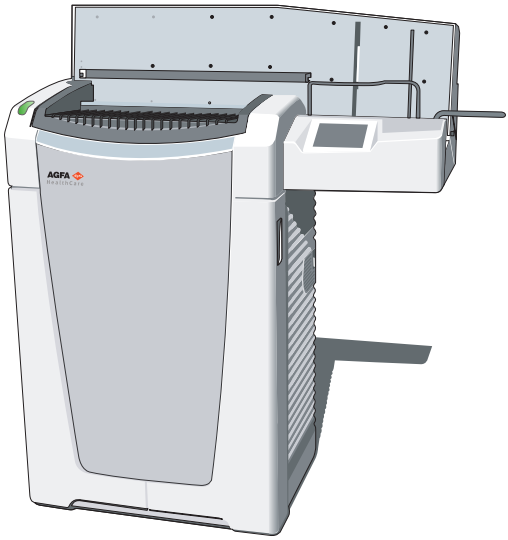
DX-G, DX-M

5170/100

5170/200

User Manual



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Legal Notice

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

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B-2640 Mortsel - Belgium.

Introduction to this Manual

Topics:

Scope

This manual contains information for safe and effective operation of the DX-G™/DX-M™ digitizers.

About the safety notices in this document

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

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

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

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

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

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

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

Disclaimer

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

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

Introduction

Topics:

Intended Use

This device must only be used to scan exposed X-ray cassettes, containing an erasable image plate (IP). The digitizer is part of a system, consisting of X-ray cassettes with erasable phosphor image plates and a workstation where the X-ray cassettes are identified and the resulting digital image information is further processed and routed. It is intended that this device is only operated in a radiological environment by qualified staff.

Related Links

Training on page 13

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.

Related Links

Training on page 13

Configuration

The digitizer is part of a CR system that has the following configuration:

- The digitizer, a digitizer for scan of image plates retaining latent X-ray images. The digitizer accepts multiple cassettes at a time, to be scanned sequentially.
- The NX workstation, one or more CR workstations with ID Tablet for cassette identification, image processing and image transmission of digitized images received from the digitizer.
- Cassette and plate system: CR HD5.x General, CR HD5.x FLFS, CR HD5.x AEC, CR HD5.x Extremities, CR MD4.xR General and CR MD4.xR FLFS.
- For DX-M additionally, CR HM5.x Mammo or CR MM3.xR Mammo - mixed use of both types in one digitizer will not be supported.
- The CR HD5.x General detector, CR HD5.x FLFS detector, CR HD5.x AEC detector, CR HD5.x Extremities detector, CR MD4.xR General plate and cassette, CR MD4.xR FLFS plate and cassette, CR HM5.x Mammo detector and CR MM3.xR Mammo plate and cassette are generically referred to as 'plates and cassettes'.

Note: The use of CR HD5.0 Extremities cassettes requires a software version ≥ NIM_2501.

Note: *For US DX-M is released in combination with CR HM5.x Mammo detectors only.*

System Documentation

The documentation consists of following items:

- DX-G and DX-M User Manual.
- DX-G and DX-M Workflow Sheets.
- AGFA CR Detectors, Plates and Cassettes (CR HD5.x, CR MD4.xR, CR HM5.x, CR MM3.xR) User Manual.
- CR Full Leg Full Spine User Manual (4408).
- NX User Manual (4420).
- CR Mammography System User Manual (2344).

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.

Training

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

Related Links

Intended Use on page 10
Intended User on page 10
Safety Directions on page 47

Product Complaints

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

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

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

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

Compatibility

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

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

Accessory equipment connected to any interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment or IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the requirements for ME systems according to IEC 60601-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements for ME systems according to IEC 60601-1. If in doubt, consult your local service organization.

ADC QS and ADC VIPS Software

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

Compliance

Topics:

General

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

Safety

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

Laser Safety

- IEC 60825-1

Electromagnetic Compatibility

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

Environmental Compliance

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

Equipment Classification

This device is classified as following:

Table 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.

Related Links

Maintenance and Cleaning on page 37

Installation

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:
Do not apply excessive shock or vibration to the digitizer during operation. This may decrease the image quality. Neither should the device be moved during operation.

WARNING:
Mechanical shocks or external vibration applied to the digitizer during mobile use or transport degrades image quality and may lead to retakes. Take care not to exceed the specified vibration conditions.

WARNING:
Failure of a protective earth connection can increase the risk of electric shock. Regularly check the connections of the protective earth connection of the mains plug. It is recommended to use and regularly check the second protective earth connector.

WARNING:
Agfa recommends the installation of a UPS (uninterruptible power supply) for the digitizer to overcome power failures of the hospital power network and to prevent a resulting image-loss.

Digitizer installation and configuration is performed by an Agfa certified service engineer.

The digitizer is foreseen to be installed in a stationary and weather protected location.

In case of an installation in a mobile environment, such as a bus, van, etc, the manufacturer of the vehicle should ensure that all components of the system are fixed or can be fixed safely for transport. There is a mobile version of the digitizer available that provides externally accessible locking systems for the fixation of the mechanics inside the device.

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:
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.

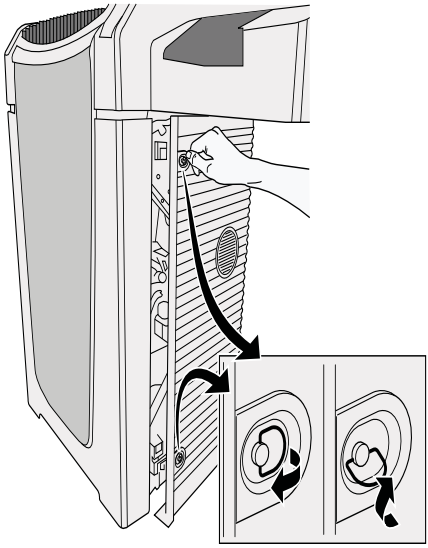
Topics:

Moving the Digitizer

To move the digitizer:

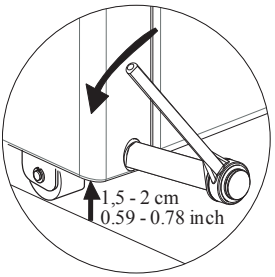
1. Switch off the digitizer.
2. Remove the power plug from the socket.
3. Unplug the ethernet cable.
4. Collect all cables together to prevent them from being crushed when moving the digitizer.
5. Remove all cassettes from the input and output buffer.
6. Open the right side cover of the digitizer.

   Open the eye of the latching and turn the latch through 90° clockwise.



7. Take the tool from the tool box at the inside of the right door.

8. Insert the tool in the opening and turn the screw counterclockwise, until the digitizer is lifted up approximately 1,5-2 cm, until you encounter resistance.



The digitizer is ready to be moved to another location.

9. Move the digitizer to the desired location.

WARNING:
Observe great care when moving the digitizer to the desired location. So please select a path free from inclinations and thresholds to prevent the digitizer from shocks during movement.

10. Once on the desired site, turn the screw clockwise until the digitizer is fixed on the ground and you encounter resistance.

Now the digitizer is ready for operation.

WARNING:
Operating the digitizer in a not-fixed condition may result in image artefacts.

WARNING:
The device has to be lowered to the ground in order to operate within specification.

11. Put back the tool.

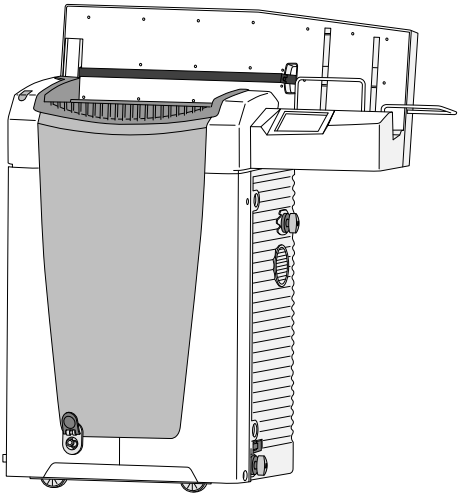
12. Reconnect all electrical connections.

- Reconnect the ethernet cable.
- Plug the power plug into the socket.

Mobile Use Installation

If the digitizer is installed in a mobile environment, a special mobile version of the DX-M is available that can be locked by the user for transport and unlocked again for use.

