CR 85-X Digitizer

User manual

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AGFA HealthCare

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Manufacturer: Agfa HealthCare NV, Septestraat 27, B-2640 Mortsel - Belgium

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Chapter 1

Introducing the CR 85-X

This chapter draws attention to important safety precautions and introduces the CR 85-X.

CR 85-X intended use

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

CR 85-X 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.

CR 85-X features

The CR 85-X™ scans the exposed CR image plate, converts the information into digital data and automatically transfers the image to the image processing station for further processing and visualization.

The CR 85-X requires but little manual interaction. All you have to do, after exposure and identification of the cassette, is to place it in the input buffer of the CR 85-X. You can deposit up to 10 cassettes of different sizes simultaneously in the input buffer. The Digitizer takes in the cassettes one by one. The Digitizer reads the demographic data and routing information from the memory chip in the cassette, opens the cassette, removes the image plate and scans the latent image by means of a sweeping laser beam.

Once the image is digitized, the cassette is returned to the output buffer to be used for new exposures. After a full Digitizer cycle, the plate has turned 180° in the cassette.

Depending on the X-ray intensity which has affected the phosphor during the exposure, more or less light will be emitted during laser scanning. The light is converted into an electrical signal. This signal is then converted into a digital bit stream. Once converted into digital form, the digitized image is transferred to the image processing station for further processing and visualization.

Further features of the CR 85-X include:

- The CR 85-X permits assigning the status ‘emergency’ to an image. An emergency image will be given priority by the image processing station.
- The CR 85-X permits re-erasing an image plate before re-using it. In specific cases, this is necessary to prevent ghost images caused by previous exposures or stray radiation from interfering with the image of interest. You can erase a batch of up to 9 image plates.

Warnings, Cautions and Notes

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

WARNING: **Warnings are directions which, if they are not followed, can cause serious or fatal injuries.**

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

Instruction : Follow the instruction literally to avoid the topic of warnings.

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

Equipment Classification

Class I Equipment	Equipment in which protection against electric shock does not rely 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 applicable: The patient does not get in contact with any part of the device.
Water Ingress	This device does not have protection against ingress of water.
Cleaning	See section "Cleaning and Disinfection" on page 22.
Disinfection	See section "Cleaning and Disinfection" on page 22.
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.
Continuous Operation	The unit is suitable to run continuously.

Training

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

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

- CR 85-X intended use
- CR 85-X intended user
- Safety precautions

Product Complaints

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

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

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

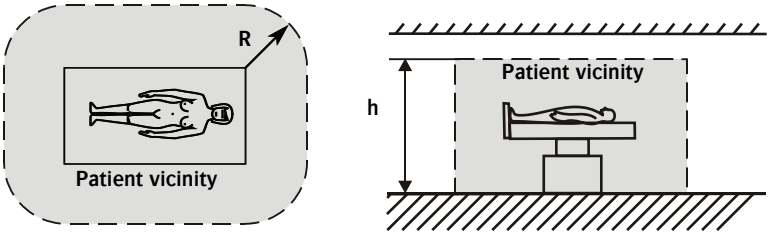
Agfa HealthCare N.V. - Septestraat 27 - 2640 Mortsel, Belgium.
Agfa HealthCare N.V. - Fax +32 3 444 7094.

Safety precautions

General safety instructions

- For software and other technical platforms, and/or in combination with any consumable, which constitute, after installation, a system for the interpretation of medical image data: such system is used by trained and qualified professionals. It is the user's responsibility to ensure that image quality, display quality, environmental lighting and other possible distractions are consistent with the clinical application.
  The user must be aware, that automatic collimation could possibly lead to misinterpretation of the image.
- Make sure that the CR 85-X 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 CR 85-X.
- If there is any visible damage to the machine casing, do not start nor use the CR 85-X.
- If you want to connect the CR 85-X with other devices, components or assemblies and if the technical data do not permit determining whether the combination with these devices, components or assemblies involves hazards, you must consult the respective manufacturers to avoid danger for operating personnel or the environment.
- Do not override or disconnect the integrated safety features.
- As is the case for all technical devices, the CR 85-X must be operated, cared for and serviced correctly.
- If you do not operate the CR 85-X correctly or if you do not have it serviced correctly, Agfa is not liable for resulting disturbances, damages or injuries.

- When installing the CR 85-X, 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 CR 85-X and that it is easily accessible.
- If you notice conspicuous noise or smoke, disconnect the CR 85-X immediately.
- Check that the mains voltage is within the specified range of the self adapting power supply of the machine.
- 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).

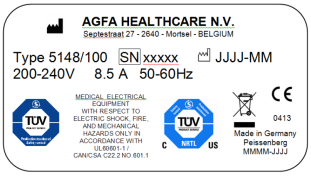
h = 2.5 m/8.2 feet (EN 60601-1) or 2.29 m/7.5 feet (UL 60601-1).

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

Markings and 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 CR 85-X 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 the appropriate IEC 601-1 and IEC 601-1-1 harmonized national standard. In addition all configurations must comply with the medical electrical systems standard IEC 601-1-1. The party that makes the connections acts as system configurator and is responsible for complying with the systems standard. If required contact your local service organization.
	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 CR 85-X and the potential equalization busbar of the electrical system as found in medical environments. This plug should never be unplugged before the power is turned off and the power plug has been removed. It is recommended to use the supplementary protective earth connection as additional safety measure.
	Intergrounding connector: Provides a connection between the Digitizer and other equipment which might exhibit minor ground potential differences. These differences may degrade the quality of communication between different equipment. Never remove connections to this terminal.

	Protective earth (ground): Provides a connection between the Digitizer and the protective earth of the mains. Do not remove this connection, because this will have a negative influence on the leakage current.
	Power on
	Power off Note that the power cord has to be disconnected from the wall outlet in order to disconnect the unit entirely from the mains.
	Precautions for use in USA only: Make sure that the circuit is single-phase center-tapped, if the Digitizer is connected to a 240 V/60 Hz source instead of a 120 V/60 Hz source.
	Type label
	Date of manufacture
	Manufacturer
	Serial number
	WEEE symbol, see section Environmental Protection
	Device contains a transmitter module

- You can hurt your fingers if they are caught between the CR cassette and the edge of the input slot. Insert the cassette in the input buffer as described in *'Reading an image plate'* on page *38*. At all times, keep your fingers clear of the input slot. As soon as the CR 85-X takes in the cassette, release it.

Safety instructions for laser products

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

Under normal operating conditions - when both doors are closed - there can be no laser radiation outside the CR 85-X. It is nonetheless imperative that the local radiation safety regulations regarding the protection of staff against scattered radiation are complied with, if the CR 85-X is located in the immediate vicinity of an X-ray room.

Open the front left and right door only to solve cassette or image plate jams. When you open either of the doors, the power supply of all critical components is switched off automatically as a precaution.

Observe the Caution instructions on the Optical module label:

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

Safety compliance

The CR 85-X complies with:

- general safety standards:
  IEC 60601-1: 2005,
  EN 60601-1: 2006,
  EN 60601-1:1990+A1:1993+A2:1995,
  IEC 60601-1:1988+A1:1991+A2:1995,
  IEC 60601-1-1 / EN 60601-1-1,
  EN 60601-1-2,
  UL 60601-1;
- laser safety standards:
  EN 60825, DHHS/FDA 21 CFR, Parts 1040.10 and 1040.11, ANSI Z 136-1980.

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 valid version of the system standard IEC 60601-1-1 respectively IEC 60601-1:2005. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1 respectively IEC 60601-1:2005. If in doubt, consult your local service organization.

