

User Manual

Easy DR

Rev.: 17-04-2020



CE 0344

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List of revisions

| | |
|-----------------|-----------------|
| Equipment | Easy DR |
| Document | User Manual |
| Document number | ODB-100-5070ENG |

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| 05 | 31-05-2016 | Changed Sedecal interface to CPI interface Added detailed power on/off instructions. Updated collimator info. |
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| 08 | 07-09-2018 | Add Variant 183cm arm/correction environment conditions /correction WEEE symbol |
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Preface

Identification

Manuals are identified by a part number.

ODB-100-5040ENG-04





The part number is printed at the bottom of the title page. Numbers printed on other pages are for internal revision control and may differ.









CE Classification

Manuals made for products that have been CE (Conformité Européenne) marked have the CE mark on the front page. The number behind the CE Mark defines the responsible notified body.

Oldelft Benelux B.V. systems are classified according to IEC 60601-1 as Class I, type B. Oldelft Benelux B.V. systems meet the relevant provisions of the European Medical Device Directive 93/42/EEC; this is based on conformity of the products and the quality system according to ISO 13485:2016.

Symbols


| Symbol | Meaning | Remarks |
|---|--|---|
| Location: Near or on the type identification plate.  | Symbol for separated collection of electrical and electronic equipment per Directive 2002/96 of the European Parliament and the Council of the European Union (Directive on Waste of Electrical and Electronic Equipment - WEEE). If applicable to the type of device, it indicates legally imposed obligations within EU member states, Iceland, Norway and Switzerland when the equipment is disposed of, at the end of its life-time. | Owners of marked equipment should contact the organization that imported the equipment into their country, when they want to dispose of the equipment, at the end of its lifetime. The Directive prioritizes re-use of equipment over re-use of components over re-use of materials over disposal as waste. Article 5 part 2d allows producers to decline the return of any used equipment that is or may be biologically or radiologically contaminated. |
|  | Legal manufacturer | |

| | | |
|---|--|--|
|  | Date of manufacture | |
|  | Serial number | |
|  | This mark indicated that this is a Type B Applied Part according to EN60601-1. This unit can be installed in the patient environment. | |
|  | Caution: Consult Instructions for Use | |
|  | Consulting the accompanying documents is advised. | |
|  | Consulting the accompanying documents is a mandatory action. | |
|  | General warning sign | Placed together with a supplementary symbol or text. The text associated shall be an affirmative statement (i.e., a safety notice) describing the principal risk(s) foreseen (e.g. "Causes burns", "Risk of explosion", etc.). |
|  | The CE Mark is a declaration by the manufacturer that the product complies with the requirements of the applicable European Union (EU) medical device directive and that the product has been subject to conformity assessment procedures as provided in that directive. | The number behind the CE Mark defines the responsible notified body. |

Conventions






The Easy DR has been designed to meet all safety requirements applicable to medical equipment. However, anyone using the Easy DR must be fully aware of potential safety hazards. The information contained in this chapter is provided to help users to operate the Easy DR safely.



Throughout this manual certain conventions are used. These are Warnings, Cautions and Notes. They provide a means of prioritizing information to be brought to the attention of the user. They are given as follows:

| | |
|--|---|
|  WARNING: | Indication of an important warning that is to be obeyed to eliminate the risk of personal injury or an incorrect clinical diagnosis. |
| CAUTION: | Indication of important information to avoid serious system equipment damage. |
| Note: | Additional information for reader understanding or simplification of a task. |

Precautions

The user is expected to use the product (soft and hardware) in accordance with the instructions given in this manual, which must be read before the system is used. Any unauthorized deviation from the procedures laid down in this manual can affect the contractual obligations between purchaser and vendor.

| | |
|--|--|
|  WARNING: | This product was designed and manufactured to ensure maximum safety of use. It should be installed and serviced in strict compliance with safety instructions described in this Document. |
|  WARNING: | Never attempt a shortcut to procedures which may degrade the safety considerations of the system. |
|  WARNING: | Class 1 MD: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. |
|  WARNING: | The user shall take care that potential electromagnetic or other interferences between the unit and other equipment is avoided. If necessary certain actions must be taken. |
|  WARNING: | Only trained and qualified personal are allowed to operate the Easy DR system. |

| | |
|---|--|
|  WARNING: | <p>Do not modify any part of Oldelft Benelux supplied hardware, software or software configuration. Any modification, installation or running an application that has not explicitly been approved by Oldelft Benelux may compromise patient safety and will result in termination of all warranty and service contracts.</p> <ul style="list-style-type: none"> a. If this equipment is modified, repaired or maintained, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment. b. Do not leave problems unattended that may affect the safety of the product. In case you have doubts concerning the Easy DR's save operation, call the service number of your vender for further instructions. c. The Easy DR should be cleaned regular to prevent the accumulation of dust. The contact surface should be cleaned after each patient for hygienic reasons. |
|  WARNING: | <p>The Oldelft Benelux products are designed for use and maintenance using only parts available from Oldelft Benelux. No liability for failure can be accepted by Oldelft Benelux through the use of parts obtained from other suppliers unless written permission is obtained from Oldelft Benelux.</p> <p>Copyright All rights reserved. No part of this manual may be reproduced or transmitted in any form whatsoever, including photocopying and recording without written permission of the copyright holder: Oldelft Benelux B.V., Wiltonstraat 41, 3961 KW VEENENDAAL, The Netherlands.</p> <p>Concerning this Publication Information contained in this publication is subject to change without notice. Whenever the equipment is delivered with a documentation medium such as a CD or DVD, the user shall always check the medium for latest information. This information is part of Release Notes and Document Upgrade files.</p> <p>Neither Oldelft Benelux B.V. and its subsidiaries nor anyone else who has been involved with the development, production or delivery of the documentation be liable for any special, incidental or consequential damages, whether based upon breach of warranty, breach of contract, negligence, strict liability in tort or any other legal theory.</p> <p>This manual was originally drafted in the English language.</p> |

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1 Introduction

1.1 Variants

The Easy DR is produced in two variants:

| Easy DR | FDD | Rotation | Use |
|---------|-------|--------------|---------------------------------|
| 1 | 145cm | 0° ~ -90° | Chest screening Multipurpose |
| 2 | 183cm | Non-rotation | Chest screening |

FDD = Focus Detector Distance (distance between Focal spot of X-ray tube to the detector)

| | |
|--------------|--|
| Note: | <p>This manual is based on the variant 1.</p> <p>When the Easy DR is Variant 2: the 145cm have to be substituted by 183cm; rotation of the arm is not possible and can be skipped.</p> |
|--------------|--|

All other functions are similar as variant 1.

1.2 About this manual

This user manual is a guide for the operator of the Easy DR multifunctional X-ray unit. In this manual it is assumed that the operator is a professional and trained X-ray user, who has gained sufficient knowledge to operate Easy DR system safely.

In particular this document describes the daily operation and interpretation of the user interface for the Easy DR. It also contains:

- A brief description of the Easy DR system
- System safety
- Operating procedures
- User maintenance procedures

Please study this manual carefully before attempting to use the Easy DR. Proper functioning of the apparatus can be guaranteed only if the instructions in this manual are adhered to.

1.3 Classification

The system is classified according to Class 1 type B.

The system meets the relevant provisions of the European Medical Device Directive 93/42/EEC.

