

MYONYX



USER GUIDE

For use with BioGraph® Infiniti version 6.7 or later



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Product Name MyOnyx System

Device Name MyOnyx



SA9020



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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.



Catalogue number

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Chapter 1 Overview

The MyOnyx System is a dedicated device designed for biofeedback and rehabilitation treatments.

It can be used as a standalone device in electrostimulation (ES) sessions.

Connected to a PC (computerized mode), you can use it in biofeedback sessions with BioGraph® Infiniti. Connected to a tablet (remote-control mode), you can use it in biofeedback, ES, and EMG-triggered Stimulation (ETS) sessions with the MyOnyx Mobile App.

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

Product Types

The MyOnyx is available in Basic and Extended, shown under **Settings > About**.

Basic can be used in standalone mode or with the MyOnyx Mobile App. It supports recording EMG in RMS.

Extended is required for BioGraph Infiniti. It supports RAW data recording. Up to four devices can be connected to a computer.

Installing the MyOnyx Mobile App



The MyOnyx Mobile App can be used with the basic or extended version of the device. A QR Code is included on a separate information sheet shipped with the device. Use this for installing the app.

Minimum Requirements

- Android tablet, at least seven inches in landscape view
- Android version 7, 8, or 9
- Bluetooth v 4.1
- An internet connection

Android Version 9

Version 9 has a built-in QR Code Scanner

1. Select **Settings > Scan QR Code**.
2. Turn on the feature.
3. Turn on the camera.
4. Hover your device over the QR Code until a link to the MyOnyx app appears in the browser.
5. Wait for a link to Google Play to appear.
6. Tap **Google Play** and wait for the MyOnyx Mobile App installation page to appear.
7. Tap **Install**.

Android Version 7 or 8

For versions 7 or 8, you can download and install a QR Code scanning app from Google Play.

1. Turn on your QR Code scanning app.
2. Follow the steps under the procedure for version 9.

Chapter 2 Safety Information

Indications for Use

- 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
- Reduction of pain, both acute and chronic
- 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, during incontinence treatment
- The MyOnyx System is to be used only under medical supervision in adjunctive therapy for the treatment of medical diseases and conditions.

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

Patient Population

Age: 5 years and older

Health Conditions:

- 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.
- Children 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.

Contraindications

- The device is not designed or intended for diagnostic purposes or life support.
- Avoid stimulation on patients with cardiac-demand pacemakers, symptoms of bladder infection, lesions or skin conditions (in the

area of intended electrode placement), or undiagnosed pain conditions.

- Avoid using stimulation over the following:
 - **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.
- Avoid stimulation over, or in proximity to, cancerous lesions.
- Avoid stimulation on women who are or suspect to be pregnant. Safety of powered muscle stimulators for use during pregnancy has not been established.
- Do not apply stimulation transcerebrally.
- Do not apply stimulation transthoracically. The introduction of electrical current into the heart may cause cardiac arrhythmias.
- Do not use on a patient undergoing MRI, electrosurgery, or defibrillation.

Adverse Reactions

- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

Intended Use Environment and Operator Profile

- The device is intended for use under medical supervision in a healthcare facility.
-

Note: It is advisable to continuously monitor the patient's physiological signals while the device is being used. The clinician must have the necessary education to be able to assess and monitor the effectiveness of training programs and be able to make necessary adjustments.

- Pediatric use is permitted only under the supervision of an appropriately trained health-care provider.

Warnings and Precautions

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

Warnings

- The long-term effects of electrical stimulation are unknown. Use under competent medical supervision.
- Do not apply stimulation during any activity in which involuntary muscle contractions may put the patient at undue risk of injury.
- Be attentive to patient sensation—prolonged noxious stimuli may cause skin irritation. This is especially relevant in TENS because of prolonged continuous stimuli (as opposed to NMES where stimuli are delivered in an

on/off or work/rest pattern). Although this is generally not dangerous, it is not recommended.

- Stop using the device immediately if the patient shows any sign of distress or discomfort.
- Do not use the Pressure Sensor in conjunction with electrical stimulation. When using the Pressure Sensor, do not touch it for more than 10 seconds as it may become hot to the touch.
- Do not use the pressure probe for six weeks following childbirth or pelvic surgery as this may interfere with healing.
- The vaginal pressure probe is sold only in sealed packages. Do not accept or use the device if the seal was not intact upon delivery. Contact Technical Support at Thought Technology Ltd. or your local authorized distributor for a replacement.
- It is recommended to use the MyOnyx device and Pressure Sensor on a hard surface such as a desk or a cart.
- Do not attempt to service or modify the device. It has no user-serviceable parts.
- If a device appears damaged, do not use it. Contact Technical Support at Thought Technology Ltd. or your local authorized distributor for a replacement.
- Do not expose the device to extreme environmental conditions. Do not allow contact with water or other liquids.

