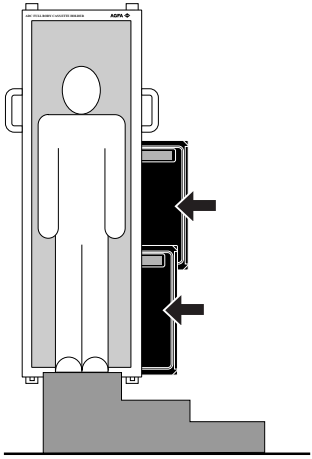
CR Full Leg Full Spine

User Manual



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Contents

Legal Notice

CE

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

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Introduction to this manual

Topics:

Scope of this Manual

This Manual contains information for the effective operation of the Full Leg Full Spine application. It provides detailed information on how the Full Leg Full Spine application works and it gives you many practical notes and examples.

Find additional information in the following documents: NX User Manual (4420).

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

The Full Leg Full Spine application allows performing a Full Leg Full Spine examination using a single exposure. As a result the cumulative dose to which the patient is exposed can be reduced considerably.

The intended use of the FLFS application is to provide quality images for diagnostic measurements in the orthopedic field (skeleton). The software also incorporates some basic measurement and annotation capabilities to allow the physician to evaluate patient status and progression. A hardware cassette holder is included to facilitate the image acquisition of the full leg/ full spine images prior to stitching. The indications for use to provide diagnostic images to aid the physician in diagnose remains unchanged for the original indications contained in the clearance of the Digitizer.

Orthopedic clinicians will benefit from this application software in areas such as the assessment of scoliosis. Potential application include, for instance: accurate measurement of spine angles and distances between skeletal entities, assessment of the evolution of therapy over time and identification of orthopedic surgery indications.

Intended User

This manual is written for trained users of Agfa products and trained clinical personnel. Users are considered as the persons who actually handle the equipment as well as the persons having authority over the equipment. Before attempting to work with this equipment, the user must read, understand, note and strictly observe all warnings, cautions and safety markings on the equipment.

Configuration

Topics:

Cassette and Plate set

The Agfa Full Leg Full Spine application operates with two types of cassettes:

- General CR cassettes
- FLFS CR cassettes

The procedure is identical for both, but the dedicated CR FLFS cassettes, recognizable by its yellow labeling and yellow dots, are specifically designed for the Full Leg Full Spine application and will help to reduce the white stitching line between the images.

Other Full Leg Full Spine application components

- NX FLFS license (incl. Stitching software)
- CR Full Body Cassette Holder
- Anti-scatter grid (optional)
- CR EasyLift (optional)

Compliance

General

- The product has been designed in accordance with Regulation (EU) 2017/745 on medical devices (MDR)
- ISO 13485
- ISO 14971

Performance

Note: For specific information on performance with regard to particular digitizers, refer to the respective digitizer (system) User Manuals.

The composite, stitched image which results from the image stitching process of the Full Leg Full Spine application is compressed. Furthermore, technical acquisition factors vary greatly with Full Leg Full Spine imaging; for example, a Full Leg Full Spine image may be intentionally acquired with low dose or no anti-scatter grid to reduce exposure to a pediatric patient.

The resulting image quality is generally suboptimal for most skeletal studies when compared to normal computed radiographic techniques.

The composite, stitched image is created to allow accurate softcopy measurement of distances and angles by qualified medical practitioners.

WARNING:
Any incidental clinical findings that are seen on the original or stitched images, beyond the scope of measurements of angles and distances between skeletal entities, should be verified or further evaluated by additional diagnostic methods.

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.

