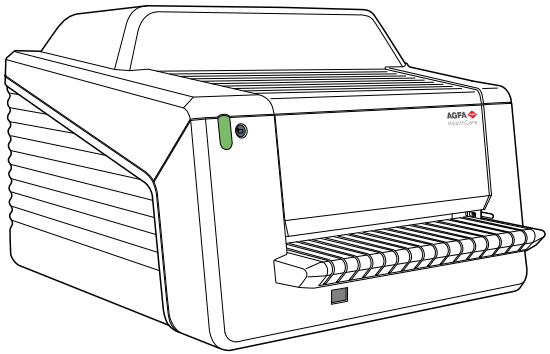
CR 30-X, CR 30-Xm

5175/200

5175/205

5179/100

User Manual



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Contents

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Agfa NV, Septestraat 27, B-2640 Mortsel - Belgium

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Introduction to this Manual

Topics:

Scope

This manual contains information for safe and effective operation of the CR 30-X™ and CR 30-Xm™ digitizer.

About the safety notices in this document

The following samples show how warnings, cautions, instructions and notes appear in this document. The text explains their intended use.

DANGER:
A danger safety notice indicates a hazardous situation of direct, immediate danger for a potential serious injury to a user, engineer, patient or any other person.

WARNING:
A warning safety notice indicates a hazardous situation which can lead to a potential serious injury to a user, engineer, patient or any other person.

CAUTION:
A caution safety notice indicates a hazardous situation which can lead to a potential minor injury to a user, engineer, patient or any other person.

An instruction is a direction which, if it is not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.

A prohibition is a direction which, if it is not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.

Note: *Notes provide advice and highlight unusual points. A note is not intended as an instruction.*

Disclaimer

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Every care has been taken to ensure the accuracy of the information in this document. However, Agfa assumes no responsibility or liability for errors, inaccuracies or omissions that may appear in this document. To improve reliability, function or design Agfa reserves the right to change the product without further notice. This manual is provided without warranty of any kind, implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

Note: *In the United States, Federal law restricts this device to sale by or on the order of a physician.*

Introduction to CR 30-X/CR 30-Xm

Topics:

Intended Use

This digitizer must only be used to scan exposed X-ray cassettes, containing an erasable image plate (IP). The digitizer is part of a system, consisting of X-ray cassettes with erasable phosphor image plates and a workstation where the X-ray cassettes are identified.

The CR system is used in a radiological environment by qualified staff to read-out, process and route static X-ray radiographic images.

Intended User

This manual has been written for trained users of Agfa products and trained diagnostic X–Ray clinical personnel who have received proper training.

Users are those persons who actually handle the equipment and those who have authority over the equipment.

Before attempting to work with this equipment, the user must read, understand, note and strictly observe all warnings, cautions and safety markings on the equipment.

System Configuration

Topics:

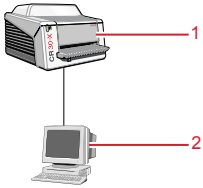
Main System Configuration

The system has the following configuration:

- The CR 30-X or CR 30-Xm digitizer, a digitizer for image plates retaining latent X-ray images. The digitizer accepts one cassette containing one image plate at a time.
- The NX workstation, either a dedicated CR workstation or two CR workstations with ID Tablet, for cassette identification, image processing and image transmission of digitized images received from the digitizer.
- Cassette and plate system: CR MD4.0T General and CR MD4.0T FLFS.
- For CR 30-Xm additionally: CR MM3.0T Mammo and CR MM3.0T Extremities.

Configuration with Fast ID

The digitizer is dedicated to a single workstation, on which the identification software as well as the image processing software is running. The identification data are transmitted from the workstation to the digitizer via DICOM Ethernet. For more information, refer to the workstation's On-line Help manuals or contact your local service organization.



1. Digitizer
2. Control PC

The digitizer must not be connected to any version of the Agfa ADC QS™ or ADC VIPS™ software.

Configuration with ID Tablet

Two workstations can serve a shared digitizer, provided that each workstation has an ID Tablet. There is no physical link required between the workstation and the digitizer.

In this configuration, a cassette can be identified using any of the workstations. The patient demographic data and examination data are entered via the identification software and stored on the RF-tag of the cassette via the ID Tablet.

The image is sent to the workstation where the cassette has been identified. The image can not be rerouted to the other workstation.

Optional System Components

Topics:

Powerware 5115 UPS

The system can be extended with the Powerware 5115 uninterruptible power system (UPS). The UPS is available in two voltage types: 110 V and 230 V.

The Powerware 5115 uninterruptible power system (UPS) protects the PC when the main power supply has crashed, and avoids the loss of images. UPS configuration requires special software. This software will be installed and configured by an Agfa service technician.

With the Powerware 5115, you can safely eliminate the effects of power disturbances and guard the integrity of your system.

To install the Powerware 5115 UPS into the system, proceed as follows:

1. Plug the UPS power cord into the input connector at the UPS rear panel.
2. Plug the other side of the UPS power cord into a power outlet.
3. Plug the digitizer and the NX workstation into the appropriate UPS output receptacles.

   In case of power failure, the batteries of the UPS supplies power to the digitizer and the NX workstation.

Full Leg Full Spine Application Components

- CR FLFS Cassette and Plate set (e.g. CR MD4.0T FLFS).
- NX FLFS license (including Stitching software).
- CR Full Body Cassette Holder.
- Anti-scatter grid (optional).
- CR EasyLift (optional).

For more information and instructions on the FLFS application, refer to the document 4408, CR Full Leg Full Spine User Manual.

Equipment Classification

This device is classified as following:

Table 1: Equipment classification

Class I equipment	Equipment in which protection against electric shock does not relay on basic insulation only, but includes a power supply cord with protective earth conductor. For earth reliability always plug the main power cord into an earthed mains power outlet.
Type B equipment	Not classified. The patient does not get in contact with any part of the equipment.
Water ingress	This device does not have protection against ingress of water.
Cleaning	See section on cleaning and disinfecting.
Disinfection	See section on cleaning and disinfecting.
Flammable anesthetics	This device is not suitable for use in the presence of a flammable anesthetic mixture with air, or in presence of a flammable anesthetic mixture with oxygen or nitrous oxide.
Operation	Continuous operation.

System Documentation

The documentation shall be kept with the system for easy reference. The most extensive configuration is described within this manual, including the maximum number of options and accessories. Not every function, option or accessory described may have been purchased or licensed on a particular piece of equipment.

Technical documentation is available in the product service documentation which is available from your local support organization.

For safety precautions on stitching FLFS (Full Leg Full Spine) images, refer to the “Safety Directions” section of the NX User Manual and the CR Full Leg Full Spine User Manual.

The user documentation consists of:

- CR 30-X/CR 30-Xm User Documentation CD (digital media)
- NX User Documentation CD (digital media)

The CR 30-X/CR 30-Xm user documentation:

- CR 30-X/CR 30-Xm User Manual, (this document)
- CR 30-X/CR 30-Xm Plates and Cassettes User Manual, document 2387
- Getting Started with the ID Tablet, document 2287

The NX user documentation:

- NX User Manual, document 4420 and NX Key User Manual, document 4421
- CR Full Leg Full Spine User Manual, document 4408
- CR Mammography System User Manual, document 2344

Training

The user must have received adequate training on the safe and effective use of the system before attempting to work with it. Training requirements may vary from country to country. The user must make sure that training is received in accordance with local laws or regulations that have the force of law. Your local Agfa or dealer representative can provide further information on training.

The user must note the following information in the system documentation:

- Intended Use.
- Intended User.
- Safety Directions.

Product Complaints

Any health care professional (for example a customer or a user) who has any complaints or has experienced any dissatisfaction with the quality, durability, reliability, safety, effectiveness, or performance of this product must notify Agfa.

If the device malfunctions and may have caused or contributed to a serious injury, Agfa must be notified immediately by telephone, fax or written correspondence to the following address:

Agfa Service Support - local support addresses and phone numbers are listed on www.agfa.com

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

Compatibility

The equipment must only be used in combination with other equipment or components if these are expressly recognized by Agfa as compatible. A list of such equipment and components is available from Agfa service on request.

Changes or additions to the equipment must only be carried out by persons authorized to do so by Agfa. Such changes must comply with best engineering practices and all applicable laws and regulations that have the force of law within the jurisdiction of the hospital.

Accessory equipment connected to any interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment or IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the requirements for ME systems according to IEC 60601-1. 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 for ME systems according to IEC 60601-1. If in doubt, consult your local service organization.

