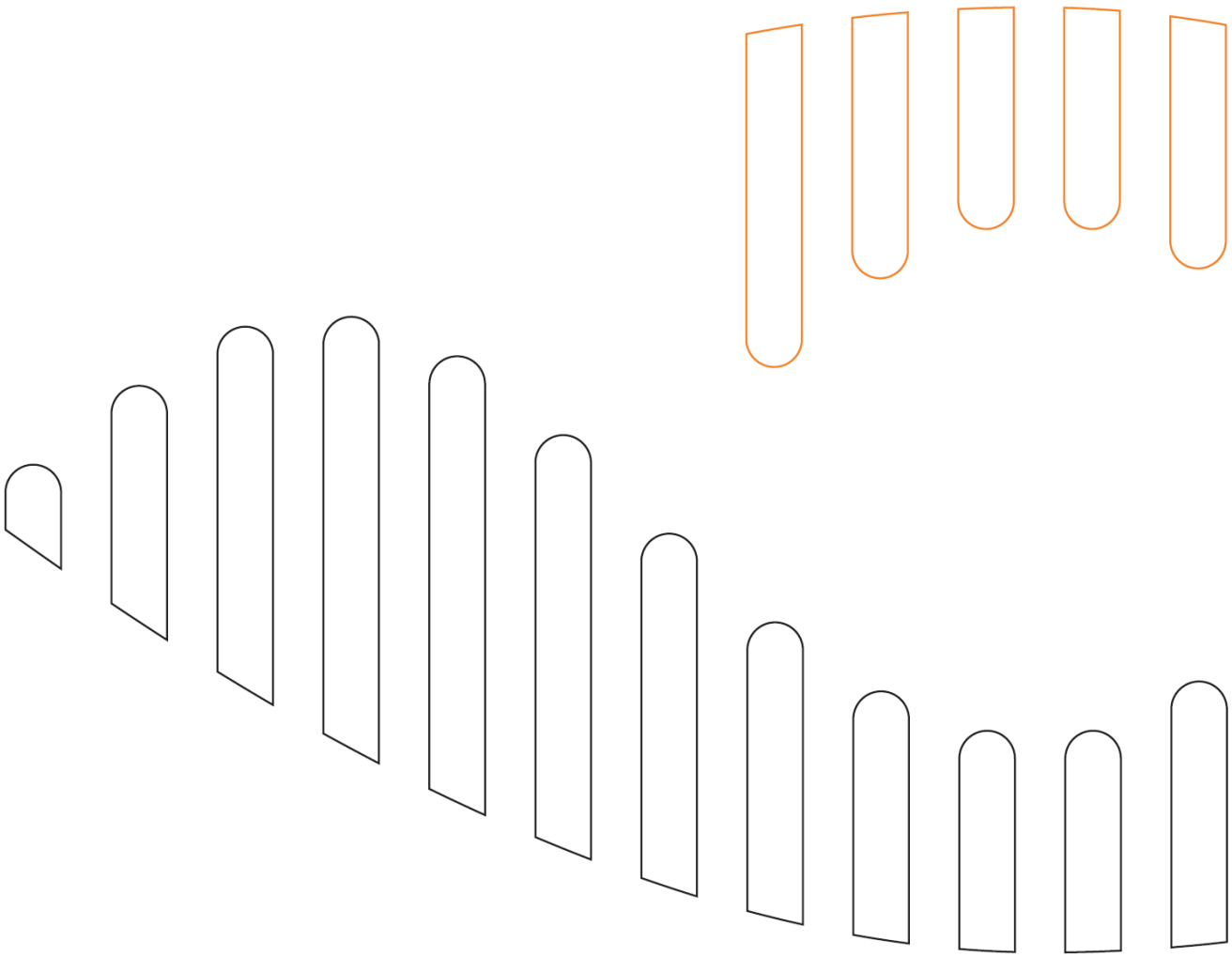
okuvision

OkuStim® Pulse Kit

Instructions for Use



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Brief Guide to Using OkuStim Pulse

This section gives you an overview of the steps for determining and saving the stimulation parameters of a patient. For each step, you will find a reference to the respective chapter in which the instructions are described in detail.

1. Start the OkuStim Pulse software. (Chapter 8)
2. Plug the OkuStim wireless dongle into the USB port of your PC. (Chapter 9)
3. Switch on OkuStim 2 by pressing and holding the on/off button for at least 6 seconds until the side LED flashes blue. (Chapter 9)
4. Connect OkuStim 2 to OkuStim Pulse. (Chapter 9)
5. Create and select a patient:
   - Either by creating and selecting a new patient (Chapter 10)
   - Or by selecting an existing patient (Chapter 18)
6. Determine the tolerance threshold (Chapter 11)
7. Save the therapy parameters on OkuStim 2 (Chapter 15)
8. Disconnect OkuStim 2 from OkuStim Pulse (Chapter 16)
9. End OkuStim Pulse (Chapter 16)

See Appendix 3: Operation with USB cable connection for information about programming the OkuStim 2 via cable connection (only for countries in which the wireless connection is not permitted).

Contents

Important Note

This document must be read in conjunction with Document OK210011 – OkuStim 2 System Instructions for Use.

Every user of OkuStim Pulse software must be instructed in accordance with the present manual (OkuStim® Pulse Instructions for Use, OK210041) on how to operate the software.

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Intended Purpose of the OkuStim 2 System and OkuStim Pulse

Intended purpose of OkuStim Pulse

OkuStim Pulse is intended to be used by a healthcare professional to determine, save and manage the specific stimulation parameters for the OkuStim 2 System.

Intended purpose of OkuStim Pulse Kit

The OkuStim Pulse Kit is intended to be used by a healthcare professional to determine, save and manage the specific stimulation parameters with the OkuStim 2 System of each patient. The OkuStim Pulse Software controls the OkuStim 2 output while connected via wireless. The individual patient stimulation parameters are written onto a OkuStim 2 Memory.

Intended purpose of OkuStim 2

OkuStim is intended for the electrical stimulation of the eye of patients with retinitis pigmentosa in an outpatient or home setting.

Users and Environment of Use

The OkuStim 2 System is suitable for performance of electrical stimulation by trained lay persons and specialists in hospitals, private practices, or the home environment. The use of the OkuStim 2 System with OkuStim Pulse for programming stimulation parameters is limited exclusively to trained personnel. There is no age limit for the use of OkuStim Pulse. An age restriction for the use of OkuStim 2 is defined in the OkuStim 2 instructions for use, see OK210011.

Transcorneal electrostimulation (TES) as neuroprotective therapy should be applied on an ongoing basis. Therapeutic doses for patients with retinitis pigmentosa are administered once weekly for 30 minutes. The age limit for the use of the OkuStim 2 System is defined in the OkuStim 2 System instructions for use.

Important Safety Notes

1. Before using OkuStim Pulse and the OkuStim 2, familiarize yourself with these Instructions for Use and respect the notes about electromagnetic compatibility (Chapter 27).
2. This document is to be read in connection with the document OK210011 OkuStim 2 System Instructions for Use.
3. Use exclusively the accessory parts listed in the "Accessories" list accompanying the product. Do not connect any unlisted cables or parts to the device.
4. For charging (and also for transmitting data by cable connection), use only the charging cable with mains plug contained in the supplied kit.
5. No stimulation is possible while the batteries of the OkuStim 2 are charging or while data are being transmitted by cable connection (USB C connection to the PC).
6. No wireless connection can be established while the batteries of the OkuStim 2 are charging.
7. To transmit larger volumes of data, use a cable connection to the PC; radio transmission may take several minutes.
8. The therapeutic current intensity must not exceed 950 µA.

9. The current intensity must not exceed the individual pain threshold.
10. Keep the device and its accessories out of the reach of children. Small parts such as the memory card or the OkuEl M could be swallowed.
11. Do not use the OkuStim 2 if it feels hot around the battery or if the device is deformed.
12. The device and its electronic accessories must not be opened or modified under any circumstances.
13. Do not attempt any repair or maintenance on the device, but if necessary, contact your dealer or the manufacturer.

Warning

- Depending on ambient temperature, the housing of the OkuStim 2 can become very hot during the charging process and even during data transmission by cable. Therefore, after disconnecting the cable, wait 10 minutes for the device to cool before you put on and use the OkuStim 2.
- Do not wear the device during charging or while data are being transmitted by cable connection.

Version Note

This document relates to software version 2.0.3 and higher.

Minimum System Requirements of OkuStim Pulse

- Intel® 1.3 GHz processor or comparable
- 1 GB RAM; 50 MB available hard disc memory
- 1 USB port type A USB 2.0 for OkuStim Wireless Dongle or connecting cable.
- Supported operating systems: Microsoft® Windows® 11.
  - If technical support (including security updates) of Microsoft® Windows® 10 is ensured, the installation is possible.
  - Other operating systems are not permitted for the installation of OkuStim Pulse. Administrator rights are required for installation.
- Framework: Installation of Microsoft .NET 6.0 or higher (6.x) must be possible or available.
  - Additionally, at least 300 MB free hard disc space is required.
- Responsibility for IT safety and updates rests with the operator of the PC on which the software will be installed.

Explanation of Symbols

The following symbols are used on the packaging and in the description of the components:

	Packing unit
MD	Medical device
	Not for reuse
	Ref. To instructions for use
	Sample für temperature range (Storage and Use)
	Ref. To instructions for use
	Manufacturer
	General warning symbol
REF	Part number
LOT	Batch designation
	Do not use if packaging is damaged
SN	Serial number
	Note waste disposal specifications
	Use by date
	Applied Part: Type BF
	Date of manufacture
UDI	Unique Product Identifier
CE 0197	The CE mark confirms compliance with the Medical Device Regulation (EU) 2017/745 MDR. Notified body: TÜV Rheinland (= 0197)
IP22	Casing protection class: protected against foreign objects with a diameter of 12.5 mm or above and against dripping water with 15° angle.
	Example for storage temperature
	FCC-conform

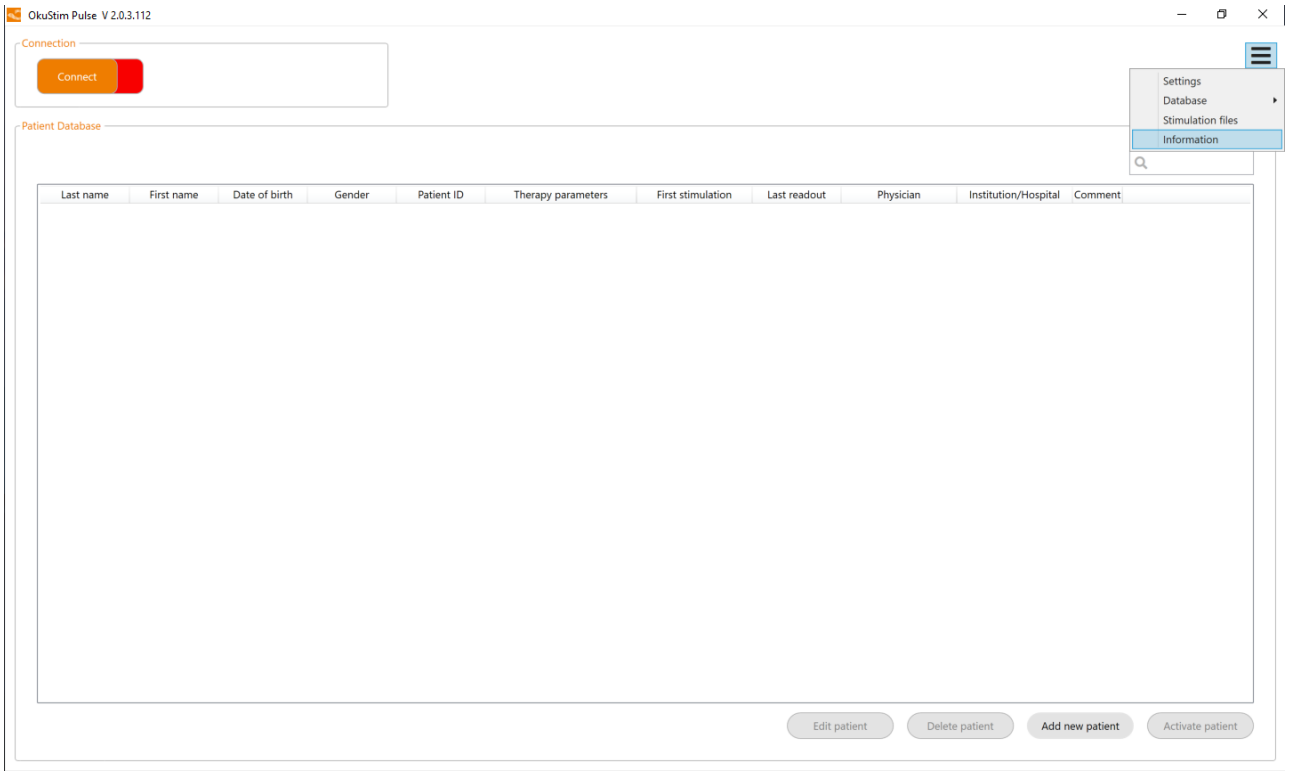
Terms and Designations

The meanings of important terms you will encounter in these Instructions for Use are explained in this section:

- *Tolerance threshold, tolerance amplitude:* This is the maximum current value measured in the clinic, expressed in µA, that the patient can tolerate for the duration of stimulation.
- *Tolerance threshold measurement:* This is the process, described in Chapter 11, for determining the tolerance threshold/tolerance amplitude.
- *Stimulation amplitude, stimulation intensity:* This is the current amplitude, expressed in µA, that is used during therapy sessions. It is generally the same as the tolerance amplitude, but in some cases can also be lower (see Chapter 19.2.1).
- *Phosphene threshold:* This is the value of the current amplitude, expressed in µA, with which the retina must be stimulated in order to perceive light phenomena (phosphenes).
- *Phosphene threshold measurement:* This is the process, described in Appendix 2: Phosphene threshold measurement, for determining the phosphene threshold.
- *Patient database:* This is the home screen of OkuStim Pulse, in which you can view the patient database.
- *Activated patient view:* This is the window that opens when a patient is selected from the database and activated. From here, it is possible to change already existing stimulation parameters and to view the adaptation of OkuStim 2, the therapy history and other parameters and data records.
- *OkuStim Settings:* OkuStim Settings denotes [in this software] the adaptation parameters of OkuStim 2 (Chapter 13).
- *Stimulation File:* File in which the stimulation parameters are specified; for the "Retinitis Pigmentosa" stimulation file, these are: symmetric biphasic (anodic first) square-wave pulse, frequency 20 Hz, pulse duration 10 ms, maximum stimulation amplitude 1000 µA, stimulation duration 30 minutes.
- *Radio module:* USB stick (OkuStim Wireless Dongle) for establishing a wireless connection between OkuStim Pulse and OkuStim 2.
- *OkuStim 2 radio module:* Radio component integrated in OkuStim 2, for establishing a wireless connection (with OkuStim Pulse in combination with the OkuStim Wireless Dongle); can be activated with the On/Off button.
- *Pairing mode:* This is the operating condition for OkuStim 2 to be coupled with OkuStim Pulse via the radio modules.
- *OS/OD:* OS (Oculus Sinister) stands for the left eye, OD (Oculus Dexter) for the right eye.

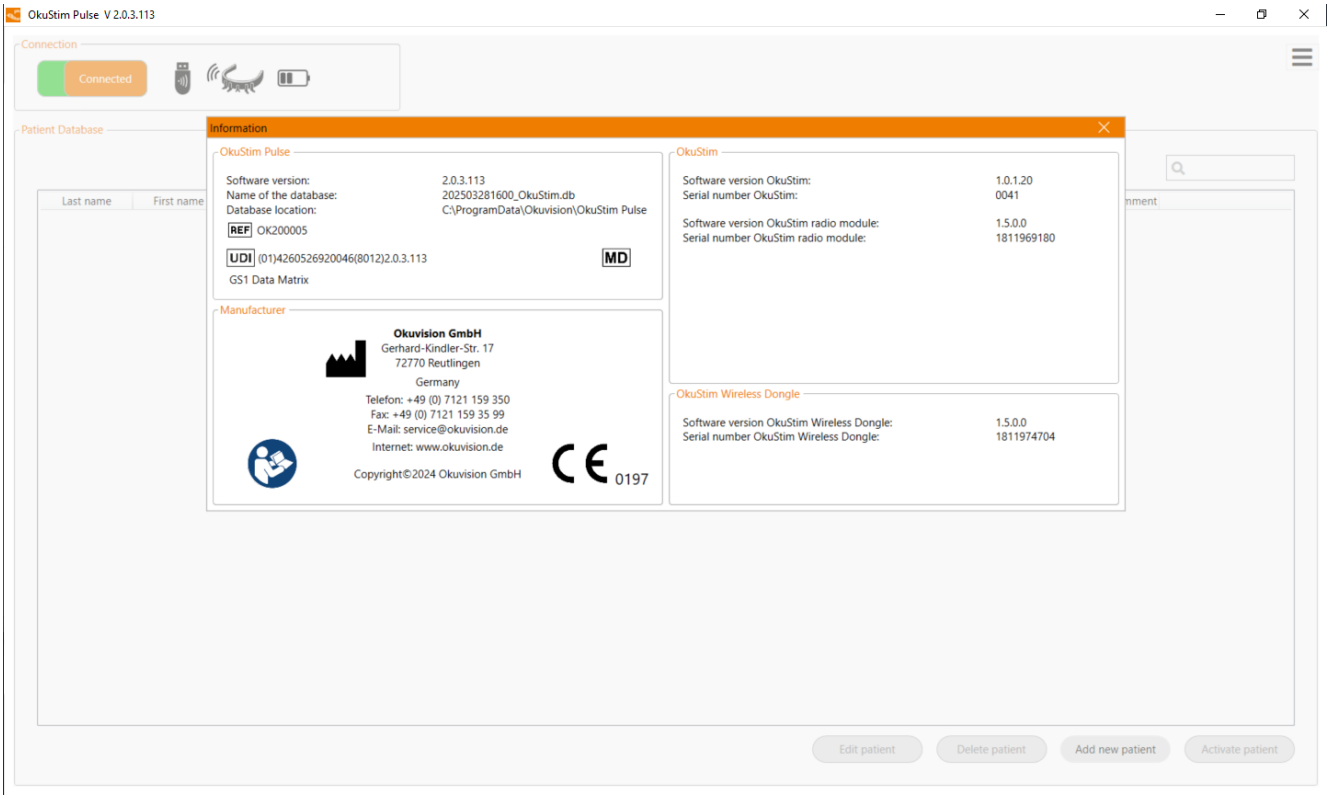
Help and Further Information

If you need help, click on the menu symbol and then on "Information".



A window will open in which you can find all relevant information, such as:

- Software (software version, patient database name and storage path)
- Information about the radio module built into OkuStim 2
- Information about the OkuStim 2 if connected
- Okuvision contact information (for technical support)



1 What is OkuStim Pulse?

OkuStim Pulse is designed to control OkuStim 2 or to influence the use of the OkuStim 2, hence OkuStim Pulse, just as OkuStim 2, is classified according to Rule 3.3 as a class IIa medical device.

The OkuStim 2 is a class IIa medical device according to Annex VIII Rule 10 of European Medical Device Regulation (EU) 2017/745.

Items supplied in the OkuStim Pulse Kit:

- OkuStim® Pulse (USB-Stick with installation file OkuStim Pulse® Software; on the product label: OkuStim® Pulse, Part No.: OK200005)
- Radio module (on the product label: OkuStim® Wireless Dongle, Part No.: OK000133)
- USB cable (on the product label: OkuStim® 2 USB Cable, Part No.: OK000022)

2 Installation of OkuStim Pulse

2.1 Installation

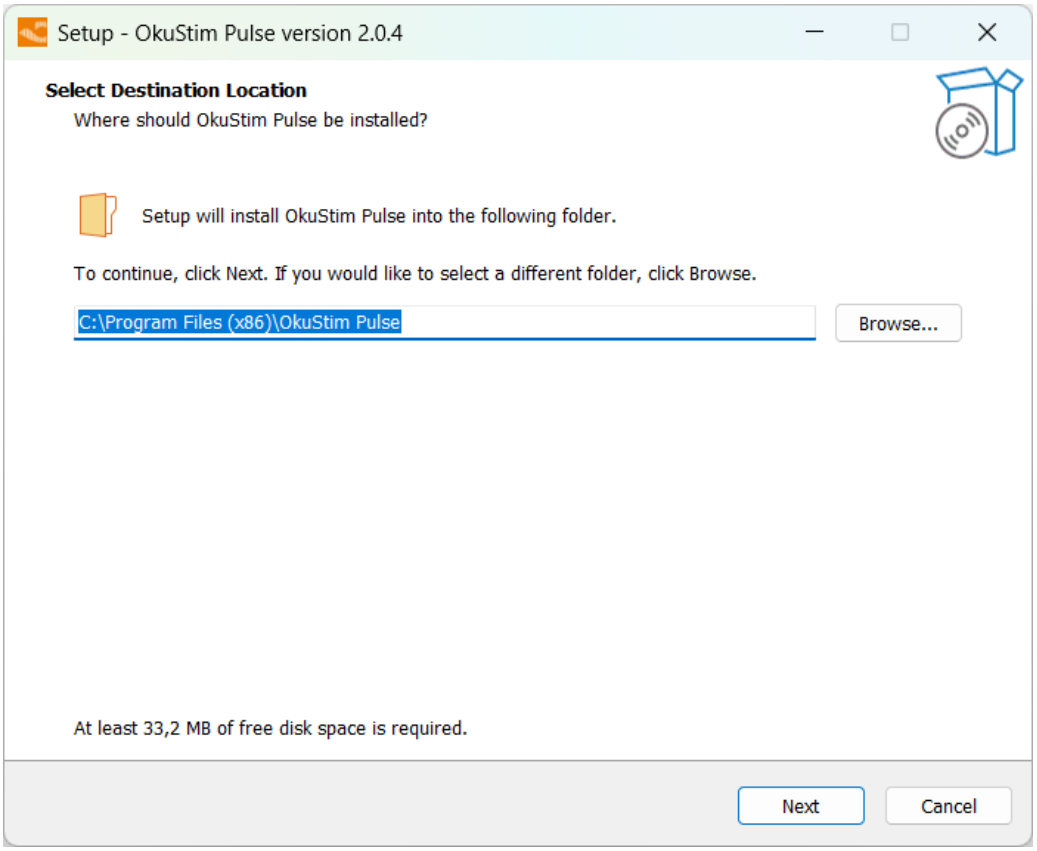
Prerequisite: Administrator rights for the computer are required for installation of OkuStim Pulse.

Insert the USB stick with the current version of OkuStim Pulse into a USB port of the computer.

Access the content by double-clicking on the folder with the current version of OkuStim Pulse. Start the installation process by clicking on the Setup file: **OkuStimPulse_[version]_Setup.exe**

The installation wizard starts and will guide you through the installation process. At this time the following steps will be executed:

1. The installation path is created: **[Program Files]\OkuStim Pulse**.
2. The device drivers will be installed. Your confirmation is required for this.
3. A shortcut can be created in the Windows Start menu. Your confirmation is required for this.



Select the desired installation location and tick the box if you would like a shortcut to be created. Continue with the setup, confirm your installation settings and wait until the setup wizard has completed the installation process. The setup wizard can now be closed.

In addition to OkuStim Pulse, two further components need to be installed for OkuStim Pulse to be used:

- Microsoft .NET 6
- FTDI USB port driver for OkuStim 2

These installation packages are third-party components and are not part of the medical device OkuStim Pulse.

Installation of the two components on a PC with internet access:

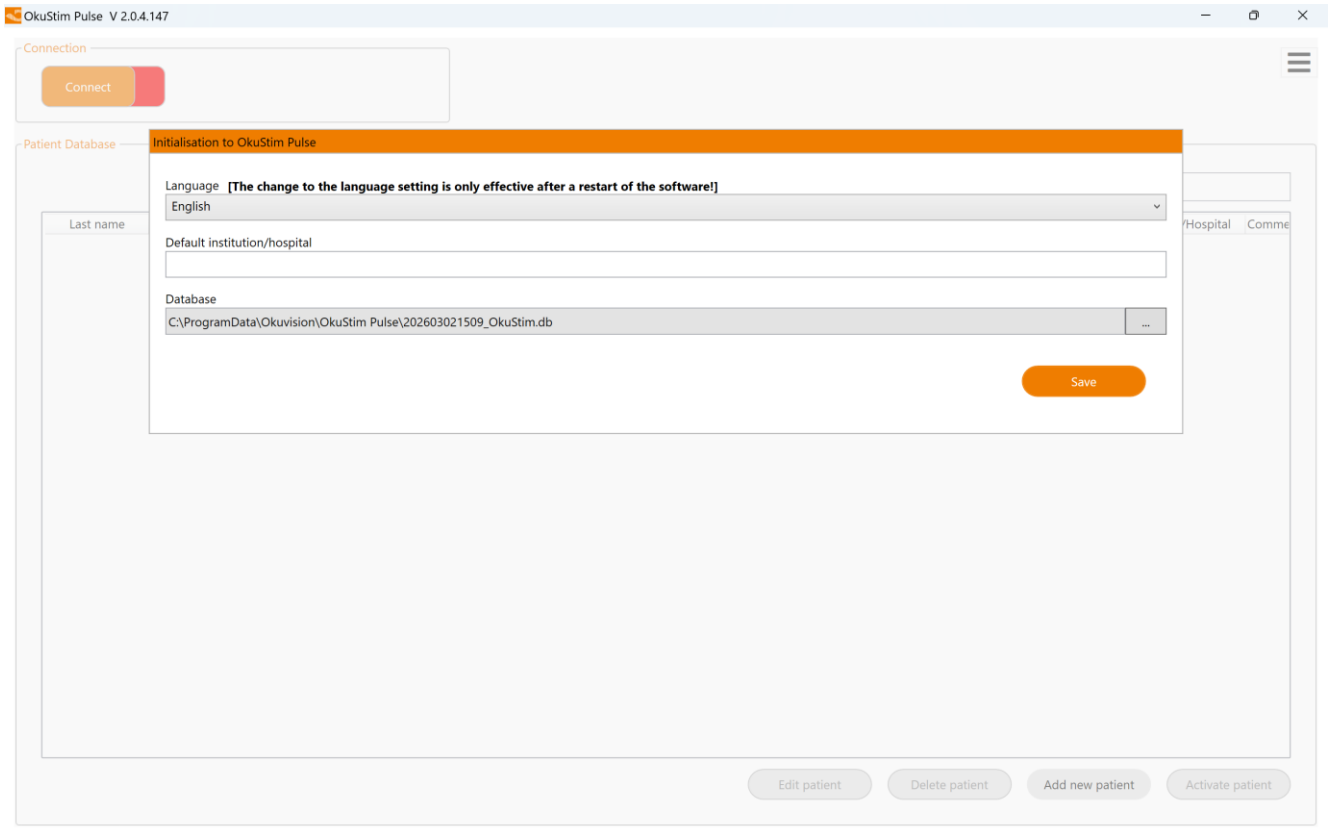
- Microsoft .NET 6: When you start OkuStim Pulse for the first time, you may be prompted to download and install the Microsoft .NET 6 runtime if it is not already installed on the PC.
- FTDI USB port driver: The driver is installed automatically the first time you connect either the dongle or OkuStim 2 to the PC using a USB cable.

Installation of the two components on a PC without internet access:

- If no internet connection is available, the supplied OkuStim Pulse USB stick contains - along with the OkuStim Pulse software - the two installation packages mentioned above. Use the two setup files to complete the installation.
- If possible, check for the latest USB port driver version and the latest .NET 6.x version before installation.

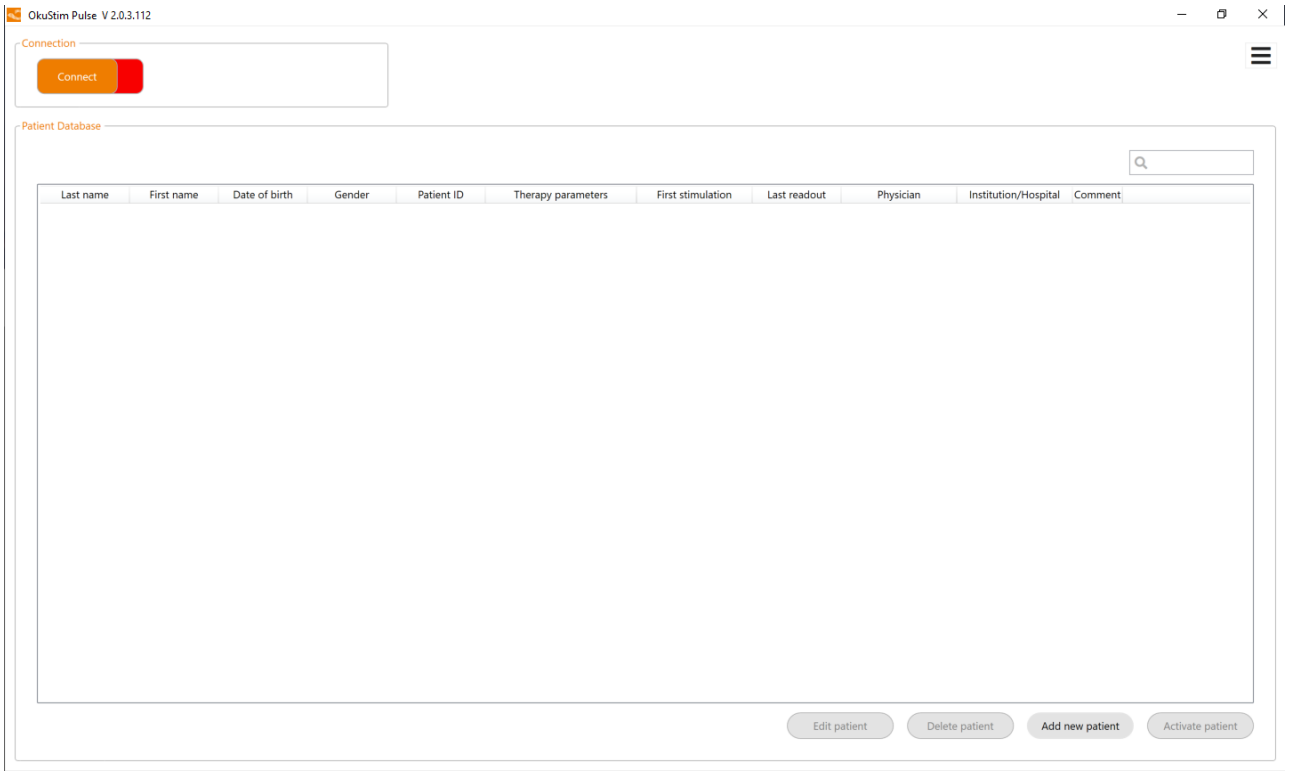
2.2 Initial operation

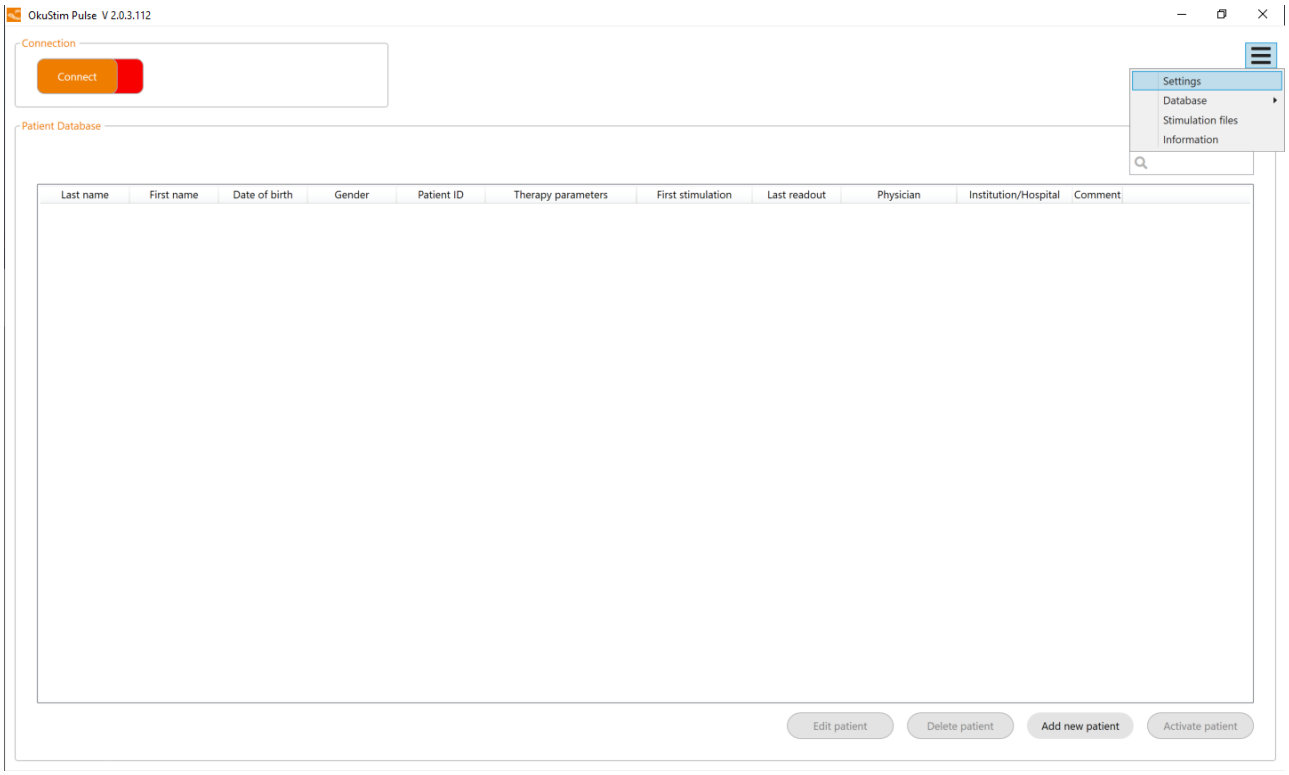
Upon the first start of the application, the language, the clinic name and the database storage path (C:\ProgramData\OkuVision\OkuStim Pulse is automatically suggested) must be selected, and the function of the software (OkuStim Pulse) must be checked with an OkuStim 2.



Initially, the software starts in German or English. If you want to change the language, please select the appropriate language and save the selection by pressing the orange button. To activate the selected language, the software must be restarted. To do this, close the software using the cross in the top right-hand corner and restart the software.

3 Selection of Language and Clinic Name



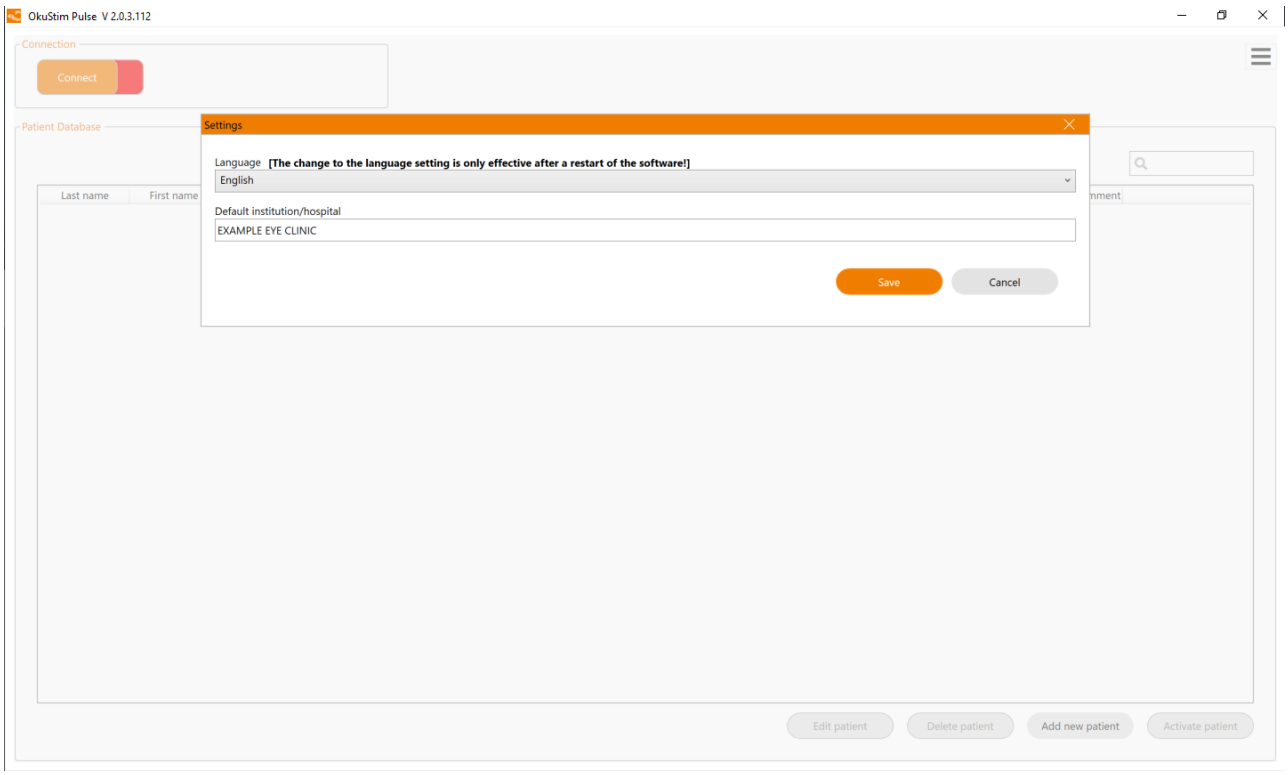


In order to change the language and the clinic name at a later time after the first software start, click on the menu symbol and then on "Settings".

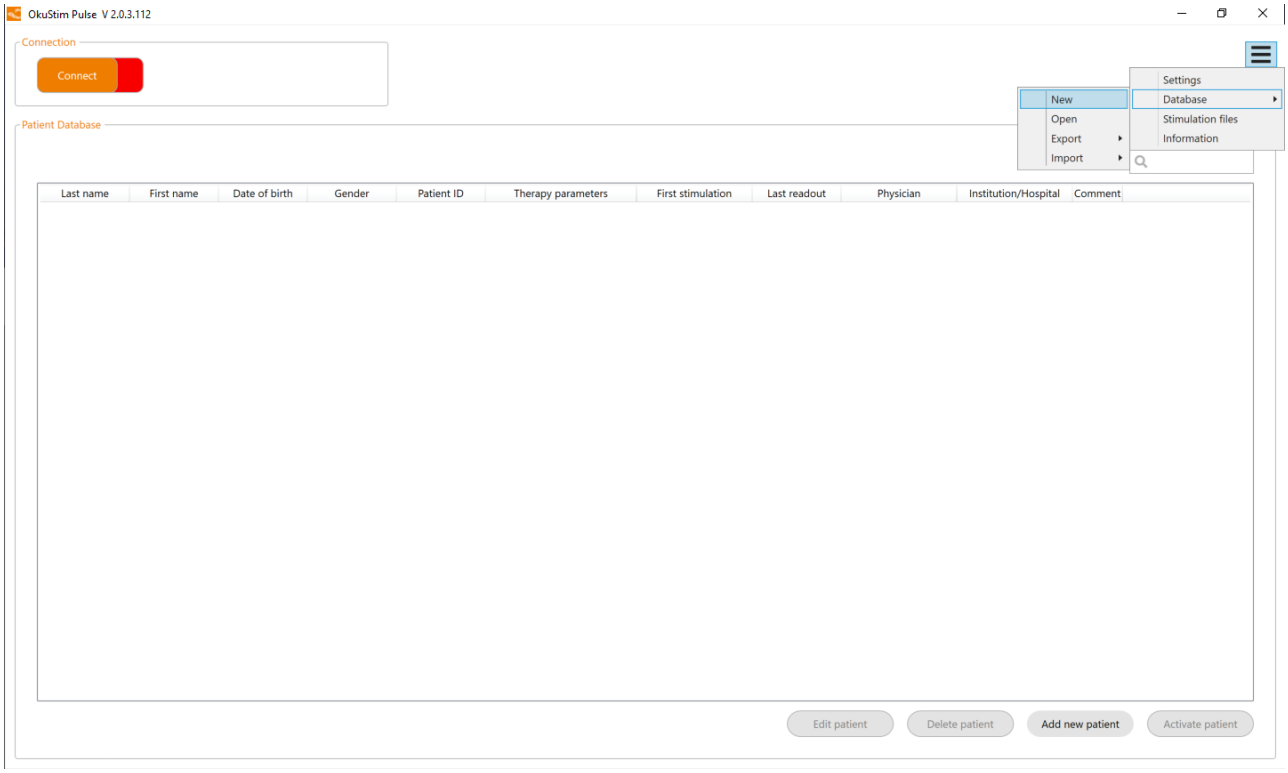
A window opens in which you can select the language and enter the name of the clinic (see figure).

Use the drop-down menu to select the language. You can enter the clinic name (such as "EXAMPLE EYE CLINIC") under "Default Patient Institution". Click on "Save" in order to save this information (see figure).

Note: The language change will take effect after the software is restarted.



4 Selection of the Database Directory

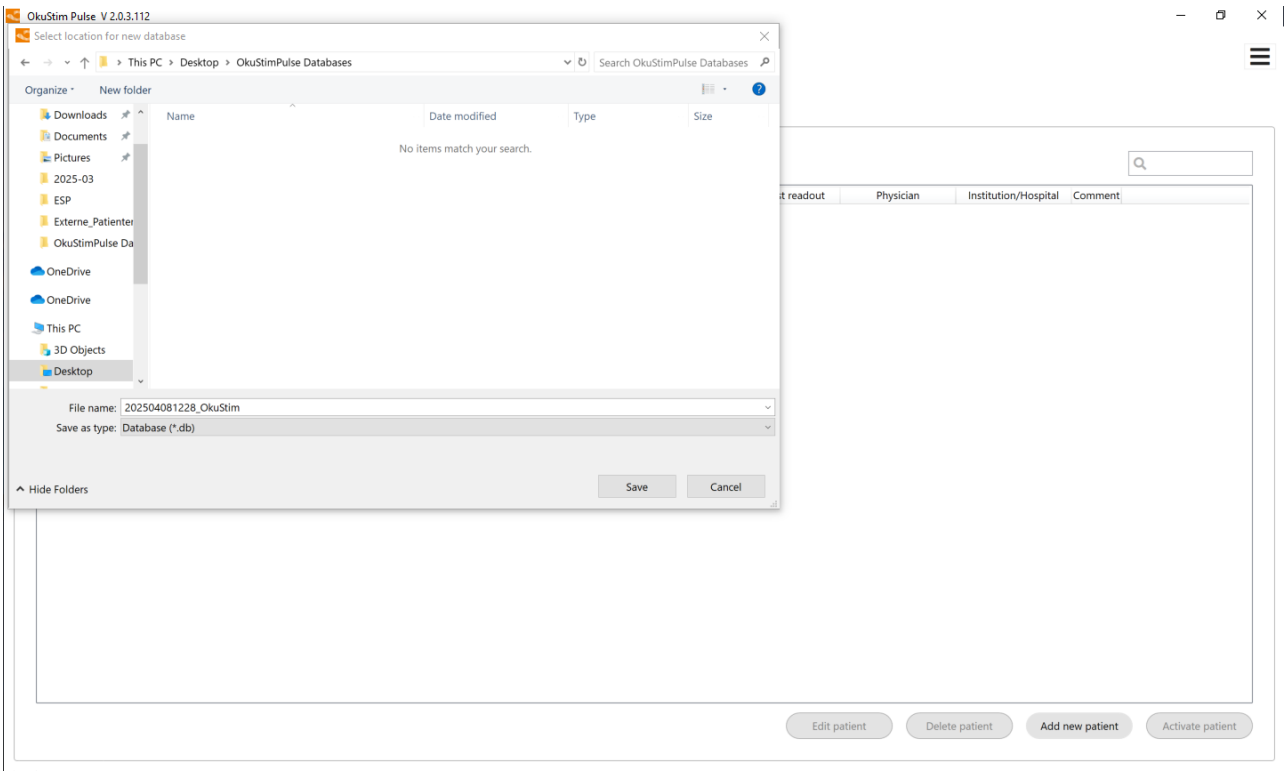


In order to select the storage path for your database, click on the menu symbol and then on "Database".

