

# THYMATRON® SYSTEM IV INSTRUCTION MANUAL

Richard Abrams, M.D.

Conrad M. Swartz, Ph.D., M.D.



ECT is a complex medical procedure. Its proper and safe conduct requires a staff of professionals who are experienced with the procedures and familiar with the medical literature concerning the risks, benefits, complications, and methods of ECT. This literature includes the major textbooks of ECT and of psychiatry, the Journal of ECT, and publications about ECT that have appeared in the major journals of psychiatry. As with other aspects of medical practice, knowledge about ECT continues to change and clinicians are responsible for maintaining awareness of these changes from these publications and other sources.

Reports in the medical literature describe the incidence of death associated with ECT as about 1 in 40,000. Other serious adverse events have occurred, including cardiac arrhythmia, myocardial infarction, acute hypertension, aspiration, pneumonia, hypoxia, respiratory obstruction such as laryngospasm, pulmonary embolism, prolonged apnea, tardive seizure, non-convulsive status epilepticus, partial relief of depressive anergia enabling suicidal behavior, and falls. Concurrent administration of antipsychotic (neuroleptic) medication may increase the risks of adverse cardiac, pulmonary, and neurological events, and falls. Concurrent administration of stimulants may increase the risks of cardiac and neurological complications, such as prolonged seizure.

Sixteenth Edition, Revised February, 2013

Copyright© 1999; 2000; 2001; 2002; 2003; 2004; 2005; 2006; 2009; 2013 Somatics LLC. All rights reserved. No portion of this manual may be reproduced by any means without the permission of Somatics LLC.

*Technical Support*  
USA and Canada  
(800) 642 – 6761  
Fax: (847) 234 – 6763  
E-mail: [sales@thymatron.com](mailto:sales@thymatron.com)

# TABLE OF CONTENTS

TOPIC	PAGE
Safety Information.....	3
Specifications.....	5
Indications for Use.....	6
Installation.....	7
Operating Instructions.....	7
Percent Energy Dial.....	8
Safety Monitor Test.....	9
FlexDial™ Operation.....	10
FlexDial™ Model Procedure.....	11
FlexDial™ Flow Chart.....	13
Paper Loading Instructions.....	14
Monitoring Electrodes Application.....	15
Stimulus Electrodes Application.....	17
Impedance Test.....	18
Baseline EEG Collection.....	19
Stimulus Dose Selection.....	20
Stimulus Programs, Factory Programmed.....	20
Treatment Stimulus Administration.....	24
Seizure Monitoring, EEG.....	24
Ictal Line™ Indicator.....	25
Gain and Position Settings.....	26
Change EEG Gain Rapidly.....	27
Seizure Quality Measures.....	27
EEG Frequency Measures.....	28
Printer Paper Speed.....	29
User Specified FlexDial™ Selections.....	29
Reset to Factory Specifications.....	30
Transferring Data to PC.....	30
Input Hospital's Name.....	31
Upload Treatment Data.....	31
Monitor EEG/ECG/EMG on PC.....	32
Reprint Last Treatment.....	34
Set Date and Time.....	34
Table 1, Standard Dose Parameters.....	35
Table 2, Double Dose Parameters.....	48
EMC Supplement.....	49
EMC Declaration.....	50
EC Declaration of Conformity.....	51
Index.....	52
Addendums.....	55

## SAFETY INFORMATION

Please read the following important safety requirements before using the Thymatron® System IV ECT Instrument.

**⚠ CAUTION:** Do not subject the Thymatron® System IV to extreme moisture or use it after it has been partially or totally immersed in liquid or when a significant amount of liquid has been spilled on it. Power the unit off and have it checked by a qualified technician before powering it on or using it again.

**WARNING:** Do not remove the top or bottom covers of the Thymatron® System IV. There are no user serviceable parts inside. Any servicing must be performed by qualified service personnel.

**CAUTION:** Only use with the Somatics' Treatment or Monitoring Cables.

**CAUTION:** The Treatment and Monitoring Cables are not interchangeable, and can not be inserted into the wrong front panel connector. Attempting to insert the Treatment Cable into the connector intended for the Monitoring Cable (and vice versa) will damage both the connector and the cable.

**WARNING:** Do not use any cables or lead wires that appear to be damaged.

**WARNING:** The Thymatron® System IV is defibrillator protected.  Nevertheless, for safety reasons, all cable connections between the Thymatron® System IV ECT Instrument and the patient must be disconnected prior to initiation of the defibrillation stimulus.

**CAUTION:** Do not dispose of your Thymatron® System IV in the general waste. As per Directive 2002/96/EC for the disposal of electrical and electronic equipment please contact the manufacturer for instructions.

**WARNING:** Avoid the risk of accidental shock to medical personnel. Do not contact the patient, or any conductive surface touching the patient, unless wearing electrically insulated gloves. If holding the patient's jaw or touching the patient's head during the electrical stimulus, make sure to use electrically insulating gloves.

**CAUTION:** Prior to initiating ECT on a patient with a cochlear implant, healthcare professionals should discuss the issue with an otolaryngologist or audiologist and review the cochlear implant Instructions for Use.

The Thymatron® System IV Treatment Cable, Monitoring Cable and lead wires can be cleaned by wiping them off with a Germicidal Disposable Cloth. Steel stimulus electrodes may be cleaned with soapy water or alcohol. Thymapad® electrodes are single use only and must be discarded after the treatment.

The Thymatron® has no special requirements for restricted environment during transport or storage, beyond Standard Sub-clause 10.1 criteria.

## DISCLAIMER

Please note that nothing in this manual constitutes, or should be construed as, a claim by Somatics LLC that confusion, cognitive impairment, or memory loss (short-term, long-term, recent, remote, transient, or persistent) can not occur as the result of ECT. Many patients experience temporary loss of recent or remote memories with ECT, particularly with traditional bilateral ECT. A few patients have reported experiencing persisting loss of memories or memory functions after ECT. These are subjective symptoms that have not been related to observable structural brain changes. Mental and physical illnesses, anesthesia, medications, and postponement of treatment each have their own adverse effects, which can be substantial.

*The 0.3 ms pulsewidth is available as an option at no charge. If the Thymatron® System IV has 0.3 pulsewidth enabled, please change all 0.25 in the manual listing to be 0.3.*

## SPECIFICATIONS

The Thymatron® System IV is *Class 1, Type BF* 

### STIMULUS OUTPUT

**Current:** 0.9 amps constant current, limited to 450 volts, isolated from line current

**Frequency:** 10 to 70 Hz, in 10 Hz increments (to 140 Hz in *LOW 0.25/0.3 Programs*)

**Pulsewidth:** 0.25 to 1.5 ms, in 0.25 ms increments (0.3 ms is available)

**Duration:** 0.14 to 7.99 s in increments of equal charge

**Maximum output:** Standard maximum output across 220 ohms impedance, 504 mC (99.8 joules). Output for double dose modes (where available) across 220 ohms impedance: 1008 mC (199.6 joules). Actual (delivered) treatment output shown on printed report in mC

### RECORDING

4 recording channels: channels 1 & 2, EEG; channel 3, EMG; channel 4, ECG.

8 user selectable gain positions for EEG channels (10, 20, 50, 100, 200, 500, 1,000 and 2000  $\mu\text{V}/\text{cm}$ ) and EMG or ECG channels (50, 100, 200, 500, 1000, 2000, 5000 and 10,000  $\mu\text{V}/\text{cm}$ )

**REQUIREMENTS** 100-130 volts (120 volts) AC, 60 Hz, single phase. 150 VA.  
(220-240 volt, 50/60 Hz, switchable)

### STIMULUS GENERATION

**Waveform:** bipolar, brief pulse, square wave

### IMPEDANCE

**Static Impedance Test:** 0 to 3000 ohms static (+/- 100 ohms) at 800 Hz  
(L.E.D. and printed report)

**Dynamic Impedance Measure:** 0 - 500 ohms (printed report)

### SEIZURE MONITORING

**Channel specifications:**

**Maximum gain:** EEG, 10  $\mu\text{V}/\text{cm}$ ; EMG 50  $\mu\text{V}/\text{cm}$ ; ECG 50  $\mu\text{V}/\text{cm}$

**Common mode rejection:** 80 dB

**Isolation:** full, opto-electronic

**Printer paper speed:** user selectable: 5 - 50 mm/s

**Seizure Quality Measures:**

**Postictal Suppression Index (EEG):** range, 0-100%

**Average Seizure Energy Index (EEG)**

**Maximum Sustained EEG Power and Time to Peak EEG Power**

**Maximum Sustained EEG Coherence and Time to Peak EEG Coherence**

**Duke University EEG Measures**  
**Power Spectral Analysis by Fast Fourier Transform, (FFT)**  
**Peak Heart Rate: beats/min**  
**Computer Seizure Endpoint Estimates by EEG and EMG**

### **EEG FREQUENCY MEASURES**

**95% Spectral Edge Frequency**  
**Median Frequency**  
**Relative Delta Power**

### **DIMENSIONS**

**Weight: 22 lb**  
**Height: 5.5"**  
**Width: 17.5"**  
**Depth: 13.0"**

### **INDICATIONS FOR USE**

We recommend that doctors planning to use the Thymatron® System IV read and follow the recommendations of the Task Force Report of the American Psychiatric Association as set forth in "The Practice of Electroconvulsive Therapy" (American Psychiatric Association, 2001). To briefly summarize these recommendations here, the Thymatron® System IV is intended to be used to administer electroconvulsive therapy (ECT) to patients suffering from mental disorders in which a rapid, definitive response is desired. ECT is most often indicated in patients who have not responded to adequate courses of appropriate pharmacotherapies, but is also indicated as the primary treatment for patients in whom a rapid or high probability of response is desired (as when they are severely medically ill or in danger of harming themselves) or who are known by their treatment history to respond only to ECT, or who have expressed a valid preference for ECT over alternate therapies.

### **PATIENT SELECTION CRITERIA**

The principal diagnostic indications for ECT as outlined in the Task Force Report of the American Psychiatric Association (APA, 2001) are Major Depression (all types), Mania, and Schizophrenia (characterized by abrupt or recent onset, catatonic features, psychotic symptoms, or a history of ECT response).

### **CONTRAINDICATIONS AND WARNINGS**

The Task Force Report of the American Psychiatric Association (APA, 2001) recognizes no absolute medical contraindication to ECT. It does warn about specific conditions that may be associated with substantially increased risk, including unstable or severe cardiovascular conditions (recent myocardial infarction, unstable angina, poorly-compensated congestive heart failure, severe

valvular cardiac disease), vascular aneurysms susceptible to rupture with increased blood pressure, increased intracranial pressure, recent cerebral infarction, severe chronic obstructive pulmonary disease, asthma, pneumonia and anesthesia risk level ASA 4 or 5.

## INSTALLATION

Unpack the instrument, open the black case, and place the instrument on a firm, flat surface such as a hospital cart. Check the instrument for any damage, and make sure the rear panel voltage designation matches that of the electrical outlet to be used. Determine that all manuals and items are present. If required, have the Safety Check performed as described in the Service Manual, Section 2.

Connect the power cable to the rear of the unit. Power the unit on and observe that the POWER switch light comes on, the self test runs successfully and "BASELINE" is displayed. Load a pad of thermal paper as per the instructions inside the paper door (see page 12). Turn the power switch off and on again to verify that the recorder prints the date and software version. This completes the installation.

## OPERATING INSTRUCTIONS

The new Thymatron® System IV features two front panel controls for display and selection of all treatment choices: the PERCENT ENERGY stimulus dose dial and the FLEXDIAL™ function and option selector.

In addition, you will see a POWER switch (power on/off), an IMPEDANCE TEST button, a START/STOP button (to manually control the 4-channel printer), a TREAT button (to deliver the treatment stimulus), two alphanumeric L.E.D.s (the left one with 8 characters, the right one with 4 characters), and 5 individual dot L.E.D.s (to indicate activation of the *FlexDial*™ selection mode, activation of the *Safety Monitor* alarm, activation of monitoring ECG in channel 4, and whether the *preset* program or a *user set selection* is in effect).

## POWER ON/OFF

Be sure the power cable is plugged into a grounded, 3-prong hospital-grade socket. Press the top half of the front-panel POWER switch (labeled "I") to turn the unit on; press the bottom half of the POWER switch (labeled "0") to turn the unit off.

## SELF TEST

The Thymatron® System IV automatically tests the integrity of all circuits. When the unit is powered on, a flashing nonsense symbol appears for several seconds in the 8-character L.E.D., followed by the flashing message "SELFTEST" for a few seconds, then a self-test confirmation report is printed and the words "NO BASE" appear, indicating that baseline EEG collection still has yet to be accomplished. (See IMPEDANCE TEST procedure section for baseline EEG collection.)

The printed SELF TEST confirmation report will appear on the paper strip as:

Thymatron® System IV S/N [serial number here]

Date - Time S-IV version [software version] / [the number 60 or 50 Hz]

The Thymatron® S/N line can be replaced with the hospital's name (see page 30).

## PERCENT ENERGY DIAL

The PERCENT ENERGY dial is used to select the treatment stimulus dose. This dial has three functions that are displayed in the 4 character L.E.D. above the dial.

1. *Rotating* the dial displays the PERCENT ENERGY settings for each stimulus dose, followed by a brief display of the corresponding stimulus charge in mC.
2. *Pressing* the dial displays the stimulus program currently in effect.
3. *Pressing, holding in* and then *rotating* the dial enables the operator to rapidly change stimulus programs without using the *FlexDial™*.

*To display the corresponding charge in mC again, rotate the PERCENT ENERGY dial in either direction and then back again to the desired setting.*

## LIGHT-EMITTING FUNCTION DISPLAYS

The Thymatron® System IV front panel has two alphanumeric L.E.D.s (the left one, with 8 characters, and the right one with 4 characters), plus 5 individual dot L.E.D.s 8-character L.E.D. Located above the IMPEDANCE TEST button

1. It displays the message "SELFTEST" immediately after the unit is powered on.
2. It displays the message "NO BASE" following completion of the self-test procedure and before baseline EEG collection has been initiated.
3. It displays the message "TESTING" for 1 second when the IMPEDANCE TEST button is pressed.
4. It then displays the static impedance value in ohms, and maintains it until the button is released.
5. It displays the message "BASELINE" from the time the IMPEDANCE TEST button is released until baseline EEG is obtained, about 6-10 seconds.
6. It displays the message "READY" when baseline EEG collection has been successfully accomplished.
7. After the "TREAT" button is pressed and released, it shows the *time elapsed in seconds* since the end of the treatment stimulus.
8. It displays the flashing message "REPORT" when the START/STOP button is pressed to generate and print the end-of-treatment report.
9. It displays the designations and values of all *FlexDial™* functions and options during their selection.

**4-character L.E.D.** Located above the PERCENT ENERGY dial

1. It displays the different PERCENT ENERGY values as the dial is *rotated*.
2. It then briefly displays the mC of *charge* corresponding to each PERCENT ENERGY dial setting.
3. It displays the *stimulus program in effect* when the dial is *pressed*.
4. It displays the options for the stimulus programs when the dial is *pressed, held in and rotated*. Releasing the dial, selects that program.

**Dot L.E.D.s** Located on the front panel

1. The L.E.D. labeled "FLEXDIAL" flashes when the *FlexDial™* is activated.
2. The L.E.D. labeled "SAFETY MONITOR ACTIVATED" flashes when the *Safety Monitor* has been activated.
3. The L.E.D. labeled "PRESET" lights when the *LOW 0.5 program* is in effect.
4. The L.E.D. labeled "USER SET" lights when a *user set selection* is in effect.
5. The L.E.D. directly above the "EEG/ECG/EMG" monitoring jack stays lit unless channel 4 is being used to monitor the patient's ECG. When channel 4 is connected, the light goes off.

#### SAFETY MONITOR CIRCUIT ALARM TEST

The Thymatron® System IV has a *Safety Monitor Circuit* test button on the back panel labeled "ALARM TEST". This test can be performed annually or as hospital regulations require. The *Safety Monitor Circuit* test is performed as follows:

1. Power on the Thymatron® System IV and connect the ECT stimulus cable.
2. *Rotate* the PERCENT ENERGY dial to any setting.
3. Connect the ECT stimulus cable banana plugs to a 200 ohm, 10 watt load resistor (or insert these banana plugs into the designated jacks of the ECTOBRAIN™ II testing device).
4. First *press and hold down* the rear panel "ALARM TEST" button. Next, *press and hold* the "TREAT" button, and then *release* the "ALARM TEST" button.
5. Continue *pressing* the "TREAT" button while the Thymatron® System IV goes through the full cycle of stimulus warning signal and stimulus indicator tones, then *release* the "TREAT" button.

At the end of the stimulus indicator tones the "SAFETY MONITOR ACTIVATED" dot L.E.D. will go on and a high-pitched, continuous signal tone will sound until the unit is powered off. *This shows the alarm signal is operating correctly.* If the indicator light and alarm signal tone do not occur, do not use the unit to treat patients until it has been examined and cleared by authorized biomedical personnel.

## FRONT PANEL JACKS

### *ECT Stimulus Jack*

This 2-pin jack labeled "ECT" is located below and to the *left* of the IMPEDANCE TEST button. It accepts the plug from the *ECT stimulus cable*.

### *EEG/ECG/EMG Monitoring Jack*

This 9-pin jack labeled "EEG/ECG/EMG" is located below and to the *right* of the IMPEDANCE TEST button. It accepts the plug from the *EEG/ECG/EMG monitoring cable*.

△ CAUTION: It is impossible to insert the plug from the stimulus cable into the monitoring jack and vice versa. Forcing the wrong cable in will break the connector.

## FLEXDIAL™ OPERATION

The *FlexDial™* has 18 different user-selectable functions, plus the ability to change EEG gain *while the printer is running*. All functions and options can be displayed, then selected with alternating *rotations* and *presses* of the *FlexDial™*, according to the following general principles:

1. *Rotating the FlexDial™* in either direction provides a sequential display of all functions or options in that particular level. You can reach any other function or option in the same level by *rotating* the dial.
2. *Pressing the FlexDial™* selects the function or option displayed in the 8-character L.E.D. and advances to the next choice.
3. *Pressing, holding in, and rotating the FlexDial™ while the printer is running* allows the operator to rapidly change the gain in all EEG channels.

### TO ENTER FLEXDIAL™ MODE:

With power on, *press* the *FlexDial™*. The most recently selected *function* in the "SETTING" level will appear in the 8-character L.E.D. The *FlexDial™* dot L.E.D. will flash to indicate that you are now in the *FlexDial™* mode.