For a patient/user/third party in the European Union and in countries with identical regulatory regimes (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Manufacturer address:

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

Agfa - Septestraat 27, 2640 Mortsel, Belgium

Agfa - Fax +32 3 444 7094

Labels

 **Figure 1: Example of the type label**	Type label on the CR Full Body Cassette Holder
CE	This mark shows compliance of the equipment with Regulation 2017/745 (for European Union).
	Date of manufacture
	Manufacturer
MD	Medical device
LOT	Production lot number
UDI	Unique device identifier, in text format and in machine readable format
	The most recent version of this document is available on *http://www.agfa-healthcare.com/global/en/library/index.jsp*

Cleaning and Disinfecting

All appropriate policies and procedures should be followed to avoid contamination of the staff, patients and equipment. All existing universal precautions should be extended to avoid potential contaminations and to avoid patients coming into (close) contact with the device. The user is responsible for selecting a disinfection procedure.

Topics:

Cleaning

To clean the exterior of the equipment:

Wipe the exterior of the device with a clean, soft, damp cloth. Use a mild soap or detergent if required. Do not use any corrosive, dissolving or abrasive cleaning or polishing agents. Make sure no liquid gets in the device.

CAUTION:
Clean the equipment with only a little moisture. Do not spray disinfectants or detergents directly on the equipment. Do not pour liquid directly on the equipment.

Using unsuitable cleaning agents or methods can damage the property when surface becomes dull and brittle (e.g. alcohol-containing agents).

Disinfecting

WARNING:
To disinfect the device, use only disinfectants and disinfection methods that are approved by Agfa and that correspond to the national regulation and guidelines as well as explosion protection.

If you plan to use other disinfectants, approval of Agfa is needed before use, as most disinfectants can damage the device. UV disinfection is also not allowed.

Perform the procedure following the instructions for use, the disposal instructions and the safety instructions of the selected disinfectants and tools and of the hospital.

Items contaminated with blood or body fluids, which may contain blood-borne pathogens, should be cleaned and then receive intermediate level disinfection with a product having an EPA-registered claim for activity against hepatitis B.

Approved disinfectants

Refer to the Agfa website for specifications on the disinfectants that have been found compatible with the cover material of the device and can be used on the outer surface of the device.

http://www.agfahealthcare.com/global/en/library/overview.jsp?ID=41651138

Environmental protection

The stitching grid contains lead, can be taken out, and disposed separately.

For more detailed information about disposal of this product, please contact your local Agfa service organization.

Safety Directions

See also "Safety precautions concerning Full Leg Full Spine functionality" in the NX User Manual.

The Full Leg Full Spine application should preferably be used in conjunction with a cassette holder and cassettes. To reduce the white stitching line in the resulting image, the special Full Leg Full Spine (FLFS) CR cassettes should be used by preference.

Safety Directions for using the cassette holder

WARNING:
When you are using a cassette holder, always take into account the following safety precautions to avoid physical injury.

- Make sure that the rack for the cassette holder is mounted firmly onto a wall before attaching the cassette holder to it.
- When you are using the Agfa EasyLift, read the safety precautions mentioned in the EasyLift User manual.
- As the cassette holder is heavy, always handle it with two persons. Especially, handle the cassette holder with two persons when you wish to adjust its vertical position on the rack (not necessary when you use the Agfa EasyLift). Take care to hold the cassette holder upright, with the slots at the sides, to prevent the leaden anti-scatter grid from falling out of the cassette holder.
- Only insert (FLFS) CR cassettes into the cassette holder if the latter is attached properly to the rack.
- When transporting the cassette holder, always remove the (FLFS) CR cassettes and the leaden anti-scatter grid from the cassette holder to prevent them from falling out of the cassette holder.
- The cassette holder is not suited to support a patient. If you wish to make a Full Leg Full Spine exposure of a patient in horizontal position, use a dedicated X-ray translucent carrier.

