



ZIEHM QUANTUM

USER'S MANUAL

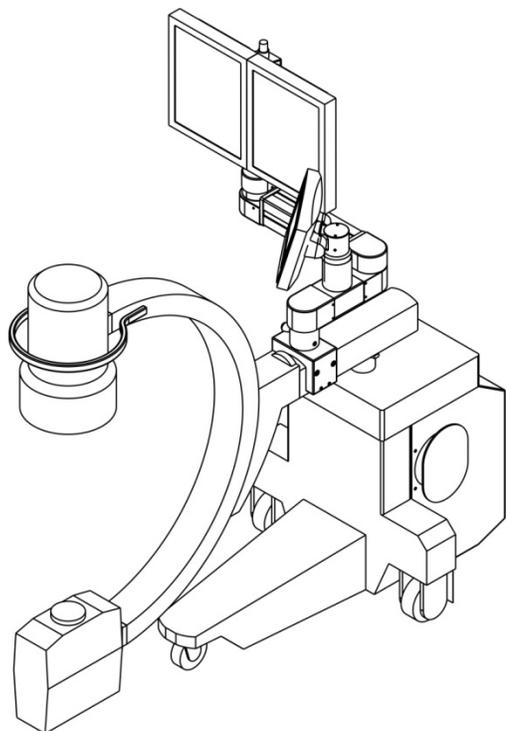


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ABOUT THIS MANUAL

This manual is designed to enable owners and operators of a **ZIEHM QUANTUM** c-arm to operate the systems described herein safely and efficiently. This manual is written for Service Engineers, System Users, Equipment Owners, and Hospital Administrators, and all other individuals responsible for the safe operation of x-ray equipment. All are responsible for carefully reading this manual, paying special attention to Warnings, Cautions, and Notes. Operator must read and be familiar with this material before operating this equipment.

Purpose of this manual

ZIEHM QUANTUM Software Package

- Software and Optional modules
- Options: Image formats, laser alignment device
- External storage DICOM, USB and DVD
- Option: Sequential Imager Capture (CINE)
- Option: Digital Subtraction Angiography (DSA)

Scope of validity of this manual

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

Separate operating instructions

Copyright

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Quality Standards

This manual was produced in compliance with the quality principles ISO 13485:2003, IEC 60601, and UL:60601. The information provided in this manual may be updated at regular intervals and is subject to change without prior notice.

Registered Trademarks

This manual may contain the names of registered trademarks or brands, the use of which by third persons for their purposes may infringe the rights of their respective owners.

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1.0 SAFETY & RESPONSIBILITIES

This manual does not constitute a complete catalog of all safety and responsibility measures necessary for the operation of the respective medical equipment, since special operating conditions may require further measures. However, it does contain an overview of responsibilities and instructions that must be observed in order to ensure the personal safety of operating staff and patients as well as avoiding damage to property when operating the **ZIEHM QUANTUM** Mobile C-Arm. These are highlighted as follows:



WARNING

This is the highest level of risk. Personal injury or damage to property may occur if the operator does not observe the instructions provided here.



CAUTION

This means that a situation exists which may require a decision or action on the part of the user for optimum equipment performance or to avoid a minor hazard.



NOTE

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

1.1 INTENDED USE

The **ZIEHM QUANTUM** Mobile C-arm, is a medical device intended for fluoroscopic imaging in the field of surgical procedures, e.g. trauma, orthopedics, neurology, urology, pain management, gastroenterology, ERCP, simple peripheral vascular and limited interventional procedures such as pacemakers.

Third-party devices and components used in combination with the system must comply with the safety requirements according to IEC 60601-1 and/or IEC60601-1-1 or furnish proof of an equivalent degree of safety before use.

Proper and safe operation of the system requires adequate transportation, storage, assembly and installation as well as appropriate use and maintenance. The limiting values indicated in this user manual must not be exceeded; this applies also when putting the system into service.

1.2 OPERATION (U.S.A.)

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

1.3 AUTHORIZED PERSONNEL

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

1.4 EQUIPMENT OWNER RESPONSIBILITIES

The *Equipment Owner* is responsible for ensuring that the x-ray system complies with the applicable sections of CFR 21, Subchapter J - Radiological Health. Compliance is periodically verified by subjecting the system to various test procedures defined by the Center for Disease and Radiological Health (CDRH).

The *Equipment Owner* is responsible for ensuring that only persons who are trained and qualified are allowed to operate the x-ray system.

When required, System Users must obtain credentials from local, state, and federal authorities before operations of the device.

If the system fails to operate correctly, or fails to respond to system controls as outlined in this manual, notify the local, authorized **Ziehm Imaging, Inc.** dealer representative.

1.5 HOSPITAL ADMINISTRATION

Hospital Administration is responsible for verifying that the equipment continues to operate within the correct calibration of mA, kV, time/mAs, and alignment of the useful beam.

Hospital Administration is responsible for ensuring that the system complies with applicable local, federal, statutory, and regulatory requirements. Hospital administration is responsible for consulting with local, state, and federal agencies regarding requirements and regulations applicable to the system's use.

Ziehm Imaging, Inc. assumes no responsibility or liability for after-sale operating and safety practices and is not responsible for personal injury or damage resulting from the misuse of its systems.

If you have any safety-related questions, contact your authorized **Ziehm Imaging, Inc.** dealer representative.

1.6 MANUFACTURER

The manufacturer is responsible for the safety, reliability and efficiency of the equipment only when:

- Installation, alterations or repairs are carried out by persons authorized by the manufacturer.
- The electrical installation in the room in which the **ZIEHM QUANTUM** is used corresponds to the power requirements listed in Appendix A.
- The equipment is used in accordance with this manual and the operator follows said manual.

1.7 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 room where the system is operated complies with the requirements of VDE 0107, or the corresponding national regulations of the respective

country;

- The system is used in accordance with the User Manual.

The warranty becomes invalid when any repair, modification, or installation work is carried out by unauthorized personnel. No consequential damages will be accepted either. The equipment conforms to Class IIb according to the Council Directive 93/42/EEC. This User Manual has been written and reviewed originally in German and translated.

1.8 USA REGULATORY RESPONSIBILITIES

1.8.1 SERVICE ENGINEERS/TECHNICIAN

Service Engineers/Technicians are responsible for installing, calibrating, and maintaining the C-Arm system. In order to be qualified to perform the procedures described in the Service Manual, Service Engineers must attend formal training provided by **Ziehm Imaging, Inc.** (hereafter referred to as the manufacturer).

1.8.2 SYSTEM USERS

System Users are responsible for reading and following each section of this manual that applies to them. The user should not attempt any procedures in this manual that are described as a service task. USERS shall contact manufacturer to perform service related tasks described in this manual.

1.9 CDRH REPORT

The CDRH Maintenance Manual contains or may refer to test procedures that the Center of Disease and Radiological Health (CDRH) requires to be performed as the system is installed and prior to customer acceptance. A list of the equipment required to conduct these tests is included. Use only this equipment, or approved substitutes. This manual includes reference to forms for recording required tests. Make copies of these forms and safeguard the original. As tests are conducted, record the results onto a blank copy of the form. Keep the original, and send a copy to the manufacturer at the following address: **Ziehm Imaging, Inc.**; 3468 Webster Avenue; Perris, CA 92571. If you have any questions concerning testing, call the manufacturer at: 951-781-2020, and ask for the Service department. Maintain original copies of completed forms for future reference.

1.10 PROBLEMS

If **System Users** have an equipment-related problem, they must immediately stop using the system and notify a Service Engineer. The system must not be operated until repairs have been made and the proper functioning of the system is verified.

1.11 REGULATORY /NOTIFIED BODY

Ziehm Imaging, Inc. USA

1. The Food and Drug Administration (FDA) is our Regulatory Body.

1.12 RECORD KEEPING USA

Service Engineers are responsible for:

1. Completing the records listed below,
2. Filing the original, and for
3. Forwarding copies to the indicated recipient.

Record	When Required	Recipient
Service log	Whenever any service is performed on the system	<ul style="list-style-type: none"> • Original to Service files. • Copy to Manufacturer for DHR
FDA Form 2579, Report Of Assembly Diagnosis X-Ray System	Whenever the system is installed, or when any of the following certified components are replaced or added: <ul style="list-style-type: none"> • New system • X-ray tube housing, high-voltage generator • Beam-limiting assembly • Image receptor • X-ray control unit 	Original to Service files. Copies to: <ul style="list-style-type: none"> • FDA • Manufacturer • State • Hospital Must be filed within 15 days
Equipment Locator Card	When system installation is complete	<ul style="list-style-type: none"> • Original to Service files. • Copy to Manufacturer for DHR

2.0 SYSTEM OVERVIEW SECTION

2.1 FIELDS OF APPLICATION

The **ZIEHM QUANTUM** is a Mobile C-Arm X-Ray System with Image Intensifier which is suitable for all surgical applications, pain management, traumatology, orthopedics, neurology, urology, gastroenterology, ERCP, simple peripheral vascular and simple interventional procedures such as pacemaker.

2.2 FEATURES

2.2.1 MOBILITY

With its compact design and combined steering & braking system, the **ZIEHM QUANTUM** offers the operator unrestricted mobility in positioning at the operating table, even if space is scarce.

The easy adjustability and accurate counterbalancing of the ample C-Arm profile and stand makes it possible to access even the most difficult positions.

2.2.2 ORGAN PROGRAMS

Computer-controlled anatomical programs ensure optimal exposure rate and image quality control as well as high operating comfort. A “LP” program for visualization of larger adipose patients and a ‘Metal’ program for suppressing image flare resulting from the use of metal implants and surgical instruments complete the automatic functions.

2.2.3 RADIATION REDUCTION

The superior penetration capabilities of the **ZIEHM QUANTUM** High-Frequency Generator enable a significant reduction in the patient skin dose.

Radiation-free digital image rotation is provided by the system’s state of the art image processing.

LPD operation allows larger adipose patient penetration without incorporating boost or high mA modes of radiation.

2.2.4 IMAGE QUALITY

18" flat-panel LCD Monitors with anti-reflection coating guarantee clear flicker-free images. The advanced LCD TFT Technology, CCD camera, 16 bit image processing, and 1K x 1K up-scan image system matrix, provides the operator with higher resolution images.

2.2.5 IMAGE ADJUSTMENT

Comprehensive real-time image processing functions, customizable noise and area filtering, electronic contrast and brightness adjustment, zooming, radiation-free horizontal and vertical image reversal, digital image rotation ensure perfect adaptation of the image quality and orientation on the screen to the surgeon’s needs.

Further image processing functions are available for saved images by means of Post-processing.

2.2.6 IMAGE MANAGEMENT

A patient-based image management system providing an image Mosaic (thumbnails) view and menu-controlled user guidance guarantees efficient image data handling.

2.2.7 DOCUMENTATION AND OUTPUT

For documentation purposes, optional USB image port is available, as well as an optional DVD re-writer allowing film less archiving in PC compatible full resolution digital BMP image format. You also have the option to save your images in DICOM format and/or other optional image formats depending on system configurations. Patient-related data, data (e.g. the fluoroscopy parameters) are included in the stored image. In addition, all systems have a video BNC output.

2.2.8 NETWORKABILITY

The optional DICOM 3.0 interface (Quantum FlexNet) enables integration into any network supporting DICOM 3.0, e.g. PACS. Thanks to “**Primary Capture**” support, the original fluoroscopic images can be archived without changes to the image that may have been applied to them later. The following DICOM Classes are available:

- Storage
- Work list
- Print



WARNING

Do not touch the USB or DICOM ports and the patient at the same time. Failure to observe this warning may result in **serious injury to patient or operator**.



WARNING

Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment.) Furthermore, all configurations shall comply with the system standard IEC 60601-1-1.

Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of IEC 60601-1-1. If in doubt, consult the technical services department of your local representative.

2.3 OPTIONS

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

The following options can be integrated into the system upon request:

- The DICOM 3.0 interface **ZIEHM QUANTUM** FlexNet (Primary Capture)

Depending on the system configuration chosen, the following functions, features and DICOM Classes are supported:

- DICOM
- Print Class
- Storage Class including multi-frame capability
- Media Class (images for DSA and Cine sequences)
- Worklist Class
- Laser targeting device on the generator and/or image intensifier
- USB DVD writer
- CINE with 5/10/15 frames per second (15 frames per second only with DSA option)
- DSA with final Max Opacification (MSA) image on reference monitor.
- Additional image storage: 1000/5,000/10,000/20,000 images (20,000 images only with DSA option)
- USB Port using certified USB 2.0 USB Memory storage device
- Image export of AVI image format for motion studies (Cine)
- JEG, BMP and DIOCM 3.0 media image formats. (Available image formats vary depending on system configurations)



WARNING

Do not touch the USB or DICOM ports and the patient at the same time. Failure to observe this warning may result in **serious injury to patient or operator**.



WARNING

The Optional USB port does not support externally powered USB devices.



WARNING

Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1.

Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of IEC 60601-1-1. If in doubt, consult the technical services department of your local representative.

2.4 OPTIONAL ACCESSORIES

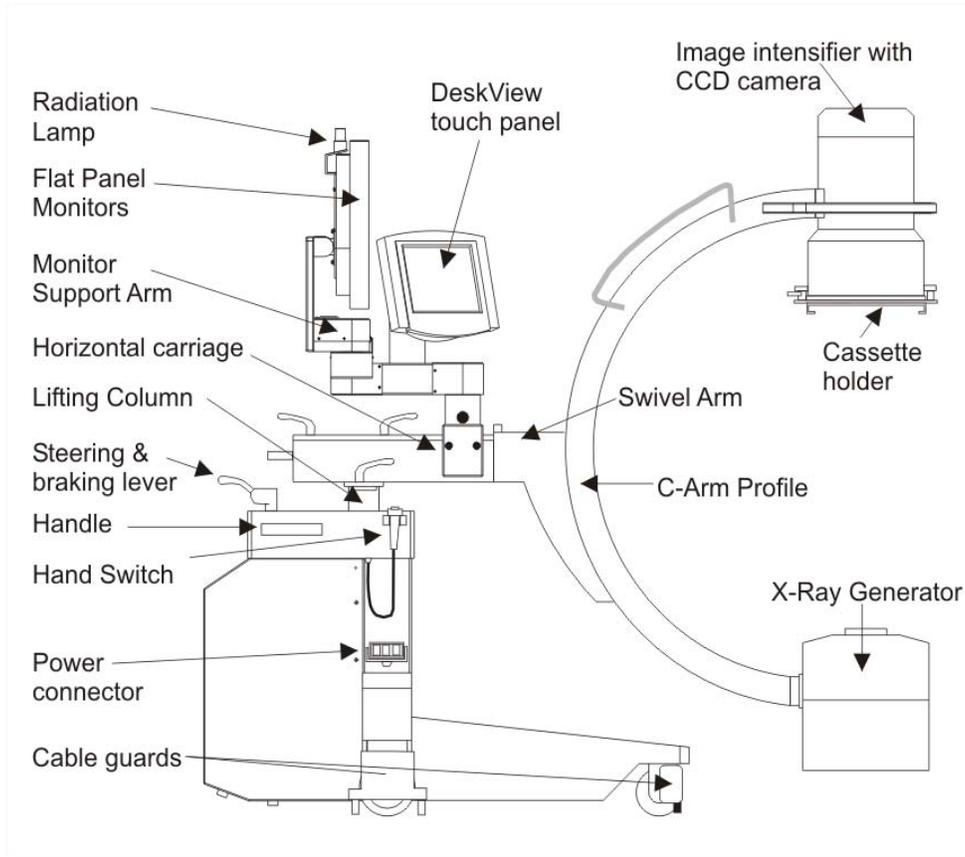
The following accessories are optionally available for the **ZIEHM QUANTUM**:

- Sterile disposable covers
- Radiographic Cassette holder

2.5 PARTS OF THE SYSTEM

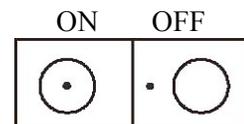
2.5.1 C-ARM STAND

Fig 2.1: ZIEHM QUANTUM Mobile Stand



2.5.2 TWIN FLAT PANEL MONITORS

On the rear side of each flat-screen monitor, there is an ON/OFF switch.



NOTE

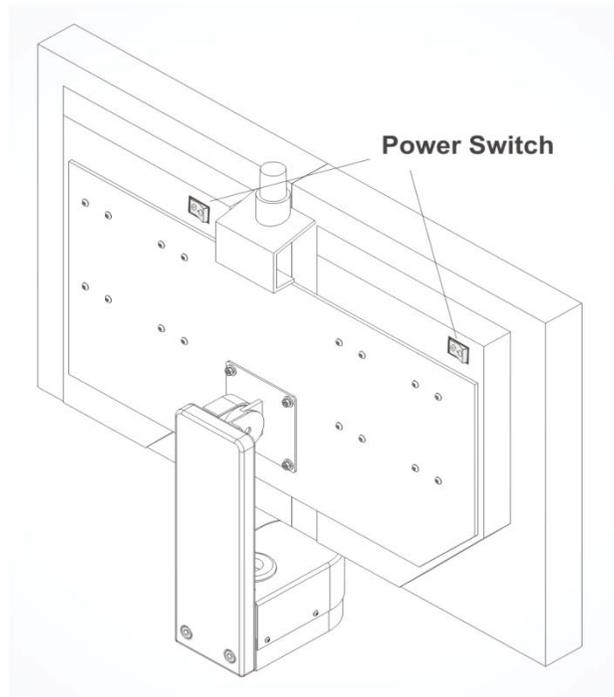
Newer models may not have the Power Switch.



CAUTION

Always set the ON/OFF switches on the flat-screen monitors to **ON** in order to ensure that the monitors are switched on automatically during power-up of the system. If power is turned off after initial turn on of the system, operator must switch off both monitors and then back on again at the same time, to make sure both monitors start at the same time.

Fig 2.2: Power Switch On Flat Panel Monitors



2.5.3 MONITOR POSITION

Movement of the Flat-Screen Monitors

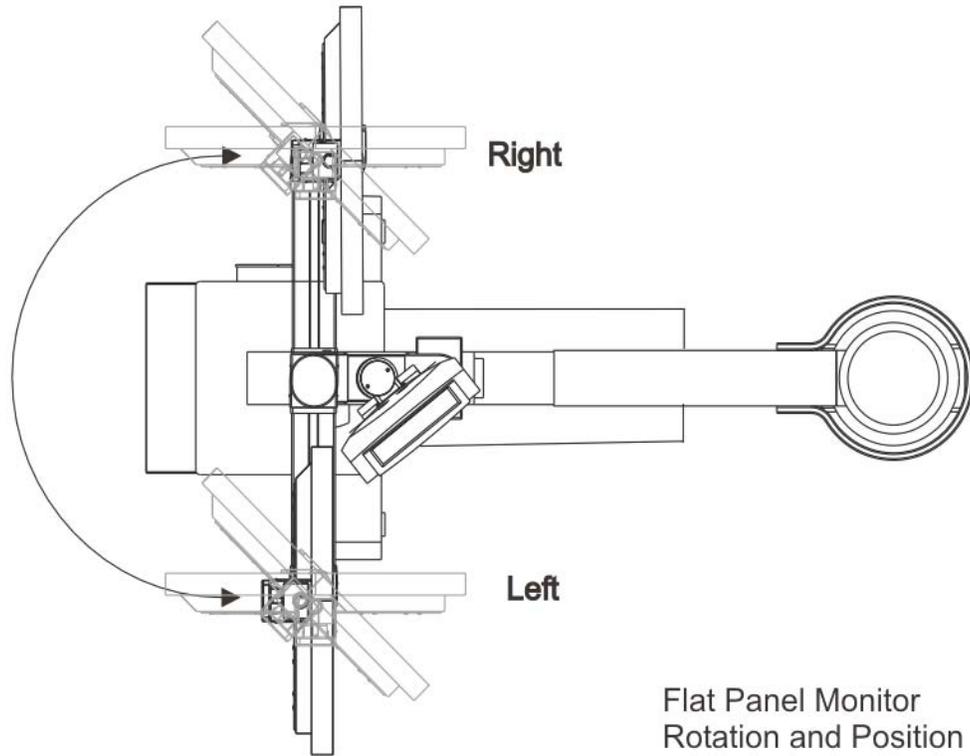
The flat-screen Monitors are mounted on a pivot and can be swiveled by approximately 300 degrees to the right or to the left to position the monitor on the right or left side of the C-Arm Profile depending on the doctor's needed viewing angle.



CAUTION

The standard mounting of the Flat-screen Monitors are on a pivot and can be swiveled approximately 180 degrees; please use caution when moving the monitors as collision with other devices may occur as well as collision with the Desk View Touch Screen.

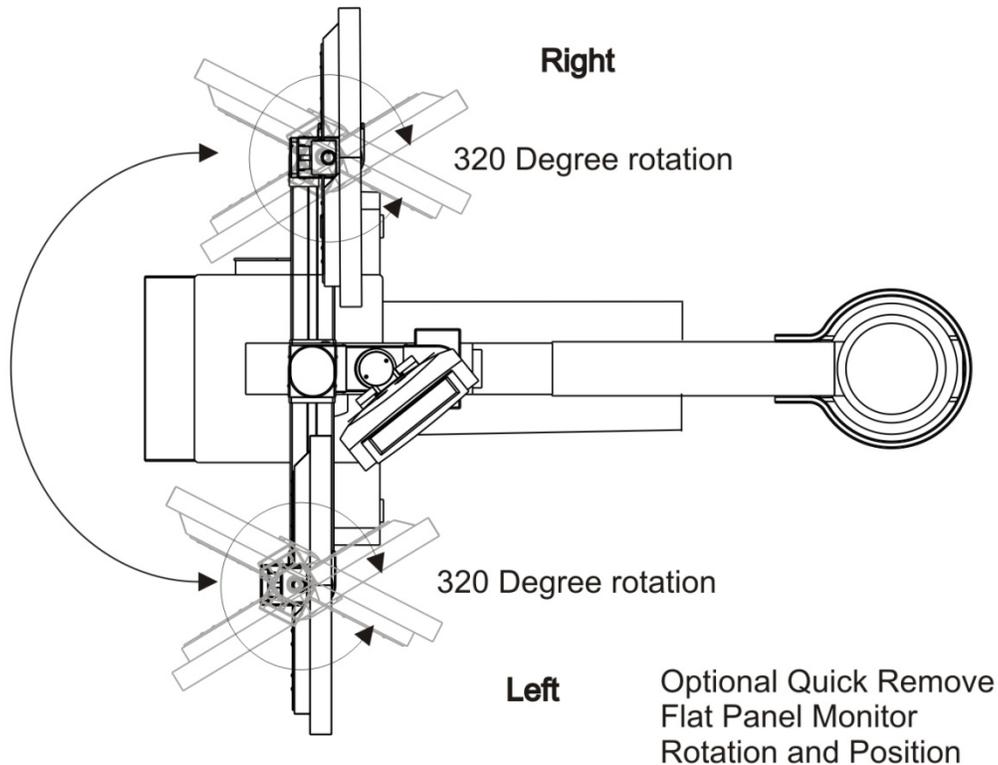
Fig 2-3a Monitor Pivot



CAUTION

The Optional Quick Release mounting of the Flat-screen Monitors are on a pivot and can be swiveled approximately 320 degrees; please use caution when moving the monitors as collision with other devices may occur as well as collision with the Desk View Touch Screen.

Fig 2-3b Optional Quick Release Monitor Pivot



2.5.4 DUAL FLAT PANEL LCD MONITORS

The default operation of the **ZIEHM QUANTUM C-Arm**;

Left monitor is the live monitor and the right monitor is the reference monitor.

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

- **Live monitor:** Live images and transferred images, Cine/DSA loops as full-screen image.
- **Reference monitor:** The reference images are full-screen size, with a Thumbnail mosaic on the lower part of the image display.
- **Desk View Touch Screen:** Displays live image in the center and thumbnails on right side of the touch screen. The center image will always follow the image on the live monitor.



NOTE:

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

2.5.5 CHANGING THE MONITOR SETTINGS

You can change the monitor assignment in the **Configuration** operating mode by pressing the Live Monitor Swap button on the touch screen.

You can customize the contrast and brightness settings of the 18.1" flat-screen monitors.

2.5.6 ZIEHM QUANTUM FP MONITORS ADJUSTMENTS

2.5.6.1. MONITOR SETTINGS

You can change the following monitor settings yourself:

- Brightness
- Contrast
- Backlight brightness
- Menu language for monitor settings in addition, you can restore the factory settings. The factory-set menu language is English.

The following monitor settings cannot be changed by the user:

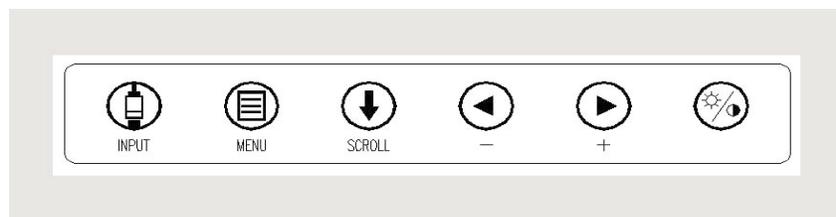
- Video input (Inputs)
- Gamma
- Picture settings (Picture), e.g. vertical position/horizontal position, sharpness, scaling
- Menu setup (Setup), e.g. menu lock (exception: language setting)

If you want to change one or more of these monitor settings, please contact your Service Engineer.

2.5.6.2. INTEGRATED BUTTON PANEL

Each flat-screen Monitor has an integrated button panel with six buttons, which are used for accessing the monitor setting menus.

Figure 2.4: Integrated Button Panel of the Flat Screen Monitor

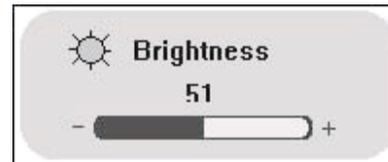
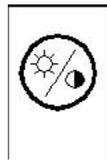


2.5.6.3. SETTING THE BRIGHTNESS, CONTRAST AND BACKLIGHT BRIGHTNESS

To set the brightness of the monitor, do the following:

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

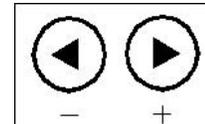
- The **Brightness** menu appears on the screen.



Set the value to “**26**” for Brightness

- Press the **Plus** or **Minus** button to increase or decrease the screen brightness.

The settings become immediately valid on the monitor. After a few seconds, the **Brightness** menu disappears automatically.



To set the contrast of the monitor, do the following:

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

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



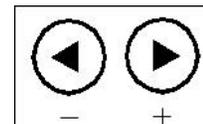
Contrast



Set the value to “**69**” for Contrast

- Press the **Plus** or **Minus** button to increase or decrease the contrast.

The settings become immediately valid on the monitor. After a few seconds, the **Contrast** menu disappears automatically.



To set the backlight brightness of the monitor, do the following:

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

The **Backlight Brightness** menu appears on the screen.



Set the value to “**69**” for Backlight Brightness

- Press the **Plus** or **Minus** button to increase or decrease the backlight brightness. The settings become immediately valid on the monitor. After a few seconds, the **Backlight Brightness** menu disappears automatically.



NOTE

Lowering the backlight level will increase the backlight lifetime.

2.5.6.4. SETTING THE MENU LANGUAGE

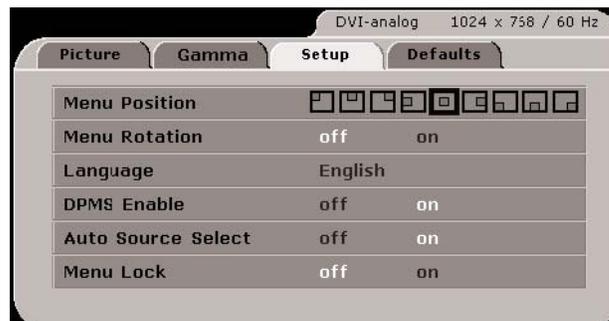
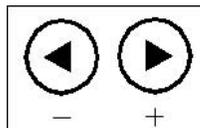
The factory-set menu language is English. You can choose one of the following languages as menu language:

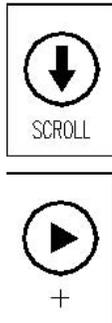
- German
- French
- Italian
- Spanish
- Dutch
- Swedish



To define the menu language, do the following:

- Press the **Menu** button.
The menu selection window appears on the screen.
- Select the **Setup** menu with the help of the **Plus** or **Minus** button.





- Move to the **Language** menu item with the help of the **Scroll** button.
- Press the **Plus** button until the desired language is displayed. All menus and menu items are displayed immediately in the chosen language.
- Press the **Menu** button. The menu selection window disappears



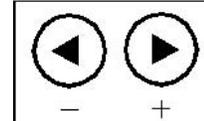
2.5.6.5. RESTORING THE FACTORY SETTINGS

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

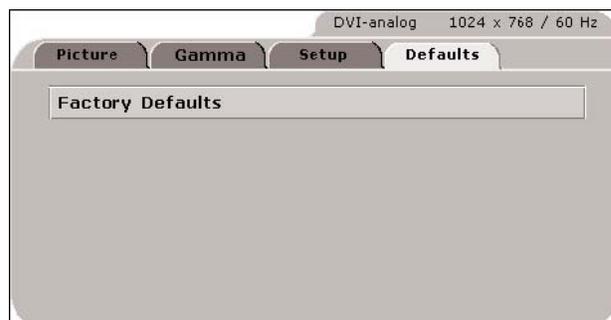
To restore the factory settings, do the following:

- Press the **Menu** button.

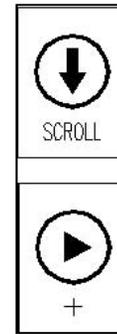
The menu selection window opens.



- Select the **Defaults** menu with the help of the **Plus** or **Minus** button.



- Press the **Scroll** button.
The **Factory Defaults** menu item is selected.
- Press the **Plus** button.
The menu selection window disappears. All settings are reset to the factory-set values



2.5.7 BNC SOCKET VIDEO OUTPUT

A BNC socket that is used for Video Connection (VIDEO PRINTER OUT) is located on the right side of the mobile stand above the power connector.

The VIDEO OUT BNC Video Port supplies a video signal of the live/left monitor image. The image (live/Left monitor image) is available for, use with Video Printers Sony 980 or 960.



WARNING

Any supplementary, third-party devices, and or components used in combination with the **ZIEHM QUANTUM** 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. Combining the **ZIEHM QUANTUM** with equipment which does not comply with IEC 60601-1 and/or IEC 60601-1-1, will lower the safety classification, compromising the safety of the whole system, which may result in **death or serious injury!**

Non-compliance with IEC 60601-1 and or IEC 60601-1-1 may also result with invalidation of warranty!

3.0 SAFETY INSTRUCTIONS

3.1 GENERAL SAFETY INSTRUCTIONS

This chapter must be read by Service Engineers, System Users, and Equipment Owners, Hospital Administrator, and all other individuals responsible for the safe operation of x-ray equipment. Disconnect equipment from the power supply before opening and/or removing safety covers.



WARNING

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

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

3.1.1 OPERATION

Only properly trained personnel are allowed to operate the system.

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

3.1.2 OPERATION (U.S.A.) 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.

3.1.3 WARRANTY VOIDED

Warranty will not be given for equipment that has been repaired by non-authorized persons, or that has been damaged through misuse.



WARNING

Always observe the relevant regulations of the country of the 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!



WARNING

Never pull at the Power Cable of the Mobile Stand in order to move the Mobile Stand to another position; otherwise severe equipment damage may result.

3.2 X-RAY AND ELECTRICAL SAFETY

3.2.1 GENERAL RADIATION SAFETY

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

3.2.2 HAZARDS

3.2.2.1. X-RAY TUBE HOUSING

Tube housings have the following hazards:

1. **High voltage.** Normal operating voltages can be deadly.
2. **Hot oil.** Tube housings contain die electric oil which can reach high temperatures. If the tube housing ruptures due to overload, the oil that leaks out can cause serious burns.
3. **X-ray radiation.** X-ray tubes produce x-radiation that is dangerous and potentially fatal.

3.2.2.2. X-RAY TUBE

The x-ray tube has a stationary anode, with dual focus. Here are some specific qualities of the x-ray tube:

1. Focal spot size, for fluoroscopy 0.6 mm²
2. Radiography 1.5 mm²
3. Inherent filtration equivalent 110kV > 2.5 mm AL

3.2.2.3. RADIATION WARNING

This equipment produces x-rays, which are dangerous to operators and others in the vicinity, if relevant safety procedures are not strictly adhered to. Useful and scattered beams can cause serious or fatal injuries to any persons in the surrounding area if the equipment is used by unskilled operators. Take appropriate precautions to avoid exposure to the radiation beam, and radiation leakage from the generator housing.

Only authorized personnel should operate, or direct the operation of, this equipment. Persons become authorized, in part, by becoming completely familiar with, and adhering to, 21 CFR, Subchapter J - Radiological Health; and National Council on Radiation Protection (NCRP) document 33 - Medical X-ray and Gamma-Ray Protection for Energies up to 10 MEV: Equipment Design and Use.

Persons responsible for planning the installation of x-ray equipment must be completely familiar with, and adhere to, NCRP 49 - Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma-rays of Energies up To 10 MEV.

Take care to keep patient radiation exposure to a minimum and to use the lowest-possible dose rates. Maintain the highest possible focus-skin distance. The stipulated minimum focus-skin distance is 20 cm and is ensured by the design of the generator, with the required special skin cone. Additional objects in the path of the x-ray (e.g. operating table) will lead to an increase in radiation dose.

3.2.2.4. PROTECTION-OF STAFF

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

The radiation controlled area depends upon the size of the Image Intensifier installed and has the following radius:

–23 cm Image Intensifier. **Requires 4 meter control area.**

3.2.2.5. FLAMMABLE GAS

Never use the system in the presence of flammable anesthetics, or other flammable gasses, liquids, or vapors. Gasses and vapors can be ignited by electrical arcs that can occur during the normal operation of power contacts, switches, circuit breakers, and other circuit components.

1. **Before the system is turned on.** If flammable liquids, gasses, or vapors are present before the system is turned on, do not unplug the system and do not turn it on!
2. **After the system is turned on.** If flammable substances are detected after the system has been turned on, DO NOT turn the system off! DO NOT touch any of the controls, switches, or knobs! DO NOT unplug the system! Remove all personnel immediately and then ventilate the room. Remove any liquids that are producing flammable vapors to a safe storage area.

3.3 MECHANICAL AND ELECTRICAL WARNINGS

Operate moveable assemblies and parts with caution. Inspect moveable assemblies and parts at the intervals stated in this manual.

To prevent un-wanted movement of the mechanical c-arm assembly, always maintain control by holding on to and then slowly releasing the mechanical locks.

Transport C-arm system as outlined in this manual. Never transport the C-arm without first locking the mechanical brakes and Monitor support arm into the transport position. Failure to perform the necessary steps to position and then lock the C-arm for transport can result in **death or serious injury** to the operator and or patients.

3.3.1 ELECTRICAL SAFETY

Only allow properly trained and qualified service personnel to access any internal parts. Live electrical terminals are deadly! Be sure that line disconnect switches are open (off) and that precautions are taken before opening access doors, removing enclosures and panels, and attaching accessories. Do not remove access covers from the generator, control unit, or main power assembly until the main and auxiliary power supplies have been disconnected. If you fail to follow these instructions, you may be seriously injured or killed. There is always high voltage in certain components of the system's equipment, even when the system is disconnected from a power source. Touching these components can cause **death or serious injury**.

Any Supplementary, third-party devices, and or components used in combination with the **ZIEHM QUANTUM** 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. Combining the **ZIEHM QUANTUM** with equipment which does not comply with IEC 60601-1 and/or IEC 60601-1-1, will lower the safety classification, compromising the safety of the whole system, which may result in **serious injury or even death!**

Non-compliance with IEC 60601-1 and or IEC 60601-1-1 may also result with invalidation of warranty!

3.3.2 GROUNDING

The equipment may only be connected to power supplies with separate equipment grounding.

3.3.3 HIGH VOLTAGE COMPONENTS

High Voltage system Components (50-60Hz)

- High-voltage transformer and x-ray tube assemblies (110,000 volts)
- Power transformers (220-230 VAC and 120 VAC)

- Image power supply control assemblies (220-230 VAC and 120 VAC)
- Generator inverter control (300 VDC, at 20 KHz)

3.3.4 PERFORMING INTERNAL SERVICE

Only Trained Service Engineers are to perform any internal service, the Service Engineers must be trained in the Emergency Power Removal procedure. Service Engineers must fully understand equipment circuits and voltages.

Safety rules that must be followed:

- Before removing equipment covers, disconnect the power cord from the power source.
- Never assume that a capacitor is discharged. Use a ground shorting device when working on circuits with capacitors, even when the equipment is disconnected from a power source.
- Make sure that equipment connections are made as described in the Installation section of the Installation and service manual.

3.4 GENERAL SAFETY

Do not, under any circumstances, remove, by-pass, jumper, or disable safety interlocks.

Before cleaning the equipment, ALWAYS unplug the AC power cable from the wall. If liquid drips into system equipment, it will cause electrical short circuits that may result in electrical shock or fire hazard. Therefore, NEVER allow beverage or food containers to be placed on system equipment.

Never operate the system in a location where conductive fluids, such as water, or saline solution, may come into contact with any part of the equipment, unless the equipment is covered in protective waterproof draping.



WARNING

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



WARNING

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



WARNING

The relevant safety regulations of the country of installation should be observed.



WARNING

Ambient temperature greater than 60 degrees centigrade may cause irreversible damage to the Image Intensifier tube.



WARNING

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



WARNING

This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.

3.4.1 GETTERING

If the system is stored for more than 6 uninterrupted months, we recommend that you turn it on for at least one hour *before* using it. Doing so will significantly prolong the useful life of the image intensifier.

We also recommend that you keep a logbook of operating hours, gettinger times, and maintenance details.

3.4.2 BONDING

If the equipment is used in combination with other equipment for the examination of the heart or brain, or their proximity, a potential bonding conductor is required for the safety of patients and operators (IEC and VDE regulations).

You must ensure that the x-ray system meets the requirements of IEC 601 part 1 through a program of regular maintenance and periodic inspection. You can find a schedule for periodic inspection in the Technical Manual.

Mobile Stands, and its integrated components (such as monitor, touch screen, USB image storage devices) are not AP-version. They may not be used in the presence of flammable gasses.



WARNING

Any Supplementary, third-party devices, and or components used in combination with the **ZIEHM QUANTUM** 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. Combining the **ZIEHM QUANTUM** with equipment that does not comply with IEC 60601-1 and/or IEC 60601-1-1, will lower the safety classification, compromising the safety of the whole system, which may result in **death or serious injury!**

Non-compliance with IEC 60601-1 and or IEC 60601-1-1 may also result with invalidation of warranty!

3.5 PROTECTION OF THE PATIENT

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



WARNING

Make sure that no additional material (e.g. an operating table not suitable for X-raying) is located in the beam path.

Additional material located in the beam path may result in a dose increase when using a fluoroscopy mode with automatic exposure rate control.



WARNING

Do not touch the USB or DICOM ports and Patient at the same time. Failure to observe this warning may result in serious injury to patient or operator.



WARNING

Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment.) Furthermore, all configurations shall comply with the system standard IEC 60601-1-1.

Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of IEC 60601-1-1. If in doubt, consult the technical services department of your local representative.

3.5.1 ELECTROMAGNETIC COMPATIBILITY

This equipment has been tested to comply with the limits for medical devices IEC 601-2:1994 for CE devices.

These limits are designed to provide reasonable protection against harmful interference in typical medical installation. This equipment generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment causes harmful interference to other devices, which can be determined by turning equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

3.5.2 PROTECTIVE EARTHING (PE)

The system must be connected only to power systems having a separate PE conductor.

3.5.3 EQUIPOTENTIAL EARTHING HEART AND BRAIN EXAMINATIONS

If you use the system for examinations of the heart or brain or the surrounding anatomical regions in combination with other equipment, equal potential Earthing is required for patient and operating staff safety (IEC 60601-1-1:1992/A1:1995).

3.6 LASER RADIATION

3.6.1 LASER TARGETING DEVICE

As an option, the system may be equipped with a laser targeting device at the Image Intensifier and/or generator.

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

The laser targeting device is a Class 2 laser product according to IEC 60825-1:2001 and CLASS II, in accordance with FDA 21 CFR, Subchapter J, Section 1040.10 - you must comply with all operating precautions when operating the laser device.

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



WARNING

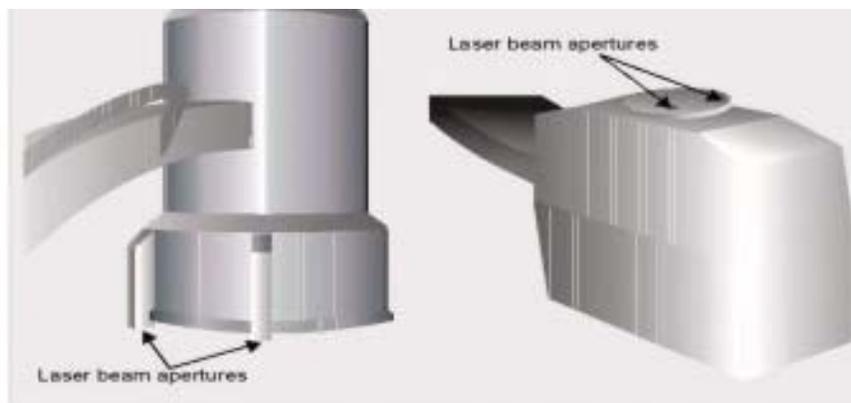
LASER RADIATION – DO NOT LOOK INTO THE BEAM!

Please observe the provisions of IEC 60825-1:2001, Section 3 and 21CFR 1040.10-11. Guidelines for the User of the laser devices.

3.6.2 MAINTENANCE

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

Figure 3.1: Laser Beam Aperture on the Image Intensifier (left) and on the Generator (right)



3.6.3 LASER RADIATION

The laser alignment device incorporates the use of diode laser modules that emit laser radiation. **Do not, under any circumstances**, look directly at the laser beam or any scattered laser radiation -either with naked eyes or with optical instruments.



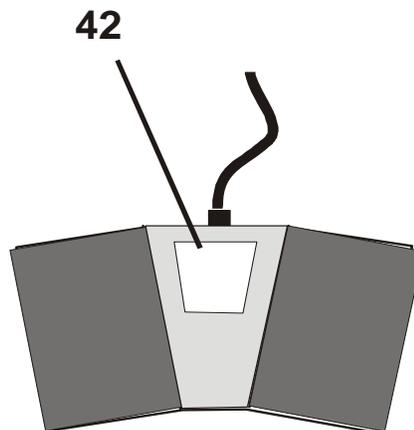
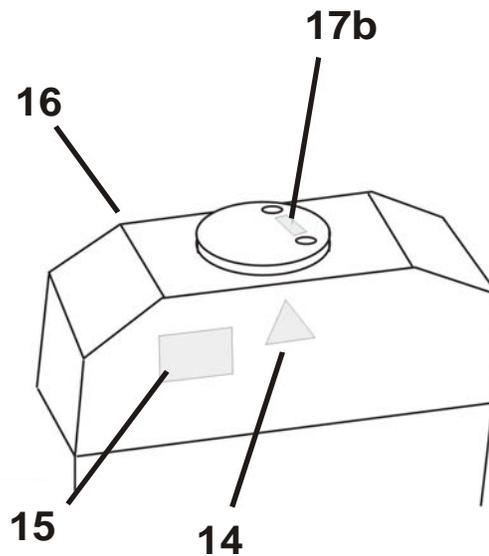
WARNING:

LASER RADIATION DO NOT LOOK INTO THE BEAM! LASER CLASS II, IN ACCORDANCE WITH FDA 21 CFR, Subchapter J, Section 1040.10 - 11 and EN60825 - 1:1994.

You must comply with all operating safety precautions when operating the laser device. The maximum output of continuous laser radiation, measured at the laser beam exit is <1 mW. The

wavelength of the emitted radiation is 635 nm. The laser device is maintenance-free. However, if adjustment or repair work becomes necessary, it must be performed by the manufacturer or other authorized persons.

Figure 3-2: Position of Visible Laser Light Window and Labels



3.7 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 must be observed.

4.0 UNPACKING INSTALLATION

4.1 INSTALLATION PROCEDURE

4.1.1 AUDIENCE

This Installation section of the manual is written to Service Engineers. It does not contain any procedures that can be performed by the System Users. **DO NOT** allow System Users to perform any of the service tasks described in this installation section of this manual, or any tasks that are not described in the User Manual.

In order to be qualified to perform the Installation procedures described in this section of the manual, Service Engineers must attend formal training provided by **Ziehm Imaging, Inc.** (hereafter referred to as the manufacturer).

4.1.2 DETAILED INFORMATION

More Detailed Instructions of how to unpack and assemble the system are supplied with the system Service Manual.

4.1.3 ROOM TEMPERATURE

In case of major differences in the system 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.



WARNING:

Do not operate the system until the equipment has reached a safe operating temperature of +15°C to +35°C with no condensation present. Otherwise severe equipment damage may result.



WARNING:

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

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



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. 4, Unpacking and System Power On* and *Ch. 5, Mechanical Handling*.

4.1.4 SHIPPING CONTAINER UNPACKING

The system is shipped on a single pallet and contains the Mobile Stand (C-Arm), Monitor assembly, and 18" LCD Monitors (un-mounted).

Carefully inspect the equipment for damage. If you find any damage, immediately report it to the shipping carrier in the form of a damage claim.

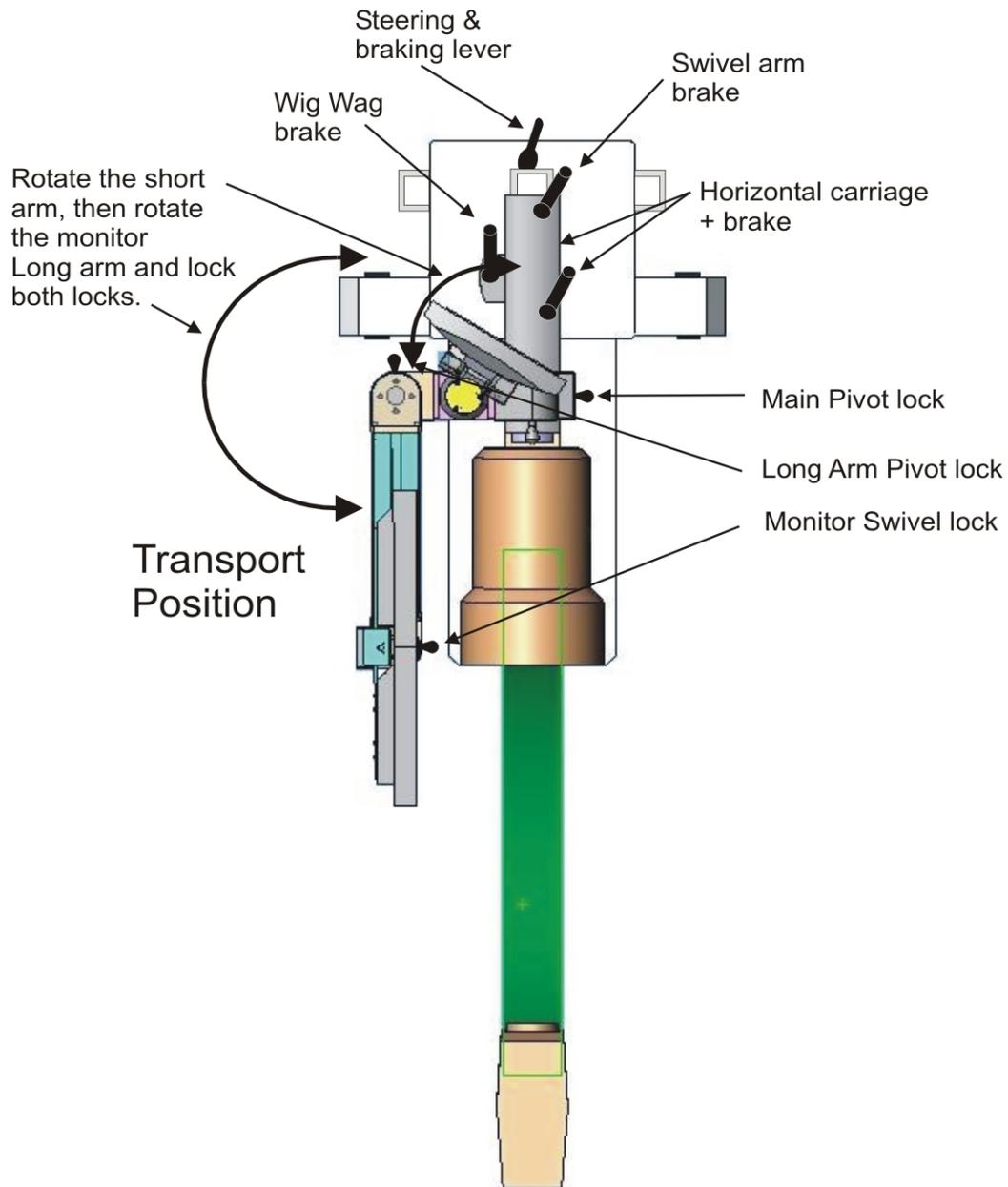
4.1.5 UNPACKING

Unpacking of the x-ray system is to be carried out by authorized, qualified personnel.

1. To avoid damage to the equipment by condensation of moisture resulting from temperature differences, make sure that all parts of the equipment have reached room temperature before turning the equipment on.
2. Remove the outside of the shipping container and inspect for damage.
3. Lower the unloading ramp into position.
4. Remove the metal brackets that hold the C-Arm mobile stand to the pallet. Take care not to scratch the mobile stand.
5. Remove the two straps that hold the monitors and take the monitors off the pallet.
6. Remove all of the brackets from the pallet.
7. Loosen the Wig-Wag knob and straighten the C-Arm. This will keep the C-Arm from tipping over as it is removed from the pallet.
8. Lift the lever located in the center of the control panel (the hand brake) and carefully move the mobile stand off the pallet and onto the floor.

4.2 MOUNTING MONITORS

Fig 4.1 C-Arm in the Transport Position



4.2.1 MOUNTING STANDARD MONITORS

The monitors are the only components that need to be mounted. They are clearly marked Left and Right (as viewed from the front of the C-arm mobile stand). Before switching on the system for the first time, or after each removal of the monitors for shipment, **generally** you must establish the monitor cable connections.

1. Remove the monitors from the shipping pallet.
2. Have a qualified person help you place the monitor assembly onto the Mobile Stand Monitor Support Arm Mounting Bracket.
3. There are two screw holes located on the bottom of the monitor support bracket. Attach the monitor assembly with the two Allen screws.
4. Route the monitor wiring to the monitor housing for right and the left monitor.
5. Connect the DC power cords and video BNC connectors to their respective monitors (left and right).
6. Attach right and left labeled monitor Video BNC Connectors to their respective monitor.
7. Attach the Safety ground wires to the rear panel of the monitors.

4.2.2 MOUNTING QUICK RELEASE MONITORS

The monitors are the only components that need to be mounted.

After you remove the display monitors from the shipping pallet perform the following steps.