These function headings (e.g., "SETTING", "PROGRAMS", "INDEXES", etc.) do not change a particular setting, but are the *FlexDial™* locations from which to select a range of related options. For example, selecting the "PROGRAMS" function, leads you to the options of: the traditional *DGx program*, three *Low Charge Rate programs*, the *Intermittent (Pulse Volley)* stimulus mode, the *double dose program (where available)* and the *USER* mode.

*NOTE: Pressing the FlexDial™ will select the above program being displayed. Once a function or option is selected with the FlexDial™ it remains in effect until changed, even when the unit is powered off.*

## TO EXIT FLEXDIAL™ MODE:

There are two ways to exit *FlexDial™* mode: *Pressing* the START/STOP button of the printer or *pressing* the IMPEDANCE TEST button. The *FlexDial™* dot L.E.D. will stop flashing upon exit.

1. *Pressing* the START/STOP button locks in the selection, generates a printed report of the 13 *FlexDial™* selections in effect and exits the *FlexDial™* mode.
2. *Pressing* the IMPEDANCE TEST button locks in the selections and exits the *FlexDial™* mode *without* generating a printed report.

## FLEXDIAL™ MODEL PROCEDURE

For the remainder of this manual, selection of *FlexDial™* functions and options will be shown by the following shorthand notation with the explanation listed below:

FLEXDIAL™ → [function] → [options]

1. *Press* the *FlexDial™* to display the most recently adjusted *FlexDial™* function.
2. *Rotate* the *FlexDial™* in either direction to display the desired function.
3. *Press* the *FlexDial™* to flash-display the option in effect for that function.
4. *Rotate* the *FlexDial™* to flash-display the other options.
5. *Press* the *FlexDial™* to select the desired option and advance to the next option (if there is one) or to return to *FlexDial™* function level.
6. *Press* the IMPEDANCE TEST or START/STOP button to lock in the option and to exit the *FlexDial™* mode.

*Example:*

FLEXDIAL™ → CH 3-4 → EMG-ECG, EEG-EEG means

1. *Press* the *FlexDial™* to display the most recently-adjusted *FlexDial™* function.
2. *Rotate* the *FlexDial™* in either direction to display the “CH 3-4” function.
3. *Press* the *FlexDial™* to flash-display the option in effect.
4. *Rotate* the *FlexDial™* to flash-display the options, EMG-ECG or EEG-EEG.
5. *Press* the *FlexDial™* to select the desired option and return to *FlexDial™* function level, “CH 3-4”.
6. *Press* the IMPEDANCE TEST or START/STOP button to lock in the option and to exit the *FlexDial™* mode.

## FLEXDIAL™ FUNCTIONS AND WHAT THEY CONTROL

### FLEXDIAL™

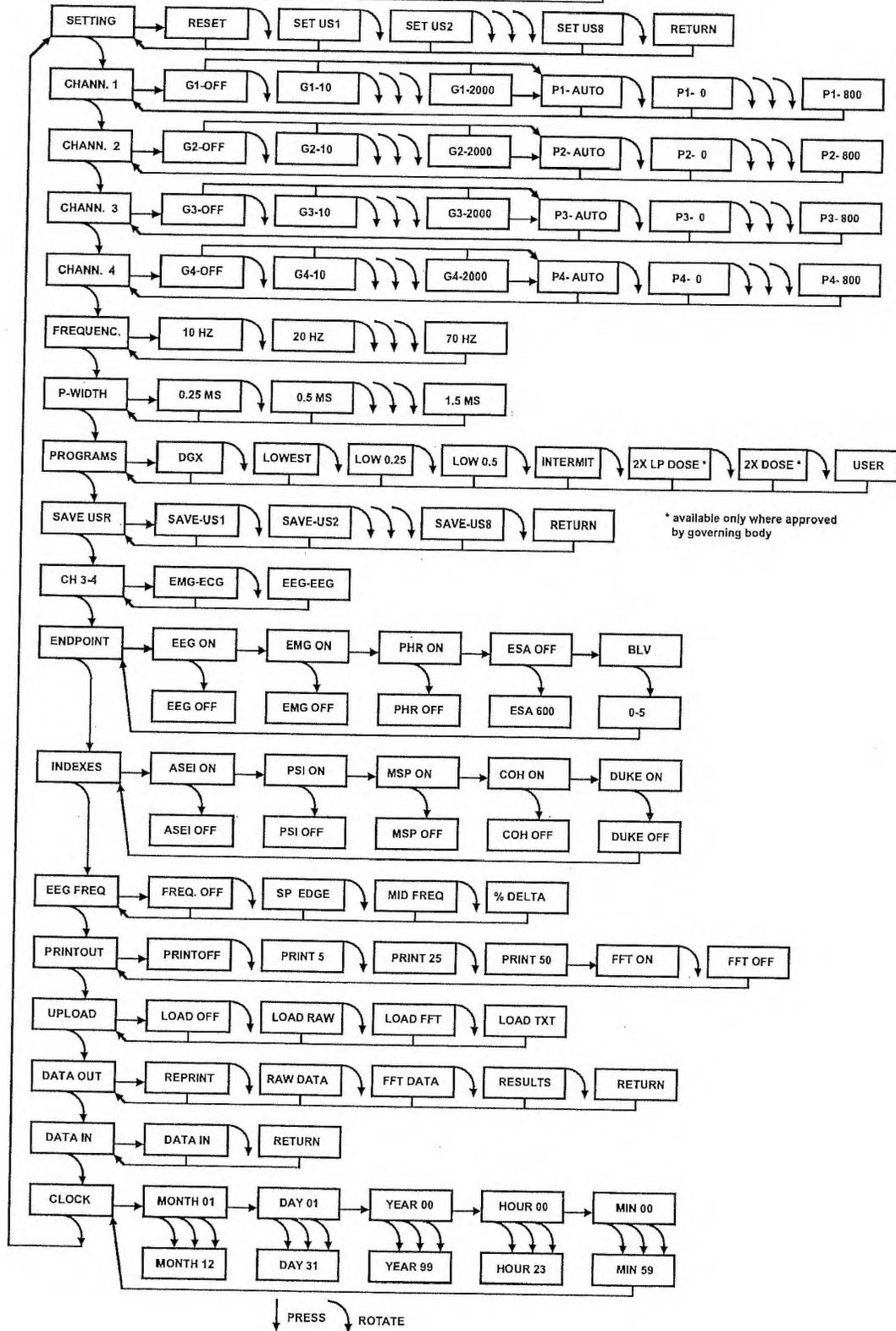
#### FUNCTION      SELECTS THESE OPTIONS

<b>SETTING</b>	Resets to factory specifications, loads up to 8 user set selections
<b>CHANN. 1</b>	Channel 1 gain and position settings
<b>CHANN. 2</b>	Channel 2 gain and position settings
<b>CHANN. 3</b>	Channel 3 gain and position settings
<b>CHANN. 4</b>	Channel 4 gain and position settings
<b>FREQUENC</b>	Stimulus frequency (10 Hz – 70 Hz in 7 steps)
<b>P-WIDTH</b>	Stimulus pulsewidth (0.25 ms – 1.5 ms in 6 steps) (0.3 ms available)
<b>PROGRAMS</b>	Selects from 7 factory pre-programmed or user stimulus programs
<b>SAVE USR</b>	Stores up to 8 user set selections
<b>CH 3-4</b>	Enables channels 3-4 to monitor either EMG-ECG or EEG-EEG
<b>ENDPOINT</b>	Enables endpoint detection of EEG, EMG, HR measures, prolonged seizure alert signal and Baseline Retention, BLV
<b>INDEXES</b>	Enables seizure quality measures
<b>EEG FREQ</b>	Selects one of three EEG measures
<b>PRINTOUT</b>	Enables printer and FFT printout, sets paper speed
<b>UPLOAD</b>	Enables sending treatment data to a PC automatically
<b>DATA OUT</b>	Reprints treatment just given; sends treatment data to PC
<b>DATA IN</b>	Accepts hospital's name from PC for the printed report; Accepts treatment data for re-printing treatment record
<b>CLOCK</b>	Sets month, day, year, hour, and minute on printed report

*Additionally, pressing, holding in, and rotating the FlexDial™ while the thermal printer is running will change the gain in all EEG monitoring channels.*

*If the 0.3 ms pulsewidth is enabled, there are no 0.25 ms pulsewidth settings. All other pulsewidths are available.*

Release 5.61, December 2009



## PAPER LOADING INSTRUCTIONS

The Thymatron® System IV printer paper holder is located just below Somatics' logo on the right side of the front panel. Press the arrow on the top cover release bar to open the printer cover door. Remove the cardboard sheets and place the fan folded paper pad inside. Make sure the black squares are on the right side and the warning strips on the bottom of the pad. Fold over the top sheet and feed these double sheets into the printer, just below the roller. The printer will automatically advance the paper to the correct point and stop. *Press and release* the START/STOP button to feed a sheet of paper.

## STIMULUS CABLE CONNECTION

Connect the plug of the *black* ECT stimulus cable into the jack labeled "ECT", located on the lower left front panel.

## MONITORING CABLE CONNECTION

Connect the plug of the *gray* EEG/ECG/EMG monitoring cable into the jack labeled "EEG/ECG/EMG", located on the lower left front panel, just to the right of symbol of the human figure inside a box.

**CAUTION:** The Treatment and Monitoring Cables are not interchangeable. They can not be inserted into the wrong connector. However, forcing them into the wrong place will damage the connectors or the cables.

## LEAD-WIRE CONNECTIONS

The Thymatron® System IV is shipped with 9 standard length (24 inch) lead-wires: 4 red, 4 black, and 1 green. Also included are 2 extra length (60 inch) brown lead-wires for recording EMG from the leg, if desired. Any combination of channels (from 1 to 4) can be used to monitor the patient. *Not all channels need to be used.* However, channel 1 *must* be used to obtain baseline EEG and seizure endpoints.

Plug the red lead-wires into the receptacles for channels 1, 2, 3 & 4 indicated by red dots at the flared end of the *gray* monitoring cable, and plug the black lead-wires into the *corresponding* receptacles for channels 1, 2, 3 & 4 indicated by black dots. Plug the green lead-wire into the green receptacle marked "*Iso Gnd*". If monitoring EMG from the leg, insert the brown lead-wires into the channel 3 receptacles (in any order) instead of the red and black lead-wires. The ordinary lifespan of a lead-wire is one year. With infrequent use some will last longer. Replacement lead-wires are available separately from the entire monitoring cable.

## SEIZURE MONITORING CONSIDERATIONS

Somatics' stick-on, snap monitoring electrodes, [Cat. # EEDS] are ideal for EEG, ECG and EMG monitoring. Their size and rectangular shape facilitate fronto-mastoid and bifrontal application without interfering with the stimulus electrodes. Prepare the skin sites by vigorously rubbing with an alcohol swab and wiping dry.

Polarity of recording electrodes can be important for EEG recording, so carefully follow the instructions below. Each recording channel takes one negative and one positive lead-wire, designated as black and red, respectively. On the monitoring cable, the holes facing the label are designated red (positive), and those on the side opposite from the label are designated black (negative). The 2 long lead-wires for recording EMG from the foot are color-coded brown for quick recognition since polarity is not an issue with either EMG recording.

The green ground lead-wire always plugs into the green-coded socket labeled ISO-GRND; only one ground is required no matter how many channels you monitor.

### Monitoring Electrode Placement:

We recommend two-channel EEG monitoring because it takes full advantage of all the special and unique monitoring features of the Thymatron® System IV, and with the splitter included, requires only one more lead-wire than single-channel EEG monitoring. If you do choose single-channel EEG monitoring we recommend a left fronto-mastoid placement because it can demonstrate seizure generalization to the left hemisphere when giving right unilateral ECT.

Regardless of how many channels you choose to monitor, Channel 1 must always be used for EEG in order to obtain a baseline EEG sample for the determination of the EEG endpoint and the EEG indexes, channel 3 must always be used to monitor EMG, channel 4 must always be used to monitor ECG, and the green ISO-GRND channel must always be used for the ground.

*The preferred 4-channel monitoring configuration using the splitter (EEG in channels 1 & 2, EMG in channel 3, and ECG in channel 4)*

**EEG:** fronto-mastoid EEG electrode placements are recommended. Place a monitoring electrode in the center of the forehead, another electrode over the left mastoid bone, and a third electrode over the right mastoid bone. Plug the two narrow ends of the splitter into the black positions for channel 1 and 2. Then connect a black lead-wire to the channel 1 position on the splitter, leaving the channel 2 position on the splitter empty. Connect this black lead-wire to the top front forehead monitoring electrode. Connect two red lead-wires to channel 1 & 2 red positions and clip the ends to the corresponding mastoid electrodes. Apply a monitoring electrode to either shoulder as a ground and connect it to the green lead-wire.

**ECG:** The great advantage of monitoring ECG with the Thymatron® System IV rather than (or in addition to) equipment provided by the anesthetist is that you get a permanent record of the heart rate printed every three seconds on the recording strip, plus an end-of-treatment printout of the baseline and peak heart rates, to help you assess the efficacy of the seizure just given.

Apply two monitoring electrodes over the anterior chest above and below the heart, spaced about 8" apart. Connect the channel 4 red and black lead-wires to the precordial electrodes in any order of polarity, and insert in the channel 4 holes.

**EMG:** The purpose of monitoring EMG is to provide an automated and highly accurate estimate of the motor seizure duration. Apply two monitoring electrodes spaced about 3" apart to a limb that has been cuffed to prevent the effects of the muscle-relaxant drug. Connect the channel 3 red and black lead-wires in any order of polarity to monitor from the patient's arm and plug into the channel 3 holes. (Use the brown 60 inch lead-wires to monitor from the patient's foot, as illustrated.)

*A 3-channel monitoring setup (EEG in channel 1, EMG in channel 3, and ECG in channel 4)*

For the preferred left fronto-mastoid EEG configuration, place one monitoring electrode above the left eyebrow and the other electrode over the left mastoid bone. Connect the channel 1 lead-wires to the monitoring electrodes in any order of polarity (no splitter is used), and connect the ECG and EMG electrodes, ground electrode, and lead-wires as described above.

*For 3 or 4-channel EEG monitoring* (primarily used for research) use the electrode placements of your choice, remembering to keep the polarity (relationship of red and black lead-wires) consistent for corresponding channels on each side of the head. If you connect the red and black lead-wires to frontal and temporal monitoring electrodes, respectively, on the *left* side of the head, be sure to maintain the same polarity relationship when connecting the corresponding pair of frontal and temporal electrodes on the *right* side of the head. Apply a monitoring electrode to either shoulder as a ground and connect it to the green lead-wire clip.

#### CHANNELS 3 & 4 SELECTION

EEG is always monitored from channels 1 & 2 and they are not user selectable. Channels 3 & 4 can monitor either EMG and ECG or two more channels of EEG. To select the monitoring options for channels 3 & 4, follow the procedure below:

**FlexDial™ → CH 3-4 → EMG-ECG; EEG-EEG**

## STIMULUS ELECTRODE APPLICATION

Apply the Thymapad™ adherent stimulus electrodes [Cat. # EPAD] supplied with the Thymatron® System IV, according to the directions, “Use of Thymapad™ Disposable ECT Stimulus Electrodes”. Clean the patient’s skin sites by rubbing vigorously with a *saline* moistened swab and pat dry. *Do not use solvents (e.g., alcohol) with Thymapad™ stimulus electrodes.* Spread 1-2 drops of Pre-Tac solution over the site and rub into the skin with a fingertip *until dry.* Remove a Thymapad™ from its wrapper, peel it from the plastic backing, and apply it firmly to the bare skin.

Insert the banana plug from the ECT stimulus cable into the plastic receptacle at the end of each Thymapad™ wire, until the entire conducting surface of each banana plug is covered and no metal shows. *Press* firmly once more on each Thymapad™ to ensure that it is properly applied and then test impedance.

For conventional *bitemporal* stimulus electrode placement, clean the skin sites over the temples as above. Remove a Thymapad™ from its wrapper and apply it firmly to the bare skin of the temple. Apply a second Thymapad™ to the other temple.

For *bifrontal* placement, place the center of each Thymapad™ 5 cm above the lateral angle of each orbit, about 14-15 cm apart. Before peeling the Thymapad™ from the backing, bend it to match the shape of the skull at each electrode site.

For Swartz’ *left-anterior right-temporal (LART)* placement, place the left-sided Thymapad™ above the left eye, with its lateral edge bordering the bony ridge between the forehead and the temple. Before peeling the left Thymapad™ from its backing, bend it to match the forehead’s curve. Place the right frontotemporal electrode exactly as described above for bitemporal ECT.

For *right unilateral* stimulus electrode placement, the d’Elia placement is recommended. Clean and dry the skin over the patient’s right temple as above. Remove a Thymapad™ from its wrapper, peel it from its plastic backing, and apply it firmly to the bare skin at the right temple. Part the hair on the right side of the head near the vertex and moisten the scalp thoroughly with a saline-soaked gauze pad or saline solution spray. Patients with dense, wiry hair may require full saline saturation of the hair and scalp area directly under the electrode. Apply a Thymapad™ to the site, holding it firmly in place with the special foam handle applicator supplied. (If the patient is bald at the near-vertex site, the upper Thymapad™ can be applied directly to the bare scalp after cleaning and drying as described above.)

## IMPEDANCE TEST (FOR *STATIC* IMPEDANCE)

Be sure the front panel POWER button is on, the ECT stimulus cable connected to the front panel and both stimulus electrodes are firmly applied. *Press* the front panel IMPEDANCE TEST button and observe the static impedance displayed in ohms, in the 8-digit L.E.D. Repeatedly checking impedance does not prevent ongoing monitoring or affect baseline EEG collection.

### **CAUTION: DO NOT PRESS THE “TREAT” BUTTON WHEN TESTING THE IMPEDANCE**

The static impedance test checks the quality of the skin-to-electrode contact. With the Thymatron® System IV, the static impedance should be greater than 100 ohms and less than 3000 ohms before the treatment stimulus dose is administered. A static impedance reading of less than 100 ohms suggests a short circuit, probably in the stimulus cable. An impedance reading of 3000 ohms or more appears as the flashing number 3000; if this occurs the impedance should be reduced by the following steps:

- a) Try pressing firmly on each Thymapad™ again while testing the impedance. This is especially important for the vertex electrode with unilateral ECT, which should be pressed vigorously in place with the foam handle applicator provided. Also for unilateral ECT, make sure that the hair and scalp under the vertex stimulus electrode are thoroughly moistened with a saline-soaked pad.
- b) If necessary, remove the Thymapad™, pass it under running water, shake off the excess water, wait a few minutes and then reapply the Thymapad™ by pressing it firmly into place.
- c) Check to make sure the electrodes have not slipped or twisted.
- d) Reposition the stimulus electrodes to minimize the amount of hair underneath.
- e) Increase pressure on the stimulus electrode by pressing harder with the foam handle applicator.
- f) Gently rub the skin under the stimulus electrodes with a fine emery board or Skin Prep tape (3-M) to remove the top layer of dead cells and sebum. Reapply the stimulus electrodes exactly as before.