Compliance

Topics:

General

- The product has been designed in accordance with the MEDDEV Guidelines relating to the application of Medical Devices and have been tested as part of the conformity assessment procedures required by 93/42/EEC Medical Device Directive (European Council Directive 93/42/EEC on Medical Devices).
- ISO 13485
- IEC 62366
- IEC 62304
- ISO 14971

Safety

- IEC 60601-1
- UL 60601-1
- AAMI/ANSI ES 60601-1 1st Edition
- CAN/CSA C 22.2 No.60601.1

Laser Safety

- IEC 60825-1

Electromagnetic Compatibility

- IEC 60601-1-2
- FCC Rules 47 CFR part 15 subpart B
- CAN/CSA 22.2 No. 60601-1-2

Environmental Compliance

- WEEE 2012/19/EC
- RoHS 2 Directive 2011/65/EU

Equipment Classification

This device is classified as following:

Table 2: Equipment classification

Class I equipment	Equipment in which protection against electric shock does not relay on basic insulation only, but includes a power supply cord with protective earth conductor. For earth reliability always plug the main power cord into an earthed mains power outlet.
Type B equipment	Not classified. The patient does not get in contact with any part of the equipment.
Water ingress	This device does not have protection against ingress of water.
Cleaning	See section on cleaning and disinfecting.
Disinfection	See section on cleaning and disinfecting.
Flammable anesthetics	This device is not suitable for use in the presence of a flammable anesthetic mixture with air, or in presence of a flammable anesthetic mixture with oxygen or nitrous oxide.
Operation	Continuous operation.

Harmonization

This document has been prepared to comply with the Study Group 1 guidance document of the Global Harmonization Task Force (GHTF) (www.ghtf.org). To assist development of a consistent, harmonized definition for a medical device that could be used within a global regulatory model would offer significant benefits to the manufacturer, user, patient or consumer, and to Regulatory Authorities and support global convergence of regulatory systems.

Connectivity

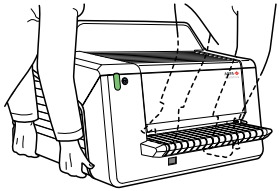
The digitizer is connected to the workstation via Ethernet connection and uses the DICOM protocol to communicate with the workstation.

Installation

WARNING:
When installing the digitizer, care must be taken to ensure that there is either a mains plug or an all-cable disconnecting device in the internal installation fitted near the digitizer and that it is easily accessible.

WARNING:

The digitizer is equipped with 2 handles at the bottom left and right sides to move the device easily to another location. It is recommended to have at least two persons lift the digitizer.



WARNING:
The digitizer and the cassette storage shall be protected against direct radiation in such a way, that the annual dose equivalent at the place of installation will not exceed 1 mSv/a.

WARNING:
Do not lift the device by holding the input tray.

WARNING:
If the digitizer is installed inside an X-ray room it must be protected from stray radiation by proper shielding.

WARNING:
The device is a table-top digitizer. The structure and stability of the table used, need to be suitable in relation with the size and weight of the system. The table should not be subject to excessive shock and vibrations from other sources, as this may disturb the operation of the digitizer.

Topics:

Mobile Use Installation

In case of an installation in a mobile environment, such as a bus, van, etc, the manufacturer of the vehicle should ensure that all components of the system are fixed or can be fixed safely for transport.

If the digitizer is installed in a mobile environment, it has to be secured against moving. The optional earthquake kit for wall fixation should be used.

WARNING:

Do not use the digitizer during transport.

Image quality check after transport

WARNING:

The image quality check must be performed after installation of the digitizer in a mobile environment and is recommended to be repeated after transport.

The check is done with a flat field exposure and should be performed with a cassette of the largest format used at customer site.

X-Ray source	Exposure conditions
General radiography	It is recommended to expose the cassette with 2 exposures of 10 μGy or 1 mR each. Rotate the cassette 180° after the first exposure to compensate for the heel effect. Typical settings for 10 μGy or 1 mR are: • 75 kV • 12 mAs • 130 cm SID • large focus • 1.5 mm Copper filter Identify the cassette as System Diagnosis GenRad - Flat Field.
Mammography	For Mammography only 1 exposure is needed and no rotation of the cassette. Remove the compression paddle before the exposure. Tape an Aluminum filter at the tube exit. Insert the cassette in the bucky and make an exposure with the following settings: • 28 kV • 200 mAs • Mo/Mo • large focus • 2.0 mm Aluminum filter If this leads to an overexposure, the mAs setting can be reduced, but it should not be lower than 50 mAs. Identify the cassette as System Diagnosis Mammo - Flat Field Mammo.

Check the flat field image on the NX workstation for homogeneity and stripe artifacts. In case of problems, please inform your local Agfa service representative.

Product Identification

CR 30-X product description	
Type of product	Table-top digitizer
Commercial name	CR 30-X
Model number	5175/200 5175/205
Original seller / manufacturer	Agfa NV Septestraat 27 2640 Mortsel Belgium

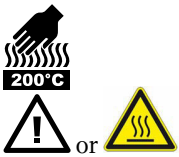
CR 30-Xm product description	
Type of product	Table-top digitizer
Commercial name	CR 30-Xm
Model number	5179/100
Original seller / manufacturer	Agfa NV Septestraat 27 2640 Mortsel Belgium

Labels

Topics:

General

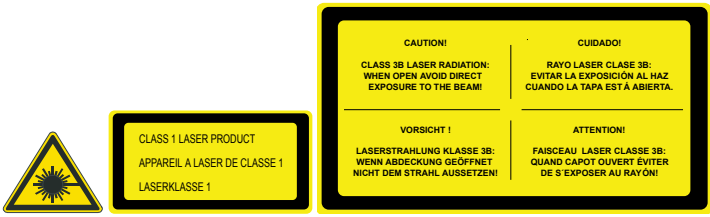
Always take into account the markings and labels provided on the inside and outside of the machine. A brief overview of these markings and labels and their meaning is given below.

	Safety warning, indicating that the manuals should be consulted before making any connections to other equipment. The use of accessory equipment not complying with the equivalent safety requirements of this digitizer may lead to a reduced level of safety of the resulting system. Consideration relating to the choice of accessory equipment shall include: • Use of the accessory equipment in the patient vicinity, • Evidence that the safety certification of the accessory equipment has been performed in accordance with respective IEC standards (e.g. IEC 60950 for data processing equipment or IEC 60601-1 for medical equipment). In addition all configurations must comply with the requirements for medical electrical systems according to IEC 60601-1. The party that makes the connections acts as system configurator and is responsible for complying with the systems standard. If required contact your local service organization.
	In order to reduce the risk of electric shock, do not remove any covers.
	Caution hot: Keep hands clear from the erasure unit.
	Supplementary protective earth connector: Provides a connection between the digitizer and the potential equalization busbar of the electrical system as found in medical environments. This plug should never be unplugged before the power is turned off and the power plug has been removed. It is recommended to use the supplementary protective earth connection as additional safety measure.

	Do not put your fingers in the input slot of the digitizer, they can get hurt when caught between the cassette and the fixation. Insert the cassette as described in the basic workflow chapter.
	Cassette positioning. Insert the cassette as described in the basic workflow chapter.
○	Off (power: disconnection from the mains)
I	On (power: connection to the mains)
	Type label
	Date of manufacture
	Manufacturer
	Serial number
	WEE Symbol, see section about Environmental protection.
	Device contains a transmitter module
	Laser Warning Indicates the presence of a laser device.

Note: *The type label of the CR 30-Xm digitizer is placed at the chassis in the upper left corner when opening the front cover.*

Safety Instructions for Laser Products



The digitizer is a Class 1 Laser Product. It uses one laser diode of a 80 mW type, classification class IIIb, wavelength 640-670 nm. The laser beam's deflection frequency is 120 1/s up to 170 1/s. The laser beam divergence is 12 mrad.

Under normal operating conditions - device with all covers - there can be no laser radiation outside the digitizer.

The technical concept does not allow the user to remove the top cover. The concept provides maximum reliability that no image plate jam can occur in the post scan area.

However, the user is allowed to open the front cover, e.g. to solve cassette or image plate jams at the front side. When opening the front panel, all motor driven system movements will be stopped (including the laser).

CAUTION:
User interventions other than those described in this manual can be hazardous with regard to laser radiation.

Cleaning and Disinfection

All appropriate policies and procedures should be followed to avoid contamination of the staff, patients and device. All existing universal precautions should be taken to avoid that the digitizer and its accessories come into contact with potential contaminations. Details about cleaning can be found in the following pages.

To clean the exterior of the digitizer:

1. Switch off the digitizer.
2. Remove the power plug from the socket.

CAUTION:
Damage or deterioration of safety provisions can cause injury of the operator.

Remove the power plug from the socket before cleaning the exterior of the device.

Switch off the UPS, if installed.

3. Wipe the exterior of the digitizer with a clean, soft, damp cloth.

   Use a mild soap or detergent if required but never use ammonia-based cleaner.

CAUTION:
Make sure no liquid gets in the digitizer.

Note: *Do not open the digitizer for cleaning. No components inside the digitizer require cleaning by the user.*

4. Plug the power plug into the socket.

   Switch on the UPS, if installed.

System components

For cleaning and disinfection instructions of the plates and cassettes, refer to the CR 30-X/CR 30-Xm Plates and Cassettes User Manual.

For cleaning and disinfection instructions of the ID Tablet, refer to the document Getting Started with the ID Tablet.

Patient data security

The user must ensure that the patients' legal requirements are met and that the security of the patient data is guarded.

The user must define who can access patient data in which situations.

The user must have a strategy available on what to do with patient data in case of a disaster.

