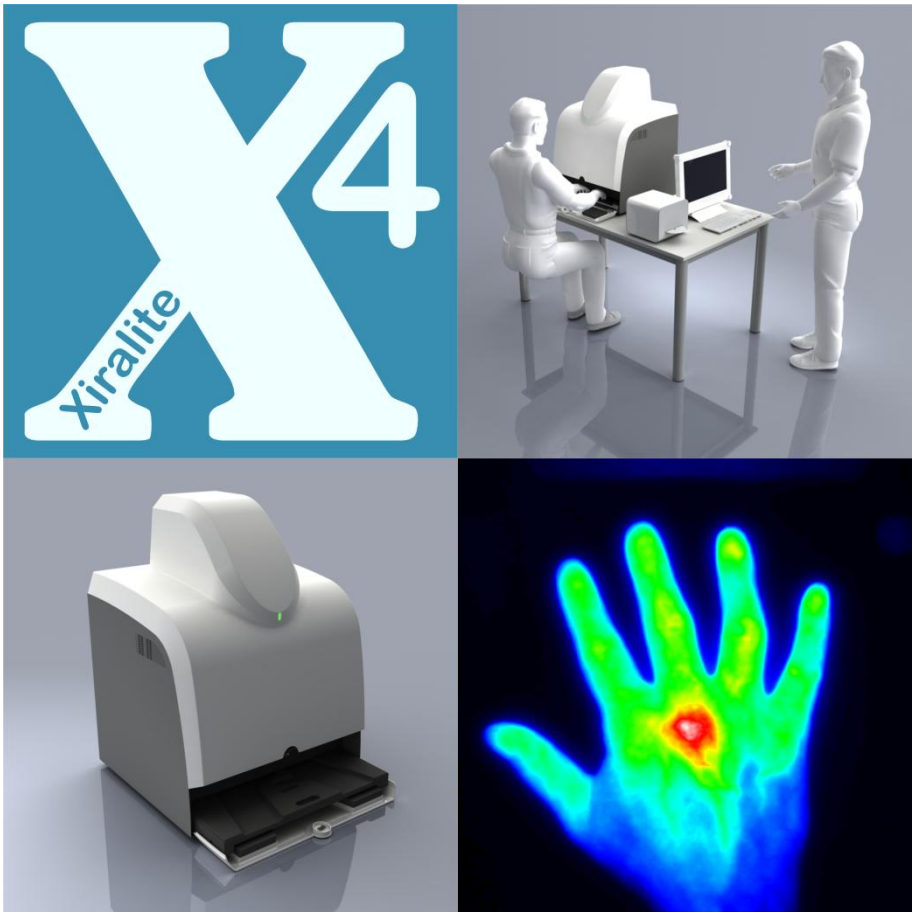
# Xiralite® Fluorescence Imaging System X4

## Xiralite® Fluorescence Imager X4

## **Operator's Manual**




Revision 22 - 2017-08-23

**CAUTION! Federal law (USA) restricts this device to sale by or on the order of a physician.**

**CAUTION! Read this manual carefully before using the Xiralite® Fluorescence Imaging System X4.**

The information in this manual 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 manual and the products it describes at any time, without notice or obligation.

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# 1. Introduction

## 1.1 List of applied standards

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

1. ANSI/AAMI ES 60601-1:2005 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2:2007 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests
3. ISO 14971:2007 Medical devices – Application of risk management to medical devices
4. IEC 62471:2007 Photobiological safety of lamps and lamp systems.
5. AAMI/ANSI/ IEC 62304:2006 Medical device software – Software life cycle processes.

## 1.2 Scope of supply

- Xiralite® Fluorescence Imager X4 with power cord and USB cable, control computer (PC) with monitor, keyboard, mouse, power cord and monitor cables
- Xiralite® X4 Kit
- Xiralite® Fluorescence Imager X4 Operator's Manual
- Quick Reference Guide
- Xiralite® X4 Kit Instructions for Use
- Training material for Xiralite® Fluorescence Imaging System X4

## 1.3 Safety instructions and symbols

### 1.3.1 Introduction

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.

### 1.3.2 Alerts for Warning, Caution and Note

| | | |
|---|---|---|
| Pictogram for danger | **Warning**<br>WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. | Pictogram for precautions |
| Pictogram for danger | **Caution**<br>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 unsuitablepractices. | Pictogram for precautions |
| | **Note**<br>NOTE is used to call attention to notable information, which is necessary for the intended application and that should be followed. | |

**Table 1-1 Alerts for Warning, Caution, Note**

Table 1-1 describes the used alerts for warning, caution and note in this manual.

### 1.3.3 Warning Symbols

The following safety information focuses on Xiralite® Fluorescence Imager X4. For safety information of the components of Xiralite® X4 Kit, please refer to the Xiralite® X4 Kit Instructions for Use that is provided with the system.

Warning 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 |
|  | Refer to instruction for use |
|  | Disconnect main plug |

**Table 1-2 Used warning symbols**

### 1.3.4 General Warnings

**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**

Administration of ICG is necessary to acquire fluorescence images. With no dye administered, no images can be recorded.

- Consider the medical contraindications of the used fluorophore ICG

**Warning**

Open wounds on the hands are a possible danger of infection on the hand rest.

- Don't examine patients with open wounds on the hands.

### 1.3.5 General Cautions

**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
- Read the labeling "Xiralite® X4 Kit Instructions for Use"

**Caution**

The highly sensitive camera can be damaged by intense light output.

- Don't light up with intense light sources into the device.
- Don't expose the camera to sunlight or other intense light sources.

| | | |
|---|---|---|
|  | **Caution**<br>High performance LED array emit intense optical radiation.<br>➢ Don't open the device and don't look into LEDs.<br>➢ Don't view with and don't introduce optical instruments into the device. | |

| | | |
|---|---|---|
| | **Caution**<br>There is danger of jamming between the tableau and hand rest by pulling out the tableau.<br>➢ Pull out the tableau with the centrally located recessed grip of the hand rest.<br>➢ Inform the patient. | |

### 1.3.6 Contraindications

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

For contraindications of the components of Xiralite® X4 Kit, please refer to the Xiralite® X4 Kit Instructions for Use that is provided with the system.

## 1.4 Safety Officer for medical devices

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## 1.5 Disposal

The Xiralite® Fluorescence Imager 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 proper disposal.

## 1.6 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 operator's manual is observed and the maintenance is carried out at regular intervals.

# 2. Device description

## 2.1 Indications for Use

The Xiralite® Fluorescence Imaging System X4 is an imaging system indicated to acquire fluorescence images for the visual assessment of circulation as a method for the evaluation of tissue perfusion and related tissue microcirculation in hands.

The Xiralite® Fluorescence Imaging System X4 consist of The Xiralite® Fluorescence Imager X4 and the Xiralite® X4 Kit. The Xiralite® X4 Kit is indicated for use with the Xiralite® Fluorescence Imager X4.

The content and the use of the Xiralite® X4 Kit with the Xiralite® Fluorescence Imager X4 is described in the labeling "Xiralite® X4 Kit Instructions for Use".

## 2.2 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 specific fluorophore, 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 receiving side, whereas the fluorescence light should freely reach the detector. For this purpose a long pass filter is installed in front of the camera lens. Light emitting diodes may have a relatively broad emission spectrum. Hence, it is advisable to install a short pass filter in front of the LEDs to suppress excitation light from the spectrum of the detection wavelength band.

Through the filter combination no unnecessarily interfering background signals occur during the fluorescence measurement. Therefore extremely sensitive measurements are possible.