Operating modes

The CR 85-X can be operated in three modes: operator mode, key-operator mode and service mode.

Operator mode

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

- Reading an image plate;
- Reading an emergency image plate;
- Re-erasing an image plate.

A normal image plate is read automatically after it is placed in the CR 85-X input buffer; the other functions of the operator mode can be accessed via the keypad. All functions of the operator mode are described in *Chapter 2, 'Basic operation ('Operator mode')'*.

Key-operator mode

The key-operator mode groups advanced functions which are aimed at technicians.

The key-operator mode can be accessed via the Key-operator key on the keypad and is menu-driven. The key-operator functions are described in *Chapter 3, 'Advanced operation ('Key-operator mode')'*.

Service mode

The service mode functions are reserved for trained service personnel. They are password protected.

Maintenance

Preventive maintenance

Regular preventive maintenance needs to be done once per 6 months or after 25000 cycles (whatever comes first).

You cannot perform this maintenance yourself. It has to be done by an Agfa certified field service engineer.

Not performing the regular maintenance by appropriately certified people can have impct on warranty commitments.

Recurrent safety tests

The digitizer 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.

Cleaning and Disinfection

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

To clean the exterior of the digitizer:

1 Switch off the digitizer.

2 Remove the power plug from the socket.
Switch off the UPS, if installed.

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

Caution: Make sure no liquid gets in the digitizer.

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

4 Plug the power plug into the socket.
Switch on the UPS, if installed.

Patient data security

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

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

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

Environmental Protection

WEEE end user information

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

The directive on Waste Electrical and Electronic Equipment (WEEE) aims to prevent the generation of electric and electronic waste and to promote the reuse, recycling and other forms of recovery. It therefore requires the collection of WEEE, recovery and reuse or recycling. This directive has to be implemented into national law by the individual European countries by August 13, 2005.

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

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

For more detailed information about take-back and recycling of this product please contact your local Agfa service organization and/or Agfa dealer. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources.

Battery Notice

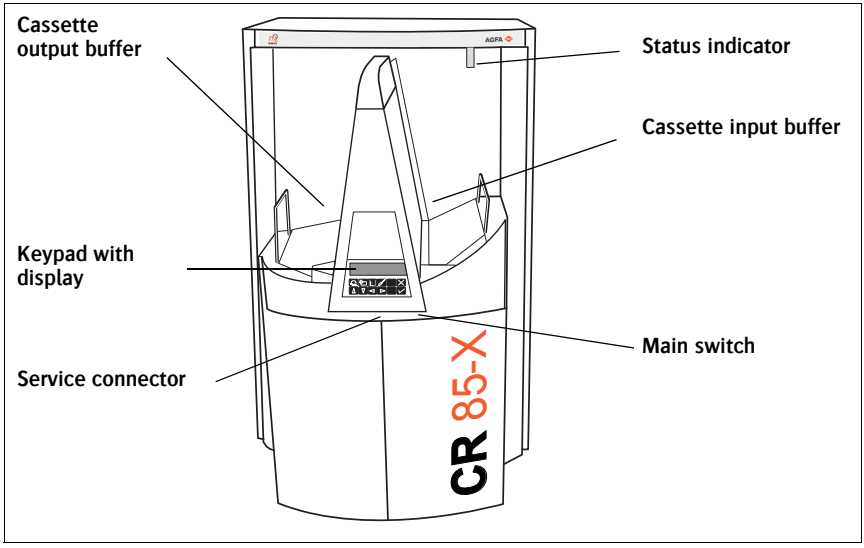
This wheeled bin symbol on the products, and/or accompanying documents means that the used batteries should not be treated as, or mixed with general household waste.

This wheeled bin symbol on batteries or its packaging may be used in combination with a chemical symbol. In cases where a chemical symbol is available it indicates the presence of respective chemical substances. If your equipment or replaced spare parts contain batteries or accumulators please dispose of them separately according to local regulations.

For battery replacements please contact your local sales organization.

The user interface

Main components of the Digitizer



The main components of the CR 85-X are:

- Cassette input buffer

  The cassette input buffer accepts up to 10 cassettes - even of different sizes - for digitizing and up to 9 cassettes for erasure.

- Keypad

  As the handling of the cassettes is fully automated, normal operation is a zero-button operation. The keys on the keypad are only used to activate special

functions such as reading an emergency image plate or erasing an image plate.

- Status indicator

  A light indicates the status of the CR 85-X.

- Cassette output buffer

  The cassette output buffer receives cassettes which have been handled by the Digitizer.

The control panel

The control panel of the CR 85-X consists of a backlit LCD display and 10 keys.

As the handling of the cassettes is fully automated, normal operation is a zero-button operation. Only when you are performing special functions or in the event of problems (e.g. a cassette or image plate jam), you will need the keys.

The keypad

Special functions can be accessed via the keypad. The keypad features the following keys:

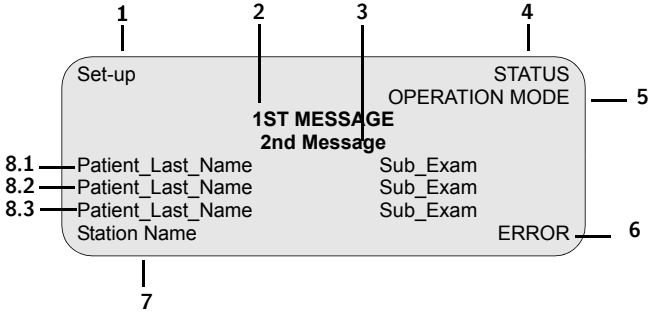
	**Emergency** key	To give an image the status 'emergency' when it is sent to the image processing station.
	**Erase** key	To erase images without digitizing them. This must be done if: • an image plate has not been used for more than 3 days; • an image plate has been exposed to an exceptionally high X-ray dose.
	**Key-operator** key	To access advanced functions ('key-operator functions').
	**Service** key	To access service-level functions. Reserved for trained service personnel.
	**Escape** key	To quit the current function or exit a menu without saving modifications.
	**Confirm** key	In key-operator mode: • to select a menu. • to accept an entry in a menu and go back to operator mode.

	**Up** key	• To move the cursor to the previous entry field. • To scroll upwards. • To increment the number in a numeric entry field.
	**Down** key	• To move the cursor to the next entry field. • To scroll downwards. • To decrement the number in a numeric entry field.
	**Left** key	• To scroll backwards through multiple choices within a field. • To move the entry position in a numerical entry field from right to left. • To toggle between values in a field.
	**Right** key	• To scroll forwards through multiple choices within a field. • To move the entry position in a numerical entry field from left to right. • To toggle between values in a field.

The display

The CR 85-X control panel has a backlit LCD display with 8 lines of 40 characters each. Its lay-out depends on the operating mode.

In **operator mode**, the display has dedicated areas for specific information:



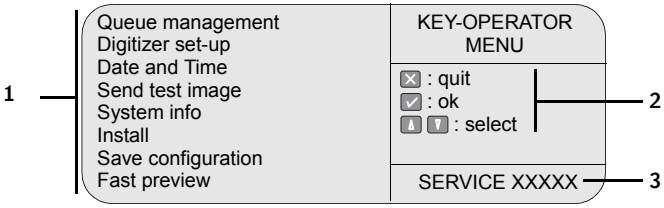
1	Set-up of image processing station: • [blank]: Default image processing station selected. • Off line: Transmission to all image processing stations disabled. • [process.station] not ready: Image processing station not available. • [process.station] rerouted: Images rerouted to other image processing station.
2	Type of message
3	Extra comment or action to take
4	System status: • READY: The CR 85-X is ready for operation. • BUSY: The CR 85-X is busy with scanning or erasing. • ERROR: An error has occurred. • LOCKED: id. • WARNING: id.

