Contents

ziehmimaging
dedicated to clinical innovation

Ziehm Solo

Technical Manual

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This document was produced in accordance with a certified QM system as per DIN EN ISO 13485. They conform to the requirements of Council Directive 93/42 EEC, Annex I, and other applicable norms. The information provided in this document may be updated at regular intervals. Subject to change without prior notice.

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Rev. 052010

Preface

With the Ziehm Solo, Ziehm Imaging GmbH provides an active medical device connected to the mains power supply. The above listed medical device is a non-contact device. 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.

Intended use

The Ziehm Solo is a mobile C-arm. Using a non-invasive X-ray method during surgical intervention, it provides image information and stores this temporarily.

The Ziehm Solo 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 can be used for the whole human body without restriction (e.g. organs, tissue, bones, implants) depending on the medical indication. This device is not intended for use in performing mammographic exposures.

Indications for use

The Ziehm Solo is intended to provide contactless fluoroscopy imaging, capturing, temporarily storing and display of non-invasive X-ray imaging of the patient using pulsed and continuous fluoroscopy during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room fluoroscopy procedures. Radiographic film examinations can be made with an accessory cassette device when attached to the image intensifier. This device does not support and is not intended for use in performing mammographic imaging.

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.

Exclusions

The system is not suitable for interventional procedures acc. to IEC 60601-2-43.

The monitors are not suitable for diagnostic purposes.

Operation

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

Operation (USA)

In the USA, Federal law restricts use of this device to trained personnel on the order of a physician.

Authorized personnel

Only authorized personnel are allowed to assemble and/or repair the medical equipment described in this document. Authorized personnel are persons who have attended an appropriate training course provided by the manufacturer.

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 not suitable for diagnostic purposes.

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 Ziehm Imaging's specifications 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.

CE 1275

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.

1 General Information

This manual is designed to enable owners and operators of the system to operate the systems described herein safely and efficiently.

Scope of validity of this manual

Ziehm Solo, software version 5.28.2 or higher.

All illustrations in these Operating Instructions are exemplary only, and may differ from the actual situation.

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

Separate operating instructions

For several system options, separate operating instructions may be available. They are supplied with the system, provided that the system configuration includes the respective option. You will find a corresponding reference to those operating instructions in the relevant sections of this manual.

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, please contact the Ziehm Imaging Service department.

The useful service life defined for this medical device is seven years. For this period Ziehm Imaging GmbH warrants that spare parts can be supplied. After this period, Ziehm Imaging GmbH must check whether the technology used is appropriate.

1.1 Typographical conventions

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

Element	Format	Example
Solo Centerelements (buttons and boxes), operating modes, functions, modes	Bold	**Fluoro**
Cross-references	Italic, preceded by an arrow	→ *Ch. 5, p. 5-1*
Procedure steps	Preceded by a •	• Press the **OK** button.
Text input	Courier, bold	**Administrator**

Table 1-1 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:

DANGER

DANGER

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

WARNING

WARNING

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

CAUTION

CAUTION

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

NOTICE

NOTICE

NOTICE indicates a property damage message.

NOTE

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

1.3 Accessories

The accessories are in a separate cardboard box on the pallet. Depending on the system configuration (options), the cardboard box contains the following accessory items:

	Accessories	Qty.
All systems	Operating Instructions	1
	DVD (Operating Instructions)	1
	DVD (Technical Manual)	1
	DVD (Service Manual: Sweden, Iceland and Ukraine)	1
	Specifications and Certificates	1
	Quick Guide	3
	Equipotential grounding cable (6 m) (Art. No. 24054)	1
	Touch-up paint RAL 9001 (Art. No. 89655)	1
	Touch-up paint RAL 6027 (Art. No. 89615)	1
	USB stick	1
Options	Mounting material (for systems on pallet: Art. No. 88711)	1
	Cassette holder	
	Cassette holder for a 23 cm image intensifier, format 18 × 24 (Art. No. 88113)	1
	Video printer	
	Operating instructions for video printer	1
	Printer paper	1 roll
	DVD writer	
	DVD (4.7 GB)	1
	DICOM	
	RJ45 interface with Cat.5 patch cable (10 m) (Art. No. 24452)	1
	Wireless LAN: Transceiver	1

Table 1-2 Accessories

	Accessories USA:	Qty.
All systems	Operating Instructions	1
	DVD (Operating Instructions)	1
	Technical Manual	1
	DVD (Technical Manual)	1
	DVD (Service Manual)	1
	CDRH Maintenance Report	1
	Specifications and Certificates	1
	Quick Guide	3
	Equipotential grounding cable (6 m) (Art. No. 24054)	1
	Mounting material (Art. No. 88711)	1 set
	Skin cone with safety label (Art. No. 89694)	1
	Touch-up paint RAL 9001 (Art. No. 89655)	1
	Touch-up paint RAL 6027 (Art. No. 89615)	1
Options	**Cassette holder**	
	Cassette holder for a 23 cm image intensifier, format 18 × 24 (Art. No. 88113)	1
	Video printer	
	Operating instructions for video printer	1
	Printer paper	1 roll
	DVD writer	
	DVD (4.7 GB)	1
	DICOM	
	RJ45 interface with Cat.5 patch cable (10 m) (Art. No. 24452)	1

Table 1-3 Accessories USA

2 Safety Instructions

2.1 General safety instructions

WARNING

WARNING

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

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

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

NOTICE

NOTICE

Supplementary equipment used in combination with the Ziehm Solo must comply with the safety requirements according to IEC 60601-1 and/or IEC 60601-1-1 or furnish proof of an equivalent degree of safety.

To ensure CE conformity, these components must have a CE approval in accordance with Council Directive 93/42/EEC. In addition, a declaration in compliance with Article 12 of the said directive must be provided.

For components without CE approval, a conformity assessment procedure is obligatory.

If you combine the Ziehm Solo with equipment which does not comply with these requirements, the safety of the entire system is no longer given and the warranty will become invalid.

Please note that a combination with third-party devices must be approved by Ziehm Imaging. A combination must be possible in particular by the intended use of the two devices.

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

The system may only be operated by properly trained personnel under the direction of a physician. **Operation (USA)**

Assembly and service

Only authorized personnel are allowed to assemble the system 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.

WARNING

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

2.2 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

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.

WARNING

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

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.

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.

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 (USA: 30 cm).

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

When you initiate radiation and no live image is displayed although all necessary settings have definitely been made, please contact your after-sales service center!

2.3 Electromagnetic compatibility

Medical electrical equipment requires special precautionary measures with respect to 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.

Only conductors, connecting cables and accessories that are specified by the manufacturer may be used.

WARNING

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

Please observe also *Ch. A.1, Manufacturer's Declaration concerning Electromagnetic Compatibility according to IEC 60601-1-2 (Class A)*!

2.4 Protective grounding

The system must be connected only to power systems having a separate ground connection.

2.5 Equipotential grounding

Heart and brain examinations

If you use the system in combination with other equipment for examinations of the heart or brain or the surrounding anatomical regions, equipotential grounding is required for patient and operating staff safety (IEC 60601-1-1).

2.6 Laser radiation

Laser positioning device

As an option, the system may be equipped with a laser positioning device at the image receptor and/or generator.

The laser positioning device uses diode laser modules which emit laser radiation. **Do not under any circumstances** look directly at the laser beam or any scattered laser radiation – either with the naked eye or with optical instruments.

The laser positioning device is a Class 2M laser product according to IEC 60825-1. Make sure to comply with all operating safety precautions when using the laser positioning device.

The maximum power output of continuous laser radiation, measured at the laser beam apertures, is <1 mW. The wavelength of the emitted radiation is 635 nm.

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 IEC 60825-1, Section 3, “User’s Guide” for operation of the laser positioning device.

Viewing the laser output 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 II LASER PRODUCT (in accordance with FDA 21 CFR, Subchapter J, Section 1040.10-11)

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.

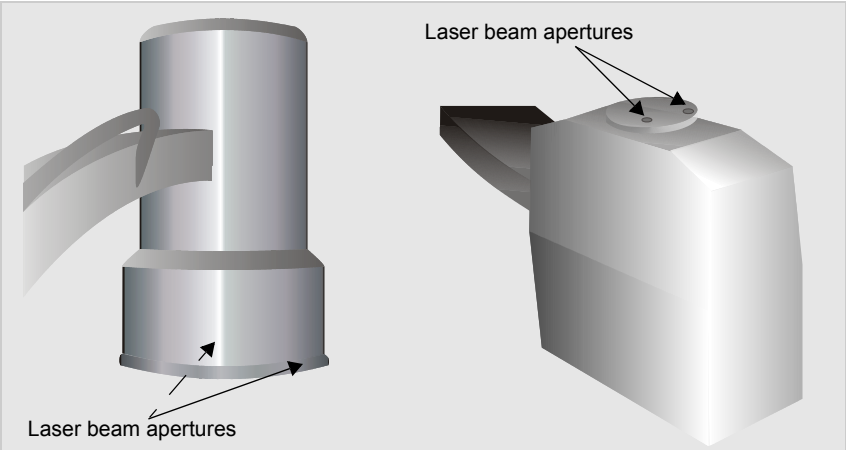


Fig. 2-1 Laser beam apertures on the image intensifier (left) and on the generator (right)

2.7 Temperature

Generator housing

CAUTION

CAUTION

The generator housing can reach a temperature of 48°C.

Prolonged contact with the generator housing (longer than 1 minute) may result in burns.

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

2.8 Printers

CAUTION

CAUTION

Risk of injury by cutting device!

You can hurt yourself 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.

NOTICE

NOTICE

When printing, tear off the printer paper on the Sony ® UP-897.

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

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.

2.9 System failure

CAUTION

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.

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.

2.10 Mechanics

CAUTION

Risk of stumbling due to improper cable laying.

This may cause obstructions to the operational procedure.

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

CAUTION

Keep in mind that the C-arm stand may roll away on uneven floors.

Leave the C-arm 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 C-arm stand.

3 Unpacking the System

WARNING

Only authorized personnel (→ *p. 1-3*) are allowed to unpack and assemble the system.

During assembly, the system may be handled only by trained personnel who have studied the contents of *Ch. Putting the System into Service* of the present document and *Ch. Mechanical Handling* of the Operating Instructions.

3.1 Contents of the pallet

Upon delivery, the pallet contains the following system parts:

- Solo Center (→ *Ch. 3.4, p. 3-8*)
- Monitor head (→ *Ch. 3.5, p. 3-10*)
- C-arm stand (→ *Ch. 3.6, p. 3-11*)
- Ramp (for drop shipments) (→ *Ch. 3.3, p. 3-4*)
- Accessories (→ *Ch. 1.3, p. 1-4*)

3.2 Unpacking the pallet on delivery to distributors

To unpack the full pallet, do the following:

Fig. 3-1 Packed pallet

- Cut the plastic straps and remove them.
- Check the two shock watch devices in the presence of the transport company representative. In case of a triggered shock watch device (indicators are red), the transport company is held liable for transport damages. If the indicators are white, keep on unpacking the pallet.

  USA: The second shock watch device is on the inside of the cardboard box.
- Remove the shipping tape from the cardboard box and open the box.
- **USA:**

  Remove the boards which have been provided for additional stabilization of the cardboard box (→ *Fig. 3-2, p. 3-2*).

Fig. 3-2 Boards for cardboard box stabilization (USA)

- Remove the clout nails holding the cardboard box to the pallet.
- Lift the cardboard box off the pallet.
- **USA**:
  Remove the small wooden blocks from both sides of the pallet
  (→ *Fig. 3-3, p. 3-3*).

Fig. 3-3 Small wooden blocks on the pallet (USA)

Fig. 3-4 System with foil wrapping

- Cut the wrap foil open and fold it back.

3.3 Unpacking the pallet on drop shipments

Prerequisites

Before unpacking the pallet, make sure that the following prerequisites are met:

- Loading ramp
- Forklift truck or manual pallet jack
- Sufficient space for assembling the system
- Tools required
- At least two persons for assembling the system
- Disposal of packing material

In drop shipments the pallet is equipped with a ramp. This ramp is required to move the C-arm stand off the pallet.

To unpack the full pallet, do the following:

Fig. 3-5 Packed pallet

- Cut the plastic straps and remove them.
- Check the two shock watch devices.
- Remove the shipping tape from the cardboard box and open it.
- Unfasten the screws that attach board 4 to boards 3 and 2 and remove board 4 (→ *Fig. 3-6*).

Fig. 3-6 Ramp packing in the cardboard box

- Unfasten the screws on the outside of the box, attaching board 3 on the inside of the cardboard box
  (→ *Fig. 3-7*), and remove board 3.

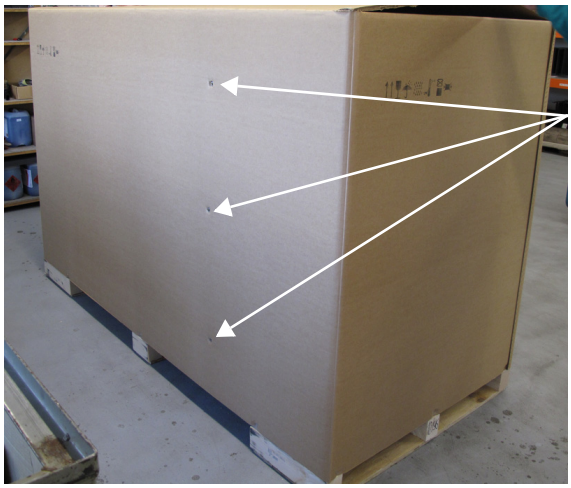


Fig. 3-7 Screws for attachment of the lateral boards

- Unfasten the screws on the outside of the box, attaching board 2 on the inside of the cardboard box
  (→ *Fig. 3-7*), and remove board 2.

- Remove the clout nails holding the cardboard box to the pallet.

- Lift the cardboard box off the pallet.

Fig. 3-8 System and ramp with foil wrapping

- Unfasten the two screws attaching board 1 on the ramp, and remove board 1.

- Lift the ramp off the pallet and place it to the short front side of the pallet.

- Remove the fixing clamps from the drill holes on the pallet.

Fig. 3-9 Fixing clamp hooked up in the drill holes on the pallet

- Attach the ramp to both sides of the pallet using the fixing clamps (→ *Fig. 3-10*).

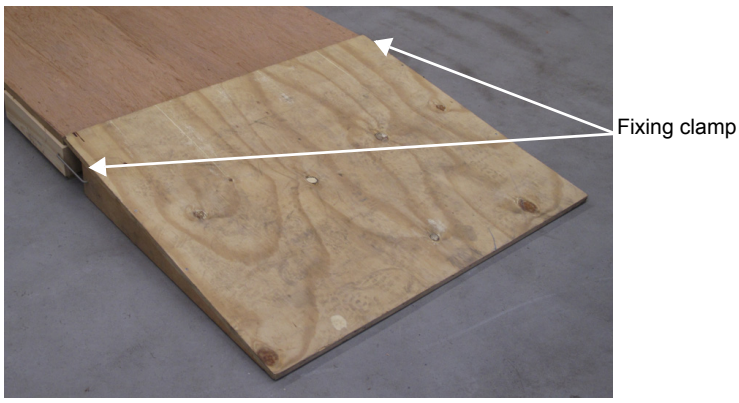


Fig. 3-10 Fixing clamps attaching the ramp

- Cut the wrap foil open and fold it back.

3.4 Unpacking the Solo Center

The Solo Center is in a cardboard box on the pallet.

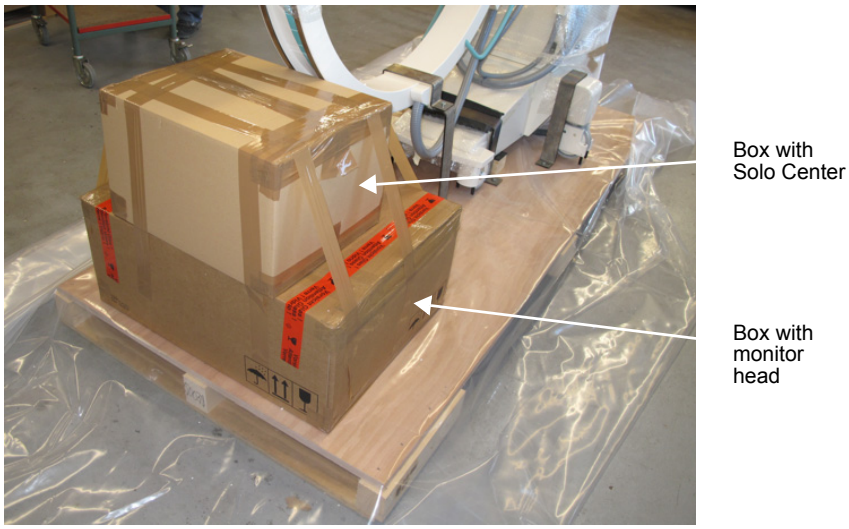


Fig. 3-11 Cardboard box with Solo Center and monitor head on the pallet

To unpack the Solo Center, do the following:

- Remove the shipping tape, attaching the cardboard box including Solo Center to the monitor head.
- Remove the foam rubber and styrofoam material used for padding the cardboard box on the outside.
- Lift the cardboard box off the pallet.
- Remove the shipping tape from the cardboard box and open the box.
- Remove the paper on top of the Solo Center.

Fig. 3-12 Wrapped Solo Center in cardboard box

- Carefully lift the Solo Center out of the box.
- Remove the bubble wrap from the Solo Center.
- Place the Solo Center, screen side up, on a suitable soft surface.

3.5 Unpacking the monitor head

The monitor head is located inside a cardboard box on the pallet.

To unpack the monitor head, do the following:

The monitor head is located inside a cardboard box on the pallet (→ *Fig. 3-11*).

- Remove the shipping tape from the cardboard box and open the box.
- Remove the foam rubber wrapped around the monitor head.
- Carefully lift the monitor head out of the box.

WARNING

Risk of injury!

The monitor head cannot be lifted by one person alone. With the help of a second person, lift the monitor head out of the box.

- Remove the bubble wrap from the monitor head.
- Place the monitor head, screen side up, on a suitable soft surface.

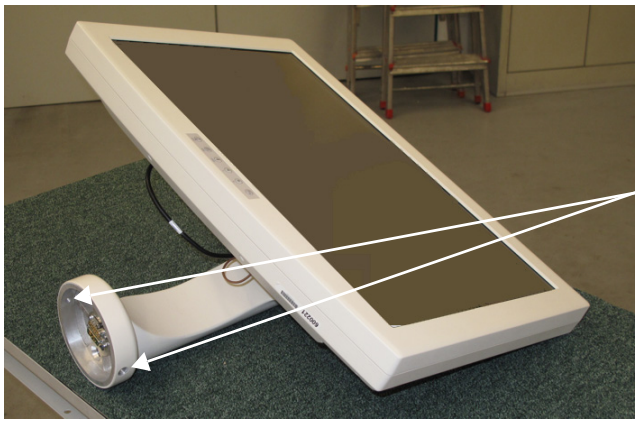


Fig. 3-13 Monitor head

3.6 Unpacking the C-arm stand

The C-arm stand is attached to the pallet by means of retaining brackets.

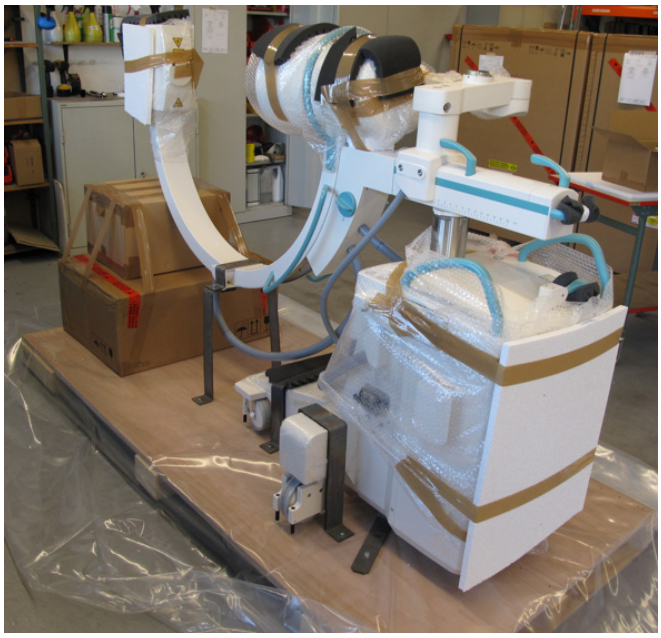


Fig. 3-14 Mobile C-arm stand on the pallet

To unpack the C-arm stand, do the following:

- Remove all packing materials (bubble wrap, foam rubber, styrofoam).
  The C-arm stand is attached to the pallet by means of 5 retaining brackets:

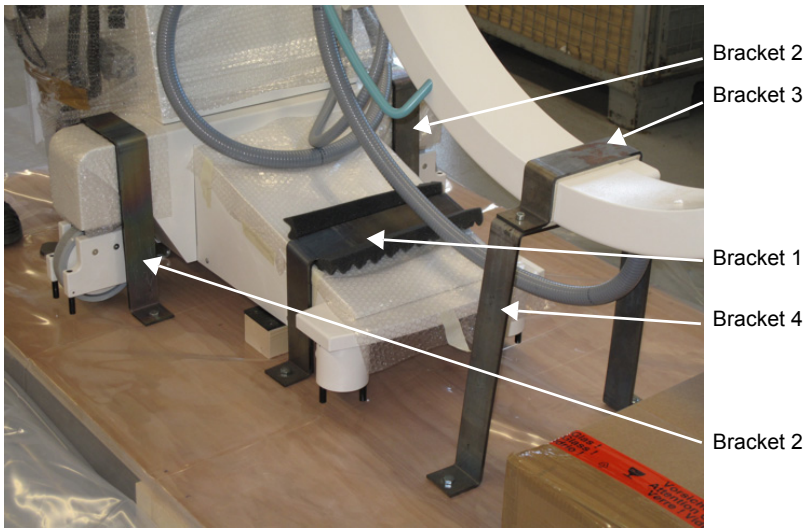


Fig. 3-15 Overview of all retaining brackets

- Undo the screws holding retaining bracket 3 to retaining bracket 4, and remove retaining bracket 3.
- Undo all screws holding retaining brackets 1, 2 and 4 to the pallet.
  USA: All retaining brackets are attached to the pallet from below.
- Remove all retaining brackets from the pallet.
- **USA**:
  Remove the two small wooden blocks placed below retaining bracket 2 on the left side from the pallet.
- Unscrew and remove the two mounting levers on the left and the right side from below the C-arm stand as illustrated in *Fig. 3-16*.
- Remove the square timber from below the C-arm stand. Lift the C-arm stand slightly for that purpose.

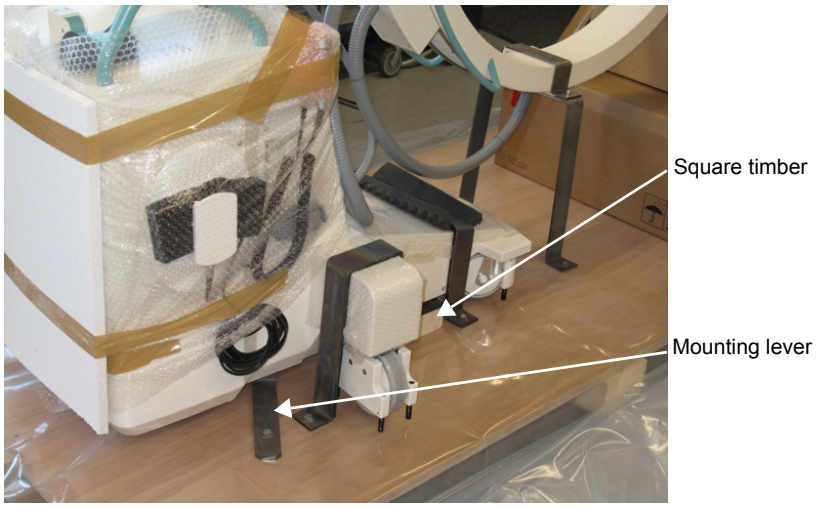


Fig. 3-16 C-arm stand with underlaid square timber and secured mounting lever.

- Put the C-arm into an upright position (orbital rotation).
- Remove the styrofoam block jammed between the image receptor and the horizontal carriage.
- Carefully push the C-arm stand down from the pallet using a ramp.

4 Assembling the System

4.1 Overview

WARNING

Only authorized personnel are allowed to unpack and assemble the system.

During assembly, the system may be handled only by trained personnel who have studied the contents of *Ch. Putting the System into Service* of the present document and *Ch. Mechanical Handling* of the Operating Instructions.

To assemble the system, you must perform the following steps:

- Mount the monitor head (→ *Ch. 4.2, p. 4-2*)
- Mount the Solo Center (→ *Ch. 4.3, p. 4-4*)
- Establishing a DICOM connection, if applicable (→ *Ch. 4.4, p. 4-8*)

4.2 Mounting the monitor head

NOTICE

NOTICE

Always wear cotton gloves when installing, testing or making settings on displays or screens.

To mount the monitor head to the monitor support arm, do the following:

- With the help of a second person, lift the monitor head and place it on the monitor support arm.

WARNING

WARNING

Risk of injury!

The monitor head cannot be lifted by one person alone. With the help of a second person, lift the monitor head and place it on the monitor support arm.

