Heidelberg Retina Camera (HRC)

Installation Instructions

Version 001, May 2009

Art. No. 20924

QM-Nr. 97 128-001

HEIDELBERG ENGINEERING

CE 0482

The manufacturer hereby declares that this product conforms to the requirements of Directive 93/42/EEC of the Council of the European Community dated 14 June 1993 regarding medical products (MDD 93/42/EEC).

Caution! Do not use the Heidelberg Retina Camera without reading this manual. This manual contains important safety information.

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1 General Introduction

1.1 The Heidelberg Retina Camera

The Heidelberg Retina Camera (HRC) is a scanning digital opthalmoscope for the examination of the anterior and the posterior-segment of the eye with or without contrast or fluorescence agent. The resulting images aid the physician in the diagnosis and the follow up of various diseases of the anterior and the posterior-segment of the eye.

1.2 Safety Information: Cautions and Warnings

⚠ Please read this section carefully and always follow its contents!

1.2.1 General Safety Information

WARNING The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 30 minutes.

IMPORTANT Before you start working with the instrument, make sure that you know the correct procedures for turning the instrument on and off (Chapter 5).

IMPORTANT Carefully read the instructions for use before operating the device. Misuse of the device may lead to hazards for the patient or the operator or can lead to wrong diagnostic results. Use outside the “intended use” scope may also lead to instrument damage.

The instrument must not be used if there is a mechanical, electrical, or optical defect. Modifications or additions lead to loss of the CE mark. Heidelberg Engineering does not take responsibility for modified HRC devices.

Any repair, especially of the instrument's electric and electronic systems, and any service work on the instrument components, must only be carried out by Heidelberg Engineering or an authorized distributor.

1.2.2 Contraindications for Performing Angiography

- Always ask the patient for known allergies and compare it with the contraindications of the contrast or dye fluid.
- **Be aware of possible allergic reactions when contrast or dye fluid is injected.**

1.2.3 Cautions, Warnings, and Contraindications

WARNING Carefully read the operation manual before operating the device. Misuse of the device may lead to incorrect diagnostic results.

WARNING Do not examine a patients eye longer then 30 minutes. A too long examination time might lead to damages of the retina.

WARNING The camera housing can get very hot after continuous operation. It is recommended to switch off the device between examinations. Caution is recommended when touching the camera housing.

WARNING Do not open the device component housings. Doing so may result in electrical shock.

WARNING Do not use the device outside the scope of its “Intended use”. Doing so may lead to malfunctions or damage of the device.

WARNING Do not use PCs, components or accessories that have not been approved by Heidelberg Engineering. Do not install other software, as this may interfere with the functionality of the Heidelberg Engineering software or equipment, cause damage to the system or lead to incorrect measurement results.

WARNING Always use a network connection with network isolation in accordance with IEC 60601-1 (isolating transformer). Without isolation transformer, user and patient could be at risk of electrical shock in the event of an error.

WARNING Make sure that the environmental requirements are met when the system is operated. Exceeding environmental conditions may damage the system or lead to incorrect measuring results.

WARNING Wrong examination preparation of the device and the patient may lead to bad or insufficient pictures.

WARNING Be aware of possible allergic reactions, when contrast or dye fluid is injected. Closely follow the package information leaflet. Do not perform more than one examination per day on the same patient. Multiple injections of the contrast or dye fluid may result in allergic reactions or shock.

WARNING Incorrect application of contrast / dye fluid may cause allergic reactions or shock, injury or illness. It may also cause follow up treatment or bad examination results.

WARNING Make sure the patient is correctly positioned in front of the device before starting the examination. Wrong positioning may lead to poor images and incorrect diagnostic results.

WARNING Artefacts on the images could falsify the measured results. Do not use the measured results if there are artefacts in the images.

WARNING Do not make a diagnostic decision on the basis of one single examination. The device is not clinically evaluated for the diagnosis of specific pathologies. So always use alternative information; history data etc. to assist in a final diagnostic determination.

WARNING Prepare safeguards to ensure that only authorized personnel can access the patient data. Data loss impedes follow-up analyses and may result in inappropriate diagnostic decisions.

WARNING Be sure to perform periodic data backup procedures. Check the success of the backup to avoid data loss caused by backup errors.

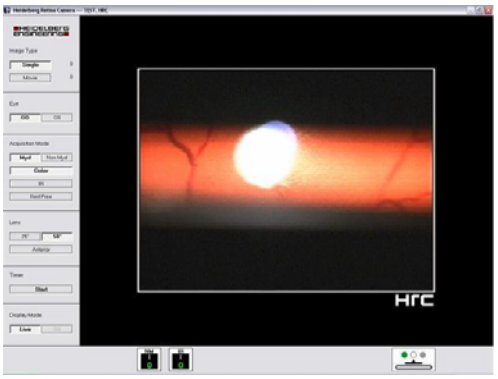
WARNING To avoid the risk of electric shock, this equipment must only be connected to a grounded power supply.

WARNING To avoid the risk of electric shock, do not touch conductive parts of connectors and the patient simultaneously.

WARNING Do not operate the system directly after large temperature changes. Let the device acclimate itself for a minimum of two hours to avoid device damage or incorrect measurement results.

WARNING Clean and disinfect chin rest and headrest or other soiled parts after each examination, Contaminated parts may lead to infections or disease contraction.

CAUTION In the rare event of defective illumination slit, the live image will appear as shown to the right. The image shows a small streak in horizontal direction on the monitor, whereas the upper and lower parts of the live image are dark. In this case, please turn the instrument off immediately and contact Heidelberg Engineering or the local distributor. Do not attempt to repair the instrument yourself.



CAUTION Please evaluate all images concerning their image quality (e.g. brightness, noises, artifacts) before making a diagnostic decision.

CAUTION Please note that the distance or diameter values issued by the Imaging software are only pixel values and not correlating to a linear dimension. The real distances are depending on the camera setup, patient distance and image quality.

CAUTION If the camera or the objective were fallen off, please contact the Heidelberg Engineering Service for a device check.

CAUTION Please note that vibrations of the device location (e.g. caused by strong machines) might lead to bad or distorted images.

CAUTION Never leave the patient alone with the instrument during the examination!

CAUTION The instrument must not be used under any circumstances if mechanical, optical or electrical faults occur. Any change or addition to the system must comply with the relevant legal guidelines. Repairs, particularly to the electronic and optical components, must be carried out only by Heidelberg Engineering authorized, trained personnel.

CAUTION Unusual noises and/or vibrations can indicate a fault. Should this happen, please turn the instrument off immediately and contact Heidelberg Engineering or the local distributor. Do not attempt to repair the instrument yourself in the event of a fault.

CAUTION This equipment was tested in accordance to IEC 60601-1-2, Electromagnetic Compatibility (EMC). Nevertheless, it might be affected by strong electromagnetic fields. Portable high frequency communication devices may affect the device.

CAUTION The operator must be sure that the device settings and adjustments are correct before starting an examination and making any diagnostic decision. Wrong settings and adjustments may lead to poor image quality or incorrect examination information.

CAUTION The physician must be sure to have the correct patient data before making a diagnostic decision. Mismatched patient data may lead to inappropriate diagnostic decisions.

CAUTION Do not start an examination without informing the patient about the examination procedure. Inappropriate patient behaviour during the examination may lead to poor image quality and incorrect diagnoses.

CAUTION Read subsection 1.5 " Maintenance, Cleaning and Service" carefully. A failure to carry out maintenance or incorrect adjustment of the device may lead to poor image quality and incorrect diagnoses.

CAUTION Before starting the system, check the regional power supply specifications to verify that they comply with the required tolerances. Wrong power supply conditions may lead to malfunctions of the system.

CAUTION A computer failure during image acquisition or analysis could lead to incorrect results.

CAUTION Please note that the effect of environment light might influence the image quality.

United States of America:
Federal law restricts this device to sale by or on the order of a Physician or Practitioner.

IMPORTANT The HRC light bulb is an especially modified component and not an over the counter product. Only original spare parts from Heidelberg Engineering GmbH shall be used.

CONTRAINDICATIONS No contraindications are known.

1.3 Maintenance, Cleaning and Service

The Heidelberg Retina Camera is a precision optical instrument. Protect the instrument against dust and moisture, and avoid shocks and the action of strong forces.

Beyond the procedures described in this chapter, the operator should not work on the instrument. Please be aware that only authorized service personnel can do service and repair of the HRC device. Do not open the camera or power supply unit. If the device is opened by someone other than an authorized service personnel, the warranty will be discontinued. For maintenance, adjustment and repair of the equipment contact Heidelberg Engineering or your local distributor.

A yearly inspection of the device by a Heidelberg Engineering service engineer is highly recommended to ensure proper and exact operation.

1.3.1 Cleaning and Disinfection

Before cleaning the instrument, turn the instrument off and disconnect the power plug.

