NERBIO

iTOF®

Wireless Quantitative Neuromuscular Transmission (NMT) Monitor

User Manual

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The iTOF® consists of a quantitative neuromuscular transmission monitoring app (software) and a Bluetooth connected nerve stimulation device (hardware) designed to be used by an anesthesiologist to monitor neuromuscular blockade to assess the effects of Neuromuscular Blocking Agents (NMBA).

Warnings 

- **Read the entire User Manual before using the device.**
- **The iTOF should only be used by qualified medical personnel.**
- **Apps, cables, or accessories NOT supplied by Nerbio may result in serious injury.**
- **Maintenance on this device is to be performed by Nerbio or persons authorized by Nerbio.**
- **Do not use iTOF in proximity (e.g., 3 feet) to high frequency, shortwave, or microwave therapy surgical equipment.**
- **Using iTOF while simultaneously connected to high frequency surgical equipment can result in burns and potential damage to the iTOF device.**
- **The patient should avoid contact with metallic objects that are grounded, produce an electrically conductive connection with other equipment and/or enable capacitive coupling.**
- **The cables should be positioned in such a way that they do not contact either the patient or other cables.**
- **The iTOF device enclosure should not be placed in contact with the patient.**
- **Do not use the iTOF in a flammable environment or in locations where flammable anesthetics may be accumulated.**
- **Application of electrodes near the thorax may increase the risk of cardiac fibrillation.**
- **Only standard 9V alkaline batteries in 6LR61 (or 1604A / PP3) format should be used.**
- **Any modifications to the app or device is NOT allowed without the authorization of Nerbio.**
- **The iTOF is a non-sterile device.**

Cautions

- Before changing the iTOF battery, turn OFF the device and remove the cables.
- Remove battery when storing the iTOF device for long periods.
- iTOF is compatible with standard ECG electrodes that must not be damaged or dried out.
- iTOF and all accessories are certified latex free.
- Do not use the iTOF device if the device has been damaged or manipulated.
- The recovery period delay is set to a minimum of 10 seconds to prevent repeating stimulation while the nerve synapse is recovering from the previous stimulation.
- iTOF is not protected against liquid penetration. Do not submerge or spray the iTOF or any of its parts with liquids.
- In the event of accidental spillage of liquid on the iTOF, dry the device immediately and check that it is working properly before using it. If in doubt, contact Nerbio for service.
- Avoid placing objects of any kind on the iTOF device.
- Avoid rough handling of the iTOF device.
- Never put the ITOF device or any of its parts or accessories into an autoclave.
- Secure the iTOF device during normal use. A standard threaded camera mount is integrated into the bottom of the enclosure.
- The device must not be used near other electronic devices. If it is necessary to use it next to or above other electronic devices, verify its normal working condition prior to use.
- Never open the iTOF as this could damage the circuits and internal parts. When it is necessary to replace the internal battery, carefully follow the instructions in this manual.

Checks Pre-Use

- Make sure that the iTOF is clean for use.
- Make sure that iTOF usage is compatible with the treatment drugs or other devices used on the patient.

- Make sure you are connected to the correct iTOF device. If not, disconnect from the current device using the app (do NOT turn OFF the currently connected device) and reconnect to the correct iTOF device you are trying to use.
- Arrange cables so that they are not subject to abnormal strain, pulling and bending.

Checks During Usage

- If the Bluetooth connection is lost, re-connect to the device using the App. The Bluetooth connection will be reliable if the distance between the iTOF and the mobile device is within fifteen meters, but may be affected by obstructions such as thick walls or equipment that disturb wireless signals.
- None of the parts of the iTOF should be serviced or maintained during use with a patient.

Application Specification

- The patient population includes patients of all ages.
- The iTOF user must be a medical professional with knowledge of anatomy.
- The iTOF use environments include the professional healthcare facility environment, such as the Operating Room (OR), Intensive Care Unit (ICU) or Emergency Medical Services.

Contraindications

- Unstable bone fractures.

iTOF External Cleaning

This section provides the user with the information necessary to use the iTOF correctly and safely. It is recommended to clean the device before and after each use.

- Switch OFF the device. Be sure the LED stops blinking.
- Clean the outside of the instrument with a soft cloth (e.g., cotton) or a sponge dampened with a mild detergent solution or mild disinfectant solution, taking care that no liquid enters the device, and the cables are not subject to excessive tension which could damage them or cause them to come loose.
- Clean any accessories being used in the same way as the device, taking care not to immerse them in water/cleaning liquids and taking particular care that the connectors DO NOT have contact with liquids.
- In case of disinfection, use non-aggressive products. You can use a diluted solution based on sodium hypochlorite or other disinfectants, such as diluted chlorine bleach. Try first on a small surface of the device to verify that no damage is caused.
- Make sure the instrument and any accessories are completely dry before switching it on again.
- Do not use toxic and/or corrosive products, solvents (alcohol, acetone) or other similar substances.
- Do not expose the device to excessively high or low temperatures.

iTOF Circuit Diagrams, Component Part Lists, etc.

- Nerbio shall make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist Service Personnel to repair those parts designated by Nerbio as repairable by Service Personnel.

Contents

General Symbols:


Requires separate treatment of end-of-life waste

Serial number

Batch code

Catalogue reference


Manufacturer


Date of manufacture


Caution

Non-sterile


See User Manual


Electronic Instructions for Use


Type BF Applied Parts


Temperature limit


Humidity limit


Pressure limit

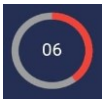
Prescription use device

Symbols Used in iTOF App:


App settings menu

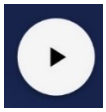

Re-scan for available iTOF devices

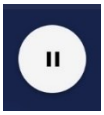

iTOF battery level
(Green = Good, Red = Low)



Recovery/Refractory delay
timer countdown

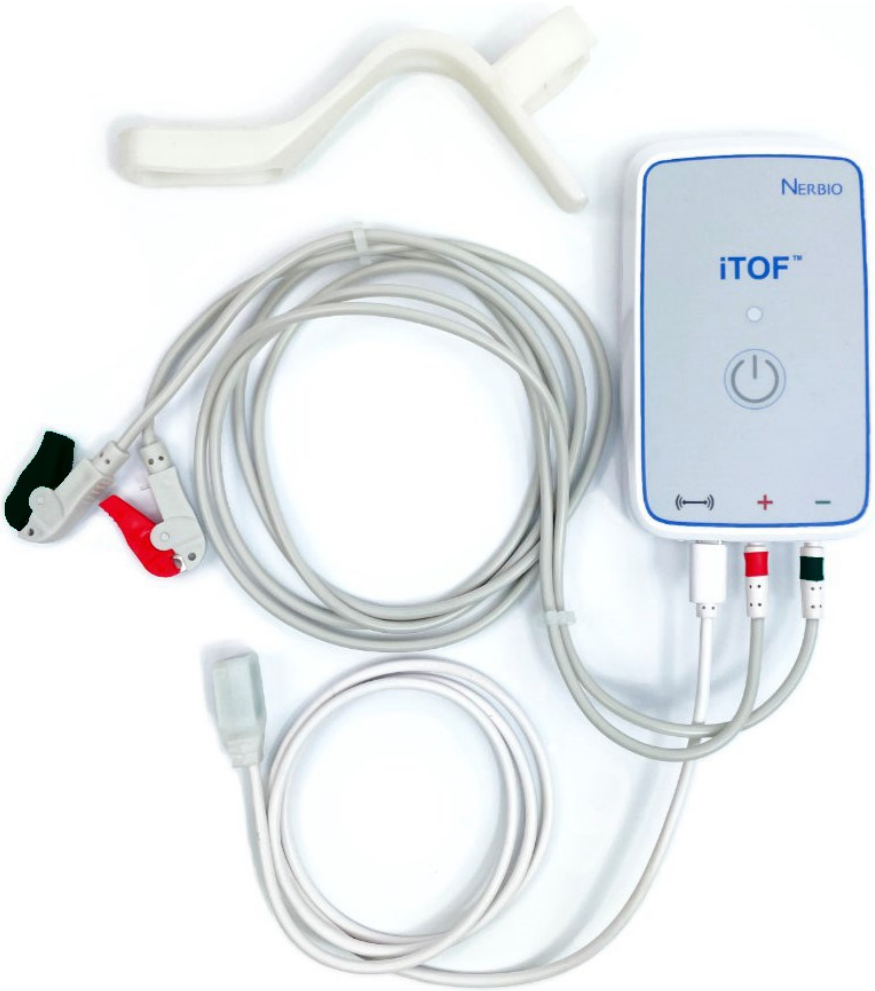
Repetition interval timer countdown


Start stimulation “Play” button


Stop stimulation “Pause” button

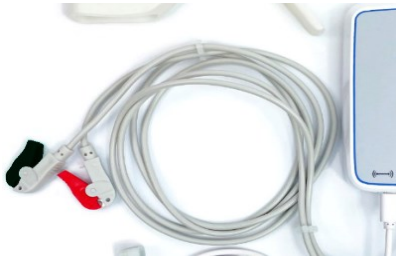
Product

iTOF Set

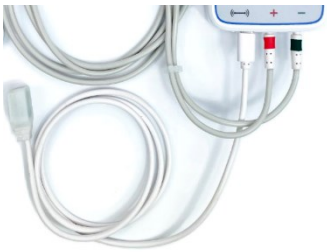


- The iTOF Set consists of the **iTOF device**, the **Stimulation Cables**, the **Accelerometer Sensor**, and the **Splint**.
- The device is powered by a standard Alkaline 9V Battery. Only alkaline type batteries should be used.
- The case is fitted with a standard threaded camera mount to allow it to be fixed in position as required.

iTOF Set Components



Stimulation Cables - The red (anode) and black (cathode) connectors are designed to clip onto standard button-style, ECG electrodes (not included).



Accelerometer Sensor - The 3-axis accelerometer attaches to the thumb when stimulating the ulnar nerve. The accelerometer can also be attached to the big toe or eyebrow when stimulating alternative sites such as the posterior tibial nerve or facial nerves.

Splint – The optional splint holds the accelerometer sensor on the thumb. It is ergonomically designed for correct and optimal positioning on the thumb when stimulating the ulnar nerve. Surgical medical tape is generally used to secure the Accelerometer Sensor to the splint, opposite the area of contact with the thumb.

Accessories Intended for Use with Nerbio iTOF medical device

Product No.	Description
iTOF-SPT-01	Splint
iTOF-ACL-01	Accelerometer Sensor
iTOF-STC-01	Stimulation Cables

***Not included: ECG Electrode Pads – such as 3M RED DOT electrodes 2560**

***Not included: Surgical/Medical Tape – such as 3M Micropore Surgical Tape 1530**

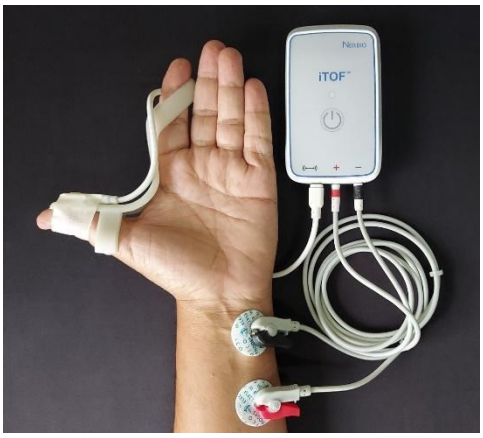
QUICK START

In-app Training – Demo Mode: The Demo Mode (available in the app Settings Menu ☰) allows you to experience all aspects of the iTOF App using a "virtual" iTOF device. You can quickly learn all functions of the iTOF device, complete with typical patient responses, anytime – anywhere, without connecting to a real iTOF device.

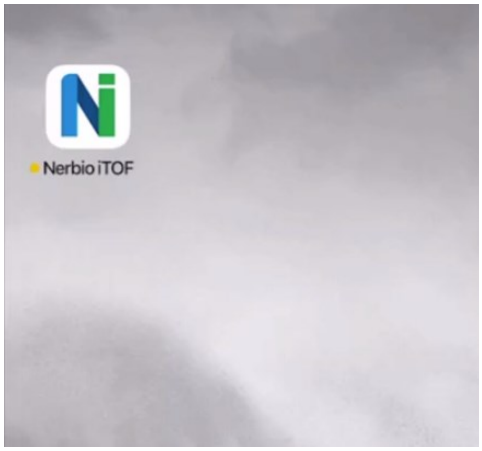
The iTOF App is available at https://nerbio.com/app (minimum 35MB required)

1 **Turn on the iTOF device by pressing the power button for 2 seconds.**

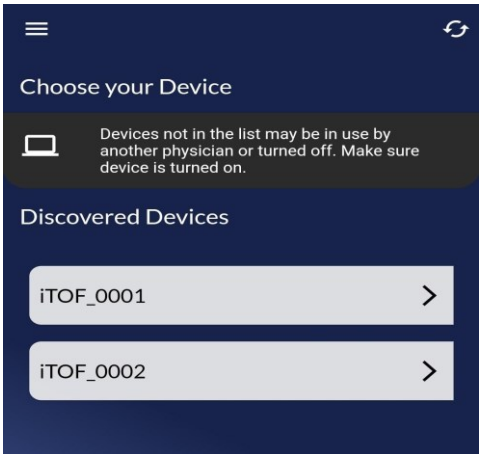
2 **Fit splint to patient's hand and secure accelerometer to thumb with tape. Connect stimulation electrodes observing correct polarity (Black lead towards wrist).**