5	Operation mode: • [blank]: Normal operation mode. • EMERGENCY: Emergency function for image plates with ID data. • ERASURE: Re-erasure function.
6	Error status: service code (SERVICE XXXXX) or error code (CODE XXXXX)
7	Station name of the CR 85-X
	Identifier of image plate being treated:
8.1	After image ID data is read;
8.2	During scanning of image plate and transmittal of image data;
8.3	During transmittal of image data to image processing station.

If the system has been idle for 5 minutes, the backlit LCD display dims. The display lightens if:

- The display message changes, e.g. if the Digitizer receives a message from the image processing station.
- You place a cassette in the input buffer.
- You press a key on the keypad.

In **key-operator mode**, operation is menu driven. The menu displays the key-operator functions, the active keys, and the service code.



1	Key-operator functions
2	Active keys
3	Service code

The status indicator

The light at the top of the CR 85-X indicates the status of the CR 85-X.

Color	Constant/ Flashing	Status	Action
Green	Constant	Ready.	Proceed.
	Flashing	Busy (treating image plate).	Proceed.
Red	Constant	Error.	• Check display for messages. • Refer to *'General procedure in case of malfunction'* on page *51*.
	Flashing	• Locked or warning. • Power on/self-test in progress. • Key-operator mode. • Service mode. • CR 85-X not connected to image processing device.	• Check display for messages. • Refer to *'General procedure in case of malfunction'* on page *51*.

Audio signals

The CR 85-X gives status information via beeps. The length of the beep indicates the response of the system to a key command.

- A **short** beep means that CR 85-X has accepted the key command and is starting the operation.
- A **long** beep means that you have pressed a non-active key or that the CR 85-X has rejected the key command.
- An **interval** beep accompanies an error, locked or warning message. Refer to *Chapter 3, 'Advanced operation ('Key-operator mode')'*.

Switching on the CR 85-X

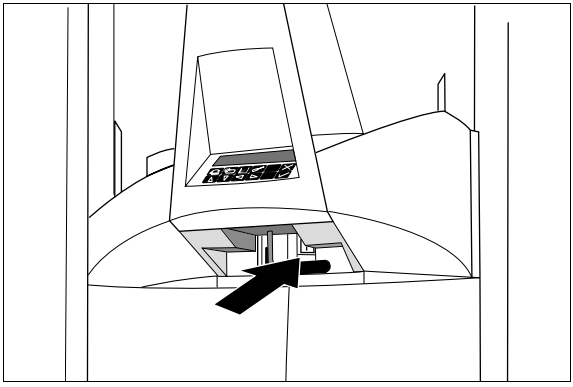
Before switching on

Make sure that the following conditions are met before you switch the CR 85-X on:

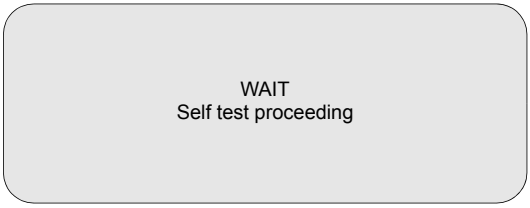
- A service technician has appropriately connected the CR 85-X and has carried out a performance test.
- You have read the safety precautions at the beginning of this manual and you will observe them while working with the CR 85-X.
- You are acquainted with the basic functions of the Digitizer.

Switching on the CR 85-X

Locate the main switch and place it in position ‘ON’.



After the Digitizer has been switched on, the following screen is displayed:



The CR 85-X executes a self-test, initializes all the Digitizer components, goes through a start-up procedure and checks for cassettes, image plates and images still to be transmitted in the image queue. During this stage, the status indicator is red and flashing.

If the CR 85-X has completed the self-test successfully, the CR 85-X enters the operator mode and displays the main operator screen:

The status indicator is constant green. The CR 85-X is ready for use.

If the CR 85-X displays:

An error has occurred during the self-test. Refer to Chapter 3, 'Advanced operation ('Key-operator mode')'.

Switching off the CR 85-X

Before switching off

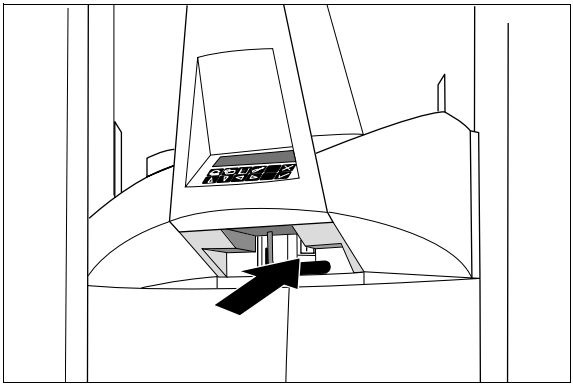
Check that the CR 85-X is not scanning an image plate. If the CR 85-X is scanning an image plate, the status indicator at the top of the machine is green and flashing.

Switching off

It is recommended to switch off the CR 85-X at the end of the day.

WARNING: Only switch off the CR 85-X if you do not intend to digitize emergency image plates overnight. Switching on the CR 85-X takes a few minutes. During this time emergency digitizing is not possible!

Place the main switch in position 'OFF'.



Note: To remove the device from the mains supply disconnect the mains plug.

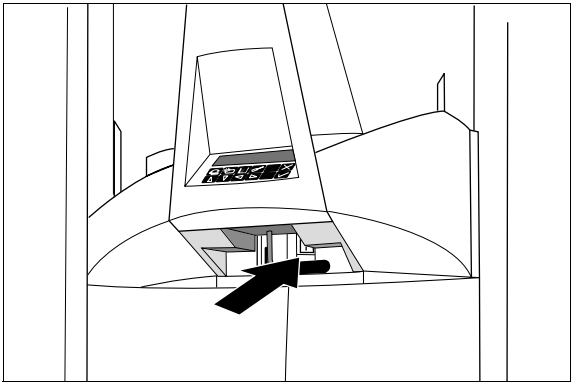
Resetting the CR 85-X

In exceptional circumstances you may be prompted to reset the CR 85-X, either by a message on the keypad or as part of a troubleshooting procedure in this manual.

Caution: Never reset the Digitizer to solve a plate or cassette jam. If you would do so, the plate inside the Digitizer might get damaged. In case of a plate or cassette jam, always follow the procedures described in *Chapter 4, 'Preventive maintenance and troubleshooting'* of the Reference manual.

To reset the Digitizer:

1 Locate the main switch and place it in position 'OFF'.



2 Wait 30 seconds.

3 Place the main switch in position 'ON'.

Chapter 2

Basic operation (‘Operator mode’)

This chapter provides basic information on how to digitize image plates under normal conditions and in emergency situations. It also treats how to erase an image plate to prevent ghost images caused by previous exposures or by scattered radiation. These functions are available in operator mode.

- Reading an image plate
- Reading an emergency image plate
- Re-erasing an image plate

Reading an image plate

The main function of the CR 85-X is digitizing image plates and transmitting the digital image data to the preview station and the image processing station.

