Patient Guide for the

iTear® 100

Neurostimulator™

Manufactured by: Olympic Ophthalmics
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Please read this entire guide. If you have any questions, contact your eye care provider. RX Only. Federal law restricts this device to sale by or on the order of a physician

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GLOSSARY

Adverse event: An undesirable effect associated with the use of a medical product.

Contraindications: Cases where iTEAR®100 Neurostimulator™ should not be used.

Cornea: Clear tissue that covers the front of the eye.

iTEAR®100 Neurostimulator™: Medical device which applies vibration to an area of the nose to temporarily stimulate the flow of tears.

OD: Oculus dexter; right eye

OS: Oculus sinister; left eye

OSDI: Ocular Surface Disease Index; 12-item questionnaire designed to assess the symptoms of ocular irritation consistent with dry eye disease and their impact on vision-related functioning.

OU: Oculus uterque; both eyes

Warnings: A warning alerts the user about serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

INTRODUCTION

This guide is intended to help you use the iTEAR®100 Neurostimulator device to provide a temporary increase in tear production.

The device applies a gentle vibration to a nerve on the side of the nose, called the external nasal nerve, to temporarily stimulate tear flow.

FACTS ABOUT TEAR PRODUCTION

In some people, the eye does not make enough tears to ensure sufficient moisture of its surface. Other patients do not produce enough lipids (fats) in their tears and so the tears evaporate too quickly. The end result can be pain and burning and, over time, damage to the cornea. Treatments such as artificial tears are helpful but they usually wash away quickly and may need to be applied several times per day. iTEAR®100 Neurostimulator works by temporarily increasing the quantity of natural tears.

DEVICE DESCRIPTION

The iTEAR®100 Neurostimulator is a portable electromechanical medical device intended to upregulate tear production through vibratory stimulation of the external nasal nerve in adult patients. The device (Figure 1) is comprised of a power source which is provided in place and within the device, a motor attached to a cantilever beam made from acrylonitrile butadiene styrene (ABS), a control circuit to charge the battery and deliver power to the motor, and a housing also made from ABS. The motor and cantilever beam move together to produce a linear vibration at the tip of the cantilever (oscillating tip). To produce the intended effect, the patient applies the device to the lateral aspect of the nose and pushes a button to commence a therapeutic session. The tip of the cantilever retracts into the device housing as increasing force is applied against the skin. The battery, a lithium-ion rechargeable battery, is supplied inside the device, and is not removable or replaceable. A USB-C port on the device allows for charging.

The frequency of operation without any force applied is approximately 270 Hz. The amplitude of movement is approximately 0.5 mm without force applied. In the optimal force range, the cantilever tip is depressed approximately 1 mm and the frequency is approximately 250 Hz. Below is a list of stimulation parameters for the device:

Parameter	Control – In air	With Force
Frequency	270 Hz	250 Hz
Amplitude	0.6 mm	Not tested
Acceleration (g)	50	5
Tip Retraction (maximum force) (100%)	<6N	N/A
Acoustic	<35 db	<35 db

Table 1. Key parameters for the iTEAR®100 neurostimulator

Figure 1. iTear® 100 Neurostimulator

INDICATION FOR USE

The iTEAR®100 Neurostimulator is an electromechanical nerve stimulator device, indicated for temporary use (up to 30 days) to increase acute tear production during vibratory stimulation of the external nasal nerve in adults, under prescription of an eyecare provider.

POTENTIAL BENEFITS OF THE iTEAR®100 NEUROSTIMULATOR DEVICE

Use of iTEAR®100 Neurostimulator should temporarily increase acute tear production although not all patients respond to the same degree.

POTENTIAL COMPLICATIONS WITH USING THE iTEAR®100 NEUROSTIMULATOR DEVICE

- Skin discomfort or irritation at site of application
- Headache
- Dizziness
- Facial Pain
- Itching/Tickling sensation of nose
- Sneezing
- Worsening of underlying ocular conditions
- Blurred vision
- Worsening of
- dry eye symptoms
- Nausea
- Lightheadedness

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS

Contraindications: None

⚠ Warnings

- Warning: Do not use the device if you have skin irritation where the device would be placed. In addition, new skin irritation may result from the device. Use for durations specified; stop using device and contact your health professional should you observe skin irritation.
- Warning: If numbness or pain in the nasal skin occurs, stop using the device and contact your prescribing eye care provider.
- Warning: Do not modify iTEAR®100 Neurostimulator. The device contains no user-serviceable components!
- Warning: Do not place iTEAR®100 Neurostimulator near heat sources, including lit fireplaces or radiant heaters. Follow the Instructions for Use when operating the device.
- Warning: This device includes a lithium-ion battery, which carries a risk of overheating, explosions, or fire.
- Warning: Do not use the iTEAR®100 Neurostimulator while in the bath or shower. iTEAR®100 Neurostimulator is not waterproof and is minimally water resistant.
- Warning: Do not use the iTEAR®100 Neurostimulator while driving, operating machinery, or during any activity in which sneezing or watery eyes may put you at risk for injury.
- Warning: Do not apply the iTEAR®100 Neurostimulator to areas other than the nose.
- Signs of deterioration in essential performance (vibration frequency, amplitude) include decrease in the pitch of the motor.

