

The Streamlined Somatics Thymatron[®] System Saves Time and Effort

U.S. District Court
Middle District of Florida
PLAINTIFFS EXHIBIT
Exhibit Number: PL- 87
Case Number: 8:20-cv-01724
JEFFREY THELEN v. SOMATICS, LLC
Date Identified: _____
Date Admitted: _____



Your Time is Valuable...Save It With:

- Thymapad[™] single use stimulus electrodes, for all placements
- Ventil-A[™] single use compressible mouth protectors
- Recording electrodes, single use, for EEG, ECG and EMG
- Thymatron[®] remote treat handle
- Steady increment stimulus adjustment for dosing & titration

Single use = no cleanup, no sterilization, no contamination.

Made for use with Thymatron[®] System IV.



SOMATICS, LLC
720 Commerce Drive, Suite 101
Venice, Florida 34292

USA & Canada toll-free 1-800-642-6761
(847) 234-6761
FAX (847) 234-6763
sales@thymatron.com



Cat. #EDIV

The Thymatron® System IV: Description and Specifications

Choose ultrabrief (0.25 msec or 0.3 msec) or brief (0.5, 0.75, 1.0, 1.5 msec) at each dose setting. Each pulsewidth is available at every dose from minimum dose to maximum.

One dial sets the dose. Pulsewidth and frequency are individually assigned for each dose setting. Store your preferences for them in system memory or choose a factory-set group of pulsewidths and frequencies (called "stimulus programs.")

Print your choice of any of these, or change among them as you wish: 1 or 2 channels of EEG alone or with ECG or EMG or both, or 4 channels of EEG.

The Thymatron's 900 mA stimulus current induces seizure at just 60% of the charge needed with 800 mA stimuli. Moreover, greater seizure induction occurs at 900 mA than 800 mA, including at maximum device settings.

About our Ventil-A single-use mouth protectors: "Contemporary disposable foam bite block provides superior protection compared with the rubber bite blocks of the past, as well as increased convenience." – Paparone P, et al. JECT; 35:224.(2019)

- **SINGLE FRONT-PANEL DIAL** lets you select the traditional Thymatron® functions plus important new ones, including *Optimal Stimulus* programs that automatically set the most efficient combination of stimulus parameters at every stimulus dose setting.
- **ELECTRONIC MEDICAL RECORD-KEEPING** is simple with the included Genie™ IV EMR software. Patient treatment records created and stored with the Genie™ IV are easily incorporated into hospital database systems.

- **EXTENDED LOWER STIMULUS RANGE** with pulsewidth and frequency to 0.25 or 0.3 msec and 10 Hz allows you to deliver *stimuli up to 8 seconds long*.
- **EEG COHERENCE MEASURES** of *maximum sustained coherence*, and *time to peak coherence*, inter-hemispheric cross-correlation measures reported to reflect seizure quality and clinical impact (Krystal & Weiner, 1994; Krystal et al, 1995; Krystal, 1998).
- **EEG AMPLITUDE** measures of *maximum sustained EEG power*, and *average seizure energy*, with separate values for *early*, *mid-* and *postictal seizure phases*, found by the Duke University group to be important correlates of seizure quality and efficacy (Krystal & Weiner, 1994; Krystal et al, 1995; Krystal, 1998).
- **HEART RATE MEASURES**, including *peak heart rate*, a key measure of cerebral seizure duration and quality (Larson, Swartz & Abrams, 1984; Swartz, 1993; 1996; Swartz and Manly, 2000) that reflects the autonomic (brainstem) response to ECT. This is supplemented by *digital heart rate* monitoring for safety and seizure generalization, printed each second.

All of the above measures are automatically printed.

- **A POWERFUL 32-BIT INTERNAL COMPUTER** employs *Power Spectral Analysis* to process and store up to 10 minutes of digitized EEG for the special features described here. You can send this data to your IBM PC-compatible computer via a rear-panel serial port for further comprehensive EEG analysis, using Somatics' proprietary Genie™ IV software.