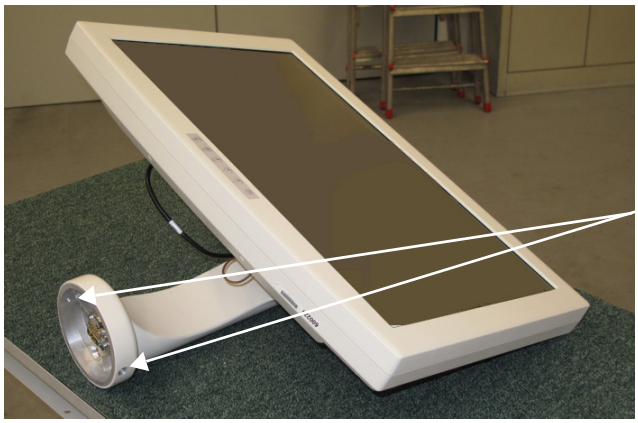


Fig. 4-1 Monitor head

- Place the monitor head on the alignment pin of the monitor support arm.

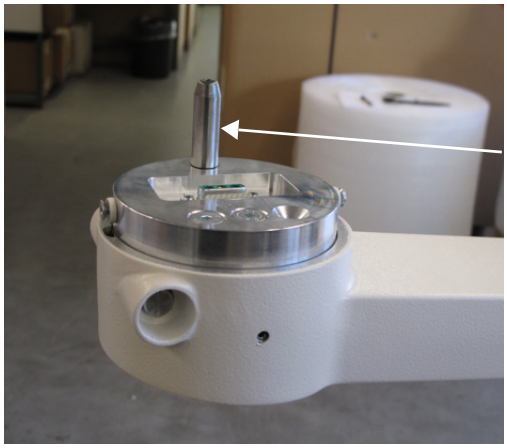


Fig. 4-2 Alignment pin on the monitor support arm

- Fasten the monitor head to the monitor support arm using two Allen screws.

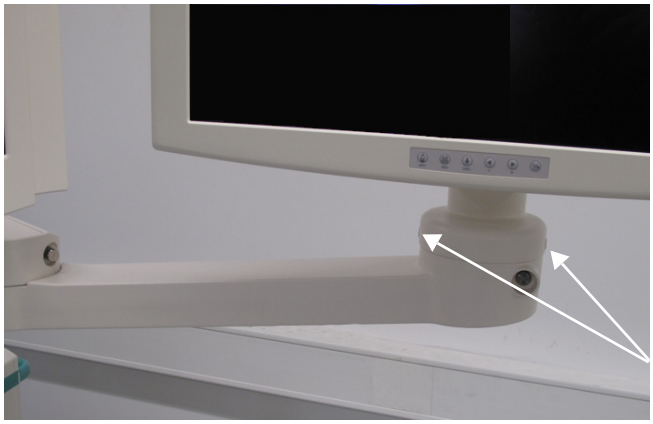


Fig. 4-3 Monitor head attachment

4.3 Mount Solo Center

NOTICE

NOTICE

Always wear cotton gloves when installing, testing or making settings on displays or screens.

To mount the Solo Center to the C-arm stand, do the following:

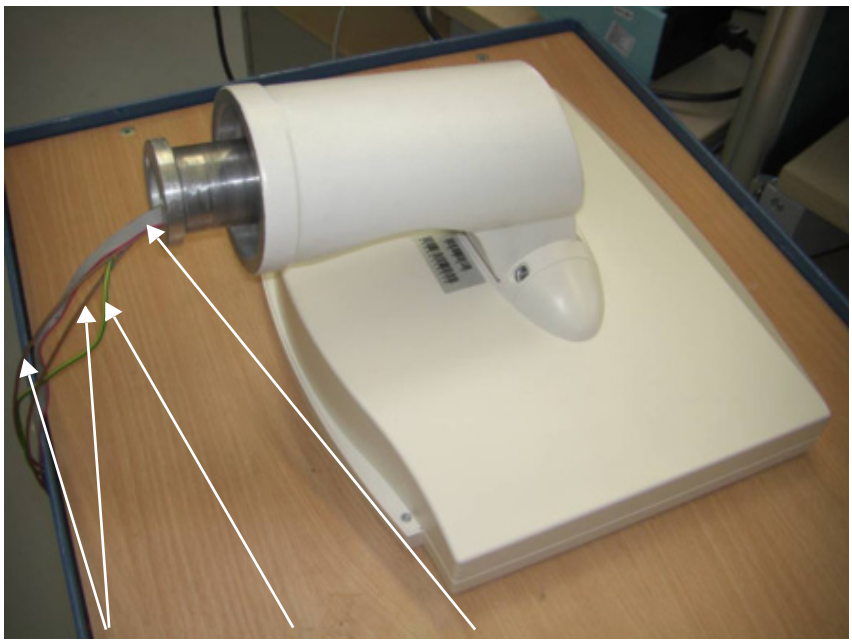


Fig. 4-4 Dismounted Solo Center

- Remove the cover plate at the bottom of the Solo Center support arm (→ *Fig. 4-5*).

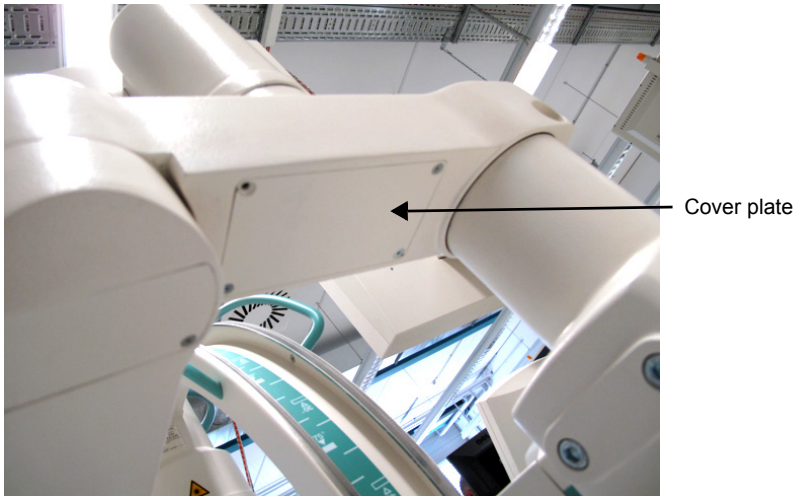


Fig. 4-5 Solo Center support arm with cover plate

- Loosen the three screws on the Solo Center, remove the screws, the flange and the spacer rings (→ *Fig. 4-6*).

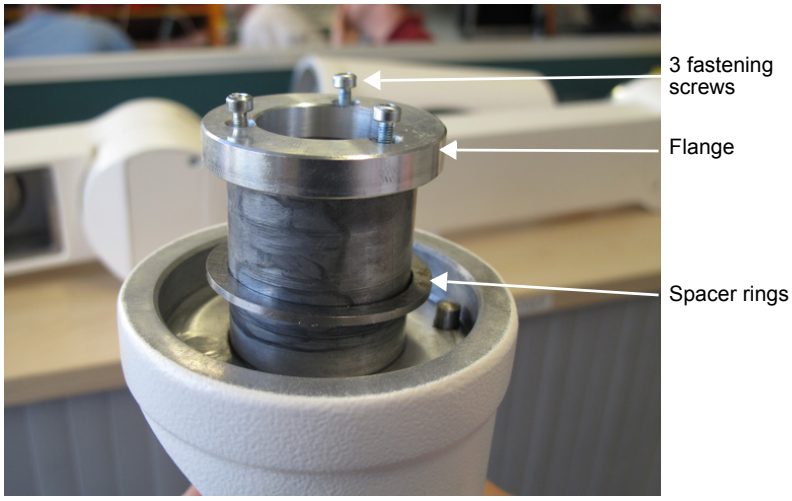


Fig. 4-6 Items for attachment of the Solo Center

- Take the Solo Center (→ *Fig. 4-4*) in your hand and stand next to the Solo Center support arm.
- Place the Solo Center above the opening that is provided for mounting it on the Solo Center support arm.
- With the help of a second person from above pull in the coaxial cables protruding from the support arm until they come out at the opening of the cable duct.
- Carefully lift the Solo Center on to the Solo Center support arm.
- Apply the spacer rings and the flange (→ *Fig. 4-7*).

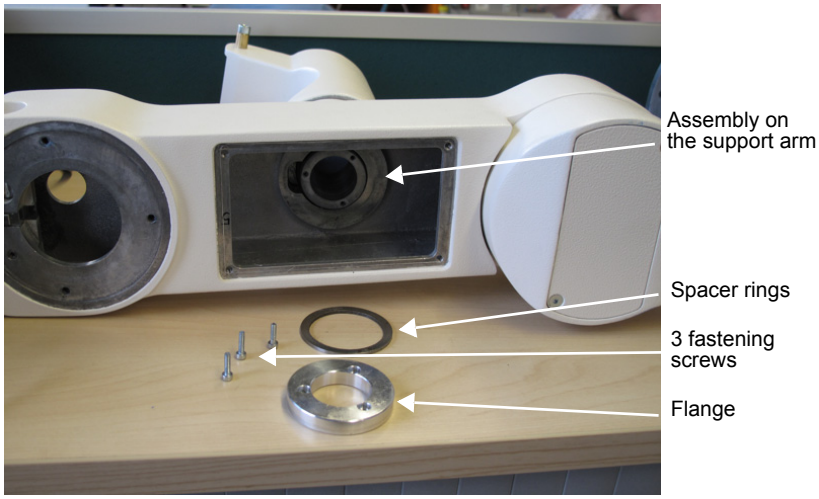


Fig. 4-7 Support arm with Solo Center from below

- Apply the flange on the Solo Center support arm by using the screws.

- Connect the ground wire to the grounding point on the circuit board mounted on the cover plate (→ *Fig. 4-8*).

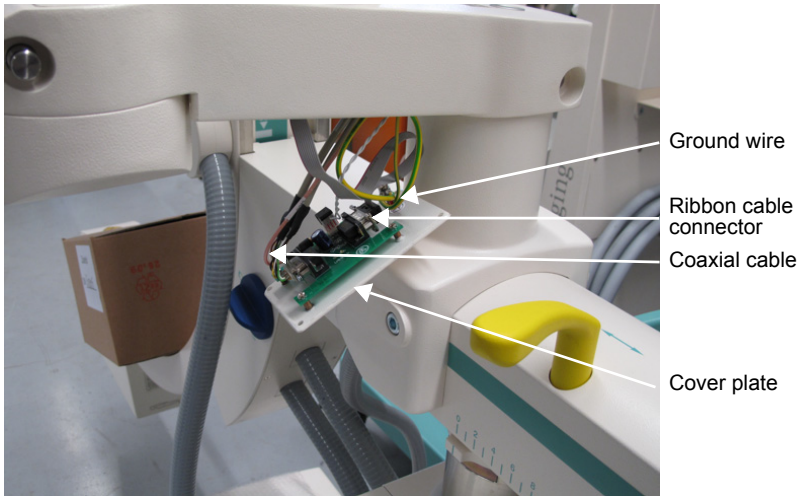


Fig. 4-8 Connections on the circuit board of the cover plate

- Connect the ribbon cable with the corresponding connector on the circuit board.
- Connect both coaxial cables with the coaxial cables on the circuit board mounted on the cover plate (the red one with Giga link +; the black one with Giga link -).

WARNING

WARNING

Cable damage!

Take care not to squash and damage the cables while doing this.

- Fasten the cover plate at the bottom of the Solo Center support arm using four screws (→ *Fig. 4-5*).

WARNING

WARNING

Cable damage!

Take care not to squash and damage the cables while doing this.

- Fasten the lateral clamping screw on the Solo Center in such a way, so you can still swivel the Solo Center smoothly (→ *Fig. 4-9*).

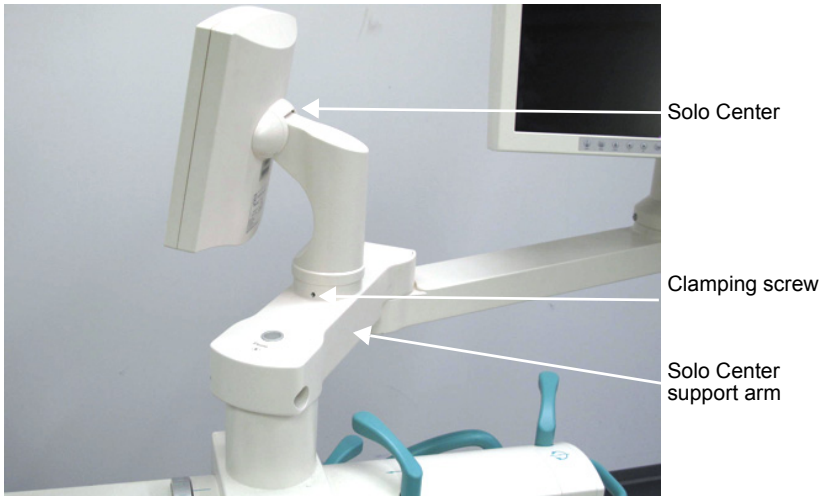


Fig. 4-9 Solo Center support arm

4.4 DICOM connection (option)

General

Depending on the system configuration, different technologies are used for connecting the system to the hospital's DICOM network:

- an RJ-45 connection (Twisted Pair, 100 Mbit/s)
- a Wireless LAN connection

RJ-45 connection

On systems with an RJ-45 connection, a network cable runs directly from the network interface card of the image memory module out over a terminal clamp and terminates in an RJ-45 socket. The system must be connected to the hospital's DICOM network via this socket.

To connect the system to the DICOM network, do the following:

- Connect the RJ-45 socket on the terminal clamp to a DICOM network socket using the appropriate cable.

Wireless LAN

On systems with Wireless LAN, a transceiver is located on the C-arm stand. A second transceiver comes with your accessories and must be connected to the hospital's DICOM network.

To connect the system to the DICOM network, do the following:

- Connect the transceiver included in the accessories to a DICOM network socket.

5 Putting the System into Service

5.1 Operating temperature

Room temperature

In case of major differences in temperature, all parts of the system must have reached room temperature before the system is put into service in order to avoid damage to the system as a result of condensation.

NOTICE

NOTICE

Do not operate the system until the equipment has reached a safe operating temperature of +13 °C to +35°C with no condensation present.

Otherwise severe equipment damage may result.

NOTICE

NOTICE

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

5.2 Power supply connection

General

Before switching on the system for the first time, or after each transport, you must connect the system to the power supply.

To connect the system, do the following:

- Unwind the power cable from the cable support.
- Make sure that a suitable supply voltage is available and that the socket-outlet is properly grounded and fused.
- Check the power plug on the C-arm stand power cable and the socket-outlet for compatibility (*Ch. 2.8 of the Operating Instructions*).
- Connect the system to the power supply.
  The **OFF** switch on the C-arm stand is illuminated in white.

5.3 First power-up of the system

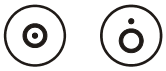
Preparation

NOTE

The doors of the room, in which the system is operated should not be provided with interlocks.

To avoid unintentional interruption, do the following:

- Make sure that the inclination of the system does not exceed 5° from the level in operating position.
- Ensure that all electrical connections are properly established (→ *Ch. 5.2, p. 5-1*).
- Put on suitable protective clothing.



- Switch on the system.

  The keys for switching the system on and off are located on the left side of the C-arm stand next to the handle.

The default settings after power-up vary from system to system, according to the customer-specific setup.

NOTICE

NOTICE

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

NOTE

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

5.4 Setting up the system

Configuration

You have the possibility to adjust various basic and operation settings so as to meet your special working requirements. If these settings have not already been made at the factory, you can make them yourself in the **Configuration** operating mode (→ *Ch. 6, p. 6-1*).

Entering the hospital data

In order to avoid having to enter the invariable hospital data (i.e., name of the hospital, department and doctor) again and again for each new patient, you can record this data once in the **Configuration** operating mode under **Basic Settings**. Each time you create a new patient folder, the hospital data which has been entered there will appear automatically in the corresponding boxes.

Further settings

For a detailed description of all other setting options, please refer to (→ *Ch. 6, p. 6-1*).

5.5 EMERGENCY STOP button

There is an EMERGENCY STOP button on the Ziehm Solo C-arm stand, enabling you to switch off all electrical functions of the unit in case of emergencies.

The shape of the EMERGENCY STOP buttons differs significantly from all the other buttons thus preventing an accidental actuation. In addition, the EMERGENCY STOP buttons are surrounded by yellow rings bearing an “EMERGENCY STOP” label.

NOTE

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

5.6 Radiation indication lamp

A radiation indication lamp is mounted on the flat-screen monitors of the system. It is lighting every time you initiate radiation with the hand or the foot switch.

6 Configuration

6.1 Overview

General

A large number of parameters can be preset for the Ziehm Solo. The following controls are provided for this purpose:

- **Configuration** operating mode – **Operation Settings** (*Ch. 6.2*)
- **Configuration** operating mode – **Basic Settings** (*Ch. 6.3*)
- **Configuration** operating mode – **Cine/DSA/Dose** (*Ch. 6.4*)
  (for Germany - **Cine/SUB/Dose**)
- Managing storage media (**Configuration** operating mode – **Storage Media**, (*Ch. 6.5*)
- Setting the 24" flat-screen monitor (*Ch. 6.6*)
- Setting the 18" flat-screen monitors (*Ch. 6.7*)

Service settings

The control panel provides access to the **Service Settings**. This area is password-protected or only accessible via the service key (USB stick). Consequently, the following settings and/or actions can and must be made by trained service engineers only:

- Settings for anatomical programs
- DICOM settings
- Collimator adjustments

6.2 User settings

Function

Under **Operation Settings** you define the settings which determine the operational conditions during fluoroscopy.

- Press the **Config** tab.

  The **Configuration** operating mode is activated. The **Operation Settings** controls appear.

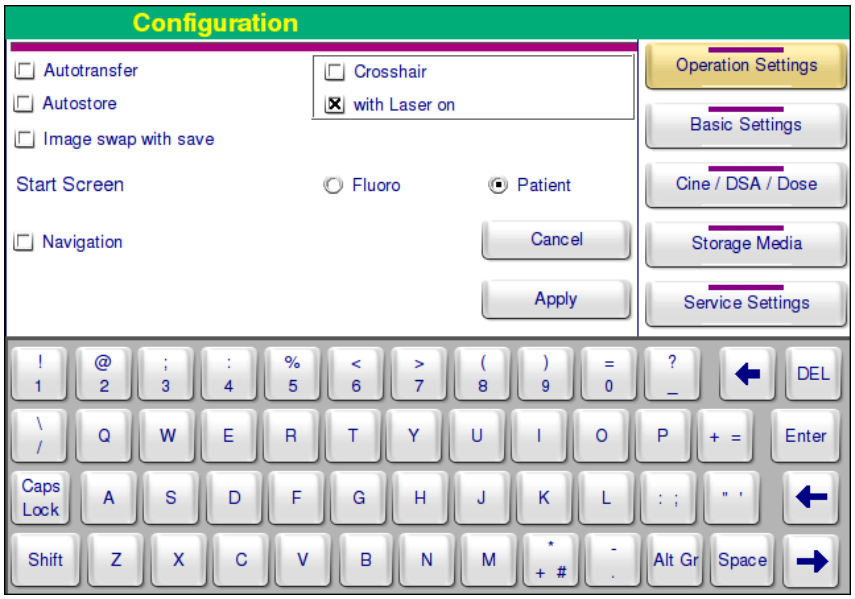


Fig. 6-1 **Configuration** operating mode

Fig. 6-2 **Configuration** operating mode (Germany only)

6.2.1 Autotransfer

Moving the fluoroscopic image

Under **Autotransfer** you activate or deactivate the **Autotransfer** (automatic image swapping) function.

Fig. 6-3 Autotransfer

– **Autotransfer** activated:

  When you initiate radiation, the fluoroscopic image on the live screen is moved automatically to the reference screen.

– **Autotransfer** deactivated:

  When you initiate radiation, the prior fluoroscopic image on the live screen is replaced with a new live image.

When you switch on the system, the **Autotransfer** function is deactivated by default.

To activate the Autotransfer function, do the following:

- Press the **Config** tab.

  The **Configuration** operating mode is activated. The **Operation Settings** controls appear.

- Press the **Autotransfer** check box.

  The check box is checkmarked.

- Press the **Apply** button.

  The **Autotransfer** function is activated.

6.2.2 Autostore

Under **Autostore** you activate or deactivate the **Autostore** (automatic saving) function.

Fig. 6-4 Autostore

– **Autostore** activated:

  During each fluoroscopy, a new image will be saved automatically as soon as you terminate radiation.

– **Autostore** deactivated:

  The system does not save the images automatically. You must save the desired fluoroscopic images manually.

When you switch on the system, the **Autostore** function is deactivated by default.

Alternatively, you can activate the **Autostore** function by means of the **Save** button.

To activate the Autostore function, do the following:

- Press the **Config** tab.

  The **Configuration** operating mode is activated. The **Operation Settings** controls appear.

- Press the **Autostore** check box.

  The check box is checkmarked.

- Press the **Apply** button.

  The **Autostore** function is activated.

6.2.3 Displaying a crosshair

Positioning aid

Under **Crosshair** you determine whether a crosshair is displayed as positioning aid (e.g. for foreign body localization) in the image on the live screen during fluoroscopy. The central point of the crosshair corresponds to the position of the central X-ray beam. In addition you can set whether you want to activate the crosshair together with the laser positioning device when pressing the **Laser** button.

Fig. 6-5 Crosshair

The following table shows the crosshair setting options and their meanings.

			
The crosshair is permanently hidden. The **Laser** button (in the operating mode **Fluoroscopy**) only switches on the laser positioning device.	The crosshair is permanently shown. The **Laser** button (in the operating mode **Fluoroscopy**) only switches on the laser positioning device.	If you switch to the operating mode **Fluoroscopy**, the laser positioning device is hidden. By pressing the **Laser** button, the crosshair is shown and hidden.	If you switch to the operating mode **Fluoroscopy**, the laser positioning device is shown. By pressing the **Laser** button, the crosshair is shown and hidden.

Table 6-1 Correlation of crosshair and **Laser** button

To display the crosshair, do the following:

- Press the **Config** tab.
  The **Configuration** operating mode is activated. The **Operation Settings** controls appear.

- Press the **Crosshair** option.
  The check box is checkmarked.

- Press the **Apply** button.
  The crosshair remains displayed until you switch off the system.

To have the crosshair activated with the Laser button, do the following:

- Press the **Config** tab.
  The **Configuration** operating mode is activated. The **Operation Settings** controls appear.

- Press the **Crosshair – with Laser on** option.
  The check box is checkmarked.

- Press the **Apply** button.
  When you press the **Laser** button, the crosshair is activated together with the laser positioning device. The laser positioning device switches off automatically after 1 minute.

6.2.4 Defining the start screen

Under **Start Screen** you determine which operating mode is activated by default after power-up of the Ziehm Solo.

Fig. 6-6 Start screen

The following options are available:

– **Fluoro**:

  After power-up of the system, the **Fluoroscopy** operating mode is activated.

or

– **Patient**:

  After power-up of the system, the **Patient** operating mode is activated.

The default start screen is configured according to the customer's wishes.

To define the start screen, do the following:

- Press the **Config** tab.

  The **Configuration** operating mode is activated. The **Operation Settings** controls appear.

- Press the option for the desired operating mode.

- Press the **Apply** button.

  As from the next power-up of the system, the selected operating mode will be activated automatically.

6.2.5 Discarding the operation settings

After having defined or modified the operation settings, these settings must be applied explicitly in order to become valid in the system. As long as the settings or changes have not been applied yet, you can discard them, so that the previous settings remain valid.

To discard the operation settings which have not been applied yet, do the following:

- Press the **Cancel** button.

or

- Quit the **Configuration** operating mode without applying the settings.

6.3 Basic settings

Function

Under **Basic Settings** you make different settings which directly affect the user interface, e.g. default data for the date or hospital department.

Usually, the basic settings are made by a service engineer when putting the system into service. However, you can modify the basic settings if you wish to.

- Press the **Basic Settings** button.
  The Basic Settings controls are displayed in the dynamic control area.

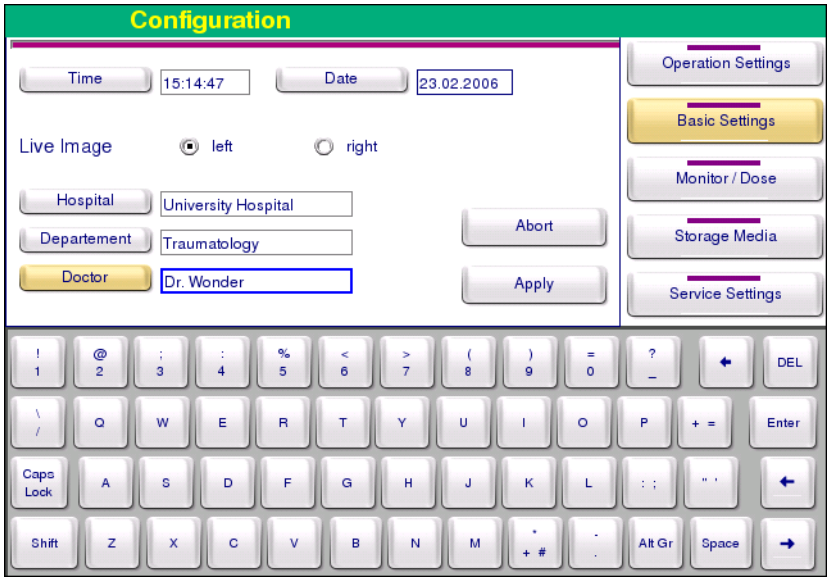


Fig. 6-7 Basic settings

Fig. 6-8 Basic settings (Germany only)

6.3.1 Setting the system date and the system time

The system date and the system time must be entered once in order to enable the system to store and display the date and time of saving together with the image data.

