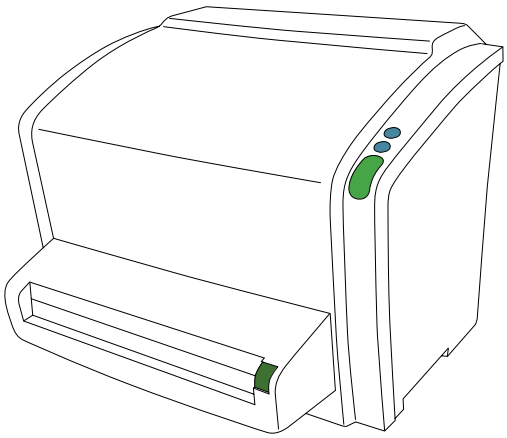
CR Reader, CR Advanced Reader, CR Multiformat Reader

5151/110
5151/210
5151/310

User Manual



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Contents

Legal Notice

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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 Reader™, CR Advanced Reader™ and CR Multiformat Reader™ digitizers, further referred to as the digitizer, unless the information applies to a specific type.

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.*

Safety icons

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

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 Reader, CR Advanced Reader and CR Multiformat Reader

Topics:

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.

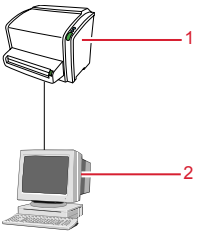
Configuration

The system consists of:

- the digitizer for scanning 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
  - CR MD1.0F General
  - CR DD1.0 Vet
  - CR HD5.0S Genrad (CR Multiformat Reader only)

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 trained service technician.



1. Digitizer
2. Control PC

Topics:

Image Acquisition Software

The digitizer can be used in combination with software for image acquisition, identification, image processing and image transmission of digitized images received from the digitizer. This manual uses examples for a combination with the NX workstation.

To install the UPS into the system

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”.

Cassette adapter

The cassette adapter is required for using a 24 cm x 30 cm cassette, depending on the digitizer model.

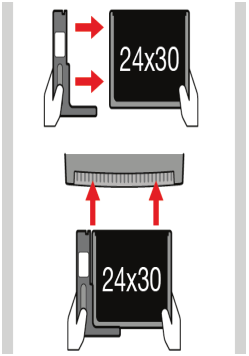


Figure 1: Cassette adapter

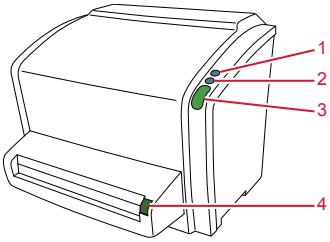
Related Links

Cassette formats on page 82

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

Topics:

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.

Related Links

Re-erasing an Image Plate on page 56

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.
	Blinking	Busy with erasing and return of the IP into cassette	Wait.
Green	Constant	Standby mode (Ready) Cassette is ready for removal	Proceed. Remove cassette.
Yellow	Blinking	Busy with scanning, erasing and return of the IP into cassette	Wait.
Red	Constant	Error	Consult the Digitizer Remote Display UI (User Interface) messages on the control PC. Refer to section 'Troubleshooting'.
	Blinking slowly	Digitizer not ready	
	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 on page 63

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 Reader, CR Advanced Reader, CR Multiformat Reader User Documentation CD (digital media).
- NX User Documentation CD (digital media).

The CR Reader, CR Advanced Reader, CR Multiformat Reader User Documentation CD contains:

- CR Reader, CR Advanced Reader, CR Multiformat Reader User Manual (this document), document 2591.
- AGFA CR Plates and Cassettes User Manual, document 2492.
- Getting started with CR Reader, CR Advanced Reader, CR Multiformat Reader, document 2593.

The NX User Documentation CD contains:

- NX user documentation
- CR Full Leg Full Spine User Manual, document 4408 (available on NX User Documentation CD).
- Getting Started with NX, document 4417.

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 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, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Manufacturer 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 / IEC 62368-1 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 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 Medical Device Directive (European Council Directive 93/42/EEC on Medical Devices).
- The cassette adapter has been designed in accordance with Regulation (EU) 2017/745 on medical devices (MDR).
- ISO 13485
- IEC 62366
- IEC 62304
- ISO 14971

Safety

- IEC 60601-1
- UL 60601-1
- AAMI/ANSI ES 60601-1
- 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 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.