- Because each ECT treatment session is **STORED IN MEMORY**, you can retrieve it if you run out of paper during a treatment—just slip in another pad after the treatment and *press a button for a complete printout.*
- **INDEPENDENT SAFETY MONITOR CIRCUIT** prevents the patient from receiving an excessive electrical dose regardless of the operation of the regular circuits.
- **TRUE EMG RECORDING OF THE MOTOR SEIZURE.** Unlike simple movement detectors, the Thymatron® System IV's EMG can measure seizure muscle activity that is not visible to the naked eye, and which typically continues substantially longer than optically-detectable movements (Couture et al, 1988).
- Because the special computer-automated programs of the Thymatron® System IV are stored on **REPLACEABLE MICROCHIPS**, updates are easily accomplished on-site via chip replacement. Somatics has already provided 4 advanced microchip upgrades for the System IV including: Genie™ IV computer software, and real-time digital EEG display.
- The **POSTICTAL SUPPRESSION INDEX** reports the degree of EEG flattening immediately following the seizure, which correlates with clinical efficacy (Nobler et al, 1993; Krystal & Weiner, 1994; Krystal et al, 1995; Krystal, 1998; Nobler et al, 2000). A study of the Thymatron®'s *Postictal Suppression Index* found that it significantly differentiated ECT remitters from non-remitters (Petrides et al, 2000). The authors concluded: *"higher PSI values (more abrupt ending of ictal EEG) are correlated with better clinical outcome of ECT in depression"*.
- **COMPUTER DETERMINATION AND PRINTOUT OF EEG AND MOTOR SEIZURE DURATIONS.** The integral computer EEG analyzer continually measures the EEG and EMG and automatically prints the EEG and motor seizure durations with precision and reliability (Swartz et al, 1994; Krystal et al, 1995).
- **JUST SET ACCORDING TO AGE AND TREAT.** Setting the Thymatron® System IV according to the patient's age facilitates easy selection of the correct stimulus charge.
- Alternatively, **RAPID STIMULUS TITRATION** is facilitated with the Thymatron® System IV using a simple method-of-limits procedure (McCall et al, 1993; Rasmussen et al, 1994) that employs research based dose increments: 5, 10, 15, 25, 40, 80, and 100% Energy at your choice of pulsewidth.

(see next page for references)

THYMATRON® SYSTEM IV FEATURES CHECKLIST¹

	Thymatron® System IV	
Choose 0.25 or 0.3 msec Ultrabrief Pulsewidth	☒	☐
Genie™ IV Software	☒	☐
Four-Channel Monitor/Printer	☒	☐
Stimulus Programs	☒	☐
Maximum Sustained EEG Amplitude	☒	☐
Continuous Digital Heart Rate Monitor	☒	☐
Peak Heart Rate Printout	☒	☐
EEG Coherence Analysis	☒	☐
Seizure Energy Index	☒	☐
Postictal Suppression Index	☒	☐
Maximum Dose Available at all Pulsewidths	☒	☐
Interictal Frontal Delta Analysis	☒	☐
Computer EEG Seizure Duration	☒	☐
Computer Motor Seizure Duration	☒	☐
True EMG Monitor	☒	☐
EEG Ictal Line Seizure Indicator	☒	☐
Light-Emitting Elapsed Time Display	☒	☐
Up to 8 Seconds of Stimulation	☒	☐
Change Waveform without Altering Dose	☒	☐
Audible EEG™ monitor	☒	☐
Instant Impedance Test	☒	☐
Extended Seizure Alert	☒	☐
Patented Safety Monitor Circuit	☒	☐

SPECIFICATIONS

STIMULUS OUTPUT:

Current: 0.9 amp constant, limited to 450 volts, isolated from line current.

Frequency: 10 to 70 Hz in 10 Hz increments (to 140 Hz for 0.25 msec pulse).

Pulsewidth: 0.25 or 0.3 msec (choose one) and 0.5 - 1.5 msec in 0.25 msec increments.

Duration: 0.14 to 8.0 sec in increments of equal charge.

Maximum output: Standard maximum output is typically 504 mC current with 99.8 joules energy across 220 ohms impedance. Output for double dose modes (where available) is typically 1008 mC current with 199.6 joules energy across 220 ohms.

RECORDING: 8 user-selectable gain positions: 10, 20, 50, 100, 200, 500, and 2000 µV/cm.

REQUIREMENTS: 100-130 volts (120 volts) A.C., 60 Hz, single phase. 100 VA. /220-240 volt, 50/60 Hz switchable.

