

MYONYX



REFERENCE MANUAL

For use with BioGraph® Infiniti version 6.7 or later



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Product Name MyOnyx System

Device Name MyOnyx



SA9000

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Labeling Symbols



Refer to the instruction manual.



Caution. Consult accompanying documents



Type BF Applied Parts

RxOnly

US Federal Law restricts this device to sale by or on order of licensed health-care practitioners.



Includes RF transmitter or applies RF electromagnetic energy for treatment.



Do not dispose with general household waste. Dispose according to local recycling initiatives.



Manufacturer



Date of manufacture



Catalogue number

Table of Contents

Chapter 1 Overview	1
Product Versions.....	1
Chapter 2 Precautionary Information.....	2
Warnings and Precautions.....	2
Intended Purpose.....	4
Adverse Reactions.....	5
Contraindications	5
Maintenance and Care.....	5
Patient Population.....	6
Operator Profile.....	6
Chapter 3 Basic Functionality.....	8
An Overview of the MyOnyx Features	8
Handling the Device	9
Turning the MyOnyx On and Off.....	9
Stopping a Session.....	9
Upgrading and Updating the Device.....	9
Chapter 4 Configuring the MyOnyx.....	10
Charging the Device or Using It with AC Power	10
Connecting Electrodes and Probes	10
Connecting the Patient Drive (PD) Cable	11
Chapter 5 Adjusting the Settings	12
Settings Menu	12
Home Screen	12
Status Bar	13
Adjusting the Audio	13

Adjusting the Brightness and Contrast	14
Connecting to a PC or Tablet via Bluetooth.....	15
Recording Sessions	19
Reverting to the Original Settings and Firmware Version.....	20
Battery Savings	21
Haptic Feedback	22
About the Device.....	22
Chapter 6 Sessions.....	24
Running Sessions in Computerized Mode.....	24
Running Sessions in Remote Mode.....	25
Running ES Sessions in Standalone Mode	28
Single and Dual Exercise Modes	31
Electrostimulation Delivery Types.....	32
Predefined Electrostimulation Programs	33
Chapter 7 Troubleshooting	35
Battery Level	35
Error Messages.....	36
Appendix A Technical Specifications	39
General Specifications	39
Electromyography (EMG) Specifications	40
Electrostimulation (ES) Specifications	40
ETS Specifications	41
Notes on Electrostimulation and ETS Specifications.....	42
Operating Environmental Conditions	42
Transport and Storage Environmental Conditions.....	42
Safety Specifications.....	42
Electromagnetic Compatibility.....	43

Guidance and manufacturer's declaration – electromagnetic emissions.....	43
Guidance and manufacturer's declaration – electromagnetic immunity	44
Electromagnetic environment – guidance.....	44
Appendix B Accessories	45
Appendix C Copyright and Warranty	46
Infiniti Hardware Copyright Notice	46
Warranty.....	47
Contacting Thought Technology	47
Returning Equipment for Repair	47

Chapter 1 Overview

The MyOnyx is a dedicated hand-held device designed for biofeedback and rehabilitation treatments.

It can be used as a standalone device. It can also be paired via Bluetooth to a PC and used with BioGraph® Infiniti or to a tablet and used with the MyOnyx app.

The full solution includes BioGraph Infiniti, the MyOnyx app, the Rehab Suite, and various cables and accessories.

In standalone mode, you can use the device in electrostimulation (ES) sessions. Connected to a PC, you can use it in biofeedback sessions with BioGraph® Infiniti. Connected to a tablet, you can use it in biofeedback, ES, and EMG-triggered Stimulation (ETS) sessions with the MyOnyx app.

Product Versions

Basic and Extended

The basic version can be used in standalone mode or with the MyOnyx app. It supports recording in RMS.

The extended version is required for using the MyOnyx with BioGraph Infiniti. It supports RAW data recording. Up to four devices can be connected to a computer.

Chapter 2 **Precautionary Information**

This chapter contains the following sections:

- Warnings and Precautions
- Intended Purpose
- Adverse Reactions
- Contraindications
- Maintenance and Care
- Patient Population
- Operator Profile

Warnings and Precautions

Read and follow all the warnings and cautions provided in this section.

Warnings

- Do not attempt to service or modify the device. It has no user-serviceable parts.
- If it appears damaged, do not use it. Contact Technical Support at Thought Technology Ltd. or your local authorized distributor for a replacement.
- Do not allow contact with water.
- Do not use it in the presence of a flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.
- Always transport, store, and use the device within the specified temperature and humidity ranges only. Otherwise, it might not meet the performance specifications.
- When delivering electrostimulation, the MyOnyx is to be placed on a hard surface such as a desk or a cart and never touched for longer than one minute.
- It is isolated from line (110 or 220VAC) power due to battery operation or use of the Class 2 power adapter. However, many hospitals and the FDA require that computers, printers, and other equipment used with medical devices be electrically isolated from line voltage to UL or CSA medical safety standards.
- Use only the power adapter/charger provided with the device by Thought Technology.

- Ensure that the PC used with the device is placed outside the patient/client environment (more than 10 feet or 3 meters) or that the PC complies with EN60601 1 (system safety).
- Use cables and electrodes provided by Thought Technology only.
- Use of accessories, transducers, and cables other than those specified or provided by Thought Technology could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Only use electrostimulation electrodes for electrostimulation or ETS (not EMG electrodes). Using the wrong electrodes may cause discomfort, skin irritation, or burns if prolonged.
- This device is not intended for diagnosis and it is not a substitute for proper medical advice and diagnostic testing. If you have any health concerns, consult your doctor.
- Be attentive to patient sensation – prolonged noxious stimuli may cause skin irritation. Although this is generally not dangerous, it is not recommended.
- Stop using the MyOnyx immediately if the patient shows any sign of distress or discomfort.
- To diminish the risk of spreading communicable diseases, always use good hygiene practices with reusable electrodes, particularly if abrasive substances are used. In all cases, refer to your facility's infection control procedure.
- Vaginal and rectal probes are to be used with same patient only and cleaned before and after each use.
- EMG electrodes are all single use only.
- Electrostimulation electrodes are disposable. However, they may be used more than once with the SAME patient (single patient).
- Reusable electrodes present a potential risk of cross-infection especially when used on abraded skin, unless they are restricted to a single patient.
- After use, disposable electrodes are a potential biohazard. Handle and dispose of them in accordance with accepted medical practice, as well as applicable laws and regulations.

Precautions

Read all precautions and instructions carefully before use. Follow operating and maintenance guidelines as described in this document.

- The device may be susceptible to electrostatic discharges (ESD) and radiated radio frequency (RF) fields. Electrostatic discharge is common in conditions of low

humidity. Discharge yourself by touching a grounded bare metal surface before touching the unit.

- Do not operate active sensors within 10 feet (3 meters) of powerful radio interference producing sources such as arc welders, radio thermal treatment equipment, X-ray machines, or any other equipment that produces electrical sparks.
- Operation close (e.g. 3.5 feet or 1 meter) to a shortwave or microwave therapy ME EQUIPMENT may produce instability in the STIMULATOR output.
- Do not expose to extreme weather.
- Bluetooth operation may be interrupted by the presence of interfering devices in the 2.4 GHz ISM band.
- To avoid the risk of electrical shock, inspect the AC power adapter / charger and AC power cord on a regular basis. If you detect damage or excessive heating, remove from the wall outlet immediately and contact Technical Support at Thought Technology Ltd. or your local authorized distributor for replacement.
- Never position the AC power adapter / charger near combustible materials. Ensure that the charger is always accessible and that it can be easily disconnected from the wall outlet.

Intended Purpose

MyOnyx is intended for the following:

- Biofeedback, relaxation, and muscle re-education
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increase in local blood circulation
- Stroke rehabilitation through muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion
- Treatment of stress, urge, or mixed urinary incontinence, acute and ongoing, where the inhibition of the detrusor muscle, through reflexive mechanisms, may improve urinary control; assessing EMG activity of the pelvic floor and accessory muscles, such as abdominal or gluteal.

Note: The device is intended for use in a healthcare facility. There are no risks associated with normal use.

However, it is not designed or intended for diagnostic purposes or life support. It is not defibrillator-proof. It is not a substitute for proper medical advice. For any health concerns, consult a doctor.