Connectivity

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

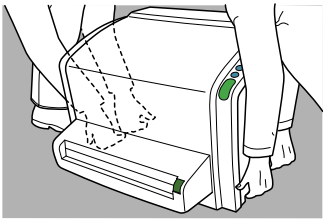
Installation

WARNING:
When using the power supply, 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 device and that it is easily accessible in case of emergency.

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.



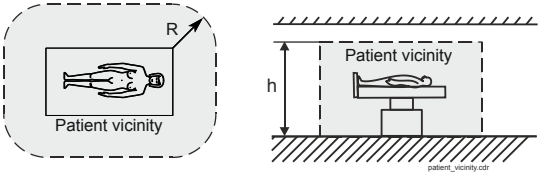
WARNING:
The device is a table-top digitizer. The structure and stability of the table used need to be suitable in relation with the size and weight of the system. Do not use excessive force when inserting cassettes in the digitizer as the device may slip or drop off the table. Use a non-slip-mat below 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.

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.

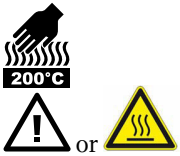
The classification of this product according to the medical electrical equipment standard IEC 60601-1 requires installation outside the patient vicinity. For definition of patient vicinity see dimensions below.

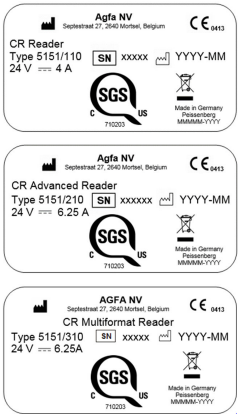


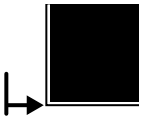
R = 1.5 m / 4.9 feet (EN 60601-1) or 1.83 m / 6 feet (UL 60601-1)
h = 2.5 m / 8.2 feet (EN 60601-1) or 2.29 / 7.5 feet (UL 60601-1)

Labels

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.

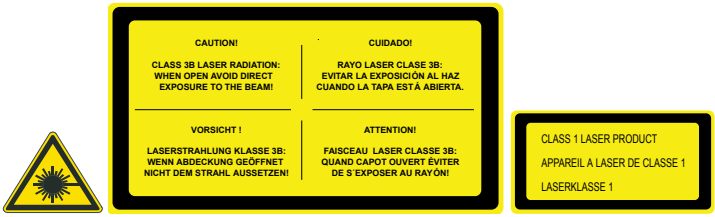
	Safety warning, indicating that the manuals should be consulted before making any connections to other equipment. The use of accessory equipment not complying with the equivalent safety requirements of this digitizer may lead to a reduced level of safety of the resulting system. Consideration relating 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.
	Power button

	Type label
	This mark shows compliance of the equipment with Directive 93/42/EEC (for European Union).
	Date of manufacture
	Manufacturer
	Medical device
	Serial number
	Production lot number
	Unique device identifier, in text format and in machine readable format
	The most recent version of this document is available on *http://www.agfahealthcare.com/global/en/library/index.jsp*
	WEEE Symbol, see section about Environmental protection.

	This mark indicates how to insert the cassette in the slot, depending on the cassette size that is indicated in the mark (CR Multiformat Reader only).

Topics:

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.

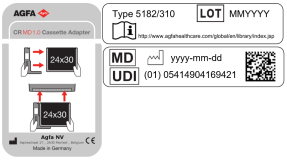
Under normal operating conditions - device with all covers - there can be no laser radiation outside the digitizer.

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.

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

Additional labeling of the casette adapter

 **Figure 2: Example of type labels**	Type labels
CE	This mark shows compliance of the equipment with Regulation 2017/745 (for European Union).

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.

Cleaning the cassette adapter

To clean the cassette adapter:

Wipe the cassette adapter with a clean, soft, damp cloth. Use a mild soap or detergent if required but never use ammonia-based cleaner.

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

Related Links

Cleaning and Disinfection on page 33

Topics:

Preventive Maintenance

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

The digitizer informs you when preventive maintenance is required and displays the following message "Maintenance interval expired. Please contact service."

Preventive maintenance should be performed by an Agfa certified service engineer.

Cleaning the Optical Unit

CAUTION:
Dust can cause stripes in the image, parallel to the image plate movement.

When you recognize this type of artefact, clean the optic unit using the cleaning brush.