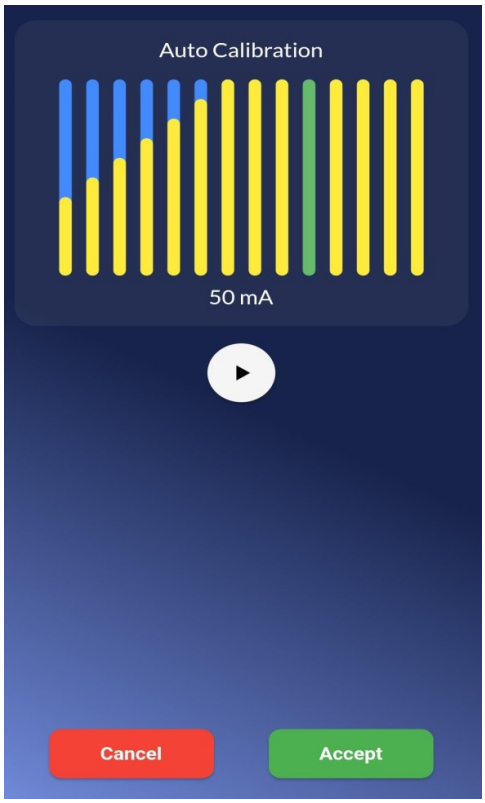
3 **Launch the Nerbio iTOF App (Download: nerbio.com/app)**



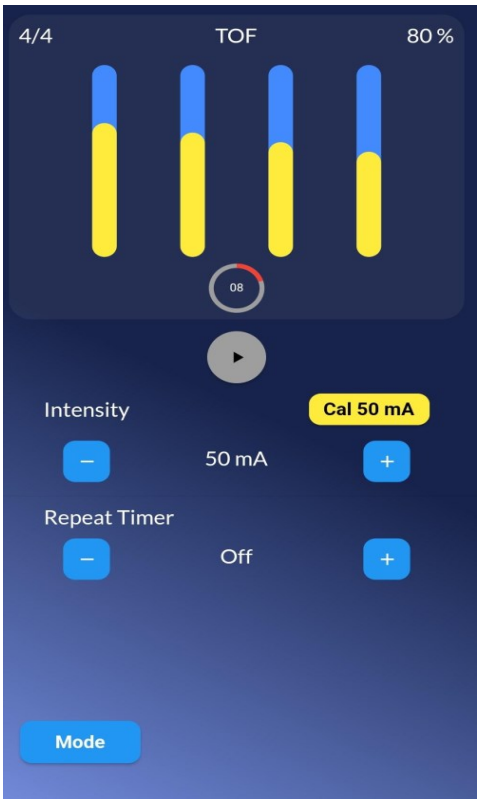
4 **Choose iTOF device to connect**



5 **Tap the “Calibrate” button on the Select Mode screen and select “Auto Calibration”. Tap the “Play” button to start Auto Calibration and "Accept" once calibration completes.**



6 **Select a stimulation mode such as TOF, PTC, DBS, TWI or TET from the Select Mode screen then begin stimulations by tapping the “Play” button.**



Introduction to Nerbio's iTOF®

Device Overview

The iTOF system consists of a quantitative neuromuscular transmission monitoring app (software) and a Bluetooth connected nerve stimulation device (hardware) designed to be used by an anesthesiologist to quantitatively assess the effects of Neuromuscular Blocking Agents (NMBA) used during General Anesthesia.

The iTOF device provides electrical stimulation patterns via the stimulation cables and quantitatively measures the resulting twitch via a 3-axis accelerometer sensor cable. The device has a single button and a multi-color LED for basic operations such as switching the device ON/OFF and displaying its activity status.

The iTOF device is controlled with a special App for mobile devices (smartphones and/or tablets). The App controls the stimulation signals and displays the results in a clear and easy to use graphical format with optional voice alerts (voice alerts are ON by default). The iTOF device connects with the App via Bluetooth, allowing wireless connections up to 15 meters depending on the environment.

Use of the App does not require or use Internet access. An Internet connection is only used for limited features (e.g., firmware updates or viewing instructional videos). Internet connection is not necessary for clinical functions. No user or patient data is stored on the mobile device, iTOF device or transmitted over the Internet.

How it Works

Stimulation

To effectively monitor the level of residual Neuromuscular Block, an electrical stimulation is applied along a neural pathway that facilitates a twitch contraction response. The relative strength of the twitch resulting from a specific stimulus intensity and waveform allows an objective evaluation of the efficacy of an injected Neuromuscular Blocking Agent. Depending on accessibility during surgery, different stimulation sites can be used; however, the typical stimulation site is the ulnar nerve which causes the thumb muscle to contract.

Accelerometer Sensor

An advanced 3-axis accelerometer sensor is used to provide objective quantitative monitoring of the twitch response to stimulation. The accelerometer sensor is attached to the patient's thumb when providing stimulation to the ulnar nerve. The iTOF calculates the magnitude of each twitch and sends this information to the App for display to the user. Since the magnitudes are computed from 3-Axis, the orientation of the sensor is not critical. The sensor can optionally be used in conjunction with the supplied splint to stabilize the twitch responses for better correlation to the baseline calibration.

Twitch responses are displayed as a column plot with the twitch ratios or counts displayed above the plot to assist in the judgment of neuromuscular blockade. The twitch ratio and count information are also available via voice announcements.

Recovery or Refractory Delay Period

A minimum recovery period delay is set after the last stimulation to prevent potentiation of the twitch responses which may cause inaccurate measurements. After completing a stimulation, the App starts the countdown timer for the recovery period and prevents initiating the next stimulation until the countdown reaches zero. A 10 second minimum delay is used for TOF, DBS and TWI stimulations, while a 30 second minimum delay is used for PTC and TET stimulations.

Single Stimulus and Repeating Stimulus Modes

The App provides the option of auto-repeating a stimulus. When the Repeat Timer is set as Off, the App provides a **single stimulus**. To automatically apply the desired stimulus pattern and intensity at a specified **repeating interval**, the App allows the user to set the Repeat Timer in increments up to a maximum of 1 hour and a minimum which equals the recovery period (see above). When a Repeat Timer is set, the countdown timer represents the time remaining until the next repeated stimulation begins.

Installation

The iTOF device does not require special installation. All that is required is to insert a standard alkaline 9V battery into the device and switch it ON by holding down the power button for two seconds.

The App is available on Google Play and the Apple App Store, where it is released after being digitally signed to guarantee that it is original and has not been modified.

Instructions for obtaining the App are available at: https://www.nerbio.com/app

Battery Replacement

The iTOF device is powered by a standard 9V Alkaline battery in 6LR61 (or 1604A / PP3) format. It is necessary to periodically check the state of charge of the battery and promptly replace it if the App indicates that the remaining charge is less than 5%. In normal use (up to 20 TOF tests per day) the battery should last up to one year.

Follow these steps to replace the 9V Alkaline battery:

1. Be sure the device is turned OFF (LED not blinking).

2. Open the battery compartment at the back by sliding the battery cover to the side of the case.

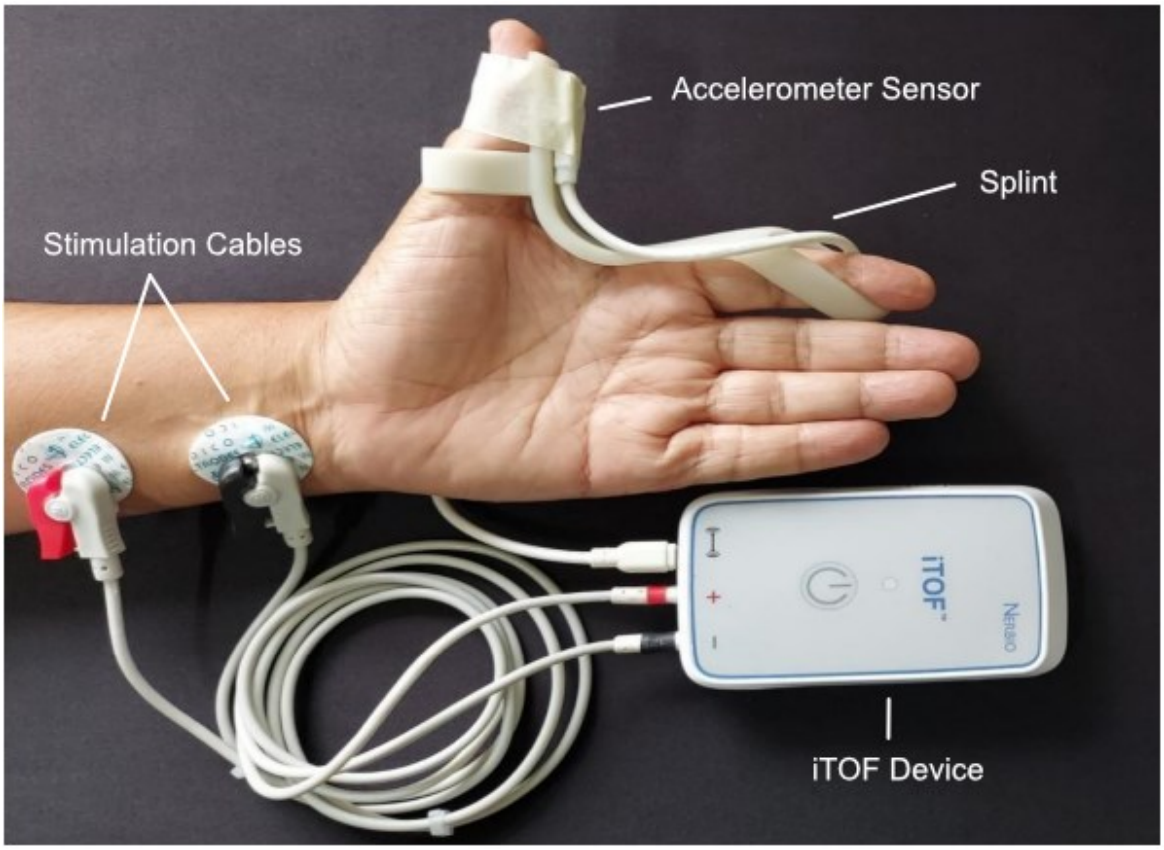
3. Remove the discharged battery and replace it with a new battery of the same type (Alkaline 6LR61) taking care to respect the correct polarities and applying pressure so that it is fully inserted.

4. Close the battery compartment by sliding the battery cover back in place.

5. Check the correct operation of the device by switching it ON (hold the power button for 2s) and connecting it to the Nerbio iTOF App, making sure to be within range (preferably less than 6 meters).

DO NOT dispose of batteries in the environment and DO NOT use normal waste containers for disposal. Batteries can severely pollute the environment.

Neuromuscular Transmission Monitoring with the iTOF



Device Setup

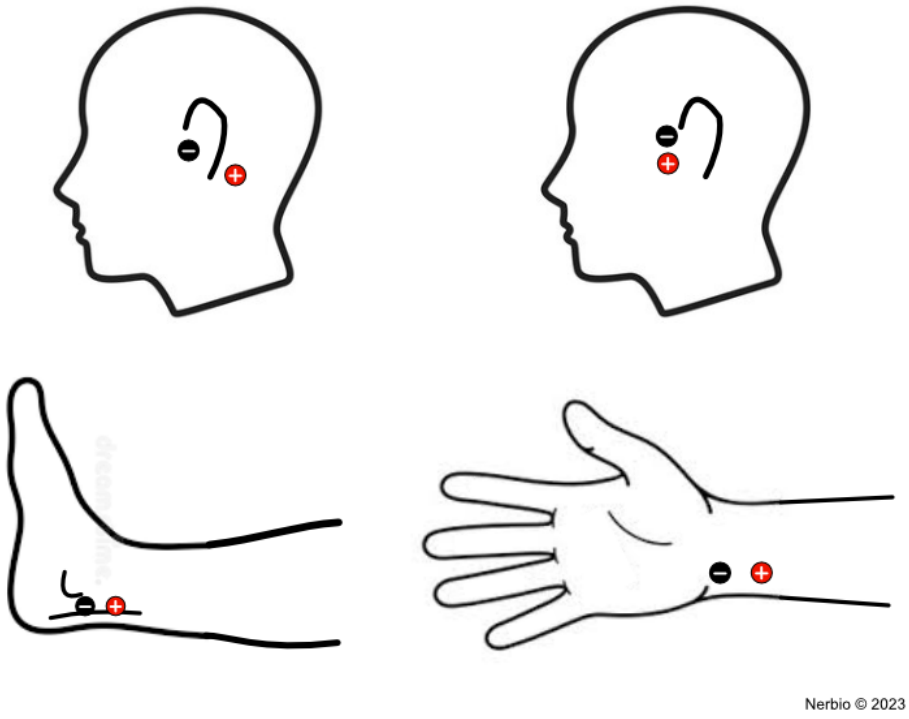
Cable Connections

Connect the Accelerometer Sensor and Stimulation Cables to the iTOF device prior to use. The user should make sure the cables are connected properly to the iTOF device.

Positioning of the Electrodes

NMT blockade may be monitored by stimulating various nerves and observing the response of muscles.

The Red-colored positive electrode clip should be proximal while the Black-colored negative electrode clip should be distal. Electrode placement relies on the cathode (**black plug and black electrode clip**) to be as close to the targeted nerve as possible to effectively depolarize the nerve. The anode (**red plug and red electrode clip**) should be away from the targeted nerve.



The most used technique is stimulation of the ulnar nerve with measurement of acceleration in the adductor muscle of the thumb.

When stimulating the ulnar nerve, the electrodes should be positioned along the ulnar nerve on the inner arm near the wrist (see illustration above). The electrodes should be spaced 2 to 5 cm (1 to 2 inches) apart and the polarity should be observed such that the black negative electrode is closest to the wrist.

When stimulating the facial nerves, position the black electrode on the root of the facial nerve next to the tragus and space apart the red electrode by 2 to 5 cm (1 to 2 inches). See illustration below.

When stimulating the posterior tibial nerve, place the electrodes along the posterior tibial nerve with the black electrode close to the ankle and the red electrode spaced apart by 2 to 5 cm (1 to 2 inches). See illustration below.

