



**OPACITOMETER 3.0
EQUIPMENT FOR
OECD TEST GUIDELINE 437
TO DETERMINE EYE IRRITATION *IN VITRO* (BCOP)**

Chemical hazard identification includes the assessment of eye irritation potential. As of September 2009, the OECD permits *in vitro* tests with isolated bovine cornea to be used as a replacement of *in vivo* tests on rabbit eyes. During the in-house validation of the BCOP assay, BASF discovered that it was difficult to commercially obtain reliable state-of-the-art equipment. Therefore BASF redefined the state-of-the-art by designing and optimizing the instrumentation for BCOP evaluation. The BCOP Opacitometer Kit offers a solution, including standardized equipment calibrated by certified glass filters, to generate reproducible and comparable results across laboratories. Since the adoption of OECD TG 437, many labs have recognized the value of our Opacitometer kit and have requested it to ensure the quality of their data.

Since January 2014 DURATEC Analysentechnik GmbH is the authorized manufacturer and distributor of the Opacitometer.




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Opacitometer

We hereby certify, that as of January 2014 the production and distribution of the opacitometer used to perform studies according to OECD 437, which had been developed at BASF, has been transferred to DURATEC Analysentechnik GmbH.



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Robert Landsiedel



.....
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PART 1: LIST OF CONTENTS AND GENERAL INFORMATION

Attention: This instruction manual is composed of several parts.

In order to guarantee a safe operation of the measuring device, please make sure to read and adhere to all parts of the instruction manual.

Prior to the start-up or initial operating of the device please ensure to thoroughly read part 2 "Basic safety instructions". It is imperative that all given information, suggestions, safety precautions and warnings are attended. This instruction manual has to be made available to all users.

This instruction manual only covers the parts of soft and hardware that are essential for operating the device. For information on the general operation of the software and the „testo 545“ light intensity measuring device please turn to the included manuals of the Testo measuring device and adhere to the safety instructions therewithin.



Additional informations you will receive in the training movie .

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General Data

Identification data	Type	Device
	Model	Opacitometer Kit OP3.0
	Serial Number	
	Order Number	
	Year of manufacture	2014ff
Customer Data	Inventory number	
	Location	
Address of manufacturer	Company name	DURATEC Analysentechnik GmbH
	Street	Rheinauer Strasse 4
	Town	D-68766 Hockenheim (Germany)
	Tel	+49 6205 9450 – 0
	Fax	+49 6205 9450 – 33
	E-mail	info@duratec.de
	Spare parts und customer service	See above
Document data	Document name	Opacitometer Instruction Manual
	Version	2.0
	Date of issue	19.12.2014
	Last modification	19.12.2014
Purpose of document	This instruction manual aims to familiarise the operator of the Opacitometer <ul style="list-style-type: none"> <input type="checkbox"/> with its operating principles <input type="checkbox"/> its operation <input type="checkbox"/> the safety instructions <input type="checkbox"/> and its maintenance 	
Operating personnel	The Opacitometer must only be operated by authorised laboratory personnel!	
Life cycle	The life cycle of the individual components depends on the strain of the individual components and can not be predicted. In case of electrotechnical malfunctions please make sure to contact DURATEC in order to discuss further measures.	




Part 2: Essential safety precautions

Follow the instructions in the operating instructions

Prior to the start-up or initial operating of the Opacitometers please ensure to thoroughly read this instruction manual. It is imperative that all given information and suggestions are attended. Please pay particular attention to the safety precautions and warnings. This instruction manual has to be made available to all users.

This instruction manual only covers the parts of soft and hardware that are essential for operating the device. For information on the general operation of the software and the „testo 545“ light intensity measuring device please turn to the included manuals of the Testo measuring device and adhere to the safety instructions there within

Symbols within the instruction manual

	<p>Information</p>	<p>Information concerning the operation of the device. This information covers features of the device. Following the instruction given generally simplifies your work.</p>
	<p>Important</p>	<p>Is used when a certain action for a safe and failure-free operation is required.</p>
	<p>Warning / Danger</p>	<p>Is used when life or health of the user are in danger or significant property damage can occur.</p>

Intended use



Danger due to misuse or unintended use:

The Opacitometer must only be used in order to measure the cloudiness of the cornea or the corneal opacity by means of the BCOP testing method.

Only closed and totally leak-proof cornea holders with the designated substances must be inserted into the Opacitometer and measured.

The Opacitometer or the substances to be measured might be dangerous if it is operated by untrained or at least uninstructed personnel or due to improper or unintended use.

Therefore actions like start-up, operation and maintenance of the Opacitometers must only be carried out by authorized laboratory personnel!

All instructions concerning operation and maintenance given in this manual must be strictly adhered to.

A faulty device must be returned to the manufacturer. Self-repairing the device is not permitted.

Should there be any doubt concerning the use of the device, please ask the manufacturer to determine, whether the particular case constitutes an intended purpose of use or not.

Obligations of the user



The user commits to:

- ✓ not carry out any self-modifications and self-updates
- ✓ have the manufacturer carry out any modifications of any kind
- ✓ have only specially trained and authorised laboratory personnel operate the Opacitometer!
- ✓ only operate the Opacitometer when in perfect condition!
- ✓ carry out any maintenance only according to the maintenance instructions!
- ✓ have only personnel work with the system who have received and understood the instruction manual.

!

Training of personnel



The operator must make sure that every user is familiar with the operation and maintenance of the device and the handling of cornea holders. This also includes knowledge on how to proceed should a cornea holder be faulty or what the criteria are to evaluate the holder so it must not be inserted into the device any more. It also includes knowledge of the location of the instruction manual of the product or the product data sheet.

Dangers operating the Opacitometer



Should the cornea holder be damaged, leak-unproof or any other kind of faulty, damages caused by its ingredients may occur. Therefore the instructions of the respective ingredients have to be adhered to.

The Opacitometer must only be use if:

- ✓ the cornea holder is faultless
- ✓ only the components defined below are used
- ✓ only the equipment defined below is used
- ✓ the device is only used according to the below mentioned definition

Safety measures and precautions



Power rating plates, precautions and safety symbols are attached to the device. The cables within the device carry name tags. All these plates and symbols are safety relevant. The operator is responsible to guarantee that they stay attached at the designated spot for the entire life cycle of the device and are well visible.

It is prohibited to remove, paste over, paint over or in any other kind obstruct the clear readability of,

- ✓ Power rating plates
- ✓ Precautions
- ✓ Safety symbols
- ✓ Name tags and
- ✓ Cable lables.

Individual protective equipment



Safety clothing



Eye protection



Nitril rubber gloves

The operating personnel must wear this protective equipment when handling cornea holders

Illustration and explanation of hazard symbols

Warning: dangerous electric voltage



Danger to life or health of the operator due to life-endangering electric voltage

Dangers due to electric energy



The Opacitometer is run with a voltage that can cause a life-threatening electric shock when coming in contact with it.

Unauthorised removal of required covers or opening the housing of the device can cause severe injury of personnel or property damage.

All tasks concerning installation, start-up and maintenance may only be carried out by trained qualified personnel.