Related Links

Cleaning the Optical Unit on page 75

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 3: WEEE symbol

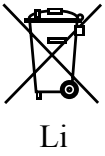


Figure 4: Battery symbol

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

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

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

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 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.

CAUTION:
The digitizer is not suitable for scanning imaging plates (IPs) exposed with a dose higher than 5000 μG and for CR HD5.0S General a dose higher than 2500 μG.

CAUTION:
Pushing the release button during scanning or during erasure stops operation immediately and can cause an image being lost, a need to retake the image or delayed diagnosis.

Do not push the release button during scanning (status indicator is blinking yellow) or during erasure (status indicator blue).

CAUTION:
Power failure can cause an image being lost.

Connect the workstation and the digitizer to an uninterrupted power supply (UPS) or an institutional standby generator.

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.

WARNING:
Device failure and image loss can cause a need to retake the image or cause delayed diagnosis. Perform no other operations on the digitizer than those described in this document.

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 force when inserting a cassette into the digitizer.
- 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.
- 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

Quality control can be performed by means of the Auto QC2 tool.

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

Apply regular quality control according local regulations.

Getting started

Topics:

Starting the Digitizer

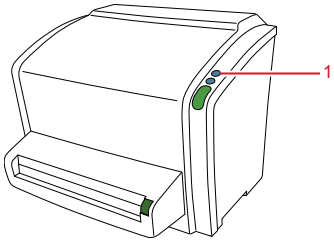
To start the Digitizer:

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.

   Note: Make sure not to insert a cassette if the device is switched off or starting up.

2. Press the power button.



   1. 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.

Topics:

Step 1: Select a patient and start the exam

At the NX workstation:

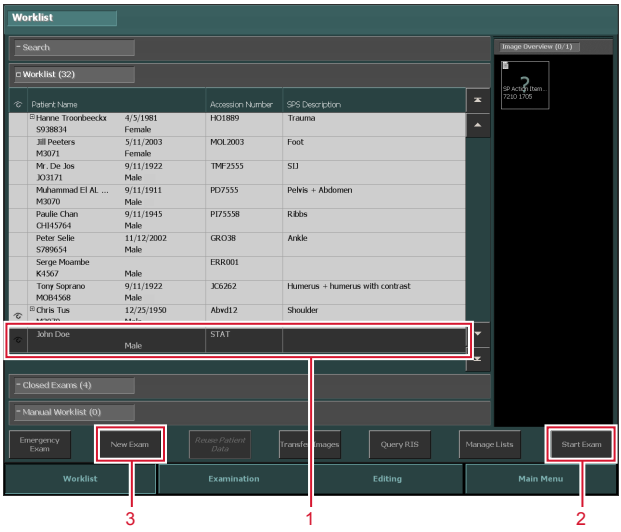
1. Open the Worklist window of NX.

   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.

   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 (X-ray tube side) to the top and with the shutter opening mechanism and the locking mechanism inside the digitizer. Small cassettes must be pushed to the right side of the slot.

   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.

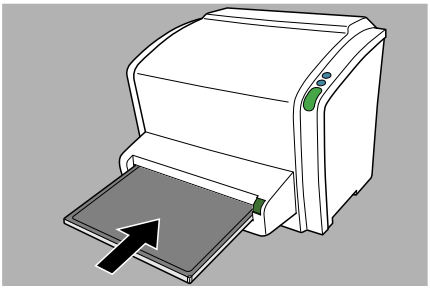


Figure 5: Inserting 35 cm x 43 cm cassette

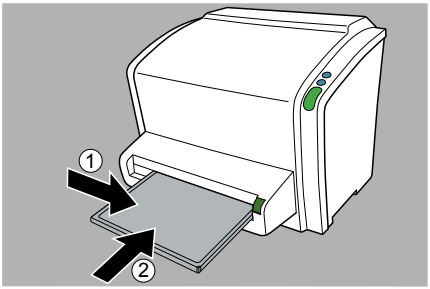


Figure 6: Inserting small cassette

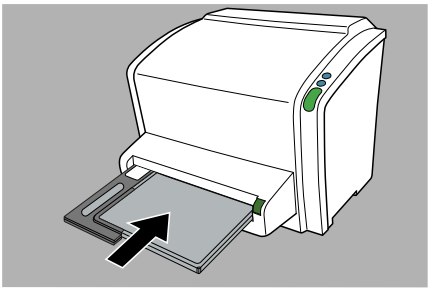


Figure 7: Inserting 24 cm x 30 cm cassette using the cassette adapter

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.