Adverse Reactions

- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.
- The long-term effects of chronic electrical stimulation are unknown.

Contraindications

These contraindications must be followed.

- Avoid using this equipment adjacent to or stacked with other equipment. This could result in improper operation. If such use is necessary, you must observe all equipment to verify normal operation.
- Avoid using powered muscle stimulators on patients with cardiac-demand pacemakers, symptoms of bladder infection, or undiagnosed pain conditions.
- Avoid stimulation over
 - **Carotid sinus nerves**, particularly in patients with a known sensitivity to carotid sinus reflex.
 - **Neck or mouth.** Severe spasm of the laryngeal and pharyngeal muscles may occur. The contractions may be strong enough to close the airway or cause difficulty in breathing.
 - **Swollen, infected, or inflamed areas or skin eruptions**, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
 - **Cancerous lesions.** Also avoid stimulation in proximity to these lesions.
- Do not apply stimulation transcerebrally or transthoracically. The introduction of electrical current into the heart may cause cardiac arrhythmias.
- Do not use on a patient undergoing MRI, electrosurgery, or defibrillation or on women who are pregnant.

Maintenance and Care

- If the device is not used for a long time, make sure that it is charged at minimum every two to three months.



To ensure safety, use only the charging adapter provided.

Do not leave a battery on prolonged charge when it is not in use.

Discard the device and battery following your local waste management legislation and guidelines.

Patient Population

- **Age:** Infant to geriatric
- **Weight:** Not relevant
- **Health:** The following:
 - Young women with urinary incontinence (UI) and pelvic organ prolapse (POP), sexual dysfunctions, and pelvic pain, the elderly with fecal/urinary incontinence, post-partum women, and males post prostatectomy.
 - Infants and children under five years old with cerebral palsy (permanent movement disorders)
 - People suffering from neurological injuries like Traumatic Brain Injury, stroke, or spinal cord injury, with lack of ability to adequately recruit or deactivate/shut off their hypertonic muscles and/or with hemiparesis (weakness of one entire side of the body), and/or foot drop.
 - People suffering from neurological deficits, chronic pain, musculoskeletal conditions and injuries, post operations and injuries.
 - Contraindicated for pregnant women or patients with skin condition (in the area of the electrode placement), patients under treatment for cancer, or with pacemakers.
- **Patient state:** Not relevant, unless the patient is agitated.
- **Nationality:** Multiple

Operator Profile

- Powered muscle stimulators are to be used only under medical supervision in adjunctive therapy for the treatment of medical diseases and conditions.

Notes: It is advisable to continuously monitor the raw signals, in time and/or frequency domain, while the device is being used for biofeedback or other purposes.

- If anomalies are observed on acquired signals, and if you suspect a problem with electromagnetic interference, contact Thought Technology for a technical note on identification and remediation.

- Pediatric use is permitted only under the supervision of an adult, preferably a health-care provider.

Caution


RxOnly US Federal Law restricts this device to sale by or on order of a licensed health-care practitioner.

Chapter 3 Basic Functionality

This chapter contains the following sections:

- An Overview of the MyOnyx Features
- Handling the Device
- Turning the MyOnyx On and Off
- Stopping a Session

An Overview of the MyOnyx Features

 <p>The diagram shows a black handheld device with a screen at the top. Below the screen are four buttons labeled A, B, C, and D. In the center is a circular dial with an 'OK' button in the middle and four arrows pointing up, down, left, and right. At the bottom left of the screen is a curved arrow icon. At the bottom of the device are five ports: two labeled '8' on the left, one labeled '9' in the center, and two labeled '8' on the right. Numbered callouts (1-9) point to these features: 1 points to a power button at the top; 2 points to the top edge; 3 points to the screen; 4 points to the A, B, C, and D buttons; 5 points to the four directional arrows of the dial; 6 points to the 'OK' button; 7 points to the curved arrow icon; 8 points to the side ports; and 9 points to the bottom center port.</p>	<p>1- On/Off: Power button. Press and hold it for three seconds to turn the device on or off.</p> <p>Emergency Stop (1): The On/Off button is also the emergency stop. Press and hold it for less than one second to stop the current session.</p> <p>2 Power Adapter Port: To charge the device and / or use it with AC Power.</p> <p>3 Screen: To show current session or setting information.</p> <p>4 Channel Buttons: A, B, C, D buttons, above the dial, to adjust the amplitude of the physical channels.</p> <p>5 Main Dial and Arrows: A lit circle and arrows to navigate to menu items or settings by “scrolling” clockwise or counterclockwise or by pressing the up/down/ left/right arrow.</p> <p>6 OK: Center of the main dial, to select and save a setting or activate and resume a session.</p> <p>7 Back: Bottom left of the screen. When it is visible, you can select it to return to the previous screen.</p> <p>8 Channel Ports Physical Channel Ports on the bottom of the device.</p> <p>9 REF Port: Bottom of the device in the center of the channel ports to connect the patient drive.</p>
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Handling the Device

When delivering electrostimulation (ES), place the MyOnyx on a hard surface, such as a desk or a cart, and do not touch it for longer than one minute.

Turning the MyOnyx On and Off

To turn the device on or off, press and hold the **On/Off** power button for at least three seconds.

Stopping a Session

To stop a session, press the On/Off power button for one second or less. You can do this in an emergency. It has the following effect:

Stopping an ES Session in Standalone Mode

If you stop an ES session in standalone mode, the session ends, electrostimulation (ES) is no longer delivered, and recording stops. The Select Program screen is displayed on the device.

Stopping a Session in Computerized or Remote-Control Mode

If you stop a session while you are in computerized or remote-control mode, the current session stops, the Bluetooth connection ends, and recording stops. The Home screen is displayed on the MyOnyx.

Upgrading and Updating the Device

Basic to Extended

To use the MyOnyx with BioGraph® Ininiti, you must have the MyOnyx Extended. For details on upgrading from the basic to the extended version, consult our website.

Updating the Device

When new features become available for the MyOnyx, updates to the firmware will be made available on our website. Consult our website periodically.

A Bluetooth connection is required for upgrades and updates.

Chapter 4 Configuring the MyOnyx

This chapter describes the following sections:

- Charging the Device or Using It with AC Power
- Connecting Electrodes and Probes
- Connecting the Patient Drive (PD) Cable

Charging the Device or Using It with AC Power



Be sure to use the original power adapter and cable provided with the device.

To connect the device to AC power

1. Connect the AC power adapter to the Power Adapter Port at the top right of the device.
2. Plug the power adapter into an AC power outlet.

Note: Battery charging is disabled during Biofeedback and ETS sessions.

Connecting Electrodes and Probes

Make sure to use the approved cables specified in Appendix B.

Note: Only use electrostimulation (ES) electrodes for electrostimulation or ETS. Do not use EMG electrodes for electrostimulation. Using the wrong electrodes may cause discomfort, skin irritation, and/or burns if use is prolonged.

To connect a cable

1. Insert one end of the cable into the required channel.



- **Channel A & B:**
EMG / ES /ETS
- **Channel C & D:** Electrostimulation (ES)

2. Ensure that the cable is securely in place.
3. Connect the other end of the cable to the electrodes:
 - For **ES/ ETS** surface electrodes, connect the two pins on the other end of the cable to standard electrostimulation electrodes.
 - For **EMG surface electrodes**, either connect the two pins to EMG electrodes or connect the two pins to the DIN-to-snap connector. Then, connect the "snap on" Uni-Gel electrodes.
 - For **all electrodes**, make sure the patient's skin is clean, shaved, if necessary, and abraded. Peel the backing from the electrodes and place them on the patient.
 - Make sure **ES electrodes** are not touching each other.
 - If you are using the **vaginal/ rectal probe**, connect two pins to the applicable insert on the probe. Then, ask the patient to insert the probe.

Connecting the Patient Drive (PD) Cable

For Electromyography (EMG) or EMG-Triggered Stimulation (ETS) sessions, be sure to connect the patient drive (PD) cable to the MyOnyx device.

To connect the Patient Drive (PD) cable:

1. Insert the PD cable into the REF port on the MyOnyx.



REF The REF port is in the center of the channel ports at the bottom of the device.

2. Connect the snap connection on the other end of cable to an EMG Uni-Gel electrode.
3. Peel the backing from the Uni-Gel electrode.
4. Place it on a bony area, such as the patient's elbow, knee, ankle, or shoulder. Make sure the electrode is away from the area of the EMG reading.