The lenses should be carefully cleaned at regular intervals. For this purpose, it is best to use a cotton swab slightly moistened with 99% ethanol. Do not use disinfection alcohol for cleaning the optics, as deposits may remain on the lens surface.

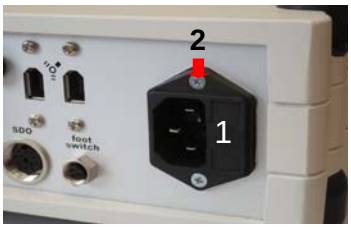
The non-optical surfaces of the instrument can be cleaned and/or disinfected as necessary. Any standard cleaning product appropriate for plastic surfaces which does not contain acetone or hydrogen peroxide (e.g. ethanol and isopropyl alcohol disinfectants) may be used for this purpose. Make sure that no cleaning agent penetrates into the equipment.

1.3.2 Changing the Fuse

WARNING: Before changing a fuse the HRC must be switched off and disconnected from the mains!

The fuses are located in a cartridge (1) in the socket for the mains supply (2) at the back of the power supply unit.

Remove the cartridge by inserting a small screwdriver behind the flap of the cartridge and lift the cartridge out of the fuse socket. After exchanging the fuses, insert the cartridge into the socket.




IMPORTANT: Only fuses with the following specifications are to be used:
100 V-240 V: 2x T 2.0 AL; Size: 5 x 20 mm each, 2-pole fuses.
Always exchange both fuses.

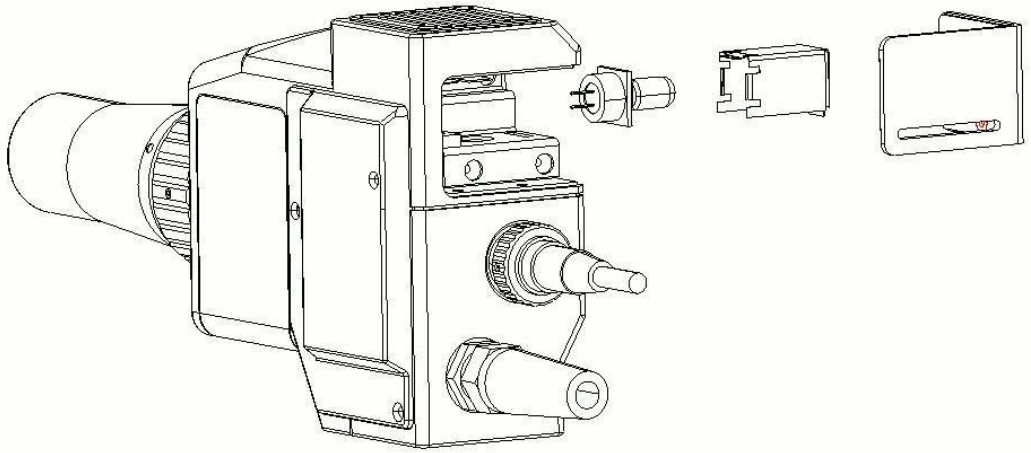
1.3.3 Changing the Halogen Lamp

WARNING: Before changing a halogen lamp, the HRC must be switched off and disconnected from the mains!

WARNING: The halogen lamp can be very hot! Wait until the halogen lamp is cool and use a cloth or metal tweezers to replace the halogen lamp. Only touch the metal socket of the new halogen lamp, never touch the bulb directly.

To remove the halogen lamp, open the cover which is fixed with a magnet. Remove the sheet metal protective covering by lifting it up and pressing the lever inside upwards. Pull the halogen lamp out of the socket in an upward direction.

Insert the new halogen lamp into the ceramic socket using tweezers. Insert the sheet metal protective covering again, then mount the cover (a pin clasps into position).



IMPORTANT: The HRC bulb is an especially modified component and not an over the counter product. Only original spare parts from Heidelberg Engineering GmbH shall be used.

1.4 Accessories

The following accessories and spare parts are available:

- Adjustable camera mount with joystick
- Headrest with fixation light
- Exchangeable lenses
    - 50° lens for retinal imaging - standard
    - 25° lens for ONH imaging - optional
    - Anterior segment lens - optional
- Adapter for the following slit lamps
    - HS BM/BC 900
    - HS BQ 900
    - Variable adapter for HS
    - CZ 20/30 SL
    - CZ 120/160 SL
    - RO 2000
    - RO 4000/5000
    - CSO SL 980
- Halogen lamp 6V/35W, item order no. 18947

2 Electrical System Configuration

The HRC together with the connected computer and other connected devices constitutes a medical electrical system (*ME-system*) according to IEC 60601-1-1. This system must meet specific safety criteria as detailed in the standards and in this document. *Note that every connected device will become part of the ME-system, even if the only connection is the power supply cord leading to a shared multiple socket outlet.*

Example: The HRC is connected to a laptop computer, the laptop computer is connected to a printer (via USB or WLAN). All devices are connected to the main power supply using a multiple socket outlet. An electrical table is also connected to the same multiple socket outlet. In this case, the "ME-system" consists of all devices: HRC, laptop, printer and table.

The basic principle when setting up a ME-system is that the overall safety of the system inside the patient environment is comparable to the safety of a single medical device. To ensure this, nonmedical devices that are part of the system must conform to their respective IEC or ISO standards (e. g. IEC 60950) and *additionally* must conform to the leakage current limits of the 60601-standard for medical devices.

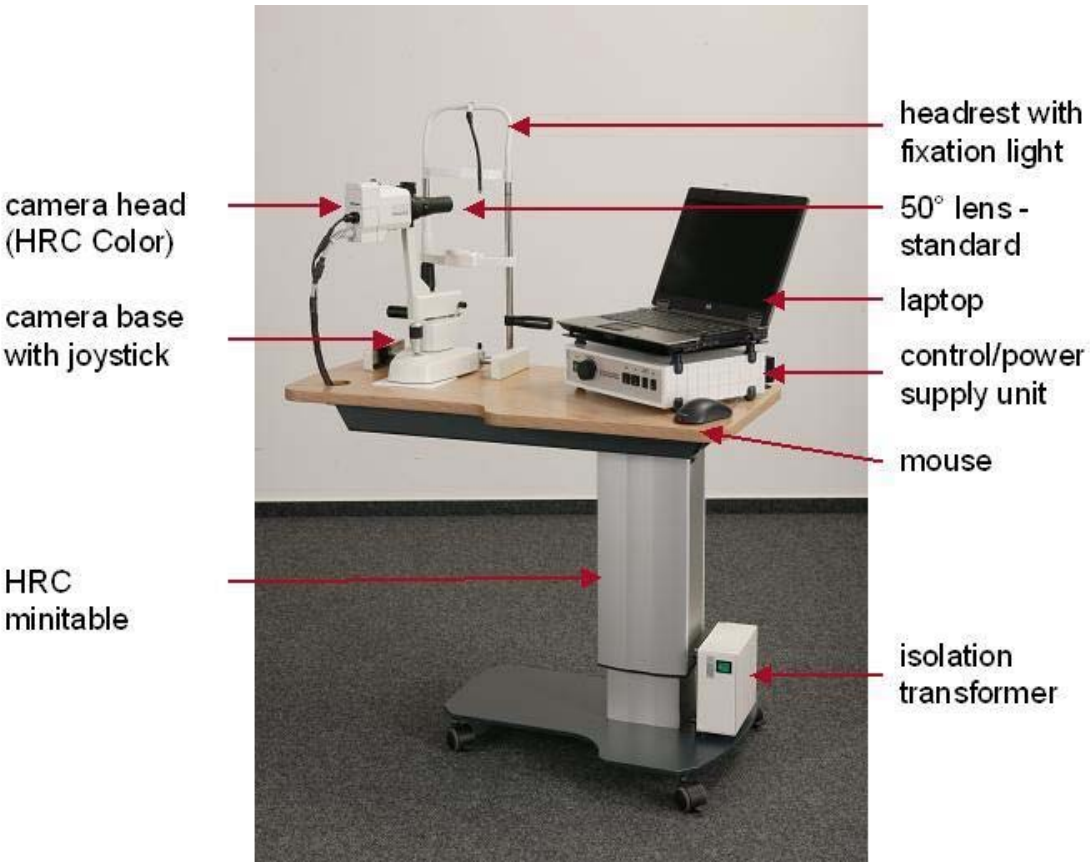
Caution: Use isolation transformer conforming to IEC 60601-1.

