)

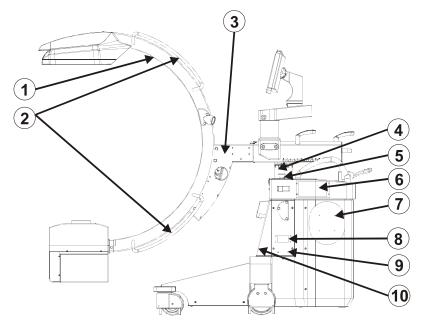


Fig. 8: Mobile stand with Solo Center support arm, side view (left)

- 1 C-arm
- 2 C-arm handles
- 3 Swivel arm
- 4 Lifting column
- 5 EMERGENCY STOP push button
- 6 Video printer
- 7 Cable support
- 8 Power supply connection
- 9 Equipotential grounding
- 10 Circuit breaker

#### **Ziehm Solo Option** Portable, side view (right)

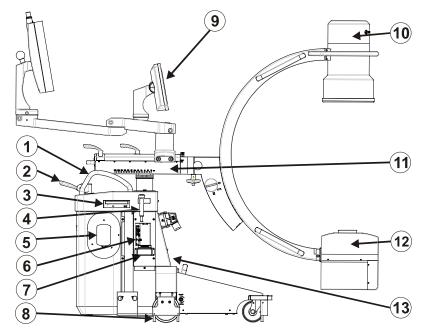


Fig. 9: Mobile stand, side view (right)

- Handle
- Steering & braking lever DVD writer
- 3
- Hand switch
- Support for foot switch
- Interface panel
- Coupling cable connection (Viewing Station / Remote Solo Center)
- a if required by norm

- Cable guards
- Solo Center control panel
- 10 Image intensifier with integrated CCD camera
- 11 Horizontal carriage
- 12 Generator
- 13 Skin protection resting positiona

#### Ziehm Solo Option Portable, side view (left)

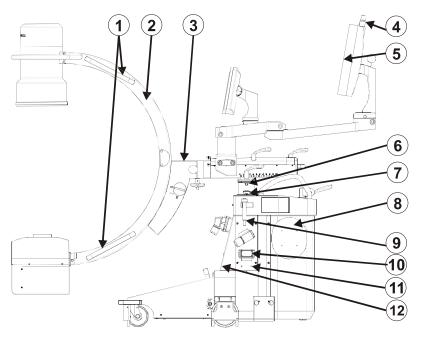


Fig. 10: Mobile stand, side view (left)

- 1 C-arm handles
- 2 C-arm
- 3 Swivel arm
- 4 Radiation indication lamp
- 5 Flatscreen monitors
- 6 Lifting column
- 7 EMERGENCY STOP push button
- 8 Cable support
- 9 Hand switch
- 10 Power supply connection
- 11 Equipotential grounding
- 12 Circuit breaker

Increased floor clearance (USA only)

The system can be equipped with larger wheels allowing a floor clearance of 90 mm.

Larger wheels for increased floor clearance are not available for Ziehm Solo Option Portable.

Ziehm Solo Option Portable M2 is equipped with larger wheels for increased floor clearance.

#### Ziehm Solo

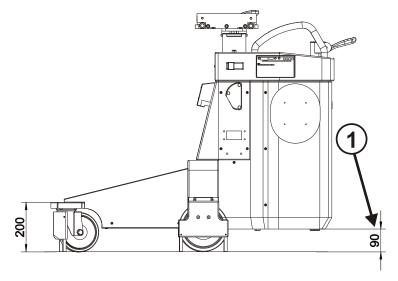


Fig. 11: Wheels for increased floor clearance (1)

### Ziehm Solo Option Portable M2

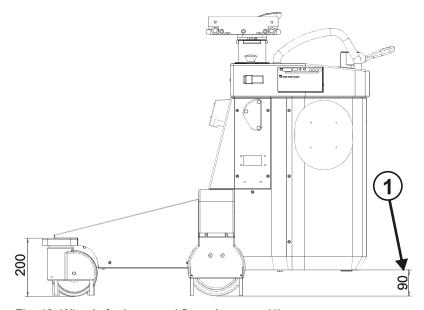


Fig. 12: Wheels for increased floor clearance (1)

# Connections on the mobile stand

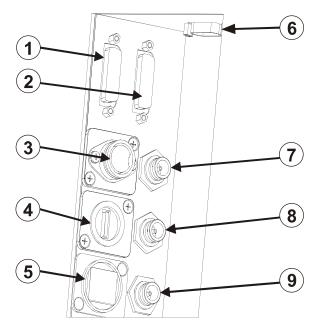


Fig. 13: Detailed view interface panel (example)

- 1 VIDEO OUT DVI / LM
- 2 VIDEO OUT DVI / RM
- 3 Connection for external radiation indication lamp
- 4 USB port
- 5 DICOM connection (RJ-45)
- 6 SERCAN connection
- 7 VIDEO OUT 1 LM or split screen
- 8 VIDEO OUT 2 RM
- 9 VIDEO OUT

# Equipotential grounding

Your system is equipped with a plug connection for equipotential grounding, e.g. with a hospital bed.

In addition, a screw connection for equipotential grounding (equipotential grounding 2) is available.

# WLAN on the mobile stand

If your system is equipped with WLAN, a transceiver is integrated into the mobile stand. If necessary, the other transceiver is supplied with your accessories and must be connected to the hospital's DICOM network.

Parts of the system > Individual components (Ziehm Solo Option Portable)

# 2.2.2 Individual components (Ziehm Solo Option Portable)

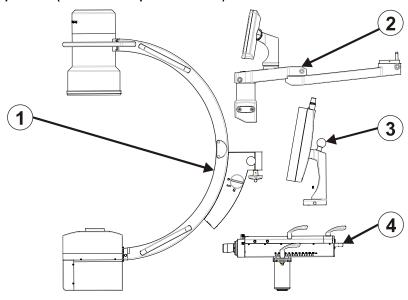


Fig. 14: Individual components (example)

- 1 C-arm
- 2 Solo Center on the monitor support arm
- 3 Monitor head
- 4 Horizontal carriage

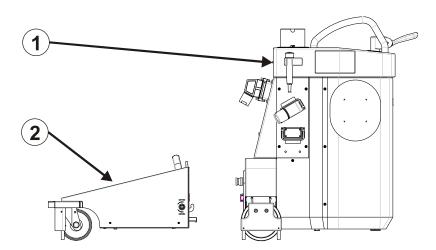


Fig. 15: Mobile stand (1) and stand foot (2)

## 2.2.3 Individual components (Ziehm Solo Option Portable M2)

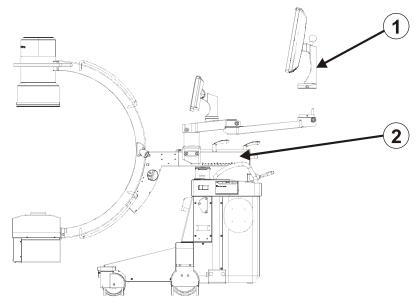


Fig. 16: Individual components

1 Monitor head

2 Mobile stand

#### 2.2.4 Screen assignment

# Live and reference screen

By default, the live screen function has been assigned to the left screen, and the reference screen function to the right screen.

During operation, the following images will be displayed on the screens:

- Live screen: Live images and saved images, both at full size
   While the radiation indication lamp is illuminated, you always see a live image.
- · Reference screen: Thumbnail mosaic, reference images at full size



### **NOTE**

To avoid confusion, the neutral terms 'live screen' and 'reference screen' are used throughout this document, regardless of your custom setting.

### Last Image Hold

When you terminate radiation, a composite image made up of 1 to 16 individual images (LIH – Last Image Hold) is displayed on the live screen. The amount of images that are used for computing the LIH depends on the selected anatomical program. The default values are preset in the anatomical programs. You can modify these settings using the LIH filter controls.

## 2 System Information

Parts of the system > Video inputs and outputs

The kV and mA values that are displayed on the user interface are the values set by the system upon termination of radiation emission. The number that appears under **LIH** on the screen indicates how many individual images have been used for computing the LIH ( $\rightarrow$  Chapter 16.2.3 "Lower left corner of the screen" on page 282).

# Changing the screen settings

You can change the screen assignment in the **Configuration** operating mode under **Basic settings** ( $\rightarrow$  Chapter 19.3.2 "Selecting the live screen" on page 310).

You can also set the contrast and brightness of the flatscreen monitors according to your preferences.

### 2.2.5 Video inputs and outputs

The connections for video inputs and outputs are located at the rear of the mobile stand ( $\rightarrow$  "Mobile stand, side view (right)" on page 24).

#### **VIDEO OUT**

The VIDEO OUT SDI socket in the interface panel supplies a digital video signal of the live screen and the reference screen image.

The VIDEO OUT BNC socket in the interface panel supplies a CCIR video signal of the live screen image.

The fluoroscopic image (live or stored) is available there for further processing by external recording devices, external monitors, video printers, etc.

### **VIDEO OUT 1 LM**

The VIDEO OUT 1 LM BNC socket in the interface panel supplies a video signal of the left screen image. A second flatscreen monitor supplied by Ziehm Imaging GmbH can be connected to this image memory output.

#### **VIDEO OUT 2 RM**

The VIDEO OUT 2 RM BNC socket in the interface panel supplies a video signal of the right screen image. A second flatscreen monitor supplied by Ziehm Imaging GmbH can be connected to this image memory output.

#### VIDEO OUT DVI 1/LM

The VIDEO OUT DVI 1/LM socket in the interface panel supplies a digital video signal of the left screen image. A second flatscreen monitor complying with SXGA Standard (60 Hz, 1280 × 1024 pixels) can be connected to this image memory output.

#### VIDEO OUT DVI 2/RM

The VIDEO OUT DVI 2/RM socket in the interface panel supplies a digital video signal of the right screen image. A second flatscreen monitor complying with SXGA Standard (60 Hz, 1280 × 1024 pixels) can be connected to this image memory output.

## 2.2.6 Removable anti-scatter grid

#### 2.2.6.1 Ziehm Solo

The system's image intensifier is equipped with an externally visible, removable anti-scatter grid. When using a suitable application, the anti-scatter grid can be removed, so the patient input dose can be reduced significantly. Independent from using the anti-scatter grid, for voltage values up to 60 kV you can achieve similar image quality. Especially in pediatrics you can achieve remarkably lower radiation with similar image quality by removing the anti-scatter grid.



#### **ACAUTION** CAUTION

Risk to the patient

Do not remove or attach the anti-scatter grid above the patient.

# To remove the anti-scatter grid from the image intensifier, do the following:

1. Rotate the C-arm to the zero position.



Fig. 17: Attached anti-scatter grid (view from above)

Parts of the system > Removable anti-scatter grid

- 2. Consecutively push the lock slides (2) at the image intensifier outwards until the red signal bars become visible. Press the antiscatter grid (1) firmly against the image intensifier.
  - ⇒ The anti-scatter grid is unlocked.

#### **ACAUTION** CAUTION



Anti-scatter grid damage!

Ensure the anti-scatter grid does not drop down while attaching or removing it.

- 3. Let the anti-scatter grid lightly tilt down at the side of the lock slides (2) and pull it from the recess.
  - A labeling becomes visible in the recess, indicating that the anti-scatter grid has been removed.



#### CAUTION



Risk of injury!

The anti-scatter grid may drop down.

Ensure that the anti-scatter grid is securely locked to prevent it from dropping.

### Repository

For storage keep the anti-scatter grid in a safe place in the close proximity.

# To attach the anti-scatter grid to the image intensifier, do the following:

**1.** Push the lock slides (1) at the image intensifier outwards.



Fig. 18: Anti-scatter grid attachment

- 2. Hold the anti-scatter grid such that the recess marked in white (2) shows towards the pin (3) located on the supporting ridge of the image intensifier. On the opposite side of the anti-scatter grid the red signal bars (4) must be visible.
- Insert the anti-scatter grid in the direction of the pin exactly into the provided recess and keep it pressed against the image intensifier.
- **4.** Consecutively push the two lock slides (1) with your free hand in the direction of the anti-scatter grid until they engage.
  - ⇒ The red signal bars on the anti-scatter grid are hidden. The anti-scatter grid is attached.



#### **ACAUTION** CAUTION

Risk of injury!

The anti-scatter grid may drop down.

Ensure that the anti-scatter grid is securely locked to prevent it from dropping.

Parts of the system > Removable anti-scatter grid

#### 2.2.6.2 Ziehm Solo FD

The system's flat panel detector is equipped with an externally visible, removable anti-scatter grid. When using a suitable application, the antiscatter grid can be removed, so the patient input dose can be reduced significantly. Independent from using the anti-scatter grid, for voltage values up to 60 kV you can achieve similar image quality. Especially in pediatrics you can achieve remarkably lower radiation with similar image quality by removing the anti-scatter grid.

### **ACAUTION** CAUTION



Risk to the patient

Do not remove or attach the anti-scatter grid above the patient.

### To remove the anti-scatter grid from the flat-panel detector, do the following:

Rotate the C-arm to the zero position.

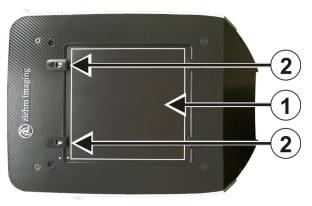


Fig. 19: Attached anti-scatter grid (view from above)

- Consecutively push the lock slides (2) at the flat-panel detector outwards until the red signal bars become visible. Press the antiscatter grid (1) firmly against the flat-panel detector.
  - The anti-scatter grid is unlocked.

## **ACAUTION** CAUTION



Anti-scatter grid damage!

Ensure the anti-scatter grid does not drop down while attaching or removing it.

- Let the anti-scatter grid lightly tilt down at the side of the lock 3. slides (2) and pull it from the recess.
  - A labeling becomes visible in the recess, indicating that the anti-scatter grid has been removed.

Parts of the system > Removable anti-scatter grid

### Repository

For storage keep the anti-scatter grid in a safe place in the close proximity.

#### To attach the anti-scatter grid to the flat-panel detector, do the following:

1. Push the lock slides (2) at the flat-panel detector outwards until the red signal bars become visible.

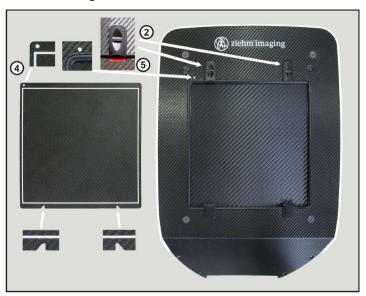


Fig. 20: Anti-scatter grid attachment

- 2. Hold the anti-scatter grid in such a way that the direction marking (4) points to the corresponding marking (5) at the flat-panel detector.
- 3. Insert the anti-scatter grid in the direction of the locking lugs exactly into the provided recess and keep it pressed against the flat-panel detector.
- Consecutively push the two lock slides (2) with your free hand in the direction of the anti-scatter grid until they engage.
  - ⇒ The red signal bars on the anti-scatter grid are hidden and the anti-scatter grid is attached.