A common reason for high impedance is that one or more steps were omitted from skin site preparation. Please be sure to follow each instruction step when using Thymapad™ stimulus electrodes.

During cold weather skin thickens and hardens, causing the static impedance to rise. Also, some patients have high readings despite all procedures. Try applying skin lotion to the electrode sites between treatments and shortly after waking on ECT days.

If the static impedance reading remains >3000 ohms after trying the above procedures, try replacing each Thymapad™, the lead-wires or the stimulus cable, in that order.

## BASELINE EEG COLLECTION

Prior to collecting a baseline EEG, be sure the automatic EEG endpoint detection feature of the Thymatron® System IV is enabled; the EEG monitoring electrodes are properly applied to the patient; the monitoring cable with attached lead-wires is connected to the front panel; and the lead-wires are clipped to the monitoring electrodes.

When the IMPEDANCE TEST button is pressed and held, the word “TESTING”, will briefly appear in the 8-digit L.E.D. Then a number ranging from 0 to >3000 ohm, representing the static impedance, will appear. When the IMPEDANCE TEST button is released, the number is replaced by the message “BASELINE”. The “BASELINE” message indicates that baseline EEG collection *is in progress*. When baseline EEG collection has been accomplished, the word “READY” will appear in the L.E.D. It normally takes about 6-10 seconds for “READY” to appear.

*However, moving the patient’s head, touching or moving the monitoring electrodes, lead-wires, or monitoring cable during baseline EEG collection will prolong the process by introducing EEG artifact. The less the patient and monitoring connections are moved or touched during baseline EEG collection, the sooner the “READY” message will appear and the patient will be ready to treat. If necessary, stop ventilating the patient for the few seconds it takes for the “READY” message to appear. Place the lead-wires so that they will not be disturbed by the anesthetist. Each pair of wires can be taped together about every 6 inches to minimize movement and artifact.*

*NOTE: If the “READY” message does not appear before the treatment stimulus dose is administered, there will be neither an Ictal Line™ nor EEG endpoint determinations or seizure quality measurements because an adequate baseline was not obtained. However, the treatment itself will not be affected.*

It is *not* necessary for the Thymapad™ stimulus electrodes to be applied in order to obtain a baseline EEG collection. Do not be concerned with an impedance reading >3000 ohms when no stimulus electrodes have been applied; baseline EEG collection will proceed anyway. Static impedance will be tested *after* the stimulus electrodes have been applied. Repeated pressing of the IMPEDANCE TEST button does not interfere with baseline EEG collection.

*TIP: It is strongly recommended to initiate baseline EEG collection by pressing the IMPEDANCE TEST button on the Thymatron® System IV’s front panel as soon as the monitoring electrodes and a ground electrode have been applied, even before applying the Thymapad™ stimulus electrodes (e.g., while the patient is fully awake and before anesthesia has been administered). This will provide the longest possible period of baseline EEG collection, maximizing the likelihood that a good baseline will be collected by the time the treatment stimulus is administered.*

## STIMULUS DOSE SELECTION

The Thymatron® System IV is shipped with the *LOW 0.5* program enabled. This is the recommended choice for the first treatment in all patients for whom there is no prior information concerning ECT response or seizure threshold. When desired, the *FlexDial™* can be used to select stimulus parameters specifically tailored to the patient's established requirements, or to select from among other factory- or user-set stimulus programs. However, we recommend use of the *LOW 0.5* program wherever possible, because it provides a broadly effective stimulus that is in the physiological range for most patients.

*Rotate* the PERCENT ENERGY dial to display the available stimulus settings (range: 5% to 100% ENERGY in 5% increments). Stop *rotating* the dial at the desired PERCENT ENERGY setting. A 1-second display then appears of the charge (mC) that corresponds to the PERCENT ENERGY setting, followed by a return to the PERCENT ENERGY number.

**NOTE:** The stimulus dose in mC that corresponds to any PERCENT ENERGY figure shown in the L.E.D. can be viewed again for 1 second by *rotating* the PERCENT ENERGY dial to either side and then back again.

Because stimulus duration is limited to a maximum of 8 seconds, the higher PERCENT ENERGY settings may not be available when the user selects pulsewidth or frequency values at the lower end of their ranges. Whenever the PERCENT ENERGY setting for a given pulsewidth and frequency would deliver a stimulus exceeding 8 seconds, the message ">8 S" will appear.

*However, all the factory-programmed preset programs shown in the next paragraph will work at all PERCENT ENERGY settings.*

Table 1 shows all the standard dosages and stimulus parameters for each PERCENT ENERGY setting.

## STIMULUS PROGRAMS: FACTORY PROGRAMMED

There are 7 factory set stimulus programs. The "LOW" programs automatically adjust the frequency to provide the longest stimulus duration available for a given PERCENT ENERGY setting; providing the optimum stimulus for each dose. The *LOW 0.5* program is the *only* preset program that will show as "PRESET" on the front panel L.E.D. (*Both Double Dose Programs are not available in USA or Canada*)

DGX	Reproduces the standard stimulus of the Thymatron® DGx
LOWEST	Automatically adjusts parameters to provide the lowest charge rate
LOW 0.25	Fixed 0.25 ms pulsewidth varies frequency to maximize duration
LOW 0.5	Fixed 0.5 ms pulsewidth, varies frequency to maximize duration
INTERMIT	Intermittent pulse-volley stimulus mimics the Siemens <i>Konvulsator</i>
2X LP	Double dose stimulus program using the lowest pulsewidth available*
2X DOSE	Double dose stimulus program* ( <i>*not available in USA or Canada</i> )

## STIMULUS PROGRAM SELECTION

Any standard (factory-programmed) setting can be selected using the procedure listed below. Or, to quickly change programs without the *FlexDial™*, *press, hold in* and *rotate* the PERCENT ENERGY dial. *Releasing* it selects the program displayed.

**FLEXDIAL™ → PROGRAMS → DGX, LOWEST, LOW 0.25,  
LOW 0.5, INTERMIT, 2X LP, 2X DOSE, USER**

*Press and hold in* the PERCENT ENERGY dial at any time to display the stimulus program in effect. *Release* the dial to return to the PERCENT ENERGY display.

## FREQUENCY SELECTION

When a factory-programmed preset stimulus is in effect, frequency is *automatically adjusted* for any given PERCENT ENERGY setting. Selecting a specific frequency takes the Thymatron® System IV out of any preset program. To select a specific stimulus frequency:

**FLEXDIAL™ → FREQUENC → 10, 20, 30, 40, 50, 60, 70 Hz**

## PULSEWIDTH SELECTION

When a factory-programmed preset stimulus is in effect, the pulsewidth is *automatically adjusted* for any given PERCENT ENERGY setting. Selecting a specific pulsewidth takes the Thymatron® System IV out of any preset program. To select a specific stimulus pulsewidth:

**FLEXDIAL™ → P-WIDTH → 0.25, 0.5, 0.75, 1.0, 1.25, 1.5 ms**

Because stimulus duration is limited to a maximum of 8 seconds, the higher PERCENT ENERGY settings will not be available when *manually* setting the 0.25 ms pulsewidth, which will provide stimuli only up to the 50% ENERGY. However, when the LOW 0.25 program is in effect, stimuli of up to 100% ENERGY can be delivered because, for this program only, the frequency can go as high as 140 Hz.

## STIMULUS DOSE FOR *BILATERAL*, *BITEMPORAL*, *BIFRONTAL*, *LART ECT*

For the initial treatment, select the LOW 0.5 program. The PERCENT ENERGY dial should be set to approximately one-half the patient's age (e.g., 25% for a 50 year-old). If no seizure activity results, the PERCENT ENERGY setting should be increased to 100% and the patient re-stimulated within 30-60 seconds to maximize the likelihood of obtaining a therapeutically satisfactory seizure at the first treatment session.

Before the next treatment day, the patient's history and records should be reviewed to ensure that dehydration or ingestion of sedative-hypnotic or anticonvulsant medications have not contributed to the difficulty in obtaining a good seizure. Consideration should be given at the next treatment session to administering a stimulus dose at the patient's age or at maximum charge.

#### **STIMULUS DOSE FOR UNILATERAL ECT**

Satisfactory therapeutic results can be obtained with right unilateral ECT by simply setting the PERCENT ENERGY dial to approximate the patient's age in years (e.g., 75% for a 72 year-old patient). If a satisfactory seizure is not obtained to the initial stimulus with right unilateral ECT, proceed as described in the paragraphs above for bilateral ECT.

**NOTE:** Once a patient obtains a satisfactory seizure with a given PERCENT ENERGY stimulus dose with unilateral ECT, we *do not* recommend administering subsequent treatments with progressively lower settings in an attempt to deliver the smallest stimulus that will still induce a seizure. This is because minimum stimulus dosing has been associated with inadequate therapeutic efficacy for right unilateral ECT.

#### **STIMULUS TITRATION PROCEDURE**

For those who prefer to set the initial stimulus dose relative to the seizure threshold, a simple and practical stimulus titration schedule for unilateral ECT starts with an initial setting of 5% ENERGY, followed by re-stimulations at 5% ENERGY increments until a seizure occurs, to a maximum of 4 stimulations in a treatment session (on average, fewer than three stimuli are required). Once the seizure threshold is determined for a specific PERCENT ENERGY setting, the recommended dosing level for unilateral ECT is 4-6 times that threshold value (e.g., 60% to 90% ENERGY for a threshold value of 15% ENERGY).

Because seizure thresholds for bitemporal and bifrontal ECT are higher than those for right unilateral ECT, the initial dose for stimulus titration with bitemporal ECT should be 10% Energy, with 5% ENERGY increments as described above. The subsequent treatments should be administered at doses approximately 2 times this threshold (e.g., 40% ENERGY for a patient with 20% ENERGY seizure threshold).

#### **"BENCHMARK" METHOD FOR SETTING AND ADJUSTING STIMULUS**

Because neither seizure duration nor seizure threshold are systematically related to the clinical efficacy of an ECT treatment, you may wish to consider regulating the stimulus dose according to a physiological measurement that has been reported to correlate with treatment response (the "target measurement"). Possible target measurements include Postictal Suppression Index (PSI), Maximum Sustained Power (MSP), or peak heart rate (PEAK HR).

Unlike stimulus threshold titration, the benchmark method does not require administering consecutively increasing sub-threshold stimulus doses until a seizure is obtained. Rather, at the first ECT treatment a high enough stimulus dose is given to induce an expected vigorous and effective seizure in virtually all patients. The value for the benchmark measurement reported in the end-of-treatment report for this first ECT treatment is then used as a target for all subsequent treatments.

Selection of the initial stimulus dose for the benchmark method can be made by the fixed-dose method or an age-based method. A fixed dose of 75-90% ENERGY should be high enough for most patients, regardless of treatment electrode placement. Alternatively, the PERCENT ENERGY dial can be set to the patient's age for unilateral ECT, or to 50-75% ENERGY of the patient's age for the various bilateral placements: bitemporal, bifrontal, or LART.

Dosage should be adjusted for subsequent treatments to maintain the selected variable (PSI, MSP, peak HR) within about 5% of the established target, keeping in mind the often dramatic rise in seizure threshold across a course of treatment. Lower target values suggest that the treatment was less than fully effective; this might be acceptable for selected patients, but is clearly a matter of medical judgment.

Of course, as everywhere in medicine, clinical response is overriding. Patients whose EEG or peak heart rate reflect a high seizure quality at lower dosage levels, but who are not showing clinical improvement, might benefit from higher doses. Those who are enjoying a satisfactory clinical response despite apparently poor quality seizures may require no dose adjustment.

#### **DOUBLE DOSE STIMULUS PROGRAM** (*Not Available in USA or Canada*)

The double dose programs *automatically* vary the pulsewidth and frequency to obtain the longest duration possible for any given PERCENT ENERGY dial setting, up to 200% ENERGY or 1008 mC. The PERCENT ENERGY settings are in increments of 5% up to 100% ENERGY and then in increments of 10% up to 200% ENERGY. The double dose programs are selected as follows:

**FLEXDIAL™ → PROGRAMS → 2X DOSE**  
**FLEXDIAL™ → PROGRAMS → 2X LP**

Table 2 of this manual shows the doses, pulsewidths, and frequencies that correspond to the PERCENT ENERGY dial settings for the double dose programs. The pulsewidth varies between 0.5 ms and 1.0 ms, while the frequency varies between 10 and 140 Hz.

## TREATMENT STIMULUS ADMINISTRATION

Flip up the clear plastic hinged cover over the "TREAT" button. *Press and hold* the button down until the treatment light comes on and then goes off again. While the "TREAT" button is held down, the following events will occur:

- a. A one second continuous tone warning signal comes on, during which no current is delivered. If the impedance is  $>3000$ , the warning tone is extended to 3 seconds. If the "TREAT" button is still pressed, the treatment will be delivered.
- b. The "TREAT" button lights up *and* an intermittent buzzing tone sounds while the current is being delivered.
- c. The "TREAT" button light and buzzing tone both turn off when the treatment stimulus ends. The "TREAT" button can then be released.
- d. The *Audible EEG*<sup>TM</sup> seizure monitor is activated (unless the volume is turned off) and the 4-channel printer automatically starts to provide a paper recording. If the printer is already running when the treatment stimulus is delivered, the printer will stop and automatically resume when the stimulus current ends.
- e. The 8-digit L.E.D. on the front panel automatically displays the number of seconds elapsed since the end of the stimulus.

*NOTE: It is important to continue pressing the "TREAT" button until the light and buzzing tone stop. Releasing the button early terminates the stimulus and delivers a smaller charge than intended. However, keeping pressure on the "TREAT" button after the stimulus ends, will not deliver additional stimulation. When holding the patient's jaw or touching the patient, make sure electrically insulated gloves are used.*

## SEIZURE MONITORING

The Thymatron® System IV allows the physician to monitor the physiological variables of EEG, ECG, and EMG. The paper tracing provides the wave forms and beats per minute for the ECG. The EEG and EMG also appear on the tracings, with additional information provided.

### EEG SEIZURE MONITORING

- 1) The *Audible EEG*<sup>TM</sup> seizure monitor
- 2) The EEG paper recording
- 3) The Ictal Line<sup>TM</sup> seizure indicator
- 4) The EEG endpoint and indexes determined values

#### *Audible EEG*<sup>TM</sup> Seizure Monitor

This feature operates automatically when the "TREAT" button is pressed and released. The knob marked "VOLUME" on the back panel controls the volume of the tone. To inactivate this feature, turn the volume control knob all the way counterclockwise.

The pitch of the *Audible EEG*<sup>TM</sup> signal varies with the amplitude of the EEG. It will waver and warble intensely and rapidly during the initial tonic phase. It becomes increasingly irregular, with superimposed staccato bursts, during the clonic phase, and tends to correspond to each muscular contraction. Seizure termination is marked by a change to a nearly steady tone with little modulation or variability. Each Thymatron® System IV is supplied with a cassette tape guide for the interpretation of the *Audible EEG*<sup>TM</sup> seizure monitor.

### *EEG paper recording*

- a) *Paper EEG recording prior to the treatment stimulus* can be initiated (after the EEG electrodes have been properly applied) by pressing the “START/STOP” button on the front panel. This will provide a paper record of the patient’s baseline recording. The printer stops during treatment stimulus administration.
- b) *Automatic paper EEG recording* begins or resumes when the treatment stimulus ends. The EEG recording continues through ictal and postictal periods, until the “START/STOP” button is pressed, which generates the end-of-treatment report.

**NOTE:** Obtaining a paper baseline EEG record does not replace *the baseline EEG collection* procedures described above.

### *Ictal Line*<sup>TM</sup> *Seizure Indicator*

After baseline EEG collection is completed by the Thymatron® System IV and the “READY” message light appears, a thin black line is printed along the top of the paper recording strip when the EEG amplitude exceeds a specified baseline value. An unbroken, solid black line reflects continuous seizure activity. A broken or intermittent line reflects waxing and waning, or intermittent seizure activity. Complete cessation of the black line reflects EEG seizure termination, as determined by the Thymatron® System IV. *Wait several seconds before pressing the “START/STOP” button to terminate recording because the computer takes that long to process and report the seizure endpoints and indices.*

### *Endpoints and Indices*

A unique feature of the Thymatron® System IV, (U.S. patents: 4873981, 4878498, 5269302 and 5871517), provides two computer-determined estimates of the duration of the induced seizure, derived from the EEG and EMG data.

### *Automatic EEG Seizure Endpoint Determination*

The Thymatron® System IV continuously monitors the EEG for the endpoint of seizure activity and prints the EEG seizure duration, in seconds, on the end-of-treatment report, *provided the baseline EEG collection procedures have been properly followed and the “READY” message has appeared. (If the treatment stimulus is administered before the “READY” message appears, automatic EEG analysis will not occur and the end-of-treatment report will state the message “Baseline not available.”)*

In about 10-20% of ECT treatments, the EEG endpoint is not readily determined (Abrams, 1997). This typically occurs when paroxysmal activity decreases too gradually to provide a clear visual endpoint, or when the immediate post-seizure EEG contains high amplitude activity. In these circumstances, inability to detect a precise EEG endpoint is expected with any method of examination. The Ictal Line™ might show an on-again-off-again broken line pattern, and the end-of-treatment report might state: “EEG Endpoint is not detected”.

### Automatic EMG (Motor) Seizure Endpoint Determination

The Thymatron® System IV is shipped with the EMG monitor enabled in channel 3. When EMG monitoring electrodes have been properly applied, the lead-wires and monitoring cable connected, then EMG tracing automatically appears on the paper record after the treatment stimulus ends.

The Thymatron® System IV continuously monitors the EMG for motor seizure activity and prints the EMG endpoint seizure duration in seconds, on the end-of-treatment report. Baseline EMG collection is neither required, nor possible, in obtaining this measure.