The Xiralite® Fluorescence Imager 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 is only present during the short exposure time of the sensor, while during readout of the sensor there is no illumination present. This improves image quality as the sensor is not exposed while shifting information to the readout area of the sensor chip.

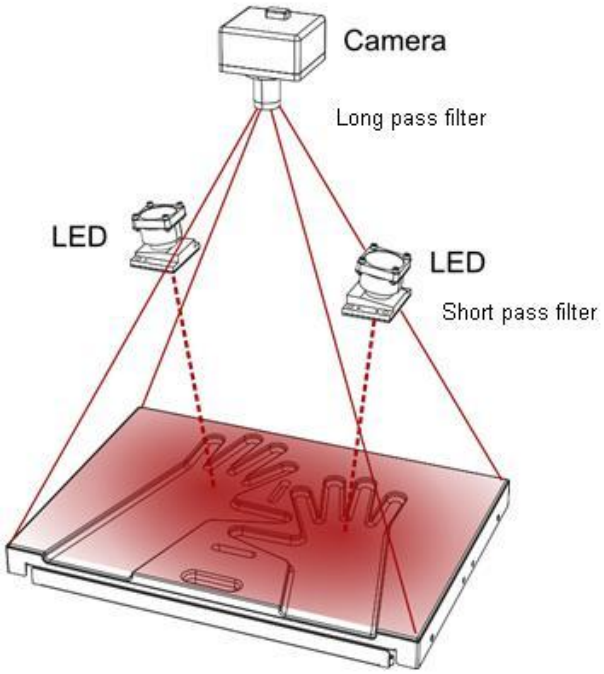



**Figure 2-1 Working principle of the Xiralite® Fluorescence Imager X4.**

The fluorescence signals are recorded with a camera with an extremely sensitive CCD chip. High performance LED-arrays are used to excite the fluorescence signals from the ICG. The LEDs emit near infrared radiation. The radiation is riskless at the level of imaging area on the hand rest area. The maximum radiation is less than 50W/m$^2$. This is assured because the LED radiation is not focused with other optical instruments and a direct exposure of the eyes is not possible during the operation of the system.

**Figure 2-2 The Xiralite® Fluorescence Imager X4 with control computer**

## 2.3 Technical description

**Warning**

The Xiralite® Fluorescence Imager 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.

### 2.3.1 Front View

Figure 2-3 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.

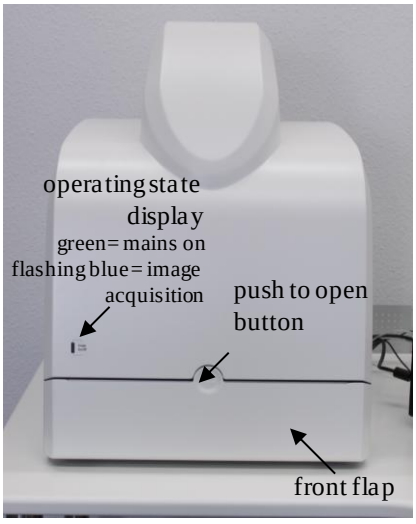



**Figure 2-3 Front view of the Xiralite® Fluorescence Imager X4 with closed lid.**

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 produced from a skin compatible certified material. In addition, the hand rest is profiled with a hand for precise placement. Additionally to placement support, the division bars between the fingers provide light shielding of the fingers among each other. Therefore, only the supplied hand rest may be used. The hand rest and the drawer are labeled accordingly.

The instrument with pull out hand rest drawer is shown in figure 2-4.


**Figure 2-4 View of the Xiralite® Fluorescence Imager X4 with opened flap and pulled out drawer with hand rest.**

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 2-5).

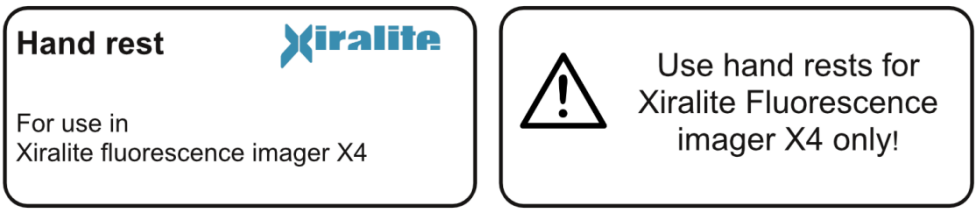



**Figure 2-5 Labeling of the hand rest (left) und drawer (right) of the Xiralite® fluorescence imager X4**

## 2.3.2 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 2-6 shows the rear view of the Xiralite® Fluorescence Imager 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.

Switch-on and switch-off are described in chapter 4.1. For complete disconnection from supply, disconnect the power plug and the USB cable after switch-off. 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.

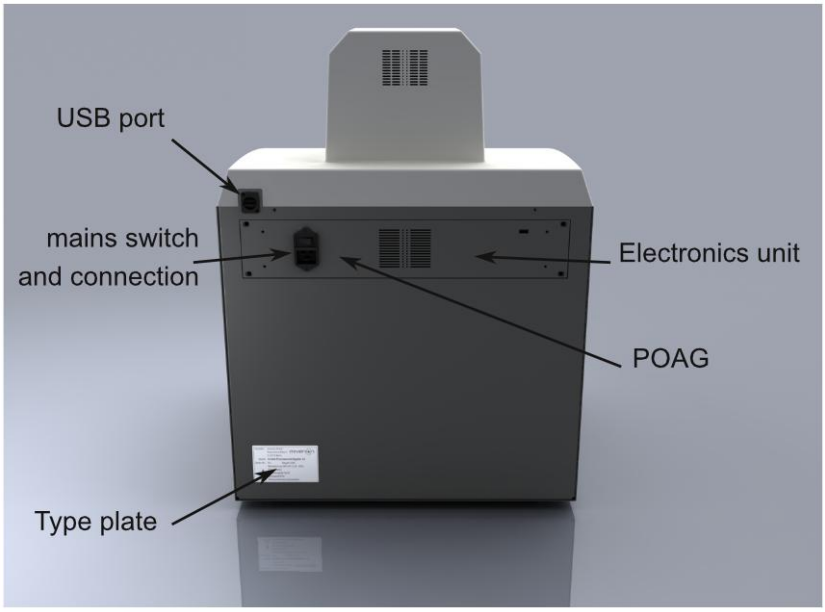



**Figure 2-6 Rear view of the Xiralite® Fluorescence Imager X4**

### 2.3.3 Control Computer

For execution of XiraView software a control computer is needed that fulfills the requirements of ANSI/AAMI ES 60601-1:2005. The specifications must meet or exceed the parameters listed in table 2-1. Currently, the PC MCD Medical Line PANA.ceia (Model T100215 or T100222) is supplied and used. The use of other PCs with the Xiralite ®fluorescence imager X4 is allowed only after approval by the manufacturer.

Presently, a monitor of the company AG Neovo (Model X-19) is used. The PANA.ceia has a low voltage output for power supply of a monitor. The use of other monitors is allowed only after approval by the manufacturer.

Furthermore, only manufacturer-approved peripheral components, optionally be connected via the network isolator, may be used.

| | |
|---|---|
| CPU | Pentium Core 2 duo , 2,93 GHz |
| Operating system | Windows 7 |
| RAM | 4 GB |
| Video card | ATi HD4350 |
| Connectors | USB 2.0 Port High Speed |
| Hard disk | min. 100MB for software<br>hard disk space for exams, ~ 500MB per exam |

**Table 2-1 Specifications of the used PC.**

### 2.3.4 Type Plate

Figure 2-7 shows the attached type plate on the Xiralite® Fluorescence Imager X4.