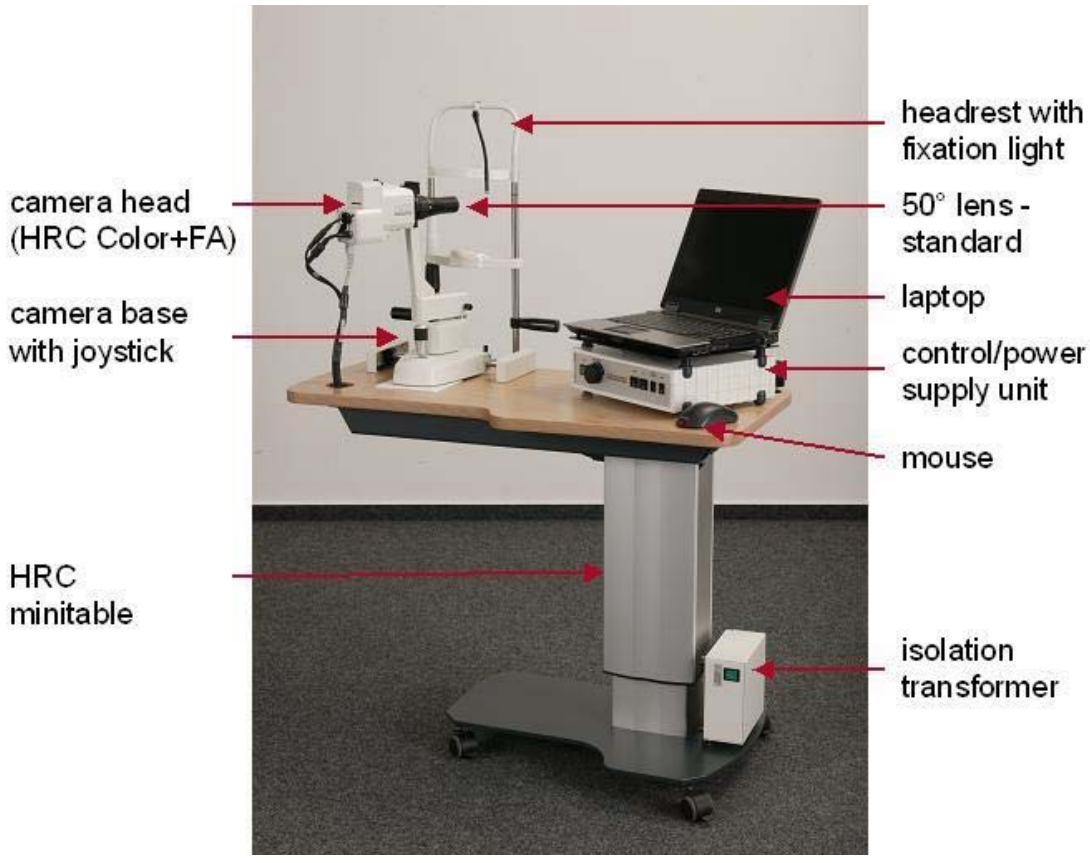
3 PC Requirements

The laptop or desktop computer to be used for the HRC must mee the following requirements:

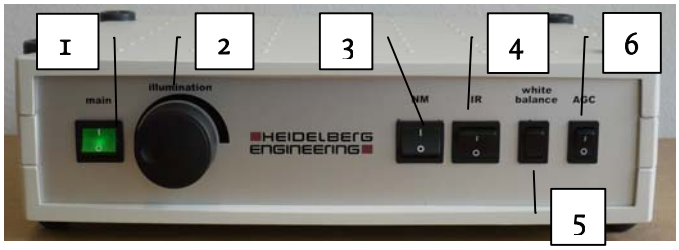
Operating System:	Windows 2000 professional or Windows XP professional
Processor:	1.7 GHz Intel Pentium III (minimum)
RAM:	512 MB minimum
VGA Board:	High performance VGA board with at least 1024 x 768 resolution, 16 bit
Monitor:	1024 x 768 minimum resolution
High-Speed Interface:	IEEE1394 (FireWire / i.LINK) interface (1 port required)

4 Hardware Installation





4.1 Control Unit (Power Supply Unit)



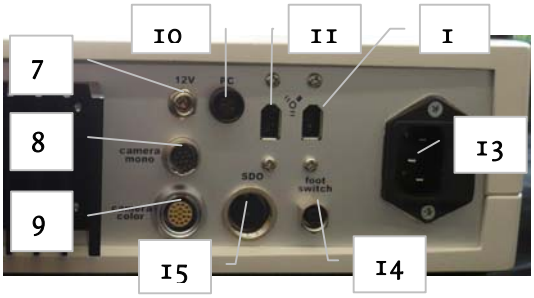


Illustration Part No.	Part Description
1	Main - on-/off switch
2	Illumination / brightness control knob (0 ▲)
3	NM switch
4	IR switch
5	White balance switch
6	AGC (Automatic Gain Control) camera switch
7	12V output / max. 500 mA
8	B&W camera socket (intended for HRC Color+FA use only)
9	Color camera socket
10	Socket for PC interface cable
11	Socket for Fire Wire Cable (power Supply Unit to PC/Laptop)
12	Socket for Fire Wire Cable (Power Supply Unit to PC/Laptop)
13	Mains supply socket with fuse socket
14	Socket for foot switch
15	Color camera socket Connection socket for power supply to HRC instrument head labeled 'SDO'

4.2 HRC Camera

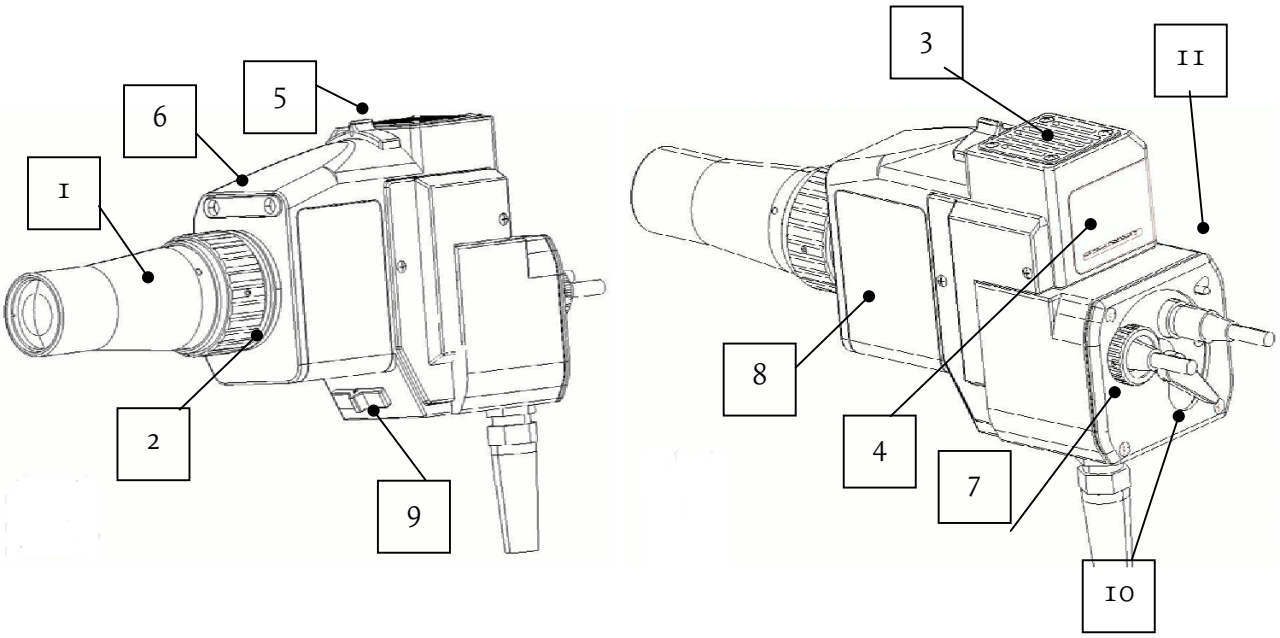
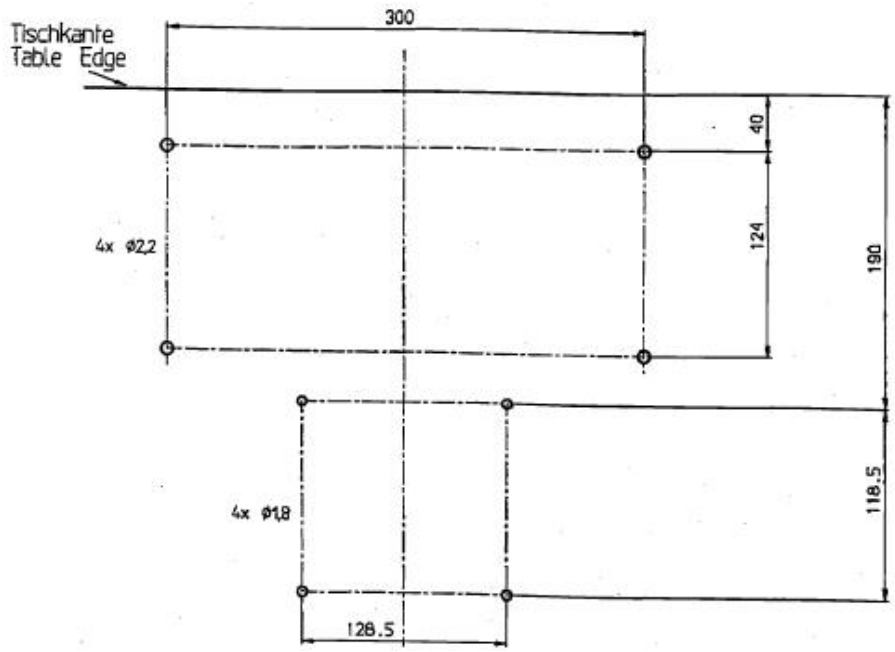