Date format

The displayed date format may vary depending on the customer-specific settings (order of day, month and year; dot or slash as date separator). The set date format also applies to patient data displayed in the **Patient** and **Archive** operating modes. Throughout this document, the **DD.MM.YYYY** date format is used.

- If you want to change the date format, please contact your in-house service engineer.

To set the system date and system time, do the following:

- Press the **Config** tab.
  The **Configuration** operating mode is activated.

- Press the **Basic Settings** button.
  The Basic Settings controls are displayed in the dynamic control area.

- Press the **Time** button.
  The button is highlighted in yellow, and the cursor jumps to the **Time** input box.
- Enter the system time in the **Time** input box using the format hh:mm:ss.

- Press the **Date** button.
  The button is highlighted in yellow, and the cursor jumps to the **Date** input box.
- Enter the system date in the **Date** input box.

- Press the **Apply** button.

6.3.2 Selecting the live screen

Under **Live Image** you determine which screen will act as the live screen.

The live screen is the screen where the live fluoroscopic image is displayed. The other screen serves as reference screen, where the saved fluoroscopic images from the image memory are opened and displayed.

Fig. 6-9 Determining the live screen

The following options are available:

– **Live Image left**:

  The left screen is the live screen, and the right screen is the reference screen

– **Live Image right**:

  The right screen is the live screen, and the left screen is the reference screen

To determine the live screen, do the following:

- Press the **Config** tab.
  The **Configuration** operating mode is activated.

- Press the **Basic Settings** button.
  The Basic Settings controls are displayed in the dynamic control area.

- Press the **Live Image left** or **Live Image right** option.

- Press the **Apply** button.

6.3.3 Entering the hospital data

In order to avoid having to type the same hospital data for each new patient folder you create, you can enter default data for the **Hospital**, **Department** and **Doctor** input boxes. This data appears automatically in the **Patient** operating mode.

To define default data for the Hospital, Department and Doctor input boxes, do the following:

- Press the **Config** tab.
  The **Configuration** operating mode is activated.

- Press the **Basic Settings** button.
  The Basic Settings controls are displayed in the dynamic control area.

- Press the **Hospital** button.
  The button is highlighted in yellow, and the cursor jumps to the **Hospital** input box.

- Enter the desired name in the **Hospital** input box.
- Press the **Department** button and enter the desired name in the **Department** input box.

- Press the **Doctor** button and enter the desired name in the **Doctor** input box.

- Press the **Apply** button.

6.3.4 Discarding the basic settings

After having defined or modified the basic settings, these settings must be applied explicitly in order to become valid in the system. As long as the settings or changes have not been applied yet, you can discard them, so that the previous settings remain valid.

To discard the basic settings which have not been applied yet, do the following:

- Press the **Cancel** button.

or

- Quit the **Configuration** operating mode without applying the settings.

6.4 Cine/DSA/Dose (for Germany - Cine/SUB/Dose)

Function

Under **Cine/DSA/Dose** (for Germany - **Cine/SUB/Dose**) you make various settings for the cine loop and the subtraction modes.

- Press the **Cine/DSA/Dose** button (for Germany - **Cine/SUB/Dose** button).

  The controls for the cine loop and subtraction modes are displayed in the dynamic control area.

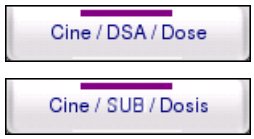


Fig. 6-10 Cine/DSA/Dose

Fig. 6-11 Cine/SUB/Dose (Germany only)

6.4.1 Cine loop settings

Under **Cine** you preset the frame rate (speed) and the number of frames (length) that are used for generating cine loops. You can change these preset values during operation for each cine loop you acquire.

Fig. 6-12 Cine loop settings

Length of cine loops

As cine loop length you can set the values 100, 200, 300, 400 frames or Auto.

If you activate the **Auto** option, all images that are generated during the time of exposure are automatically saved. With this option, you do not need to set the recording length prior to fluoroscopy.

To preset the frame rate for cine loops, do the following:

- Press the **Config** tab.
  The **Configuration** operating mode is activated. The **Operation Settings** controls appear.

- Press the **Cine/DSA/Dose** button (for Germany - **Cine/SUB/Dose** button).

  The cine loop controls are displayed in the dynamic control area.

- Select the desired frame rate (number of frames per second) under **Rate** with the help of the arrow buttons.

- Press the **Apply** button.
  When you acquire a cine loop, the selected value is preset under **Frames/s**.

To preset the length of cine loops, do the following:

- Press the **Config** tab.
  The **Configuration** operating mode is activated. The **Operation Settings** controls appear.

- Press the **Cine/DSA/Dose** button (for Germany - **Cine/SUB/Dose** button).

  The cine loop controls are displayed in the dynamic control area.

- Select the desired number of frames under **Length** with the help of the arrow buttons.

- Press the **Apply** button.

When you acquire a cine loop, the selected value is preset under **Length**.

6.4.2 Showing or hiding the native image

Under **DSA** (for Germany - **SUB**) you determine whether the native image is displayed on the reference screen during generation of a DSA (for Germany - **SUB**).

Fig. 6-13 Showing or hiding the native image

Fig. 6-14 Showing or hiding the native image (Germany only)

– **Native on** activated:

  When you generate a DSA cine loop (for Germany - SUB cine loop), the native image is displayed on the reference screen.

– **Native on** deactivated:

  When you generate a DSA cine loop (for Germany - SUB cine loop), the native image is not displayed. Before switching to the subtraction mode, you may open a reference image on the reference screen, which remains displayed there during the entire subtraction process.

To display the native image in the subtraction mode, do the following:

- Press the **Config** tab.

  The **Configuration** operating mode is activated. The **Operation Settings** controls appear.

- Press the **DSA Native on** check box.

  or

or

- Press the **SUB Native on** check box (Germany only).

  The check box is checkmarked.

- Press the **Apply** button.

  When you generate a DSA cine loop (for Germany - SUB cine loop), the native image is displayed on the reference screen.

6.4.3 Discarding the cine loop and subtraction mode settings

After having defined or modified the settings on this tab, these settings must be applied explicitly in order to become valid in the system. As long as the settings or changes have not been applied yet, you can discard them, so that the previous settings remain valid.

To discard the settings which have not been applied yet, do the following:

- Press the **Cancel** button.

or

- Quit the **Configuration** operating mode without applying the settings.

6.5 Storage media

Function

Under **Storage Media** you can define the graphics formats used for saving images to different storage media. Furthermore, you can delete data from different external storage media.

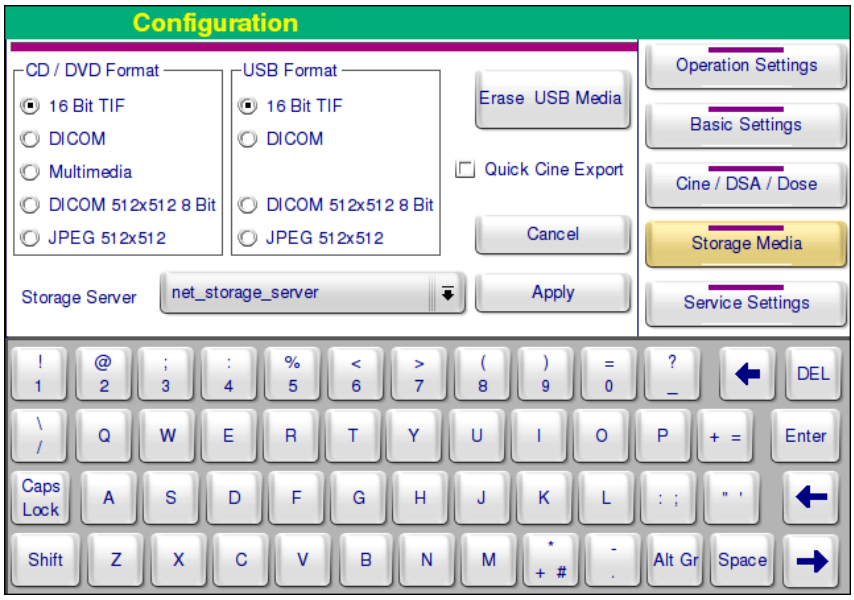


Fig. 6-15 Storage media

Fig. 6-16 Storage media (Germany only)

Storage formats

Depending on your chosen system configuration, you can save one or more images in various storage formats to different storage media. Some formats with reduced resolution and color depth are also available.

Storage format	File extension	Resolution	Color depth	File size/ image	Storage medium	
					CD/DVD	USB
16 Bit TIF	*.tif	1024 × 1024	16 Bit	2 MB	•	•
DICOM	—	1024 × 1024	16 Bit	2 MB	•	•
Multimedia: Cine loop	*.avi	512 × 512	8 Bit	depends on the length of the cine loop	•	—
DICOM	—	512 × 512	8 Bit	256 kB	•	•
JPEG	*.jpg	512 × 512	8 Bit	256 kB	•	•

Table 6-2 Storage formats

NOTE

Saving image data with a resolution of 512 × 512 pixels may lead to information loss.

6.5.1 Defining the USB stick storage format

Storage formats

For saving selected images to a USB storage medium in the **Archive** operating mode, the following storage formats are available:

- TIF with a color depth of 16 bit (for further use on a PC)
- JPEG with a resolution of 512 × 512 pixels and a color depth of 8 bit (for further use on a PC)
- DICOM (for further use on a DICOM network or viewing with a DICOM viewer in 1024 × 1024 pixels/16 bit original format)
- DICOM with a resolution of 512 × 512 pixels and a color depth of 8 bit (for further use on a DICOM network or viewing with a DICOM viewer)

Under **USB Format** you determine which of these storage formats is used for saving images to a USB stick. There is no possibility to set the desired storage format on the spot in the **Archive** operating mode when saving images.

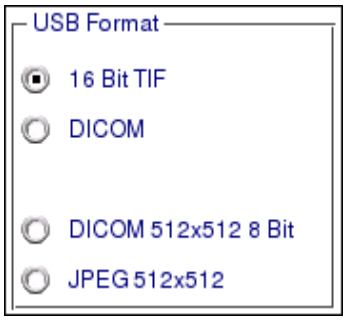


Fig. 6-17 USB format

To define the USB stick storage format, do the following:

- Press the **Config** tab.
  The **Configuration** operating mode is activated.

- Press the **Storage Media** button.

- Press the desired storage format option under **USB Format**.
- Press the **Apply** button.

6.5.2 Defining the CD/DVD storage format

DVD writer

With the DVD writer, data can be written to or retrieved from both CDs and DVDs.

Storage formats

For writing selected images to CD/DVD in the **Archive** operating mode, the following storage formats are available:

- TIF with a color depth of 16 bit (for further use on a PC)
- JPEG with a resolution of 512 × 512 pixels and a color depth of 8 bit (for further use on a PC)
- DICOM (for further use on a DICOM network or viewing with a DICOM viewer in 1024 × 1024 pixels/16 bit original format)
- DICOM with a resolution of 512 × 512 pixels and a color depth of 8 bit (for further use on a DICOM network or viewing with a DICOM viewer)
- Multimedia (Video CD or MPEG2 format, for playback on a PC and DVD player)

Under **CD/DVD Format** you determine which of these storage formats is used for writing images to CD or DVD. There is no possibility to set the desired storage format on the spot in the **Archive** operating mode when saving images.

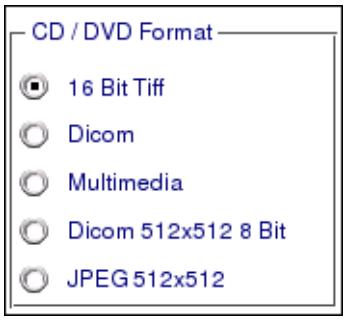


Fig. 6-18 CD/DVD format

To define the CD/DVD storage format, do the following:

- Press the **Config** tab.
  The **Configuration** operating mode is activated.

- Press the **Storage Media** button.
- Press the desired storage format option under **CD/DVD Format**.

- Press the **Apply** button.

6.5.3 Deleting data from storage media

To delete data from a USB stick, do the following:

- Press the **Config** tab.
  The **Configuration** operating mode is activated.

- Press the **Storage Media** button.

- Press the **Erase USB Stick** button.
  The following confirmation prompt is displayed: **Do you really want to erase the USB Stick?**

- Confirm by pressing the **Yes** button.
  All data is deleted from the USB stick.

NOTICE

NOTICE

If you press the **Yes** button, all data will be deleted.

6.6 Setting the 24" flat-screen monitor

6.6.1 Overview

Safety measures

NOTICE

NOTICE

The system may only be set up and put into service by service engineers who are authorized by the manufacturer.

If service is needed, the system may only be repaired by authorized service engineers.

WARNING

WARNING

When the system is opened, there is a risk of electric shock. The system may only be opened by qualified service personnel.

To prevent fire or electric shock, the system must not be exposed to rain or moisture.

The system must not be operated next to flammable anesthetic gas mixtures of air, oxygen and nitrogen oxides.

Built-in keypad

The flat-screen monitor has a built-in keypad (→ *Fig. 6-19*) with six keys, which are used for accessing the screen setting menus.

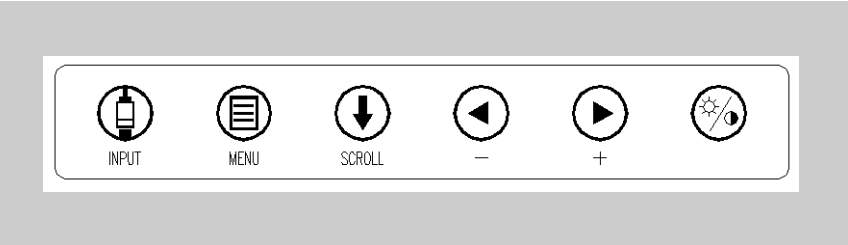


Fig. 6-19 Built-in keypad of the flat-screen monitor

Screen settings

On systems with flat-screen monitors, the screen settings are made directly on the monitors using a built-in keypad.

You can change the following screen settings yourself:

- Brightness
- Contrast
- Backlight
- Menu language for screen settings

In addition, you can restore the factory settings.

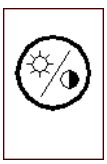
The factory-set menu language is English. Therefore, the English designations are used in this document.

Please contact your in-house service engineer if you wish to change any of the following screen settings:

- Video source (*Inputs*)
- Display settings (*Picture*), e.g. vertical position/horizontal position, sharpness, scaling
- Gamma
- Menu setup (*Setup*), e.g. menu lock (exception: language setting)

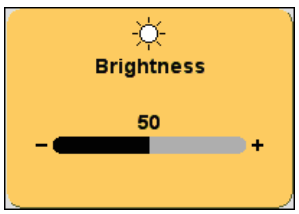
6.6.2 Setting the brightness, contrast and backlight

Brightness



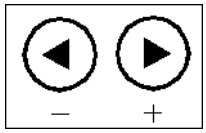
To set the screen brightness, do the following:

- Press the **Brightness/Contrast** key.
  The **Brightness** control appears on the screen.



- Press the **+** or **–** arrow key to increase or decrease the screen brightness.

  The settings become immediately active on the screen. After a few seconds, the **Backlight Brightness** control disappears automatically.

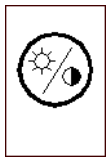


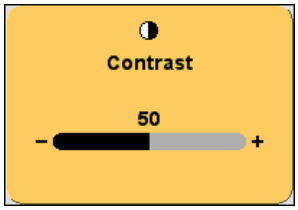
To set the screen contrast, do the following:

Contrast

- Press the **Brightness/Contrast** key twice.

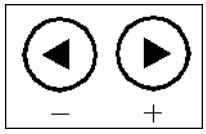
  The **Contrast** control appears on the screen.





- Press the **+** or **–** arrow key to increase or decrease the contrast.

  The settings become immediately active on the screen. After a few seconds, the **Contrast** control disappears automatically.

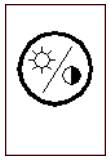


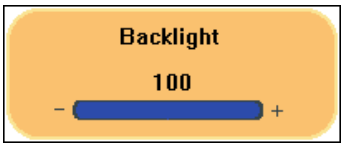
To set the screen backlight brightness, do the following:

Backlight

- Press the **Brightness/Contrast** key three times.

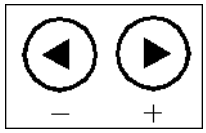
  The **Backlight** control appears on the screen.





- Press the **+** or **–** arrow key to increase or decrease the backlight.

  The settings become immediately active on the screen. After a few seconds, the **Backlight** control disappears automatically.



NOTE

Lowering the backlight level will increase the backlight lifetime.

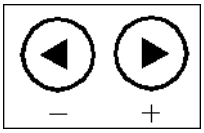
6.6.3 Setting the menu language

The factory-set menu language is English. You can choose one of the following languages as menu language:

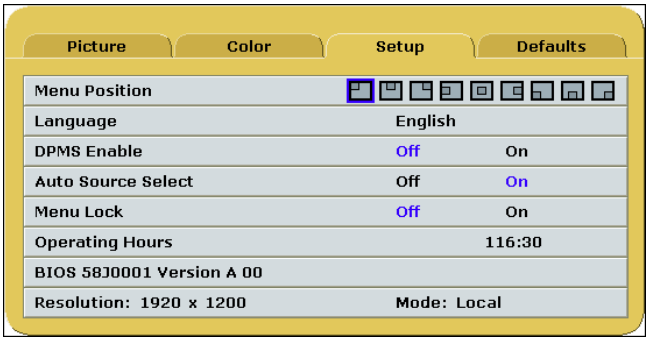
- German
- French
- Italian
- Swedish
- Spanish
- Dutch

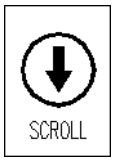
To define the menu language, do the following:

- Press the **MENU** key.
  The on-screen menu appears.

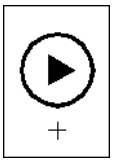


- Select the **Setup** tab with the help of the **+** or **–** arrow keys.





- Move to the **Language** item with the help of the **SCROLL** key.



- Press the **+** arrow key until the desired language is displayed.
  All on-screen menu elements and controls are displayed immediately in the chosen language.

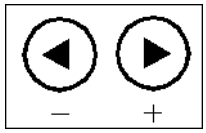
- Press the **MENU** key.
  The on-screen menu disappears.

6.6.4 Restoring the factory settings

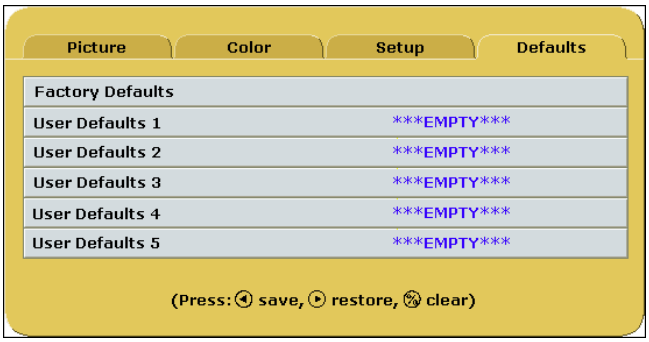
After having changed the screen settings, you may restore the factory-set values at any time.

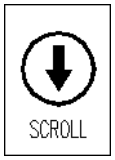
To restore the factory settings, do the following:

- Press the **MENU** key.
  The on-screen menu appears.

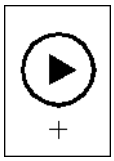


- Select the **Defaults** tab with the help of the **+** or **–** arrow keys.





- Press the **SCROLL** key.
  The **Factory Defaults** item is selected.



- Press the **+** arrow key.
  – The on-screen menu disappears. All settings are reset to the factory values.

6.7 Setting the 18" flat-screen monitors

Screen settings

You can change the following screen settings yourself:

- Brightness
- Contrast
- Backlight brightness
- Menu language for screen settings

In addition, you can restore the factory settings.

The factory-set menu language is English. Therefore, the English designations are used in this document.

If you want to change any of the following screen settings, please contact your in-house service engineer:

- Video source (*Inputs*)
- Gamma
- Display settings (*Picture*), e.g. horizontal and vertical position, sharpness, scaling
- Menu setup (*Setup*), e.g. menu lock
  (exception: language setting)

6.7.1 Flat-screen monitors of type 1

Fig. 6-20 Flatscreen monitor of type 1

Safety measures

NOTICE

NOTICE

The system may only be set up and put into service by service engineers who are authorized by the manufacturer.

If service is needed, the system may only be repaired by authorized service engineers.

WARNING

WARNING

When the system is opened, there is a risk of electric shock. The system may only be opened by qualified service personnel.

To prevent fire or electric shock, the system must not be exposed to rain or moisture.

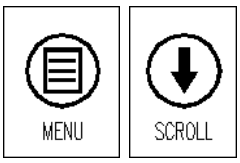
The system must not be operated next to flammable anesthetic gas mixtures of air, oxygen and nitrogen oxides.

Enabling the menu

NOTE

The menu display for setting the brightness and contrast is locked by default to ensure optimum display settings. To display this menu again you must first enable it.

To re-enable the menu display, do the following:



- Simultaneously press the **MENU** and **SCROLL** keys until the message is displayed saying that the menu is unlocked.

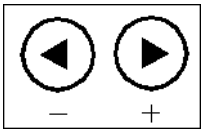
  When you press one of the keys on the keypad, the corresponding on-screen menu appears.

Locking the menu

To lock the menu, do the following:

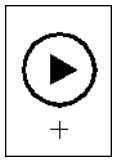
- Press the **MENU** key.

  The on-screen menu appears.



- Select the **Setup** tab with the help of the **+** or **–** arrow keys.

- Press the **SCROLL** key until the **Menu Lock** item is highlighted.



- Press the **+** arrow key.

  The menu disappears. A message saying that the menu is locked is displayed.

  As long as the menu is disabled, the message MENU LOCKED is displayed whenever you press one of the keys on the keypad.

Built-in keypad

Each flatscreen monitor has a built-in keypad with six keys, which are used for accessing the screen setting menus.

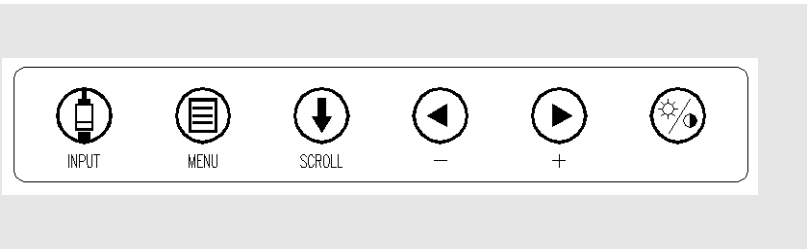
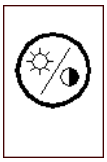


Fig. 6-21 Built-in keypad of the flatscreen monitor

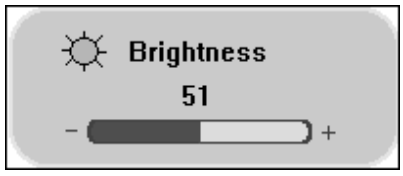
Brightness

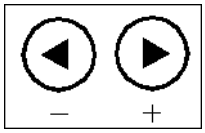
To set the screen brightness, do the following:



- Press the **Brightness/Contrast** key.

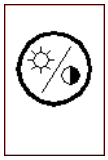
The **Brightness** control appears on the screen.





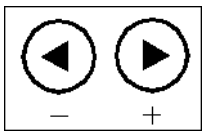
- Press the **+** or **–** arrow key to increase or decrease the screen brightness.
  The settings become immediately active on the screen. After a few seconds, the **Backlight Brightness** control disappears automatically.

Contrast



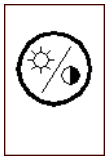
To set the screen contrast, do the following:

- Press the **Brightness/Contrast** key twice.
  The **Contrast** control appears on the screen.



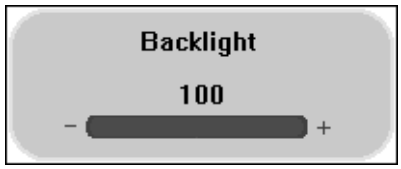
- Press the **+** or **–** arrow key to increase or decrease the contrast.
  The settings become immediately active on the screen. After a few seconds, the **Contrast** control disappears automatically.

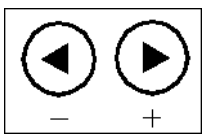
Backlight brightness



To set the screen backlight brightness, do the following:

- Press the **Brightness/Contrast** key three times.
  The **Backlight Brightness** control appears on the screen.





- Press the **+** or **–** arrow key to increase or decrease the backlight brightness.
  The settings become immediately active on the screen. After a few seconds, the **Backlight** control disappears automatically.

NOTE

Lowering the backlight level will increase the backlight lifetime.

