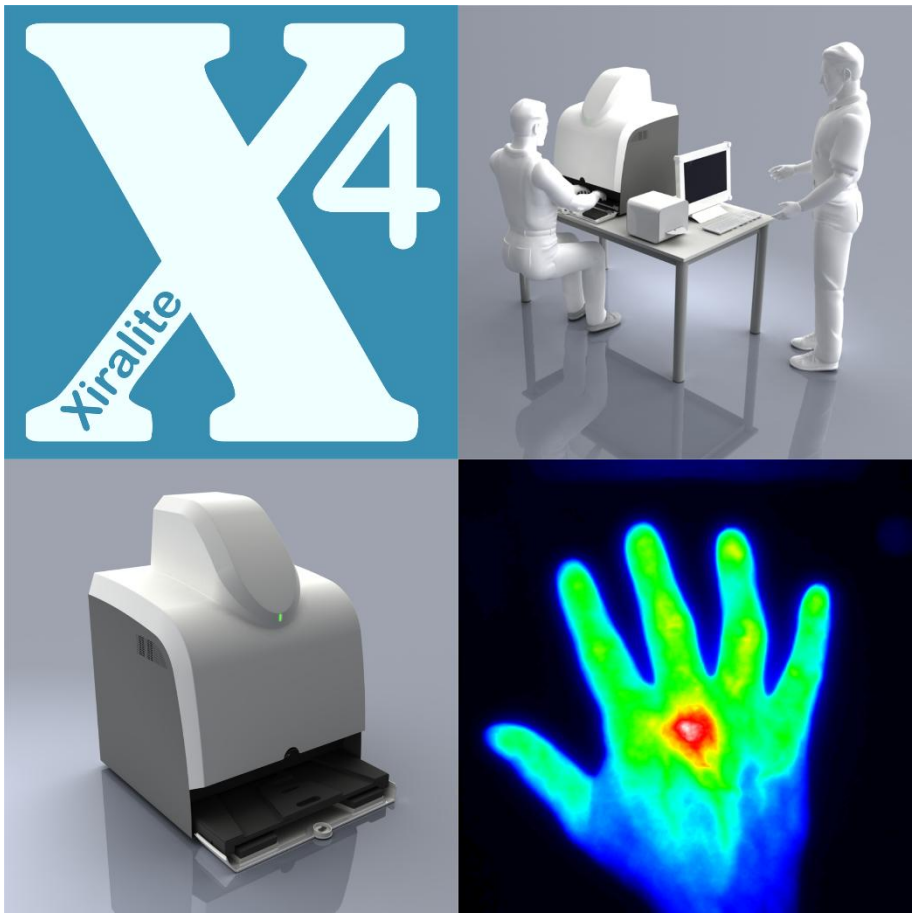
Instruction for Use

Xiralite® Fluorescence Imaging System X4



CE

Keep the manual for future consultation

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The information in this instruction for use has been carefully checked and is believed to be accurate. In the interest of continued product development, Xiralite GmbH reserves the right to make changes and improvements to this instruction for use and the products it describes at any time, without notice or obligation.

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1. Introduction

1.1 Short Description

The Xiralite® Fluorescence Imager X4 is an instrument for optical imaging of microcirculation of human hands with unwounded skin e.g. in a joint with rheumatoid arthritis. The Xiralite® fluorescence imaging system X4 detects fluorescence signals in the defined field of view using a high-sensitivity camera for signal detection and light emitting diodes (LED) for excitation. Fluorescence signals typically result from illumination of a fluorophore, for example the fluorescence dye indocyanine green (ICG) , which is administered intravenously. Fluorescence signals are recorded periodically, thus, giving an image sequence. The frame rate is between half a second and a few seconds, typically one second. The duration of the entire image acquisition is dependent on the pharmacokinetics of the administered fluorophore, with ICG typically six minutes. The acquisition is controlled by a computer with dedicated software. The software runs on Windows 7.

During examination, the patient hands are positioned on the pulled out hand rest. Than the hand rest with the hands of the patient is pushed back into the device. The fluorescent dye is administered intravenously, 10 seconds after the start of the image acquisition. The image acquisition ends automatically after the specified duration of acquisition or image number.

The room for set-up must be closed, dry and frost-free and equipped with a special lighting (see Section 2.1).

The operation of the device shall be carried out only by qualified medical professionals!

1.2 Indications for Use

The indication for use of the Xiralite® Fluorescence Imager X4 is diagnostic imaging of the altered microcirculation of human hands with intact skin, e.g. in a joint with rheumatoid arthritis, as a method for the evaluation of tissue perfusion and related tissue microcirculation.

The use of the Xiralite® Fluorescence Imaging System X4 requires the application of a special fluorophore in the blood, which has an absorbance between 720 nm and 760 nm and a resulting fluorescence emission between 800 nm and 860nm. In addition, the fluorophore must be approved for human use.

Currently, the indocyanine green (ICG) is permitted as contrast agent for intravenous application during the examination with the Xiralite® Fluorescence Imaging System X4. ICG is available as a drug and the approved indications are cardiac diagnostics, cardiovascular diagnostics, diagnostics of microcirculation, and liver function testing and ophthalmic angiography. The relevant regulations must be observed. **The contrast agent is not part of the Xiralite® Fluorescence Imaging System X4 or its software.**

1.3 Contraindications

The use of the Xiralite® Fluorescence Imager X4 is without significant risk. In regular operation no unacceptable impairments are known. There is no contraindication for the use of the device from a technical point of view.

A contraindication for fluorescence diagnosis with the Xiralite® fluorescence imager X4 results indirectly from a contraindication for the administered fluorescent dye ICG, but only in that way, that images cannot be recorded without dyes.

Another contraindication is open wounds on the hands by reason of a possible danger of infection on the hand rest. In addition, the described medical contraindications of the used fluorophore ICG must be considered.

1.4 Medical Device Classification

According to the classification rules in Annex IX, Rule 12 of the Directive 93/42/EEC of 14 June 1993 concerning medical devices the Xiralite® Fluorescence Imaging System X4 is a medical device in Class I.

1.5 Scope of Supply

1. Xiralite® Fluorescence Imaging System X4 with power cord and USB cable
2. Control computer (PC) with monitor, keyboard, mouse, power cord and monitor cables
3. Optionally, a color printer on small cart with UMTS-router, network isolator, network cables and, optionally, an external UMTS antenna for installation outside of the patient environment
4. Table with angled shape, width 143 cm, depth 91 cm either in right- or left-sided. Alternatively, the system can also be placed on a table, which is provided by the customer.
5. Instruction for Use in printed and digital form
6. Quick Reference Guide
7. Dosage card (ICG)
8. Training material for Xiralite® Fluorescence Imaging System X4

1.6 Safety Instructions and Symbols

1.6.1 Description of Warning and Safety Instructions

Warning and safety instructions are highlighted in this manual by graphical symbols. Table 1.1 describes the used alerts for warning, caution and notices in this manual.

This safety notice summarizes information basic to the safe operation of the device described in this manual. The international symbol is a reminder that all safety instructions should be read and understood. When you see the symbol on other pages, pay special attention to the safety information presented. Observance of safety precautions will also help to avoid actions that could damage or adversely affect the performance of the device and to prevent injury or death.

Pictogram for danger	**Warning**	Pictogram for precautions
	WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.	

to be continued

Table continued

Pictogram for danger	**Caution** CAUTION indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsuitable practices.	Pictogram for precautions

	Notice NOTICE is used to call attention to notable information, which is necessary for the intended application and that should be followed, but with little hazardous potential for user and patient.	

Table 1.1: Alerts for Warning, Caution, Note in this manual

1.6.2 Warning and Pictorial Symbols

Warning and pictorial symbols in this manual and on the device are explained in Table 1.2.

	Attention
	Indoor use only
	Potential Equalization
	Applied Part Type B
	Warning of flammable material hazards
	Warning of explosive atmosphere hazards
	Warning of optical radiation hazards
	Warning of dangerous voltage hazards
	Follow the instruction for use
	Disconnect main plug

Table 1.2: Explanation of symbols used in this instructions for use

1.6.3 General Warning and Safety Instructions

Warning

By opening the electronics unit, the mains voltage is accessible. Death by electrocution is possible.

- Do not open the electronics unit. Disconnect the mains plug.
- Pull mains plug immediately if damaged.
- Maintenance and repairs are to be carried out by the manufacturer.

Warning

The Xiralite® Fluorescence Imaging System X4 shall not be altered without the permission of the manufacturer. Modifications of the system require appropriate tests and checks to ensure the continued safe use.

- Maintenance is carried out by the manufacturer.
- Changes in location must be made by the manufacturer or by trained and authorized persons.

Caution

The device may be used only by trained personnel to avoid not evaluable images.

- Read the instruction for use from the manufacturer and perform training measurements on phantoms
- Training by the manufacturer

1.7 Malfunctions, Incidents

The manufacturer and the relevant national competent authority should be informed in the case of serious malfunctions or incidents, especially those in which people can suffer injuries. Risk situations, malfunctions and events are preferably reported to the manufacturer in writing informally. The message should include a detailed description of the case (Injured people?; Instrument damaged or defective?; Measurement error? etc.), including suspected causes and risk factors. The contact details of the relevant national competent authority may be requested by the safety officer for medical devices.

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1.8 Disclaimer

The manufacturer is not liable for damages caused by incorrect use of the product or the result of modifications to the product by unauthorized third parties. Intended use also means that this instruction for use is observed and the maintenance is carried out at regular intervals.

1.9 Disposal

The Xiralite® Fluorescence Imaging System X4 will be taken back, professionally disassembled and disposed of by the manufacturer. The electronic components of the instrument are ROHS compliant, yet they require appropriate waste disposal.

2. Installation

The installation, initial operation, and training are carried out by the manufacturer. An appropriate installation guide is available to the installation personnel. A change in location of the instrument shall be made by the manufacturer or by trained and authorized persons. However, the instrument is a stationary device as defined in EN 60601-1:2006. Thus, it is not designed for frequent changes in location. If the systems location must be changed, appropriate measures must be taken to move the instrument safely and to prevent damage. To lift the instrument two persons grab the device from the sides at the corners. Appropriate measures should be taken to avoid slipping of the hands, such as using non-slip gloves.

2.1 Location Requirements

The Xiralite® Fluorescence Imaging System X4 must be installed in a room equipped with lighting with wavelengths outside the excitation and fluorescence emission range of the applied fluorophore ICG. Light in the wavelength range of excitation and fluorescence emission of ICG with wavelengths between 720 nm and 900 nm can disturb acquired images and must be avoided or shielded. Daylight, light bulbs and fluorescent tubes are not suitable for room lighting. Monochrome (except for red) or cool white LEDs are suitable as light sources. The operator must provide suitable installation space.

	Notice	
	The instrument is sensitive to wavelengths λ> 700 nm. Stray light can disturb the images in this spectral range. ➢ Ensure room lighting with wavelengths λ <700 nm, i.e. white light with no infrared component. ➢ No sunlight or light from light bulbs (incandescent lamp)	

Further, the device must be installed in a low-interference environment, since a stable position of the hands during the image acquisition time of six minutes is essential for recording informative image sequences. All factors that could cause disturbances or a distraction of the patient should be avoided. Patient instruction about the calm hand position is also necessary.

The Xiralite® Fluorescence Imaging System X4 must be installed on a robust table with a footprint of at least 1200 mm x 750 mm (W x D). The table must provide sufficient space for

the device and the supplementary computer. We recommend a 90 ° arrangement for the Xiralite® Fluorescence Imaging System X4 and the computer, as shown in Figure 2.1.

When positioning the instrument it should also be ensured that the opened flap is fully supported by the table. Only this way the patients forearm can sufficiently be supported by the cushion in the flap.

A tilt resistant and height adjustable seat for the patient must be adjusted to the right height for an uncramped sitting position for the duration of an examination including preparation time of about 15 minutes.

Figure 2.1: Right-sided set-up of the Xiralite® Fluorescence Imaging System X4.

It is also strongly recommended to place the table in such way that the patient sitting in front of the instrument is accessible from two sides. Thus, the patient can be reached and supported by *two* assistants in the unlikely case of a general circulatory weakness. The installation of the instrument in a corner of the installation room is inappropriate.

