

Spectralis

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Spectralis HRA+OCT

Spectralis HRA

Spectralis OCT

Hardware

Operating Instructions

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The logo for Heidelberg Engineering, featuring the company name in a bold, sans-serif font. The word "HEIDELBERG" is on the top line and "ENGINEERING" is on the bottom line. A small red square is positioned to the left of "HEIDELBERG" and another to the right of "ENGINEERING".



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



Caution! Do not use the Spectralis without reading this manual.



This product is manufactured under one or more of the following patents:  
US 5,170,276; DE 41 03 298 C2; EP 0 498 280 B1.



Corporate Headquarters

Heidelberg Engineering GmbH • Tiergartenstr. 15 • 69121 Heidelberg • Germany  
Phone +49 6221 6463-0 • Fax +49 6221 646362 • [www.HeidelbergEngineering.de](http://www.HeidelbergEngineering.de)

US Main Office

Heidelberg Engineering, Inc. • 1499 Poinsettia Avenue, Suite 160 • Vista, CA 92081  
Phone 760 598-3770 • Fax 760 598-3060 • [www.HeidelbergEngineering.com](http://www.HeidelbergEngineering.com)

US Service Center

Heidelberg Engineering, Inc. • 410 Harris Road • Smithfield, RI 02917  
Phone 401 349-0500 • Fax 401 349-0504 • [www.HeidelbergEngineering.com](http://www.HeidelbergEngineering.com)

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# 1 General Information

This is an introduction to the Heidelberg Spectralis family of devices (Spectralis HRA, Spectralis OCT and Spectralis HRA+OCT). These operation instructions also contain important safety information.

## 1.1 Intended Use

The Spectralis devices are a diagnostic devices for imaging the retina of the human eye and for aiding in the assessment and management of various diseases of the posterior segment, such like age-related macular degeneration, diabetic retinopathy, and glaucoma.



### The Spectralis HRA

is a confocal laser scanning angiography system. It offers the following imaging modes:

- Fluorescein angiography (FA)
- Indocyanine green angiography (ICGA)
- Infrared reflectance imaging (IR)
- Blue or “red-free” reflectance imaging (RF)
- Fundus autofluorescence imaging (AF)
- Simultaneous FA and ICGA
- Simultaneous FA and IR
- Simultaneous ICGA and IR
- Simultaneous AF and IR

In each of the above imaging modes, single images or image sequences can be acquired and stored.

### The Spectralis OCT

is a spectral-domain (also called Fourier-domain) optical coherence tomography system that allows high-speed, high-resolution cross-sectional imaging of the retina, offering the following imaging modes:

- Simultaneous OCT and infrared reflectance imaging
- Infrared reflectance imaging alone

OCT imaging can be single cross sections of the retina (“B-scans”), patterns of single cross sections, or complete three-dimensional images.

### The Spectralis HRA+OCT

is a combination of the Spectralis HRA and Spectralis OCT, allowing angiography, reflectance imaging, autofluorescence imaging, and OCT cross sectional imaging, alone or in various combinations. The imaging modes of the Spectralis HRA+OCT comprise all imaging modes listed above for the Spectralis HRA and for the Spectralis OCT, plus:

- Simultaneous OCT and FA imaging
- Simultaneous OCT and ICGA imaging
- Simultaneous OCT and BR imaging
- Simultaneous OCT and AF imaging

## 1.2 Principles of the Technology

### 1.2.1 Confocal Laser Scanning

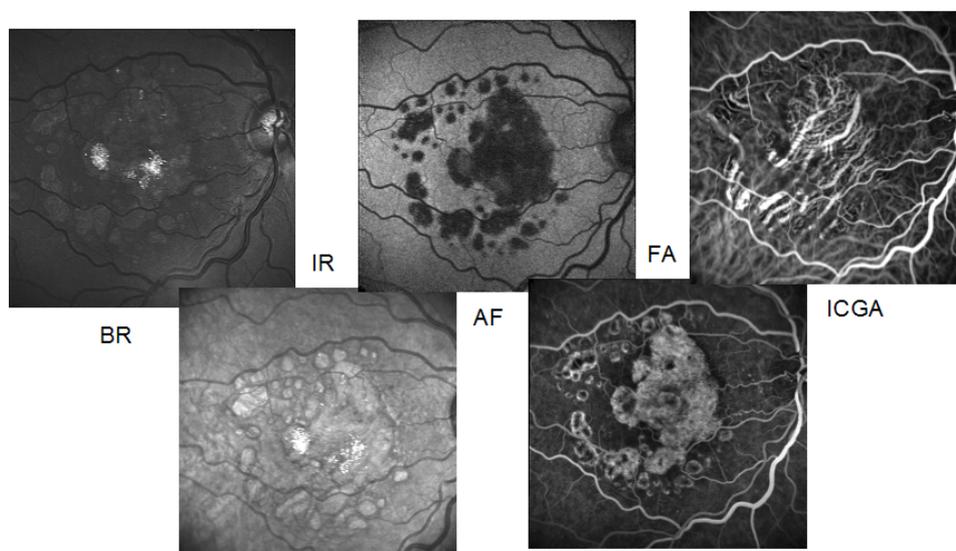
For acquisition of the digital confocal images, a laser beam is focused on the retina. The laser beam is deflected periodically by means of oscillating mirrors to sequentially scan a two-dimensional section of the retina. The intensity of the reflected light or of the emitted fluorescent light at each point is measured with a light sensitive detector. In a confocal optical system, light reflected or emitted outside of the adjusted focal plane is suppressed, resulting in high contrast images. Furthermore (especially during indocyanine green angiography), the confocal optical system allows to acquire a layer-by-layer three-dimensional image.

