Installation Guide

SPECTRALIS HRA+OCT

What is new compared to the HRA2?

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This document refers to the Manual “Heidelberg Retina Angiograph 2, Installation and System Configuration”, Art. No. 96 037-006.

HEIDELBERG ENGINEERING

Table of Contents

1 PC Requirements

The motherboard must to be equipped with an Intel 975X chip set and two PCI Express Graphics (PEG) slots. One PEG hosts the graphic card. The other PEG hosts a PCI Express Card with IEEE-1394b standard interface (“FireWire800”). Additionally, a second IEEE-1394a bus with an own controller has to be available.

To allow operation of SPECTRALIS OCT and SPECTRALIS HRA+OCT it is important that these minimum requirements are met.

Complete PC requirements are as follows:

Motherboard:

Processor: Intel Core 2 CPU Q6700

Chip set: Intel 975X

RAM: 2 GiByte

PCI Express Graphics (PEG) slots: 2

Graphic card: Chip set Geforce 8800 GTX or comparable

Memory 512 MB; 768 MB recommended

Fire Wire Cards:

1 PCI or PCI Express Card IEEE-1394a or on-board IEEE-1394a interface (FireWire 400)

1 PCI Express Card IEEE-1394b (FireWire 800)

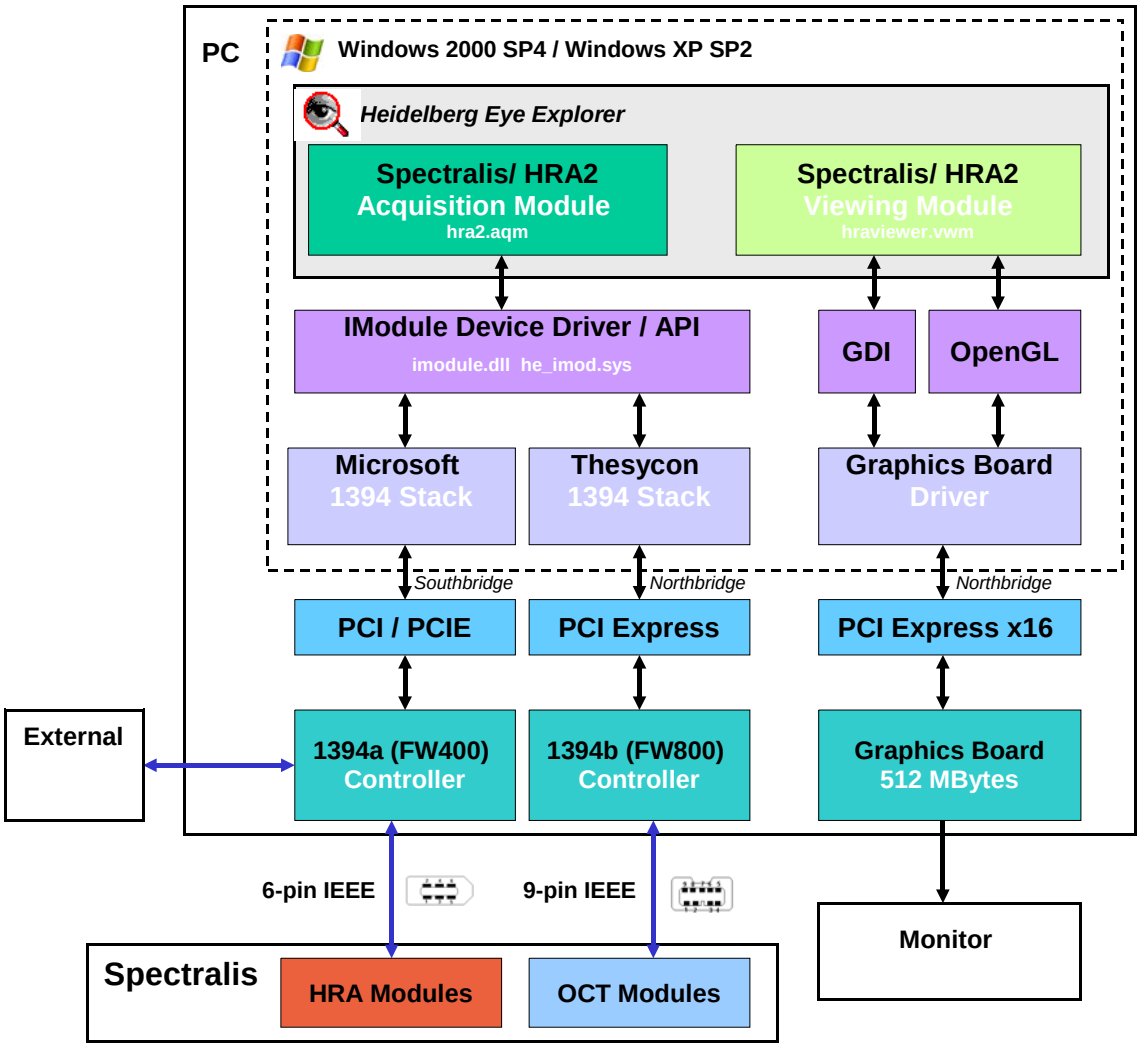
Internal HDD 40GB

Windows XP

2 Software and Driver Installation

2.1 Overview

The following chart gives you an overview of the Spectralis PC software architecture.

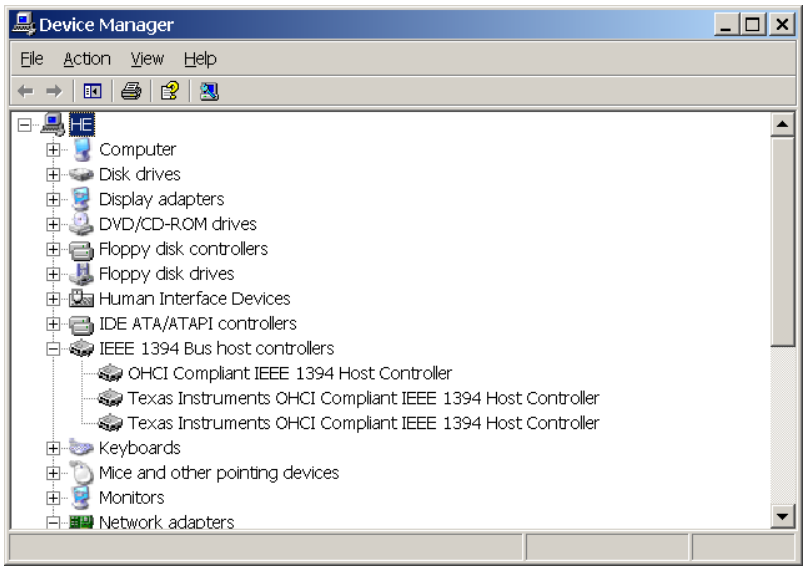


2.2 HRA2 and OCT Driver Installation:

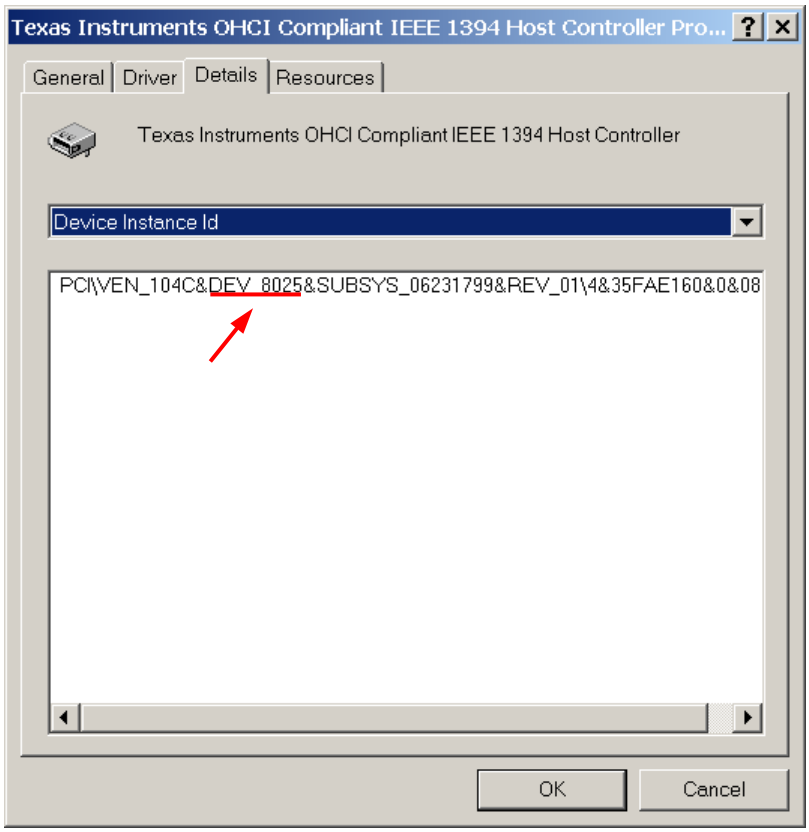
Proceed Page 38 and 39 in the HRA2 Installation Instructions. The only difference is that you have to do this step twice. First for the HRA2 and then for the OCT Module.

2.3 Tesycon Driver Installation (additional FireWire Controller driver)

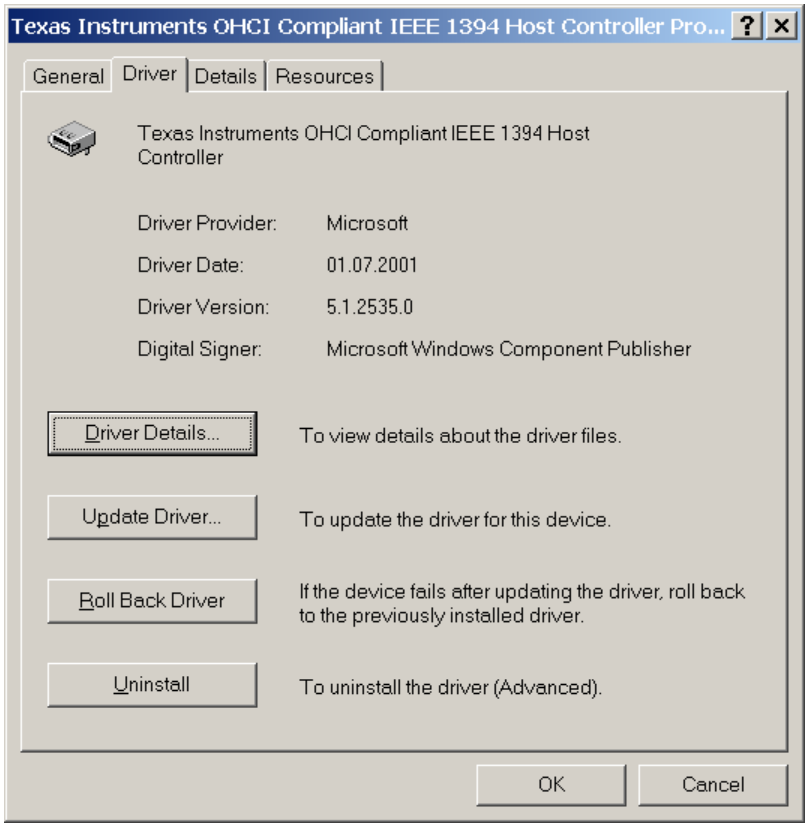
Open the Windows device manager (e.g. from the control panel) and check open the group IEE 1394 Bus host controllers. Here you have to identify the FireWire 1394B Controller Card (see next step).



