okuvision

OkuStim® System

Instructions for Use

EN

Important Notice

Intended Use

The OkuStim system is intended for electrical stimulation of the retina of patients suffering from retinitis pigmentosa in an outpatient or home environment.

Clinical Benefit

In patients with retinitis pigmentosa and other hereditary retinal diseases, electrical stimulation therapy with the OkuStim system can help to slow down the loss of the visual field and thus preserve usable vision for longer.

Users and Places of Use

The OkuStim system is suitable to be used for electrical stimulation by trained laypersons and specialists in a professional healthcare or home environment. The programming of the stimulation parameters must be performed by healthcare professionals.

Purpose of this Manual

This user manual provides the necessary instructions for safely operating the OkuStim in accordance with its function and intended use. These instructions include:

- An explanation of the function of controls and indicators
- Instructions on handling the OkuStim system
- Instruction of the application of electrical stimulation sessions
- Instructions on maintenance and troubleshooting

Notes

Las presentes instrucciones de uso son aplicables para OkuStim a partir de la versión de Firmware 2.03.

Manufacturer

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Explanation of Symbols

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

MD	Medical device
	Ref. to instructions for use
	Ref. to instructions for use
	General warning symbol
LOT	Batch designation
SN	Serial number
	Use by date
	Date of manufacture
CE 0197	The CE identification documents agreement with the Medical Device Directive 93/42/EWG, notified body code: TUV Rheinland (= 0197)
	Example for storage temperature

	Packaging unit
	Not for reuse
	Sample for temperature range
	Manufacturer
REF	Part number
	Do not use if packaging is damaged
	Note waste disposal specifications
	Applied Part: Type BF
IP22	Casing protection class: protected against foreign objects with a diameter of 12.5 mm or above and against dripping water with 15° angle.
UDI	Unique Product Identifier

Important Safety Notes

- This product may be used only according to the instructions and prior setting-up by a healthcare professional. Patients must use only the device especially intended for them.
- The OkuStim system is subject to mandatory prescription and may be given to patients only as prescribed by a doctor.
- Before using the device please familiarize yourself with the user manual and note the information about electromagnetic compatibility (page 33).
- Only use the accessories supplied with the product or those listed in the accessories list Chapter 17. Do not connect any cables or parts to the device that are not mentioned in the list.
- The OkuEl electrode consists of a silver thread. Users with silver allergies may only use the OkuEl electrode after medical consultation.
- The use of local anaesthetics on the eye and the application of the therapy when wearing contact lenses are not permitted.
- When using the OkuStim System with an endotamponade of the eye with silicone oil, the functionality of the stimulation cannot be ensured.
- Only healthcare professionals are allowed to 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).
- The device must not be opened or modified.
- During an electrical stimulation session with OkuStim it is not allowed to undergo any additional treatment using electrical stimulation.
- Use the device only while seated or lying down. Do not move around and try to stay clear of objects on which the OkuSpex electrode could get caught. Beware of strangulation with the cables.
- Please note that the density of electric current can exceed 2 mA/cm2 at the OkuEl electrode.
- Please note that the device can heat up to 42°C during use.
- Attach the plug of the OkuSpex cable fully to the connector of the OkuStim.
- Keep the device and accessories outside of reach of children. Small parts like the mini-USB-Stick could be swallowed.
- Check the seams of the individual OkuEl Electrode packaging. Use only OkuEl electrodes with intact packaging.
- The OkuEl electrodes are single-use products and must not be used more than once. In case of reprocessing and/or usage of an OkuEl for more than one therapy session the functionality of the OkuEl cannot be ensured. Multiple use may result in ineffectiveness of the therapy and/or lead to an infection of the eyes.

Indications / Contraindications

Indications

The TES-Therapy with the OkuStim system is indicated for the treatment of

- retinitis pigmentosa (also syndromic, e.g. Usher syndrome)
- similar retinal diseases like cone-rod dystrophy or choroideremia[1]

Contraindications

The TES-Therapy must not be applied:

- in patients with blood vessels with growth processes that could be accelerated by electrical stimulation, like:
  - ocular neovascularization of any origin,
  - macular edema,
  - artery or vein occlusion,
  - diabetic retinopathy,
  - age-related macular degeneration.
- in patients who have a severe acute or chronic disease according to their medical evaluation (medical, psychiatric, other abnormal clinical findings) that could be worsened by the therapy.
- in patients with active implants[2],
- in case of current pregnancy,
- whilst breastfeeding,
- in case of acute eye inflammation.

Conditions for the application of transcorneal electrical stimulation therapy are:

- Minimum age requirement: 18,
- Visual acuity of at least light perception,
- Patients must be able to sit still for 30 minutes.

[1] In the current S1 Guideline 25 (AWMF 045/23) for hereditary diseases of the retina, choroid and visual pathways of the German Ophthalmological Society (DOG), the Retinological Society (RG) and the Professional Association of Ophthalmologists in Germany (BVA), electrical stimulation is listed as a treatment recommendation (German Ophthalmological Society, 2021)

[2] The OkuStim System should not be used if you have an electrical implant that is classified as an applied part according to EN 60601-1. Please contact the implant manufacturer.