1.4 Installation

The installation procedure can be found in the:

- Service Manual / ODB-100-5080ENG

1.5 Technical description











The technical description can be found in the:

- Technical specifications Easy DR / ODB-100-5090ENG

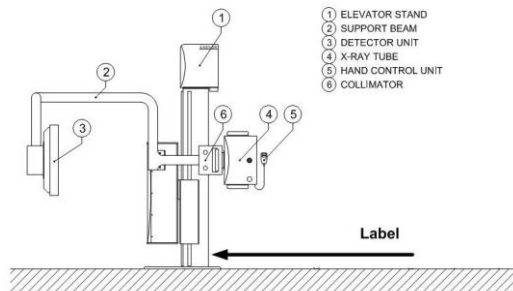
1.6 Label and symbols

Label

Location

| | | | |
|---|---|---|---------------------------------|
| Type / Model: | Easy DR |  Oldelft Benelux | |
| Serial number: |  E-DR-2013-13xx | | |
| Date of manufacture: |  YYYY | | |
| Manufactured By: |  Oldelft Benelux BV , Wiltonstraat 41, 3905 KW, Veenendaal, The Netherlands | | |
| Power supply stand: | Powered by generator, 230 VAC, 50 Hz, 6.3 A | | |
| Power supply detector:* | 100/240 VAC $\pm 10\%$, 50/60 Hz, 2.5 A | | |
| Power supply X-Ray generator:* | 3 phase 400/480 VAC $\pm 10\%$, 50/60 Hz, 65 kVA Momentary Current: 100 A/phase at 400 VAC Nominal Current: ≤ 5 A Mains Resistance max: 0.17 Ω | | |
| Operating Conditions | | Storage Conditions | |
| Temperature: | +10 to +35 °C | Temperature: | -25 to +60 °C |
| Humidity: | 30 to 75% RH (no condensing) | Humidity: | 10 to 60% RH (no condensing) |
| Atmospheric pressure: | 700 to 1060 hPa | Atmospheric pressure: | 700 to 1060 hPa |
|  <p>Only qualified personnel authorized by Oldelft Benelux BV or its local representative is authorized to repair and maintain the apparatus.</p> <p>Unpacking, assembly and transport of the apparatus must be carried out by qualified personnel.</p> | | | |
|  | |    | |
|  0344 | | | |

*For more detailed information we point out to use the installation manuals of the generator and the digital detector.



1 ELEVATOR STAND
2 SUPPORT BEAM
3 DETECTOR UNIT
4 X-RAY TUBE
5 HAND CONTROL UNIT
6 COLLIMATOR

Label

This label is described in document: Labels / ODB-100-5100ENG

1.7 Reference manuals

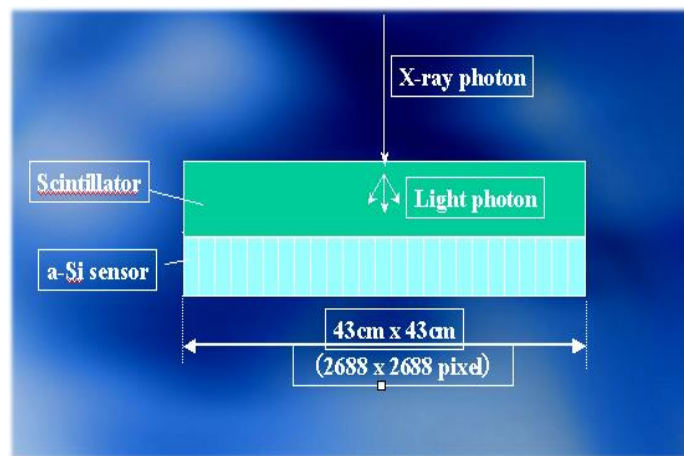
| | |
|--------------|--|
| Note: | <p>This document complements the reference manuals provided with this system and cannot replace these manuals. The user should therefore take note of the reference manuals, especially the safety rules before using the system. When this document and the reference manual differs, the reference manuals are considered as leading.</p> |
|--------------|--|

| List with manuals delivered with the Easy DR | |
|--|--|
| ODB-100-5070ENG | User manual |
| | Key-User Manual Easy DR |
| | Operation manual HF Generator |
| | Computer |
| | Monitor |
| | Detector, CXDI-401G/C Compact |
| | Power box PB-6 |
| | CXDI Control Software Operation manual |
| | CXDI Control Software Setup guide |
| | Harmony3-ST Docking |

1.8 General description/indications for use

The Easy DR is a film-less X-ray system suitable for a wide range of radiological exams. The design is based on the WHO recommend WIS-RAD system and together with the Rogan ROX and VPX viewing station is very suitable for (mass) screening on TBC.

X-ray photons arrive at the DR plate (sensor) and the scintillation cause a reaction in which light is released. This light is absorbed and converted into a current through a photoelectric converter, a SI-sensor.

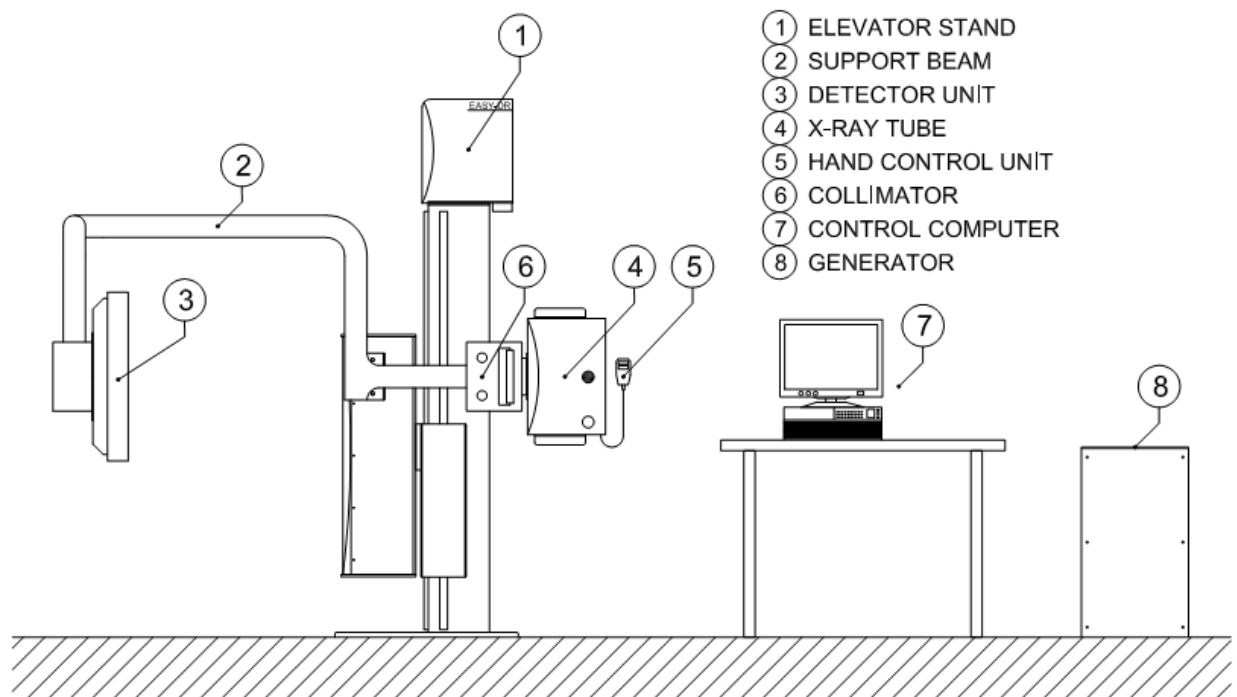


Example of a DR sensor

A sensor contains lines and rows with pixels. These pixels are read out directly after exposure. All the different currents from the pixels are converted into a corresponding value so the computer can display an image. The captured X-ray image is stored in digital memory. Digitized images are transferred as DICOM 3.0 compatible files to a Picture Archive and Communication system (PACS). The PACS system is used to distribute to diagnostic viewing station.

The Easy DR is equipped with an elevator stand, which is firmly bolted to the floor. It can lift the support frame to the desired height. The support frame can also turn between 0 and -90 degree. This allows for a bed trolley to be placed over the detector so bed patients can be done. The support frame consists of the detector unit and the X-ray tube unit.

The X-ray generator may be installed outside the operator area. The X-ray generator control panel (on/off) is located in the X-ray protected area. Both the detector and X-ray unit are controlled by the control computer.



Easy DR system main components

Depending on the configuration the Easy DR System may contain the following sub-systems:

- The Easy DR unit (Elevator stand and support frame)
- The Control computer (separate manuals)
- X-ray equipment (separate manuals)
- Optional PACS and Diagnostic Viewing Station (separate manuals)
- Optional printer (separate manuals)
- Optional UPS/battery system

1.9 Physical description

In this paragraph only the Easy DR main hardware items are described. These are:

- Elevator stand
- Support frame
- Control computer
- X-ray tube unit
- X-ray generator and control panel
- Collimator unit

1.9.1 Elevator stand

The support frame is mounted on the elevator stand. The detector and X-ray tube can move vertically on the elevator stand to adapt the chin rest to the patient height suitable for PA Thorax imaging. The support frame can also turn from 0 to -90 degree. Rotation can only be done when the support frame is between 850 and 1350 mm above the ground. This prevents the unit from being damaged by the floor or ceiling.