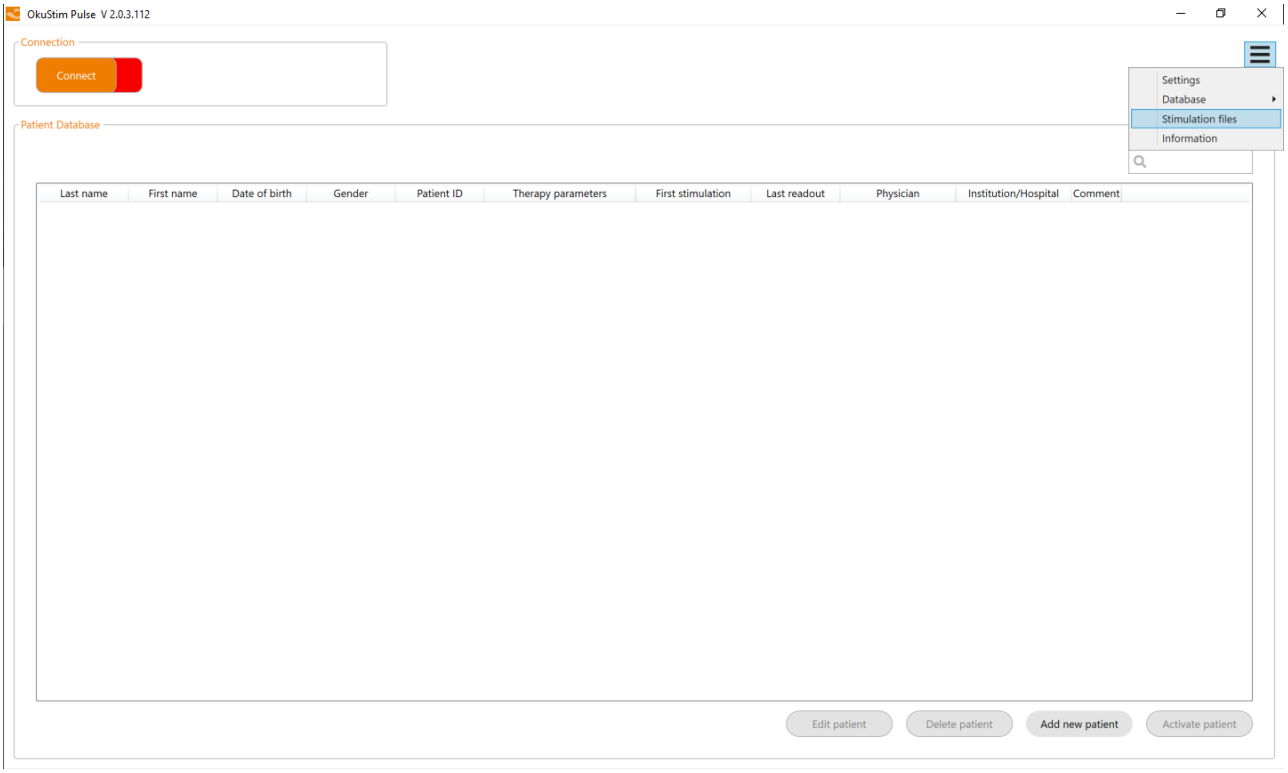
Now click on "New", whereupon a window opens (see figure) in which you can select the storage location of the patient database.

The patient database is a folder in which all patient data, including stimulation parameters and log files about patient stimulation, are saved.

It is recommended to select a local storage directory, so that other users can also access it. The storage location can be changed at any time (see Chapter 4).



5 Stimulation Files

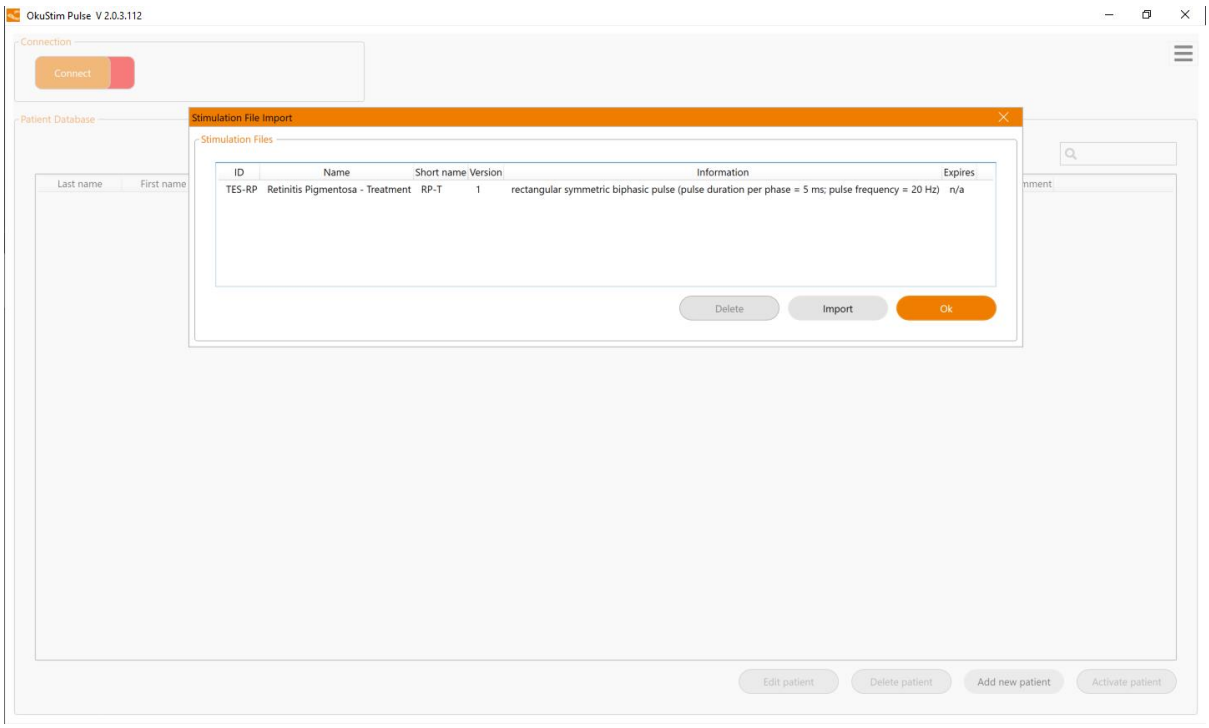


Click on the menu symbol and then on "Stimulation Files".

Here you will find the overview of imported stimulation files and be able to read stimulation information. Via the "Import" button, it is possible to import further stimulation files released by Okuvision. This could be necessary, for example for use in the context of clinical studies.

Insert the USB stick - with the actual version of OkuStim Pulse - into an USB port of the computer. Integrate the recent stimulation file which is also on the USB-Stick.

Test OkuStim Pulse according to Chapter 6.



Note: The stimulation file contains only information about the waveform, pulse duration, frequency and length of the start ramp. Programming of stimulation amplitudes is explained in Chapters 11 to 15.

6 Installation Test

To test if the Software was installed successfully:

1. Start OkuStim Pulse
2. Connect OkuStim 2 with OkuStim Pulse
3. Create a new patient “Test Patient; 11.11.1111”. Choose the included stimulation file.
4. Switch to “Threshold Detection” (please refer to Chapters 9 to 11 for detailed instructions).
5. The Amplitude is pre-set to 100 µA on OS and OD.
   - Start the threshold detection on OS. Check if the software displays any errors. Pause detection.
   - Start threshold detection on OD. Check if the software displays any errors. Pause detection.
   - Check if the therapy amplitude is now set to 100 µA on both eyes.
6. Go to the patient overview:
   - Check if the therapy amplitude and tolerance threshold are 100 µA on both eyes.
   - Press “Write to OkuStim” and check, if the “successfully transferred” window opens.

If all tests are passed, the installation was successful.

7 Before Use

7.1 Determination of the tolerance threshold

To determine the tolerance threshold, you need:

1. PC with OkuStim Pulse
2. OkuStim Wireless Dongle for a wireless connection between OkuStim 2 and a PC
3. OkuStim 2
4. OkuEl M package
5. Eye drops
6. Alcohol pads for cleaning the forehead

   Optional: Instead of alcohol pads, abrasive skin prep paste or electrode gel can be used for placement of the counter electrodes.
7. Cotton bud for opening the lower eyelid

Determination of the tolerance threshold and adaptation of the OkuStim 2 require approximately 10 minutes time.

7.2 Adaptation of the OkuStim 2 and attachment of the OkuEl M and OkuEl counter electrodes

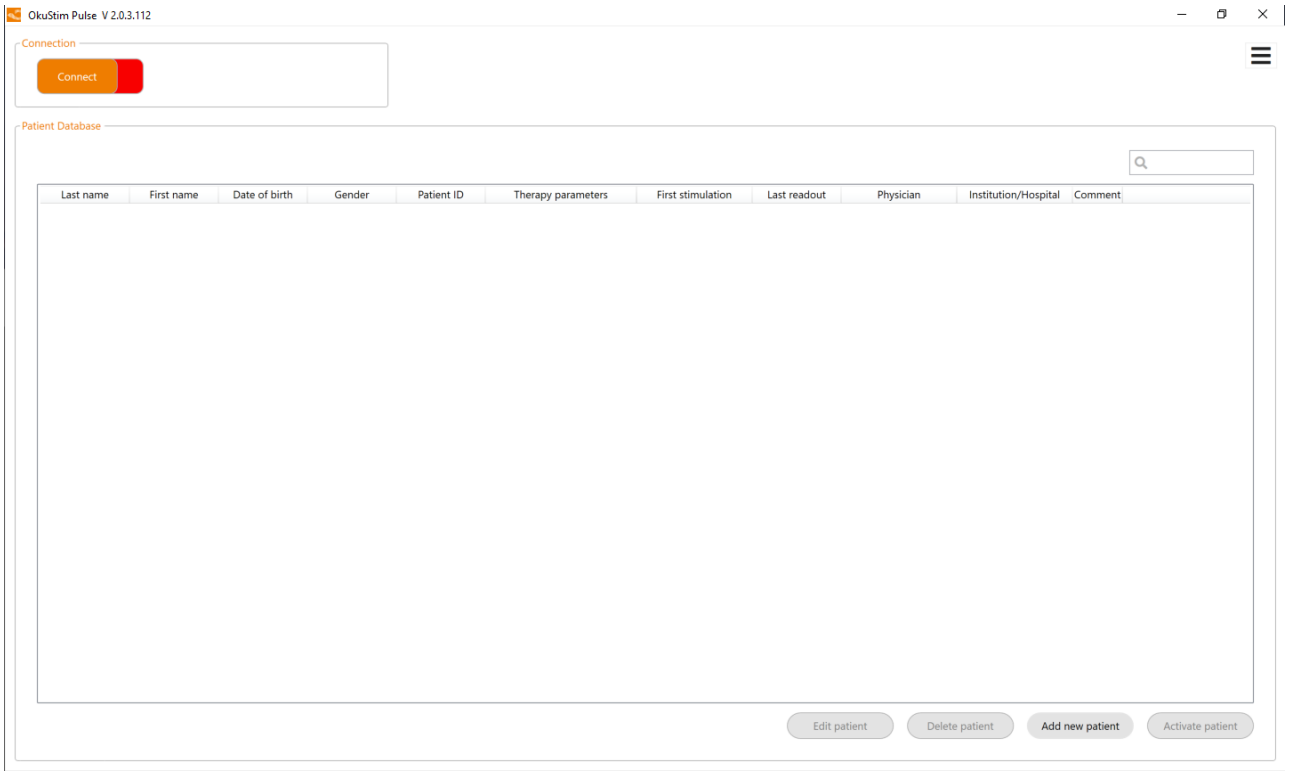
For use and handling of the OkuStim 2 as well as of the OkuEl M and OkuEl counter electrodes, please proceed according to the instructions in the OkuStim 2 System Instructions for Use, Chapter 5 “Step-by-step instructions: Stimulation by the patient themselves”.

While doing so, please follow exactly the steps for preparation and conduct of a therapy session.

8 Starting OkuStim Pulse

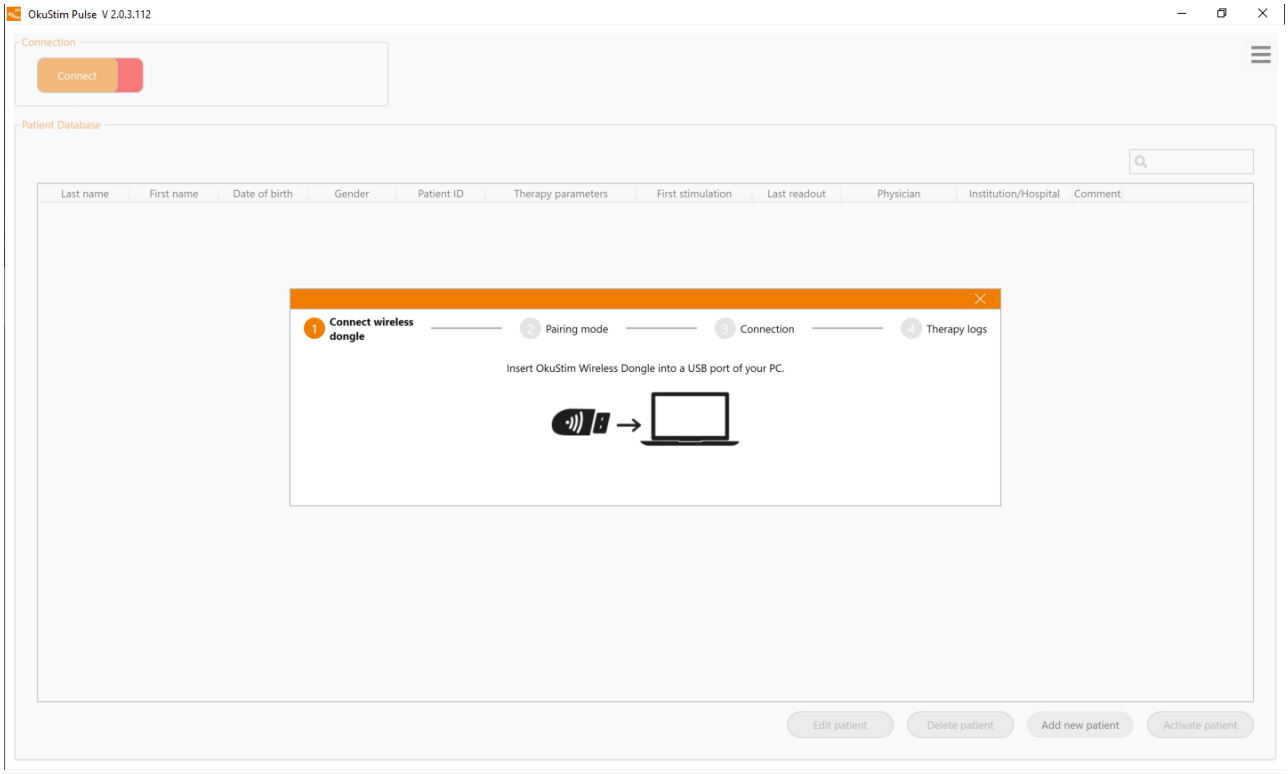
Start OkuStim Pulse.

First, you will see the patient database as the home screen of the software. Here you have the option of creating a new patient ("Add new patient" button), activating a patient ("Activate patient" button), deleting a patient ("Delete patient" button) or revising the information about a particular patient in the database ("Change Patient" button).



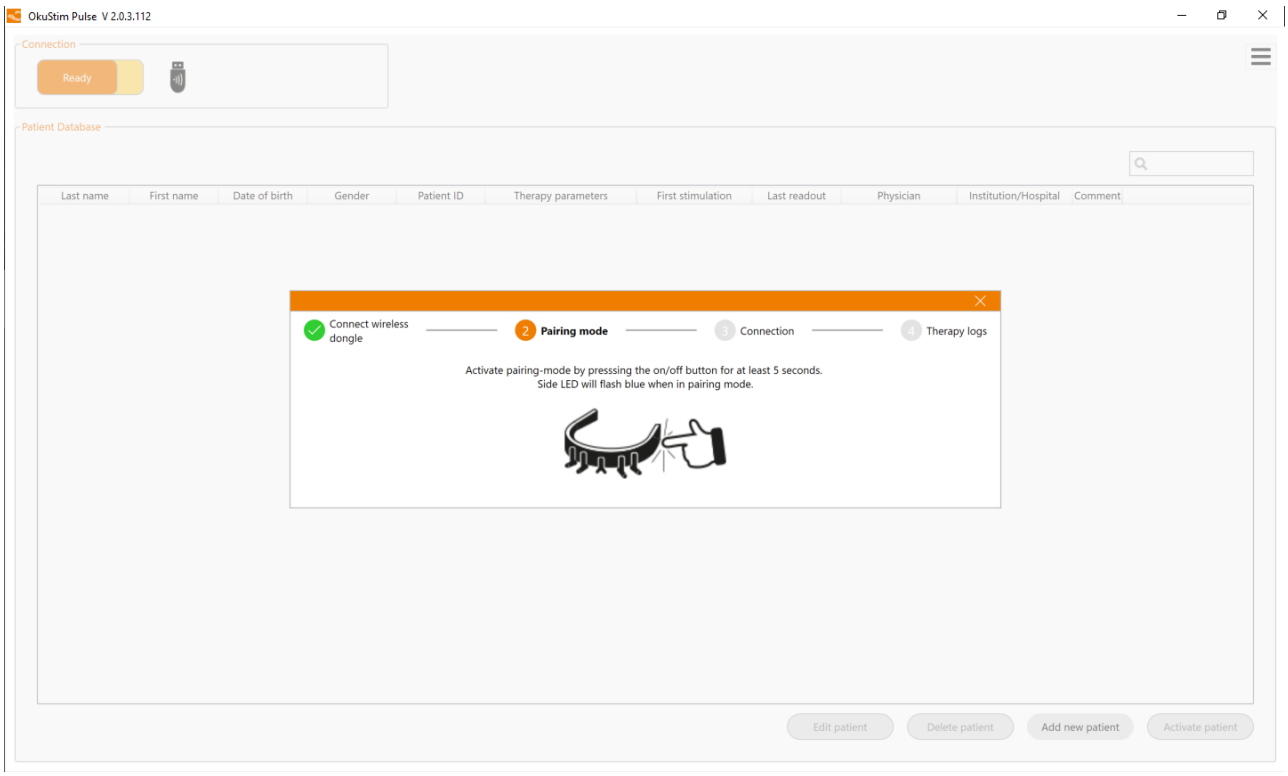
9 Connecting OkuStim 2 to OkuStim Pulse

To connect OkuStim 2 to OkuStim Pulse, click on the "Connect" button in the software.
The Pairing window opens (see figure). Follow the illustrated steps.



1. Connect wireless dongle:

Connect the OkuStim wireless dongle to a free USB socket of your PC.
If the OkuStim Wireless Dongle is recognised, a green tick mark appears for confirmation.
This process may take up to 5 seconds.



2. Pairing mode:

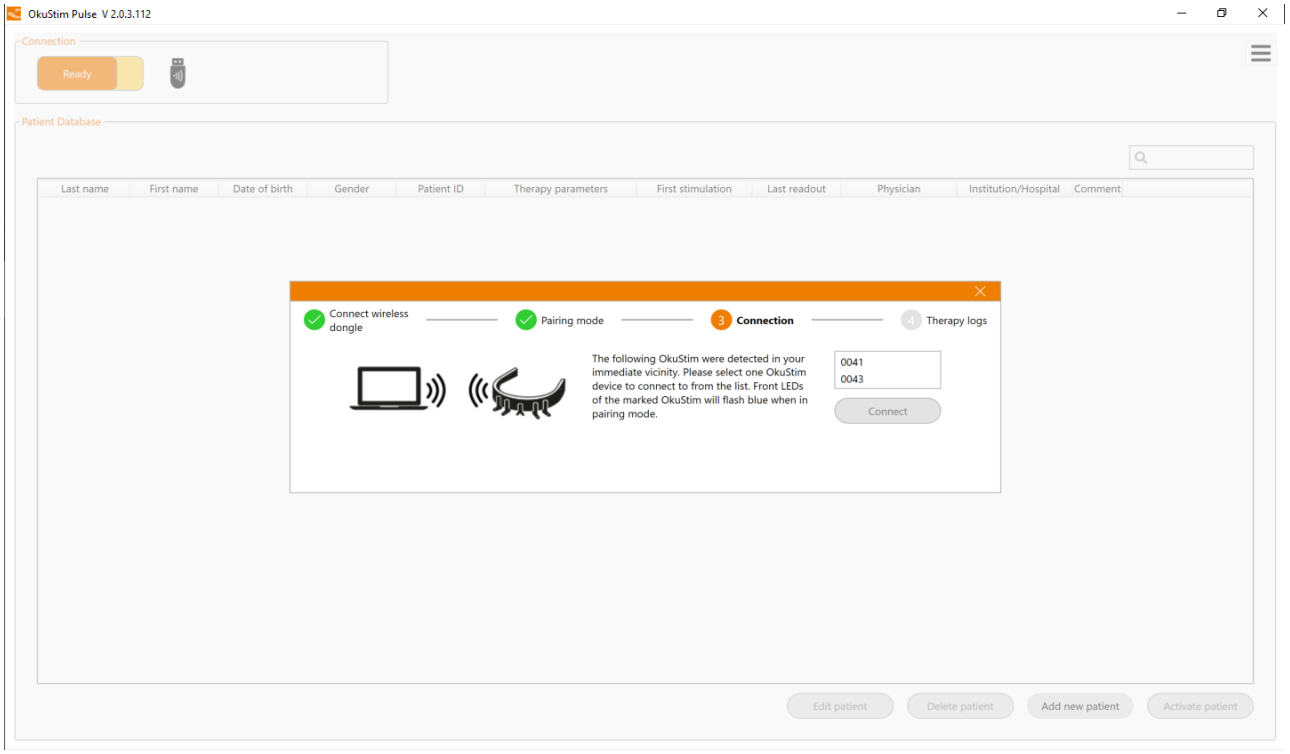
OkuStim 2 must be set to Pairing mode. For this purpose, hold down the on/off button of the OkuStim 2 for 6 seconds. The LED on the side of OkuStim 2 will then flash blue to indicate that it is in Pairing mode.

Note: OkuStim 2 must be switched off, so that it can be set to Pairing mode.

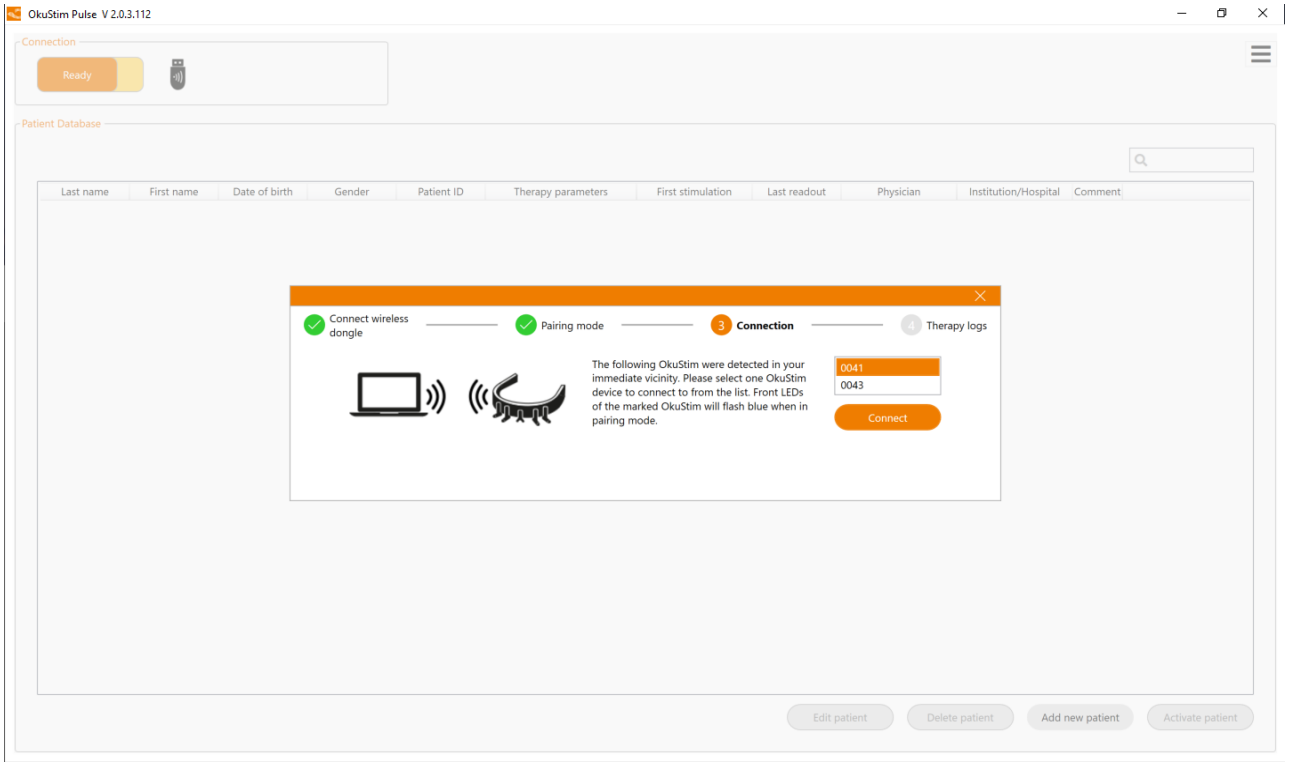
3. Connection:

The OkuStim 2 will now automatically establish a connection with the OkuStim Pulse software and move on to step 4 below.

Note: It is possible that several OkuStim 2s are in Pairing mode. This will be displayed to you by OkuStim Pulse. At this point you can select which OkuStim 2 you wish to connect with (see figure).

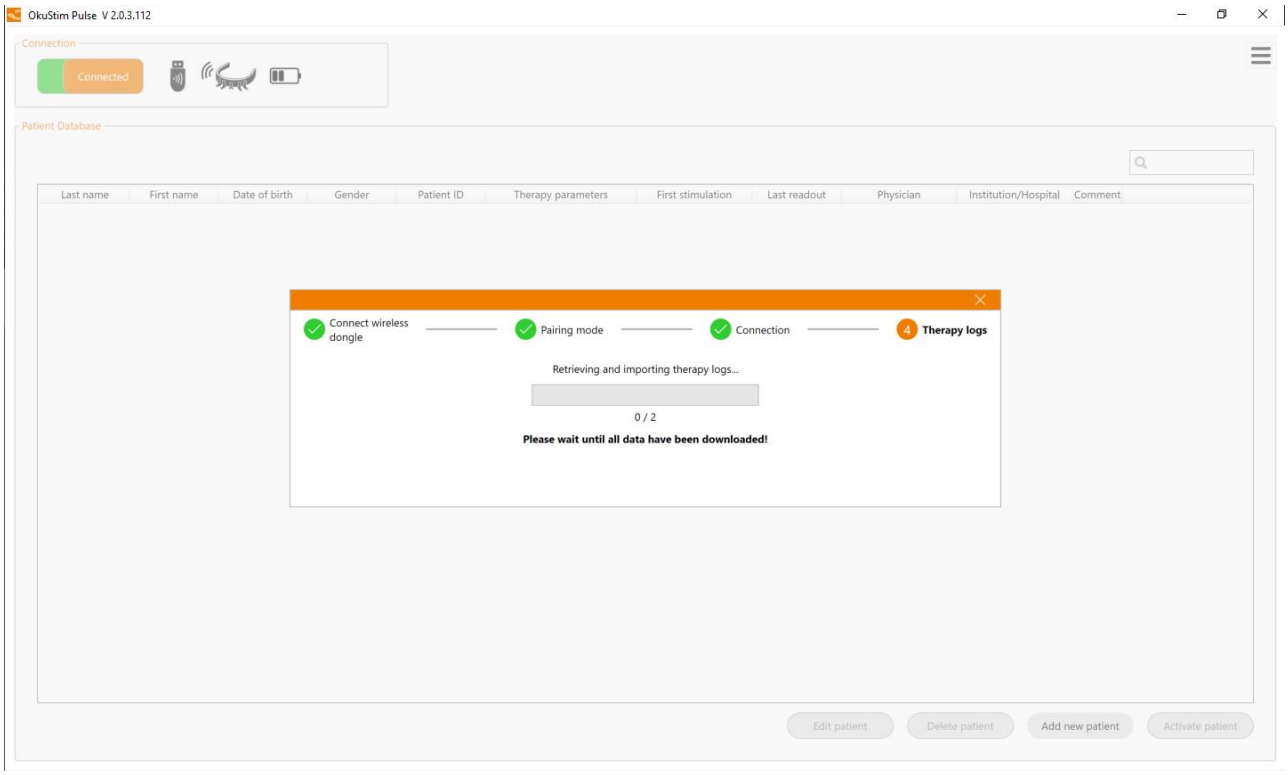


Select the desired OkuStim 2 in the list and confirm with the "Connect" button (see figure).

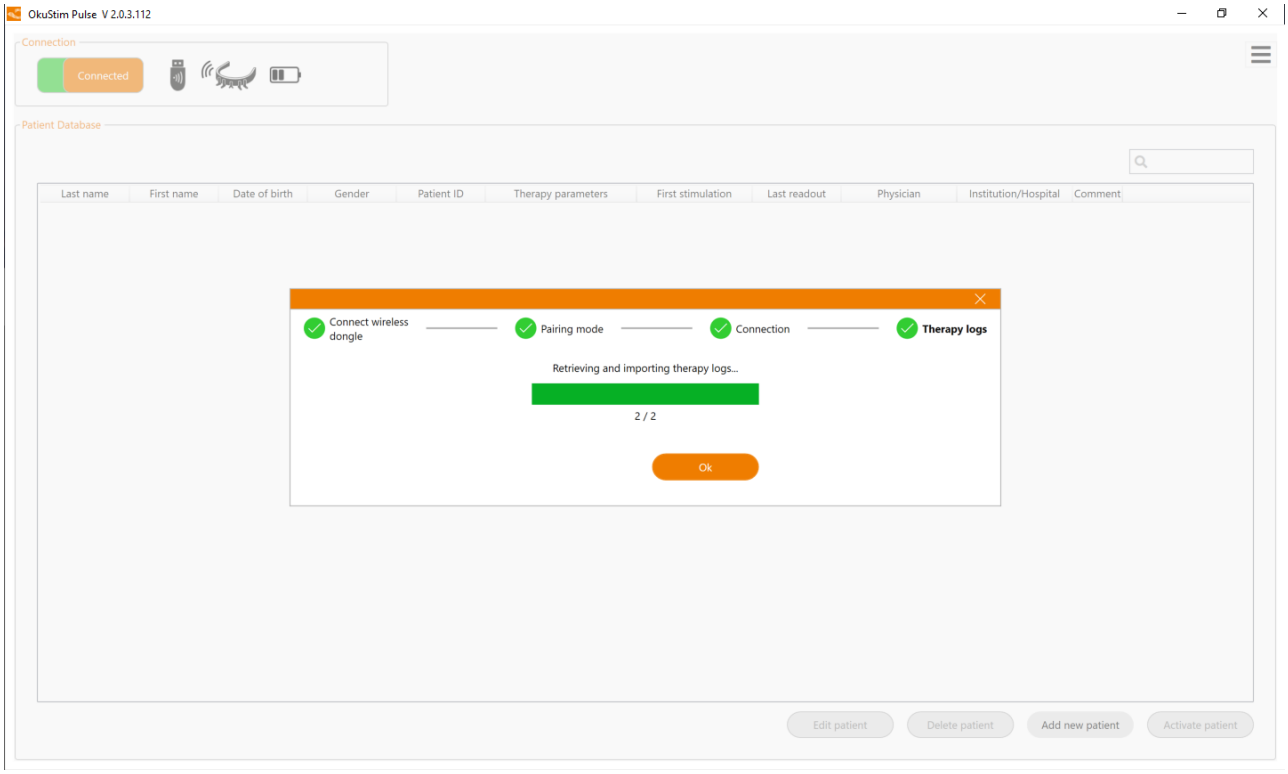


4. Therapy Logs:

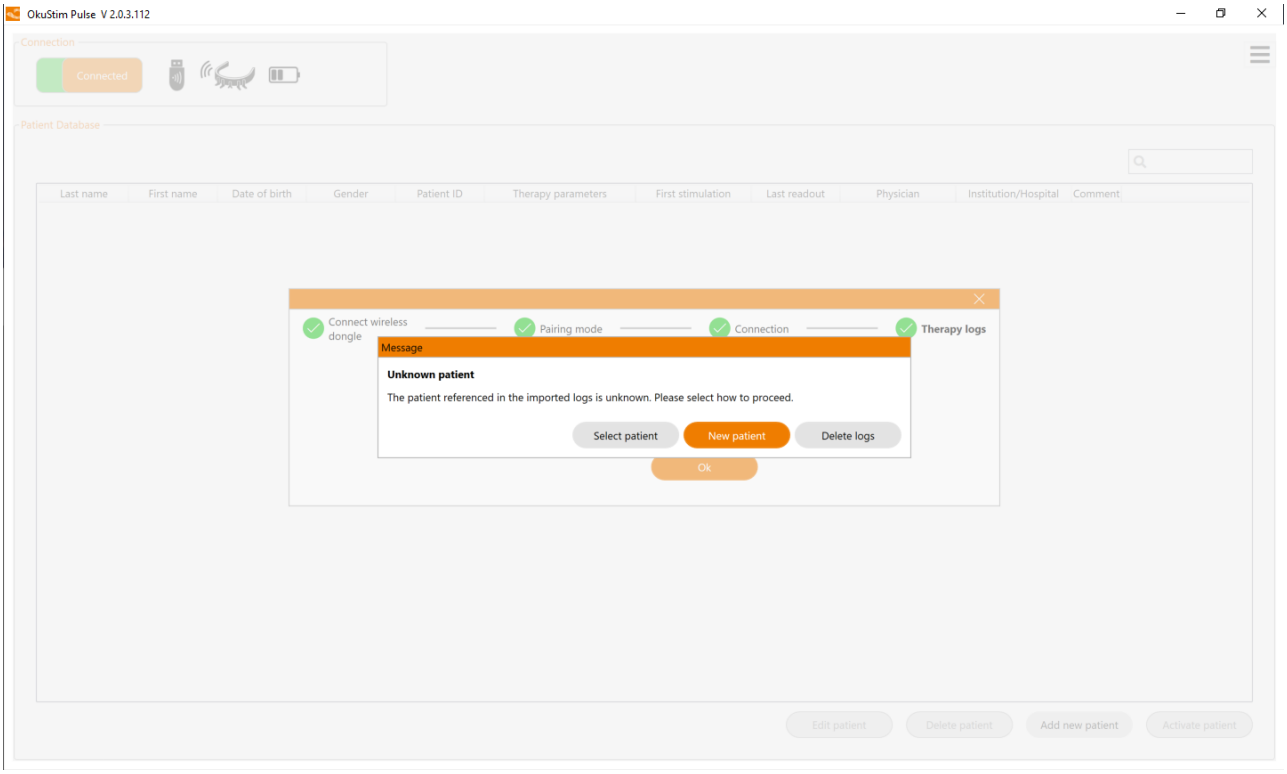
If the patient has never been stimulated with the OkuStim 2 before, or if it is a new OkuStim 2, a window similar to the one below will open. Log files are present on the OkuStim 2 by default.



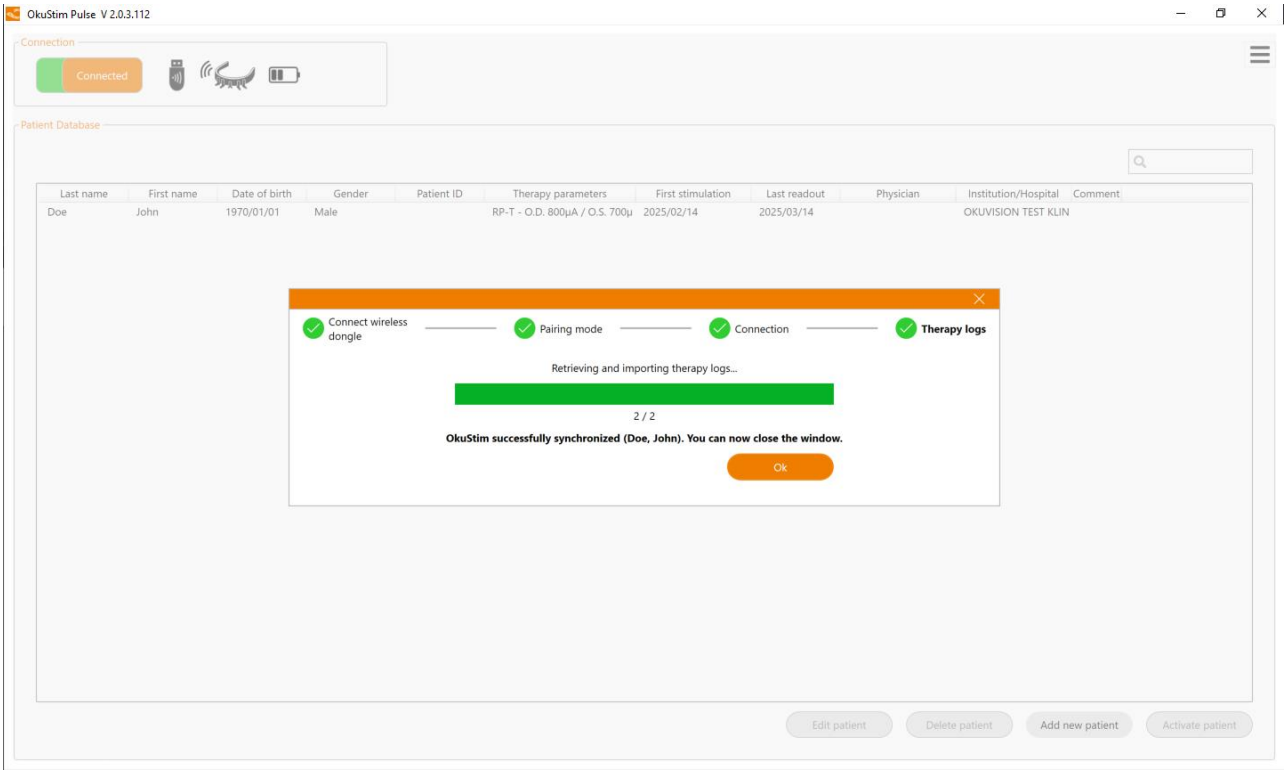
Wait until the log file is downloaded. Now you only need to click "OK".



The log file can be deleted if it is a new OkuStim 2 to start the tolerance threshold measurement.



If, for example, you have connected OkuStim Pulse with an OkuStim 2 of a patient who has had stimulation sessions at home, the software recognises that log data exist for therapy sessions that have not yet been saved in the database. If the patient is already saved in your database, the data can be automatically associated with the patient (see figure).

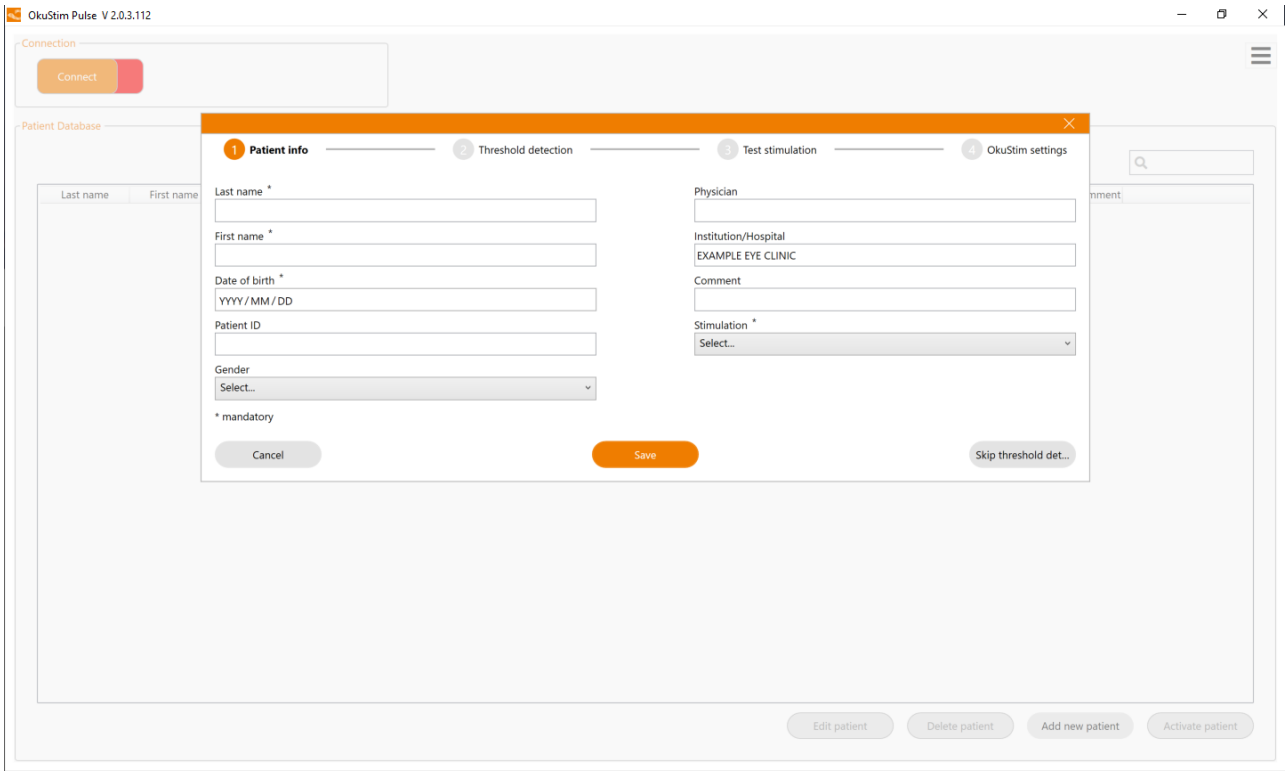


If the data cannot be associated with any patient, the following options are available:

- Delete the log data: Data is not associated with anyone in the database and deleted from OkuStim 2.
- Assign log data to a new patient: A new patient must be created. The workflow to create a new patient opens automatically; see Chapter 10.
- Assign log data to an existing patient: The log data is assigned to a patient already existing in the database. A table opens listing all patients of the opened database.

10 Workflow for Creating a New Patient

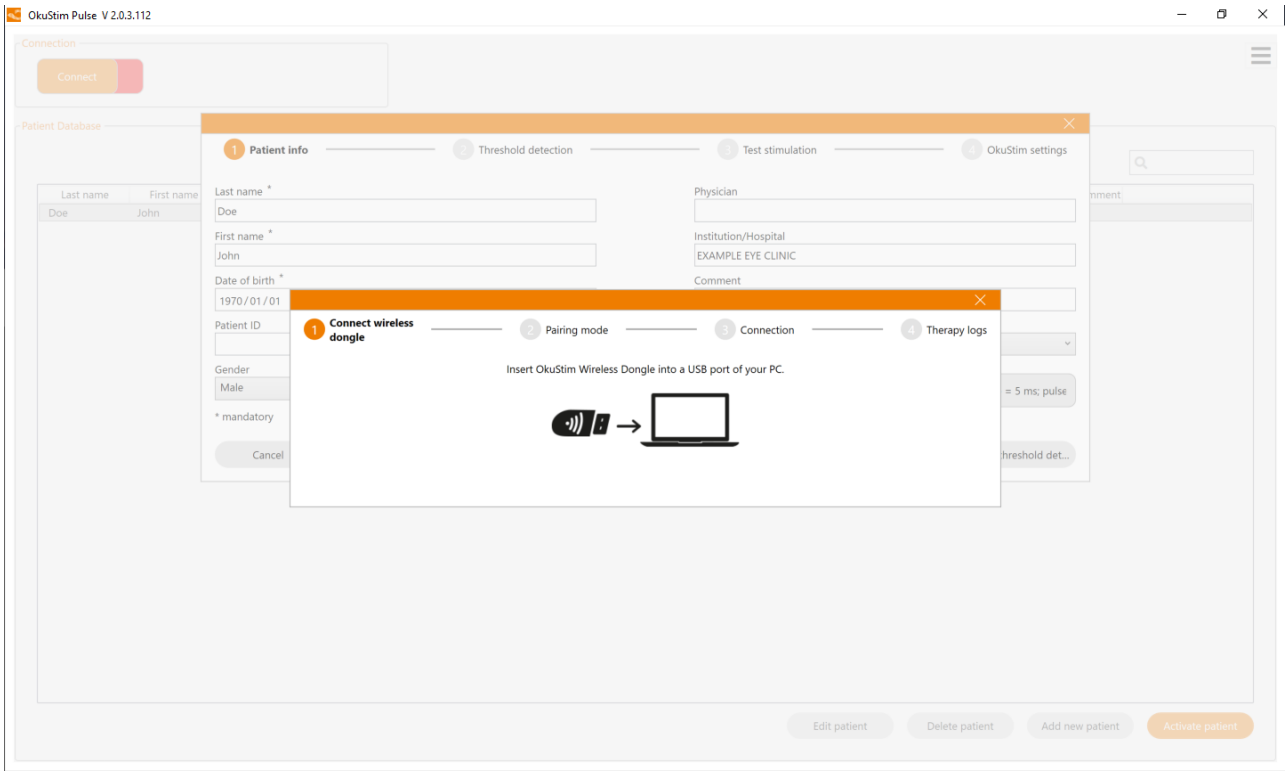
Click on "Add new Patient". The following window opens.



The upper part of the window (frame) shows the stations of the workflow that OkuStim Pulse offers the user to create a new patient (here "1 Patient info", i.e. the entry of patient information).

Enter the patient data. Fields marked with (*) are mandatory fields. If you have specified a clinic name in Settings (see Chapter 3), this will be entered automatically in advance for each patient. Click "Save" to proceed to the next step.

If you have not yet connected any OkuStim 2 with OkuStim Pulse, you will now be prompted to do so. For this purpose, follow the description in Chapter 9.



11 Determination of the Tolerance Threshold

Notes:

- Before you start the determination of the tolerance threshold, explain the procedure to the patient.
- Explain to the patient that stimulation cannot cause any damage.
- Ask the patient to tell you immediately about any pain sensations.
- Stop the stimulation immediately if the patient complains about pain.
- The tolerance threshold is the current intensity level that the patient can tolerate for the full stimulation session without sharp or intense pain. For TES therapy, the highest tolerable stimulation intensity should be targeted. In this respect, the highest tolerable value is to be selected, not the most comfortable. The stimulation intensity cannot be set to exceed 1000 µA.

Explain to the patient that it is normal to feel the stimulation and that it may be perceived as unpleasant. The stimulation may be continued as long as it remains tolerable and does not cause sharp or strong pain. Tolerance may change over time, and an acclimation effect is possible; therefore, it is possible that the tolerance threshold will become higher with time and can be adapted.