Particular dangerous spots



Do not open any cornea holders and do not touch any liquids (leaking) from the cornea holder. In case of damages or leakages the instructions of the product data sheet need to be adhered to.

Service, maintenance, trouble-shooting



Prior to carrying out any maintenance the power plug needs to be removed from the mains or the device needs to be disconnected from the power source. After taking this precaution it is permitted to carry out maintenance of the Opacitometer.

Constructional modifications



Constructional modifications may decrease the safety and reliability of the device and shorten its life-cycle. Carrying out any of the below mentioned modifications result in the expiration of any warranty claims for all components, of which the damage can be traced by DURATEC to a modification.

Modification of a cable

Modification of the housing

Modification of a component

Modification of an electrical component or a board of the system.

Laying any additional tubes, cables or wires through the device

Modifications of components and accessory kits and communication cable.

Transport



The device must be packaged for transport in a manner to avoid damages during transport.

The device must be transported shock-free and must not be thrown. It is recommended that during transport foot protection or safety boots are worn.

Noise level



The device runs silently

Unavoidable risks



DANGER

There are no unavoidable risks that may be caused by the Opacitometer.

Risks can be caused by faulty cornea holders and their contents. That is why the instruction manual of the product or the product data sheet need to be adhered to during each measurement.

Behaviour in case of emergency



DANGER




Adhere to the instruction manual of the product to be measured or the product data sheet.




Switch off the device or remove the power plug and then follow the internal proceedings in case of emergency of your company or your organisation.

In case of fire, extinguish it using CO₂.

PART 3: DEVICE INFORMATION

Equipment

Component	Description
<p>Opacitometer with R232 interface</p>	 <p>Opacitometer with certified light intensity measuring device and PC interface for the communication with the programme or the management of measured data</p>
<p>cornea holder</p>	 <p>Cornea holder for insertion of the samples</p>
<p>Screw driver (for window locking ring)</p>	

<p>3 optic grey filters incl. holder</p>	 <p>Filter with different shades of grey for calibration of the measuring device with receptacle in cornea holder format</p> <ol style="list-style-type: none"> 1. F2 (NG11) 2. F3 (NG5) 3. F4 (NG4)
<p>USB-Adapter</p>	 <p>RS232 USB - converter USB - Adapter for PCs without RS232 – interface</p>
<p>Power cable</p>	
<p>Documentation USB Stick</p>	<p>The USB Stick contains</p> <ul style="list-style-type: none"> • the instruction manual • the installation software for the program for data transfer or for the management of the measured data "ComSoft 3 Professional" • the driver for the USB-Adapter • the manual of the Testo 545 measuring device • the training video

Declaration of conformitiy

EG-Konformitätserklärung
gemäß der EG-Niederspannungs-Richtlinie 2006/95/EG
gemäß Anhang III B

Die

BASF Societas Europaea
Robotic based Automation
GTF/ED - C 109
Carl-Bosch-Str. 38
67056 Ludwigshafen

Anschrift des Ausstellers

bescheinigt hiermit, dass das Gerät

Opacitometer, Kit BASF-OP3.0, RO 130176

Bezeichnung, Typ oder Modell, Seriennummer

aufgrund seiner Konzipierung und Bauart den grundlegenden Sicherheits- und Gesundheitsanforderungen der nachfolgend aufgeführten EG-Richtlinien entspricht.

Niederspannungsrichtlinie	2006/95/EG
EMV-Richtlinie	2004/108/EG

Bevollmächtigter für die Zusammenstellung der technischen Unterlagen,
sowie für die Ausstellung der Konformitätserklärung:

Dipl.-Ing. Harald Rödel, Fachgruppenleiter Robotic based Automation GTF/ED-C109

Ludwigshafen, den 15.04.2013
Ort, Datum

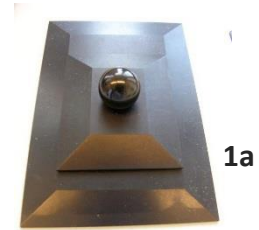


Unterschrift

Device overview



Top View



- 1: Optical compartment**
- 1a: cover for optical compartment**
- 2: Testo measuring device**



Front View

- 3: Power Switch**
- 4: Serial Number**
- 5: Calibration Knob**



Rear View

- 6: Power Cord Jack**
- 7: Serial RS232 (DB9 female)**

Connection to power

Electrics

Mains voltage: 85V - 264V
Mains frequency: 47 Hz bis 63 Hz
Required power: ca. 10W

Disruption of voltage: max. 8 ms at nominal load

The voltage of ripple amplitude of the main supply must not exceed 1000V. Pulse duration must always be below 1µs.

The device must not be located close to big transformers, high frequency oscillators or welding machines, which produce intensive electromagnetic scattered radiation.



Attention: High electric voltage!

Possible consequences. Danger to life and property damage!

Handling in areas of voltage-carrying parts is life-endangering!

Activities at the electrical part of the device must only be carried out by electrically qualified personnel. Prior to activities carried out at the device connections the mains plug must be removed. Prior to starting any activities a suitable measuring device must be used to verify if any parts of the device still carry any voltage (e.g. capacitors, solenoids etc.)

Ambient conditions during operation

Temperature

The ambient temperature must be between 5°C and 40°C

The device must not be subjected to sun exposure or other sources of heat.

Humidity

The relative humidity must be between 45% and 85%

At very low humidity conditions measures against electrostatic charge have to be initiated or at very high humidity conditions measures against condensation formation

Ambient air

The ambient air must not show any excess dust or oil mist or aggressive gases.

No metal cuttings or any other conducting materials must be scattered.

In the ambient area no flammable or explosive gases must be released.

Liquids

Water or other liquids must not get in contact with the device.

The device must not be dipped into water or other liquids.



Substantial property damage may be caused by contact of the device with any liquids.

Ambient air pressure

The device must not be operated at very low air pressure or in a vacuum.

Operating materials

No operating materials are required.

Corrosion prevention

The coating of the housing serves as corrosion protection and has to be preserved.

Space requirement

The device has the following dimensions:

Width:	260 mm
Height:	160 mm
Depth:	320 mm

Emissions (radiation, gases, dusts, fumes etc.)