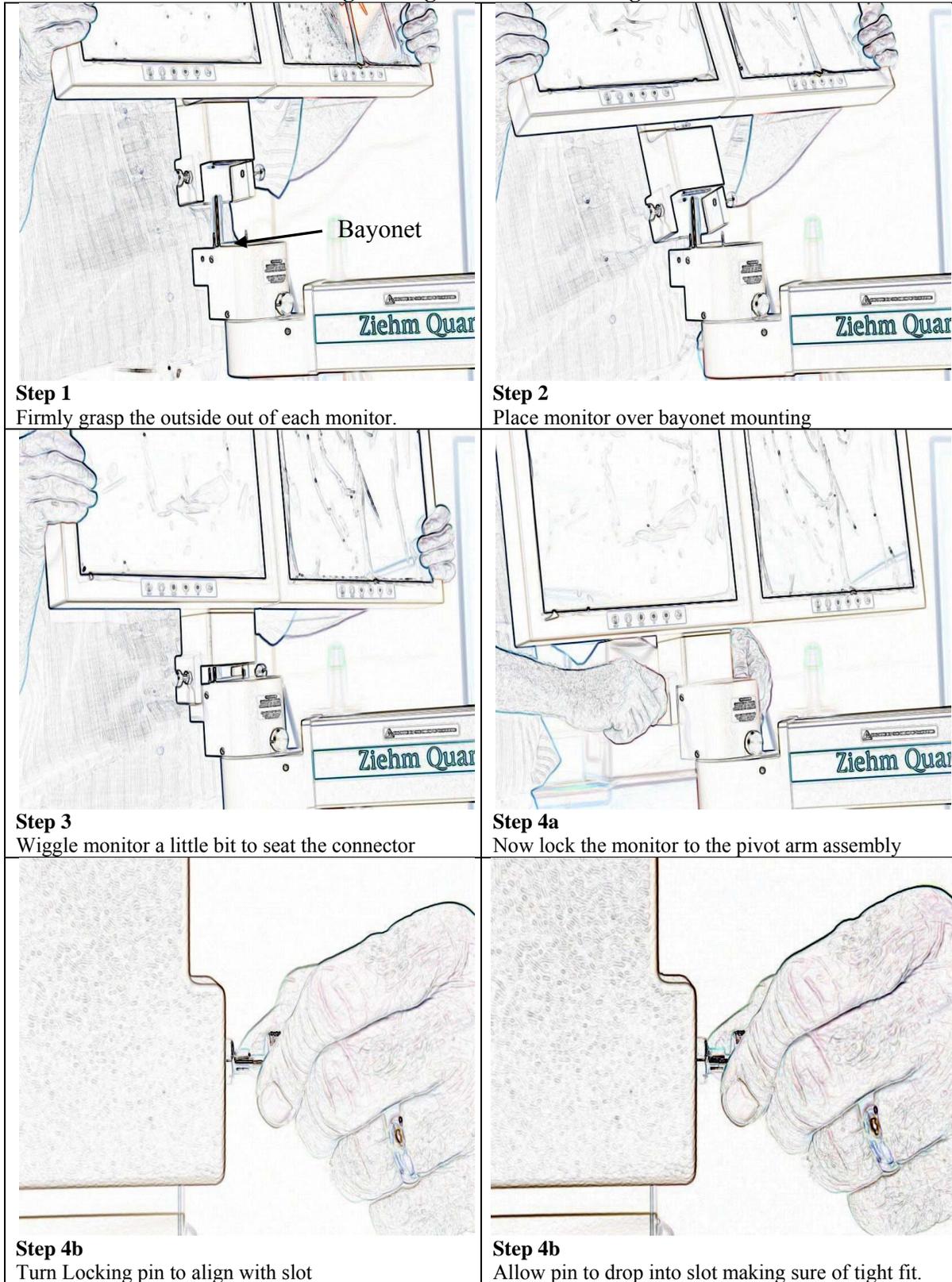
1. Hold the monitors from the rear with one hand on each side to stabilize them. See Fig 4.2.
2. Place the pre-wired connector assembly over the bayonet connector and wiggle the monitor assembly a little bit to encourage the mating of the monitor assembly to the support arm pivot assembly. See Fig 4.2.
3. After monitors are seat, take lock pin and twist to allow the pin to fall into slot and seat to lock monitor assembly in place. See Fig 4.2.
4. Connection to the DC power, video signals, and ground are made automatically by the mating connector of the monitor support arm and the monitor assembly for their respective monitors (left and right).



NOTE

Make sure the quick release monitor locking pins are full seated after installation, and shall be inspected to make they are fully seated before movement of the C-arm for transport of use.

Fig 4.2 Align Monitor Mounting



4.3 POWER CABLE CONNECTIONS



WARNING:

Do not use a 3-prong to 2-prong adapter, unless properly installed by a qualified and licensed electrician. Failure to comply may result in **serious or fatal injuries** to the System and or User and other persons in the surrounding area.

Ensure that the AC line voltage is compatible with the power requirements of the system. Line voltage must be set for a line voltage of 120 VAC + 10% and Line resistance is ≤ 0.6 Ohms.

Verify power input to the Mobile stand Module 1 and adjust the AC wall Line voltage accordingly to correct the wall outlet drop in power. (For example, if the wall outlet idles at 120 VAC and drops to i.e. 108 VAC when the x-ray system produces fluoroscopy at 90 to 110 kV, then the line voltage must be adjusted at the wall for constant 120 VAC.)



WARNING:

Failure to properly supply line voltage to the C-arm mobile stand may result in damage to the system's electronic components. Wired for 120VAC @ 20 amps

4.4 PREPARING THE SYSTEM

Before switching on the system, e.g. during initial installation or after transport, you must connect the system to the wall power outlet.



WARNING:

Never disconnect the Mobile stand when it is already connected to the power supply and switched on.

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

4.4.1 TO PREPARE THE UNIT, DO THE FOLLOWING:

- Unwind the power cable from the cable support on the side of the Mobile Stand.
- Make sure the power cable connector is properly mating with the connector located at the side of the C-arm stand and lock the connector.
- Check the power plug, and the power wall outlet for compatibility. Make sure that a suitable supply voltage is available and that the wall socket outlet is properly earthed and fused.
- Connect the system to the wall outlet power supply.
- Make sure that the inclination of the system does not exceed 5° from the level in operating position or **death or serious injury** may occur.
- Put on suitable protective clothing to limit exposure to indirect and or direct radiation.



WARNING:

Never operate the C-arm system if inclination of the floor exceeds 5°. **Death or serious injury** may result if the **ZIEHM QUANTUM** is operated with a tilt of greater than 5°

4.5 SWITCHING ON THE SYSTEM



WARNING:

Do not operate the system until the equipment has reached a safe operating temperature of +15°C to +35°C with no condensation present. Otherwise severe equipment damage may result.

The C-arm stand has two buttons for switching the system ON or OFF See Fig 4.2 for location of the two switches. Buttons numbered 3 and 4.

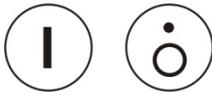
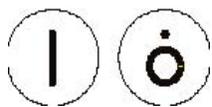
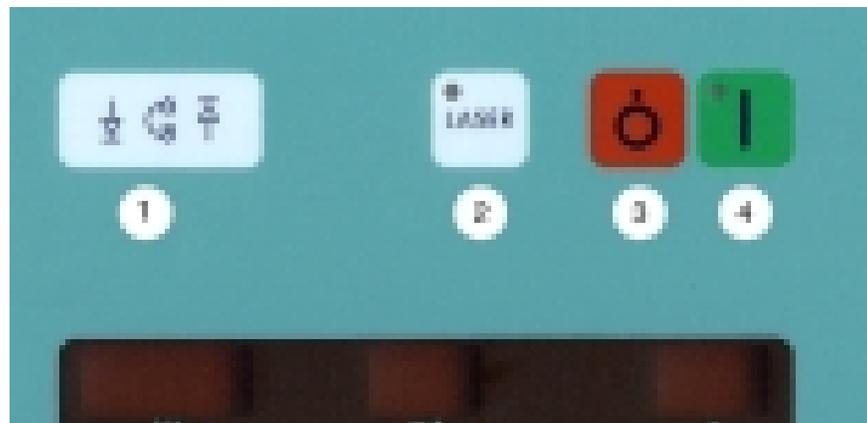


Fig 4.2: C-Arm Mobile stand control keyboard



- 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.
- Put on suitable protective clothing.
- Switch on the system using the Power ON buttons on the mobile stand C-arm. The button switches on or off all the systems components simultaneously.

4.5.1 CUSTOMER-SPECIFIC INITIAL SETTINGS

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

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

4.5.2 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 by entering the **File**, then entering the **Configuration** operating mode.



NOTE

Please contact your service engineer if you wish to make modifications to the initial settings

4.5.3 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 Via the Configuration screen by pressing the Authorization button. After entering the Facility name the hospital data will appear automatically in the corresponding fields whenever you create a new patient file.

4.6 TEST OPERATION

4.6.1 CHECK LEAKAGE CURRENT

We recommend that during the initial installation phase and then at least twice a year after that the Service engineer check for leakage current, using a calibrated leakage meter, in the following manner:

1. Inspect ground leads to ensure that ground connections are solid.
2. Insert the meter (with 100 ohm input impedance) in series with the **ZIEHM QUANTUM** line cord, per the meter manufacturer's instructions.
3. Turn the meter on and verify that leakage current does not exceed 100 μ A, in either normal or reversed line polarity.
4. Connect the Grounding lead of the meter to an exposed metal surface on the **ZIEHM QUANTUM**.
5. Turn the meter on and verify that leakage current does not exceed 100 μ A.

4.6.2 C-ARM OPERATION

X-ray equipment operators must observe all safety rules. Exposure to the x-ray beam must be strictly avoided. Equipment operators, and others in the area, should protect themselves with such devices as lead aprons or shields.

When the x-ray system is first turned on and warming up, the control panel displays zeros, the collimator shutters open to maximum, and the monitor rotation is set to zero (normal position). The following default operating mode will be selected:

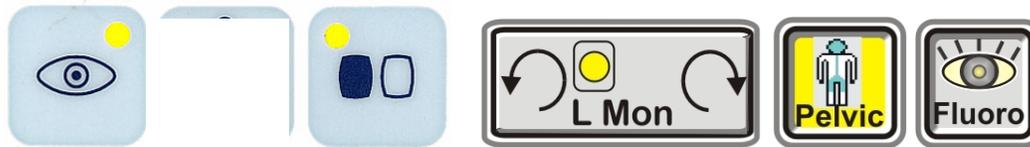
4.6.3 FLUOROSCOPY IS SELECTED;

1. **Pelvic** organ program is selected with fluoroscopic mode;
2. **Full** automatic dose rate control;
3. **Live Image on the Left Monitor**, with Last Image Hold;
4. **MAG** image intensifier normal (no magnification);

5. **75 kV** tube voltage is set;
6. Radiographic time is set to One second.

The control panel keys on the Mobile stand, shown in Figure 4.2, will light up.

Keys Activated in Default Mode.



Mobile stand keyboard

DeskView touch panel control

After 40 to 60 seconds of filament preheating (approximately), you may begin fluoroscopy by pressing either the hand switch or foot switch. The kV/mA will be automatically adjusted and the technique will be displayed on the C-Arm control panel display.

4.6.4 PERFORM THE FOLLOWING OPERATIONAL TESTS & VERIFY THAT THE FOLLOWING RESULTS OCCUR:

1. During fluoroscopy, the live image appears on the left monitor.
2. When exposure occurs (either during fluoroscopy or radiography) the amber light on top of the left monitor lights up, and the radiation indicator on the C-Arm control panel lights up.
3. Open and close the slot and iris collimators. (Perform Collimation test with Fluoroscopy on)
4. After fluoroscopy is completed, the last image is held.
5. Rotate the slot collimator during radiation to make sure it is operational.
6. Reverse the image.
7. Rotate the monitor image using the Image rotation buttons on the touch screen control of the DESK VIEW.
8. Select manual kV mode. Press hand switch to start radiation, while radiation is on press the kV up key, the kV value must change.



WARNING:

To prevent the camera from being over-driven by high light-levels, do not perform fluoroscopy in the kV manual mode at a kV levels higher than needed.

4.7 ACCESSORIES

Depending on the integrated options, the following accessories are included in the scope of delivery:

Table 4-1: Accessories		
Item	Accessory	Amount
All systems	User Manual	1
	Technical Manual	1
	CE-Specifications and Certificates (Not applicable for the U.S.A.)	0
	Power cable (7.5 m)	1
	Equipotential bonding conductor (6 m)	1
Options	USB DVD writer (Option)	
	DVD/CD DVD (4.7 GB) actual memory size may vary CD (.74GB) actual memory size may vary	1
	DICOM Option	
	RJ45 interface with Cat.5 patch cable (10 m)	0
	USB 2.0 Memory Stick Port (Option)	
USB 2.0 Image storage port Capacity changes with memory stick model and manufacturer. (32MB to 1 GB) Note: only approved memory sticks are guaranteed to work with the ZIEHM QUANTUM . Check with Manufacturer for list of approved memory stick devices.	1	

5.0 MECHANICAL HANDLING

5.1 TRANSPORT POSITION

For safety reasons, you must return the C-Arm Monitor Support Arm assembly to its respective transport position before transporting the **ZIEHM QUANTUM** C-arm system.

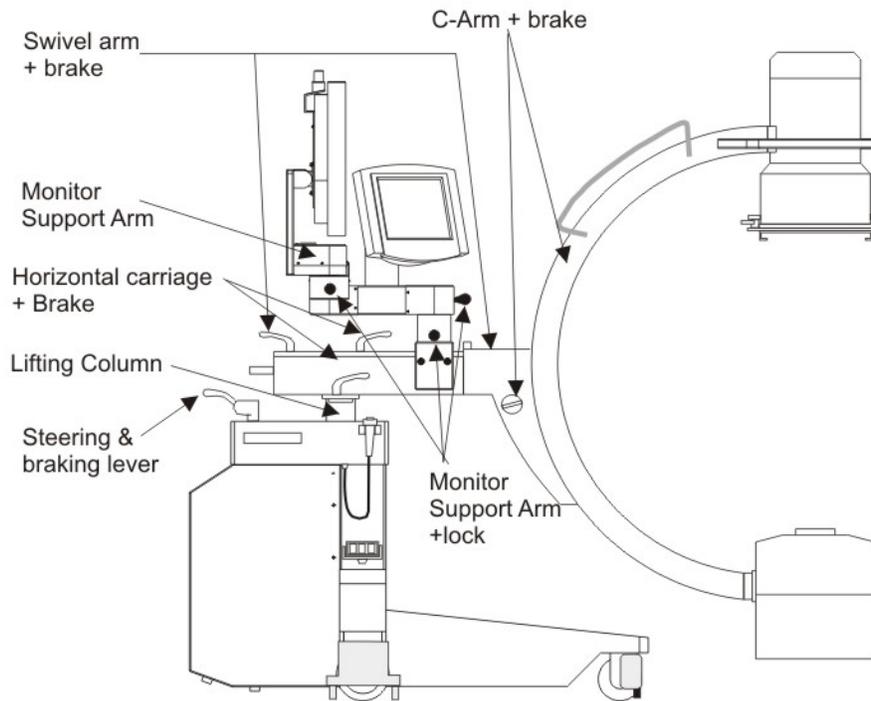
5.1.1 TRANSPORT POSITION OF THE C-ARM MOBILE STAND

To return the C-arm stand to its transport position, do the following:

How to proceed

- Wind the footswitch cable onto the foot switch support and hang up the foot switch in the cradle.
- Rotate the C-arm until the image intensifier is positioned directly above the generator and secure it with the relevant brake. See *Fig. 5.1 and Fig 5.2*.
- Put the swivel arm of the C-arm into an upright position and secure it with the relevant brake. See *Fig. 5.1 and Fig 5.2*.
- Swivel the horizontal carriage into a central position and secure it with the relevant brake. See *Fig. 5.1 and Fig 5.2*.
- Retract the horizontal carriage completely and secure it with the relevant brake See *Fig. 5.1 and Fig 5.2*.
- Lower the lifting column completely using the **LIFT** buttons.
- Switch off the system and disconnect the power cable from the power wall outlet.
- Unlock the main Pivot arm lock and swivel the monitor arm assembly until it is 90 degrees and relock the arm. See *Fig 5.2*.
- Unlock the monitor swivel lock and rotate the monitors until they are in line with the long arm and reseat the lock.
- Unlock the long arm pivot lock and swivel the arm until it is along side of the C-Arm profile and relock the arm. See *Fig 5.2*
- Release the parking brake by lifting the steering & braking lever. See *Fig 5.1*.
- You cannot move the C-arm stand over very soft or uneven floors as the cable guards will drag the floor. e.g., rugs, doorways, uneven elevator doors.

Fig 5.1 Mobile Stand transport positioning



WARNING:

The monitors must be placed in the transport position with all locks engaged before transporting the **ZIEHM QUANTUM** C-arm mobile stand.

Failure to lock all the **ZIEHM QUANTUM** c-arm locks and monitor support arm pivot locks as show in Fig 5.2 may result in serious injury to patient or operator.



CAUTION

System should never be operated on floors with an inclination greater than 5° from level. This applies to the C-arm stand with the monitors in the locked operational position. The system must be in the proper operating position before use.

Exercise extreme caution when moving the mobile C-arm stand that the cable guards do not drag and the wheels do not catch or tilt causing damage to the equipment.



CAUTION

Do not move the system over floors with an inclination of more than 10° from level during transport. This applies to the **ZIEHM QUANTUM** C-arm mobile stand.

Exercise extreme caution when moving the **ZIEHM QUANTUM** mobile C-arm stand over rough surfaces such as tile flooring, concrete pavement, or carpet. Take care that the cable guards do not drag and the wheels do not catch or tilt causing damage to the equipment.

Exercise extreme caution when moving the **ZIEHM QUANTUM** mobile C-arm stand over rough surfaces such as asphalt paving as this will cause damage to the wheels.

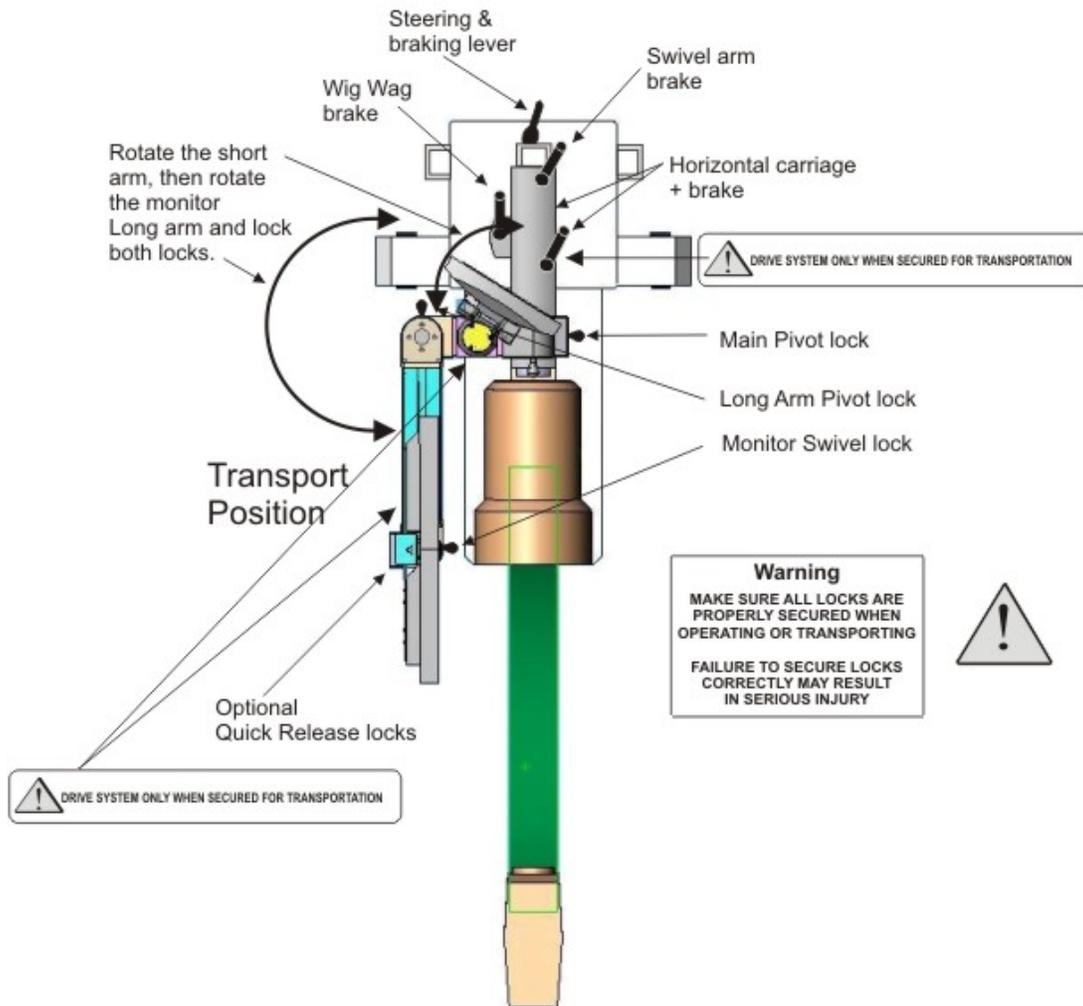


WARNING:

Operate moveable assemblies and parts with caution.

Exercise extreme caution when releasing mechanical locks or brakes. To prevent unwanted movement of the mechanical c-arm assembly, always maintain control by holding on to the mechanical component and then slowly releasing the mechanical lock(s) before moving any of the mechanical components of the **ZIEHM QUANTUM** mobile C-arm. Failure to observe this warning may result in serious injury to patient or operator.

Fig. 5.2 Transport position for Monitors



WARNING LABELS

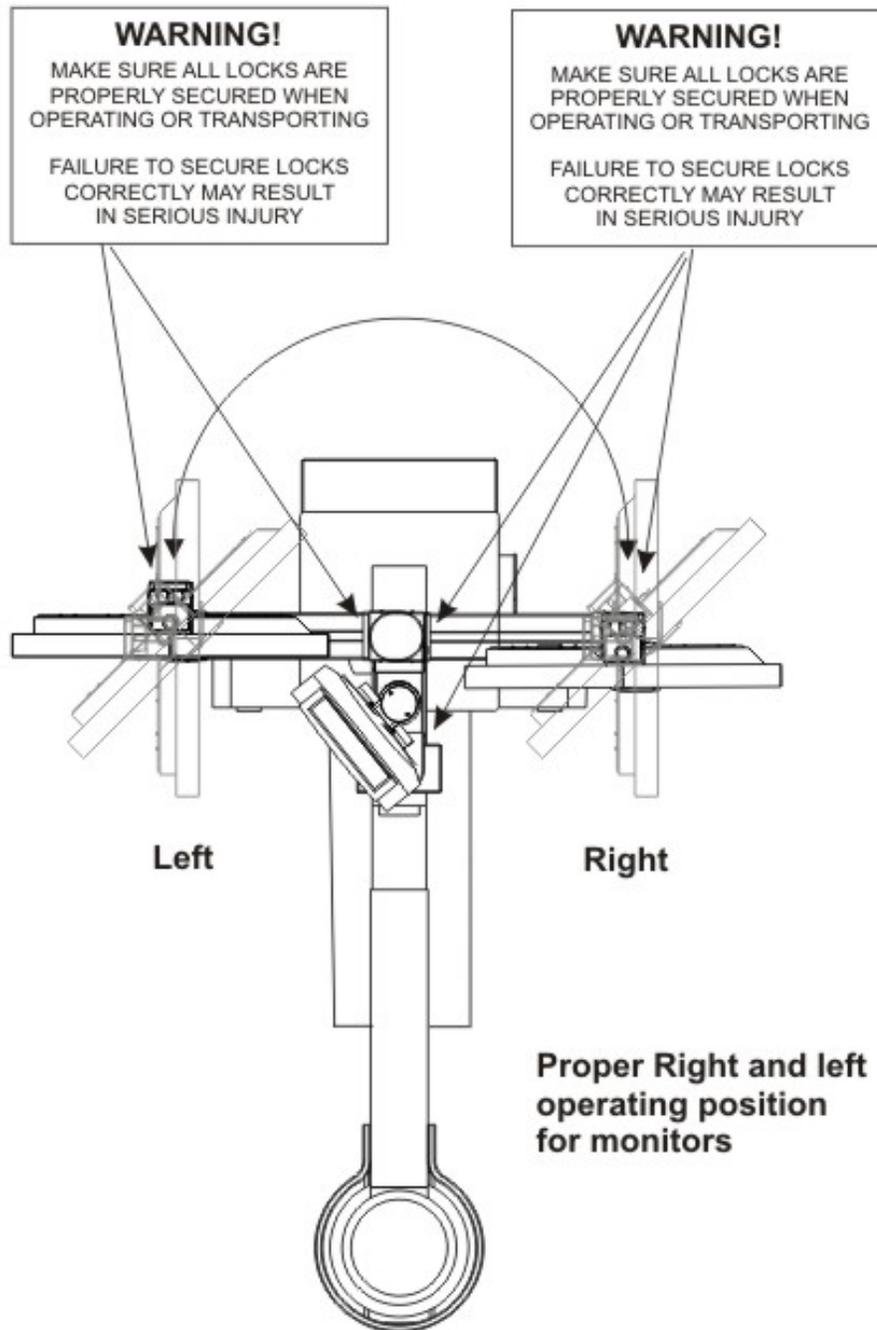
Labels are mounted and visible on the monitor arm and pivot lock areas.



NOTE

Make sure all monitor pivot locks are correctly set for operation of the mobile stand. Placement of the monitors on the right or left side of the mobile stand will require that the locks be set correctly for right or left operation.

5.1.2 TRANSPORT POSITION FOR ZIEHM QUANTUM



5.2 BRAKING AND STEERING THE C-ARM STAND

5.2.1 STEERING & BRAKING

The C-arm stand has a combined steering & braking lever. It is located **lever** at the rear of the C-arm stand. See fig 5.1 & 5.2.

5.2.1.1. PARKING BRAKE

The C-arm stand parking brake operates as follows: –Steering & braking lever lowered: Rear wheels are locked –Steering & braking lever raised: Rear wheels can move freely.

5.2.1.2. STEERING

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

- Lift the steering & braking lever and turn it until reaching the desired position. The lever can be turned freely; however, detents are placed at 90° increments. The rear wheels will always stay parallel to one another aligned exactly in parallel with the steering & braking lever.
 - To maneuver the C-arm stand freely, ensure that the steering & braking lever has engaged in its central position, pointing directly backwards from the unit See Fig 5.3.
 - To move the C-arm stand in an exactly-defined direction, rotate the steering & braking lever until it points towards the desired direction Fig. 5.3 Push the C-arm stand in the desired or predefined direction using the lateral handles, or use the hand rail around the image intensifier to pull the C-arm stand.

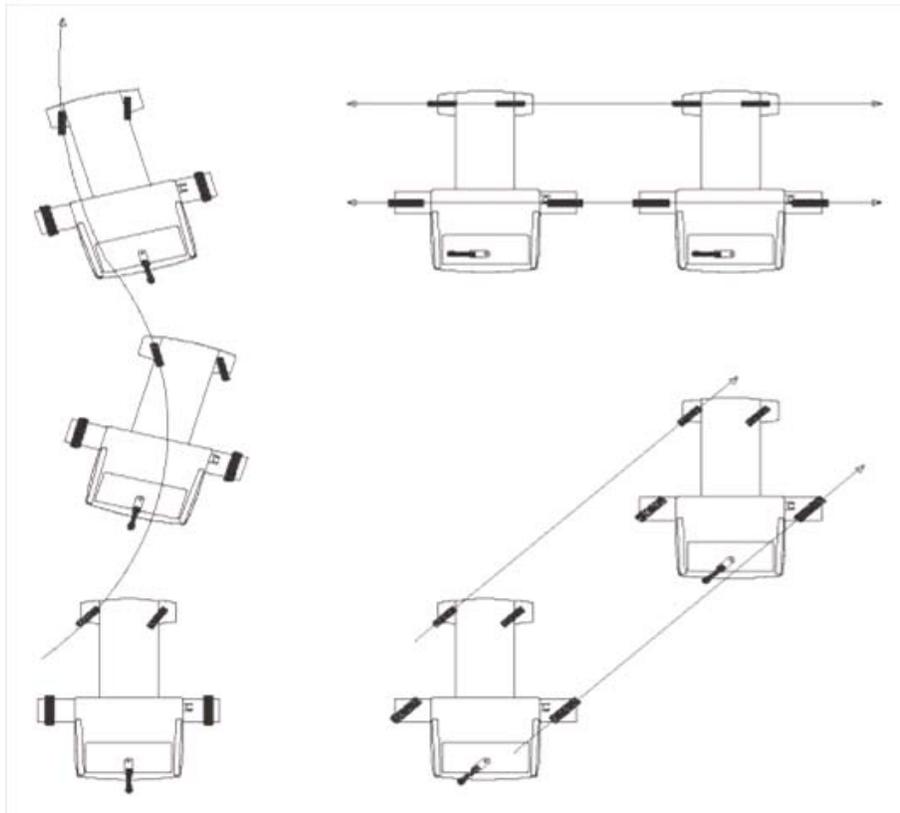


CAUTION

Release the parking brake only to move or position the C-arm.
Operate moveable assemblies and parts with caution.

Exercise extreme caution when releasing mechanical locks or brakes. To prevent un-wanted movement of the mechanical c-arm assembly, always maintain control by holding on to and then slowly releasing the mechanical locks before moving any of the mechanical components of the **ZIEHM QUANTUM** mobile C-Arm. Failure to observe this warning may result in **serious injury to patient or operator**.

Fig 5.3: C-Arm Stand Steering (schematic representation, view from above)



5.3 MOVEMENT OF THE C-ARM, MECHANICAL BRAKES

The C-Arm can be moved in virtually any plane. For each movement, a separate brake is available, allowing you to secure the C-Arm in any position.

To release the corresponding brake, turn it counter-clockwise.

The limit stop of the brake handles can be adjusted individually. To do so, lift the spring-locking brake handle, turn it until reaching the desired limit stop position and release it to re-engaged it at the new position.



CAUTION

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



WARNING

Release the mechanical brakes only for positioning.

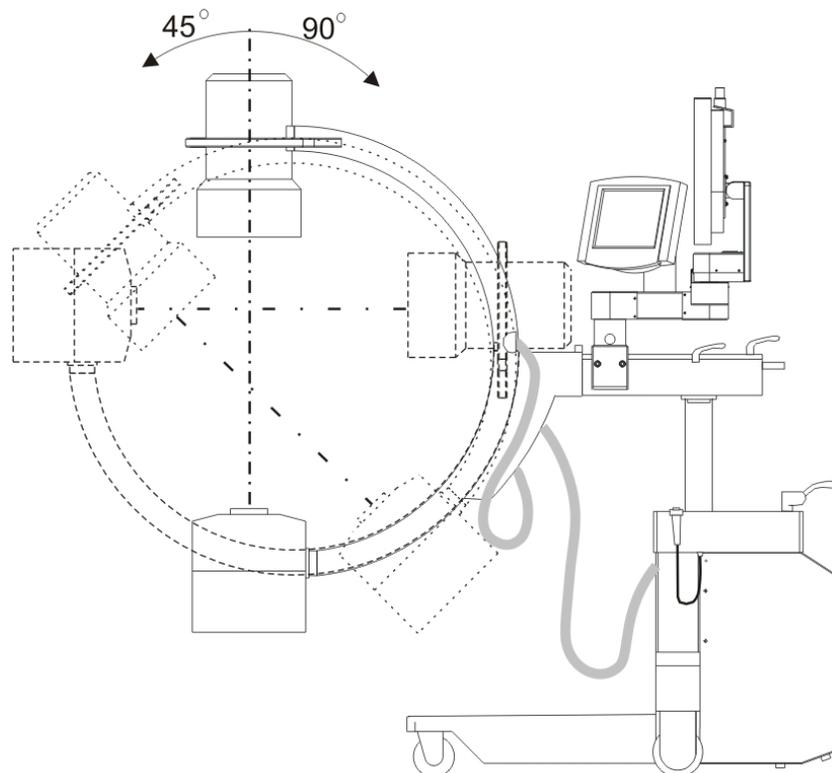
Make sure there is enough room to maneuver the C-arm stand and Monitor assembly before positioning!

Exercise extreme caution when releasing mechanical locks or brakes. To prevent unwanted movement of the mechanical c-arm assembly, always maintain control by holding on to and then slowly releasing the mechanical locks before moving any of the mechanical components of the **ZIEHM QUANTUM** mobile C-arm. Failure to observe this warning may result in serious injury to patient or operator.

5.3.1 ORBITAL ROTATION

The C-arm can be rotated in an orbital motion by 135° for 23 cm I.I.: -90° from vertical to horizontal position and +45° forward. A scale with 5° divisions on the outside of the C-arm profile as well as a mechanical detent at the 'zero' position are provided to facilitate precise positioning.

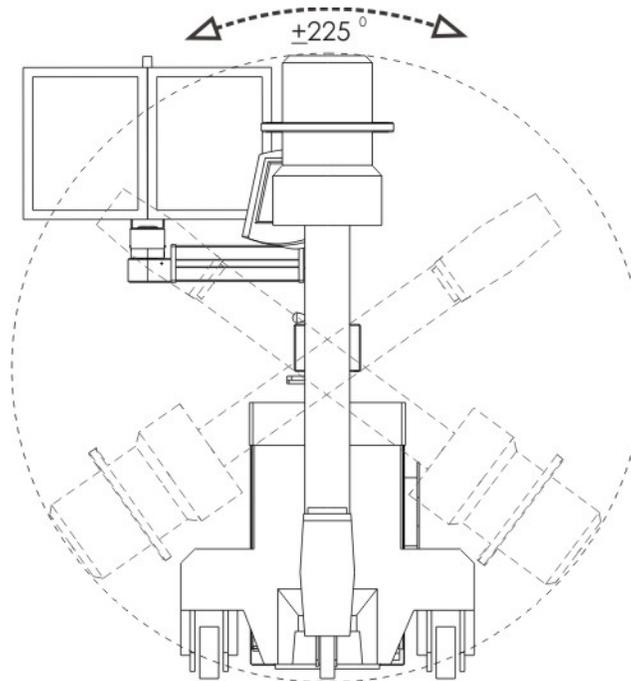
Fig 5.4 Orbital rotation of the C-Arm



5.3.2 ANGULATION

The C-arm can be rotated by $\pm 225^\circ$ in the vertical plane around the horizontal axis (i.e., the horizontal carriage). A scale with 10° divisions is provided at the pivot joint of the horizontal carriage to facilitate precise positioning.

Fig 5.5 Angulation of the C-Arm



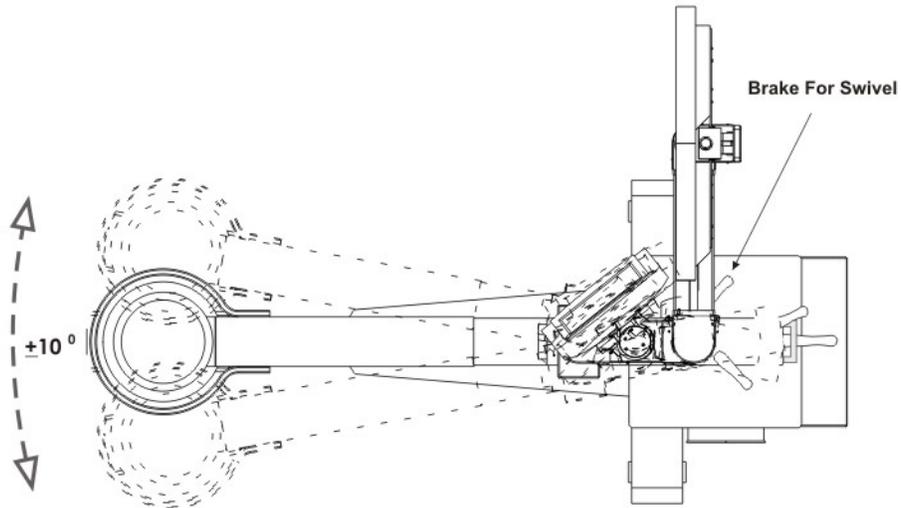
NOTE

Rotation Brake for angulations is on the horizontal arm of the Mobile stand See Fig 5.1

5.3.3 SWIVELING (PANNING)

The C-arm can be swiveled 10° to the left or to the right around the vertical axis of the lifting column.

Figure 5.6: Swiveling (panning) of the C-Arm (view from above)

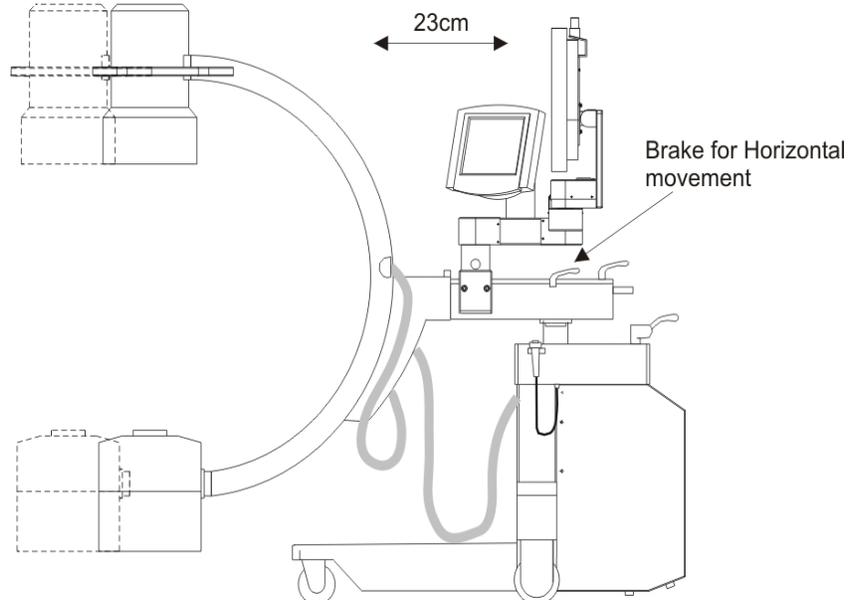


When using the **Swivel** or **Panning** function for the c-arm you may need to reposition the monitors for a clear view of the image displays.

5.3.4 HORIZONTAL MOVEMENT

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

Fig 5.7 Horizontal movement



5.3.5 VERTICAL MOVEMENT

The C-arm can be moved up and down by 43 cm. This movement is motorized. A scale with 1 cm divisions is provided on the lifting column to facilitate precise positioning.

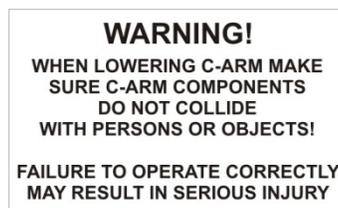
The **LIFT** buttons are on the C-arm stand next to the lateral handles. To move the C-arm up or down, you must press and hold down the corresponding **LIFT** button.

5.3.5.1. VERTICAL OVERRIDE:

The **ZIEHM QUANTUM** provides an additional feature of a lower limit position.

The lower limit position for vertical travel uses a safety override switch located on and just forward of the UP and Down vertical travel buttons located on the mobile stand console.

Normal operation prevents the Image Intensifier from hitting the front foot of the mobile stand. In certain procedures the operator can override the standard down position by pressing one of the Two Override buttons at the same time they press the Down Button. This will allow the operator to lower the Vertical height by approximately 3”.



Safety Override Warning Label



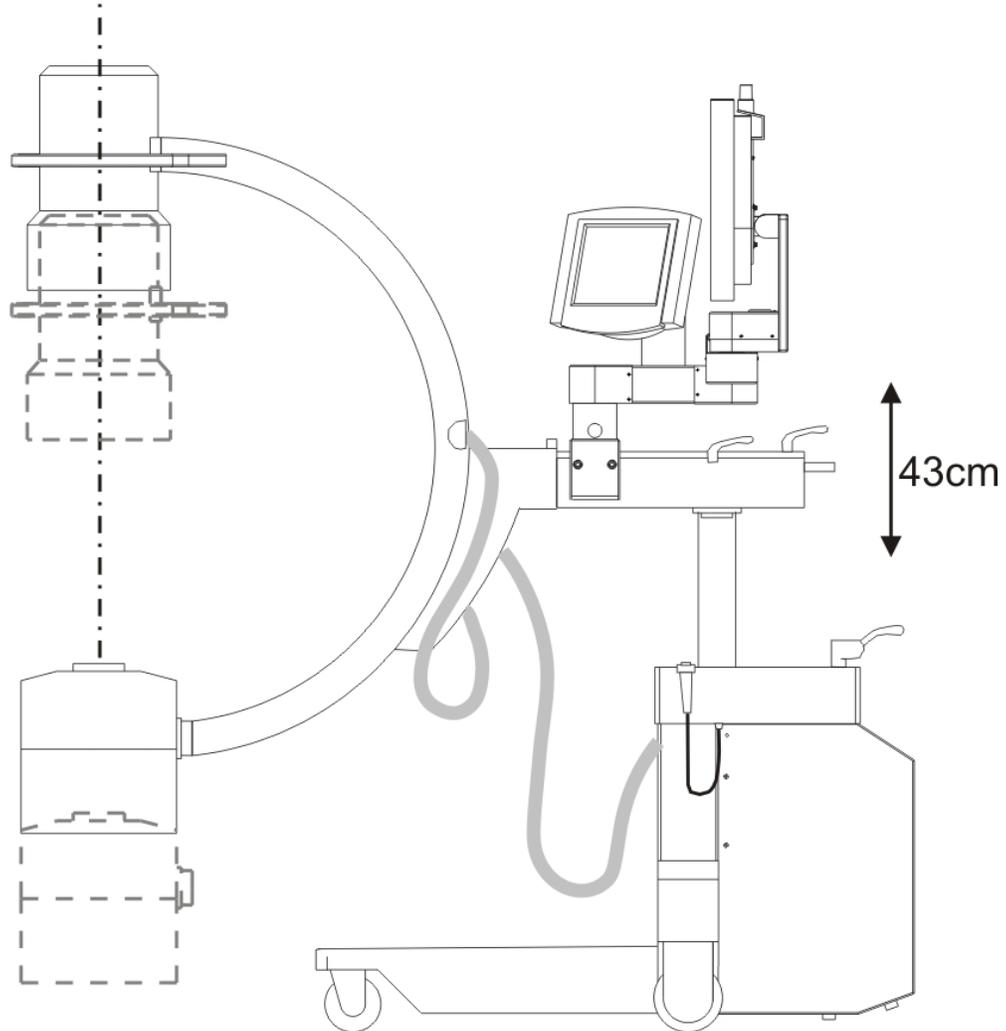
Safety Override Switch Label



CAUTION

Before pressing the override switch and lowering the C-arm further, make sure that it does not collide with any persons or objects!

Fig 5.8 Vertical movement of C-Arm



CAUTION
Before moving the C-arm up or down, make sure that it does not collide with any persons or objects!

6.0 USER TOUCH AND CONSOLE KEYBOARDS

6.1 DESKVIEW™ CONTROL PANEL

The **DeskView** control panel is designed as a touch screen. For system operation, just press the desired button directly on the screen. Depending on the selected function, different buttons, display fields and input fields will appear on the screen.

6.2 DESKVIEW CONTROL PANEL

6.2.1 ELEMENTS OF THE CONTROL PANEL

The **DeskView** control panel is designed as a touch screen. Its operation covers a wide range of functionality, system operations, image processing, and dose control.

The simple design and ease of use provides the operator with direct press and system response of desired functionality. Depending on the selected function, different buttons, display fields and input fields will appear on the screen.



NOTE

The **DeskView** touch screen offers automatic display of relevant buttons and removes all but the buttons not relevant or operative for any individual mode, or functional process.

When radiation is active only those functions that are available during the exposure on time will be visible and accessible. See figure 6-3 for example of main touch screen with Fluoroscopy selected and radiation on.

The Buttons will have two states of operation:

- Inactive or off state; Button is light gray and is available for selection
- The active or on state; Button is yellow to indicate the active state, in some cases the text will change with the toggling of the button through several states.

Example; in this case the noise reduction button has four (4) states (Off, Low, Med and High)



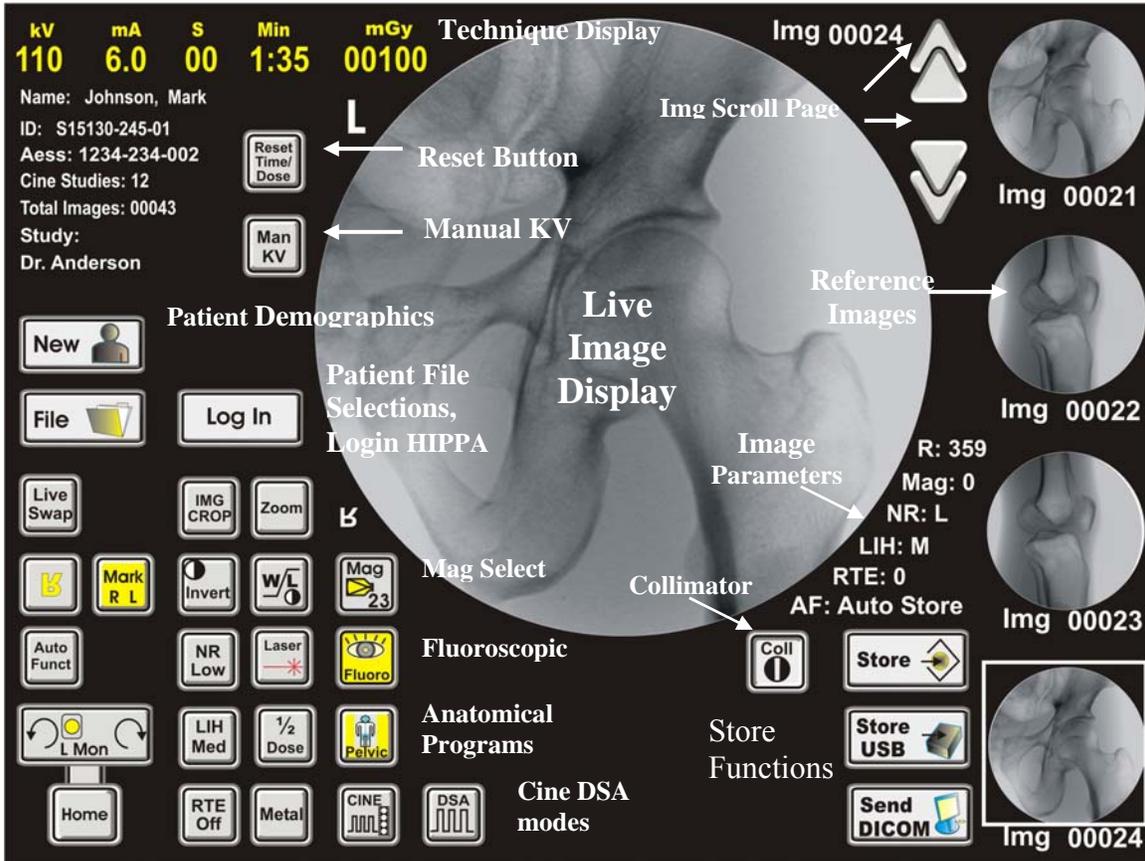
Inactive



Active

The Main screen elements of operation are shown in the figure 6-1,

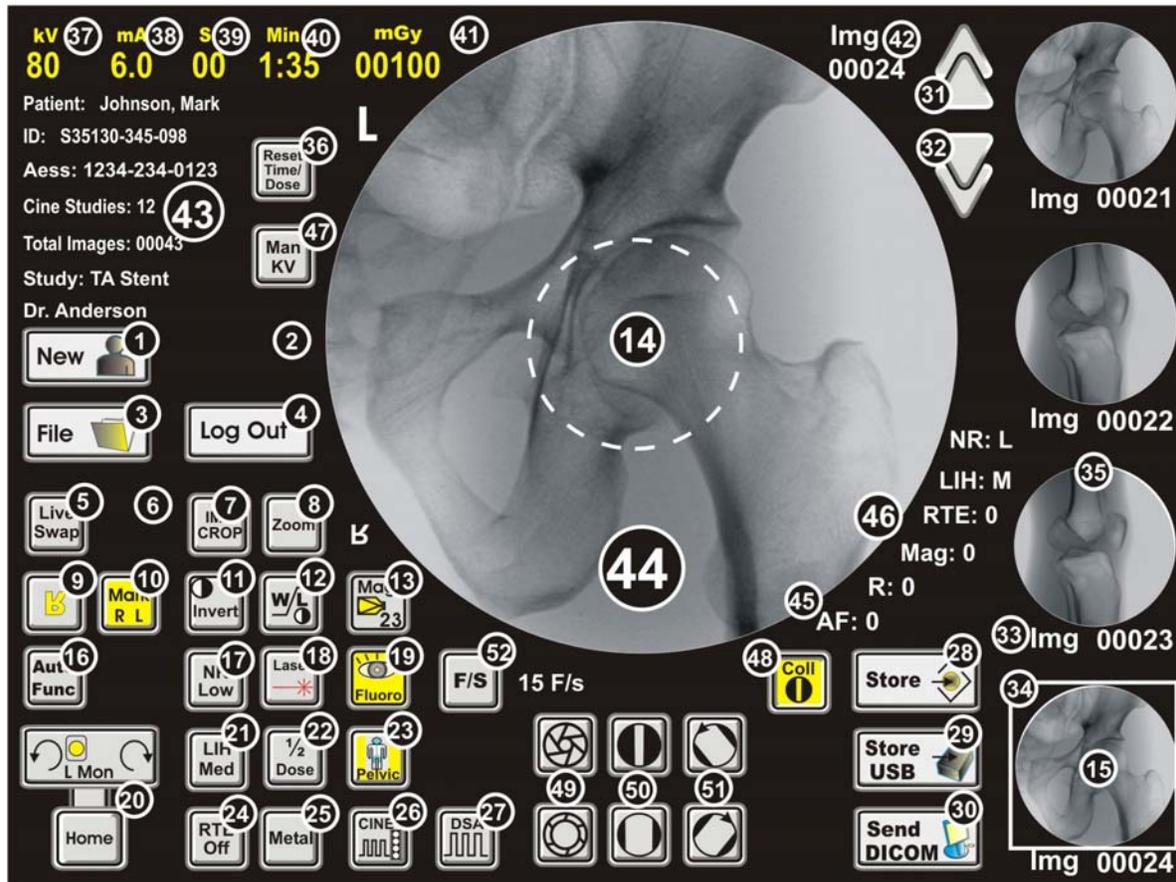
Figure 6.1: Main Touch Panel Screen



6.3 DESKVIEW MAIN SCREEN BUTTONS

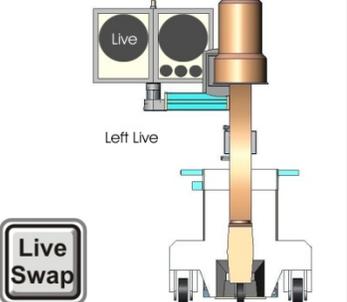
The Main screen is displayed in the Fig 6-2 below. Operator can make different settings for organ program, Fluoroscopic mode, Image Magnification size, etc. The following Table gives a description of the different functions and modes available to the operator.

Fig 6.2: Control Panel Main Screen Button Layout

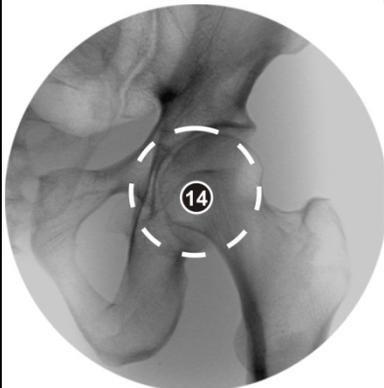
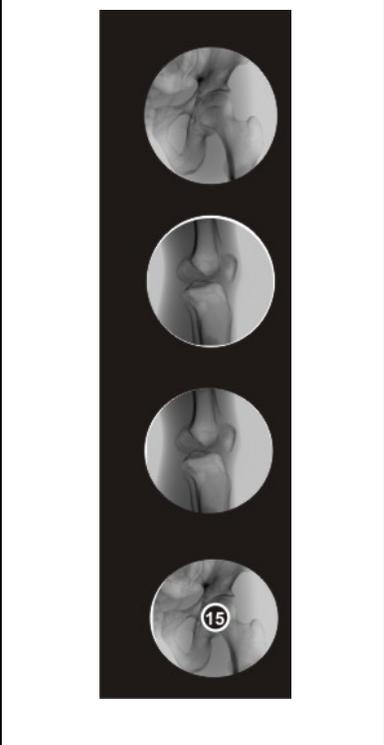


6.4 MAIN SCREEN BUTTON IDENTIFICATION TABLE:

Control No.	Symbol(s)	Description
Button 1		New Patient Activates the new patient entry screen, Enter new patient information and set other parameters for patient demographics
Button 2		Delete Image Deletes the highlighted (selected) reference image on the right side of the touch screen (collage) Note: This may not be available on some system configurations.