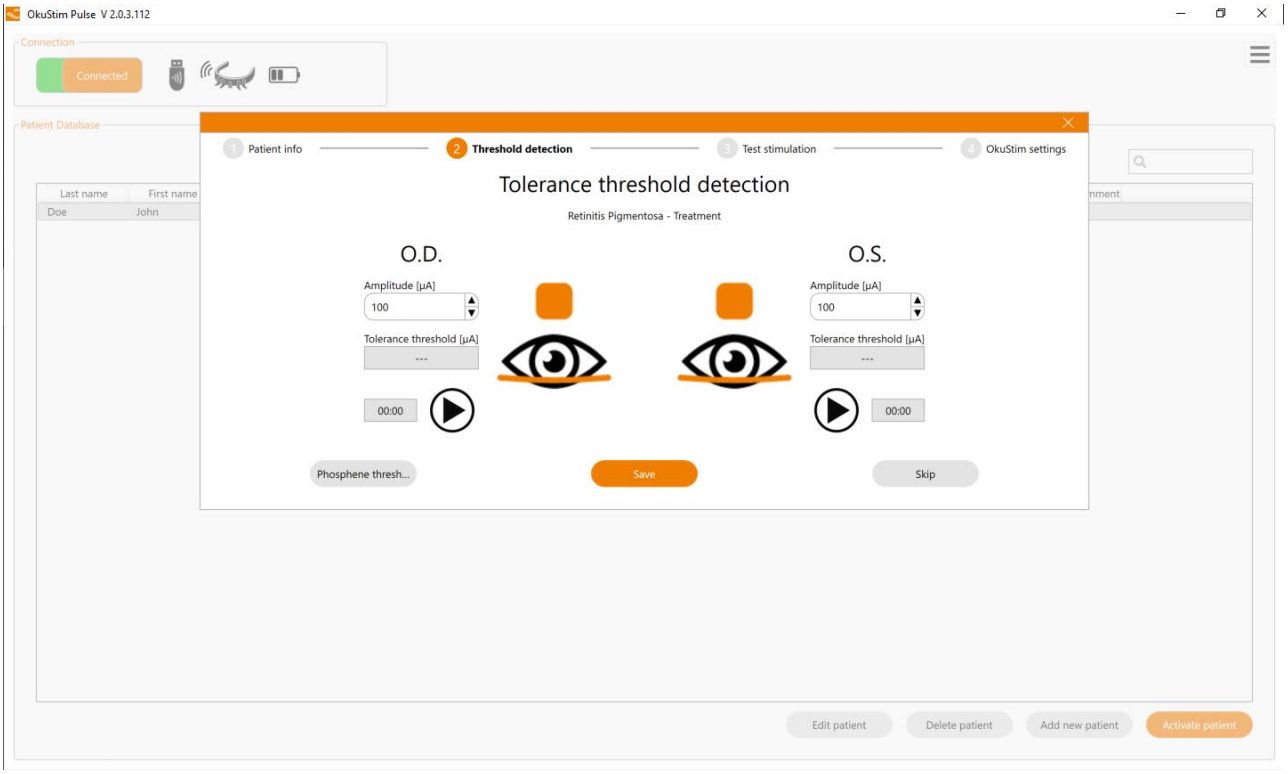
Related workflows:

Chapter 11 Change of Tolerance Threshold

Chapter 15 Change of Stimulation Parameters

Note: For patients requiring only monocular stimulation, see Appendix 1 (Monocular Stimulation) for the corresponding workflow.

Tolerance threshold measurement procedure

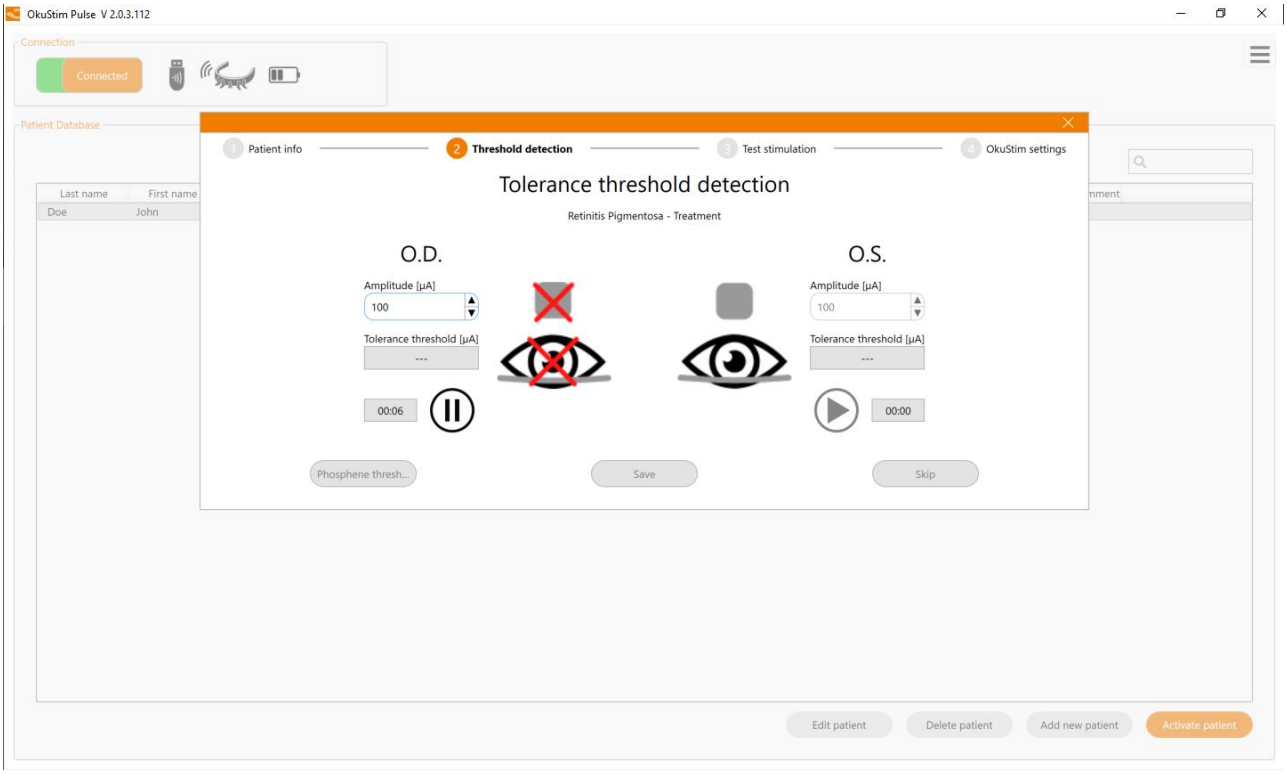


The tolerance threshold is determined separately for each eye. To do so, proceed as follows:

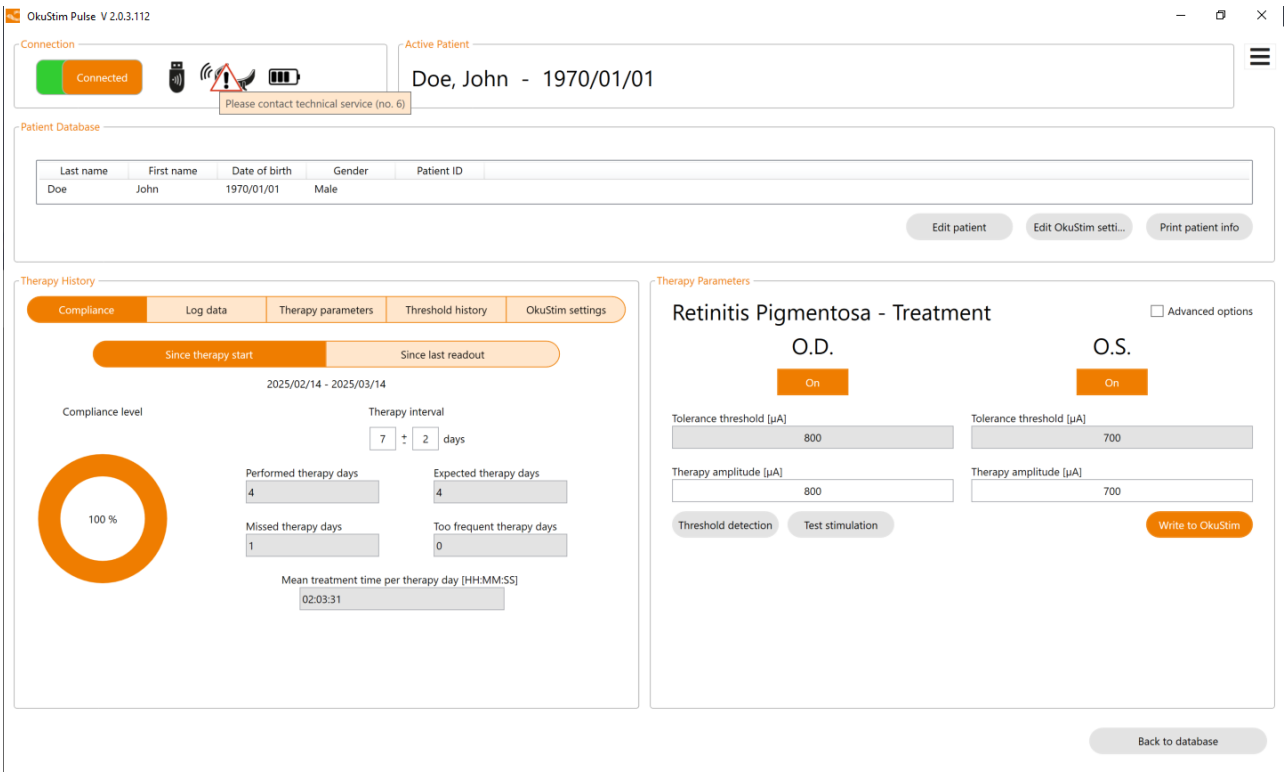
1. Choose the eye for which the tolerance threshold is to be determined (OS: left, OD: right).
2. Start with the Start/Pause button, e.g. with stimulation under OD.

If an error message appears (e.g. resistance error, see figure below), the software will display where the problem lies. See Chapter 21 for troubleshooting.

Note: In monocular stimulation, the system cannot determine whether there is a resistance error at the OkuEl M or OkuEl counter electrode. This is also the case for the tolerance measurement in which the current values are tested monocularly. If a resistance error is detected in such cases, only the side will be indicated (left or right).



Other errors will be displayed in the software, as shown in the picture. Hover the mouse over the error prompt to receive more information about the error.



Note: See Chapter 21 for an overview of possible errors and their corresponding solutions.

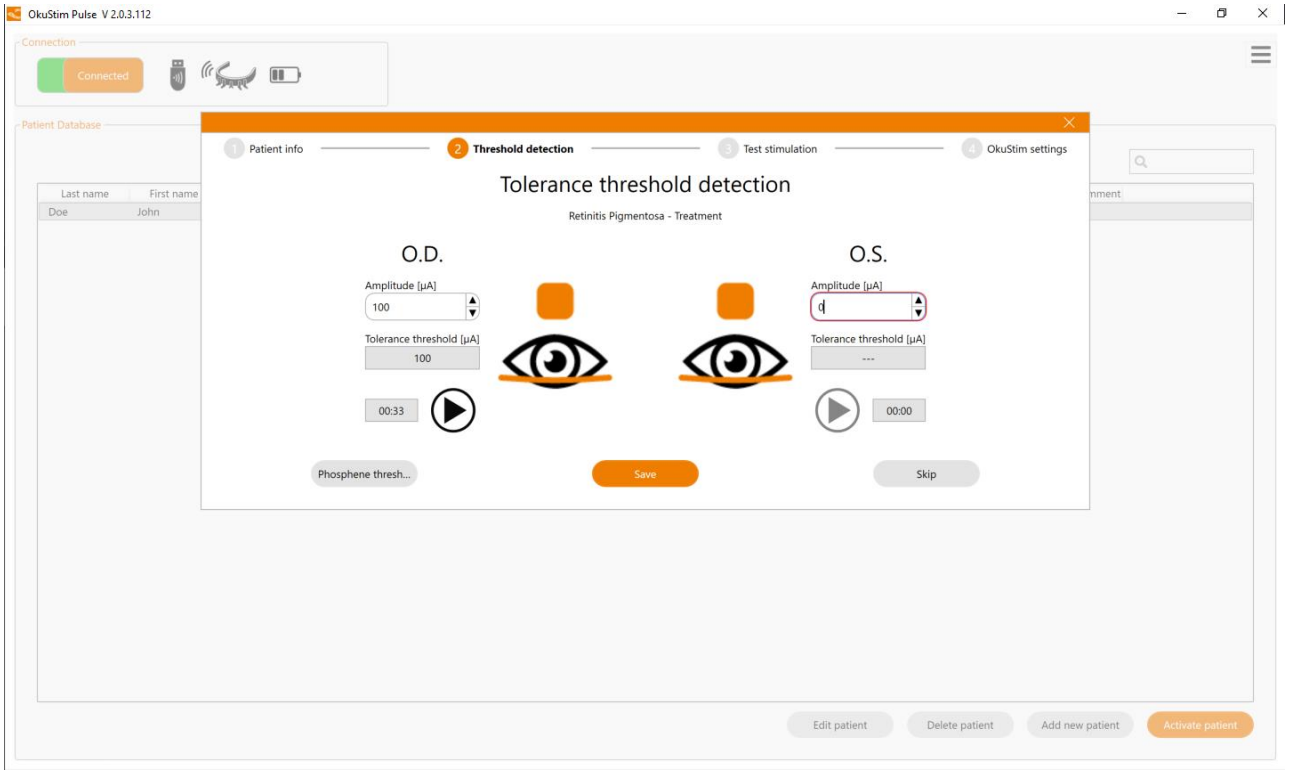
3. Once you press Start, stimulation with OkuStim 2 will begin (for OD in this case).

4. Use the corresponding arrow buttons to adapt (raise and lower) the stimulation amplitude. You do not have to pause the stimulation for this purpose.
   - Between 50 µA and 500 µA, the stimulation intensity (or amplitude) increases by 50 µA with each click.
   - From 500 µA upward, the amplitude increases by 20 µA with each click.

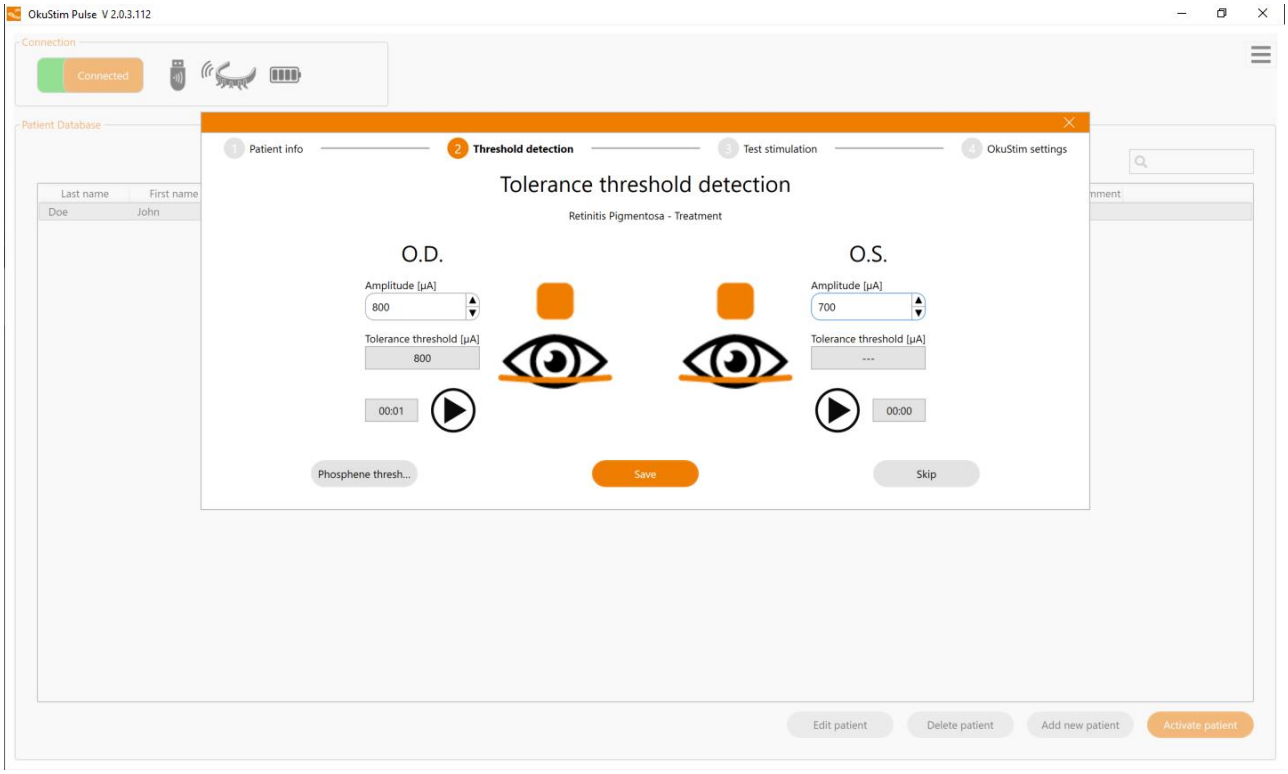
     Note: At currents of 500 µA and above, a 5-second ramp is always applied. This is also indicated by the ramp symbol next to the time counter.
   - You can also enter the stimulation amplitudes manually in the field. For this purpose, you have to interrupt the stimulation (by pausing it with the Start/Pause button), enter the new value and then press the Start/Pause button in order to test it.
   - Ask patients how they feel.
   - To begin with, introduce the patient slowly to the therapy to allow the patient to become accustomed to the stimulation. Apply stimulation for approximately 5–10 seconds at a time.

In the process, always watch out for the patient's reaction.

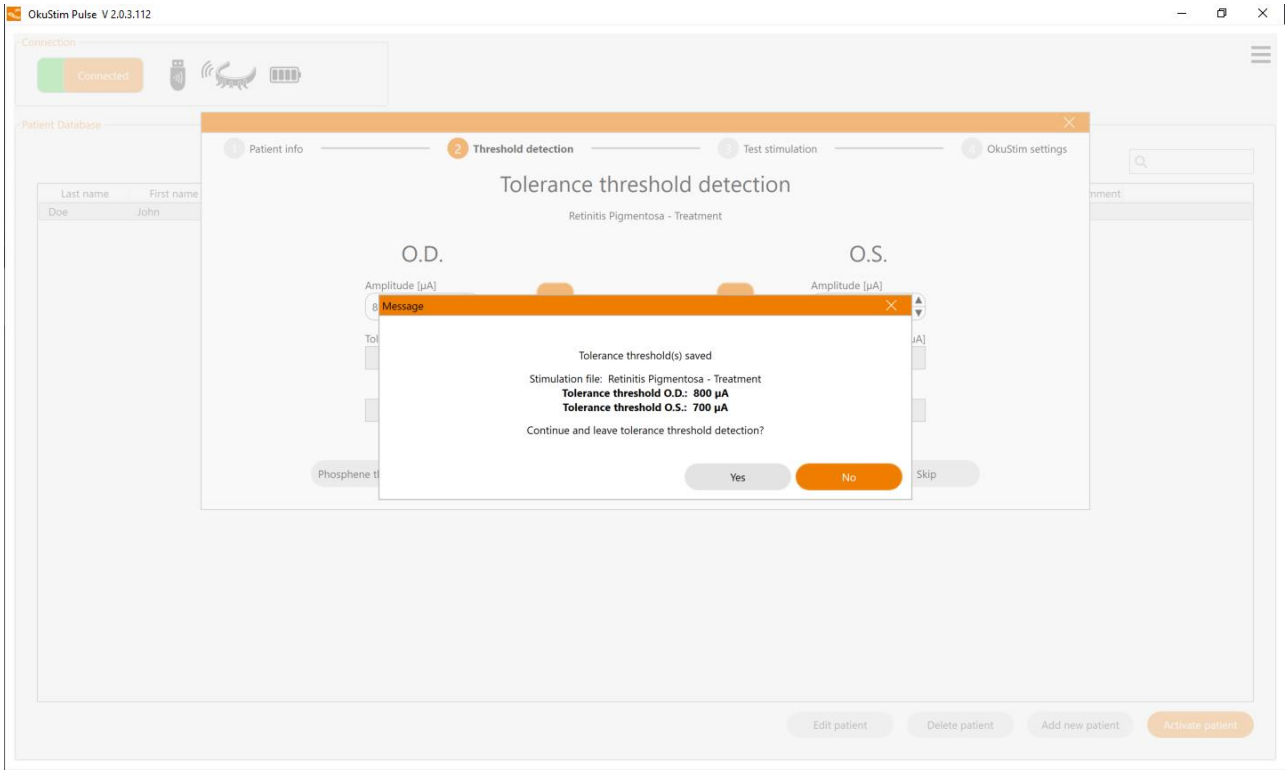
As soon as the tolerance level has been found, test it once again for 20–30 seconds (see figure).



5. Repeat the process for the second eye.

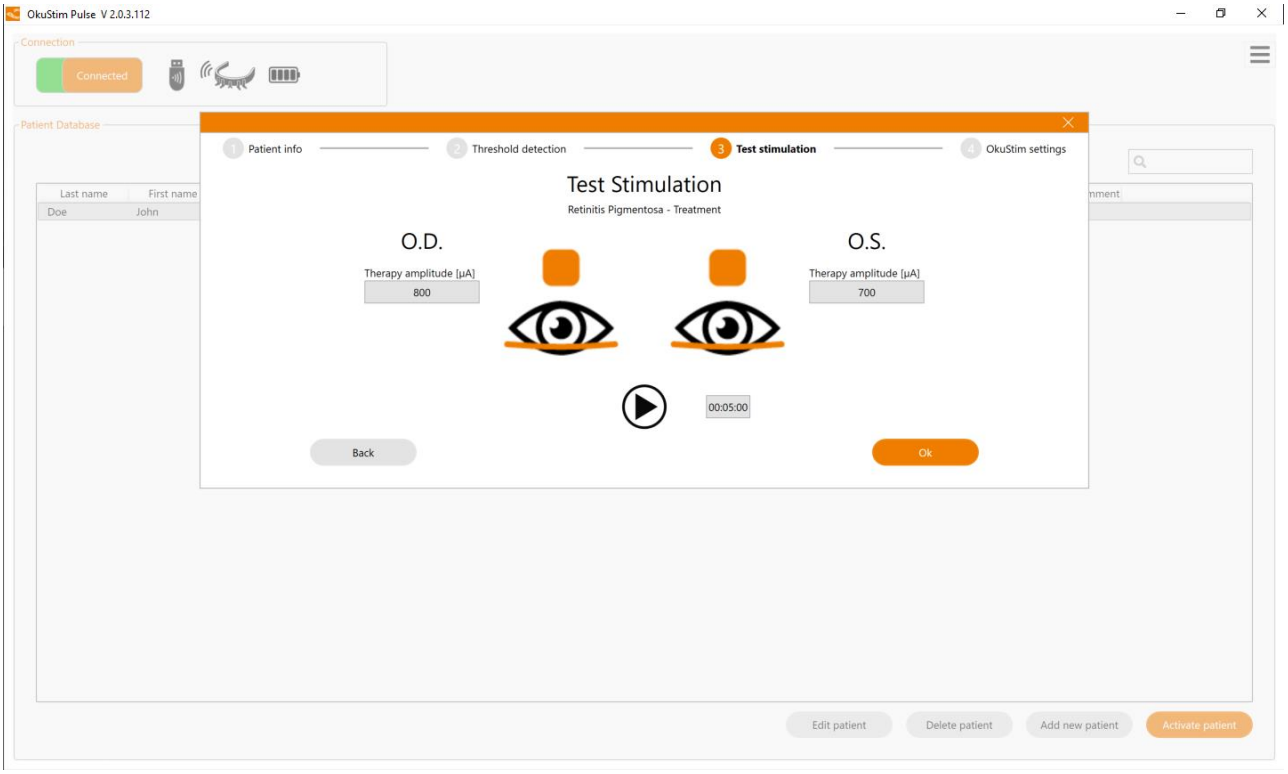


6. As soon as you have found the tolerance threshold for the second eye, click on "Save".
   - A confirmation window opens (see figure).
7. Click on "Yes" to proceed to the next step.
   - If you intend to re-test the tolerance threshold, click on "No".



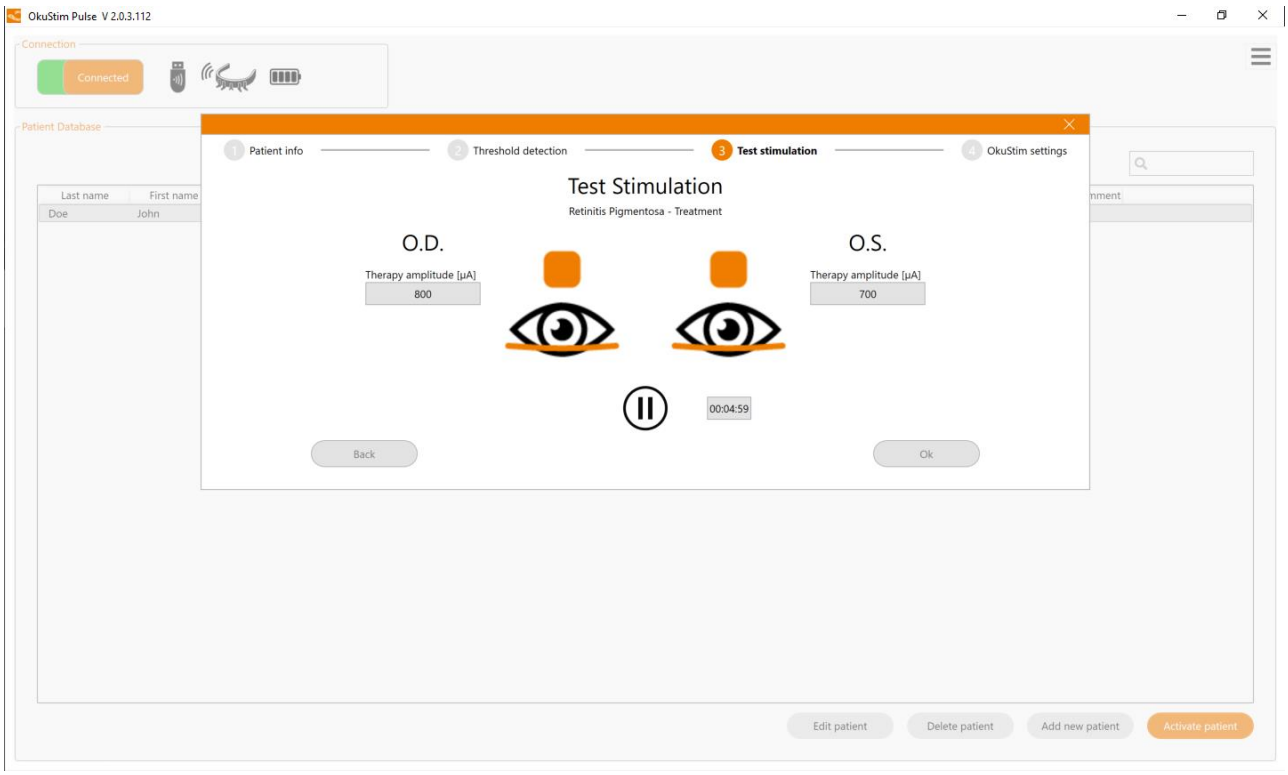
12 Testing of Binocular Stimulation

After you have clicked on "Yes", proceed to the next step: Test stimulation (see figure).

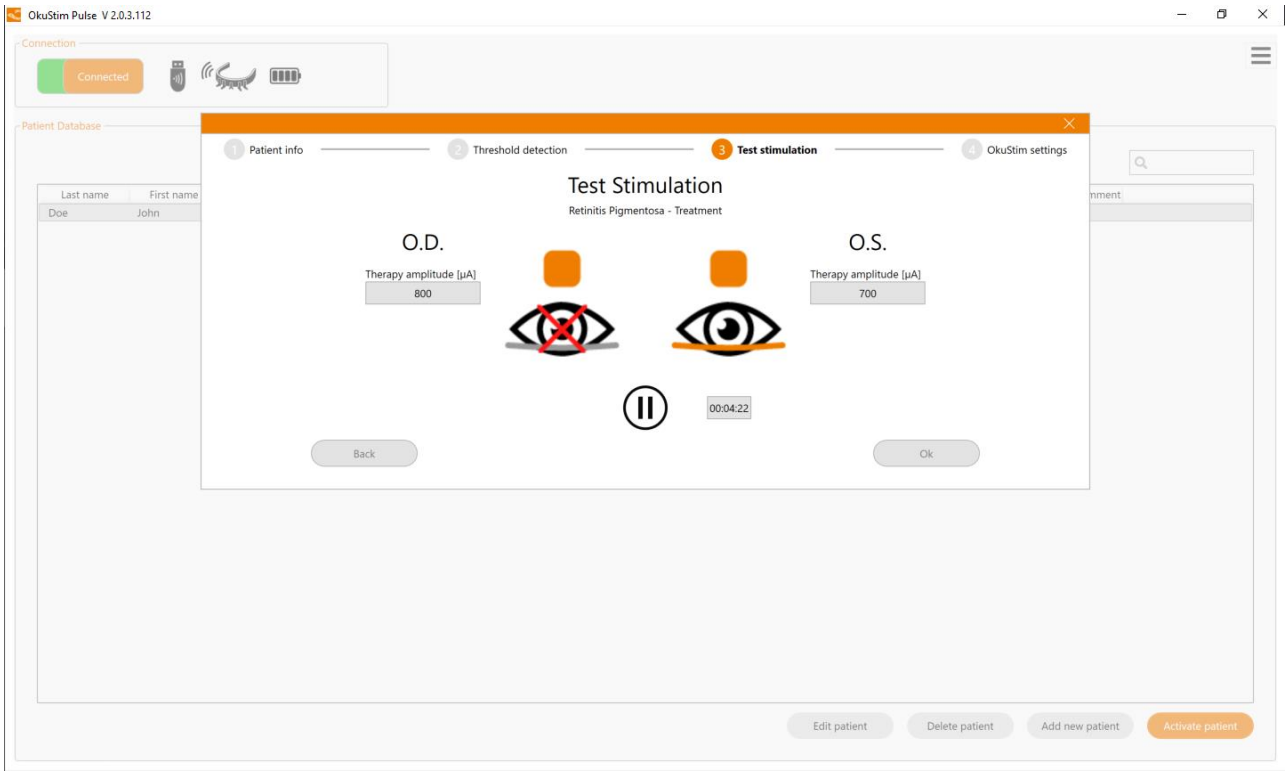


1. Click on "Start" to begin the test stimulation (see figure).
2. Click on "Pause" to stop the test stimulation.

Use the "Back" button to return to the tolerance measurement if you have to change the tolerance thresholds.
To confirm the tolerance thresholds after the test stimulation, click on "OK".
In the next step, you can enter the adaptation parameters for OkuStim 2 (Chapter 13).



Note: If a resistance error occurs, the exact position will be displayed (in this case eye OD, see below). See Chapter 21 for how you can eliminate the error.

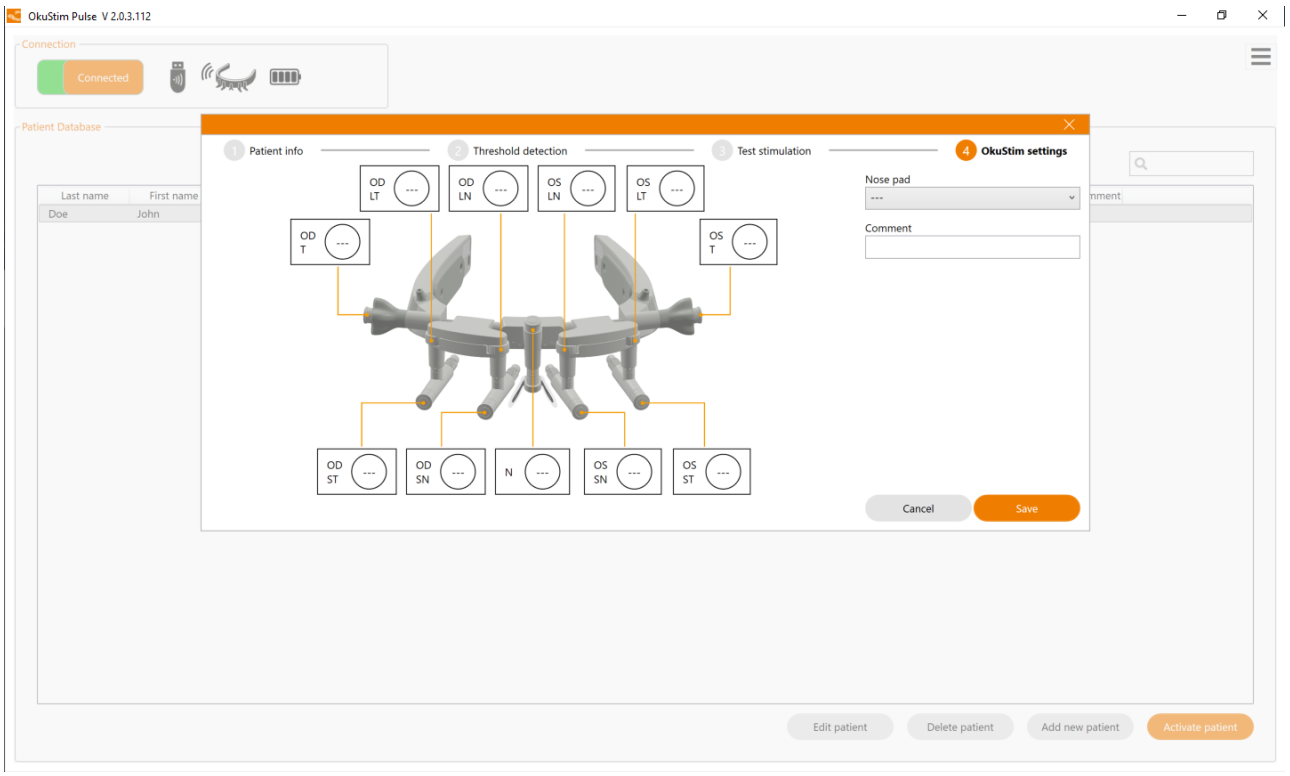


13 OkuStim 2 Adaptation Parameters

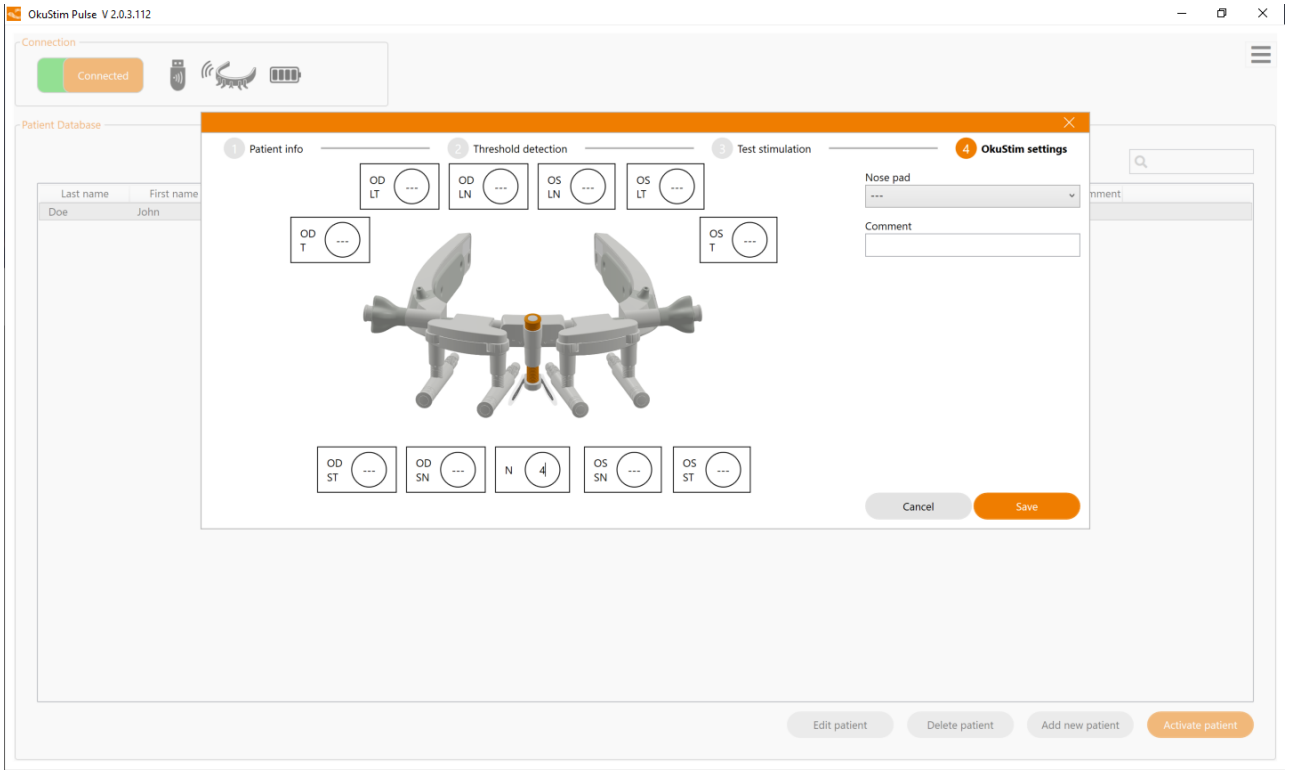
In this step, you can enter the OkuStim 2 adaptation parameters, in order to save them in the database. In this way, the data will always be available in case the patient's OkuStim 2 has to be readjusted.

Remove the OkuStim 2 from the patient's head, read the scale and enter the respective number of lines you can count in the corresponding fields.

You can enter comments and use the dropdown menu to choose the size of nose pads selected for the patient (S, M or L).



1. Click on a field, e.g. N, and enter the number of lines on the scale.
   - For visual aid, the rotary knob used for the adjustment (in this case N) changes colour when you select the field in which you want to enter the value (see figure).

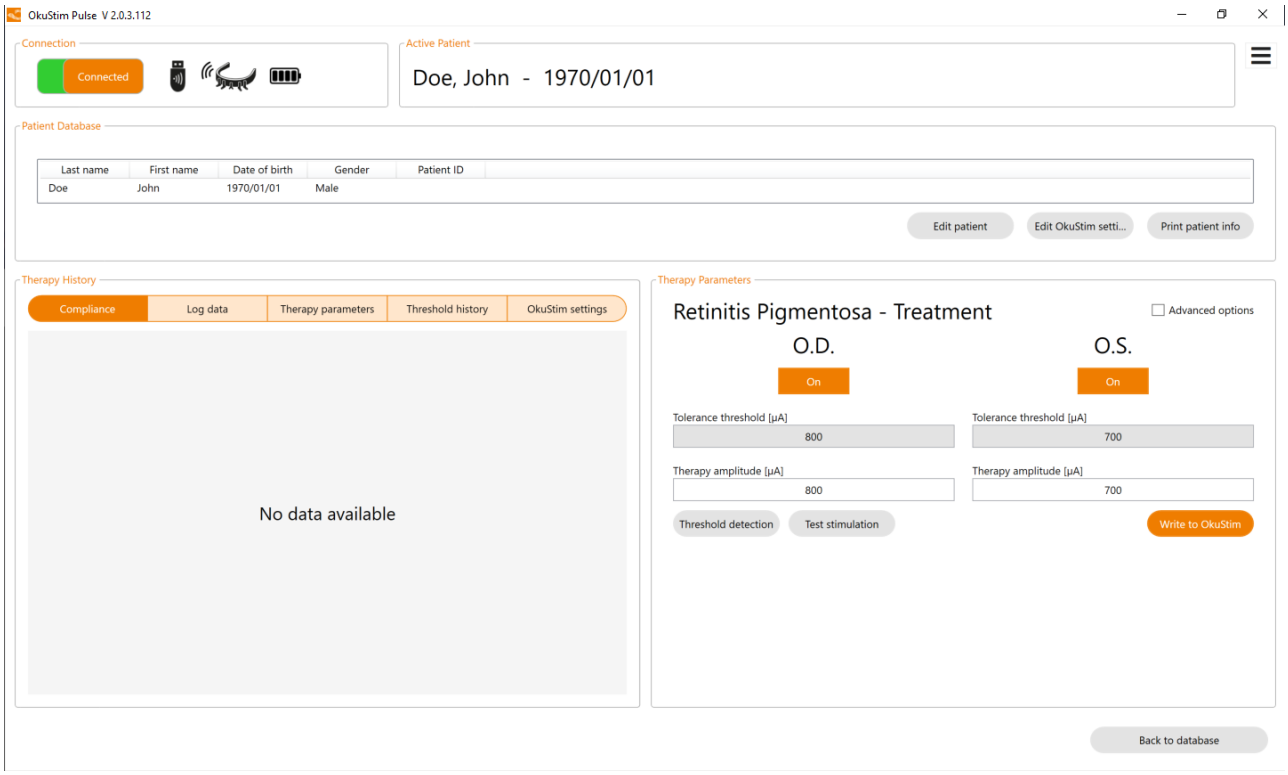


2. Continue with the other fields and enter the further scale values.
3. Then select the desired size of nose pad, enter any comments as needed, and confirm with "Save".

14 Activated Patient View (New Patient)

You have now defined the tolerance thresholds as well as adaptation parameters and can also save and print them. To print, click “Print patient info”. You can then save the file as a PDF. Give one printout to the patient so that they may order the OkuStim 2 and communicate all required information; see figure below.

See Chapter 15 for how you save the data in OkuStim 2.



OkuStim - Therapy Details

Patient information

Name: Doe, John
Date of birth: 1970/01/01
ID:
Gender: Male
Comment:

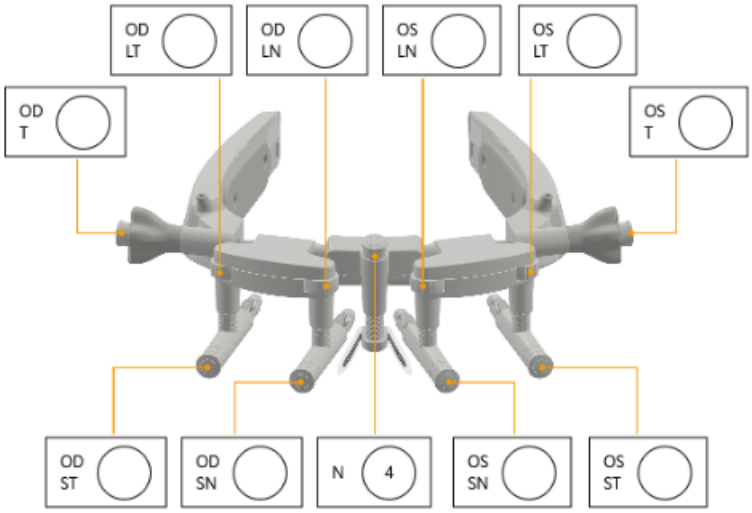
Clinic information

Institution: EXAMPLE EYE CLINIC
Physician:

Therapy parameters

Stimulation file: Retinitis pigmentosa (ID: EW-RP-007 V1)
Therapy amplitudes: O.D. 800 µA / O.S. 700 µA
Therapy duration: 00:30 HH:MM
Lower limit: 400 µA

OkuStim settings



Nose pad type: ☐ S (small) ☐ M (medium) ☐ L (large)

Comment:

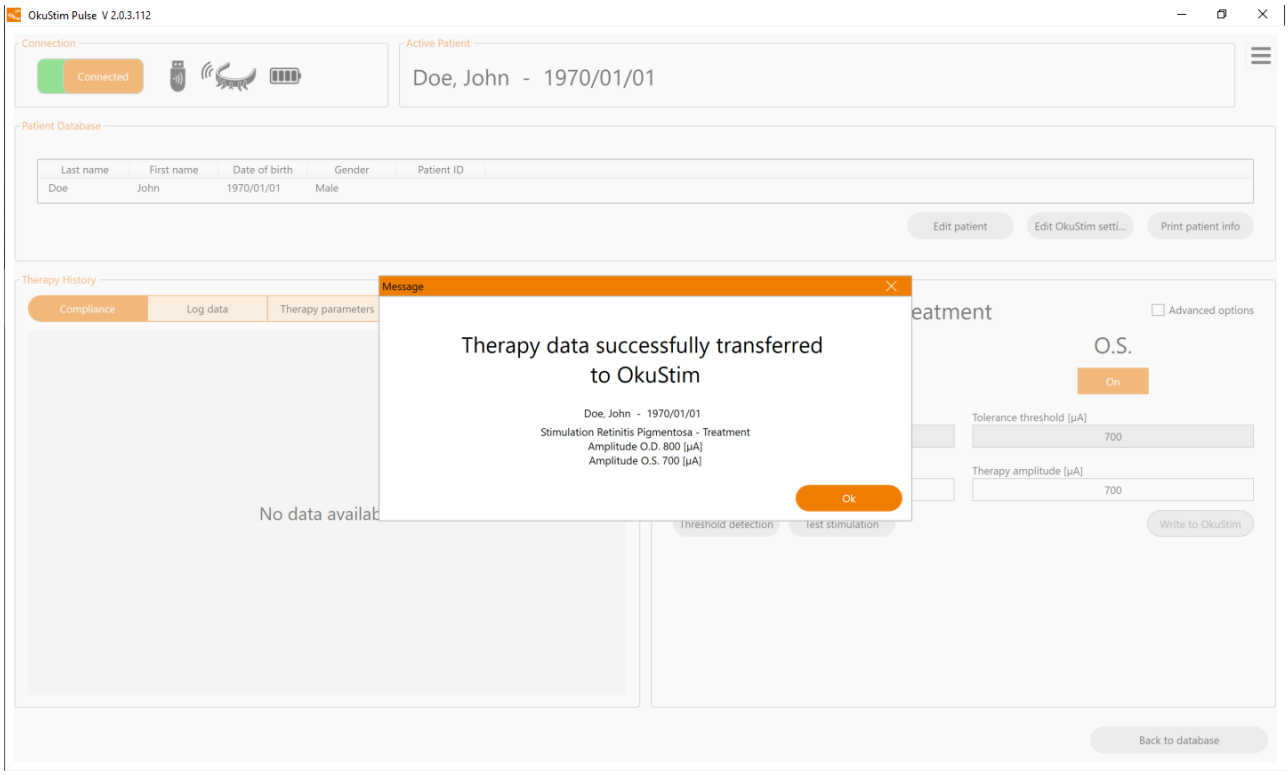
Created by OkuStim Pulse 2.0.0.50 on 2024/01/10 4:12:59 PM

See Chapter 19 for everything that you can still revise in the activated patient view.