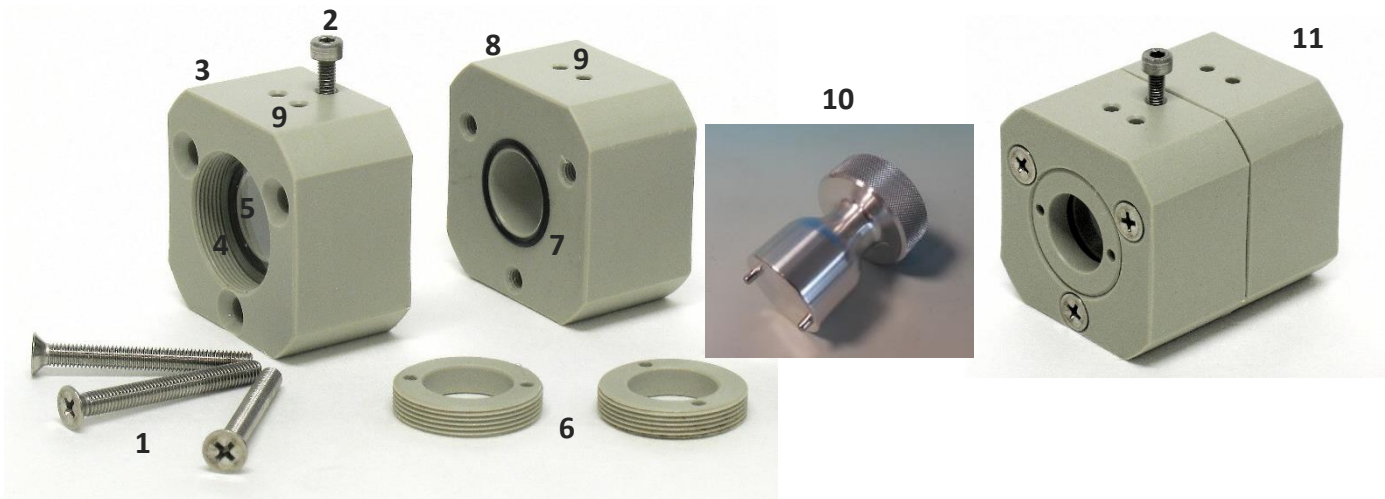
During failure-free operations there are no emissions.

PART 4: OPERATION AND HANDLING



For the operation of the device and the execution of the test please have closer look at the training movie.

Cornea holder overview



- 1: Screw (3x) for mounting cornea holder (modified M5*40)
- 2: Screw (1x) for handling cornea holder (M4*15)
- 3: Posterior chamber (1x)
- 4: Seal window 2,5mm (2x) for anterior and posterior chamber
- 5: Cell window (2x) for anterior and posterior chamber
- 6: Window locking ring (2x) for anterior and posterior chamber
- 7: Seal cornea holder (1x) between both chambers
- 8: Anterior chamber
- 9: Fluid ports
- 10: Screw driver (for window locking ring)
- 11: Cornea holder fully assembled

Instruction for the insertion or removal of a cornea holder




For the insertion or removal of the cornea holder please use the screw. The orientation of the holder you can see at the picture.

Correctly switching the device on and off

Switching the device on


1. Flip the main switch (Power) from 0 to I - Switch background lighting is on



2. Switch on Testo measuring device via the button ()



Switching the device off

1. Switch off the Testo measuring device via the button ()



2. Flip the main switch (Power) from I to 0 - Switch background lighting is off



Instruction for the calibration or a functional test

General

A calibration has to be carried out prior to each series of measurement in order to test and guarantee that the device works faultlessly and delivers reliable measurements.

Required equipment for the calibration

Empty filter holder



Filter Set (Grey Glas)



Calibration/Carry out device test

1. Switch on the Opacitometer (the device should be turned on 10-30 minutes before measurement)
2. Insert empty filter housing
3. Set lighting via control knob (Calibrate) to 1000 lux (Accuracy +/-10)
4. Insert filter F2 (NG11) : value should be between 540-560
5. Remove filter F2
6. Insert filter F3(NG5) : value should be between 295-315
7. Remove filter F3
8. Insert filter F3 (NG4) : value should be between 90-100
9. Remove filter F3

If all values are within the required value range the measurement of the samples can commence. Values not reaching the required value range is a sign of malfunction or device error and the Opacitometer must not be used any more. In a case like that please contact DURATEC.

Quick Start with Testo Comfort Software

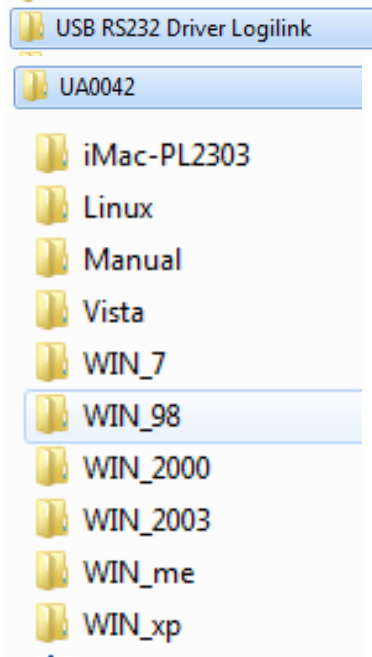
For data acquisition you can use the Testo Comfort Software.

It is not necessary to use the software you can also read the values from the measuring device.

Software Installation

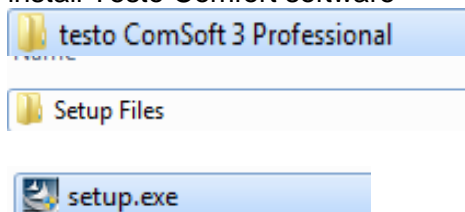
For software installation you should

- install Logilink driver (USB Stick)



Choose the folder with the wright operating System

- plug in USB-serial adapter
- install Testo Comfort software

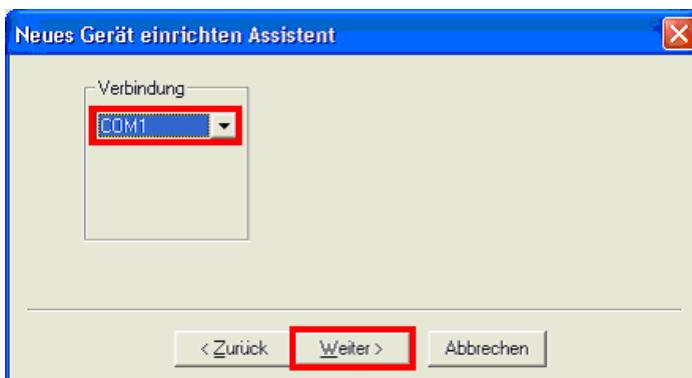
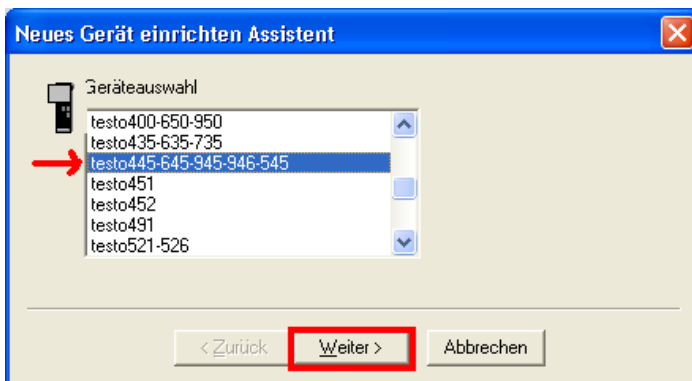
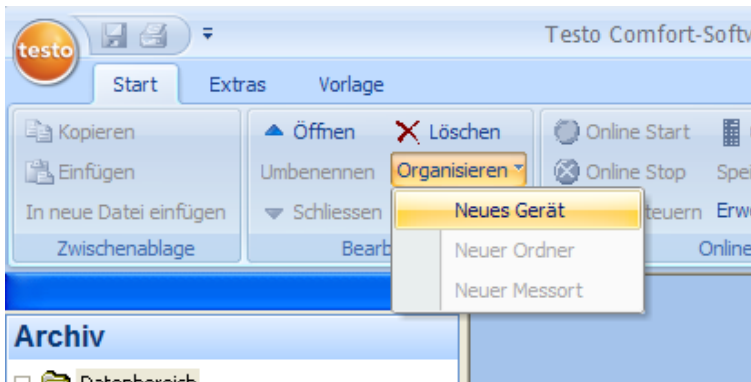