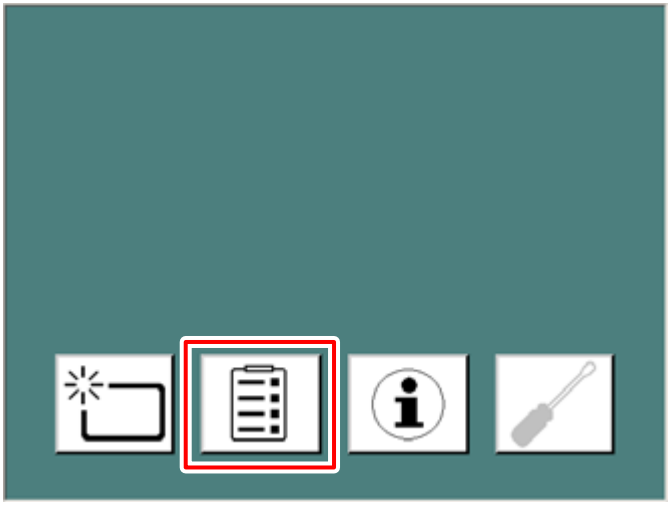
The locking system consists of two handles on both sides of the digitizer and a locking mechanism for the scan unit. The locking mechanism for the scan unit is accessible on the front side of the digitizer and requires a locking tool which is delivered with the mobile version.



Locking the digitizer before transport

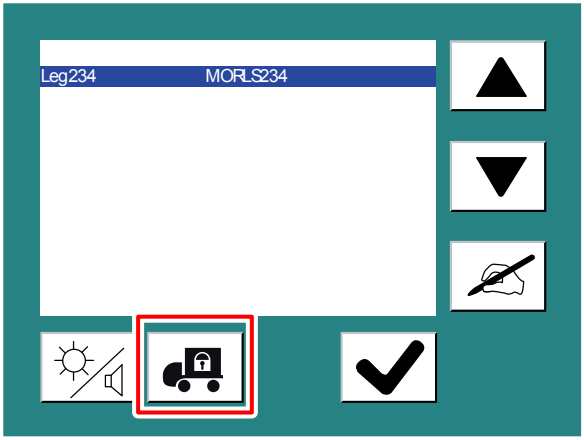
To lock the digitizer before transport:

1. In the Standby window, click the Configuration button.



The Rerouting window appears.

2. Click the Mobile use button.



3. Wait for the following message to be displayed: “Ready to fix transport locks. Switch off the digitizer and fix transport locks.”

   Switch off the digitizer with the main switch.

4. On the right side of the digitizer, turn the two handles 180° clockwise till they reach the locked position:

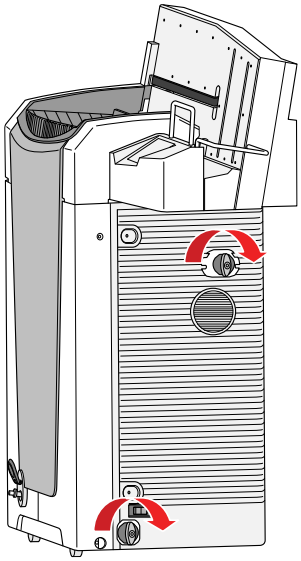
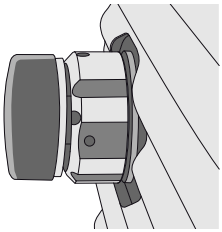
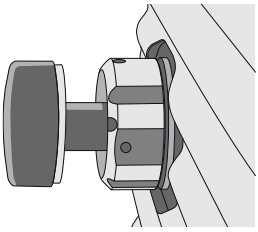
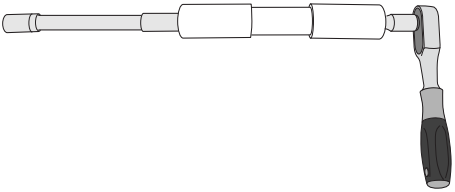


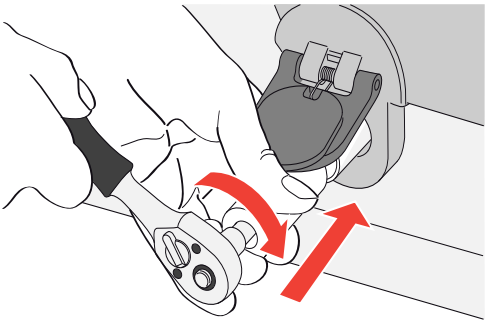
Table 2: Locked and unlocked position of the handles

Locked	Unlocked
	

5. Repeat the same using the two handles on the left side of the digitizer.
6. Insert the locking tool in the round opening in the front cover.



7. Push the tool towards the end and pull tight clockwise by use of the ratchet:



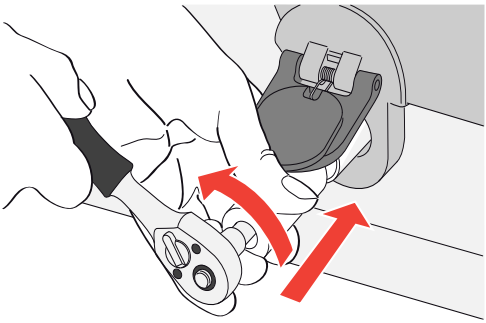
8. Remove the tool. The digitizer is now ready for transport.

WARNING:
If the digitizer is transported without the transport locks attached the device can be damaged.

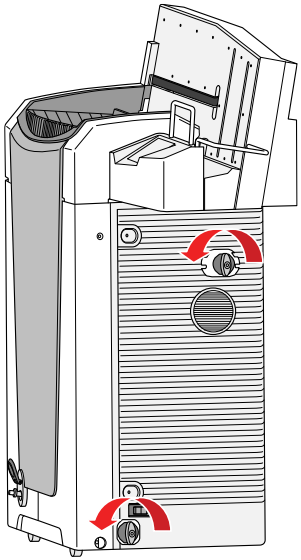
Unlocking the digitizer after transport

To unlock the digitizer after transport:

1. Insert the locking tool in the round opening in the front cover.
2. Push the tool towards the end and turn it counterclockwise till mechanical resistance can be felt.



3. On the right side of the digitizer, turn the two handles 180° counterclockwise till they reach the unlocked position:



4. Repeat the same using the two handles on the left side of the digitizer.
5. Switch on the digitizer.

Note:

If the digitizer is switched on without removing the transport lock on the front side, the following warning message is displayed:

“Transport locks are attached. Switch off the digitizer and remove transport locks.”

Image quality check after transport

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

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

Table 3: Image quality check after transport

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

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

Labels

Topics:

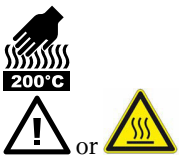
Product Identification

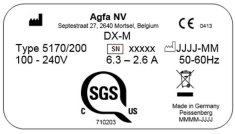
DX-G - Product description	
Type of product	Floor-mounted buffer digitizer
Commercial name	DX-G
Model number	5170/100
Original seller/manufacturer	Agfa NV Septestraat 27 2640 Mortsel Belgium

DX-M - Product description	
Type of product	Floor-mounted buffer digitizer
Commercial name	DX-M
Model number	5170/200
Original seller/manufacturer	Agfa NV Septestraat 27 2640 Mortsel Belgium

General

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

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

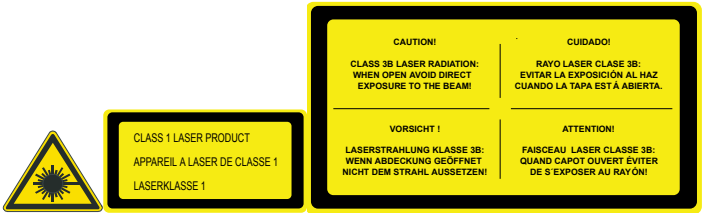
	ged before the power is turned off and the power plug has been removed. It is recommended to use the supplementary protective earth connection as additional safety measure.
	Do not put your fingers in the input slot of the digitizer, they can get hurt when caught between the cassette and the fixation. Insert the cassette as described in the basic workflow of the DX-G/DX-M Workflow Sheets.
○	Off (power: disconnection from the mains)
I	On (power: connection to the mains)
 **Figure 1: example of type label**	Type label
	Date of manufacture
	Manufacturer
	Serial number
	WEEE Symbol
	Device contains a transmitter module, see section

Cassette handling

Observe great care when handling the cassettes. The needle image plate is shock sensitive and drops should be avoided. When the cassette has been dropped, put it aside and contact your local service to check for functionality.

WARNING:
Do not use the detector again, a corrupt detector can damage the digitizer!

Safety Instructions for Laser Products



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

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.

However, the user is allowed to open the side cover, e.g. to clean the optical unit or to change an air-filter. When opening the side panel, all motor driven system movements will be stopped (including the laser).

