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# **PERI**CAM PSI

## Operator's Manual

CE 2862

# Contents

# 1 Introduction

## Intended Purpose - Europe

Applicable for Europe and other countries where compliance with European regulations are required.

### Intended purpose

The PeriCam PSI is intended for non-invasive two-dimensional imaging of peripheral tissue blood perfusion. It is intended as an aid in assessment of microcirculation.

The measurements obtained with PeriCam PSI must be used in conjunction with other clinical data and observations for proper assessment.

PeriCam PSI is used for:

- Clinical and clinical research applications involving assessment of micro-circulation
- Assessment of healing potential in burns
- Assessment of ischemia before, during and after plastic surgery; for example flap transplantation and breast reconstruction
- Assessment of ischemia before, during and after vascular surgery
- Assessment of endothelial function/dysfunction
- Assessment of oral blood flow
- Assessment of Raynaud's syndrome and scleroderma
- As an aid in assessing wound healing potential
- As an aid in diagnosing peripheral tissue ischemia caused by for example peripheral artery disease (PAD), claudication or chronic limb-threatening ischemia (CLTI)
- Assessment of skin diseases and treatment

### Patient population

PeriCam PSI can be used for visualization of peripheral tissue blood perfusion in patients with any of the medical indications listed above.

### Duration of use

The PeriCam PSI is intended for continuous use for less than 8 hours.

## Intended Use / Indications for Use - Rest of the World

Applicable for countries where compliance with European regulations is not required.

### Intended Use / Indications for use

The PeriCam PSI is intended for non-invasive two-dimensional imaging of peripheral tissue blood perfusion.

### Patient population

The PeriCam PSI can be used for visualization of peripheral tissue blood perfusion in patients of all ages.

## Context of Use - Europe and Rest of the World

### Body contact

The PeriCam PSI is never in contact with the patient.

### Intended user

The PeriCam PSI is intended to be used by healthcare professionals, e.g. technicians, nurses and physicians. The device is also used by researchers in universities and other research institutions.

### Intended environment

The PeriCam PSI is intended to be used in hospitals and healthcare clinics/facilities. The device is also used in universities and other research institutions.

### Contraindications

There are no contraindications to the use of the PeriCam PSI.

## How to Use This Manual

This operator's manual is intended for the operator of the PeriCam PSI and provides information necessary for everyday use. For installation instructions, advanced administrative tasks, and technical information, please refer to the Technical Description (part number 44-00638).

If any information in this manual is believed to be faulty or missing, please contact Perimed AB.

## Operator Profile

The PeriCam PSI must only be handled by qualified, trained personnel who have carefully read this manual and other accompanying documents.

## Accompanying Documentation

| | |
|---|---|
| PeriCam PSI Operator's Manual | This document |
| PeriCam PSI Technical Description | 44-00638 |
| ITD Operating Manual, for mobile equipment carts uni-cart, vexio-cart, pro-cart, duo-cart, compact-cart, classic-cart, symbio-cart and endo-cart, with and without isolating transformer | Documentation for Vexio cart |
| ITD Operating Manual, for stationary carrier systems (including the variable height support arms flexion-port and lf-port) | Documentation for adjustable cart arm |
| Instructions for use for isolating transformers and earth-leakage guard, ITD | Documentation for isolation transformer for cart |
| Installation & Operation Manual for VHM™ Series Arms | Documentation for adjustable table arm |
| Leica swing-arm stands, User manual | Documentation for Leica swing-arm stand |
| Isolation Station 300VA – 3000VA Instruction Manual, Powertronix | Documentation for isolation station for table configurations |

## Abbreviations

| | |
|---|---|
| DICOM | Digital Imaging and Communications in Medicine (standard protocol for management and transmission of medical images and related data) |
| LOI | Line Of Interest |
| PSI | Perfusion Speckle Imager |
| PU | Perfusion Unit |
| ROI | Region Of Interest |
| TOI | Time period Of Interest |

## Definitions

In this operator's manual the following terminology is used.

⚠

| | |
|---|---|
| ***WARNING!*** | Used to indicate a situation where incorrect handling of the PeriCam PSI could result in death or serious injury, or potential serious adverse reactions and safety hazards. |
| ***Caution!*** | Used to indicate a situation where incorrect handling of the PeriCam PSI could result in minor or moderate injury to the user or patient or damage to the equipment or other property. |
| *NOTE!* | Used to indicate helpful information that is important for optimal use. |

# Safety

## Essential Performance

Performance of certain functions is regarded as essential for safe operation of the PeriCam PSI. The following is regarded as essential performance:

- Perfusion accuracy
- Correct handling of perfusion values
- Correct handling of patient information

Perfusion accuracy should be verified regularly, see "Verification of the PeriCam PSI" on page 78.

## Operator's Responsibility

The PeriCam PSI will perform as designed and intended only if it is used in accordance with the manufacturer's instructions. All warranties are voided if the equipment is not used in accordance with these instructions.

*NOTE!*

*Any serious incident that has occurred in relation to the PeriCam PSI should be reported to Perimed AB and the competent authority in the country in which the incident has occurred.*

***WARNING!***

⚠ *A residual risk exists that faulty measurement results from the PeriCam PSI may lead to lack or delay of further investigations and/or treatments for a patient. The measurements obtained with the PeriCam PSI must therefore be used in conjunction with other clinical data and observations*

⚠ *In order to ensure safe operation, no modification of this equipment is allowed.This specifically applies to the laser and electronic parts.*

## Laser Safety

The PeriCam PSI is a Class 1 laser product according to IEC 60825-1:2014+A11:2021, which means that it is safe during use, including long-term intrabeam viewing, even when using telescopic optics.

Intrabeam viewing of Class 1 laser products which emit visible radiant energy may still produce dazzling visual effects, particularly in low ambient light.

## Connection of Equipment

The PeriCam PSI with its components must be configured so that electrical safety is achieved, especially in relation to the patient environment, see Figure 1-1.

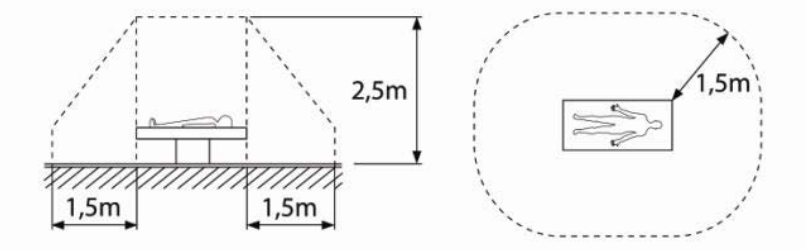



*Figure 1-1 Patient environment.*

See the Technical Description (part no 44-00638) for more information.

The PeriCam PSI should be placed so that it can be disconnected from mains without difficulty.

**WARNING!**

⚠ *The PeriCam PSI must only be connected to a supply mains with protective earth, in order to avoid the risk of electric shock.*

⚠ *Only connect equipment supplied by Perimed as part of the PeriCam PSI to the isolation station, if present. If any other equipment is connected it may result in a reduced level of safety unless compliance with IEC 60601-1 is ensured.*

⚠ *Do not touch the enclosure of the computer and the patient simultaneously.*

## Isolation Station for Table Configurations

Special attention must be paid when using the isolation station for a table configuration.

**WARNING!**

⚠ *To prevent electrical shock, do not remove the cover of the isolation station.*

⚠ *Ensure adequate cooling by keeping a minimum clearance of 5 cm (2 inch) on all sides with air ventilation holes.*

⚠ *Risk of explosion exists if used in presence of flammable anesthetics, or other flammable gases or liquids.*

⚠ *While in use, do not touch the top and bottom surfaces of the enclosure as it may reach temperatures which cause discomfort when touched for more than 1 second.*

⚠ *In an emergency, turn the power switch off, or cut off the mains supply by unplugging the unit from the wall outlet.*

⚠ *Do not place the isolation station for table configurations (if present) on the floor.*

## Electromagnetic Compatibility

Special attention must be paid regarding the electromagnetic compatibility of the PeriCam PSI and installation and use must be according to the EMC information in the Technical Description (part no. 44-00638).

**WARNING!**

⚠ *Do not use PeriCam PSI close to high frequency (HF) surgical equipment.*

⚠ *Do not use PeriCam PSI close to short-wave physiotherapy equipment*

⚠ *Do not use PeriCam PSI in an RF shielded room together with magnetic resonance imaging (MRI) equipment*

⚠ *Do not use PeriCam PSI with or in the vicinity of any equipment that is likely to generate high levels of electromagnetic disturbances.*

⚠ *Do not use portable RF equipment closer than 0.3 m from the PeriCam PSI.*

⚠ *Do not use the PeriCam PSI adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the PeriCam PSI and other equipment should be observed to verify normal operation before use on patients.*

Interference may occur in the vicinity of equipment marked with the symbol in Figure 1-2.

*Figure 1-2 Electromagnetic radiation.*

**Caution!**

*The optical parts of the PeriCam PSI head may be sensitive for electrostatic discharge (ESD) and should not be touched during measurement.*

## Markings and Symbols

### General

The following symbols are available on several parts of the PeriCam PSI.

| Symbol | Definition |
|---|---|
| CE 2862 | Complies with the requirements of the Medical Device Regulation (EU) 2017/745 (MDR) and 2011/65/EU (RoHS Compliant). |
| MD | The instrument is a medical device. |
|  | At the time of disposal, this product shall not be treated as household waste, but shall be returned to Perimed AB for recycling or otherwise disposed of according to the European Directive 2012/19/EU (WEEE) |
|  | Name and address of the manufacturer |
|  | Date of manufacture |
|  | Consult instructions for use. |
| REF | Catalogue number |
| SN | Serial number |
|  | Unique Device Identifier (UDI) in machine-readable form using GSI DataMatrix (accompanied by a human-readable form) |

## Markings on the PeriCam PSI Head

| Symbol | Definition |
|---|---|
|  | The instrument complies with Chinese RoHS standards SJ/T 11363-2006 Requirements for Concentration Limits for Certain Hazardous Substances in Electronic Information Products, and SJ/T 11364-2006 Marking for Control of Pollution Caused by Electronic Information Products |
| Rx Only | Prescription use only.<br>***WARNING!***<br>*Federal law restricts this device to sale by or on the order of a physician.*<br>(only applicable for the US) |
|  <br>EXM 80 5118 | External power supply type is EXM 80 5118 |

## LI 724 Calibration Box and LI 721 Calibration Box Lid

| Symbol | Definition |
|---|---|
|  | Read manual before use. |
|  | Batch code for the calibration box lid. |
|  | Use-by date for the calibration box lid. |
|  <br>0°C | Lower temperature degree of the calibration box lid is 0°C. Do not freeze! |

## Power Supply Unit

| Symbol | Definition |
|---|---|
|  | The power supply has high voltage parts inside. |
|  | Intended for indoor use only. |
|  | Double isolated. |
| IP 21 | IP 21 protection against dust and dripping water from above. |

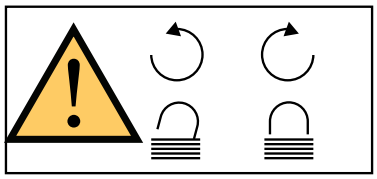
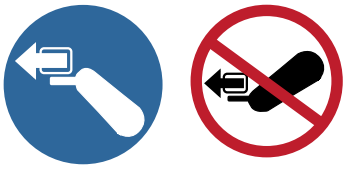
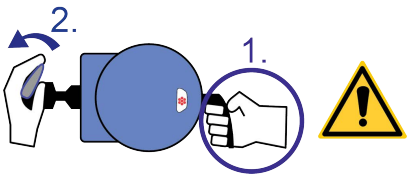
## Isolation Transformer on Cart

| Symbol | Definition |
|---|---|
|  | "I" - The isolation transformer is switched on<br>"0" - The isolation transformer is switched off |
|  | To alert the user of important functions, mainly refers to maintenance regulations in the operating instructions for the isolation transformer (DS.0143.799). |
|  | Follow operating instructions for the isolation transformer (DS.0143.799). |
|  | Connection point for potential equalization.<br>The purpose of connection to potential<br>equalization is to reduce the potentials of different metal parts that can be touched at the same time, or reduce the potential differences that may arise during application between the body, electromedical devices and external conductive parts. |
|  | This is not an Ethernet connection! The connection should not be used for the PeriCam PSI. Misuse can lead to damage to the isolating transformer as well as to the network! |

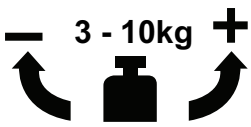
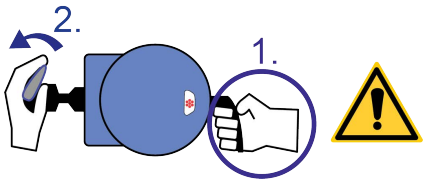
## USB Memory Stick with PIMSoft

| Symbol | Definition |
|---|---|
|  | Read manual before use (Operator's Manual). |

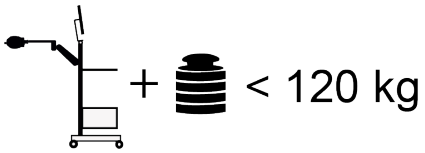
## Adjustable Table Arm

| | |
|---|---|
|  | Placed on the side of the arm.<br>Stand to the side of the adjustable arm and mounted instrument and use caution when disengaging the height locking lever. A change in the total load can cause a sudden downward or upward movement of the arm when the height locking lever is disengaged. |
|  | Placed on the side of the arm, close to the height locking lever.<br>The height locking lever is disengaged by turning it clockwise and engaged by turning it counterclockwise. |
|  | Placed on the side of the arm.<br>The adjustable arm must be positioned in up or highest position and locked when device is removed. |
|  | Placed underneath the arm.<br>Maximum load of the adjustable arm is 30 lbs /13.6 kg. |
|  | Placed adjacent to the ball joint.<br>***WARNING!***<br>*Always support the imager head with one hand when unlocking the ball joint. Otherwise the head may hit the surface below with great force and cause damage to the equipment and/or personal injury.* |

Adjustable Cart Arm

| | |
|---|---|
|  | Placed on the side of the arm.<br>**WARNING!**<br>*Arm should be positioned in highest position and locked before removing device.* |
|  | Placed on the top of the arm.<br>Maximum load of the adjustable arm is 6.6 lbs /3 kg. |
|  | Set load: Load range 3-10 kg. Arrows indicate direction for changing the load.<br>*NOTE!*<br>*The load is set by Perimed and should normally not be changed.* |
|  | Placed adjacent to the ball joint.<br>**WARNING!**<br>*Always support the imager head with one hand when unlocking the ball joint. Otherwise the head may hit the surface below with great force and cause damage to the equipment and/or personal injury.* |

Imager Cart

| | |
|---|---|
|  | Pushing prohibited, placed on the back of the column. To avoid the risk of tipping, always use the handle when relocating the cart. |
|   | Maximum mass of mobile equipment, placed on the front of the column.<br>The PeriCam PSI on Vexio cart loaded with its safe working load weighs maximum 120 kg.<br>The safe working load is the sum of the maximum load on the drawer, the shelf and the accessory box, see below. |
|   | Maximum load bottom shelf/drawer |
|   | Maximum load top shelf |
|   | Maximum load, accessory box, box in drawer |

# 2 Introducing the PeriCam PSI

## Introduction

The PeriCam PSI is an imager based on LASCA technology (LAser Speckle Contrast Analysis). The instrument measures superficial blood perfusion over large areas at fast capture rates. This makes it ideal for investigations of both the spatial and temporal dynamics of microcirculation in almost any tissue.

Since there is no physical contact with the target tissue and no dyes or tracers are used, the influence on blood perfusion can be kept to a minimum. This means that repeated investigations over a longer period can be followed without the additional risk of contamination, infection or discomfort to the subject/patient.

The PeriCam PSI is available in two versions: normal resolution (NR) and high resolution (HR). Both versions can be provided with an optional zoom functionality, enhanced handling of patient information including data security functions, and DICOM connection.

The normal resolution version is a general purpose imager suitable for medium-resolution imaging of areas of variable size (from a few square centimeters to a few hundred square centimeters) in both humans and animals. It uses an adjustable arm for flexible positioning of the instrument head and permits measurement distances from 13 to 41.5 cm.

The high resolution version is designed for high-resolution imaging of small areas (up to a few square centimeters), particularly in mouse and rat brain applications. It uses a microscope stand for stability and requires a fixed measurement distance of 13 cm.

When provided with zoom functionality, both versions support high resolution, large measurement areas, and a flexible measurement distance of 13 to 41.5 cm.

The PeriCam PSI can be configured according to customer needs. The recommended configurations are presented in the following sections.

## PeriCam PSI on Vexio-cart

The PeriCam PSI mounted on a cart consists of the components shown in Figure 2-1.

A special configuration of the PeriCam PSI on cart is available for clinical use and clinical research applications, where several options are included. In this configuration, zoom functionality and the clinical package (with enhanced handling of patient data and data security functions) are included. DICOM connectivity is optional for this configuration.

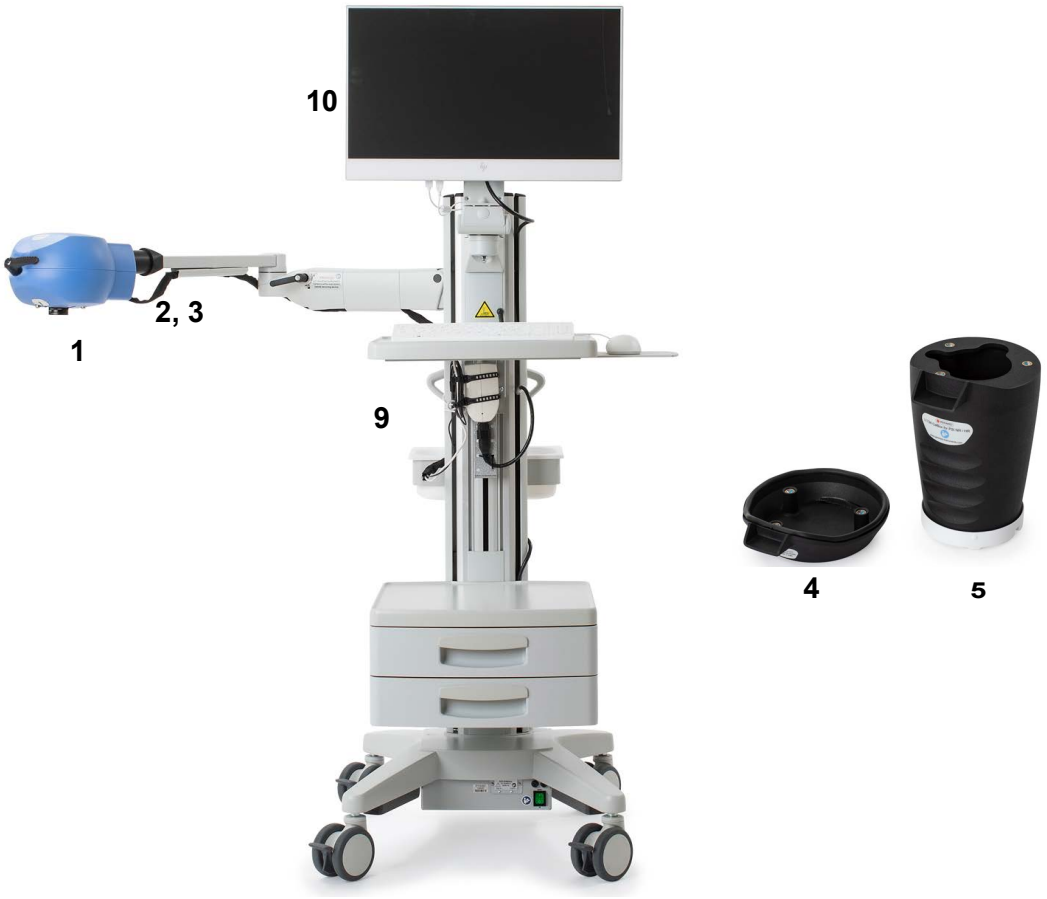



*Figure 2-1 PeriCam PSI NR on a Vexio Cart.*

| | Part | Information |
|---|---|---|
| 1 | PeriCam PSI Head | With PF 6108 Detachable External Power Supply: Powerbox EXM 80 5118 |
| 2 | LI 726 Data Cable for PSI NR/HR | To connect the PSI head to the computer. |
| 3 | Zipper Sleeve 0.50 In, 5 Ft | Protective sleeve for power supply cable and data cable. |
| 4 | LI 725 Protective Cap for PSI NR/HR | |
| 5 | LI 724 CalBox (calibration box) for PSI NR/ HR | Including LI 721 CalBox Lid for PSI NR, PSI HR, PIM 3 |
| 6 | Background Reference Pad | Not in figure. |

| | Part | Information |
|---|---|---|
| **7** | Optical Cleaning Kit for Imager | Not in figure. |
| **8** | PIMSoft, data acquisition and analysis software | Not in figure. |
| **9** | Vexio-cart Plus for Imager | Included in the package for clinical use and clinical research.<br>Optionally height adjustable.<br>Including isolation transformer. |
| **10** | Computer | Including mouse and keyboard.<br>Alternatives:<br>High-end Panel PC for PeriCam PSI (*)<br>High-end Desktop PC for PeriCam PSI (*) |

(*) See "Introducing the PeriCam PSI" in the Technical Description (part no 44-00638) for detailed information about model.