- Do not use the device 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.
- MyOnyx is isolated from line power (110 or 220VAC) due to battery operation or use of the Class 2 power adapter. Use only the power adapter/charger provided with the device by Thought Technology.
- Electrical safety codes for health-care facilities require that computers, printers, and other equipment used with medical devices be electrically isolated from line voltage to UL, CSA or other recognized consensus medical safety standards.
- Ensure that the PC used with the MyOnyx device is placed outside the patient/client environment (more than 10 feet or 3 meters) or that the PC system complies with IEC/EN 60601-1 (medical electrical equipment safety standard).
- Use cables and electrodes provided by Thought Technology only.
- Use of accessories 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 ES or ETS, not EMG electrodes. Using the wrong electrodes may cause discomfort, skin irritation, or burns if prolonged.
- To diminish the risk of spreading communicable diseases, always use good hygiene practices. In all cases, refer to your facility's infection control procedure.
- Do not clean the devices with alcohol or abrasive detergents. Follow manufacturer instructions to disinfect the reusable vaginal and rectal probes. Do not sterilize.
- The vaginal, rectal and pressure probes are to be used with the same patient only and cleaned thoroughly with water and mild soap before and after each use.
- EMG electrodes are for 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 clinical practice, applicable laws and regulations.

Precautions

- Read all precautions and instructions carefully before use. Follow operating and maintenance guidelines as described in this document.
- Keep the device out of the reach of children.
- Exercise caution when using the device,
 - For patients with suspected or diagnosed heart problems
 - For patients with suspected or diagnosed epilepsy
 - Where there is a tendency to hemorrhage following acute trauma or fracture
 - Following recent surgical procedures, when muscle contraction may disrupt the healing process
 - Over the menstruating uterus
 - Over areas of the skin which lack normal sensation.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrically conductive medium. The irritation can usually be reduced by using an alternate conductive medium or alternate electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing medical practitioner.
- Before using the pressure probe, it is recommended that a proper evaluation of the patient be performed by a qualified

medical practitioner. This would include, if relevant, a proctologic, urologic, and/or gynecological evaluation. Determining whether to use pressure feedback is left to the discretion of the medical practitioner based upon his or her professional judgment.

- Use pressure biofeedback only after consulting a medical doctor, when patients are:
 - Pregnant, menstruating, or using contraceptives, such as diaphragms, cervical caps, or pessaries
 - Undergoing artificial insemination
 - Experiencing active symptoms of any pelvic disease, such as herpes, a sexually transmitted disease, vaginitis, or yeast infection as it may aggravate symptoms.
 - Have inflammation, infection, or dilated veins in the area of the vagina, tumors, prolapsed uterus, or sustained hypertension of the pelvic floor.
- If the patient feels the pressure in the probe is so high that she feels uncomfortable, she should pull out the tube connector immediately. This will deflate the probe.
- There are no known adverse effects due to pressure biofeedback for urinary incontinence. If irritation occurs, notify the attending medical practitioner and discontinue its use.
- 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.

- 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.
- 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.

- Bluetooth operation may be interrupted by the presence of interfering devices in the 2.4 GHz ISM band.
- 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.

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.



The device contains a Li-ion Polymer battery certified against IEC 62133.

To ensure safety, use only the charging adapter provided.

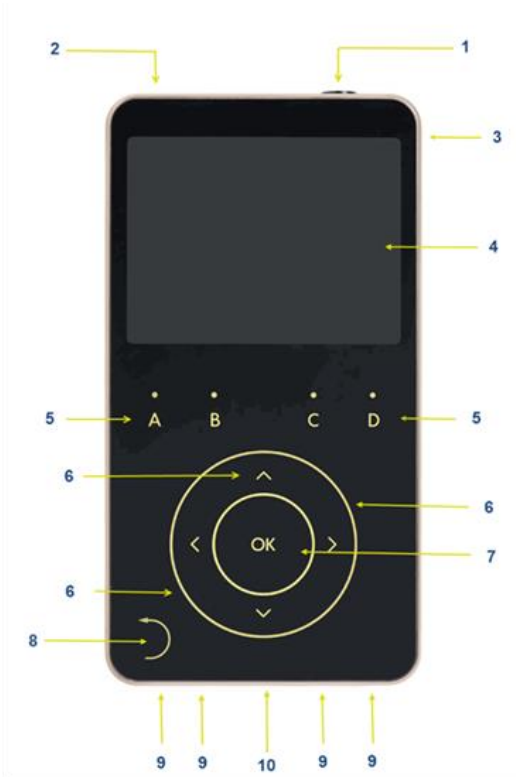
Do not leave the device charging for prolonged periods of time when it is not in use.

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

- Discard disposable accessories following your local waste management legislation and guidelines.
- Wipe the hand-held MyOnyx device, pressure sensor and cables with a damp cloth after each use. Do not clean the devices with alcohol or abrasive detergents.

- Clean the vaginal, rectal and pressure probes thoroughly with water and mild soap before the first use and immediately after each use.
- Never subject the probe to extreme temperatures or abrasive detergents. Contact the manufacturer for instructions to disinfect the probes. Do not sterilize.
- Wash and lather your hands with soap in flowing lukewarm water. Then liberally apply the same lather to the probe. Rinse all soap residue from the probe and your hands.
- Dry the probe with a clean cloth or paper towel. Allow it to completely air dry. Store it in a plastic bag at room temperature.
- The probes are designed for single patient use. Follow the manufacturer's instructions for determining the useful life of the vaginal and rectal probes. It is recommended to replace the pressure probe after six weeks of regular use.
- Store the devices in accordance with the recommended storage environmental conditions. See *Transport and Storage Environmental Conditions* on page 61.