The Product Key for the installation is on the CD

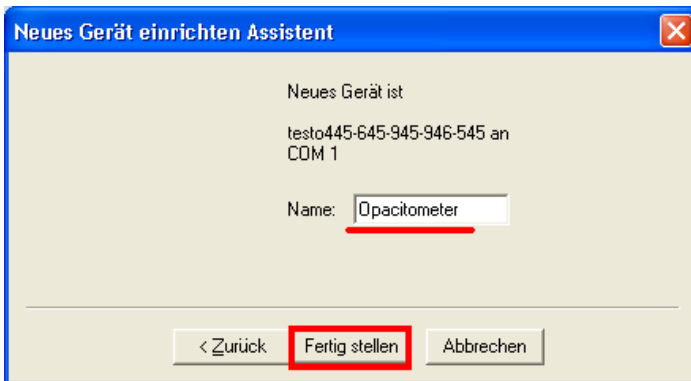
- Start the Opacitometer
- Start the Testo Comfort Software
- **Software Installation**

Using the software

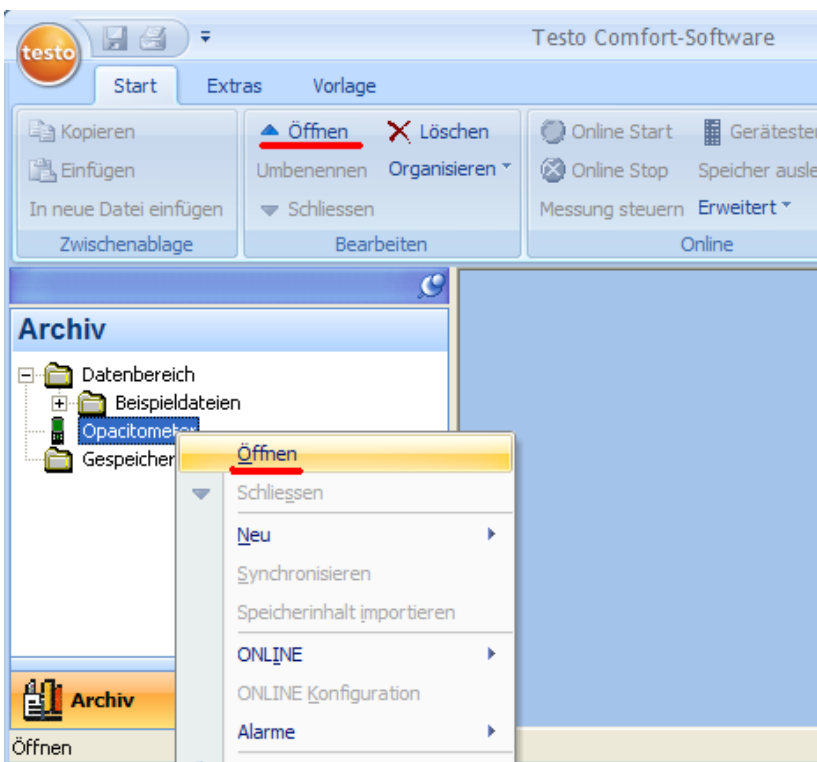
Connect your Opacitometer to the software



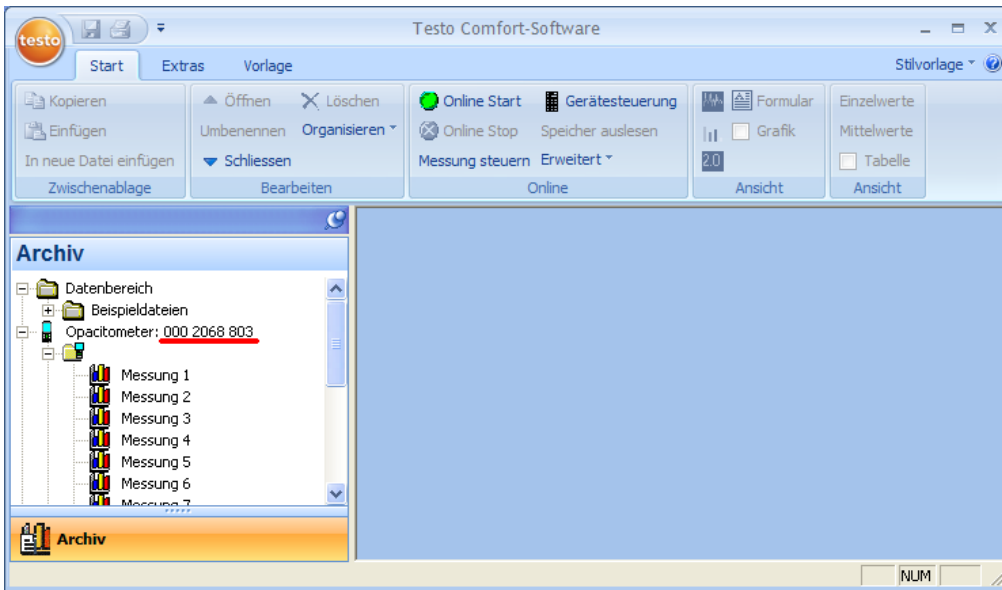
choose the port your Opacitometer is connected to. When using the USB to serial converter, this usually connects to COM3 (if no other converter was already attached to your PC)



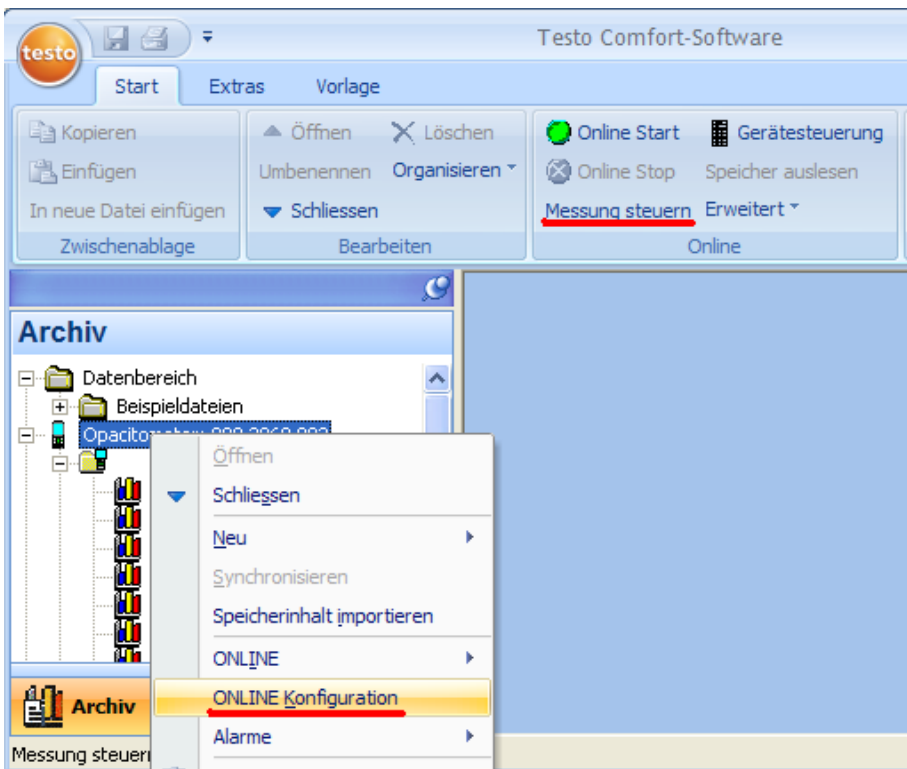
Type in a name for your Opacitometer. May be any text.