Content

Important Notice 2
Manufacturer 2
Intended Use 2
Clincal Benefit 2
Users and Places of Use 2
Purpose of this Manual 2
Version Note 2
Explanation of Symbols 3
Important Safety Notes 4
Indications / Contraindications 5

1 What is OkuStim? 8
2 Scope of Delivery 10
3 Before First Use 11
4 Brief Guide to Performing a Therapy Session 12
5 Use 13
5.1 Adapting the OkuSpex to the Patient 13
5.2 Attaching the OkuEl Counter Electrodes to the Body 14
5.3 Opening the OkuEl Electrode Package 14
5.4 Inserting the OkuEl Electrode Into the OkuSpex Frame 15
5.5 Putting on the OkuSpex 16
5.6 Connecting the OkuSpex with the OkuStim 17
5.7 Stimulation According to Doctor's Prescription 18
5.8 Storing the OkuSpex 19
5.9 Removing the OkuEl Counter Electrodes from the Skin 19

6 Side Effects 20
7 Explanation of the Display Information of the OkuStim 21
8 Acoustic Signals 23
9 Inserting and Changing Batteries 24
10 Storage 25
10.1 The Electrode Package 25
11 Cleaning Instructions 26
11.1 Cleaning, Disinfection, and Care of the OkuSpex 26
11.2 Cleaning and Care of the OkuStim 26
11.3 OkuEl Electrodes and OkuEl Counter Electrodes 26
12 Repair and Maintenance 26
13 Troubleshooting 27
13.1 Display Messages 27
13.2 Acoustic Signals 28
14 Technical Data 29
15 Disposal of Used Devices and Batteries 30
16 Warranty 30
17 Accessories 31
18 Information Regarding Electromagnetic Compatibility 32

1 What is OkuStim?

OkuStim is a system for transcorneal electrical stimulation (TES) for the treatment of retinal dystrophies. The externally applied therapy is designed for independent use at home.

Electrical stimulation therapy with the OkuStim System can help to slow down the narrowing of the visual field and thus retain usable vision for longer in patients suffering from retinitis pigmentosa and other generalized inherited retinal disease.

Electrical stimulation with weak currents can activate signalling pathways and the release of substances in the diseased retina that have a protective effect on retinal cells.
This neuroprotective effect can maintain physiological functions in the retina for longer and slow down the retinal degeneration. Permanent use is required to maintain this effect.

In TES therapy, retinal stimulation is achieved by transcorneal application of a weak current (< 1mA) to the surface of the eye, which spreads in towards the retina. The current is applied by a thin electrode thread.

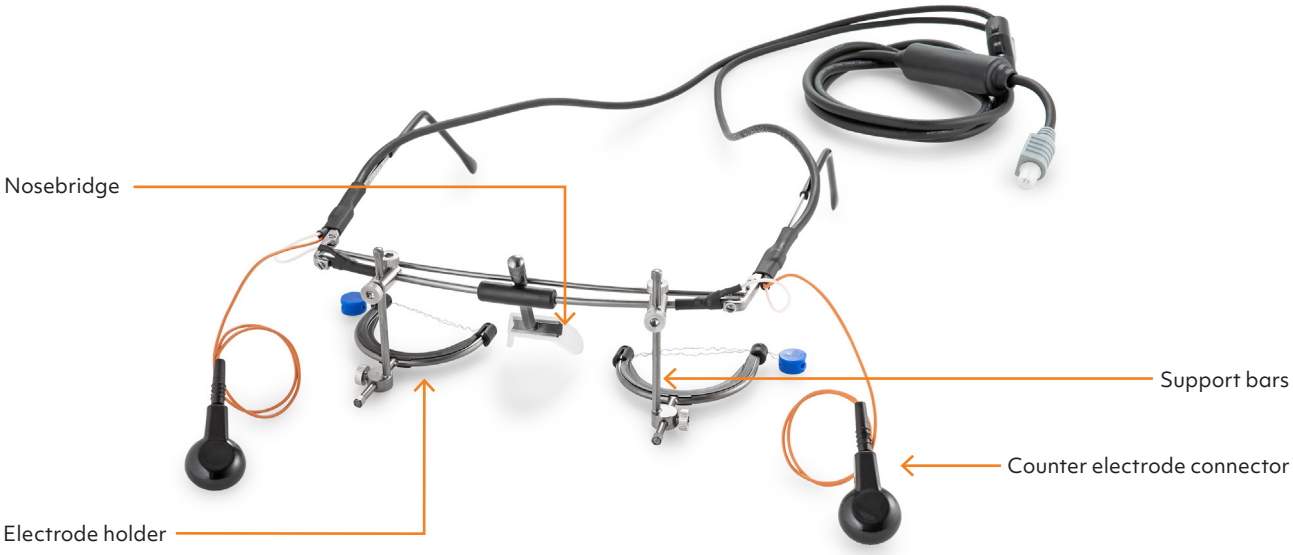
System Components

Fig 1-1: OkuStim handheld device

Fig. 1-2: OkuEl electrode

Please note: the depictions of the components in this booklet may differ slightly from the actual products.

Fig 1-3: OkuSpex frame



The OkuEl electrode is comprised of an arched clip with two fine threads, which are placed below the pupil on the surface of the eye.

The OkuSpex frame serves as a holder for the OkuEl electrodes. It is connected to the Oku-Stim with a cable. The OkuSpex can easily be adjusted to fit the individual facial shape. Similarly, the OkuEl electrodes can be inserted easily into the electrode holder of the OkuSpex frame even by visually impaired persons.

For hygienic reasons, the OkuEl electrodes and OkuEl counter-electrodes may only be used once.

Therapy

Upon turning on the OkuStim the eyes will be electrically stimulated with the pre-set parameters over a time of 30 minutes. During the stimulation, the perception of white and bright light sensations (so-called 'phosphenes') is probable.

The individual treatment parameters for the patient will be determined and programmed on the USB-stick of the OkuStim device by a healthcare professional.

The data generated during stimulation, such as electrical resistance values, are stored on the USB-stick. This way the healthcare professional can monitor the course of the therapy.

The OkuStim device features a display and acoustic output for all essential operating states, so that patients at advanced stages of visual impairment can use the device without problems.

2 Scope of Delivery

You will receive your OkuStim system in a sturdy transport box which also serves as storage for the individual system components. After use, place the OkuSpex open and not folded back into its compartment. Do not wrap the cable around the OkuSpex as this may cause misalignment of the electrode holders.

Package Contents:

- OkuStim® handheld device (on the product label: **OkuStim®**)
- **OkuSpex®** frame with cable
- Hexagon socket screw key for adjustment of OkuSpex and replacing batteries in OkuStim
- Mini-USB stick (on the product label: **OkuStim® USB-Stick**)
- Transport box
- 4 Batteries AA
- Instructions for use

Required accessories (available separately):

- OkuEl® electrode package (on the product label: **OkuEl® Electrode Package**), contains:
  - 10 OkuEl® electrodes (on the product label: **OkuEl® Electrode**)
  - 12 OkuEl® counter-electrodes (on the product label: **OkuEl® Counter-Electrode**)

Abb. 2-1: Abb. 2-1: Transport- and storage box for the OkuStim system.

