Heidelberg Retina Angiograph 2

Installation and System Configuration

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HEIDELBERG ENGINEERING

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1 General Information

1.1 The Medical Device HRA 2

The Heidelberg Retina Angiograph 2 (HRA 2) is a confocal laser-scanning device for the acquisition and analysis of retinal images of the eye. The instrument allows to acquire reflection images with infrared and blue light as well as fluorescein and ICG angiography images (even simultaneously).

1.2 The HRA 2 System

The HRA 2 cannot be used alone. The minimum system configuration consists of a HRA 2 device, a personal computer with a display (e.g. a laptop or a desktop PC with a monitor) and the interconnecting cables.

The HRA 2 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 standard 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.*

WARNING The ME system may only be assembled by qualified personnel with training and knowledge in electrical safety, heeding all instructions and safety warnings contained in this document. It is especially important that all users that de-install and reinstall the system (for example in a mobile use scheme) are trained to do this in a safe way.

For setting up a safe system it is essential to read and understand the below sections

Electrical System Configuration **and** ***Safety Information.*** **These sections summarize the standard's requirements.**

1.3 Regulatory Issues

The HRA 2 complies with the international IEC 60601 standard series concerning medical electrical equipment. These standards are published by the International Electrotechnical Commission and are the base of most national and regional standards for medical electrical equipment worldwide.

Some local standards contain deviations from the IEC versions. These standards include UL 60601-1 (USA), CAN/CSA C22.2 No. 601.1 (Canada), JIS T 0601-1 (Japan), AS 3200.1.0. (Australia) and others. *Wherever IEC 60601-Standards are mentioned inside this document, the according regulations of respective local standards are also implied.*

NOTICE Even though the HRA 2 already conforms to most local standards for medical devices in its default configuration, actual conformance can only be ensured by buying it from your authorized local Heidelberg Engineering distributor.

1.4 Safety Information

This section contains important safety information. Please read it carefully!

WARNING To avoid the risk of electric shock, the system must be installed in accordance to IEC 60601-1-1 or the corresponding local standard particularly with regard to the electrical leakage currents (see section “leakage currents”). Every modification to the system requires a new evaluation of the requirements of said standard.

WARNING If your system configuration includes a multiple socket outlet, do not place it on the floor as this entails the risk of liquid ingress or accidental mechanical damage.

WARNING Do not connect an additional multiple socket outlet or an extension cable to the system. This would lead to increased protective earth impedance and therefore to an increased risk of electric shock.

WARNING Do not connect additional devices to the system that are not part of the system or not specified as compatible to the system.

WARNING Do not use multiple socket outlets that are part of the HRA 2 system for other devices that are not part of the system (e.g. office equipment, domestic appliances). This would lead to increased electrical leakage currents and therefore to an increased risk of electric shock for both patient and operator.

WARNING Devices intended to be used together with a separating transformer (or ‘*isolating transformer*’) may not be used without that transformer. A bypass of the separating transformer may lead to excessive electrical leakage currents and therefore to an increased risk of electric shock.

WARNING Do not touch the patient and parts inside access covers or contacts of connectors of nonmedical devices simultaneously.

WARNING Carry out all cleaning, adjustment, sterilization and disinfection procedures as specified in the enclosed instructions for use of the particular system components. Refraining from that may lead to infections or to bad measurement results that again may lead to a false diagnosis.

If a multiple socket outlet is used as part of the system, it must conform to IEC 60601-1-1, in particular it must only allow connection of power cords by using a tool.

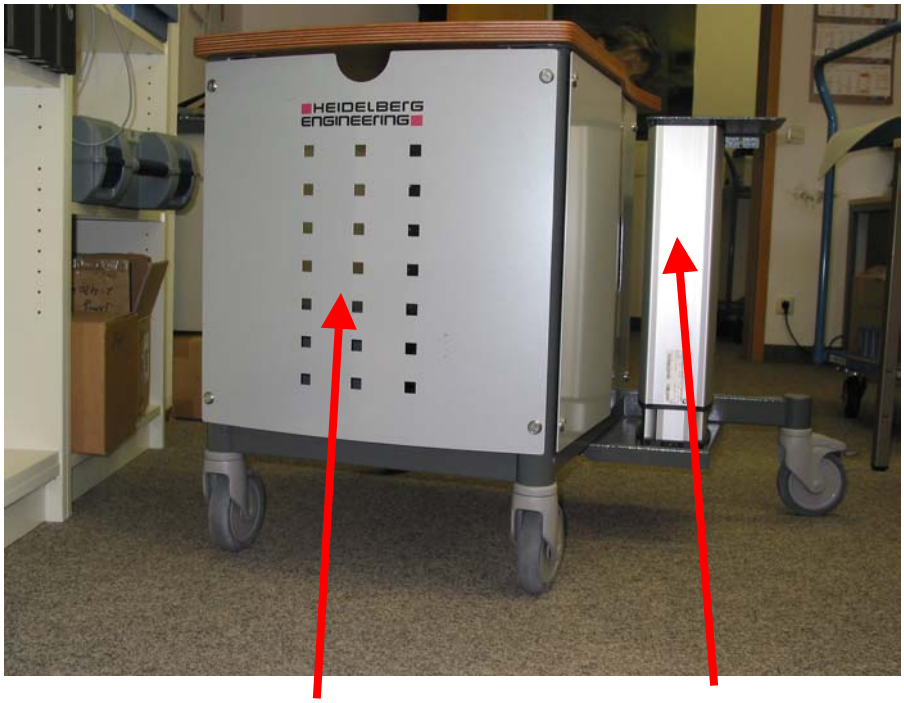
All parts of the system can be used inside the patient environment if the requirements defined in this document and in the according standards are met.

For instructions for cleaning and permissible environmental conditions, see the enclosed instructions for use of the particular system component.

2 Set-up of Lift Table

In order to allow the user for a compact but ergonomic set-up of the unit, we strongly recommend the use of an Heidelberg Engineering table, which has been optimised for the HRA2 application.

The assembly of the Heidelberg table is described on a separate sheet.



Detachable front cover held by four magnets

Lifting column

3 Unpacking the System

Top layer of the HRA2 box containing

- the documentation of your HRA2,
- an allen wrench to fasten the circular arc of the camera to the instrumentation base,
- four power line cables.

Middle layer of the HRA2 box containing

- the HRA2 power supply and laser unit,
- the HRA2 camera and the mounted cable loom (including the laser fiber) and
- the HRA2 touch panel

Bottom layer of the HRA2 box containing

- HRA2 instrumentation base,
- another power line cable,
- an isolation transformer,
- the foot switch and
- HRA2 interconnection cables, namely (PCI Framegrabber version)
    - cable touchpanel - power supply
    - cable power supply - framegrabber (PC)
    - cable power supply - RS232 (PC)

  (FireWire version)
    - cable touchpanel - power supply
    - cable Power supply – PC (FireWire)

4 Installation Instrumentation Base and Camera

4.1 Two Instrumentation base versions

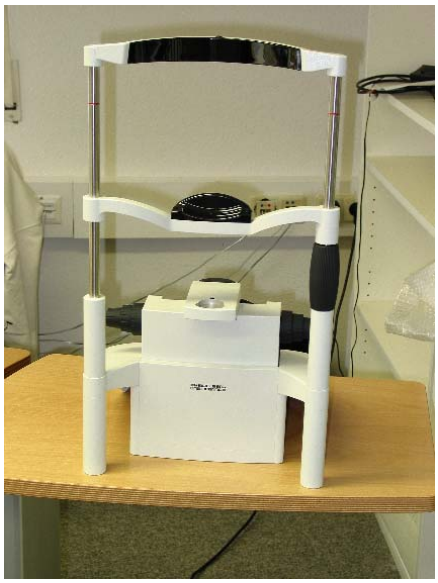
There are two different versions of the instrumentation base available:

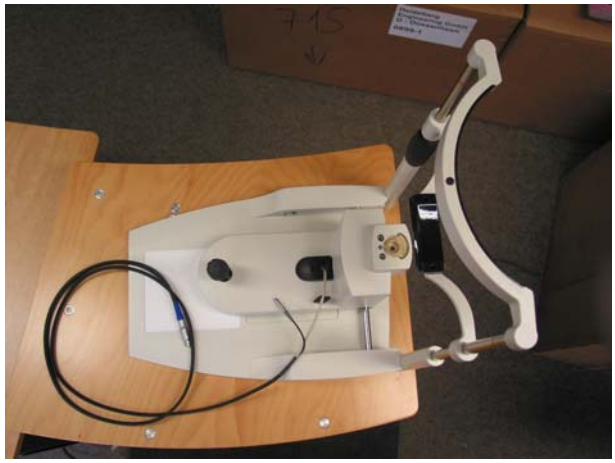
- instrumentation base with XYZ Unit (with handles for X, Y and Z fine adjustment)
- instrumentation base with joystick for operating the camera

Both versions have exactly the same threads at the same locations for mounting on the table. However the joystick version requires a wider slit in the table, as the cable looms follows the sidewise movements of the camera. Therefore actual tables can be used with both instrumentation bases, whereas older table tops with narrow slit can not be used for the joystick instrumentation base version.

Both versions have the identical mechanical interface to the circular arc guide and the camera.

Therefore in the following the common installation steps are only shown for the joystick version, however it will be stated explicitly, what needs to be considered in case of an instrumentation base with XYZ-Unit.

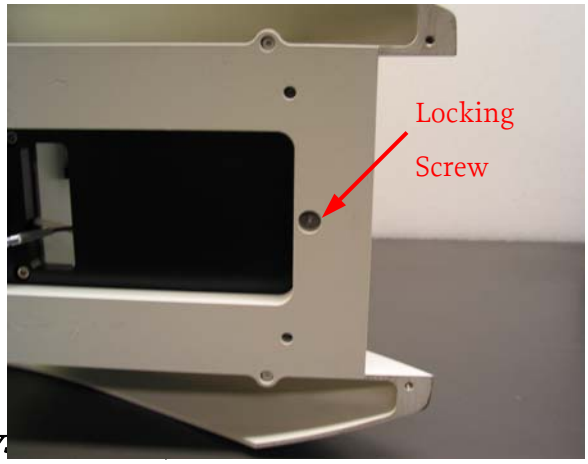




Left: Instrumentation base with XYZ unit Right: joystick version

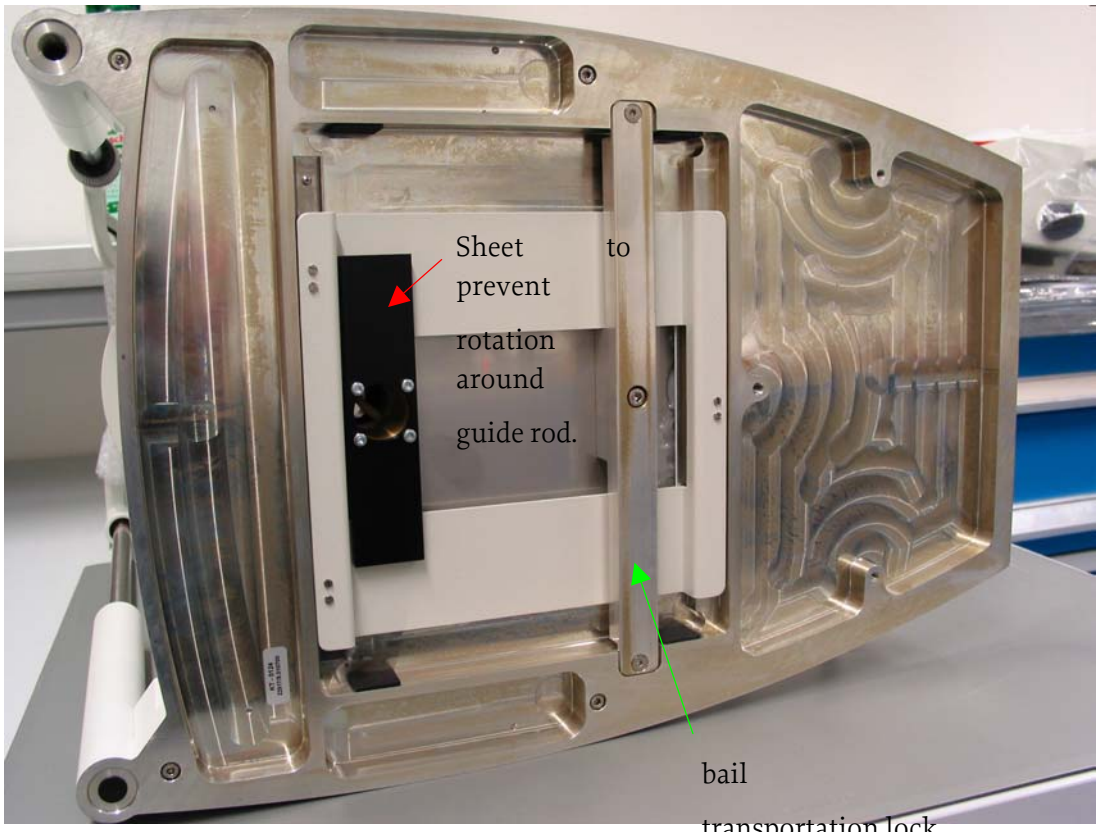
4.2 Release of transportation lock (only version with XYZ-Unit)

On the bottom side of the instrumentation base there is a locking screw, which secures the Z – slide during transportation. In order to release the transportation lock, this screw has to be released by about 4 turns (M8, 4 mm allen wrench) , until the XYZ-block can move unrestricted. The screw should be left in the thread, in order to have it always available, if the instrumentation base needs to be shipped.