15 Saving the Therapy Amplitudes on OkuStim 2

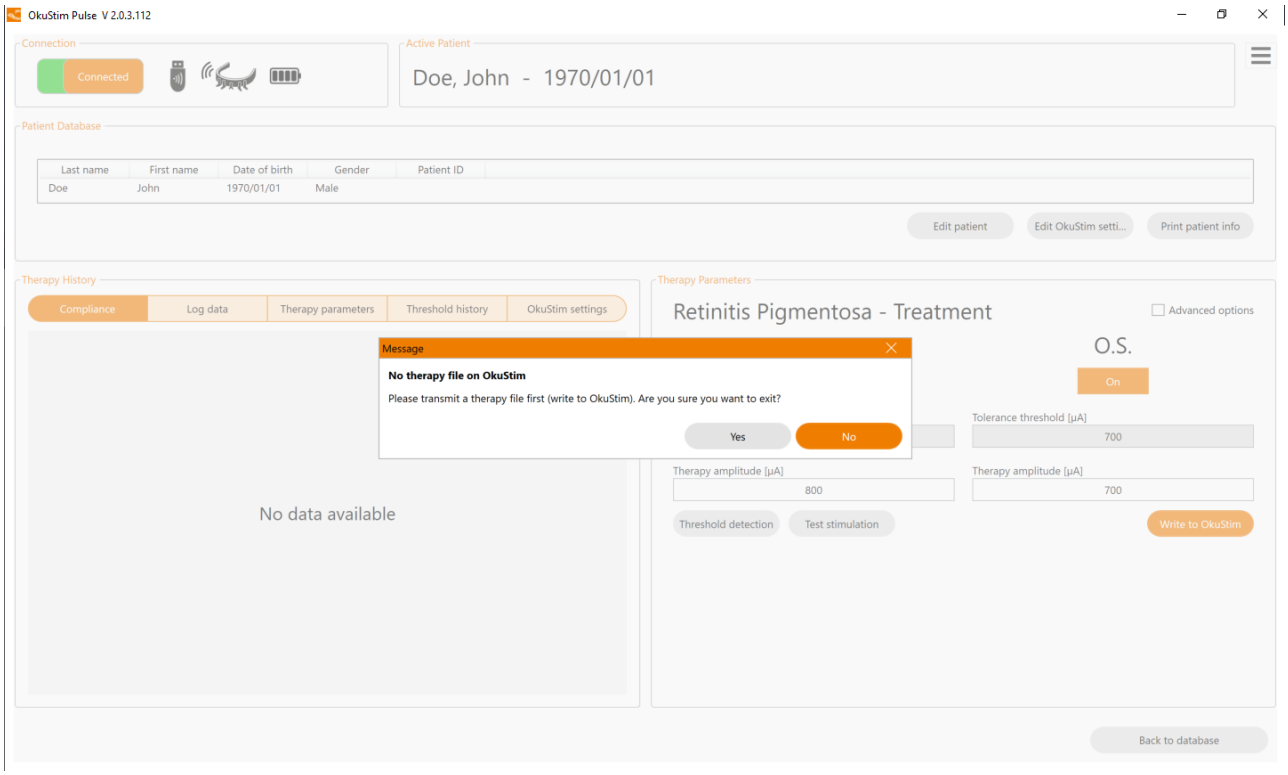
In order to transfer the data to OkuStim 2 and save them in the database on your PC, you must always click on "Write to OkuStim" in the activated patient view.

Note: Make sure that OkuStim 2 is connected with OkuStim Pulse. If transmission is successful, a confirmation window opens.

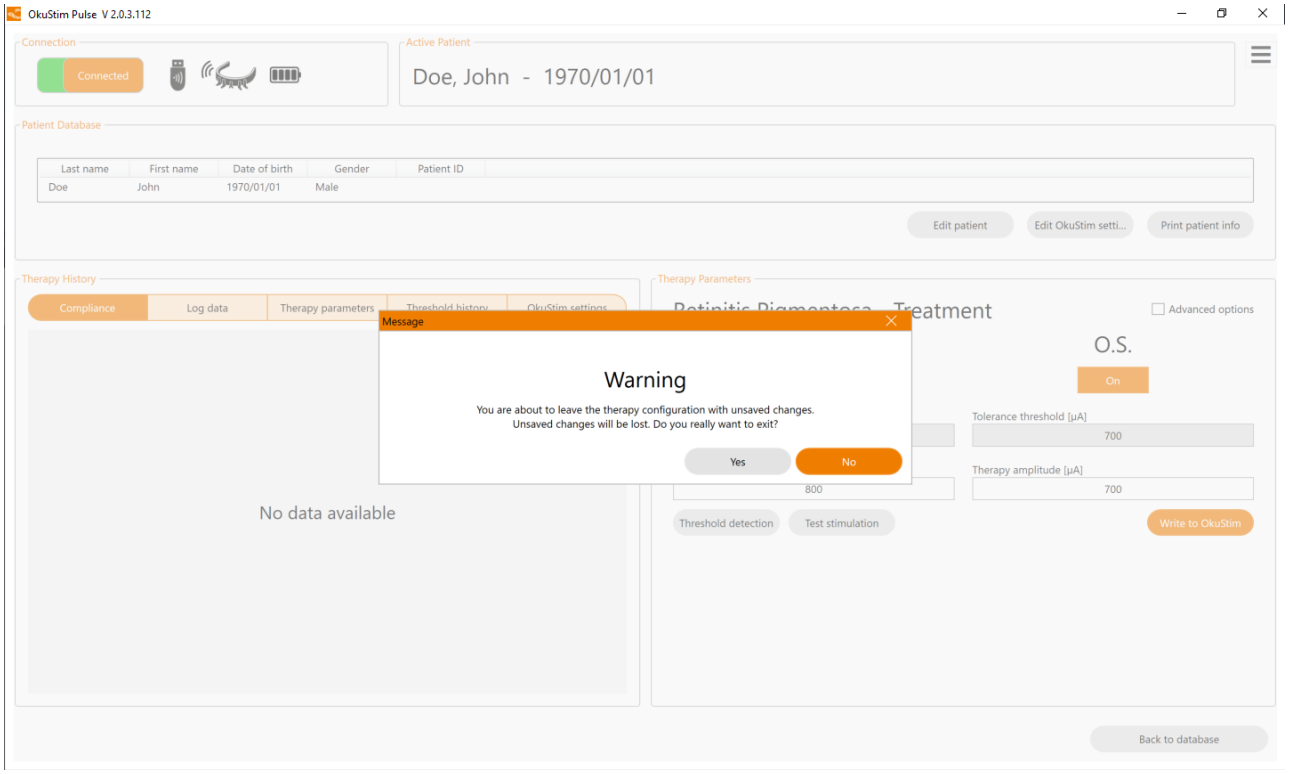


Confirm with "OK".

If you forget to click on "Write to OkuStim", the following warnings can appear.



Click on "No" if you want to save the changes. You will then return to the activated-patient-view. Otherwise, no stimulation with the OkuStim 2 is possible and a system error will appear.

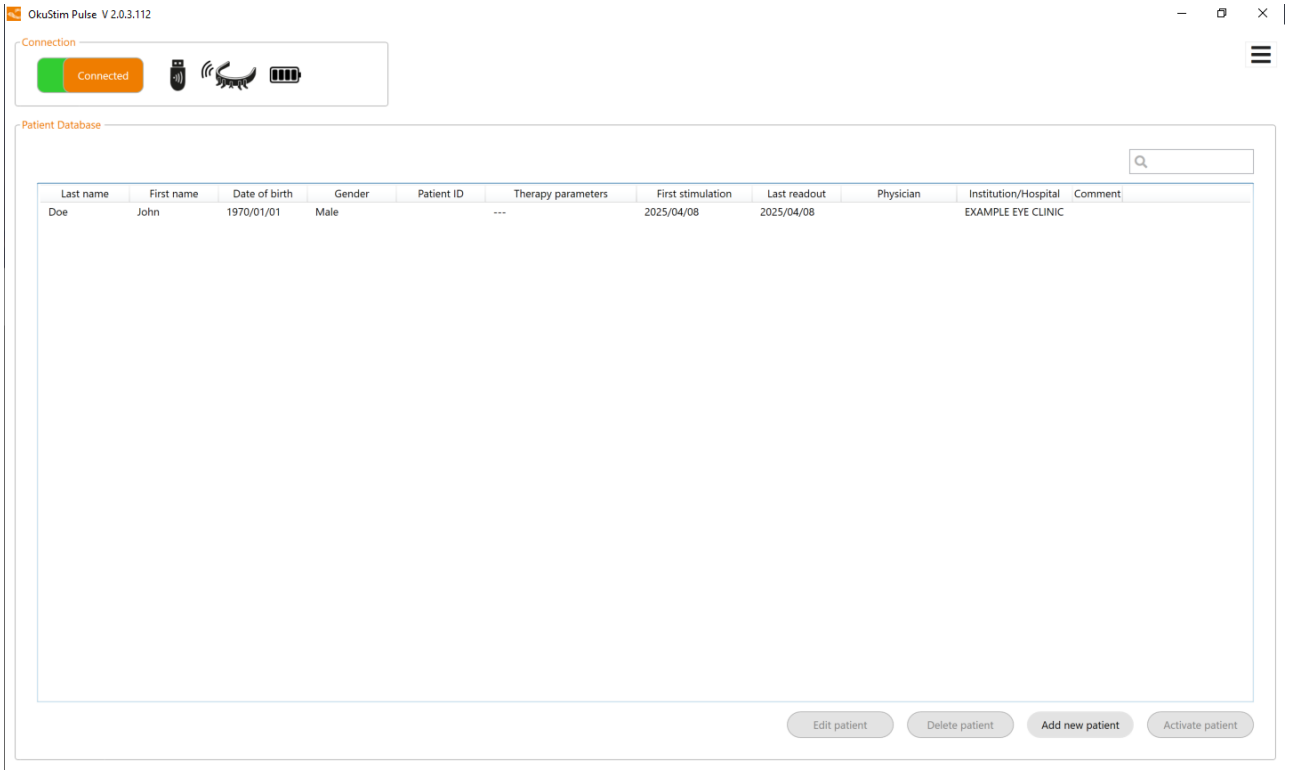


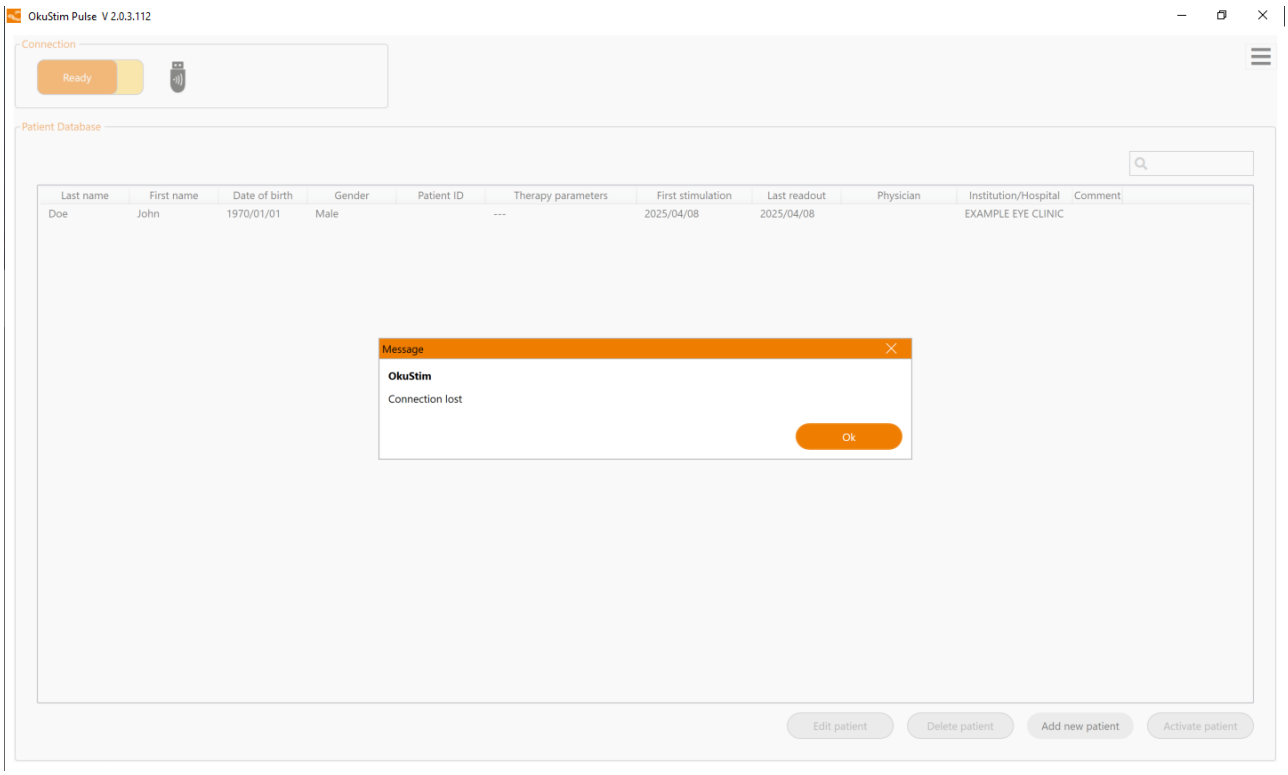
The window will close and you can now click on "Write to OkuStim".

The data will then be transferred to OkuStim 2 and saved in your database.

16 Decoupling OkuStim 2 and Ending OkuStim Pulse

To disconnect OkuStim 2 from OkuStim Pulse, click on the orange "Connected" slider. A message window opens for confirmation (see figure). Click on "OK".





17 Starting a Stimulation Session

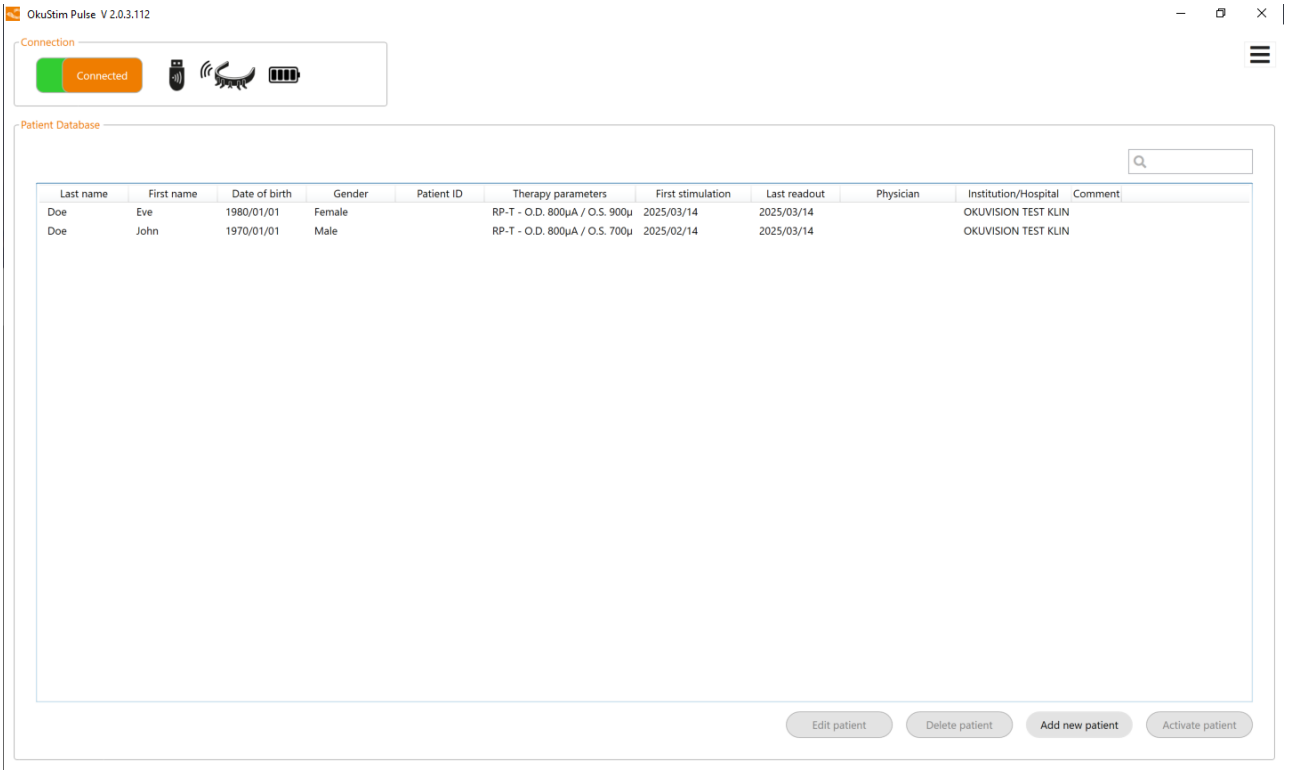
After you have disconnected OkuStim Pulse and OkuStim 2, you can start a stimulation session.

Note: Please note that the OkuEl M electrode is intended for use in one 30-minute stimulation session. Therefore, if necessary, use a new electrode for any therapy session carried out immediately after the tolerance threshold measurement.

18 Changing the Data of an Existing Patient

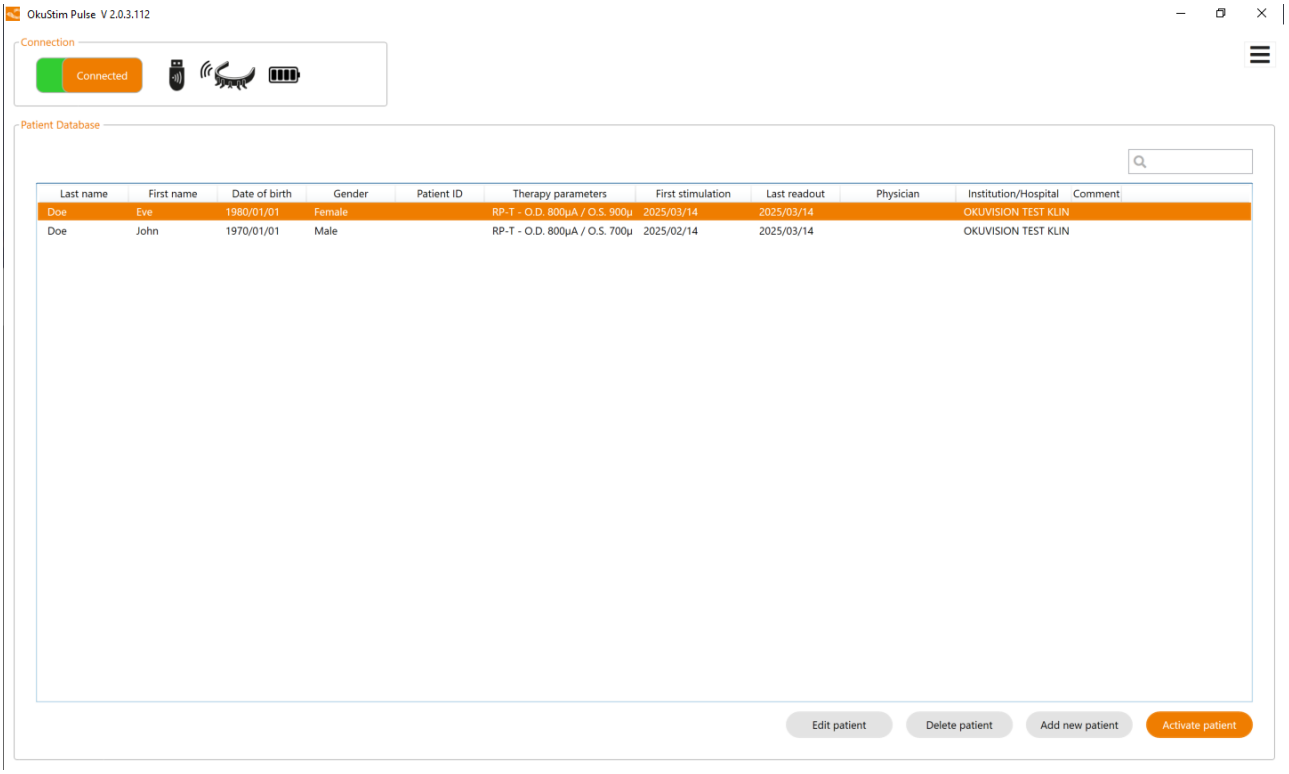
Stimulation parameters (tolerance thresholds, stimulation amplitudes), OkuStim 2 adaptation data (adaptation parameters) and/or general patient data can always be changed/ revised later.

Note: Please remember that you must connect the patient's OkuStim 2 with OkuStim Pulse, so that the changes can also be saved to OkuStim 2. See Chapter 9 how to establish a connection with OkuStim 2.

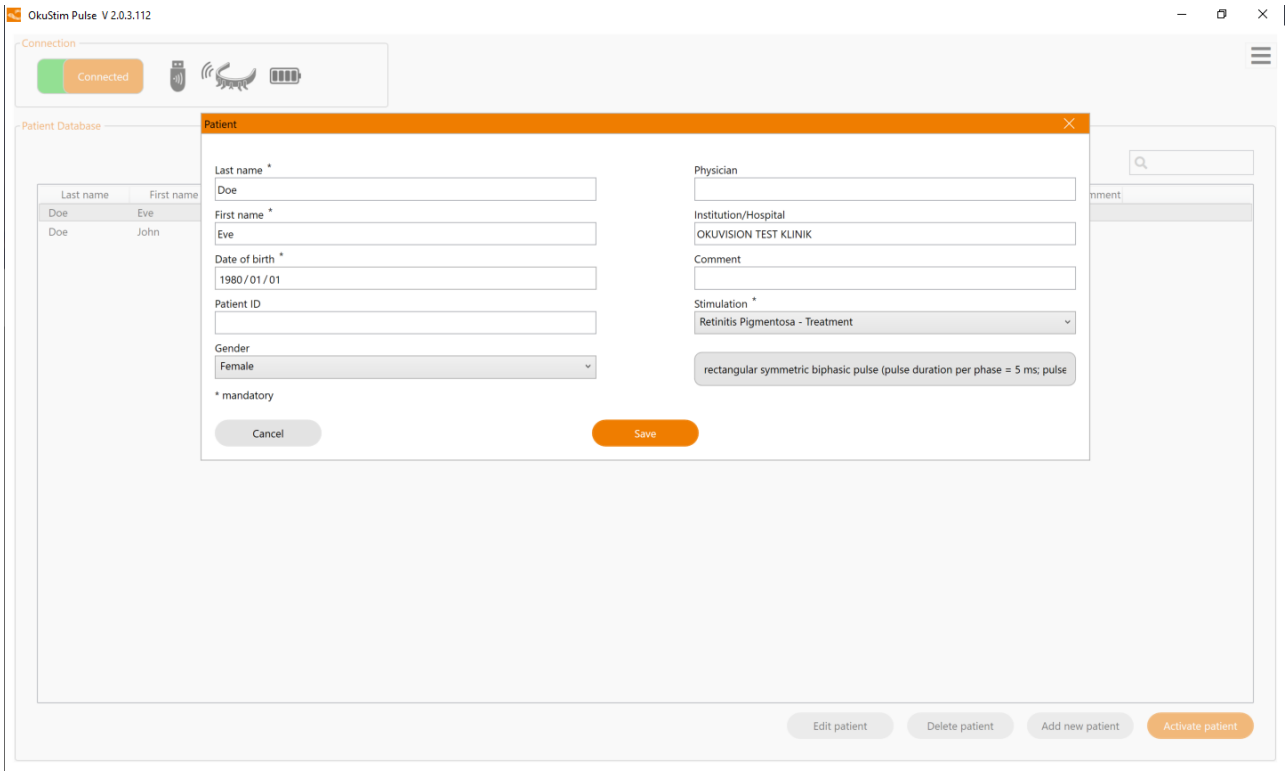


18.1 Changing patient data

In order to change patient data, select the desired patient from the database.



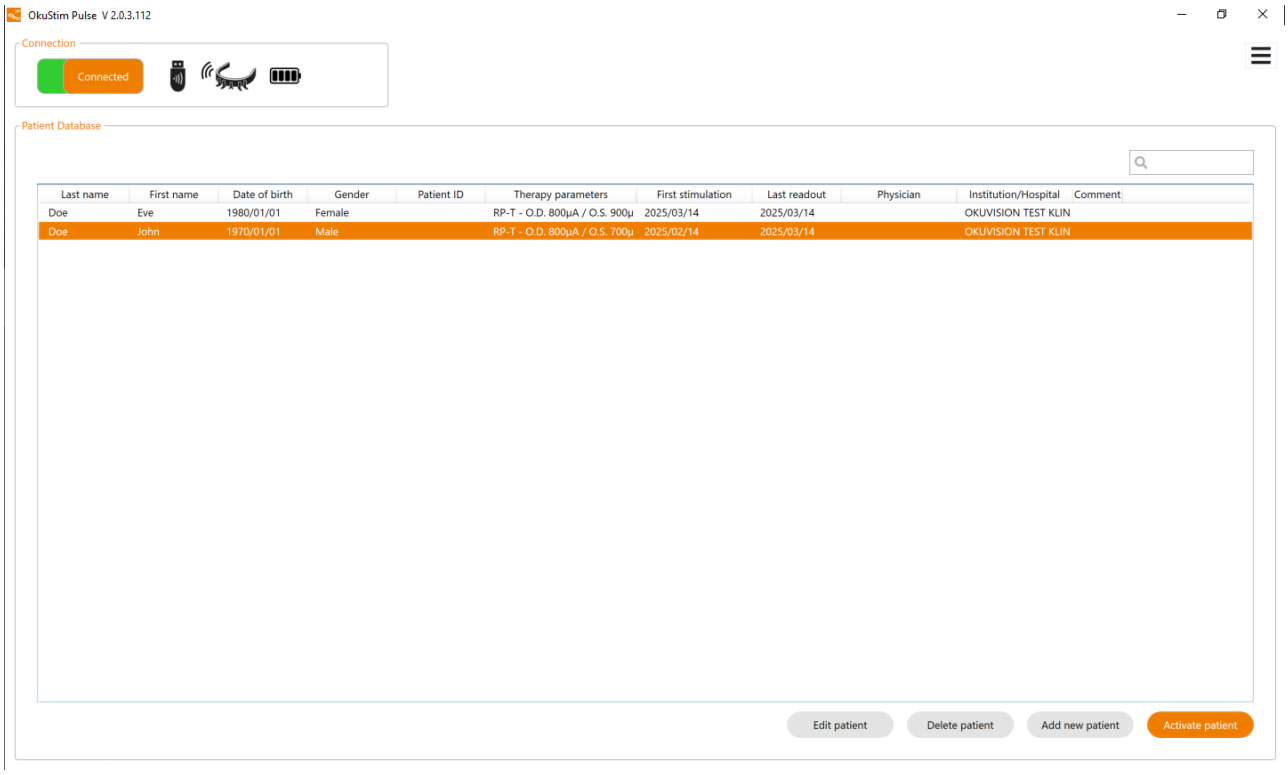
Click on "Edit Patient".
The "Patient" window opens. Here you can change the patient data. To finish, save the changes made via the "Save" button.



You can also reach the change mode via the "activated patient" view (see Chapter 19).

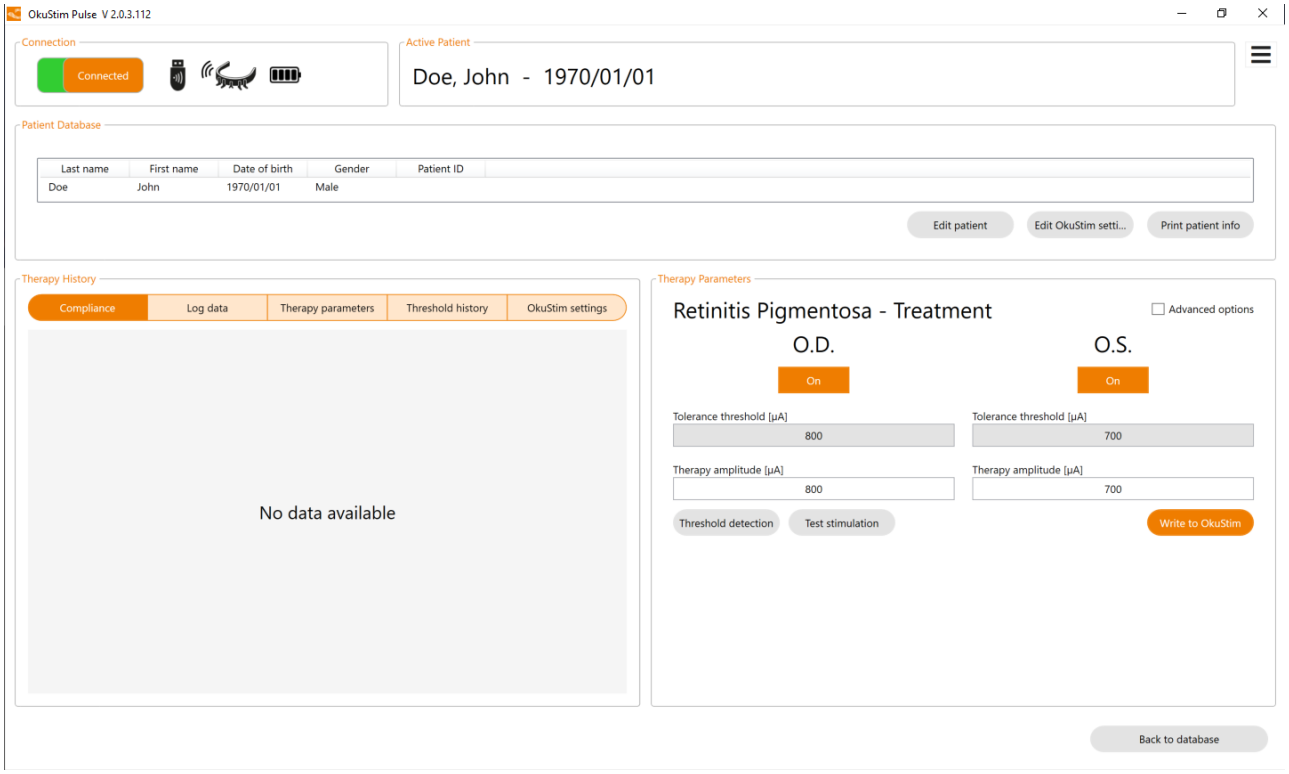
18.2 Changing stimulation parameters

Stimulation parameters (tolerance thresholds, stimulation amplitudes) and the OkuStim 2 adaptation data (adaptation parameters) can always be changed/revised later.
Select the desired patient from the patient database and click on "Activate patient" (see figure).



You are now in the activated patient view (see figure).

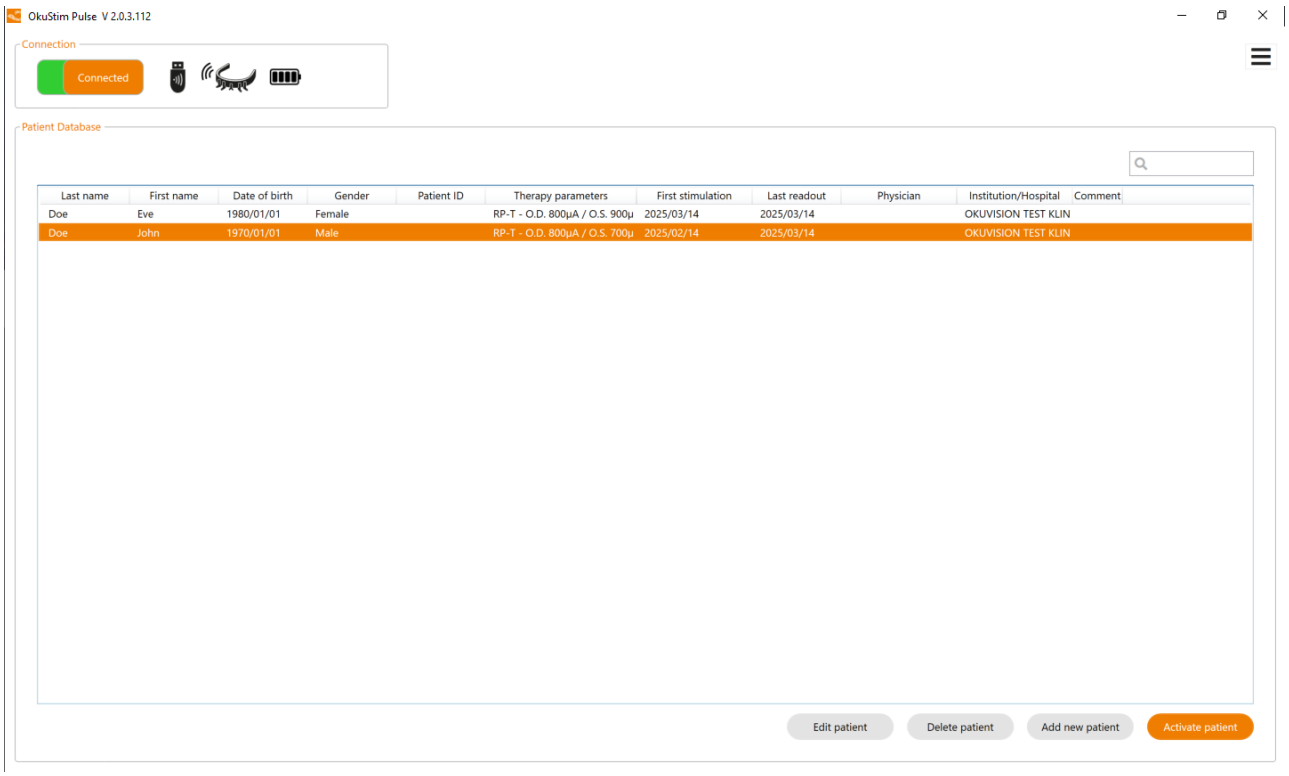
See Chapter 19 for how you can change the stimulation amplitudes of an existing patient in the activated patient view.



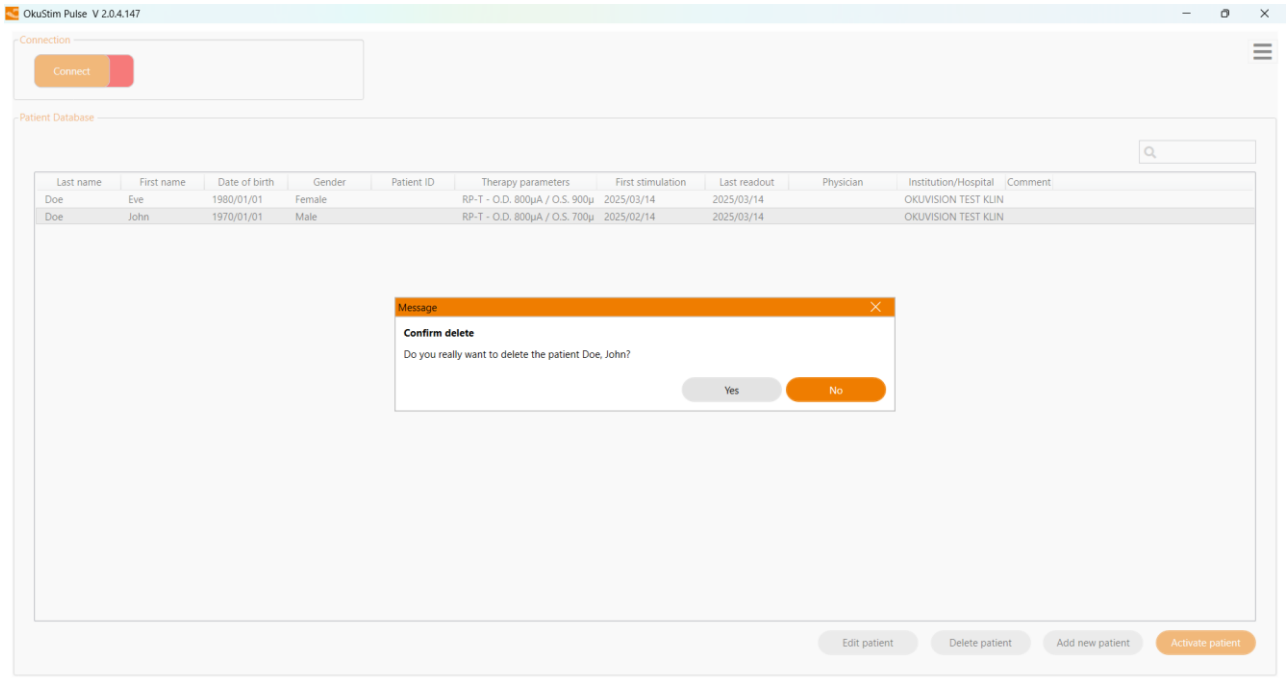
18.3 Deleting patients from the database

Patients can be deleted from the database.

Select the desired patient from the patient database and click on "Delete patient“ (see figure).



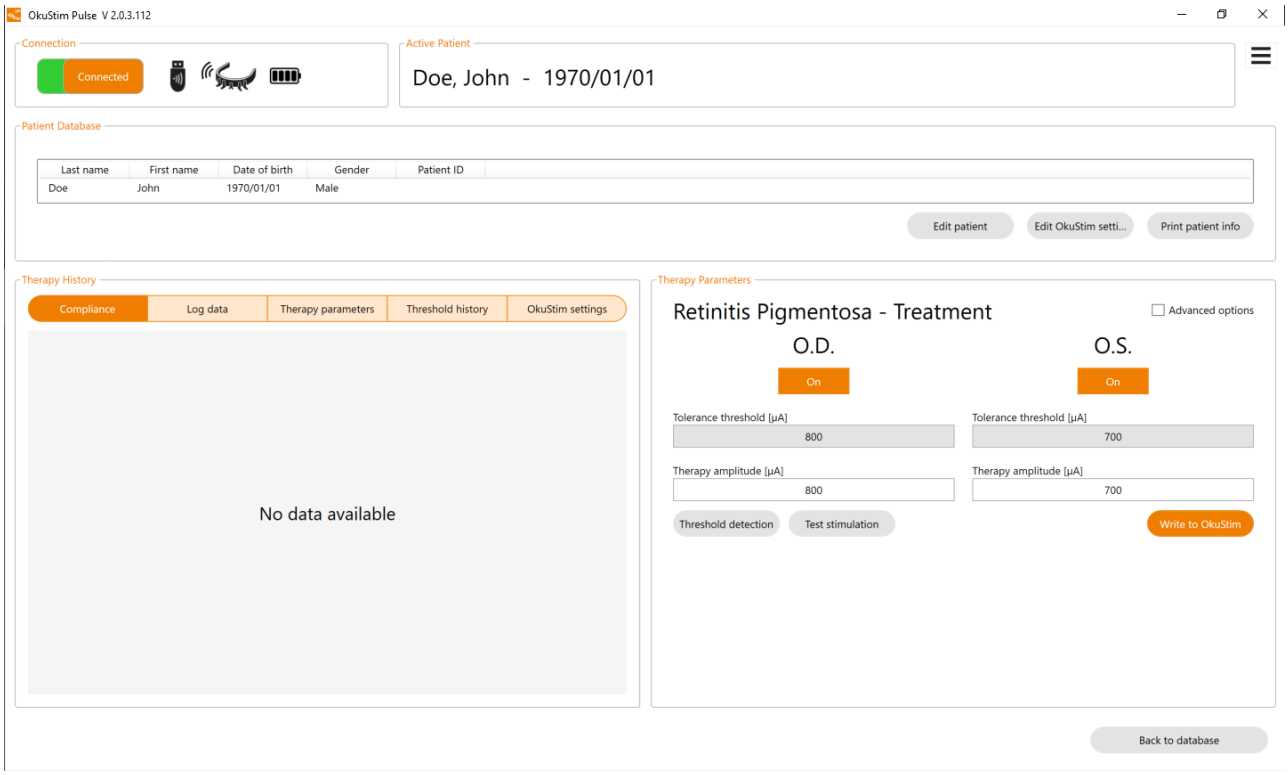
A window opens with the query as to whether you really want to delete the patient. Confirm accordingly (see figure).



Note: Only delete patients when the software is not paired with OkuStim 2. Always end the connection before deleting a patient.

19 Activated Patient View (Patient from the Database)

Note: In order to access the activated patient view, do not forget to connect OkuStim 2 with OkuStim Pulse (see Chapter 9).



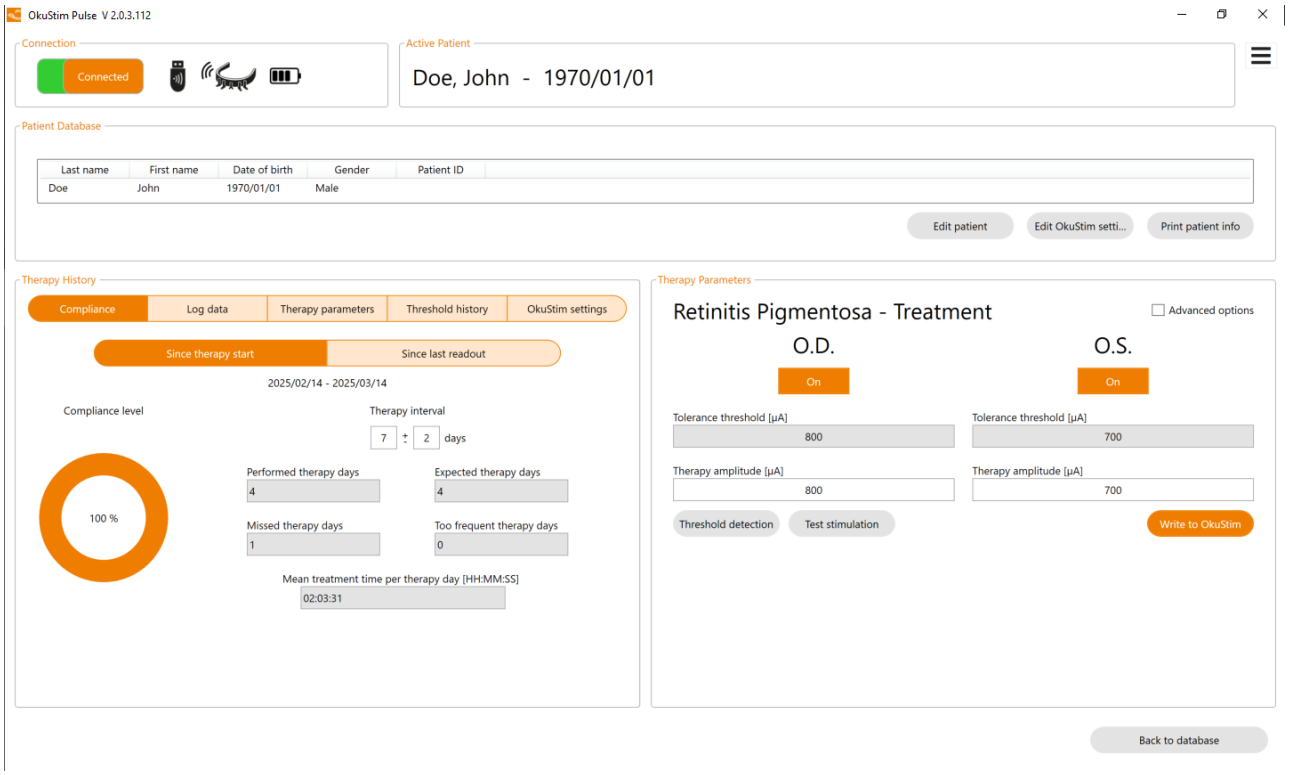
19.1 Explanation of the Buttons of the Activated Patient View

In the activated patient view, you can make various adjustments:

1. "Write to OkuStim": With this you can transfer data to OkuStim 2.
2. "Threshold detection: With this you access the tolerance threshold measurement and, if necessary, the phosphene threshold measurement. When you click on the "Threshold detection" button, the "Tolerance threshold detection" window opens. Here you can measure the tolerance threshold again (see Chapter 11, Measurement of the tolerance threshold).
3. "Test stimulation": With this you can run a test stimulation. When you click on the "Test stimulation" button, the "Test stimulation" window opens. Here you can test the stimulation amplitudes once again (in Chapter 12).
4. "Edit patient": With this you can change patient information. When you click on this button, the "Patient" window opens; see Chapter 10.
5. "Edit OkuStim setting": With this you can edit the adaptation parameters of OkuStim 2; see Chapter 13.
6. “Print patient info”: With this you can print all information about the patient as a PDF file.
7. “Back to database”: With this you return to the patient database.