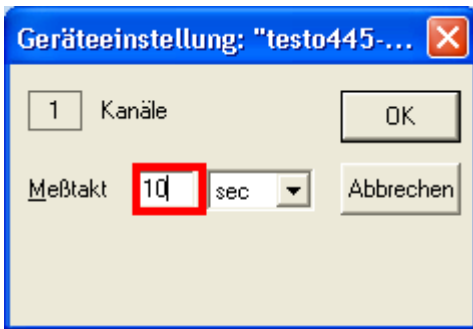
„Open“ the connection.



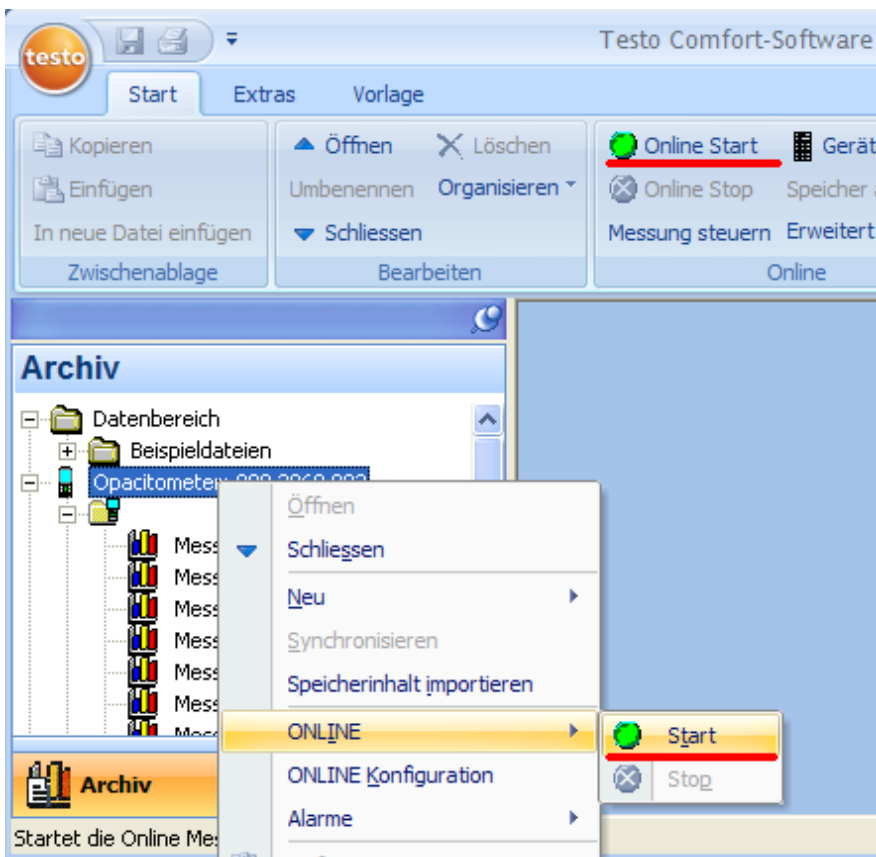
If „open“ was successful, you'll see the serial number of the Testo device.



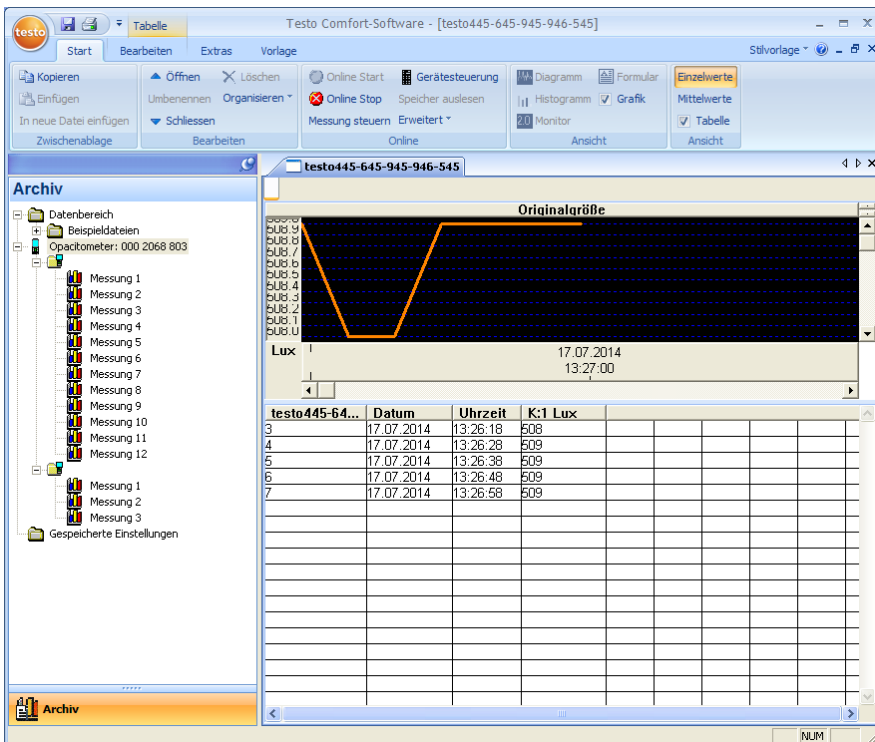
Configure data acquisition.