When an obstacle touches the safety switch that is mounted at the bottom side of the detector unit, the downward and/or rotation movement of the unit immediately stops. The down and/or rotation control switch on the hand control unit is overruled as long as the safety switch is activated.

Another way to stop the operation of the elevator stand and support frame is pressing the emergency switch located next to the collimator unit.

1.9.2 Support frame

The support frames holds the detector and X-ray unit. The system has a fixed focus detector distance (FFD) of 145cm. This allows for a wide range of radiological exams. The support frame is designed in such a way that in all positions patient placement is flexible and no cables or frames are in the way.

1.9.3 Control computer

The control computer is used to operate the detector and X-ray unit. The system comes with a wide range of preconfigured protocols for an optimal image quality. By selection of a protocol the correct X-ray settings (kV, Ma and Ms) are automatically set. The Automatic Exposure Control (AEC) will give the most optimal image quality at the lowest possible patient dose. The Control computer is also used to temporarily store the X-ray images. It is interfaced via a network to the PACS and Diagnostic Viewing stations.

1.9.4 X-ray tube unit

The X-ray tube unit consists of a X-ray tube, a filter unit and a collimator unit. The X-ray tube is mechanically aligned with the detector unit. The X-ray tube focus is always directed to the detector unit.

The filter unit contains a rotating disc with four types of X-ray filters. The filter unit is intended for maintenance purposes only; its setting should not be changed by the operator.

1.9.5 X-ray generator and control panel

The X-ray generator has its own documentation.



Advice to consult the accompanying documentation:

- Operation manual HF generator.

A two-step radiation exposure switch is connected to the (mini) generator interface panel. The following functions are available on the generator control panel:

- Switching the X-ray system ON or OFF

1.9.6 Collimator unit

The collimator unit comprises an adjustable diaphragm and a field illumination indicator.

The adjustable diaphragm has two setting knobs: one to adjust two vertical shutters for symmetrical lateral adjustment, the other to move the horizontal shutters to adjust vertical field size.

The field illumination indicator delineates the total extent of the field to be exposed. It can be switched on and off by a push button. If left on, the light will turn off automatically.




In general, the lateral diaphragm is adjusted to maximum for Posterior-Anterior (PA) exposures of normal patients, and to less than maximum for lateral exposures or for exposures of small patients.

1.9.7 Lateral Positioning Arm.

As an option, for the Easy DR, a Lateral Positioning Arm can be mounted to the detector frame. The mounting hardware is already set by the manufacturer when the equipment is ordered with this option. It only requires to insert the arm bar into its working position.

To do this:

- Insert the Lateral positioning Arm into the support block located on the detector frame.
- Lock the Lateral Positioning Arm into the extension rod by using the control knob.

| | |
|--|--|
|  WARNING: | Ensure the Lateral Positioning Arm is properly secured before using the system with patients. |
|  WARNING: | In cases where it is deemed necessary the use of the Lateral Positioning Arm, take caution before making any movement of support frame mounted on the elevator stand, in order to make sure that there is no risk of collision. |
|  WARNING: | Max Load 15kg |

1.10 Functional description

The Easy DR operates without X-ray film: the X-ray image is captured with the X-ray detector and stored in digital memory. Digitized images are stored as DICOM 3.0 compatible files a local hard disk (short term) and automatically via a network link to the PACS and diagnostic viewer station.

After positioning the patient, the operator prompts the Easy DR to make an X-ray exposure. Before the actual X-ray exposure can be made the patient's data have to be entered on the control computer. After patient data is entered the X-ray exposure is taken.

1.10.1 Exposure interval

The actual exposure starts when the two stage exposure switch is pressed. The AEC automatically switch of the radiation as soon as the desired dose is measured by the system.

1.10.2 Elevator stand

The elevator stand moves the support frame up and down to accommodate the patient height. This movement is controlled by means of the elevator control switches on the hand control unit. When actuated, a safety switch fitted to the bottom of the detector unit prevents the elevator from moving down.

In case of emergency an emergency stop button, located just next to the collimator unit, can be pushed. Pushing the emergency stop button will immediately stop the movement of the scanner unit. After removing the threat, and after releasing the emergency stop button, the unit is ready for use again.

1.10.3 Support frame

The support frame holds the detector and X-ray unit. The X-ray tube unit is placed on a fixed, 145 cm, distance from the detector unit. The support frame can be turned from 0 to -90° . In the -90° positions a bed can be placed over the detector to accommodate other radiological procedures. When actuated, a safety switch fitted to the bottom of the detector unit prevents the elevator from moving down.

In case of emergency an emergency stop button, located just next to the collimator unit, can be pushed. Pushing the emergency stop button will immediately stop the movement of the scanner unit. After removing the threat, and after releasing the emergency stop button, the unit is ready for use again.

1.10.4 Control computer

The control computer is the controlling device for the Easy DR rather than a means for advanced diagnostics, which would require very high resolution/brightness as in fast viewing stations. These are beyond the scope of this manual.

The control computer offers a graphical user interface to perform the following functions:

- Input of patient data, either directly (touch screen) or via import from peripheral systems (network, barcode scanner)
- Control of X-ray detector (Data acquisition, post processing and display)
- Control of X-ray unit (kV, mA and mS settings)
- Database management for patient data and related X-ray images
- Export of digital X-ray images to peripheral systems (network)

Radiation on/off switching is controlled by the Control computer and X-ray generator interface but always executed by the two stage exposure switch. Generator technique settings are controlled by the control computer. However Radiographers should follow well-known guidelines and procedures for operating the X-ray generator and are supposed to have read and understood the manufacturer's instructions for that device.



Advice to consult the accompanying documentation:

- Operation manual HF generator.

2 Safety devices

2.1 General safety

The Easy DR and X-ray generator are equipped with safeguards to prevent injury to operator and patient during use and in case of system malfunctions. For the safeguards of the X-ray generator refer to the X-ray generator documentation.



Advice to consult the accompanying documentation:

- Operation manual HF generator.

In case of equipment malfunction, bring the patient into safety and seek the assistance of a qualified technician.

2.1.1 Radiation precautions

Always take radiation safety precautions following the local safety rules.

ALARA is a philosophy of excellence used in one's day-to-day work with radiation sources. It is when one strives to keep one's radiation exposure **As Low As Reasonably Achievable**.

2.1.2 Biocompatibility

To prevent infections, clean all parts of the equipment that are touched by the patient (such as handgrips, chin rest, front plate), before the next patient is examined. Do this according the instructions in par.:5.1 Cleaning

2.2 System safety

2.2.1 Safety switch

A safety switch is mounted underneath the detector unit. When the pressure of an obstacle pushes on this plate, the control switch for downward and rotation movement on the hand control unit becomes inactive. The upward movement, however, remains possible.

2.2.2 Emergency stop button

An emergency stop button is part of the scanner unit and is located just next to the collimator unit. In case of an emergency this button can be pressed and it will stop any movement. To release the button, rotate it a quarter of a turn.

Before releasing the button, bring the patient into safety. Then clear the area from obstacles.






2.2.3 Transport locking

Mobile units: Underneath the locking device bolted on the floor a switch is mounted. When the system is locked for transport this switch is open and functions the same way as the E-stop e.g. no movements possible.

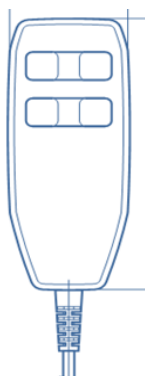
3 Operating controls

There are hardware (buttons and LED indicators) and computer controls. The hardware controls are located on the hand control unit, on the X-ray generator mini control panel, and on the collimator. The computer controls are the touch screen buttons provided in the user interface of the control computer unit.

