User Manual

Thymatron® System IV

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UM-TS4, Rev. 22
For Domestic (USA/CANADA)

User's Manual for Thymatron® System IV

⚠ CAUTION

Prescription use only – Federal law restricts this device to sale by or on the order of a physician.

Electroconvulsive Therapy (ECT) is a complex medical procedure. Its proper and safe conduct requires a staff of licensed healthcare professionals who are trained and have experienced in-person supervision with the associated procedures, have received clinical privileges for ECT from the appropriate hospital committee, and have carefully read and are thoroughly familiar with the medical literature concerning the risks, benefits, complications, and methods of ECT. Specifically, practitioners intending to use the Thymatron System IV should be familiar with ECT-related concerns including medical conditions that affect risks, adverse effects, pre-ECT evaluation, medications used during ECT, ECT procedures and techniques, physiological phenomena, consent, ECT unit staffing, evaluation of outcome, and post-course ECT management. Practitioners should keep current with information about these concerns published in major textbooks, in major journals of psychiatry, and by professional psychiatric organizations. They should also be familiar with the FDA final order of December 26, 2018 (83 FR 66103-66124). Clinicians who administer ECT should participate in continuing education about ECT.
It is essential that doctors planning to use the Thymatron® System IV device read and follow the warnings and recommendations of the Task Force Report of the American Psychiatric Association as set forth in "The Practice of Electroconvulsive Therapy" (APA, 2001), which states, in part, that "A small minority of patients treated with ECT later report devastating cognitive consequences. Patients may indicate that they have dense amnesia extending far back into the past for events of personal significance or that broad aspects of cognitive function are so impaired that the patients are no longer able to engage in former occupations…in some patient self-reports of profound ECT-induced deficits may reflect objective loss of function…In rare cases, ECT may result in a dense and persistent retrograde amnesia extending to years..."
It is essential to read all of the information in the **Safety Information** section of this manual, pages 6–10.

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Contents

INTENDED USE

Type of Device:	The Thymatron® System IV is an ECT device
Device usage:	Therapeutic device
Application area:	For use in treating catatonia, severe major depressive episodes (MDE) associated with major depressive disorders (MDD) or bipolar disorder (BPD) in patients age 13 years and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition. Alternative available treatments that may or may not be as effective as ECT include various behavioral and pharmacological interventions.
Users:	Medical Doctors, Psychiatrists, Neurologists

INTENDED PATIENT POPULATION

This device is intended to be used as part of the ECT treatment procedure with patients of age 13 years and older, under treatment by a medical doctor, a psychiatrist or a neurologist, with a condition as described in the Intended Use. Patients must be capable of giving informed consent or have a legally recognized substitute. For each ECT session, patients should be assessed to be in sufficiently good medical condition to tolerate the procedure.

ECT does not reliably treat PTSD, other anxiety disorders, personality disorders, or medical disorders that cause symptoms of major depression, and the Thymatron System IV is not intended for use in treating such disorders. Anxiety disorders, PTSD, personality disorders, and medical disorders can underlie major depression or coexist with it, causing suicidality or other depressive symptoms.

SAFETY INFORMATION

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

WARNINGS

WARNING

Various medical conditions are associated with substantially increased risk from ECT, including risk of death. These include 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. Pulmonary risks of ECT associated with general anesthesia and neuromuscular blocking agents include hypoxemia, hypoventilation, aspiration, and upper-airway obstruction.

WARNING

ECT device use may be associated with disorientation, confusion, and memory problems.

WARNING

When used as intended this device provides short term relief of symptoms. The long-term safety and effectiveness of ECT treatment has not been demonstrated, and long-term follow-up may be needed.

WARNING

Some patients who were suicidal before receiving ECT eventually committed suicide after receiving ECT, including after receiving ECT with a Thymatron® device.

WARNING

Administering ECT to a patient with an implanted DBS device can damage the DBS device or cause it to malfunction and cause injury to the patient.

PRECAUTIONS

CAUTION

For patients with brain tumor, brain aneurysm, myocardial infarction, coronary insufficiency, heart failure, or aortic aneurysm medical specialists in Neurology or Cardiology should be consulted to determine additional precautions needed, if any.

CAUTION

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

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

CAUTION

The Thymatron® System IV device 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

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

Do not subject the Thymatron® System IV device to extreme moisture, and do not 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.

CAUTION

Only use the Thymatron® System IV device with the Somatics' Treatment and Monitoring Cables.

CAUTION

The Treatment and Monitoring Cables are not interchangeable and cannot be inserted into the wrong front panel connector. Attempting to force the Treatment Cable into the connector intended for the Monitoring Cable (and vice versa) will damage both the connector and the cable.

CAUTION

The ECG function of the Thymatron® System IV device is used only to obtain a heart rate to help assess the efficacy of the seizure; it is not intended to be used to make diagnoses. Do not use the Thymatron® System IV ECG function to monitor the patient's heart for any other purpose.

CAUTION

The EMG function of the Thymatron® System IV device is used only to obtain an estimate of the motor seizure duration to help assess the efficacy of the seizure; it is not intended to be used to make diagnoses. Do not use the Thymatron® System IV EMG function to monitor the patient's muscle or nerve activity for any other purpose.

CAUTION

The built-in electroencephalogram (EEG) functions are used only to assist in identifying the efficacy of the induced seizure and its endpoint. Do not use these EEG functions for any other purpose. Absence of EEG activity does not prove that seizure activity is absent, because seizure may occur outside EEG detectability. Seizure can occur while EEG shows nothing.

CAUTION

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

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.

CAUTION

Thymapad® electrodes are single-use only and must be discarded after the treatment. 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. The Thymatron® device has no special requirements for restricted environment during transport or storage, beyond Standard Sub-clause 10.1 criteria.

CAUTION

EEG, EMG and ECG are shown only to assess treatment quality and must not be used for monitoring or diagnosis.

In English speaking countries: Please check annually on the website Thymatron.com for the latest version of the Thymatron User's Manual.

It is the policy of Somatics LLC, recorded in 2018, that the product life of the Thymatron(R) System IV device is ten years from invoice date, after which it is no longer suitable for clinical use.

In the USA: In the interests of avoiding litigation we provide here our warning that Scientology and its affiliate CCHR have threatened to sue ECT device makers and psychiatrists in the USA who do not deliver a warning that ECT can cause brain damage, regardless of any evidence about it. 7/3/24.

ADVERSE EVENTS

As with any therapy, ECT has risks. Certain patients will experience adverse events in conjunction with electroconvulsive therapy. Patients should be made aware of these risks and confirm that they fully understand them prior to consenting to therapy.

Per FDA requirements, the treating doctor should include in the written Informed Consent form of each ECT patient a statement of the potential adverse effects from ECT as described in this manual.

The most common reported adverse effects of ECT are: Headache. Muscle soreness. Mild to moderate pain/discomfort, including jaw pain. Nausea. Disorientation immediately after seizure induction. Memory dysfunction (see further discussion below).

SERIOUS ADVERSE EVENTS

Recent estimates in the medical literature of the mortality rate associated with ECT are 1 per 10,000 patients or 1 per 80,000 treatments.

Other serious adverse events have occurred, including adverse reaction to anesthetic agents / neuromuscular blocking agents; adverse skin reactions (e.g., skin burns); cardiac complications, including arrhythmia, ischemia/infarction (i.e., heart attack), acute hypertension, hypotension, and stroke; cognition and memory impairment; brain injury; dental/oral trauma; general motor dysfunction; physical trauma (i.e., if inadequate supportive drug treatment is provided to mitigate unconscious violent movements during convulsions) including fractures, contusions, injury from falls, dental or oral injury; hypomanic or manic symptoms (e.g., treatment- emergent mania, postictal delirium or excitement); neurological symptoms (e.g., paresthesia, dyskinesias); tardive seizures; prolonged seizures; non-convulsive status epilepticus; pulmonary complications (e.g., aspiration/inhalation of foreign material, pneumonia, hypoxia, respiratory obstruction such as laryngospasm, pulmonary embolism, prolonged apnea); visual disturbance; auditory complications; onset/exacerbation of psychiatric symptoms; partial relief of depression enabling completed suicide; homicidality; substance abuse; coma; falls; and device malfunction (creating potential risks such as excessive dose administration), and death.

Certain patients are more likely to experience severe adverse events, including those with pre-existing cardiac illness, compromised pulmonary status, a history of brain injury, or medical complications after earlier courses of anesthesia or ECT. 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. All of this information should be assessed in developing the treatment plan for a particular patient.

OTHER RISKS

Completed suicide in ECT patients has a reported rate of 0.5 per 100 patient years, but higher in patients recently discharged after hospitalization with suicidality. Studies have shown that partial improvement along the course of ECT, before remission is obtained, can enable suicidal behavior or suicide in patients previously

too ill to plan or commit suicide. Likewise, suicide is a concern after ECT treatment; for instance, one study found that ECT patients had a slightly higher suicide rate within seven days after their last ECT treatment than non-ECT inpatients (Munk-Olsen et al., 2007). A meta-analysis found that 30% of patients with treatment-resistant depression attempt suicide, with a rate for completed suicide of 0.47 per 100 patient years which included similar incidence following DBS, VNS and ECT (Bergfeld et al., 2018).

ECT may result in worsening of an underlying medical condition either by: (1) ineffective treatment or (2) the treatment itself, particularly when it exacerbates the symptoms.

RISKS OF COGNITIVE MEMORY EFFECTS

Cognitive side effects are experienced in varying types and severity by ECT patients. ECT treatment may be associated with disorientation, confusion and memory problems, including short-term (anterograde) and long-term (retrograde or autobiographical) memory loss following treatment. These side effects tend to go away within a few days to a few months after the last treatment with ECT. However, incomplete recovery is possible. In rare cases, patients may experience permanent memory loss or other deficiency in cognition or function.

FDA regulations require that each patient receiving ECT have his cognitive status monitored prior to beginning ECT and throughout the course of treatment via a formal neuropsychological assessment which includes evaluation of specific cognitive functions (e.g., orientation, attention, memory, executive function). Neuropsychology consultation should help select tests for individual patients. One tool that may be helpful in monitoring along the course is the MoCA (Moirand et al, 2018). Maximum MoCA score is 30, normal is 26 or higher. Add one point if patient is not educated past high school. See **Addendum V** and: https://www.parkinsons.va.gov/resources/MOCA-Test-English.pdf. Additional tests may be desirable, such as for autobiographical memory.

Studies have shown that the methods used in ECT administration have a significant impact on the nature and magnitude of cognitive deficits. In general, the American Psychiatric Association recognizes that the following treatment parameters are each independently associated with more pronounced cognitive side effects:

- Bilateral electrode placement;
- Sine wave stimulation;
- High electrical dosage relative to seizure threshold;
- Closely spaced treatments;
- Larger numbers of treatments;
- Concomitant psychotropic medications;
- High dosage of barbiturate anesthetic agents.

TECHNIQUE OF ECT

Users of ECT devices should carefully follow the specific ECT treatment techniques and procedures outlined in Chapters 6-11 of the American Psychiatric Association's "The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training and Privileging – A Task Force Report" (2001).

ECT requires general anesthesia with neuromuscular blocking agents and supported ventilation. These should be administered by a qualified anesthetic specialist.

Requisite pre-ECT medical and psychiatric assessments in every patient include pertinent medical and psychiatric history, complete physical examination, ECT anesthesia assessment, dental assessment, and any other clinically appropriate studies as determined by the treating psychiatrist.

Prior to ECT, the patient should ingest nothing by mouth for at least eight hours. At the start of the ECT procedure, monitoring and stimulus electrodes are attached. Then general anesthesia is given with a neuromuscular blocking agent and hyperventilation with oxygen. When the muscles are fully relaxed, a mouth protector is inserted and the electrical stimulus then applied.

During the treatment, EMG, ECG and EEG are monitored for occurrence of generalized seizure and until the seizure terminates. ECG usually shows heart rate acceleration at seizure onset and deceleration at seizure end. Typical minimum motor seizure is 20 sec. If the seizure lasts less than 20 sec., consider repeating the stimulus at an appropriately higher dose. EEG shows brain electrical activity. Endpoints can differ among these because they reflect different locations in the brain. If seizure continues beyond about 100 seconds, consider termination by infusing intravenous propofol, midazolam, methohexital or similar short-acting agent. Ventilation is continued until spontaneous respiration returns. After ECT, the patient is observed for an hour or longer, with vital sign, lung auscultation, and cognitive function checks.

TO THE TREATING PHYSICIAN

The U.S. Food and Drug Administration (FDA) requires that patients receive in writing and understand the statements listed in Addendum III before receiving ECT. You may duplicate and disseminate these "Instructions to Patients" without limitation. Delivery of this required information about ECT should be witnessed and documented in medical records.

RISK REDUCTION FEATURES

RISK OF PROLONGED SEIZURES AND CARDIAC ARRHYTHMIAS

The two most frequent complications during an ECT treatment session are excessively long seizures and irregular heart rhythms (Nuttall et al, 2004), both of which can be detected by routine monitoring during the treatment. The Thymatron®'s integral brain-wave monitor (electroencephalogram, EEG) enhances the safety of ECT by allowing the treating doctor to detect signs of a prolonged seizure so it can be terminated with intravenous medication. However, a brain seizure can occur or continue without accompanying EEG activity. Likewise, a heart monitor (electrocardiogram, ECG) allows the treating doctor to detect irregular heartbeat patterns as they occur so that they can be managed with intravenous medication. The Somatics Thymatron®

monitors start recording automatically as soon as the ECT stimulus is delivered and continue until they are turned off by the doctor.