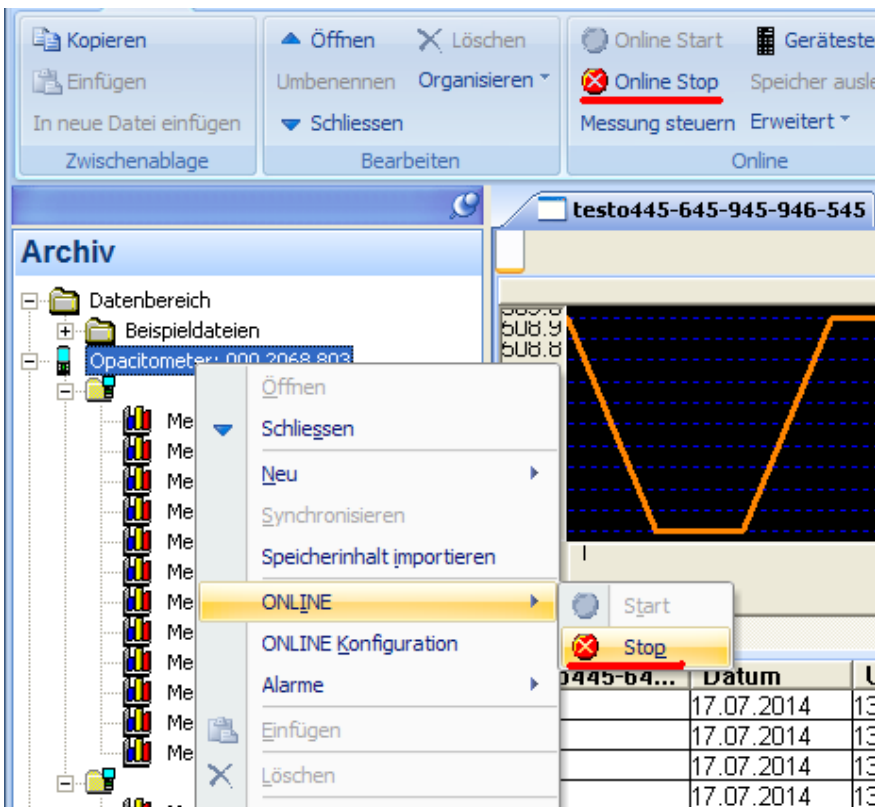
Get Data every 10 seconds.



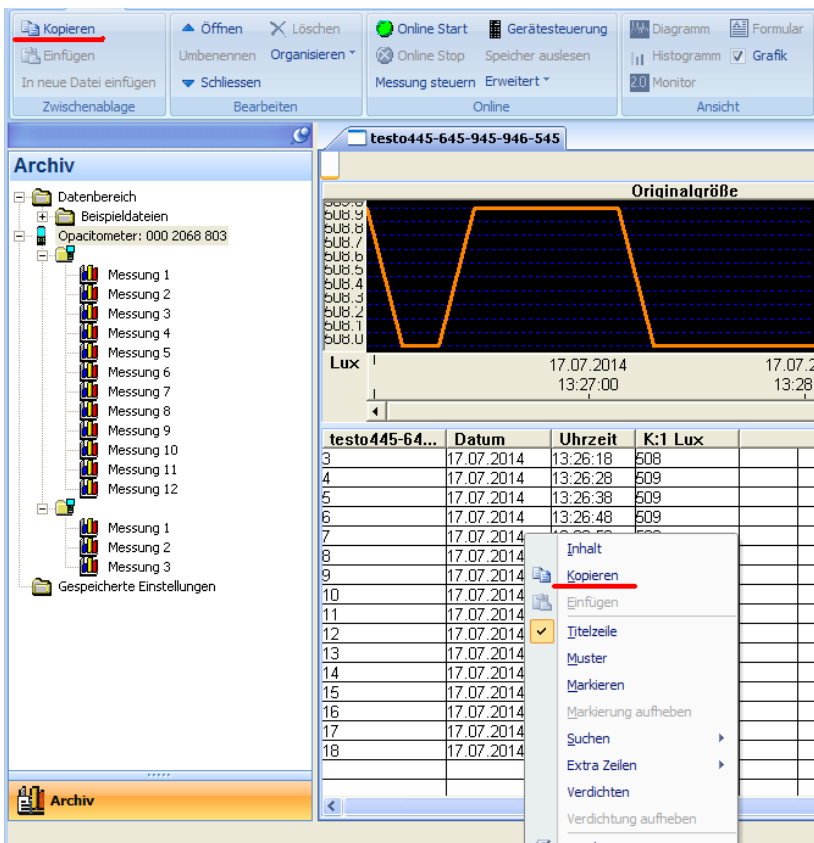
Select your Opacitometer and start data acquisition.



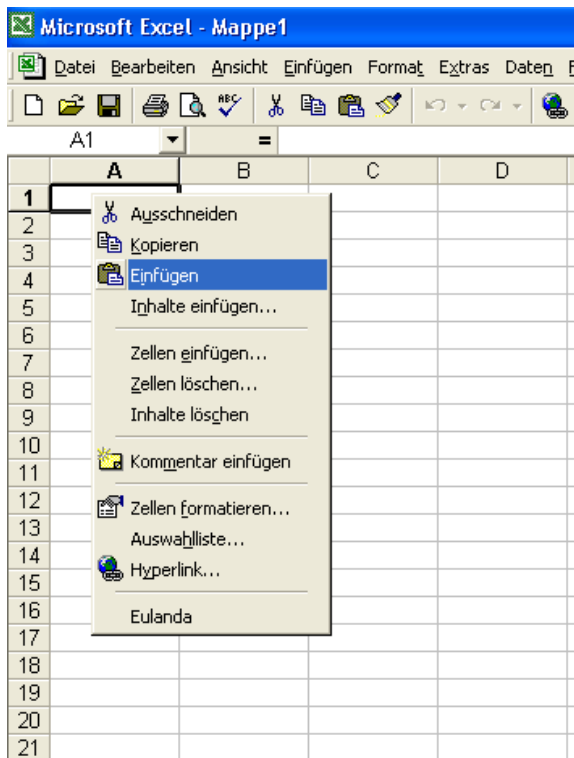
Data is being collected.....



Select your Opacitometer and stop data acquisition.



Click into the table and copy your data.



Insert copied data into EXCEL or any other program you like...

PART 5: SERVICE AND MAINTENANCE

General

For the Opacitometer no servicing is required and can be cleaned with a moist cloth if needed. Contamination with substances and product residue have to be recorded, cleaned /decontaminated and disposed of according to the product data sheets or the instruction manual of the product. The cornea holder has to be cleaned according to the cleaning instructions. Soiling of the filters and filter holders has to be cleaned carefully using a soft cloth suitable for the cleaning of optical lenses.

Dismounting, disposal of the Opacitometers after taking out of operation

Please follow the steps listed below when disposing of the device:

1. Adhere to latest valid country-specific waste disposal regulations
2. Dismount devices
3. Recycle recycable material (metals, plastics, etc.)
4. Dismount electrical assemblies and connection cables
5. All electrical assemblies and connection cables have to be disposed of as special (hazardous) or electrical waste



Electrical waste (assemblies, batteries, screens, etc) can damage the environment.

Warranty and customer service

The purchasing price of the device does not include any cost for the secondment of technicians to the customer. During the warranty period of the device extra costs occur for the following services:

Service and maintenance

Any other services not specifically included in the sales agreement

Fixing of damages caused by faulty handling or wrong use

Fixing of damages caused by mistakes made by the user or inadequate maintenance

Fixing of damages caused by unauthorised modifications

Fixing of damages caused by fire or any other natural disasters or accidents



Only completely clean devices may be sent in for repair. Contaminated devices can not be accepted.