3 Before First Use

Note:

- The individual treatment parameters have to be determined and programmed by a healthcare professional.
- Patients with dry eyes (e.g. conjunctivitis sicca) are recommended to apply tear eye-drops during TES-therapy.
- Patients with limited physical mobility (e.g. advanced rheumatism, Parkinson) may require help when applying the TES-Therapy with the OkuStim.

You will have to have your OkuSpex individually adapted. For subsequent adjustments of the electrode holders at home, the assistance of a second person might be helpful. If you have any difficulties, please contact the doctor or optician/dealer from whom you purchased the OkuStim system.

Once you have received your OkuStim system and the OkuSpex has been fitted, you may need to make an appointment with your doctor for an introduction and have your therapy parameters written to the USB stick supplied with the system. Your physician or dealer will inform you about the next steps.

Make sure that your USB stick is inserted correctly in the OkuStim. The USB stick has a white and a black side. The white side must face upwards when inserted into the socket on the bottom of the OkuStim.

Insert the batteries with correct polarities into the battery compartment at the rear of the OkuStim.

Insert the USB stick into your OkuStim device and stimulate according to the instructions of your healthcare professional. **It is recommended that you leave the USB memory card in the OkuStim unless it is absolutely necessary to remove it. Always ensure that the OkuStim is switched off when inserting or removing it.**

Arrange regular follow-up visits with your doctor to control settings and the application of the therapy.

Fig. 3-1: The white side of the USB-stick must face upwards when inserted into the OkuStim.

4 Brief Guide to Performing a Therapy Session

Please follow exactly the steps to prepare and conduct a stimulation session. You may otherwise experience a spontaneous and strong phosphene perception.

Preparation before stimulation:

- Clean the skin before attaching the OkuEl counter electrode(s).
- Attach the OkuEl counter electrode(s) to the cleaned skin area(s).
- Insert the OkuEl electrode(s) into the electrode holder of the OkuSpex.
- Assume a comfortable and stable seated or reclined position.
- Put on the OkuSpex. You may want to pass the cable of the OkuSpex from behind around your head.
- Switch on the OkuStim.
- Plug the OkuSpex cable into the OkuStim.
- Connect the OkuEl counter electrodes to the cables on the OkuSpex.
- Start the stimulation. It is recommended to keep the eyes closed during stimulation.

After stimulation

- The stimulation stops automatically after 30 minutes.
- Carefully remove the pushbutton connectors from the OkuEl counter electrodes. Never pull the cables to remove the connectors as the cables may tear.
- Disconnect the OkuSpex cable from the OkuStim.
- Take off the OkuSpex and remove the electrodes from it.
- Put the OkuSpex back into the box. Do not fold the OkuSpex.
- Roll-up the cable loosely and do not wrap it around the OkuSpex as this may cause the electrode holders to misalign. Put it into the designated compartment in the box.
- Switch off the OkuStim device (in case it has not already switched off automatically).
- Remove the counter electrodes from your forehead and dispose of them together with the OkuEl eletrodes with the general waste.

5 Use

5.1 Adapting the OkuSpex to the Patient

Your OkuSpex has to be adapted by a healthcare professional (at the eye clinic or optician) so that the electrodes come to rest on the conjunctiva, below the pupil (see fig. 5-1 and fig. 5-5). To do this, the hexagon socket screws at the joints of the OkuSpex are slightly opened to allow the vertical and horizontal support rods to be moved smoothly. The OkuSpex is then carefully fitted with the eyes closed and the vertical support rods adjusted to the correct height. If necessary, the height of the nose bridge of the OkuSpex can be adjusted.

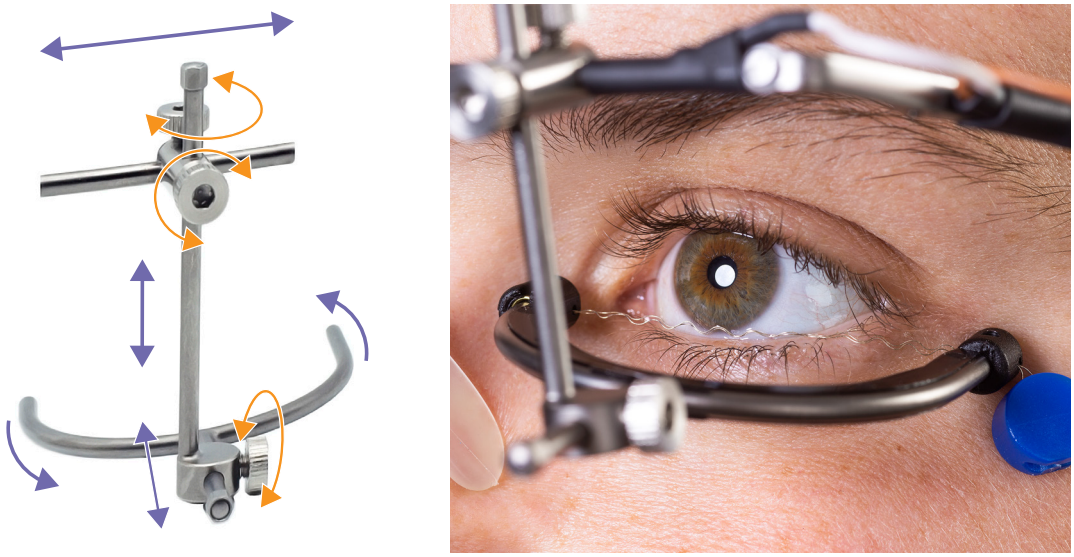


Fig. 5-1: Adjustment of the OkuSpex electrode holder; Position of the electrode thread on the conjunctiva.