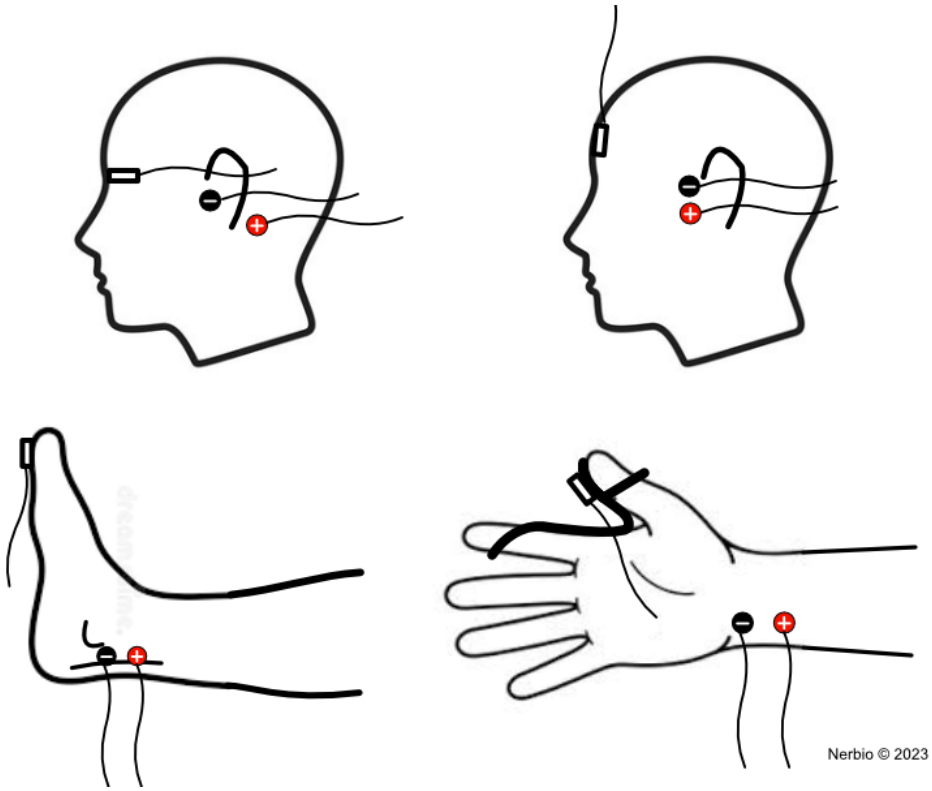
Caution: It is vital to position the electrodes properly to stimulate the nerve and not the muscle.

Positioning of the Accelerometer Sensor

When stimulating the ulnar nerve, attach the sensor to the thumb.

When stimulating the facial nerves, attach the sensor to the eyelid or eyebrow.

When stimulating the posterior tibial nerve, attach the sensor to the big toe.



When positioning the Accelerometer Sensor, the cable must not apply undue restriction to the sensor movement. The sensor must be able to move freely with the contracting appendage.

When using the optional splint, it must be fitted to follow the shape of the hand as closely as possible and attached to the last phalanx of the thumb. Use tape to secure the accelerometer sensor to the splint, opposite to the thumb side as shown. If the splint does not fit the hand, the accelerometer sensor can be fixed directly to the thumb with medical adhesive tape to maintain the desired position. When using tape make sure it is not wrapped too tight to avoid injuring the patient. The last three fingers can be immobilized with an adhesive tape to improve the range of motion of the thumb.

Note:
During use, the user should check that the sensor is keeping the same position as the initial set-up. This also applies to the patient's arm, leg or head where the sensor is placed, which should not change position during monitoring.

Skin Impedance

The iTOF performs electrical stimulation with a constant current allowing stimulation of a wide range of skin impedances (resistance) up to 5K ohms at 70 mA.

The iTOF App checks for skin impedance before each stimulation. An error will be displayed, and a voice alert will be announced if the impedance is too high. Verify that the electrode pads are positioned properly and have not dried out or install new pads if this error occurs.

Note:
Cleaning the patient’s skin prior to positioning the electrode pads significantly reduces skin resistance. The user should ensure that the patient's skin has been cleaned before attaching the electrode pads. The conductive condition of the electrode pads is essential in maintaining low skin impedance.

iTOF Device Interface Overview

LED Status Indicator

A single button on the iTOF device allows the device to be turned ON or OFF by firmly pressing it for 2 seconds.

The device may also be switched OFF remotely from the App.

A multi-colored LED indicates the device's operating status. No light indicates the iTOF device is switched OFF.

LED Indications:

Flashes **Blue**, **Green**, **Blue**	Device is being turned ON
Steadily flashes **Blue**	Device is available for connection to app
Rapidly flashes **Green** and **Blue**	Device is connecting to the app
Steadily flashes **Green**	Device is connected to the app and ready for use
Rapidly flashes **Yellow**	Stimulation in progress – High voltage is present
Rapidly flashes **Purple**	Delivering stimulation pulses – High voltage is present
Steady **Red**	Fault condition, such as low battery or device is being turned off

In-app Training:

A Demo Mode is available from the Settings Menu. It allows you to experience using a “virtual” iTOF device without being connected to an actual device or actual patient.

You can quickly learn all functions of the iTOF device, complete with typical patient responses, exactly as when using a real iTOF device.

A quick start training video and full user manual are also available in the HELP section under the Settings Menu.

iTOF App Overview

Connecting to the iTOF Device using the iTOF App

To use the device, you must connect to it using the iTOF app installed on a smartphone or tablet. The iTOF app is available at www.nerbio.com/app

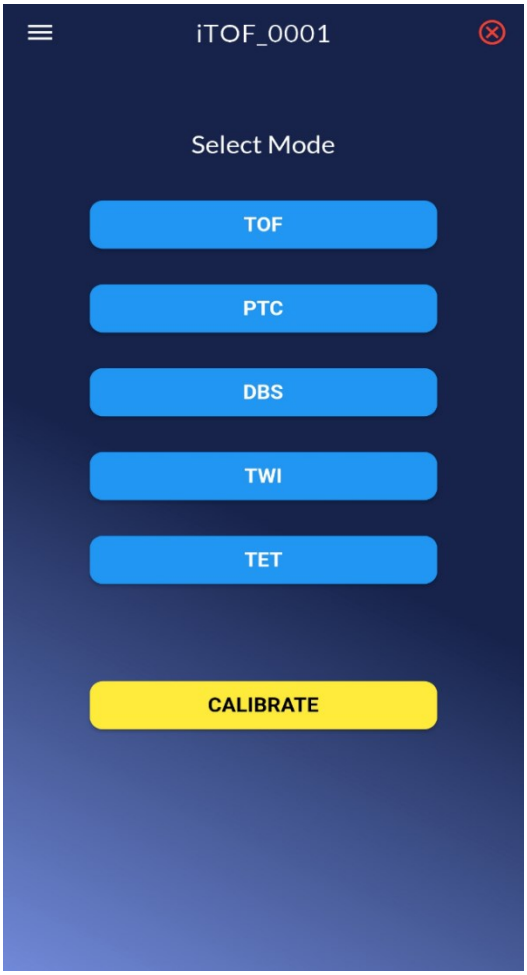
Make sure the iTOF device is turned ON by pressing the power button for 2 seconds.

Launch the app and search for the device in the apps list of discovered devices. All iTOF devices that are within range and are available to be connected to will be displayed in the list.

If the app is not able to discover the device, make sure the device is not connected to any other phone or tablet by checking that the LED on the device is flashing **Blue**. If the LED is flashing **Green** another user may still be connected to the device.

If the app was able to find the device, click on the device's name to connect to it. When connecting, the LED will rapidly flash **Green** and **Blue** to indicate it is being connected to. Once connected, the LED will steadily flash **Green**.

Select Mode Screen



Once connected, the iTOF App provides an easy-to-use interface for quantitative monitoring of neuromuscular blockade using acceleromyography through Train-of-four (**TOF**), Post Tetanic Count (**PTC**), Double Burst Stimulation (**DBS**), Twitch (**TWI**) or Tetanus (**TET**) stimulation modes.

Additionally, the SupraMaximal Current (SMC) is set in the **Auto Calibrate** mode.

Note: Use the top-left Settings Menu ☰ to access video tutorials under the Help sub-menu.

Select Mode Screen

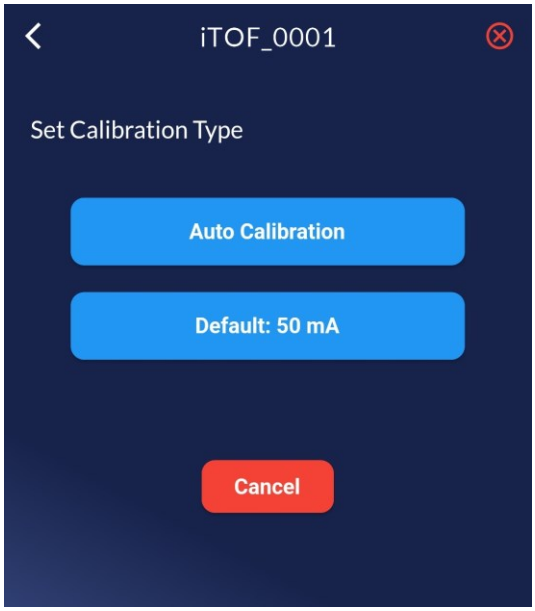
The default screen (shown on left) is the Select Mode screen wherein the desired stimulation modes such as TOF, PTC, DBS, TWI and TET or Calibrate can be selected.

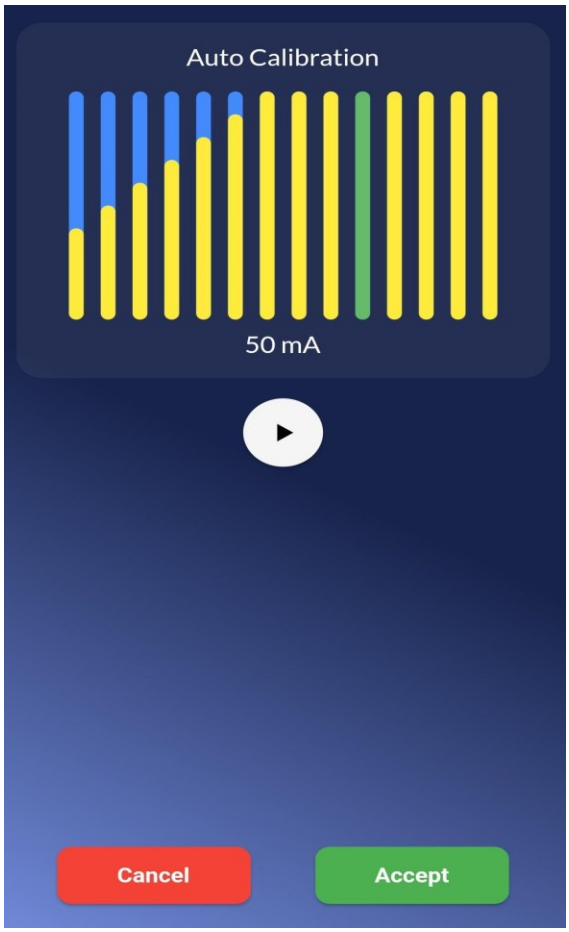
Next select CALIBRATE if the SupraMaximal Current if it has not been previously set.

After calibration (See **Auto Calibration** below), select the mode of stimulation you wish to use.

The default Mode is TOF.

Auto Calibration





Choose the Auto Calibration option to ensure that the intensity chosen is supramaximal.

It is recommended to do an Auto Calibration instead of manually adjusting the intensity. Perform Auto Calibration only after the patient is anesthetized, but before administering NMBA. There is no need to recalibrate when resuming a session if calibration was already performed and the patient is still under NMBA.

To perform a calibration, tap the Calibrate button on the Select Mode screen. Two options will be presented, namely Auto Calibration and Default: 50 mA.

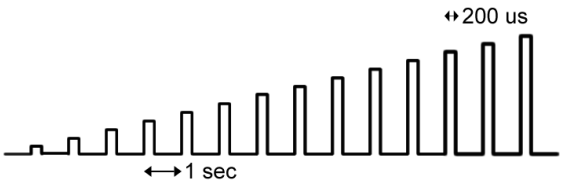
Default: 50 mA will set the supramaximal intensity to 50 mA and use an internal reference for scaling the TOF, PTC, DBS and TWI plots.

Note: When no previous calibration has been performed, the intensity will be set to the default of 50 mA. The previous calibration will be retained on the device, the user needs to re-perform a calibration when starting a session with a new patient.

Choosing Auto Calibration and pressing the Play button will allow a special algorithm to automatically determine the supramaximal intensity by performing stimulations at intensities from 5 mA to 70 mA incremented in steps of 5 mA. The twitch response at the determined supramaximal intensity will be used for scaling the TOF, PTC, DBS and TWI plots.

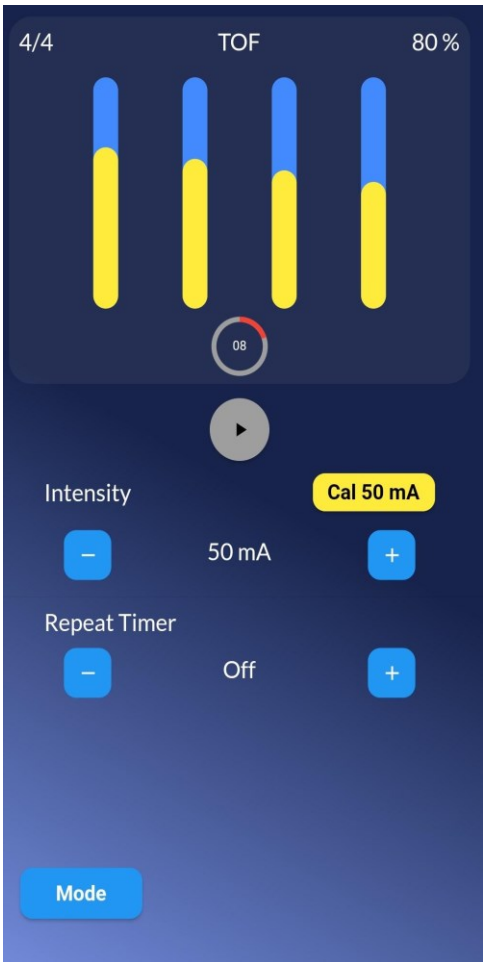
The chosen intensity is displayed below the plot and the corresponding twitch response is highlighted in Green. Click the Accept button to use this intensity or press the Play button again to re-calibrate.