Chapter 3 Device Controls



(1) On/Off Power button and Emergency Stop: Press and hold it for three seconds to turn the device on or off. Press and hold this button for less than one second to stop the current session.

(2) Daisy-chain Ports: Link multiple MyOnyx devices together through these ports.

(3) Power Adapter Port: Charge the device and / or use it with AC Power via this port.

(4) Screen: View current session or setting information on the screen.

(5) Channel Buttons: Adjust the amplitude of the physical channels by pressing the A, B, C, and D buttons above the dial.

(6) Main Dial and Arrows: Press the up/down/left/right arrows or “scroll” clockwise or counterclockwise on the circle to navigate to menu items or settings.

(7) OK: Select and save a setting, pause a session, or activate and resume a session by pressing **OK**.

(8) Back Button: When it is visible, press the Back button to return to the previous screen.

(9) Channel Ports: Connect the cables to the Physical Channel Ports on the bottom of the device.

(10) REF Port: Connect the patient drive to the REF port in the center of the channel ports.

Chapter 4 Basic Functionality

Handling the Device

It is recommended to use the device on a hard surface, such as a desk or a cart and not to touch it for longer than one minute as it may become hot to the touch.

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.

Stopping an ES session in standalone mode, ends the session, stops electrostimulation (ES), and ends recording.

Stopping a session in computerized or remote-control mode stops the Bluetooth connection and the recording.

Chapter 5 Setting Up the Device

Charging the Device



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.

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.



Channels A & B,
EMG/ Pressure/ ES /ETS
Channels 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** or **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 PD Cable

For EMG, and 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. Connect the other end of cable to an electrode.
5. 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.

Daisy Chaining Devices

To increase the number of channels available for ES, you can connect a maximum of four MyOnyx devices together in a daisy chain.

Note: The daisy chain can be used only for electrostimulation in standalone mode.

- Starting, pausing, or resuming a session on one device automatically starts, pauses or resumes the sessions on all devices in the chain simultaneously.
- You can run different programs on each device.

- Sessions end as defined by the program.
This can be different for each device.

To Run Programs in a Daisy Chain

Use a Daisy-Chain Cable (SA9006) to connect two devices together. Each device has two identical daisy-chain ports.

1. Insert one end of the daisy-chain cable into the Daisy-chain port of the first MyOnyx device.
2. Insert the other end of the cable into the Daisy-chain port of a second.
3. Repeat steps 1 and 2 for every MyOnyx device in the chain.
4. Select the program you want to run on each device.
5. Adjust the amplitude on each device.
6. Press **OK** on any MyOnyx in the chain.



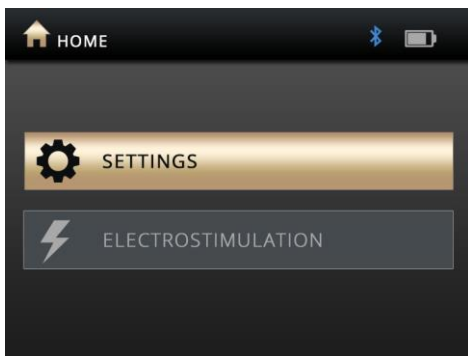
The daisy-chain icon is displayed on all devices and programs start on all devices simultaneously.

- If a cable disconnects on one device, the session pauses on all devices in the chain.
- If a critical error occurs on one device, the session stops on all devices.

Chapter 6 Adjusting the Settings

This chapter describes the MyOnyx screens and settings:

Home Screen



The Home screen appears when the device is booted up. It has two buttons for access to all settings and electrostimulation programs:

- Settings
- Electrostimulation

Status Bar



The status bar shows the following:

- **Current** screen: By icon and name
- **Status:** Bluetooth connection
- **Battery** Level

- **Recording:** A red dot is displayed when you are recording a session with the MyOnyx Mobile App.

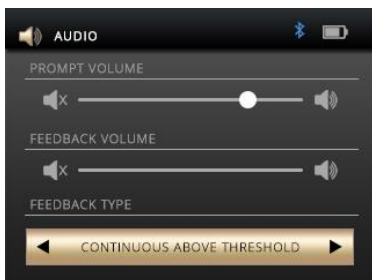
Adjusting the Audio

You can adjust the following settings and enable or disable audio prompts and feedback on the device as well as the app.

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

To adjust the audio on the device

1. Go to the **Home** screen.
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

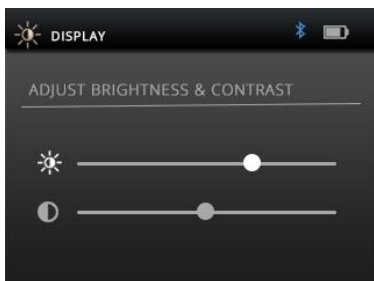
You can use either a proportional or single tone for the threshold notification.