4.3 Release of transportation lock (only joy

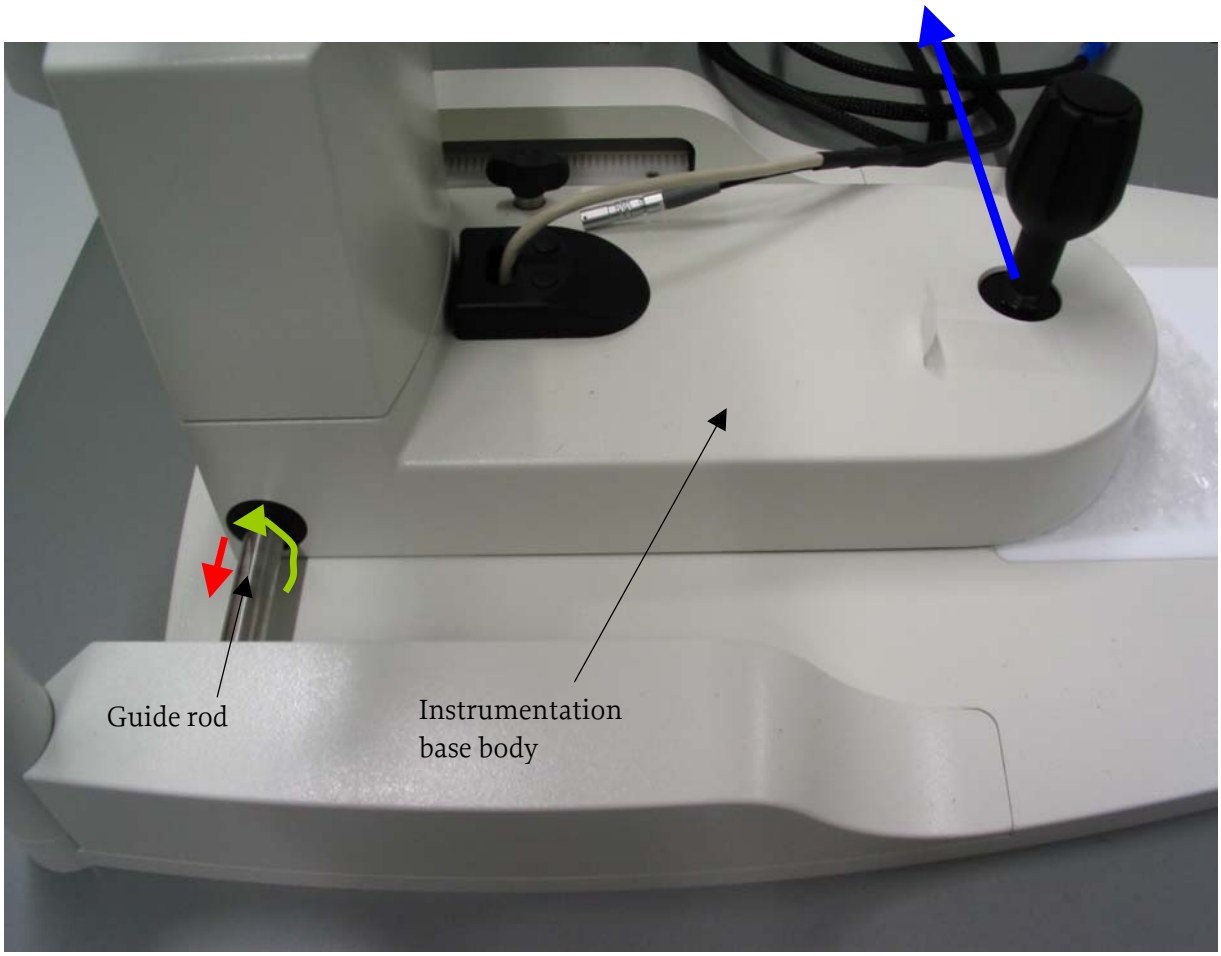
In order to make sure, that the instrumentation base is optimum protected during transportation the instrumentation base body is attached to the bottom plate via a locking bail.



Bottom side of the instrumentation base: green arrow: bail for transportation locking, red arrow: sheet to avoid rotation around guide rod.

The locking bail (green arrow) needs to be removed before installation (3 mm and 4 mm allen screw) and remounted for each transportation or shipment.

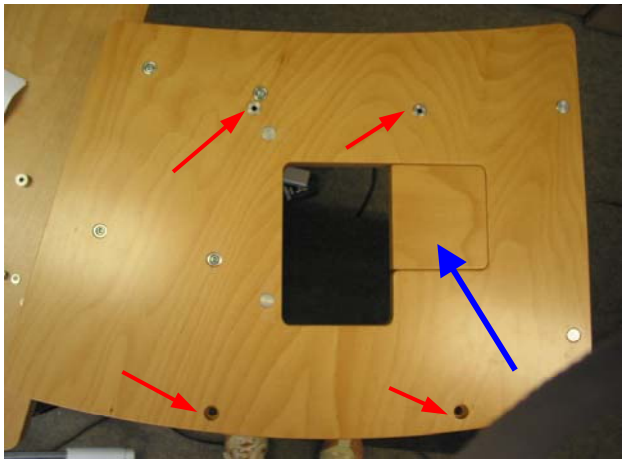
Please note, that an additional sheet is mounted, which should prevent, that the instrumentation base body can be lifted. This metal sheet remains mounted during normal use of the HRA2.
Lifting the joystick (blue arrow) leads to a rotational movement around the guide rod (green arrow) and could possibly lead to a deformation of the bottom plate in the front area (red arrow) close to the location, where the left right microswitches are mounted. This is prevented by the additional metal sheet (see figure above).



4.4 Preparation of the table top

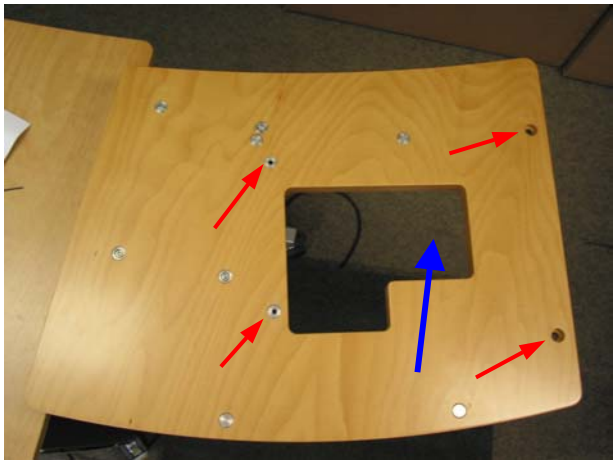
The table needs to be prepared slightly different, depending on if the camera should be operated in en-face configuration or in sidewise configuration.

En-Face configuration, where the user sits opposite to the patient, behind the camera

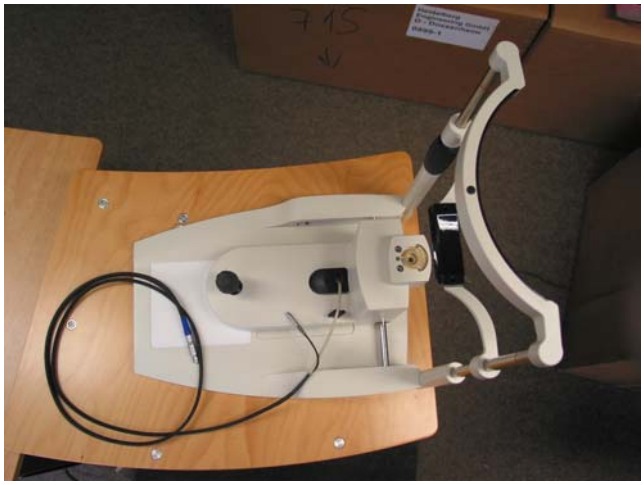


Red arrows are pointing on the holes for mounting the instrumentation base from below.

Sidewise configuration, where the user sits at the side of the angiography system

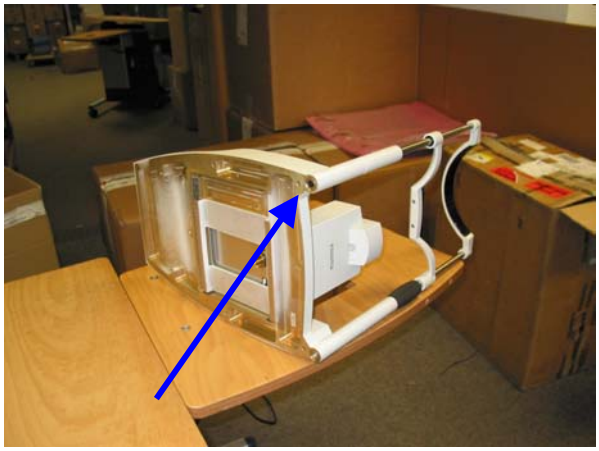


Blue arrow is pointing on a table top element, which is left in the table in the en-face configuration, but has to be removed (6 screws from below) for the sidewise configuration.

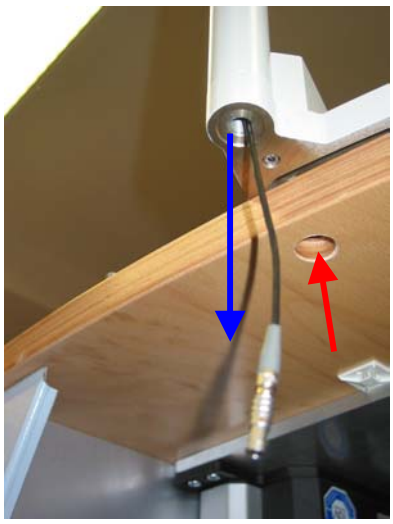


4.5 Cable External Fixation Target

All instrumentation bases delivered before summer 2005 are not equipped with an external fixation target, although they are already prepared for being upgraded in future. The cable for the external fixation light is guided inside the left post (patients view) up to the head rest.



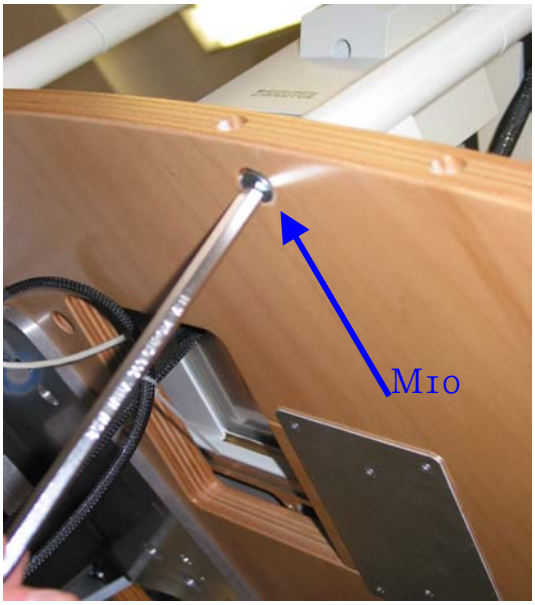
To assemble the cable for the external fixation light remove the black cap from the inside thread of the headrest foot (see blue arrows). Then take for example a tweezers to get the cable out of the head rest foot. (see picture below). Now move the cable through the drill hole in the table where the instrumentation base must be fixed. (see red arrow).

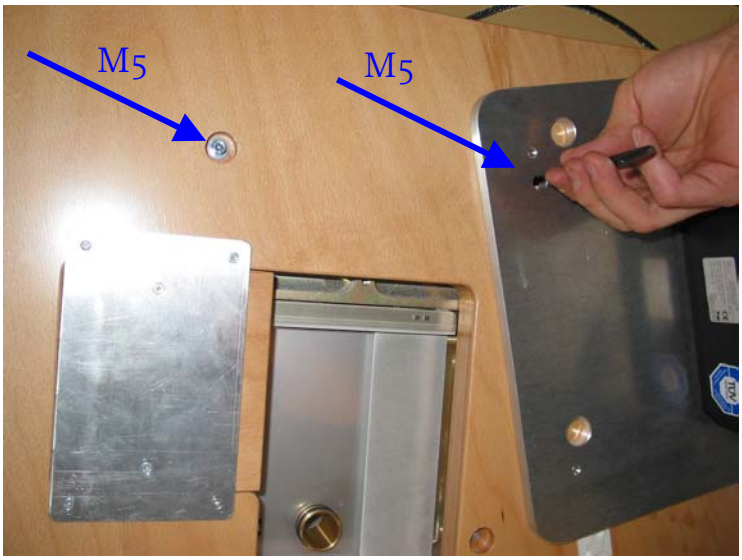


For the fixation of the instrumentation base push the cable through the drill hole of the screw and fix the left foot of the instrumentation base (See pictures above)

4.6 Fixation of the instrumentation base

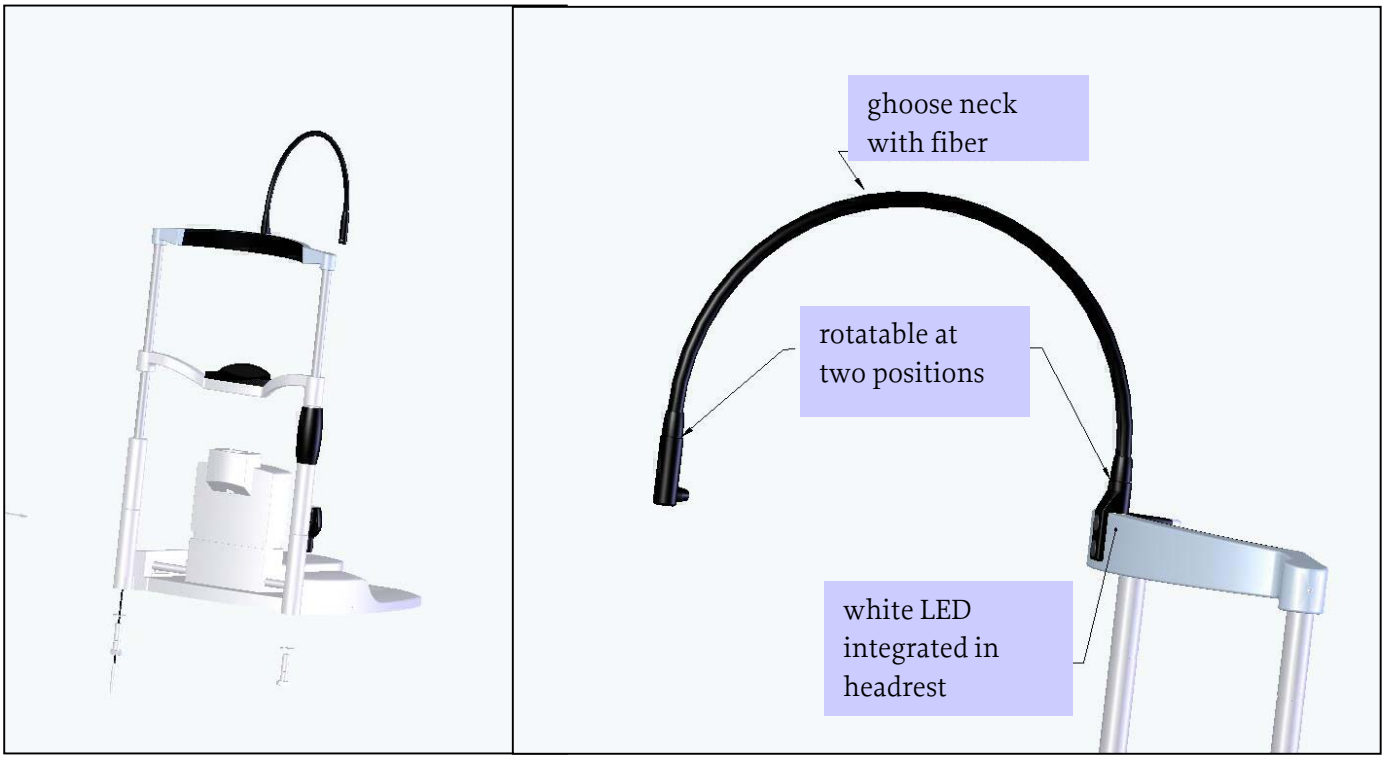
The instrumentation base is now screwed down with the second M10 screw (right post) and 2 x M5 screws.