Risk of injury!

The anti-scatter grid may drop down.

Ensure that the anti-scatter grid is securely locked to prevent it from dropping.

Parts of the system > Skin protection

#### 2.2.7 Skin protection

To keep the radiation burden of the patient as low as possible, you must keep the source/skin distance as large as possible. If required by norm, use the skin protection to ensure a minimum source/skin distance of 30

You can easily attach the skin protection to the generator top cover using a bayonet mount.

To attach the skin protection to the generator, do the following:

# **ACAUTION** CAUTION

Do not remove or attach the skin protection above the

- Place the skin protection on the generator top cover in a way that the pins are located directly above the recesses of the skin protection.
- 2. Press the skin protection onto the pins until it rests firmly on the generator top cover.
- 3. Turn the skin protection in clockwise direction to the limit stop.
  - ⇒ The skin protection is attached to the generator.



Fig. 21: Generator with attached skin protection (1)

Parts of the system > Skin protection

### To remove the skin protection from the generator, do the following:

- **1.** Turn the skin protection in counter-clockwise direction until the pins are located directly above the recesses.
- 2. Remove the skin protection.

## **Resting position**

For the resting position of the skin protection, refer to the figures of the system components.

The attachment corresponds to the one on the generator top cover.

2 System Information	
Parts of the system > Skin protection	

## 3 Regulatory Requirements

## 3.1 Classification of image display systems

DIN 6868-157 (Germany only)

In order to use monitors as image display systems of a certain application category, you must inspect them according to the legal regulations of DIN 6868-157.

For the use of image display systems within the scope of medical imaging, the legal regulations of DIN 6868-157 determine the following classifications:

- Image display systems suitable for diagnostic purposes
- · Image display systems suitable for viewing purposes

For this reason, the regulation uses room classifications, depending on the most demanding tasks usually to be performed there.

The room classification is performed by the radiation protection officer of the medical facility. The following table shows the classification depending on C-arm system and image display system (flatscreen type).

System	Flatscreen type			
	19" DUO	26"	27" Standard Full HD	27" High-Brightness Full HD
Vision / FD / R	•	•		
Vision FD Vario (3D)	•			
Vision RFD	•	•		
Vision RFD 3D	•			
Solo	•			•
Solo FD	•			•
Solo Portable (M2)	•			
Viewing Station	•			•
8000	0		0	

Table 2: Classification of C-arm system and image display system

## 3 Regulatory Requirements

Classification of image display systems

## Legend

The used image display systems fully comply with the requirements of the legal regulations of DIN 6868-157 and meet room classification 2 (examination rooms with

- immediate diagnostics) or room classification 3 (examination rooms limited to performing examinations). The image display systems are suitable for diagnostic purposes.
- The used image display systems meet room classification 4. For this reason, they are limited to tasks, such as tracking a known and assessed medical finding repetitively (e.g. repositioning in the operation room, pedicle screw removal in the emergency surgery etc.). The image display systems are suitable for viewing purposes.

#### Safety Instructions 4

## **General safety instructions**

#### AWARNING WARNING



You must be familiar with the contents of this document in order to be able to operate the system as intended. Study this document thoroughly before operating the system.

It is important to observe all directions, safety instructions and warnings!

The responsibility for any C-arm-assisted medical measures lies with the physician in charge.

#### NOTICE NOTICE

A combination of the system with third-party components is limited to those explicitly authorized for use by Ziehm Imaging GmbH (  $\rightarrow$  Chapter 21 "Appendix B" on page 379). A combination must be covered in particular by the intended use of the two devices.

If you combine the system with unauthorized equipment, the safety of the entire system is no longer given and the warranty will become invalid.

#### Operation

Only trained and instructed qualified personnel are allowed to operate the system.

#### Operation (USA)

According to federal laws the system may only be operated by properly trained personnel under the direction of a physician.

#### Assembly, putting into service, installation and service

Only authorized personnel are allowed to assemble the system, to put it into service, to run its installation and to provide technical service. The necessary qualifications can only be obtained by attending a training course provided by the manufacturer.

# **▲ CAUTION**

Always observe the relevant regulations of the country of installation for putting the system into service, training of personnel and maintenance.

General safety instructions

## **AWARNING WARNING**



Never use the system if you suspect any electrical or radiation-generating components to be defective or if the system exhibits unexpected malfunctions!

#### **WARNING**



You are not allowed to make any changes to the system!

### NOTICE NOTICE

Changes on system components may result in damages of system parts. Avoid the following operations while the system is connected to the power supply and is switched on:

- Connecting external components with the system
- Disconnecting external components from the system

#### NOTICE NOTICE

Data loss!

In the case of unforeseen events, data may be lost.

Back up your data on a regular basis. The equipment owner is held liable for performing data backups.



### NOTE

The requirements in accordance with the current edition of IEC 60601-1 apply.



### **NOTE**

For further information as to putting the system into service and installation refer to the Technical Manual.

## X-rays

#### General

The system produces X-rays. If you do not observe the safety measures and precautions required by your local radiation protection regulatory body or other national radiation protection measures and precautions, these X-rays can be hazardous both to operating staff and other persons within the radiation zone of occupancy.

## **▲** WARNING WARNING



The system is intended for procedures where the skin dose may be so high that there is a risk of deterministic effects, even if the system is used as intended.

## **AWARNING WARNING**



The system may only be operated by personnel who has undergone radiological training.

#### **AWARNING WARNING**

### (USA)

The system may only be operated by properly trained personnel under the direction of a physician.

## WARNING



The relevant radiation protection regulations of the country of installation must be observed.

#### **AWARNING WARNING**



In order to avoid unintentional radiation, the foot switch must be hung up on the foot switch support when the system is switched on, but not in use.

#### **Protection of staff**

Staff members who stay within the radiation controlled area must wear X-ray protective clothing.

The radiation controlled area has a radius of 4 m (national regulations may differ).

Electromagnetic compatibility

# Protection of the patient

To minimize the radiation burden of the patient, you must keep the source/skin distance as large as possible. The generator design guarantees a minimum source/skin distance of 20 cm.

If required by norm, always use the skin protection to ensure a minimum source/skin distance of 30 cm. Thus, you can reduce the patient exposure by more than 50 percent as the dose rate decreases with the square of the distance from the source.

## ▲ WARNING

#### WARNING



If required by norm, always use the skin protection to ensure a minimum source/skin distance of 30 cm. This requirement applies in general, unless specific surgical applications require shorter distances.

## **▲** WARNING

#### MARNING WARNING



Additional material located in the beam path (e.g. an operating table not suitable for X-raying) may result in a dose increase when using a fluoroscopy mode with automatic exposure rate control.

### **▲** WARNING

#### **WARNING**



When you initiate radiation and no live image is displayed although all necessary settings have definitely been made, please contact the Service department of the Ziehm Imaging GmbH.

## 4.3 Electromagnetic compatibility

Medical electrical equipment requires special precautionary measures with respect to electromagnetic compatibility (EMC) and must be installed and put into service in accordance with the EMC guidelines contained in the accompanying documents.

Portable and mobile RF communications equipment may interfere with medical electrical equipment.

All operating modes of the system have been considered in the EMC tests. There are no exceptions to the rules.

The following overview contains all manufacturer-specific cables provided by Ziehm Imaging GmbH independent from the system version:

- Power cable 7 m
- Coupling cable for mobile stand 7.5 m
- Coupling cable for Remote Solo Center (RSC) 7.5 m
- · Foot switch cable 7.5 m
- Hand switch cable 3.6 m

Electromagnetic compatibility

## **▲** WARNING

#### WARNING



Using components other than those specified may result in increased electromagnetic emissions or reduced electromagnetic immunity.

## **▲** WARNING

#### **WARNING**

**WARNING** 



The system is not intended for use near MRI systems.

## **▲** WARNING



The system is intended for use by health care professionals only.

The system may cause radio interferences or may disturb the operation of adjacent devices. If required, perform appropriate corrective actions, e.g. by re-positioning or rearranging the system or its shielding.

## ▲ WARNING

#### **WARNING**



The system was tested for electromagnetic emissions and immunity. Do not operate the system adjacent to or stacked with other equipment. If system operation adjacent to or stacked with other equipment is required, ensure that in this constellation normal operation can be performed.

## ▲ WARNING

### WARNING



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the system, including cables specified by the manufacturer.

Otherwise, degradation of the performance of the system could result.

## WARNING WARNING



The system may be interfered with by other third-party devices, even if these other third-party devices comply with CISPR emission requirements.

Protective grounding



#### NOTE

The characteristics of the system, as determined by emissions, allow its use in the industrial sector and in hospitals (CISPR 11, Class A). When used in residential areas (for which Class B is usually required according to CISPR 11), the system may not provide adequate protection for radio services. If required, the user must take remedial measures such as reorienting or relocating the system.



#### **NOTE**

The system is designed to run its intended function at normal operation. Electromagnetic interferences may slightly affect the displayed live image. The system returns to normal operation after eliminating the interference. Users instantly recognize any loss of function, which does not cause a safety hazard. Electromagnetic interference does not damage the system permanently.

Please observe also the Manufacturer's Declaration concerning Electromagnetic Compatibility according to IEC 60601-1-2 in the Technical Manual.

## Protective grounding





To reduce the risk of electric shock, this system must only be connected to protectively grounded power supplies.

#### 4.5 **Equipotential grounding**

**Heart and brain** examinations

If the system is used for examinations of the heart or brain or the surrounding anatomical regions in combination with other equipment, equipotential grounding is required for patient and operating staff safety



#### NOTE

The requirements in accordance with the current edition of IEC 60601-1 apply.

Laser radiation

### 4.6 Laser radiation

# Laser Positioning Device

The system may be equipped with a laser positioning device at the image receptor and/or generator.



#### **WARNING**

Laser radiation – Do not stare into beam or view directly with optical instruments (Laser Class 2M according to IEC 60825-1).

Please observe the provisions of the IEC TR 60825-14 for operation of the laser positioning devices as well as national legislation and regulations.

Viewing the laser beam apertures with certain optical instruments (e.g. eye loupes, magnifiers and microscopes) within a distance of 100 mm may pose an eye hazard.



# CAUTION (USA)

#### LASER RADIATION - DO NOT STARE INTO BEAM

Class 2M Laser Product (Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007)

#### Maintenance

The laser positioning device is maintenance-free. Any adjustment or repair work which might become necessary must be carried out by the manufacturer or a person who has been authorized to do so by the manufacturer.



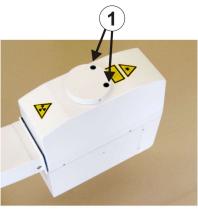


Fig. 22: Laser beam apertures (1) on the image intensifier and on the generator (Ziehm Solo)

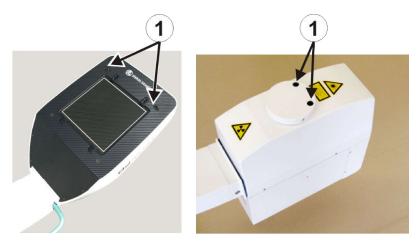


Fig. 23: Laser beam apertures (1) on the flat-panel detector (left, bottom view) and on the generator (right) (Ziehm Solo FD)

#### 4.7 **Temperature Generator housing**

### **ACAUTION** CAUTION



The generator housing may reach temperatures, that may cause burns during prolonged contact.

Make sure that the patient does not get in contact with the generator housing.

#### **Printers** 4.8

## **ACAUTION** CAUTION



### Risk of injury by cutting device!

You can hurt yourself when touching the cutting device.

Do not touch the cutting device when adding or removing paper.

Please refer to the Operating Instructions of the corresponding printer model.

System failure

### NOTICE NOTICE

On video printers with cutting function (characterized by **CUT** button) use the **CUT** button for cutting off the printer medium (paper or transparency film) in order to avoid damaging the video printer.

On video printers without cutting function you must always tear off the printer medium (paper).

Please refer to the Operating Instructions of the corresponding printer model.

### NOTICE NOTICE

Temperatures of 40°C or higher and relative air humidity of 60% or higher may cause stains on the printer's heat-sensitive paper.

## System failure

## **ACAUTION** CAUTION



The system is a highly complex medical device that in rare cases can fail like any other electrical device in spite of comprehensive tests and maintenance.

This may cause obstructions to the operational procedure.

Please keep an emergency plan ready for this case.

#### **▲** CAUTION

### CAUTION



Data transmission of the system can fail.

This may cause obstructions to the operational procedure.

Please keep an emergency plan ready for this case.

## **ACAUTION** CAUTION



The system can fail due to mechanical defects.

This may cause obstructions to the operational procedure.

Please keep an emergency plan ready for this case.

## **4 Safety Instructions**

Mechanics

#### 4.10 **Mechanics**

#### **ACAUTION** CAUTION



Trip hazard due to improper cable placement!

Obstructions to the operational procedure

Avoid laying cables on walking areas from and to the system. Avoid tension when laying the cables.

#### **ACAUTION** CAUTION



Keep in mind that the mobile stand may roll away on sloping floors.

Leave the mobile stand behind only on even floors and lock its brakes (inclination  $\leq 0.25^{\circ}$ ).

Release the parking brake only to move or position the mobile stand.

### **ACAUTION** CAUTION



Risk of injury by monitor support arm!

The monitor support arm may break and fall down due to overload.

Do not place any kind of objects on the monitor support arm. Do not lean on the monitor support arm.

#### 5 **Mechanical Handling**

#### 5.1 **Transport position**

#### General

For safety reasons, you must return the system to its respective transport position before transporting it.

#### NOTICE NOTICE

Do not move the system over floors with an inclination of more than 10° from level during transport.

Exercise extreme caution when moving the system over rough surfaces such as tile flooring, pavement, asphalt or carpet.

Take care that the cable guards do not drag and the wheels do not catch or tilt causing damage to the equipment.



#### **NOTE**

Optimum mobility of the system is given on even and solid floors. To move the system over obstacles, such as door thresholds, use adequate auxiliary means, e.g. wedges or ramps.

#### 5,1,1 Transport position of the mobile stand with monitor support arm

#### How to proceed

#### To prepare the mobile stand for a transport, do the following:

- 1. Wind the foot switch cable onto the foot switch support and hang up the foot switch there.
- Rotate the C-arm orbitally until the image receptor and generator 2. are in an upright position and secure it with the relevant (blue) brake (Fig. 1).



Lower the lifting column to ≤ 1 cm using the Move Up/Down 3. arrow buttons.

Transport position > Transport position of the mobile stand with monitor support arm

4. Tilt the swivel arm of the C-arm by approx. 5° away from the monitor head (angulation) and secure it with the relevant (red) brake.