The instrument is not designed for use in an oxygen-enriched atmosphere.

The system is not intended to be integrated into a local or wide area network except for XiraNet.

2.2 Electrical Requirements

Two separate wall outlets with protective earth connection are needed for mains power supply of the Xiralite® Fluorescence Imaging System X4. For the Xiranet functionality another outlet near the printer location, outside the patient environment, is required. The outlets should be no more than 1.5 meters apart from the respective component.

Warning

To avoid the risk of electric shock, the power supply must be equipped with a protective earth terminal. Each unit must be connected individually.

If a multi-outlet power strip is used, all connected devices must have additional protective earth connection to provide basic safety, to minimize the risk of electric shock and to fulfill all relevant requirements of EN 60601-1.

Warning

To avoid the risk of electric shock, extension cables must not be used for the power supply.

The Xiralite® Fluorescence Imaging System X4 is powered by single-phase alternating current from 100 V to 240 V with 50 Hz or 60 Hz. Power consumption is 40 W. The power supply must be equipped with protective earth terminal. The associated PC and monitor are also connected to the 100 V AC to 230 V AC power supply. Their power consumption is about 60 W. After installation of the instrument the mains plug must be accessible.

By default, the PC and the Xiralite® fluorescence imager X4 are each connected to its own permanently installed earthed socket. The use of multiple-outlet power strips or extension cables is not allowed and not provided. If the use of a multiple-outlet power strip is required, the power strip and the connection to the unit have to meet the requirements of EN 60601-1 (Individual solution of the manufacturer, not described in detail here).

Damaged power cords must not be used and must be replaced immediately.

The provided USB cable has to be used exclusively for USB connection from the included control computer to the instrument. The USB cable provides a necessary high-frequency connection for operation stability and shielding of the USB data cable.

The installation location of the system has to be designed by the operator so that no other devices are within the patient environment, which do not meet the requirements of the standard DIN EN 60601-1. In particular, the peripheral components router and printer must be installed outside of the patient environment. The connection is made exclusively via the supplied network isolator. The Figure 2.2 shows the schematic arrangement of the components with respect to the patient environment. The printer and the router may also

be placed on the opposite side or the table with PC and Xiralite® fluorescence imager X4 can be designed in mirror symmetry.

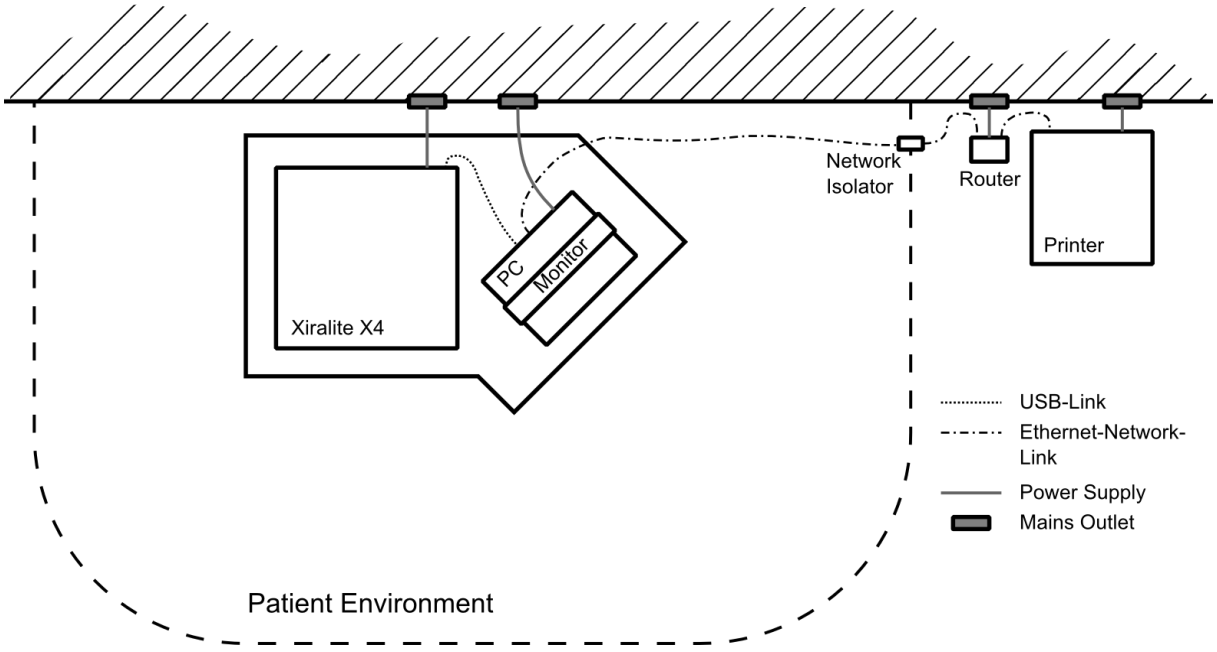

Figure 2.2: Schematic arrangement of the components with respect to the patient environment.

Within the patient environment no non-medical devices may be placed, which either intentionally or unintentionally may be touched at the same time with the patient.

	Caution
	To avoid the risk of electric shock, don't touch the patient and other electrical devices simultaneously.

3. Operation

3.1 Start-up and Shutdown

The instrument is switched on at the rear (see also Section 5.2.3). Powered-on state is indicated by green light on the indicator panel on the front. The respective area is marked with „On/Off“. The image acquisition process is displayed by flashing blue light. This area is marked with „Image“. Figure 3.1 shows the labeling of the indicator panel on the front of the instrument. After switching the instrument on, the operating software has to be started. The operating software is described in detail in Section 3.5.

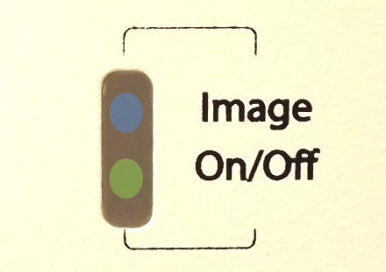

Figure 3.1: Labeling of the indicator panel on the front. Green light indicates powered-on state. Flashing blue light indicates image acquisition in progress.

To switch off the instrument, the operating software has to be terminated, if needed. Then turn off the instrument at the rear side. After approximately one second the green light disappears from the display on the front.

3.2 General Preparation of an Examination

	Caution The device shall be used only by trained personnel to avoid not evaluable images. ➢ Read the instruction for use from the manufacturer and perform training measurements on phantoms. ➢ Training by the manufacturer.	

The operation of the device shall be carried out only by qualified medical professionals! Additional training is offered by the manufacturer.

Further, the device must be installed in a low-interference environment, since a calm position of the hands during the image acquisition time of six minutes is necessary for the

recording of images of adequate information content. Patient instruction about the calm hand position is also necessary.

The seat for the patient must be adjusted to the right height for an uncramped sitting position for the duration of an examination (typically 6 minutes). A sitting test should be performed before each examination.

	Notice	
	Stable position of the hands is necessary for meaningful images. ➢ Instruct patients. ➢ Adjust the chair of the patient. ➢ Avoid distraction of patients. ➢ Choose an undisturbed or low-interference installation site.	

- Switch on the Xiralite® Fluorescence Imaging System X4 and the provided control computer.
- Open the front flap of the Xiralite® Fluorescence Imager X4.
- Start the control software XiraView (see Section 3.5).

3.3 Preparation for Image Acquisition

- Enter data for identification of patient and operator. Optionally, take over patient data from an existing case record.
- If necessary enter time from image to image, acquisition duration, and an additional comment for the examination.
- Clean the hands of the patient before examination using soap and water.

- Prepare ICG for the examination. Prepare ICG with great care. Don’t spill any ICG .

Caution

ICG is transmitted by contaminated hands of the physician (e.g. by shaking hands on the patient and may result in images with numerous interfering signals. ICG, spilled on the skin, cannot be eliminated.

- ➢ Work carefully during the preparation of ICG.
- ➢ Avoid shaking hands in greetings with contaminated hands (contamination can be checked in the operation mode camera preview).
- ➢ Wear gloves during and only during the preparation of ICG.

- Prepare an intravenous line for administration of the fluorescent contrast agent to the patient.
- Pull out the hand rest drawer and position the patient hands on the hand rest. Slide in the hand rest with patient hands into the device. It must be ensured that the drawer is locked in the final position. To prevent possible risk of the patient getting caught between the movable drawer and the armrest in the front flap, the hand rest should be moved in and out slowly. Before operating, the patient has to be informed about the risk of getting caught.

Caution

Risk of getting caught on the drawer with the hand rest.

- ➢ Inform the patient about the risk of getting caught.
- ➢ The hand rest should be moved in and out slowly.

- Where applicable start image preview to check position of hands, position of light protection curtain and amount of unwanted stray light.

3.4 Image Acquisition Process

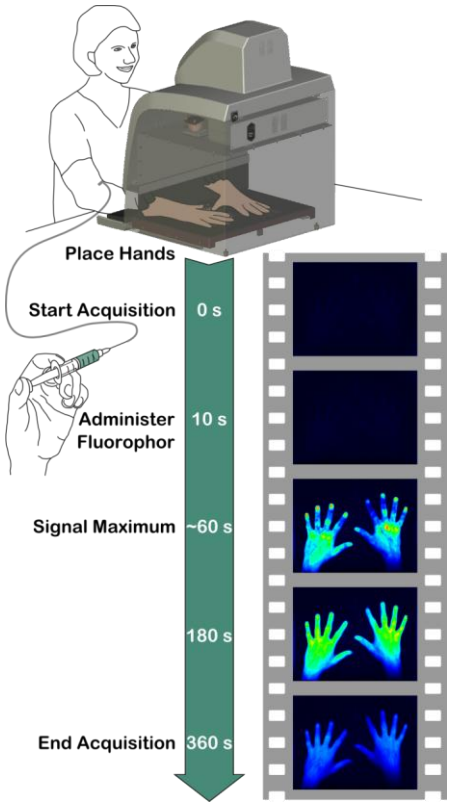

Figure 3.2: Examination procedure

- Start acquisition of the image sequence.
- Intravenous administration of fluorescence contrast agent 10 seconds after start of image acquisition
- Image acquisition terminates automatically after acquiring selected number of images respectively after selected acquisition duration. In addition, it is possible to stop manually image acquisition at any time.
- After image acquisition the user has to select the images without signs of contrast agent. Images at the start of the image sequence before the fluorophore flows in contain only a background signal for which all images have to be corrected for. Details on image correction are found in section 5.6

A quick reference guide is supplied as a laminated card. It is additionally printed in the Appendix A.1 “Quick reference guide”.

3.5 Operating Software

3.5.1 Starting

Start the associated operting software "XiraView 3.7" either on the desktop icon (see figure 3-3) or by selecting from the start menu.

XiraView 3.7

Figure 3.3: Desktop icon of the control software

Before starting the software for capturing image sequences turn on the Xiralite® Fluorescence Imaging System X4. Otherwise, an error message appears and no images can be recorded. Despite this error, XiraView can be used to view image sequences of already recorded cases. If the Xiralite® Fluorescence Imaging System X4 was mistakenly not switched on, the device can be activated later as described in Section 3.5.3.

Figure 3.4 shows the user interface after startup. The user interface of the program is divided into a wide input and viewing area and a narrower control panel on the right side. In the control panel, additional controls become visible in some modes of operation that are

hidden for clarity first. At the lower end of the control panel there are three squared information displays that indicate the device status.