Note: Using EMG and ETS without the patient drive will cause false readings.

Chapter 5 Adjusting the Settings

This chapter describes

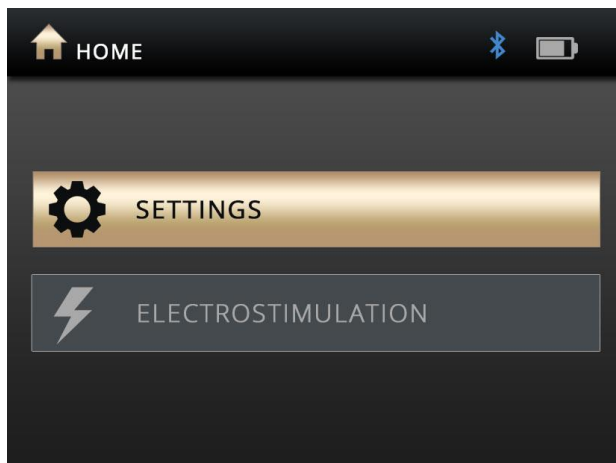
- Adjusting the Settings
- Adjusting the Amplitude

Settings Menu

The settings menu provides access to the following screens:

- Audio
- Display
- Bluetooth Pairing
- Recording
- Factory Reset
- Battery Savings
- Haptic
- About

Home Screen

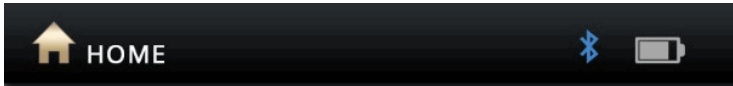


The Home screen appears once the device is booted up. You can access all settings and electrostimulation programs by pressing the following buttons:

- Settings

- Electrostimulation

Status Bar



The status bar along the top of the screen shows the following:

- **Current screen:** By icon and name
- **Status:** Bluetooth connection
- **Battery Level**
- **Recording:** Displayed when you are recording a session with the MyOnyx app.

Adjusting the Audio

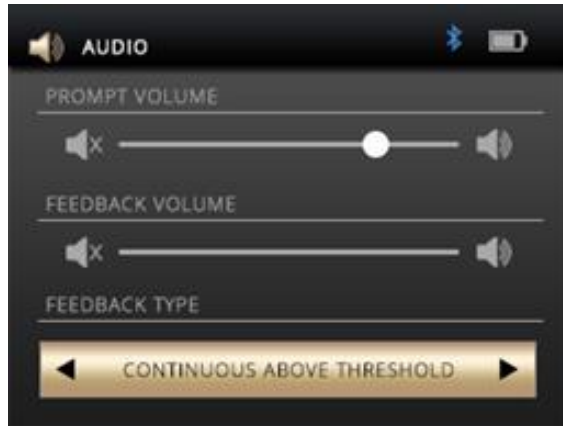
You can enable or disable audio prompts and feedback on the MyOnyx and adjust the following settings:

- Prompt Volume
- Feedback Volume
- Feedback Type (Channel A)
- Single or Proportional

Note: You can control the audio from the MyOnyx app as well.

To adjust the setting from the device

1. Go to the **Home** screen on the MyOnyx.
2. Press **Settings** > **Audio**.



Prompt Volume

Audio prompts are available to guide the client through the predefined programs. They include Session Started, Session Paused, Session Resumed, Session Ended, Work, Rest, and Relax.

To disable the prompts, press the left arrow to move the slider all the way to the left. To increase the volume, press the right arrow to move the slider to the right.

Feedback Volume

The feedback volume setting controls the notification tone for the threshold. You can enable or disable the tone, adjust the volume, and select the type of tone.

To disable the tone, press the left arrow to move the slider all the way to the left. To increase the volume, press the right arrow to move it to the right.

Proportional / Single Tone

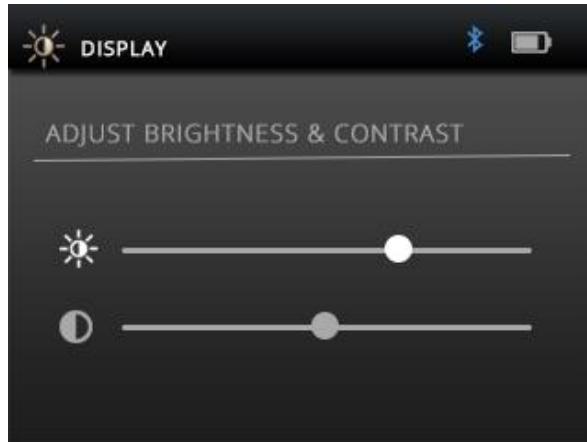
You can use either a proportional or single tone for the threshold notification.

Select proportional if you want the client to be notified by a series of tones

Adjusting the Brightness and Contrast

To change the brightness and contrast on the screens.

1. Select **Settings > Display** on the Home screen of the MyOnyx.



The Display icon and title are shown on the status bar.

2. Use the Up and Down arrows to select brightness or contrast.

By default, Brightness is set to 50 and Contrast to 26 on a scale of 0 to 100.

3. Scroll the wheel clockwise to increase the brightness or contrast. Scroll counterclockwise to decrease it.

Your settings are applied in real time.

4. Press **OK** to save the current settings, so that they are applied after rebooting

Connecting to a PC or Tablet via Bluetooth

You must pair the MyOnyx with a PC or tablet to use it with BioGraph® Infiti or the MyOnyx app, to upgrade the device or to update the firmware.

Note: Bluetooth v 4.1 must be available on the computer or tablet you are pairing with the MyOnyx.

Pairing the MyOnyx with a PC or Tablet

To pair the MyOnyx device with a PC or tablet, you must enable settings on both the device and the PC or tablet. The first step is to make the MyOnyx device discoverable. A PIN is generated during the procedure. It is displayed on both the device and the PC or tablet. You must confirm that the PINs match.

To pair the MyOnyx with a PC or Tablet

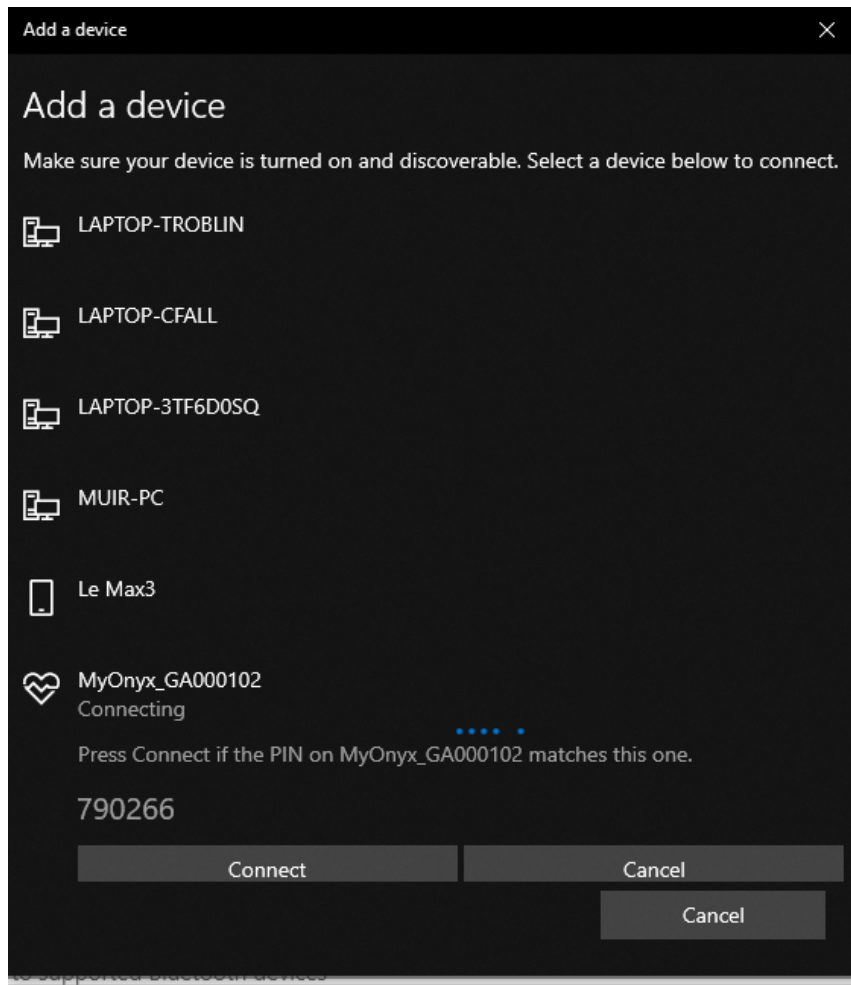
1. Turn on the MyOnyx device and the PC or tablet.
2. Press **Settings > Bluetooth Pairing > OK** on the device.