If you experience an adverse event while using the device please contact the manufacturer using the contact information on the cover page of this manual. You may also contact MedWatch at the following link https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

⚠ Precautions

- This device should be kept out of reach of children.
- The safety of the iTEAR®100 Neurostimulator device has not been established in the following patient populations:
  - Patients who are pregnant;
  - Patients under 22 years of age;
  - Patients with Sjogren's syndrome or other rheumatologic conditions;
  - Patients with eyelid function abnormalities or history of facial nerve palsy;
  - Patients with history of neuromuscular disorders;
  - Patients with history of uncontrolled ocular or systemic disease;
  - Patients with clinically significant local skin conditions at the treatment site (e.g., infection).
  - Patients with intraocular surgery within 6 months of use;
  - Patients with intraocular or periocular injection within 6 months of use;
  - Patients with any acute infectious or non-infectious ocular condition of the anterior or posterior segments in either eye within 30 days of use;
  - Diseases/conditions of ocular surface associated with clinically significant scarring/destruction of conjunctiva/cornea.
- Device use may elicit migraine symptoms.
- Patients should read this document carefully and talk with their eye care provider to understand how to use the device correctly.
- In the main clinical study, the safety and effectiveness of the iTEAR®100 Neurostimulator device was adequately characterized over a 30-day time period. The safety and effectiveness of the device for longer periods of use have not been established.

Environmental and Operating Conditions

- iTEAR®100 Neurostimulator is operable within the temperature range of 15-35°C (60-95°F)
- If iTEAR®100 NeuNeurostimulator has been stored below its minimum use temperature, allow 15 minutes at room temperature (approximately 20°C or 68°F) to warm prior to use.
- If iTEAR®100 Neurostimulator has been stored above its maximum use temperature, allow 20 minutes at ambient temperature (approximately 20°C or 68°F) to cool prior to use.
- iTEAR®100 Neurostimulator is rated IP22 which means the unit is water resistant to light dripping water for less than 10 minutes.

INSTRUCTIONS FOR USE

Prior to the health care professional prescribing this device, it is recommended that your health care professional assist you in the first use of this device in the clinic, in order for the professional to determine whether you are a good candidate for using this device and to instruct you on the proper use of the device.

Figure 1 depicts the iTEAR®100 Neurostimulator device. It includes a USB-C charging cord and microfiber pouch. The battery, a lithium-ion rechargeable battery, is supplied inside the device, and is not removable or replaceable. The device is removed from its package and held as depicted in Figures 2 & 3. The **blue** button is an **ON/OFF** switch. When pressed, the device is **ON**, when released the device

is **OFF**. The device is supplied with full charge but in a sleep mode. Hold the power button for at least 5 seconds, release and press again; you should see an orange light which means a prescription needs to be downloaded. In case no lights are seen, then plug into power and press the power button both on and off power after 15 minutes of charging; if no lights at this point, contact the company. As described below, download the iTEAR® mobile phone application (Android or iPhone store), then create, and then log into your account; if your doctor sent a prescription to the company and you paid for a prescription, then a 30-day prescription will be available on the home screen. Download this prescription on the mobile phone application by pressing on the prescription button and then pressing on the 30-day prescription in the menu (Figure 7).

The indicator LEDs should turn be green once your prescription has been loaded and when the power button is pressed. If the device does not function, contact the company using the email or the number provided, and a new device will be immediately shipped. Otherwise, practice turning the device on and off with this switch, as depicted in Figure 2. While **ON**, the vibration will briefly stop every 10 seconds. This allows you to time your treatment.