Control No.	Symbol(s)	Description
Button 3		<p>Patient File</p> <p>Activates the patient database screen for review, DICOM print /send, Delete complete patient file, etc.</p>
Button 4		<p>Log In</p> <p>Activates the Log In Screen for password protection for storing and send images from patient file to external storage devices, i.e. DICOM server/printers, USB memory sticks, or DVD writer.</p> <p>Provides security of patient file records (images) from being removed without permission (HIPAA)</p>
Button 5		<p>Live Swap</p> <p>Activates the Live monitor swap function. This simply moves the live functions from the left to the right monitor. The main use of this function is to allow the outer monitor to be the live monitor to avoid interference with the Image intensifier when viewed from the doctors position</p>
Button 6	Future Function Location	Future
Button 7		<p>Image Crop</p> <p>Activates the post processing function. Several additional buttons will be displayed on the touch screen to allow the operator to crop the image.</p>
Button 8		<p>Zoom</p> <p>Pressing the Zoom button will open a digital magnification window on the left monitor and display on the right monitor the magnified image.</p>

Control No.	Symbol(s)	Description
Button 9		<p>Image Mirror</p> <p>Pressing the button several times will allow operator to flip mirror image head to foot, or right to left or combination of these.</p> <p>The button symbol will display the setting of the button.</p>
Button 10		<p>Mark Anatomical "Right Left"</p> <p>Activates an "L" or "R" marker in the upper left corner of the image and is stored with image.</p> <p>Press button several times to mark or un mark the image.</p>
Button 11		<p>Invert Image</p> <p>Displays the active image (positive) image in a negative (inverted) grayscale or vice versa. Inverts black to white and white to black.</p>
Button 12		<p>Window and Level</p> <p>Activates Window and level buttons to allow change in the image contrast and brightness levels.</p>
Button 13	 <p>Optional 10cm</p>	<p>Set Magnification</p> <p>Controls the Image Intensifier's electronics magnification size in three steps. Hides of shows buttons for selecting</p> <p>Size. (23, and 15cm)</p> <p>Optional (23, 15, 10cm)</p>

Control No.	Symbol(s)	Description
Button 14		<p>Image Transfer L to R</p> <p>Transfers image from the left monitor to the right monitor</p> <p>Press the center of touch screen image to transfer image from left to right.</p> <p>Only live images can be transferred to the Reference or Right Monitor</p>
Button 15		<p>Image Transfer R to L</p> <p>Transfers image from the right monitor to the left monitor</p> <p>Press the image Icon on the right to select a Reference image it will then be displayed on the right monitor, then the second press will transfer image from right to left monitor</p>
Button 16		<p>Auto Function</p> <p>Activation of the Auto function button allows the selection of three functions.</p> <p>Note: Certain ZIEHM QUANTUM models will not have all the automatic functions</p>
Button 17		<p>Noise Reduction</p> <p>Press / toggle the button to adjust the level of noise reduction during live Fluoroscopy.</p>

Control No.	Symbol(s)	Description
Button 18		<p>Laser ON/OFF</p> <p>Activates the laser(s) on the generator and the image intensifier. Press the button once to activate and again to turn it off, or wait for automatic timer to turn off after 1 minute.</p>
Button 19		<p>Radiation Modes</p> <p>Pressing the active fluoroscopic mode button will open the selection of the following modes.</p> <ul style="list-style-type: none"> • Fluoroscopy • Pulse Fluoroscopy (<3F/S) • Snap Shot
Button 20		<p>Image Rotation</p> <p>Rotate “CW” Rotates the Image in Clockwise direction.</p> <p>Rotate “CCW” Rotates the image in a Counter Clock Wise direction.</p> <p>The button informs the operator to the active live monitor. L-Mon or R-Mon.</p> <p>Home Position</p> <p>Button is only visible when the image has been rotated from its zero “0” position.</p> <p>Resets the angle of rotation in one step to 0 degrees.</p>
Button 21		<p>Last Image Hold</p> <p>Press / toggle the button to adjust the level of radiation hold on noise reduction when footswitch or hand switch is released.</p>
Button 22		<p>Half Dose 1/2</p> <p>Activates lower dose mode, allows the system to use a working dose that is nearly half that of the standard auto dose rate.</p>

Control No.	Symbol(s)	Description
Button 23		<p>Organ Program</p> <p>Activating the button will open all four buttons for selection.</p> <ol style="list-style-type: none"> 1) Bone or Extremity 2) Pelvic 3) Heart or Thorax 4) LPD or Adipose Patient
Button 24		<p>Real Time Edge (RTE)</p> <p>Press /toggle to activate the level of edge enhancement (Sharpen)</p> <p>Off, Low, Med, High.</p> <p>Level is indicated on button</p>
Button 25		<p>Metal</p> <p>Activates the metal artifact correction function.</p> <p>This supplementary to the organ program image quality.</p>
Button 26		<p>Optional Cine</p> <p>Activates or deactivates the cine loop mode.</p> <p>Is a supplementary button to the organ and fluoroscopy modes.</p>
Button 27		<p>Optional DSA Subtraction</p> <p>Activates or deactivates the DSA (SUBTRACTION) mode.</p> <p>Additional buttons are opened on the touch screen whenever the DSA button is activated.</p>
Button 28		<p>Store</p> <p>Stores the active live image to the hard disk</p> <p>Operator can press Store button during live fluoroscopy to store image on the fly.</p>

Control No.	Symbol(s)	Description
Button 29		<p>Store USB (Option)</p> <p>Store active image to a certified ZIEHM QUANTUM USB device</p> <p>Optional: Store to external USB memory stick storage device.</p>
Button 30		<p>SEND DICOM (Option)</p> <p>DICOM images can be sent to DICOM server or printer. Depending on selection at time of installation</p>
Button 31		<p>Image Scroll</p> <p>Page image scroll button displays and selects the next four lower image numbers in the active patient folder and displays them as Thumbnail images on touch screen and full size on the reference display monitor.</p>
Button 32		<p>Image Scroll</p> <p>Page image scroll button displays and selects the next four higher image numbers in the active patient folder and displays them as Thumbnail images on touch screen and full size on the reference display monitor.</p>
Button 33	<p>Img 00023</p>	<p>Image number</p> <p>Identifies the image number on the touch screen and reference monitor</p> <p>“C” in front of the number indicates this is a CINE/DSA sequence (study)</p>
Button 34		<p>Active Image Indicator</p> <p>Denotes the active image by placing the White Square around the touch screen reference image.</p> <p>Moves over the active image by pressing the Image scroll buttons. Or when an image is stored</p>

Control No.	Symbol(s)	Description
Button 35		<p>Reference Image</p> <p>Four images are displayed on the touch screen right side and are identical to the reference images displayed on the reference display monitor.</p> <p>Press once to recall image to Reference monitor.</p> <p>Press again after ½ to 1 sec delay then image is transferred to the Live monitor and DeskView.</p>
Button 36		<p>Reset Time/Dose</p> <p>Resets the 5 minute Fluoroscopic timer, and if pressed more than 2 seconds, resets both the fluoroscopic timer and the dose area product meter value.</p>
Button 37	<p style="text-align: center;">kV 110</p>	<p>Tube kV value</p> <p>Shows the automatically determined or manually set tube voltage in kV</p> <p>After Fluoroscopy, the last kV value remains stored and displayed.</p>
Button 38	<p style="text-align: center;">mA 6.0</p>	<p>Tube Current mA</p> <p>Shows the automatically determined tube current in mA.</p> <p>After Fluoroscopy, the last value remains stored and displayed.</p>
Button 39	<p style="text-align: center;">s 00</p>	<p>Radiography Time</p> <p>Displays the radiography exposure time in seconds</p>
Button 40	<p style="text-align: center;">Min 1:35</p>	<p>Radiation Time (fluoroscopy)</p> <p>Display of the accumulated radiation time for Fluoroscopy and direct radiography for the active patient folder in minutes and seconds.</p>

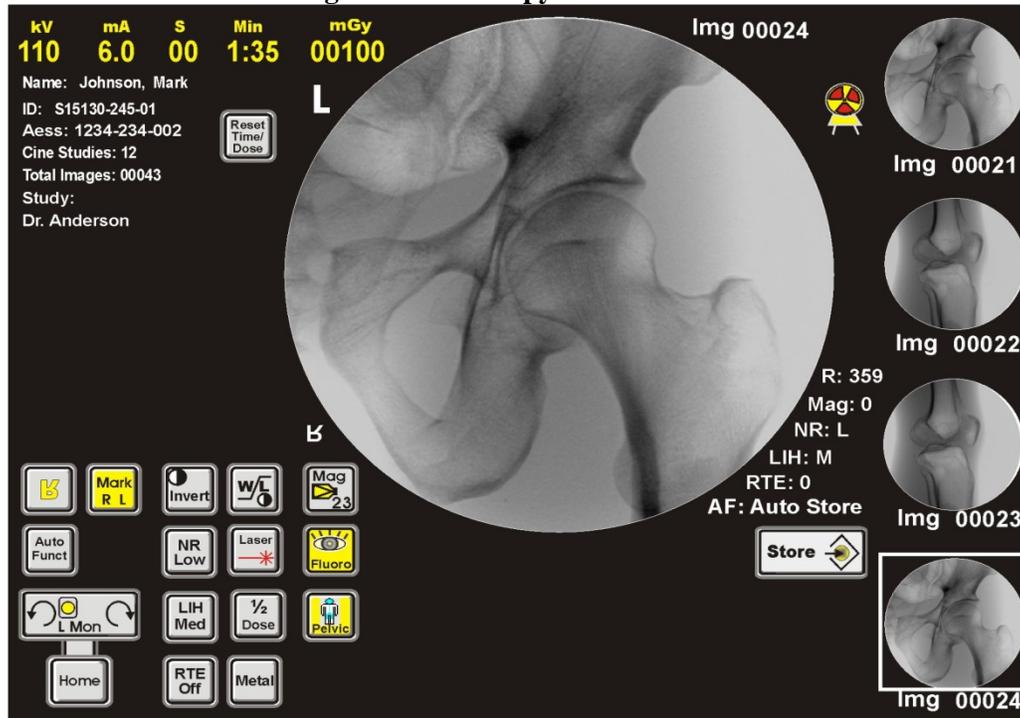
Control No.	Symbol(s)	Description
Button 41	00000 mGy/min	<p>Dose Air Kerma</p> <p>Displays the dose in Air Kerma rate for active patient. The display reads in mGy/min when radiation is on and when off displays the accumulative dose in mGy.</p>
Button 42	Img 00023	<p>Image Number</p> <p>Displays the image number of the image displayed on the Desk View touch screen</p>
Button 43	<p>Patient: Hecklebotom, Heberthinkle ID: S35130-345-098 Aess: 1234-234-0123 Cine Studies: 12 Total Images: 00043 Study: TA Stent Dr. Anderson</p>	<p>Patient Demographic</p> <p>Display of the active patient demographic information, Name, ID, Accession number, total Cine studies, Total images, study name and Dr. Name.</p>
Button 44		<p>Live Image Display</p> <p>Operator display area for live and processed image viewing.</p> <p>Image represents the live fluoroscopic image and also allows the operator to view and set the cine loop playback and reference images.</p>
Button 45	<p>AUTO STORE</p> <p>AUTO TRANSFER</p>	<p>Auto Function</p> <p>Display of the Auto function selected</p> <ul style="list-style-type: none"> • Auto Store • Auto Transfer
Button 46	<p>R: 359</p> <p>Mag: 0</p> <p>NR: L</p> <p>LIH: M</p> <p>RTE: 0</p>	<p>Image Attributes</p> <p>Image attributes displays the values of Noise reduction, Last image hold, and Real time edge enhancement, image rotation and Image Intensifier magnification size.</p>

Control No.	Symbol(s)	Description
Button 47		<p>Manual KV /</p> <p>Pressing the Manual kV button will lock the technique at the time you press the button</p> <p>To increase or decrease the kV level press the up or down arrow key when they are displayed</p>
Button 48		<p>Radiation Collimator</p> <p>Press this button to open the collimator function, press again to close the collimator functions</p> <p>If user/operator do not use the buttons in 10 Seconds the collimator selection is automatically closed</p>
Button 49		<p>Iris Collimator shutters</p> <p>Press the Iris collimator buttons to close or open the collimator Iris.</p>
Button 50		<p>Slot Collimator shutters</p> <p>Press the slot collimator buttons to open or close the slot shutters</p>
Button 51		<p>Rotation Slot Collimator</p> <p>Press the CCW button to rotate the slot collimator counter clockwise, or press the CW button to rotate the slot collimator clockwise.</p>
Button 52		<p>Frame Rate</p> <p>Pressing the frame rate button will speed up or slow down the replay</p> <p>The button Toggles by pressing multiple times to set frame rate speed.</p>

6.5 CONTROLS IN FLUOROSCOPIC OPERATION MAIN SCREEN

Fluoroscopic Main Screen Operation with Radiation ON

Fig 6.3: Fluoroscopy Radiation ON



The function/buttons that are not relevant to modes of operation and during radiation are removed from the screen to assist the operator in making and effecting easier control decisions.



NOTE

In certain modes, function buttons may not be active and therefore will be removed from the active screen.

6.6 TOUCH CONTROL KEYBOARD

In the **Patient entry**, **Patient File Search**, **Configuration** operating modes a touch screen alphanumeric keypad is displayed allowing you to enter text as the text keyboard is needed for patient information, search criteria, etc.

6.6.1 ALPHANUMERIC KEYPAD

Fig 6.4: Alphanumerical Touch Display on the DeskView Control Panel



NOTE

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

6.6.2 UPPERCASE LETTERS AND SPECIAL CHARACTERS

To generate uppercase letters and special characters, first press and release the **Shift** key and then the corresponding key.



The **Shift** key is valid for subsequent letter or special character.



To deactivate the **Shift** mode, press the **U-Shift** key before entering the letters or characters.



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

6.7 MOBILE STAND CONTROL KEYBOARD

The **Mobile Stand** control panel is designed as a fixed mechanical keyboard. For system operation, just press the desired button directly on the button symbol. Depending on the selected function, different button LED's may light to show they are active.

The C-arm mobile stand control panel is different in operation and selection of functions than the touch screen. However, the same buttons on the touch screen and the mobile stand control panel affect the same function and operations enabling the operator to use the touch or mobile stand control panel.

Fig 6.5: Elements Of The Mobile Stand Control Panel



6.7.1 MAIN KEYBOARD ELEMENT GROUPS

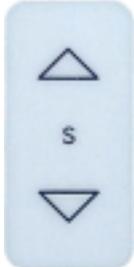
- Lower left “Fluoroscopic modes”
- Lower left “Collimator”
- Lower Middle Left “Radiographic”
- Lower Middle Right “Image position”
- Lower Right “Organ /Anatomical Programs”
- Lower Right “Image Processing”
- Upper Right “Vertical Lift”
- Upper Right “Image Mag and ½ Dose”
- Upper Middle Left “Power ON/OFF”
- Upper left “Laser”
- Upper Left “Vertical Lift”

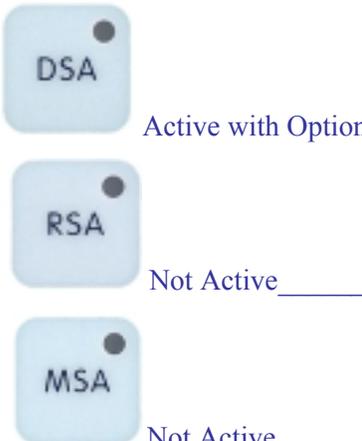
6.8 MOBILE STAND CONTROL KEYBOARD TABLE

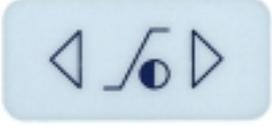
Control No.	Symbol(s)	Description
Button 1		<p>Vertical Lift</p> <p>UP/Down</p> <p>Provide motorized lift for the vertical column of the C-arm</p> <p>Safety Override</p> <p>Vertical Down Override button. Located on each side of the mobile stand forward of the standard Vertical Lift Buttons.</p> <p>Use only when it is required to go lower than normal operating height.</p>
Button 2		<p>Laser ON/OFF</p> <p>Activates the laser(s) on the generator and the image intensifier. Press the button once to activate and again to turn it off, or wait for automatic timer to turn off after 1 minute.</p>
Button 3		<p>Power OFF</p> <p>Deactivates the power off circuit for the system.</p>
Button 4		<p>Power ON</p> <p>Activates power on circuits</p>
Button 5		<p>Timer Reset;</p> <p>Resets the 5 minute Fluoroscopic timer and Dose area Product display reset.</p> <p>Press once reset timer, Press and hold for more than 2 seconds resets the timer and Dose Area Product Meter</p>
Button 6		<p>Print Button</p> <p>Not active on ZIEHM QUANTUM model</p>

Control No.	Symbol(s)	Description
Button 7		<p>Set Magnification</p> <p>Controls the Image Intensifier's electronics magnification size in three steps.</p> <p>Size. (23, 15, and 10 cm)</p>
Button 8		<p>Half Dose 1/2</p> <p>Activates lower dose mode, allows the system to use a working dose that is nearly half that of the standard auto dose rate.</p>
Button 9		<p>Radiation Modes</p> <p>Selects Fluoroscopic mode of operation</p>
Button 10		<p>Manual Fluoroscopy</p> <p>Press the manual button to lock automatic dose regulation and allow setting of manual kV level.</p>
Button 11		<p>Radiation Modes</p> <p>Selects Pulse Fluoroscopy mode of operation (<3F/S)</p>
Button 12		<p>Radiation Modes</p> <p>Selects Snap Shot mode of operation</p>
Button 13		<p>kV Adjustment</p> <p>Press the up button to increase the kV level</p> <p>Press the Down button to lower the kV level</p>
Button 14		<p>Close slot Collimator</p> <p>Press and hold the button to close the radiation slot collimator</p>

Control No.	Symbol(s)	Description
Button 15		<p>Open slot Collimator</p> <p>Press and hold the button to Open the radiation slot collimator</p>
Button 16		<p>Rotate Slot Collimator CCW</p> <p>Press and hold the button to rotate counter clockwise the radiation slot collimator</p>
Button 17		<p>Rotate Slot Collimator CW</p> <p>Press and hold the button to rotate clockwise the radiation slot collimator</p>
Button 18		<p>Close Iris Collimator</p> <p>Press and hold to close the iris collimator</p>
Button 19		<p>Open Iris Collimator</p> <p>Press and hold to open the iris collimator</p>
Button 20		<p>Radiography</p> <p>Sets the system into the radiographic mode of operation.</p> <p>Optional setting for this function. May not be available on all systems.</p>
Button 21		<p>Image Receptor</p> <p>Selects the Maximum image receptor size for film exposure, using the Radiography mode.</p> <p>USA only 24cm button is active.</p> <p>30 and 40 cm are blocked from use.</p> <p>Optional setting for this function. May not be available on all systems.</p>

Control No.	Symbol(s)	Description
Button 22		<p>Radiography Time Select</p> <p>Sets the timer for radiography in seconds 0.2-5 seconds</p> <p>Press Up arrow to increase time</p> <p>Press Down arrow to reduce time</p>
Button 23	 <p>Not Active</p>	<p>Image Mirror</p> <p>The Image mirror buttons do not work on this keyboard, to mirror image use the Desk View touch screen image mirror button</p>
Button 24	 <p>Not Active</p>	<p>Image Mirror</p> <p>The Image mirror buttons do not work on this keyboard, to mirror image use the Desk View touch screen image mirror button</p>
Button 25	 <p>Not Active</p>	<p>Left Monitor</p> <p>Not Active. Touching this buttons will not activate any function.</p>
Button 26	 <p>Not Active</p>	<p>Right Monitor</p> <p>None active touching this buttons will not activate any function</p>
Button 27	 <p>May not be active</p>	<p>Digital Image Rotation</p> <p>Image rotation of CCW or CW,</p> <p>This will rotate the image of the live monitor only.</p> <p>May not be active with some options.</p>

Control No.	Symbol(s)	Description
Button 28	 <p>DSA Active with Option</p> <p>RSA Not Active _____</p> <p>MSA Not Active _____</p>	<p>Subtraction Functions (Option)</p> <ol style="list-style-type: none"> 1) Press DSA, Pressing this button will activate the DSA function 2) RSA, Pressing this button will not activate function (NOT ACTIVE) 3) MSA, pressing this button will not activate function (NOT ACTIVE)
Button 29	 <p>SOFT</p>	<p>Anatomical Programs</p> <p>Activating the button will open all four buttons for selection.</p> <ol style="list-style-type: none"> 1) Bone or Extremity 2) Pelvic/Spine 3) Heart or Thorax 4) Soft Tissue / LPD or Adipose Patient setting <p>See Also Button 33</p>
Button 30		<p>Save / Store image</p> <p>Press button to store image to patient file. The LED will light when button is pressed.</p>
Button 31	 <p>Not Active</p>	<p>Image Transfer</p> <p>Pressing this button will not activate functions</p>

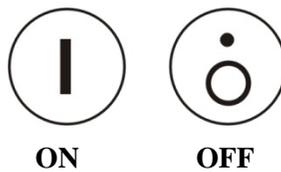
Control No.	Symbol(s)	Description
Button 32		<p>Metal</p> <p>Activates the metal artifact correction function.</p> <p>This is a supplementary operation to the organ program image quality.</p>
Button 33		<p>Soft</p> <p>The Soft button has been reprogrammed to penetrate larger patient anatomy (Adipose patients) and is called “LPD” on the Desk View touch screen</p> <p>See also Button 29</p>
Button 34	 <p data-bbox="565 968 699 999">Not Active</p>	<p>Window/Level</p> <p>Will not activate a function, this button is blocked</p>
Button 35		<p>Tube kV value</p> <p>Shows the automatically determined or manually set tube voltage in kV</p> <p>After Fluoroscopy, the last kV value remains stored and displayed.</p>
Button 36		<p>Tube Current mA</p> <p>Shows the automatically determined tube current in mA.</p> <p>After Fluoroscopy, the last value remains stored and displayed.</p>
Button 37		<p>Radiography Time</p> <p>Displays the radiography exposure time in seconds</p>

Control No.	Symbol(s)	Description
Button 38	 USED ONLY FOR ERROR CODE READ OUT	Dose Area Product (Option) USED ONLY FOR ERROR CODE READ OUT in the UNITED STATES See Desk View Touch screen for AKR dose display.
Button 39	 min	Radiation Time (fluoroscopy) Display of the accumulated radiation time for Fluoroscopy and direct radiography for the active patient folder in minutes and seconds. Max (66 or 99 Min) Depending on System settings.
Button 40		Thermometer Thermal indicator, will light up when the system has reached maximum level of thermal loading.
Button 41		Radiation indicator Lights when radiation is active, This indicator is a representative of the radiation on and may lead and follow by a < 0.5 seconds of actual radiation.

6.9 SWITCHING ON THE ZIEHM QUANTUM

During power up the system will display information on the Main Display monitors and will flash, the touch screen “DESK VIEW” will display depending on system options either, a black screen until fully powered up, or a sequence of Blue screens and system operation screens, Once the system has fully powered up the touch screen will display the Main User interface Screen, and the two main viewing monitors will have text but no images displayed.

The Power **ON** and **OFF** buttons are located in the upper left are of the Keyboard. The system can only be turned at the C-arm Mobile Stand keyboard.





CAUTION

Do not touch the touch screen during start up as system operation may be effected, and improper start up may occur.

If this occurs turn off the unit and restart the system, remembering to not touch the screen during power up sequence.



CAUTION

Do not insert a CD/DVD disk into the CD/DVD writer or USB Memory devices into the USB interface until after the system has fully completed its power –up sequence. Failure to follow this caution will result in the system not being fully functional.



NOTE

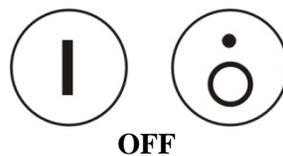
Always set the ON/OFF switches on the flat-screen monitors to ON in the order to ensure that the monitors are switched on automatically during power-up of the system.

6.10 SWITCHING OFF THE ZIEHM QUANTUM

To shut down the **ZIEHM QUANTUM** make sure you have allowed several seconds after the last image was stored or a new patient was entered to avoid possible loss of this information.

To shut down do the following:

- Close any open screen and return to the main user interface screen.
- Make sure you have allowed at least 30 Seconds from the last image saved, acquiring a work list, or have entered a new patient record.
- Press the OFF button on the mobile stand control panel.
- The entire system is switched off now.



6.11 VERTICAL LIFT

The C-arm can be moved up and down by 43 cm. This movement is motorized. A scale with 1 cm divisions is provided on the lifting column to facilitate precise positioning.



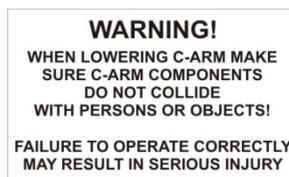
The **LIFT** buttons are on the C-arm stand next to the lateral handles. To move the C-arm up or down, you must press and hold down the corresponding **LIFT** button.

6.11.1 VERTICAL OVERRIDE:

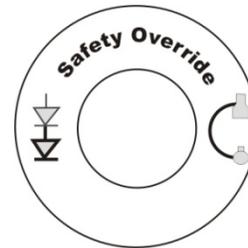
The **ZIEHM QUANTUM** provides an additional feature of a lower limit position.

The lower limit position for vertical travel uses a safety override switch located on the mobile stand just forward of the **UP** and **Down** vertical travel buttons of the mobile stand console.

Normal operation prevents the Image Intensifier from hitting the front foot of the mobile stand. In certain procedures the operator can override the standard down position by pressing one of the two **Override Buttons** at the same time they press the **Down Button**. This will allow the operator to lower the **Vertical** height by approximately 3”.



Safety Override Warning Label



Safety Override Switch Label



CAUTION

Before pressing the override switch and lowering the C-arm further, make sure that it does not collide with any persons or objects!



CAUTION

Before moving the C-arm up or down, make sure that it does not collide with any persons or objects!

6.12 HAND SWITCH AND FOOT SWITCH

The **ZIEHM QUANTUM** is equipped with a standard hand switch and a two-position pedal foot switch.

Fig 6.6: Hand Switch



Fig 6.7: Two Position Foot switch



Radiation is initiated either with the hand switch or the fluoroscopy pedal of the foot switch.

The standard pedal assignment of the two-pedal foot switch is as follows:

- **Left pedal:** Fluoroscopy
- **Right pedal:** Save/Store image (OPT: Laser and snapshot)
 - **Optional two settings can be made:**
 - Laser on/off
 - Snapshot mode



NOTE

The foot switch pedals can be assigned with three individual customer-specific functions. If second footswitch is active the respective function will be indicated on labels on the foot switch itself and on the C-arm stand.

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7.0 STANDARD FLUOROSCOPIC OPERATIONS

7.1 GENERAL DESCRIPTION

The **ZIEHM QUANTUM** family of x-ray systems has digital processing systems that are designed to extend the advantages of digital image technology to C-Arm Fluoroscopy. Their image enhancement capabilities answer the specific needs of a variety to clinical fluoroscopic applications.

The **ZIEHM QUANTUM** is a mobile x-ray system developed for surgical and diagnostic applications such as fluoroscopy and spot-film radiography. It is not to be used in the presence of flammable anesthetics or other explosive gases.

7.2 SPECIAL FEATURES

The **ZIEHM QUANTUM** has been engineered to provide superior quality and performance. Here are some of its outstanding features:

- High-frequency generator that produces a precise spectrum of radiation capable of superior penetration.
- Efficient generator design that allows the **ZIEHM QUANTUM** to perform fluoroscopy at maximum kV for nearly 20 minutes.
- A 1/2 Dose function that reduces the working dose rate by approximately half.
- Optimum adjustment for various diagnostic requirements made possible by the system's Anatomical programming.
- Reducing dose for extended procedures through pulsed fluoroscopy. (<3 F/sec).
- Digital memory featuring digital image rotation, and 16 bit image processing.
- Noise filtering is available through Frame integration.
- Greater resolution is achieved through the image intensifier's electronic focus and magnification.
- Easier system positioning and maneuvering, due to the compact design of the image intensifier and unique monitor mounting system.
- Easier cleaning, clean design and unique cable arrangement.
- Quick access to fluoroscopy in less than 1 minute from powering on.

7.3 IMAGE SYSTEM DESIGN

The **ZIEHM QUANTUM** image processing system is a modular "FSRU" (Field Service Replaceable Unit) and allows for quick repair and upgrade. Components were selected for their reliability to promote long service life.

7.4 IMAGING PROCESSING

The imaging system is an integral part of the C-Arm and is designed to work hand-in-hand with the C-Arm control. The image processor is activated by the foot switch or hand switch and is controlled by the C-Arm control panel or the DeskView touch panel. Video is acquired through

the C-Arm video camera. Images are displayed on two high-resolution, TFT LCD, antiglare monitors.

Proprietary software improves image quality by:

- Reducing noise
- Acquiring images at a true 14-bit grayscale
- Digital acquisition image matrix up-scan to a 1K² Image with 980 x 980 active pixels.
- Digital display of 1024 H x 1280 V
- Real-time edge enhancement.

The image can be manipulated, stored, or displayed onto the monitors. Images that have been saved to the hard drive can be edited (enhance edges, Widow and level, Invert image, etc.).

7.5 THUMBNAIL IMAGE DISPLAY

The image system places 4 images onto the right side of the DeskView touch screen monitor, and along the bottom of the larger display monitors for image review and selection. The Touch screen ICON Thumbnails are used to control the transfer of the images so the user operator can perform post processing functions, i.e. magnification, hard copy selection, invert, zoom, crop, etc.

7.6 LIVE IMAGES

Live images are acquired and displayed during CINE loop acquisition (from 1 to 30 frames) on the live monitor.

7.7 FLUOROSCOPY

Using the **ZIEHM QUANTUM** to perform fluoroscopy is easy: turn the system on, give the cathode filament and image system around 45 - 60 seconds to warm-up, when desk view control buttons are displayed on the touch screen just press the hand switch or foot switch to start radiation and view the first images!

The following are some of the standard and optional features, described in detail later in this chapter, are also available:

- Several fluoroscopy programs
- Snapshot technique
- Pulsed fluoroscopy
- Manual control of kV
- Image integration for noise reduction
- Image Magnification
- Store image to patient file
- Image reversal
- Digital Image rotation
- Iris collimation

- Slot collimation, with rotation
- Real-time edge enhancement
- Imaging mirroring (after image is acquired)
- Opt: USB Memory Stick (external image storage)
- Opt: USB DVD

7.8 BASIC OPERATION

Turn on the C-Arm, as described in section 7.6 “Switching on the system”

- Fluoroscopy is activated (or, radiation is released) by pressing either the hand switch or the foot switch.
- When you stop pressing the hand or foot switch, the generator stops releasing radiation and the last image is displayed (held) by the left monitor. This image will continue to be displayed until a new fluoroscopic image is obtained.
- Contrast and brightness levels are set at the factory and are, generally, best left alone. However, to change contrast or brightness levels, simply push the brightness button on the front of the LCD display monitors and adjust the settings to obtain the desired effect.

Factory Setting: Brightness = 26, Contrast = 69, Backlight Brightness = 69

7.8.1 STEPS AND SETTINGS

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

- Create a new patient folder in the **Patient File** mode, or activate the desired patient folder in the **Patient File** operating mode.
- Select the desired **Fluoroscopy** mode or **Subtraction** operating mode. If you have not activated a patient folder before, the system automatically creates and activates a patient folder.
- Select the **Anatomical program** desired (Pelvic, Bone, Thorax, LPD).
- Generate the fluoroscopic image.
- **Save** the fluoroscopic image.
- Save image to external storage **USB** device or optional **DICOM** server.

The **ZIEHM QUANTUM** offers the following functions for adjusting the **Individual** appearance of the live image to your individual needs

7.8.2 ADJUSTMENTS THAT CAN BE MADE:

- **Contrast/Brightness:** Monitor settings (Cont = 69, Brightness =25, and backlight=69)
- **W/L** adjustment of individual images (default can be stored to change the next acquisition values)
- **Filter:** Recursive filter, stack filter and edge filter
- **Mag 2:** Electronic image magnification (Option with three level I.I.)
- **Zoom:** To enlarge a selected image detail (Option)

- **Grayscale Inversion:** To display an image with negative grayscale
- **Iris Collimator:** Touch control for iris collimator allows tight collimation
- **Slot Collimator:** Touch control for closing off the blooming effects at the edge of the image in hip and long bone procedures
- **Change orientation of image on the live monitor:**
 - **Reverse Top/Bottom:** Vertical image
 - **Reverse Left/Right:** Horizontal image reversal
 - **Image Rotation:** Rotate image to align the image for correct viewing



NOTE

Any adjustments that are applied to a live image on the live monitor remain valid for all subsequent live images until you choose other settings.



NOTE

Any adjustments that are made to a recalled or none live image will only apply to that image and will not apply when radiation is started again.



NOTE

When you save an image, it will be saved with all rotations, reversals, filter settings, and markers, etc. All the modifications to the live image when stored are visible when the image is displayed as a thumbnail in the mosaic.



NOTE

When you save an image, it will be displayed on the reference (right) monitor as a thumbnail image on the lower part of the screen as well as on the larger display area.

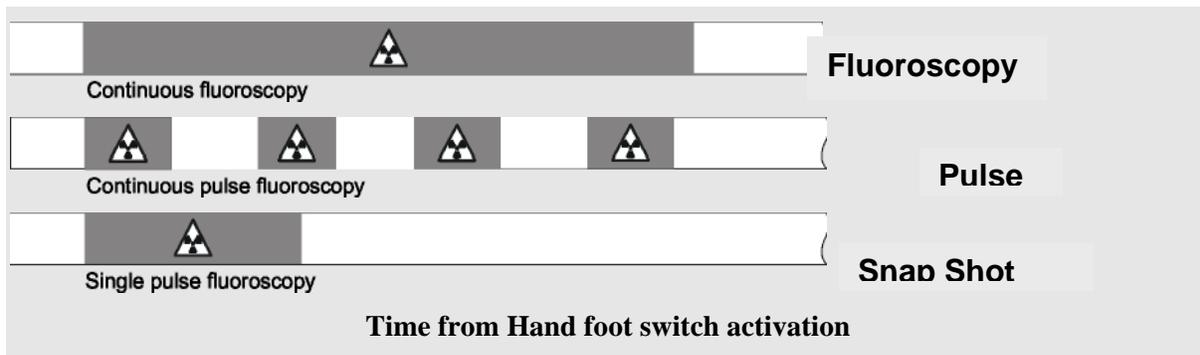
7.9 FLUOROSCOPY MODES

7.9.1 CONTINUOUS AND PULSE FLUOROSCOPY

Both fluoroscopy modes work with automatic exposure rate control (AERC), unless manual exposure rate setting has been selected explicitly by the user.

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

Automatic exposure rate control (AERC) is active on all three Fluoroscopic modes, and reduces the radiation burden of both patient and operating staff to a minimum and prevents overexposure of the screened body region.



7.9.1.1. CONTINUOUS FLUOROSCOPY



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

- Press the **Fluoroscopy** button.

The preset selected organ/anatomical program is indicated on the touch control panel.

- Press the desired organ /anatomical program.
- Initiate radiation.

For each individual organ program, certain noise filter factors can be set for the continuous **fluoroscopy mode**. This is done by selecting the level from the touch screen.

- Please contact your service engineer if you wish to set or modify the filter factors for the low, med, high, levels.

7.9.1.2. PULSE FLUOROSCOPY



In pulse **fluoroscopy mode**, the system emits radiation pulses as long as you press the radiation hand or footswitch. Rate < 3 F/sec.

The pulse rate is fixed. The lower the pulse rate setting, the lower the radiation dose per second.

Pulsed fluoroscopy reduces the effective dose rate. Press the **Pulsed Fluoroscopy** button on the mobile stand and then press the hand or foot switch. Radiation is released for an interval of time, approximately, one to maximum of 3 pulses per second depending on program time set for pulses.

Press the **Fluoroscopy** button on the mobile stand keyboard or press the **Pulsed Fluoroscopy button** on the touch panel to return to standard fluoroscopy. When programmed by a service engineer, pulsed fluoroscopy can make up to three pulses per second.

- Please contact your service engineer if you wish to set or modify the **pulse rate factor**.

7.9.2 SNAPSHOT

In **snapshot** mode, the radiation time does not depend on how long you press the radiation switch. For each organ program, a specific AERC characteristic is stored on the system for the Snap Shot or digital radiography mode. The fluoroscopy parameters are adjusted using the respective AERC characteristic, and radiation is terminated automatically afterwards.



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



NOTE

Snapshot is only activated by the hand switch; it is **not** activated by the foot switch. Unless optional footswitch programming has been activated.

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

- Press the **Snapshot** button.
- Initiate radiation by pressing the hand switch. Factory presets of 8 mA fluoroscopy and maximum image integration produce images of excellent quality.
- To deactivate the **Snapshot** mode, press the **Snapshot** again to open the touch screen fluoroscopic selection or press one of the other fluoroscopic function buttons to select a new Fluoroscopy mode.



NOTE

When you activate the **Snapshot** mode, certain touch screen buttons will disappear from the touch control panel depending on the system options.

7.10 FLUOROSCOPY ANATOMICAL PROGRAMS

7.10.1 ACTIVATING ANATOMICAL/ORGAN PROGRAM

Press the displayed **Anatomical Program** button on the touch panel, the system will display all the **Anatomical Program** selections.

Press the desired organ program, the button is highlighted in yellow and the other buttons will close.

The selected **Anatomical Program** remains active until you choose another program. The corresponding button LED will light on the mobile stand keyboard.

If required, a number of supplementary functions can be combined with each organ program:

- Metal artifact correction
- Mag factor 23, 15, (Optional 10cm version of I.I.)
- Noise Filters
- Fluoroscopy modes

The following organ programs are available on the Touch Screen and the Mobile stand Keyboard:

7.10.2 BONE/EXTREMITY

The **Bones** organ program is optimized for visualizing any part of the human skeleton. It is used mainly in orthopedics.



7.10.3 PELVIS/ABDOMEN

The **Abdomen** organ program is optimized for visualizing any organ in the abdominal region. It is used e.g. in urology, for cholangiographies and for preparing dilatations and implantations.



7.10.4 HEART/THORAX

The **Heart** organ program is optimized for visualizing the heart and the thorax. It is used e.g. in heart surgery, pacemaker, and dilatations in the heart region.



7.10.5 LPD LARGE PATIENT ADIPOSE PATIENT FUNCTION

When the x-ray system is used on a large patient (for example, a patient who weighs more than 300 pounds), kV may run to the maximum setting (110 kV) and the resulting image may be too dark. If this happens, press the **LPD** button on the **DeskView** or the **Soft** button on the control keyboard of the mobile stand to maximize the system image capture. Since the image will be very noisy, system noise reduction will automatically engage at the highest setting. In most cases, this will result in an image of diagnostic quality. Noise reduction returns to the previously-selected level when another anatomical program is selected.



To activate the adipose patient function (LPD), do the following:

- Press the **LPD** The organ program buttons are displayed by the system, select the **LPD** button, the button is highlighted in yellow and the other buttons close. Pressing the **Soft** button on the mobile stand control panel will select the LPD button on the DeskView at the same time.

To deactivate the adipose patient function, do the following:

- Press any of the other Organ program buttons on the mobile stand keyboard to exit and enter the new organ program selection.

When deactivating the LPD button on the DeskView touch panel you press the **LPD** button again, the other Anatomical/Organ program buttons will appear, now select the new anatomical/Organ program button, the button will be highlighted in yellow and all the other buttons will be closed, and the **LPD** function will be off.

7.11 DIGITAL NOISE FILTERS

7.11.1 NOISE FILTER FACTORS

Operator may select any combination of filter levels by pressing the **NR noise reduction**.

The number of frames for each level of Low, Med, and high settings are done in the Configuration operating mode under Service Settings. You cannot make these individual pre-settings yourself.

- Please contact your service engineer if you wish to set or modify the filter factors for one or more organ programs.



7.12 LAST IMAGE HOLD NOISE FILTER

Operator may select combination of filter levels by pressing the **LIH noise reduction** button on the touch panel.

The number of frames for each level of Low, Med, and high settings are made in the Configuration screen under the Service Settings. You cannot make these individual presetting yourself.

- Please contact your service engineer if you wish to set or modify the filter factors for one or more organ program.



7.13 METAL ARTIFACT CORRECTION



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

The **metal artifact** correction function can be combined with each organ program.

In the case of collimation using the Slot or Iris collimator using the **METAL** button may help restore the black level in the image.



To activate the **Metal Artifact** correction function, do the following:

- Press the **Metal** button. The button is highlighted in yellow.

To deactivate the Metal Artifact correction function, do the following:

- Press the **Metal** button again. The button returns to its gray color, and the **Metal Artifact** correction function is deactivated.

7.14 MANUAL EXPOSURE RATE SETTING

The tube voltage and the tube current are usually adjusted automatically by the system's automatic exposure rate control. You may, however, set the exposure rate also manually, if necessary. The Manual exposure mode can only be set from the Mobile Stand control panel.



WARNING

To protect the health of patients and staff against high radiation dosages, the **manual dose rate setting** mode remains blocked until you have initiated radiation in one of the fluoroscopy modes with automatic exposure rate control at least once.

Only use the **manual exposure rate setting** mode in exceptional circumstances. The automatic exposure rate control provides optimum image quality whilst minimizing the dose rate.



kV



To generate an image in the manual exposure rate setting mode, do the following:

- Select the desired organ program
- Select one of the fluoroscopy modes with automatic exposure rate control:
 - Continuous Fluoroscopy
 - Pulsed Fluoroscopy
 - Snap Shot
- Initiate radiation for a brief moment.
- Press the **Manual Exposure Rate Setting** button on the mobile stand and touch screen control keyboard. The kV value that has been automatically determined is saved for subsequent fluoroscopic initiations, and the system switches to the manual mode.
- Select the desired kV and mA values using the kV **Up Arrow** and **Down Arrow** buttons located on the Mobile stand control keyboard. Each time you press an arrow button, the value is increased/decreased by 1 kV, and the mA follows the preset kV/mA curve for the selected anatomical program selected.
- Initiate radiation.

To deactivate the manual exposure rate setting mode, do the following:

- Press the **Manual Exposure** button on the mobile stand control keyboard or on the DeskView touch screen.

7.15 SCREEN DISPLAY DURING RADIATION

7.15.1 FLUOROSCOPIC



While radiation is active, the current fluoroscopic image is displayed on the live monitor screen and the **DeskView** touch screen. See Fig 7.2.

When you terminate radiation (by releasing the hand or foot switch), the last fluoroscopic image is displayed on the live monitor and the DeskView touch screen (Last Image Hold).

This image remains displayed until it is replaced by a new fluoroscopic image or a reference image is transferred to the live monitor display. See Fig 7.2.

7.15.2 FLUOROSCOPY FACTORS

During the exposure, the tube voltage and the tube current are determined by system, and the technique values are shown on the displays for **Voltage** and **Current, Fluoroscopy time, and AKR (dose)** in the upper left corner of Fig 7.2.

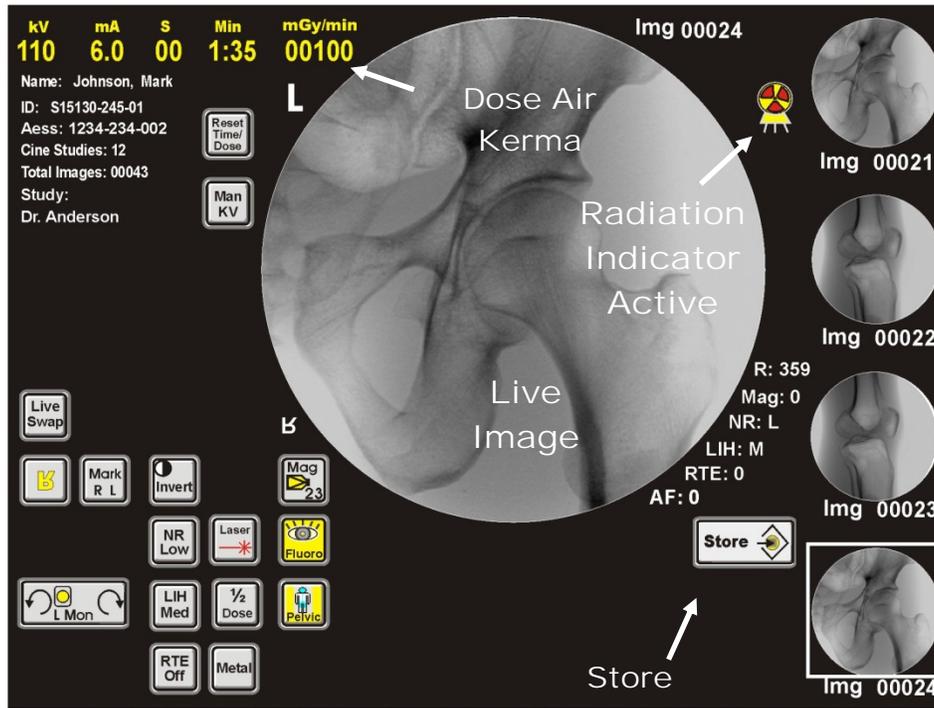
During the exposure (fluoroscopy or direct radiography), the yellow radiation **Warning Lamp** on the monitor assembly and the **X-ray Symbol** on the DeskView control panel are illuminated. See Fig 7.2.



NOTE:

AKR dose display is not active and is not displayed on systems manufactured before June 2006.

Fig 7-2 DeskView-Radiation Lamp On, Image Displayed In Center



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8.0 USER FUNCTIONALITY

8.1 SPECIAL FUNCTIONALITY

The system is equipped to perform various special functions. These functions are activated by pressing the buttons shown below.

8.1.1 METAL

If any metal is in the path of the x-ray, the displayed image will be too bright and patient detail will be lost. To compensate, press the **Metal** button on the **DeskView** or **Mobile Stand** Control Panel to add contrast to the image.



8.1.2 1/2 DOSE

One-half dose is the standard mode. It is automatically selected when the **ZIEHM QUANTUM** is turned on.

The ½ (One-half) dose function reduces the amount of working dose used by 50 percent. If you need access to full dose, press the **1/2 Dose** button again to turn it off. This button is only available on the mobile stand control panel.



8.2 MAGNIFICATION ELECTRO-OPTICAL IMAGE INTENSIFIER

The system's image intensifier can magnify images electronically. Press the **Mag** button on the **DeskView** or **Mobile Stand** Control Panel keyboard to magnify the image 1.5 times.

The **Mag** button LED on the mobile stand will illuminate to show that zoom is on. Systems that have the optional Triple Mode image intensifier can zoom 1.5 and 2.0 times.



8.1.3 MOBILE STAND CONTROL PANEL:

Press the **Mag** button once to select level one zoom (1.5). The **Mag** button's indicator light will illuminate to show that level one zoom is on. Press the **Mag** button again to select level two zoom (2.0), The **Mag** button's indicator light will flash to show that level two zoom is on.

8.1.4 DESKVIEW TOUCH PANEL:

Press the **Mag** button to open the selection of available image intensifier **Mag** size. Depending on the Options of your system three could be two or three magnification modes (sizes) available.



NOTE

Mag 2 function is only available with Optional purchase of the three mode image intensifier.

8.3 IMAGE ROTATION

These buttons may not be active on the mobile stand control keyboard.

The DeskView Touch Panel **Image Rotation** buttons are active with the live monitor and removed for certain modes and functions where they are not active for that mode or function.



The Mobile control keyboard image rotation buttons are operational for left and right monitor rotation. Only with ZQ_Global version ≤ 2.50 .



NOTE

With Version below ZQ_Global 2.5.0 The user may notice that if both buttons are pressed that the image will continue to rotate in CCW or CW direction and can be stopped by simply pressing either the CW or CCW rotation button momentarily.

8.4 IMAGE REVERSAL / IMAGE MIRROR

These buttons are not active on the mobile stand control keyboard.

The Touch Panel **Image Mirror** button is active with the live monitor and is removed from the DeskView touch panel when certain modes and functions would not be active in that mode or function.



The two Image Mirror buttons on the mobile stand are not operable on the **ZIEHM QUANTUM**.



8.5 IRIS COLLIMATOR

The Iris Collimator can be manually opened and closed.

To **open** the Iris Collimator, press the **Iris Collimator Open**. Each press opens the collimator one step. To make a larger adjustment, press and hold the button down to advance through several steps.



To **close** the Iris Collimator, press the **Iris Collimator Close** button. Each press closes the collimator one step. To make a larger adjustment, press and hold the button down to advance through several steps.



To fully open the iris, briefly press both buttons simultaneously on the mobile stand control keyboard.

8.6 SLOT COLLIMATOR

The Slot Collimator can be manually opened, closed, and rotated.

To **open** the Slot Collimator, press the **Slot Collimator Open** button.



To **close** the Slot Collimator, press the **Slot Collimator Close** button



To **rotate** the Slot Collimator **counter-clockwise**, press the **Slot Collimator Counter-Clockwise Rotation** button



To **rotate** the Slot Collimator **clockwise**, press the **Slot Collimator Clockwise Rotation** button



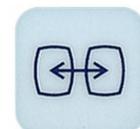
8.7 MARK IMAGE

Mark Image function turns on the “**R**” for right or “**L**” for Left anatomical marker. The display is located in the touch panel display on the upper left corner of the live image display. On the main display monitor the "R" and "L" marker is displayed on the left monitor. Pressing the "R" or "L" button several times will cycle the "R" and "L" makers on and off. Turning the “**R**” or “**L**” maker display off will remove the Right (R) or Left (L) marker off.



8.8 LIVE SWAP

This button is not active on the mobile stand



NOTE

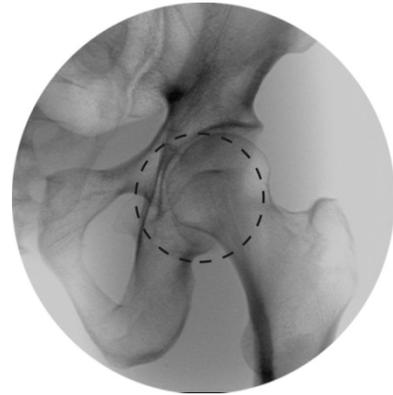
Live Swap should not be activated when the system is making radiation. Image flash may appear.

8.9 MONITOR L TO R

Press the **Center of Image** of the touch screen to transfer image from the left/live monitor to the reference or right monitor.

The image can only be transferred from left to right if the image was not yet stored or recalled, (live transit image).

In certain conditions the transfer of the image will be inactive for a particular mode or function.



8.10 MONITOR R TO L

Press one of the four **Image Icon's** on right side of the touch screen once to select image and recall image to the right monitor then touch the image icon a second time after a 1/2 to 1 sec delay to transfer image from the reference or right monitor to the live or left monitor.

In certain conditions the transfer function may not be active for particular modes or functions.



8.11 INV VIDEO

The INV Video function can be used with both stored images and real-time fluoroscopy.