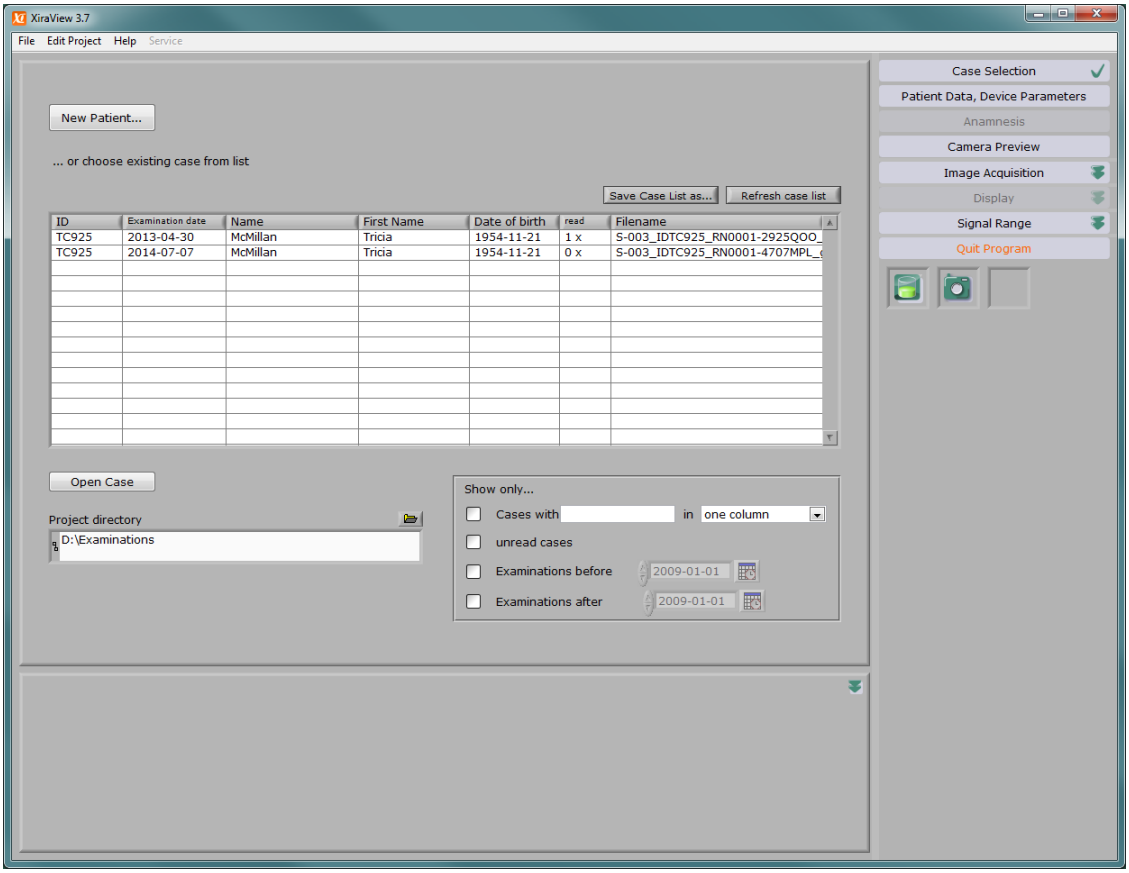

Figure 3.4: User interface of XiraView after start and for case selection.

3.5.2 Modes of Operation

The functionality and interface of the input and viewing area will change depending on the mode the program is in. In the control panel, the following modes of operation are available (see Table 3.1).

Case Selection
Patient Data, Device Parameters
Anamnesis
Camera Preview
Image Acquisition
Display (Prima Vista/ Film)
Signal Range
Quit Program

Table 3.1: XiraView modes of operation

The modes of operation are described in detail in subsequent chapters. The first four modes are displayed by selecting them with a check mark. Selecting the last four modes, additional controls are displayed. The status displays are described in Section 3.5.3.

The program is terminated either by selecting the menu item "File > Quit", or by simultaneously pressing "Ctrl" and "Q", or by pressing the "Quit Program" button in the control panel, or by closing the program window.

The double arrow buttons  release additional areas with more control elements. Repressing the buttons will hide the control elements again.

3.5.2.1 Case-Selection

The operation mode "Case Selection" after start-up or after pressing the control button "Case Selection" is shown in Figure 3.4. It is possible to start a new examination of a patient by pressing the button "New Patient...". Alternatively, an already completed case can be loaded for review. Therefore a list of available cases is shown in the middle of the input and viewing panel. Listed cases are retrieved from the folder selected in the “Project directory” input field and its subfolders. Double clicking or marking and selecting “Open case” open the desired case.

The input field “Project directory” for the folder to be scanned is found on the left below the case list. If the folder is changed, the new folder and its subfolders will be scanned for case record files and the case list is refreshed. Right above the case list the user can rescan the current project directory by pressing “Refresh case list”. Please note that after examination the new case does not automatically appear in the case list and the case list has to be updated manually.

On the right below the case list several input fields are found. They are used for filtered views of the case list. Thus, e. g. only case records containing a certain string can be shown. Thereby the search can be restricted to a single column. Furthermore, cases without reading can be shown only or case records can be selected by examination date. Several criteria can be combined.

If a case is selected and opened from the list the program switches to the display mode. Now the captured image sequence can be scrolled (see also Section 3.5.2.6). If the user chooses

"New Patient…", the program will show the "Patient Data, Device Parameters" mode on the input and viewing panel. This mode will be described in the following section.

3.5.2.2 Patient Data and Device Parameters

In the mode "Patient data, Device parameters" data of the patient, the physician's office, the physician, the equipment operator and the acquisition parameters can be entered or viewed (see Figure 3.5). Entering this information is mandatory. Optionally, a comment can be recorded.

In this view patient data is displayed if a case is opened. But the data cannot be altered in this case. The button "New for current patient" can be pressed if a new examination on basis of the displayed data shall be started. Now the data in the input field can be edited.

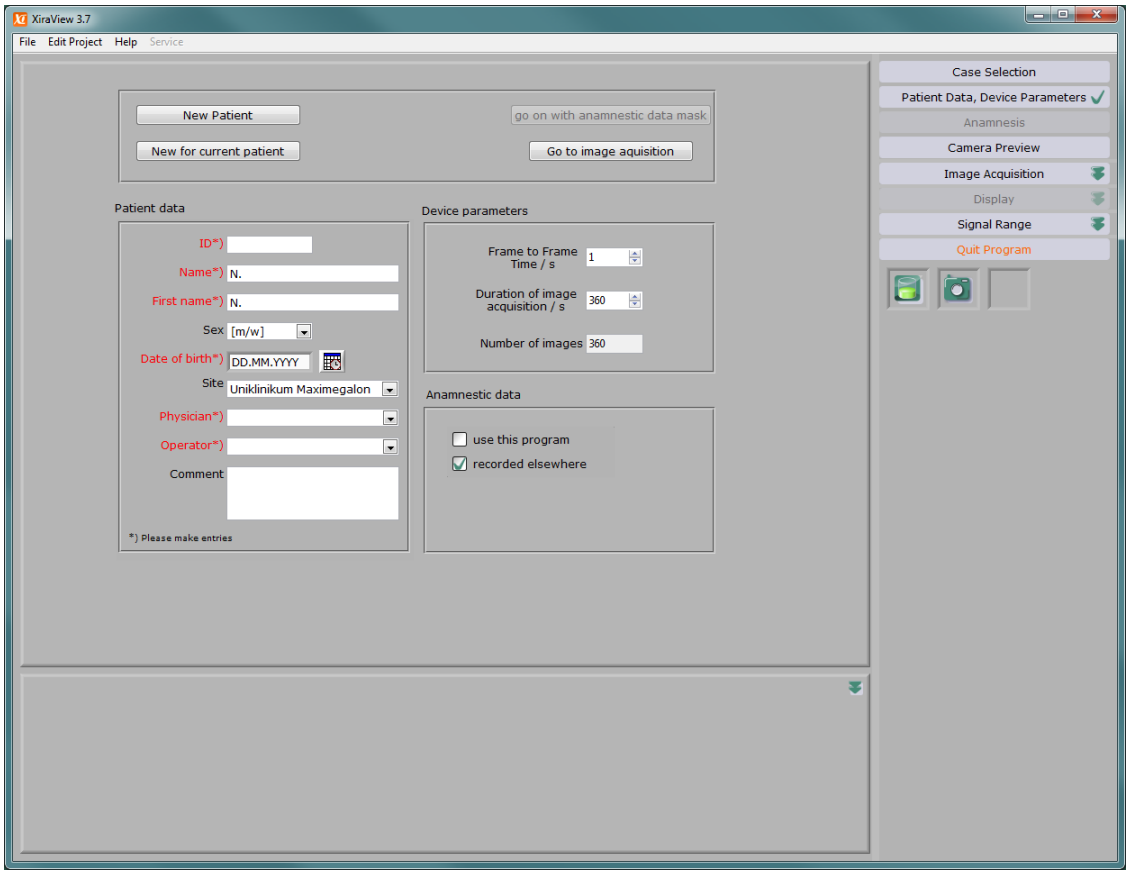

Figure 3.5: View of program window in "Patient data, Device Parameters" mode to enter patient data and to review device parameters before start of image acquisition

Patient Data:

The fields "ID", "Name", "First name", "Sex", "Date of Birth", "Site", "Physician" and "Operator" are used to track examinations. Therefore, they have to be filled out absolutely correct and complete. The software can only monitor the completeness. Required, not yet completed fields are displayed with red titles (see Figure 3.5, left). The following list describes the fields:

ID: Internal labeling of a physician's office for a patient or his file. The ID can be entered by the physician without restrictions.

Name, First Name: Name of Patient.

Sex: male (= m) or female (= f)

Date of Birth: Birthday of patient.

Site: Name of the clinic or physician's office where the examination is performed. The name is entered in the configuration file and is automatically displayed.

Physician: Name of the physician who carried out the examination. Here, additional names can be entered and are automatically added to the list. The names are stored in the configuration file when the program is finished.

Operator: Person who operated the equipment during the examination. Newly entered names are stored in the configuration file when the program is quit.

Comments: Comments on the current image acquisition can be entered.

Device Parameters:

On the right side of the “Patient Data, Device Parameters” view the device parameters can be altered if required for special cases. Under normal circumstances the default values are completely sufficient (see Figure 3.5).

Time interval of images: The time interval of images in an image sequence is set. The interval is specified in seconds and the values may be between 0.5 s and 9 s. Default value is 1 second.

Image acquisition time: The image acquisition time is set and specified in seconds. The resulting number of images is displayed in the field below.

Number of images: The number of images is displayed, which will be captured.

The measurement is stopped automatically by the software after the image acquisition time or after acquisition of the specified number of images. An image sequence can be interrupted at any time by the user. The number of images can range from 1 to 10000.

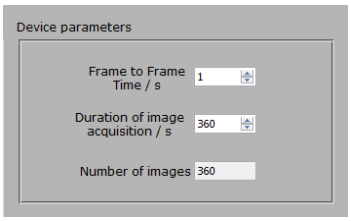

Figure 3.6: Standard device parameter of the image acqusition.

Additional Fields:

Anamnesis: In addition, there are two fields for anamnesis. The user can specify whether a patient's medical anamnesis is already available or whether the recording should be made using the software in the mode "Anamnesis". In the first case, the mode "Anamnesis" is disabled.

To continue with the anamnesis, either the button “Go on with anamnestic data” or the button "Anamnesis" in the control panel has to be pressed. In the mode "Anamnesis", respective data to the hands can be entered.

With the button "Go to image acquisition" in the control panel, the mode "Image Acquisition" is opened. A blue notice (see Section 0 and Figure 3.9) will appear and the image acquisition cannot be started if the descriptive patient data fields are not completely filled.

Both modes are described in the following sections.