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

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 to a PC via Bluetooth to update it or use it with BioGraph Infiniti or to a tablet to use it with the MyOnyx Mobile App.

Note: Bluetooth v 4.1 is required on the computer or tablet you are pairing with the MyOnyx.

In these procedures, PINs (or passcodes) are generated and displayed on both the MyOnyx

device and the PC or tablet. You must confirm that the PINs match.

Pairing the MyOnyx with a PC

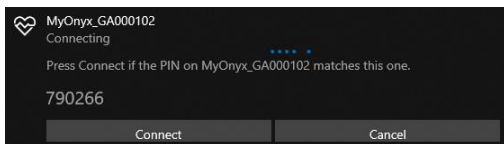
Note: This procedure describes the steps for Windows 10. Steps may vary slightly for other versions of Windows.

1. Turn on the MyOnyx device and the PC.
2. On the device, press **Settings > Bluetooth Pairing > OK**
3. Wait for a message to appear on the device stating it is now discoverable.
4. On the PC, select **Settings > Devices > Bluetooth** and turn on Bluetooth.

The Add a device screen appears on the PC listing all the Bluetooth devices that can be paired.

5. Select your MyOnyx device in the list.

PINs are displayed on both the MyOnyx device screen and the PC.



6. Make sure the two PINS are the same.
7. Press **OK** on the device.
8. Click **Connect** on the PC.

A message appears on the PC stating your device is ready to go.

9. Click **Done** on the PC.

A message appears on the MyOnyx device stating the device paired successfully. Then the Home screen appears.

Pairing the MyOnyx with a Tablet

Note: The procedure is slightly different on each tablet.

To pair the MyOnyx with a Tablet

1. Turn on the MyOnyx device and the tablet.
2. Press **Settings** > **Bluetooth Pairing** > **OK** on the device.
3. Wait for a message to appear on the device stating it is now discoverable.
4. Select **Settings** and turn on **Bluetooth** on the tablet

A list appears on the tablet with all the Bluetooth devices that can be paired.

5. Select your MyOnyx device in the list.

PINs are displayed on both the MyOnyx device screen and the PC.

6. Make sure the two PINS are the same.
7. Press **OK** on the device.
8. Click **Connect** on the tablet.
9. Click **Done** on the tablet.

A message appears on the MyOnyx stating the device paired successfully. Then the Home screen appears.

Troubleshooting Bluetooth Pairing

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

EXITING DISCOVERY MODE

Try pairing the device to the tablet again.

Recording Sessions

By default, the recording feature is disabled. Enable recording if you are performing biofeedback and ETS sessions with the app and would like to save these sessions for play back and review. It is helpful to record on the device in case you lose the Bluetooth connection during a session.

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

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

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

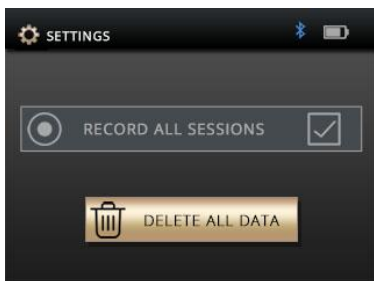
For further details on the recording feature, refer to the MyOnyx Mobile App Help.

Enabling Recording

When recording is enabled, the biofeedback and ETS sessions you run on the MyOnyx Mobile App 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. Select **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 asks you to confirm that you want to revert to the factory firmware and settings.

By default, **Cancel** is highlighted.

To cancel, press the **Back** arrow 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.

A new message appears on the MyOnyx showing the number of seconds before the

MyOnyx begins to revert back to the factory settings.

To cancel at this point, press the **Back** button.

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

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 turns off.

The device returns to normal mode if it detects any action including

- Pressing a button
- Charging the device
- Connecting or Disconnecting the power charger
- Receiving a command
- Uploading a session
- Updating the device
- Connecting or disconnecting Bluetooth

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 the product type and lists the unique IDs and the following information for troubleshooting, upgrading, and connecting your device.

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

Chapter 7 Running Sessions

Using the MyOnyx Device

You can use the MyOnyx autonomously for electrostimulation (ES).

You can pair it via Bluetooth to a PC running BioGraph® Infiniti or to a tablet running the MyOnyx Mobile App. Connect to the PC for running biofeedback sessions.

Connect to the tablet for use with all modalities, biofeedback, Electromyography (EMG), Electrostimulation (ES), and EMG-Triggered Stimulation (ETS).

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

| Channels | Modality |
|-----------------|-----------------|
| A and B | EMG, ES, or ETS |
| C and D | ES |

Running Biofeedback Sessions in Computerized Mode

Computerized Mode has the following features:

- Available with MyOnyx Extended only. See page 1.
- Requires a Bluetooth connection. See page 25.
- Manages the device from a computer using BioGraph Infiniti.

- Provides biofeedback and physiological data acquisition.
 - Does not support ES.
 - Records data on the computer.
-

Note: Before running a session in BioGraph Infiniti, you must register the MyOnyx in the software. Refer to the *BioGraph Infiniti Getting Started Guide*.

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.

