

CR 10-X

(type 5151/100)

User Manual





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Remarks for HF-emission and immunity 62

Introduction

This chapter covers the following topics:

- [Introduction to this Manual](#)
- [Introduction to CR 10-X](#)

Introduction to this Manual

This section covers the following topics:

- Scope
- Warnings, Cautions, Instructions and Notes
- Disclaimer

Scope

This manual contains information for safe and effective operation of the CR 10-X™ digitizer, further referred to as the digitizer.

Warnings, Cautions, Instructions and Notes

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



WARNING: Warnings are directions which, if they are not followed, can cause fatal or serious injuries to a user, engineer, patient or any other person or can lead to a mistreatment.

The purpose of safety icons is to indicate at a glance the type of caution, warning or danger.





Caution: Cautions are directions which, if they are not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.



Instruction: This sign is used typically in combination with the warning sign when providing a specific instruction, which if followed exactly, should avoid the subject of the warning.



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

Disclaimer

Agfa assumes no liability for use of this document if any unauthorized changes have been made to the content or format.

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 stipulates that medical devices should only be sold to, distributed and used by or by order of a licensed physician.

Introduction to CR 10-X

This section covers the following topics:

- [Intended Use](#)
- [Intended User](#)
- [Configuration](#)
- [Operation Controls](#)
- [System Documentation](#)
- [Training](#)
- [Product Complaints](#)
- [Compatibility](#)
- [Compliance](#)
- [Connectivity](#)
- [Installation](#)
- [Labels](#)
- [Cleaning and Disinfection](#)
- [Patient data security](#)
- [Maintenance](#)
- [Environmental Protection](#)
- [Safety Directions](#)
- [Quality Control](#)

Intended Use

The digitizer is part of a CR system, further containing a cassette, image plate and modality workstation. The CR system is used in a radiological environment by qualified staff to read-out, process and route static X-ray radiographic images.

The cassette is used to protect the image plate from light and damages during X-ray exposure, transport and handling.

The image plate is used to capture the static X-ray radiographic images; the image plate is scanned by the digitizer.

The digitizer is used to scan an X-ray exposed image plate; it results into a digital image which is sent to the dedicated workstation.

The modality workstation is used to process and route the digital images from the digitizer.

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.

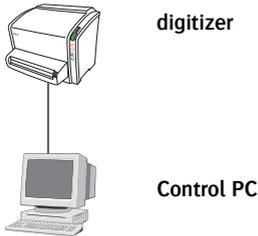
Configuration

The system consists of:

- the CR 10-X digitizer for image plates retaining latent X-ray images. The digitizer accepts one cassette containing one image plate at a time.
- cassette and plate system: CR MD1.0 General.

The digitizer can be used in combination with:

- the NX workstation, a CR workstation for image acquisition, identification, image processing and image transmission of digitized images received from the digitizer.
- UPS (optional): the 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.



Dedicated configuration

To install the UPS into the system:

- 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, NX workstation and monitor into the appropriate UPS output receptacles.

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

Full Leg Full Spine Application Components

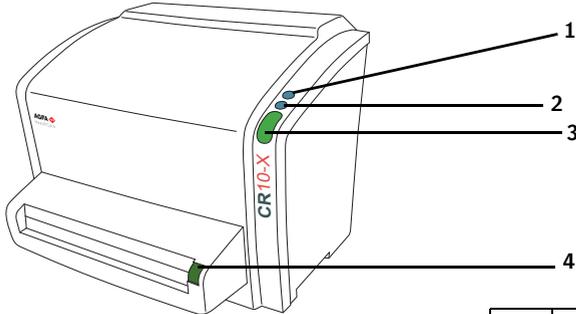
- CR Full Body Cassette Holder
- Anti-scatter grid (optional)
- CR EasyLift™ (optional)

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

Operation Controls

The digitizer interfaces with the user via:

- a power button,
- an erase button,
- a status indicator,
- a cassette release button.



1	Power button
2	Erase button
3	Status indicator
4	Cassette release button

The Erase Button

Press the erase button  to start the erasing cycle of an image plate. After pressing the erase button, 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.

For more information, refer to *'Re-erasing an Image Plate'* on page 41.

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.

Color	Constant/ Blinking	Status	Action
Blue	Constant	Activating the erasing cycle	Insert cassette to erase the image plate.
Green	Constant	<ul style="list-style-type: none"> Standby mode (Ready) Cassette is ready for removal 	<ul style="list-style-type: none"> Proceed. Remove cassette.
	Blinking	Busy with scanning, erasing and return of the IP into cassette	Wait.
Red	Constant	Error	Consult the Error Viewer UI (User Interface) messages on the control PC. Refer to section <i>'Troubleshooting'</i> .
	Blinking slowly	Digitizer not ready	
	Blinking fast	Digitizer not connected to Error Viewer UI	Refer to section <i>'Troubleshooting'</i> .
	Blinking - 3 pulses	Digitizer not connected to control PC	

System Documentation

The documentation shall be kept with the system for easy reference. Technical documentation is available in the product service documentation which is available from your local support organization.

The user documentation consists of:

- CR 10-X User Documentation CD (digital media).
- NX User Documentation CD (digital media).
- Getting Started material.

The CR 10-X User Documentation contains:

- CR 10-X User Manual (this document), document 2491.
- AGFA CR Plates and Cassettes (CR MD1.0 General) User Manual, document 2492.
- CR Full Leg Full Spine User Manual, document 4408 (available on NX User Documentation CD).