APPROVALS: CSA, CE, ISO 13485:2016, IEC 60601

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#EEDS

SOMATICS' OWN SINGLE USE STICK ON EEG/ECG/EMG ELECTRODES

Easy and quick to use, "the pregelled electrodes provided in the Thymatron DG starter kit. . . reduce preparation time" (*Convulsive Therapy* 2:53, 1986), compared to metal electrodes and ordinary disposable paper ECG electrodes. They are small enough not to interfere with treatment electrode placement. Ideal for recording EEG, ECG, and EMG, they are conveniently packaged 5 per strip. Instantly adherent, they will remain in place throughout the seizure.

Updated "Guide to ECT" E-book Gratis

Get your copy of the "Guide to ECT" E-book revised by Conrad Swartz PhD MD. It contains essential written information, according to Dr. Swartz, and is suitable for physicians, residents and nurses. It details organization, patient selection, pretreatment procedures, electrical aspects, electrode placement, anesthesia, monitoring, complications, side effects, and post-ECT considerations.

It's the first ECT guide to include the 2019 FDA ECT regulations ("special controls"). These describe new details of clinical practice the FDA expects ECT practitioners in the USA to know and follow.

For a gratis PDF copy just email a request to edu@thymatron.com with your name, degree, city and affiliated hospital name.

#ENSI



NEW REMOTE TREAT HANDLE FOR THYMATRON®

You asked for a remote treat handle and here it is. You can press the TREAT button on this handle instead of reaching over to the Thymatron® itself: a simple thumb press safely triggers the stimulus for any electrode placement, including unilateral.

A ONE-PAGE COURSE IN ADVANCED ELECTROCONVULSIVE THERAPY

% Energy set45%
 % Energy delivered.....45%
 Charge delivered.....308 mC
 Current.....0.90 A
 Stimulus Duration.....7.2 sec
 Frequency.....70 Hz
 Pulse Width.....0.3 msec
 Static Impedance.....1440 ohms
 Dynamic Impedance.....260 ohms
 EEG Seizure Endpoint.....48 sec
 EMG Endpoint.....45 sec

Peak Heart Rate128/min
 Average Seizure Energy Index.....72 V²
 Postictal Suppression Index.....96%
 Maximum Sustained Power.....77841 μ V²
 Time to Peak Amplitude.....33 sec
 Maximum Sustained Coherence.....95%
 Time to Peak Coherence.....33 sec
 Early Ictal Amplitude.....133 μ V
 Midictal amplitude.....264 μ V
 Post-ictal amplitude.....10 μ V

This sample ECT report of the Thymatron® System IV shows that the doctor set the % Energy dial to his patient's age of 45 years, yielding a 308 mC stimulus charge. The *Optimal Stimulus Program* selected a 0.3 msec pulsewidth, 70 Hz frequency stimulus delivered over 7.2 sec. Prior to stimulus administration the impedance measured a safe 1440 ohms, which dropped to 260 ohms during stimulus delivery.

The EEG seizure lasted 48 seconds. Peak seizure amplitude was reached at 31 sec, with a mid-ictal amplitude of 264 μ V, a *Maximum Sustained Power* of 77841 μ V², and an *Average Seizure Energy Index* of 72 V² reflecting strong seizure intensity.

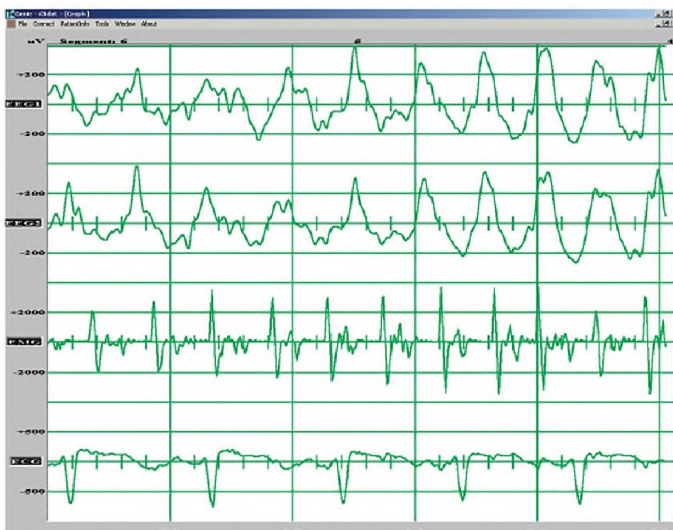
Peak Interhemispheric Coherence reached at 33 sec was consistent with the seizure amplitude peak at 31 sec. The *Maximum Sustained Coherence* value of 95% reflected synchronous participation of both hemispheres in the seizure. The rapid drop of EEG seizure amplitude to 10 μ V postictally yielded a high *Postictal Suppression Index* of 96%. Power Spectral Analysis was not enabled.