*CAUTION: The computer-derived endpoint seizure duration measures, including the Ictal Line™ seizure indicator, are derived solely by calculation and are provided to aid, not replace, the physician’s judgment. It is possible for seizure activity to continue in the brain after any or all of the computer reports indicate seizure termination. It is also possible for artifact to be interpreted by the computer programs as seizure activity.*

### GAIN AND POSITION SETTINGS

The factory preset “GAIN” and “POSITION” settings should produce the best results. For those who prefer individualized settings, please note that “POSITION” is always set *after* “GAIN”, because positioning of the tracing on the recording paper depends on the amplitude, or gain of the signal. Thus, it is always necessary to set the “GAIN” in a specific channel *before* setting the “POSITION”.

**FLEXDIAL™ → CHANN. [n] → G[n]-10 to G[n]-2000 → P[n]-AUTO, P[n]-0 to P[n]-800**

G[n]-OFF	Turns off printing in channel [n]
G[n]-10 to G[n]-2000	Adjusts channel [n] gain (in microvolts)
P[n]-AUTO	Selects <i>automatic</i> positioning for printing channel [n]
P[n]-0 to P[n]-800	Adjusts position on strip from 0 (bottom) to 800 (top)

*NOTE: The amplitudes of the tracings decrease as the gain numbers increase.*

## TURN OFF PRINTING IN A CHANNEL

To turn off printing in a given channel, set the gain for that channel to "OFF". If a given channel has been turned off, the other channels should be set to the "AUTO" position in order to evenly space the remaining tracings on the paper.

**FLEXDIAL™ → CHANN. [n] → G[n]-OFF**

## CHANGING EEG GAIN RAPIDLY

***TIP:** To rapidly change the gain in all EEG channels, while the printer is running, press, hold in and then rotate the FlexDial™ to print successive new gain values on the paper chart; release the FlexDial™ to lock in the desired value when it appears.*

## SEIZURE QUALITY MEASURES

The Thymatron® System IV provides 7 Seizure Quality Measures under the "INDEXES" function level that can be individually enabled/disabled. EEG monitoring must be enabled to obtain these measures. Their names and FlexDial™ designations are as follows:

<i>Average Seizure Energy Index</i>	ASEI ON/OFF
<i>Postictal Suppression Index</i>	PSI ON/OFF
<i>Maximum Sustained Power and Time to Peak Power</i>	MSP ON/OFF
<i>Maximum Sustained Coherence and Time to Peak Coherence</i>	COH ON/OFF
<i>Duke University Amplitude Measures</i>	DUKE ON/OFF

The AVERAGE SEIZURE ENERGY INDEX (ASEI) integrates the total ictal EEG power across the entire seizure and divides the result by the total seizure duration.

The POSTICTAL SUPPRESSION INDEX (PSI) measures the percentage decrease in ictal EEG amplitude immediately following seizure termination.

The MAXIMUM SUSTAINED POWER (MSP) measure reports the mean value of the 10-second EEG segment with the highest average power recorded during the seizure.

TIME TO PEAK POWER is the time elapsed from stimulus termination to the point of maximum EEG power.

The MAXIMUM SUSTAINED COHERENCE (COH) measure reports the mean value of the 5-second EEG segment with the highest average coherence recorded during the seizure.

**TIME TO PEAK COHERENCE** is the time elapsed from stimulus termination to the point of maximum EEG coherence.

**DUKE UNIVERSITY AMPLITUDE MEASURES** display the amplitudes of the 3 seizure segments (early ictal, mid-ictal, and post-ictal) reported by Duke University investigators to correlate with ECT treatment response.

#### **BASELINE RETENTION**

Baseline Retention, BLV, found under **ENDPOINTS**, is the length of time the EEG baseline will be kept in memory after the treatment. It can be set from 0 - 5 minutes. After this time a new EEG baseline must be acquired. This feature is useful for re-stimulation without acquiring a new EEG baseline.

#### **TO ENABLE/DISABLE SEIZURE QUALITY MEASURES**

**FLEXDIAL™ → INDEXES → AESI ON/OFF, PSI ON/OFF, MSP ON/OFF, COH ON/OFF, DUKE ON/OFF**

In the “INDEXES” function level, repeatedly *pressing* the *FlexDial™* will show a sequential flashing status display (ON/OFF) for ASEI, PSI, MSP, COH, and DUKE measures, in that order. *Rotating* the *FlexDial™* will flash-display the enable/disable (ON/OFF) options, for each index. *Press* the *FlexDial™* to select “ON” or “OFF” for each index and advance to the next. When the last index (DUKE) is enabled/disabled the display returns to INDEXES function level.

#### **EEG FREQUENCY MEASURES**

The Thymatron® System IV provides a continuously updated display of the user’s choice of one of 3 additional EEG measures: the *95% Spectral Edge Frequency* (the EEG frequency below which 95% of the total EEG power is found), the *Median Frequency* (the EEG frequency above and below which 50% of power is found) and the *Relative Delta Power* (the % EEG power found in the delta bandwidth: 1.5–3.5 Hz).

**FLEXDIAL™ → EEG FREQ → SP. EDGE, MID FREQ, % DELTA**

<b>SP. EDGE</b>	95% Spectral Edge Frequency
<b>MID FREQ</b>	Median EEG frequency
<b>% DELTA</b>	Relative EEG power in the delta bandwidth

When EEG FREQ is enabled with one of these options, baseline EEG collection has been obtained and the “READY” message appears, the values are continuously displayed in the 8-character L.E.D. After several seconds, the “READY” is replaced with the letter “R” to the right of the EEG values being displayed.

## PRINTER PAPER SPEED SELECTION

The Thymatron® System IV is shipped with the paper speed set to 25 mm/sec. Alternate paper speeds of 5 mm/sec and 50 mm/sec may be selected *or the printing turned off entirely*, as follows.

**FLEXDIAL™ → PRINTOUT → PRINT 5, PRINT 25, PRINT 50  
TURN OFF PRINTING ENTIRELY**

**FLEXDIAL™ → PRINTOUT → PRINTOFF**

## POWER SPECTRAL ANALYSIS (FFT) SELECTION

After the paper speed has been selected by *rotating* and then *pressing* the *FlexDial™*, the FFT option (“ON” or “OFF”) flash-displays. FFT (“Fast Fourier Transform”) is an algorithm for extracting frequency information from the EEG signal to perform a *Power Spectral Analysis* that displays the EEG frequencies in various bandwidths for advanced clinical or research purposes. The Thymatron® System IV is shipped with the FFT printout disabled; to enable this feature:

**FLEXDIAL™ → PRINTOUT → FFT ON, FFT OFF**

## USER SPECIFIED FLEXDIAL™ SELECTIONS

This feature allows the user to save and then recall up to 8 user-specified *FlexDial™* selections in the Thymatron® System IV memory. Individual doctors’ preferred range of *FlexDial™* settings can be saved as “USER” selections, or specific *FlexDial™* settings within a factory program can be saved, (e.g., turn channel 4 “OFF” and “UPLOAD” automatically.) Once the different user-specified selections have been made and locked in by *pressing* the IMPEDANCE TEST button or the START/STOP button, they may be saved as a USER selection as follows:

**FLEXDIAL™ → SAVE USR → SAVE US1-SAVE US8**

After they have been saved, these user-specified selections can be recalled using the “SETTING” function of the *FlexDial™* shell by selecting from the options “SET US1” through “SET US8”. *Be sure to remember or write down which number this specific configuration was saved as, so it can easily be recalled.*

**FLEXDIAL™ → SETTING → SET US1 – SET US8**

When a user-specified *FlexDial™* selection is in force, the “USER SET” dot L.E.D. on the front panel will light.

## RESET FLEXDIAL™ SETTINGS TO FACTORY VALUES

The factory-programmed values listed below for the 13 *FlexDial™*-selectable settings can be *reset* as a group as follows:

### FLEXDIAL™ → SETTING → RESET

Chann. 1.....G1--200  $\mu$ V; P1--AUTO  
Chann. 2.....G2--200  $\mu$ V; P2--AUTO  
Chann. 3.....G3--1000  $\mu$ V; P3--AUTO  
Chann. 4.....G4--1000  $\mu$ V; P4--AUTO  
FREQUENC.....Variable with LOW 0.5 program  
P-WIDTH.....0.5mS  
PROGRAMS....LOW 0.5 program  
CH. 3-4.....EMG-ECG  
ENDPOINT.....EEG-ON; EMG-ON; HR-ON; PHR-ON; ESA-OFF; BLV-2  
INDEXES.....ASEI-ON; PSI-ON; MSP-ON; COH-ON; DUKE-OFF  
EEG FREQ.....FREQ. OFF  
PRINTOUT.....PRINT-25; FFT-OFF  
UPLOAD.....LOAD - OFF

**TIP:** To quickly reset all values to factory settings right after the “SELFTEST” has been performed at power-on, *press* the *FlexDial™* three times in a row, then *press* the IMPEDANCE TEST button.

To print a report showing all the *FlexDial™* settings in effect at any given time, simply *press* the *FlexDial™* to enter any function level and then *press* the START/STOP button.

## TRANSFERRING DATA BETWEEN A PC AND THYMATRON® SYSTEM IV

The Thymatron® System IV allows the operator either to send data (upload) or to receive data (input or download) from a personal computer. The data transfers all require using GENIE™ IV software, which is included with the Thymatron® System IV. The data can be *alphanumeric*, such as the name of the hospital or patient information, or it can be *digitized* EEG, ECG, or EMG.

With the exception of the hospital's name, all data to be downloaded must have been first uploaded to a PC using the GENIE™ IV software. One reason for downloading this data to the Thymatron® System IV would be to print a paper copy of an earlier treatment.

**NOTE:** All procedures listed below require the GENIE™ IV software to be installed on a PC connected to the Thymatron® System IV through the rear panel RS 232 serial port and the GENIE™ IV software program opened to the proper section. Please consult the GENIE™ IV manual for further details.

## INPUT HOSPITAL NAME FOR THE PRINTED REPORT

This name will replace the Thymatron® System IV, S/N line on the start-up report.

### FLEXDIAL™ → DATA IN → DATA IN

1. Press the *FlexDial*™ to display the most recently adjusted *FlexDial*™ function.
2. Rotate the *FlexDial*™ until “DATA IN” is displayed.
3. Press the *FlexDial*™ once; “DATA IN” will flash-display.
4. Press the *FlexDial*™ again; “IN ← ← ←” will flash-display.
5. On the PC, from the GENIE™ IV software main menu, click on CONNECT → SEND NAME.
6. Type in hospital name in the “Name to Send” box and click “Send”.
7. Press the “IMPEDANCE TEST” or “START/STOP” button to exit the *FlexDial*™ mode.

## DOWNLOAD PRE-RECORDED TREATMENT DATA FROM PC FOR REPRINTING BY THYMATRON® SYSTEM IV

### FLEXDIAL™ → DATA IN → DATA IN

This feature allows for previously recorded treatment data to be sent back to the Thymatron® System IV. Once the data has been received back in the Thymatron® System IV, it can then be reprinted using the “REPRINT” option in the “DATA OUT” function level.

1. Press the *FlexDial*™ to display the most recently adjusted *FlexDial*™ function.
2. Rotate the *FlexDial*™ until “DATA IN” is displayed.
3. Press the *FlexDial*™ once; “DATA IN” will flash-display.
4. Press the *FlexDial*™ again; “IN← ← ←” will flash-display.
5. On the PC, from the GENIE™ IV software main menu, click on FILE → OPEN. Highlight the file to be sent and click OPEN. From the main menu, click on CONNECT → SEND DATA.
6. Transfer is complete when the display stops flashing and returns to “DATA IN”.
7. Press the “IMPEDANCE TEST” or “START/STOP” button to exit the *FlexDial*™ mode.

This treatment data will now replace that of the last treatment given and will stay in the Thymatron® System IV memory until the unit is turned off or another treatment is given. To reprint this treatment on a paper record, see the DATA OUT section below.

## UPLOAD TREATMENT DATA AUTOMATICALLY TO A PC

This feature allows for the automatic transfer of the treatment data to a PC after the printed end-of-treatment report. The PC must be connected to the Thymatron®

System IV and the Genie™ IV software opened to the correct function; please review the GENIE™ IV manual for further details. The options are as follows:

LOAD OFF	Disables UPLOAD function and no data will be transferred.
LOAD RAW	Sends all EEG data, including the FFT points and end-of-treatment report.
LOAD FFT	Sends all FFT points and end-of-treatment report.
LOAD TXT	Sends ASCII file of the end-of-treatment report.

### **FLEXDIAL™ → UPLOAD → LOAD OFF, LOAD RAW, LOAD FFT, LOAD TXT**

1. Press the *FlexDial*™ to display the most recently adjusted *FlexDial*™ function.
2. Rotate the *FlexDial*™ until “UPLOAD” is displayed.
3. Press and rotate the *FlexDial*™ to flash-display the above options.
4. Press the *FlexDial*™ to select the desired option, usually “LOAD RAW”.
5. Press the “IMPEDANCE TEST” or “START/STOP” button to exit the *FlexDial*™ mode.

After the patient is treated and the end-of-treatment report is printed, the Thymatron® System IV is ready to send the data to the PC. Make sure all the connections are correct and the GENIE™ IV software is opened. From the GENIE™ IV main menu click on CONNECT → AUTO UPLOAD. A small screen will pop up showing the progress of the transfer. When the transfer is complete a new REPORT screen pops up with the treatment date and time.

*Note: The transferred file will be automatically saved as the “date and time” of the treatment. This file can then be renamed and saved under the proper patient’s file by selecting from the GENIE™ IV main menu FILE → SAVE AS.*

### **MONITOR EEG/EMG/ECG ON THE PC SCREEN**

This feature allows for real-time monitoring of all enabled EEG/EMG/ECG channels via the PC screen, providing a constantly updated display of the actual EEG/EMG/ECG tracings before and after the treatment stimulus has been administered. *This monitoring will not affect the printed paper recording.*

Before starting to monitor, make sure all the connections are correct and the GENIE™ IV software is opened. From the GENIE™ IV main menu, click on WINDOW → GRAPH. From the main menu, click on TOOLS → PLAY CONTROL and then TOOLS → CHANNEL SETTING. Adjust the size of the graph screen to allow for these two pop up screens. To start the monitoring, follow the procedure below:

1. Press the IMPEDANCE TEST button to begin sending data.
2. Click on MONITOR in the PLAY CONTROL section.

The monitoring will stop while the treatment stimulus is given with the “TREAT” button and it will automatically re-start after the stimulus is completed. The monitoring function will not interfere with the paper recording function as both will proceed at the same time. When the “START/STOP” button is pressed, the monitoring will also stop.

*NOTE: To combine the monitoring and automatic upload features, go to the GENIE™ IV main menu, click on CONNECT → AUTO UPLOAD. A small screen will pop up with the date & time for the name. Re-name the file using the patient’s information, if desired and click UPLOAD. From the GENIE™ IV main menu, click on WINDOWS → GRAPH and then TOOLS → PLAY CONTROL and TOOLS → CHANNEL SETTING as above.*

## OUTPUT TREATMENT DATA MANUALLY

This feature allows for manual transfer of the treatment data after the end of a given treatment. The Thymatron® System IV stores only the last treatment in memory. *If the unit is turned off or another treatment is given before data transfer, this data will be lost.* This feature can be used when an occasional treatment is to be stored on the PC. Make sure all the connections are correct and the GENIE™ IV procedures are followed. Please review the GENIE™ IV manual. The options for “DATA OUT” are:

- REPRINT Reprints a complete record of the treatment just given, or can be used to reprint the treatment data just received from the PC.
- RAW DATA Sends all data including the FFT points and end-of-treatment report.
- FFT DATA Sends the FFT points and end-of-treatment report.
- RESULTS Sends ASCII files of end-of-treatment report.
- RETURN Returns to the DATA OUT function level of the *FlexDial™*.

## FLEXDIAL™ → DATA OUT → REPRINT, RAW DATA, FFT DATA, RESULTS, RETURN

1. Press the *FlexDial™* to display the most recently adjusted *FlexDial™* function.
2. Rotate the *FlexDial™* until “DATA OUT” is displayed.
3. Press and rotate the *FlexDial™* to flash-display the options listed above.
4. Press the *FlexDial™* to select the desired option, usually “RAW DATA”.
5. The message “OUT → → →” appears as the data is transferred to the computer.
6. *If no treatment data is stored in memory the message “EMPTY” will flash and no data transfer will occur.*
7. From the GENIE™ IV main menu, click on CONNECT → RECEIVE DATA. The small pop up screen will display the transfer progress. When finished, a new pop up screen, REPORT will contain the data. This file may be saved using the main menu FILE → SAVE AS feature.
8. When the transfer is complete, the *FlexDial™* display returns to “DATA OUT”.
9. Press the “IMPEDANCE TEST” or “START/STOP” button to exit the *FlexDial™* mode.

## REPRINT THE LAST TREATMENT

The Thymatron® System IV automatically stores the last treatment in memory. If the recording paper runs out or is damaged, the last treatment can be reprinted using this feature. This “REPRINT” feature also allows for the reprinting of the treatment data *just* transferred to the Thymatron® System IV from the PC. In either case, the only treatment reprinted will be the last one in the memory. *If the unit is turned off, another treatment is transferred from the computer or another treatment is given, the earlier treatment data will be lost.* The procedure for reprinting the treatment data is:

### FLEXDIAL™ → DATA OUT → REPRINT

While the treatment data is being reprinted, the “REPRINT” message will flash until all the data has been reprinted, after which the printer will automatically stop, providing the original data contained an end-of-treatment report.