The Getting Started material contains:

- Getting Started with NX, document 4417.
- Getting started with CR 10-X, document 2493.

Training

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

The user must note the following information in the preliminary section of this manual:

- [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 in 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 of a patient, Agfa must be notified immediately by telephone, fax or written correspondence to the following address:

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

Agfa HealthCare N.V. - Septestraat 27 - 2640 Mortsel, Belgium.
Agfa HealthCare N.V. - Fax +32 3 444 7094.

Compatibility

The digitizer 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 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult your local service organization.

Compliance

The digitizer 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 MDD (European Council Directive 93/42/EEC on Medical Devices).

The digitizer has been designed in accordance with the IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety.

The digitizer complies with the safety regulations for:

Quality Management

- ISO 13485:2003 + Cor. 1: 2009 Medical devices - Quality management systems - requirements for regulatory purposes
- IEC 62366 Medical devices - application of usability engineering to medical devices, first edition, October 2007
- IEC 62304 Medical Software Life Cycle Processes

Medical Electrical Equipment

- IEC 60601-1: second edition 1988-12 Medical electrical equipment, General requirements for safety, incl. amendment 1 1991-11 and amendment 2,1995-03
- IEC 601-1-1:1992/A1:1995 / EN 60601-1-1:1993/A1:1996 Medical electrical equipment - Part 1: General requirements for safety -1. Collateral standard: Safety requirements for medical electrical systems
- IEC/EN 60601-1-4:1996 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems, inclusive amendment 1:1999
- IEC 60601-1: third edition 2005-12 Medical electrical equipment, General requirements for safety
- UL60601-1:2005 Medical electrical equipment, General requirements for safety (Adopted IEC 60601-1:2005, third edition, 2005-12), Includes Corrigendum 1:2011
- CAN/CSA-C22.2 NO. 60601-1-08 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition 2005-12)

Laser Products

- IEC 60825-1: 1993 Safety of laser products Part 1: Equipment classification, requirements and user's guide + corr. February 1995 + amendment A1: 1997 + amendment A2. 2001

Electromagnetic Compatibility

- IEC 60601-1-2:2007 Medical electrical equipment -part1.2: General requirements for safety - collateral standard: electromagnetic compatibility - requirements and tests
- FCC part 15 (USA)
- CSA 22.2 No. 601.1.2 (Canada)

Waste

- WEEE 2002/96/EC, amended by Directive 2003/108/EC
- RoHS Directive 2002/95/EC

Labeling

- EN 980:2008 Symbols for use in the labeling of medical devices
- EN 1041:1998, Information supplied by the manufacturer with medical devices



Note: The CR 10-X is in compliance with the EG regulation 93/42/EEC Directive (Medical Device).

Radio Interference Suppression

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.



WARNING: 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.

Connectivity

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

Installation

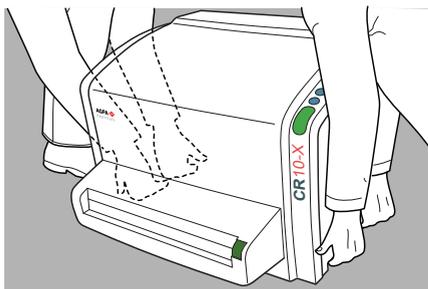


Caution: When installing the digitizer, care must be taken to ensure that there is either a mains plug or an all-cable disconnecting device in the internal installation fitted near the digitizer and that it is easily accessible.

The digitizer is equipped with handles at the bottom left and right sides to move the device easily to another location.

For two persons to lift the digitizer, each should stand at the side of the digitizer and hold it by the handle with both hands.

For one person to lift the digitizer, remove the cassette unit to reduce the weight, stand in front of the digitizer and hold it by the handles.



Caution: Do not lift the device by holding the cassette unit or by holding the back cover.



Caution: 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.

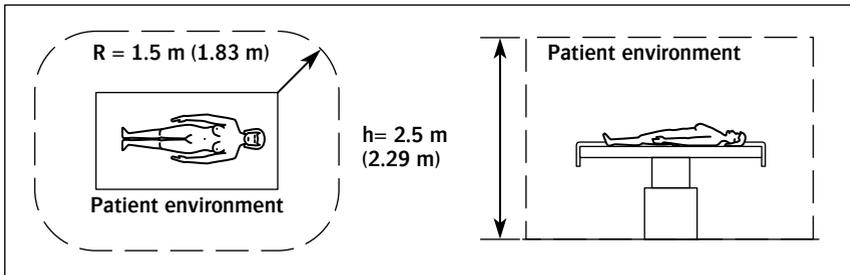


Caution: If the digitizer is installed inside an X-ray room it must be protected from stray radiation by proper shielding.



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. Do not use excessive force when inserting cassettes in the digitizer as the device may slip or drop off the table. Use a non-slip-mat below the digitizer or other anti-skid measures. The table should not be subject to excessive shock and vibrations from other sources, as this may disturb the operation of the digitizer.

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).



Labels

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.

	<p>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:</p> <ul style="list-style-type: none"> • Use of the accessory equipment in the patient vicinity, • Evidence that the safety certification of the accessory equipment has been performed in accordance with the appropriate IEC 601-1 and IEC 601-1-1 harmonized national standard. <p>In addition all configurations must comply with the medical electrical systems standard IEC 601-1-1. 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.</p>
	<p>In order to reduce the risk of electric shock, do not remove any covers.</p>
	<p>Caution hot: Keep hands clear from the erasure unit.</p>
	<p>Power button</p>

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 divergence is 120 - 350 mrad. The laser beam's deflection frequency is 70 1/s up to 90 1/s.

