ThoughtTech

MYONYX

USER GUIDE

For biofeedback with BioGraph® Infiniti version 6.7 or later
and for the treatment of urinary incotinence

Thought Technology Ltd.
5250 Ferrier, Suite 812,
Montréal, Quebec
H4P 1L3 Canada
+1 (514) 489-8251
mail@thoughttechnology.com

Product Name	MyOnyx System
Device Name	MyOnyx
REF	SA9020
Manual Number/ Revision	MyOnyx User Guide SA9028 Rev.9 (November 2024)

Labeling Symbols

Symbol	Title: Meaning	Standard (Reference)
	Refer to instruction manual/booklet – Follow instructions for use	ISO 7010 (M002)
	Consult operator's manual; operating instructions	ISO 7000 (1641)
	Caution: Caution is necessary when operating the device or control close to where the symbol is placed, or the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ISO 7000 (0434A)
	Type BF Applied Parts: To identify a type BF applied part complying with IEC 60601-1	IEC 60417 (5333)
RxOnly	Caution: US Federal law restricts this device to sale by or on the order of a licensed health-care practitioner.	21 CFR 801 (801.109)
	Device includes RF transmitter.	IEC 60417 (5140)
	Do not dispose with general household waste. Dispose according to local recycling initiatives or return to the manufacturer.	WEEE Directive
	Manufacturer	ISO 15223-1 (5.1.1)
	Date of Manufacture	ISO 15223-1 (5.1.3)
REF	Catalogue Number	ISO 15223-1 (5.1.6)
SN	Serial Number	ISO 15223-1 (5.1.7)

Table of Contents

Chapter I Overview

The MyOnyx System is a dedicated device designed for biofeedback and electrostimulation (ES) treatments for the treatment of incontinence, as a power muscle stimulator for training and rehabilitation, and for pain relief using TENS or microcurrent stimulation.

Connected to a PC via Bluetooth (computerized mode), the MyOnyx System can be used with the Rehab Suite of the BioGraph Infiniti software in biofeedback sessions.

Connected to an off-the-shelf tablet via Bluetooth (remote-control mode), the MyOnyx System can be used with the MyOnyx Mobile App in biofeedback, electrostimulation (ES), and EMG-Triggered Stimulation (ETS) sessions.

Product Configurations

Two device configurations are available:

- The basic configuration for use with the MyOnyx Mobile App. In this configuration the device calculates and records the root-mean-square (RMS) amplitude of the Electromyography (EMG) signal, which provides a simple method of interpreting muscle activation levels; and

- The extended configuration for use with the Rehab Suite of the BioGraph Infiniti software running on a PC. This configuration supports RAW EMG data recording and allows up to four devices to be connected to a single PC.

Your product type is displayed in the About screen on the device. To view it, select **Settings** > **About**.

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

These are the minimum requirements for installing the MyOnyx Mobile App.

1. Android tablet, at least 7 inches in landscape view
   Note: Version 9 has a built-in QR Code scanner
2. Android version 6 or above
3. Bluetooth v4.1 or later
4. An internet connection

To install the App on an Android device with version 9

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

To install the App on an Android device with version 7 or 8

For devices with version 7 or 8, you need a QR Code scanning app. If you don't have one already, download and install one from Google Play.

1. Turn on your QR Code scanning app.
2. Hover your device over the QR Code.
   A link to the MyOnyx Mobile App will appear in the browser of your device.
3. Wait for a link to Google Play to appear.
4. Tap **Google Play**.
   The MyOnyx Mobile App installation page appears.
5. Tap **Install**.

Chapter II Safety Information

This chapter contains the following sections:

Indications for Use

The MyOnyx System is intended for use as a powered muscle stimulation device for relaxation of muscle spasms and muscle re-education, prevention, or retardation of disuse atrophy, maintaining or increasing range of motion, increasing local blood circulation, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

The MyOnyx System is indicated for acute and ongoing treatment of stress, urge, or mixed urinary incontinence, where urinary control may be improved through electrical stimulation that strengthens the pelvic floor muscles or inhibits the detrusor muscle through reflexive mechanisms. The system also uses EMG-based or pressure-based biofeedback to help control and strengthen the pelvic floor muscles in the treatment of urinary incontinence.

The MyOnyx System may also be used for transcutaneous electrical nerve stimulation (TENS) and microcurrent electrical stimulation (MET) for the symptomatic relief of acute and chronic intractable pain.

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

Third Party Applications

Applications developed by third parties for use with the MyOnyx system may be subject to medical device regulations and must be classified separately by the developer.

For instructions, refer to the developer's documentation. Thought Technology is not responsible for any intended use other than the above listed.

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. The 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 arrhythmia.
- Do not use on a patient undergoing MRI, electrosurgery, or defibrillation.

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 training to be able to assess and monitor the effectiveness of treatment programs and be able to make necessary adjustments.

