ThoughtTech

# MYONYX


# HARDWARE MANUAL

For use with BioGraph® Infiniti version 6.7 or later

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

| | |
|---|---|
| Product Name | MyOnyx System |
| Device Name | MyOnyx |
| REF | SA9000 |
| Manual | SA9007 (October 2019) |

# Labeling Symbols

Refer to the instruction manual.

Caution. Consult accompanying documents

Type BF Applied Parts

RxOnly

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

Includes RF transmitter or applies RF electromagnetic energy for treatment.

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

Manufacturer

Date of manufacture

# Table of Contents


About the MyOnyx 1

Precautionary Information 1

An Overview of the Features 15

Using the Device 17

Configuring Sessions 18

Running Sesssions 20

Connecting to a PC or Tablet 25

Troubleshooting 27

Technical Specifications 29

Accessories 35

Hardware Copyright Notice 36

# About the MyOnyx

The MyOnyx is a dedicated hand-held device designed for biofeedback and rehabilitation treatments. It can be used as a standalone device. It can also be paired via Bluetooth to a PC and used with BioGraph® Infiniti or to a tablet and used with the MyOnyx app.

# About this Manual

The *MyOnyx Hardware Manual* describes how to use the MyOnyx device safely. Further details on using the device are provided in the *MyOnyx Reference Manua*l. Information on using the specific apps and software is provided in the *MyOnyx App Help*, the *MyOnyx Rehab Suite* guide, and the BioGraph Infiniti® Help.

# Precautionary Information

Read all warnings, precautions, and instructions carefully before use.

## Warnings

- Do not attempt to service or modify the device. It has no user-serviceable parts.
- If it appears damaged, do not use it. Contact Technical Support at Thought Technology Ltd. or your local authorized distributor for a replacement.
- Do not allow contact with water.
- Do not use it in the presence of a flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.
- Always transport, store, and use the device within the specified temperature and humidity ranges only. Otherwise, it might not meet the performance specifications.
- When delivering electrostimulation (ES), place the MyOnyx on a hard surface, such as a desk or a cart, and do not touch it for longer than one minute.

- It is isolated from line (110 or 220VAC) power due to battery operation or use of the Class 2 power adapter. However, many hospitals and the FDA require that computers, printers, and other equipment used with medical devices be electrically isolated from line voltage to UL or CSA medical safety standards.
- Use only the power adapter/charger provided with the device by Thought Technology Ltd.
- Ensure that the PC used with the device is placed outside the patient/client environment (more than 10 feet or 3 meters) or that the PC complies with EN60601 1 (system safety).
- Use cables and electrodes provided by Thought Technology only.
- Using accessories, transducers, or cables not specified or provided by Thought Technology could result in increased

electromagnetic emissions or decreased electromagnetic immunity of this equipment and in improper operation.

- Only use ES electrodes for ES or ETS, not EMG electrodes. Using the wrong electrodes may cause discomfort, skin irritation, and burns if prolonged.
- Be attentive to patient sensation– prolonged noxious stimuli may cause skin irritation. Although this is generally not dangerous, it is not recommended.
- Stop using the MyOnyx immediately if the patient shows any sign of distress or discomfort.
- To diminish the risk of spreading communicable diseases, always use good hygiene practices with reusable electrodes, particularly if abrasive substances are used. In all cases, refer to your facility's infection control procedure.
- Vaginal and rectal probes are to be used

with the same patient only and cleaned before and after each use.

- EMG electrodes are all single use only.
- Electrostimulation electrodes are disposable but may be used more than once with the SAME 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. Always handle and, when applicable, dispose of these materials in accordance with accepted medical practice, as well as local, state, and federal laws and regulations.

## Precautions

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

- The device may be susceptible to electro-static discharges (ESD) and radiated radio frequency (RF) fields. Electrostatic discharge is common in conditions of low humidity. Discharge yourself by touching a grounded bare metal surface before touching the unit.
- Do not operate active sensors within 10 feet (3 meters) of powerful radio interference producing sources such as arc welders, radio thermal treatment equipment, X-ray machines, or any other equipment that produces electrical sparks.
- Operation close (e.g. 3.5 feet or 1 meter) to a shortwave or microwave therapy ME EQUIPMENT may produce instability in the STIMULATOR output.
- Do not expose to extreme weather.
- Bluetooth operation may be interrupted by the presence of interfering devices in the 2.4 GHz IsM band.