## PeriCam PSI NR Table Configuration

The PeriCam PSI NR for mounting on a table consists of the following components, as shown in Figure 2-2:


*Figure 2-2 PeriCam PSI NR table configuration.*

| | Part | Information |
|---|---|---|
| **1** | PeriCam PSI NR Head | With PF 6108 Detachable External Power Supply: Powerbox EXM 80 5118 |
| **2** | LI 726 Data Cable for PSI NR/HR | To connect the PSI head to the computer. |
| **3** | Zipper Sleeve 0.50 In, 5 Ft | Protective sleeve for power supply cable and data cable. |
| **4** | LI 725 Protective Cap for PSI NR/HR | |
| **5** | LI 724 CalBox (calibration box) for PSI NR/HR | Including LI 721 CalBox Lid for PSI NR, PSI HR, PIM 3 |
| **6** | Background Reference Pad | Not in figure. |
| **7** | Optical Cleaning Kit for Imager | Not in figure. |
| **8** | PIMSoft, data acquisition and analysis software | Not in figure. |
| **9** | Adjustable Table Arm | |
| **10** | Table mount | |
| **11** | Computer | Including mouse and keyboard.<br>Alternatives:<br>High-end Laptop PC for PeriCam PSI (*)<br>High-end Panel PC for PeriCam PSI (*)<br>High-end Desktop PC for PeriCam PSI (with Monitor) (*) |

(*) See "Introducing the PeriCam PSI" in the Technical Description (part no 44-00638) for detailed information about model.

## PeriCam PSI HR Table Configuration

The PeriCam PSI HR configuration for mounting on a table consists of the following components, as shown in Figure 2-3:

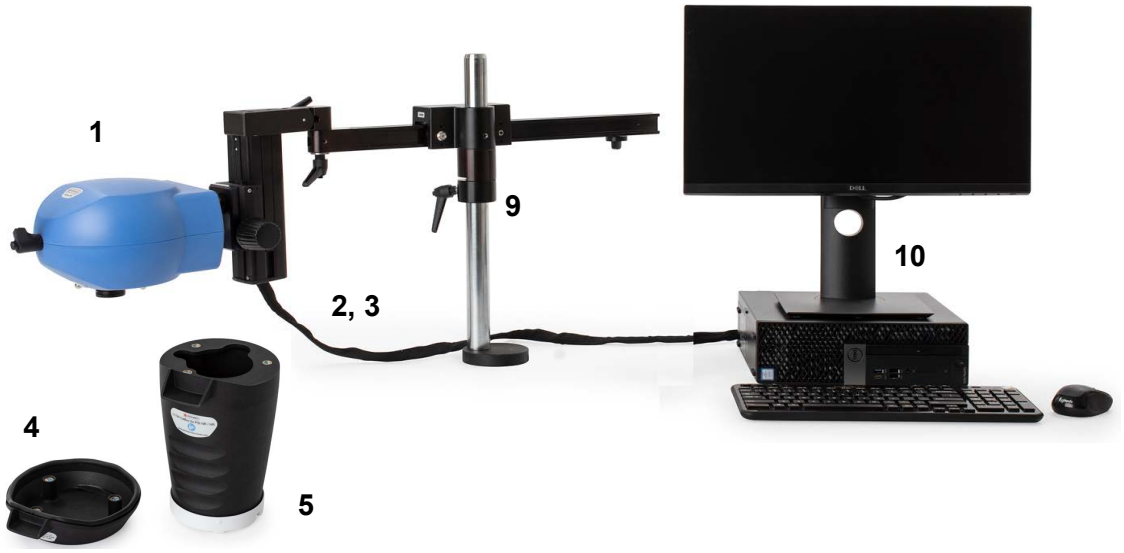



*Figure 2-3 PeriCam PSI HR table configuration.*

| | Part | Information |
|---|---|---|
| **1** | PeriCam PSI HR Head | With PF 6108 Detachable External Power Supply: Powerbox EXM 80 5118 |
| **2** | LI 726 Data Cable for PSI NR/HR | To connect the PSI head to the computer. |
| **3** | Zipper Sleeve 0.50 In, 5 Ft | Protective sleeve for power supply cable and data cable. |
| **4** | LI 725 Protective Cap for PSI NR/HR | |
| **5** | LI 724 CalBox (calibration box) for PSI NR/HR | Including LI 721 CalBox Lid for PSI NR, PSI HR, PIM 3 |
| **6** | Background Reference Pad | Not in figure. |
| **7** | Optical Cleaning Kit for Imager | Not in figure. |
| **8** | PIMSoft | Data acquisition and analysis software. Not in figure. |
| **9** | Leica swing-arm stand | |
| **10** | Computer | Including mouse and keyboard.<br>Alternatives:<br>High-end Laptop PC for PeriCam PSI (*)<br>High-end Panel PC for PeriCam PSI (*)<br>High-end Desktop PC for PeriCam PSI (with Monitor) (*) |

(*) See "Introducing the PeriCam PSI" in the Technical Description (part no 44-00638) for detailed information about model.

# Options, Consumables and Spare Parts

| Options |
|---|
| Isolation Station (for table configuration, not with laptop): Powertronix X1BTWFHNOC1 |
| Network Isolator: EMO Systems EN-1005+ |
| Positioning Pillow 55X30cm White (included in the package for clinical use and clinical research) |
| Vacuum Hand Pump GE (for Positioning Pillow, included in the package for clinical use and clinical research) |
| Medical Keyboard and Mouse (included in the package for clinical use and clinical research) |
| Zoom factory configuration for PSI NR/HR (included in the package for clinical use and clinical research) |
| Zoom upgrade for PSI NR/HR |
| Clinical Package (included in the package for clinical use and clinical research) |
| Clinical Connectivity Package |

| Spare Parts |
|---|
| PF 6108 Detachable External Power: Powerbox EXM 80 5118 |
| Background Reference Pad |
| LI 725 Protective Cap for PSI NR/HR |
| LI 724 CalBox for PSI NR/HR |
| LI 721 CalBox Lid for PSI NR, PSI HR, PIM 3 |
| LI 726 Data cable for PSI NR/HR |
| Zipper Sleeve 0.50 In, 5 Ft (Protective sleeve for power supply cable and data cable) |

## PeriCam PSI Head Front and Rear

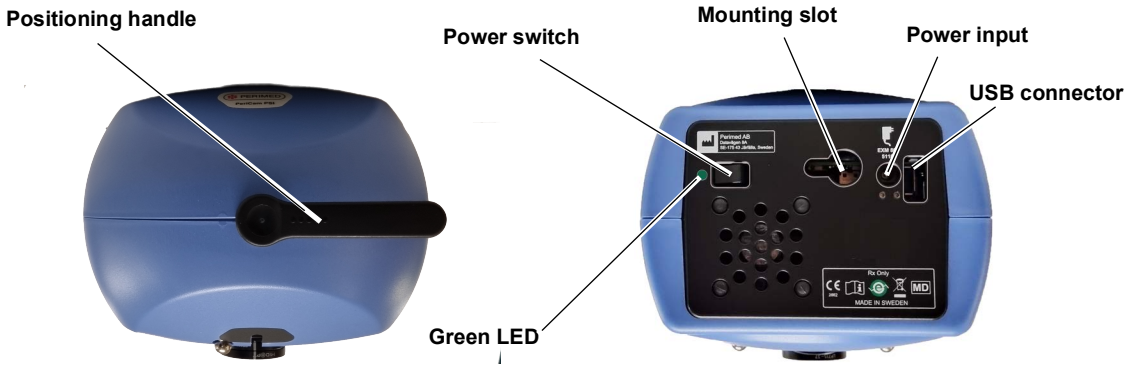



*Figure 2-4 PeriCam PSI head front and rear..*

| Part | Function |
|---|---|
| Positioning handle | For holding while positioning the head. |
| Power switch | For turning the imager on/off. |
| Mounting slot | For attachment of the head to the adjustable arm/swingarm. |
| Power input | For connecting the power supply cable. |
| USB connector | For data communication.<br>*NOTE!*<br>*Use only the USB data cable supplied by Perimed.* |
| Green LED | Flashes during initialization and warm-up, lit solid when the imager is ready for measurement. |

## Optical Parts

The optical parts of the PeriCam PSI are shown in Figure 2-5.

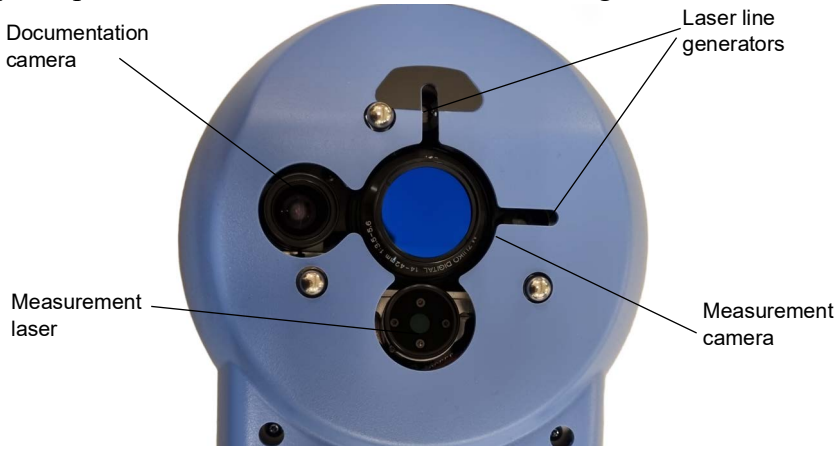



*Figure 2-5 Optical parts - view of the PeriCam PSI head from underneath.*

## PIMSoft Overview

The PIMSoft software runs on a PC connected to the PeriCam PSI head. An overview of PIMSoft is given below. The different functions are described in detail in the respective section of this manual, and in the Technical Description (part no. 44-00638).

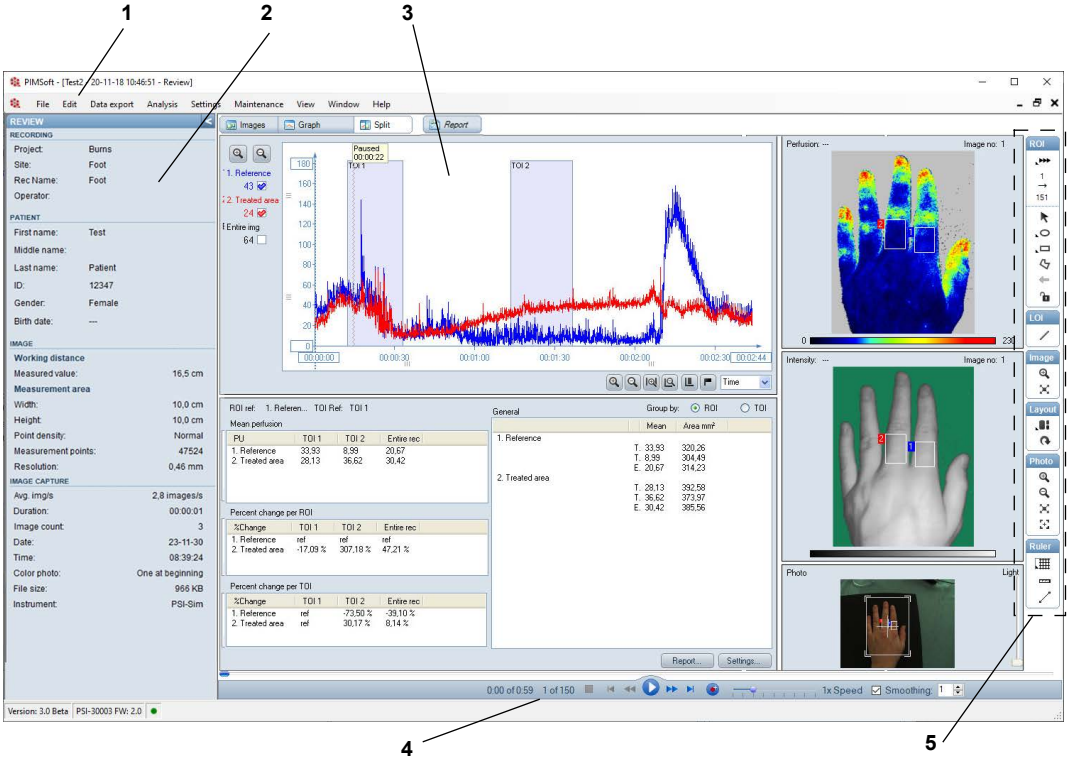



*Figure 2-6 The PIMSoft window (review mode).*

| | Part | Function |
|---|---|---|
| **1** | Menus | For file handling, data export, analysis, settings, maintenance and other actions. |
| **2** | Setup/Review/Recording panel | Used for selection of recording parameters during setup. Displays the selected parameters during recording and review. Changes color depending on the mode (setup/recording/review). |
| **3** | Measurement window | Displays images, graphs and tables. Changes color depending on the mode (setup/recording/review). |
| **4** | Recording panel | For control of the current recording.<br>Changes depending on the mode (setup, recording, review, etc.). Not all buttons and functions are available at all times. |
| **5** | Tools panel | Tools for visualization and data analysis. |

# 3 Operation of Cart and Arm

Depending on the specific configuration, the PeriCam PSI is delivered with either

- A cart with an adjustable arm (NR)
- An adjustable arm for table mount (NR)
- A swing-arm stand for table mount (HR)

The adjustable arm for PeriCam PSI NR provides easy positioning and a wider range for measurement on larger subjects, while the microscope type swing-arm stand for PeriCam PSI HR allows for detailed positioning for smaller subjects.

## Operation of the Ball Joint

The PeriCam PSI head is attached to the arm with a ball joint for easy repositioning of the head. The ball joint has a locking lever to lock the joint in a specific position, see Figure 3-1.

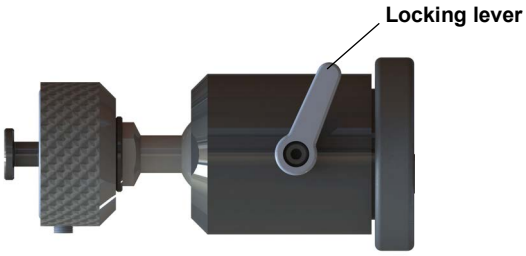



*Figure 3-1 Ball joint with locking lever.*

To reposition the head, do as follows.

1. Support the PeriCam PSI head with one hand, see Figure 3-2.
2. Release the locking lever, see Figure 3-2.

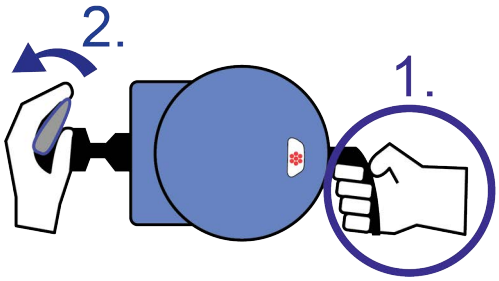



*Figure 3-2 Support the PeriCam PSI when unlocking the ball joint.*

3. Reposition the head to the desired position.
4. Carefully fasten the locking lever.

***WARNING!***

⚠ *If the locking lever is not released before repositioning the head, the joint will be subject to severe wear and may break. If the head falls it may potentially cause damage to the instrument and/or personal injury.*

⚠ *Always support the PSI head when unlocking the ball joint, and carefully fasten the locking lever after repositioning of the head, otherwise the head may suddenly move downwards and potentially cause damage to the instrument and/or personal injury.*

# Operation of the Cart with Adjustable Arm

## Connection and Disconnection to Mains

The cart includes an on/off switch on the isolation transformer mounted under the front side of the wheel stand. Before connecting or disconnecting the isolation transformer to/from supply mains, make sure it is switched off, see Figure 3-3.


*Figure 3-3 Position of on/off switch on the cart.*

***WARNING!***

⚠ *The PeriCam PSI on cart must only be connected to a supply mains with protective earth.*

***Caution!***

*The isolation transformer mounted on the cart requires adequate air cooling. Make sure the ventilation holes are not covered.*

## Use of the Cart and Adjustable Arm During Operation

The cart with the adjustable arm can be used to position the PeriCam PSI head correctly in the room and over the tissue to be measured.

Release the brakes of the wheels before moving the cart, and be sure to tighten the brakes again before starting a measurement. Always use the handle to move the cart.

The following adjustments can be made of the adjustable arm, see Figure 3-4:

- Changing the angle of the head (1) by means of the ball joint.
- Swiveling the upper part of the arm in relation to the main part (2).
- Adjusting the height (3). Loosen the height locking lever before adjustment and fasten the lever to lock the arm in the desired position.
- Pivoting the arm in relation to the cart (4). Friction may be adjusted by the friction control.

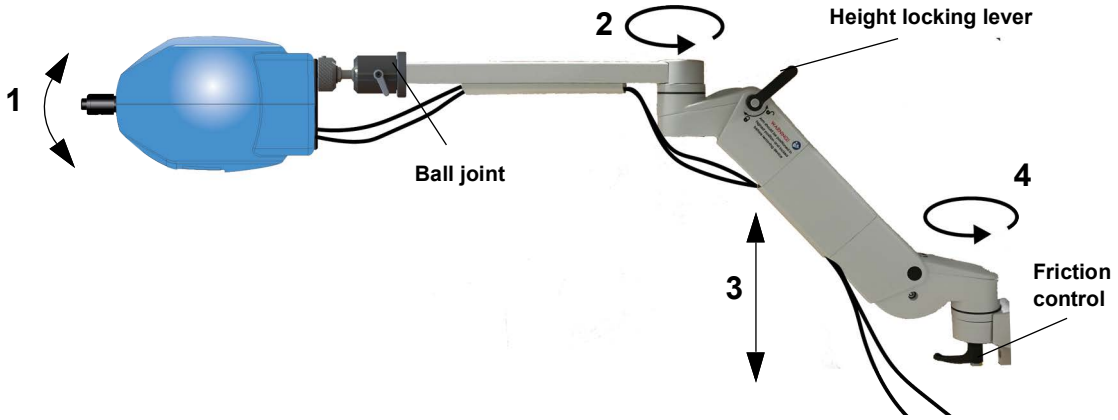



*Figure 3-4 Adjustment of the cart arm.*

## Height Adjustment of the Vexio Cart

As an option, the cart can be height adjustable.

To raise or lower the adjustable part:

1. Loosen the lever above the top shelf, see Figure 3-5 below.
2. Grasp the rear of the shelf, near the column.
3. Push the shelf up or down, as desired.

## Transport of the PeriCam PSI on the Cart

The PeriCam PSI may be transported on the cart inside buildings. Use the handle for pulling the cart, not for lifting. Do not use any protruding cables as handles.

It is recommended to pull the cart instead of pushing it in front of you, as it can be difficult to look over the equipment.

Take extra care when moving the cart over thresholds. Pay attention to unevenness in the floor, door frames, cables, and other objects in order to prevent accidents.