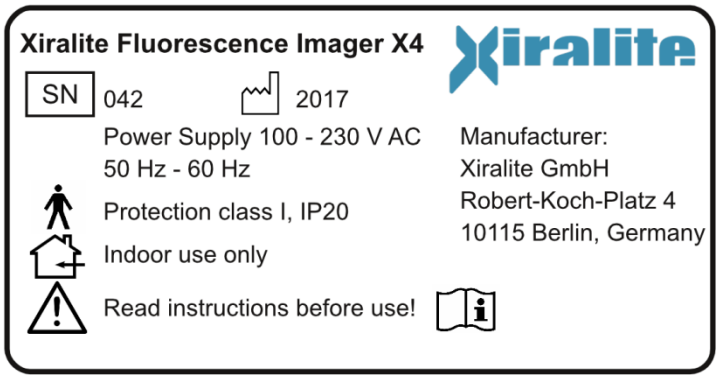



**Figure 2-7 Type plate of the Xiralite® Fluorescence Imager X4**

## 2.4 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, 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. Accuracy of reading depends mostly on the experience of the reader.

## 2.5 Image signal correction

### 2.5.1 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 ICG in human hands starts typically 20 seconds after intravenous injection. Hence, approximately 30 images are recorded without the fluorophore ICG 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 the fluorophore ICG is done immediately after image acquisition (see Section 4.5.2.5). The selected images will be stored for subsequent use in the respective case record file.