Position the horizontal support rod so that the ends of the electrode holder come to rest near the nasal and temporal canthus (corner of the eye); that is, just before the skin directly to the right and left of the eye. Carefully move the horizontal support rod towards the eye.
The OkuSpex are correctly adapted to the patient when the OkuEl thread rests below the pupil and above the lower eyelid, against the cornea, free of pressure, with at least 1cm contact.

After fitting, carefully tighten the hexagon socket screws on the joints of the OkuSpex frame again. To tighten the screws, hold the OkuSpex frame in the hand again.

Note:

Always take the OkuSpex off first before using the hexagon screwdriver.

5.2 Attaching the OkuEl Counter Electrodes to the Body

The OkuEl counter electrodes are attached in the area of the temple. If only one eye is to be stimulated, the OkuEl counter electrode is only required on the respective side.

Before attaching the OkuEl counter electrodes thoroughly clean and dry the area of the skin where the electrodes are to be attached. The use of alcohol pads is recommended for cleaning since water and soap may be insufficient.

Pull the OkuEl counter electrode off the carrier film and attach with slight pressure to the cleaned area of the temple.

Please close the sachet of the OkuEl counter electrodes after taking them out by folding the side that was torn open to protect remaining electrodes from drying out.

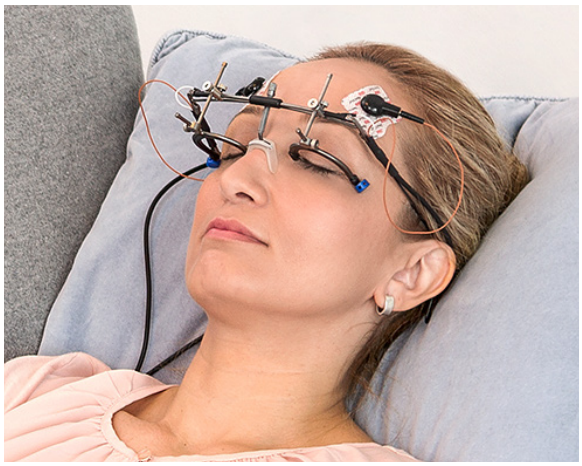


Fig. 5-2: Position of the counter electrode; Fig. 5-3: Contact surface of the OkuEl

5.3 Opening the OkuEl Electrode Package

Before opening the individual OkuEl electrode packaging check if it is undamaged. Use only OkuEl electrodes with intact packaging.

To unpack an OkuEl electrode, carefully peel away the film from the paper until the entire electrode can be freely removed from above.

For hygienic reasons, the OkuEl electrode may only touched on the black plastic clip.
The electrode thread (arrow), which makes contact with the eye, must not be touched with the fingers (see fig. 5-2).

5.4 Inserting the OkuEl Electrode Into the OkuSpex Frame

To insert the OkuEl electrode into the electrode holder, the OkuEl electrode is pushed from the face-side of the OkuSpex onto the u-shaped arm of the electrode holder. The electrode side with the blue seal has to face outward in this case. The electrode must be pushed completely onto the u-shaped arm, so that it finishes flush with the electrode holder.

In case of the stimulation of only one eye, only one OkuEl electrode and one OkuEl counter electrode are required. If both eyes are stimulated, two OkuEl electrodes and two OkuEl counter electrodes are required (see fig.1-2 & 1-3, page 9).