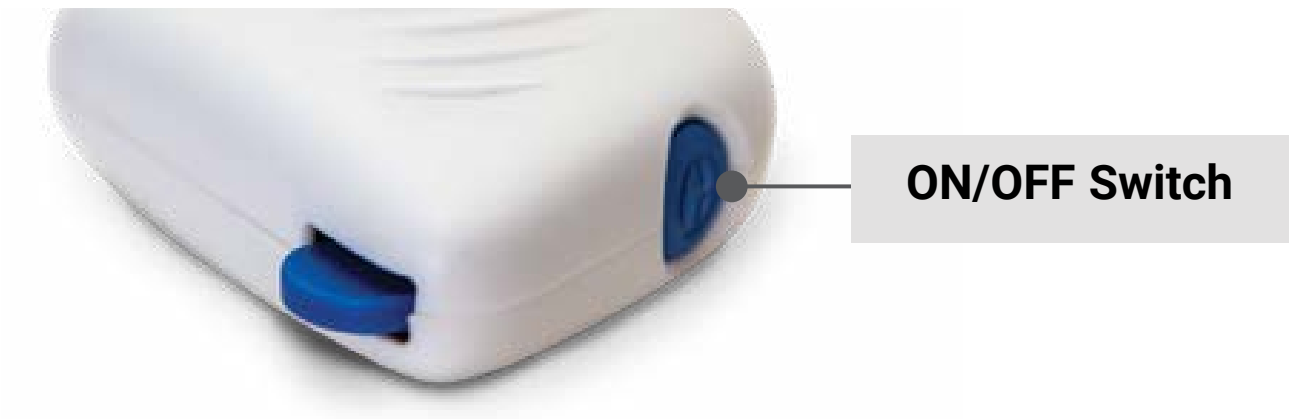


Figure 2: iTEAR®100 Neurostimulator on-off switch

Figure 3: Suggested Hand Position

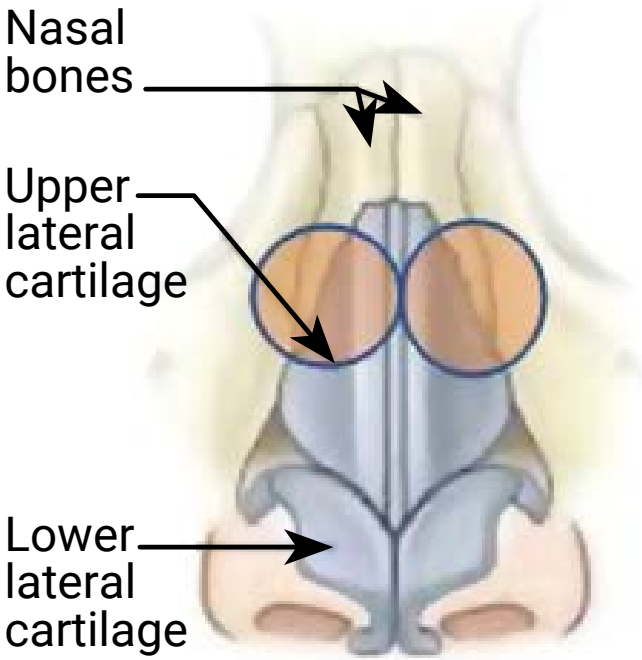


Figure 4A

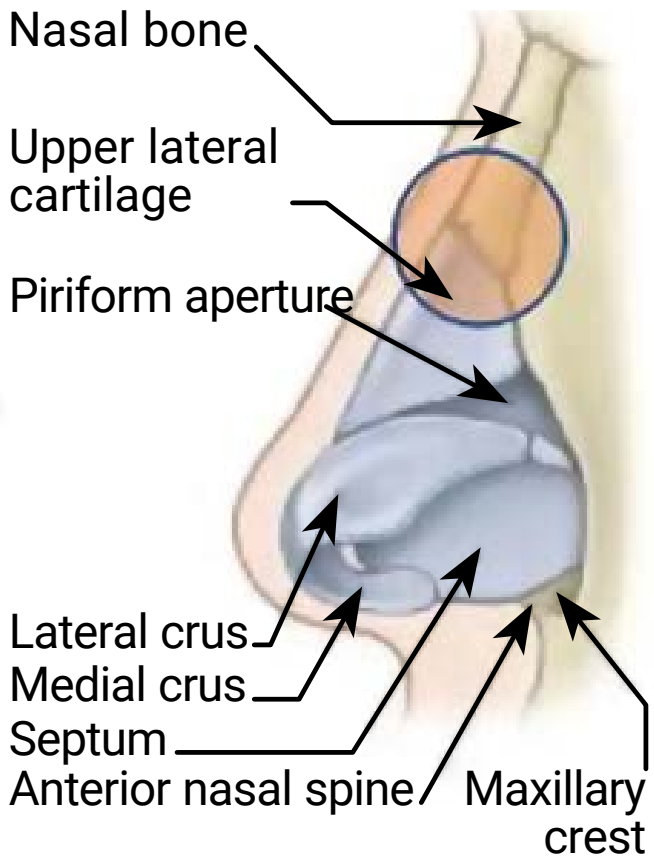


Figure 4: Treatment position for iTEAR®100 Neurostimulator

Figure 4B.

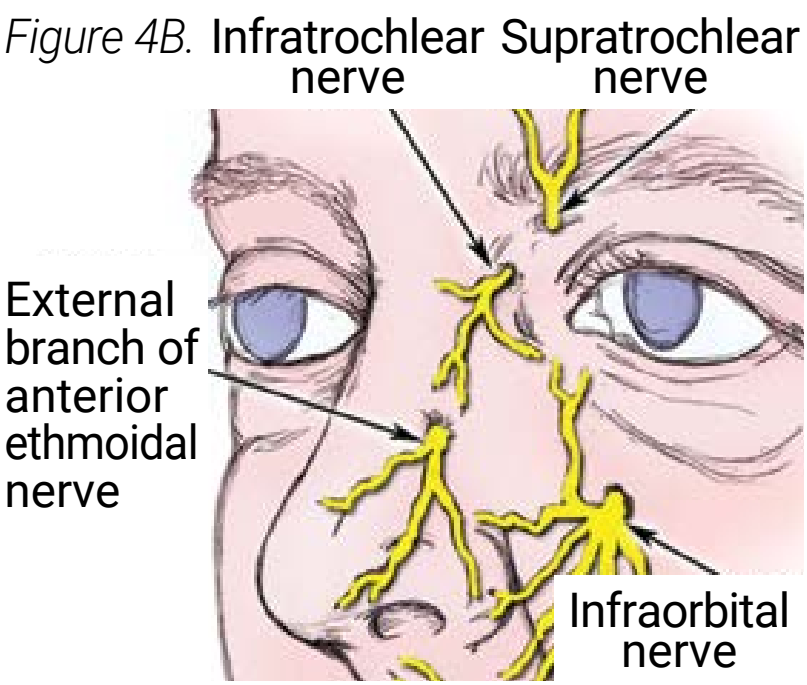


Figure 5

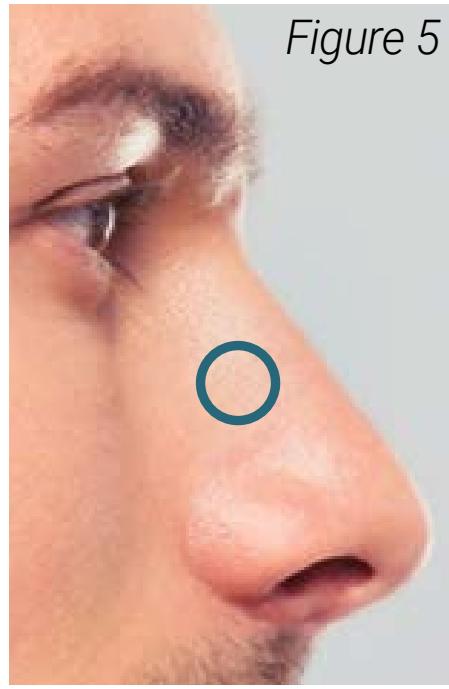


Figure 5: Recommended position on the nose and expected tearing which can be visualized in mirror during treatment. Junction of nasal bone (the hard part of the nose) and cartilage (softer part).