Before transport, make sure that:

- All equipment on the cart is secured in order to not fall off
- In the case of a height adjustable cart, the adjustable part is in its lowest position
- The adjustable arm is folded up and secured
- The cart is disconnected from mains
- The brakes of the wheels are released

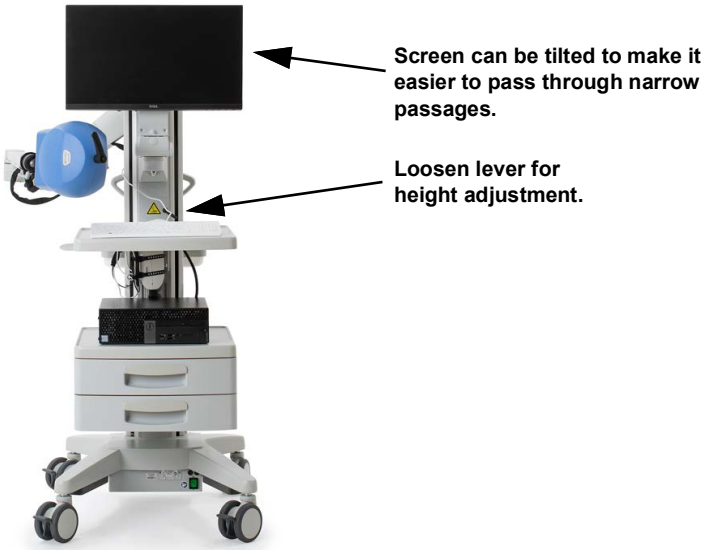



*Figure 3-5 Cart in transport position.*

## Load Capacity

The cart is designed to carry the weight of the PeriCam PSI and accessories supplied by Perimed. In case any other items are placed on the cart, ensure that the load capacity marked on the cart, the drawer, the shelf and the accessory box is not exceeded.

If additional heavy objects are placed on the cart, also consider the increased risk of the cart tipping over.

## Operation of the Adjustable Table Arm

The arm may be adjusted in the following ways, see Figure 3-6:

- Changing the angle of the head (1) by means of the ball joint.
- Swiveling the upper part of the arm in relation to the main part (2).
- Adjusting the height (3). Loosen the height locking lever before adjustment and fasten the lever to lock the arm in the desired position.
- Pivoting the arm in relation to the table mount (4).

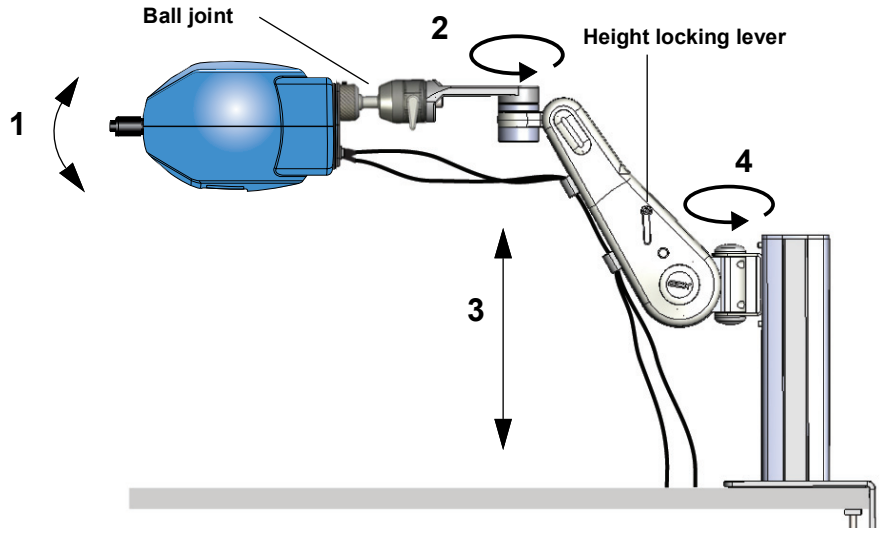



*Figure 3-6 Adjustment of the table arm.*

## Operation of the Swing-arm Stand

The following adjustments can be made, see Figure 3-7:

- Fine-adjusting the working distance (1) using knob A. This is the recommended method to adjust the working distance on a daily basis. The working distance may also be adjusted by changing the position of the horizontal arm on the vertical column (2), using lever D to move the safety ring and then knob C to move the horizontal arm. **Be extremely careful, and hold on firmly to the horizontal arm, when opening knob C**.
- Adjusting the range of the horizontal arm (3) using knob B.
- Swinging the horizontal arm laterally (4) using knob C.
- Changing the angle of the head vertically (5) using lever E, and horizontally using lever F.

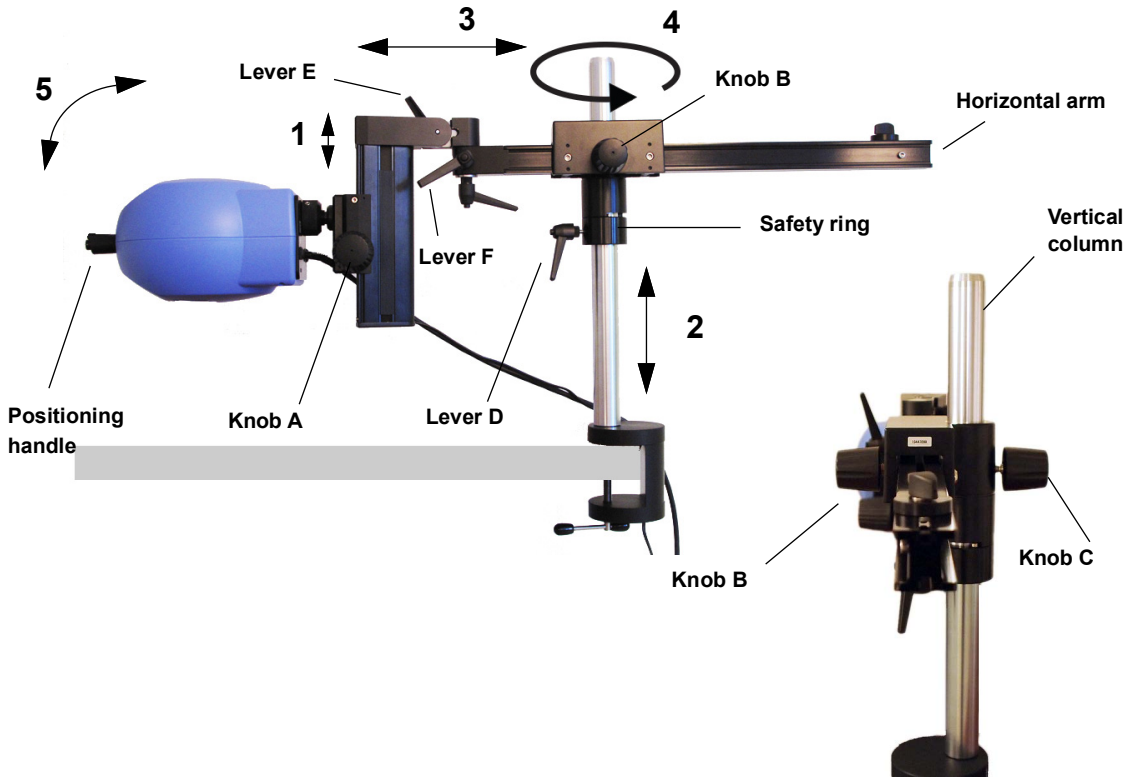



*Figure 3-7 The swingarm stand seen from the SIDE (top left) and from BEHIND (bottom right).*

***Caution!***

*To protect the horizontal arm from inadvertently falling down, reposition the safety ring after every change in position of the horizontal arm, and tighten the clamping lever.*

*Be careful when loosening the focus drive (lever E), otherwise the PeriCam PSI head may fall downwards with force.*

*When leaving the workplace, return the swing-arm stand to the starting position and fix all knobs and clamping levers.*

*Check the firm attachment of the stage clamp at the worktop at regular intervals.*

*NOTE!*

*If the head needs to be positioned in an angle not horizontal to the table, it is recommended to set the angle correctly before adjusting the working distance.*

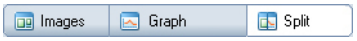
*Hold the positioning handle when repositioning the head.*

# 4 Measurement Functions

Measuring with the PeriCam PSI is controlled using the PIMSoft data acquisition and analysis software.

During setup, recording and review, the Measurement Window is used. It has three alternative views:

| View | Displays | Keyboard shortcut |
|---|---|---|
| Images | Perfusion image, intensity image, color photo. | F2 |
| Graph | Perfusion graphs and calculations. | F3 |
| Split | Combination of the Images and Graph views. | F4 |

Change view by selecting the desired view tab 

.

## Images View

The Images view has three subviews: the perfusion image, the intensity image and the color photo, see Figure 4-1. Each subview can be manipulated with specific tools.

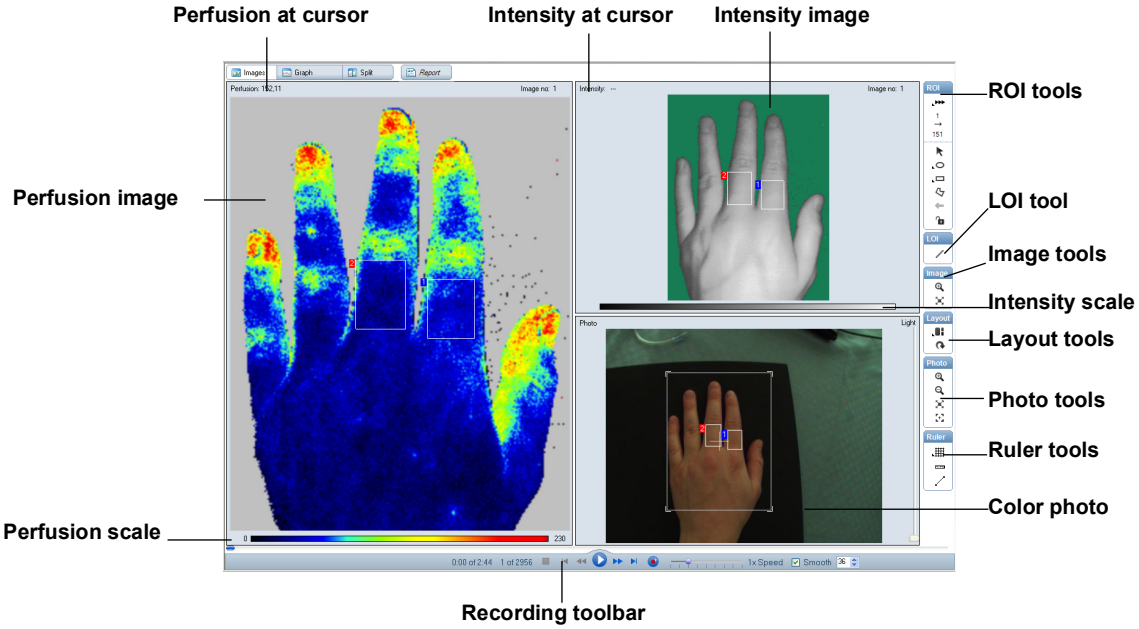



*Figure 4-1 The Images view.*

*NOTE!*

*You can copy any image to the clipboard, or export it as a png file, by right-clicking on the image and selecting the appropriate option.*

### Perfusion Image

The perfusion image is a color-coded representation of the blood perfusion in the measured tissue. By default, areas of high perfusion are shown as red and areas of low perfusion are shown as blue.

Areas or points that are outside the threshold values for the perfusion and intensity filters are shown as gray and are not included in any results or calculations.

### Perfusion at Cursor

Shows the perfusion value at the location of the cursor.

### Perfusion Scale

The perfusion scale allows adjustment of the color range of perfusion images. Changes to the perfusion scale only affect how perfusion is visualized in the images; the measured perfusion values are unaffected.

**WARNING!**

⚠ *Make sure the selected color scale is suitable for the specific application. Faulty interpretation of the color scale may lead to faulty input to diagnosis.*

To adjust the perfusion color scale, double-click on the perfusion scale, or select *Analysis | Filters and color scales…*. The Filters dialog is displayed.

Adjustment is made by a color scale drop-down list, see Figure 4-2, and three radio buttons.

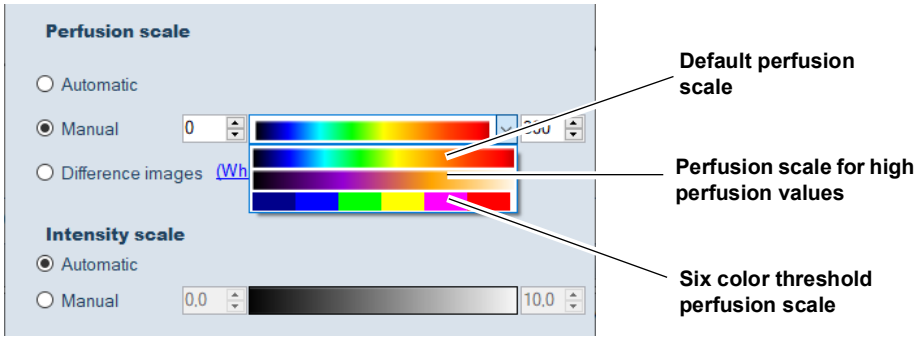



*Figure 4-2 The Perfusion color scales.*

### Default Perfusion Scale

The default color scale is suitable for most applications. Select one of the following options:

- Automatic - the color scale will automatically adjust the range according to the highest and lowest values found in the recording.
- Manual - the range is chosen manually. This alternative is usually preferred, especially when comparing recordings.

If you selected a manual scale, enter the upper and lower limits in the corresponding text boxes.

*NOTE!*

*When comparing different recordings based on their colors, it is important to use the manual color scale and the same upper and lower limits.*

### High Perfusion Scale

This is a black–purple–white continuous scale that emphasizes high perfusion values. Select one of the following options:

- Automatic - the color scale will automatically adjust the range according to the highest and lowest values found in the recording.
- Manual - the range is chosen manually. This alternative is usually preferred, especially when comparing recordings.

If you selected a manual scale, enter the upper and lower limits in the corresponding text boxes.

### Six Color Threshold Scale

This is a perfusion scale with up to six different colors and custom threshold values. It is suitable, for example, when studying cortical spreading depolarization (CSD).

Select *Edit* to open the dialog for change of colors, number of thresholds, and threshold values, see Figure 4-3.

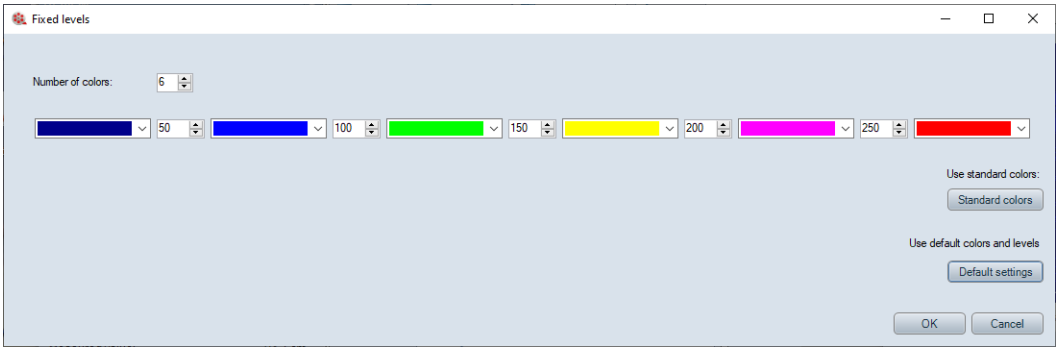



*Figure 4-3 Perfusion threshold settings.*

### Difference Images

This is a relative color scale suitable for studying small local variations in heterogeneous tissues. The scale is symmetrical around zero and the limits are chosen manually.

When this alternative is selected, the average image of the current reference TOI (see"Time Period of Interest (TOI)" on page 60) is subtracted from all images, pixel by pixel. Each perfusion image then shows only the change in perfusion compared to that reference. A prerequisite for accurate use of this function is therefore that a reference TOI has been defined.

*NOTE!*

*When difference images are selected, an additional check box is added for each ROI (see "Region of Interest (ROI)" on page 54) in the graph. When selected, the mean value for that particular ROI within the reference TOI is shown as a dotted line.*

### Intensity Image

The intensity image is created by the total back scattered laser light. It corresponds exactly with the perfusion image and is useful for orientation and for identifying details in the perfusion image.

### Intensity at Cursor

Shows the intensity value at the location of the cursor.

### Intensity Scale

The intensity scale affects the brightness and contrast of the intensity image. To adjust the intensity scale:

1. Double-click on the intensity scale or select *Analysis* | *Filters and color scales*…. The Filters dialog is displayed.
2. Under Intensity scale, select either automatic or manual.
   - Automatic – the intensity scale will automatically adjust the range according to the highest and lowest values found in the recording. This alternative works well in most cases.
   - Manual – the range is chosen manually. This alternative could be used, for example, to exclude extreme measurement values.
3. If you selected a manual scale, enter the upper and lower limits in the corresponding text boxes.
4. Close the Filters dialog by clicking *OK*.

### Color Photo

This displays a color photo of the measurement object. It presents a wider angle view of the measurement site and is recorded with a separate camera. It therefore doesn't correspond pixel-to-pixel with the perfusion and intensity images, but is useful for a general orientation of the measurement site.

During setup and recording, you can adjust the light sensitivity of the color camera using the vertical gain slide bar located to the right of the photo. When the recording is finished, the brightness of the image can be further adjusted with a light control in the same position.

### Image Tools

| Tool | Description |
|---|---|
|  | Select to activate zooming of the perfusion/intensity image. To zoom in, then click in the perfusion or intensity image and draw a rectangle to select the area to zoom in to. Available in recording mode and review mode. |
|  | Fits the image to frame. |

## Layout Tools

Changes the image layout. Different layouts may be applied to the image view and the split view..

| Tool | Description |
|---|---|
|  | Default layout: Arranges the perfusion image to the left and the intensity and photo images together on the right. |
|  | Alternative layout: Arranges the perfusion and intensity images together above and the photo image below. |
|  | Horizontal layout: Arranges the images horizontally. |
|  | Vertical layout: Arranges the images vertically. |
|  | Rotates all images in the active recording in steps of 90 degrees clockwise. |

## Photo Tools

| Tool | Description |
|---|---|
|  | Zooms in. |
|  | Zooms out. |
|  | Fits the photo to the frame. |
|  | Fits the measurement area to the frame. |

## Ruler Tools

These tools are also available in the menu, under "View".

| Tool | Description |
|---|---|
|  | Displays a grid over the images to aid in estimating size. To change the size of the grid, click the small triangle at the lower left corner of the tool. (0.1 mm, 0.5 mm, 1 mm, 5 mm, 10 mm, 15 mm, 20 mm) |
|  | Displays a ruler in the lower left corner of the perfusion and intensity images. Click repeatedly to toggle ruler on and off. |
|  | Allows the distance between two points to be measured in the perfusion or intensity images. Click in an image at the position where the distance measurement should start, and drag to a new position. The distance between the two points is displayed in a small text frame next to the cursor. |

*NOTE!*

*A distance is measured on the image, not the object itself, and dependent on other measurement setup details (i.e. depth between points). Therefore, calculated values may not exactly represent the actual distance between two points.*

## Graph View

Figure 4-4 shows the Graph view. The view displays a graph, the general table, the mean value table and percent change tables.

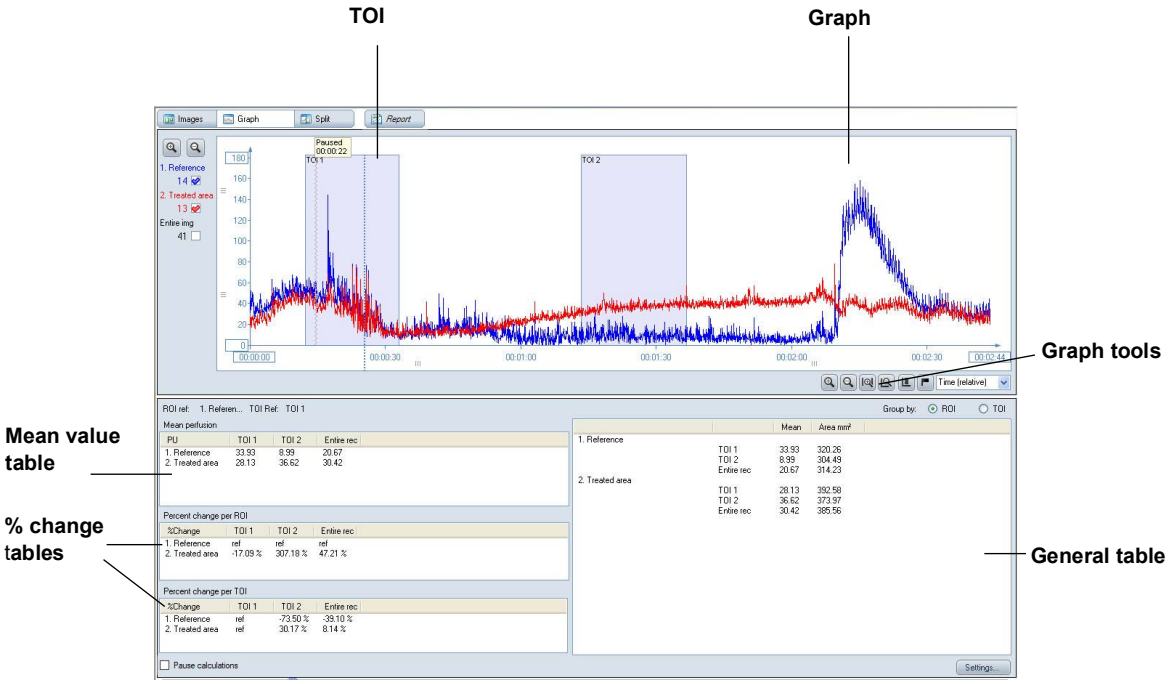



*Figure 4-4 Graph view.*

## Split View

Figure 4-5 shows the Split view, which combines the Images view and the Graph view.