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 cassette unit and the back cover can be removed e.g. to solve cassette or image plate jams. The digitizer must be switched off before removing the cassette unit or opening the back of the device.



WARNING: 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 comes 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.
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.

Patient data security

It is the responsibility of the hospital to ensure how the patients' legal requirements are to be met, how the security of the patient records are:

- maintained and tested,
- audited,
- administered locally to cover risks from third party access,
- how the availability of the services is to be maintained in the event of disaster.

It is the responsibility of the hospital to ensure how types of access are identified, classified and reasons for access are justified.

Maintenance

Preventive Maintenance

No regular preventive maintenance is required other than described further in this chapter.

Cleaning and Disinfection

Refer to section '[Cleaning and Disinfection](#)' on page 24.

Environmental Protection

WEEE end user information

On August 13, 2005, the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, amended by Directive 2003/108/EC came into force.



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. This directive has to be implemented into national law by the individual European countries by August 13, 2005.

Due to the implementation into national law, specific requirements can be different within the European Member States.

This 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 Agfa service organization and/or Agfa 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



Li

This wheeled bin symbol on the products, and/or accompanying documents means that the used batteries should not be treated as, or mixed with general household waste.

This wheeled bin 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: The user must strictly observe all warnings, cautions, notes and safety markings within this document and on the product.

WARNING: Safety is only guaranteed when trained Agfa personnel has installed the digitizer.

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

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

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

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

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



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



Caution: 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.



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

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 force when inserting a cassette into the digitizer.
- Do not push the release button during scanning (status indicator is blinking green) or during erasure (status indicator blue).
- Do not insert a cassette when the digitizer is switched off.
- 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.
- Do not allow the digitizer to be subject to excessive vibration during operation, due to unstable ground (e.g. vibration of nearby equipment or footsteps).
- 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 do not operate the digitizer correctly or if you do not 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.
- 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.
- Do not transport the digitizer without packaging or without mounting it in a mobile kit.

Quality Control

Apply regular quality control according local regulations.

Getting Started with the CR 10-X

This chapter explains how to perform the first basic actions on the digitizer.

This chapter covers the following topics:

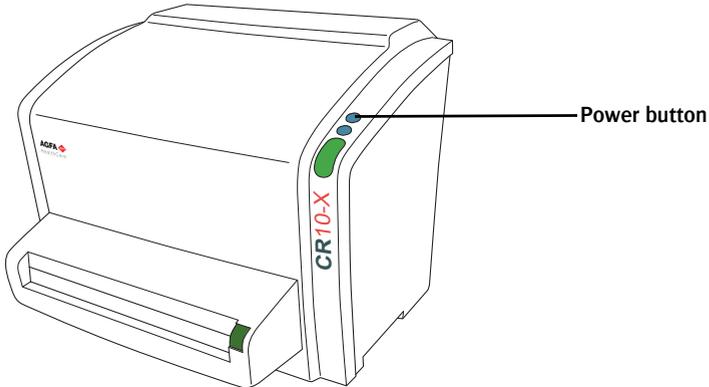
- [Starting the Digitizer](#)
- [Basic Workflow](#)
- [Stopping the Device](#)

Starting the Digitizer

- 1 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.

- 2 Press the power button.



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 3 minutes, the digitizer status indicator is blinking 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.

Basic Workflow

The main functions of the system are digitizing image plates and transmitting the digital image data to the image processing station, where you can perform an image quality control.

The workflow consists of the following successive steps:

- **Step 1: Select a patient and start the exam.**
- **Step 2: Digitize the image.**
- **Step 3: Perform a quality control.**
- **Step 4: Remove the cassette and insert the next one.**

Step 1: 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.

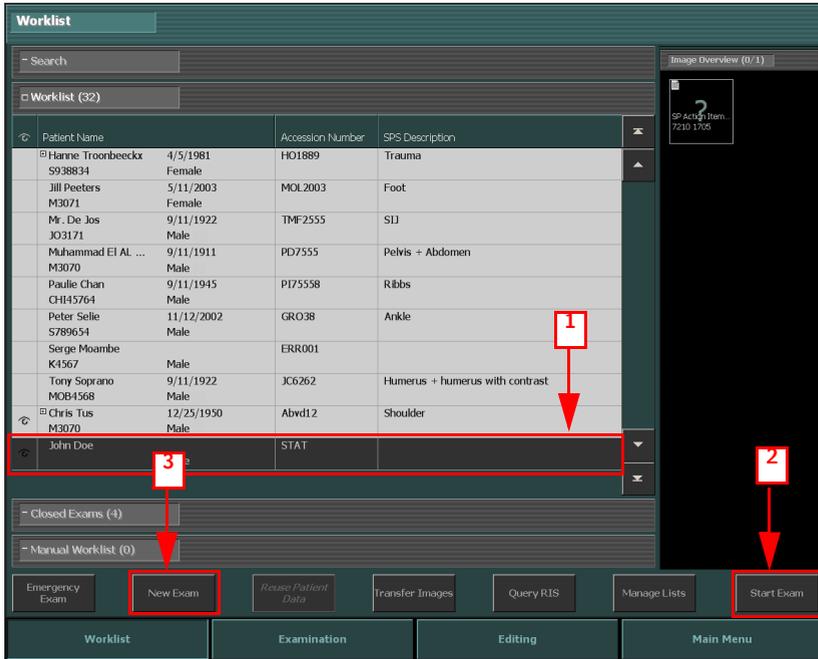


Note: When starting the NX software, the Worklist window is the first window that appears after the NX splash screen.