APPLYING THE DEVICE

- Before using iTEAR®100 Neurostimulator for the first time, run your index finger along the sides of your nose and feel the transition between the hard part (nasal bone) and the softer part (lateral nasal cartilage), which is the point where the vibrating tip of the device should be applied (Figure 5).
- Next, turn on iTEAR®100 Neurostimulator by depressing the button, and briefly touch the tip to the palm of your hand to get a sense of the vibration. The device should be applied lightly; when too heavy a pressure is exerted against the skin, the sound of the motor will change to a dampened pitch. Practice listening for this change while applying the device to the palm of the hand. You can then practice

applying the device lightly to the side of your nose, as shown in Figures 4-5, just where the hard part (nasal bone) meets the softer part. Use your left hand for the left side of your nose & right hand for the right side of your nose. Do not apply the device outside of the circles shown on Figure 4. The safety of the device has not been studied outside this region. Note that your eyes may tear and your nose may water. This response may feel dramatic at first but will subside over time. If any or all of these occur, then the device is positioned correctly. If not, then move the device lightly along the side of the nose until the correct location is found, ensuring that you keep the position of the device within the target region shown in Figures 4 & 5. Once in the correct spot, you are ready to perform a full treatment.

- To view your usage and allow your Doctor to view your usage, press the "upload usage" button in the iTEAR® app (Figure 7).

ACTIVATING THE iTEAR®100 DEVICE

- To activate your prescription, you must download the iTEAR® mobile device application to your phone through the Apple App store or Google Play store and create an account through your phone or tablet. You will receive an email with a security code which you will enter into the app to confirm your email, after which you will be registered. Now you can enter the iTEAR® app using your user name and password.
- The iTEAR® app will prompt you for your Doctor's name. Now you can see your device in the Bluetooth device menu. If you do not have a Doctor or your doctor is not recognized, press the help button and a company representative will contact you.
- After your Doctor is entered, you should see the screen in

7a. If you do not see a device, press the refresh arrow to the left of the menu on top right of the screen and make sure there are lights on your device. If you do not see the device after checking these things, then contact the company. Press the arrow to the right of the device and you should enter the screen in Figure 7b. If there is a prescription, you will see it when pressing the menu button which will allow you to download a prescription. Now you should see the active device time-period (see Figure 7) and your device should be active when the power button is pressed until the time indicated on the device for the active prescription. Contact the company if you have trouble with this step.

Figure 6

Figure 6: Sign up for an account on your phone after loading the application from the Google Play or Apple App store. Enter an email address and password. Check the email in a minute and then enter the sign-up code. Login with email and password to then see your device.

Figure 7A

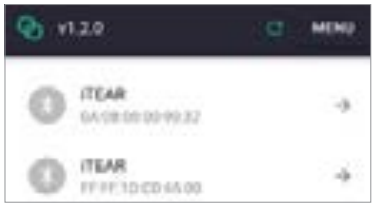


Figure 7: Mobile application screens at login (a) showing serial number of iTEAR® devices, (b) before prescription download, and (c) after prescription download. The serial number of the device shows up on the home screen when the iTEAR® device is either not claimed by an account or the account holder logs in to a device which is already attached to a user account. "Update firmware" appears when there is a firmware update available. "Disconnect" is to disconnect the iTEAR®100 from the mobile device. Intensity level 5 is the intensity that was used in the clinical trials.