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



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

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

Running Remote-Control Sessions

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

- Users can connect remotely to a tablet, running the MyOnyx Mobile App, from a MyOnyx device.
- Bluetooth is required.
- Biofeedback data are recorded on the tablet.
- Session data can be recorded and saved on the tablet.
- If the Bluetooth connection is lost, recording stops on the app but continues uninterrupted on the device.

Running Biofeedback Sessions in Remote-Control Mode

To run a biofeedback session in Remote-Control Mode

1. Connect the required cables to the device and place the electrodes on the client, as described on page 18.
2. Turn on the MyOnyx and your tablet.
3. Ensure that the two devices are paired. See page 25.
4. Make sure the Home page is displayed on the MyOnyx device.
5. Launch the MyOnyx Mobile App on the tablet.
6. Tap **Connect** on the status bar at the top of the app and select your MyOnyx device from the list.

The following screen appears on the MyOnyx device.



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

Running ES or ETS Sessions in Remote-Control Mode

You must perform the following on the device:

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

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

To run an ES or ETS session in Remote-Control Mode

Before running a session

- Make sure the MyOnyx and tablet are paired. See page 25.
- Set up the MyOnyx with the cables, electrodes, and/or other accessories required for the program you are running. See page 18.

1. Turn on both the MyOnyx and your tablet.
2. Go to the Home page on the MyOnyx device.
3. Launch the MyOnyx Mobile App.

The Connected to Device screen appears on the MyOnyx device.

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

The Amplitude Adjustment screen appears on the MyOnyx device.

5. On the device, press the letters above the dial corresponding to the channels you want to adjust. For example, press **A** and **B** to adjust channels A and B.
6. Adjust the amplitude using the wheel or up/down arrows.
 - Set and Live values are adjusted.
 - The electrostimulation is felt as you are setting it, so you can determine the appropriate level.
7. Once the amplitude is adjusted, wait three seconds.
 - The Set amplitude value is saved.
 - The Live amplitude returns to 0.
8. Press **OK** on the device or **Play** on the app.

Control the program from the app as described in the *MyOnyx Mobile 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 or 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.
- During sessions, you can use the device without connecting to a PC or tablet. However, a Bluetooth connection to a computer is required for updating the firmware.
- It can be used for ES only.
- It does not support EMG, ETS, or pressure biofeedback.
- Provides electrostimulation, sound, and visual biofeedback.
- ES sessions are run according to preconfigured programs, selected on the device. The program settings are defined under Predefined Electro-stimulation Programs on page 45.
- The clinician controls the Session Start, Pause, Resume, Stop, Emergency Stop, and adjust the amplitude.

Note: It is recommended to use the device on a hard surface such as a desk or a cart, and not to touch it for longer than one minute as it may become hot to the touch.

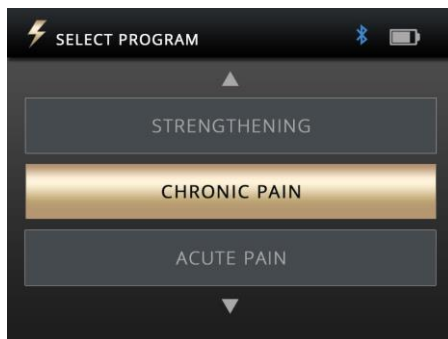
In an emergency, you can press the **On/Off** power button to stop the session completely.

To run an ES session in standalone mode

1. Turn on the MyOnyx.
 2. Connect the cables to the device and place the electrodes on the patient, following the instructions on page 18.
-

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 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.

- **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. Wait three seconds after adjusting the amplitude.
9. Press **OK** to start the session.



During the session, the following information is displayed:

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

Note: The session pauses automatically if a cable disconnects from an active channel on the device or contact between the electrodes or the probe and the patient is lost.

To pause a session manually, press the **OK** or **Back** button on the device.

To stop a session completely, press the **On/Off** button, or, If the session was paused, press the **Back** button again.

Single and Dual Program Modes

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

Single Program Mode



In single program 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 Program Mode



In dual program mode, 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 modality, delivery type, number of cycles, program duration, and the current session phase can be different for each program.

To run a session in dual program mode:

1. Configure the MyOnyx for the session.
2. Navigate to the Home screen.
3. Select **Electrostimulation**.
4. Press **OK**.
5. Select the pair of channels for the first program, A and B or C and D.

To do this, press one of the corresponding channel letters for the pair.

Tip: Press the right or left arrow to select a pair of channels.

The selected channels light up.

6. Navigate to a program and select it.
The second pair of channels lights up, A and B or C and D.
7. Navigate to and select the second program.
8. Adjust the amplitude.
9. Press **OK** to start the session.

The screen displays the session information for both programs, including the time remaining, session phase and progress, and the set and live amplitude.

Electrostimulation Delivery Types

The following ES delivery types are available:

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.

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.

Alternating

Alternating mode also delivers the stimulation in a work/ rest fashion. However, in this mode odd channels A and C alternate with even channels B and D. When odd channels are in a work

phase, even channels are in a rest phase, and vice versa

Notes on Alternating ES

The following conditions apply to Alternating electrostimulation delivery but not to Synchronous or Continuous.

