eVu

TPS

USER GUIDE

ThoughtTech

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CE

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Product Name: eVu TPS System

Device Name: eVu TPS

REF SA4500

EC REP EMERGO EUROPE
Westervoortsedijk 60,
6827 AT Arnhem
The Netherlands

Manual No/Rev SA4504 Rev. 8 (January 2023)

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About this User Guide

Audience

The *eVu TPS® User Guide* is intended for licensed health-care practitioners who are trained and qualified in biofeedback techniques. Experience in this field and knowledge of commonly used devices and standard practices are prerequisites.

It 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) Standby 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.

Warning! Not suitable for children under 3 years.

Overview

The eVu TPS® system is a device that is composed of the eVu TPS® Sensor that is worn on the user's finger and the eVu Senz® App, a self-training application that encourages on-screen breath pacer through the ability to visualize breathing patterns.

The eVu TPS system provides feedback on biosignals: Heart Rate Variability, Temperature and Skin Conductance. It is not intended for monitoring, diagnosis or treatment. Furthermore, it is not intended to measure quantitatively the value of physiological parameters.

The eVu TPS can also be used with BioGraph® Infiniti.

INTENDED PURPOSE

The eVu TPS system is intended for visualization and real-time feedback (biofeedback) of physiological parameters to assist a patient in developing a degree of conscious control over

typically involuntary functions. It is intended for relaxation training and to provide information to aid in stress reduction.

PATIENT POPULATION

- **Age**: Adults and children, aged five years and older, prescribed the use of biofeedback devices

CONTRAINDICATIONS

- None.

OPERATOR PROFILE

- This device is intended to be operated by health-care providers or adult patients following their instructions.
- Pediatric use only under supervision of an adult / a health-care provider.

CAUTION

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

PRODUCT CONTENTS

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

Note: Visit the following link for further information on the eVu TPS along with the software and mobile apps we have designed for it www.evutps.com.

TECHNICAL SPECIFICATIONS

Weight	Approx. 20g (without the charger)	
eVu 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 5 BLE	

OPERATING ENVIRONMENTAL CONDITIONS

- Standard — EN/IEC 60601-1-11
- Temperature — +5˚C – +40˚C
- Relative humidity — 15 % – 93% (non-condensing)
- Atmospheric pressure — 70 kPa – 106 kPa

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 — 70 kPa – 106 kPa

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 (eVu TPS with built-in sensors)

• 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
• 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 A	
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 using the device. 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 it; 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 it.
- Do not immerse in water.
- Do not connect to a patient undergoing MRI, electrosurgery or defibrillation.
- Do not use in the presence of a flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.
- The 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 is accessible at all times and may be disconnected easily from the wall outlet.
- 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 the 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 the 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, and typically 500 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 the built-in battery following your local waste management legislation and guidelines. The battery cannot be replaced.

Instructions for Use

Charging the eVu TPS

- Charging time: 2-3 hours
- Battery run time: 7-8 hours

Plug the charger into the power source and connect it to the power port on the eVu TPS. The green light beside this port has two states, indicating the following:

- Green LED solid and bright: needs charging
- Green LED is off: charging is complete.

Note: The functionality of the eVu TPS is disabled during charging. To ensure safety, do not charge the device while wearing it.

eVu TPS Power Button / Operating Modes

When the eVu TPS is disconnected from the power adapter, the power button displays a blue LED. When it is on, the light can be steady, blinking quickly, or blinking slowly.

- From power off, press the power button on the eVu TPS to turn it on; wait for the short blinking sequence to stop. When the blue LED is steady, the device is in standby state.
- Standby state is used in several ways: This is the discovery or pairing mode of the device. See Pairing the eVu TPS on page 18. If it is paired, you can connect the device to a software or mobile app. When it connects to an app, it enters standby state and is ready to transmit data.
- When the device is transmitting data, the blue LED blinks slowly.
- To turn the device off, press the power button.

Note: The eVu TPS shuts off automatically if there is no Bluetooth connection for five minutes. It also shuts off if the battery level is critical.