Related Links

Cassette formats on page 82
Cassette adapter on page 14

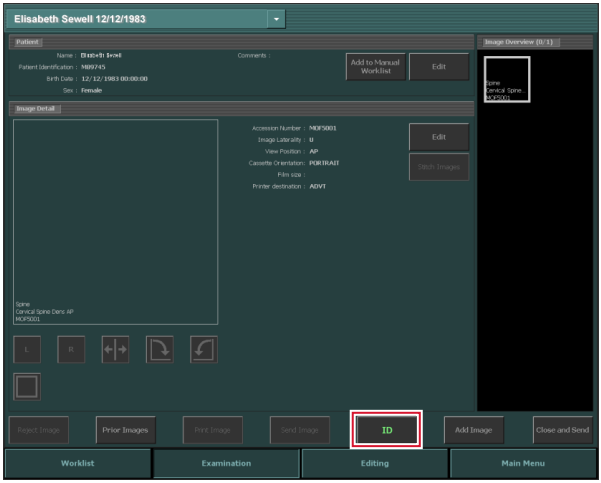
At the NX workstation:

1. In the Examination window of NX, select the thumbnail in the Image overview pane.
2. On CR Advanced Reader and CR Multiformat Reader the scan resolution can be modified.

   Note: The availability of the scan resolution field is configured in the NX software. A default scan resolution is configured in the NX software for Genrad and for FLFS examinations. Refer to the NX Key User Manual.

   Note: CR HD5.0S General image plate does not support 150µm scan resolution. If 150µm scan resolution is displayed on the NX Image Detail Pane, the actual scan resolution is 100µm and for further processing the actual scan resolution of 100µm is used.

   a) Click Edit in the Image Detail Pane
   b) Edit the scan resolution field.
   c) Click OK.
3. Click ID to send the data to the digitizer.



4. 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.

5. 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.
   - 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.

CAUTION:
Pushing the release button during scanning or during erasure stops operation immediately and can cause an image being lost, a need to retake the image or delayed diagnosis.

Do not push the release button during scanning (status indicator is blinking yellow) or during erasure (status indicator blue).

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.

Related Links

Re-erasing an Image Plate on page 56

Stopping the Device

Topics:

Before Switching Off

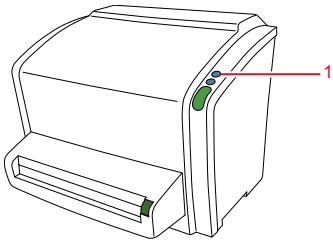
Check that the digitizer is not scanning an image plate. If the digitizer is scanning an image plate, the status indicator is blinking yellow.

Note: *A clamped cassette should be removed before switching off the device.*

Switching Off

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

To switch off, press the power button.



1. Power button

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

Note: *The optical components of the digitizer are switched off automatically after not been used for 3 hours. Restarting the digitizer takes approximately 3 minutes. During this time emergency digitizing is not possible!*

Operating CR Reader, CR Advanced Reader and CR Multiformat Reader

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.*

Note: *The optical components of the digitizer are switched off automatically after not been used for 3 hours. Restarting the digitizer takes approximately 3 minutes. During this time emergency digitizing is not possible!*

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 (X-ray tube side) to the top and with the shutter opening mechanism and the locking mechanism inside the digitizer. Small cassettes must be pushed to the right side of the slot.

   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.