Pressing the Cancel button will return the user to the main interface without accepting the new value and restore the previous calibration or default intensity of 50 mA.



Auto Calibration Stimulation Waveform

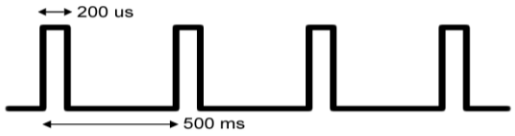
TOF Mode - Train of Four



In TOF mode, the device delivers 4 stimulation pulses with a pulse width of 200 microseconds spaced apart by 500 milliseconds (2 Hz).

The twitch response will be plotted as yellow vertical bars with the TOF Ratio displayed in the top right corner above the plot and the TOF Count displayed in the top left corner.

Recovery Interval for TOF: 10 seconds



TOF Stimulation Waveform

Tap the **+** and **–** Intensity controls for raising and lowering the Stimulation Intensity current. To reset the intensity to the last calibrated value, press the yellow Cal button above the intensity **+** button.

Tap the **+** and **–** Repeat Timer controls to adjust the automatic repeat time between stimulations.

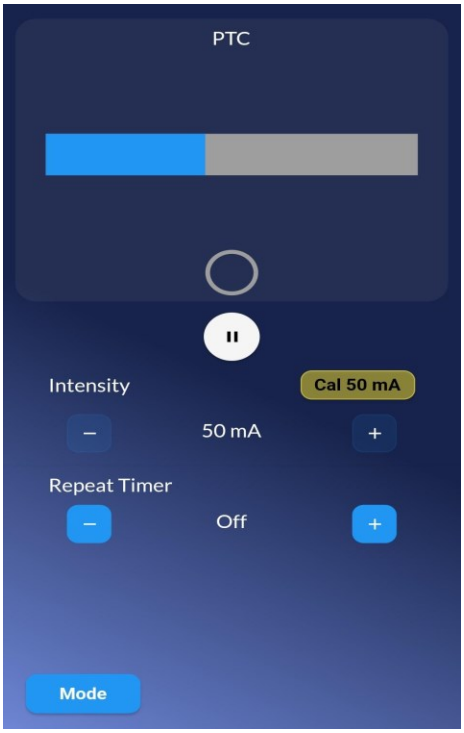
Tap the “Play” button to start stimulation and “Pause” to stop stimulations.

Tap the “Mode” button to change the stimulation mode.

A recovery period delay will be activated following stimulation to prevent potentiation of the twitch response. TOF, DBS and TWI have a 10 second recovery period, while PTC and TET have a 30 second recovery period.

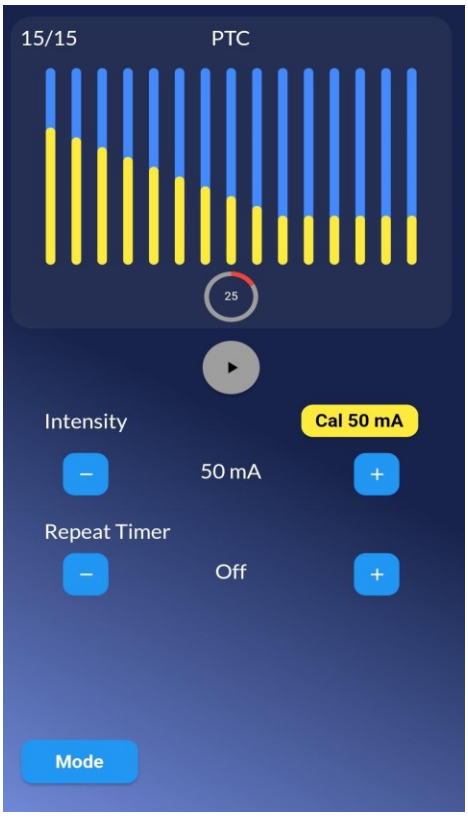
The recovery interval countdown is displayed in a circle below the plot. The repetition interval countdown is also displayed in the same circle. The circle turns red during the recovery countdown and turns yellow while doing a repetition countdown.

PTC Mode Post Tetanic Count - Phase 1 and 2



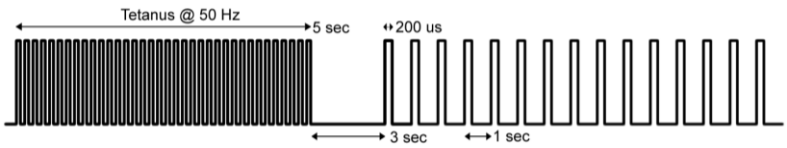
The PTC stimulation begins with a 50 Hz Tetanus (TET). During the TET stimulation the device delivers a burst of pulses with a pulse width of 200 microseconds spaced apart by 20 milliseconds for 5 seconds.

No twitch response is displayed during the TET stage. A horizontal progress bar shows the TET stimulation is in progress.



After the TET stimulation is completed, there is a 3 second delay and then there are 15 pulses with a pulse width of 200 microseconds spaced apart by 1 second to complete the PTC stimulation. Each evoked twitch response is then plotted during this stage with the PTC Count displayed in the top left corner above the plot.

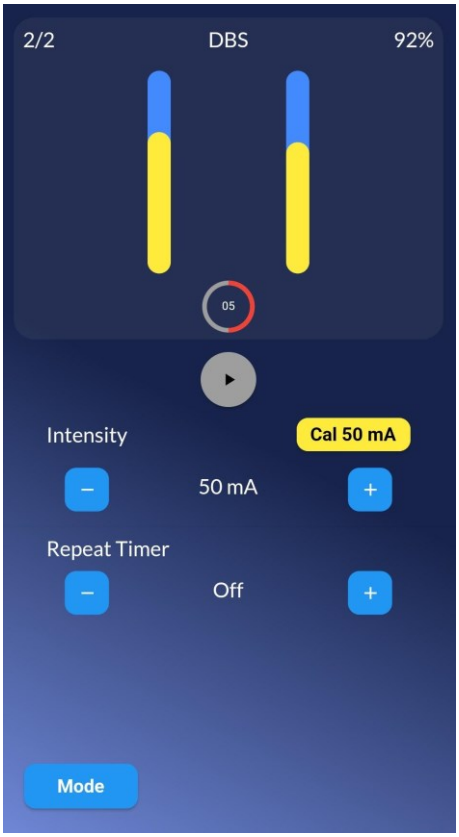
Recovery Interval for PTC: 30 seconds



PTC 50 Hz Stimulation Waveform

Caution: PTC stimulation should not be used when stimulating facial nerves

DBS Mode - Double Burst Stimulation



In DBS mode, the device delivers 2 bursts of 3 pulses with a pulse width of 200 microseconds spaced apart by 20 milliseconds (50Hz) with the burst separated by 750 milliseconds.
The DBS mode can be used to quickly detect a possible residual blockade.

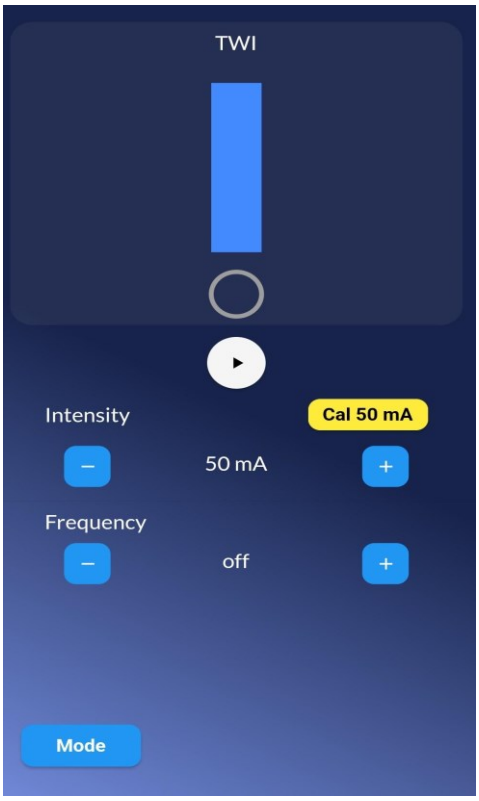
The twitch response along with the DBS Count and Ratio will be displayed in the plot area.

Recovery Interval for DBS: 10 seconds

DBS Stimulation Waveform

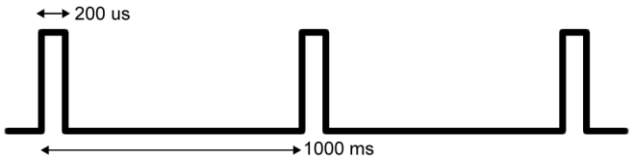
Caution: DBS stimulation should not be used when stimulating facial nerves.

TWI Mode - Single Twitch

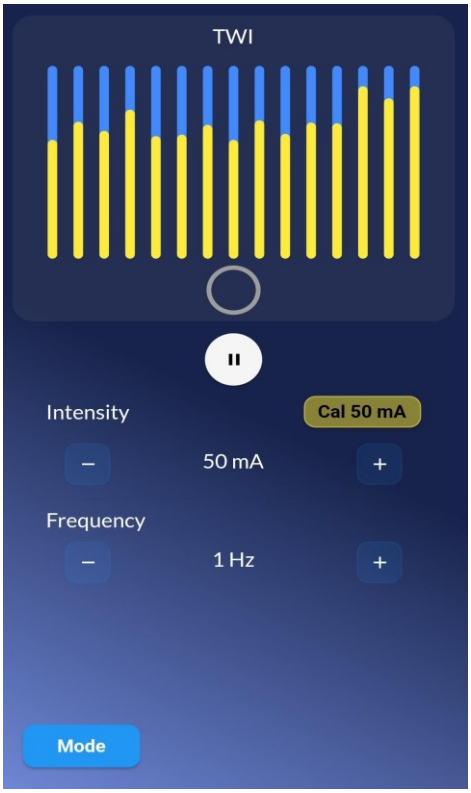


In TWI mode, the device delivers a single pulse with a pulse width of 200 microseconds. TWI can also be performed at frequencies of 0.1 Hz, 1 Hz or 2 Hz.

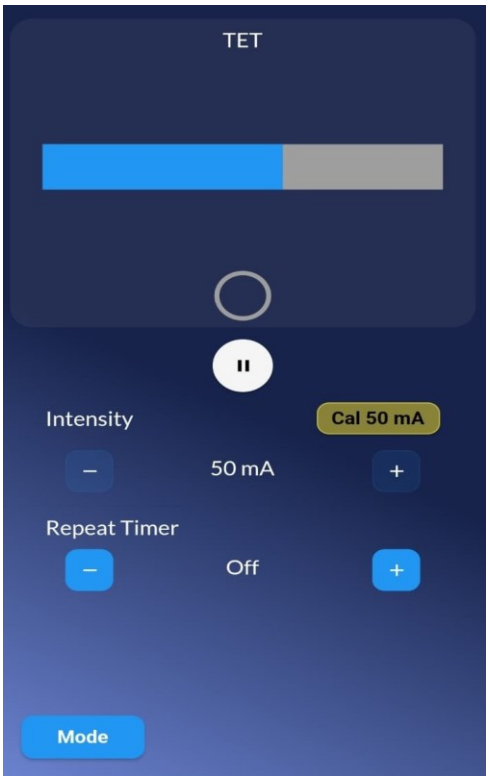
Recovery Interval for TWI: 10 seconds



TWI 1 Hz Stimulation Waveform



TET Mode – Tetanus



In TET mode, the device delivers a burst of pulses with a pulse width of 200 microseconds spaced apart by 20 milliseconds for 5 seconds. A horizontal progress bar shows the TET stimulation is in progress. No twitch response is measured or displayed in TET mode, it is up to the user to subjectively assess the response.

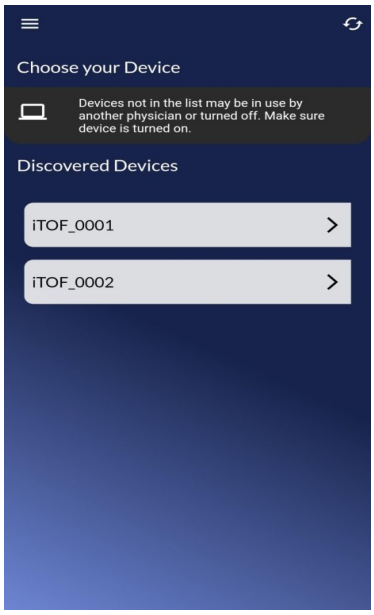
Recovery Interval for TET: 30 seconds

TET 50 Hz Stimulation Waveform

Caution: TET stimulation should not be used when stimulating facial nerves.

iTOF App In-depth Guide

Device Selection Screen



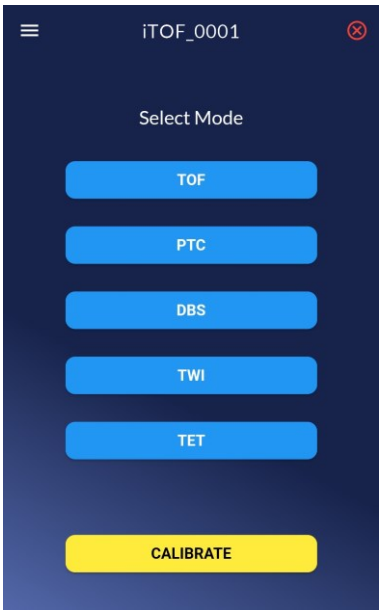
Launch the iTOF App if it is not already running.