3.5.2.3 Anamnesis

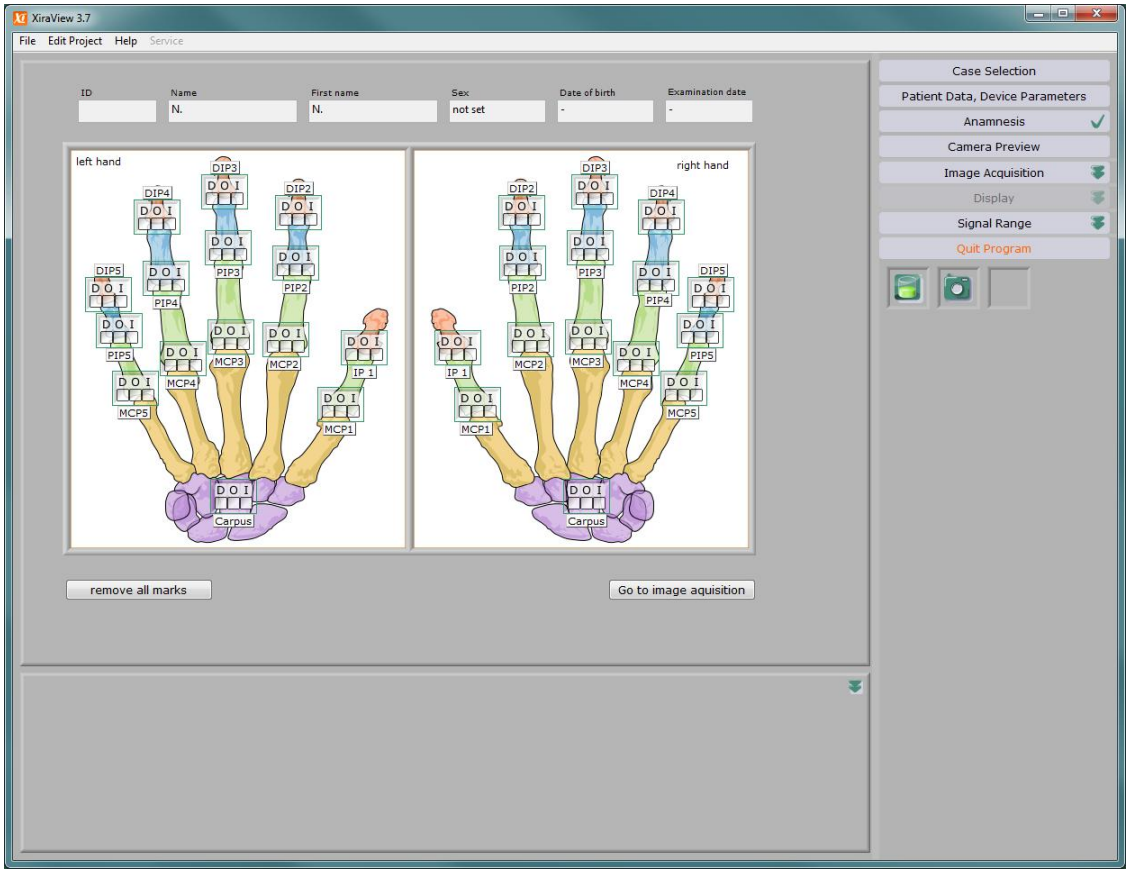

Figure 3.7: View of program window for anamnesis input for both patient hands

Figure 3.7 shows the interface for entering anamnestic data after activation of the "Anamnesis" mode. For each joint, the physician can mark whether the joint is painful (dolor = D), is swollen (oedema = O) or immobile (immobilitas = I). The information is stored in the case record file.

Patient data is shown above the anamnesis hands. They can be edited in “Patient Data, Device Parameters” mode until the image sequence has been acquired. Anamnesis data is not deleted if the user is going to edit patient data in the meantime.

Additional Control Buttons:

Button „Remove all check marks“: removed all marks for all joints to possibly start over.

Button „Go to image acquisition“: With the button "Go to image acquisition" the mode "Image acquisition" is opened. A blue notice (see Section 0 and Figure 3.9) will appear and the image acquisition cannot be started if the descriptive patient data fields are not completely filled.

3.5.2.4 Camera Preview

The “Camera preview” mode is designed for a quick visual check whether the connection between the PC and the device is ready for acquisition. Additionally the correct position of hands in the device and the amount of unwanted ambient stray light can be judged. The light protection curtain should not be seen in the imaging area and should block as much ambient light as possible.

The button "Camera Preview" in the control panel starts the camera preview of the Xiralite® Fluorescence Imaging System X4. Then, images of the working area are captured with high frame rate. Pressing the button again, terminates the preview mode. In preview mode no images are recorded. Therefore, contrast agent must **not** be administered in preview mode.

Caution

In the operation mode “Camera Preview”, no image data is stored.

- Do not inject contrast agent.
- Images are only recorded after pressing the button "Start" in the operation mode “Image acquisition”.

3.5.2.5 Image Acquisition

The user interface of the “Image acquisition” mode is shown in Figure 3.8. The respective control panel shows two buttons, “start” and “terminate”. The inactive field appears grayed out and is deactivated.

start: The button "start" starts the image acquisition. The image acquisition will end automatically after recording the preselected image number.

terminate: The button “terminate” has to be pressed if the image acquisition shall be stopped early. In any case due to technical reasons another capture cycle and the acquisition of another image is performed.

After the end of image acquisition, the program switches automatically to the “Display (Prima Vista/ Film)” mode to view the image data.

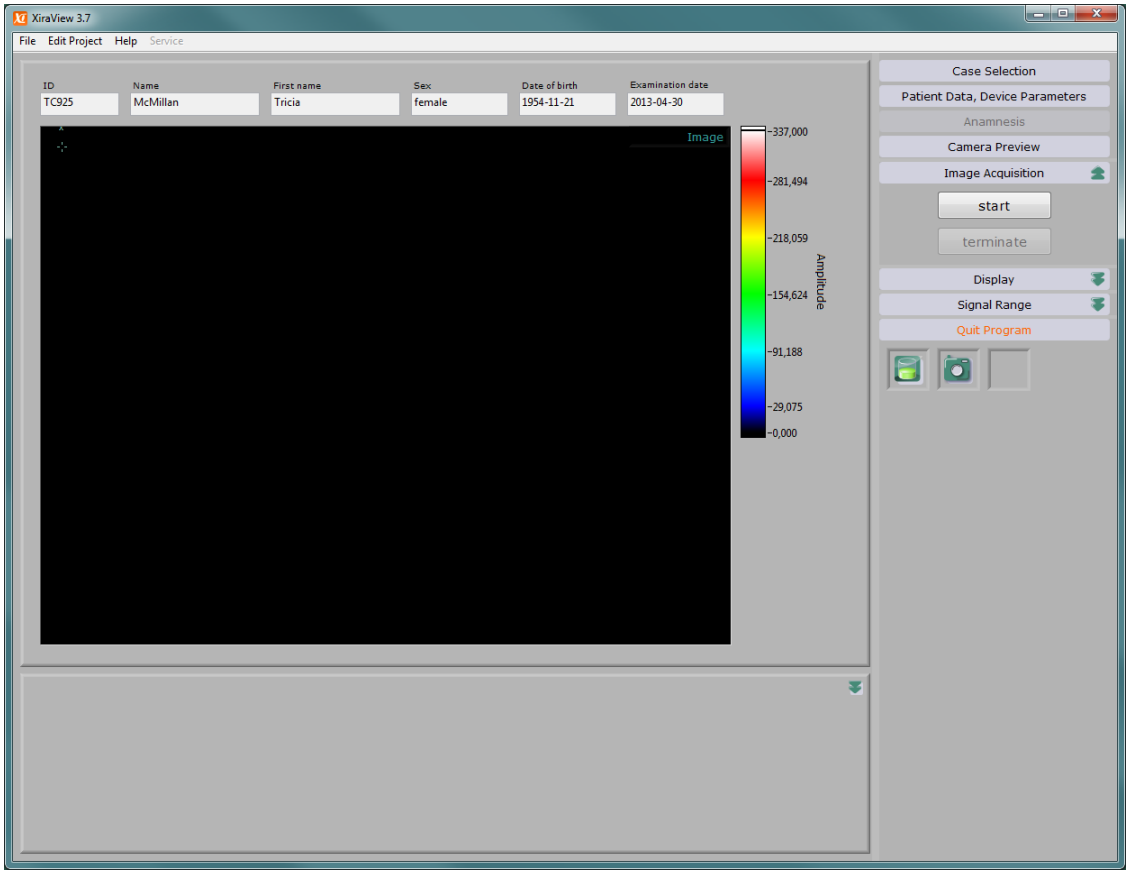

Figure 3.8: View of the program window before starting an image acquisition process.

If the patient data are not completed or information on operator and/or physician aren't properly specified, a blue notice appears (see Figure 3.9), that information must be entered. The notice covers the "start"- and "terminate"-button, so that the image acquisition process cannot be started. The image acquisition can be started only after entering all required information. The software can only verify the completeness. The user is responsible for the content of the information.

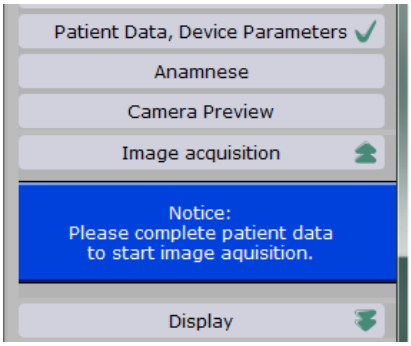

Figure 3.9: Notice: Image acquisition cannot be started

The acquired images contain a background signal and possibly ambient stray light. Both unwanted signals need to be subtracted before interpretation of image sequences.

Images at the beginning of the captured sequence (before the fluorescent contrast agent wash in) contain only this background signal and ambient stray light. The images without signs of contrast agent need to be selected.

At the end of the image acquisition, a dialog window (see Figure 3.10) is opened. The user has to select the last image without any signal from the fluorescent contrast agent. The image is searched and selected with the slider below the display. If necessary, signal range of the images can be rescaled. Additional information on image correction can be found in Section 5.6 “Image Signal Correction”.

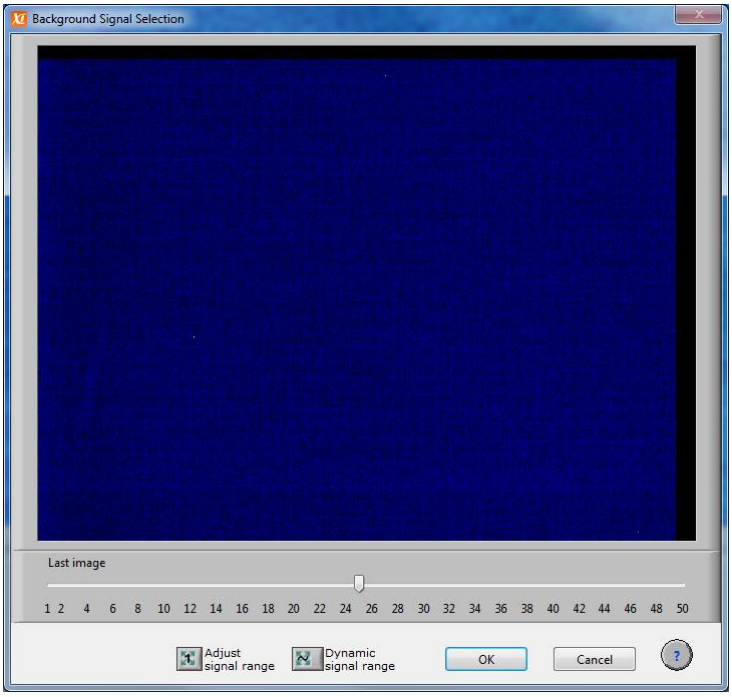

Figure 3.10: Pop-up window for background image correction

The pop-up window comprises the following buttons:

, **:** see Section 3.5.2.7 “Signal Range”

OK: the selected image will be used for background image correction and will be stored in the case record file.

Cancel: Cancels the selection. The project file is annotated with the information that no background-image correction is performed.

?: Detailed help for background correction image is displayed.

3.5.2.6 Display (Prima Vista/ Film)

In the “Display” mode, there are two possibilities for viewing the images of an examination: "Prima Vista" and "Film". “Prima Vista” is the default view after opening a stored image sequence. The program also switches to the “Prima Vista” mode after finishing acquisition of an image sequence.