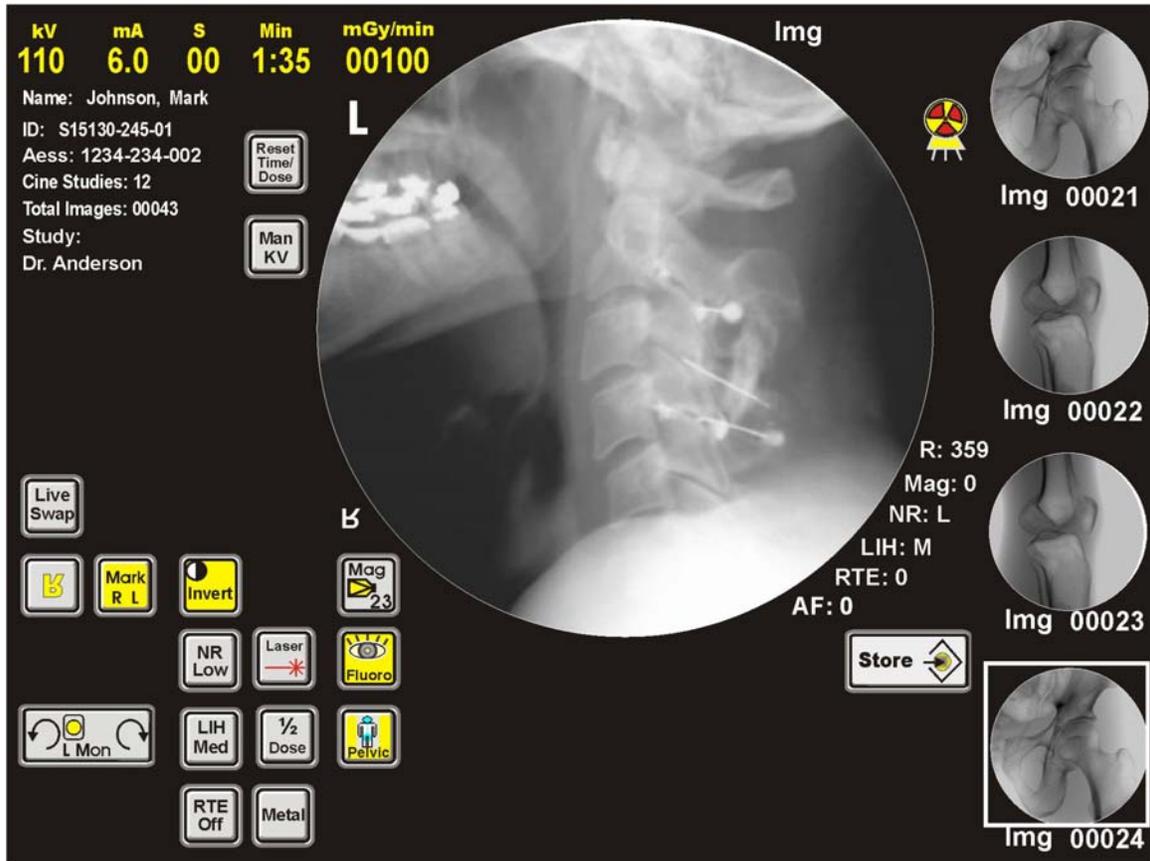
Press the **INV Video** button to reverse the light and dark areas of the image and create an image that resembles a film negative.

The effect can be changed latter by recalling the image and pressing the **INV** button again.

When you press store button the image will be stored with the **INV** image attribute so the image will be recalled with the Black and White levels inverted.



Fig 8.1: Fluoroscopic radiation with Invert on and Dose display /rate



8.12 STORING/SAVING



CAUTION

When the hard disk is full, the system will give a message that you need to delete patient images to free space on the hard disk.

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

To store/save the last image displayed on the live monitor to the active patient folder:

- Press the **Save** button.

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

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

Images can be stored to the system hard drive. When you press the **Image Store** button, the image on the Live/left monitor will be stored and copy of the image as a small Thumbnail will be display on the reference or right monitor and on the touch screen. Image number will be assigned to the image.

Use Image Store to:

- Save a live fluoroscopic image, Store on the Fly
- Save the last image held on the left or live monitor



NOTE

When storing images during Radiation (Live fluoroscopy) the images will not be displayed on the touch or the reference monitors until the fluoroscopic hand or footswitch is released. This will take a few seconds depending on how many images were stored during live Fluoroscopy.

8.13 STORE USB IMAGE



The system can store images directly to an external **Ziehm Imaging, Inc.** certified USB storage media. To store to the external USB media memory device you must first insert a certified USB memory Stick/Device, Thumb drive memory device, or USB mini thumb drive memory device.

When you have an image that is ready to be stored just press the USB button on the main Touch screen to store the image directly to the USB device

When you store an image to the external USB memory device the system does not make a copy to the system hard drive as a back up to the external image.



NOTE

User must Log In to the system before USB memory devices can store images. The system incorporates a feature of protection from unauthorized user removing medical images from the system.



NOTE

As there are many different types and sizes of USB memory media, and each different make and model requires different software drivers, to allow use of all makes and models of USB device is impossible. Therefore, **Ziehm Imaging, Inc.** will not guaranty that all USB media memory device will be compatible.

Please contact **Ziehm Imaging, Inc.** for list of certified USB devices. Ziehm Imaging may at its convenience supply at time of delivery a list of certified devices.



WARNING

Do not touch the USB or DICOM ports and Patient at the same time. Failure to observe this warning may result in serious injury to patient or operator.



WARNING

Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment.) Furthermore, all configurations shall comply with the system standard IEC 60601-1-1.

Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of IEC 60601-1-1. If in doubt, consult the technical services department of your local representative.

8.14 MOBILE STAND AND TOUCH INFORMATION DISPLAYS

The Mobile Stand Control Panel has two display windows:

1. The left window displays numeric kV and mA information, and exposure time (S).
2. The right window displays numeric and graphic information regarding dose, fluoroscopic time, and temperature, and includes fault and exposure indicators.

Left Display Window



Right Display Window



8.14.1. KV DISPLAY

The default setting is 75 kV. During fluoroscopy, the **ZIEHM QUANTUM** adjusts kV levels automatically using dose rate control circuitry, unless manually overridden. After fluoroscopy, the last kV value used is stored in the system and is shown in the kV section of the display window. See left display window above for sample of display values.

8.14.2. MA DISPLAY

The **ZIEHM QUANTUM** controls mA level in relation to kV level. The mA value is displayed in the left window during live fluoroscopy.

The last value used by the system is stored and recalled when the system returns to fluoroscopic mode. This value will continue to be used until either new kV values are entered or until a new operating mode is selected. See left display window above for sample of display values.

8.14.3. EXPOSURE TIME(S)

In Radiographic mode, the system sets the current to 20 mA and an exposure time from 0.1 to 4.0 seconds can be selected using the **Up/Down Arrow** button. This exposure time is then stored and displayed. See left display window above for sample of display values.

8.14.4. CGYCM2 / ERROR

The **cGycm²** display window has two functions one to show dose area product value in Grays. The other function provides the user with a way to see system error codes. The dose display function is not operational on the U.S. models. The error codes however will be displayed in this window. See right display window above for sample of display values.

8.14.5. MIN FLUOROSCOPY TIME DISPLAY



Fluoroscopy and radiography time are displayed in minutes and seconds. Every five minutes of fluoroscopic time an alarm will sound to warn the user that 5 minutes of fluoroscopic time has elapsed. This will continue every five minutes. The sound will not stop until the operator reset the alarm.

See right display window above for sample of display values.

8.14.5.1. AUDIBLE ALARM



After five minutes of radiation have accumulated, an alarm is triggered and an LED in the **Min** button begins to flash and the **Reset Timer** button turns red on the DeskView.

To turn off the alarm, press the **Min** button on the mobile stand or the **Reset Timer** button on the DeskView touch screen. The LED and the Reset button will continue to flash on the mobile stand; the touch screen button will turn red. To turn off both the alarm and the LED, press and hold the **Min** or **Reset Timer** button.



CAUTION

If you do not switch off the alarm after 30-60 seconds max., radiation could be terminated automatically (Can be set by service technician)



WARNING FUNCTION

In order to prevent radiation from being accidentally generated over a long time, the system has a warning function. After each 5 minutes of elapsed total radiation time, the system issues an interval warning at every 5 minutes of fluoroscopic time accumulated up to maximum of 99 minutes.



NOTE:

Pressing and holding the **Min/Reset Timer** button for more than 2 seconds clears both Radiation Timer and the Dose displays on the control panel and touch panel indicator displays.

8.14.6. GENERATOR OVERHEATING

If the generator overheats, the system will automatically:

1. Flash the overheating indicator,
2. Revert to fluoroscopy mode, and
3. Limit tube voltage 0.5 mA.

If the generator reaches a high level of thermal loading the system will flash the thermometer symbol at which time the system will reduce the generator mA to 0.5 mA, at which time the image may become dark and noise. The generator will require cooling time to recover and be able to perform at normal operational technique levels.

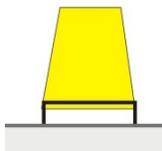
If the indicator does not stop flashing, turn off the **ZIEHM QUANTUM** and let the generator cool.



NOTE:

Systems are programmed to continue operating fluoroscopy until the maximum heat overload is reached, and then turn off fluoroscopy. The indicator will flash as the generator begins to overheat but, when the generator reaches the maximum heat limit, it will automatically turn off fluoroscopy.

8.14.7. RADIATION EXPOSURE INDICATOR



Active radiation (both during fluoroscopy and direct radiography) is indicated by three optical signals:

- The yellow radiation warning lamp on the dual monitor assembly is illuminated when radiation is being released. In the case of Pulse Fluoroscopy the Radiation indicator will pulse with the radiation on time.



–The **X-ray symbol** on the Desk View touch control panel is illuminated when radiation is being released. The Radiation Exposure indicator is located in the right upper area of the touch panel. The symbol on the touch screen is only visible when radiation is on. In the case of Pulse Fluoroscopy the Desk View Radiation indicator will be on all the time. There may be times where this indicator will be on longer and come on a bit latter than the other two radiation indicators this is normal.



–The third **X-Ray symbol** radiation indicator is located on the Mobile Stand control keyboard on the right side in the technique display area. The indicator is illuminated when radiation is being released. In the case of Pulse Fluoroscopy the Radiation indicator will pulse with the radiation on time.



NOTE:

The Radiation lamp indicators may not all come on at the exact same time. There can be a very short time period just before and after radiation is on, this is normal and is a result of having three separate back up indicators for the system.

There can be some cases where the radiation indicators are on but the radiation is not active. In these cases it would indicate a failure in the system and would require re-starting the system. If this occurs again after turning on the system and performing radiation, the operator should then call for service repair.

8.15 DESKVIEW DISPLAYS FOR KV/MA, TIME AND DOSE

The DeskView and Control Panel have similar technique and system displays. The touch panel has one main area of display for the technique values of kV / mA, radiograph exposure time Fluoroscopic time and Air Kerma dose display. The control panel displays dose in “mGy/min” or “mGy”.



8.15.1. kV:

Displays will show the kV of the system both in automatic and manual kV selection modes of dose control.

8.15.2. mA:

Displays will display the selected mA for both Fluoroscopic and radiographic exposure modes.

8.15.3. S or Seconds:

Displays for the radiographic exposure time.

8.15.4. Min:

Displays the actual fluoroscopic accumulated time.

8.15.5. mGy / mGy/min: (Active only on system manufactured after June 10, 2006)

During the exposure, the **air Kerma rate** display showing the current air Kerma rate in mGy/min. appears on the control panel. Accumulated air Kerma readings of the fluoroscopy, pulse fluoroscopy and radiographic exposure modes are displayed when ever the user releases radiation.

8.16 LASER AIMING DEVICE



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

The laser targeting 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 targeting device is a Class 2 laser product according to IEC 60825-1:2001. and FDA 21 CFR, Subchapter J, Section 1040.10 - 11



NOTE:

The laser is a class II laser product, subject to 21 CFR Subchapter J, 1040. Its peak power is <1 mW, and operates at a wavelength of 635 nm.

You must comply with all operating safety precautions when using the laser device. The maximum output of continuous laser radiation, measured at the beam exit, is <1 mW. The wavelength of the emitted radiation is 635 nm.

The laser Aiming device generates a laser-beam crosshair, the central point of which marks the position of the central X-ray beam on the patient.

For safety, the laser targeting device is switched off automatically after 1 minute.

Laser Class II in accordance with FDA 21 CFR, Subchapter J, section 1040.10-11.

Please observe the provisions of IEC 60825-1:2001, Section 3, “Guidelines for the User” for operation of the Laser Aiming device.



WARNING:

DO NOT stare into the laser beam! Eye damage may result! The use of optical instruments with this product increases eye hazard.

8.16.1. RANGE OF APPLICATIONS

You can use the laser targeting device for the following tasks:

- As alignment aid for positioning the C-arm
- For foreign body localization –As a targeting aid for nail fixations

8.16.2. POSITIONING AID

The laser targeting device allows you to locate and position the C-arm to anatomical locations on the patient without having to initiate radiation:



Press the **Laser** button. A laser-beam crosshair is generated, the central point of which corresponds to the position of the central X-ray beam.

Position the C-arm in such a way above the patient that the central point of the laser-beam crosshair is exactly in the center of the region to be screened.

8.17 DOSE DISPLAY FOR AKR AND ACCUMULATED AIR KERMA

8.17.1. AKR /Cumulative Air Kerma Dose Display (Active only on system manufactured after June 10, 2006)

The **ZIEHM QUANTUM** calculates the dose values based on the kV, mA as well as time of the radiation exposure. The display automatically changes between live display of **Air Kerma (AKR)** or the **Cumulated Air Kerma** values (**AKR x Fluoroscopic Time**) automatically sets the decimal point according to the dose rate and the accumulative values depending on whether radiation is on or off. This also includes the dose for all images which have not been saved but are part of the radiation accumulated since the last reset of the **Dose/Timer** display. See also **Section 12** technical information of this manual.

8.17.2. DISPLAY FUNCTIONS:

The AKR/Cumulative air Kerma display performs two functions for displaying the dose the patient is receiving or has received.

- Radiation on: The system will calculate the **AKR (Air Kerma Rate)** or live dose rate based on the displayed kV, mA. The air Kerma is displayed in units of **mGy/min** and will continue to display at least once every two seconds until the user /operator releases the radiation switch.
- Radiation is turned off: The system will display the cumulated air Kerma dose value within 5 seconds with units of **mGy**.

8.17.3. DOSE DISPLAY USER/OPERATOR

Using and resetting the Dose display:



- Activate a patient by entering a new patient in the system or recalling and opening a previous patient file.
- Before starting radiation on a patient Press the **Min or Reset Timer** button for more than 2 seconds to reset the dose and timer display to zero (0).
- When radiation is released for any of the following radiation modes **Fluoroscopy, Pulse Fluoroscopy, Snap Shot or Radiographic**, the total dose received by the patient is automatically updated in the **Dose** display irrespective of the mode.
- As part of completing an exam it is advised that the user store an image at the end of the exam that represents the total cumulative dose for the exam as a means of documentation. Press the “**Store**” button to capture the image and dose reading.
- The air Kerma display can also be automatically reset when a new patient file is selected; this option is set in the system configuration screen.

8.17.4. RESET DOSE DISPLAY

To reset the Fluoroscopy Time and Dose display, press and hold the **Min or Reset Time/Dose** button for 2 sec. on the DeskView or mobile stand.



CAUTION:

Not resetting the dose display just before starting a new exam on a new patient can result in incorrect dose reading for that patient.



NOTE:

The Dose value stored for each image will be the accumulated **cGy** dose value of the system at that moment the store button is pressed. This means each image stored will have a different total accumulated value for dose.

The last image stored by the user will have the highest dose value associated with it, but not necessarily the maximum dose value for the complete patient exam.



NOTE:

Re-storing a previously stored image after post processing will not change the dose value associated with the image.



NOTE:

During Snap shot and Pulse Fluoroscopic imaging the system will display the AKR value during the exposure; however there may be some flicker to the display as the pulse operation and the snap shot operation do not allow enough time for the display to become steady during radiation on. The cumulative values will be displayed with in 5 seconds after releasing the radiation switch.



NOTE:

Pressing and holding the **Min/Reset Timer** button for more than 2 seconds clears both Radiation Timer and the Dose displays on the control panel and touch panel indicator displays.



NOTE:

The air Kerma display can also be automatically reset when a new patient file is selected; this option is selected in the system configuration screen.

8.18 IMAGE FILTERS:

8.18.1. RTE (REAL-TIME EDGE ENHANCEMENT)

The RTE function increases the edge sharpness of anatomical structures in images. This function provides four levels of adjustment: Off, Low, Med, and High.

The RTE selection will also enhance in a post-processing function with the replay of the Cine DSA image sequence or a single recalled image.



Press the **RTE** button toggles between RTE Off, Low, Med, and High, edge sharpness.

- 1 = Off
- 2 = 10 %
- 3 = 20%
- 4 = 30%

Once pressed, the monitor displays the message “EDGE” in the live monitor. Best results are obtained when a noise level of at least Edge 1 is used.

8.18.2. NOISE REDUCTION



The amount of noise in fluoroscopic images can be reduced by three levels: NR Low, NR MED, and NR HIGH. The **Noise** button can be pressed before or during fluoroscopy.

Noise reduction is accomplished by using weighted frame averaging of the current and previous images, which may cause an increase in image lag-time in the video display. It is not a post-processing function and cannot be used to change a previously stored image.

When the **Noise** button is pressed, the message “NR LOW, NR MED, and NR HIGH” is displayed in the left monitor.

8.18.3. LIH NOISE (LAST IMAGE HOLD NOISE)



The LIH Noise reduction function reduces noise in the image when the radiation switch is released. It is used to reduce noise and distortions that arise from the movement of the C-Arm or patient during a fluoroscopic procedure. It is not a post-processing function and cannot be used to change a previously stored image.

The system may be configured to apply low noise reduction for live images and a higher level of noise reduction when the foot switch is released.

There are four LIH setting available: LOW, MED, HIGH, and OFF. If you do not wish to have the image displayed on the monitor after the foot switch is released, press the **LIH Noise** button several times until the message “LIH OFF” is displayed on the right monitor and the button is not highlighted in yellow.



NOTE:

The LIH function can be set to a default value in the Service Menu. This must be performed by certified Service personnel.

8.19 AUTO FUNCTIONS



The Auto function has two modes of operation. You can configure the **ZIEHM QUANTUM** so that a new image will be stored or transferred automatically as soon as you terminate radiation.

Simply press the Auto Function button to open all the auto functions available for the particular system configuration.



NOTE:

Some of the Auto functions may not be available depending on the configuration of your system and optional features that may or may not be available on a particular system model.

8.19.1. SETTING AUTO STORE:

To activate the Auto store function, do the following:

- 1) Press the **Auto Function** button. The **Auto store** function buttons will be displayed in a row.
- 2) Select **Auto Store**, the **Auto Store** button is highlighted in yellow. The un-selected buttons will then close.

Additional activation of Fluoroscopic radiation will save a new image automatically as soon as the user release the foot or hand switch.

When Active Auto Function button is indicated by yellow color, and is indicated by a small message below and to the right of the image on the touch screen panel.

To deactivate the Auto Store function, do the following:

- 1) Press the **Auto Store** button.
- 2) The **Auto Function** buttons will be displayed in a row.
- 3) Select **Auto OFF**, Auto **Function** buttons are closed.
- 4) The **Auto Store** function is deactivated. The **Auto Function** button returns to its inactive gray color.

8.19.2. AUTO OFF

All auto functions are inactive when the Auto function button is not highlighted in yellow.

8.19.3. AUTO STORE

Auto Store automatically stores images on the left monitor to the hard drive, when the exposure switch is released. If there is no more space on the hard drive, a warning is displayed whenever an attempt is made to store an image to the hard drive, whether by using the Auto Store function or the Store buttons. To make more room on the hard drive delete images from the hard drive.



NOTE:

Auto Store function will automatically store image to the hard drive and transfer image to the reference or right monitor as part of the auto store function

8.19.4. AUTO TRANSFER

Auto Transfer automatically transfers images from the left monitor to the right monitor. The last image on the left (live or process) monitor is transferred to the right (or reference) monitor the next time fluoroscopy is initiated.

8.19.5. EXIT AUTO

To exit Auto Store functions, presses the Auto Function button then select the Auto Off button.

8.20 POST PROCESSING FUNCTIONS

With all Post processing functions you can process or make changes to the transient image (meaning an image that was captured at the end of fluoroscopy and is not yet stored) or to a recalled or reference image.

There is a difference between these two sets of images. The reference or recalled image can have all ready stored image processing attributes such as **invert, window/ level**. As a recalled image you may wish to make additional changes or remove a change to an image; however doing so would or could affect the next fluoroscopy image captured as they would affect both transient and live images.

Therefore, we have separated the live or transient image from the effects of the recalled image with regard to the image processing operations. (**Invert, W/L, Image mirror, Crop, Zoom**)

When you select a recalled image the system will only effect and display changes to the recalled image, therefore with regard to **W/L** the values changed on the image will not affect the next captured image.

However, if the operator were to make fluoroscopy and turn on Invert the change would affect the image

If the user/operator were then to select **W/L** for a live or captured transient image the changes would then also affect the next captured image, but would have no effect on the recalled image.



NOTE:

Any adjustments which are applied to a live image on the live monitor remain valid for all subsequent live images until you choose other settings.



NOTE:

Any adjustments which are made to a recalled or none live image will only apply to that image and will not apply when radiation is started again



NOTE:

When you save an image, it will be saved with all rotations, reversals, filter settings, and markers, etc. All the modifications to the live image when stored are visible when the image is displayed as a thumbnail in the mosaic

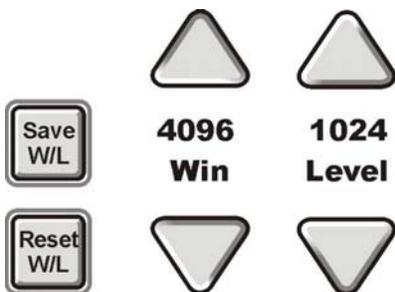
8.20.1. W/L (WINDOW LEVEL)



Pressing the **W/L** button changes the contrast of the video image by changing the window of gray scale. It modifies the brightness of the video by changing the level of brightness within the window of gray scale.

When the **W/L** button is pressed, the Live and DeskView displays the values in relative numbers to the level set.

8.20.1.1. ADJUSTING WINDOW



Press the **Left UP** Arrow button to increase the image's relative contrast scale. Press the **Left DWN** Arrow button to decrease the image's relative contrast scale.

8.20.1.2. ADJUSTING LEVEL

Press the **Right UP** Arrow button to increase the image's relative brightness. Press the **Right Down** Arrow button to decrease the image's relative brightness.

8.20.1.3. USING THE WINDOW/LEVEL FUNCTION

1. Select an image to be windowed and leveled.
2. Transfer the image it to the live monitor using the R to L monitor transfer button or just

double tap the image on the DeskView to have it become the active image.

3. Press the **W/L** button. The system will open the adjustment buttons. Use the function buttons to adjust the image contrast and brightness level to a relative image level. The image can then be stored to the hard drive, transferred to the right monitor, USB device or DICOM server.
4. Press the **Reset W/L** button to return the image to its original contrast and brightness levels.
5. To save the new window and level values as the new defaults for image display press the **Save W/L** button.
6. To exit the Window Level function, press the **W/L** button again or one of the other post processing buttons to close **W/L** and open the new function.

8.20.2. INVERT



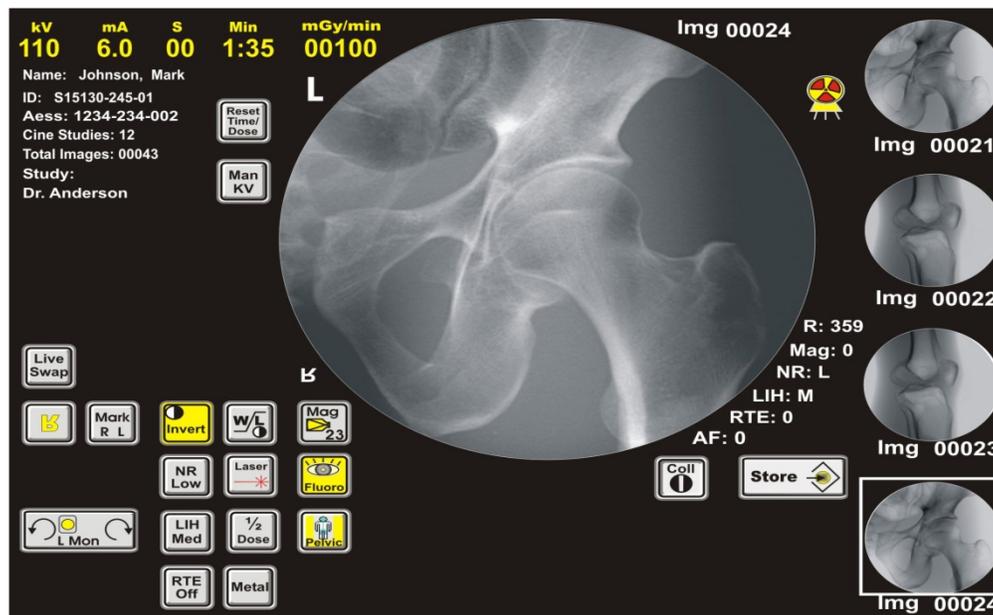
The **INVERT** Video function can be used with both stored images and real-time fluoroscopy.

Press the **INVERT** Video button to reverse the light and dark areas of the image and create an image that resembles a film negative.

The effect can be changed latter by recalling the image and pressing the **INVERT** button again.

When you press store the image will be stored with the **INVERT** image attribute so the image will be recalled with the Black and White levels inverted.

Fig 8.2: INVERT Touch Screen Display



8.20.3. IMAGE CROP



The Image **CROP** function collimates the image systems electronic shutters to **CROP** out unwanted parts of the image.



Positioning the Electronic Shutters

The electronic shutters are located just outside the image circle. The shutters are positioned with the **UP/DOWN, LEFT RIGHT** Arrow buttons in the following manner:

- Close Vertically: press the **DOWN** Arrow button
- Open Vertically: press the **UP** Arrow button
- Close Horizontally: press the **RIGHT** Arrow button
- Open Horizontally: press the **LEFT** Arrow button



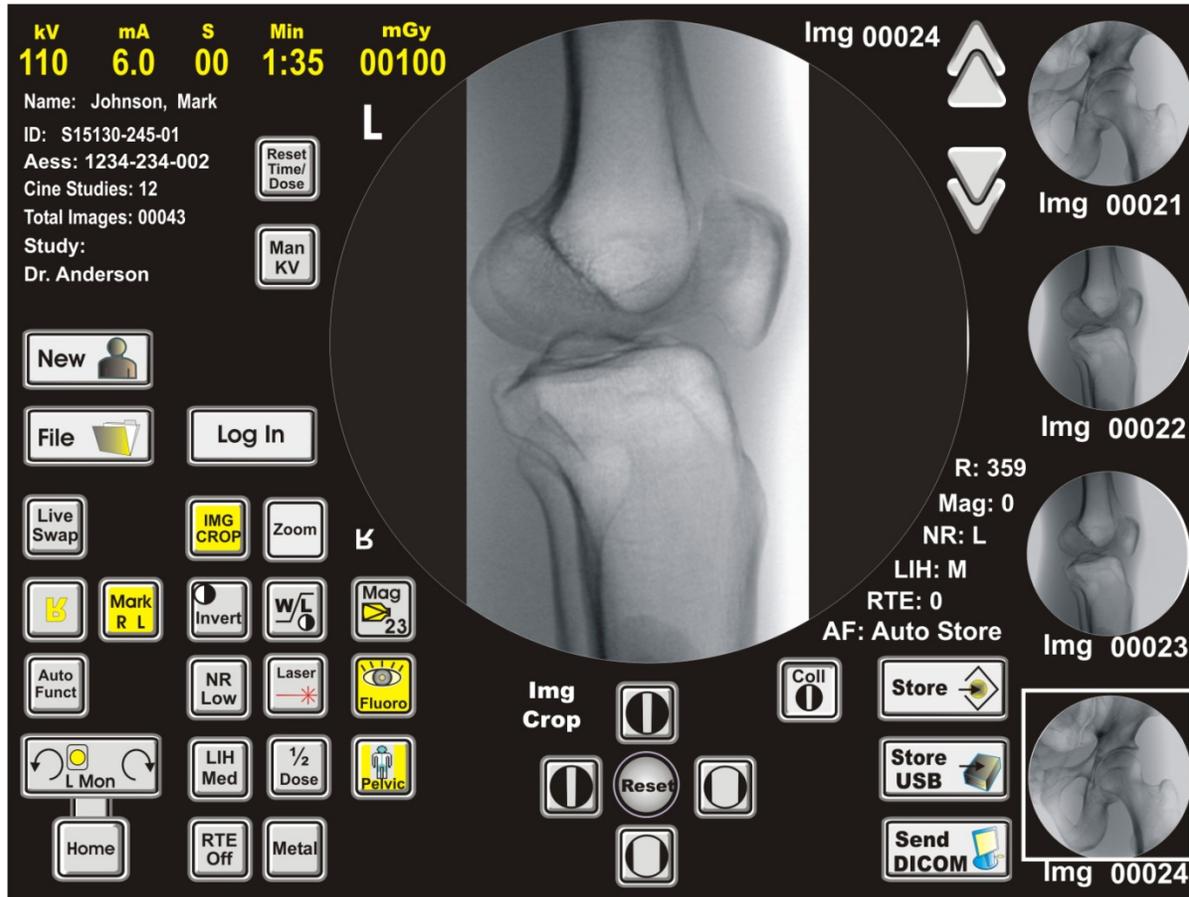
Store Image Crop

Press the **Image Store** button to store the cropped image. The image is stored with the crop area and when recalled will have this as part of the image

Transfer Image Crop

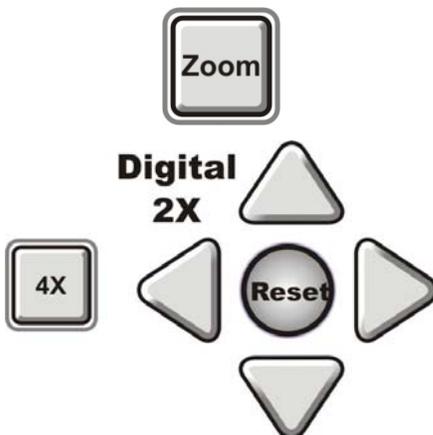
When the shutters are positioned correctly, Touch the center of the touch screen image to transfer the image to the right monitor

Fig 8.3: IMAGE CROP Touch Screen Display



8.20.4. ZOOM (DIGITAL MAGNIFICATION)

The Live monitor will display a circle the size of the magnification factor **2X** or **4X** selected. The Arrow buttons for **UP/DOWN** and **RIGHT/LEFT** moves the Circle and the reference screen will display the area within the circle of the live monitor at the magnification factor



To activate the ZOOM mode:

1. Select Image or use the present image on the Live monitor
2. Press the ZOOM button
3. The image on the live monitor and DeskView will have a circular area that defines the magnification area that will be displayed on the reference display monitor.

The system selects 2X factor as the default setting for magnification

4. To increase magnification four times, press the 4X button. The window on the left window will be smaller, representing the area on the reference monitor.

Press the ZOOM button or press ESC to exit the function. The right monitor will continue to display the last magnified image.

Magnified images can be stored to the hard drive or USB storage device by pressing the respective store function. The operator can store the image to the patient file as a magnified image and can be recalled later and exported.

Fig 8.4: ZOOM Touch Screen Display

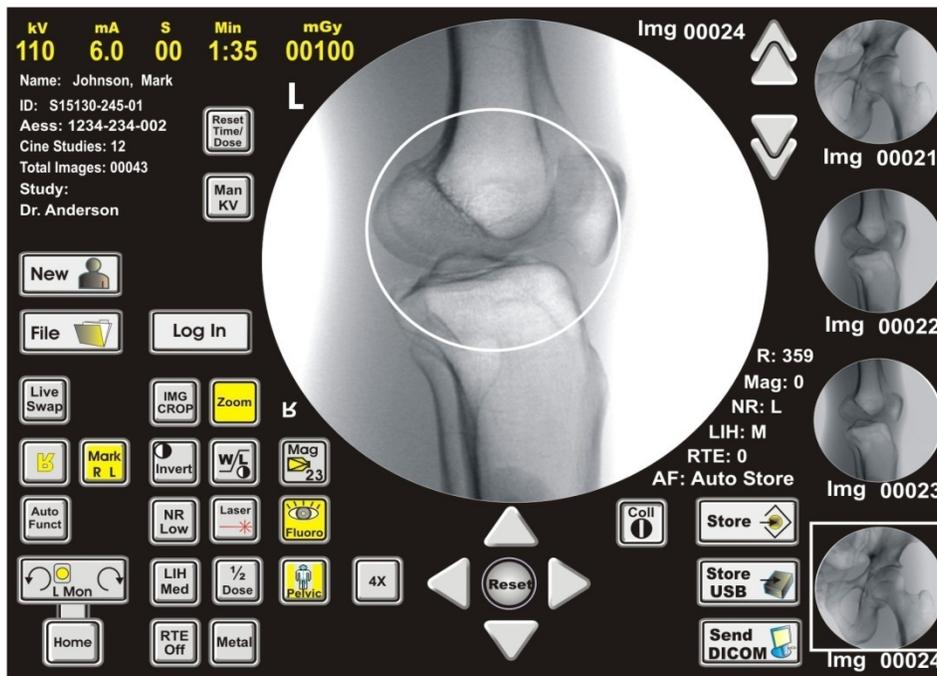
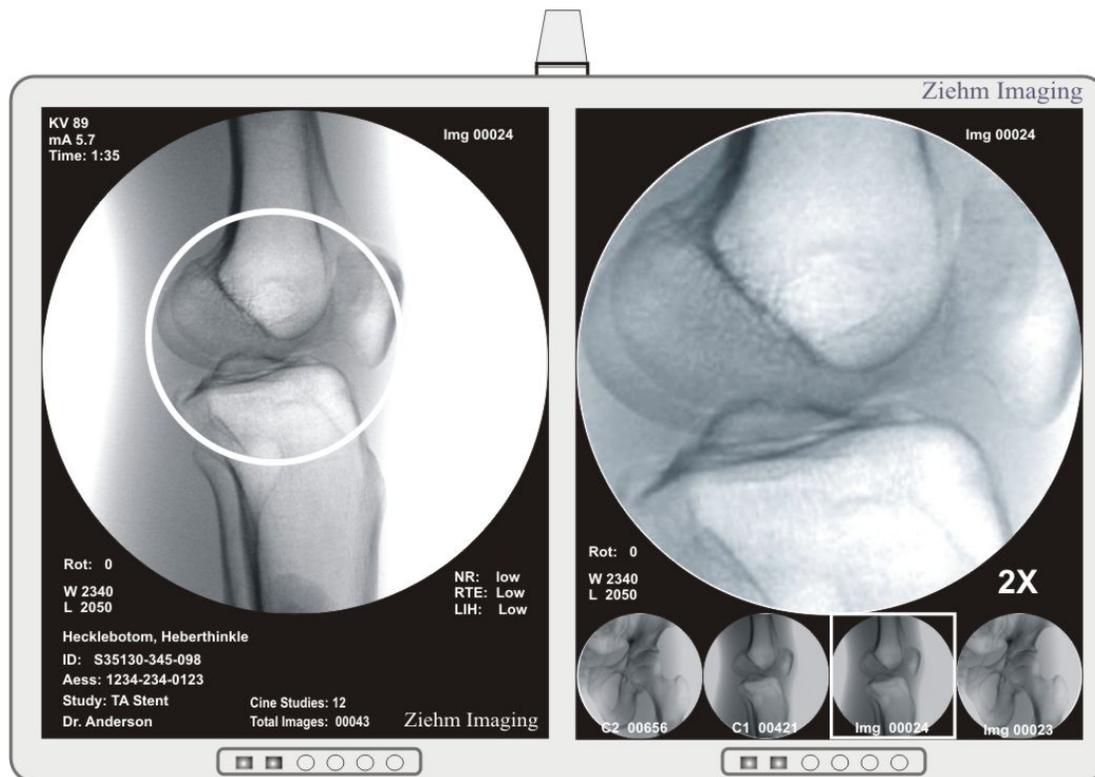


Fig 8.5: ZOOM Display Monitors and Operation



8.21 SELECTING THUMBNAIL IMAGES

8.21.1. THUMBNAILS

The **Thumbnail** images on the right side of the DeskView and on the lower part of the reference display monitor have corresponding image numbers for individual images or display a "C" and number to indicate a cine DSA run, as shown below.

The Reference images displayed will be the images for the active patient only. You cannot view other patient images in this screen.

Use the **Image Single** or **Page Forward/Reverse** buttons on the **DeskView** touch panel to move the selection box through the images. When the selection box moves off the screen, in either direction, the system displays another set of images.

For example, with images 1-4 displayed, moving the selection box from image 5 will cause the system to display images 5 to 8. See Fig 8.1 on the next page

The number of reference images to be displayed on the right side and lower portion of the display monitor depends on the number of stored images in the active patient file.

Until an image or cine run is stored in the patient file the touch screen and display monitor will not have thumbnail images to view.

8.21.2. TO VIEW OR SELECT A SPECIFIC IMAGES

Allows images of an active patient file to be viewed. If images have been stored for this patient)

Move the activity box to the desired image by touching the Thumbnail Icon Image or press the page **Image Scroll Arrow** buttons to view the next four images of the patient file.

8.21.3. DELETE IMAGE (ACTIVE ONLY WITH SYSTEMS HAVING SOFTWARE VERSION 2.5.0 OR ABOVE)

Deletes a single image or CINE run from the patient file.

Use the page **Image Scroll Arrow** buttons to open the next four images or if already on the screen touch the Thumbnail Icon Image to highlight the Image with the selection box menu. Once the image is highlighted by the selection box just press the **Delete** button to delete the selected image/or run.

No message is given for a single image delete operation

Confirmation Message is displayed for user when deleting a Cine/DSA run, the user must confirm delete request before the system will delete Cine/DSA run

8.21.4. STORE TO OR MAKE A COPY OF AN IMAGE

Copies images from patient file to USB or DICOM storage devices.

Place a **Ziehm Imaging, Inc.** Certified USB storage device in the USB port located on the front of the mobile stand. Select the image by using the **Image Scroll Arrow** buttons to highlight the image then press the store to USB or Send to DICOM button.

(Availability of these two functions depends on system option configuration)

Reference Thumbnail Images

Image Scroll Arrow keys,

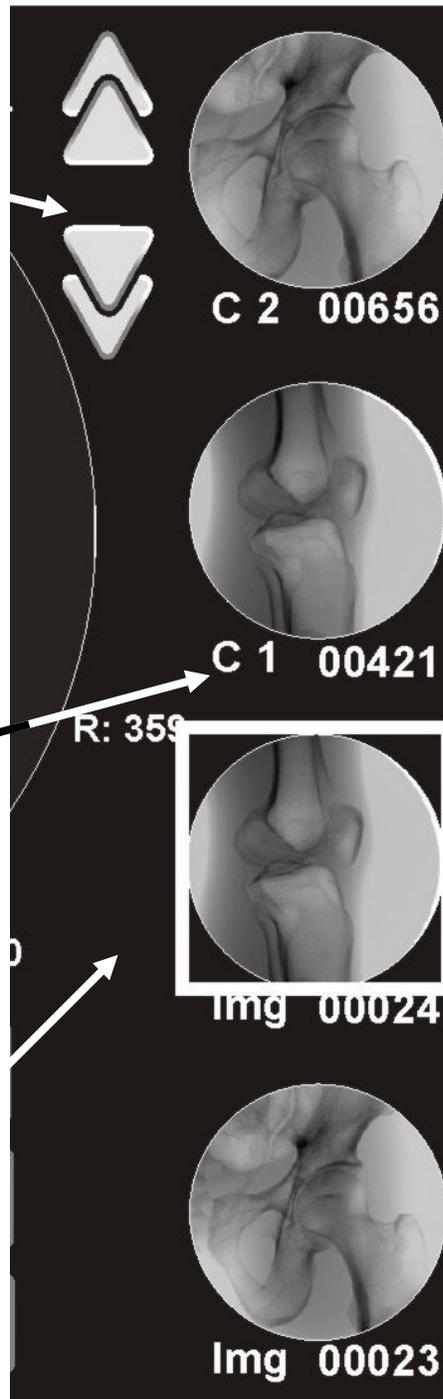
Selects the next four reference images from the patient file

These keys are available only when more than 4 images are stored in the patient file.

Reference Cine Run Image

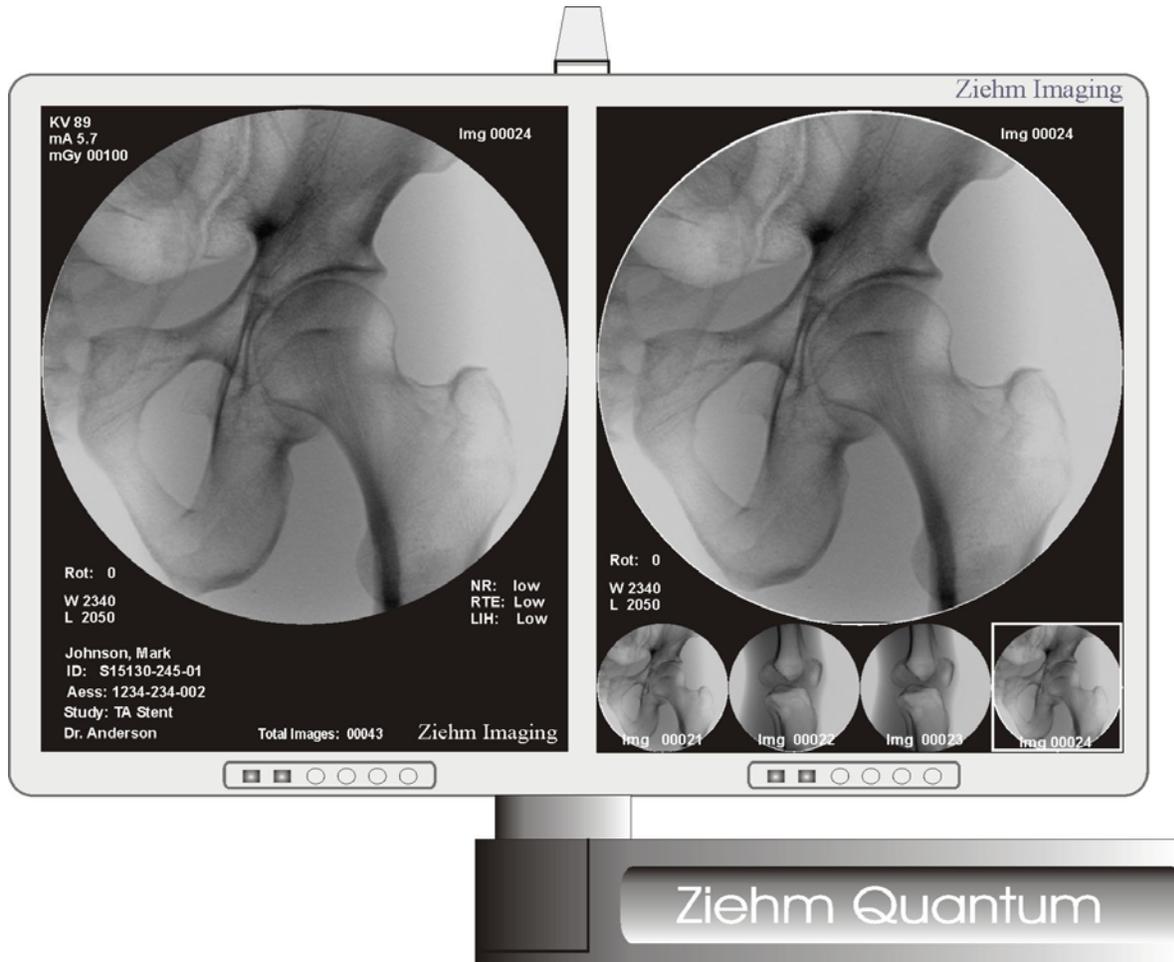
Reference Single Image

Highlighted Reference Image



8.22 MONITOR IMAGE DISPLAYS

Fig 8.6: Monitor Displays



Live monitor (Left in normal mode)

Reference (Right in normal mode)

The Left monitor is normally the live monitor and the Right monitor is normally the reference monitor.

In certain circumstances such as when **LIVE SWAP** button is active then the right and left monitors switches display functions and the live function display is on the right.

This mode of **LIVE SWAP** is used when the operator needs to view the monitors from either the right or left side of the image intensifier. The **LIVE SWAP** allows the technologist to switch the live monitor display to the outside monitor for better viewing.



NOTE:

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

8.23 DIRECT RADIOGRAPHY OPTION

8.23.1. OVERVIEW:

The **ZIEHM QUANTUM** can also be used for making direct radiographic film exposures.

Direct radiographies are only possible if your system is equipped with a film cassette holder (optional accessory).

8.23.2. FITTING THE FILM CASSETTE HOLDER

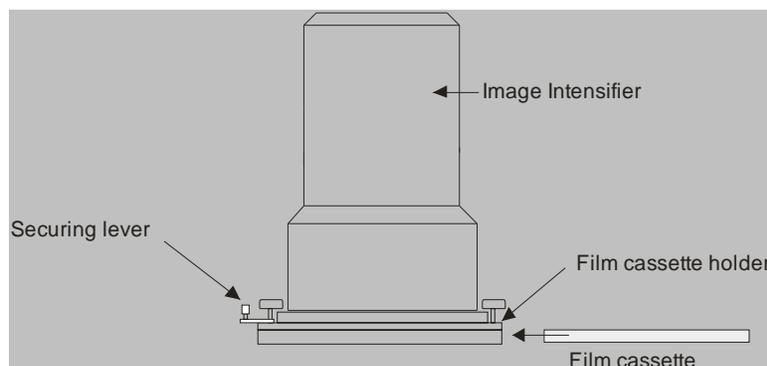
To fit the film cassette holder for direct radiographic exposures onto the image intensifier, do the following:

- Pull the spring-loaded securing lever on the film cassette holder outward.
- Slide the film cassette holder over the supporting ridge on the image intensifier.

8.23.3. MANUAL SETTINGS

- Release the spring-loaded securing lever.
- The securing lever engages above the supporting ridge.
- Insert film and cassette fully into the film cassette holder from the side.

Fig. 8.7: Fitting The Film Cassette Holder And Inserting The Film Cassette



8.24 MAKING A DIRECT RADIOGRAPHIC EXPOSURE (OPTIONAL)

For direct radiography, you can set the following maximum collimator apertures for the film or cassette size used:

- 24 cm; the visible image has a diameter of 22 cm
- 30 cm image intensifier (not available in the USA)

For tube voltage, use the value that the system has automatically selected during the previous fluoroscopy. If necessary, you can correct this value manually.

The **mAs** value (tube current in mA × time in s) is always set manually.

Set exposure time in **Seconds** using the **SEC** up/down arrows.

The tube current ranges from 20 mA. The system automatically adjusts this value to reach the manually set value. The exposure timer automatically updates the display from the manually set value and appears rounded to the first digit after the decimal point on the display.

To make a direct radiographic exposure, do the following:

- Press the **Radiation** Mode button on the main touch Screen.

The **Radiography** operating mode is activated. The buttons for controlling the direct radiography functions are displayed.



WARNING:

Make sure that the film cassette holder is properly attached to the image intensifier that the cassette cannot fall down onto the patient



NOTE:

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

Fig 8.8: Main Screen Radiography Operating Mode, DeskView Touch Panel.

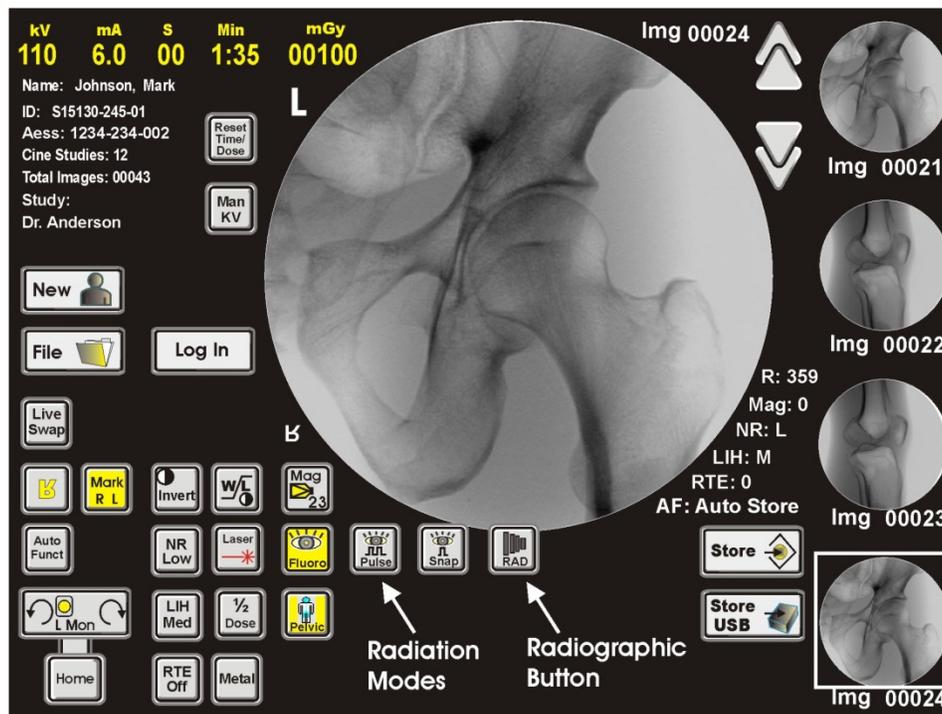
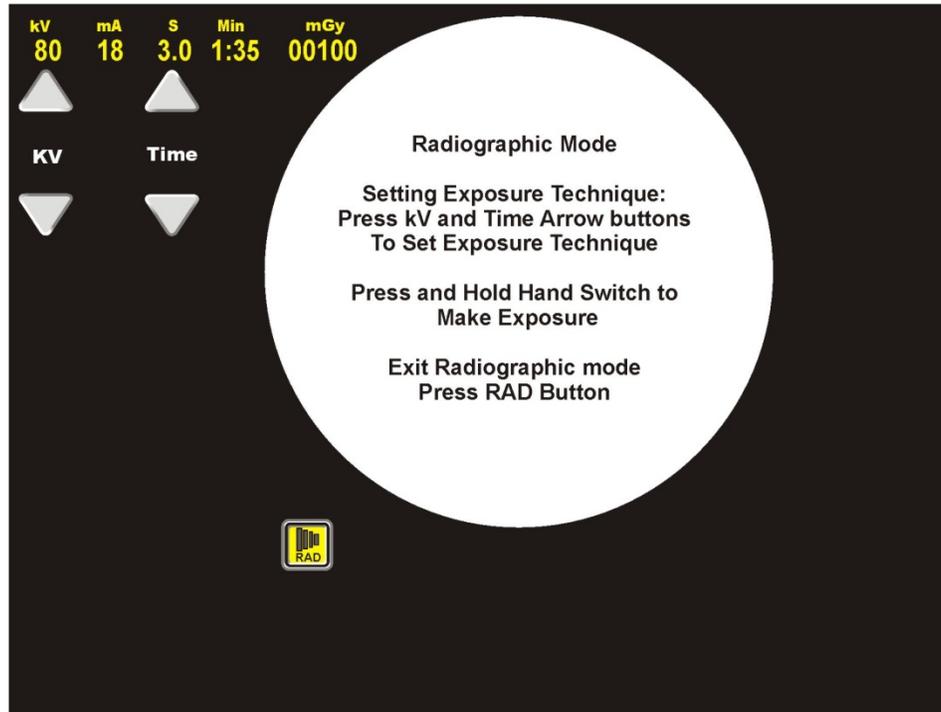


Fig 8.9: Radiography Operating Mode, DeskView Touch Panel



8.24.1. SET TECHNIQUE FACTORS:

- Set the desired tube voltage value using the kV arrow buttons. The selected value appears on the **Voltage** display. **Example 80 kV**
- Set the desired **tube current (20mA) × time (mAs)** value using the Time arrow buttons.

Example 3.0 Seconds or 20 x 3 = 60 mAs



- Initiate radiation using the hand switch. In the **Radiography** operating mode, you **cannot** initiate radiation with the foot switch.

An audible alarm will sound throughout the entire exposure time. Radiation is terminated automatically after the preset exposure time. You can interrupt the exposure before the selected exposure time has elapsed by releasing the hand switch.