The confocal imaging system allows to image the retina with non or poorly dilated pupils. This is especially important for diabetics because they typically do not dilate very well and account for a large number of patients seen in the retina clinic.

Fluorescence dyes are excited in relatively narrow wavelength bands. Using a laser is the most efficient means for excitation, since all the energy is concentrated at one specific wavelength rather than in a broad continuum as with ordinary flash photography light. Therefore, the retinal light exposure required for angiography with the Spectralis HRA is considerably less than that required with a photographic system, thus allowing for safer and more patient-friendly examination.

The laser sources of the Spectralis HRA emit laser light with three different wavelengths:

1. For excitation of fluorescein, a blue solid state laser (wavelength 488 nm) is used. A barrier filter at 500 nm separates excitation and fluorescence light. The same wavelength (but without the barrier filter) is used to create blue reflectance images (also called red-free images). Furthermore, the Spectralis HRA is capable of high quality autofluorescence (488 nm) imaging.
2. For excitation of indocyanine green, a diode laser at 790 nm wavelength is used, together with a barrier filter at 830 nm to separate excitation and fluorescence light.
3. A second diode laser at 820 nm wavelength serves to produce infrared reflectance (IR) images.



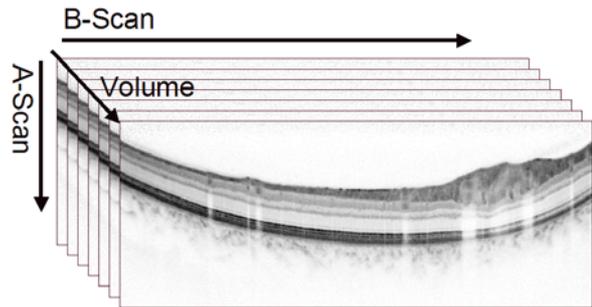
RPE Atrophy

In the simultaneous imaging modes, each image line is scanned twice subsequently with alternating lasers. For example, during simultaneous fluorescein and indocyanine green angiography, only the 488 nm laser is switched on for the first scan of a line, while during the second scan only the 790 nm laser is switched on.

In every acquisition mode, individual images, temporal image sequences, or a focal series of images (layered three-dimensional images) can be acquired.

### 1.2.2 Optical Coherence Tomography (OCT)

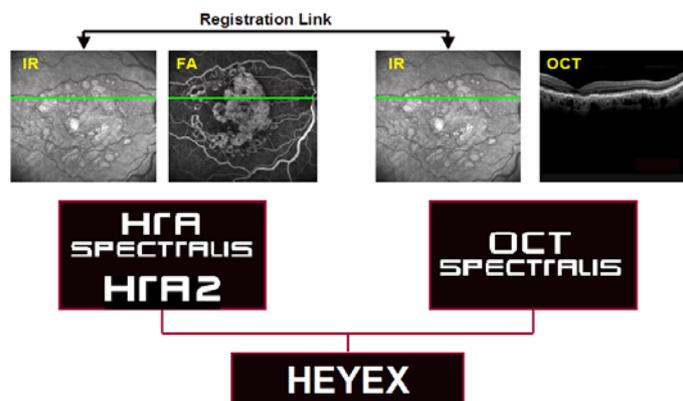
The Spectralis OCT and the Spectralis HRA+OCT use spectral domain optical coherence tomography (SD-OCT) technology, also referred to as Fourier domain OCT (FD-OCT). The beam of a super luminescence diode (SLD) scans across the retina to produce a cross sectional B-scan image. To create three dimensional images of the retina, up to 768 equally spaced B-scans can be sequentially acquired. The infrared beam of the SLD has an average wavelength of 870nm



### 1.2.3 Use of Several Devices, Registration Link

All Heidelberg Engineering imaging products use the Heidelberg Eye Explorer (HEYEX) software platform and database to store patient information and images. Image acquisition and analysis is controlled by HEYEX plug-in software modules that are specific to each device.

Network connections between devices of the Spectralis family allow access to the common HEYEX database, as well as registration of OCT images to angiography images taken with simultaneous IR images on a separate HRA2, Spectralis HRA or Spectralis HRA+OCT system. The simultaneously acquired IR image serves as the registration link between the images obtained at separate devices.



For simultaneous use of the software on several computers within a network, additional networking licenses can be obtained. One network license can cover all modules installed in the network.

In addition to the complete operating software (image acquisition and viewing) provided with each device, optional HEYEX viewing software is available for each module. This viewing software enables users to open E2E files and to review images and patient data on PCs which are not connected to the Spectralis or HRA device.