In summary, the record shows a synchronous, high-intensity, well-developed, and well-generalized EEG seizure pattern with a strong midictal phase, pronounced postictal suppression, and a substantial tachycardia response.

GENIE™ IV ELECTRONIC PATIENT DATABASE AND EEG DISPLAY SYSTEM

Designed to meet your clinical and research needs, the Genie™ IV enables you to enter complete patient information at each treatment for storing, printing or incorporating into a hospital-based electronic patient database system.

Equally important is the Genie™ IV's comprehensive real-time display of up to 4 channels of EEG, ECG, and EMG on a PC screen (not included), allowing you to see and then store each treatment session.



(GENIE™ IV Patient Information Data File/Printout)

Date: 12-16-05 Name: Laurenz Smarba Age: 58 Sex: M
 Somewhat improved but still has insomnia & poor appetite
 Oriented, alert, coherent and cooperative
 ECT #3 (R-UNI x 1) Anesthesia: Dr. Jones ECT: Dr. Smith
 Atropine 0.2 mg - Brevital 50 mg - Succinylcholine 40 mg
 Thymatron IV 85% Energy (LOW 0.5 program)
 Moderately strong seizure-symmetrical, well developed
 Good heart rate response with rapid return to baseline
 No complications, quick recovery
 Recommendation for ECT #4: same as above

DOES YOUR ECT DEVICE DELIVER THE DOSE YOU SPECIFY? DO YOU TRAIN DOCTORS OR NURSES IN ECT QUALITY?



Device malfunction can cause ineffective ECT treatments or excessive side-effects. Now you can check your ECT device yourself with Somatics' easy-to-use, ECTOBRAIN™II, which performs the same current output check professional engineers use. A single button press instantly tells you if your ECT device is operating safely— providing reassurance and peace of mind. ECTOBRAIN™II works with any Thymatron®.

ECTOBRAIN™II also features a Patient Simulator mode that generates EEG, ECG, and EMG signals derived from real patients for testing up to 4 channels of your monitor/printer tracing display and for training and demonstration purposes. Both good- and poor-quality seizures can be selected.

The good-quality seizure shows a high amplitude EEG followed by electrical silence at termination, with a pronounced tachycardia response and a high-amplitude EMG that terminates shortly before EEG termination. The poor-quality recording exhibits a low-amplitude abortive-type EEG seizure lasting only 10 sec, followed by continued but lower-amplitude EEG

fluctuations after termination; there is no tachycardia response, and an initial low-amplitude EMG response lasts only a few seconds.

A device checkup can cost \$600 to \$800 but real costs are more. How often does the question arise in treating a difficult patient whether the ECT device is stimulating properly or the EEG tracing recording correctly? Most ECT units sent to us for presumed malfunction have nothing wrong with them! ECTOBRAIN™II can quickly determine whether or not the device is working. It can reveal problems in technique (e.g., recording electrode application) that are correctable on site or with user-replaceable parts (e.g., lead wires). Just connect the stimulus and recording cables and press the TREAT button as for a patient.

The chart recorder of your ECT device will display samples of EEG, ECG, and EMG tracings as described above. The printed report will show the values of the stimulus parameters and other printed variables of your ECT device, including the measured stimulus charge output in mC.

Special price when ordered together with a Thymatron® System IV.

Trouble-Shooting with the ECTOBRAIN™II

Problem **How to test using Ectobrain™II ***

No Stimulus output	Section I
Impedance test error	Section II
ECT stimulus cable failure	Section III
No EEG, EMG endpoint	Section IV
ECG channel doesn't print	Section IV
No Ictal Line	Section IV
Special feature doesn't print	Section IV
EEG amplifiers require calibration	Section VI
ECT stimulus requires calibration	Section VI

The 2019 User's Manual for the Thymatron® System IV ECT device is now available for free download at Thymatron.com. Click "Downloads" in the left column then click "Instruction Manual". It includes these FDA-mandated statements:

- Specific "Instructions to Patients" (see manual Addendum III).
- ECT patients should have cognitive status assessed prior to ECT and along the course with formal neuropsychological assessment (see manual page 11).
- Cautions, warnings and risks, pp 1 and 7-11.
- Review of Thymatron® ECT device efficacy publications, pp 13-15
- Review of Thymatron® ECT device safety publications, pp 15-19
- Specific indications for use of ECT on patients, p6

*See specified sections of Ectobrain™ II manual on www.thymatron.com downloads page

MOUTHGUARD ORAL PROTECTORS IN TWO SIZES



SOMATICS THYMATRON® INSTRUMENTS IMPORTANT RESEARCH TOOLS

Since the Thymatron® was first introduced in 1983 hundreds of research studies have appeared in the medical literature using a Thymatron® instrument. Prominent among these is the series of publications by the multi-hospital CORE research group, a consortium of academic psychiatric centers.