- A cable must be connected to at least one-odd and one even channel in a group.
- The amplitude for at least one-odd channel in the group must be greater than zero.

Predefined ES Programs

Electrostimulation (ES) programs are defined by the following:

Modality: The modalities are NMES, TENS, and MET. See Electrostimulation (ES) Specifications on page 57.

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 or electrostimulation phase without variation
- **Burst** delivered at a rate of two bursts/second
- **Frequency Modulated:** Following a predefined pattern, the pulse rate (frequency) and pulse width increase and decrease. The amplitude may also decrease.
- **Freq. + Amp. Low:** The pulse width, pulse width, and amplitude decrease slightly, and then return to the set value.
- **Freq. + Amp. High:** The pulse width, pulse width, and amplitude decrease to a greater extent, then return to the set value.

Ramp Up / Down Time: Time it takes to reach maximum set value and time it takes to reach zero at the end of phase.

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 intensity high enough to induce motor contraction. The delivery type is synchronous, in work and rest phases. The pattern is continuous, delivered without variation throughout the work phase.

The following tables list the available programs and show the values for the work and rest

phases, ramp up and ramp down times, and the pulse width and rate.

Small Muscle Strengthening

Total Time: 1250 seconds. **Cycles:** 50

| Phases | | Ramp | | Pulse | |
|-----------|------|-----------|------|-------|------------|
| Work | Rest | Up | Down | Rate | Width |
| (Seconds) | | (Seconds) | | (Hz) | (μ s) |
| 10 | 15 | 3 | 1 | 50 | 150 |

Large Muscle Strengthening

Total Time: 1750 seconds. **Cycles:** 50

| Program | | Ramp | | Pulse | |
|-----------|------|-----------|------|-------|------------|
| Work | Rest | Up | Down | Rate | Width |
| (Seconds) | | (Seconds) | | (Hz) | (μ s) |
| 15 | 20 | 3 | 1 | 50 | 200 |

Circulation

Total Time: 300 seconds. **Cycles:** 60

| Program | | Ramp | | Pulse | |
|-----------|------|-----------|------|-------|------------|
| Work | Rest | Up | Down | Rate | Width |
| (Seconds) | | (Seconds) | | (Hz) | (μ s) |
| 3 | 2 | 0 | 0 | 5 | 200 |

Atrophy

Total Time: 1300 seconds. **Cycles:** 100

| Program | | Ramp | | Pulse | |
|-----------|------|-----------|------|-------|------------|
| Work | Rest | Up | Down | Rate | Width |
| (Seconds) | | (Seconds) | | (Hz) | (μ s) |
| 5 | 8 | 2 | 1 | 35 | 250 |

Endurance

Total Time: 1800 seconds. Cycles: 200

| Program | | Ramp | | Pulse | |
|-----------|------|-----------|------|-------|------------|
| Work | Rest | Up | Down | Rate | Width |
| (Seconds) | | (Seconds) | | (Hz) | (μ s) |
| 6 | 3 | 2 | 2 | 15 | 150 |

Stress Incontinence

Total Time: 1280 seconds. Cycles: 80

| Program | | Ramp | | Pulse | |
|-----------|------|-----------|------|-------|------------|
| Work | Rest | Up | Down | Rate | Width |
| (Seconds) | | (Seconds) | | (Hz) | (μ s) |
| 6 | 10 | 2 | 1 | 45 | 200 |

Urge Incontinence

Total Time: 1280 seconds. Cycles: 80

| Program | | Ramp | | Pulse | |
|-----------|------|-----------|------|-------|------------|
| Work | Rest | Up | Down | Rate | Width |
| (Seconds) | | (Seconds) | | (Hz) | (μ s) |
| 6 | 10 | 2 | 1 | 15 | 200 |

Transcutaneous Electrical Nerve Stimulation (TENS) Programs

Designed to treat acute or chronic pain, TENS is applied at either high frequency with an intensity too low to produce motor contraction or at low frequency with an intensity high enough to produce motor contraction.

The TENS programs are Chronic Pain and Acute Pain. The delivery type for both is

continuous. ES is delivered at the same rate with no rest phase.

For the chronic pain program, ES is delivered in a burst pattern at two bursts per second.

The pattern for the acute pain program is called frequency modulated. The pulse rate and width increase and decrease following a predefined pattern. The parameters for these programs are:

Acute Pain

Total Time: 1800 seconds. Cycles: 1

| Program | | Ramp | | Pulse | |
|-----------|------|-----------|------|-------|------------|
| Work | Rest | Up | Down | Rate | Width |
| (Seconds) | | (Seconds) | | (Hz) | (μ s) |
| 1800 | 0 | 0 | 0 | 100 | 150 |

Chronic Pain

Total Time: 1200 seconds. Cycles: 1

| Program | | Ramp | | Pulse | |
|-----------|------|-----------|------|-------|------------|
| Work | Rest | Up | Down | Rate | Width |
| (Seconds) | | (Seconds) | | (Hz) | (μ s) |
| 1200 | 0 | 0 | 0 | 100 | 200 |

Microcurrent Electrostimulation Therapy (MET) Program

Like TENS, MET is used for treating pain. However, it is applied at much lower intensities.