CAUTION:

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

Maintenance and Cleaning

Related Links

Equipment Classification on page 18

Topics:

Preventive Maintenance by the Service Engineer

Regular preventive maintenance needs to be done once a year or after 25000 cycles (whatever comes first). This maintenance can not be done by the user but has to be done by an Agfa certified field service engineer. Not performing the regular maintenance by appropriately certified people can have impact on warranty commitments.

Maintenance by the User

Topics:

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.

For cleaning and disinfection instructions of the plates and cassettes, refer to the “AGFA CR Detectors, Plates and Cassettes (CR HD5.x, CR MD4.xR, CR HM5.x, CR MM3.xR) User Manual”.

Cleaning the exterior of the digitizer

CAUTION:
The cleaning or disinfecting may deteriorate safety provisions of the digitizer. Remove the power plug from the socket. Switch off the UPS, if installed. 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.

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.

WARNING:
Make sure no liquid gets in the device.

CAUTION:
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 touch panel

To clean the touch panel:

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

   Switch off the UPS, if installed.
3. Wipe the touch panel of the digitizer with a clean, soft, damp cloth. Use a commercially available screen cleaner for monitors to clean the touch panel.

WARNING:
Do not pour liquid directly on the touch panel.

4. Plug the power plug into the socket.

   Switch on the UPS, if installed.

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.

WARNING:
Dust in the optical unit on the light collecting mirror can create stripes parallel to the image plate movement within the digitizer. When you recognize this type of artefact, when using the digitizer, clean the optical unit using the cleaning brush.

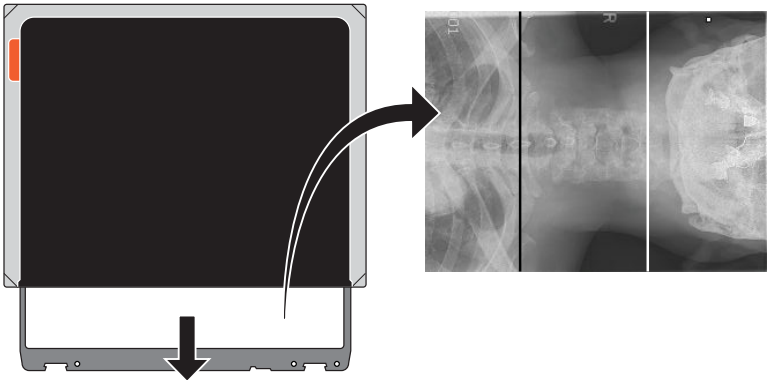


Figure 2: Image with two artefacts on it, a black line and a white line

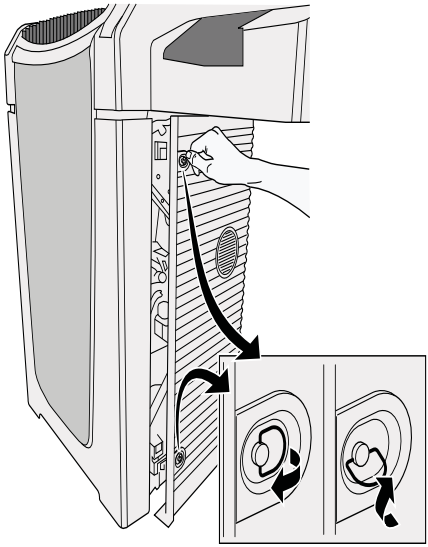
WARNING:
Environmental light falling into the digitizer may create image artefacts leading to retakes. Do not open the digitizer during operation.

To clean the optical unit:

1. Switch off the digitizer.
2. Remove the power plug from the socket.
3. Open the right side cover of the digitizer.

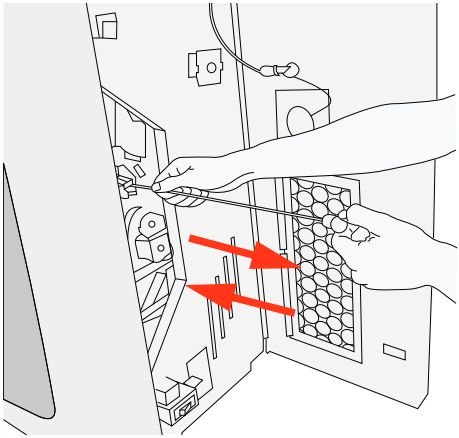
   Open the eye of the latching and turn the latch through 90° clockwise.

Note: *In case of a mobile device the upper right lock has to be locked before the side cover can be opened.*



4. Pull out the cleaning brush until you feel the stop position and put it back in the digitizer.

   Repeat this action 5 times.



5. Close the right side cover.

   To close the right side cover, proceed as follows:

   - Close the cover.
   - Turn the latch through 90° counterclockwise and close the eye of the latching.

   In case of a mobile device, unlock the upper right lock.
6. Plug the power plug into the socket.

Replacing the air-filter element

Note:

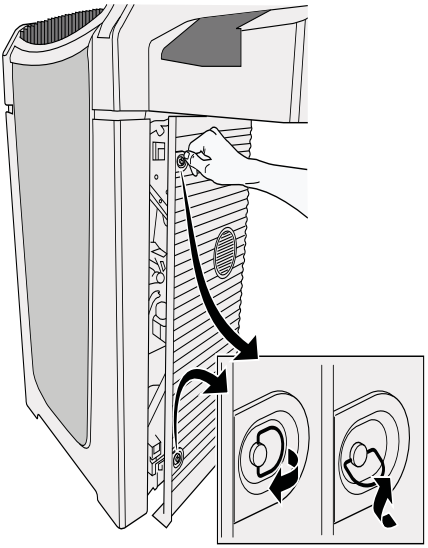
It is advised to replace the air-filter element at least once a year.

To change the air-filter element:

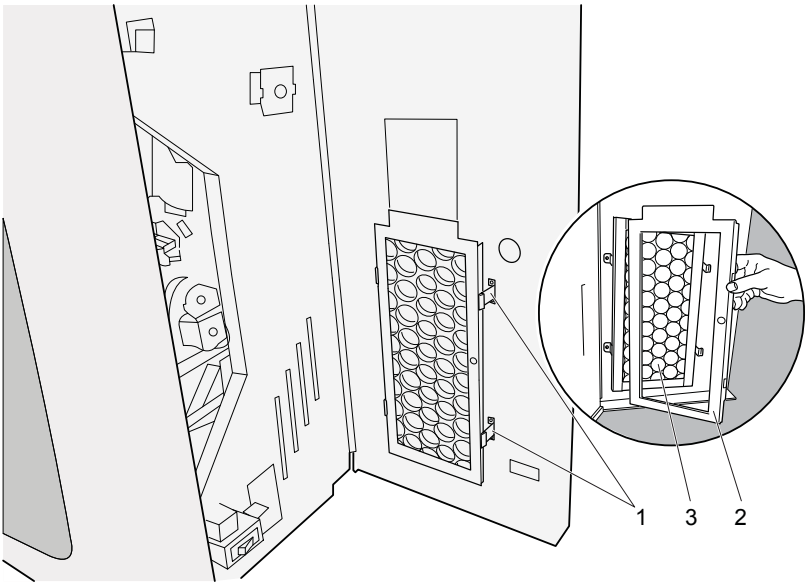
1. Switch off the digitizer.
2. Remove the power plug from the socket.
3. Open the right side cover of the digitizer.

   Open the eye of the latching and turn the latch through 90° clockwise.

   In case of a mobile device, lock the upper right lock before opening the side cover.



4. Open the right side door and locate the air-filter element inside the door opening.
5. Release the 2 clamps (1) to be able to remove the air filter frame (2).



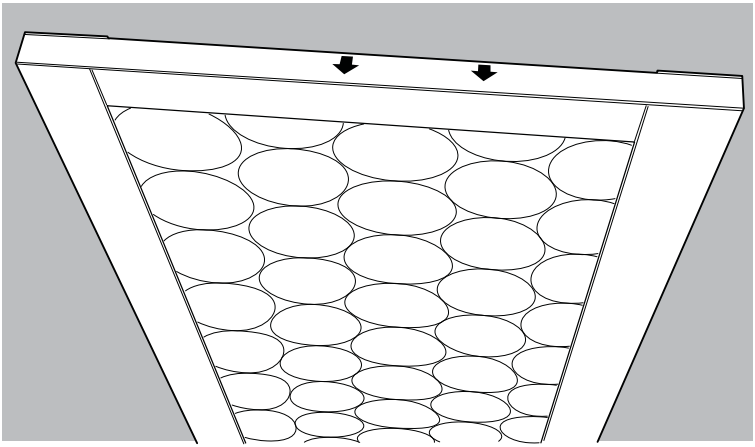
6. Remove the old air-filter element (3).
7. Take-out the new air-filter element.