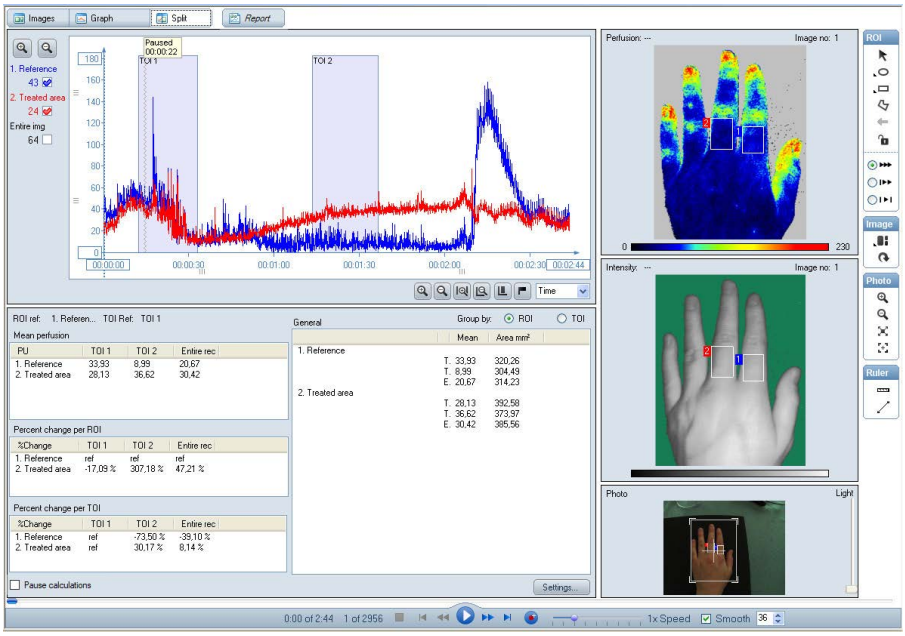


*Figure 4-5 Split view.*

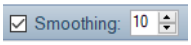
## Recording Toolbar

The recording toolbar is located at the bottom of the Image Window.

*NOTE!*

*The recording toolbar changes depending on the mode (setup, recording, review, etc.). Not all buttons and functions are available at all times.*

| Symbol | Description | Keyboard shortcut |
|---|---|---|
| 00:38 of 00:48 | Shows the current time position and the total length of the recording. | - |
| 1 of 2728 | Shows the current image number and the total number of images in the recording. | - |
| | Stops recording. | F5 |
| | Skips to the first image in the recording. | F6 |
| | Rewinds the recording. Click to step back one image at a time, click and hold to rewind. | F7 |
| | Plays the recording. | F8 |

| | | |
|---|---|---|
|  | Pauses the recording. | F8 |
|  | Starts recording and resumes a paused recording. | F8 |
|  | Appearance of recording symbol when Record with averaging is enabled. | - |
|  | Fast forwards the recording. Click to step forward one image at a time, click and hold to fast forward. | F9 |
|  | Skips to the last image in the recording. | F10 |
|  | Resumes a stopped recording. | F11 |
|  | Controls playback speed. Use the slider to adjust playback speed. | - |
|  | Turns smoothing on/off. When smoothing is on, the perfusion is averaged (moving average) over a number of images for a smoother appearance of the perfusion image. Use the check box to turn smoothing on and off. Set the number of images to average over in the text box.<br>*NOTE!*<br>*Smoothing is only a visual effect and has no effect on the actual recorded perfusion values.* | - |
|  | Shows the current position in the recording. Click and drag on the position indicator to move backward and forward in the recording. | - |

## The Graph

The graph shows real-time blood perfusion traces for the entire recording and/or each region of interest (ROI) in the recording. Use the check boxes to the left of the graph to show/hide a particular trace.

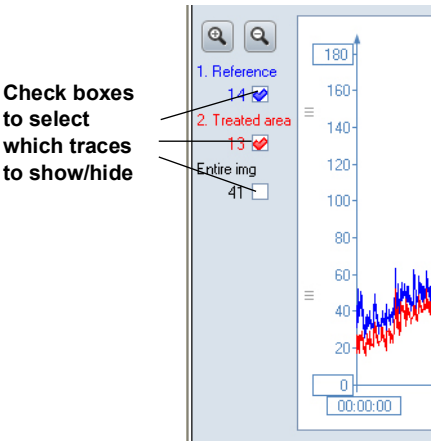



*Figure 4-6 Selection of traces to show.*

*NOTE!*

*Traces are only shown during recording if "Live calculations" is selected. No traces are shown during setup.*

### Vertical Graph Scale

To adjust the vertical scale, enter the top and bottom values in the text boxes and press enter on the keyboard, or click and drag the handles shown in Figure 4-7. The top handle affects the top value, and the bottom handle affects the bottom value of the scale.

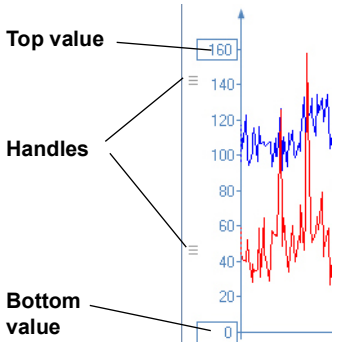



*Figure 4-7 Adjusting the vertical graph scale.*

## Horizontal Graph Scale

To select relative time (from the start of the recording), absolute time, or number of images on the horizontal axis, use the selection box to the right of the graph tools, shown in Figure 4-8.

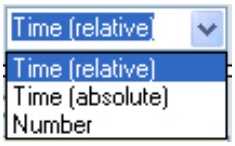



*Figure 4-8 Selection of scale on the horizontal axis.*

*NOTE!*

*The horizontal scale will display the elapsed time excluding any pauses in the recording. Pauses in the recording are marked with a wavy line. However, the time and duration figures in the general table, the mean value table and the percent change tables described below will show the elapsed time including any pauses.*

## Graph Tools

| Tool | Description |
|---|---|
|  | Zoom in. |
|  | Zoom out. |
|  | Zoom in to area. |
|  | Zoom out to entire trace.<br>(Keyboard shortcut "C") |
|  | Add Reference Line in the graph, as a visual aid. Several lines can be added in a graph Right click on the line to change the value, add a name, change the color, or delete the line. |
|  | Add TOI (Time period Of Interest, see "Time Period of Interest (TOI)" on page 37). |
|  | Add Event Marker.<br>(Keyboard shortcut "Ctrl + M" for marker with manually entered text, or F12 for marker with predefined text). |

### Add Event Marker

Event markers can be used to mark important events (for example, the time of an applied stimulus). To insert an event marker during recording:

1. Click the button. A marker is inserted at the time when the button is clicked, and a text box opens.
2. Enter a comment in the text box.
3. Click *OK*.

If an event marker is inserted in analysis mode, it will be placed at the location of the cursor.

To insert an event marker with a predefined text, press F12 on the keyboard while recording. The predefined text can be edited in the Options dialog (*Tools | Options...)*. Note that insertion of markers also may be triggered by external software programs able to generate the F12 keyboard command.

*NOTE!*

*To adjust the position of an event marker, click and drag the marker head to a new position.*

## Selecting a Specific Image or Point in Time

In order to navigate to a specific image or point in time, click the corresponding position in the graph. A dotted line will appear at the selected point, and the perfusion values for this image will be displayed to the left of the check box for the respective trace, see Figure 4-9. This line can also be dragged backwards and forwards in order to step through the recording.

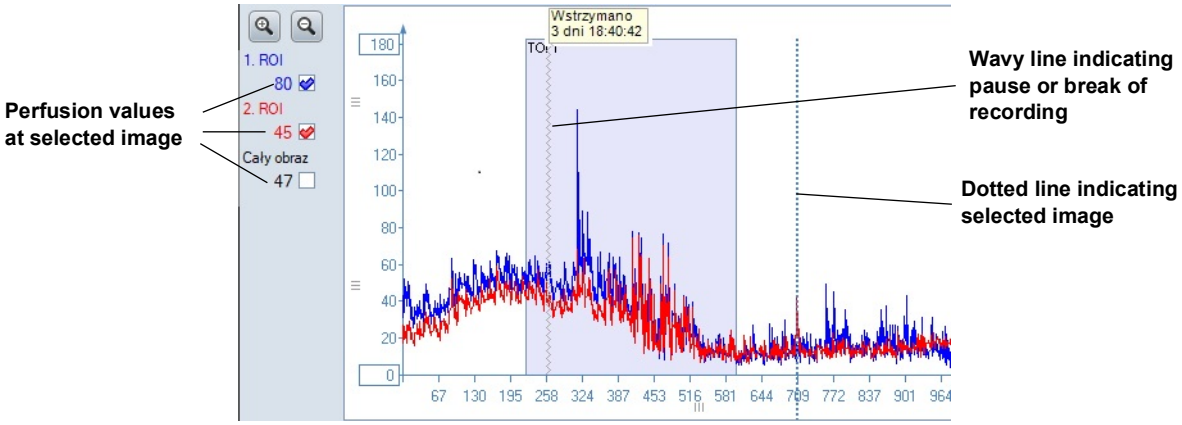



*Figure 4-9 Selection of a specific image or point in time.*

*NOTE!*

*If you click inside a TOI, the TOI is selected instead of the position in the graph being selected. To select a position within a TOI, click outside the TOI, and drag the line to the desired position.*

## Miscellaneous Functions

### Change user account

Select *File* | *Logout.* The login window opens and allows you to select another account.

### Duplicate a recording

Select *File* | *Open recording* to open the recording you want to duplicate. Then select *File* | *Duplicate current recording...*

### Delete a recording

Select *File* | *Open recording* to open the recording you want to delete. Then select *File* | *Delete current recording...*

### Select window

Under *Window*, you can select which window (recording) that is active. Actions selected in the menu will be applied to the active window.

# 5 Recording Blood Perfusion Images

It is recommended to use standardized recording settings for the PeriCam PSI. See "Setting of Recording Parameters" on page 49 for more information on how to change the settings.

Measurements can be performed in normal ambient light, e.g. from ceiling lamps.

***WARNING!***

⚠ *Movement of subject or instrument during measurements may cause erroneous measurement data.*

⚠ *Vibrations and unstable measurement conditions may disturb the measurement. Do not place the instrument close to any sources of vibration, such as machines or ventilation systems.*

⚠ *Strong ambient light, such as direct sunlight, may affect the measured blood perfusion values.*

⚠ *Dirty and/or damaged optics may affect the measured blood perfusion values.*

## Start the PeriCam PSI

1. If present, switch on the isolation transformer/station.
2. Turn on the computer.
3. Remove the protective cap before switching on the PeriCam PSI head to ensure good ventilation.
4. Turn on the PeriCam PSI head via the switch on the back side.
5. Allow the instrument at least 5 minutes for warm-up. The instrument is ready for measurement when the green LED on the back side has stopped flashing.
6. Start the PIMSoft software via the  icon on the desktop or go via the Start menu. Login, if login functionality is used.

*NOTE!*

*Do not start PIMSoft until at least about 15 seconds after the PeriCam PSI head has been switched on, as it may take some time for the computer to detect the connection to the USB port.*

*In case of large recordings, it is recommended that all other programs are closed during recording.*

## Prepare the Patient/Subject

It is recommended to:

- Make sure the patient/subject is in a comfortable sitting or lying position.
- If possible, allow the patient/subject to rest and acclimatize to the room for 20-30 minutes before taking measurements.
- Inform the patient/subject that they will need to keep still and avoid talking during measurement. If necessary, use a vacuum cushion for stabilization.
- Ensure the patient's/subject's extremities are warm.

## Prepare the instrument

- Use a light-absorbing background material if you want to remove the background.
- Position the instrument head within the recommended measurement distance from the tissue (13 cm for the PeriCam PSI HR, 13-41.5 cm for the PeriCam PSI NR or PeriCam PSI HR with zoom). The head should be parallel to the tissue being measured.

***Warning!***

⚠

*Be careful when moving the PeriCam PSI head over the patient/subject, so that the head or the arm does not hit or fall down on the patient/subject.*

***Caution!***

*When adjusting the PeriCam PSI head, handle the delicate fiber optic data cable with care. If the cable is damaged, communication to the PC may be impaired.*

*Avoid touching the head during recording.Touching the PeriCam PSI head may cause an electrostatic discharge (ESD) that may cause interruption of the communication to the PC. If that happens, restart the PeriCam PSI and PIMSoft.*

*Do not position the PeriCam PSI head with the optics turned upwards or sideways if there is a risk of splashing water, as the water then may enter the electronics inside the PeriCam PSI head.*

*NOTE!*

*The angle between the laser beam and the tissue being measured should preferably be 90 degrees, but must be larger than 45 degrees in order to achieve correct measurement values.*

*Do not touch the PeriCam PSI head, including arm and cart (if used) with hands that might be contaminated, for example after touching the patient.*

## Start a New Recording

1. Click *File* | *New recording*, or press Ctrl+N on the keyboard. A new Image Window opens and the Setup panel is displayed.

### Enter Recording Information

2. Under Recording Setup (Figure 5-1), select a Project and Site (optional). If these choices are not available, either create a project following the instructions in "Project Settings" in the Technical Description (part no. 44-00638), or simply continue without one.
3. If enhanced handling of patient data is not used, select a subject/patient (may be optional or mandatory depending on settings).
   Alternatively, create a new subject/patient by selecting <*New*> from the *Subject/Patient* drop-down list. The *Select subject /patient* dialog appears.
   - Click *New*.
   - Enter the name of the subject in the *New subject/patient* dialog and click OK.
   - Click *OK* to close the *Select subject/patient* dialog.
4. Enter a name for the recording in the *Rec Name* field, or leave blank. If no name is entered, the recording can be identified by the recording time and date.
5. Enter the name of the operator in the *Operator* field, or leave blank.

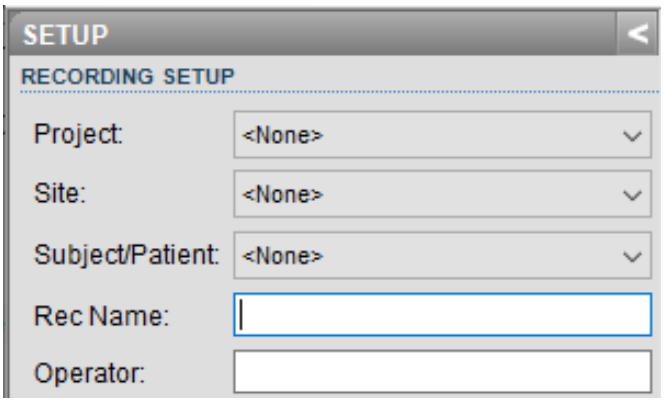



*Figure 5-1 Recording information (research use).*

### Enter Patient Information

6. If enhanced handling of patient information is used, use one of the following options to enter patient information.
   a) Click the *Enter Patient* button. In the dialog that opens, enter the required fields and any optional field, then click *Confirm*.

*NOTE!*

*When you start typing in any of the fields, a drop-down list displays a list of previous patients with similar names/identities. If a patient returns for a follow-up test, simply select his or her name from the list. This patient information cannot be edited.*

b) If DICOM is used, click the *Worklist* button. In the dialog that opens, select the appropriate patient in the list of planned patients. For search options, click *Advanced Search*. When ready, click *Select*.

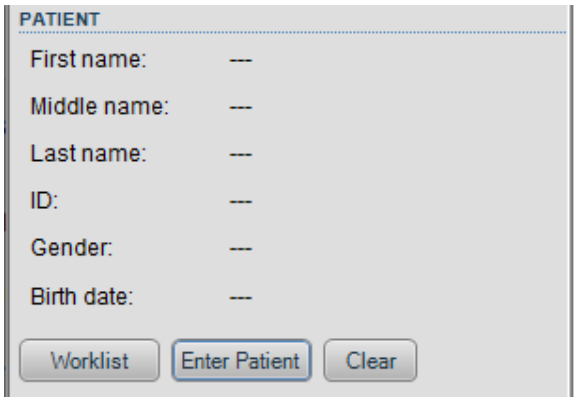



*Figure 5-2 Patient information.*

*NOTE!*

*Patient information received from DICOM Worklist cannot be edited.*

## Setup of working distance

7. Under IMAGE SETUP, the current working distance is displayed (i.e. the distance between the instrument head and the measurement object), measured once per second. If a project is selected, the required working distance is displayed. Adjust the working distance if necessary, by moving the instrument in relation to the tissue.


*Figure 5-3 Working distance.*

*NOTE!*

*The distance measurement is based on measurement in the center spot where the two laser beams are crossing. This point has to rest on the tissue to be measured, not on the background, otherwise the distance measurement and focus setting will not be correct.*

*If the software is unable to detect the center spot (indicated by a misplaced central cross indicator on the color photo), use the "Manual distance" option to enter the distance manually.*

### Start the Recording

8. Click the record button to start recording. The background color will switch to red to indicate recording mode.

*NOTE!*

*If the snapshot function is used (duration is set to "Snapshot"), the recording button has a different look, with a camera icon .*

9. The recording can be paused at any time by clicking the pause button in the recording toolbar. Click the button again to resume recording.
10. Finish the recording by clicking the stop button in the recording toolbar.
11. When the recording is finished, the background color will switch to blue to indicate review mode.

## Handling of the Report

When the recording is finished, click the report button Report to review the report and edit it if needed, see "Reports" on page 66.

To edit recording information, select *Edit* | *Edit recording info...*. You can edit:

- Project name
- Site name
- Subject/Patient (not possible if enhanced handling of patient data is used)
- Rec name
- Operator

To delete single images that are faulty, select the image to delete so that it is displayed, then select *Edit* | *Delete current image* or *Edit* | *Delete current photo,* respectively. Alternatively, right click on the image/photo and select the desired action.

After the review, save or print the report, or send it to an image storage if DICOM connection is used.

*NOTE!*

*Before closing the recording, carefully check that the correct patient is associated with the recording. Once a recording is closed and saved, patient information cannot be changed.*

## Shut Down the PeriCam PSI

To shut down the equipment:

1. Exit PIMSoft by choosing *File* | *Exit*.
2. Switch off the instrument using the switch on the rear panel.
3. Switch off the computer.
4. Switch off the isolation transformer/station (if present). Let it cool down for at least one minute before switching it on again.

## Resume Recording

This function is useful when continuing a measurement on the same subject/patient at another point in time. It enables direct comparison of results.

To resume a recording:

1. Open the recording you wish to resume.
2. Click the resume button. A resume panel is displayed.
3. Set the duration of the recording in the resume panel.
4. Click the record button to start recording.

When resuming a recording, IMAGE CAPTURE parameters may be changed. For PSI with Zoom options, also zoom and focus may be changed, see Figure 5-4.

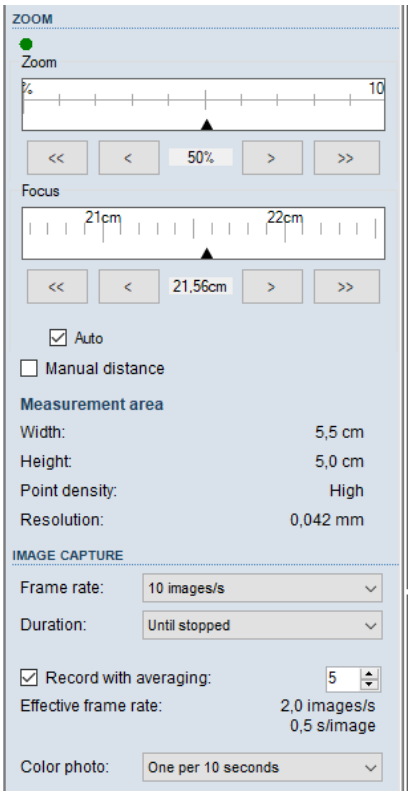



*Figure 5-4 Parameters that can be changed when resuming a recording.*

## Measuring During Iontophoresis

For research, the PeriCam PSI can be used in combination with the PeriIont Micropharmacology System in order to study the influence of drugs on the vascular bed. For more information, see the *PeriIont Micropharmacology System Extended User Manual* (part no. 44-00714).