Warnings and Precautions

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

Warnings

- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.
- 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.
- It is recommended to use the MyOnyx device and Pressure Sensor on a hard surface such as a desk or a cart. Do not hold the MyOnyx device for longer than one minute as it may become hot to the touch.
- When using the Pressure Sensor, do not hold 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.
- Do not attempt to service or modify the device. It has no user-serviceable parts.
- Inspect devices and accessories prior to each use. If a device or accessory, including cables, 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, sensors and electrodes provided by Thought Technology only. Use of accessories 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.
- 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 or accessories with alcohol or abrasive detergents. Follow manufacturer instructions to clean 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 (Uni-Gel™) electrodes are for single-use only. Do not re-use. Handle and dispose of them immediately after use in accordance with accepted clinical practice, applicable laws, and regulations for biohazardous waste.
- Only use electrostimulation electrodes for ES or ETS, not EMG electrodes. Using the wrong electrodes may cause discomfort, skin irritation, or burns if prolonged.
- 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.

- Electrode placement and stimulation settings should be based on the guidance of the prescribing medical practitioner. 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.

- 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, as appropriate, a urological 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. ESD 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.

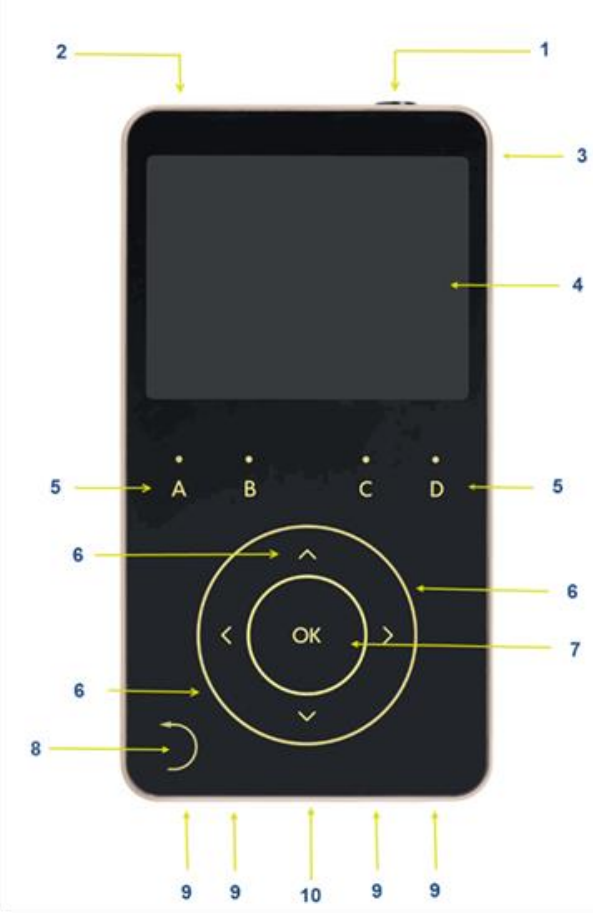
Maintenance and Care

- 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.

- Discard the device and 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 first use and immediately after each use.
- Never subject the probe to extreme temperatures or abrasive detergents. Do not sterilize.
- Wash and lather your hands with soap in flowing lukewarm water and 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 and store it in a plastic bag. Store at room temperature.
- The vaginal, rectal and pressure probes are designed for single patient use only. Follow manufacturer 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**.
- When not in use, store the devices in accordance with the recommended storage environmental conditions. See Transport and Storage Environmental Conditions.

Chapter III Overview of Device Controls



1- On/Off: Power button. Press and hold it for three seconds to turn the device on or off.

Emergency Stop (1): Press and hold this button for less than one second to stop the current session.

2- Daisy-chain Port: Reserved use (to link multiple MyOnyx devices together).

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 counter clockwise 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 IV Basic Functionality

This chapter contains the following sections:

Handling the Device

It is recommended to use the device on a hard surface, such as a desk or a cart, and not to hold 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

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 MyOnyx 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 device.

Chapter V Setting Up the Device

This chapter describes the following sections:

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.

Connecting Electrodes and Probes

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

Note: Do not use EMG electrodes for electrical stimulation. Use only the specified probes/electrodes for electrostimulation (ES) or EMG-Triggered Stimulation (ETS). Using the wrong electrodes for ES or ETS 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 Biofeedback/ Pressure Biofeedback/ 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 the **electrodes** are not touching each other.
- If you are using the **vaginal / rectal probe**, connect the two pins of the MyOnyx EMG/STIM cable to the cable receptors of the probe. Then, ask the patient to insert the probe as indicated.

Connecting the Patient Drive (PD) Cable

For EMG biofeedback 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.

