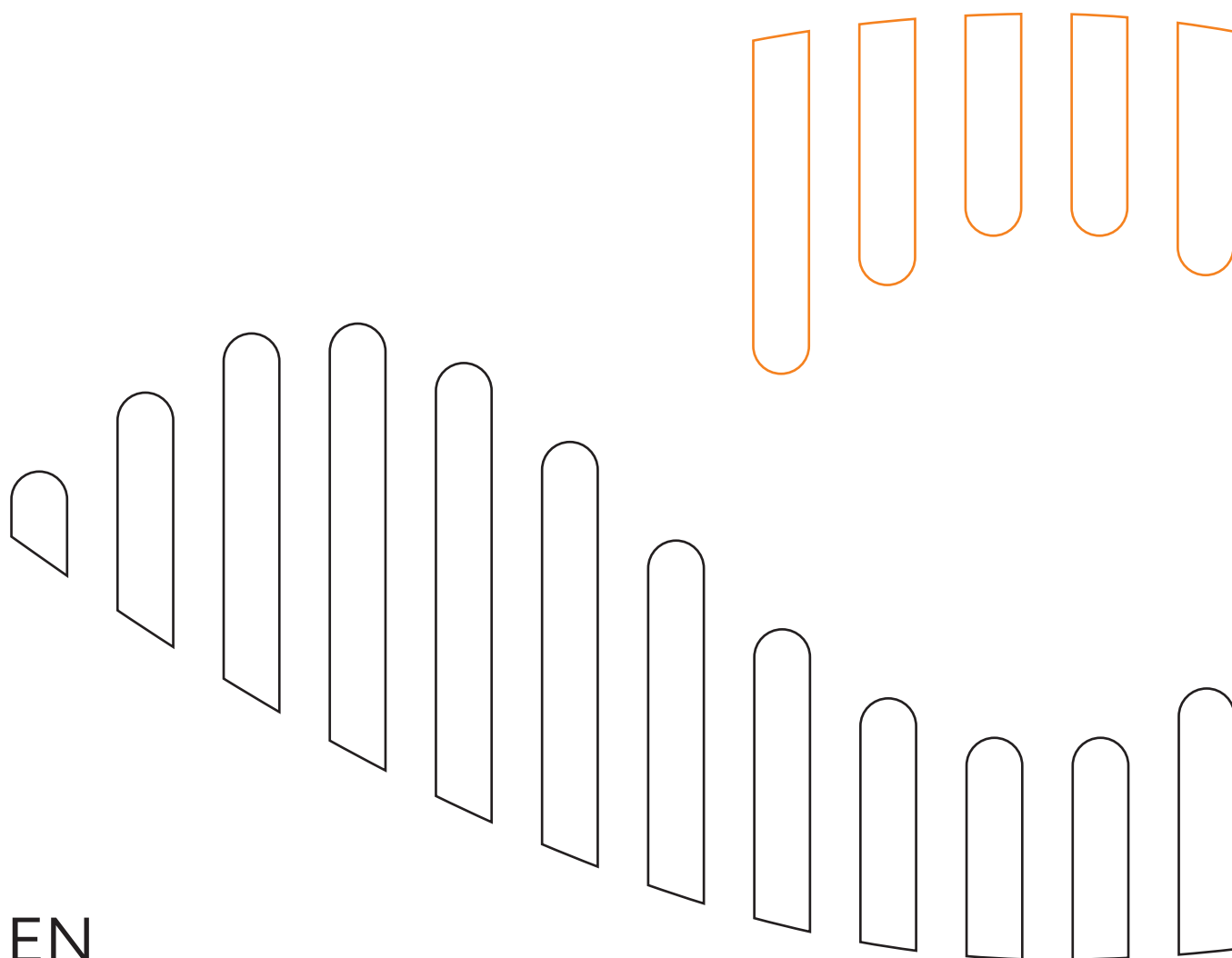


# OkuStim<sup>®</sup> Software

## Instructions for Use



EN

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## Important Notice

**This document must be read in conjunction with the document OkuStim System Instructions for Use (see 9.2).**

**Every user of the OkuStim software must be instructed in the use of the software in accordance with this manual (OkuStim® Software – Instruction for Use).**

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## Intended Use of the OkuStim System and Software

The OkuStim Software is intended to be used by a healthcare professional to determine, save and manage the specific stimulation parameters with the OkuStim System of each patient. The OkuStim Software controls the OkuStim output while connected via USB Cable OK100182. The individual patient stimulation parameters are written onto a USB stick OK100083 via OkuStim Software.

## User and Place of Application

The OkuStim system is suitable to be used for electrical stimulation by trained laypersons and specialists in a professional healthcare or home environment. The use of the OkuStim system with OkuStim software to program the stimulation parameters is restricted to healthcare professionals in a professional healthcare environment.



## Important Safety Notes

- Only use the accessories supplied with the product or those listed in the accessories list, Chapter 9.2. Do not connect any cables or parts to the device that are not mentioned in the list.
- Only healthcare professionals may connect a certified USB-cable (with electrical safety according to EN60601-1, 3rd ed. with 4kVrms to connect the OkuStim device with a PC) with the USB-plug (Type B).
- Before using the device, familiarize yourself with the user instructions and note the information about electromagnetic compatibility.
- Please note: The current density can exceed 2 mA / cm<sup>2</sup> at the OkuEl electrode.
- Please note: The OkuStim can heat up to 42 °C during use.
- Keep the device and accessories outside of reach of children. Small parts like the mini-USB-stick could be swallowed.
- Do not carry out any repairs or maintenance work on the device. If needed, contact your dealer or the manufacturer.
- The therapeutic current amplitude must not exceed 950 µA.
- The current strength must not exceed the individual pain threshold.
- The threshold tests can be carried out with up to 1600 µA, since the current is only switched on for a few seconds.
- This document is to be read in conjunction with the document OkuStim System Instructions for Use (see 9.2).

## Version Note

This manual applies to software version 1.8.0.0 and higher.

## System Requirements of the OkuStim Software

- Intel® 1.3 GHz CPU or better
- 1 GB RAM; 10 MB available hard drive space
- 2 USB-Ports Type USB 2.0
- Supported OS: Microsoft® Windows® 7, 8.1 or 10 (both 32 and 64 bit)
- Recommended screen resolution: 1024x768 or higher for full scale view of the user interface
- Local machine administrator rights are required for the installation.