To measure with the PeriCam PSI during iontophoresis, proceed as follows.

1. Turn on the computer and the PeriCam PSI.
2. Set up the PeriIont Micropharmacology System and prepare the patient according to the *PeriIont Micropharmacology System Extended User Manual*, see Figure 5-5.

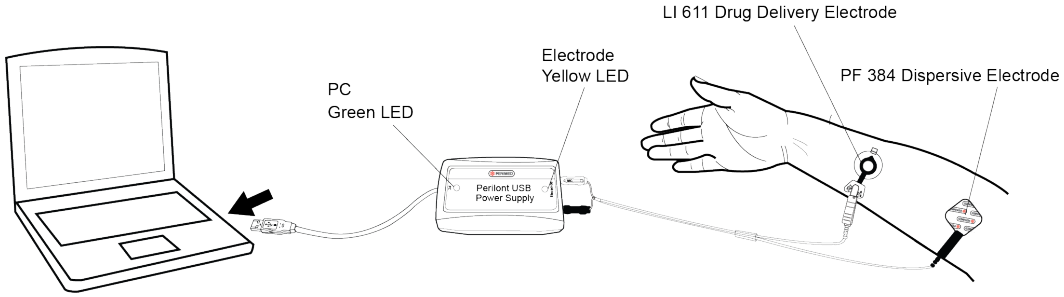



*Figure 5-5*

3. Set up a new recording in PIMSoft, see "Start a New Recording" on page 44.
4. Define desired ROI:s, for example, a ROI over the LI 611 Drug Delivery Electrode and a reference ROI.
5. Run the iontophoresis according to the *PeriIont Micropharmacology System Extended User Manual* and run the recording in PIMSoft simultaneously. Be careful to note the start of iontophoresis in PIMSoft using an event marker, see "Add Event Marker" on page 40.

***WARNING!***

⚠ *Do not place the ROI over the black rim of the LI 611 Drug Delivery Electrode, as this may result in faulty measurement values.*

⚠ *Make sure that the laser beam from the PeriCam PSI is not reflected into the camera from the LI 611 Drug Delivery Electrode, as this will result in faulty measurement values.*

# 6 Setting of Recording Parameters

For maximum reproducibility, it is recommended to standardize the following:

- working distance
- measurement area
- frame rate
- point density
- use of averaging
- zoom setting (for PSI with Zoom option only)

The project editor can be used to create predefined settings, see "Project Settings" in the Technical Description (part no. 44-00638).

## Setup of Image Area

1. Set the size of the measurement area by entering the desired width and height in the corresponding text boxes. You can also click and drag a corner of the white rectangle in the color photo to adjust the size.
   Select *Max image size* to achieve the largest possible image, depending on other settings. The maximum image size is marked with a red rectangle in the color photo.

*NOTE!*

*Setting of the measurement area (width and height) may be automatically changed during measurement setup, due to zooming in and out or changes in measurement distance. This must be considered when analyzing the results.*

2. Select a point density (resolution). The default setting is Normal. Higher point density gives more detailed images but requires higher PC performance and increases file size.

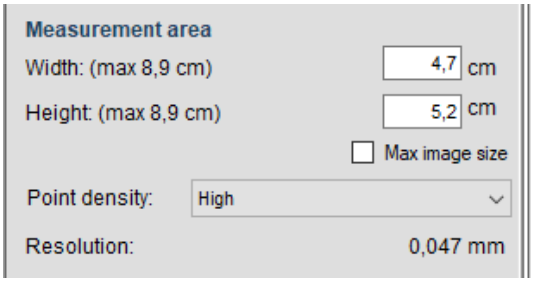



*Figure 6-1 Image setup.*

*NOTE!*

*If a high frame rate is selected, this may impact the maximum size of the image. If the set measurement area exceeds this maximum image size, the size is automatically decreased.*

3. **For PSI with Zoom option only:** Use the zoom control and adjust the positioning of the PeriCam PSI until the desired measurement area is displayed, see Figure 6-2. Focus is normally set automatically (*Auto* check box is selected).

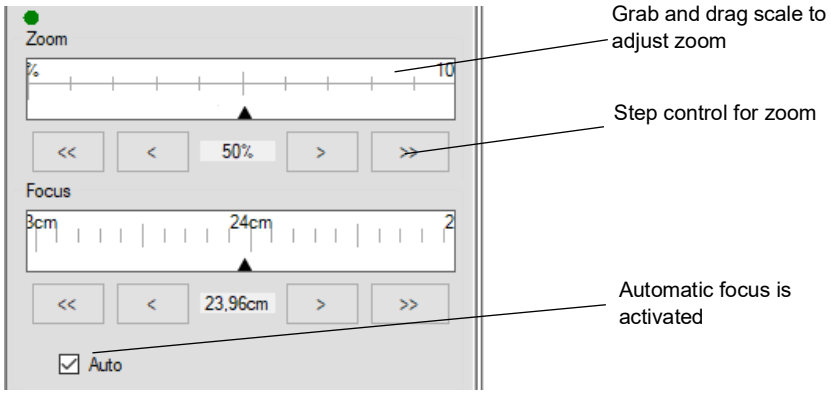



*Figure 6-2 Zoom controls.*

For measurement distances larger than 32.5 cm, the zoom capacity is limited, which is displayed with a yellow area in the zoom control, see Figure 6-3. For distances > 32.5 cm, a good focus is guaranteed only at 0% and 100% zoom. For distances >35 cm, a good focus is guaranteed only at 0% zoom.

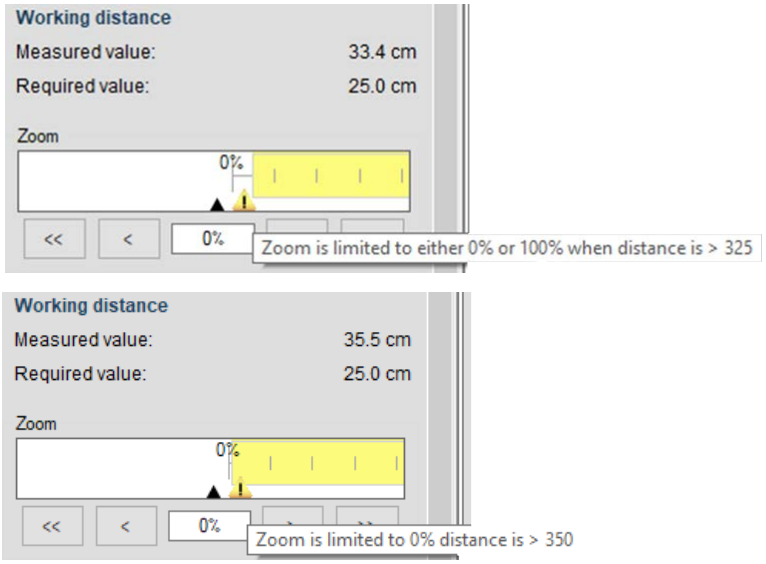



*Figure 6-3 Limited zoom capacity.*

## Setup of Image Capture

1. Under IMAGE CAPTURE SETUP (Figure 6-4), select the number of images per second to record from the *Frame rate* drop-down list.

*NOTE!*

*If averaging is used, the frame rate selected above will not be the effective frame rate. The effective frame rate will be displayed below the averaging factor.*

*The available frame rates are related to the mains frequency and will therefore differ depending on your location in the world. The reason for this is that the measurements are synchronized to the background light for optimal background compensation.*

*The performance of your computer may limit the possible frame rates.*

2. In the *Duration* drop-down list, select one of the following:
   - Until stopped – recording will continue until manually stopped by the user.
   - Number of images – lets the user specify the number of images to record.
   - Time – lets the user specify the duration of the recording in hh:mm:ss.
   - Snapshot – captures an image each time the record button is pressed. It is recommended to use averaging in conjunction with snapshot, see step 3 below.
   - Intervals - Time
   - Intervals - Number of images

   Depending on your choice above, specify number of images or time interval(s) if requested.

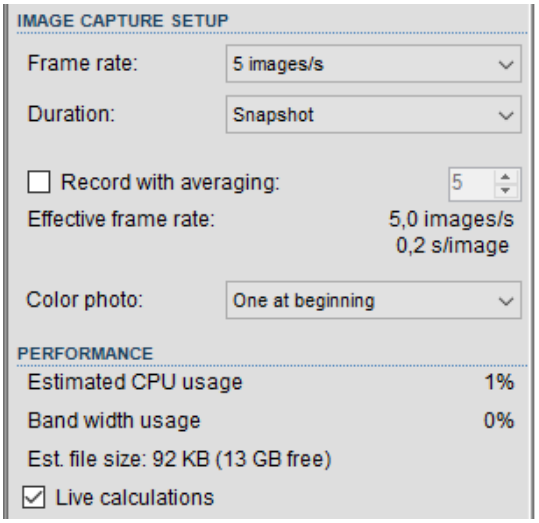



*Figure 6-4 Image capture setup.*

3. To use averaging, select *Record with averaging* and specify a number of images to average over. Note that averaging effects the effective frame rate. For most applications and moderate requirements on measurement speed and noise cancellation, it is recommended to start with a frame rate of 21 images/s and an averaging of 21.

*NOTE!*

*Averaging is recommended unless very fast changes need to be recorded. It cancels out noise, thereby improving the quality of data and the appearance of images. It also severely limits the file size.*

4. Select the capture rate of the color photo.
5. If the estimated CPU usage exceeds 100%, do one of the following:
   - Select a lower frame rate.
   - Decrease the size of the measurement area.
   - Turn off live calculations (no real time graph will be displayed during recording, only real time perfusion images).
   - Select a lower point density.
   - Zoom out (if *Max image size* is **not** selected) (for PSI with Zoom option only)
6. If needed, adjust the intensity filter to remove any background values, see "Adjusting the Intensity Filter" on page 61.

***WARNING!***

⚠

*If the background values are not filtered, background noise may affect the measured mean perfusion value and lead to a faulty input to diagnosis.*

## Change Parameters During a Recording

When pausing an ongoing recording, the IMAGE CAPTURE parameters may be changed. see Figure 6-5.

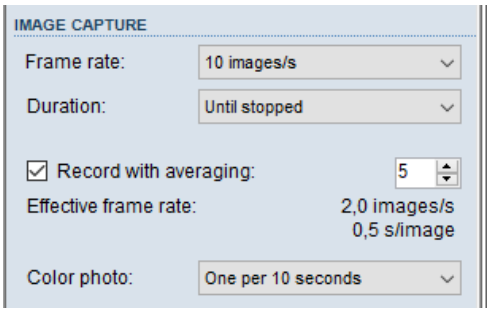



*Figure 6-5 Parameters that can be changed when pausing a recording.*

## Setting of Focus (for PSI with Zoom option only)

**WARNING!**

⚠ *If focus is not set correctly and the image is blurred, measurement results may be faulty.*

Distance measurement is based on measurement in only one point, where the indication laser beams meet. Thus it is important that this point rests on the tissue to be measured, otherwise distance measurement and automatic focus setting may be incorrect. In that case, the manual focus control could be used. To return to automatic setting, select the *Auto* check box. See Figure 6-6

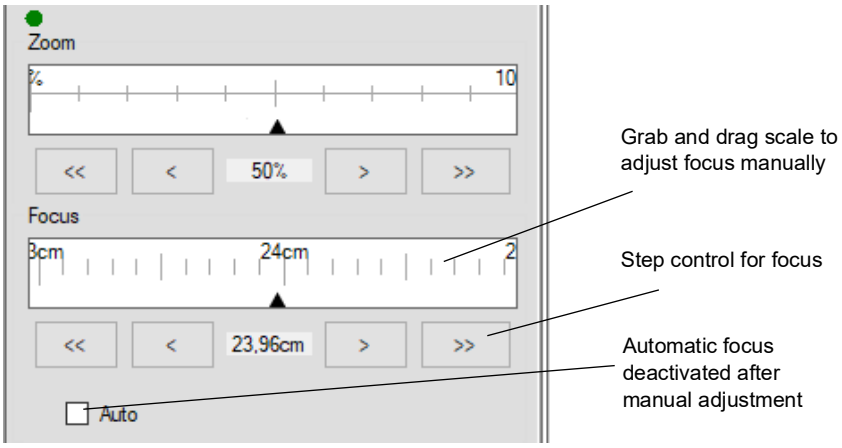



*Figure 6-6 Setting of zoom and focus.*

If averaging is activated, the perfusion image may be an aid in setting the focus correctly.

In some cases, for example, when measuring on a large, even surface, it may be hard to judge whether focus is correct or not. In that case, it may be helpful to put a distinct object within the measurement area and check that it is clearly visible in the intensity image. The object could, for example, be a piece of white paper with black text, or the image in Figure 6-7.

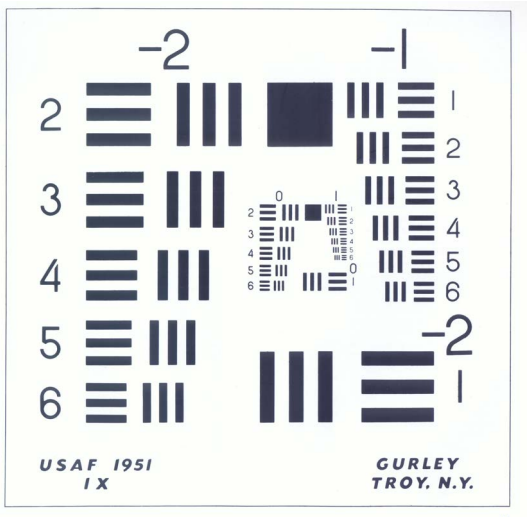



*Figure 6-7 Image for check of focus.*

# 7 Analyzing Data

## Open an Existing Recording

Click *File* | *Open recording…* in PIMSoft to open an existing recording.

The database can be searched using different recording properties. Click *Columns...* to select which properties should be displayed in the search window. Click the column title to sort by a certain property.

The graph and color photo are previewed in the *Open recording* dialog to facilitate searching. Photo tools are available to zoom in, zoom out, fit the preview photo to frame, and to fit measured area to frame.

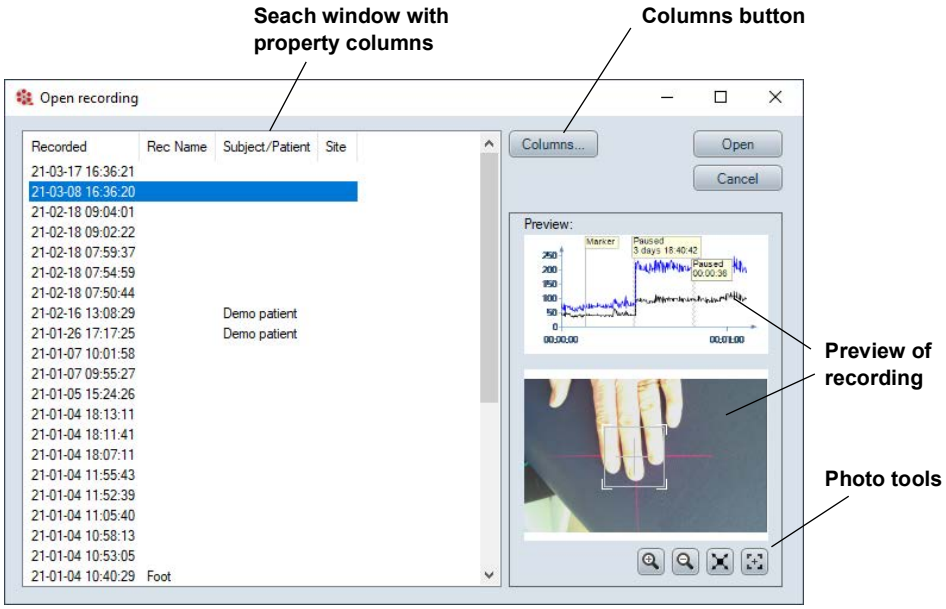



*Figure 7-1 The Open recording dialog.*

## Region of Interest (ROI)

Areas within a perfusion image can be quantified by defining regions of interest (ROI:s). ROI:s can be added at any time (setup, recording, review).

The ROI tools are found in the upper right corner of the PIMSoft window.


*Figure 7-2 The ROI Tools.*

## Selecting an Existing ROI

A ROI can be selected in one of the following ways:

- Select the selection tool , if not already selected. Click on the ROI in one of the images.
- Click on the ROI name in one of the tables.

## Adding a ROI

To add a ROI:

Select one of the ROI shapes:

| Tool | Description |
|---|---|
| | Draws an elliptical or circular ROI. Click the small triangle at the lower left corner of the tool to select either the ellipse or the circle from the menu that appears. |
| | Draws a rectangular or square ROI. Click on the small triangle at the lower left corner of the tool to select either the rectangle or the square from the menu that appears. |
| | Draws a free form ROI. Click repeatedly in the image to place nodal points, double-click to close the shape. |

Then select one of the change options:

| Tool | Description |
|---|---|
| | Application of ROI operation (such as move, resize or delete): |
| | on the entire recording |
| | on this image to the end of the recording |
| | on image x to image y |

*NOTE!*

*The selected apply option also applies to any changes to an existing ROI.*

### Elliptical, circular, rectangular or square ROI

1. Draw the ROI by clicking and holding the mouse button in one of the images, dragging the ROI out to the desired size, and releasing the mouse button (click and double-click for free form ROI:s). You can draw ROI:s on either of the images (perfusion, intensity or photo image). Figure 7-3 shows a rectangular ROI on a perfusion image.

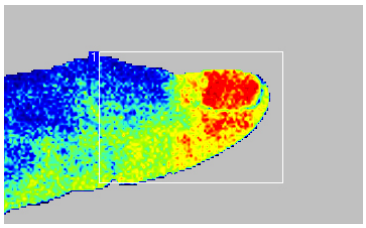


*Figure 7-3 ROI on perfusion image.*

2. If needed, adjust the position of the ROI: select the ROI, then click and hold within its boundaries and move it to the desired location, see Figure 7-4.

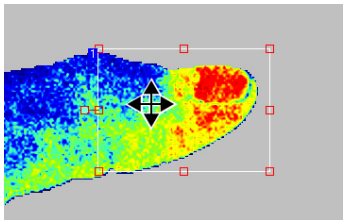


*Figure 7-4 Move a ROI.*

3. If needed, resize the ROI: select the ROI, place the cursor on its boundary until it becomes a double-ended arrow. Click and drag out to the desired size, see Figure 7-5.

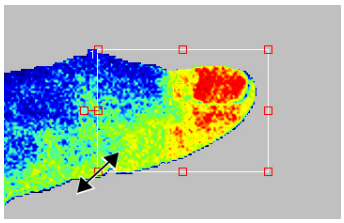


*Figure 7-5 Resize a ROI.*

4. If needed, rotate the ROI: select the ROI, place the cursor on top of the green handle. When the cursor symbol changes to four arrows in a circle, click and hold, then move in the desired direction of rotation, see Figure 7-6.

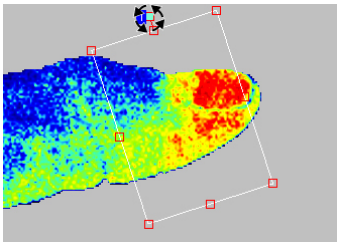


*Figure 7-6 Rotate a ROI.*

## Free Form ROI

Free form ROI:s are very useful for creating irregularly shaped ROI:s. To create a free form ROI:

1. Select the free form shape.
2. Click where you want to start drawing the ROI.
3. Click for each node to be placed.
4. Use Escape to delete the previous node.
5. Double-click to finish the ROI.

In order to edit the nodes of a free form ROI:

1. Select the ROI.
2. Right-click on the ROI and select *Edit nodes*.
3. Place the cursor on top of a node. When the cursor symbol changes to four arrows, click and drag the node to the desired position, see Figure 7-7
4. To exit the edit mode, right-click inside the ROI and select *Exit edit nodes*.

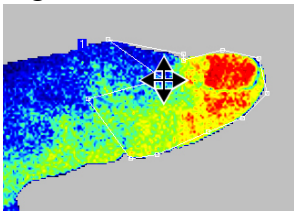


*Figure 7-7 Edit a node of a free form ROI.*

## Handling Several ROI:s

1. To select more than one ROI, click and hold Shift and then click on the ROI:s in one of the images or one of the tables. Alternatively, use the cursor to draw a rectangle that covers at least part of each ROI, see Figure 7-8. You may also right-click in an image and click *Select all*.