- To avoid the risk of electrical shock, inspect the AC power adapter / charger and AC power cord on a regular basis. If you detect damage or excessive heating, remove them 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 it is always accessible and can be disconnected easily from the wall outlet.

## Intended Purpose

- Biofeedback, relaxation, and muscle re-education
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increase in local blood circulation

- Stroke rehabilitation through muscle re-education

- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

- Maintaining or increasing range of motion

- Treatment of stress, urge, or mixed urinary incontinence, acute and ongoing, where the inhibition of the detrusor muscle, through reflexive mechanisms, may improve urinary control; assessing EMG activity of the pelvic floor and accessory muscles, such as abdominal or gluteal.

**Note**: The device is intended for use in a healthcare facility There are no risks associated with normal use. However, it is not designed or intended for diagnostic purposes or life support. It is not defibrillator-proof. It is not a substitute for proper medical advice. For any health concerns, consult a doctor.

## Adverse Reactions

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

- The long-term effects of chronic electrical stimulation are unknown.

## Contraindications

These contraindications must be followed.

- Avoid using this equipment adjacent to or stacked with other equipment as this could result in improper operation. If such use is necessary, all equipment must be observed to verify normal operation.

- Avoid using powered muscle stimulators on patients with cardiac-demand pacemakers, symptoms of bladder infection, or undiagnosed pain conditions.

- Avoid stimulation over
  - **Carotid sinus nerves**, particularly in patients with a known sensitivity to carotid sinus reflex.
  - **Neck or mouth**. Severe spasm of the laryngeal and pharyngeal muscles may occur. The contractions may be strong enough to close the airway or cause difficulty in breathing.
  - **Swollen, infected, or inflamed areas** or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
  - **Cancerous lesions**. Also avoid use in proximity to these lesions.
- Do not apply stimulation transcerebrally or transthoracically. The introduction of electrical current into the heart may cause cardiac arrhythmias.

- Do not use on a patient undergoing MRI, electrosurgery, or defibrillation or on women who are pregnant.

## Maintenance and Care

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

  To ensure safety, use only the charging adapter provided.

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

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

## Patient Population

**Age**: Infant to geriatric

**Weight**: Not relevant

**Health**: The following:

- Young women with urinary incontinence (UI) and pelvic organ prolapse (POP), sexual dysfunctions, and pelvic pain, the elderly with fecal/urinary incontinence, post-partum women, and males post prostatectomy.
- Infants and children < 5 years old with cerebral palsy (permanent movement disorders)
- People suffering from neurological injuries like Traumatic Brain Injury, stroke, or spinal cord injury, with lack of ability to adequately recruit or deactivate/shutoff their hypertonic muscles and/or with hemiparesis (weakness of one entire side of the body), and/or foot drop.
- People suffering from neurological deficits, chronic pain, musculoskeletal conditions and injuries, post operations and injuries.

- Contraindicated for pregnant women or patients with skin condition (in the area of the electrode placement), patients under treatment for cancer, or with pacemakers.

**Patient state**: Not relevant, unless the patient is agitated.

**Nationality**: Multiple

## Operator Profile

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

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

If you observe anomalies on acquired signals or suspect a problem with electromagnetic interference, contact Thought Technology for a