19.2 Functionalities of the activated patient view

19.2.1 “Therapy amplitude [µA]" field



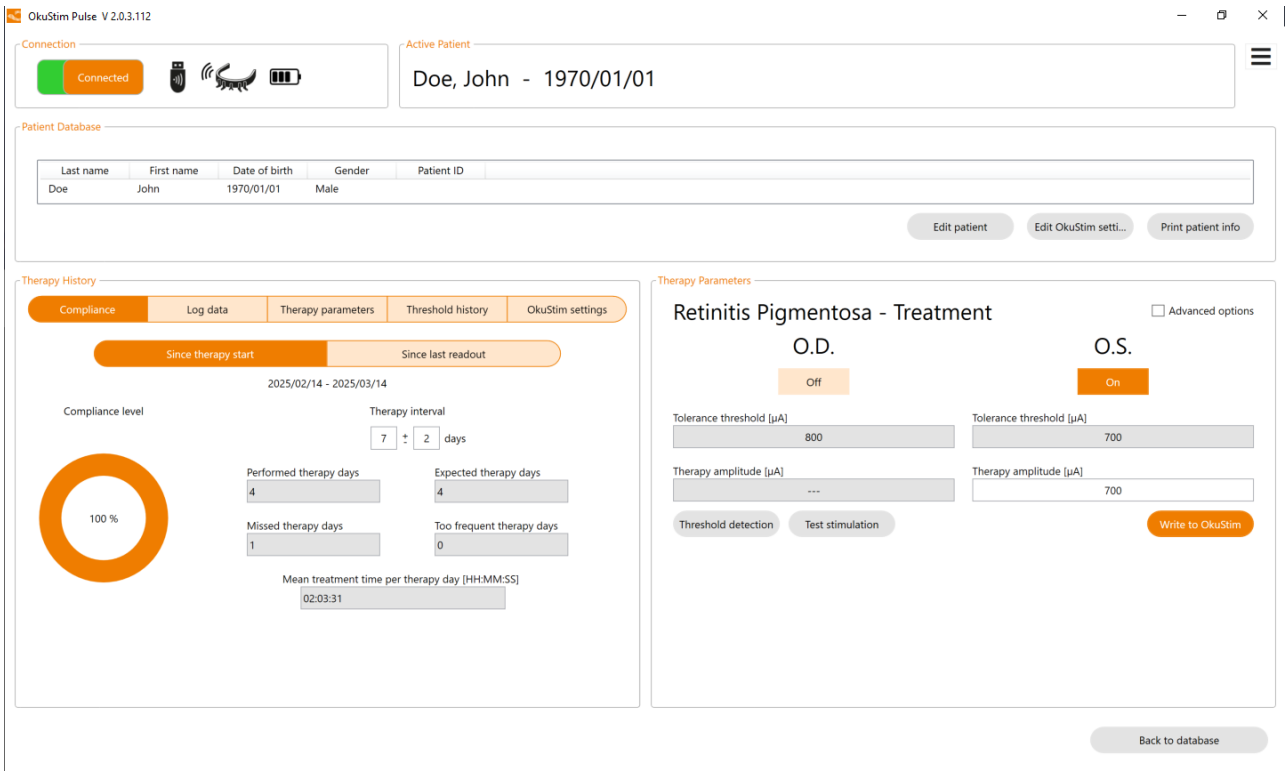
Tolerance thresholds in the "Tolerance Threshold [µA]" fields cannot be changed manually.

If required, you can enter new stimulation amplitudes directly (manually) in the "Therapy amplitude [µA]" fields for OD and OS without first testing them.

Click on "Write to OkuStim", in order to save the data on OkuStim 2.

Notes:

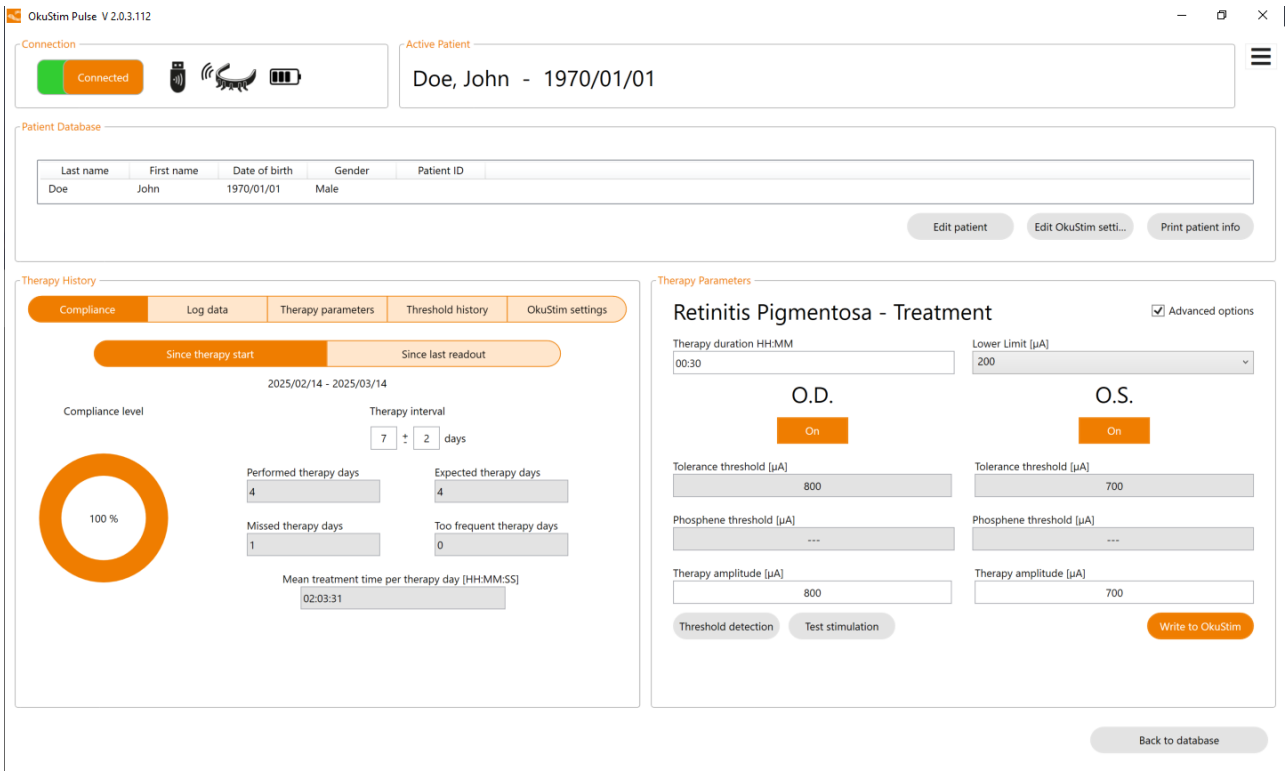
- Please remember that the tolerance threshold should always be higher than or equal to the respective stimulation amplitudes.
- You can deactivate OS or OD stimulation via the orange "On" button. This way you can switch OkuStim 2 to monocular stimulation; see figure.



Use this button when you are treating a patient who, for e.g. medical reasons, can only receive stimulation to one eye. See Appendix 1 to learn more about monocular stimulation.

19.2.2 Advanced Options

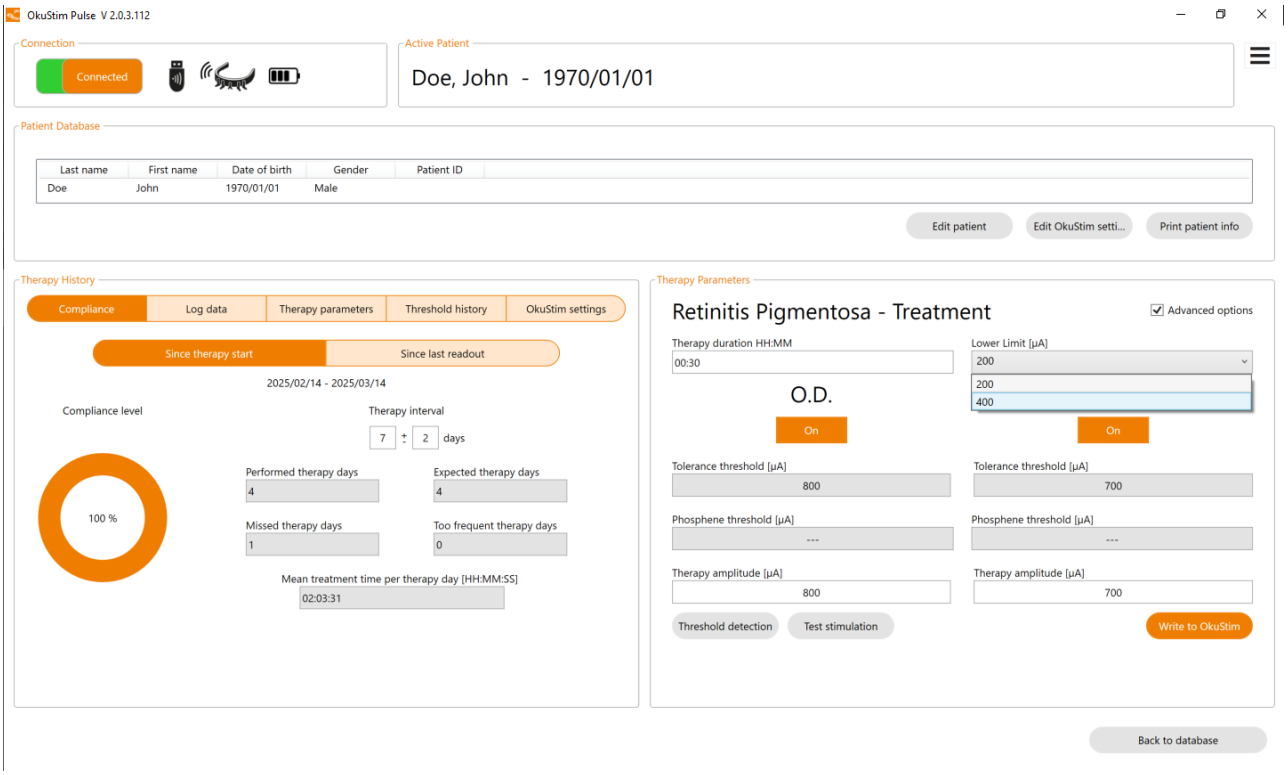
You can define further stimulation parameters, by activating the "Advanced Options" boxes.



You can now see and optionally change additional settings.

1. Therapy duration HH:MM: Displays the therapy duration (which is preprogrammed in the stimulation file).
2. Lower limit [µA]: Here you can define the lower limit.
   - The patient can use the minus button on OkuStim 2 to reduce the stimulation amplitude if they feel pain for various reasons on any day.
   - Via the dropdown menu, you can choose the lowest stimulation amplitude that the patient is able achieve;200 µA or 400 µA (see figure).
   - The preset value is 400 µA.

   Notes:
   - No stimulation amplitudes below 200 µA can be programmed when the lower limit is set to 200 µA.
   - Advise the patient always to stimulate with the predetermined current intensity. The patient is permitted to reduce the current intensity only in exceptions. During stimulation, the current intensity can also be reset to the starting level.
   - The next time OkuStim 2 is switched on, the stimulation intensity will be reset to the preset value; any reduced value will not be saved.
3. Phosphene threshold [µA]: The phosphene thresholds are displayed here (if they were measured for the patient).



19.3 Therapy History

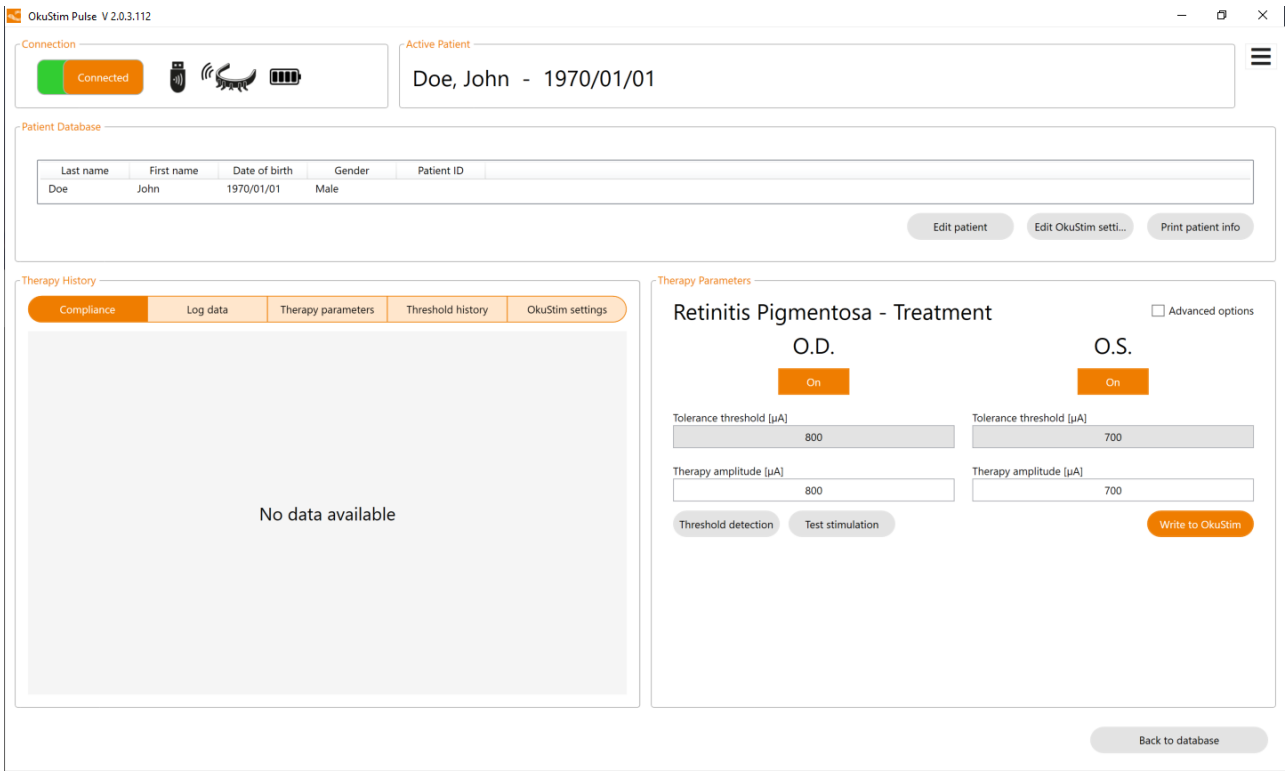
In the "Therapy History" window you will find information about:

- Adherence of the patient to the therapy ("Compliance" tab)
- Detailed information about the stimulation sessions ("Log Data" tab)
- Information/History about the stimulation amplitudes and their changes ("Therapy parameters" tab)
- Information/History about the tolerance thresholds ("Threshold History" tab)
- Information about OkuStim 2 settings ("OkuStim settings" tab)

19.3.1 Compliance

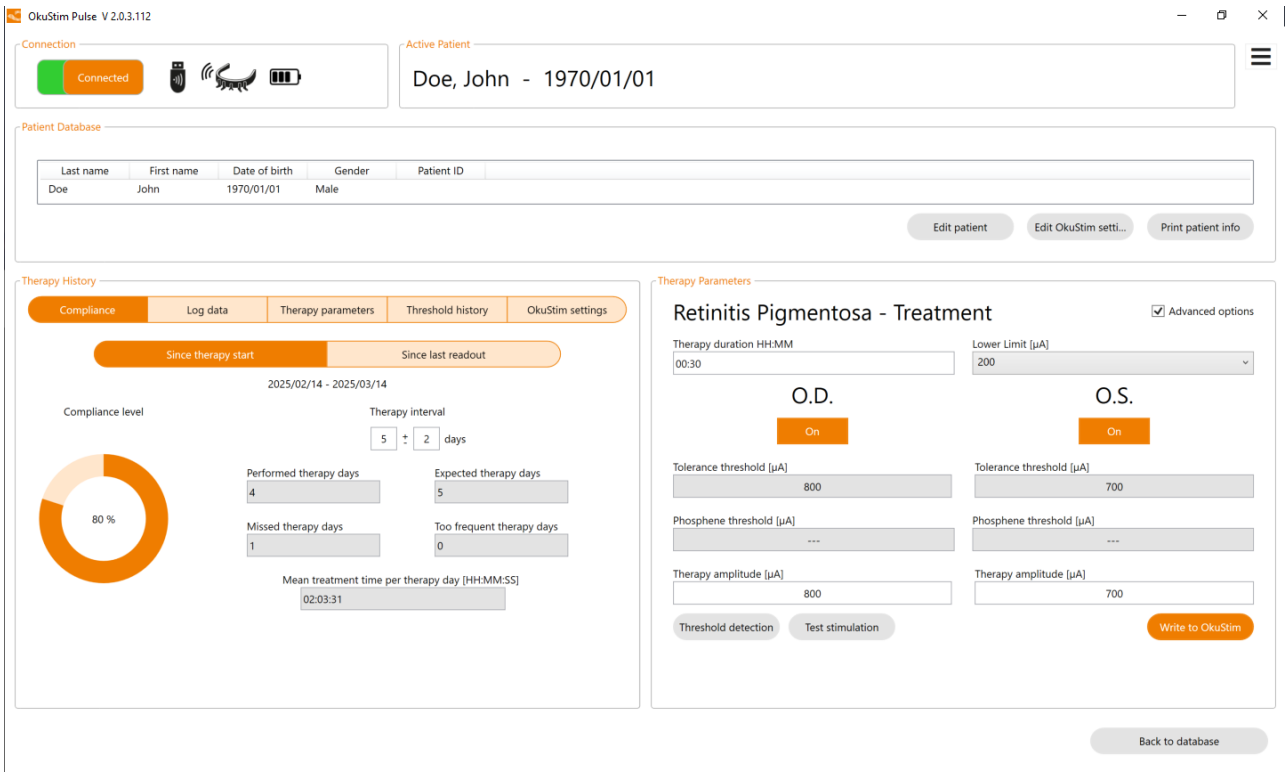
When you click on "Compliance" under Therapy History, you can view the patient's adherence (whether they have been stimulating according to plan).

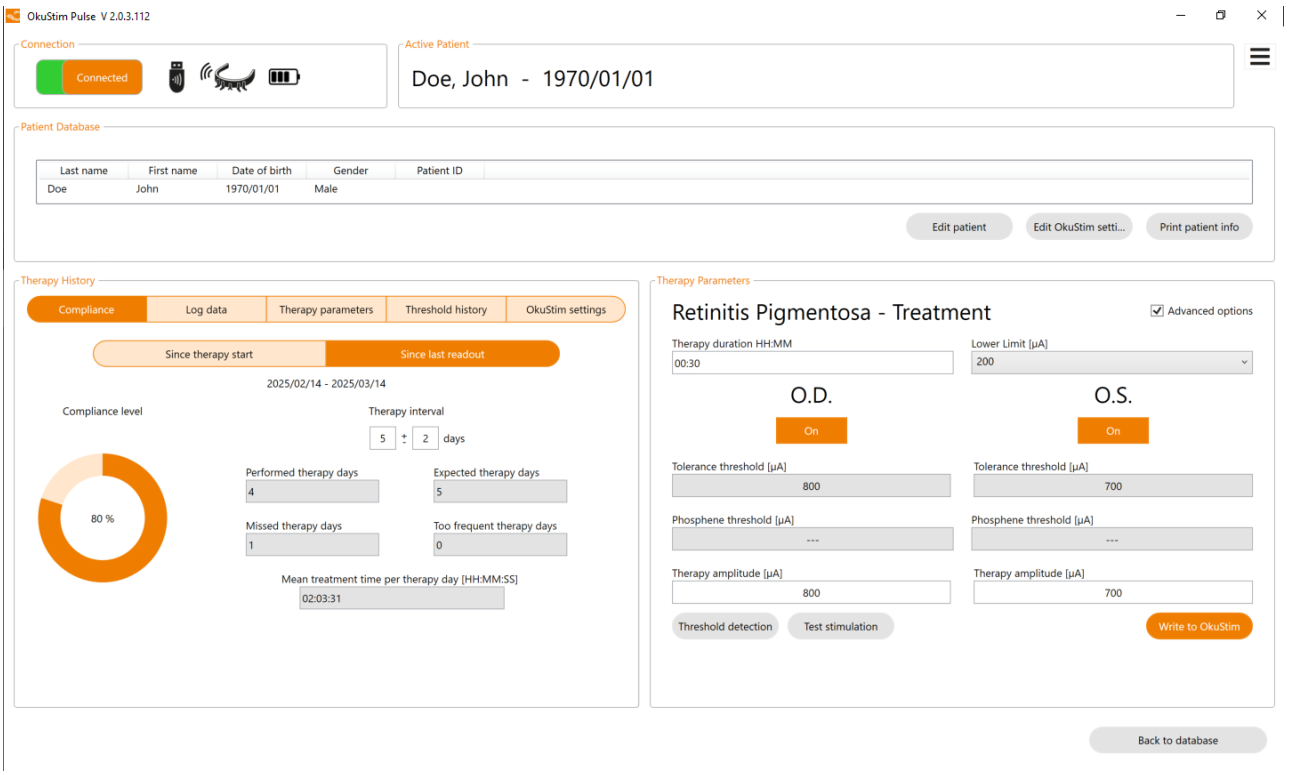
If the patient has not yet had a stimulation session no information will be found on the memory card, and you will see the note below).



In contrast, if the patient returns to the clinic for a checkup after a stimulation phase, details about the "Therapy Compliance" will be displayed in the window.

Here you can choose, if you want to view the compliance information since the therapy began ("Since therapy start" tab) or only since it was last read out ("Since last readout" tab); see figures below.





19.3.2 Log data

You can find information about individual stimulation sessions in this tab (all stimulation sessions are recorded here).

A green tick indicates that the stimulation session was completed successfully (see figure below).

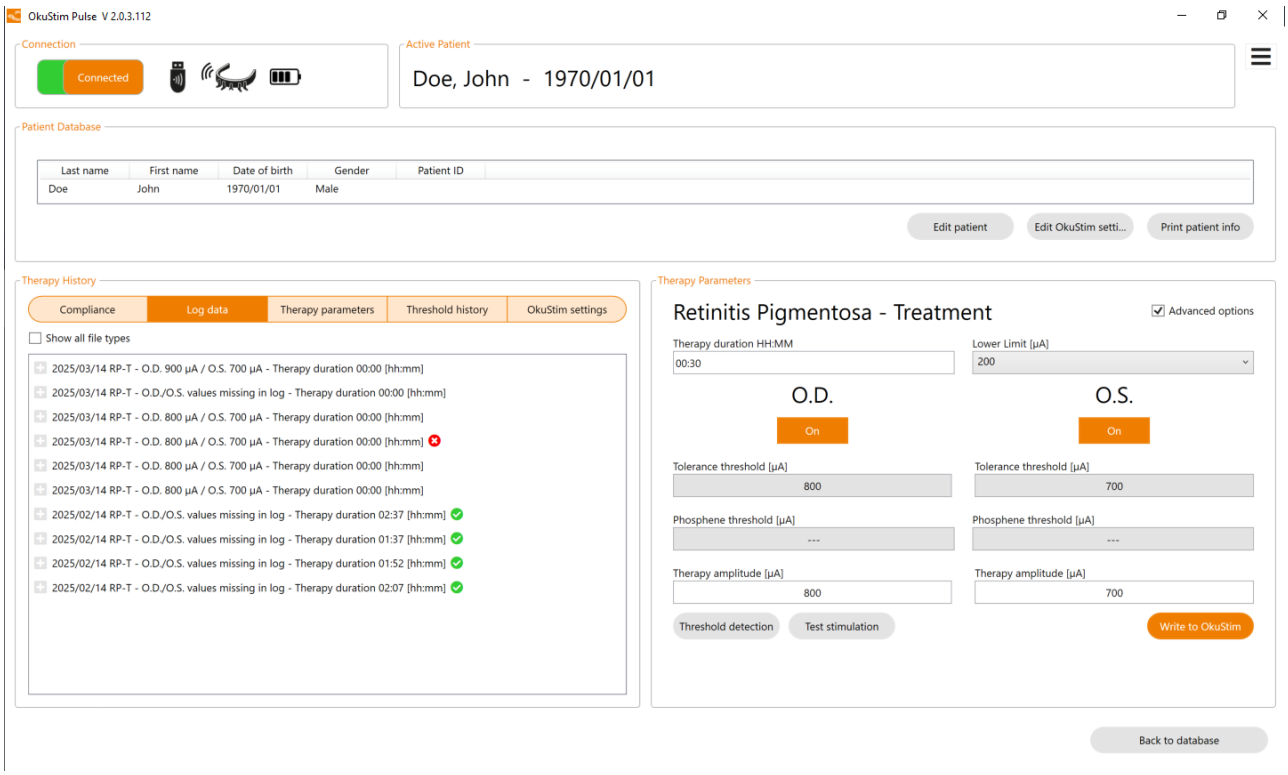
A red cross indicates that a session was started but not completed.

OkuStim 2 counts only the actual stimulation time, i.e., it excludes time lost due to resistance errors and ramps.

The software, however, also excludes error time but does include the initial ramps (e.g., when the patient resumes a session after a pause).

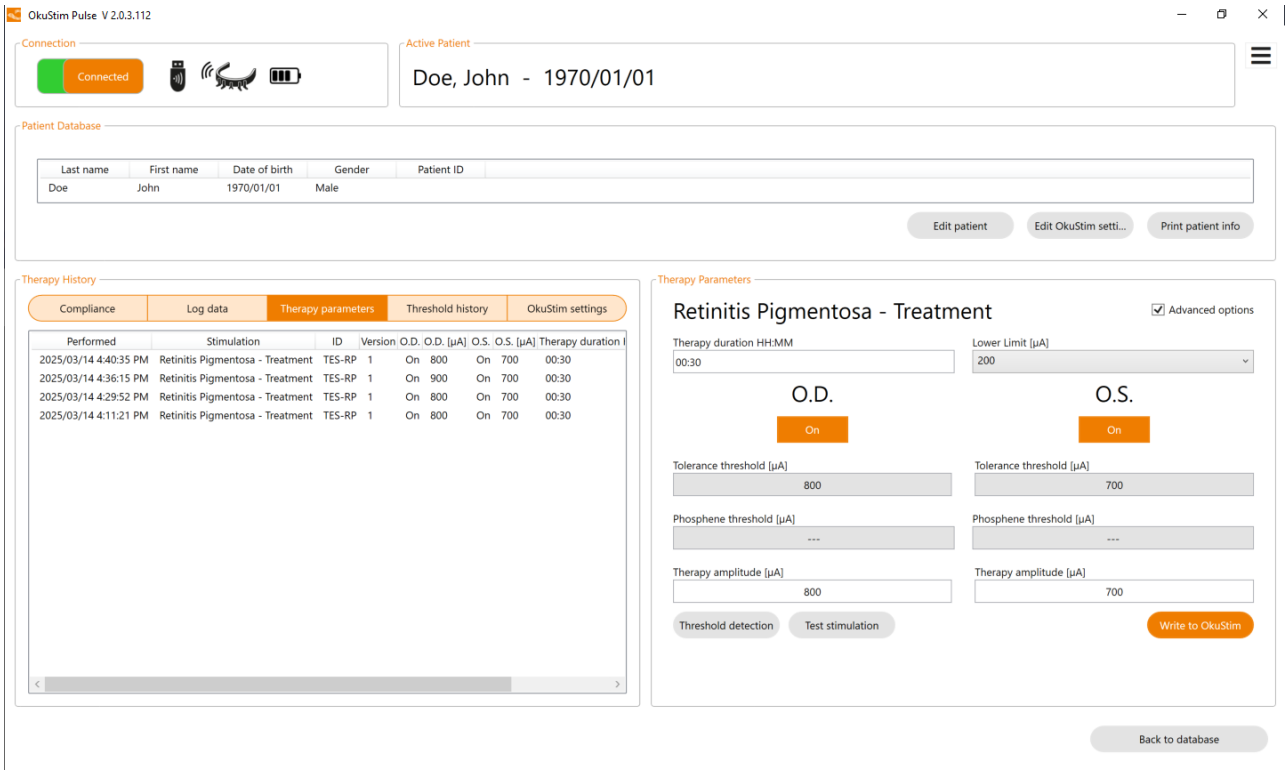
If there is no symbol next to a log entry, no session was started. For example, the device was only switched on and then switched off again.

If you click on the "+" symbol, you can view further details.



19.3.3 Therapy parameter

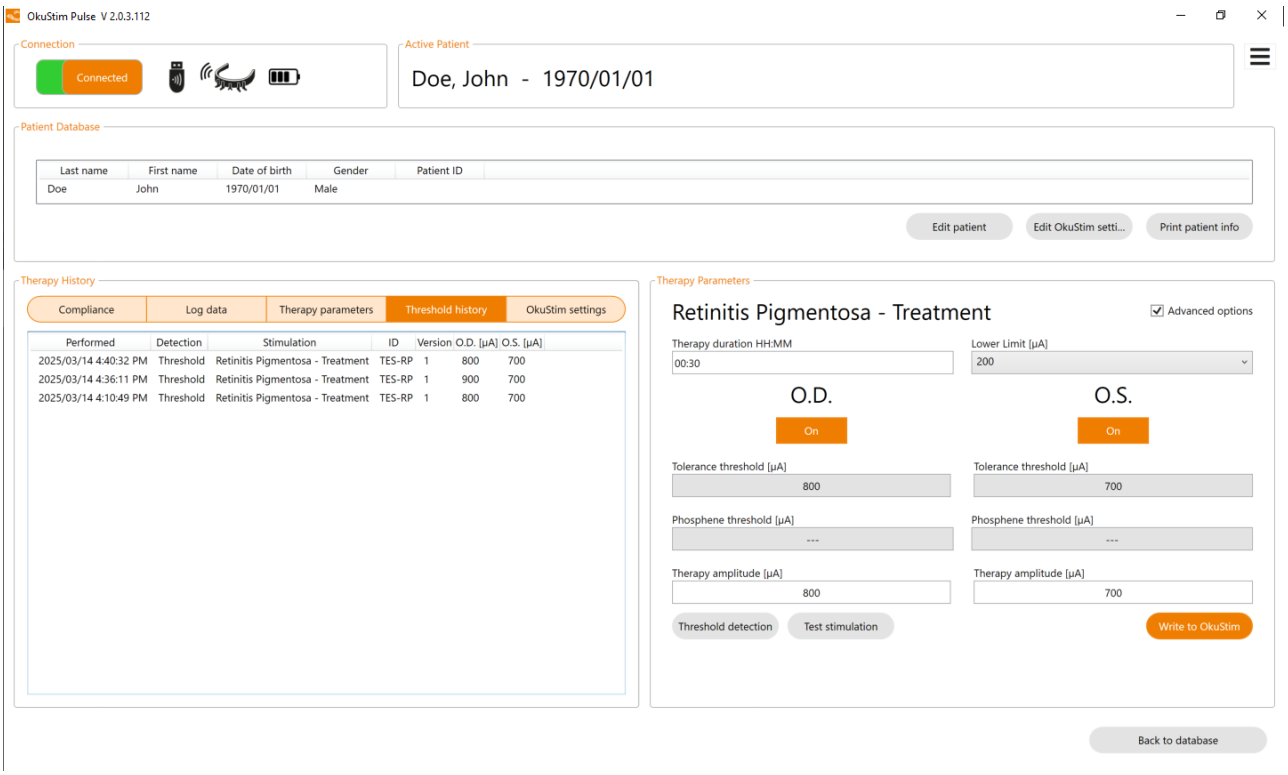
Under "Therapy parameters" you will find the stimulation amplitudes saved on the patient's OkuStim 2 with which the therapy sessions were conducted, as well as all stimulation amplitudes saved in the past if these have been changed over time.



19.3.4 Threshold history

Under "Threshold history" you will find the applied tolerance threshold values as well as phosphene threshold values, which were observed on the basis of the tolerance/phosphene threshold measurement.

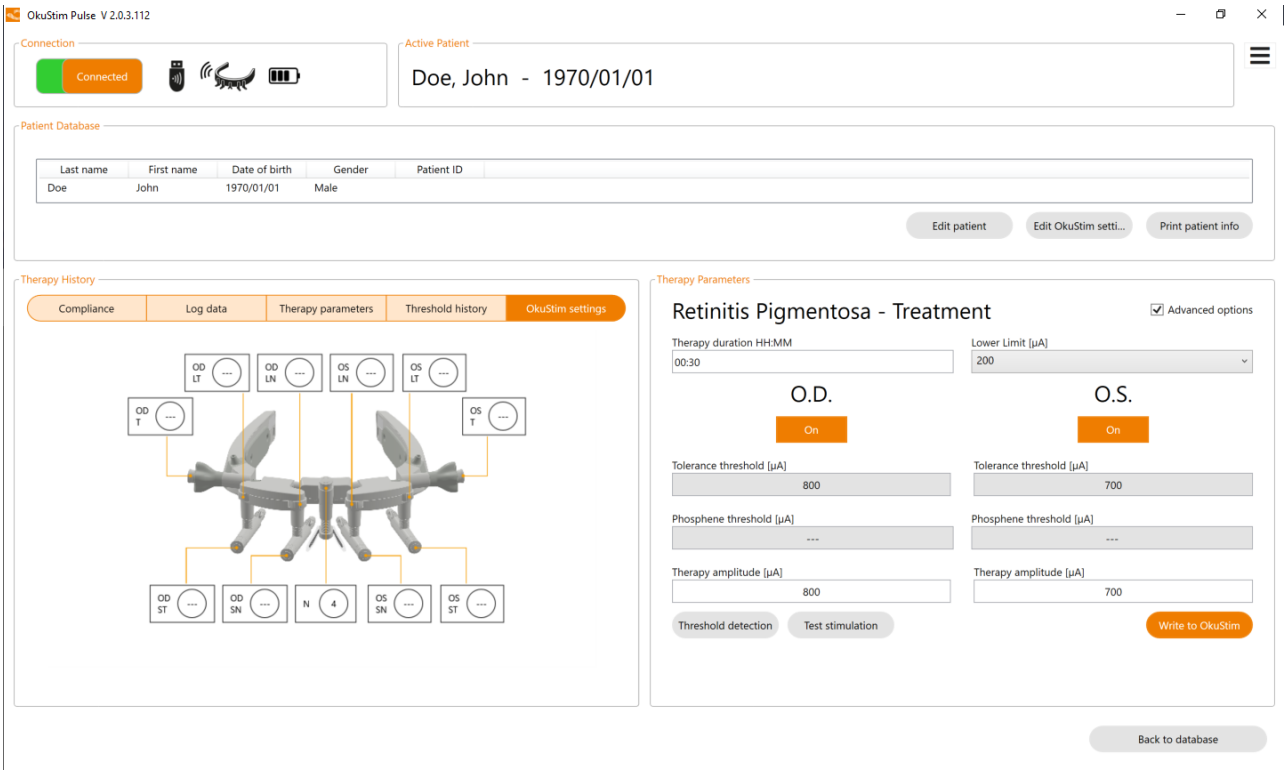
Each new tolerance measurement is saved separately. In the following example (see figure below), the patient was subjected to three tolerance measurements.



19.3.5 OkuStim Settings

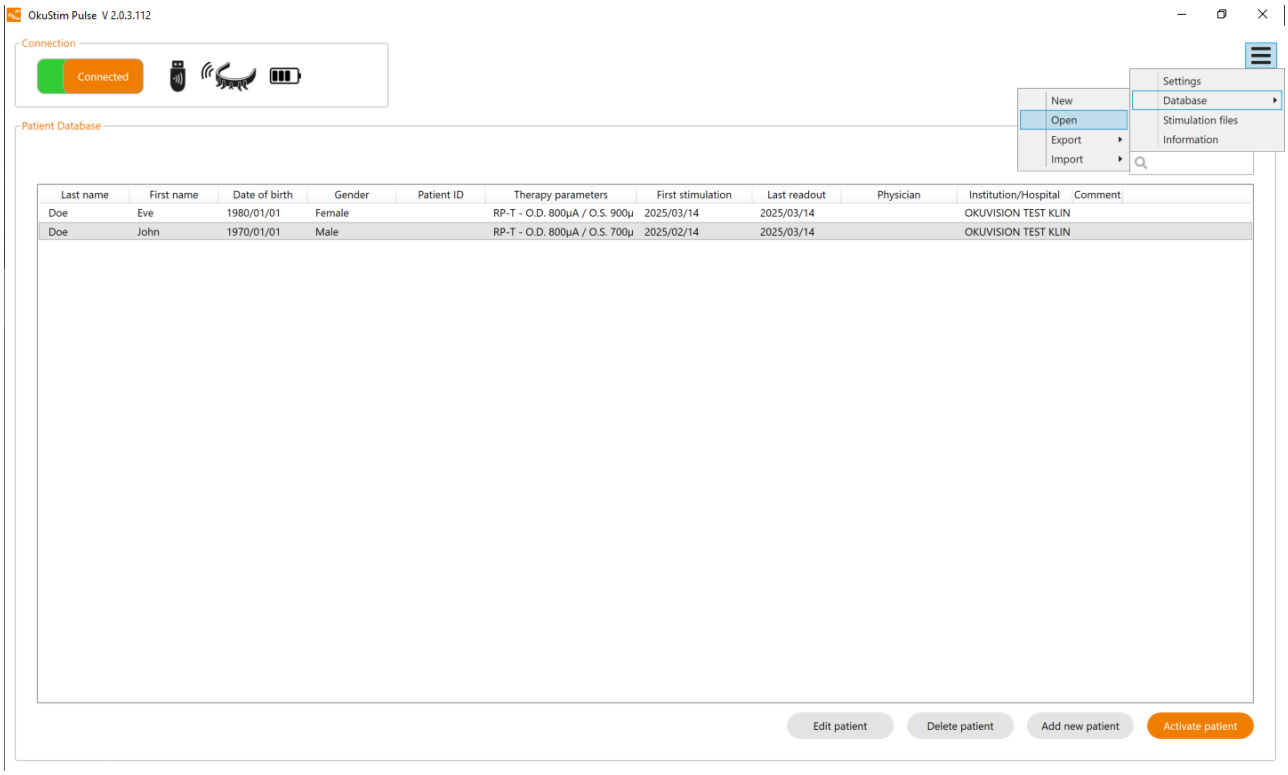
When you click on "OkuStim settings" under Therapy History, you can view the adaptation parameters of a patient. In this way you can quickly view and readjust the OkuStim 2 adaptation parameters:

- If something has been maladjusted on the OkuStim 2 of a patient who is already saved in the database or
- if the patient already saved in the database is to be stimulated as an out-patient.



20 Opening the Database

If you want to open a database in OkuStim Pulse, click on the menu symbol, then on "Database" and then on "Open".

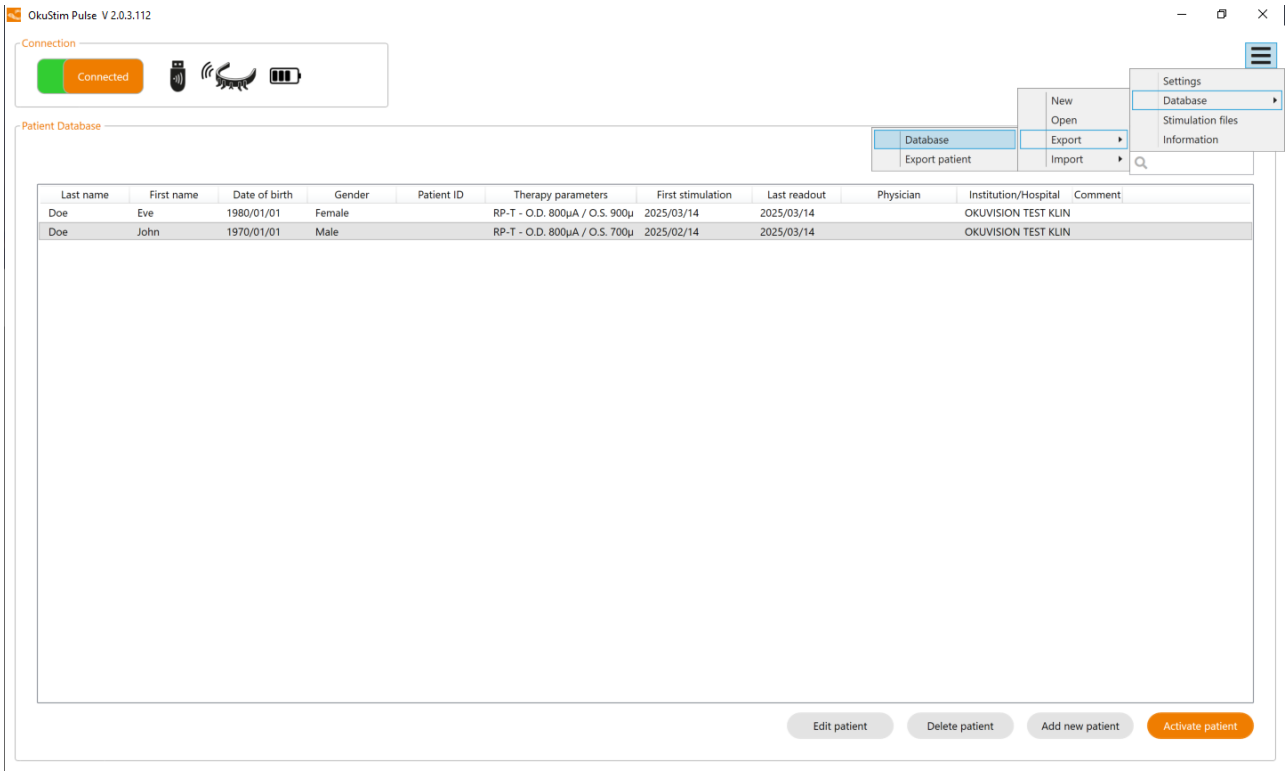


A window opens in which you can view the path of your database and other details.

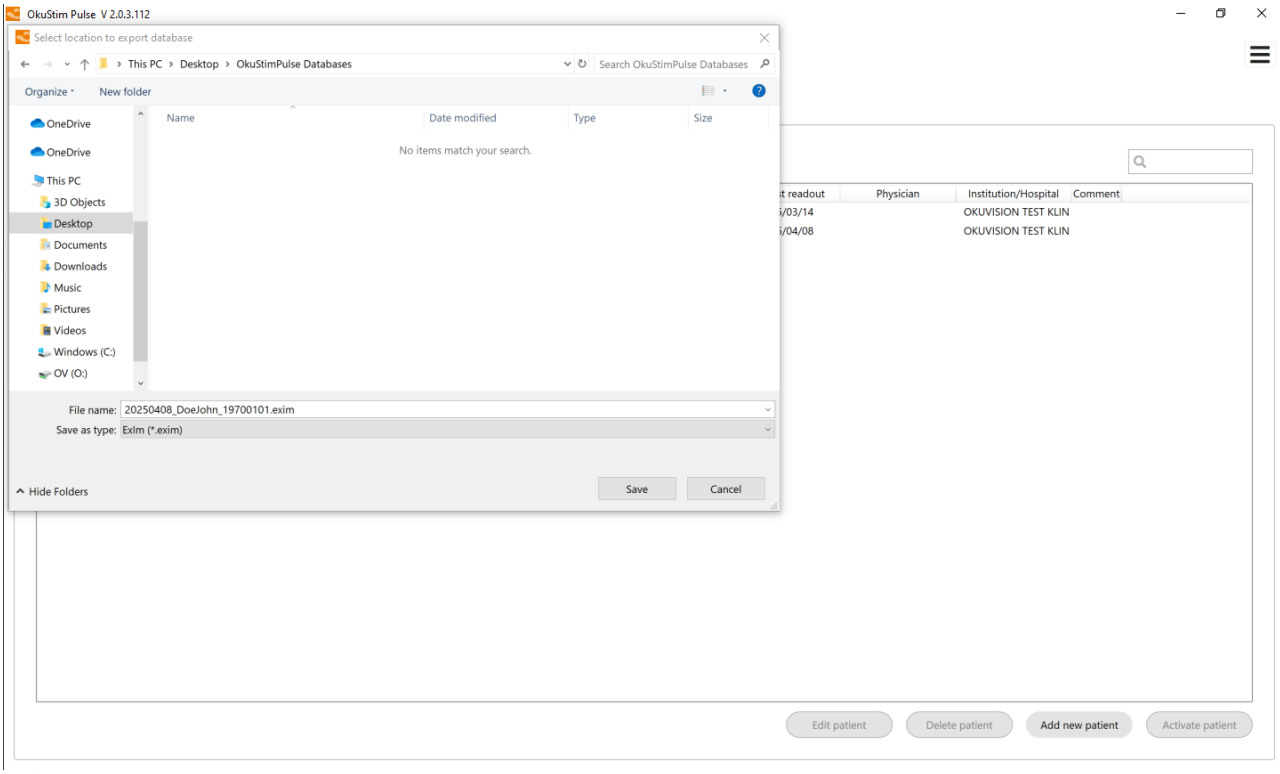
20.1 Exporting the database and/or individual patients

20.1.1 Exporting the complete database

If you want to export the database, select, in the menu, "Database", then "Export" and then "Database" again (see figure).



Select the folder in which you want to save the exported database and click on "Save"; see figure.