- Withdraw the film cassette.
- Remove the film cassette holder from the image intensifier.
- Process image.



NOTE:

Adjustment of exposure factors will result in different image quality, adjustment of the technique factors maybe necessary to archive a good quality image

9.0 CINE & DIGITAL SUBTRACTION MODE

DSA Mode of Subtracted Angiography

The **DSA** functionality.

9.1 DSA/CINE FUNCTIONS

Subtracted Dynamic Image Acquisition (DSA/CINE)



Digital Subtraction Angiography (DSA)

DSA is always performed by storing a sequence of images captured at a specified rate, between 1 to 15 Frames per second. The **DSA** function is used to acquire high quality dynamic subtracted images, which is important when viewing Pain Management images of the spine and simple peripheral injections.

When **DSA** is selected, the imaging system optimizes the CCD camera's operating parameters for subtracted image acquisition, and the imaging system selects values for LUT, Window/Level, Noise Reduction, and other parameters which make the image suitable for **DSA**.

Frame Rates of 1 to 15 Frames Per Second (FPS) can be selected, depending on the options included with the system and on the rate that is appropriate for the medical procedure.

During **DSA** the system will automatically display on the reference monitor a representative native image with some of the **DSA** special settings for CCD camera, making the image on the reference monitor a little flatter than a normal fluoroscopic image but provides a live native un-subtracted image during **DSA** acquisition. The subtracted (**DSA**) image will be displayed on the live monitor. This provides the operator with both a live un-subtracted and subtracted image at the same time.

Optionally: The user may have the service installer select in the service mode one of two Input Look Up Tables and set Window and Level values to suit individual needs of image contrast and brightness. Factory defaults are set to normal viewing range for most operators.

Optionally: When selected for operation, the **DSA** injection of the vascular anatomy is normally fully opacified when the operator releases the foot switch or hand switch. The reference monitor will continue to display the regions of the vascular anatomy that had the greatest contrast during injection; this is considered a Maximum Opacified image.

Fig 9.1: DSA touch Screen in Replay (Stop)

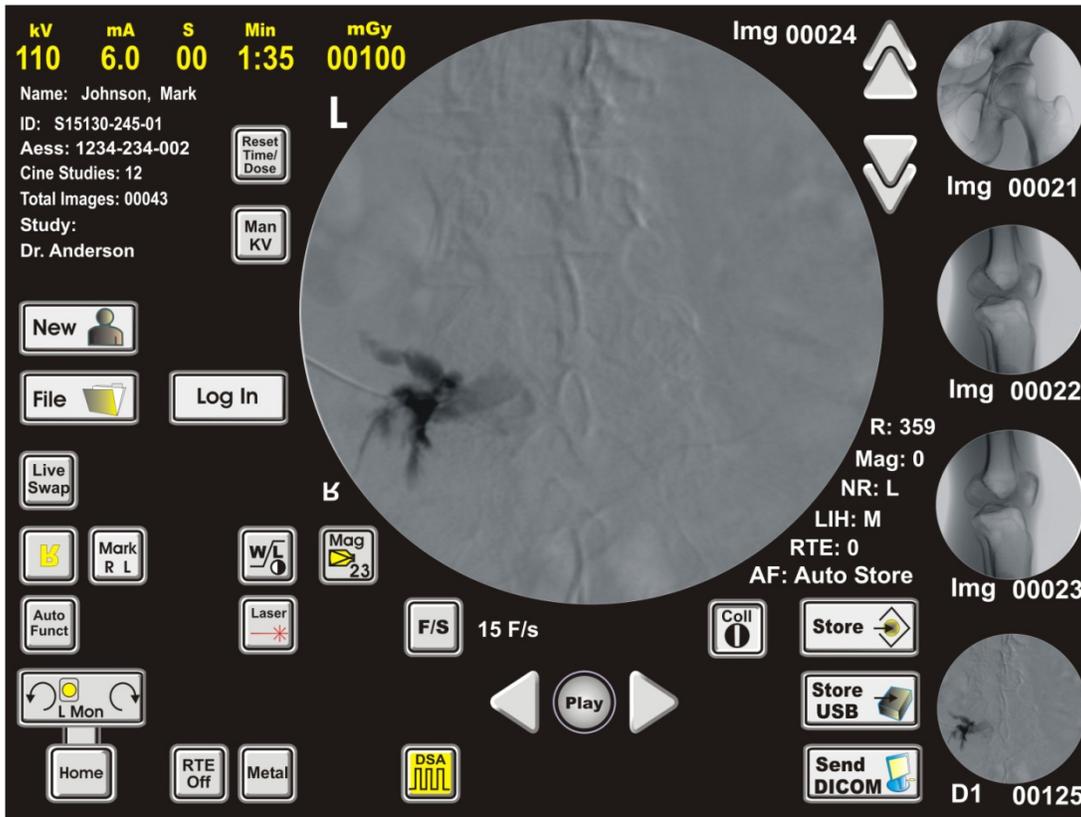
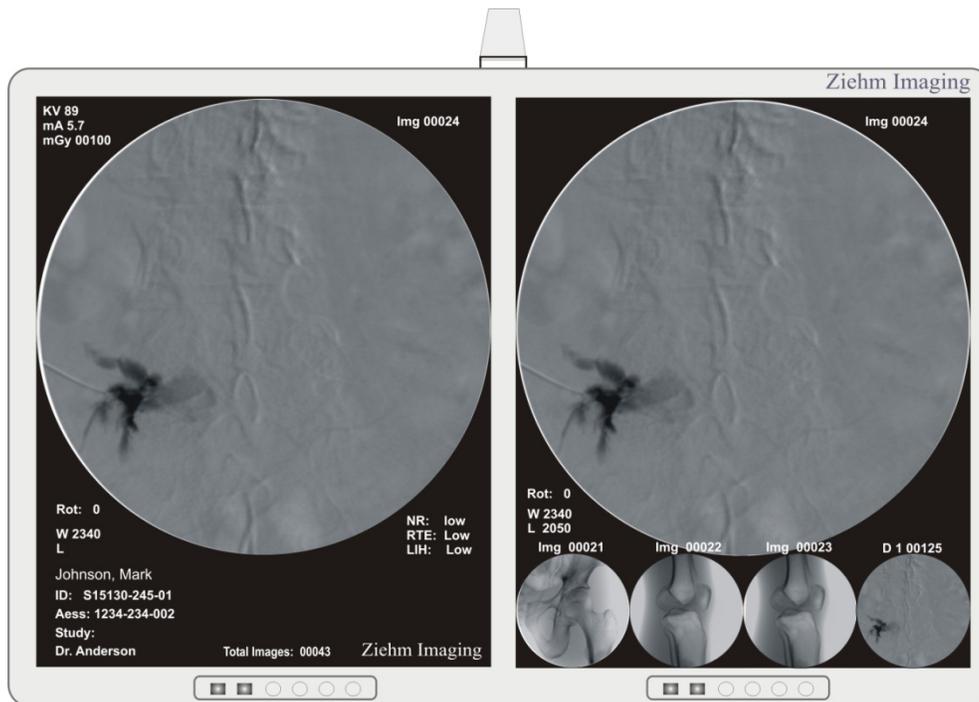


Fig 9.2: DSA Flat Panel Display



9.2 CINE AND DSA NAVIGATION BUTTONS

BUTTON DESCRIPTION

BUTTON FUNCTION



15 F/s

Press to store dynamic images at the selected frame rate,

During replay the operator can change the replay rate, however when returning to capturing a new run the system will reset to the default frame rate.

The **ZIEHM QUANTUM** capture image at 1, 4, 7, 15 F/S

Maximum frame rate may be dependent on optional software packages.



Press to display dynamically-stored images in a single step

LEFT arrow steps images forward by one

RIGHT arrow steps images backward by one

Center Button:

STOP: Press “STOP” to stop playback of image sequence

PLAY: Press “PLAY” to start replay of image sequence.



MSA

The MSA buttons of the Mobile Stand is not functional



RSA

The RSA button of the Mobile Stand is not functional

9.3 PERFORMING DSA

1. Perform a scout fluoroscopy of the anatomical region, using the appropriate body-region button. This sets the dose (kV/mA) values for **DSA** acquisition,
2. Press the **DSA** button on the on the DeskView or Mobile Stand Control Panel. The **DSA** button will turn Yellow on the DeskView and the frame rate button will be displayed.
3. Ensure that the frame rate is appropriate. If it is not, press the **Frame Rate** button on the DeskView Control Panel and set the rate for capture.
4. Press either the hand switch or the foot switch. The C-Arm releases radiation
5. The live monitor will display a count down, after three or four seconds. During this time the system allows the generator to stabilize the image will be dark gray,
 - The system captures a mask for DSA and when the system is ready for the injected bolus the display turns light gray and the image is subtracted

6. The system starts acquiring the image “Mask” at this time the kV/mA is locked
7. After the “Mask” is acquired, the system displays the real-time image on the reference display monitor. The subtracted image will be displayed on the live display monitor. When the DSA image is displayed on the live monitor, Operator starts injection and the display shows the contrast media as it is injected. The system will capture at the selected or default rate.
9. When you have obtained the desired imaging, release the hand or foot switch. The acquired images will automatically replay in a continuous loop, until you either exit **DSA** or start a new acquisition. This takes a few seconds to start the replay.
- 10 To exit **DSA** mode, press either the **DSA** button again on the DeskView Control Panel, or press one of the Fluoroscopic mode buttons.

Only the subtracted image will be displayed during capture and replay. The user cannot remove the mask from the DSA.

To change the capture or replay rate use the Frame Rate button to change from 1 to 15 f/sec



NOTE:

During acquisition, image intensity and contrast looks different than during normal fluoroscopy and is normal for the images to look this way. The contrast and brightness and Gamma curves are set to provide better visualization of the contrast media during the image capture in DSA.



NOTE:

All Cine/DSA Image Acquisitions are Protected. The **ZIEHM QUANTUM** protects all sequential image acquisitions (DSA, Cine Studies) are automatically stored to the Hard Drive for immediate review of the image sequences or can be recalled at a latter time.



NOTE:

When performing DSA image acquisitions it is important to make sure the patient does not move. The motion of the patient will disrupt the image quality.

9.4 **STORING OF DSA/CINE IMAGES**

The system will automatically stores the entire dynamic image acquisition to the hard drive therefore the operator is not required to select a storing method for the DSA or Cine image sequences.

9.5 STORING INDIVIDUAL IMAGES TO THE PATIENT FILE DIRECTORY

1. Press the **Image LEFT or RIGHT Arrow** button on the DeskView Control Panel. This places the system into the single step playback mode, operator can then step through images one at-a-time.
2. When image playback has stopped, select the image to transfer to the patient file and press one of the two **Store** buttons (DeskView or on the mobile stand keyboard)
3. The left monitor will display the message “Stored to XXXX”, which indicates that the image has been copied to the patient file with an image number



9.6 CINE FUNCTIONS

The CINE function selects the dynamic acquisition mode for acquiring and replaying images in a sustained sequence. Images can be acquired at a rate of 1 to 15 fps, and can be replayed at either 1 to 15 fps, depending on the optional software. Images acquired at 1 to 15 fps are stored directly to the hard drive.

When the CINE function is selected, the system does not change its image properties. The C-Arm stays in the fluoroscopic body region that was selected. The CINE function allows the operator the ability to perform procedures such as Cholangiography, Barium Swallows, Urinary Studies, ERCP, or any procedure that requires a sequence of images to be acquired without DSA.



9.6.1. CINE MESSAGES

All messages are displayed on the left monitor.

FRAME RATE DISPLAY 1-15 F/SEC: Indicates the selected frame rate. To change the frame rate, press the **Frame Rate** button before starting an acquisition or during replay of a captured loop.

When the hard drive fills to the point that it cannot store at least 20 seconds of Cine images, the system will display a message;

“Dynamic image acquisition cannot be started until more space is available”

To make room on the hard drive, delete Cine, images, or DSA image runs, or patients from the system.

To exit the CINE function, press the **CINE** button to close the function and return to normal fluoroscopic operation.

9.6.2. IMAGE STOP/PLAY AND STEP

Press the **Image LEFT/RIGHT** Arrow buttons to step through the image sequence of the CINE run one at a time.

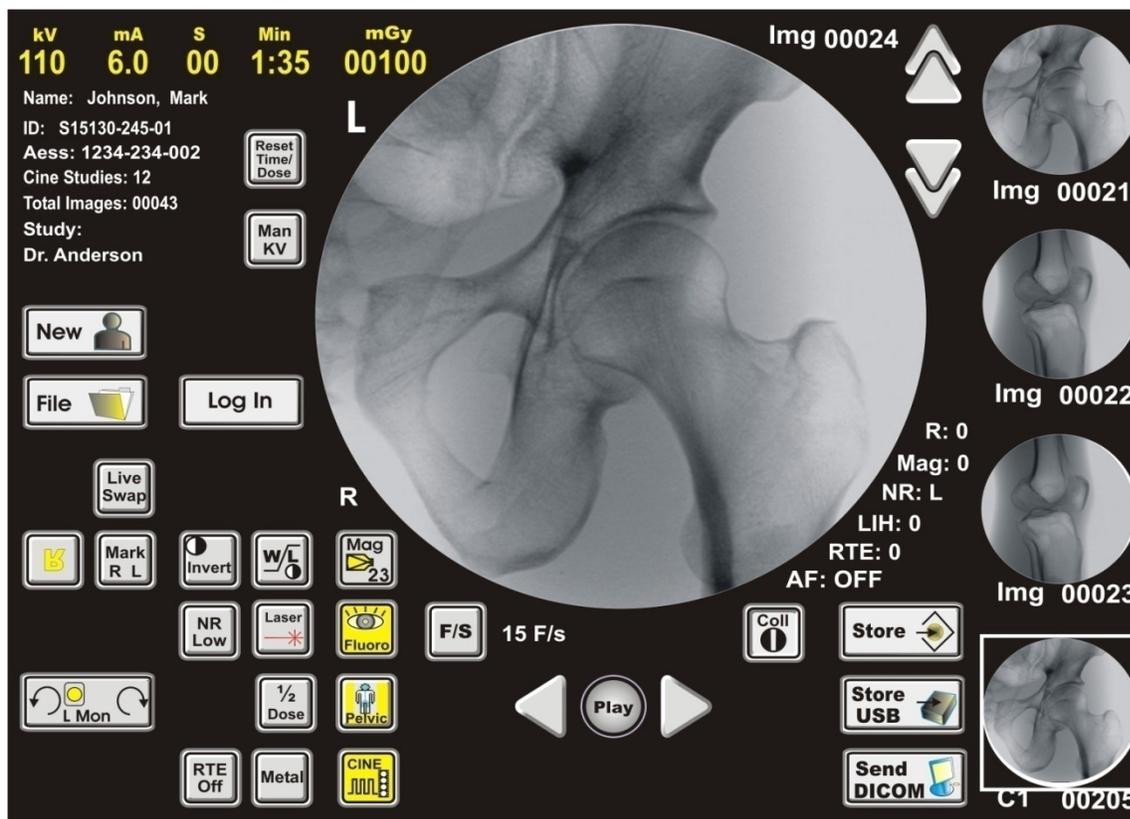


NOTE:

All Cine Image Acquisitions are protected. The **ZIEHM QUANTUM** protects all sequential image acquisitions (Cine Studies) they are automatically stored to the Hard Drive for immediate review of the image sequences images.

DeskView –Cine Operation Screen

Fig 9.3: Touch Screen Cine Select And Replay Back



9.7 PERFORMING CINE ACQUISITION

1. Position the C-Arm over the selected anatomical region and select the appropriate **Anatomical** region button. Use fluoroscopy to verify optimum C-Arm positioning.
Press the **CINE** button on the DeskView Control Panel
2. Select the frame rate for dynamic image acquisition:

The **CINE** Button will be highlighted on the DeskView screen and the selected frame rate will be display on the touch screen.

3. Press and hold the hand or foot switch. The left monitor will display the message “INJECT” in the lower center of the screen to indicate that the system has started capture of images.
4. Start the injection of contrast media.
5. Continuing holding the exposure switch until the desired vascular anatomy has been visualized.
6. The acquired images will begin to play back in a continuous loop from the hard drive or from memory, depending on frame rate selected and the system’s optional equipment.

9.7.1. ACQUIRING A NEW CINE RUN

If scout fluoroscopy is necessary between runs, press the **CINE** button to exit and return to normal fluoroscopy.

Repeat the Cine procedure above. To acquire another study /cine run

9.7.2. IMAGE STEP

During CINE replay, image playback can be stopped and individual images can be reviewed and or stored to the patient file.



1. Press one of the **Contrast** buttons on the Mobile Stand Control Panel or the **Arrow playback** buttons on the DeskView Control Panel. This places the system into a playback mode that steps through images one at-a-time.
 - 1) The message “F/R OFF” will display in the upper right corner of the monitor, indicating that the image loop has stopped and that the operator can now step through the images.

Press either button to step through the images. Hold down either button to step through the images at nearly the selected frame rate.
 - 2) When image playback has stopped, select the image to transfer to the patient file and press either of the **Image Store** buttons.
 - 3) The message “Stored to XXXX” is displayed on the left monitor which indicates that the image has been copied to the patient file as image number XXXX.

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10.0 PATIENT FILE OPERATIONS



10.1 PATIENT FILE OVERVIEW

The Patient file allows the user to select patients that have already been entered into the patient file database via the New Patient entry screen.

Patient Name		ID	Accession			Procedure		
Name	Ident	Accession	DOB	CDATE	Sex	PROCEDURE	Image	Status
Heaberthinkle, Abby	212050321		21/02/1953	02/10/2005	F	Triple A / Stent	00023	A
Heaberthinkle, Betty	212050322		21/02/1960	02/10/2005	F	Aortic Stent	00010	P A
Heaberthinkle, Carol	212050332		21/02/1962	02/10/2005	F	Femoral stick	00010	
Heaberthinkle, Daniel	212050324		21/02/1963	02/10/2005	M	C-Spine	00009	
Heaberthinkle, Ethel	212050327		21/02/1964	02/10/2005	F	Renal Left	00018	P
Heaberthinkle, George	212050329		21/02/1966	02/10/2005	M	Spine L5 -S1	00015	
Heaberthinkle, Hector	21205032		21/02/1953	02/10/2005	M	Triple A / Stent	00008	

! 1 @ 2 # 3 \$ 4 % 5 [6] 7 * 8 (9) 0 ← Del
 Q W E R T Y U I O P →
 Shift A S D F G H J K L Enter ESC
 \ _ Z X C V B N M , > .
 ? / SPACE Shift Lock Clear

Patient Scroll

File Screen allows the user/operator to perform many different functions that are related to patient records. The user/operator may add then select any of the patients in the data base and perform the following operations;

- 1) **WORKLIST** allows the user/operator to select via a DICOM server connection the patient list and load the patient names into the system database.
- 2) **EDIT/MODIFY** allows the user/operator to edit/modify the patient record (name, ID, etc) for a patient that has already been entered.
- 3) **PATIENT SEARCH** allows the user/operator to search the data base for a patient record using the Patient Name, ID, Accession Number, or Procedure.
- 4) **PROTECT** allows the user/operator to protect a patient file from deleting or changing unless they choose to override this protection

- 5) **DELETE PATIENT** allows the user/operator to select and delete a single patient file from the database.
- 6) **ADD TO LIST** allows User/Operator to select patients for archiving.
- 7) **ARCHIVE** opens the archive screen to allow the User/Operator to export images to external storage devices.
- 8) **CONFIGURE** allows the user operator to select start up functions for the system as well as Authorization of operators for export operation logging.

The rest of this section will discuss and outline the above listed functions for the PATIENT FILE screen.

Selection of a Patient from the file list:

When you need to select a different patient from the present active patient file the user should open the file screen, then using the **PATIENT SCROLL** arrow keys or the Right side File selection **SCROLL BAR** to locate the patient file/record that you would like to make the active.

Once you have located the patient record simple touch the patient record line on the file screen or use the **PATIENT SCROLL** arrow buttons to move the patient record then stop. The system will then if selected by touching the patient record line or stopping on the patient record will try to recall images from this record and then display the patient name and images on the display monitors.

To make this the active patient press the **ENTER** button on the right side of the text entry keyboard. The system will then make this the active patient close the file screen and return of the Main Screen.

The patient is now active and all image stored will be placed in this patient record for exporting or printing.

Closing the file without selecting a new patient:

The user can select different patients and their images by selecting them from the file list without leaving the file screen. However, if the user does not want to make the newly highlighted file the active patient and wishes to return to the original patient before entering the file screen they must press the **EXIT** button to leave the screen and return to the previously active patient.

The File screen sections can be adjusted by pressing the top edge of the file section on the touch screen between header listings (name, ID, Accession, etc) to see more information for this column.

To return the header section to the original size just press the same area again then move the column back the original placement.

The lower SCROLL BAR will change to accommodate changes in the information screen area if the columns get to large for a single screen. Pressing and moving the scroll bar will allow the user/operator to view more information if needed.

Please see the individual sections below for more information on the functions of the buttons on the file screen.

10.2 NEW PAT (NEW PATIENT)



The **NEW PAT** button is located on the upper left side of the Desk View Control Panel.

Press the **NEW PAT** button to enter the New Patient Information screen.

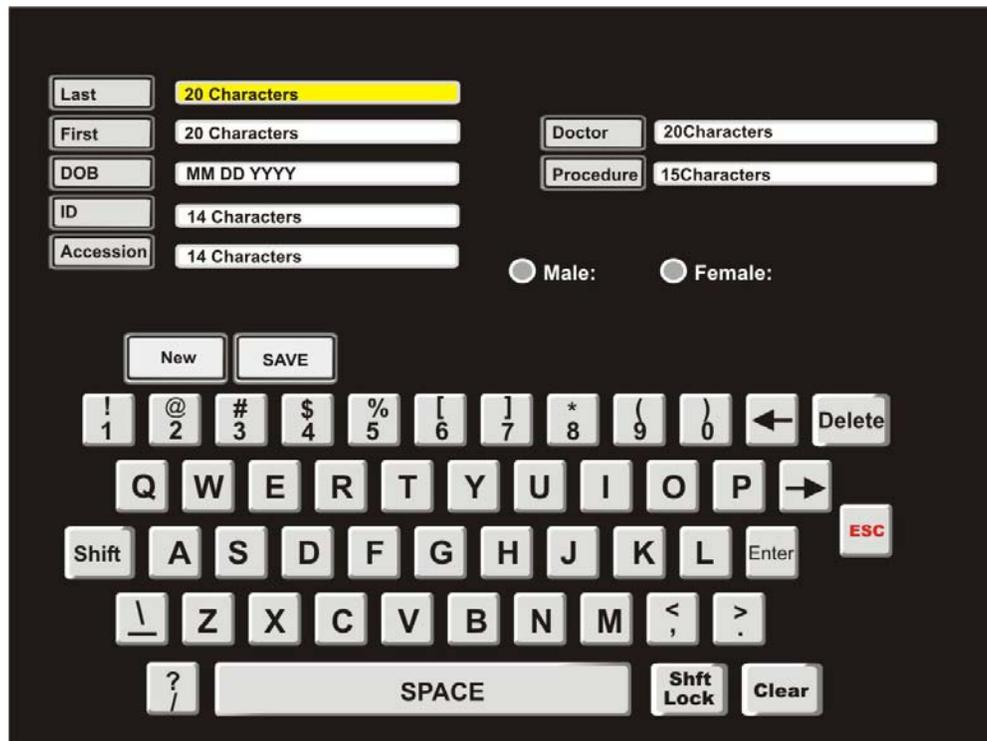
The system will default to the patient last name as the first input field. If you choose to start in a different input field just touch the button next to the entry field to select the appropriate input field.

Press **ENTER** button to move to the next input field, or press the button next to the entry field that you would like to enter information into.

After the last line has been completed, you have the opportunity to review the entered data before it is added to the data file. To save the new patient information press the **SAVE** button to accept. The Screen will remove all information from the fields to allow the user to enter another new patient.

Press **ESC** button to escape the new patient screen and return to the main Fluoroscopic screen.

Fig 10.1



10.3 NEW PATIENT ENTRY

10.3.1 PATIENT NAME

Enter the Last Name of the patient's name, and then press **Enter** to move to the next patient entry field.

Enter the patients First Name; press **Enter** to move to the next patient entry field.

Enter Date of Birth “**DOB**” MM/DD/YYYY.

Enter Patients ID number, the press **Enter** to move to the next entry field.

Enter Patients Accession number; press **Enter** to move to the next field (Accession used mainly with DICOM and certain other PAC systems that require ID and ACCESSION numbers for identification of the patient.

Enter Dr. Name and press **Enter** to move to the next entry field.

Enter Procedure title and press **Enter** to move to the next field.

Enter Sex “Male” or “Female” by pressing the small button next to the female or male in.

10.3.2 FACILITY NAME



NOTE:

By default, the Facility Name is entered in the system by service and then is automatically displayed until you request a change the information.

10.3.3 ESCAPE (ESC)

To exit the New Patient Information screen without saving the information added to the data entry fields, press the ESC key.

10.4 NO NAME FOLDER

10.4.1 FUNCTION

If you have not activated a patient during power-up cycle and prior to saving an image, the image is automatically saved to the NO NAME folder. In this case, the image is assigned to specific patient folder but a date time stamp is used to identify this patient folder and can be EDITED later to add the patients name and ID.

With the NO NAME folder active the user can save both single images as well as save CINE/DSA loops to the NO NAME folder.

10.4.2 STORAGE CAPACITY

When the system starts it always creates a new patient file/record. This new file/record will contain information for the Name and ID sections of the record and will be numerical in nature allowing the system to track this record separate from the other records. This is commonly referred to as the NO NAME patient record.

The NO NAME patient record or a selected named patient record both have an image capacity that is limited only by present hard drive storage capacity and or system limits (What is left in system image storage capacity).

10.5 EDIT PATIENT RECORDS

Edit Patient File:

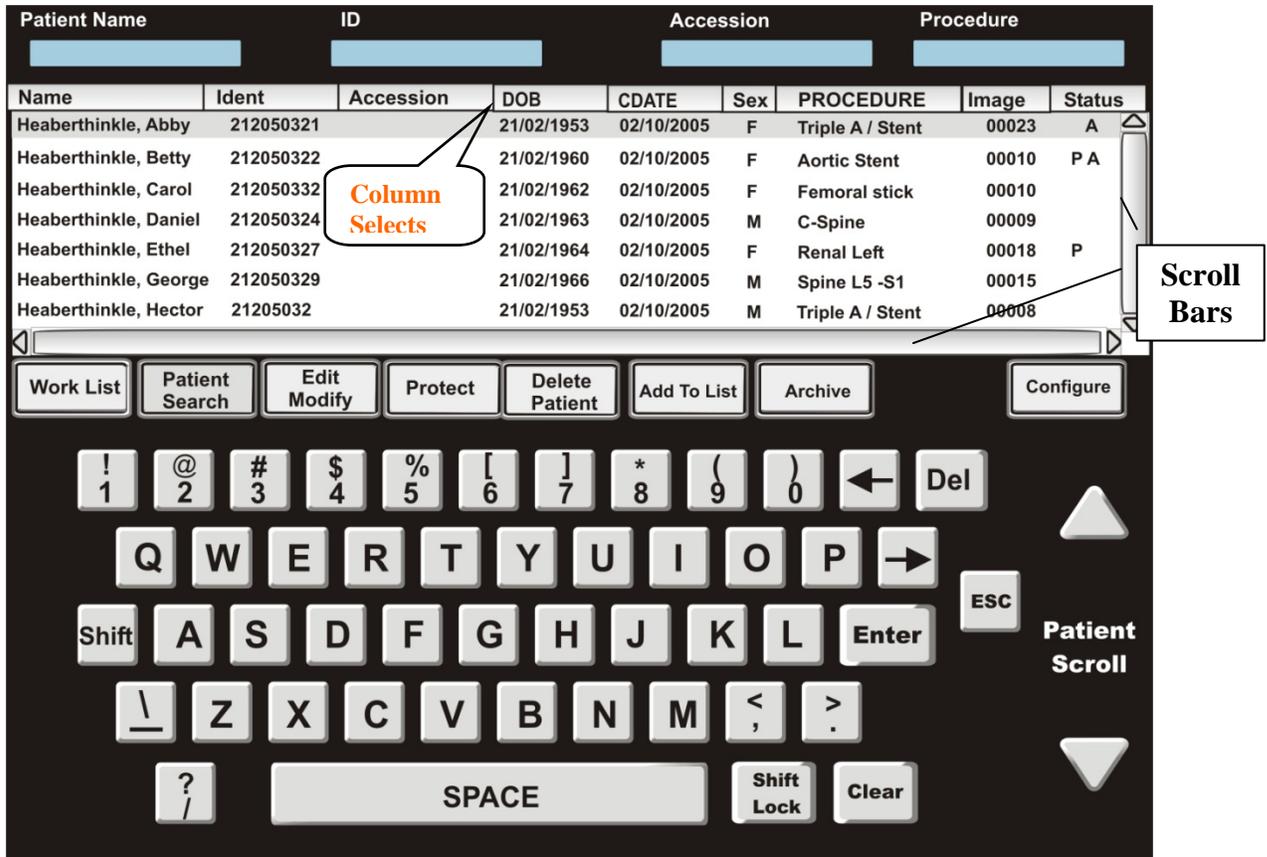
The Patient File /Records can be edited by searching and then opening the patient file for editing.

Search Patient Files

Press the File Button to open the systems Patient File Screen



Fig 10.2: Patient File Screen



There are two ways to search for a patient file. The system can search for a patient by using the SCROLL BAR on the right side of the patient list or by pressing the Patient Search button.

To search using the Patient Scroll buttons touch and then slide the shaded area inside the bar in the center of the scroll bar to scroll through the patient files for the correct patient file.

To use the text entry boxes at the top of the screen press the Patient Search button, the system will place a cursor in the Last Name text entry search box located on the top edge of the patient file screen.

The Operator may move the columns to allow viewing of additional data that may be too long for a particular column by using the **COLUMN SELECT** points

The user will need to use the text entry keyboard to type in the last name.

To search by name press the text entry box “Last Name”, now type in the name you are looking for into the test field. As the user enters the name the system will start to sort the patient records

to find a match.

As a match is found the list will start to grow, with each new character entered if there is a patient record with those letters in the last name.

Likewise the user can use the ID, Accession Number, or the procedure to find a specific patient or group of patients depending on the search criteria used.

Edit/Modifying Patient file continued:

Once you have found the patient file you wish to modify press the Edit/Modify. The system will change screens information to allow access to all the data entry fields.

The DeskView will display the patient file information and allow the user to select and then modify the content of the file.

Once the user has entered the file information screen the user will need to select the patient file to be changed.

The user needs to touch the patient on the list or use the scroll buttons on the right side of the keyboard to move to a patient file.

User must wait until the image system has displayed the patient images on the Right monitor. Then user can proceed to with modifying the record.

Touch the field you need to modify and once cursor is in the text field then type in the new information using the test keyboard.

The Enter button will close and move the cursor to the next field.

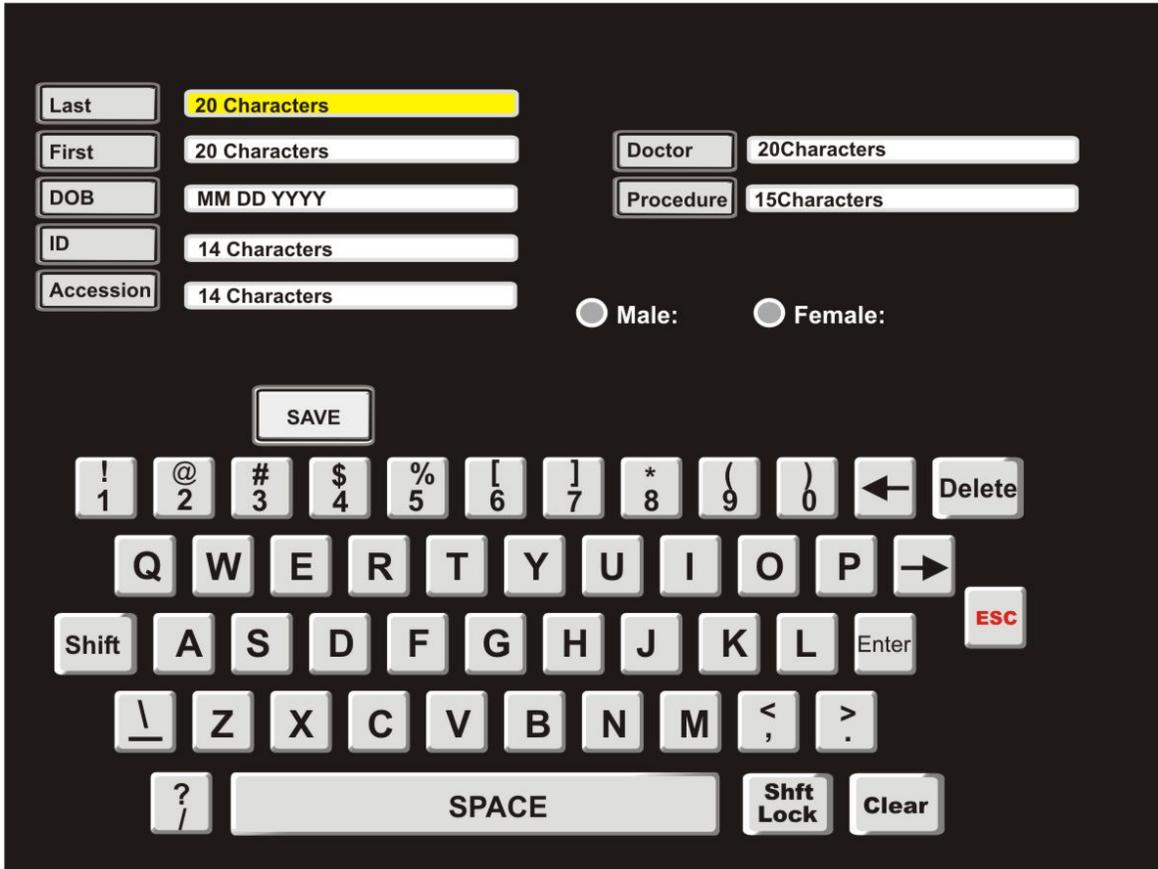
Edit/Modify Patient Records

Once you have made all the necessary changes, press the save button the system will open a message box and asking to accept the changes. If you accept the changes the system saves the data and then closes the patient screen and returns to the search screen to allow the user to Edit/Modify another patient file.

Once you have made all the changes necessary to patient records and have saved the changes press the ESC button to exit the Edit Modify patient information screen to return to the patient file screen.

To exit the Edit/Modify patient information screen without saving the information added to the data entry fields, press the ESC button. Note: you will lose all the entered data if not stored.

Fig 10.3



10.6 DELETING PATIENT RECORDS

- Button 1 Press the PAT FILE button on the DeskView main control panel to open patient files.
- Button 2 Use the up/down Arrow buttons or just touch the patient file to select a specific patient record.
- Button 3 Press the Delete button from the activity menu bar on the DeskView. The following message will be displayed.

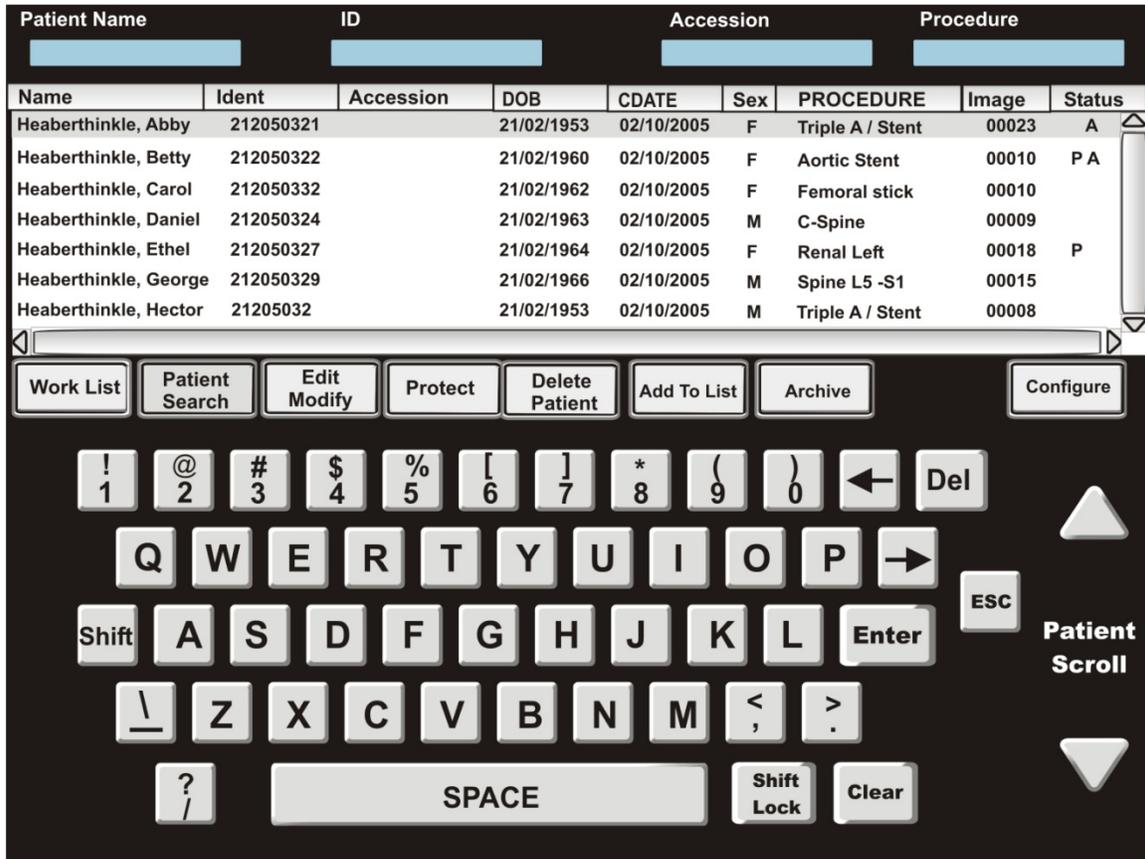


WARNING:

Be sure you are deleting the correct patient record file. You cannot recover deleted patient records or images!"

- Button 4 At the prompt, press the Yes key. The system deletes all images and patient information for the selected patient file or No to stop the delete operation and return to the screen.

Fig 10.4



10.1 DELETING PATIENTS TO FREE UP SPACE

When you attempt to SAVE an image and there is not enough space on the hard disk the system will display a message for a few seconds to alert the operator.

You must delete patient images before you can store”

- The SAVE operation is aborted.
You can make space for new patient images by deleting older patient folders and/or images on the hard disk.
- Press the File button on the main touch screen to open the Patient File screen. Once this screen is open the user can select a patient and delete the complete patient file or portions of the file if images are protected.
- If a patient folder contains protected images, only the unprotected images are deleted, but not the protected images or the folder itself.
- If it is not possible to free up enough space on the hard disk for the save operation due to the large number of protected images, a message appears on the control panel to warn the user.

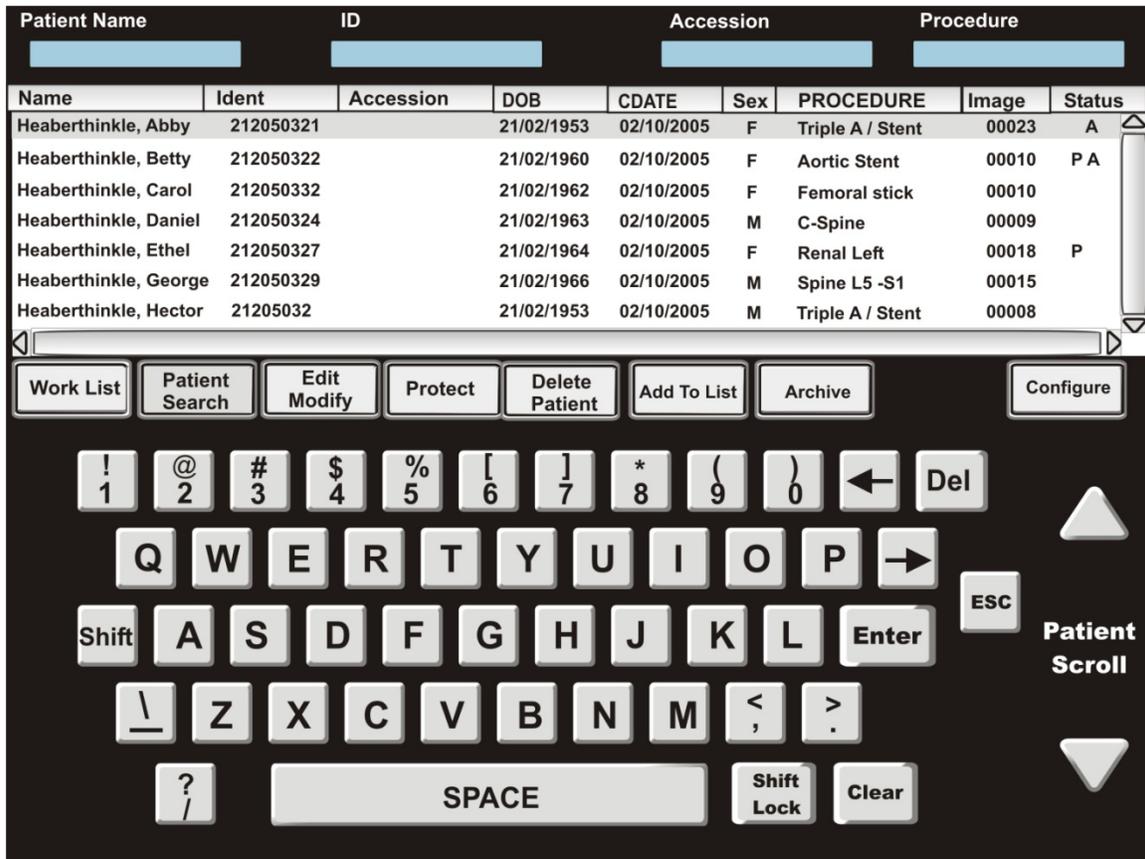
10.8 PROTECTING A PATIENT FILE

The user can choose to protect a patient or many patient files by first selecting the patient on the screen then pressing the PROTECT button.

The system will place a mark in the far right edge of the file screen "P" to alert the user this patient is protected from deleting without confirmation and resetting the PROTEC mode for that patient.



Fig 10.5



Patient Name		ID	Accession			Procedure		
Name	Ident	Accession	DOB	CDATE	Sex	PROCEDURE	Image	Status
Heaberthinkle, Abby	212050321		21/02/1953	02/10/2005	F	Triple A / Stent	00023	A
Heaberthinkle, Betty	212050322		21/02/1960	02/10/2005	F	Aortic Stent	00010	P A
Heaberthinkle, Carol	212050332		21/02/1962	02/10/2005	F	Femoral stick	00010	
Heaberthinkle, Daniel	212050324		21/02/1963	02/10/2005	M	C-Spine	00009	
Heaberthinkle, Ethel	212050327		21/02/1964	02/10/2005	F	Renal Left	00018	P
Heaberthinkle, George	212050329		21/02/1966	02/10/2005	M	Spine L5 -S1	00015	
Heaberthinkle, Hector	21205032		21/02/1953	02/10/2005	M	Triple A / Stent	00008	

Work List **Patient Search** **Edit Modify** **Protect** **Delete Patient** **Add To List** **Archive** **Configure**

! 1 @ 2 # 3 \$ 4 % 5 [6] 7 * 8 (9) 0 ← Del
 Q W E R T Y U I O P →
 Shift A S D F G H J K L Enter ESC
 \ _ Z X C V B N M , > .
 ? / SPACE Shift Lock Clear

Patient Scroll

10.9 LOG IN SECURITY PERMISSION

The introduction of HIPAA regulations in the United States requires that all patient records be protected; therefore the system does not permit image transfers outside the systems internal memory storage. See Fig 10.6 Log In screen below.



The user must Log In to the system to copy or extract images from patient files.

Log In by the user will allow the user access to all patient files and the ability to store images to external USB storage devices, External DVD devices, and DICOM networks.

The Log In will allow the user this access until power is turned off or they log off.



WARNING:

The system comes with a single permission to allow the doctor or other individual in charge of the department to set up permissions for use of the device.

The owner operator is responsible for maintaining control of all medical records and if the owner operator does not set permissions then control has not been established to limit accesses to patient's images, which are medical records



NOTE:

The user must understand that until the system is turned off or they log off the system. Their name will be used to identify who copied images to external image storage devices. User is encouraged to log off the system whenever they are finished storing to external devices.



NOTE:

When exporting images to any outside media or devices (DICOM server, USB device, and DVD/CD disk) the system creates an administrative log of the person who exported using their Log in name and the date of the export. The export date is also placed on the exported image as a means to identify when images were exported from the device.

To Log In and out of the system;

The User must press the Log In button located on the main touch screen.

The Log In screen will appear after a few seconds. Once the screen is displayed the user can select one of the names on the screen and then enter their password.



Once the password has been entered press the Enter button to accept the security password.

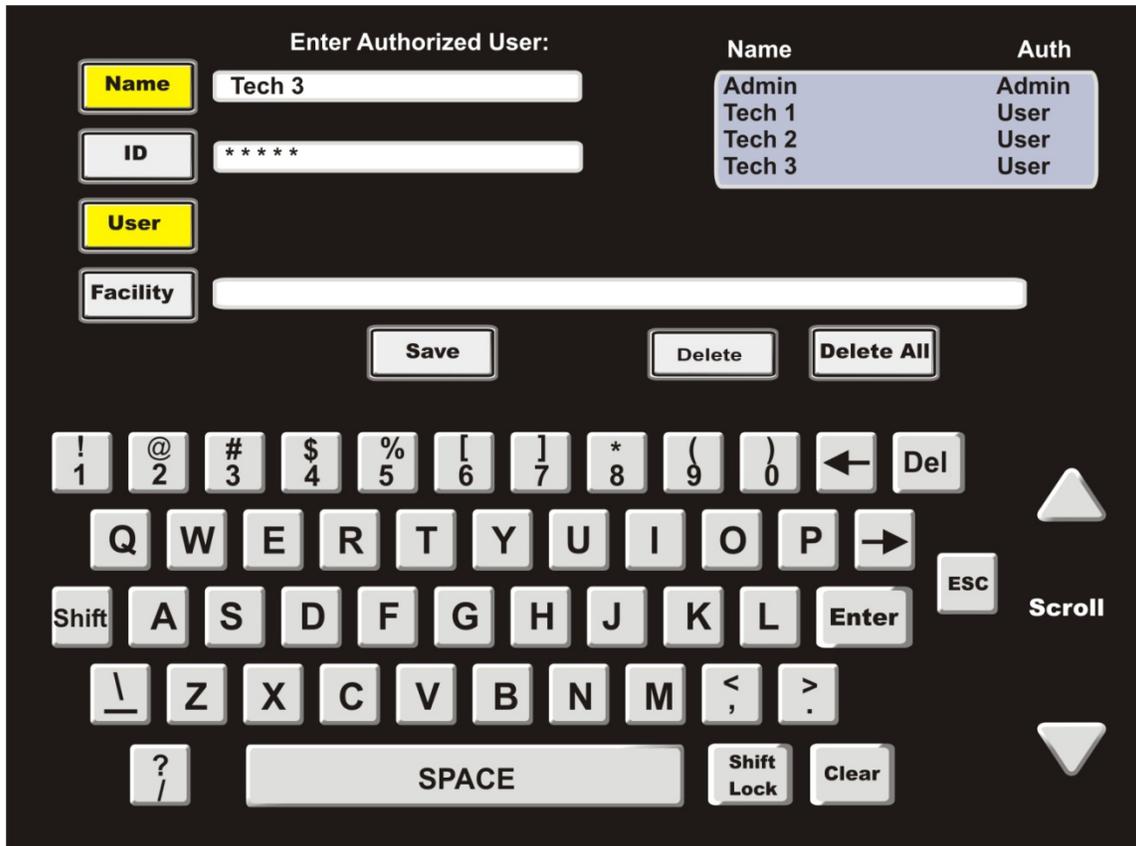
The system will return to the main touch screen and the button will change from Log In to Log Out.

The user should Log Out of the system whenever the system is left unattended.



In all cases the system will not keep the Log In active if the power is turn off. You must reenter your password after each power on cycle.

Fig 10.6



10.10 IMAGE EXPORT

The **ZIEHM QUANTUM** has three specific ways to EXPORT Patients records/images from the image system. The following instructions will assist the user in using these three methods of exporting image record from the system.



WARNING:

The user operator should use only medical grade CD and DVD disk as they have been checked for flaws in the media and will be more successful in completing a store to the disk.

Standard off the shelf CD and DVD disks may fail to write on occasion or may lose or have defective media that will cause patient records to be lost when using these disks.

Some Media types may perform all the steps but fail to complete the TOC operations, Make sure you check all disk in a PC to make sure data has been transferred before deleting any images from the image system.

Ziehm Imaging, Inc. is not responsible for lose of patient information/data or poor performance of the export function if common, non-medical grade DVD and CD disk are used.



WARNING:

The **ZIEHM QUANTUM** is not to be used as a long term “Archiving Device”, its primary use is in capturing and storing for limited time patient information and should not be considered a mass storage or image server for patient data.

Ziehm Imaging, Inc. recommends the owner operator make backs of up all images for patients using achievable media for long term image storage.

This could be Archival CD and DVD’s or by using Optional DICOM interface or by using USB memory devices to transfer the images to a PAC’S image server or to other computer systems having Archiving capabilities.



WARNING:

The **Ziehm Imaging, Inc.** recommends storing images to the USB device during the procedure, transferring patient images after the procedure or transferring images at least at the end of each day to prevent loss of these important medical records.



NOTE:

When exporting images to any outside media or devices (DICOM server, USB device, and DVD/CD disk or video port, the system provides a date of export on image as a means to identify when images were exported from the device.

10.10.1 OVERVIEW OF THE USB AND DVD EXPORT FUNCTIONS:

USB 2.0 data port is provided for the user so they may use simple USB memory devices such as USB thumb drives USB peripheral hard drives that are not direct drive devices.

The USB port is located on the side o the Mobile C-arm directly in blow the control keyboard.

The USB port will allow the user/operator to transfer images from the c-arm to another computer in several image formats. (JPEG, TIFF, BMP for still images and AVI and DICOM media for motion images (Cine/DSA).

You must first select the LOG IN button and log into the system to activate the USB memory

A complete CD-R with 600MB of data can take more than 30 minutes.

A complete DVD-R with 4.0GB of data can take greater than 1 hour

The Export functions are located on a single screen and can be accessed from the patient File screen.

The USB and DVD buttons on the Archive screen will not be displayed if the user is not logged into the system.

10.10.2 ENTER ARCHIVE

To enter the ARCHIVE screen to export patient records/images the operator must first Log In into the system using one of the assigned permissions.

The user/operator must then select the FILE button from the main touch screen.

Once the patient file screen is open the user must select a patient that has images attached to its file by pressing one of the patients listed on the screen.

