

ON/VOL L

U-Control™

EMG Home Trainer

User's Manual

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THRESHOL

Thought Technology Ltd.

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0413

The Manufacturer:

Thought Technology Ltd.
8205 Montreal/ Toronto Blvd.
Suite 223. Montréal West,
Québec, Canada H4X 1N1

Product Name:

U-Control System

Product #:

T8800, T8825, T8875,

Device Name:

U-Control Incontinence/Muscle Re-education Unit

Device #:

SA8800, SA8825, SA8875



EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands
Tel: +31.70.345.8570
Fax: +31.70.346.7299



- Type BF Equipment
- Internally powered equipment
- Continuous operation



- Read Instruction Manual

WARNING

- Do not use in the presence of a flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.
- Not to be immersed in water.

PRECAUTIONS

- To prevent static discharge from damaging the sensor and/or encoders, use anti-static mats or sprays in your working area. A humidifier may also be used to prevent static environments by conditioning hot, dry air. Sensors damaged by static electricity are not covered under warranty!
- Do not apply any electrode gel or equivalent directly on the sensor snaps. Always use electrodes as a medium between the sensor and the client.
- Do not operate U-Control Unit within 10 feet of an operating cellular phone, similar radio transmitting device, other powerful radio interference producing sources such as arc welders, radio thermal treatment equipment, x-ray machines or any other equipment that produces electrical sparks etc.

ATTENTION

- To prevent voiding warranty by breaking connector pins, carefully align white guiding dot on sensor plug with slot on sensor input.
- Make sure to remove electrodes from sensor snaps immediately after use.
- Apply conductive gel only to electrodes, never put gel directly to sensor snaps.

- For best results, keep the sensor cable as short as possible by folding it in a tight loop held with an elastic or twist tie. Hold the measuring device close to your body at hip level.
- Always use electrodes between the subject and the sensor.
- Do not plug third party sensors directly into instrument inputs. Plug only Thought Technology Active Sensor cable connectors into instrument inputs. All EMG electrodes and third party sensors must be connected to MyoScan sensors, either directly or through an adapter.

IMPORTANT

- US Federal Law restricts this device to sale by or on order of licensed health care practitioners
- All encoders are totally isolated from line (110 or 220VAC) power due to battery operation and fiber optic connections to computers. However, many hospitals and the FDA require that computers, printers and any other equipment used with medical devices be electrically isolated from line voltage to UL or CSA medical safety standards.
- Radiated radio frequency electromagnetic fields can cause performance degradation in the U-Control Unit. In the worst case, an RF field strength of 22mV/M can cause a degradation of 1 μ V in the signal from the U-Control Unit. Be sure to keep in mind that a very relaxed muscle should provide an EMG reading of approximately 1-3 μ V.
- After use, the Vaginal Sensor, Rectal Sensor and Extension Surface Cable may be a potential biohazard. Handle, and when applicable, dispose of these materials in accordance with accepted medical practice and any applicable local, state and federal laws and regulations.

- Remove batteries when the device is not being used for extended period of time. Please dispose of batteries following national regulations.

CONTRAINDICATIONS

- Not for diagnostic purposes
- Pregnancy
- Patients with limited or impaired physical and mental capacity.
- Bladder or Vaginal infection
- Menstrual period

INTENDED PURPOSE

- Urinary Incontinence including:
 - Stress, urge, mixed incontinence
- Fecal Incontinence
- Muscle reeducation

ADVERSE REACTIONS

- There are no known adverse effects in using EMG for urinary incontinence.

NOTE

- No preventative inspections required, qualified personnel must perform maintenance.
- The supplier will make available, upon request, circuit diagrams, component parts lists and description or other information required for the repair of product by qualified personnel.

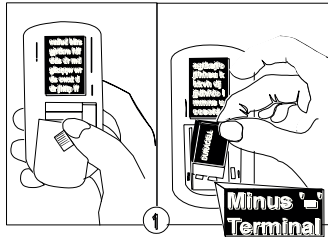
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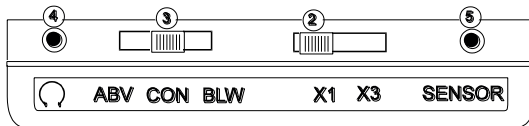
“Quick Start” Instructions

Medical Precautions:

Before using the equipment, it is recommended that a proper evaluation of the user be performed by a qualified medical practitioner. This would include, if relevant, a proctologic, urologic and/or gynecological evaluation. The determination of whether to use EMG feedback using this equipment must be left to the medical practitioner.