The following message appears on the device.

ENABLING DISCOVERY MODE
DEVICE IS NOW DISCOVERABLE

3. Select **Settings > Devices > Bluetooth** on the PC or tablet.
4. Turn on Bluetooth.

The Add a device screen appears on the PC or tablet with a list of all the Bluetooth devices that can be paired.



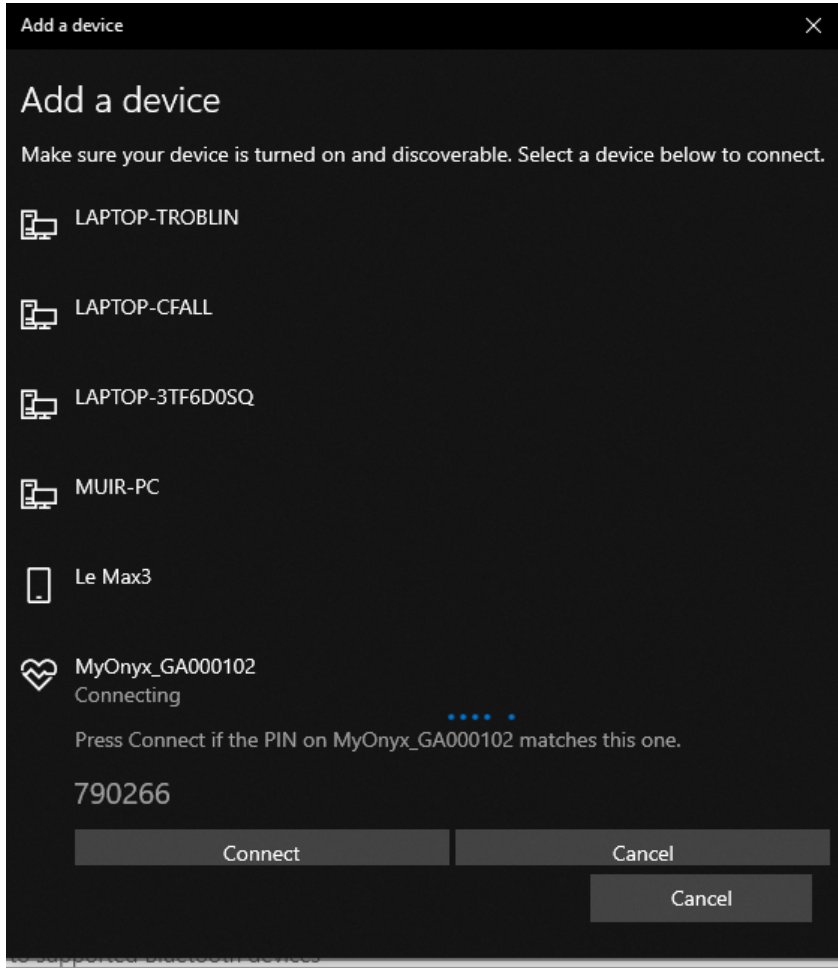
5. Select your MyOnyx device in the list.

On the screen of the MyOnyx device, a PIN is displayed with the following message.

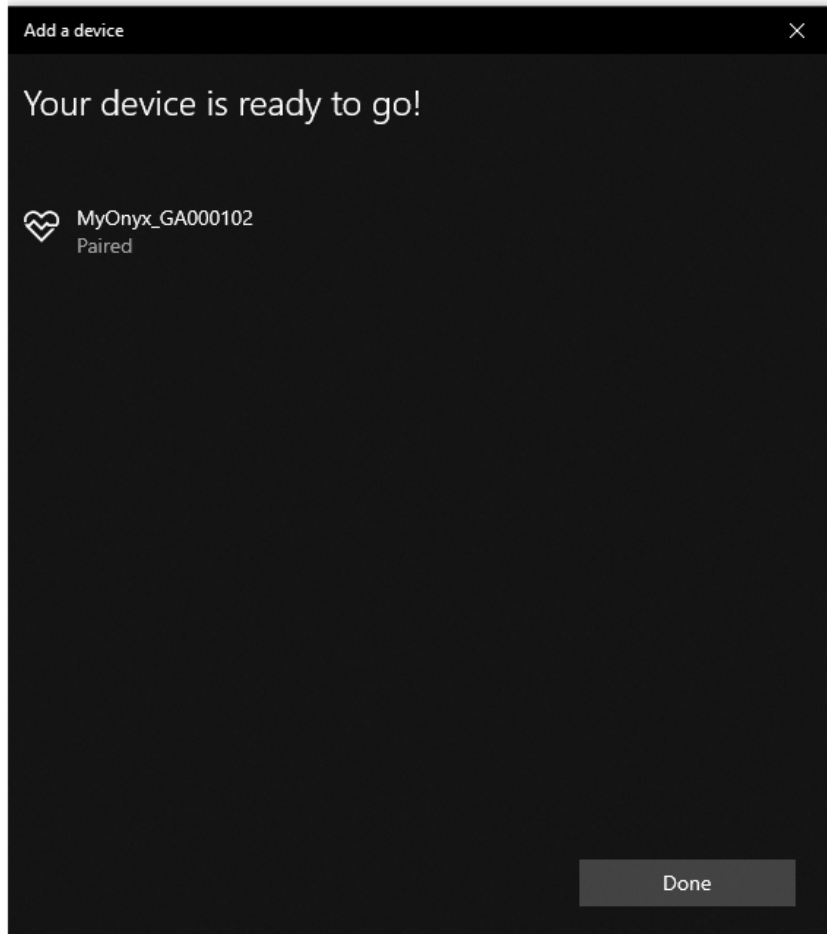
PRESS OK TO CONTINUE

On the PC or tablet, the same PIN is displayed if the procedure is successful.

6. Ensure that the two PINS are the same.
7. Press **OK** on the device and click **Connect** on the PC or tablet.



The following message appears on the PC or tablet.



8. Click **Done** on the PC or tablet.

The following message appears briefly on the MyOnyx device:

DEVICE PAIRED SUCCESSFULLY! EXITING...

Then, the Home screen is displayed on the device.

Troubleshooting Bluetooth Pairing

If the connection is not successful, the following message appears:

EXITING DISCOVERY MODE

Try pairing the device to the PC again.

Recording Sessions

By default, the recording feature is disabled. Enable it if you are performing biofeedback and ETS sessions with the app, and you would like to save these sessions for playback and review in the app. It is helpful to record device in case you lose the Bluetooth connection during a session. As well, you can transfer biofeedback sessions to BioGraph.

Sessions are saved on the MyOnyx device. They can be transferred to any MyOnyx app on any tablet. You can also transfer biofeedback sessions to BioGraph.

You can record biofeedback data in RAW 2048 Hz for transfer to BioGraph and RMS 20 Hz for playback on the app.

Note: ES sessions are never recorded or saved on the device.

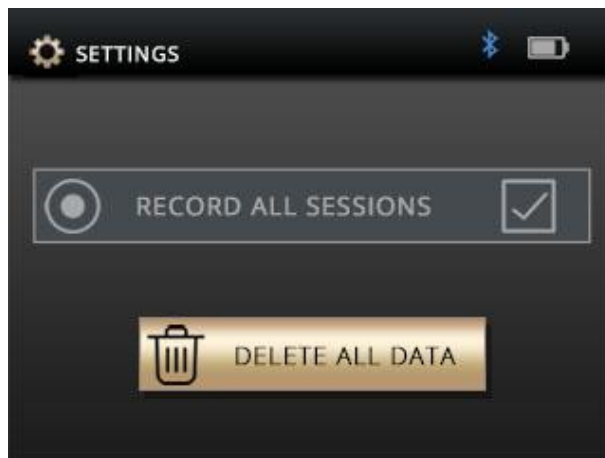
For further details on the recording feature, refer to the MyOnyx app and BioGraph Infiniti Help files.