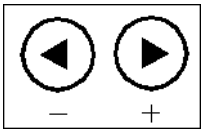
Setting the menu language

The factory-set menu language is English. You can choose one of the following languages as menu language:

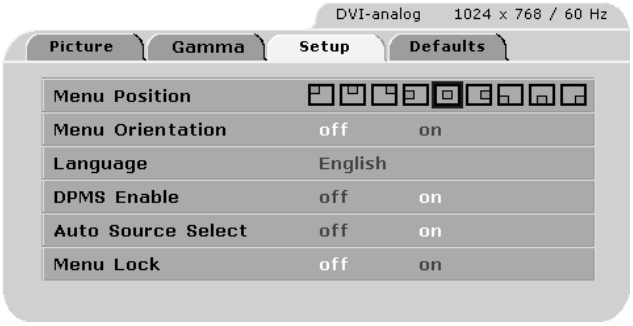
- German
- French
- Italian
- Swedish
- Spanish
- Dutch

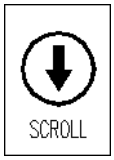
To define the menu language, do the following:

- Press the **MENU** key.
  The on-screen menu appears.

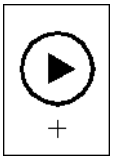


- Select the **Setup** tab with the help of the **+** or **–** arrow keys.





- Move to the **Language** item with the help of the **SCROLL** key.

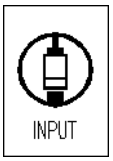


- Press the **+** arrow key until the desired language is displayed.
  All on-screen menu elements and controls are displayed immediately in the chosen language.

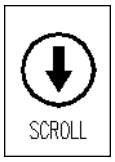
- Press the **MENU** key.
  The on-screen menu disappears.

Setting the video source

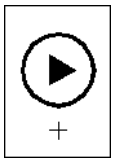
To set the video source, do the following:



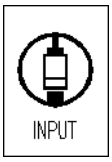
- Press the **Input** key.
  The **Inputs** on-screen menu with the following options appears:
  - DVI – analog
  - BNC
  - DVI – digital



- Press the **SCROLL** key until the desired item is highlighted.



- Press the **+** arrow key.
  The highlighted item is marked as **selected**.



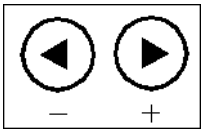
- Press the **Input** key.
  The **Inputs** on-screen menu disappears.

Setting the gamma value

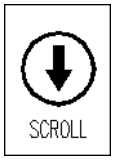
The gamma value determines the contrast between the lightest and the darkest point of the screen display.

To set the gamma value, do the following:

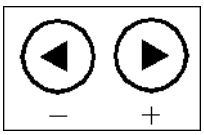
- Press the **MENU** key.
  The on-screen menu appears.



- Select the **Gamma** tab with the help of the **+** or **–** arrow keys.
  On the **Gamma** tab, the following gamma value options are available:
  - 1.5
  - 1.7
  - 2.2
  - 2.6
  - 3.0



- Press the **SCROLL** key until the desired value is highlighted in white.



- Press the **+** or **–** arrow key.
  The desired value is set.

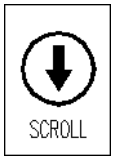
- Press the **MENU** key.
  The on-screen menu disappears.

Setting up the display

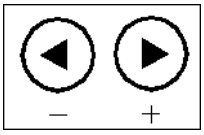
To set up the display, do the following:

- Press the **MENU** key.
  The on-screen menu with the **Picture** tab displayed on top appears.

  Depending on the set video source (), the **Picture** tab shows the following items as a maximum (→ *p. 6-29*):
  - **Horizontal Position**
  - **Vertical Position**
  - **Sharpness**
  - **Phase**
  - **Frequency**
  - **Scaling**
  - **SmartSync**



- Press the **SCROLL** key until the desired item is highlighted.



- Press the **+** or **–** arrow key until the desired setting is displayed or marked as selected.
  The desired value is set.
- Repeat these two steps for any further parameter you want to set.

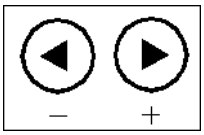
- Press the **MENU** key.
  The on-screen menu disappears.

Setting up the menu

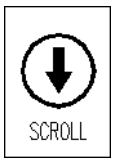
On the **Setup** tab you can make different settings that affect the menu display. In addition, you may lock the menu (→ *p. 6-26*) and select the menu language (→ *p. 6-28*).

To make the basic menu settings, do the following:

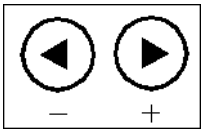
- Press the **MENU** key.
  The on-screen menu appears.



- Select the **Setup** tab with the help of the **+** or **–** arrow keys.
  On the **Setup** tab, the following controls are available:
  - **Menu Position**
  - **Menu Rotation**
  - **Language** (→ *p. 6-28*)
  - **DPMS Enable**
  - **Auto Source Select**
  - **Menu Lock**, (→ *p. 6-26*)



- Press the **SCROLL** key until the desired item is highlighted.



- Press the **+** or **–** arrow key until the desired parameter value is selected.
  The desired parameter value is set.
- Repeat these two steps for any further parameter you want to set.

- Press the **MENU** key.
  The on-screen menu disappears.

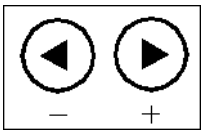
Restoring the factory settings

After having changed the screen settings, you may restore the factory-set values at any time.

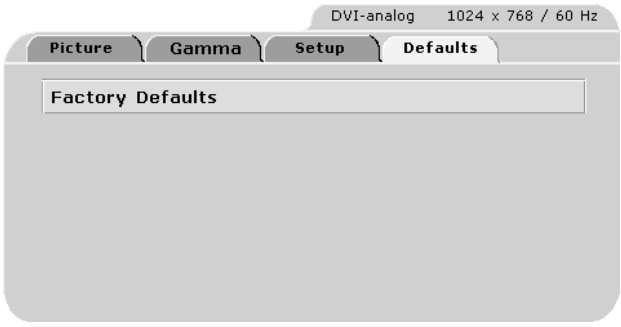
The **Defaults** tab furthermore shows the backlight operating hours clocked up so far and the BIOS version of the monitor.

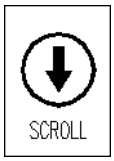
To restore the factory settings, do the following:

- Press the **MENU** key.
  The on-screen menu appears.

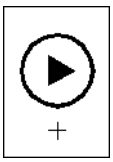


- Select the **Defaults** tab with the help of the **+** or **–** arrow keys.





- Press the **SCROLL** key.
  The **Factory Defaults** item is selected.



- Press the **+** arrow key.
  The on-screen menu disappears. All settings are reset to the factory values.

NOTE

To obtain a decent picture set the phasing value to '26' only if the on-screen display (OSD) shows '50 Hz' in the upper right corner.

You can adjust the phasing settings in the **Picture** menu.

6.7.2 Flat-screen monitors of type 2

Fig. 6-22 Flatscreen monitor of type 2

Safety measures

NOTICE

NOTICE

The system may only be set up and put into service by service engineers who are authorized by the manufacturer.

If service is needed, the system may only be repaired by authorized service engineers.

WARNING

WARNING

When the system is opened, there is a risk of electric shock. The system may only be opened by qualified service personnel.

To prevent fire or electric shock, the system must not be exposed to rain or moisture.

The system must not be operated next to flammable anesthetic gas mixtures of air, oxygen and nitrogen oxides.

Menu display

NOTE

The menu display for setting the brightness and contrast is not locked. Do not change the values in order to ensure optimum display settings.

Built-in keypad

Each flat-screen monitor has a built-in keypad with four keys, which are used for accessing the screen setting menus.

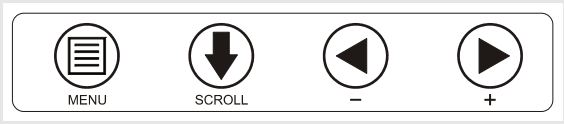
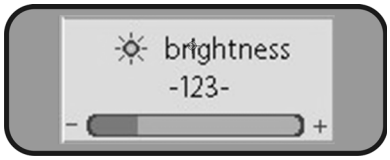


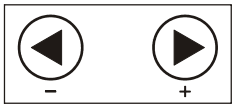
Fig. 6-23 Built-in keypad of the flatscreen monitor

Brightness

To set the screen brightness, do the following:

- Press the **SCROLL** key.
  The **Brightness** control appears on the screen.



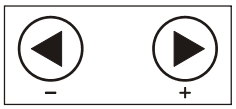


- Press the **+** or **–** arrow key to increase or decrease the screen brightness.
  The settings become immediately active on the screen. After a few seconds, the **Backlight Brightness** control disappears automatically.

Contrast

To set the screen contrast, do the following:

- Press the **SCROLL** key twice.
  The **Contrast** control appears on the screen.



- Press the **+** or **–** arrow key to increase or decrease the contrast.
  The settings become immediately active on the screen. After a few seconds, the **Contrast** control disappears automatically.

Backlight brightness

To set the screen backlight brightness, do the following:

- Press the key sequence **MENU**, **SCROLL**, **MENU**.
  The OSD (Onscreen Display) appears on the screen.

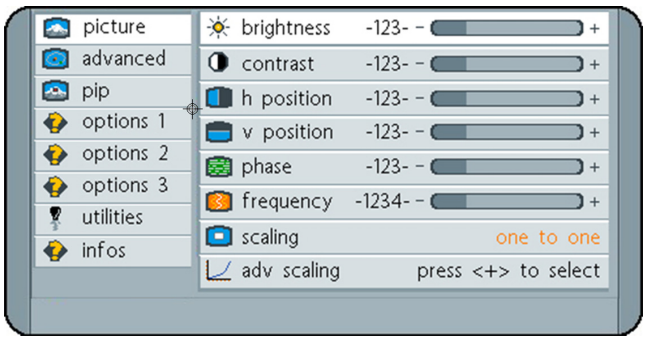
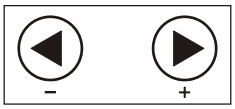


Fig. 6-24 Onscreen Display

- Press the **SCROLL** key three times.
  The **options 1** submenu is highlighted in white.

- Press the **MENU** key.
  The first function in the **options 1** submenu is selected.

- Press the **SCROLL** key three times.
  The **Backlight cd/m²** function is selected.



- Press the **+** or **–** arrow key to increase or decrease the backlight brightness.
  The settings become immediately active on the screen. After a few seconds, the control disappears automatically.

NOTE

Lowering the backlight level will increase the backlight lifetime.

Setting the menu language

The factory-set menu language is English. Alternatively, you can choose German as the menu language:

To define the menu language, do the following:

- Press the key sequence **MENU**, **SCROLL**, **MENU**.
  The OSD (Onscreen Display) (→ *Fig. 6-24, p. 6-35*) appears on the screen.

- Press the **SCROLL** key six times.
  The **utilities** submenu is highlighted in white.

- Press the **MENU** key.
  The first function in the **utilities** submenu is selected.

- Press the **SCROLL** key until the desired language is displayed.
  All on-screen menu elements and controls are displayed immediately in the chosen language. After a few seconds, the control disappears automatically.

Restoring the factory settings

After having changed the screen settings, you may restore the factory-set values at any time.

To restore the factory settings, do the following:

- Press the key sequence **MENU**, **SCROLL**, **MENU**.
  The OSD (Onscreen Display) (→ *Fig. 6-24, p. 6-35*) appears on the screen.

- Press the **SCROLL** key six times.
  The **utilities** submenu is highlighted in white.

- Press the **MENU** key.
  The first function in the **utilities** submenu is selected.

- Press the **SCROLL** key three times.
  The **Factory reset** function is selected.

- Press the **+** arrow key.
  All settings are reset to the factory values.

7 Technical Data

7.1 General technical data

Image intensifier	**Tube**	
	Scintillator	Cesium iodide
	Nominal sizes	23 / 15 / 10 cm
	Anti-scatter grid	Pb 8/40
Monitors	**24" flat-screen monitors**	
	Display measurements	520 mm × 325 mm (20.4" × 12.8")
	Screen size (diagonal)	610 mm (24")
	Resolution in pixels	1920 × 1200
	18.1" flat-screen monitors	
	Display measurements	300 mm × 360 mm (11.45" × 14.28")
	Screen size (diagonal)	460 mm (18.1")
	Resolution in pixels	1280 × 1024 / 50 Hz or 60 Hz
Video standard output	CCIR, 50 Hz refresh rate, like PAL, no color EIA 343, 60 Hz refresh rate, like NTSC, no color	
Environmental conditions	**During storage/transport**	
	Temperature	–5°C to +55°C
	Relative air humidity	20 % – 70 %
	Pressure	500 mbar – 1060 mbar
	Maximum vibration	10 Hz – 150 Hz
	Shock / vibration	25 g at 6 ms / 0.35 mm peak
	During operation	
	Temperature	+13°C to +35°C
	Relative air humidity	20 % – 70 %

Table 7-1 General technical data

Dimensions	**C-arm**	
	Source/image receptor distance	
		970 mm
	Vertical free space (generator/i.i.)	
		760 mm
	C-arm depth	680 mm
	Orbital rotation	135° (+45° – -90°)
	Angulation	±225°
	Swiveling (panning)	±10°
	Horizontal movement	220 mm
	Vertical movement	420 mm
Weight	**C-arm stand**	
		approx. 310 kg

Table 7-1 General technical data (cont.)

7.1.1 Systems with a voltage rating of 100 V, 120 V, 200 V

Systems with a voltage / frequency rating of:		100 V_{AC} ± 10%, 50/60 Hz	120 V_{AC} ± 10%, 50/60 Hz	200 V_{AC} ± 10%, 50/60 Hz
System	**Power supply fuse rating**	C 20 A or C 32 A (tripping characteristic C acc. to VDE 0641, Part 11; DIN EN 60898 + IEC 898)		
	Maximum line impedance	≤ 0.3 Ω	≤ 0.3 Ω	≤ 0.6 Ω
	Required residual current circuit breaker (RCD)	I_N ≥ 20 A, I_{AN} = 30 mA	I_N ≥ 20 A, I_{AN} = 30 mA	I_N ≥ 16 A, I_{AN} = 30 mA
	Typical power consumption, momentary			
		1980 VA	1950 VA	2040 VA
	Power supply in standby mode			
		350 VA (3.5 A)	350 VA (3 A)	360 VA (2 A)
	The values depend on the integrated documentation systems.			
	Power input fuse			
		20 A slow (circuit breaker)	20 A slow (circuit breaker)	15 A slow (circuit breaker)
	Equipment protection classification	Protection Class I, Type B, ordinary equipment, continuous operation		
	Radiation controlled area (with generator in lowermost position and C-arm vertical)			
		23 cm image intensifier 4 m		
Generator	**Power**			
	Direct radiography			
		40–110 kV 12 mA min./ 20 mA max., 1.5 mAs min./ 100 mAs max.	40–110 kV 15 mA min./ 20 mA max., 1.5 mAs min./ 100 mAs max.	40–110 kV 15 mA min./ 20 mA max., 1.5 mAs min./ 100 mAs max.
	Fluoroscopy			
		40–110 kV 1.5–10 mA 1.5–20 mA (USA)	40–110 kV 1.5–10 mA 1.5–20 mA (USA)	40–110 kV 1.5–10 mA 1.5–20 mA (USA)
	Pulsed fluoroscopy			
		Pulse width 10–30 ms 1, 2, 4, 8, 12.5, 25 pulses/s (on systems with 50 Hz) 1, 2, 5, 10, 15, 30 pulses/s (on systems with 60 Hz)		

Table 7-2 Systems with a voltage rating of 100 V, 120 V, 200 V

Systems with a voltage / frequency rating of:		100 V_{AC} ± 10%, 50/60 Hz	120 V_{AC} ± 10%, 50/60 Hz	200 V_{AC} ± 10%, 50/60 Hz
Generator	Digital radioscopy (snapshot)			
		40–110 kV 0.1 mA min./ 20 mA max.		
	Operating frequency	20 kHz		
	Typical operating data with patient phantom			
	Fluoroscopy			
		80 kV / 9 mA		
	Direct radiography			
		80 kV / 9 mA		
	Max. operating data			
	Fluoroscopy			
		110 kV / 10 mA 110 kV / 18 mA (USA) 65 kV / 10 mA	110 kV / 10 mA 110 kV / 18 mA (USA) 80 kV / 10 mA	110 kV / 10 mA 110 kV / 18 mA (USA) 80 kV / 10 mA
	Direct radiography			
		110 kV / 12 mA 65 kV / 20 mA	110 kV / 15 mA 80 kV / 20 mA	110 kV / 15 mA 80 kV / 20 mA
	Digital radioscopy			
		110 kV / 12 mA 65 kV / 20 mA	110 kV / 15 mA 80 kV / 20 mA	110 kV / 18 mA 80 kV / 20 mA
	Max. power output			
	Fluoroscopy			
		1100 W (110 kV / 10 mA)	1100 W (110 kV / 10 mA)	1100 W (110 kV / 10 mA)
	Direct radiography			
		1320 W (110 kV / 12 mA)	1650 W (110 kV / 15 mA)	1650 W (110 kV / 15 mA)
	Digital radioscopy			
		1320 W (110 kV / 12 mA)	1650 W (110 kV / 15 mA)	1980 W (110 kV / 18 mA)
	Nominal electric power (IEC 60601-2-7)			
		1000 W at 100 kV / 10 mA / 0.1 s	1000 W at 100 kV / 10 mA / 0.1 s	1000 W at 100 kV / 10 mA / 0.1 s

Table 7-2 Systems with a voltage rating of 100 V, 120 V, 200 V (cont.)

Systems with a voltage / frequency rating of:		100 V_{AC} ± 10%, 50/60 Hz	120 V_{AC} ± 10%, 50/60 Hz	200 V_{AC} ± 10%, 50/60 Hz
Generator	**X-ray tube**			
		Single-focus stationary-anode tube		
	Focal spot nominal size, in relation to reference axis			
		0.6 acc. to IEC 336		
	Focal spot horizontal tolerance, in relation to reference axis			
		± 0.5 mm (controlled)		
	Anode angle, in relation to reference axis			
		8°		
	Anode material			
		Tungsten		
	Total filtration			
		≥ 3.9 mm Al equivalent incl. Cu ≥ 0.1 mm		
	Maximum X-ray tube loading factors for			
		1h; 3 mA at 110 kV		10800 mAs/h

Table 7-2 Systems with a voltage rating of 100 V, 120 V, 200 V (cont.)

7.1.2 Systems with a voltage rating of 220 V, 230 V, 240 V

Systems with a voltage / frequency rating of:		220 V_{AC} ± 10%, 50/60 Hz	230 V_{AC} ± 10%, 50/60 Hz	240 V_{AC} ± 10%, 50/60 Hz
System	**Power supply fuse rating**	C 16 A (tripping characteristic C acc. to VDE 0641, Part 11; DIN EN 60898 + IEC 898)		
	Maximum line impedance	≤ 0.6 Ω		
	Required residual current circuit breaker (RCD)	$I_N \geq 16$ A, I_{AN} = 30 mA		
	Typical power consumption, momentary			
		2040 VA	2060 VA	2080 VA
	Power supply in standby mode			
		360 VA (approx. 16 A)	370 VA (approx. 16 A)	370 VA (approx. 16 A)
	The values depend on the integrated documentation systems.			
	Power input fuse	15 A slow (circuit breaker)		
	Equipment protection classification	Protection Class I, Type B, ordinary equipment, continuous operation		
	Radiation controlled area (with generator in lowermost position and C-arm vertical)			
		23 cm image intensifier: 4 m		
Generator	**Power**			
	Direct radiography			
		40–110 kV 15 mA min./ 20 mA max., 1.5 mAs min./ 100 mAs max.		
	Fluoroscopy			
		40–110 kV 1.5–10 mA 1.5–20 mA (USA)		
	Pulsed fluoroscopy			
		Pulse width 10–30 ms 1, 2, 4, 8, 12.5, 25 pulses/s (on systems with 50 Hz) 1, 2, 5, 10, 15, 30 pulses/s (on systems with 60 Hz)		

Table 7-3 Systems with a voltage rating of 220 V, 230 V, 240 V

Systems with a voltage / frequency rating of:		220 V_{AC} ± 10%, 50/60 Hz	230 V_{AC} ± 10%, 50/60 Hz	240 V_{AC} ± 10%, 50/60 Hz
Generator	Digital radioscopy (snapshot)			
		40–110 kV 0.1 mA min./ 20 mA max.		
	Operating frequency	20 kHz		
	Max. operating data			
	Fluoroscopy			
		110 kV / 10 mA 110 kV / 18 mA (USA) 80 kV / 10 mA		
	Direct radiography			
		110 kV / 15 mA 110 kV / 18 mA (USA) 80 kV / 20 mA		
	Digital radioscopy			
		110 kV / 18 mA 80 kV / 20 mA		
	Typical operating data with patient phantom			
	Fluoroscopy			
		80 kV / 9 mA		
	Direct radiography			
		80 kV / 9 mA		
	Max. power output			
	Fluoroscopy			
		1100 W (110 kV / 10 mA)		
	Direct radiography			
		1650 W (110 kV / 15 mA)		
	Digital radioscopy			
		1980 W (110 kV / 18 mA)		
	Nominal electric power (IEC 60601-2-7)			
		1000 W at 100 kV / 10 mA / 0.1 s		
	X-ray tube			
		Single-focus stationary-anode tube		

Table 7-3 Systems with a voltage rating of 220 V, 230 V, 240 V (cont.)

Systems with a voltage / frequency rating of:		220 V_{AC} ± 10%, 50/60 Hz	230 V_{AC} ± 10%, 50/60 Hz	240 V_{AC} ± 10%, 50/60 Hz
Generator	**Focal spot nominal size, in relation to reference axis**			
		0.6 acc. to IEC 336		
	Focal spot horizontal tolerance, in relation to reference axis			
		± 0.5 mm (controlled)		
	Anode angle, in relation to reference axis			
		8°		
	Anode material			
		Tungsten		
	Total filtration			
		≥ 3.9 mm Al equivalent incl. Cu ≥ 0.1 mm		
	Maximum X-ray tube loading factors for			
		1h; 3 mA at 110 kV		10800 mAs/h

Table 7-3 Systems with a voltage rating of 220 V, 230 V, 240 V (cont.)

7.2 Focal spot position

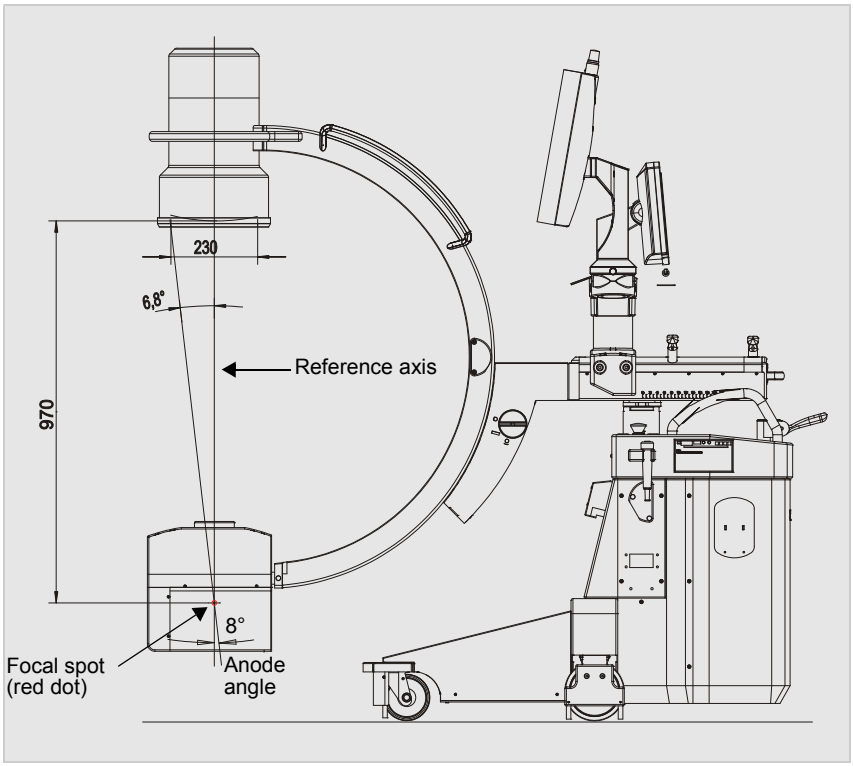


Fig. 7-1 Focal spot position

7.3 Power plug specification

7.3.1 Systems with a voltage rating of 100V and 120V

Cables	2.5 mm^2 three-wire supply voltage: two wires ground wire: one wire
Phase	single-phase
Strain relief	required
Voltage	125 V_{AC}
Dielectric strength	$\geq$ 2000 V
Current-carrying capacity	15 A continuous (min.)
Flammability rating	acc. to UL 2305 OEM
Temperature	-40 °C to +80 °C
Mark of conformity	VDE or equivalent safety testing and national mark of conformity of country of installation (if required)
Equipment protection classification	IP 20 or higher

Table 7-4 Power plug specification

7.3.2 Systems with a voltage rating of 200V, 220V, 230V and 240V

Cables	2.5 mm^2 three-wire supply voltage: two wires ground wire: one wire
Phase	single-phase
Strain relief	required
Voltage	250 V_{AC}
Dielectric strength	$\geq$ 2000 V
Current-carrying capacity	16 A continuous (min.)
Flammability rating	acc. to UL 94 V0
Temperature	-40 °C to +80 °C
Mark of conformity	VDE or equivalent safety testing and national mark of conformity of country of installation (if required)
Equipment protection classification	IP 20 or higher

Table 7-5 Power plug specification

7.4 Connections for additional monitors and external radiation indication lamp

Interface panel on the C-arm stand

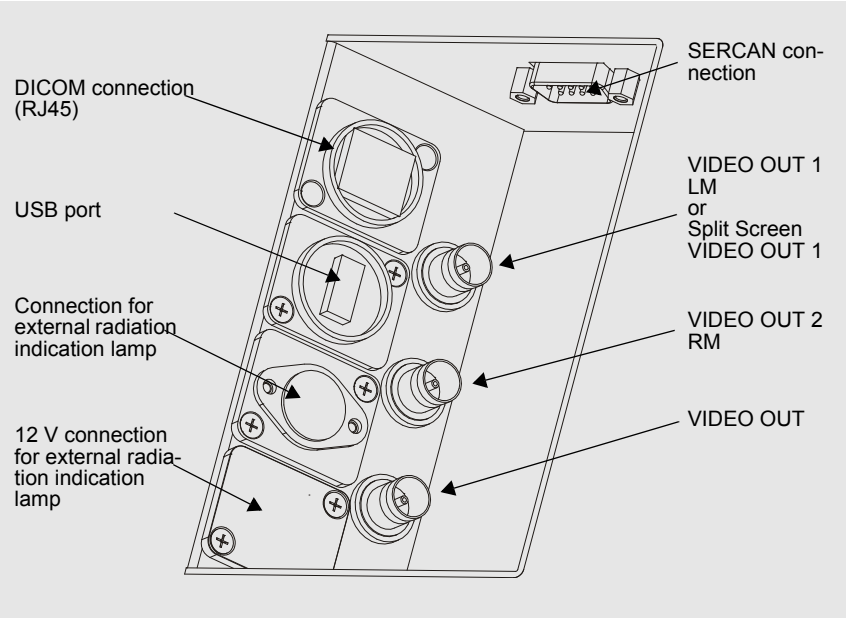


Fig. 7-2 Detailed view interface panel

Wiring diagram

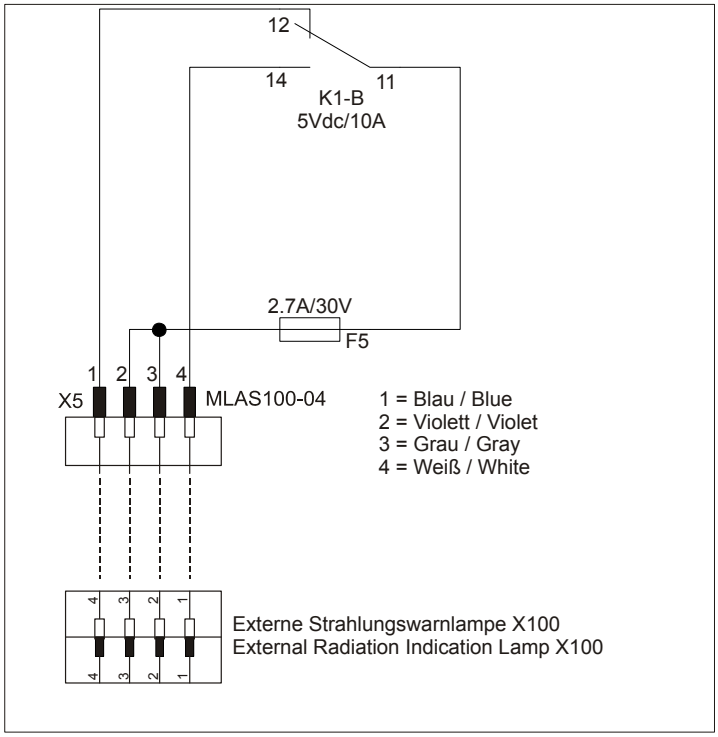


Fig. 7-3 Wiring diagram

The safety relay is able to isolate up to 250 V_{AC} max. The maximum admissible switching voltage is 24 $V_{AC/DC}$ with a maximum current of 2 A.