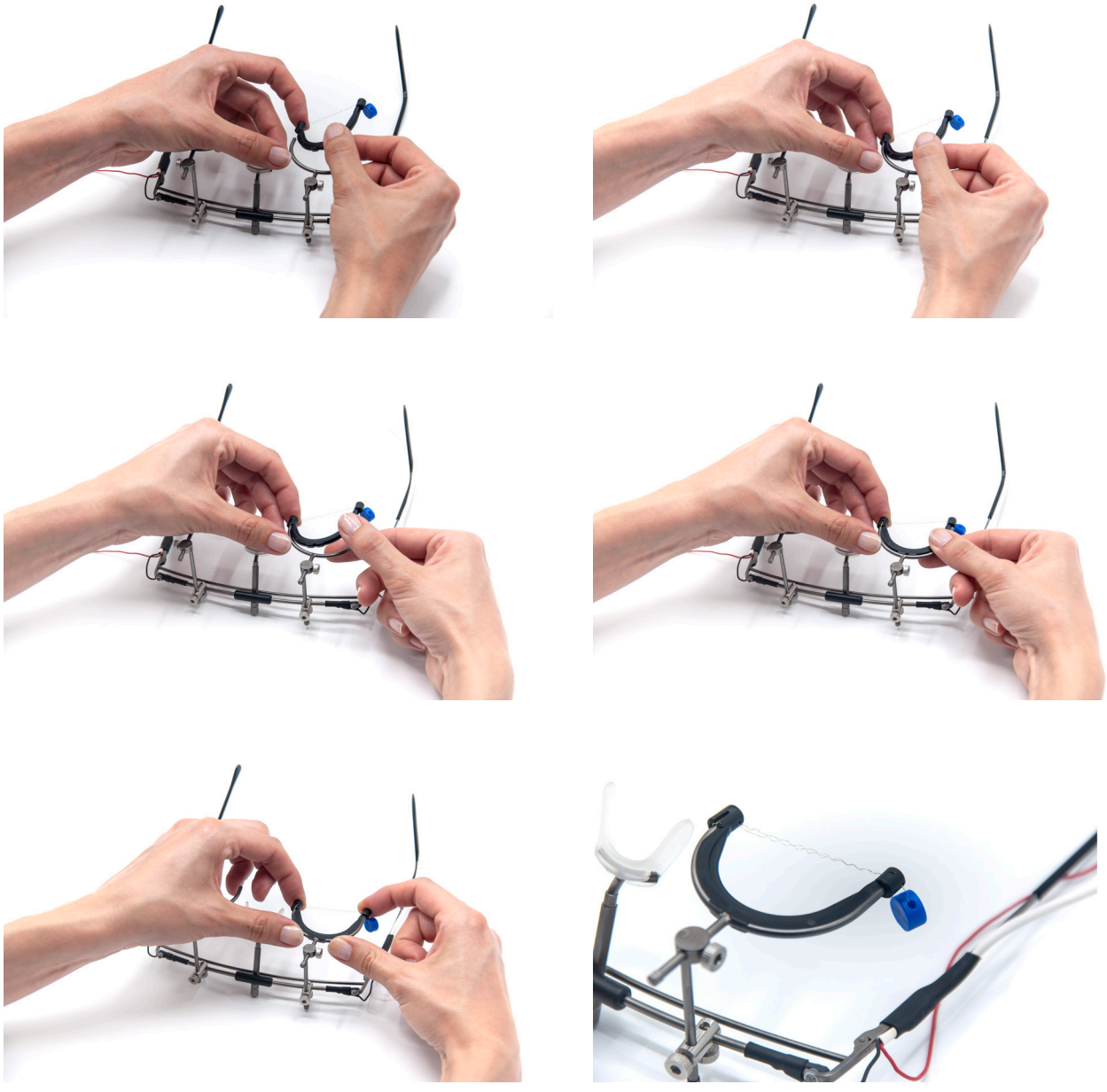


Fig. 5-4: Inserting the OkuEl electrode into the OkuSpex

5.5 Putting on the OkuSpex

The OkuSpex must be put on as it has been explained to you by a healthcare professional at your induction appointment.

To put the OkuSpex on, place your head in the neck and open your eyes wide. The OkuSpex will fit correctly when the nose bridge is fully resting on the nose. Please ensure that the outer edges of the black OkuEl electrode clip do not come into contact with the eyes. Only the electrode thread must touch the conjunctiva above the lower eyelid (Fig. 5-5). You can close the eyes during stimulation.

When receiving your OkuStim system, the correct way of putting on the OkuSpex should have been explained to you by a healthcare professional.

Fig. 5-5: OkuEl electrode on the eye touches only the conjunctiva under the pupil

5.6 Connecting the OkuSpex with the OkuStim

Connect the plug of the OkuSpex cable with the connector on the top of the OkuStim. Ensure that the flat surface of the plug is facing up. The plug can only be inserted easily when oriented correctly.

Please ensure that the plug is inserted fully into the connector. A correct application of the therapeutic stimulation can otherwise not be guaranteed.

Fig. 5-6: Plug of the OkuSpex attached to the OkuStim

You can now turn on the OkuStim.

Lastly, the OkuEl counter electrode at the temple is connected with the pushbutton of the OkuSpex.

5.7 Stimulation According to Doctor's Prescription

Switch on the OkuStim device by pressing the "ON/OFF/STOP" button (left) for at least one second. A sequence of long and short beeps confirms that the device is switched on.
If possible, check if your name is shown in the OkuStim display when switching on. Depending on the treament pathway for your region, the stimulation parameters will appear in the display instead of your name. This will be changed at the first follow-up visit in the eye clinic.

Connect the counter electrodes if you haven't done so, yet. Begin your therapy session by pressing the "START" button (right).

During the stimulation, a regular sound – 1 beep per second – indicates the correct function of the device. The remaining therapy time is shown in the display. The stimulation strength increases slowly, at the beginning, until the therapeutic stimulation strength is reached. This ramping-up phase is indicated in the display with a ramp symbol.

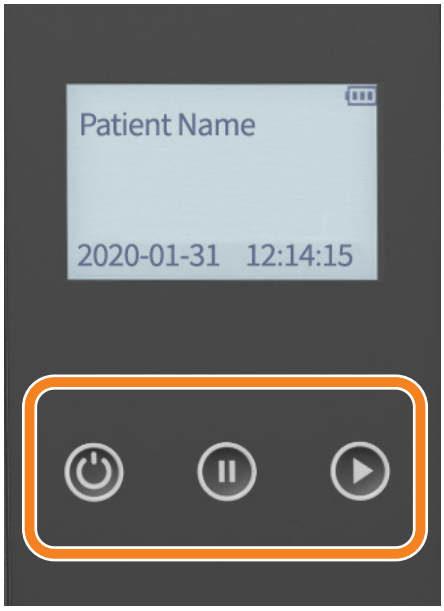


Fig. 5-7: The three buttons on the OkuStim device from left to right: ON/OFF/STOP, PAUSE, START

If the device cannot carry out the stimulation properly, this is signaled by acoustic signal. You can find an overview of the acoustic signals and their meanings on page 23.

In such a case, interrupt the stimulation by pressing the „PAUSE" button (middle) and:

- check if the OkuSpex is fitted correctly and the OkuEl electrodes are well positioned with good contact to the eyes,
- lubricate your eyes with eye drops,
- check if the cable of the counter electrode is connected,
- check if the plug of the OkuSpex is connected with the OkuStim,
- resume stimulation by pressing "START" (right).

If the acoustic signal persists and OkuStim does not stimulate correctly, please contact your optician/dealer.

The termination of the stimulation session is signaled by a long beep, followed by a short beep.

The stimulation can be interrupted by pressing the „PAUSE“ button (middle). Pause-mode is indicated by 2 short and recurring beeps. In order to continue your stimulation session, press the „START“ button (right). The stimulation time counter will stop while paused and continue when stimulation is resumed.

Three minutes after completion of the therapy, the OkuStim device switches off automatically.

You can terminate the stimulation at any time by pressing “ON/OFF/STOP” (left).

5.8 Storing the OkuSpex

Remove the plug of the OkuSpex from the connector of the OkuStim device.

Disconnect the cables of the OkuEl counter-electrodes by pulling off the pushbuttons. Never pull the cables as they can tear. When taking off the OkuSpex open the eyes wide so the OkuEl electrodes can be removed easily from the eyes. After that, the OkuEl electrodes can be removed from the OkuSpex and disposed of with the general waste.

The OkuEl electrodes and OkuEl counter electrodes are single use items and must not be used multiple times for hygienic and technical reasons.

Only store the OkuStim and OkuSpex in the designated box. It is best to store OkuEl electrodes in their box - the OkuEl Electrode Package - until use.