### 2.5.2 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).
```

## 2.6 Data Safety

To avoid data loss during examination each image is stored immediately after acquisition in a temporary directory on hard disk (D:\Temp). In the unlikely event of power loss or software failure during examination 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.

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.

## 2.7 Technical Data

| | |
|---|---|
| **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 | 750 nm |
| Half width | 30 nm |
| Maximal output | 1 W |
| Adjusted output | 0,5 W |
| **Filter** | |
| Edge wavelength emission filter | 760nm short pass |
| Edge wavelength fluorescence filter | 800nm 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 or 60 Hz |
| Power consumption | |
| Idle state | 25 W |
| Image acquisition | 40 W |
| Fuse | T 2 AL / 250 V (2x) |
| Protection class | I |
| Medical device classification | II |
| Device type | stationary |
| **Ambient Data** | |
| Operating temperature | 50°F to 95°F, no condensation |
| Storage and transport temperature | 14°F to 122°F, no condensation |
| Humidity | 30% to 90%, no condensation |
| Operating storage and transport pressure | 700 hPa to 1060 hPa |
| Protection rating | IP20 |
| Operational Altitude | 0m to 2000m |

**Table 2-2 Technical Data**

# 3. Installation

## 3.1 Installation Requirements

The installation, initial operation, and training are carried out by the manufacturer. A change in location of the instrument shall be made by the manufacturer or by authorized persons. However, the instrument is a stationary device as defined in ANSI/AAMI ES 60601-1:2005. 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 have to grab the device below the corners. For this purpose, appropriate measures should be taken to avoid slipping of the hands, such as using non-slip gloves. The operator must provide suitable installation space.

### 3.1.1 Location Requirements

Ensure room light with wavelengths λ <700 nm.

**Note**

The instrument is sensitive to wavelengths λ> 700 nm. Stray light can disturb the images in this spectral region.

- Ensure room light with wavelengths λ <700 nm, i.e. white light with no infrared component.
- No sunlight or light from light bulbs (incandescent lamp)

The Xiralite® Fluorescence Imager 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 lubes are not suitable for room lighting. Monochrome or cool white LEDs are suitable as light sources.

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. 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 Imager 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 Imager X4 and the computer, as shown in Figure 3-1.

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. A sitting test should be performed before each examination.

**Figure 3-1 Recommended set-up of the Xiralite® Fluorescence Imager 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.

Additionally, for mains power supply two separate wall outlets with protective earth connection are required. The system is not intended to be integrated into a local or wide area network.

### 3.1.2 Electrical Requirements

**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, do not use extension cables for the power supply.

**Caution**

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

The Xiralite® Fluorescence Imager 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 can also be 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 ANSI/AAMI ES 60601-1:2005 (Individual solution, not described in detail here).

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 ANSI/AAMI ES 60601-1:2005. 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 3-2 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.

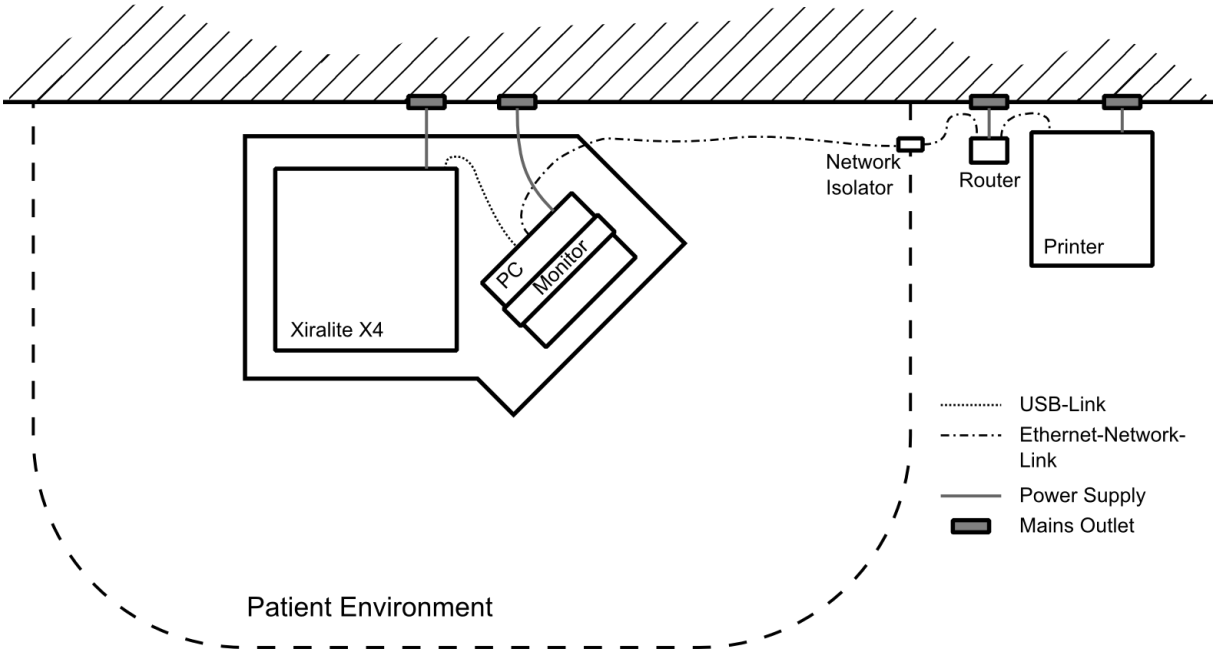



**Figure 3-2 Schematic placing of the components in the patient environment**

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.