Illustration Part No.	Part Description
1	Lens (standard 50°, optional 25°, anterior segment)
2	Focus ring wheel knob
3	Air vent incl. cover plate
4	Lamp cover with magnetic clasp
5	Filter adjustment lever for filters: Red Free and Neutral Density Filter
6	Adapter plate for mounting to a slit lamp
7	Color camera cable
8	Fixture plate to attach handle for mobile usage or other optional accessories
9	Lever to swivel in Fluorescein filter (HRC Color+FA only)
10	Lever to switch between Black & White and color cameras (HRC Color+FA only)
11	Lock-in lever to fixate camera (HRC Color+FA only)

4.3 Assembly Instructions

4.3.1 Drill Holes for Basis with Joystick

Before assembly, holes must be drilled into the table plate (see diagram below for measurements in cm).



4.3.2 Assembly of the base

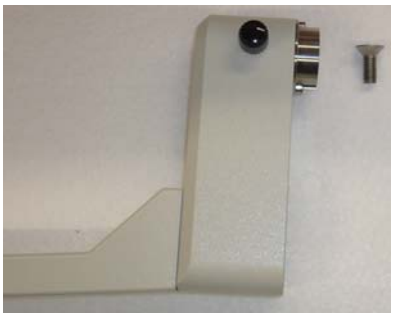
Parts:

2x gear rail with 2 Phillips screws each
2x protective cover
1x white friction surface with 4 Phillips screws
1 base with joystick
1x camera support with Allen screw
1 guide rail with 2 gears, Allen screws and washers
1x protective hood for the device

Open the cardboard box. Take out the individual parts of the base.

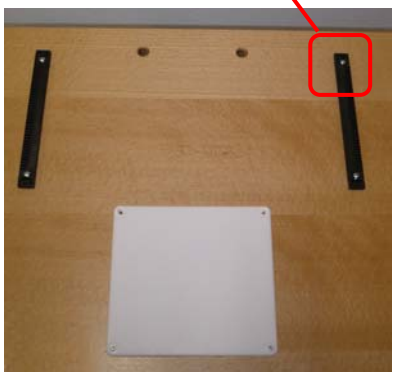
Mount the camera support to the basis with the joystick using the Allen screw.

Remove the white plastic ring. It is only necessary for transport.

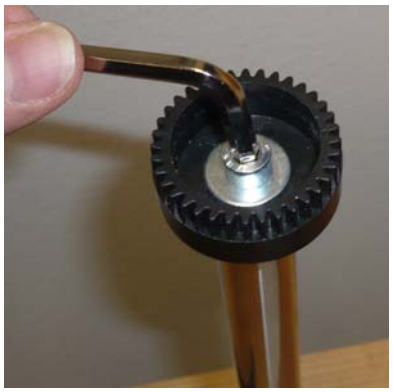


Screw down the gear rails on the table surface with two Phillips screws each. The sides of the gears must face outward (see drilling jig)

Screw the white friction surface to the table surface using the four Phillips screws (see drilling jig). The upper side of the friction plate can be identified by the countersinks for the screws.



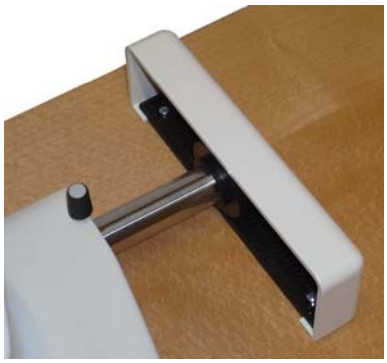
Remove the gear from the guide rail.



Slide the guide rail through the base. Screw on the gear again.

Place the base on the table so that the joystick is located above the friction surface and the gears rest on the gear rail.

Fit one of the protective covers on the mounted gear rail at the side and slide the base forward up to the stop.



Check if the opposite gearwheel also rests on the last tooth of the gear rail, i.e. if both gears are parallel.

Fit the second protective cover on the gear rail.

4.3.3 Assembly of the Head Rest

Parts:

- 1x head rest with ext. fixation lamp
- 1 package of chin rest paper
- 2x fastening screws

Open the box and remove the packaging material from the chin rest.

Fasten the chin rest to the table using 2 Allen screws (see drilling jig and corresponding holes in the table).

The head rest is screwed to the table from below .

4.3.4 Assembly of the Camera with Control Unit and the Laptop/PC

Parts:

- Camera head
- Control unit
- PC interface cable
- Halogen lamp (spare)
- Foot switch
- FireWire cable
- 50° lens

Take out all parts and remove the packaging material.

Fasten the camera head to the camera support on the base by placing the head on the two retention pins.

Guide the camera cable through the appropriate openings into the cable duct of the table and from there to the back of the control unit.

Remove the control unit from the box and the plastic packaging and place the unit on the table.

Place the laptop plate on the power unit.

Place the laptop on the plate.

4.4 Cable Connections

IMPORTANT: Before connecting the cables, be sure the mains supply switch is turned OFF.

Ensure that the contact pins in the sockets are not bent or otherwise damaged.
Both the sockets and the plugs have guides to ensure alignment and when these are in the proper position, they are easily connected without resistance.

IMPORTANT: Never use force to connect the cables.

NOTE: HRC and Spectralis devices can be operated from the same PC using one HEYEX installation. For further information, pleaser refer to the "Supplement for installation of Spectralis and HRC on the same PC".

USB-serial adapter

If the PC/Laptop does not have a serial port, use a USB-serial adapter which gets delivered with the HRC.

The PC interface cable of the HRC is connected to a USB port of the PC via the USB-serial adapter.

To install the driver of the USB-serial adapter, insert the CD-ROM *"Software Device Driver & Utilities Release 3.04"* into the CD drive and start the installation.

Figure 1a and 1b:

USB-serial adapter PC interface cable

4.4.1 Isolating Transformer

Connect the low heat devices i.e. HRC control unit, laptop / PC and monitor, the height adjustable table and printer (if applicable) to the isolating transformer using the cables for low heat devices.

Connect the power cable to the isolating transformer. Do not connect the power cable to the mains yet.

4.4.2 Control Unit

Connect control unit and laptop/PC using the PC interface cable and the FireWire cable.

NOTE: Use a USB-to-serial-adapter and install the appropriate driver if the laptop has no serial interface.

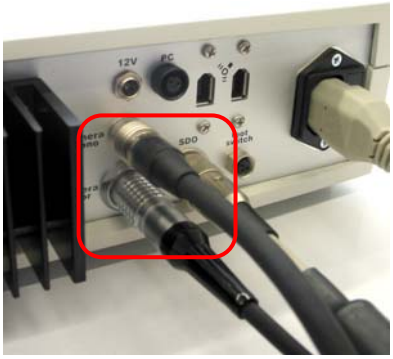
PC interface cable

HRC Color

Connect the plugs of the SDO cable and HRC Color Camera to the HRC control unit. Secure the plugs against an involuntary disconnection by tightening them in place.

HRC Color+FA

Connect all three plugs (SDO cable, Camera color, Camera mono) to the power control unit as shown in the illustration below. Secure the plugs against an involuntary disconnection by tightening them in place.



Connect the foot switch to the socket „foot switch“.

Check if all units are correctly connected, then connect the isolating transformer to the mains and switch it on.
NOTE: The line voltage adjusts automatically to the local power outage.

4.4.3 12 V - Output

The 12 V output is available to connect further electrical DC voltage loads that have a maximum of 500mA (i.e. fixation lamps).

4.5 Software Protector (Dongle)

The software protector (dongle) must be inserted into the parallel or USB port of the computer. Please note that the software protector (dongle) must remain connected at all times while operating the HRC.

4.6 Mobile Application

For mobile use, the HRC Color is operated as a hand-held video camera (e.g. on lying patients).

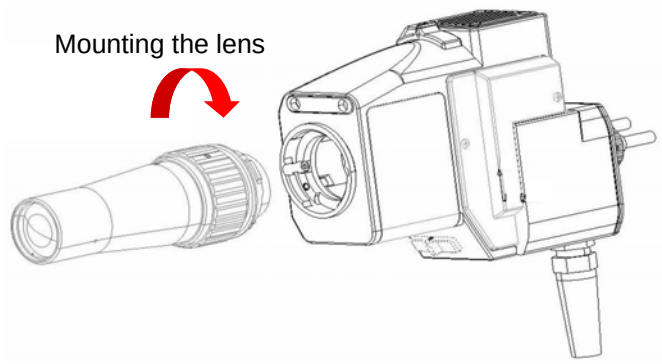
For HRC mobile use, the handle is attached to the unit. To do this, the cover plate is removed by loosening the two screws and the handle is inserted and attached in its place.