## Explanation of Symbols

On the packaging you will find the following symbols and description of the components of the OkuStim system: OkuStim device / OkuSpex frame / OkuEl electrode / OkuEl counter electrode



Medical Device



Ref. to instructions for use



Ref. to instructions for use



General warning symbol



Batch designation



Serial number



Use by date



Date of manufacture



Manufacturer



Packaging unit



Not for reuse



Example for temperature range



The CE identification documents agreement with the Medical Device Directive 93/42/EEG, notified body code: TUV Rheinland (= 0197)



Part number



Do not use if packaging is damaged



Note waste disposal specifications



Casing protection class: protected against foreign objects with a diameter of 12.5 mm or above and against dripping water with 15° angle.



Applied Part: Type BF



# 1 Installation of the OkuStim Software

## 1.1 Installation

Requirements: Administrator rights for the computer are required for the installation.

Start the installation by clicking the setup file: OkuStim\_[version]\_Setup.exe

The installation-wizard starts. It will guide you through the installation process and carry out the following steps:

- Creation of the installation path: [Program Files]\Okuvision\OkuStim.
- Installation of the device drivers. Your confirmation is required for this.
- Creation of a shortcut in the Windows start menu: [Documents and Settings\All Users\Start Menu\Programs]\Okuvision.
- Creation of a shortcut on the Windows Desktop.

When the application is started for the first time, the storage location for the patient data-base (i.e. the folder for Patient Data and Protocols) must be specified by the user. The default is Windows Desktop. It is recommended that you choose a network storage location so that other users have access to the data. The storage location can be changed at any time (see chapter 1.5).

## 1.2 Installation Test

Take the following steps to check if the OkuStim software and device driver are installed correctly.

- Start the OkuStim software.
- Connect the OkuStim with the PC (see Chapter 2.1).
- Check if the 5-digit serial number is displayed in the top left corner of the software user interface next to "Device No.:".
- Check if the fields "o.s. / o.d. Resistance" are both green.
- Create and select a test-patient. Detailed information can be found Chapter 6.1 and 6.2.
- Select tab "Threshold".
- Set the "Amplitude" value to 10 and activate the "o.s." radio button and click "Start".
- The field "o.s. Resistance" changes colour to red. Click "Stop".
- Set the "Amplitude" value to 10 and activate the "o.d." radio button and click "Start".
- The field "o.d. Resistance" changes colour to red. Click "Stop".

If you can perform this test without any problems the installation was successful.

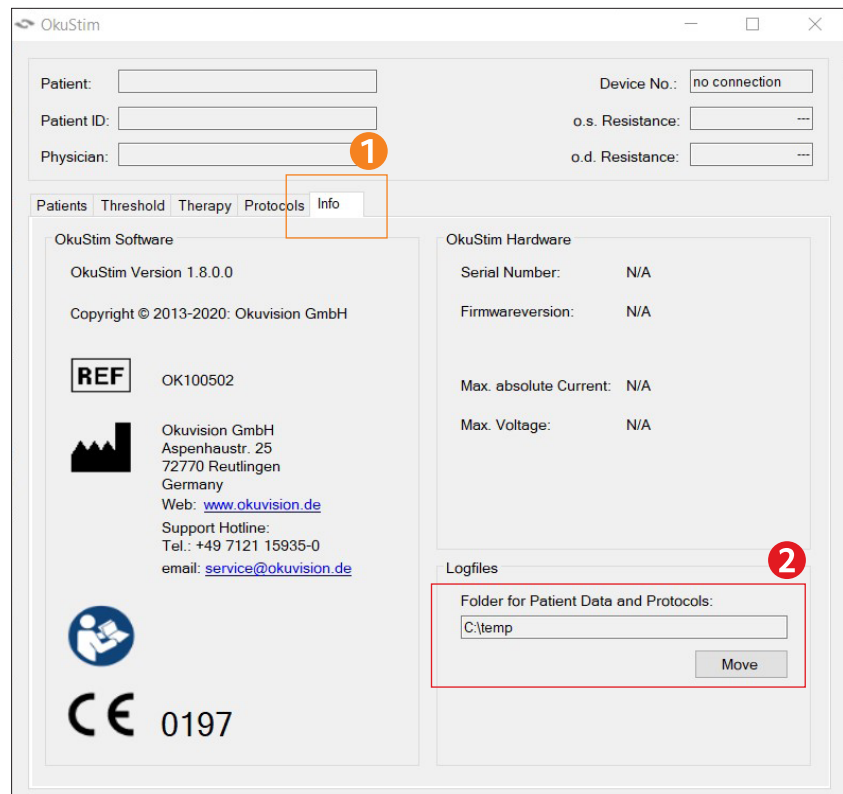
## 1.3 Update

1. Install the new software version as described in Chapter 1.
2. Test the new software version as described in Chapter 1.2.

**Note:** It is not necessary to uninstall the previous version as it will be overwritten by the installation of the new version. The existing patient database will be automatically adopted.

## 1.4 Help

1. Activate the tab "Info" to view the device information. Here you can find the manufacturer contact for technical service.



## 1.5 Changing the storage location of the database

Activate the "Info" tab to display the device information. You will find the current storage location of the patient database under "Log files - Folder for Patient Data and Protocols". Click "Move" to change the location of the database.



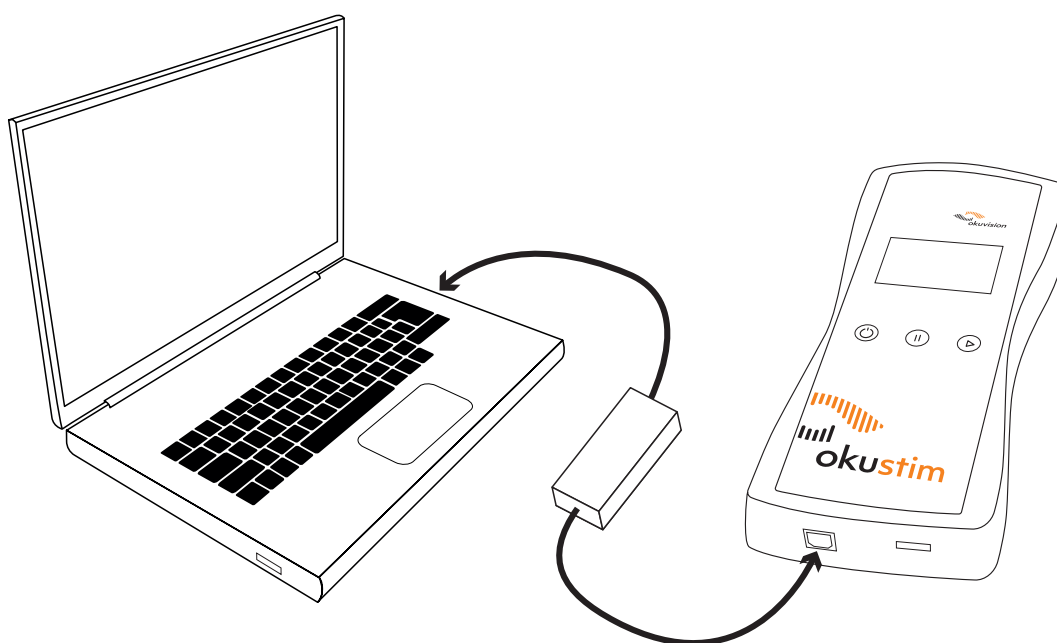


## 2 Preparation of the OkuStim and OkuSpex

### 2.1 Connecting the OkuStim device with the PC

The OkuStim is connected to the PC using the USB-cable supplied. Please use only the cable (OK100182) provided as part of the OkuStim Pro Kit.