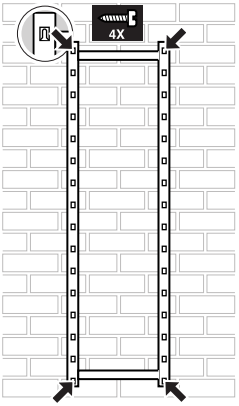


Figure 2: Mounting the rack onto a wall

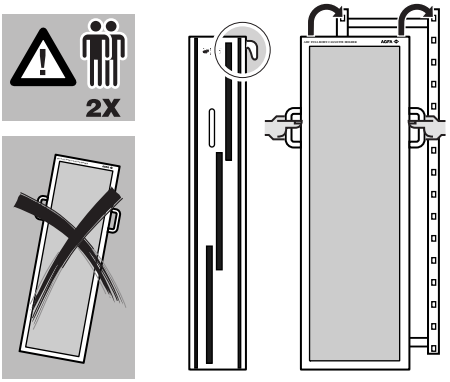


Figure 3: Attaching the cassette holder to the rack

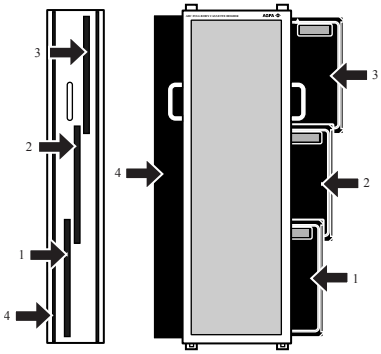


Figure 4: Inserting the cassettes and - if necessary - the anti-scatter grid

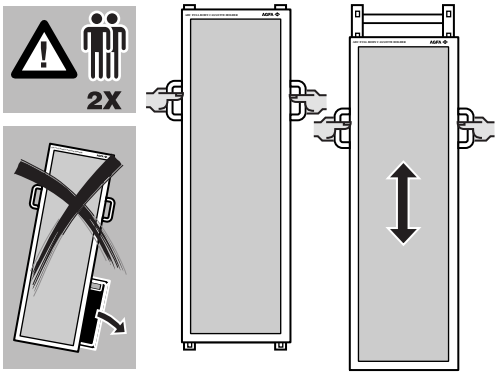


Figure 5: Adjusting the vertical position of the cassette holder

Getting started

Topics:

Basic Features

The key elements of the image stitching algorithm used in the Full Leg Full Spine application are the following:

- First, the sub-images are input to the user interface of NX. If the order of the images is not correct, you can easily shift the images.
- From here, the stitching process proceeds automatically. The grid lines are extracted from each image and stored in analytical form. In the grid calibration step, horizontal and vertical periodicity vectors are extracted and new target coordinate positions of all grid lines in each sub-image are determined. A de-skewing operation follows, in which firstly the vertical grid lines and secondly the horizontal grid lines are shifted to their associated perfect target positions. Linear interpolation determines how much each pixel in the target image should be adjusted.
- A further interpolation process is now needed to re-sample the input image. The selected method for this (known as the cubic B-spline interpolating kernel) computes the value of the target pixels from the input image pixels in such a way as to maintain maximum image resolution.
- The result of this process is an image with equidistant and perfectly horizontal/vertical grid lines. When the Agfa holder is used, the overlap is set to 0. After this has been done, the image stitching module finally builds a composite total body image from the adjusted sub-images.

Basic Workflow

Full Leg and Full Spine imaging requires the use of two or three (FLFS) CR cassettes in an especially-built cassette holder. The sub-images that are created are then combined into a single image with the help of attenuated grid lines to ensure accurate alignment during exposure. The Full Leg Full Spine application compensates the various sources of misalignment, like shift, rotation and perspective foreshortening.

When performing Full Leg Full Spine imaging, take into account the instructions below. These will ensure that the exposure and the subsequent stitching of images in Full Leg Full Spine mode will be optimal.

Topics:

Using FLFS CR cassettes

By preference, special FLFS CR cassettes should be used. Using these cassettes will help to significantly reduce or will take away the white bands at the seams of the stitched images.

Using an anti-scatter grid

If required, you can use an anti-scatter grid to increase image contrast. However, an anti-scatter grid should only be used when absolutely necessary as it will necessitate a higher exposure dose.

When using a focussed grid, take into account the following guidelines:

- Respect the film-focus distance (FFD), i.e. the cassette-focus distance, as specified for the anti-scatter grid.
- Consult the documentation delivered with the grid.