To read one or more image plates:

1 Make sure the cassette has been properly identified via the ID Station.
Refer to the User manual of the ID Software.

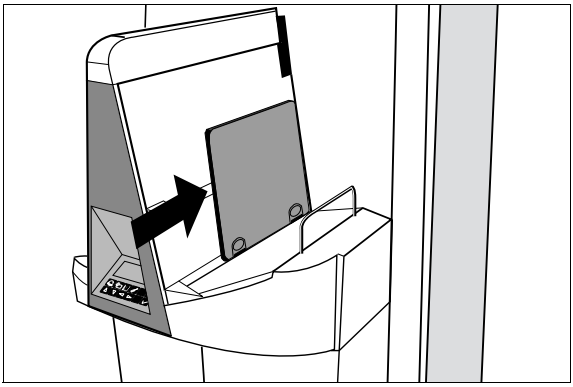
2 Check that the CR 85-X is ready for operation:

- the CR 85-X must display the operator screen with 'Ready' or 'Busy' status.

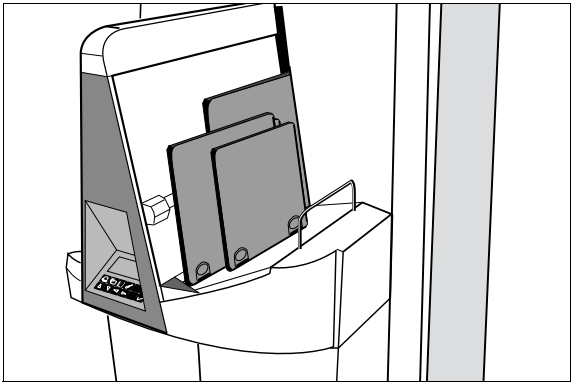
- the status indicator at the top of the CR 85-X must be constant or flashing green.

Note: The CR 85-X is operational if the status field equals 'READY', even if status messages of the destination are shown (e.g. 'VIPS not ready').

3 Place one or more cassettes in the input buffer.



You can insert up to 10 cassettes, even of different sizes. Make sure that the cassette opening mechanism is at the bottom.



The Digitizer automatically takes in the first cassette, reads the image plate, and forwards the digital image data to the preview station for fast precheck and to the image processing station for image processing.

If fast preview is enabled, the CR 85-X transmits the digital image data in blocks of typical 100 lines to the preview station.

When the CR 85-X has treated the cassette, it displays the operator main screen.

4 Remove the cassette(s) from the output buffer.

Note: When the CR 85-X returns the cassette, it is ready to be re-used immediately. However, if you leave it for more than 3 days before re-using it, you must re-erase it first. Refer to 'Re-erasing an image plate' on page 44.

Reading an emergency image plate

You may have an image plate which you wish to give priority over other image plates which are being processed by the image processing station. Such image plates are referred to as 'emergency image plates'.

Note: The emergency status will only be assigned to the first image plate which you insert into the CR 85-X cassette slot after pressing the Emergency key.

To read an emergency image plate:

1 Check that the CR 85-X is ready for operation:

- the CR 85-X must display the operator screen with 'Ready' or 'Busy' status.

- the status indicator at the top of the CR 85-X must be constant or flashing green.

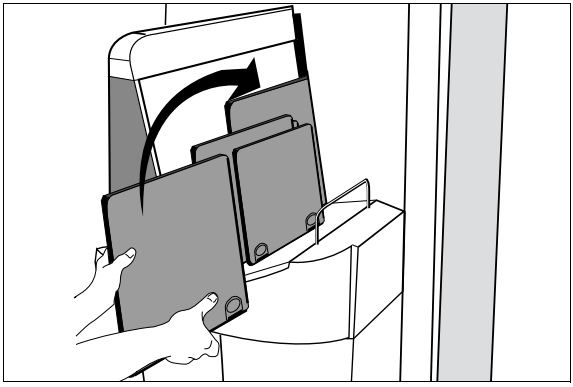
Note: The CR 85-X is operational if the status field equals 'READY', even if status messages of the destination are shown (e.g. 'VIPS not ready').

2 Press the Emergency key on the keypad.

The display will read:

3 Place the cassette you want to give emergency status first in the stack of cassettes in the input buffer.

Do not place the cassette with emergency status in the stack while the input mechanism is busy getting a cassette from the stack.



Note: If you do not enter a cassette within 1 minute after pressing the Emergency key, the CR 85-X will quit the emergency function and return to the operator main screen.

If fast preview is enabled, the CR 85-X transmits the digital image data in blocks of typical 100 lines to the preview station.

When the CR 85-X has read the identification data of the emergency cassette, it displays the operator main screen. The Digitizer resumes processing the remaining cassettes in the cassette input buffer.

If you decide not to assign emergency status to a cassette after having pressed Emergency, you can quit the Emergency function by either pressing Escape or by pressing the Emergency key a second time ('toggle' key).

Note: If a 'WARNING' or 'LOCKED' message is displayed during the Emergency procedure, the CR 85-X will not quit the Emergency mode. Refer to the Reference manual.

4 Remove the cassette from the output buffer.

Re-erasing an image plate

At the end of a normal or emergency digitizing cycle, the CR 85-X 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 3 days.
  In this case, the image plate may have been exposed to scattered radiation.
- 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.

You can erase image plates which you have given the status ‘to be erased’ via the ID Station or image plates which have the status ‘erased’. You can erase an image plate or a batch of up to 9 plates.

Re-erasing image plates with status 'erased'

To erase one or more image plates which have been erased as part of a normal or emergency digitizing cycle:

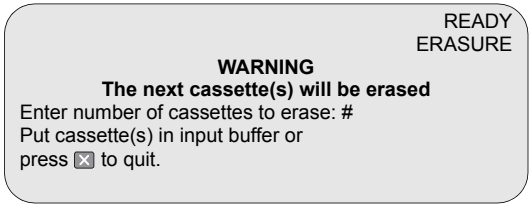
1 Check that the CR 85-X is ready for operation:

- the CR 85-X must display the operator screen with 'Ready' or 'Busy' status.

- the status indicator at the top of the CR 85-X must be constant or flashing green.

2 Press the Erase key on the keypad.

The display will read:



3 Use the Up and Down keys to set the number of image plates to be erased. The default value is 1; the maximum is 9.

4 Place the cassettes which you want to erase in the cassette input buffer.

After a cassette has been erased, the # digit on the display decreases.

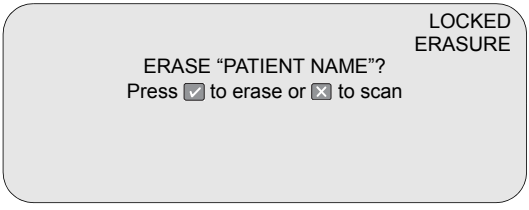
While erasing, the CR 85-X will still display the above screen and the status indicator will be green flashing. When the CR 85-X has erased the image plate, it displays the operator main screen.

You can now add (exposed) cassettes to the batch of cassettes. The Digitizer will only erase as many cassettes as you have specified.

If you place fewer cassettes in the cassette input buffer than you have specified, the Digitizer will erase the cassettes in the buffer and revert to normal mode after a time-out of 1 minute.

You can quit the Erase function by either pressing Escape or by pressing the Erase key a second time ('toggle' key).

If the above screen is not displayed but the display reads:

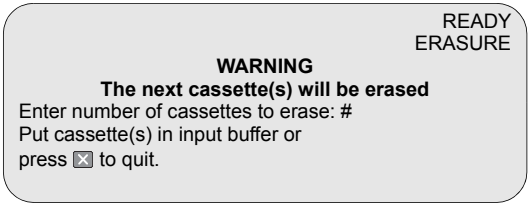


you have entered an identified cassette not having the status ‘erased’. You now have the choice: either cancel erasing or erase the image plate.

- To cancel erasing and make a regular scan: press the Escape key.