3.1 Hand control

| | |
|--|---|
|  WARNING: | Motorized movements are only allowed if operator stands in front of and outside the working area of the Easy DR. |
|  WARNING: | Motorized movements are only allowed if patient and system are observed by the operator, because of squeezing hazards. |
|  WARNING: | Operating the Easy DR from the hand control unit is only allowed when patient and system are observed and are under supervision of personnel because of squeezing hazards. |
|  WARNING: | Due to squeezing hazard, patients shall always be placed outside the Working area during motorized rotation of the Easy DR. |
|  WARNING: | Special precautions from the user has to be taken when using the Easy DR together with a table. Squeezing hazards exists in these situations. |

The hand control unit has four push buttons they control the following functions:



Support frame height up and down controls. With these buttons the system can be positioned to a convenient height for the patient

Support frame rotation controls. With these buttons the system can be positioned from 0 to -90 ° to accommodate multiple radiological exams. The rotation buttons only work when the support frame is between 850 and 1350 mm above the ground

3.2 X-ray generator control panel

The description in this paragraph applies to the CPI MP200 generator with a special interface to the Easy DR system. For more details, see the documentation of the X-ray generator.



Advice to consult the accompanying documentation:

- Operation manual HF generator.

The X-ray unit may be dangerous to the patient and operator unless safe exposure factors and operating instructions are observed.

The generator mini control panel contains various indicators and controls. The relevant controls are:

- ON/OFF switch
- Exposure switch and indicator (audible). Starting X-ray radiation.

3.3 Collimator controls



The collimator unit contains three control knobs, a push button and a filter.

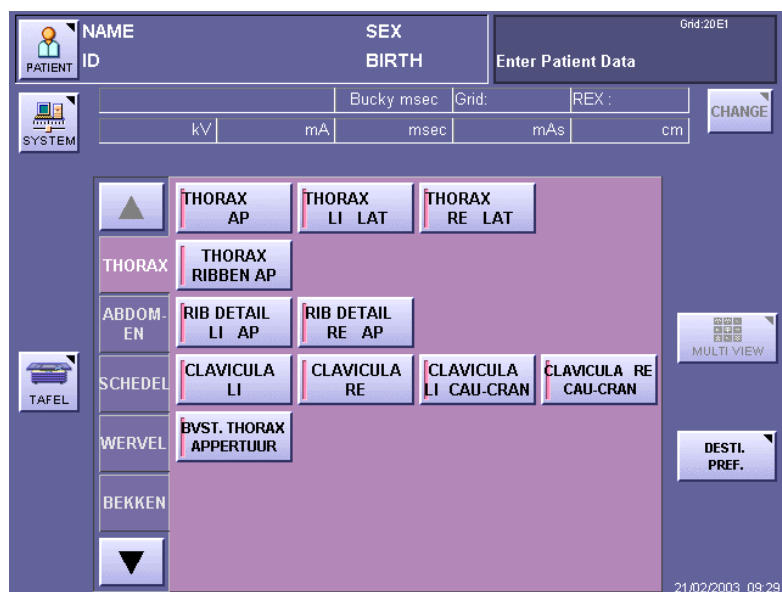
- Control knob (1) controls both lateral X-ray field collimator blades
- Control knob (2) controls the upper X-ray field collimator blade
- Control knob (3) controls the lower X-ray field collimator blade
- Push button (4) switches on the field illumination. The field illumination switches off automatically after a brief time interval.
- An additional filter can be selected by 5, rotating the disk will change the filter. The amount of actual filtering is shown on the disk.

3.4 The user interface of control computer

| | |
|--------------|--|
| Note: | Canon Inc. is the legal manufacturer of the CXDI Control Software used on the Easy DR Acquisition/Control Computer. |
|--------------|--|

The control computer is operated by;

- touch screen buttons



4 Operating instructions

4.1 Releasing the shipping locks

Mobile Easy DR units are fitted with a two shipping locks: a locking screw or bolt to secure the elevator (only used during installation/transport) and a locking device for the support frame bolted on the floor. Fixed units do not have shipping locks.

When the Easy DR is locked in the locking device the e-stop switch is activated by the switch underneath the locking device, this will prevent the movements.

4.2 Powering up

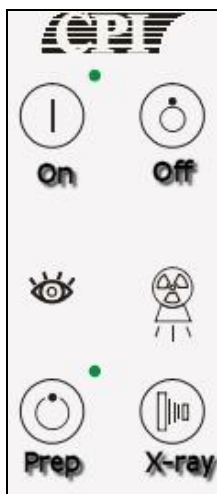
Power up the system. The X-ray generator, Elevator stand and support frame are all powered on by the control of the generator.

In some cases a separate (optional) UPS is provided for the computer. Switch on UPS first, and then switch on the control computer. Log on to the control computer (see Paragraph 0).

Several indicators, including the ON/OFF indicator on the X-ray generator mini control panel, light up.


There is no power switch on the Elevator stand.

Turning on the x-ray generator

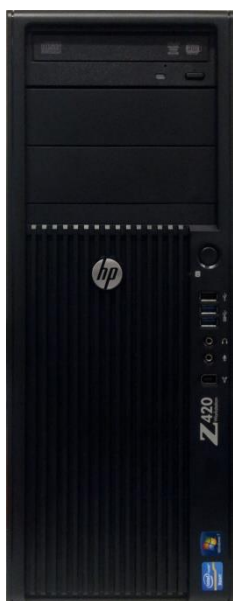


The generator mini console is a small box with on the upper side the on and off button and on the lower side the prep and exposure button.

In the middle there are indicators for fluoro and exposure when active the indicator will light.

Turn on the generator by pressing .

Turning on the Acquisition computer (THOxxxx or BUCxxxx)



Or



Turn on the acquisition computer Marked with THOxxxx or BUCxxxx by pressing the power button.

After power on the control computer windows will start. After a few checks have been made, the main program will start. The user interface contains a touch screen. After startup the start screen will displayed. From this screen, all functions such as patient worklist, patient data entry, protocols and exposure data can be selected.

Note:

A computer system with identification PACxxxx is never the acquisition computer

4.3 Switching off, applying the shipping locks

On mobile Easy DR units there is a shipping lock bolted on the floor that must be applied before the Easy DR is transported. Fixed units do not have shipping locks.

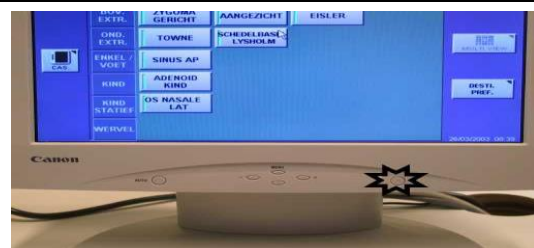
Proceed as follows:


- Mobile Easy DR: Rotate the support frame to the -90° position (X-ray tube is up –detector unit is down). Move the elevator stand downwards till it stops, and the support frame can be locked.
- Log off the control computer (see Paragraph 0).
- Switch off the main power switch for the Easy DR (depending on installation).

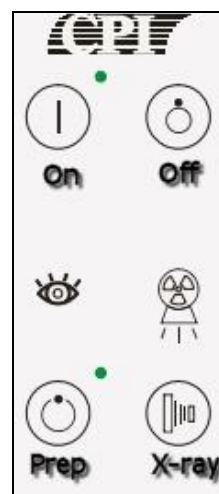


Select on the acquisition station **system**. Select **shutdown** or **shutdown after trans**. Press **ok**. The computer will shutdown automatically.

Power down the Acquisition Stations monitor.



Press  in the upper right corner for power down the generator.