Maintenance

Topics:

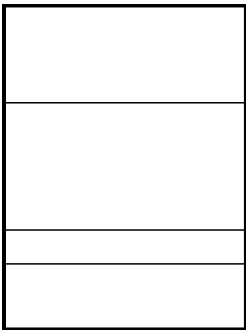
Preventive Maintenance

Regular preventive maintenance needs to be done once a year or after 12000 cycles (whatever comes first). This maintenance can not be done by the user but has to be done by an Agfa certified field service engineer. Not performing the regular maintenance by appropriately certified people can have impact on warranty commitments.

Cleaning the optical unit

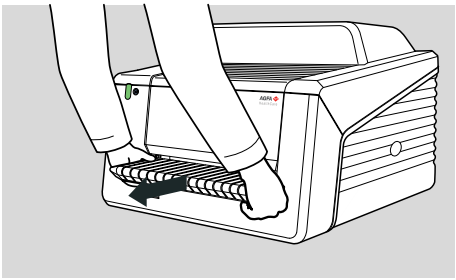
The only maintenance action which you must perform is checking the image quality. Refer to the User Manual of the NX™ Software.

Cleaning the optic unit is required if stripes parallel to the image plate movement can be seen in the image. When you recognize this type of artefact, when using the digitizer, clean the optic unit using the cleaning brush.

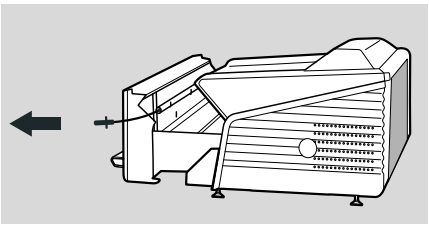


To clean the optic unit, proceed as follows:

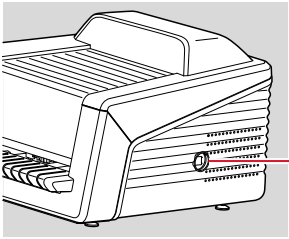
1. Open the cassette unit.



2. Take out the cleaning brush.

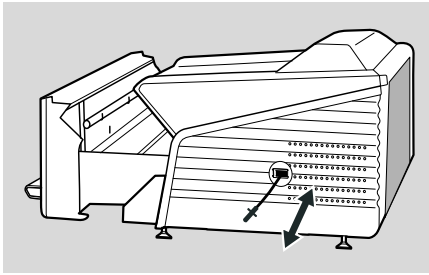


3. Open the lid positioned at the right side.

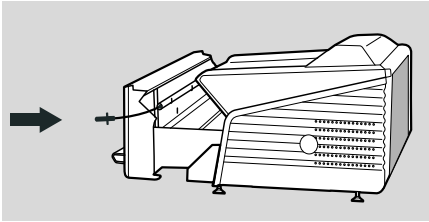


1. Open lid

4. Clean the scan line. Your last movement must be continuous from the rear to the front.

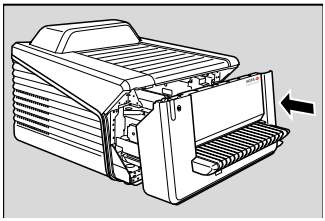


5. Re-insert the cleaning brush.



6. Close the cassette unit

CAUTION:
Misuse of the bowden wire leads to bending, which causes a complicated replacement of the cleaning brush.



Recurrent safety tests

The device shall be tested according to IEC 62353* in a time interval of at least 36 months or less if local regulations are different.

* Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment.

Environmental protection

Figure 1: WEEE symbol

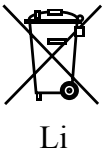


Figure 2: Battery symbol

WEEE end user notice

The directive on Waste Electrical and Electronic Equipment (WEEE) aims to prevent the generation of electric and electronic waste and to promote the reuse, recycling and other forms of recovery. It therefore requires the collection of WEEE, recovery and reuse or recycling.

Due to the implementation into national law, specific requirements can be different within the European Member States. The WEEE symbol on the products, and/or accompanying documents means that used electrical and electronic products should not be treated as, or mixed with general household waste. For more detailed information about take-back and recycling of this product please contact your local service organization and/or dealer. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources.

Battery notice

The battery symbol on the products, and/or accompanying documents means that the used batteries should not be treated as, or mixed with general household waste. The battery symbol on batteries or its packaging may be used in combination with a chemical symbol. In cases where a chemical symbol is available it indicates the presence of respective chemical substances. If your equipment or replaced spare parts contain batteries or accumulators please dispose of them separately according to local regulations.

For battery replacements please contact your local sales organization.

Safety Directions

WARNING:
Safety is only guaranteed when an Agfa certified field service engineer has installed the product.

WARNING:
The user is responsible for judging image quality and controlling environmental conditions for diagnostic softcopy or print viewing.

WARNING:
The user must follow the hospital quality assurance procedures for covering the risks resulting from errors in the image processing

WARNING:
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING:
Position the digitizer so that it is possible to disconnect it from the mains power if required.

WARNING:
The following actions may lead to serious risk of injury and damage to the equipment as well as making the warranty void:

Changes, additions or maintenance to the Agfa products carried out by persons without appropriate qualifications and training.

Using unapproved spare parts

WARNING:
To avoid images being lost due to a power failure, the workstation and the digitizer have to be connected to an uninterruptable power supply (UPS) or an institutional standby generator.

WARNING:
Operation outside of the specified environmental conditions may lead to deterioration of image quality. For best results, keep the environmental conditions within these specifications.

CAUTION:
Strictly observe all warnings, cautions, notes and safety markings within this document and on the product.

CAUTION:
All Agfa medical products must be used by trained and qualified personnel.

WARNING:
The user must be aware that any error (crash / lock up) leading to an image processing failure can cause loss of diagnostic information.

CAUTION:
The digitizer is not suitable for scanning imaging plates (IPs) exposed with a dose higher than 5000 μG.

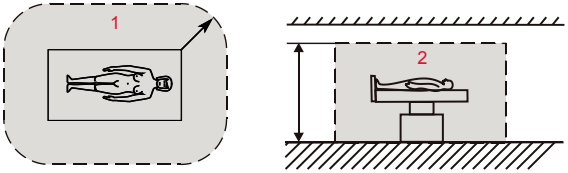
CAUTION:
Excessive light falling on the digitizer during operation may create image artefacts leading to retakes. Do not expose the digitizer to direct sunlight, max. 2500 Lux.

CAUTION:
While every care has been taken, it is possible that minor errors still exist in the product. It is unlikely that a minor error could result in incorrect (unexpected) device operation.

General safety instructions

- Make sure that the digitizer is constantly monitored in order to avoid inappropriate handling, especially by children.
- Only trained service personnel must make repairs. Only authorized service personnel must make changes to the digitizer.
- If there is any visible damage to the machine casing, do not start nor use the digitizer.
- Do not override or disconnect the integrated safety features.
- Do not apply excessive shock or vibration to the digitizer during operation (e.g. putting cassettes on top of the device). This may decrease the image quality. Neither should the device be moved during operation.
- Switch off the device before performing any maintenance work or repairs. Disconnect the digitizer from the mains before making repairs or performing any maintenance activities during which live electrical components may be exposed.
- As is the case for all technical devices, the digitizer must be operated, cared for and serviced correctly. A regular quality control is recommended.
- If you don't operate the digitizer correctly or if you don't have it serviced correctly, Agfa is not liable for resulting disturbances, damages or injuries.

- If you notice conspicuous noise or smoke, disconnect the digitizer immediately.
- Do not pour water or any other liquid over the device.
- The digitizer complies with the EN 60601-1 and UL 60601-1 standards for Medical Electrical Equipment. This means that, although it is absolutely safe, patients may not come in direct contact with the equipment. Therefore the operator console must be placed outside a radius of 1.5 m (EN) or 1.83 m (UL) around the patient (according to the local valid regulation).



1. Patient environment: R = 1.5 m (1.83 m)
2. Patient environment: h = 2.5 m (2.29 m)

- Position the digitizer in a way, that it could be easily unplugged in order to achieve separation from mains.
- Perform no other operations on the digitizer than those described in this document.
- Switch the system off before moving it. When reaching the new position, switch the system on again.

Quality Control

WARNING:
Unnoticed image quality degradation can cause false negative diagnosis.

Apply regular quality control according local regulations.

If no specific regulations are valid, a regular quality control by means of the Agfa Auto QC2 tool is required at least once a month to maintain a safe and effective system.

For mammography, Agfa recommends to use the “Routine Quality Control Tests for Full Field Digital Mammography Systems” document, created by the NHSBSP (National Health Service Breast Screening Program, UK).

Getting started

Topics:

Basic Features

Topics:

CR 30-X/CR 30-Xm Features

The digitizer reads out the latent X-ray images on image plates and sends them to the workstation.