Choose one of the available iTOF devices listed.

Be sure the device you wish to connect to is turned ON. The LED will be flashing **Blue** when it is ready to be connected to. Once connected, the LED will flash Green.

After confirming your connection, you are taken to the Select Mode screen.

Select Mode Screen

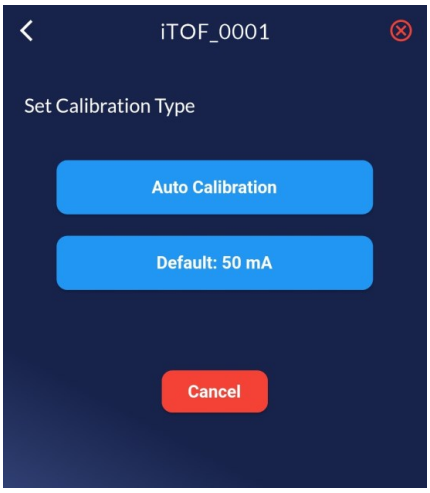


The Select Mode screen is the default start screen once you are connected to the iTOF device.

Select the desired stimulation mode such as TOF, PTC, DBS, TWI or TET.

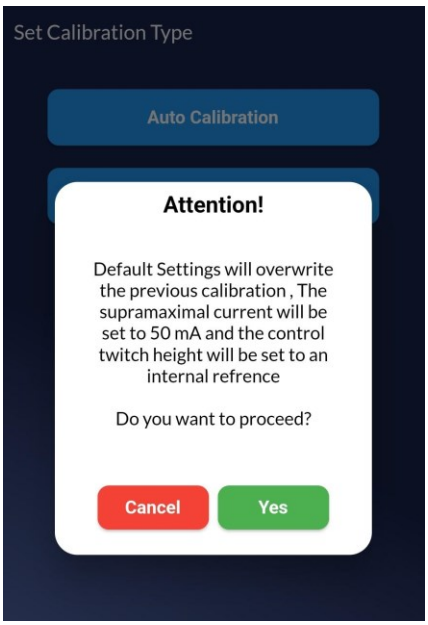
When starting a new session with a patient, select the Calibrate option to perform a baseline calibration for the patient.

Calibration Type Screen



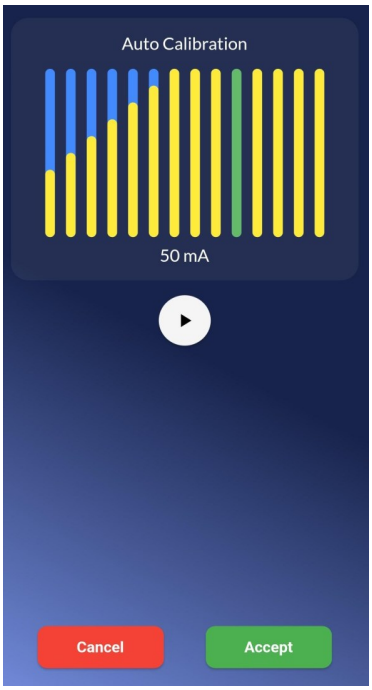
Tap the "Auto Calibration" button to automatically find the Supramaximal intensity and a reference for scaling the plots.

Default Stimulation Current is 50 mA



Tap the "Default: 50 mA" to set the intensity to a default of 50 mA which will be treated as the supramaximal intensity. This setting can be changed later. An internal reference will be used for scaling the plots.

Auto Calibration Screen



Auto Calibration mode finds the proper Supramaximal intensity, by incrementing the stimulation current in 5 mA steps, from 5 mA to 70 mA.

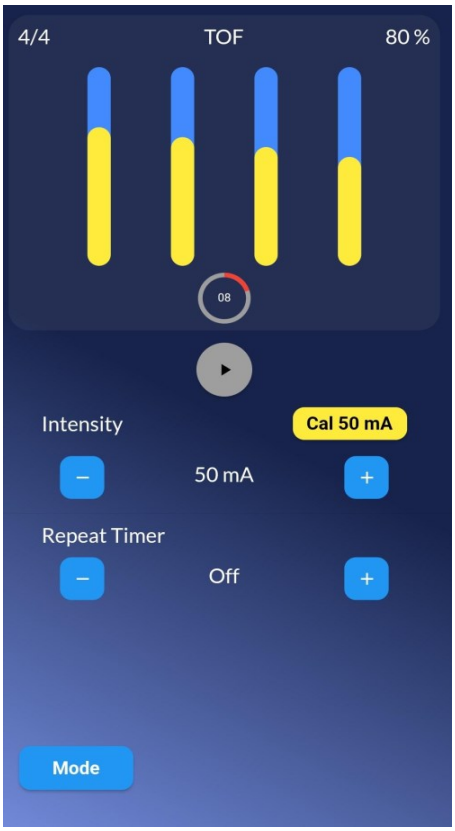
Auto Calibration should be performed after the patient is anesthetized but NOT YET under the effect of a neuromuscular blocking agent.

Press the Play button to begin calibration. Once the calibration process completes, the chosen intensity is displayed below the plot and the corresponding twitch response is highlighted in Green. Click the Accept button to use this intensity as the supramaximal or press the Play button again to re-calibrate.

Pressing the Cancel button will return the user to the main interface without accepting the new value and will restore the previous calibration.

Caution: Performing a calibration will overwrite the previous calibration. Make sure you are connected to the right device before performing a calibration. Perform calibrations only after the patient is anesthetized, but before administering NMBA.

TOF Screen



Selecting TOF on the Select Mode screen will present the TOF stimulation screen.

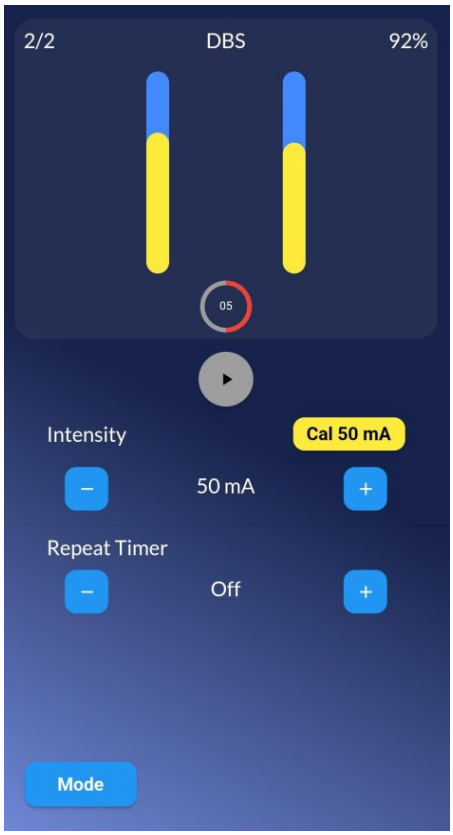
Manually adjust the Intensity using the “+” and “-” Intensity control buttons.

Press the “Play” button to start a stimulation. The “Pause” button immediately stops stimulations.

Automatic timed TOF simulations are set with the Repeat Timer. Adjust the repetition rate using the “+” and “-” Repeat Timer control buttons. The minimum repeat interval for TOF is 10 seconds and maximum is 1 hour.

To change the stimulation mode or to perform a calibration tap the Mode button is the bottom left corner of the screen.

DBS Screen

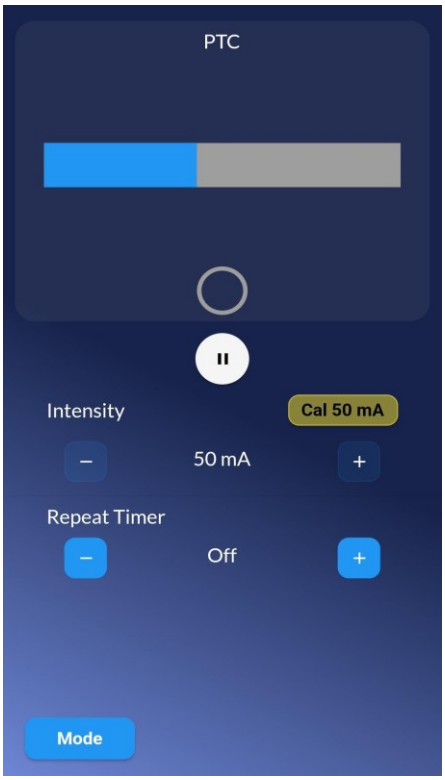


Selecting DBS on the Select Mode screen will present the DBS stimulation screen.

Press the “Play” button to begin stimulation.

The minimum repeat interval for DBS is 10 seconds and maximum is 1 hour.

PTC Phase 1 Screen

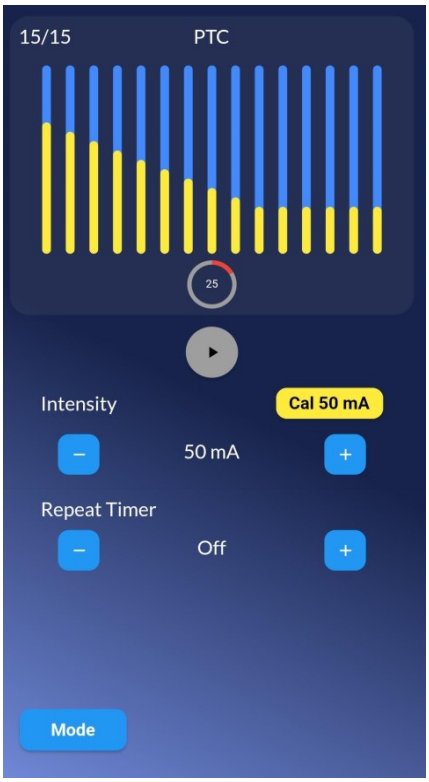


PTC – Phase 1:

The PTC stimulation begins with a 50 Hz Tetanus (TET). During the TET stimulation the device delivers a burst of pulses with a pulse width of 200 microseconds spaced apart by 20 milliseconds for 5 seconds.

No twitch response is displayed during the TET stage. A horizontal progress bar shows the TET stimulation is in progress.

PTC Phase 2 Screen



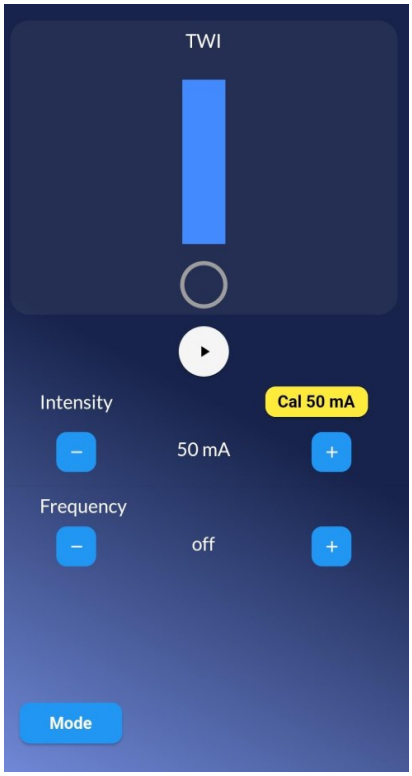
PTC – Phase 2:

After a 3-second pause there are 15 single twitch stimulations.

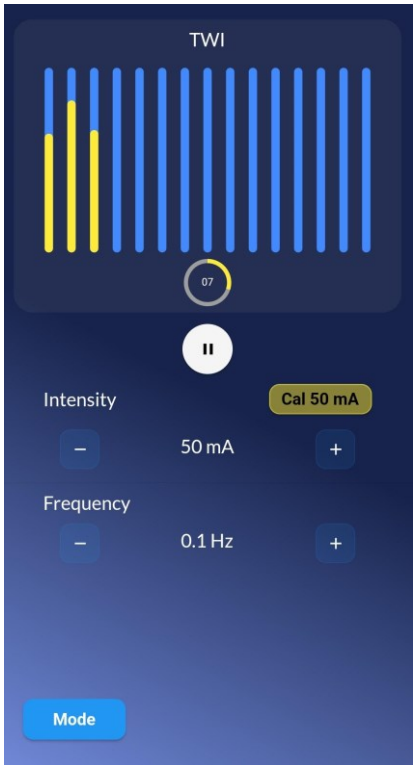
The twitch responses will be plotted as yellow vertical bars and the PTC count will be displayed in the top left corner above the plot.

The minimum repeat interval time for PTC is 30 seconds and maximum is 1 hour.

TWI Phase 1 Screen



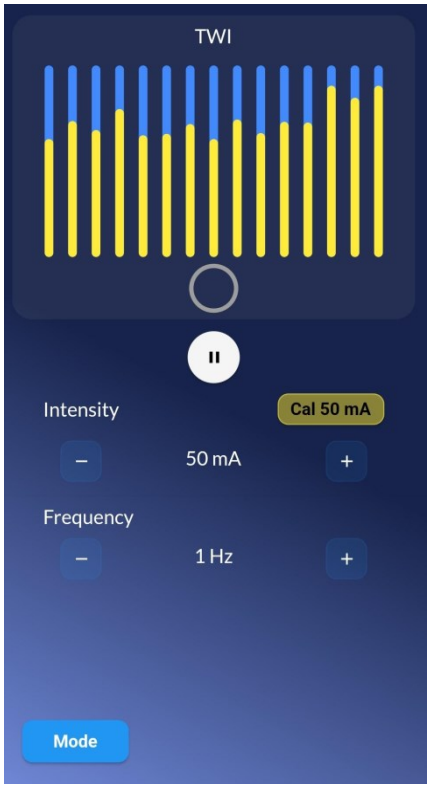
TWI Phase 2 Screen



TWI at 0.1 Hz

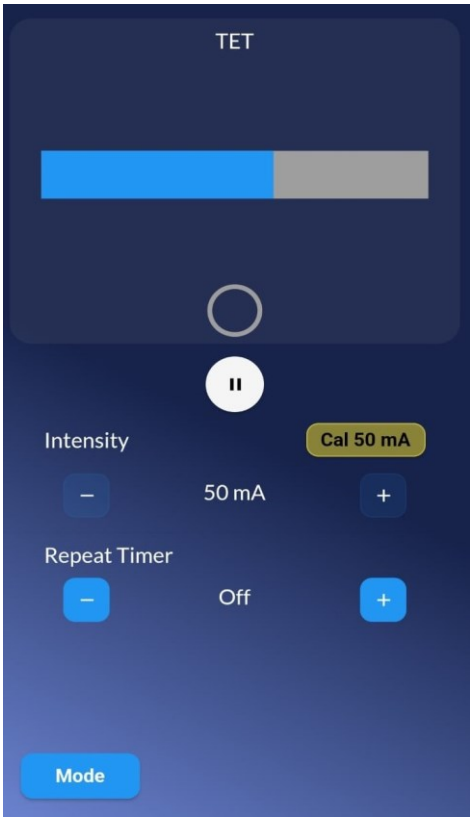
Selecting TWI on the Select Mode screen presents the TWI stimulation screen.