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

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



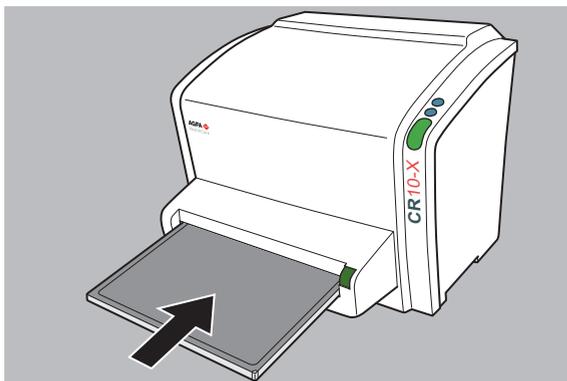
- To open a patient from the RIS, select an Exam from the list (1) and click on Start Exam (2).
- To enter patient data manually, click New Exam (3) and enter patient data and image data manually.

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

Step 2: Digitize the image

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 of the digitizer.
Make sure to insert the cassette with the black side (X-ray tube 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 into the slot, so that it is locked (you should hear a click). Otherwise, the digitizer cannot read the image plate.

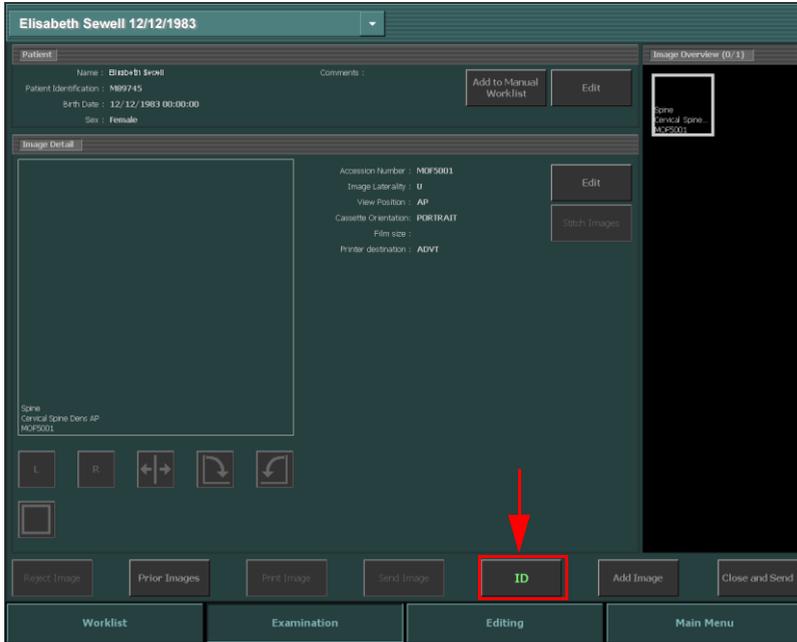


Note: The cassette is unidentified, so the digitizer will send a request to the NX station. The NX software must be operational, otherwise the digitizer is locked and the status indicator is blinking red.

The digitizer sends a request to the NX station.

At the NX workstation:

- 1 In the Examination window of NX, select the thumbnail in the Image overview pane and click ID to send the data to the digitizer.



- 2 As soon as the digitizer has received the complete identification data from the NX station (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.

Step 3: Perform a quality control

At the NX workstation:

- 1 Select the 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).

Step 4: 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 Push the Cassette release button and remove the cassette from the cassette slot.



Note: When you unlock the cassette, it is ready to be re-used immediately. However, if you leave it for more than 2 days before re-using it, you must re-erase it first. The procedure how to re-erase an image plate is described in ['Re-erasing an Image Plate'](#) on page 41.

Stopping the Device

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 blinking green.

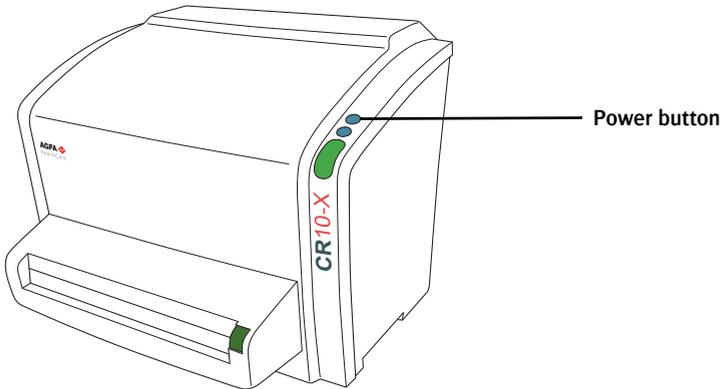
Switching Off

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 3 minutes. During this time emergency digitizing is not possible!

To switch off, press the power button.



Operating CR 10-X

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

- [Reading an Emergency Image Plate](#)
- [Re-erasing an Image Plate](#)
- [Reading the Initialization Data of an Image Plate](#)
- [Expiry of Image Plates](#)
- [Troubleshooting](#)

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:

- If the image plate has not been used for more than 48 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.

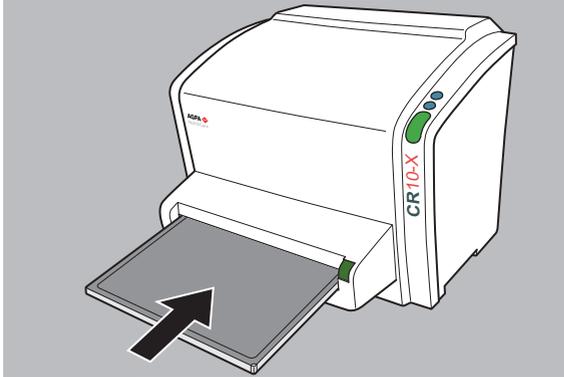
- 2 Press the erase button  at the front side.