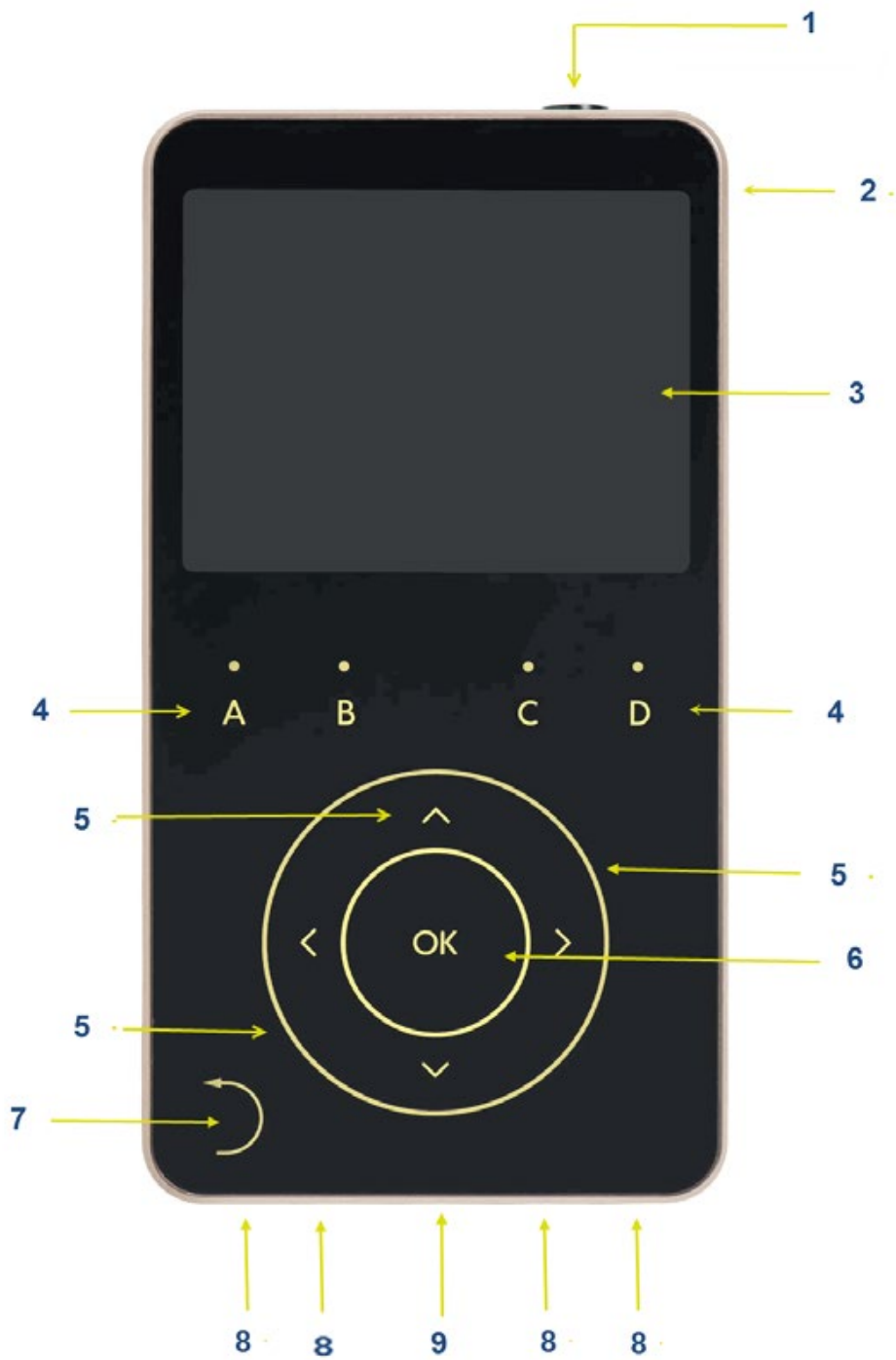
technical note on identification and remediation.

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

**Caution**


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

# An Overview of the Features



| | | |
|---|---|---|
| **1** | **On/Off** | On/Off, Emergency Stop |
| **2** | **Power Adapter Port** | To charge and use the device with AC power. |
| **3** | **Screen** | To show session and setting information. |
| **4** | **Channel Buttons** | A & B or A, B, C, & D buttons, above the dial, to adjust the amplitude of the physical channels. |
| **5** | **Main Dial and Arrows** | To navigate to programs and adjust settings. |
| **6** | **OK** | To save a setting |
| **7** | **Back** | To return the last screen. |

| | | |
|---|---|---|
| 8 | **Channel Ports** | Two or four physical channel ports on the bottom the device. |
| 9 | **REF Port** | To connect the patient drive. |

# Using the Device

## Turning the MyOnyx On and Off

**To Turn the Device On or off,** press and hold the power button for three seconds or more.

## Stopping an ES Session

To stop an electrostimulation (ES) session, press the **On/Off** button once for one second or less. You can do this in an emergency.

## Connecting Electrodes or Probes

1. Insert the cable into the required channel.


- **Channel A & B**: EMG, ES, and ETS
- **Channel C & D** ES

2. Ensure that it is securely in place.
3. Do one of the following to connect the cable to the electrodes:

- Connect the two pins on the other end of the cable to electrostimulation electrodes.
- Connect the two pins to the DIN-to-snap connector. Then, connect the "snap on" Uni-Gel electrodes.