CAUTION

Exceeding the maximum voltage and current values indicated above may lead to damage or failure of the unit!

7.5 Laser positioning device

Laser Class	Class 2M acc. to IEC 60825-1
Max. power output of continuous laser radiation, measured at the laser beam apertures	< 1 mW
Wavelength of the radiation	635 nm

Table 7-6 Technical data of laser positioning device

7.6 Dose meter

Additional absorption	3 mm Al
Sensitivity (75 kV; 2.7 mm Al HVL)	≥ 700 pC / mGy•cm^2
Measuring range of DAP power	0.1–10^4 mGy • cm^2/s
Voltage range	40–150 kV
Voltage correction	→ *Fig. 7-4, p. 7-14*
Aluminum equivalent	< 0.4 mm

Table 7-7 Technical data of VacuDAP C dose meter

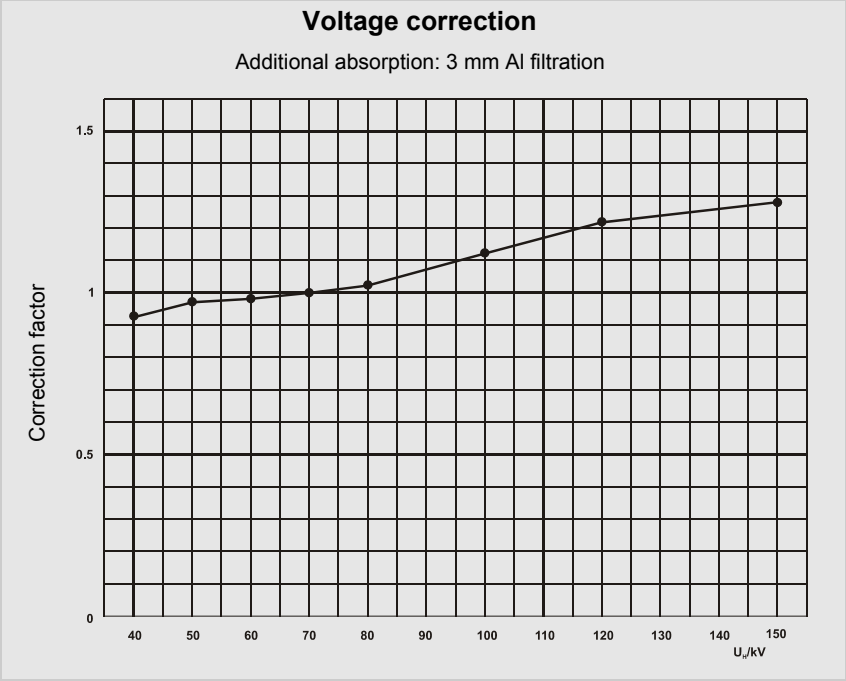


Fig. 7-4 Voltage correction of VacuDAP C dose meter

7.7 Failure of the power supply

If the power supply fails, the system switches off automatically. Any unsaved patient data and/or images are lost.

Patient data and images that were saved to hard disk with the **Save** function are preserved even after a power supply failure.

NOTE

Save all images that you might need later to hard disk with the **Save** function during operation of the unit.

7.8 Air kerma

In compliance with the requirements of international standards (e.g. 21 CFR 1020.32-d (1) Ziehm fluoroscopy systems with automatic exposure rate control are not operable at any combination of tube voltage and tube current which will result in an exposure rate in excess of 88 mGy/min at the point where the center of the useful beam enters the patient, measured at the reference point.

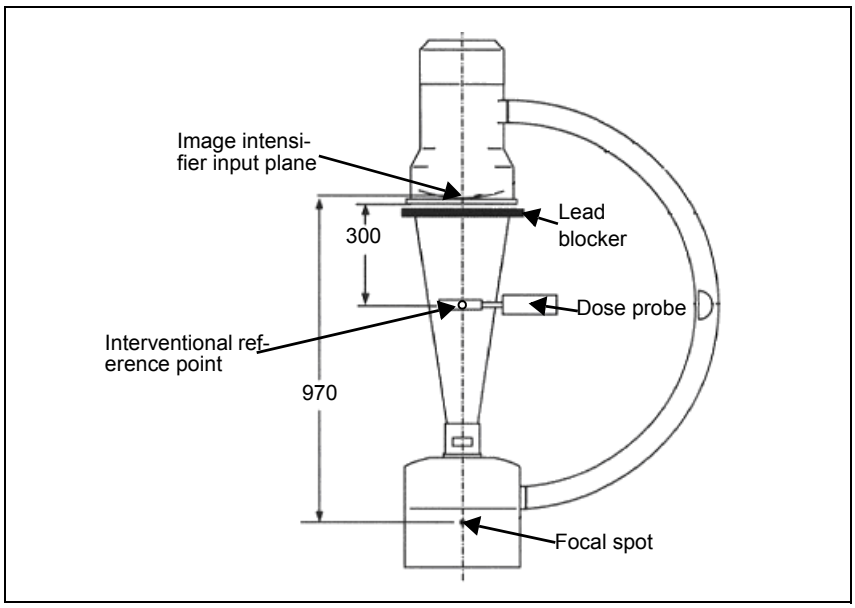


Fig. 7-5 Interventional reference point

The air kerma that is displayed on the system's user interface refers to the interventional reference point according to 21 CFR 1020.32-d. The manufacturer has chosen this location for said reference point, as experience has shown that, in most applications, this is a typical point for the patient surface.

Test phantom

A test phantom is required to carry out the reference measurements for the air kerma rate. The test phantom consists of a polymethyl-methacrylate (PMMA) cube. In the test setup this cube is placed directly in front of the image intensifier.

Normal mode

Setting 25 pulses/s at 50 Hz or 30 pulses/s at 60 Hz corresponds to standard control mode.

Low-level control mode

Setting 8 or less pulses/s at 50 Hz or 10 or less pulses/s at 60 Hz corresponds to low-level control mode.

Test geometry

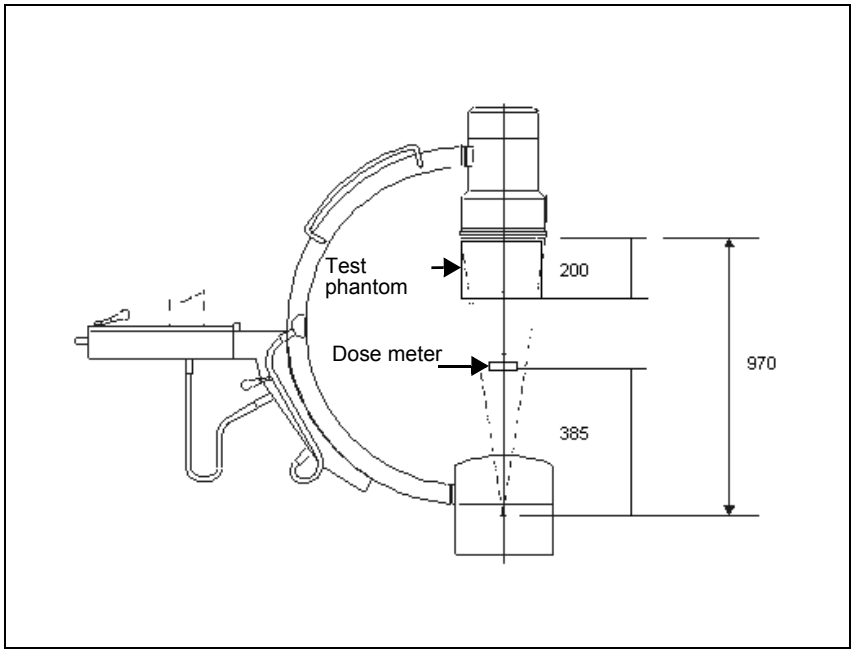


Fig. 7-6 Test geometry for measuring the air kerma rate

Change of air kerma rate at 50 Hz (Service Settings)

Autom. Mode	Program	Voltage in kV	Current in mA	Pulses/ s	Pulse width in ms	Air kerma rate in mGy/s
x	Heart	89	3.4	25	30	0.57
x	Heart Magnification 1	88	3.3	25	30	0.55
x	Heart Magnification 2	101	3.8	25	30	0.84
x	Heart / LPK [a]	67	8.0	25	30	0.64
x	Heart / LPK [a] Magnification 1	70	9.0	25	30	0.83

Table 7-8 Change of air kerma rate based on input field size at 50 Hz

Autom. Mode	Program	Voltage in kV	Current in mA	Pulses/ s	Pulse width in ms	Air kerma rate in mGy/s
x	Heart / LPK [a] Magnification 2	80	9.2	25	30	1.18
x	DSA / SUB[b] / LPK[a]	82	14.6	25	30	1.98
x	DSA / SUB[b] / LPK[a] Magnification 1	84	15.1	25	30	2.15
x	DSA / SUB[b] / LPK[a] Magnification 2	85	15.4	25	30	2.25

Table 7-8 Change of air kerma rate based on input field size at 50 Hz

a. LPK = **Large Patient Key** button
b. for Germany only (instead of DSA)

Pulse rate at 50 Hz (Service Settings)

You can use the factors for the different pulse rates in all anatomical programs. After measuring the air kerma rate at 8 pulses/s, you can use these factors to compute the other air kerma rates.

Autom. Mode	Program	Voltage in kV	Current in mA	Pulses/ s	Pulse width in ms	Air kerma rate in mGy/s	Factor
x	Heart	89	3.4	25	30	0.57	1
x	Heart	92	3.5	12.5	30	0.31	0.54
x	Heart	92	3.5	8	30	0.21	0.37
x	Heart	93	3.5	4	30	0.11	0.19
x	Heart	94	3.6	2	30	not measurable	—
x	Heart	93	3.5	1	30	not measurable	—

Table 7-9 Factors for the different pulse rates at 50 Hz

Change of air kerma rate at 60 Hz (Service Settings)

Autom. Mode	Program	Voltage in kV	Current in mA	Pulses/ s	Pulse width in ms	Air kerma rate in mGy/s
x	Heart	87	3.3	30	30	0.6
x	Heart Magnification 1	87	3..3	30	30	0.6
x	Heart Magnification 2	102	3.9	30	30	1.0
x	Heart / LPK [a]	66	7.6	30	30	0.68

Table 7-10 Change of air kerma rate based on input field size at 60 Hz

Autom. Mode	Program	Voltage in kV	Current in mA	Pulses/ s	Pulse width in ms	Air kerma rate in mGy/s
x	Heart / LPK [a] Magnifi-cation 1	70	9.0	30	30	0.91
x	Heart / LPK [a] Magnifi-cation 2	80	9.2	30	30	1.33
x	DSA / SUB[b] / LPK[a]	82	14.5	30	30	2.23
x	DSA / SUB[b] / LPK[a] Magnificati on 1	83	14.5	30	30	2.36
x	DSA / SUB[b] / LPK[a] Magnificati onv2	85	15.4	30	30	2.26

Table 7-10 Change of air kerma rate based on input field size at 60 Hz

a. LPK = **Large Patient Key** button
b. for Germany only (instead of DSA)

Pulse rate at 60 Hz (Service Settings)

You can use the factors for the different pulse rates in all anatomical programs. After measuring the air kerma rate at 10 pulses/s, you can use these factors to compute the other air kerma rates.

Autom. Mode	Program	Voltage in kV	Current in mA	Pulses/ s	Pulse width in ms	Air kerma rate in mGy/s	Factor
x	Heart	88	3.3	30	30	0.62	1
x	Heart	90	3.4	15	30	0.34	0.5
x	Heart	91	3.5	10	30	0.23	0.37
x	Heart	91	3.5	5	30	0.12	0.19
x	Heart	92	3.5	2	30	not mea-surable	—
x	Heart	92	3.5	1	30	not mea-surable	—

Table 7-11 Factors for the different pulse rates at 60 Hz

Maximum air kerma rate in Radiography operating mode at 50 Hz (Service Settings)

Manual mode	Program	Voltage in kV	Current in mA	Product of current and time in mAs	Air kerma in mGy
x	Radiography	110	14.9	100	32.58

Table 7-12 Maximum air kerma rate in Radiography operating mode at 50 Hz

Maximum air kerma rate in Radiography operating mode at 60 Hz (Service Settings)

Manual mode	Program	Voltage in kV	Current in mA	Product of current and time in mAs	Air kerma in mGy
x	Radiography	110	14.9	100	35.44

Table 7-13 Maximum air kerma rate in Radiography operating mode

7.9 Dimensions

C-arm stand

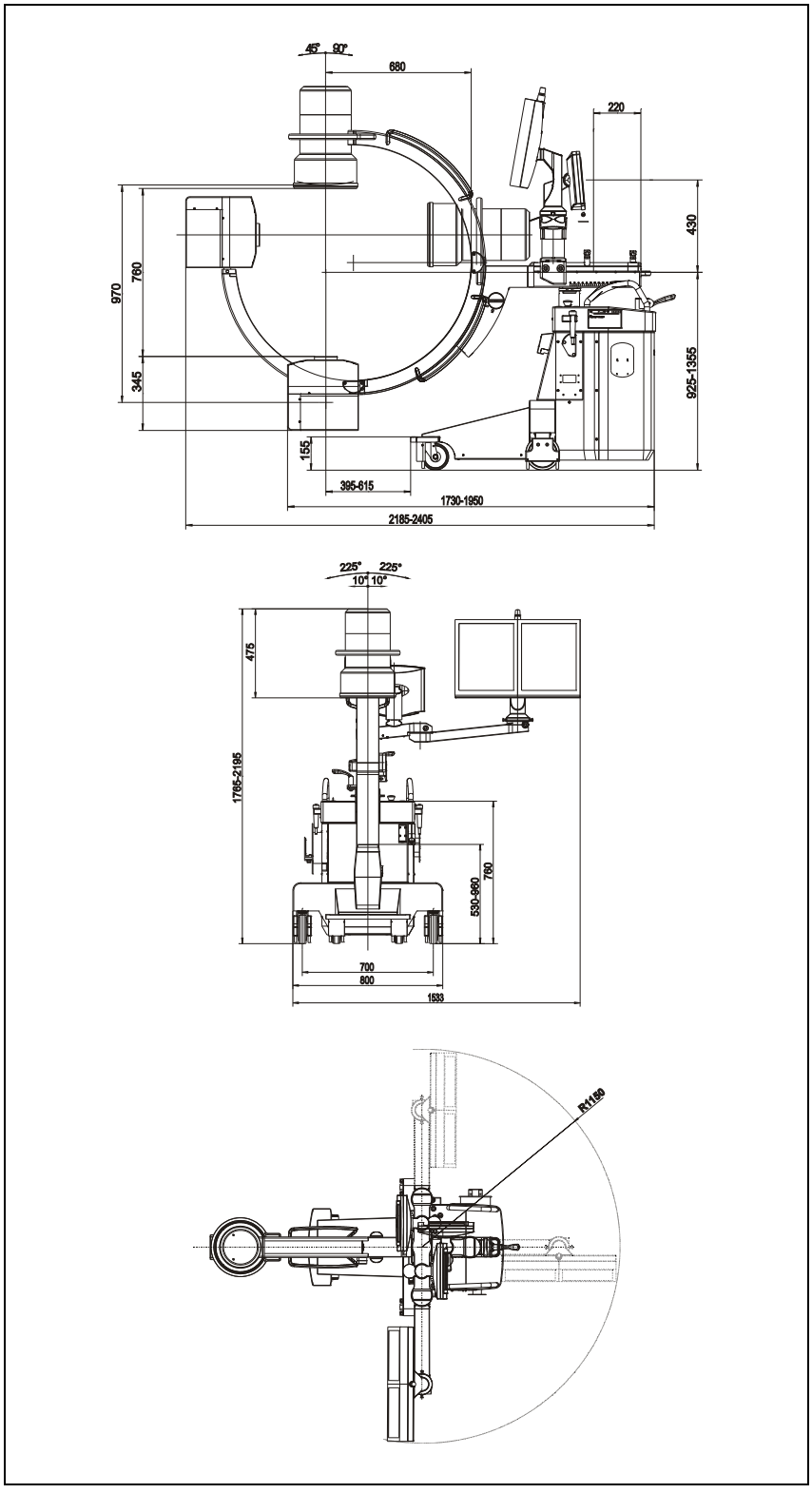


Fig. 7-7 Dimension of a C-arm stand

8 Maintenance

8.1 General requirements

WARNING

Maintenance of this system must be carried out by trained personnel only.

Some checks may only be performed by authorized service engineers. Those checks are marked accordingly.

The regulation for designing, operating and using medical devices (MPBetreibV) in Germany or other relevant federal regulations applicable in other countries require regular inspections (safety-related inspections). The equipment owner is held liable for performing them.

Ziehm Imaging GmbH recommends safety-related inspections every 12 months and will gladly assist you in performing them.

Keep a record of all checks and inspections the equipment is subject to and include them with the medical devices log book, which you are obliged to keep as the equipment owner.

USA

The Food and Drug Administration (FDA) requires that the checks and inspections described in the related document *CDRH Maintenance Report*. be performed at least every six months, in order to ensure that the X-ray system complies with federal regulations (specifically, the applicable sections of CFR 21, Subchapter J – Radiological Health).

The equipment owner is responsible for ensuring that the maintenance steps described in the said document are performed every six months. Failure to comply with this requirement relieves the Manufacturer and his agents of all responsibility in this matter.

The equipment owner is furthermore responsible for ensuring that only service engineers certified by the manufacturer perform the tests and adjustments described in the above document.

Service engineers are responsible for performing the procedure in the sequence shown in the *CDRH Maintenance Report*.

8.2 Electrics

Check the following functions at the specified time intervals:

Person in charge	Object	Action required	Whenever necessary	Monthly	Yearly
Trained personnel	Consistency test	Perform according to relevant national regulation of the country of installation		X	
	Power cable	Inspect for physical damage		X	
	Electrical safety	Check according to relevant national regulation of the country of installation			X
	Hand switch	Inspect cable for damage		X	
	Foot switch	Inspect cable for damage		X	
	Motorized vertical travel	Move up and down to respective limit stops		X	
	Solo Center control panel	Activate all operating modes and check whether they display correctly		X	
	Flatscreen monitors	Contrast and brightness can be adjusted		X	
		Clean screens with a mild detergent mixed with water	X		
Trained personnel	Fluoroscopy modes	Activate each mode, corresponding button must be highlighted in yellow			X
	Swivel harness	Inspect hose for physical damage		X	

Table 8-1 Regular electrical checks without radiation release

Checks involving radiation

To be able to check the following functions, you must initiate radiation:

WARNING

Always observe the safety and precautionary measures required by the relevant national X-ray and radiation protection regulations.

Person in charge	Object	Action required	Whenever necessary	Monthly	Yearly
Trained personnel	Radiation indication lamp	Must be lit during radiation		X	
	Hand switch	Must function in fluoroscopy mode		X	
		Must function in fluoroscopy mode		X	
		Dead man's control for direct radiography		X	
	Foot switch	Must not release radiation in **direct radiography** operating mode		X	
Trained personnel	Fluoroscopy	The X-ray symbol on the control panel is lit			X
		The **radiation time** display is counting up during radiation			X
		After 4 min 55 s of radiation, the following message appears on the control panel: **The radiation time is 5 minutes. Switch off alarm?** 5 seconds later, an audible alarm sounds.			X
		Press the **Yes** button in the message window: The audible alarm is switched off, the total radiation time remains indicated on the **Radiation Time** display.			X
	Iris Collimator	Open and close			X
	Slot collimator	Open and close, turn in both directions until reaching the right/left limit stops			X
	Direct radiography (option)	Tube current × time (mAs) value can be set			X
		All film sizes can be selected, corresponding button is highlighted in yellow			X
		An audible alarm sounds throughout the exposure time		X	

Table 8-2 Regular electrical checks with radiation release

8.3 Mechanics

Check the following functions or perform the following maintenance work at the specified time intervals:

Person in charge	Object	Action required	Whenever necessary	Monthly	Yearly
Trained personnel	Generator	Inspect for physical damage (e.g. oil leakage)		X	
	C-arm stand wheels	Clean tread surfaces, cable guards and bearings	X		
		Clean tread surfaces, cable guards and bearings	X		
		Check proper locking of the parking brake		X	
	C-arm	Clean gliding surface		X	
		Check retention force of orbital rotation brake in all C-arm positions		X	
		Check C-arm bearing for running noise			X
	Motorized vertical travel	Clean gliding surface of lifting column	X		
	Labels on the unit	Check whether all warning and information labels are legible		X	
Authorized service engineer	C-arm stand wheels	Readjust or replace brake blocks	X		
		Check firm seat of wheel brackets		X	
	Steering	Check mechanical play between steering lever and wheels			X
	Clamping levers of mechanical brakes	Grease thread with *Varilub extreme pressure lubricant*			X
	Motorized vertical travel	Grease lifting spindle with *Varilub extreme pressure lubricant*			X
		Inspect bearings for damage			X

Table 8-3 Regular mechanical checks

8.4 Seasoning the generator X-ray tube

Various influences, such as heavy load and increasing age, affect the performance level of the generator X-ray tube. Idle periods, leaving the system unused, may cause air pockets or loose particles inside the X-ray tube. This may produce X-ray tube arcing. Usually, arcing can be perceived as an acoustic signal, resembling the sound of a bang. Furthermore arcing may cause error messages of the system.

To guarantee smooth operation, you must season the X-ray tube in order to re-initialize it under the following conditions:

- Idle periods exceeding 2 months' time
- Occurrence of arcing
- Occurrence of power fluctuations

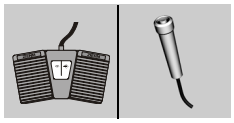
To season the X-ray tube, do the following:

- Switch to the **Fluoroscopy** operating mode.

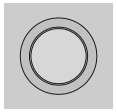
WARNING

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.



- Initiate radiation by pressing and holding the hand switch for at least 5 seconds.



CAUTION

CAUTION

Risk of injury by X-rays!

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

- Press the **Manual Exposure Rate Setting** button.