## SET DATE & TIME IN PRINTED REPORT

To change/reset the time or date, use the following procedure. Enter the *FlexDial™* mode, *rotate* to the “CLOCK” function level and then alternate *pressing* and *rotating* the *FlexDial™* to make the following selections:

### FLEXDIAL™ → CLOCK → MONTH → DAY → YEAR → HOUR → MIN

MONTH	01 - 12
DAY	01 - 31
YEAR	00 - 99
HOUR	00 - 24
MIN	00 - 60

**TABLE 1: STANDARD DOSE STIMULUS PARAMETERS: STIMULUS DURATION (in seconds), CHARGE (in mC), AND JOULES (AT 220 OHMS IMPEDANCE) AT EVERY PERCENT ENERGY DIAL SETTING FOR ALL PW AND FREQUENCY COMBINATIONS**

FREQ = 10	PW= .25		
DIAL	DURATION	mC	JOULES
5 %	5.60	25.2	5.0
FREQ = 20	PW= .25		
DIAL	DURATION	mC	JOULES
5 %	2.80	25.2	5.0
10 %	5.60	50.4	10.0
FREQ = 30	PW= .25		
DIAL	DURATION	mC	JOULES
5 %	1.87	25.2	5.0
10 %	3.73	50.4	10.0
15 %	5.60	75.6	15.0
20 %	7.47	100.8	20.0
FREQ = 40	PW= .25		
DIAL	DURATION	mC	JOULES
5 %	1.40	25.2	5.0
10 %	2.80	50.4	10.0
15 %	4.20	75.6	15.0
20 %	5.60	100.8	20.0
25 %	7.00	126	24.9
FREQ = 50	PW= .25		
DIAL	DURATION	mC	JOULES
5 %	1.12	25.2	5.0
10 %	2.24	50.4	10.0
15 %	3.36	75.6	15.0
20 %	4.48	100.8	20.0
25 %	5.60	126	24.9
30 %	6.72	151.2	29.9
35 %	7.84	176.4	34.9
FREQ = 60	PW= .25		
DIAL	DURATION	mC	JOULES
5 %	0.93	25.2	5.0
10 %	1.87	50.4	10.0
15 %	2.80	75.6	15.0
20 %	3.73	100.8	20.0
25 %	4.67	126	24.9
30 %	5.60	151.2	29.9
35 %	6.53	176.4	34.9
40 %	7.47	201.6	39.9
FREQ = 70	PW= .25		
DIAL	DURATION	mC	JOULES
5 %	0.80	25.2	5.0
10 %	1.60	50.4	10.0
15 %	2.40	75.6	15.0

20 %	3.20	100.8	20.0
25 %	4.00	126	24.9
30 %	4.80	151.2	29.9
35 %	5.60	176.4	34.9
40 %	6.40	201.6	39.9
45 %	7.20	226.8	44.9
50 %	8.00	252	49.9

FREQ =	10	PW= .5		
DIAL		DURATION	mC	JOULES
5 %		2.80	25.2	5.0
10 %		5.60	50.4	10.0

FREQ =	20	PW= .5		
DIAL		DURATION	mC	JOULES
5 %		1.40	25.2	5.0
10 %		2.80	50.4	10.0
15 %		4.20	75.6	15.0
20 %		5.60	100.8	20.0
25 %		7.00	126	24.9

FREQ =	30	PW= .5		
DIAL		DURATION	mC	JOULES
5 %		0.93	25.2	5.0
10 %		1.87	50.4	10.0
15 %		2.80	75.6	15.0
20 %		3.73	100.8	20.0
25 %		4.67	126	24.9
30 %		5.60	151.2	29.9
35 %		6.53	176.4	34.9
40 %		7.47	201.6	39.9

FREQ =	40	PW= .5		
DIAL		DURATION	mC	JOULES
5 %		0.70	25.2	5.0
10 %		1.40	50.4	10.0
15 %		2.10	75.6	15.0
20 %		2.80	100.8	20.0
25 %		3.50	126	24.9
30 %		4.20	151.2	29.9
35 %		4.90	176.4	34.9
40 %		5.60	201.6	39.9
45 %		6.30	226.8	44.9
50 %		7.00	252	49.9
55 %		7.70	277.2	54.9

FREQ =	50	PW= .5		
DIAL		DURATION	mC	JOULES
5 %		0.56	25.2	5.0
10 %		1.12	50.4	10.0
15 %		1.68	75.6	15.0
20 %		2.24	100.8	20.0
25 %		2.80	126	24.9
30 %		3.36	151.2	29.9
35 %		3.92	176.4	34.9
40 %		4.48	201.6	39.9
45 %		5.04	226.8	44.9

50 %	5.60	252	49.9
55 %	6.16	277.2	54.9
60 %	6.72	302.4	59.9
65 %	7.28	327.6	64.9
70 %	7.84	352.8	69.9

FREQ = 60		PW= .5	
DIAL	DURATION	mC	JOULES
5 %	0.47	25.2	5.0
10 %	0.93	50.4	10.0
15 %	1.40	75.6	15.0
20 %	1.87	100.8	20.0
25 %	2.33	126	24.9
30 %	2.80	151.2	29.9
35 %	3.27	176.4	34.9
40 %	3.73	201.6	39.9
45 %	4.20	226.8	44.9
50 %	4.67	252	49.9
55 %	5.13	277.2	54.9
60 %	5.60	302.4	59.9
65 %	6.07	327.6	64.9
70 %	6.53	352.8	69.9
75 %	7.00	378	74.8
80 %	7.47	403.2	79.8
85 %	7.93	428.4	84.8

FREQ = 70		PW= .5	
DIAL	DURATION	mC	JOULES
5 %	0.40	25.2	5.0
10 %	0.80	50.4	10.0
15 %	1.20	75.6	15.0
20 %	1.60	100.8	20.0
25 %	2.00	126	24.9
30 %	2.40	151.2	29.9
35 %	2.80	176.4	34.9
40 %	3.20	201.6	39.9
45 %	3.60	226.8	44.9
50 %	4.00	252	49.9
55 %	4.40	277.2	54.9
60 %	4.80	302.4	59.9
65 %	5.20	327.6	64.9
70 %	5.60	352.8	69.9
75 %	6.00	378	74.8
80 %	6.40	403.2	79.8
85 %	6.80	428.4	84.8
90 %	7.20	453.6	89.8
95 %	7.60	478.8	94.8
100 %	8.00	504	99.8

FREQ = 10		PW= .75	
DIAL	DURATION	mC	JOULES
5 %	1.87	25.2	5.0
10 %	3.73	50.4	10.0
15 %	5.60	75.6	15.0
20 %	7.47	100.8	20.0

FREQ = 20 PW= .75

DIAL	DURATION	mC	JOULES
5 %	0.93	25.2	5.0
10 %	1.87	50.4	10.0
15 %	2.80	75.6	15.0
20 %	3.73	100.8	20.0
25 %	4.67	126	24.9
30 %	5.60	151.2	29.9
35 %	6.53	176.4	34.9
40 %	7.47	201.6	39.9

FREQ = 30 PW= .75

DIAL	DURATION	mC	JOULES
5 %	0.62	25.2	5.0
10 %	1.24	50.4	10.0
15 %	1.87	75.6	15.0
20 %	2.49	100.8	20.0
25 %	3.11	126	24.9
30 %	3.73	151.2	29.9
35 %	4.36	176.4	34.9
40 %	4.98	201.6	39.9
45 %	5.60	226.8	44.9
50 %	6.22	252	49.9
55 %	6.84	277.2	54.9
60 %	7.47	302.4	59.9

FREQ = 40 PW= .75

DIAL	DURATION	mC	JOULES
5 %	0.47	25.2	5.0
10 %	0.93	50.4	10.0
15 %	1.40	75.6	15.0
20 %	1.87	100.8	20.0
25 %	2.33	126	24.9
30 %	2.80	151.2	29.9
35 %	3.27	176.4	34.9
40 %	3.73	201.6	39.9
45 %	4.20	226.8	44.9
50 %	4.67	252	49.9
55 %	5.13	277.2	54.9
60 %	5.60	302.4	59.9
65 %	6.07	327.6	64.9
70 %	6.53	352.8	69.9
75 %	7.00	378	74.8
80 %	7.47	403.2	79.8
85 %	7.93	428.4	84.8

FREQ = 50 PW= .75

DIAL	DURATION	mC	JOULES
5 %	0.37	25.2	5.0
10 %	0.75	50.4	10.0
15 %	1.12	75.6	15.0
20 %	1.49	100.8	20.0
25 %	1.87	126	24.9
30 %	2.24	151.2	29.9
35 %	2.61	176.4	34.9
40 %	2.99	201.6	39.9
45 %	3.36	226.8	44.9

50 %	3.73	252	49.9
55 %	4.11	277.2	54.9
60 %	4.48	302.4	59.9
65 %	4.85	327.6	64.9
70 %	5.23	352.8	69.9
75 %	5.60	378	74.8
80 %	5.97	403.2	79.8
85 %	6.35	428.4	84.8
90 %	6.72	453.6	89.8
95 %	7.09	478.8	94.8
100 %	7.47	504	99.8

FREQ = 60 PW= .75

DIAL	DURATION	mC	JOULES
5 %	0.31	25.2	5.0
10 %	0.62	50.4	10.0
15 %	0.93	75.6	15.0
20 %	1.24	100.8	20.0
25 %	1.56	126	24.9
30 %	1.87	151.2	29.9
35 %	2.18	176.4	34.9
40 %	2.49	201.6	39.9
45 %	2.80	226.8	44.9
50 %	3.11	252	49.9
55 %	3.42	277.2	54.9
60 %	3.73	302.4	59.9
65 %	4.04	327.6	64.9
70 %	4.36	352.8	69.9
75 %	4.67	378	74.8
80 %	4.98	403.2	79.8
85 %	5.29	428.4	84.8
90 %	5.60	453.6	89.8
95 %	5.91	478.8	94.8
100 %	6.22	504	99.8

FREQ = 70 PW= .75

DIAL	DURATION	mC	JOULES
5 %	0.27	25.2	5.0
10 %	0.53	50.4	10.0
15 %	0.80	75.6	15.0
20 %	1.07	100.8	20.0
25 %	1.33	126	24.9
30 %	1.60	151.2	29.9
35 %	1.87	176.4	34.9
40 %	2.13	201.6	39.9
45 %	2.40	226.8	44.9
50 %	2.67	252	49.9
55 %	2.93	277.2	54.9
60 %	3.20	302.4	59.9
65 %	3.47	327.6	64.9
70 %	3.73	352.8	69.9
75 %	4.00	378	74.8
80 %	4.27	403.2	79.8
85 %	4.53	428.4	84.8
90 %	4.80	453.6	89.8
95 %	5.07	478.8	94.8
100 %	5.33	504	99.8

FREQ = 10		PW= 1	
DIAL	DURATION	mC	JOULES
5 %	1.40	25.2	5.0
10 %	2.80	50.4	10.0
15 %	4.20	75.6	15.0
20 %	5.60	100.8	20.0
25 %	7.00	126	24.9

FREQ = 20		PW= 1	
DIAL	DURATION	mC	JOULES
5 %	0.70	25.2	5.0
10 %	1.40	50.4	10.0
15 %	2.10	75.6	15.0
20 %	2.80	100.8	20.0
25 %	3.50	126	24.9
30 %	4.20	151.2	29.9
35 %	4.90	176.4	34.9
40 %	5.60	201.6	39.9
45 %	6.30	226.8	44.9
50 %	7.00	252	49.9
55 %	7.70	277.2	54.9

FREQ = 30		PW= 1	
DIAL	DURATION	mC	JOULES
5 %	0.47	25.2	5.0
10 %	0.93	50.4	10.0
15 %	1.40	75.6	15.0
20 %	1.87	100.8	20.0
25 %	2.33	126	24.9
30 %	2.80	151.2	29.9
35 %	3.27	176.4	34.9
40 %	3.73	201.6	39.9
45 %	4.20	226.8	44.9
50 %	4.67	252	49.9
55 %	5.13	277.2	54.9
60 %	5.60	302.4	59.9
65 %	6.07	327.6	64.9
70 %	6.53	352.8	69.9
75 %	7.00	378	74.8
80 %	7.47	403.2	79.8
85 %	7.93	428.4	84.8

FREQ = 40		PW= 1	
DIAL	DURATION	mC	JOULES
5 %	0.35	25.2	5.0
10 %	0.70	50.4	10.0
15 %	1.05	75.6	15.0
20 %	1.40	100.8	20.0
25 %	1.75	126	24.9
30 %	2.10	151.2	29.9
35 %	2.45	176.4	34.9
40 %	2.80	201.6	39.9
45 %	3.15	226.8	44.9
50 %	3.50	252	49.9
55 %	3.85	277.2	54.9
60 %	4.20	302.4	59.9

65 %	4.55	327.6	64.9
70 %	4.90	352.8	69.9
75 %	5.25	378	74.8
80 %	5.60	403.2	79.8
85 %	5.95	428.4	84.8
90 %	6.30	453.6	89.8
95 %	6.65	478.8	94.8
100 %	7.00	504	99.8

FREQ = 50		PW= 1	
DIAL	DURATION	mC	JOULES
5 %	0.28	25.2	5.0
10 %	0.56	50.4	10.0
15 %	0.84	75.6	15.0
20 %	1.12	100.8	20.0
25 %	1.40	126	24.9
30 %	1.68	151.2	29.9
35 %	1.96	176.4	34.9
40 %	2.24	201.6	39.9
45 %	2.52	226.8	44.9
50 %	2.80	252	49.9
55 %	3.08	277.2	54.9
60 %	3.36	302.4	59.9
65 %	3.64	327.6	64.9
70 %	3.92	352.8	69.9
75 %	4.20	378	74.8
80 %	4.48	403.2	79.8
85 %	4.76	428.4	84.8
90 %	5.04	453.6	89.8
95 %	5.32	478.8	94.8
100 %	5.60	504	99.8

FREQ = 60		PW= 1	
DIAL	DURATION	mC	JOULES
5 %	0.23	25.2	5.0
10 %	0.47	50.4	10.0
15 %	0.70	75.6	15.0
20 %	0.93	100.8	20.0
25 %	1.17	126	24.9
30 %	1.40	151.2	29.9
35 %	1.63	176.4	34.9
40 %	1.87	201.6	39.9
45 %	2.10	226.8	44.9
50 %	2.33	252	49.9
55 %	2.57	277.2	54.9
60 %	2.80	302.4	59.9
65 %	3.03	327.6	64.9
70 %	3.27	352.8	69.9
75 %	3.50	378	74.8
80 %	3.73	403.2	79.8
85 %	3.97	428.4	84.8
90 %	4.20	453.6	89.8
95 %	4.43	478.8	94.8
100 %	4.67	504	99.8

FREQ = 70		PW= 1	
DIAL	DURATION	mC	JOULES
5 %	0.20	25.2	5.0
10 %	0.40	50.4	10.0
15 %	0.60	75.6	15.0
20 %	0.80	100.8	20.0
25 %	1.00	126	24.9
30 %	1.20	151.2	29.9
35 %	1.40	176.4	34.9
40 %	1.60	201.6	39.9
45 %	1.80	226.8	44.9
50 %	2.00	252	49.9
55 %	2.20	277.2	54.9
60 %	2.40	302.4	59.9
65 %	2.60	327.6	64.9
70 %	2.80	352.8	69.9
75 %	3.00	378	74.8
80 %	3.20	403.2	79.8
85 %	3.40	428.4	84.8
90 %	3.60	453.6	89.8
95 %	3.80	478.8	94.8
100 %	4.00	504	99.8

FREQ = 10		PW= 1.25	
DIAL	DURATION	mC	JOULES
5 %	1.12	25.2	5.0
10 %	2.24	50.4	10.0
15 %	3.36	75.6	15.0
20 %	4.48	100.8	20.0
25 %	5.60	126	24.9
30 %	6.72	151.2	29.9
35 %	7.84	176.4	34.9

FREQ = 20		PW= 1.25	
DIAL	DURATION	mC	JOULES
5 %	0.56	25.2	5.0
10 %	1.12	50.4	10.0
15 %	1.68	75.6	15.0
20 %	2.24	100.8	20.0
25 %	2.80	126	24.9
30 %	3.36	151.2	29.9
35 %	3.92	176.4	34.9
40 %	4.48	201.6	39.9
45 %	5.04	226.8	44.9
50 %	5.60	252	49.9
55 %	6.16	277.2	54.9
60 %	6.72	302.4	59.9
65 %	7.28	327.6	64.9
70 %	7.84	352.8	69.9

FREQ = 30		PW= 1.25	
DIAL	DURATION	mC	JOULES
5 %	0.37	25.2	5.0
10 %	0.75	50.4	10.0
15 %	1.12	75.6	15.0
20 %	1.49	100.8	20.0
25 %	1.87	126	24.9

30 %	2.24	151.2	29.9
35 %	2.61	176.4	34.9
40 %	2.99	201.6	39.9
45 %	3.36	226.8	44.9
50 %	3.73	252	49.9
55 %	4.11	277.2	54.9
60 %	4.48	302.4	59.9
65 %	4.85	327.6	64.9
70 %	5.23	352.8	69.9
75 %	5.60	378	74.8
80 %	5.97	403.2	79.8
85 %	6.35	428.4	84.8
90 %	6.72	453.6	89.8
95 %	7.09	478.8	94.8
100 %	7.47	504	99.8

FREQ = 40		PW= 1.25	
DIAL	DURATION	mC	JOULES
5 %	0.28	25.2	5.0
10 %	0.56	50.4	10.0
15 %	0.84	75.6	15.0
20 %	1.12	100.8	20.0
25 %	1.40	126	24.9
30 %	1.68	151.2	29.9
35 %	1.96	176.4	34.9
40 %	2.24	201.6	39.9
45 %	2.52	226.8	44.9
50 %	2.80	252	49.9
55 %	3.08	277.2	54.9
60 %	3.36	302.4	59.9
65 %	3.64	327.6	64.9
70 %	3.92	352.8	69.9
75 %	4.20	378	74.8
80 %	4.48	403.2	79.8
85 %	4.76	428.4	84.8
90 %	5.04	453.6	89.8
95 %	5.32	478.8	94.8
100 %	5.60	504	99.8

FREQ = 50		PW= 1.25	
DIAL	DURATION	mC	JOULES
5 %	0.22	25.2	5.0
10 %	0.45	50.4	10.0
15 %	0.67	75.6	15.0
20 %	0.90	100.8	20.0
25 %	1.12	126	24.9
30 %	1.34	151.2	29.9
35 %	1.57	176.4	34.9
40 %	1.79	201.6	39.9
45 %	2.02	226.8	44.9
50 %	2.24	252	49.9
55 %	2.46	277.2	54.9
60 %	2.69	302.4	59.9
65 %	2.91	327.6	64.9
70 %	3.14	352.8	69.9
75 %	3.36	378	74.8
80 %	3.58	403.2	79.8

85 %	3.81	428.4	84.8
90 %	4.03	453.6	89.8
95 %	4.26	478.8	94.8
100 %	4.48	504	99.8