Prima Vista

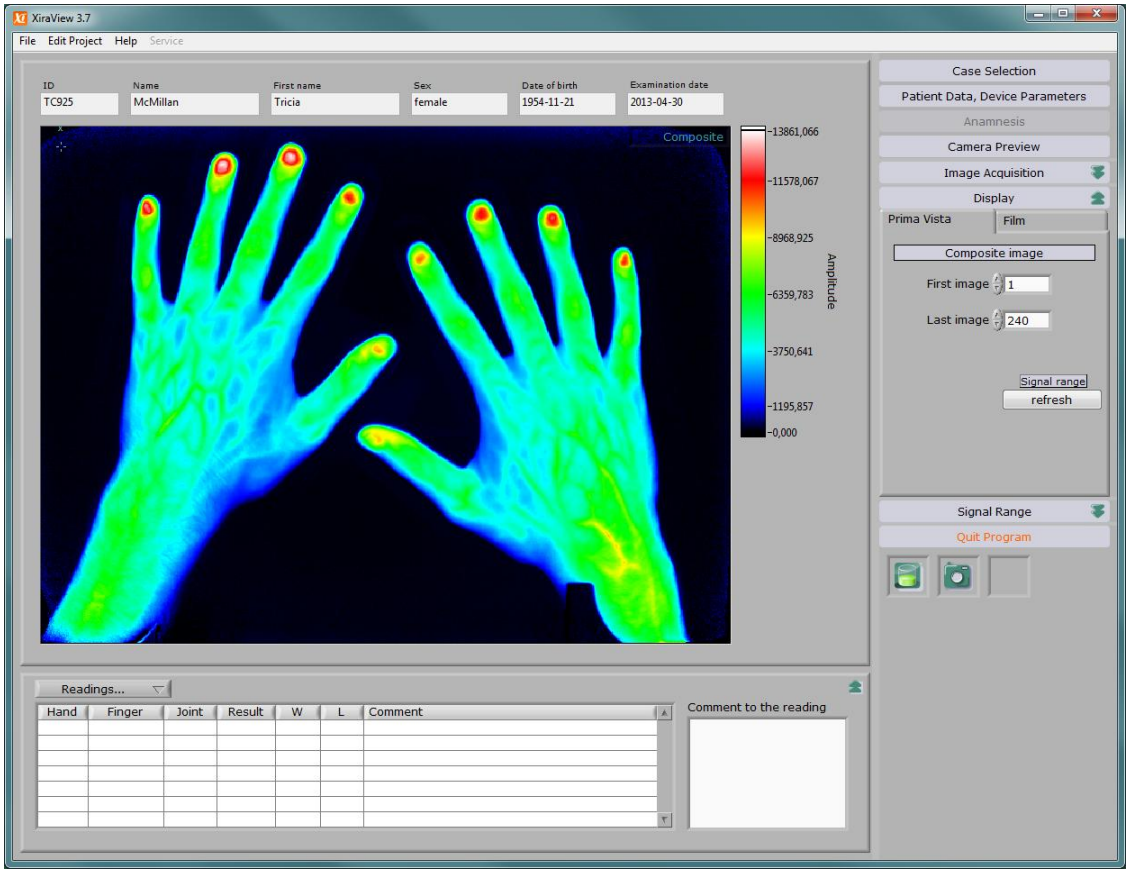

Figure 3.11: Display mode “Prima Vista”

In the display mode “Prima Vista” the images of an examination are summed up. The user can select the first and the last image of the summation range. By default the first 240 images of a sequence are used for summing up. User modified values will be maintained during program run time and not reset to default value. Figure 3.11 shows the “Prima Vista” display mode.

Particular attention has to be paid to moving hands during acquisition. In this case the “Prima Vista” image appears to be blurred and cannot be used for diagnosis. Then, the reading must be based on the image sequence by looking at single images. Moving artifacts become easily visible when the film is scrolled quickly in the “Film” mode. Usually the hands rest motionless or with very little motion so that the “Prima Vista” view can be used without difficulty.

Film

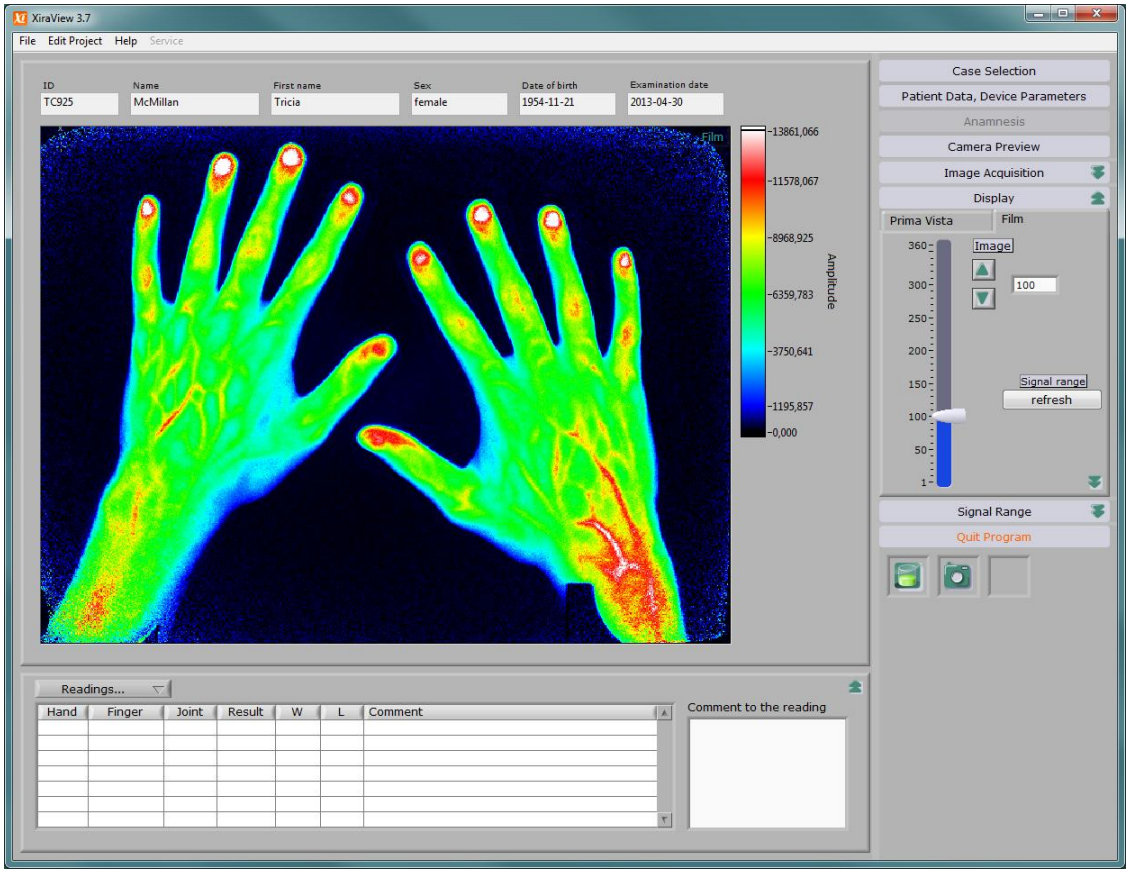

Figure 3.12: View of program in display mode “Film”

In the display mode “Film” a slider is visible. It is used for scrolling the image sequence. and to show individual images. With the arrow button beside the slider the sequence can be scrolled image by image. Current image number is display to the right. A specific image number can be entered as well and the respective image will be shown.

The mouse wheel can be used for scrolling the image sequence if the mouse is positioned over the image display or over the slider.

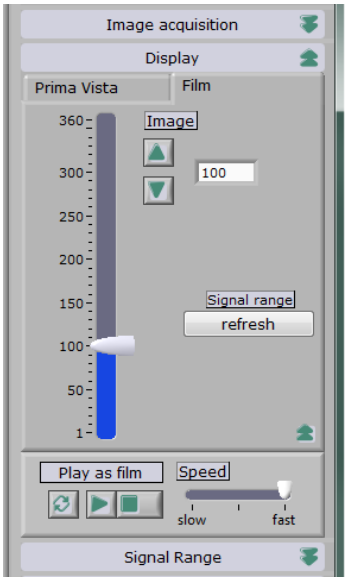

Figure 3.13: Additional functions for scrolling: Play sequence as a film.

Another part of the control panel is opened for additional functionality (see Figure 3.13), if the double arrow button (buttom, right) is pressed. With these control elements the image sequence can be played as a film. They frame rate is selectable.

 Plays image sequence continuously.

 Plays image sequence once.

 Terminates playing image sequence.

3.5.2.7 Signal Range

The displayed signal range can be optimized (see Figure 3.14). The individual functions are described below.

Refresh: Current image will be scaled from zero to its maximum signal intensity. The colors of the current palette are distributed accordingly. The scale will be maintained while scrolling and displaying other images.

Dynamic: If the button “Dynamic” is selected then each displayed image will be scaled from zero to its maximum signal intensity. The scale is dynamically adjusted while scrolling the image sequence.

Palette: The coloring of image pixels according to signal intensity can be altered with selection of a color palette. Pixels with intensity values outside the scaling range are displayed in the color for the smallest and largest intensity, respectively.

The color scale is displayed on the right side of the image, with the color representing the lowest signal values on the bottom end of the scale and the color representing the highest signal values on the top end of the scale. Grayscale and different color scales are available to allow the

physician to adapt the image color coding to the individual viewing preference. Examples are shown in Section 3.6.

Gain: With this slider the largest shown signal intensity value is determined. The color palette is applied accordingly. The smallest shown signal intensity remains fixed at zero.

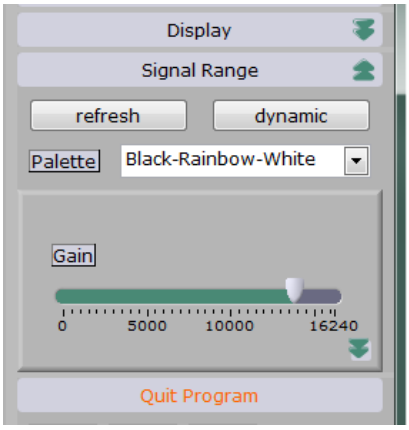

Figure 3.14: Part of control panel for controlling of signal range and pixel coloring

To vary the minimum of the signal range, additional controls need to be made visible by pressing the double arrow button. Now, minimum and maximum of the display signal range can be modified. Alternatively, displayed signal range can be controlled by brightness and contrast (see Figure 3.15):

Brightness/Level: With this slider the range of the displayed intensity values can be shifted. To adjust the control range of the slider to the signal range in the displayed image, “Adapt scale range to image intensity range” has to be selected from the context menu.

Contrast/Window: With this slider the width of the displayed intensity value range will be modified. To adjust the control range of the slider to the signal range in the displayed image, “Adapt scale range to image intensity range” has to be selected from the context menu.

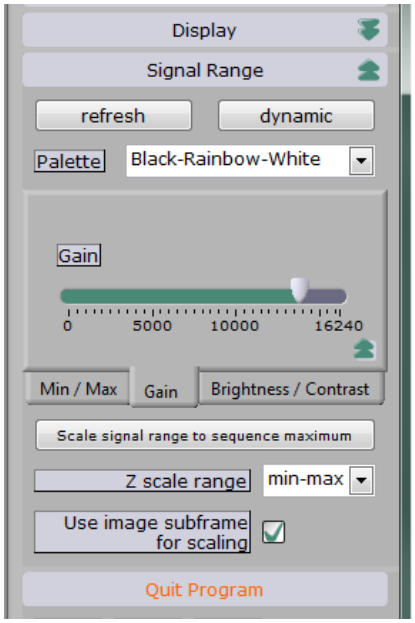

Figure 3.15: Extended functions for signal range control

If one of the advance signal range controls “Min/Max” or “Brightness/Contrast” is used the functionality of the buttons refresh and dynamic is different. Now, the scaling affects not only the maximum but also the minimum.

Use image subframe for scaling: The check box determines whether signal values from a rectangular part of the image are used for scaling or not. The subframe is set during installation and stored in the configuration file.

3.5.3 Status Indicators

The status of the camera and the amount of free disk space is displayed at the bottom of the control panel.

Hard disk status

This indicator shows how many examinations still can be saved in the data directory (depending on the number of images per acquisition). The hard disk icon will change the color gradually from green to yellow to red. Notices appear if fewer than 80 examinations can be stored. If there is not enough space on the drive, the icon turns red and no further examinations can be started. It is possible to free disk space by archiving image sequences.

/ Availability of the camera

This indicator shows whether the camera of the device is available or not. The left icon appears when a camera has been detected. The symbol appears crossed out (right icon) if no camera was detected at startup or the camera link produced an error. A pop-up window appears for information by clicking on the indicator. The camera can activated by pressing the [Shift] button + clicking the crossed out icon.

State temperature of the camera

The camera temperature status display is only applicable for systems with temperature stabilized cameras.

The status display shows the temperature of the sensor chip of the camera. Investigations should be performed if the field is green. The indicator remains yellow if the temperature is unstable or not below -17 ° C. By clicking onto the thermometer icon a message window will pop up and the temperature is given in °C.