In addition to the paper EEG record, the Somatics Thymatron® device has an auditory EEG monitor that allows the user to tell without looking at the paper EEG whether or not EEG signs of seizure have stopped. In a study of 82 consecutive ECTs using this auditory EEG, physicians determined the occurrence and the duration of the induced EEG seizure with a high degree of accuracy (Swartz and Abrams, 1986).

RISK OF THYMATRON® COMPONENT FAILURE

In the extremely rare event of catastrophic failure of an ECT device component, there is a remote possibility of delivering an electrical stimulus dose in excess of that set by the operator, potentially causing excessive memory disturbance. To prevent such an occurrence, the Somatics Thymatron® device includes an independent separate redundant safety circuit that automatically measures the electrical charge of the output each time the stimulus button is pressed and prevents delivery of any stimulus charge exceeding by more than 5% that set by the operator. To test the integrity of the electrical connection to the patient, the Somatics Thymatron® device includes a static impedance test initiated by a button press. The test current is too small to be felt. This test helps assure good electrode contact and prevent excessive heat release onto the skin.

EFFICACY AND SAFETY OF THE THYMATRON® ECT DEVICE

The below review of the clinical research literature on electroconvulsive therapy (ECT) focuses on the risks and benefits of the most widely-used Thymatron® ECT device models: the DG, DGx, and System IV.[1] This review emphasizes controlled studies with random assignment, blind ratings and statistical validation; older impressionistic reports without validated observations are not included. For each of the three topics (i.e., Efficacy of the Thymatron® ECT Device, Risks of Brain Injury, and Memory and Cognitive Risks) the most pertinent study on the topic is summarized first, followed by brief summaries of other studies that are germane to the topic.

Several old reports not involving a Thymatron® ECT device stated concern about potential adverse effects of ECT on brain function, but the technique of ECT and electronic design of the devices used for this treatment have since advanced to mitigate those concerns. An old study claiming brain injury in cats receiving electrically-induced convulsions (Alpers and Hughes, 1942) failed to use muscle-relaxant drugs before stimulation or proper comparison animals. Breggin (1979) emphasized cerebral petechial hemorrhages (small blood spots on the brain), but when animals were restrained from banging their heads no petechiae occurred (Siekert et al, 1950).

A prospective study in patients receiving modern ECT that employed blindly-analyzed serial magnetic resonance images obtained before, 2-3 days after ECT, and 6 months later did not support the existence of brain injury (Coffey et al, 1991).

EFFICACY OF THE THYMATRON® ECT DEVICE

Petrides et al (2001), in a National Institutes of Mental Health (NIMH)-supported 4-hospital collaborative study,

[1] The DG, DGx and Thymatron System IV deliver the same electricity. The Thymatron IV differs from previous models in monitoring and in ways that the doctor can select the electrical stimulus. Somatics no longer sells the DG or DGx

used a Thymatron® DGx device to prospectively treat 253 patients with nonpsychotic (n=176) and psychotic (n=77) unipolar major depression with bilateral ECT at 50% above titrated threshold. Included were patients aged 18 to 85 years with primary major depression, unipolar type, with or without psychosis, and a baseline Hamilton Depression scale score >20. Excluded were those with a lifetime diagnosis of bipolar illness, schizophrenia, or schizoaffective disorder, a medical contraindication to ECT, a systemic or neurological condition that might affect mood, failure to respond to a trial of ECT or a lithium-tricyclic antidepressant combination during the present episode, and substance dependence during the past year. Of the total sample, 56% were female and mean age was 56 years.

A standard ECT protocol was administered with bilateral electrode placement, seizure threshold determination, dosing at 50% above the titrated seizure threshold, and monitoring seizure efficacy by the duration of EEG-and EMG-monitored seizures. Patients were rated with the 24-item Hamilton depression scale and a neuropsycholical test battery 24-72 hours before the first ECT and after each subsequent ECT before the following treatment. Remission was defined as 2 consecutive post-ECT-treatment Hamilton Depression Rating Scale scores <11, and a decrease of at least 60% on this scale from baseline on this scale. Chi-squared analyses were used to evaluate the relationship between unadjusted remission status and psychosis status. Multivariate logistic regression analyses were used to evaluate the relationship between remission status and psychosis status, adjusted for the effects of confounding or moderator variables; such analysis compared the longitudinal profile of total Hamilton scale scores measured 24-72 hours after each ECT for the psychotic and nonpsychotic depression groups. Most patients achieved scores of ≤10 and >60% reduction in scores for the first 8 ECTs administered, meeting the criteria for remission. For 217 completers of the acute treatment course, the overall remission rate was 87%, with a 95% remission rate for psychotic depression and 83% for non-psychotic depression patients. Side effects among study dropouts included confusion, memory loss, headache, and nausea.

Earlier, the efficacy of ECT had been supported by several controlled trials against antidepressant medications and by several double-blind, random assignment comparisons of genuine versus sham ECT. Some of these studies are summarized below.

ECT versus Antidepressants

Greenblatt, Grosser, and Wechsler (1964) included for study all severely depressed patients admitted to 3 state hospitals in Boston. All patients were randomly assigned to receive a course of 9 ECTs (n=28), or imipramine 200-250 mg/day (n=73). At the end of the one-year study period (after which systematic treatment assignment was discontinued), 76% of the ECT sample was rated markedly improved by a central team of Massachusetts Mental Health Center physicians, compared with 37% of the imipramine sample ($p<.01$ by chi-square).

Shepherd M et al. (1965) conducted a collaborative double-blind trial designed by the Clinical Psychiatry Committee of the British Medical Research Council, in which patients with endogenous depression were randomly assigned to receive a minimum of 4 weeks of treatment with ECT (n=58), the tricyclic antidepressant imipramine (n=58), or placebo (n=58). On completion of 4 weeks of treatment physicians' blind global outcome assessments showed 84% of the ECT group to be improved, compared with 72% of those on imipramine; 71% of the ECT group showed no or only slight depressive symptoms, compared with 52% of the imipramine group (chi-squared = 8.75, $p<0.0005$).

Genuine ECT vs. Sham ECT

Brandon et al. (1984) randomly assigned 95 major depressives to courses of either genuine (n=53) or sham (n=42) bilateral ECT. Eighteen patients failed to complete a full course of treatment, leaving 77 who

completed the trial. Treatment was administered twice per week with a maximum of 8 ECT treatments. On the blindly-administered Hamilton depressive rating scale, the improvement in the group given real treatment was significantly greater than that in the group given simulated (sham) treatment both at 2 weeks ($p=0.014$) and at 4 weeks ($p=0.0001$). At follow-up at 12 and 28 weeks, there was no difference between the treatment groups. At the end of the 4-week trial consultants who were blind to the allocation of treatment rated the patients who had received real treatment as having made a significantly greater improvement than the patients who had received simulated treatment ($p<0.0005$).

In the Nottingham study, Gregory et al. (1985) randomly assigned 60 depressives to genuine unilateral ECT (n=19), genuine bilateral ECT (n=21) or sham ECT (n=20) to be administered twice weekly, with approximately 8 ECTs in total per patient. Results on the blindly-administered Hamilton Depression Rating Scale showed improvements of 31 points in the unilateral ECT group, 28 points in the bilateral ECT group, and 14 points in the sham ECT group. However, longer-term follow-up did not identify such differences between the groups.

Abbott et al (2013) reported twelve DSM-IV manic-depressive depressed patients treated with a Thymatron® System IV, rated on the Hamilton scale before and after a course of ECT. They exhibited a statistically significant mean depression scale improvement of 27.6 points. Nine patients achieved remission; three did not.

Azuma et al (2007) studied 14 treatment-resistant depressives who received bilateral ECT with a Thymatron® System IV. Statistically significant improvement in Hamilton Depression Scale scores was achieved, with 43% scoring under 8 points on this scale post-ECT. Postictal suppression measured by the Thymatron® System IV significantly predicted therapeutic outcome.

Heikman et al (2002) used a Thymatron® DGx ECT device to treat 24 major depressives randomly assigned to high-dose right unilateral ECT, moderate-dose right unilateral ECT, or low-dose bifrontal ECT. Blindly-obtained Hamilton Depression scale scores at baseline and after the ECT course showed an overall 66% improvement, with the highest improvement (73%) recorded for the high-dose right unilateral group. 13 patients experienced remission from depression and nine did not.

Heikman et al. (2002b) separately reported that depression showed remission to ECT with a Thymatron® DGx ECT device in 2 of 24 patients whose depression was of low severity or was accompanied by a somatic or psychiatric comorbidity. Among patients with higher severity and no comorbidity remission was achieved in ten and not in six.

Huang CJ et al (2017) studied 95 inpatients with depression receiving at least 6 ECT sessions with a Thymatron® device. Quality of life, symptom severity, and functioning were assessed before and after ECT on the Hamilton Depression scale and the Modified Work and Social Adjustment Scale CT. All measures showed statistically significant improvements after treatment without notable adverse effects. After ECT, HAMD scores averaged 6.6 (normal) and ranged from 1 to 34 (severe depression).

Kellner, et al (2005) used a Thymatron® DGx to administer ECT to 131 highly suicidal unipolar major depressives, out of 455 unipolar depressives admitted to hospital for ECT. Suicidal intent was scored at baseline and before each ECT session with item 3 on the 24-item Hamilton Depression Rating Scale. Suicide ratings of these 131 patients ultimately dropped to zero, including for the 13 patients who had actually attempted suicide. Of the 355 patients who received ECT during the study, 304 achieved remission – defined

as two consecutive Hamilton depression scale ratings ≤10 and a ≥60% reduction in Hamilton depression scale total score – and 51 did not. Two males, aged 76 and 80, suicided during the study.

Lin CH et al (2013) studied 55 treatment-resistant major depressives (44 unipolar, 11 bipolar) who received ECT with a Thymatron® System IV. Treatment-resistant depression was defined as a failure to respond to aggressive interventions of three or more kinds of antidepressants with adequate dosages and durations. The severity of depression was measured using the 17-item Hamilton Rating Scale for Depression (HAMD-17) and the Clinical Global Impression-Severity (CGI-S) administered by trained psychiatrists before ECT, after every 3 sessions of ECT, and at the end of ECT. The intraclass correlation coefficient of between-rater reliability was 0.95. Scores on both scales showed statistically significant reductions in depression severity after the end of ECT: The HAMD-17 fell from 30.8 to 7.3 ($p<0.001$) and the CGI-S fell from 6.3 to 2.8 ($p<0.001$).

Lin CH et al. (2018) compared responses to depression in patients treated with ECT using a Thymatron® System IV and patients treated with fluoxetine. ECT produced response in 96 of 104 patients (92%) and not 8 patients, versus a response in 66 of 112 patients (59%) and not in 46 with fluoxetine. ECT patients responded faster and more frequently experienced headache.

Prudic et al. (2004) performed a study using undisclosed ECT devices including sine wave devices, in which clinical remission from depression was obtained in 30.3% to 46.7% at hospitals in the New York City community. Relapse after initial remission was more frequent in patients with a comorbid personality disorder. The authors hypothesized but did not establish a cause of the low efficacy.

Ranjkesh et al (2005) randomly assigned 39 DSM-IV patients with major depression to receive courses of 8 bifrontal, bitemporal, or right unilateral ECT with a Thymatron® DGx ECT device. Blindly-obtained Hamilton Depression scale ratings at baseline and after the 8th ECT revealed 73% improvement overall.

In Sackeim et al. (1993), a study that did not did not use a Thymatron device, 59% of patients who responded to ECT relapsed within twelve months.

Tran et al (2017) presented the case of a 25-year-old woman hospitalized for a major depressive episode and suicidality in the context of bipolar 1 disorder, whose symptoms fully remitted with 1 ECT with a Thymatron® device.

Williams et al (2008) used a Thymatron® DGx ECT device to administer 1.5 times threshold bitemporal ECT to 515 patients with DSM-IV unipolar major depression, obtaining a 68% reduction in Hamilton Depression scale scores after treatment. Remission occurred in 329 patients (64%) and not in 186.

In Winokur, et al. (1990), a study conducted before Thymatron devices were available and when sine wave ECT devices were common, patients experienced more rehospitalizations after ECT than matched patients who did not receive ECT. The authors did not establish a cause.

SAFETY OF THE THYMATRON® ECT DEVICE

RISK OF BRAIN INJURY

Sartorius et al. (2016) conducted a prospective, MRI-based study of whole brain gray matter volume and voxel-based cortical thickness in depressed patients with a mean age of 52 years who received a course of titrated right unilateral ECT with a Thymatron® System IV device. 20 psychiatric inpatients with a Major Depressive Episode (mean Hamilton Depression Scale score=31.8, mean Mini-Mental State Examination score=27.9) entered the study, of whom 18 received pre- and post-ECT MRIs. Statistically significant whole brain gray matter increases were observed in the temporal lobe regions of interest, including hippocampus, amygdala, and habenula, as well as an increase of cortical thickness in temporal lobe and insula. The authors concluded that the data (1) widely excluded white matter loss as an indirect cause of grey matter growth, and (2) added support to the hypothesis that ECT enables cerebral plasticity, in contrast to older claims that ECT induces brain damage. No adverse side effects were reported.