   Contact your Agfa representative to order the air-filter element.

   AGFA ordering code: CM+ 9.5170.9855
8. Mount the air-filter element inside the rights side door as illustrated below.

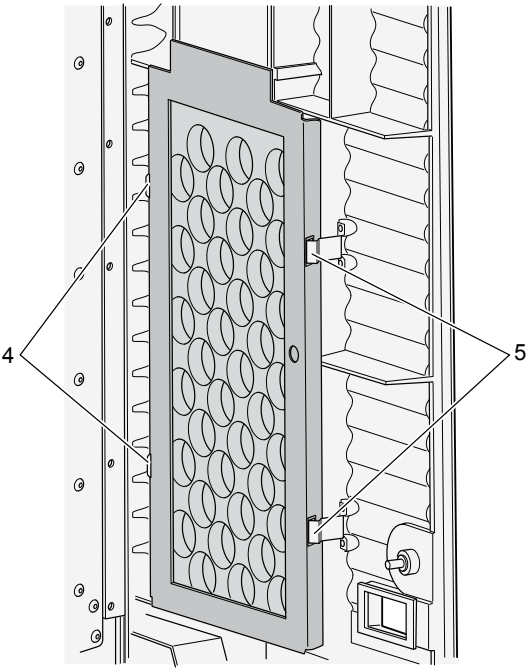
Note:

Mind the air flow arrows imprinted on the air filter when positioning the air-filter inside the door. The air flow arrows should always point to the inside of the machine.



9. Put back the air-filter frame.

- Insert the left side of the air-filter frame into the provided holes (4).
- Lock the right side of the air-filter frame using the 2 clamps (5).



10. Close the right side cover.

To close the right side cover, proceed as follows:

- Close the cover.
- Turn the latch through 90° counterclockwise and close the eye of the latching.

In case of a mobile device, unlock the upper right lock.

11. Plug the power plug into the socket.

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.

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.

Safety Directions

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

WARNING:
Improper changes, additions, maintenance or repair of the equipment or the software can lead to personal injury, electrical shock and damage to the equipment. Safety is only guaranteed when changes, additions, maintenance or repairs are carried out by an Agfa certified field service engineer. A non certified engineer performing a modification or service intervention on a medical device, acts on his own responsibility and makes the warranty void.

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.

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

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

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

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

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

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

Using unapproved spare parts

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

WARNING:
System unavailability due to hardware or software failure. If the product is used in critical clinical workflows, a backup system has to be foreseen.

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:
If there is any visible damage to the machine casing, do not start nor use the digitizer.

WARNING:
Do not override or disconnect the integrated safety features.

WARNING:
Switch off the digitizer 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.

CAUTION:
Switch the system off before moving it. When reaching the new position, fix the digitizer in place and switch the system on again.

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.

CAUTION:
Make sure that the digitizer is constantly monitored in order to avoid inappropriate handling, especially by children.

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

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.

CAUTION:
If you notice conspicuous noise or smoke, disconnect the digitizer immediately.

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.

Related Links

Training on page 13

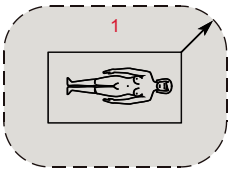
General Safety Instructions

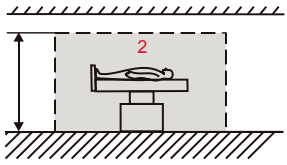
- Only service personnel with certified Agfa training must make repairs. Only authorized service personnel must make changes to the digitizer.
- As is the case for all technical devices, the digitizer must be operated, cared for and serviced correctly.
- If you do not operate the digitizer correctly or if you do not have it serviced correctly, Agfa is not liable for resulting disturbances, damages or injuries.
- Do not pour water or any other liquid over the device.

Note:

The DX-M only supports one type of mammography plates and cassettes at a time. It has to be decided to use either CR HM5.x or CR MM3.xR.

- The digitizer complies with the EN60601-1 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 the radius as listed below around the patient (according to the local valid regulation).





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

Figure 3: Patient environment

- 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 warning concerning radio interference in the paragraph 'Safety Directions' is heeded.

Quality Control

WARNING:
Regular Quality Control has to be applied according the local regulations. If no specific regulations are valid, a regular quality control applied with the Agfa Auto QC² tool at least once a month is required to maintain a safe and effective system.

WARNING:
For Mammography, constant quality control can be applied with the Agfa Auto QC Mammo tool or with the “Routine Quality Control Tests for Full Field Digital Mammography Systems” document, created by the NHSBSP (National Health Service Breast Screening Program, UK).

Getting started

Topics:

Basic Features

Topics:

DX-G/DX-M Features

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

- The digitizer has an input and output buffer for 5 cassettes. Consecutively on each cassette in the buffer, the digitizer:
  - takes the cassette from the input buffer in the digitizer.
  - locks the cassette containing the image plate in the cassette slot,
  - removes the image plate from the cassette,
  - scans the image plate,
  - converts the information of the latent image to digital data,
  - erases the image plate and re-inserts it into the cassette,
  - gives the image plate ID data the status 'erased',
  - unlocks the cassette,
  - transmits the digital image data to the workstation.
  - pushes the processed cassette into the output buffer.
  - permits re-routing of images to another workstation (limited demographic data of the image).
- The digitizer permits re-erasing an image plate before reusing it. In specific cases, this is necessary to prevent ghost images caused by previous exposures or scattered radiation from interfering with the image of interest.

Related Links

Re-erasing an Image Plate on page 66

Operating Modes

The digitizer can be operated in two modes:

Topics:

Operator Mode

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

- Re-erasing an image plate.
- Rerouting of images.
- Retrieving information with the information button.
- Changing touch panel properties (brightness and loudness of beeper).

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

Service Mode

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

The User Interface

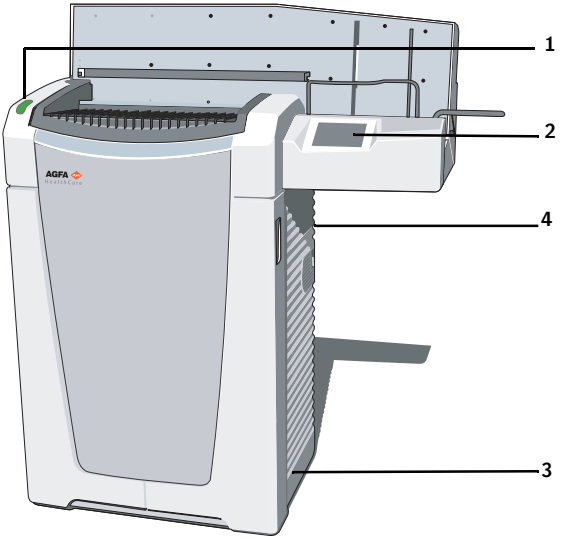
The digitizer has two operation modes:

- the **operator mode** for basic operation,
- the **service mode** reserved for trained service personnel.

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

The digitizer interfaces with the user via:

- a touch panel which enables access to all functions,
- a status indicator.



1. Status indicator.
2. Touch panel.
3. On/Off switch (main switch).
4. Ethernet connection (located at the rear side).

Figure 4: User interface

Status Indicator

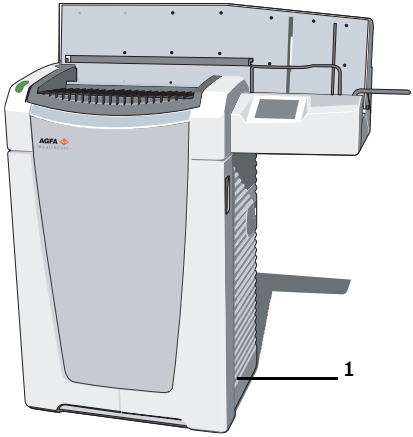
The indicator informs the user by light signals about the status of the digitizer (e.g. image plate erasing cycle progress, operational indications such as warm up,...). It is positioned at the front of the digitizer, so that it is visible from a distance.