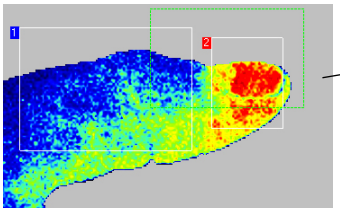



*Figure 7-8 Selecting several ROI:s using a rectangle.*

*NOTE!*

*When more than one ROI is selected, you cannot resize or rotate the ROI:s.*

2. To select a ROI that is placed below another one, first ensure that neither of the overlapping ROI:s are selected, press Ctrl and then click on the lower ROI, see Figure 7-9. Alternatively, select the lower ROI in one of the mean value, percent change or general tables.

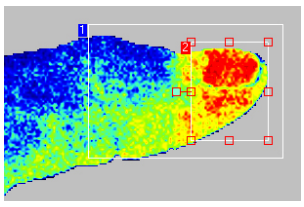


*Figure 7-9 Selecting a ROI placed below another one.*

## Other ROI operations

Available in the ROI tools panel:.

| Tool | Description |
|---|---|
|  | Undo ROI operation. |
|  | Click once to lock ROI:s, click once more to unlock. When locked, ROI:s cannot be edited in any way. |

Available by right-clicking on a ROI in the perfusion and intensity images:.

| Tool | Description |
|---|---|
|  | Cut ROI |
|  | Copy ROI (alternatively, select ROI and use the keyboard shortcut Ctrl + C) |
|  | Paste ROI (alternatively, use the keyboard shortcut Ctrl + V) |
|  | Delete ROI (alternatively, select ROI and press *Delete* on the keyboard) |
|  | Select all ROI:s |
|  | Rename ROI (alternatively, right-click the ROI in a table) |
|  | Flip ROI vertically |
|  | Flip ROI horizontally |

*NOTE!*

*You can paste ROI:s between perfusion images in the same recording, or between different recordings.*

## Selecting a Reference ROI

A reference ROI is used in the percent change tables. To select a reference ROI:

1. Right-click on the ROI you wish to use as reference in any of the tables.
2. Select *Set "ROI name" as reference*.

## Line Of Interest (LOI)

To quantify the variation of perfusion along the length of a tissue, a Line Of Interest (LOI) may be defined.

To define a LOI:

1. Click the LOI icon . The dialog in Figure 7-10 will open.

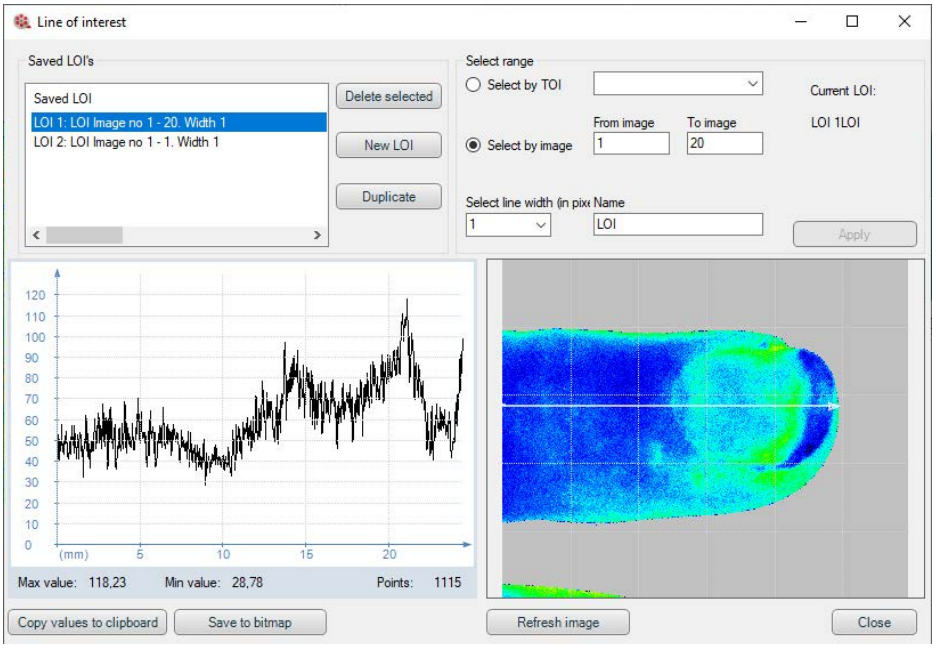



*Figure 7-10 Line of Interest dialog.*

2. The following actions are possible:
   - Add new LOI
   - Move the endpoints of an existing LOI
   - Delete selected LOI
   - Duplicate selected LOI
   - Select range by TOI
   - Select range by image number
   - Select line width
   - Name the LOI
   - Copy LOI values to clipboard
   - Save graph and image to bitmap image

## Time Period of Interest (TOI)

Time periods of interest (TOI:s) allow you to average the perfusion in a ROI over a period of time/number of images. A TOI can be defined during recording or during review.

### Adding a TOI

To add a TOI:

1. Go to the Graph or Split view.
2. Select the TOI tool .
3. Click and hold on the graph at the position where you want the TOI to begin and drag the cursor to the desired end position, see Figure 7-11. Then release the mouse button.

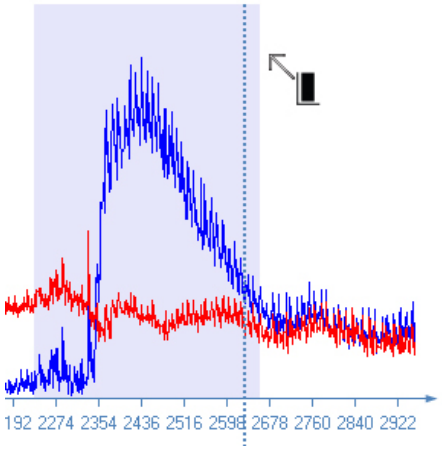



*Figure 7-11 Defining a new TOI.*

4. If needed, adjust the position and size of the TOI. To do this, select the TOI by clicking on it. Grab either of the handles that appear at the edges of the TOI, and move it to the desired location.

### Deleting a TOI

To delete a TOI:

1. Click on the TOI to select it.
2. Press Delete on the keyboard, or right-click on the TOI and select *Delete*.

### Renaming a TOI

To rename a TOI:

1. Right-click on the TOI you wish to rename, either in one of the data tables, or in the graph.
2. Select *Rename TOI*.
3. Enter a name in the Rename dialog and click *OK*.

### Selecting a Reference TOI

The reference TOI is used in the percent change tables. To select a reference TOI:

1. Right-click on the TOI, either in one of the data tables, or in the graph.
2. Select *Set "TOI name" as reference*.

## Adjusting the Intensity Filter

The intensity filter is used to discriminate between tissue and background in a recording. It is especially important to adjust the intensity filter when a region of interest includes parts of the background, as in the example below.

In the left image of Figure 7-12, background noise will contribute to the perfusion value in the region of interest, causing an incorrect mean value. In the image on the right, the intensity threshold has been appropriately adjusted and the mean value will be correct.

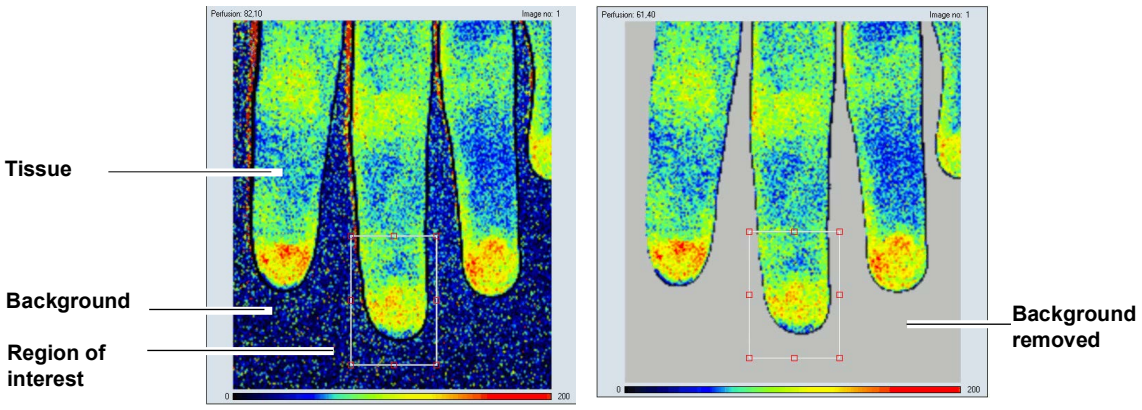



*Figure 7-12 Before and after adjustment of Intensity filter.*

To adjust the intensity filter:

1. Select *Analysis* | *Filters and color scales*….from the menu. The *Filters* dialog is displayed.
2. Select the *Intensity filter* checkbox.
3. Make the appropriate settings. Under normal circumstances, this is achieved by adjusting the lower limit until the background areas are displayed as gray.

*NOTE!*

*Use a light-absorbing background material when recording, for example the black measuring pad supplied by Perimed, so that the background can be eliminated using an appropriate intensity threshold setting.*

## Perfusion Overlay

It is possible to overlay the perfusion image, or just the ROI perfusion, on the color photo and the intensity image, see Figure 7-13.

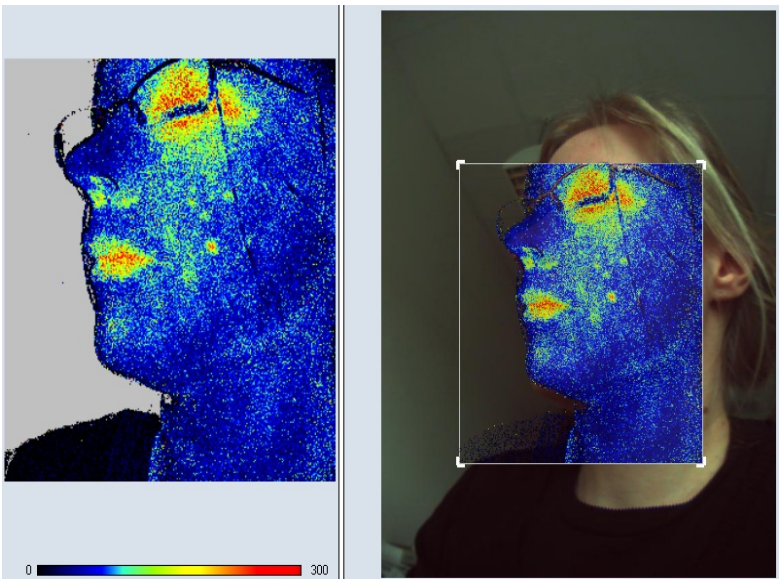



*Figure 7-13 Perfusion overlay example.*

To use overlay:

1. Select *Analysis* | *Overlay*….
2. In the *Overlay* dialog, Figure 7-14, select the option "Show perfusion values on intensity and color photo".
3. Select whether to overlay the entire perfusion image, or only the perfusion in the ROI:s.
4. Set the transparency of the overlayed perfusion by dragging the *Transparency* slider to the preferred location.
5. Click *OK* to confirm and exit the *Overlay* dialog.

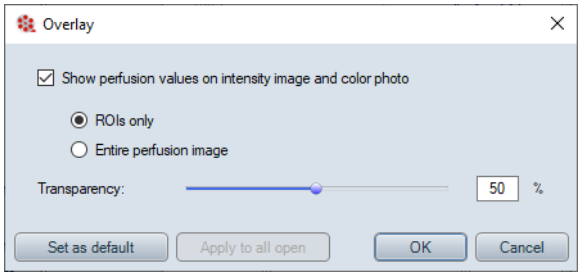



*Figure 7-14 Overlay dialog.*

*NOTE!*

*If you have more than one open recording and wish to use the overlay feature on all of them, click "Apply to all open".*

## Tables and Calculations

The tables in PIMSoft can be used to display numerical measured and calculated values.

*NOTE!*

*To avoid delays when adjusting ROI:s or TOI:s, calculations can be temporarily paused in analysis mode.* ☑ Pause calculations

### Mean Value Table

Shows the mean perfusion values in each ROI and TOI.

### Percent Change Tables

| Table | Displays |
|---|---|
| Percent change per ROI | The percentage difference between each ROI and the reference ROI. The table is visible when there is one or more ROI:s in a recording. One ROI must be selected as the reference ROI. |
| Percent change per TOI | The percentage change between each TOI and the reference TOI. The table is visible when there is one or more TOI:s in a recording. One TOI must be selected as the reference TOI. |

If the percent change tables do not appear, click the *Settings* button below the general table in the Graph area and select the option "Show % change tables".

### General Table

The general table can be configured to display all, or a subset of, the parameters listed below under "General Statistics" and "Flare Statistics". By default, only the mean value and area are displayed. See "Calculation Settings" on page 65 on how to configure the general table.

### General Statistics

The following parameters are calculated and can be displayed in the general table.

| Parameter | Description |
|---|---|
| Mean | The mean value of the perfusion in a ROI during a TOI or the entire recording. |
| Area $mm^2$ | The area of a ROI in $mm^2$. |
| StdDev | The mean of the standard deviation in a ROI during a TOI or the entire recording. |
| Points | The number of measurement points in a ROI. |
| Int. Mean | The mean value of the intensity in a ROI during a TOI or the entire recording. |
| Time | Time when a TOI starts, relative to the start of the recording. |
| Duration | Duration of a TOI. |
| AUC PU*s | Area under curve, expressed as perfusion units * seconds. |
| Avg. img/s | The number of images in a recording divided by the recording duration. Note that this parameter is not the same as the frame rate, which is the image capture rate used by the hardware during recording. |

## Flare Statistics

Certain stimuli (e.g. induced pain or application of a drug) may cause an increasing perfusion, visible as a flare, over a certain area as a result of an axon reflex.

Flare statistics in PIMSoft may be used to evaluate the reaction by estimating the total area and the mean perfusion value, during a specified time period, for all measurement points with a perfusion above a certain threshold. There are two defined thresholds, which are calculated as the mean value for a reference area (e.g. a ROI) before the stimulus was applied (i.e. in the reference TOI/image), plus one or two standard deviations respectively.

The following flare statistics parameters can be calculated and shown in the general table:

| Parameter | Description |
|---|---|
| Flare-1 Threshold | A threshold calculated as:<br>**Mean + 1 StdDev in reference TOI/image** |
| Flare-1 Area $mm^2$ | The total area of measurement points with a perfusion value exceeding the Flare-1 Threshold. |
| Flare-1 Mean | The mean perfusion value of measurement points exceeding the Flare-1 Threshold. |
| Flare-2 Threshold | A threshold calculated as:<br>**Mean + 2 StdDev in reference TOI/image** |
| Flare-2 Area $mm^2$ | The total area of measurement points with a perfusion value exceeding the Flare-2 Threshold. |
| Flare-2 Mean | The mean perfusion value of measurement points exceeding the Flare-2 Threshold. |

*NOTE!*

*The flare parameters are not updated automatically when editing a recording. Use the "Update flare" button located directly below the general table to update these parameters. Note that the button is only visible when flare statistics are enabled.*

## Calculation Settings

To set which parameters should be displayed in the general table:

1. Click on the *Graph* or *Split* tab.
2. Click the *Settings* button below the general table in the Graph area. The *Calculation settings* dialog is displayed, see Figure 7-15.
3. Select a parameter in the list to include it in the calculations. When a parameter is selected, use the up and down arrow buttons to change the order in which the parameters should appear.
4. Select the preferred options, described in the table below.

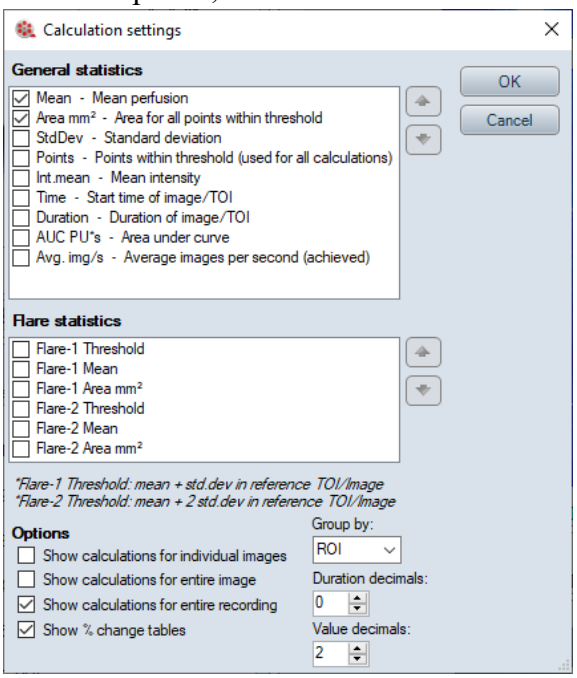



*Figure 7-15 Calculation settings..*

| Option | Description |
|---|---|
| Show calculations for individual images | Displays parameters for individual images, not just for TOI:s. Maximum number of images displayed is10 images during recording, 150 images during review; |
| Show calculations for entire image | Displays parameters for the entire image, not just for ROI:s. |
| Show calculations for entire recording | Displays parameters for the entire recording, not just for TOI:s. |
| Show % change tables | Shows/hides the % change tables. |
| Group by | Sorts the table by either ROI:s or TOI:s. |
| Duration decimals | Number of decimals for any results specified as time. |
| Value decimals | Number of decimals for any other results. |

*NOTE!*

*Right-click on a table to copy its contents to the clipboard*

# 8 Reports

A report is created for each recording. Select the *Report* button to view the report.


*Figure 8-1 Report view selected.*

The report view can be adjusted using the zoom function at the bottom right of the report window.

Figure 8-2 shows an example of a report.

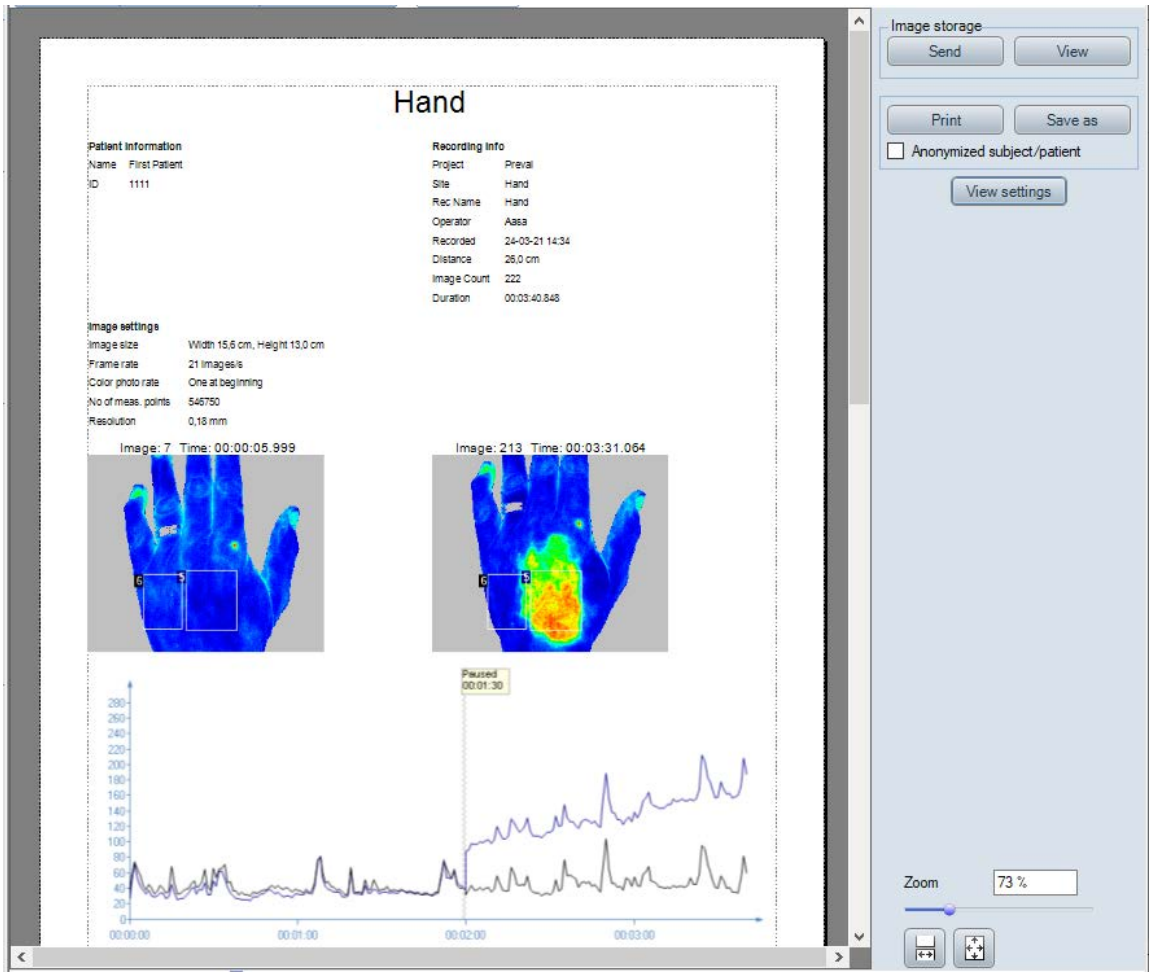



*Figure 8-2 Report example.*

## Sharing the Report

The following functions are available for sharing the report.

| Function | Description |
|---|---|
| Send | Send the report to an image storage. Only available if DICOM connection is used. |
| View | View DICOM parameters sent with the report. Only available if DICOM connection is used. |
| Print | Printout the report. |
| Save as | Save the report in a local folder. Select PDF, XML or excel format. |
| **Anonymized subject/ patient** | Select to save the report without patient information. |

## Editing the Report

To change settings for the report, click the *View settings* button. The page margins of the report can be adjusted using the *Margins* tool.