When using a non-focussed grid, allow for a distance of 2 meter between the X-ray source and the cassette. If the source-to-cassette distance is too small, the extreme parts of the image can be blurred.

Using a wedge-shaped tube filter

To ensure that the image-stitching is optimal, it is highly recommended to use a wedge-shaped tube filter for both Full Leg and Full Spine examinations. The filter will compensate for the variation in thickness between the neck and the pelvis in a full spine examination, and between the pelvis and the ankles in a full leg examination.

The filter will enhance the contrast in the thinner body parts and prevent overexposure and saturation of non-relevant, directly exposed areas. Saturation of directly exposed areas must be avoided as this hinders correct stitching.

The wedge-shaped filter should be made of aluminum and attached to a plexiglass plate. Mount the plexiglass plate in front of the X-ray source as shown below.

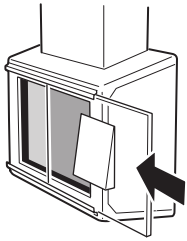


Figure 6: Mounting the plexiglass plate with the wedgeshaped filter

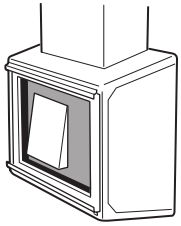


Figure 7: Wedge-shaped filter mounted for a full leg examination

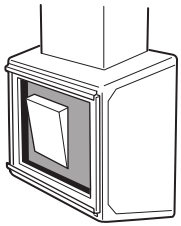


Figure 8: Wedge-shaped filter mounted for a full spine examination

Using source collimation and radio protective objects

In Full Leg Full Spine exposures, collimation is often used to selectively expose only the relevant areas and shield vulnerable parts. However, the image-stitching algorithm relies on the vertical grid lines of the stitching grid showing up in the image. Therefore, take into account the following guidelines for collimation:

Topics:

Collimation of X-ray source

When you use source collimation, consider that stitching grid lines necessary for correct stitching will not be present in the shielded image areas. A trade-off must therefore be made between shielding body parts and exposing sufficient grid lines of the stitching grid to ensure correct stitching.

Practically, minimum 3 vertical grid lines must be visible in the area of interest.

If you are using the CR cassette holder, the stitching grid is built in into the cassette holder. As the grid lines of the stitching grid are 50 mm apart, the area of interest must be at least 11 cm wide (with a tolerance of 1 cm) in the direction perpendicular to the vertical grid lines.

Furthermore, tilt the source collimator slightly (approx. 5°). This will result in a collimation parallelogram which the Full Leg Full Spine application will easily distinguish from the stitching grid lines.

Attenuating objects covering the patient

When you use radio protective objects to shield vulnerable body parts, use curved objects, e.g. circles for breasts and pear-shaped objects for the uterus as illustrated below. Radio protective objects with straight borders parallel to the stitching grid lines can be confused with the grid lines, resulting in incorrect stitching.

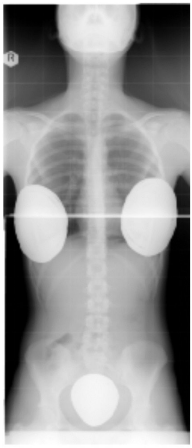


Figure 9: Curved protective objects

Note: If stitching grid lines are largely masked by highly attenuating materials (e.g. long metal prostheses), this may cause minor (but still noticeable) inaccuracies in stitching.

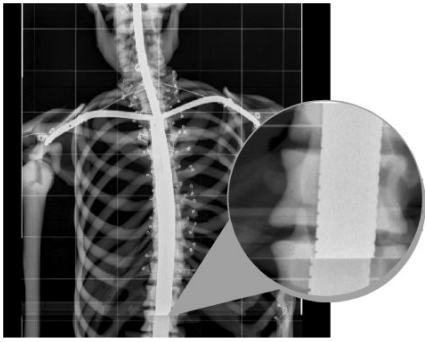


Figure 10: Stitching inaccuracy caused by masked grid lines

Using the cassette holder for a patient in vertical position

Using the cassette holder for a patient in vertical position The cassette holder allows you to easily make Full Leg or Full Spine exposures of both adults and children in vertical position.

