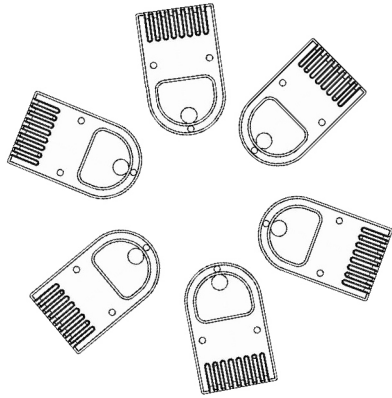




Physician's
Electronic
Prescription
Station

Operator's Manual



The ERGYS Data Management System

Physician's Electronic Prescription Station (PEPS)

ERGYS Token Data Management System

Catalog Number: 07-1001

Address comments, questions, or requests pertaining to this manual to:

Therapeutic Alliances Inc.
Customer Service Department
333 North Broad Street
Fairborn, Ohio 45324

(937) 879-0734
(937) 879-5211 fax

www.ERGYS.com

info@ergys.com

The ERGYS is an FDA registered medical device for use in hospitals and clinics under the supervision of a qualified medical practitioner. The ERGYS may be used at home under the prescription of a physician.

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Product design and specifications may be changed without notice.

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1. Introduction



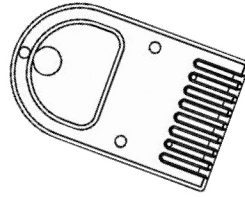
1.1 Overview

The ERGYS Physician Electronic Prescription Station (PEPS) allows the physician and clinician to safely control and monitor patient sessions on the ERGYS Rehabilitation System. Limits to the therapy can be programmed on the Data Token to ensure that parameters such as workload and stimulus levels cannot be set to inappropriate levels. Session information is stored back to the Data Token for review at the PEPS.

The “rewritable memory” technology of the Data Token System allows parameter settings from one session to be saved for automatic recall the next session. This means that thresholds, max stim settings, and other parameters do not have to be reentered every session. The stopping point of one session is the starting point for the next session.

1.2 The ERGYS Data Token

The Data Token forms the “information bridge” between the ERGYS and the PEP Station. It stores the prescription (therapy limits), the last parameter entries made at the ERGYS, and the results of up to 144 ERGYS sessions.



ERGYS Data Token
Actual Size

1.3 Precautions

- 1. Users should fully understand the operation of the ERGYS before using the PEP Station.***
- 2. After programming a Data Token, it should be plugged into an ERGYS to verify that the limits are set properly.***



1.4 System requirements

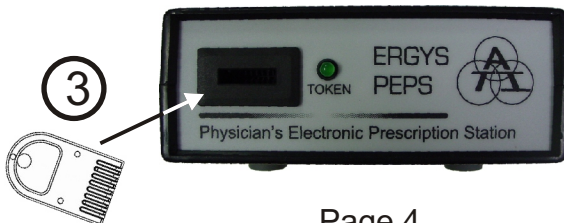
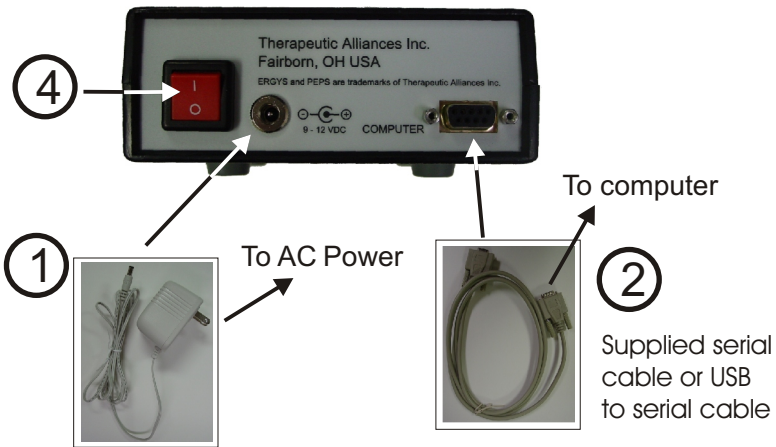
The PEPS requires a Windows XP, Vista, or ‘7’ computer with a USB connection or a 9-pin COM serial port. Contact Therapeutic Alliances if help is needed to configure the computer or install the software.