Color	Constant/ Flashing	Status	Action
Blue	Constant	Activating the erasure cycle.	Enter cassettes into the input buffer for erasing.
	Flashing	Proceeding with the erasure cycle.	Remove cassettes from the output buffer.
Green	Constant	Stand-by mode (READY).	
	Flashing	Busy with scanning and transporting cassette and image plate.	Enter cassettes into input buffer for scanning. Remove cassettes from output buffer.
Red	Constant	Service mode	Check digitizer touch panel and workstation display for further information and detailed instructions.
		Fatal error	Contact an Agfa certified service engineer.
	Flashing	• Warm up / Self-test • Processing Software down • Error	Check digitizer touch panel and workstation display for further information and detailed instructions.

Starting the Digitizer

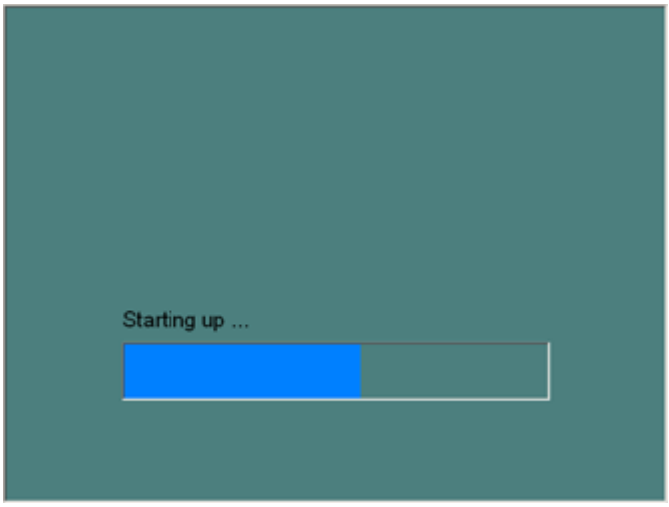
Procedure:

1. Make sure the digitizer is connected to a workstation and that the workstation is running the appropriate NX Software.
2. Make sure that the power plug is plugged into the socket.
3. Remove cassettes from the input buffer and input slot of the digitizer.
4. Press the main switch.



- Main switch

The Start Up screen is visible on the Touch panel:



The digitizer starts the following operation sequence:

- initialization of all components,
- functional test of all components,
- check for presence of cassettes and/or IPs.

During the warm-up and self-test, which may take up to 3 minutes, the digitizer status indicator is flashing red.

Note:

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

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

Note:

The brightness of the touch panel is temporarily reduced after not being used for a while.

Basic Workflow (Scanning Images)

Note: *The basic workflow is described in the DX-G/DX-M Workflow Sheets.*

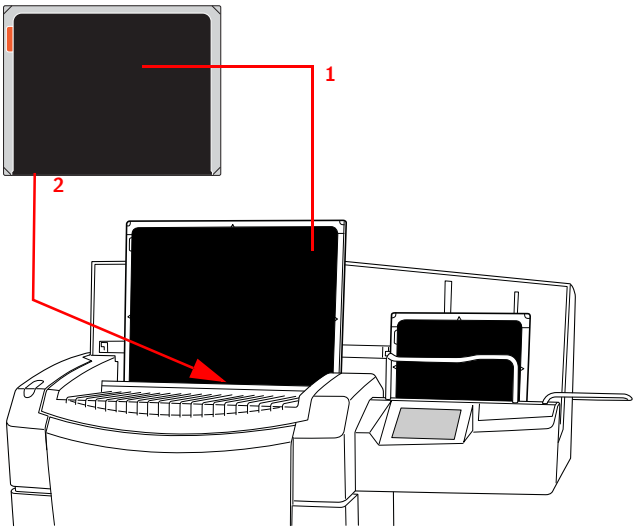
Workflow:

1. Identify the cassette with the ID Tablet and on a workstation.
2. Check that the digitizer is ready for operation.

   The status indicator must be continuously lighting up green or green flashing.
3. Put the cassettes with the exposed and identified image plates in the input buffer on the left side of the digitizer.

   There can be up to five cassettes in the input buffer.

   WARNING:
   Do not apply excessive shock or vibration to the digitizer, for example dropping of cassettes into the buffer during operation. This may decrease the image quality. Lower cassettes gently into the buffer.
4. Be aware of the orientation of the cassettes:



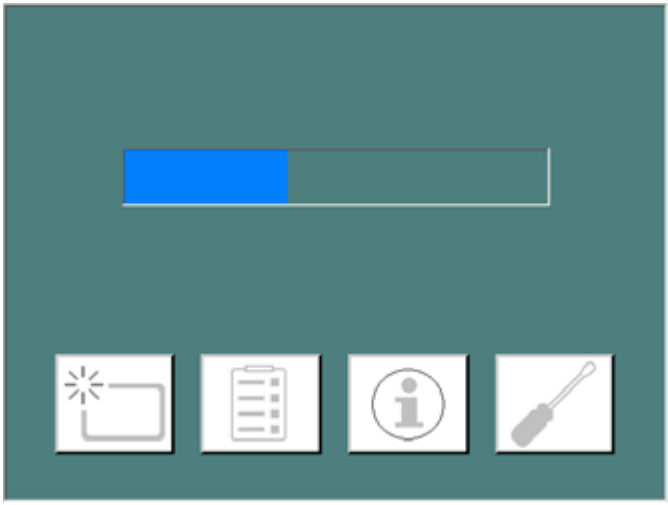
1. Tube side must be faced to the operator.
2. The shutter opening mechanism and locking mechanism must be pointed down, to the slot of the digitizer.

Figure 5: Cassette orientation

5. The cassettes are digitized subsequently:

   - The status indicator is green and blinking.
   - The digitizer stores images to disk.
   - The digitizer erases cassettes.

   The progress of the digitizing is shown, per cassette, on the touch panel:



6. Take the processed cassettes from the output buffer on the right side.

   When the digitizer has finished, the status indicator is continuously lighting up in green.

Stopping the digitizer

Topics:

Before Switching Off

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

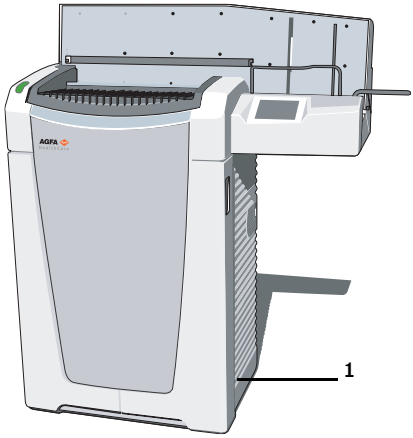
Switching Off

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

Note:

Only switch off the digitizer if you do not intend to digitize emergency image plates overnight. Switching on the digitizer takes approximately 3minutes. During this time emergency digitizing is not possible!

To switch off, press the main switch to the Off (“0”) position.



- Main switch

Advanced Operation

Topics:

Re-erasing an Image Plate

At the end of a digitizing cycle, the digitizer returns an erased image plate.

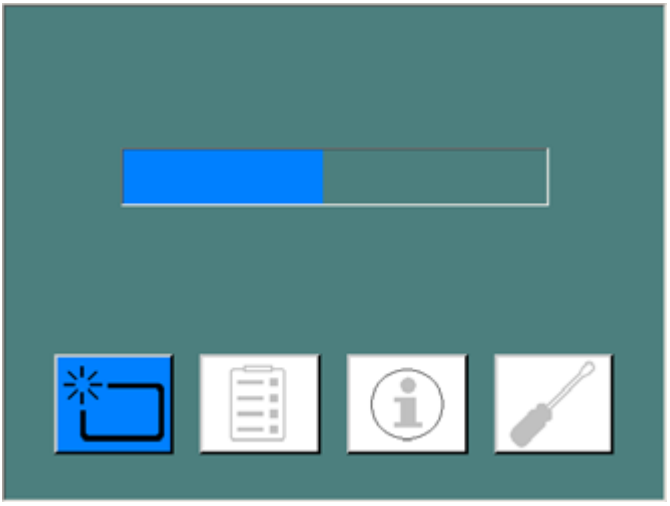
WARNING:
In specific cases, you must re-erase the image plate before re-using it in order to prevent ghost images from interfering with the image of interest.

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

To re-erase an image plate:

1. Check that the digitizer is ready for operation:

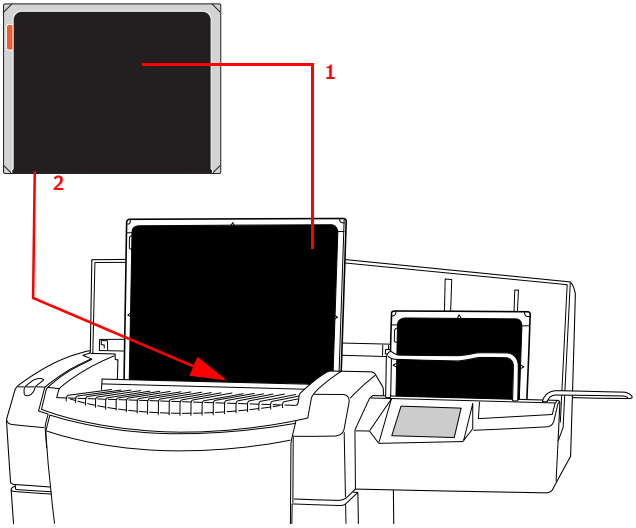
   The status indicator is continuously lighting up in green.
2. Press the Erase button on the touch panel at the front side of the digitizer.