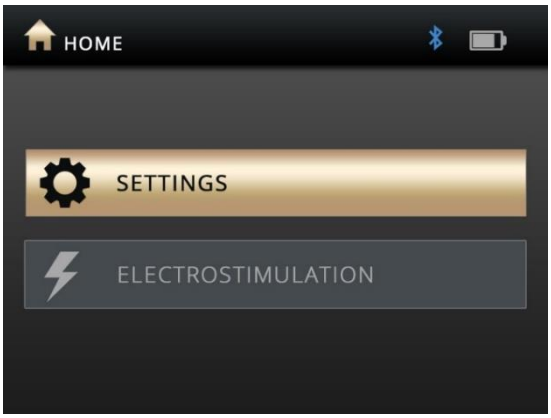
2. Connect the snap connection on the other end of cable to an EMG Uni-Gel electrode.
3. Peel the backing from the Uni-Gel electrode.
4. Connect the other end of cable to an electrode.
5. Peel the backing from the electrode.
6. Place it on a bony area, such as the patient's elbow, knee, ankle, or shoulder.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

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

Chapter VI Adjusting the Settings

This chapter describes the following:

Home Screen



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

- Settings
- Electrostimulation

Status Bar

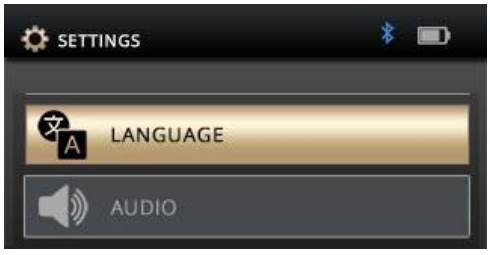
The status bar along the top of the screen shows the following:

- **Current screen:** By icon and name
- **Status**: Bluetooth connection
- **Battery Level**: By icon
- **Recording**: A red dot is displayed when you are recording a session with the MyOnyx Mobile App.

Changing the Display Language

You can change the display language of the MyOnyx device to any of the supported languages. To do this:

1. Go to the **Home** screen.
2. Press **Settings**.



The Language setting is at the top of the list.

3. Press **Language**.

The supported languages are displayed.

4. Scroll through the list using the arrows or scroll wheel.

- For English, select **ENGLISH**.
- For French, select **FRANÇAIS**.
- For Spanish, select **ESPAÑOL**.
- For Polish, select **POLSKI**.
- For Italian, select **ITALIANO**.
- For Japanese, select **日本語**.
- For Chinese, select **中文**.
- For German, select **DEUTSCH**.

5. Press **OK** when the language you want to use is highlighted**.**

6. Press the **Back** button to return to the Home screen and view the settings and electrostimulation programs in the selected language.

   Note: This setting changes the displayed language on the device only. It does not change the language of the computer app or mobile app you're connected to.

Adjusting the Audio

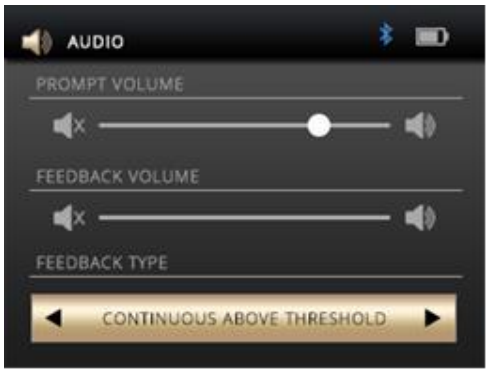
You can enable or disable audio prompts and feedback on the MyOnyx and adjust the following settings:

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

Note: You can control the audio from the MyOnyx Mobile 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

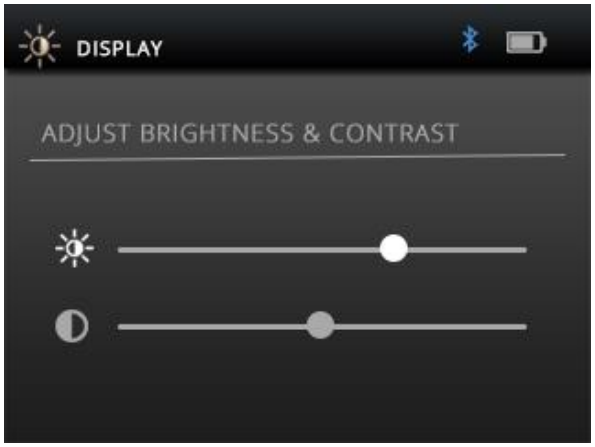
You can use either a proportional or single tone for the threshold notification.

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

To update the MyOnyx device, or to use it with BioGraph Infiniti, you must connect it to a PC via Bluetooth. To use the device with the MyOnyx Mobile App, you must pair the device with a tablet.

Note: Bluetooth v4.1 must be available on the computer or tablet you are pairing with the MyOnyx. The MyOnyx device must remain within 5m line-of-sight from the computer or tablet to maintain a functional connection.

Pairing the MyOnyx with a PC

To pair the MyOnyx device with a PC, you must enable settings on both the device and the PC. 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. You must confirm that the PINs match.

The following procedure is for Windows 10. It is slightly different if you have a different version of Windows.

To pair the MyOnyx with a PC

1. Turn on the device and the PC.
2. On the device, press **Settings** > **Bluetooth Pairing** > **OK**.

   The following message appears on the device.