FREQ = 60		PW= 1.25	
DIAL	DURATION	mC	JOULES
5 %	0.19	25.2	5.0
10 %	0.37	50.4	10.0
15 %	0.56	75.6	15.0
20 %	0.75	100.8	20.0
25 %	0.93	126	24.9
30 %	1.12	151.2	29.9
35 %	1.31	176.4	34.9
40 %	1.49	201.6	39.9
45 %	1.68	226.8	44.9
50 %	1.87	252	49.9
55 %	2.05	277.2	54.9
60 %	2.24	302.4	59.9
65 %	2.43	327.6	64.9
70 %	2.61	352.8	69.9
75 %	2.80	378	74.8
80 %	2.99	403.2	79.8
85 %	3.17	428.4	84.8
90 %	3.36	453.6	89.8
95 %	3.55	478.8	94.8
100 %	3.73	504	99.8

FREQ = 70		PW= 1.25	
DIAL	DURATION	mC	JOULES
5 %	0.16	25.2	5.0
10 %	0.32	50.4	10.0
15 %	0.48	75.6	15.0
20 %	0.64	100.8	20.0
25 %	0.80	126	24.9
30 %	0.96	151.2	29.9
35 %	1.12	176.4	34.9
40 %	1.28	201.6	39.9
45 %	1.44	226.8	44.9
50 %	1.60	252	49.9
55 %	1.76	277.2	54.9
60 %	1.92	302.4	59.9
65 %	2.08	327.6	64.9
70 %	2.24	352.8	69.9
75 %	2.40	378	74.8
80 %	2.56	403.2	79.8
85 %	2.72	428.4	84.8
90 %	2.88	453.6	89.8
95 %	3.04	478.8	94.8
100 %	3.20	504	99.8

FREQ = 10		PW= 1.5	
DIAL	DURATION	mC	JOULES
5 %	0.93	25.2	5.0
10 %	1.87	50.4	10.0
15 %	2.80	75.6	15.0
20 %	3.73	100.8	20.0

25 %	4.67	126	24.9
30 %	5.60	151.2	29.9
35 %	6.53	176.4	34.9
40 %	7.47	201.6	39.9

FREQ = 20		PW= 1.5	
DIAL	DURATION	mC	JOULES
5 %	0.47	25.2	5.0
10 %	0.93	50.4	10.0
15 %	1.40	75.6	15.0
20 %	1.87	100.8	20.0
25 %	2.33	126	24.9
30 %	2.80	151.2	29.9
35 %	3.27	176.4	34.9
40 %	3.73	201.6	39.9
45 %	4.20	226.8	44.9
50 %	4.67	252	49.9
55 %	5.13	277.2	54.9
60 %	5.60	302.4	59.9
65 %	6.07	327.6	64.9
70 %	6.53	352.8	69.9
75 %	7.00	378	74.8
80 %	7.47	403.2	79.8
85 %	7.93	428.4	84.8

FREQ = 30		PW= 1.5	
DIAL	DURATION	mC	JOULES
5 %	0.31	25.2	5.0
10 %	0.62	50.4	10.0
15 %	0.93	75.6	15.0
20 %	1.24	100.8	20.0
25 %	1.56	126	24.9
30 %	1.87	151.2	29.9
35 %	2.18	176.4	34.9
40 %	2.49	201.6	39.9
45 %	2.80	226.8	44.9
50 %	3.11	252	49.9
55 %	3.42	277.2	54.9
60 %	3.73	302.4	59.9
65 %	4.04	327.6	64.9
70 %	4.36	352.8	69.9
75 %	4.67	378	74.8
80 %	4.98	403.2	79.8
85 %	5.29	428.4	84.8
90 %	5.60	453.6	89.8
95 %	5.91	478.8	94.8
100 %	6.22	504	99.8

FREQ = 40		PW= 1.5	
DIAL	DURATION	mC	JOULES
5 %	0.23	25.2	5.0
10 %	0.47	50.4	10.0
15 %	0.70	75.6	15.0
20 %	0.93	100.8	20.0
25 %	1.17	126	24.9
30 %	1.40	151.2	29.9
35 %	1.63	176.4	34.9

40 %	1.87	201.6	39.9
45 %	2.10	226.8	44.9
50 %	2.33	252	49.9
55 %	2.57	277.2	54.9
60 %	2.80	302.4	59.9
65 %	3.03	327.6	64.9
70 %	3.27	352.8	69.9
75 %	3.50	378	74.8
80 %	3.73	403.2	79.8
85 %	3.97	428.4	84.8
90 %	4.20	453.6	89.8
95 %	4.43	478.8	94.8
100 %	4.67	504	99.8

FREQ = 50		PW= 1.5	
DIAL	DURATION	mC	JOULES
5 %	0.19	25.2	5.0
10 %	0.37	50.4	10.0
15 %	0.56	75.6	15.0
20 %	0.75	100.8	20.0
25 %	0.93	126	24.9
30 %	1.12	151.2	29.9
35 %	1.31	176.4	34.9
40 %	1.49	201.6	39.9
45 %	1.68	226.8	44.9
50 %	1.87	252	49.9
55 %	2.05	277.2	54.9
60 %	2.24	302.4	59.9
65 %	2.43	327.6	64.9
70 %	2.61	352.8	69.9
75 %	2.80	378	74.8
80 %	2.99	403.2	79.8
85 %	3.17	428.4	84.8
90 %	3.36	453.6	89.8
95 %	3.55	478.8	94.8
100 %	3.73	504	99.8

FREQ = 60		PW= 1.5	
DIAL	DURATION	mC	JOULES
5 %	0.16	25.2	5.0
10 %	0.31	50.4	10.0
15 %	0.47	75.6	15.0
20 %	0.62	100.8	20.0
25 %	0.78	126	24.9
30 %	0.93	151.2	29.9
35 %	1.09	176.4	34.9
40 %	1.24	201.6	39.9
45 %	1.40	226.8	44.9
50 %	1.56	252	49.9
55 %	1.71	277.2	54.9
60 %	1.87	302.4	59.9
65 %	2.02	327.6	64.9
70 %	2.18	352.8	69.9
75 %	2.33	378	74.8
80 %	2.49	403.2	79.8
85 %	2.64	428.4	84.8
90 %	2.80	453.6	89.8

95 %	2.96	478.8	94.8
100 %	3.11	504	99.8

FREQ = 70

PW= 1.5

DIAL	DURATION	mC	JOULES
5 %	0.13	25.2	5.0
10 %	0.27	50.4	10.0
15 %	0.40	75.6	15.0
20 %	0.53	100.8	20.0
25 %	0.67	126	24.9
30 %	0.80	151.2	29.9
35 %	0.93	176.4	34.9
40 %	1.07	201.6	39.9
45 %	1.20	226.8	44.9
50 %	1.33	252	49.9
55 %	1.47	277.2	54.9
60 %	1.60	302.4	59.9
65 %	1.73	327.6	64.9
70 %	1.87	352.8	69.9
75 %	2.00	378	74.8
80 %	2.13	403.2	79.8
85 %	2.27	428.4	84.8
90 %	2.40	453.6	89.8
95 %	2.53	478.8	94.8
100 %	2.67	504	99.8

**TABLE 2: DOUBLE DOSE PARAMETERS: Frequency (in Hertz), Pulsewidth (in milliseconds) and Stimulus Duration (in seconds), for each Energy Dial Setting above 100%. *\*(Not available in USA or Canada)***

The 2X Dose and 2X LP programs provide the only method for exceeding the 100% Energy maximum of the Thymatron® System IV. When selected, either program automatically chooses the requisite frequency and pulsewidth, which are then NOT user-selectable. It is not possible to further set either frequency or pulsewidth because the Thymatron® System IV will not go past 100% Energy with manual (FlexDial) selection of these variables.

% Energy	2X Dose			2X Dose Lowest Pulsewidth		
	Freq. Hz	Pulse Width	Duration Sec.	Freq. Hz	Pulse width	Duration Sec.
5	10 Hz	0.5 ms	2.75 sec	10 Hz	0.25 ms	5.55 sec
10	10	0.5	5.55	20	0.25	5.58
15	20	0.5	4.18	30	0.25	5.58
20	20	0.5	5.58	30	0.25	7.45
25	30	0.5	4.65	40	0.25	6.99
30	30	0.5	5.58	50	0.25	6.71
35	30	0.5	6.52	50	0.25	7.83
40	30	0.5	7.45	60	0.25	7.46
45	40	0.5	6.29	70	0.25	7.19
50	40	0.5	6.99	70	0.25	7.99
55	50	0.5	6.15	80	0.25	7.69
60	50	0.5	6.71	90	0.25	7.46
65	50	0.5	7.27	100	0.25	7.28
70	50	0.5	7.83	100	0.25	7.84
75	60	0.5	6.99	110	0.25	7.63
80	60	0.5	7.46	120	0.25	7.46
85	70	0.5	6.79	120	0.25	7.93
90	70	0.5	7.19	130	0.25	7.75
95	70	0.5	7.59	140	0.25	7.60
100	70	0.5	7.99	140	0.25	8.00
110	60	0.75	6.83	100	0.4	7.70
120	60	0.75	7.46	110	0.4	7.63
130	70	0.75	6.83	120	0.4	7.58
140	70	0.75	7.46	100	0.5	7.84
150	70	0.75	7.99	110	0.5	7.63
160	60	1.0	7.46	120	0.5	7.46
170	60	1.0	7.93	120	0.5	7.93
180	70	1.0	7.19	110	0.6	7.63
190	70	1.0	7.59	120	0.6	7.38
200	70	1.0	7.99	100	0.7	8.00

## EMC SUPPLEMENT

- 1. An externally generated artifact is indicated if all the channels exhibit the same pattern superimposed on or interfering with the signal. Try repositioning the electrode leads to eliminate this pattern.**
- 2. A power mains artifact is indicated if all channels exhibit a thick solid line. Try repositioning the electrode leads to eliminate this.**
- 3. A large static discharge may cause the system to reset. The system would go through the “SELFTEST” again and be ready to treat in about five seconds. To minimize static electricity make sure to maintain sufficient humidity in the treatment room and have a good grounding system on your mains.**
- 4. A large high frequency pulse (e.g., as from electromagnetic imaging equipment) may cause the system to reset. The system would go through the “SELFTEST” again and be ready to treat in about five seconds. If this occurs make sure to identify the device(s) producing these pulses and maintain sufficient distance between the Thymatron® System IV and the device(s) to prevent reoccurrence; if this is not possible, shielding may be required.**

## EMC DECLARATION

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
<p>Thymatron® ECT Systems are intended for use in the electromagnetic environment specified below. The customer or the user of a Thymatron® System should assure that it is used in such an environment.</p>		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	Thymatron® Systems use RF energy only for internal functions. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Thymatron® Systems are suitable for use in all establishments other than domestic 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	

**EC DECLARATION OF CONFORMITY  
To the Medical Device Directive 93/42/EEC**

**SOMATICS, LLC.  
910 Sherwood Drive  
Lake Bluff IL 60044, USA**

**Represented in EEC by Fred Berninger Importe OHG, Bergstrasse 12,  
82024 Taufkirchen, Germany**

**Declares that the distributed CE marked products conform to the types covered by the  
EC Certificate Number 86253CE01  
issued by DEKRA, in accordance with Annex II of the  
Medical Directive 93/42/EEC**

**In addition, we ensure and declare that the distributed CE marked products,  
as mentioned and falling within Class IIb meet the provisions of  
the EC-Directive which apply to them.**

**This declaration is based on the application of the Quality System approved  
for the manufacture and final inspection of the products concerned, in  
accordance with Annex II of the EC-Directive. The conformity of the  
production quality assurance set out in Annex II.**

**This declaration is supported by the Quality System certification based on the  
harmonized standards ISO 13485:2003  
Quality System Certificate No. 160440.01**

**This Declaration of Conformity covers Thymatron Electroconvulsive Therapy Devices and  
is valid for all products distributed by Somatics, LLC. bearing the CE mark, including the  
Thymatron® System IV, starting with serial No. 40020 and Thymatron System® II,  
starting with serial No. 40236 and ending with serial No. 41950**

INDEX	PAGE
% DELTA, EEG POWER IN THE DELTA BANDWIDTH.....	28
2X DOSE STIMULUS PROGRAM.....	23
2X LP DOSE STIMULUS PROGRAM.....	23
ADDENDUM I (SOFTWARE UPGRADES).....	55
ADDENDUM II ELECTRODE PLACEMENTS.....	56
AUDIBLE EEG™ SEIZURE MONITOR.....	24
AVERAGE SEIZURE ENERGY INDEX (ASEI).....	27
BASELINE EEG COLLECTION.....	19
BASELINE RETENTION.....	28
BENCHMARK METHOD FOR SETTING AND ADJUSTING STIMULUS.....	22
CHANGING EEG GAIN RAPIDLY.....	27
CHANNELS 3 & 4 SELECTION.....	16
CONTRAINDICATIONS AND WARNINGS.....	6
DATE--HOW TO SET.....	34
DECLARATION OF CONFORMITY.....	51
DOUBLE DOSE STIMULUS PARAMETERS.....	48
DUKE UNIVERSITY AMPLITUDE MEASURES.....	28
ECG MONITORING ELECTRODES.....	16
EEG ENDPOINT SEIZURE DURATION.....	25
EEG FREQUENCY MEASURES.....	6, 28
EEG MONITORING ELECTRODES.....	15
EEG SEIZURE MONITORING.....	24
ELECTRODE PLACEMENTS.....	56
EMC DECLARATION.....	50
EMC SUPPLEMENT.....	49
EMG ENDPOINT SEIZURE DURATION.....	26
EMG MONITORING ELECTRODES.....	16
FFT SELECTION.....	29
FLEXDIAL™ FACTORY SETTINGS.....	30
FLEXDIAL™ FUNCTIONS AND WHAT THEY CONTROL.....	12
FLEXDIAL™ MODE	
TO ENTER.....	10
TO EXIT.....	11
FLEXDIAL™ MODEL PROCEDURE.....	11
FLEXDIAL™ OPERATION.....	10
FREQUENCY SELECTION.....	21
FRONT PANEL JACKS.....	10
GAIN AND POSITION SETTINGS.....	26
ICTAL LINE™ SEIZURE INDICATOR.....	25
IMPEDANCE TEST.....	18
INDICATIONS FOR USE.....	6
INPUT HOSPITAL'S NAME.....	31
INPUT PRE-RECORDED TREATMENT DATA.....	31
INSTALLATION.....	7
LEAD-WIRE CONNECTIONS.....	14

LIGHT-EMITTING FUNCTION DISPLAYS .....	8
MAXIMUM SUSTAINED COHERENCE (COH).....	27
MAXIMUM SUSTAINED POWER (MSP).....	27
MEDIAN EEG FREQUENCY (MF) .....	28
MONITOR DATA ON PC SCREEN.....	32
MONITORING CABLE CONNECTION.....	14
MONITORING ELECTRODES APPLICATION.....	15
OPERATING INSTRUCTIONS.....	7
OUTPUT DATA AUTOMATICALLY .....	31
OUTPUT DATA MANUALLY .....	33
PAPER LOADING INSTRUCTIONS.....	14
PAPER SPEED SELECTION.....	29
PATIENT SELECTION CRITERIA .....	6
PERCENT ENERGY DIAL .....	8
POSTICTAL SUPPRESSION INDEX (PSI).....	27
POWER ON/OFF .....	7
POWER SPECTRAL ANALYSIS SELECTION.....	29
PROGRAM SELECTION .....	21
PULSEWIDTH SELECTION .....	21
REPRINT LAST TREATMENT .....	34
RESET .....	30
SAFETY MONITOR CIRCUIT ALARM TEST .....	9
SEF-95 (95% SPECTRAL EDGE FREQUENCY).....	28
SEIZURE MONITORING .....	24
SEIZURE MONITORING, PAPER RECORDING .....	25
SEIZURE QUALITY MEASURES .....	27
SEIZURE QUALITY MEASURES ENABLE/DISABLE.....	28
SOFTWARE UPGRADES.....	55
SOFTWARE VERSION—HOW TO DETERMINE.....	55
SPECIFICATIONS.....	5
SPECTRAL EDGE FREQUENCY (SEF-95) .....	28
STANDARD DOSE STIMULUS PARAMETERS.....	35
STIMULUS CABLE CONNECTION .....	14
STIMULUS DOSE FOR <i>BILATERAL</i> ECT: .....	21
STIMULUS DOSE FOR <i>UNILATERAL</i> ECT: .....	22
STIMULUS DOSE SELECTION .....	20
STIMULUS ELECTRODES APPLICATION .....	17
STIMULUS OUTPUT—SPECIFICATIONS .....	5
STIMULUS PROGRAM SELECTION .....	21
STIMULUS PROGRAMS, FACTORY PROGRAMMED .....	20
STIMULUS TITRATION PROCEDURE .....	22
TABLE 1 (STANDARD DOSE PARAMETERS) .....	35
TABLE 2 (DOUBLE DOSE PARAMETERS).....	48
TABLE OF CONTENTS .....	2
TIME TO PEAK COHERENCE .....	28
TIME TO PEAK POWER.....	27

<b>TIME--HOW TO SET.....</b>	<b>34</b>
<b>TRANSFERRING DATA .....</b>	<b>30</b>
<b>TREATMENT STIMULUS ADMINISTRATION .....</b>	<b>24</b>
<b>TURN OFF PRINTING ENTIRELY .....</b>	<b>29</b>
<b>TURN OFF PRINTING IN A CHANNEL.....</b>	<b>27</b>
<b>UPGRADES.....</b>	<b>55</b>
<b>UPLOAD DATA AUTOMATICALLY .....</b>	<b>31</b>
<b>USER SPECIFIED FLEXDIAL™ SELECTIONS .....</b>	<b>29</b>