There is one MET program: Microcurrent. The delivery type is continuous. ES is delivered at the same amplitude throughout the program. The pattern is continuous. ES is delivered without variation throughout the work phase.

Microcurrent

Total Time: 900 seconds. Cycles: 1

| Program | | Ramp | | Pulse | |
|-----------|------|-----------|------|-------|------------|
| Work | Rest | Up | Down | Rate | Width |
| (Seconds) | | (Seconds) | | (Hz) | (μ s) |
| 900 | 0 | 0 | 0 | 0.5 | 500000 |

Chapter 8 Troubleshooting

The section lists the error messages and provides the recommended procedures. If after you follow the steps, a problem persists, contact technical support.

Battery Level

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

Below 50%

The device is fully operational, but to update the firmware, you must plug in the charger.

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%

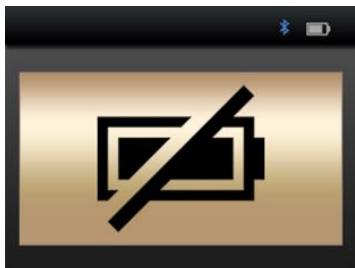


Below 5%, the device cannot be booted. If it is turned on, you have 15 seconds to connect it to a power adapter before it

The following message appears:

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

If you boot up the device without connecting the power adapter when the battery level is below 5%, the following screen appears.



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

Bluetooth

The MyOnyx can be paired with only three devices at a time.

If you are unable to connect to BioGraph Infiniti® or to the MyOnyx Mobile App via Bluetooth, try unpairing the MyOnyx from the PC or a tablet and pairing it again.

Error Messages

The following errors can be displayed:

Session Paused

The session pauses in the following situations:

- Electrodes **are not placed properly on the patient.**
- Electrodes disconnect from the cables.
- Cables **disconnect** from the device.
- Bluetooth connection is lost.

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

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 Condition on page 61.

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 specifications defined on page 61.
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 Home.

If the problem persists, contact technical support.

Appendix A Specifications

General Specifications

- **Weight:** Approx. 272 g
- **Device size:** Approx. L 155 mm x W 83 mm x D 20.95 mm
- **Wireless communication:** Bluetooth Class 1 v4.1 Low Energy and Classic
- **Screen:** LCD, 24-bit color, backlit
Resolution: W 320 pixels x L 240 pixels
Size: 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, 2 W
- **Internal Memory for data storage:** eMMC, 8 GB
- **Channels:**
 - 2 channels for EMG, pressure biofeedback, ES and/or ETS
 - 2 additional channels for ES only
- **Power Consumption:** 3.2 A @ 4.2 Vdc max.

EMG Specifications

- **Signal Processing:** 16-bit ADC, Bipolar
- **Output rates:** 2048 samples/sec (RAW), 20 samples/sec (RMS)
- **Signal Range and Bandwidth:**

±6250 μ V RAW, 12 Hz – 1600 Hz
(Hardware Filter, Notch filter at 50/60 Hz)

0 - 4420 μ V RMS, 20 Hz – 500 Hz (Band-Pass Filter)
- **Accuracy (error):** $\pm 3\%$ or $\pm 1 \mu$ V
- **Noise:** $< 1 \mu$ V rms
- **Input impedance:** $> 10 \text{ M}\Omega$
- **CMMR:** $\geq 100 \text{ dB}$

Pressure Biofeedback Specifications

- **Principle of operation:** Electronic pneumatic pump and sensor
- **Size, Weight:** 10 cm x 7 cm x 2 cm, 90g
- **Pressure range:** 0 - 200 mmHg
- **Sampling rate (RAW):** 2048 samples/sec
- **Output rates:** 2048 samples/sec (RAW), 20 samples/sec (decimated)
- **Nominal pressure (auto-set):** 55 mmHg $\pm 10\%$

- **Power** consumption:
140 mA @ 5 VDC (700 mW) when the pump is operating
- 50 mA @ 5 VDC (250 mW) when idle
- **Pressure Probe** (vaginal bulb/removable cover):

Size, Weight: 33 mm x 105 mm, 35 g

Material: Medical grade silicon

ES Specifications

- **Standard Electrostimulation (0 – 100 mA)**
- **Impedance range:** 250 Ω to 750 Ω . Above this, the maximum amplitude is limited.
- **Safety mechanisms: triggered** at 200 Ω and below and at 4000 Ω and above.