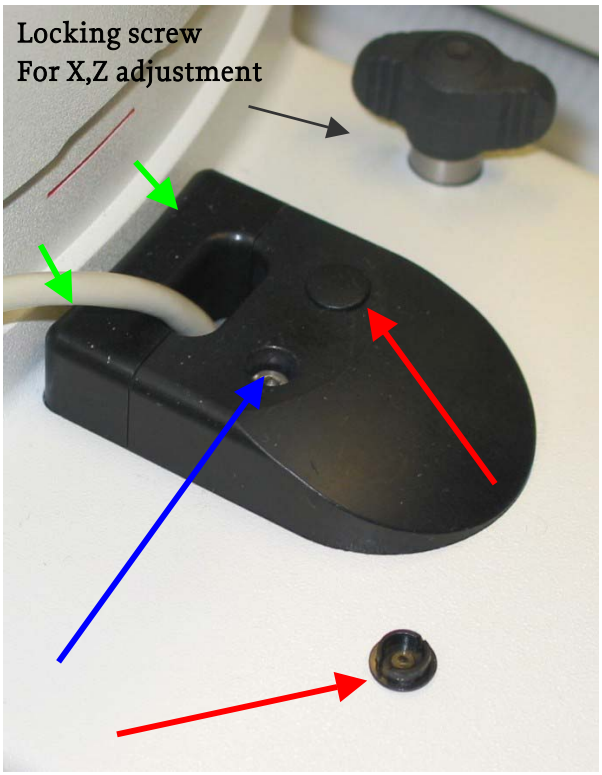


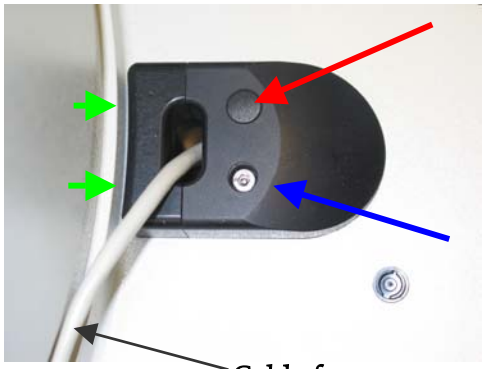
4.7 Mounting the external fixation light

The ghoose neck fiber is attached to the adapter at the head rest.



4.8 Disassembly Cable Mount (only joystick version)



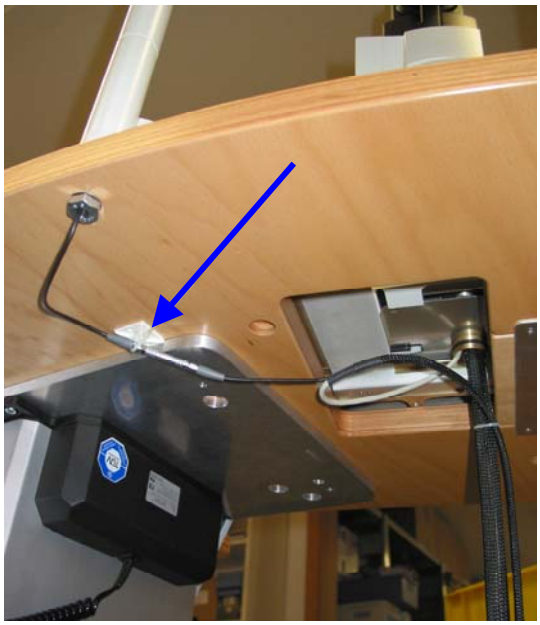


Open the cable mount as follows:

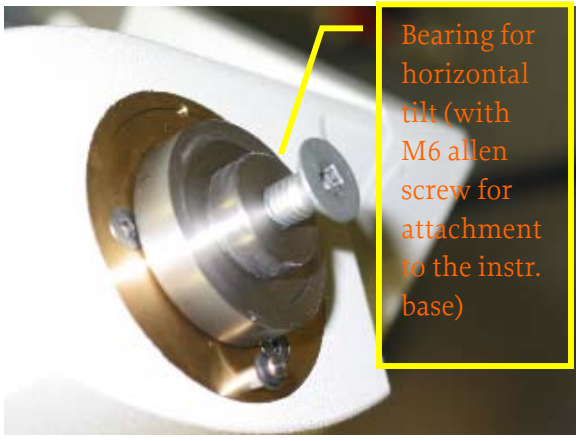
- Remove the black plastic caps (red arrows)
- Remove the two screws (blue arrows)
- The cable mount can be tilted now in order to have access to the 2 screws, holding the cable mount together. (green arrows)
- Remove the cable mount completely.

The cable for the left/right eye detection (which is configured at one side with a blue marked ODU connector and which splits on the other side into the left/right eye detection cable and into the voltage supply for the external fixation target) is launched through the cable tube.

If the instrumentation base is equipped with an external fixation target, connect the two cables below the table and attach the connectors with a cable binder below the table (blue arrow), in order to avoid, that a patient could detach by accident the cables with his knees. However, you have to make sure, that the free movement range of the camera is not hindered by the cable binder fixation.



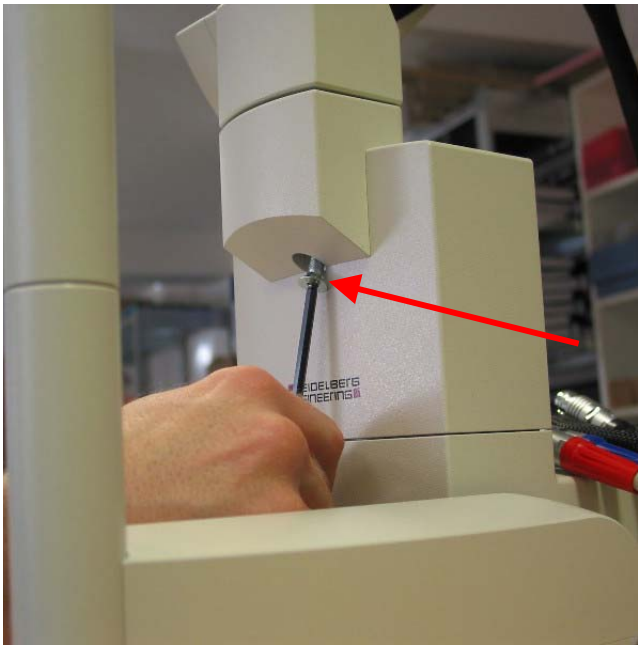
4.9 Mounting the camera head



The camera head should remain always attached to the circular arc guide. (see left image).

As mentioned above, the mechanical interface is the same for both versions of the instrumentation base.

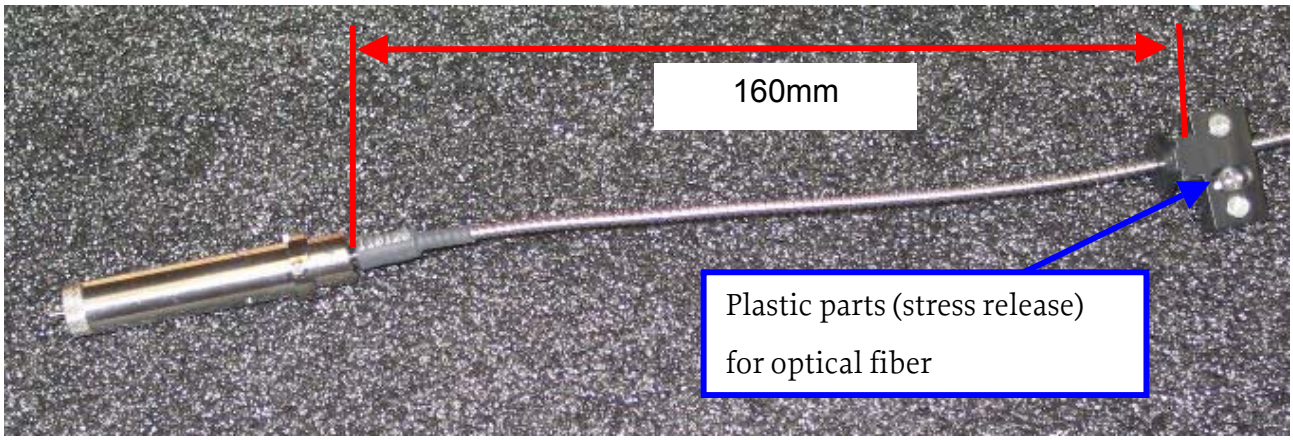
- Remove the M6 screw from the rotational bearing at the bottom of the arc guide
- mount the camera unit onto the instrumentation base
- screw in again the M6 allen screw
- Tighten the screw in order to secure the camera mounted on the instrumentation base.



HRA2 camera unit mounted on a joystick instr. base (left) and an inst. base with XYZ-unit (right).

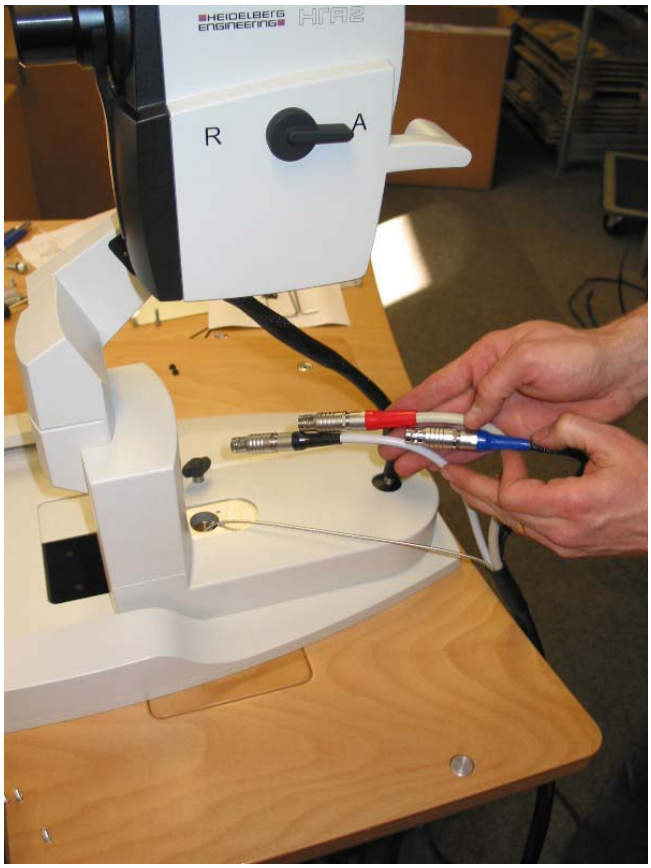
4.10 Launching the cable loom (only joystick version)

.In the next step the complete cable loom has to be launched through the cable tube. First the optical fiber is launched through the tube. Therefore the plastic parts (stress release) for attaching the fiber to the power supply housing need to be removed, as they do not fit through the cable channel. Please mount them after launching the fiber through the cable tube at the same position i.e. at a distance of 160 mm from the fiber coupler.