## ADDENDUM I

### SOFTWARE UPGRADES TO THYMATRON® SYSTEM IV

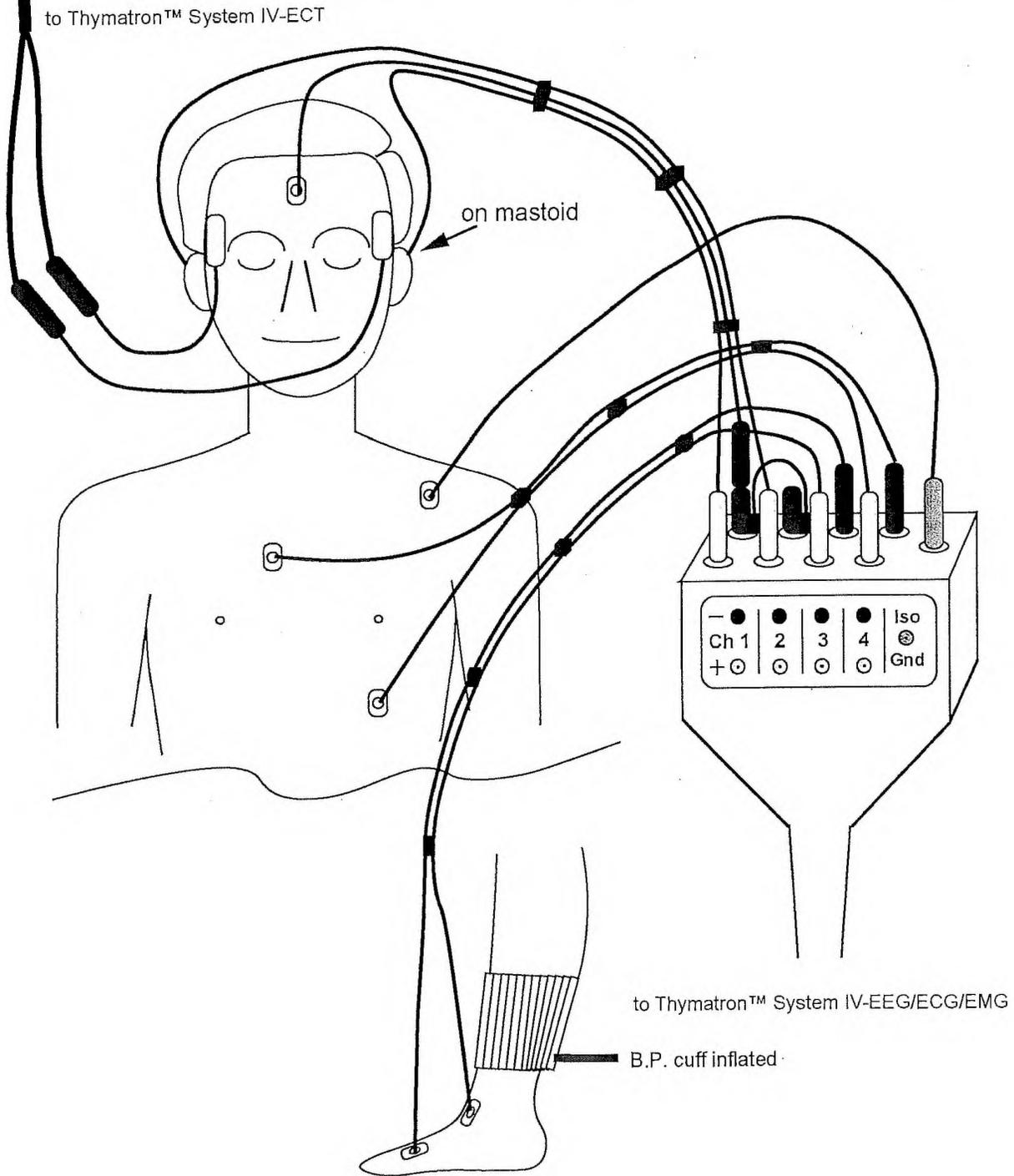
***NB: The software version of your Thymatron® System IV is automatically printed at power-up.***

Each of the following Thymatron® System IV and GENIE™ IV software upgrades includes all previous upgrades.

SOFTWARE VERSION	DATE	DESCRIPTION	REQUIRES GENIE VERSION
4.31	6/1/99	The initial software	4.5
4.32	6/15/99	DOS-compatible	4.5
5.00	9/1/00	Real time PC monitoring Palm® connection.	5.0
5.10	5/1/01	Diagnostic messages for EEG endpoint.	5.0
5.20	8/1/01	LOW 0.25 program	5.0
5.30	5/1/02	Automatic upload to PC SEI upgraded to ASEI, SGI retired Impedance test increased to 800 Hz.	6.3
5.40	11/15/02	EEG Frequency Measures	6.3
5.41	2/1/03	Eliminates recalibration after chip upgrade.	6.3
5.50	7/1/04	Improved algorithm for PSI Change program via Percent Energy Dial Change EEG gain <i>while</i> recording 2X Dose, (where available) changes by 5% increments, up to 100%, then by 10% to 200%	6.3
5.60	6/15/09	Adjust baseline retention (BLV), 0-5 minutes Reset EEG Baseline when pushing Impedance Test & Energy Buttons simultaneously Allows for 0.25 or 0.3 & 2X-LP Program	6.3
5.61	12/1/09	USER programs display up to 70 Hz	6.3
5.62	09/07/10	Reset "USER" mode to last frequency	6.3
5.63	11/03/10	Changes Baseline Validity settings	6.3

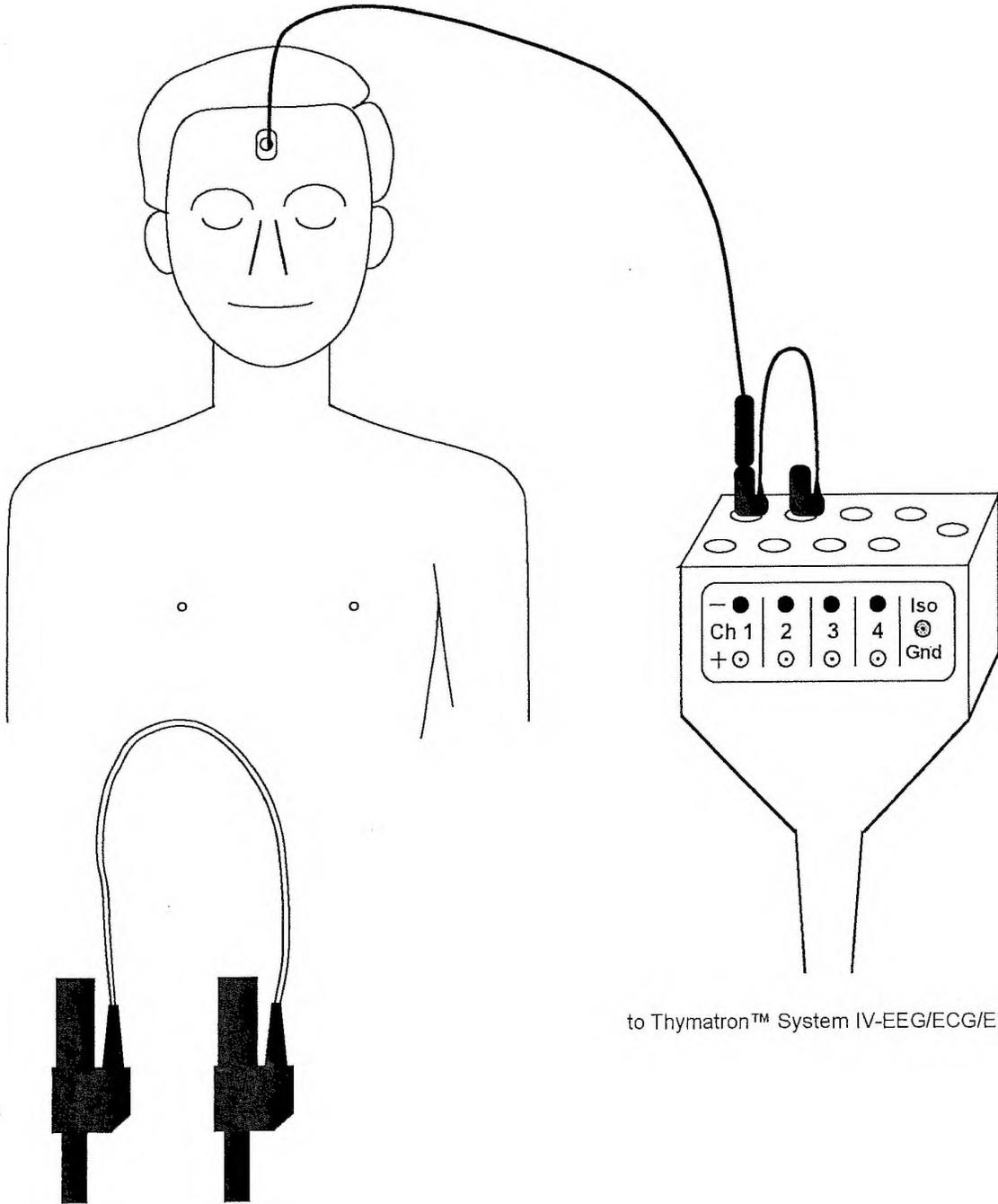
## ADDENDUM II ELECTRODE PLACEMENTS

4 channel setup with Splitter---2 EEG, 1 EMG, 1 ECG channel\*



\*Electrode connections for channel 1, 2 EEG, channel 3 EMG, channel 4 ECG recording

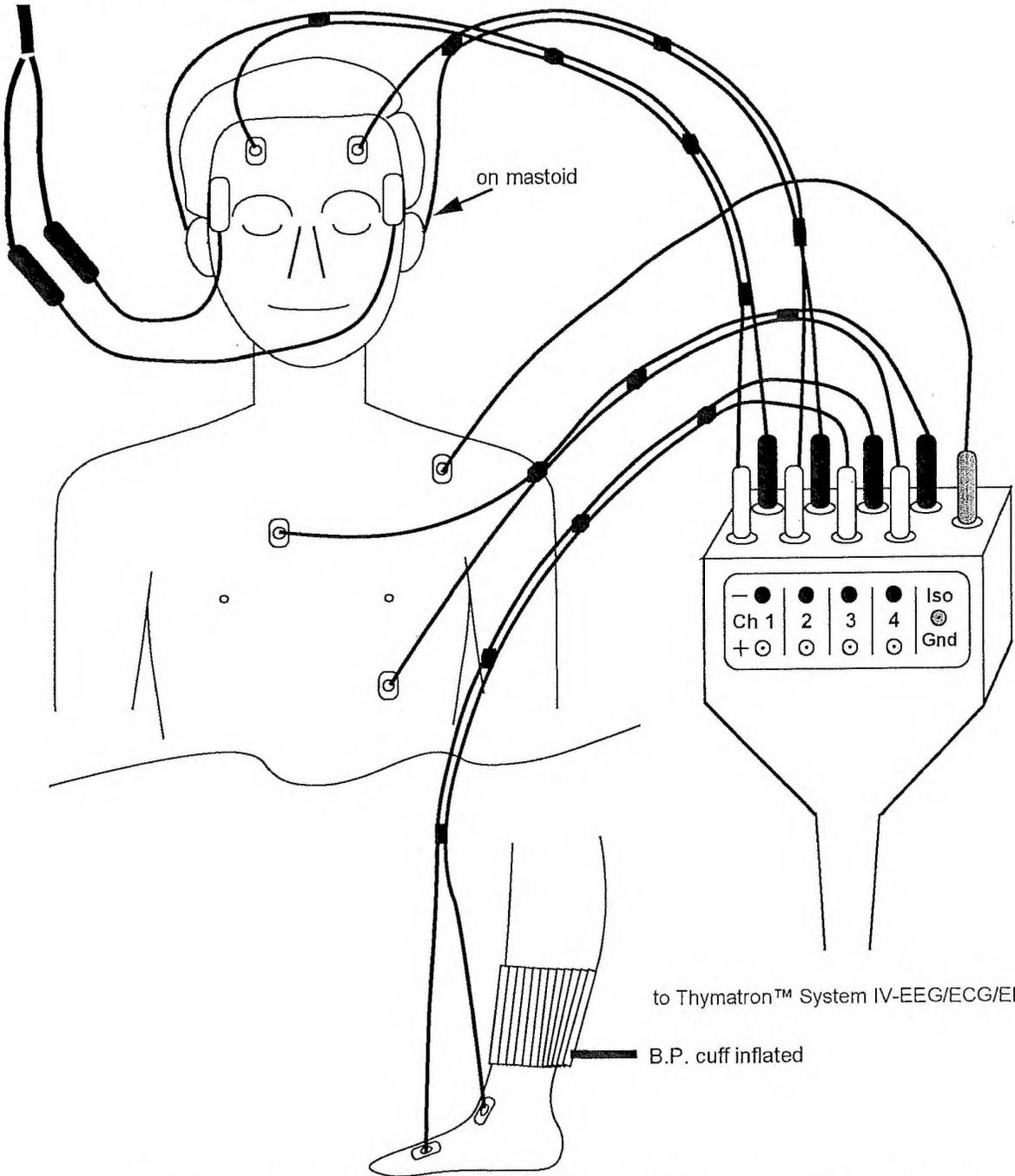
# Electrode Splitter



to Thymatron™ System IV-EEG/ECG/EMG

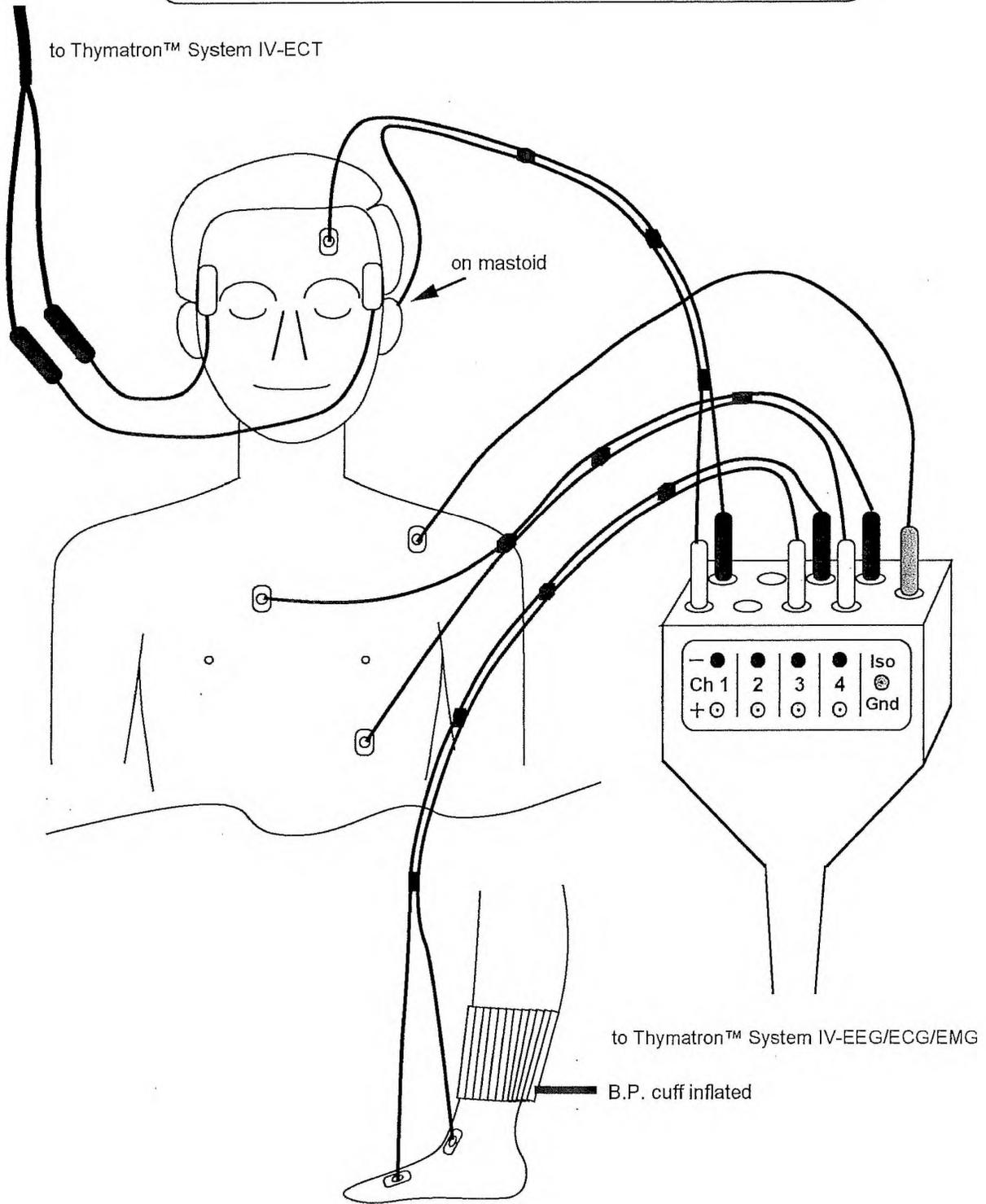
4 channel setup---2 EEG, 1 EMG, 1 ECG channel \*

to Thymatron™ System IV-ECT



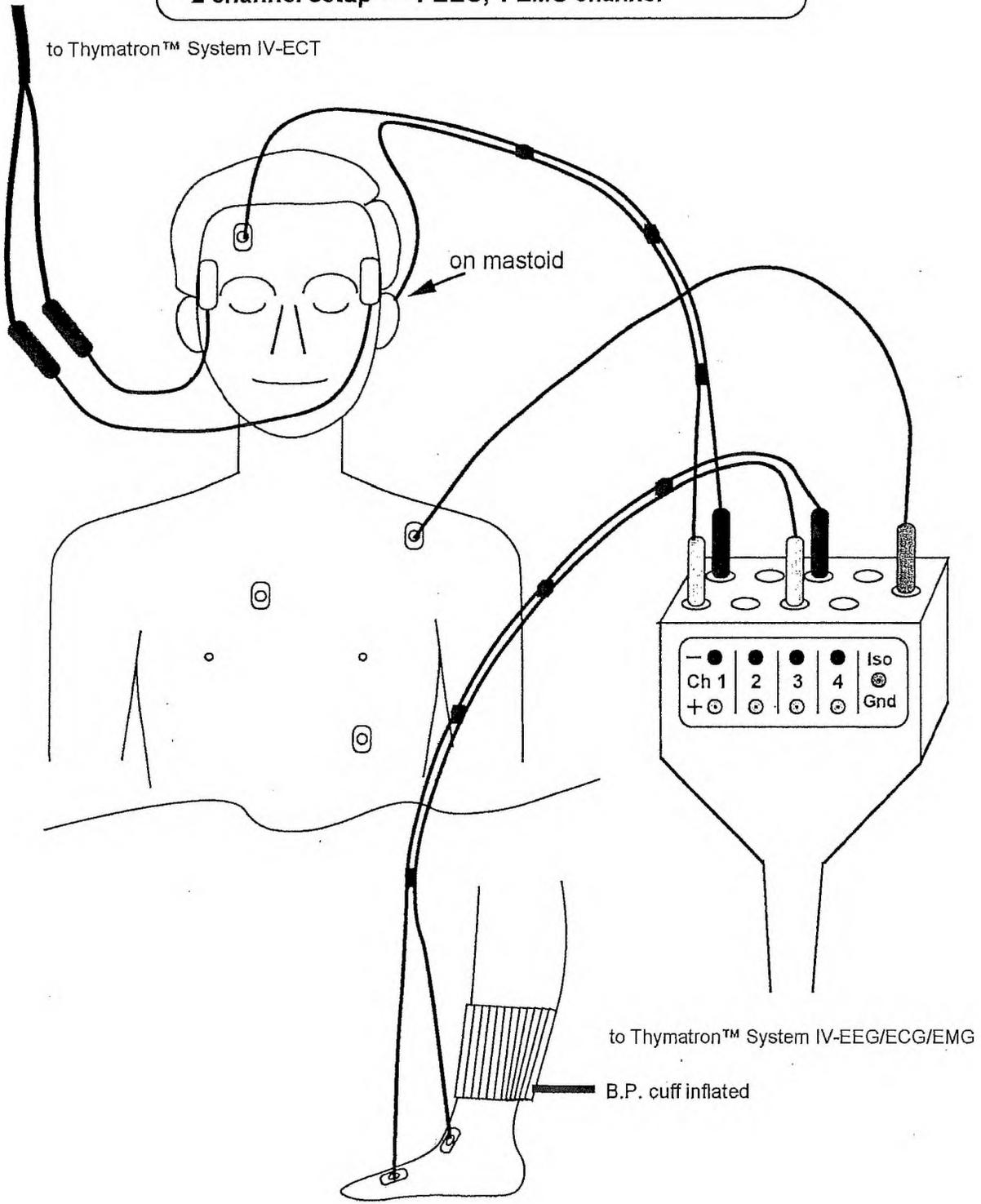
\*Electrode connections for channel 1, 2 EEG, channel 3 EMG, channel 4 ECG recording