Furthermore, the optional Image Capture Module software enables the import of digital images or documents from other devices (fundus cameras, perimeters etc.) into the HEYEX patient file.

## 1.3 Safety Information, Cautions and Warnings



Please read this section carefully and always heed its contents!

### 1.3.1 General Safety Information

**IMPORTANT** Before you start working with the instrument, make sure that you know the correct procedures for turning the instrument on and off (Chapter 2 “General Operating Information”).

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

**IMPORTANT** Never leave the patient alone with the instrument during the examination.

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

Any repair, especially of the instrument's electric and electronic systems, and any service work on the instrument components, must only be carried out by appropriately qualified and authorized staff.

**CAUTION** Unusual noises and/or vibrations may be symptoms of a fault in the instrument. Please turn the instrument off and contact your local service office. Do not attempt to repair any faults with the instrument yourself.

### 1.3.2 Contraindications for Performing Angiography

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

### 1.3.3 Warnings

**IMPORTANT** Do not make a diagnostic decision on one single examination. Always use alternative information, history data etc. to assist in a final diagnosis.

**CAUTION** Do not use PCs, components or accessories that have not been approved by Heidelberg Engineering. Do not install other software programs as they may interfere with the functionality of the Heidelberg Engineering software or equipment. This could include damage to the system as well as incorrect measurement results.

**CAUTION** Make sure that the environmental requirements are met when the system is operated. Exceeding environmental conditions might damage the system or lead to decreased image quality. (See chapter 3 “Technical specifications”).

- CAUTION Make sure the patient is correctly placed in front of the camera before starting the examination. Incorrect positioning may lead to poor images and abnormal diagnostic results.
- CAUTION This equipment was tested in accordance to 60601-1-2, Electro Magnetic Compliance (EMC). Nevertheless it might be influenced by strong electromagnetic fields. Portable high frequency communication devices might influence the device.
- CAUTION Artifacts (e.g. reflexes) on the images might be misleading. Do not use images with artifacts.
- WARNING Do not operate the system without connecting the System over an IEC 60601-1 approved isolation transformer. Do not place the isolation transformer on the floor and do not operate other devices that are not part of the Heidelberg Engineering system with the same isolation transformer.
- WARNING Do not use a network connection without network isolation in accordance to IEC 60601-1. In case of a failure in the network, there could be a hazard of electrical shock to the user and patient.
- WARNING Do not open the device component housings. Doing so can lead to the possibility of electrical shock or exposure to harmful laser radiation.
- WARNING To avoid the risk of electric shock, this equipment must only be connected to a grounded power supply.
- WARNING To avoid the risk of electric shock, do not touch conductive parts of connectors and the patient simultaneously.
- WARNING Do not use the device outside of the scope of intended use. Doing so may pose a risk to the patient or operator and may lead to malfunctions or damage of the device.

For the United States of America only:

- CAUTION Federal law restricts this device to sale by or on the order of a Physician or Practitioner.

#### 1.3.4 Precautions

- The operator shall be sure that the device settings and adjustments are correct before examination and diagnostic decision. Incorrect settings and adjustments may lead to poor image quality or abnormal examination information.
- Make sure the scanners are working (high pitched sound) before sitting a patient in front of the device. No laser beam should be visible, when the scanners are off. A hazard for an injury of the retina would exist if the laser beam hits the retina without being scanned.
- The physician shall be sure to have the correct patient data before a diagnostic decision. Mismatched patient data may lead to incorrect diagnostic decisions.
- Read chapter “Preparing the patient“ of the Software Operation Instructions carefully before starting the examination. Incorrect preparation of the patient may lead to poor image quality and incorrect diagnoses.
- Do not start an examination without informing the patient about the examination procedure. Incorrect patient behavior during the examination may lead to poor image quality and incorrect diagnoses.
- Clean and disinfect chin rest and headrest after each examination. Contaminated parts may lead to infections or disease contraction.
- Read chapter 1.6 “Maintenance, Cleaning and Service” carefully. Missing maintenance or incorrect adjustment of the device may lead to poor image quality and incorrect diagnoses.
- Prepare safeguards to ensure that only authorized personnel can access the patient data. Data loss impedes follow up analyses and may result in wrong diagnostic decision.
- Be sure to perform periodic data backup procedures. Check the success of the backup to avoid data losses caused by backup errors.
- Do not operate the system directly after large temperature changes. Let the device acclimate itself for a minimum of 2 hours to avoid device damage or incorrect measurement results.
- For the application of contrast or dye fluid, closely follow the package information leaflet. Because of possible adverse effects of drug injections (as allergic reactions or shock), we recommend to limit the number of angiography examinations per day to the minimum necessary. In most cases one injection will be sufficient.
- Before starting the system check the regional power supply specifications to verify that they fit the required tolerances ( $100V < U < 240V$ ;  $50Hz < f < 60Hz$ ). Incorrect power supply conditions might lead to malfunctions of the system.
- Be aware that the influence of other physical effects (vibrations, strong electromagnetic fields as caused by big machines etc. running close-by) might disturb the proper operating of the device.
- Note that a computer failure during picture acquisition or analysis could lead to incorrect results.