4.4 Entering patient and exposure related data

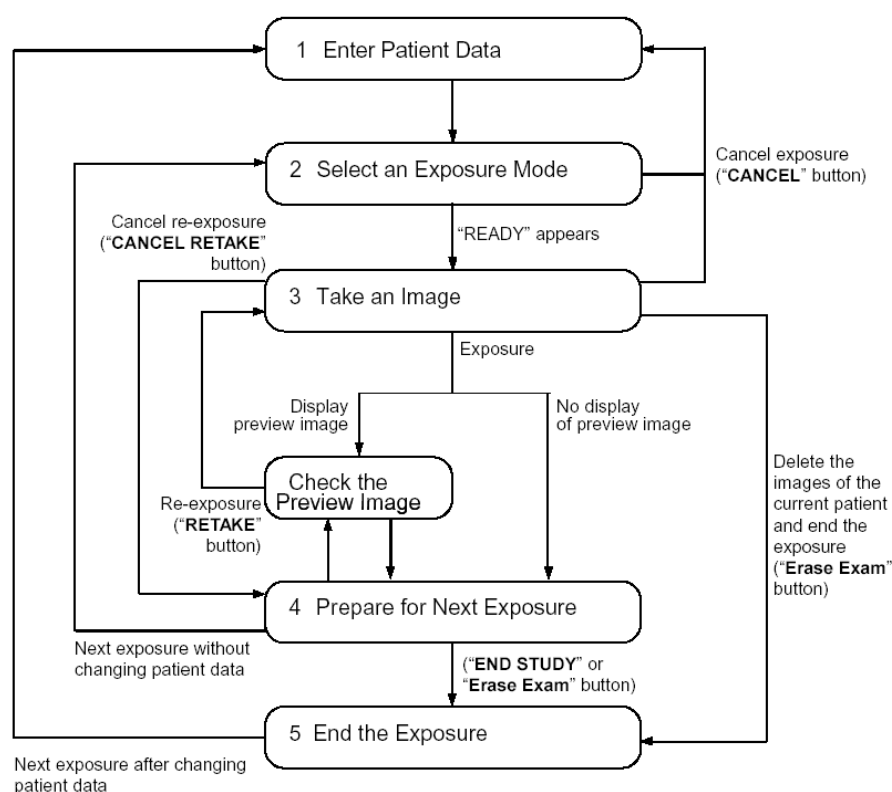
The patients' demographic data are stored locally in a master database, which may be connected to a Hospital Information System, a Radiology Information System, filled by typing in the individual patient record, or filled using a barcode scanner.

The procedure described below is based on a PA thorax patient

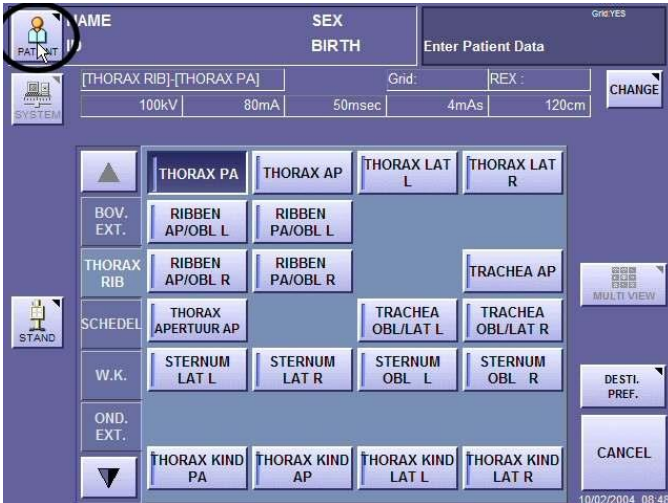
| | |
|--------------|--|
| Note: | This procedure described below complements the reference manuals provided with this system and cannot replace these manuals. The user should therefore take note of the reference manuals, especially the safety rules before using the system. When the procedure described below and the reference manual differs, the reference manuals are considered as leading. |
|--------------|--|

workflow

The figure on the next page gives an overview of the workflow on the control computer;



4.5 Patient data entry



Press the patient button to retrieve the patient worklist (optional)

EXAM ID: 12
P ID: 34441
Conny Kallblad
MALE 26/08/1948 #EXP: 1

Select Exam Data.

>> CUSTOM

| EXAM ID | P ID | NAME |
|---------|-------|------------------|
| 12 | 30331 | Dave Visser |
| 12 | 30631 | Marcel Lantinga |
| 12 | 30635 | Hiro Shiohara |
| 12 | 30639 | Gregor Baggio |
| 12 | 39931 | Neil Staff |
| 12 | 30881 | Manfred Quast |
| 12 | 31111 | Michael Lysholdt |
| 12 | 22231 | Jose Louis Sanz |
| 12 | 34441 | Conny Kallblad |
| 12 | 20631 | Luigi Napolitano |
| 12 | 30638 | Hesther Koopman |
| 12 | 30431 | Stein Espedalen |

01/02

MANUAL CANCEL OK

If no worklist is available a patient input screen will be shown.

NUM Name

ID

MALE FEMALE OTHER

Accession No.

Birth. Day Month Year

Age Years Old

q w e r t y u i o p

a s d f g h j k l

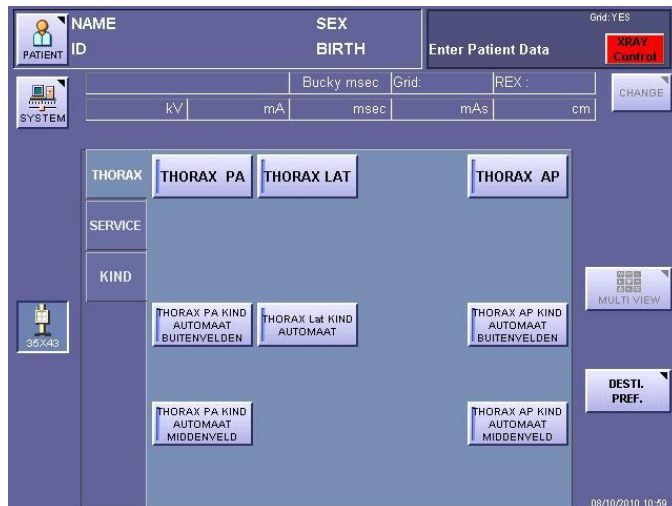
z x c v b n m . :

Caps Home End

TAB BS < > CANCEL OK

4.6 Protocol selection

Select a category tab and the appropriate organ protocol.
The exposure data for the selected protocol is displayed next to the system button.



For changing the exposure settings press the CHANGE or XRAY CONTROL button

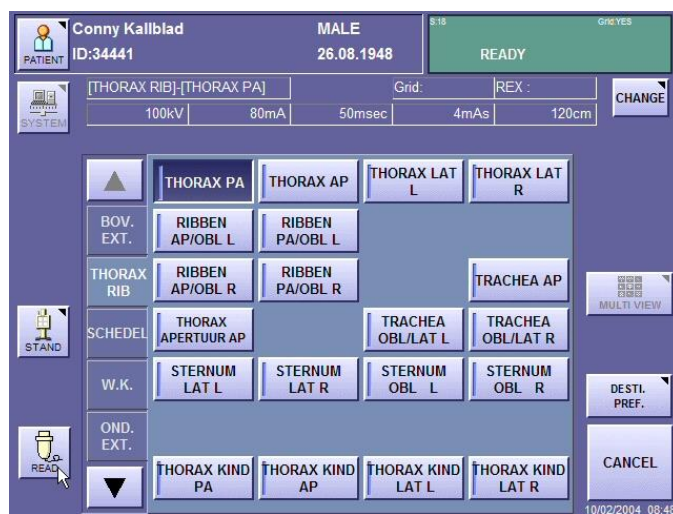
4.7 Changing exposure settings

Press the Change button to get to this screen to change simple exposure settings like kV and mA

Press the + - buttons to incrementally adjust exposure values. One can press into the number field to get a list to choose from. Be aware to choose an exposure within the power limits of the X-ray generator and tube.



When the upper right corner shows READY the system is standby for taking an exposure.








4.8 Making an exposure

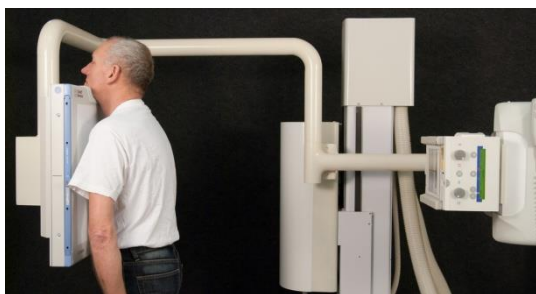
Setting Up:

- Insert the patient data (see paragraph 4.6)
- Select the appropriate protocol (see paragraph 4.7)

4.9 Making a pa thorax X-ray

| | |
|--|---|
|  WARNING: | Check patients on open wounds before placing them to the detector, if open wounds are detected, wear surgical gloves during procedure and cleaning. |
|  WARNING: | Motorized movements are only allowed if operator stands in front of and outside the working area of the Easy DR. |
|  WARNING: | Operating the Easy DR from the hand control unit is only allowed when patient and system are observed and are under supervision of personnel because of squeezing hazards. |
|  WARNING: | Due to squeezing hazard, patients shall always be placed outside the Working area during motorized rotation of the Easy DR. |
|  WARNING: | Special precautions from the user has to be taken when using the Easy DR together with a table. Squeezing hazards exists in these situations. |

- To prevent infections, clean all parts of the equipment that are touched by the patient. (handgrips, chin rest, front plate).
- Place patient in the correct position.