Note: Please leave one of the PC's easily accessible USB-ports free (e.g. in the front/side) for plugging in and programming the USB-stick in a later step.



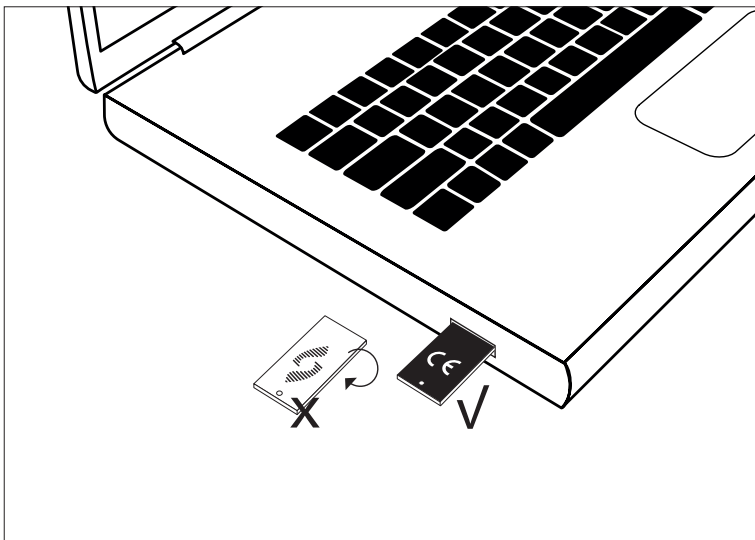
### 2.2 Connecting the OkuSpex with the OkuStim

Please ensure that the plug is inserted fully into the connector. A correct application of the therapeutic stimulation can otherwise not be guaranteed. For more information, please refer to the OkuStim system Instruction for Use (TD60K06-03), Chapter 5.6.

## 2.3 Inserting the mini-USB-stick into the PC

Please ensure the mini-USB-stick is inserted correctly into the PC. It will otherwise not be registered.

Should a window open upon insertion, you can close it.



## 3 Before Use

### 3.1 Checklist: Determination of the tolerance threshold

To determine the tolerance threshold, you need:

- PC with OkuStim software
- USB cable for connecting the OkuStim device to the PC
- OkuStim system
- OkuEl electrode package
- Eye drops (artificial tears)
- Electrode gel for counter electrodes (optional)
- Alcohol swabs to clean the temples
- Cotton buds to open the lower eyelid
- Approx. 20 minutes including time for adjusting the OkuSpex



## 3.2 Adjusting the OkuSpex and inserting the OkuEI

For the application and handling of the OkuSpex as well as the OkuEI electrodes and counter electrodes, please follow the instructions in Chapter 5 of the OkuStim system Instruction for Use.

Please follow the steps for preparing and conducting a therapy session exactly. Otherwise the patient may experience a spontaneous and strong perception of phosphenes.

# 4 Brief Instructions and Overview of Software Handling

This section gives you an overview of the steps involved in determining and storing patients' stimulation parameters. For each step you will find a reference to the respective chapter in which the instructions are described in detail.

### Brief instructions for determining the tolerance threshold:

1. Starting the software (Chapter 5)
2. Creating and selecting a new patient (Section 6.1), or
3. selecting existing patient (Chapter 6.2)
4. Determining the tolerance threshold (Sections 6.3 – 6.5)
5. Checking and setting the therapy parameters (Chapter 6.6)
6. Saving therapy parameters on the mini-USB-stick (Chapter 6.7)
7. Reading out user protocols and assigning a mini-USB-stick to a patient in your database (Chapter 7)
8. Removing the mini-USB-stick and exit the OkuStim software (Chapter 8)

In the **Appendix**, at the end of the document, you will find additional information on how to conduct a phosphene threshold measurement.

## 5 Starting the Software

Start the OkuStim software. The OkuStim device should be automatically recognized by the software.

The screenshot shows the OkuStim software window. At the top, there are input fields for Patient, Patient ID, and Physician. To the right, the Device No. is displayed as 00338. Below these, the o.s. Resistance and o.d. Resistance fields are highlighted in green. The main area has tabs for Patients, Threshold, Therapy, Protocols, and Info. The Patients tab is active, showing a 'Select Patient' list on the left and an 'Edit Patient's Data' form on the right. The 'Edit Patient's Data' form includes fields for Last Name, First Name, Date of Birth (with a format hint), Sex (a dropdown menu), Patient ID, and Physician in Charge / Institution. At the bottom of the 'Select Patient' list are buttons for Select, New, and Delete. At the bottom of the 'Edit Patient's Data' form are buttons for Save and Cancel.

- Check if the serial number of the connected device is displayed (in this case, Device No: 00338)
- The fields "Resistance" are highlighted green. Green= device / stimulation OK.



## 6 Tab "Patient"

### 6.1 Create a new patient

(editable entry)

(information)

(default value)

- (1) Click "New" to create a new patient dataset.
- (2) Enter patient data. At least one line has to be filled in.
- (3) Save entries with "Save"
- (4) The patient is now in the patient database and appears in the info panel.

#### Note:

This step can be skipped if you want to continue with a patient already in the database.

#### Further functions:

Use the "Cancel" button to discard creating a new patient.

## 6.2 Selecting an existing patient

(editable entry)

(information)

(default value)

- (1) Select a patient by clicking on the name.
- (2) Click "Select".
- (3) The patient is shown top left in the info panel.

### Further functions:

With the "Delete" button you can delete a selected patient from the database. All associated data will be deleted with this step.

The screenshot shows the OkuStim software interface. The 'Patients' tab is selected, and a list of patients is displayed. The patient '1: Doe, John (m) - 01.01.1985' is selected. The 'Info' panel on the right displays the patient's details, including Last Name, First Name, Date of Birth, Sex, Patient ID, and Physician in Charge. The 'Patient' field in the top left is highlighted with an orange box and a red circle with the number 3, indicating it is an editable entry. The 'Select Patient' button is highlighted with a red box and a red circle with the number 1, indicating it is the next step. The 'Device No.' field is highlighted with an orange box and a red circle with the number 3, indicating it is an editable entry. The 'o.s. Resistance' and 'o.d. Resistance' fields are highlighted with orange boxes and red circles with the number 3, indicating they are editable entries.