4. Make sure the patient's skin is clean, shaved, if necessary, and abraded.

5. Peel the backing from the electrodes and place them on the patient.

- If you are using ES electrodes, make sure they 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.

For EMG or ETS sessions, be sure to connect the patient drive (PD) cable to the REF port of the MyOnyx device.


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

## Adjusting the Amplitude

Adjust the amplitude to deliver the right level of electrostimulation in ES and ETS sessions.

1. Ensure that all cables are inserted securely in the applicable channels.

2. Place the electrodes on the patient or ask the patient to insert the probe.

- Make sure the electrodes are not touching each other.

3. Press the buttons on the front of the MyOnyx for the channels you want to adjust. For example, press **A** and **B** to adjust channels A and B.

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

- Both **Set** and **Live** values are adjusted.

- The patient feels the electrostimulation as you are setting it. This helps determine the appropriate level.

5. Once the correct values are shown, deselect the channel(s) or wait three seconds.

- **The Set amplitude** value is saved.
- **The Live amplitude** value returns to 0.

6. Press **OK** to start the session.

---

**Note:** Session pause automatically if:

- 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, press **OK**.

- To **resume** a paused session, press **OK**. Then, press **Back** to go back to program selection screen.
- To stop a session, press the **On/Off** power button once.

## Running Sessions in Standalone Mode

- Electrostimulation only.
- Sessions are defined by preconfigured programs selected on the device.
- Updates and modifications to programs and settings are downloaded from a computer outside the session.

**Note**: When delivering ES, place the MyOnyx on a hard surface, such as a desk or a cart, and do not touch it for more than one minute.

1. Connect the cables and electrodes, following the instructions on page 18.

2. Turn on the MyOnyx.
3. Select **Electrostimulation** on the Home screen.
4. Navigate to your program and press **OK**.
5. Adjust the amplitude as described on page 20.
6. Press **OK** to start the session.

The screen shows

- Total remaining session time
- Current session work or rest phase
- Progression of the current phase
- The **Set amplitude** on and **Live amplitude** all active channels:

**Note**: The Live value can differ from the Set value due to various factors, such as ramp-up/ramp-down or amplitude modulation.

## Running Sessions in Dual STIM

To run two ES programs at the same time

1. Configure the MyOnyx for the session.
2. Navigate to the Home screen.
3. Select **Electrostimulation**.
4. Press the left arrow.

   Channels A and B light up.
5. Navigate to a program and select it.

   Channels C and D light up.
6. Navigate to the second program and select it.
7. Adjust the amplitude.
8. Press **OK** to start the session.

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

# Connecting to a PC or Tablet

The MyOnyx Extended can be paired to a PC and used with BioGraph Infiniti. Both versions, Extended and Basic can be paired to a tablet and used with the MyOnyx app.

---

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

---

## Pairing the MyOnyx to a PC or Tablet

1. Select **Settings** > **Devices** > **Bluetooth** on the PC or tablet.

2. Press **Settings** > **Bluetooth Pairing** > **OK** on the device to enable discovery mode.

3. On the PC or tablet, select **Add Bluetooth or other devices**.
   The Add a device screen appears.

4. Select **Bluetooth**.
   A list appears showing all Bluetooth devices that can be paired.

5. Select your MyOnyx device in the list.

6. When you see a PIN on the device, press **OK** to continue.
   A message appears on the PC or tablet asking you to confirm the PIN and click Connect.

7. Click **Connect** if the PINs match...

8. Click **Done** on the PC or tablet.
   A message appears briefly on the MyOnyx to inform you the pairing is successful.

## Computerized Mode: Direct Control with BioGraph Infiniti

For instructions on running a session in computerized mode, refer to the guide, *Getting Started with BioGraph Infiniti.*

## Remote Mode from the MyOnyx app

For details, refer to the *MyOnyx app Help*.

# Troubleshooting

## Battery Level

**Below 20%,** the battery icon is red.
**Below 10%,** a low battery message appears. ES sessions pause. They resume when the MyOnyx is connected to power
**Below 5%,** the critical battery message appears. The device shuts down in 15 seconds unless it is connected it to a power adapter.

## Session Paused

The session pauses in the following conditions:

- Electrodes disconnect from the cable.
- Electrodes are displaced on the patient
- The Bluetooth connection is lost.

Follow the on-screen instructions. If the problem persists, contact technical support.