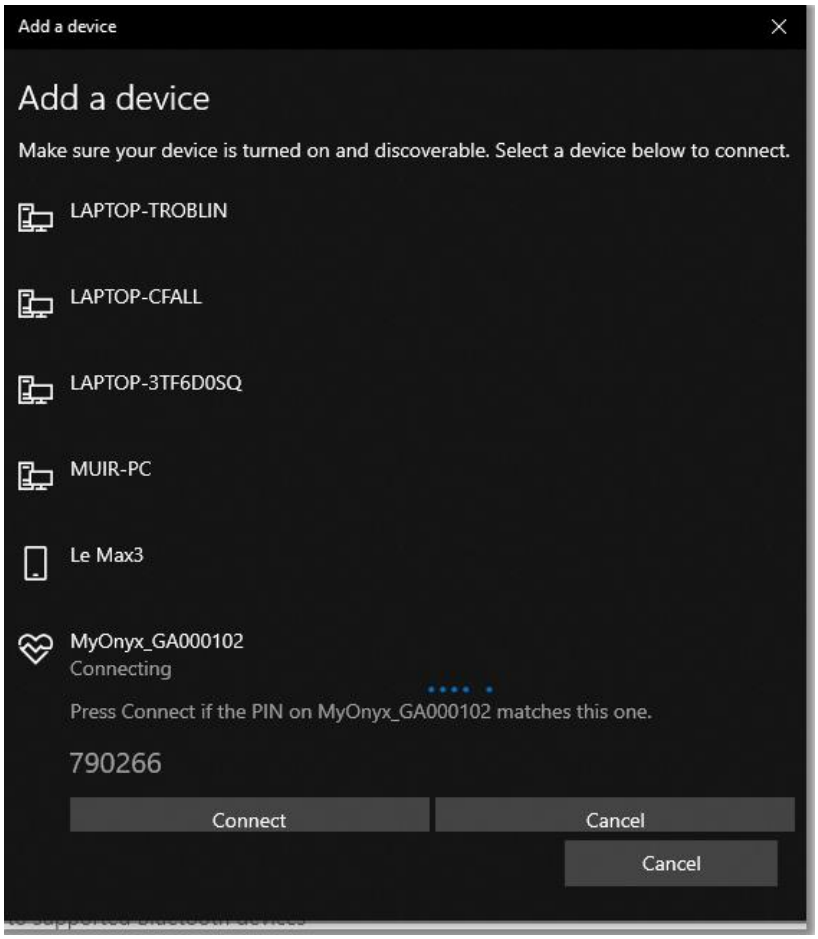
   DEVICE IS NOW DISCOVERABLE

   BLUETOOTH NAME: (with the name of the device)

   ---

3. On the PC, select **Settings** > **Devices** > **Bluetooth**.
4. Turn on Bluetooth.

   The Add a device screen appears on the PC or tablet with a list of 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.

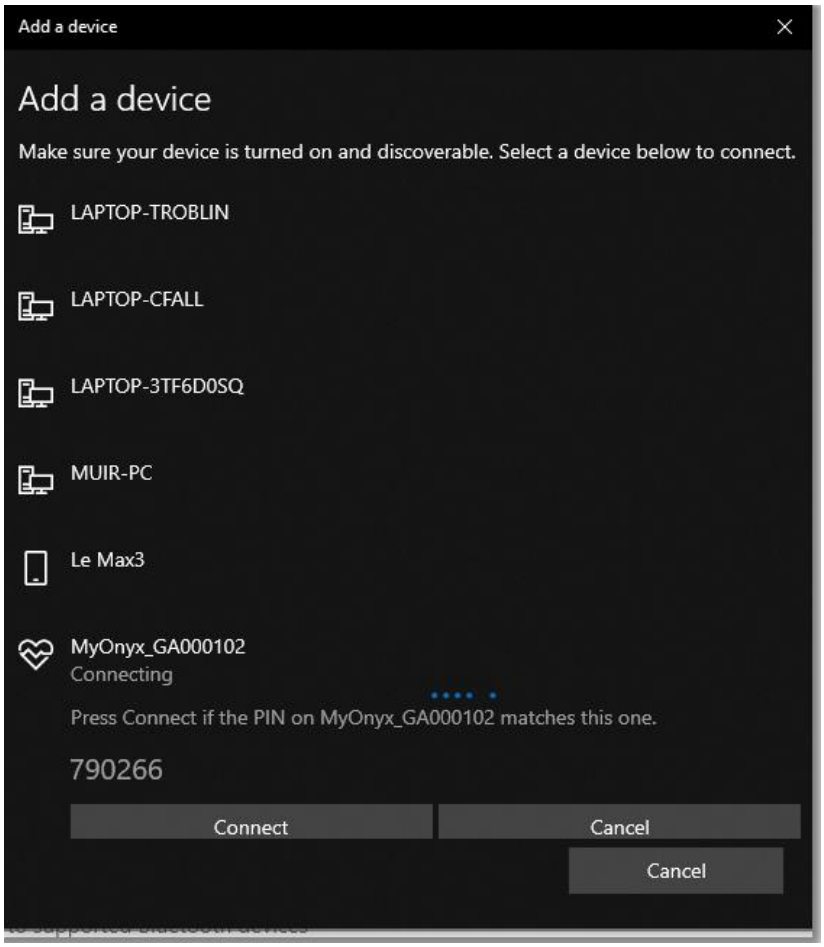
PRESS OK TO CONTINUE

   The same PIN is displayed on the PC.