- The digitizer accepts one cassette containing one image plate at a time. The digitizer:
  - locks the cassette containing the image plate in the cassette slot,
  - removes the image plate from the cassette,
  - scans the image plate,
  - converts the information of the latent image to digital data,
  - transmits the image data to the preview station,
  - erases the image plate and re-inserts it into the cassette,
  - gives the image plate ID data the status 'erased',
  - unlocks the cassette,
  - transmits the digital image data to an image processing station (‘destination’).
- The digitizer permits assigning the status ‘emergency’ to an image.
- The digitizer permits re-erasing an image plate before reusing it. In specific cases, this is necessary to prevent ghost images caused by previous exposures or stray radiation from interfering with the image of interest.
- With the dedicated ID station of the CR 30-X/CR 30-Xm, the following features are available:
  - quickly identifying cassettes without the need for an ID Tablet,
  - reading the identification data of a cassette.

Operating Modes

The digitizer can be operated in two modes: operator mode and service mode.

Topics:

Operator Mode

The operator mode groups all basic functions which are aimed at radiographers:

- Reading an image plate,
- Reading an emergency image plate,
- Re-erasing an image plate,
- Reading the identification data of a cassette.

All functions of the operator mode are described in this manual.

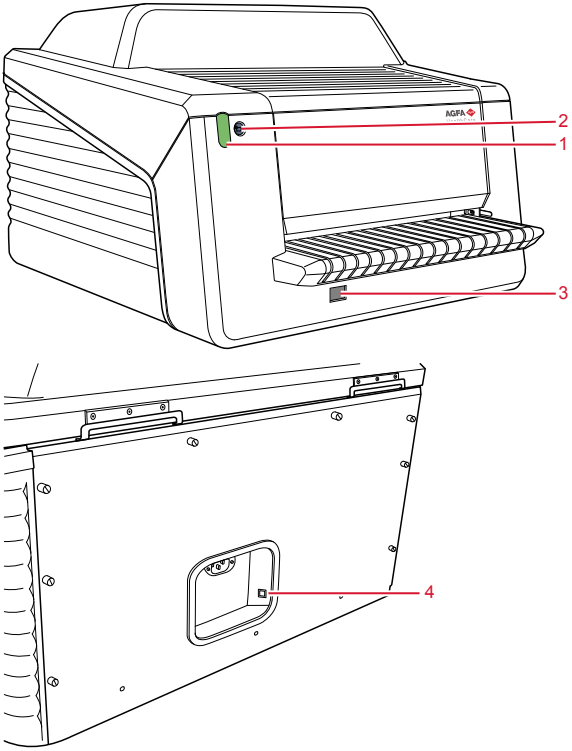
Service Mode

The service mode functions are reserved for trained service personnel. They are password protected, and they are described in a separate document.

The User Interface

The digitizer interfaces with the user via:

- an erase button,
- a status indicator,
- a main switch.



1. Status indicator
2. Erase button
3. Main switch
4. DICOM Ethernet connection

Topics:

The Erase Button

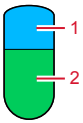
Press the erase button to start the erasing cycle of an image plate. After pressing the erase button, the upper part of the status indicator is continuously lighting up in blue and the digitizer starts erasing the image

plate of the cassette inserted next. If no cassette with image plate has been inserted after 60 seconds, the system automatically returns to standby mode.

Status Indicator

The indicator informs the user by light signals about the status of the digitizer. It is positioned at the front of the digitizer, so that it is visible from a distance.

The indicator is divided in two parts. The upper part is used to inform the operator about the image plate erasing cycle progress and is only then lit. The lower part is used for all other operational indications.



1. Blue
2. Green or red

Color	Constant/ Blinking	Status	Action
Blue	Constant	Activating the erasing cycle	
Green	Constant	• Standby mode (Ready) • Cassette is ready for removal	• Proceed. • Remove cassette.
	Flashing	Busy with scanning, erasing and return of the IP into cassette	Wait.
Red	Constant	Service mode	Check workstation for further information and detailed instructions.
	Blinking	• Warm up / Self-test • Processing Software down • Error	
	Blinking fast	Digitizer not connected to Digitizer Remote Display UI	Refer to section 'Troubleshooting'.
	Blinking - 3 pulses	Digitizer not connected to control PC	

Related Links

Troubleshooting Checklist on page 81

Starting the device

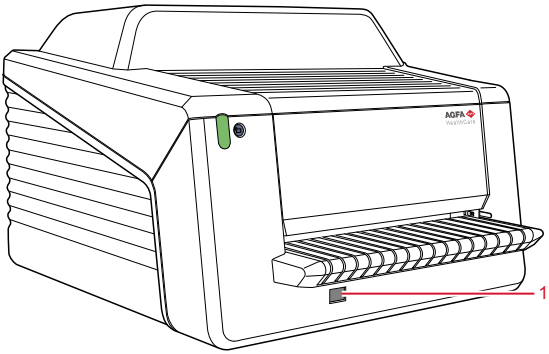
1. Turn on the UPS (optional accessory) to supply electricity to the control PC and the digitizer.

   Check whether the UPS is connected to a power outlet.

   Press and hold the On button approximately one second until you hear the UPS beep.

   Note: Step 1 is only applicable if your system is extended with an uninterruptible power supply (UPS).

2. Switch on the digitizer by pressing the main switch.



   1. Main switch

   The machine starts the following operation sequence:

   - initialization of all components,
   - functional test of all components,
   - check for presence of cassettes and/or IPs,
   - establish connection to the control PC.

   During the self-test, which may take up to 60 seconds, the digitizer status indicator is flashing red.

   Note: During the self-test, you cannot activate any functions.

   If the digitizer has completed the self-test successfully, the digitizer enters the operator mode and the status indicator is continuously lighting up in green.

3. Switch on the ID Tablet.

   Only in a configuration with ID Tablet.

   For more information, refer to the document Getting Started with the ID Tablet.

4. Make sure the digitizer is connected to the control PC and that the control PC is running the appropriate NX software.
   For more information, refer to the NX User Manual.

5. Start NX.

   For detailed information about starting up NX, refer to the NX User Manual, document 4420.

Basic Workflow using Fast ID

Topics:

Select a patient and start the exam

At the NX workstation:

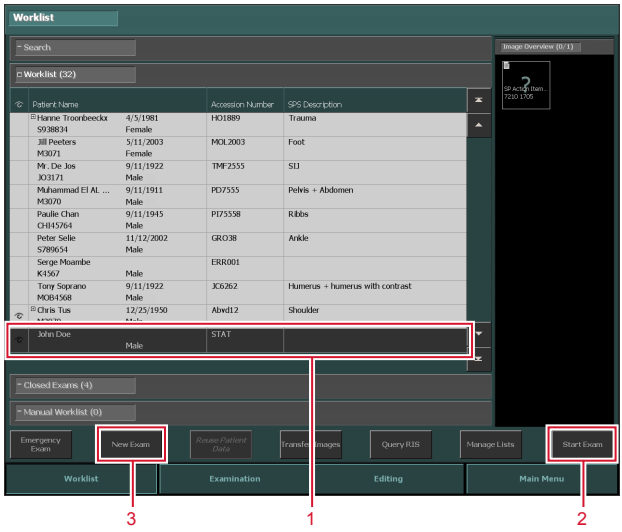
1. Open the Worklist window of NX.

   In the Worklist window, you can view and manage the exams that are scheduled via the Worklist pane.

   Note: When starting the NX software, the Worklist window is the first window that appears after the NX Splash screen.

   Note: Start the NX software on the NX workstation. Refer to the NX User Manual, document 4420.

2. In the Worklist window, open a patient from the RIS or enter patient data manually.



   To open a patient from the RIS, select an Exam from the list (1) and click on Start Exam (2).

   To enter patient data manually, click New Exam (3) and enter patient data and image data manually.

   For more information, refer to the NX User Manual, document 4420.

Insert the Cassette in the Digitizer

CAUTION:
Image quality may suffer if a cassette and plate is not scanned soon after exposure. The Agfa phosphor has excellent dark decay characteristics. Two hours after exposure, approximately 80% of the energy stored upon exposure is still available. The image retention is better than 50% up to 24 hours after irradiation. However, in order to preserve image quality, a cassette and plate should be scanned no later than 2 hours after exposure.

At the digitizer:

1. Check that the digitizer is ready for operation:

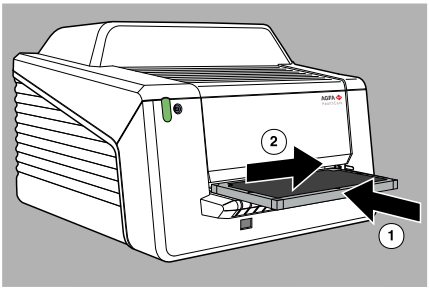
   The status indicator on the digitizer constantly lights up in green.
2. Insert the cassette containing the exposed image plate into the cassette slot [1] of the digitizer.

   CAUTION:
   Using a not supported cassette format can cause an image being lost, a need to retake the image or delayed diagnosis.

   Only insert cassettes of a supported format in the digitizer.

   Make sure to insert the cassette with the black side to the top and with the shutter opening mechanism and the locking mechanism inside the digitizer.

   Make sure that the cassette is firmly pushed to the right side of the slot [2]. Otherwise, the digitizer cannot read the image plate.