Bai T et al. (2019) studied 61 depressed patients receving ECT with a Thymatron® System IV device compared with 23 healthy controls. ECT was found to increase local activity of the dorsomedial prefrontal cortex and enhanced connectivity with the posterior cingulate cortex that was positively correlated with clinical improvement. These findings support the functional plasticity of the dorsomedial prefrontal cortex and its potential reorganization by ECT that may underlie its antidepressant effect. The study reported no signs of injury.

Bouckaert et al. (2016) obtained structural magnetic resonance images in 88 severely depressed elderly patients who received courses of ECT with a Thymatron® System IV device. Following ECT, there was a statistically significant improvement in Montgomery-Asberg Depression Rating Scale (MADRS) scores, a statistically significant but short-lived increase in hippocampal volume, and no change in serum levels of brain-derived neurotrophic factor. The authors concluded that ECT-induced hippocampal growth is a transient phenomenon possibly related to ECT-induced normalization of physical activity levels. They reported no signs of injury.

Cano et al. (2017) studied 12 patients with treatment-resistant depression who received bilateral ECT with a Thymatron® System IV device and compared them with 10 healthy controls on high-resolution structural MRI and hippocampal metabolite concentrations before and after a course of treatment. ECT-induced regional gray matter volume increases in the left medial temporal lobe revealed a statistically significant positive association with clinical improvement, which was not true for neuroinflammatory changes as measured by hippocampal metabolites. The authors concluded that structural, but not metabolic, changes in the left medial temporal lobe are useful neuroimaging biomarkers of ECT-induced clinical improvement in treatment-resistant depression.

Cano et al. (2018) used MRI to assess whole-brain gray matter volume in 24 subjects with treatment-resistant depression before and after courses of bilateral or right-unilateral ECT given with a Thymatron® System IV device. Bilateral ECT induced bilateral gray matter volume increases in the limbic system, compared with gray matter volume increases limited to the right hemisphere after right-unilateral ECT, which may reflect the occurrence of neuronal increase.

Doddi SR et al. (2018) reported a 72 year old man with severe depression following a subarachnoid hemorrhage demonstrated on CT who received 9 bifrontal ECTs 33 days post-hemorrhage with a Thymatron® System IV

device, with dramatic improvement in sequential Montgomery-Asberg Depression Scale scores, and Mini-Mental State Scores that ranged from 28-30, all within the normal range. A repeat CT scan after the first ECT showed no intracranial hemorrhage or any other acute intracranial process. Five months later he remained in full remission without signs of injury.

Ende et al. (2000) used proton magnetic resonance spectroscopic imaging to study hippocampal effects of the Thymatron® DG ECT device as reflected in N-acetylaspartate signals. In 17 patients receiving either unilateral or bilateral ECT (all of whom improved with treatment), no differences were found from 30 control subjects in hippocampal N-acetylaspartate signals, failing to provide evidence for ECT-induced hippocampal atrophy or cell death.

Gryglewski G et al. (2018) carried out Magnetic Resonance Imaging scans in 14 patients with unipolar treatment-resistant depression before and after courses of right unilateral ECT administered with a Thymatron® System IV device. Increases in volume of the right hippocampus, right amygdala, and right putamen by were observed, localized in the basal and lateral nuclei, and the corticoamygdaloid transition area of the amygdala, the hippocampal-amygdaloid transition area and the granule cell layer of the dentate gyrus. Cortical thickness increased in the temporal, parietal and insular cortices of the right hemisphere. These lateralized ECT-induced structural changes occurred in hippocampal subfields and amygdala nuclei that have been implicated in the pathophysiology of depression and support the potential for neuroplasticity in adulthood.

Hirano J et al. (2017) used task-related functional near-infrared spectroscopy to compare 108 healthy controls with 30 patients with major depressive disorder or bipolar depression before and after an ECT series administered with a Thymatron® System IV device. Pre-ECT, patients exhibited statistically significantly smaller oxyhemoglobin values in the bilateral frontal cortex during a verbal fluency task than healthy controls, values that increased statistically significantly after ECT. A decrease in depression severity was significantly correlated with an increase in oxyhemoglobin values in the right ventrolateral prefrontal cortex. Impaired functional responses, observed during the cognitive task in depressed patients, were normalized after ECT, suggesting that the acute therapeutic effects of ECT may reduce abnormal functional responses to cognitive tasks in the frontal brain regions of depressives.

Kranaster L et al. (2014) analyzed serum levels of the established brain injury markers protein S-100 and neuron-specific enolase in 19 patients with depression at baseline and throughout courses of ECT administered with a Thymatron® System IV ECT device. Protein S-100 and enolase levels remained stable throughout the treatment course, failing to support the presence of neuronal cell injury markers in patients receiving ECT.

Sartorius et al. (2018) obtained whole brain magnetic resonance imaging scans in 92 major depressives before and after ECT administered with a Thymatron® System IV device. Stastically significant gray matter volume increases were observed in the hippocampus and amygdala that did not correlate with psychopathology, age, gender or number of ECT sessions.

MEMORY AND COGNITIVE RISKS

Possible cognitive side effects of ECT include disorientation, orbital-frontal syndrome, forgetting (retrograde amnesia), learning impairment (anterograde amnesia), and delirium. Possible causes of delirium include tardive seizure and occult seizure. Cognitive side effects can be affected by treatment method including stimulus dose,

electrode placement, stimulus pulse width, anesthesia details, long seizure duration, neurological and medical conditions, and medications. Case reports suggest that some medications (e.g., lithium) predispose to cognitive deficits, and others (e.g., memantine, rivastigmine) may decrease them (Alizadeh et al., 2015; van Schaik et al. 2015).

Nuninga et al. (2018) compared 48 depressed patients and 19 healthy controls to investigate the effects of bilateral ECT on cognition in depression in a longitudinal case-controlled study. Included were patients aged >18 years with a diagnosis of unipolar or bipolar depression and an indication for ECT. Excluded were those with past or present medical condition or brain pathology, prior ECT within 6 months, or present pregnancy/lactation. Patients underwent various cognitive tests – including of working memory, verbal fluency, visuospatial abilities, verbal/visual memory and learning, processing speed, inhibition, attention and task-switching, and premorbid IQ – at baseline (n = 43), after ten bitemporal ECT sessions with a Thymatron® System IV (n = 39), and six months after the tenth ECT session (n = 25). Healthy controls underwent the same cognitive assessment at baseline and after five-weeks. Clinical response was defined as a 50% reduction in Hamilon depression scale score compared to baseline. The overall effects of ECT on cognition were assessed via a multivariate repeated measures mixed model; a univariate mixed model was used to investigate the effects of ECT separately on each cognitive variable. Within the patient group, transient adverse cognitive side effects were observed for verbal memory and learning, and verbal fluency. None of the cognitive domains tested showed persisting impairments after six months. Autobiographical memory was not assessed. The authors concluded that the data show that although bilateral ECT has short-term negative cognitive effects that could be explained by a decrease in cognitive performance, a lack of learning effects, or a combination of both, these negative effects on cognition appear to recede 6 months post-ECT.

Ng et al (2000) used a Thymatron® DGx to treat 32 major depressives with courses of right-unilateral ECT (mean = 9.4). The mean percentage recall of Personal Memory test items recorded at baseline was 68% after 6 ECTs, 72% at treatment endpoint, and 87% one month later. Wechsler Adult Intelligence Scale scores did not change with ECT.

Obbels J et al. (2018) assessed 110 subjects (mean age 73) with unipolar major depression who were referred for ECT. Subjects underwent baseline cognitive testing and then received an average of 14 treatments with a Thymatron® System IV device (right unilateral, 60%; bilateral, 7%; initially unilateral switched to bilateral, 33%). The same cognitive testing was repeated 6 months after the last ECT, though 26% of subjects declined retesting at this follow-up. There were no statistically significant changes from baseline to 6 months post-ECT in any of the neuropsychological assessments (visual memory, verbal memory, delayed recall, and executive function). In examinations of patient-level data, cognition statistically significantly improved in 14% of patients and significantly declined in 12%.

In a series of 81 elderly depressed patients treated with a Thymatron® System IV device, Mini-Mental State Examination scores were not below pretreatment levels one week post-ECT, although some patients had exhibited preexisting brain atrophy (Oudega et al., 2014). In another series of 65 similarly treated elderly patients, deficits in executive function and processing speed appeared only transiently (Dybedal et al., 2016).

Schat et al (2007) used a Thymatron® DGx ECT device to treat 83 DSM-IV medication-free patients with unipolar depression who had been evaluated at baseline on tests of behavioral (everyday) and semantic memory. One year after a course of bilateral or unilateral ECT, neither everyday nor semantic memory scores

were reduced from baseline; bilateral ECT was associated with improved semantic memory scores.

Mohn & Rund (2016) evaluated a group of 31 patients with major depressive disorder prior to and 6 weeks after non-standardized ECT. Statistically significant improvements were found six weeks after ECT in processing speed, attention/vigilance, and visual learning, with other cognitive domains unchanged from baseline.

Smith GE et al (2010) conducted a randomized controlled trial in unipolar major depressives, comparing multiple memory test effects after 12 and 24 weeks of ECT with the Thymatron® System IV device and pharmacotherapy with a nortriptyline-lithium combination. Twelve-week objective anterograde memory scores and 24-week subjective memory scores were statistically significantly improved for both treatment groups compared with baseline. There were no clinically significant memory outcome differences between ECT and drug therapy for depression.

van Oostrom et al (2018) studied 19 medication-free treatment-resistant major depressives. They underwent a whole-brain magnetic resonance imaging scan and a neuropsychological examination one week before and within 1 week after the course of ECT with a Thymatron® System IV device. With ECT, hippocampal volumes increased statistically significantly; this increase correlated with a decrease in cognitive functioning. The authors concluded that their findings tentatively suggested that the temporal increase in hippocampal volum after treatment, which may result from neurotrophic processes and is thought to be crucial for the anti-depressive effect, is also related to the temporary cognitive side effects of ECT. Earlier, Bouckaert et al. (2016) had reported statistically significant but short-lived ECT-induced increases in hippocampal volume, concluding that their data suggested that hippocampal volume increase after ECT was a transient phenomenon possibly related to ECT-induced normalization of physical activity levels. They reported no signs of injury.

Verwijk et al (2014) assessed global cognitive function, memory, and executive functions in 42 depressed patients before and one week and 6 months after courses of ECT administered with a Thymatron® System IV device. There was no decline for any of the neurocognitive tests after ECT. Medium to large post-ECT improvements in neurocognitive functioning one week post-ECT were statistically significant for the Mini-Mental State Examination, Visual Association Test, 10 Words Verbal Learning Test, and Expanded Mental Control Test.

Ziegelmayer C et al (2017) examined neurocognitive performance in a sample of 20 treatment-resistant ECT-naive depressed subjects. Cognitive functioning was assessed at baseline, 1 week, and 6 months after 12 to 15 unilateral ECTs with a Thymatron® System IV device. No adverse effects were observed in any of the cognitive domains examined.

Falconer et al (2010) treated 24 patients with severe depression with a course of bilateral ECT administered with a Thymatron® DGx device. Patients were assessed before ECT, during ECT, within the week after ECT and 1 month after ECT with a battery of visual memory tests including spatial and pattern recognition memory, pattern-location associative learning, and delayed matching. Patients showed significant impairments in visual and visuospatial memory both during and within the week after ECT. Other deficits resolved within 1 month following ECT, but not those in spatial recognition memory. Later testing was not reported.

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DISCLAIMER / WARRANTIES

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), or structural brain change (brain injury) cannot occur as the result of ECT or the general anesthesia administered with 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. Mental and physical illnesses, anesthesia, medications, and postponement of treatment each have their own adverse effects, which can be substantial.

The outcome of ECT treatment depends on many clinical aspects outside the ECT device, including the physical, psychiatric and emotional condition of the patient prior to and at ECT, details of the ECT treatment other than the ECT device settings, including anesthesia and medication exposure. By using the Thymatron® System IV device, the user accepts responsibility for describing details of those and of pre-existing conditions including brain injury and atrophy, and cognitive difficulties, and for disclosing all appropriate information about risks of ECT to patients, their families and their guardians (if any).

Somatics, LLC warrants that reasonable care has been used in the design and manufacture of this medical device. Handling, storage and preparation of this medical device as well as other factors relating to the patient, diagnosis, treatment, and other matters beyond the control of Somatics, LLC directly affect this medical device and the results obtained from its use. Further, no representation or warranty is made that a Somatics, LLC product will not fail or cause temporary or permanent cognitive deficits. Somatics, LLC disclaims responsibility for any medical complications directly or indirectly resulting from the use of this product.