### 3.1.3 System Requirements

For execution of XiraView software a control computer is needed that fulfills the requirements of ANSI/AAMI ES 60601-1:2005 and IEC 60601-1-2:2007 as it is used within the patient environment. The computer should have the system requirements given in Table 3-1. Typically the computer is delivered with the Xiralite® Fluorescence Imager X4 by the manufacturer.

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

**Table 3-1 Recommended system requirements for the complementary computer**

### 3.1.4 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.

# 4. Operation

| | | |
|---|---|---|
| | **Caution**<br>The device may be used only by trained personnel to avoid not evaluable images.<br>➢ Refer to Operator's Manual from the manufacturer and perform training measurements on phantoms.<br>➢ Read the labeling "Xiralite® X4 Kit Instructions for Use". |  |

## 4.1 Power Switch

The instrument is switched on at the rear. 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 display by flashing blue light. This area is marked with „Image". Figure 4-1 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.

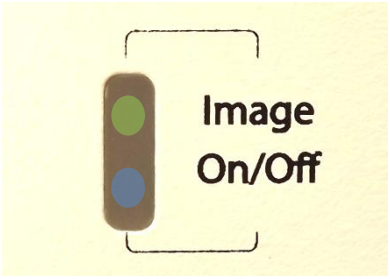



**Figure 4-1 Labeling of the indicator panel on the front. Green light indicates powered-on state. Flashing blue light indicates image acquisition in progress.**

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 in the cap.

## 4.2 General preparation of an examination

- Switch on the Xiralite® Fluorescence Imager X4 and the provided computer.
- Open the front flap of the Xiralite® Fluorescence Imager X4.
- Start the software XiraView.

## 4.3 Preparation for an examination

**Notice**

Stable position of the hands is necessary for meaningful images.

- ➢ Instruct patients.
- ➢ Avoid distraction of patients.
- ➢ Choose an undisturbed or low-interference installation site.
- ➢ Adjust the chair of the patient.

**Caution**

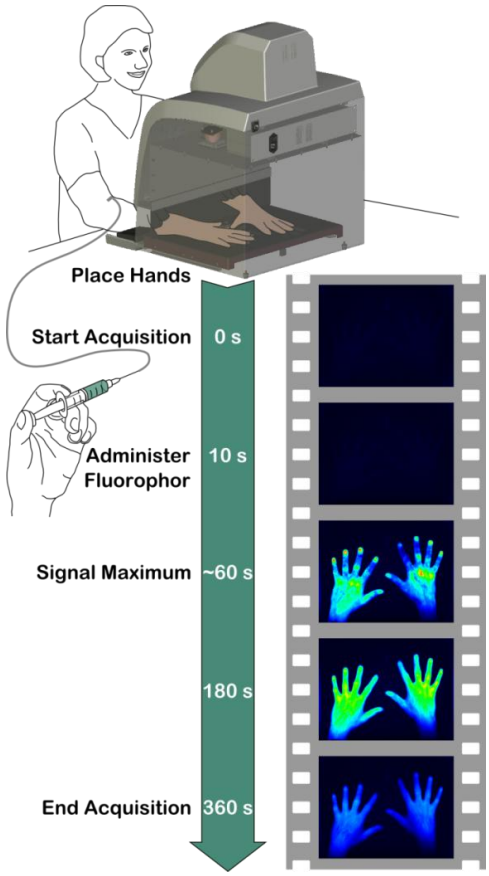
Risk of getting caught on the drawer with the hand rest.

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

- 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. Handling, preparation and dosage of ICG is described in the labeling "Xiralite® X4 Kit Instructions for Use"
- Position the patient in front of the device.

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

## 4.4 Image Acquisition Process




- Start the image acquisition.
  - Intravenous administration of Indocyanine Green 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 manually stop the 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 contrast agent flows in contain only a background signal for which all images have to be corrected for. Details on image correction are found in section 2.5

**Figure 4-2 Examination procedure**

## 4.5 Control software

### 4.5.1 Starting

The associated control software "XiraView 3.6j" is started either on the desktop icon (see figure 4-3) or by selecting the Start menu.

XiraView 3.6j

**Figure 4-3 Desktop icon of the control software**

Before starting the software for capturing image sequences turn on the Xiralite® Fluorescence Imager 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 Imager X4 was mistakenly not switched on, the device can be activated later as described in Section 4.5.3.

Figure 4-4 shows the user interface after startup. The user interface of the program is divided into a wide input and view range and a narrower control panel (right side). In the control panel, additional controls are visible in some modes of operation that are hidden for clarity. At the lower end of the control panel there are three squared information displays that indicate the device status.

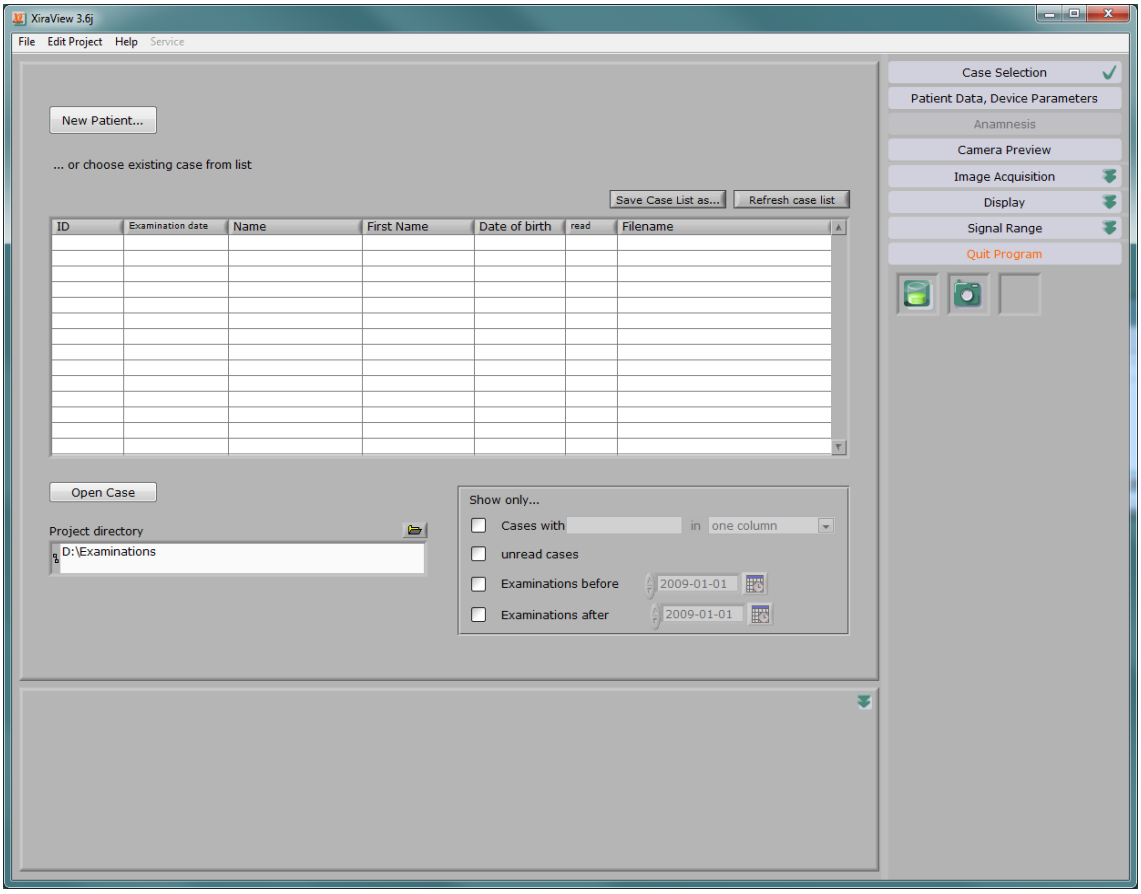