For stationary use, the HRC is anchored to a slit lamp. Please proceed as instructed in the operating instructions paragraph “Mounting the HRC to a slit lamp” (Point 4.2). Slit lamp adapters are optional equipment and available as an accessory.

NOTE: Angiography should be carried out only with the HRC in stationary use.

4.7 Mounting and Changing the Lens

Several lenses are available: one for the anterior segment of the eye and lenses for the posterior segment of the eye (e.g. 25°, 50°).



The white dot on the lens indicates the 12 o’clock position of the lens when inserting it into the camera. Insert the lens. Turn the lens clockwise until the bayonet clasp snaps into place.

Remove the lens by turning it counterclockwise until it can be taken off.

4.8 Foot Switch

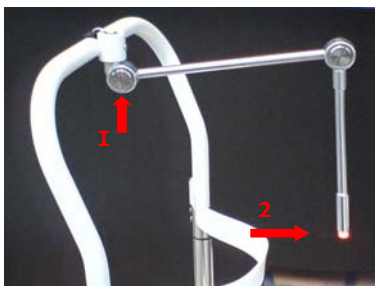
The foot switch is used to acquire images. The 3-pin plug is connected to the socket „foot switch“ on the back side of the power control unit.

NOTE: If the camera is in the non-mydriatic mode (see Operation Instructions), the infrared filter will swivel out as long as the foot switch is pressed, enabling acquisition of color images.

4.9 External Fixation Lamp

The external fixation lamp is mounted on the head rest (1).

Once the cable is connected to the power supply unit, the lamp (2) is turned on by starting the device.



4.10 Installation of the HRC onto a Slit Lamp

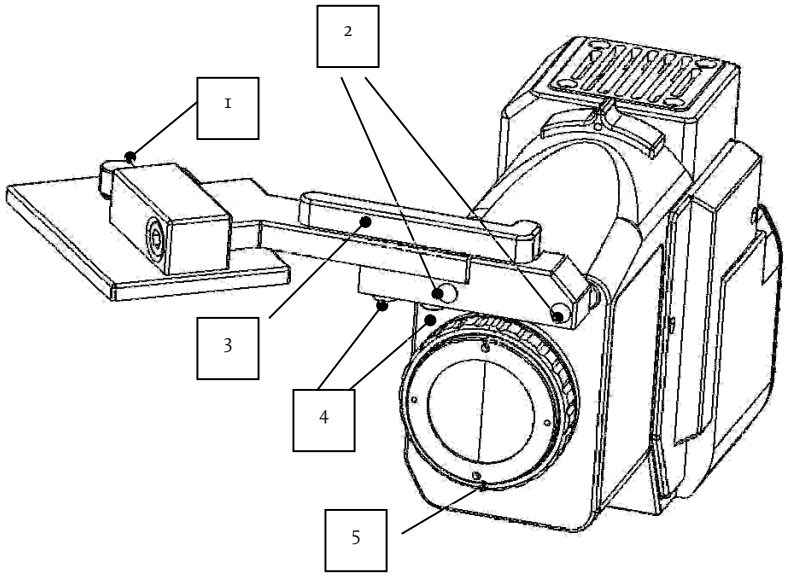
Alternatively, the HRC can be mounted onto a slit lamp, and is thus in an anchored position for stationary use.

Depending upon the slit lamp manufacturer or type, the following instructions for mounting the HRC to a particular slit lamp may vary.

Provided here is a general instruction guideline for the purpose of this manual. A detailed instruction manual for mounting each particular slit lamp adapter is included with appropriate adapter shipment.

1. Connect the adapter to the body of the microscope with the screw knob (1).
2. Slide the HRC (F/A) onto both pins (2) of the adapter until it has resistance. The HRC is fixed by magnet into this position.
3. To release the HRC, push the handle which releases the magnet (3).
4. To center the HRC with the slit lamp (only for anterior eye segment applications), the lens for the anterior segment of the eye is attached to the HRC.
5. Should the slit lamp have a focus adjustment, it should be attached now.
6. The slit lamp is turned on and adjusted to show a small slit.
7. To focus, use the focus ring on the HRC objective lens tube. To center the slit light view, adjust the screws (4) on the adapter accordingly.
8. Once you have the slit light view centered and focused, you can secure this setting with the screw on the objective lens tube (5).

Should your slit lamp not have a focus adjustment, then you can focus and center the slit light view by placing a piece of paper onto the headrest, viewing the slit light view through the slit lamp's microscope and making the appropriate focus adjustments by using the cross sledge.



5 Turning the Instrument On and Off

Start-Up Procedure

To turn the HRC on, proceed as follows:

- Turn on the power supply of the device. The power switch is the green switch on the front side of the power supply unit.

- Turn the computer on. After the boot sequence has been completed, the computer will start the Windows operating system.
- Start the Heidelberg Eye Explorer (HEYEX) software. Use the Heidelberg Eye Explorer shortcut on the desktop to start the application by double left-clicking on the Eye Explorer icon on your desktop

  or by using the windows ***Start*** menu:

  Start - ***Programs*** - ***Heidelberg Eye Explorer*** - ***Heidelberg Eye Explorer***
- Wait until the software opens to the database view.
- Before an examination, switch on the halogen lamp by turning the illumination knob clockwise. It is recommended to switch off the lamp between examinations.

Shut Down Procedure

To turn the HRC off, proceed as follows:

- If the acquisition dialog is open and the live image is visible on the screen, stop the image acquisition by closing the acquisition window.
- To close the software program, select the option ***Exit*** from the menu item ***File*** or click the ***Exit*** button ✕ at the top right corner of the screen.

- Turn off the power supply unit.

6 Driver and Operating Software Installation

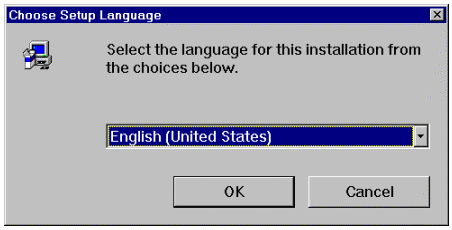
After the Heidelberg Retina Camera hardware has been unpacked and connected to the computer, switch on the computer and the HRC device and wait until the Windows operating system has been started up.

To install the software for the Heidelberg Retina Camera, insert the CD-ROM “Heidelberg Retina Camera” into the CD-drive and wait for the automatic startup of the installation program or manually run the “setup.exe” program from the root directory of the CD.

6.1 Operating Software - First Installation

Module Language

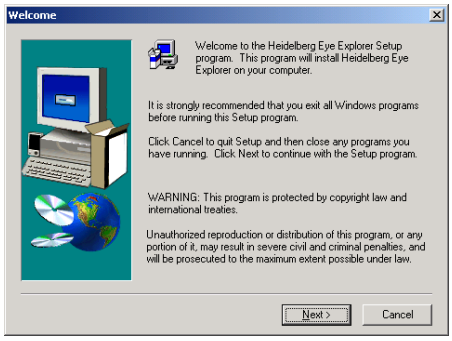
Select your language from the drop down list of the installation program dialog.



Welcome

The ***Welcome*** dialog appears on the screen.

Click “***Next***” to continue the installation.

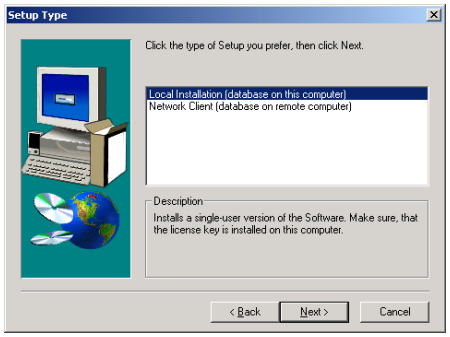


Select Setup Type

Select one of the following setup types:

“***Local Installation (database on this computer)***”
Choose this setup type, if you want to install the Heidelberg Eye Explorer on a single workstation without network clients. This installation will install an empty database.

“***Network Client (database on remote computer)***”
Choose this setup type to install the Heidelberg Eye Explorer on a workstation in a network. The “***Network Client***” installation will not install a database, because all workstations in the network will share the same database on a server.
Install a “***Local Installation***” on the server – PC. The setup program will install an empty database. Install a “***Network Client***” on all additional workstations.