For ease of use, position the cassette holder on the rack so that it is suited for a full spine examination of an adult.

Note: For easy height manipulation of the cassette holder, we advise the use of the Agfa EasyLift.

To make a full leg examination or an examination of a child, place a stepladder in front of the cassette holder.

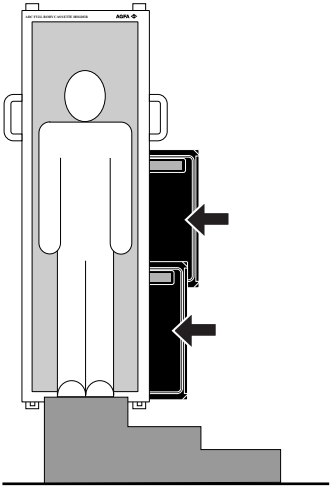


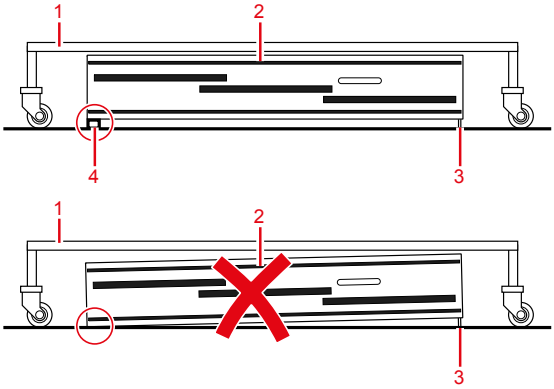
Figure 11: Using the cassette holder for a small person in vertical position

Using the cassette holder for a patient in horizontal position

The cassette holder is not suited to support a patient. If you wish to make a Full Leg Full Spine examination of a patient in horizontal position, you must use a dedicated X-ray translucent carrier. A possible implementation of such a carrier is shown below.

Note: The X-ray translucent carrier is not an Agfa product. The illustration below only suggests a possible implementation; the hospital is responsible for the actual implementation.

Make sure that the cassette holder is perfectly parallel to the floor and to the carrier. Pay special attention to the mounting brackets of the cassette holder.



1. X-ray translucent carrier
2. Cassette holder
3. Mounting bracket
4. Aligning object

Figure 12: Using the cassette holder for a patient in horizontal position

Performing the examination using the cassette holder

The Full Leg Full Spine application requires the use of a special stitching grid during exposure. The line distance of this grid must be 50 mm. You can use several (FLFS) CR cassettes in an especially designed cassette holder to perform the exposure.

Note: The stitching grid is built in into the cassette holder

WARNING:
Before using the cassette holder, read the sections "Safety Directions" and "Getting Started" in this manual.

To perform a Full Leg Full Spine exposure using the cassette holder:

1. Select the (FLFS) CR cassettes which you will use in combination with the cassette holder.

   The (FLFS) CR cassettes used for this method are typically 14 x 17" cassettes.

   For an adult, you will need three (FLFS) CR cassettes; for a Full Leg Full Spine exposure of a child, you may need only two (FLFS) CR cassettes.
2. Insert the (FLFS) CR cassettes in the cassette holder, as shown in the illustrations below.

   Pay special attention to the orientation of the cassettes:

   - Facing the cassette holder, hold the cassettes with the black side facing you.
   - Hold the cassettes with the label at the top, if the type of CR cassette having lockers is being used (e.g. cassette for CR25, CR75, CR35, CR85, … as shown in the image below).

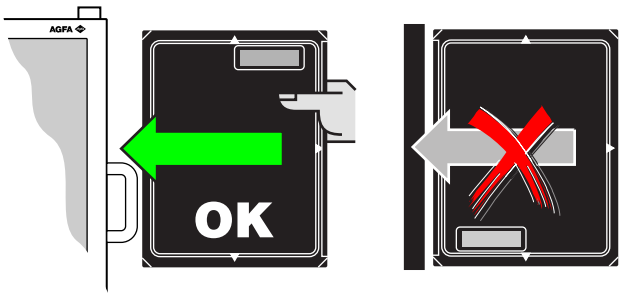


Figure 13: Hold the cassettes with the label at the top

When you insert the (FLFS) CR cassettes with the label at the bottom, the metal parts of the cassette lockers will show up in the stitched image, as shown below.