The status indicator is continuously lighting up in blue.

- 3 Insert the cassette containing the image plate into the cassette slot 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 into the slot. Otherwise, the digitizer cannot read the image plate.



As a result, the digitizer starts erasing the image plate: the status indicator switches to the state “blue blinking”.

When the digitizer has finished erasing the cassette, the status indicator is constantly lit in green.

- 4 Push the cassette release button and 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

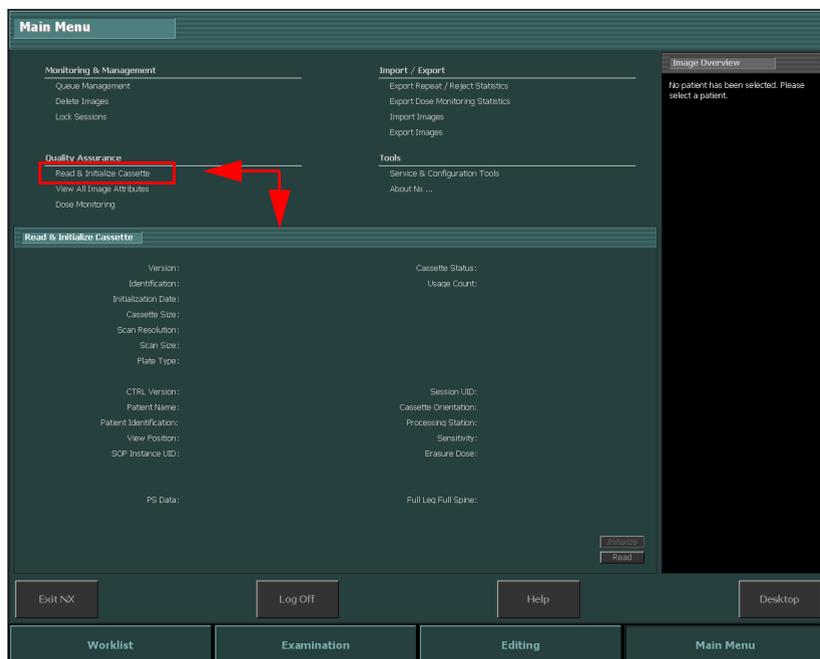
The initialization data stored in the IP barcode can be read via the digitizer.

Reading the initialization data of an image plate can be necessary in case you want to find a specific IP.

To read the initialization data:

- 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** in the Functionality Overview pane of the Main Menu window of the NX station.

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



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

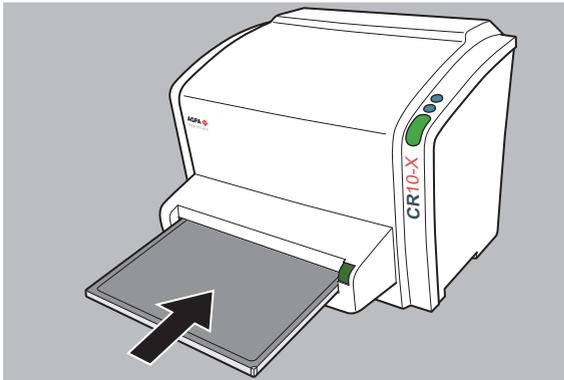
3 Click on the Read button at the NX workstation.

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 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 into the slot. Otherwise, the digitizer cannot read the image plate.



Once the cassette is locked, the status indicator on the digitizer is blinking green. The digitizer starts reading the initialization data.

5 When the digitizer has finished reading the initialization data, the status indicator constantly lights up in green and the cassette can be unlocked.

6 Push the Cassette release button and remove the cassette from the cassette slot.



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

Expiry of Image Plates

Upcoming Expiry of the Image Plate

The digitizer Error Viewer informs you about upcoming expiry of the image plate 90 and 30 days before the expiry date. Please replace the image plates before expiry to avoid reduced system performance.

Expired Image Plate

The digitizer Error Viewer informs you about reduced system performance whenever you use an expired image plate.

The expiry date is printed on the image plate.

Refer to the Agfa CR Plates and Cassettes (CR MD1.0 General) User Manual (document 2492).

Troubleshooting

In case of a malfunction of the digitizer, consult the Error Viewer UI (User Interface) messages on the control PC.

Error messages are displayed in a dialog box in the middle of the screen or in a fixed part of the screen. These messages will tell that either a problem has occurred or that a requested action cannot be performed.

The user must read these messages carefully. They will provide information on what to do from then on. This will be either performing an action to resolve the problem or to contact your local service organization.

Details on the contents of messages can be found in the service documentation which is available to Agfa service personnel.

Error Viewer

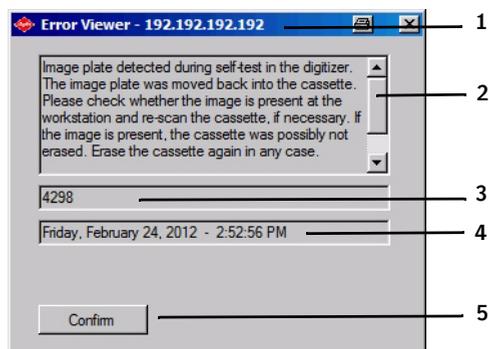
Error Viewer is an application running on the NX PC.