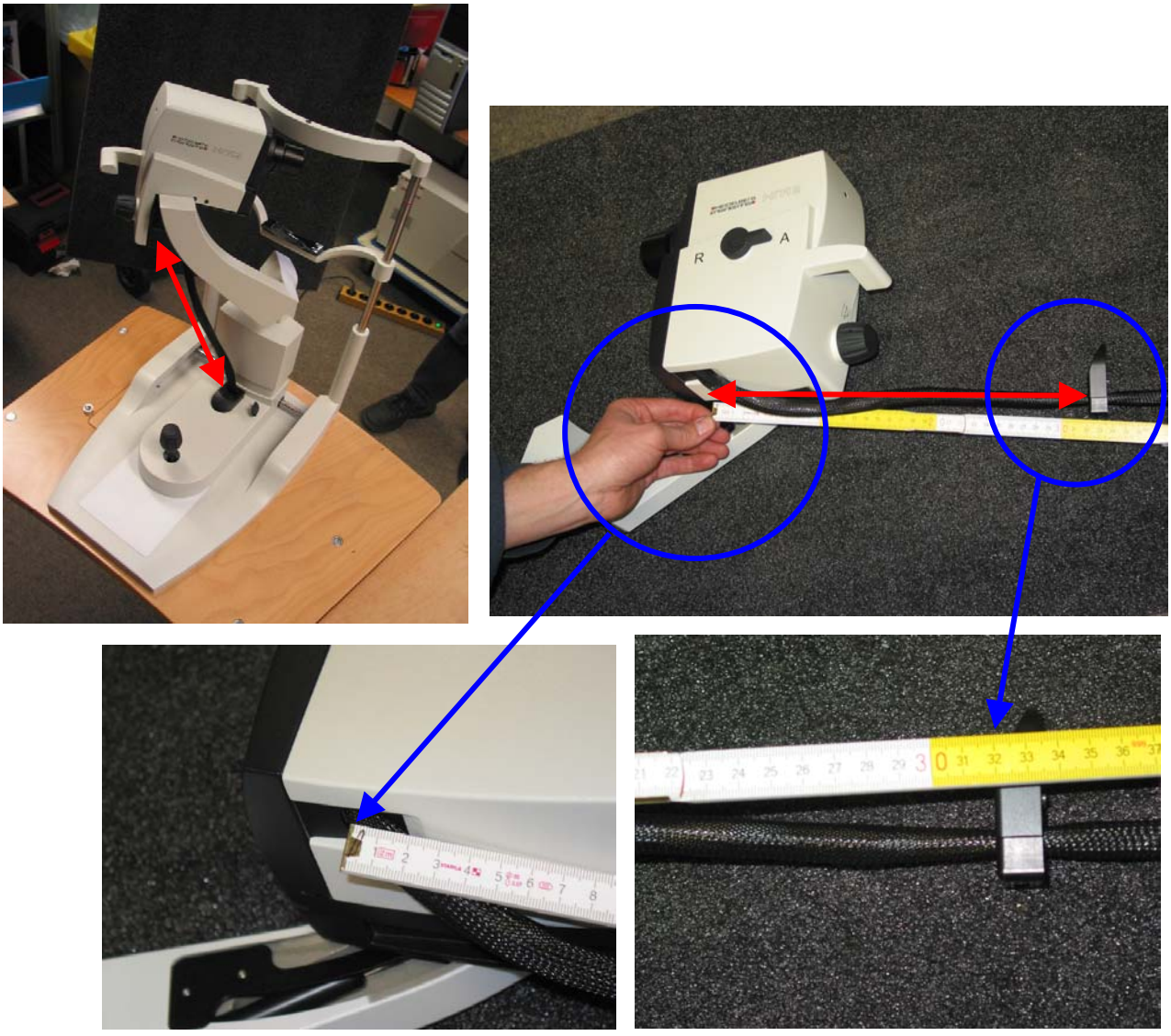
The fiber is launched through the cable tube (see images below)

Finally the three connectors are launched through the cable channel. It is recommended to arrange them as shown on the images: first the black connector, then the red and finally the blue connector.



4.11 Reassembly of the cable mount (only joystick version)

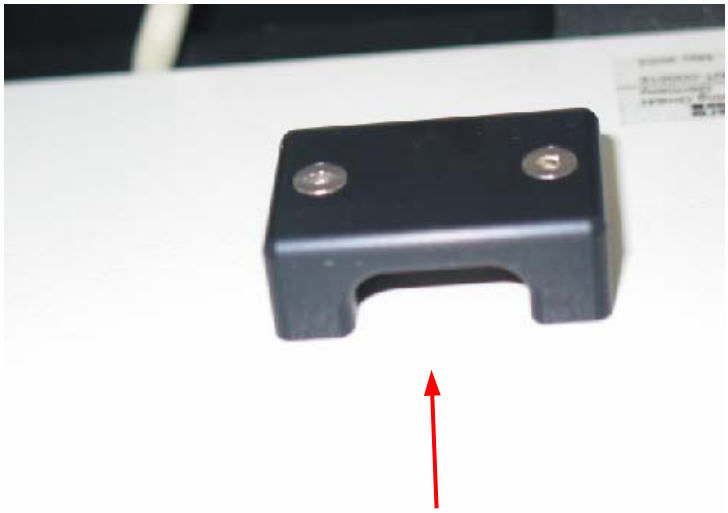
The cable mount is reassembled in a way, that it squeezes softly the cable loom in a distance of minimum 320 mm measured from the camera head. It is important, that the movement range of the camera is not reduced due to a limited cable length. On the other hand, it is advantageous to keep the cable length above the table as short as possible. Please check after screwing down the cable mount, that also the extreme position (photo below) can still be reached.



4.12 Stress release for cable loom (only version with XYZ-unit)

In the case of the XYZ-unit instrumentation base, the cable loom is just launched through the slit between XYZ-block and the home position of the touch panel.

The cable loom is fixed with a cable bracket against the XYZ-block. Again it should be checked, that the free cable length is sufficient in order to allow the user to reach also the extreme positions for optimum adjustment of the camera.



Cable loom

4.13 Cable loom below table

The cables can now be launched though the vertical slits next to the lifting column. (see right photo). It should be tested, that the cable is not squeezed or under stress, when the table is moved to itś extreme positions.

5 Electrical System Configuration

The HRA 2 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 HRA 2 is connected to a desktop computer, the computer is connected to a printer (via USB or WLAN). All devices are connected to an separating transformer. An electrical table is also connected to the separating transformer. In this case, the "ME-system" consists of all devices: HRA 2, desktop computer, printer, table and transformer.

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.

5.1 Leakage Currents

The main concern for patient safety is the unintentional presence of accessible harmful electrical currents (*leakage currents*). Medical devices must show much lower leakage currents than ordinary office equipment.

Leakage currents are classified as follows:

- ***Earth leakage current*** is the current flowing from mains through or across the insulation into the protective earth conductor.
- ***Enclosure leakage current / touch current*** is the current flowing from accessible parts of the enclosure through an external part (*other than the protective earth conductor*) to earth or another part of the enclosure.
- ***Patient leakage current*** is the current flowing from patient connections through an applied part and from there via the patient to earth (applied parts of the HRA 2 are chinrest and headrest).

The permissible leakage currents are summarized in the following table:

[Current in mA]	Normal condition	Interrupted prot. earth conductor	Interrupted neutral conductor
Touch current between parts of the system*	0.1	0.5 *(0.3§)*	-
Touch current of each device* separately	0.1	0.5 *(0.3§)*	0.5 *(0.3§)*
Earth leakage current of each device	0.5 *(0.3§*+)*	-	1.0
Earth leakage curr. in multiple socket outlet	0.5 *(0.3§*+)*	-	1.0
Patient leakage curr. AC (type B appl. part)	0.1	0.5	0.5
Patient leakage curr. DC (type B appl. part)	0.01	0.05	0.05

**Inside the patient environment.* §*Deviation USA.* +*Only if conductive surfaces inside the patient environment exist that are likely to be contacted by patient or operator*

5.2 Mains Power Connection

The following options for a safe system configuration (conformant leakage currents) exist:

a) **Separation Transformer (recommended).** A separation transformer is used to reduce leakage currents that are too high. Connect devices with excessive leakage currents to the mains power over the transformer.

b) **Multiple wall sockets.** All devices (e.g. HRA 2, PC with monitor/computer, printer, table) are connected to separate power sockets on the wall. This is the optimal configuration to reduce the risk of electrical shocks and leakage currents, but has the disadvantage that an appropriate number of wall sockets must be installed. In this configuration it is especially important to check the electrical installation: ***No significant potential difference must exist between the different protective earth terminals***.

c) **Multiple socket outlet.** All devices (e.g. HRA 2, PC with monitor, printer, table) are connected to a single multiple power socket outlet. In this case, the multiple socket outlet must conform to IEC 60601-1-1, in particular it may only allow connection of power cords by using a tool. The multiple socket outlet can be part of the table, but can also be a separate device. Below is an example of an IEC 60601-1-1 conforming multiple socket outlet with 4 receptacles:

Example of a medical multiple socket outlet open and closed (*POPP Powerline Medica*)

d) **Fixed protective earth conductor.** If the touch current of a device is too high, it can be decreased by the connection of an additional protective earth conductor. This conductor must be fixed to both the device in question and to the mains protective earth conductor. The connection must only be detachable by use of a tool.

e) **A combination of the above.** Also a combination of configuration a), c) and d) can be in conformance with IEC 60601-1-1 (e.g. HRA 2 is connected to a wall power socket, all other devices (e.g. laptop and printer) are connected using a multiple socket outlet). This configuration might be necessary to reduce the systems electrical leakage currents (see section leakage currents below). Any multiple power socket outlet must meet the criteria mentioned under configuration c).

WARNING Always make sure that the local electrical installation is conforming to the applicable local safety standards for medically used rooms (e. g. VDE 0700-710, JIS 1022...). The electrical installations should be checked in regular intervals (this is legally required in some countries).

WARNING For countries with regulations according to UL 60601-1, only use power plugs and sockets marked “hospital only” or “hospital grade”. Additionally plugs and receptacles must meet the requirements of UL 498. A violation may lead to an increased risk of electric shock due to a decreased earthing reliability.

5.3 Electromagnetic Compatibility

Make sure that only cables delivered with the HRA 2 or as specified in the HRA 2 installation manual are used to connect the HRA 2 to other system components. Make sure that all system components comply with their respective electromagnetic compatibility standards.

CAUTION The usage of improper cables can lead to increased electromagnetic emission and/or decreased electromagnetic immunity possibly leading to malfunction of the HRA 2 or other close-by devices.

5.4 System Conformance

When the system is set up, the organization or person that assembled the system must declare conformance of the system to IEC 60601-1-1 and/or further applicable local laws and standards.

Conformance to the aforementioned standard requires setting up a list with all system components. To meet this, please fill out the table below or add a separate sheet with the list of system components. Additionally the accompanying documents of each system component must be enclosed and the maximum permitted load of each multiple socket outlet must be specified.

5.5 List of System Components

The medical electrical system containing the HRA 2 was first set up on _____ *(date)*

It consists of the following components:

Component / Model	Serial Number	Comments
Heidelberg Retina Angiograph 2		

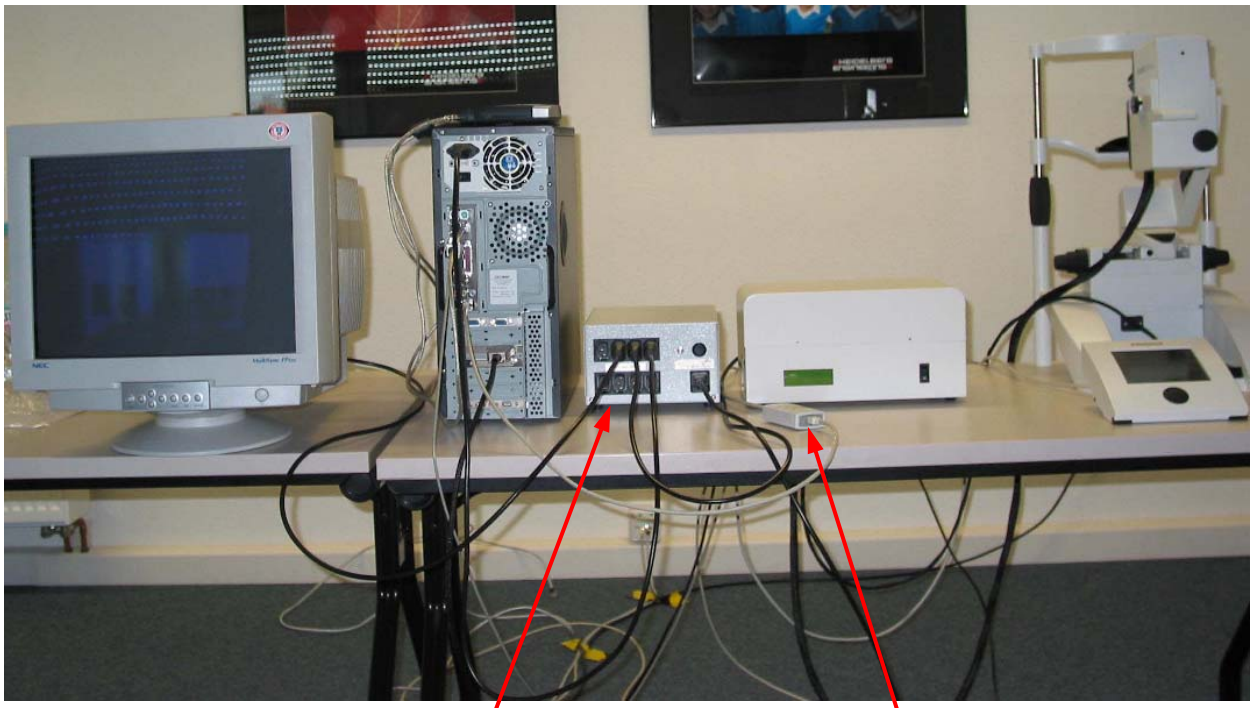
Multiple Socket Outlet (if not using a separation transformer)	Serial Number	Maximum load [VA]	Comments