Right click on each FireWire Controller, select Details and search for 'DEV_8025'. This Value means that this Card is the FireWire B Controller.

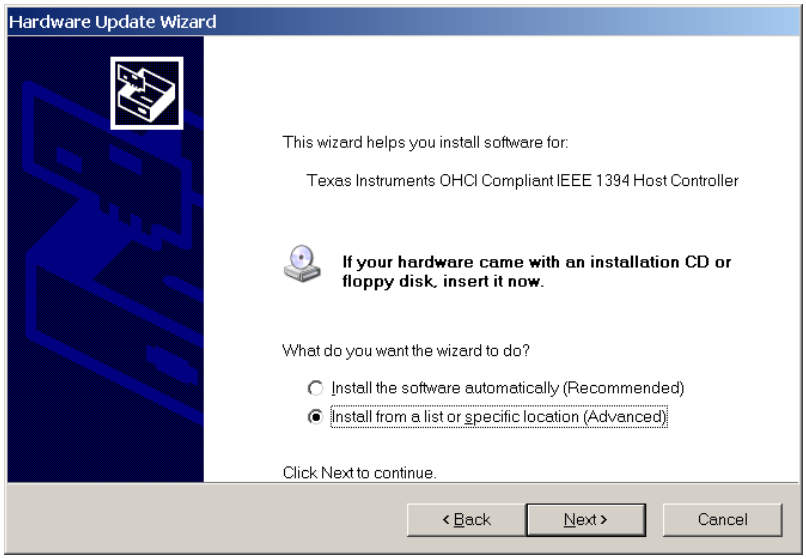


After you found the FireWire B Controller, click on ‘Driver’ and then on ‘Update Driver’

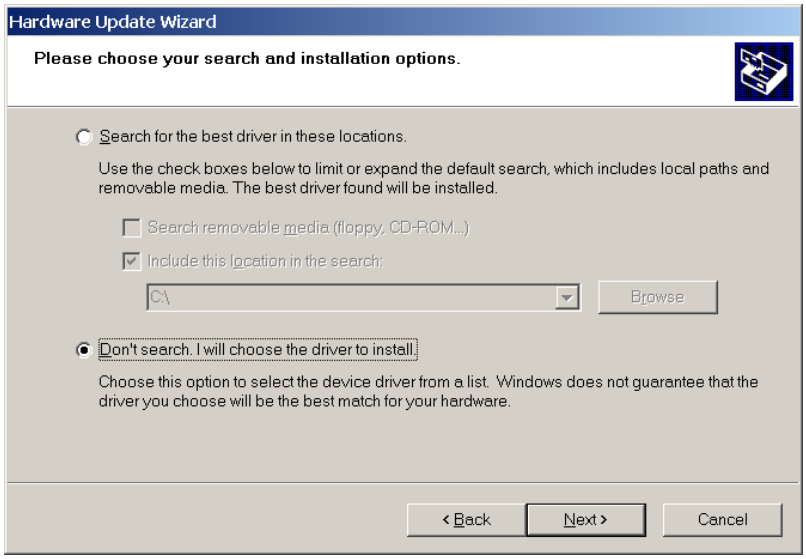


Select ‘No, not this time’ and click on ‘Next’

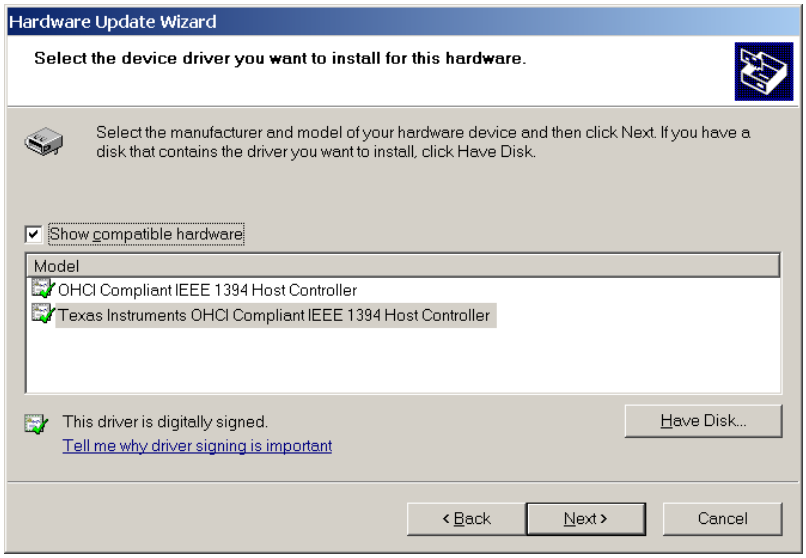
Select ‘Install from a list or specific location’ and click on ‘Next’



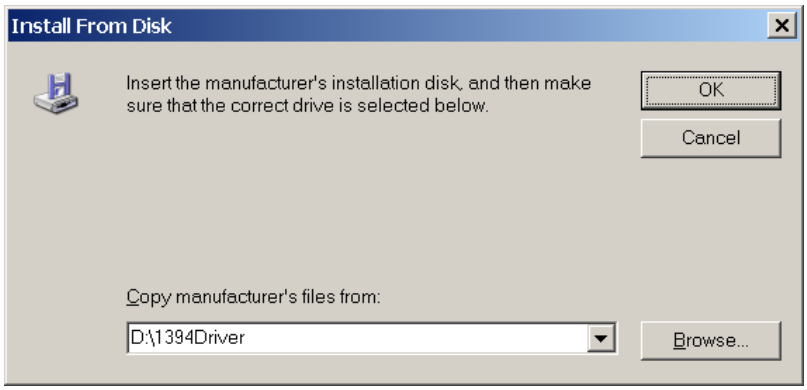
Select ‘Don’t search. I will choose the driver to install’ and click on ‘Next’



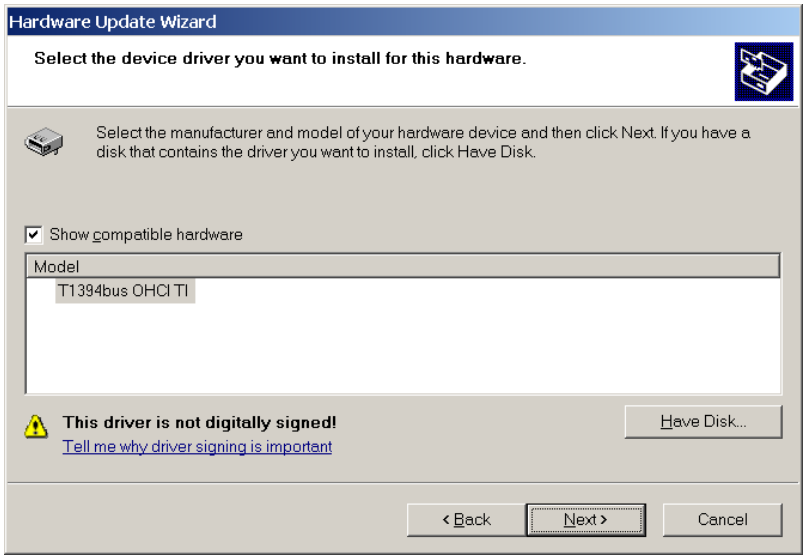
Click on ‘Have Disk’



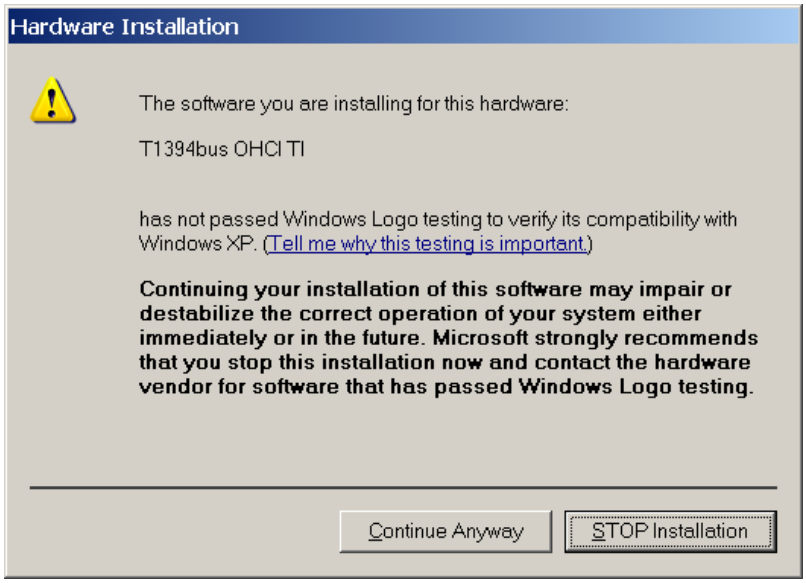
Insert the SPECTRALIS Installation Software CD into you CD/DVD-Drive and browse on this CD to the Folder ‘1394Driver’.