TWI allows you to perform a single twitch stimulation or repetitive stimulations by setting a frequency of 0.1 Hz, 1 Hz or 2 Hz.



TWI at 1 Hz

TET Screen



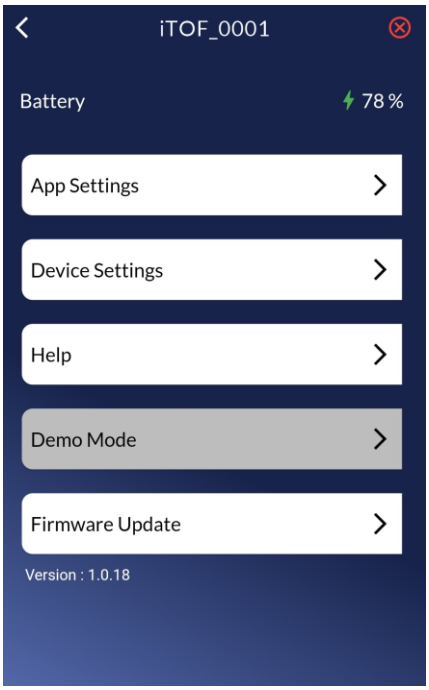
Selecting TET on the Select Mode screen presents the TET stimulation screen.

No twitch responses are plotted for TET stimulations. A horizontal progress bar will be displayed to show the progress of the 5 second tetanus stimulation.

The minimum repeat interval time for TET is 30 seconds and maximum is 1 hour.

Settings Menu

Top Level Settings Menu Screen



Battery level is indicated above the sub menu items. Warnings are given whenever the battery life is less than 100 TOF stimulations or when the level is below 15 percent.

App settings adjust only the App features.

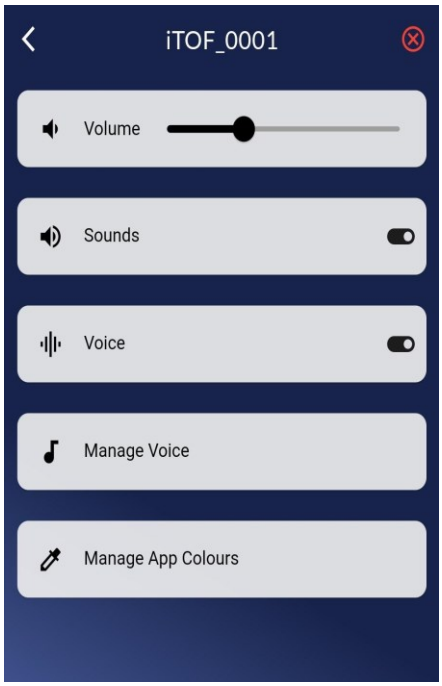
Device settings adjust only the Device settings.

The Help section contains video tutorials, the User Manual and a Demo Mode for training.

Demo Mode allows the user to learn the app functionality through use of a “virtual” iTOF device. Demo Mode is only enabled when the app is not connected to an iTOF device.

Firmware Update checks for available updates to the device's firmware.

App Settings Sub-Menu Screen



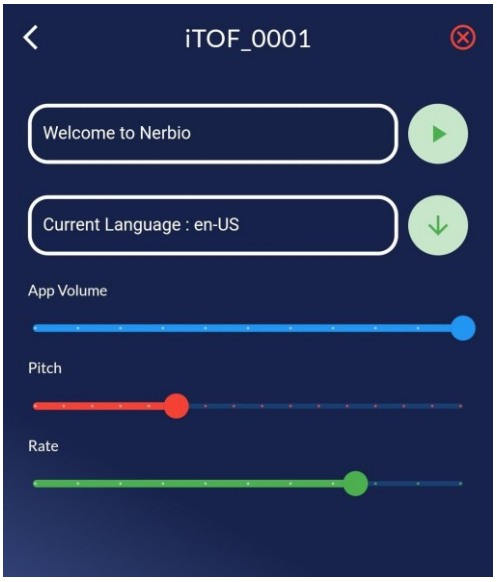
Sound turns sounds such as beeps ON or OFF (default is ON).

Voice controls voice announcements (default is ON).

Manage Voice adjusts the voice volume, voice type and speed.

Manage App Colors adjusts the display colors.

Managing Voice Settings Screen



Voice Settings:

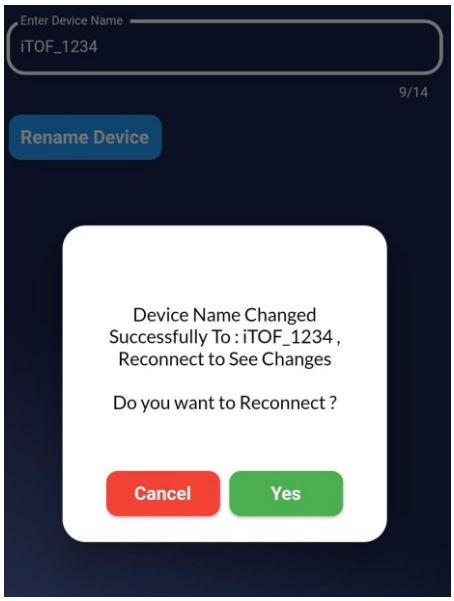
Play welcome message to check voice settings.

Set voice language (depends on phone/tablet settings).

Control the voice volume, pitch and speech rate.

Device Settings Screen

Enter new device name



Rename and reconnect to device

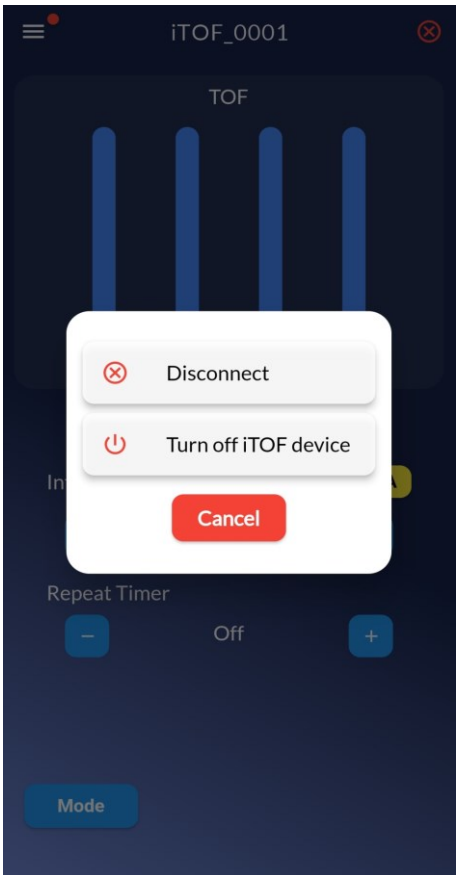
Rename Device:

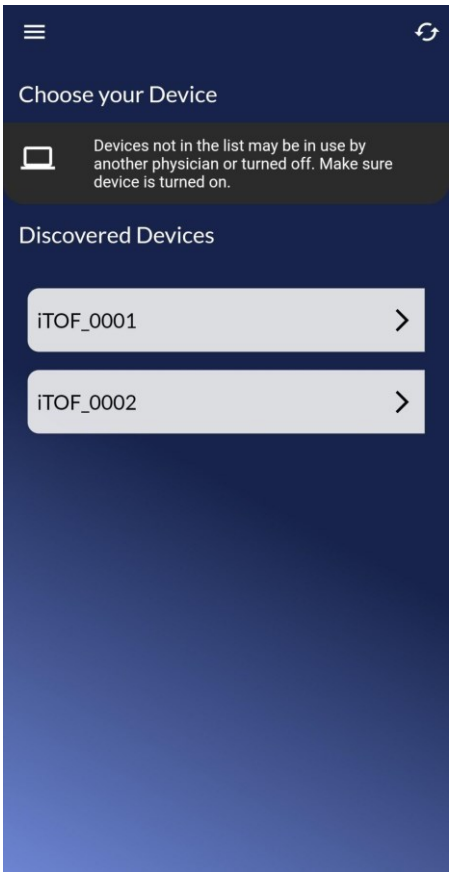
Naming or Renaming of each iTOF device should only be done by administration personnel.

To rename a device, type the new name in the “Enter Device Name” field. Then tap the “Rename Device” button.

The device name will be changed, and the App will prompt you to reconnect to the device to see the change in the device's name.

Ending a Session – Disconnecting or Turning the iTOF Device OFF





Disconnecting From the iTOF Device:

Use the ⊗ icon at the top right to end a session.

To disconnect from the current iTOF device, tap the red X in the upper right corner.

Then choose to either disconnect and leave the device running so someone else can connect or turn off the device.

If no one will be using the device, choose Turn OFF Device to save battery life. The iTOF device will turn itself OFF after 30 minutes if no phone is connected to it.

After disconnecting from the iTOF device, the app returns to the initial device selection screen.

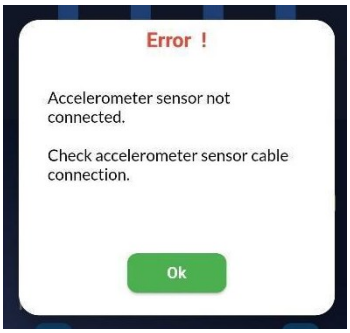
You can either choose a device to connect to, or close the App.

Warning Screens - Troubleshooting

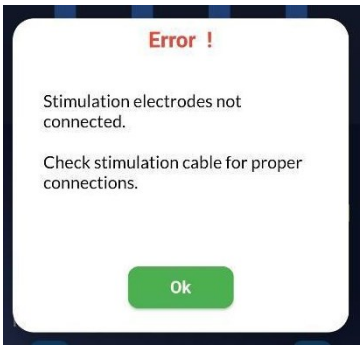
Before each stimulation a complete diagnostic test of the iTOF device, the stimulation leads, and the accelerometer is performed. Any problems found are reported, along with suggested actions.

Accelerometer sensor failure. The accelerometer sensor is not responding properly. Replace the Accelerometer sensor.

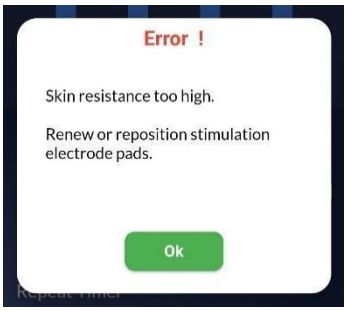
Check that the accelerometer sensor cable is connected properly. Make sure no wrong device is connected to the accelerometer port.



The accelerometer sensor cable is not connected or not connected properly. Try reconnecting the accelerometer sensor cable.

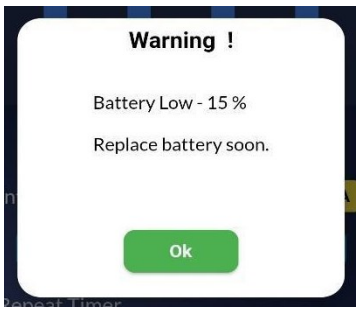


Check that the stimulation electrode cables are connected to the iTOF device's sockets, and the other ends are clipped securely to the electrode pads on the patient's skin.

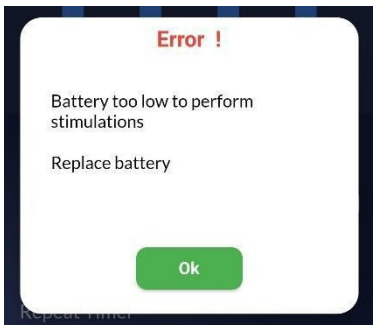


Reposition or renew the electrode pads after cleaning the patient's skin to lower skin contact resistance.

The iTOF device is not responding properly. Try restarting or replacing the device.



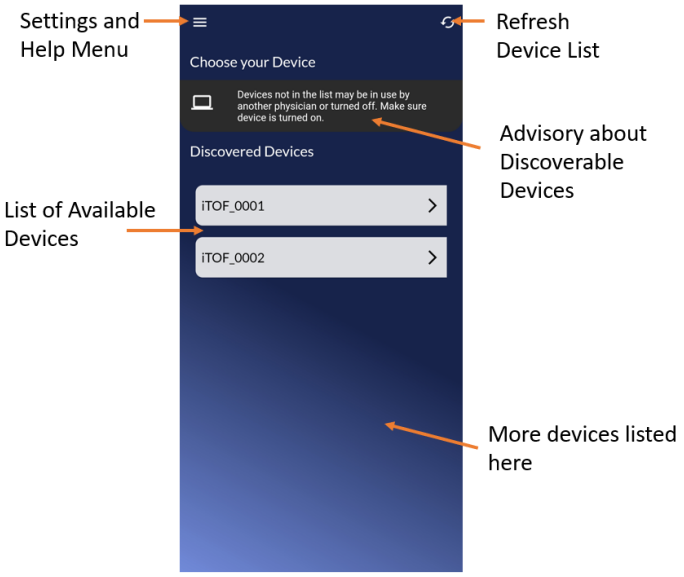
The battery is below 15% capacity. While several TOF stimulations may be available, it should be replaced soon.