**Figure 4-4 User interface of XiraView after start and for case selection**

### 4.5.2 Modes of Operation

The functionality and interface of the input and view range will change depending on the mode the program is in. In the control panel, the following modes of operation are available (see table 4-1).

| |
|---|
| Case-Selection |
| Patient data and device parameters |
| Anamnesis |
| Camera Preview |
| Image acquisition |
| Display (Prima Vista/ Film) |
| Signal range |
| Quit program |

**Table 4-1 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. The last four modes appear by selecting further controls.

The status displays are described in Section 4.5.3.

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 close the control elements again.

#### 4.5.2.1 Case-Selection

The operation mode "Case Selection" after start-up or after pressing the control button "case selection" is shown in Figure 4-5. It is possible to start a new imaging study 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. 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 con 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. If the user chooses "New Patient…", the program will show the "Patient Data, Device Parameters" mode in the input and viewing panel. This mode will be described in the following section.

### 4.5.2.2 Patient data and device parameters

In the mode "Patient data, Device parameters" data of the patient, the physician's office, the physician and the equipment operator can be entered or viewed. If a new case record shall be created, the user has to choose "New Patient" either in the "Case selection" view or in the "Patient Data, Device Parameters" view before data can actually be entered. Otherwise data of the currently loaded case are displayed but cannot be altered.

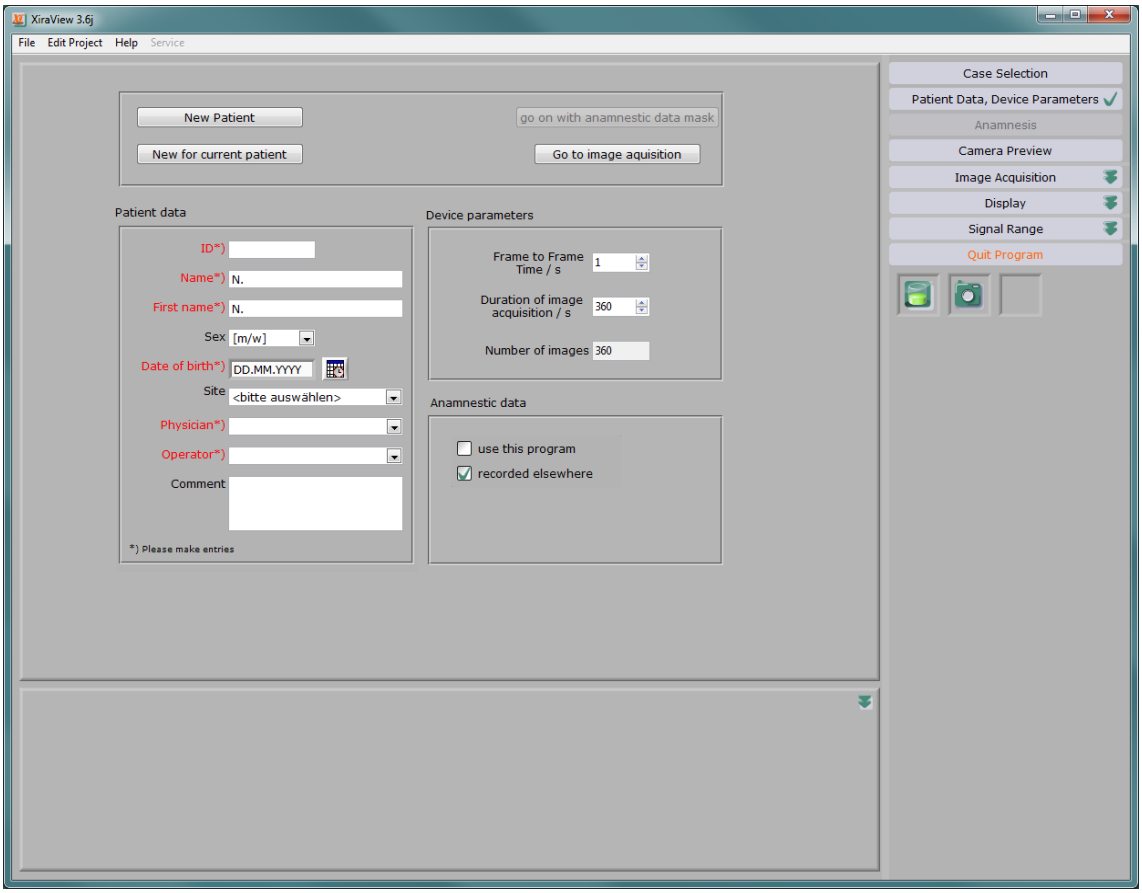



**Figure 4-5 View of program window in "Patient data, Device Parameters" mode to enter patient data and to review device parameters before start of image acquisition.**

## 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 4-4, 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.

## Configuration fields:

## 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.

**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.

**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 should 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 be between 1 and 10000.

| Parameter | Value |
|---|---|
| Image time interval / s | 1 |
| Acquisition duration / s | 360 |

**Table 4-2 Standard parameter for acquisition of an image sequence.**

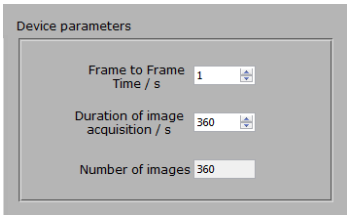



**Figure 4-6 Device parameter in the "Patient Data, Device Parameters" view.**

## 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. Are the descriptive patient data fields not completely filled, a blue notice will appear and the image acquisition cannot start.

Both modes are described in the following sections.

### 4.5.2.3 Anamnesis

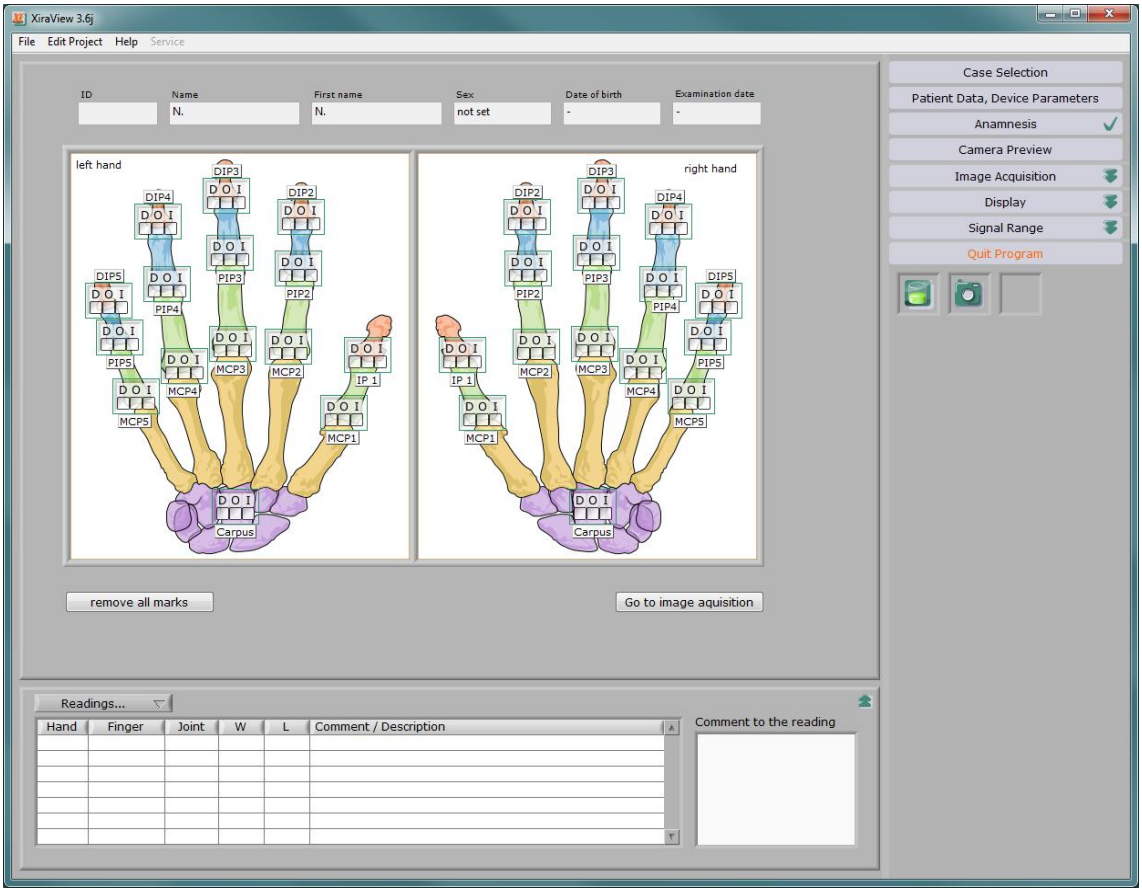



**Figure 4-7 View of program window for anamnesis input for both patient hands**

Figure 4-7 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 „Continue with image acquisition":** With the button "Continue with image acquisition" the mode "image acquisition" is opened. Are the descriptive fields not completely filled, a blue notice will appear and the image acquisition cannot be started.

### 4.5.2.4 Camera Preview

| | | |
|---|---|---|
| | **Caution**<br>In the operation mode camera preview, no image data are stored.<br>➢ Don't inject contrast agent.<br>➢ Images are only recorded after pressing the button "Start" in the operation mode "image acquisition". | |

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 visible 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 Imager X4. Then, the working area is 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.

### 4.5.2.5 Image acquisition

The user interface of the "Image acquisition" mode is shown in Figure 4-8. 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.