A report can contain the following items:

- Title
- Patient information (in case of enhanced handling of patient information)
- Recording information
- Image settings
- Images
- Perfusion graphs
- ROI reference key
- ROI calculation tables
- Mean perfusion table
- Percent change tables
- Event marker texts
- Free text
- Line of interest

To include an item, select it from the list of contents, see the example in Figure 8-3.

Use the up and down arrows to change the order in which the items appear.

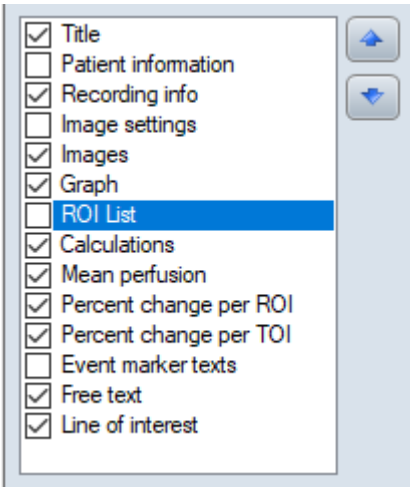



*Figure 8-3 Report contents.*

To select which images to include in the report, use the *Image selection* tool, see Figure 8-4. The selected images may also be saved in a local folder by using the *Save images...* button.

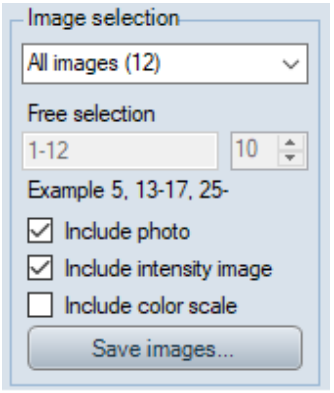



*Figure 8-4 Image selection tool.*

# 9 Export to External Formats

Images from recordings can be exported, both as separate images and as videos. They can then be viewed using standard video and image tools and be included in, for example, presentations and reports.

Numerical data can be exported to the clipboard for export, for example, to an excel sheet, or as a binary file.

## Exporting Video Files (AVI)

1. Open the recording that should be exported as a movie file.
2. Select *Export* | *Export recording to .avi…*. A new dialog is displayed.
3. Under *Settings*, mark the items that should be included in the movie file. (The perfusion image is always included.) The graphical preview shows what a still frame in the video would look like.
4. Note the information under *Settings from current view*. The settings listed here are inherited from the current view in PIMSoft. For example, if the graph is currently zoomed in on images 1-10, the exported video file will only contain 10 images, even if there are more images in the recording. Similarly, the play-back speed, and the smoothing settings are inherited.
5. Click the browse button, see Figure 9-1. Select a location and a name for the exported file and click *Save*.
6. Select whether or not the folder to which the exported file is saved should be opened after export.
7. Click *Export*.

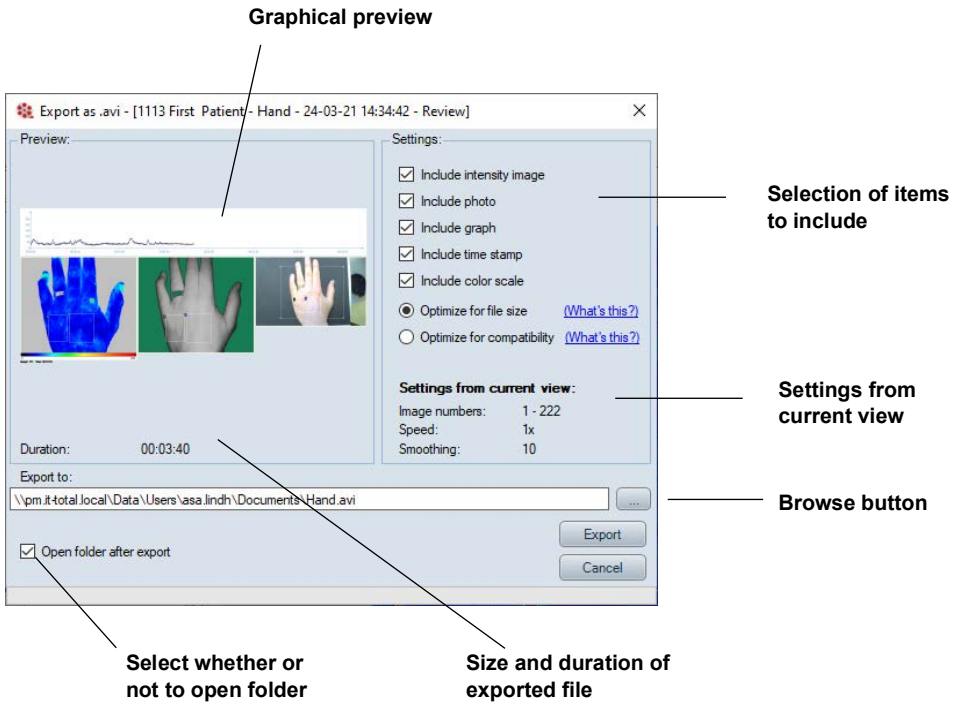



*Figure 9-1 Export as AVI dialog.*

# Export of Images

## Export to PNG file

To export a perfusion image, intensity image, or color photo to a png file, right click on the image and select *Export image*. Then select size (1x, 2x, 4x, or 8x the original size).

## Copy to Clipboard

To export individual images from an open recording, the following options are available under the *Data export* menu..

| | |
|---|---|
| **Copy image to clipboard** | Copies the currently displayed perfusion image/intensity image/color photo to the clipboard. |
| **Copy graph to clipboard** | Copies the graph to the clipboard as an image. |
| **Copy review panel info** | Copies the currently displayed review panel information to the clipboard. |

Most copy options are also available on the right-click menu of each object.

*NOTE!*

*Copying large, high resolution images to clipboard may take a considerable time.*

## Full screen image

To get an image with higher resolution when copying to clipboard, an image or photo can be opened with the same resolution as the computer screen.

To open a full screen image, select *View | Full screen image*. Select perfusion image, intensity image or photo. Select *Copy image/photo to clipboard* in the right-click menu.

The size and resolution of the resulting image depends on the resolution of the computer screen.

Export to PNG file can also be done from the full screen image.

## Export of Numerical Data

### Copy image data to clipboard

To export numerical data from an open recording to the clipboard, select *Data export* | *Copy image data to clipboard*. Select one of the following.

| | |
|---|---|
| **Perfusion data** | Copies the perfusion value of each measurement point in the currently displayed perfusion image. |
| **Intensity data** | Copies the intensity value of each measurement point in the currently displayed intensity image. |
| **ROI perfusion data** | Copies the perfusion value of each measurement point inside the ROIs of the currently displayed perfusion image. |
| **ROI intensity data** | Copies the intensity value of each measurement point inside the ROIs of the currently displayed intensity image. |

*NOTE!*

*Copied image data can be pasted into an external program (e.g. MS Excel). The data is organized in rows and columns according to the format of the original image*

### Copy graph data to clipboard

Copies all data points in the graph to the clipboard.

### Export binary recording

To export a binary file containing the raw data values for all measurement points and all images in a recording, select *Export/Export binary recording*. Contact Perimed for a description of the file format.

# 10 Reduce File Size

Recording high resolution images at fast capture rates can make PeriCam PSI files very large, and therefore slow to process. The Reduce file size utility offers different options to decrease file size, such as downsampling or deleting undesired parts.

*NOTE!*

*Individual images or photos can be deleted by right-clicking on the image and selecting Delete, or go to the Edit menu and select Delete current image/ photo.*

## Downsample a Recording

1. Open the recording you wish to downsample.
2. Select *Edit* | *Reduce file size*....The *Reduce file size* dialog is displayed.
3. Use the slide bar to select how much the recording should be downsampled. How the recording is affected is displayed above the slide bar and in the columns *Current* and *New* to the right.
4. If you wish to remove only the color photos, select "Downsample color photos only". The slide bar then affects only the color photos.
5. Select "Create averaged images" if you wish to use averaging. The slide bar is replaced by a text box where a reduction factor can be set, using the up and down arrows.

*NOTE!*

*This has the same effect as using "Record with averaging".*

6. Enter a file name in the text box, or select "Overwrite existing file". Note that this cannot be undone.
7. When satisfied, click OK.

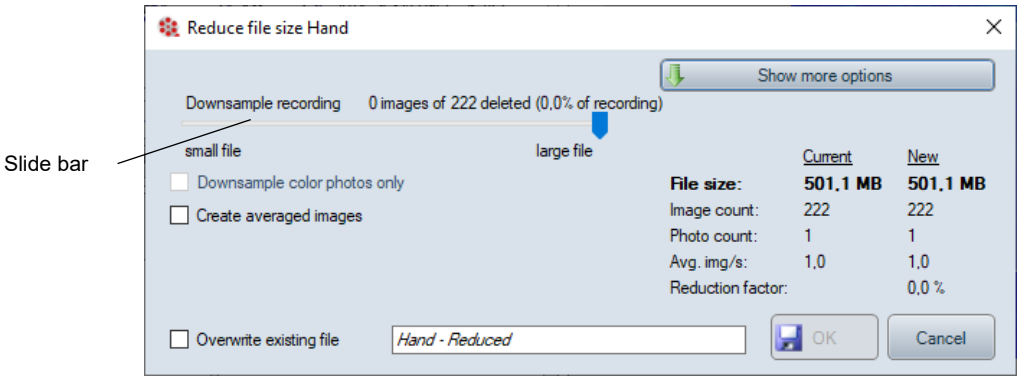



*Figure 10-1 The Reduce file size dialog.*

*NOTE!*

*Downsampling deletes data permanently and cannot be undone.*

## Downsample Parts of a Recording

1. Open the recording you wish to downsample.
2. Select *Edit* | *Reduce file size*….The *Reduce file size* dialog is displayed.
3. Click the button *Show more options* to display more options.
4. Select a *Selection method*.

   The default option, *Select in graph*, allows you to mark a part of the recording for downsampling in the graphical preview.

   The option *Select everything but TOIs* selects the whole recording except TOIs.
5. If the option *Select in graph* was chosen, click and drag in the graph to mark the time period to be downsampled.
   Fine adjust the selected image interval if needed, by using the up and down arrows next to the *Selected images* text boxes.
6. Select *Downsample selection*.

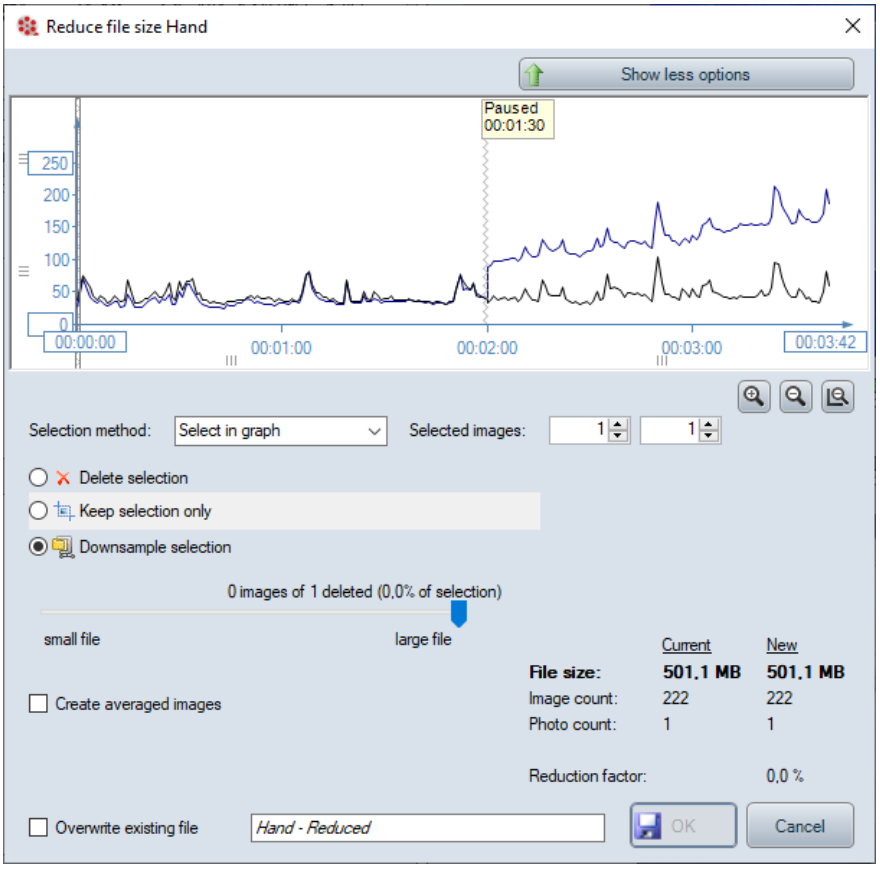



*Figure 10-2 The Reduce file size dialog - show more options.*

7. Use the slide bar to select how much the recording should be downsampled. How the recording is affected is displayed above the slide bar and in the columns *Current* and *New* to the right.

*NOTE!*

*The reduction factor shown here applies to the whole recording, while the reduction factor shown within brackets above the slide bar applies to the selection only.*

8. Select "Create averaged images" if you wish to use averaging. The slide bar is replaced by a text box where a reduction factor can be set, using the up and down arrows.

*NOTE!*

*This has the same effect as using "Record with averaging".*

9. Enter a file name in the text box, or select "Overwrite existing file". Note that this cannot be undone.
10. When satisfied, click *OK*.

## Delete Parts of a Recording

1. Open the recording you wish to edit.
2. Choose *Edit* | *Reduce file size*....The *Reduce file size* dialog is displayed.
3. Click the button *Show more options* to display more options.
4. Select a *Selection method*.

   The default option, *Select in graph*, allows you to mark a part of the recording for deletion in the graphical preview.

   The option *Select everything but TOIs* selects the whole recording except TOIs.
5. If the option *Select in graph* was chosen, click and drag in the graph to mark the time period to be deleted.
   Fine adjust the selected image interval if needed, by using the up and down arrows next to the *Selected images* text boxes.
6. To delete the selected part/parts, select *Delete selection*. To delete everything but the selected part/parts, choose *Keep selection only*. The columns *Current* and *New* show how the recording is affected.
7. When satisfied, click *OK*.

# 11 Maintenance

*NOTE!*

*Do not perform any maintenance while the instrument is in use.*

## Cleaning

In case cleaning and disinfection is required for the intended application, ensure you are using a medical keyboard and mouse. If using a non-medical keyboard and mouse, they may be cleaned per the instructions below, but it is not recommended to do any disinfection, as it might damage the electronics.

It is advisable to clean parts of the system between patients to reduce the risk of cross-contamination, especially if the operator has been in contact with broken or infected areas of skin. Cleaning must be performed without touching optical surfaces. Cleaning and disinfection between patients is recommended for parts that are touched by the operator during a measurement:

- Instrument head including handle
- Arm (Adjustable arm including locking levers or Leica swing-arm including locking levers)
- Medical keyboard & mouse

Weekly cleaning and disinfection is recommended for parts that are not touched, or used less often:

- Accessible parts of the cart (if used)
- Protective Cap
- Calibration Box (clean before and after usage)
- Panel PC

If using a desktop or laptop computer, use a damp cloth and mild detergent to gently remove visible dirt and dust.

*NOTE!*

*When the instrument is not in use, it is recommended to use the protective cap to protect the instrument from dirt on the lens surface (e.g. finger prints) and dust.*

***Caution!***

*Take care to prevent the ingression of fluids while cleaning. Do not soak the cloth in cleaning solution.*

*Do not touch optical surfaces.*

### Cleaning Procedure

Exterior parts of the instrument, the adjustable arm for PeriCam PSI NR or the swingarm stand for PeriCam PSI HR, locking levers, medical keyboard and mouse, the power supply, accessible parts of the cart (if used), protective cap, calibration box, and panel PC may be cleaned:

1. **Cleaning:** Wipe down the parts that are in operator contact with a lint-free disposable cloth/paper wipe and mild, diluted detergent until no visible dirt remains.
2. **Disinfection:** Wipe down the parts that are in operator contact with a lint-free disposable cloth/paper wipe soaked in one of the following disinfectants:
   - Isopropanol (70%), for 1 minute, or for 5 minutes in case of suspected infection
   - Hydrogen peroxide based agent (e.g. Oxivir Excel®) for 1 minute in case of suspected infection

***Caution!***

*Disconnect the cart from supply mains before cleaning and disinfection!*

*Be careful not to let any moisture or wetness penetrate the isolation transformer. Use only slightly damp cloths on the housing surface.*

## Ball Joint

The ball joint on the adjustable arm for the PeriCam PSI NR may, if needed, be cleaned with a mild detergent and a soft cloth. Remove any dust or other contaminations from all locking threads and sliding segments.

The joint does not need regular lubrication, but if required, use standard lubricant oils or grease.

## Optical Parts

If the optical components become dusty or contaminated, use the provided Optical Cleaning Kit, Figure 11-1, to clean the contaminated surface. The Optical Cleaning Kit contains one antistatic brush and one microfiber cleaning cloth. Use the antistatic brush to remove dust, particles and other debris from the contaminated surface. To remove fingerprints or similar, breathe gently on the surface and wipe clean with the microfiber cloth.

***Caution!***

*Do not use acetone or benzine on optical surfaces, as this may damage the plastics.*

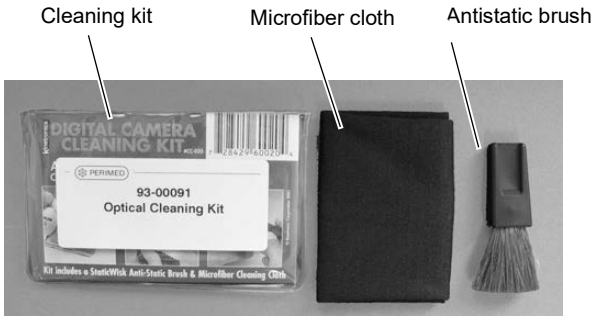



*Figure 11-1 Optical cleaning kit.*

Keep the antistatic brush and microfiber cleaning cloth in the resealable plastic pouch when not in use. The antistatic brush may be washed in a mild shampoo and allowed to air-dry. The microfiber cloth may be washed with a gentle soap or detergent.

## Isolation Transformer for Table Mount

Clean the power isolation unit surface with a soft, slightly dampened, lint-free cloth. Do not use any cleaning agent as they may have a corrosive effect. Use a soft lint-free cloth to dust your power isolation unit.

Do not expose the power isolation unit to humidity, rain, sand or excessive heat (caused by heating equipment or direct sunlight).

## Verification of the PeriCam PSI

It is recommended to perform verification monthly to ensure the accuracy and stability of your PeriCam PSI.

The verification allows for measurement values slightly outside the specified accuracy, as ideal environmental conditions cannot be guaranteed.

When starting up the PeriCam PSI, you will be prompted to perform the verification procedure 30 days after the latest verification.

***WARNING!***

⚠ *The instrument must be stable during verification, as any movement or vibrations will cause erroneous measurement values.*

### The Calibration Box

A calibration box is used for verification and calibration of the PeriCam PSI. The calibration box has a detachable lid, with two perfusion reference areas, see Figure 11-2.