- To erase the image plate: press the Confirm key.

While erasing, the CR 85-X will display:



When the CR 85-X has erased the image plate, it displays the operator main screen.

5 Remove the cassette(s) from the output buffer.

Re-erasing image plates with status ‘to be erased’

To re-erase one or more image plates which you have given the status ‘to be erased’ via the ID station:

1 Check that the CR 85-X is ready for operation:

- the CR 85-X must display the operator screen with ‘Ready’ or ‘Busy’ status.

- the status indicator at the top of the CR 85-X must be constant or flashing green.

2 Place the cassettes in the input buffer.

The CR 85-X will automatically erase the image plates. The display will read:

When the CR 85-X has erased the image plates, it displays the operator main screen.

3 Remove the cassette(s) from the output buffer.

Chapter 3

Advanced operation (‘Key-operator mode’)

This chapter gives an overview of the key-operator functions and troubleshooting. For detailed information on these topics, refer to the Reference manual.

Survey of advanced functions

A survey of the functions which are available in key-operator mode is given below. For detailed information, refer to *Chapter 3, 'Advanced operation ('Key-operator mode')'* of the CR 85-X Reference manual.

Function in key-operator main menu	Section in Reference manual	Page
Queue management	*'Consulting the images in the queue'*	*48*
Digitizer set-up	*'Customizing the CR 85-X ('Digitizer set-up')'*	*52*
Date and Time	*'Setting the date and time'*	*58*
Send test image	*'Sending test images'*	*59*
System info	*'Consulting information on the CR 85-X'*	*60*
Install	*'Installing a new software version'* *'Installing a new language'* *'Installing new customer parameters'*	*64* *69* *74*
Save configuration	*'Saving the configuration data on a diskette (backup)'*	*80*
Fast preview	*'Enabling/disabling fast preview'*	*83*

General procedure in case of malfunction

In exceptional situations the CR 85-X display provides comprehensive information concerning errors and ways of correcting them. The Digitizer status changes from 'READY' to one of the following:

Message	Status indicator	Meaning	Action
Warning	Red flashing	Further operation is possible without impairing the image quality.	Follow the instructions on the display. The warning disappears as soon as the problem has been solved.
Locked	Red flashing	The Digitizer no longer takes cassettes from the input buffer. You can solve this problem without resetting the Digitizer.	Follow the instructions on the display.
Error	Constant red	This status normally requires service or key operator intervention.	Follow the instructions on the display.

Caution: Never reset the Digitizer to solve a cassette or image plate jam nor to solve communication problems with the image processing station.

Troubleshooting

A survey of errors is listed below. For more detailed information, refer to the Reference manual.

To	Refer to section	Page
Solve 'SERVICEXXXXX' errors	*'Solving the 'ERROR' status'*	*87*
Solve 'ERRORXXXXX' errors		

Clearing cassette jams

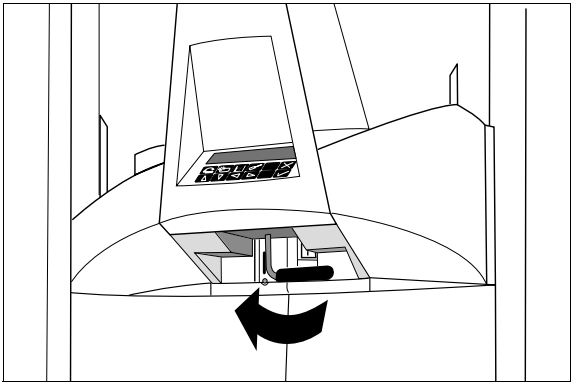
A cassette can get jammed when the CR 85-X takes in a cassette or when it returns a cassette to the output buffer. If this is the case, you see part of the cassette either in the input buffer or in the output buffer.

To clear a cassette jam:

1 Switch off the CR 85-X.

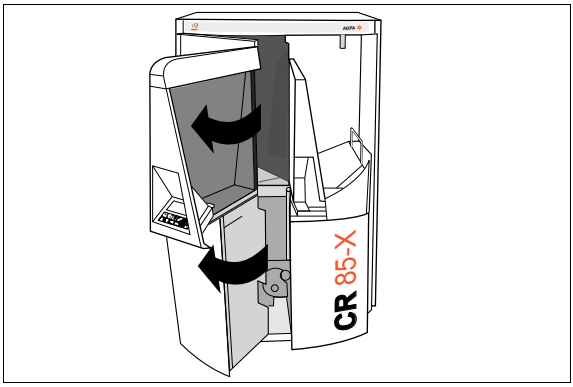
Refer to *'Switching off the CR 85-X'* on page *34*.

2 Push the black handle located under the control panel gently to the left to unlock the front doors of the CR 85-X.

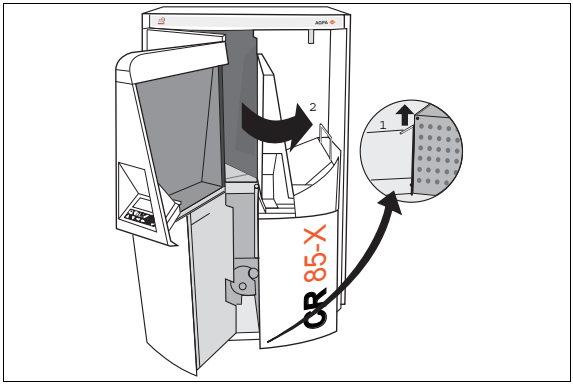


3 Open the left front door of the Digitizer.

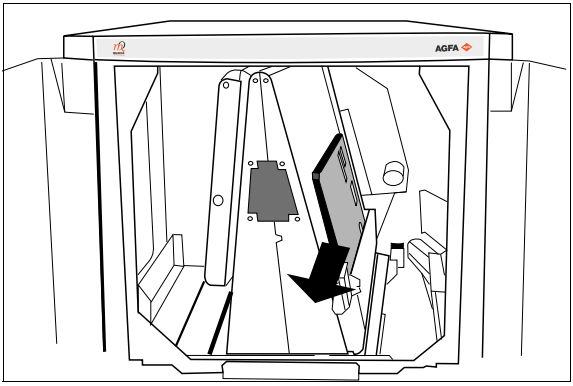
Make sure you open the left front door first. When you open the left front door, the power supply of all critical components is switched off automatically.



4 Lift the bottom door bolt and open the right front door.

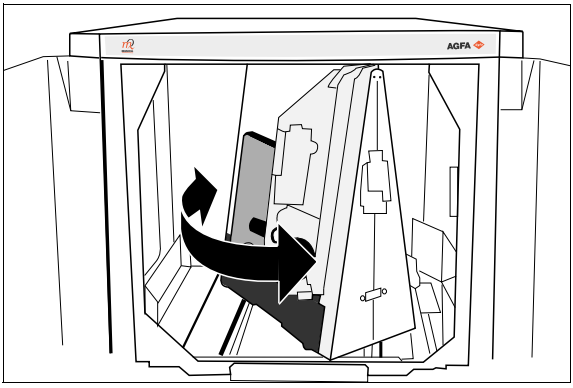


5 Gently remove the jammed cassette.



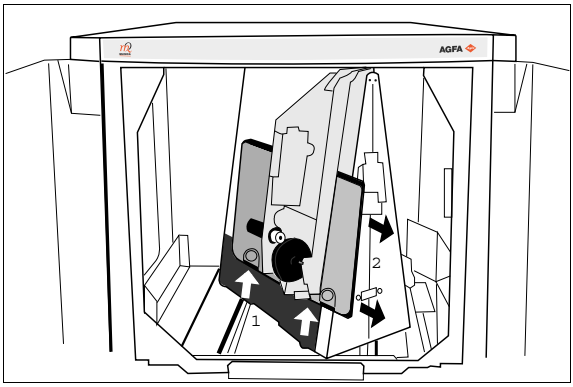
If the cassette is jammed in the output slot, the cassette might be hard to reach. In this case, continue with steps *6* to *7*.