Destination Folder

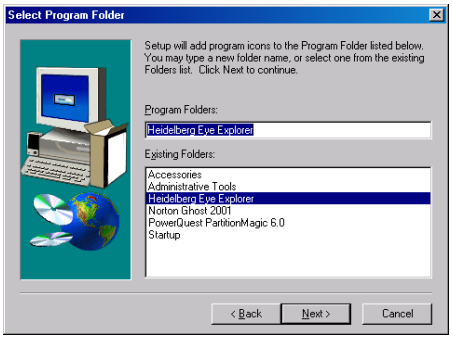
The installation program will ask for an installation folder. The default is "***C:\HEYEX***", which is highly recommended. Do not change the installation folder if it is not absolutely necessary!

Click "***Next***" to continue the installation.

Program Folder

Select the program folder. The folder name will be accessible by the Windows "***Start***" button.

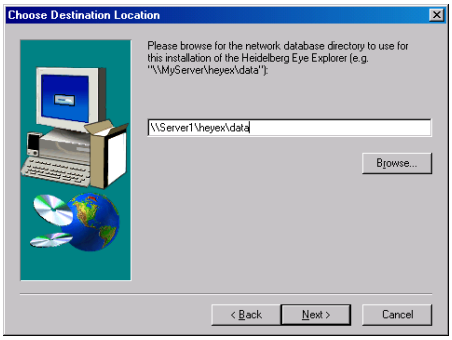
Click "***Next***" to continue the installation.



Database Location (Local Installation only)

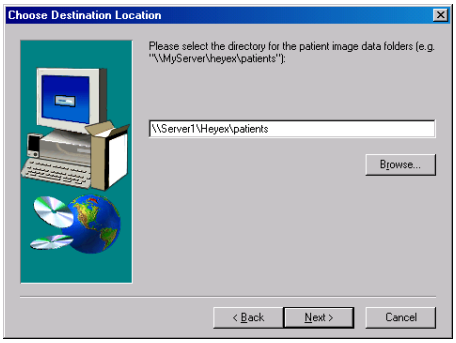
In the case of a local installation, a path to the root folder of the database and the patient data folders must be entered. The installation program will automatically create the subfolders ***DATA*** and ***PATIENTS*** in this specified folder. ***DATA*** contains the database file and ***PATIENTS*** will take up the patient data (acquired images etc.). If an external hard drive (e.g. FireWire hard drive) shall be used to store the database and patient data, you can enter the drive letter followed by a colon (e.g. F:).

Click "***Next***" to continue the installation.



Database Location (Network Client only)

In the case of a Network Client installation, a path to the database folder and a path to the patient folder must be entered.



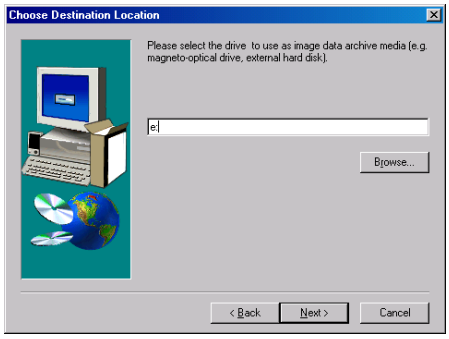
For a network installation, the database and the patient folder on the server PC **must** be shared to allow **unrestricted** file access for client PCs. There are two ways to enter the server's database and patient folder on the client computer:

Map the shared database folder of the server PC to a local drive (e.g. drive letter 'J'). Use the "***Browse***" button to navigate to the shared database folder on that mapped local drive (e.g. J:) and select it.

Enter the UNC path of the shared database and patient folders. A UNC path begins with a double backslash and consists of the following elements:

\\SERVER_NAME\SHARE_NAME\PATH

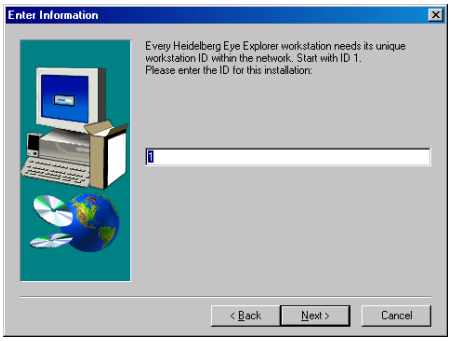
The usage of UNC network path specification is highly recommended, because a mapping of the shared file resources on the client PCs is not required. In addition, drive mapping can be easily lost if the client PC will be started before the server PC is running. Another problem with mapped network drives is that the drive letter may change if an additional disk device (e.g. Zip-drive) is temporarily attached.



Click "***Next***" to continue the installation.

Workstation ID (Network Client only)

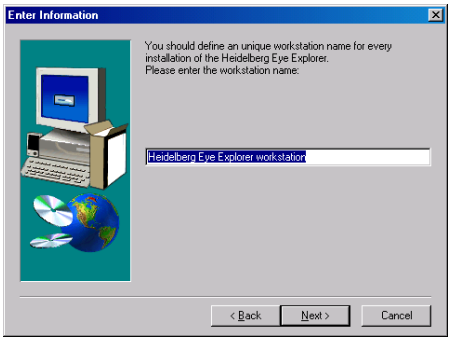
A unique workstation ID is required for every client PC. Start numbering the clients with 2 and increment this value by 1 for every new client installation. The number of workstations, which can run at the same time, depends on the number of licenses purchased. The workstation ID must never exceed the number of licenses.



Click "***Next***" to continue the installation.

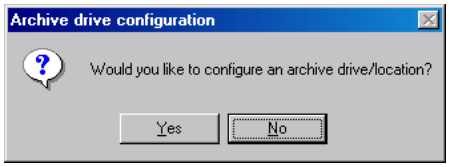
Workstation Name (Network Client only)

Enter a unique workstation name for every client installation.



Click "***Next***" to continue the installation.

Archive Media

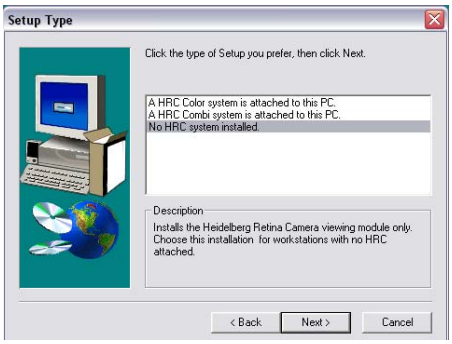


The installation program will ask for an archive drive. If you would like to configure a drive for archiving (e.g. magneto optical drive, or external hard drive), click on "***Yes***" to continue with the configuration of the archive drive.

Enter the drive letter followed by a colon (e.g. E:) and click "***Next***" to continue the installation.

Attention: This dialog looks nearly identical to the previous dialog for the patient data directories. However, at this screen, it is necessary that a drive/directory of the archiving device is specified. If the archiving device (Magneto-optical disks, external hard disk but no CD-RW) is assigned to drive letter E, then enter "***E:***" here.

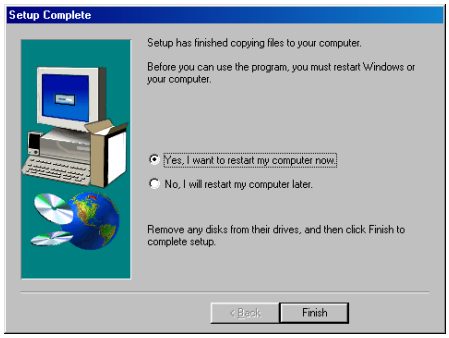
Select Setup Type



Select the appropriate setup type. If an HRC Color device is attached to the computer, choose "***A HRC Color system is attached to this PC***". If an HRC Combi device is attached to the computer, choose "***A HRC Combi system is attached to this PC***". If no HRC device is attached to the computer, choose "***No HRC system installed***" (usually on network clients and pure viewing stations).

Click "***Next***" to continue the installation

Setup Complete



The installation is finished now. You must reboot the computer before you try to operate the system

Confirming the Installation

In order to use the Heidelberg Retina Camera, the hardware and software must first be correctly installed. Under ***Start – Settings – Control Panel – Add/Remove Programs***, the following items must be listed:

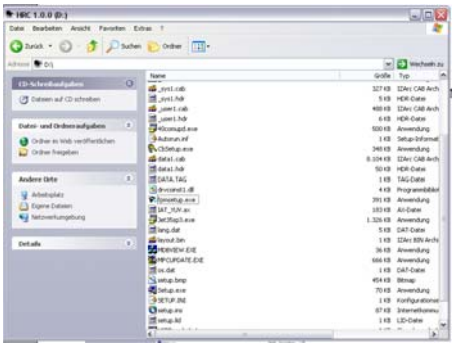
- Heidelberg Eye Explorer
- Heidelberg Eye Explorer License Manager

6.2 FireWire Perfomance Mangager - Installation

If the Heidelberg Retina Camera is connected to laptop, you have to install an additional FireWire Perfomance Manager software.

Please open the inserted CD-Rom "***Heidelberg Retina Camera***" and double-click on ***"fpmsetup.exe"*** to start the installation.