3.5.4 Reading

For reading a case record must be opened and the image sequence loaded into memory. By moving the mouse over the image display and pressing the left mouse button a mark is set into the image. In a pop up window the user should specify the joint (right/left hand, finger number counting from thumb, joint) and can give the degree of inflammation visibility (see Figure 3.16). Thus, a lesion can be described and marked by position. Image, coloring and scaling are recorded.

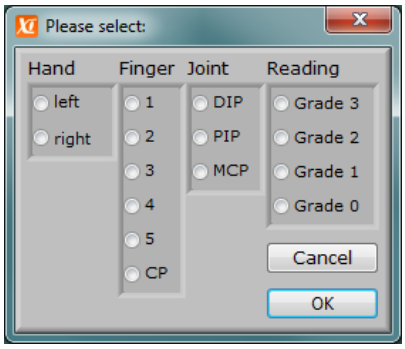

Figure 3.16: Pop-up window for marking joint and reading

Below the image display all readings are listed in a table. This table is only visible if cases are reviewed. With a simple click an entry can be selected. Now, pressing the right mouse button displays a pop-up window for adding a comment to the selected reading or altering the grade of inflammation visibility (see Figure 3.17). The comment field allows the description of decreased or increased microcirculation.

A double click on a reading item restores the image, image coloring and the image scaling which was present during marking the lesion. Additionally the respective mark in the image display is highlighted.

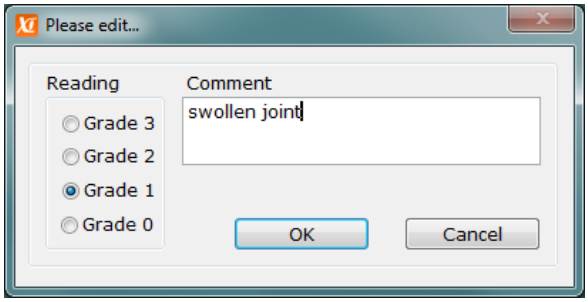

Figure 3.17: Input mask for a comment to a reading item

Left above the reading table a pull-down menu is ("Reading") is placed with the following functions:

Save readings: Saves all reading items with the case record file.

Print readings: Formats the readings list as a report and stores it as an HTML-file which will be loaded in the Internet-Explorer afterwards. Printing is done with the print operation of the Internet-Explorer.

Delete marked element: Deletes the marked item from the readings list.

Normal reading: Denotes that there a no lesions found and the hands appears healthy in imaging.

The table of readings can be hidden or shown clicking the double arrow button on the right above the table.

3.5.5 Main Menu Functions

File

Open case record file…: opens a dialog window for selection of any case record file on disk. Selected case file will be opened and displayed.

View case record file: Display the entire structured content in XML format of the current case record file in a separate window.

Save image as…: Stores current view of the loaded image sequence in PNG format.

Print Window…: Prints the program window.

Quit: Quits the program.

Edit Project

Underground and reference image selection: Opens a dialog window for editing background and reference image correction of the current case record file (see Figure 3.18).

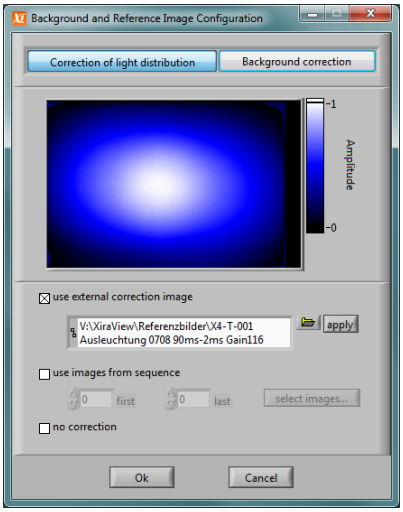

Figure 3.18: Dialog window for editing background and reference image correction

Help

Help: Currently out of use. Please use the function "Description and Tip" from the context menu of the respective control panel or indicator for additional help.

Language: In the submenu you can select the displayed language. Currently, you can select the languages "German" and "English". Thus, the labeling of all operating and display element is switched to the chosen language.

About…: Displays information about manufacturers and developers of the software.

3.5.6 Context Menu Functions

For all controls on the front panel the function “Description and Tip…” can be called from the context menu. This will open a pop-up window to display a short description and the tip strip for the respective field. The tip strip is also displayed if the mouse pointer stays for a couple of seconds over the control.

Some controls have additional functionality which will be described below.

Case List Context Menu

Open selected case: Opens selected case (same as with double clicking an item).

Anonymize selected case: Opens a dialog window for anonymizing the selected case and saving to a new location on disk.

	Notice	
	Please note that the option “anonymous” has	

	to be set for anonymization. Otherwise the case record file will just be copied to the new location on disk.	

The option „Copy images to new location copies the image sequence belonging to the case record to the new location on disk. Due to the amount of image data waiting times have to be expected.

New examination for selected case: starts a new examination and takes over patient data of the selected case. The case record file will be loaded completely. Then, the program switches to “Patient data, Device Parameters” mode (see Section 3.5.2.2).

Advanced… > Find image file(s):

Warning

Use this function with extreme care as mixing image files may occur. This could lead to wrong diagnosis and mal treatment of patients.

- Under normal circumstances it is not necessary to use this function.
- Please contact manufacturer for further support if in doubt.

This function starts searching for image sequence file(s) of the selected case. In a dialog window matching files and other image sequence files are listed. By marking and pressing “Use selected file” (double click serves as a shortcut) a new image sequence is linked to the case record.

Button “Cancel scanning” terminates scan of hard disk.

Button “Cancel” terminates dialog and no new image sequence file is referenced by the case record file.

Advanced… > Show case file of selected case: display the entire structured content in XML format of the current case record file in a separate window.

Context Menu For Signal Range Control Sliders

Adapt scale range to image intensity range: The scale of the slider is adjusted, so that the entire signal range of the image can be controlled with a reserve of 15% beyond that. The scale can also be changed manually by entering a new value in the label at begin or end of the scale.

3.5.7 User Support and Help

If the mouse pointer stays for a moment over controls and indicators a tip strip with a brief description will be displayed. Using “Description and tip…” from the context menu of a control additional information on the functionality is displayed.

3.6 Reading Procedure

Step	Description	Comment
1	Finish the image acquisition process or load a case record	Standard view is “Prima Vista”. As standard, the summation of the first 240 images is shown as an overview.
2	Verify correct scaling of the signal intensities	In most patients the automatic scaling will lead to adequately scaled images. Verify that at least one finger tip shows high signal intensity colors (see top end of color bar on the right side of the image) or white when using grey scale. See Figure 3.19 a.
3	If necessary, adapt signal scaling	If no finger tip shows high signal intensity colors, adapt the gain by using the sliders until at least one finger tip shows high signal intensity colors (see top end of color bar on the right side of the image) or white when using grey scale.
4	Visually assess the image	Normal microcirculation will appear in a medium signal intensity color or grey (see middle part of the color bar on the right side of the image). See Figure 3.19 b. Regions with increased microcirculation will show colors or grey values of the upper part of the color bar (see Figure 3.19 c), while regions with decreased microcirculation will show colors or grey values of the lower part of the color bar (see Figure 3.19 d).
5	Switch to film mode	You may switch to film mode where the 100 seconds point in time is shown.
6	Verify and adapt signal scaling	Scroll through the image stack and select the image with the highest visible signal intensity. Repeat steps 2 and 3 on this image.
7	Visually assess the image stack	Scroll through the image stack from image 1 to image 360. This allows visualizing the first pass and the recirculation of the ICG. Repeat step 4.

Table 3.2: Reading procedure

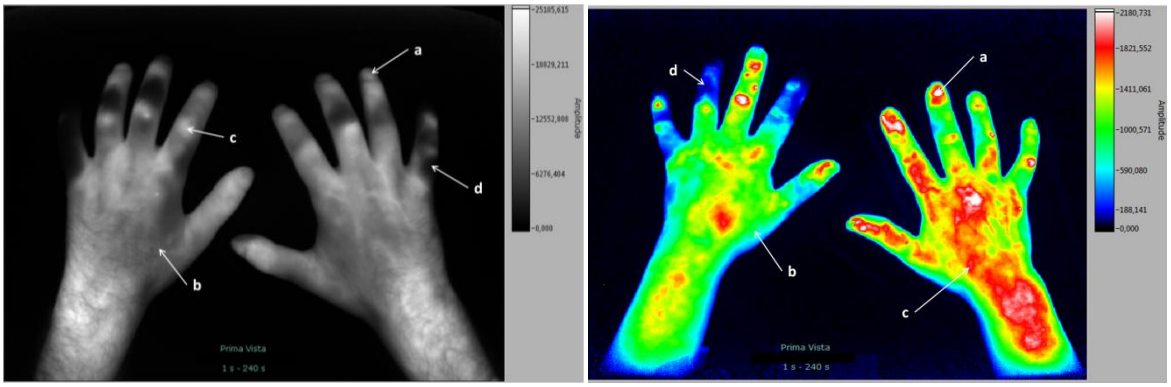

Figure 3.19: Example images in grey scale (left) and color scale (right). Correct scaling with high signal in at least one finger tip (a). Normal microcirculation appears as medium signal intensity (b), while increased microcirculation shows colors or grey scales of the upper part of the color bar (c), and decreased microcirculation shows colors or trey scales of the lower part of the color bar (d). The color bar is on the right side of the image.

4. Maintenance and Cleaning

4.1 Maintenance

All cable connections have to be checked regularly to maintain functionality of the device.

Annually the operator shall perform a metrological inspection of the instrument which is done by the manufacturer.

For electrical safety the instrument has to be checked at least every two years.

All maintenance work is done by the manufacturer. The instrument may only be opened by trained maintenance staff. The replacement of fuses is also done by the manufacturer or by trained personnel.

Hand rests with damaged surface must be replaced. Please contact the manufacturer's service.

4.2 Cleaning and Disinfection

The hand rest has to be checked for splashed fluorescent dye remainders after each examination. If there is a contamination of the hand rest, it must be replaced and the old one is sent back to Xiralite GmbH for disposal.

Generally, disinfection of the hand rest is not necessary. In case of suspected contamination with unwanted germs the hand rest has to be replaced. The use of the old hand rest may not be continued, but must be disinfected outside the instrument and returned for disposal to Xiralite GmbH.

Warning

Use of alcohol-based disinfectants for cleaning the hand rest can lead to explosive alcohol-air mixtures inside of the instrument. There is a risk of burns.

- No spray or wipe disinfection on installed hand rest.

If required, surfaces of the Xiralite® Fluorescence Imaging System X4 are cleaned with a damp cloth, if necessary, with a mild detergent. Make sure that the instrument is switched of and no water gets into the housing.

4.3 Troubleshooting

Message/Definition/Result	Possible Cause	Recommended action
Monitor does not work.	Monitor was switched off.	Switch-on.
	Monitor cables are not plugged-in correctly.	Check signal cable and power cable for correct fit.
	12V power supply connector is inserted upside down on the voltage outlet at the PC.	Plug-in connector in correct orientation. Pay attention to beveled edges.
Camera is not found.	USB cable is not fixed	Plug in USB cable properly and restart Software after ten seconds.
Error 5003: Camera cannot be accessed.	USB connection between computer and Xiralite device is interrupted. The Xiralite device is switched off or the power supply is missing for other reasons.	Check USB link and ensure the power supply of the Xiralite instrument. Then restart the XiraView software.
	Xiralite device was intentionally not switched on, because XiraView shall be used for reading only.	Ignore error and use XiraView for reviewing cases only.
Error 5201: Frames*.lvclass: File Format not available.	File extention of a image sequence file was changed by mistake.	Reverse changes. File extention must be ".rhi".
Error 5202: Reference image file for illumination correction not found.	If the error occurs after an image acquisition, a nonexistent illumination correction file is referenced in the configuration file "xira.cfg".	The missing illumination correction file must be copied to the hard disk or the reference in the configuration file has to point to an existing file. Please contact technical support.

Table 4.1: User Message Chart

Note
The user shall not modify the configuration file. ➢ Please contact technical support if an

	error is suspected to be in the configuration file.	