## 6.3 Tab "Threshold"

(editable entry)

(information)

(default value)

- (1) Go to tab "Threshold". Here you find the default stimulation parameters.
- (2) "Pulse Duration": 10 ms
- (3) "Pulse Rate": 20 Hz
- (4) Select under "Stimulate" the eye to be stimulated:  
o.s.: left eye o.d.: right eye

OkuStim

Patient: Doe, John (01.01.1985) Device No.: 00338

Patient ID: o.s. Resistance:  

Physician: o.d. Resistance:  

Patients **Threshold** Therapy Protocols Info

**Detection Procedure & Parameters**

Pulse Duration: 10 ms

Pulse Rate: 20 Hz

Amplitude: 0 µA

max. Abs. Current: 0 µA

Duration: 1800 s

**Detection**

Stimulate ... ☒ o.s. ☐ o.d.

Start Detection Stop

Present Current: 0 µA

Remaining Time: --- mm:ss

Present Voltage: N.M. V

Threshold: --- µA

Apply new Threshold(s) Reset

## 6.4 Tab “Threshold”: Determination of the tolerance threshold

### Important Note:

- Before starting the determination of the tolerance threshold, explain the procedure to the patient.
- Explain to the patient that the stimulation cannot harm them.
- Ask the patient to report immediately if they experience any pain.
- Stop stimulation immediately if the patient complains about pain.
- The tolerance threshold is the current value that the patient can tolerate well for the entire stimulation time without severe pain.
- A stimulation amplitude between 600 - 850 $\mu$ A should be aimed for TES therapy. The highest tolerable value should be selected, not the most comfortable. The stimulation strength can be set higher but must never exceed 950 $\mu$ A.

Explain to the patient that it is normal to feel the stimulation or to find it uncomfortable. However, this is not a reason to stop the stimulation unless they feel severe pain. The tolerance can change over time and there is the possibility of a habituation effect (i.e. it is possible that the tolerance threshold increases over time).

(editable entry)  
(information)  
(default value)

The screenshot displays the OkuStim software interface with the 'Threshold' tab selected. The interface is divided into several sections:

- Patient Information:** Fields for Patient (Doe, John (01.01.1985)), Patient ID, and Physician.
- Device Information:** Device No. (00338), o.s. Resistance (7238 Ohm), and o.d. Resistance.
- Tab Navigation:** Patients, Threshold (selected), Therapy, Protocols, Info.
- Detection Procedure & Parameters:**
  - Pulse Duration: 10 ms
  - Pulse Rate: 20 Hz
  - Amplitude: 200  $\mu$ A** (highlighted with a red box and number 2)
  - max. Abs. Current: 40  $\mu$ A
  - Duration: 1800 s
- Detection:**
  - Stimulate ...** (highlighted with a red box and number 1): Radio buttons for 'o.s.' (selected) and 'o.d.'.
  - Start** (highlighted with a red box and number 3) and **Stop** (highlighted with a red box and number 4) buttons.
  - Present Current: 200  $\mu$ A
  - Remaining Time: 29:51 mm:ss
  - Present Voltage: 1.44 V
  - Threshold: ---  $\mu$ A
  - Buttons: Apply new Threshold(s), Reset





The tolerance threshold is determined separately for both eyes. Proceed as follows:

- (1) Select the eye for which the tolerance threshold is to be determined (o.s.: left, o.d.: right).
- (2) Enter the value 50  $\mu\text{A}$  in the "Amplitude" field.
- (3) Click on Start.
  - Make sure that the resistance display is always highlighted in green. In the event of an error, this field changes to red (see Section 6.4.1).
- (4) Click "Stop" to stop stimulation.
  - Ask the patient how they feel.
  - In the "Amplitude" field, increase the value to 100  $\mu\text{A}$  and repeat steps 2-4.
  - It is important that patients slowly get used to the stimulation. Initially, slowly introduce the patient to therapy. Stimulate each time for about 10-15 seconds.
  - Repeat steps 2-4. Increase the amplitude in 100  $\mu\text{A}$  steps. Depending on the patient's sensitivity, you can also choose 50  $\mu\text{A}$  or smaller steps. Always pay attention to the patient's reaction. Stimulate for about 10-15 seconds at a time.
  - Once the tolerance value is found, test it again for 20-30 seconds.
  - Repeat the process for the second eye.

#### 6.4.1 Resistance Error

In case of resistance error:

- Check if the proper eye was selected in the software and all cable connections are OK.
- Check the position of the OkuEI electrode and reposition it if necessary (contact of the electrode thread with eye should be at least 1 cm).
- Check if the OkuEI electrode is correctly inserted into the electrode holder.
- Check the position of the counter electrode (try monitoring the resistance while pressing on the counter electrode). If necessary clean the skin again and:
  - attach new counter electrode
  - choose another position
  - use conductive gel before placing the counter electrode.
- In case of dry eye use artificial tears (patient can keep the OkuSpex on).
- Repeat the resistance test.

You can find an overview of all display messages of the OkuStim and advice for troubleshooting in the OkuStim system Instructions for Use in chapters 7 and 13 respectively.

## 6.5 Tab “Threshold”: Entering and saving the tolerance threshold

(editable entry)

(information)

(default value)

The screenshot shows the 'OkuStim' software window with the 'Threshold' tab selected. The interface is divided into several sections:

- Patient Information:** Fields for Patient (Doe, John (01.01.1985)), Patient ID, and Physician.
- Device Information:** Device No. (00338), o.s. Resistance (7238 Ohm), and o.d. Resistance.
- Detection Procedure & Parameters:**
  - Pulse Duration: 10 ms
  - Pulse Rate: 20 Hz
  - Amplitude: 200  $\mu$ A (highlighted with a red box and number 2)
  - max. Abs. Current: 40  $\mu$ A
  - Duration: 1800 s
- Detection:**
  - Stimulate ...: Radio buttons for o.s. (selected, highlighted with a red box and number 1) and o.d.
  - Buttons: Start (highlighted with a red box and number 3), Detection (highlighted with a red box and number 4), and Stop.
  - Present Current: 200  $\mu$ A
  - Remaining Time: 29:51 mm:ss
  - Present Voltage: 1.44 V
  - Threshold: ---  $\mu$ A (highlighted with a red box and number 5)
  - Buttons: Apply new Threshold(s) (highlighted with a red box) and Reset.