Figure 14: Metal parts of the cassette lockers

- Hold the cassette with the red marker line at the bottom (as prescribed on its cover label) when the CR cassette type without lockers is being used (e.g. cassette for CR30, … as shown in the image below).

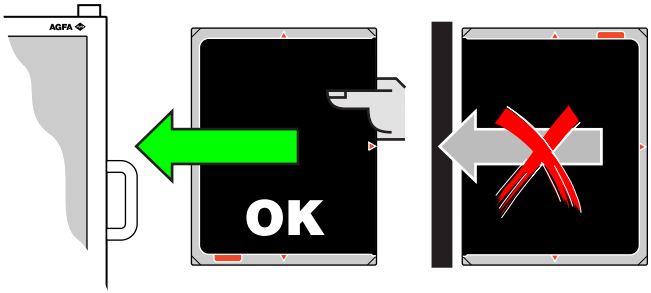
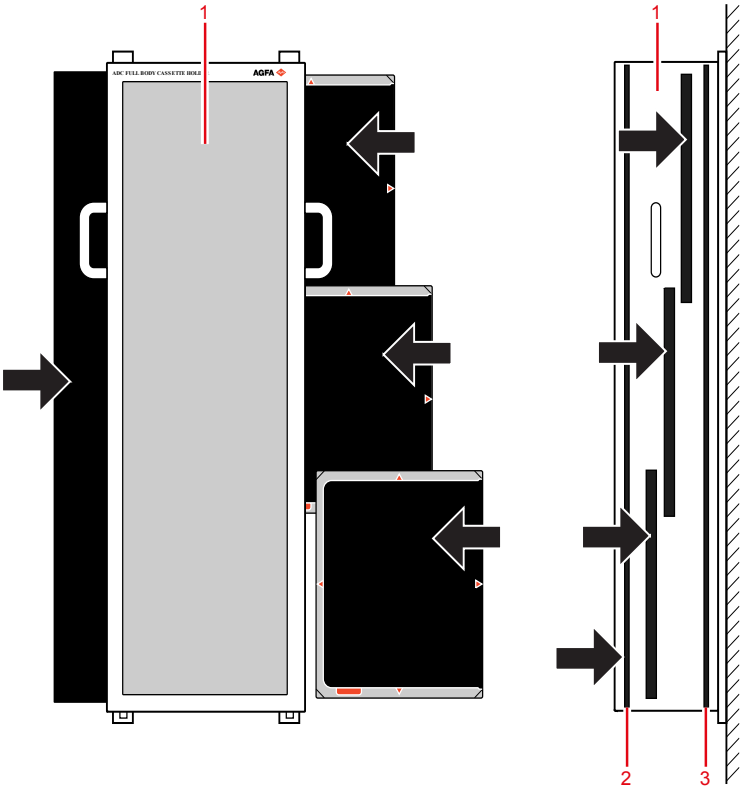


Figure 15: Hold the cassette with the red marker line at the bottom

3. If necessary for the exposure, insert the anti-scatter grid in the front slot of the cassette holder.



1. Cassette holder
2. Slot for ant-scatter grid when in use
3. Slot for ant-scatter grid when not in use

Figure 16: Slots for anti-scatter grid

4. Perform the Full Leg Full Spine exposure.

   The cassette holder may have 4 yellow stickers at the edges of the cassette holder, which are visible from the front. These stickers show the location of the cassette overlap zones and will enable the radiographer to take care of the positioning of the patient in order to avoid that critical patient body parts (joints) will be in this overlap area, where particular items will be visible in the stitched image (e.g. cassette frame).

