eVu

TPS

USER GUIDE

Thought Technology Ltd.

www.thoughttechnology.com

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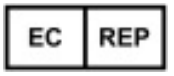
Product Name: eVu TPS

T4500



EMERGO EUROPE
Molens traat 15, 2513 BH
The Hague, The Netherlands

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Manual No. SA4504 (June 2016)

Audience

This User Guide is intended for eVu TPS® users (licensed health care practitioners) who are trained and qualified in Biofeedback techniques. Experience in this field and knowledge of commonly used equipment and standard practices are prerequisites.

The User Guide includes a technical description of system parts and accessories, and instructions about system setup and maintenance.

It also includes important information about the safe and effective use of the system with designated software which may be downloaded from the company's web site at www.evutps.com.

Labeling Symbols

Operating instructions [consult accompanying documents]

Caution, consult accompanying documents

[Enter / Exit] Stand-by mode

Type BF Applied Parts

Keep dry

Keep away from sunlight

Fragile, handle with care

Waste Electrical Items bearing this symbol must not be disposed of with general household waste. Dispose according to local recycling initiatives.

Indicates that the product is manufactured in conformity with the Medical Device Directive and other applicable European Community directives.

EC REP

Authorized Representative in the European Community

Manufacturer

Date of manufacture

REF

Catalogue number

Warning! Not suitable for children under 3 years

Overview

The eVu TPS® system contains a miniaturized self-contained battery-operated finger-worn biofeedback device. The TPS senses skin conductance, skin temperature, and heart rate by photoplethysmography, transmitting these signals wirelessly using Bluetooth. The TPS works with a software app on a mobile device to display the signal.

INTENDED PURPOSE

- Biofeedback and relaxation.
- The device is not intended to measure quantitatively the value of physiological parameters; measurements are relative to each other, indicating short-term trends rather than absolute values.

CONTRAINDICATIONS

- None.

OPERATOR PROFILE

- This device is intended to be operated by adult patients only.
- Pediatric use only under supervision of adult / healthcare provider.

CAUTION

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

PRODUCT CONTENTS

- 1 x SA4500 TPS
- 1 x SA4505 Strap
- 1 x SA45XX Charger (Medical Grade Universal Power Supply / AC Power Adapter)
- 1 x MI1134 Carrying case, Black

Note: The usage of the device requires an Android app which can be found at the following link www.evutps.com. The app runs on an Android platform using Version 4.4 or above. The recommended tablet / phone screen size is from 4.5 to 9.7 inch.

TECHNICAL SPECIFICATIONS

Weight	Approx. 20g (without the Charger)	
TPS size	Approx. 50mm x 30mm x 20mm	
Li-ion Polymer Battery	Nominal voltage	3.7V
Skin conductance measurement	Range	0 – 30 uS
Temperature measurement	Range	10 – 40 ˚C
Accelerometer	Number of Axes	3 (X, Y, Z)
Wireless communication	Bluetooth Classic	

OPERATING ENVIRONMENTAL CONDITIONS

- Standard — EN/IEC 60601-1-11
- Temperature — +5˚C – +40˚C
- Relative humidity — 15 % – 93% (non-condensing)
- Atmospheric pressure — 700 hPa – 1060 hPa

TRANSPORT AND STORAGE ENVIRONMENTAL CONDITIONS

- Standard — EN/IEC 60601-1-11
- Store in its 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 and IEC60601-1-11
- Type of protection against electric shock — Internally powered equipment
  CLASS II (when connected to Charger)
- Degree of protection against electric shock — Type BF Applied Parts
  (TPS with built-in sensor)

• Mode of operation	Continuous
• Degree of protection against ingress of water	IPX0 (no protection)
• Protection against ignition of flammable anaesthetic mixtures	EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYZEN OR NITROUS OXIDE
• Charger Power Rating (Medical Grade Universal Power Supply / AC Power Adapter)	UL/IEC 60601-1 ***Input:*** 100-240Vac, 60/50Hz, 0.6A ***Output:*** 5Vdc, 1.2A