To save the tolerance threshold:

- (1) Select the eye (o.s. = left resp. o.d. = right), for which you wish to enter the threshold.
- (2) Enter the calculated threshold in the field “Amplitude”.
- (3) Click “Start”.
- (4) Click “Detection” to set the threshold value.

**Note:** Detected thresholds can be deleted with the "Reset" button.

Repeat steps 1-4 to enter the threshold for the second eye.

- (5) Click "Apply new Threshold(s)", to use these thresholds as basis for the therapy.

**Note:** The OkuSpex does not have to be connected to the OkuStim device to enter the threshold value. The message of a resistance error can be ignored here.



## 6.6 Tab "Therapy": Control of the therapy parameters

(editable entry)

(information)

(default value)

- (1) Switch to tab "Therapy".
- (2) Double-check stimulation parameters. They were saved when you clicked "Apply new Threshold(s)" in tab "Threshold" before.
- (3) Make sure that 100% is entered in the field "rel. Amplitude", for both eyes (o.s./ o.d.).

An explanation of the "rel Amplitude" function and the "Stimulate ..." buttons can be found in the Appendix.

- (4) Optional: by activating this function, you can set a minimum interval for therapy sessions. The stimulation can then only be carried out every x days (+/-2 days).

## 6.7 Tab “Therapy”: Saving the therapy parameters on the USB-stick

(editable entry)  
(information)  
(default value)

OkuStim

Patient: Doe, John (01.01.1985) Device No.: 00338

Patient ID: o.s. Resistance: 0.00

Physician: o.d. Resistance: 0.00

Patients Threshold Therapy Protocols

Stimulation Parameters Threshold History

Pulse Duration: 10 ms

Pulse Rate: 20 Hz

o.s. Threshold: 800  $\mu$ A

o.s. rel. Amplitude: 100 % Threshold

o.d. Threshold: 800  $\mu$ A

o.d. rel. Amplitude: 100 % Threshold

Application Duration: 00:30 hh:mm

Stimulate ... ☒ o.u. ☐ o.s. ☐ o.d.

Restriction of Stimulation Intervals: off days

Memory Card

+++ Reading configuration from USB memory ...

Patient

o.s.:

- Threshold: 0  $\mu$ A
- Amplitude: 0  $\mu$ A (not stimulated)

o.d.:

- Threshold: 0  $\mu$ A
- Amplitude: 0  $\mu$ A (not stimulated)

Pulse Duration: 1 ms

Pulse Rate: 20 Hz

Application Duration: 0h 1min

Stim. interval restriction: off

Absolute Output Current: 0  $\mu$ A

Write Configuration

Insert the USB Stick into the PC

(1) Click "Write Configuration"

(2) Check if the newly written parameters in the window "Memory Card" are correct.

You can also adjust therapy parameters at a later point in the treatment process, should this be necessary. In such case, follow Chapters 6.2 - 6.7.

### 6.7.1 Tab “Therapy”: Threshold History

In the Tab “Threshold History” (3) the course of the patient’s thresholds can be monitored.



## 7 Reading out of User Protocols (logs)

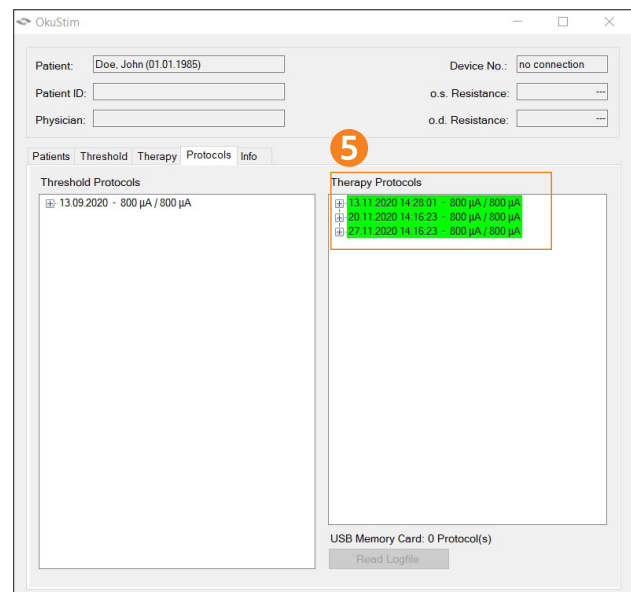
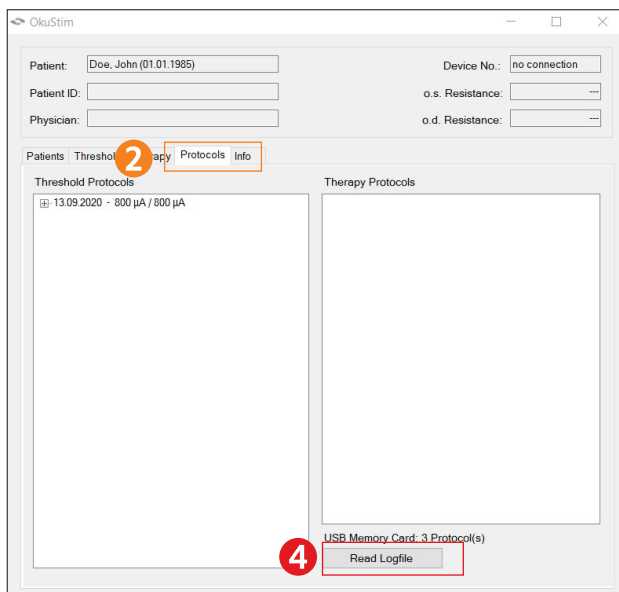
- (1) Select the corresponding patient in the "Patients" tab (see chapter 6.2).

**Note:** If you want to read out patient information and user protocols of a patient who has not yet been created in your database, proceed as described in Chapter 7.2.

- (2) Click on the "Protocols" tab.
- (3) Insert the patient's mini-USB-stick into an USB port of your PC. The number of user logs on the mini-USB-stick is now displayed above the "Read Logfile" button.
- (4) Click the "Read Logfile" button.

**Note:** If the mini-USB-stick is not assigned to a patient in your database, the "Unknown Patient ID" dialog opens. Further information can be found in chapter 7.1 and chapter 7.2. Should the mini-USB-stick contain data of another patient in your database it opens the dialogue "Differing Patient ID".

- (5) The user protocols are now displayed in the "Therapy" tab in the "Therapy Protocols" field. Click on "+" to view the therapy data.