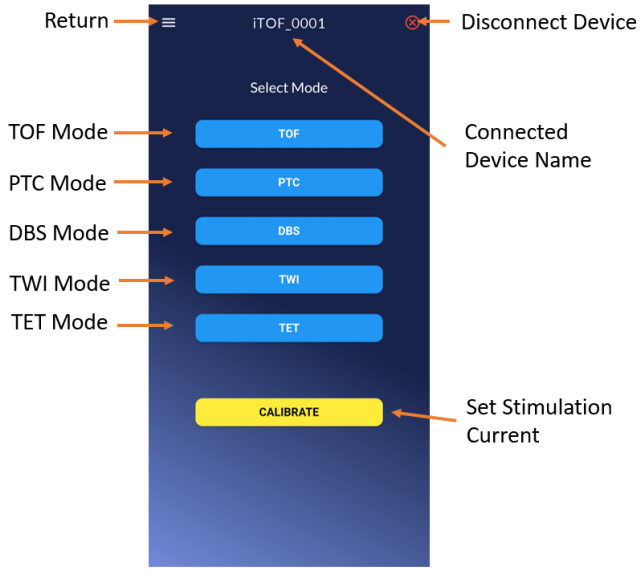
The battery must be replaced before any further stimulations can be performed.
Replace with 9V Alkaline type only