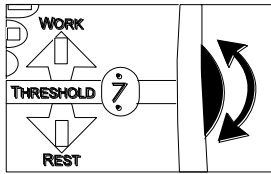


- 1) Insert a 9 volt battery into the battery compartment. (see page 7 for additional instructions).
- 2) Set scale switch to X1 for incontinence or X3 for large muscle groups.



- 3) Set tone switch to CON (continuous) unless directed otherwise by your healthcare professional.
- 4) Plug earphones into headphone jack if desired.
- 5) Plug only the Thought Technology Ltd. vaginal, rectal or extension surface cable into sensor jack.
- 6) Insert hand into wrist strap.

- 7) Your sensor should be cleaned before its first use.
Follow the instructions included with the sensor.



- 1) Set threshold value by rotating threshold dial to desired value.*

- 2) Turn unit on by rotating on/vol dial clockwise.



Follow your healthcare professional's treatment instructions.

IMPORTANT: If irritation or discomfort persists, discontinue use and notify your physician or health care professional immediately.

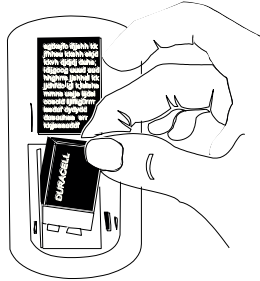
- 3) After use:
- Turn unit off.
 - Unplug sensor.
 - Clean vaginal or rectal sensor by washing in flowing warm, soapy water per instructions included with sensor
 - Store unit and sensor in carrying case.

***Note:** If you have NOT been instructed to use a specific threshold level by your healthcare provider, contact your healthcare professional for the appropriate setting.

Detailed Instructions

Battery Installation

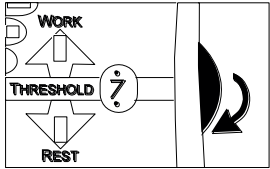
Remove battery panel by pressing on arrow and sliding panel down. Insert a rechargeable Ni-Cad 9 volt battery or an alkaline battery, making sure to properly connect the + and - on the battery to the appropriate terminal. Replace battery panel cover. Regular 9 volt batteries are not recommended due to short battery life. *If the LEDs do not illuminate, replace with a new battery.* To prevent battery leakage, remove battery when the U-Control unit will not be used for one month or longer.



Volume Adjustment/ Turning Unit On

Turn on/vol dial clockwise to turn unit on. The volume can be increased by continuing to turn the dial clockwise. Turning the

dial counterclockwise will decrease the volume or turn the unit off. Plugging in the earphone allows for privacy and prevents anyone present from hearing any sound. Note: If unit doesn't work, check to ensure that the battery is connected to the proper terminal.

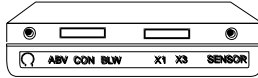


Setting Threshold Values

The threshold value is set by rotating the pictured dial until the desired value appears in the window next to the word threshold. The light bar left of the word threshold will illuminate

when your muscle activity reaches the threshold level.

End-Panel Controls



Tone

The U-Control unit allows the user to designate when a tone will be activated. Slide the switch to the desired setting. The three choices are as follows:

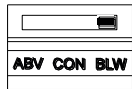
ABV - A tone is activated when the illuminated light appears next to letters **H-N** or **ABOVE** threshold.



CON - A tone is active **CONTINUOUSLY**.



BLW - A tone is activated when the illuminated light appears next to letters **A-G** or **BELOW** threshold.

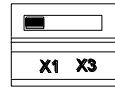


Scale Range -

The U-Control unit offers two choices for range. The range refers to the values (in microvolts) of letters A-N on the U-Control label.

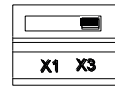
X1 Range 0.2 - 37.5 microvolts

Usually appropriate for pelvic floor muscles



X3 Range 0.6 - 112.5 microvolts

Ideal for large muscle groups



See the attached scale on pages 12 and 13 for reference microvolt values for different threshold settings.

5, 10 Second Work/Rest Switch

Located under the battery panel, this switch sets the work and rest cycles at 5 or 10 seconds. When set at 5 seconds, the light bar will illuminate under the rest arrow on the front panel for 5 seconds and then the light bar will illuminate above the work arrow for 5 seconds. The work/rest lights will illuminate for 10 seconds when the switch is set at 10.



Wrist Strap

Use wrist strap to position U-Control near the body to avoid breakage and to minimize outside signal interference.