### 1.3.5 Laser Safety

This instrument contains a solid-state laser and two diode lasers as well as a super luminescence diode. The instrument emits visible and invisible laser light through the objective lens on the front of the laser scanning camera. The Spectralis is a Class 1 laser system. It does not pose any safety hazard whatsoever. The laser class label is located on the rear panel of the camera housing and the rear panel of the laser module.

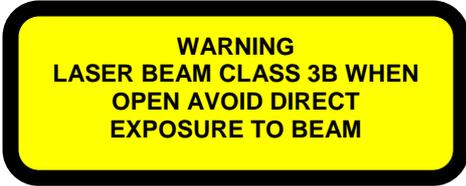


**LASER CLASS 1**

However, hazardous laser radiation may be accessible when the camera housing or the housing of the laser module is open.

**WARNING** Never open the housing of the laser scanning camera or the laser module. When the camera housing or the laser module housing is open, visible and/or invisible laser radiation of Class IIIB is accessible and can lead to injuries. The camera housing and laser module housing must only be opened by qualified service staff.

Laser warning labels to this effect are positioned on the cover of the camera housing (underneath the electronics card which is located there) and on the back side of the laser module.



**WARNING  
LASER BEAM CLASS 3B WHEN  
OPEN AVOID DIRECT  
EXPOSURE TO BEAM**

To guarantee the safety of the user and the patient at all times, a limit has been imposed on the maximum period of time for which the laser beam can be switched on. If this limit is exceeded, the screen shows the message: 'Laser Safety; laser timed out'. Image acquisition is automatically interrupted and can only be continued after a specified waiting period (about 3 hours). However, this will not usually occur during normal use of the instrument.

## 1.4 Components of the Instrument, Scope of Delivery

The Spectralis conforms to all applicable safety standards such as IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, UL 60601, and IEC 60825.

The basic components of the Spectralis are:

- Laser scanning camera
- Control Panel (also called Touch Panel)
- Foot switch
- Camera mount with integrated headrest
- Power supply / laser box (PSW PS410 or PWS/FW)
- Cable connecting Control Panel and power supply
- Power Supply Model PWS / FW, IEEE 1394 cable to PC
- CD containing operation software
- Software protector
- Operation Manuals
  - Hardware Operation Instructions (this document)
  - Software Operation Instructions (Spectralis QuickGuide)
  - Manual “Installation and System Configuration”

The Spectralis is operated by a personal computer, in combination with an IEC 60601-1 approved isolation transformer (see chapter 1.5 “System Installation”, as well as chapter 1.3.3 “Cautions and Warnings” for further details). The computer receives the image data generated by the laser scanning camera and performs the entire image analysis.

The operation software includes functions to communicate with the user, to control image acquisition, to store images and data, to process and analyze the acquired images, and to document the examination results.



## **1.6 Maintenance, Cleaning and Service**

The Spectralis is a precision optical instrument. Please protect the instrument from dust and moisture, and avoid subjecting it to shocks or strong forces.

The non-optical surfaces of the instrument can be cleaned and/or disinfected whenever necessary. Any standard cleaning product appropriate for plastic surfaces that does not contain acetone or hydrogen peroxide (e.g. ethanol and isopropyl alcohol disinfectants) may be used for this purpose. Before doing this, please turn the instrument off and pull out the power plug.

The lens surface at the front of the laser scanning camera should be carefully cleaned at regular intervals. For this purpose, it is best to use a cotton swab slightly moistened with pure (99.9%) ethyl alcohol.

Please be aware that only authorized service personnel can do service and repair operations of the Spectralis. Do not open the device. If the device is opened by someone other than an authorized service personnel, the warranty will be discontinued. If the device fails please call your local distributor or the Heidelberg Engineering support department.

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

## 2 General Operating Information

### 2.1 Turning the Instrument On and Off

#### 2.1.1 Start Up Procedure

To turn the Spectralis on, proceed as follows:

- (1) Turn the computer on. After the boot sequence has been completed, the computer will start the Windows operating system.
- (2) Turn on the power supply of the device. The power switch is located on the front panel of the power supply. The 'On' position is marked I.
- (3) Start the Heidelberg Eye Explorer software.



Use the Heidelberg Eye Explorer shortcut on the desktop to start the application by double left-clicking on the Eye Explorer Icon on your desktop



or by using the windows start menu:

Start → Programs → Heidelberg Eye Explorer →  Heidelberg Eye Explorer

Wait until the software opens to the database view.

**Note:** It is not recommended to turn the instrument on and off frequently. Even if you are not using the instrument constantly during the course of a day, it is best to turn it on in the morning and not to turn it off again until the evening.

#### 2.1.2 Shut Down Procedure

To turn the Spectralis off, proceed as follows:

- (1) If the acquisition dialog is open and the live image is visible on the screen, stop the image acquisition with the green button at the lower right corner of the Control Panel display.

To close the software program, select the option Exit from the menu item File or by clicking the Exit button  at the top right corner of the screen.