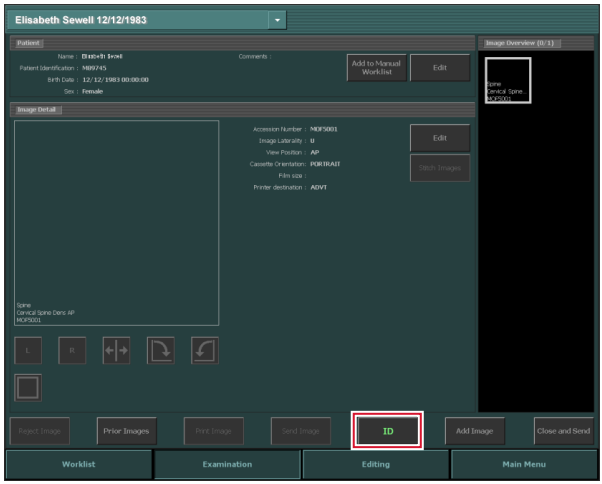
Identify and Digitize the Image

An unidentified cassette is inserted in the digitizer. The NX software must be operational, otherwise the digitizer is locked and the status indicator is flashing red.

At the NX workstation:

1. Click ID in the examination window of NX.

   In the Examination window, select the thumbnail in the Image overview pane and click on ID to send the data to the digitizer.



2. As soon as the digitizer has received the complete identification data from the NX workstation (via Ethernet) it will start digitizing the image plate.

   The digitizer converts the information of the latent image to digital data.

3. After digitizing, the digitizer:

   - Transmits the digital image data to the image processing station (‘destination’).
   - Erases the image plate and re-inserts it into the cassette.
   - Gives the cassette ID data the status 'erased'.
   - Unlocks the cassette.

Check the image

At the NX workstation:

1. Select the relevant image on which quality control is to be performed.
2. Prepare the image for diagnosis by using e.g. L/R markers or annotations.
3. If the image is OK, send the image to a hardcopy printer and/or PACS (Picture Archiving and Communication System).

Remove the cassette and insert the next one

At the digitizer:

1. When the digitizer has finished treating the cassette, the status indicator constantly lights up in green.
2. Remove the cassette from the cassette slot.

   When the digitizer unlocks the cassette, it is ready to be re-used immediately.

CAUTION:
When CR MD4.xT plates and cassettes have not been used for 48 hours, they must be erased manually. When CR MM3.xT plates and cassettes have not been used for 24 hours, they must be erased manually.

Related Links

Re-erasing an Image Plate on page 73

Basic Workflow using ID Tablet

Topics:

Select a patient and start the exam

At the NX workstation:

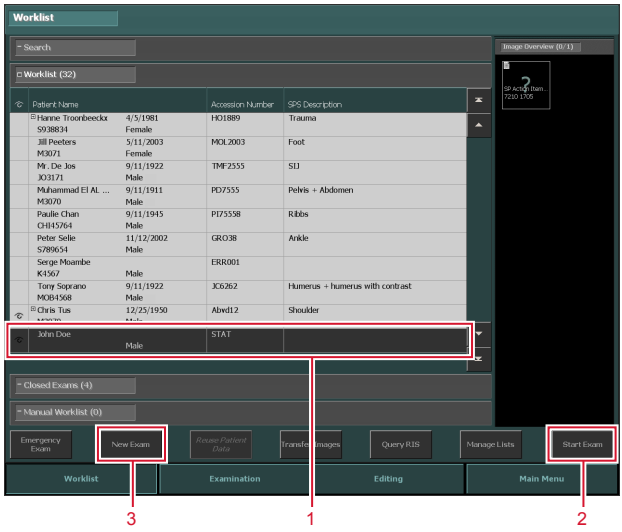
1. Open the Worklist window of NX.

   In the Worklist window, you can view and manage the exams that are scheduled via the Worklist pane.

   Note: When starting the NX software, the Worklist window is the first window that appears after the NX Splash screen.

   Note: Start the NX software on the NX workstation. Refer to the NX User Manual, document 4420.

2. In the Worklist window, open a patient from the RIS or enter patient data manually.



   To open a patient from the RIS, select an Exam from the list (1) and click on Start Exam (2).

   To enter patient data manually, click New Exam (3) and enter patient data and image data manually.

   For more information, refer to the NX User Manual, document 4420.

Identify the cassette

At the NX workstation:

1. Insert a cassette in the ID Tablet.
2. In the Examination window, select the right thumbnail in the Image Overview.
3. Click ID or press F2.

The thumbnail is labelled with the code 'ID'. The patient data is written to the cassette.

Insert the Cassette in the Digitizer

CAUTION:
Image quality may suffer if a cassette and plate is not scanned soon after exposure. The Agfa phosphor has excellent dark decay characteristics. Two hours after exposure, approximately 80% of the energy stored upon exposure is still available. The image retention is better than 50% up to 24 hours after irradiation. However, in order to preserve image quality, a cassette and plate should be scanned no later than 2 hours after exposure.

At the digitizer:

1. Check that the digitizer is ready for operation:

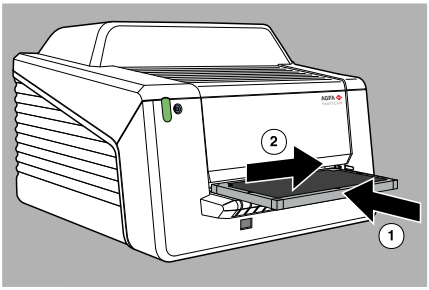
   The status indicator on the digitizer constantly lights up in green.
2. Insert the cassette containing the exposed image plate into the cassette slot [1] of the digitizer.

   CAUTION:
   Using a not supported cassette format can cause an image being lost, a need to retake the image or delayed diagnosis.

   Only insert cassettes of a supported format in the digitizer.

   Make sure to insert the cassette with the black side to the top and with the shutter opening mechanism and the locking mechanism inside the digitizer.

   Make sure that the cassette is firmly pushed to the right side of the slot [2]. Otherwise, the digitizer cannot read the image plate.



Digitize the Image

1. The digitizer will start digitizing the image plate.

   The digitizer converts the information of the latent image to digital data.
2. After digitizing, the digitizer:

   - Transmits the digital image data to the image processing station (‘destination’).
   - Erases the image plate and re-inserts it into the cassette.
   - Gives the cassette ID data the status 'erased'.
   - Unlocks the cassette.

Check the image

At the NX workstation:

1. Select the relevant image on which quality control is to be performed.
2. Prepare the image for diagnosis by using e.g. L/R markers or annotations.
3. If the image is OK, send the image to a hardcopy printer and/or PACS (Picture Archiving and Communication System).

Remove the cassette and insert the next one

At the digitizer:

1. When the digitizer has finished treating the cassette, the status indicator constantly lights up in green.
2. Remove the cassette from the cassette slot.

   When the digitizer unlocks the cassette, it is ready to be re-used immediately.

CAUTION:
When CR MD4.xT plates and cassettes have not been used for 48 hours, they must be erased manually. When CR MM3.xT plates and cassettes have not been used for 24 hours, they must be erased manually.

Related Links

Re-erasing an Image Plate on page 73

Stopping the Device

Topics:

Before Switching Off

Check that the digitizer is not scanning an image plate. If the digitizer is scanning an image plate, the status indicator is flashing green.

Switching Off

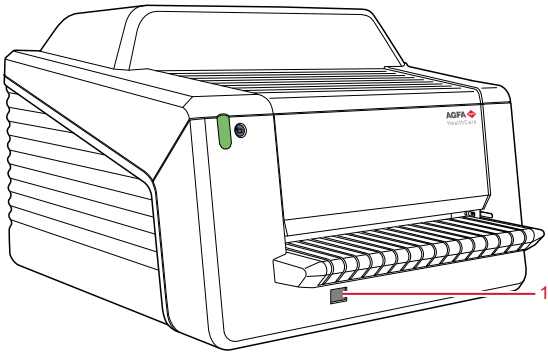
It is recommended to switch off the digitizer at the end of the day.

Note: Only switch off the digitizer if you do not intend to digitize emergency image plates overnight. Switching on the digitizer takes approximately 60 seconds. During this time emergency digitizing is not possible!

Note: After switch off, the device is still in stand-by mode. To remove the device from the mains supply disconnect the mains plug.

To stop the system:

1. Switch off the digitizer by pressing the main switch.



   1. Main switch

2. Switch off the ID Tablet.

   Only in a configuration with ID Tablet.

   For more information, refer to the document Getting Started with the ID Tablet.

3. Stop NX.

   NX can be stopped in two ways:, either by logging out of Windows or by using the Exit NX action button.

   For detailed information about stopping NX, refer to the NX User Manual, document 4420.

4. Turn off the UPS (optional accessory) to disconnect the control PC and the digitizer.

   Press and hold the Off button until the long beep ceases (approximately five seconds).

Note: Step 3 is only applicable if your system is extended with an uninterruptible power supply (UPS).

Operating CR 30-X/CR 30-Xm

This chapter provides information about functions that are available in operator mode. Finally you will find some preventive maintenance and troubleshooting guidelines.