Then the following Screen should appear. Click on ‘Next’

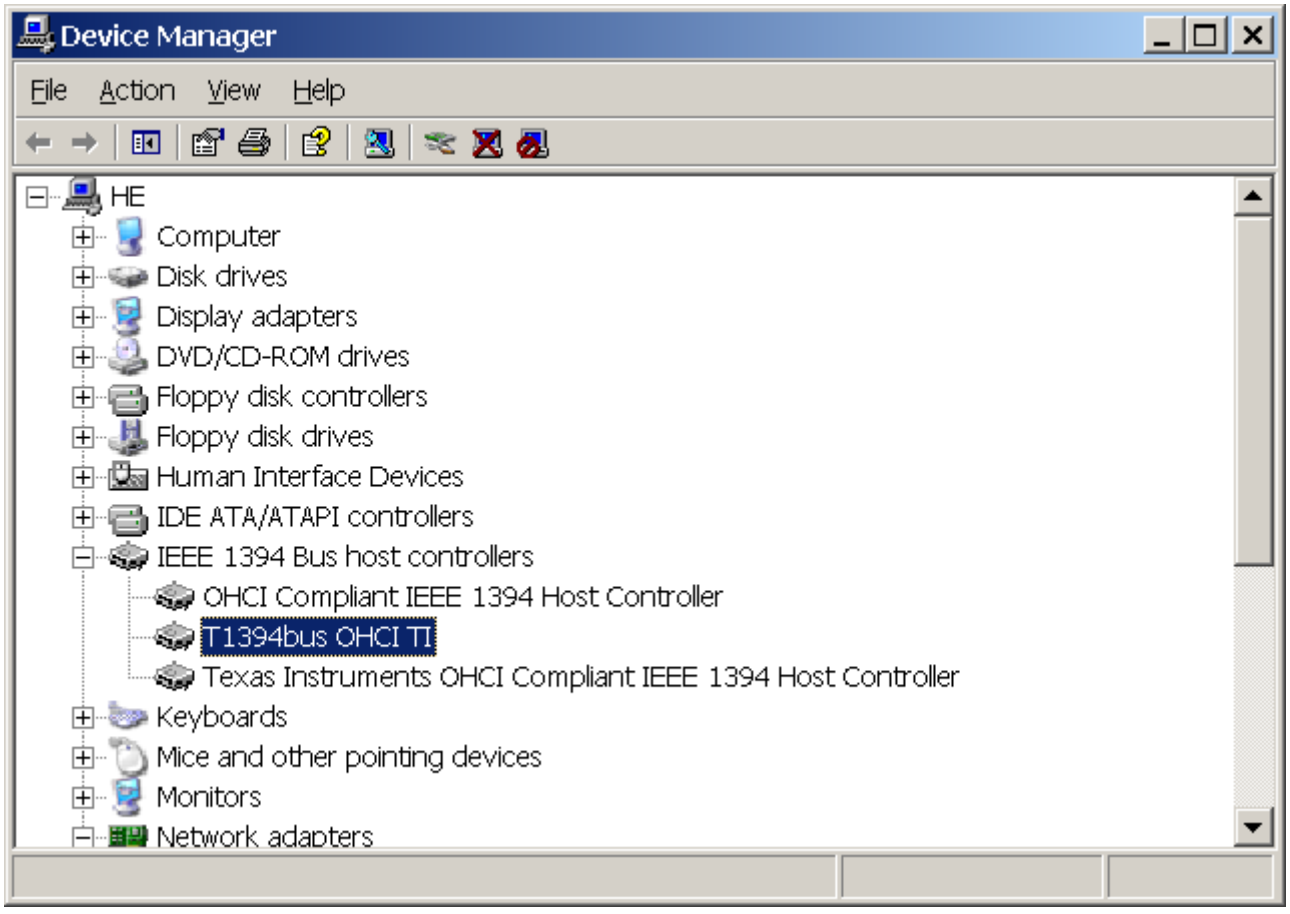


Click on ‘Continue Anyway’



Click on 'Finish'

To verify that the Driver is correctly installed, you now have to see that the Device name changed to 'T1394bus OHCI TI'



After installing this Driver it could be necessary to turn off the PC completely include removing the power cable for 1 minute.

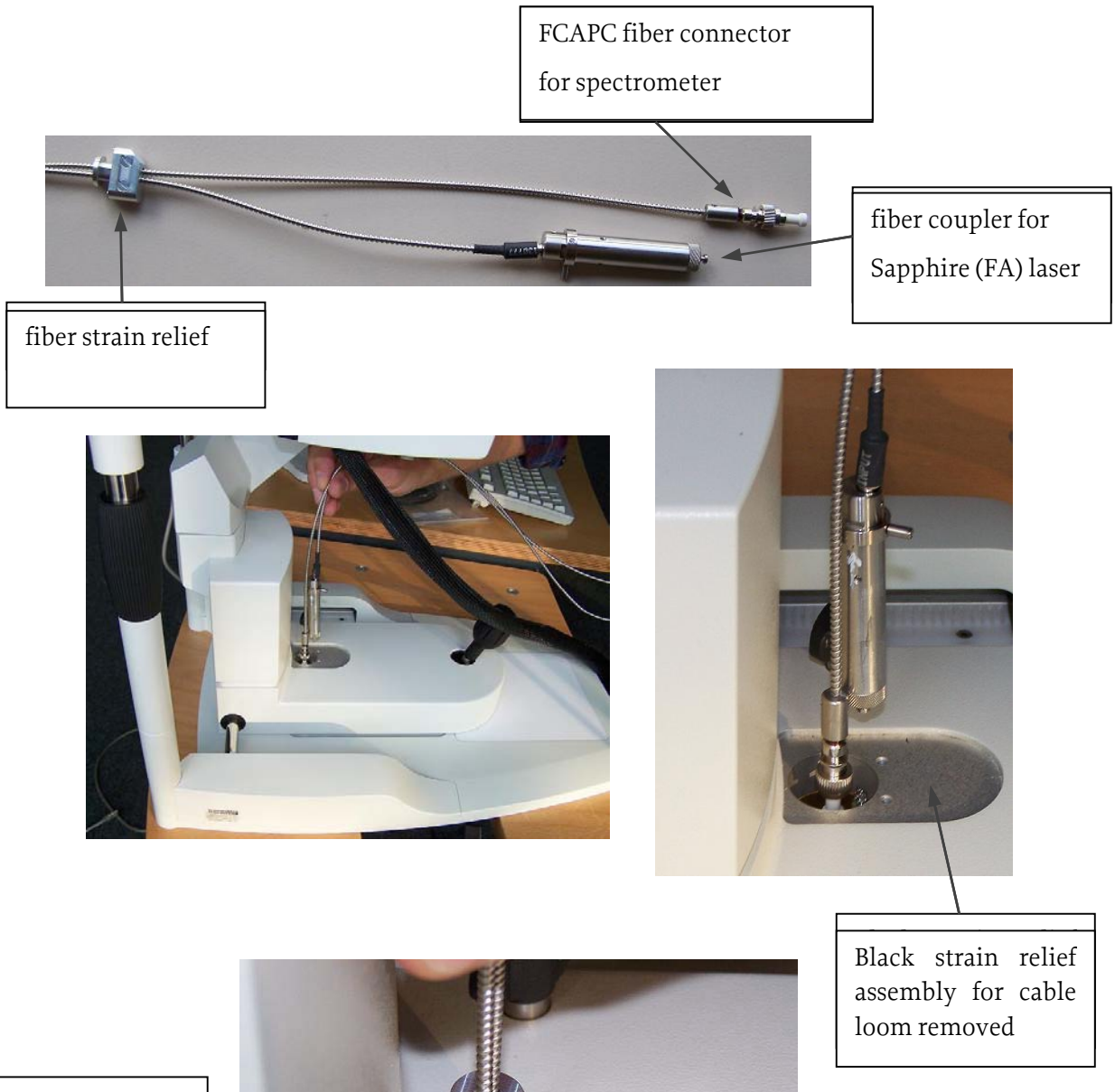
Now Proceed with Page 40 in the HRA2 Installation Instructions.

3 Set-Up Instrumentation Base and Camera

3.1 SPECTRALIS with instrumentation base (joystick version)

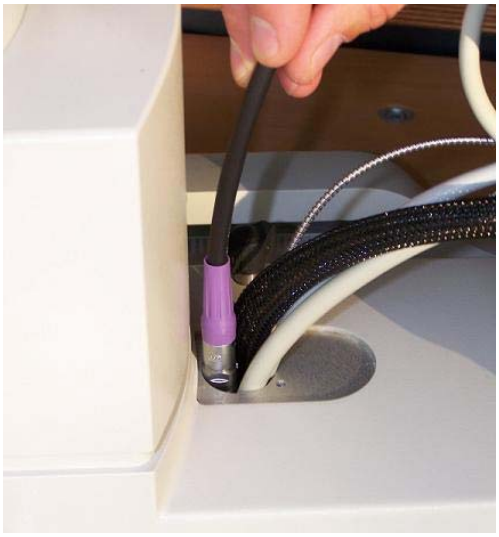
3.1.1 Launching the cable loom through the instrumentation base

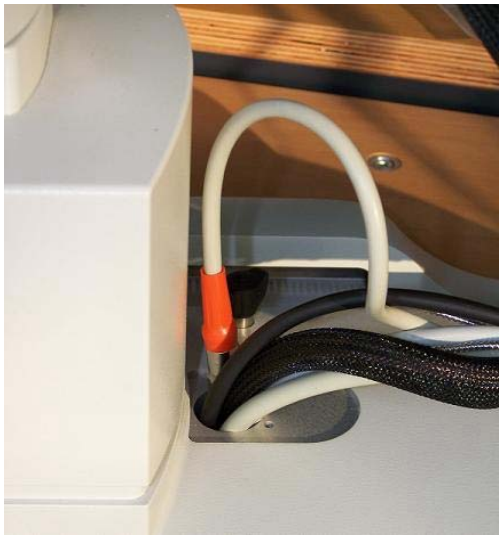
After the camera head is mounted onto the instrumentation base the complete cable loom is launched through the cable feedthrough (brass tube channel) as shown in the following pictures. First the black strain relief assembly (for cable loom) needs to be removed. Then the optical fibers are threaded through:



Then the three bigger HRA connectors are threaded through the cable channel. The order black, red, blue connector is recommended.

Finally the purple and orange connectors (OCT unit) are inserted:





3.1.2 Modified strain relief for SPECTRALIS cable loom

Strain-relief assembly for cable loom:

Strain relief assembly for **HRA II** and **SPECTRALIS HRA** (small cut-out)

Strain relief assembly for **SPECTRALIS OCT** and **SPECTRALIS HRA+OCT** (larger cut-out)

Mount the cable loom strain relief assembly as shown in the HRA2 installation manual. Make sure, that the cable loom is not twisted and that the cable loop is long enough to allow the movement of the camera to its extreme positions.

3.2 SPECTRALIS with instrumentation base (XYZ-unit)

Similar as for the joystick version, also for the XYZ-style instrumentation base a cable bracket with a larger cut out for the thicker cable loom (with the OCT cables) is required.