ELECTROMAGNETIC COMPATIBILITY

• Standard	EN/IEC 60601-1-2

Guidance and manufacturer's declaration – Electromagnetic emissions		
The eVu TPS is intended f or use in the electromagnetic environment specified below. The customer or the user of the eVu TPS should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The eVu TPS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The eVu TPS 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	Class B	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The eVu TPS is intended for use in the electromagnetic environment specified below. The customer or the user of the eVu TPS should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ±15 kV air	± 8kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Warnings and Precautions

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

WARNINGS:

Intended Use

- There are no user serviceable parts. Do not attempt to service or modify the equipment. If the equipment appears damaged, do not use; contact Technical Support at Thought Technology Ltd. or your local authorized distributor for replacement.
- Functionality is disabled during charging. To ensure safety, do not charge the device while wearing.
- Do not immerse in water.
- Do not connect to a patient undergoing MRI, electro-surgery or defibrillation.

- Do not use in the presence of a flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.
- Device might not meet its performance specifications if transported, stored or used outside the specified temperature and humidity ranges.
- Skin temperature readings are sensitive to air movement and incident radiation.
- Use of any equipment in a biofeedback context should be immediately terminated upon any sign of distress or discomfort.
- This device is not intended for diagnosis and it is not a substitute for proper medical advice and diagnostic testing. If you have any health concerns, consult your physician.

PRECAUTIONS

- The eVu TPS may be susceptible to electrostatic discharges (ESD) and radiated radio frequency (RF) fields.

Electrostatic discharge is common in conditions of low humidity. Always discharge yourself by touching a grounded bare metal surface before touching the unit. Do not operate active sensors within 10 feet (3m) of a powerful radio interference producing sources such as arc welders, radio thermal treatment equipment, x-ray machines or any other equipment that produces electrical sparks.

- Bluetooth operation may be interrupted by 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. Ensure they are not damaged. 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 remains accessible at all times and may be easily disconnected from the wall outlet.
- Do not expose to extreme weather conditions.
- To diminish the risk of spreading communicable diseases, always use good hygiene practices with electrode surfaces. In all cases, refer to your facility's infection control procedure.

WARNINGS:

Battery

- To ensure safety, use only the charging adapter provided with the device.
- Do not leave a battery on prolonged charge when not in use.

- Discard the device with built-in battery following your local waste management legislation and guidelines. The battery cannot be replaced.

Maintenance and Care

- There are no user serviceable parts.
- Wipe sensor pads with a clean cloth after each use. Do not clean with alcohol or abrasive detergents. Do not immerse, soak or expose the sensor to disinfectants for periods of time that exceed manufacturer's specifications. Do not sterilize.
- If the device is not used for a long time, ensure the device is charged at minimum every 2-3 months.
- The battery can maintain the performance characteristics for a minimum of 300 charge cycles.
- After extended periods of storage, it may be necessary to charge and discharge the device several times to obtain maximum performance.

- To ensure safety, use only the charging adapter provided with the device.
- Do not leave a battery on prolonged charge when not in use.

- Discard the device with built-in battery following your local waste management legislation and guidelines. The battery cannot be replaced.

Wearing the device

Step 1:

Attach the TPS fabric strap to the TPS sensor by slipping the two loops at the one end of the strap onto the two outer hooks of the TPS sensor.

Step 2:

Place the TPS sensor on your finger so that the sensor label faces up and the ON button points toward your hand.

It does not matter upon which finger the sensor is placed.

The sensor should be placed at the end of your finger. The two metal plates on the underside of the sensor rest against the palm surface of your skin as shown.

Step 3:

Secure the TPS sensor to your finger by wrapping the fabric strap around your finger and back over the TPS sensor. The fabric strap is perforated with loops. Slip an appropriately positioned loop onto the central hook of the sensor.

Do not choose a loop that holds the sensor too tight to your finger, such that it hurts. Similarly, do not choose a loop that holds the sensor too loosely to your finger, to prevent it from shifting position or falling off.

When properly fastened, the fabric strap covers the TPS sensor logo, but the sensor light remains visible when the sensor is turned on.

TPS Power button / operating modes

- From power off: press the power button on the TPS to turn on; wait for short blinking sequence to stop, blue LED should go solid. This is the “stand by” state.
- From stand by state: press the power button and hold until fast repetitive blinking starts. This is pairing mode.
- Exit pairing mode either by pairing with host (see below, ***Connecting TPS to Android phone***) or by turning off the unit.
- Blue LED slow blink: connected and transmitting.