5.9 Removing the OkuEl Counter Electrodes from the Skin

Pull off the OkuEl Counter electrodes carefully, starting on one side, and dispose of them with the general waste.

6 Side Effects

Common side effects of the therapy are dry eye symptoms and / or a foreign body sensation (in studies in > 70% of treated patients). In these cases, commercially available eye drops usually help. If the symptoms do not subside after 1-2 days, we recommend that you consult a doctor.
Other side effects that occurred in clinical studies or were reported by regular users of the therapy are listed in the following table.

Side effect	**Frequency**
Sensation of electricity / itching / burning / pain or other discomfort in or around the eye during therapy	10-50
(Partially subjective) deterioration in visual acuity or disturbances in visual perception	50-100
Headache / other discomfort in the head or at the counter electrode	50-100
Cataract	100-200
Makula edema	100-200
Retinoschisis oder retinal cysts	200-400
Increased tear production	200-400
Nausea / feeling faint / dizziness	200-400
Changes in the lens	>400
Gliosis	>400

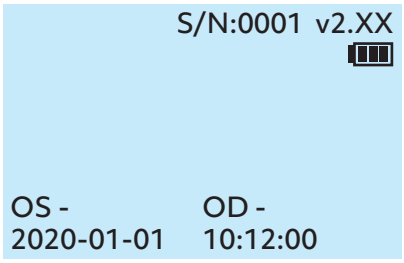
The frequency indicates in how many years of use a side effect occurred exactly once.
A frequency of 10 means that the side effect occurred once in 10 years of therapy use.

If side effects occur, please inform your doctor and, if necessary, Okuvision GmbH. If events occur that are listed as contraindications (e.g. pregnancy), TES therapy must be discontinued. Please inform your doctor in this case.

If visual acuity drops below light perception, TES therapy should no longer be used.

7 Explanation of the Display Information of the OkuStim

When switching on the OkuStim , the following information is shown in the display:



Serial number of OkuStim:
- here S/N: 0001

Firmware Version of the OkuStim:
- here v2.XX

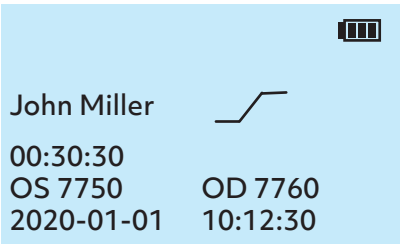
Battery status:
-

Left eye (oculus sinister OS):
- OS -

Right eye (oculus dexter OD):
- OD -

Current date and time:
- here 2020-01-01 10:12:00

When starting and resuming stimulation after a break, the following information is shown in the display:



Battery status:
-

Patient's name:
- here John Miller

remaining time incl. ramping duration (hh:mm:ss)
- here 00:30:30

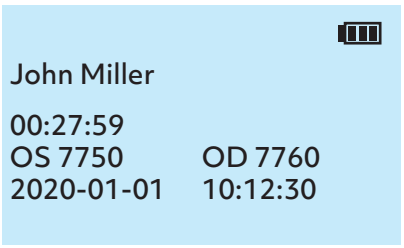
Stimulation status:
- Ramping (slow increase of stimulation strength)

Resistance left eye [Ohm]:
- here OS 7750

Resistance right eye [Ohm]:
- here OD 7760

Current date and time:
- here 2020-01-01 10:12:30

During stimulation with the OkuStim , the following information is shown in the display:



Battery status:
-

Patient's name:
- here John Miller

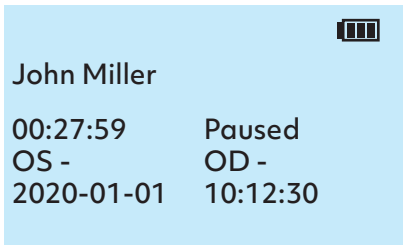
Remainig time of the stimulation (hh:mm:ss):
- here 00:27:59

Resistance left eye [Ohm]:
- here OS 7750

Resistance right eye [Ohm]:
- here OD 7760

Current date and time:
- here 2020-01-01 10:12:30

While pausing the stimulation with the OkuStim, the following information is shown in the display:



Battery status:
- 

Patient's name:
- here John Miller

Remainig time of the stimulation (hh:mm:ss):
- here 00:27:59

Stimulation status:
- Paused

Left eye:
- OS -

Right eye:
- OD -

Current date and time:
- here 2020-01-01 10:12:30

When prematurely terminating a stimulation session with the OkuStim, the following information is shown in the display:

Battery status:
- 

Patient's name:
- here John Miller

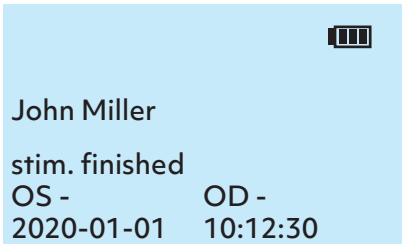
Stimulation status:
- stim. stopped

Left eye:
- OS -

Right eye:
- OD -

Current date and time:
- here 2020-01-01 10:12:30

After ending a stimulation with the OkuStim, the following information is shown in the display:



Battery status:
- 

Patient's name:
- here John Miller

Stimulation status:
- stim. finished

Left eye (oculus sinister OS):
- OS -

Right eye (oculus dexter OD):
- OD -

Current date and time:
- here 2020-01-01 10:12:30

8 Acoustic Signals

Acoustic signal	**Meaning**
13x beep from long to short L-L-L-L-L-S-S-S...	Device switches on
13x beep from short to long S-S-S-S-L-L-L-...	Device switches off
S---S---S(...)	Stimulation running
SS---SS---SS (...)	Stimulation paused
LS	Stimulation was terminated or stimulation ends after automatic shutdown

Explanation of the symbols:

L	= long beep
S	= short beep
-	= pause
(...)	= sequence is repeated permanently

9 Inserting and Changing Batteries

Please only change the batteries when the device is turned off.

Please remove the mini-USB stick previous to changing or inserting the batteries for the first time.