- (2) Turn off the power supply. The power switch is located on the front panel of the power supply. The 'Off' position is marked 0.

**IMPORTANT** Never turn off the power supply while the scanning laser camera is acquiring images. This can result in damage to the camera. Never turn the computer off without exiting out of the Spectralis operation software first. This can result in the loss of data stored on the computer's hard disk. Before you turn off your computer, select "Shut Down" from the Windows "Start" menu.

## 2.2 Operating the Hardware

### 2.2.1 Spectralis Camera and Headrest

The laser scanning camera is mounted on a special camera mount which also includes the headrest for the patient. Familiarize yourself with handling the camera using the joystick or micromanipulator adjustment controls (x, y, z movement of the camera). Confident handling of the controls reduces the time required for the examination, increases patient comfort and leads to optimal image quality.

#### Joystick

Turn the joystick clockwise to move the camera up. Turn the joystick counter-clockwise to move the camera down.

Move the joystick left / right and forward / backwards to direct the camera in the same direction.

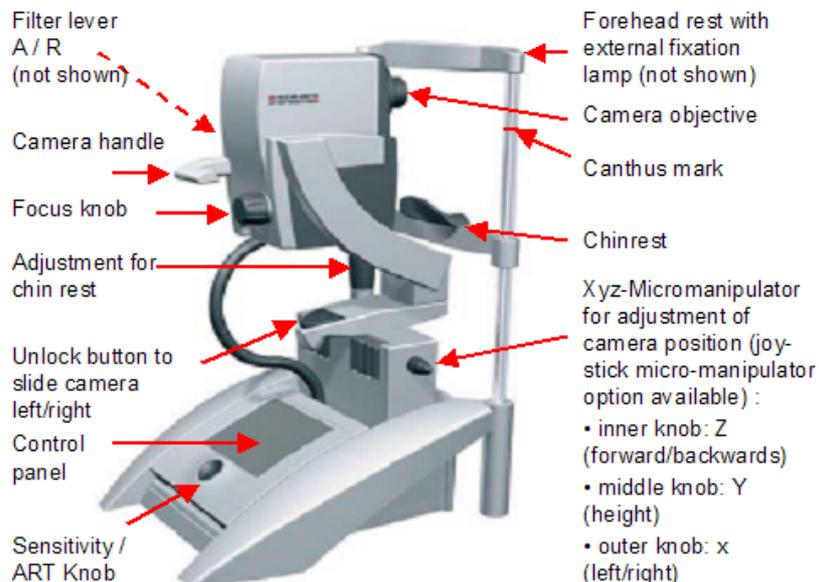
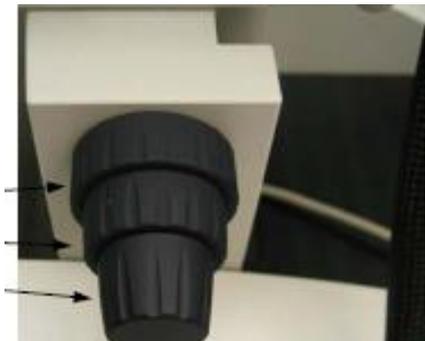


#### xyz-Micromanipulator

Use the xyz-Micromanipulator for the adjustment of the camera position:

- inner knob: Z adjustment (forward/backward)
- middle knob: Y adjustment (height)
- outer knob: x adjustment (left/right)

To change the camera position in order to examine the other eye of the patient, move the camera backwards, press the unlock button and slide the camera mount to the other side of the headrest.



### 2.2.2 Exchanging Objectives

In order to remove the Spectralis Standard Objective, rotate the objective by about 50° to the left (counter clockwise) and remove it (bayonet connector). Make sure that the objective is retained properly; a special wooden box is delivered for the lenses.



The optional 55° wide angle lens for IR, RF and angiography wide-field imaging is mounted the same way: it has to be inserted with the red dot orientated upwards (12 o'clock) and then rotated by about 50° clockwise until it snaps in.

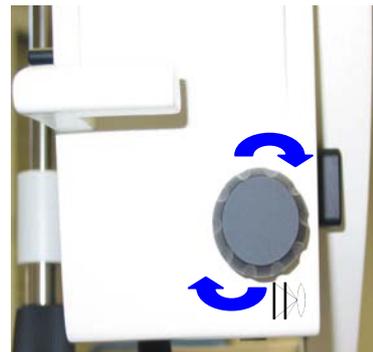
The Spectralis automatically detects which lens is mounted on the system. For the standard objective, the field sizes 15°, 20° and 30° are offered on the Control Panel, whereas with the optional 55° objective the scan angles 25°, 35° and 55° are displayed.

For further information, please refer to the “55° lens” Release Notes.

NOTE: The optional 55° lens is not suitable for OCT imaging.

### 2.2.3 Focus Knob

The black knob at the backside of the camera head (away from the patient) is the Focus knob. By turning this knob, refractive errors of the patient’s eye can be compensated. The current focus compensation is shown at the lower left side of the monitor in the PC Acquisition screen in diopters.