   The digitizer switches to erase mode.

   The status indicator is continuously lighting up in blue.
3. Put the cassettes containing the image plate on the cassette buffer [1] of the digitizer as shown below.

Make sure to insert the cassette with the black (tube) side to the front and with the shutter opening mechanism and the locking mechanism down, towards the cassette slot.



1. Tube side must be faced to the operator.
2. The shutter opening mechanism and locking mechanism must be pointed down, to the slot of the digitizer.

Figure 6: Cassette orientation

As a result, the digitizer starts erasing the image plate and the status indicator is blue flashing.

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

4. Remove the cassette with the erased image plates from the cassette output buffer.
5. Press the Erase button again to switch to normal mode.

   One minute after the last cassette has been processed, the digitizer switches from “erasure” mode to “normal mode”.

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 10 seconds to enter a cassette. If you do not, the digitizer returns to the standby mode.

Related Links

DX-G/DX-M Features on page 54

Re-routing of an Image

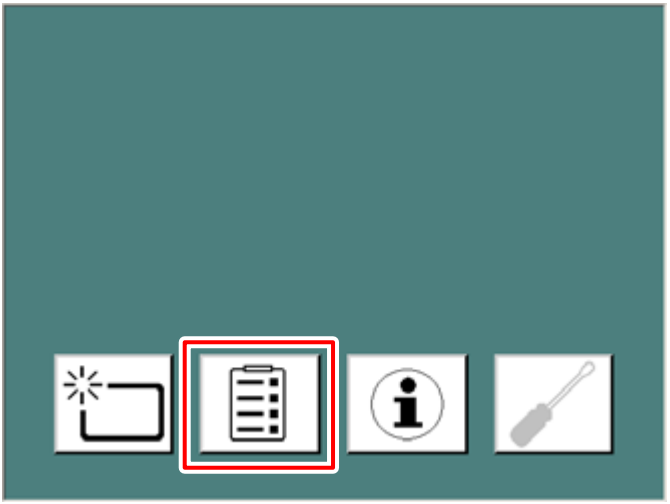
Normally, an image is sent to the workstation where it was identified. But in case of transmission problems, the image can be rerouted on the digitizer and sent to an alternative workstation.

WARNING:

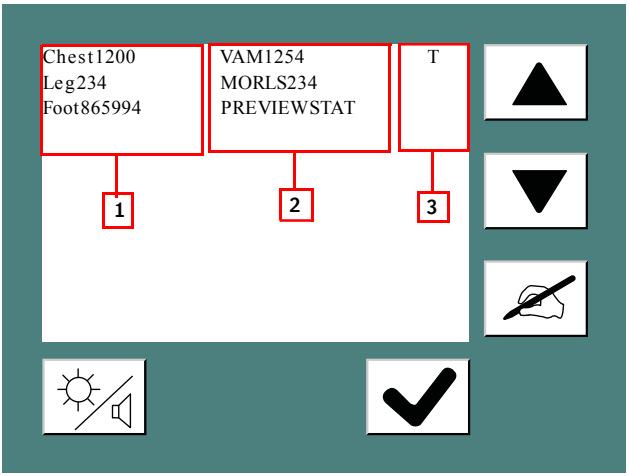
The demographic data selected during original identification are lost. On the new workstation, the demographic data have to be filled in manually.

To reroute an image

1. In the Standby window, click the Configuration button.

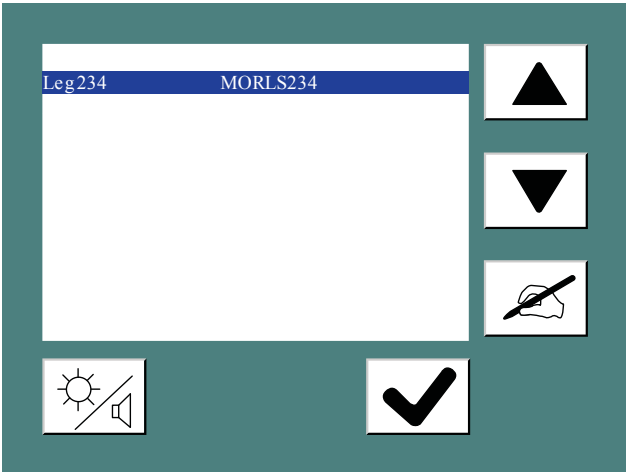


The Rerouting window appears.



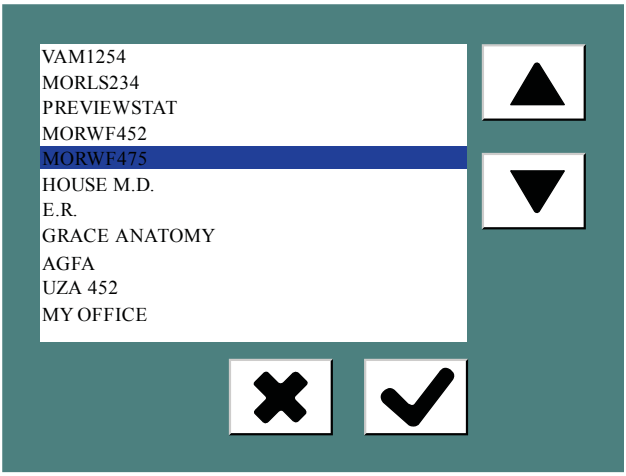
1. Image UID.
2. Workstation.
3. Status: T - Transmitting (the digitizer is busy transmitting the image) / W - Warning (the image transmission has failed; manual re-transmission to a new workstation necessary) / Q - Queued (the image is in the transmission queue; a manual transmission to another workstation is possible).

2. Select the image you want to reroute.



3. Click the Destinations button.

The following window appears.



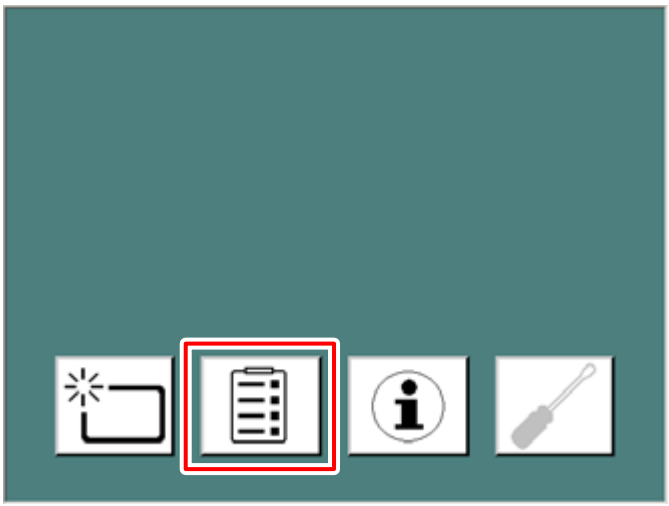
4. Select the new workstation and confirm by clicking the Confirm button.

Turning the Volume of the Digitizer Signals and Beeps On or Off

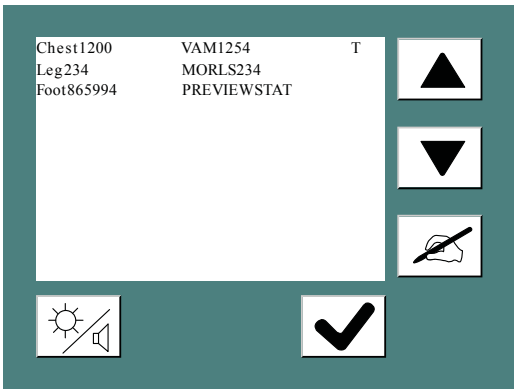
You can turn the volume of digitizer signals and beeps on or off.

To turn the volume on or off:

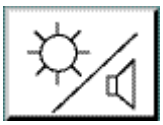
1. In the Standby window, click the Configuration button.