Enabling Recording

When recording is enabled, all biofeedback and ETS sessions are recorded and saved on the device.

To enable recording:

1. Turn on the MyOnyx.
2. Go to the **Home** screen.
3. Select **Settings > Recording**.



4. Press **OK** to go to the Recording screen.

5. Press **OK** to select the **Record all sessions** checkbox.

Disabling Recording

The OK button is a toggle.

To **disable** recording

1. Follow the same procedure to disable recording if it enabled.
2. Press **OK** to disable recording if it is enabled.

Deleting Recorded Sessions

To delete recorded sessions from the MyOnyx device:

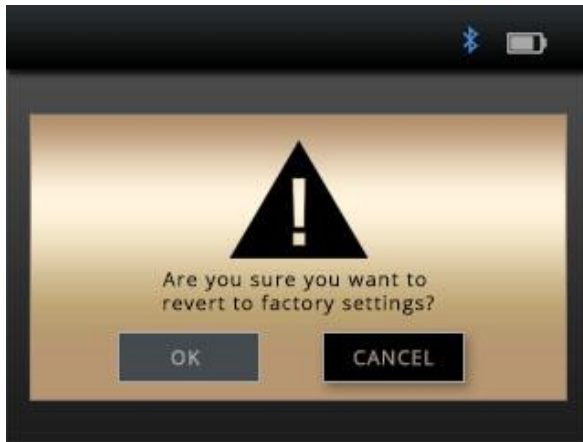
1. Select **Settings > Recording**.
2. Press **OK**.
3. Press **Delete all data**.
A confirmation message appears.
4. Press **OK**.
A second message appears confirming all data are deleted.

Reverting to the Original Settings and Firmware Version

If necessary, use the **Factory Reset** button to revert to the firmware version and settings that were on the MyOnyx when you purchased it.

To revert to the original settings and firmware version

1. Go to the MyOnyx Home screen.
2. Press **Settings > Factory Reset**.
3. Press **OK**.



The confirmation screen contains a confirmation message:

ARE YOU SURE YOU WANT TO REVERT TO FACTORY FIRMWARE AND SETTINGS?

By default, Cancel is highlighted.

Press **Back** or the **OK** button on the MyOnyx to cancel.

4. Press the left arrow to highlight the **OK** button on the Factory Reset screen.
5. **Press OK** on the MyOnyx.

The following message appears:

SYSTEM WILL REVERT TO FACTORY VERSION IN < TIME > SECONDS.
PRESS BACK TO CANCEL.

To cancel at this point, press the Back button.

If you are continuing with the Factory Reset, the device shuts down and powers up automatically. The original firmware version is restored.

Note: The Factory Reset does not affect upgrades from Basic to Extended.

Battery Savings

To reduce the power consumption of your device, enable Sleep Mode and / or Auto shutdown.

In Sleep Mode, brightness is reduced after two minutes. After five minutes, the LCD is turned off.

When any of the following actions take place, the device wakes up.

If Auto shutdown is enabled, the device shuts down after 15 minutes of inactivity.

To enable these settings.

1. Go to the **Home** screen.
2. Press **Settings > Battery Savings > OK**.
3. Select the setting and press the **OK** button.

To disable these settings if they are enabled, follow the same procedure. Highlight the setting and press the **OK** button. It acts as a toggle.

Haptic Feedback

To add vibration to the action buttons on the MyOnyx, use the Haptic Feedback setting.

To enable Haptic Feedback.

1. Go to the **Home** screen.
2. Press **Settings > Haptic > OK**.
3. Select the setting and press the **OK** button.

To disable Haptic Feedback if it is enabled, follow the same procedure. Highlight the setting and press the **OK** button.

About the Device

The About screen displays information for troubleshooting, upgrading, and connecting the device.

To view the About screen, select **Settings > About > OK** on the Home screen.

The following information is displayed:

About

Product Number

Serial Number

Product Type

Hardware Configuration

Firmware Part Number

Main Firmware Version

STIM Firmware Version

Hardware Version

Protocol Version

Chapter 6 Sessions

The MyOnyx can be used autonomously for electrostimulation (ES). It can be paired to a PC via Bluetooth for use with BioGraph® Infiniti for biofeedback. It can be paired to a tablet via Bluetooth for use with all modalities, biofeedback, ES, Electromyography (EMG), Electrostimulation (ES), EMG-Triggered Stimulation (ETS).

The four channels, A, B, C, and D are configured as follows:

Channels	Modality
A and B	Electromyography (EMG), Electrostimulation (ES), EMG-Triggered Stimulation (ETS), or support for external sensors.
C and D	Electrostimulation (ES)

This chapter details the three ways of running sessions with MyOnyx:

- Running Sessions in Computerized Mode
- Running Sessions in Remote Mode
- Running ES Sessions in Standalone Mode

Running Sessions in Computerized Mode

You can run biofeedback sessions in computerized mode, connected to BioGraph® Infiniti. This is.

- Available on the MyOnyx Extended only.
- Requires a Bluetooth connection. See page 15.
- Manages the device from a computer using BioGraph Infiniti.
- Provides biofeedback and physiological data acquisition.
- Does not support electrostimulation (ES).
- Records physiological data on the computer.

Running a Session with BioGraph Infiniti

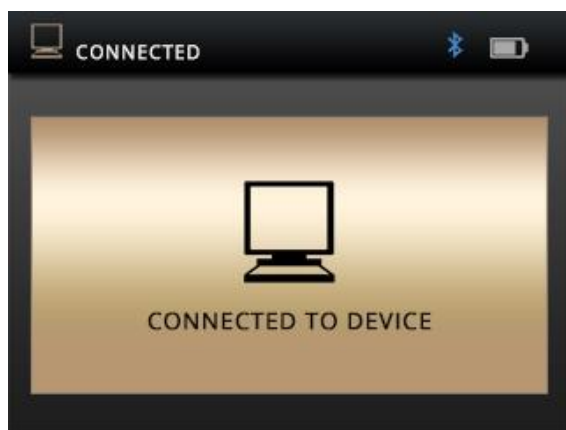
Note: Before running a session in BioGraph Infiniti, you must register the MyOnyx. For details, refer to the *BioGraph Infiniti Getting Started Guide* or the *MyOnyx Rehab Suite Manual*.

Also, the MyOnyx device and PC must be paired. See page 15.

To run a session in computerized mode:

1. Connect the cables and electrodes required for the session you are running.
2. Turn on the MyOnyx and make sure the Home screen is displayed.
3. Launch BioGraph on the PC.

The PC Connected to Device screen is displayed on the MyOnyx throughout the session.



4. During the session, follow the instructions in BioGraph.
-

Note: You can use the power button on the device to stop the session or turn off the device. All other functionality is controlled from BioGraph.

Running Sessions in Remote Mode

You can run Biofeedback, electrostimulation (ES), and ETS sessions remotely from a tablet running the MyOnyx app. In remote sessions

- Users can connect remotely to a tablet, running the MyOnyx app, from any MyOnyx device, either Basic or Extended.
- Bluetooth is required.

- Records biofeedback data on the tablet.
- When you run a session on the tablet, you can record and save it on the device.
- If the Bluetooth connection is lost, recording stops on the app but continues on the device.

Running Biofeedback Sessions in Remote Mode

To run a biofeedback session in Remote Mode

1. Connect the required cables to the device and place the electrodes on the client, as described on page 10.
2. Turn on both the MyOnyx and your tablet.
3. Ensure that the two devices are paired. See page 15.
4. Make sure the Home page is displayed on the MyOnyx device.
5. Launch the MyOnyx app on the tablet.

The following screen appears on the MyOnyx device.



6. Set up and start the session on the app following the instructions in the *MyOnyx App Help system*.

Running an ES or ETS Sessions in Remote Mode

For ES and ETS, you must perform the following on the device:

- Turning the device on and off
- Adjusting the amplitude
- Starting a session

- Stopping a session
-

Note: You can run two programs at the same time using Dual STIM.

To run an ES or ETS session in Remote Mode

1. Set up the MyOnyx with the cables, electrodes, and/or other accessories required for the program you are running. See page 10.
2. Turn on both the MyOnyx and your tablet.
3. Ensure that the two devices are paired. See page 15.
4. Go to the Home page on the MyOnyx device.
5. Launch the MyOnyx app.