For examination of most patients, an initial focus setting of ‘0’ (zero diopters) is suitable. Then make focus adjustments as necessary. (Note: when imaging high myopes it might be necessary to increase the focusing span – use the Control Panel ‘More’ option).

Keep in mind that the focal planes for blue and infra-red light differ slightly. Therefore, it is recommended to check the focus when changing from red free or FA to infrared or ICGA mode or vice versa.

### 2.2.4 Filter Lever

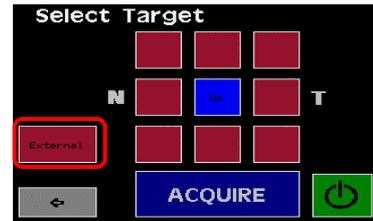
By changing the position of this lever at the left side of the camera head, the filters needed for angiography are brought in to position. In the position marked ‘A’ the angiography modes (FA, ICGA) are available, in the position marked ‘R’ only reflectance modes (IR, RF) are available.



NOTE: When the filter lever is not properly locked in to one of the above positions, it will not be possible to acquire any images. A notice to this effect will appear at the bottom of the acquisition screen.

## 2.2.5 External Fixation Target Lamp

The flexible external fixation target can be activated from within the Control Panel by double tapping on the 3x3 matrix of blue dots and then selecting 'External fixation'.



## 2.2.6 Control Panel

The Control Panel is used to control image acquisition. All image acquisition parameters such as imaging mode, laser intensity, detector sensitivity and size of the scanning field are specified. Image acquisition itself may be activated from the Control Panel.

To switch the laser on and off tap on the square 'On-Off' button at the lower right corner of the screen on the Control Panel.



### 2.2.6.1 Sensitivity Knob

Turning this knob increases (clockwise) or decreases (counterclockwise) the light sensitivity of the camera. Thus by turning the knob the image brightness changes (high sensitivity = high brightness, low sensitivity = low brightness).



The current sensitivity value is displayed on the lower left side of the monitor in the PC Acquisition module window.

By pressing the sensitivity knob, you can change into the optional ART (Automatic Real-Time) modes:

- ART Composite (Pan Retinal Composite)
- ART Mean (Noise Reduction) imaging mode

### 2.2.6.2 Starting the Laser

Immediately after switching on the device., the Control Panel display will appear as shown on the right ("System Start" Screen).

To open the HEYEX Acquisition window on the computer, start the HEYEX. Enter a new patient or open an existing patient file and start a new examination. (please refer to chapter 2.2 "Patient File" of the Spectralis Software Operating Instructions).



Once a patient file is open and entries for an acquisition are made, the Acquisition Window with the live image will open (see chapter 3.6 “Acquisition Window” of the Software Operation Manual), and the ‘Start/Stop’ button (0), on the “System Start” screen of the Control Panel will change from red to white. Press the white ‘Start/Stop’ button in order to turn on the laser.



The live image of the camera will be visible on the computer monitor and the main screen of the Control Panel will open.

NOTE: FA/Red Free modes are not available during warm-up (approx. 1/2 minute).



The Control Panel menus are explained in the chapter 3 “Image Acquisition” of the Spectralis Software Operating Instructions).

### 2.2.6.3 Control Panel Calibration

After the first installation of the Spectralis, a calibration of the Control Panel is required. This procedure is started automatically upon first startup of the Acquisition module. 12 marks will appear in the corners of the screen during the calibration procedure. Please touch them as precisely as possible.



### 2.2.6.4 Interlock

An interlock can be triggered if the FA/red free laser power rises above the pre-set values or if one or both of the scanners are not working properly.

Stop using the system and contact technical service.



### 2.2.7 Foot Switch

The foot switch may be used to acquire images. Its function is identical to pressing the ‘Acquire’ button on the Control Panel.

### 2.2.8 Keyboard

To use the Spectralis operation software, you need a computer keyboard in order to enter text and to control certain software functions. The function keys and special keys are often used and are identified as 'F1', 'F2', etc. in this operation manual.

### 2.2.9 Mouse

The Spectralis operation software is controlled via a graphical user interface (menu). To interact with the software and to select a specific menu field, use the mouse to move the pointer to the field and press either the left or right mouse button for different menus.

### 3 Technical Specifications

Manufacturer	Heidelberg Engineering GmbH Tiergartenstraße 15 69121 Heidelberg / Germany
Model Types	Spectralis HRA+OCT, Spectralis HRA, Spectralis OCT
Application Parts Type B:	Spectralis chin rest and headrest (integrated in instrument base) 
Dimensions and Weight	Camera head approx. 100 mm x 235 mm x 205 mm, 5.6 kg  Instrument base (Micromanipulator) 184 mm x 393 mm x 561 mm, 13.5 kg  Power supply (PS410)  Spectralis HRA+OCT 350 mm x 180 mm x 220 mm, 6.5 kg  Spectralis HRA and Spectralis OCT 350 mm x 180 mm x 170 mm, 6.5 kg  Control Panel: 180 mm x 166 mm x 92 mm, 2 kg
Power Supply	100 – 240 V~, 50/60 Hz
Power Consumption	70 VA
Protection Against Electric Shock	Class I
Power Outlets	2 IEEE 1394 (FireWire1/ i.LINK) ports: 12 V  , 1.25 A (power supply model PWS/FW only)
Ingress Protection Class	IPX0
Mode of Operation	Suited for continuous operation <sup>2</sup>
Operating Environmental Conditions	Temperature: 16°C – 35°C / 61°F – 95°F Relative Humidity: 10% – 90% non condensing Air Pressure: 700 hPa – 1060 hPa
Non operating Environmental Conditions	Temperature: -30°C to 60°C / -22F to 140F Relative humidity: 10% to 100% Air Pressure: 500 hPa – 1060 hPa