iTOF App Screens Overview

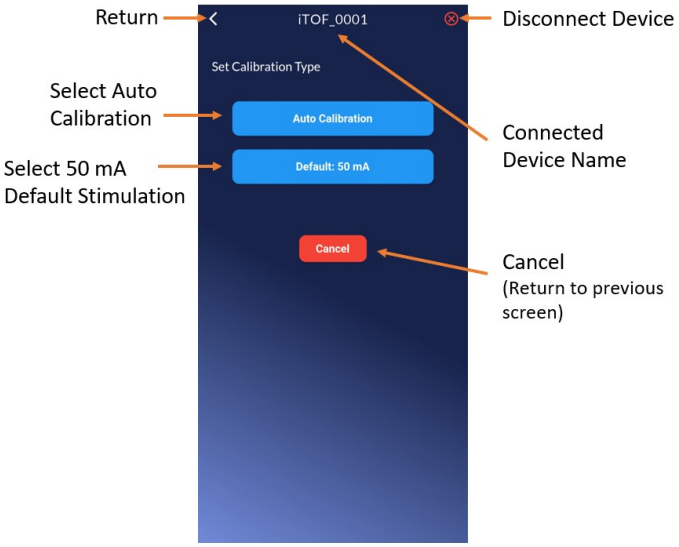
Start-Up Screen



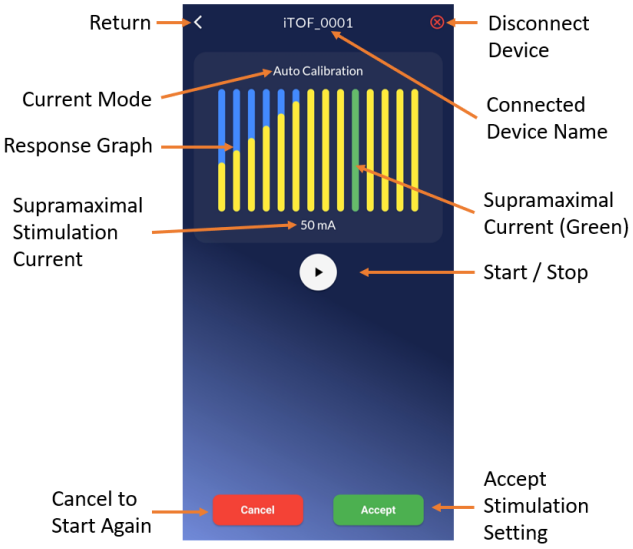
Select Mode Screen



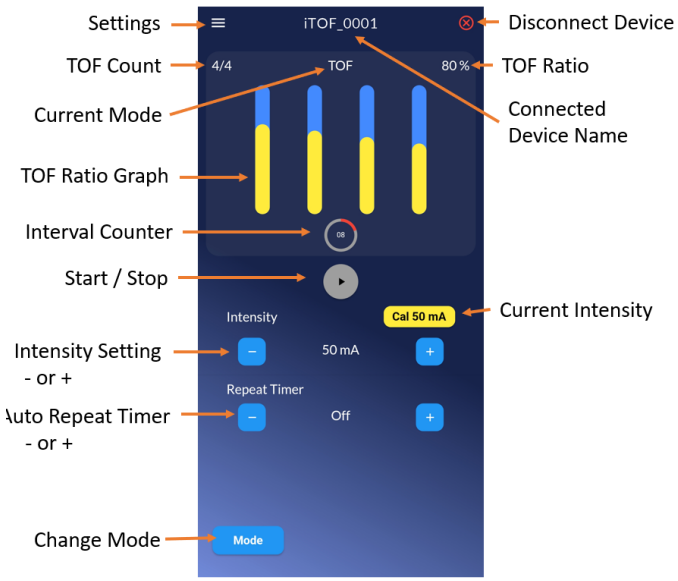
Select Calibration Screen



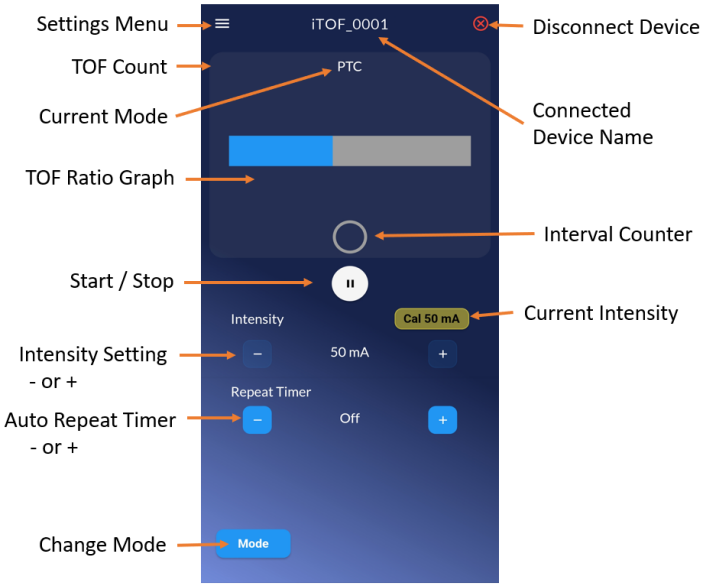
Auto Calibration Screen



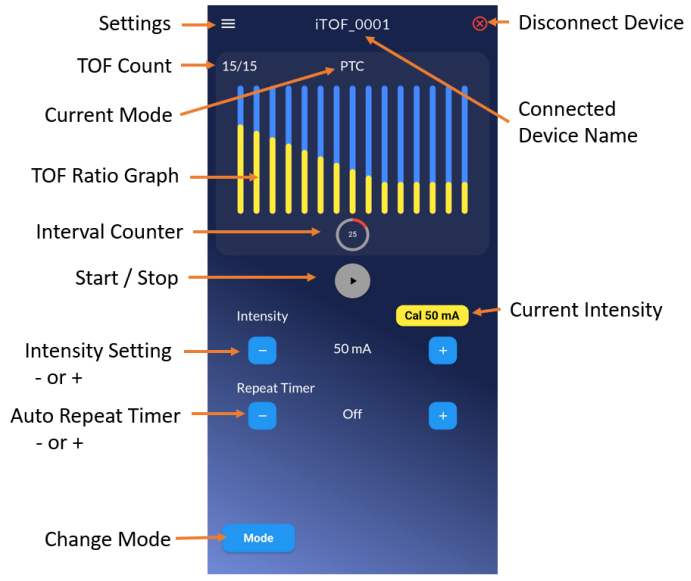
TOF Mode Screen



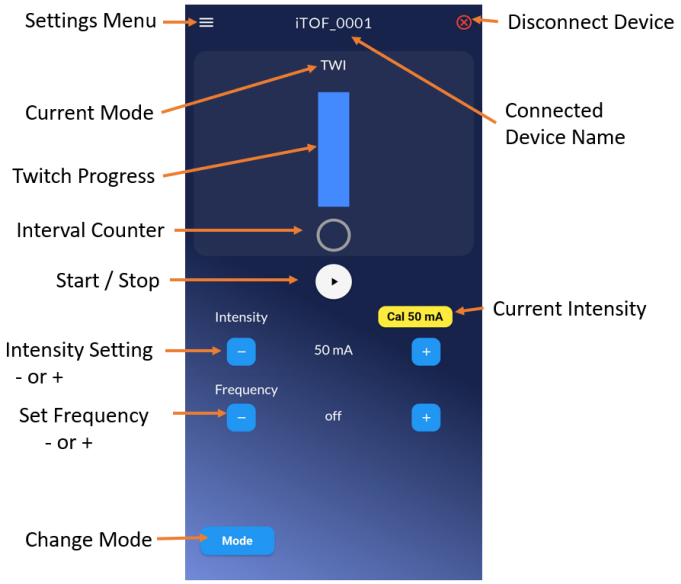
PTC Mode Phase 1 Screen



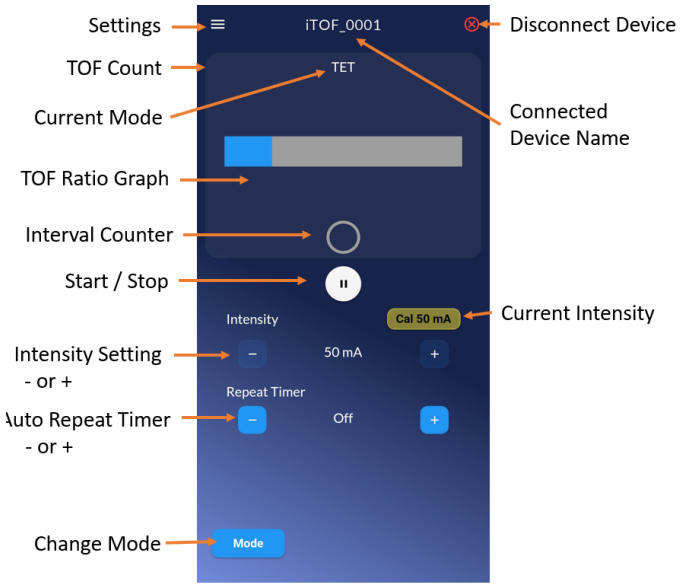
PCT Mode Phase 2 Screen



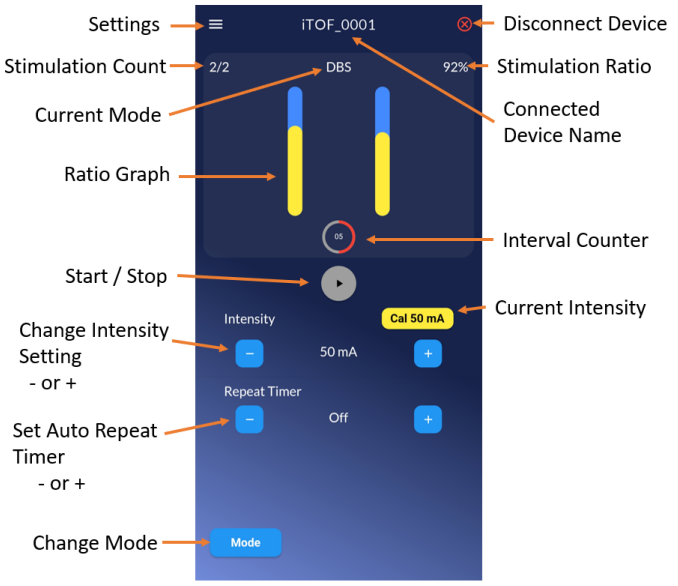
TWI Mode Phase 1 Screen



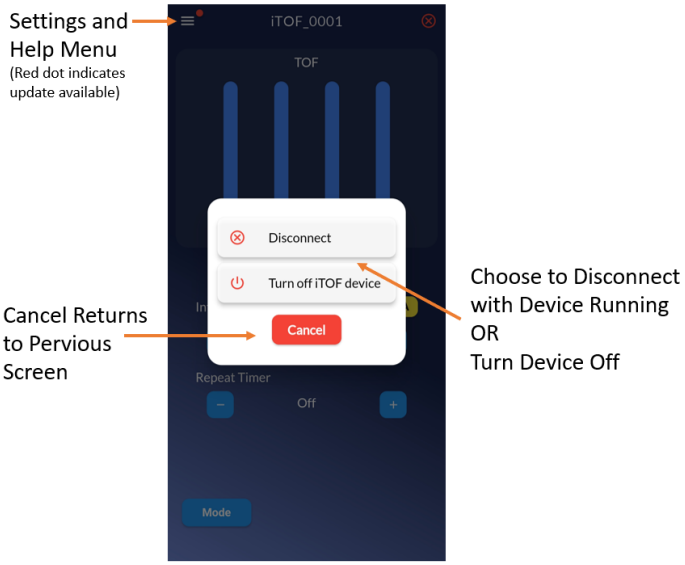
TET Mode Screen



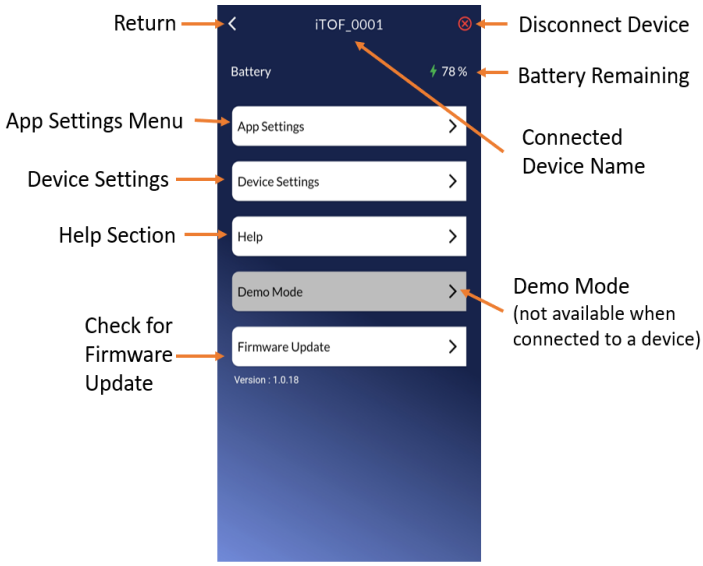
DBS Mode Screen



Disconnect Screen

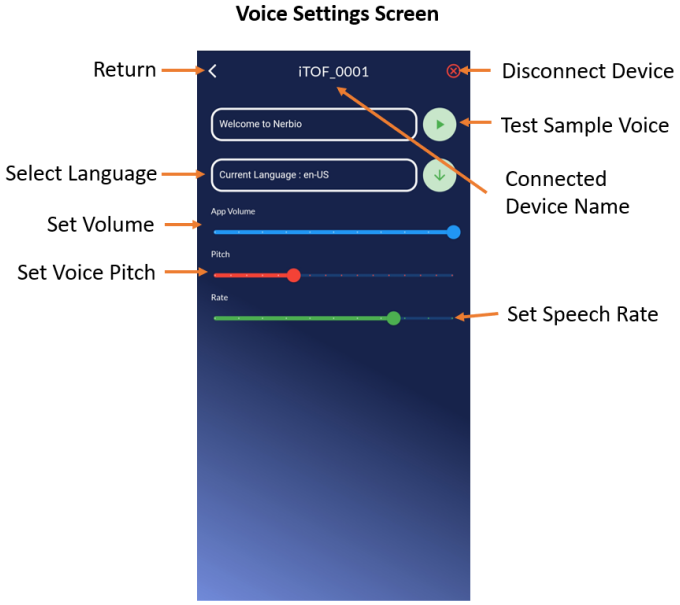


Settings Menu

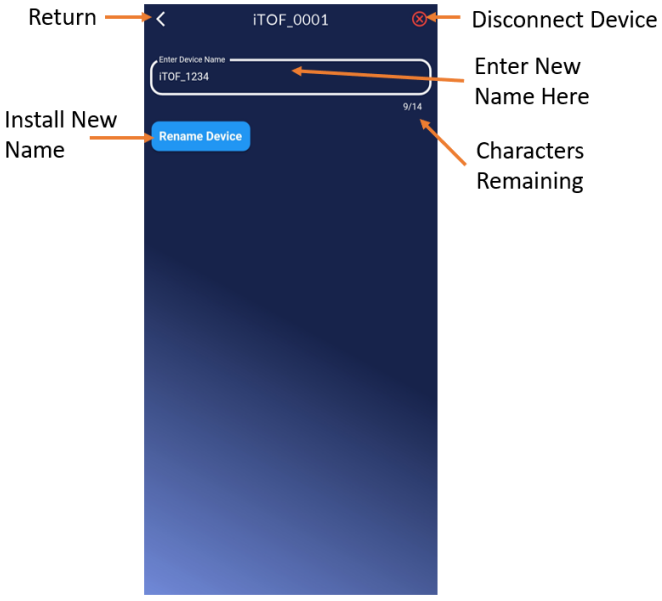


App Settings Menu

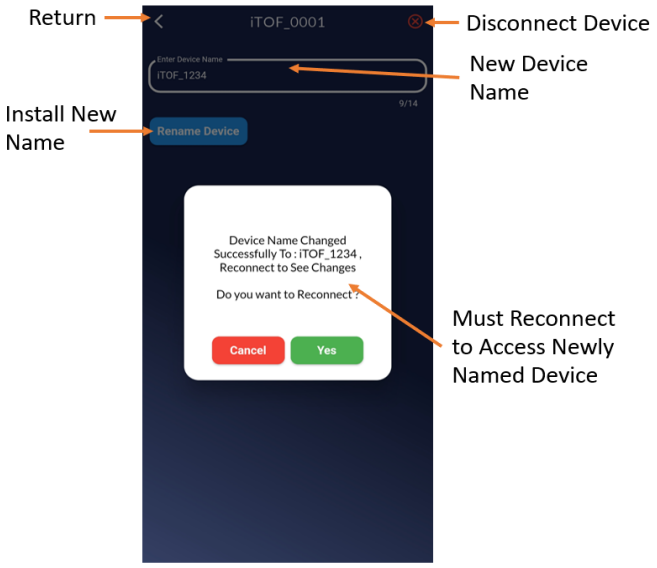
Voice Settings Screen



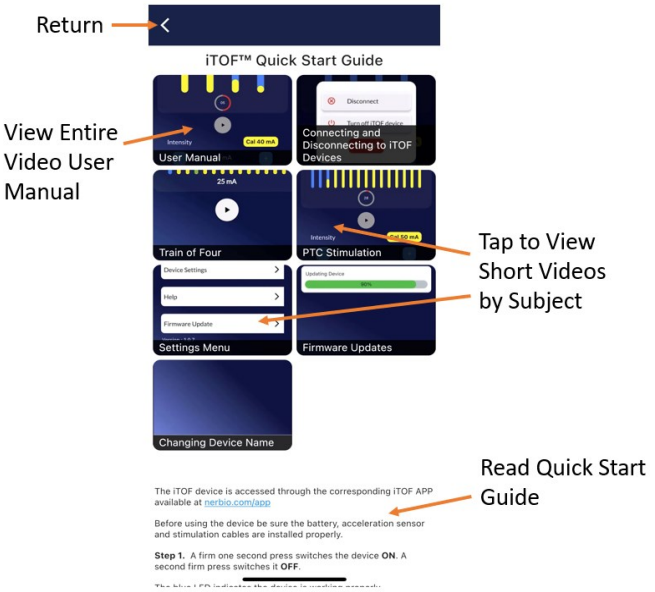
Rename Device Screen



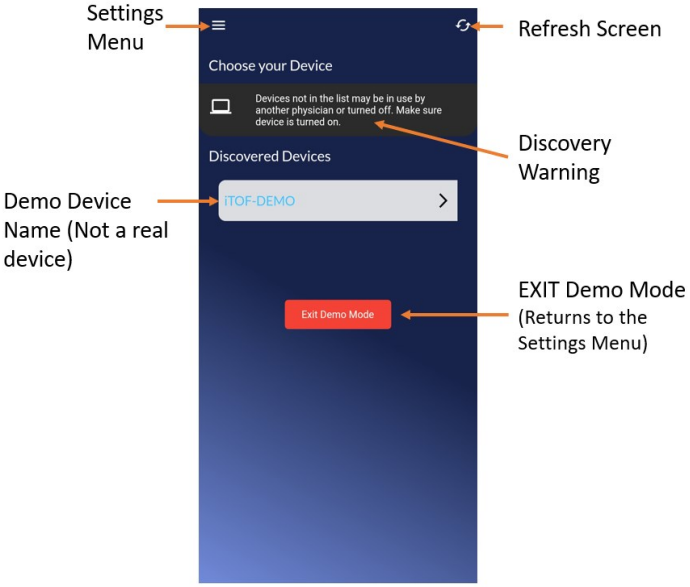
Renamed Device Reconnect Screen



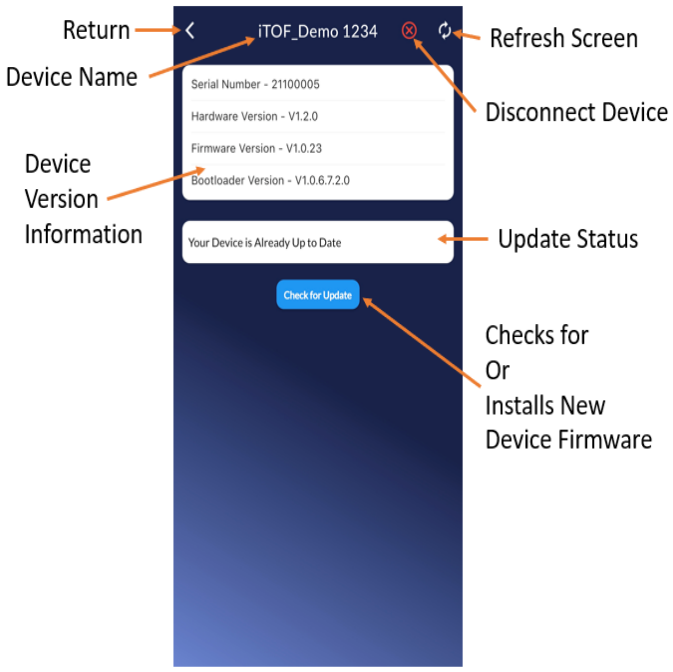
Help Screen



Demo Mode Start Screen



Firmware Update Screen



In-app Training – Demo Mode

The Demo Mode allows you to experience all aspects of the iTOF App using a “virtual” iTOF device, without being connected to an actual device or actual patient.

You can quickly learn all functions of the iTOF device, complete with typical patient responses, exactly as when using a real iTOF device.

Technical Specifications and Warranty

Power Supply	9V Alkaline Battery (6LR61, 1604A or PP3) Life expectancy of 9 to 12 months under normal use of 20 TOFs per day.
Stimulation Waveform	Constant Current, Monophasic Square Wave
Pulse Width	200 µS
Current Intensity	5 to 70 mA ± 5 %
Maximum Load	5K Ohms
Maximum Voltage	370V
Stimulation Modes	**TOF** (Train-of-four), TOF ratio calculated as T4/T1 **PTC** (Post Tetanic Count) @ 50 Hz **DBS** (Double Burst Stimulation) **TET** (Tetanus) @ 50 Hz **TWI** (Twitch) @ 1 Hz and Single
Repetition Interval	0 to 60 Minutes
Recovery/Refractory Delay	10 Seconds for TOF, DBS and TWI 30 Seconds for PTC and TER
Wireless Connectivity	Bluetooth 5 (TX Power: 8 dBm, BLE 5 Long Range Capable)
Stimulation Cable **Type BF** 	Capable of supporting up to 450 volts with 70 mA current. Recommended Electrode Pads: - RED DOT electrodes ref.2560 from the company 3M - F9047 electrodes from the company FIAB
Twitch Monitoring Sensor **Type B**	3-Axis Accelerometer (± 4 g at 12 Bits, Frequency: 400 Hz)
Protective Features	Over-Voltage protection Over-Current protection Battery reverse polarity and short circuit protection Sensor cable disconnect detection Electrode open circuit detection Intensity absolute error detection
Dimensions	60 x 150 x 55 mm (Device only)
Weight	320 gm (Inclusive of battery, stimulation cables and accelerometer sensor cables)

The iTOF conforms to the following standards:

Safety

Compliant with standards IEC 60601-1 and IEC 60601-2-10 Class II equipment.

EMC: IEC 60601-1-2 Class A.

Manufactured under ISO 13485.

Class 2a device.

Splint (part in contact with the patient) – Type B – Latex Free – Biocompatibility Certified.

Guidance and manufacturer's declaration - electromagnetic emissions

Emissions testing	Compliance	Electromagnetic environment - driving
RF Emissions CISPR 11	Group 1, Class A	The iTOF uses radio frequency energy only for its internal operation. Therefore, its radio frequency emissions are very low and should not cause any interference in nearby electronic equipment.

EMC Immunity

Phenomenon	Basic EMC Standard	Professional healthcare facility environment Immunity Test Levels	Compliance Levels	EMC Instructions/Precautions
Electrostatic Discharge (ESD)	IEC 61000-4-2	± 8 kV contact	± 8 kV contact	In order to reduce ESD, the device must be used in a 35% humidity environment or more
		± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 2 kV, ± 4 kV, ± 8 kV air	
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	
NOTE: The iTOF device is powered by an internal replaceable battery. Under normal usage the device is completely isolated from power mains and from power mains ground.				

Physical Integrity

N1	Protected against penetration by solid foreign bodies of 50 mm diameter and above.
IP53	Protected from limited dust ingress. Protected from water spray less than 60 degrees from vertical.

Lifetime Limited Warranty

- The iTOF device and accelerometer sensor carries a Lifetime Warranty against defects, provided that the device was used in accordance with the operating instructions, and the annual software license payment is current. If the product proves defective, Nerbio will repair or replace the iTOF device at no charge.
- The stimulation cables included in the iTOF Set carry a 6 Month Warranty against defects and are not covered by the above unlimited lifetime warranty.
- Opening the iTOF case, except to change the battery, voids the warranty.
- All service or maintenance requests must be referred to authorized Nerbio representatives.

General Data Security

- The iTOF App and Device do not collect any patient or user information and are HIPPA compliant**.**
- Special Bluetooth protocol only allows the device to be discovered by, or connected to the authenticated iTOF app**.**
- Firmware updates can only be installed when signed and authenticated by industry standard security protocols**.**
- The device only supports Bluetooth communications within a limited range. Typically, less than 15 meters.

Environment

Shipping and Storage Conditions

The iTOF and its accessories must be stored or transported under the following restrictions and conditions:

Temperature -10°C to +40°C

Humidity 15% to 95% (without condensation)

Pressure 500 hPa to 1060 hPa

Operating Environment

Risk of explosion: Do not use the iTOF in a flammable environment or in locations where flammable anesthetics may be accumulated.

The iTOF is not designed to operate in an environment where there are M.R.I. SCANNERS or any other devices creating large magnetic fields.

The iTOF is designed to operate safely under the following conditions. Conditions other than those described are likely to reduce the reliability of the device.

Temperature 10°C to +40°C

Humidity 35% to 90% (without condensation)

Pressure 700 hPa to 1060 hPa