6. Ensure that the two PINS are the same.

7. Press **OK** on the device and click **Connect** on the PC.

   The following message appears on the PC or tablet.



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

   The following message appears briefly on the MyOnyx device:

   DEVICE PAIRED SUCCESSFULLY! EXITING…

   Then, the Home screen is displayed on the device when the procedure is complete.

Pairing the MyOnyx with a Tablet

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

The procedure is slightly different on each tablet but is close to the following:

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.

   The following message appears on the device.

   ENABLING DISCOVERY MODE

   DEVICE IS NOW DISCOVERABLE

3. Select **Settings** and turn on **Bluetooth** on the tablet.

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

4. 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 tablet, the same PIN is displayed if the procedure is successful.

5. Ensure that the two PINS are the same.

6. Press **OK** on the device and click **Connect** on the tablet.

   The following message appears on the tablet.

7. Click **Done** on the 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 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 you would like to save these sessions for playback and review in the App. It is helpful to record on the device in case you lose the Bluetooth connection during a session. As well, you can later transfer biofeedback sessions to BioGraph Infiniti.

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 Infiniti.

You can record raw biofeedback data at a sampling rate of 2048 Hz for transfer to BioGraph Infiniti and at 20 Hz for playback on the App.

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

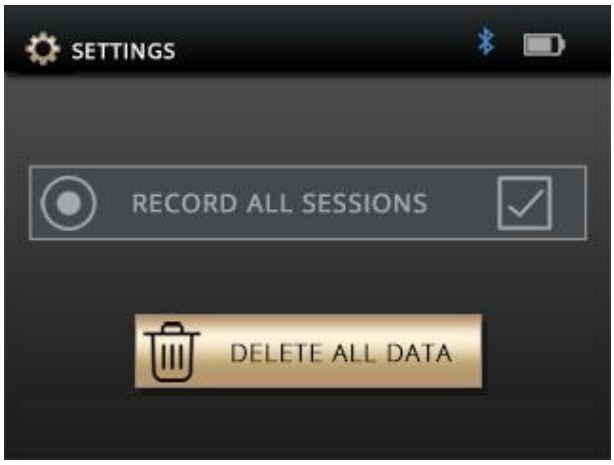
For further details on the recording feature, refer to the MyOnyx Mobile App Help.

Enabling Recording

When recording is enabled, and you are connected to the MyOnyx Mobile App, 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:

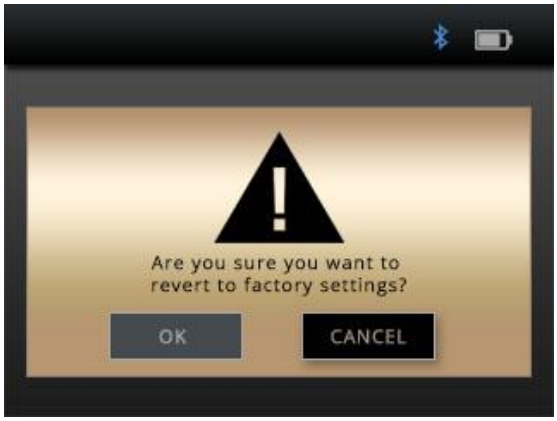
1. Select **Settings** > **Recording.**
2. Press **OK**.
3. Select **Delete all data**.
   A confirmation message appears.
4. Press **OK**.
   A second message appears confirming all data are deleted.

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 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.

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 shuts off.

The device wakes if it detects an activity, 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 information for troubleshooting, upgrading, and connecting the device. You may be asked for this information when you are upgrading the device or if you talk with the technical support team at Thought Technology Ltd.

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

The following information is displayed:

About

- **Product Number**: The part number assigned to the product.
- **Serial Number**: The unique ID number assigned to your device.
- **Product Type**: Basic or Extended

- **Hardware Configuration**: The number of channels.
- **Firmware Part Number**: The part number assigned to the firmware.
- **Main Firmware Version**: The version of the main firmware.
- **STIM Firmware Version**: A separate version number assigned to the STIM firmware.
- **Hardware Version**: A separate version number for the hardware.
- **Protocol Version**: The version number assigned to the communication protocol.

Chapter VII Running Sessions

This chapter describes the following:

Using the MyOnyx Device

You can use the MyOnyx device 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 the MyOnyx device to a tablet for EMG biofeedback, pressure biofeedback, electrostimulation (ES), and EMG-Triggered Stimulation (ETS).

Connect to the PC for running biofeedback sessions.