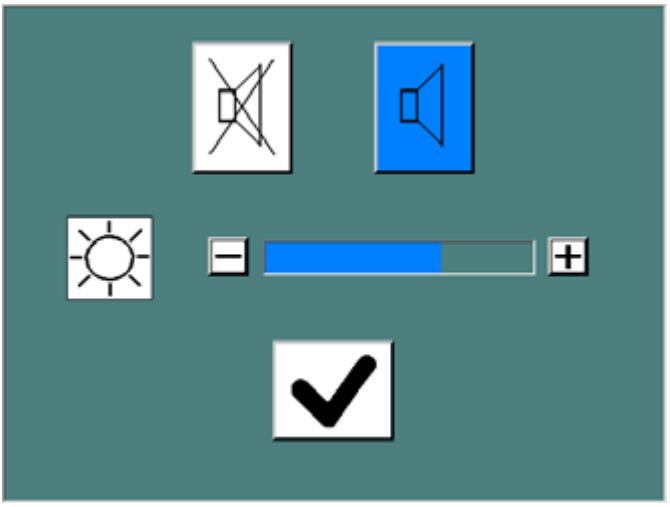
The Configuration window appears:



2. Click the brightness/loudness button.



The following window appears.



3. Do one of the following:

   - 

     Turn the volume on.
   - 

     Turn the volume down.

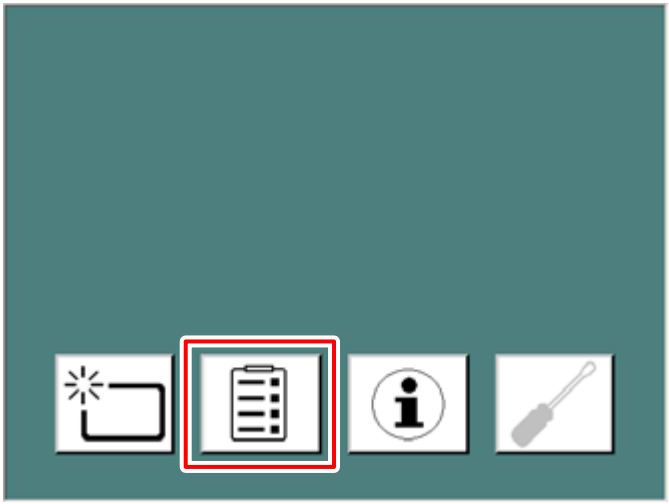
   As a result the selected button lights up in blue.

Changing the Brightness of the Touch Panel

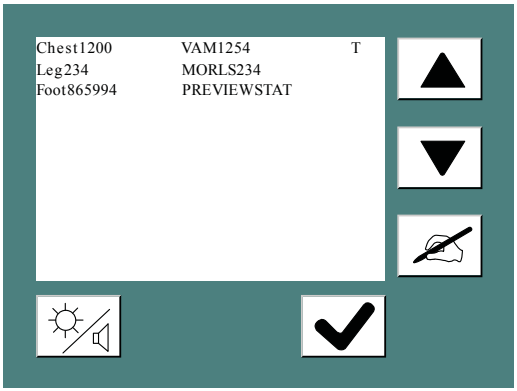
You can change the brightness of the touch panel on the digitizer.

To change the brightness:

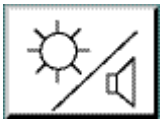
1. In the Standby window, press the Configuration button.



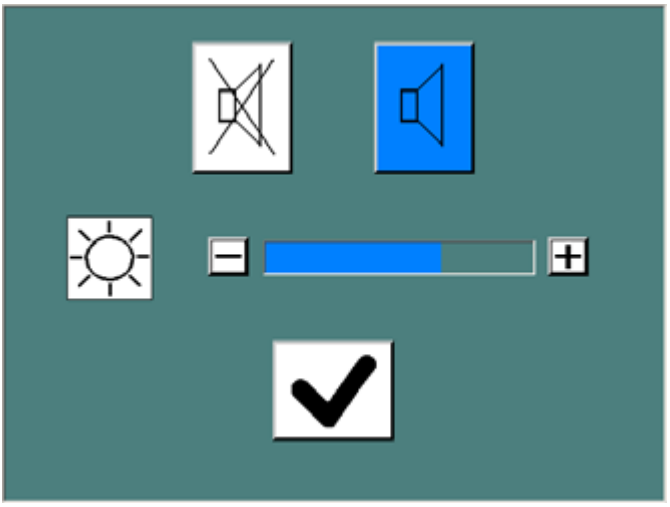
The Configuration window appears:



2. Click the brightness/loudness button.



The following window appears.

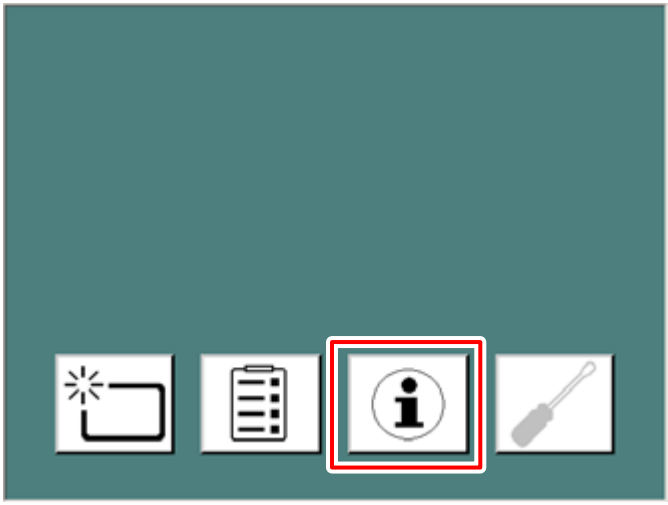


3. In the Brightness section on the lower part of the Configuration window, use the + or - buttons to adjust the brightness.

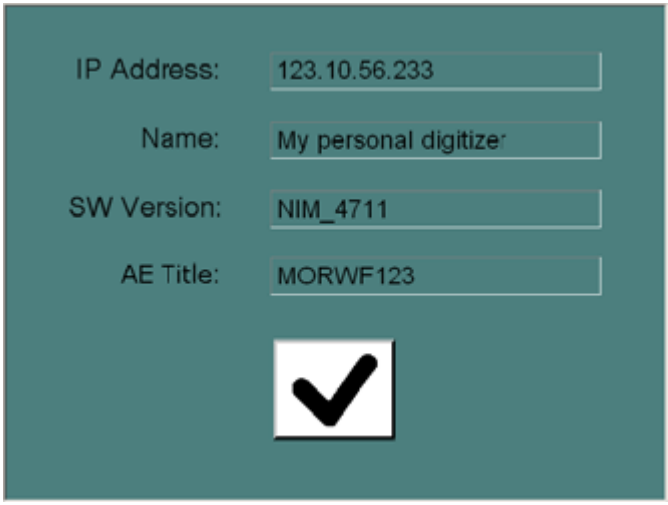
Retrieving Information About the Digitizer

To retrieve information:

1. In the Standby window, press the Information button.



The Information window appears, showing the IP Address, Name, Software version and name of the primary NX workstation:



2. Click the Confirm button to go back to the Standby window.

Troubleshooting and Errors during Operation

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

- The first is always to check the status indicator on the digitizer: during errors it will continuously lighting up in red or flashing red.
- The second is checking why the digitizer does not start-up.
- Finally you can check the connection to the NX workstation.

Topics:

Status Indicator: continuously red

If the status indicator is continuously lighting up in red, your digitizer deals with a fatal error.

Proceed as follows:

1. Do not try to solve this problem.
2. Contact immediately your Agfa certified service engineer for more information.

Figure 7: Example fatal error (status indicator continuously red)

Status Indicator: flashing red

If the status indicator is flashing red, your digitizer deals with an error that can be remedied by the operator. Always follow the instructions that appear on the touch panel.

For example; if you wrongly insert the cassette, with the exposed and identified image plate, in the input buffer, the following instructions will appear on the touch panel:

Proceed as follows:

1. Put the cassettes with the exposed and identified image plates wrongly in the input buffer on the left side of the digitizer.
2. As a result, the digitizer moves the cassette into the intermediate position and the following error message appears.