Fpmsetup.exe



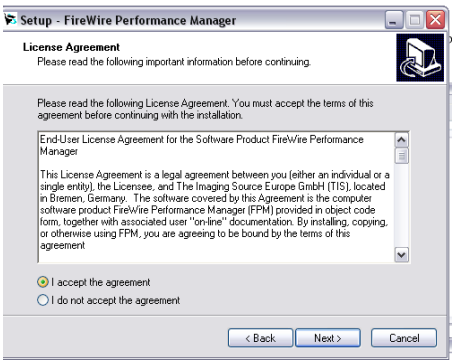
The ***Setup-FireWire Perfomance Manager*** dialog appears on the screen. Click "***Next***" to continue the installation.

License Agreement

Please read the License Agreement.

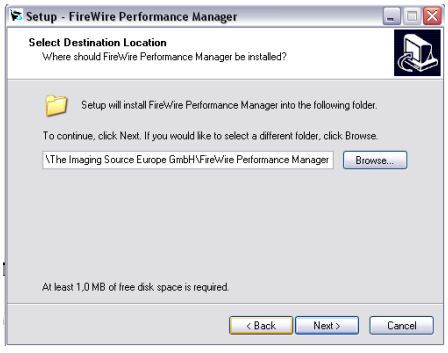
You must accept the terms of this agreement before continuing with the installation.

Click "***Next***" to continue.



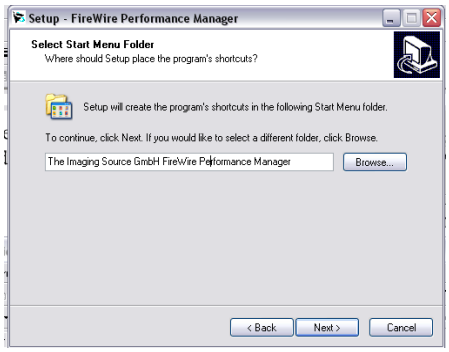
Setup Destination Location

To continue, click "***Next***". If you would like to select a different folder, click "***Browse***".



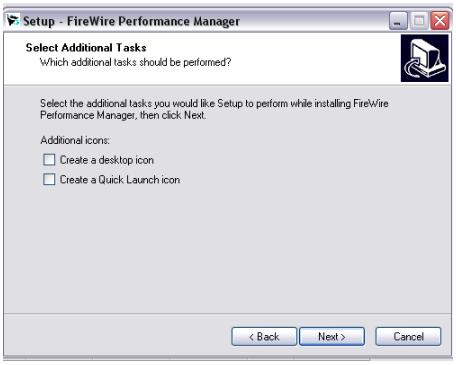
Select Start Menu Folder

To continue, click "***Next***". If you would like to select a different folder, click "***Browse***".



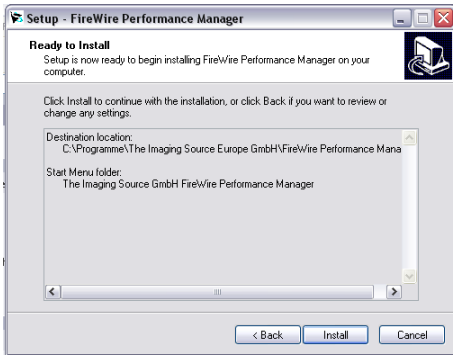
Select Additional Tasks

Select the additional tasks you would like ***Setup*** to perform while installing FireWire Performance Manager, then click "***Next***".



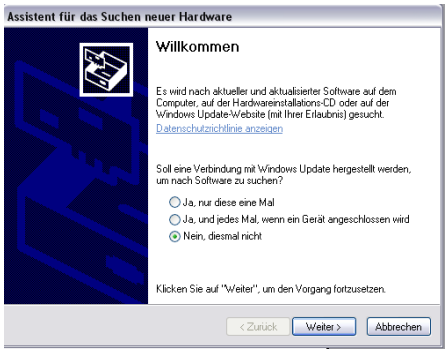
Ready to Install

Click "***Install***" to continue with the installation.



6.3 Video Converter - Driver Installation

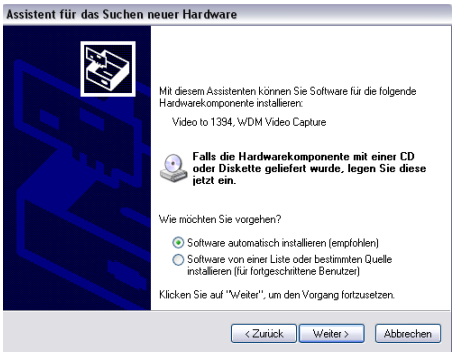
At the first installation of the Heidelberg Retina Camera device, the appropriate driver has to be installed. Because the HRC is a plug & play device, the Windows hardware installation wizard will be started automatically.



Windows 2000: Click on "***Weiter***" to start the installation.

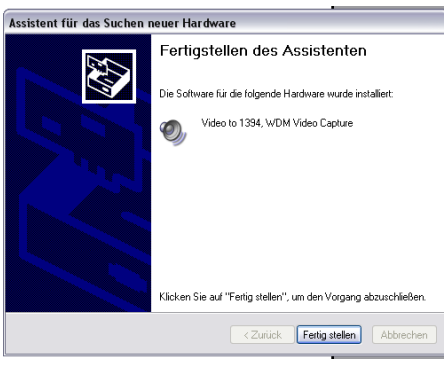
Windows XP: The installation wizard offers to connect to the Windows Update Web Site. Select "***Nein, diesmal nicht***" and click on "***Weiter***" to continue.

Select: "***Software automatisch installieren***" to install the driver software automatically and click on "***Weiter***" to continue.



The Window ***Hardware installation*** appears, please click on "***Installation fortsetzen***" to continue the installation.

Please click on "***Fertig stellen***" to finish the installation.



6.4 Software Settings

The COM port setting for the footswitch connection in the hrc.ini file has to match the COM port indicated in the Windows Device Manager. Otherwise the HEYEX software will not find the footswitch when opening the acquisition window.

The COM port default setting in the hrc.ini file is COM1.

Please check the COM port setting in the device manager upon installation. If it does not match the setting in the hrc.ini file, change the setting in the hrc.ini accordingly (see red circles in figure 3 and 4 below).

The USB-serial adapter has to stay connected to the same USB port for the system to operate.

Figure 2:

My computer > right click > properties (=System Properties) > Hardware > Device Manager

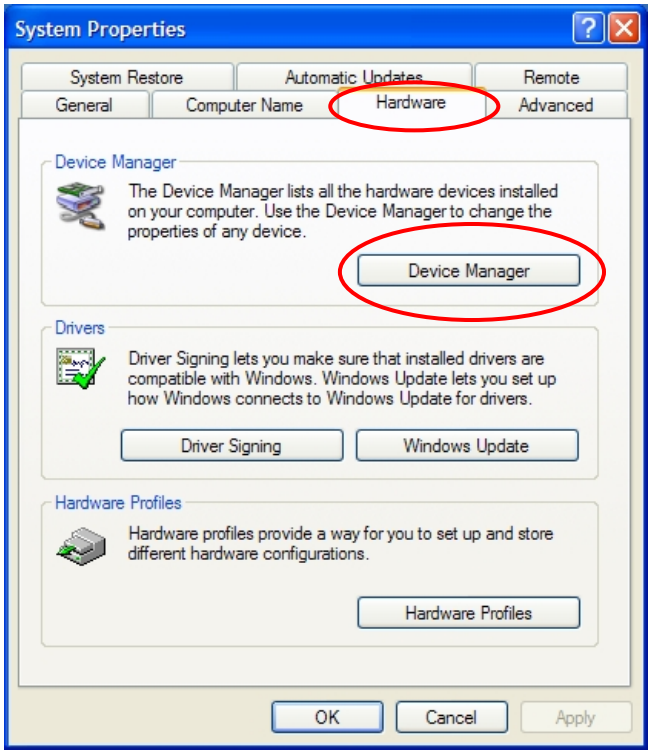


Figure 3:

Device Manager > Ports (COM & LPT) >

Profilic USB-to-Serial Bridge (COM *X*)