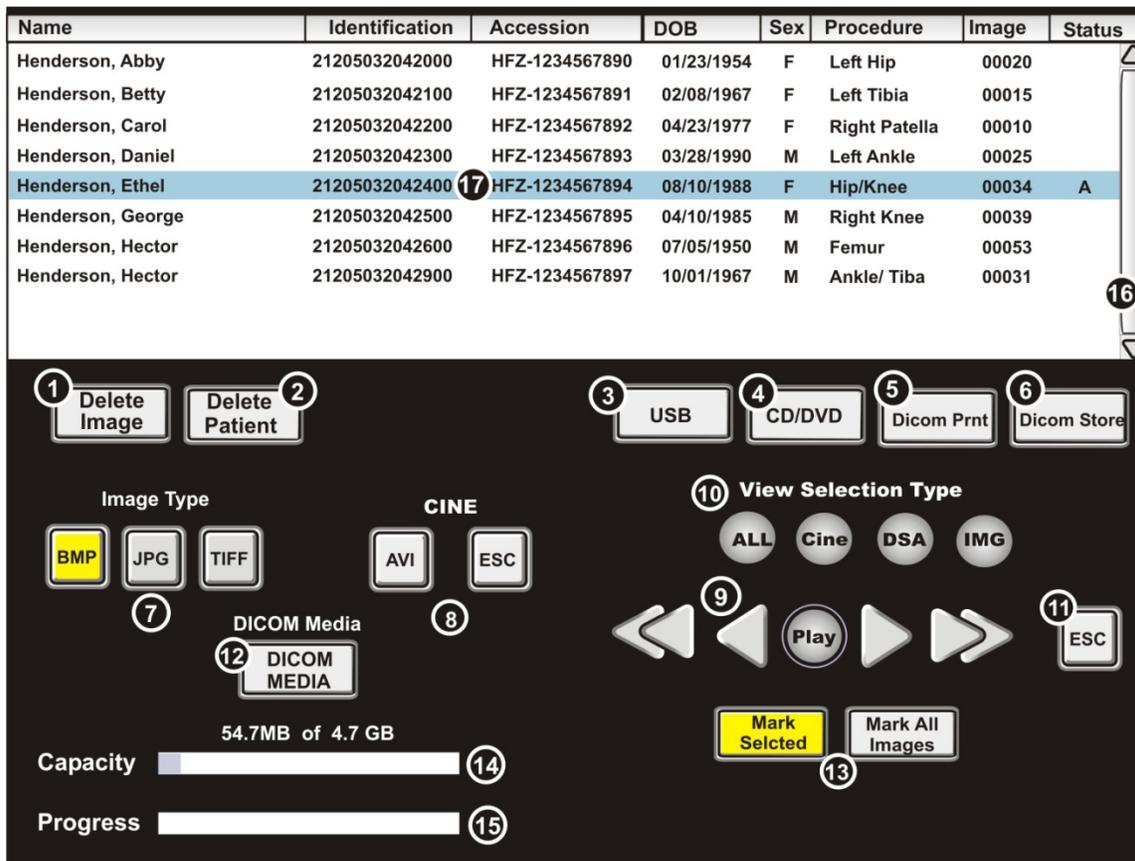
Now press the PRE_SELECT/ADD TO LIST button to select the patient to make active the ARCHIVE button on the screen.

At least one patient file must be selected/added to the list before the archive button will be active.

Once you have selected all the patients for the Archive list, now press the ARCHIVE button, the user/operator is presented with the Archive screen See Fig 10.5 below.

Note: the system will update the Display Monitors with the last four images of the patient file to confirm the patient file and images. This may take 2 to 3seconds for the update between selections on the Patient file screen.

Fig 10.7: Archive Screen (Image Export)



10.10.3 IMAGE ARCHIVE SCREEN BUTTON DESCRIPTION:

Control No.	Symbol(s)	Description
Button 1		Delete Image Allows user to delete a single image from the active patient file in the Archive Screen
Button 2		Delete Patient Allows user to delete a patient from the database. Not: Deleting the patient is a permanent operations the patient records cannot be recovered.

Control No.	Symbol(s)	Description
Button 3		<p>Optional: USB Device Port USB 2.0 Image storage port Capacity changes with memory stick model and make. (32MB to 1 GB) Note: only approved memory sticks are guaranteed to work with the ZIEHM QUANTUM. Check with Manufacturer for list of approved memory stick devices.</p>
Button 4		<p>Optional: DVD/CD This option is available in the Archive mode screen</p>
Button 5		<p>Optional: DICOM Print The DICOM Print button allows the user to send images to a DICOM printer. System has separate AE address for the printer</p>
Button 6		<p>Optional: DICOM Store The DICOM store button allows the user to send images to the hospital PAC server for archiving. System has separate AE address for the Server.</p>
Button 7		<p>Image Format There are three standard image formats for export BMP is the highest resolution and dynamic range 1K x 1K pixels JPG is the lowest resolution and low dynamic range 512x 512 pixels TIFF is a high resolution but has a lower dynamic range, 1k x 1k pixels</p>
Button 8		<p>Cine/DSA Image formats Press the AVI button to export a Cine/DSA image sequence as a Windows Media motion picture. Press the BMP button to export the Cine/DSA image sequence as individual single images.</p>

Control No.	Symbol(s)	Description
<p>Button 9</p>		<p>Image Scroll Single Step There are two buttons one for forward arrow pointing to the left and one reverse arrow button pointing to the right</p> <p>Recall Scroll by 4 images There are two buttons one for forward arrow pointing to the left and one reverse arrow button pointing to the right</p> <p>Play Button Allows the user to play back and stop the play back of CINE/DSA image sequences</p> <p>When the user selects a CINE or DSA, run system will start replay of the image sequence, the button will then change to STOP, When the user presses the button the CINE/DSA run will STOP, and the button will display PLAY.</p> <p>The Recall keys are then used to step through the images.</p>
<p>Button 10</p>		
<p>Button 11</p>		<p>Escape The Escape button allows the user to leave the Archive screen. If images were selected for any or all the patients in the Archive list and the user Escapes this screen the3 image marker will be removed.</p>

Control No.	Symbol(s)	Description
Button 12		<p>DICOM Media The DICOM media button allows the user/operator to select all images (still, Cine, DSA) and export them as a standard DICOM image format.</p> <p>In the Case of DSA and Cine image sequences they will be exported as an image sequence that can be reviewed using the Ziehm DICOM viewer.</p> <p>The DICOM Viewer will be exported whenever the DICOM Media image format is selected.</p>
Button 13		<p>Mark-All Allows user to select all the images in a patient file with one button. Select a patient that has already been marked the press the Mark-All button again to remove all the image marks in the patient file.</p> <p>Mark Image Press the Mark Image button to mark the image for exporting. Select and image already marked then press the mark image buttons again to remove the image mark for export. If an image is not marked it will not be exported to the USB, DICOM or DVD devices.</p>
Button 14	<p style="text-align: center;">54.7MB of 4.7 GB</p> <p>Capacity </p>	<p>Capacity Indicator the Capacity indicator provides the user with the ability to determine what can fit on to a given memory device. USB memory or DVD disk.</p>
Button 15	<p>Progress </p>	<p>Progress Indicator The progress indicator gives the user an indication of the progress of writing to the USB or DVD</p>

Control No.	Symbol(s)	Description
Button 16	<p style="text-align: center;">File Scroll Bar</p> 	<p>File Scroll Bar</p> <p>When there are more patient records than can be seen on one screen the Scroll Bar will be seen,</p> <p>The center indicator gives a reference of the placement in the file.</p> <p>Touch then slide the small marker in the center of the Scroll Bar to view more patients</p>
Button 17	<p style="text-align: center;"> Name Henderson, Ethel Identification 21205032042400 Accession HFZ-1234567894 DOB 08/10/1988 Sex F Procedure Left Elbow Image 00034 Marker A </p>	<p>Patient Data:</p> <p>The patient information for Archive functions is located on the upper part of the Archive screen. To select a patient for archive and to mark images for export just touch the patient information line on the screen. Wait a second to update the system and display images.</p>

10.10.4 SELECTING IMAGE FORMAT:

In the archive screen there are three types of Bit Mapped Graphic image formats that can be exported.

1. **BMP:** This is a full 1 k x 1k image. This provides an image with no image data lost. BMP image format provides the best possible image. Image size is about 3.1Mega Bytes
2. **JPG:** This is a 512 x 512 image. By its nature the contrast has been reduced so there is a loss in image quality. This image format should not be used where high quality imaging is required. Image size ranges is approximately 310 KB.
3. **TIFF:** This is a 1k x 1k image with some image quality lost in the conversion of the Dynamic range. The image size ranges about 1.05 MB.
4. **DICOM Media (Option):** This is a special image format that requires a special image viewer (DICOM 3) to view images. The image has full resolution 1K x 1K. Image size is 1.05MB. Some quality lost in the conversion of the Dynamic range.

The DICOM MEDIA export function when completed will copy a special image viewer to the USB device or DC/DVD disk so the operator may view these images without having a DICOM server workstation. The viewer is simple to use and is more or less self explanatory in use.



WARNING:

The JPG and TIFF image formats will by nature have some loss of resolution and dynamic range of the original image or compared to the higher lossless BMP image.

It is the Physician that should make the decision weather to use a particular image format.

The BMP image is the most universal image format and can be read by almost all image processing software packages. Windows Media player, Paint, Adobe Photo Shop, Corel Paint, MS Word can import the image, as well as many other software programs.

BMP has one disadvantage in that it is large in size, approximately 3 MB of data.

The Archive screen allows the user to select one of the three image formats per-export session. You cannot select multiple formats during a single export session for USB.

To select a new image format open the archive screen and press the Image format required. The doctor/operator can choose to use any of the three image formats.



The user/operator can select only one image format per recording session on the CD/DVD. This means if you wish to save the images as JPG all the images saved for this particular burn to CD/DVD must all be the same image format.

If the user wishes to save in different formats they will need to copy to USB memory stick or CD/DVD with the selection of format changed for that particular burn cycle of the CD/DVD

10.10.5 SELECT PATIENT IMAGES FOR EXPORT:

First the user must be logged into the system using a permission code.

Now the user must enter the patient file screen and select a patient by touching a patient listed on the screen.

Once a patient is selected the user must then use the Pre-Select button to mark that patient file or additional patients and then the ARCHIVE button will be displayed.

Press the Archive button to enter the Archive screen.

Once the user is in the Archive screen they can select a patient by touching one of the patients on the list. Once the patient is selected the patient images are loaded and displayed on the right monitor.

The user must now decide which external storage device they will use to export image with in order to see how much memory is available. Otherwise the user could select more images than the external device can handle. See the capacity indicator located on the lower left side of the screen.



As the user selects images the indicator will show an indicator bar. When using a DVD with less

than 150 MB of data selected it may not indicate on the capacity indicator. Therefore, there is a second indicator of how much actual data is being selected on the top left side of the indicator bar. In the example above the indicator shows 4.7GB of data capacity that can be stored, and the system is informing the user that only 54.7MB have been selected for export.

If the USB memory device will be used, place the device into the USB port just below the mobile stand keyboard. The user must wait for a few seconds for the USB button to be displayed on the screen.



If the Optional DVD/CD device will be used, insert a disk into the disk drive and wait for about 40 seconds for the disk to be recognized by the system. When the system identifies the disk the system will display the DVD/CD button just below the patient list.



If both are present at the same time the USB memory device and the DVD/CD button will be displayed but the Capacity indicator will display the USB device capacity not the DVD/CD device.

The user can now use the image scroll arrow keys to move the image selection box to the image to be selected view the images on the right monitor.



Once the user has moved the selection box to an image they want to export they can use the Mark-Img to mark a single image from the patient file or they can use the Mark-All button to select the images to be exported.



Once the user has selected all the images for a particular export device, the user must then press the device button USB or DVD to actual start the export of the images to the external storage device. The button pressed will stay yellow during the operation.



10.10.6 USB MEMORY DEVICE PROBLEMS (THUMB DRIVE)

There can be several reasons a particular USB Memory device will not be active and allow storage of images; therefore user/operator should be aware of the following:

1. USB option is not enabled (need to purchase option).
2. No user is logged in (Go to the main screen Log In)
3. File format of the device does not support 255 character length (try another manufacture of the USB memory device)
4. The device is to set to read only (turn off lock on memory device)
5. The device does not have enough memory to hold a single image(3.5MB) (user should make sure there are no other images of files on the memory device when attempting to load images)

6. USB memory devices stops working after being used many times (Check device in another PC to make sure the device is still operational before trying to use it again in the **ZIEHM QUANTUM**)
7. USB memory stops working after being inserted several times (Windows OS may have lost driver information and therefore user operator must restart the system so the Windows OS can load the driver again)



NOTE:

The USB is generally very fast taking only a few minutes to transfer images however, the DVD can take as much as 30 min to greater than 1 hour to transfer several Giga Bytes (GB) of data.

The DVD also needs to write a Table Of Contents (TOC) at the end of the image transfer process. This unfortunately takes nearly the same time if you have just a few images stored or many hundreds of images.

In both cases the system must obtain the image from the hard drive and then convert the images from the RAW format into the particular image format selected and then add all text and graphics to the image. This takes a few minutes depending on the number of images selected.



WARNING:

If the user chooses to use non medical grade CD-R or DVD disks they do so at their own risk.

The non medical grade DVD and CD disks have a potential to loose information or not be recordable and may after a time not be readable.

“THESE NON MEDICAL GRADE DISKS ARE NOT RECOMMENDED FOR USE BY ZIEHM IMAGING, INC.”.



NOTE:

The Embedded Windows operating system can in most cases determine the type and model as well as find a driver to operate the USB memory device. However not all USB memory device models and types can be accommodated Therefore, the **ZIEHM QUANTUM** cannot use all USB memory devices.

10.10.7 OPTIONAL: SEND DICOM IMAGES TO THE PAC’S SERVER

First the optional DICOM package must be active and the system has been programmed for the correct AE and Server addresses in the service configuration screen.

The user follows the above instructions up to the point of selecting the USB or DVD buttons.

The user has merely to press the press the DIOCM SEND button to send and image to the facility PACS Server.

The user can also choose to send an image to a DICOM printer by pressing the DICOM PRINT button.

In all cases the image is also stored automatically to the image system when user/operator presses

the DICOM store or Print button.



NOTE:

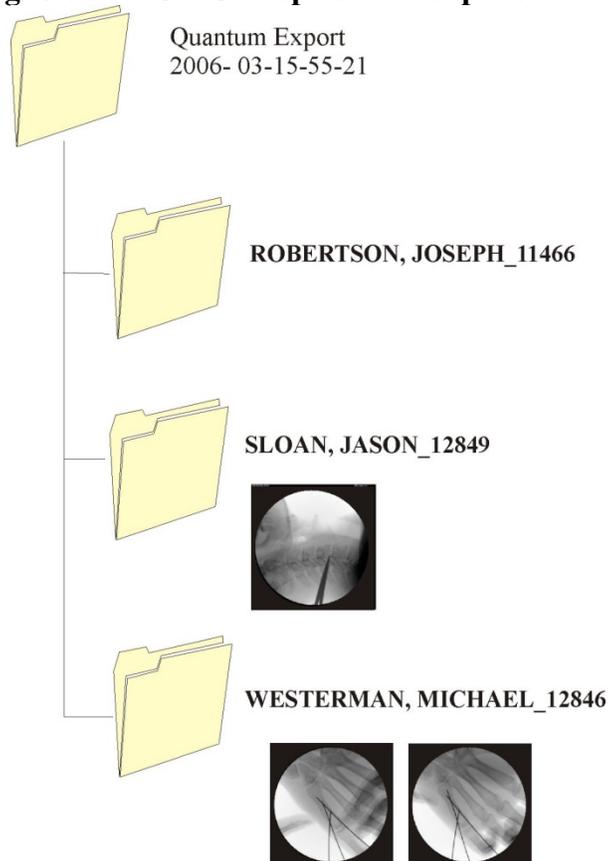
In all cases with DICOM the system must have prior programming and settings made to identify and provide correct addresses for the DICOM network server and printer.

10.11 PATIENT FOLDERS:

The **ZIEHM QUANTUM** will create on the USB and DVD files folders for the images exported to the devices. The Patient folders made by the archive /export function on both the DVD and USB memory Peripheral are made in a file tree structure. The actual folders stored on the disk or USB device will be similar to the example below.

Within each folder the individual images are listed and can be identified by Name ID and Date of creation. The following is just an example not to infer actual patient information.

**Fig 10.8: Example of typical file naming structure
(Following folders DO NOT represent real patient information)**



Escape

The **ESCAPE** button allows the user to leave the Archive screen at any time.

If images were selected for any one or all the patients in the Archive list and the user Escapes from this screen the image marker will be removed and the user will have to re-establish the image markers before they can export images.



10.12 CONFIGURING SYSTEM: (CONFIG)

The system has certain functions and values of image operations that can be set as defaults at start up and for common setting for such functions as noise and edge enhancement which have preset noise processing levels.

The **CONFIGURATION** screen has two basic functions, to support user operations and settings and for administrator use in performing system permissions, DICOM settings, and disc utilities.

We will discuss the Administrative functions first.

There must be at least one administrator for the system to allow input of system permissions and setup of DICOM addresses, USB log of Image export activities, and erasing the hard drive. (See Section 10.8 Log In)

The following items can only be set by the system Administrator; User can not set these listed functions.

- Erase Disc: this function will erase all the patient data from the system hard drive.
- DICOM 1 and DICOM 2 Settings
- Set user permission/passwords for the log in file
- Save export log to USB
- Clear Export Log file
- All of the configuration values for image capture and processing

The ERASE disk operation must be done only in extreme cases where you need to remove all patient data from the system image disk.

This operation is considered a destructive operation in that it will remove all the patient information from the system and cannot be retrieved after it has been erased.



CAUTION

The Administrator should use caution when performing the Erase Disk operation as this operation will remove all the patient information from the system and cannot be retrieved after it has been erased.

10.12.1 ERASING DISK AND ACTIVATING DATABASE AFTER ERASE DISK OPERATION

When using the **ERASE DISK** function the user must perform this in the following manner to avoid errors in the database.

- Never perform this if the patient images have not been saved/removed from the C-arm memory as they will be lost. Once the images are erased they cannot be retrieved.
- Once all patient images have been exported and are safe the administrator should

enter the configuration screen of the Desk view.

ERASING DISK

- Press the **ERASE DISK** button and respond to the message box YES to erase the Disk and NO to cancel the operation. After you press the YES button you will be asked again a second time to make sure you wish to proceed with Disk Erase operation.
- Once the disk operation has been completed, the user will be instructed to turn off the c-arm and re-start the c-arm. After system is turned off Wait at least 10 seconds before turn on power again.
- After you turn on the power and the system has fully booted, press the hand switch to start fluoroscopic exposure for 1 second, release hand switch and then store the image by pressing the **STORE** button on the main touch screen. The right monitor will display the image and small icon on the bottom.

ACTIVATING DATABASE

- Go to the configuration screen and perform the Erase Disk operation a second time and then turn off power when directed to do so.
- Wait 10 seconds and then press the power on switch again. Wait until the system is fully booted.
- Now press the **NEW PATIENT** button to establish a new patient in the image system database. Recommend entering for patient name “TEST” and For ID 123.
- Now press the **SAVE** button to save patient file.
- Press the hand switch to start fluoroscopic exposure for 1 second, release hand switch and then store the image by pressing the **STORE** button on the main touch screen. The right monitor will display the image and small icon on the bottom.
- System is now ready to enter additional patients and store images.



CAUTION

The Administrator should use caution when performing the Erase Disk operation as this operation if not performed correctly may cause incorrect data base operations.

DICOM Settings

If the system has DICOM option and the administrator can use his/her permission to allow the facility Information Technologist (IT) access to change and configure the DICOM settings for **DICOM 1** and **DICOM 2** to match their DICOM port and AE TITLE information.



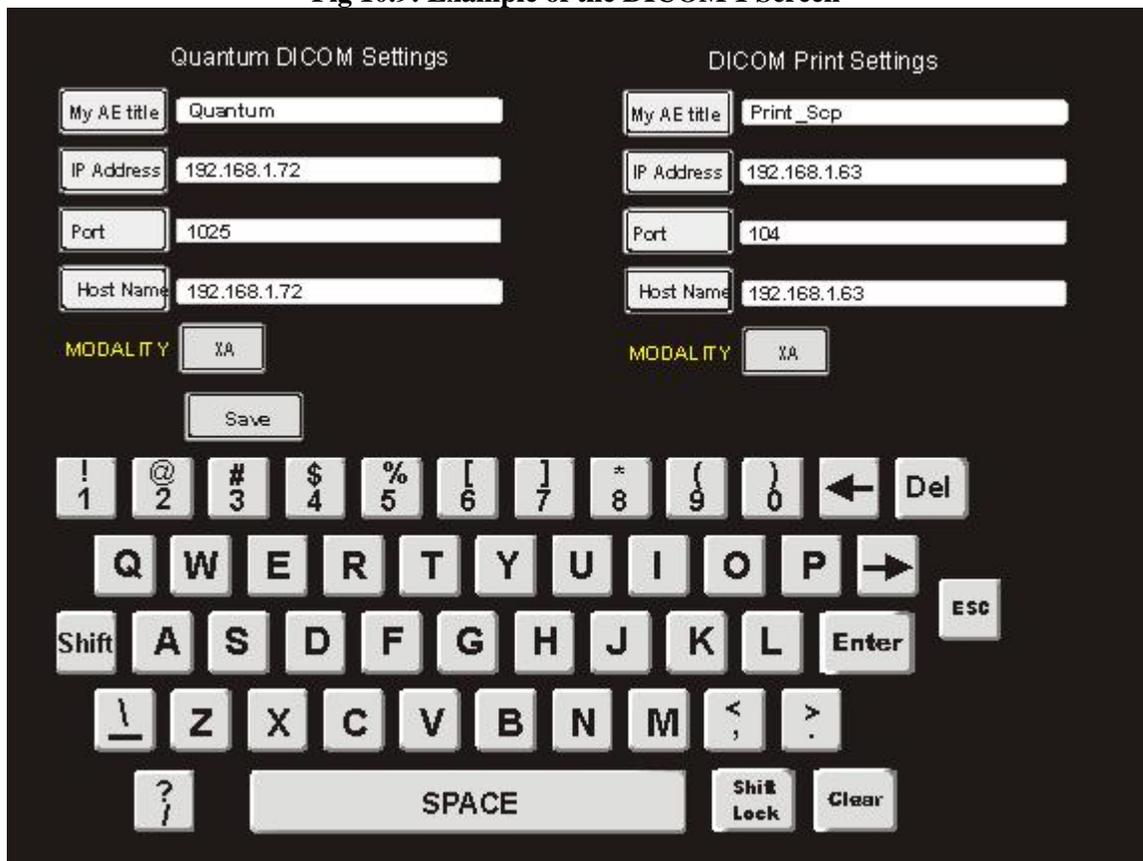
Please see example of settings for **DICOM 1& 2** Screen Fig 10.9 and Fig 10.10.

The following are the fields available for DICOM.

DICOM 1 Screen settings

	Quantum DICOM Settings	DICOM Print Settings
My AE TITLE	Quantum	Print_scp
IP ADDRESS	192.168.1.72	192.168.1.63
PORT	1026	104
Host Name	192.168.1.72	192.168.1.63
Modality	XA, CR,OT, RF, ALL	XA,CR, OT, RF, ALL

Fig 10.9: Example of the DICOM 1 Screen



DICOM 2 Screen settings

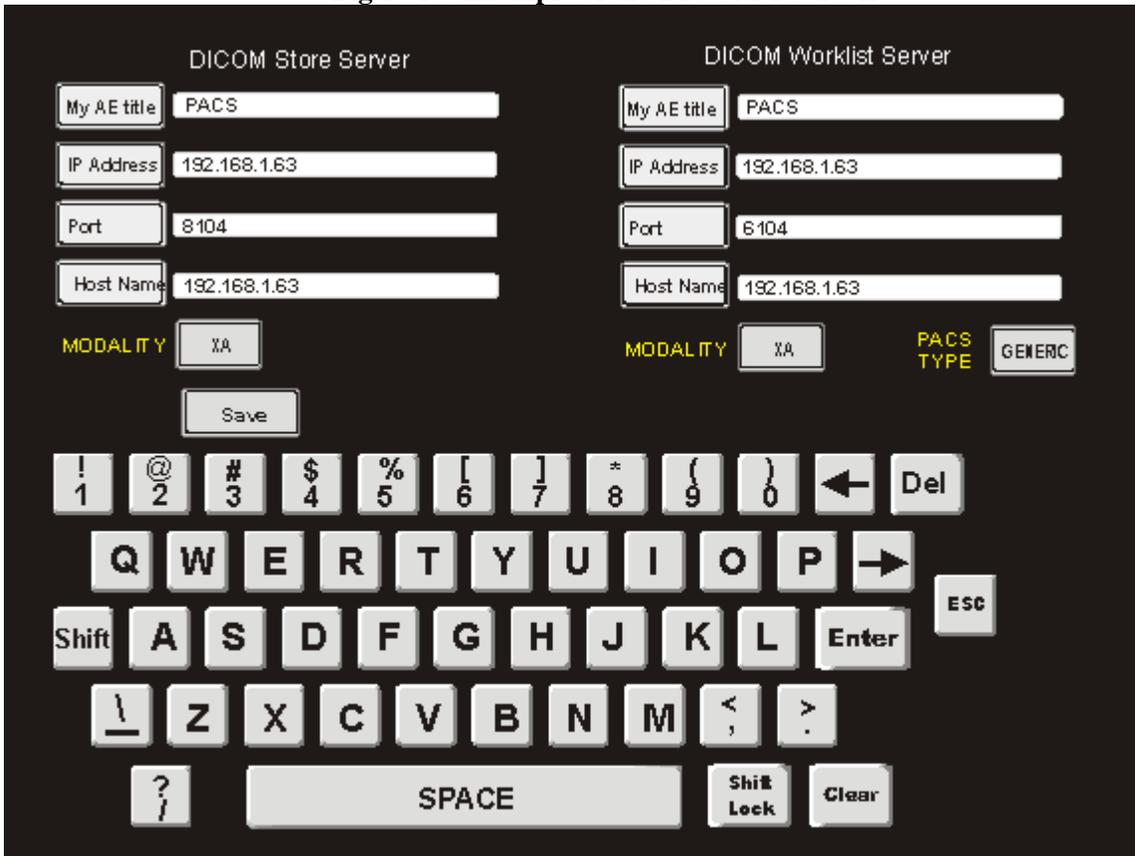
	Storage Settings	Worklist Settings
My AE TITLE	Storage_scp	Worklist_scp
IP ADDRESS	192.168.1.64	192.168.1.66
PORT	107	108
Host Name	192.168.1.64	192.168.1.66
Modality	XA, CR, OT, RF, ALL	XA, CR, OT, RF, ALL
Pacs Type		Generic, McKesson



NOTE:

McKesson: Removes (*) asterisk from DICOM (C-Find) worklist query. Allows retrieval of work list, vendor specific solution for non-DICOM 3 complaint server.

Fig 10.10: Example of the DICOM 2 Screen



The screenshot displays two columns of configuration fields for DICOM servers. The left column is for the 'DICOM Store Server' and the right column is for the 'DICOM Worklist Server'. Both columns have identical input fields: 'My AE title' (value: PACS), 'IP Address' (value: 192.168.1.63), 'Port' (value: 8104), and 'Host Name' (value: 192.168.1.63). Below these fields are two dropdown menus: 'MODALITY' (value: XA) and 'PACS TYPE' (value: GENERC). A 'Save' button is located below the 'MODALITY' dropdown. A full QWERTY keyboard overlay is positioned at the bottom of the screen, with a 'Clear' button to its right.

All AE, IP, Port, Host names, Modality and Pacs Type are just examples in this manual the actual values for each must be obtained from the Information Technologies department of the facility and then entered accordingly.

To enter and set up DICOM services please contact your “Ziehm Imaging, Inc. Service Representative” for details and to schedule the installation and testing of the DICOM settings.

10.13 Setting User/Administrative Log in Permissions

10.13.1 RESTRICTIONS:

There are two levels of Permission allowed for facility operation:

1. Administration level:

This level allows the facility to have one person responsible as the system administrator; the administrator will be able to add USER permission for USB, DVD and DICOM options to extract images from patient records.

The Administrator can also erase all patient records by entering the configuration screen and activating the “**ERASE DISK**” function

Select and export Log In file from system, gives log of patient and images as well as permission used to copy images from the system

2. User level:

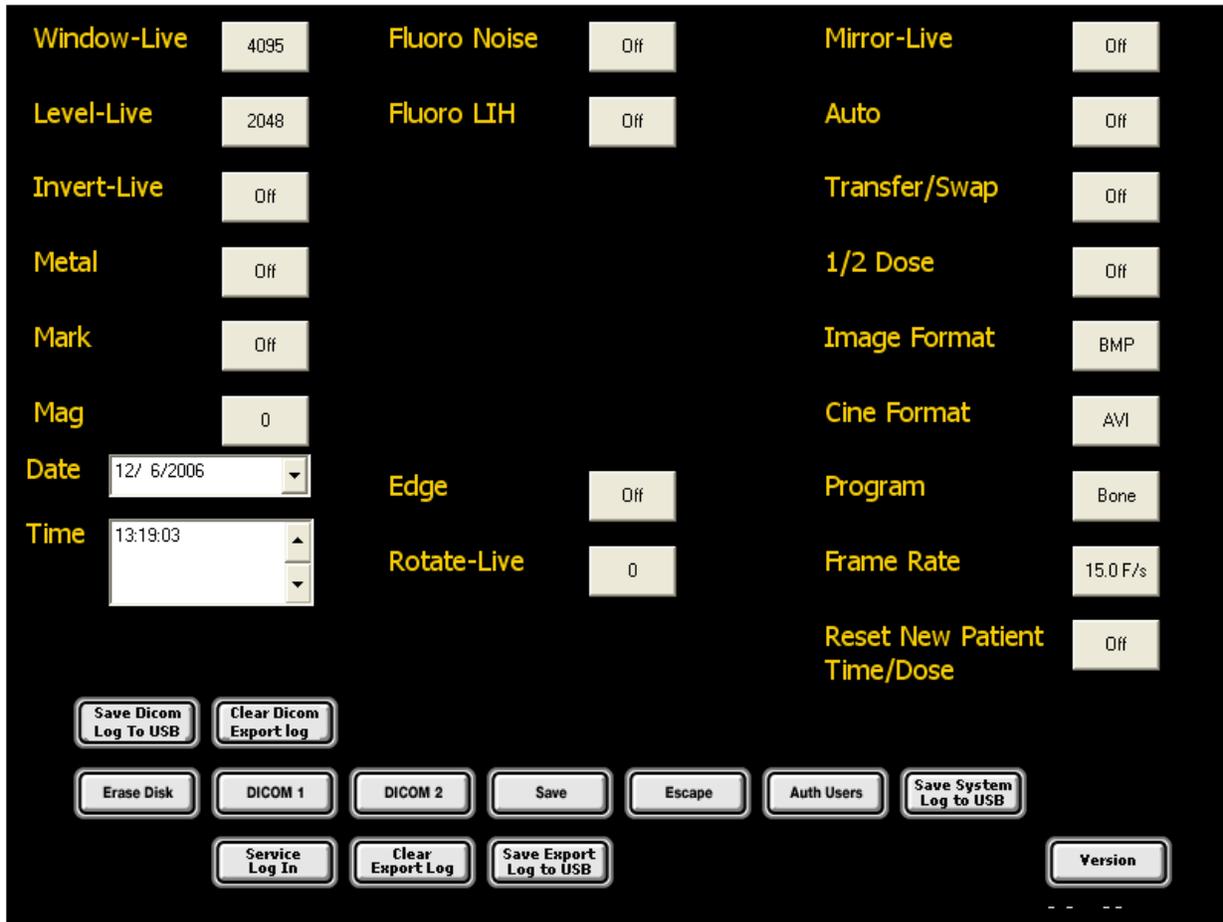
Allows user to enter password and extract by means of DICOM and USB devices. But they cannot enter other users

Enter Authorization Screen:

To view Administrative selections you must first go to main screen and Log In using the “**Administration Password**”

The button to enter the configuration screen can be found on the **PAT FILE** screen center right side “**CONFIGURATION**”. Once the administrator presses the **CONFIGURATION** button the Configuration screen will be displayed with all selection available to the Administrator. See Example below.

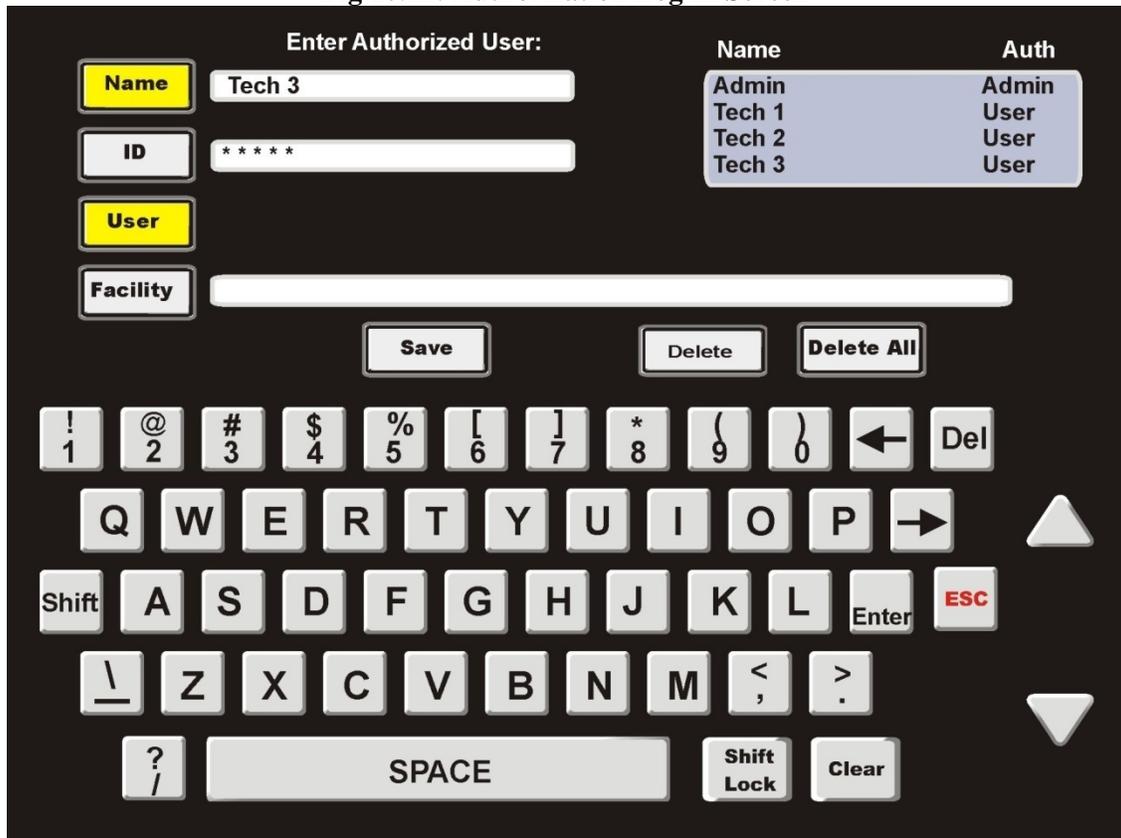
Fig 10.11: Main Configuration Screen



The Administrator now presses the AUTH USERS Button on the configuration screen to enter the Authorization screen to setup up user permissions to the system for performing Archive/Export functions.



Fig 10.12: Authorization Log In Screen



10.13.2 SETTING USER PERMISSIONS

Step 1

- Make sure the Authorization Log In screen is visible, see figure 10.12 above.
- Press the text entry box for the name and then type in the name of a new user. (must be more than 4 alphanumerical characters long)
- Next enter a password (must be more than 4 alphanumerical characters long)
- Next select the Permission level button twice to toggle through the selection for “ADMIN” or “USER”.
- Once the name, password and permission level is set, press the **SAVE** button to save the new Log In permission

10.13.2.1 DELETE SINGLE LOG IN PERMISSION:

- Press the Log In button on the main screen
- Once the Log In screen is visible on the touch panel select from the name and permission field the particular permission to delete
- Once the name is highlighted press the **DELETE** button confirm message
- Permission is now removed from the list.

10.13.2.2 DELETE ALL PERMISSIONS:

Administration Permission can also delete all but the Administrative person that is logged into the screen.

- Once the Log In screen is visible on the touch panel press the **DELETE ALL** button.
- If you wish to continue Press yes in the message box

The system will remove all but the present logged in administrative person.

10.13.2.3 SAVE AND CLEAR EXPORT LOG FILES:

The System creates Log In files for each export of images from the archive and USB, DICOM functions.



The Administrator has permission to Copy the Log file to a USB memory device and to delete the log file.



CAUTION

The log file should be copied once a week to keep it from getting too large. The system will stop acquiring the log files when the file reaches its maximum capacity. There is no alert for this so the Administrator is encouraged to copy and then reset the Log file once a week.

The Log files can be found at the bottom of the Configure screen center and will only be visible if the Administrator has logged into the system. See example of the configuration screen above in this section of the manual.

User configurations

The Administrator and the User may select the start up default settings for several of the image operations, such as, set the NR to start at low, med, or high. Select invert, image mirror operations, Last image Noise reduction "LIH", etc.

See Configuration screen below for selections and location of the buttons.

Fig 10.13: Configuration Screen

Window-Live	<input type="text" value="4095"/>	Fluoro Noise	<input type="text" value="Off"/>	Mirror-Live	<input type="text" value="Off"/>
Level-Live	<input type="text" value="2048"/>	Fluoro LIH	<input type="text" value="Off"/>	Auto	<input type="text" value="Off"/>
Invert-Live	<input type="text" value="Off"/>			Transfer/Swap	<input type="text" value="Off"/>
Metal	<input type="text" value="Off"/>			1/2 Dose	<input type="text" value="Off"/>
Mark	<input type="text" value="Off"/>			Image Format	<input type="text" value="BMP"/>
Mag	<input type="text" value="0"/>			Cine Format	<input type="text" value="AVI"/>
Date	<input type="text" value="12/ 6/2006"/>	Edge	<input type="text" value="Off"/>	Program	<input type="text" value="Bone"/>
Time	<input type="text" value="13:15:16"/>	Rotate-Live	<input type="text" value="0"/>	Frame Rate	<input type="text" value="15.0 F/s"/>
				Reset New Patient Time/Dose	<input type="text" value="Off"/>

10.13.4 SETTING TIME AND DATE:

The system time and date must be set using the configurations screen.

- Select the Date by pressing on the right side over the arrow on the drop box
- The system will display a calendar.
- Use the right and left arrows to move to the month and year
- Now press the date within the month desired.
- The system will display the **SET TIME** button.
- Press this button to update the system time and date.
- Now press the **SAVE** button on the configuration screen and restart the system.

Set Time 

VERSION:

Press the lower right button **VERSION** on the configuration screen and a message box will open with the current software versions. Press “OK” to clear the screen; you may have to do this twice



SAVE

The User and Administrator must press the **SAVE** button to save any changes to the configuration screen before leaving otherwise the changes will not take effect when the system is rebooted.



ESCAPE

The user can escape the screen without changes by pressing the **ESCAPE** button. The system will close the configuration screen and then return to the Patient File screen.

- Press the selection buttons to toggle the functions ON or OFF, or to set a mode like noise LOW, MED, or High.
- The sections are used at startup and are the default settings when the system boots.
- After you make changes press the save button to save the changes.





NOTE:

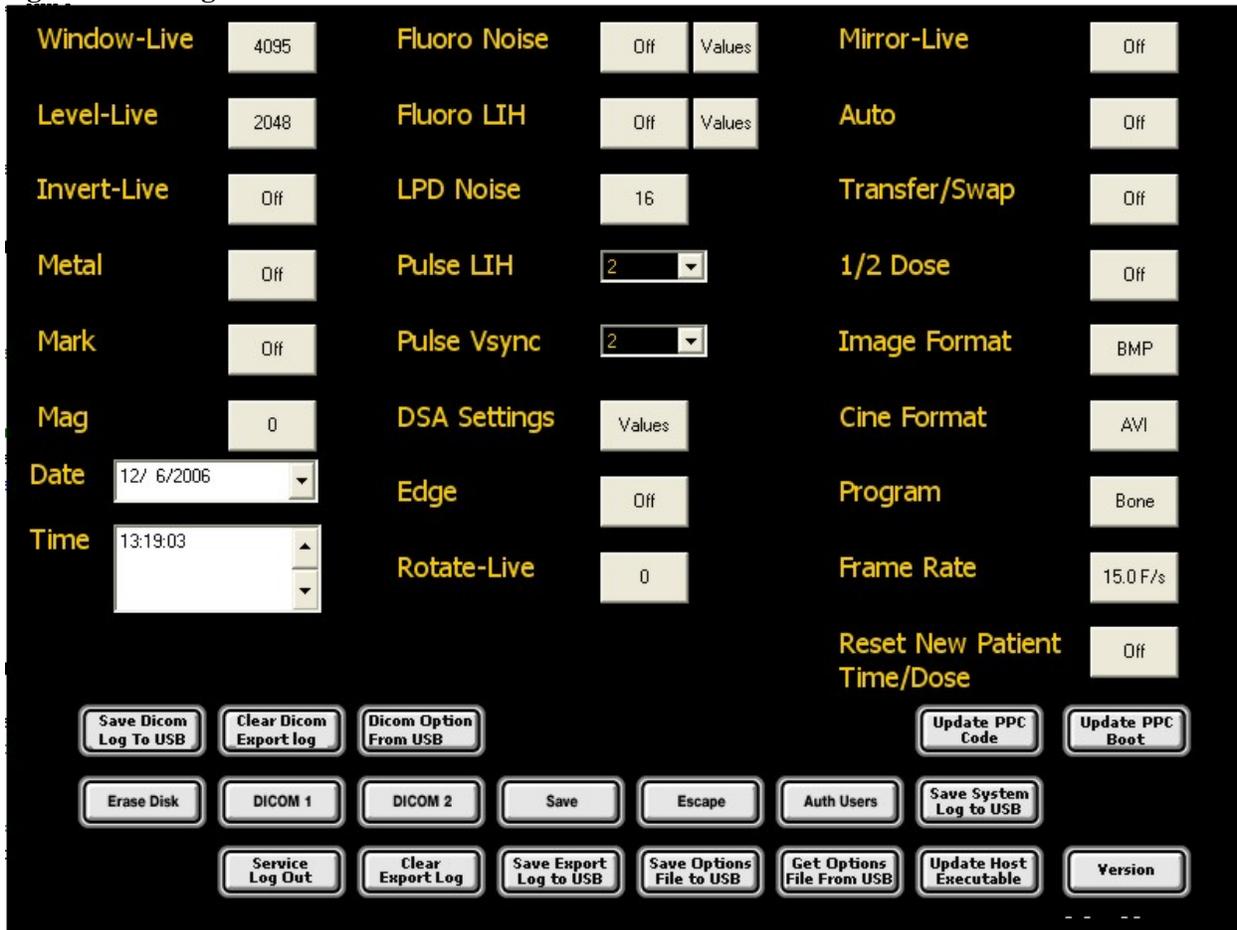
Some selections will have no effect if the owner operator did not purchase certain product options. Such as CINE, DSA, DICOM, etc.

10.13.3 SETUP SERVICE KEY AND SERVICE LOG IN

These are for service use only and are not intended for the User/operator or Administrator to use.



Fig 10.14: Configuration Screen



10.13.4 SETUP SERVICE KEY AND SERVICE LOG IN

The system service defaults and operational software Log In screen.

- Service screen requires special rights and training to set the correct values and update of software.
- Only qualified Service Engineers can access the service areas of the configuration file and set optional settings for DSA, Window level, and LUT tables.
- Instructions to enter and changes to be made can be found in the service documentation.

11.0 ZIEHM QUANTUM OPTIONAL TRANSPORT BRACKETS

The **ZIEHM QUANTUM** transport brackets were developed as an option to the standard transport packaging. This option may be preferred if frequent location changes are required and where floor, truck, or container transport is required. The transport brackets consist of floor and C-Arm mounted components as well as a hard-shell foam lined container for the display monitor assembly. The floor-mounted components are a large plate of aluminum, C-Arm and floor mounting brackets are all secured through the plate and into the floor or pallet. The generator cradle is also secured to the floor or pallet and securely holds the generator in place during transport. The C-Arm mounted components consist of brackets to secure the monitor arm and DeskView control panel in place during transport. The hard-shell foam lined container for the monitor assembly is secured to the floor with banded strapping and is used to contain the monitors during transport. If this option is ordered a hole layout diagram may be requested to allow modification of the floor, truck or transport container.

11.1 FLOOR MOUNTED INSTALLATION

- Ensure that the C-Arm base plate and generator cradle bracket are securely mounted to the floor. Example Fig 11.1

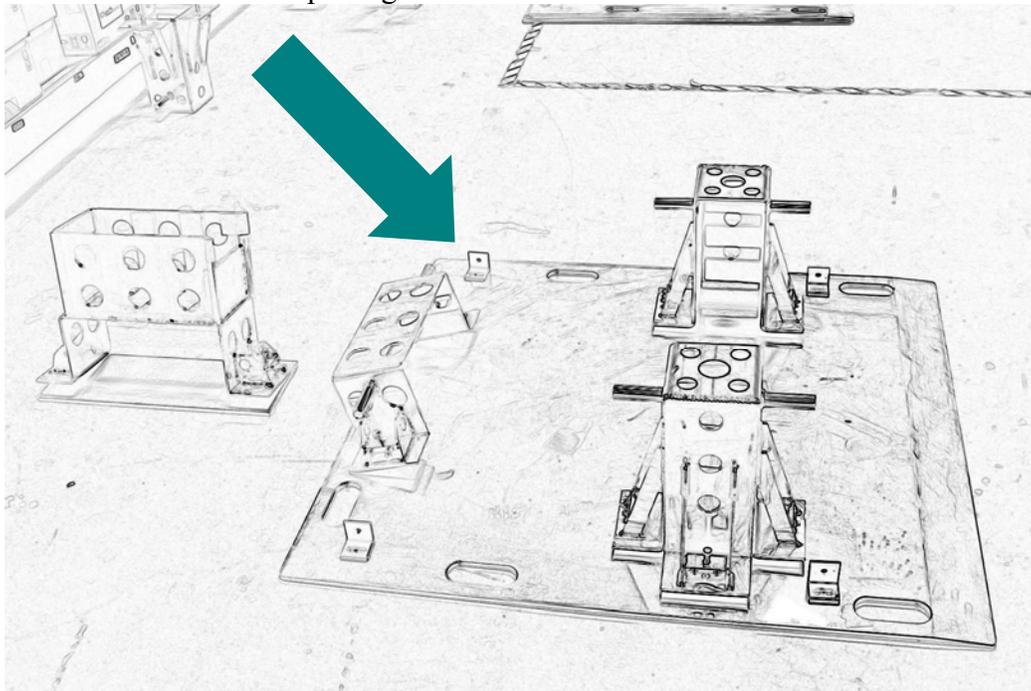


Figure 11.1

- Power up the C-Arm and adjust the vertical height to 14cm. Example Fig 11.2



Figure 11.2

- Slowly but firmly push the front C-Arm wheels up the base plate ramp while guiding the generator assembly to the generator cradle bracket Example Fig 11.3.

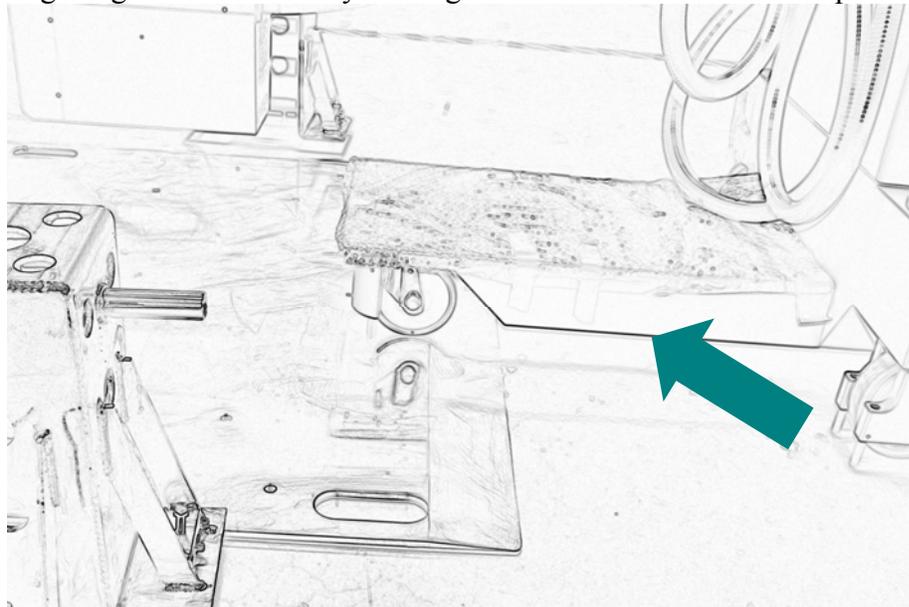
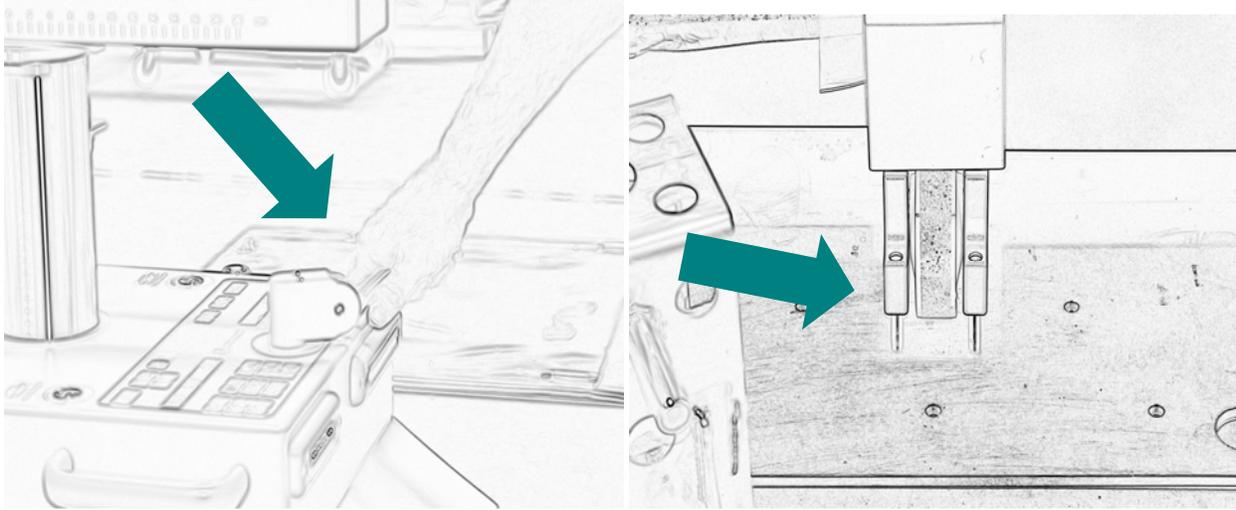
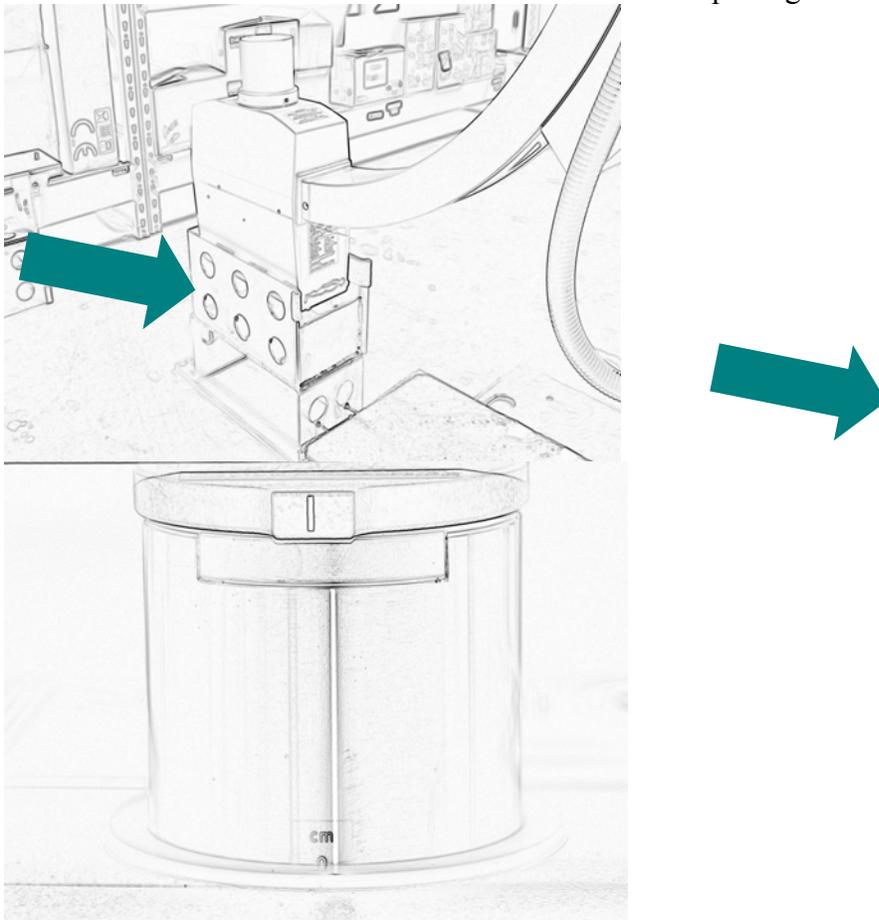


Figure 11.3

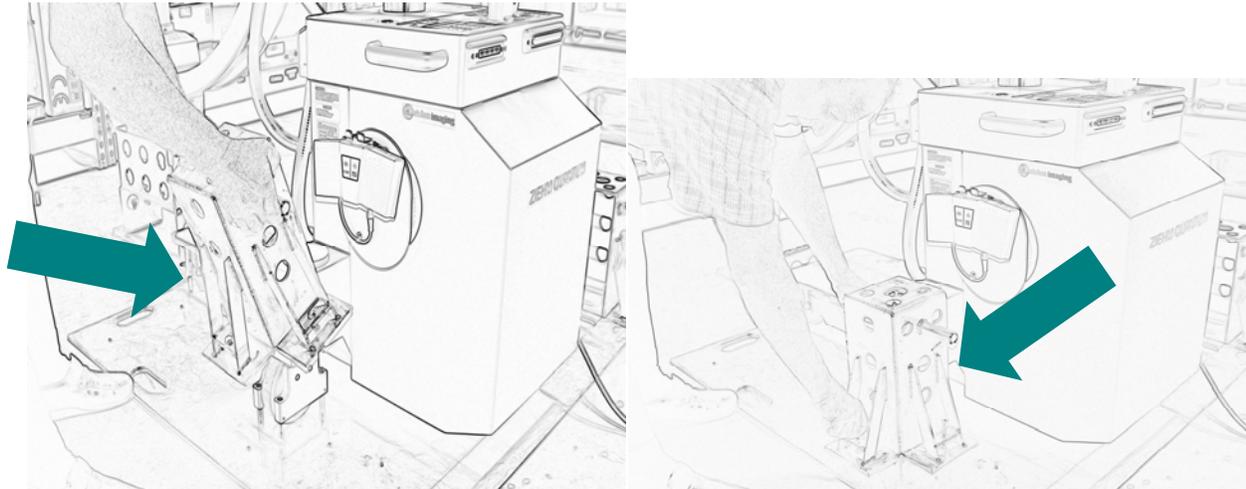
- Adjust the steering lever to position the steering wheels at 90 degrees to the C-Arm body. Example Fig 11.4.