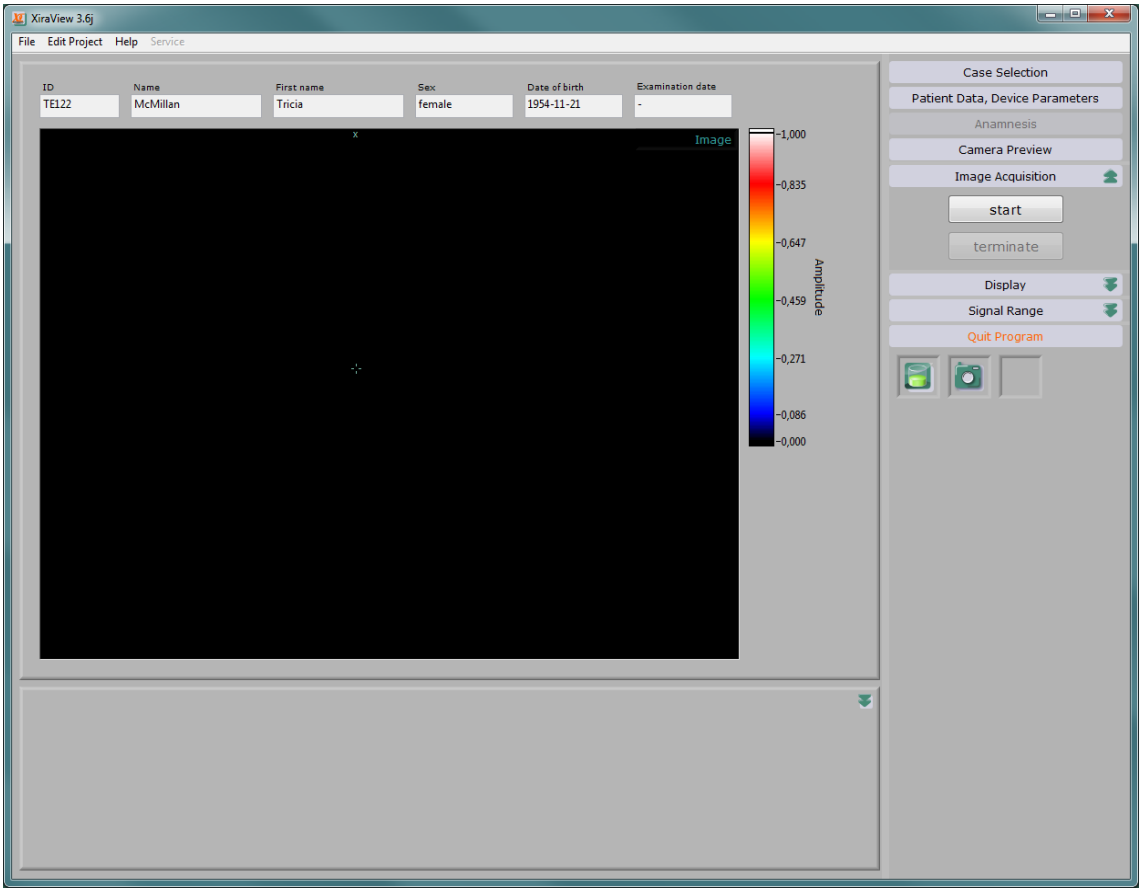



**Figure 4-8 View of the program window before starting an image acquisition process.**

If the patient data are not completed or information on operator and/or physician aren't properly specified, a blue notice appears (see Figure 4-9), 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.

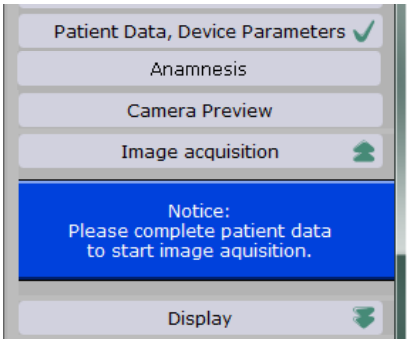



**Figure 4-9 Notice: Image acquisition cannot be started**

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

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

Thus, a dialog window (see Figure 4-10) is opened at the end of the image acquisition. The user has to select the last image without any signal by 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 2.5.

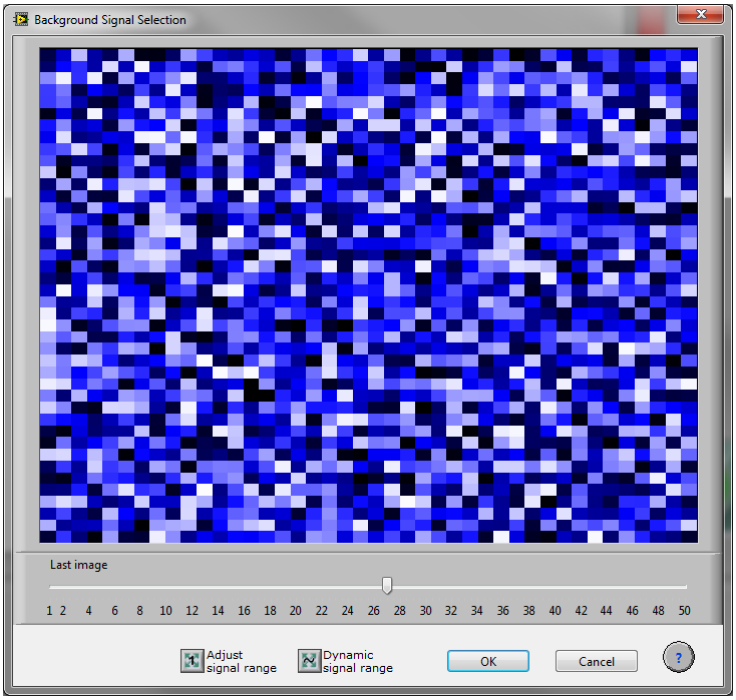



**Figure 4-10 Pop-up window for background image correction**

The opened window has the following buttons:

**"Adjust signal range"**

**"Dynamic 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.

### 4.5.2.6 Display (Prima Vista/ Film)

In the "Display" mode, there are two possibilities for viewing the images of an examination: "Prima Vista" and "film". First a composite image called "Prima Vista" is calculated from the first 240 images of an image sequence. This is the default view after opening a stored image sequence. Secondly any image of the sequence can be scrolled or played as a film. This is the default view after acquisition.

## Prima Vista

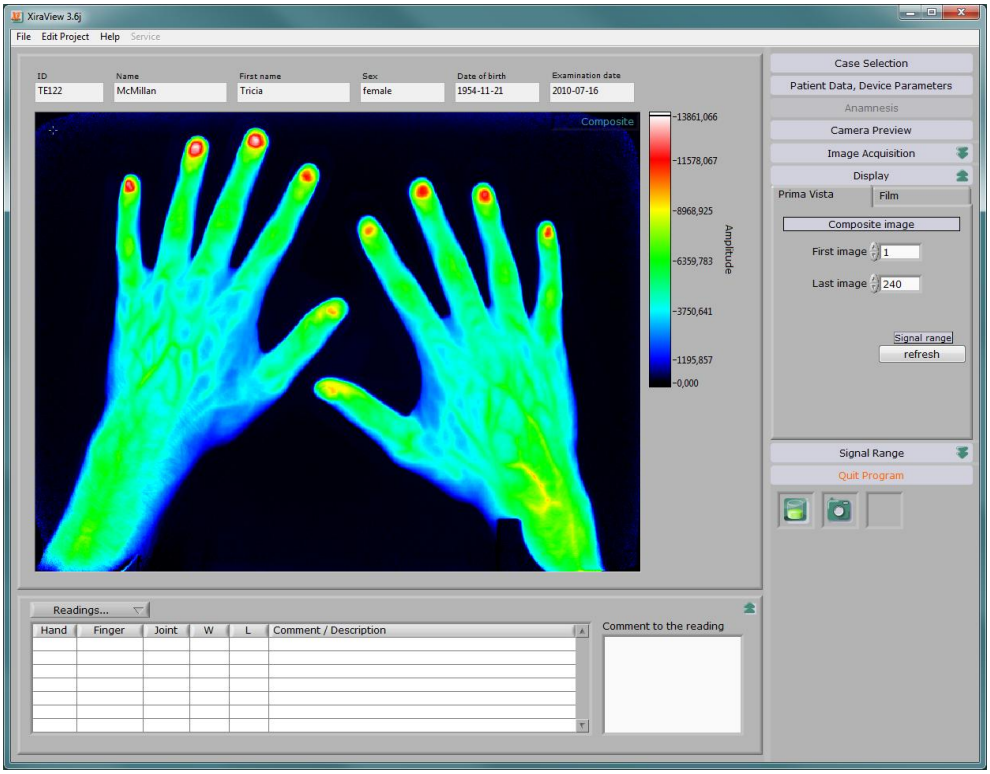



**Figure 4-11 Display mode „Prima Vista"**

In the display mode "Prima vista" (see figure 4-11), the images of an examination are summed up. 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.

Particular attention has to be payed 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 artifact 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

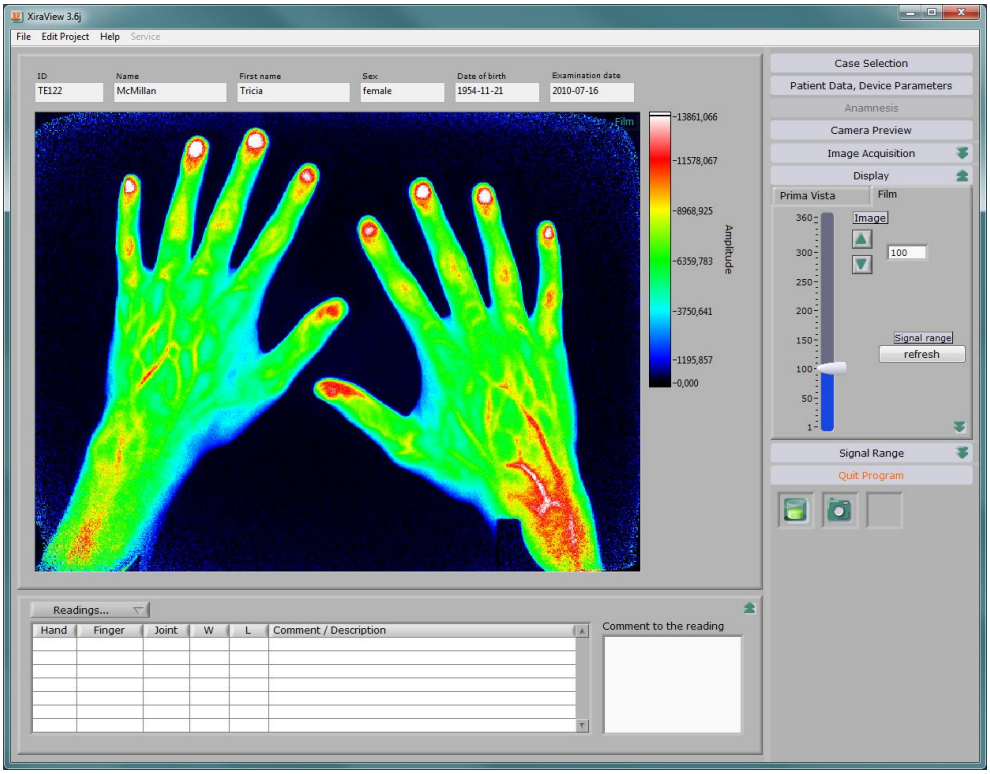



**Figure 4-12 View of program in display mode "Film"**

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.

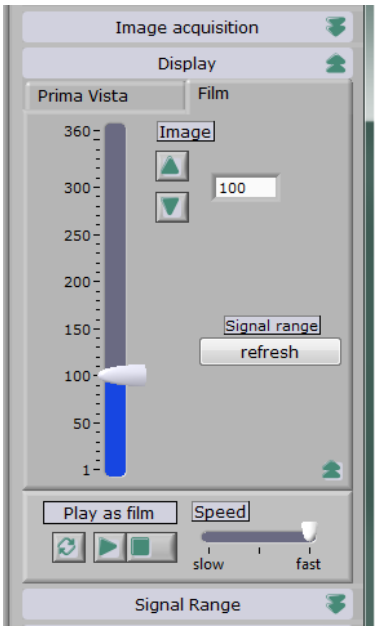



**Figure 4-13 Additional functions for scrolling: Play sequence as a film.**

Another part of the control panel is opened for additional functionality (see figure 4-13), if the double arrow button (bottom, 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.

### 4.5.2.7 Signal range

The displayed signal range can be optimized (see figure 4-14). The following individual functions can be used.

**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 scaling is dynamically adjusted during the scrolling.

**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. Greyscale 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 chapter 4.6.

**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.

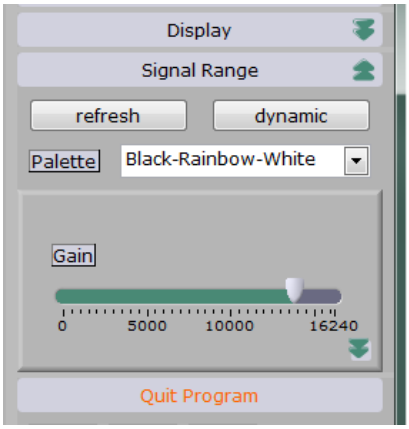



**Figure 4-14 Part of control panel for controlling of signal range and pixel coloring**

To vary the display minimum of the signal range, additional controls need to be made visible by pressing the double arrow button (see figure 4-14). Now, minimum and maximum of the display signal range can be modified. Alternatively, displayed signal range can be controlled by brightness and contrast:

**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.

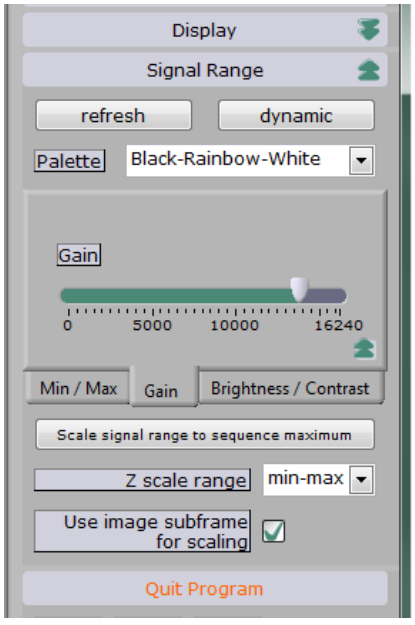



**Figure 4-15 Extended functions for signal range control**

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.

### 4.5.3 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.

 **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.

 **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 crossed-out icon. The camera can activated later by pressing the [Shift] button + clicking the crossed out icon.

### 4.5.4 Reading

For interpretation of a case the dataset 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 may specify the region (right/left hand, finger number counting from thumb, joint) and may subjectively judge the visibility of the altered circulation, including the microcirculation (see figure 4-16). The lesion can be textually described using the "Comment / Description" input field. Thus, a disturbed microcirculation can be described and marked by position. Image, coloring and scaling are recorded.