## Session Stopped

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

Under normal use, the MyOnyx overheats only when recommended temperatures are exceeded. See the Safety Specifications on page 31

**If the overheating message** appears

1. Disconnect the charger if it is connected to the device.
2. Move the MyOnyx away from heat.
3. Let it cool for 5-10 minutes or until the heat dissipates.
4. Make sure your environment meets the specifications.
5. Press **OK** or **Back** to return to Home.
6. Restart your session.

**If the critical error message** appears

1. Write down the error code.
2. Contact technical support.

# Technical Specifications

- **Weight:** Approx. 272g
- **Device size**: Approx. L 155mm x W 83mm x D 20.95mm
- **Wireless communication**: Bluetooth Class 1 v4.1 Low Energy and Classic
- **Power Consumption**: 3.2A @ 4.2V max.

## Notes on ES and ETS Specifications

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

## Operating Environmental Conditions

- **Standard**: EN/IEC 60601-1
- **Temperature**: +5˚C – +31˚C
- **Maximum Temperature of Applied Parts**: 48°C
- No condition for safe contact.
- **Relative Humidity**: 10% – 93% (non-condensing)
- Atmospheric Pressure: 700 hPa – 1060 hPa

## Transport and Storage Environmental Conditions

- **Standard:** EN/IEC 60601-1
- **Store in its original case.**
- **Temperature and Relative Humidity:** -25˚C without relative humidity control

+60˚C at relative humidity up to 93%, non- condensing

- **Atmospheric Pressure**: 700 hPa – 1060 hPa

## Safety Specifications

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

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

## Electromagnetic Compatibility

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

## Guidance and manufacturer's declaration – electromagnetic emissions

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

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

- **Harmonic emissions IEC 61000-3-2**: The electromagnetic environment guidance is the same as for RF emissions CISPR 11 Class B Compliant.
- Voltage fluctuations flicker emissions IEC 61000-3-3: The electromagnetic environment guidance is the same as for RF emissions CISPR 11 Class B Compliant.

## Guidance and manufacturer's declaration – electromagnetic immunity

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

## Electromagnetic environment – guidance

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

## Accessories

Use the MyOnyx with the following approved accessories only:

- SA9391 EMG/STIM Cable (4 required)
- SA9393-1500 1.5m DIN to SNAP Patient Drive Cable
- SA9817 DIN to SNAP Cable Adapter (Bag of 4)
- SA9001 15W, 5V Multiplug Medical Grade Power Supply
- SA9811 AxelGaard Electrode 5x5cm Sq Model 895220 (Bag of 4)
- T3425 Electrodes 100 Uni-Gel Single

- SA9572 – SA9572CAN Vaginal STIM Sensor
- SA9571 – SA9571CAN Anal STIM Probe
- SA7900 BioGraph® Infiniti Software
- SA9013 MyOnyx Mobile App
- SA9014 MyOnyx Rehab Suite

## 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. It is protected by copyright law. Reverse engineering of the software or the resulting output data stream is prohibited.

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

client and remains the exclusive property of Thought Technology Ltd.

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



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 (RA) 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 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 caused by obvious mechanical mistreatment.

**Optional Extended Warranty**

Contact Thought Technology Ltd. for details.

## Contacting Thought Technology

**For orders or technical support**

E-mail: mail@thoughttechnology.com

**Outside USA**

Tel: 1-514-489-8251

Fax: 1-514-489-8255

**In USA Toll-Free**

Tel: 1-800-361-3651

Or contact your local authorized distributor.

For technical support, refer to the frequently asked questions section of our website at www.thoughttechnology.com. If your support issue is not covered e-mail or call us.

## Returning Equipment for Repair

Call for a Return Authorization (RA) number before returning any equipment! Send the unit(s) postage prepaid and insured, with a copy of the original invoice to applicable address, listed 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 incurred by sending the unit to the wrong address will be billed to you.

Provide a detailed description of the problem you are experiencing along with your name, company, address, phone and fax numbers, model name and serial number.

**In the USA**, ship insured to:
Thought Technology Ltd.
Cimetra LLC
8396 State Route 9
West Chazy, New York
12992, USA

**In Canada and all other countries**, contact your dealer or ship insured to:
Thought **Technology** Ltd.
5250 Ferrier. Suite 812,
Montreal, Quebec
H4P 1L3 Canada

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