Cable bracket for **HRA II** and **SPECTRALIS HRA** (small cut-out)

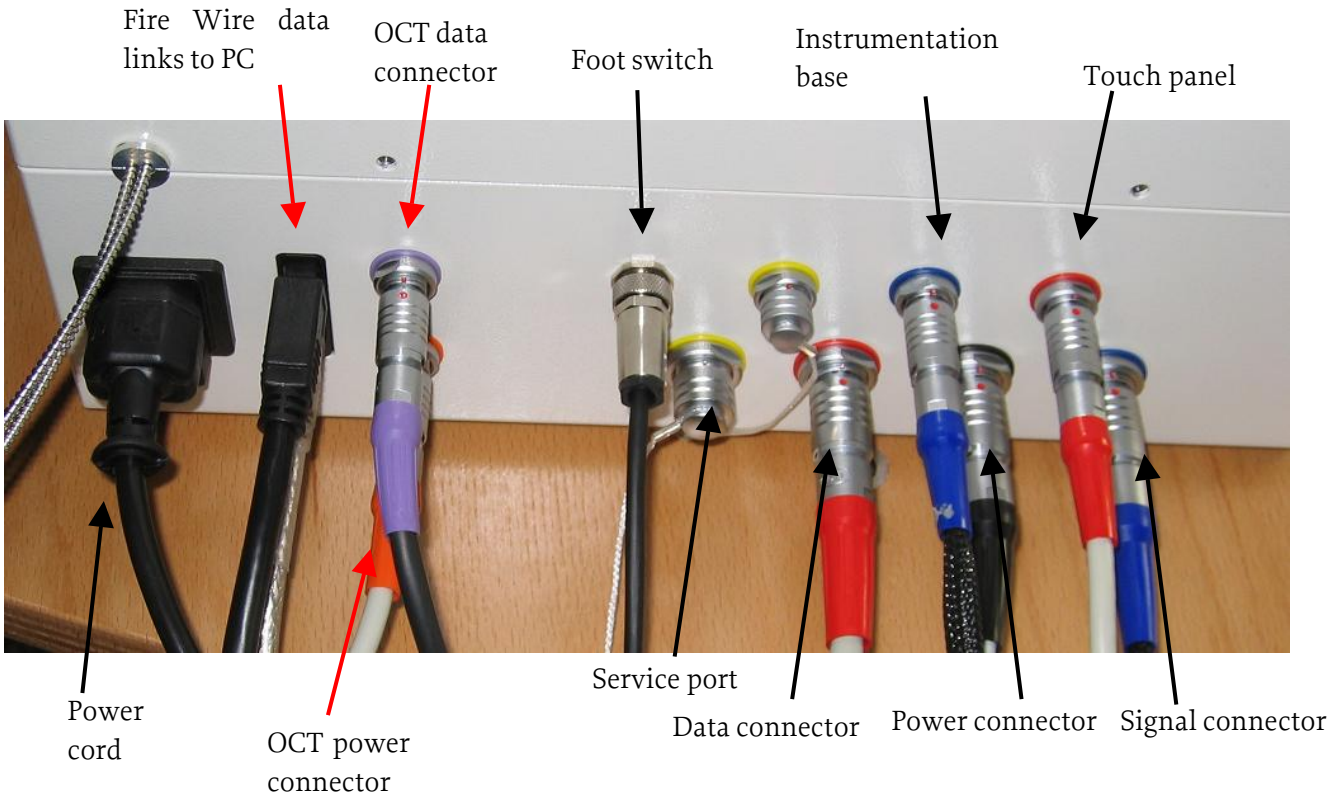
Cable bracket for **SPECTRALIS OCT** and **SPECTRALIS HRA+OCT** (larger cut-out)

4 Electrical Wiring

The electrical wiring of the SPECTRALIS system is very similar to the wiring of the HRA2 system; please therefore follow the HRA2 installation manual for details. The only differences for the SPECTRALIS HTA+OCT resp. SPECTRALIS OCT systems are listed below:

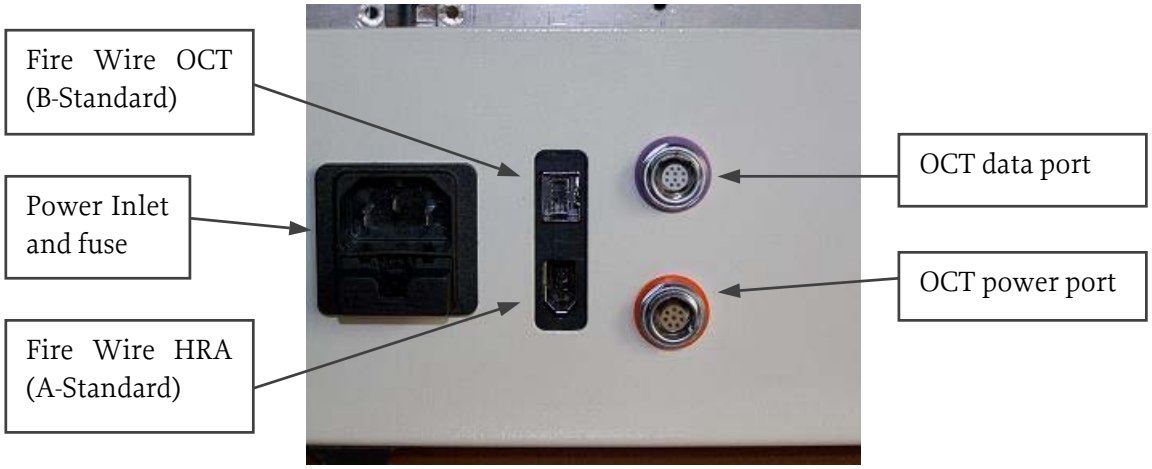
4.1 Additional OCT cables in the cable loom

The cable loom includes two additional cables: the OCT data cable (purple connector) and the OCT power connector (orange connector).

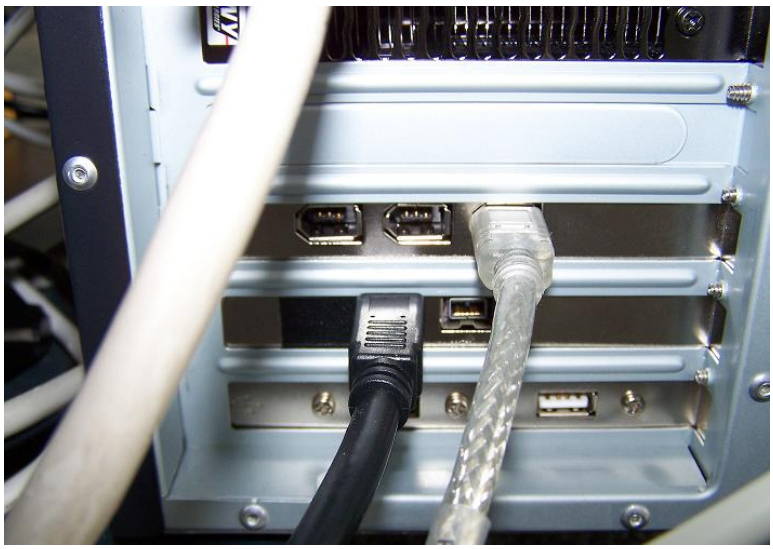


4.2 Fire Wire links to the computer

In addition to the HRA2 Fire Wire cable (IEEE 1394, A-Standard, 200 MBit/s), there is now an additional Fire Wire cable for the OCT data transfer (IEEE 1394b, B-Standard, 800 MBit/s).



Fire Wire cables connected to the power supply



Fire Wire cables connected to the computer:

B-Standard cable connected to the PCI Express Card (IEEE-1394b)

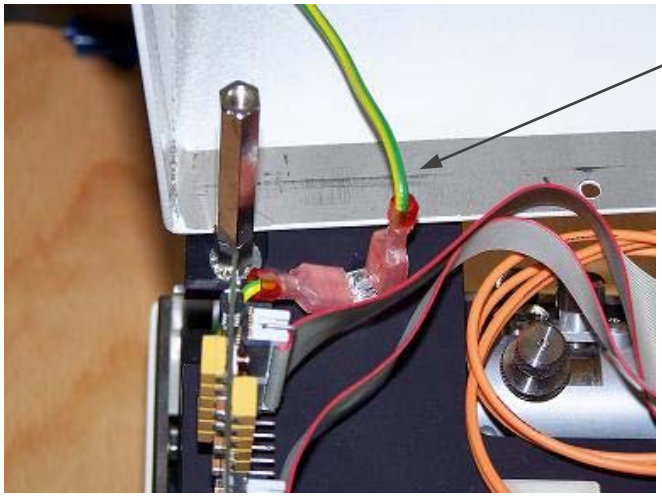
Please note: The external hard disks are connected to additional FireWire ports of the computer. As laptops usually do not provide electrical power at the FireWire interface, there was in the HRA2 the possibility to connect external hard disks without intrinsic power supply to the power supply. This option does not exist anymore for the SPECTRALIS system.

5 Installation of the Sapphire and Spectrometer Fibers

5.1 Remove the cover of the power supply box

Make sure, that the power is switched off! After removal of the 8 allen screws (2mm allen wrench), the power supply cover can be carefully removed as shown in the pictures below. Make sure, that the cover is tilted to the side opposite to the cable connectors, as on this side the protective earth cable is attached. Extreme care has to be taken for not touching and misaligning the sensor board.

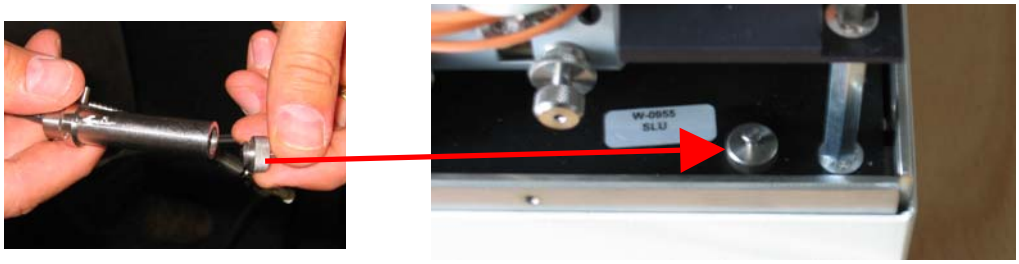
Sensor board (close to the power supply housing)



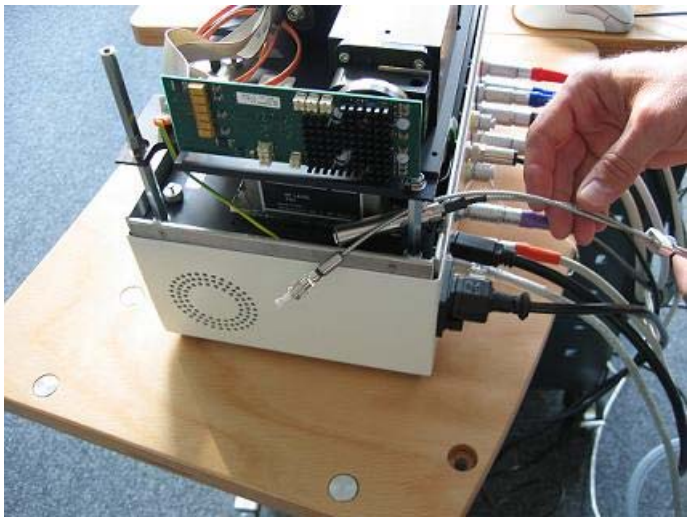
Remove protective earth wire

5.2 Through Feeding and Installation of Fiber Cables

The metallic fiber protection cap is removed from the Sapphire fiber coupler and saved in the provided thread next to the distance bolt.



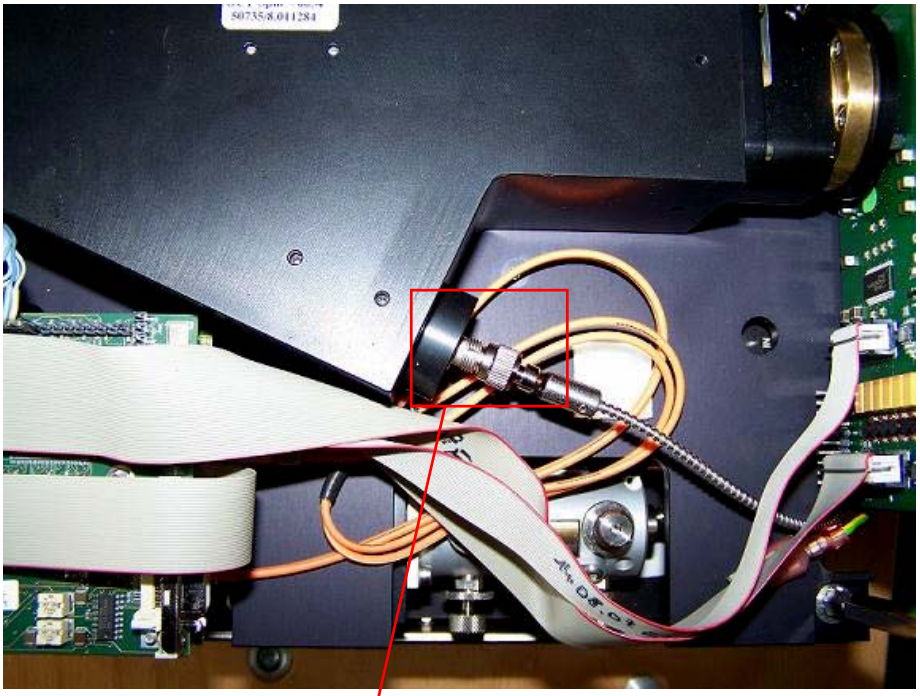
The two fiber cables are threaded behind the distance bolt into the power supply unit.

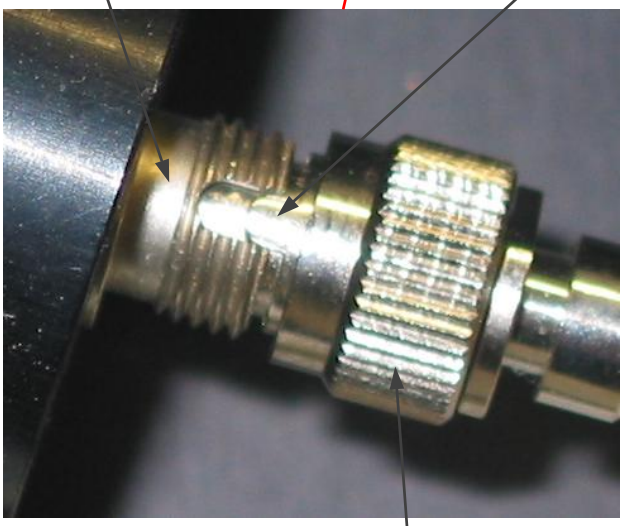


The OCT fiber is laid through the cut-out up to the spectrometer level, just next to the protective earth wire.

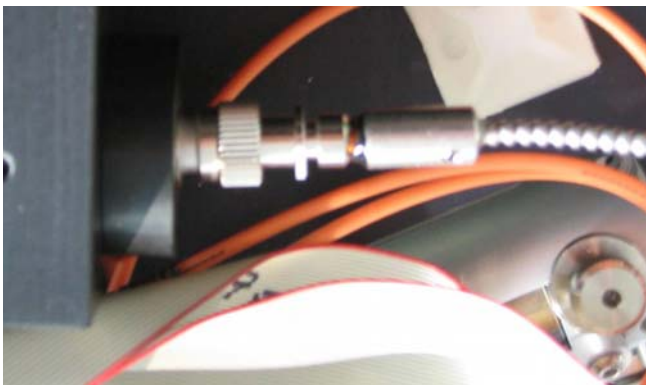
Cut-out for the protective earth and the fiber

5.3 Attachment of Spectrometer Fiber





- Remove the plastic fiber protection cap
- Insert the FCAPC fiber connector into the spectrometer fiber port.
- Make sure, that the connector key fits into the keyway of the fiber port.
- Carefully tighten the threaded nut while slightly pushing the fiber into the port.

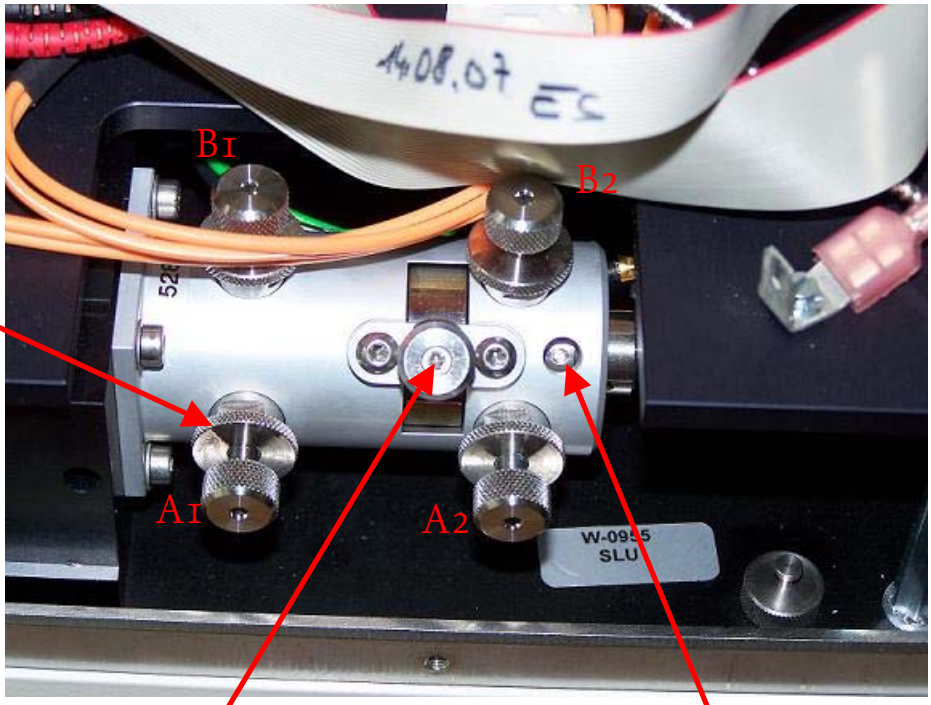


5.4 *Installation of Laser Coupler to the Kineflex*

The installation of the Sapphire coupler is described in detail in the HRA2 installation manual. Please note the following two differences:

- The access to the alignment screws is more difficult due to the orange fiber cable and the flat ribbon cables of the OCT spectrometer unit. It is recommended to use allen screws (2mm allen wrench) for the alignment.
- The locking screw for the retaining pin is omitted, as the access is more difficult.

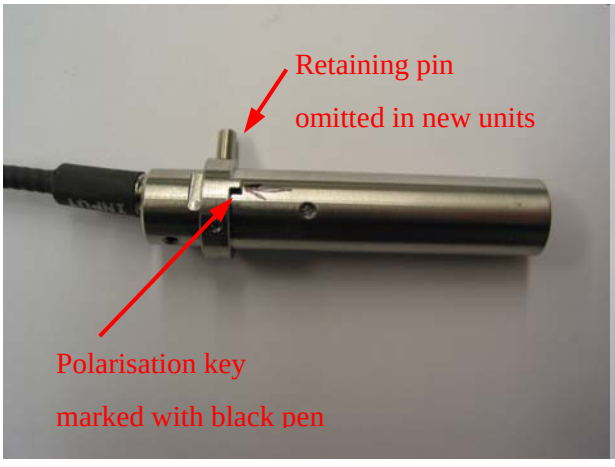
Push the spring button in order to launch in the fiber optics. Make sure, that the polarisation key fits properly into the polarising key-way. The button can be released as soon as the fiber is properly positioned. Once the fiber is positioned, the 4 screws can be aligned in a wide range without readjusting 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.

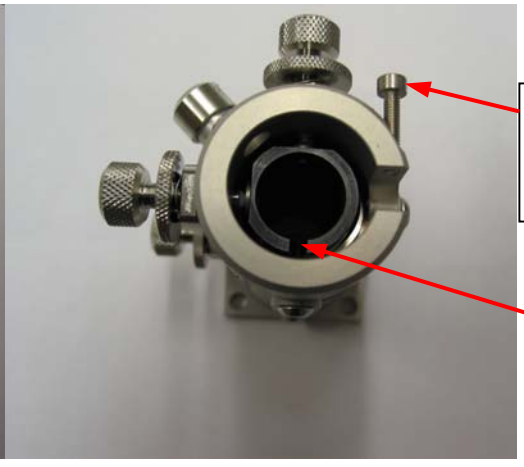


4 x locking nuts to secure alignment of A1.....B2

Push this spring button down for inserting the fiber coupler or pre-alignment tool

If the fiber coupler is inserted properly, the little set screw on the polarisation ring should be centered within the bore





Screw for locking retaining pin is omitted

Nut for polarisation key

5.5 Measurement of FA-Laser Power at objective

1. Start the SPECTRALIS 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.

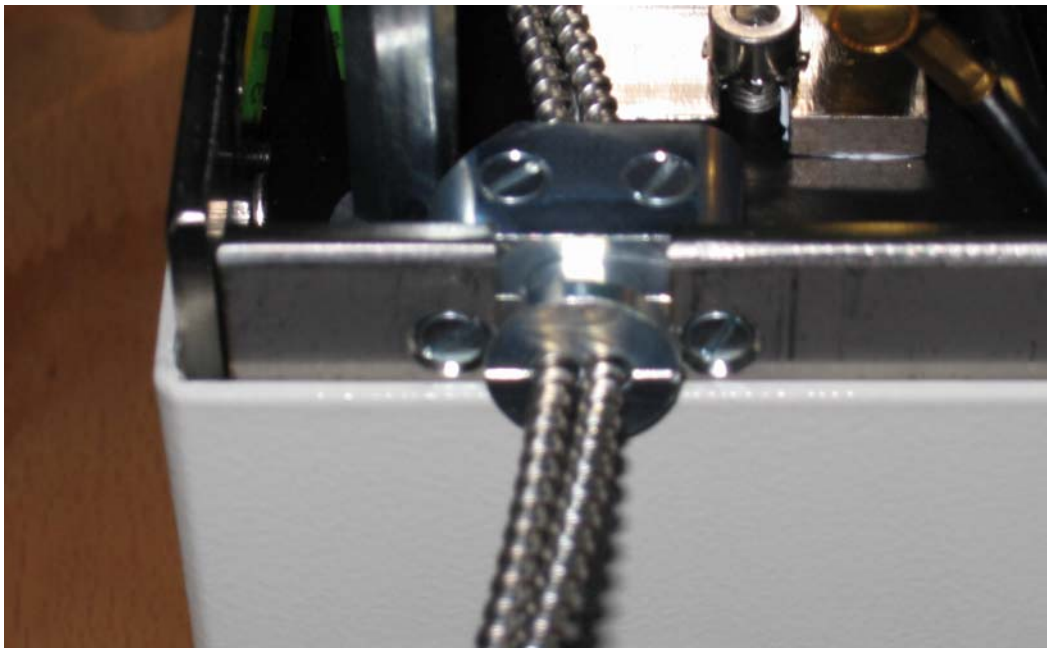
2. Mount the Ophir-Powermeter (with the special Camera-Adapter) on the camera objective. Select the wavelength 488 nm and the range max. 3 mW. Set the camera to 30°, HR-Mode and 0 diopters. Measure the laser output by using the average procedure (10 seconds). The specified power range is 260 ²W – 300 ²W.

Please note: For the alignment procedure we recommend to use the Heidelberg Engineering TSE-sensor equipped with an special Camera adapter fitting on the SPECTRALIS 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.
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.

3. 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 HRA2 service manual for a detailed description of this procedure.

5.6 Attachment of the fiber strain relief unit

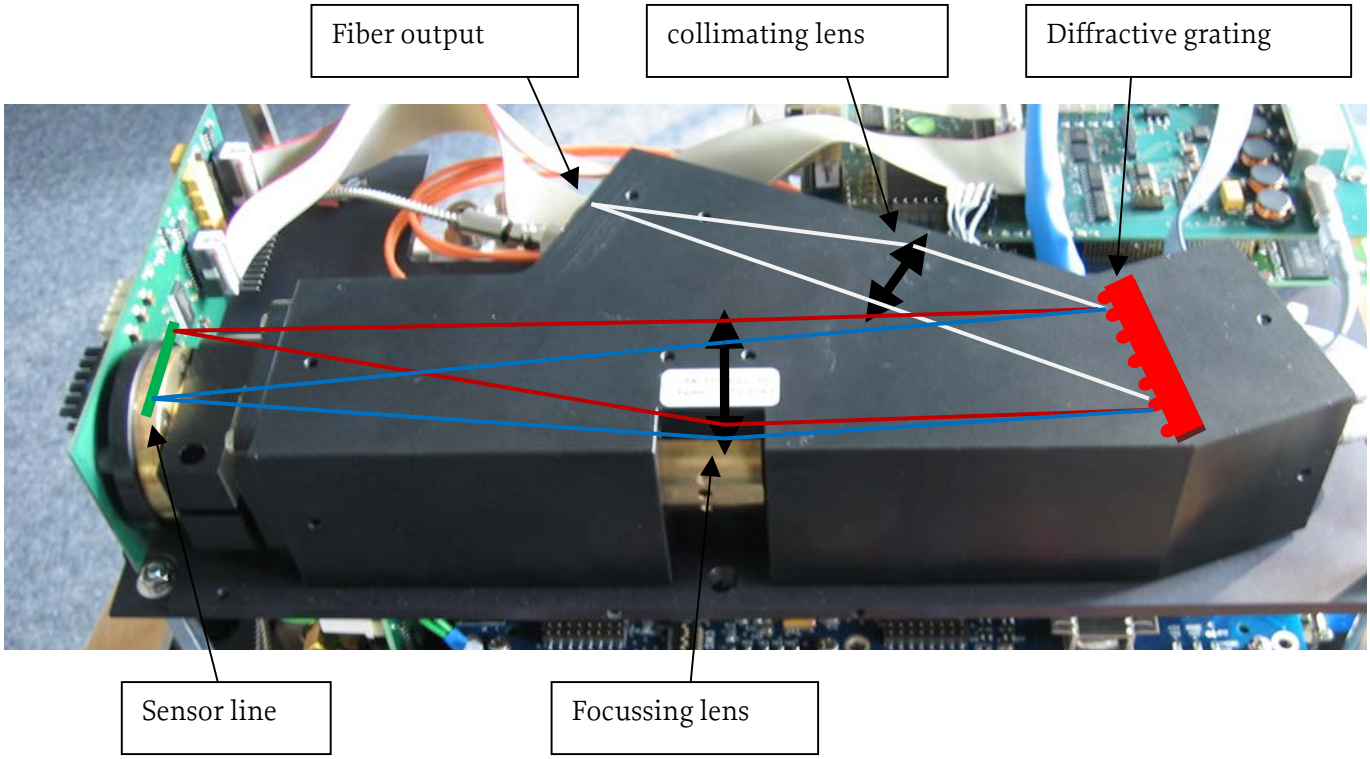
The fiber strain relief unit is mounted to the steel band with two M2.5x8 screws as shown is the picture below.



6 Spectrometer

6.1 Principal set-up

The OCT signal is detected by a spectrometer inside the power supply box. An optical fiber is inserted into the spectrometer, the collimated light beam is then impinging on a diffraction grating. The diffracted beam is imaged onto a line sensor. Due to the very small pixel size of the detector (14 microns in height) the adjustment of the grating and the adjustment of the sensor itself is crucial.



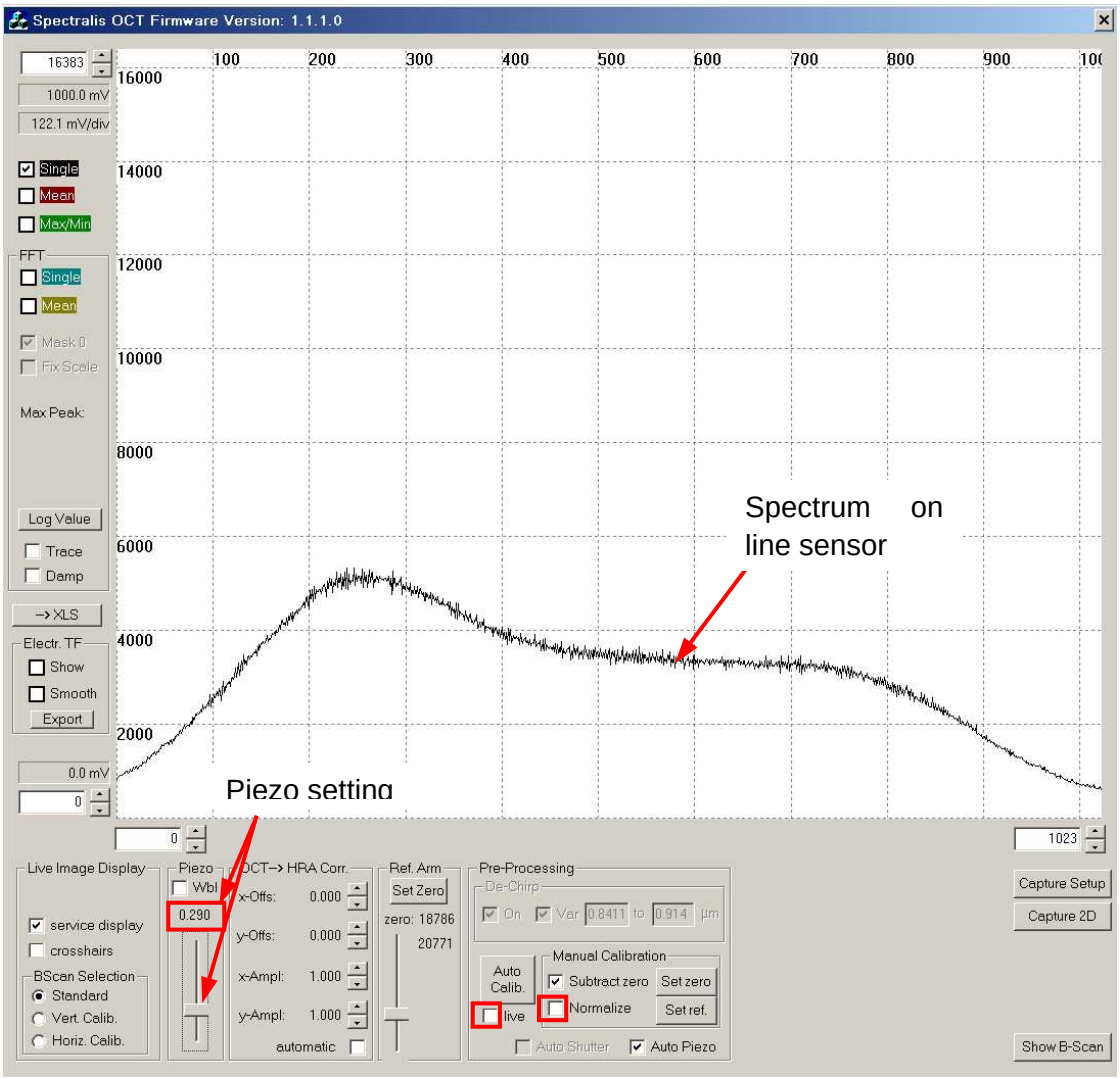
The line which is imaged onto the line sensor will drift vertically during operation due to th effects. The piezo drive of the diffraction grating mount should compensate for this automatically. The actual piezo setting is displayed on the OCT service screen.

6.2 *Check of the optical alignment*

- The OCT Service Screen

OCT image acquisition is started by selecting *IR + OCT* on the touch panel. The OCT service screen will show up by pressing *Ctrl, Alt, Shift* and *O* at the same time (provided that the acquisition window is active). The service screen is showing the actual A-Scan image, i.e. one line detector output.

To check the optical alignment of the spectrometer the settings *live* and *Normalize* have to be *un*checked. Now the raw spectrum should be visible.

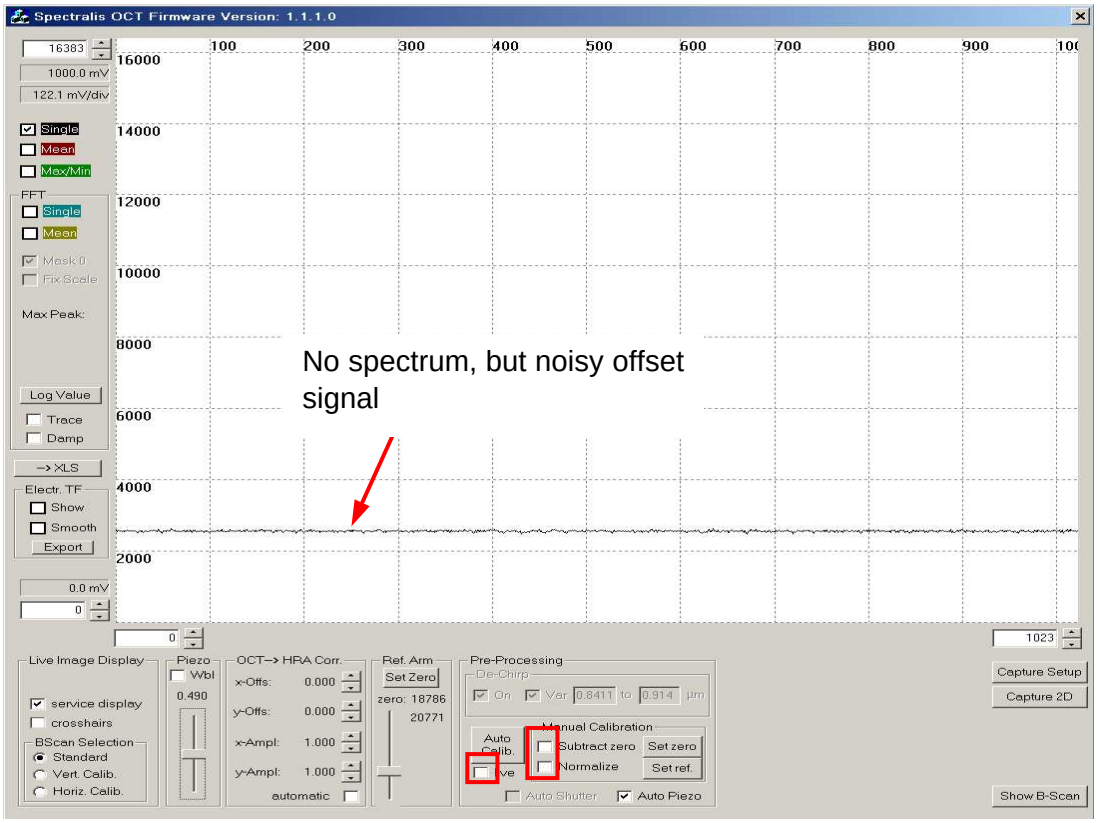


Every time *IR + OCT* is pressed on the touch screen, the auto calibration will start. This procedure can take a few seconds depending on the grade of misalignment or drift. During this procedure the piezo setting is changed from 0 to 1.0 to find an optimum signal intensity on the detector (A*uto piezo* must be checked).