Comments: _____

_____

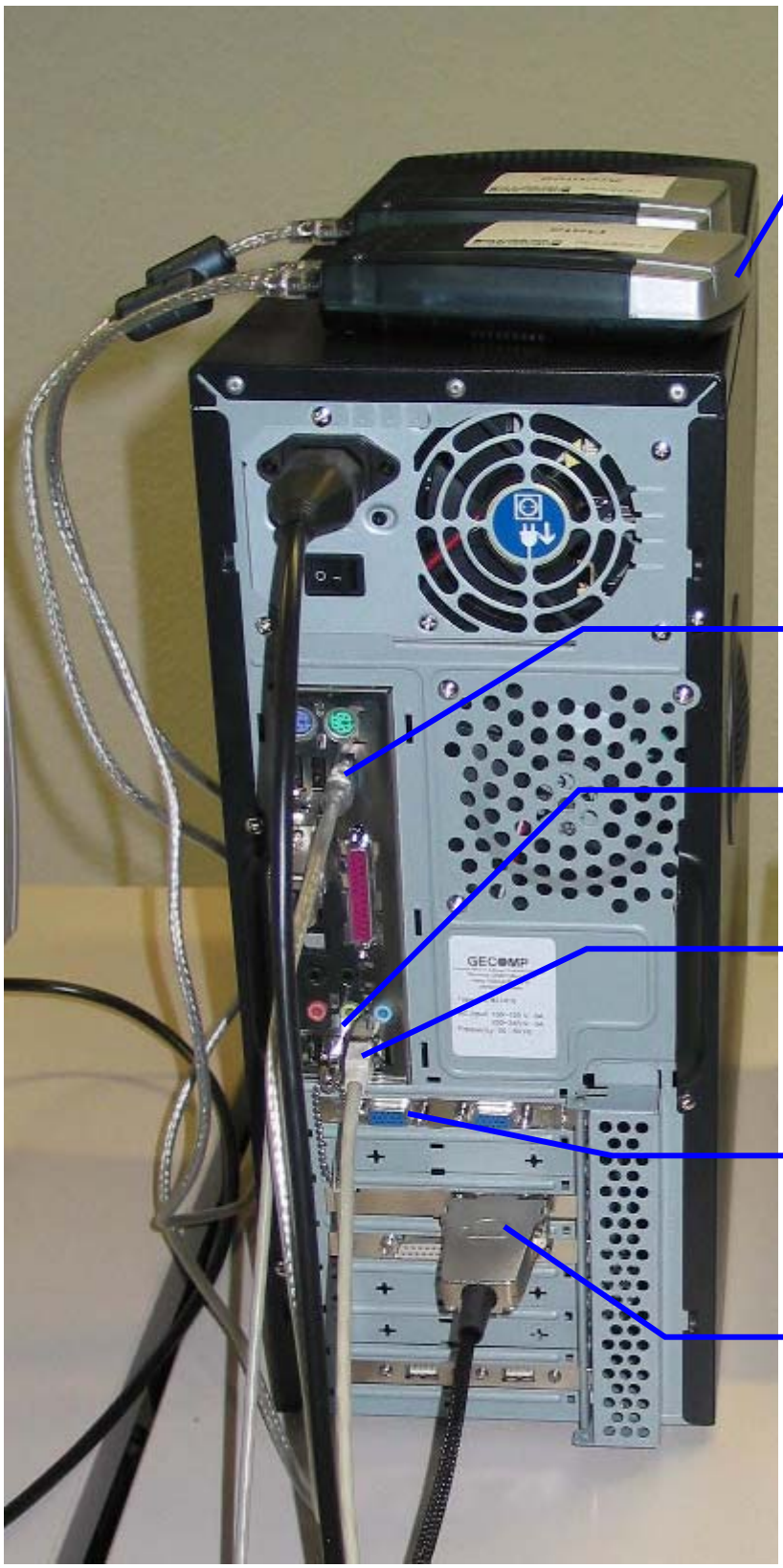
6 Attachment of the electrical cables

6.1 Cabling of the HRA2 (version with Frame Grabber)



HRA2 Power supply, PC, Monitor, Printer etc. connected to the Isolation

Network Isolator (if the PC is connected to a network)



External Hard disks (Data and Archive

Fire Wire connector connected to external Hard disk

HRA2 USB- Software Dongle

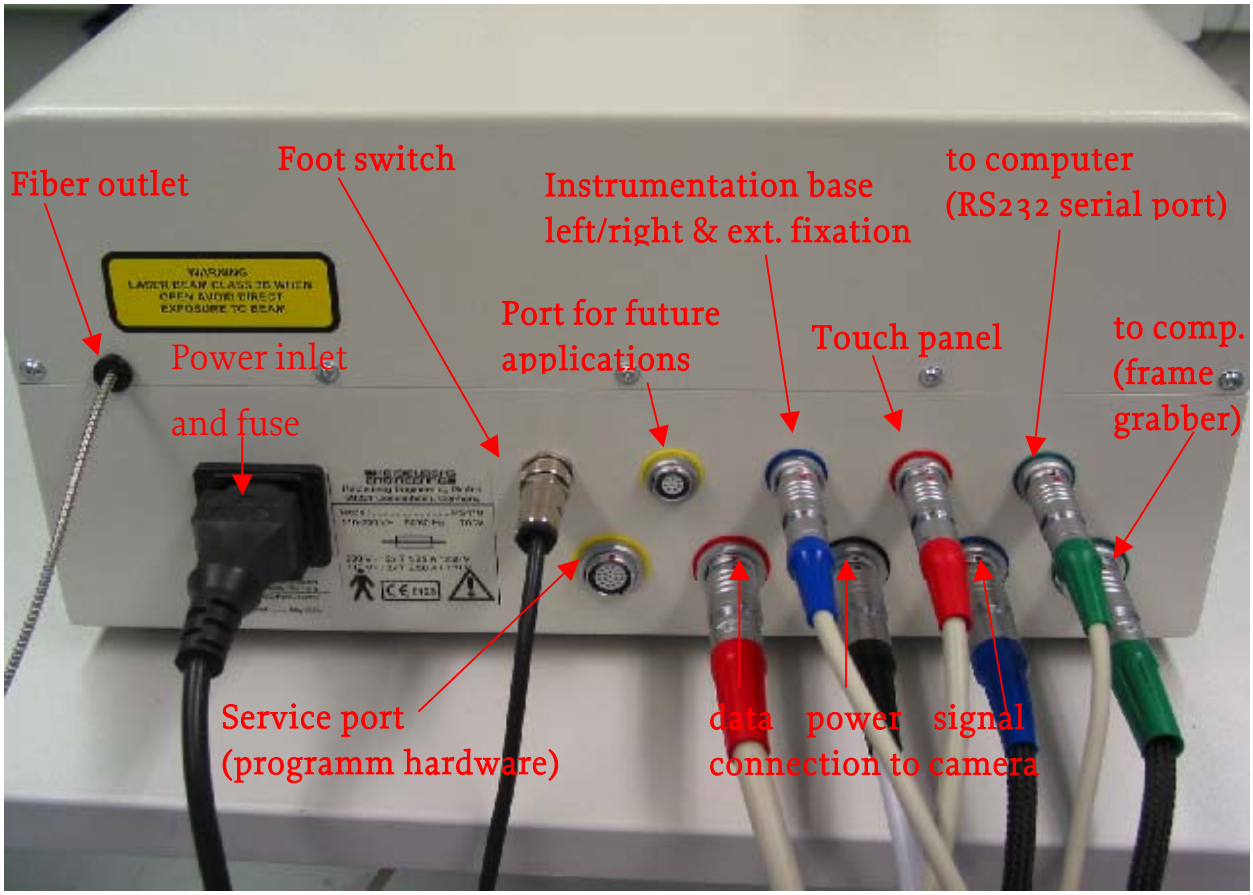
Network connector goes to the network

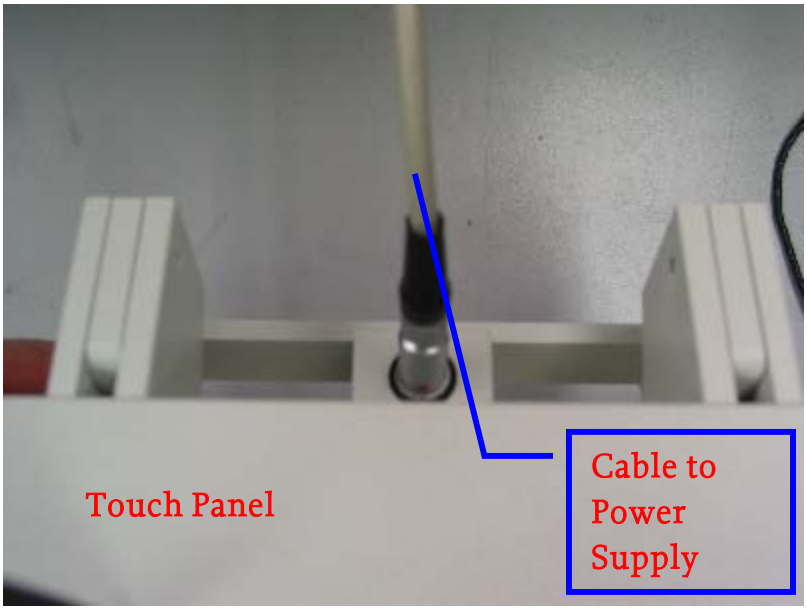
To be connected with Power Supply serial port

Framegrabber cable to HRA2 Power Supply

(not in HRA2 with FireWire)

Attach the connectors from the camera cable loom to the appropriate ports (red, black, blue) at the power supply box. Attach the cables to the touch screen panel (red), to the instrumentation basis (blue), to the frame grabber (green) and to the serial port of the computer (green). Attach the foot switch cable.



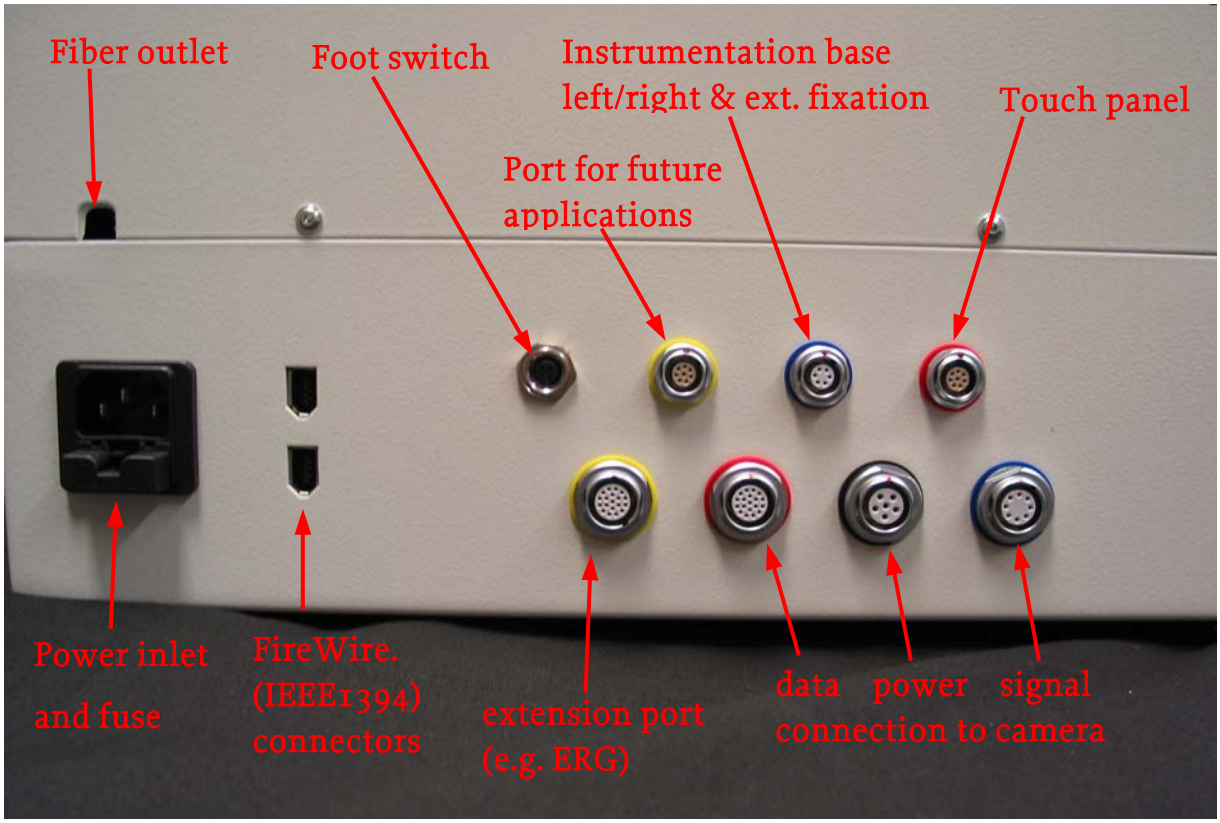


6.2 Cabling of the HRA2 (version with FireWire)

The cabling of the system is unchanged except for the following:

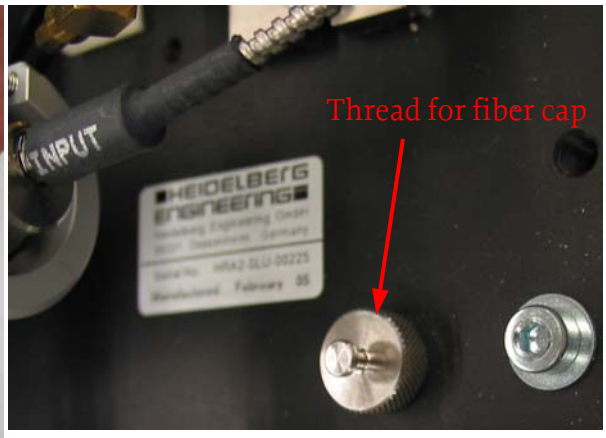
Instead of the Frame Grabber and RS232 cables (cables with green connectors) the HRA2 (version with FireWire) is equipped with two FireWire (IEEE 1394) connectors. One of them has to be connected to the FW interface of the computer the other one is provided for the hard disks (daisy chain).

Note: The external hard disks can also be connected to a second FireWire port of the computer. However, laptops usually do not provide electrical power at the FireWire interface. Therefore external hard disks without intrinsic power supply have to be connected to the HRA2 power supply and not to the laptop.