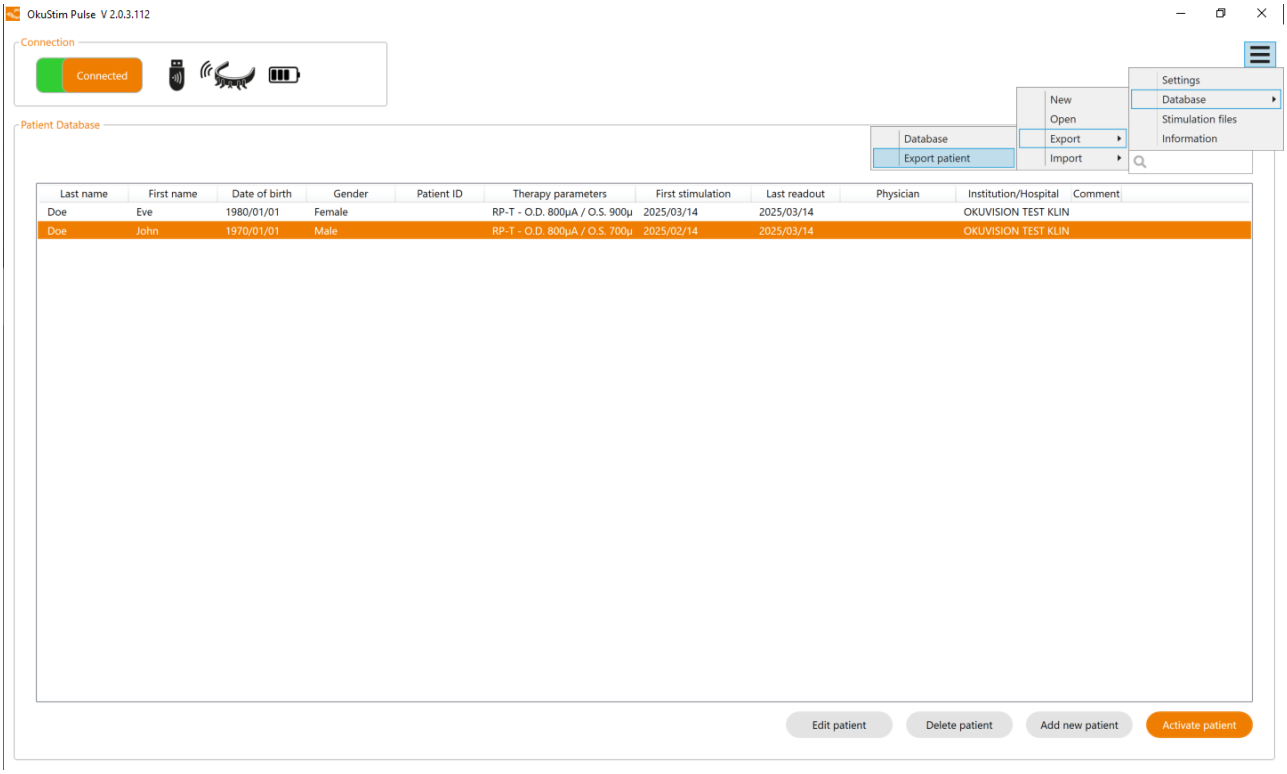
You will then find the database as an **.exim file** in the selected folder.

Note: You can then send the database if necessary or file it on an external storage medium.

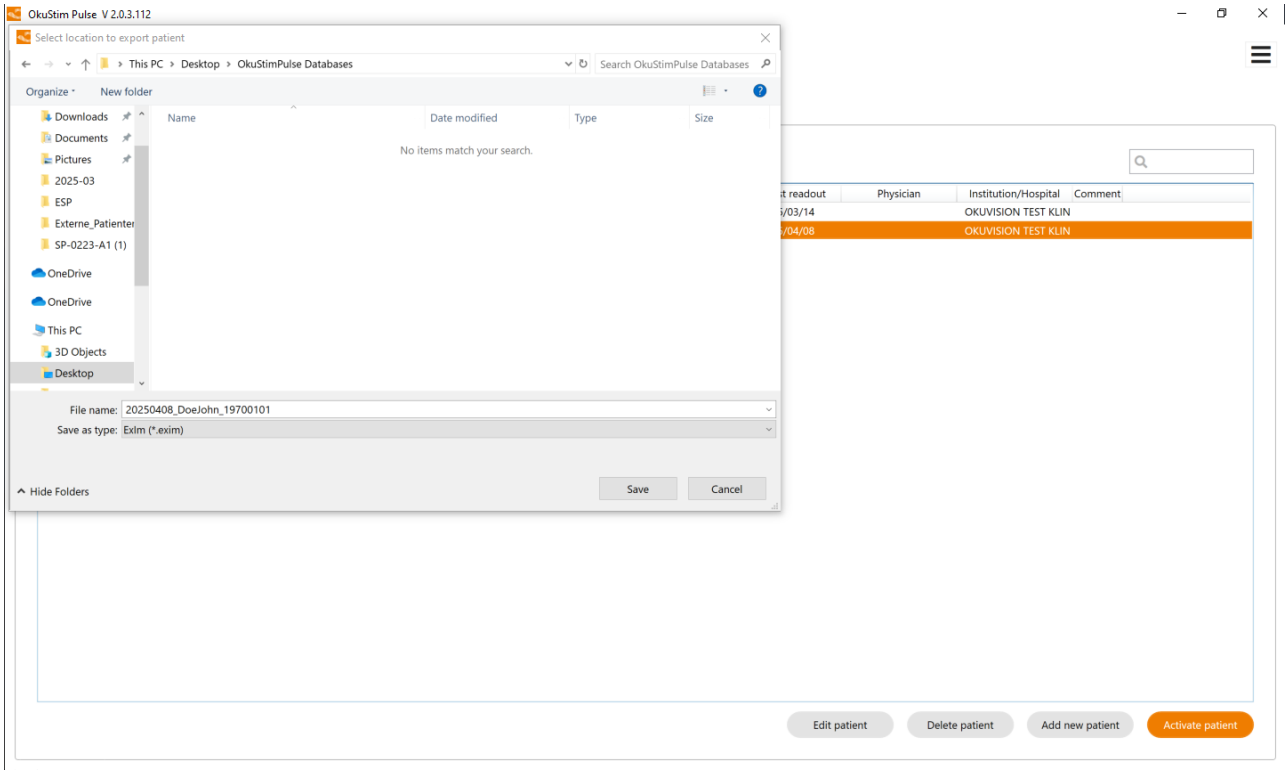
20.1.2 Exporting a patient

If you want to export the data records of individual patients, select the patient, e.g. John Doe (see figure).

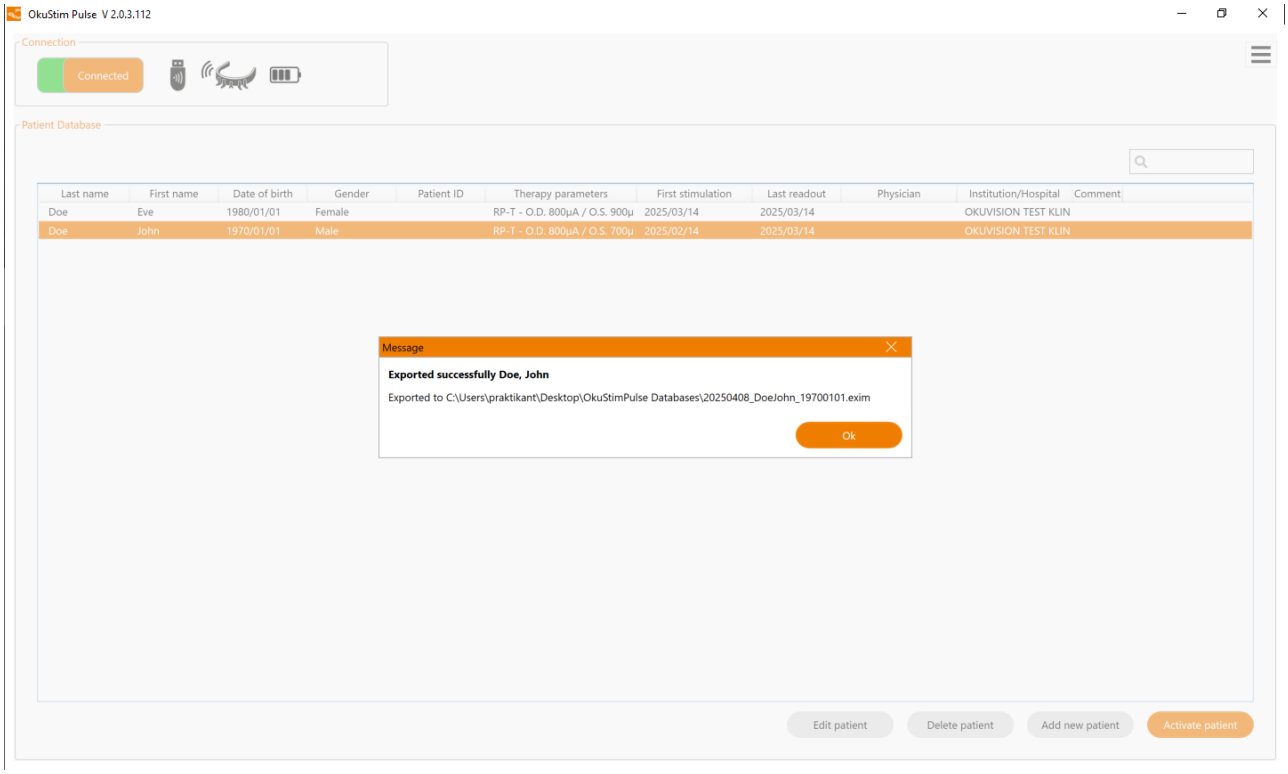
Click on the menu symbol, then on "Database", on "Export" and then on "Export patient"; see figure.



Select the storage location (in this case the "OkuStimPulse Databases" folder) and click on "Save" (see figure).



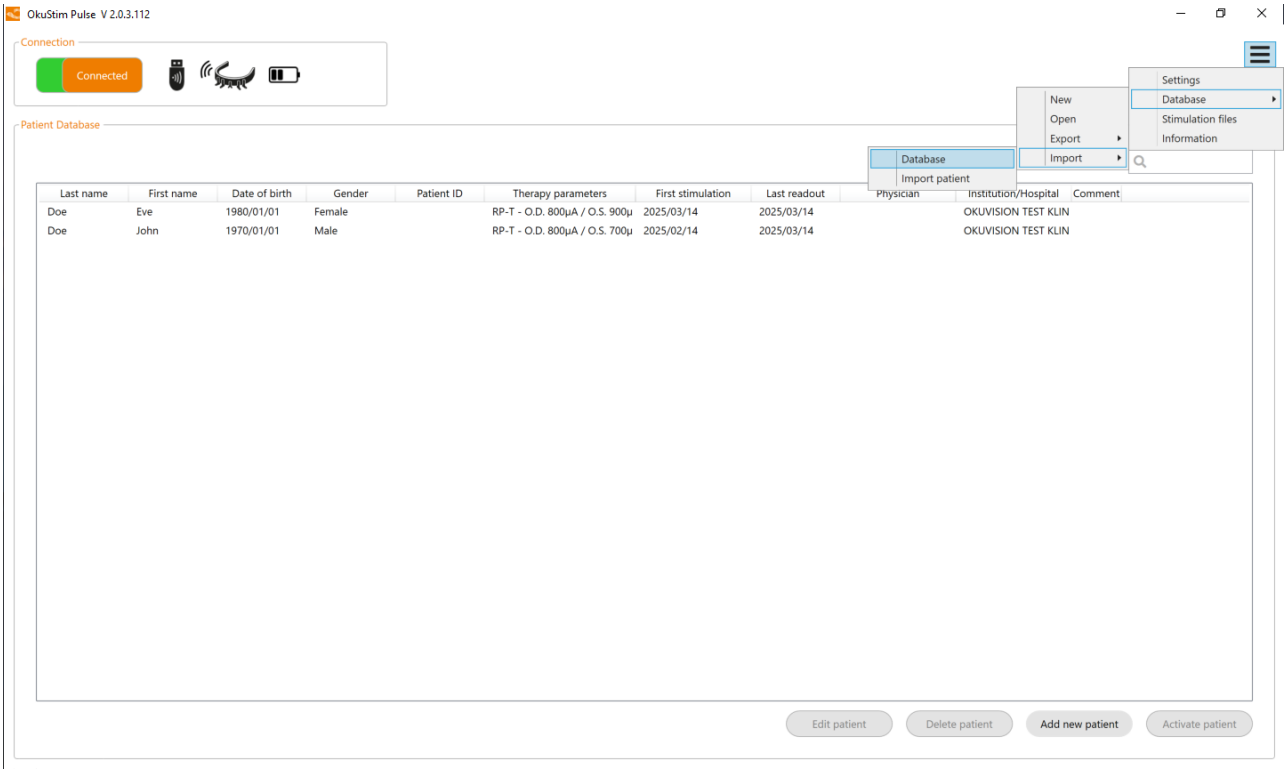
A notification window opens confirming that the patient has been exported (see figure).
Now click on "OK".



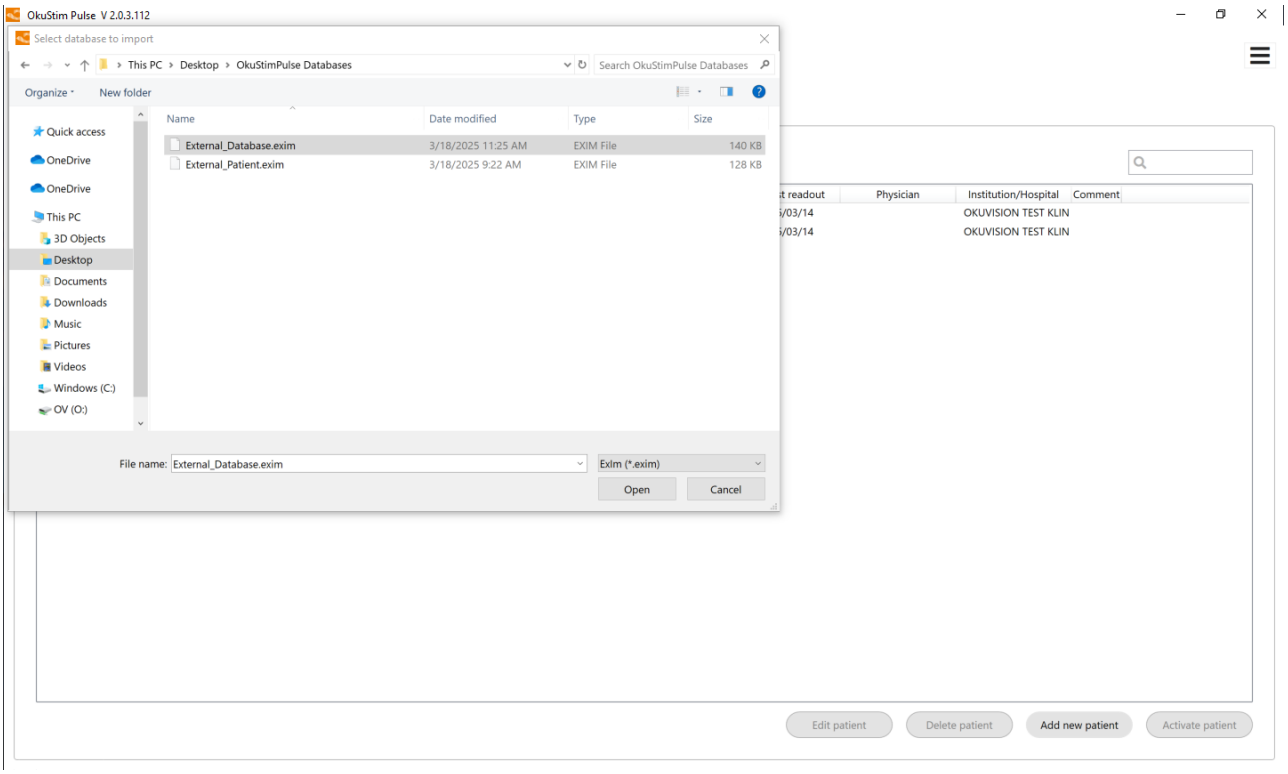
20.2 Importing a database and/or individual patient

20.2.1 Importing a complete database

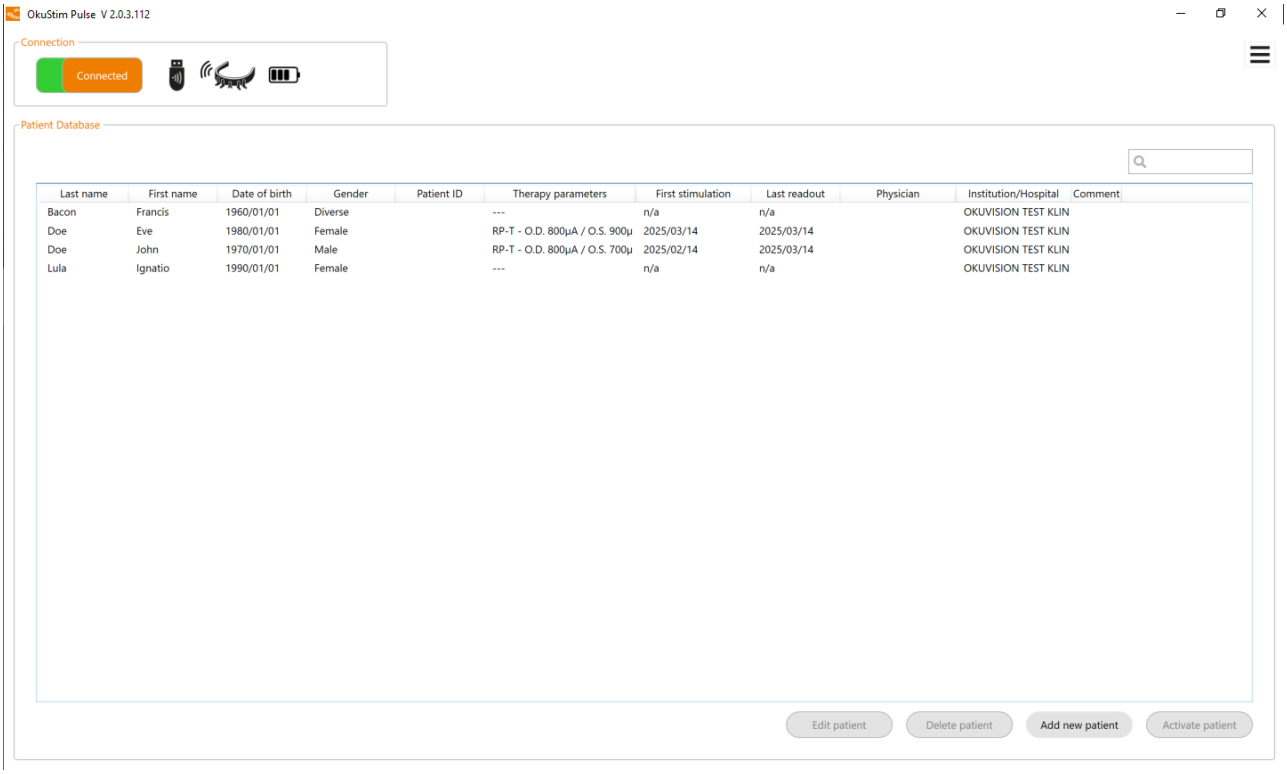
If you want to import a database, click on the menu symbol, then on "Database", on "Import" and then on "Database" (see figure).



Look for the database to be imported (.exim file); in this case it will be in the "OkuStimPulse Databases" folder (see figure). Select the database and click on "Open".

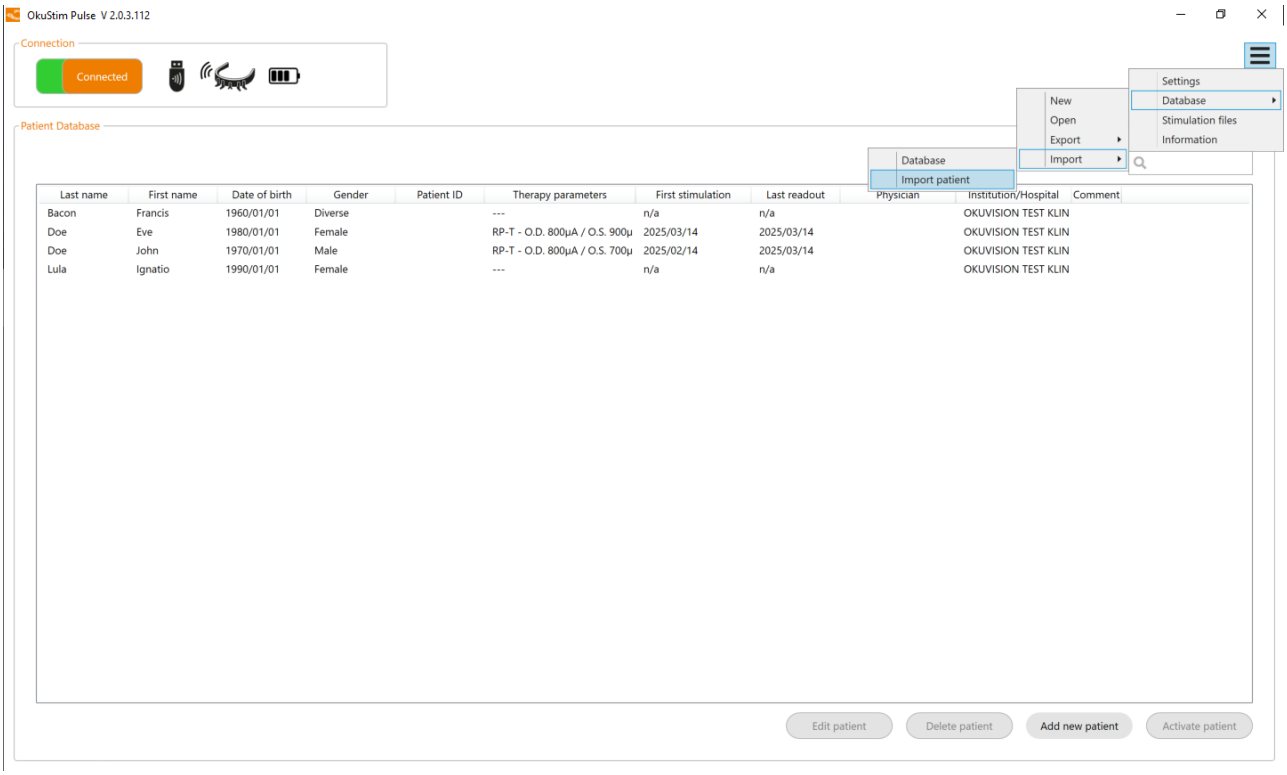


All patients saved in the database will then automatically be imported into the opened OkuStim Pulse database and displayed in the patient database.



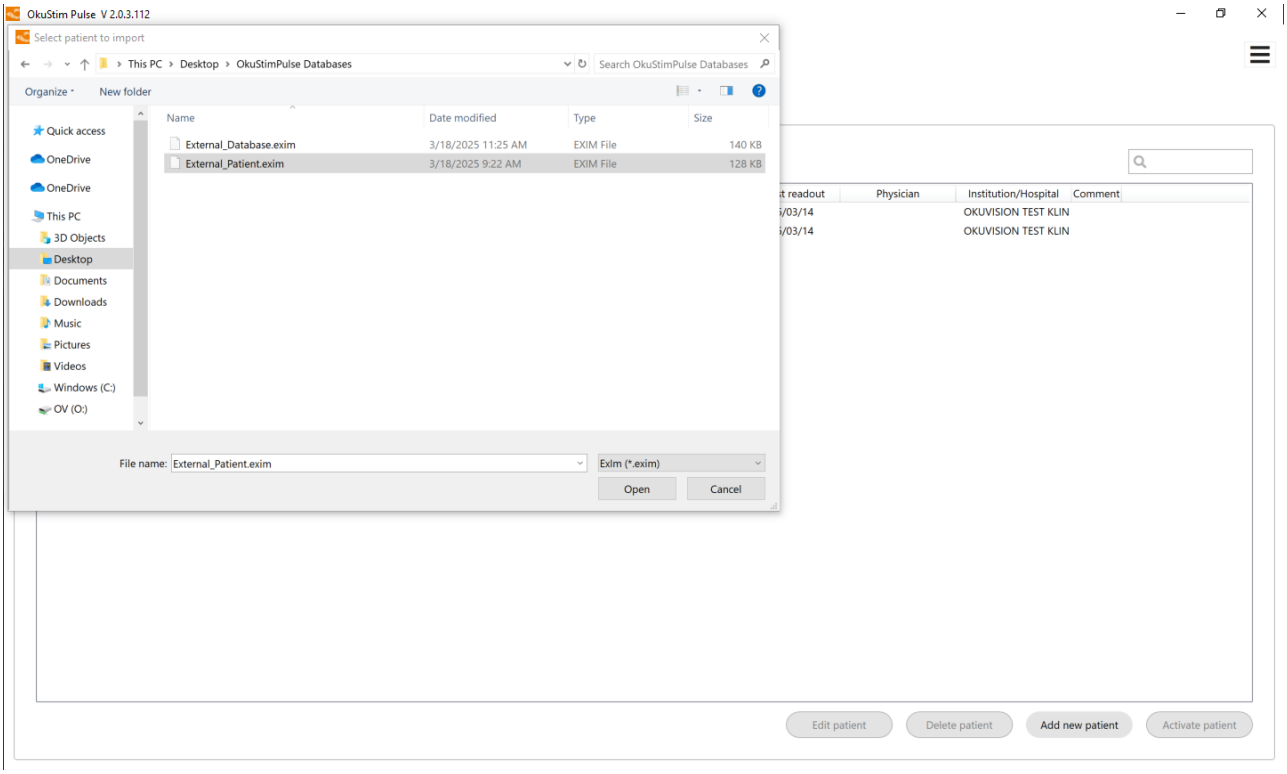
20.2.2 Importing a patient

If you want to import the data records of a patient, click on the menu symbol, then on "Database", on "Import" and then on "Patient" (see figure).



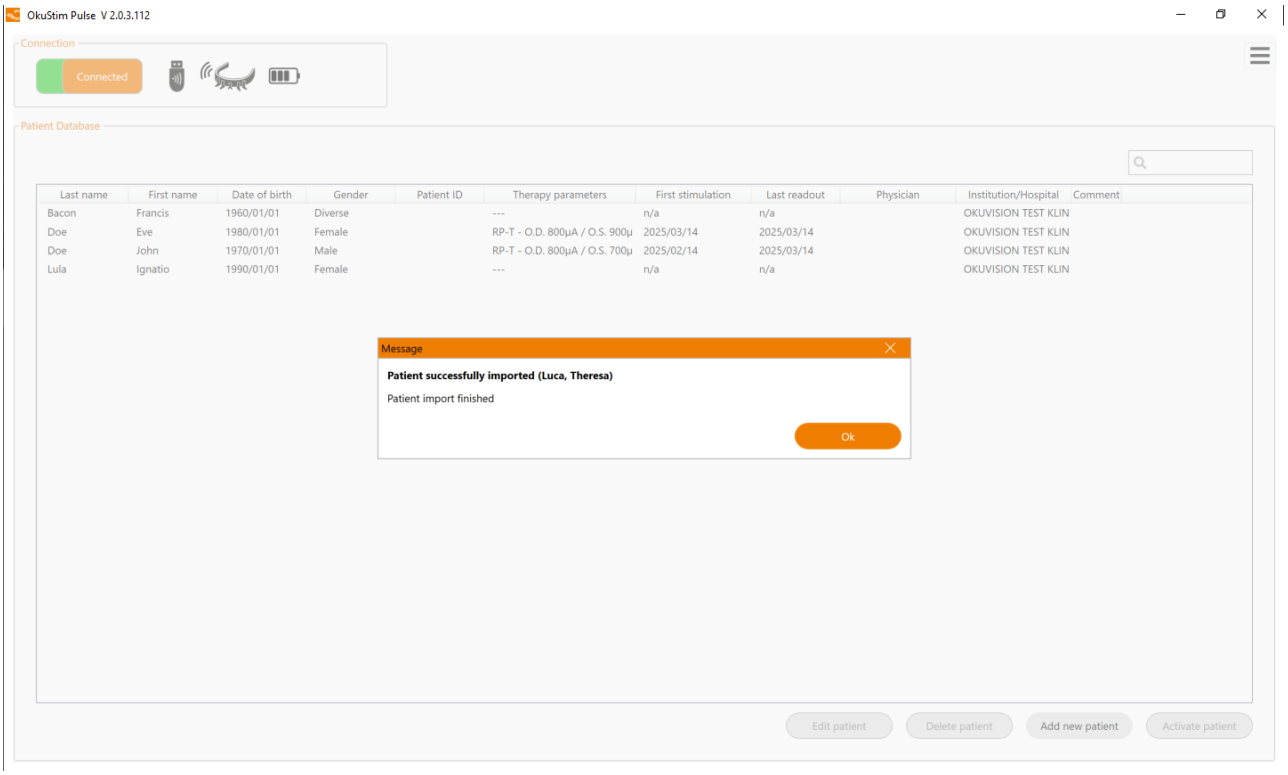
Search for the folder (.exim file) in which the patient to be imported is located (in this case the "OkuStim Pulse Databases" folder); see figure.

Select the patient and click on "Open".

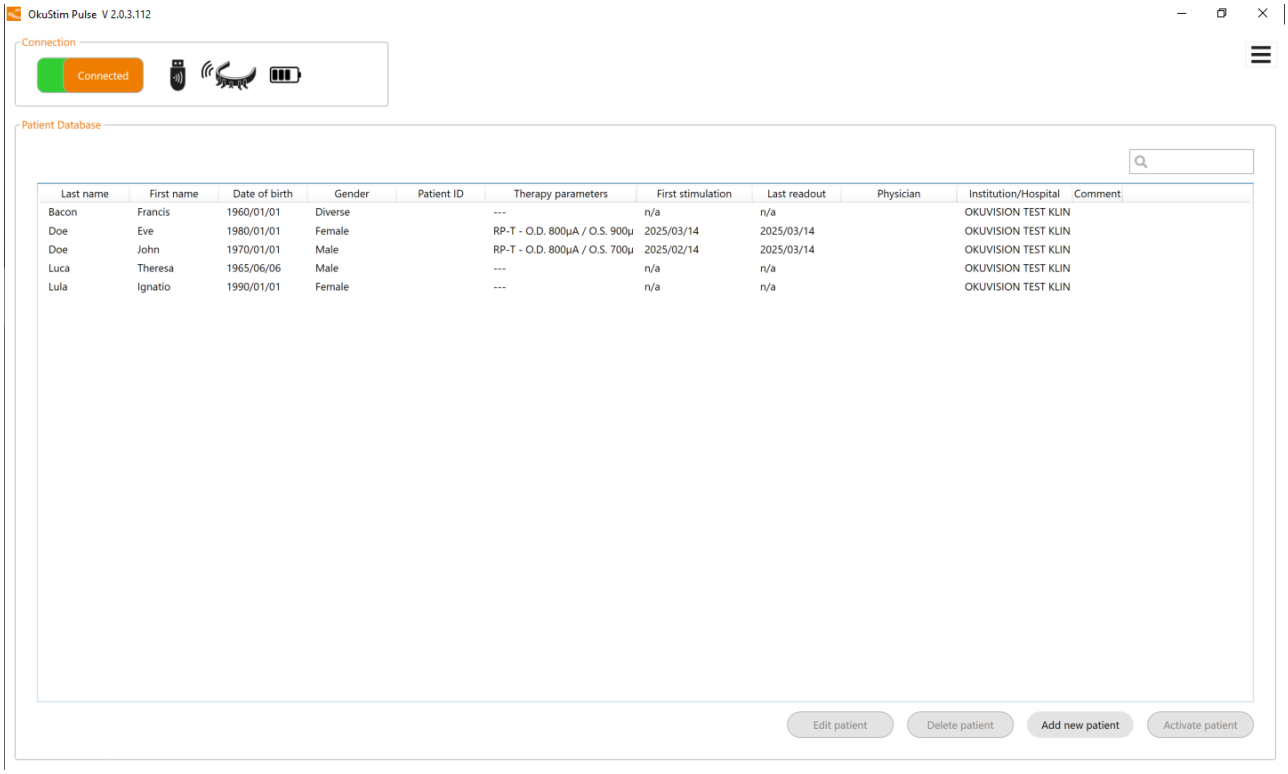


A "Message" window opens confirming that the patient has been imported (see figure).

Now click on "OK".



The imported patient (in this case Theresa Luca) will now be visible in the patient database (see figure).



21 Errors and Troubleshooting

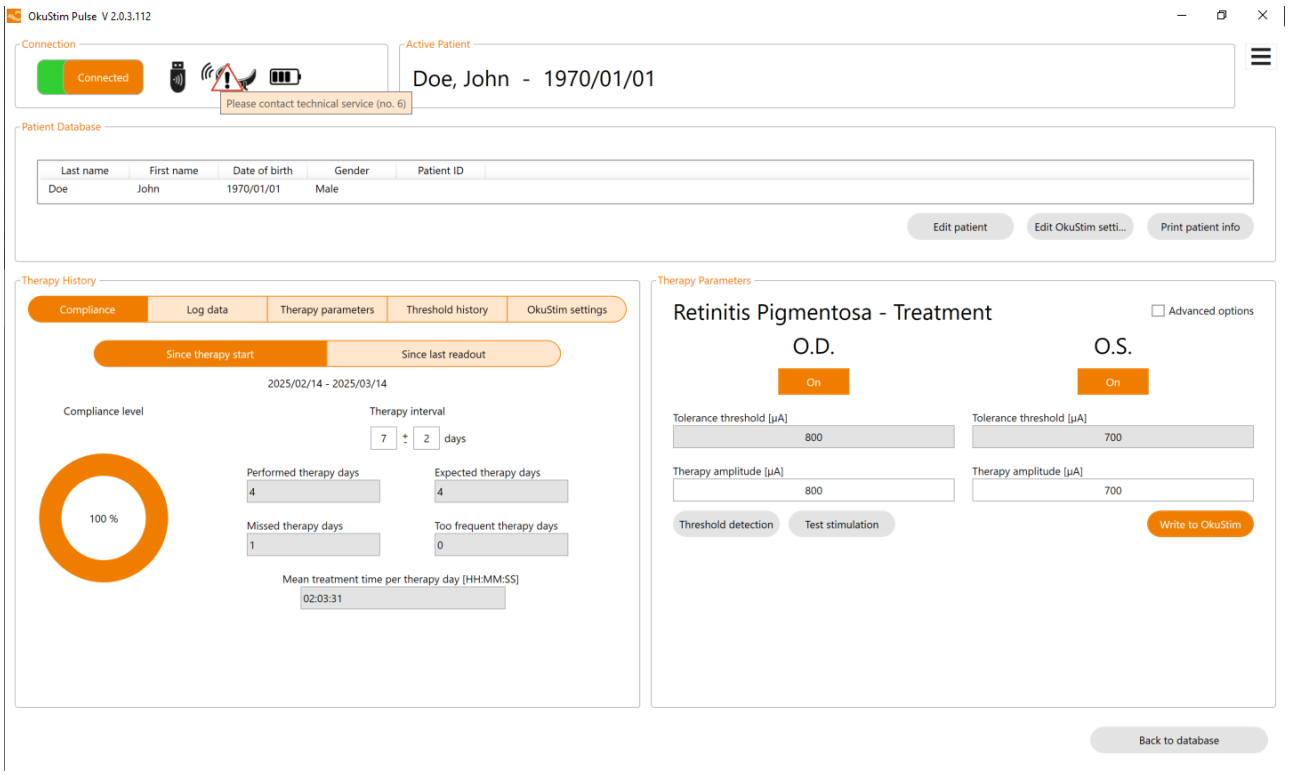
21.1 System errors

If a system error is displayed (see figure below), hover over the OkuStim 2 icon showing the error notification and read the pop-up-note.

Firstly, you can try to switch OkuStim 2 off and then back on.

You can also let the patient touch a metallic object (electrostatic discharge) and again switch OkuStim 2 off and back on.

If the system error continues to appear, please contact Okuvision or your dealer and report the error number.

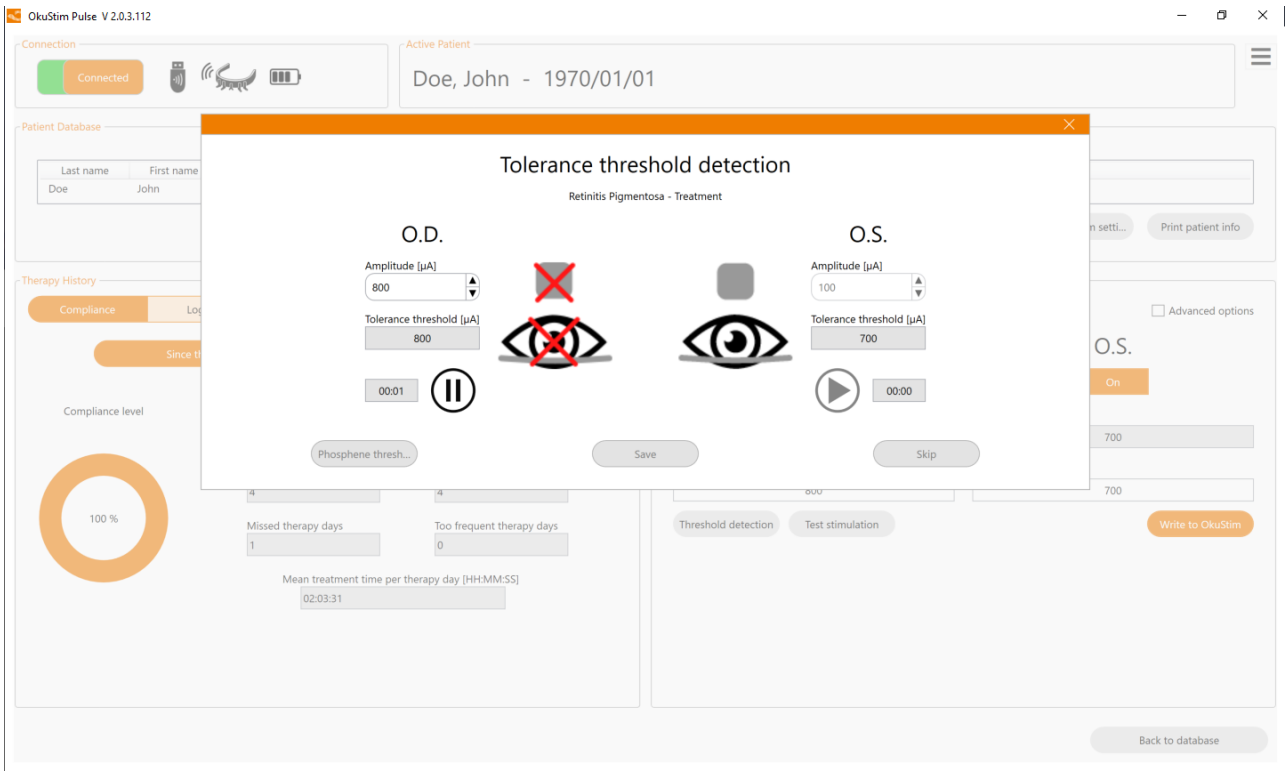


21.2 Resistance errors

21.2.1 Resistance errors during a tolerance measurement

If a resistance error is displayed during a tolerance measurement (see figure below), check whether:

- OkuStim 2 is properly fitted.
- The OkuEl M and counter electrodes have good contact.
- If necessary, see the OkuStim 2 instructions for use for further measures to improve resistance.
- If the OkuStim 2 continues to emit a sound signal, please contact Okuvision or your dealer.

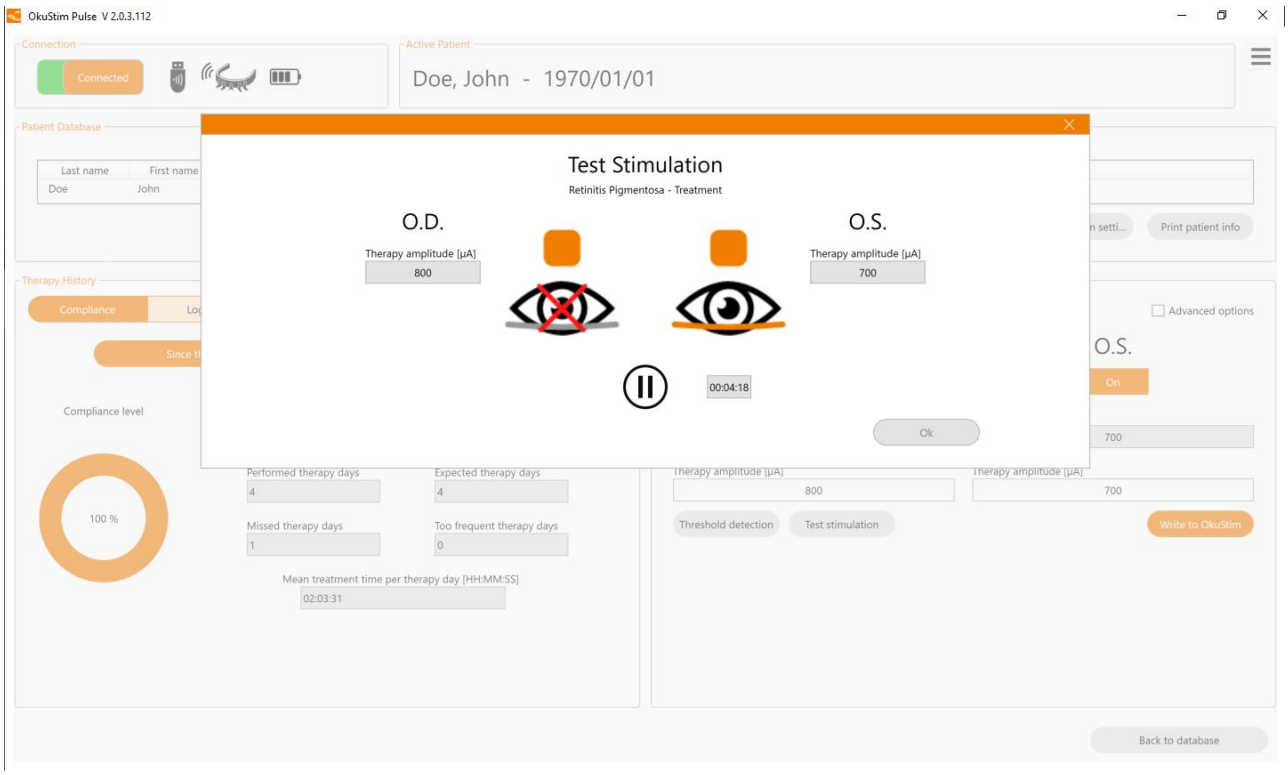


21.2.2 Resistance errors during a test stimulation

If a resistance error is displayed during a test stimulation, check the component(s) of the OkuStim 2 that is/are being displayed in OkuStim Pulse.

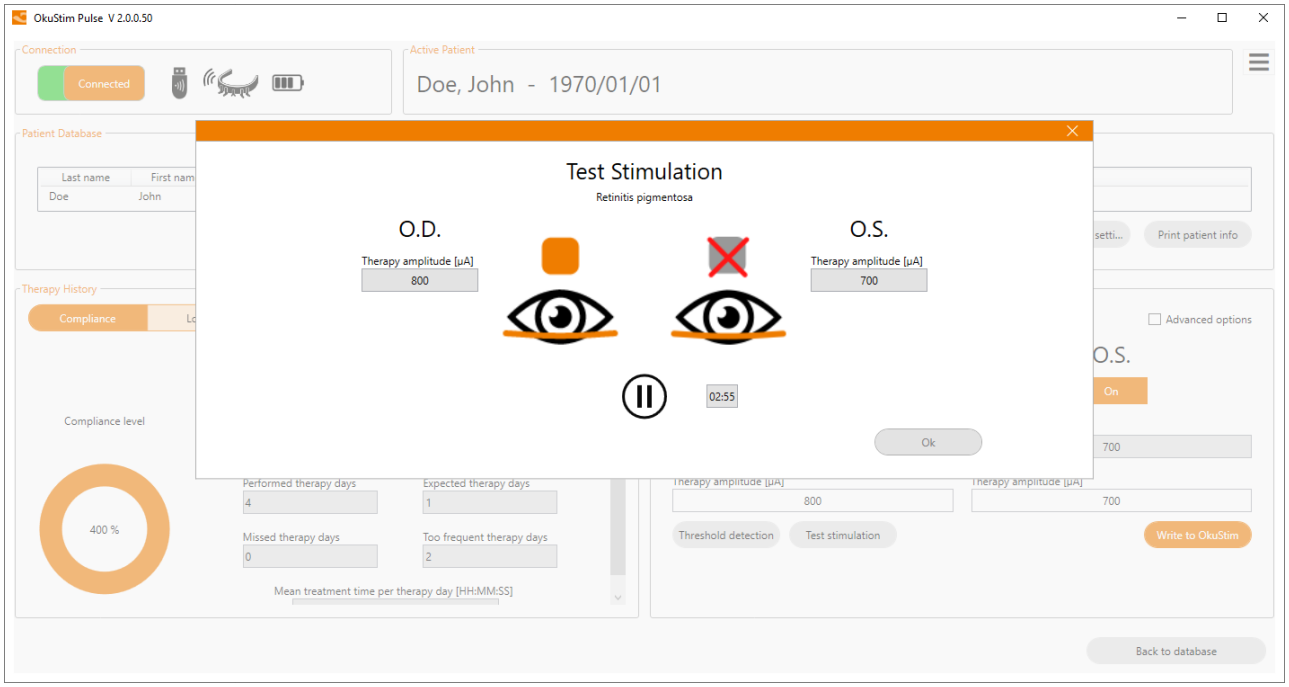
See below for two examples of resistance errors (one for the OkuEl M and one for the OkuEl counter electrode).