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

Channels	**Modality**
A and B	Pressure Biofeedback, EMG Biofeedback, or EMG-Triggered Stimulation (ETS)
C and D	Electrostimulation (ES)

Running Sessions in Computerized Mode

Note: Refer to the *BioGraph Infiniti Getting Started Guide* for instructions on using the BioGraph® Infiniti software package for running exclusively biofeedback sessions that require raw EMG data.

You can connect the MyOnyx device to BioGraph® Infiniti to run EMG biofeedback sessions in computerized mode. This mode:

- Is available with the MyOnyx Extended configuration only. See page 11.
- Requires a Bluetooth connection. See page 19.

- Manages the device from a computer using BioGraph Infiniti.
- Provides EMG biofeedback and raw EMG data acquisition.
- Records EMG data on the computer.
- Does not support electrical stimulation (ES)**.**

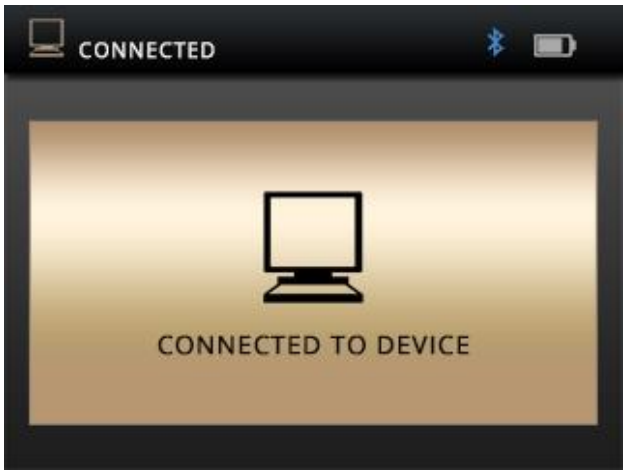
Running a Session with BioGraph Infiniti

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 Infiniti 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 Infiniti.

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 Infiniti.

Running Sessions in Remote-Control Mode

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

- Users can connect remotely the MyOnyx device to a tablet running the MyOnyx Mobile App.
- Bluetooth is required.
- Biofeedback data are displayed in real time and recorded along with session data on the tablet for future review and documentation purposes.
- If the Bluetooth connection is lost, recording stops on the App but it 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 14.
2. Turn on the MyOnyx and your tablet.
3. Ensure that the two devices are paired. See page 19.
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* manual.

Running ES or ETS Sessions in Remote-Control Mode

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

- Turning the device on and off

- Selecting a predefined program
- Adjusting the amplitude
- Starting a session
- Stopping a session

Note: You can run two programs at the same time using Dual Program Mode. Refer to the "Programs" section of the MyOnyx Mobile App Help for instructions on creating, modifying, and transferring (loading) ES & ETS programs onto the device.

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

1. Set up the MyOnyx with the cables, electrodes, and/or other accessories required for the program you are running. See page 14.
2. Turn on both the MyOnyx and your tablet.
3. Ensure that the two devices are paired. See page 19.
4. Go to the Home page on the MyOnyx device.
5. Launch the MyOnyx Mobile App.

   The Connected to Device screen appears on the MyOnyx device.
6. Select the program you want to run on the App.

   The Amplitude Adjustment screen appears on the MyOnyx device.
7. 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.
8. Adjust the amplitude using the wheel or up/down arrows.
   - 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, wait three seconds.
    - The Set amplitude value is saved.
    - The Live amplitude value returns to zero (0).
10. To start the session, press **OK** on the device or **Play** on the App.
11. 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 in the following conditions:

- 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

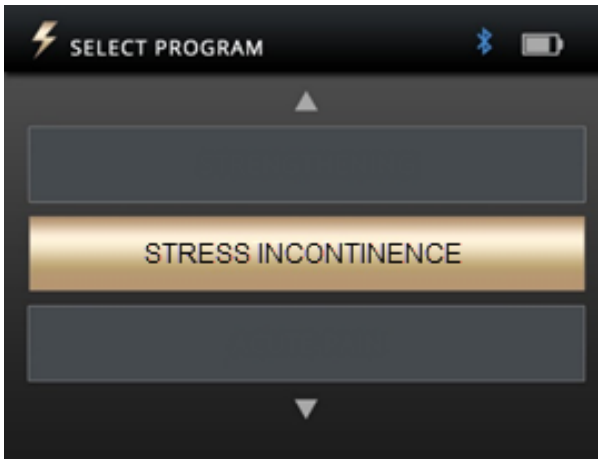
- Standalone mode is available on both the Basic and Extended configurations.
- During sessions, you can use the device without connecting to a PC or tablet. However, a Bluetooth connection to a computer is required for updating the firmware.
- It can be used for ES only.
- It does not support ETS, EMG biofeedback, or pressure biofeedback.
- Provides electrostimulation, sound, and visual biofeedback.
- ES sessions are run according to preconfigured programs, which can be selected on the device. The settings for these programs are defined under Predefined Electrostimulation Programs on page 39.
- The clinician controls the Session Start, Pause, Resume, Stop, and Emergency Stop. The amplitude has to be adjusted on the MyOnyx as well.