Note: ES specifications vary according to type (TENS, NMES, MET)

Transcutaneous Electrical Nerve Stimulation (TENS)

- **Channels:** 4 max (A, B, C, and D)
- **Waveform:** Rectangular, Bipolar, Biphasic, Symmetrical
- **Frequency Range:** 2 - 150 Hz
- **Pulse Width Range:** 50 - 250 μ s
- **Amplitude Range:** 0 - 100 mA^(*)
- **Pattern:** Continuous, Burst, Frequency Modulation, Low Frequency and Amplitude

Modulation, and High Frequency and Amplitude Modulation

- **Delivery:** Continuous
- **Ramp Up/Down Time:** 0 – 10 seconds with 0.1s increments
- **Program mode:** Single or dual

Microcurrent Electrostimulation Therapy (MET)

- **Channels:** 2 max (A, B, C, or D but only 2 channels simultaneously). In standalone, only Channels A & B can be used
- **Impedance range:** 1 k Ω to 20 k Ω is recommended for the full-scale stimulation range, 0 - 600 μ A.
- **Waveform:** Rectangular, Bipolar, Monophasic, Symmetrical, Polarity reversal
- **Frequency Range:** 0.5 Hz
- **Pulse Width Range:** 500 ms
- **Amplitude Range:** 0 - 600 μ A (*)
- **Pattern:** Continuous
- **Delivery:** Continuous
- **Ramp Up/Down Time:** None
- **Program Mode:** Single mode only

Neuromuscular Electrostimulation (NMES)

- **Channels:** A, B, C, and D
- **Waveform:** Rectangular, Bipolar, Biphasic, Symmetrical
- **Frequency Range:** 5 - 80 Hz
- **Pulse Width Range:** 150 - 400 μ s
- **Amplitude Range:** 0 - 100 mA (*)
- **Pattern:** Continuous
- **Delivery:** Synchronous or Alternating
- **Ramp Up/Down Time:** 0 – 10 seconds with 0.1s increments
- **Program Mode:** Single or dual

ETS Specifications

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

Note: ETS can be performed in computerized or remote-control mode only, not standalone.

- **EMG Channel:** A or B
- **Electrostimulation Channels:** A, B, C, D
- **Waveform:** Rectangular, Bipolar, Biphasic, Symmetrical
- **Frequency Range:** 5 - 80 Hz
- **Pulse Width Range:** 150 - 400 μ s
- **Amplitude Range:** 0 - 100 mA(*)

- **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:** 20 Hz with EMG RMS
- **Program Mode:** Single mode only

Notes on ES and ETS Specifications

- **Amplitude range:** For all types of electrostimulation, except MET, up to 100mA into 500 Ohm to 750 Ohms load – beyond 750 Ohms, the amplitude is limited. However, the amplitude displayed is accurate. The tolerance is $\pm 80\%$ for 0 – 1 mA, $\pm 60\%$ 1 – 4 mA, and $\pm 20\%$ for 4 – 100 mA.
- For MET, the tolerance is $\pm 20\%$
- **Frequency and pulse width deviation:** $< \pm 20\%$

Operating Environmental Conditions

- **Standard:** EN/IEC 60601-1
- **Temperature:** +5°C – +31°C
- **Maximum Temperature of Applied Parts:** 48°C
- **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
+70°C at relative humidity up to 93%, non-condensing
- **Atmospheric Pressure:** 700 hPa – 1060 hPa

Electrical 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, or

Internally powered equipment (when not connected to external power source)

- **Degree of Protection Against Electric Shock:** Type BF, not defibrillator proof
- **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, IEC 62133 Certified
- **Internal Battery Capacity:** 3200 mAh
- **Nominal Voltage:** 3.7 VDC
- **External Power Source:**
Medical Grade Universal Power Supply / AC Power Adapter
Model: GlobTek GTM96180-1507-2.0, UL/IEC 60601-1 Certified
Input Power: 100-240 VAC, 60/50 Hz
Output Power: 15 W (5 VDC, 3A)

Electromagnetic Compatibility

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

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.

Guidance and manufacturer's declaration – electromagnetic emissions

- **RF emissions CISPR 11 Group 1**
Compliant: The device uses RF energy for its internal function only. 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

- Immunity to electrostatic discharge (ESD) per IEC 61000-4-2
- IEC 60601 test level: ± 8 kV 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 following approved accessories only:

| | |
|-------------|---|
| SA9030 | MyOnyx Mobile App with the minimum requirements: Android tablet, at least 7 inches in landscape view Android version 7, 8, or 9 Bluetooth v 4.1 An internet connection is required for installing the app. A wireless internet connection or USB port is needed to access the Thought Technology website |
| SA7900 | BioGraph® Infiniti Software |
| SA9001 | 15W, 5V Multiplug Medical Grade Power Supply |
| SA9391 | EMG/STIM Cable (x 4) |
| SA9393-1500 | 1.5m DIN to SNAP Patient Drive Cable |
| SA9006 | Daisy-Chain Cable |
| SA9817 | DIN to SNAP Cable Adapter (Bag of 4) |
| SF01 | Disposable ECG Electrodes (Bag of 50) |
| 895220 | PALS® Neurostimulation Electrodes (2" x 2" / 5cm x 5cm) |
| PR-02A | Life-care Vaginal Probe |
| PR-13A | Life-care Anal Probe |
| SA9003 | Pressure Sensor |
| SA9011 | JP06A to JP06A Cable, 610mm |
| SA9005 | Vaginal Pressure Probe |

Appendix C Warranty, and Contact Information

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.

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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

Tel: 1 514 489 8251

Fax: 1 514 489 8255

In USA Toll Free

Tel: 1 800 361 3651

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, with your telephone or fax number and email.

In the USA,
ship insured to the following address:

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 the following:

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

The package must be marked:

“Broker: Livingston International – 133461”