Figure 7B

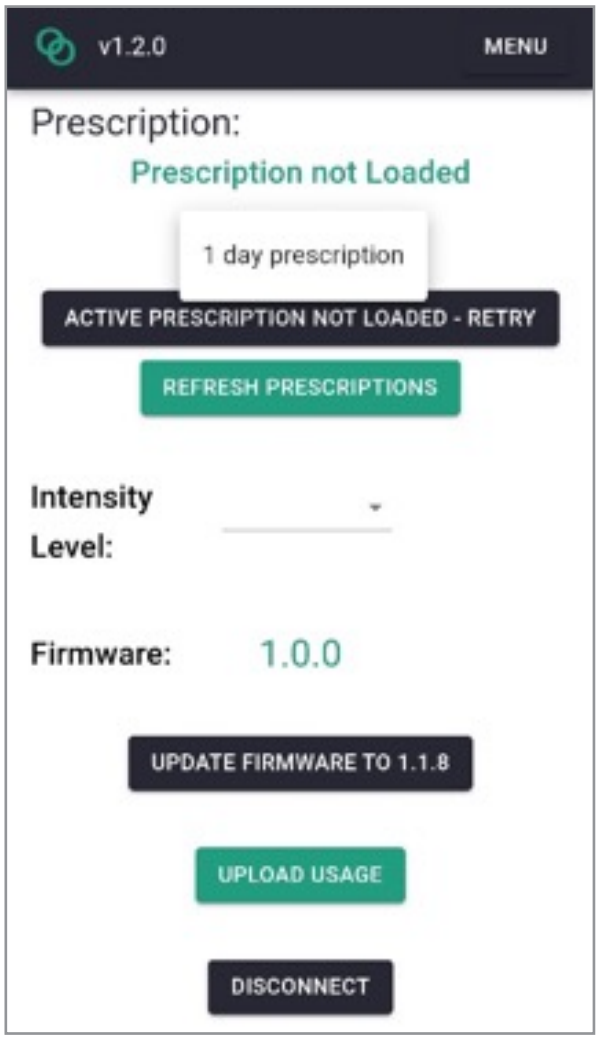
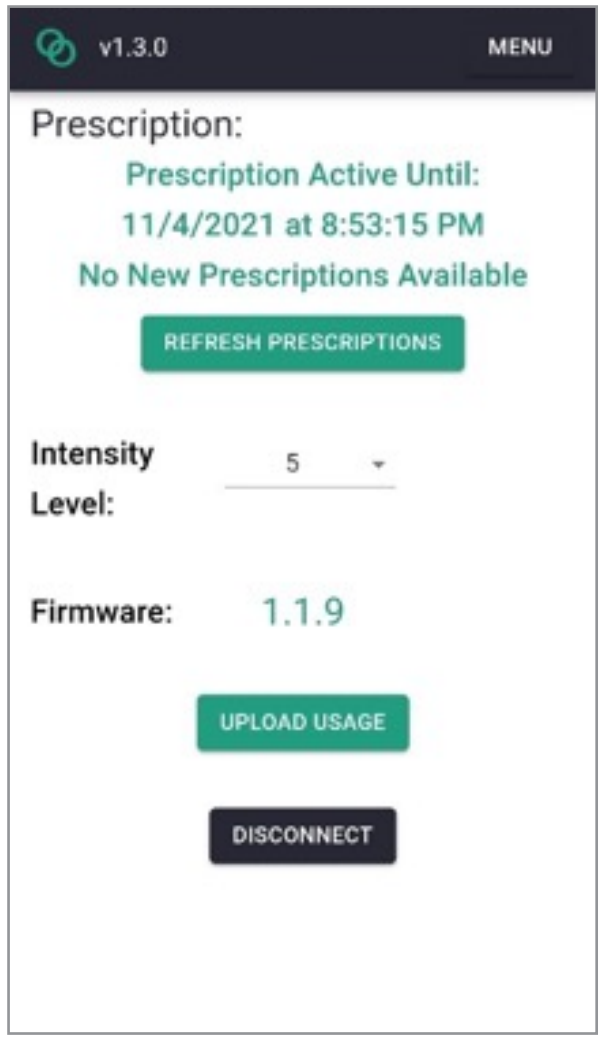


Figure 7C



RECOMMENDED REGIMEN

The maker of the device recommends using iTEAR®100 Neurostimulator up to twice a day, as needed. Applying it longer than 30 seconds per side is not recommended, and you should wait for at least 60 minutes before proceeding to the next application. iTEAR®100 Neurostimulator has, so far, not been used in clinical studies more than about 2 minutes per day, and longer use is not recommended. Note that patients will have individual sensitivity to the device, and some may note decreased response after several days of use. Please contact your physician if you notice a diminished response to the device.

In the main clinical study, the safety and effectiveness of the iTEAR®100 Neurostimulator device was adequately characterized over a 30-day time-period. The safety and effectiveness of the device for longer periods of use have not been established. The device is programmed to turn off after 30 days. Consult your doctor after the device shuts off.

CHARGING YOUR DEVICE

- With typical twice daily usage at 30 seconds per side twice per day, a fully charged iTEAR®100 Neurostimulator is expected to last up to the entire 30 days.
- The charge level is determined by looking at the light flashing from within the device near the USB-C port. The light can be activated by pressing the ON/OFF switch.
  - Blue flashing light indicates power to the device.
  - Green light indicates full charge when plugged in
  - Yellow light indicates the device is charging while plugged in. When fully charged, the light will turn green when plugged in.
  - When not plugged in, an orange light flashing 3 times indicates that the power level is below approximately 20%. Charge the device.
- iTEAR®100 Neurostimulator can be charged using the supplied USB-C cable or one of your own.
- The USB-C connector of the charging cable is inserted into the device and the USB connector is inserted into the USB port of a wall charger, computer, or a portable charger. Power adapters intended for non-U.S. current are acceptable. If the iTEAR®100 Neurostimulator is plugged into a computer, it will not be recognized by

the computer. No information from the computer to the iTEAR®100 Neurostimulator or iTEAR®100 Neurostimulator to the computer will occur. The iTEAR®100 Neurostimulator will only be charged from the computer.

CLINICAL DATA

Two clinical studies, CLP-002 and CLP-007, have been completed with the iTEAR®100 Neurostimulator and are discussed below.

CLP-002

CLP-002 was a clinical study performed at 8 clinics in the United States. In the first stage of the study, subjects used the device at home for 30 days. After 30 days, subjects were given the option to participate in an additional 150 days of follow-up while using the device (180 days in total).

The subject was provided a take-home device to perform the study treatment per the instructions for use. It was recommended that subjects use the study device for 30 seconds on each side twice per day for the 30-day follow-up period. After 30 days, subjects were asked to use the device at least once every other day for the remaining 150 days.

To be enrolled in this study, subjects must be twenty-one (21) years of age or older; have reduced tear production in at least one eye; be able to produce tears upon using the device, and be in good general health. Subjects were not included in the study if they had Sjogren's syndrome or other rheumatologic condition, eyelid problems, active eye infections or conditions, eye conditions that cause problems with the eye surface; history of facial nerve palsy, neuromuscular disorder, uncontrolled ocular

or systemic disease, or other clinically significant local skin condition (e.g., skin infection) at target treatment site.