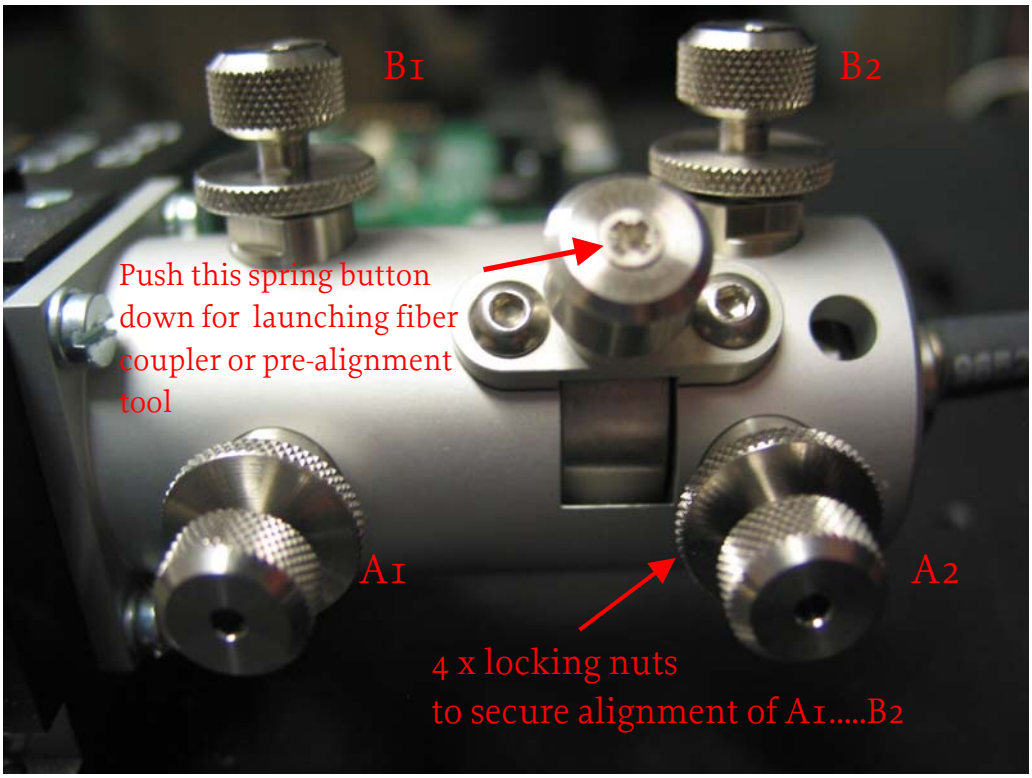
7 Installation of the Fiber

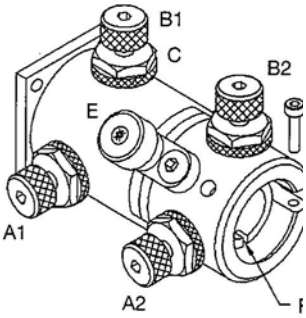
1. Remove the cover of the power supply box .
2. Remove the threaded fiber cap from the cylindrical fiber coupler. Screw the fiber cap into the provided thread in order to have it always available, if the unit needs to be shipped.

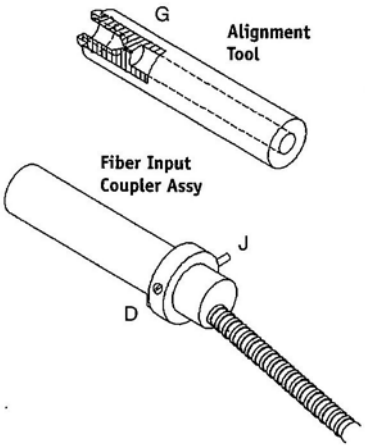


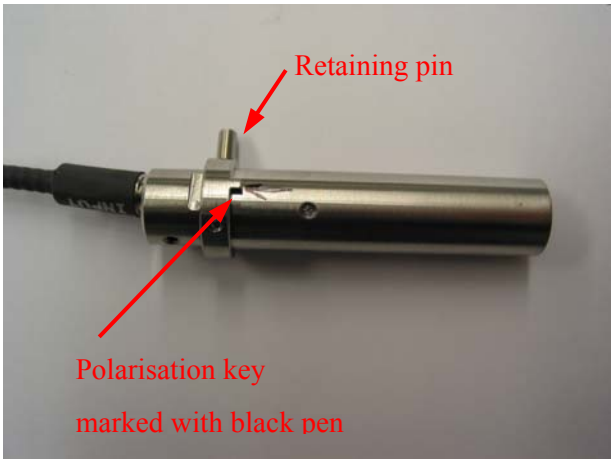
3. Push the spring button in order to launch in the fiber optics. Make sure, that the polarisation key fits properly into the polarising key-way. The button can be released as soon as the fiber is properly positioned. Once the fiber is positioned, the 4 screws can be aligned in a wide range without readjusting the preload tension. However, usually after shipment only very slight readjustments of A1 and B1 are required, often the specified output power values are obtained without any readjustment.

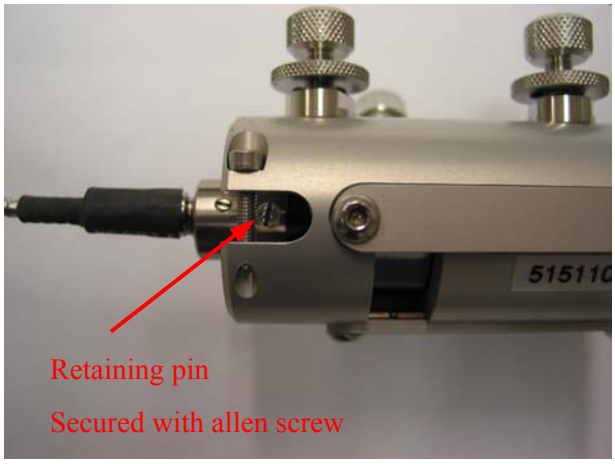
Please note: Usually small adjustments of the alignment screws A1...B2 can be done without loosening the locking nuts.



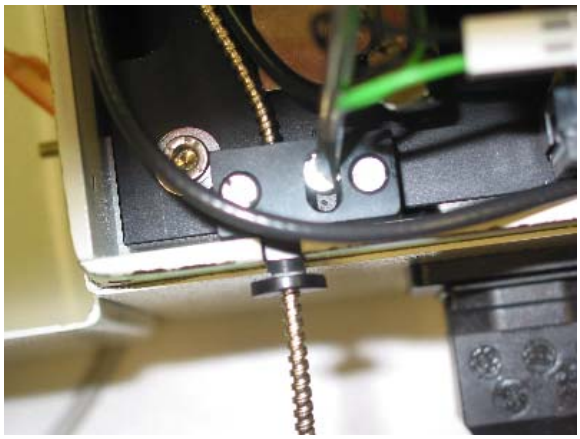






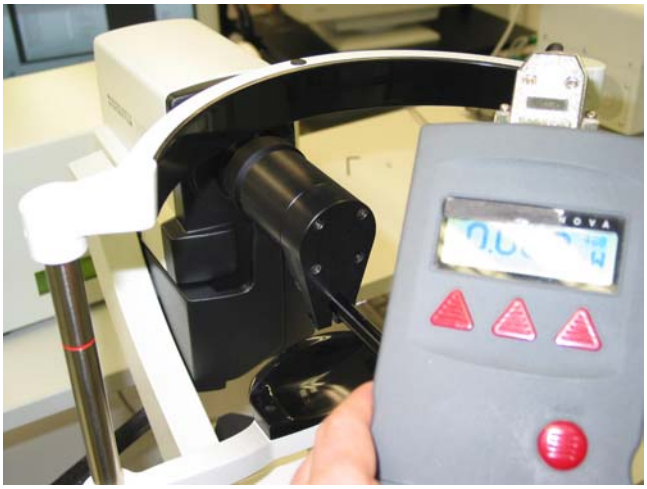


4. Fix the fiber at the housing outlet by mounting the fiber strain relief.



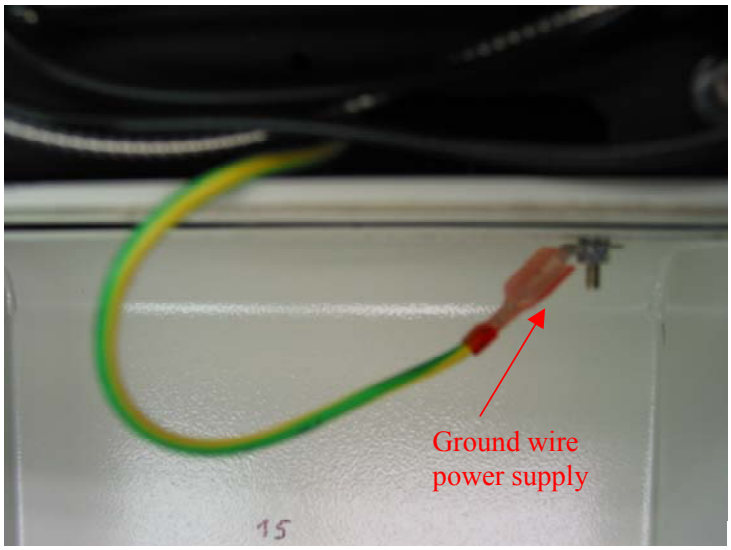
5. Start the HRA2 system and the computer, open the acquisition module, and wait until the message *warmup* on the LCD at the power supply is replaced by *no error*. Then switch to Live-Mode and select fluorescein angiography (FA) mode. Some blue light should be visible at the camera objective.

6. Mount the Ophir-Powermeter (with the special HRA2-Adapter) on the camera objective. Select the wavelength 488 nm and the range max. 3 mW. Measure the laser output by using the average procedure. For the alignment procedure we recommend to use the Heidelberg Engineering TSE-sensor equipped with an special HRA2 adapter fitting on the HRA2 objective. The TSE sensor significantly facilities the adjustment procedure, as the reading of the sensor is less affected by the fluctuation due to laser modulation. However, the TSE-sensor is not calibrated and can be used only for relative power measurements and for adjustment procedures. For the final power check during installation a calibrated Ophir power meter is absolutely required.
   Please note: If the TSE sensor is not available, the adjustment can be done with the Ophir laser power meter in the "Tune"-Mode in order to reduce the fluctuations on the display due to the modulation of the laser.



7. Optimise the fiber coupling by aligning the adjustment screws B1 (vertical tilt) and A1 (horizontal tilt) of the manipulator to maximum laser output at the objective in FA-mode (30° HR-mode at 0 diopters). Compare the measured values with the data given on the datasheet delivered with each system. If the power values are not reached, a control of the translation adjustment in horizontal and vertical direction of the fiber coupler has to be done. Refer to the service manual for a detailed description of this procedure.

8. Close the cover (without screws) and make sure, that the ground wire is properly attached to the cover housing. Close the cover with the allen screws (wrench size 2.0). Recheck after about 30 min. the laser power in Fa mode.



9. Check the laser power in the following modes:
    1. FA mode, 488 nm, high resolution mode, 30° field:
    2. ICG mode, 790 nm, high resolution mode, 30° field, laser intensity 100%
    3. IR-Refl. mode, 790 nm, high resolution mode, 30° field, laser intensity 100%

    Compare the measured values with the power values given on the data sheet for the unit. Document the values on an installation protocol and fax this protocol to Heidelberg Engineering.

8 PC Requirements

HRA 2 with PCI Framegrabber board and COM port interface

Operating System	Windows 2000 professional or Windows XP professional
Processor	2 GHz Intel Pentium or AMD Processor
RAM	512 MB minimum
VGA Board	High performance VGA board with DVI interface for up to 1600x1200 resolution (e.g. ATI Radeon 8500 or better)
Framegrabber	HE framegrabber (same as for HRT II system), requires 1 PCI slot
Ports	1 serial COM port required
High-Speed Interface	IEEE1394 (FireWire / i.LINK) interface controller
Internal hard disk	40 GB hard disk (for operating system and HRA 2 software only!)
Patient data storage	external FireWire hard disk (> 200 GB)
Archive data storage	2nd external FireWire hard disk (same size as data disk)

HRA 2 with IEEE1394 (FireWire, i.LINK) interface

Operating System	Windows 2000 professional or Windows XP professional
Processor	2 GHz Intel Pentium or AMD Processor
RAM	512 MB minimum
VGA Board	High performance VGA board with DVI interface for up to 1600x1200 resolution (e.g. ATI Radeon 8500 or better)
High-Speed Interface	IEEE1394 (FireWire / i.LINK) interface controller
Internal hard disk	40 GB hard disk (for operating system and HRA 2 software only!)
Patient data storage	external FireWire hard disk (> 200 GB)
Archive data storage	2nd external FireWire hard disk (same size as data disk)

Monitor:

Technology

TFT (recommended), connected by DVI:

- 19 “ Iiyama AU 4831D
- 20 “ Viewsonic VP 201m

CRT:

- 21 “ high quality monitor

Resolution: 1600 x 1200 pixels required

9 PC- Hardware Installation (HRA2 with PCI Framegrabber board)

The following board has to be installed in the PC for the operation of the Heidelberg Retina Angiograph 2 (HRA 2):

- Matrix Vision frame grabber PCimage-SG (PCI), attach the HRA 2 video cable to the framegrabber board.

In addition, attach the HRA2 via cable to the serial interface (COM1 or COM2).

9.1 Frame grabber installation

9.1.1 Hardware Installation

1. Turn off the computer.
2. Remove the cover from your computer and insert the Matrix frame grabber into a free 32-bit PCI slot.
3. Secure the board in place at the rear of the system unit using the screw removed from the slot cover.

9.1.2 Driver Installation

Since the board is a Plug-and-Play card, Windows will automatically detect this board during the first boot sequence after the installation of the board. The following describes the procedure to install the device driver.

9.1.2.1 Windows 2000/XP

1. Turn on the computer and wait until Windows starts. Windows will detect that a new hardware (PCI Multimedia Device) has been installed in the system.
2. Wait until Windows' "Add new hardware wizard" comes up and follow the instructions on the screen.
3. Insert the "Heidelberg Retina Angiograph 2" CD-ROM into the CD-ROM drive.
4. In the following dialog box select "Search for the best driver for your device" and click on "Next".
5. In the next dialog box ("Search location") check the "CD-ROM drive" option and click on "Next".
6. The hardware wizard will now recognize the driver location (MVSG32.INF) and copies the appropriate files from the diskette to hard disk.
7. Finish the hardware wizard and reboot the system.
8. After a successful driver installation you will find the driver "PCimage-SG MV Win32 Driver" in Windows' device manager under "Sound video and game controllers".

9.2 Video board configuration

The HRA 2 acquisition software requires a specific configuration of the computer video board (VGA). The software will only work appropriately with the following settings (go to Windows control panel, Display, Settings):

1. Video resolution 1600 x 1200 pixels
2. Color depth of 16, 24 or 32 bits (32 Bits recommended)
3. Large fonts (which is 125 % of normal size, 120 dpi) (go to "Advanced" to be able to change the font size)

10 PC- Hardware Installation (HRA2 with FireWire interface)

If the computer is equipped with a standard IEEE1394 (FireWire, i.LINK) interface, no extra hardware must be installed to the computer for the operation of the Heidelberg Retina Angiograph 2 (HRA 2) with FireWire interface.