In a series of important articles over the last decade the CORE group used Thymatron® ECT instruments to demonstrate the striking efficacy of ECT in the treatment of psychotic depression (Petrides et al, 2001), to determine that age had a strong positive association with the response to bilateral ECT (O'Connor et al, 2001), to show that DSM III melancholic features are unreliable predictors of ECT response (Fink et al, 2007), to find that unipolar and bipolar depressives respond equally well to ECT (Bailine et al, 2010), and to report that, although fewer black than white depressed patients received ECT, there was no overall racial difference in treatment response (Williams et al, 2008).

Hundreds of other studies used a Thymatron® instrument to demonstrate, among other things, that:

ECT given twice a week was equally effective as three times a week, but with fewer cognitive side-effects (Lerer et al, 1995).

Antidepressant potency of high-dose right unilateral ECT was equal to bilateral ECT (Abrams et al, 1991).

Caffeine lengthened seizure duration but did not change the convulsive threshold (McCall et al, 1993).

Bilateral ECT did not yield any evidence for brain damage as measured by levels of neuron-specific enolase and S-100 protein (Agelink et al, 2001).

None of 7 patients with intracranial masses were neurologically adversely affected by ECT (Rasmussen et al, 2007).

In 28 severely depressed patients given a course of unilateral ECT, only responders showed elevations of N-acetylaspartate, suggesting that ECT exhibits positive neurotrophic effects (Michael et al, 2003).

In 32 consecutive patients seizure durations automatically reported by the Thymatron instrument correlated highly with determinations made by trained physicians (Rosenquist et al, 1998).

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Thymatron Others

2015	183	137
2014	572	369
2013	246	149
2012	302	179
2011	355	222
2010	416	255

This yield of articles from a 6-year Google Scholar search on the terms *electroconvulsive+year+device* demonstrates that the Somatics Thymatron® is the ECT instrument most preferred by ECT scholars and experts over all other ECT devices.



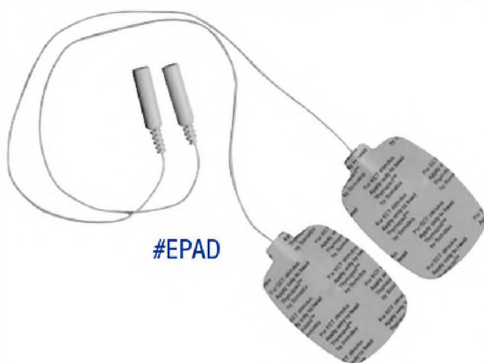
SOMATICS, LLC
720 Commerce Drive, Suite 101
Venice, Florida 34292
www.thymatron.com

USA & Canada toll-free 1 (800) 642-6761
(847) 234-6761
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“Thymatron® System IV: The most advanced ECT device technically and operationally.”

SAFE, TIME-SAVING SINGLE USE ITEMS FOR ECT



THYMAPAD™ Stick-On Stimulus Electrodes

Thymapads™ are much faster and easier to use than the old-fashioned disk, headstrap, and jelly method.

They remain exactly where applied and have no exposed metal surfaces to cause accidental shocks. There's no mess to clean up afterwards, nothing to wash, dry, or sterilize, no sticky hands - just remove them and discard.

Thymapads™ flexibly conform to the surface of the head.

VENTIL-A™ Mouth Protector

The *Ventil-A™*'s thick 100% closed-cell foam construction protects all the teeth. Fits easily under any anesthesia mask and features a non-collapsible air channel for free flow oxygen. One-piece design for dimensional stability and looped end for fast and easy insertion/removal. One size fits >98% of adults.

Both of these single-use ECT aids save the time and expense of washing and sterilization and eliminate the risk of cross-infection that occurs with re-usable products.



#VENT

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1,000,000 SOLD**