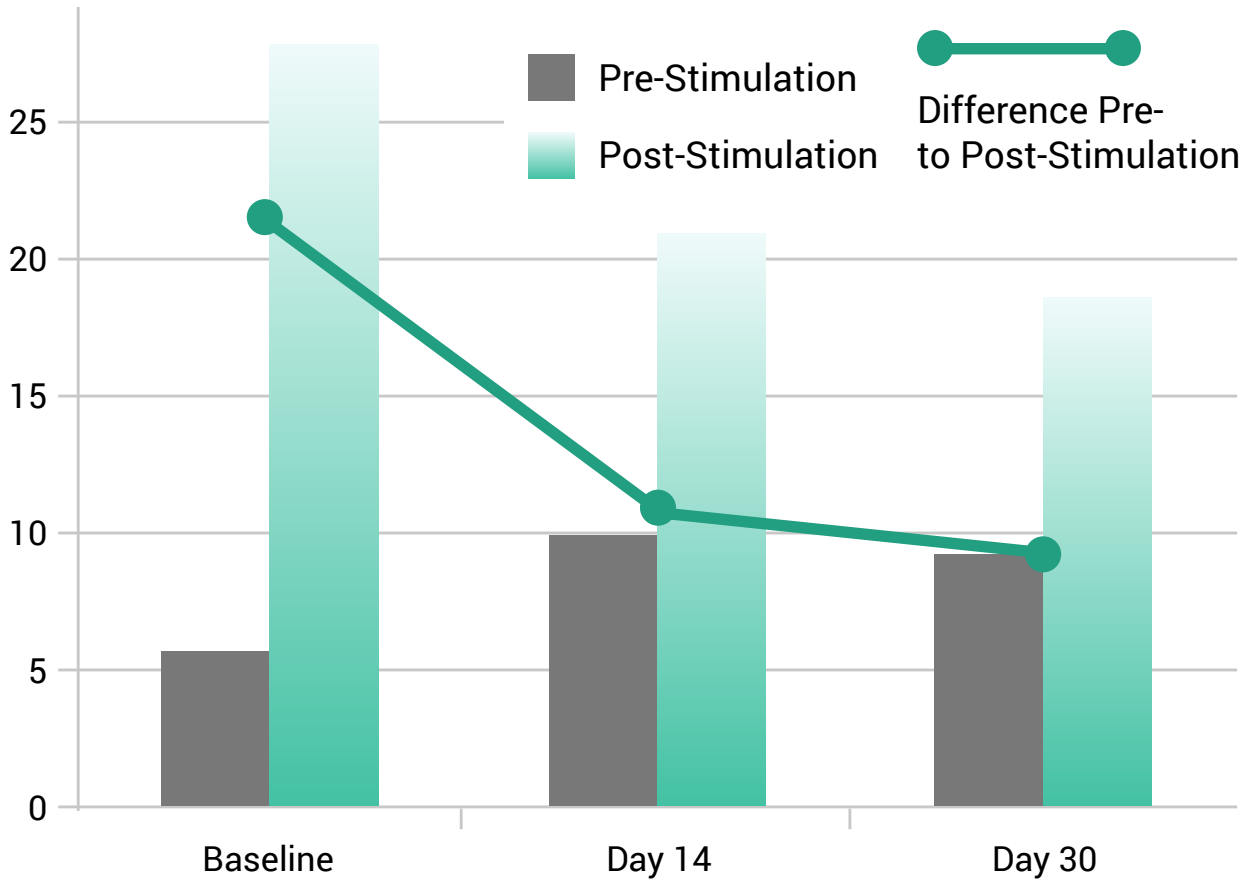
The study enrolled 108 subjects, of which 101 subjects completed the 30 days of follow-up. The majority of people who enrolled in the study were female. Tear production was increased in response to stimulation with the device (Figure 8). This effect was demonstrated at each study visit through the 30-day follow-up period. A test for tears called the Schirmer's test, where a Schirmer strip is placed in the subject's eye to measure tear production, demonstrated that subjects produced more tears with the device through the 30-day follow-up period.

During the 180-day follow-up period, 15 adverse events of the eye were reported. Three eye infections occurred. One of each of the following adverse event types also occurred: blurred vision, corneal abrasion, corneal medicamentosa (corneal damage from too much medication use), dry eye pain, eyelid irritation, floater in eye, inflammation of eyelids, severe itching and sensitive eyes, Sjogren's syndrome, eyelid stye, bleeding in the back of the eye. The eyelid stye and severe itching were considered to be possibly related to the device. There were an additional 7 device-related adverse events reported: headache/sneezing/tickling sensation; intermittent nose soreness; lightheadedness/dizziness; nausea/dizziness/lightheadedness/headache; dry eye pain; pain on side of head; and headache. After a single device treatment, one subject experienced continuous nausea, dizziness, lightheaded and headache for a 30-day duration. The subject was instructed to seek neurological evaluation, stop device use, and discontinue from the study. This adverse event

was considered to be a serious unanticipated adverse event, possibly related to the device. The subject stopped device use, was discontinued from the study, visited an acupuncturist, and experienced subsequent symptom resolution.

Additionally, 4 subjects experienced a decrease in visual acuity of two or more lines, and 5 subjects experienced an increase in visual acuity of 2 lines or more. All 4 subjects who lost vision returned to baseline during the follow-up period. Investigators believe that this decrease in vision was because of temporary worsening of dry eye disease, but they could not determine this with certainty because of limitations in the study design.