Switch on the Heidelberg Retina Angiograph 2 (HRA 2) hardware and connect it to the computer using the supplied FireWire cable. Then switch on the computer and wait until the Windows operating system has been started up.

10.1 Driver Installation

At the first installation of the Heidelberg Retina Angiograph 2 device, the appropriate driver has to be installed. Because the HRA 2 is a plug & play device, the Windows hardware installation wizard will be started automatically.

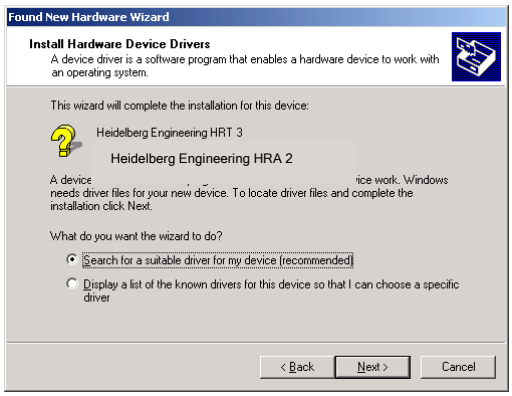
Windows 2000: Click on “Next” to start the installation.

Windows XP: The installation wizard offers to connect to the Windows Update Web Site. Select “No, not this time” and click on “Next” to continue.

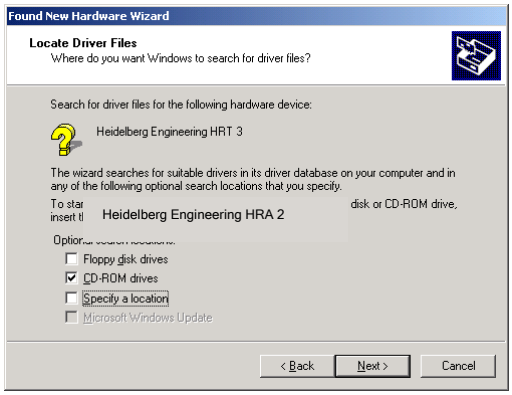
Insert the CD ROM labelled “Heidelberg Retina Angiograph 2” into the CD drive and select

on Windows 2000: “Search for a suitable driver for my device (recommended)”. Click on “Next” to proceed with the next step.

on Windows XP: “Automatic software installation (recommended)” Click on “Next” and Windows will automatically install the driver from the CD ROM.

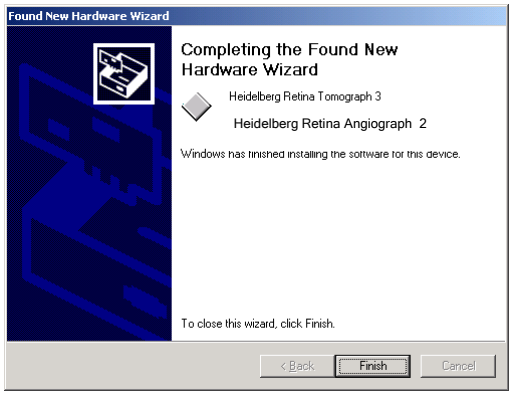


Only Windows 2000: Select “CD-ROM drives” as search location and select “Next” to continue with the driver installation.

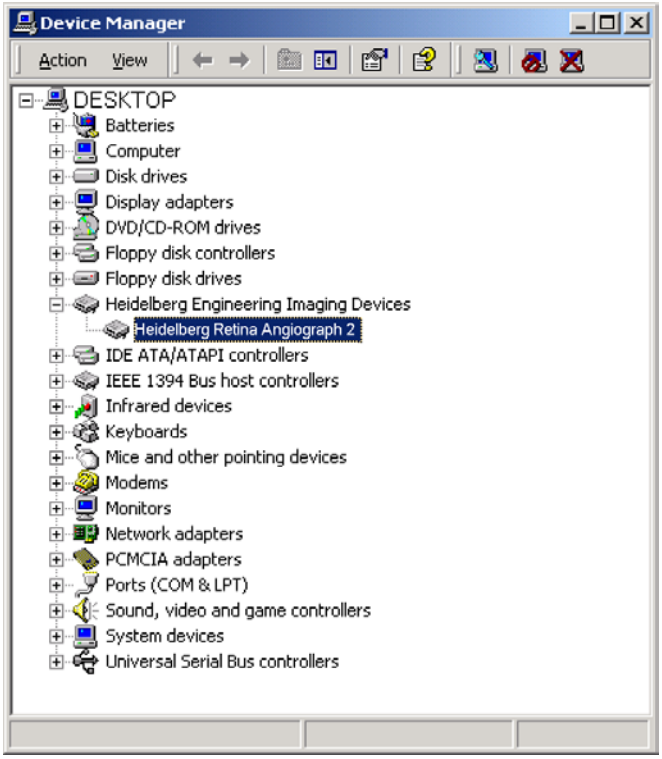


Only Windows 2000: The device driver information file “HE_IMOD.INF” for the Heidelberg Retina Angiograph will be found on the CD ROM. Click on “Next” to proceed.

Finally the driver for the Heidelberg Retina Angiograph 2 is installed properly.



To ensure the correct installation, open the Windows device manager (e.g. from the control panel) and check for the group named “Heidelberg Engineering Imaging Devices”. In this group, an entry “Heidelberg Retina Angiograph 2” should be listed.



10.2 Video board configuration

The HRA 2 acquisition software requires a specific configuration of the computer video board (VGA). The software will only work appropriately with the following settings (go to Windows control panel, Display, Settings):

4. Video resolution 1600 x 1200 pixels
5. Color depth of 16, 24 or 32 bits (32 Bits recommended)
6. Large fonts (which is 125 % of normal size, 120 dpi) (go to "Advanced" to be able to change the font size)

11 Software Installation

After the hardware and the appropriate drivers have been installed, the operating software for the Heidelberg Retina Angiograph has to be installed from the CD ROM.

11.1 Software Update

In case of a software update (i.e. any older version of the Heidelberg Retina Angiograph 2 is already installed on the computer), the software will automatically detect the old version and asks for updating:

If you click on “Yes”, the software will silently update all software components required for the Heidelberg Retina Angiograph 2. If you click on “No”, the installation program will continue with an interactive installation procedure (see below).

11.2 First Installation of the Heidelberg Retina Angiograph 2

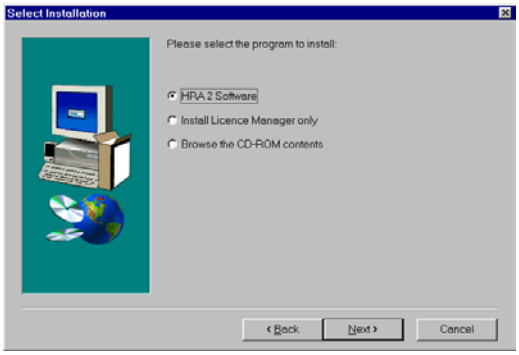
To install the Heidelberg Eye Explorer software, insert the enclosed CD-ROM into the CD-drive and wait for the automatic startup of the installation program or manually run the “setup.exe” program from the root directory.

Module Language

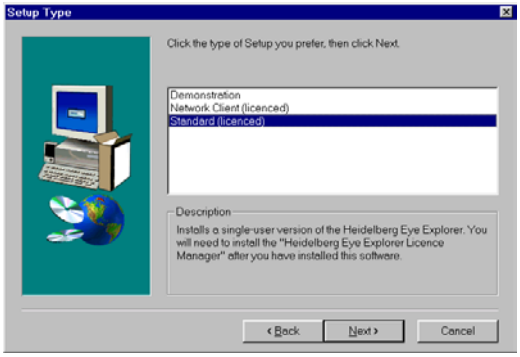
Select your language from the drop down list of the installation program dialog.

11.2.1 Select Software

Select “HRA Software” if the installation program asks for the program to install.



11.2.2 Select Setup Type



Select one of the following setup types:

11.2.2.1 "Demonstration"

There is a demonstration database on the CD-ROM (about 250MB disk space is required). The demonstration database can be installed in addition to the standard HRA software. This software does not need any software protector for running. It includes demonstration images for the HRA and HRT II (ONH and MEM modules) devices.

11.2.2.2 "Network Client (licensed)"

Install a "Standard" setup type on the server – PC. The setup program will install an empty database. Install a "Network Client" on all additional workstations. A "Network Client" installation will not install an empty database, because all workstations in the network will use the same database.

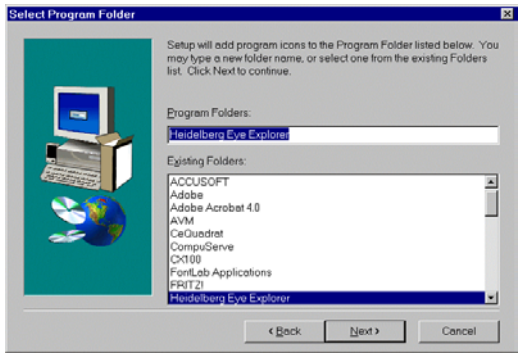
11.2.2.3 "Standard (licensed)"

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.

11.2.3 Destination Folder

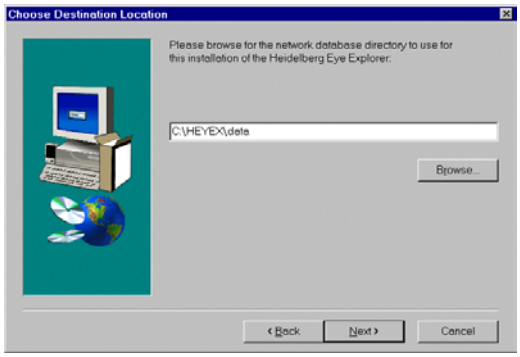
The installation program will ask for the installation directory. The default is "C:\HEYEX", which is highly recommended. Do not change the installation directory if it is not absolutely necessary!

11.2.4 Program Folder



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

11.2.5 Database Location



(Network installation only) Enter the path to the database directory, which contains the database file.

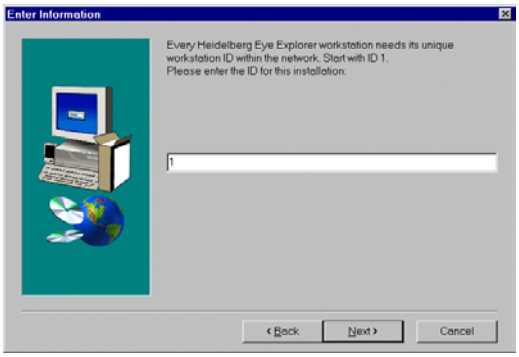
For a network installation, the database directory on the server PC **must** be shared to allow **unrestricted** file access for client PCs. There are two possibilities to specify the servers database directory on the client computer:

1. Map the shared database directory of the server PC to a local drive (e.g. drive letter 'J'). Use the "Browse" button to open directory J: and select the database directory.
2. Enter the UNC path of the shared server directory. A UNC path begins with a double backslash and consists of the following elements:

   \\SERVER_NAME\SHARE_NAME\PATH

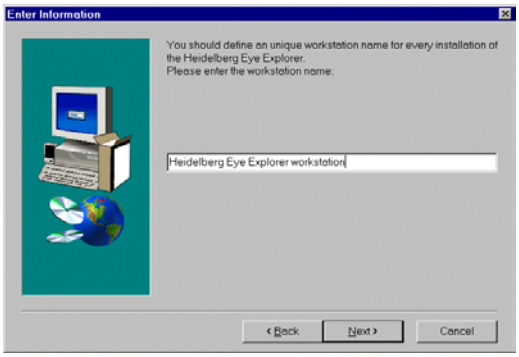
The usage of UNC network path specification is **highly recommended**, because a mapping of the shared file resources on the client PCs is not required. In addition, drive mapping can be easily lost if the client PC will be started before the server PC is running. Another problem with mapped network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

11.2.6 Workstation ID



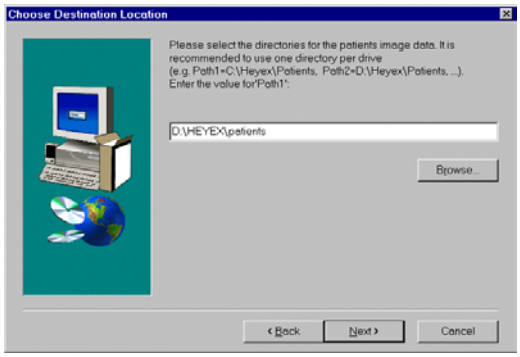
(Network installation only) A unique workstation ID will be required for every client PC. Start numbering the clients with 1 and increment this value by 1 for every new client installation.

11.2.7 Workstation Name



(Standard and Network installations only) You should define a unique workstation name for every client installation.

11.2.8 Patient Data Directories



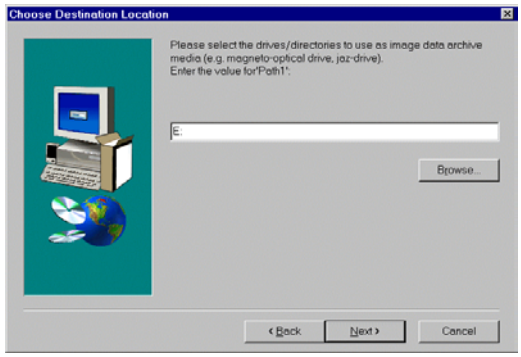
(Standard and Network installations only) This dialog allows defining one or several directories for the patient's data. At least one patient directory is required. The following configuration is recommended for a system with one hard disk:

- One small partition (2 GB) for the operating system, Eye Explorer software and database directory (assumed to be drive C:)
- One big partition (>20 GB) for the patient directories (assumed to be drive D:)

For this configuration, enter "D:\HEYEX\patients" in the dialog asking for "**Path1**". After that, click on "Next". The software will ask if you want to add an **additional** patient directory (e.g. "E:\HEYEX\patients" for another partition or hard disk). Enter the next path in the dialog asking for "**Path2**". After you have entered the last patient path, click on "No" when the software asks for another patient directory.

11.2.9 Archive Media

(Standard and Network installations only.)