X1 Threshold Microvolt Approximate Values

N	2.5	7.5	12.5	17.5	22.5	27.5	37.5
M	2.2	6.6	11.0	15.4	19.8	24.2	33.0
L	1.9	5.7	9.5	13.3	17.1	20.9	28.5
K	1.7	5.1	8.5	11.9	15.3	18.7	25.5
J	1.5	4.5	7.5	10.5	13.5	16.5	22.5
I	1.3	3.9	6.5	9.1	12.9	14.3	19.5
H	1.1	3.3	4.4	7.7	9.9	12.1	16.5

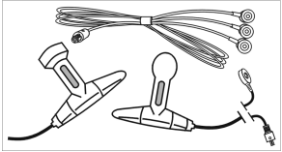
THRESHOLD

	1.0	3.0	5.0	7.0	9.0	11.0	15.0
G	0.8	2.4	4.0	5.6	7.2	8.8	12.0
F	0.7	2.1	3.5	4.9	6.3	7.7	10.5
E	0.6	1.8	3.0	4.2	5.4	6.6	9.0
D	0.5	1.5	2.5	3.5	4.5	5.5	6.5
C	0.4	1.2	2.0	2.8	3.6	4.4	6.0
B	0.3	0.9	1.5	2.1	2.7	3.3	4.5
A	0.2	0.6	1.0	1.4	1.8	2.2	3.0

X3 Threshold Microvolt Approximate Values

N	7.5	22.5	37.5	52.5	67.5	82.5	112.5
M	6.6	19.8	33.0	46.3	59.4	72.6	99.0
L	5.7	17.1	28.5	39.9	51.3	62.7	85.5
K	5.1	15.3	25.5	35.7	45.9	56.1	76.5
J	4.5	13.5	22.5	31.5	40.5	49.5	67.5
I	3.9	11.7	19.5	27.3	35.1	42.9	58.5
H	3.3	9.9	16.5	23.1	28.1	36.3	49.5
THRESHOLD							
	3.0	9.0	15.0	21.0	27.0	33.0	45.0
G	2.4	7.2	12.0	16.8	21.6	26.4	36.0
F	2.1	6.3	10.5	14.7	18.9	23.1	31.5
E	1.8	5.4	9.0	12.6	16.2	19.8	27.0
D	1.5	4.5	7.5	10.5	13.5	16.5	22.5
C	1.2	3.6	6.0	8.4	10.8	13.2	18.0
B	0.9	2.7	4.5	6.3	8.1	13.2	13.5
A	0.6	1.8	3.0	4.2	5.4	6.6	9.0

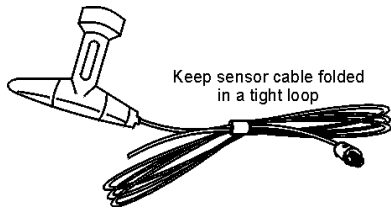
Sensor Use



The Thought Technology Ltd. U-Control™ home trainer is designed and approved for use only with the Thought Technology Ltd. Vaginal Sensor (Catalog No. T6050), Thought

Technology Ltd. Rectal Sensor (Catalog No. T6051) or the Thought Technology Ltd. Extension Surface Cable (Catalog No. T8820). Any of these sensors will fit the custom sensor jack located on the top panel of the device.

Use of other manufacturer's sensors with the U-Control home trainer are not approved and may be unsafe to use. Also, do not alter or modify the sensor cable and/or connector as it may affect the product safety and also will invalidate the warranty.



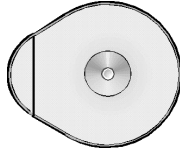
For best results, keep the sensor cable as short as possible by folding it in a tight loop held with an elastic or twist tie. Hold the measuring device close to your body at hip level.

Instructions for use are included with the sensors.

IMPORTANT: If irritation or discomfort persists, discontinue use and notify your physician or health care professional immediately.

Disposable Uni-Gel Electrodes:

These individual reference electrodes (Catalog No. T3425 (100)) snap directly onto the Thought Technology Ltd. Extension Surface Cable or the Thought Technology Ltd. Vaginal or Rectal sensor reference wires. For best results, wipe the skin area with a moist cloth before applying the electrode.



Earphones:

To use earphone, plug earphone into headphone jack located at the top of the Thought Technology Ltd. U-Control EMG home trainer. This will allow for privacy as the sound will only be heard through the earphone.