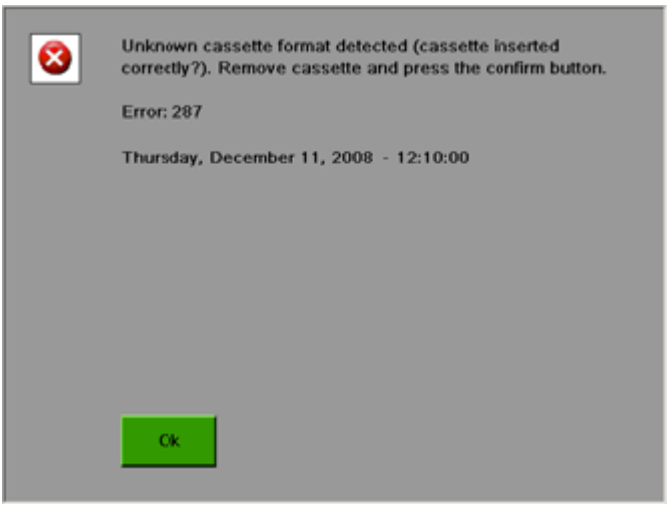


Figure 8: Example remediable error (status indicator flashing red)

3. Click the Confirm button.
4. Remove the cassette from the output buffer.
   Now you can re-enter the cassette correctly.

Digitizer does not Start up

If the digitizer does not start up, check the power supply, wall socket and safety fuse.

If the power supply is ok, call your local Service engineer.

Technical Data

Topics:

Specifications

Dimensions	
Max. Height	1229mm (48.4 inch)
Max Floor space WxD	660mm x 510mm (26.0inch x 20.1inch)
Max Projected Floor space WxD	1150mm x 510mm (45.3inch x 20.1inch)
Weight	
Unpacked	approximately 180.0kg (396.8 lb)
Buffer	
Input/output cassette buffer	5 cassettes
Integrated data buffer	If the connection to the workstation is interrupted (e.g. workstation is shut off), the digitizer will finish actual scanning-job and temporary store the image until the connection to the NX workstation is re-established. A new cassette will only be accepted if the previous transmission job has been finished.
Greyscale resolution	
Output to workstation	16 bits/pixel square root compressed
Electrical connection	
Operating voltage	Autosensing power supply from: 100Vto 240V, AC +/-10%
Operating current	6.3 A (100 - 120 V) 2.6 A (220 - 240 V)
Mains fuse protection	Europe: 16A USA Japan: 15A
Mains frequency	50-60Hz
Network connectivity	
Ethernet connector	
Power consumption (typical values)	

220V - 240V / 50-60Hz configuration	
Standby	87W
Average continuous scanning	237W
During scanning	590W max.
100V - 120V / 50-60Hz configuration	
Standby	92W
Average continuous scanning	245W
During scanning	621W max.
Environmental conditions (during operation)	
In line with IEC721-3-2: 2M2 and 2K2 with following restrictions:	
Room temperature	Agfa CR HM5.x Mammo: between +20°Cand+30°C (68 - 86°F) Other plates and cassettes: between +15°Cand +30°C (59 - 86°F)
Maximum temperature change rate	max. 0.5°C/min (0.9°F/min)
Relative humidity	between 15%and75% (non-condensing)
Light	no exposure to direct sunlight, max. 2500Lux
Environmental conditions (during storage)	
Room temperature	between -25 °C and 55 °C
Relative humidity	between 10% and 95%
Barometric pressure	between 70 kPa and 106 kPa
Environmental conditions (during transport)	
Room temperature	between -25 °C and 55 °C
Relative humidity	maximum 85%
Barometric pressure	minimum 70 kPa
Environmental conditions for mobile installation (during transport)	
In line with IEC721-3-5: 5M1 and 5K1 with following restrictions:	

Room temperature	between 10 °C and 40 °C
Environmental conditions for mobile installation (during operation)	
In line with IEC721-3-3: 3M1 and 3K2 with following restrictions:	
Room temperature	Agfa CR HM5.x Mammo: between +20°Cand+30°C (68 - 86°F) Other plates and cassettes: between +15°Cand +30°C (59 - 86°F)
Relative humidity	between 15%and75% (non-condensing)
Vibration	40 - 200 Hz; 1 m/s²; sinusoidal vibration
Barometric pressure/altitude	
Highest pressure	106 kPa (at sea level)
Lowest pressure	70 kPa (3000 m above sea level)
Warming-up time	
Cold start	3min.
Physical emissions	
Noise emission (sound power level according to ISO7779)	
During scanning	max. 65dB(A)
Standby	max.45dB(A)
Heat emission per hour (typical values)	
During continuous operation (with standard erasure time)	245 Wh / 836 BTU
Standby	92Wh / 314BTU
RFID reader	
Frequency	13.56 MHz
Bandwidth	14 kHz
Maximum power	290 pW
Protocol	MIFARE
Plates and cassettes	
Compatible cassette/IP types DX-G	Agfa CR HD5.x General, FLFS, AEC, Extremities.

	Agfa CR MD4.xR General, FLFS.
Compatible cassette/IP types DX-M	Agfa CR HD5.x General, FLFS, AEC, Extremities. Agfa CR MD4.xR General, FLFS. Agfa CR HM5.x Mammo. Agfa CR MM3.xR Mammo.
Throughput (using the default erasure cycle)	
The cassette throughput (plates/hour) depends on the cassette format and is based on the standard image plate erase dose.	• 35 x 43SR (HD5.x/MD4.xR): 83 • 35 x 43HR (HD5.x/MD4.xR): 72 • 35 x 35SR (MD4.xR): 83 • 35 x 35HR (MD4.xR): 71 • 24 x 30 (HD5.x): 85 • 24 x 30 (HD5.x Extremities): 43 • 24 x 30 (MD4.xR): 83 • 18 x 24 (HD5.x): 93 • 18 x 24 (HD5.x Extremities): 51 • 18 x 24 (MD4.xR): 90 • 15 x 30 (HD5.x): 100 • 15 x 30 (MD4.xR): 97 • 24 x 30 (HM5.x): 41 • 24 x 30 (MM3.xR): 40 • 18 x 24 (HM5.x): 49 • 18 x 24 (MM3.xR): 48
End of Life	
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	7 yrs.
Preventive maintenance	
Preventive maintenance frequency. Needs to be done by an Agfa certified field service engineer.	Once a year or 25000 cycles, whatever comes first.

BTU: British Thermal Unit

Pixel Matrix Size

Cassette type	Format (cm)	Resolution (pixel/mm)	Width x Length (pixels)	Width x Length (mm)
CR MD4.0R General	35x43 HR	10	4248 x 3480	424.8 x 348.0
	35x35 HR	10	3480 x 3480	348.0 x 348.0
	35x43 SR	6.66	2832 x 2320	424.8 x 348.0
	35x35 SR	6.66	2320 x 2320	348.0 x 348.0
	24x30	10	2928 x 2328	292.8 x 232.8
	18x24	10	2328 x 1728	232.8 x 172.8
	15x30	10	2928 x 1440	292.8 x 144.0
CR MD 4.0R FLFS	35x43	10	4392 x 3480	439.2 x 348.0
CR HD5.0 General/AEC	35x43 HR	10	4200 x 3408	420.0 x 340.8
	35x43 SR	6.66	2800 x 2272	420.0 x 340.8
	24x30	10	2880 x 2256	288.0 x 225.6
	18x24	10	2280 x 1656	228.0 x 165.6
	15x30	10	2880 x 1344	288.0 x 134.4
CR HD5.0 FLFS	35x43	10	4368 x 3408	436.8 x 340.8
CR HD5.0 Extremities	24x30	20	5760 x 4512	288.0 x 225.6
	18x24	20	4560 x 3312	228.0 x 165.6
CR MM3.xR Mammo	24x30	20	5844 x 4710	292.2 x 235.5
	18x24	20	4644 x 3510	232.2 x 175.5
CR HM5.x Mammo	24x30	20	5844 x 4708	292.2 x 235.4
	18x24	20	4644 x 3508	232.2 x 175.4

Connectivity

The digitizer is connected to one or more NX workstations via an ethernet connection and uses a dedicated protocol to communicate with the workstation.

Environmental protection

Figure 9: WEEE symbol

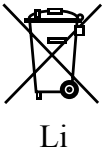


Figure 10: Battery symbol

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.

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 might not offer adequate protection to radio-

Harmonic emission in accordance with IEC 61000-3-2	Class A	frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Voltage fluctuations / flickering in accordance with IEC 61000-3-3	Fulfilled	

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Topics:

- *Immunity to RF wireless communication equipment*

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

Immunity to RF wireless communication equipment

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

Precautions on EMC

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

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

Cables, transducers and accessories

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

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

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

No additional accessories available.

Maintenance on EMC relevant parts

Concerning the EMC safety of the DX-G and DX-M devices, no relevant parts could be inspected by the operator. EMC relevant parts will be inspected from AFGA service engineer within the regular service interval until the end of lifetime. The needed verifications are described in the service manual.