- The manual exposure rate setting controls appear in the dynamic control area.

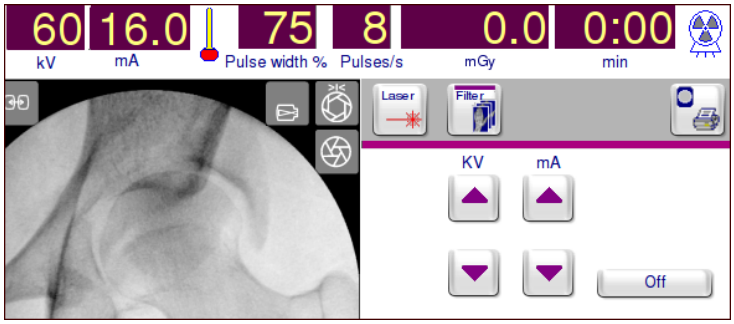
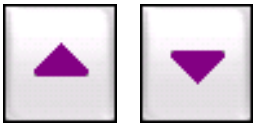
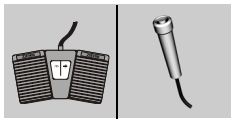


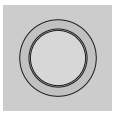
Fig. 8-1 Settings in the **Manual Exposure Rate Setting** mode



- Select 50 kV and 0.5 mA using the **Up/Down Arrow** buttons. By pressing one of the arrow buttons the value increases or decreases by 1 kV resp. 0.1 mA.



- Initiate radiation by pressing and holding the hand switch for at least 5 seconds.



CAUTION

CAUTION

Risk of injury by X-rays!

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

NOTICE

NOTICE

If arcing occurs or an error message from E1050 to E1095 appears, immediately terminate radiation and repeat the procedure after 5 minutes.

If the error message persists, please contact the Ziehm Imaging Service department.

- Repeat all previous steps of these instructions, increasing the voltage respectively by 10 kV according to the following table:

Tube voltage	Tube current	Exposure time in seconds
50 kV	0.5 mA	5 s
60 kV	0.5 mA	5 s
70 kV	0.5 mA	5 s
80 kV	0.5 mA	5 s
90 kV	0.5 mA	5 s

Table 8-4 Setting values for seasoning the X-ray tube

Tube voltage	Tube current	Exposure time in seconds
100 kV	0.5 mA	5 s
110 kV	0.5 mA	5 s

Table 8-4 Setting values for seasoning the X-ray tube (cont.)

The seasoning procedure has been successful if the testing series was completed using the indicated values and no error messages or arcing have occurred.

If the testing series fails repeatedly, please contact your in-house service engineer.

9 Data Security (HIPAA)

9.1 Overview

In order to provide data security for patient data according to the „Health Insurance Portability and Accountability Act“ (HIPAA), the system supports a password-protected user login (factory-set), if required. Depending on the type of user login with the **Login** button you can get full or restricted access to patient data in the **Patient** operating mode.

Log file

A Log File serves to record all modifications of the patient data performed by which user using a time and date stamp.

The log file acquires the following data:

- System logins and logouts
- Creating, modifying and deleting patient data
- Exporting patient data
- Creating, modifying and deleting user data

If the log file exceeds a size of 1 MB it will be automatically compressed and stored. Simultaneously a new log file is created.

Log file data must be stored for at least 30 days.

9.2 Exporting and deleting log files

Administrators can delete or export log files to a USB stick.

To export a log file, do the following:

- Log in as an administrator.
  Buttons and input boxes appear on the control panel of the user administration.

Fig. 9-1 Buttons and input boxes of the user administration

- Plug the USB stick into the USB port of the system.
- Wait until you hear a sound signal.

Export Log File

- Press the **Export Log File** button.
  The log file HIPAA.log is stored to the USB stick. You will find the log file in a folder indicating the system's serial number.

To delete a log file, do the following:

- Log in as an administrator.
  Buttons and input boxes appear on the control panel of the user administration (*Fig. 9-1*).

Delete Log File

- Press the **Delete Log File** button.
  The log file HIPAA.log on the hard disk will be deleted. A new log file is created.

NOTE

Only delete log files, the entries of which are older than 30 days.

9.3 Log file structure

The log file records all modifications of the patient data. The log file records every operation, the user performing it, the corresponding patient data as well as time and date stamp of the operation.

```
Logfile created by instance: HIPAA-Logger

Logfile Number: 1

Current entry count: 1918

Last entry: 25.11.2008 14:35:20
Last entry (t_time): 1227652520

Last change by: HIPAA-Logger

Log file structure:
%id - %dt (%to) - %msg
equals to:
<EntryID> - <Date/Time> (<Offset to Date/Time>) - <Log Message>

----------------------------------------

*** 1 - 25.09.2008 23:27:57 - HIPAA-Logger - Started HIPAA-Logger ***
2 - 25.09.2008 23:28:09 () - Anmeldung Benutzer 'Default User' erfolgreich.
3 - 25.09.2008 23:28:56 () - Default User: Patient ' P23:28_25.09.08' (ID '15') der Datenbank hinzugefügt.
4 - 25.09.2008 23:29:45 () - Default User: Patient ' ' (ID '16') der Datenbank hinzugefügt.
*** 5 - 26.09.2008 0:10:26 - HIPAA-Logger - Started HIPAA-Logger ***
6 - 26.09.2008 0:10:27 () - Anmeldung Benutzer 'Default User' erfolgreich.
7 - 26.09.2008 0:11:14 () - Default User: Patient ' P00:11_26.09.08' (ID '17') der Datenbank hinzugefügt.
8 - 26.09.2008 0:12:22 () - Default User: Patient ' Dauer' (ID '18') der Datenbank hinzugefügt.
*** 9 - 26.09.2008 0:15:51 - HIPAA-Logger - Started HIPAA-Logger ***
10 - 26.09.2008 0:15:51 () - Anmeldung Benutzer 'Default User' erfolgreich.
11 - 26.09.2008 0:16:38 () - Default User: Patient ' P00:16_26.09.08' (ID '19') der Datenbank hinzugefügt.
12 - 26.09.2008 0:17:48 () - Default User: Patient ' Dauer' (ID '20') der Datenbank hinzugefügt.
*** 13 - 26.09.2008 0:19:28 - HIPAA-Logger - Started HIPAA-Logger ***
14 - 26.09.2008 0:19:28 () - Anmeldung Benutzer 'Default User' erfolgreich.
15 - 26.09.2008 0:20:15 () - Default User: Patient ' P00:20_26.09.08' (ID '21') der Datenbank hinzugefügt.
*** 16 - 26.09.2008 0:55:0 - HIPAA-Logger - Started HIPAA-Logger ***
17 - 26.09.2008 0:55:0 () - Anmeldung Benutzer 'Default User' erfolgreich.
18 - 26.09.2008 0:55:47 () - Default User: Patient ' P00:55_26.09.08' (ID '22') der Datenbank hinzugefügt.
*** 19 - 26.09.2008 01:30:29 - HIPAA-Logger - Started HIPAA-Logger ***
20 - 26.09.2008 01:30:29 () - Anmeldung Benutzer 'Default User' erfolgreich.
21 - 26.09.2008 01:31:16 () - Default User: Patient ' P01:31_26.09.08' (ID '23') der Datenbank hinzugefügt.
*** 22 - 26.09.2008 02:06:0 - HIPAA-Logger - Started HIPAA-Logger ***
23 - 26.09.2008 02:06:0 () - Anmeldung Benutzer 'Default User' erfolgreich.
24 - 26.09.2008 02:06:47 () - Default User: Patient ' P02:06_26.09.08' (ID '24') der Datenbank hinzugefügt.
*** 25 - 26.09.2008 02:40:34 - HIPAA-Logger - Started HIPAA-Logger ***
26 - 26.09.2008 02:40:34 () - Anmeldung Benutzer 'Default User' erfolgreich.
27 - 26.09.2008 02:41:21 () - Default User: Patient ' P02:41_26.09.08' (ID '25') der Datenbank hinzugefügt.
*** 28 - 26.09.2008 03:13:37 - HIPAA-Logger - Started HIPAA-Logger ***
29 - 26.09.2008 03:13:37 () - Anmeldung Benutzer 'Default User' erfolgreich.
```

Fig. 9-2 Content of a log file (example)

Besides the header information the log file stores the following data:

Entry	Meaning
Column 1	Consecutive number of the entry
Column 2	Date and time
Column 3	Time difference that the system time was changed (in parentheses)
Column 4	Log entry indicating user, affected patient data and description of the operation

Table 9-1 Meaning of the log file entries

10 Replacing Components

10.1 Hand switch and foot switch

The Ziehm Solo has two hand switches, one on the left side and one on the right side.

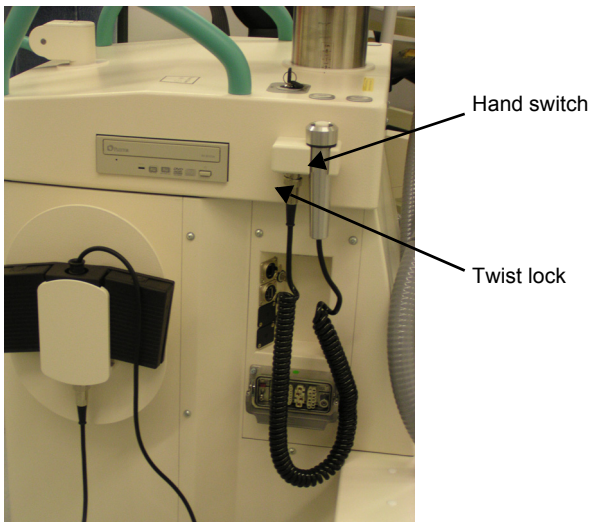


Fig. 10-1 Connection of hand switch cable (right)

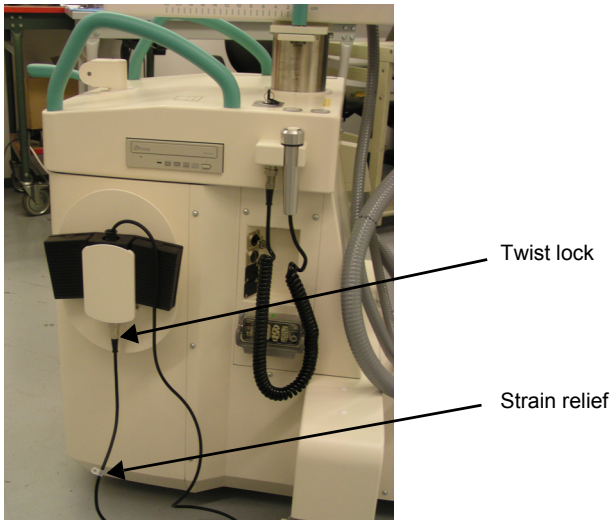


Fig. 10-2 Connection of foot switch cable

To replace the hand or foot switch, do the following:

- **Foot switch**: Unscrew the strain relief using an Allen key (2.5 mm).
- Open the twist lock.
- Unplug the cable.
- Plug in the cable of the new switch.
- Close the twist lock.
- **Foot switch**: Screw down the strain relief using an Allen key (2.5 mm).

10.2 Fuses

10.2.1 Mains fuse on the C-arm stand

The system is equipped with a circuit breaker on the C-arm stand.

- 2 × 15 A at 200 V_{AC}, 220 V_{AC}, 230 V_{AC}, 240 V_{AC}
- 2 × 20 A at 100 V_{AC}, 120 V_{AC}

ON-OFF-circuit breaker with rocker switch

If the mains fuse on the C-arm stand (→ *Fig. 10-3*) has triggered (rocker switch in **OFF** position, circuit breaker is not illuminated), you can switch it on again.

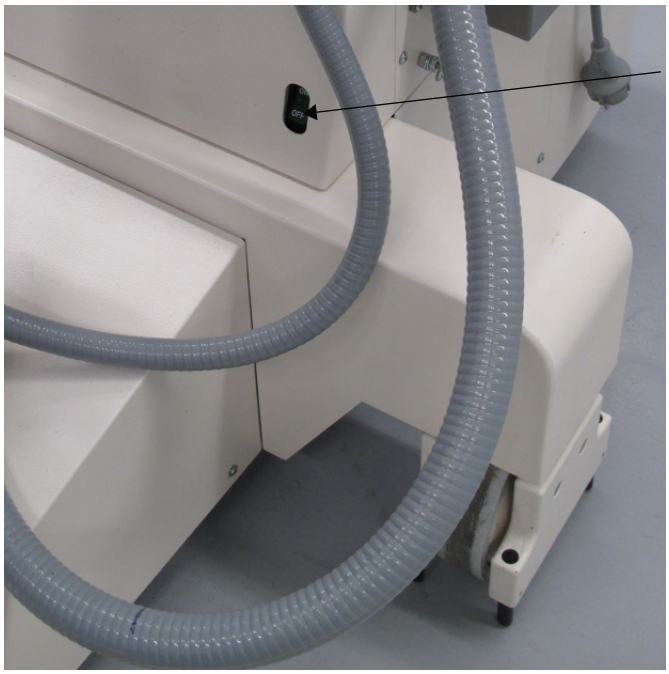


Fig. 10-3 C-arm stand with mains fuse

To switch on the mains fuse, do the following:

- Press rocker switch to **ON** position.
- The circuit breaker is illuminated.

10.2.2 Fuses on the C-arm stand

<table>
<tr><th colspan="4">U579 module</th></tr>
<tr><th>Name</th><th>Rating</th><th colspan="2">Function</th></tr>
<tr><td>F1</td><td>0.1 A, slow</td><td colspan="2" rowspan="4">F1, F2, F3: only one of the fuses may be used at the same time!
If TR2 is equipped, then F4 and one of the fuses F1, F2 or F3 are used.</td></tr>
<tr><td>F2</td><td>0.1 A, slow</td></tr>
<tr><td>F3</td><td>0.1 A, slow</td></tr>
<tr><td>F4</td><td>0.315 A, fast</td></tr>
<tr><td>F5</td><td>2 A, slow</td><td>45 V_{AC}</td><td rowspan="2">Rotating anode drive
F5, F6: only one of the fuses may be used at the same time!</td></tr>
<tr><td>F6</td><td>2 A, slow</td><td>55 V_{AC}</td></tr>
<tr><td>F7</td><td>2 A, slow</td><td colspan="2">160 V_{AC} rotating anode drive</td></tr>
<tr><td>F8</td><td>2 A, slow</td><td colspan="2">Image intensifier and Solo Center / U515 module (+24 V TFT)</td></tr>
<tr><td>F9</td><td>2 A, slow</td><td colspan="2">CCD</td></tr>
<tr><td>F10</td><td>2.5 A, slow</td><td colspan="2">reserved</td></tr>
<tr><td>F12</td><td>2 A, slow</td><td colspan="2">U515 module (12 V_{AC})</td></tr>
<tr><td>F13</td><td>4 A, slow</td><td colspan="2">FG 9938 module</td></tr>
<tr><td>F14</td><td>3.15 A, slow</td><td colspan="2">external 220 V (flat-panel detector, printer, screens)</td></tr>
<tr><td>F16</td><td>1 A, slow</td><td colspan="2">Bias supplies</td></tr>
<tr><td>F18</td><td>15 A, slow</td><td colspan="2">Generator (230 V_{AC})</td></tr>
<tr><td>F19</td><td>10 A, slow</td><td colspan="2">Lifting motor (24 V_{AC})</td></tr>
<tr><td>F20</td><td>500 mA, slow</td><td colspan="2">Lifting motor (+24 V lift)</td></tr>
<tr><td>F22</td><td>3.15 A, slow</td><td colspan="2">20 V_{AC}</td></tr>
</table>

Table 10-1 Transformer fuses on the U579 module

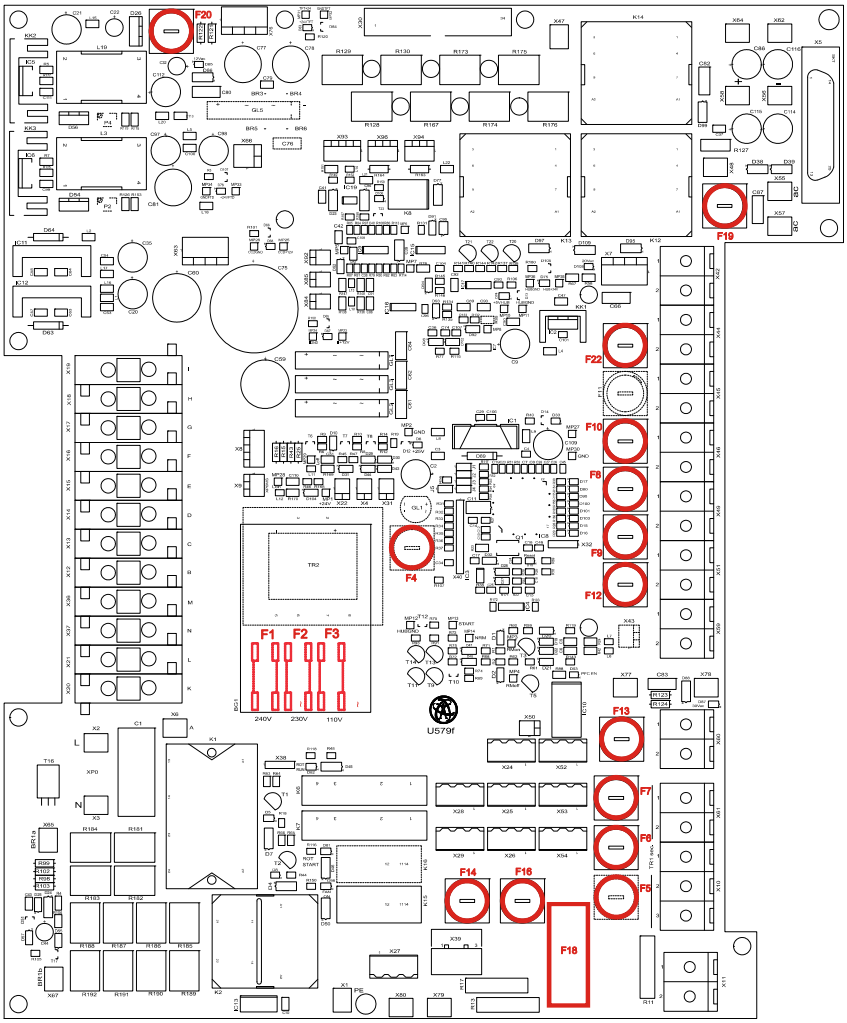


Fig. 10-4 Fuse positions on the U579 module

11 Troubleshooting

11.1 List of error and alert messages

If an alert or status message is displayed, do the following:

- Press the **Yes** button in the message window.

  The message window is closed. You may continue to work. The system is not fully operational.

If an error occurs, do the following:

- Contact your after-sales service center.

Code	Type	Description
E1000	Error	Thin filament defective
E1001	Error	Thick filament defective
E1002	Error	No VSync!
E1003	Error	Operating temperature not yet reached. Please, wait...
E1004	Alert	Cooling phase in process. Please, wait...
E1005	Error	Temperature 2 too low
E1006	Alert	Temperature 2 too high
E1007	Error	Machine data corrupt
E1008	Error	Interrupt 1 flipflop defective
E1009	Error	Interrupt 2 flipflop defective
E1010	Error	HW signal X-ray active during power-up
E1011	Error	CAN X-ray Enable active during power-up
E1012	Error	D/A converter reference voltage defective
E1013	Error	D/A converter kV defective
E1014	Error	Oil overtemperature switch active
E1015	Error	Wrong machine data version
E1016	Error	Moisture sensor alarm
E1017	Error	Test of ‘FAULT’ signal failed
E1018	Error	Debug switch is on
E1019	Error	Monitoring anode rotation does not work.

Table 11-1 List of errors and alerts

Code	Type	Description
E1050	Alert	High-voltage fault
E1051	Alert	High-voltage fault (anode)
E1052	Alert	High-voltage fault (cathode)
E1053	Alert	mA peak value fault
E1054	Alert	kV nominal/actual value fault
E1055	Alert	mA nominal/actual value fault
E1056	Alert	X-ray Enable fault
E1057	Alert	Life monitoring missing
E1058	Alert	Hardware monitoring missing
E1059	Alert	External radiation interrupt (X-ray Break)
E1060	Alert	Signal / X-ray missing
E1061	Alert	High-voltage arc
E1062	Alert	Nominal kV value greater max. kV value
E1063	Alert	Nominal mA value greater max. mA value
E1064	Alert	Nominal power value greater max. power value
E1065	Alert	Nominal kV value less min. kV value
E1066	Alert	CAN fault line active
E1067	Error	Basic heating faults
E1068	Error	VSync faults
E1069	Alert	Temperature sensor 1
E1070	Alert	Temperature sensor 2
E1071	Error	Signal / X-ray without radiation
E1072	Error	Oil overtemperature switch active
E1073	Error	Moisture sensor alarm
E1074	Error	kV value too high (no radiation)
E1075	Error	Test of rotating anode failed
E1082	Alert	Nominal kV value less min. kV value
E1083	Error	Rotating anode could not be started.
E1084	Error	Rotating anode failed
E1085	Alert	Average power in Burst mode > 600 Watt
E1086	Alert	mA-Value too high for thin filament
E1087	Alert	Max. anode capacity in Burst mode reached
E1095	Alert	Generator overheated, recovery time %d seconds [a]

Table 11-1 List of errors and alerts (cont.)

Code	Type	Description
E1098	Error	Generator power-up fault
E1099	Error	Generator fault
E1100	Alert	Hand switch 1 pressed during power-up
E1101	Alert	Hand switch 2 pressed during power-up
E1102	Alert	Foot switch 1 pressed during power-up
E1103	Alert	Foot switch 2 pressed during power-up
E1104	Alert	Foot switch 3 pressed during power-up
E1105	Alert	Foot switch 4 pressed during power-up
E1106	Alert	Foot switch 5 pressed during power-up
E1107	Alert	Foot switch 6 pressed during power-up
E1108	Error	Short circuit in hand switch 1
E1109	Error	Short circuit in hand switch 2
E1110	Error	Short circuit in foot switch 1
E1111	Error	Short circuit in foot switch 2
E1112	Error	Short circuit in foot switch 3
E1113	Error	Short circuit in foot switch 4
E1114	Error	Short circuit in foot switch 5
E1115	Error	Short circuit in foot switch 6
E1116	Error	CAN X-ray Enable active during power-up
E1117	Error	External I/O fault
E1118	Error	Wrong EEPROM checksum
E1132	Alert	Short circuit in hand switch 1
E1133	Alert	Short circuit in hand switch 2
E1134	Alert	Short circuit in foot switch 1
E1135	Alert	Short circuit in foot switch 2
E1136	Alert	Short circuit in foot switch 3
E1137	Alert	Short circuit in foot switch 4
E1138	Alert	Short circuit in foot switch 5
E1139	Alert	Short circuit in foot switch 6
E1140	Alert	X-ray Enable not active
E1141	Alert	CAN fault line active
E1142	Alert	External I/O fault
E1143	Error	Error Life Monitoring Imaging System

Table 11-1 List of errors and alerts (cont.)

Code	Type	Description
E1148	Alert	Timeout post-fluoro time (LIH)
E1164	Error	Short circuit in hand switch 1
E1165	Error	Short circuit in hand switch 2
E1166	Error	Short circuit in foot switch 1
E1167	Error	Short circuit in foot switch 2
E1168	Error	Short circuit in foot switch 3
E1169	Error	Short circuit in foot switch 4
E1170	Error	Short circuit in foot switch 5
E1171	Error	Short circuit in foot switch 6
E1172	Error	X-ray Enable without switch
E1173	Error	CAN fault line active
E1174	Error	External I/O fault
E1175	Error	Error Life Monitoring Imaging System
E1176	Error	Fan blocked
E1197	Error	Main interface X-ray Break fault
E1198	Error	Main interface power-up fault
E1199	Error	Main interface fault
E1200	Error	Timeout main interface (1)
E1201	Error	Timeout main interface (2)
E1202	Error	Timeout while reading power-up errors
E1203	Error	Timeout generator machine data (1)
E1204	Error	Timeout generator machine data (2)
E1205	Error	Timeout generator machine data (3)
E1206	Error	Timeout generator pulse width
E1207	Error	Timeout filament selection
E1208	Error	Timeout measuring range selection
E1209	Error	Timeout kVmA setpoint value
E1210	Error	Timeout while reading collimator limit value (1)
E1211	Error	Timeout while reading collimator limit value (2)
E1212	Error	Timeout ack system running
E1213	Alert	Timeout while reading X-ray Break errors
E1214	Alert	Timeout X-ray Break: interface busy
E1215	Error	Internal error %d [a]

Table 11-1 List of errors and alerts (cont.)