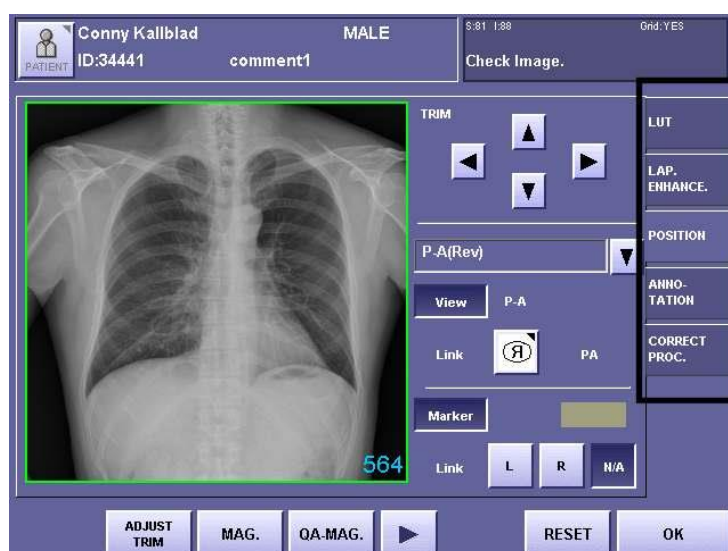


- Press the field illumination button on the collimator unit. The field illumination will be projected on the patient.
- Position the patient well in the centre (use the cross-wire of the field illumination indicator).
- Adjust the height using the up/down buttons on the hand control unit.

- Adjust the collimator using the collimator control.
- Go to a "X-ray free" position.
- Push the exposure button halfway for preparing the exposure.

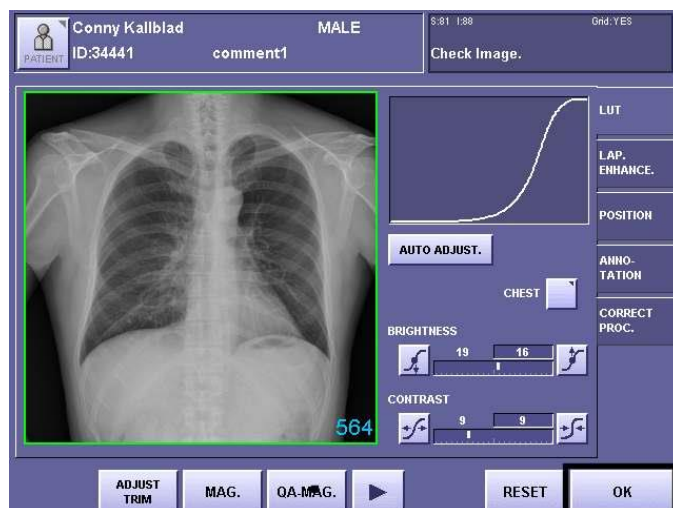


- If needed give breathing instructions.
- Press the exposure button further down for exposure. The recording is accompanied by an audible and visual signal.
- Within 3 seconds after exposure the image is displayed on the screen.



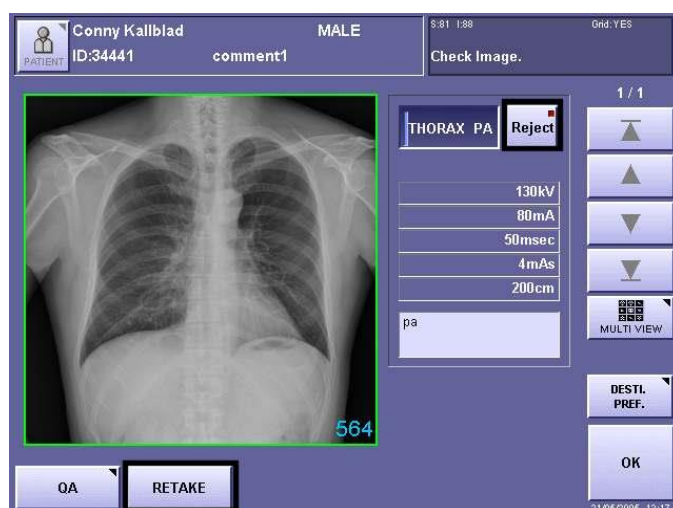
4.10 Reviewing images

On the tabs on the right one can optimize the image and add left or right markers in the image. The left or right marker may vary per protocol, the position of the marker is shown above the L and R button.



If the image is too light or too dark; the picture can be made lighter or darker by changing the brightness inside the LUT tab; Select two opposite corners inside the preview image to change the green TRIM box. The new TRIM box is presented as a red box. The image inside the TRIM box will be exported/stored to the PACS system. Everything outside the TRIM box will not be exported.

Press **OK** to go to the next screen



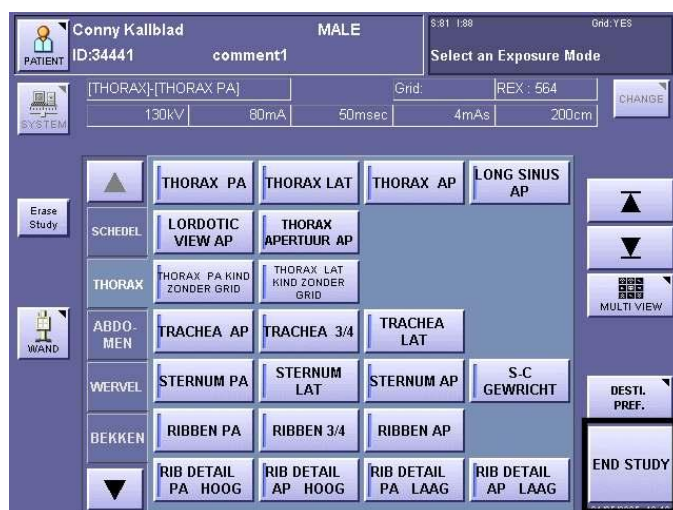
Press the **Reject** button if the image is bad. A rejected image will not be sent to the PACS.

When an image has been rejected one can return to the main screen via the OK button and select the appropriate organ protocol for a retake. A rejected image is not deleted from the system and can be un-rejected by pressing the reject button again.

The **RETAK** button does the same as the Reject button. The system returns to the main screen and the organ protocol is automatically selected and ready for exposure

Images retaken with the retake button cannot be un-rejected!

Press **OK** to go to the next screen



For taking a new exposure with the same patient select the appropriate organ protocol.

To close this study and send it to the PACS system, press **END STUDY**.

5 Maintenance

All maintenance to the Easy DR system is described in the relevant manufacturer's manuals.



Advice to consult the accompanying documentation:

- relevant manufacturer's manuals.

No corrective maintenance should be performed by the operator, other than solving problems as mentioned in Paragraph 5.3

5.1 Cleaning

To prevent infections, clean all parts of the equipment that are touched by the patient (such as handgrips, chin rest, front plate), before the next patient is examined. Do this according to local and hospital regulations, using an ethanol or glutaraldehyde solution to disinfect and as the cleaning agent.

The front plate of the detector unit, which comes into contact with patients, should be clean for each patient (hygiene). For example, cover the front plate with clean sheets of paper and remove a sheet after each patient. Alternatively, patients could wear a hospital gown.

5.2 Safety switch check

A safety switch is mounted underneath the detector unit.