Change in pre-stimulation and post-stimulation tear production (Schirmer score)



	Pre-Stimulation		Post-Stimulation		Change Pre- to Post-Stimulation
Visit	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**Mean (SD)**
Baseline	108	6 (3.8)	108	28 (8.5)	22 (7.8)
Day 14	101	10 (7.1)	100	21.1 (11.7)	11.1 (8.4)
Day 30	101	9.4 (7.6)	101	18.8 (11.8)	9.4 (9.3)

Figure 8: Primary results from CLP-002 study

CLP-007

CLP-007 was a single visit clinical trial that enrolled 60 subjects. In this clinical study, some subjects received a fully functional device (Active device), and other subjects received a device that looked identical and made noise similar to a fully functional device but had a tip that did not vibrate (Inactive device).

To be enrolled in this study, subjects must have met all of the following criteria:

① 18 years of age or older;
② willing and able to provide an English language written informed consent;
③ able to safely use the study device and be free of any condition that, in the opinion of the investigator, could impair study participation.

Additionally, patients could not meet any of the following criteria, or they were excluded from the study:

① presence of clinically significant nasal/facial skin conditions (e.g., infection, ulceration, wound);
② Under arrest or was otherwise in custody;
③ presence of any other condition, which in the judgment of the Principal Investigator would prevent a potential subject from safely completing the study or tolerating device use, such as mental illness, dementia, severe agitation, etc.).

The study demographics are below.

Summary[a]	Randomized Treatment		All Subjects (N=60)
	Active (N=28)	Sham (N=32)	
Sex, n (%)			
Female	16 (57.1%)	24 (75.0%)	40 (66.7%)
Male	12 (42.9%)	8 (25.0%)	20 (33.3%)
Age (Years)			
Mean (SD)	49.7 (15.99)	50.0 (16.25)	49.9 (16.00)
Median	51	50	51
Min, Max	24, 79	21, 77	21, 79
Ethnicity, n (%)			
Hispanic or Latino	3 (10.7%)	7 (21.9%)	10 (16.7%)
Not Hispanic or Latino	25 (89.3%)	25 (78.1%)	50 (83.3%)
Race, n (%)			
Asian	5 (17.9%)	7 (21.9%)	12 (20.0%)
Black	2 (7.1%)	1 (3.1%)	3 (5.0%)
Caucasian	18 (64.3%)	21 (65.6%)	39 (65.0%)
Other	3 (10.7%)	3 (9.4%)	6 (10.0%)
Subjects using Eye Treatment, n (%)	21 (75.0%)	25 (78.1%)	46 (76.7%)
OSDI at Screening			
Mean (SD)	49.3 (24.64)	50.3 (24.27)	49.8 (24.24)
Median	48	48	48
Min, Max	8, 96	3, 92	3, 96

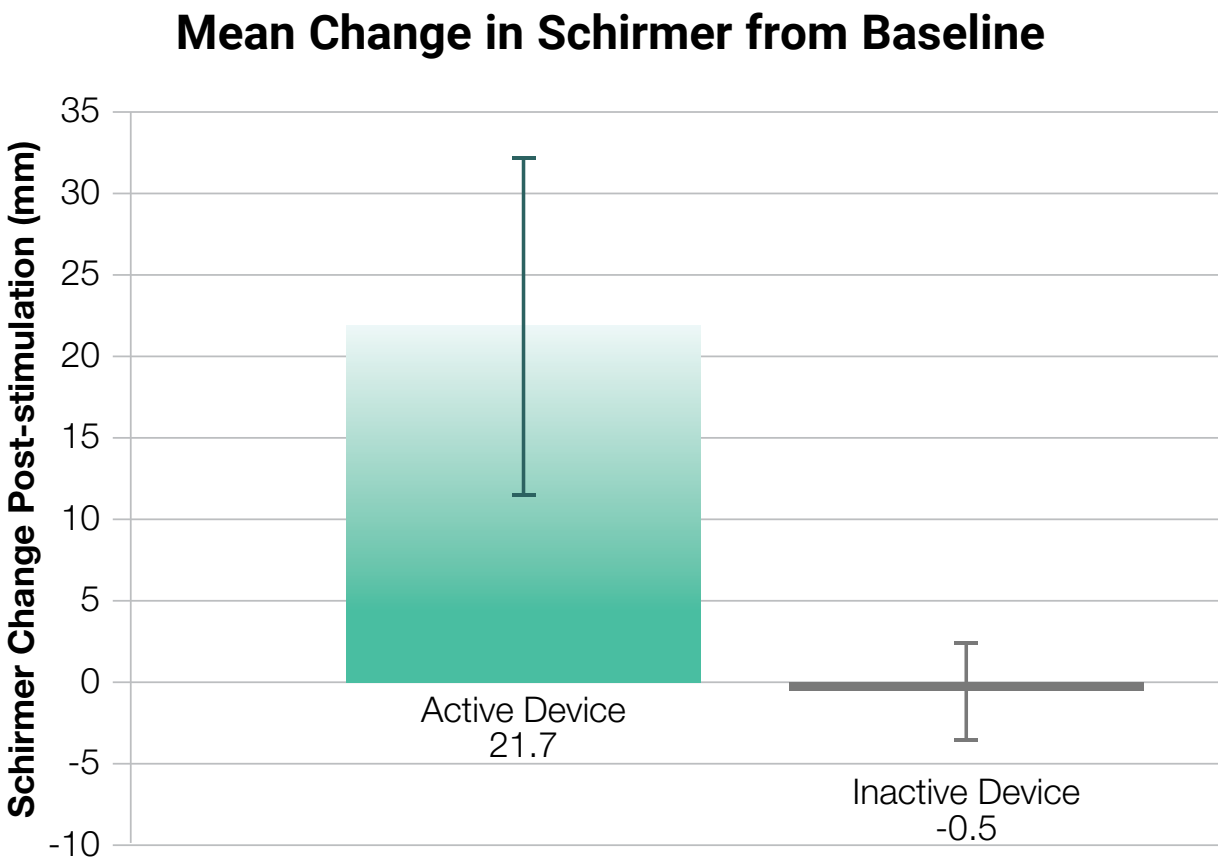


Figure 9. Schirmer's Test Score Change in Active Compared to Sham Groups

The results showed that, on average, subjects who had an Active device had a larger increase in tearing compared to the subjects who used the Inactive device. As shown in the figure below, subjects using a functional device had an average increase in tear production of 21.7 mm compared to the group with an inactive device (around 0 mm increase in tear production, on average).