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SPECIFICATIONS

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: 0.08 to 8.00 s in increments of equal charge

Maximum output: Standard maximum output across 220 ohms impedance, 504 mC (99.8 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 μV/cm) and EMG or ECG channels (50, 100, 200, 500, 1000, 2000, 5000 and 10,000 μV/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 μV/cm; EMG 50 μV/cm; ECG 50 μV/cm Common mode rejection: 80 dB
Isolation: full, opto-electronic
Printer paper speed: user selectable: 10 - 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”

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

EXPLANATION OF SIGNS AND SYMBOLS

FRONT PANEL

Warning note: Caution observe accompanying paperwork

Defibrillation proof applied part type BF (“Body Floating”).
B-The device has a special protection against electric shock, especially in regard to the permissible leakage current and the reliability of the protective earth conductor connection
F-The device has and insulated (floating) application part.

REAR PANEL

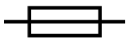
Declaration of conformity with the provisions of council directive 93/42/EEC concerning medical devices

CSA (“Canadian standard association”) certified device

Waste Electrical and Electronic Equipment. Do not throw in standard garbage. Recycle or dispose of equipment according to regulatory requirements of your country.

Adhere to manual

The device must only be opened by manufacturer or an authorized representative



Fuses

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 SELFTEST 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 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.

The 8-character L.E.D. is located above the IMPEDANCE TEST button.

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

The 4-character L.E.D. is located above the PERCENT ENERGY dial.

- It displays the different PERCENT ENERGY values as the dial is rotated. It then briefly displays the mC of charge corresponding to each PERCENT ENERGY dial setting.
- It displays the stimulus program in effect when the dial is pressed.
- 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 are located on the front panel.

- The L.E.D. labeled "FLEXDIAL" flashes when the FlexDial™ is activated.
- The L.E.D. labeled "SAFETY MONITOR ACTIVATED" flashes when the Safety Monitor has been activated.
- The L.E.D. labeled "PRESET" lights when the LOW 0.5 program is in effect.
- The L.E.D. labeled "USER SET" lights when a user set selection is in effect.
- 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, 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™ Mode 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]

- Press the FlexDial™ to display the most recently adjusted FlexDial™ function.
- Rotate the FlexDial™ in either direction to display the desired function.
- Press the FlexDial™ to flash-display the option in effect for that function.
- Rotate the FlexDial™ to flash-display the other options.
- 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.
- 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

Function	**Selects these options**
SETTING	Resets to factory specifications, loads up to 8 user set selections
CHANN. 1	Channel 1 gain and position settings
CHANN. 2	Channel 2 gain and position settings
CHANN. 3	Channel 3 gain and position settings
CHANN. 4	Channel 4 gain and position settings
FREQUENC	Stimulus frequency (10 Hz – 70 Hz in 7 steps)
P-WIDTH	Stimulus pulsewidth (0.25 ms – 1.5 ms in 6 steps) (0.3 ms available)
PROGRAMS	Selects from 5 factory pre-programmed or user stimulus programs
SAVE USR	Stores up to 8 user set selections

CH 3-4	Enables channels 3-4 to monitor either EMG-ECG or EEG-EEG
ENDPOINT	Enables endpoint detection of EEG, EMG, HR measures, prolonged seizure alert signal and Baseline Retention, BLV
INDEXES	Enables seizure quality measures
EEG FREQ	Selects one of three EEG measures
PRINTOUT	Enables printer and FFT printout, sets paper speed
UPLOAD	Enables sending treatment data to a PC automatically
DATA OUT	Reprints treatment just given; sends treatment data to PC
DATA IN	Accepts hospital's name from PC for the printed report; Accepts treatment data for re-printing treatment record
CLOCK	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.

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.

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

Flow Chart for FLEXDIAL™ controller: See **Addendum IV**.

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 and to the left side. Feed a double sheet into the printer, just below the roller. The printer will automatically advance the paper and stop. Press the START/STOP button twice to feed the paper to the next black square. The display will show "FORMFEED" when it advances to the next black square. The "FORMFEED" will always indicate that the paper will advance to the next black square and stop.

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 cannot 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 ELECTRODES APPLICATION

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.

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

<u>EEG</u>: 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 ELECTRODES APPLICATION

Instructions for legacy metal old type stimulus electrodes are in **Addendum VI**.

Apply Thymapad™ adherent stimulus electrodes [Cat. # EPAD] electrodes 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 again on each Thymapad™ to ensure it is fully applied and then test the static impedance. Impedance testing is necessary for safety.

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)

Static impedance testing is necessary for safety. 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:

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.

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.

Check to make sure the electrodes have not slipped or twisted.

Reposition the stimulus electrodes to minimize the amount of hair underneath.

Increase pressure on the stimulus electrode by pressing harder with the foam handle applicator.

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.

MOUTH PROTECTION

During the ECT stimulus and seizure the jaw muscles commonly clench tightly. This poses risks of tooth fracture or displacement and biting of tongue and cheeks. These can cause mouth bleeding with pulmonary aspiration of blood. These risks are mitigated by inserting a mouth protector prior to the electrical stimulus. Somatics' mouth protectors have channels for ventilation and are available in reusable (sterilizable) and single-use types. They are accompanied by instructions for insertion.

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 nor 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 in Addendum VII shows all the standard dosages and stimulus parameters for each PERCENT ENERGY setting.

STIMULUS PROGRAMS: FACTORY PROGRAMMED

There are 5 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. All of these factory set programs can go to 100% and 504 millicoulombs where available.

DGX Reproduces the standard stimulus of the Thymatron® DGx

LOWEST Automatically adjusts parameters to provide the lowest charge rate

LOW 0.25 Fixed 0.25/0.3 ms pulsewidth varies frequency to maximize duration (1 – 100%)

LOW 0.5 Fixed 0.5 ms pulsewidth, varies frequency to maximize duration

INTERMIT Intermittent pulse-volley stimulus mimics the Siemens Konvulsator

Please see **Addendum VII** for the Program Tables for the frequencies, pulse widths, pulse numbers and durations for each Energy setting.

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 0.25/0.3, LOW 0.5, INTERMIT, 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 to 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 (0.3) to 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 (0.3) ms pulsewidth, which will provide stimuli only up to the 50% ENERGY. However, when the LOW 0.25 (LOW 0.3) 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 between 1% and 5% ENERGY, followed by re-stimulations at between 5% and 10% ENERGY. Increase 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 between 5% and 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.

TYPICAL COURSE OF TREATMENT

A typical acute course of treatment is two or three ECT sessions per week for between 6 and 10 total

sessions. Some patients may need more treatments to achieve maximum improvement. Patients with catatonia of malignant severity may benefit from more frequent ECT sessions at the beginning of their course.

TARDIVE SEIZURE

A tardive seizure is a seizure that occurs after the ECT session. It is sometimes called a delayed onset seizure. It is rare but dangerous, and fatality can occur. When it begins after an ECT session earlier that day clonus or worsening delirium may be seen. Anticonvulsant treatment is typically immediate and vigorous, such as full anesthesia with propofol. These patients should be considered for transfer to the ICU because of high risk for sudden cardiopulmonary arrest, a risk that lasts several days.

A different presentation of tardive seizure is onset of seizure at an ECT session in response to anesthesia alone, without an electrical stimulus. This can be managed in the same way an ECT seizure is, with insertion of a mouth protector, vigorous ventilation and seizure monitoring. If the seizure lasts longer than about 100 sec consider termination with propofol.

WORSENING OF PSYCHIATRIC SYMPTOMS

As with any treatment, some patients may show worsening along the course of ECT, and discontinuation of the treatment becomes a consideration. Patients showing worsening should be suspected of having delirium from the treatment or from combination with a complicating medical condition such as Parkinson's disease or a medication such as a sympathomimetic agent, aminophylline or L-DOPA. New onset of a medical condition should be considered, e.g., pneumonia, pulmonary embolus, MI, nonconvulsive status epilepticus, urinary tract infection. Patients with motor retardation or poverty of thought before ECT may show apparent worsening when ECT decreases these initial symptoms, with agitation, self-harm or suicidal behavior that should mitigate with further ECT; suicide risk can increase during this time. Unrecognized alcohol or substance use disorder with withdrawal symptoms can also cause worsening during a course of treatment.

MANIC SYMPTOMS

Patients treated with ECT may experience manic symptoms (including euphoria and/or irritability, impulsivity, racing thoughts, distractibility, grandiosity, increased activity, talkativeness, and decreased need for sleep) or a worsening of the psychiatric symptoms they are being treated for. Manic symptoms can appear during a course of ECT for major depression or catatonia. When the full syndrome of manic episode develops during ECT this is sometimes treated by simply continuing the course of ECT. Another possibility is to stop ECT and treat the manic episode with medications. Sometimes only disinhibition, intrusiveness, overfriendliness, impatience or indiscreet behavior appear. This may represent orbital-frontal syndrome rather than mania. Orbital-frontal syndrome typically clears spontaneously within one to two weeks after the ECT course is over, but can take a month or two.

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:

1. 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.

2. The "TREAT" button lights up *and* an intermittent buzzing tone sounds while the current is being delivered.

3. The "TREAT" button light and buzzing tone both turn off when the treatment stimulus ends. The "TREAT" button can then be released.

4. The *Audible EEG*™ 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.

5. 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*™ seizure monitor
2. The EEG paper recording
3. The Ictal Line™ seizure indicator
4. The EEG endpoint and indexes determined values

AUDIBLE EEG™ 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*™ 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*™ seizure monitor.

EEG PAPER RECORDING

1. *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.

2. *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™ 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".

Enter the FlexDial function and rotate to Channel (n) where (n) is 1,2,3 or 4.

Press the FlexDial to display the current gain setting for channel (n).

Setting the gain for channel number [n] to off turns off printing of that channel.
You can adjust the gain for channel number [n} to between 10 and 2000 (microvolts).

Push the FlexDial in to display the Position of the tracing.

Setting the Position for channel number [n] to Auto selects automatic positioning

Setting Position for channel number [n} to a value between 0 and 800 determines its position.

Push the FlexDial in again to return to channel selection.

Push the Impedance Test Switch to lock in new settings for gain and position.

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.

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:

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

SP. EDGE	95% Spectral Edge Frequency
MID FREQ	Median EEG frequency
% DELTA	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 10 mm/sec and 50 mm/sec may be selected *or the printing turned off entirely,* as follows.

FLEXDIAL™ PRINTOUT: PRINT 10, 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: Simply push the *FlexDial*™ three (3) times and press the Impedance Switch.

FLEXDIAL™ SETTING: RESET SETTING including channel Gain (G) and Position (P)

Chann. 1……..G1--200 µV; P1--AUTO

Chann. 2……G2--200 µV; P2--

AUTO Chann. 3……G3--1000 µV;

P3--AUTO Chann. 4……G4--1000

µV; 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 UPLOADLOAD -

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 the GENIE™ IV software tool,

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 tool. 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 tool 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 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 tool 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 FFTSends 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 tool 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.

DISPLAY EEG/EMG/ECG ON THE PC SCREEN

This feature allows for real-time display 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 display will not affect the printed paper recording.*

Before starting to display, make sure all the connections are correct and the GENIE™ IV software tool 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 display, follow the procedure below:

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

The display will stop while the treatment stimulus is given with the "TREAT" button and it will automatically re- start after the stimulus is completed. The display 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 display will also stop.

NOTE: To combine the display 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.

Please note, if the Thymatron printer is re-started after the last treatment is printed and it runs for over thirty (30) seconds, that data will be considered the last treatment and the previous treatment just printed before the re- start will be deleted from memory. Also, 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

ELECTROMAGNETIC COMPATIBILITY (EMC)

GENERAL NOTES

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.

5. This medical electrical equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this chapter.

6. Portable and Mobile RF communications equipment can affect medical electrical equipment.

LIST OF CABLES AND ACCESSORIES

Article Number	Description
#ECET-P	ECT Treatment Cable, black, Thymatron® System IV Plastic connector
#ECEF-4	EEG/ECG/EM Monitoring Cable, gray, for System IV Plastic connector
#ELDSC-9	Monitoring Lead Wires for Thymatron® System IV, 24" leads, set of 9
#ELDS-BR	Monitoring Lead Wires for Thymatron® System IV, 60" leads, set of 2
#ELDS-SP	Monitoring Lead Wire, Splitter, two wires into one
#ERTH	Remote Treatment Handle / Cable

⚠ CAUTION

Use of accessories and cabling other than those specified above, with the exception of those sold by Somatics LLC or its authorized representatives as replacement parts, may result in increased emissions or decreased immunity of the Thymatron® System.

ELECTROMAGNETIC EMISSIONS

Guidance and manufacturer's declaration – electromagnetic emissions		
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.		
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	

CAUTION

Thymatron® System should not be used adjacent to or stacked with any other equipment. If adjacent or stacked use is necessary, performance of the Thymatron® System should be observed to verify normal operation in the configuration in which it will be used.

ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity			
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.			
Immunity Test	**IEC 60601 – Testing level**	**Compliance level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±15 kV (Air) ±8 kV (Contact)	±8 kV (Air) ±8 kV (Contact)	Electrostatic discharge over air at ±15 kV required in some cases a system re-start. After the system restart the system returned to normal mode of operation.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for Power ports ±1 kV for In/Out ports	±2 kV for Power ports ±1 kV for In/Out ports	EFT's may cause artifacts on the printed waveforms. These can be differentiated from physiological waveforms. To minimize these effects, mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential Mode ±2 kV Common Mode	±1 kV Differential Mode ±2 kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0,5 cycles 0% U_T for 1 cycle 70% U_T for 25 cycles 0% U_T for 250 cycles	Fulfilled	Mains power quality should be that of a typical commercial or hospital environment. If the Thymatron® System shall be used continuously during mains power interruptions, it is recommended to power it from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field	30 A/m		Power frequency magnetic fields should be at levels characteristic of typical commercial or hospital environment.
REMARK: U_T is the main alternating voltage prior the application of the testing level			

Guidance and manufacturer's declaration – electromagnetic immunity			
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.			
Immunity Test	**IEC 60601 – Testing level**	**Compliance level**	**Electromagnetic Environment - Guidance**
Conducted HF disturbances IEC 61000-4-6 Radiated HF disturbances IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2,5GHz	V1 = 3 Vrms E1 = 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Thymatron® System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left(\frac{3,5}{V1}\right)\sqrt{P}$ $d = \left(\frac{3,5}{E1}\right)\sqrt{P}$ $80MHz\ to\ 800MHz$ $d = \left(\frac{7}{E1}\right)\sqrt{P}$ $800MHz\ to\ 2,5\ GHz$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol. 
Note 1: At 80 MHz and 800 MHz, the higher frequency applies. Note 2: These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. [a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Thymatron® System is used exceeds the applicable RF compliance level above, the Thymatron® System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Thymatron® System. [b] Over the frequency range 150 kHz to 80MH, field strengths should be less than [V1] V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Thymatron® System

Thymatron® ECT Systems are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Thymatron® System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) ant the Thymatron® System as recommended below, according to the maximum output power of the communications equipment specified below. The customer or the user of a Thymatron® System should assure that it is used in such an environment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = \left(\frac{3,5}{V1}\right)\sqrt{P}$	**80 MHz to 800 MHz** $d = \left(\frac{3,5}{E1}\right)\sqrt{P}$	**800 MHz to 2,5 GHz** $d = \left(\frac{7}{E1}\right)\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1,0	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800MHz, the separation distance for the higher frequency range applies

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 3 Stated separation distances will assure safe operation of the Thymatron® System. However some noise may be present on the printed waveforms.

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

SOMATICS, LLC.
720 Commerce Drive
Venice, Florida 34292 USA

Represented in EEC by Schwind Benelux Medical Electronics B.V.,
Benedendorpsweg 117, 6862 WE Oosterbeek, The Netherlands

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 13485:2016

Quality System Certificate No. 3819575

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

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ADDENDUM I (FIRMWARE CHANGES)

History of Firmware Changes to THYMATRON® SYSTEM IV

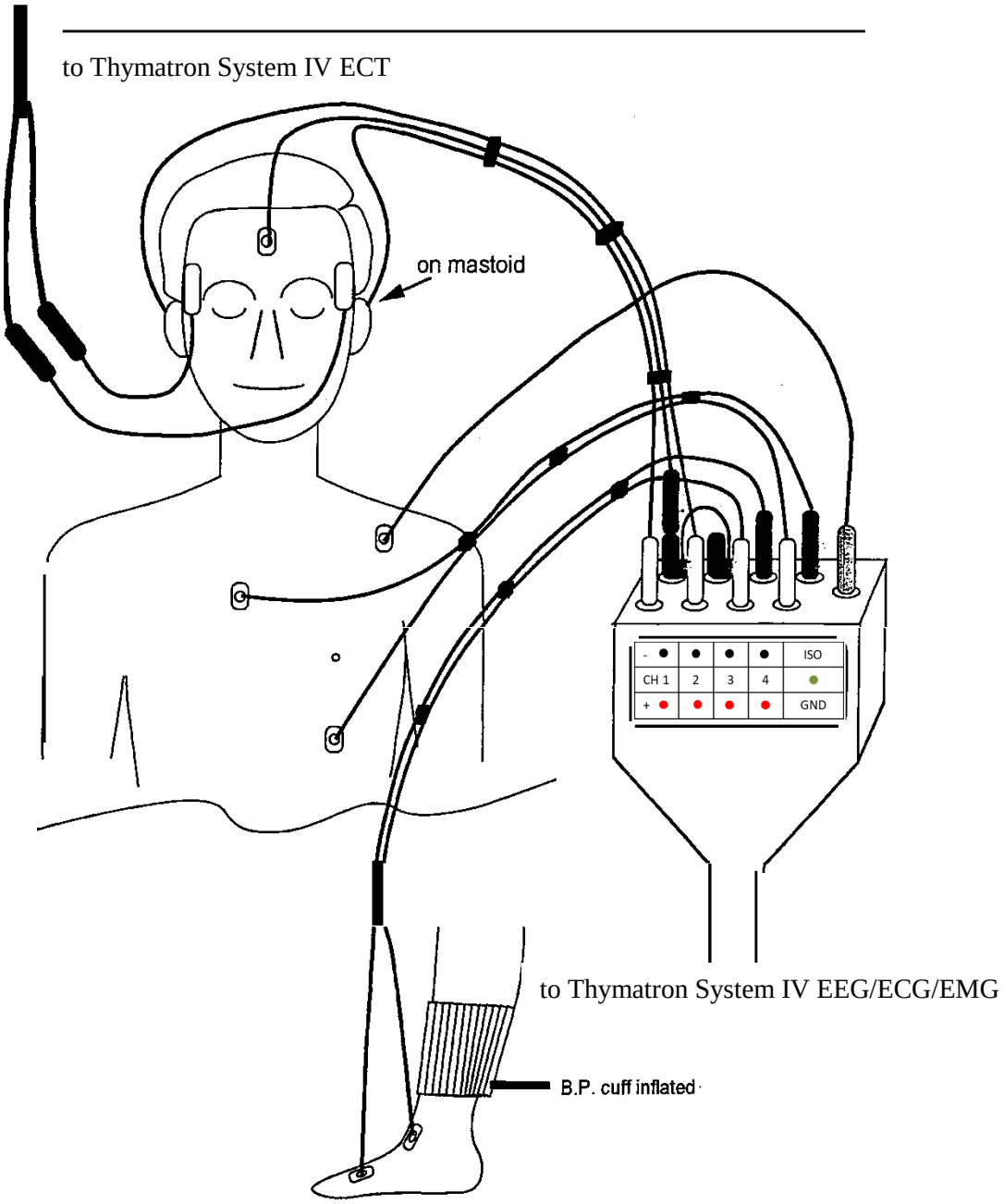
The software version of your Thymatron® System IV is printed at power-up.

Each of the following software upgrades includes all previous upgrades.

SOFTWARE VERSION	DATE	DESCRIPTION	REQUIRES GENIE VERSION
4.31	6/1/99	Initial software	4.5
4.32	6/15/99	Made DOS-compatible	4.5
5.00	9/1/00	Added Real time PC monitoring Palm® connection.	5.0
5.10	5/1/01	Added Diagnostic messages for EEG endpoint.	5.0
5.20	8/1/01	Added LOW 0.25 program	5.0
5.30	5/1/02	Added Automatic upload to PC SEI upgraded to ASEI, SGI retired Impedance test increased to 800 Hz.	6.3
5.40	11/15/02	Added EEG Frequency Measures	6.3
5.41	2/1/03	Eliminates need for recalibration after chip upgrade.	6.3
5.50	7/1/04	Improved algorithm for PSI Change program via Percent Energy Dial Change EEG gain *while* recording 2X Dose, (where available)	6.3
5.60	6/15/09	Adjusted baseline retention (BLV), 0-5 minutes Reset EEG Baseline when pushing Impedance Test & Energy Buttons simultaneously Either 0.25 or 0.3 pulsewidths & 2X-LP	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	Changed Baseline Validity settings	6.3
5.71	03/22/16	Added Driver code for rev B printer & 2X-DGx	6.8
5.72	01/10/18	Enabled Restart printer automatically	6.81b
5.80	11/12/18	Added 1% increments standard	6.81b

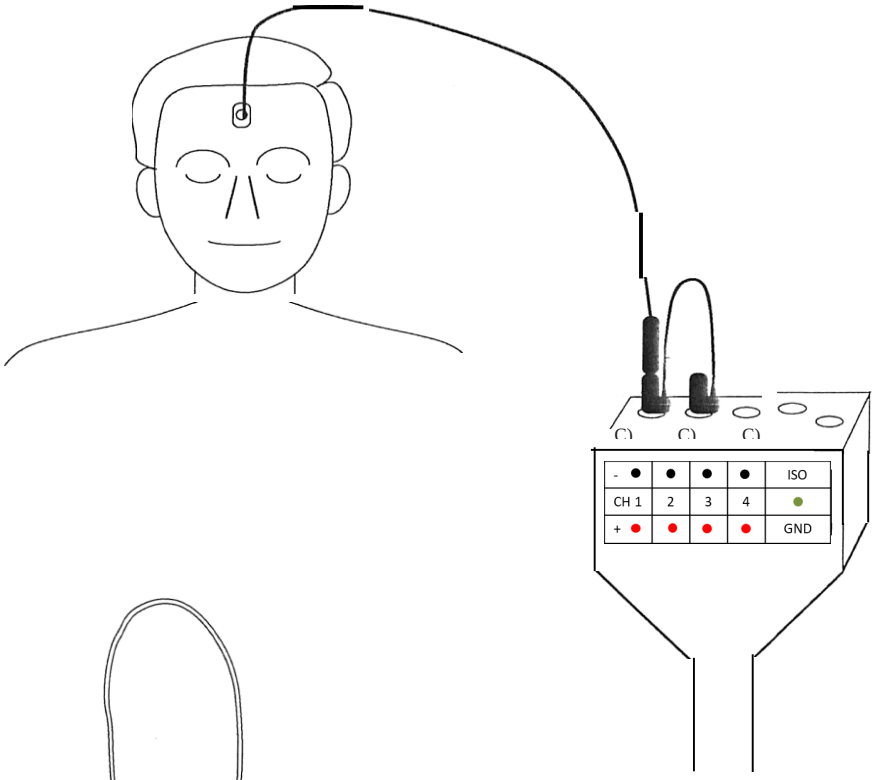
ADDENDUM II (ELECTRODE PLACEMENT)

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

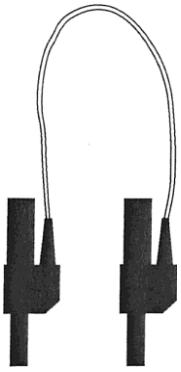


*Electrode connections for channel 1, 2 EEG, channel 3 EMG, channel 4 ECG recording