To verify if Error Viewer is running, check if the Error Viewer icon is present in the Windows taskbar:



To start the Error Viewer, go to the Windows Start menu > **Startup** and click **ErrorViewer**.

The Error Viewer dialog contains information about the status of the digitizer.



1	Digitizer IP address (example)
2	Scroll bar to show complete message
3	Error code
4	Date and time of error
5	Confirm button

Connection Problems

In case the status indicator of the digitizer is blinking red, the user should look at the “status” of the Error Viewer 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	Error Viewer message	Status indicator	Action
Connection problem between digitizer and the Error Viewer.	No error message on NX PC.	Red blinking fast	Check if Error Viewer is running. Start/restart Error Viewer.
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.

Cassette Could Not Be Identified

Details	<p>This error message is displayed on the NX PC:</p> 
Cause	<p>A cassette has been inserted in the digitizer and the ID button was clicked directly afterwards.</p>
Solution	<p>Wait until the digitizer has read the data on the cassette and sent it to the NX PC. This may take a few seconds. The error message will disappear.</p>

Removing a Jammed Image Plate



Note: The technical concept does not allow the user to remove the top cover.



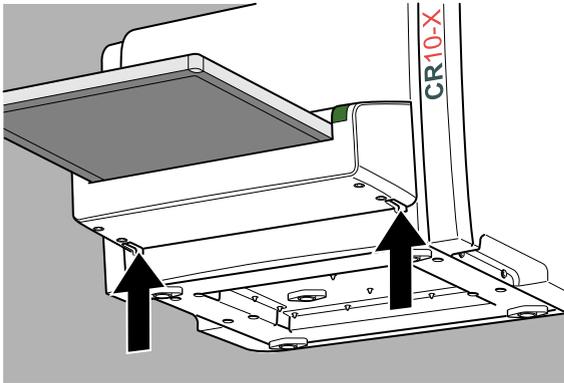
Note: The digitizer always reads and digitizes the plate first, then erases it and transports it back into the cassette. If a plate jam occurs before the plate is scanned, there is a fair chance that you can recover the image by putting the image plate back into the cassette and digitizing it again.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

To remove a jammed image plate:

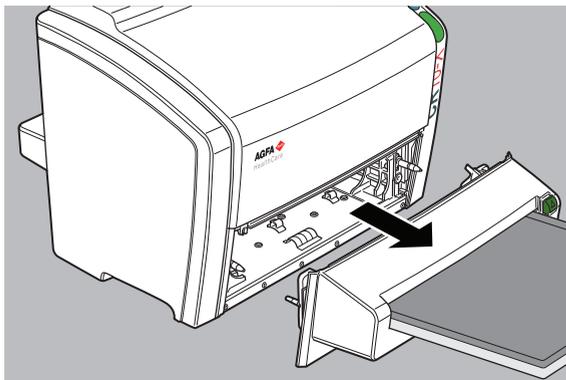


Caution: In case of an image plate jam, do not push the release button unless the status indicator constantly lights up in green. Pushing the cassette release button while the status indicator is blinking may damage the image plate.

- 1 Switch off the digitizer and switch it on again.
During startup, the digitizer tries to return the image plate into the cassette.
- 2 If the status indicator constantly lights up in green, the image plate is returned into the cassette. Push the cassette release button and remove the cassette from the cassette slot.
- 3 If the status indicator does not constantly light up in green, continue with the next steps.
- 4 Switch off the digitizer.
- 5 Simultaneously press the two buttons positioned underneath the cassette unit.



- 6 Slide out the cassette unit with the cassette attached.



- 7 Remove the jammed image plate and insert it in the cassette.

- If the image plate is inside the cassette:



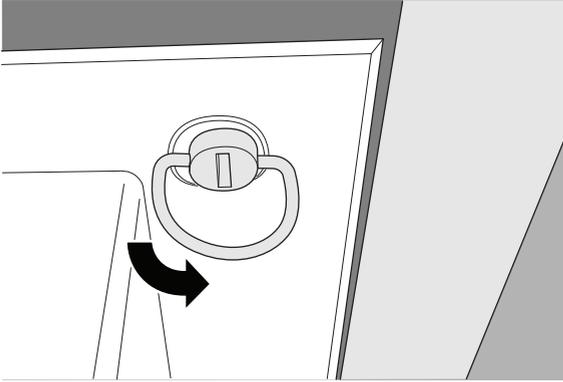
Caution: The image plate may slide out of the cassette. Be careful not to drop the image plate.

- 1 Put the cassette unit with the cassette on a table.
- 2 Slide the image plate completely into the cassette.
- 3 Push the release button to detach the cassette from the cassette unit.

- If the image plate is in the digitizer and visible from the front side:

- 1 Put the cassette unit with the cassette on a table.
- 2 Gently remove the image plate from the digitizer.
- 3 Slide the image plate completely into the cassette.
- 4 Push the release button to detach the cassette from the cassette unit.

- If the image plate is in the digitizer but not visible from the front side:
 - 1 Put the cassette unit with the cassette on a table.
 - 2 Open the back of the device by turning the four fixation rings by 90 degrees:



- 3 Gently remove the image plate from the back of the digitizer.
- 4 Slide the image plate completely into the cassette.
- 5 Close the back of the device.
- 6 Push the release button to detach the cassette from the cassette unit.