2. Installation

2.1 Component installation

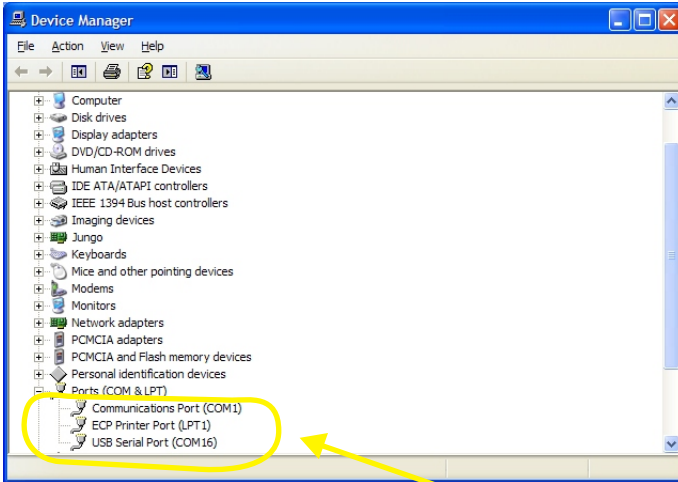
Follow these steps to install the PEP Station components.

1. Connect the power adapter to an AC power outlet and the barrel-shaped power connector to the back of the PEP Station.
2. Connect one end of the serial cable to a computer and the other end to the back of the PEP Station. **If using a USB to serial cable, check to see if its driver must be installed before plugging the USB connector into the computer.**
3. Insert a pre-programmed ERGYS Data Token (e.g., the one that came with the PEPS package) into the Token receptacle.
4. Turn on the power to the PEPS and observe that the green TOKEN light blinks once then comes on to stay.



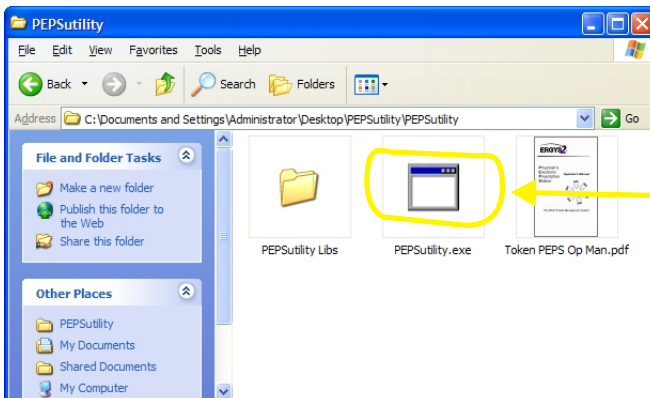
2.2. Software setup

Before installing the PEPS software on the computer, a valid COM port must be available.



My Computer → Control Panel → System → Hardware → Device Manager

Create an *ERGYS PEPS* folder on the computer and copy the files on the CD-ROM to this folder.



Once the PEPS software has been copied to a directory, double-click the PEPSutility icon to launch the PEPS program

3. Operation

3.1 Main display

After the PEPS program is launched, the *Main Display* will appear. All major PEPS functions are controlled from this screen.

The screenshot shows the 'Main Display' window for 'TAI ERGYS PEPS Utility 1.0.0'. The interface is organized into several sections:

- Patient Information:** Fields for Patient Name (PATIENT NAME), Physician Name (CLINIC/PHYSICIAN NAME), and Prescription Date (7/16/2009). A 'Date' button and a 'Help' button are also present.
- Treatment Protocol:** Includes 'Days/Week' (7), 'Max Session Time' (60 min), 'Max Run Time' (60 min), and 'Rest Time' (5 min). A 'Workload' section has a dropdown set to 7, '1/8Kp', and radio buttons for 'Automatic' (selected) and 'Manual'.
- Waveform and RPM:** A checkbox 'Allow ERGYS rider to change' is checked. The 'Waveform' dropdown is set to 'SINE 500', with '60 Pulses/s'. Below, 'RPM' settings are shown: Control (49 RPM), Resistance (46 RPM), and Fatigue (35 RPM).
- Max Stimulus:** Six dropdown menus for muscle groups: RQUAD, LQUAD, RGLUT, LGLUT, RHAM, and LHAM, all set to 140 mA.
- Threshold:** Six input fields for the same muscle groups, all set to 0 mA (0-70).
- Control Buttons:** 'Read Prescription', 'Write Prescription', 'Read Session Data', and 'Exit'.

Main Display

3.2 Menu commands

Help	Display this operator's manual.
Read Prescription	Read the previously programmed prescription on the Data Token.
Write Prescription	Erase the Data Token and write a prescription to it using the parameters on the <i>Main Display</i> . All session data on the Data Token will be lost.
Read Session Data	Read the session data stored on the Token during the ERGYS sessions. <i>Read Session Data</i> and <i>Save it</i> <u>before</u> writing a new prescription to the Data Token.
Exit	Exit the PEPS program.

3.3 Description of prescription parameters

The following section provides a field-by-field description of the prescription parameters. It is not intended to be an exhaustive examination of these parameters. Users should fully understand the operation of the ERGYS before using the PEP Station.

Patient Name	Physician Name	Prescription Date
<input type="text" value="PATIENT NAME"/>	<input type="text" value="CLINIC/PHYSICIAN NAME"/>	<input type="text" value="7/16/2009"/> <input type="button" value="Date"/>

Patient Name This name is stored on the Data Token and is appears at the ERGYS on one of its introductory displays. The *Patient Name* is limited to 25 characters. Often times, if the Data Token is for evaluation of patients or is meant as a generic token, the name of the clinic or hospital will be typed here instead of a real or fictitious patient.

Physician Name This name appears only at the PEP Station; it is not displayed by the ERGYS.

Prescription Date This date should be set to the date that the prescription is written to the Data Token. A 'date picker' is provided to simplify the entry.

Treatment Protocol

Days/Week	Max Session Time	>= Max Run Time	Rest Time
<input type="text" value="7"/>	<input type="text" value="60"/> min (3-60)	<input type="text" value="60"/> min (3-60)	<input type="text" value="5"/> min (3-60)

Days per week (1 - 7) This field is used only for reference on PEPS printouts; the ERGYS does not use Days Per Week.

Max Session Time (3 - 60 minutes) This parameter limits the maximum accumulated run time per session on the ERGYS. Up to 5 runs are allowed in the accumulation of this total.

Max Run Time (3 - 60 minutes) This parameter limits the maximum time allowed before the ERGYS rider must Cool Down and Rest. This setting cannot exceed the Max Session Time.

Rest Time (3 - 60 minutes) This parameter sets the amount of suggested Rest Time after each run on the ERGYS. The Rest may be abbreviated on the ERGYS by pressing the STOP key.

Workload

7 1/8Kp

Automatic

Manual

Workload (0/8 - 7/8 Kiloponds) This parameter limits the maximum braking load the ERGYS will apply during a run. The ERGYS will always set the Selected Load to 0 Kiloponds when a newly programmed Data Token is inserted. The ERGYS rider has the option to set the Selected Load up to the limit set by this parameter.

Automatic/Manual This parameter sets the default resistance mode to manual or automatic application. In the Manual mode, the rider must use the ERGYS keypad during a run to change the braking force. In the Automatic mode, the ERGYS will adjust the braking load based on the rider's performance. In both cases the braking load limit will be the maximum braking load set on the Data Token.

Allow ERGYS rider to change

Waveform

SINE 500 60 Pulses/s

Waveform This parameter sets the default stimulus waveform on the ERGYS. Most often the SINE 500 waveform is a good choice as it relates to patient comfort and the strength of the muscle contraction..

Pulses per Second (30, 40, 50, 60) This parameter sets the number of stimulus pulses per second. Typically this is set to 60. Some researchers and clinicians believe 50 pulses per second will offer comparable results while delaying the onset of fatigue.