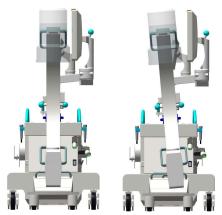


Fig. 24: Zero position (left) and transport position (right) on Ziehm Solo

- 5. Swivel the horizontal carriage into its initial position and secure it with the relevant (gray) brake.
- 6. Retract the horizontal carriage completely and secure it with the relevant (yellow) brake.
- 7. Put monitor head and Solo Center into an upright position.
- 8. Unlock the plunger blocks in order to be able to freely move both support arms and monitor head (Fig. 47). For this purpose press the corresponding plunger block until a green ring is revealed.

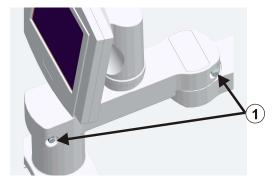


Fig. 25: Plunger blocks (1) on the support arm

- Align the monitor head exactly in parallel with the monitor head support arm.
- Lock the monitor head by pressing the plunger block until a black 10. ring is revealed. Keep swiveling the monitor head until it engages with an audible click.
- Swivel the Solo Center support arm into a position of 90° to the 11. horizontal carriage.

Transport position > Transport position of the mobile stand with monitor support arm

**12.** Lock the Solo Center support arm by pressing the plunger block until a black ring is revealed. Keep swiveling the monitor head until it engages with an audible click.

### NOTICE NOTICE

When swiveling the monitor head it may collide with the C-arm.

This may damage the monitor head.

To avoid damages on the monitor head while swiveling, you must put it into an upright position, so it does not collide with the C-arm.

- Align the monitor head support arm exactly in parallel with the horizontal carriage (Fig. 26).
- Lock the monitor head support arm by pressing the plunger block until a black ring is revealed. Keep swiveling the monitor head until it engages with an audible click.
- 15. Align the Solo Center in parallel with the horizontal carriage.
- Switch off the system and disconnect the power cable from the power supply.
- 17. Unlock the coupling cable connector on the mobile stand and unplug the connector (only in combination with a Viewing Station).
- 18. Release the parking brake by lifting the (green) steering & braking lever (Fig. 26).



Transport position > Transport position of the mobile stand with monitor support arm

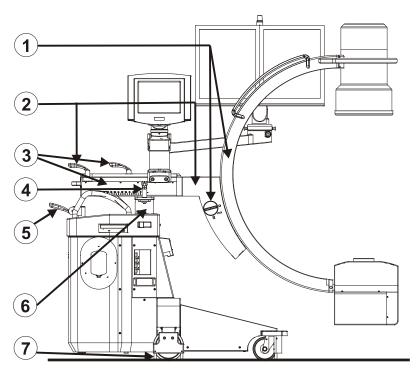


Fig. 26: Mobile stand transport position (Ziehm Solo)

- C-arm + orbital rotation brake
- Swivel arm + brake Horizontal carriage + brake
- Swivel brake

- 5 Steering & braking lever
- Lifting column Cable guards 6

### 5.1.2 Transport position of the mobile stand with Solo Center

#### How to proceed

#### To prepare the mobile stand for a transport, do the following:

- 1. Wind the foot switch cable onto the foot switch support and hang up the foot switch there.
- Rotate the C-arm orbitally until the image receptor and generator are in an upright position and secure it with the relevant (blue) brake).



- 3. Lower the lifting column completely using the **Move Up/Down** arrow buttons.
- **4.** Put the swivel arm of the C-arm into an upright position and secure it with the relevant (red) brake.
- **5.** Swivel the horizontal carriage into its initial position and secure it with the relevant (gray) brake.
- **6.** Retract the horizontal carriage completely and secure it with the relevant (yellow) brake.
- **7.** Swivel the Solo Center support arm into a parallel position to the horizontal carriage.
- **8.** Align the Solo Center in parallel with the horizontal carriage.



- **9.** Switch off the system and disconnect the power cable from the power supply.
- **10.** Unlock the coupling cable connector on the mobile stand and unplug the connector.
- **11.** Release the parking brake by lifting the (green) steering & braking lever.

Transport position > Transport position of the mobile stand with Solo Center

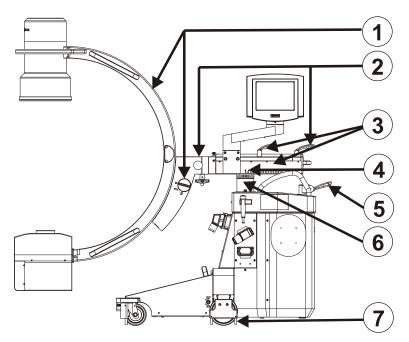


Fig. 27: Mobile stand transport position (Ziehm Solo)

- 1 C-arm + orbital rotation brake
- 2 Swivel arm + brake
- 3 Horizontal carriage + brake
- 4 Swivel brake<sup>a</sup>
- <sup>a</sup> covered by horizontal carriage
- 5 Steering & braking lever
- 6 Lifting column
- 7 Cable guards

System equipped with transport wheels

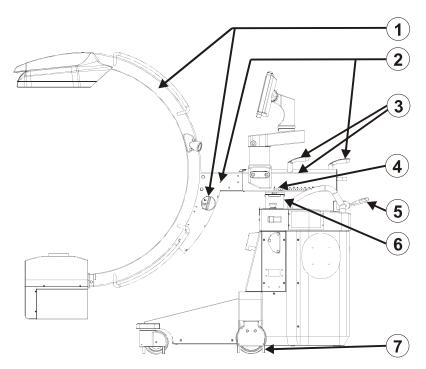


Fig. 28: Mobile stand transport position (Ziehm Solo FD)

- 1 C-arm + orbital rotation brake
- 2 Swivel arm + brake
- 3 Horizontal carriage + brake
- 4 Swivel brake<sup>a</sup>
- <sup>a</sup> covered by horizontal carriage
- 5 Steering & braking lever
- Lifting column
- 7 Cable guards

## 5.2 System equipped with transport wheels

The system may be equipped with transport wheels. The transport wheels allow moving the system on uneven floors.

The transport wheels are attached to the front of the mobile stand foot and behind the standard wheels on the mobile stand.



Fig. 29: Ziehm Solo Option Portable with transport wheels

- 1 Shaft/lifting device
- 2 Transport wheels

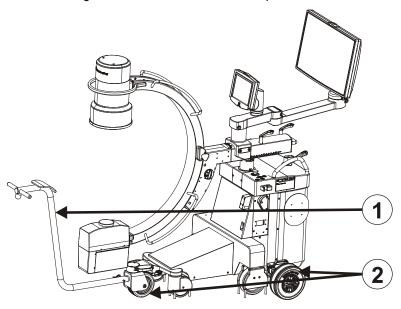


Fig. 30: Ziehm Solo Option Portable M2 with transport wheels

- 1 Shaft/lifting device
- 2 Transport wheels

## To move the mobile stand on transport wheels, do the following:

- 1. Ensure that the steering & braking lever of the mobile stand engages in its initial position.
- **2.** Use the shaft to pull the mobile stand to the desired or given direction.

#### NOTICE NOTICE

#### Risk of collision!

If you use the shaft to pull the mobile stand on transport wheels, you may not be able to stop the system in time.

Always move the mobile stand with transport wheels with the help of a second person.

#### 5.3 Braking and steering the mobile stand

#### Steering & braking lever

The mobile stand has a combined steering & braking lever. It is located at the rear end of the mobile stand.

#### Parking brake

The mobile stand parking brake operates as follows:

- Steering & braking lever lowered: Rear wheels are locked
- Steering & braking lever raised: Rear wheels can move freely





Fig. 31: Parking brake of steering & braking lever

#### Steering

#### To steer the mobile stand, do the following:

- Lift the steering & braking lever and turn it until reaching the 1. desired position. The lever can be turned freely; however, detents are placed at 90° increments. The rear wheels will always stay parallel to one another aligned exactly in parallel with the steering & braking lever.
  - To maneuver the mobile stand freely, ensure that the steering & braking lever has engaged in its initial position, pointing directly backward from the unit (Fig. 32, left).
  - To move the mobile stand in an exactly-defined direction, rotate the steering & braking lever until it points toward the desired direction (Fig. 32, right).

Braking and steering the mobile stand

2. Push the mobile stand in the desired or predefined direction using the lateral handles, or use the hand rail around the image receptor to pull the mobile stand.

# **▲ CAUTION** CAUTION



Keep in mind that the mobile stand may roll away on sloping floors.

Leave the mobile stand behind only on even floors and lock its brakes (inclination  $\leq 0.25^{\circ}$ ).

Release the parking brake only to move or position the mobile stand.

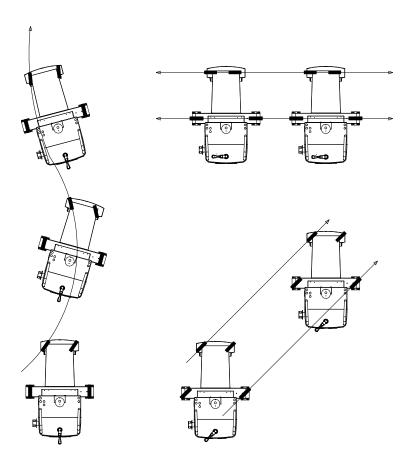


Fig. 32: Mobile stand steering (schematic representation)

C-arm movements > Orbital rotation

#### 5.4 C-arm movements

#### **Mechanical brakes**

The C-arm can be moved in different directional planes. For each direction level, a separate brake is available, allowing you to secure the Carm in any position.

To release the corresponding brake turn it in the direction indicated.

The direction that the brake handle points to at the limit stop position can be easily adjusted. To do so, lift the spring-loaded brake handle, turn it until reaching the desired limit stop position and release it to reengage it at the new position.

## **ACAUTION** CAUTION



Before moving the C-arm, make sure that there is nobody within its range of movement.

### **▲** WARNING

#### WARNING



Release the mechanical brakes only for positioning.

Take care to always seize the C-arm at its handle during any adjustment in order to prevent the C-arm from hitting the respective limit stop at full speed!

When you move the C-arm, do not put your hand in its quide rail.

Make sure that all mechanical brakes are locked when transporting the mobile stand!

#### 5.4.1 **Orbital rotation**

## **ACAUTION** CAUTION



Before rotating the C-arm, ensure that it cannot collide with people or objects.

#### Ziehm Solo

You can rotate the C-arm orbitally by 135°, from the zero position (0°) by -90° in clockwise direction and by +45° in counter-clockwise direction.

C-arm movements > Orbital rotation

### Ziehm Solo FD

On a you can rotate the C-arm orbitally by 165°, from the zero position (0°) by -120° in clockwise direction and by +45° in counter-clockwise direction.

A scale with  $5^{\circ}$  divisions on the outside of the C-arm as well as a mechanical catch at the zero position are provided to facilitate precise positioning.

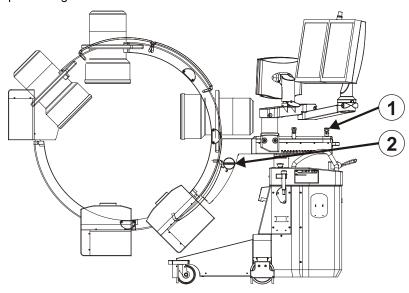


Fig. 33: Orbital rotation of the C-arm

### 1 Angulation brake

2 Orbital rotation brake

This caption also applies to the following illustration.

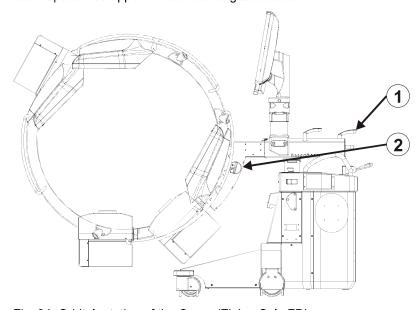


Fig. 34: Orbital rotation of the C-arm (Ziehm Solo FD)





Fig. 35: Color-coded brake handles for orbital rotation

1 Release brake

2 Engage brake

## 5.4.2 Angulation

## **▲**CAUTION CAUTION



Before tilting the C-arm, ensure that it cannot collide with people or objects.

You can tilt the C-arm by  $\pm$  225° in the vertical plane around the horizontal axis (i.e., the horizontal carriage).

A scale with 15° divisions at the front end of the horizontal carriage facilitates precise positioning.

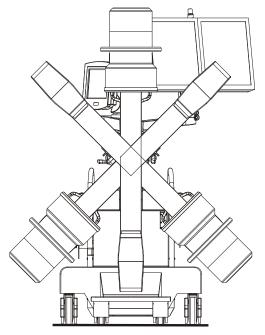


Fig. 36: Angulation of the C-arm (Ziehm Solo)

C-arm movements > Angulation

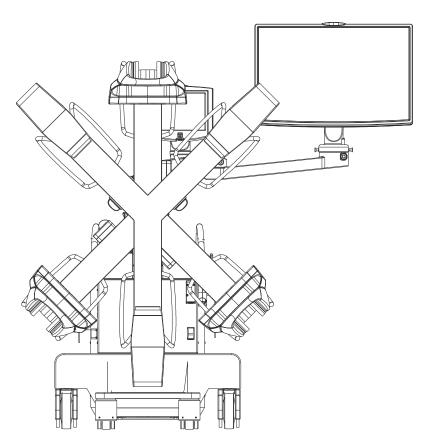


Fig. 37: Angulation of the C-arm (Ziehm Solo FD)

The angulation brake is located on the horizontal carriage.



Fig. 38: Color-coded brake handles for angulation

1 Release brake

2 Engage brake

C-arm movements > Swiveling (panning)

#### 5.4.3 Swiveling (panning)

# **ACAUTION** CAUTION



Before swiveling the C-arm, make sure that it cannot collide with any persons or objects.

In the horizontal plane you can swivel the C-arm  $\pm$  10° to the left or to the right around the lifting column.

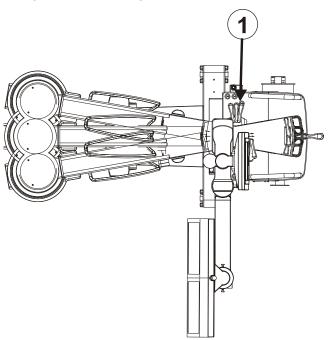


Fig. 39: Swiveling (panning) of the C-arm (view from above) (Ziehm Solo)

### 1 Swivel brake

This caption also applies to the following illustration.

C-arm movements > Horizontal movement

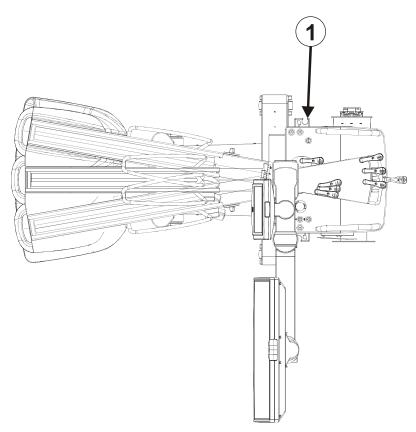


Fig. 40: Swiveling (panning) of the C-arm (view from above) (Ziehm Solo FD)

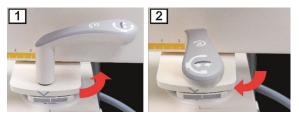


Fig. 41: Color-coded brake handles for swivelling

1 Release brake

Engage brake

#### 5.4.4 **Horizontal movement**





Before moving the C-arm horizontally, ensure that it cannot collide with people or objects.