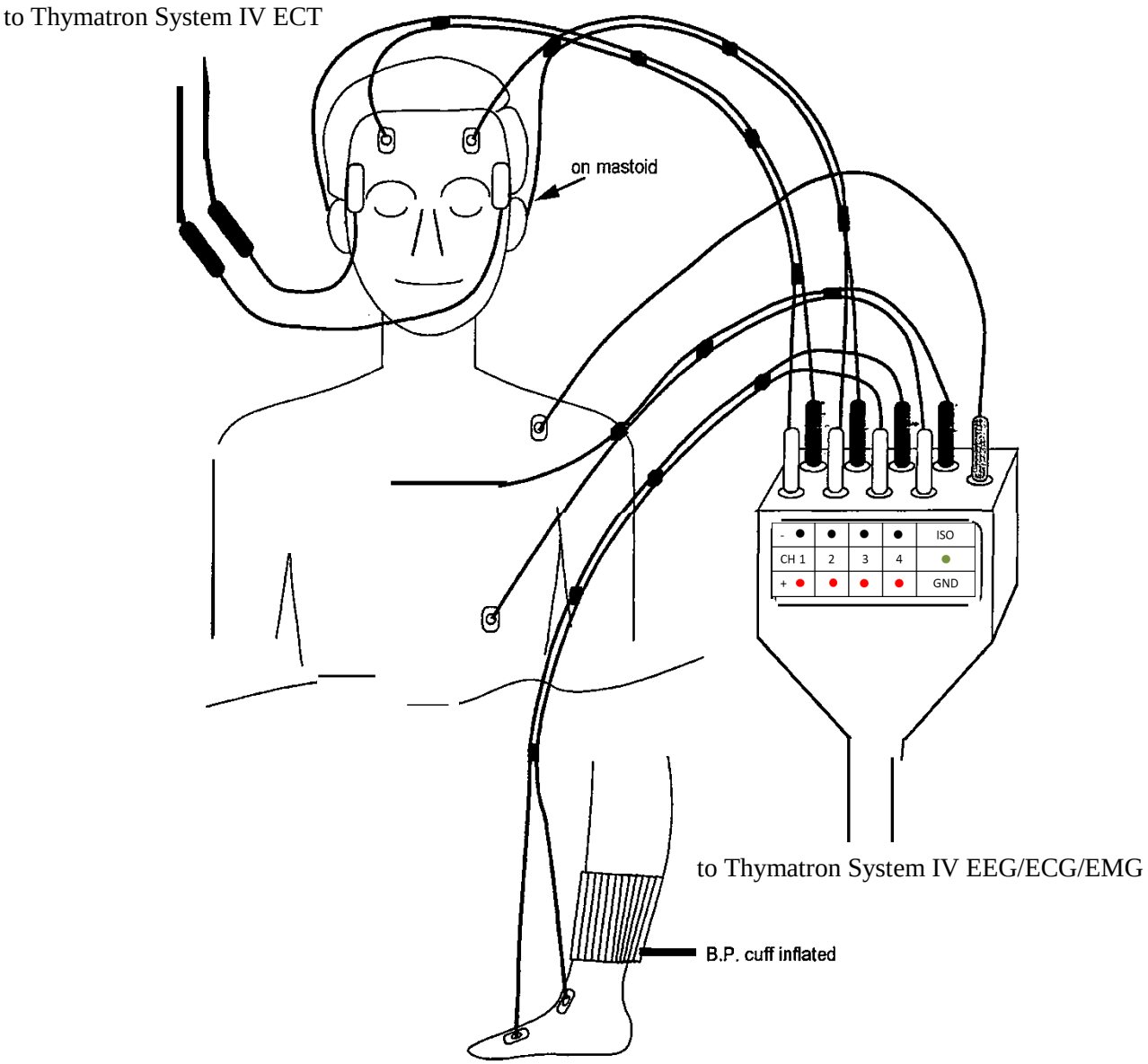
Electrode Splitter



to Thymatron System IV EEG/ECG/EMG



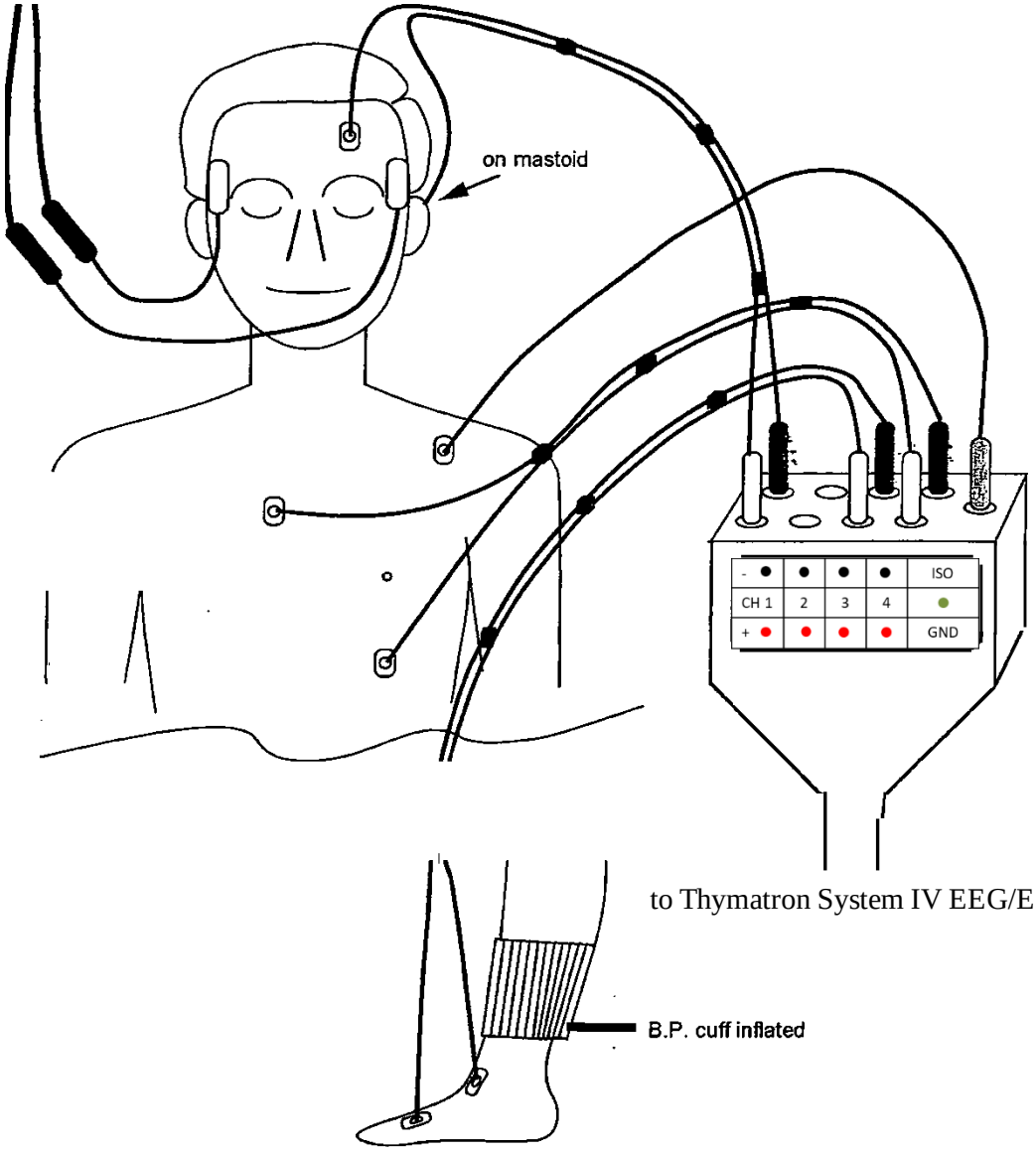
4-channel setup -> 2 EEG, 1 EMG, 1 ECG channel*



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

3 channel setup -> 1 EEG. 1 EMG, 1 ECG channel*

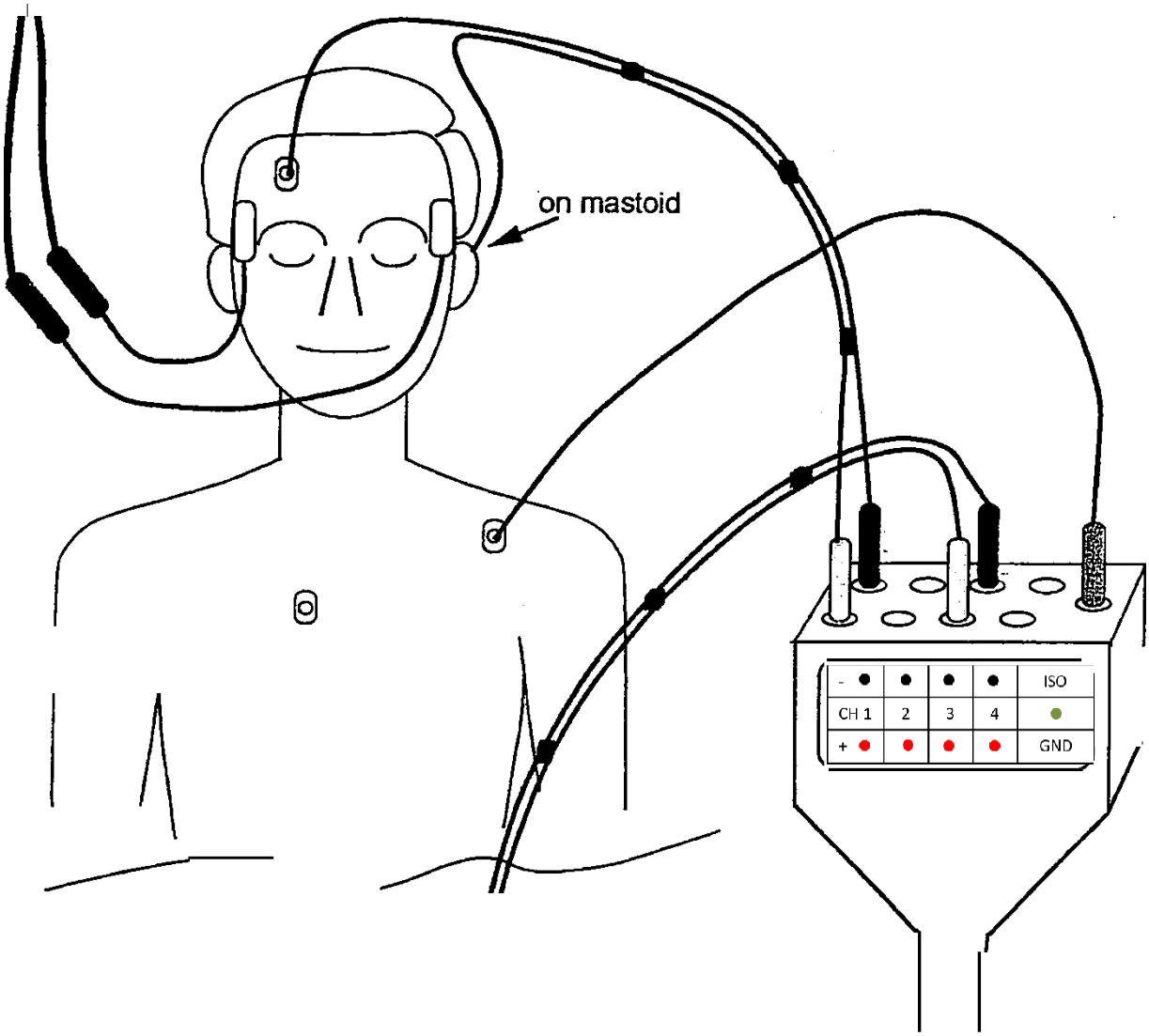
to Thymatron System IV ECT



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

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

to Thymatron System IV ECT

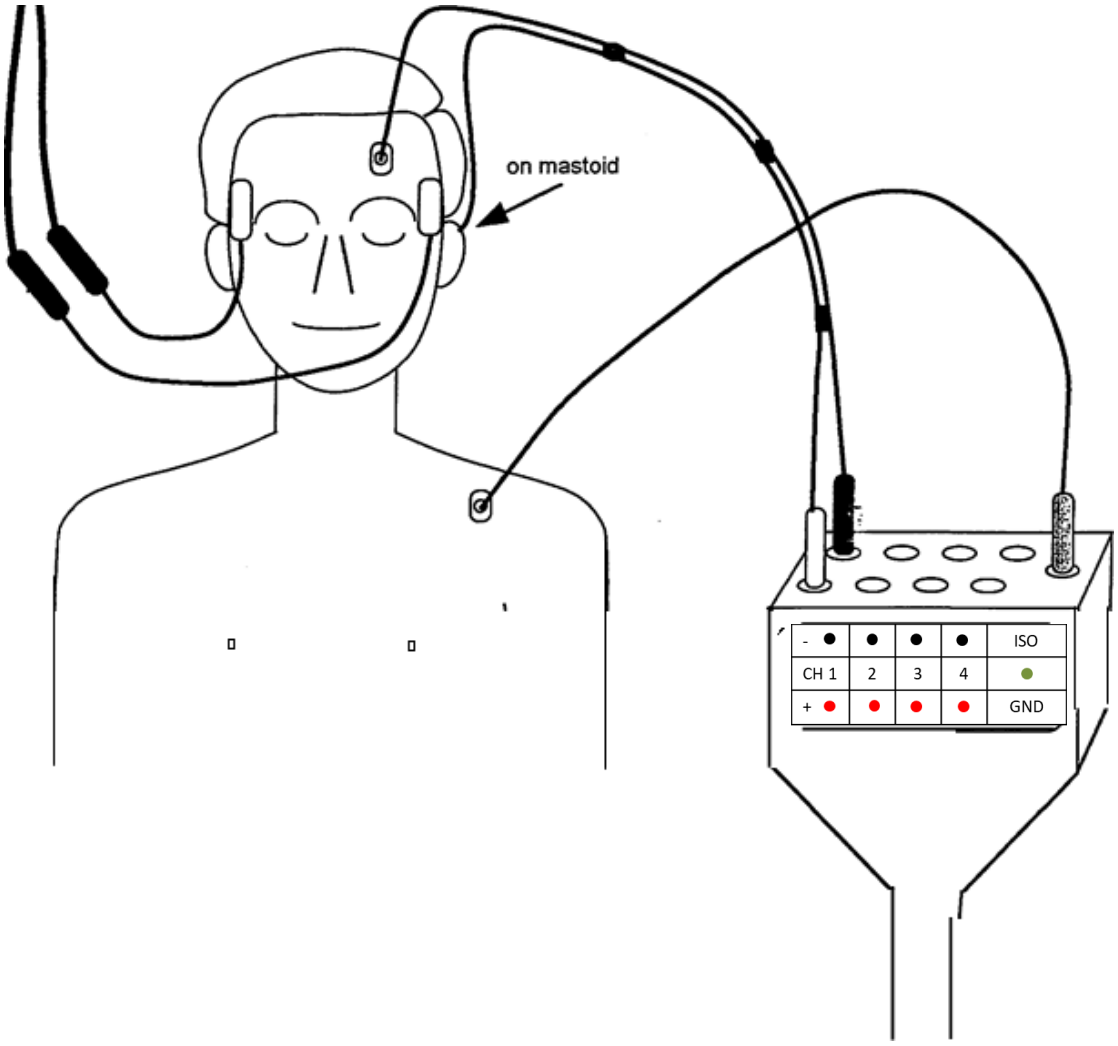


to Thymatron System IV EEG/ECG/EMG

*Electrode connections for channel 1 EEG, channel 3 EMG recording

1 channel setup -> 1 EEG channel*

to Thymatron System IV ECT



to Thymatron System IV EEG/ECG/EMG

*Electrode connections for channel 1 EEG recording

ADDENDUM III (INSTRUCTIONS TO PATIENT)

Safety Information

CAUTION — For patients with brain tumor, brain aneurysm, myocardial infarction, coronary insufficiency, heart failure, or aortic aneurysm medical specialists in Neurology or Cardiology should be consulted to determine additional precautions needed, if any.