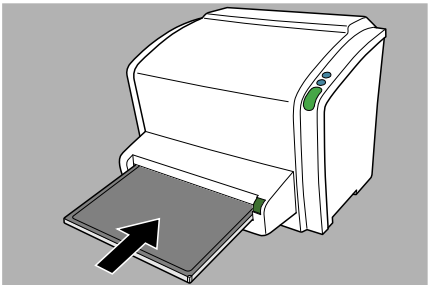


Figure 8: Inserting 35 cm x 43 cm cassette

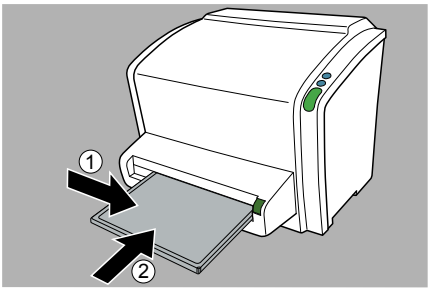


Figure 9: Inserting small cassette

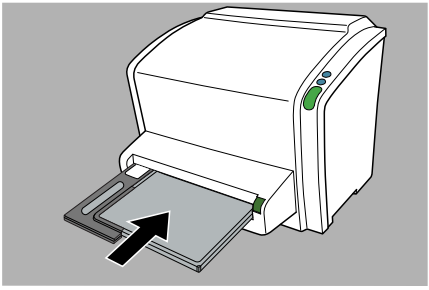


Figure 10: Inserting 24 cm x 30 cm cassette using the cassette adapter

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.

Related Links

Cassette formats on page 82
Cassette adapter on page 14

Reading the Initialization Data of an Image Plate

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

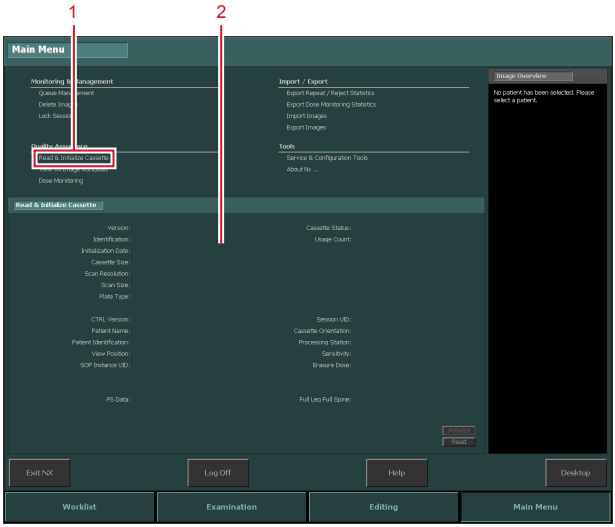
Reading the initialization data of an image plate can be necessary in case you want to find a specific IP.

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** (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 of the digitizer as shown below.

   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. Small cassettes must be pushed to the right side of the slot.

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.

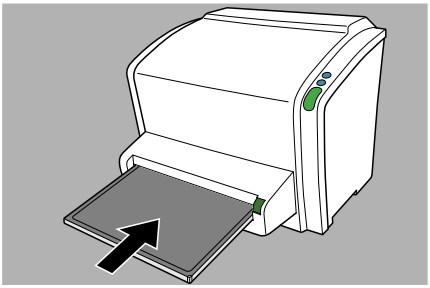


Figure 11: Inserting 35 cm x 43 cm cassette

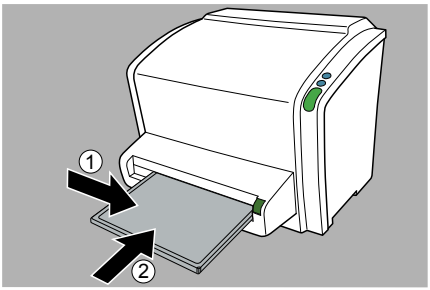


Figure 12: Inserting small cassette

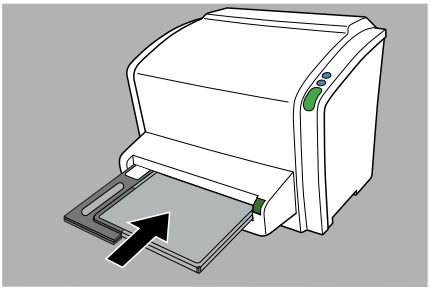


Figure 13: Inserting 24 cm x 30 cm cassette using the cassette adapter

Once the cassette is locked, the status indicator on the digitizer is blinking yellow.

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.*

Related Links

Cassette formats on page 82
Cassette adapter on page 14

Expiry of Image Plates

Topics:

Upcoming Expiry of the Image Plate

The Digitizer Remote Display 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 Remote Display 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 User Manual (document 2492).

Troubleshooting

In case of a malfunction of the digitizer, consult the Digitizer Remote Display 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 trained service personnel.

Topics:

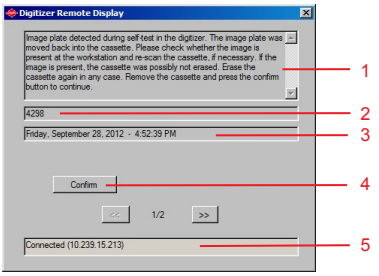
Digitizer Remote Display

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

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 and the Digitizer Remote Display.	No error message on NX PC.	Red blinking fast	Check if Digitizer Remote Display is running. 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.