TPS Charging

- Charging time: 2-3 hours
- Battery life: 4-5 hours

When plugged in the power adapter:

- Green LED solid and bright: needs charging
- Green LED is off: charging is done

Functionality is disabled during charging. To ensure safety, do not charge the device while wearing.

Connecting TPS to Android phone

- From the main desktop, click the phone's menu button and click **Settings** (from the bottom right corner).
- Click **Wireless & Networks**.
- Click **Bluetooth Settings**.
- Ensure Bluetooth is turned on (the first option in the list).
- If TPS is already ON, press and hold the TPS power button until the blue LED starts blinking (when released it should continue blinking); this puts it in discovery mode. (If the TPS unit is off,

press to turn on, wait until short blink sequence ends, then press and hold to enter discovery mode).

- Click **Scan Devices**.
- When the scan is complete, you should see an item in the list named **TPS TP00xxxx** (where xxxx is the serial number of the TPS unit).
- Click that entry to pair your TPS unit with the phone.
- Your phone and TPS unit are now paired.
- The instructions for using the app are provided inside the application which can be downloaded from www.evutps.com.

TPS isn’t paired

- Turn off the TPS and try to pair the device again by following the steps in Connecting TPS to Android phone (page 23).
- If the problem persists, contact Technical Support or your local authorized distributor.

TPS doesn’t appear in the application device list

- Make sure that the TPS is already paired with the phone / tablet.
- If the TPS is already in the Bluetooth Paired Devices list on the phone / tablet, terminate the application.
- Turn off the TPS.
- Turn on the TPS again and relaunch the application.
- If the problem persists, contact Technical Support or your local authorized distributor.

BLUE LED is not ON when the device is turned on

- Plug in the power adapter for charging.
- If the GREEN LED is ON, let the device continue charging.
- If no LED is ON, contact Technical Support or your local authorized distributor.

When the TPS has just been turned ON, BLUE LED continues blinking after 10 seconds without entering discoverable mode or streaming.

- Turn off the TPS.
- Turn it back on.
- If the error cannot be resolved, contact Technical Support or your local authorized distributor.

Placing Orders and Technical Support

Outside USA and Canada

Tel: +1-514-489-8251

Fax: +1-514-489-8255

Toll-Free in USA and Canada

Tel: 1-800-361-3651

E-Mail: mail@thoughttechnology.com

Or contact your local authorized distributor.

Warranty

The TPS is guaranteed to be free from defects in material and workmanship for 1 year from the date of purchase.

In the unlikely event of hardware failure, 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.

This warranty does not cover damage to TPS caused by obvious mechanical mistreatment of the system.

This warranty does not apply to performance degradation of batteries. Please contact Technical Support at Thought Technology Ltd. to learn more.

Disposal

Appropriate disposal of the device and sensors should be done in accordance with accepted medical practice and any applicable local, state and federal laws and regulations.

Returning Equipment

Before returning the equipment, please contact first our service department and get an authorization number (RA number).

☎ Canada and International
+1 514 489 8251

☎ Toll Free USA and Canada
1 800 361 3651

💻 service@thoughttechnology.com

Then fill in the return form (the form can be found at the end of the manual). You must provide a detailed description of the problem you are experiencing, and your telephone/fax number and e-mail.

The unit(s) must be sent postage prepaid and insured, with proof of purchase to one of the addresses below.

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

In the USA, ship insured to:

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

In Canada, ship insured to:

Thought Technology Ltd.
8205 Montreal/Toronto Blvd. Suite 223
Montreal West, Quebec
Canada H4X1N1

For international:

- Package must be marked **"Broker: Livingston International – 133461".**
- Ship insured to:

  Thought Technology Ltd.
  8205 Montreal/Toronto Blvd. Suite 223
  Montreal West, Quebec
  Canada H4X1N1

Service Return Form

Be sure to call for authorization before returning any equipment!

Copy and complete this form and include it with the unit(s).

Include a copy of original invoice and return to the address in the Returning Equipment section.

Name _____

Company _____

Address _____

_____

_____

_____

Phone No. _____

Fax No. _____

Date Purchased _____

From Whom _____

Model Name _____

Serial No. _____

Problem _____

_____

_____

_____

_____

_____