C-arm movements > Horizontal movement

# ▲ CAUTION

### **ACAUTION** CAUTION

The system is only balanced on even floors (tolerance:  $\pm$  0.25°).

Release the horizontal movement brake only to position the C-arm.

You can move the C-arm forward and backward by 22 cm in the horizontal plane by means of the horizontal carriage. A scale with 1 cm divisions facilitates precise positioning.

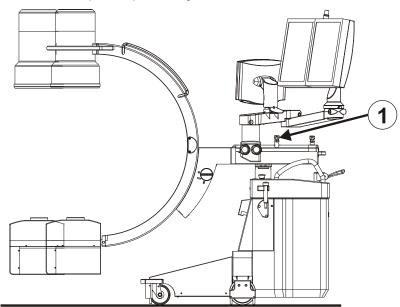


Fig. 42: Horizontal movement of the C-arm (Ziehm Solo)

1 Horizontal movement brake (carriage brake)

This caption also applies to the following illustration.

C-arm movements > Vertical movement

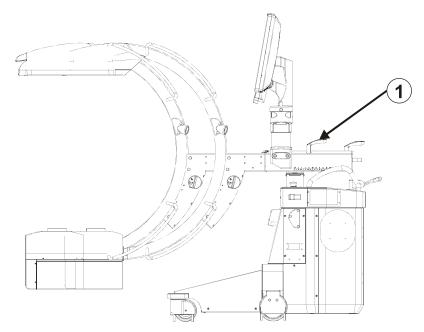


Fig. 43: Horizontal movement of the C-arm (Ziehm Solo FD)

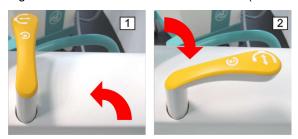


Fig. 44: Color-coded brake handles for horizontal movement

Release brake

Engage brake

#### 5.4.5 **Vertical movement**



### **ACAUTION** CAUTION

Before moving the C-arm vertically, ensure that it cannot collide with people or objects.

When you move down the C-arm, the clearance between the mobile stand base and the horizontal carriage may get so tight that there is a risk of bruising your hands and fingers.

You can use the motor drives to move the C-arm up and down respectively.

For further information refer to the Technical Data section.

The **Move Up/Down** (1) arrow buttons are on the mobile stand next to the lateral handles. To move the C-arm up or down, you must press and hold down the corresponding **Move Up/Down** button.

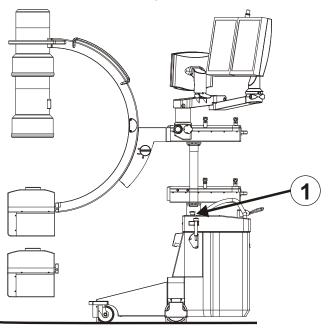


Fig. 45: Vertical movement of the C-arm (Ziehm Solo)

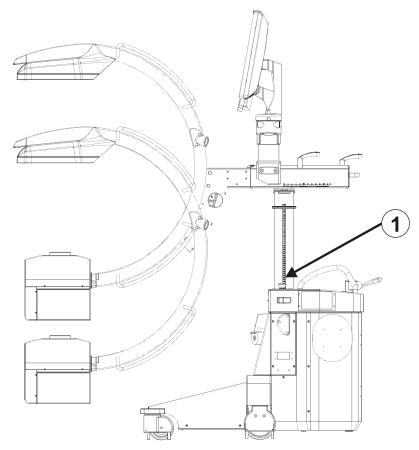


Fig. 46: Vertical movement of the C-arm (Ziehm Solo FD)

## Lowering the system completely

On systems with transport wheels, you must lower the C-arm in two steps in order to prevent the generator from colliding with the stand foot.



#### WARNING WARNING



Make sure that the generator does not collide with the mobile stand foot. There is an increased risk of bruising yourself, and the system may be damaged.

To move the C-arm to the lowermost vertical position (with C-arm position at 10 cm height), do the following:



- Press and hold down one of the Move Down arrow buttons until the downward movement stops automatically.
  - Both Move Down arrow buttons are flashing.



- Press and hold down both Move Down arrow buttons until the Carm reaches the desired vertical position or until the downward movement stops automatically.
  - ⇒ Both **Move Down** arrow buttons are flashing.

# 5.5 Movement of the monitor support arms

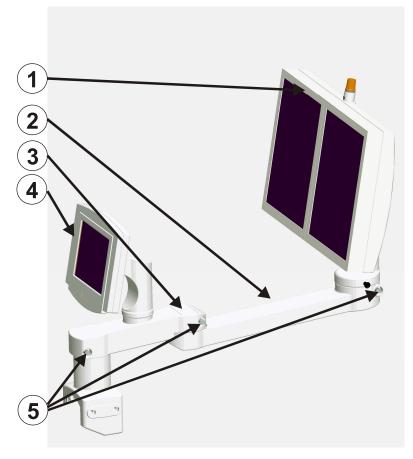


Fig. 47: Monitor support arm

- 1 Monitor head
- 2 Monitor head support arm
- 3 Solo Center support arm
- 4 Solo Center
- 5 Plunger block

# 5.5.1 Solo Center support arm

You can swivel the support arm  $\pm 90^{\circ}$  to the left or to the right around its horizontal axis. The support arm can be locked in increments of  $90^{\circ}$ .

You can unlock the support arm by pressing the plunger block until a black ring is revealed.

Movement of the monitor support arms > Tilting the monitor head

To lock the support arm, press the plunger block until a black ring is revealed and swivel the support arm until it engages with an audible click.

### 5.5.2 Swiveling the Solo Center

You can swivel the Solo Center  $\pm 135^{\circ}$  to the left or to the right around its horizontal axis.

## 5.5.3 Tilting the Solo Center

You can tilt the Solo Center appx. 0° - 20° around its vertical axis.

### 5.5.4 Monitor head support arm

You can swivel the support arm of the monitor head  $\pm 90^{\circ}$  around its horizontal axis. The support arm can be locked in increments of  $90^{\circ}$ .

You can unlock the support arm by pressing the plunger block until a black ring is revealed.

To lock the support arm, press the plunger block until a black ring is revealed and swivel the support arm until it engages with an audible click.

## 5.5.5 Swiveling the monitor head

You can swivel the monitor head  $\pm 160^\circ$  to the left or to the right around its horizontal axis. The monitor head can be locked in increments of  $90^\circ$ .

You can unlock the support arm by pressing the plunger block until a black ring is revealed.

To lock the monitor head, press the plunger block until a black ring is revealed and swivel the monitor head until it engages with an audible click.

# 5.5.6 Tilting the monitor head

You can tilt the monitor head  $\pm 10^\circ$  to the left or to the right around its vertical axis.

# 6 Controls

# 6.1 Control panel

The control panel is located on the mobile stand. Depending on the selected function, different controls (tabs, buttons, input boxes, displays, etc.) will appear on the control panel screen.

The Solo Center control panel is designed as a touchscreen. For system operation, just press the desired button or option directly on the touchscreen.



Fig. 48: Solo Center



The Solo Center has additionally an integrated radiation button (1), an EMERGENCY STOP button (2) and an integrated radiation indication lamp (3). In these Operating Instructions, the adjacent symbol is shown when you need to initiate radiation using the radiation button.

# 6.1.1 Elements of the control panel



#### **NOTE**

The display of buttons on the control panel may differ in order to comply with specific national regulations.

Control panel > Elements of the control panel

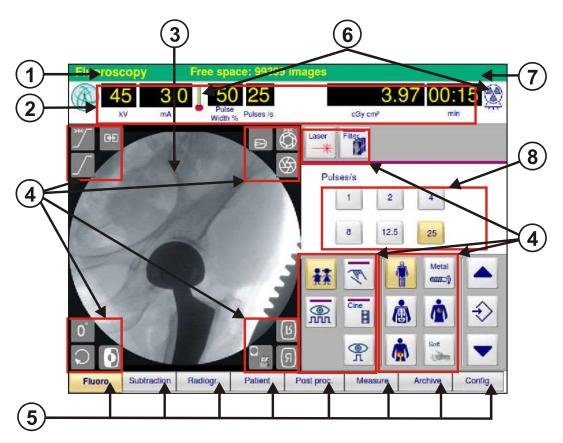


Fig. 49: Elements of the control panel

- Selected operating mode
- Displays
- 2 3 4 SmartÉye
- Keys

- Tabs for operating mode selection
- Warning symbols 6
- 7 Title bar
- Dynamic control area

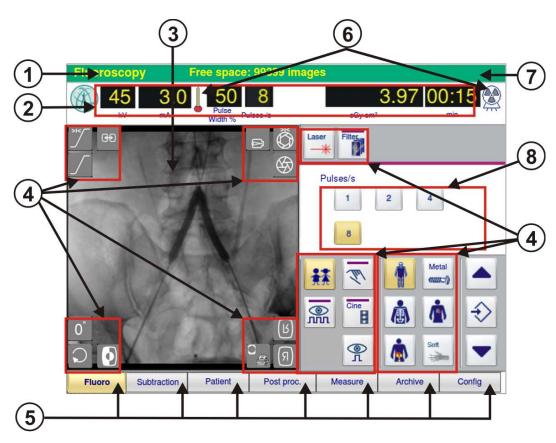


Fig. 50: Elements of the control panel

- 1 Selected operating mode
- 2 Displays
- 3 SmartÉye
- 4 Keys

- 5 Tabs for operating mode selection
- 6 Warning symbols
- 7 Title bar
- 8 Dynamic control area

Symbol(s)	Meaning
Laser **	<b>Buttons with a gray background</b> : When you press one of these buttons, an action is executed immediately on the screen, or a mode is activated. If a certain function is active, the corresponding button is highlighted in yellow.
nn.	<b>Buttons with a gray background and a purple bar at the top</b> : When you press one of these buttons, new controls appear in the dynamic control area, allowing you to make further settings.
Text	<b>Buttons with a gray background and a green bar at the top</b> : When you press this button, you activate another function.

Control panel > Controls in the Fluoroscopy and Subtraction operating modes

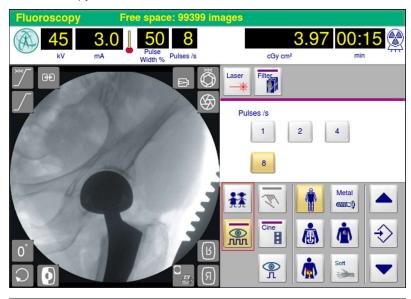
Symbol(s)	Meaning
$\int$	<b>SmartEye controls</b> : There are two types of buttons, which you must handle in different ways. Depending on the type used, you activate its function either by pressing the button or by touching it and gently gliding your finger across the touchpad.

Table 3: Button types

# 6.1.2 Controls in the Fluoroscopy and Subtraction operating modes

Fluoroscopy operating mode

In the **Fluoroscopy** operating mode, you can select different settings for fluoroscopy:



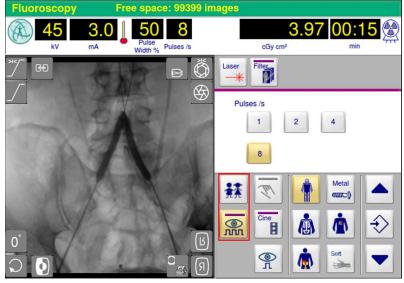


Fig. 51: Fluoroscopy operating mode

In the left column, the buttons for additional functions are arranged according to their related radiation dose, starting from top position with the lowest radiation dose down to bottom position with the highest radiation dose.  $\rightarrow$  Chapter 8.6 "SmartDose" on page 119

Symbol(s)	Meaning
nnn Onn	Pulsed fluoroscopy
	Activates the <b>Pulsed fluoroscopy</b> mode and displays the corresponding controls in the dynamic control area.
	Snapshot (digital radiography)
m m	Activates the <b>Snapshot</b> mode.
	Manual Exposure Rate Setting
In	Enables manual setting of tube voltage and tube current.
	Caution: Use only in exceptional cases!
Cine	Cine
B	Activates or deactivates the <b>Cine Loop</b> mode.
	Pediatrics / Low Dose
11	Activates or deactivates the <b>Low Dose</b> supplementary function (n/a for
T.T.	USA).
Low	Low Dose
Dose	Activates or deactivates the <b>Low Dose</b> supplementary function (USA only).
_	Obese Patient
	Allows you to manually deactivate the <b>Automatic LPK</b> function (with automatically activated <b>Automatic LPK</b> function only).
2	Extremities / cervical spine / head (Ziehm Solo FD)
	Activates the anatomical program for visualizing extremities, cervical spine and head.
	Trunk (Ziehm Solo FD)
	Activates the anatomical program for visualizing the trunk.
i	Bones (Ziehm Solo)
	Activates the anatomical program for visualizing any part of the skeleton.
•	Heart
	Activates the anatomical program for visualizing the heart and thorax region.

Control panel > Controls in the Fluoroscopy and Subtraction operating modes

Symbol(s)	Meaning
	Abdomen
	Activates the anatomical program for visualizing the abdominal region.
*	Uro
	Activates the anatomical program for visualizing soft tissues and surgical instruments during interventional urologic procedures.
Metal	Metal
ann=1)	Activates the <b>Metal Correction</b> supplementary function.
•	Motion
40	Activates the <b>Motion</b> supplementary function.
Satt	Soft
	Activates the anatomical program for visualizing soft tissues.
LP	Long Procedure Spine
	Activates the anatomical program for extended exposure time
	Arrow Up / Arrow Down
	Shows all images of the active patient folder as thumbnail image mosaic.
	Save
₹/	Saves the active image to the hard disk.
Laser	Laser
-*	Activates or deactivates the laser positioning device(s).
Filter	Filters
	Shows or hides the controls for raw image processing (recursive filter, edge filter, LIH filter) in the dynamic control area.
60	Voltage display
lev.	Shows the automatically determined or manually set tube voltage in kV.
kV	After fluoroscopy, the last kV value remains stored.