Note: It is recommended to use the device on a hard surface such as a desk or a cart, and not to hold 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 14.
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.



Note: Refer to the "Programs" section of the MyOnyx Mobile App Help for instructions on creating, modifying, and transferring (loading) ES programs onto the device.

---

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.

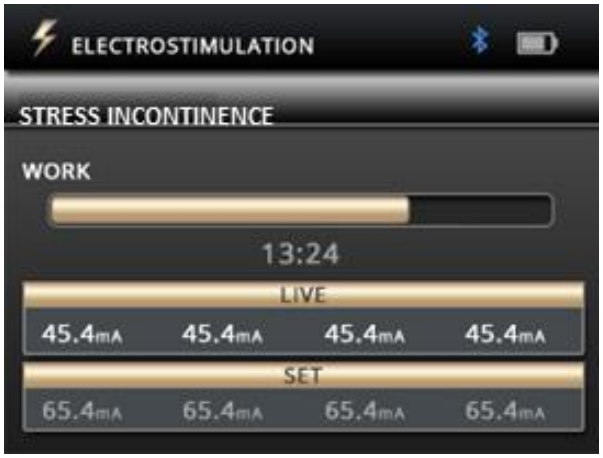
   Both the Set and Live amplitude values are adjusted.

   - 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. 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 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.

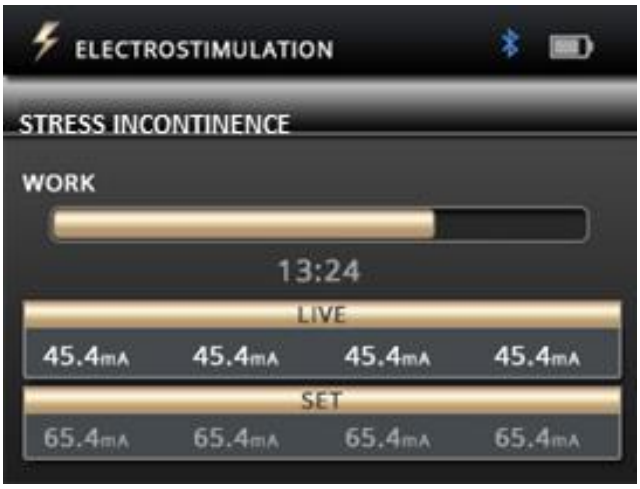
To pause a session manually, press the **OK** or **Back** button on the device.

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 two programs can have the following differences, the modality, delivery type, number of cycles, program duration, and the current session phase.

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 the second program and select it.
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 Electrostimulation (ES) Programs

ES programs are defined by

Modality: The modalities are NMES, TENS, and microcurrent electrostimulation (MET). See Electrostimulation (ES) Specifications on page 49.

Delivery Type: For the predefined ES programs, the delivery type is:

- **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 rate, and amplitude decrease slightly, and then return to the set value.
- **Freq. + Amp. High**: The pulse width, pulse rate, 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 modulation is continuous, delivered without variation throughout the work phase.

The following table lists the available programs:

Program Name	Time (min and sec)	Cycles	STIM phase (sec)	Rest phase (sec)	Delivery	Modulation	Ramp -up (sec)	Ramp-down (sec)	Pulse Rate (Hz)	Pulse Width (µs}
Atrophy	21:40	100	5	8	Synch	Continuous	2	1	35	250
Circulation	5:00	60	3	2	Synch	Continuous	0	0	5	200
Endurance	30:00	200	6	3	Synch	Continuous	2	2	15	150
Strengthening Large muscle	29:10	50	15	20	Synch	Continuous	3	1	50	200
Strengthening Small muscle	20:50	50	10	15	Synch	Continuous	3	1	50	150
Stress Incontinence	21:20	80	6	10	Synch	Continuous	2	1	45	200
Urge Incontinence	21:20	80	6	10	Synch	Continuous	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 at two bursts per second. The modulation 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 shown in the following table:

Program	Total Time (sec)	Cycles	STIM time (sec)	Delivery	Modulation	Rest time (sec)	Ramp-up (sec)	Ramp-down (sec)	Pulse Rate (Hz)	Pulse Width (µs)
Acute Pain	1800	1	1800	Continuous	Modulated	0	0	0	100	150

Program	Total Time (sec)	Cycles	STIM time (sec)	Delivery	Modulation	Rest time (sec)	Ramp-up (sec)	Ramp-down (sec)	Pulse Rate (Hz)	Pulse Width (µs)
Chronic Pain	1200	1	1200	Continuous	Burst	0	0	0	100	200

Microcurrent Electrostimulation (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 modulation is continuous. ES is delivered without variation throughout the work phase.