The Connected to Device screen appears on the MyOnyx device.

6. Select the ES program or programs you want to run on the app.

The Amplitude Adjustment screen appears on the MyOnyx device.

7. Press the channel buttons above the dial on the MyOnyx device that correspond to the channels you want to adjust. For example, press **A** and **B** to adjust channels A and B.
8. Adjust the amplitude using the wheel or up/down arrows.
 - Both Set and Live values are adjusted.
 - The patient feels the electrostimulation as you are setting it, so you can determine the appropriate level.
9. Once the amplitude is adjusted, deselect the channel(s) or wait three seconds.
 - The Set amplitude value is saved.
 - The Live amplitude value returns to 0.
10. Press the **OK** button on the device to start the session.
11. Control the program from the app as described in the MyOnyx App Help, unless you need to stop the session.

Note: The session pauses automatically if

- A cable disconnects from an active channel on the device.
-

-
- Contact between the electrodes or the probe and the patient is lost.

You can pause a session manually from the app.

You can stop a session completely by pressing the On/Off button the device for one second.

Running ES Sessions in Standalone Mode

- Standalone mode is available on both the Basic and Extended versions of the device.
- No computer or mobile device is required during sessions. However, a Bluetooth connection to a computer is required for upgrading the firmware on the device or for transferring recorded sessions to BioGraph.
- It can be used for electrostimulation (ES) only.
- It does not support EMG or EMG-Triggered Stimulation (ETS).
- Provides electrostimulation, sound, and visual feedback.
- ES sessions are run according to preconfigured programs, which can be selected on the device. The settings for these programs are defined under Electrostimulation Programs on page 33.
- The clinician controls the Session Start, Pause, Resume, Stop, Emergency Stop, and the amplitude adjustment are managed on MyOnyx.

For all ES and ETS sessions, you must adjust the amplitude on the MyOnyx.

Note: When delivering electrostimulation, the MyOnyx is to be placed on a hard surface such as a desk or a cart and never touched for longer than one minute.

In an emergency, you can press the **On/Off** power button to stop the session completely. When you do this, the recording stops, and electrostimulation is no longer delivered.

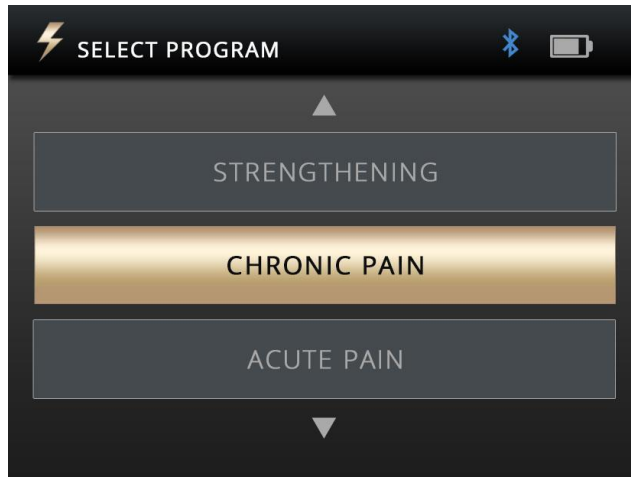
To run an ES session in standalone mode

1. Turn on the MyOnyx.
2. Connect the cables to the device and place electrodes on the patient, following the instructions on page 10.

Note: Make sure the electrodes are not touching each other.

3. Go to the Home screen and select **Electrostimulation**.
4. Press **OK**.

5. Use the **Up** and **Down** arrows or the **wheel** to navigate to the applicable program. The words Select Program appear at the top left of the screen.



6. Press **OK** to select the program.

The Amplitude Adjustment screen appears.

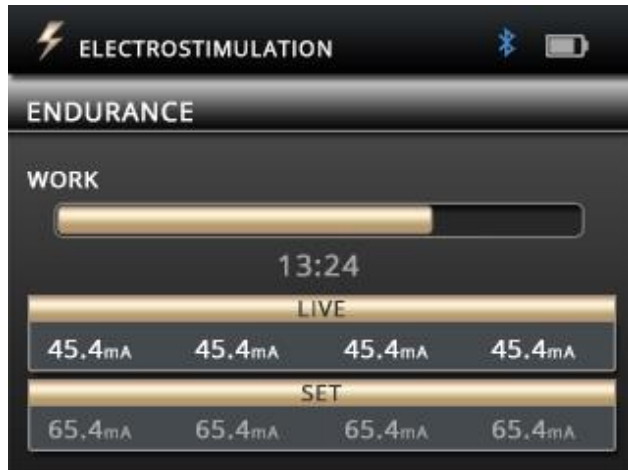
7. Scroll the dial or use the up/down arrows to adjust the current amplitude.

Both the Set and Live amplitude values are adjusted.

- The **Set amplitude** is the maximum intensity of ES generated during the work phase.
- The **Live** amplitude is the real-time level of the electrostimulation generated. It is at zero during the rest phase. It changes during the ramp-up/ramp-down periods and due to amplitude modulation.

The patient feels the electrostimulation as you are setting it. You can determine the appropriate level.

8. Deselect the channel(s) or wait three second once you have selected the amplitude.
9. Press **OK** to start the session.



During the session, the following information is displayed:

- The **Set amplitude**.
- The **Live amplitude**.
- Total remaining session time
- Current session work or rest phase
- Progression of the current phase

Note: The session pauses automatically in the following situations:

- A cable disconnects from an active channel on the device.
- Contact between the electrodes or the probe and the patient is lost.

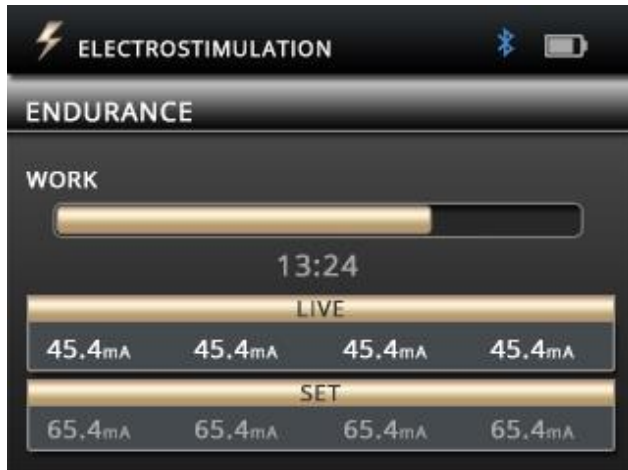
To pause a session manually, press the **OK** button.

To stop a session completely, press and hold the On/Off button on the device for one second.

Single and Dual Exercise Modes

ES sessions can be run in single or dual exercise mode.

Single Exercise Mode



In single exercise mode, the set and live amplitude are displayed for all selected channels. The current work or rest phase is displayed above the amplitude settings with the total remaining time.

Dual Exercise Model



In dual exercise mode, the two programs are displayed side by side. The channels are grouped into pairs, Channels A and B for the program on the left and C and D for the program on the right.

The two programs can have different modalities and different delivery types. As well, the number of cycles, the duration of the program, and the current session phase can be different.

The pattern, pulse width and rate, and ramp up and down can be different on all channels in both single and dual exercise modes.

To run a session in dual Electrostimulation mode:

Follow the instructions under Running ES Sessions in Standalone Mode on page 28.

1. Turn on the MyOnyx.
2. Connect the cables to the device and place the electrodes on the patient, following the instructions on page 10.

Note: Make sure the electrodes are not touching each other.

3. Navigate to the Home screen on the device and select **Electrostimulation**.
4. Press **OK**.
5. Press the left arrow.
The lights for Channels A&B flash and the words Select Programs for A&B appear.
6. Use the **Up** and **Down** arrows or the **wheel** to navigate to the applicable program.
7. Select the program and press **OK**.

The lights for Channels C&D flash and the words Select Programs for C&D appear.

8. Navigate to the program. Select it and press **OK**.

The two programs are shown, side by side, with the session duration for each. The Live and Set amplitude are at zero (0.0) for all channels.
9. Select the channels for each program and adjust the amplitude as described under Running ES Sessions in Standalone Mode on page 28.
10. Scroll the dial or use the up/down arrows to adjust the current amplitude.
11. Deselect the channel(s) or wait three second once you have selected the amplitude.
12. Press **OK** to start the session.