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

<sup>2</sup> Note: If the examination time of a patient exceeds 50 minutes within a given three hours interval, the camera will go to standby mode. It can be started again directly with a new patient or with the same patient after an appropriate waiting period.

<p>Light Sources</p>	<p>ICG excitation: Diode laser, wavelength 790 nm, laser class I</p> <p>IR reflectance: Diode Laser, wavelength 820nm, laser class 1</p> <p>FA excitation and blue reflectance: Solid state laser, wavelength 488nm, laser class 1</p> <p>Super luminescence diode (SLD), average wavelength 870 nm, laser class I</p> <div data-bbox="624 521 880 651" style="border: 2px solid black; padding: 5px; text-align: center; margin: 10px 0;"> <p><b>LASER CLASS 1</b></p> </div> <p>The Laser safety class is approved and defined in accordance to IEC 60825 part 1 and part 2 and complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No.50, dated June 24, 2007”.</p>
<p>OCT Scanner Specifications</p>	<p><u>A-Scans</u></p> <p>Scan rate: 40 kHz</p> <p>Scan depth: 1.8 mm</p> <p>Scan size: 512 pixels</p> <p>Axial resolution: 7 μm optical 3.5 μm/pixel digital</p> <p>Lateral resolution: 14 μm optical</p> <p><u>B-Scans</u></p> <p>Scan angle: 30 / 15 / 10 degrees</p> <p>Scan width: up to 9 mm</p> <p><u>High speed mode</u></p> <p>Scan width: 768 A-Scans</p> <p>Acquisition time: 19 ms / B-Scan</p> <p>Lateral resolution: 11 μm/pixel digital</p> <p>Scan rate: 48 B-Scans/sec</p> <p><u>High resolution mode</u></p> <p>Scan width: 1,536 A-Scans</p> <p>Acquisition time: 38 ms / B-Scan</p> <p>Lateral resolution: 6 μm/pixel digital</p> <p>Scan rate: 25 B-Scans/sec</p>

<p>Scanning Laser Specifications (30°/ 20°/ 15°)</p>	<p><u>Transversal field of view</u> Scan angle: 30°x30°, 20°x20°, 15°x15° Wide field composite image to 120°</p> <p><u>High speed mode</u> Digital image size: 768x768 / 512x512 / 384x384. Scan time per image: 96ms / 64 ms / 48 ms Lateral resolution 10 µm/pixel digital Image Acquisition Frequency 9 Hz / 12.5 Hz / 16 Hz</p> <p><u>High resolution mode</u> Digital image size: 1536x1536 / 1024x1024 / 768x768. Scan time per image: 192 ms / 128 ms / 96ms. Lateral resolution 5 µm/pixel digital Image Acquisition Frequency 5 Hz / 7 Hz / 9 Hz</p> <p><u>Maximum Scan Depth</u> 8 mm</p>
<p>Focus Adjustment range</p>	<p>-12 diopters to +12 diopters spherical</p>
<p>Fuses</p>	<p>240V~: 2 x T 1.25 A / 250 V~ 100V~: 2 x T 2.5 A / 250 V~ Please contact your local Heidelberg Engineering distributor when the fuses are blown.</p>
<p>Mains Isolation Switch</p>	<p>Rocker switch at power supply front side</p>
<p>Data and Control Interface to PC (power supply type PWS/FW only)</p>	<p>IEEE 1394 (FireWire3 , i.LINK4)</p> <div style="text-align: center;">   </div>

<sup>3</sup> FireWire and the FireWire symbol are trademarks of Apple Computer, Inc., registered in the U.S. and other countries. The FireWire logo is a trademark of Apple Computer, Inc.

<sup>4</sup> The i.LINK logo is a trademark of Sony Corporation, registered in the U.S. and other countries.