Error: Resistance at the right OkuEl M too high (see figure)



- Check whether OkuStim 2 is properly fitted and whether the OkuEl M has good contact (length of contact of electrode thread and eye surface should be at least 1 cm).
- If necessary, moisten the eye once again with tear substitute fluid (e.g. eye drops).
- If the OkuStim 2 continues to emit a sound signal, please contact Okuvision or your dealer.

Error: Resistance at the left OkuEl counter electrode too high (see figure)



- Check whether the counter electrode cable is connected to the OkuEl counter electrode.
- Check whether the OkuEl counter electrode sticks well to the skin.
- Always be sure to thoroughly clean the skin on the forehead where you are attaching the OkuEl counter electrodes, beforehand.
- If the OkuStim 2 continues to emit a sound signal, please contact Okuvision or your dealer.

21.2.3 Errors while connecting/Break of connection of the OkuStim 2 with OkuStim Pulse

If the OkuStim 2 cannot be connected wirelessly with OkuStim Pulse, or if the connection is disrupted during use:

1. Switch the OkuStim 2 off and back on.
2. Check whether the OkuStim Wireless Dongle is plugged in on the PC.
3. Check whether the OkuStim 2 is in connection mode.

In case of a disrupted connection, check the saved data in the software and if necessary, run a test stimulation. In each case, save the data on OkuStim 2 once again; see Chapter 15.

You can also transmit data over the cable connection.

If the problem persists, please contact Okuvision or your dealer.

22 Update

Install the most recent software version as described in Chapter 2.

Note: There is no need to uninstall the previous version because it will be overwritten by installing the new version. The existing patient database will be automatically taken over.

23 Uninstallation

The software can be uninstalled via "Settings" in your operating system or the control panel under "Installed programmes or apps". To do this, select OkuStim Pulse, click on the "Uninstall" function and follow the instructions. Please note that admin rights may be required for this. The existing database is not deleted automatically; if necessary, it must be deleted separately in the storage path.

After uninstallation, a connection with OkuStim 2 is no longer possible.

24 Technical Data

Stimulation parameters

- Symmetric biphasic square-wave pulse (anodic first)
- Frequency 20 Hz
- Pulse duration 10 ms
- Maximum stimulation amplitude 950 µA
- Stimulation duration 30 minutes
- Tolerance measurement function +/- 10 %

Operating and storage conditions for OkuStim 2

Temperature:	+ 5 °C – + 40 °C
Atmospheric humidity:	15 % – 93 % relative humidity (non-condensing)
Air pressure:	600 hPa – 1060 hPa

Operating conditions OkuStim Wireless Dongle

Temperature:	- 40 °C – + 85 °C
Atmospheric humidity:	< 90 % relative humidity

Storage and transport conditions OkuStim Wireless Dongle

Temperature:	- 40 °C – + 85 °C
Atmospheric humidity:	< 90 % relative humidity

Essential performance feature

The OkuStim 2 does not deliver any currents higher than 10 mA. Loss of essential performance may result in serious injury. The essential performance feature is monitored and maintained continuously and automatically by the OkuStim 2 hardware.

The OkuStim 2 performs self-checks and does not have to be tested externally. External testing is not possible.

25 Disposal of Old Device

Used OkuEl Ms as well as OkuEl counter electrodes may be disposed of in general waste.

Further information is available from Okuvision GmbH or your OkuStim 2 System point of sale.

Disposal of electrical and electronic devices

The crossed-out dustbin means that you are legally obliged to collect such devices separately from unsorted municipal waste. Disposal with the general waste or the household recycling waste is prohibited. If the products contain non-rechargeable and rechargeable batteries that are not permanently built in, these must be removed prior to disposal and disposed of separately as batteries.

Data protection

We advise all end users of electrical and electronic equipment that they are responsible for deleting personal data from old equipment they wish to dispose of.

Further information is available from Okuvision GmbH or your OkuStim 2 System reference source.

26 Accessories

Part number	Product name
OK200007	OkuStim® Pulse Kit (contains OkuStim Pulse® Software)
OK200000	OkuStim® 2 System
OK200004	OkuEl® M Package
OK200009	OkuStim® 2 Nosepad Kit

OkuStim 2 System is available in different variants. Ask your local distributor for your required configuration.

27 Notes on Electromagnetic Compatibility

During operation of the OkuStim 2 System, compliance with the EMC rules and regulations is absolutely mandatory. This device has been tested and found to comply with the requirements for a medical electrical device according to CISPR 11, Group 1, Class B. The applicable limit values are intended to offer appropriate protection against electromagnetic interference when the device is operated in a domestic environment or in medical practices in residential areas. This device generates and uses radiofrequency energy and may also emit such; if it is not used in compliance with the operating manual, it may cause harmful interference with radio communications.

The OkuStim 2 System is suitable for use in clinics, private practices or a home environment.

Normal condition and initial error condition (EMC):

The OkuStim 2 System delivers stimulation currents with preset current intensities. In case of an error that leads to delivery of stimulation currents deviating from the set value, the device is able to switch off the stimulation, although the essential performance feature is still ensured.

Warning:	
	Use of the OkuStim 2 System immediately next to other devices or together with other devices in stacked form should be avoided, because this could cause a defective mode of operation. If use is nevertheless necessary in the manner described above, this device and the other devices should be monitored in order to be certain that they are working properly.
Warning:	
	The use of accessories and cables other than those specified in the accessories list or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this system and cause it to operate defectively.
Warning:	
	Portable RF communication devices (incl. accessories such as antenna cables or external antennas) must be kept at least 30 cm (12 inches) away from the OkuStim 2 System and all of its components, including the cables. Otherwise, the performance of the system could be compromised. See table in this section.

The system is intended for use in an electromagnetic environment as specified below. The purchaser or the user of the system must ensure that it is used in such an electromagnetic environment.

Table 1 – IEC 60601-1-2:2014: Electromagnetic immunity – ESD, conducted and radiated disturbances

Immunity Test	Test level	Compliance Level	EMC information
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV and ±15 kV air discharge	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV and ±15 kV air discharge	Floors should be made of wood, concrete or ceramic tile. If floors consist of synthetic material, the relative humidity must be at least 30 %.
Conducted RF disturbances according to IEC 61000-4-6	3 V_{RMS} 150 kHz – 80 MHz 6 V_{RMS} 150 kHz – 80 MHz within ISM and amateur frequency bands 80 % AM at 1 kHz	3 V_{RMS} 150 kHz – 80 MHz 6 V_{RMS} 150 kHz – 80 MHz within ISM and amateur frequency bands 80 % AM at 1 kHz	Portable and mobile RF communication devices should not be used closer than 30 cm (12 inches) to any part of the system, including the cable.
Radiated RF disturbances according to IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	
Magnetic fields with energy frequencies IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz; 60 Hz	
Magnetic fields at close range IEC 6100-4-39	30 kHz, Modulation CW, 8 A/m 134.2 kHz, Pulse modulation 2.1 kHz, 2.1 kHz, 65 A/m 13.56 MHz, Pulse modulation 50 kHz, 7.5 A/m	30 kHz; Modulation CW, 8 A/m 134.2 kHz, Pulse modulation 2.1 kHz, 2.1 kHz, 65 A/m 13.56 MHz, Pulse modulation 50 kHz, 7.5 A/m	

Table 2 – IEC 60601-1-2:2014: Immunity to radio-frequency electromagnetic fields in the direct vicinity of wireless communication devices						
Test frequency [MHz]	**Band [MHz]**	**Radio channel**	**Modulation**	**Separation distance [m]**	**Maximum output power [W]**	**Immunity test level [V/m]**
385	380 - 390	TETRA 400	Pulse modulation at 18 Hz	0.3	1.8	27
450	430 - 470	GMRS 460, FRS 460	5 kHz deviation 1 kHz sine wave	0.3	2	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation at 217 Hz	0.3	0.2	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation at 18 Hz	0.3	2	28
1720 1845 1970	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation at 217 Hz	0.3	2	28
2450	2400 - 2570	Bluetooth, Wi-Fi, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation at 217 Hz	0.3	2	28
5240 5500 5785	5100 - 5800	Wi-Fi 802.11a/n	Pulse modulation at 217 Hz	0.3	0.2	9

Table 3 – IEC 60601-1-2:2014: Immunity to magnetic fields in the near field		
Test frequency [kHz/MHz]	**Modulation**	**Immunity test level [A/m]**
30.0 kHz	CW	8.0
134.2 kHz	Pulse modulation at 2.1 kHz	65.0
13.560 MHz	Pulse modulation at 50.0 kHz	7.5

28 Notes on Radio Technology

Radio module: 2611011021000, Würth Elektronik eiSos GmbH & Co. KG
Contains FCC ID: R7T1101102
Frequency: 2445 MHz (±0.5 MHz)
Modulation: GFSK
Power (e.r.p.): -16 dBm (radio module integrated in the OkuStim 2)
Power (e.r.p.): +8 dBm (OkuStim Wireless Dongle (Article no. OK000133))

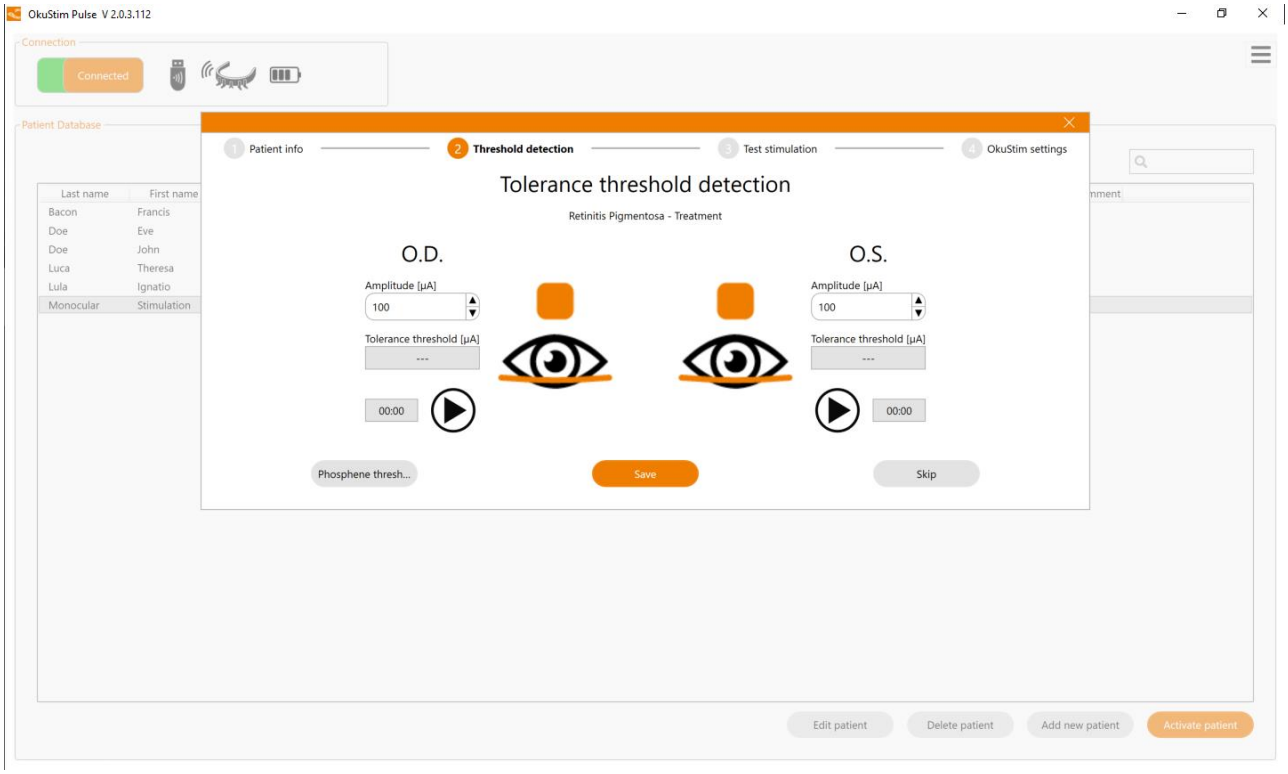
This device complies with Part 15 of the FCC Rules. Operation depends on the following two conditions: this device is not permitted to cause any harmful interference and this device must accept all received interference, including interference that may cause undesired operation.

Appendix 1: Monocular stimulation

If you are treating a patient whom you want to stimulate monocularly for medical or other reasons, proceed as described below.

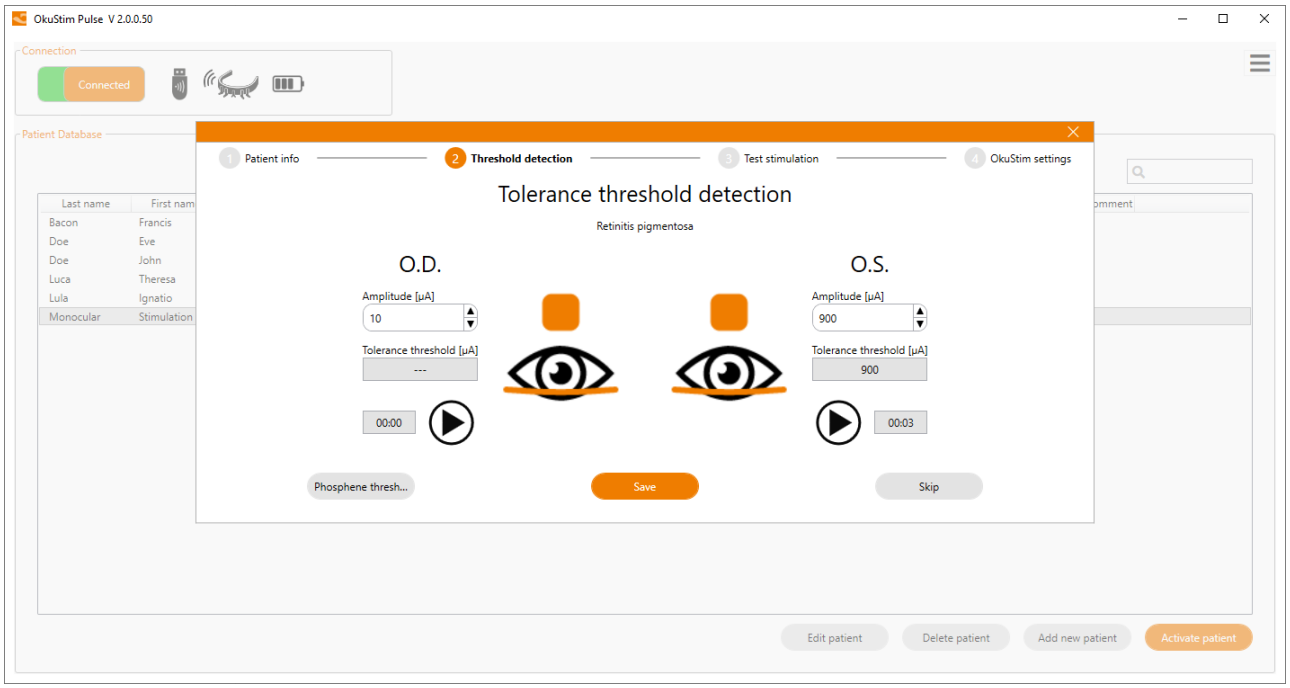
Create a new patient if necessary (as described in Chapter 10).

After you have created and saved the patient, the "Tolerance Threshold detection" window opens (see figure).



Start measuring the tolerance threshold for the selected eye (e.g. OS).

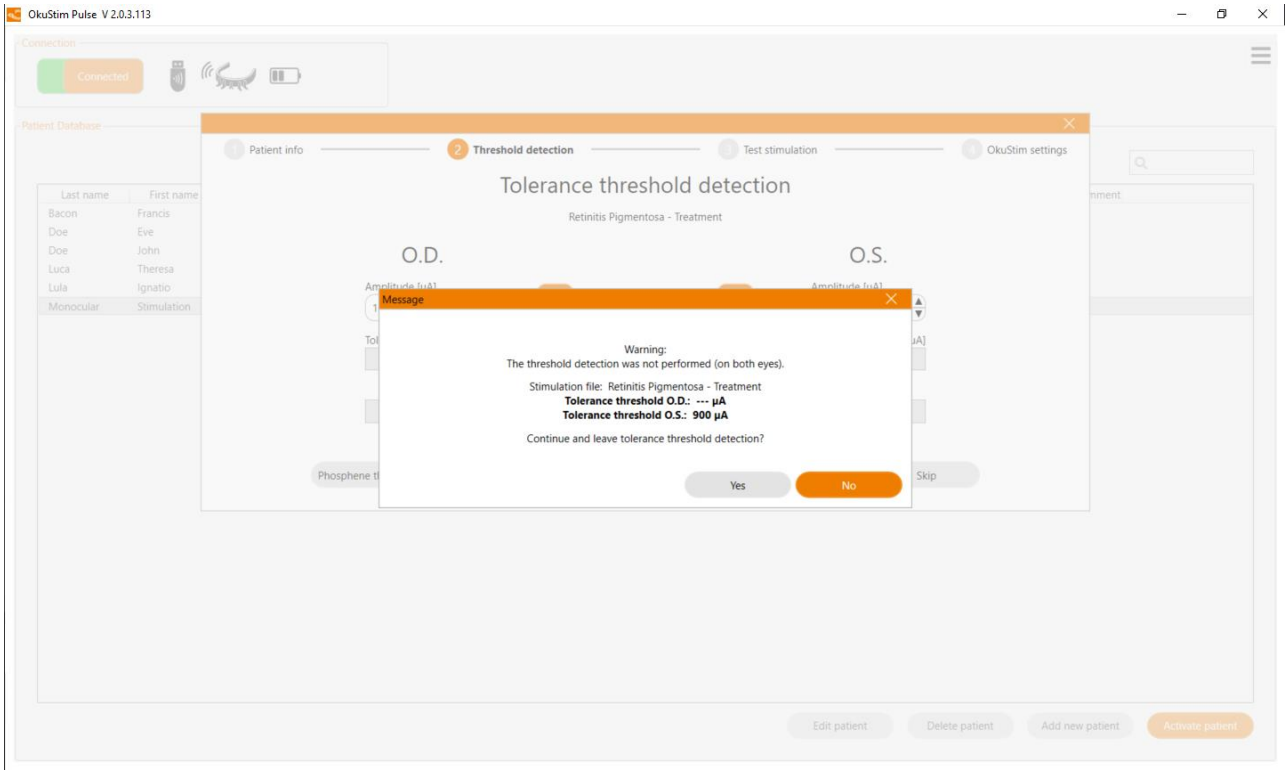
Proceed as described in Chapter “Tolerance threshold measurement procedure”.



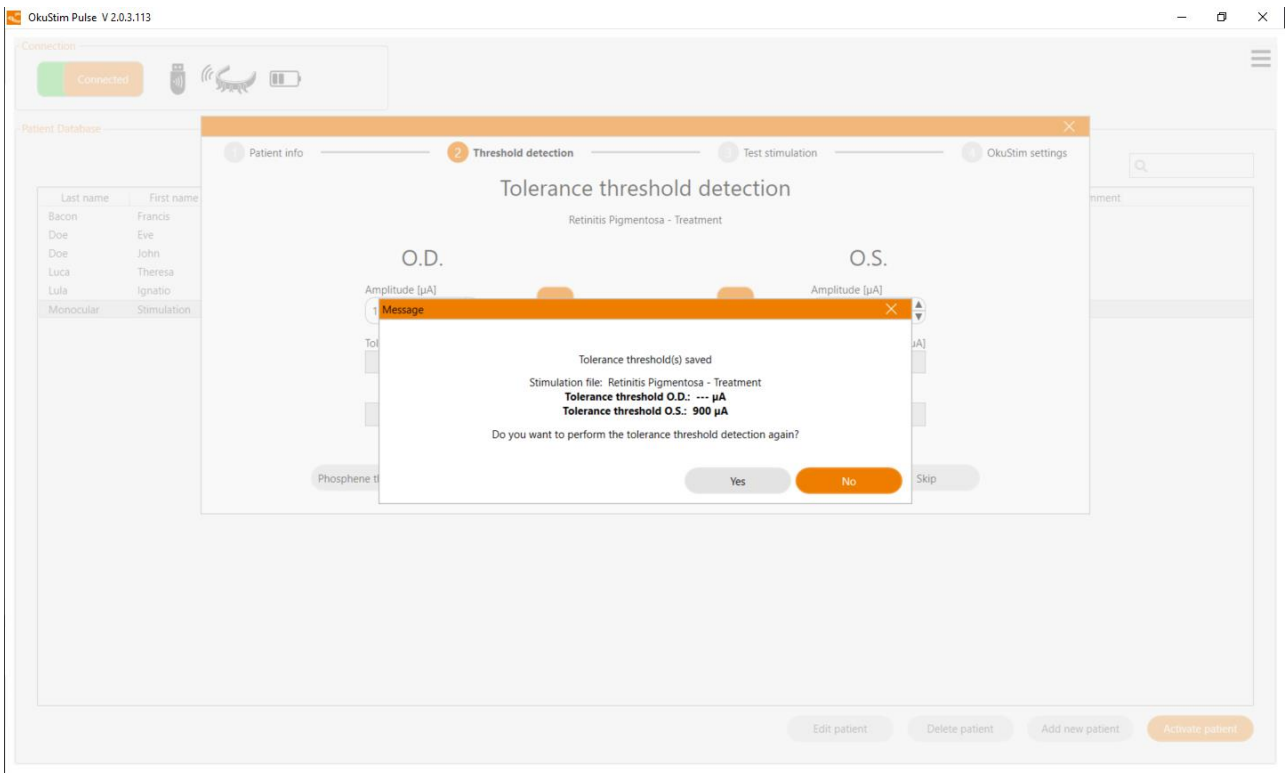
You have now found the tolerance amplitude for the selected eye (OS) (in this case 900 µA; see figure).

Click on "Save" in order to define this value.

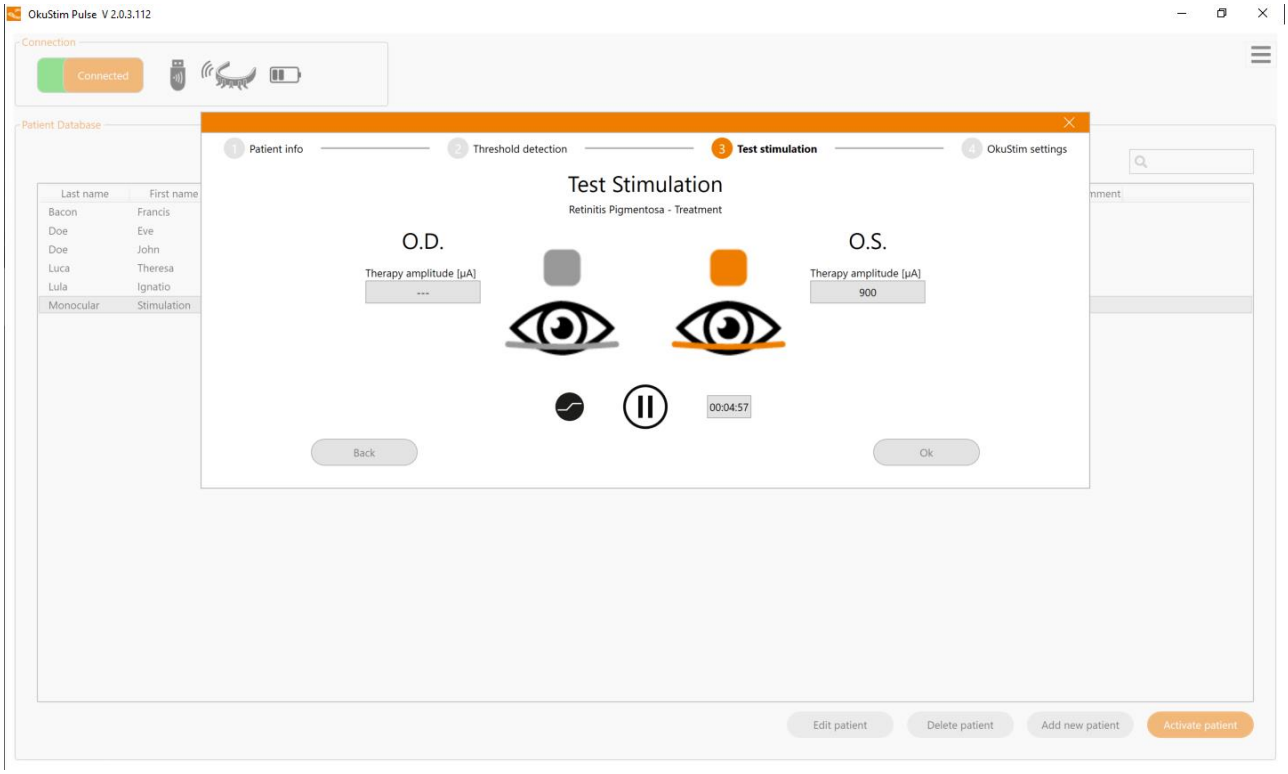
A confirmation window opens with a warning, in which you can see that no tolerance value has been defined for OD (see figure).



Confirm by clicking on "Yes". In the next window click on "No" to confirm the tolerance threshold definitively.



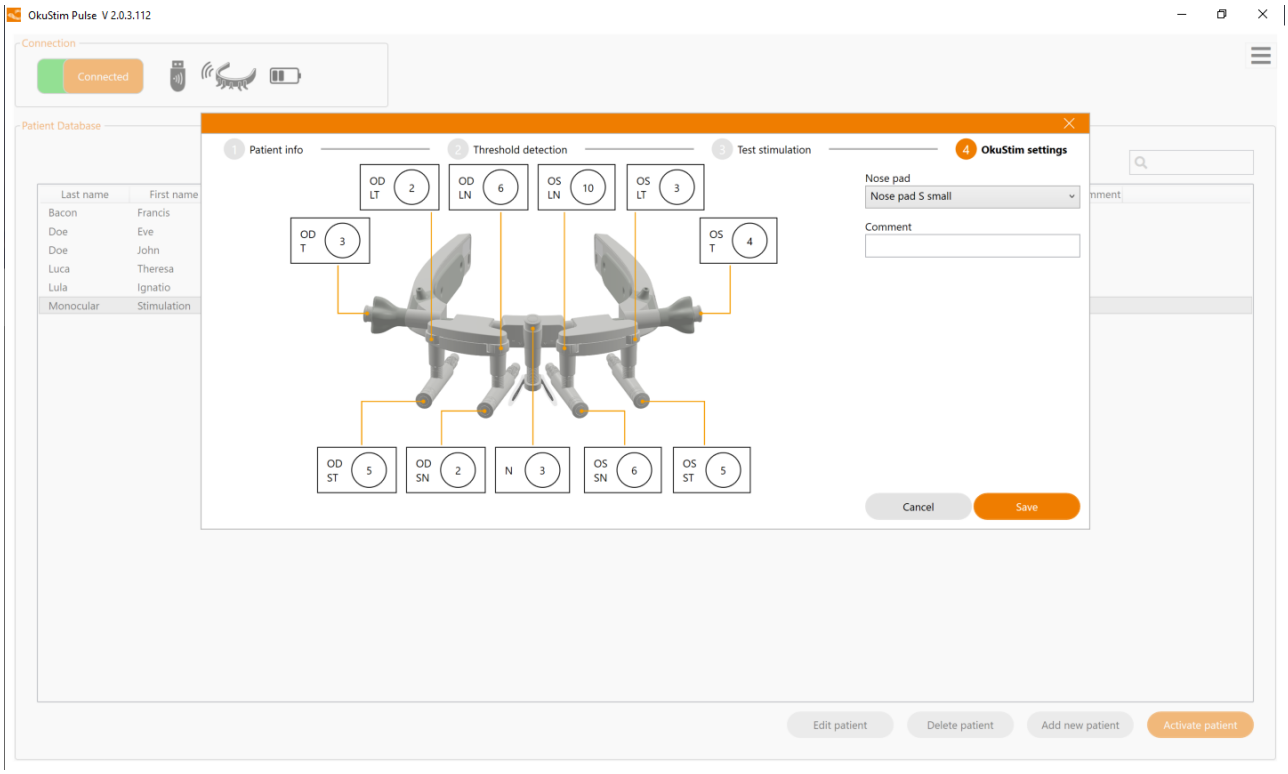
The "Test stimulation" window opens automatically. You can now test the monocular stimulation (see figure).



Test the stimulation and click on "OK" if this seems acceptable for the patient.

Note: If the patient feels pain, click on "Back" and remeasure the tolerance threshold. For this purpose, reduce the amplitudes.

After you have clicked on "OK", the "OkuStim Settings" window opens, in which you can enter the adaptation parameters (see figure).



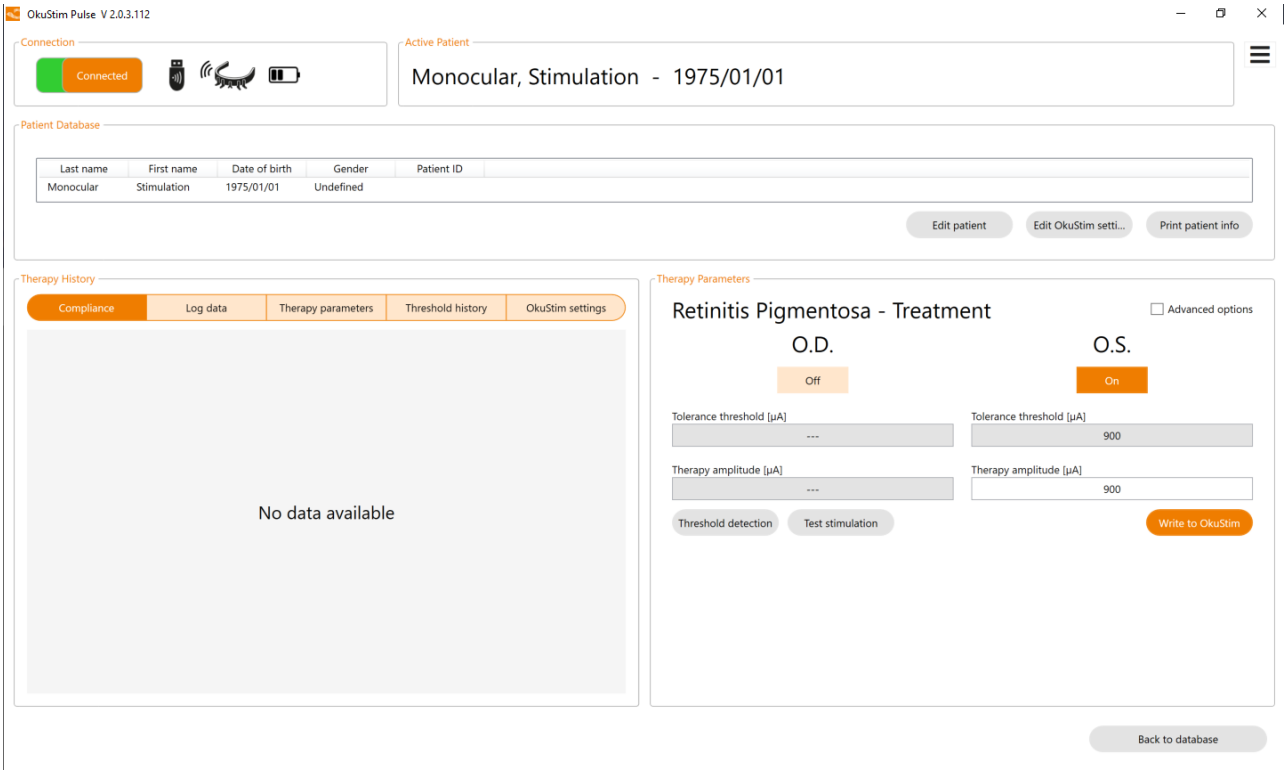
Proceed as in Chapter 13 and click on "Save" when you are done.

Note: It is not necessary to fit the OkuStim for both eyes if the patient will not receive binocular stimulation (e.g. for medical reasons).

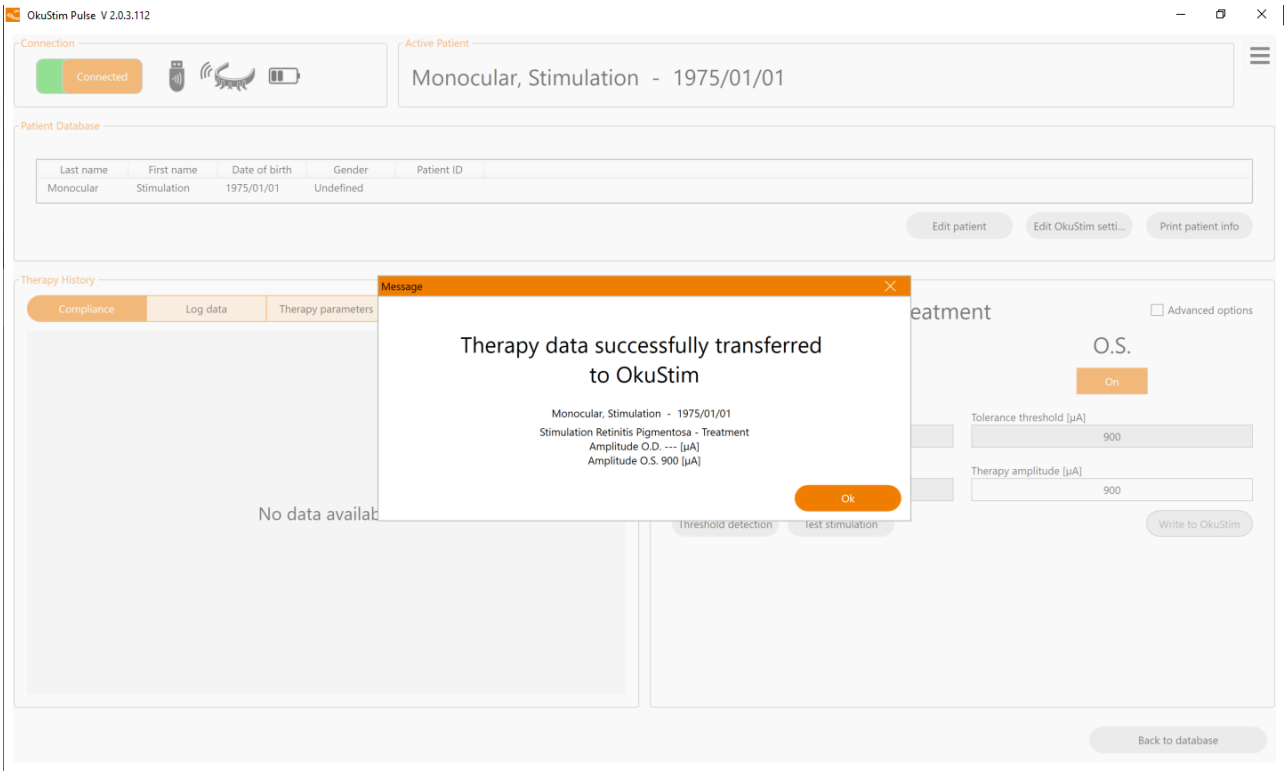
After clicking "Save", you will automatically be taken to the activated patient view.

The right eye (OD) is pre-set to "Off". Both the "Tolerance threshold [µA]" and "Therapy amplitude [µA]" fields are "blocked". Also, no changes can be made in the "Therapy amplitude [µA]" field.

Note: Patients already saved in the database who have previously received binocular stimulation can be given monocular stimulation by deactivating one eye. To do this, click on the orange 'On' button in the activated patient view (see Chapter 19.2.1).

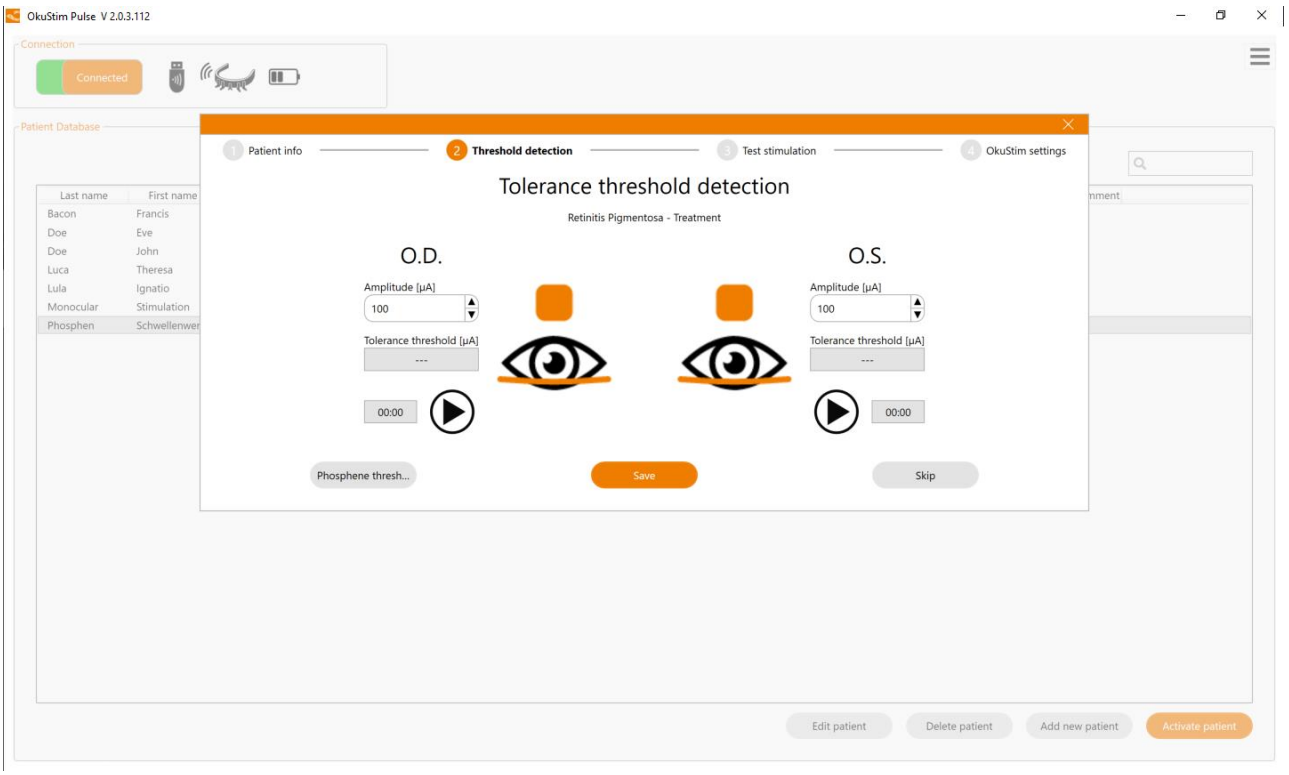


Now click on "Write to OkuStim", in order to program the OkuStim 2 and to save the data (see figure).
Click on "OK" to confirm this definitively (see figure).

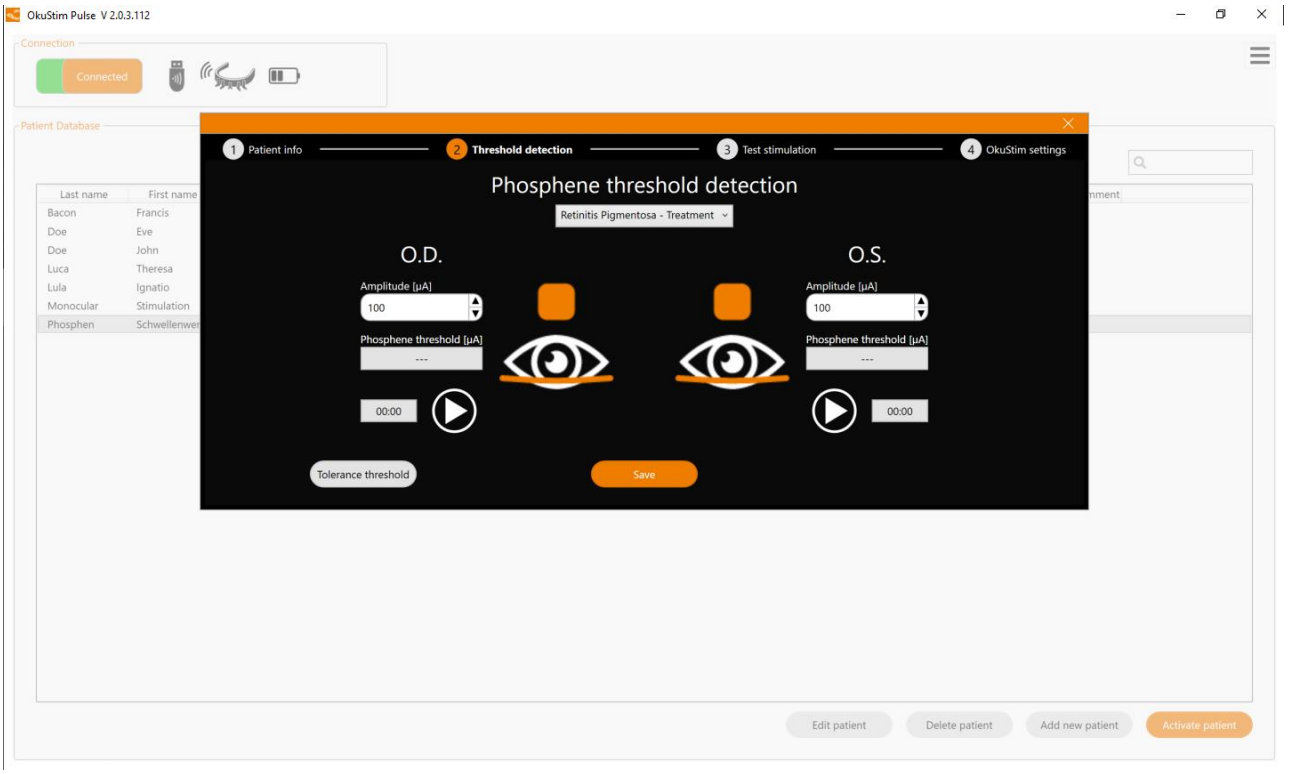


Appendix 2: Phosphene threshold measurement

Create a new patient if necessary. See Chapter 10 concerning how you can proceed for this purpose. Follow the steps up to "Tolerance threshold detection". The following window opens; see figure.



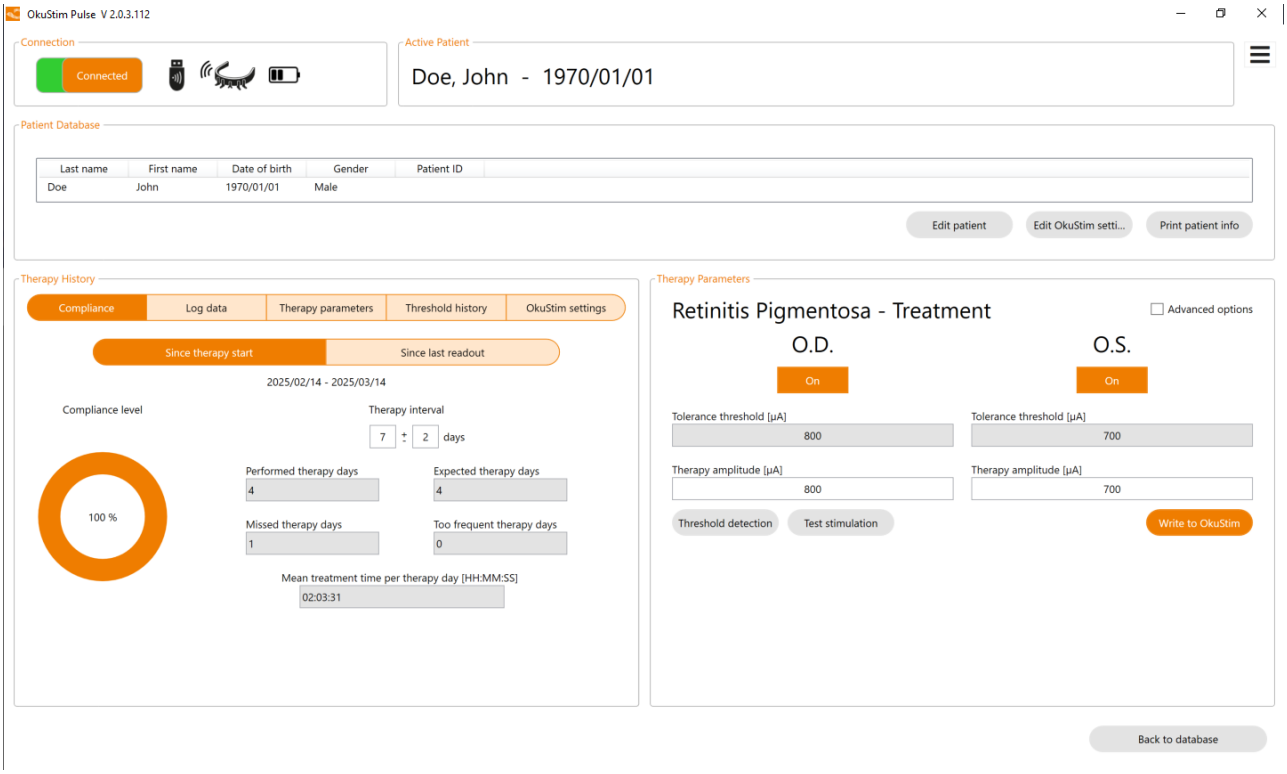
Now click on "Phosphene threshold", in order to start the "Phosphene threshold detection" mode (see figure).