Electrostimulation Delivery Types

ES delivery is categorized into the following types:

Synchronous

In Synchronous mode, the MyOnyx delivers ES in a cycle of work and rest phases throughout the session. If you resume a paused session, it continues from the beginning of the phase that was active when it paused.

Continuous

In continuous mode, there is no rest phase. The MyOnyx delivers ES without stopping for the entire session. If you resume a paused session, it picks up and continues from the same point at which it was paused.

Alternating

Alternating mode targets opposing muscles, such as biceps and triceps. The ES delivery alternates between the two sets of muscles, so that one set of muscles is always at work while the other is at rest. Like synchronous delivery, a paused session resumes from the beginning of the active phase.

Restrictions on Alternating ES

The following restrictions apply to Alternating ES delivery but not to Synchronous or Continuous.

- Both channels in a group, either A&B or C&D must be set to a valid modality.
- A cable must be connected to both channels in a group.
- The amplitude for both channels in the group must be greater than zero.

Predefined Electrostimulation Programs

Electrostimulation programs are defined by

Delivery Type: For the predefined ES programs, the delivery types are:

- **Synchronous**, delivered in a cycle of work and rest phases repeated throughout the session,
- **Continuous**, delivered directly with no rest phase, at the same amplitude throughout the session.

Total Time: The time spent at work and rest multiplied by the number of repetitions.

Pattern The following patterns are available:

- **Continuous** delivered directly during the work phase without variation.
- **Burst** delivered at a rate of two bursts/second.
- **Modulated:** the pulse rate and pulse width increase and decrease following a predefined pattern.

Ramp Up / Down Time: Time before and after amplitude is delivered at the set value.

Pulse Rate and Pulse Width: The frequency and length of time the current is active.

Neuromuscular Electrostimulation (NMES) Programs

Typically used in physiotherapy for muscle rehabilitation, NMES is applied at an intensity high enough to induce motor contraction. The following Neuromuscular Electrostimulation programs are available. The delivery type is synchronous, delivered in a cycle of work and rest phases. The pattern is continuous, delivered without variation throughout the work phase.

Program	Total Time (sec)	Reps	Work time (sec.)	Rest time (sec.)	Ramp-up (sec)	Ramp-down (sec)	Pulse Rate (Hz)	Pulse Width (µs)
Small Muscle Strengthening	1250	50	10	50	3	1	50	150
Large Muscle Strengthening	1750	50	15	20	3	1	50	200
Circulation	300	60	3	2	0	0	5	200
Atrophy	1300	100	5	8	2	1	35	250
Endurance	1800	200	6	3	2	2	15	150
Stress Incontinence	1280	80	6	10	2	1	45	200
Urge Incontinence	1280	80	6	10	2	1	15	200

Chapter 7 Troubleshooting

The section lists the error messages and provides the recommended procedures. If after you follow the steps, a problem persists, contact technical support. The following errors can be displayed:

Battery Level

It is recommended to keep the battery at 50% or higher.

Below 50%

The MyOnyx is fully operational, but the firmware cannot be updated at this level.

Below 20%



When the battery level drops below 20%, the icon turns red.

Below 10%, ES sessions are paused and cannot be resumed until the power adapter is connected. All other sessions are stopped.

The following message appears:

BATTERY LEVEL LOW.
CHARGE DEVICE TO CONTINUE OPERATION. PRESS OK TO DISMISS.

Below 5%



Below 5%, the device cannot be booted. If it is turned on, you have 15 seconds to connect it to a power adapter before it shuts off.

The following message appears:

BATTERY LEVEL CRITICAL. DEVICE SHUTTING DOWN IN <x> SECONDS

If the battery level is below 5% and the power charge is not connected when you boot up the device, the following screen appears.



To use the MyOnyx, you must connect it to the AC Power via the AC Power adapter.

Bluetooth

The MyOnyx can be paired with only three devices, PCs or tablets, at a time.

If you are unable to connect to BioGraph or the MyOnyx app via Bluetooth, try unpairing the MyOnyx from the tablet or PC and pairing it again.

Error Messages

The following errors can be displayed:

- Session Paused
- Session Stopped
- Critical Error

Session Paused

The session pauses in the following situations:

Follow the instructions displayed on the screen of the MyOnyx. If the problem persists, contact technical support.

- **Electrodes are no longer placed properly on the patient.**
Electrodes disconnect from the cables.
- Cables disconnect from the device.
- Bluetooth connection is lost.

If the session paused message is displayed, follow the online instructions. If the problem persists, contact technical support.

Electrodes are not placed properly on the patient

Session Paused

Make sure electrodes are attached properly.

Press **OK** to resume
or **BACK** to dismiss.

If this message occurs, follow the instructions on the screen. If the problem persists, contact technical support.

Electrodes disconnect from the cables

Session Paused

Sensor disconnection detected.

Press **OK** to resume
or **BACK** to dismiss.

The Bluetooth connection is lost.

Session Paused

Bluetooth connection lost.

Press **OK** to resume
or **BACK** to dismiss.

Session Stopped

The session stops if the device is overheating or if a critical error occurs.

Overheating

The full message for the device overheating reads:

Session Stopped (if running)

Device Overheating

Let cool 5-10 minutes

Under normal use, this message appears only if you are using the MyOnyx in an environment exceeding the recommended temperature. This is defined under Operating Environmental Conditions *on page 42*.

If this message appears

1. Disconnect the charger if it is connected to the device.
2. Move the MyOnyx away from any heat source.
3. Let it cool for 5-10 minutes or until the heat dissipates.

When the device has cooled down, the following message appears:

Device temperature is back to normal.

Verify operating conditions are within specifications.

Press **OK** or **BACK** to dismiss.

When you see this message:

1. Make sure your environment meets the match the specifications defined in the Operating Environmental Conditions section on page 42.
2. Press **OK** or **Back** to return to the Home screen and dismiss the message.
3. Restart your session.

Critical Error

The following message appears, with an error code, if a critical error occurs.

Session Stopped.
Critical Error Detected
Press **OK** or **BACK** to dismiss.

If you see this message:

1. Write down the error code.
2. Press **OK** or **Back** to return to the Home screen.

If the problem persists, contact technical support.

Appendix A Technical Specifications

This appendix lists the following specifications:

- General Specifications
- Electromyography (EMG) Specifications
- Electrostimulation (ES) Specifications
- ETS Specifications
- Notes on Electrostimulation and ETS Specifications
- Operating Environmental Conditions
- Transport and Storage Environmental Conditions
- Safety Specifications
- Electromagnetic Compatibility
- Guidance and manufacturer's declaration – electromagnetic emissions
- Guidance and manufacturer's declaration – electromagnetic immunity
- Electromagnetic environment – guidance

General Specifications

- **Weight:** Approx. 272g
- **Device size:** Approx. L 155mm x W 83mm x D 20.95mm
- Wireless communication: Bluetooth Class 1 v4.1 Low Energy and Classic
- Screen: LCD, 24-bit color, backlighted
W 320 pixels wide x L 240 pixels
W 72 mm x L 54 mm
- **Controls:** Physical On/Off button
Capacitive touch:
 - Channel selection (4 buttons)
 - OK/Select
 - Back/Cancel
 - Wheel with up/down/left/right arrows

- **Audio:** Speaker, Mono, 2W
- **Internal Memory for data storage:** eMMC, 8GB
- **Channels:** 2 channels of EMG and/or electrostimulation and/or EMG-Triggered Stimulation (ETS), or support for external sensors (such as Perineometer)
- 4 channels of electrostimulation (SA9000 only)
- **Power Consumption:** 3.2A @ 4.2V max.

Electromyography (EMG) Specifications

- **Range:** 0-2000 μ V, 20Hz-500Hz
- 16-bit ADC, 2048 samples/sec
- Output rates: 2048 samples/sec (raw), 20 samples/sec (RMS)
- Accuracy (error): $\pm 3\%$ or $\pm 1\mu$ V
- Noise: $< 1\mu$ Vrms
- Input impedance $> 10M\Omega$
- CMMR > 100 dB

Electrostimulation (ES) Specifications

Standard Electrostimulation (0 mA – 100 mA)

- **Impedance range:** 250 Ω to 750 Ω . Above this, the maximum amplitude becomes limited.
- **Safety mechanisms:** triggered at 200 Ω and below and at 4000 Ω and above.