PC Requirements	<p>Motherboard:</p> <p>Processor: Intel D975XBX2, BIOS Version 2770 or higher  Chip set: 975x  RAM: 2 GB  2 PCI-Express x16 slots (PCT-Express for Graphics, PEG)  Graphic card: Chip set Geforce 8800 GTX, memory 768 MB recommended; minimum Open-GL 2.0, 256 MB  Fire Wire Cards: 1 PCI Card IEEE-1394a  1 PCI Express Card IEEE-1394b</p> <p>Internal HDD 40 GB  DVD/CD-RW drive  Keyboard, Mouse  Operating system: Windows XP professional (SP 2 recommended)  Monitor: High quality TFT or CRT, minimum resolution 1600 x 1200 pixels (e. g. 19" Iiyama AU 4831D or 20" viewsonic VP 201m)  Patient data storage: External IEEE 1394 hard disk (750 GB recommended)  Archive data storage: 2nd external IEEE 1394 hard disk (same size as data disk)</p> <p>For power supply model PWS/FW only:  Free IEEE 1394 port (1394a or 1394b bilingual)</p> <p>For power supply model PS410 only:  Serial COM port (RS232)  Free PCI slot for HE frame grabber  IEEE 1394 port for external hard disk connection recommended</p>
Data Storage: File Size	<p>B-scan: 1.4 MB  Volume scan: 60 MB</p>
Type Labels	See chapter 3.3
Type Label Application	<p>Power supply: At the back side  Camera head: At the bottom side</p>



**WARNING:** Do not modify this equipment without express authorization from the manufacturer!



Read accompanying documents!



### 3.1 Recommended Isolation Transformers for PC-Components

The isolation transformer has to be certified in accordance to the standards IEC 60884-1, IEC 60601-1 and / or UL 60601-1. Heidelberg Engineering recommends the following models:

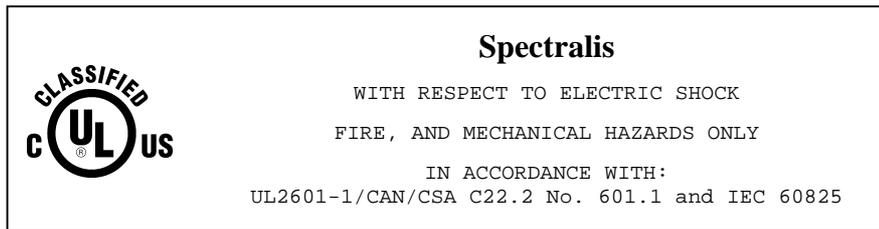
<b>Voltage / Manufacturer</b>	<b>Type / Capacity</b>
230V / DEMETEC GmbH	Pps-1000R3-8K (1000 VA)
110V / TSi Power Corporation	ILC-1000 (1000W)

### 3.2 User Training

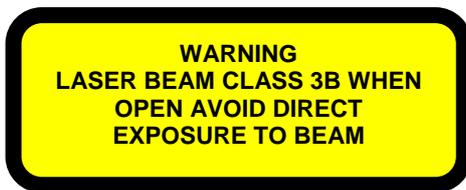
A qualified Heidelberg Engineering employee or distributor shall initially train the final user.

Heidelberg Engineering periodically offers user trainings for doctors and physicians and physician assistants.

### 3.3 Labels



UL- Label on the  
Power Supply /  
Laser unit



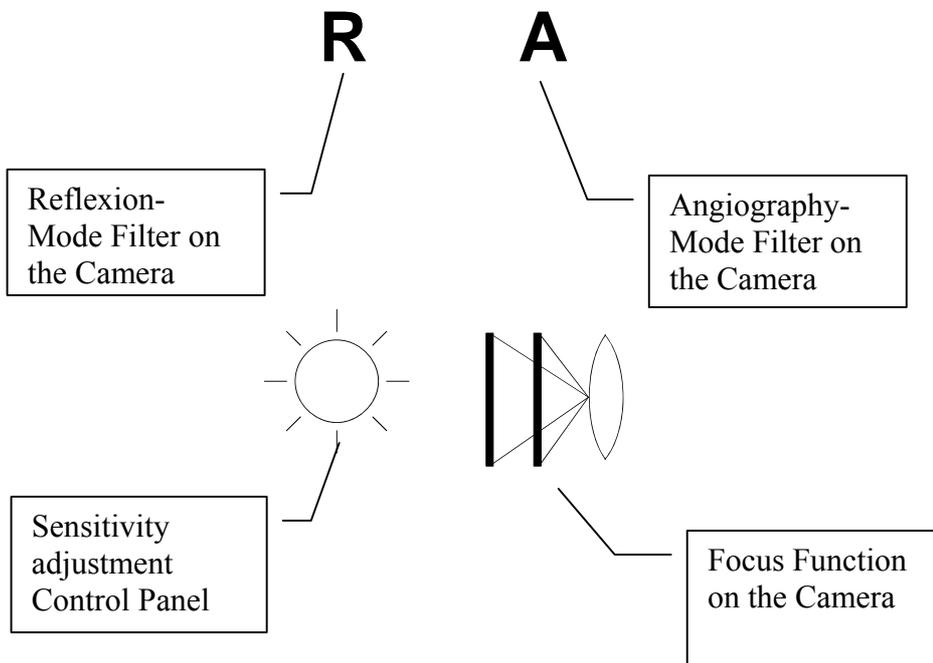
Warning Label on  
the Power Supply /  
Laser unit

Complies with 21 CFR 1040.10 and  
1040.11 except for deviations  
pursuant to Laser Notice No. 50,  
dated June 24, 2007.

21 CFR compliance  
Label on the camera



Laser Class 1  
label on the  
Camera



### 3.4 Disposal



Only Heidelberg Engineering shall dispose the device.