WARNING — When used as intended, this device provides short-term relief of symptoms. The long-term safety and effectiveness of ECT treatment has not been demonstrated.

WARNING — ECT device use may be associated with disorientation, confusion, and memory problems.

ECT treatment may be associated with disorientation, confusion and memory loss, including short-term (anterograde) and long-term (autobiographical) memory loss following treatment. Based on the majority of clinical evidence, these side effects tend to go away within a few days to a few months after the last treatment with ECT. Although the incidence of permanent cognitive memory loss was not supported by the clinical literature, some patients have reported a permanent loss of memories of personal life events (i.e., autobiographical memory).

Patients treated with ECT may experience manic symptoms (including euphoria and/or irritability, impulsivity, racing thoughts, distractibility, grandiosity, increased activity, talkativeness, and decreased need for sleep) or a worsening of the psychiatric symptoms they are being treated for. Depressed patients have committed suicide even after ECT. Partial decrease in depression may increase risk of suicide.

The physical risks of ECT may include the following (in order of frequency of occurrence): Pain/somatic discomfort (including headache, muscle soreness, and nausea); Skin burns; Physical trauma (including fractures, contusions, injury from falls, dental and oral injury); Prolonged or delayed onset seizures; Pulmonary complications (hypoxemia, hypoventilation, aspiration, upper-airway obstruction); Cardiovascular complications (cardiac arrhythmias, heart attack, high or low blood pressure, and stroke); and death.

Clinical testing

Since FDA cleared the Somatics Thymatron ECT device for marketing in 1984, more than 4,300 Thymatron devices have been used worldwide. Numerous clinical studies have evaluated use of the device in treating severe depression. Rates of improvement for depressive illness have ranged from negligible to complete recovery, with most studies reporting substantial improvement. No reports of significant clinical worsening have occurred.

No major adverse events or deaths have been reported in the medical literature naming the Thymatron ECT device, nor have significant adverse effects been found in the numerous brain imaging and brain biochemical studies performed to assess the impact of these treatments. The primary adverse effects of ECT with a Thymatron device have been limited to relatively short-term, reversible disturbances of verbal and nonverbal memory and general cognition, and most studies actually show improvement in these functions several weeks or months after treatment. A single study found impairment in spatial recognition memory continuing one month after ECT.

Typical course of treatment:

The Thymatron System IV works while the patient is unconscious from anesthesia, by delivering a brief, controlled dose of electric current to the scalp in order to induce a brain seizure. This seizure changes chemicals in the brain called neurotransmitters, which are understood to be effective in treating depression and catatonia. During the seizure, the device measures the brain, muscle, and heart response to the electrical stimulus. The seizure usually ends by itself after a minute or two; if not, it may be halted by the clinician via administration of a known medication. A typical course of treatment is two to three sessions a week for two to three weeks. Some patients require a longer treatment course.

Potential benefits:

Potential benefits of ECT include relief of the symptoms of catatonia, major depressive disorder, or bipolar disorder for which the treatment was given.

Alternative treatments:

Alternatives to ECT treatment, depending on the primary diagnosis and the patient's condition, may include antidepressant drugs, antianxiety drugs, lithium, antipsychotic drugs, behavioral therapy, and/or psychotherapy.

Selected References

Petrides et al (2001), in a National Institutes of Mental Health (NIMH)-supported 4-hospital collaborative study, used a Thymatron® DGx device to prospectively treat 253 patients with nonpsychotic (n=176) and psychotic (n=77) unipolar major depression with bilateral ECT at 50% above titrated threshold. Included were patients aged 18 to 85 years with primary major depression, unipolar type, with or without psychosis, and a baseline Hamilton Depression scale score >20. Excluded were those with a lifetime diagnosis of bipolar illness, schizophrenia, or schizoaffective disorder, a medical contraindication to ECT, a systemic or neurological condition that might affect mood, failure to respond to a trial of ECT or a lithium-tricyclic antidepressant combination during the present episode, and substance dependence during the past year. Of the total sample, 56% were female and mean age was 56 years.
A standard ECT protocol was administered with bilateral electrode placement, seizure threshold determination, dosing at 50% above the titrated seizure threshold, and monitoring seizure efficacy by the duration of EEG-and EMG-monitored seizures. Patients were rated with the 24-item Hamilton depression scale and a neuropsycholical test battery 24-72 hours before the first ECT and after each subsequent ECT before the following treatment. Remission was defined

as 2 consecutive post-ECT-treatment Hamilton Depression Rating Scale scores <11, and a decrease of at least 60% on this scale from baseline on this scale. Chi-squared analyses were used to evaluate the relationship between unadjusted remission status and psychosis status. Multivariate logistic regression analyses were used to evaluate the relationship between remission status and psychosis status, adjusted for the effects of confounding or moderator variables; such analysis compared the longitudinal profile of total Hamilton scale scores measured 24-72 hours after each ECT for the psychotic and nonpsychotic depression groups. Most patients achieved scores of ≤10 and >60% reduction in scores for the first 8 ECTs administered, meeting the criteria for remission. For 217 completers of the acute treatment course, the overall remission rate was 87%, with a 95% remission rate for psychotic depression and 83% for non-psychotic depression patients. Side effects among study dropouts included confusion, memory loss, headache, and nausea.

Earlier, the efficacy of ECT had been supported by several controlled trials against antidepressant medications and by several double-blind, random assignment comparisons of genuine versus sham ECT. Some of these studies are summarized below.

ECT versus Antidepressants

Greenblatt, Grosser, and Wechsler (1964) included for study all severely depressed patients admitted to 3 state hospitals in Boston. All patients were randomly assigned to receive a course of 9 ECTs (n=28), or imipramine 200-250 mg/day (n=73). At the end of the one-year study period (after which systematic treatment assignment was discontinued), 76% of the ECT sample was rated markedly improved by a central team of Massachusetts Mental Health Center physicians, compared with 37% of the imipramine sample (p<.01 by chi-square).

Shepherd M et al. (1965) conducted a collaborative double-blind trial designed by the Clinical Psychiatry Committee of the British Medical Research Council, in which patients with endogenous depression were randomly assigned to receive a minimum of 4 weeks of treatment with ECT (n=58), the tricyclic antidepressant imipramine (n=58), or placebo (n=58). On completion of 4 weeks of treatment physicians' blind global outcome assessments showed 84% of the ECT group to be improved, compared with 72% of those on imipramine; 71% of the ECT group showed no or only slight depressive symptoms, compared with 52% of the imipramine group (chi-squared = 8.75, p<0.0005).

Genuine ECT vs. sham ECT

Brandon et al. (1984) randomly assigned 95 major depressives to courses of either genuine (n=53) or sham (n=42) bilateral ECT. Eighteen patients failed to complete a full course of treatment, leaving 77 who completed the trial. Treatment was administered twice per week with a maximum of 8 ECT treatments. On the blindly-administered Hamilton depressive rating scale, the improvement in the group given real treatment was significantly greater than that in the group given simulated (sham) treatment both at 2 weeks (p=0.014) and at 4 weeks (p=0.0001). At follow-up at 12 and 28 weeks, there was no difference between the treatment groups. At the end of the 4-week trial consultants who were blind to the allocation of treatment rated the patients who had received real treatment as having made a significantly greater improvement than the patients who had received simulated treatment (p<0.0005).

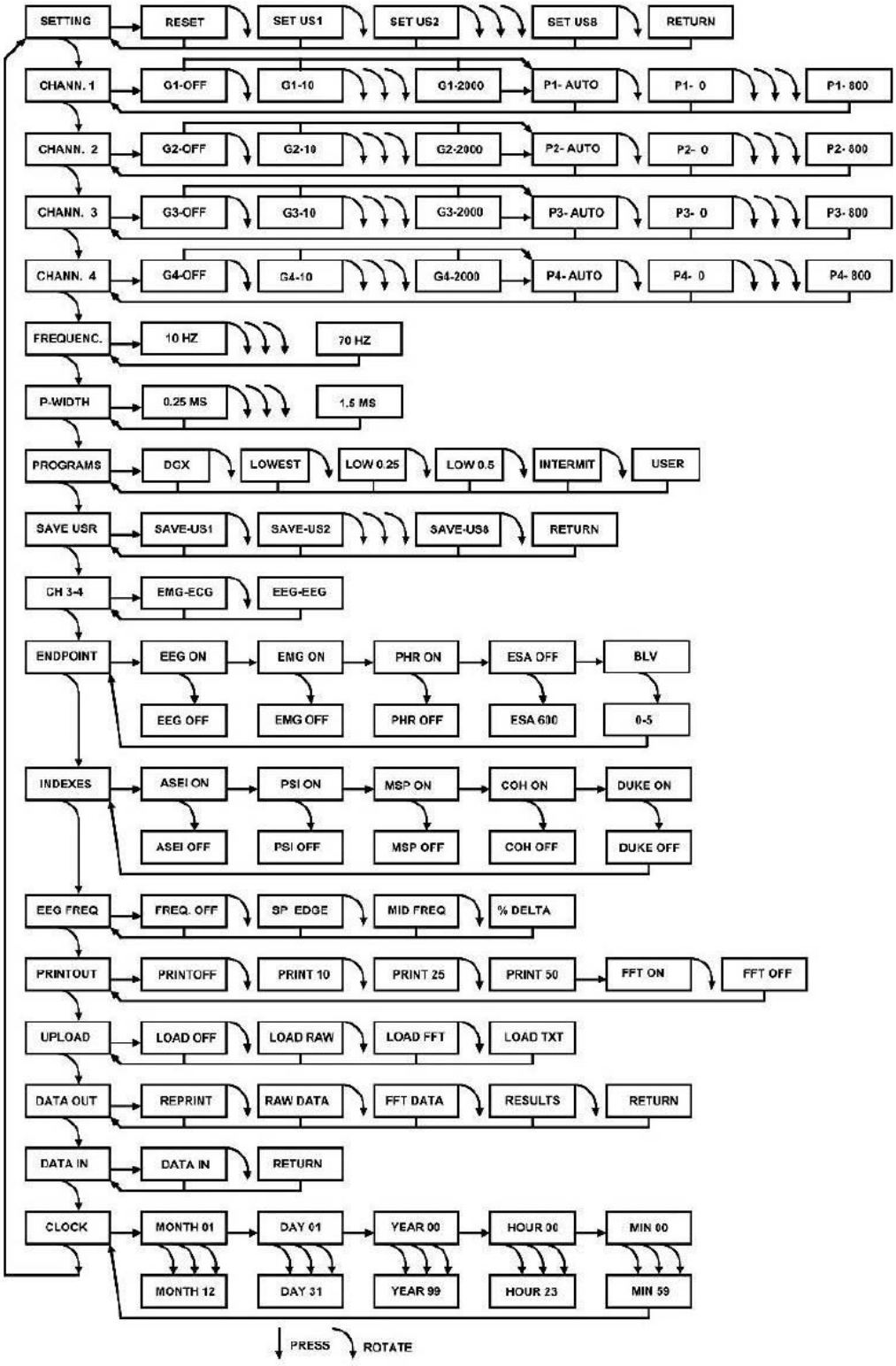
In the Nottingham study, Gregory et al. (1985) randomly assigned 60 depressives to genuine unilateral ECT (n=19), genuine bilateral ECT (n=21) or sham ECT (n=20) to be administered twice weekly, with approximately 8 ECTs in total per patient. Results on the blindly-administered Hamilton Depression Rating Scale showed improvements of 31 points in the unilateral ECT group, 28 points in the bilateral ECT group, and 14 points in the sham ECT group. However, longer-term follow-up did not identify such differences between the groups.

Sartorius et al. (2016) conducted a prospective, MRI-based study of whole brain gray matter volume and voxel-based cortical thickness in depressed patients with a mean age of 52 years who received a course of titrated right unilateral ECT with a Thymatron® System IV device. 20 psychiatric inpatients with a Major Depressive Episode (mean Hamilton Depression Scale score=31.8, mean Mini-Mental State Examination score=27.9) entered the study, of whom

18 received pre- and post-ECT MRIs. Statistically significant whole brain gray matter increases were observed in the temporal lobe regions of interest, including hippocampus, amygdala, and habenula, as well as an increase of cortical thickness in temporal lobe and insula. The authors concluded that the data (1) widely excluded white matter loss as an indirect cause of grey matter growth, and (2) added support to the hypothesis that ECT enables cerebral plasticity, in contrast to older claims that ECT induces brain damage. No adverse side effects were reported.