Neuromuscular Electrostimulation (NMES)

- **Channels:** A, B, C, and D
- **Waveform:** Symmetrical, rectangular, bipolar, biphasic:
- **Frequency Range:** 5-80Hz
- **Pulse Width Range:** 150-400 microseconds
- **Amplitude Range:** 0-100mA (*)
- **Pattern:** Continuous

- **Delivery:** Synchronous or Alternating
- **Ramp Up/Down Time:** 0 – 10 seconds with 0.1s increments
- **Exercise Mode:** Single or dual

ETS Specifications

In ETS, Biofeedback signals are read from the client and electrostimulation is delivered using NMES in Continuous delivery mode.

Note: ETS can be performed in computerized or remote mode. It cannot be performed in standalone mode.

- **EMG Channel:** A or B
- **Electrostimulation Channels:** A, B, C, or D
- **Waveform:** symmetrical, rectangular, bipolar, biphasic
- **Frequency Range:** 5-80Hz
- **Pulse Width Range:** 150-400 μ s
- **Amplitude Range:** 0-100mA*
- **Pattern:** Continuous
- **Delivery:** Continuous
- **Electrostimulation Duration:** 1-7,200 seconds (1 second increase)
- **Rest Duration:** 1-7,200 seconds (two hours), (1 second increase)
- **Total Session Duration:** 36,000 seconds (10 hours)
- **Electrostimulation Ramp Up/Down Time:** 0.1 – 9.9 seconds (0.1s increase)
- **Sample Rate:** 2048 samples/sec
- **Output Rate:** With EMG RMS: 20 Hz
- **Exercise Mode:** Single mode only

Notes on Electrostimulation and ETS Specifications

- **Amplitude range:** (*) For all types of electrostimulation, up to 100mA into 500 Ohm to 750 Ohms load – beyond 1000 Ohms, the amplitude is limited. However, the amplitude displayed is accurate.
- **Frequency, pulse width and amplitude deviation** < $\pm 20\%$

Operating Environmental Conditions

- **Standard:** EN/IEC 60601-1
- **Temperature:** +5°C – +40°C
- **Maximum Temperature of Applied Parts:** 48°C
- No condition for safe contact.
- **Relative Humidity:** 15% – 93% (non-condensing)
- **Atmospheric Pressure:** 700 hPa – 1060 hPa

Transport and Storage Environmental Conditions

- **Standard:** EN/IEC 60601-1
- **Store in the original case.**
- **Temperature and Relative Humidity:** -25°C without relative humidity control +60°C at relative humidity up to 93%, non- **condensing**
- **Atmospheric Pressure:** 700 hPa – 1060 hPa

Safety Specifications

- **Standard:** EN/IEC 60601-1, EN/IEC 60601-2-10
- **Type of Protection Against Electric Shock:** Class II Double Insulated External Power Source Internally powered equipment (when not connected to external power source)
- **Degree of Protection Against Electric Shock:** Type BF: separated from earth, not defibrillator proof
- **Mode of Operation:** Continuous
- **Degree of protection against ingress of water:** IPX0 (no protection)

- **Protection against ignition of flammable anesthetic mixtures:** EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE
- **Internal Battery:** Li-ion Polymer battery certified against IEC62133
- **Capacity:** 3200mAh
- **Nominal Voltage:** 3.7V
- **External Power Source (Medical Grade Universal Power Supply / AC Power Adapter):** GlobTek GTM96180-1507-2.0
UL/IEC 60601-1
15W
Input: 100-240VAC, 60/50Hz
Output: 5VDC, 3A

Electromagnetic Compatibility

Standard: EN/IEC 60601-1-2 4th edition

Guidance and manufacturer's declaration – electromagnetic emissions

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

- **RF emissions CISPR 11 Group 1 Compliant:** The device uses RF energy only for its internal function. Therefore, RF emissions are very low and unlikely to cause interference in nearby electronic equipment.
- **RF emissions CISPR 11 Class B Compliant:** The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
- **Harmonic emissions IEC 61000-3-2:** The electromagnetic environment guidance is the same as for RF emissions CISPR 11 Class B Compliant.
- **Voltage fluctuations flicker emissions IEC 61000-3-3:** The electromagnetic environment guidance is the same as for RF emissions CISPR 11 Class B Compliant.

Guidance and manufacturer's declaration – electromagnetic immunity

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

- **Immunity test:** Electrostatic discharge (ESD) IEC 61000-4-2
- IEC 60601 test level: □□8kV contact □□15 kV air
- Compliance level: ±8 kV contact ±15 kV air

Electromagnetic environment – guidance

Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Appendix B Accessories

Use the MyOnyx with the following approved accessories only:

- SA9391 EMG/STIM Cable (4 required)
- SA9393-1500 1.5m DIN to SNAP Patient Drive Cable
- SA9817 DIN to SNAP Cable Adapter (Bag of 4)
- SA9001 15W, 5V Multiplug Medical Grade Power Supply
- SA9811 Axelgaard Electrode 5x5cm Sq Model 895220 (Bag of 4)
- T3425 Electrodes 100 Uni-Gel Single
- SA9572 – SA9572CAN Vaginal STIM Sensor
- SA9571 – SA9571CAN Anal STIM Probe
- SA7900 BioGraph® Infiniti Software
- SA9013 MyOnyx Mobile App
- SA9014 MyOnyx Rehab Suite

Appendix C Copyright and Warranty

Infiniti Hardware Copyright Notice

This hardware contains proprietary embedded software code, which is the property of Thought Technology Ltd.; it is provided under a license agreement containing restrictions on use and disclosure and is also protected by copyright law. Reverse engineering of the software or the resulting output data stream is prohibited.

Due to continued product development, the embedded software may change without notice. The information and intellectual property contained herein is confidential between Thought Technology Ltd. and the client and remains the exclusive property of Thought Technology Ltd.

If you find any problems in the documentation, please report them to us in writing. Thought Technology Ltd. does not warrant that this document is error-free.

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BioGraph® Infiniti is a registered trademark of Thought Technology Ltd.

Warranty

The hardware is guaranteed to be free from defects in material and workmanship for one year from the date of purchase.

In the unlikely event that repair is necessary, contact Thought Technology Ltd. to receive a Return Authorization number. Then send the unit back by a traceable method. Thought Technology will not be responsible for items not received. We will repair or replace your unit(s) that are still under warranty free of charge.

This warranty does not apply to damage incurred through accident, alteration, or abuse. It does not cover damage to the encoder or accessories caused by obvious mechanical mistreatment of the system.

Optional Extended Warranty

Please contact Thought Technology Ltd. for further details.

Contacting Thought Technology

To place orders or contact technical support

Outside USA

In USA Toll Free

Tel: 1 514 489 8251

Tel: 1 800 361 3651

Fax: 1 514 489 8255

Email: mail@thoughttechnology.com

Or contact your local authorized distributor.

Strictly for technical support

For technical support please refer to the Thought Technology Ltd. website at www.thoughttechnology.com for frequently asked questions. If your support issue is not covered please email or call us.

Returning Equipment for Repair

Be sure to call for an authorization number (RA) before returning any equipment!

Send the unit(s) postage prepaid and insured, with a copy of the original invoice to one of the addresses below.

If you are shipping from outside Canada or the USA to Canada, mark the package "**Goods to be repaired – Made in Canada**" to avoid unnecessary customs charges.

All customs and duties charges will be billed to you if they are incurred by sending the unit to the wrong address.

Provide a detailed description of the problem you are experiencing, and your telephone/fax number and email (see form on the next page of this manual).

In the USA, ship insured to:

Thought Technology Ltd.
Cimetra LLC
8396 State Route 9
West Chazy, New York
12992, USA

In Canada and all other countries, contact your dealer or ship insured to:

Thought **Technology** Ltd.
5250 Ferrier, Suite 812
Montreal, Quebec
Canada H4P 1L3

The package must be marked:

“Broker: Livingston International – 133461”

Service Return Form

Be sure to call for authorization number (RA) before returning any equipment!

Copy and complete this form. Send it with the unit(s) and a copy of original invoice to one of the addresses listed above.

Name _____

Company _____

Address _____

Phone No. _____

Fax No. _____

Date Purchased _____

Purchased From _____

Model Name _____

Serial No. _____

Problem _____