Check ones a month the correct functioning of this safety switch:

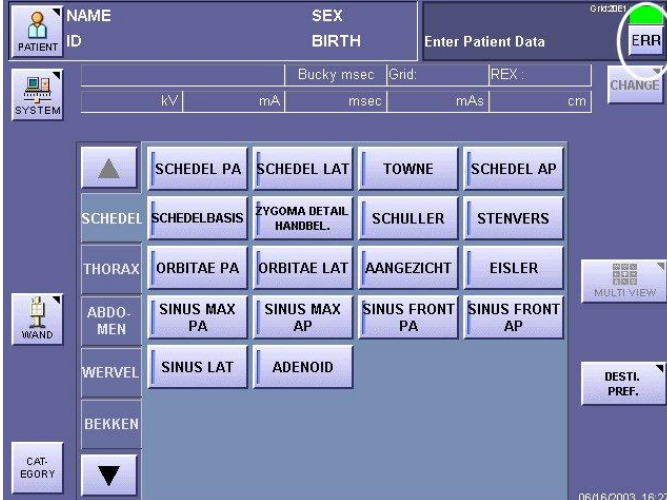
Press the button to move the stand height down and press up the safety switch.

Make sure that the downward movement of the stand is blocked.

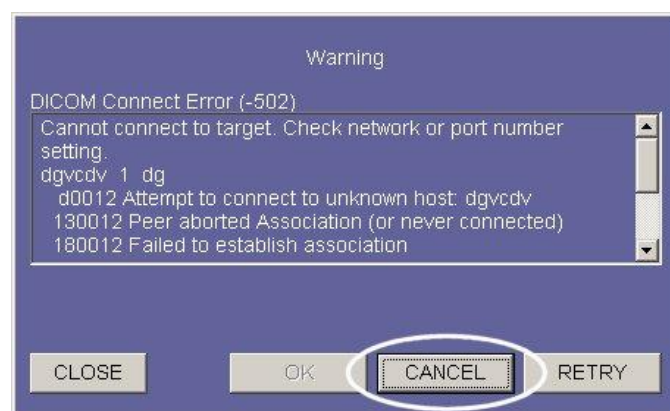
5.3 Troubleshooting

When a fault has occurred in the connection to the PACS; the system will display an error in the upright corner.

Because the system cannot send the images to the PACS these examinations will not be shown in the history list of the system, the Study list

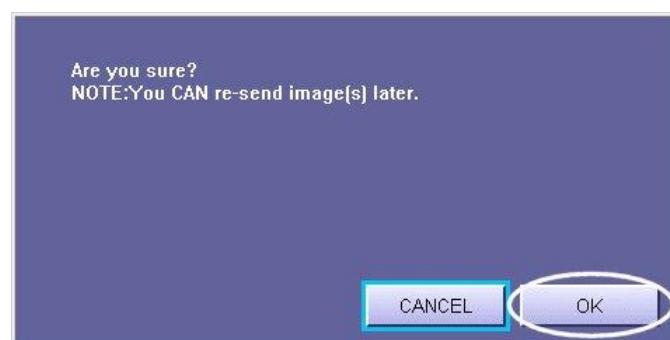


To display the studies in the study list, first the transmission to the PACS must be cancelled. Press the **ERR** button



Press the **CANCEL** button

Press **OK**



This will interrupt the transmission to the PACS and the patient can now be found in the Study list.

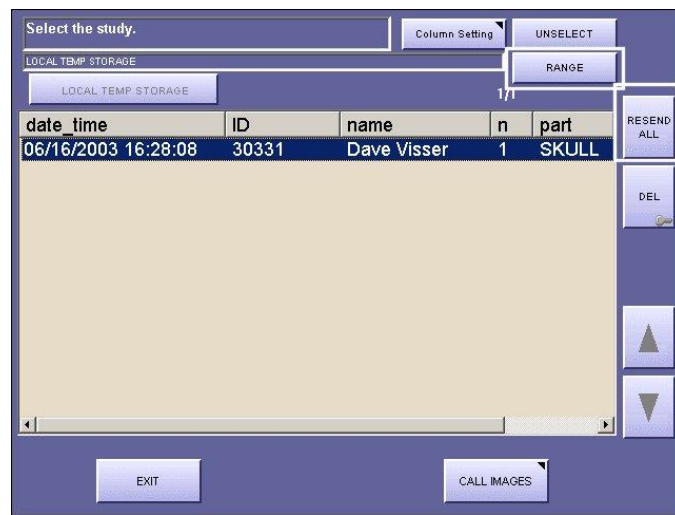
This message applies for each successive patient as long as the network connection is interrupted

If the PACS system is reachable again the studies can be resend from the Study List.

5.4 Sending images afterwards

If a fault on the network did not sent the images to the PACS, it is necessary to send these image manually after the fault has been corrected.

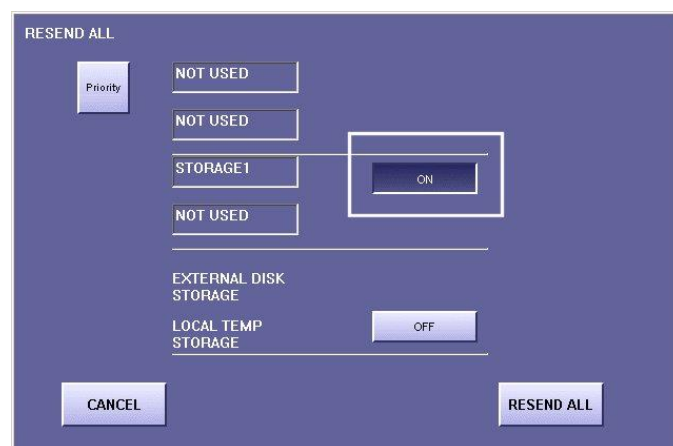
If several patients have to be selected: Select the top patient and press the **RANGE** button



Select the lower patient; all patients in between the upper and lower will be selected.

Press the **RESEND ALL** button to send all selected images.

Rejected images will not be send to the PACS system this requires the button to be set to ON. In the example below ; the images will be send to "storage 1" (the PACS system)



"Storage 1" is an example in this manual only. The name can differ from site to site

5.5 Calibrate

To maintain a consistent image quality is important to regularly perform a calibration procedure.

Calibration equalizes the individual differences of the pixel units. These differences are calculated for each pixel so that individual differences are not visible in a photograph.

It is recommended to calibrate once a year.

Before calibration takes place:

- The room is at normal operating temperature.
- The equipment is turned on for at least 30 minutes to carry out a stable calibration.
- Between X-ray tube and sensor are no materials such as mattresses or patches.
- No lead markers between x-ray tube and sensor

During calibration:

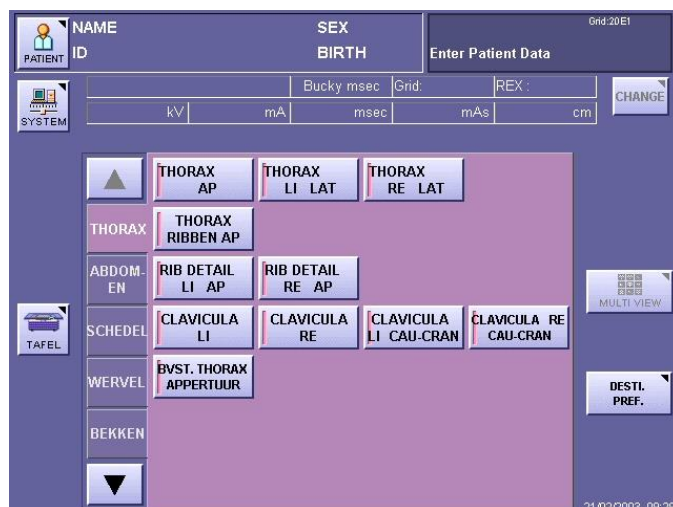
Use the supplied parameters (kV, mAs, focus-film distance) of the system.

Set the collimator open so that the whole sensor is exposed.

If the error "Calibration Error. Too much / little Or Exposure Collimation is Used" appears after calibration, check the focus-sensor distance and exposure settings. Increase or decrease the exposure settings if necessary.