Allow ERGYS rider to change? Setting this field to NO will prevent the ERGYS rider from changing the Waveform and the Pulses Per Second fields. Additionally, the rider will be prevented from changing the RPM settings.

RPM

Control RPM > Resistance RPM > Fatigue RPM

RPM Settings These advanced parameters control the rider's cadence. The settings should be 49 and 35 unless you understand them completely. Likewise, if the ERGYS rider is not trained on the meaning of these settings, the 'Allow ERGYS Rider to Change' setting should be set to NO.

Max Stimulus

RQUAD

LQUAD

RGLUT

LGLUT

RHAM

LHAM

mA

Max Stim Settings (0 - 140 mA) These are the most important parameters when it comes to the patient's sensation to stimulus. These settings will almost always be pre-determined on the ERGYS before programming a Data Token for a particular patient. It is important not to set these at a high level without knowing the patient's ability to tolerate that intensity.

Threshold

RQUAD

LQUAD

RGLUT

LGLUT

RHAM

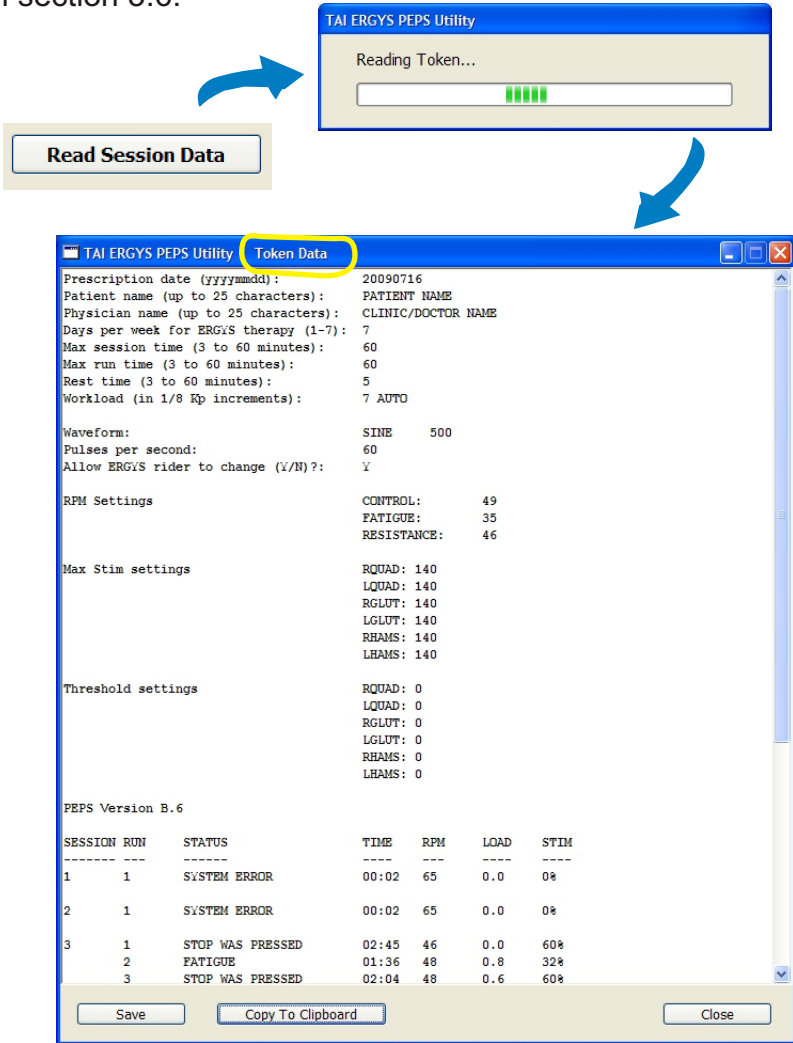
LHAM

mA (0-70)

Threshold Settings (0 - 70 mA) These are the minimum stimulus settings for the ERGYS. Typically they should be programmed to 0 on a new Data Token unless the Thresholds have been previously determined for a patient.