Topics:

Reading an Emergency Image Plate

Note: *Reading an emergency image plate is a licensed functionality, necessary to facilitate the emergency cases and to improve the workflow.*

In emergency situations, it is possible to open an emergency exam at the NX workstation without patient details and to digitize the image plate without having identified the cassette.

For detailed information about the emergency license, refer to the NX manuals.

Re-erasing an Image Plate

At the end of a normal or emergency digitizing cycle, the digitizer returns an erased image plate. However, in the following cases, you must re-erase the image plate before re-using it in order to prevent ghost images from interfering with the image of interest:

- GenRad: If the image plate has not been used for more than 48 hours.
- Mammography: If the image plate has not been used for more than 24 hours.
- If an image plate has been exposed to an exceptionally high X-ray dose. In this case, deep layers of the image plate may still retain a latent image after standard erasure. Leave the image plate to rest at least one day before re-erasing it.

Note: *To re-erase an image plate, you must push the Erase button at the front side before you insert the cassette. After that, you have 1 minute to enter a cassette. If you do not, the digitizer returns to the standby mode.*

To re-erase an image plate:

1. Check that the digitizer is ready for operation:

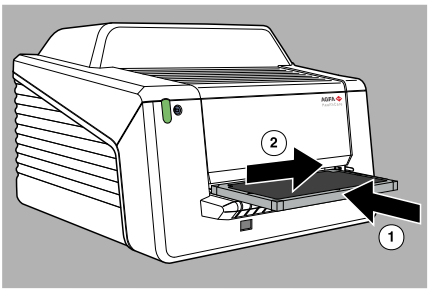
   The status indicator is continuously lighting up in green.
2. Press the erase button at the front side.

   The upper part of the status indicator is continuously lighting up in blue.

   The lower part of the status indicator is continuously lighting up in green.
3. Insert the cassette containing the image plate into the cassette slot [1] as shown below.

   Make sure to insert the cassette with the black side to the top and with the shutter opening mechanism and the locking mechanism inside the digitizer.

   Make sure that the cassette is firmly pushed up to the right side of the slot [2]. Otherwise, the digitizer cannot read the image plate.



As a result, the digitizer starts erasing the image plate:

- The upper part of the status indicator is continuously lighting up in blue.
- The lower part of the status indicator is flashing green.

When the digitizer has finished erasing the cassette, the upper part of the status indicator is not lit and the lower part is constantly lit in green.

4. Remove the cassette from the cassette slot.
5. To erase a second cassette, the erase mode has to be accessed again.

Reading the Initialization Data of an Image Plate

The initialization data stored in the RF-tag of the tray can be read by means of an RFID reader and transmitted to the NX workstation.

Reading the initialization data of an image plate can be necessary in the following cases:

- to find a specific cassette,
- to check if the IP sensitivity code (printed on the rear side of the IP) is corresponding with the initialized data on the chip,
- to check if the correct IP was inserted after cleaning (in case of doubt),
- to check the cycle counter of the cassette,

Topics:

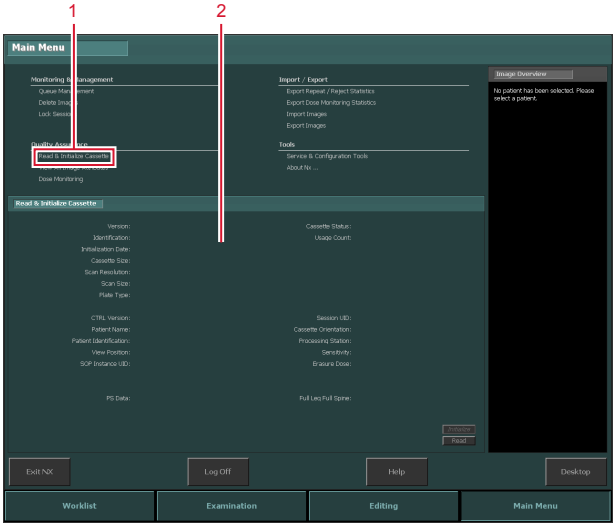
Reading the Initialization Data in a Configuration with Fast ID

1. Check that the system is ready for operation:

   The status indicator on the digitizer constantly lights up in green.

2. Click on **Read and Initialize Cassette** (1) in the Functionality Overview pane of the Main Menu window of the NX station.

   The Read and Initialize Cassette pane (2) is opened in the middle section of the Main Menu window:



   For more information, refer to the NX Key User Manual, document 4421.

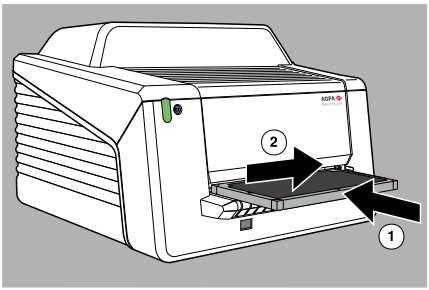
3. Click on the Read button at the NX workstation.

   The digitizer waits for the cassette and the status indicator constantly lights up in green.

4. Insert the cassette containing the image plate into the cassette slot [1] of the digitizer as shown below.

   Make sure to insert the cassette with the black side to the top and with the shutter opening mechanism and the locking mechanism inside the digitizer.

   Make sure that the cassette is firmly pushed up to the right side of the slot [2]. Otherwise, the digitizer can not read the image plate.



Once the cassette is locked, the status indicator on the digitizer is flashing green.

The digitizer starts reading the initialization data.

5. When the digitizer has finished reading the initialization data, the cassette is unlocked.

   Once the cassette is unlocked, the status indicator constantly lights up in green.

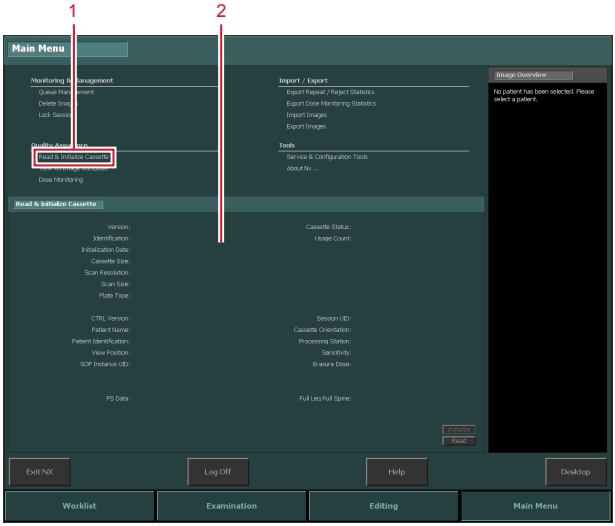
6. Remove the cassette from the cassette slot.

Note: *You can only remove the cassette from the cassette slot when the cassette is unlocked.*

Reading the Initialization Data in a Configuration with ID Tablet

1. Click on **Read and Initialize Cassette** (1) in the Functionality Overview pane of the Main Menu window of the NX station.

   The Read and Initialize Cassette pane (2) is opened in the middle section of the Main Menu window:



   For more information, refer to the NX Key User Manual, document 4421.

2. Insert a cassette in the ID Tablet.
3. Click on the Read button at the NX workstation.

Troubleshooting

Topics:

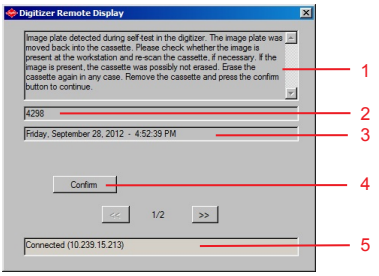
Digitizer Remote Display

Digitizer Remote Display is an application running on the NX PC.

To verify if Digitizer Remote Display is running, check if the Digitizer Remote Display icon is present in the Windows taskbar:

To start the Digitizer Remote Display, go to the Windows Start menu > **Startup** and click **DigitizerRemoteDisplay**.

The Digitizer Remote Display dialog contains information about the status of the digitizer.



1. Error message
2. Error code
3. Date and time of error
4. Confirm button
5. Connection status and IP address

Digitizer Remote Display in a configuration with ID Tablet

If two workstations serve a shared digitizer, the Digitizer Remote Display is available on only one of the workstations. In order to view the messages or to perform an action required by an error condition, this workstation must be started.

Troubleshooting Checklist

The troubleshooting for a malfunction of the digitizer consists of two parts:

- The first is always to check the status indicator on the digitizer.
- Other errors need more detailed information and instructions to repair the malfunction, or they can only be fixed by a Service engineer. In this case, consult the Digitizer Remote Display messages on the control PC.

Related Links

Status Indicator on page 51

Topics:

General Errors

Error	Action
The digitizer does not start up.	Check the power supply. If the power supply is ok, call your local Service engineer.

Connection Problems

CAUTION:
Operation failure of the device can cause delayed diagnosis.

Check if Digitizer Remote Display is running.

In case the status indicator of the digitizer is blinking red, the user should look at the “status” of the Digitizer Remote Display to decide whether digitizer internal problems or connection problems occurred.

If an error message is displayed on the NX PC, the user is informed which actions to perform to solve the problem.