Cassette Could Not Be Identified

Details	This error message is displayed on the NX PC: 
Cause	A cassette has been inserted in the digitizer and the ID button was clicked directly afterwards.
Solution	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.

Cassette release button pressed before end of cycle

Details	The following error message is displayed in the Digitizer Remote Display: Do not press the cassette release button before end of cycle. Please clamp the cassette again by pushing it towards the digitizer. Restart the digitizer.
Cause	You pressed the cassette release button before the end of the cycle.
Solution	Do not press the cassette release button before the end of the cycle. If you did, clamp the cassette again by pushing it towards the digitizer and restart the digitizer.

Cannot read data on the image plate

Details	The following error message is displayed in the Digitizer Remote Display: Error during read out of data on the image plate. Remove the cassette and press the confirm button. Do not use the cassette again before an inspection.
Possible causes	Defect/soiled bar code on image plate Optics cleaning lever in optical path and not positioned at left side.
Solutions	Remove the plate from the cassette -as described in the AGFA CR Plates and Cassettes User Manual- and check if the barcode is fully legible. If necessary, remove any dirt (conform the plate cleaning instructions). At the left side, put the optics cleaning lever back to the "home" position so that the digitizer can read the barcode on the image plate.

Related Links

Cleaning the Optical Unit on page 75

Image Plate Transport Problems

Details	The following error message is displayed in the Digitizer Remote Display: Image plate is not erased! Remove the cassette and press the confirm button. Do not use the cassette again before an inspection. Image plate is not scanned and erased! Remove the cassette and press the confirm button. Do not use the cassette again before an inspection.
Possible causes	A problem occurred when transporting the image plate in the digitizer.
Solutions	Remove the cassette and press the confirm button and perform following checks: **1.** Check the cassette for damages. **2.** Open the cassette and check the shutter for damages. **3.** Check if image plate is bent. Put the image plate on a flat surface. The entire image plate must touch the surface. The image plate must be exchanged if there is a gap between surface and a part of the image plate e.g. if you can see a lifted edge or a sharp bend.

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:

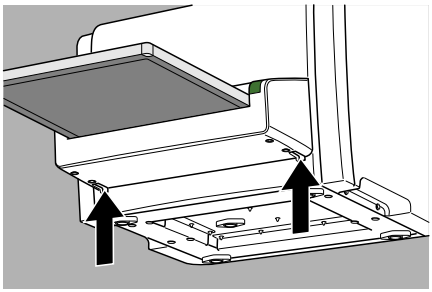
CAUTION:
In case of an image plate jam, do not push the release button unless the status indicator constantly lights up in green. Pushing the cassette release button while the status indicator is blinking may damage the image plate.

1. Switch off the digitizer and switch it on again.

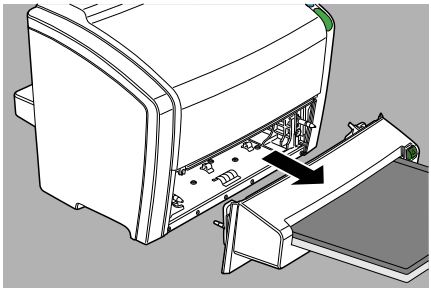
   During startup, the digitizer tries to return the image plate into the cassette.
2. If the status indicator constantly lights up in green, the image plate is returned into the cassette. Push the cassette release button and remove the cassette from the cassette slot.
3. If the status indicator still lights up in red after startup, continue with the next steps.
4. Switch off the digitizer.
5. Remove the power plug from the socket.

   CAUTION:
   A finger getting caught in the device can cause injury of the operator.

   Remove the power plug from the socket before removing a jammed image plate.
6. Simultaneously press the two buttons positioned underneath the cassette unit.



7. Slide out the cassette unit with the cassette attached.



WARNING:
The cassette unit and/or the cassette falling down can cause injury of the operator.

Take safety precautions to avoid injury.

8. 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.