The parameters for this program are listed in the following table:

Program	Total Time (sec)	Reps	Delivery	Modulation	STIM time (sec)	Rest time (sec)	Ramp-up (sec)	Ramp-down (sec)	Pulse Rate (Hz)	Pulse Width (µs)
Microcurrent	900	1	Continuous	Continuous	900	0	0	0	0.5	500,000

EMG-Triggered Stimulation (ETS) Programs

A combination of EMG biofeedback and electrostimulation (ES) may be used as part of a sequenced treatment strategy to restore pelvic floor muscle function or in instances where the clinician determines that assisted contractions using ES and EMG biofeedback will improve clinical outcomes.

EMG-Triggered Stimulation (ETS) sessions may therefore be used to provide the patient with EMG biofeedback during a session. The modulation is continuous, delivered without variation throughout the STIM period of the work phase.

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

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.

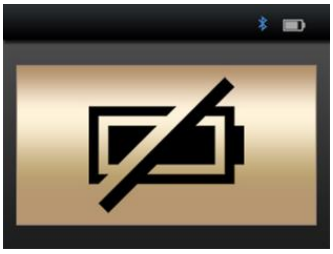
Below 5%

	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 at a time, including the PC used for updates and all tablets.

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
- 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 instructions on the device. 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** 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** 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 51.

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 51.
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

- **Weight:** Approx. 272 g
- **Device size**: Approx. L 155 mm x W 83 mm x D 20.95 mm
- **Wireless communication**: Bluetooth® v4.1, Class 1 radio
  Max throughput: 1.5Mbps data, 128-bit encryption security
  Nominal functional range (Indoors): up to 5m Line-of-Sight
- **Screen**: LCD, 24-bit color, backlighted
  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:**

  Two channels for EMG, pressure biofeedback, ES and/or ETS

  Two 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 µV RAW, 12 Hz – 1600 Hz (Hardware Filter, Notch filter at 50/60 Hz)

  0 - 4420 µVRMS, 20 Hz – 500 Hz (Band-Pass Filter)
- **Accuracy (error)**: ±3% or ±1 µV
- **Noise**: < 1 µVrms
- **Input impedance:** > 10 MΩ
- **CMMR**: ≥ 100 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 ± 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, or 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 µs
- **Amplitude Range**: 0 - 100 mA(*)
- **Modulation**: 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 (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 kΩ to 20 kΩ is recommended for the full-scale stimulation range, 0 - 600µA.
- **Waveform**: Rectangular, Bipolar, Monophasic, Symmetrical, Polarity reversal
- **Frequency Range**: 0.5 Hz
- **Pulse Width Range**: 500 ms
- **Amplitude Range**: 0 - 600 µA (*)
- **Modulation**: 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 µs
- **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

(*) See Notes on ES and ETS Specifications, page 51

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-control mode. It cannot be performed in standalone mode.

- **EMG Channel**: A or B
- **Electrostimulation Channels**: A, B, C, or D
- **Waveform**: Rectangular, Bipolar, Biphasic, Symmetrical
- **Frequency Range**: 5 - 80 Hz
- **Pulse Width Range**: 150 - 400 µs
- **Amplitude Range**: 0 - 100 mA(*)
- **Pattern**: Continuous
- **Delivery**: Continuous
- **Electrostimulation/Rest Duration**: 1 - 7,200 seconds (1 second increase)
- **Rest Duration**: 1 - 7,200 seconds (two hours), (1 second increase)
- **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**: 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 ± 80% for 0 – 1 mA, ± 60% 1 – 4 mA, and ± 20% for 4 – 100 mA.

  For MET, the tolerance is ± 20%

- **Frequency and pulse width deviation:** < ± 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

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 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 MyOnyx System with the following approved accessories only:

SA9030	MyOnyx Mobile App
SA7900	BioGraph® Infiniti Software
SA9001	15W, 5V Multiplug Medical Grade Power Supply
SA9376	EMG/STIM Cable, 1.8m (x 4)
SA9393-1800	1.5m DIN to SNAP Patient Drive Cable
SA9817	DIN to SNAP Cable Adapter (Bag of 4)
T3425	Electrodes 100 Uni-Gel™ Single
895220	PALS® Neurostimulation Electrodes (2” x 2” / 5cm x 5cm)
SA9571CAN	Anal Stim Probe
SA9572CAN	Vaginal Stim Sensor
SA9003	Pressure Sensor
SA9011	JP06A to JP06A Cable, 610 mm
SA9005	Vaginal Pressure Probe

Appendix C Copyright, Warranty, and Contact Information

This appendix includes the

- Hardware Copyright Notice
- Warranty
- Optional Extended Warranty
- Contact Information
- Information on returning equipment for repair

Hardware Copyright Notice

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 Fax: 1 514 489 8255	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, and your telephone/fax number and email (see form on the next page of this manual).

In the USA, ship insured to:	**In Canada and all other countries**, contact your dealer or ship insured to:
Thought Technology Ltd. Cimetra LLC 8396 State Route 9 West Chazy, New York 12992, USA	Thought **Technology** Ltd. 5250 Ferrier, Suite 812 Montreal, Quebec H4P 1L3 Canada

The package must be marked: **"Broker: Livingston** International **– 133461"**