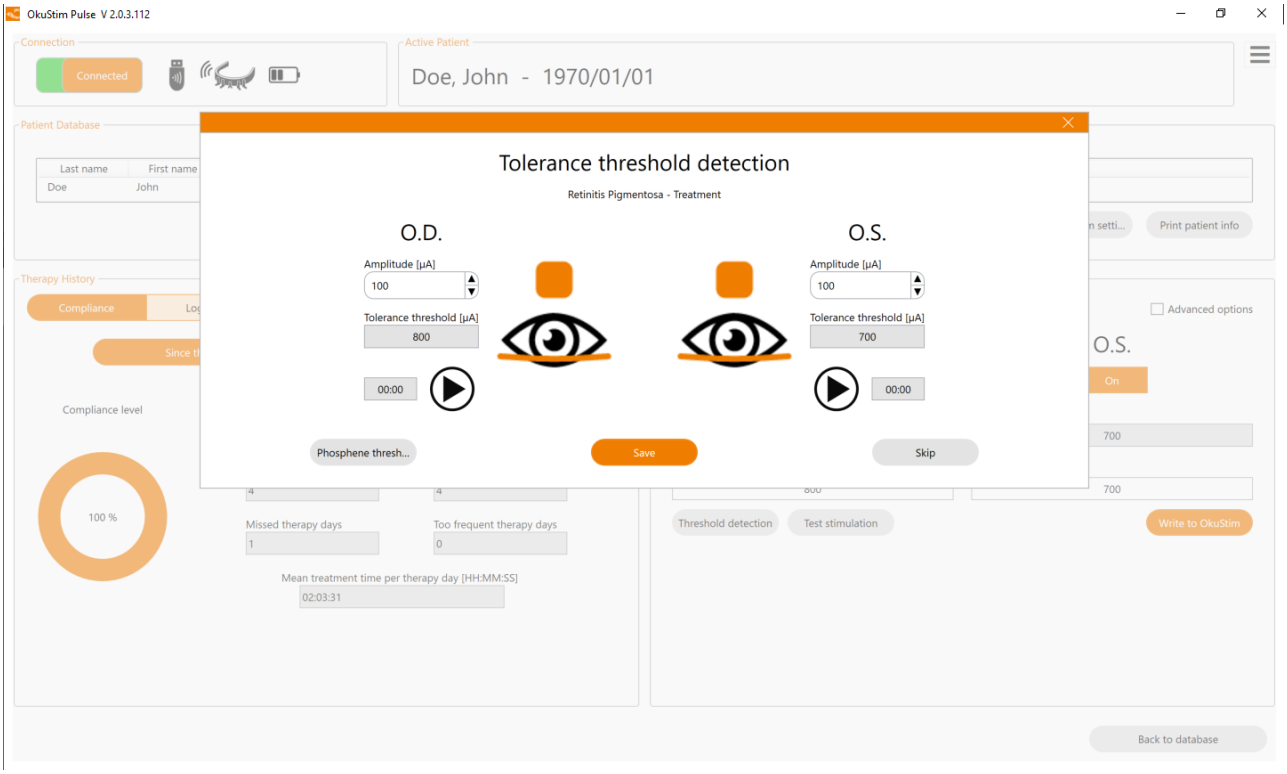
See the next Chapter “Performing a phosphene threshold measurement“ for how to carry out a phosphene threshold measurement.

Alternatively, if the patient is already saved in your database, you can select, from the database, that patient for whom you want to carry out a phosphene threshold measurement.

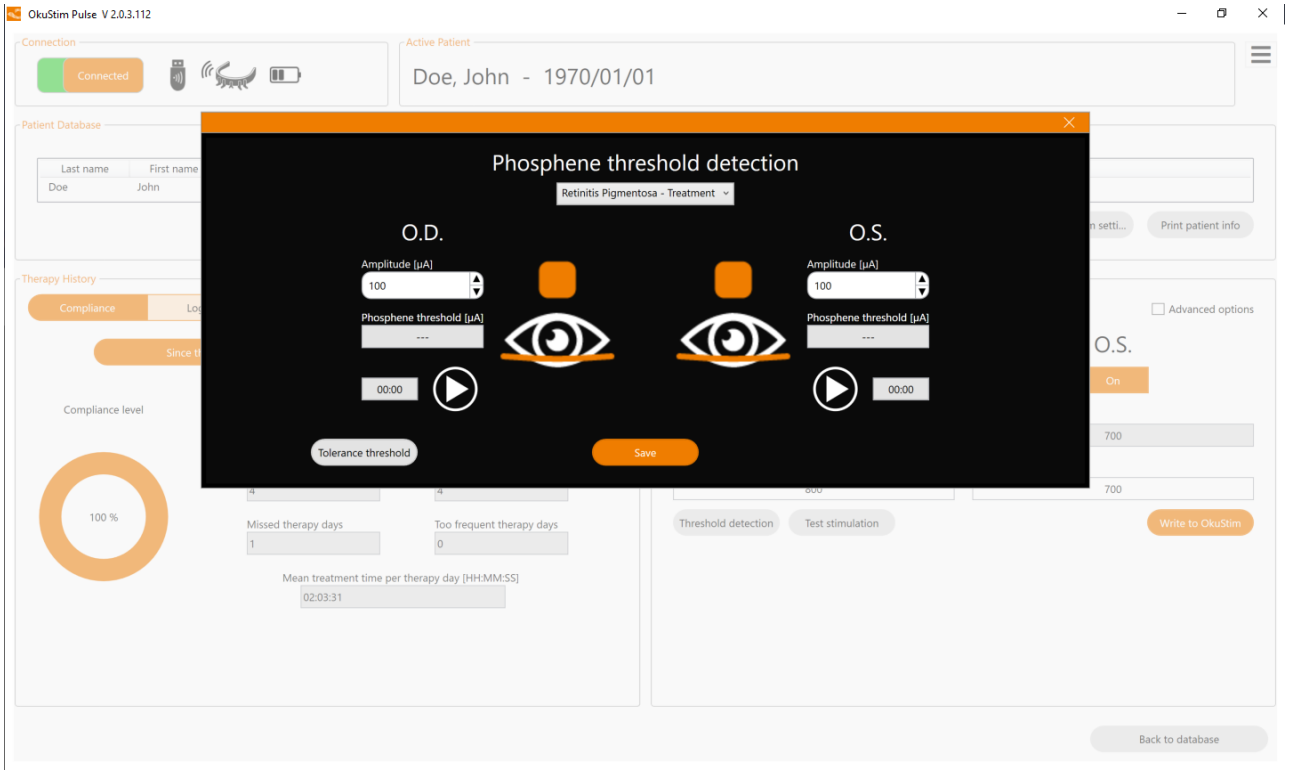
Click on "Activate patient", in order to open the activated patient view (see figure).



Click on "Threshold detection", in order to start the "Tolerance threshold detection" mode.



Now click on "Phosphene threshold", in order to start the "Phosphene threshold detection" mode (see figure).



Performing a phosphene threshold measurement

You can perform a phosphene threshold measurement with OkuStim Pulse. The procedure is very similar to that for tolerance value determination (Chapter “Tolerance threshold measurement procedure”), but in this case the objective is to check for the perception of light phenomena (phosphenes).

After the patient has been created and saved (as explained in Chapter 10), proceed as described below.

While doing so, pay attention to the following points:

- The room must be dark.
- Explain to the patient in your own words what phosphenes are and what to watch out for during stimulation.
- In each case, warn the patient before beginning stimulation or before you click on "Start".
- Ask during stimulation whether they perceive phosphenes – as previously described.

The phosphene threshold is determined separately for each eye. To do so, proceed as follows:

1. Choose the eye for which the phosphene threshold is to be determined (OS: left, OD: right).
2. Start with the Start/Pause button, e.g. with stimulation under OD.

   Notes:

   - If an error message appears (e.g. resistance error), the software will display where the problem lies.
   - See Chapter 21 for the errors that can occur, together with the corresponding suggestions for solutions:
3. After a few seconds (less than 5 seconds!) click on "Pause" to stop the stimulation.
4. Enter the next value to be checked in the "Amplitude [µA]" field and click on Start.
5. Repeat steps 3 and 4 until the patient sees a light flash.

   Notes:

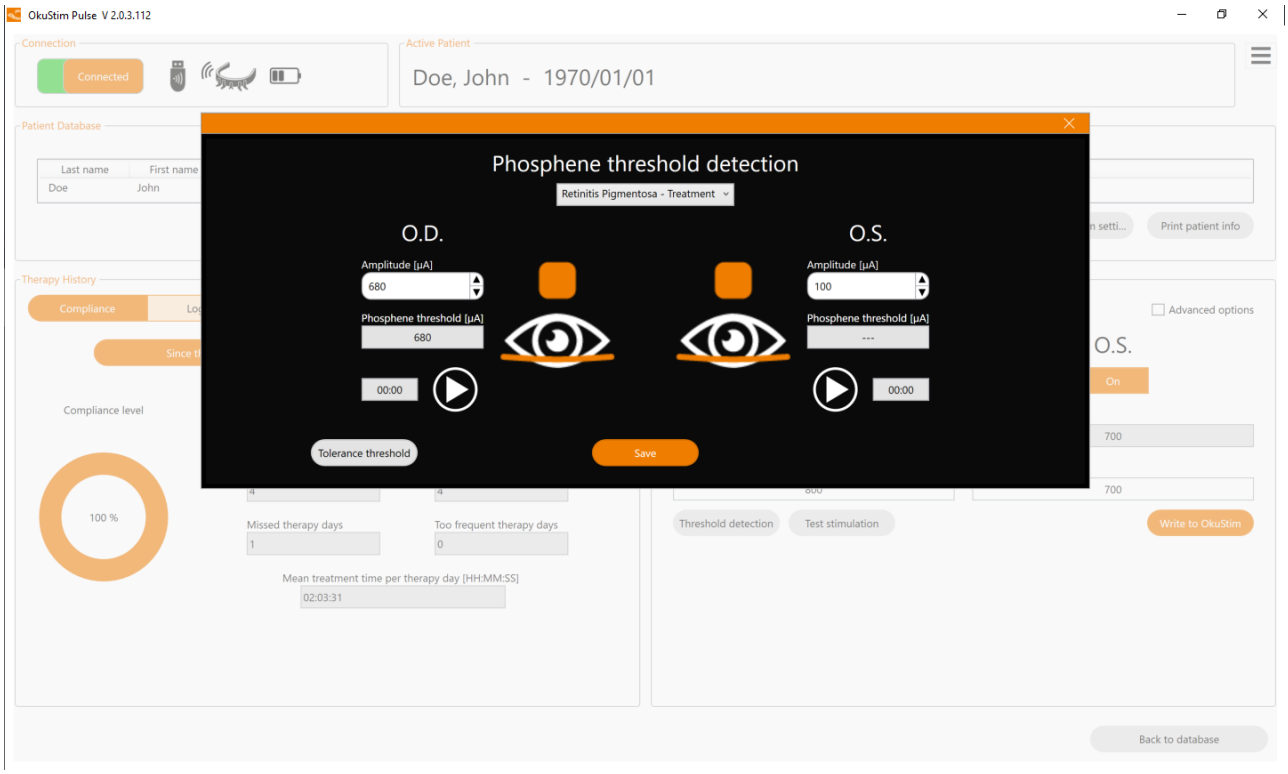
   - Increase the amplitude, at first in 50 µA steps. Then in 100 µA steps from 300 µA on. Repeat this until the patient sees a light flash. At this point the threshold has been found.
   - If the patient feels intolerable pain during stimulation, the measurement must be stopped. In such a case, a stimulation intensity must be selected on the basis of the tolerance threshold.
   - Experienced users can change the rate at which they increase the amplitude to match the disease status or the sensitivity of the patient – if known.

The phosphene threshold value is determined in three cycles:

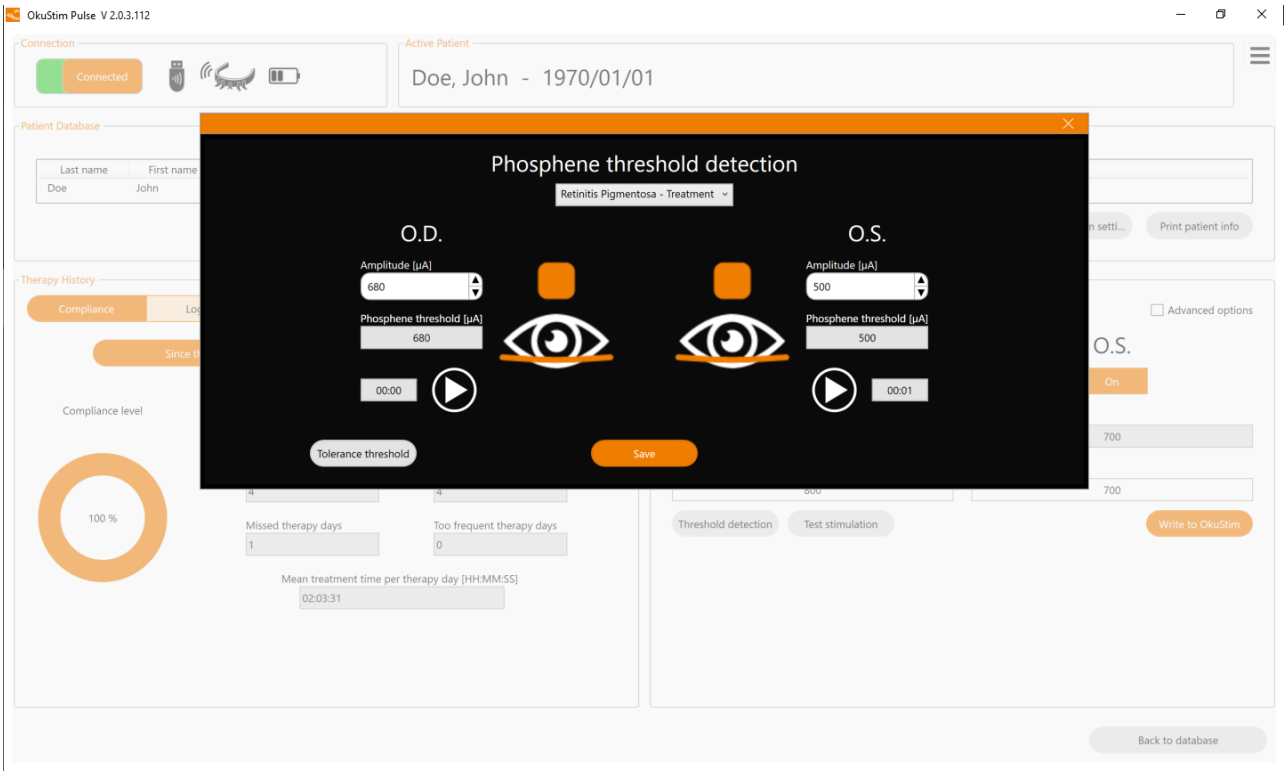
1. By increasing the amplitude until the threshold value is reached (patient perceives a phosphene for the first time).
2. By decreasing the amplitude to below the threshold value (in this case the threshold value is the last value at which the patient still perceived a phosphene).
3. By increasing the amplitude slightly once again until the threshold value is reached or phosphenes are perceived.

The mean value of these three values is to be used as the threshold value (e.g. 680 µA in this case).

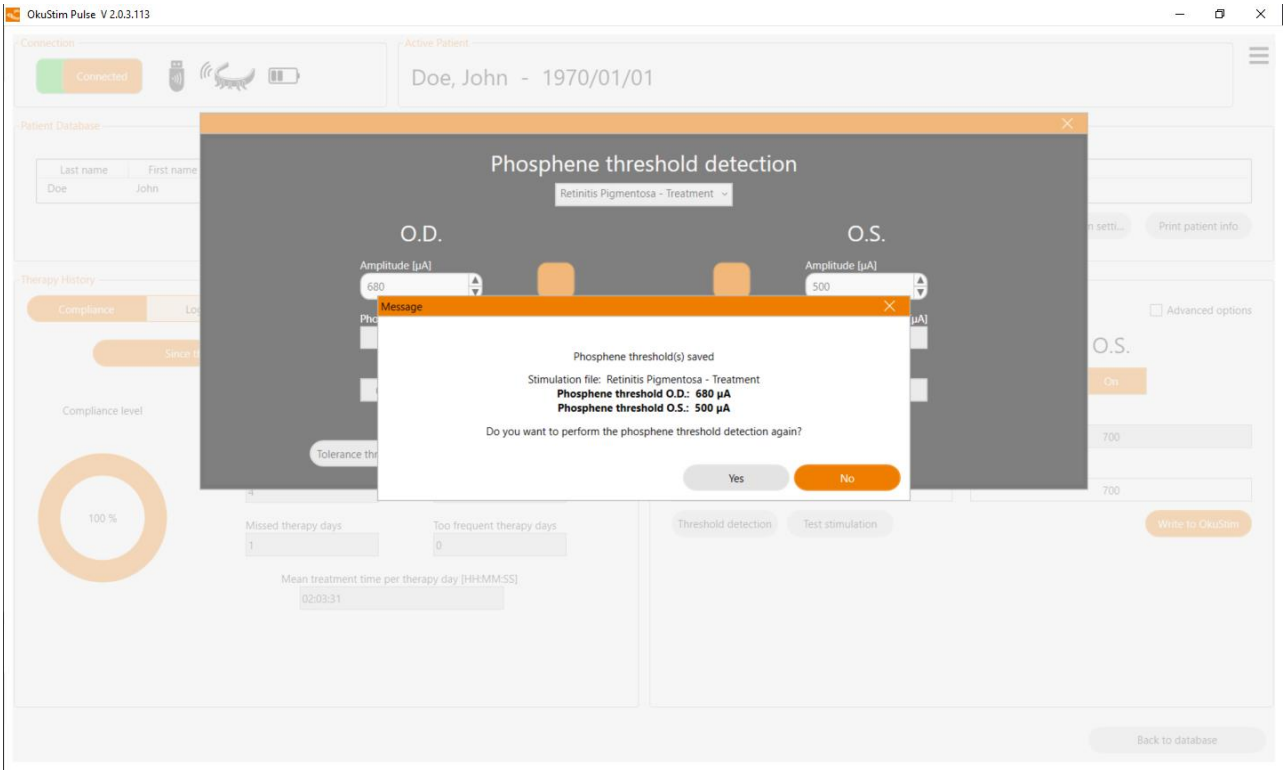
Note: If you have calculated this mean value, remember to enter it in the "Amplitude [µA]" field and to test it (press the start button), otherwise it will not be applied.



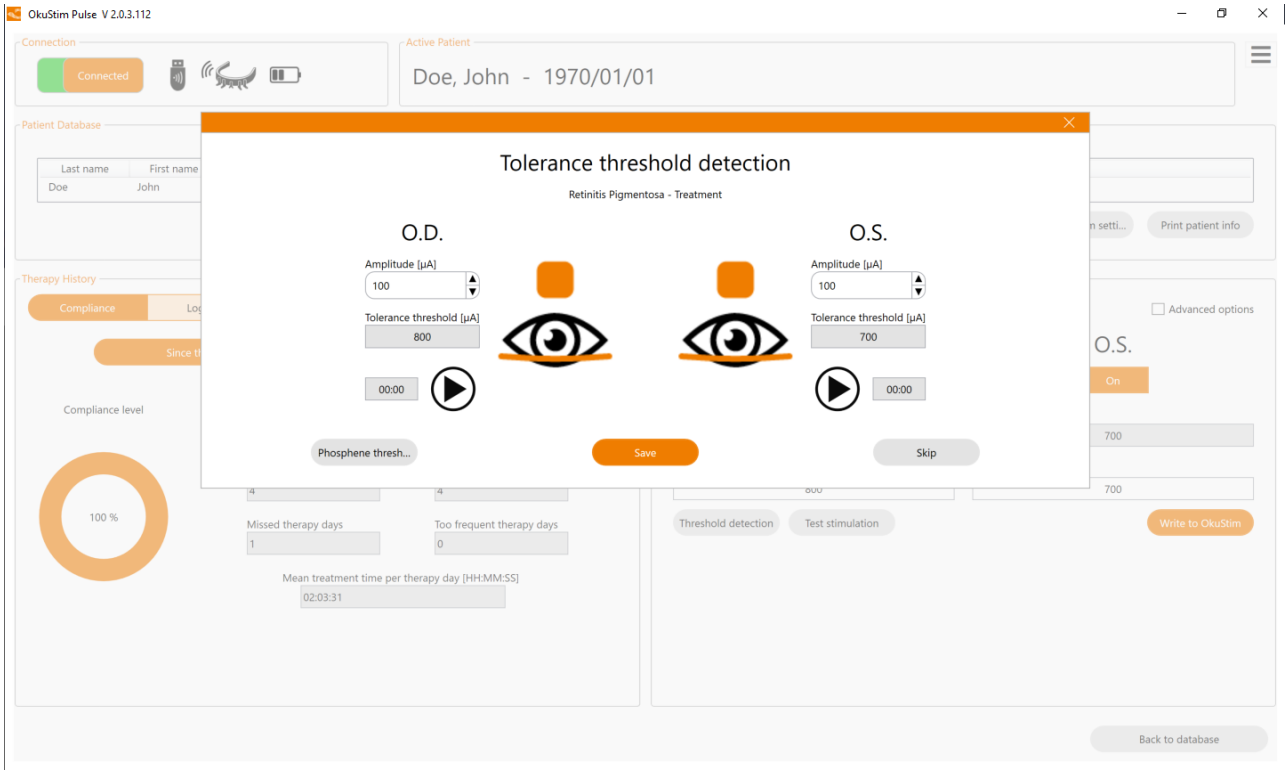
Repeat the process for the other eye (in this case OS).
Once you have also found the phosphene threshold for the second eye (see figure), click on "Save".



A confirmation window opens (see figure). If the measured phosphene thresholds are correct, click on "No".

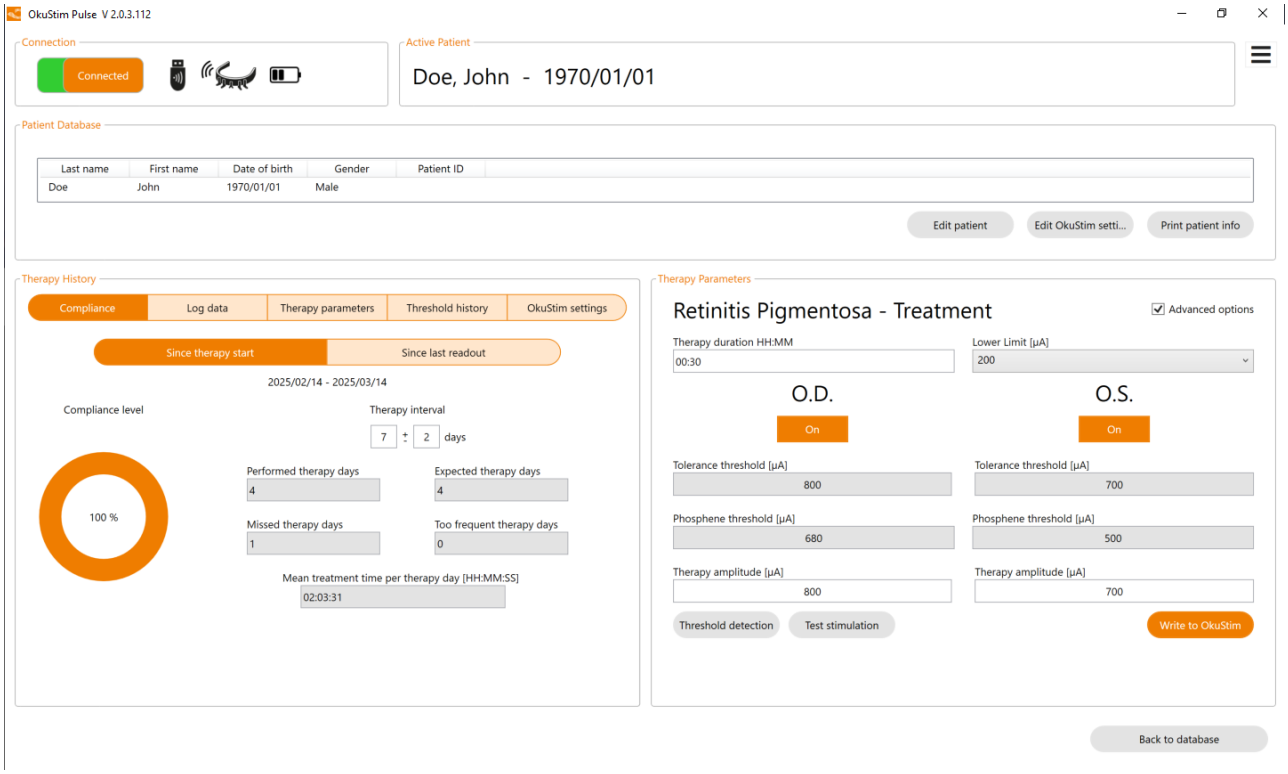


You will be returned automatically to the "Tolerance threshold detection" mode.

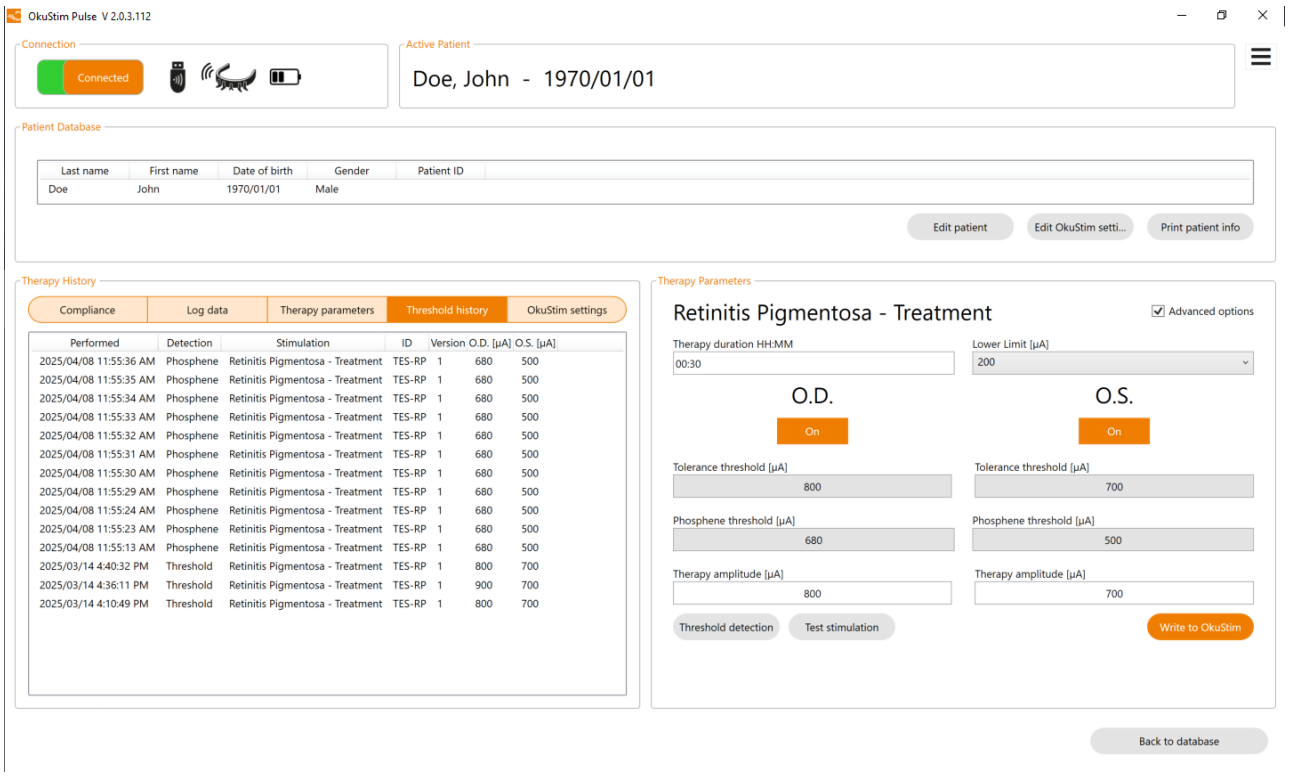


If you do not want to perform a tolerance measurement, click on "Skip". You will then arrive automatically in the "activated patient view".

When you click on "Advanced options" (see figure), you will see the measured phosphene thresholds once again.



Under "Therapy History", you can see in the "Threshold history" tab that the measured threshold values are also saved there.

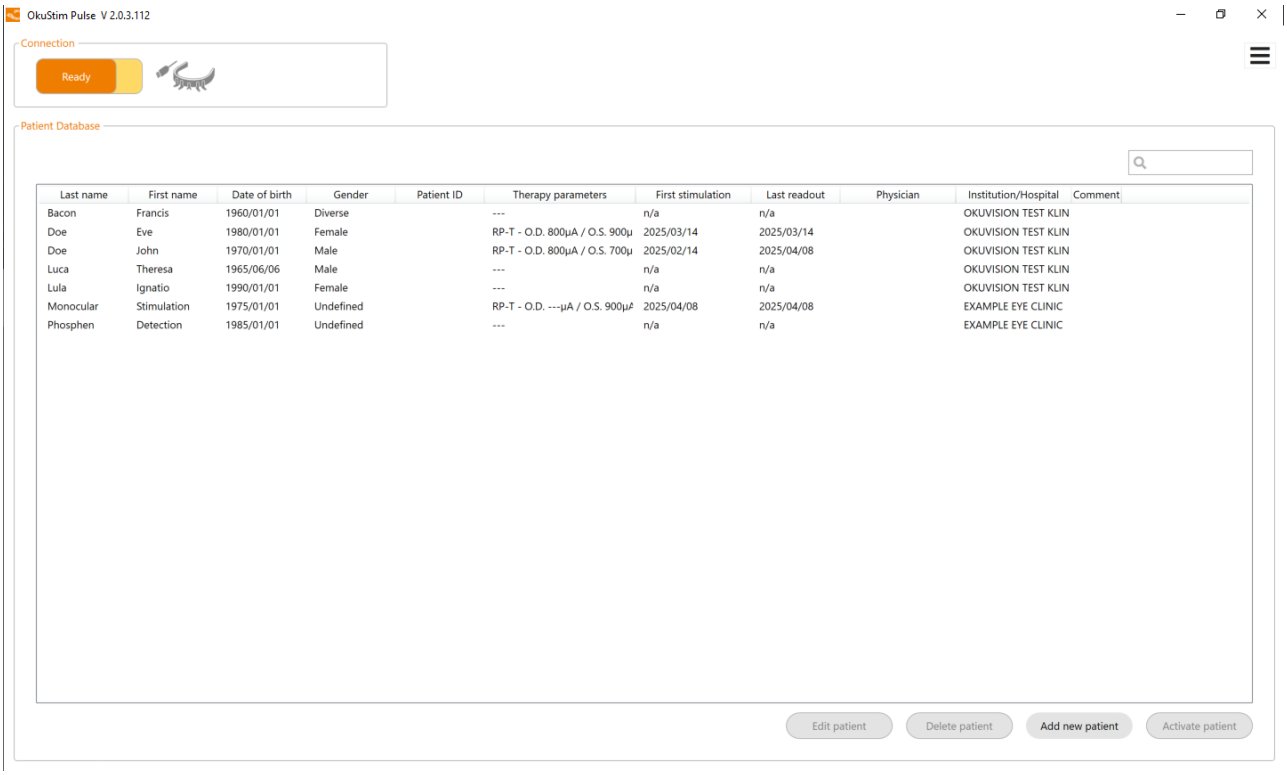


Appendix 3: Operation with USB cable connection

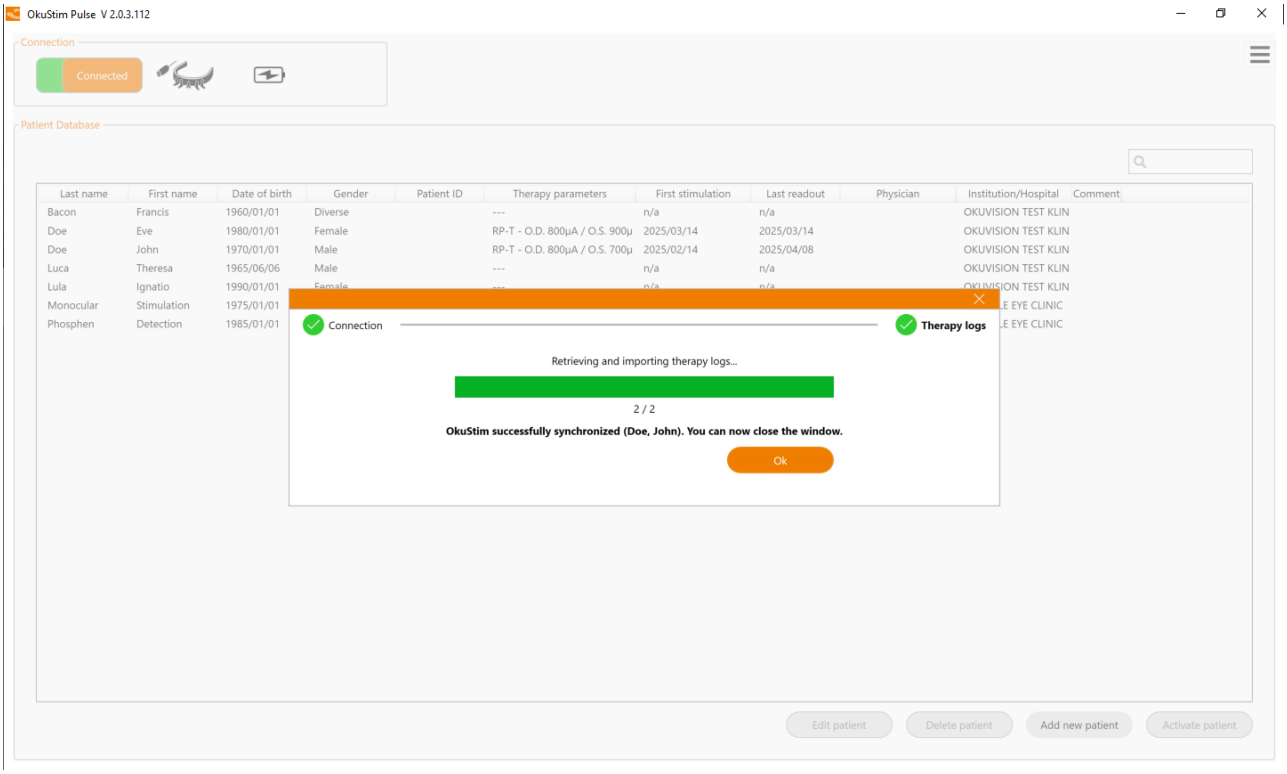
Programming OkuStim 2 via cable connection

Note: In countries in which the wireless connection is not permitted, or if it fails, you can program the OkuStim 2 by USB cable.

Plug the supplied USB cable into a USB socket on your PC and connect it with OkuStim 2. Switch on OkuStim 2. Click on the orange "Ready" button in the software to establish the connection with OkuStim 2.

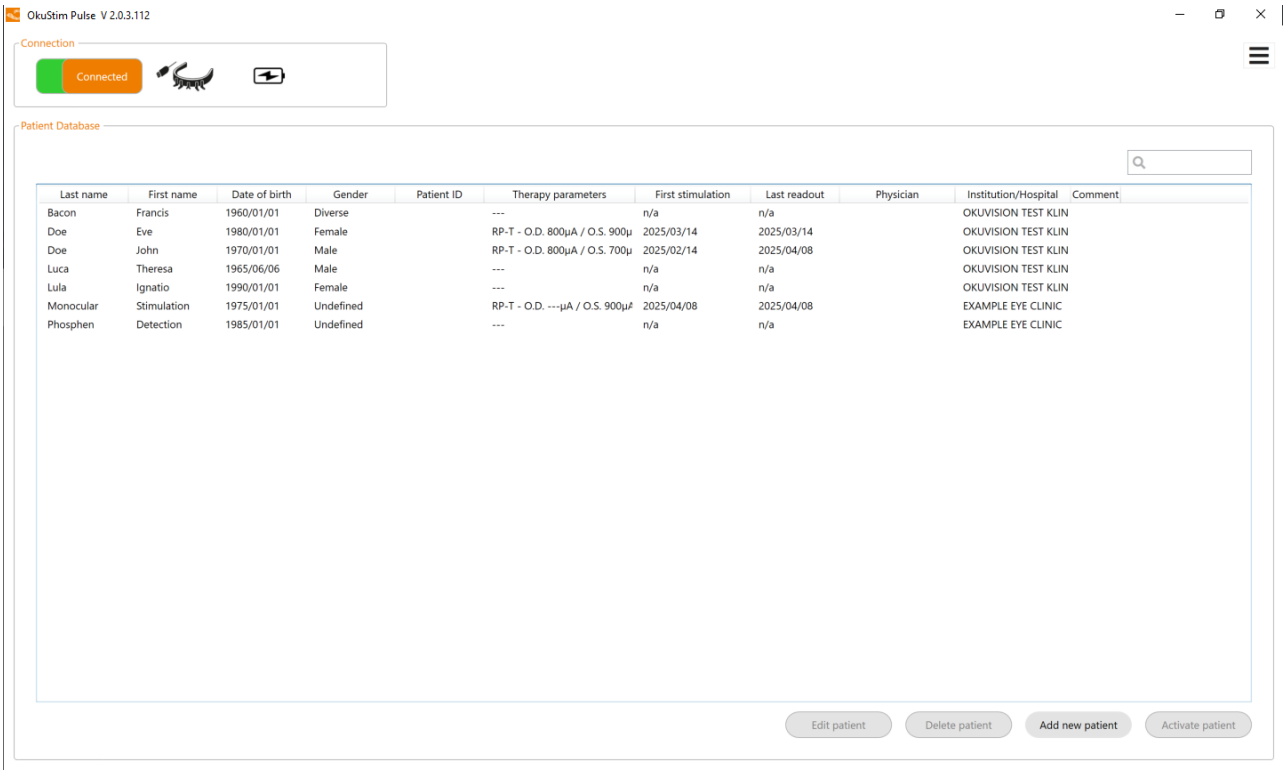


If the OkuStim 2 contains data to be imported, see Chapter 9 on data import.



Click on "OK" once the process has ended (see figure).

A successful cable connection between OkuStim 2 and OkuStim Pulse is indicated by a connection symbol (see figure).



Tolerance measurement via USB cable connection

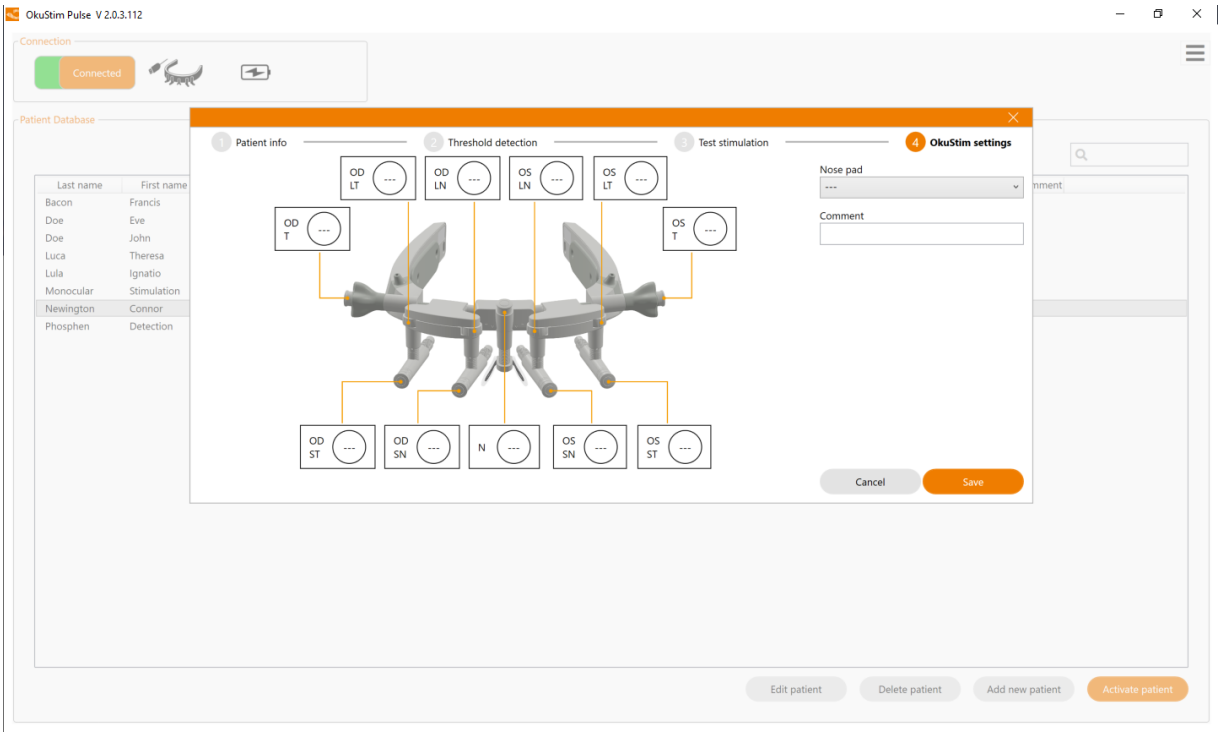
Note: It is not permitted to stimulate a patient when the OkuStim 2 is connected by cable to a PC.

New patient

See Chapter 10 for creating a new patient.

Note: When connected by cable, it is not possible to perform any regular tolerance measurement or test the stimulation (as described in Chapter ”Tolerance threshold measurement procedure” and Chapter 12).

After you have saved the new patient, you will arrive directly in "OkuStim settings" view (see figure).



After you have entered the OkuStim adaptation parameters and clicked on "Save", you will be guided directly to the activated patient view (see Chapter 19).

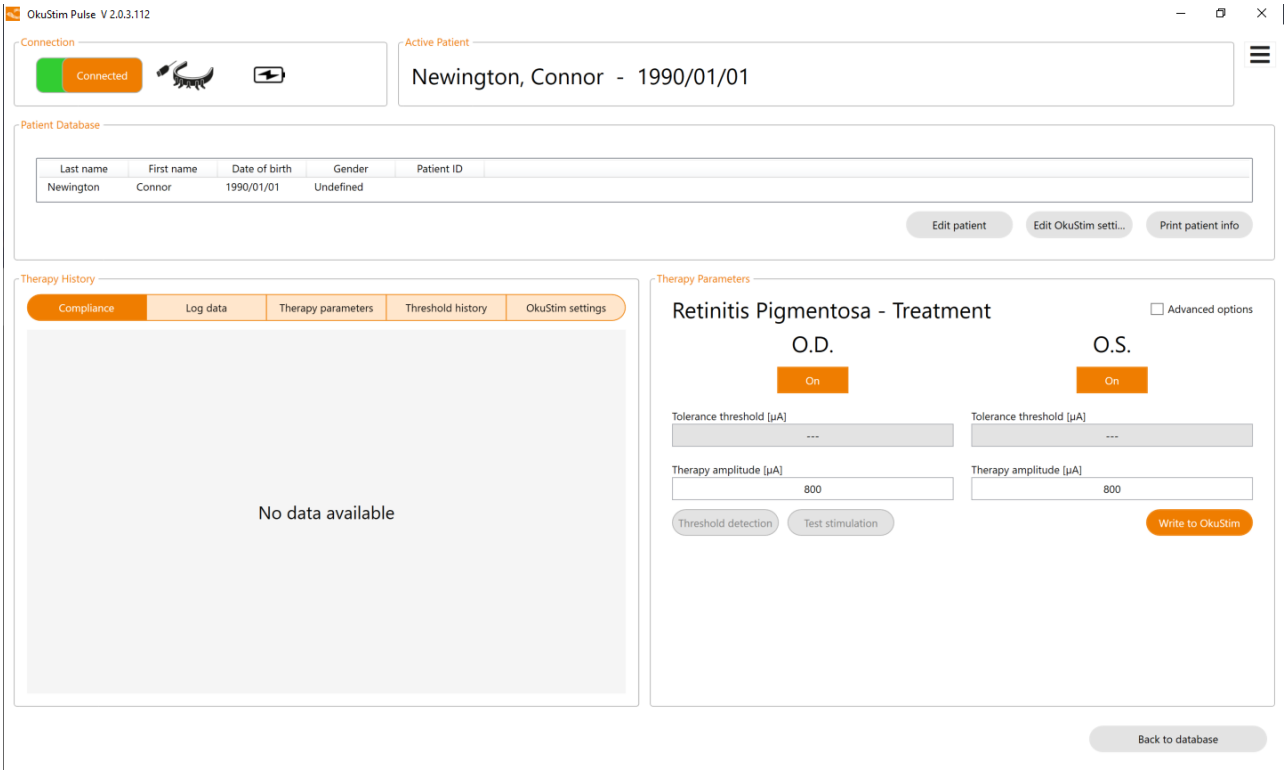
See Chapter “Programming and testing stimulation amplitudes by USB cable“ below on programming and testing of stimulation amplitudes by cable.

Existing patient

See Chapter 18.2 on changing stimulation amplitudes for an existing patient. See Chapter “Programming and testing stimulation amplitudes by USB cable” below.

Programming and testing stimulation amplitudes by USB cable

You are now in the "activated patient view".



Because OkuStim 2 is connected by cable to the PC, it is not possible, in this view, to run a regular "Test stimulation" or a regular "Threshold detection". The buttons are blocked.

In order to measure the tolerance threshold via the USB cable, you have to:

1. Program OkuStim 2 with OkuStim Pulse (by entering the amplitude to be tested in the "Therapy amplitude" field).
2. Then click on the "Write to OkuStim", in order to transmit the current value to OkuStim 2 and to save it in the database.
3. Now disconnect OkuStim 2 from the PC.
4. Apply OkuStim 2 to the patient and start the stimulation (by pressing the Start/Pause button), in order to test the stimulation amplitude.
5. This process should be repeated until the optimum stimulation value for the patient has been found.