During operation the image line will drift downward due to thermal effects which has to be compensated by an increased value of the piezo setting. After some hours of operation the optimum piezo setting will have been run from about 0.3 (or 0.4 depending on its initial setting) towards 1.0.

A failure of calibration is indicated by a piezo setting of 1.0: the piezo has been moved upwards from 0 to 1.0 but no spectrum signal has been detected. If *Normalize* and *Subtract Zero* are unchecked only a flat line with some noise shows up.

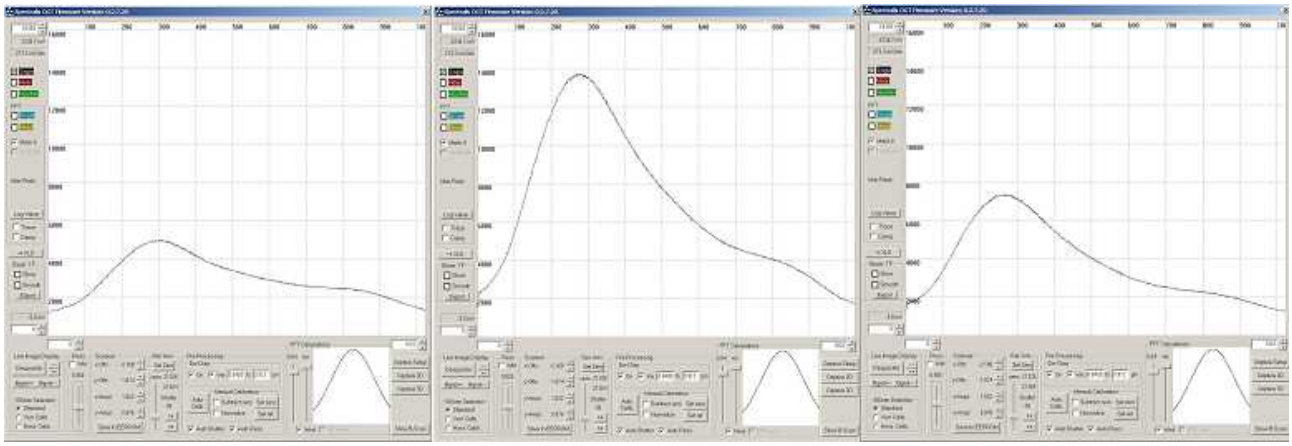
If automatic calibration fails and only a flat noisy line is visible the spectrometer has to be re-aligned.



IMPORTANT: Do *not* start to re-adjust the optical setting *before* having verified that data transfer *and* fiber output power delivered to the spectrometer are correct. Uncheck *Live*, *Normalize* and *Subtract Zero*. If any offset signal, i.e. a flat, but noisy signal which is updating continuously, is missing then data transfer is interrupted! In this case, check cables, restart the power supply, and check the device drivers. If data is transferred check the fiber output power with a powermeter (about 2²W @ 880nm).

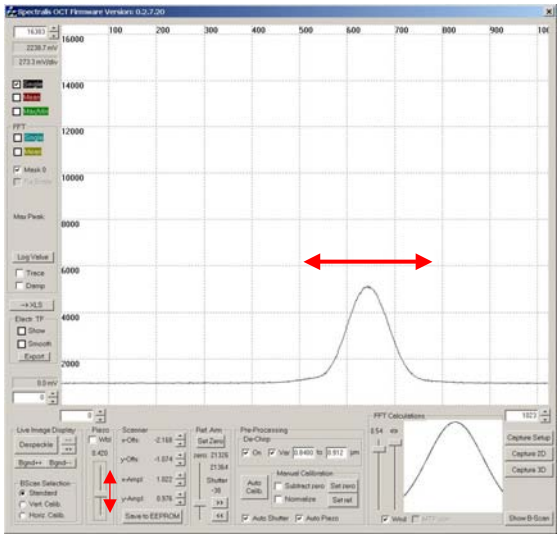
- Check Sensor Alignment

If a spectrum is visible in the service screen (at any piezo setting) then check, if the sensor is aligned parallel to the incident line spectrum: Varying the piezo slider the position of the maximum and the shape of the curve should stay constant (see figure).

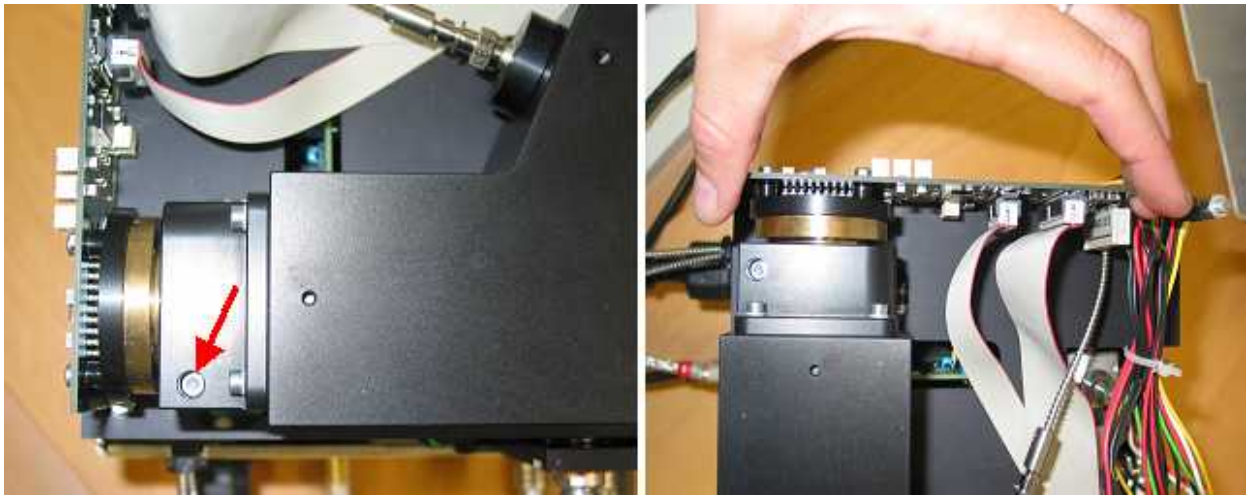


Piezo: 0,460 Piezo: 0,520 Piezo: 0,560

A tilt of the line sensor is evident if the spectrum is narrowed (compared to the spectrum of your data sheet) and its maximum moves from left to right (or the other way round) while moving the piezo slider (see figure).



To align the sensor board, loosen the screw of the black mount only to the extent that the sensor board can be turned but is held in its position. Turn the sensor board slightly to broaden the spectrum. Possibly the micrometer screw has to be turned slightly (by only a few degrees) at the same time if the piezo range is not sufficient to match the change in image height.



Check the adjustment by moving the piezo slider and observing the spectrum as is described above. Then fasten the screw carefully and check the alignment again.

- Check Piezo Setting

The piezo setting can be varied within a range from 0 to 1.0 corresponding to a positioning shift of 0 to 25 microns. To compensate for thermal drift the automatic piezo setting will move towards 1.0 during operation. The initial setting therefore should be in the lower range (about 0.300 to 0.350) at system start which has to be adjusted by the micrometer screw.

Check the actual optimum piezo setting. This can be done automatically by checking *Live* or *Auto Calib.* or manually by pushing the slider upwards starting from 0 and identifying the maximum signal.

IMPORTANT: Due to hysteresis of the piezo the slider has always to be moved upwards starting at setting 0. Maximum intensity occurs at a different piezo setting while moving downwards!

If the optimum piezo setting is at its upper limit (1.0 or near), the micrometer screw has to be turned very slightly and very slowly clockwise. This is a sensible procedure: One complete turn of the micrometer screw corresponds to a shift of 500 microns. What is needed is a shift of about 10 microns – so only a few degrees are required.

Then, move the slider to find the position of maximum signal intensity or use the automatic calibration. If the system has been run for some hours the slider should be in the upper range (about 0.7), for a cold system the maximum signal should be at a slider position of about 0.3.

If the optimum signal is at a slider position which is too large to meet these requirements, turn the micrometer screw clockwise. Correspondingly, if the optimum signal is at a slider position which is too low, turn the micrometer screw counterclockwise.

- Check OCT Image Quality

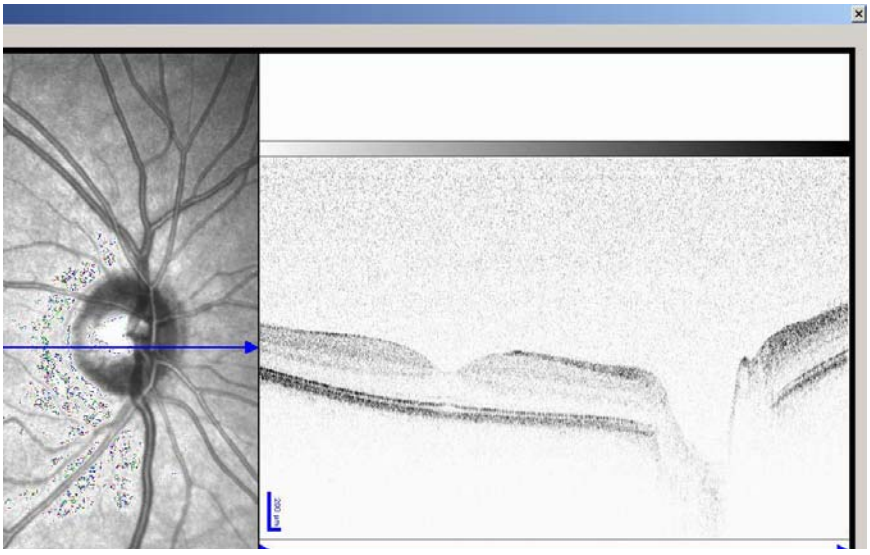
To assess OCT image quality check *Service Display* in the Service Screen. A SNR value is now displayed below the OCT image.