There were no device-related side effects reported in this study.

CARING FOR iTEAR®100 NEUROSTIMULATOR

Clean the device daily, and as needed, using Sani-Cloth® disinfectant wipes, or similar, to gently wipe the tip and the housing. **Note: Do not submerge iTEAR®100 Neurostimulator in water, or any liquids!**

DEVICE AND BATTERY DISPOSAL

- iTEAR®100 Neurostimulator is warrantied for 1 year of use.
- Olympic Ophthalmics will supply a shipping envelope to return the expired device to the company.
- The device contains no user-serviceable parts!
- Users should not tamper with the casing or attempt to access the battery.

TROUBLESHOOTING GUIDE AND WARRANTY INFORMATION

- If the charge light does not come on when the USB cable is plugged in, try a different USB power source.
- If iTEAR®100 Neurostimulator does not activate when the ON/OFF button is depressed, charge the device for at least 2 hours and try again.

- If iTEAR®100 Neurostimulator does not activate when the ON/OFF button is depressed, check that the USB cable is disconnected from power. iTEAR®100 Neurostimulator will not operate when plugged in and charging.
- Your iTEAR®100 Neurostimulator device comes with a 1 year warranty for mechanical and shipping failure.

The warranty email is warranty@oo-med.com

ELECTRICAL SPECIFICATION

iTEAR®100 Neurostimulator Unit	Max current	300 mA
	Max rail voltage	5.5V DC
Charging	Max current	100 mA
	Max voltage	6V DC

Electromagnetic Compatibility

iTEAR®100 Neurostimulator has been tested for immunity to electrostatic discharge, radio frequency (RF) interference, proximity RF fields from wireless equipment, and power-frequency magnetic fields as specified in the table below. All tests passed satisfactorily. Emissions of energy are not likely to cause interference with nearby electrical equipment.

IEC 61000-4-2	Electrical discharge	ESD - Contact: +/- 8 kV
		ESD - Air: +/-2 kV; +/-4 kV; +/-8 kV & +/-15 kV
IEC 61000-4-3	Radiated RF electromagnetic fields	RS : 10 V/m, 80-2700 MHz, 1 kHz @ 80% AM.
IEC 61000-4-4	Power Line Electrical Fast Transient	EFT: +/- 2 kV
IEC 61000-4-5	Power Line Surge	S: +/-0.5/1 kV L/L; +/-0.5/1.0/2.0 kV L/E
IEC 61000-4-6	Conducted Immunity	CS: 3 Vrms, 0.15-80 MHz, 1 kHz @ 80% AM; 6 Vrms, 1 kHz @ 80% AM in ISM Band
IEC 61000-4-8	Magnetic fields	MS: 30A @ 60 Hz
IEC 61000-4-11	Power Line Dips & BO	Dips: At 0°, 45°, 90°, 135°, 180°, 225°, 270°, & 315°. Brownouts: 0% Ut; 0.5 Cycle
ANSI C63.27	RF Communication	BTLE: Co-Existence

Table 4: Tested electromagnetic compatibility standards

SYSTEM SYMBOLS

	Manufacturer
	Consult instructions for use
	Federal Law (USA) restricts this device to sale by or on the order of a physician
IP22	Keep away from splashing water. Do not submerge.
	Meets FCC guidelines
	Do not throw away, send it back to the manufacturer
	Store between 15 and 35°C

CYBERSECURITY

Risk exists for unauthorized entry into the device circuit. However, the USB port has had its access to the circuit removed and is only used for charging the device. The device firmware has been locked and is not accessible to

the end user except when company firmware updates are available. In this case, the updates are double encrypted and must be associated with the unique identifier of your device to be downloaded. These identifiers are stored on the AMAZON AWS server platform, a well-established and widely utilized platform for database and storage. NEVER GIVE YOUR PASSWORD OUT. IF YOU FEEL THERE WAS A SECURITY BREACH CONTACT THE COMPANY IMMEDIATELY. CHANGE YOUR PASSWORD FREQUENTLY.

a. Olympic Ophthalmic uses industry-standard instructions to protect the device, including its hardware, system development servers, and the data on those servers by using access enforced firewalls, and SSH secure communications. In addition, the company will provide security patches for firmware, if required.

b. It is the responsibility of the authorized user to ensure that the device is not left unlocked, or otherwise unsecured when not in use, to ensure that non-authorized medical, professional, or otherwise unapproved personnel are not exposed to, or gain access to the device.

c. Operators should immediately contact the prescribing provider, or the company using the contact information listed on the cover page of this guide, to disclose any suspected or confirmed usage by persons other than those to whom the device has been prescribed.

d. When devices are lost, the user should immediately contact the prescribing provider, or the company using the contact information listed on the cover page of this guide.

Please read this entire guide. If you have any questions, contact your eye care provider. RX Only. Federal law restricts this device to sale by or on the order of a physician

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