In case no error message is displayed on the screen, a connection problem occurred.

Condition	Message at Digitizer Remote Display	Status indicator	Action
Connection problem between digitizer	No error message on NX PC.	Red blinking fast	Check if Digitizer Remote Display is running.

Condition	Message at Digitizer Remote Display	Status indicator	Action
and the Digitizer Remote Display.			Start/restart Digitizer Remote Display.
Connection problem between digitizer and NX PC.		Red blinking - 3 pulses	Check the Ethernet cables. If the error remains, restart PC and digitizer or call service.

Errors During Operation

If errors occur during operation, you can consult the Digitizer Remote Display messages on the control PC. The Digitizer Remote Display is independent from the NX Software.

Condition	Control PC message	Status indicator	Action
Cassette error			
Empty cassette (no image plate in cassette)	"Empty cassette found at start-up. Remove cassette."	Red, flashing	Remove the cassette
Empty cassette (no image plate in cassette) or image plate jam.	"Open digitizer to check for image plate jam or check for an empty cassette and restart the digitizer."	Red, constant	Switch off the digitizer and open the front cover. If there is no image plate visible in the transport unit close and switch on the digitizer. After restart remove the cassette from the digitizer and check if there is an image plate inside the cassette. In case of an image plate jam remove the plate from the transport unit manually and close the digitizer. Switch on the digitizer. After restart remove the cassette and

Condition	Control PC message	Status indicator	Action
			put the image plate back into the cassette.
Errors concerning Identification			
Error during read-out of the ID data	“Error during read-out of cassette chip data. Remove cassette.”	Red, flashing. After unlocking: green, constant	Confirm the message with the OK button and re-identify the cassette.
Error during writing on RF-tag after scanning process	“Error during writing on cassette chip after successful scan. Erase the image plate again.”	Red, flashing. After unlocking: green, constant	Confirm the message with the OK button on PC, remove the cassette, push the erase button on the digitizer and re-enter the cassette for a manual erase cycle.
Digitizer errors			
Erasure lamp failed during scanning cycle	“Failure at erasure module. Please restart digitizer. If error remains, please contact service. Image plate must be erased after repair again.”	Red, constant	Restart the digitizer or call service.
Image plate detected in the digitizer during self-test	“Image plate during self-test in the digitizer detected. The image plate was moved back into the cassette. Please check whether the image is present at the PC and re-scan the cassette, if necessary. If the image is present, the cassette was not erased possibly. Erase the cassette again in any case.”	Red, flashing. After unlocking: green, constant	After power failure a remaining image plate, in the digitizer, will be detected and the forementioned error message will be displayed. In order to release the cassette, confirm the message.

Condition	Control PC message	Status indicator	Action
Digitizer cannot detect the cassette chip on the image plate tray e.g. tray is missing or was not inserted correctly.	"Cassette chip not readable or cassette tray is missing. Remove cassette."	Red, flashing After unlocking: green, constant	Open the cassette and check if the tray is inserted correctly or use another cassette and call service.
Communication error, Ethernet cable is not plugged in	"Image transmission failed. System is retrying. If image does not appear, please restart the PC."	Red, flashing	Check if Ethernet cable is plugged in at PC and digitizer. Visually check if the Ethernet cable is damaged. If the error remains restart PC and digitizer or call service.
Time-out after 5 minutes if the ID button of the image processing software was not pressed.	"ID button not pressed within the timeout period. Image plate was not scanned. Cassette stays clamped until ID data are supplied by the operator."	After ID button has been pressed: green, flashing	Confirm the message on the PC and press the ID button of the image processing software.

Messages will stay active until the problem is solved or the dialog box message on the control PC is confirmed by clicking the confirm button.

Note: For error messages not listed in the table above, please refer to the instructions within the displayed error message text.

Removing a Jammed Image Plate

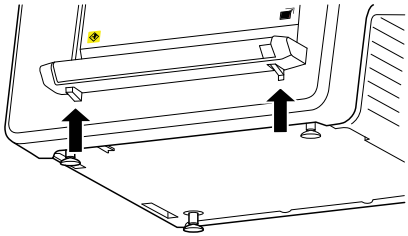
The user is allowed to open the front cover, e.g. to solve image plate jams at the front side. When opening the front panel, all motor driven system movements will be stopped (including the laser).

Note: *The technical concept does not allow the user to remove the top cover. The concept provides maximum reliability that no image plate jam can occur in the post scan area.*

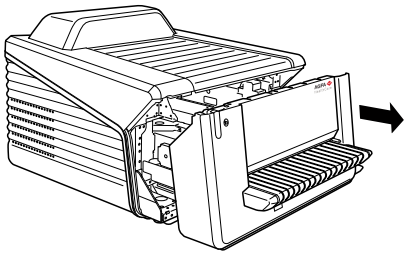
Note: *The digitizer always reads and digitizes the plate first, then erases it and transports it back into the cassette. If a plate jam occurs before the plate is scanned, there is a fair chance that you can recover the image by putting the image plate back into the cassette and digitizing it again. While handling the image plate, prevent exposing it to daylight as much as possible.*

To open the front cover:

1. Simultaneously press the two buttons positioned underneath the feed table.



2. Slide out the front cover.



3. Remove the jammed image plate.

Note: Never use force to clear the jammed image plate. If it is not possible to gently remove the image plate, call your local service organization.

Note: After a jam, the image plate can be used again if not damaged.

4. Close the front cover.

Behavior in Case of Power Failure

Note: *The description below is only applicable if an uninterruptible power supply (UPS) is put into the CR 30-X/CR 30-Xm System configuration.*

In case of a power failure, the system is still connected to the UPS. Two situations are possible:

- Power failure after cassette insertion and before identification with the NX workstation. The digitizer pushes the image plate back in the cassette without scanning and releases the cassette. After the power supply returns, the cassette must be inserted into the digitizer and identified again to read out the image.
- Power failure after identification with the NX workstation. The image plate is scanned and erased as usual. The scan cycle finishes when the cassette is released. If the power supply is still not available, the digitizer will refuse scanning other cassettes.

Technical Data

Topics:

Specifications

Labelling	
CE	93/42 EEC 'Medical Devices' (Europe), EN 60601-1
c ETL us	ETL us certified, UL 60601-1 Second Edition (North America), AAMI ES 60601-1
c ETL us	c ETL certified, CSA C 22.2 No 601.1, CSA C 22.2 No.60601-1
Dimensions	
Length	786 mm
Width	693 mm
Height	525 mm
Weight	
Unpacked	approximately 72 kg (158.73 lb)
Electrical connection	
Operating voltage	Autoranging power supply from: 100 V to 240 V, ac ± 10% Class I with protection earth Connect to earthed supply circuitry only.
Mains frequency	50-60 Hz
Current rating	1A 2A
Mains fuse protection	Europe: min. 10 A, max. 16 A USA & Japan: min. 10 A, max. 15 A
Operating current	2 A (100-120 V), 1 A (220-240 V)
Network connectivity	
Ethernet connector	RJ45 female, 10/100 Mbit/s autosensing, shielding CAT5
Power consumption	

Standby	
• 220 V - 240 V / 50-60 Hz configuration	60 W
• 100 V - 120 V / 50-60 Hz configuration	60 W
During operation	
• 220 V - 240 V / 50-60 Hz configuration	CR 30-X: max. 190 W CR 30-Xm: max. 220 W
• 100 V - 120 V / 50-60 Hz configuration	CR 30-X: max. 190 W CR 30-Xm: max. 220 W
Uninterruptible power supply (optional)	
UPS Powerware 5115	120 V ABC ordering code: EGPSE
UPS Powerware 5115	230 V ABC ordering code: EGPTG
Environmental conditions	
Room temperature	recommended: 20 °C to 25 °C allowed: 15 °C to 30 °C
Maximum temperature change	0.5 °C/min.
Relative humidity	recommended: 30 % to 60 % allowed: 15 % to 75 % (non-condensing)
Magnetic field	compliant with EN 61000-4-8, Level 2
Sunlight exposure	not to be operated in direct sunlight, max. 2500 lux
Barometric pressure during operation	70 kPa to 106 kPa
Related altitude on site	3000 m to 0 m
Environmental conditions (during storage)	
In line with IEC721-3-1: 1K2 (CR 30-X) / 1K4 (CR 30-Xm) and 1M2	

Temperature	-25 °C to +55 °C
Environmental conditions (during transport)	
In line with IEC721-3-2: 2K2 and 2M2 with following restrictions:	
Temperature	-25 °C to +60 °C
Vibration	5-200 Hz (vertical, longitudinal, transversal axis)
Environmental conditions for mobile installation (during transport)	
In line with IEC721-3-5: 5K2 and 5M2 with following restrictions:	
Vibration	5-150 Hz (all axis), 1m/s², sinusoidal vibration
Environmental conditions for mobile installation (during operation)	
In line with IEC721-3-3: 3K2 and 3M1 with following restrictions:	
Temperature	+15 °C to +30 °C
Relative Humidity	15% to 75% (non-condensing)
Vibration	40-200 Hz; 1m/s²; sinusoidal vibration
Warming-up time	
Cold start	fully operational after max. 30 min.
Warm start	fully operational after self-test, on condition that the digitizer: • has not been switched off for more than 3 minutes. • has been operational for at least 30 minutes.
Throughput	
CR MD4.0T 35 x 43 cm	60 plates/hour
CR MD4.0T 35 x 35 cm	60 plates/hour
CR MD4.0T 24 x 30 cm	71 plates/hour
CR MD4.0T 18 x 24 cm	76 plates/hour
CR MD4.0T 15 x 30 cm	82 plates/hour
CR MM3.0T 24 x 30 cm	32 plates/hour
CR MM3.0T 18 x 24 cm	38 plates/hour