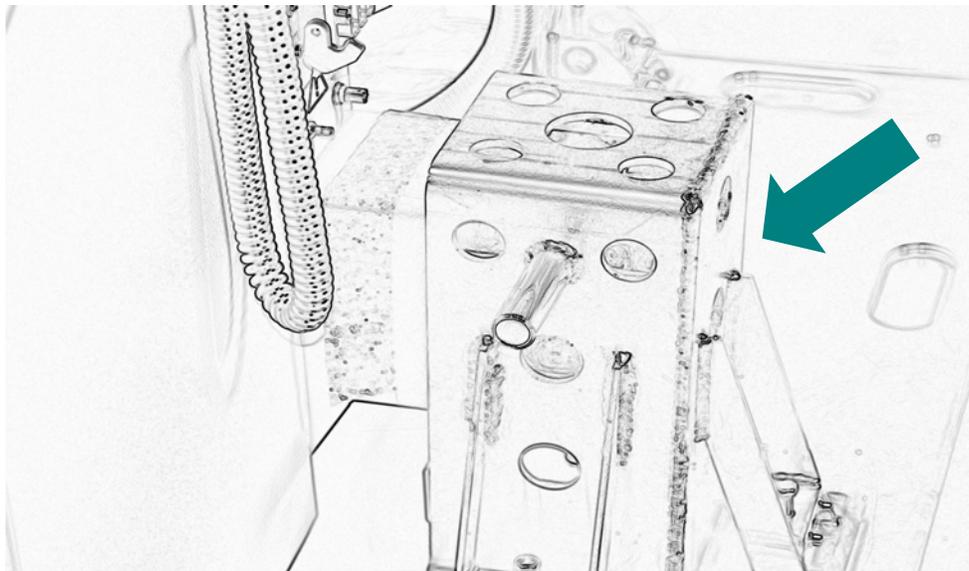
- Lower the vertical shaft while guiding the generator assembly into the generator cradle. Continue until the vertical shaft is at 0cm. Example Fig 11.5



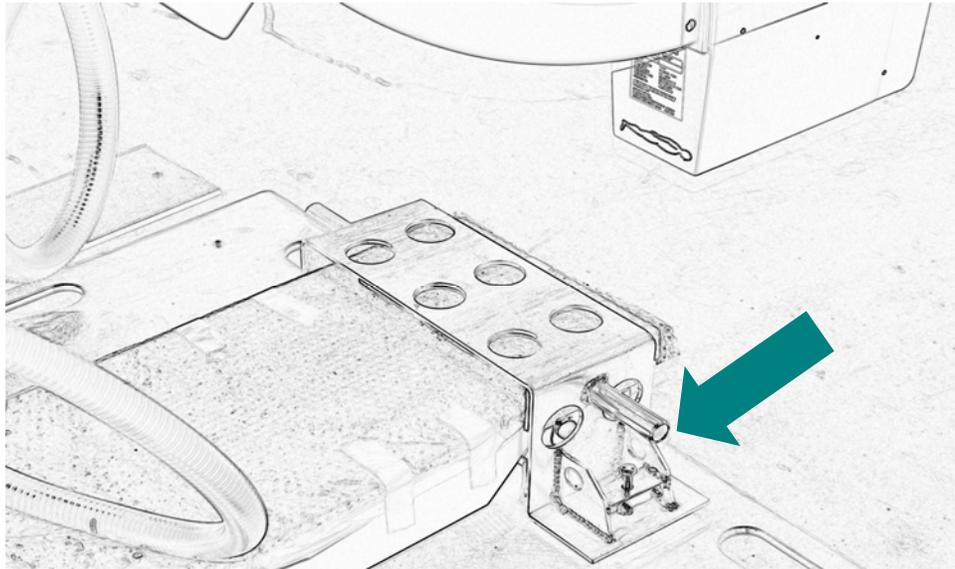
- Position the bracket with stencil # 4 over the left wheel hub assembly. Example Fig 11.6



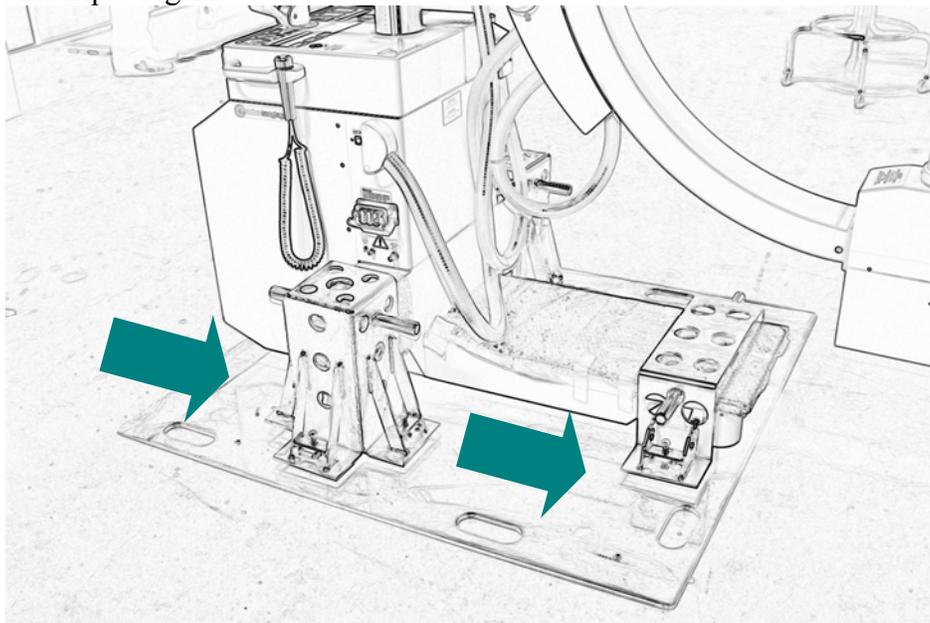
- Position the bracket with stencil #3 over the right wheel hub assembly. Example Fig 11.7



- Position the bracket with stencil #2 over the front wheel assembly. Example Fig 11.8



- Tighten the 2 bolts to secure the front wheel bracket to the floor mounting plate and the 3 bolts to secure the left and right wheel brackets to the floor mounting plate. Example Fig 11.9

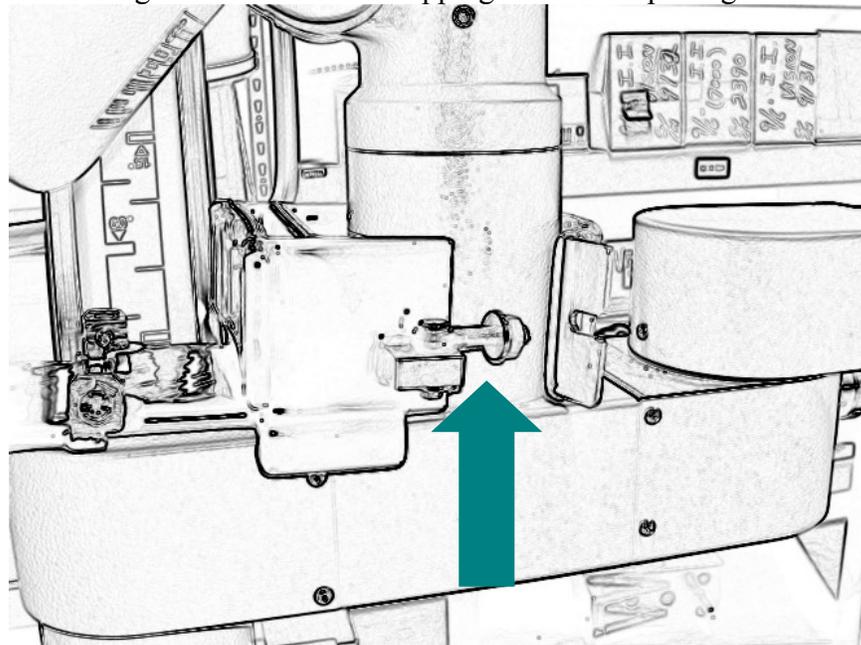


11.2 SHIPPING LOCKS INSTALLATION

- Push the shipping lock forward and while simultaneously pulling the curved portion of the bracket around the DeskView support shaft. Example Fig. 11.10.



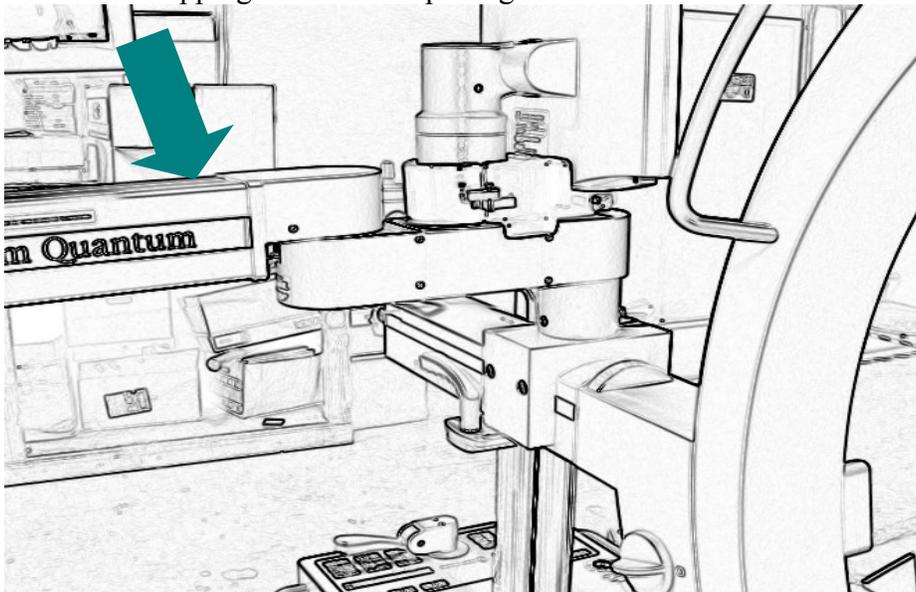
- Tighten the locking bolt to secure the shipping lock. Example Fig 11.11



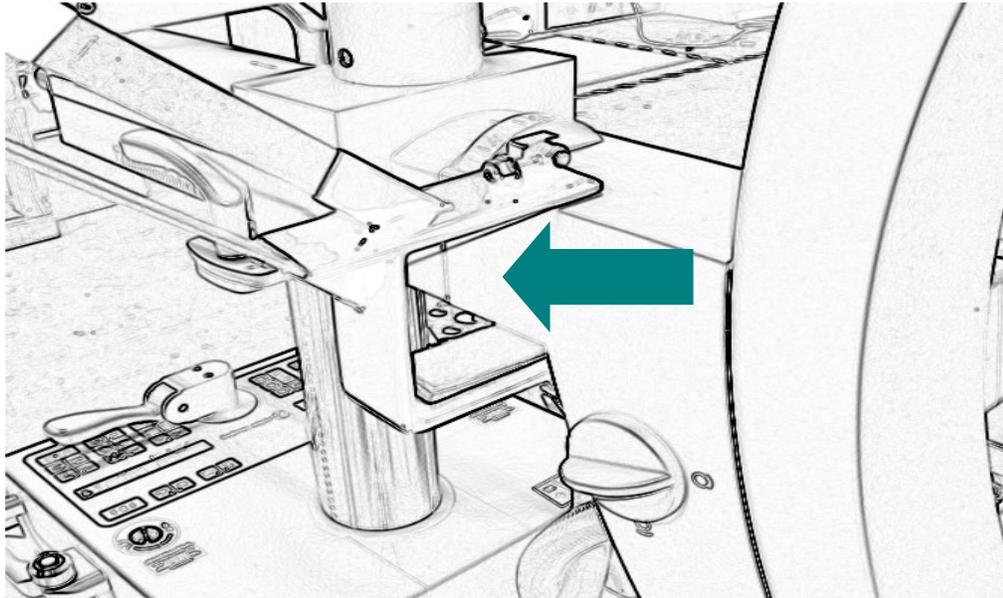
- Press the DeskView assembly into the home position and lift the lever to securely locate the DeskView to the transport position. Tighten the two bolts to keep the lever in position. Example Fig 11.12



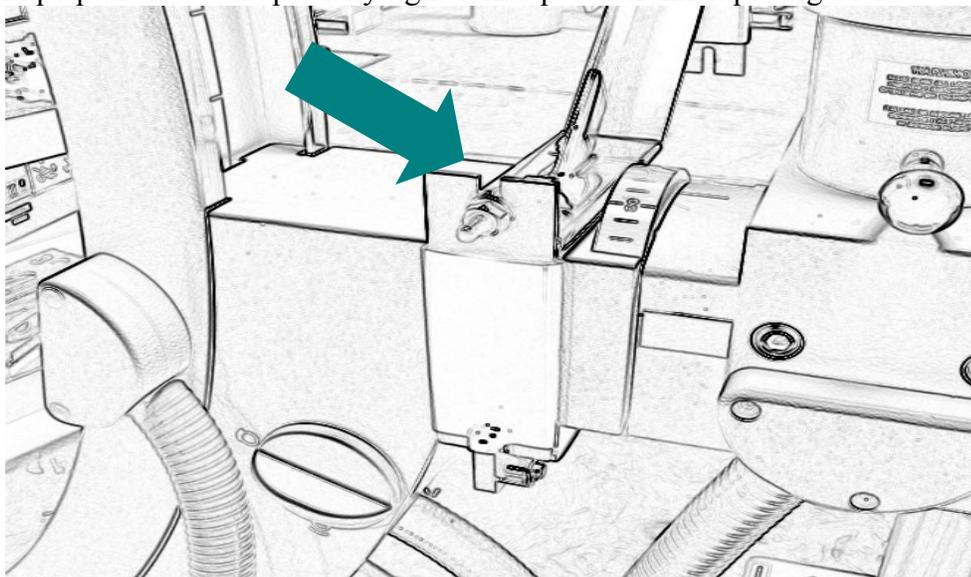
- Ensure the C-Arm monitor arm assembly is fully extended after securing the DeskView shipping locks. Example Fig 13



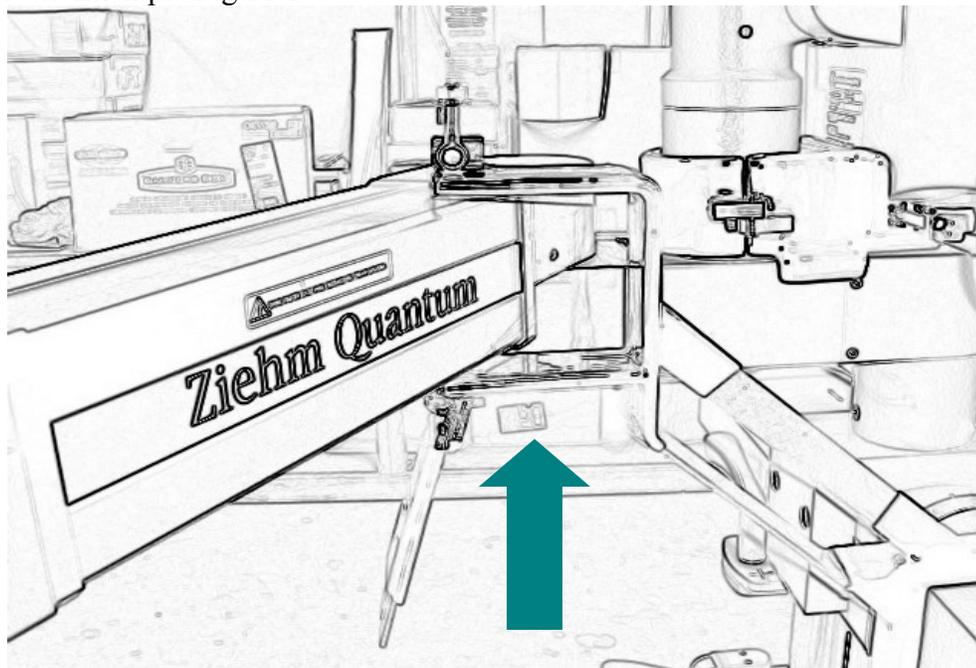
- Slip the Arm Support Shipping lock onto the horizontal arm assembly. Example Fig 11.14



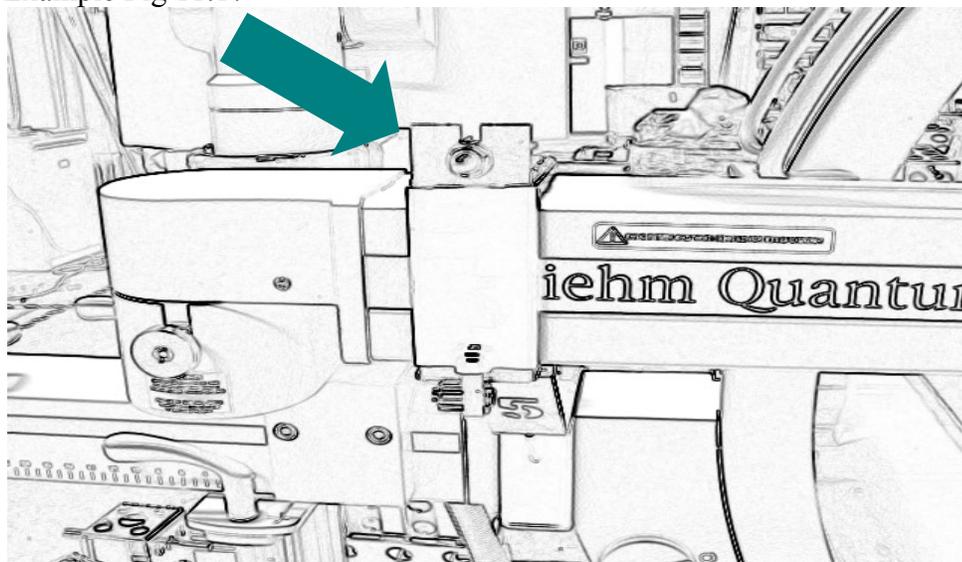
- Flip up the lever and partially tighten into position. Example Fig 11.15



- Slowly rotate the monitor arm into the top portion of the Arm Support Shipping lock. Example Fig 11.16



- Flip up the lever and secure into position and tighten bolt from step 7 above. Example Fig 11.17



- For removal instructions perform the above steps in reverse order starting with the shipping locks and then the floor brackets.

11.3 SHIPPING LOCKS REMOVAL

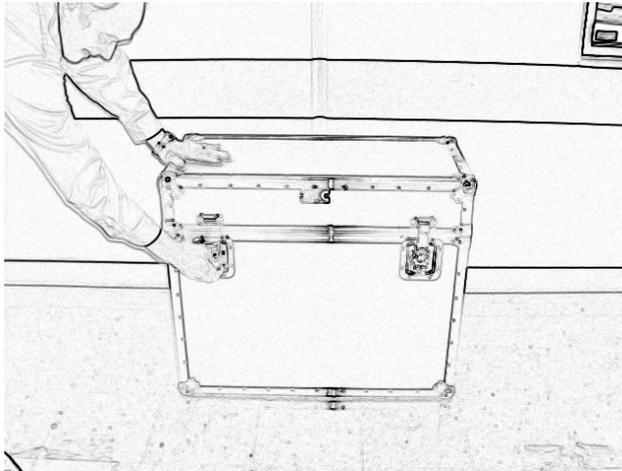
- Loosen the bolt and flip down the lever to allow the monitor arm to be rotated out of the shipping lock. Example Fig 11.18
- Slowly rotate the monitor arm entirely out of the top portion of the Arm Support Shipping lock. Example Fig 11.17
- Loosen the bolt and flip down the lever to allow the Arm Support Shipping lock to be removed from the horizontal arm assembly. Example Fig 11.16
- Slowly remove the Arm Support Shipping lock from the horizontal arm assembly. Example Fig 11.15
- Loosen the two bolts from the DeskView and lower the lever. Example Fig 11.13
- Loosen the locking bolt to secure the shipping lock. Example Fig 11.12
- While simultaneously pulling the curved portion of the bracket around the DeskView support shaft. Pull the shipping lock forward to remove. Example Fig, 11.11

11.4 FLOOR MOUNTED REMOVAL

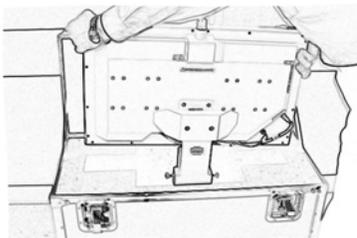
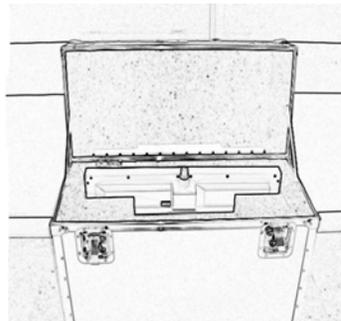
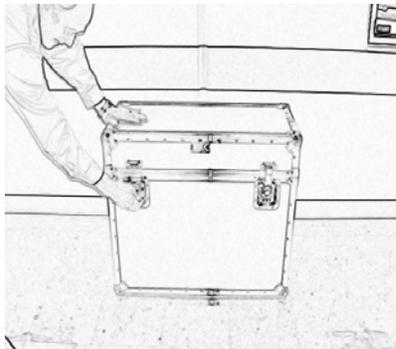
- Loosen the 2 bolts that secure the front wheel bracket to the floor mounting plate and the 3 bolts that secure the left and right wheel brackets to the floor mounting plate. Example Fig 11.9
- Remove the bracket with stencil #2 from the front wheel assembly. Example Fig 11.8
- Remove the bracket with stencil #4 from the left wheel hub assembly. Example Fig 11.7
- Remove the bracket with stencil #3 from the right wheel hub assembly. Example Fig 11.6
- Power up the C-Arm and adjust the vertical height to 14cm. Example Fig 11.2
- Adjust the steering lever to position the steering wheels at 0 degrees to the C-Arm body. Example Fig 11.4
- Slowly but firmly pull the C-Arm wheels down the base plate ramp while guiding the generator assembly out of the generator cradle bracket. Example Fig 11.3

11.5 MONITOR TRANSPORT CONTAINER

- Open the Monitor Transport Container



- Remove monitor assembly from the c-arm monitor arm and insert the monitor assembly into the transport container. (see section 4.2.2 for how to mount and un mount the monitor assembly)
- Make sure the monitor seat fully into the transport container
- Close the Container and lock the locks on the front side of the container then strap the container to the shipping floor, truck, or pallet



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12.0 TECHNICAL DATA

This chapter presents technical information for the **ZIEHM QUANTUM** C-Arm, and includes heating and cooling charts and dose display.

Ziehm Imaging, Inc. reserves the right to make changes in specifications at anytime without prior notification.

Technical data Ziehm Vision (U.S.A.)

12.1 SAFETY CLASSIFICATION

12.1.1 STATEMENT OF COMPLIANCE IEC STANDARDS:

- IEC 601-1:
- IEC 601-2-7:
- IEC601-2-8:
- IEC 601-2-32:

The **ZIEHM QUANTUM** is classified as Class I, continuous-use, type B equipment.

12.1.2 FDA PRODUCT CLASSIFICATION NAME / CODE:

- Complies with FDA/CDRH radiation performance standards, 21 CFR Subchapter J, as of the date of manufacture.
- System, X-Ray, Fluoroscopic, Image Intensifier,
- Product Code: JAA
- Regulation number: 892.1650



WARNING:

The **ZIEHM QUANTUM** is not suitable for use in a flammable atmosphere.



WARNING:

Rapid changes to temperature can damage system components. **DO NOT** operate system until equipment has reached a safe operating room temperature. Severe damage may occur! Failure to observe this warning will result in loss of warranty and sever damage to the device. Several hours may be required for system to reach safe temperatures.



NOTE:

Environmental limits for system.

Transport: -10⁰ –60⁰C, Humidity 10% - 95% non condensing, Pressure: 500 – 1060mbar

Operational: +10 – 35⁰C Humidity 35% - 75% non condensing

12.2 TECHNICAL SPECIFICATION

 Table -Technical data of the **ZIEHM QUANTUM U.S.A.)**

Power	120 VAC 60Hz	Option: 230 VAC 60Hz
Direct radiography:	40–110 kV	40–110 kV
Tube Current	2 mA min/ 20mA max.	2 mA min. /20 mA max.
mAs Range	.4 mAs min./100 mAs max	.4 mAs min. /100 mAs max.
Fluoroscopy:	40–110 kV	40–110 kV
	0.1–6 mA	0.1–6 mA
–Pulsed mode:	Pulse Max 3F/s	Pulse Max 3 F/s
Digital radiography	40–110 kV	40–110 kV
(snapshot):	0.2 mA min./20 mA max.	0.2 mA min./20 mA max.
Operating frequency:	20 kHz	20 kHz
Required residual current	$I_N \geq 16 \text{ A}, I_{AN} = 30 \text{ mA}$	$I_N \geq 20 \text{ A}, I_{AN} = 30 \text{ mA}$
Line resistance	$\leq .6 \text{ Ohms}$	$\leq .6 \text{ Ohms}$
Max. operating data		
Fluoroscopy Generator	110 kV / 6 mA	110 kV / 6 mA
	80 kV / 6 mA	80 kV / 6 mA
Direct radiography:	110 kV / 8 mA	110 kV / 8 mA
	80 kV / 8 mA	80 kV / 8 mA
Radiography:	110 kV / 18 mA	110 kV / 20 mA
	80 kV / 18 mA	80 kV / 20 mA
Max. power output		
Fluoroscopy:	660 W (110 kV / 6 mA)	660 W (110 kV / 6 mA)
Direct radiography:	880W (110 kV / 8 mA)	880 W (110 kV / 8 mA)
Direct radiography:	1980 W (110 kV / 18 mA)	2200 W (110 kV / 20 mA)
Nominal electric power	2000 W at 100 kV / 20 mA / 0.1 s	
X -ray tube	Dual-focus stationary-anode tube	
Focal spot nominal size	Nagel 0.6 acc. to IEC Small 1.5 acc to IEC Large	Toshiba 0.5 acc. to IEC Small 1.5 acc to IEC Large
Total filtration	$\geq 39 \text{ mm Al @ 110kV}$	

Image Intensifier Tube	Input screen: Cesium iodide
Image intensifier	Nominal sizes: 23 / 17 / opt (10) cm
Anti-scatter grid	Pb 8/40
C-arm	Source-image receptor distance: 970 mm Source-image receptor Opt 31: 1007mm Vertical free space: 750 mm Vertical free space: 787.4mm Immersion depth: 680 mm
Dimensions	Orbital rotation: 135° a Angulation: ± 225° Swiveling (panning): ±10° Horizontal movement: 220 mm Vertical movement: 430 mm
C-arm stand	With 23 cm I.I.: approx. 260 kg
Environmental	
During Storage conditions	Temperature: -10°C to +60°C Relative air humidity: 10% - 95% non Condensing max.
During operation Environmental	Temperature: +10°C to +35°C Relative air humidity: 35%-75% non Condensing max.

12.3 X-RAY GENERATOR X-RAY GENERATOR, HOUSING AND TUBE WITH BEAM-LIMITING DEVICE

Device: ZIEHM QUANTUM C-Arm with x-ray source assembly Maxipuls 3-110 Generator

Manufacturer:	Ziehm GmbH
ZIEHM Maxipuls 3-110	
- Total filtration	> 4 mm AL
- Focal spot	06./1.5 mm or 0.5 /1.5mm
- Tube type Nagel & Goller	EP-F 181-0.6/1.5 - 125-60
- Tube type Toshiba	DF-151-R-0.5/1.5-110-40
- Registration no.	BY 287/84/RO
- Target material	Tungsten
- Target angle	12°
- Radiation leakage	< 1 m Sv/h at 110 kV/7200 mAs/ hr

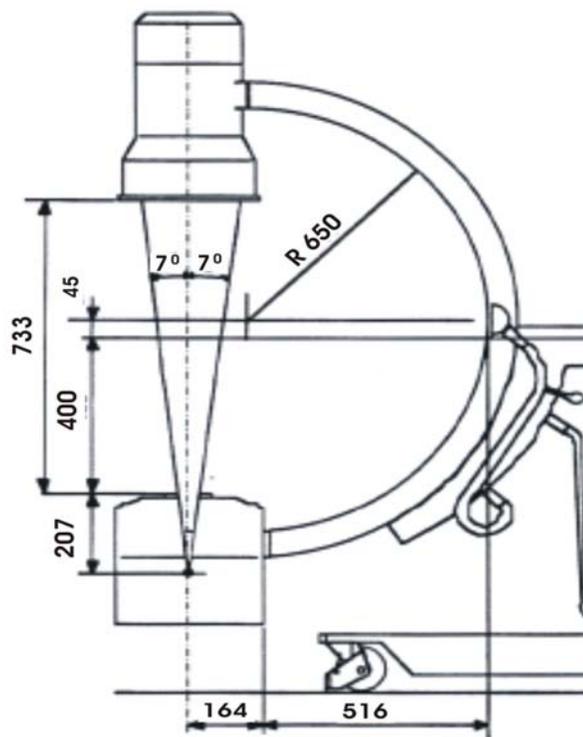
Manufacturer:	Ziehm GmbH
- Maximum admissible high voltage	110 kV
Dose Rate Control	kV - mA are constant pairs and is set by the factory.

12.4 MECHANICS

Weight Monitors (Pair)	With 18.1" flat-screen monitors: approx. 12.6 kg
18.1" flat-screen monitors Screen size: Resolution:	460 mm (18.1") 1280 × 1024 / 60 Hz
During storage Conditions	Temperature: -10°C to +60°C Relative air humidity: 95% max.
During operation Environmental	Temperature: +15°C to +35°C Relative air humidity: 75% max

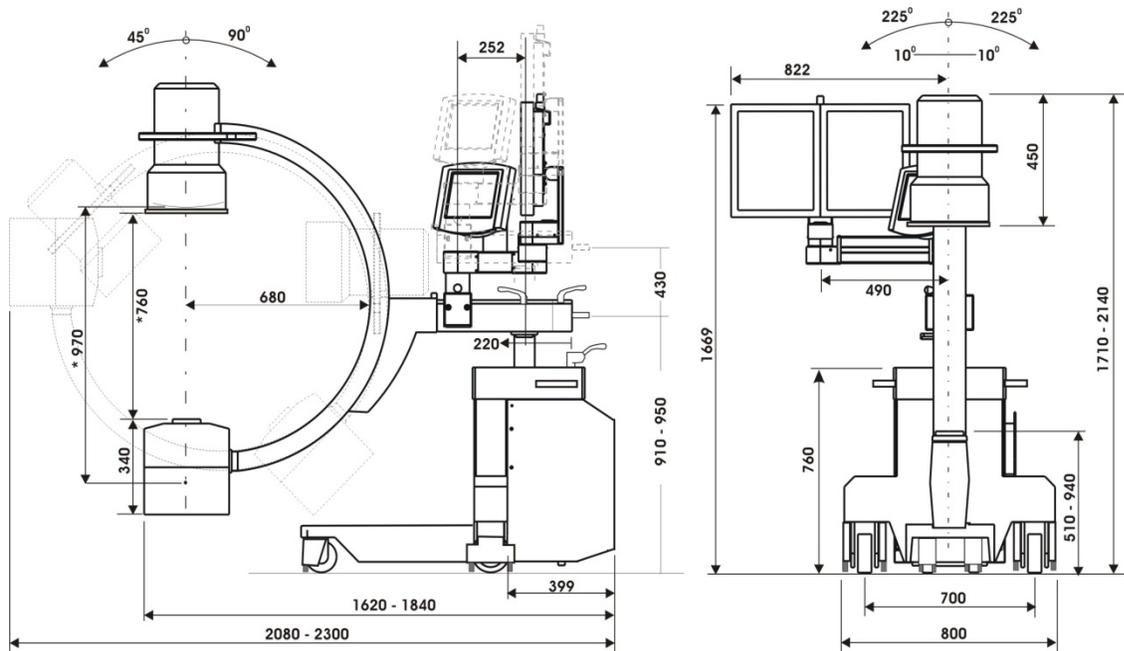
X-Ray Tube Focal Spot and Reference Axis 30" C-profile opening

Fig 12.1: Focal Spot Reference



12.5 C-ARM OVERALL DIMENSION

Fig 12.2



12.5.1. CONVERSION TABLE MM TO INCHES

MM	Inches		MM	Inches
220	9.00		822	19.30
252	9.94		910	35.75
340	13.375		940	37.00
399	15.70		950	37.40
430	17.00		970	38.25
450	17.75		1669	66.90
490	19.30		1710	67.25
510	20.00		1840	72.50
680	26.75		2080	81.875
700	27.50		2140	84.25
760	30.00		2300	90.50
800	31.50			

12.6 SCATTERED RADIATION IN THE SIGNIFICANT ZONE OF OCCUPANCY

Fig 12.3: Radiation Scatter Pattern

Distribution of scattered radiation in the significant zone of occupancy of the C-arm stand.

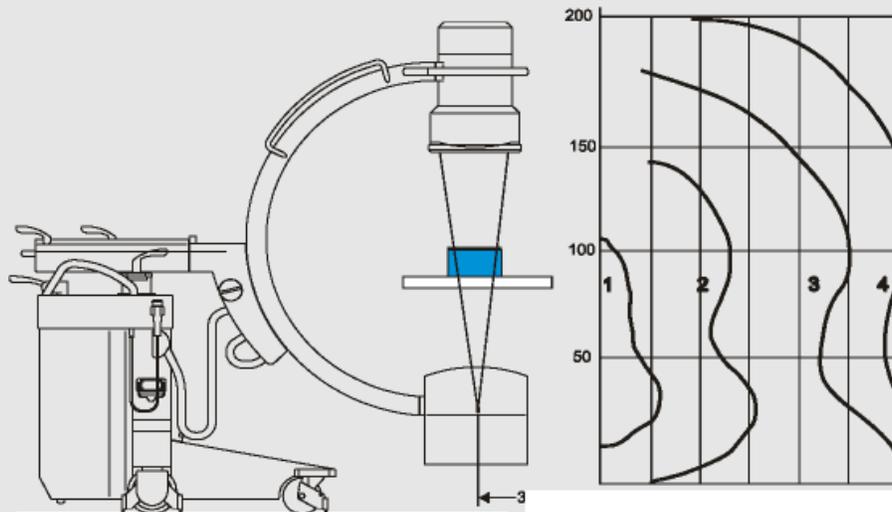
Measurement conditions in accordance with EN 60601-1-3:1994

Exposure conditions: 84 kV / 3.90 mA / 327 W

Rectangular water phantom 25 cm × 25 cm × 15 cm + 1.5 mm Cu Distance phantom/image intensifier: 50 cm

Measuring instrument: Radcal 1515 S/N 15-1 427

Height above floor in cm



Distance to focus / central ray beam

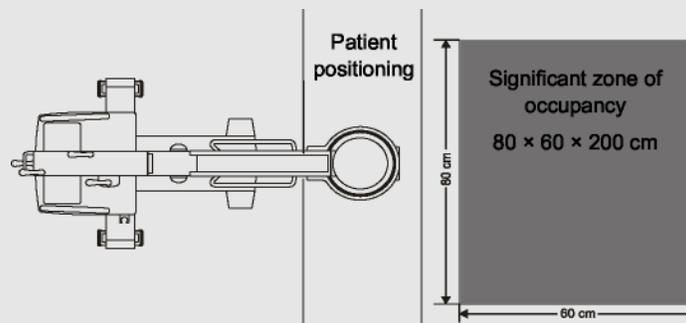
Number Level in mGy/h

1 < 10

2 < 5

3 < 2

4 < 1



12.7 LASER ALIGNMENT

Laser Class 11 < 1mW

Standards:
IEC 60825-1:2001
FDA 21CFR1040

Max. power output

of continuous laser radiation, measured at the laser beam apertures <1 mW

Wavelength of the radiation

635 nm

12.8 DOSE AKR AND CUMULATIVE AIR KERMA MEASUREMENT

Technical data of Dose measurement

Accuracy	The displayed AKR and cumulative air Kerma shall not deviate from the actual values by more than ± 35 percent
Compliance	Compliance shall be determined with an irradiation time greater than 3 seconds.
Measuring range AKR	6mGy/min to max
Measuring range Cumulative	100mGy to max

12.8.1. Calibration of calculated dose measurement 21CFR 1020.33 (k) (4) (ii)

The Equipment Owner is responsible for ensuring that only persons who are trained and qualified are allowed to service and make adjustments.

The Equipment Owner is responsible for ensuring that the x-ray system complies with the applicable sections of CFR 21 1020.30 (h) (6) (i), Compliance must be periodically verified by subjecting the system to various test procedures defined by the Center for Disease and Radiological Health (CDRH) including the calculated dose measurement system

If the system fails to operate correctly, or fails to respond to system controls as outlined in this manual, notify the local, authorized **Ziehm Imaging, Inc.** dealer representative.

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

Calibration of the generator or the dose measurement system shall only be performed by trained and authorized personnel. Calibration procedures are part of the technical documentation and are not outlined in this manual.

12.8.2. AKR / CUMULATIVE DOSE DISPLAY CALCULATION

The **ZIEHM QUANTUM** calculates the dose values based on the kV, mA as well as time of the radiation exposure. The display automatically changes between live display of **Air Kerma (AKR)** or the **Cumulated Air Kerma** values (**AKR x Fluoroscopy Time**) automatically sets the

decimal point according to the dose rate and the accumulative values depending on whether radiation is on or off. This also includes the dose for all images which have not been saved but are part of the radiation accumulated since the last reset of the **Dose/Timer** display.

12.8.3. TEST INTERVAL:

In accordance with FDA 21 CFR 1020.30(h)(6)(i), a schedule of maintenance for any system instrumentation associated with the display of air Kerma information necessary to maintain the displays of AKR and cumulative air Kerma. Therefore, the automatic dose rate must be tested at regular intervals. Every month is recommended, however owner/operator must comply with local and national standards that may apply.

The AKR Dose Display must be tested twice yearly by a qualified and authorized Service Representative to insure the dose display accuracy and perform Calibration if required.

12.8.4. OPERATOR MONTHLY TEST PROCEDURE:

- Turn on the C-arm and wait for the system to become fully operational
- Select Fluoroscopy program (Extremities)
- Insert a patient-equivalent phantom (2.5 cm x 15 cm square aluminum plus 1.5 mm copper) or equivalent in the beam at approximately 30 cm from the image intensifier on top of a radiation translucent table.
- Position the c-arm image intensifier over the phantom with generator under the table making sure the phantom it is in the middle of the radiation beam.



CAUTION

Observe all radiation safety procedures during the text test steps.

- Perform radiation by pressing the hand switch and holding it for at least 20 seconds.
- Observe the control panel display values. They should resemble the following. (Actual values may be slightly different) 70 ± 2 kV / 5.7 mA ± 0.4 mA Dose display will be in mGy/min.
- Write down the value of kV/mA and dose mGy/min in your log.
- Press and hold the **Reset Timer** button for 2 seconds to reset the fluoroscopic timer and the dose display on the touch panel.
- Press and hold down the radiation hand or foot switch to initiate radiation. The test takes **1 min**. Do not interrupt the test. During the test, the system calculates and displays the dose rate in mGy/min. Release hand switch when fluoroscopic timer reaches 1 minute “stop the radiation as fast as possible”
- View and record the cumulated dose rate displayed from the touch panel
- Compare the new data with the previous monthly data test record.



NOTE:

If this is the first time you are doing this test then just record the information in your log as the reference value then compare the next months test to this value

12.8.5. TEST RESULTS:

Example of testing is shown below:

If a radiation reading AKR of 6.5 mGy/min was seen during radiation test and was held on for 1 min the results would then equal 6.5mGy for the accumulated value.

mGy/min rate for 1 min = 6.5mGy accumulated. Rate **mGy/min** x time = accumulated **mGy**.

The value calculated during the test should be within $\pm 10\%$ for the previous monthly recorded test value. If the system fails to calculate the dose within the tolerance of the previous monthly test record, notify your local, authorized **Ziehm Imaging, Inc.** service center or dealer representative for service.

12.8.6. DOSE CALIBRATION POINT:

Dose measurement calculation requires a fixed point that represents patient entry location.

The normal point would be 15 cm from the ISO center toward the source. However, the **ZIEHM QUANTUM** does not have a single ISO center rather it has an elliptical ISO point. Therefore, the measurement point has been determined by **Ziehm Imaging, Inc.** to be located 51 cm from the source/focal spot toward the image receptor and represents the patient entry location for the entry point. See Figure 12-4 below for location and dimensions.

The twice yearly service calibration and test requires specialized measurement hardware and software to accurately determine the actual to calculated dose display values. Therefore, only authorized **Ziehm Imaging, Inc.** service or a trained dealer service representative should attempt to perform these operations

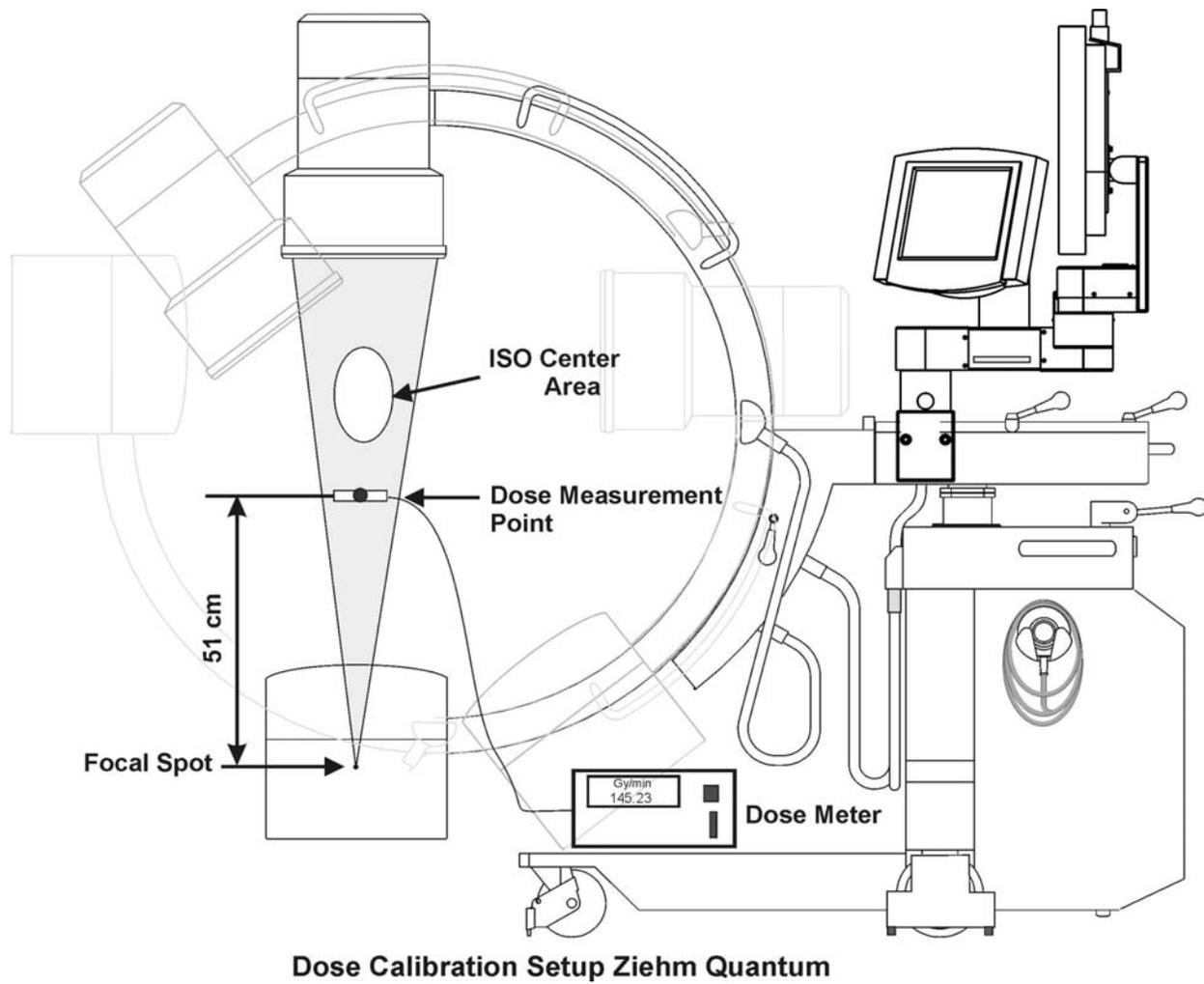
Compliance with the requirements of international standards (e.g. 21 CFR 1020.32-d (1), IEC 60601-2-43), Ziehm fluoroscopy systems with automatic dose rate control are not operable at any combination of tube voltage and tube current which will result in an exposure rate in excess of 88 mGy/min at the point where the center of the useful beam enters the patient.

**NOTE:**

Calibration instruction can be found in the product technical manuals as Work Instructions and should only be performed by authorized **Ziehm Imaging, Inc.** services or a trained dealer representative.

Dose Air Kerma Setup Diagram 21CFR 1020.33 (k), (4), (ii)

Fig 12-4: AKR Dose Calibration Setup



12.9 HEAT/COOLING CAPACITY

Fig. 12.5: Heating curve (with Active Cooling)

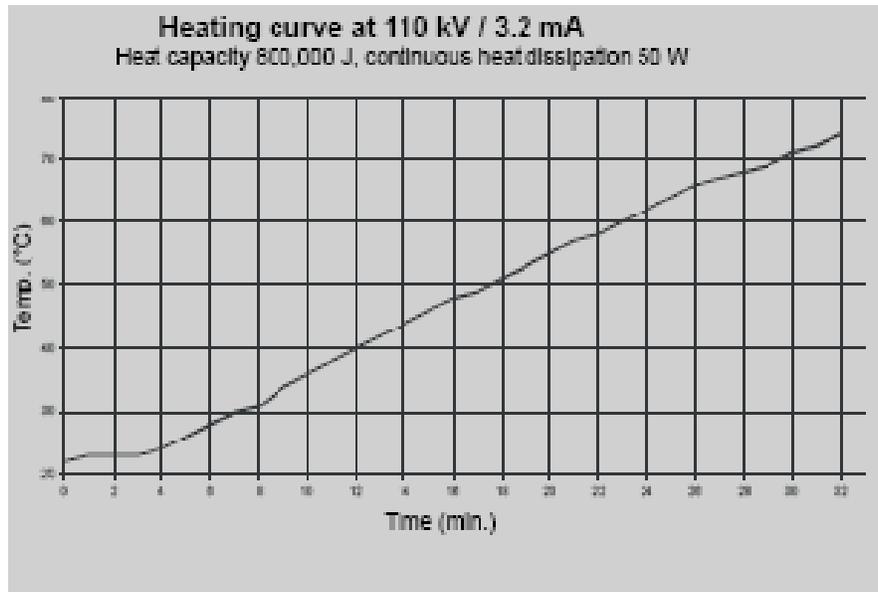
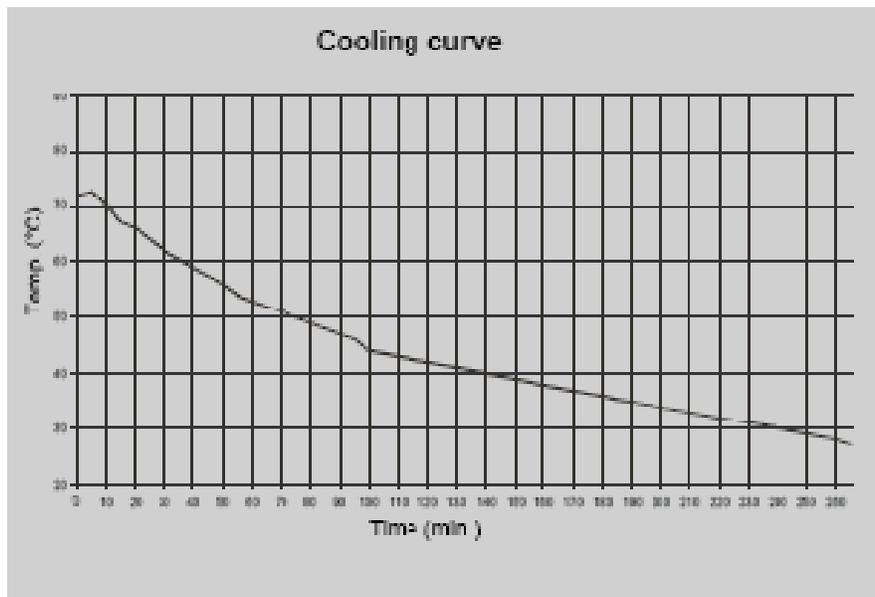


Fig. 12.6



12.10 ANATOMICAL PROGRAM KV/MA DOSE CURVES

The Anatomical Program curve below is representative of the mA/kV curves in the system and may not be the actual kV/mA levels programmed for a specific c-arm. The mA/kV curve values depend on the image quality needs of procedures and anatomical density. Therefore, we have only given this curve as an example for user to understand that KV and MA are match pairs.