5.6 Calibration procedure

Press the **SYSTEM** button on the main screen

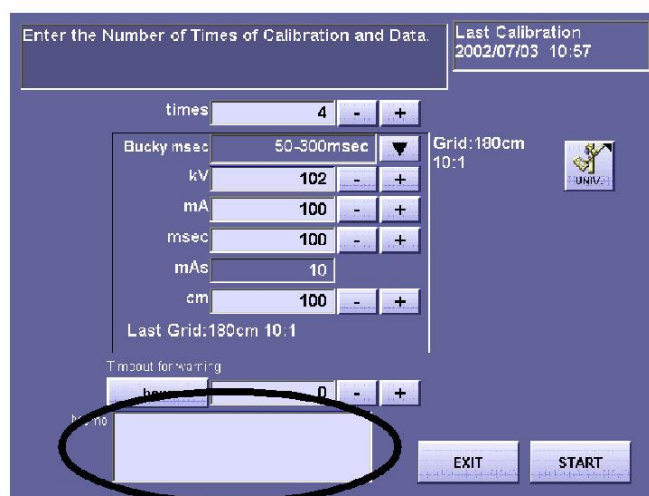


Select **CALIBRATION**

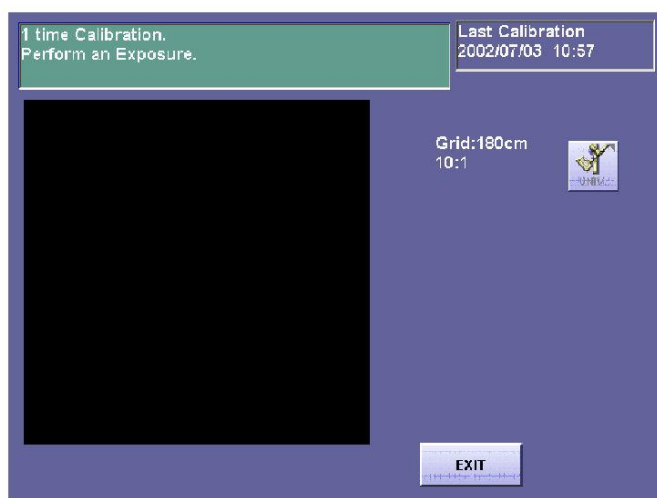


Collimate so that the complete sensor is radiated.
Check the remarks in the memo field

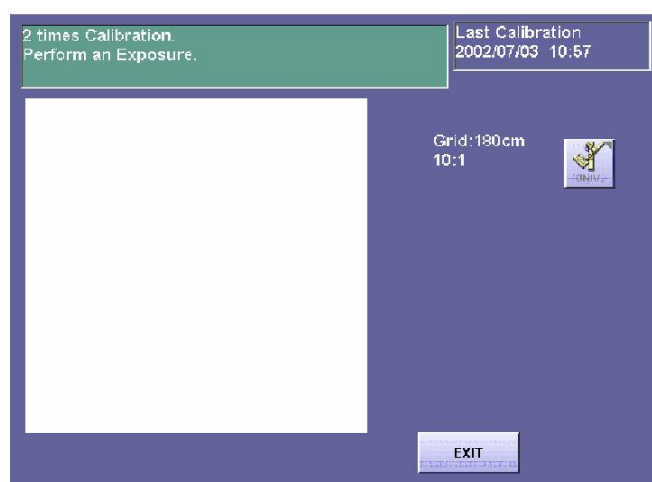
Press the **START** button



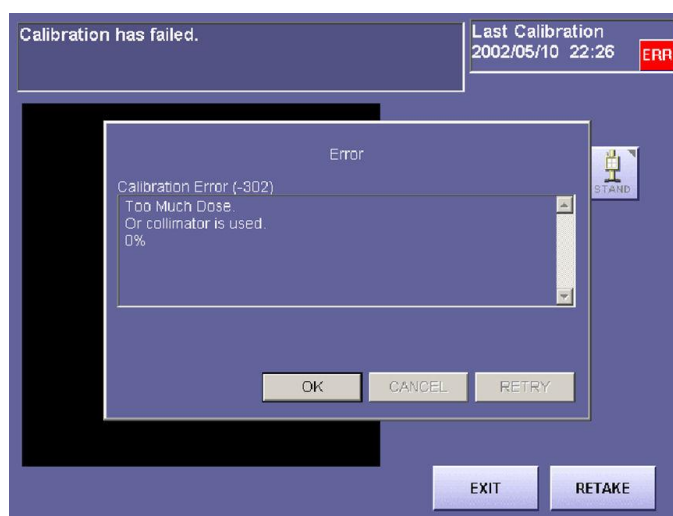
Press the Exposure switch for exposure



If calibration data is correct a notification "Perform an Exposure" appears. A full calibration cycle contains 4 exposures



If calibration data is incorrect. An error appears. Press **OK** to continue. Choose **RETAKE** and check settings, change exposure settings if appropriate



Calibrate ready. The system shows "Calibration has succeeded"



Press **CHECK**

Set exposure settings and memo field as desired

5.7 Troubleshooting after calibration procedure

Problem: There is a marker in the image continually while I do not use a marker.

The calibration is performed with a lead marker. This is calibrated along and is shown in the image

Remedy: Calibrate again without marker

Problem: There is a square or rectangle shape on each image with large fields.

The calibration is performed with the sensor partially radiated

Remedy: Calibrate again with collimator wide open so the complete sensor is radiated.

Problem: The image quality is generally lower after calibration

Calibration occurred with something between the X-ray tube and the sensor, like a mattress

Calibration occurred within 30 minutes after system switch on. The system needs at least 30 minutes to stabilize

Remedy: Calibrate again, make sure nothing is between X-ray tube and sensor and/or wait for at least 30 minutes.

6 Technical specifications

| | | |
|--|--|--|
| Stand | Vertical travel | 675 mm |
| | Kind of movement | Electrical |
| | Kind of balancing | By gas springs |
| | Braking | By motor unit |
| | Travel speed | 50 mm/s |
| | Up and down end stop | Adjustable by microswitches |
| | Down safety | Knee switch at detector side |
| | Continues operation | Max 20 complete up/down movements per hour |
| C arm | Angle of rotation around the telescope vertical axis | 0° - 90° |
| | Condition | Rotation, depending on stand height (Adjustable) |
| | Braking of rotation movements | Electrical with permanent magnet |
| | Focus/film distance | 145 cm |
| | Travel speed | 17,5 °/s |
| | Rotation safety | Knee switch at detector side |
| | Continues operation | Max 3 complete rotations per hour (0° - 90°) |
| Control box | Hand control | With up/down and rotation membrane switches |
| Powering | Voltage, frequency | 230 VAC +/-10%, 50/60Hz single phase |
| | Max. absorbed power | 1600 VA |
| Colors | Painted parts | RAL 9002 |
| | Adhesive membrane | Pantone 658 |
| Weight | Stand including, tube, collimator and detector | 375 kg |
| Equipment identification (according to EN 60601) | Classification | Class I type B |
| | Typology of installation | Permanently connected |
| | Operation mode | Continuous with intermittent load |
| Note: Easy DR 183cm / Non-Rotation | | |
| C arm | | |
| | Focus/film distance | 183cm |
| | Angle of rotation around the telescope vertical axis | Non-Rotation |

| | | |
|---------------------------------|----------------------------|-----------------------------|
| Standard compliance | Safety | EN 60601 |
| Transport and stock environment | Temperature range | -10 °C ~ 50 °C |
| | Relative humidity range | 10 % ~ 95 %, non-condensing |
| | Atmospheric pressure range | 700 ~ 1060hPa |
| Operative environment | Temperature range | 10 °C ~ 35 °C |
| | Relative humidity range | 30 % ~ 80 %, non-condensing |
| | Atmospheric pressure range | 700 ~ 1060hPa |

*Note: The Easy DR may only be used in combination with generator:

1. Manufacturer CPI, type: CMP200D
2. Manufacturer Sedecal, type: SHF515C

| | | |
|--|--------------------|-------------------------------------|
| Powering CPI generator | Voltage, frequency | 3x 400 VAC + zero + ground, 50/60Hz |
| | Protection | 35 A slow |
| See for more information: Site planning manual / ODB-100-5075ENG | | |

| | |
|---------------|--|
| Installation: | Installation instructions are provided in the Maintenance Manual: ODB-100-5080ENG-xx |
|---------------|--|