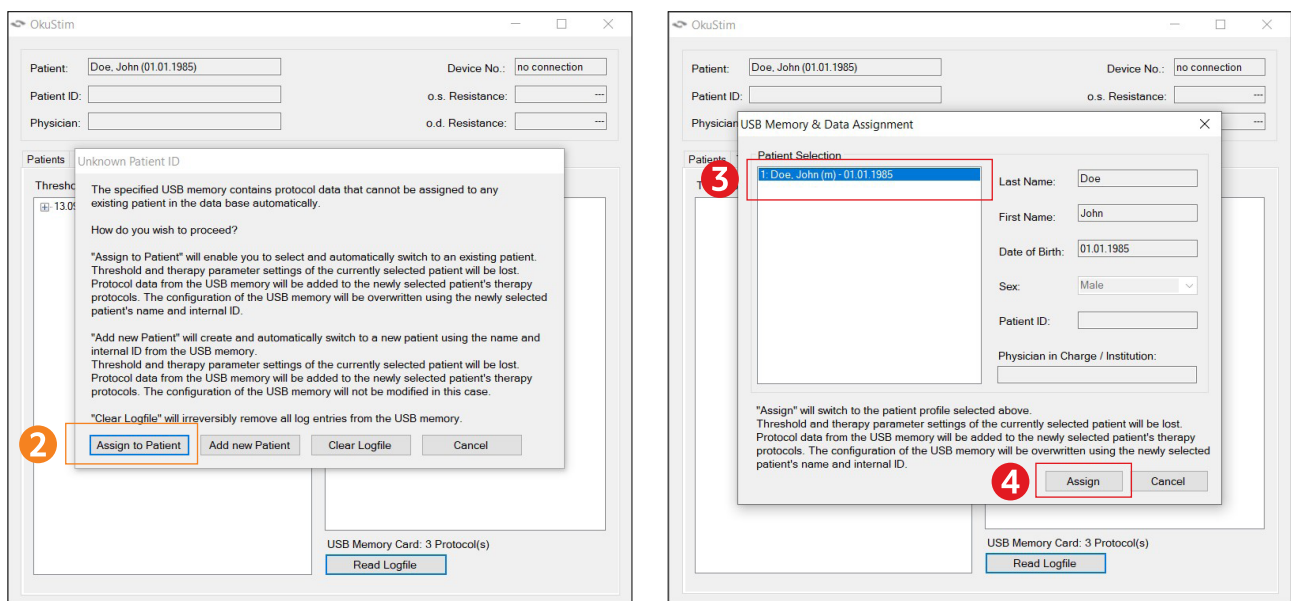
**Note:** User logs with a green background indicate that the therapy session has been completed. Fields with a red background indicate that the stimulation was terminated prematurely. In the subfolder "Resistances / Pauses" (click "+" to expand) you can view resistance values (green: resistance values in the range 200  $\Omega$  - 15 k $\Omega$ ; red: resistance values < 200  $\Omega$  or > 15 k $\Omega$ ).

**Note:** The user logs are transferred to the database when they are read from the mini-USB-stick. The user logs cannot be read out a second time from the mini-USB-stick.

## 7.1 Assignment of a mini-USB-stick to a patient in your database

When the user protocols of a patient are read out for the first time, it is possible that the mini-USB-stick is not yet assigned to any patient in your database.

- (1) Proceed as described in chapter 7, steps 1 to 4.
- (2) The "Unknown Patient ID" dialog opens. To assign the mini-USB-stick to a patient, click the "Assign to Patient" button.



- (3) In the "USB Memory & Data Assignment" dialog box, select the patient from your database to whom the data from the mini-USB-stick will be assigned and
- (4) click the "Assign" button.

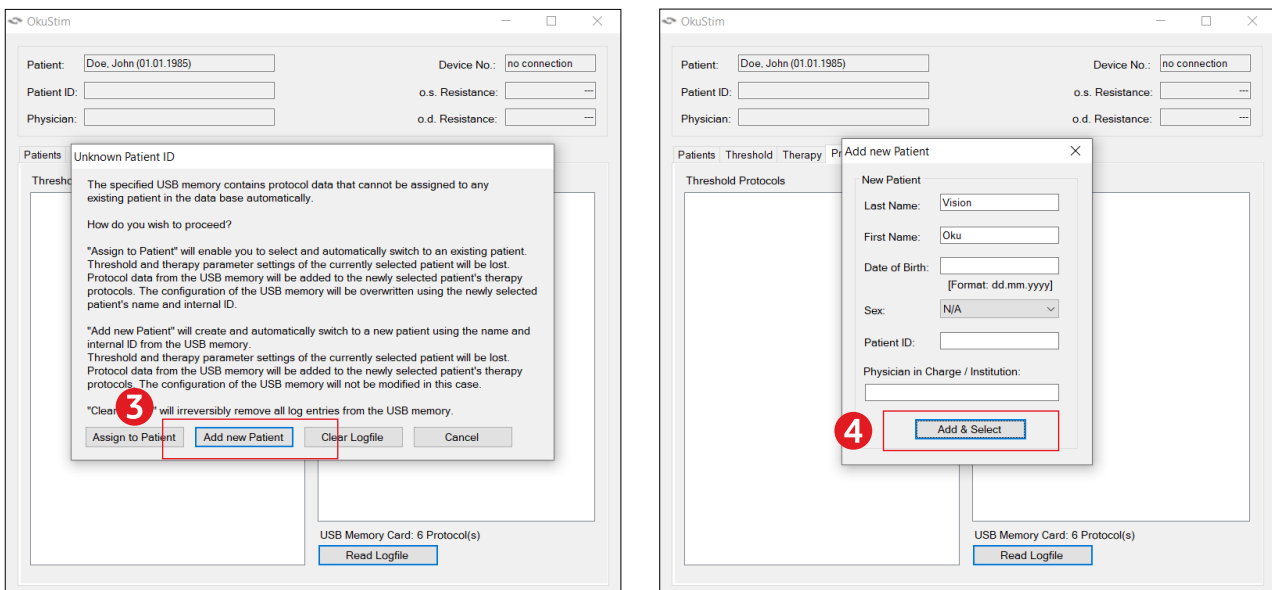
The user protocols are now assigned to the patient and have been imported into the database. You can view these in the "Protocols" tab in the "Therapy Protocols" field. The mini-USB-stick is also now assigned to the patient, so that no new assignment is necessary the next time the mini-USB-stick is read out.



## 7.2 Reading out user protocols of unknown patients

To read out data of a patient who has not yet been created in your database, proceed as follows.