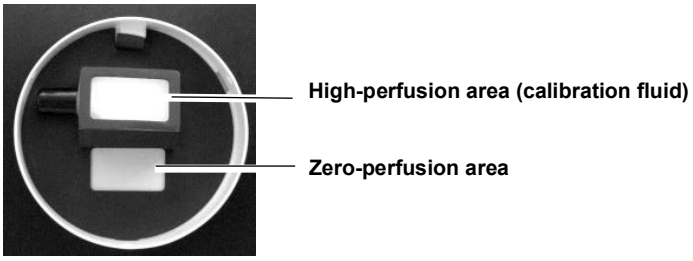



*Figure 11-2 Calibration box lid.*

*NOTE!*

*Do not allow the calibration fluid (Motility Standard) to freeze.*

*Store the calibration box at room temperature.*

*The calibration box lid should be replaced every two years, as the calibration fluid has a limited life span. Check the expiry date.*

### Routine Verification

To start verification:

1. Power the instrument on at least 5 minutes before verification.
2. Start PIMSoft.
3. Click *Maintance* | *Verification* | *Verify instrument*.

4. Prepare for verification by following the instructions in the wizard, see Figure 11-3. Then click *Next*.

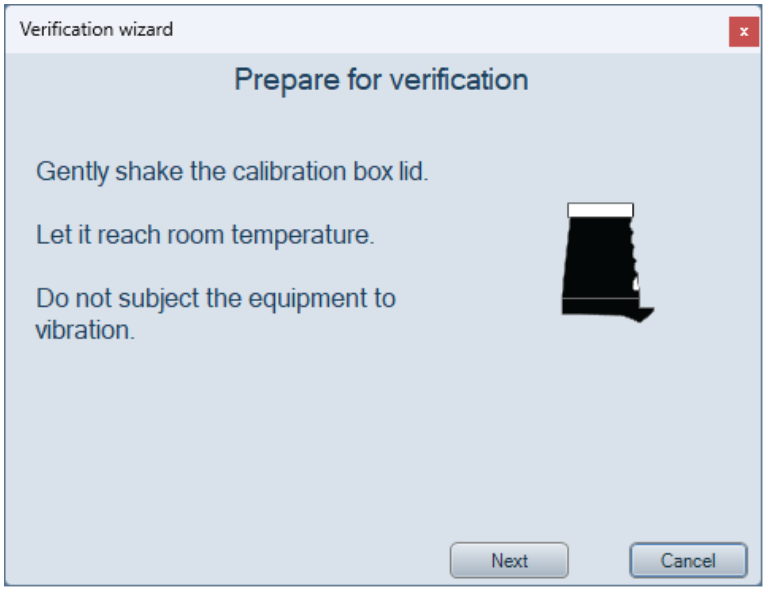



*Figure 11-3 Prepare for verification.*

5. Support the imager head with one hand when unlocking the joint, see Figure 11-4.

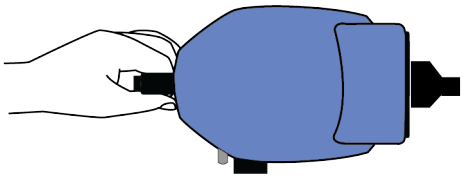


*Figure 11-4 Support head.*

6. Turn the head with the handle up, see Figure 11-5.

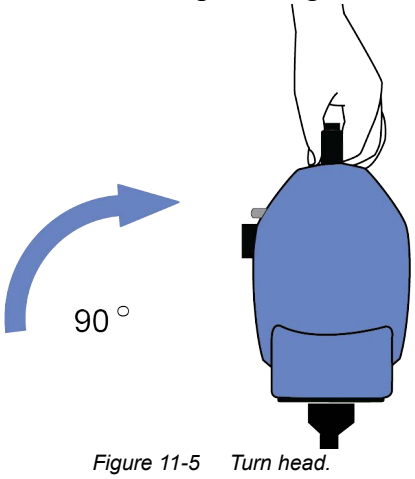



*Figure 11-5 Turn head.*

7. Attach the calibration box using the integrated magnets, see Figure 11-6. Then click *Next*.

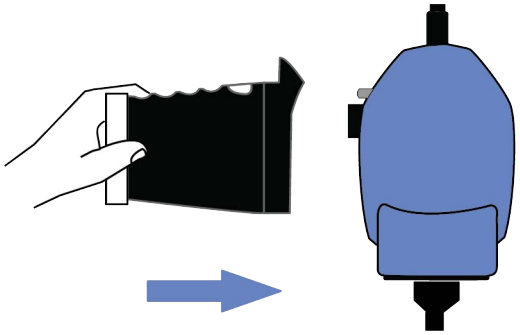


*Figure 11-6 Attach calibration box.*

*NOTE!*

*The head and the calibration box must be in this position to avoid air bubbles in the calibration fluid in the calibration box lid, which may cause faulty verification results.*

8. Enter the room temperature, select °C or °F and click *Next*, Figure 11-7.

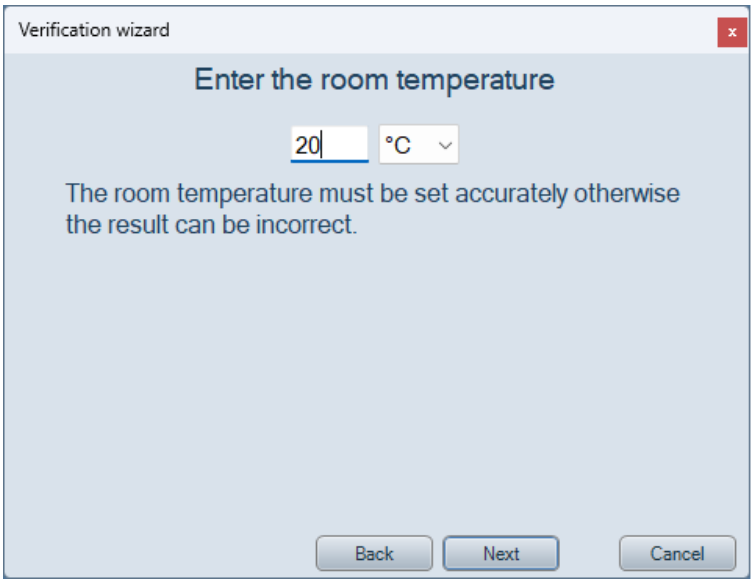



*Figure 11-7 Enter room temperature.*

*NOTE!*

*Measure the room temperature as accurately as possible. The temperature specified by the user is used by the verification algorithm to calculate perfusion. A room temperature specified incorrectly by one degree Celsius, will give an error of 4.2 PU in the measured perfusion value (valid in the temperature range of 24 ±5°C).*

9. Wait while the wizard completes the verification procedure.

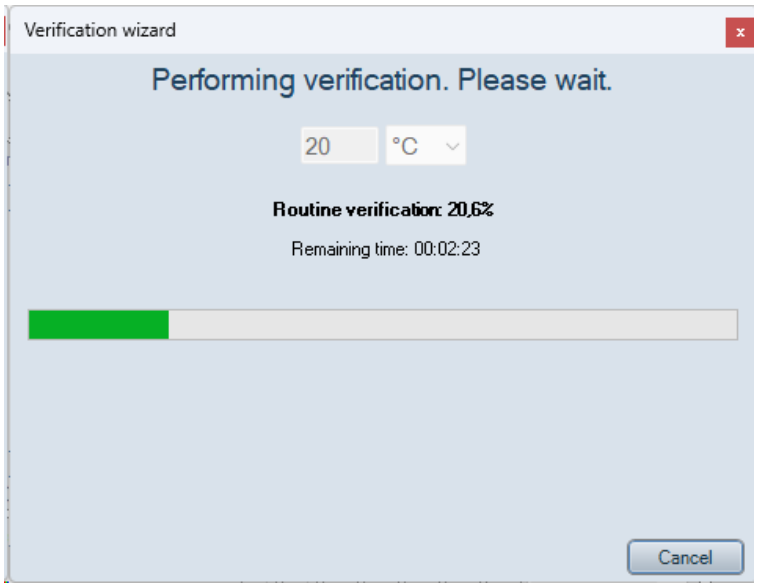



*Figure 11-8 Performing verification.*

10. If the verification is successful, close the wizard by clicking *Finish*. A verification report is automatically stored and is accessible through a link in the dialog (see Figure 11-9).

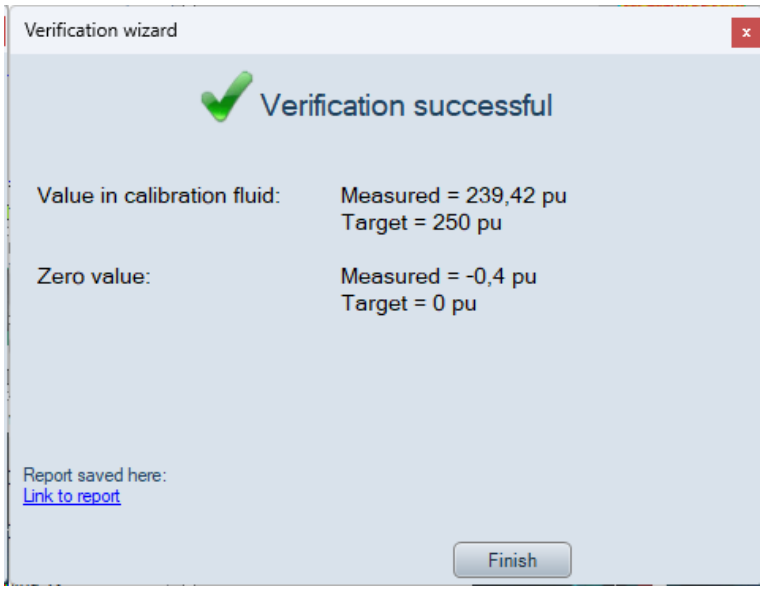



*Figure 11-9 Successful verification.*

## Failed Verification

If verification fails, the wizard will prompt you to make a second attempt. A list of items to check before restart will be presented, see Figure 11-10.

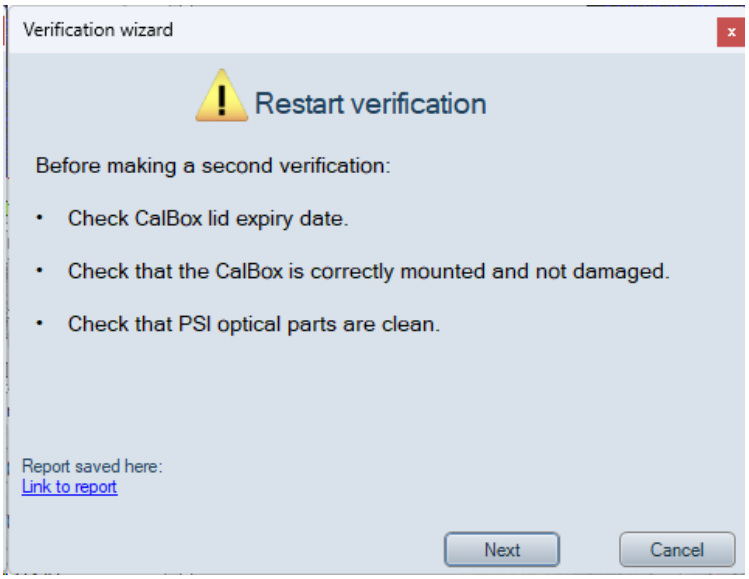



*Figure 11-10*

If these issues can be excluded as the reason for the failed verification, and verification is repeated with the same result, please contact your Perimed representative for further assistance.

*NOTE!*

*If there are frequent or intermittent occurrences of failed verification, contact your Perimed representative as this could indicate a faulty instrument.*

# 12 Troubleshooting

## General

| Problem | Possible cause | Action |
|---|---|---|
| The images are only displayed in dark blue color. | PeriCam PSI set to Manual perfusion scale with a high upper perfusion limit. Measurements performed on a tissue with low or no perfusion. All pixels in the image may then appear dark blue indicating that values recorded are low relative to upper perfusion limit. | Adjust (decrease) the upper level of the Manual perfusion scale, or set perfusion scale to Automatic. The automatic perfusion scale will scale between the lowest and highest measurement values. |
| Computer stops responding in the middle of a measurement. | May be due to a screen saver. | Turn off the screen saver function in Windows or extend the time interval for activation of the screen saver. |
| | A cable has come loose during measurement. | Make sure all cables are firmly connected. |
| | Other active programs are using CPU power. | Close all other programs when measuring with the PeriCam PSI. |
| | Lost connection with the communication device in the imager head. | Unplug the USB cable between the PSI and the PC, and then reconnect it. |
| PIMSoft cannot make contact with the PSI. | USB cable disconnected. | Make sure the USB cable is firmly connected. |
| | The PSI is turned off. | Check that the power switch on the back of the PSI head is set to On and the green LED on the PSI head is illuminated and not flashing. |
| No laser light output from the imager head. | The PSI is turned off. | Check that the power switch on the back of the PSI head is set to On and the green LED on the PSI head is illuminated and not flashing. |
| | The power supply isn't connected properly. | Check that the cable from the imager head is properly connected to the power supply |
| No measurement image. | Lens cap still on. | Remove the lens cap. |

| Problem | Possible cause | Action |
|---|---|---|
| Perfusion images have only gray background color or there is a loss of measurement sites in the image. | The lower Intensity Filter threshold is set too high. | Reduce the lower Intensity Filter threshold value and repeat the measurement.<br>If the problem persists, contact Perimed regarding service. |
| | The distance between the measured object and the imager head is too great. | Reduce the distance between the object and the imager head or reduce the lower Intensity Filter threshold.<br>If the problem persists, contact Perimed regarding service. |
| Negative perfusion values. | Unnaturally high contrast in the image, for example, a mixture of tissue and white surface such as a piece of paper or fabric. | Make sure the different surfaces are not included in the same ROI. |
| Red spots appear on the image. | Back scattered Light Intensity is too high (Overload). | Increase the measuring distance or/and reduce the ambient light.<br>If the problem persists, contact Perimed. |
| Measurement values recorded from background reference pad. | The lower Intensity Filter threshold is set too low. | Adjust the Intensity Filter thresholds to give a better definition of the borderline between object and background. |
| The output signal seems too high or low. | The PeriCam PSI might be out of calibration. | Perform verification according to "Routine Verification" on page 78. If the verification fails, take further actions according to "Failed Verification" on page 82. |

## PIMSoft Error Messages

When an unexpected condition occurs, the PIMSoft software will display an informative error message, see example in Figure 12-1. If the information in the messages does not help you solve your problem, please contact a Perimed representative.

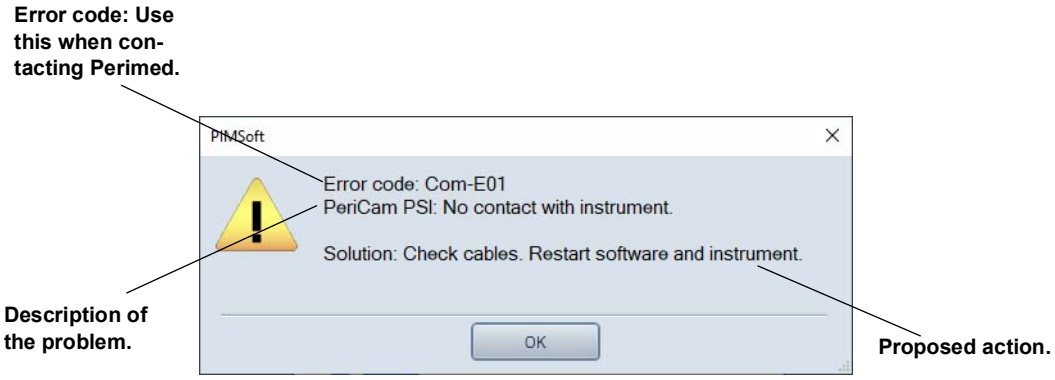



*Figure 12-1 Example of error message.*

# 13 Technical Specifications

## Expected Lifetime

The expected lifetime is the time period during which the PeriCam PSI can be expected to remain suitable for its intended use. After this lifetime Perimed AB will not guarantee spare part availability, and basic safety and essential performance.

It is recommended to replace the equipment after the expected lifetime has expired.

Expected lifetime under normal operation is 10 years for the PeriCam PSI.

Perimed's softwares are maintained for the current and the previous minor release; but it will always be maintained for a minimum of two years or for a maximum of five years. The maintenance includes safety related and some non-safety related bug fixing, and will be available as a patch release.

## General

| | |
|---|---|
| **Dimensions, PeriCam PSI head:** | Length: 22 cm (26 cm including handle)<br>Height: 15 cm<br>Width: 21 cm |
| **Weight:** | |
| PeriCam PSI head | 2.0 kg |
| Adjustable table arm and stand | 9.1 kg |
| Swing-arm stand | 10 kg |
| Isolation station (for table mount) | 6.2 kg |
| PeriCam PSI on Vexio cart | With fixed height cart: 75 kg<br>With height adjustable cart: 80kg |

## Classifications

| | |
|---|---|
| **Type of protection against electric shock:** | With isolation transformer/station: Class I Equipment<br>Without isolation transformer/station: Class II Equipment |
| **Degree of protection against electric shock:** | Type B Equipment<br>The instrument has no applied parts. |
| **Protection against harmful ingress of water or particulate matter** | IP20 |
| **Suitability for use in an oxygen rich environment** | The PeriCam PSI is not intended for use in an oxygen-enriched environment. |
| **Mode of operation** | Continuous |

*NOTE!*

*Perimed cannot guarantee the function of the instrument if it is exposed to radiation above the levels tested in IEC 60601-1-2.*

## Measurement Performance

| | |
|---|---|
| **Range:** | 0 - 3000 PU<br>*NOTE!*<br>*PU (Perfusion Unit) is an arbitrary measurement unit. As the unit is defined in the PeriCam PSI, this range covers the range of perfusion in all living tissue. There is no theoretical upper limit in the perfusion that can be measured.The limitation to 3000 PU is set to limit the impact of noise.* |
| **Image acquisition rate:** | Up to 94 frames per second (fps) at 50 Hz mains frequency<br>Up to 113 fps at 60 Hz mains frequency |
| **Startup time:** | 30 s, full accuracy reached within 5 minutes |
| **Accuracy of distance measurement:** | Better than ± 5% |
| **Accuracy in calibration box:** | ± 4% in calibration fluid (Motility Standard)<br>± 3 PU in Zero |
| **Precision in calibration box:** | ± 4% in calibration fluid (Motility Standard)<br>± 3 PU in Zero |

### PeriCam PSI NR

| | |
|---|---|
| **Working distance:** | 130–415 mm |
| **Measurement area:** | Up to 240 mm (W) x 200 mm (H) |
| **Object resolution:** | Up to 33 µm / pixel |

### PeriCam PSI HR

| | |
|---|---|
| **Working distance:** | 130 mm, fixed distance |
| **Measurement area:** | 25mm (W) x 21 mm (H) |
| **Object resolution:** | 10 µm / pixel |

### PeriCam PSI with Zoom Functionality

| | |
|---|---|
| **Working distance:** | 130–415 mm |
| **Measurement area:** | Up to 240 mm (W) x 200 mm (H) |
| **Object resolution:** | Up to 10 µm / pixel |

## Laser Specifications

| | |
|---|---|
| **Classification:** | Class 1 - IEC 60825-1:2014 |

### Measurement Laser

| | |
|---|---|
| **Wavelength:** | 785 nm |
| **Direct output power:** | 100 mW |
| **Irradiation beam power:** | < 5.4 mW |
| **Divergence:** | ± 20° |

### Indicator Laser

| | |
|---|---|
| **Wavelength:** | 635 nm |
| **Direct output power:** | < 1 mW |
| **Irradiation beam power:** | < 0.39 mW |
| **Divergence:** | Fan angle = 60° |

## Maximum Cable Lengths

Cables connected to the PeriCam PSI may pick up noise emitted by other electrical equipment. Use only cables supplied by Perimed.

| | |
|---|---|
| **Vexio Cart Mains cable (power supply to power outlet):** | 5 m |
| **Table Mount Isolation transformer to power outlet:** | 5 m |
| **Table Mount Isolation transformer to Power Supply:** | 1 m |
| **Table Mount Isolation transformer to Desktop Computer:** | 1 m |
| **Table Mount Isolation transformer to Monitor / Panel PC:** | 2 m |

***WARNING!***

⚠

*Use of accessories, transducers and cables other than those specified or provided by Perimed could result in increased electromagnetic emissions or decreased electromagnetic immunity of the PeriCam PSI, and result in improper operation.*