Symbol(s)	Meaning	
20.0	Current display	
	Shows the automatically determined or manually set tube current in mA.	
mA	After fluoroscopy, the last mA value remains stored.	
	Temperature symbol	
	Shows the thermal conditions in the generator.	
50	Pulse Width % display	
Pulse Width %	Shows the current pulse width.	
05	Pulses/s display	
Pulses /s	Shows the current pulse rate.	
1 28	Air Kerma display	
mGy	Shows the cumulative air kerma for the active patient folder in mGy.	
sy	If the cumulative air kerma exceeds a threshold value previously defined by you, the font color of the display changes from yellow to orange.	
	and	
2.20	Air Kerma Rate display	
mGy/min	Shows the current air kerma rate in mGy/min.	
	or	
579.20	Dose Area Product display	
cGy cm²	Shows the dose area product for the active patient folder in cGy cm <sup>2</sup> (default setting).	
	Further units are available in the service settings:	
	Gy cm <sup>2</sup> , dGy cm <sup>2</sup> , cGy m <sup>2</sup> , mGy cm <sup>2</sup> , mGy m <sup>2</sup>	
	If you want to modify the unit of the dose area product, contact your inhouse service engineer.	
01.30	Radiation Time display	
min	Shows the accumulated radiation time for fluoroscopies and direct radiographies for the active patient folder in minutes and seconds.	
	X-ray symbol	

Table 4: Controls in the Fluoroscopy operating mode

Lights up yellow during X-ray exposure.

Touch the X-ray symbol to display the software version of the system.

Control panel > Controls in the Fluoroscopy and Subtraction operating modes

# Subtraction Operating Mode

The **Subtraction** operating mode screen is to a large extent identical to the **Fluoroscopy** operating mode screen. Different from it, the anatomical programs key pad shows buttons tailored for the subtraction workflow (see red frame):

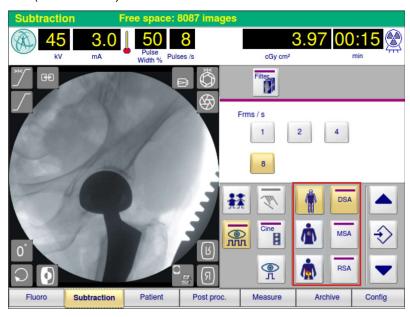


Fig. 52: Subtraction Operating Mode

Symbol(s)	Meaning		
DSA	DSA		
	Generates a DSA cine loop. Displays the corresponding controls in the dynamic control area		
MSA	MSA		
	Generates an MSA image. Displays the corresponding controls in the dynamic control area		
RSA	RSA		
	Generates an RSA image. Displays the corresponding controls in the dynamic control area		

Table 5: Additional buttons in the **Subtraction** operating mode

# Unavailable controls

Controls may be locked in certain operating situations (e.g. playback of a saved cine loop), i.e. they cannot be pressed.

#### 6.1.2.1 SmartArchive function

Using the **SmartArchive** function, in the **Fluoroscopy** and **Subtraction** operating modes you get to see all images and cine loops of the active patient folder at a glance.

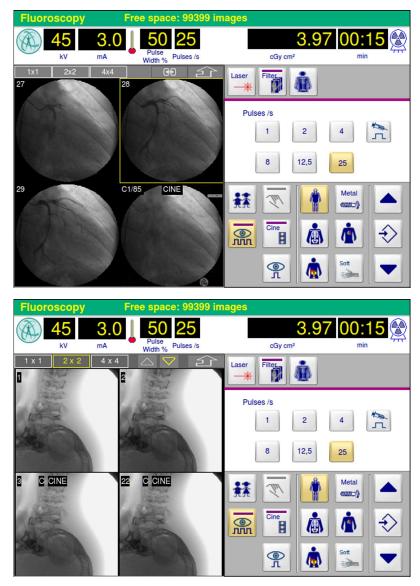


Fig. 53: Display of images and cine loops in the SmartEye

Control panel > Controls in the Fluoroscopy and Subtraction operating modes

# To show images or cine loops of the active patient folder in the SmartEye, do the following:





Press the Up Arrow or Down Arrow button.

⇒ If the **Up Arrow** or **Down Arrow** are highlighted in *yellow*, this means, that there are more images above or below the images shown.

If the **Up Arrow** or **Down Arrow** are highlighted in *gray*, this means, that there are no more images above or below the images shown.

- 2. Scroll through the selection, by touching on the SmartEye and gliding your finger gently across the touchpad way up or down.
- Touch the desired image or cine loop with your finger in the SmartEye.
  - ⇒ The desired image or cine loop is highlighted in yellow and is displayed on the reference screen.

If you select a cine loop (labeled **CINE**), the cine loop setting and editing controls appear in the dynamic control area.



#### NOTE

In the **Subtraction** operating mode you cannot select DSA cine loops. This is indicated by a frame highlighted in red.



- 4. Press one of the buttons shown in the margin, to display one image (1 × 1 button) at full size, 4 images (2 × 2 button) or a maximum of 16 images (4 × 4 button) as thumbnail image mosaic.
- **5.** Press the **Back** button or initiate radiation, to exit and return to the original display mode.



#### **ACAUTION** CAUTION



Risk of injury by X-rays!

Put on X-ray protective clothing before you initiate radiation.

The SmartArchive function is deactivated and the controls for the previously used anatomical program appear in the dynamic control area.

# 6.1.3 Buttons in the SmartEye with SmartControl



Active SmartEye buttons can be identified by their yellow contours. Assigned button functions can be executed by gliding your finger gently across the touchpad.

Symbol(s)	Meaning			
<b>⊕</b> Đ	Image Swapping Swaps the images of live and reference screens.			
$\int$	Contrast/Brightness (windowing)  Sets the number of gray levels and the image brightness.			
>1<	Reset Contrast/Brightness Restores the original image (by pressing once) or resets the Windowing settings to their factory defaults (by pressing twice).			
	Magnify Magnifies the image receptor's fluoroscopic image electronically. The buttons always show the current image magnification level.			
1				
2				
₩	Iris Collimator  Activates the Collimator mode and displays the buttons Adjust Iris Collimator, Adjust Slot Collimator and Rotate Collimator.			
Ö	Reset Collimator Resets iris and slot collimator to their initial settings.			
	Adjust Iris Collimator  Opens and closes the iris collimator.			
	Adjust Slot Collimator  Opens and closes the slot collimator.			
$\bigcirc$	Rotate Collimator  Rotates the slot collimator, resp. iris collimator.			

Control panel > Buttons in the SmartEye with SmartControl

Symbol(s)	Meaning
$\bigcirc$	Image Rotation  Rotates the image by following your finger movements in clockwise or
	counter-clockwise direction.  Grayscale Inversion
•	Displays the active (positive) image with a negative grayscale or vice versa.
	Back
21	Returns to the previously used SmartEye display mode.
0°	Reset Image Rotation
	Resets the image rotation angle to 0°.
	Print Live Screen image
	Prints the image displayed on the live screen on the video printer.
R	Reverse Up/Down
	Mirrors the image vertically around the horizontal axis.
	Reverse Left/Right
(列)	Mirrors the image horizontally around the vertical axis.

Table 6: Controls in the Fluoro operating mode SmartEye

Available controls on the SmartEye are displayed in a lighter gray such as the **Iris Collimator** button in the figure below.

Unavailable controls on the SmartEye are displayed in a darker gray such as the **Image Swapping** button in the figure below.

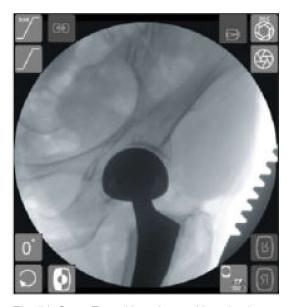


Fig. 54: SmartEye with active and inactive buttons

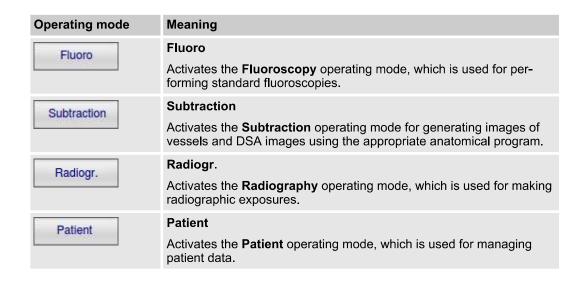
# 6.1.4 Operating mode selection

The user interface provides the necessary operating controls. Depending on the respective task they are grouped as different operating modes. The name of each operating mode indicates its main task or function, e.g. **Fluoro** or **Patient**.

You can choose between the following operating modes:



Fig. 55: Operating mode bar



Control panel > Alphanumeric keypad

Operating mode	Meaning		
Post proc.	Post proc.		
100,000	Activates the <b>Post processing</b> operating mode, which is used for post-processing saved images.		
Measure	Measurement		
	Activates the <b>Measurement</b> operating mode, which is used for measuring distances and angles in saved images.		
Archive	Archive		
	Activates the <b>Archive</b> operating mode, which is used for managing saved images.		
Config	Config		
	Activates the <b>Configuration</b> operating mode, which is used for adjusting the operation settings and the basic settings and for deleting data from storage media.		

Table 7: Operating mode selection

# 6.1.5 Alphanumeric keypad

If you have selected **Patient**, **Text**, **Archive Search**, **Archive Backup** or **Configuration**, an alphanumeric keypad is displayed, allowing you to enter texts.



Fig. 56: Alphanumeric keypad displayed on the control panel



#### NOTE

It is not possible to press two buttons on the keypad simultaneously. To combine a button with the **Shift** button, first press and release the **Shift** button and then the desired button.

Uppercase letters and special characters

To type an uppercase letter or a special character, press and release the **Shift** button before entering the respective character.



The Shift button acts on one subsequent letter or special character.

Buttons and switches on the unit > General





To type several consecutive uppercase letters or special characters, press the **Caps Lock** button before entering the letters or characters. To deactivate the Caps Lock mode, press the **Caps Lock** button once again.

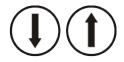
To generate a blank space, press the **Space** button.

### 6.2 Buttons and switches on the unit



The mobile stand is equipped with main switches for switching the system on or off. The **ON** switches are **green**, while the **OFF** switches are **white**.

Once you have switched off the unit, you cannot switch it back on until after a delay of 5 seconds.



On the mobile stand, there are two **Move Up/Down** arrow buttons, which are used for lifting and lowering the C-arm on its mobile stand.

### 6.3 Hand switch and foot switch

#### 6.3.1 General



#### **NOTE**

The foot switch pedals can be assigned with customer-specific functions. If this applies, the respective functions are illustrated by labels on the foot switch.



#### **NOTE**

After switching or exchanging the foot switch, ensure that appropriate functions are assigned to it. Contact an authorized service engineer to change the foot switch assignment.



### **NOTE**

In case you initiate radiation with hand or foot switch, releasing the switch instantly terminates the radiation.

Hand switch and foot switch > Two-pedal foot switch

### 6.3.2 Hand switch



Fig. 57: Hand switch
Use the hand switch for initiating radiation.

# 6.3.3 Two-pedal foot switch

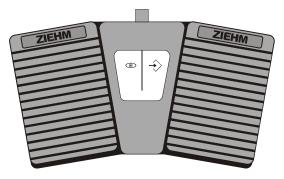


Fig. 58: Two-pedal foot switch

# **Default assignment**

The default pedal assignment of the two-pedal foot switch is listed in the following table. The assignment of your two-pedal foot switch may deviate from this standard assignment. The respective assignment is marked on the foot switch.

Left pedal: Initiate radiation Right pedal: Save image

Table 8: Default assignment of two-pedal foot switch

# Foot switch labeling

The following table lists the labels which may appear on the two-pedal foot switch:

Symbol(s)	Meaning
	Fluoroscopy Initiates radiation.

Symbol(s)	Meaning
	Cine
	Generates a cine loop.
DSA	DSA
DON	Activates the <b>DSA</b> mode.
DSA	DSA/MSA/RSA
MSA RSA	Switches to DSA, MSA and RSA.
	Image Swapping
	Swaps the images of live and reference screens.
п	Press Briefly
	Stepping briefly on the foot switch activates the indicated function.
	Press and Hold Down
J L	Stepping on the foot switch pedal and holding it down for a while activates the indicated function.
	Magnify
	Activates the electronic image magnification of the image receptor.
OFF	OFF
OH	Deactivates the respective function.
	ON/OFF
	Activates or deactivates the respective function.
( <u>•</u> )	Snapshot
Ĭ.	Acquires a snapshot.
$\rightarrow$	Save
	Saves the active image to the hard disk.

Table 9: Symbols on the two-pedal foot switch

Hand switch and foot switch > Dual Plus foot switch

# 6.3.4 Dual Plus foot switch

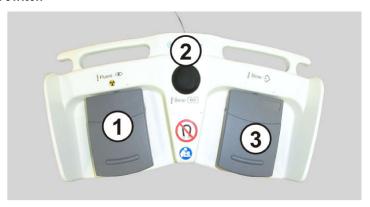


Fig. 59: Dual Plus foot switch

### **Default assignment**

The default pedal assignment of the Dual Plus foot switch is listed in the following table. The assignment of your Dual Plus foot switch may deviate from this standard assignment. The respective assignment is marked on the foot switch.

Pedal	Standard	SmartVascular		
		Fluoro operating mode	Subtraction Operating Mode	
Left (1)	Fluoroscopy (ini- tiates radiation) <sup>a</sup>	Fluoroscopy (ini- tiates radiation) <sup>a</sup>	Fluoroscopy or RSA (initiates radiation)	
			(use pedal 2 to switch assignment)	
Center (2)	Image swapping <sup>a</sup>	Image swapping <sup>a</sup>	Switches the functions assigned to pedal 1 from Fluoro to RSA	
Right (3)	Save image <sup>a</sup>	Save image <sup>a</sup>	DSA	
			(initiates radiation)	
			Save image (T)	
			Tap function	

Table 10: Default assignment Dual Plus foot switch

a.lf you want to change the foot switch assignment, contact your in-house service engineer.

# Foot switch labeling

The following table lists the labels which may appear on the Dual Plus foot switch:

Symbol(s)	Meaning				
Press	Press and Hold Down				
	Stepping on the foot switch pedal and holding it down for a while activates the indicated function.				
Тар	Press Briefly				
	Stepping briefly on the foot switch activates the indicated function.				
Fluoro	Fluoroscopy operating mode				
	Foot switch assignment in the <b>Fluoro</b> operating mode				
Fluoro	Fluoroscopy				
	Initiates radiation.				
Swap 🕕	Image Swapping				
	Swaps the images of live and reference screens.				
Store ->	Save				
	Saves the active image to the hard disk.				
Cine	Cine				
	Activates the <b>Cine</b> supplementary function.				
Cine 🖭	Cine Play/Pause				
	Starts or stops the cine loop playback.				
DSA	DSA on/off				
	Activates or deactivates the DSA workflow.				

Table 11: Symbols on the Dual Plus foot switch

# **6 Controls**

Hand switch and foot switch > Dual Plus foot switch

#### Switching the System On and Off 7

#### Preparing the system 7.1

#### General

Before switching on the system, e.g. after transporting to a new location, the power supply must first be connected to the C-arm.

#### NOTICE NOTICE

Never connect the mobile stand with the Viewing Station when the mobile stand is already connected to the power supply and switched on.

Damage to the electronics of the system cannot be excluded if this warning is ignored!

#### NOTICE NOTICE

Changes on system components may result in damages of system parts. Avoid the following operations while the system is connected to the power supply and is switched

- Connecting external components with the system
- Disconnecting external components from the system



On systems versions with Viewing Station always ensure to only operate components that were ordered together.