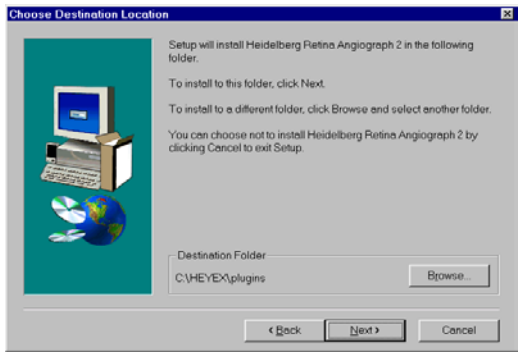


If you would like to configure a drive for archiving (e.g. Magneto optical disks), click on "Yes" when the software asks for.

Attention: This dialog looks nearly identical with the previous dialog for the patient data directories. But now, it is required to specify a drive/directory of the archiving device. If the archiving device (Magneto-optical disks, Jazz but no CD-RW) is assigned to drive letter E, then enter "E:" here.

As before, there is the possibility to specify more than one archive disk. This makes only sense in very rare cases. After the last path has been entered, leave the "Path" entry empty to proceed with the installation.

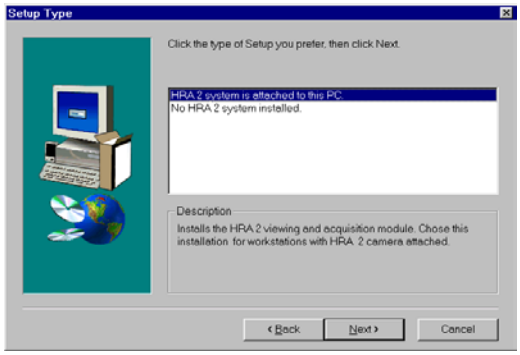
11.2.10 Destination Folder



The installation program will ask for the destination folder for the plugin modules. The default is "C:\HEYEX\PLUGINS", which is fine for the most cases.

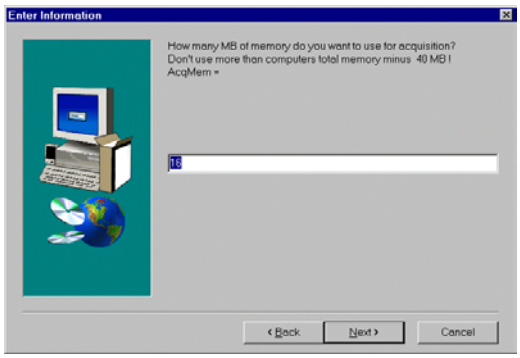
11.2.11 Select Hardware Configuration

Select the appropriate hardware configuration from the list and click on “Next”. Select “No HRA 2 system installed.” on network client installations or viewer installations.



11.2.12 Image Acquisition Memory

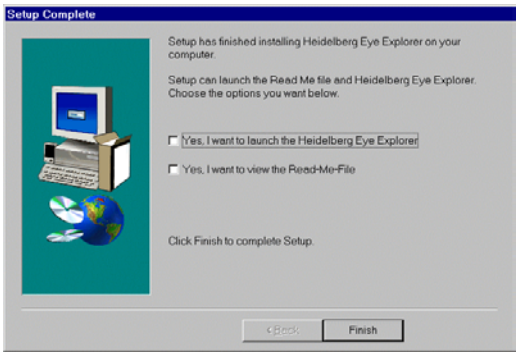
You can specify how many Mbytes of physical RAM shall be used for the image acquisition. Please note that the frame grabber itself already reserves 32 Mbytes for it and that you will significantly lose computer performance, if you configure the acquisition memory to high. Recommended memory settings are:



Recommended Memory Settings	Installed System RAM
64 MB	256 MB
192 MB	512 MB
512 MB	1 GB

11.2.13 Setup Complete

The installation is finished. After that, you should proceed with the installation of the “Heidelberg Eye Explorer License Manager” software.



12 Archiving on external hard disk with the Heidelberg Eye Explorer

12.1 Concept

A large capacity hard disk is used for "Archiving" instead of the current solution of magneto optical disks. The Heidelberg Eye Explorer software will be used in a special configuration so that no patient data will be removed from the hard disk (e.g. the cleanup process and the deletion of series data after archiving is disabled). Thus all important files will be kept redundant. To ensure data security it must be possible to remove the archive hard disk from the PC to be able to put it in a fire and thief-proof place. There are *removable* and *external* hard disks available:

A *removable* hard disk is a standard 3.5 inch IDE drive that is mounted in a special case that can be moved into a slot at the front side of the PC. The interface to the main board is typically standard IDE so that the drives may not be attached/removed while the PC is powered on. Even if the interface is IDE, the electrical connector between the drive housing and the PC slot is manufacturer dependant and not compatible between different types of removable hard disk mountings. Thus, removable hard disks are ***not recommended*** for archive disks!

An *external* hard disk is a standard 2.5 or 3.5 inch IDE hard disk that is mounted in a special housing and connected to the PC via a high speed serial interface. Two different technologies for the interface are available:

1 IEEE1394 (also called Firewire / I-link / DV digital video): 400 Mbit/sec, 4 pin or 6 pin (including current supply 8-40 Volt at 1,5 Ampere max.) connectors. It is possible to connect up to 16 devices in one firewire chain, up to 63 devices in a IEEE1394 network.

2 USB 2.0: 480 Mbit/sec, 4 pin connector (including 5V, 500mA max.)
USB 1.1: 12 Mbit/sec, 4 pin connector (including 5V, 500mA max.)
Every USB device requires its own USB port. If required, a USB hub must be used.

Both technologies are available in different sizes:

1 3.5 inch standard IDE hard disks: These drives are connected to 220V / 110V AC current via standard power supply cable. These drives have an USB 2.0 or Firewire interface. Capacity up to 400 GB per drive currently available.

2 2.5 inch laptop IDE hard disks: Most drives support both interfaces (USB 2.0 and Firewire). *An external power supply is required in case of the USB 2.0 interface, while the power supply provided with the firewire cable is sufficient in all tested drives*. Capacity up to 100GB per drive currently available. Because of the possibility to provide the electrical power to small 2.5 inch external hard

disks, Heidelberg Engineering recommends to use IEEE1394 (Firewire) as interface for small external hard disks.

12.2 PC Configuration

While the hard disk used for archiving **must** be external / removable, there are two different PC configurations for the hard disk used for the patient data and the database.

Configuration A): The internal harddisk containing the operating system is also used for the storage of the patients data. The advantage is, that only one external harddisk is required (archive). The disadvantage is, that it is much more complicated to replace the PC in case of a PC or operating system failure.

Configuration B): Two external harddisk are used . One for the patient data, one as archive. This configuration allows to replace the PC in case of a software or hardware failure very easily. **This configuration is recommended**.

Recommended disk configuration for HRA / HRA2 systems:

Two external hard disks: 3.5" firewire / USB 2.0 case (including 220/110 V power supply), max. capacity (currently 400 GB each)

500 GB: ~ 1.600.000 images @ 512x512 pixels (HRA)

500 GB: ~ 680.000 images @ 768x768 pixels (HRA 2, high speed)

500 GB: ~ 170.000 images @ 1536x1536 pixels (HRA 2, high resolution)

12.3 Requirements for hard disk archiving

To avoid that drive letters are changing for the external drive(s) Windows 2000 or XP is required. Windows 98 assigns hard disk drive letters automatically at boot time. If hard disks are attached after boot (i.e. hot plugging devices like firewire or USB) or other devices have been added (e.g. Zip / Jazz Drive) drive letters will be different. **Windows 98 is not recommended**.

The **NTFS** file system should be used for the patient data and archive disk to ensure data security on the hard disks. FAT32 is not suitable, because Windows 2000 does not allow to create FAT32 partitions larger than 32 GB.

This has the side effect, *that external disks cannot be attached to Windows 9X, Me* operating system computers for viewing purposes.

12.4 Configuration of the Heidelberg Eye Explorer Software

The Heidelberg Eye Explorer software (**version 1.3.5 or above is required**) ***must*** be configured as defined below to ensure data security (i.e. to keep patient data on both hard disks).

Permanent drive letter assignments should be made for the attached external hard disks:

The data hard disk (patient folder and database directory) should be marked with a printed label (HE logo, "DATA" and a "Name" field) and also the disk volume name should be set to "DATA", too. The recommended drive letter for the patient data disk is "G:". The recommended drive letter for the archival disk is "H:". The archive disk should be labeled "ARCHIVE" as volume name and should have also a printed label. To assign or change drive letters or volume names for the external drives use the ***Windows disk drive manager*** (Control Panel / Administrative Tools / Computer Management / Disk Managment).

Configure the HEYEX.INI file appropriately, i.e.:

```
[Settings]
HardDiskArchive=1

[System]
DataPath=G:\data

[PatDir]
Count=1
Path1= G:\patients /M:5000

[ArchiveDir]
Count=1
Path1=H:\
```

The setting "/M:5000" at "Path1=" defines a disk reserve of 5 GB. As soon as the free amount of memory on the patient data disk is smaller than the configured reserve, the user will get disk space warnings but is able to continue working until the disk space is completely off. To increase disk space, the contents of the two external disks must be copied to another set of two disk with at least twice the capacity of the first set. After copying of the files, the new disks have to be configured as described above.

12.5 Upgrading from a set of existing MO archive disks

An existing configuration with a set of archive disks (e.g. HXD00001 to HXD00025) can be upgraded to external hard disks. The contents of all MO disks should be copied to the root directory of the external archive disk (i.e. the archive disk will have directories with names HXD00001 to HXD00025).

Configure the Eye Explorer (HEYEX.INI) as shown above (do not forget to add the “HardDiskArchive=1” key in section [Settings]).

Start the Eye Explorer and select “Retrieve” from the “Database” menu. Select **all** image types from the retrieve selection dialog and start the “Retrieve” process. This procedure will copy all relevant files from the external archive disk to the external patient data disk to have all data redundant on both drives.

13 Appendix A: HEYEX.INI Settings

The text file "HEYEX.INI" is the main configuration file for the Heidelberg Eye Explorer. By default, it is located in the "C:\HEYEX" directory. The following list contains a description about all important configuration keys:

13.1 Section [Settings]

Workstation

This key specifies the workstation name.

Example:

Workstation=HRA 2 PC

WorkstationID

This key specifies the workstation ID number. This number has to be a positive number and must be unique within a network installation. If two workstations have the same **WorkstationID**, only one of them can run the HEYEX software at the same time.

For a single user installation, this value has to be set always to 1.

Example:

WorkstationID=1

User

This key specifies the login name of the user last logged in. This key should not be changed manually.

Example:

User=smith

13.2 Section [System]

DataPath

This key specifies the complete directory, where the database file (normally 'hr.mdb') is located. The path can be either a DOS-style path, including a drive letter, or a UNC (Universal Name Convention) file name like `\\servername\path`. In case of a network installation, please make sure, that the workstation/user has full access (read/write/delete) to `DataPath`. In a network environment, all HEYEX installations have to use the same `DataPath` setting.

Example:

DataPath=c:\heyex\data

Or

DataPath=\\nt_server\heyex\data

13.3 Section [PatDir]

Count

This key specifies the number of patient directories specified within this section.

Example:

Count=3

Path1, Path2, Path3,…

These keys specify the different paths to be used to store the patients image data. The number of keys must match the value of the **Count** key described above. In case of a network installation, please make sure, that the workstation/user has full access (read/write/delete) to all `DataPaths`. The Path can be specified in DOS or UNC file name convention. In a network environment, all HEYEX installations have to use the same `Path1, Path2`, ... settings. To optimize the HEYEX performance, minimize the number of paths (**Count**-value) and don't use more than one path per partition. In any case, do not use root directories as patient data folders, their capacity is limited by some operating systems.

Example:

Path1=c:\heyex\patients

Path2=d:\heyex\patients

Path3=\\nt_server\heyex\patients

13.4 Section [ArchiveDir]

Count

This key specifies the number of archive directories/drives specified within this section. Typically the Count value is `1` (i.e. one archive device)

Example:

Count=2

Path1, Path2, Path3, …

These keys specify the different paths to be used to archive/access/retrieve patients image data. The number of keys must match the value of the `Count` key described above. In a typical installation, there is only one key. The Path can be specified in DOS or UNC file name convention. ***The path must specify the root of the archive drive, do not specify subdirectories.*** To be able to archive to one of the specified paths, the workstation/user needs write-access to the device.

Example:

Path1=e:

Path2=\\nt_server\opt_disk_drive

14 Appendix B: HRA2.INI Settings

The text file "HRA2.INI" is the main configuration file for the Heidelberg Retina Angiograph software. By default, it is located in the plugin directory of the Heidelberg Eye Explorer "C:\HEYEX\plugins". The following list contains a description about all important configuration keys:

14.1 Section [HRA]

AcqMem

Specifies how many megabytes of physical RAM shall be used for the image acquisition. You will significantly loose computer performance, if you configure the acquisition memory too high. Recommended memory settings are:

Recommended Memory Settings	Installed System RAM
64 MB	256 MB
192 MB	512 MB
512 MB	1 GB

Example:

AcqMem=128

15 Appendix C: HRA2 Installation Protocol

Find attached a copy of the HRA2 Installation Protocol. During installation this form should be filled out and faxed back to the Heidelberg Engineering head quarter (fax: +49 6221 646362).

HRA 2 Installation Report

A: Serial Numbers HRA2 Camera: _____ Combined Laserbox and Power Supply: _____

Touch Panel _____ Camera Mount and Headrest _____

B Installation Report Date: _____

- Outer appearance of the system after transportation Ok ? ☐
- All cables properly connected ? ☐
- PC connected to Isolation transformer and Laserbox ? ☐

C: Test of the Laser Power (after 30 min Warm- Up)

- ICG 30° HS (2.35 – 2.65 mW) _____
- ICG 30° HR (2.5 – 2.8 mW) _____
- IR 30° HS (<150µW) _____
- IR 30° HR (<150µW) _____
- FA 30° HS (240 – 280 µW) _____
- FA 30° HR (260 – 300 µW) _____

D: Institution / Name / Address of the Customer

Institution: _____ Name, First name _____

Street: _____ ZIP / City / Country

Name of the Installer _____ Signature: _____