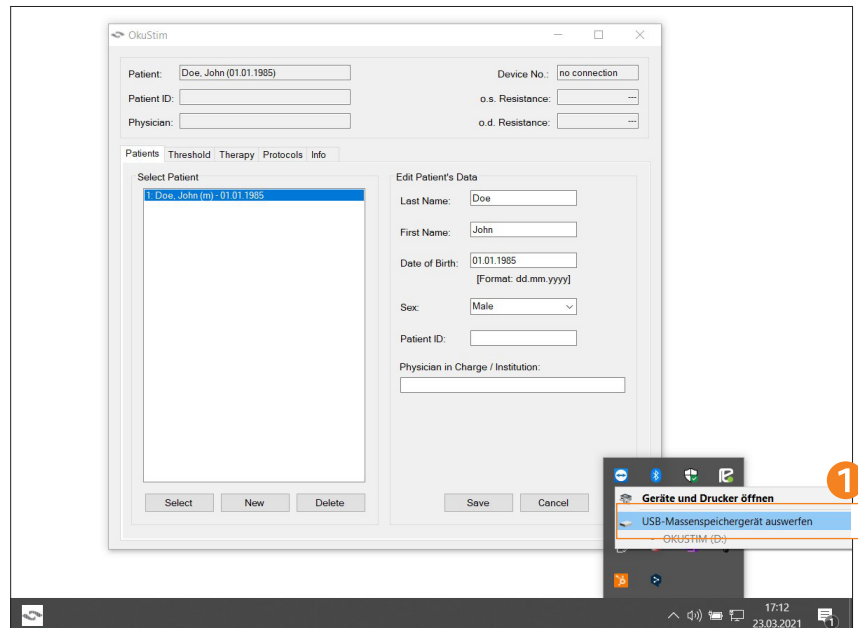
- (1) Select any patient in your database (see Chapter 6.2).
- (2) Proceed as described in Chapter 7, steps 2 to 4.



- (3) The dialogue "Unknown Patient ID" opens. Click on the button "Add new Patient".
- (4) The "Add new Patient" window opens. The patient information on the USB memory card is now displayed. You can accept or change this information. Click on "Add & Select" to create the patient and read out the user protocols.
- (5) The patient and his user protocols have now been added to your database.

## 8 Removing the Mini-USB-Stick and Exiting

(editable entry)  
(information)  
(default value)



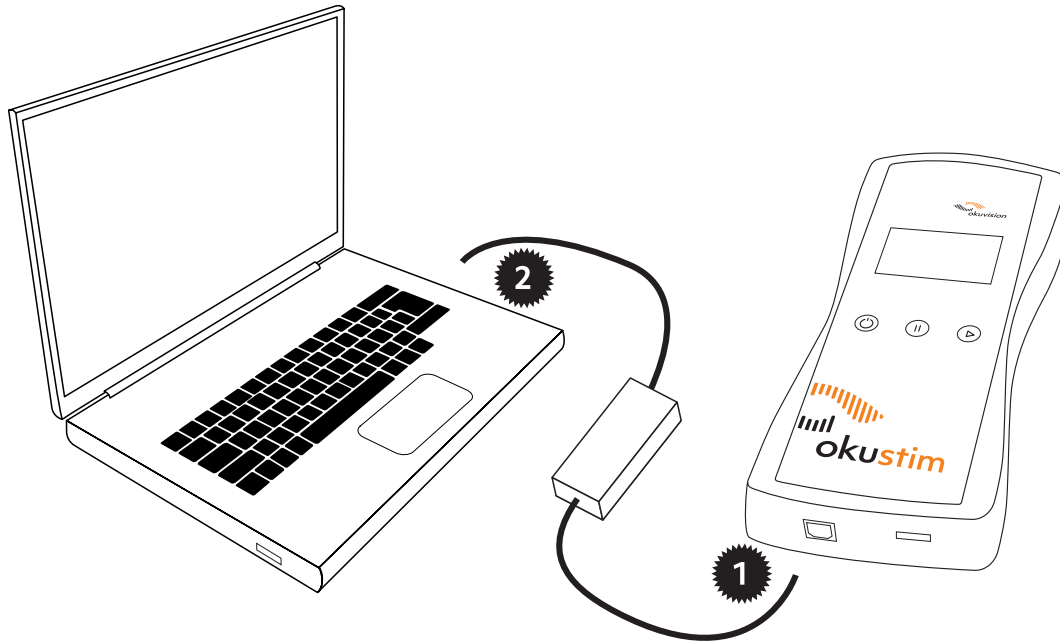
Remove the USB-stick in Windows:

- (1) Click the USB-Symbol "Safely remove hardware" in the Windows-Taskbar.
  - Click "Eject USB-mass storage device".
  - Remove the mini-USB-stick from the PC.
  - Quit the software only after the mini-USB-stick has been removed.





## 8.1 Disconnecting OkuStim from PC



1

- Unplug the USB cable from the OkuStim device.

2

- Unplug the USB cable from the PC.
- Switch off the device.

## 9 Appendix

### 9.1 The phosphene threshold measurement

#### Procedure for determining the threshold value

You can carry out a phosphene threshold measurement with the OkuStim software and use this as a basis for the therapeutic stimulation. The procedure is very similar to that for determining tolerance values, but in this case, attention must be paid to the patient's perception of flickers of light (phosphenes).

After the patient has been created and saved with the software (as described in Chapter 6.1), proceed as described below.

Please note the following important points:

- The room must be darkened.
- Please inform the patient before starting the stimulation or before you click on "Start".
- During the stimulation, ask if the patient sees a flicker of light anywhere.
- After a few seconds (less than 5 seconds!) click on "Stop" to stop the stimulation.
- Analogue to determining the tolerance threshold, start with 50µA to test the resistance. First increase the amplitude in 50µA steps. From 300µA in steps of 100µA. Repeat this until the patient perceives the first flicker of light. This is the phosphene threshold.
- If the patient experiences intolerable pain during stimulation, the process must be stopped. In such a case, a stimulation amplitude according to the tolerance threshold should be selected in consultation with the attending physician.
- Experienced users may increase the amplitude to find the threshold in accordance with the patient's individual level of disease progression.

The phosphene threshold is determined in 3 steps:

- By increasing the amplitude until the threshold is reached (patient sees a flicker of light for the first time).
- By decreasing the amplitude until it drops below the threshold (the threshold in this case is the last value where the patient still reports a flicker of light).
- By increasing the amplitude again until the threshold is reached. The mean of these 3 values is used as the phosphene threshold.



### 9.1.1 Determining the threshold values with the software: "Threshold" tab

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(information)  
(default value)

- (1) Select the eye for which the phosphene threshold should be determined.  
(o.s.: left, o.d.: right).
- (2) Enter the desired amplitude in the field "Amplitude".
- (3) Click "Start" to start the stimulation.
- (4) Ask the patient for any flicker of light, resp. the perception of phosphenes.
- (5) Click "Stop".  
If no phosphenes were perceived, increase the amplitude.

Repeat steps (2) to (4) until the phosphene threshold is reached.