3 channel setup-----1 EEG, 1 EMG, 1 ECG channel



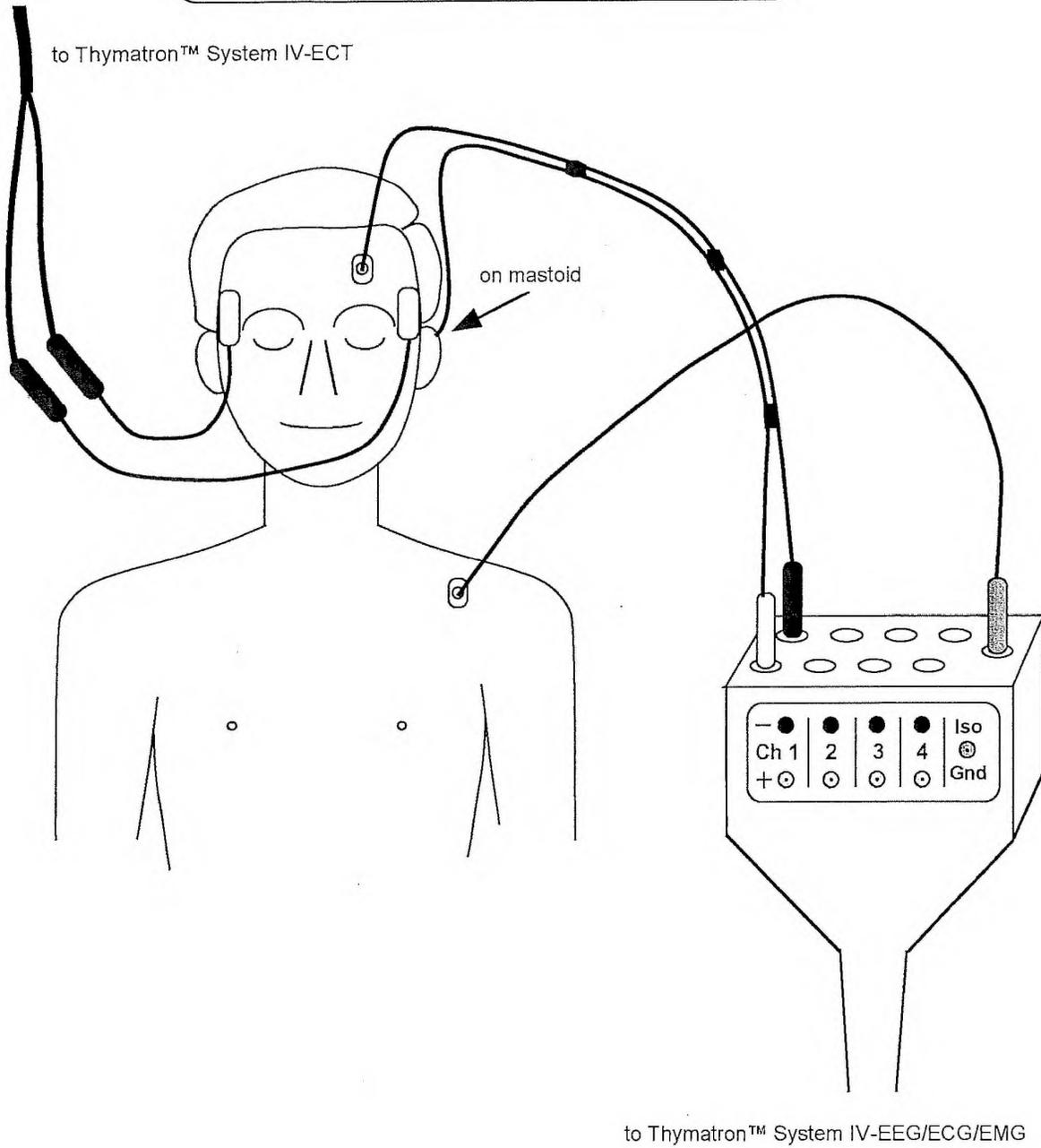
Electrode connections for channel 1 EEG, channel 3 EMG, channel 4 ECG recording

2 channel setup-----1 EEG, 1 EMG channel



Electrode connections for channel 1 EEG, channel 3 EMG recording

1 channel setup-----1 EEG channel



Electrode connections for channel 1 EEG recording

# GENIE™ IV

EEG Analysis Software for the Thymatron® System IV

©1999-2006 Somatics, LLC

December 8, 2006

## Table of Contents

1. Introduction.....	1
2. Installation.....	1
2.1. Program Files.....	1
2.2. Connecting the Serial Cable.....	1
3. User Interface.....	2
4. Collecting Data.....	2
4.1. Auto Upload.....	3
4.2. Automatic Operation.....	3
5. Analysis Screens.....	4
6. Loading and Saving Data to Disk.....	4
6.1. Exporting as Text.....	5
7. Sending and Receiving Data from the Thymatron.....	5
8. Monitoring and Playback Controls.....	6
8.1. Control Panel.....	6
8.2. Settings Panel.....	6
8.3. Keyboard Shortcuts.....	7

## 1. Introduction

The Genie IV program allows you to collect, analyze, and display EEG, EMG, and ECG data from the Thymatron System IV in real-time. It also has functions to save and playback treatment sessions, and edit the patient information associated with a set of data. If desired, Genie IV can automatically collect the data of multiple treatment sessions, eliminating the need for any operator intervention in between patients.

## 2. Installation

### 2.1. Program Files

Genie IV works with MS Windows 95/98/ME/2K/XP. If you don't already have a floppy disk containing the Genie IV software, you can download it from

[http://thymatron.com/sub\\_downloads.asp](http://thymatron.com/sub_downloads.asp)

The program is self-contained, and does not require you to run an installer. Just create a folder on your computer called "Genie" and drag the `Genie[xxx].exe`<sup>1</sup> and `Sample.dat` files from your floppy or download into that folder. Any data files you save will be kept in that directory, as well as a `Genie.cfg` file that stores your settings when you quit the program. To run Genie IV, double-click the `Genie[xxx]` file.

### 2.2. Connecting the Serial Cable

The Genie IV software communicates with the Thymatron System IV using a 9-pin serial cable. Connect one end to the serial port, labeled RS232, on the rear panel of the Thymatron, and the other end to a 9-pin port on your computer. If your computer does not have a built-in serial port, you can use a USB-to-Serial converter: we have tested the Genie with Keyspan's USA-19QW and USA-19HS adapters; these can also be purchased through Somatics, if you wish.

You will need to know the "COM Number" of your serial port, the first time you run Genie. Though this number varies from computer to computer, there are some guidelines that might help you:

- If you have a built-in serial port, try COM1.
- If you are using a USB-to-Serial converter, and also have a modem on your computer, try COM5.
- If you are using a USB-to-Serial converter, but do not have a modem, try COM1 or COM2.

---

<sup>1</sup> The [xxx] represents the version number of the particular Genie you are using; for instance, `Genie641.exe`. Also, depending on how your Windows installation is configured, the `.exe` extension may be hidden.

- You can also find the COM ports available on your computer by using the Device Manager function of Windows

To set the COM port, open the Connect menu once you have run the program, and choose the Set Port item to display a list of COM ports from which you can select one. Note that if you select an invalid COM port, the Genie software will give you a warning, and you can try another. There is no harm in trying different COM ports until you find the correct one.

### 3. User Interface

The first time you run Genie IV, it will attempt to detect your COM port, and then you will see a gray screen with a menu bar at the top. The menus are:

- File** Used to load and save data to disk, print, and exit the program.
- Connect** For sending to and receiving data from the Thymatron.
- PatientInfo** Allows you to set patient information, such as the name, age, and sex, stored with the data.
- Tools** This menu is available only when a window is open. It contains commands for recording and playing back data.
- Window** Used to open various types of windows (Graph, FFT, etc.) for viewing the collected data, and for selecting among the windows you have open. These are discussed individually in section 5 on page 4.
- About** Shows the version number of the Genie IV.

In the Tools menu there are two items, Play Control and Channel Settings, that open floating “control panels” that allow you to more easily activate recording and playback functions. These controls are discussed in section 8 on page 6.

### 4. Collecting Data

To monitor in real-time the channels of the Thymatron,

1. Run the Genie program as described above
2. Open the Window menu and select the Graph item. A four-channel graph screen will appear, as well as the Control and Setting floating panels.
3. Acquire an impedance reading by holding the Impedance button on the Thymatron until a value is shown on the LED display. Note that the patient does not have to be hooked up to the stimulus electrodes—you can continue monitoring with a 3000 $\Omega$  reading.
4. On the Control panel, click the Monitor button. The Genie will begin to display data, organized into 1.28 second epochs, or segments.
5. When you wish to stop monitoring, click on the Stop Mon button in the Control panel.

To upload the collected data from the Thymatron to Genie,

1. Press the FlexDial™ on the Thymatron, and rotate the dial until “DATA OUT” is displayed on the 8-character LED.
2. Press the FlexDial, and then rotate it until “RAW DATA” is shown.
3. In the Genie program, open the Connect menu and click Receive Data.
4. Press the FlexDial to begin the data upload process.
5. When the transfer finishes, press the Start/Stop button on the Thymatron to exit the FlexDial menu.
6. If you wish, you can use the PatientInfo menu to store information such as the name, sex, age, etc. of the patient before saving the data.

See section 8 on page 6 for detailed information on how to review the collected data, alter the playback speed and channel gain, and mark any artifacts found; and see section 6 on page 4 for instructions on saving and loading data to files on your computer.

#### **4.1. Auto Upload**

Auto Upload is the feature that provides for operator-free data collection from multiple patients. To use it,

1. From the Connect menu, select Auto Upload.
2. Your files will be named according to the date, time, and a sequence number. You can choose the directory in which you want to store the files.
3. When you have chosen the directory, click Upload.

At this point, the Genie IV is ready: it will begin collecting data when treatment is initiated, and will end when the Start/Stop button on the Thymatron is pressed after treatment. It then saves the data to a file, and is ready for the next patient.

#### **4.2. Automatic Operation**

Using the monitoring and automatic upload features together provides a convenient method of operating the Genie IV when treating several patients in a row. To set up the software,

1. Turn on Auto Upload as described in section 4.1.
2. Begin monitoring the patient according to the directions in section 4.
3. The graph screen will show real-time traces of selected channels.
4. While the stimulus is being delivered, the graph will pause.
5. After the Start/Stop button on the printer is pressed, Genie will automatically upload data from the Thymatron, save it, and then wait for the next patient to be treated.
6. When the impedance has been acquired on the next patient, the Genie will automatically begin monitoring again.

If you would like to perform post-treatment monitoring on a patient, obtain another impedance reading and the Genie will resume monitoring.

At the end of the day, you will have a number of files saved by Genie in a folder on your computer. It is often a good idea to go through these files and rename them to more descriptive names; also, you can open the saved data files in Genie and use the PatientInfo menu to enter more detailed characteristics (name, age, etc.).

## 5. Analysis Screens

In addition to the Graph window, you can view real-time analyses of the data in the FFT, Bands, and Spectrum windows; and a summary of the treatment, similar to the one printed out by the Thymatron, in the Report window. To open any of these displays, use the Window menu. When you are looking at the FFT, Bands, or Spectrum display, an additional Spectrum menu will be available. It allows you to choose between an analysis of the accumulated spectrum data thus far (Accumulated Spectrum), or just the current segment (Current Segment). Depending on the type of window you have open, the Spectrum menu may have additional functions, as described below.

**Graph** The Graph window displays traces from EEG channels 1 & 2, and up to two more EEG channels, or EMG and ECG channels. See section 8 on page 8 for instructions on how to configure the graph display.

**FFT** The FFT window shows a 32-bar display of the FFT analysis of EEG channels 1 & 2.

**Bands** The Bands window displays the numeric values of the absolute EEG power, relative EEG power, % interhemispheric coherence, and % interhemispheric asymmetry, for each of the four standard frequency bands (delta, theta, alpha, beta) plus 2 additional user-assignable bandwidths. These variables are used to assess the relative interhemispheric symmetry in EEG amplitude and phase.

When you are collecting in four-channel mode, you can use the Spectrum menu to select any pair of EEG channels to analyze. Also the Spectrum menu will contain a Set Bands item that lets you choose the range (in Hz) for each of the frequency bands.

Any number of separate Bands windows may be opened simultaneously by using the Window menu and selecting the Bands item.

**Spectrum** The Spectrum displays numeric values for absolute power, relative power, asymmetry, and coherence, for each of 32 frequency points, in steps of 0.78 Hz.

When you are collecting in four-channel EEG mode, you can use the Spectrum menu to select any pair of EEG channels to analyze.

Any number of separate Spectrum windows may be opened simultaneously by using the Window menu and selecting the Spectrum item.

## 6. Loading and Saving Data to Disk

The File menu has items that relate to loading and saving data to your computer.

<i>Menu Item</i>	<i>Function</i>
New	Clears any data you have collected so far, and readies the Genie IV to accept new data.
Open	Allows you to choose a file from which to load saved data.
Save	Writes your current data to disk.
Save As	Allows you to choose a file name under which to save.
Save As Text	Exports data as text (see the next section).
Print	Lets you choose among the various windows, and sends your selection to a printer.
Exit	Closes the software.

### 6.1. Exporting as Text

Normally, Genie IV saves data in a binary format in files with a .DAT or .EDT extension, which are readable only by the Genie software. It may be useful to export the raw data, analysis windows, or summary report as a text file, so that it can be read by other software, for instance MS Excel.

To export a specific window as a text file<sup>2</sup>,

1. Open the appropriate display (Graph, FFT, etc.) using the Window menu.
2. Choose Save As Text... from the File menu.
3. You will be asked if you would like to include the patient information with the text output, and also for a file name.

If you want to import this text file into Excel

1. Choose Open from Excel's file menu, select the appropriate file name, and then use Excel's data import wizard to continue the process.
2. On the first page, choose the "Delimited" data type.
3. On the next page, ensure that only "Comma" is selected as the delimiter—by default Tab will be selected, so uncheck it
4. On the third page you may accept the default of "General" column types.

## 7. Sending and Receiving Data from the Thymatron

In the Connect menu are a number of functions related to transferring data between the computer and the Thymatron.

<i>Menu Item</i>	<i>Function</i>
Send Data	Transmits data from Genie to the Thymatron (see below).
Receive Data	Uploads data from the Thymatron to Genie, as described above.

- 2 Specifically, these will be in Comma-Separated Value (CSV) format, which is a standard for text files that is interoperable among many programs.

Send Name	Sets the name printed on the Thymatron summary report.
Auto Upload	Toggles auto-upload mode, as described above.
Set Port	Specifies to which COM port the Thymatron is connected.

To use the Send Data and Send Name functions, you must prepare the Thymatron to receive data:

1. Press the FlexDial on the Thymatron, and rotate the dial until “DATA IN” is displayed on the 8-character LED.
2. Press the FlexDial; DATA IN will flash on the display.
3. Press the FlexDial again to make the Thymatron ready to receive data.
4. In the Genie program, open the Connect menu and click Send Data or Send Name.
5. When the transfer finishes, press the Start/Stop button on the Thymatron to exit the FlexDial menu.

To use the Receive Data function, follow the steps given previously in the discussion of Collecting Data.

## 8. Monitoring and Playback Controls

### 8.1. Control Panel

Once you have uploaded data from the Thymatron or loaded a file from disk, you can playback that data at a variety of speeds and mark any segments that contain artifacts.

On the Control panel, available from the Tools menu, you can select a subset of the data to review and change the speed at which it is played back. To view only a specific time range, type in the desired value into the Time Set field. From the Speed drop-down box, you can choose the playback speed from 25%—500% of real time.

There are also certain controls available while you are playing back data:

<b>PlayBack/StopBack</b>	Starts and stops playback, respectively.
<b>Monitor/StopMon</b>	Begins and ends monitoring of the Thymatron, respectively.
<b>Reset</b>	Jumps to the beginning of the collected data.
<b>Reject</b>	Marks the segment currently being viewed as an artifact, so that it won't factor in to the statistical analyses performed on the data set.

### 8.2. Settings Panel

From the Settings panel, available through the Tools menu, you can customize the behavior and display of the input channels. To enable a channel, ensure that there is a checkmark next to its On label. For channels 3 & 4, you can select among EEG, EMG, and ECG inputs. The Scale dropdown box lets you change the display scale of each channel, in  $\mu\text{V}$ . The Artifact field contains a value in

$\mu\text{V}$  above which a segment will be automatically flagged as an artifact.

### 8.3. Keyboard Shortcuts

Most common operations have equivalent keyboard shortcuts, which can make using the Genie software much more efficient; a table of these shortcuts is given.

<i>Function</i>	<i>Shortcut</i>
New	Ctrl+N
Open	Ctrl+O
Save	Ctrl+S
Print	Ctrl+P
Send Data	Ctrl+F2
Receive Data	Ctrl+F3
Auto Upload	Ctrl+U
PlayBack/Stop Playback	Ctrl+B
Monitor/Stop Monitoring	Ctrl+T
Reset	Ctrl+R
Reject	Ctrl+J