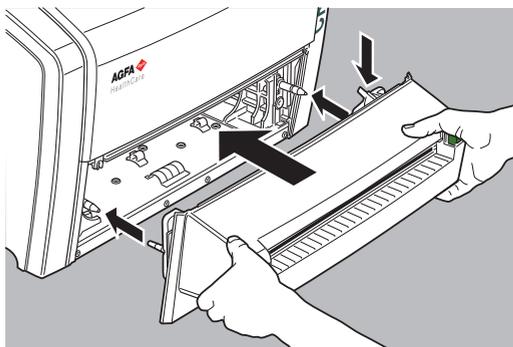
Note: Never use force to clear the jammed image plate. If it is not possible to gently remove the image plate, call your local service organization.

Note: Make sure not to bend the image plate when removing it from the device.

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

8 Place back the cassette unit.

Note that the protruding elements of the cassette unit should be positioned correctly in line with the digitizer: if the cassette unit is positioned too high, the protruding elements on the cassette unit may become damaged.



9 Switch on the digitizer.



Note: After removing a jammed image plate, erase the image plate before the next exposure.

Behavior in Case of Power Failure



Note: The description below is only applicable if an uninterruptible power supply (UPS) is put into the CR system configuration.

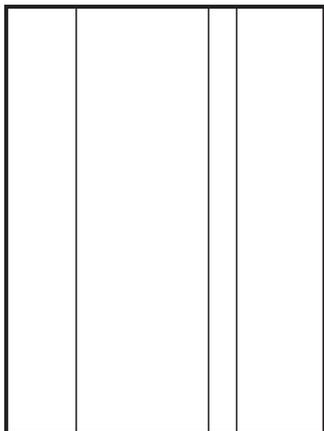
In case of a power failure, the system is still connected to the UPS. Two situations are possible:

- 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.

Cleaning the Optical Unit

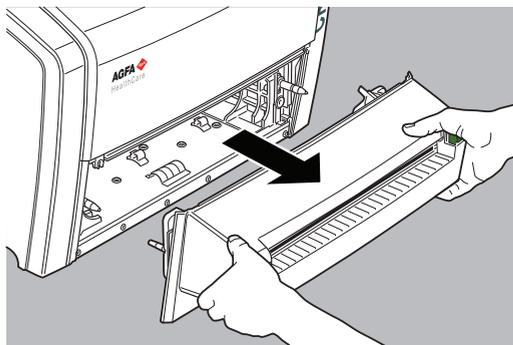
The only maintenance action which you must perform is checking the image quality. Refer to the User Manual of the NX™ software.

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.

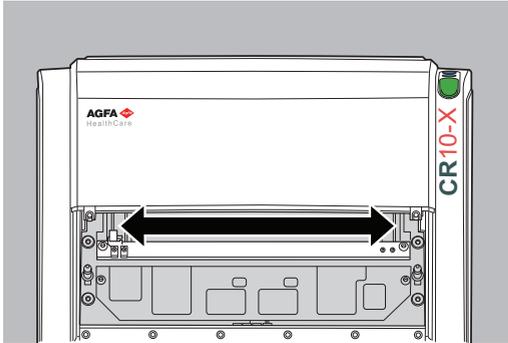


To clean the optic unit, proceed as follows:

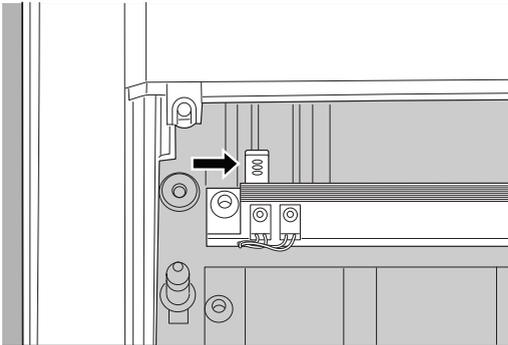
- 1 Remove the cassette unit.



- 2** Move the cleaning lever from left to right and back.

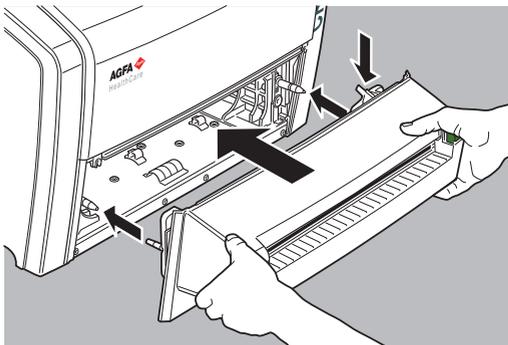


This is the location of the cleaning lever:



- 3** Place back the cassette unit.

Note that the protruding elements of the cassette unit should be positioned correctly in line with the digitizer elements: if the cassette unit is positioned too high, the protruding elements on the cassette unit may become damaged.



Equipment Information Sheet

This appendix covers the following topic:

- [Specifications](#)

Specifications

Labelling	
CE	93/42 EEC 'Medical Devices' (Europe), EN 60601-1
c ETL us	ETL us certified, UL 60601-1 (North America)
c ETL us	c ETL certified CSA 22.2 No 601.1
Dimensions	
Length	70 cm
Width	58 cm
Height	50 cm
Weight	
Unpacked	approximately 30 kg (66 lb)
Electrical connection of CR 10-X	
Operating voltage	24 Vdc
Operating current	4 A
Electrical connection of external power supply	
Operating voltage	Autoranging power supply from: 100 V to 240 V, ac \pm 10% Class I with protection earth Connect to earthed supply circuitry only.
Mains frequency	50/60 Hz
Current rating	max. 2 A
Mains fuse protection	Europe: min. 10 A, max. 16 A USA & Japan: min. 10 A, max. 15 A
Network connectivity	
Ethernet connector	RJ45 female, 10/100 Mbit/s autosensing, shielding CAT5