Pairing the eVu TPS

The eVu TPS communicates with software or mobile apps on your PC or mobile device via Bluetooth.

To connect with BioGraph or eVu Senz for Android, first you must pair the eVu TPS through the Bluetooth settings of your PC or Android device.

To connect with eVu Senz for iOS, just launch the app and follow the instructions on the screen. eVu Senz for iOS guides you through the process.

Before starting:

- Make sure the eVu TPS is charged. See Charging the Device on page 16.
- Make sure it is disconnected from the charger.
- Press the power button to turn it on.
- Wait for the blue LED to become steady, indicating that is in standby state.

See Power Button / Operating Modes on page 17.

In standby state, it is visible to other Bluetooth-enabled devices. This is discovery or pairing mode.

When the eVu TPS is paired successfully, it is listed on the Bluetooth screen of your PC or mobile device as TPS with the last six digits of the serial number, such as TPS000136.

To pair the eVu TPS to an Android device

1. Follow the steps under Before Starting on page18.
2. Select **Settings** > **Connections** on the Android device.
3. Turn on **Bluetooth**.
4. Scroll to the **Available Devices** list.
5. Select your eVu TPS in the list.
   It appears in the Paired Devices list. It is ready-to-wear and to connect to the mobile app. Make sure Bluetooth is on when you are ready to connect.

To pair the eVu TPS to an iOS device

1. Follow the steps under Before Starting on page 18.
2. Launch the eVu Senz app and follow the instructions on the screen.

Or

1. Follow the steps under Before Starting on page 18.
2. Select **Settings** > **Bluetooth** on your iOS device.
3. Turn on **Bluetooth**.
4. Select your device under **My Devices**.

   It is listed as TPS with the last six digits of the serial number, such as TPS123456.

To pair the eVu TPS to a PC

Note: The following steps describe the procedure on Windows 10. It varies slightly for other versions of Windows.

1. Follow the steps under Before Starting on page 18.
2. Select **Settings** > **Bluetooth** on the PC.
3. Turn on Bluetooth.
4. Click **Add Bluetooth or other device**.

5. Select **Bluetooth** from the Add a device screen.
6. Select the eVu TPS.

   A new window appears, and the TPS is listed under **Your device is ready to go!**
7. Click **Done**.
   Your device is ready-to-wear and to connect to a software app. Make sure Bluetooth is on when you are ready to connect.

Wearing the device

Step 1:

Attach the eVu TPS fabric strap to the eVu TPS sensor by slipping the two loops at the one end of the strap onto the two outer hooks of the eVu 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 eVu TPS sensor to your finger by wrapping the fabric strap around your finger and back over the eVu 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.

Troubleshooting

The eVu TPS doesn’t appear in the list of paired devices on the PC or mobile device.

1. Turn off the eVu TPS and try to pair the device again, following the steps in Pairing the eVu TPS on page 18.
2. Install and run a Bluetooth scanning app. Several free apps are available on the internet, Google Play, and the App Store.
3. If the problem persists, contact Technical Support or your local authorized distributor.

The eVu TPS doesn't appear in the device list for the application.

1. Make sure the eVu TPS is paired with the PC or smart device.
2. If the eVu TPS is in the Bluetooth Paired Devices list on the PC or smart device, terminate the application.
3. Turn off the eVu TPS.
4. Turn on the eVu TPS again.
5. Launch the application.
6. If the eVu TPS still does not appear in the list, terminate the application.
7. Unpair the eVu TPS.
8. Pair the eVu TPS again.
9. Launch the application.

10. If the problem persists, contact Technical Support or your local authorized distributor.

BLUE LED is not ON when the device is turned on.

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

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

1. Turn off the eVu TPS.
2. Turn it back on.
3. If the error cannot be resolved, contact our Technical Support or your local authorized distributor.

Technical Support and Contacts

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 eVu 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 eVu 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.
5250 Ferrier, Suite 812
Montréal, Québec
H4P 1L3
Canada

For international:

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

  Thought Technology Ltd.
  5250 Ferrier, Suite 812
  Montréal, Québec
  H4P 1L3
  Canada

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 the 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 _____

_____

_____

_____

_____