### To prepare the system for operation, do the following:

- Unwind the power cable from the cable support on the left side of the mobile stand.
- 2. Make sure that a suitable supply voltage is available and that the socket-outlet is properly grounded and fused.
- 3. Check the power plug and the socket-outlet for compatibility.

#### **External monitors**

- Connect the external monitors to the interface panel of the mobile 4. stand.
  - Left monitor to VIDEO OUT 1 LM
  - Right monitor to VIDEO OUT 1 RM
  - 27" monitor to split screen VIDEO OUT 1

Switching the System On and Off

# External radiation indication lamp

5. Connect the radiation indication lamp to the interface panel of the mobile stand (connection for external radiation indication lamp).

# **▲**CAUTION



Risk of injury by X-rays!

The radiation indication lamp must be clearly visible for all persons in the room.



#### **NOTE**

The connection of a radiation indication lamp is mandatory when you operate the system only with external monitors.

- **6.** Connect the system to the power supply.
- 7. Make sure that the inclination of the system does not exceed 0.25° from the level in operating position.
- 8. Put on suitable protective clothing.

# 7.2 Switching the System On and Off





The mobile stand is equipped with main switches for switching the system on or off. Each of the two keys switches on or off both system components simultaneously.

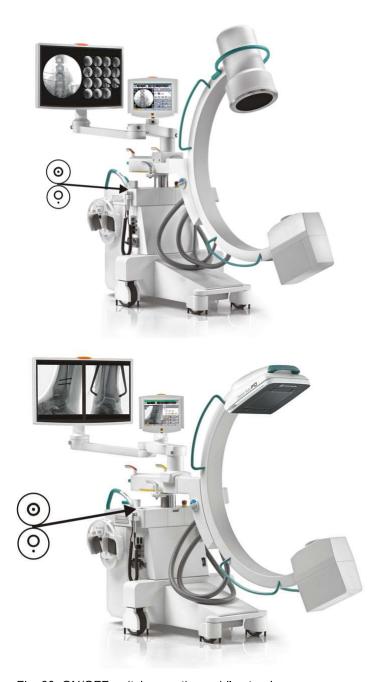


Fig. 60: ON/OFF switches on the mobile stand

# NOTICE NOTICE

Do not plug any USB stick into the USB port until the system has fully completed its power-up sequence.

Switching the System On and Off



#### NOTE

Due to background radiation, the Air Kerma, Air Kerma Rate or Dose Area Product display may indicate some small value after power-up of the system.

### To switch on the system, do the following:



Press the ON switch.

The system is switched on. The **ON** switch is illuminated now.

## **ACAUTION** CAUTION



If during power-up the system detects the mobile stand is equipped with a generator that does not match the system, an alert message appears. During operation this may result in an unpredictable increase of the exposure rate or may affect the image quality.

You can continue working with the system, by pressing the Yes button in the message window. The responsibility lies with the physician in charge only.

Before putting the system into service the next time, ensure that the appropriate generator is connected to the mobile stand and for this purpose contact the Service department of the Ziehm Imaging GmbH.

#### Customer-specific default settings

The default settings after power-up vary from system to system, according to the customer-specific setup. You may e.g. choose your preferred start screen yourself.

Furthermore, you may choose to have a certain anatomical program and various live image settings preset as default after power-up. You cannot make these presettings yourself.

Please contact your in-house service engineer if you wish to make or modify the default settings.

**Emergency Stop Device** 

### To switch off the system, do the following:



Press the **OFF** switch.

⇒ The system switches off after a few seconds.



#### NOTE

Any unsaved patient data and/or images are lost.

# 7.3 Emergency Stop Device

The system provides several **EMERGENCY STOP buttons**, enabling you to switch off all electrical functions of the unit in case of emergencies.

The mobile stand is equipped with a latching **EMERGENCY STOP push button**.

Further momentary **EMERGENCY STOP buttons** are located

- · on the Solo Center
- on the Remote Solo Center.

#### Switching off in emergency situations

To switch off the system in an emergency situation, do the following:

Fully press down one of the **EMERGENCY STOP push buttons**.

⇒ A latching EMERGENCY STOP push button is locked. The system switches off immediately. All electrical functions of the system are disabled. Any unsaved patient data and/or images are lost.

# Restarting after an emergency

To restart the system after having pressed an EMERGENCY STOP push button, do the following:

To unlock a latching **EMERGENCY STOP push button**, press the red knob with a slight twist in clockwise direction.

⇒ The unit remains switched off. You can switch the unit back on with the ON switch. Key switch



#### **NOTE**

If the system cannot be switched on, the **EMERGENCY STOP push button** may have been actuated inadvertently, e.g. during a transport. Check whether the **EMERGENCY STOP push button** is locked and unlock it, if applicable.

# 7.4 Key switch

The mobile stand is optionally equipped with one of the following key switches:

- X-ray
  - Locks the radiation function of the system
- · Power on

Locks the system completely

# **▲ CAUTION** CAUTION



Make sure to always use the key switch (if present) in order to prevent unauthorized persons from switching on the system or initiating radiation, respectively.



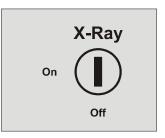


Fig. 61: Key switch for locking the entire system (left) or the radiation function (right), **Lock** or **Off** position

#### Power on

With the **Power on** key switch you can completely lock the system when it is switched off. When the key is in the **Lock** position, the system can no longer be switched on with the **ON** switch.

#### NOTICE NOTICE

#### NOTICE

Risk of danger to property

Hard disk damage

 To switch off the system use the OFF switch only to avoid damaging the hard disk.

Key switch

To be able to switch on and operate the system, you must first insert the key and turn it to the **Unlock** position. While in the **Unlock** position, the key cannot be removed.

### X-Ray On/Off

With the **X-ray** key switch, you can lock the radiation function of the unit. When you remove the key while it is in the **Off** position, it is possible to switch on the system and to use functions such as patient data management or image post-processing. However, it is not possible to initiate radiation with the hand or foot switch.

To be able to initiate radiation, you must first insert the key and turn it to the **On** position. While in the **On** position, the key cannot be removed.



#### **NOTE**

To comply with the safety requirements of IEC 60601-2-43, you may use the system only when it is equipped with an X-Ray key switch.

7 Switching t			

# 8 Standard Fluoroscopic Operations

# 8.1 Overview

# Steps and settings

To perform a standard fluoroscopy, you must always make the following steps and settings:

- If the password-protected user administration (HIPAA) is activate and you have obtained your access data in the **Patient** operating mode, log in by entering User ID and Password.
- Create a new patient folder in the Patient operating mode, or activate the desired patient folder in the Patient or Archive operating mode.
- Select the desired fluoroscopy mode in the Fluoroscopy operating mode.
- Select standard control mode or low-level control mode using the pulse rate setting function.
- **5.** Select the fluoroscopy program.
- **6.** Generate the fluoroscopic image.
- 7. Save the fluoroscopic image.
- **8.** Print the fluoroscopic image, if desired.

# 8.2 Fluoroscopy modes

# Fluoroscopy modes

During fluoroscopy, radiation is interrupted at certain intervals (pulsed). The length (pulse width) and frequency (pulse rate) of the radiation interval are preset for each anatomical program and are displayed on the control panel.

The system provides the following fluoroscopy modes:

- Pulsed fluoroscopy
- Digital radiography (snapshot)

# Automatic exposure rate control

Both fluoroscopy modes work with automatic exposure rate control (AERC), unless you explicitly activate the **Manual Exposure Rate Setting** mode.

The tube voltage and the tube current are adjusted automatically, taking into account the selected fluoroscopy program as well as the object subject to fluoroscopy.

The radiation quality is determined by the selected settings and automatically adjusts to the body region or imaging details indicated by the anatomical program.

Automatic exposure rate control (AERC) reduces the radiation burden of both patient and operating staff to a minimum and prevents overexposure of the screened body region.

Fluoroscopy modes > Pulsed fluoroscopy

# ▲ WARNING

# WARNING WARNING

Using the **Manual Exposure Rate Setting** mode influences the radiation quality, image quality, air kerma and air kerma rate.

Automatic Dose Reduction (with ODDC only) The **Extremities/cervical spine/head** anatomical program includes a motion detection function, which automatically reduces the pulse rate when the screened object does not move.

# 8.2.1 Pulsed fluoroscopy

In pulsed fluoroscopy mode, the system emits radiation pulses as long as you press the radiation button.

Pulse rate

You may adjust the pulse rate. The lower the pulse rate setting, the lower the radiation dose.

Pulse width

The pulse width is indicated in percent and cannot be modified. A pulse width of 100% corresponds to 40 ms (USA: 30 ms).

Pulse settings for anatomical programs

The pulse width and pulse rate for each anatomical program are preset in the **Configuration** operating mode under **Service settings**. You cannot make these presettings yourself.

Contact your in-house service engineer if you wish to preset or modify the pulse width and/or pulse rate values for any anatomical program.

To generate an image in pulsed fluoroscopy mode, do the following:



- Press the Pulsed fluoroscopy button.
  - ⇒ The preset pulse width and pulse rate for the selected anatomical program are indicated on the Pulse width % and Pulses/s displays on the control panel.

The corresponding controls appear in the dynamic control area.

2

Press the button for the desired pulse rate, e.g. 2 pulses/s (standard control mode = 25 or 30 pulses/s; low-level control mode ≤ 8 or ≤ 10 pulses/s).

Fluoroscopy modes > Pulsed fluoroscopy



3. Initiate radiation.

# **ACAUTION** CAUTION



Risk of injury by X-rays!

Put on X-ray protective clothing before you initiate

**Automatic Dose** Reduction (with ODDC only)

Dedicated anatomical programs include an Automatic Dose Reduction function.

The system detects whether the fluoroscopy object is moving or not and automatically readjusts the pulse rate.

# To generate an image in pulsed fluoroscopy mode with Automatic Dose Reduction, do the following:



- 1. Press the **Pulsed fluoroscopy** button.
  - ⇒ The preset pulse width and pulse rate for the selected anatomical program are indicated on the Pulse width % and Pulses/s displays on the control panel.

The corresponding controls appear in the dynamic control area. The AUTO button is active. You need not make any further settings.



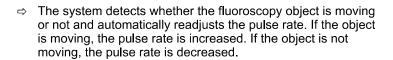
2. Initiate radiation.

# **ACAUTION** CAUTION



Risk of injury by X-rays!

Put on X-ray protective clothing before you initiate radiation.



# Filter factors

For each individual anatomical program, certain filter factors can be preset for pulsed fluoroscopy mode. This is done in the Configuration operating mode under Service settings. You cannot make these presettings yourself.

Contact your in-house service engineer if you wish to preset or modify the filter factors for any anatomical program.

Fluoroscopy modes > Digital radiography (snapshot)

# 8.2.2 Digital radiography (snapshot)



### NOTE

This function has not been tested for interventional procedures in accordance with IEC 60601-2-43.

In **Snapshot** mode, the radiation time does not depend on how long you press the radiation button. For each anatomical program, a specific AERC characteristic is stored on the system for the digital radiography mode. The fluoroscopy parameters are adjusted using the respective AERC characteristic, and radiation is terminated automatically afterwards. Every setting you make in the dynamic control area will have no effect, because all fluoroscopies are acquired at maximum pulse rate.

# Fields of application

The **Snapshot** mode is suitable for examinations involving no patient movement. The aim of snapshot mode is to generate high-quality static images, e.g. for printing / documentation purposes.

# To generate an image in snapshot mode, do the following:



1. Press the Snapshot button.



2. Initiate radiation.



# **ACAUTION** CAUTION

Risk of injury by X-rays!

Put on X-ray protective clothing before you initiate radiation.

To deactivate the Snapshot mode, press the Pulsed fluoroscopy button.

# Filter factors

For each individual anatomical program, certain filter factors can be preset for the **Snapshot** mode. This is done in the **Configuration** operating mode under **Service settings**. You cannot make these presettings yourself.

Contact your in-house service engineer if you wish to preset or modify the filter factors for any anatomical program.

Manual Exposure Rate Setting

#### 8.2.3 Dose reduction

# Manual dose reduction

Using the pulse rate setting function you can choose whether you want to work in standard control mode or low-level control mode. For standard control mode select 25 pulses/s or 30 pulses/s, for low-level control mode  $\leq$  8 pulses/s or  $\leq$  10 pulses/s.

If you select 8 pulses/s or less, you reduce the dose rate. It is recommended that you always use the lowest possible pulse frequency according to the type of examination to be performed. The lower the pulse rate the greater the dose reduction to the patient.

# **Automatic Dose** Reduction (with ODDC only)

Dedicated anatomical programs include an Automatic Dose **Reduction** function. The system detects whether the fluoroscopy object is moving or not and automatically readjusts the pulse rate. If the object is moving, the pulse rate is increased. If the object is not moving, the pulse rate is decreased.

#### 8.3 Manual Exposure Rate Setting

The tube voltage and the tube current are usually adjusted automatically by the system's automatic exposure rate control. You may, however, set the exposure rate also manually, if necessary.

# **WARNING WARNING**



To protect patients and staff against high radiation doses. the Manual Exposure Rate Setting mode remains blocked until you have initiated radiation in one of the fluoroscopy modes with automatic exposure rate control at least once.

Only use the Manual Exposure Rate Setting mode in exceptional circumstances. The automatic exposure rate control provides high image quality while minimizing the dose rate

Using the Manual Exposure Rate Setting mode influences the radiation quality, image quality, air kerma and air kerma rate.

# To aquire an image in Manual Exposure Rate Setting mode, do the following:



- 1. Press the button for the desired anatomical program, e.g. Heart.
- 2. Select the button for the desired fluoroscopy mode with automatic exposure rate setting:

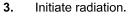


# Pulsed fluoroscopy

Manual Exposure Rate Setting









### ACAUTION CAUTION

Risk of injury by X-rays!

Put on X-ray protective clothing before you initiate radiation.



- 4. Press the Manual Exposure Rate Setting button.
  - The kV value which has been automatically determined is saved for subsequent fluoroscopies, and the system switches to the manual mode.

The corresponding controls appear in the dynamic control area.

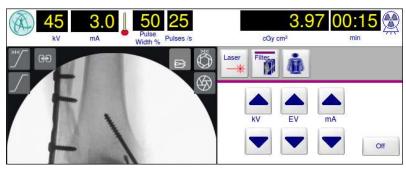




Fig. 62: Manual Exposure Rate Setting



Select the desired kV and mA values using the Up Arrow and Down Arrow buttons. Each time you press an arrow button, the value is increased/decreased by 1 kV or 0.1 mA.

If the selected anatomical program is configured accordingly in the system settings, the arrow buttons for **EV** (exposure values) are displayed.

Under EV you can optionally use the Up Arrow and Down Arrow buttons to set the exposure values. Each time you press an arrow button, the kV and mA value is increased/decreased according to the system settings.

Object-Detected Dose Control > Anatomical programs



Initiate radiation. 6.

### **ACAUTION** CAUTION



Risk of injury by X-rays!

Put on X-ray protective clothing before you initiate

To deactivate the Manual Exposure Rate Setting Mode, do the following:



Press the Manual Exposure Rate Setting button.

or



Press the **Off** button in the dynamic control area.

⇒ The Manual Exposure Rate Setting mode is deactivated.

### 8.4 **Object-Detected Dose Control**

### **Function**

The Extremities/cervical spine/head anatomical program includes a grid control which automatically detects objects in the entire field of view and accordingly sets optimum exposure parameters for the ROI.

This is achieved through a grid of 256 measuring cells covering the entire field of view. This means that even objects that are located offcenter are optimally visualized.

## Automatic metal correction

The **Automatic Metal Correction** function that is implemented in the Extremities/cervical spine/head anatomical program corrects a possible flaring of the fluoroscopic image resulting from metal objects in the beam path and increases contrast at tube voltages above 50 kV.

### Fluoroscopy programs 8.5

Using the pulse rate setting function you can choose whether you want to work in standard control mode or low-level control mode. For standard control mode select 25 pulses/s or ≤ 30 pulses/s, for low-level control mode  $\leq$  8 pulses/s or  $\leq$  10 pulses/s.

#### 8.5.1 **Anatomical programs**

The following anatomical programs are optionally available:

Fluoroscopy programs > Anatomical programs

Symbol(s)	Meaning
•	Bones (Ziehm Solo)
110	The <b>Bones</b> anatomical program is optimized for visualizing any part of the human skeleton. It is used mainly in orthopedics.
	Automatic Dose Reduction and Automatic Noise Filter Adjustment functions are included.
	<b>Extremities/cervical spine/head (Fluoroscopy</b> operating mode) (Ziehm Solo FD)
	The <b>Extremities/cervical spine/head</b> anatomical program is optimized for visualizing bones of extremities, cervical spine and head. It is used mainly in orthopedics.
	<b>Automatic Dose Reduction</b> and <b>Automatic Noise Filter Adjustment</b> functions are included.
•	Trunk (Fluoroscopy operating mode) (Ziehm Solo FD)
	The <b>Trunk</b> anatomical program is optimized for visualizing bones of the trunk. It is used mainly in orthopedics.
•	Heart
	The <b>Heart</b> anatomical program is optimized for visualizing the heart and the thorax. It is used in general chest imaging or pacemaker implant imaging.
•	Abdomen
	The <b>Abdomen</b> anatomical program is optimized for visualizing any anatomical structure in the abdominal region. It is used e.g. for cholangiographies, dilatations and stent implantations.
•	Uro
	The <b>Uro</b> anatomical program is optimized for visualizing soft tissues and medical instruments during urologic procedures.
Soft	Soft
- Jan	The <b>Soft</b> anatomical program is optimized for visualizing soft tissues. It is used e.g. for foreign body localization and implants and for visualization of injection needles and skin contours.
LP.	Long Procedure Spine
	The <b>Long Procedure Spine</b> anatomical program is intended for extended exposure time.

# To activate an anatomical program, do the following:

Press the button for the desired anatomical program.

 $\ \Rightarrow\$  This adjusts the fluoroscopy parameters to the body region to be examined.

The button is highlighted in yellow.

The anatomical program will remain active until you choose another program.

Fluoroscopy programs > Motion function

# Filter factors

For each of these anatomical programs, certain filter factors can be preset. This done in the **Configuration** operating mode under **Service settings**. You cannot make these presettings yourself.

Contact your in-house service engineer if you wish to preset or modify the filter factors.

# **Supplementary** functions

If required, a number of supplementary functions can be combined with any anatomical program:

- Metal Correction
- Motion (n/a for Subtraction operating mode)
- Low Dose

In the **Extremities/cervical spine/head** (Ziehm Solo FD) / **Bones** (Ziehm Solo) anatomical program, the following function is enabled by default:

Automatic Noise Filter Adjustment

If you wish to disable the **Automatic Noise Filter Adjustment** function in the **Extremities/cervical spine/head** (Ziehm Solo FD) / **Bones** (Ziehm Solo) anatomical program, contact your in-house service engineer.

# 8.5.2 Metal Correction function

The **Metal Correction** function corrects a possible flaring of the fluoroscopic image on the screen resulting from metal objects in the beam path and increases contrast at tube voltages above 50 kV.

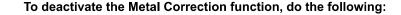
The **Metal Correction** function can be combined with any anatomical program.

To activate the Metal Correction function, do the following:



Press the Metal button.

⇒ The button is highlighted in yellow.





Press the Metal button again.

⇒ The button returns to its gray color, and the Metal Correction function is deactivated.

# 8.5.3 Motion function

The **Motion** function uses special filter settings to reduce motion blurring in the fluoroscopic images.

Fluoroscopy programs > Low Dose function

The **Motion** function can be combined with any anatomical program (n/a for **Subtraction** operating mode). When the **Automatic Noise Filter Adjustment** function is enabled in the **Extremities/cervical spine/head** (Ziehm Solo FD) / **Bones** (Ziehm Solo) anatomical program, the **Motion** function is not available.

# To activate the Motion function, do the following:



Press the Motion button.

⇒ The button is highlighted in yellow.

# To deactivate the Motion function, do the following:



Press the Motion button again.

The button returns to its gray color, and the Motion function is deactivated.

# 8.5.4 Low Dose function

The **Low Dose** function limits the dose during screening to the minimum value. Depending on application and situation, you can use the function either for applications with adults or pediatric applications. The function can be combined with any frame rate or anatomical program.

# To activate the Low Dose function, do the following:



- n/a for USA: Press the Pediatrics / Low Dose button.
  - ⇒ The button is highlighted in yellow.



- 2. USA only: Press the Low Dose button.
  - ⇒ The button is highlighted in yellow.

# To deactivate the Low Dose function, do the following:



Press the **Pulsed fluoroscopy** button.

⇒ The **Low Dose** or **Pediatrics / Low Dose** button returns to its gray color, and the **Low Dose** function is deactivated.

Further information regarding application-dependent dose reduction → Chapter 8.6 "SmartDose" on page 119

# 8.5.5 Automatic Dose Reduction function (optional)

The **Automatic Dose Reduction** function controls the pulse rate during fluoroscopy. The system detects whether the fluoroscopy object is moving or not and automatically readjusts the pulse rate. If the object is moving, the pulse rate is increased. If the object is not moving, the pulse rate is decreased.

If you wish to disable the **Automatic Dose Reduction** function in the **Extremities/cervical spine/head** (Ziehm Solo FD) / **Bones** (Ziehm Solo) anatomical program, contact your in-house service engineer.

# 8.5.6 Automatic Noise Filter Adjustment function

The **Automatic Noise Filter Adjustment** function controls recursive and LIH filter during fluoroscopy. The system detects whether the fluoroscopy object is moving or not and automatically readjusts the filters. If the object is moving, the filter levels are decreased. If the object is not moving, the filter levels are increased.

The **Automatic Noise Filter Adjustment** function is enabled by default in the **Extremities/cervical spine/head** (Ziehm Solo FD) / **Bones** (Ziehm Solo) anatomical program.

If you wish to disable the **Automatic Noise Filter Adjustment** function in the **Extremities/cervical spine/head** (Ziehm Solo FD) / **Bones** (Ziehm Solo) anatomical program, contact your in-house service engineer.

# 8.6 SmartDose

SmartDose is a conception designed to achieve dose reduction. It provides different tools which may be pursued for dose reduction to the patient implying the ALARA (As Low As Reasonably Achievable) principle. It is up to you either to use every tool on its own or combine it with others in order to achieve further dose reduction.

The actual dose reduction to the patient depends on whether you use a single SmartDose tool or combine it with others. Additional factors are duration and type of the procedure performed as well as patient size, weight and anatomical region.

# Dose reduction disclaimer (USA)

In clinical practice, the use of SmartDose may reduce patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

# 8 Standard Fluoroscopic Operations

SmartDose

### **ZAIP** filters

On flat-panel systems, dose is reduced by using the ZAIP filters automatically activated during fluoroscopy. ZAIP uses hardware-based filters and the latest algorithms for noise filtering, edge enhancement and dose optimization to achieve optimum image quality with the lowest dose possible. ZAIP helps you to obtain better noise reduction when screening moving objects without increasing the dose. Therefore lower frame rates are possible, allowing lower dose.

The actual dose you save depends on the program settings you would normally use as opposed to using the automatically activated ZAIP filters. Using the automatically activated ZAIP filters you can maintain image quality during procedures with lower dose and lower frame rates. This results in a lower dose received by the patient during the course of a procedure.

# **High Speed ADR**

In addition to the mentioned tools, SmartDose always uses the automatic exposure rate control High Speed ADR. This feature accelerates image regulation, allowing the system to achieve the determined pulse rate much faster.

The following table summarizes dose reduction recommendations depending on application and anatomical program. Use this table to find the most suitable and efficient way of reducing the dose depending on the clinical case of application. The final decision which tools to apply lies with the attending physician or attending surgeon.

Anatomical program	Clinical case of application				Sm	SmartDose tools	sloc			
(APR) <sup>a</sup>		Laser Positioning Device	Anatomical program	PreMag	Оррс	Pulse frequency reduction	Low Dose	Removable anti-scatter grid <sup>a</sup>	Virtual Collimation	Automatic LPK
Extremities/cervical spine/head (Fluoroscopy)	Hand / amr / elbow / oervical spine / head / thigh / knee / ankle joint / foot (upper and lower extremities)	•	•	•	•	•	•	•	•	
Trunk	Spine / hip / shoulder / pelvis	•	•	•		•			•	•
Heart	Cardiological application	•	•	•		•			•	
Abdomen / Uro	Universal program for abdomen and urology examination	•	•	•		•			•	•
Endo	Universal program for endoscopy / urology examination	•	•	•		•			•	•
Soft	Soft tissue, e. g. foreign body localization	•	•	•	•	•	•	•	•	•
Extremities, arteria carotis, cerebral vessels (Vascular)	Native program for vascular applications on arms or legs (upper and lower extremities)	•	•	•		•	•	•	•	
Trunk Vascular	Native program for vascular applications on trunk	•	•	•		•			•	
Bolus	Vascular native program to follow a contrast medium bolus	•	•	•		•		•	•	
DSA Extremities	Digital subtraction angiography of vessels for arms and legs using contrast media	•	•			•		•	•	
DSA Trunk	Digital subtraction angiography of vessels for trunk using contrast media	•	•			•			•	

Anatomical program	Clinical case of application				Sr	SmartDose tools	sloo			
(APR) <sup>a</sup>		Laser Positioning Device	Anstomical msrgorq	PreMag	ODDC	Pulse frequency reduction	Low Dose Function	Removable anti-scatter grid <sup>a</sup>	Virtual Collimation	Automatic LPK
RSA Extremities	Roadmap of arms or legs		•					•		
RSA Trunk	Roadmap of trunk		•							
DSA Extremities CO2	Digital subtraction angiography of vessels for arms and legs using $\mathrm{CO}_2$ as negative contrast medium	•	•			•		•	•	
DSA Trunk CO2	Digital subtraction angiography of vessels for trunk using CO <sub>2</sub> as negative contrast medium	•	•			•			•	
RSA Extremities CO2	Roadmap of arm or leg vessels with $\mathrm{CO}_2$ as contrast medium		•					•		
RSA Trunk CO2	Roadmap of trunk vessels with CO <sub>2</sub> as contrast medium		•							
Bone3D	3D program	•	•				•		•	
Bone3D 2	3D program	•	•				•		•	
2										

### SmartDose tools

The following sections briefly describe the different SmartDose tools and how you can reduce the dose with them:

# Laser Positioning Device

You can reduce dose by using the laser positioning device to align the radiation beam area to the center of the anatomical region of interest without initiating radiation ( → Chapter 17 "Laser Positioning Device" on page 295). It is recommended you always use the laser positioning device during the alignment of the C-arm to the anatomical regions of the patient.

The actual dose you save depends on the program settings selected and the time it takes under live fluoroscopic screening to locate the correct anatomical region as opposed to using the laser to localize the center of the anatomical region of interest without exposing the patient to radiation. Dose is saved even if there is only one less fluoroscopic exposure required.

# Anatomical program

You can reduce dose in general by choosing the suitable anatomical program for each clinical case of application, anatomical region and patient size. For each anatomical program the system is adjusted in a way that kV and mA levels are always in a range where optimum penetration can be achieved, yet avoiding overexposure or image undersaturation (  $\rightarrow$  Chapter 8.5.1 "Anatomical programs" on page 115).

The actual dose you save depends on the application and chosen anatomical program for your procedure.

# Low Dose Function

You can reduce dose by using the **Low Dose** function. This function amplifies the image signal generated by the image receptor in order to achieve constant image quality with reduced dose ( $\rightarrow$  Chapter 8.5.4 "Low Dose function" on page 118).

It is generally recommended to use this function for all applications in pediatrics but also for all other applications provided the image quality is sufficient for the procedure.

The actual dose you save using the **Low Dose** function depends on the radiation time during a procedure. It is finally the decision of the physician or surgeon if the image quality using the **Low Dose** function is sufficient to perform the actual procedure.

### Removable anti-scatter grid

You can reduce dose by removing the anti-scatter grid, especially for examinations where the voltage is expected not to exceed 60 kV (  $\rightarrow$  Chapter 2.2.6 "Removable anti-scatter grid" on page 39).

Such examinations are typically pediatric applications (except overweight children) or examinations of adult patients of the hand, foot, forearm, upper arm and the lower legs.

The actual dose you save when removing the anti-scatter grid depends on the program settings you would normally use as well as the anatomical region and patient population being screened.

# Pulse Frequency Reduction

You can reduce dose by manually changing the pulse frequency from 25 pulses/s to a lower value. Pulse frequency is directly proportional to the applied dose, therefore lowering the pulse frequency results in a significant reduction of dose (  $\rightarrow$  Chapter 8.2.1 "Pulsed fluoroscopy" on page 110).

It is recommended that you always use the lowest possible pulse frequency according to the type of examination to be performed. The lower the pulse rate the greater the dose reduction to the patient.

In a static situation the pulse frequency could be reduced down to 8 p/s or 4 p/s or further. In situations with a moving object, e. g. during a procedure of the heart or with pediatric patients, at least 8 p/s to 12.5 p/s might be required.

Pulse frequency in p/s	Relative dose rate	Calculated dose reduction
25	100%	0%
12.5	50%	50%
8	32%	68%
4	16%	84%
2	8%	92%
1	4%	96%

Table 12: Relation between pulse frequency and statistical dose reduction

# Object Detected Dose Control (ODDC)

You can reduce dose in the **Bones** (Ziehm Solo) / **Extremities**/ **cervical spine/head** (Ziehm Solo FD) anatomical program by using the **ODDC** function. **ODDC** when activated in the system provides object position detection within the beam and motion detection. When the object is not moving the pulse frequency is automatically reduced, therefore reducing the dose to the patient (  $\rightarrow$  Chapter 8.4 "Object-Detected Dose Control" on page 115).