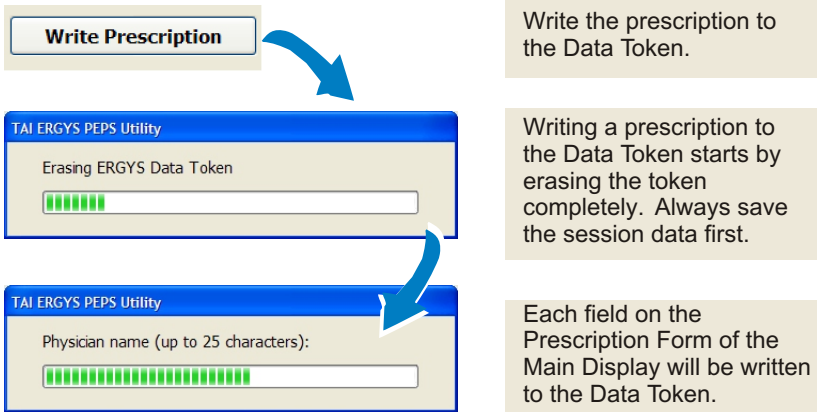
3.4 Reading the session data

After pressing the *Read Session Data* button, session information is read from the Data Token and listed session by session, and, within a session, run by run. Up to 5 runs will be listed for each session. This information can be copied or saved and imported into other Windows programs as detailed in section 3.6.



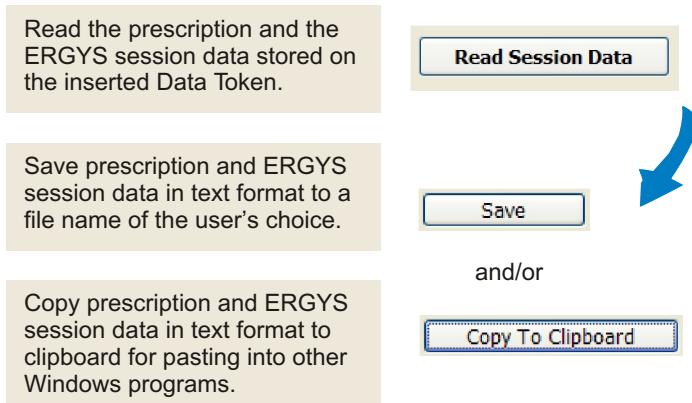
3.5 Prescribing (writing to) a Data Token

Pressing the *Write Prescription* button on the *Main Display* will cause the Data Token to be erased and then programmed with the prescription parameters found on the *Main Display*. **All session data on the Data Token will be lost.**



3.6 Using other programs

It is easy to copy or save ERGYS data for use in other programs such as Microsoft Word. After importation into a Windows program, it may be necessary to select a monospaced font such as *Courier New* to align the text and columns of a PEPS “printout.”



4. Troubleshooting

4.1 Getting help

The PEPS will normally operate without trouble. In those rare instances when this is not the case, we strongly encourage you to contact Therapeutic Alliances. We can usually get the PEPS back in operation in a matter of minutes. Before you contact us, please collect the information listed below.

1. Serial number on back of unit
2. Behavior of green light on front panel (at power up it should blink once then stay on)
3. Error code reported by PEP Station (i.e., the number of beeps). See section 4.2 for a list of error codes.
4. History of the Data Token plugged into the PEPS

Therapeutic Alliances Inc.
333 North Broad Street
Fairborn, OH 45324 USA

(937) 879-0734 • fax (937) 879-5211
www.ERGYS.com • info@ergys.com

4.2 List of error codes (number of beeps)

MISSING TOKEN	1
MISSING PARAMETERS	2
TOKEN FULL	3
MISMATCHED TOKEN	4
UNKNOWN MSG	5
ILLEGAL 2ND CHAR	6
QUERY TIMEOUT	7
BAD QUERY RESPONSE	8
ILLEGAL CONVERSION	9
EE READ ERROR	10
EE WRITE ERROR	11

THERAPEUTIC ALLIANCES INC.



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