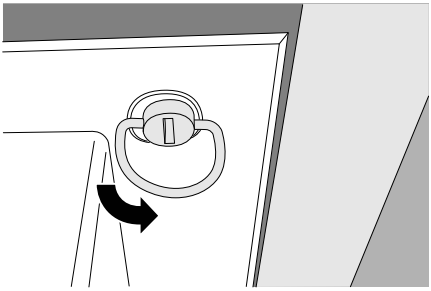
- If the image plate is in the digitizer and visible from the front side:

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.

   Verify that the white phosphor side is oriented to the tube side of the cassette and that the shutter does not scratch the image plate.
5. Close the back of the device.
6. Push the release button to detach the cassette from the cassette unit.

Note:

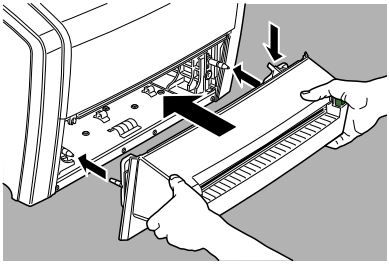
Never use force to clear the jammed image plate. If it is not possible to gently remove the image plate, call your local service organization.

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

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

9. 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.



10. 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:

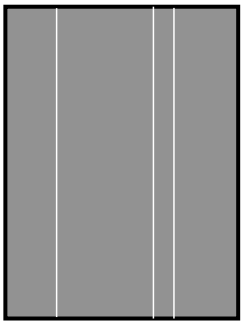
- Power failure after cassette insertion and before identification with the NX workstation. The digitizer pushes the image plate back in the cassette without scanning and releases the cassette. After the power supply returns, the cassette must be inserted into the digitizer and identified again to read 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.

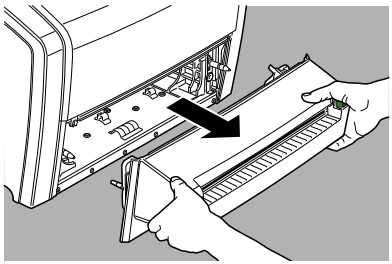
CAUTION:
Dust can cause stripes in the image, parallel to the image plate movement.

When you recognize this type of artefact, clean the optic unit using the cleaning brush.

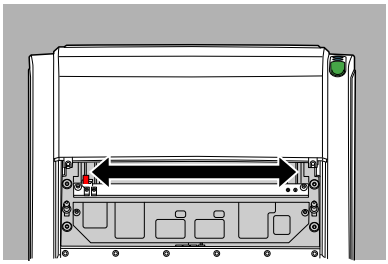


To clean the optic unit, proceed as follows:

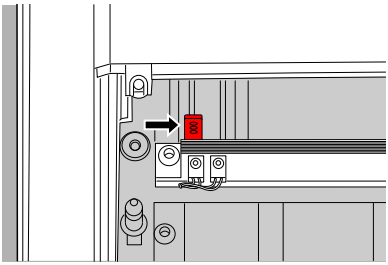
1. Remove the cassette unit.



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



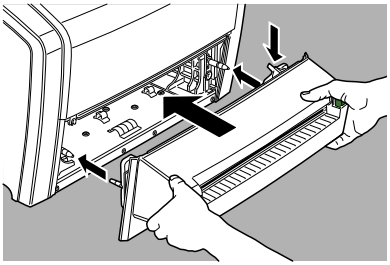
This is the location of the cleaning lever:



Make sure to return the lever completely to the left, where it is locked in position.

3. 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.



Technical Data

Topics:

Specifications

Labelling		
CE	93/42 EEC 'Medical Devices' (Europe), EN 60601-1	
c NRTL us	NRTL us certified, UL 60601-1 (North America)	
c NRTL us	c NRTL certified CSA 22.2 No 601.1	
Dimensions		
Length	700 mm	
Width	580 mm	
Height	471 mm	
Weight		
Unpacked	approximately 31 kg (68 lb)	
Electrical connection	CR Reader	CR Advanced Reader CR Multiformat Reader
Operating voltage	24 V	24 V
Operating current	4 A	6.25 A
Electrical connection of external power supply		
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	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	CR Reader	CR Advanced Reader CR Multiformat Reader
110 V - 240 V / 50-60 Hz configuration	max. 41 W	max. 22 W
During operation	CR Reader	CR Advanced Reader CR Multiformat Reader
110 V - 240 V / 50-60 Hz configuration	max. 108 W	max. 140 W (absolute peak)
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	
Atmospheric pressure	70 kPa to 106 kPa	
Related altitude on site	3000 m to 0 m	
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: 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/s², sinusoidal vibration	
Environmental conditions for mobile installation (during operation)		
In line with IEC721-3-3: 3K2 with following restrictions:		
Temperature	+15 °C to +35 °C	
Relative Humidity	15% to 75% (non-condensing)	
Physical emissions		
Noise emission (sound power level according to ISO 7779)		
During scanning	max. 65 dB(A)	
Standby	max. 55 dB(A)	
Heat emission	CR Reader	CR Advanced Reader CR Multiformat Reader
Standby	41 W ≈ 140 BTU/h[1]	22 W ≈ 75 BTU/h[1]
Average power consumption during scanning	65 W ≈ 222 BTU/h[1]	78 W ≈ 266 BTU/h[1]
Peak power consumption during scanning	108 W ≈ 368 BTU/h[1]	140 W ≈ 478 BTU/h[1]
Cycle time Cassette format 35 cm x 43 cm		
Scan resolution	CR Reader	CR Advanced Reader CR Multiformat Reader
200 μm	-	58 s
150 μm	-	70 s

(not applicable for CR HD5.0S General image plate)		
100 μm	118 s	88 s
End of Life		
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	7 yrs.	

1. BTU: British Thermal Unit

Cassette formats

Table 2: Supported cassette formats

Cassette format	CR Reader CR Advanced Reader	CR Multiformat Reader
35 cm x 43 cm	yes	yes
35 cm x 35 cm	no	yes
24 cm x 30 cm	yes, using the cassette adapter	yes
18 cm x 24 cm	no	yes
15 cm x 30 cm	no	yes

Cassette adapter

Note: The cassette adapter can only be used on digitizers with specified serial numbers.

Table 3: Minimum serial numbers to support the cassette adapter

CR Reader	CR Advanced Reader
20500	40500

CR HD5.0S General

Note: The CR HD5.0S General Detector can only be used on CR Multiformat Reader digitizers with specified serial numbers or after installation of an upgrade.

Table 4: Minimum serial numbers to support the CR HD5.0S General Detector

CR Multiformat Reader
46000

Related Links

Cassette adapter on page 14

Pixel matrix size

Table 5: CR MD1.0 General, CR MD1.0F General and CR DD1.0 Vet

Format (cm)	Scan resolution (μm)	Width x Length (pixels)	Width x Length (mm)
35x43	100	3420 x 4218	342,0 x 421,8
	150	2280 x 2812	342,0 x 421,8
	200	1710 x 2109	342,0 x 421,8
35x43 (FLFS)	100	3420 x 4380	342,0 x 438,0
	200	1710 x 2190	342,0 x 438,0
35x35	100	3420 x 3420	342,0 x 342,0
	150	2280 x 2280	342,0 x 342,0
	200	1710 x 1710	342,0 x 342,0
24x30	100	2886 x 2304	288,6 x 230,4
	150	1924 x 1536	288,6 x 230,4
	200	1443 x 1152	288,6 x 230,4
15x30	100	2886 x 1398	288,6 x 139,8
	150	1924 x 932	288,6 x 139,8
	200	1443 x 699	288,6 x 139,8
18x24	100	2280 x 1698	228,0 x 169,8
	150	1520 x 1132	228,0 x 169,8
	200	1140 x 849	228,0 x 169,8

Table 6: CR HD5.0S General

Format (cm)	Scan resolution (μm)	Width x Length (pixels)	Width x Length (mm)
35x43	100	3348 x 4188	334,8 x 418,8
	200	1674 x 2094	334,8 x 418,8
35x43 (FLFS)	100	3348 x 4380	334,8 x 438,0
	200	1674 x 2190	334,8 x 438,0
24x30	100	2820 x 2268	282,0 x 226,8

Format (cm)	Scan resolution (μm)	Width x Length (pixels)	Width x Length (mm)
	200	1410 x 1134	282,0 x 226,8
18x24	100	2232 x 1668	223,2 x 166,8
	200	1116 x 834	223,2 x 166,8

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 digitizer 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:
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING:
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.

WARNING:
The DR detectors might be interfered with by other equipment.

Cables, transducers and accessories

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

CAUTION:
Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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 Reader, CR Advanced Reader and CR Multiformat Reader devices, no relevant parts could be inspected by the operator or by a service engineer before the end of the digitizer lifetime.