4.4 Technical Support

If you experience any problems or questions, please contact us:

Dr. Jörn Berger

Xiralite GmbH

Robert-Koch-Platz 4

10115 Berlin

Germany

Phone +49 30 890 497 435
Fax +49 30 890 497 499

Email: xiralite@xiralite.com

We kindly ask you to post a message to us in case of errors or suggestions for improvements concerning the operating and control software.

5. Technical Device Description

Warning

The Xiralite® Fluorescence Imaging System X4 must not be altered without the permission of the manufacturer. Modifications of the system require appropriate tests and checks to ensure the continued safe use.

- Maintenance is carried out by the manufacturer (see Sections 2 and 4).
- Relocation is done by the manufacturer or by trained and authorized persons (see Section 2)

5.1 Working Principle

The working principle of the Xiralite® Fluorescence Imaging System X4 is based on fluorescence excitation by light-emitting diodes (LED) and two-dimensional detection of fluorescence signals by a sensitive CCD camera. A fluorophore (e.g. the contrast agent Indocyanine green) is administered intravenously. It is important to separate fluorescence light and reflected excitation light regarding the wavelengths. The excitation light is suppressed on the detector, whereas the fluorescence light should reach the detector not attenuated. For this purpose a long pass filter is installed in front of the lens of the camera. Light emitting diodes have a broadband emission. Hence, it is necessary to install a short pass filter in front of the LEDs to reject excitation light in the detection wavelength band. With such a filter combination unwanted interfering background signal is suppressed to a maximum and extremely sensitive measurements can be performed.

The Xiralite® Fluorescence Imaging System X4 is connected to a computer. A control software provides a user interface and controls the acquisition process. The software acquires and stores fluorescence signals captured by the camera via an USB link. By means of a trigger pulse LED illumination occurs only during exposure. On readout of the sensor no illumination is present. As a result of this procedure image quality is improved as no light reached the sensor during shifting information to the readout area of the sensor chip.

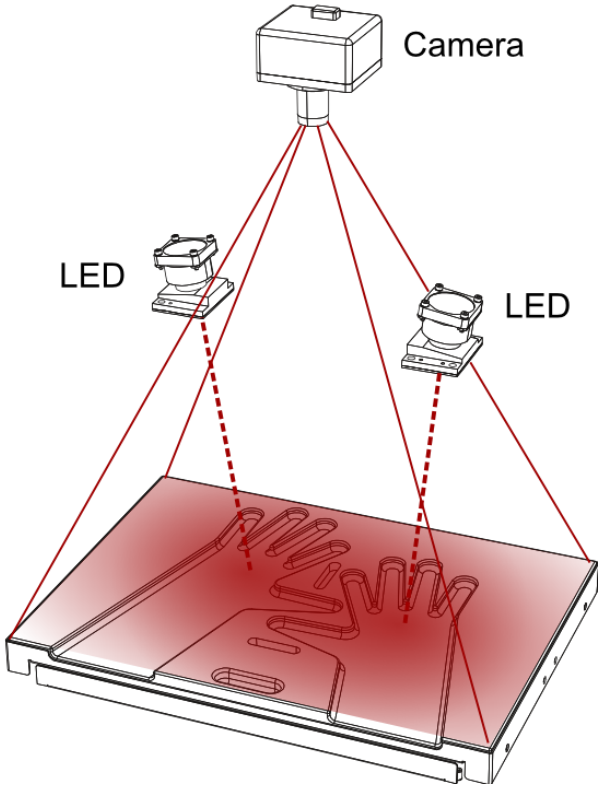

Figure 5.1: Working principle of the Xiralite® Fluorescence Imager X4.

The fluorescence signals are recorded with a camera with an extremely sensitive CCD chip.

	**Caution** The highly sensitive camera can be damaged by intense light. ➢ Do not light up inside of the instrument with intense light sources. ➢ Do not expose camera to sunlight or other intense light sources.	

High performance LED-arrays are used to excite the weak fluorescence signals from ICG. The LEDs emit red light close to near infrared radiation. The radiation is riskless at the level of imaging on the hand rest. The maximum radiation is less than 50 W/m^2. Nevertheless it is not allowed to focus the LED radiation with optical instruments and to look into the LEDs during operation.

	**Caution** High power LED-Array emits intense optical radiation. ➢ Do not look into LED with optical instruments. ➢ Do not put any optical instruments into the instrument. ➢ Do not open instrument and look into the LED.	

5.2 Views of the Instrument

5.2.1 Front View

Figure 5.2 shows the closed instrument. Operating state display is found left above the front flap. It displays two states: green light = mains are switched on, and flashing blue light = image acquisition.

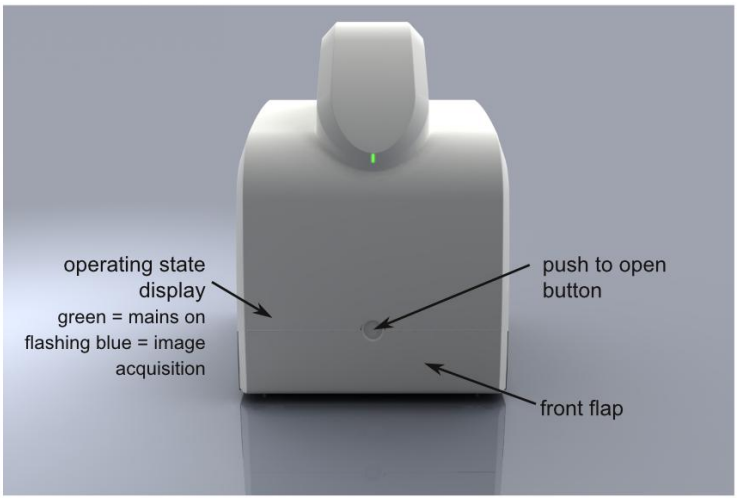

Figure 5.2: Front view of the Xiralite® Fluorescence Imager X4 with closed front flap.

For use of the instrument the front flap has to be opened by pressing the round button of the flap. Now, the drawer with the hand rest can be pulled out and the patient hands can be positioned on the hand rest. The hand rest is profiled to provide precise placement of the hands. Additionally to placement support, the division bars between the fingers provide optical shielding of the fingers among each other. The instrument with pull out hand rest drawer is shown in Figure 5.3.

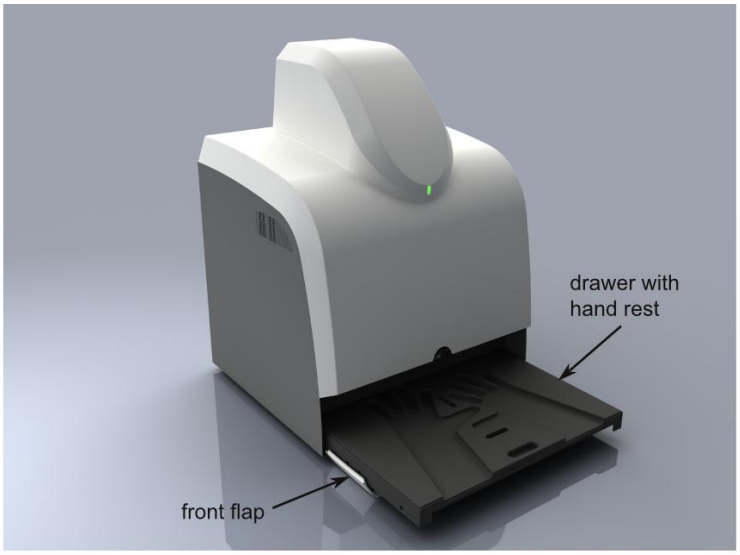

Figure 5.3: View of the Xiralite® Fluorescence Imagers X4 with opened flap and pulled out drawer with hand rest.

5.2.2 Tableau with Hand Rest

	Caution There is a hazard of jamming fingers between the drawer and the arm rest cushion in the flap. ➢ Pull out the drawer with the centrally located recessed grip of the hand rest.	

The drawer with the hand rest is the applied part of the Xiralite® Fluorescence Imaging System X4 according to EN 60601-1:2006. It is a type B applied part.

The hand rest is made of a skin compatible certified material. The hand rest is profiled with a positioning help for precise placement of the hands. Additionally to placement support, the division bars between the fingers provide optical shielding of the fingers among each other. Due to these properties only the supplied hand rest may be used. The drawer (inside) and the hand rest (on the bottom) are marked with the following labels (see Figure 5.4).

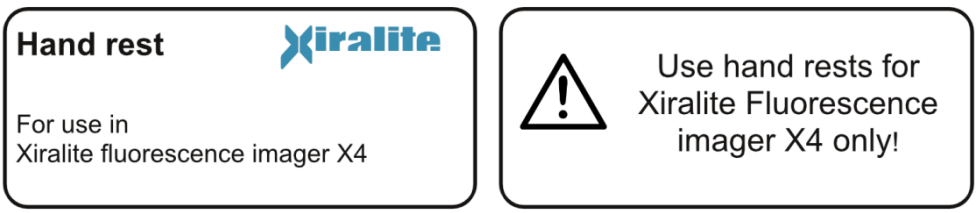

Figure 5.4: Labeling of the hand rest (left) und drawer (right) of the Xiralite® fluorescence imager X4

5.2.3 Rear View

On rear view of the instrument are the mains supply with switch, the potential equalization connection (POAG), an USB port and the type plate. The POAG is marked with the symbol ⏚. Figure 5.5 shows the rear view of the Xiralite® Fluorescence Imaging System X4.

If necessary, the ground potential of neighboring devices that are connected to the electricity grid is compensated by the potential equalization connection on the rear side.

Start-up and shutdown are described in Section 3.1. For complete disconnection from supply, disconnect the power plug and the USB cable after shutdown. The complete disconnection from supply is required for maintenance and transportation. If the system is regularly used, a complete disconnection from supply is not necessary.

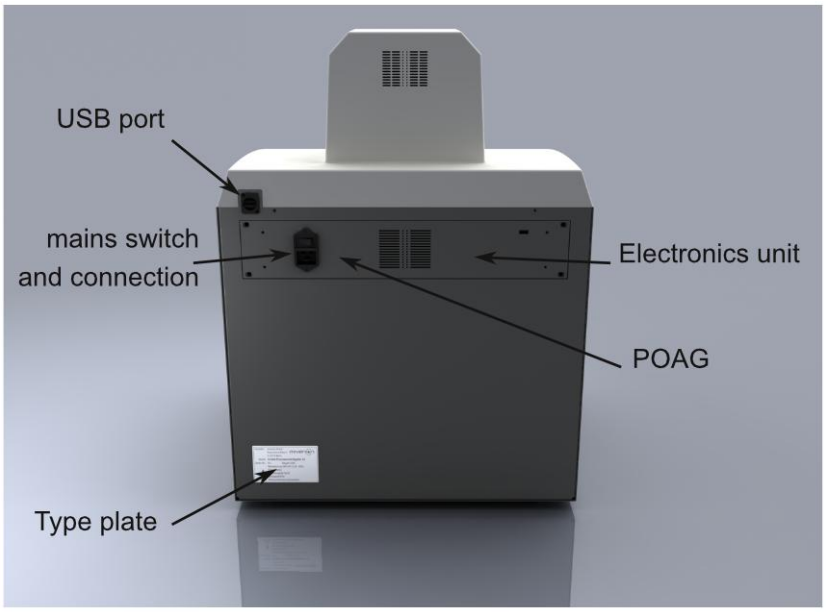

Figure 5.5: Rear view of the Xiralite® Fluorescence Imager X4

5.2.3.1 Electronics Unit

The electronics unit may only be opened by authorized personnel of the manufacturer.

	**Warning** By opening the electronics unit, the mains voltage is accessible. Death by electrocution is possible. ➢ Do not open the electronics unit. Disconnect the mains plug. ➢ Pull mains plug immediately if damaged. ➢ Maintenance and repairs are to be carried out by the manufacturer.	

5.3 Peripheral Components

The peripheral components are placed outside the patient environment. The network connection between these components and the control computer is electrically isolated through a network isolator.

5.3.1 UMTS-Router

The UMTS-Router is used for two tasks:

- It connects the supplementary printer with the computer.
- On request, a secure wireless connection can be established to a server of the manufacturer. Using this connection remote support can be provided as soon as the operator has started the installed TeamViewer-Software.
- Depending on availability, different routers are in use.