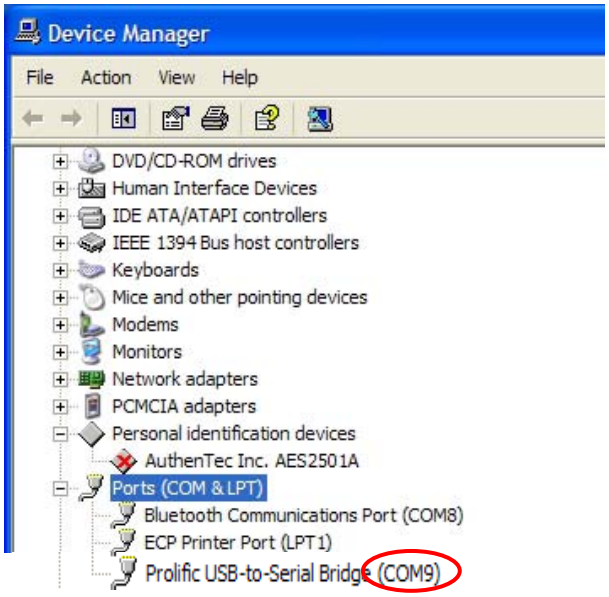
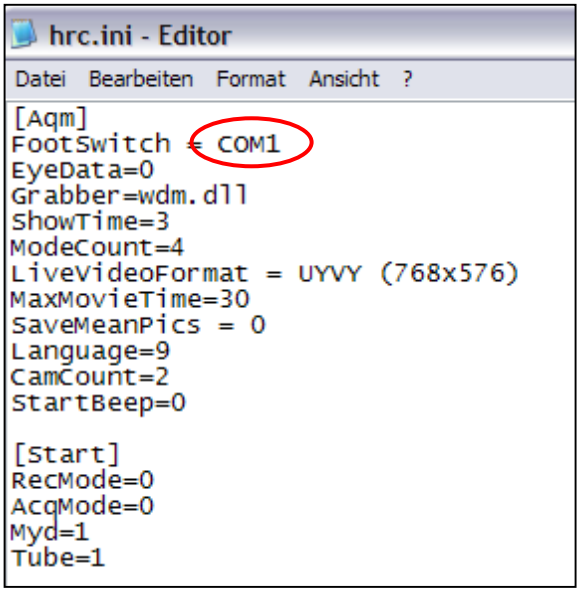


Figure 4:

C:\HEYEX\plugins\hrc.ini



Please note:

A new software version that will identify the correct COM setting automatically will be available soon. In the meantime, please change the COM setting manually as described above.

Technical Specifications

Angle with lens for retina examination with lens for anterior segment with lens for optic nerve head examination	 50° (30° x 40°) 12 x 16 mm 25° (20° x 15°)
Refraction compensation	± 15 dpt
Distance to cornea 50°/25° lens lens for anterior eye segment	 10 mm 117 mm
Filter: Exciter and barrier filter (optional) for fluorescein angiography Red free filter Neutral density filter T=25%	
Halogen Lamp	6V / 35W with justified socket item order no. 18947
Safety Analysis for the HRC Light source in accordance to ISO 15004 2:2007 "Opthalmic instruments – Fundamental requirements and test methods"	The light emitted from the HRC is potentially hazardous. The longer the duration of exposure, the greater the risk f ocular damage. Exposure to light from this instrument when operated at maximm intensity will exceed the safety guideline after 30 minutes.
Video system: Color camera Black and white camera	 PAL/CCIR 768 x 576 pixel, 25 fps PAL/CCIR 768 x 576 pixel, 25 fps (fps - frames per second)
Mechanical data: HRC: height: width length weight Power supply unit: height: width depth weight	 approx. 120 mm approx. 70 mm approx. 150 mm approx. 1.8 kg approx. 67 mm approx. 281 mm approx. 220 mm approx. 2.5 kg
Electrical data: Input Voltage fuse Input Voltage fuse	 110V – 115 V 2 x T 2.0 AL 220V – 240 V 2 x T 2.0 AL

Frequency Maximum Power Consumption	50/60 Hz 115 W
PC Requirements	Operating System: Windows 2000 professional or Windows XP professional Processor: 1.7 GHz Intel Pentium III (minimum) RAM: 512 MB minimum VGA Board: High performance VGA board with at least 1024x768 resolution, 16 bit High-Speed Interface: IEEE1394 (FireWire[1] / i.LINK[2]) interface (1 port required)
Monitor Requirements	1024 x 768 minimum resolution
Applied Parts Type B:	HRC Head Rest
Protection against electric shock	Class I
Operating environmental conditions Temperature Relative humidity: Air pressure:	 10°C - 30°C / 50°F - 186°F 30% - 75% 700 hPa - 1060 hPa

WARNING:
Do not modify this equipment and do not open the housing!

6.1 Operational Environment and User Training

The intended operational environment of the device is a clinical setting, medical practice or similar location under the direction of a trained ophthalmologist or optometrist.

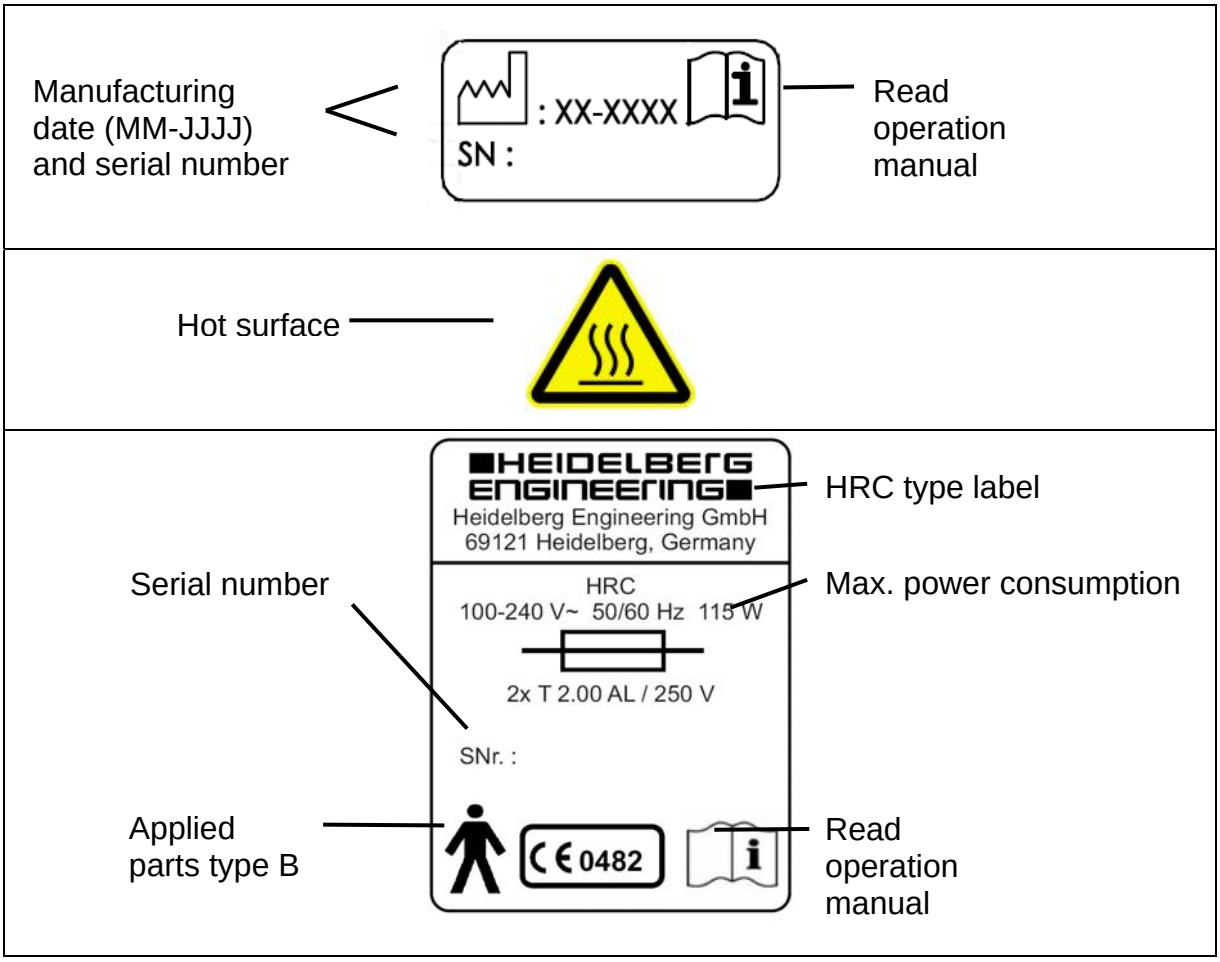
Only a qualified Heidelberg Engineering employee or authorized distributor shall initially train the user.

Heidelberg Engineering periodically offers user training courses for clinicians, researchers, physician assistants and technicians.

[1] FireWire and the FireWire symbol are trademarks of Apple Computer, Inc., registered in the U.S. and other countries. The FireWire logo is a trademark of Apple Computer, Inc.

[2] The i.LINK logo is a trademark of Sony Corporation, registered in the U.S. and other countries.

6.2 Labeling


Manufacturing date (MM-JJJJ) and serial number
: XX-XXXX
SN :
Read operation manual
Hot surface
HEIDELBERG ENGINEERING
Heidelberg Engineering GmbH
69121 Heidelberg, Germany
HRC type label
Serial number
HRC
100-240 V~ 50/60 Hz 115 W
Max. power consumption
2x T 2.00 AL / 250 V
SNr. :
Applied parts type B
CE 0482
Read operation manual