Power consumption	
Standby	
• 110 V - 240 V / 50-60 Hz configuration	max. 30 W
During operation	
• 110 V - 240 V / 50-60 Hz configuration	max. 85 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 - 25 °C allowed: 15 °C - 35 °C
Maximum temperature change	0.5 °C/min.
Relative humidity	recommended: 30 % - 60 % allowed: 15 % - 80 %
Magnetic field	compliant with EN 61000-4-8, Level 2
Sunlight exposure	not to be operated in direct sunlight, max. 2500 lux
Environmental conditions (during storage)	
In line with IEC721-3-1: class 1K4.	
Temperature	-25 °C - +55 °C
Environmental conditions (during transport)	
In line with IEC721-3-2 (1997): class 2K2 and 2M3, with following restrictions:	
Temperature	-25 °C - +55 °C
Vibration	5-200 Hz (vertical, longitudinal, transversal axis)

Environmental conditions for mobile installation (during transport)	
In line with IEC721-3-5: 5K1 and 5M3 with following restrictions:	
Vibration	5-150 Hz (all axis), 1m/s ² , sinusoidal vibration
Environmental conditions for mobile installation (during operation)	
In line with IEC721-3-3 (1997): 3K2 and 3M1 with following restrictions:	
Temperature	+ 15 °C to +35 °C
Relative Humidity	15% to 75% (non-condensing)
Vibration	40-200 Hz; 1m/s ² ; sinusoidal vibration
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	30 W ≈ 102 BTU/h ¹
• Average power consumption during scanning	45 W ≈ 153 BTU/h ¹
• Peak power consumption during scanning	85 W ≈ 290 BTU/h ¹
End of Life	
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	7 yrs.

1. BTU: British Thermal Unit

Remarks for HF-emission and immunity

This appendix contains technical information. It is only available in English.

Remarks for HF-emission and immunity

The device has been tested for a normal hospital environment as described below.

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

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

Emissions test	Compliance	Electromagnetic Environment Guidelines
RF emissions in accordance with CISPR 11	Group 1	The digitizer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions in accordance with CISPR 11	Class A	The digitizer is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded. 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 digitizer or shielding the location.
Harmonic emissions in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions in accordance with IEC 61000-3-3	Complies	

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.

Resistance to Jamming Test	IEC 60601 Test Level	Level of Agreement	Electromagnetic Environment Guidelines
Discharge of static electricity in accordance with IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 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 for network leads ± 1 kV for entry and outlet leads	± 2 kV for network leads ± 1 kV for entry and outlet leads	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 push-pull voltage ± 2 kV common mode voltage	± 1 kV push-pull voltage ± 2 kV common mode voltage	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage breakthroughs, short term interruptions and variations in the voltage supplied in accordance with IEC 61000-4-11	<ul style="list-style-type: none"> • $< 5\% U_r$ ($> 95\%$ breakthrough of U_r) for $\frac{1}{2}$ period • $40\% U_r$ ($> 60\%$ breakthrough of U_r) for 5 periods • $70\% U_r$ (30% breakthrough of U_r) for 25 periods • $< 5\% U_r$ (95% breakthrough of U_r) for 5 s 	<ul style="list-style-type: none"> • $< 5\% U_r$ ($> 95\%$ breakthrough of U_r) for $\frac{1}{2}$ period • $40\% U_r$ ($> 60\%$ breakthrough of U_r) for 5 periods • $70\% U_r$ (30% breakthrough of U_r) for 25 periods • $< 5\% U_r$ (95% breakthrough of U_r) for 5 s 	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 interrupted, it is recommended to use an uninterruptible power supply or a battery.
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic field at the network frequency should correspond to the typical values as they are in a commercial and clinical environment.
<ul style="list-style-type: none"> • 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	IEC 60601 Test Level	Level of Agreement	Electromagnetic Environment
			Use portable and mobile radio sets at a safe distance from the device (including the leads) not closer than the recommended protective distance, which is calculated according to the equation suitable for the transmission frequency. Recommended protective distance:
Conducted high frequency disturbance variables in accordance with IEC 61000-4-6	$3 V_{\text{eff}}$ 150 kHz to 80 MHz	$3 V_{\text{eff}}$	$d = 1.2 \sqrt{P}$
Radiated high frequency disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
			With P as the rated power of the transmitter in watts (W) in accordance with the manufacturer information on the transmitter and d as the recommended protective distance in metres (m). The field strength of stationary radio transmitters is lower than the level of the agreement ^a at all frequencies in accordance with an on-site investigation ^b . Disruptions are possible near devices that carry the following symbol: <div style="text-align: center;">  </div>

- REMARK 1: The higher value will apply at 80 MHz and 800 MHz.
- REMARK 2: These Guidelines may not apply to all situations. The dispersion of electromagnetic waves is influenced by absorption and reflections from buildings, objects and people.

- a. 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 level of agreement 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.
- b. The field strength will be lower than 3 V/m above the frequency range from 150 kHz to 80 MHz.

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.

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 Transmission Frequency m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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 1 : An additional factor of 10/3 has been used to calculate the recommended protective distance of transmitters in the frequency range from 80 MHz to 2.5 GHz, to reduce the probability that mobile portable communication equipment unintentionally brought into the area of the patients will lead to a disruption.
- REMARK 2 : 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.



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