5.3.2 Color Laser Printer

The supplementary printer HP LaserJet CP1525n is connected via the UMTS-Router and the network isolator with the control computer. The printer is for printing reports generated with XiraView software. Different printer models are in use according to their availability.

5.4 XiraNet

XiraNet is a service for supporting customers. With the use of the installed TeamViewer software online support can be provided. The support team of Xiralite GmbH can have a

connection to the control computer, only if the TeamViewer software is started by the operator. The TeamViewer connection can only be made from the control computer to a server via a protected encrypted virtual network. The server is located in a datacenter and can be operated only by service personnel of Xiralite GmbH via a protected connection. The link is encrypted to ensure that no external person can access data on the control computer.

5.5 Accuracy of Measurement

The technical accuracy of the measurement, i.e. the accuracy of the excitation in terms of stability of the LEDs and the accuracy of the signal recording in respect to the integrated camera is given to be ± 5% of each measured value.

The measured fluorescence intensities in biological tissue depend on absorption at excitation and emission wavelength of the tissue, scattering of the tissue, and the distribution and the concentration of fluorophore molecules at the measurement location. The concentration of fluorophore depends on the administered amount, the circulation time, patho-physiological factors, such as in inflammatory processes, body weight, sex, and pharmacokinetics of the used fluorophore for intravenous administration. These factors also determine the accuracy of an absolute measurement of fluorescence intensities.

Local fluorescence intensity as a direct correlate to a local fluorophore quantity cannot be absolutely determined for a patient due to these very complex parameters in the biological system. Hence, fluorescence intensities should only be compared within one set of images, i. e. one examination, although similar behavior and intensity can be observed for patient groups.

5.6 Image Signal Correction

5.6.1 Background Signal Correction

The recorded fluorescence signals contain a number of unwanted interference signals. A constant value derives from the offset of the AD converter in the sensor chip of the camera. Second, the camera records also a weak reflection signal image of the hands and the hand rest, as the long-pass filters in front of the camera have a limited suppression of the excitation light. Third, despite the light protection curtain, a certain degree of ambient light falls into the device. This stray light has usually spectral parts in the detection wavelength range of the fluorophore so that a reflection image is obtained. All three interference signals are additive and can be eliminated by subtraction, if they were measured independently from the fluorophore signal.

Incident ambient light varies from one investigation to another (different position of various hands, different ambient light conditions). Therefore, it must be determined independently for each investigation. In addition, it cannot be easily separated from the reflection signal. It is useful to capture images of the hands without the fluorophore, which contain only the interference signals.

The inflow of the fluorophore in human hands starts typically 20 seconds after intravenous injection. Hence, approximately 30 images are recorded without fluorophore after start of image acquisition (image rate one image per second injection after 10 seconds). These images contain the reflection light component, incident ambient light and the AD converter offset of the camera. They are averaged and subtracted from the images of the sequence. This is called background signal correction.

The selection of the last image without fluorophore is done immediately after image acquisition (see Section 3.5.2.5). The selected images will be stored for subsequent use in the respective case record file.

5.6.2 Illumination Distribution

Due to the construction, the high performance LEDs don't provide uniform illumination of the two hands. Lesions closer to the border of the image appear darker than lesions with the same intensity in the middle of the image, because illumination intensity is weaker at the image borders. The illumination distribution is in multiplicative relation to the captured fluorescence signal intensity. The illumination distribution can be determined with gray glasses and a matt white surface. During image correction, the measured fluorescence signals are divided by the distribution of illumination, after the additive stray light signals have been subtracted.

The illumination distribution changes only slightly with aging of the LED. The illumination distribution is determined during manufacture and maintenance of the instrument. It is stored in an image file on the hard disk of the associated control computer. The configuration file of the control software refers to this image file (`[Image Correction] ReferenceImageFile=file name with path`).

5.7 Data Safety

To avoid data loss during examination each image is stored immediately after acquisition in a temporary directory on hard disk. Not until termination of the image acquisition, all image data is copied to the image sequence file referenced in the case record file.

This procedure also protects against data loss if an unwanted termination of the acquisition process occurs. In the unlikely event of power loss or software failure during examination only the very recent acquired image might be affected and might not be readable and the image sequence can be reconstructed up to this moment. Please contact Xiralite GmbH for assistance to reconstruct image sequences. During maintenance these files are deleted if no further action is required.

Single images are stored in a subfolder of "D:\Temp" during acquisition process. If no unwanted abortions of the acquisition process have occurred, these temporary files are deleted during maintenance. In case of low memory the operator can delete these temporary files.

The supplied computer is equipped with a RAID level 1 system. Stored image data is mirrored on two hard disks to prevent data loss if one disk fails.

5.8 Technical Data

5.8.1 Technical Data of the Xiralite® Fluorescence Imager X4

Imaging area	
Image acquisition area (working area)	400 mm x 300 mm (W x D)
Opening to the imaging area	90 mm x 545 mm (H x W)
Performance-LED-Array (2x)	
Excitation wavelength	740 nm
Half width	30 nm
Maximal output	1 W
Adjusted output	0,5 W
Filter	
Edge wavelength emission filter	760 nm short pass
Edge wavelength fluorescence filter	800 nm long pass
Detector	
Type	CCD – Camera
Manufacturer	ABS
Model	1158
General Data	
Dimensions (W x D x H)	550 mm x 510 mm x 745 mm
Weight	38 kg
Mains supply	100 V to 230 V AC, 50 Hz - 60 Hz
Power consumption	
Idle state	25 W
Image acquisition	40 VA
Fuse	T 2 AL / 250 V (2x)
Protection class	I
Device type	Stationary
Medical device classification	I
Ambient Data	
Operating temperature	10°C to 35°C, no condensation
Storage and transportation temperature	-10°C to 50°C, no condensation
Humidity	30 to 90%; no condensation
Operation, storage and transport pressure	700 hPa bis 1060 hPa
Protection rating	IP20
Operational Altitude	0 m to 2000 m

Table 5.1: Technical Data

5.8.2 Technical Data of the Computer

For execution of XiraView software a control computer is used that fulfills the requirements of directive 93/42/EEC as well as the standards EN 60601-1:2006 and EN 60601-1-2:2007 as it is used within the patient environment. The computer has got at least the system requirements given in Table 5.2. Typically a MCD Medical Line PANA.ceia computer is delivered with the Xiralite® Fluorescence Imager X4 by the manufacturer. The use of different computers is only allowed with written consent from the manufacturer.

The PANA.ceia has got a low voltage output for power supply of the monitor. Currently a monitor of AG Neovo, model X-19 is used.

Likewise only peripheral components approved by the manufacturer are allowed to be connected to the system, if applicable via the network isolator.

Processor	Pentium Core 2 duo , 2,93 GHz or better
Operation system	Windows 7
Memory	4 GB RAM
Graphic board	ATi HD4350
Data links	• USB 2.0 Port High Speed • At least 100 MBit/s Ethernet
Hard disk	• At least 100 MB space for installation of the XiraView software • approximately 500 MB hard disk space per examination (parameter dependent) • Two equivalent disks for RAID 1

Table 5.2: Recommended system requirements for the complementary computer

5.8.3 Type Plate

Figure 5.6 shows the type plate of the Xiralite® Fluorescence Imaging System X4.

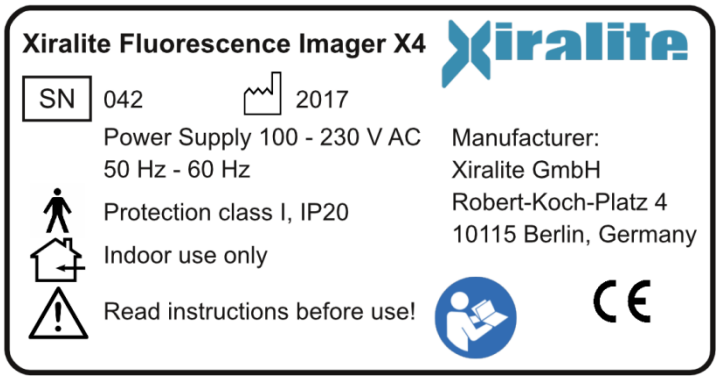

Figure 5.6: Type plate of the Xiralite® Fluorescence Imager X4

5.9 Electromagnetic Compatibility

The Xiralite® fluorescence imaging system X4 was successfully tested for electromagnetic compatibility according to IEC 60601-1-2. The system can be operated reliably at workplaces with permissible electromagnetic environment, without interfering equipment or systems situated in that environment. If malfunctions in the operation of the Xiralite® fluorescence imaging system X4 or other devices occur, the manufacturer must be informed.

5.10 List of Applied Standards

The Xiralite® Fluorescence Imaging System X4 was developed in accordance with the following standards:

DIN EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005); German version EN 60601-1:2006
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007, modified); German version EN 60601-1-2:2007
ISO 14971:2007	Medical devices - application of risk management to medical devices
DIN EN 62471:2009	Photobiological safety of lamps and lamp systems
ISO 639-3:2007	Codes for the representation of names of languages — Part 3: Alpha-3 code for comprehensive coverage of languages

6. Glossary

CCD camera

CCD cameras comprise a sensor which consists of a two dimensional arrangement of small photo diodes (small light sensitive elements).

CCD cameras have many applications areas. These are digital cameras, mobile phone with cameras, television broadcast, production control, remote sensing as well as scientific application in astronomy, just to name a few examples.

Edge filter

Edge filters are optical filters, which are characterized by a sharp transition between the transmitted and the blocked wavelengths. Differentiation is made between long-pass filters that transmit light of longer wavelength than its cut off wavelength, and short-pass filters, that transmit light of shorter wavelength than its cut off wavelength. Steep filters are mostly thin film multilayer systems, which reflect not appropriate wavelength ranges due to interference effects instead of absorbing them.

Fluorophore, fluorescent dye

A fluorescent dye is a chemical structure, which has the ability to absorb light of a specific wavelength (e. g. ultra violet to red light) and transfer it to light with longer wavelength (lower energy) for emission (e. g. visible to infra red light).

Imaging area (working area)

Imaging area is the area which is illuminated with fluorescence excitation light and is imaged during acquisition.

The imaging area is equipped with a shaped hand rest which is the applied part according to EN 60601-1:2006.

RAID

RAID (**redundant array of independent disks**, originally **redundant array of inexpensive disks**) is a storage technology that combines multiple disk drive components into a logical unit. Data is distributed across the drives in one of several ways called "RAID levels", depending on what level of redundancy and performance (via parallel communication) is required.

In ***RAID 1*** (mirroring without parity or striping), data is written identically to two drives, thereby producing a "mirrored set"; the read request is serviced by either of the two drives containing the requested data, whichever one involves least seek time plus rotational latency. Similarly, a write request updates the strips of both drives. Excerpt from RAID. (2012, September 14). In *Wikipedia, The Free Encyclopedia*. Retrieved 14:38, September 21, 2012, from http://en.wikipedia.org/w/index.php?title=RAID&oldid=512509489

7. Index

A. Appendix

A.1 Quick Reference Guide

Initial Examination	Repeat Examination	Image Reading
Turn on device and PC and start the program	Turn on device and PC and start the program	Turn on PC and start the program
"Case Selection"	**"Case Selection"**	**"Case Selection"**
	Select an existing patient and load data	Select an existing patient and load data
"New Patient"	**Patient Data & Device Parameters ⇒ "New for current patient"**	
Enter patient data and operator name	Check operator information and change if needed	
Check device parameters	Check device parameters	
"Go to image acquisition"	**"Go to image acquisition"**	
Optional **"Start Camera Preview" / "Stop Camera Preview"**	Optional "**Start Camera Preview" / "Stop Camera Preview"**	
"Start Image Acquisition"	**"Start Image Acquisition"**	
Injection of ICG 10 s after starting the image acquisition	Injection of ICG 10 s after starting the image acquisition	
Set background signal; accept with "OK"	Set background signal; accept with "OK"	
Evaluate images	Evaluate images	
Open result page	Open result page	Open result page
Highlight the individual result using the left mouse button	Highlight the individual result using the left mouse button	Highlight **saved result** with the left mouse button
"Save Result"	**"Save Result"**	**"Delete Result"**
"Print Results"	**"Print Results"**	**"Save Results"**