Code	Type	Description
E1216	Alert	Internal alert %d [a]
E1217	Error	Error while clearing hard disk %d [a]
E1218	Error	Timeout CAN module %d CAN bus switched off by host! [a]
E1219	Error	Unexpected ACK from CAN module %d [a]
E1220	Alert	Function assigned to X-ray switch (%d), ignored! [a]
E1221	Alert	X-ray command assigned to function switch (%d), ignored! [a]
E1222	Alert	Temperature limit alert: Reduce radiation power!
E1223	Error	CAN bus cannot be addressed during power-up!
E1224	Error	CAN module missing:
E1225	Alert	Radiation allowed after mode values are displayed!
E1226	Error	CAN modules missing:
E1227	Error	CAN module faulty: %d [a]
E1228	Error	CAN module 6 (U544) faulty
E1229	Error	CAN Bus faulty BUS OFF
E1230	Error	Only CAN module 6 (U544) detected
E1231	Error	CAN module(s) not connected properly (standalone?)
E1232	Error	Timeout: Timeout: no answer from a CAN module
E1233	Error	Out of memory. Image can not be stored!
E1234	Error	dis8000.ini missing!
E1235	Error	No acknowledge to %d from %d [a]
E1236	Error	vision.md does not match U544 firmware
E1237	Error	vision.md does not match dongle
E1238	Error	Machine data missing
E1239	Message	Service task performed by:
E1240	Message	Database OK
E1241	Error	Database damaged. Please clear hard disk !
E1242	Error	Mobile stand not detected, but Main Interface present!
E1243	Error	Iris calibration error!
E1244	Error	vision.md: Section missing!
E1245	Error	Radiation blocked by key switch
E1246	Alert	Flat-panel detector not ready.
E1247	Message	Signature check completed
E1248	Alert	Radiation warning lamp not functional!

Table 11-1 List of errors and alerts (cont.)

Code	Type	Description
E1249	Error	X-ray Break from module %d
E1299	Error	Image system fault
E1300	Error	SPI Interface MAX 504
E1301	Alert	Overtemperature
E1302	Error	Reference voltage MAX 504
E1303	Error	Output voltage MAX 504
E1304	Error	Wrong EEPROM checksum
E1350	Error	SPI Interface MAX 504
E1351	Alert	Overtemperature
E1352	Alert	Actual value too high
E1353	Alert	Actual value too low
E1354	Error	Output voltage MAX 504
E1355	Error	CAN fault line active
E1358	Alert	Output voltage beyond tolerance
E1398	Error	PPS power-up fault
E1399	Error	PPS fault
E1400	Error	Servo %d position fault [a]
E1401	Error	Servo %d not connected [a]
E1402	Error	Servo %d not ready [a]
E1409	Alert	CAN communication failure with collimator
E1410	Alert	Collimator startup error
E1420	Alert	DAP meter error %d [a]
E1421	Alert	DAP meter startup error %d [a]
E1448	Alert	Unknown DAP meter error
E1449	Error	Vision Track fault
E1450	Error	Servo position fault
E1451	Error	Servo not connected
E1452	Error	Servo not ready
E1499	Error	II power supply fault
E1500	Alert	Radiation warning lamp defective
E1501	Alert	CRT high voltage
E1502	Alert	Video voltage
E1503	Alert	Video signal

Table 11-1 List of errors and alerts (cont.)

Code	Type	Description
E1504	Alert	CRT filament
E1505	Alert	Horizontal deflection
E1506	Alert	150V supply
E1507	Alert	Vertical deflection
E1508	Error	Wrong EEPROM checksum
E1509	Alert	VBlank signal missing
E1516	Alert	Radiation warning lamp defective
E1517	Alert	CRT high voltage
E1518	Alert	Video voltage
E1519	Alert	Video signal
E1520	Alert	CRT filament
E1521	Alert	Horizontal deflection
E1522	Alert	150V supply
E1523	Alert	Vertical deflection
E1599	Error	Monitor fault
E1600	Alert	Busy printer 1 active
E1601	Alert	Busy printer 2 active
E1602	Error	Wrong EEPROM checksum
E1620	Alert	Printer 1 busy error
E1621	Alert	Printer 1 busy error
E1622	Alert	Printer 1 busy error
E1628	Alert	Printer 2 busy error
E1629	Alert	Printer 2 busy error
E1630	Alert	Printer 2 busy error
E1649	Error	Error U525
E1700	Alert	kVmA table: kV not ascending
E1701	Alert	kVmA table: Power not ascending
E1702	Alert	kVmA table not finished
E1703	Alert	Max. kV value too high.
E1704	Alert	Max. mA value too high.
E1705	Error	No external video signal
E1708	Error	Generator pulse error
E1709	Error	No VSync!

Table 11-1 List of errors and alerts (cont.)

Code	Type	Description
E1710	Error	No Interrupt!
E1711	Error	No Communication PPC generator
E1712	Error	mA value from generator invalid
E1713	Error	X-ray not allowed
E1714	Error	Max mA value cannot be read.
E1716	Error	SDRAM PPC defective
E1717	Error	GammaLUT PPC defective
E1718	Error	Offset adjustment not possible
E1719	Error	Gain adjustment not possible
E1720	Error	Hardware Version, Release
E1721	Error	IRQ3 error!
E1722	Error	VSync corrupt 30/25 Hz!
E1723	Error	Video standard unknown!
E1724	Error	Boot program unknown!
E1725	Error	M-Data unknown!
E1726	Alert	Collimator does not support DAP values!
E1727	Error	Flat-panel detector not supported by this version!
E1728	Alert	Internal communication error!
E1732	Error	Reference voltage defective!
E1733	Error	AD14 Offset adjustment defective!
E1734	Error	AD14 Gain adjustment defective!
E1735	Error	AD14 Gain*4 adjustment defective!
E1736	Error	AD8 Offset adjustment defective!
E1737	Error	AD8 Gain adjustment defective!
E1738	Error	No external video signal
E1740	Error	Hardware does not support grid regulation!
E1741	Error	Hardware does not support motion detection!
E1742	Error	Hardware does not support DAP calculation!
E1743	Error	Hardware does not support automatic dose reduction!
E1744	Error	Histogrammer hardware defective!
E1747	Error	Black level >= White level! Check connectors on command processor.
E1756	Error	FFC board not available.

Table 11-1 List of errors and alerts (cont.)

Code	Type	Description
E1757	Error	FFC board does not respond.
E1799	Error	Error PPC
E1800	Alert	Radiation warning lamp defective!
E1801	Alert	Wrong checksum EEPROM!
E1802	Alert	Interrupt PTA5 active during power-up.
E1803	Alert	Interrupt PTA6 active during power-up.
E1804	Alert	No communication with left flatscreen!
E1805	Alert	No communication with right flatscreen!
E1806	Alert	SPI interface for left flatscreen defective!
E1807	Alert	SPI interface for right flatscreen defective!
E1809	Alert	Printer busy!
E1850	Alert	Radiation warning lamp defective!
E1865	Alert	U578 execution failed!

Table 11-1 List of errors and alerts (cont.)

a. %d is a placeholder for a number

11.2 What to do if ...

Situation	Remedy
The Solo Center on the C-arm stand keeps on tilting down-wards, thus not remaining in the desired position.	• Fasten tightly the two Allen screws located at the bottom on the rear of the Solo Center pivot.

Table 11-2 Troubleshooting

12 Disassembling the System

12.1 Dismounting the monitor head

NOTICE

NOTICE

Always wear cotton gloves when installing, testing or making settings on displays or screens.

To disassemble the monitor head, do the following:

- Align the monitor support arm to 180°, and lock the monitor support arm by pressing the plunger blocks (→ *Fig. 12-1*).

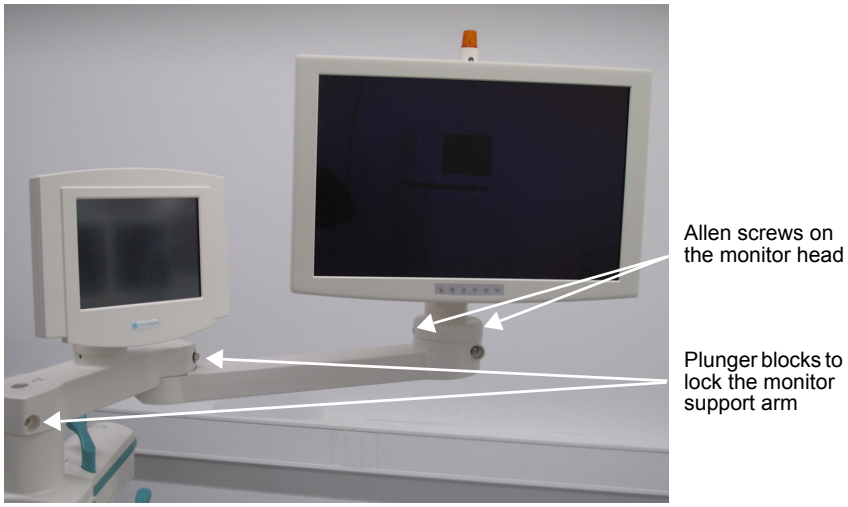


Fig. 12-1 Assembling the monitor support arm

- Unscrew both Allen screws on the monitor head base (→ *Fig. 12-1*).

- With the help of a second person, lift the monitor head and place it on a suitable soft surface.

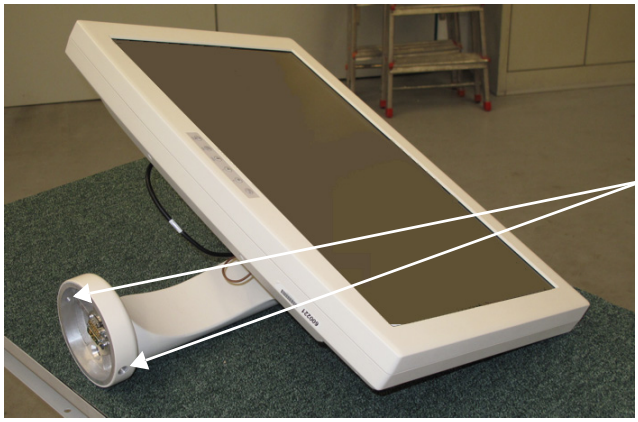


Fig. 12-2 Monitor head

WARNING

Risk of injury!

The monitor head cannot be lifted by one person alone. With the help of a second person, lift the monitor head off the monitor support arm.

- Fasten both Allen screws on the monitor support arm again.

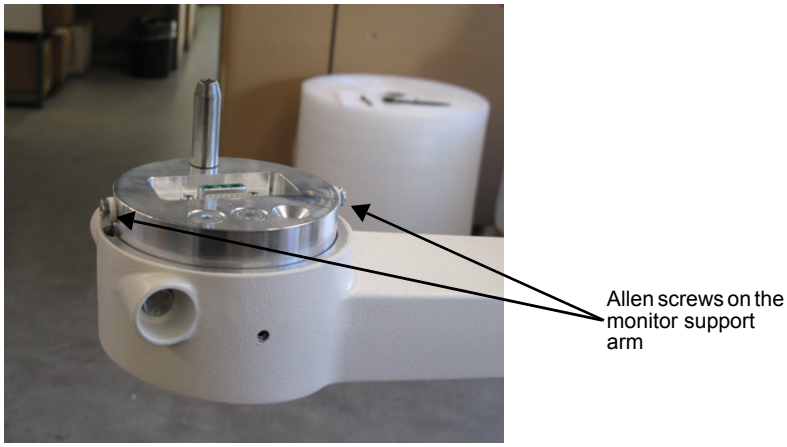


Fig. 12-3 Fastened Allen screws on the monitor support arm (secure from loss)

12.2 Dismounting the Solo Center

NOTICE

NOTICE

Always wear cotton gloves when installing, testing or making settings on displays or screens.

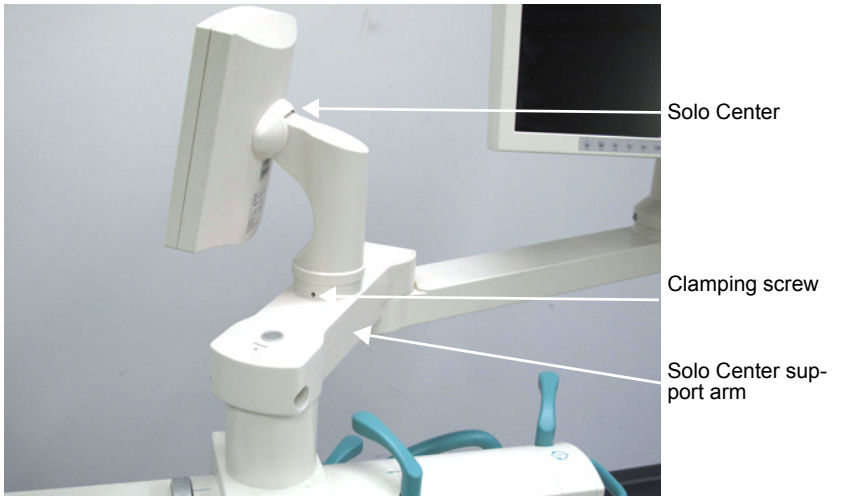


Fig. 12-4 Solo Center support arm

To dismount the Solo Center from the C-arm stand, do the following:

- Remove the cover plate at the bottom of the Solo Center support arm (→ *Fig. 12-5*).

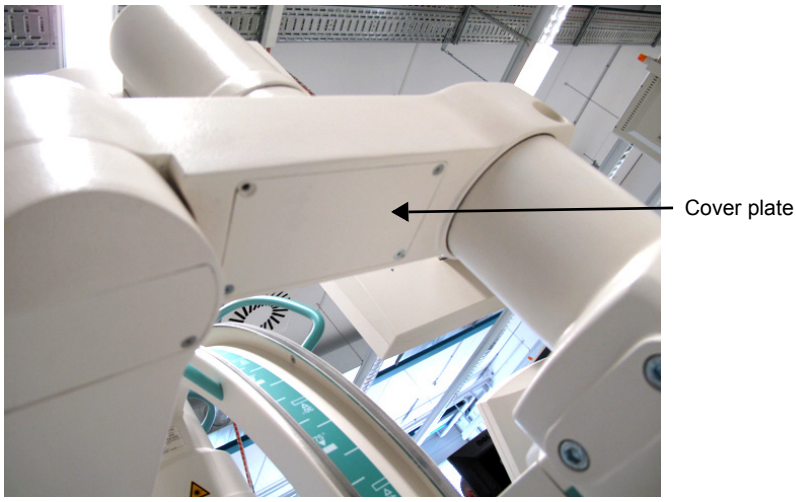


Fig. 12-5 Solo Center support arm with cover plate

- Carefully remove the cover plate with attached circuit board.

- Disconnect the ground wire from the grounding point on the circuit board attached to the cover plate (→ *Fig. 12-6*).

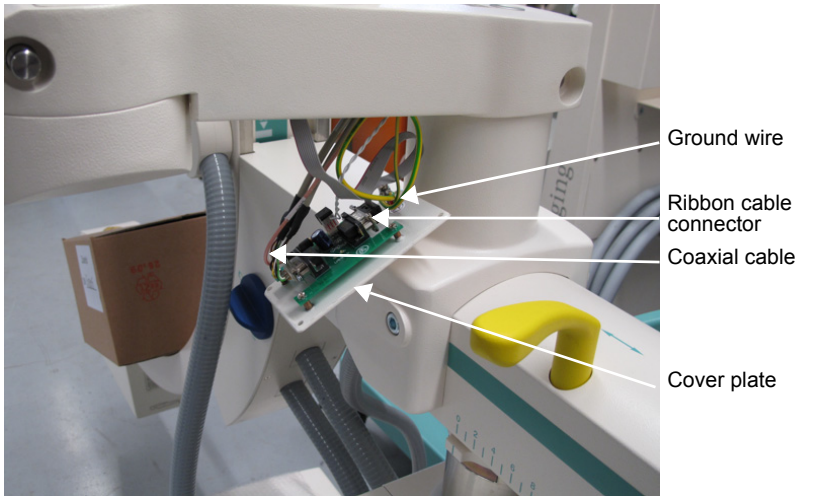


Fig. 12-6 Connections on the circuit board attached to the cover plate

- Plug off the ribbon cable from the corresponding socket on the circuit board attached to the cover plate.
- Disconnect both coaxial cables from the coaxial cables on the circuit board attached to the cover plate.
- Undo the round head square neck bolts attaching the flange to the Solo Center support arm.

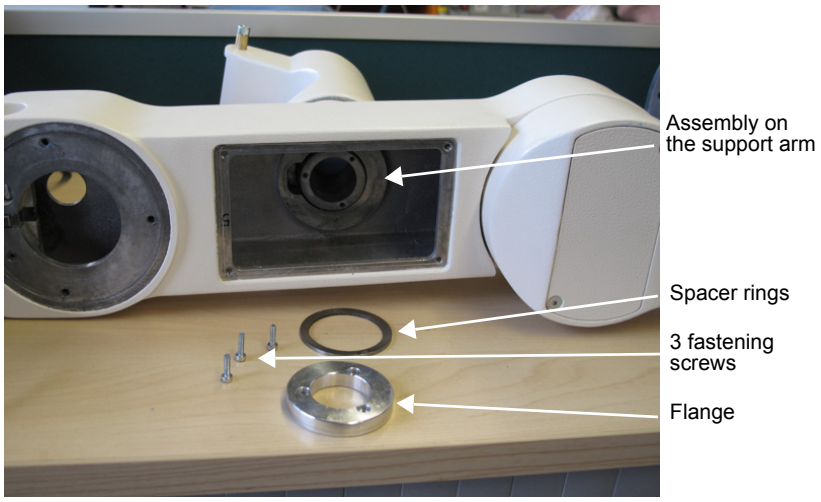


Fig. 12-7 Support arm with Solo Center from below

- Remove the spacer rings and the flange (→ *Fig. 12-7*).
- With the help of a second person, carefully lift the Solo Center and pull it out upward.

When pulling out the cables, take particular care not to get them stuck in the Solo Center support arm, which may damage them.

WARNING

Cable damage!

Take care not to squash and damage the cables while doing this.

- Apply the spacer rings and the flange to the Solo Center using three screws (→ *Fig. 12-8*).

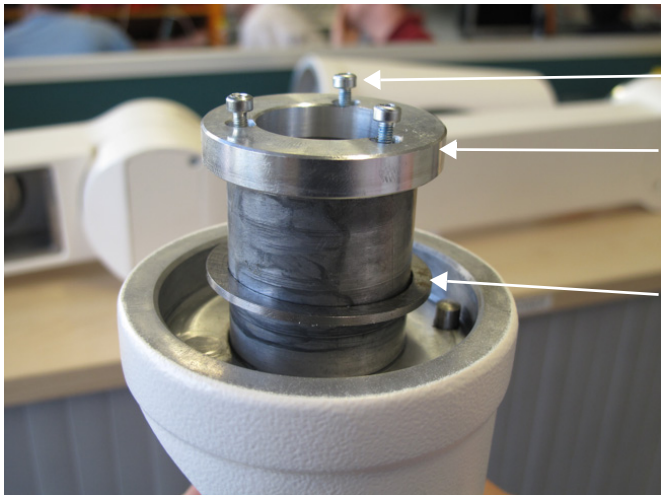


Fig. 12-8 Items for attachment of the Solo Center

- Place the Solo Center, screen side up, on a suitable soft surface.

13 Mounting the System on a Pallet

13.1 Safety instructions and information

13.1.1 Safety instructions

Make sure to comply with the following safety instructions when packaging.

WARNING

WARNING

Only authorized personnel is allowed to pack and unpack the system. Authorized personnel are persons who have attended an appropriate training course provided by the manufacturer.

WARNING

WARNING

Always observe the general occupational safety and accident prevention regulations!

WARNING

WARNING

When handling detergents and solvents, strictly observe the safety instructions provided by the respective manufacturer!

13.1.2 Information

Scope of validity

These instructions apply to the shipment of Ziehm Solo and Viewing Station on pallets.

13.1.3 Environmental conditions

The system must not be exposed to extreme ambient conditions. The following minimum/maximum values must not be exceeded during storage or operation:

Storage/transport:

- Temperature: –5 °C to +55 °C
- Relative air humidity: 20 % – 70 %

Operation:

- Temperature: +13 °C to +35 °C
- Relative air humidity: 20 % – 70 %

WARNING

Do not operate the system until the equipment has reached a safe operating temperature of +13 °C to +35 °C with no condensation present.

Otherwise severe equipment damage may result.

NOTICE

CAUTION

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

13.2 Packing material and contents

13.2.1 Material

List

Article	Article number
Pallet	26374
Steel retaining brackets:	
Retaining bracket 1 with	65827
2 hexagon wood screws 10 × 40	56285
2 retaining brackets 2 with	65828
4 hexagon wood screws 10 × 40	56285
Retaining bracket 3 with	65829
2 Allen screws M8 × 20	56137
Retaining bracket 4 with	65830
2 hexagon wood screws 10 × 40	56285
2 mounting levers for C-arm stand	60418
2 hexagon wood screws 10 × 40	56285
USA:	
Retaining bracket 1 with	65827
2 round head square neck bolts M10 × 40	56286
2 hexagon nuts M10	57008
Retaining bracket 2 with	65828
2 round head square neck bolts M10 × 40	56286
2 hexagon nuts M10	57008
Retaining bracket 2 with	65828
2 round head square neck bolts M10 × 60	56287
2 hexagon nuts M10	57008
Retaining bracket 3 with	65829
2 Allen screws M8 × 20	56137
Retaining bracket 4 with	65830
2 round head square neck bolts M10 × 40	56286
2 hexagon nuts M10	57008
1 square timber 380 mm × 80 mm × 60 mm, with	13112
rubber strip lining	54067

Table 13-1 Packing material

Article	Article number
Cardboard box for the pallet	26372
Cardboard box for monitor head 2 × edge protection for cardboard box 4 drywall screws 5 × 40 4 washers	 57065
Cardboard box for accessories	26392
Bubble wrap	
Foam rubber	
Styrofoam material	
USA: 2 small wooden blocks	
Clout nails	
2 boards	
Cross lath	
2 shock watch devices	26149 / 26150
Label “Transportkontrolle – Monitored shipment”	
Address label	
Label “Vorsicht Glas” [Glass – Handle With Care]	26082

Table 13-1 Packing material (cont.)

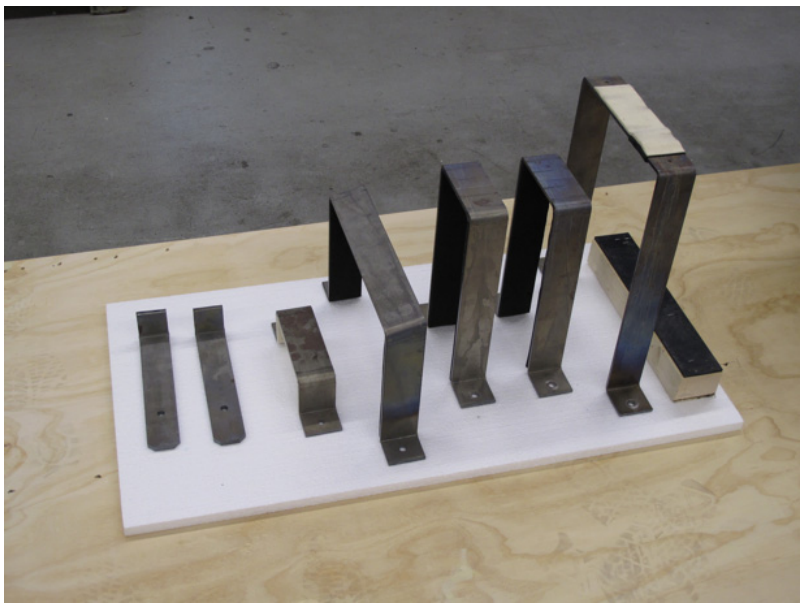


Fig. 13-1 Packing material

13.2.2 Parts to be packed

- C-arm stand
- Monitor head
- Solo Center
- Ramp (for drop shipments)
- Accessories (→ *Ch. 1.3, p. 1-4*)

13.3 Packing the C-arm stand

To mount the C-arm stand on the pallet, do the following:

- Place the ramp to the short front side of the pallet.

NOTE

If you use the ramp supplied with a drop shipment, then attach the ramp to the sides of the pallet using both fixing clamps (→ *Fig. 13-2*).

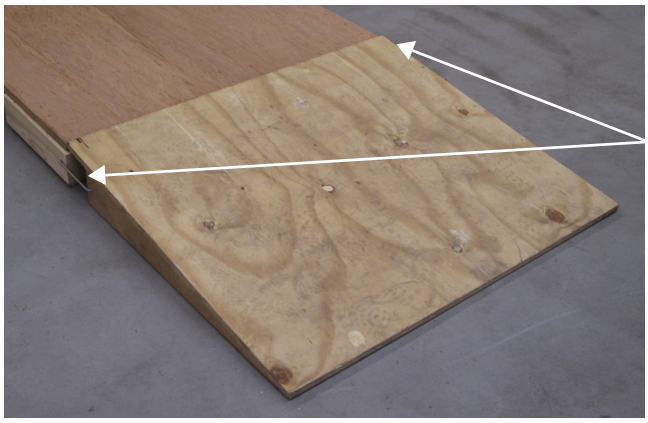


Fig. 13-2 Pallet with attached ramp

- Place a sufficiently dimensioned piece of wrap foil on the pallet.
- Fold the excessive wrap foil to the sides of the pallet.

Fig. 13-3 Pallet with wrap foil

- Carefully push the C-arm stand onto the pallet using a ramp.
- Position the C-arm stand as illustrated in *Fig. 13-4*.

- Position the C-arm as illustrated in *Fig. 13-4*.