6 If the cassette is jammed in the output slot and is hard to reach, swivel the cassette unit anti-clockwise.



7 Remove the cassette by pulling it towards you [2] while gently lifting it upwards [1].

Caution: If you cannot easily remove a cassette at this point, do not dismantle the unit any further. Contact your local service organization.



8 Close the front doors.

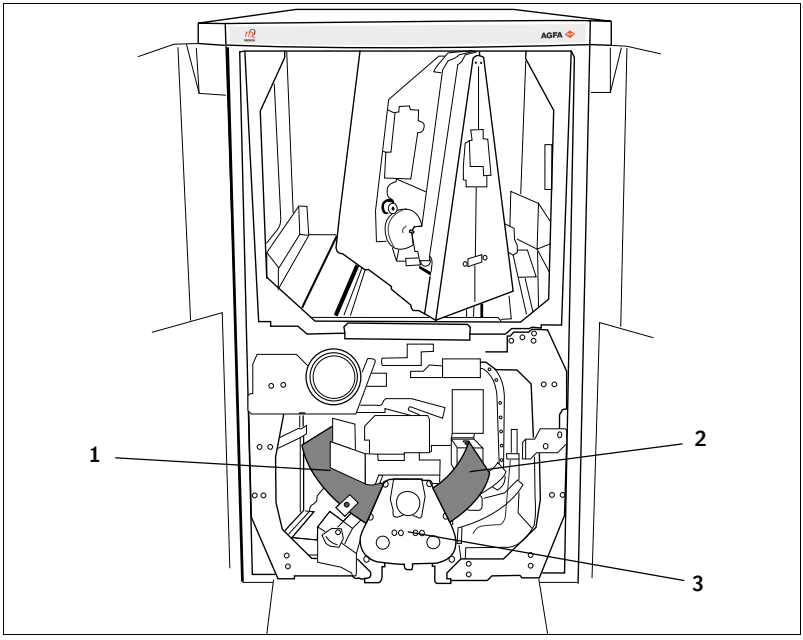
The CR 85-X will restart automatically.

After start-up, the operator main screen is displayed.

Clearing image plate jams

The CR 85-X always reads and digitizes the plate first, then erases it and feeds it to the output buffer. 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.

The diagram below shows the possible locations of a jammed image plate and the probable status of the image.



	Status	Action
1	Plate jam in the post-scan unit. Image is OK.	Erase the image plate.
2	Plate jam in the pre-scan unit. Image plate is not erased but cassette status is set to 'erased'.	**1** Re-identify cassette via ID Station. **2** Digitize cassette.
3	Plate jam in the scanner. Cassette status is set to 'erased'. Image is damaged.	**1** Erase the image plate. **2** Redo the patient exam.

To clear an image plate jam:

1 Remove the cassette.

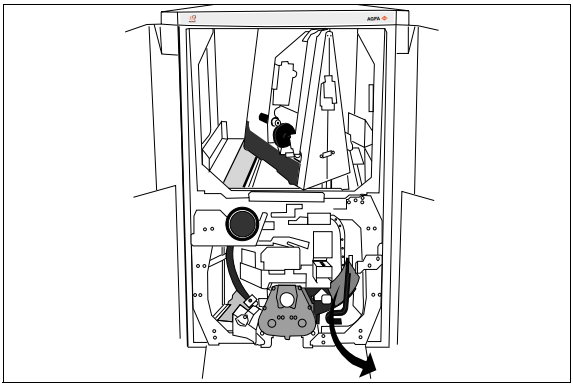
Refer to *'Clearing cassette jams'* on page *53*.

2 Check whether the image plate is jammed in the pre-scan or in the post-scan unit.

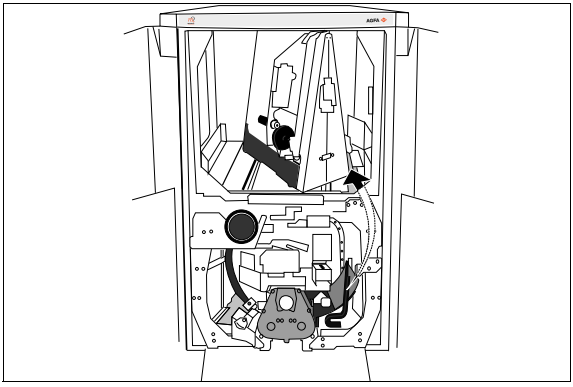
Refer to the diagram above.

- If the image plate is jammed in the pre-scan unit, continue with step *3*.
- If the image plate is jammed in the post-scan unit, continue with step *4*.

3 If an image plate is jammed in the pre-scan unit, remove the jammed image plate by pulling it carefully towards you.

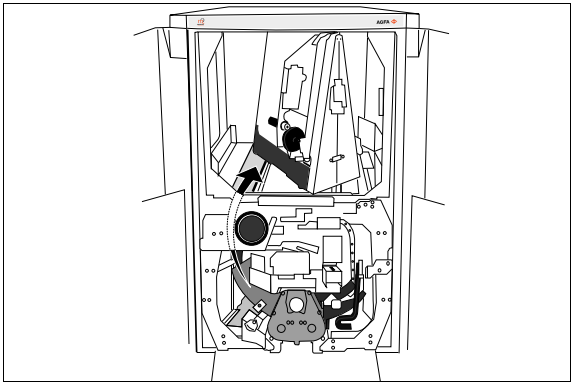


If the image plate cannot be removed by pulling it towards you, lift the jammed plate and remove it through the upper part of the Digitizer.



4 If an image plate is jammed in the post-scan unit, try to remove the jammed image plate by pulling it carefully towards you.

If the access is too narrow, lift the jammed plate over the erase unit and remove it through the upper section of the Digitizer.



Caution: If it is still not possible to remove the image plate, do not dismantle the unit any further. Contact your local service organization.

5 Close the front doors.

The CR 85-X will restart automatically.

After start-up, the operator main screen is displayed.

Appendix A

Equipment information sheet

Specifications

Product description	
Type of product	Digitizer
Commercial name	CR 85-X
Model number	5148/100
Original seller/manufacturer	Agfa HealthCare N.V.
Labelling	
CE/TÜV	93/42 EEC 'Medical Device Directive' (Europe), EN 60601-1:2006
cNRTLus	US: UL certified, UL 60601-1 CAN: CSA 22.2 No. 601.1 M90
Dimensions	
Length	• at cassette buffer: 1141 mm • at foot: 840 mm
Width	840 mm
Height	1420 mm
Weight	
Unpacked	320 kg
Power consumption	
Standby	approx. 300 W
Maximum	approx. 1700 W (=8.5 A)
Self-adapting power supply range	• 200 V (-10%) to 240 V (+10%) • 50-60 Hz
Operating current	8.5 A (200-240 V)