If you are planning not to use the OkuStim for more than 4 weeks, please take out the batteries.

Four type AA batteries (Mignon) are inserted into the compartment on the back of the OkuStim. To open the compartment, you will need the hexagon socket screw key that is provided as part of the system.

Loosen the two screws of the battery compartment cover and remove it.

ATTENTION: One screw is located under the rubber edging of the OkuStim (fig. 8-1). Please do not open with force. Insert batteries ensuring correct orientation (alternate polarity).
The Oku-Stim device switches on automatically with insertion of the fourth battery with an acoustic signal of long and short beeps.

Should the batteries be inserted incorrectly the switch-on acoustic signal will not be heard. In this case, the polarity of the batteries must be corrected.

When the OkuStim is not being used, it will switch off automatically after three minutes, resp. can be switched off by holding the left "ON/OFF STOP" button. Switch off will be acknowledged by an acoustic signal of short and long beeps.

A battery change is not required until the display indicates only one of three bars .
The batteries should last for several weeks with normal use.

Battery status in the display: :

100% / 75% / 25% / 0%

After inserting the batteries close the battery compartment cover and tighten the screws.

Notes:

Always replace all batteries. Do not use rechargeable batteries.

Keep batteries out of the reach of children. Alkaline batteries are toxic. Contact your doctor or local toxic treatment unit immediately in case of consumption. Dispose of used batteries correctly.

Fig. 9-1: Battery compartment cover

10 Storage

Keep the OkuStim and OkuSpex in the box supplied.

Handle the entire system carefully in order to avoid any damage to the electronics or causing other malfunctions.

Do not expose the OkuStim, OkuEl or the OkuEl counter electrodes to excessive moisture, heat, cold or dirt accumulation.

Switch off the device before cleaning (see 11).

Never immerse the device in water and do not expose it to any excessive moisture.

10.1 The Electrode Package

The OkuEl counter electrodes and OkuEl electrodes are supplied in a package for storage.

The OkuEl electrodes OK100305 are individually packaged in the electrode package.

The shelf life of the OkuEl electrodes is indicated on the label, on the front of the individual package.

Please store the OkuEl electrodes at 20°C-25°C ambient temperature.

10.1.1 Storage of the OkuEl Counter Electrodes

The OkuEl counter electrodes are supplied on a carrier film in sachets containing 3 electrodes in the electrode package.

The shelf life of the OkuEl counter electrodes is indicated on the label, on the front of the electrode package. The OkuEl counter electrodes can be stored at temperatures between 5°C-40°C.

After taking out an OkuEl counter electrode please close the sachet of the OkuEl counter electrodes by folding the side that was torn open to protect the remaining electrodes from drying out.

11 Cleaning Instructions

11.1 Cleaning, Disinfection, and Care of the OkuSpex

Clean the OkuSpex frame with a soft, lint-free cloth. Use commercially available dish soap to remove sticky dirt.

For wipe-down disinfection of the OkuSpex we recommend:

- Schülke mikrozid sensitive wipes premium or
- Schülke Pursept-A Xpress wipes.

Both Schülke & Mayr GmbH, Robert-Koch Straße 2, 22851 Norderstedt, Germany.

Wipe down the surface to be disinfected thoroughly with disinfectant wipes. Ensure complete cover! The surface must remain moist during the entire working time. For adequate disinfection, enough disinfectant must be available on the surface.

Warning:

Please do not use aggressive, chloride, abrasive or harsh cleaners. Gasoline, alcohol, or ether solvents must not be used. Ultrasonic cleaning is not permitted.

11.2 Cleaning and Care of the OkuStim

Switch off the OkuStim before cleaning.

The OkuStim and the OkuSpex cable can be cleaned using a soft, lint-free cloth. The cloth should be damp at most, never wet. It is important to ensure that no moisture gets inside the device, however if moisture enters the OkuStim must undergo a safety and function check before the next use. Please contact your optician or dealer as necessary.

11.3 OkuEl Electrodes and OkuEl Counter Electrodes

The OkuEl electrodes and OkuEl counter electrodes are single-use items and must not be reused for hygienic and technical reasons.

12 Repair and Maintenance

No maintenance is required for private use. Commercial users have to follow the regulations for the usage of medical electrical devices.

Warning:

Do not perform any repairs or maintenance of the device. In such a case contact your dealer.

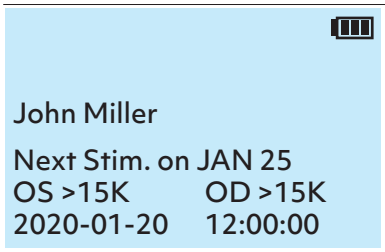
Batteries can be changed as shown in chapter 9.

13 Troubleshooting

Should the device not function properly it is indicated by a particular sequence of acoustic signals and display information (see below).

13.1 Display Messages

Display	Meaning
John Miller 00:29:59 open OS > 15K OD > 15 K 2020-01-01 12:00:00	Open contact or fault in at least one OkuEl electrode. In such a case, interrupt the stimulation by pressing the „PAUSE“ button (middle) and: • check if the OkuSpex is fitted correctly and the OkuEl electrodes are well positioned with good contact to the eyes • apply a tear substitute to your eyes • check if the cable of the counter electrode is connected • check if the plug of the OkuSpex is connected with the OkuStim • resume stimulation by pressing “START” (right)
John Miller 00:25:00 ShortCir. OS <200 OD <200 2020-01-01 12:00:00	Short circuit in at least one electrode. In such a case, please contact your optician directly.
John Miller Error Defect! OS - OD - 2020-01-01 12:00:00	This indicates that the patient can be electrostatically charged. Please switch off the device and switch on again and check whether this error reoccurs. If the error persists, touch a grounded metal object (such as a water tap), to be sure to discharge static electricity. If the error persists further, please contact your optician.
John Miller No Memory Stick OS - OD - 2020-01-01 12:00:00	There is no mini-USB stick in the device or it has not been inserted properly. Please switch off the device and check if the USB stick is inserted the right way.
John Miller Invalid config. file OS - OD - 2020-01-01 12:00:00	There is an incompatibility between your OkuStim device and the mini-USB stick that is being used, or the stimulation could not commence because the configuration file could not be found. Please check if the mini-USB stick is inserted properly. Should the error persist, please contact your optician directly.