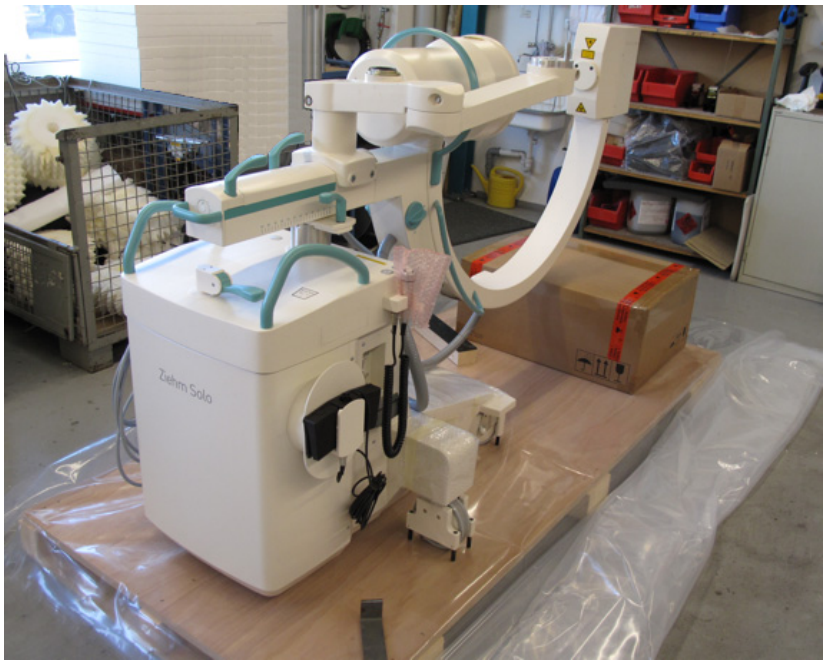


Fig. 13-4 Position of the C-arm on the pallet

- Remove the ramp.

NOTE

To use the ramp supplied with a drop shipment, do the following:

– Remove the fixing clamps attaching the ramp.

– Hook up the fixing clamps into the drill holes on the pallet provided for that purpose (→ *Fig. 13-5*).

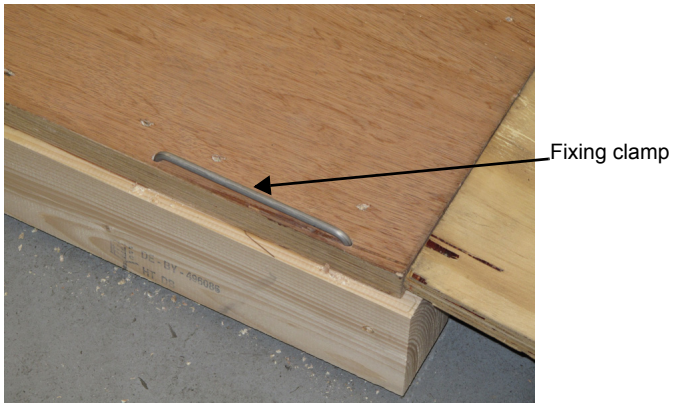


Fig. 13-5 Fixing clamp hooked up in the drill holes on the pallet

- Jam a 40 mm styrofoam block between the image intensifier and the horizontal carriage.

Fig. 13-6 Styrofoam block between image intensifier and horizontal carriage

- Place the square timber below the C-arm stand as illustrated in *Fig. 13-7*. Lift the C-arm stand slightly for that purpose.

- Place one mounting lever each on the left and right side below the C-arm stand as illustrated in *Fig. 13-7* and secure them on the pallet.

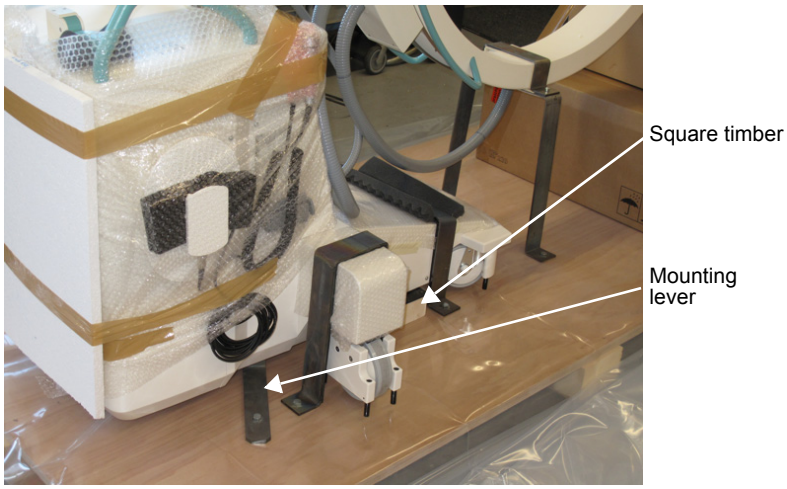


Fig. 13-7 C-arm stand with underlaid square timber and secured mounting lever.

- Place retaining bracket 1 over the C-arm stand foot as illustrated in *Fig. 13-8*.

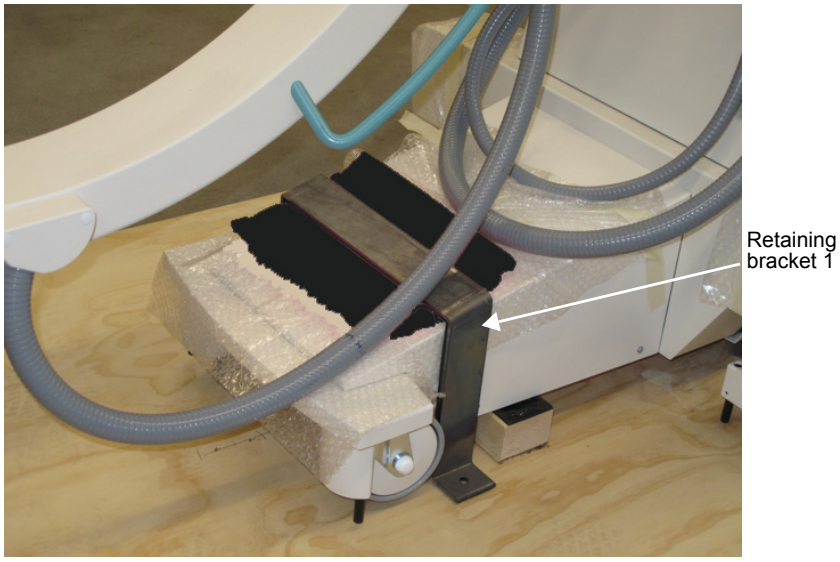


Fig. 13-8 Retaining bracket 1 over C-arm stand foot

- Place retaining brackets 2 over the laterally protruding feet of the C-arm stand.
- Connect the C-arm stand to the power supply.
- Switch on the C-arm stand.

CAUTION

When you press the hand or foot switch, the system starts to emit radiation!

- Press the **Move Up/Down** buttons to adjust the vertical position of the C-arm so that retaining bracket 4 can be placed below the C-arm.
- Place retaining bracket 3 over the C-arm so that its feet rest on retaining bracket 4.
- Attach retaining bracket 3 to retaining bracket 4 by means of the corresponding fillister head screws, as illustrated in *Fig. 13-9*.

- Press the **Move Up/Down** buttons to adjust the vertical position of the C-arm so that retaining bracket 4 rests on the pallet.

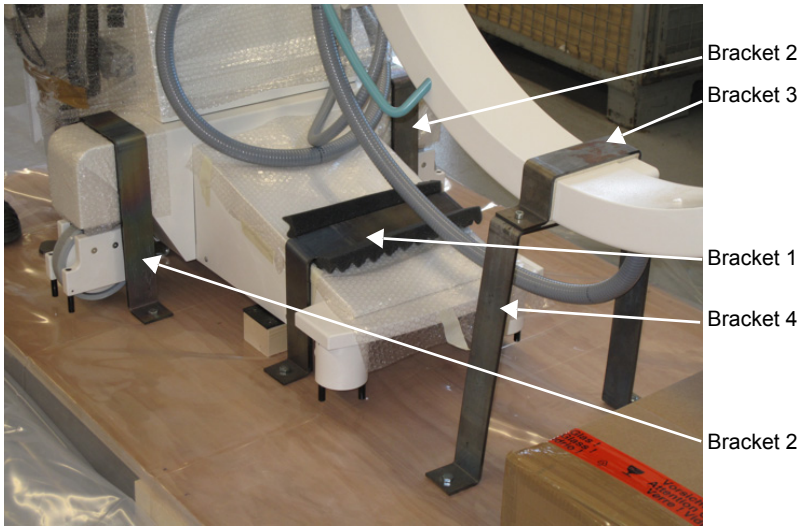


Fig. 13-9 Retaining brackets 1–4

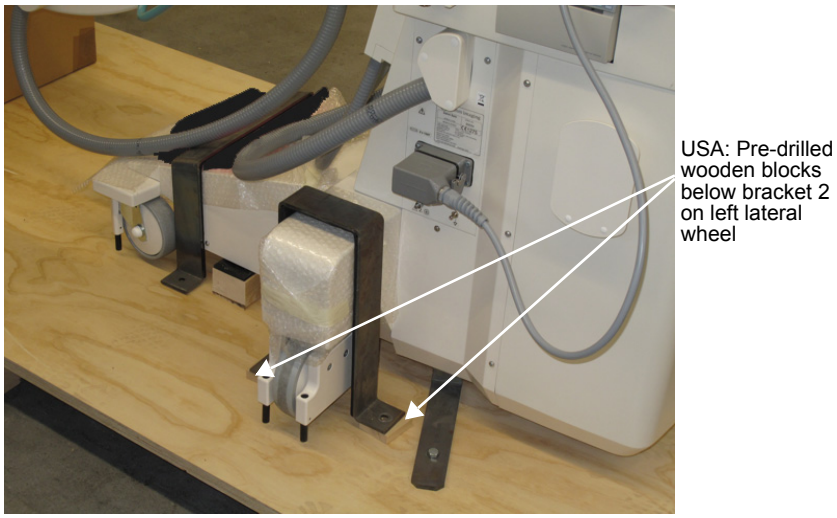


Fig. 13-10 Retaining bracket 2 over left lateral wheel for USA

- Switch off the C-arm stand.
- Disconnect the C-arm stand from the power supply
- Screw down all retaining brackets using the corresponding screws.

  USA:

  Place the small wooden blocks with pre-drilled holes below retaining bracket 2 running across the left lateral wheel (→ *Fig. 13-10*).

  Drill 8 holes for the round head square neck bolts.

  Attach all retaining brackets from below to the pallet using the corresponding round head square neck bolts.

- Clean the C-arm stand with Bioclean (n/a for USA).
- Wrap the C-arm stand in bubble wrap and pad it with foam rubber and styrofoam material.

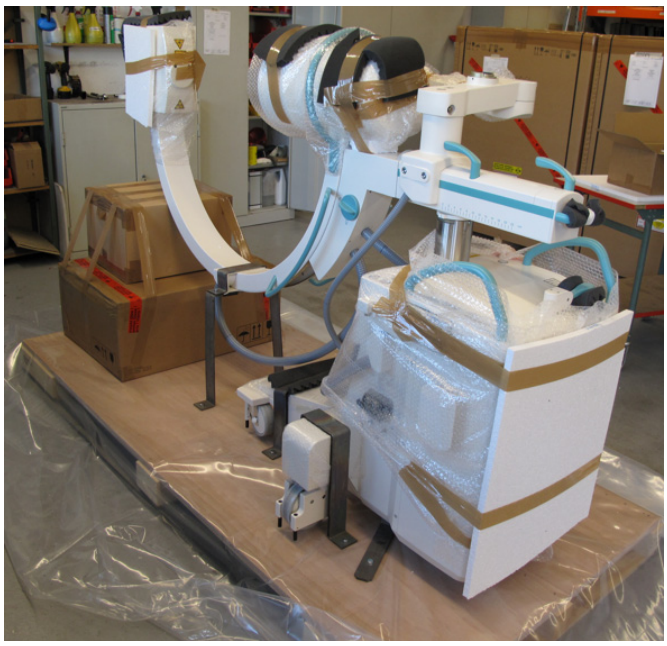


Fig. 13-11 Wrapped C-arm stand

13.4 Packing the monitor head

To pack the monitor head, do the following:

- Clean the screens with Foam-Cleaner.
- Wrap the monitor head in bubble wrap (*Fig. 13-12*).

Fig. 13-12 Monitor head, packed in bubble wrap

- Attach the monitor head cardboard box to the pallet using two edge protection strips (→ *Fig. 13-13*).
  Fasten the edge protection by means of two fastening screws.

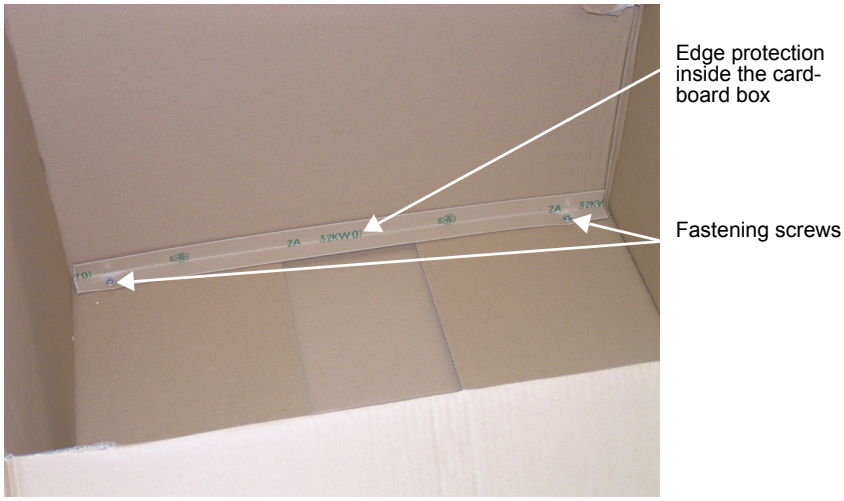


Fig. 13-13 Edge protection for the cardboard box

- Place styrofoam material with a thickness of 5 cm inside the card-board box.
- Place the monitor head inside the cardboard box.
- Pad the cardboard box with foam rubber.

- Close the cardboard box and tape shut it with shipping tape. (→ *Fig. 13-14*).

Fig. 13-14 Position of the monitor head on the pallet

13.5 Packing the Solo Center

To pack the Solo Center, do the following:

- Clean the screen with Foam-Cleaner.
- Assemble the cardboard box for the Solo Center.
- Pad the cardboard box with paper.
- Wrap the Solo Center in bubble wrap.

Fig. 13-15 Solo Center wrapped in bubble wrap

- Place the wrapped Solo Center in the cardboard box.

Fig. 13-16 Wrapped Solo Center in cardboard box

- Pad the empty space in the cardboard box above the Solo Center with paper.
- Close the cardboard box and tape shut it with shipping tape.

- Position the Solo Center cardboard box on top of the monitor head cardboard box and attach it to the monitor head cardboard box with shipping tape.

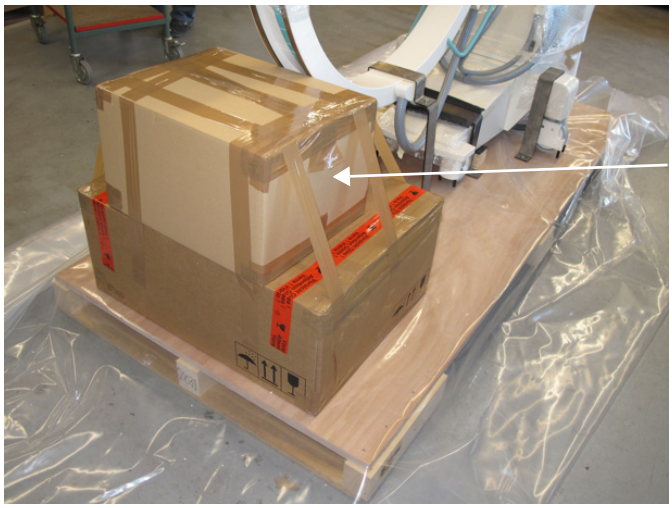


Fig. 13-17 Position of the box with Solo Center on the pallet

13.6 How to pack the accessories

- Assemble the cardboard box for the accessories.
- **USA**:
  Use the packing check list to verify that all parts are available.
- Place all accessories in the cardboard box.
  USA:
  Put a copy of the signed packing check list in the cardboard box and file the original in the folder provided for that purpose.
  Also enclose the test certificates of the acceptance test and the data disk with the setting values of the system.
- Pad the cardboard box.
- Close the cardboard box.
- After mounting the C-arm stand on the pallet and packing monitor head and Solo Center, place the accessories box below retaining bracket 4 on the pallet as illustrated in → *Fig. 13-18*.

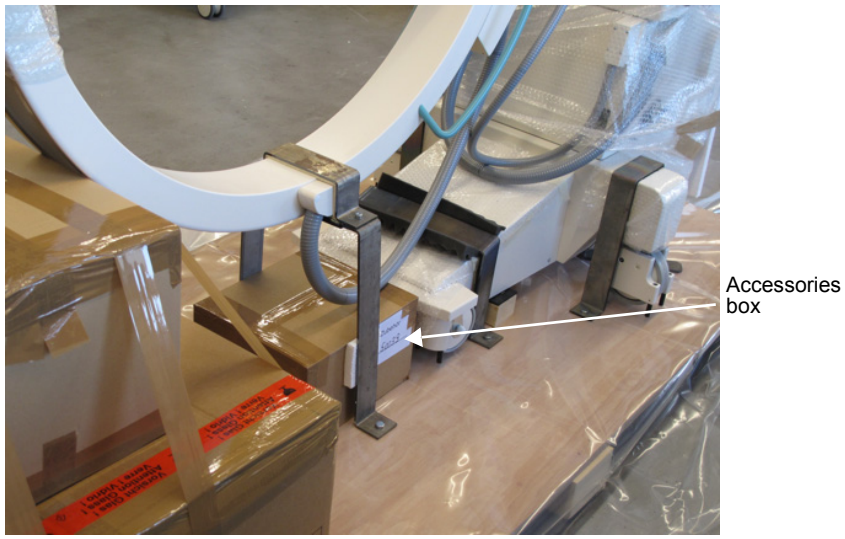


Fig. 13-18 Position of the accessories box on the pallet

13.7 Packing the ramp

Prerequisites

Before packing the ramp, do the following:

- Fold the wrap foil on the pallet around the system components and heat-seal them but leave a small opening.
- Remove the air from the wrap foil through the opening using vacuum suction.
- Heat-seal the small opening.
- Tape the wrap foil with shipping tape.

To mount the ramp on the pallet, do the following:

- Position the ramp on the pallet as illustrated in *Fig. 13-19*.

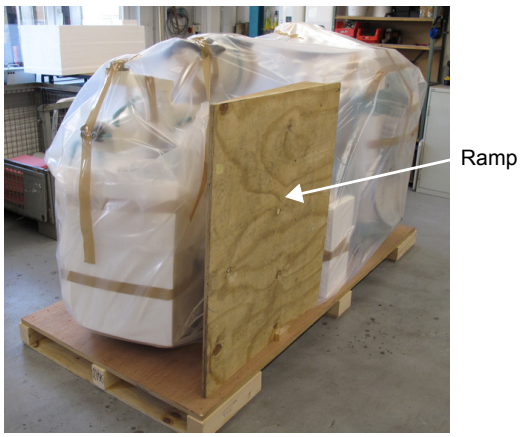


Fig. 13-19 Position of the ramp on the pallet

- Position board 1 on the side of the ramp and attach it using two screws (5 × 60 mm) (→ *Fig. 13-20*).
- Put the big cardboard box over the pallet.
- Attach the cardboard box to the pallet using clout nails.

- Position board 2 between cardboard box and board 1 already attached to the ramp.

Fig. 13-20 Packing of the ramp

- Attach board 2 to the outside of the cardboard box using three screws (5 × 40 mm) (→ *Fig. 13-21*).

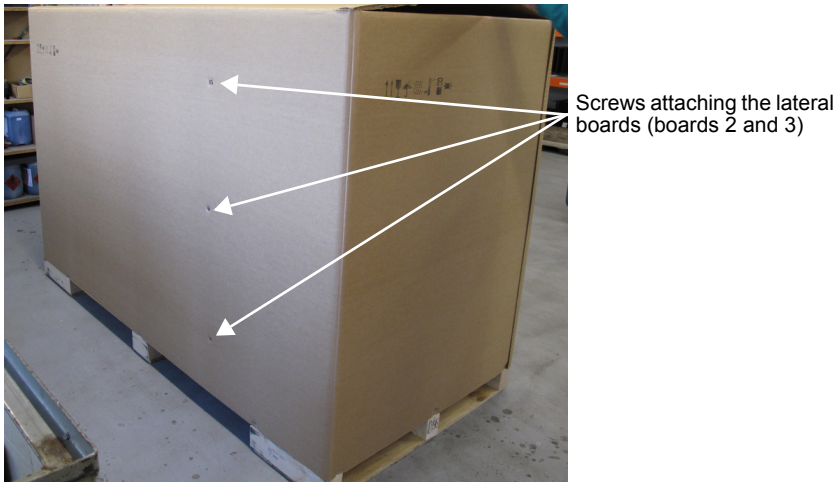


Fig. 13-21 Attachment of the lateral boards

- Position 3 on the opposite inside of the cardboard box and attach board 3 using three screws (5 × 40 mm) from the outside of the cardboard box.

- Attach board 4 to the boards 2 and 3 using two screws (4 × 40 mm).

- Now continue with the packing procedure of the full pallet not yet performed(→ *Ch. 13.8, p. 13-19*).

13.8 Packing the full pallet

To complete packing of the full pallet, do the following:

- Fold the wrap foil on the pallet around the system components and heat-seal them but leave a small opening.
- Remove the air from the wrap foil through the opening using vacuum suction.
- Heat-seal the small opening.

Fig. 13-22 Removing the air with suction

- Tape the wrap foil with shipping tape.

Fig. 13-23 Taped wrap foil

- **USA**:
  Attach the small wooden blocks with nails on both sides of the pallet as illustrated in *Fig. 13-24*.

Fig. 13-24 Small wooden blocks on the pallet (USA)

- Put the big cardboard box over the pallet.
- Attach the cardboard box to the pallet using clout nails.
- **USA:**
  Jam a board upright between the small wood block and the inside of the cardboard box on both sides, and stabilize the boards by means of a cross lath (using nails or screws).

Fig. 13-25 Cross lath for stabilizing the boards

- Close the cardboard box and tape shut it with shipping tape.

Fig. 13-26 Closed cardboard box

- Affix one of the shock watch devices on the short side of the cardboard box (→ *Fig. 13-28*), and a second one on the long side of the cardboard box.

  USA:

  Affix the second shock watch device on the inside of the cardboard box.

  To do so, cut a rectangular opening into the opposite short side of the cardboard box (→ *Fig. 13-27*).

  Re-close the opening in the cardboard box with shipping tape afterwards.

Fig. 13-27 Shock watch device on the inside (USA)

Fig. 13-28 Position of the labels on the short side

- Affix a “Transportkontrolle – Monitored shipment” label above each shock watch device on the outside of the cardboard box (→ *Fig. 13-28*).

- Affix the address label as well as the label “Vorsicht Glas” [Glass – Handle With Care] on the cardboard box as illustrated in *Fig. 13-28* and *Fig. 13-29*.

Fig. 13-29 Labels on the long side

- Secure the cardboard box together with the pallet with plastic straps as illustrated in *Fig. 13-28* and *Fig. 13-29*.

Appendix

A.1 Manufacturer's Declaration concerning Electromagnetic Compatibility according to IEC 60601-1-2 (Class A)

Guidance and Manufacturer's Declaration – electromagnetic emissions

The system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that the system is used in such an environment.

Emissions tests	Compliance	Electromagnetic environment – guidance
RF emissions acc. to CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions acc. to CISPR 11	Class A	The system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions acc. to IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions acc. to IEC 61000-3-3	Not applicable	

Table A-1 Guidance and Manufacturer's Declaration – electromagnetic emissions

Guidance and Manufacturer's Declaration – electromagnetic immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that the system is used in such an environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst acc. to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge acc. to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines acc. to IEC 61000-4-11	< 5% U_T for 0.5 cycle (>95% dip) 40% U_T for 5 cycles (60% dip) 70 % U_T for 25 cycles (30 % dip) < 5% U_T for 5 s (> 95% dip)	< 5% U_T for 0.5 cycle (>95% dip) 40% U_T for 5 cycles (60% dip) 70 % U_T for 25 cycles (30 % dip) < 5% U_T for 5 s (> 95% dip)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or battery.
Power frequency (50/ 60 Hz) magnetic field acc. to IEC 61000-4-8	3 V/m	3 V/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level			

Table A-2 Guidance and Manufacturer's Declaration – electromagnetic immunity

Guidance and Manufacturer's Declaration – electromagnetic immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that the system is used in such an environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF disturbances acc. to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	d = 1.2 × SQRT(P)
Radiated RF disturbances acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2 × SQRT(P) 800 MHz to 80 MHz
			d = 2.3 × SQRT(P) 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level[b] in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Table A-3 Guidance and Manufacturer's Declaration – electromagnetic immunity

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, it should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table A-3 Guidance and Manufacturer's Declaration – electromagnetic immunity

Recommended separation distances between portable and mobile RF communications equipment and the system Ziehm Solo

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2 \times \mathrm{SQRT}(P)$	**80 MHz to 800 MHz** $d = 1.2 \times \mathrm{SQRT}(P)$	**800 MHz to 2.5 GHz** $d = 2.3 \times \mathrm{SQRT}(P)$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed in the above table, the distance can be determined using the equation in the respective column header, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table A-4 Recommended separation distances between portable and mobile RF communications equipment and the system

Index

E

F

G

H

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L

M

N

O

P

R

S

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U

X