- **Program 1: Pelvic –kV/mA Curve 1**

EXAMPLE OF ANATOMICAL PROGRAM CURVE

Fig. 12.7 Program 1: Pelvic-kV/mA, Curve 1

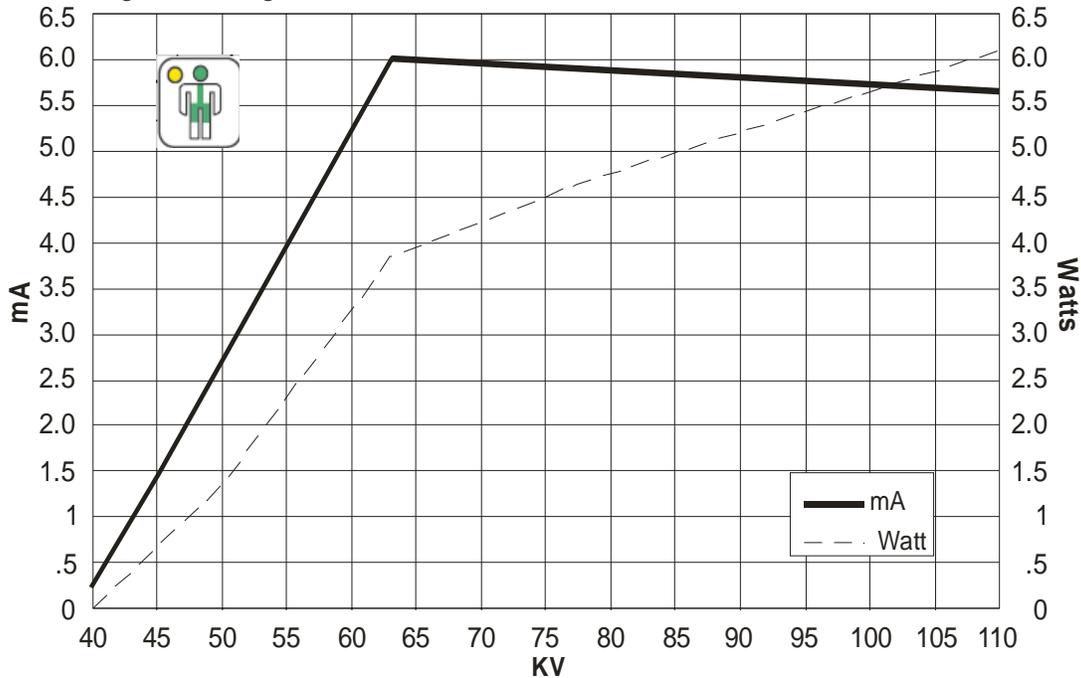


Fig. 12.8: Program 2: Thorax - kV/mA, Curve 2

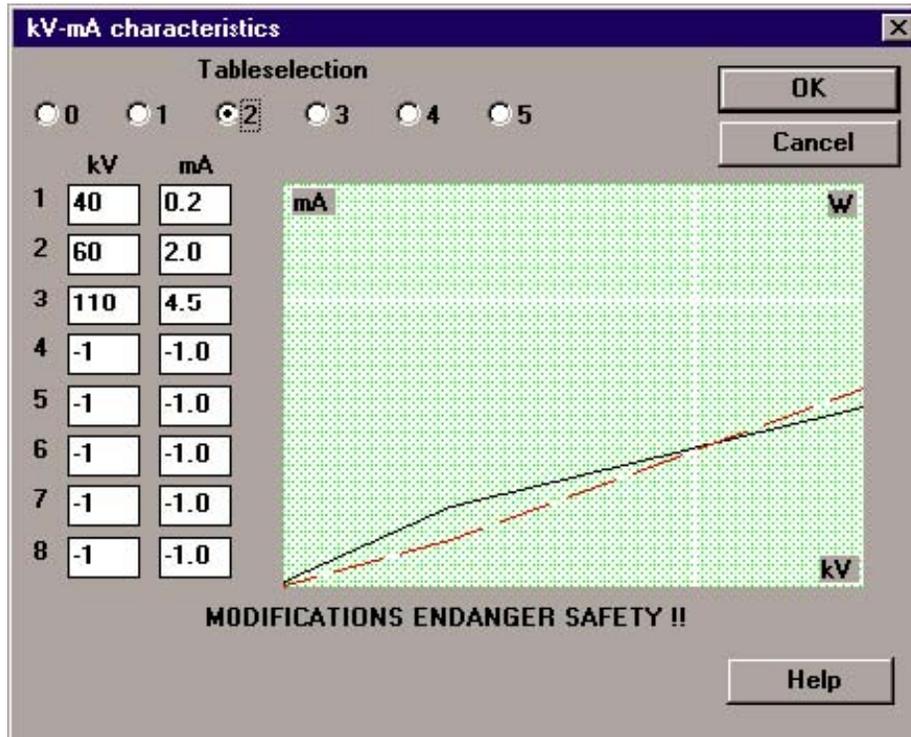


Fig. 12.9: Program 3: DSA - kV/mA, Curve 3

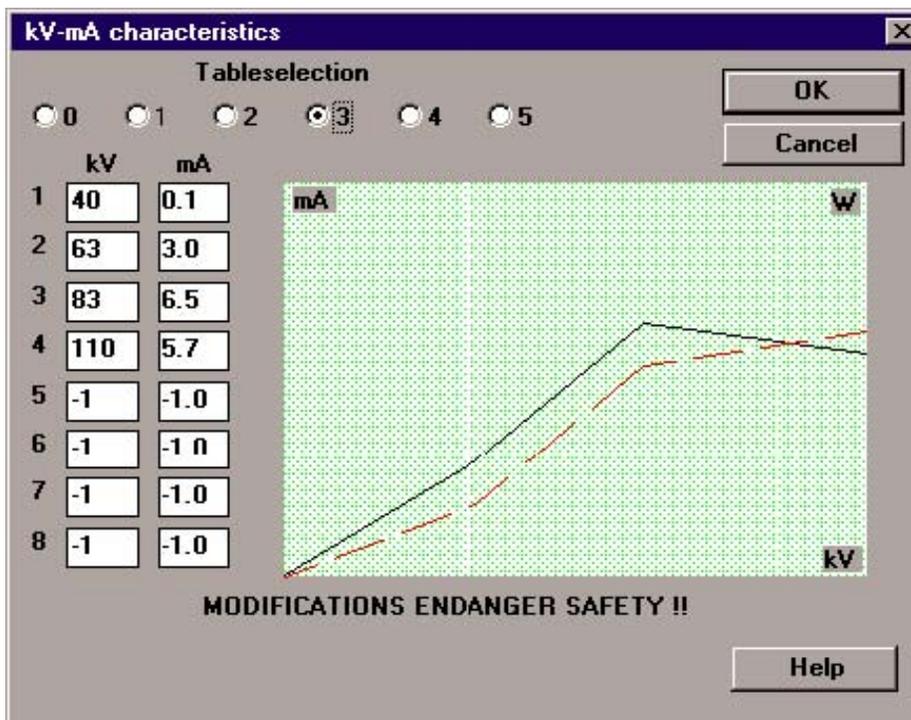


Fig. 12.10: Program 4: Soft - kV/mA, Curve 4

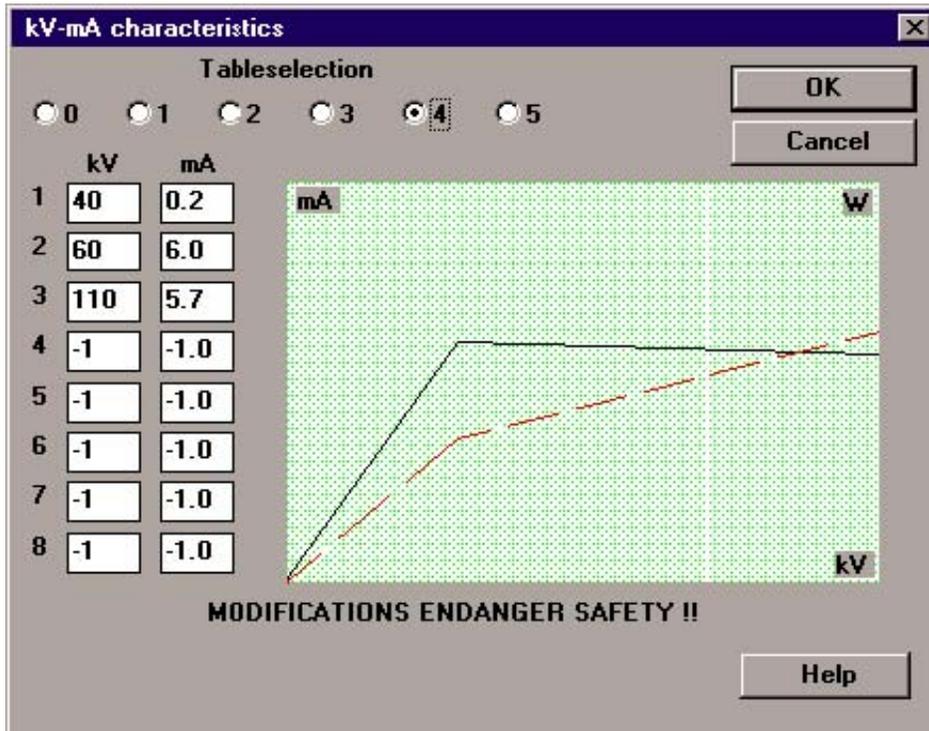
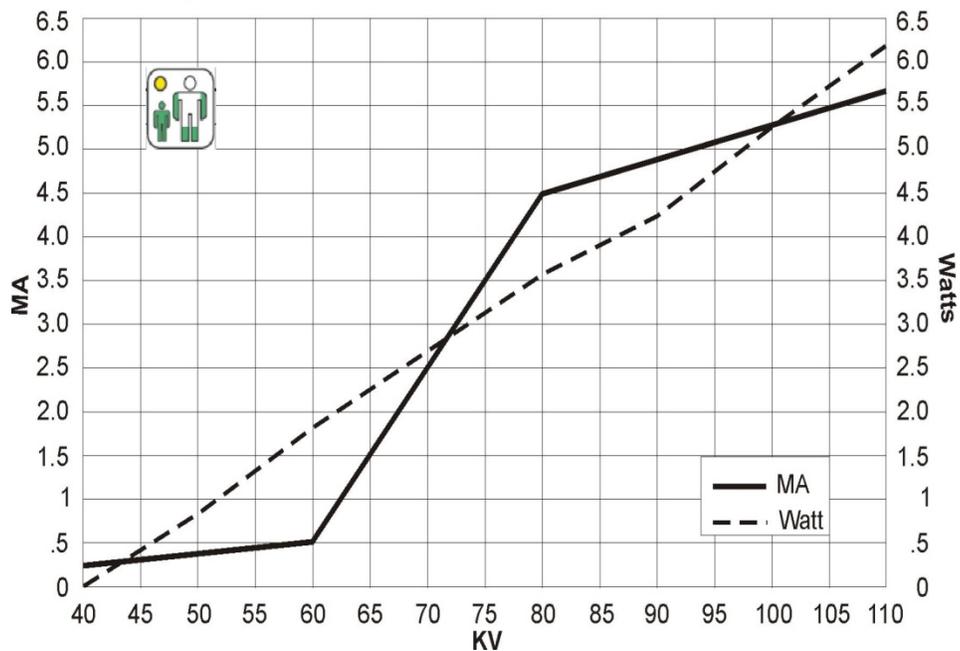


Fig. 12.11: Program 0: Extremities - kV/mA, Curve 5

Extremity and children



13.0 INSPECTION & MAINTENANCE

13.1 ROUTINE CHECKS TO BE PERFORMED BY THE USER

13.1.1 SYSTEM INSPECTION

Every month, the System User is responsible for performing the inspections listed in the table below.

13.1.2 TABLE OF REGULAR CHECKS

Check	Interval	Remarks
X-ray generator	Monthly	Check for physical damage.
Radiation switches	Monthly	Must initiate radiation only if pressed permanently. Releasing them must terminate radiation. After 1 sec max. (Depending on the stack filter settings).
Radiation signals	Monthly	During the exposure, the yellow Radiation warning lamp on top of the monitor housing and the X-ray symbol on the control panel must be illuminated.
AKR Air Kerma Display	Monthly	Dose display in rate mGy/min and accumulative mGy must be within 10 % of pervious monthly test values
Audible alarm	Monthly	Must sound in direct radiography mode during the whole exposure time, and in fluoroscopy mode after 5 min.
Information labels	Monthly	All warning and information labels must be properly attached and easily legible.
Power cable	Monthly	Must not show any signs of physical damage.
C-arm stand wheels	Whenever necessary	Clean when dirty.



NOTE:

A detailed maintenance schedule can be found in the “**ZIEHM QUANTUM** Technical Manual”. Technical information necessary to repair or upgrade the **ZIEHM QUANTUM** system will be made available by **Ziehm Imaging, Inc.** to authorized and qualified personnel upon request.

13.2 TEST RECORDING

Consistency test according to national regulations for dose level.

At regular intervals, at least once a month, you must check whether the system shows any deviations from the reference values by performing a consistency test.



NOTE:

The relevant radiation protection regulations of a country, local state, or regional authority at time of installation must be observed.

13.3 VERIFY AUTOMATIC DOSE RATE CONTROL

Quantitative Method:

In accordance with CDRH and other country regulations, automatic dose rate must be checked monthly. Power-on the C-Arm in default mode.

The control panel must display the following:

- Fluoroscopic program number one (Extremities): with patient-equivalent filter (25 mm aluminum plus .4 mm copper) inserted in the beam.
- The Control Panel technique display values should resemble the following (actual values may be different)
- 1/2 Dose: 67 + 2 kV / 4.5 mA + 0.4 mA (dose value mGy/min)
- 1/1 Dose: 70 + 2 kV / 5.0 mA + 0.4 mA (dose value mGy/min)

13.4 CHECKING THE USEFUL BEAM

13.4.1. INSPECTION INTERVAL

Together with the consistency test, it is necessary to check the size and centering of the useful X-ray beam.

13.4.2. CENTERING

To determine the correct alignment of the ray beam to the center of the image intensifier and any possible deviation, do the following:

- Angulation of C-arm by 180°, so that the X-ray generator is above and the image intensifier is below.
- Place a reference or test object (e.g. measuring board, graduated collimator test tool) exactly in the center of the image intensifier.
- Close the iris collimator as far as possible and initiate radiation by pressing the hand or foot switch. The object should appear exactly in the center of the fluoroscopic image.

13.5 COLLIMATOR DIAMETER ACCURACY

The size of the collimator diameter in the image plane must not differ from the nominal image diameter by more than 2 % of the source–image receptor distance (SID). The SID and the nominal image diameter depend on the image intensifier size.

I.I. size	SID	Nominal image diameter
23 cm	97 cm	20.1 to 21.1cm

Maximum radiation field size When the iris collimator is completely open, the edges of the collimator blades must be just visible on the monitor.



WARNING

Contact your after-sales service authorized **Ziehm Imaging, Inc.** dealer representative center in case of any non-conforming issues.

13.5.1. GETTERING THE IMAGE INTENSIFIER TUBE

To increase the useful life of the image intensifier, we recommend **Increasing the** gettering time of the image intensifier tube after a period of 6 months of **continuous** non-use or storage.

13.5.1.1. TO GETTER THE IMAGE INTENSIFIER TUBE, DO THE FOLLOWING:

- Switch on the system.
- Leave it switched on for at least 1 hour.
- Do not initiate radiation during this time!

We recommend keeping an operator's log, where all operating times, **Operator's log** gettering times and maintenance events are recorded.

13.6 PREVENTATIVE MAINTENANCE

The Owner/Operator is responsible for scheduling preventative maintenance and for ensuring that such maintenance is performed only by qualified Service Engineers.

The following list of preventative maintenance activities should be performed at six-month intervals, or whenever the equipment has been subjected to any use or conditions that may compromise the safe operation of the system.

- kV calibration
- mA calibration
- Dose AKR and Cumulative Air Kerma measurement and display
- Electrical functions
- automatic dose rate control
- mA display at default, low, and normal fluoroscopy
- radiography time control
- fluoroscopy terminates after releasing button
- collimator controls

- display functions
- line cord condition; ground
- cables condition
- mechanical movements and limits
- laser power supply voltage tests (as applicable)
- laser alignment (as applicable)

13.7 CDRH MAINTENANCE

For information on requirements imposed by the FDA, please refer to the CDRH Maintenance Manual & Report.

14.0 CLEANING, DISINFECTION, STERILIZATION

14.1 PREPARATION

Always switch off the system and disconnect it from the power supply before cleaning or disinfecting it.

14.2 CLEANING

14.2.1. RECOMMENDED DETERGENTS

For cleaning the system, use only water with mild detergents applied with a damp cloth. Never use abrasive cleansing agents, organic solvents or detergents which contain solvents (e.g. alcohol, petroleum ether, liquid stain remover).



WARNING

Take care that no liquids penetrate into the unit through sockets, plugs, ventilation holes or gaps (at integrated external devices such as video printers or video cassette recorders).

Never apply spray cleaners directly onto the unit!

14.2.2. CLEANING THE MONITOR SCREENS

For cleaning the monitor screens, use only pure alcohol or a mixture consisting of 1/3 alcohol and 2/3 distilled water. Wipe the screen and surrounding painted surfaces dry with a soft cotton cloth immediately after cleaning

14.3 DISINFECTION STERILIZATION

14.3.1. RECOMMENDED DISINFECTANTS

The following disinfectants are recommended for surface disinfection:

- Incidin (3% in water)
- Ultrasol F (5:1 in water)

14.3.2. NO ALCOHOL OR SAGROTAN

Never use pure alcohol or Sagrotan, since these substances may corrode the surfaces. If you use any other than the recommended disinfectants, we cannot guarantee the resistance of the surface paint against these substances.

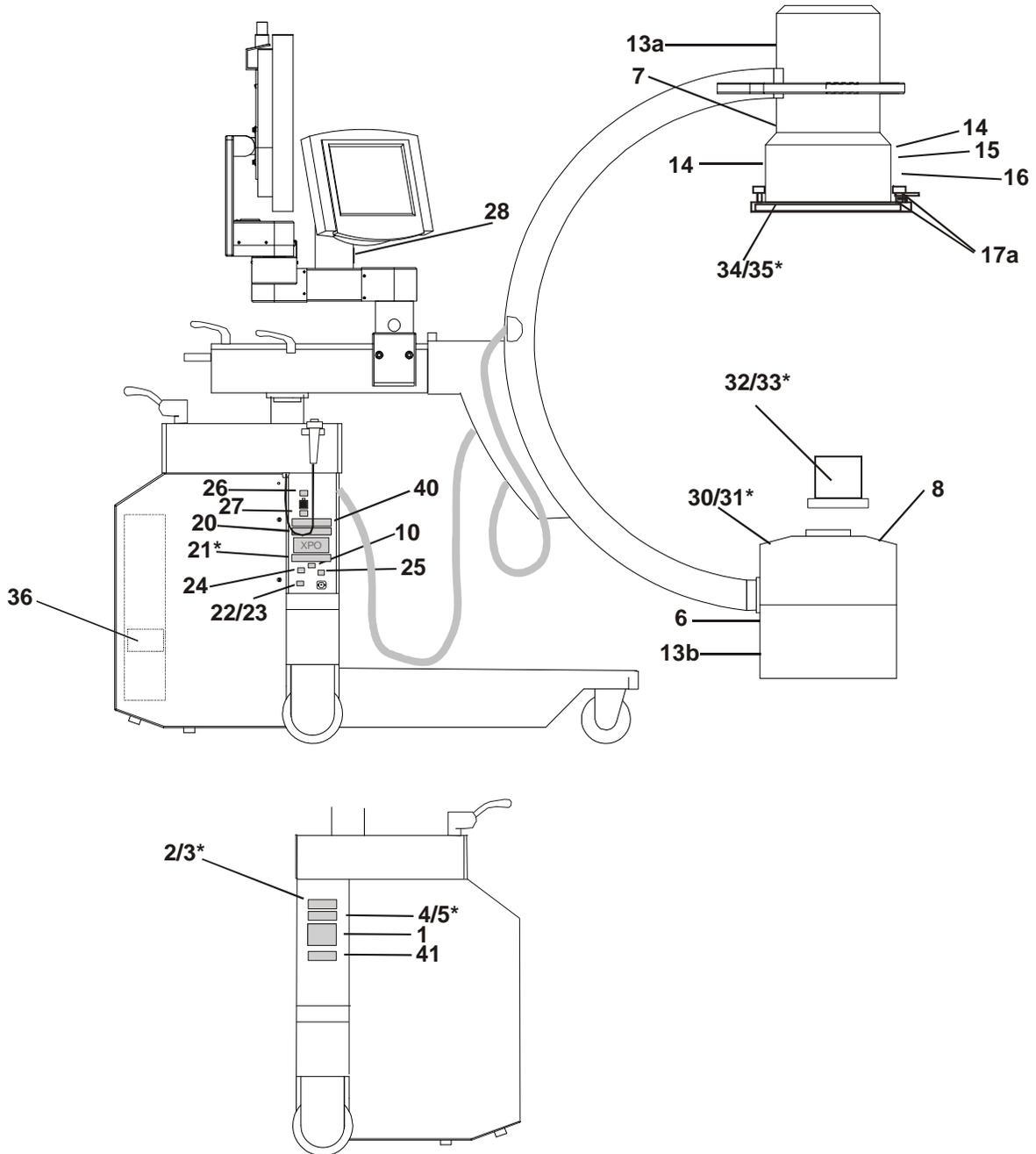
14.3.3. NO DISINFECTING SPRAYS

Never use disinfecting sprays, since the liquid droplets may penetrate inside the unit, endangering safe system operation. Electronic modules may be damaged, and explosive air/solvent vapor mixtures may develop.

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15.0 APPENDIX LABELS

Fig. 15.1: ZIEHM QUANTUM Label Location



Label with the * next to the number are only required if the system ships to Canada

Fig. 15.2: Generator Laser Alignment Labels

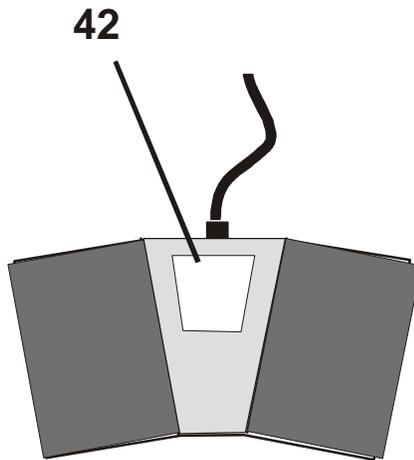
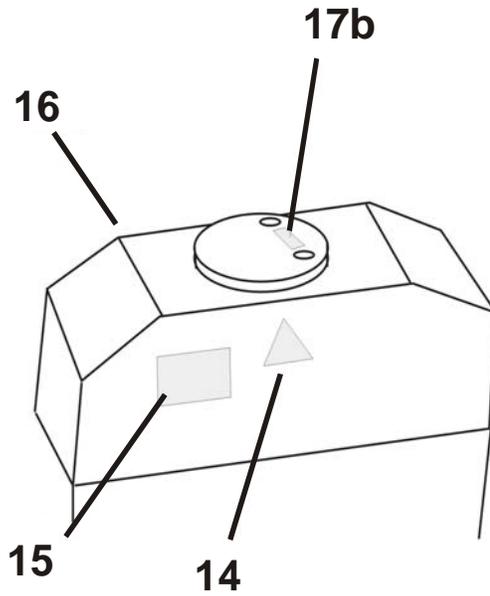
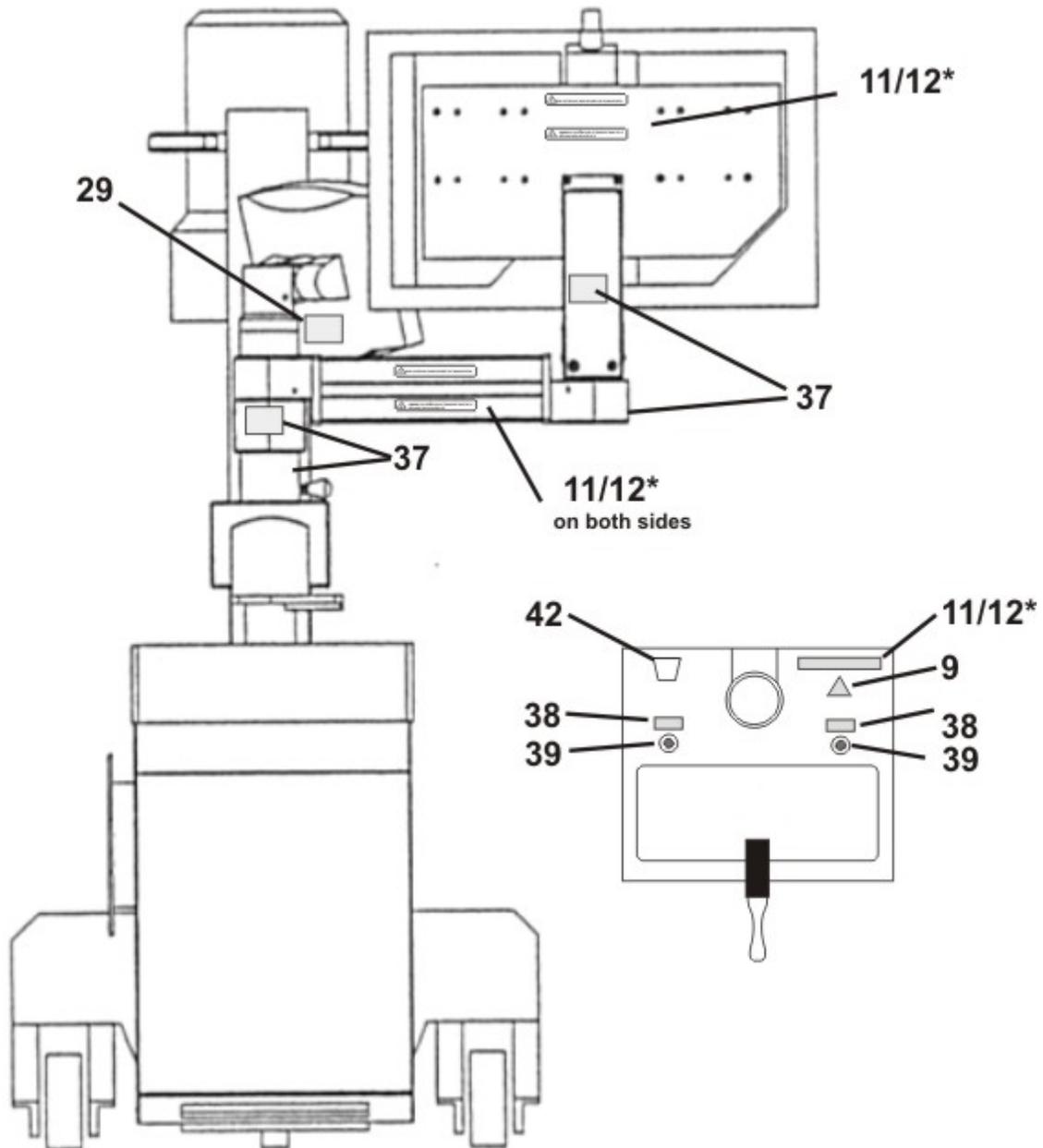
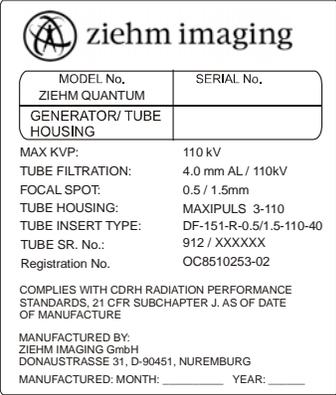
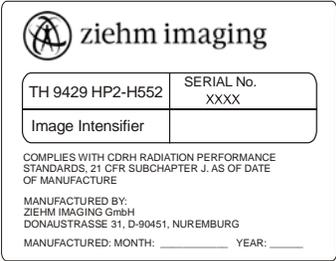


Fig. 15.3: Transport and Safety Labels

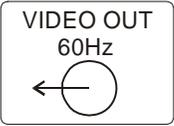


Label with the * next to the number are only required if the system ships to Canada

#	Label	Comments	Qty				
1	 <p>  ziehm imaging <table border="1" data-bbox="428 352 735 422"> <tr> <td>ZIEHM QUANTUM</td> <td>SERIAL NO.</td> </tr> <tr> <td>MOBILE STAND</td> <td></td> </tr> </table> LINE VOLTAGE: 120 VAC 60Hz LINE IMPEDANCE: <= 0.6 ohm CURRENT INPUT 12A Continuous/ 30A Momentary MAIN FUSE: 20A, 250 V COMPLIES WITH CDRH RADIATION PERFORMANCE STANDARDS, 21 CFR SUBCHAPTER J. AS OF DATE OF MANUFACTURE MANUFACTURED BY: ZIEHM IMAGING, INC. 3468 WEBSTER AVENUE, PERRIS, CA 92571 MANUFACTURED: MONTH: _____ YEAR: _____ </p>	ZIEHM QUANTUM	SERIAL NO.	MOBILE STAND		<p>Used when system is connected to 120 VAC power.</p> <p>Located left side below top cover under Label #4</p>	1
ZIEHM QUANTUM	SERIAL NO.						
MOBILE STAND							
1	 <p>  ziehm imaging <table border="1" data-bbox="428 814 735 884"> <tr> <td>ZIEHM QUANTUM</td> <td>SERIAL NO.</td> </tr> <tr> <td>MOBILE STAND</td> <td></td> </tr> </table> LINE VOLTAGE: 230 VAC 60Hz LINE IMPEDANCE: <= 0.6 ohm CURRENT INPUT 10A Continuous/ 20A Momentary MAIN FUSE: 16A, 250 V COMPLIES WITH CDRH RADIATION PERFORMANCE STANDARDS, 21 CFR SUBCHAPTER J. AS OF DATE OF MANUFACTURE MANUFACTURED BY: ZIEHM IMAGING, INC. 3468 WEBSTER AVENUE, PERRIS, CA 92571 MANUFACTURED: MONTH: _____ YEAR: _____ </p>	ZIEHM QUANTUM	SERIAL NO.	MOBILE STAND		<p>Use this label when the system is connected to 230 VAC power.</p> <p>Located left side below top cover under label #4</p>	1
ZIEHM QUANTUM	SERIAL NO.						
MOBILE STAND							
2	<p>WARNING:</p> <p>THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS, OPERATING INSTRUCTIONS AND MAINTENANCE SCHEDULES ARE OBSERVED.</p>	<p>Located on the top desk near the power ON / OFF buttons</p>	1				
3	<p>Attention danger:</p> <p>Cet appareil de radiographie peut presenter des dangers pour le patient et l'operateur si les facteurs d'exposition en securite et les instructions d'utilisation ne sont pas respectes.</p>	<p>If sold in Canada this label must be attached</p> <p>Same location as Item 2</p>	1				
4	<p>DANGER:</p> <p>EXPLOSION HAZARD! DO NOT USE IN PRESENCE OF FLAMMABLE ANESTHETICS.</p>	<p>Located left side below Top Cover above label #1a or 1b</p>	1				

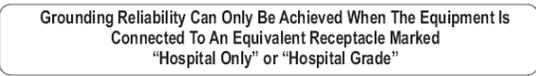
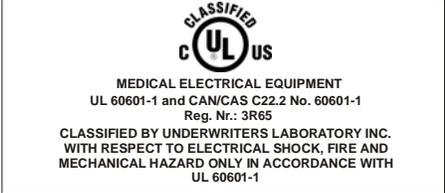
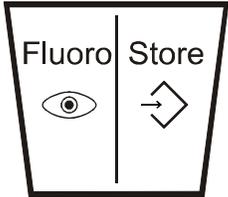
#	Label	Comments	Qty
5	<p>DANGER:</p> <p>RISQUE D'EXPLOSION! NE PAS UTILISER EN PRESENCE DE PRODUITS ANESTHESIANTS.</p>	<p>If sold in Canada this label must be attached</p> <p>Same location as Item 4</p>	1
6	 <p>MODEL No. SERIAL No. ZIEHM QUANTUM GENERATOR/ TUBE HOUSING</p> <p>MAX KVP: 110 kV TUBE FILTRATION: 4.0 mm AL / 110kV FOCAL SPOT: 0.5 / 1.5mm TUBE HOUSING: MAXIPULS 3-110 TUBE INSERT TYPE: DF-151-R-0.5/1.5-110-40 TUBE SR. No.: 912 / XXXXXX Registration No. OC8510253-02</p> <p>COMPLIES WITH CDRH RADIATION PERFORMANCE STANDARDS, 21 CFR SUBCHAPTER J. AS OF DATE OF MANUFACTURE</p> <p>MANUFACTURED BY: ZIEHM IMAGING GmbH DONAUSTRASSE 31, D-90451, NUREMBURG MANUFACTURED: MONTH: _____ YEAR: _____</p>	<p>Location on the Generator Cover near the C-Profile mounting side just below the mounting bracket</p>	1
7	 <p>TH 9429 HP2-H552 SERIAL No. XXXX Image Intensifier</p> <p>COMPLIES WITH CDRH RADIATION PERFORMANCE STANDARDS, 21 CFR SUBCHAPTER J. AS OF DATE OF MANUFACTURE</p> <p>MANUFACTURED BY: ZIEHM IMAGING GmbH DONAUSTRASSE 31, D-90451, NUREMBURG MANUFACTURED: MONTH: _____ YEAR: _____</p>	<p>Image Intensifier/ Image receptor.</p> <p>Located on the image receptor just under the mounting bracket for the C-Profile.</p>	1
8		<p>Radiation Warning</p> <p>Located on Generator</p> <p>Background is Yellow in color</p>	1
9	 <p>KEEP OUT RADIATION CONTROLLED AREA WITHIN 4M DISTANCE</p>	<p>Top Desk</p> <p>Located on top of the Mobile stand</p>	1
10		<p>Please observe accompanying documents on the side of the mobile stand below XPO cable</p>	1

#	Label	Comments	Qty
11		Transport Warning Located on support arm monitor bracket and desk top of mobile stand cover	4
12		If sold in Canada this label must be attached next to Number 11	4
13a		Image intensifier position patient orientation	1
13b		Label position Generator patient orientation (position face down)	1
14		Only on systems with Laser device Qty 1 for Laser LG Qty 2 for Laser LC Background is Yellow in color	1, 2 or 3 (depending on options)
15		Only on systems with Laser device Qty 1 for Laser LG Qty 1 for Laser LC Background is Yellow in color	1 or 2 (depending on options)
16		Only on systems with Laser device Qty 1 for Laser LG Qty 1 for Laser LC Background is Yellow in color	1 or 2 (depending on options)
17a		Only on systems with Laser device Qty 2 for Laser LC Background is Yellow in color	2 (depending on options)

#	Label	Comments	Qty
17b		Only on systems with Laser device Qty 1 for Laser LG Background is Yellow in color	1 (depending on options)
18	Reserved	Reserved	
19	Reserved	Reserved	
20	Warning: For continued protection against risk of fire. Replace only with the same type and rating of fuse.	Located on side of the Mobile Stand above XPO Connector	1
21	Attention danger: Afin d'assurer une protection permanente contre les risques d'incendie, remplacer le fusible fondu par un fusible neuf de type et calibre identique.	If sold in Canada this label must be attached next to item 20 Located below XPO Connector	1
22		Equipment bonding	1
23		Spare earth terminal. Not available on Ziehm Quantum without External Monitor. (Replaces Label 22 when this option is used)	1
24		Protection Class 1, Type B	1
25		60Hz Video output	1
26		Only on systems with DICOM option and RJ45 Connection	1
27	Reserved	Reserved	

#	Label	Comments	Qty				
28	 <p>ziehm imaging</p> <table border="1"> <tr> <td>Ziehm Quantum</td> <td>SERIAL No. XXXXX</td> </tr> <tr> <td>Monitor Arm Assembly</td> <td></td> </tr> </table> <p>MANUFACTURED BY: ZIEHM IMAGING, INC. 3468 WEBSTER AVENUE, PERRIS, CA 92571</p> <p>MANUFACTURED: MONTH: _____ YEAR: _____</p>	Ziehm Quantum	SERIAL No. XXXXX	Monitor Arm Assembly		<p>Monitor Support Arm assembly Located on Small Arm</p>	1
Ziehm Quantum	SERIAL No. XXXXX						
Monitor Arm Assembly							
29	 <p>ziehm imaging</p> <table border="1"> <tr> <td>Ziehm Quantum</td> <td>SERIAL No. DV-XXXXX</td> </tr> <tr> <td>Control Panel Desk View</td> <td></td> </tr> </table> <p>COMPLIES WITH CDRH RADIATION PERFORMANCE STANDARDS, 21 CFR SUBCHAPTER J. AS OF DATE OF MANUFACTURE</p> <p>MANUFACTURED BY: ZIEHM IMAGING, INC. 3468 WEBSTER AVENUE, PERRIS, CA 92571</p> <p>MANUFACTURED: MONTH: _____ YEAR: _____</p>	Ziehm Quantum	SERIAL No. DV-XXXXX	Control Panel Desk View		<p>Desk View touch Control Panel Located on the back of the DeskView touch screen assembly.</p>	1
Ziehm Quantum	SERIAL No. DV-XXXXX						
Control Panel Desk View							
30	<p>WARNING</p> <p>REMOVAL OF SKIN DISTANCE CONE IS AGAINST THE RULES AND REGULATIONS 21 CFR SUBCHAPTER J SECTION 1020.32;</p> <p>REMOVE ONLY FOR SPECIAL SURGICAL PROCEDURES</p> <p>MANUFACTURED BY: ZIEHM IMAGING GmbH DONALSTRASSE 31, D-90451, NUREMBURG</p> <p>MANUFACTURED: MONTH: _____ YEAR: _____</p>	<p>Located on Generator top cover</p>	1				
31	<p>ATTENTION</p> <p>LE RETRAIT DU CÔNE DISTANCE SOURCE-PEAU N'EST NORMALEMENT PAS AUTORISÉ. Réf. :21CFR sous-chapitre J section 1020.32 À NE RETIRER QUE POUR DES PROCÉDURES CHIRURGICALES SPÉCIALES</p> <p>Fabriqué par: ZIEHM IMAGING GmbH DONAUSTRASSE 31, D-90451, NUREMBURG</p> <p>Fabriqué - Mois: _____ Année: _____</p>	<p>If sold in Canada this label must be attached next to item 30</p>	1				
32	<p>WARNING</p> <p>REMOVAL OF SKIN DISTANCE CONE IS AGAINST THE RULES AND REGULATIONS. 21 CFR SUBCHAPTER J SECTION 1020.32;</p> <p>REMOVAL ONLY FOR SPECIAL SURGICAL PROCEDURES</p>	<p>Located on Skin Cone</p>	1				
33	<p>ATTENTION</p> <p>LE RETRAIT DU CÔNE DISTANCE SOURCE-PEAU N'EST NORMALEMENT PAS AUTORISÉ. Réf. :21CFR sous-chapitre J section 1020.32</p> <p>À NE RETIRER QUE POUR DES PROCÉDURES CHIRURGICALES SPÉCIALES</p>	<p>If sold in Canada this label must be attached next to Item 32</p>	1				

#	Label	Comments	Qty
34	<p style="text-align: center;">WARNING</p> <p style="text-align: center;">DO NOT USE CASSETTE LESS THAN 24 X 24 cm IN CONJUNCTION WITH 23 cm IMAGE INTENSIFIER.</p>	Located on Cassette Holder (optional)	1
35	<p style="text-align: center;">ATTENTION</p> <p style="text-align: center;">NE PAS UTILISER DE CASSETTES DE MOINS DE 24X24 cm EN ASSOCIATION AVEC UN AMPLIFICATION DE LUMINANCE DE 23 CM</p>	<p>If sold in Canada this label must be attached (optional)</p> <p>Located next to Item 34</p>	1
36	 <p> ziehm imaging Ziehm Quantum SERIAL No. XXXXX MX200 Image System COMPLIES WITH CDRH RADIATION PERFORMANCE STANDARDS, 21 CFR SUBCHAPTER J. AS OF DATE OF MANUFACTURE MANUFACTURED BY: MX IMAGING, INC. 2730 MONTEREY STREET, TORRANCE CA. 90503 FOR ZIEHM IMAGING, INC. 3468 WEBSTER AVENUE, PERRIS, CA 92571 MANUFACTURED: MONTH: _____ YEAR: _____ </p>	Image System Label is located inside the Mobile Stand on the image system	1
37	<p style="text-align: center;">WARNING!</p> <p style="text-align: center;">MAKE SURE ALL LOCKS ARE PROPERLY SECURED WHEN OPERATING OR TRANSPORTING</p> <p style="text-align: center;">FAILURE TO SECURE LOCKS CORRECTLY MAY RESULT IN SERIOUS INJURY</p>	<p>System Locks for operation and transport</p> <p>Located near pivots</p>	4
38	<p style="text-align: center;">WARNING!</p> <p style="text-align: center;">WHEN LOWERING C-ARM MAKE SURE C-ARM COMPONENTS DO NOT COLLIDE WITH PERSONS OR OBJECTS!</p> <p style="text-align: center;">FAILURE TO OPERATE CORRECTLY MAY RESULT IN SERIOUS INJURY</p>	<p>Safety Override Button label</p> <p>Located near pivots</p>	2
39		<p>Safety Override Switch label</p> <p>Located on switch cover top desk.</p>	2

#	Label	Comments	Qty
40		UL Cord Reliability label Located on side of the Mobile Stand above XPO Connector	1
41		UL Label	1
42		Foot Switch Label	2

16.0 APPENDIX ERROR CODES

16.1 ERROR AND ALERT MESSAGES

In the event of some faults, a corresponding error and alert messages will be displayed as a number in the Dose Area Product display window on the control panel. Error and alert messages always start with the letter **E**.

At the same time and in some cases an audible alarm is issued.

- In case of faults, please communicate the fault code number and the serial number of the system to your after-sales service center.
- In some cases an error or alert message can be reset by pressing the Hand switch button. This may clear the warning and allow use until next power up cycle.

Depending on the type of problem, you may or may not be able to use the system. If the error will not clear by pressing the foot or hand switch, then you must call Customer Service for equipment diagnosis and repair.

16.2 ERRORS DURING NORMAL USE

Immediately stop radiation and prevent any attempt to use radiation. You cannot erase the message or de-activate the alarm.



WARNING

Please contact your after-sales service center also if a certain error occurs frequently!

16.3 TABLE 4: LIST OF C-ARM STAND ERROR CODES

Code	Type	Message
E16	Caution	Hand switch 1 activated during start-up.
E17	Caution	Foot switch 1 activated during start-up
E18	Caution	Hand switch 2 activated during start-up.
E19	Caution	Foot switch 2 activated during start-up
E20	Error/ Fault	Cable defect hand or foot switch
E21	Caution	With compact unit, yellow monitor light defective
E22	Warning	Call Customer Service.
E23	Warning	Call Customer Service.
E24	Warning	Call Customer Service.
E25	Error/ Fault	Call Customer Service.
E26	Error/ Fault	Call Customer Service.
E27	Error/ Fault	Call Customer Service.

Code	Type	Message
E28	Error/ Fault	Call Customer Service.
E29	Warning	Generator Fault, Overheating (allow to cool off)
E30	Error/ Fault	Call Customer Service.
E51	Error/ Fault	Call Customer Service.
E52	Error/ Fault	Call Customer Service.
E53	Error/ Fault	Call Customer Service.
E54	Error/ Fault	Call Customer Service.
E55	Error/ Fault	Call Customer Service.
E56	Error/ Fault	Call Customer Service.
E57	Error/ Fault	Call Customer Service.
E58	Error/ Fault	Call Customer Service.
E59	Error/ Fault	Call Customer Service.
E60	Error/ Fault	Call Customer Service.
E61	Error/ Fault	Call Customer Service.
E62	Error/ Fault	Call Customer Service.
E63	Error/ Fault	Call Customer Service.
E64	Warning	Call Customer Service.
E65	Error/ Fault	Call Customer Service.
E90	Error/ Fault	Call Customer Service.
E91	Error/ Fault	Call Customer Service.
E92	Error/ Fault	Call Customer Service.
E15 1	Error/ Fault	Call Customer Service.

17.0 GLOSSARY

TERM	DEFINITION
Accessory	A piece of hardware used for a special function such as Radiographic Cassette holder
Activate	To make a function or mode operational/active
Active Patient	The patient file that is open and allowing capture and storing of new images
Adipose	Fatty tissue, Adipose patient large patient
Air Kerma	Air kerma is a measurement of radiation dose
Anatomical	Refers to human anatomy
Auto Function	a function that is automatically controls a function or mode
Brightness	Brightness is an attribute adjustment that allows visual perception in which the monitor source appears to emit a given amount of light
Button	A mechanical or electrical device that activates a function or mode of operation
C-Arm	A medical device that has a C shape and provides Fluoroscopic imaging
CFR	Code Of Federal Regulations
Cine	A sequential acquisition of images
Clockwise	To move or rotate something in the direction of clock movement.
Collimator	A device which collimates the radiation beam size
DELETE	A button that allows the operator to remove from memory images or patient data
DeskView	A touch control screen which allows the user to control the system functionality and modes of operation.
DICOM	Digital Imaging and Communications in Medicine (DICOM) is a standard for handling, storing, printing, and transmitting information in medical imaging
Digital Image Rotation	The electronic rotation of a displayed image.
Digital Subtraction Angiography	A type of Fluoroscopy technique used in interventional radiology to clearly visualize blood vessels in a bony or dense soft tissue environment. Images are produced
Diode Laser Modules	A small electronic devices that emits laser light
Display	See display
Display	A device that presents images or data to the operator
Dose	Amount of radiation
DSA image	Image created during Digital Subtracted Angiography
DVD	Digital Video Disk
Dynamic Image Acquisition	A capture of sequential images to memory
Emit Laser Radiation	Laser light projected from a laser device
Enter	button to accept a change
ESC	button ESCAPE
Export Function	To method to export images to external storage devices
Exposure Time	The time radiation is active or the length of a single exposure

TERM	DEFINITION
FDA	Federal Drug Administration a US government entity that is charged with regulating medical devices in the US
Fluoroscopy	Fluoroscopy is an imaging technique commonly used by physicians to obtain real-time images of the internal structures of a patient through the use of a fluoroscope
Foot Switch	A device that allows the user to press with their foot to activate radiation
Frame Rate Button	Sets the rate of image capture for Cine or DSA image capture.
Function	Function is a method, procedure, which performs a specific task
Generator	The device that houses the X-Ray tube, high voltage and mA control circuits that produce radiation
Hand Switch	A hand held object that allows the operator to activate radiation.
Hold	I.e. hold the button
ID	Identification
IEC	International Electrotechnical Commission - An international standards organization dealing with electrical, electronic and related technologies
Image Acquisition	A function of the image system that acquires the image to be stored or displayed on the monitors
Image Mirror	To flip the image head to foot or left to right
INV	Same as invert
Invert	A button that allows the operator to invert whit to black and black to white in the video image.
Iris collimator	A device that collimates radiation in to a circular beam and allows operator to limit radiation beam size to reduce exposure to the patient.
kV	Killio Voltage, high voltage used to create radiation within the generator housing
Laser	A laser is an electronic-optical device that emits coherent light radiation. It is sued as advice on the c-arm to center the patient anatomy before radiation is activated.
LIH	Last Image Hold
Live Monitor	Displays the real time image as well as recalled images that have been transferred from the reference monitor
LPD	Large Patient Diameter button allows the operator to visualize larger patient without increase in radiation dose
Ma	Milliampers
Mag	button that allows user to magnify the image
magnification	The electronic magnification performed by an image intensifier
Manual Exposure Rate Setting	A method to adjust the radiation dose by manual adjustment of the kV/mA
Medical Equipment	Devices that are designed and built for the purpose of use in medical procedures
Medical Grade	Refers to specific requirement for devices or components that can be used in conjunction with medical devices
Memory Device	A device that stores electronic data
Metal Artifact Correction	Allows the user to set a new black level in the image to correct the image as result of much metal in the radiation beam
mGy	MiliGrays a measurement of dose
Min	Minute

TERM	DEFINITION
Mobile Stand	The C-arm assembly as a whole
Mode	Distinct method of operation within a computer program, in which the same user input can produce different results depending of the selection of functional attributes
Monitor	A device that converts electronic signals into a visible image
Noise Reduction	A function that reduces quantum noise in the image during live fluoroscopic imaging
Nominal Image Diameter	the normal or standard image size.
Organ Program	A specified set of image criteria used to provide better imaging in a body region
PAC'S	
Patient Dose	The amount of radiation dose received by a patient
power supply	A device that converts one or more incoming voltage levels to another voltage level(s)
press	i.e. press the button
pulse fluoroscopy	A short burst of radiation in succession
radiate	to expose a person or object to radiation
radiation	Ionizing radiation, is a form of electromagnetic radiation which is used to view internal structures.
Radiation Exposure Indicator	A electromechanically lamp or video display ICON that is visible and may changes color to alert user that X-rays / radiation is active/on
Range	a range of operation; the difference between the highest and lowest value.
Real-Time Edge Enhancement	A function that provide electronic enhancement of edge detail in the image during live Fluoroscopic exposures
Recall Image	Image that is recovered from the image system memory and is displayed on the reference monitor
Receptor	a device that is in line with the radiation beam
Reference Monitor	The monitor that displays the recalled images and Thumbnails
Reset Timer	button that causes the radiation timer to go back to zero
Rotate	Rotate refers to a movement of an object in a circular motion. The C-profile rotates to allow positioning of the device
Safety Instructions	As set of written Instruction in the user manual or labeling that warns operator /user of possible harm if instructions are not followed
Save	button that causes the image system to store an image to memory
Scroll	To read or view extended text or images that is part of an electronic file that could be out of view in a text or electronic file window
Scroll Arrow Keys	function button allowing the operator to view in succession stored images of the image system
Service Engineer	A Qualified and trained person that can make adjustments and repairs to the c-arm
Slot Collimator	A device located in the Generator housing assembly that collimates the radiation filed on two sides to limit the radiation beam
Snapshot Mode	A mode or function of the C-arm where in the C-arm makes radiation for a specific length of time and for which noise reduction is automatically set and the image is captured and displayed
Steer	Allow the operator to steer the C-arm stand during transport or when position during use

TERM	DEFINITION
Store	button, i.e. store an image
Switch	verb, i.e. Mechanical or electrical button, lever, that activates a functional operation
Switch	Mechanical or electrical button, lever, that activates a functional operation
System Configuration	Settings which can be changed to modify the operation of the image system as defaults to functions such as, noise reduction, frame rate, Image Invert
Thumb Drive	USB flash drives, and flash memory data storage device integrated with a USB (universal serial bus) connector. USB flash drives are typically removable and rewritable and are used to externally store images from the c-arm
Thumbnail	Reduced-size versions of pictures, used to make it easier to scan and recognize them, serving the same role for stored images as a normal text index does for words
Touch Screen	Electromechanically device which is used as the Graphical User Interface for controlling the c-arm functionality. Also known as "DESK VIEW"
Transfer	Button, i.e. transfer image form left to right or right to left monitor
Tube Current	The current that is flowing in the X-ray tube between the Anode and cathode and is rated in milliamperes "mA"
Tube voltage	the voltage applied across the X-Ray tube insert. Rated in Killio Volts "kV"
USB	Noun, i.e. Universal Serial Bus is a serial bus standard to interface memory storage devices
Value	Noun, i.e. value remains stored and displayed
Vertical Lift	Noun, the c-arm mobile stand vertical support arm assembly motor drive.
Wavelength	Noun, i.e. the distance between two waves of energy, or the length of the light wave used by image intensifier and Cameras sensor
X-Ray	Noun, i.e. a type of radiation that can go through many solid substances, allowing hidden objects such as bones and organs in the body to be photographed
Ziehm Imaging, Inc.	Medical Manufacturer of Ziehm Quantum
ZIEHM QUANTUM	Medical Device Product Name
Zoom	Magnification of a captured image by means of digital imaging

End of Manual