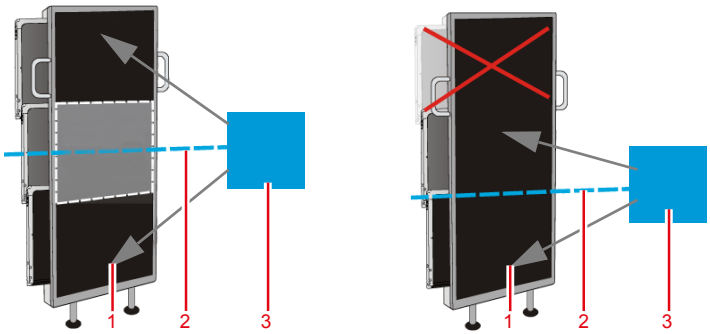
5. Remove the (FLFS) CR cassettes from the cassette holder and digitize them.

Guidelines concerning stitching grid lines

If the exposure set up is made is such a way that a horizontal stitching grid line coincides with the top border of a partial image, geometric continuity will not be guaranteed in the stitch area. Therefore the following recommendations should be kept in mind:

- Make sure that the X-ray source is positioned towards the center of the area of interest.
- If only two (FLFS) cassettes are required, make sure to use the two anatomically bottommost cassettes.

  Reason: When using the upper cassettes, there is a higher probability that a horizontal stitching grid line will coincide with the top border of a partial image, which will result in incorrect stitching.



1. Area of interest
2. Center of the area of interest
3. X-ray tube

Figure 17: Position of the X-ray tube

Using CR 10-X digitizer

The scan resolution of the digitizer may cause the automatic stitching to fail. Refer to section “Manually creating a composite CR Full Leg Full Spine image” of the NX User Manual. Here you can read how the stitching process can be fine-tuned.

Using CR 12-X or CR 15-X digitizer

The scan resolution of the digitzer must be set to 200 μm. The default FLFS scan resolution can be configured in the Digitizer settings in the NX Service and Configuration Tool.

Full Leg Full Spine image stitching

Topics:

Introduction

In order to take full advantage of the Full Leg Full Spine software, the partial exposures composing the exposure set must be configured as Full Leg Full Spine in the Examination Tree Configuration of the NX Service & Configuration Tool. For more information about activating the Full Leg Full Spine application, please refer to the NX Key User Manual or to the NX Service & Configuration Tool On-line Help or to your System Administrator or an Agfa representative.

Stitching Full Leg Full Spine Images

The process for obtaining a Full Leg Full Spine image using NX is similar to the method used in conventional radiography, except that the screen/film system is obviously replaced with phosphor plates. During exposure, an attenuated grid (stitching grid) is present in the path of the X-ray beam, which leaves the imprint of a regular framework of thin parallel horizontal and vertical lines on the images.

But once the images have reached the workstation, they cannot be easily brought into perfect alignment, as the degree of distortion is not qualified or quantified. NX automates the process of forming a geometrically accurate full body image, with as little user interaction as possible.

There are several sources of misalignment or skew, any or all of which may be present:

- Shift

  The displacement of an image in a direction perpendicular to the body axis.
- Rotation

  Image rotation is caused by slight rotation of the imaging plate in the cassette.
- Interline distance foreshortening

  Interline distance foreshortening in vertical and/or horizontal direction is caused by a slight tilt in the plates from the vertical or horizontal plane.

The digital image processing algorithm of NX has been designed to correct all these distortions simultaneously, and to assemble the constituent images into one composite image showing geometric continuity of body parts. This technique is known as image stitching, as the anatomic entities crossing image borders are rearranged in an uninterrupted and seamless way.

About the workflow for working with Full Leg Full spine examinations and stitching images of a Full Leg Full Spine examination, refer to the NX user documentation.

Technical Data

Cassette holder

Environmental conditions (IEC 721-3-3, class 3K4)	
Room temperature	between +5 °C and +40 °C
Maximum temperature change	0.5 °C/min.
Humidity (condensing)	between 10% and 95% RH
Atmospheric pressure	between 700 hPa and 1060 hPa