- As soon as the phosphene threshold has been determined, enter the value in the "Amplitude" field (2), click on "Start" (3) and then on "Detection" (5). Make sure not to click "Stop".
- Then determine the threshold value for the second eye.  
To do this, start again with step (1).
- When you are finished with the second eye, click on "Apply new Threshold (s)" (6) so that these threshold values can be used for the stimulation intensity for the therapy.

#### Before switching to the "Therapy" tab:

- Test the therapy tolerance by entering 200% of the calculated phosphene threshold in the "Amplitude" field (2) and stimulate the patient with this amplitude for 20-30 seconds.
- If the patient does not have any problems, continue with the therapy set-up.
- If the patient feels unbearable pain, click "Stop" (3) and gradually reduce the amplitude. Test the respective setting until a value is reached that the patient can tolerate.

### 9.1.2 Setting the therapy parameters: "Therapy" tab

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(information)  
(default value)

The screenshot shows the OkuStim software window. The 'Therapy' tab is active. The 'Stimulation Parameters' section contains fields for Pulse Duration (10 ms), Pulse Rate (20 Hz), o.s. Threshold (800  $\mu$ A), o.s. rel. Amplitude (100 % Threshold), o.d. Threshold (800  $\mu$ A), o.d. rel. Amplitude (100 % Threshold), and Application Duration (00:30 hh:mm). The 'Stimulate ...' section has radio buttons for o.u. (selected), o.s., and o.d. The 'Restriction of Stimulation Intervals' section has a dropdown set to 'off' and a unit set to 'days'. The 'Threshold History' tab is also visible. The 'Memory Card' section shows 'No Memory Card connected.' and a 'Write Configuration' button.

- (1) Switch to tab "Therapy".
- (2) Double-check stimulation parameters. They were saved when you clicked "Apply new Threshold(s)" in tab "Threshold" before.
- (3) In the field "rel. Amplitude" enter 200% for both eyes (o.s./ o.d.).

**Important:** Should the patient not tolerate 200% of the phosphene threshold, adjust the percentage value according to the tested therapy tolerance.

**Note:**

The stimulation amplitude must not exceed 950  $\mu$ A.

- (4) Optional: by activating this function, you can set a minimum interval for therapy sessions. The stimulation can then only be carried out every x days (+/-2 days).

The "Threshold History" tab (6) shows the previous history of the threshold values for this patient. By selecting a threshold "History" entry, the parameters are transferred to the "Stimulation parameters" tab (7).

With the buttons under "Stimulate ..." you can specify which eye should be stimulated if necessary.

o.u. – the default setting if stimulation values for both eyes have been entered. By selecting o.d. or o.s. you can limit the stimulation to the right or left side.



## 9.2 Accessories

Art. Number	Product
OK100056	OkuStim® device (on the product label: <b>OkuStim®</b> )
OK100350	OkuSpex® frame (on the product label: <b>OkuSpex®</b> )
OK100310	Elektrode package (on the product label: <b>OkuEI® Electrode Package</b> ), contains: 10 no. OkuEI® Electrodes (on the product label: <b>OkuEI® Electrode</b> ) 12 no. OkuEI® Counter electrodes (on the product label: <b>OkuEI® Counter-Electrode</b> )
OK100083	USB-Stick (on the product label: <b>OkuStim® USB-Stick</b> )
OK100504	<b>OkuStim® Pro-Kit</b> (contains OkuStim® Software and USB-Cable, see below)
OK100502	<b>OkuStim® Software</b>
OK100182	USB-Cable (with electrical safety according to EN60601-1, 3rd ed. with 4kVrms to connect the OkuStim device to a PC)
TD60K06-02	IFU OkuStim® System DE
TD60K06-03	IFU OkuStim® System EN
TD60K06-06	IFU OkuStim® System FR
TD60K06-08	IFU OkuStim® System IT
TD60K06-09	IFU OkuStim® System TR
TD60K06-10	IFU OkuStim® System EL
TD60K06-11	IFU OkuStim® System ES
TD60K06-13	IFU OkuStim® System NL
TD60K06-14	IFU OkuStim® System PL
TD60K06-22	IFU OkuStim® System NO

## 9.3 Technical data

### Stimulation Parameters

Symmetric biphasic (anodic-first) rectangular pulse; frequency 20 Hz; pulse length 10 ms; maximum current amplitude 950 µA.

Note: The output contains no d.c. component.

### Operating, Transport and Storage Conditions

Temperature: +5°C - +40°C

Humidity: 15% - 93% relative humidity (not condensing)

Air pressure: 700 hPa – 1060 hPa

### Essential Performance

The OkuStim does not emit currents above 10 mA. Loss of essential performance can cause irreversible damage to the eyes. The OkuStim continuously and automatically monitors and maintains essential performance.

## 9.4 Information about electromagnetic compatibility



### Warnings:

The emissions characteristics when using the OkuStim system with the OkuStim software (connected to PC) are suitable for use in industrial areas and hospitals (CISPR 11 class A). If the OkuStim system with the OkuStim software is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories and cables other than those specified on page 28 or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The USB cable may not exceed a length of 3 m. The OkuSpex cable has a length of 1.6 m.

Portable RF communication devices (incl. accessories like antenna cables or external antennas) should be at least 30 cm away from the OkuStim system and all its parts, including cables specified by the manufacturer. Otherwise the performance of the OkuStim system could be compromised. See table in chapter 9.5.

### Tested conformity with standards for emission and immunity

#### Emission

The device complies with the requirements for radiated and conducted RF-emissions according to CISPR 11, Group 1, Class A.



## 9.5 Guidance and manufacturer's declaration for electromagnetic compatibility

The OkuStim system is intended for the use in the electromagnetic environment specified below. The customer or the user of the OkuStim system should assure that it is used in such an electromagnetic environment.

Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD according to IEC 61000-4-2)	±8 kV contact discharge ±2, 4, 8 und 15 kV air discharge	±8 kV contact discharge ±2, 4, 8 und 15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. Portable and mobile RF communications equipment should be used no closer to any part of the OkuStim system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF-disturbances according to IEC 61000-4-6	$3 V_{rms}$ 0,15 MHz to 80 MHz $6 V_{rms}$ in ISM bands 0,15 MHz to 80 MHz 80% AM at 1 kHz	$3 V_{rms}$ 0,15 MHz to 80 MHz $6 V_{rms}$ in ISM bands 0,15 MHz to 80 MHz 80% AM at 1 kHz	$d=1,2\sqrt{P}$
Radiated RF-disturbances according to IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m 80 MHz to 2,7 GHz	Limit values for RF communication devices according to table 9 in IEC 60601-1-2 (9-28 V/m)