	You tried to start the next therapy session before it was due. A message is displayed showing when the next session can be performed. (Example here: The next session can be performed January 25th or after.)

13.2 Acoustic Signals

Acoustic signal	**Meaning**
MMM (...)	Open contact or fault in at least one OkuEl electrode.
S S S (...)	Short circuit in at least one electrode
SS - SS - SS - S	Stimulation could not commence because the configuration file could not be found. Please ensure the mini-USB stick is correctly inserted into the OkuStim with the gold contacts facing down, or consult your doctor for re-writing the programming on the mini-USB stick.
LSSS	You tried to start the next therapy session before it was due.

Explanation of the symbols:

L	= long beep
M	= medium-long beep
S	= short beep
-	= pause
(...)	= sequence is repeated permanently

14 Technical Data

The OkuStim and the OkuEl electrode are Class IIa medical devices according to Annex IX, Rule 9 and Rule 5 of the EU Medical Devices Directive 93/42/EEC, respectively.
The OkuSpex and the OkuEl counter electrode are Class I medical devices according to Annex VIII, Rule 1 of the EU Medical Devices Regulation (EU) 2017/745.

Power supply

4x 1.5V Standard AA-Type Batteries (Mignon)

Connections

Connector for electrodes; connector to OkuSpex; Mini-USB-Port; USB to standard USB-B socket

USB Memory Card

Mini-USB-Stick (specially configured by Okuvision GmbH; included in delivery scope)

Casing

Protection against dust (IP 22) Protection Class: internally powered (battery powered)

Applied Part: Type BF

Operating Life

The OkuStim system has an expected operating life of 5 years. The OkuSpex has an expected operating life of 2 years.
The OkuEl electrodes and OkuEl counter electrodes have a shelf life of 18 months. The shelf life is indicated on the packaging.

Operating Conditions OkuStim

Temperature:	+5°C – +40°C
Humidity:	15% – 93% relative humidity (not condensating)
Atmospheric pressure:	700 hPa – 1060 hPa

Storage Conditions OkuStim

Temperature:	+5°C - +40°C
Humidity:	15% - 93% relative humidity (not condensing)
Atmospheric pressure:	700 hPa – 1060 hPa

Transport conditions OkuStim system

The OkuStim system is not subject to any separate transport requirements.

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.

15 Disposal of Used Devices and Batteries

Please dispose of used batteries correctly.

OkuEl electrodes and OkuEl counter electrodes that have been in use can be disposed of as normal household waste. The OkuStim and OkuSpex are not to be treated as household waste. They have to be disposed of at a local waste collection site for the recycling of electrical waste. Further information can be obtained from Okuvision GmbH or your OkuStim system supplier.

15.1 Data protection

We would like to point out to all end users of electrical and electronic equipment that you are responsible for deleting any personal data on the equipment prior to disposal. Since the patient data on the USB memory card is encrypted and can only be displayed with the OkuStim software or the OkuStim, it is sufficient to dispose of the USB stick separately.

16 Warranty

For all components of the OkuStim system, the legal warranties apply.

Restrictions of the warranty: The warranty is subject to the following exceptions and restrictions:

- The warranty is limited to the replacement in case of material or manufacturing faults. Okuvision GmbH is not obliged to replace devices whose malfunction or damage has been caused by misuse, accidents, alterations, incorrect use, negligence or unprofessional maintenance. In addition Okuvision GmbH does not assume any liability for damages or malfunctions of OkuStim systems, which have been caused through the utilization of products other than those manufactured by Okuvision GmbH.
- Okuvision GmbH reserves the right to replace devices in the event of a warranty claim with an equivalent successor model, which may have design changes.

Regardless of the legal warranty claims, Okuvision GmbH does not issue any other guarantees for this product. Liability for damages or consequential damages, even in the case where Okuvision GmbH was informed about the possibility of such damages, exists only within the framework of the legal regulations.

17 Accessories

Part number	**Product designation**
OK100350	OkuSpex®
OK100056	OkuStim®
OK100310	OkuEl® Electrode package
TD60K06-02	OkuStim® System Gebrauchsanweisung (DE)
TD60K06-03	OkuStim® System Instructions for Use (EN)
TD60K06-06	OkuStim® System Mode d'emploi (FR)
TD60K06-08	OkuStim® System Istruzioni per l'uso (IT)
TD60K06-09	OkuStim® System Kullanım Talimatları (TR)
TD60K06-10	OkuStim® System Οδηγίες χρήσης (EL)
TD60K06-11	OkuStim® System Instrucciones de uso (ES)
TD60K06-13	OkuStim® System Gebruiksaanwijzing (NL)
TD60K06-14	OkuStim® System Instrukcja użytkowania (PL)
TD60K06-22	OkuStim® System Bruksanvisning (NO)
TD60K06-24	(תירבע) שומישל תואורה OkuStim® System (HE)
TD60K06-25	(عربي) دليل استعمال نظام OkuStim® (AR)
TD60K06-27	OkuStim® Käyttöohjeet (FI)
TD60K06-28	OkuStim® System Bruksanvisning (SE)

18 Information Regarding Electromagnetic Compatibility

The OkuStim system can be used in a professional healthcare or home environment.

Warning:

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.

Warning:

Use of accessories and cables other than those specified on page 31 or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equip ment and result in improper operation.

The OkuSpex cable has a length of 1.6 m.

Warning:

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 this chapter.

Warning:

Interference of the OkuStim is possible in the frequency range of 80 MHz to 86 MHz. In this case, the error message „Error Defect!“, see chapter 13, will be displayed.

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 B.

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 $V_{Eff.}$ 150 kHz to 80 MHz outside ISM and amateur bands	3 $V_{Eff.}$ 150 kHz bis 80 MHz outside ISM and amateur bands	d=1,2√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)

Notes

Notes