The actual dose you save depends on the program settings you would normally use as opposed to the automatically activated **ODDC** function and the motion of the anatomical region being screened.

## PreMag

You can reduce dose by using the radiation-free electronic **PreMag** function. It assists you in previewing the live image at two magnification levels (Mag 1 and Mag 2) without additionally initiating radiation (  $\rightarrow$  Chapter 9.4 "Electronic image magnification" on page 139). If you can visualize what you need to see using the **PreMag** function then you can avoid an additional fluoroscopic exposure. If you then choose to make another fluoroscopic exposure the system is already set to the proper magnification level.

The actual dose you save depends on the program settings you would normally use as opposed to using the **PreMag** function when magnified imaging is required. Using the **PreMag** function even once during a procedure saves patient dose. Continued use when required may lead to significant dose savings to the patient.

### Virtual Collimation

You can reduce dose by adjusting virtual collimators to the acquired image. The virtual collimators, the dose measurement area and the video image control area always correspond to the position of the real collimator field size. You can adjust the position of the virtual collimators without initiating radiation. Lines representing the position of the collimators are projected on the stored image on the screen. This allows you to adjust the collimator exactly to the center of the anatomical region. By this means you can avoid additional radiation beyond the marked area and achieve dose reduction (  $\rightarrow$  "Virtual collimator" on page 142). Before the next radiation is initiated, the system knows exactly the shape and area of the X-ray beam. This speeds up image regulation time and therefore contributes to both image quality and dose savings.

The actual dose you save depends on the program settings you would normally use as opposed to using the **Virtual Collimation** function when collimation is required. Using the **Virtual Collimation** function even once during a procedure saves patient dose. Continued use when required may lead to significant dose savings to the patient.

Screen display during radiation

### Automatic LPK

You can reduce dose during the examination of adipose patients by using the **Automatic LPK** function. It increases the signal amplification of the acquired images which in a certain range compensates the reduced X-ray penetration of the patient and the resulting lower image brightness. The **Automatic LPK** function is automatically activated in the background once a preset voltage value is exceeded. Screening with a voltage below a second preset value automatically deactivates the **Automatic LPK** function. Alternatively, you can deactivate the **Automatic LPK** function manually by pressing the **Adipose Patient** button, returning to **Pulsed fluoroscopy** mode again.

Although **Automatic LPK** is an automatically activated function of the fluoroscopic AERC dose system, it provides additional dose savings by implementing ALARA as part of its functions. If the LPK mode is activated, the image signal is automatically amplified increasingly within the imaging chain. By means of this, the usually required higher exposure rate for adipose patients is reduced. The LPK dose rate reduction provides an increased range of adequate image quality when screening obese patients as compared to the standard mode. Therefore **Automatic LPK** can contribute to the efforts of saving dose while performing fluoroscopic imaging of obese patients.

# 8.7 Screen display during radiation

# Fluoroscopic image

While radiation is active, the current fluoroscopic image is displayed on the live screen and as a thumbnail (SmartEye) on the control panel.

When you terminate radiation (by releasing the hand or foot switch), the last fluoroscopic image is displayed on the live screen and as a thumbnail ('SmartEye') on the control panel.

This image remains displayed until it is replaced by a new fluoroscopic image.

# Fluoroscopy parameters

During the exposure, the tube voltage and the tube current are automatically set by the system, and the values are shown on the **Voltage** (kV) and **Current** (mA) displays of the control panel.

# Visual alarms

Active radiation is indicated by the following visual alarms:

- The X-ray symbol on all control panels lights up yellow.
- The radiation indication lamp on the monitor is illuminated.
- The radiation indication lamp on the mobile stand control panel is illuminated.
- The radiation indication lamp on the accessorial control panel (if available) is illuminated.

# 8.8 Dose parameters

Depending on your chosen option, the following data are displayed on the control panel and the live screen:

Option	Display on control panel	Display on live screen
Dose area product	Dose area product	Air kerma rate and cumulative air kerma
Air Kerma	Air kerma rate and cumulative air kerma	Dose area product

# 8.8.1 Dose area product

The dose area product is saved for each patient folder and updated with each new exposure. The total dose received by a patient so far is displayed on the control panel. This also includes the dose area product for images which have not been saved.

While creating a new patient folder, the values of all cumulative dose displays are reset to zero.

# Display on the control panel

The total dose received by the patient so far is shown in the **Dose Area Product** display on the control panel.

If you want to modify the unit of the dose area product, contact your inhouse service engineer.

# Display on the live screen

The current values for air kerma rate and cumulative air kerma are always displayed on the live screen.

# 8.8.2 Air Kerma

Air kerma display on the control panel The cumulative air kerma is saved for each patient folder and updated with each new exposure. The total dose in mGy received by a patient so far is shown on the **Air Kerma** display on the control panel. This also includes the cumulative air kerma for images which have not been saved.

# Air kerma rate display on the control panel

The **Air Kerma Rate** display showing the current air kerma rate in mGy/min appears on the control panel.

# Display on the live screen

The current dose area product in the selected unit is always displayed on the live screen.

Save

# 8.9 Save



# **NOTE**

When the hard disk is full, the oldest patient folder is overwritten without warning.

Before saving an image, make sure that there is enough free hard disk space, and regularly back up the patient folders which are still needed to external storage media or to the network.

# Image number

Each saved image automatically receives an image number. These image numbers are assigned and incremented consecutively for each separate patient folder.

Unsaved images (those without a number) will be replaced by a new fluoroscopic image during the next fluoroscopy.

# Default foot switch assignment

On the two-pedal foot switch, the **Save image** function is usually assigned to the right pedal. Depending on the customer-specific configuration, the foot switch pedals may be programmed with other functions and are labeled accordingly in this case.

To save the last image displayed on the live screen to the active patient folder, do the following:



Press the Save button.





If the right foot switch pedal is programmed with the **Save image** function: Press the right pedal (2) of the two-pedal foot switch.

During the save operation, the save symbol is displayed on the live screen.

When the save operation has been completed, the image number is displayed on the screen.

### **Autostore function**

You can configure the system in such a way that during each fluoroscopy a new image will be saved automatically as soon as you terminate radiation (**Autostore** function).

## To activate the Autostore function, do the following:



Press the **Save** button for approx. 3 seconds.

The Autostore function is activated. The Save button is highlighted in yellow. During each subsequent fluoroscopy, a new image is automatically saved as soon as you terminate radiation.

# To deactivate the Autostore function, do the following:



Press the **Save** button for approx. 3 seconds.

The button returns to its gray color, and the Autostore function is deactivated.

Alternatively, you can activate and deactivate the **Autostore** function in the **Configuration** operating mode under **Operation settings**.

This setting is saved until you activate another patient folder or switch off the system.

Alternatively, you can activate and deactivate the **Autostore** function in the **Configuration** operating mode under **Operation settings**. The selected presetting persists.

# Auto-delete function (n/a for USA)

During power-up or creating new patient folders, the system will automatically check if the remaining hard disk space is sufficient. If required, patient folders and/or images on the hard disk will be overwritten automatically and without confirmation prompt in the following order:

- 1. First, the oldest patient folder is overwritten. If there is still not enough disk space for the save operation, then the second oldest, third oldest, etc., patient folder are deleted. However, the active patient folder is never deleted.
- 2. If one of the patient folder contains protected and unprotected images, only the unprotected images will be deleted. The folder itself will not be deleted.
- 3. If it is not possible to free up enough space on the hard disk due to the large number of protected images, an audible alarm sounds. The following alert message appears on the control panel:
  - ⇒ Memory full. Image can not be stored!

The save operation is aborted.

# Deactivated autodelete function (USA)

The **Auto-delete** function is not activated. If there is not enough disk space for images, you must delete images manually to free up disk space.

# Cine loop

When you attempt to generate a cine loop, the system will check whether the remaining hard disk space is sufficient for the selected number of images. If disk space is insufficient, the unprotected patient folders and/or images are deleted in the above order. If this does not free up sufficient disk space either, no cine loop is acquired.

Print Live Screen image

#### 8.10 **Print Live Screen image**

The **Print Live Screen Image** function is available in the following operating modes: Fluoroscopy, Post processing, Measurement and **Archive.** This function is only enabled if the system is equipped with a video printer. The function always prints out the image which is displayed at full size on the live screen.

The text information that is displayed on the live screen together with the image (name of the patient, angle of rotation of the image, etc.) will appear as a text block on a gray background at the left margin of the printout.

If you have performed measurements in an image and saved them subsequently, the measured values are printed on a second page.

# To print the live screen image on the video printer, do the following:





Press the Print Live Screen Image button.

The image displayed on the live screen is printed.

# **ACAUTION** CAUTION



Risk of injury by cutting device!

You can hurt yourself when touching the cutting

Do not touch the cutting device when adding or removing paper.

Please refer to the *Operating Instructions* of the corresponding printer model.

# NOTICE NOTICE

On video printers with cutting function (characterized by CUT button) use the CUT button for cutting off the printer medium (paper or transparency film) in order to avoid damaging the video printer.

On video printers without cutting function you must always tear off the printer medium (paper).

Please refer to the **Operating Instructions** of the corresponding printer model.



# NOTE

The **PRINT** key at the video printer is not functional. If you wish to initiate a print job, always press the corresponding button on the control panel.

Warning signals and malfunctions > Temperature monitoring

### 8.11 Warning signals and malfunctions

#### 8.11.1 Permanent warning during radiation

Active radiation is indicated by the following visual alarms:



- The X-ray symbol on all control panels lights up yellow.
- The radiation indication lamp on the monitor is illuminated.
- The radiation indication lamp on the mobile stand control panel is illuminated.
- The radiation indication lamp on the accessorial control panel (if available) is illuminated.

#### 8.11.2 Interval warning during radiation

# Warning function

In order to prevent radiation from being accidentally generated over a long time, the system has a warning function. After each 4:55 minutes of elapsed total radiation time per patient, the following message appears on the control panel (x is a placeholder for a number):

Radiation will stop in x seconds. Press OK to avoid/stop the alarm.

5 seconds later, an audible alarm sounds.





If you do not switch off the alarm within 30 s after its initiation, radiation will be terminated automatically.



OK

You can see the total radiation time for the active patient folder on the Radiation Time display.

To switch off the alarm, do the following:

Press the **OK** button in the message window with the following information:

⇒ Radiation will stop in x seconds. Press OK to avoid/stop the alarm.

The audible alarm is not started or stops (if it is already sounding). The total radiation time remains displayed.

#### 8,11,3 Temperature monitoring



The thermal conditions in the generator are indicated by the temperature symbol.

Create report package

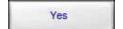
# 8.11.4 Error and alert messages

In the event of malfunctions, the corresponding error and alert messages are displayed as text in a message window on the control panel. Error and alert messages always start with the letter **E**.

At the same time, an audible alarm sounds.

For a detailed explanation of the messages, please refer to  $\rightarrow$  Chapter 20.4.2 "List of errors, alerts and status messages" on page 329.

 In case of malfunctions, please communicate the malfunction code number and the serial number of the system to the Service department of the Ziehm Imaging GmbH.



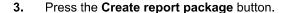
To close a message window which displays an error or alert message, press the Yes button.

# 8.12 Create report package

You can display the versions of the installed software modules and create a report package for error analysis by the Service department of the Ziehm Imaging GmbH.

# To create a report package, do the following:

- Plug a USB storage medium with sufficient storage capacity into the USB port.
- **2.** Press the X-ray symbol.
  - ⇒ A message window is displayed.



- ⇒ The report package is created and copied to the connected USB storage medium.
- 4. Press the **OK** button to close the message window.





# 9 Adjusting Live Images

# 9.1 Overview

Individual adjustment The system offers the following functions for adjusting the appearance of the live image to your individual needs:

Symbol(s)	Meaning
Filter	Filters  Recursive filter, LIH filter and edge filter
$\int$	Contrast/Brightness Contrast and brightness adjustment (Windowing)
	Magnify Electronic image magnification
<b>(5)</b>	Iris Collimator  Open and close iris collimator
	Slot Collimator  Open and close slot collimator
$\bigcirc$	Rotate Collimator  Rotates the slot collimator, resp. iris collimator.
<b>9</b> 0	Image Swapping Swaps the images of live and reference screens.
R	Reverse Up/Down Vertical image reversal
Image: section of the	Reverse Left/Right  Horizontal image reversal
	Image Rotation Rotate image in any direction

Filters > Recursive filter

Symbol(s)	Meaning
	Grayscale Inversion
9	To display an image with negative grayscale
	Any adjustments that are applied to a live screen image remain valid for all subsequent live images until you choose other settings. When you save an image, it will be saved with all rotations, reversals and markers, etc. All these modifications are visible when the image is displayed as a thumbnail in the mosaic.

Table 13: Overview of buttons

# 9.2 Filters

You may apply different filters to the live image. The following filters are available:

- Recursive filter
- · Edge filter
- LIH filter

# 9.2.1 Recursive filter

The recursive filter adds a specified number of images during fluoroscopy. Each newly-acquired image is superimposed by the result of the previous addition with a certain weighting factor.

# **Noise suppression**

The higher the number of images you select, the greater the noise suppression, but also the greater motion blurring.

There are three recursive filter levels, each corresponding to a preset number of images between 1 and 16.

# Automatic Noise Filter Adjustment

An **Automatic Noise Filter Adjustment** function is activated by default in dedicated anatomical programs. The system detects whether the fluoroscopy object is moving or not and automatically readjusts recursive and LIH filter. If the object is moving, the filter levels are decreased. If the object is not moving, the filter levels are increased.

# To set the recursive filter for the live image, do the following:



- 1. Press the **Filter** button.
  - ⇒ The corresponding controls appear in the dynamic control area.



Fig. 63: Filter settings for recursive, edge and LIH filter

- Under Recursive, select the desired recursive filter level by pressing the corresponding button.
  - ⇒ The filter setting becomes immediately visible in the live screen image. The selected level of the recursive filter appears on the screen as NR X where X is a placeholder for the selected values.



## 3. Press the Filter button.

⇒ The corresponding controls appear in the dynamic control area.

# Configuration

The individual presettings for the recursive filter levels are made in the **Configuration** operating mode under **Service settings**. You cannot make these presettings yourself.

Contact your in-house service engineer if you wish to preset or modify the individual recursive filter levels.

# 9.2.2 Edge filter

# Edge enhancement

The edge filter allows you to select a greater or lesser degree of edge enhancement within the image. There are 4 levels available:

Level	Meaning
Off	No edge enhancement (original fluoroscopic image)
1	Slight edge enhancement
2	Medium edge enhancement
3	Strong edge enhancement
-1	Unsharp mask to suppress noise

Table 14: Edge filter levels