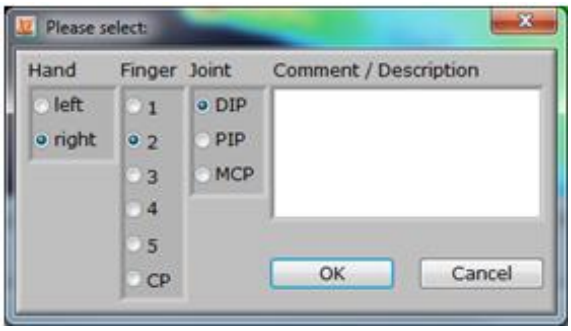



**Figure 4-16 Pop-up window for marking joint and reading**

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 or altering a comment to the selected reading (see figure 4-17). 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 mark in the image is highlighted. The comment field allows the description of decreased or increased microcirculation.

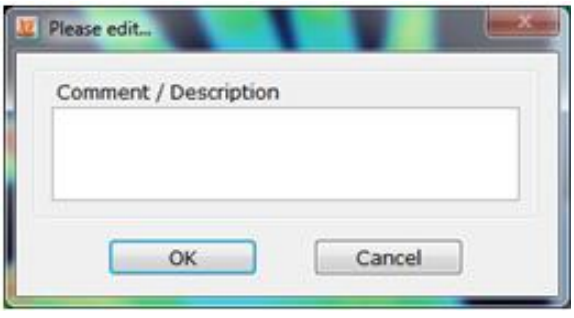



**Figure 4-17 Input mask for a comment to a reading item**

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 is no disturbed microcirculation 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.

### 4.5.5 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:** open a dialog window for editing background and reference image correction of the current case record file (see figure 4-18).

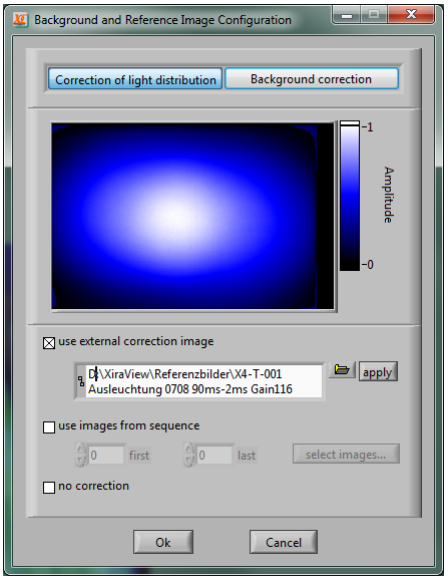



**Figure 4-18 Dialog window for editing background and reference image correction**

## 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.

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.

Please notice 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.

**Advanced… > Find image file(s):** 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.

**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 if in doubt.

**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.

## 4.5.6 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.

## 4.6 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 4-19 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 4-19 b. Regions with increased microcirculation will show colors or grey values of the upper part of the color bar (see Figure 4-19 c), while regions with decreased microcirculation will show colors or grey values of the lower part of the color bar (see Figure 4-19 d). |
| 5 | Switch to film mode | You may switch to film mode where the 100 s 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 4-3 Reading procedure**

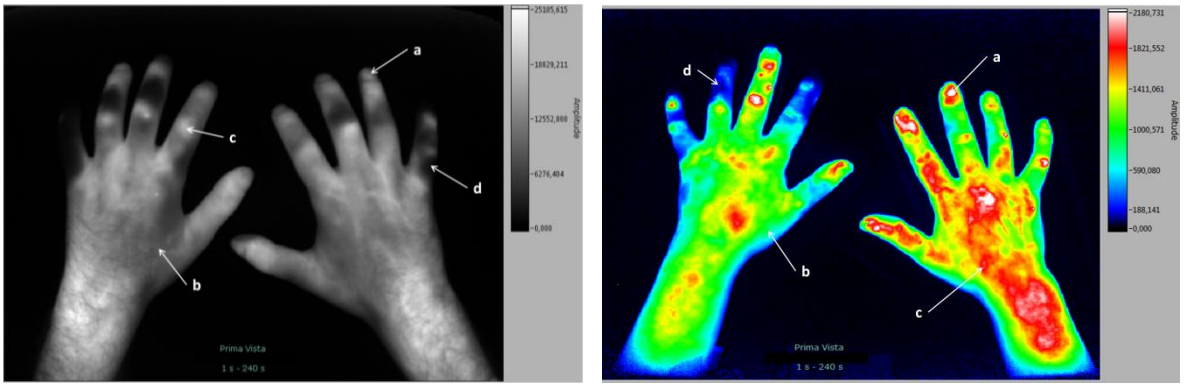



**Figure 4-19 Example images in grey scale (left) and color scale (right). Correct scaling with high signal in at least one finger tip (a). Normal microcirculation appears as medium signal intensity (b), while increased microcirculation shows colors or grey scales of the upper part of the color bar (c), 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.**

# 5. Maintenance and Cleaning

## 5.1 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.

## 5.2 Cleaning and disinfection


**Warning**

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

- No spray or wipe disinfection on installed hand rest.

The hand rest  has to be checked for splashed fluorescent dye remainders. If there is a contamination of the hand rest, then replace it and send the old one for disposal back to Xiralite GmbH.

Generally, a 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.

If required, surfaces of the Xiralite® Fluorescence Imager 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.

# 6. 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 6-1 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. | |

## 6.1 Malfunctions, Unusual Events

The manufacturer should be informed in the case of serious malfunctions or unusual events, 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.

## 6.2 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.

# 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 ANSI/AAMI ES 60601-1:2005.

### 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

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