Environmental requirements	
Room temperature	20°C - 30°C
Maximum temperature change	0.5°C/min.
Relative humidity	10% - 80%
Magnetic field	Less than 5 Gauss; compliant with EN 61000-4-8, Level 5
Sunlight exposure	Not to be operated in full sunlight
Barometric pressure during operation	70 kPa to 106 kPa
Related altitude on site	3000 m to 0 m
Physical emissions	
Noise emission (sound power level according to DIN 45635 Part.27)	
• During scanning	max. 65 dB(A)
• Standby	max. 46 dB(A)
Heat emission (at max. throughput with 35 cm x 43 cm image plates)	
• Europe	0.8 kWh
• GB	2730 BTU/hr
Cassette buffer capacity	
10 cassettes of mixed sizes, both in input and output buffer	
Performance	
Throughput for high resolution	**112 plates/h (size dependent)**
Throughput for standard resolution	**112 plates/h (size dependent)**
End of life	
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	7 years
Preventive maintenance	
Preventive maintenance frequency. Needs to be done by an Agfa certified field service engineer	Once per 6 months or 25000 cycles, whatever comes first

Grayscale resolution	
Data acquisition	12 bits/pixel
Output to processor	12 bits/pixel
Environmental conditions (during storage)	
Note: Climate conditions for storage are in accordance with EN60721-3-1 class 1K4.	
Room temperature	between -20 °C and 55 °C
Relative humidity	between 15 % and 80 %
Rate of change of temperature	1 °C/min
Barometric pressure	between 70 kPa and 106 kPa
Environmental conditions (during transport)	
Note: Climate conditions for transport are in accordance with EN60721-3-2 class 2K4.	
Room temperature	between -25 °C and 55 °C
Relative humidity	between 15 % and 100 %
Rate of change of temperature	1 °C/min
Barometric pressure	between 70 kPa and 106 kPa

Spatial resolution	
HR: High resolution; SR: Standard resolution	
35 x 43 cm (14 x 17") HR	10 pixels/mm
35 x 43 cm (14 x 17") SR	6,7 pixels/mm
21 x 43 cm HR	10 pixels/mm
35 x 35 cm (14 x 14") HR	10 pixels/mm
35 x 35 cm (14 x 14") SR	6,7 pixels/mm
30 x 24 cm HR	10 pixels/mm
24 x 18 cm HR	10 pixels/mm
30 x 15 cm HR	10 pixels/mm
10 x 8" HR	10 pixels/mm
12 x 10" HR	10 pixels/mm
30 x 24 cm Mammo	20 pixels/mm
24 x 18 cm Mammo	20 pixels/mm
30 x 24 cm Extremities	20 pixels/mm
24 x 18 cm Extremities	20 pixels/mm

Scan area (scan width x scan length)	
HR: High resolution; SR: Standard resolution	
35 x 43 cm (14 x 17") HR & SR	348 x 424 mm
21 x 43 cm HR	202 x 424 mm
35 x 35 cm (14 x 14") HR & SR	348 x 348 mm
30 x 24 cm HR	292 x 232 mm
24 x 18 cm HR	232 x 172 mm
30 x 15 cm HR	292 x 142 mm
10 x 8" HR	246 x 195 mm
12 x 10" HR	297 x 246 mm
30 x 24 cm Mammo	292 x 238 mm
24 x 18 cm Mammo	232 x 178 mm
30 x 24 cm Extremities	292 x 232 mm
24 x 18 cm Extremities	232 x 172 mm

Appendix B

CR cassettes

Safety precautions

Observe great care whenever removing the image plate from the CR cassette. Refer to the cleaning procedure described further on in this manual.

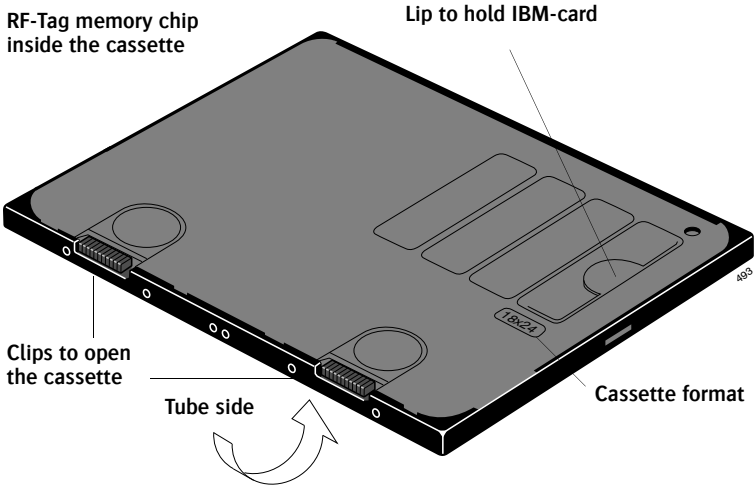
WARNING: Make sure that the automatic exposure control device is placed above the cassette, to prevent patients from receiving an overdose of X-rays. When it is located underneath the cassette, the backscatter protection (lead) contained in the red side of the cassette, retains a certain amount of X-rays. The dose measured by the cell will then be much lower than the dose actually given to the patient.

The image plate causes a specific X-ray scattering. This influences the response of the exposure control device. To compensate for this, recalibration of the device for the use with CR cassettes could be necessary.

Description of the CR cassette

The CR cassette and plate are compatible with existing X-ray tables. The exposure equipment and routines do not have to be modified when switching from conventional to digital imaging. Although compatible with existing X-ray equipment, a CR cassette is quite different from a conventional cassette. The most important difference lies inside, in the image receptor.

Note: ADC Compact cassettes and ADC 70 cassettes are not interchangeable. But the same image plates can be used for both.



Embedded memory

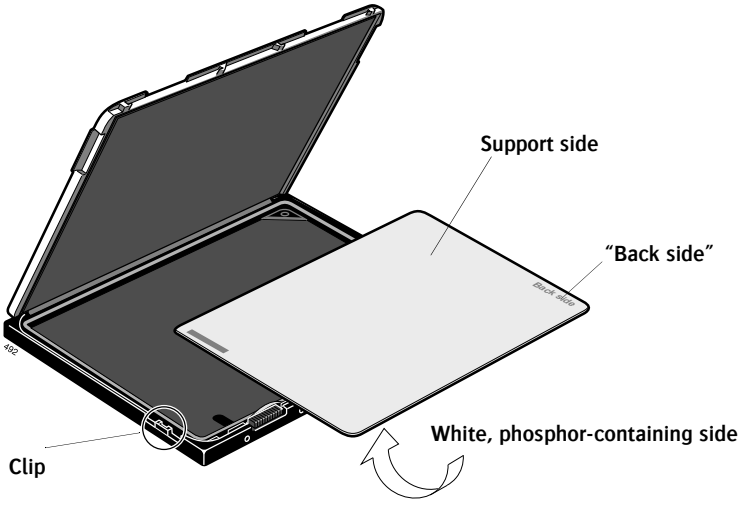
The main difference lies in the RF-tag memory chip that is permanently mounted in the cassette. Using the Agfa ID Software you can enter patient demographics and examination data into the memory chip. The identification of this data is performed by no-touch radiofrequency tagging via a built-in antenna card in the CR cassette.

Image plate

Another difference between a CR cassette and a conventional cassette is the X-ray sensitive element (image receptor). The latter is no longer a film, but an image plate that can be re-used thousands of times.

The way in which this image plate is placed into the cassette is of great importance. The side containing the white phosphor must be oriented towards the black tube side of the cassette. The support side (indicated by the text “back side“) is then oriented towards the red side of the cassette, as shown in the illustration below.

The ‘clips’ mounted on the cassette prevent the cassette from being opened by a conventional daylight system such as the Curix Capacity (Plus), so that even in hybrid conventional/digital departments the occurrence of errors is avoided.



Cleaning the image plate

Please make sure that the CR plate always goes into the same cassette when cleaning. With the introduction of new initialization codes, it is important that the CR plate does not end up in a cassette initialized for another code. In case of doubt, you should re-initialize the cassette using the initialization code on the CR plate.