Physical emissions	
Noise emission (sound power level according to ISO 7779)	
• During scanning	max. 65 dB(A)
• Standby	max. 55 dB(A)
Heat emission	
• Standby	60 W ≈ 204 BTU/h[1]
• Average power consumption during scanning	CR 30-X: 85 W ≈ 290 BTU/h[1] CR 30-Xm: 103 W ≈ 351 BTU/h[1]
• Peak power consumption during scanning	CR 30-X: 190 W ≈ 648 BTU/h[1] CR 30Xm: 220 W ≈ 751 BTU/h[1]
RFID reader	
Frequency	13.56 MHz
Bandwidth	14 kHz
Maximum power	290 pW
Protocol	MIFARE
End of Life	
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	7 yrs.
Preventive maintenance	
Preventive maintenance frequency. **Note:** Needs to be done by an Agfa certified field service engineer.	Once a year or 12000 cycles, whatever comes first.

Pixel matrix size

Cassette type	Format (cm)	Resolution (pixel/mm)	Width x Length (pixels)	Width x Length (mm)
CR MD4.0T General	35x43	10	3480 x 4248	348,0 x 424,8
CR MD4.0T General	35x35	10	3480 x 3480	348,0 x 348,0
CR MD4.0T General	24x30	10	2328 x 2928	232,8 x 292,8
CR MD4.0T General	18x24	10	1728 x 2328	172,8 x 232,8
CR MD4.0T General	15x30	10	1440 x 2928	144,0 x 292,8
CR MD4.0T Genrad + FLFS	35x43	10	3480 x 4406	348,0 x 440,6
CR MM3.0T Mammo	24x30	20	4710 x 5844	235,5 x 292,2
CR MM3.0T Mammo	18x24	20	3510 x 4644	175,5 x 232,2
CR MM3.0T Extremities	24x30	20	4656 x 5856	232,8 x 292,8
CR MM3.0T Extremities	18x24	20	3456 x 4656	172,8 x 232,8

Remarks for HF-emission and immunity

It is hereby certified that the digitizer has interference suppression according to the EN 55011 Class A as well as the FCC Rules CR47 Part 15 Class A.

This device was tested for a normal hospital environment as described above.

The user of the device should ensure that it is used in such an environment.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

WARNING:
This device is intended for use by healthcare professionals only. This device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.

WARNING:
The HF-emission and immunity can be influenced by connected data cables depending on length and the manner of installation.

This device is intended for operation in the electromagnetic environment given below. The user of the device should ensure that it is used in such an environment.

RF Emission Measurements	Agree-ment	Electromagnetic Environment Guidelines
High frequency RF emissions in accordance with CISPR 11	Group 1	The device uses high frequency energy exclu-sively for its internal functions. For this reason, its high frequency RF emission is very low and it is improbable that neighboring electronic equipment will be disrupted.
High frequency RF emissions in accordance with CISPR 11	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment

Harmonic emission in accordance with IEC 61000-3-2	Class A	might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Voltage fluctuations / flickering in accordance with IEC 61000-3-3	Fulfilled	

The device is used in a professional healthcare / radiological environment as well as mobile environment, like a bus or a truck. Environmental conditions are stated in the user manual.

This device was tested for a professional healthcare environment as described above. Nevertheless the HF-emission and immunity can be influenced by connected data cables depending on length and the manner of installation.

Resistance to Jamming Test	**Test level of professional medical equipment and basic EMC standards**	**Electromagnetic Environment Guidelines**
Discharge of static electricity in accordance with IEC 61000-4-2	± 8 kV contact discharge ± 2, 4, 8, 15 kV air discharge	Floors should consist of wood, concrete or ceramic tiles. The relative humidity must be at least 30%, if the floor is made of synthetic material.
Fast transient electrical disturbance variables / bursts in accordance with IEC 61000-4-4	± 2 kV mains ± 1 kV data lines	The quality of the voltage supplied should correspond to a typical commercial or clinical environment.
Impulse voltages (surges) in accordance with IEC 61000-4-5	± 1 kV line-line voltage ± 2 kV line-ground voltage	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage breakdown, short term interruptions and variations in the voltage supplied in accordance with IEC 61000-4-11	• 0% U_r for ½ period • 0% U_r for 1 period • 70% U_r (30% breakdown of U_r) for 25 periods at 0°	The quality of the voltage supply should correspond to that of a typical commercial or clinical environment. If the user wants the device to work continuously, even when the energy supply is

	• 0% U_r for 250 periods	interrupted, it is recommended to use an energy supply free of interruptions or a battery.
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m	Magnetic field at the network frequency should correspond to the typical values as they are in a commercial and clinical environment.
REMARK : U_r is the alternating current in the network before the application of the test level.		

This device is intended for operation in the electromagnetic environment given below. The user of the device should ensure that it is used in such an environment.

Tests of Resistance to Disruption	**Test level of professional medical equipment and basic EMC standards**	**Electromagnetic Environment** Recommended protective distance:
Conducted high frequency disturbance variables in accordance with IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V within ISM bands	
Radiated high frequency disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	
RF communication	Refer to the section "Immunity to RF wireless communication equipment"	
		Disruptions are possible near devices that carry the following symbol: 

The field strength of stationary transmitters, such as base stations of radio telephones, mobile broadcasts for rural areas, amateur stations, and AM and

FM radio transmitters, cannot be precisely predetermined theoretically. An investigation of the location is recommended, to ascertain the electromagnetic environment as a result of stationary high frequency transmitters. If the field strength of the device exceeds the test level given above, the device must be observed with regard to its normal operation at each place of use. In case of unusual performance characteristics, it can be necessary to take additional measures, such as the re-orientation of the device, for example.

This device is intended for operation in an electromagnetic environment in which the radiated high frequency disturbance variables are monitored. The user of the device can help to prevent electromagnetic disruptions by maintaining the minimum distances between portable and mobile high frequency communication equipment (transmitters) and the device as recommended below, in accordance with the maximum output power of the communications equipment. See also the section with precautions on EMC.

Recommended Protective Distances between Portable and Mobile High Frequency Communication Equipment and the Device

Rated Power of the Transmitter W	Protective Distance in accordance with RF emission Frequency m		
	150 kHz to 80 MHz $d = 1.0\sqrt{P}$	80 MHz to 800 MHz $d = 0.3\sqrt{P}$	800 MHz to 2.7 GHz $d = 0.3\sqrt{P}$
0.01	0.1	0.05	0.05
0.1	0.32	0.1	0.1
1	1.0	0.3	0.3
10	3.2	1.0	1.0

The distance can be determined through the equation for each respective column.

P is the rated power of the transmitter in watts (W) according to the manufacturer information on the transmitter, only for transmitters where the rated power is not mentioned in the above table.

REMARK : These Guidelines may not be relevant in all situations. The dispersion of electromagnetic waves is influenced by absorption and reflections from buildings, objects and people.

Topics:

- *Immunity to RF wireless communication equipment*

- *Precautions on EMC*
- *Cables, transducers and accessories*
- *Maintenance on EMC relevant parts*

Immunity to RF wireless communication equipment

ISM Band (MHz)	Service	Distance (m)	Immunity test level (V/m)
300-390	TETRA 400	0.3	27
430-470	GMRS 460; FRS 460	0.3	28
704-787	LTE Band 13, 17	0.3	9
800-960	GSM 800/900; TETRA 800, IDEN 820; COMA 850; LTE Band 5	0.3	28
1700-1990	GSM 1800; COMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	0.3	28
2400-2570	Bluetooth; WLAN; 802.11 b/g/n; RFID 2450; LTE Band 7	0.3	28
5100-5800	WLAN 802.11 a/n	0.3	9

Precautions on EMC

WARNING:
The system should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

CAUTION:
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Cables, transducers and accessories

Cables, transducers and accessories which were tested and found to comply with the collateral standard IEC60601-1-2 (EMC):

CAUTION:
Using cables and accessories not mentioned in this manual or spare parts not ordered from Agfa, may cause a higher emission of electromagnetic phenomena and/or may rise the susceptibility against it.

function	**type;** **maximum length**	**remark**
network connection	Network cable CAT5e F/UTP (shielded end) with RJ45; 10 m (or original Agfa cable F7.0477.1052; 5m)	shielded

No additional accessories available.

Maintenance on EMC relevant parts

Concerning the EMC safety of the CR 30-Xm device, no relevant parts could be inspected by the operator or by a service engineer before the end of the digitizer lifetime.