Acquire an OCT image of your eye. Make sure that refraction setting and head rest positioning are optimum to get a reliable measure. Move the Spectralis camera forward/backward until the OCT cross section appears in the upper third of the image display. Press *freeze* on the touch panel to freeze the image and to read the SNR value. It should be at least 35 on a normal healthy eye.

- Check Image Quality Decay

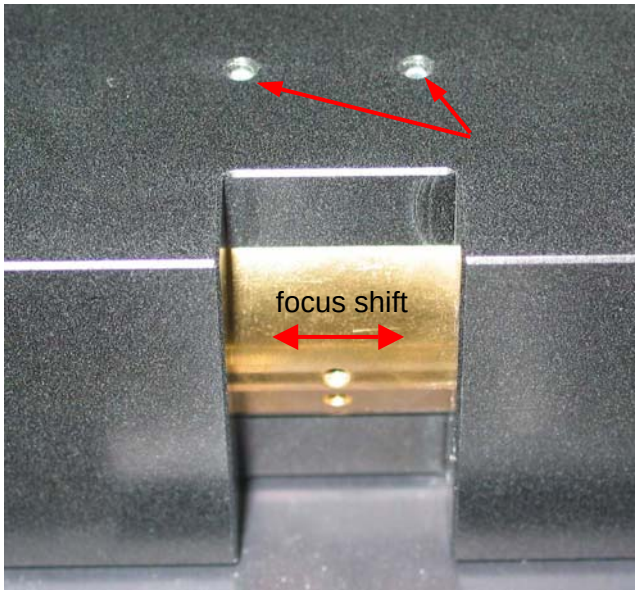
Inherent to the OCT technique is a decay in image quality with depth. Acquire an OCT image at a larger depth. Try to fixate the same position as before. Move the Spectralis camera forward/backward until the OCT cross section appears at about the center of the image display.

Check, that at this position still decent images are available.



If there is a decay in image quality with depth which is evidently stronger than described above, the focus of the spectrometer should be readjusted.

To adjust the focus, loose the two screws of the spectrometer lens. Focus position is adjusted by moving the brass lens mounting slightly forward/backward. If helpful, a pin or a screw can be inserted to shift the lens.



The depth of the focus is smaller than 400 microns. Optimum focus position can be detected by a maximum of signal intensity observed in the OCT service screen (uncheck *Live* and *Normalize*).

IMPORTANT: Shifting the lens affects the height of the image line! Move the lens as slightly as possible and simultaneously move the piezo slider up and down to compensate for any changes in height. Best focus is where maximum signal results *after* piezo optimisation.

Tighten the screws. Signal will decrease, but can be recovered by the piezo setting or a micrometer screw adjustment (then proceed with *Check Piezo Setting*).

6.3 Closing the Cover

- First attach the protective earth wire as shown in the picture in section 5.1
- Then carefully impose the cover without touching the sensor board.
- Make sure, that no cables resp. fibers are squeezed.
- Tighten the 8 allen screws (allen wrench 2 mm)

7 Final Check and Installation Report

In order to ensure an optimum performance of the SPECTRALIS units in the clinical environment, Heidelberg Engineering requests the own field service as well as the international partners to document the installation process by completing an installation report form (see appendix)

This report should be filled out during / after the installation procedure at the customers site, and should be faxed or emailed to the support department of Heidelberg Engineering. This installation report is an important element of the device history record of each instrument.

Please follow the procedures listed below:

Line 1 – Line 4:

SPECTRALIS model name and serial numbers of camera, power supply and touch screen panel. These lines are filled out by Heidelberg Engineering.

Line 5:

Fill in the serial number of the installed software protector dongle.

Line 6:

Check if the instrument is set-up with an instrumentation base joystick version, XYZ version or the new Spectralis OCT ("slim") version. Write down the corresponding serial number, if available.

Line 7:

Check, if the outer appearance of the instrument is o.k. (no transportation damage).

Line 8:

Check, if all cables are properly connected.

Line 9:

The instrument has to be connected to an appropriate isolation transformer. Check, if o.k.

Line 10 –Line 12:

Check the laser power values as follows: Set the SPECTRALIS system to 0 diopters, put the Ophir power meter with the HE adapter onto the objective, and measure the laser power in the following modes (10 seconds average):

Line 10: ICG mode, 790 nm, high resolution mode, 30° field, laser intensity 100%

Line 11:IR-Refl. mode, 790 nm, high resolution mode, 30° field, laser intensity 100%

Line 12:FA mode, 488 nm, high resolution mode, 30° field.

These values should be within the listed specification range. On the report form, the results of measurements during the end test procedure in Heidelberg are given as reference.

Line 13:

The primary Sapphire laser power is shown on the power supply display. The specification range is 7 mW – 9 mW. The value should be in agreement (+/- 0.2 mW) with the data filled in by Heidelberg Engineering.

Line 14:

Sapphire power after AOM in the 1. order beam. This value needs not to be measured during normal installation. However, it may help to locate the source of error, in case the specified range of FA power (line 12) can not be reached.

Line 15:

In order to measure the power of the SLD (OCT light source) proceed as follows:

Switch to IR / OCT-Mode, select circular scan pattern (no laser modulation) and set the IR-Laser to laser power 0%. (Therefore the Touch Panel has to be set to the service mode (see HRA2 service manual) , then press 5% and 5 times the minus button). Mount the power meter (wavelength 880 nm, range 3 mW) onto the objective. Averaging procedure is not required.

Important: For stable power reading deactivate "Live" and "automatic" buttons in Service Window.

Measure the OCT-SLD power (880 nm, circular scan, 30° field)

Line 16:

Power out of OCT fiber injected into spectrometer: This value needs not to be measured during normal installation. However, it may help to locate the source of error, in case the curve of the SLD spectra (line 17) is lower as supposed to be. (Measuring mode as in Line 15, but power range 30 ²W)

Line 17:

Screen shot of the SLD spectra

- Switch to live mode, enable the OCT feature, select OCT+IR
- Switch to 30° field, HR-mode and circular scan
- Open the OCT-Service Window (Ctrl Alt Shift O) and wait until the auto calibration procedure is finished
- Disable "live" and "normalize" by unchecking these features, in order to display the original SLD spectra
- Press Alt Prt in order to copy the window with the SLD spectra to the clipboard. Open an appropriate program (e.g. Paint, Word etc.), insert the clipboard and print and/or save the debug window with the spectra. Attach this document to the installation protocol.
- Compare the measured spectra with the delivered print-out. The shape of the curve should be very similar, the height of the maximum should agree within +/- 10%.

Line 18 – line 19:

In order to judge the quality of the instrument performance after installation, a test examination (IR-reflection and OCT image) of a normal eye should be accomplished. The following criteria allow the evaluation of the images:

Line 18, IR-reflection image:

Check, if at laser power 50% and medium detector sensitivity a well illuminated, sharp image of the retina of a test person is obtained.

Line 19, OCT image:

If the check box "service display" is enabled in the OCT service window, an arbitrary value for the signal to noise ratio (SNR) is displayed on the computer screen just below the OCT image. For a healthy eye typical values of about 35 or higher are obtained, when the OCT image is shifted to the upper range of the OCT display window. Document the obtained values of a test examination.

Line 20 – line 22:

Document the installed versions of the Heyex, the Acquisition Module, and the Viewing module. The installed versions are displayed in the Heyex/About menu.

Line 23:

Fill in address and institution of the customer, responsible person, phone number, and/or email address.

Line 24:

Date and Signature end test by Heidelberg Engineering

Line 25:

Installation o.k., Date and Signature confirmed by technician / engineer, responsible for installation.

Heidelberg Engineering GmbH

fax: +49 6221 646362 Att. Technical Support
email: Support@HeidelbergEngineering.com

Appendix: SPECTRALIS Installation Report

(Art. No. 92 733)

SPECTRALIS Datasheet and Installation Report

1. Spectralis Model: HRA+OCT ☐ HRA ☐ OCT Plus ☐ OCT☐	Heidelberg Eng. Endtest protocol	Installation at Customer site
2. SN Spectralis System (Camera Label)	S-	
3. SN Spectralis Power Supply (PWS)	S-	
4. SN Touch Panel (TSP)		
5. SN Dongle		
6. SN Instrumentation Base		KT- MNT- SL-
7. Appearance o.k.; no transportation damage *(check if correct)*		☐
8. All cables properly connected *(check if correct)*		☐
9. System (including PC) connected to isolation transformer *(check if correct)*		☐

Laser Power Measurements at objective (closed cover) (refraction 0 dpt, 100% power, 30 ° field, HR-mode)	Specification Range	Measurement Endtest HE (average 10 s)	Measurement installation (average 10 s)
10. ICG (λ=785 nm)	2.4 – 2.8 mW	mW	mW
11. IR (λ=815 nm)	40 – 80 µW	µW	µW
12. FA (λ=488 nm)	250 – 300 µW	µW	µW
13. Primary Sapphire (FA) power (display reading)	7 - 9 mW	mW	mW
14. Sapphire power after AOM (continuous diffraction into 1. Order)		mW	

SPECTRALIS Datasheet and Installation Report

SN Spectralis System (Camera Label)		S-	
15. SLD power (λ=880 nm) (IR+OCT, set IR to 0%, circular scan)	1.10 - 1.25 mW	mW	mW
16. Power out of OCT fiber injected into Spectrometer (880 nm, circular scan)		µW	
17. Copy (screen shot) of SLD spectra attached (uncheck "live" and "normalize"; spectrum acquired in 30°, HR-Mode, circ. scan)		☐	☐
18. Quality of IR image o.k. (power at 50%, medium sensitivity)		☐	☐
19. SNR-value (image quality) of OCT image o.k. (OCT image in the upper quarter of display; SNR values typically ~ 35, activate service display)		SNR:	SNR:
20. Installed Software Versions: Heyex		HEYEX-Version	
21. Installed Software Versions: Acquisition-Module		AQM-Version	
22. Installed Software Versions: Viewing-Module		VWM-Version	
23. Endtest HE o.k.	Date	Signature	
24. Installation o.k.	Date	Signature	

Address, Institution of the Customer responsible person (if possible phone and/or email)

Institution / Name		Phone	
Name, First name:		Fax:	
Street, Number:		e-mail:	
City, Zip		Remark:	

Fax or scan / email this document back to the support department of Heidelberg Engineering

Fax: +49-6221-646362 / email: support@HeidelbergEngineering.com