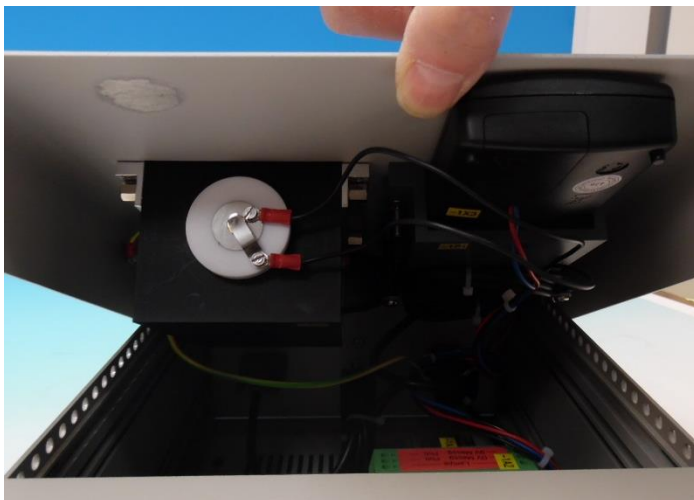
Lamp exchange (Devices manufactured by BASF)

Lamp exchange only be carried out by trained qualified personnel.

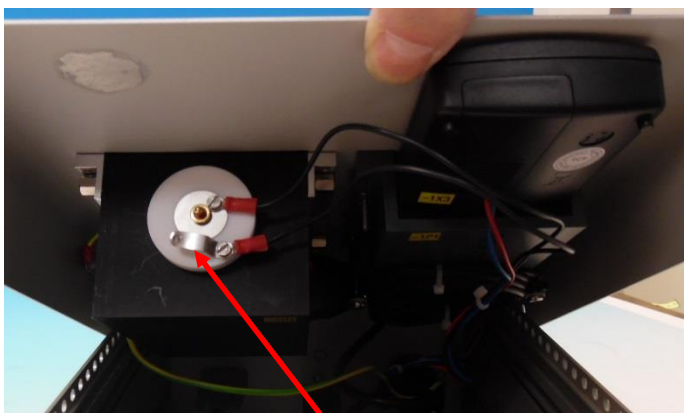
1. Disconnect the device from the power supply



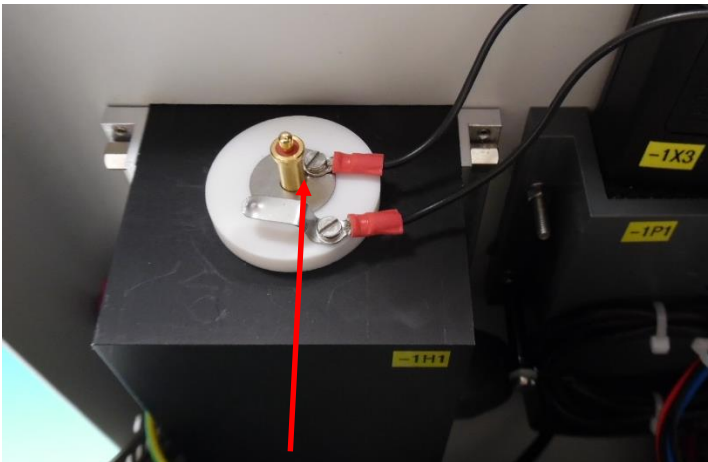
2. Loosen the 4 screws on the upper housing



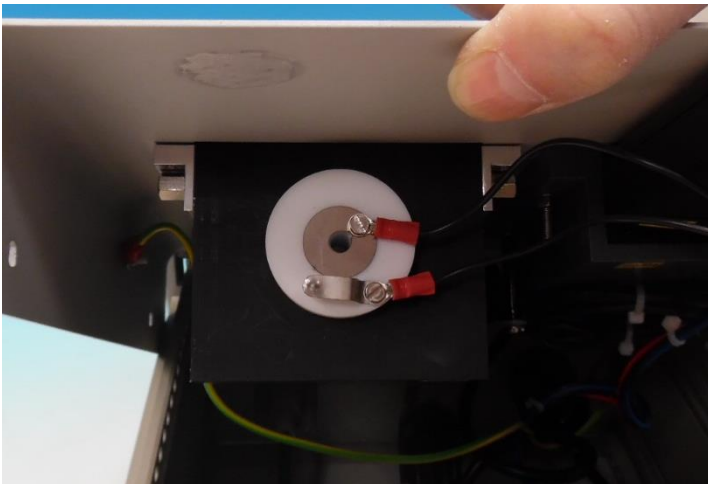
3. Lift lid, caution with cables



4. Turn the contact spring on the side



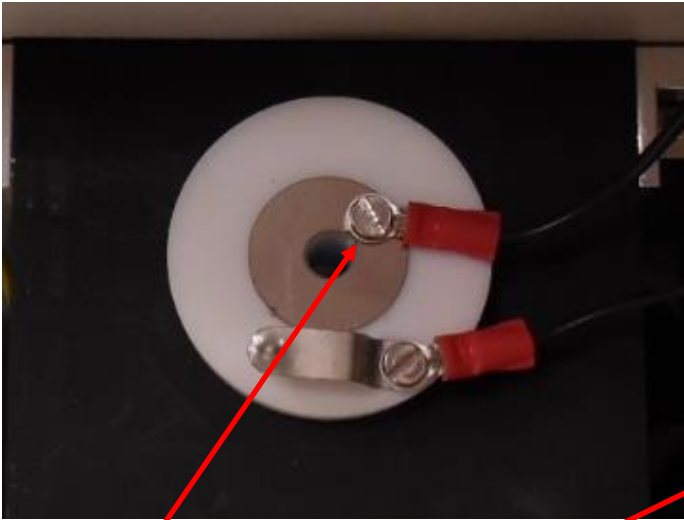
5. Pull out the defective lamp (before)



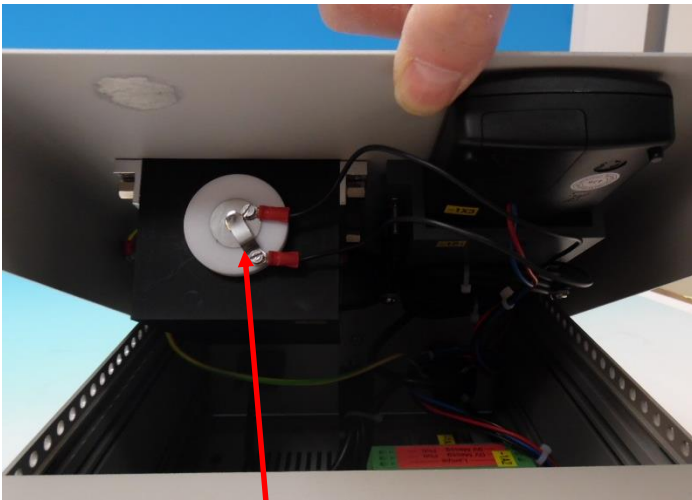
5a. Pull out the defective lamp (after)