Nuninga et al. (2018) compared 48 depressed patients and 19 healthy controls to investigate the effects of bilateral ECT on cognition in depression in a longitudinal case-controlled study. Included were patients aged >18 years with a diagnosis of unipolar or bipolar depression and an indication for ECT. Excluded were those with past or present medical condition or brain pathology, prior ECT within 6 months, or present pregnancy/lactation. Patients underwent various cognitive tests – including of working memory, verbal fluency, visuospatial abilities, verbal/visual memory and learning, processing speed, inhibition, attention and task-switching, and premorbid IQ – at baseline (n = 43), after ten bitemporal ECT sessions with a Thymatron® System IV (n = 39), and six months after the tenth ECT session (n = 25). Healthy controls underwent the same cognitive assessment at baseline and after five-weeks. Clinical response was defined as a 50% reduction in Hamilon depression scle score compared to baseline. The overall effects of ECT on cognition were assessed via a multivariate repeated measures mixed model; a univariate mixed model was used to investigate the effects of ECT separately on each cognitive variable. Within the patient group, transient adverse cognitive side effects were observed for verbal memory and learning, and verbal fluency. None of the cognitive domains tested showed persisting impairments after six months. Autobiographical memory was not assessed. The authors concluded that the data show that although bilateral ECT has short-term negative cognitive effects that could be explained by a decrease in cognitive performance, a lack of learning effects, or a combination of both, these negative effects on cognition appear to recede 6 months post-ECT.

ADDENDUM IV (FLEXDIAL FLOW CHART)

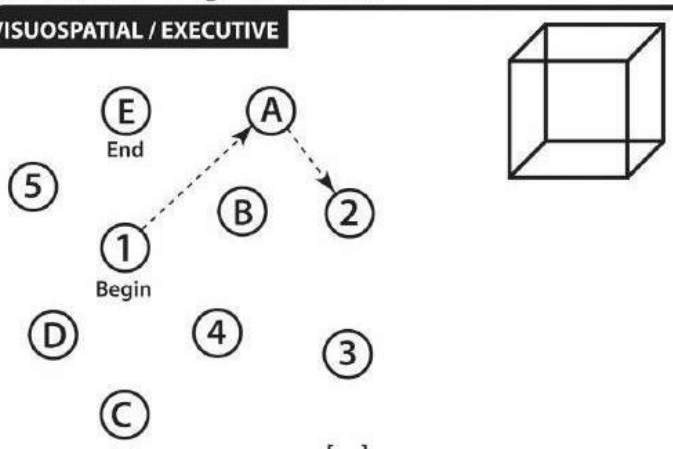


ADDENDUM V (MOCA TEST)

MONTREAL COGNITIVE ASSESSMENT (MOCA)
Version 7.1 Original Version

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE — POINTS



Copy cube

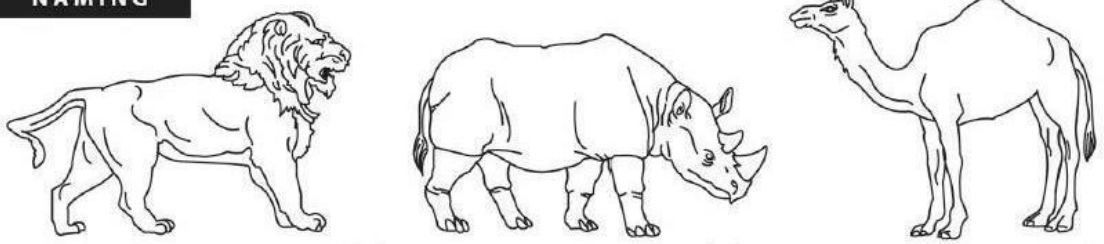
[ ] [ ]

Draw CLOCK (Ten past eleven) (3 points)

[ ] Contour [ ] Numbers [ ] Hands

___/5

NAMING



[ ] [ ] [ ]

___/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

___/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

___/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

___/3

LANGUAGE Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

___/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)

___/1

ABSTRACTION Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

___/2

DELAYED RECALL

	Has to recall words WITH NO CUE	FACE [ ]	VELVET [ ]	CHURCH [ ]	DAISY [ ]	RED [ ]	Points for UNCUED recall only
Optional	Category cue						
	Multiple choice cue						

___/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

___/6

© Z.Nasreddine MD www.mocatest.org Normal ≥ 26 / 30

TOTAL ___/30

Add 1 point if ≤ 12 yr edu

Administered by: _____

ADDENDUM VI (INSTRUCTIONS FOR LEGACY METAL OLD TYPE STIMULUS ELECTRODES)

⚠ CAUTION

In every case, be sure that before giving the electrical stimulus the patient is under anesthesia, the patient's muscles are fully relaxed, oxygen is being administered, ventilation is supported, a mouth protector is in place and the impedance is tested.

For bitemporal ECT with two electrode handles, insert one flat metal electrode in each of two handles. Plug the treatment cable into the receptacles on the handles. Apply conductive electrode gel to the smooth flat surface of each electrode. When ready to deliver the electrical stimulus hold each electrode firmly on the intended site.

With a remote treat handle the treat button is on one handle. With no remote treat handle the TREAT button is pressed by a second person familiar with its operation. For bifrontal ECT this procedure is the same except cupped metal electrodes are used. Likewise with left anterior right temporal placement the right electrode is flat and the left is cupped. For right unilateral ECT the temporal electrode is flat and the electrode near the vertex is cupped.

For bitemporal ECT using a rubber headstrap to hold the metal electrodes: This is usually done before anesthesia so the patient can assist by holding his head up. Insert one flat electrode in the first hole of the perforated headstrap and a second flat electrode 8 to 10 inches away, depending on the size of the patient's head. Position the first electrode about one inch above the mid-point of an imaginary straight line between the external auditory meatus and the outer canthus of the eye. This is usually on the flat part of the temple.

Then, while holding the first electrode in place, wrap the perforated strap across the forehead and position the second electrode over the same spot on the opposite temple. Wrap the strap around the back of the head and insert another strap perforation onto the first electrode. Adjust strap position so the electrodes are located where intended. Plug the treatment cable into the receptacles on the metal electrodes.

Then apply electrode gel to the flat surface of each electrode. When you are familiar with this method you may apply the gel after both electrodes are in the strap before they are placed on the head. For bifrontal ECT this procedure is the same except cupped metal electrodes are used. Likewise with left anterior right temporal) placement the right electrode is flat and the left is cupped.

For right unilateral ECT according to the placement of d'Elia using the perforated rubber headstrap, the headstrap is used only to hold a flat electrode on the right temple. The procedure for this is similar to bitemporal ECT except only one electrode is in the strap. Place a cupped electrode in an electrode handle, apply electrode gel, and place it over the scalp just lateral to the vertex. If the patient has hair near the vertex some physicians clip this hair. Clipping is not necessary if abundant electrode gel is used, but this makes the area slippery and after treatment the gel should be washed out.

With all methods, impedance testing is done with both electrodes firmly applied and the treatment cable plugged into the electrode receptacles. The impedance TEST button is then pressed. If the result is above 3000 ohms one or both electrodes are not properly connected to the cable or to the head. Perhaps the electrodes moved from the intended position, the cable is dislodged or broken, or more conductive gel is needed.

ADDENDUM VII. TABLES OF STIMULUS DETAILS FOR EACH % ENERGY SETTING OF THE DOSE DIAL

DGX program

% Energy	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Frequency, hz	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
Pulse width, ms	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Pulse number	6	11	17	22	28	34	39	45	50	56	62	67	73	78	84	90	95	101	106	112	118	123
Duration, sec	0.08	0.17	0.27	0.35	0.45	0.55	0.63	0.73	0.82	0.92	1.02	1.10	1.20	1.28	1.38	1.48	1.57	1.67	1.75	1.85	1.95	2.03

Energy, %	23	24	25	26	27	28	29	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Frequency, hz	30	30	30	50	50	50	50	50	50	50	50	50	70	70	70	70	70	70	70	70	70	70
Pulse width, ms	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Pulse number	129	134	140	146	151	157	162	168	196	224	252	280	308	336	364	392	420	448	476	504	532	560
Duration, sec	2.13	2.22	2.32	1.45	1.50	1.56	1.61	1.67	1.95	2.23	2.51	2.79	2.19	2.39	2.59	2.79	2.99	3.19	3.39	3.59	3.79	3.99

LOWEST CHARGE RATE program (0.25) (standard pulsewidth set)

% Energy	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Frequency, hz	10	10	10	10	10	20	20	20	20	20	30	30	30	30	30	30	30	30	30	30	40	40
Pulse width, ms	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Pulse number	22	45	67	90	112	134	157	179	202	224	246	269	291	314	336	358	381	403	426	448	470	493
Duration, sec	1.05	2.20	3.30	4.45	5.55	3.33	3.90	4.45	5.03	5.58	4.08	4.47	4.83	5.22	5.58	5.95	6.33	6.70	7.08	7.45	5.86	6.15

Energy, %	23	24	25	26	27	28	29	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Frequency, hz	40	40	40	50	50	50	50	50	50	60	70	70	40	50	50	50	60	60	60	70	70	70
Pulse width, ms	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Pulse number	515	538	560	582	605	627	650	672	784	896	1008	1120	616	672	728	784	840	896	952	1008	1064	1120
Duration, sec	6.43	6.71	6.99	5.81	6.04	6.26	6.49	6.71	7.83	7.46	7.19	7.99	7.69	6.71	7.27	7.83	6.99	7.46	7.93	7.19	7.59	7.99

LOW 0.25 CHARGE RATE program (standard pulsewidth set)

% Energy	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Frequency, hz	10	10	10	10	10	20	20	20	20	20	30	30	30	30	30	30	30	30	30	30	40	40
Pulse width, ms	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Pulse number	22	45	67	90	112	134	157	179	202	224	246	269	291	314	336	358	381	403	426	448	470	493
Duration, sec	1.05	2.20	3.30	4.45	5.55	3.33	3.90	4.45	5.03	5.58	4.08	4.47	4.83	5.22	5.58	5.95	6.33	6.70	7.08	7.45	5.86	6.15

Energy, %	23	24	25	26	27	28	29	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Frequency, hz	40	40	40	50	50	50	50	50	50	60	70	70	80	90	100	100	110	120	120	130	140	140
Pulse width, ms	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Pulse number	515	538	560	582	605	627	650	672	784	896	1008	1120	1232	1344	1456	1568	1680	1792	1904	2016	2128	2240
Duration, sec	6.43	6.71	6.99	5.81	6.04	6.26	6.49	6.71	7.83	7.46	7.19	7.99	7.69	7.46	7.28	7.84	7.63	7.46	7.93	7.75	7.60	8.00

LOW 0.50 CHARGE RATE program

% Energy	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Frequency, hz	10	10	10	10	10	10	10	10	10	10	20	20	20	20	20	20	20	20	20	20	20	20
Pulse width, ms	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Pulse number	11	22	34	45	56	67	78	90	101	112	123	134	146	157	168	179	190	202	213	224	235	246
Duration, sec	0.50	1.05	1.65	2.20	2.75	3.30	3.85	4.45	5.00	5.55	3.05	3.33	3.63	3.90	4.18	4.45	4.73	5.03	5.30	5.58	5.85	6.13

Energy, %	23	24	25	26	27	28	29	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Frequency, hz	20	20	20	30	30	30	30	30	30	30	40	40	40	50	50	50	60	60	60	70	70	70
Pulse width, ms	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Pulse number	258	269	280	291	302	314	325	336	392	448	504	560	616	672	728	784	840	896	952	1008	1064	1120
Duration, sec	6.43	6.70	6.98	4.83	5.02	5.22	5.40	5.58	6.52	7.45	6.29	6.99	7.69	6.71	7.27	7.83	6.99	7.46	7.93	7.19	7.59	7.99

INTERMITTENT program

% Energy	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Frequency, hz	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
Pulse width, ms	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Pulse number	6	11	17	22	28	34	39	45	50	56	62	67	73	78	84	90	95	101	106	112	118	123
Duration, sec	0.08	0.27	0.47	0.65	0.85	1.05	1.23	1.43	1.62	1.82	2.02	2.20	2.40	2.48	2.68	2.88	3.07	3.27	3.45	3.65	3.85	4.03

Energy, %	23	24	25	26	27	28	29	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Frequency, hz	30	30	30	50	50	50	50	50	50	50	50	50	70	70	70	70	70	70	70	70	70	70
Pulse width, ms	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Pulse number	129	134	140	146	151	157	162	168	196	224	252	280	308	336	364	392	420	448	476	504	532	560
Duration, sec	4.23	4.42	4.62	2.85	3.00	3.06	3.21	3.27	3.85	4.43	5.01	5.49	4.29	4.69	5.09	5.49	5.89	6.29	6.69	7.09	7.49	7.89

Charge and Energy at the % Energy Settings of Stimulus Dose Dial

% Energy	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Charge (mC)	5	10.1	15.1	20.2	25.2	30.2	35.3	40.3	45.4	50.4	55.4	60.4	65.5	70.1	75.6	80.6	85.7	90.7	95.8	101	106	110.9
Joules at 220Ω	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	15.0	16.0	17.0	18.0	19.0	20.0	21.0	22.0

% Energy	23	24	25	26	27	28	29	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Charge (mC)	116	121	126	131	136	141	146	151	176.4	202	227	252	277	302	328	353	378	403	428	454	479	504
Joules at 220Ω	23.0	24.0	25.0	25.9	26.9	27.9	28.9	29.9	34.9	39.9	44.9	49.9	54.9	59.9	64.9	69.9	74.9	79.8	84.8	89.8	94.8	99.8