Use only AGFA CR Phosphor Plate Cleaner and a soft lint-free cellulose cloth to clean the plate.

Caution: Do not use the AGFA CR Phosphor Plate Cleaner to clean the CR MM3.0 Mammo image plates with a batch code starting with the letter "B" or a number. These CR MM3.0 Mammo image plates require dedicated wipers. Do not use these wipers to clean non-Mammo plates!

How?

- Moisten the cloth with cleaner and wipe the plate surface softly and evenly (phosphorous side and rear side).
- Leave the plate surface to dry for about 10 minutes to allow the solvents to evaporate.
- Clean the cassette thoroughly. Use a dry cloth or blow away possible dust with compressed air. (DO NOT USE A SCREEN CLEANER TO CLEAN THE INSIDE OF THE CASSETTE.)
- Once the plate surface is dry (after about 10 minutes), check once again for particles of material and other impurities before placing the plate in the cassette.

When?

- At least once every month or whenever there is doubt about particles visible on the X ray images.
- More frequent cleaning is required for CR Mammo plates.
- More frequent cleaning is also required in case of excessive dust or under very dry conditions. (The screen cleaner contains antistatic agents which reduce buildup of static charges and dust collection.)

Cleaning the cassettes

Clean the cassette thoroughly. Use a dry cloth or blow away possible dust with compressed air. (DO NOT USE A SCREEN CLEANER TO CLEAN THE INSIDE OF THE CASSETTE.)

Technical specifications of the cassettes

Sizes

- 35 x 43 cm (14 x 17"),
- 35 x 35 cm (14 x 14"),
- 24 x 30 cm,
- 18 x 24 cm,
- 8 x 10",
- 10 x 12",
- 21 x 43 cm (by partial scan of dedicated 35 x 43 cm cassettes),
- 35 x 43 cm HR high resolution cassette,
- 35 x 35 cm HR high resolution cassette,
- 15 x 30 cm dental cassette.

Standards

- DIN 6832 part 1 & 2
- ANSI/NAPM IT 1.49-1995
- IEC 406 (draft 1995)

Weight

- 35 x 43 cm typical 1.6 kg

Material

Body	ABS (Acrylonitryl Butadiene Styrene)
Corners	Polyurethane Rubber (PUR)
Hinge	Polypropylene (PP)
Inner lining	Makrolon

Identification

- Memory chip (RF-tag card) embedded in the cassette

Backscatter protection

- 150 μ lead

Technical specifications of the image plates

Sizes

- 35 x 43 cm (14 x 17")
- 35 x 35 cm (14 x 14")
- 24 x 30 cm
- 18 x 24 cm
- 8 x 10"
- 10 x 12"
- 15 x 30 cm

Plate construction

Protective layer	Electron beam cured polymer
Phosphor	BaSrFBrI:Eu
Base	P.E.T.

Characteristics

Its luminescence spectrum is the typical Eu^{2+} -luminescence, which is at around 390 nm in lattices of the BaFBr-type. The top in the luminescence spectrum is shifted slightly to longer wavelengths due to the incorporation of iodide.

The stimulation spectrum is much broader than that of pure BaFBr and is shifted to longer wavelengths. This shift is caused in the first place by the partial replacement of Ba by Sr, and in the second place by the incorporation of iodide. Thanks to the red-shift of the stimulation spectrum, maximum stimulability is assured at 633 nm, the wavelength of the stimulating laser.

The Agfa phosphor has excellent dark decay characteristics. Two hours after exposure, approximately 80% of the energy stored upon exposure is still available. The image retention is greater than 50% up to 24 hours after irradiation.

Appendix C

Remarks for HF-emission and immunity

Remarks for HF-emission and immunity

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

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

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

Emissions test	Compliance	Electromagnetic Environment Guidelines
RF emissions in accordance with CISPR 11	Group 1	The digitizer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions in accordance with CISPR 11	Class A	The digitizer is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded. **WARNING**: This device is intended for use by healthcare professionals only. This device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the digitizer or shielding the location.
Harmonic emissions in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions in accordance with IEC 61000-3-3	Complies	

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

Resistance to Jamming Test	IEC 60601 Test Level	Level of Agreement	Electromagnetic Environment Guidelines
Discharge of static electricity in accordance with IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should consist of wood, concrete or ceramic tiles. The relative humidity must be at least 30%, if the floor is made of synthetic material.
Fast transient electrical disturbance variables / bursts in accordance with IEC 61000-4-4	± 2 kV for network leads ± 1 kV for entry and outlet leads	± 2 kV for network leads ± 1 kV for entry and outlet leads	The quality of the voltage supplied should correspond to a typical commercial or clinical environment.
Impulse voltages (surges) in accordance with IEC 61000-4-5	± 1 kV push-pull voltage ± 2 kV common mode voltage	± 1 kV push-pull voltage ± 2 kV common mode voltage	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage breakthroughs, short term interruptions and variations in the voltage supplied in accordance with IEC 61000-4-11	• < 5% U_r (> 95% breakthrough of U_r) for ½ period • 40% U_r (> 60% breakthrough of U_r) for 5 periods • 70% U_r (30% breakthrough of U_r) for 25 periods • < 5% U_r (95% breakthrough of U_r) for 5 s	• < 5% U_r (> 95% breakthrough of U_r) for ½ period • 40% U_r (> 60% breakthrough of U_r) for 5 periods • 70% U_r (30% breakthrough of U_r) for 25 periods • < 5% U_r (95% breakthrough of U_r) for 5 s	The quality of the voltage supply should correspond to that of a typical commercial or clinical environment. If the user wants the device to work continuously, even when the energy supply is interrupted, it is recommended to use an energy supply free of interruptions or a battery.
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic field at the network frequency should correspond to the typical values as they are in a commercial and clinical environment.
• REMARK : U_r is the alternating current in the network before the application of the test level.			

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

Tests of Resistance to Disruption	IEC 60601 Test Level	Level of Agreement	Electromagnetic Environment
			Use portable and mobile radio sets at a safe distance from the device (including the leads) not closer than the recommended protective distance, which is calculated according to the equation suitable for the transmission frequency. Recommended protective distance:
Conducted high frequency disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d = 1.2 \sqrt{P}$
Radiated high frequency disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
			With P as the rated power of the transmitter in watts (W) in accordance with the manufacturer information on the transmitter and d as the recommended protective distance in metres (m). The field strength of stationary radio transmitters is lower than the level of the agreement[a] at all frequencies in accordance with an on-site investigation[b]. Disruptions are possible near devices that carry the following symbol: 

			 The device uses a short range device class 1 (7 dBμA/m at 10 m) with ISM-Band 13.56 MHz).

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

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

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

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

Recommended Protective Distances between Portable and Mobile High Frequency Communication Equipment and the Device			
Rated Power of the Transmitter W	Protective Distance in accordance with Transmission Frequency m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The distance can be determined through the equation for each respective column.
P is the rated power of the transmitter in watts (W) according to the manufacturer information on the transmitter, only for transmitters where the rated power is not mentioned in the above table.

- REMARK 1 : An additional factor of 10/3 has been used to calculate the recommended protective distance of transmitters in the frequency range from 80 MHz to 2.5 GHz, to reduce the probability that mobile portable communication equipment unintentionally brought into the area of the patients will lead to a disruption.
- REMARK 2 : These Guidelines may not be relevant in all situations. The dispersion of electromagnetic waves is influenced by absorption and reflections from buildings, objects and people.

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