6. Unpack the new lamp HEINE XHL Xenon Halogen Technology 3.5 V X-002.88.070



7. Insert the new lamp. Note that the narrow pin of the lamp is guided through the slot of the lamp holder.



8. Turn back the contact spring on the lamp.



10. Tighten the screws

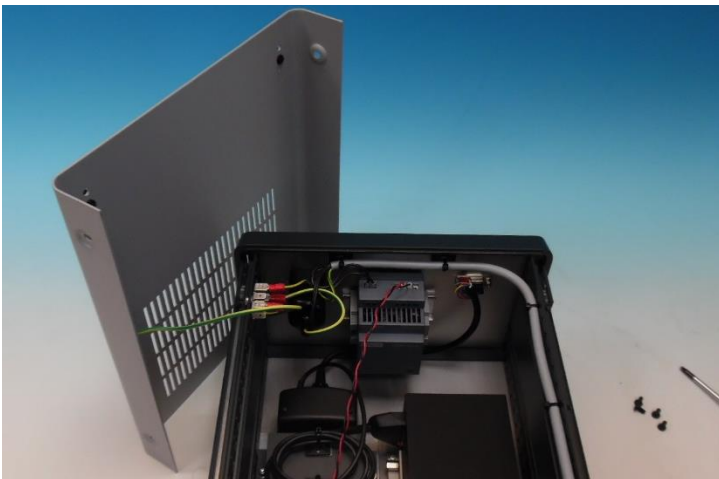
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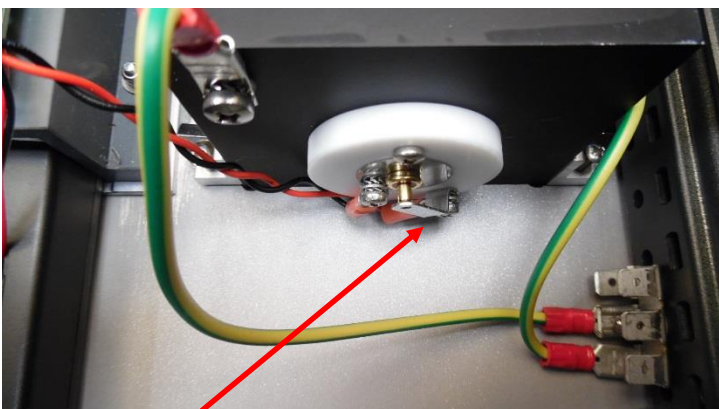
1. Disconnect the device from the power supply.
2. Turn the device.



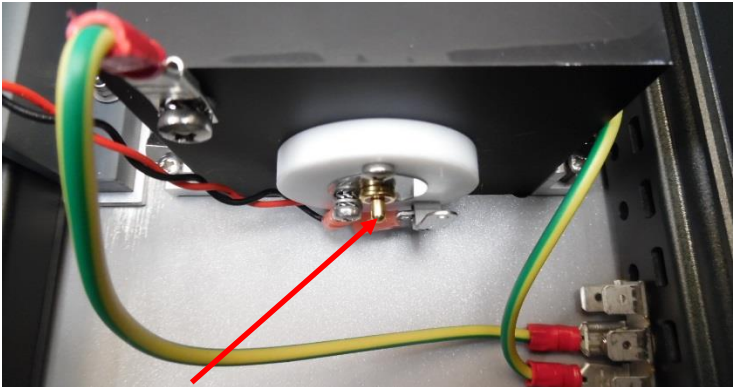
3. Loosen the 4 screws of the bottom plate



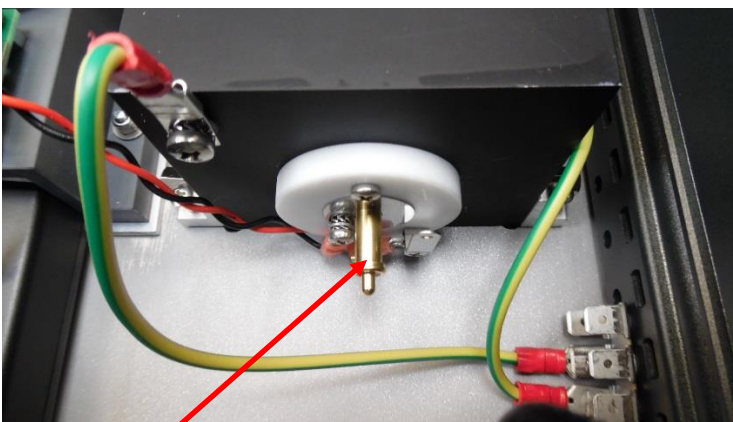
4. Remove the bottom plate



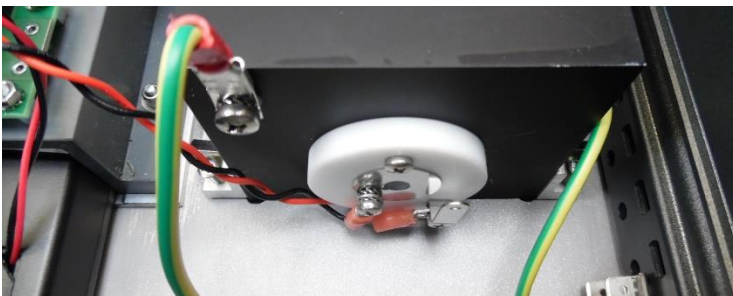
5. Turn the contact spring on the side



6.Pull out the defective lamp (before)



6a.Pull out the defective lamp (before)



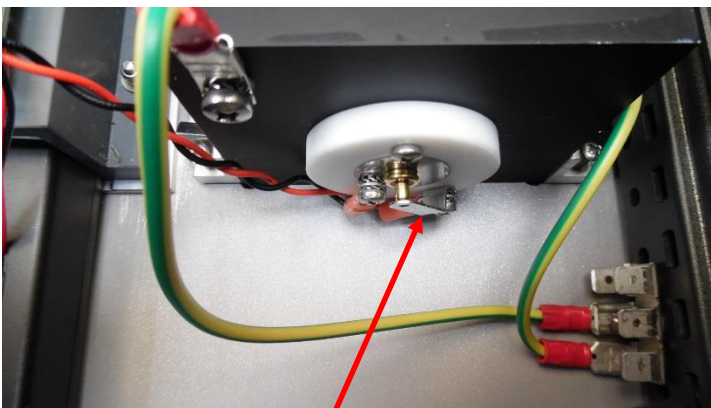
6b.Pull out the defective lamp (after)



7.Unpack the new lamp HEINE XHL Xenon Halogen Technology 3.5 V X-002.88.070



8. Insert the new lamp. Note that the narrow pin of the lamp is guided through the slot of the lamp holder.



9. Turn back the contact spring on the lamp.



10. Tighten the screws

PART 6: SPARE PARTS

P/N	Article
926500-002	Cornea Holder for Opacitometer OP3.0
926500-003	Filter Holder for Opacitometer OP3.0
926500-004	Standard Filter Set for Opacitometer OP3.0 (NG11;NG5; NG4;Dark)
926500-006	Cell Window for Opacitometer OP3.0 (10/Pk)
926500-007	Screw driver (for window locking ring)
926500-008	Lamp for Opacitometer 3.0
926500-009	Seal Window Opacitometer 3.0 (10/Pk)
926500-010	Seal Cornea Holder Opacitometer 3.0 (10/Pk)
926500-011	Refresh Kit Cornea Holder Opacitometer 3.0 (10x Cell Window, 10x Seal Window, 10x Seal Cornea Holder)

Please send all orders of spare parts to the following address:

DURATEC Analysentechnik GmbH
 Sales - Department
 Rheinauer Strasse 4

68766 Hockenheim (Germany)

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Fax +49 6205 9450 – 33
E-mail info@duratec.de