Care and Storage of your System

The Thought Technology Ltd. U-Control EMG home trainer is a sensitive piece of equipment and should be handled carefully. When removing the sensors from the jacks, never pull on any of the sensor cables. After use, clean the U-Control unit by wiping the surfaces with a damp cloth. Also, use a moistened cotton swab to remove gel from the inside of the electrode connectors for the Thought Technology Ltd. vaginal sensor, rectal sensor and Thought Technology Ltd. extension surface cable. This will extend the life of these products. For convenient transporting or storage of the U-Control device, place the device in the enclosed storage bag.

Attention: Static electricity may also damage these products.

After use, the sensor and/or electrode may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and national laws and regulations.

Specifications

Input Impedance	1,000,000 MegOhms
Accuracy	5% and 0.3 μ V
Sensitivity	<0.1 microvolts RMS
Bandwidth(frequency)	90-300 Hz.
CMRR at 60 Hz	>180 dB
CMRR > 90-300 Hz	>140 dB
Range	0.2 - 37.5 microvolts (X1); 0.6 - 112.5 microvolts (X3).
Bargraph scaling	The highest yellow LED is 2.5 times the threshold setting; the lowest green LED is 0.2 times the threshold setting; other LEDs are proportional to these extremes.
Current consumption	Approx. 15 - 30 milliamps
Outputs	Earphone (8-32 ohms), 2.5 mm mono jack
Battery	9 Volt Alkaline, or NiCad rechargeable type MN1604.

Biofeedback Equipment and Accessories

Product	Catalog No.	Description
U-Control™ 50Hz Kit	T8800	Includes: U-Control device with wrist strap, mono-earplug, soft-sided carrying case, instructions.
U-Control™ 60Hz Kit	T8825	Includes: U-Control device with wrist strap, mono-earplug, soft-sided carrying case, instructions.
Vaginal Sensor	T6050	Includes: (1) vaginal sensor, instructions with warranty.
Rectal Sensor	T6051	Includes: (1) rectal sensor, instructions with warranty.
Disposable Triode Electrode	T3402	100 foam backed self adhesive triode electrodes.
Disposable Single Electrodes	T3404	100 foam backed self adhesive single electrodes.
Disposable Uni-Gel Electrodes	T3425	100 pre-gelled foam backed self adhesive single electrodes.

Limited Product Warranty

Thought Technology Ltd. U-Control™ EMG Home Trainer Kit One Year Warranty

Thought Technology Ltd. warrants to the original purchaser that this product will be free from defects in material and workmanship for a period of one (1) year from the date of purchase. If this product proves to be so defective, purchaser may return same to Thought Technology Ltd. for repair or replacement, at Thought Technology Ltd.'s option. All returns must be authorized in advance. See PAGE 19 for the number to call for instructions on obtaining authorization and returning this product. The liability of Thought Technology Ltd. under this limited product warranty does not extend to any abuse or misuse of this product or its repair by anyone other than an authorized Thought Technology Ltd. representative.

THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED (INCLUDING, WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). SOME STATES MAY NOT ALLOW EXCLUSION OF IMPLIED WARRANTIES. YOU MAY BE ENTITLED TO ADDITIONAL REMEDIES UNDER STATE LAW. THE LIABILITY AND REMEDY STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF THOUGHT TECHNOLOGY LTD. AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND

THOUGHT TECHNOLOGY LTD. WILL NOT BE LIABLE TO PURCHASERS FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF ITS HANDLING OR USE. SOME STATES DO NOT ALLOW AN EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU. THE LIMITED PRODUCT WARRANTY GIVES YOU SPECIAL LEGAL RIGHTS REGARDING THIS PRODUCT, AND YOU ALSO MAY HAVE OTHER RIGHTS AGAINST THOUGHT TECHNOLOGY LTD. WHICH VARIES FROM STATE TO STATE.

For repairs or returns:

Please call the Thought Technology technical support department for a Return Authorization (R.A.) number before sending any equipment to us.

Send the unit *postage prepaid and insured, with proof of purchase.*

Please provide a detailed description of the problem and write your phone number and address clearly. (See the form on the following page)

In U.S.A.

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

Canada and all other countries

Thought Technology Ltd.
8205 Montreal/ Toronto Blvd.,
Suite 223/ Montreal West, West
Quebec, Canada H4X 1N1
Tel: (514) 489-8251
Fax : (514) 489-8255
E-Mail: mail@thoughttechnology.com

*Important: Remove batteries prior to shipment.

Note: Remember to remove dead batteries promptly to prevent corrosion damage.

Repair Return Form

(Remove and include with unit)

Name _____

Company _____

Address _____

Phone # _____

Date Purchased _____

Model Name _____

Serial # on Unit _____

PLEASE STATE PROBLEM:
