EXHIBIT 5

CONFIDENTIAL

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Submission Identification

This submission for reclassification of ECT devices from class III to class II was submitted by MECTA Corporation according to the following docket number.

[Docket No. FDA-2009-M-0101]

MECTA
(503) 612-6780

FDA-2009-M-0101-DRAFT-0115

CCP

IDENTIFICATION

ECT Reclassification Documentation

From MECTA Corporation

Introduction

This package of information provides a response to the FDA's request for ECT device manufacturers to submit information relevant to reclassification of ECT devices. In order to use the attached hyperlinks, www.mectacorp.com must be accessed. (b)(4) [redacted]

MECTA Corporation has defined the highest standard of excellence in the field of ECT neuromodulation devices through evidence –based research since its inception. A breakthrough by Dr. Paul Blachley with MECTA ECT research in 1973 at OHSU produced the first and only monitored (EEG.ECG), brief pulse ECT devices, MECTA C and D. Subsequent research at Columbia University was implemented into the SR/JR series in 1985. [Sackeim 2004], Finally, controlled research from Duke University [Krystal et al., 2000b] and Columbia University [Sackeim 2004] was integrated into the current MECTA spECTrum devices [home.html][1]. MECTA sells its spECTrum series ECT equipment in the United States and throughout the world, and has designed, tested and approved for use these four generations of ECT devices over the last 35 years.[home.html] MECTA ECT devices lead the ECT field in safety, meeting or exceeding all FDA, Health Canada and European Union standards. MECTA's extensive regulatory agency approvals worldwide include: U.S. (UL); Canada (CSA (cUL), Health Canada-8 Approvals, #1537, #62578, #62576); European Union, TUV (EN ISO 13485:2003+AC 2007; CMDCAS ISO 13485:2003, EC 93/42/EEC Annex II, Article 3); Korea (KFDA); Australia (TGA). MECTA equipment has been used to treat hundreds of thousands of patients with millions of treatments.

The following discussion of safety and effectiveness of ECT includes valid scientific evidence to assist in determining the reclassifications of ECT device from Class III to Class II with recommended performance standards. It represents the current standard of care and future research of new ECT modalities... MECTA provides this information solely for the purposes listed in the FDA request as stated below.

For any question regarding this submission please contact Mrs. Robin Nicol, President, or Dr. John Shaw, Director of Research and Development, at (503)-612-6780.

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[1] All html and pdf references are to MECTA's web site and should be preceded by http://www.mectacorp.com/ to make the full URL. Appendix E contains printed copies of the web pages alphabetized by URL.

Requested Information

In the following material, the underlined portions are quoted directly from the FDA request as published in the Federal Register. Each request is then followed by our response.

Any manufacturer who is aware of information that would support the reclassification of its device into class I or class II may either submit information using the format described below or may submit a formal reclassification petition, which is described in 21 CFR 860.123(a)(3) and (a)(4), should include:

1. *Identification.* **A brief narrative identification of the device. This identification should be specific enough to distinguish a particular device from a generic type of device. Where appropriate, this identification should include a listing of the materials, and the component parts, and a description of the intended use of the device.**

MECTA produces and sells four models of ECT devices:

The **spECTrum 5000Q ®** [spectrum-5000Q.html] is MECTA's top-selling device. It offers maximum flexibility to treat with four individual parameter sets of Pulse Width, Frequency, Duration and Current. The treatment dosage is set using the four knobs beneath the LCD touch screen.

The popular **spECTrum 5000M ™** [spectrum-5000M.html] offers dosing simplicity with one single Stimulus Intensity knob. This varies Frequency and Duration simultaneously, to control Charge. The other base features and options are the same as for the 5000Q.

The 5000 Q and M base units include a two channel chart recorder, and a choice of two channels of EEG and/or one EEG/ECG arrangement. Add up to four more channels of monitoring [additional-monitoring-channels.html] for four channels of EEG, one ECG and one Optical Motion Sensor [optical-motion-sensor.html]. EEG Data Analysis [eeg-data-analysis.html], Remote Monitor Software© [remote-monitor-software.html], MECTA RMS MANAGER© [rms-manager.html] and MECTA EMR© [mecta-emr.html] software options may be added for a fully loaded device.

The **spECTrum 4000Q ™** [spectrum-4000Q.html] is more economical, light-weight and portable than the 5000. It is a trimmed down version of the 5000 with no chart recorder and no physiological monitoring capability.

The **spECTrum 4000M ™** [spectrum-4000M.html], is similar to the 4000Q, but offers dosing simplicity with one single Stimulus Intensity knob. This varies Frequency and Duration simultaneously to control Charge.

*U.S. Patent #5,755,744 – U.S. Patent #6,014,587 – U.K. Patent #GB 2 307 413 B

All MECTA models provide ULTRABRIEF© (0.3 ms) pulse width settings [products.html], and titration tables are shipped with all MECTA devices.

All models include extensive redundant hardware and software testing to verify they are operating correctly.

An **extensive starter kit** [spectrum-starterkit.html] is included with every spECTrum device (kits may vary according to the model ordered). By supplying everything the clinician and biomed need to get started, MECTA ensures a turn-key startup. Manuals and visual aids, test equipment and clinical supplies assure hospital staff that treatments can begin promptly, efficiently and efficaciously. The starter kit includes:

Patient Stimulus Cable	Chart Recorder Paper
Patient Safety Monitor Cable	Bite Block
EEG and/or ECG Safety Leads	Oberto Mouth Prop
Adjustable Headband	Electrode Gel
Flat Stimulus Electrodes	Electrode Paste
Concave Stimulus Electrodes	ECG Disposable Electrode Pads
Fuse (2 or 4 Amp)	EEG Disposable Electrode Pads
Sensor Box	Dynamic Load Box

Optional Hand-Held Electrodes [hand-held-electrodes.html] are an efficient and economical accessory for initiating a stimulus during ECT treatments.

Identification of device

MECTA ECT devices are used in Electroconvulsive therapy, an effective treatment for major depression that has been in use for decades. It consists of applying a fixed current or voltage to the brain through a pair of electrodes in contact with the skin on the head. The current, duration, voltage, charge, and/or energy, and the waveform of the applied stimulus, vary subject to many variables, all of which are subject to ongoing research aimed at increasing the safety and effectiveness of the modality.

The application of the electrical stimulus produces a seizure, which provides the therapeutic benefit. Some current and future research seeks to better understand the mechanisms involved, and may eventually lead to non-convulsive treatments.

Modified ECT has been the standard of practice for the past 35 years in the United States. Modified ECT includes:

- Use of anesthesia,
- Use of a muscle relaxant,
- Oxygenation,
- Use of a byte block and mouth prop, and
- And monitoring of EEG and ECG.

Modified ECT eliminates the risks of physical injury associated with the seizure, and allows ECT to be administered as an outpatient procedure.

Intended Use

For severe endogenous depression (mania and depression)
The overwhelming consensus on efficacy and safety is for the primary or secondary use of ECT in the treatment of major depression, often times when other treatments are too risky or ineffective [APA 2001 Ch 2][Hamilton 1986][Abrams 2002][Fink 1979].

RISKS TO HEALTH

2. *Risks to health.* **An identification of the risks to health. This section should summarize all adverse safety and effectiveness information that has not been submitted under section 519 of the act, particularly the most significant information. The mechanisms or procedures that will control the risk should be described. A list of the general hazards associated with the device and a bibliography with copies of the referenced material should be provided.**

The sheer volume of research on the risks and side effects of ECT cannot be covered thoroughly in this submission. However, what is included here is an overview of the relevant issues, and an introduction to more recent research. The articles referenced here include selected citations of the tens of thousands in the field. As such, the majority of the citations include peer-reviewed randomized double-blind studies that have been published as research summaries.

The field of ECT, devices and modality, has changed significantly in the past 40 years. As research has progressed with imaging, testing, and human clinical trials, so the field has progressed. The roles of electrode placement, waveform type, dosage levels, etc. have received much attention and altered the practice of ECT markedly. The effect of most of these changes does not alter the proven 70-to 80% efficacy of ECT, but rather has resulted in greatly diminished cognitive side effects.

Risks To Health:

a) ECT and Pre-existing Medical Conditions

"No absolute medical contraindications to ECT exist; instead, an assessment of the relative risks and benefits of ECT should be undertaken in each individual case...some medical conditions substantially increase the risk of ECT treatment. In treating such high risk patients with ECT, attempts should be made to improve and stabilize the medical conditions, as well as to decrease the level of risk at the time of ECT (usually with pharmacologic intervention)" [APA 2001, p 27]. The following are examples of these medical conditions: preexisting cardiac illness, compromised pulmonary status, a history of brain insult, or medical complications after earlier courses of anesthesia or ECT [APA 2001, p 59-60].

b) Mortality and Morbidity

Current research indicates that ECT is an "extremely safe" medical practice [Nuttall et al., 2004]. The rate of mortality attributed to ECT appears to be about the same as that for minor surgery or childbirth, probably around 1 per 10,000 patients or 1 per 80,000 treatments [APA 2001, p 59]. See the beginning of chapter 5 of the APA recommendations for a discussion of this topic.

No deaths resulting from ECT treatments have been recorded in 35 years of MECTA's adverse event reporting.

c) *Cognitive side effects*

Potential cognitive side effects of ECT include short-term confusion, short-term memory loss of events within several months before and after ECT treatment, and long-term memory loss. Some degree of memory loss is nearly universal, but most often very limited in extent. However, as a rare side effect, persistent and marked memory loss has been recorded [Squire 1986][Sackeim et al., 1986, 2007][APA 2001, Ch 5].

Cognitive side effects can be reduced by use of brief or ultra-brief pulse waveforms, right unilateral electrode placement (RUL), stimulus level titration, and seizure length control [APA 2001, pp 67-68][Sackeim et al., 2007][Weiner et al., 1984][McCall et al., 2000].

The scientific data clearly shows that cognitive side effects are nearly eliminated by following these guidelines [Sackeim 2004] [APA 2001 p 67-68] [home.html]:

- Use of brief or ultra-brief pulse
- Use of right unilateral electrode placement
- Use of titration to determine minimal effective treatment levels
- Use of EEG monitoring of convulsions to determine seizure lengths and quality, so that appropriate adjustments may be made for subsequent dosing levels
- Increasing the time between treatments
- Minimizing the use of psychotropic medications

i) Waveform

Sine Wave ECT – The original form of ECT using common alternating current.

Brief pulse ECT - Refers to the use of short pulses, 0.5 ms to 2 ms, of direct current as opposed to the use of sine wave current or voltage. Use of this form began in the 1970s, and is the dominant form in use today. Brief pulse stimuli demonstrate the same efficacy as sine wave but with significantly reduced cognitive side effects [Sackeim et al., 2007][Weiner et al., 1986].

Ultra-brief ECT - Controlled research at Columbia University has shown that the use of 0.3 ms ultrabrief pulse width waveforms sharply reduces seizure threshold, allowing treatments to be given at much lower electrical dosage than had been previously possible. Most critically, when compared to standard brief pulse stimulation, use of ultrabrief parameters results in a profound reduction in cognitive side effects. Definitive research published in 2008 confirms that right unilateral ECT given at 6 times initial seizure threshold with a 0.3 ms pulse width is equivalent in efficacy to the therapeutic effects using a Robust form of bilateral brief pulse ECT (1.5 ms pulse width and 2.5 times seizure threshold), right unilateral ultrabrief ECT (RUL)(UB) is a clear advance for the

field as patients show rapid improvement with little sign of cognitive deficit [Sackeim et al., 2004, 2008].[pdf/DOM Ultrabrief.pdf] This form of ECT is rapidly becoming the standard of care.

ii) Electrode Placements

Bilateral ECT (BL) refers to the application of the stimuli by placing electrodes on each side of the forehead, thus directly affecting both sides of the brain, while right unilateral ECT (RUL) uses one electrode tangential at the vertex, and the other on the right side of the forehead, thus applying the treatment primarily to one side of the brain. The RUL form of treatment has the same effectiveness as BL, but with far less cognitive side effects [Sackeim et al., 2000, 2007] [Stoppe et al., 2006].

iii) Dosing

Several methods are used to determine the level of dosing. They include: age based approaches, fixed dosing strategies, and stimulus threshold (ST) based dosing (titration). ST dosing requires an initial determination of the necessary level required to produce a seizure, the ST, by the process of stimulus titration, and then setting the stimulus level based upon this. This approach allows use of the lowest energy possible for an effective treatment, and thereby minimizes the cognitive side effects [McCall et al., 2000][Sackeim et al., 2000] [MECTA 2008, pp 33-44].

iv) EEG Monitoring

If the stimulus does not induce a seizure, or the seizure is too short, the treatment will not be effective. Long seizures must be avoided as well. These outcomes may be modified in the next treatment by increasing or decreasing the stimulus correspondingly. The duration of the seizure is best measured using EEG monitoring [APA 2001, p 161-162]. EEG monitoring allows the clinician to see up to four channels of EEG monitoring on the spECTrum in order to assess the quality, and duration of the seizure. This is a safety feature as it allows the clinician to assess the seizure quality in the four areas of the brain. Leads off detection Is a safety feature indicating that the EEG/ECG patient electrode connection needs to be re-established. [spectrum-features.html].

Analysis of EEG signals during the seizure. ECT indices were developed with actual clinical stimulus dosing and treatment response data that have been shown to have a significant relationship to outcome. Their development and testing with seizure EEG, stimulus dosing, and outcome data from a large clinical ECT population is detailed in peer reviewed scientific literature. [Krystal et al., 1993, 1995, 1996a, 1996b, 1998, 2000a, 2000b].

This research was developed by Duke University, patented, and exclusively licensed as the EEG Data Analysis feature by MECTA for use in the spECTrum 5000 model ECT devices. This feature provides the capability to

automatically analyze EEG signals using a patented algorithm developed over years of acquired treatment data to provide seizure adequacy information that has been demonstrated to be of clinical relevance.1 These are the Seizure Adequacy** and Stimulus Level** features .
[eeg-data-analysis.html].

** Duke U.K. Patent #2 304 196 B – U.S. Patent #5,626,627

d) Claims of Brain Damage - History

This claim has not been supported by any scientific evidence. Since the 1978 APA Task Force #14 recommended brief pulse devices to be utilized with modified ECT, this has been the standard of care for ECT in the United States. The history of scientific research from 1984 to 2008 demonstrates that there are no measurable negative effect on the brain from ECT, and in fact their may be some positive effects [Weiner et al., 1984][Devanand et al., 1994][Dwork et al., 2004][Perera et al., 2007]

In an effort to better understand the effects of ECT on the brain, various research techniques provide relevant information. Some of these are listed here as examples [Nobler et al., 2001][Malitz et al., 1986 Parts II-VII][Lerer et al., 1984].

e) Device General Hazards

MECTA's Overall Quality Plan (reference Appendix F) ensures that spECTrum devices conform to the highest standards, and that every device is thoroughly tested to these standards.

i) Skin burns

Because a significant amount of electrical energy may be quickly applied through a relatively small area of the skin, there is a risk of mild skin burns. This has been a problem during much of the past, but modern ECT equipment effectively addresses this risk.

Proper connection of the electrodes to the patient ensures safe passage of the electric power through the skin. The main techniques used to eliminate skin burns include [APA 2001 pp 155-156][MECTA 2008 pg 31-32][Shaw 2009]:

- Cleaning of the skin
- Rubbing an abrasive conductant paste into the skin
- Use of the correct electrodes (flat or concave) depending on the curvature of the skull where the electrodes are applied
- Application of conductive gel to the electrodes
- Application of proper pressure to the electrodes
- Acceptable static impedance measurement before delivery
- Maintenance of the pressure throughout the stimulus delivery
- Acceptable heat flux limits during the delivery

MECTA provides the necessary paste, gel, and electrodes [spectrum-starterkit.html] with every unit, along with clinical instructions for skin preparation [clinician-em-tech-videos.html] [pdf/Fact11_Paste-Gel.pdf]. The spECTrum static impedance testing (self test) before stimulus delivery prevents delivery unless the static impedance is within an acceptable range (100-5000 ohms). Once delivery begins, the voltage monitoring of every pulse verifies good contact is maintained, and that heat flux remains below design limits. Excessive voltage results in immediate termination of the treatment [MECTA 2008 pp 19-22].

MECTA has been notified of a small number of mild burns (5 to be exact) in the last 12 years, all (except 1) are attributable to the use of dried out disposable electrodes (not approved for use by MECTA) [clinical-diagnostics.html], or use of unauthorized non-conductive gels for skin preparation[pdf/Fact11_Paste-Gel.pdf] One mild, first degree burn occurred with a 200 Joule unit in Europe (domestic units are all 100 Joule) This anomalous case remains after extensive research . Given the uncertainty surrounding the clinical practice in this case, and the rarity, we believe the present design limits provide sufficient protection, even with the 200 Joule units used internationally. Note, this is one mild burn out of hundreds of thousands of treatments with 200 Joule units.

Likely due to the rarity of skin burns, we know of no research on skin burns related to ECT. However, there is considerable research available on skin burns caused by thermal radiation on the skin. This research, done to benefit fire fighters, has direct applicability to ECT. The energy is applied differently, but results are the same: the skin absorbs energy; its temperature rises; and a burn occurs. Application of this research provides evidence that supports the current ECT practice, while at the same time showing how the various safety mechanisms interact to reduce the likelihood of skin burns [Shaw 2009].

ii) Electrical Hazards

Medical electrical equipment safety – Hazards: Controls

- General Operator safety: Addressed by adhering to IEC Standard 60601-1 and UL 2601-1
- Electromagnetic Interference and Susceptibility: Addressed by adhering to IEC Standard 60601-1-2 (EMC)
- Unintentional delivery: Addressed by adhering to relevant portions of the withdrawn IEC-601-2-14 standard specifying an audible alarm, visual alarm, and flip cover over two stage STIMULUS CONTROL PUSH BUTTON (spECTrum brochure - Appendix H) [MECTA 2008 p 77,104] [spectrum-features.html].
- Poor or no electrode connection: Addressed by verification of the patient electrode connections prior to Treatment (self test continuous static

impedance measurements) [MECTA 2008 p 5], and PATIENT IMPEDANCE DISPLAY feature which displays the impedance continuously in order to verify that it is in range prior to treatment (spECTrum brochure Appendix H) [spectrum-features.html].

- Incorrect delivery due to device malfunction: Addressed by single fault tolerance design, redundant measurement of all delivery parameters with automatic termination of delivery when out of range [MECTA p 86-89], a Voltage limit shutdown feature [MECTA PAGE 87], and internal diagnostic testing that verifies all delivery and monitoring circuits prior to and after every treatment [MECTA 2008 p 6][VDE 801-1992].
- Operator error with unexpected circumstances during the delivery: Addressed by immediate termination of the stimulus when the treat button is released [MECTA 2008 p 82,92].
- Patient leakage current or ground fault condition: Addressed by adhering to IEC Standards IEC 60601-1-2-25 (ECG), IEC 60601-2-26 (EEG) and 60601-2-27 (ECG).

Effectiveness

The APA Task Force recommendations state "The clinical literature establishing the efficacy of ECT in specific disorders is among the most substantial for any medical treatment" [APA 2001, p 5]. Clinical trials show ECT to be a highly effective treatment for severe depression with remission rates of 70%-90%, while somewhat lower rates occur in community practice of 30%-47% [Prudic et al., 2004]. A recent study of ECT with elderly patients demonstrated remission rates of 68%-88% [Stoppe et al., 2006], and another broader study showed rates of 65% [Sackeim et al., 2000]. The APA task force notes "However, no trial has ever found an antidepressant medication regimen to be more effective than ECT" [APA 2001 p 10].

A Meta-Analytic Review of 37 years of controlled clinical trials shows ECT to be the most effective treatment for major depression [Pagnin et al., 2004]. Twenty-five years of NIMH partially funded studies at Columbia University with MECTA devices from 1981-2004 confirms that ECT is the most rapidly acting and effective antidepressant treatment presently available[Sackeim 2004]. Although ECT is highly effective in treating depression, many patients relapse within a year. This rate is greatly reduced by continuation pharmacotherapy after ECT treatment is completed or by the use of continuation ECT [Sackeim et al., 2001][Kellner et al., 2006].

ECT stimuli can be given in a variety of ways including: sine wave, brief pulse, ultra-brief pulse, bilateral, right unilateral, fixed dose, age related dose, stimulus titration, etc. Research shows these all to be equivalently effective, but with substantial differences in their cognitive side effects. As noted earlier in the safety section, sine wave stimulus is not recommended. Right unilateral UltraBrief (RUL-UB) is preferred, but its effectiveness depends upon the stimulus level being sufficiently above the patient's seizure threshold [Krystal et al., 1998][Sackeim et al., 1993, 2000, 2008].

THE FOLLOWING LIST OF CITATIONS ARE ORGANIZED BY TOPIC AND ARE PRIMARILY RANDOMIZED, DOUBLE BLIND, PEER-REVIEWED STUDIES

a) Waveform

Ultrabrief pulse, brief pulse and sine wave all effective, but vary in their side effects with ultrabrief having the least side effects.

Current Standard of Care: [Sackeim et al., 2008, 2004][Sackeim et al., 2007][Weiner et al., 1986, pp 316-318]

b) Electrode Placement

Right unilateral (RUL) and bilateral (BL) electrode placements and bi-frontal placements are all effective, but RUL placements result in the least amount of cognitive effects.

Current Standard of Care [Sackeim et al., 2008][Sackeim et al., 2007] [Sackeim et al., 2000]

c) Dosing

Stimulus titration, age related, and fixed dosing strategies have been used effectively, but research shows that excessive charge/energy delivery results in more cognitive side effects. Titration enables use of the lowest necessary charge/energy while maintaining efficacy.

Current Standard of Care [Sackeim, et al 1993][MECTA 2008, pp.33-45][McCall et al., 2000][Sackeim et al., 2000]

d) Medications Pre Treat and Post Treatment

Medications affect the stimulus levels required to obtain efficacious treatments.

Current Standard of Care: [Sackeim et al., 2009][Kellner et al., 2006][Sackeim et al., 2001][Prudic et al., 1996][Prudic et al., 1990]

e) Outpatient Treatment

Outpatient ECT treatments enable patients to carry on their lives with minimal disruption.

Current Standard of Care: [Dew et al., 2004].

f) Indications for Use

Major Depression

Current Standard of Care: [Sackeim, et al, 2008][McCall, et al. 2000][Stoppe et al., 2006]

Mania

Current Standard of Care: [Mukherjee et al., 1994][APA 2001, Chapter 2]

g) Case Histories

- Shock – The healing Power of Electroconvulsive Therapy by Kitty Dukakis and Larry Tye [Dukakis 2006][clinician-em-patient-family-publications.html]
- Shock-DVD (trailer) [clinician.html]
- Dartmouth University DVD (trailer) [clinician.html]
- Undercurrents – A Life Beneath the Surface by Martha Manning (Ph.D)[clinician-em-patient-family-publications.html] [Manning 1994]
- Absence of cognitive impairment after more than 100 lifetime ECT treatments. [Devanand et al., 1991]

h) Expert Opinion (with documentation)

Current Standard of Care

- White paper -Sackeim H.A, "Electroconvulsive Therapy in Late-Life Depression" [clinician-standardofcare.html] See Appendix A.
- White paper -Coffey CE, Kellner, "Electroconvulsive Therapy Chapter" [clinician-standardofcare.html] See Appendix B.
- Clinical paper- Harold Sackeim, a leading researcher in the field of ECT for over 30 years, wrote a well documented clinical opinion paper to the TUV Clinical Affairs division as part of the submission to TUV for the CE mark approvals in the EU for the MECTA spECTrum four devices. See Appendix C.

RECOMMENDATION

3. ***Recommendation.*** **A statement whether the manufacturer believes the device should be reclassified into class I or class II.**

MECTA believes that ECT devices should be reclassified into Class II.

SUMMARY OF REASONS FOR RECOMMENDATION

4. *Summary of reasons for recommendation.* **Each manufacturer should include a summary of the reasons for requesting reclassification of its device and an explanation of why it believes the device meets the statutory criteria for reclassification into class I or class II. Each manufacturer should also identify the special controls that it believes would be sufficient to provide reasonable assurance of the safety and effectiveness of its device if it believes the device should be reclassified into class II.**

ECT devices should be reclassified out of class III for the following reasons:

1. ECT is an effective treatment for major depression, helping save or significantly improve the lives of tens of thousands of people every year. See the effectiveness section earlier for citations to the research.
2. There is no other therapy for severe endogenous depression that can replace ECT. This therapy is up to 80% effective. See the effectiveness section earlier for citations to the research.
3. It is a very effective treatment when medication is ineffective. See the effectiveness section earlier for citations to the research.
4. ECT is a safe procedure. See the risks to health section earlier for citations to the research.
5. ECT is a mature, well accepted field of psychiatric medicine. See below.
6. Further clinical trials for a PMA to demonstrate the safety and effectiveness of ECT will only add to the already existing large body of research that demonstrates the safety and effectiveness of ECT, and thus are not needed.
7. ECT research continues throughout the world, continually improving and refining the clinical aspects of ECT. As an active field of medicine, research continues at a significant rate, with typically about 200 publications per year relevant to ECT. Some of this research continues to look at aspects of ECT practice to determine if the procedure can be improved, both in terms of increased efficacy and reduced side effects [Lisanby et al., 2001][Spellman et al., 2009][Sackeim et al., 2008]. The Journal of ECT is dedicated entirely to ECT research. ECT research is also published in the most prestigious journals in medicine including Brain Stimulation, Biological Psychiatry, Neuropsychopharmacology [clinician-standardofcare.html],
8. The American Psychiatric Association strongly supports the practice of ECT through its series of recommendations, professional meetings, etc.
9. Numerous other countries, as well as the European Community, have approved ECT as a safe and effective treatment for endogenous depression, as well as other indications.

Mature Field

Since its advent in 1935 [Meduna et al., L.J. 1935] ECT has proven to be effective in treating depression. Its use increased rapidly until the 1990s when it began declining, but has begun increasing in popularity since the 1990s. In the late 1990s, it was estimated that approximately 50,000 patients received ECT treatments every year

[Beyer et al., 1998, p 4][Kalinowsky 1986, History]. The current estimate is 100,000 patients per year.

Fellowships and training courses are available for Psychiatrists and ECT nurses [clinician-training.html]:

- Electroconvulsive Therapy Training Course – Physicians and Nurses, 3-Day Mini-Fellowship, Wesley Woods Geriatric Hospital, Emory University, Atlanta-GA [http://www.med.emory.edu/CME/course/mini/ect99B.html] (1990-2009)
- Visiting ECT Fellowship Program – Physicians and Nurses, University of Pittsburgh School of Medicine, Pittsburgh-PA [http://www.wpic.pitt.edu/education/ect/default.htm] (1995-2009)
- Visiting Fellowship in ECT – Physicians and Nurses, Duke University, Durham-NC [http://psychiatry.mc.duke.edu/ECT/ectindex.html] (1995-2009)
- Visiting Fellowship in ECT – Physicians and other mental health professionals, Division of Brain Stimulation and Therapeutic Modulation, New York State Psychiatric Institute, Columbia University College of Physicians and Surgeons, New York, NY [http://www.brainstimulation.columbia.edu/education/index.html]
- CME courses have been given under the auspices of the APA for the last thirty years starting in the early the early 1980s. The US Psychiatric Congress for ten years offered a two day CME practicum in the 1980s. Medical University of South Carolina continued the two day CME courses in the 1990s, and the ACT (Association for Convulsive Therapy) currently is offering the two day CME course to its membership. This does not include grand rounds, annual psychiatric meetings where CME courses are also offered.

Many books and book chapters have been published on the practice of ECT by prominent experts and professional associations and have been available for thirty years [clinician-educational-material.html]:

CURRENT STANDARD OF CARE-BOOKS, BOOK CHAPTERS

- *The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training, and Privileging* [APA 2001][clinician-em-tech-publications.html]. This book by the APA Task Force on ECT contains extensive recommendations for ECT practitioners, covering nearly every aspect of ECT practice including:
    - Indications for use
    - Medical Conditions with Substantial Risk
    - Use in Special Population
    - Adverse Effects
    - Pre-ECT Evaluation
    - Use of Medications

- Consent for ECT
- Staffing
- Locations, Equipment, and Supplies
- Treatment Procedure
- Evaluation of Outcome
- Followup Treatment
- Documentation of Treatment
- Education and Training
- Privileging in ECT

The APA TASK FORCE will be publishing the THIRD EDITION of its Practice of Electroconvulsive Therapy in 2010

- *Clinical Manual of Electroconvulsive Therapy* (Paperback) [Mankad et al., 2009] will be available in Oct 2009.
- White paper - "Electroconvulsive Therapy in Late-Life Depression", *Clinical Geriatric Psychopharmacology* [clinician-standardofcare.html] See appendix A.
- White paper -Coffey CE, Kellner, C Electroconvulsive Therapy Chapter 35.*Textbook of Geriatric Neuropsychiatry* [clinician-standardofcare.html] See Appendix B.
- spECTrum Instruction Manual [clinician-em-tech-publications.html]
- Shock – The Healing Power of Electroconvulsive Therapy by Kitty Dukakis and Larry Tye [Dukakis 2006]. This is Kitty Dukakis's moving first hand account of her decades long struggle with depression and how ECT saved her life. [clinician-em-patient-family-publications.html]
- *Undercurrents – A Life Beneath the Surface* [Manning 1994] [clinician-em-patient-family-publications.html

HISTORICAL STANDARD OF CARE- BOOKS, BOOK CHAPTERS

- *Convulsive Therapy: Theory and Practice* [Fink, M., 1979]
- *ECT: Basic Mechanisms* [Lerer et al., 1984]
- *Electroconvulsive Therapy: A Programmed Text* [Beyer et al., 1998] [clinician-em-tech-publications.html]. The recommendations are implemented in a pragmatic hands-on workbook format. Very useful for clinical training.
- *Electroconvulsive Therapy – Clinical and Basic Research Issues* [Malitz et al., 1986]
- *The Clinical Science of ECT* [Coffey 1993].
- *Electroconvulsive Therapy, A Programmed Text* 1985 (1st ed)

Videos, DVD for practitioners, patients and families have been available for over 30 years:

CURRENT STANDARD OF CARE-VIDEOS AND DVDS

- Electroconvulsive Therapy (Patients and Families DVD) – Dartmouth Hitchcock University. This DVD helps prepare patients and their families

when a patient will be receiving ECT.[clinician-em-patient-family-publications.html]

- Shock DVD – A Documentary produced by AMS Production Group exploring the myths, mysteries and first hand account of patients and physicians and their ECT experiences. [AMS clinician-em-patient-family-publications.html] [clinician.html]
- spECTrum Technical DVD [clinician-em-tech-videos.html]

HISTORICAL STANDARD OF CARE-VIDEOS AND DVDS

- HIN video – Princeton, The Practice of ECT (training 1983)
- ECT The Treatment, the Questions and the Answers, University of Michigan. (1986)
- The Dr. Coffey video (1985)
- MECTA Model C educational video, 1976, Model D clinical video 1981, Model SR/JR technical video 1985

APA Task Force Reports

The APA actively monitors and guides the practice of ECT in the United States. It has three times created task forces to review the field, reviewing relevant publications and seeking input from many interested parties, and then publishing recommendations [APA 1978, 1990, 2001]. Its third edition is currently being reviewed for publication [http://www.psych.org].

A number of professional meetings serve the ECT community [clinician-meetings.html]:

- American Psychiatric Association Annual Meeting [http://www.psych.org]
- Association for Convulsive Therapy [http://www.act-ect.org]
- American Association for Geriatric Psychiatry Annual Meeting [http://www.AAGPmeeting.org]
- U. S. Psychiatric and Mental Health Congress [http://www.cmellc.com/psychcongress]
- American Psychiatric Nurses Association Meetings [http://www.apna.org]

MECTA believes ECT devices should be classified as Class II for the following reasons:

1. ECT equipment may present a potential unreasonable risk of illness or injury if improperly used
2. ECT equipment needs special controls for safe use
3. There is sufficient information available for the establishment of special controls

Special Controls recommended by MECTA (required for safety and effectiveness)

a. Postmarket surveillance

- Adverse event reporting (MDR)
- Monitor for problems of any type (FDA 21 CFR 800-1299)(MECTA CAPA system, MECTA Complaint Processing)
- Recommendations for equipment updates/new features

b. Patient registries

Patient registries should be kept by the doctors doing the treatments using clipboards, filing systems, ECT physiological monitoring/paper rolls, etc. ECT device manufacturers have no access to patient information of any kind.

MECTA developed and markets software options to assist practitioners in keeping patient and treatment records [remote-monitor-software.html][rms-manager.html][mecta-emr.html].

c. Guidance Documents

The APA Task Force Report published in 2001 serves as the primary guidance document in the United States for the practice of ECT in lieu of any FDA guidance document. It is used as a resource in lawsuits, in setting-up new ECT practices, in training, and as a resource for other countries' guidance documents.

In additions, various international standards required for European Community approval are relevant as well (See Appendix G).

d) Performance Standards

The FDA presently allows ECT equipment energy deliveries of 100 Joules into 220 ohms. The European Community (EU) allows 200 Joules into 220 ohms. The need for the higher energies is well documented [Krystal et al., 2000c][APA 2001, p 185-6][Stoppe et al., 2006][Sackeim et al., 2000][Abrams 2000][Lisanby et al., 2001]. A primary concern with regard to higher energies is the possibility of skin burns. Although we know of no research on this topic, there is considerable relevant research on skin burns due to absorption of thermal radiation. We provide a summary of that research and its application to ECT [Shaw 2009]. We argue that the issue is not energy, but rather heat flux into the skin (power per unit area) that should be limited, and thus subject to special control.

We propose a performance standard limiting the heat flux into the skin. The standard integrates the energy delivered, the duration of the delivery, and the size of the electrodes into a unified standard. Because the delivered energy in ECT depends upon the patient's dynamic impedance (resistance between the electrodes during the delivery), the standard also places requirements on the measurement of the dynamic impedance (or some equivalent) and subsequent limiting of the delivery accordingly. This may be done by voltage, impedance, or power limiting techniques during the delivery [Shaw 2009].

Recommended Equipment Performance Standards

MECTA recommends the adoption of a performance standard similar to the now withdraw IEC 601-2-14 (see Appendix D), but with the following changes:

- Replace section 51.1 "Limitation of output values" with: "The energy flux at the electrodes shall be limited to 75 Joules per square inch and the power density to 19 Watts per square inch" and drop section 56.101 c) that specifies minimum electrode area. [Shaw 2009].
- Add an item 4 to section 19.1 as follows: "Patient leakage and auxiliary currents should adhere to section 19 of the IEC 60601-2-26 and 27 standards.
- Under section Eight, paragraph 51.101 add "Equipment shall be designed so that stimulus delivery cannot be initiated unless the patient stimulus electrode connection is verified and stimulus delivery shall be terminated in the event patient stimulus electrode connection is not maintained during delivery of stimulus or power or energy flux limits are exceeded." [MECTA p 87] [Shaw 2009]
- All four parameters (Frequency, Pulse Width, Current, and Duration) should be allowed for use without any low end limits. The lowest parameter settings do not provide any risk to safety and effectiveness (use is determined by dosing strategies). Current research with lower parameter levels is very promising. Recommended minimum settings are : Pulse Width 0.1 ms, Frequency- one pulse, Duration –one pulse, Current-one milliamp
  (Spellman 2009, Sackeim, 2004)

SUMMARY OF VALID SCIENTIFIC EVIDENCE

5. *Summary of valid scientific evidence on which the recommendation is based.* **Manufacturers are advised that, when considering a formal reclassification petition, FDA will rely only upon valid scientific evidence to determine whether there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone (class I) or by general controls and special controls (class II). Valid scientific evidence consists of evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness (see 860.7(c)(2)).**

According to 860.7(d)(1), there is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions for use. Moreover, under 860.7(e)(1), there is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

SUMMARY OF VALID SCIENTIFIC EVIDENCE

[clinician-standardofcare.html]

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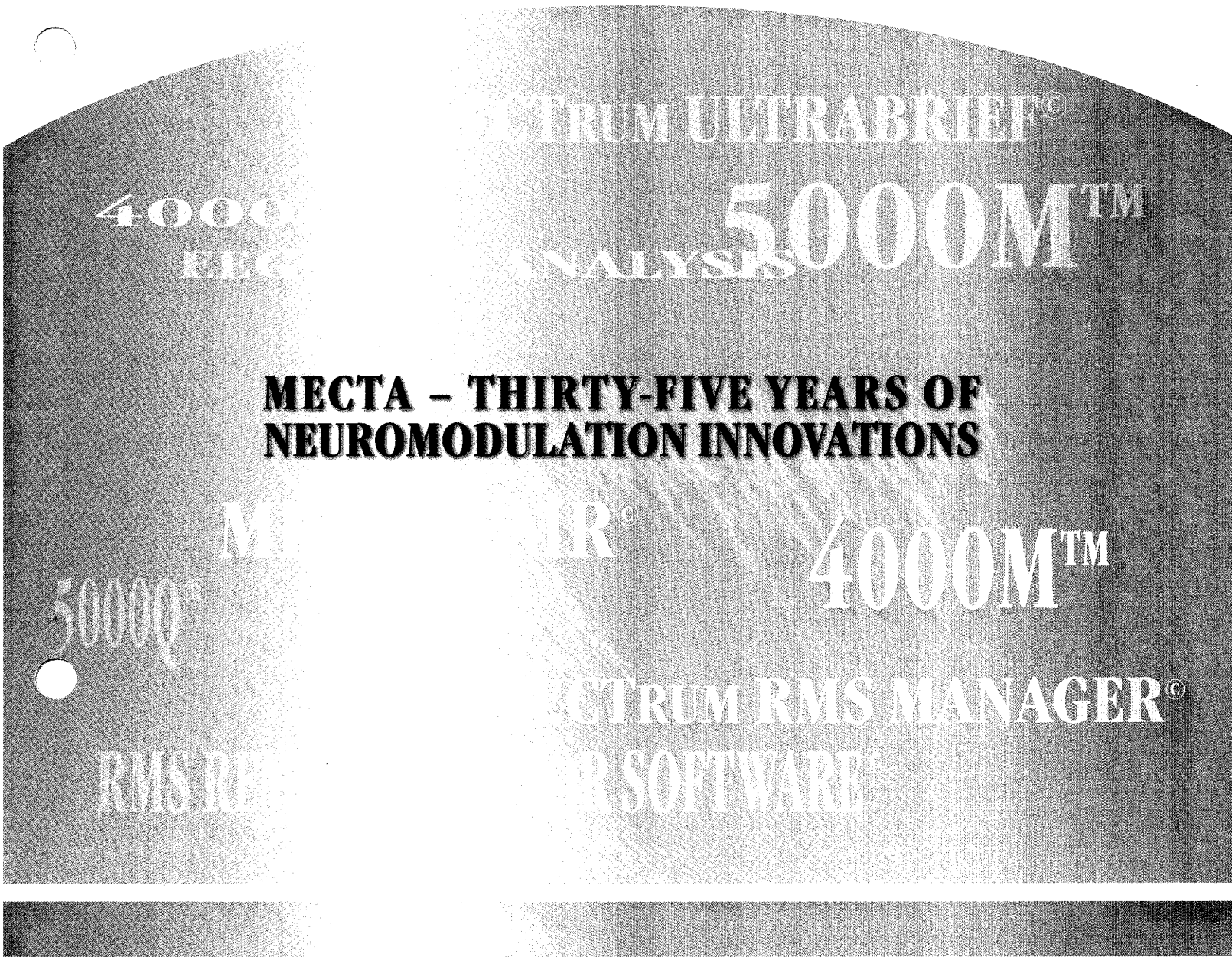
APPENDIX H

MECTA



MECTA – THIRTY-FIVE YEARS OF NEUROMODULATION INNOVATIONS

Evidence Based ECT Technology

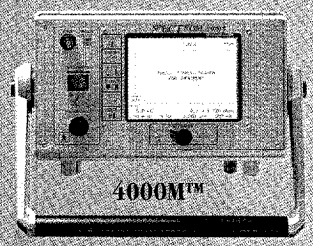
Providing up to an 80% Response[1] Rate for Endogenous Depression

EXPERIENCE OPTIMIZED PATIENT OUTCOMES WITH SPECTRUM ULTRABRIEF ECT

REDEFINING ECT

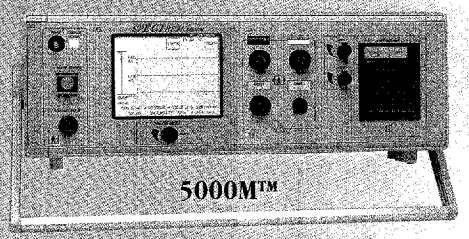
NEW AND IMPROVED DEVICES

4000 DEVICES



The 4000 models are economical, light-weight and portable. The re-designed, highly reliable tactile interface uses six membrane switches for treatment selection, and the new Water Clear technology in the display offers improved clarity and transmission of light to enhance viewing. The 4000 models are upgradable to a 5000 spECTrum.

5000 DEVICES



The 5000 models have been enhanced with new lighter-weight RoHS (lead-free) cases that provide enhanced durability (3 lbs. lighter). The new robust handle ensures easy repositioning. Touchscreen advanced technology offers increased sensitivity and clarity.

HANDHELD ELECTRODES

Third Generation

Newly re-designed with a single molded handle and flange, these MECTA Handhelds are lighter-weight, waterproof and easier to clean.

SAFETY

These new devices include extensive redundant hardware and software testing to verify that they are operating correctly. The safety of these devices is unparalleled, and as such these devices are an advance that will impact the safety and effectiveness of the ECT treatment dramatically.

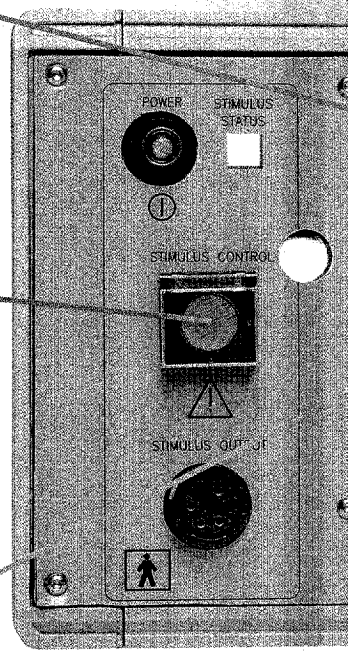
NINE EASY TO USE MENUS

Individualize patient treatments for safety and effectiveness with the 5000's nine menu options: Main, Patient Data, Date & Time, LCD Traces, LCD Gains, Chart Traces, Chart Options, EEG Data and the Parameter Selection menus. One menu display is available in the 4000 models.

MECTA HAS DEFINED THE STANDARD OF CARE FOR NEUROMODULATION DEVICES through evidence based research since its inception. A breakthrough in MECTA ECT research in 1973 at Oregon Health Sciences University produced the first and only modified, monitored, brief pulse ECT - MECTA C, D, SR and JR devices. Controlled research at Columbia University with a spECTrum 5000Q® resulted in the newest form of ECT, *spECTrum ULTRABRIEF*© ECT (UB RUL), which achieves cognitive effects that are dramatically minimized while maximizing efficacy.[2]

LCD/Touch Screen

The LCD/Touch Screen provides the user with alphanumerics, self-test and treatment results, and monitoring of EEG, ECG and OMS. The LCD/Touch Screen provides the user with an interface to set treatment parameters. This allows more flexibility, as the menu can be accessed by simply touching the display. Up to four channels of monitoring can be seen on the LCD/ Touch Screen. The stimulus parameters on the Q and M models are displayed on the LCD/Touch Screen, as well as percent intensity on the M model. Choose from nine set-up menus in the 5000 model, Main, Patient Data, Date & Time, LCD Traces, LCD Gains, Chart Traces, Chart Options, EEG Data and the Parameter Selection menus and one menu in the 4000 models, to individualize each patient's treatment. The LCD/Touch Screen also provides the user with clinical information, which can be recorded on the patient's record, to ensure greater safety.



Stimulus Control Push Button

The hinged cover on the Stimulus Control push button prevents the user from accidentally delivering a treatment. The Stimulus Status Tri-color LED offers the user a visual confirmation that the spECTrum is enabled, that the stimulus is being delivered, and indicates if there is a stimulus delivery fault. The three warning tones during the automatic self-test and the constant tone during treatment continue to offer the user enhanced safety during the treatment process.

Patient Impedance Display

The automatic self-test offers the user far greater accuracy in avoiding aborted or missed seizures, as this bio-feedback provides continuous display of the patient impedance, which results in far greater efficacy.

Leads-Off Indicator

Leads-Off indicator detects w
electrodes or the OMS are no
The trace disappears and the

THE ONLY DUKE UNIVERSITY DEVELOPED AND PATENTED ANALYSIS FEATURES. MECTA IS THE ONLY COMPANY LICENSED TO INCLUDE THE DUKE UNIVERSITY EEG SEIZURE QUALITY MEASURES IN ITS PRODUCTS.

THE SPECTRUM 5000 AND 4000 MODELS ARE THE FOURTH GENERATION OF MECTA'S ECT DEVICES. They continue to be the most advanced ECT devices technically, while continuing to offer even more safety and effectiveness clinically. The 5000 model devices offer up to five channels of ECG and EEG monitoring, and one Optical Motion Sensor. The 4000 devices are simply the 5000 devices without monitoring capability. The SPECTRUM 5000Q™ and SPECTRUM 4000Q™ offer the user flexibility with four stimulus parameter knobs to control energy and charge. The SPECTRUM 5000M™ and SPECTRUM 4000M™ units offer simplicity, with one single Stimulus Intensity knob. This varies Frequency and Duration simultaneously, to control energy and charge.

EEG Data Analysis

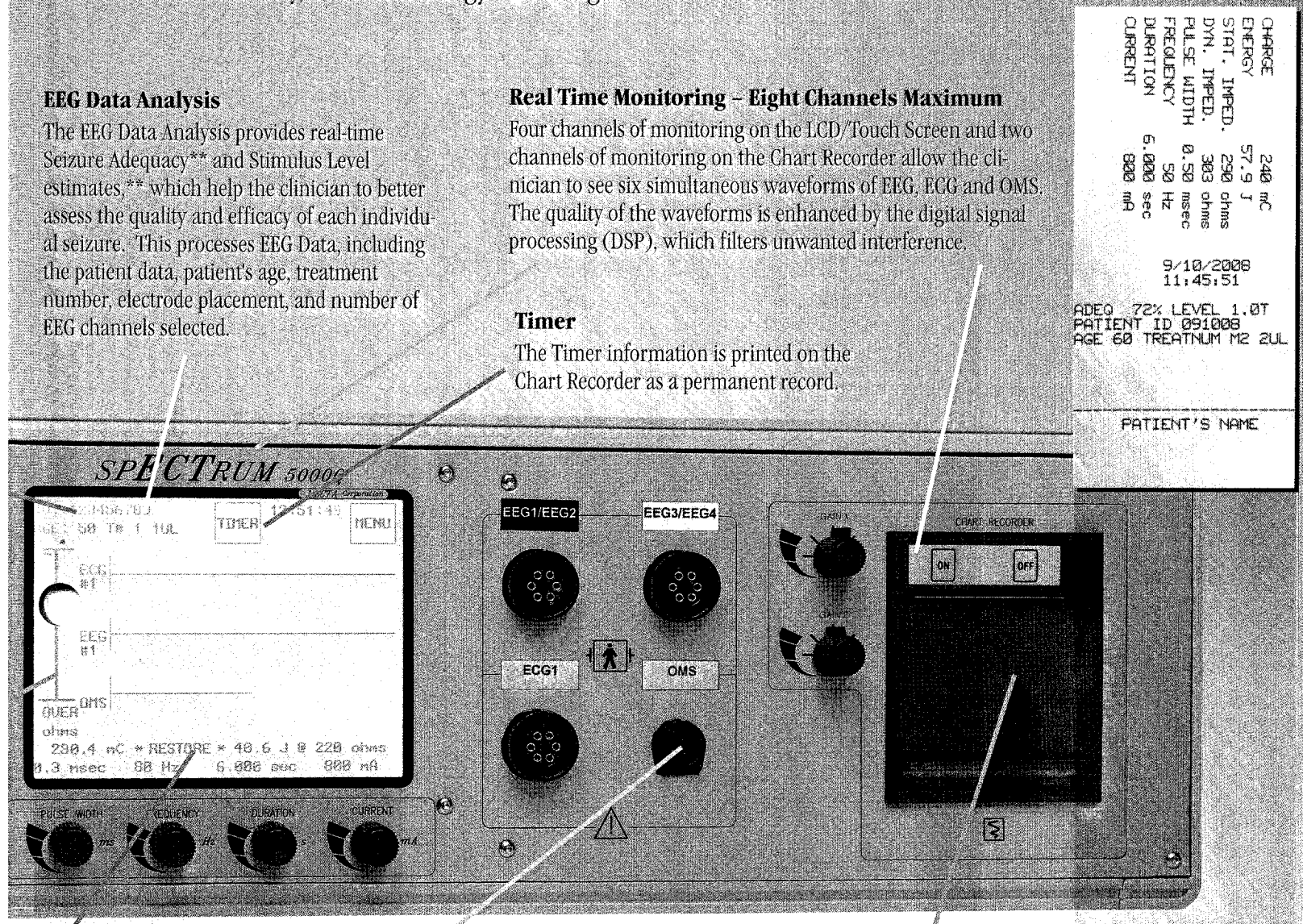
The EEG Data Analysis provides real-time Seizure Adequacy** and Stimulus Level estimates,** which help the clinician to better assess the quality and efficacy of each individual seizure. This processes EEG Data, including the patient data, patient's age, treatment number, electrode placement, and number of EEG channels selected.

Real Time Monitoring – Eight Channels Maximum

Four channels of monitoring on the LCD/Touch Screen and two channels of monitoring on the Chart Recorder allow the clinician to see six simultaneous waveforms of EEG, ECG and OMS. The quality of the waveforms is enhanced by the digital signal processing (DSP), which filters unwanted interference.

Timer

The Timer information is printed on the Chart Recorder as a permanent record.



one or more recording
nnected to the patient.
tore button will appear.

OMS

The Optical Motion Sensor (OMS) allows the user to monitor motor movement during the seizure, and provides further valuable information in assessing seizure efficacy. The velcro-wrap attachment, with the emitter and detector, wraps around a finger or toe, and detects motion. Its simplicity of use eliminates the need for electrode pads, gels, and pastes.

Chart Recorder

The two-channel thermal Chart Recorder provides the user with a hard copy of the self-test and treatment results automatically, and also optionally includes patient information and EEG Data Analysis results. The Recorder's simple ON/OFF push buttons and GAIN knobs enable manual and high resolution printing. The SPECTRUM'S printout continues to provide two channels of your choice of monitoring, showing elapsed time, timer, date, time of treatment, patient data, and EEG Data Analysis results.

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5 Krystal AD. The clinical utility of ictal EEG seizure adequacy models. Psychiatric Annals. 1998; 28:30-35.

spECTrum ULTRABRIEF© ECT

No other ECT manufacturer provides a proven evidence based methodology as simple and effective to use as the spECTrum ULTRABRIEF (0.3 ms) ECT feature. This feature was designed and tested at Columbia in the late 1990s, preliminary results were reported,[3,4] and it was introduced as a feature into MECTA spECTrum ECT (0.3 ms) devices in July of 2003. Right unilateral (0.3 ms) ultrabrief six times seizure threshold ECT is equivalent in efficacy to a robust form of bilateral ECT with little sign of cognitive deficit and is simplified by the use of the MECTA spECTrum titration tables. No other ECT device has implemented the peer-reviewed randomized double blind studies into its ultrabrief feature. Only the spECTrum ULTRABRIEF (0.3 ms) ECT is highly efficient at the lower range, with patients demonstrating seizure thresholds at 5 mC and can treat the patient across the entire range of energy from 0.3 Joules to 100 Joules. The spECTrum ULTRABRIEF (0.3 ms) ECT has 50% more energy than any other ultrabrief ECT device at the maximum setting and does not risk overdosing the patient at the minimum settings.

Stimulus Dosing Titration Tables

Five Dosage Tables specific to all M and Q spECTrums

Stimulus dose titration has been widely shown to be the most accurate method for quantifying seizure threshold and determining subsequent stimulus dosage. The group at Columbia University, who introduced the empirical titration method more than 20 years ago, has refined the procedures for titration and subsequent dosing for both standard brief pulse and ultrabrief pulse stimulation. New titration schedules are available for both the spECTrum 5000M and 5000Q models that suggest the parameters to be used at each titration step and when administering at subsequent treatment stimulations, that is, at one, two, two-and-a-half or six times seizure threshold.

EEG Data Analysis

MECTA's percent Seizure Adequacy** and Stimulus Level** estimates are the ONLY existing ECT indices that were developed with actual clinical stimulus dosing and treatment response data and that have been shown to have a significant relationship to outcome. Both indices provide clinicians with the percent Seizure Adequacy** and Stimulus Level** measures that have been demonstrated to be of clinical relevance.[5] DSP software, developed by MECTA, integrates the Duke developed algorithm into the spECTrum, providing clinicians with an empirically-based means to predict seizure adequacy and regulate stimulus dosing.These Duke University patented estimates are the culmination of more than ten years of research and are licensed exclusively to MECTA.

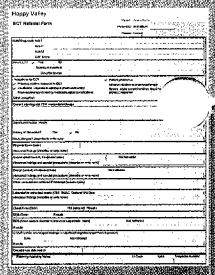
New Stringent Standards

18 regulatory agency approvals worldwide U.S. (FDA approved, UL); Canada (CSA, Health Canada 8 Approvals, #1537, #62578, #62576); European Union, TUV (EN ISO 9001:2000, EN ISO 13485:2003; CMDCAS 13485:2003, EC 93/42/EEC Annex II, Article 3); Korea (KFDA); Republic of China (SDA); Australia (TGA)

THREE ECT DATA MANAGEMENT SOFTWARE PROGRAMS

MECTA EMR© - Electronic Medical Record

Prepare for Paperless Medicine With MECTA



This MS Accress™ - based networkable Electronic Medical Record program will revolutionize your ECT team's inputting of patient data, pre-treatment, treatment and post-treatment forms.

Safety – Government and hospital organizational mandates require digitization of patient medical records to improve patient safety.

Secure – spECTrum treatment data cannot be modified after saving into the database.

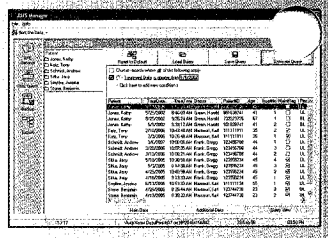
Easy to use – spECTrum data ports directly into EMR. Digital inputting of data is done pre-treatment and post-treatment in the ECT suite.

Time saving and cost saving – Default to patient's previous treatment to save time. EMR records can be saved as PDF files that may be attached to hospital patient records.

Features – Forms include: ECT Referral Form, Pre-Anesthesia Evaluation Form, Pre-ECT Nursing Checklist, ECT Administration Records, ECT Medication Log and Post-ECT Nursing Recovery Record. In addition, physiological trace data is imported from the spECTrum and can be reviewed and printed from the EMR program. Input, store, query, print and export these six patient records.

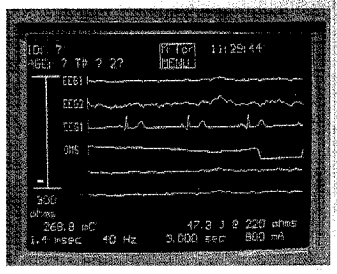
MECTA's EMR Software program works exclusively with the spECTrum 5000 ECT device to advance ECT practices for the 21st century.

MECTA RMS MANAGER©



This powerful database program automatically imports MECTA's Remote Monitor Software (RMS) data files into an extremely versatile and easy-to-use database. With RMS MANAGER you'll be able to: Collect up to 52 data fields including 10 user-defined fields, Sort, Select, Query, Print, incorporate Notes, Backup, and Export to Excel and other commonly used programs. Combined with the spECTrum device and Remote Monitor Software, RMS MANAGER organizes and analyzes your ECT treatment data! It's that easy!

RMS Remote Monitor Software©



The RMS allows the clinician to assure patient safety and excellent clinical outcomes by viewing all of the traces of physiological monitoring (up to four EEGs, 1 ECG and OMS) on any external PC monitor. Up to eight traces can be displayed. These traces of monitoring are viewed in real time throughout the treatment.

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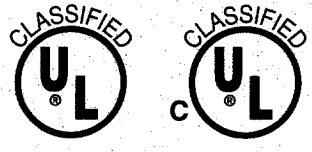
SPECTRUM

MECTA
Instruction Manual



MECTA

Instruction Manual

SPECTRUM 5000Q ®
SPECTRUM 4000Q ®
SPECTRUM 5000M ®
SPECTRUM 4000M ®

November 7, 2008
Revision 06

100 Joules Domestic

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U.S. Patent#5,755,744 - U.S. Patent#6,014,587 - U.K. Patent#GB 2 307 413 B
Duke U.K. Patent#2 304 196 B - U.S. Patent#5,626,627
(Under exclusive license from Duke University)
Foreign Patents Pending

9900-1011-06

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Preface

PREFACE & SCOPE

This manual provides information specifically related to the design and use of MECTA spECTrum devices. This manual is not intended to be used in the diagnosis of a condition or illness, in recommending the use of electroconvulsive therapy (ECT) for any given illness or condition, or to explain, demonstrate, or teach methods of practicing ECT.

The intended use of the MECTA spECTrum ECT device is solely for the treatment of "severe depression" or "major depressive episode with melancholia". (ref CFR Part 882 Part III) The clinical setting is in hospital ECT suites, or Operating Rooms.

MECTA Corporation has designed the spECTrum with patient and operator safety as our primary goals, while also optimizing the delivery of ECT. Please read this manual thoroughly. The safe and effective use of any ECT device requires that the practitioner have a thorough understanding of the instrument and the procedures involved in its use.

This manual was written for the clinician. Although it describes treatment and monitoring techniques, MECTA Corporation assumes that the reader is trained in the selection and evaluation of patients for ECT, in the administration of this treatment modality, and in the methods used in recording and interpreting EEG, ECG, and vital signs.

The purpose of administering the ECT electrical stimulus is to trigger a self-limiting generalized seizure. Scientific literature has demonstrated that the ECT procedure is an effective treatment in severe endogenous depression.

The spECTrum has been designed as a quality device. However, in using this or any other device in ECT, good clinical judgment must always prevail.

MECTA Corporation cautions the reader that:

- This manual and product specifications may be changed without notice.
- Some features described may not be available on specific models.
- Illustrations of the various display screens are general representations of their appearance. They typically depict the lowest or "default" settings. The data displayed when the device is used may differ from the representations in these illustrations.

The terms "spECTrum 4000Q", "spECTrum 4000M", "spECTrum 5000Q", "spECTrum 5000M", are trademarks of MECTA Corporation.

MECTA Corporation gratefully acknowledges the following individuals for assisting in editing the technical and clinical portions of this manual:

Dr. Harold A. Sackeim, Ph.D Dr. Richard D. Weiner, M.D., Ph.D.

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AND CAN/CSA C22.2 NO.601.1
19HJ

Overview

Overview

INTRODUCTION

The spECTRUMs are the fourth generation ECT devices provided by MECTA Corporation. They incorporate a host of new features that improve the safe and accurate delivery of the ECT stimulus, flexibility and ease of device configuration and use, and the range of patient monitoring options.

Some of these new features include:

- An LCD and Touch Screen or Membrane Switch to enter patient information and select treatment options
- Use of a menu system for device configuration and choice of treatment options
- Continuous self-test, with a Patient Impedance display that activates immediately upon stimulus electrode placement, and requires no operator intervention
- Automatic assessment of impedance during the electrical stimulus
- Accurate and safe delivery of the predetermined electrical stimulus
- User-selectable choice of different electrical stimulus parameter ranges
- Up to 6 channels of physiological monitoring (5000 series only)
- A Leads-Off indicator that provides automatic feedback when a physiological monitoring electrode has become disconnected (5000 series only)
- Advanced EEG Data Analysis for estimating the adequacy of seizure activity and the extent to which stimulus dosage exceeds seizure threshold (5000 series option)
- Capacity to display all treatment parameters and up to 6 channels of physiological traces on a Remote Monitor (PC) (5000 series option)
- Capacity to save and log all information regarding treatment parameters and digitized EEG data on an external PC with data logging (5000 series option)

This manual describes each of the features of the spECTRUM 5000 & 4000 devices. Also described is the use of optional equipment. The appendices in this manual provide a wealth of reference documentation, including technical information and detailed descriptions of each LCD screen that users will encounter.

HOW TO READ THIS MANUAL

The instructions and descriptions in this manual assume all functions and features to be "common" to all four models of the spECTRUM unless indicated otherwise. Exceptions will be identified by graphic headers, such as:

Q models **5000 models**

Where these appear, they indicate a special and/or unique condition that affects a specific part of a process, or is available only on a specific spECTRUM model.

Sometimes only a few lines or paragraphs of model-specific text occur. These will be indented, so it will be clear when discussion of that exception ends and the common information resumes. If this model-specific text is longer than a few lines, a shaded line in the margin will indicate the extent of applicable text.

DEFINITIONS

Warning Identifies conditions or practices that could result in personal injury to the patient or operator.

Caution Identifies conditions or practices that could result in damage to the equipment or other property.

Note Identifies pertinent information.

MODEL VARIATIONS

There are four different SPECTRUM models (5000Q, 5000M, 4000Q, 4000M). All four models include an ECT stimulus delivery module.

- The 5000Q and 5000M models also include a patient monitoring module. The 4000Q and 4000M models include only the ECT stimulus delivery module, and are not equipped to record patient physiology.
- The 5000Q and 4000Q devices have separate controls for setting pulse width, frequency, duration and current levels. "Q" stands for "quad" to denote independent control over four settings. The 5000M and 4000M devices have a single knob that adjusts the intensity of the ECT stimulus. "M" stands for "mono" to denote use of a single dial to control stimulus intensity.

Differences Among SPECTRUM Models	5000Q	5000M	4000Q	4000M
Physiological Monitoring	Yes	Yes	No	No
Stimulus Parameter Control / 4 Dials	Yes	No	Yes	No
Stimulus Parameter Control / 1 Dial	No	Yes	No	Yes

FEATURES ON THE 5000/4000 MODELS

The SPECTRUM models present significant advances in state-of-the-art ECT equipment. Their powerful new multi-processor architecture coupled with a Liquid Crystal Display and Touch Screen or Membrane Switch technology introduce unprecedented flexibility in allowing the practitioner control over all aspects of device operation. These devices also offer an unprecedented level of feedback to the practitioner regarding the stimulus delivered to the patient and the patient's physiological response. Despite the wealth of features offered by the SPECTRUM models, they are simpler to operate than previous generations of ECT devices.

Extensive use of digital technology provides the support for an LCD user interface, higher quality stimulus waveforms, accurate physiological monitoring, and the ability to connect a remote monitor (personal computer) to display and store patient, treatment, and physiology data. By simply touching the LCD or Membrane Switches, patient information may be entered, physiological monitoring channels may be activated or deactivated, alternate electrical stimulus parameter ranges may be selected, and a variety of other configuration options may be enabled or disabled.

A continuous self-test feature, Patient Impedance display, displays the patient impedance continuously prior to the delivery of the ECT stimulus, beginning as soon as both stimulus electrodes are placed on the head. This display is in both numerical and graphical form so that the clinician can immediately evaluate the quality of the connection between the patient and the ECT device. These "static impedance" readings change instantly as the electrodes are moved, gel is added, etc. This enables the clinician to be alerted to conditions in which the quality of electrical contact may be compromised.

Redesigned hand-held electrodes provide greater operator protection, provide the capacity to deliver the ECT stimulus by pressing a button on the hand-held electrodes, and provide water-proof connections with strain reliefs.

All SPECTRUM models offer unprecedented self-diagnostics that verify proper operation of internal components. During stimulus delivery, SPECTRUM devices measure and check every pulse for pulse width, frequency, current and voltage, as well as the duration of the pulse train and the total delivered energy. Furthermore, a backup monitoring system also checks the stimulus pulse width, frequency, duration and energy for failure conditions. In the event of a failure, the treatment is terminated and the operator notified of the problem. Between patients and at startup, the stimulus delivery system is tested internally, along with primary and backup stimulus monitoring systems.

5000 models

5000 Models

The 5000 series includes many new features related to physiological monitoring. The minimum configuration for a 5000 model includes two channels of physiological monitoring (2 EEG channels or 1 EEG and 1 ECG channel). However, the 5000 model may be ordered with up to 6 channels of physiological monitoring including 1 ECG, up to 4 EEG and 1 Optical Motion Sensor (OMS) channel. The OMS provides a new method for measuring motor activity during the seizure.

The LCD can display up to four channels of physiological signals, while two channels can be printed on the CHART RECORDER. The clinician can configure which channels are displayed on the LCD and on the CHART RECORDER. All channels selected for display or printing on the CHART RECORDER are monitored to verify that they are connected to the patient. The disappearance of traces, Leads-Off Indication, and the appearance of a separate LCD message notify the clinician of disconnected channels, when, for instance, a physiological monitoring electrode falls off.

An optional EEG DATA Analysis feature examines EEG activity during and immediately following the seizure. Based on a sophisticated algorithm, the clinician is given an estimate of the likelihood that the seizure is different from one produced by an ineffective stimulus (i.e., barely suprathreshold unilateral ECT). For unilateral ECT, this algorithm also provides an estimate of the extent to which the electrical stimulus intensity exceeded the seizure threshold of the patient just treated. This analysis option may provide valuable information to assist in determining subsequent stimulus dosage.

All patient, treatment and physiological monitoring data may be displayed using the RMS (Remote Monitor Software). Additionally, the RMS provides for the storage of all this information on the PC's hard drive. The stored patient and treatment information may be read by virtually any PC database or spreadsheet program. The RMS Manager (database software) option digitally organizes this data for the clinician and is available with the RMS.

All 5000 models include an analog output port on the rear panel where all physiological signals are available. This port may be used to send analog physiological signals to external monitoring equipment.

4000 models

4000 Models

Some newer 4000 models have Membrane Switches to the left of the LCD and do not have a Touch Screen. On these models, all "button" selections are made using the Membrane Switches, and the LCD buttons should not be touched (they do not do anything). On these units, the EXIT button should be used where the manual says to use the CLEAR or DONE button. Furthermore, no date or time will appear on these models.

INITIAL SET UP

Unpacking

When unpacking the SPECTRUM from its shipping container:

____ 1. Find the packing slip and/or list of included items, and ensure that all items listed are included in the shipment.

____ 2. If any item is not found,
- ____ Recheck the shipping container (inside all packing and inserts, etc.)
- ____ Check with your receiving department.
- ____ Otherwise, contact MECTA Tech Support.

____ 3. Save the shipping container and any packing materials in case you must re-ship the SPECTRUM for service, etc. (Otherwise, the warranty will be voided).

____ 4. Perform a visual inspection to note any possible damage that might have occurred during shipment.
- ____ Check all cables and leads for fraying, cracks or loose connections.
- ____ Replace any damaged items.

5000 models

____ 5. (5000-models only) Push the CHART RECORDER door latch (the ribbed button at the top right corner of the printer unit). It will fall open in "tailgate" fashion. See the CHART RECORDER section of this manual for help on inserting a roll of paper.

____ 6. Insert a roll of SPECTRUM thermal paper between the two cupped uprights. Make sure the roll is placed so that paper spools off the underside of the roll. (See CHART RECORDER MODULE).

____ 7. Pull out an inch of paper and lay it over the container door's top edge. It does not need to be threaded through any slots or assemblies.

____ 8. Lift the door and push it shut, leaving the paper feeding over the top of the door.

Power-up Steps

____ 1. Connect the SPECTRUM's power cord to the power input module on the back panel.

____ 2. Verify that the voltage selector on the rear panel (near where the power cord plugs in) is set for the proper line voltage (115 or 230).

____ 3. Plug the SPECTRUM into a wall socket.

___ 4. Press the POWER ON/OFF push button (upper left corner of the front panel). Ensure that the green indicator (inside the button) is now visible.

On power-up, the SPECTRUM conducts various internal tests. The INTERNAL TEST display will appear, followed by a series of internal clicks and chirps as it processes and verifies the status of software and hardware readiness. When the test steps are completed, the display will show messages stating that internal system checks and tests have passed, and the system is ready for configuring and user input.

5000 models

Systems with a CHART RECORDER will print on the paper tape a narrow vertical black bar and the COPYRIGHT display.

____ 5. Inspect the black bar and verify that it is continuous. If it is not, this indicates a problem with the CHART RECORDER.

Adjusting LCD Screen Contrast

When the SPECTRUM is powered up, the LCD Screen may appear darker or lighter than necessary for comfortable use. Several displays provide contrast control buttons (LIGHT and DARK) to adjust contrast settings.

____ 1. Touch LIGHT or DARK to lighten or darken the display, until desired contrast is reached.

Touch Screen

NOTE:

- To activate the touch screen, touch the display firmly but not excessively.

Membrane Switches

NOTE:

- To activate a Membrane Switch at the left of the LCD, touch the switch firmly but not excessively.

____ 2. Touch the CLEAR or EXIT button to proceed to the TREATMENT READY display.

5000 models

CHART RECORDER Tests

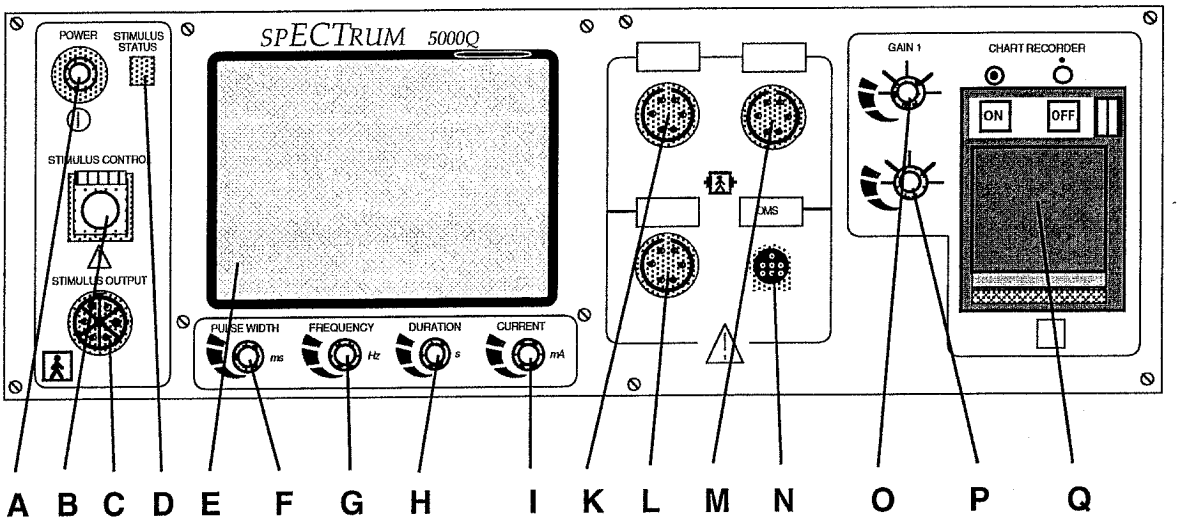
These tests confirm that the printer and printouts are operational.

____ 1. Push the ON button located on the CHART RECORDER. Verify that the Chart Recorder prints timing marks, grid patterns, and channel information. (Because a patient is not yet connected, no actual traces will appear).

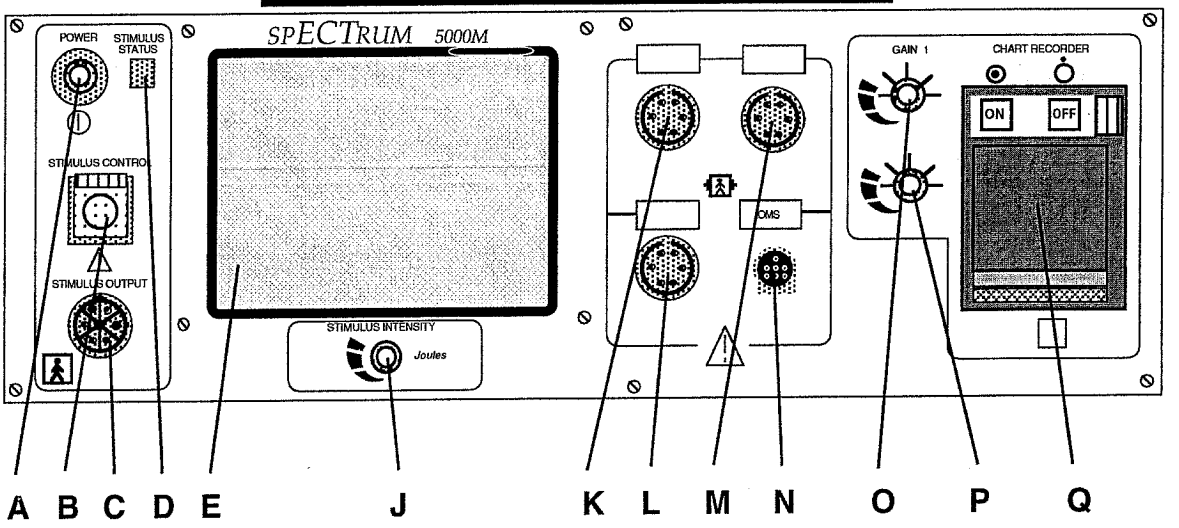
____ 2. Push the Recorder's OFF push button, and verify that the trace printing stops.

Model Diagrams

5000Q FRONT PANEL DIAGRAM



5000M FRONT PANEL DIAGRAM



A POWER ON/OFF button

B STIMULUS CONTROL push button

C STIMULUS OUTPUT connector

D STIMULUS STATUS indicator

E LCD/Touch Screen

F PULSE WIDTH knob (milliseconds)

G FREQUENCY knob (Hertz)

H DURATION knob (seconds)

I CURRENT knob (milliAmps)

J STIMULUS INTENSITY knob (M models)

K PATIENT INPUT connector

L PATIENT INPUT connector

M PATIENT INPUT connector

N OMS INPUT connector

O GAIN 1 knob

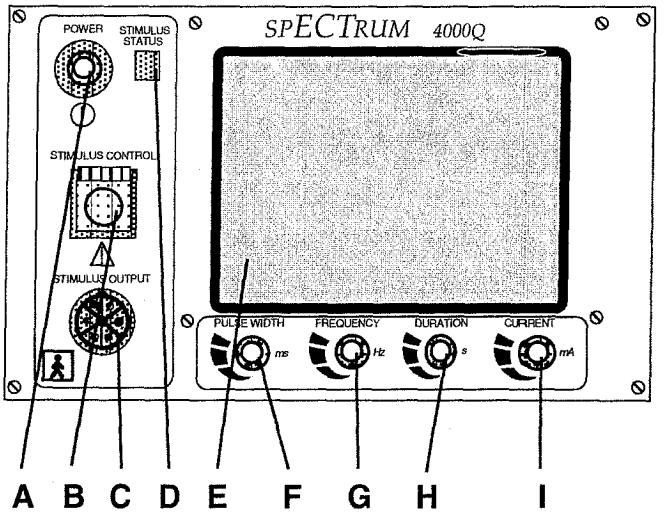
P GAIN 2 knob

Q CHART RECORDER

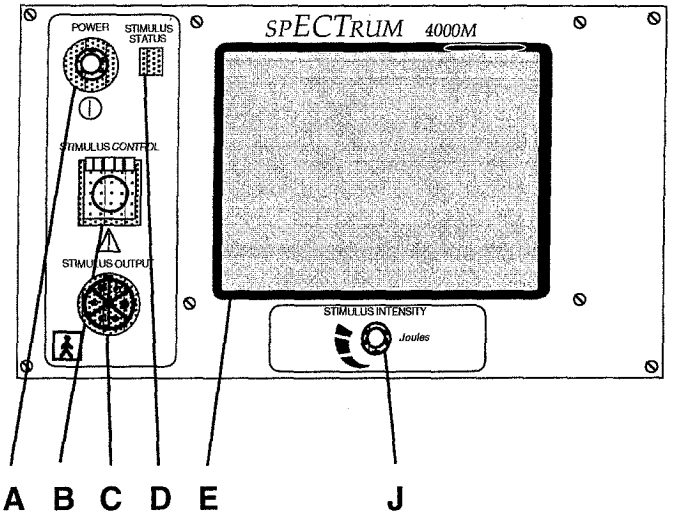
See pgs. 14-15 for descriptions

LCD TOUCH SCREEN MODELS

4000Q FRONT PANEL DIAGRAM



4000M FRONT PANEL DIAGRAM



A POWER ON/OFF button

B STIMULUS CONTROL push button

C STIMULUS OUTPUT connector

D STIMULUS STATUS indicator

E LCD/Touch Screen

F PULSE WIDTH knob (milliseconds)

G FREQUENCY knob (Hertz)

H DURATION knob (seconds)

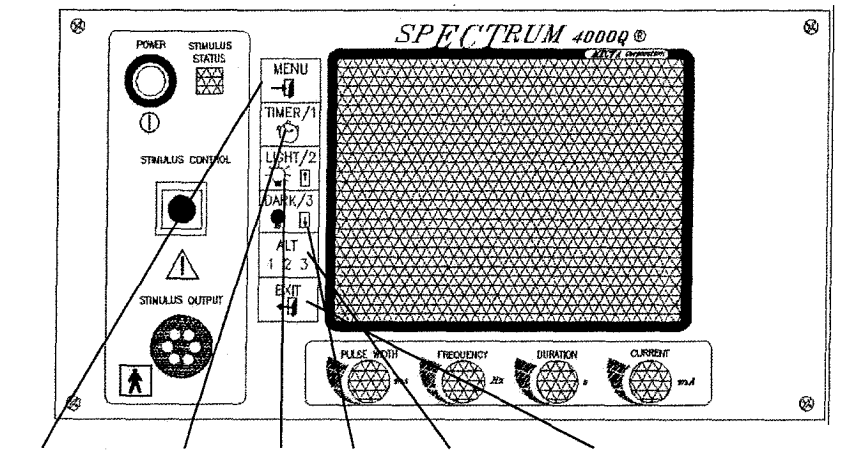
I CURRENT knob (milliAmps)

J STIMULUS INTENSITY knob (M models)

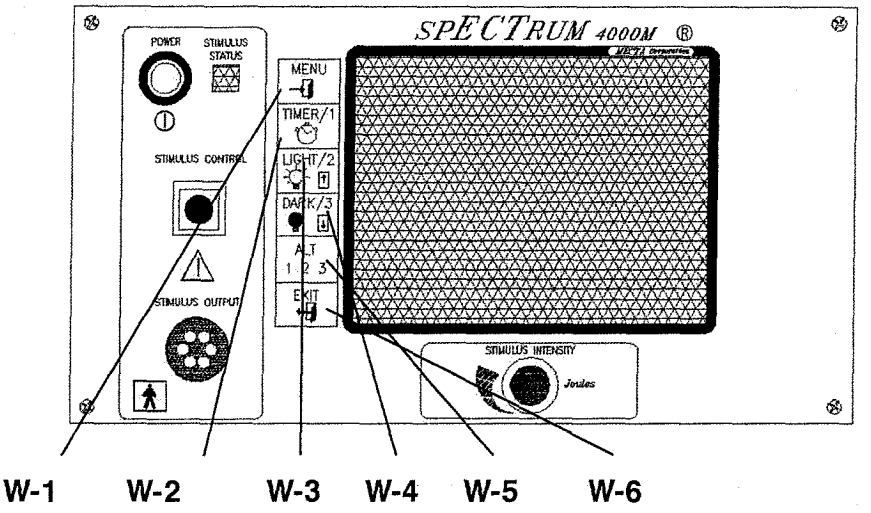
See pgs. 14-15 for descriptions

MEMBRANE SWITCH MODELS

4000Q MEMBRANE SWITCH FRONT PANEL DIAGRAM



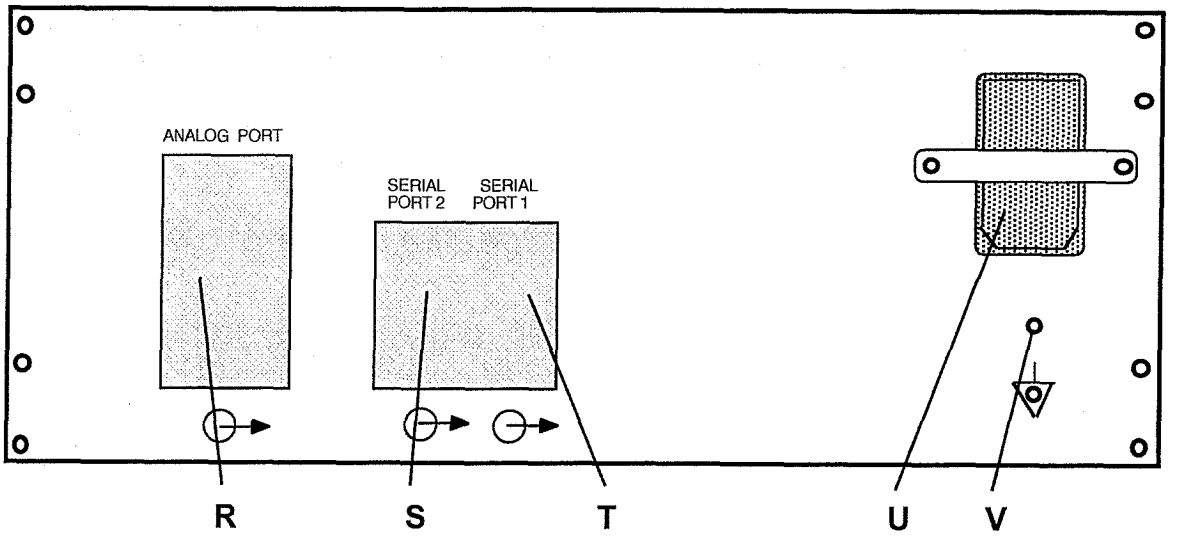
4000M MEMBRANE SWITCH FRONT PANEL DIAGRAM



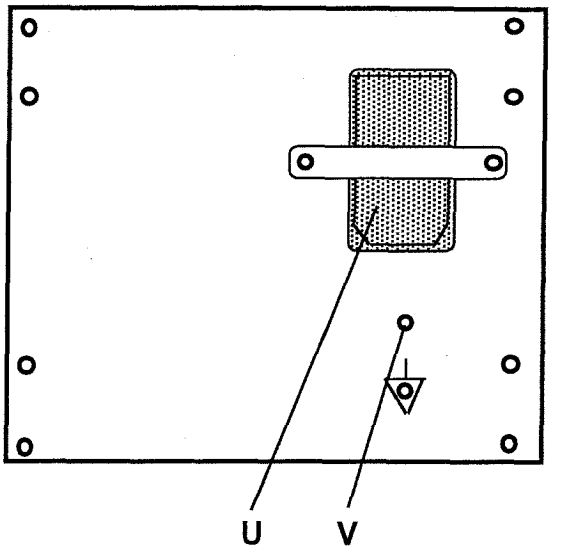
W-1	MENU	Enter the Menu system.
W-2	TIMER	TIMER Start/Stop or "1" if ALT button pressed at the same time.
W-3	LIGHT	Increase brightness or "2" if ALT button pressed at the same time.
W-4	DARK	Decrease brightness or "3" if ALT button pressed at the same time.
W-5	ALT	Select ALT button definitions. Changes TIMER to "1", LIGHT to "2", and DARK to "3".
W-6	EXIT	Exit the Menu or DONE with treatment or CLEAR.

See pg. 15 for descriptions

5000 MODEL BACK PANEL DIAGRAM



4000 MODEL BACK PANEL DIAGRAM



R ANALOG SIGNAL OUTPUT Port, DB25

S SERIAL OUTPUT Port 2, RS232, DB9

T SERIAL OUTPUT Port 1, RS232, DB9

U POWER ENTRY module
w/ user-selectable input voltage (115/230 VAC)
and fuse drawer (5 x 20mm)

V Equipotential Post

See pg. 15 for descriptions

PANEL CONTROLS AND CONNECTOR DESCRIPTIONS

To help familiarize the user with the basic controls of the SPECTRUM, a brief description follows of each control and connector located on the front and back panels.

Front Panel Diagram

A. POWER ON /OFF push button

When pushed and released, the push-button turns the unit on or off. The button is green in color when the power is on.

B. STIMULUS CONTROL push button

Once the SPECTRUM has passed internal diagnostic tests and it has been determined by the patient Self-Test that static impedance is in an acceptable range , pushing the STIMU LUS CONTROL push button and holding the button down throughout the delivery tones results in delivery of the preselected stimulus.

C. STIMULUS OUTPUT connector

The source of the electrical stimulus delivered to the patient. The Patient Stimulus Cable or the Hand-Held electrodes attach to this connector.

D. STIMULUS STATUS indicator

Indicates the current state of the SPECTRUM.
off = STIMULUS CONTROL disabled
yellow (orangish yellow) = delivery of stimulus
green (greenish yellow) = STIMULUS CONTROL enabled
red = stimulus delivery fault.

E. LCD/Touch Screen

The main interface for system usage and configuration. It provides information throughout the treatment session. Graphical display of up to four patient monitoring signals is also available.

Q models

F. PULSE WIDTH knob

Selects the width of the pulses in milliseconds (msec).

G. FREQUENCY knob

Selects the frequency or rate of pulses in pairs of pulses per second or Hertz (Hz).

H. DURATION knob

Selects the duration of the total pulse train in seconds (sec).

I. CURRENT knob

Selects the peak amplitude of the constant current delivered during each pulse in units of milliamperes (mA).

M models

J STIMULUS INTENSITY knob (M models only)

Selects the output stimulus level by simultaneously varying pulse frequency and train duration.

5000 models

K-M. PATIENT INPUT connectors

Connects the patient to the internal instrumentation amplifiers. The Patient Safety Monitor Cables are attached to this connector. In turn, the monitoring electrode leads attach to the Patient Safety Monitor Cable(s).

5000 models

N. OPTICAL MOTION SENSOR input connector
Connects the Optical Motion Sensor to the internal OMS amplifier.

O. GAIN 1 knob
Adjusts the amplitude (gain) of the first trace on the CHART RECORDER in five steps.

P. GAIN 2 knob
Adjusts the amplitude (gain) of the second trace on the CHART RECORDER in five steps.

Q. CHART RECORDER
Prints up to two selected patient monitoring channels and the self-test and treatment data using a thermal array printer and thermally sensitive paper.

Back Panel Diagram

5000 models

R. ANALOG SIGNAL OUTPUT Port, DB25 (ANALOG PORT)
Provides up to 6 analog output channels of isolated patient monitoring signals and a timing signal for use with external monitoring equipment.

S. SERIAL OUTPUT Port 2, RS232, DB 9
A serial port providing digital information necessary to recreate LCD/Touch Screen displays on a remote PC (personal computer).

T. SERIAL OUTPUT Port 1, RS232, DB 9 (For future development)

U. POWER ENTRY module
The receptacle for a shielded medical grade power line cord.

V. Equipotential Post
Connector for a Potential Equalization Conductor.

Membrane Switches

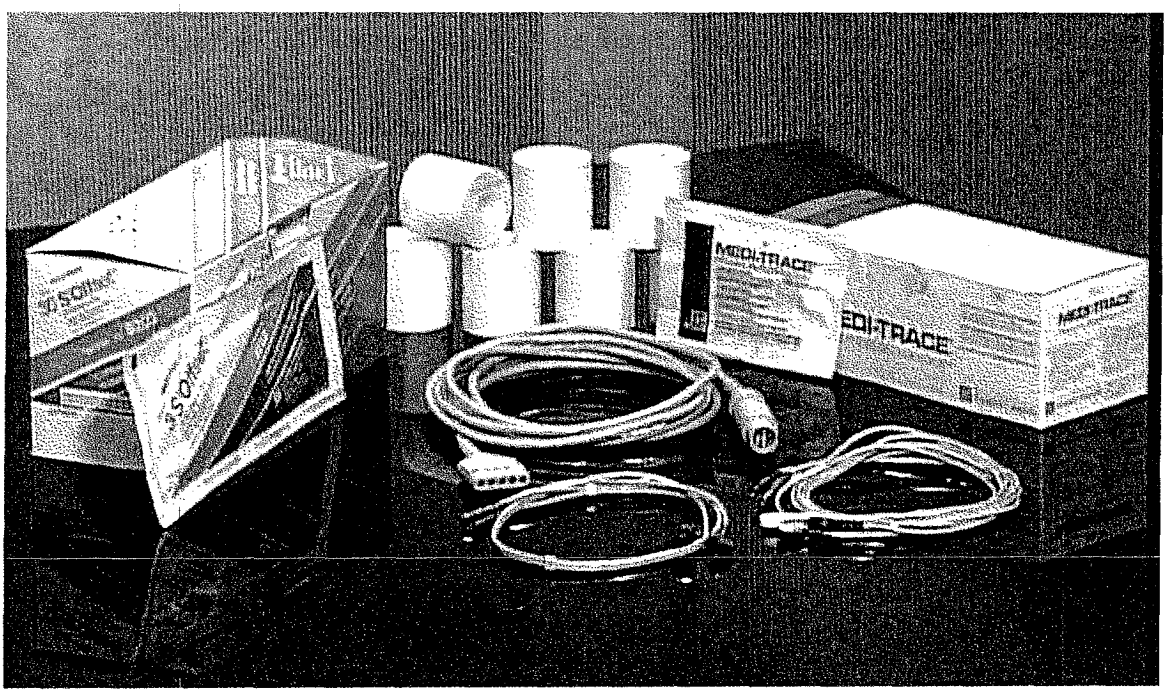
Membrane Switch Front Panel Diagram

W-1. to W-6. MEMBRANE SWITCHES
Switches used for menu navigation and system control.

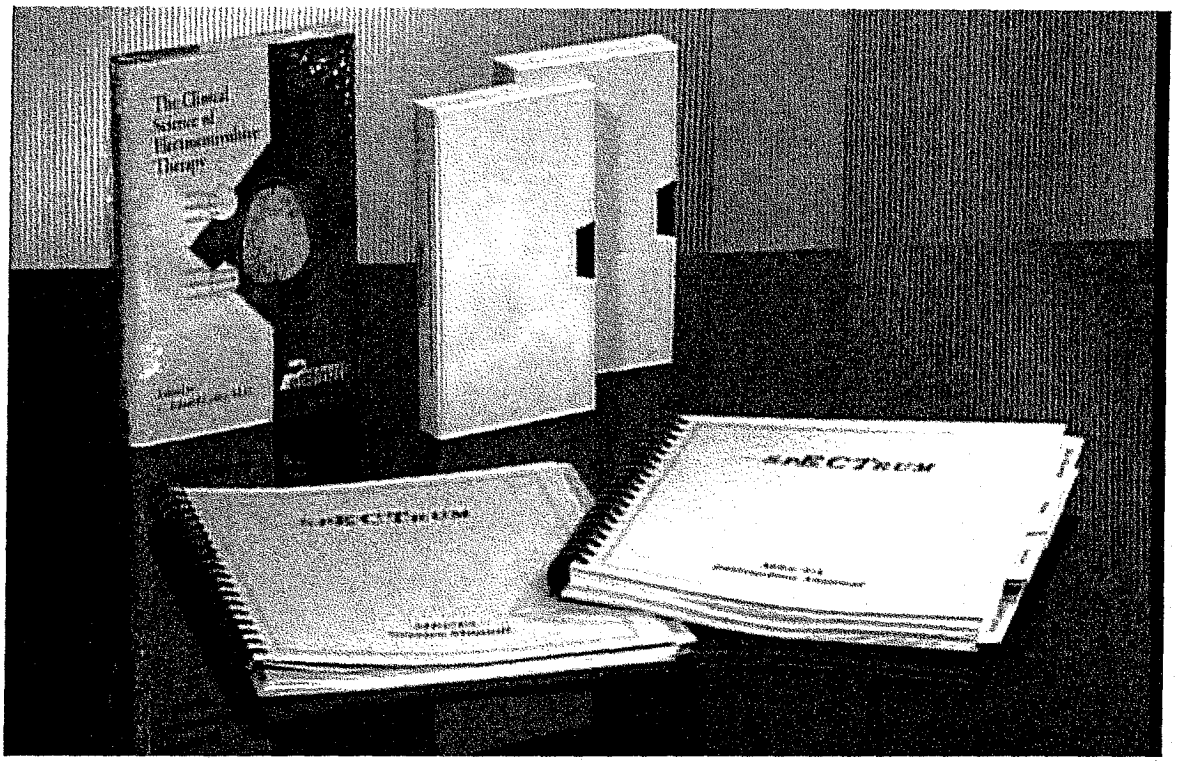
W-1	**MENU**	Enter the Menu system.
W-2	**TIMER**	TIMER Start/Stop or "1" if ALT button pressed at the same time.
W-3	**LIGHT**	Increase brightness or "2" if ALT button pressed at the same time.
W-4	**DARK**	Decrease brightness or "3" if ALT button pressed at the same time.
W-5	**ALT**	Select ALT button definitions. Changes TIMER to "1", LIGHT to "2", and DARK to "3".
W-6	**EXIT**	Exit the Menu or DONE with treatment or CLEAR.

STARTER KIT

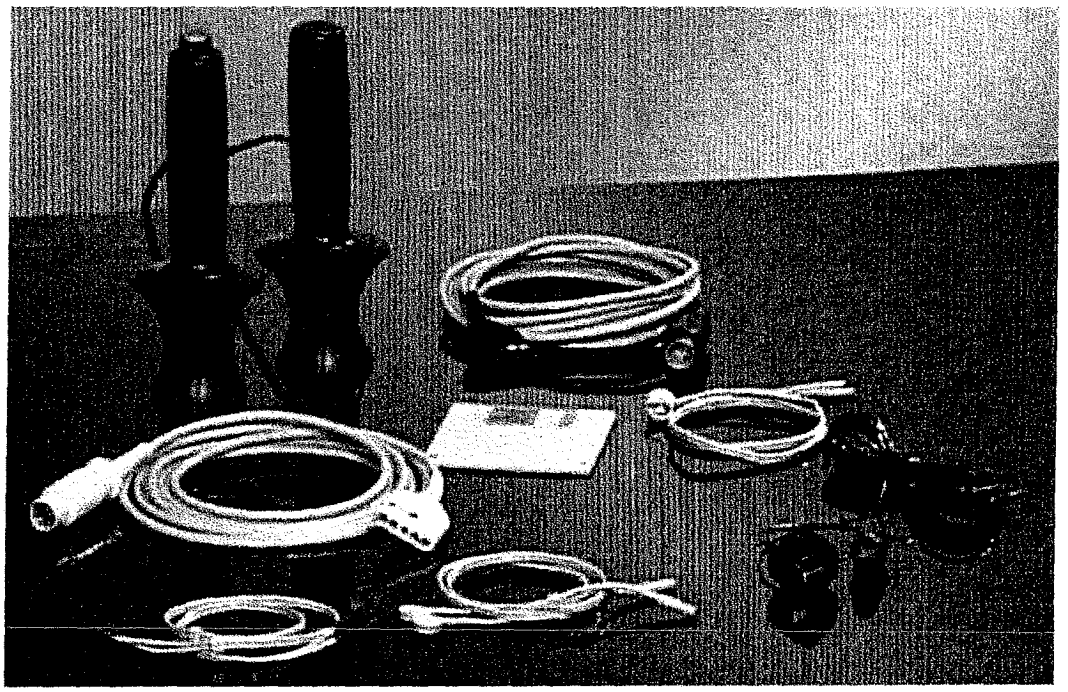
4000 AND 5000 DEVICES. One Patient Stimulus Cable, one set flat stimulus electrodes, one set concave stimulus electrodes, one headband, 2 each fuses--4 amp, 1 bite block Blachley, 1 tube electrode gel, 1 tube electrode paste.



5000 ADDITIONAL STARTER KIT. One Patient Safety Monitor Cable, one set EEG safety leads, one box EEG disposable electrode pads, one box ECG disposable electrode pads.



EDUCATIONAL MATERIALS - Two each Instruction manuals, two each Service manuals, 1 MECTA video tape (technical), 1 HIN video-tape (clinical), 1 textbook.



OPTIONAL STARTER KIT - Up to two Patient Monitor cables and up to three sets of Safety leads. One Optical Motion Sensor and cable, one set Hand-Held electrodes with or without remote. Also, the optional features include the EEG Data Analysis feature, the RMS (Remote Monitor Software), the RMS Manager (database software), and one IBM-compatible PC.

ECT Module

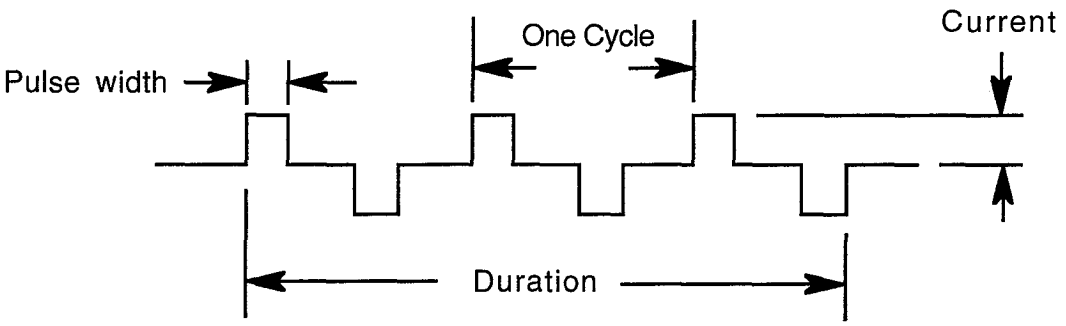
ECT Module

The ECT module includes the controls that power up the device and that generate and deliver the ECT stimulus. A continuous impedance monitoring system for the patient Self-Test feature is also included. The LCD and Touch Screen or Membrane Switches that service all interactions between the clinician and the device are part of the ECT module. This screen's display is used in configuring a variety of device settings both for delivery of the ECT stimulus and physiological monitoring.

TREATMENT PARAMETERS

Stimulus Waveform

Proper use of any ECT device requires some understanding of the pertinent electrical characteristics of the stimulus waveform. The spECTrum generates a bidirectional pulse stimulus waveform as shown in the following diagram.



NOTE:

- Frequency is the number of cycles (i.e., pairs of pulses) per second.

The pulse width (in milliseconds), frequency (in Hertz), duration (in seconds) and current (in milliamperes) may be varied to generate the optimal stimulus for any given treatment. In the Q models, all four parameters can be independently varied using the four front panel controls. In the M models, one knob is used to set overall stimulus intensity. The settings of this knob vary the pulse frequency and train duration, according to the selected parameter set (see Menu Section), while leaving pulse width fixed at 1.0 msec or 0.3 msec and current fixed at 800 mA.

The spECTrum generates a constant current waveform with a peak amplitude maintained at the specified current value. The intensity of the ECT stimulus is assessed in terms of the total delivered charge, using units of millicoulombs (mC). This total charge, indicated on the LCD/Touch Screen for the specified parameter settings, will be delivered to the patient unless the stimulus is terminated prematurely, or an electrical failure occurs. The delivered charge can be defined as:

$$Q = (I/1000) \times PW \times 2F \times D$$

where:

Q	=	CHARGE in milliCoulombs
I	=	CURRENT in milliamperes
PW	=	PULSE WIDTH in milliseconds
F	=	FREQUENCY in cycles per second (Hertz)
D	=	DURATION in seconds

There is considerable evidence that the charge delivered during an electrical stimulus determines the neuronal response in terms of likelihood of inducing a seizure and has bearing on adverse effects, such as postictal confusion and memory loss.

Patient Impedance

The electrical path of the ECT stimulus includes the ECT output device, the Patient Stimulus Cable and stimulus electrodes, scalp, skull, CSF, and brain tissue. Based upon the electrical characteristics of each of these factors, the major and most variable impediments, or "impedance" to the flow of the stimulus current are the scalp and skull. Differences in both the degree of stimulus electrode contact with the scalp and the intrinsic electrical and geometric properties of the scalp and skull contribute to the variability. This impedance is measured in ohms.

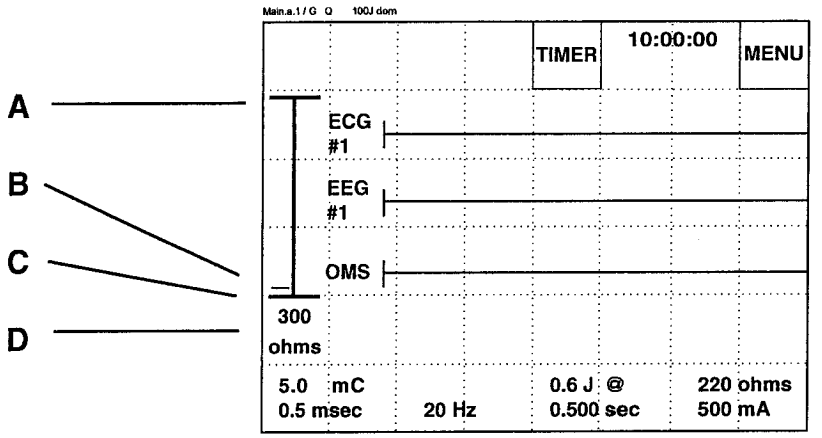
The SPECTRUM measures two types of patient impedance. One is assessed during the patient Self-Test and is displayed at all times, except during the passage of the stimulus. This type is often referred to as STATIC IMPEDANCE. The second type concerns the impedance encountered during the passage of the ECT electrical stimulus. This type is often referred to as DYNAMIC IMPEDANCE. Both forms of impedance provide the clinician with information about the adequacy of the stimulus electrode connections to the patient.

Preparing the scalp for stimulus electrode placement

To have adequate electrical contact with the scalp, take care to keep the impedance of the scalp underlying the stimulus electrodes as low as possible, while also not creating an iatrogenically low path for current to be shunted between the stimulus electrodes. Although applying a coating of conductive electrode gel to the face of the stimulus electrode which will contact the scalp is a necessary part of this process, it is not in itself sufficient to achieve this end. The treatment team should also rub in or spray on to the contact zone an electrolytic solution, while ensuring that this material does not spread outside the actual contact zone. Additionally, some practitioners also choose to mildly abrade the site with a substance designed for such use (e.g., Omniprep (R)).

Self-Test

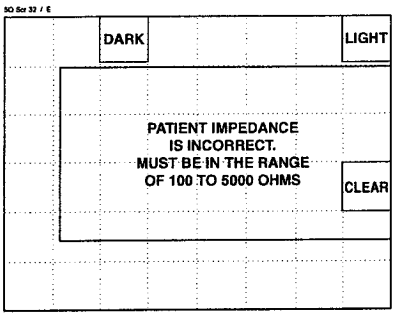
Prior to treatment, the Self-Test impedance measurement provides continuous monitoring of the stimulus electrode connection and display of the static impedance value. Static impedance is continuously assessed by passage of a high frequency, imperceptible low amplitude current through the entire circuit, including the device, Patient Stimulus cable, and patient. To help prevent poor stimulus delivery and insure that the patient receives the predetermined charge, the impedance must be in the range of 100-5000 ohms (nominal). If static impedance is outside of this range, the SPECTRUM will not deliver a stimulus. To facilitate easy monitoring of this impedance, the pre- and post-treatment displays include a graphical representation of patient impedance on the left side of the LCD Screen, as shown on the next page in the TREATMENT READY DISPLAY.



Treatment Ready Display

A. The top line indicates a 5,000 ohm level.
B. The Static Impedance pointer marks the actual static impedance level (in this case, 300 ohms).
C. The bottom line marks the 100 ohm level.
D. The static impedance numerical value appears below the graph.

If the impedance is outside the range of 100-5000 ohms, the impedance value given below the graphical Treatment Ready Display will read UNDER or OVER as appropriate. In addition, the STIMULUS STATUS indicator (on the upper left of the device's front panel) will turn off to indicate that the STIMULUS CONTROL button (on the front panel, or on the hand-held electrodes) is disabled and no electrical stimulus can be delivered. If the clinician attempts to deliver a stimulus by pressing the STIMULUS CONTROL button when the static impedance is out of range, the following display will appear on the LCD.



When the clinician notes that the impedance is out of range, it is critical to determine whether the impedance is excessively low or high. Very low static impedance values (below 200) usually indicate an unwanted current path between the two ECT stimulus electrodes due to smearing of the gel or paste used to prepare the electrode sites at the time of treatment. This circumstance can also arise when patients have hair spray, hair gels, or heavy perspiration resulting in a low impedance current bridge between the ECT electrodes. If the ECT stimulus were delivered under such conditions, virtually the total stimulus would be shunted through the low impedance bridge and little or none would enter the brain, resulting in a missed seizure. Furthermore, under such circumstances it is possible to singe the hair.

In contrast, high static impedance values (above 2,000 ohms) are obtained when there is poor stimulus electrode contact with the scalp, when the sites of the ECT stimulus electrodes have been inadequately prepared, or when there is a break or disconnection in the stimulus delivery circuit. Probably the most common cause of high impedance failure is disconnection of the

Patient Stimulus cable from the ECT electrodes. If the ECT stimulus were administered under conditions of excessive impedance, it would be impossible to safely maintain the current at the specified value. Consequently, the predetermined charge could not be delivered and patients may fail to have an adequate seizure. To protect patients against excessively low or high static impedance, the spECTrum models automatically prevent stimulus delivery unless static impedance falls within the specified range (100-5,000 ohms) at the time of initiation of the stimulus.

While the range at which the spECTrum will permit stimulus delivery is between 100-5,000 ohms, experience indicates that with adequate preparation of the ECT electrode sites and proper contact, the static impedance of patients should rarely exceed 1,500 ohms.

NOTE:

- This type of continuous impedance readout is a new feature available only on spECTrums.

Dynamic Impedance

As noted, the spECTrum also assesses dynamic impedance, which is the impedance encountered during the passage of the ECT stimulus. The spECTrum measures the delivered voltage and current during every pulse of the delivered stimulus to calculate dynamic impedance. The spECTrum later reports these measurements as DYNAMIC impedance on the TREATMENT RESULTS DISPLAY. This impedance usually is in the range of 100-300 ohms. Note that dynamic impedance values are typically substantially below those of static impedance values. With adequate preparation of the ECT electrode sites and good contact during the passage of the stimulus, average impedance values should be below 200 ohms for bilateral ECT and slightly above 200 ohms for right unilateral ECT.

With consistency in how stimulus electrode sites are prepared and electrodes applied to the scalp, dynamic impedance values should be fairly constant for each patient over the treatment course. If patients fail to have a seizure or have a brief seizure with a stimulus dosage setting that had previously been successful, inspection of the dynamic impedance value may be useful. A sharp increase in dynamic impedance may suggest that the subconvulsive stimulation or brief seizure was due to poor electrode contact as opposed to a marked elevation in seizure threshold.

Voltage

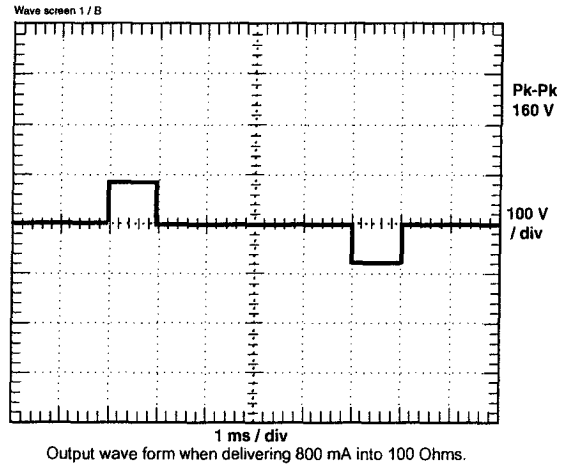
The spECTrum models use constant current principles. Independent of the dynamic impedance encountered during stimulation, the spECTrum device will maintain the peak current during each pulse at the user specified value for 5000Q and 4000Q models and at the fixed value of 800 mA for 5000M and 4000M models. Ohm's law describes the relationship among voltage, current, and resistance (or impedance). In ECT, impedance (assessed in ohms) is essentially equivalent to resistance (also assessed in ohms).

$$V = (I/1000) * R$$

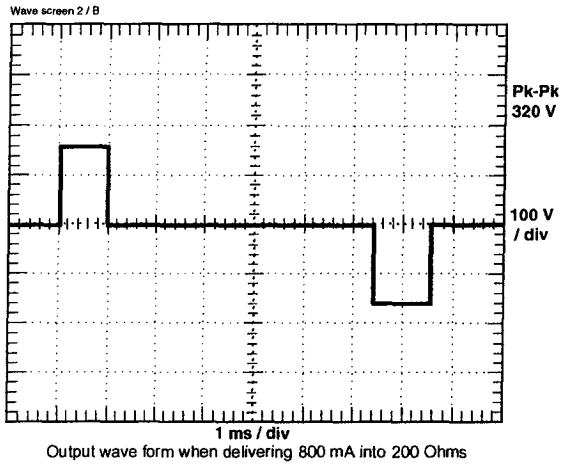
where

V is VOLTAGE in Volts,
I is CURRENT in milliamperes, and
R is RESISTANCE in ohms.

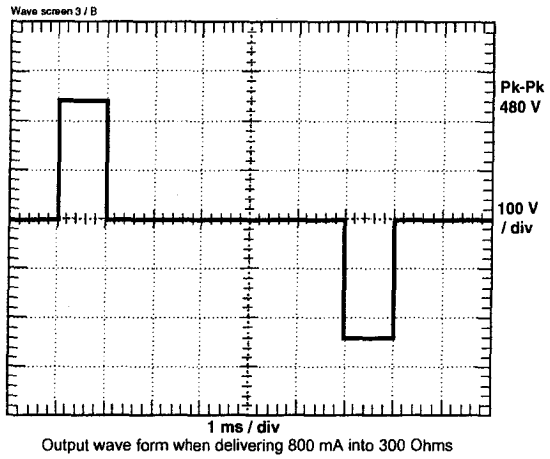
From Ohm's law, it is evident that as dynamic impedance increases, voltage must increase to keep current at a specified value. For example, when the electrical contact between the electrodes and the scalp is poor and dynamic impedance is high, the spECTrum must deliver a higher



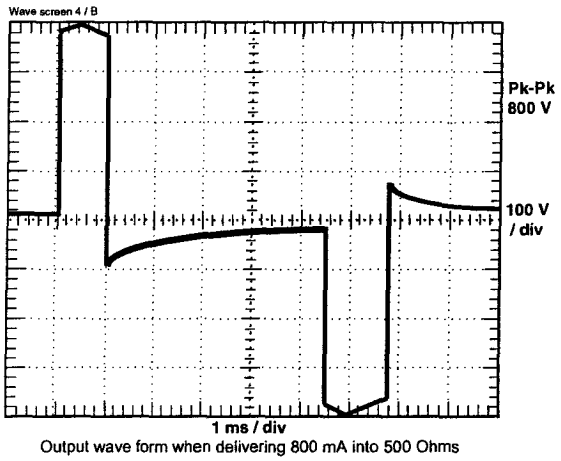
Output wave form when delivering 800 mA into 100 Ohms.



Output wave form when delivering 800 mA into 200 Ohms



Output wave form when delivering 800 mA into 300 Ohms



Output wave form when delivering 800 mA into 500 Ohms

voltage to keep the current at the specified level. Excessively high voltage can result in burns at the electrode/skin interface. For this reason, the SPECTRUM will automatically stop stimulus delivery if the voltage requirements exceed 400 Volts at any time during stimulation. The SPECTRUM will also abort stimulus delivery if the voltage at any time during stimulation is below 50 Volts, indicating a low impedance shunt, which (as indicated above) would likely result in ineffective treatment. The above graphs illustrate how the voltage output varies as a function of the dynamic impedance.

Energy

Prior to the treatment, the SPECTRUM provides an estimate of the energy to be administered during the stimulation. Like charge, energy is a unit that assesses the intensity of the total electrical stimulus. Unlike charge, the calculation of energy is dependent on the dynamic impedance encountered during stimulation. To provide the energy estimate prior to stimulation, the SPECTRUM uses an assumed dynamic impedance value of 220 ohms. The actual energy administered is later reported in the TREATMENT RESULTS DISPLAY and may differ considerably from the estimate. Energy may be calculated as follows:

$$U = (Q/1000) * (I/1000) * R$$

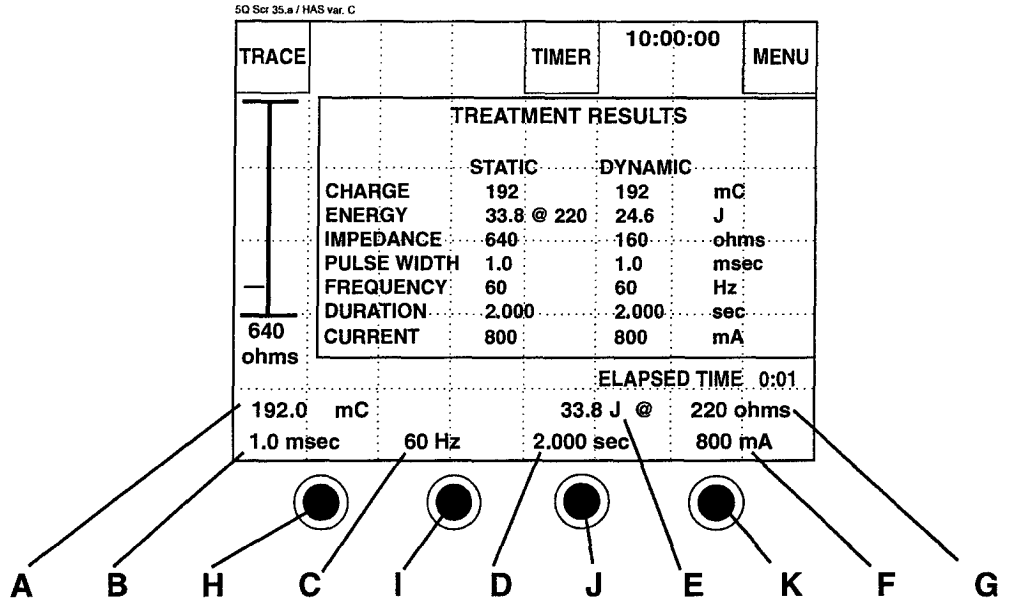
where

U is the ENERGY in Joules
Q is the CHARGE in milliCoulombs as defined previously,
I is CURRENT in milliamperes, and
R is RESISTANCE in ohms.

During the stimulus, the delivered voltage and energy will depend upon the patient's actual DYNAMIC impedance. The energy shown on the TREATMENT READY DISPLAY in the STATIC column (see figure below) provides an estimate of the energy based upon an assumed DYNAMIC impedance of 220 ohms, as indicated above. The energy and impedance shown in the DYNAMIC column are the actual measured energy and DYNAMIC impedance. If the DYNAMIC impedance is 160, then the energy shown will be smaller than the estimate (in the STATIC column) by a factor approximately equal to the DYNAMIC impedance divided by 220, i.e. 160/220 x 33.8 is approximately 24.6 in this example.

STIMULUS PARAMETER SETTINGS DISPLAY

All of the pre- and post-treatment displays show the stimulus parameter settings that will be used for the next stimulus delivery. A TREATMENT READY DISPLAY appears prior to stimulation. The TREATMENT RESULTS DISPLAY (below) appears following the treatment. With the 5000 series devices, this information is automatically printed out on the CHART RECORDER following each treatment.



Treatment Results Display and Parameter controls

A. 192.0 mC indicates the amount of charge to be delivered (in milliCoulombs) in the next stimulation.
B. 1.0 msec indicates the pulse width.
C. 60 Hz indicates the frequency of pairs of pulses being delivered per second.
D. 2.000 sec indicates the total duration of the pulse train.
E. 33.8 Joules indicates the energy that would be delivered into 220 ohms.
F. 800 mA indicates the peak current level of each pulse.
G. 220 ohms is the assumed dynamic patient impedance.
H. PULSE WIDTH knob.
I. FREQUENCY knob.
J. DURATION knob.
K. CURRENT knob.

The figure presented above of the TREATMENT RESULTS DISPLAY is from a Q series device.

Q models On the Q models, the bottom line of the display shows the value of each stimulus parameter currently selected by the knob that is just below that parameter value.

M models

On the M models, the display's bottom line shows only the frequency and duration stimulus parameters, along with the STIMULUS INTENSITY percentage. The Stimulus Intensity varies from 1 to 100% of the maximal charge/energy output of the device. The display's bottom line appears as follows:

20 Hz INTENSITY 1% 0.180 sec

When a spECTrum device is powered up, the electrical parameters that are automatically selected correspond to those last administered during a treatment.

STIMULUS CONTROL and STIMULUS STATUS INDICATORS

As noted, the clinician can deliver a stimulus whenever the STIMULUS STATUS indicator on the upper left of the front panel is "on" (green). The following conditions may cause the STIMULUS STATUS indicator to be "off" (indicating that no stimulus may be delivered):

- the spECTrum is in its power up sequence;
- the STATIC impedance shows OVER or UNDER, in which case pushing the STIMULUS CONTROL push button will generate the PATIENT IMPEDANCE error message;
- an error message is displayed, in which case it must be cleared;
- a MENU is displayed, in which case the menu system must be exited;
- the unit is performing INTERNAL TESTS, which must be successfully completed.

When the clinician is ready to deliver the stimulus, it may be initiated using the front panel STIMULUS CONTROL push button (if the remote Hand-Held electrodes are not connected to the front panel). The STIMULUS CONTROL button must be pushed and held continuously during the 3 warning beeps (STIMULUS ABOUT TO OCCUR... display is visible) and throughout the entire stimulus delivery as indicated by the stimulus delivery tone (DELIVERING STIMULUS display is visible).

Early release of the STIMULUS CONTROL push button will terminate stimulus delivery and generate a warning message on the LCD. One of the most common technical problems in ECT is premature release during stimulus delivery. If the STIMULUS CONTROL push button is released during the three distinct warning tones, the patient will not receive an electrical stimulation. If the STIMULUS CONTROL push button is released during the continuous tone, the patient will receive only a portion of the predetermined stimulus and may have an inadequate treatment. The exact duration of stimulation delivered will be accurately reported in the TREATMENT RESULTS DISPLAY, even under conditions of premature release. The aborting of the stimulus delivery with release of the STIMULUS CONTROL push button is a safety feature. This allows the clinician to stop stimulus delivery at any instant if an unsafe situation arises, such as slippage of a stimulus electrode. See the end of this section for stimulus delivery procedures when using the Hand-Held electrodes.

During stimulus delivery, the color of the STATUS INDICATOR will change from its pre-treatment green (yellowish green) to yellow (orangish yellow). A bright red color (other than during the power up test sequence) indicates an equipment failure and that the delivery system is still connected to the treatment electrodes. Do not use the spECTrum until this situation is corrected.

STIMULUS PARAMETER SETS

Each spECTrum model allows the clinician to select a range of stimulus parameters. To provide maximum flexibility, yet maintain ease of operation, the allowed parameter ranges are selected

via a PARAMETER SELECTION MENU. The operation of menus will be described later in this manual. Many clinicians will select their preferred parameter range at initial device configuration and use that range in all subsequent treatments. Other clinicians may prefer the option of using different parameter ranges for different patients. The spECTrum supports these variations in practice.

M models

The parameter ranges for the M models all use a fixed Pulse Width of 1.0 msec and a fixed peak Current of 800 mA. The parameter ranges differ in the maximal Duration of the pulse train (3, 4, 6 or 8 sec) and the maximal frequency of pulses (60, 90, or 120 Hz). Therefore, the clinician is choosing to have greater flexibility in dosing by train Duration or by pulse Frequency when selecting a specific parameter range. The exception is the fourth parameter set, which will vary the pulse width between 0.3 and 0.38 msec.

Q models

The parameter ranges for the Q models offer additional flexibility. Like the M models, the clinician has the options for the maximal Duration (3, 4, 6 or 8 sec) or the maximal Frequency (60, 90 or 120 Hz). In addition, the clinician has the option of selecting a broader range of Pulse Widths (0.37, 1.0 or 2.0 msec maximum).

It is generally felt that manipulating train Duration or pulse Frequency provides a more efficient method of altering stimulus intensity in ECT than changing Pulse Width. This is why the spECTrum models provide the greatest flexibility with respect to train Duration and pulse Frequency. However, the second parameter range for the Q models (0.5-2.0 msec) most closely approximates the parameter range used in the previous generation MECTA JR1 and SR1 devices. The first parameter range for the M models (20-90 Hz) most closely approximates that used in the previous generation MECTA JR2 and SR2 devices.

Regardless of the parameter range selected for the M or Q models, assuming a dynamic impedance of 220 ohms, 101.4 Joules will be delivered at the highest parameter setting (100J on the fourth parameter set for the Q Model). The actual energy delivered at maximal settings will reflect the actual dynamic impedance. Independent of dynamic impedance, all models deliver a maximum charge of 576 mC at the maximal parameter settings.

Q models

Q Models - 4 parameter ranges

Pulse Width	Frequency	Duration	Current	Energy (@ 220)	Charge
0.5-1.0 ms	20-90 Hz	0.5-4.0 sec.	500-800 mA	0.6-101.4 J	5.0-576 mC
0.5-2.0 ms	20-60 Hz	0.5-3.0 sec.	500-800 mA	0.6-101.4 J	5.0-576 mC
0.5-1.0 ms	20-60 Hz	0.5-6.0 sec.	500-800 mA	0.6-101.4 J	5.0-576 mC
0.3-0.37 ms	20-120 Hz	0.5-8.0 sec.	500-800 mA	0.3-100.0 J	3.0-568.3 mC

M models

M Models - 100 settings in 1% steps

1.0 ms	20-90 Hz	0.18-4.0 sec.	800 mA	1.0 - 101.4 J	5.8 - 576 mC
1.0 ms	20-120 Hz	0.18-3.0 sec.	800 mA	1.0 - 101.4 J	5.8 - 576 mC
1.0 ms	20-60 Hz	0.18-6.0 sec.	800 mA	1.0 - 101.4 J	5.8 - 576 mC
0.3-0.38 ms	20-120 Hz	0.50-8.0 sec.	800 mA	1.0 - 101.4 J	5.8 - 576 mC

Bilateral and Unilateral ECT

A pair each of flat and concave stainless steel ECT electrodes is provided in the Starter Kit Section. These electrodes connect either directly to the banana plugs at the end of the patient stimulus cable or they connect to hand-held electrode posts. First, their use with the headband will be described, followed by their use with the hand-held electrodes.

The sites for the ECT electrodes should first be noted. This principally involves determining whether a bilateral or a unilateral ECT placement will be used. Traditionally, with bilateral ECT, bifrontotemporal electrode placement is used. Position for Electrode Placement figure illustrates such a placement. The distance is measured between the auditory meatus and the external canthus on each side. The midpoint of this distance is determined and the center of the ECT electrode is placed 1.5 inches (4.8 cm) perpendicular and above this point. Since the electrodes supplied by MECTA are 2 inches in diameter, the bottom of the electrode should be just above the midpoint of the line connecting the auditory meatus and the outer canthus.

In the past, a variety of electrode placements have been used for unilateral ECT. In recent years, however, the convention in ECT has been to use the d'Elia placement. The preference for the d'Elia unilateral placement stems from the fact that it has the greatest interelectrode distance of the unilateral placements reported in the literature. The greater the interelectrode distance, the less shunting of current through the scalp. That means, as the distance between electrodes increases, the percentage of the current that enters the brain is also likely to increase. Consequently, a lower electrical intensity is needed to produce a seizure with the d'Elia placement. In addition, efficacy may be greater with the d'Elia than other unilateral electrode placements.

The d'Elia placement involves positioning one electrode at the standard frontotemporal position and the other electrode near the vertex (see Position for Electrode Placement figure). A line joining the two auditory meati should be determined, measured perpendicular to the sagital midline of the skull (the line connecting the inion and nasion). The center of the "parietal" electrode is then placed 3 cm down from the midpoint on the right side for right unilateral ECT (or the left side for the unilateral ECT).

The issue of when bilateral or a unilateral placement should be used is beyond the scope of this manual and is a matter to be considered by the individual physician. There is overwhelming evidence that right unilateral ECT results in less extensive and severe cognitive side effects than bilateral ECT. There is also considerable evidence that the efficacy of right unilateral ECT is particularly sensitive to the degree to which electrical dosage exceeds seizure threshold. The American Psychiatric Association Task Force on ECT (APA, 1990) recommended that the choice of unilateral and bilateral ECT be made on a case-by-case basis.

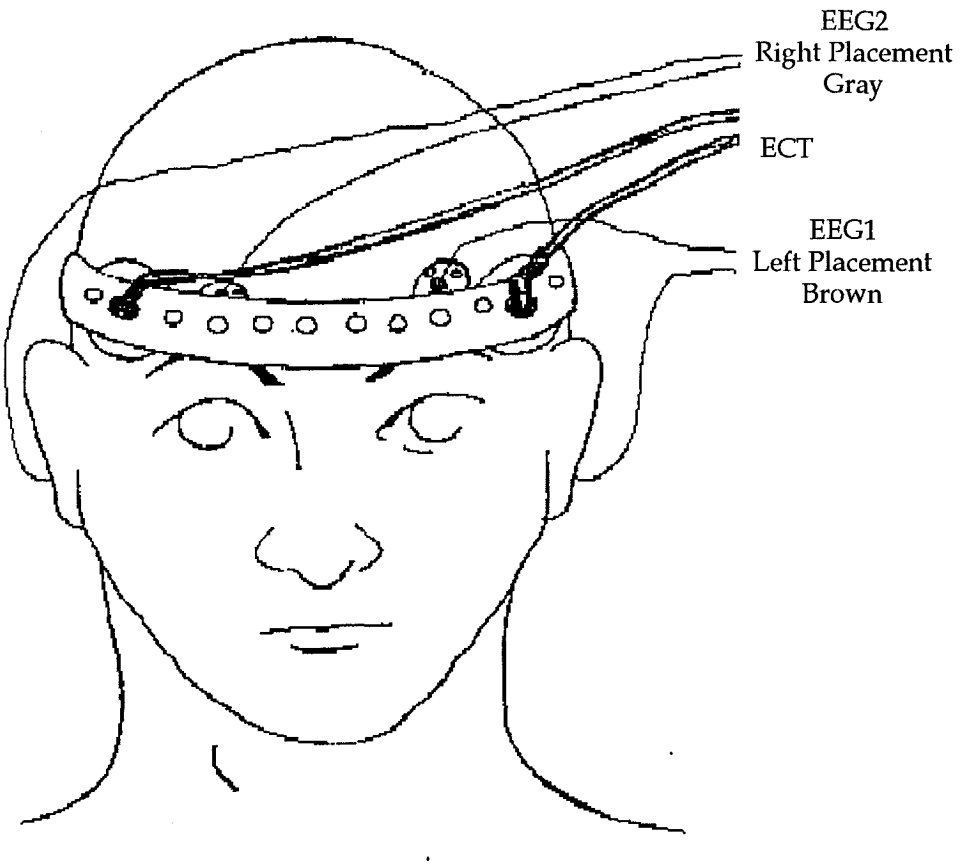


Figure 1

Headband for Bilateral ECT. Electrode placement and two channels of EEG recording. (EEG1 and EEG2)

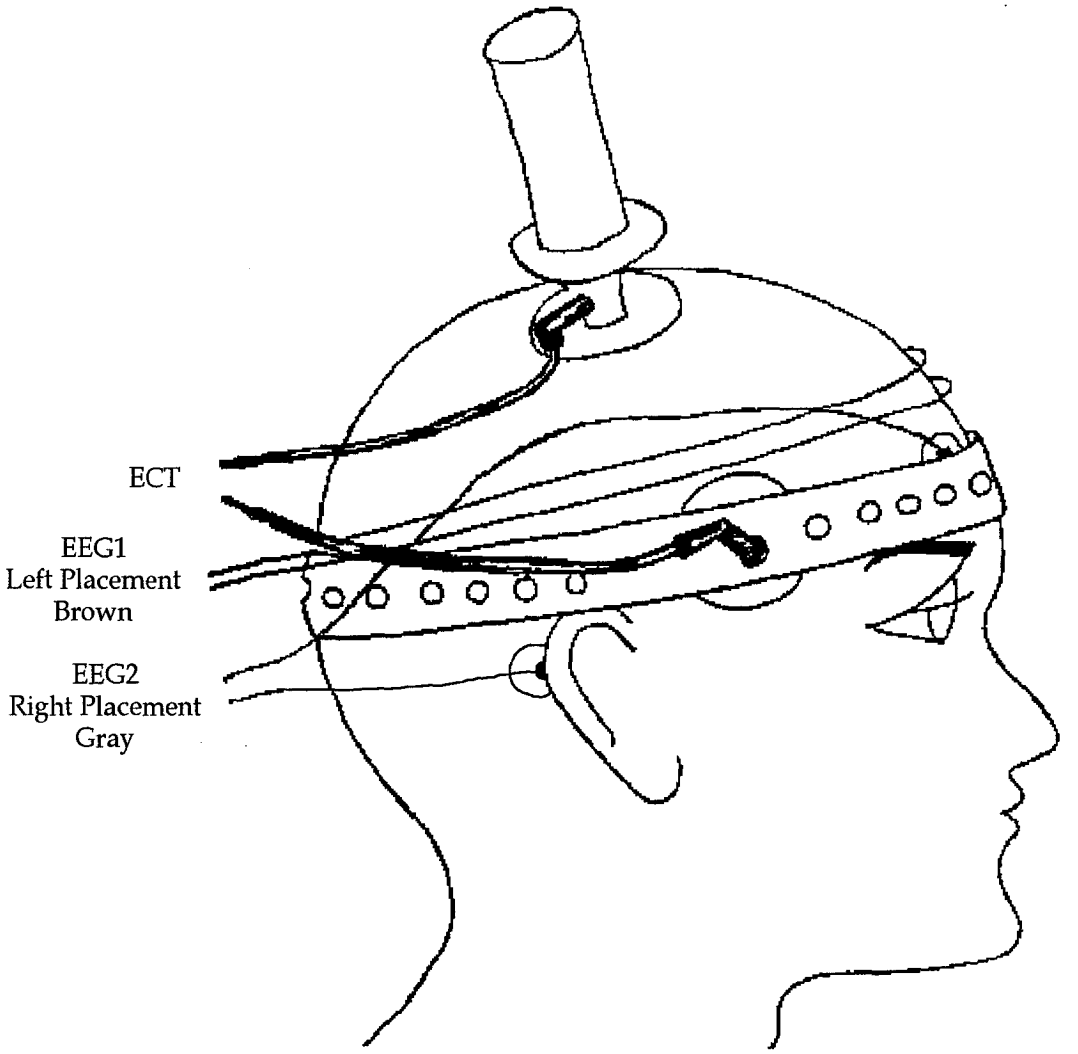


Figure 2

D'Elia unilateral non-dominant placement. The headband hold the frontotemporal ECT electrode. The Hand-Held is placed at the parietal location. The EEG2 (right gray placements) is on the right mastoid and right frontotemporal positions. The EEG1 (left brown placements) is on the left mastoid and left frontopolar position.

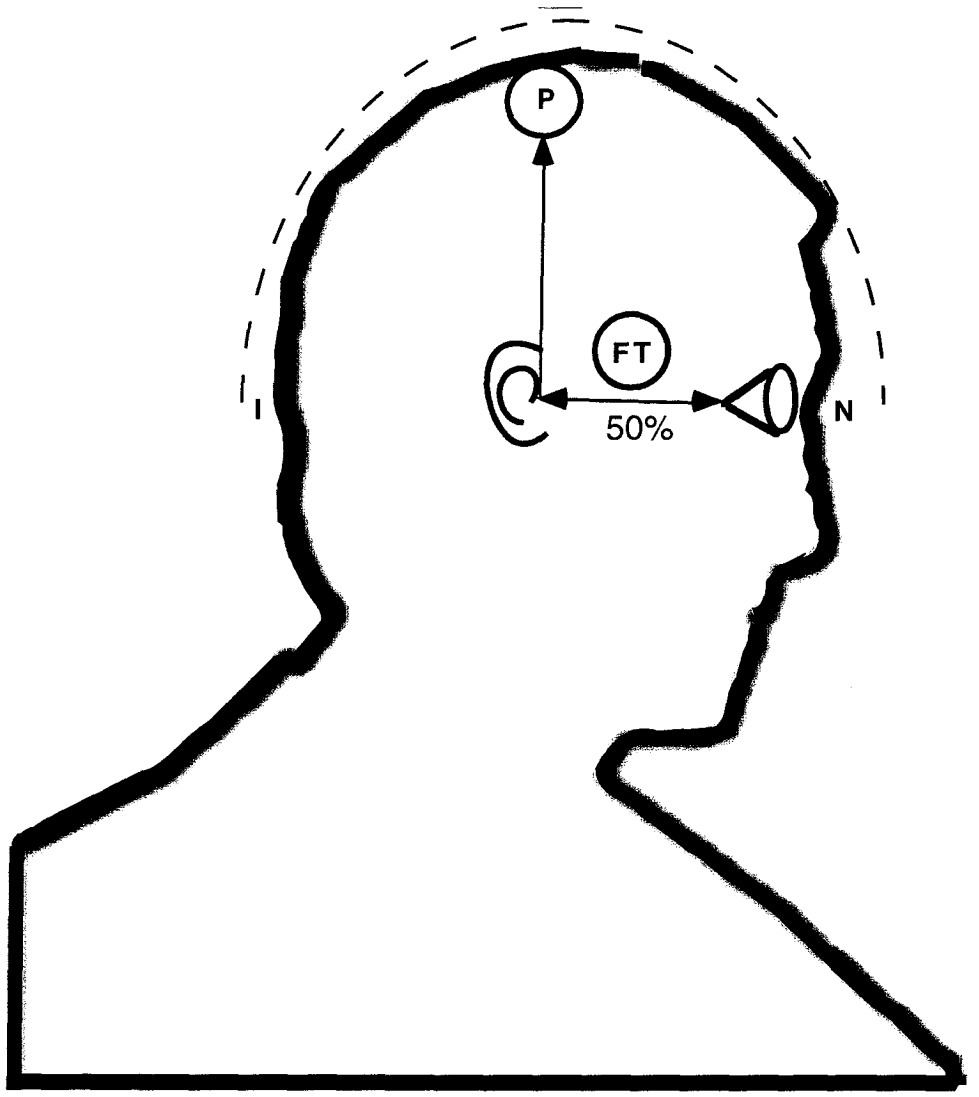


Figure 3

Positioning of electrodes for bilateral and unilateral ECT. The frontotemporal (FT) position is used for bilateral ECT. The electrode is placed just above the midpoint of the line connecting the tragus and the external canthus. For the d'Elia unilateral placement, the inferior electrode is in the FT position. The superior or parietal (P) electrode is placed adjacent to the vertex. This is determined by identifying the intersection of the line connecting the two auditory tragi and the sagital line connecting the inion (I) and nasion (N). For right unilateral ECT, the parietal electrode is just to the right of vertex.

Application of ECT Electrodes

As described above, the first issue in application of ECT is determination of electrode location. After the sites for electrodes are identified, a choice can be made between use of the flat or concave stimulus electrodes. It is preferable to use the electrode which fits the shape of the head best and which has the greatest area of contact to the scalp. In practice, the flat stimulus electrodes are often used for bilateral (frontotemporal) placements and a single concave stimulus electrode is often used for the upper electrode in a unilateral placement.

If the headband is used to secure electrodes to the scalp, the first step would be to place the bilateral electrodes (ECT) in the headband to verify accurate positioning on the patient. The electrode posts are placed through holes on the headband. The band is placed around the head and pulled until very snug. The band is overlapped over the first ECT electrode and the post of this electrode is inserted through a convenient hole. Once accurate positioning is determined, the band may be removed and the scalp and the ECT electrodes are prepared.

Preparation of the scalp for ECT electrodes follows the same principles as for EEG electrodes. The area under the ECT electrodes should first be cleaned with a solvent (alcohol or acetone). Gentle rubbing with a gauze pad soaked in the solvent will be adequate. Cleaning is particularly important in instances in which the patient's scalp is poorly washed following the previous treatment and dried conductive gel still adheres. After cleaning and drying the area, a mild abrasive conductant material is rubbed into the ECT electrode area to reduce impedance (e.g., Redux Paste). Care should be taken to ensure that the area of the abrasive conductant conforms to subsequent electrode placement. Following preparation of the scalp, a conductant gel (e.g., Redux Gel) is placed on the ECT electrodes. The electrodes should be uniformly covered in the gel and a tongue depressor may be useful to create an even spread. Care should be taken not to use too large a quantity of conductant to avoid spreading outside the electrode area when it is placed firmly against the scalp.

Once the scalp and the electrodes are prepared, the headband may be reapplied. After reapplication, correct positioning of the ECT electrodes should be verified. Of particular note, it should be determined at this point that there has been no smearing of conductant between the ECT electrodes. If such smearing occurs between the ECT stimulus electrodes, a short circuit will be created. More current will pass through this direct path between the electrodes and it may be difficult to elicit a seizure.

With the headband properly positioned, the banana plugs at the end of the patient stimulus cable can be inserted into the posts of the ECT stimulus electrode. With this accomplished, the treatment sequence is ready to proceed.

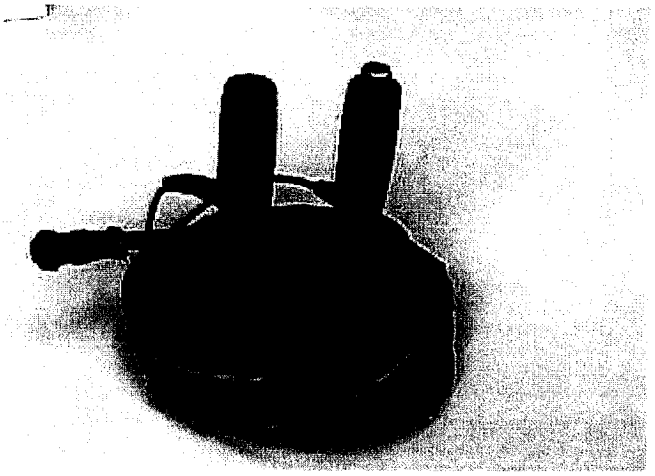
Hand-Held Electrodes

Some practitioners prefer to use hand-held electrodes and do not use the headband. One advantage of the hand-held electrodes is that preparation of the patient may be somewhat simpler. The positions for ECT electrodes are identified and the sites are prepared as described above. Conductant is placed on the stainless steel ECT electrodes and the ECT electrodes are manually held in place. The use of hand-held electrodes avoids the necessity of first determining accurate positioning of electrodes in the headband by applying the band to the patient and then removing it. Another advantage of the use of the hand-held electrodes is that, particularly for bilateral placements, the degree of contact between the scalp and the stimulus electrode may, at times, be greater than with the headband, since the hand-held electrodes can be pressed firmly against the head. It should be noted that with the MECTA SPECTRUM models, hand-held electrodes must be used to deliver unilateral ECT.

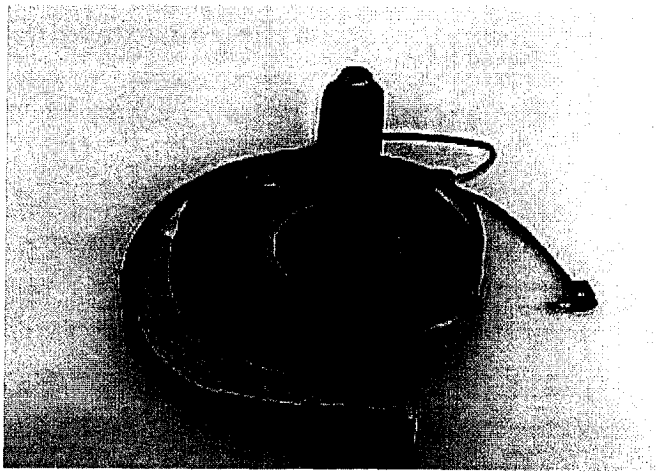
Stability of positioning or slippage may be a concern with the use of hand-held electrodes. This may be a particular problem with unilateral placements, since during the stimulation the patient's head should be projected upward and backward as a result of positive pressure applied under the chin until the stimulus delivery and the constant tone have completed. At the same time, hand-held electrodes pressing down on the right side of the head can create movement in an opposing direction. In this circumstance, one solution is for two individuals, wearing disposable surgical gloves, to coordinate their manipulation of the patient: one holding the head up and back through pressure on the chin and the other holding the two hand-held electrodes against the skull.

A pair of hand-held electrodes may be ordered from MECTA Corporation. Those supplied by MECTA are designed so that they should be used with the remote treatment option. As described below, the self-test and stimulus delivery sequences are triggered by pressing a button on top of one of the hand-held electrodes. This means that the individual who is holding the hand-held electrodes in place can administer the stimulus. An advantage of this technique is that the individual holding the electrodes and observing the patient can abort stimulus delivery at any

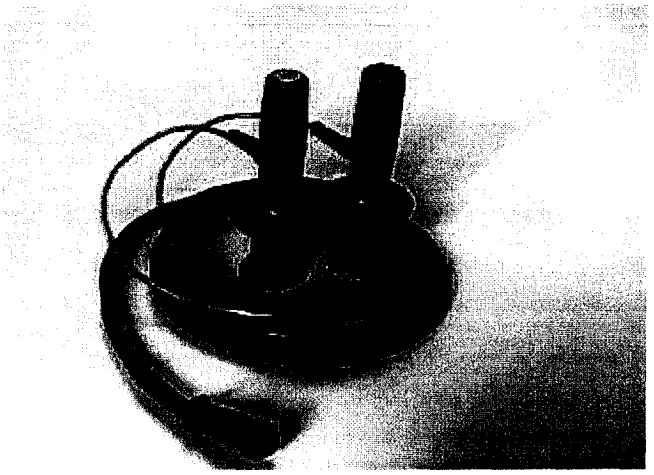
DUAL HAND-HELD WITH REMOTE TREAT SWITCH



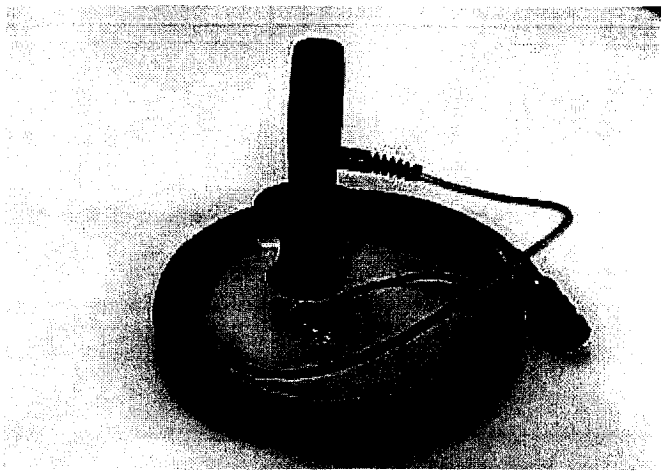
SINGLE HAND-HELD WITH REMOTE TREAT SWITCH



DUAL HAND-HELD W/OUT REMOTE TREAT SWITCH



SINGLE HAND-HELD W/OUT REMOTE TREAT SWITCH



For hand-held electrodes with the remote button, this improved design allows the user to treat with a waterproof push button having two redundant contacts, which ensure safety and detect malfunctions. While the hand-helds are connected to the SPECTRUM, the front panel STIMULUS CONTROL push button is disabled to prevent unexpected stimulation.

For all hand-held electrodes, the added insulator piece between the molded handle and the electrode provides an added safety barrier to prevent the clinician from coming in contact with the electrode gel or paste. It also prevents the electrode from touching any conductive surface that it might be laying on before or after use, thereby ensuring greater patient/clinician electrical safety. The hand-helds have watertight cable strain reliefs that are more electrically and mechanically sound.

STIMULUS DOSING

Conceptual Framework: Choice of Stimulus Parameters

Four electrical parameters can vary when delivering an electrical stimulus with the SPECTRUM 4000 and 5000 Q devices. The operator can select the values for PULSE WIDTH, FREQUENCY, DURATION, and CURRENT. In contrast, on the SPECTRUM 4000 and 5000 M models, the operator sets a single summary parameter, the value for STIMULUS INTENSITY. The setting of the STIMULUS INTENSITY control determines the duration of the pulse train and the frequency of the stimulus. In the SPECTRUM 4000 and 5000 M models, current is fixed at 800 milliamps (.8A) and pulse width is fixed at either 0.3 or 1.0 millisecond, depending on the stimulus parameter set selected during setup.

Through the use of a setup menu system, all SPECTRUM models allow the practitioner to select from among *four* ranges of stimulus parameters. These parameter sets differ in their maximum pulse frequency, pulse width, and train duration. Thus, after choosing a parameter range through the setup menu, the practitioner using a SPECTRUM 4000 or 5000 M model will set the STIMULUS INTENSITY control. The dosage given the patient (charge) will increase linearly as the single dial is altered. For example, a setting of 40% will deliver twice the charge relative to a setting of 20%. In contrast, after choosing a particular parameter set through the setup menu, the practitioner using a SPECTRUM 4000 or 5000 Q device retains control of the specific stimulus configuration by selecting the setting for each of the four major parameters (for PULSE WIDTH, FREQUENCY, DURATION, and CURRENT).

In selecting a stimulus intensity, some facts should be kept in mind. It is now accepted that a stimulus intensity that is barely above the seizure threshold has reduced efficacy, especially when using the right unilateral electrode placement. The initial evidence also suggests that when an ultrabrief stimulus is used, the traditional bilateral (bifrontotemporal) placement has reduced efficacy even when dosage is set at 2.5 times the initial seizure threshold. At a traditional pulse width of 1.0 ms or more, right unilateral ECT has been shown to match the efficacy of bilateral ECT, when dosage is 6.0 times the initial threshold. Similarly, the initial evidence indicates that with an ultrabrief stimulus (i.e., 0.3 ms) right unilateral ECT retains strong efficacy when dosage is 6.0 times initial threshold.

It should also be recognized that excessive electrical stimulation is likely to increase cognitive deficits, without contributing to efficacy. This is of particular concern when using bilateral ECT, given its greater potential for adverse cognitive effects. With a traditional pulse width (1.0 ms or greater), a stimulus that is 2.5 times initial seizure threshold is likely the maximum dose that should be routinely administered. The development of an organic brain syndrome or delirium becomes especially likely when the dosage of bilateral ECT is greater. On the other hand, efficacy was sharply reduced when this dosage level (2.5 times initial seizure threshold) was coupled with an ultrabrief stimulus (0.3 ms). Indeed, when using an ultrabrief stimulus, the dosing range at which bilateral ECT retains efficacy has yet to be identified.

These observations suggest that the goal with unilateral ECT should be to administer a stimulus that is markedly suprathreshold. With a traditional pulse width (1.0 ms and above), this range may be 4-6 times the seizure threshold identified in the first treatment. Thus, the goal with unilateral ECT is to administer stimulation that is at least 4 times the seizure threshold, with an upper limit of 6.0 times the seizure threshold. When unilateral ECT is coupled with an ultrabrief stimulus (e.g., pulse width of 0.3 ms), the initial seizure threshold is usually very low. Recent

evidence suggests that after identifying the seizure threshold, patients treated with ultrabrief right unilateral ECT should receive at subsequent treatment a dose that is approximately 6.0 times the initial threshold.

With bilateral ECT and a traditional pulse width (1.0 ms or greater), the goal should be to administer a dose that is 1.5 to 2.5 times the initial seizure threshold. Even at 2.5 times threshold, adverse cognitive effects can be excessive in some patients, and the electrical dose may have to be lowered. Note, however, that this recommendation pertains only to the use of bilateral ECT with a wide pulse width (1.0 ms and greater). The dosage at which bilateral ECT retains efficacy when using an ultrabrief stimulus has not been determined, but is probably at least 4.0 times the initial threshold.

In adopting these guidelines, the practical issue becomes how one determines for each individual patient the extent to which a particular level of stimulation exceeds the initial seizure threshold. There is marked variability among patients in seizure threshold. Seizure threshold may be influenced by concurrent medications. Further, seizure threshold usually increases markedly during the ECT course.

Some patient characteristics and the treatment parameters are associated with seizure threshold. With the type of stimulation produced by the MECTA spECTrum models (bidirectional rectangular pulses, with constant current), seizure threshold is greater in males than females. This means that when all other factors are kept constant, higher stimulus settings are necessary to produce a seizure in males compared to females. The age of the patient also makes a contribution. In general, older patients, particularly elderly patients, require higher stimulus intensities than younger patients. There is also consistent evidence that higher stimulus intensities are needed to produce a seizure with the standard bilateral placement (frontotemporal) than the right unilateral d'Elia placement. Given this information, one is more likely to require a considerably higher stimulus dose in an elderly male patient receiving bilateral ECT than in a young female patient receiving right unilateral ECT with the d'Elia placement. The factors of gender, age, and electrode placement predict about 30-40% of the variability in seizure threshold. While this power of prediction is impressive from a scientific viewpoint, the majority of the variability is still unexplained, and there are many exceptions that do not follow this pattern. For instance, it is not uncommon to discover that an elderly patient has a remarkably low seizure threshold. Determining stimulus dosage only on the basis of age will require administration of very high stimulus intensities, and likely result in excessive side effects and premature termination of the ECT course.

With the advent of ultrabrief pulse stimulation, another factor must be considered in the choice of stimulus parameters and the prediction of seizure threshold. The ultrabrief stimulus (i.e., usually defined as a pulse width less than 0.5 ms) is considerably more efficient in eliciting seizures than stimuli using a traditional pulse width (e.g., 1.0 ms or more). For example, relative to a 1.5 ms pulse width, the charge (overall intensity) that reliably induces a generalized seizure is 3-4 times less when a 0.3 ms pulse width is substituted. Compared to a 1.0 ms pulse width, use of a 0.3 ms pulse width produces a savings in the required dosage of approximately 2-3 fold. Particularly when treating female patients with right unilateral ECT and using an ultrabrief stimulus, it is not unusual to find that seizure threshold is less than 10 mC (or 1 Joule or less). In addition to its pronounced savings with respect to cognitive side effects, one of the advantages of the ultrabrief pulse width is that the low values for initial seizure threshold ensure that virtually any patient can receive a dosage at subsequent treatment that is markedly suprathreshold (e.g., 6 times threshold) and still be well within the range of maximal device output.

Ultrabrief Stimulation

For the most part, the standard width of the brief pulses used in ECT has been 1 millisecond or greater. However, the optimal pulse width for neuronal depolarization is approximately 0.1-0.3 ms. Therefore, it would seem that the standard ECT stimulus is non-physiologic, resulting in considerable excess stimulation after neurons have fired and are in a refractory and then relative refractory phase. New findings from both animal and clinical research support this view. In a randomized comparison of patients treated with either a traditional 1.5 ms pulse width or an ultrabrief 0.3 ms pulse width, the ultrabrief stimulus required on average 3-4 times less charge to produce a generalized seizure. For instance, with an ultrabrief stimulus, the seizure threshold in some patients can be remarkably low, at times less than 10 mC. This value is more than 50 times less than the maximal output of MECTA devices in the US and 100 times less than the maximal output of MECTA devices elsewhere.

The greater efficiency of the ultrabrief stimulus means that virtually all patients can be treated with right unilateral ECT at a dose markedly above seizure threshold. In other words, with an ultrabrief stimulus the maximal output of the SPECTRUM will be more than sufficient to treat patients at 6 times initial seizure threshold.

Ongoing research at Columbia University has shown that the ultrabrief stimulus (0.3 ms) results in less severe cognitive side effects than use of a traditional pulse width (1.5 ms). For several measures of cognitive change the magnitude of the advantage for the ultrabrief stimulus is as large or larger than the difference between right unilateral and bilateral ECT. In essence, in the postictal period, patients treated with an ultrabrief stimulus recover orientation and other cognitive functions much more rapidly than patients treated with a standard wide pulse width. The extent of amnesia following ECT is markedly reduced with an ultrabrief stimulus. This advantage for ultrabrief stimulation is additive to the effects of electrode placement. In other words, patients treated with right unilateral ECT and an ultrabrief stimulus have the best cognitive outcomes.

The new research from Columbia University also indicates that the efficacy of ultrabrief stimulation is quite sensitive to the extent to which dosage exceeds seizure threshold. When right unilateral ECT is given at 6 times initial seizure threshold using a 0.3 ms pulse width, efficacy is equivalent to what is obtained using a robust form of bilateral ECT (1.5 ms pulse width and 2.5 times seizure threshold). Therefore, ultrabrief right unilateral ECT is highly effective and yet has the lowest cognitive side effect profile of any clinically useful form of ECT. However, bilateral ECT has significantly diminished efficacy when coupled with an ultrabrief stimulus delivered at 2.5 times seizure threshold. This is likely the first time in which the bilateral placement has lost efficacy and right unilateral ECT has a clear efficacious advantage. The diminished efficacy of bilateral ECT under these conditions is likely due to the fact that ultrabrief stimuli recruit a smaller neuronal population in seizure initiation and that, to retain efficacy, stimulus dosage relative to seizure threshold must be higher than the 2.5 x ST used in this work. However, the ultrabrief right unilateral condition was both more effective than the ultrabrief bilateral ECT condition and had a superior cognitive side effect profile. Given these advantages, ultrabrief right unilateral ECT is a clear advance for the field. This treatment appears to preserve the efficacy of traditional ECT while also being an especially benign form of ECT with respect to cognitive side effects.

Choice of Stimulus Parameters: Practical Considerations

In practice, two general approaches have been recommended by the APA Task Force on ECT for determining ECT stimulus intensity. One approach involves empirically determining the thresh-

old value for each patient at the first treatment. This method, termed EMPIRICAL TITRATION, involves administration of subconvulsive intensities in the first treatment, finding the intensity level that produces an adequate seizure in that session, and in subsequent sessions administering an intensity that is a fixed amount above the seizure threshold identified in the first session.

An alternative to the titration method is to use the known predictors of seizure threshold (electrode placement, age, and gender) and preselect a dosage that on a probabilistic basis is likely to be in the appropriate range relative to seizure threshold. This approach should produce seizures in the great proportion of patients at the first treatment. If this intensity is successful at the first treatment, it is used in subsequent sessions unless the cognitive side effects displayed by the patient are unusually severe or the stimulus settings used fail to elicit an adequate seizure in subsequent sessions. In such cases, appropriate adjustments should be made. This approach is termed the PRESELECTED DOSAGE METHOD.

The simplest formula-based or preselected dosage method would have involved setting the single dial of a SPECTRUM M model to the age of the patient, or as some have recommended, to half the patient's age. Similar algorithms could have been devised for the SPECTRUM Q models. However, current research indicates that there is only a weak relationship between patient age and seizure threshold. Furthermore, with the ultrabrief treatment option, the available evidence indicates that age and seizure threshold have no association. Therefore, when determining dosage on the basis of age also there is likely to be substantial error. In the literature, the median correlation between age and initial seizure threshold (using a traditional pulse width) is about 0.35; thus, age accounts for about 10% of the variability in seizure threshold, and the remaining 90% is not predicted. This circumstance means that dosing based on age will intrinsically result in the oldest patients receiving the greatest excess of electrical stimulation. This approach delivers greater excessive dosage to females relative to males, as it does not take into account the gender difference.

More sophisticated formulas have been attempted. In general, none of the formula-based or preselected dosage methods yet devised provide the level of accuracy that is achieved with empirical titration. Accurate determination of dosage is one of the key aspects of ensuring efficacious treatment and minimizing side effects. For this reason, many practitioners rely on empirical titration, and use a preselected dosage method when the medical condition of the patient dictates avoidance of subconvulsive stimulation.

Titration Method

The titration method involves obtaining an estimate of the patient's seizure threshold in the first treatment session. Once this measurement is obtained, subsequent treatments may involve adjusting parameters to exceed the threshold by a desired amount. As indicated, regardless of the pulse width used, right unilateral ECT should generally be delivered at an amount that is 6 times the initial seizure threshold. If acute cognitive side effects become excessive and clinical progress is acceptable, dosing at later treatments may be reduced. However, right unilateral ECT should not be given with a dose that is less than 3-4 times the initial seizure threshold.

The greater propensity for side effects with bilateral ECT necessitates a different dosing range. With a traditional pulse width (1.0 ms or greater), the dosage of bilateral ECT should not exceed 2.5 times the initial seizure threshold. However, bilateral ECT, as delivered with an ultrabrief stimulus, appears to have weak therapeutic effects when dosage is 2.5 times the initial threshold. This suggests that this combination be given with an intensity 4-6 times seizure threshold.

There is controversy in the field as to whether use of the bifrontal electrode placement has advantages over bilateral or right unilateral ECT. Some contend that this method has both supe-

rior cognitive side effects and efficacy. However, the studies suggesting this possibility are problematic and new work could not differentiate bifrontal and bilateral ECT. If the bifrontal placement is used, it would be prudent to follow the dosing procedures recommended for bilateral ECT.

To quantify seizure threshold at the first treatment session, a stimulus should be administered that is likely to result in an adequate seizure in approximately 15-20% of patients. A seizure at this first parameter setting means that the patient's threshold is below the initial value, but the extent to which this is the case is unknown. Following a subconvulsive administration, the stimulus dosage is increased and the new stimulus is administered. By this second level, approximately 65% of patients will have had a generalized seizure. Following the titration tables provided here, approximately 90-95% of patients will have a generalized seizure if a third stimulus administration is needed. Thus, most patients require at most one subconvulsive stimulation, and the great majority have an adequate seizure before or following the third stimulation. However, the range in seizure threshold is great and exceptional patients may have very high thresholds. If the third stimulation does not produce a seizure, a fourth or fifth stimulation should be attempted. The final stimulation is at maximal device dosage.

HOW TO USE TITRATION AND PRE-SELECTED DOSING TABLES

New tables are provided for practitioners who want to base ECT stimulus dosing on empirical identification of the seizure threshold (titration) and have the electrical intensity a fixed amount above the initial threshold. Separate titration tables are given for the spECTrum 4000/5000 Q (4 parameter settings) and 4000/5000 M (1 parameter setting) models. Within each device type, separate tables are provided for devices that have an upper output limit of 100 J (576 mC) or 200 J (1,152 or 1200 mC). The lower limit on maximal stimulation pertains to the commercial devices in the US and Canada, while higher upper limit devices are commercially available in Europe, Asia, and elsewhere. Finally, separate tables are given for ultrabrief (0.3 ms) and standard (1.0 ms) stimulation.

Separate tables have been generated based on these factors to aid the practitioner in identifying the titration schedule most appropriate for the specific device in use (M or Q model) and the upper output range of the device (576, 1,152 or 1,200 mC). Furthermore, all MECTA spECTrum devices are now capable of delivering standard or ultrabrief stimuli. Since ultrabrief stimulation is considerably more efficient than use of a standard pulse width, separate titration tables should be used when patients are treated with a standard pulse width or an ultrabrief pulse width. At any one facility it is likely that only one or two of the 4 titration tables will be applicable.

The left-hand column of each table presents the stimulus settings for titration. Note that up to 8 steps are provided in the tables for devices with 200 J (1,200 mC) maximal output and 7 steps for the 100 J (576 mC) devices. Until the upper limit of 576 mC, dosing parameters are nearly identical across all the tables (except the 200 J Brit table) for the two 100 J and 200 J devices. Divergence only occurs after this limit and allows the possibility of stimulating with a charge between 576, 1,152 or 1,200 mC, with the higher output devices.

The columns to the right of the titration schedule are used to guide stimulus dosing after initial seizure threshold has been identified at the first treatment. For a given threshold value the 4 columns to the right provide dosing parameters for a stimulus that would be either 50% (1.5 x ST), 100% (2 x ST), 150% (2.5 x ST), or 500% (6 x ST) above initial seizure threshold (ST). Thus, if one wants to treat at 2.5 x ST, the stimulus level that produced an adequate seizure in the first

session is noted (e.g., Stimulus 3) and one moves to the fourth column (150% above or 2.5 x ST) to identify the stimulus parameters used in subsequent treatments.

In this way, stimulus dosing can be greatly simplified. The practitioner identifies the ST value in the first treatment and then, based on this value, selects a subsequent suprathreshold dosing level.

In reading the tables, you should note that the charge that will be delivered with each stimulus is provided as well as the exact percentage increment above initial ST for the subsequent dosing values. For spECTrum Q models, all dosing values assume that a 800 mA current setting is used. If the practitioner wishes to use a lower setting for current, the same titration and dosing schedule can be used to set the other stimulus parameters, but the values presented in the tables for the overall stimulus intensity (charge) would need correction.

A general principle is reflected in the design of these titration and dosing tables. The increases in dosing at each step of titration or in subsequent treatments is reflected preferentially in an increase in the duration of the stimulus train. The increases in dose at subsequent treatments also preferentially weights duration over pulse frequency (pulse width is set at 0.3 or 1.0 ms and current is fixed at 800 mA). This approach was taken since the available evidence suggests that incrementing train duration may be slightly more efficient in seizure elicitation than incrementing pulse frequency. Thus, the titration tables are designed to use the most efficient stimulus parameter sets available for seizure induction. The extent to which each set of parameters exceeds initial seizure threshold is provided for each parameter setting used for subsequent dosing.

For each of the tables it is suggested that the first stimulus level in titration be reserved for female patients receiving right unilateral ECT. All other patients start at the second level. Presume that you plan to treat a male patient with ultrabrief stimulation and right unilateral ECT. You have a 4-knob, 5000Q device with 100 J maximal output (576 mC). You would use the titration table for ultrabrief stimulation with a 4000/5000 Q and 100 J maximal output. Determining which titration table to use is simple: you need to know what device type you are using (1 dial: M; 4 dial Q; 100 vs 200 J) and whether you will use an ultrabrief stimulus or a standard pulse width.

This treatment strategy indicates that you will be using Table 1-the 100 Joule Titration Table - spECTrum Q - Ultrabrief. You begin titration at the first treatment at Stimulus Level 2 (pulse frequency: 20 Hz, pulse width: 0.3 ms, train duration: 2.0 s, current: 800 mA, and total charge: 19.2 mC). Following the procedures described for the titration procedure, you determine that this stimulus configuration resulted in subconvulsive stimulation (no seizure activity noted in the EEG or in motor manifestations). You ensure that there is an interval of at least 20 s between the stimulus administrations and you restimulate using the settings for Stimulus Level 3 (pulse frequency: 20 Hz, pulse width: 0.3 ms, train duration: 4.0 s, current: 800 mA, and total charge: 38.4 mC). An adequate seizure is observed following this stimulation. In subsequent treatments you plan on delivering a dose that will be approximately 6 times this initial seizure threshold. You move to the level 3 configuration for stimuli 500% above or 6 times initial seizure threshold. This is the third row of the column on the extreme right of the table. There you note that the recommended stimulus involves an increment in pulse frequency from 20 to 80 Hz (a 4-fold change) and an increase in train duration from 4.0 to 6.0 s (a one and one half-fold increase). This produces a total charge of 230.4 mC, which is exactly 6 times the threshold value of 38.4 mC.

TABLE 1

100 JOULE TITRATION TABLE - SPECTRUM Q - ULTRABRIEF (0.3 ms Pulsewidth)

	50% above or 1.5 x ST			100% above or 2 x ST			150% above or 2.5 x ST			500% above or 6 x ST		
	Q			Q			Q			Q		
Stimulus 1	Charge			Charge	%Inc		Charge	%Inc		Charge	%Inc	
Freq 20 Hz		30 Hz			40 Hz			40 Hz			40 Hz	
PW 0.3 ms		0.3 ms			0.3 ms			0.3 ms			0.3 ms	
Dur 1.0 s	9.6 mC	1.0 s	14.4 mC	50%	1.0 s	19.2 mC	100%	1.25 s	24.0 mC	150%	3.0 s	57.6 mC	500%
Stimulus 2	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc		Charge	%Inc
Freq 20 Hz		30 Hz			40 Hz			40 Hz			50 Hz		
PW 0.3 ms		0.3 ms			0.3 ms			0.3 ms			0.3 ms		
Dur 2.0 s	19.2 mC	2.0 s	28.8 mC	50%	2.0 s	38.4 mC	100%	2.5 s	48.0 mC	150%	5.0 s	120.0 mC	500%
Stimulus 3	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc		Charge	%Inc
Freq 20 Hz		30 Hz			40 Hz			40 Hz			80 Hz		
PW 0.3 ms		0.3 ms			0.3 ms			0.3 ms			0.3 ms		
Dur 4.0 s	38.4 mC	4.0 s	57.6 mC	50%	4.0 s	76.8 mC	100%	5.0 s	96.0 mC	150%	6.0 s	230.4 mC	500%
Stimulus 4	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc		Charge	%Inc
Freq 20 Hz		30 Hz			40 Hz			50 Hz			120 Hz		
PW 0.3 ms		0.3 ms			0.3 ms			0.3 ms			0.3 ms		
Dur 8.0 s	76.8 mC	8.0 s	115.2 mC	50%	8.0 s	153.6 mC	100%	8.0 s	192.0 mC	150%	8.0 s	460.8 mC	500%
Stimulus 5	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc		Charge	%Inc
Freq 40 Hz		60 Hz			80 Hz			100 Hz			120 Hz		
PW 0.3 ms		0.3 ms			0.3 ms			0.3 ms			0.37 ms		
Dur 8.0 s	153.6 mC	8.0 s	230.4 mC	50%	8.0 s	307.2 mC	100%	8.0 s	384.0 mC	150%	8.0 s	568.3 mC	500%
Stimulus 6	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc			
Freq 80 Hz		120 Hz			120 Hz			120 Hz					
PW 0.3 ms		0.3 ms			0.37 ms			0.37 ms					
Dur 8.0 s	307.2 mC	8.0 s	460.8 mC	50%	8.0 s	568.3 mC	100%	8.0 s	568.3 mC	150%			
Stimulus 7	Charge		Charge	%Inc									
Freq 120 Hz		120 Hz											
PW 0.37 ms		0.37 ms											
Dur 8.0 s	568.3 mC	8.0 s	568.3 mC	50%									

STIMULUS PARAMETERS ASSUME 800 mA AND ARE FREQUENCY(Hz), PULSE WIDTH (ms) AND TRAIN DURATION (s)

New York State Psychiatric Institute - Columbia University

TABLE 2

100 JOULE TITRATION TABLE - SPECTRUM Q - 0.5 ms Pulsewidth

Titration Parameters

Stimulus 1*		Charge
Freq	20 Hz	
PW	0.5 ms	
Dur	1.00 s	16 mC
Stimulus 2		Charge
Freq	20 Hz	
PW	0.5 ms	
Dur	2.00 s	32 mC
Stimulus 3		Charge
Freq	20 Hz	
PW	0.5 ms	
Dur	4.00 s	64 mC
Stimulus 4		Charge
Freq	40 Hz	
PW	0.5 ms	
Dur	4.00 s	128 mC
Stimulus 5		Charge
Freq	50 Hz	
PW	0.5 ms	
Dur	6.00 s	240 mC
Stimulus 6		Charge
Freq	60 Hz	
PW	0.9 ms	
Dur	6.00 s	518 mC

150% above ST (2.5 x ST) (BL ECT)		
	Charge	% above ST
40 Hz		
0.5 ms		
1.25 s	40.0 mC	150%
	Charge	%Inc
40 Hz		
0.5 ms		
2.50 s	80.0 mC	150%
	Charge	%Inc
40 Hz		
0.5 ms		
5.00 s	160.0 mC	150%
	Charge	%Inc
60 Hz		
0.6 ms		
6.00 s	346.0 mC	170%
	Charge	%Inc
600 Hz		
1.0 ms		
6.00 s	576.0 mC	140%

500% above ST (6 x ST) (RUL ECT)		
	Charge	% above ST
40 Hz		
0.5 ms		
3.00 s	96 mC	500%
	Charge	%Inc
50 Hz		
0.5 ms		
5.00 s	200.0 mC	525%
	Charge	%Inc
60 Hz		
0.7 ms		
6.00 s	403.0 mC	530%
	Charge	%Inc
60 Hz		
1.0 ms		
6.00 s	576.0 mC	350%

All stimulation given with current fixed at 800 mA and the parameter set with 6.0 second maximum duration.

*RUL ECT starts with Stimulus 1; BL ECT starts with Stimulus 2.

BL ECT at 2.5 X ST with a 0.5 ms PW may be less effective than high dose RUL (6 X ST) and a PW of 0.5 ms. New York State Psychiatric Institute - Columbia University

TABLE 3

100 JOULE TITRATION TABLE - SPECTRUM Q - 1.0 ms Pulsewidth

	Q	50% above or 1.5 x ST		Q	100% above or 2 x ST		Q	150% above or 2.5 x ST		Q	500% above or 6 x ST		Q
Stimulus 1	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc		Charge	%Inc
Freq 20 Hz		30 Hz			40 Hz			50 Hz			30 Hz		
PW 1.0 ms		1.0 ms			1.0 ms			1.0 ms			1.0 ms		
Dur 0.75 s	24.0 mC	0.75 s	36.0 mC	50%	0.75 s	48.0 mC	100%	0.75 s	60.0 mC	150%	3.0 s	144.0 mC	500%
Stimulus 2	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc		Charge	%Inc
Freq 20 Hz		30 Hz			40 Hz			50 Hz			40 Hz		
PW 1.0 ms		1.0 ms			1.0 ms			1.0 ms			1.0 ms		
Dur 1.5 s	48.0 mC	1.5 s	72.0 mC	50%	1.5 s	96.0 mC	100%	1.5 s	120.0 mC	150%	4.5 s	288.0 mC	500%
Stimulus 3	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc		Charge	%Inc
Freq 20 Hz		30 Hz			40 Hz			50 Hz			60 Hz		
PW 1.0 ms		1.0 ms			1.0 ms			1.0 ms			1.0 ms		
Dur 3.0 s	96.0 mC	3.0 s	144.0 mC	50%	3.0 s	192.0 mC	100%	3.0 s	240.0 mC	150%	6.0 s	576.0 mC	500%
Stimulus 4	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc			
Freq 20 Hz		30 Hz			40 Hz			50 Hz					
PW 1.0 ms		1.0 ms			1.0 ms			1.0 ms					
Dur 6.0 s	192.0 mC	6.0 s	288.0 mC	50%	6.0 s	384.0 mC	100%	6.0 s	480.0 mC	150%			
Stimulus 5	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc			
Freq 40 Hz		60 Hz			60 Hz			60 Hz					
PW 1.0 ms		1.0 ms			1.0 ms			1.0 ms					
Dur 6.0 s	384.0 mC	6.0 s	576.0 mC	50%	6.0 s	576.0 mC	100%	6.0 s	576.0 mC	150%			
Stimulus 6	Charge												
Freq 60 Hz													
PW 1.0 ms													
Dur 6.0 s	576.0 mC												

STIMULUS PARAMETERS ASSUME 800 mA AND ARE FREQUENCY(Hz), PULSE WIDTH (ms) AND TRAIN DURATION (s)
New York State Psychiatric Institute - Columbia University

TABLE 4

100 JOULE TITRATION TABLE - SPECTRUM M - ULTRABRIEF (0.3 ms Pulsewidth)

		50% above or 1.5 x ST			100% above or 2 x ST			150% above or 2.5 x ST			500% above or 6 x ST		
	M			M			M			M			M
Stimulus 1	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc		Charge	%Inc
2%	12 mC	3%	17 mC	50%	4%	23 mC	100%	5%	29 mC	150%	12%	69 mC	500%
Stimulus 2	Charge												
4%	23 mC	6%	35 mC	50%	8%	46 mC	100%	10%	58 mC	150%	24%	138 mC	500%
Stimulus 3	Charge												
8%	46 mC	12%	69 mC	50%	16%	92 mC	100%	20%	115 mC	150%	48%	276 mC	500%
Stimulus 4	Charge												
16%	92 mC	24%	138 mC	50%	32%	184 mC	100%	40%	230 mC	150%	96%	553 mC	500%
Stimulus 5	Charge												
32%	184 mC	48%	276 mC	50%	64%	369 mC	100%	80%	461 mC	150%	100%	576 mC	500%
Stimulus 6	Charge												
64%	369 mC	96%	553 mC	50%	100%	576 mC	100%	100%	576 mC	150%			
Stimulus 7	Charge												
100%	576 mC	100%	576 mC	50%									

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TABLE 5

100 JOULE TITRATION TABLE - SPECTRUM M - 1 ms Pulsewidth

	M	50% above or 1.5 x ST		M	100% above or 2 x ST		M	150% above or 2.5 x ST		M	500% above or 6 x ST		M
Stimulus 1	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc		Charge	%Inc
4%	22 mC	6%	34 mC	50%	8%	46 mC	100%	10%	58 mC	150%	24%	138 mC	500%
Stimulus 2	Charge												
8%	46 mC	12%	69 mC	50%	16%	92 mC	100%	20%	115 mC	150%	48%	277 mC	500%
Stimulus 3	Charge												
16%	92 mC	24%	138 mC	50%	32%	184 mC	100%	40%	230 mC	150%	96%	553 mC	500%
Stimulus 4	Charge												
32%	184 mC	48%	277 mC	50%	64%	369 mC	100%	80%	460 mC	150%	100%	576 mC	500%
Stimulus 5	Charge												
64%	369 mC	96%	552 mC	50%	100%	576 mC	100%	100%	576 mC	150%			
Stimulus 6	Charge												
100%	576 mC	100%	576 mC	50%									

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USING THE PRE-SELECTED DOSAGE TABLE

Under some circumstances the practitioner may prefer to give a preselected, suprathreshold dose at the first and all treatments, but at the same time take into account some of the factors that impact on seizure threshold. Since the vast majority of patients will have adequate seizures before or following their third stimulation following the titration procedures described above, the third level of stimulation might be assumed at the initial ST for female patients treated with right unilateral ECT and the fourth level for all other patients. For these two groups the table below presents the stimulus parameters that might be used at each treatment.

PRE-SELECTED DOSAGE TABLES

Standard Pulse Width (1.0 ms) and 100 Joule or 200 J 4000/5000 M

Patient Group	50% or 1.5 x ST	100% or 2 x ST	150% or 2.5 x ST	500% or 6 x ST
Female, Unilateral ECT				553 mC
Male Unilateral				576/1106 mC
Female Bilateral	138 mC	184 mC	230 mC	-
Male Bilateral	277 mC	369 mC	460 mC	-

Standard Pulse Width (1.0 ms) and 100 Joule or 200 J 4000/5000 Q *

Patient Group	50% or 1.5 x ST	100% or 2 x ST	150% or 2.5 x ST	500% or 6 x ST
Female, Unilateral ECT	30 Hz, 1 ms, 3 s 144 mC	40 Hz, 1 ms, 3 s 192 mC	50 Hz, 1 ms, 3 s 240 mC	60 Hz, 1 ms, 6 s 576/1152 mC
Male Unilateral	30 Hz, 1 ms, 6 s 288 mC	40 Hz, 1 ms, 6 s 384 mC	50 Hz, 1 ms, 6 s 480 mC	60/120 Hz, 1 ms, 6 s 576/1152 mC
Female Bilateral	30 Hz, 1 ms, 3 s 144 mC	40 Hz, 1 ms, 3 s 192 mC	50 Hz, 1 ms, 3 s 240 mC	-
Male Bilateral	30 Hz, 1 ms, 6 s 288 mC	40 Hz, 1 ms, 6 s 384 mC	50 Hz, 1 ms, 6 s 480 mC	-

* current fixed at 800 mA

Ultrabrief Pulse Width (0.3 ms) and 100 Joule or 200 J 4000/5000 M

Patient Group	50% or 1.5 x ST	100% or 2 x ST	150% or 2.5 x ST	500% or 6 x ST
Female, Unilateral ECT				276 mC
All others				553 mC

Ultrabrief Pulse Width and 100 Joule or 200 J 4000/5000 Q *

Patient Group	50% or 1.5 x ST	100% or 2 x ST	150% or 2.5 x ST	500% or 6 x ST
Female, Unilateral ECT				80 Hz, 0.3 ms, 6 s 230.4 mC
All others				120 Hz, 0.3 ms, 8 s 460.8 mC

* current fixed at 800 mA

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You should note that some cells of the pre-selected dosage table are blank. This follows from the findings that the efficacy of right unilateral ECT appears to be maximal when stimulus intensity is 6 times greater than initial seizure threshold. On the other hand, for most patients the maximal intensity for bilateral ECT should not be more than 2.5 times the initial threshold. Finally, the evidence to date also suggests that regardless of electrode placement, ultrabrief stimulation requires a substantial dose above initial seizure threshold.

(It is important to note that the treatment methods and stimulus parameter settings presented here are only suggestions. The likelihood of eliciting an adequate seizure at particular parameter settings is not just a function of sex, age, and electrode placement. Degree of oxygenation, dosage and type of anesthetics, concomitant psychotropic medication, quality of electrodes, site preparation, and a variety of other factors influence seizure threshold. Therefore, it is strongly recommended that each clinician note within their own setting the range of stimulus parameters that effectively result in generalized seizures. Further, the suggested settings in the Titration tables and Pre-selected Dosage table are likely to be overestimates of the stimulus intensity necessary to produce adequate seizures.)

SAFETY FEATURES

As noted, the ECT module includes numerous safety features. The continuous Self-Test feature, which is continuously updated on the Patient Impedance display, provides important information on the adequacy of the electrode connections with both the stimulus cable and the underlying scalp tissue. Under situations in which inadequate electrode connections develop during ECT stimulus delivery, the spECTrum may automatically terminate the stimulus delivery without any user intervention. The spECTrum automatically terminates delivery when the delivered voltage would be outside of the range of 50-400 Volts. The latter usually occurs due to poor electrode connections: too much gel shorting the electrodes, or a very poor connection resulting in high impedance and therefore high voltage. Appropriate error messages will appear in each of these situations, and the TREATMENT RESULTS DISPLAY will show the actual stimulus delivery parameters, not simply what was preselected.

The spECTrum measures each of the stimulus parameters during the delivery. If any parameter exceeds specification tolerances, the treatment also terminates. After each treatment session, when touching the DONE or EXIT button on the Touch Screen or Membrane Switch or the OFF button on the CHART RECORDER, an extensive set of internal diagnostics verifies that all of the safety monitoring features continue to be fully operational. Other diagnostics continuously verify proper operation of internal processors and related components. Finally, a number of redundant hardware monitors insure that stimulus delivery will remain within safe limits even if the processors fail. The spECTrum represents the state of the art in safety.

Sensor Module

Sensor Module

MONITORING CHANNELS

Features and Options

The Sensor module is part of the spECTrum 5000 models. This module provides a range of options for acquiring, displaying, analyzing, storing, and printing physiological data. There are a variety of options for configuring the Sensor module. Basic models come with two channels of monitoring and printing, either 2 EEG channels or 1 EEG and 1 ECG channel, and external access to these channels via an ANALOG OUTPUT port. However, additional features can be added at the time of purchase, or as factory upgrades at a later date. These options include:

- 1 additional channel of monitoring to make a total of 2 EEG and 1 ECG, or
- 3 additional channels of monitoring to make a total of 4 EEG and 1 ECG;
- an Optical Motion Sensor (OMS) to indicate motor activity during a seizure;
- EEG Data Analysis to provide an estimate of seizure adequacy and (for unilateral ECT) an estimate of stimulus intensity relative to stimulus threshold;
- A REMOTE MONITOR OPTION (PC and software) that enables remote display (PC) and data logging and software on disk of all patient, treatment, and physiological information.

Via easy-to-use menus, the spECTrum may be configured to simultaneously display up to four channels of monitoring on the built-in LCD/Touch Screen, and one or two channels on the CHART RECORDER. Traces disappear on both the LCD and the CHART RECORDER if selected channels are not connected to the patient, for instance when a recording electrode becomes detached (leads off condition). With the REMOTE MONITOR OPTION (PC and software) all available channels of physiology (up to 6) may be displayed, simultaneous with all the treatment information that appears on the LCD/Touch Screen.

EEG

All 5000 models include at least one channel of EEG monitoring. A patient's electroencephalogram (EEG) is monitored to give visual indication of the nature and duration of seizure activity. The LCD/Touch Screen and CHART RECORDER display this activity and the CHART RECORDER provides a permanent record. If the EEG DATA ANALYSIS option has been purchased, the spECTrum may be configured to automatically analyze the EEG signal(s) and estimate seizure adequacy, and (for unilateral ECT) to estimate stimulus dosage level relative to stimulus threshold. These optional analyses will be printed with other TREATMENT RESULTS on the CHART RECORDER and may be viewed by selecting the EEG DATA display option from the TREATMENT RESULTS DISPLAY on the LCD/Touch Screen. See the EEG DATA option description elsewhere in this section.

Most clinicians will choose to record one or two channels of EEG information with the spECTrum 5000 models. However, for practitioners who wish extra redundancy or have specific research interests in this area, up to four channels may be recorded. MECTA recommends the following EEG lead placements in each case. (Note that two recording electrodes are required for each channel of recording).

# Channels	Channel #	Electrode Placement	Comment
1	1	L. frontopolar to L mastoid	Center of frontopolar electrode 1 cm above mid-point of eyebrow
2	1	L. frontopolar to L mastoid	Center of frontopolar electrodes 1 cm above mid-point of eyebrows
	2	R. frontopolar to R mastoid	
4	1	L frontopolar (1cm rostral to Fp1) to L mastoid	Measured according to International 10-20 System, using MECTA disposable EEG electrodes. EEG electrode paste can be used over areas of hair, or gold EEG cup electrodes may be used).
	2	R frontopolar (1cm rostral to Fp1) to R mastoid	
	3	Fz (midline frontal) to R mastoid	
	4	T3 (mid-temporal) to L mastoid	

Just as with the stimulus electrodes, it is important to achieve adequate electrical coupling between the EEG recording electrodes and the scalp, particularly since the EEG signal is extremely low in amplitude. Failure to do so will result in unnecessarily high levels of signal artifact and will severely impair the practitioner's ability to interpret the resulting ictal EEG activity. The technique for achieving a low impedance scalp contact involves cleaning and mildly abrading the underlying scalp areas prior to placement of the EEG recording electrodes. This can be accomplished in a similar fashion to what has been earlier described for preparation of the scalp for the stimulus electrodes, except that spray solutions should not be used, due to the small surface area involved.

The patient's electroencephalogram (EEG) is recorded to provide visual evidence that a generalized seizure has been induced, to determine that the seizure has ended, and to provide visual evidence regarding the characteristics of the seizure, such as the presence of postictal bioelectric suppression. If the EEG DATA ANALYSIS option has been purchased, a SPECTRUM 5000 model may be configured to report analyses of the EEG signal(s). These analyses estimate the adequacy of the induced seizure and (for unilateral ECT only) the stimulus level relative to seizure threshold.

It has become standard practice in ECT to use disposable EEG electrodes. The disposable EEG electrodes provided by MECTA are included in the starter kit. Use only MECTA provided disposable electrodes. Note the replacement date on the electrodes. If the electrodes are expired, they may be dried-out and should be replaced with new electrodes. After the treatment, the electrodes should be carefully removed and disposed. Disposable EEG electrodes should not be re-used.

Recording two channels of EEG is preferable to recording only one channel. The redundancy of two channels provides back-up in cases where one channel fails due to loss of an electrode, excessive artifact, or other causes. In addition, in the case of unilateral ECT, the availability of two channels allows for visual determination of asymmetry in the expression or termination of seizures. The EEG Data Analysis option may take advantage of this additional information.

If only one channel is recorded and unilateral ECT is administered, the convention in ECT is to record activity from the hemisphere contralateral to the ECT stimulating electrodes. Specifically, when right unilateral ECT is administered, single channel EEG recordings would be taken from the left hemisphere. A single channel EEG measures the difference in the electrical potential between two electrode sites. With unilateral ECT electrode placement, it is preferable that both sites be over the portion of the brain that is contralateral to the ECT stimulation to ensure that there has been seizure generalization.

Bipolar recording from frontopolar and mastoid sites is the preferred method for ECT. If hand-held ECT electrodes are used, the frontopolar site should be approximately 1 cm above the midpoint of the eyebrow. If a headband is used for ECT electrodes, the frontopolar site can be located at the midpoint of the eyebrow and above the headband. The mastoid site should be high on the bony process behind the ear, ipsilateral to the frontopolar site. This frontopolar-mastoid montage provides higher quality recordings than frontopolar-frontopolar montages that have been used with ECT in the past. Since seizure activity is usually pronounced in prefrontal regions, synchronous changes at two prefrontal sites tend to cancel out. In contrast, the potential differences between a prefrontal and mastoid site tend to be pronounced. The upper portion of the mastoid is preferred to minimize ECG contamination of the EEG.

As indicated on the adjoining table, if two channels of EEG are used, the preferred sites involve both left and right frontopolar-mastoid montages. For practitioners who wish to record additional channels, spECTrum 5000 models can be configured to acquire up to 4 channels of EEG. Recommended recording sites for these additional channels are described on Page 47.

Preparation of the EEG sites is fundamental to obtaining clinically useful recordings. If impedance at the EEG site is excessive, EEG recordings will be characterized by artifact and poor quality. This may interfere with the capacity to determine that a seizure has been induced or that it has terminated. On the other hand, simple steps in EEG site preparation help insure high quality recordings. First, the site for each EEG electrode should be cleansed with alcohol (or acetone) and dried. Second, the EEG site should be mildly abraded. This is best accomplished by placing an abrasive agent (e.g., Redux paste) on a cotton swab and rubbing vigorously at the site. The area that is rubbed should be limited to the circumference of the active portion of the disposable EEG electrode. Abrading a wider area may result in poor adhesion of the disposable electrode to the skin. After the mild abrasion, the disposable electrodes are attached to the sites. Remove the electrode from the sealed package by tearing off the end marked "tear here". Carefully peel the electrode from the backing material and place firmly on the selected site, with the conductive center of the electrode directly over the abraded area.

With a MECTA spECTrum 5000 model, EEG channels may be displayed on the LCD/Touch Screen and/or the Chart Recorder, depending on the menu options selected. After placement of the EEG electrodes it is wise to check the integrity of recordings prior to delivery of the stimulus.

This may be done by inspection of the LCD/Touch Screen display or the Chart Recorder, depending on the display options selected. Pressing the ON button on the Chart Recorder will initiate a printout. The selected physiological monitoring channels are automatically displayed on the LCD/Touch Screen. High frequency, low voltage activity should be discernible. If amplitude is too low, the gains of the EEG channels on the LCD/Touch Screen display or the Chart Recorder should be increased. If amplitude is too great, the gains should be reduced.

EEG PLACEMENTS FOR FOUR CHANNEL

If four-channel EEG recording is used, it is preferable to locate the electrode sites according to the International 10-20 System of EEG recording, which is the standard system used by most EEG laboratories in the USA. An example of the approximate location of the eight recording electrode sites (two for each channel) is shown in Figures XX and XX. Actual measurement of EEG recording electrode site locations in the 10-20 system is detailed in both of the following references:

Jasper, H.H. "The ten-twenty electrode system of the International Federation. *Electroencephalography and Clinical Neurophysiology,* 10:371-375, 1958.

Tyner, F.S., Knott, J.R., Mayer, W.B. Jr., *Fundamentals of EEG Technology. Vol. I: Basic Concepts and Methods.* New York: Raven Press, 1983, pp. 136-145.

The following steps demonstrate how the EEG recording sites should be determined for four-channel recording (requires a suitably configured MECTA spECTrum 5000Q or 4000Q device). To make these determinations, the practitioner should use the measuring tape and colored grease pencil used to select the vertex location for the centroparietal stimulus electrode site with unilateral ECT.

1. Measure the distance from the inion to the nasion (as described in an earlier section for determining the unilateral stimulus electrode site.

2. Make short horizontal marks at the following proportions of the overall inion-to-nasion (sagittal) distance, measuring from the nasion: 10% plus 1cm, 30%, 50%, 90%.

3. Measure the transverse cranial distance between the left and right pre-auricular notch, measuring over the 50% mark from Step 2 (as described in an earlier section for determining the unilateral stimulus electrode site).

4. Make short horizontal marks at 10% and 90% of the transverse distance from ear-to-ear, measuring from the left pre-auricular notch.

5. Measure the circumference around the head, placing the tape over the 10% and 90% marks from both steps 2 and 4.

6. Make a short vertical mark across the horizontal left midtemporal mark from Step 4, midway between the inion and nasion; the location of the intersection between these horizontal and vertical marks represents the T3 electrode site.

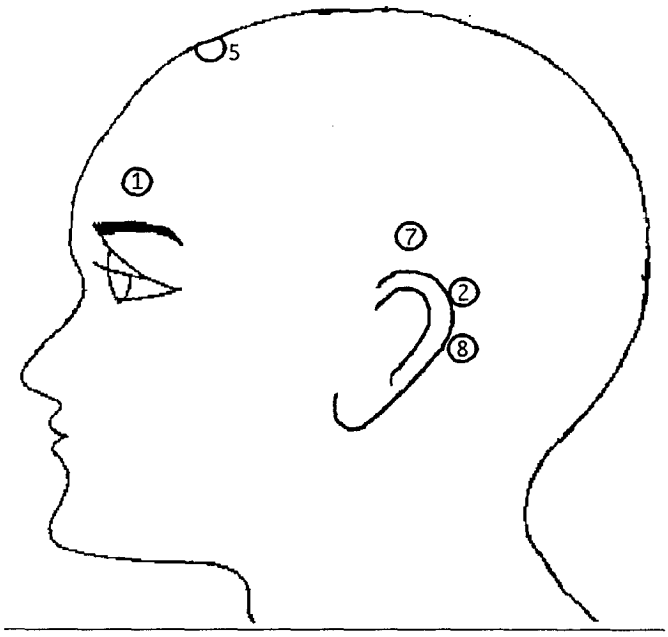
7. Make a short vertical mark through the horizontal frontopolar mark (from step 2) at a point directly over the nasion.

8. Make dots to the left and right of the intersection made by these two marks; these dots represent the L frontopolar (1cm rostral to Fp1) and R frontopolar (1cm rostral to Fp2) sites.

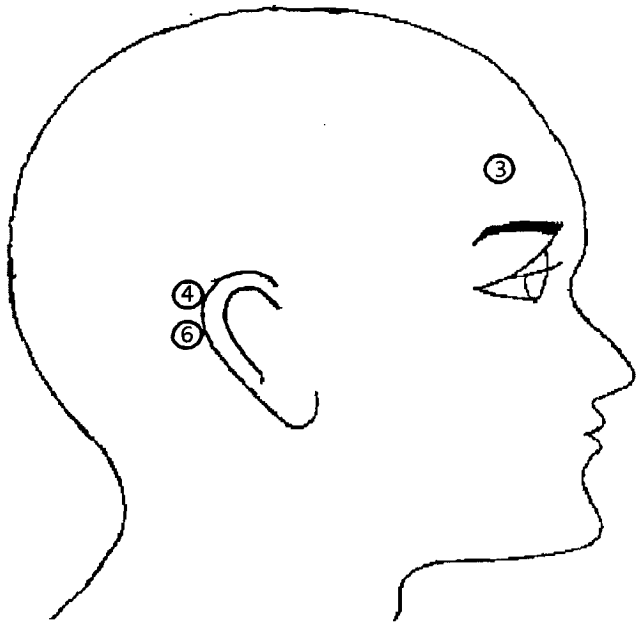
9. Measuring across the midfrontal (30%) horizontal mark from step 2, going from the left pre-auricular notch to the right pre-auricular notch; make a short vertical mark at the midpoint of this anterior transverse distance though the midfrontal horizontal mark; the intersection of these lines denotes the location of the Fz (midfrontal) EEG electrode site.

10. Note: An extra mastoid electrode will be needed on BOTH the left and right sides of the head for use with the two additional recording electrodes. It is suggested that these electrodes be located just caudal to the high mastoid sites, which are referenced to the left and right prefrontal electrodes. The second (lower) mastoid electrode on the left should be referenced to the midtemporal (T3) electrode. The second mastoid electrode on the right should be referenced to the midline frontal (Fz) electrode.

Left Side of Head



Right Side of Head



EEG Placements for Four Channels

EEG1	1-Left Frontopolar	2-Left Mastoid (Upper)
EEG2	3-Right Frontopolar	4-Right Mastoid (Upper)
EEG3	5-Midline Frontal	6-Right Mastoid (Mid)
EEG4	7-Left Mid-temporal	8-Left Mastoid (Mid)

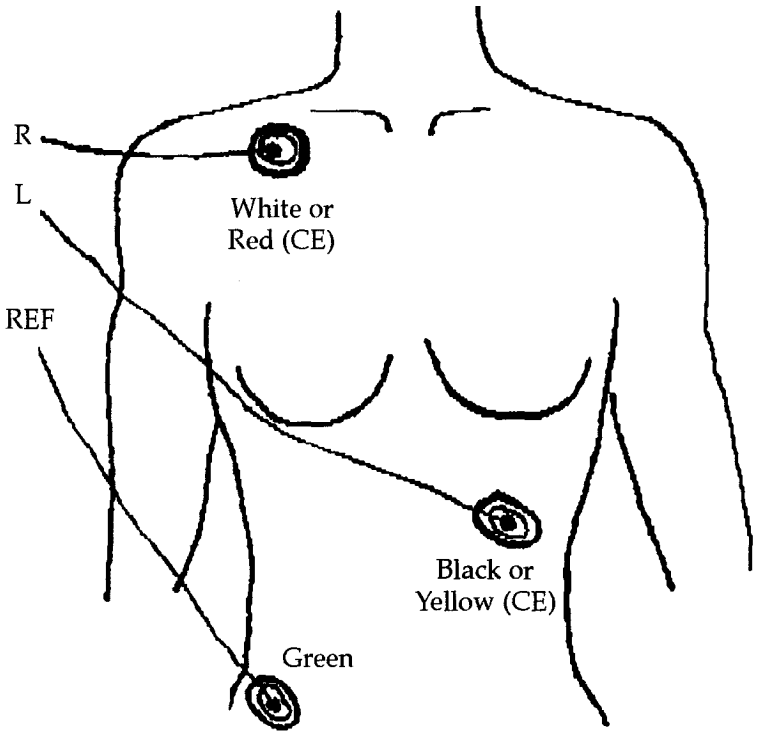
ECG

Monitoring of the electrocardiogram (ECG) and vital signs is standard in ECT. Often, practitioners prefer to place the ECG electrodes prior to placement of the EEG or ECT stimulus electrodes. If a spECTrum 5000 model is used for ECG monitoring, the ECG electrode leads should first be connected to the PATIENT MONITOR cable. The patient monitor cable is color coded indicating the positions for Red, White, and Green (reference) leads. Self adhesive ECG disposable electrodes may then be placed on the patient. Remove the electrodes from the sealed package (each package contains the three electrodes needed for one treatment) by tearing off the end of the package marked "tear here". The electrodes are soft, ventilated cloth with a pre-gelled silver/silver chloride electrode. To apply the electrode, place your thumb on the electrode side (opposite the snap) and, with the skin roughener on the right, peel off the electrode from the protective backing by grasping the white paper gripper. One convention is to place the electrodes in the right shoulder (clavicular) area, the left rib (below the costal margin) area, and over the hip or abdomen, and connect the White (right shoulder), Black (ribs), and Green (hip) electrode snaps to the ECG electrodes. This placement will produce the traditional ECG monitoring placement (lead 1). Other configurations may also prove satisfactory. See Electrode Plaement Figure for lead 1 electrode placement.

The ECG disposable electrodes are included in the starter kit. Use only MECTA provided disposable electrodes. The electrodes are ready to use, and pre-gelled with an electrical conductant. In the context of ECT, this simple preparation is often adequate for ECG monitoring. However, occasionally the recording quality may be poor. In such cases, the most common source of difficulty is poor contact between the ECG electrode and the patient. Other possibilities include poor connection between the ECG electrode and snap-on lead, or poor connection between the ECG lead and the patient monitor cable. In the case of poor contact between the electrode and the patient, cleanse the skin area with alcohol, pat dry, and if needed, add a drop of conducting gel onto the electrode to improve ECG recordings.

If disposable electrodes are used after the expiration date, the gel may be dried out. In this case, a fresh set of electrodes should be used. However, after the treatment, the electrodes should be removed and disposed. Disposable ECG electrodes should not be re-used. The electrode site should be cleaned to remove any remaining gel.

With a MECTA spECTrum 5000 model, ECG may be displayed on the LCD/Touch Screen and/or the Chart Recorder, depending on the menu options selected.

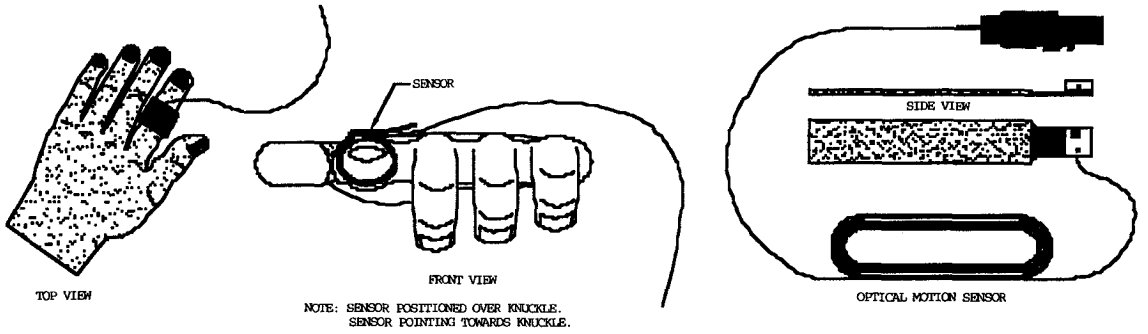


Placement of ECG electrodes.
CE - Red (right), Yellow (left), Green (reference)
cUL - White (right), Black (left), Green (reference)

OMS

Motor Activity Monitoring

Motor activity during a seizure provides some indication of the duration of the seizure. MECTA's optional Optical Motion Sensor (OMS) provides a means to monitor motor activity in a finger or toe. A Velcro strip on the sensor promotes easy attachment of the sensor to the patient.



Like the EEG and ECG channels, the OMS channel may be displayed on the LCD/Touch Screen, printed on the CHART RECORDER, and displayed and/or stored on an Remote Monitor (PC). Setup of these features is with easy-to-use menus available via the LCD/Touch Screen as described in a later section.

The OMS works by illuminating the surface of the finger or toe with infrared light and monitoring the amount of light reflected from that surface. When the sensor is attached to a joint that flexes during a seizure, a signal indicative of motor activity is available.

NOTES:

- Unlike the other Patient Monitor cables, the OMS's cable connector locks into its OMS INPUT connector. Squeeze the small latch on the underside of the connector to release the OMS cable connector from its input or to connect it to the SPECTRUM.
- Sensor placement should be on the top of a knuckle of the big toe or thumb, with the portion of the OMS sensor that has the black dots on it toward the knuckle. This is the side opposite to the Velcro. Use the Velcro strap to hold the sensor snugly (but not tightly) in place. After attaching the sensor in this way, manually flex the knuckle while observing the SPECTRUM's OMS trace display to verify proper motion detection, and to adjust the display and printer gains accordingly. Once this is completed, verify that the sensor is oriented so room light cannot leak into the sensor.
- Using the top surface of a knuckle minimizes artifact from the pulse, and maximizes sensitivity to flexing motion.

WARNINGS

- The OMS sensor supplied with the SPECTRUM has its metal case electrically isolated from its electrical connections. Always avoid using another manufacturer's sensor in place of that supplied by MECTA Corporation with the SPECTRUM. Using another manufacturer's sensor may compromise the safety patient isolation barrier and may provide a shock hazard to the patient or operator.
- Wrapping the OMS sensor too tightly on the digit may cause tissue damage.

NOTES:

- Although the SPECTRUM detects complete disconnection and some partial disconnections and cable faults, the user must exercise reasonable measures to ensure that the OMS is working properly. This is why manual knuckle-flexing is recommended to test the OMS setup.
- Changes in ambient light levels entering the OMS (including that caused by movement of staff around the OMS sensor) can cause false signals (artifact) to appear in the OMS channel. Alternatively, if enough ambient light (particularly sunlight) enters the OMS, the OMS monitoring channel may saturate and give a flat line signal or a noisy signal that may mask real motion.

EMG

The SPECTRUM 5000 series EEG and ECG amplifiers are also capable of monitoring electromyographic (EMG) activity. EMG activity offers a complimentary means of monitoring the ictal motor response, in addition to that provided by the OMS. To record the EMG, two recording electrodes, consisting of pediatric ECG pads, should be placed distal to the cuff used to prevent the flow of the muscle relaxant to a foot or hand. The two recording electrodes should be placed approximately 3 inches apart, with at least one of the electrodes located over muscle tissue. Skin preparation should be as with EEG recording.

MONITORING FEATURES

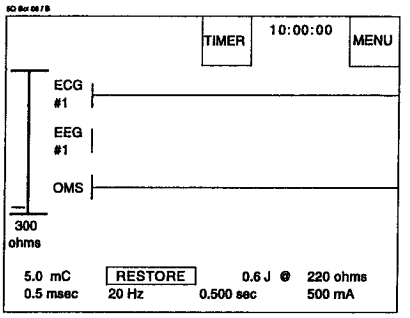
Leads-Off Indication

All channels selected for display or printing on the CHART RECORDER or for display on the LCD/Touch Screen are monitored for proper connection to the patient. In the case of EEG and ECG, this monitoring process will detect when one or more recording electrodes are not connected to the patient or if the Patient Safety Monitor cable is disconnected from the device. In the case of the OMS, disconnection of the OMS cable from the device will be detected, but not improper connection to the patient.

When a selected channel is disconnected, its trace disappears from the LCD and CHART RECORDER, indicating that the channel is improperly connected. In addition, a RESTORE button will appear on the TREATMENT READY and POST TREATMENT displays (see the following figure). When all selected channels are properly connected to the device and the patient, the RESTORE button will ordinarily disappear. If it remains after reconnecting all the leads selected for both the LCD and the RECORDER display, touching it should cause all selected traces to reappear, and the RESTORE button should go away. If it does not, then there is still a connection problem with one of the selected leads. The Leads-Off Indication provides important feedback to the clinician. However, this does not interfere with the conduct of treatment and the electrical stimulus can be administered regardless of the state of the monitoring leads.

NOTE:

- If a selected monitoring lead (EEG/ECG/OMS) is too close to other electrical equipment, the SPECTRUM may fail to detect a proper lead connection and may display a leads-off condition. In the following display, EEG#1 lead is disconnected.



Auto Trace Restore

When physiological monitoring leads are first connected or disconnected, the channel trace may go to the top or bottom of its display area and stay there for a few seconds. This is caused by "pegging," where the electrical signal sticks at its maximum or minimum possible value. The SPECTRUM detects this condition and automatically resets the electronics, thus bringing the channel trace back to the center of its display range.

When the Auto Trace Restore feature activates, up to four channels of monitoring are simultaneously reset. EEG1, EEG2, ECG1 and the OMS are always reset as a group, and all others are reset as a group. If any channel in the group activates the autotrace restore, all channels in the group are restored and their corresponding display or printing traces will all shift at the same time.

During routine monitoring, trace restores should not occur unless a lead becomes disconnected.

Automatic Calibration Verification

During the SPECTRUM power up sequence, verification of the gains of all signal amplifiers occurs. The gains must be within 10% of their design values or an error message informs the operator which channels have failed the test. The SPECTRUM may still be used, but the specified CHART RECORDER and screen gains will be incorrect. The device should be returned for recalibration or repair as soon as possible.

Physiological Monitoring Channel Input Configurations

The SPECTRUM may have one of four possible configurations of physiological monitoring channels. The following diagrams illustrate the four possible input connector options, as well as the type of cables that should be used with each connector.

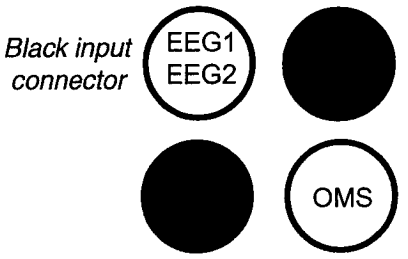
The top 2 configurations are the basic 2 channel configurations shown with an optional OMS channel. The OMS, if included, comes with its own cable and connector. The other active connector uses a 5 lead cable to connect the two monitoring channels to the patient. The green REF lead should be used in a standard ECG configuration if an ECG channel is used. Otherwise, it should be connected to the patient as a forehead or shoulder reference lead when assessing EEG.

CAUTIONS:

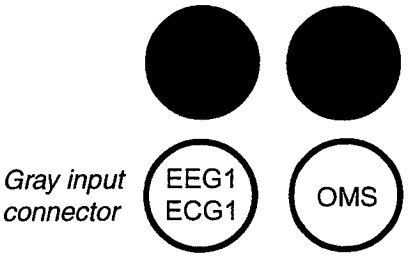
- In patient cables that combine an EEG and an ECG channel in the same cable, be careful to connect EEG and ECG leads correctly to the patient, and to the Patient Monitor cable.
- Confirm that the patient monitor cables are connected to the appropriate connectors (i.e., the cable connector color matches the front-panel connector label color).

Front Panel Input Configuration Options

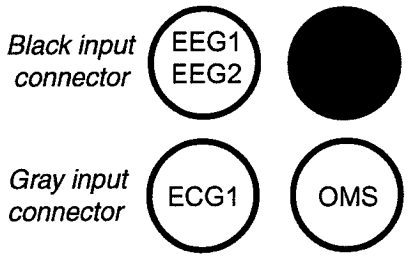
- 2 EEG channels:
  One cable - Black connector
  Optional OMS sensor



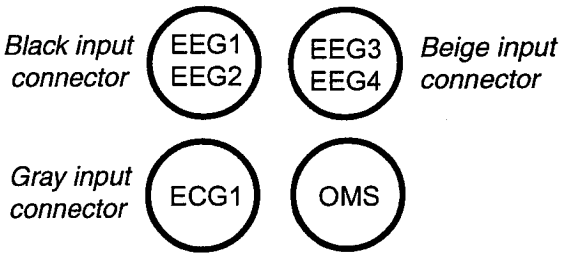
- 1 EEG and 1 ECG channels
  One cable - Gray connector
  Optional OMS sensor



- 2 EEG and 1 ECG channels:
  One cable - Black connector
  One cable - Gray connector
  Optional OMS sensor



- 4 EEG and 1 ECG channel
  One cable - Black connector
  One cable - Beige connector
  One cable - Gray connector
  Optional OMS sensor



Via the menu system, the user selects the channels to display on the LCD/Touch Screen and on the CHART RECORDER. Different channels can be displayed on both. The equipment monitors all the selected channels for the purpose of Auto Trace Restore and Leads-Off Indication.

SIGNAL OUTPUT PORTS

The physiological monitoring signals are accessible to external equipment via the analog and SERIAL OUTPUT ports on the rear panel of the sPECTrum. An additional timing signal enables the triggering of external equipment either when stimulus delivery begins or ends.

The ANALOG SIGNAL OUTPUT PORT may be used with external CHART RECORDERs, display units, cardiac monitors, etc. and for independent digitization with an external computer. See the Service Manual for connector pinouts and signal levels.

SERIAL OUTPUT PORT provides digital data for use with the REMOTE MONITOR OPTION (PC and software). See the REMOTE MONITOR MANUAL for details. See the Service Manual for connector pinouts.

EEG DATA ANALYSIS*

Description

The EEG DATA ANALYSIS feature, available as an option with the 5000 series, provides the capability to automatically analyze post-stimulus EEG signals, using a patented algorithm, to provide seizure adequacy information that may be useful in the determination of ECT stimulus dosing, which is known to affect both therapeutic response and cognitive effects. Two such measures are included, STIMULUS ADEQUACY and STIMULUS LEVEL. If the user wishes, this algorithm is able to increase it's accuracy by taking into account effects of a number of patient and treatment specific parameters including the patient's age, the treatment number, whether the treatment is part of an index (acute) or maintenance (prophylactic) series, stimulus electrode placement (unilateral or bilateral), and the number of EEG channels processed (1 or 2). These parameters are specified through the PATIENT DATA MENU and EEG DATA MENU (see below and Menu System section).

The STIMULUS ADEQUACY measure provides an estimation, for both unilateral and bilateral ECT, of the likelihood that the induced seizure differs from that associated with barely suprathreshold unilateral ECT (a type of ECT shown by Sackeim and colleagues to be subtherapeutic). As such, this information, which was developed on the basis of actual treatment data (see below), allows the practitioner a means to assess whether the unilateral or bilateral ECT stimulus was sufficiently intense, and can thereby serve as a means to assist in stimulus dosing.

Because the extent to which the stimulus is suprathreshold is a particularly important issue with unilateral (UL) ECT, a second EEG seizure adequacy measure, STIMULUS LEVEL, is provided exclusively for use with UL ECT. This second seizure adequacy measure estimates the actual amount by which the stimulus intensity exceeds the unilateral ECT seizure threshold, and thereby provides a measure of how suprathreshold the preceding stimulus was.

If activated via the EEG DATA Menu with parameter sets 1, 2 and 3 (as will be shown below), these measures are displayed on the trace printout after the end of the seizure as "ADEQ XX%", for STIMULUS ADEQUACY, and "LEVEL X.XT", for STIMULUS LEVEL, (present only with unilateral ECT. The data can also be displayed on the LCD panel, using the SZ DATA button on the TREATMENT RESULTS display. STIMULUS ADEQUACY values range from 0% to 99%, with higher numbers associated with a greater likelihood of seizure adequacy. The numbers have been scaled so that a cut-off of 50% can be used as a general criterion. The STIMULUS LEVEL values estimate the multiplicative factor by which the preceding stimulus is likely to have exceeded seizure threshold, e.g., "LEVEL 2.5T" means that the feature has estimated that the stimulus producing the seizure was 2.5 times UL seizure threshold. It is important to note that estimates of stimulus intensity become less accurate as the administered intensity is increased. This reflects the physiologic property that as stimulus intensity increases, there is less and less change in the ictal EEG. The reasons for this phenomenon are not understood. There is preliminary evidence that identifying the stimulus level above which no further changes in EEG measures occur may be helpful for optimizing clinical stimulus dosing. This possibility is the subject of ongoing research that will be incorporated into future algorithm updates.

EEG DATA Analysis use with ULTRABRIEF PARAMETER MENU - SET 4

While the EEG DATA Analysis features were developed from a substantial body of research, it is important to note that for ultrabrief pulse ECT, the relationship of the ictal EEG and both ECT stimulus level and seizure therapeutic adequacy are unknown. As a result, the EEG DATA analysis will be turned off automatically if you select the fourth ultrabrief parameter set. It must be turned back on again using the touch screen menus when the first three parameter sets are used. (See page 85 for instructions on using the menu set). Research studies of the relationship of

the ictal EEG and seizure adequacy for ultrabrief pulse ECT are being carried out with the aim of developing new ictal EEG DATA analysis measures. As these studies are completed, the results will be reflected in future updates to the algorithm.

NOTE:

- For the algorithm data to be valid, the following conditions must be met:

1. EEG leads for channel 1 must be connected to the left prefrontal area (1 inch above midline of left eyebrow) and left mastoid bone. If two channels of data are used (this will slightly increase the accuracy of the estimates), channel 2 electrodes should be placed over the right prefrontal and mastoid areas.
2. Care should be taken to minimize artifact.
3. The CHART RECORDER's OFF button or LCD's DONE button (POST TREATMENT TRACE display) should not be pushed until at least 20 seconds of relatively artifact-free postictal data have been recorded. This is essential to increase the accuracy of the algorithm.

* **Protected by US Patent #5,626,627**
UK Patent #2 304 196B

To engage the algorithm, do the following:

- Using the EEG DATA MENU, turn the algorithm on and specify the number of EEG channels connected to the patient (1 for EEG1 only, 2 for EEG1 and EEG2)
- Using the PATIENT DATA MENU, enter all of the items there.

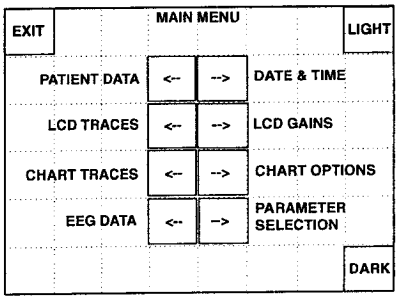
NOTES:

- When the EEG DATA ANALYSIS option is ON (as selected in the EEG DATA MENU), the patient data will appear in the upper left corner of the TREATMENT READY display. If a data item has not been entered, "?" will be displayed in its place.
- Patient data will not be saved when the spECTrum power is turned off. Further, it will automatically be erased under certain conditions to prevent accidental use of the same information with two different patients. Erasure will occur when in the TREATMENT READY display if a stimulus has been done (after the information was entered) and 15 minutes has elapsed since the last stimulus completed.
- It takes 8.5 seconds for the spECTrum to calculate and display the first EEG results. Touching the DONE button before that time will cause only zeros to be printed on the EEG printout and display.
- The CHART RECORDER continues to print while you view these displays. Touching the DONE button or the CHART RECORDER's OFF button stops the trace data printout, and prints the Treatment Result Report, but it also closes out these displays, resets the spECTrum for further treatment, and the TREATMENT READY display reappears.

When the EEG DATA ANALYSIS is enabled, some buttons on the TREATMENT RESULTS display change and the EEG DATA display becomes available.

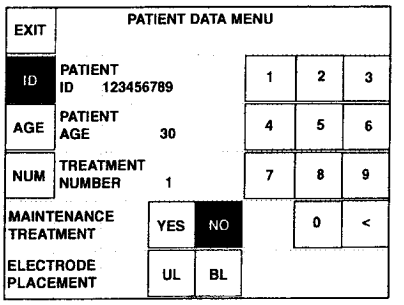
MAIN MENU

When the EEG DATA option is present in the spECTrum, the MAIN MENU (accessible by touching the MENU button whenever it appears) displays an EEG DATA button, as shown here:



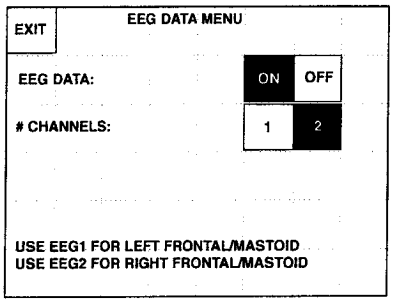
PATIENT DATA MENU

For best results, all items in the PATIENT DATA MENU (see Menu System section) should be entered before the treatment begins.



EEG DATA MENU

Touching the EEG DATA button on the MAIN MENU displays the EEG DATA MENU.



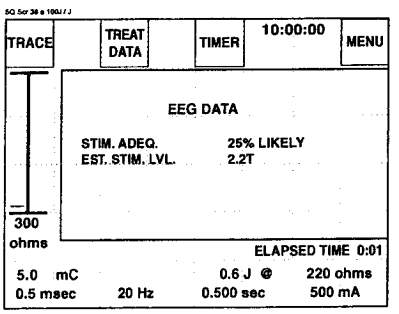
The ON/OFF buttons enable or disable the EEG DATA processing. A dark button with the light lettering indicates the current state.

The numbered buttons select the number of EEG monitoring channels being used: 1 for EEG1 only (left frontal/mastoid location), and 2 for EEG1 (left frontal/mastoid location) and EEG2 (right frontal/mastoid location).

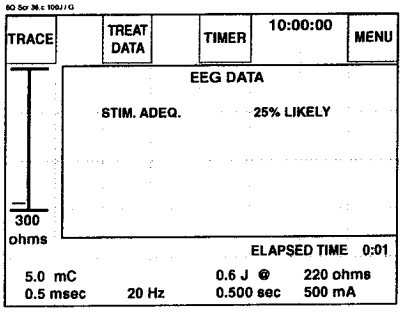
When done entering the EEG DATA, touch the EXIT button to return to the MAIN MENU.

EEG DATA display

Touch the SZ DATA button on the TREATMENT RESULTS display for the EEG DATA display:



EEG Data display
Unilateral



EEG Data display
Bilateral or Not Specified

Estimates will update every two seconds beginning 8.5 seconds after stimulus delivery ends.

Touch the TRACE button to go back to the POST TREATMENT TRACE display.
Touch the TREAT DATA button to go back to the TREATMENT RESULTS display.

EEG Lead Off and Artifacts

During the analysis of the EEG data, if the algorithm senses the existence of gross artifact, an ARTIFACTS message will appear on the EEG DATA display (see sample above), and on the CHART RECORDER printout (see below), indicating that the analysis results may be invalid.

Further, if an EEG lead selected for analysis disconnects from the patient at any time during the analysis, LEAD OFF will appear instead of ARTIFACTS. When the lead is reconnected, LEAD OFF will change to ARTIFACTS. These messages indicate that the analysis results should not be used.

For illustrations, see "Printouts" in the Chart Recorder Module section of this manual.

CAUTIONS:

- The EEG data option is available as a guide to estimate the seizure-inducing potency of the ECT stimulus, based on the monitored EEG signal(s). This automated analysis has been validated by much clinical testing, but cannot be assumed to be of uniform accuracy. In addition, variations in individual patients and possible signal artifacts from a variety of sources may cause erroneous indications of stimulus adequacy. The ultimate responsibility for determining treatment adequacy rests on the clinician.
- The EEG data option does not make a determination regarding whether a seizure has occured. Consequently, the analyses and data display/printout will occur even in the case of a missed seizure, so that the presence of such data should not be viewed as indicating that a seizure has taken place.

Scientific basis of algorithm

Because the therapeutic response and cognitive side-effects associated with ECT treatments are generally only evident after a delay of a number of treatments, there is a need to predict whether the treatments being administered will be effective and to ensure that the treatments will not cause excessive cognitive side-effects. Recent research indicates that the degree to which treatment stimulus intensity exceeds the seizure threshold affects both therapeutic outcome and cognitive side-effects (Sackeim et al., 1991, Sackeim et al., 1993, Krystal et al., 1995a). In fact, for UL ECT, evidence indicates that barely suprathreshold treatments have low efficacy and that those that are administered at higher levels above the seizure threshold are significantly more effective. At the same time, treatments which exceed seizure threshold to a great extent, for both UL and BL ECT, appear to be associated with greater cognitive side-effects.

A number of studies have demonstrated that attributes of the ictal EEG significantly differ as a function of treatment stimulus intensity relative to the seizure threshold and also with respect to treatment therapeutic efficacy (Nobler et al., 1993, Krystal et al., 1993, Krystal et al., 1995a,b, Krystal et al., 1996a,b, Suppes et al., 1996, Krystal In Press, Krystal et al., In Press, Folkerts 1996, Hrdlicka et al., 1996). Further, ictal EEG indices have been found to identify when UL ECT treatments become associated with diminished therapeutic potency over the ECT treatment course due to rises in the seizure threshold (Krystal et al., 1995b). In this regard, preliminary ictal EEG models, including the EEG indices used in the MECTA 5000 series have been found to differentiate seizures as a function of relative stimulus intensity with an accuracy of 90% (Krystal

In Press, Krystal et al., In Press) and to be significant predictors of therapeutic outcome (Krystal et al., 1995a,b, Krystal et al., 1996a, Krystal In Press, Krystal et al., In Press).

The present ictal EEG seizure adequacy features were developed based upon the above research. The estimates of the stimulus intensity relative to the seizure threshold, STIMULUS LEVEL, are derived from a multiple regression model which predicts how high the UL ECT stimulus is above the seizure threshold (in terms of multiples of the seizure threshold) on the basis of these ictal EEG attributes and also takes into account the patient's age, the electrode placement, and the treatment number (Krystal et al., 1995a, Krystal et al., 1996b, Krystal In Press, Krystal et al., In Press). The estimates of STIMULUS ADEQUACY are derived from a logistic regression model and predict the likelihood that the index ECT seizure being analyzed is therapeutically effective (from 0-100% likelihood), taking into account, age, and treatment number (Krystal In Press). Both estimates were developed through analysis of ictal EEG data on over 200 patients and have been tested on data from over 80 patients, confirming their validity. As such, these seizure adequacy features allow the user the unique opportunity to compare the EEG recorded during the present treatment to ictal EEG data from a large data base where the stimulus intensity compared to both seizure threshold and therapeutic efficacy was known.

REFERENCES:

Folkerts H. "The ictal electroencephalogram as a marker for the efficacy of electroconvulsive therapy." Eur. Arch. Psychiatry Clin. Neurosci. 1996; 246:155-164.

Hrdlicka M, Moran M, Vachutka J, Blatny M, Rozinkova J. "EEG in electroconvulsive therapy: Is more intensive paroxysmal activity associated with a higher therapeutic response?" Neuropsychobiol. 1996; 33:138-141.

Krystal AD. "Clinical utility of ictal EEG seizure adequacy." Psychiatric Annals. In Press.

Krystal AD, Coffey CE, Weiner RD, Holsinger T. "Changes in seizure threshold over the ECT course affect therapeutic response and are detected by ictal EEG ratings." J. Neuropsychiatr. Clin. Neurosci. In Press.

Krystal AD, Weiner RD, McCall WV, Shelp FE, Arias R, Smith P. "The effects of ECT stimulus dose and electrode placement on the ictal electroencephalogram: An intra-individual cross-over study." Biological Psychiatry. 1993; 34:759-767.

Krystal AD, Weiner RD, Coffey CE. "The ictal EEG as a marker of adequate stimulus intensity with unilateral ECT." J. Neuropsychiatry Clin. Neurosci. 1995a; 7:295-303.

Krystal AD, Weiner RD, McCall WV, Coffey CE. "Studies on the potential of ictal EEG measures as an index of ECT seizure adequacy." Convulsive Therapy. 1995b; 11:68.

Krystal AD, Weiner RD, Gassert D, McCall WV, Coffey CE, Sibert T, Holsinger T. "The relative ability of three ictal EEG frequency bands to differentiate ECT seizures on the basis of electrode placement, stimulus intensity and theraputic response." Convulsive Therapy. 1996a; 12:13-24.

Krystal AD, Weiner RD, Coffey CE, McCall WV. "Effect of ECT treatment number on the ictal EEG." Psychiatry Research. 1996b; 62:179-189.

Nobler MS, Sackeim HA, Solomou M, Luber B, Devanand DP, Prudic J. "EEG manifestations during ECT: Effects of electrode placement and stimulus intensity." Biological Psychiatry. 1993; 34:321-330.

Sackeim HA, Devanand DP, Prudic J. "Stimulus intensity, seizure threshold and seizure duration: Impact on the efficacy and safety of electroconvulsive therapy." Psychiatr. Clin. North Am. 1991; 14:803-843.

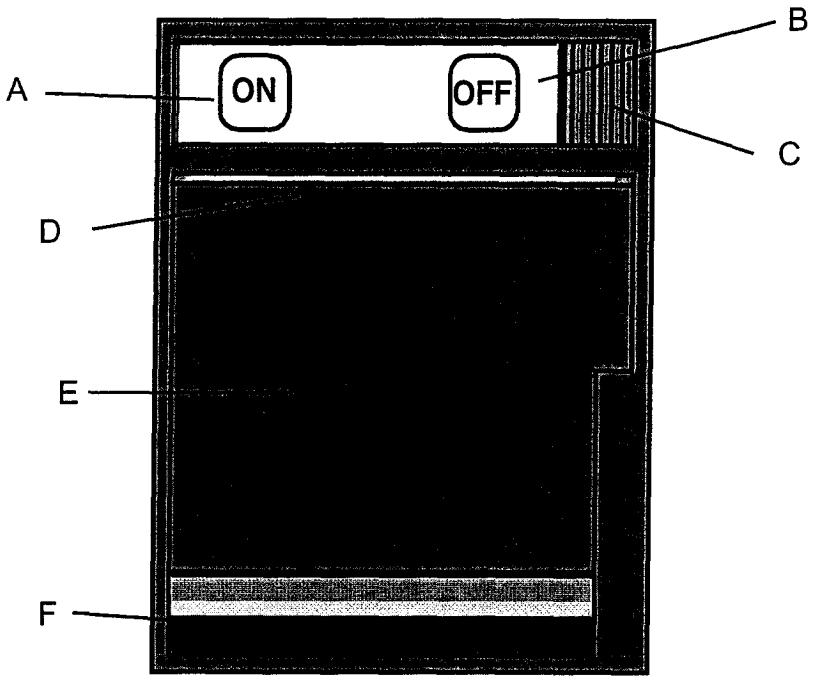
Sackeim HA, Prudic J, Devanand DP, Kiersky JE, Fitzsimons L, Moody BJ, McElhiney MC, Coleman EA, Settembrin JM. "Effects of stimulus intensity and electrode placement on the efficacy and cognitive effects of electroconvulsive therapy." New Eng. J. Med. 1993; 328:839-846.

Suppes T, Webb A, Carmody T, Gordon E, Gutierrez-Esteinou R, Hudson JI, Pope HG. "Is postictal electrical silence a predictor of response to electroconvulsive therapy?" J Affective Disorders. 1996; 41:55-58.

Chart Recorder Module

Chart Recorder

5000 models



Description

The CHART RECORDER produces hard-copy printouts for the SPECTRUM 5000Q and 5000M on thermally-sensitive recording paper.

NOTE:

- If the CHART RECORDER is set to "OFF" via the CHART OPTIONS menu (see Menu System section), no hard copy printouts will be available, and the ON and OFF buttons will be inactive.

A - ON button. Push this button to begin manually-initiated printing of trace data at any time. (Prints physiological traces only, without patient or self-test reports). The CHART RECORDER will also automatically initiate following stimulus delivery. In this case, "Self Test" and "Treatment Data" will be printed, unless this has been disabled via the CHART OPTIONS menu.

B - OFF button. Push here to stop printing of trace data. Pushing this button initiates printing of TREATMENT RESULTS while a Post Treatment display is on the LCD/Touch Screen. This button is inactive when the CHART RECORDER is set to OFF, via the CHART OPTIONS menu. If the recorder was automatically initiated, termination of trace data printing can also be effected by touching the DONE button on the POST TREATMENT display. (See Usage section).

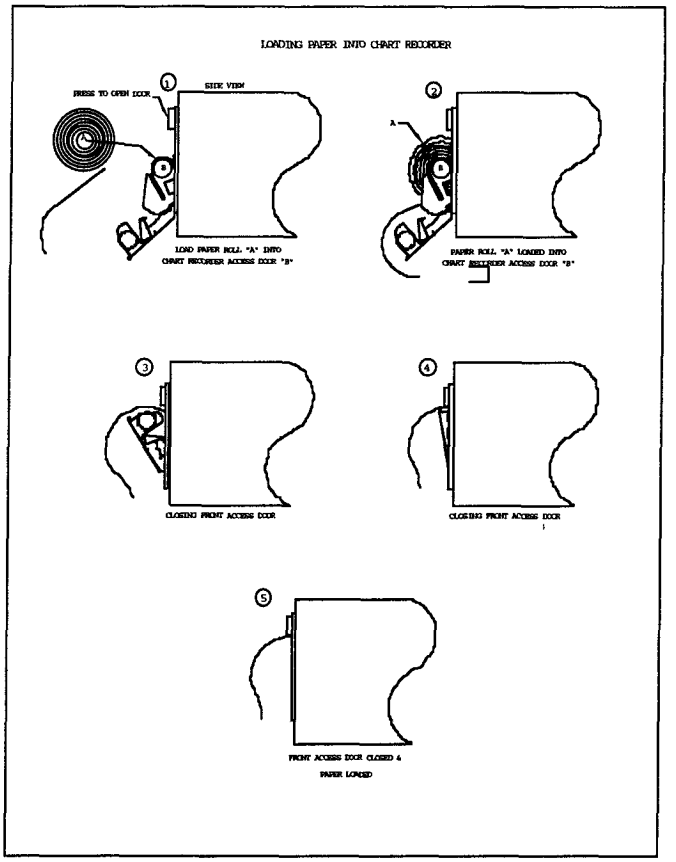
C - CHART RECORDER door latch.

D - Paper issue slot.

E - CHART RECORDER door.

F - CHART RECORDER door hinge.

Loading paper into the CHART RECORDER



Changing paper is a simple operation.
(1) Push in the CHART RECORDER door latch (the ribbed button at the top right corner of the printer unit). The door will fall open in "tailgate" fashion. (2) Remove the used roll core (if present) by gently spreading the two cupped uprights that hold the used roll in place. (3) Take a new roll of thermally-sensitive paper and insert it between these two cupped uprights. Make sure the roll is placed so that paper spools off the underside of the roll. (4) Pull out a few inches and lay it over the container door's top edge. The paper is not threaded through any slots or assemblies. (5) Lift the door and push it shut, leaving a bit of paper feeding over the top of the door. If no information appears when the CHART RECORDER has been engaged, the paper has been inserted backwards, with the heat-sensitive side away from the print head.

The top of the CHART RECORDER contains a sharp edge. When a tracing is complete, pulling the recorded strip upward and to the right against the top edge will result in a clean cut.

A colored line appearing on the right margin of the recording paper indicates that the paper will run out in a couple of minutes.

CAUTIONS:

- Use only low-debris paper, sold or recommended by MECTA Corp. Improper paper may cause unclear printing, damage to the printhead, or possible CHART RECORDER failure.
- Store all printer paper in an environment that complies with the paper storage specifications. Paper discoloration and possible damage to the printer may result from improper paper storage.
- Storing a SPECTRUM for extended times with paper still installed in its CHART RECORDER may cause permanent damage to the printer head. Before storing a SPECTRUM 5000, remove the printer paper.

Printouts

Individual treatment information is displayed on spECTrum CHART RECORDER printouts with up to two (2) channels of physiological trace data. The CHART TRACE menu is used to choose which channels are printed, and the order in which they appear (see Menu System section). The CHART RECORDER prints at a speed of 25mm of paper per second.

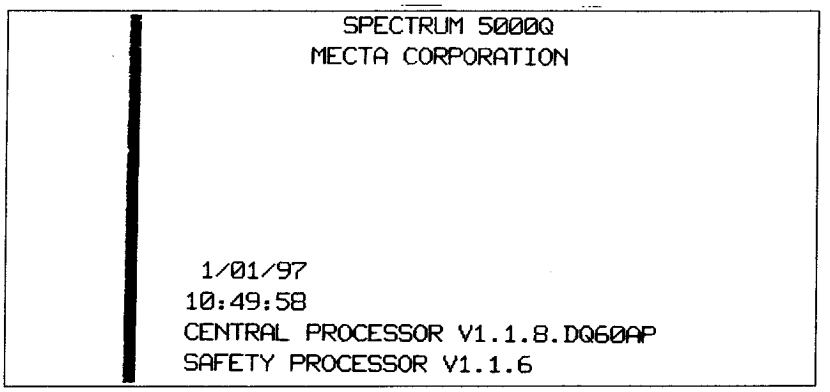
The typical sequence of automatically-initiated printouts is:

- SELF TEST results
- Physiological traces after stimulus
- Treatment Results
- EEG Data
- Patient Data

This sequence repeats for each stimulus until the DONE button is touched on the LCD/Touch Screen, or the CHART RECORDER's OFF button is pushed. At that time, a line is printed for the patient's name.

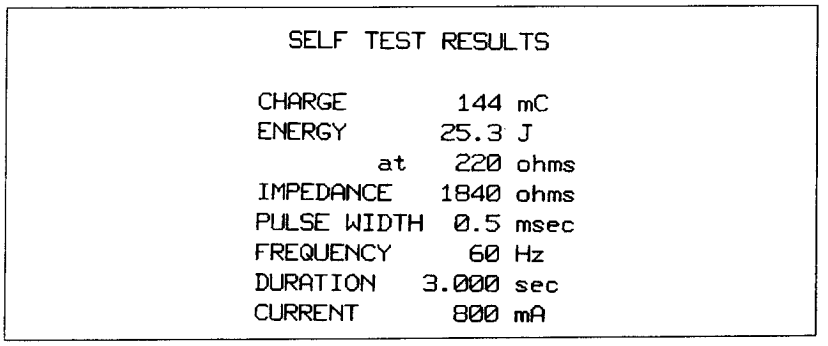
Initial Power-up printout

Each time the spECTrum is powered-up, the CHART RECORDER (if set to ON in the CHART OPTIONS menu) prints out a narrow, vertical solid black bar. Any non-uniformity in the solid black bar indicates a problem in the recorder's thermal array print head.



SELF TEST RESULTS printout

A SELF TEST RESULTS report is printed each time the STIMULUS CONTROL push button is pushed. It appears just before the physiological trace printout. The impedance printed is the static impedance value just prior to the stimulus delivery. This report of Self Test results is automatically provided when the delivery of the ECT electrical stimulus is initiated, and requires no action on the part of the operator.



Trace printout

The CHART RECORDER will produce a physiological trace record similar to the one pictured here:

- following the end of delivery of the ECT electrical stimulus (with CHART OPTIONS MENU set to ON)
- when the ON button on the CHART RECORDER face is pushed to activate the Recorder (with CHART OPTIONS MENU set to ON).

The top line displays the channel identification and other relevant information:

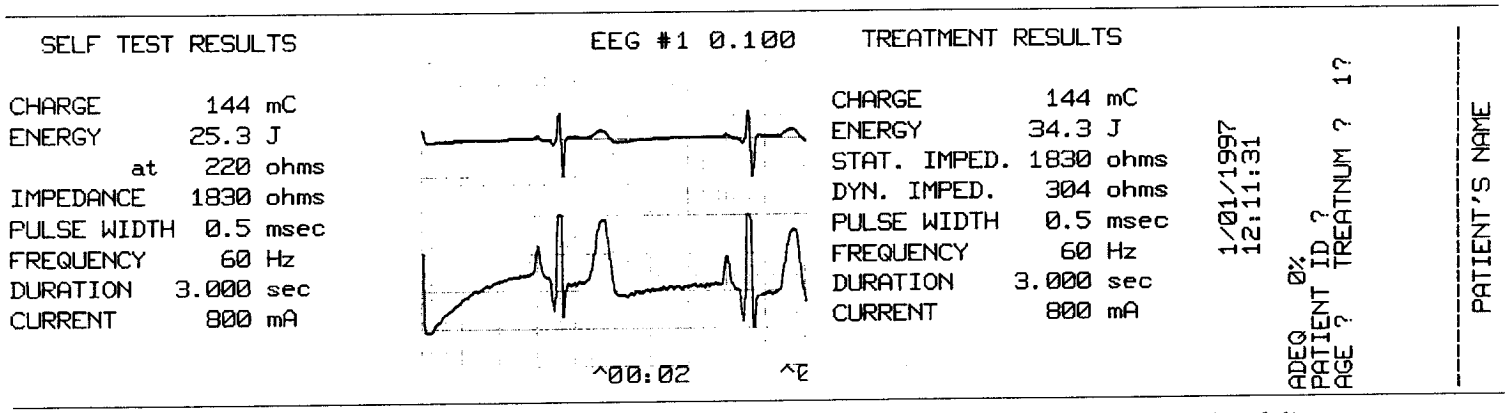
- Channel ID. The ECG and EEG inputs will show type, lead number (for multiple EEG channels), and millivolt/millimeter division. (The OMS sensor, having no voltage, will show only "OMS".)
- One or two traces will be printed, depending on the number of traces selected in the CHART TRACE MENU. The trace sizes are adjusted using the GAIN 1 and GAIN 2 adjustment knobs on the right-side of the SPECTRUM front panel.

The bottom line displays timing information. When trace recording starts automatically immediately following the end of the electrical stimulus, the timing information is relative to the end of the electrical stimulus. For example, when a 6 sec stimulus has been given and the chart print out indicates 00:12, this indicates that it is 18 seconds since the start of the stimulus and 12 seconds since its termination.

When the trace recording is started by pressing the ON button on the CHART RECORDER, the timing information on the bottom line reflects real time readings (using military time). For example, 14:46:23 corresponds to 23 seconds after 2:46 p.m.. This distinction in use of real time vs. timing relative to the end of the seizure has clinical utility. Typically, the clinician will time the duration of the seizure using one or more EEG channels. Relative timing is of greatest value in this circumstance. The clinician may need to manually engage trace recordings to conduct physiological monitoring in the context of medical complications (e.g., cardiac arrhythmia, tardive (recurrent) seizures). In such circumstances, documentation of the real time of recordings may be most helpful.

NOTES:

- The upper (or only) waveform trace is always GAIN 1.
- The size of printed traces is controlled only by the GAIN 1 and GAIN 2 gain adjustment settings. Printed trace size is not affected by the gain settings selected for the LCD/Touch Screen.

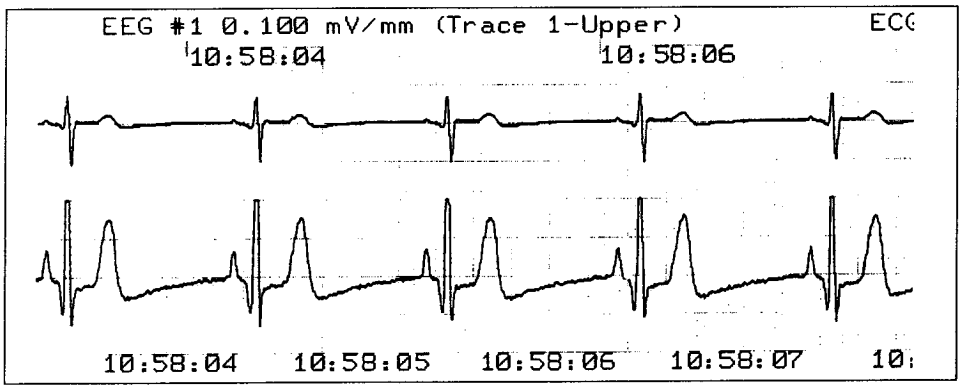


The figure above is an example of the printout that occurs immediately after stimulus delivery. The bottom line gives the elapsed time in seconds since the stimulus delivery. The SELF-TEST RESULTS were automatically obtained by pressing the STIMULUS CONTROL push button to

deliver the stimulus. The physiological trace recordings start automatically following the end of the delivered stimulus.

Real-time Marks

The figure below shows the printout that occurs when the CHART RECORDER's ON button is pushed. The bottom line gives the time of day in one-second real time intervals.



TIMER Markers

The figure above also shows (along the upper margin) the start and stop timestamps that are printed to show that the TIMER button was used to time an event.

Any time the TIMER button on the LCD/Touch Screen is pressed while traces are printing, a mark and the real time of the event are recorded on the trace printout. This behavior is somewhat different than the event timing provided on the LCD/Touch Screen itself. On the LCD/Touch Screen, the first activation of the TIMER button starts a timing clock (timed in seconds-since-activation). Pressing the TIMER button again stops the timing clock, leaving the time stopped visible (until the TIMER is re-toggled, or a different display is called) on the LCD/Touch Screen. Pressing the button a third time restarts and activates the timing at 00:00 second. These timing sequences may be engaged and stopped as many times as desired.

TREATMENT RESULTS printout

This report is always printed after the Post-Treatment Trace printout. When the operator presses the OFF button on the CHART RECORDER or the DONE button on the LCD/Touch Screen, the TREATMENT RESULTS will be printed by the CHART RECORDER (unless the CHART RECORDER has been set to OFF in the CHART OPTIONS menu). However, if another electrical stimulus is delivered (by pressing the STIMULUS CONTROL push button) prior to obtaining the TREATMENT RESULTS from the previous stimulation, the spECTrum will automatically print the previous TREATMENT RESULTS prior to the SELF-TEST RESULTS for the current electrical stimulation. This feature protects the operator from losing TREATMENT RESULTS. It is particularly useful when the empirical stimulus titration technique is used to determine seizure threshold, and any time that restimulation is required within a treatment session.

NOTE:

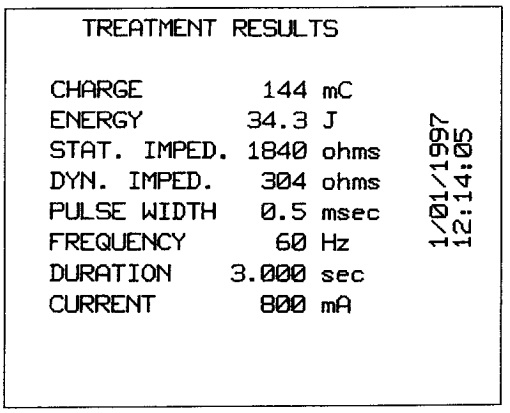
- When the spECTrum is powered down (by pressing the POWER button on the front panel) prior to obtaining TREATMENT RESULTS, the TREATMENT RESULTS are lost.

PATIENT DATA and EEG DATA are printed after each stimulus if the EEG DATA ANALYSIS

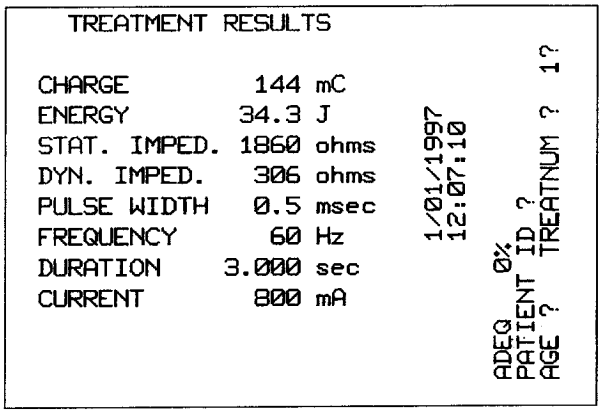
option has been purchased and is set to ON in the EEG DATA MENU. Patient data follows after the last stimulus (when the DONE button on the LCD is touched, or the Recorder's OFF button is used) if PRINT PATIENT DATA is set to YES in CHART OPTIONS MENU and the EEG DATA ANALYSIS option is OFF or not available.

The following CHART RECORDER samples show various forms of the TREATMENT RESULTS printout. The variations depend on:

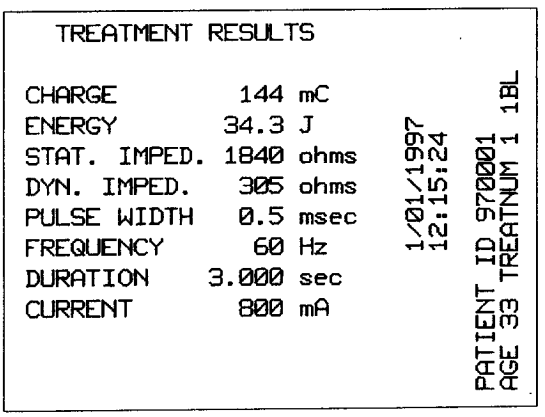
--setting of PRINT PATIENT DATA in the CHART OPTIONS menu;
--setting of EEG DATA ON in the EEG DATA menu;
--setting of ELECTRODE PLACEMENT in the PATIENT DATA menu.
--status of the EEG leads (ON or OFF) used in the EEG DATA analysis.



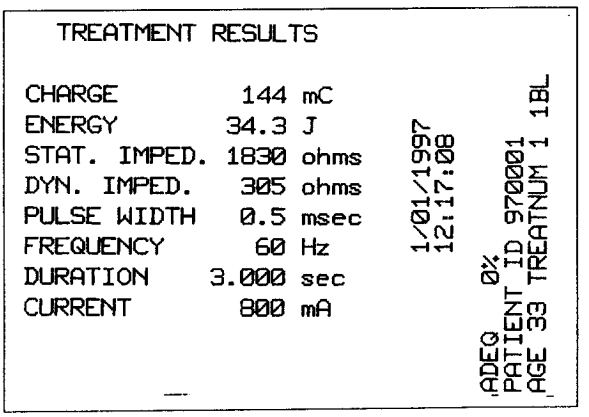
A. Date and time only appears. Both "Print Patient Data" and "EEG Data" are set to OFF. No EEG or patient data is printed.



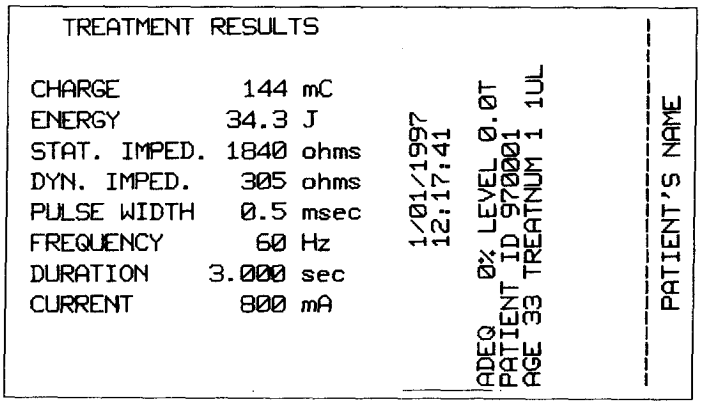
B. Both options are set to ON, but Patient Info displayed shows "?" because no information was entered in the PATIENT INFO menu.



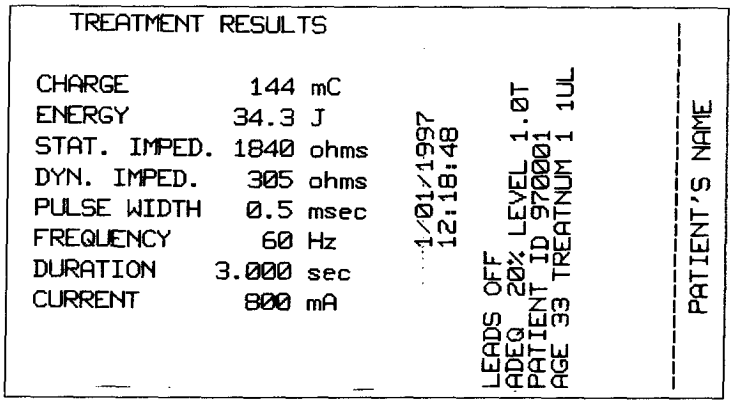
C. "Print Patient Data" is ON; "EEG Data" is set to OFF. Patient information appears. No EEG data is printed.



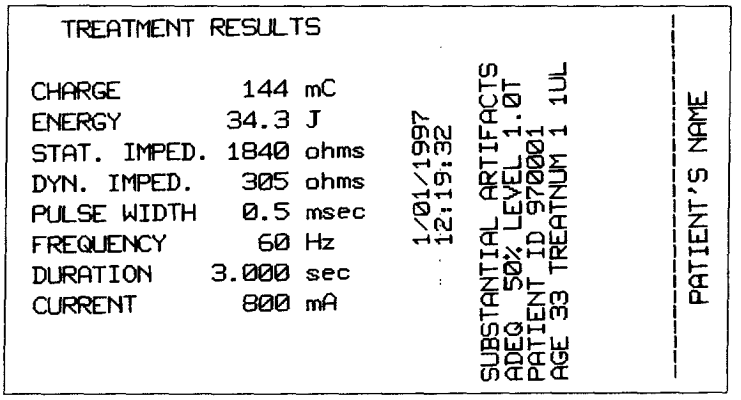
D. Both options are set to ON, and all info appears. "Adequacy" entry shows that BL was entered in the PATIENT INFO menu.



E. Both "Print Patient Data" and "EEG DATA" are set to ON, and all info appears. "Adequacy" and "Level" entries show that UL was entered in the PATIENT INFO menu.



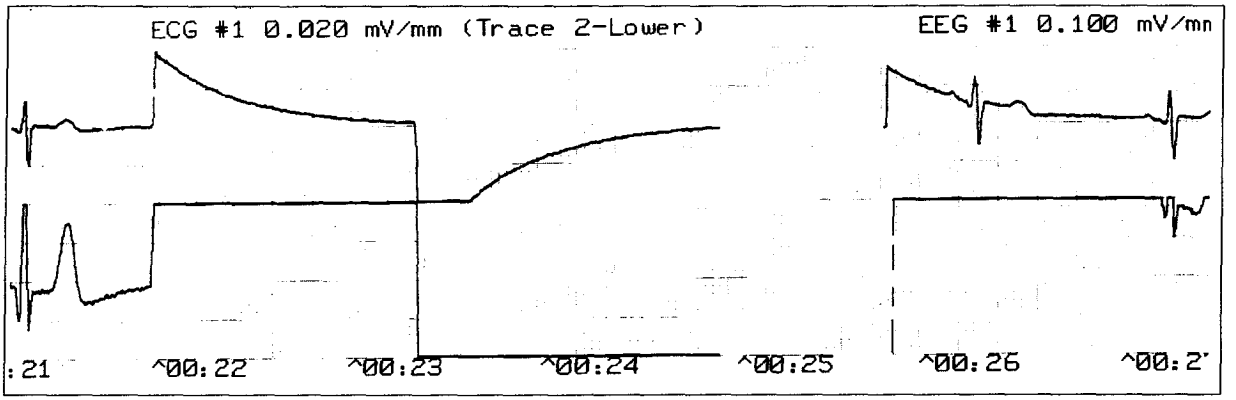
F. When EEG DATA is set to ON, if the EEG1/EEG2 connector is unplugged from its Front Panel connector, the message "LEADS OFF" appears on the EEG DATA display when the EEG DATA is updated (8.5 seconds after treatment ends). If the lead remains unplugged when DONE or OFF is touched, LEADS OFF prints on the CHART RECORDER printout. This shows that the EEG DATA results may not be accurate.



G. If the EEG1/EEG2 lead is unplugged and replugged before DONE or OFF is touched, the LEADS OFF message changes to ARTIFACTS on the EEG DATA display. This new message prints as SUBSTANTIAL ARTIFACTS on the CHART RECORDER printout. This shows that the EEG DATA results may not be accurate.

Lead disconnect / RESTORE

Whenever a channel lead is unplugged (disconnected) from the Front Panel connectors, its trace disappears from the LCD/Touch Screen. A RESTORE button also appears at the bottom of the display. If the printer is running, the trace disappears on the printout as in the example below.



Usage

OPERATION OF SPECTRUM SERIES ECT DEVICES SIMPLIFIED FLOW SHEET

NOTE:

- The clinical aspects of ECT delivery, including anesthesia, are beyond the scope of this user manual, which focuses on the use of the SPECTRUM ECT device. A number of clinical guides to the practice of ECT are available, including the most recent recommendations by the American Psychiatric Association (APA). This is available from American Psychiatric Press, Inc.

1. Push the POWER ON/OFF button located in the upper left corner of the SPECTRUM front panel. The unit will conduct an internal test which lasts approximately 35 seconds. During this test, a series of tones and clicking sounds will be heard. When the test is completed, a CLEAR button appears on the screen.

2. Adjust the LCD Screen contrast for best viewing during the internal test sequence by touching the LIGHT or DARK buttons.

3. Touch the CLEAR or EXIT button when the test sequence completes. This advances the system to the TREATMENT READY display. (No traces will appear yet on 5000 models).

4. If patient data is to be entered, touch the MENU button to get the MAIN MENU display, then touch PATIENT DATA to get the PATIENT DATA display. Enter patient data by touching applicable buttons (see Menu System section).

5. Apply monitoring electrodes to the patient. (Traces will appear on 5000 models only).

6. Set the STIMULUS INTENSITY knob (M models) or the four STIMULUS PARAMETER knobs (Q models). The settings for these knobs are shown on the display, directly above each control.

7. Apply blood pressure cuff to distal extremity (ankle or wrist).

5000 models

8. Apply OMS (Optical Motion Sensor) to the patient if option is available, and monitoring is desired.

9. Anesthetize the patient.

10. Inflate the cuff well over systolic pressure.

11. Inject muscle relaxant.

12. Apply stimulus electrodes.

13. Check static impedance.

14. Make sure anesthetic and muscle relaxant effects are complete, and that individual holding stimulus electrodes and/or patient's head is aware that stimulus delivery is about to occur.

15. Push and hold the STIMULUS CONTROL push button to deliver the stimulus. The unit will emit three short warning tones indicating that the stimulus is about to occur, and then one continuous tone during the actual delivery of the stimulus.

16. Release the STIMULUS CONTROL push button once the continuous treatment tone stops. (Stimulus has been fully delivered).

17. Observe the treatment results and patient monitoring to determine treatment adequacy.

18. Perform additional stimulation (if appropriate) by repeating steps 6 and 12-17.

19. When the treatment session is completed, touch the DONE or EXIT button to initiate a system internal test, and print the treatment results from the last stimulation.

20. Deflate and remove the blood-pressure cuff.

21. Remove the stimulus and monitoring electrodes and the OMS.

CAUTIONS:

- Hand-Held stimulus electrodes may need to be removed immediately following each stimulus to allow the patient to be safely ventilated.
- Make sure that blood pressure cuff is deflated in a timely fashion. Otherwise, vascular or tissue damage can occur.

MENU DEFAULTS

Any time a button labeled MENU appears on an LCD screen, you may access the menu system to confirm and/or customize any of the various system and CHART RECORDER settings. Each SPECTRUM is configured with defaults on each of the nine menus. These defaults can be changed at any time to individualize treatment.

See the MENU SYSTEM section of this manual for detailed instructions on using the menus.

1. Enter the menu system's Main Menu by touching a MENU button. Defaults for each menu are:

2. DATE & TIME MENU default option is the current date and time.

5000 models

3. LCD TRACES MENU default option displays all available channels, up to a total of four. If there are more than four monitoring channels, or not all channels are desired, then go to the LCD TRACES menu to verify or set the traces required. Assign their monitoring channels as they are to appear on the LCD/Touch Screen.

4. LCD GAINS MENU default option is set to MEDIUM gain for each selected channel.

5. CHART OPTIONS MENU allows the system to automatically print patient monitoring traces. Default is set to ON. To turn off the CHART RECORDER, go to the CHART OPTIONS MENU and set CHART ON/OFF to OFF.

6. CHART TRACES MENU default option is 2. Assign the monitoring channels that you want to appear on the CHART RECORDER printouts. Up to two traces may be displayed.

7. EEG DATA MENU default option is ON, with one channel of monitoring. Go to the EEG DATA menu to verify and set or change the EEG DATA options.

5000 models 8. EEG DATA MENU default option is set to ON, with 1 channel active.

9. PARAMETER SELECTION MENU default options for the Q and the M models are one millisecond Pulse Width; 90 Hertz frequency, 4 seconds duration and 800 milliamps of current. Four parameter ranges are available. Go to the PARAMETER SELECTION MENU to select a different parameter range.

Exit the menu system. Touch EXIT twice to return to the currently active display.

TREATMENT SETUP

After unpacking a new spECTrum, perform a visual inspection to note any possible damage that occurred during shipment.

spECTrum Preparation

Check all cables and leads for fraying, cracks or loose connections. Replace any damaged items. Verify that the cables are plugged into their proper (EEG/ECG) connectors. Verify proper match of colors on the EEG and ECG leads to the color dots on their Patient Safety Monitor cables.

WARNINGS:

- Use of patient cables with loose or faulty detachable leads may cause fluctuations of EEG and ECG waveforms due to intermittent lead connections. Check these connections frequently for integrity by wiggling the connections while observing their displayed traces. (A certain amount of trace fluctuation is to be expected when the wires are wiggled, but the trace should remain visible on the screen).
- For patient safety, use only MECTA electrode leads. Do NOT plug these electrodes into an AC mains outlet, or into any other equipment other than the spECTrum.

Power-Up Procedures

If all relevant materials have been received, the next step is the power-up procedure. When reading the steps described below, refer to the front and back panel diagrams when necessary.

1. Connect the Patient Stimulus cable to the spECTrum.

5000 models 2. Connect the Patient Safety Monitor cable(s) and EEG electrodeleads to the spECTrum.

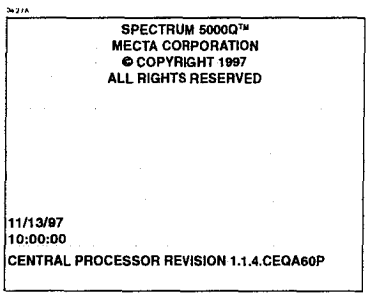
3. Connect the Optical Motion Sensor (OMS) (if used) to the proper front panel connector.

4. Confirm that CHART RECORDER paper is loaded.

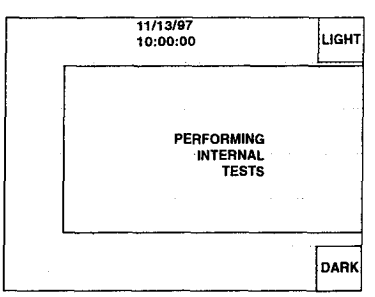
5. Push the POWER ON/OFF push button.

5000 models (5000 models only) Each time the machine is powered-up, the CHART RECORDER will print out a narrow, vertical solid-black bar, and model and version information. See the Printouts section for pictures and details. The solid black bar verifies correct operation of all printer pixels.

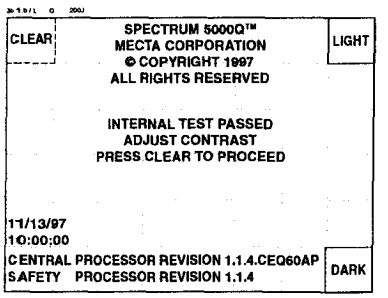
During the power-up steps, three tones will sound and the STIMULUS STATUS indicator on the front panel should flash yellow--green--red in quick succession, then go out. The LCD Screen will display messages stating that the internal tests have passed.



Copyright display



Internal Tests message



Copyright display

Contrast Adjustment

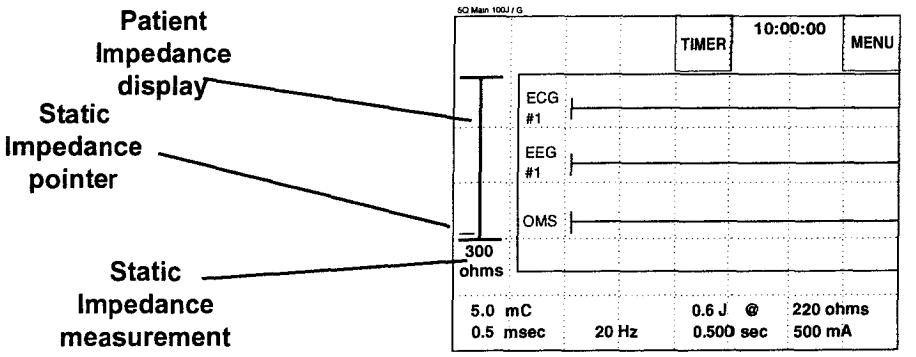
The LCD Screen may appear darker or lighter than necessary for comfortable use. The INTERNAL TEST display (pictured above) provides contrast control buttons (LIGHT and DARK) that allow 11 steps of contrast adjustment settings. Touch LIGHT to lighten the display, or touch DARK to darken it, until desired contrast is reached.

NOTE:

- If the display is so dark that it cannot easily be read at system power-up, the LIGHT and DARK buttons will still function even though they may not be visible. The user may still use them to correct the display's contrast.

Treatment Ready Display

Touch the CLEAR or EXIT button to proceed to the TREATMENT READY display. Directly below the Patient Impedance display is the static impedance measurement in ohms. This should be continuously updating and operating in the nominal range of 100 to 5000 ohms, when the stimulus electrodes are connected to the patient.



Treatment Ready display (5000 model)

This display shows the patient impedance and patient monitoring signals for up to four inputs at once, as selected on the LCD TRACE MENU. Traces will be visible only for those electrodes connected to the patient. When the STIMULUS STATUS indicator is illuminated "green", the STIMULUS CONTROL push button is active.

Touching the TIMER button toggles a stopwatch timer that can mark the extent and duration of any phenomenon the user may want to have specifically noted. Beginning and ending marks are also placed on the CHART RECORDER printout (if enabled). Touch the button again to stop timing.

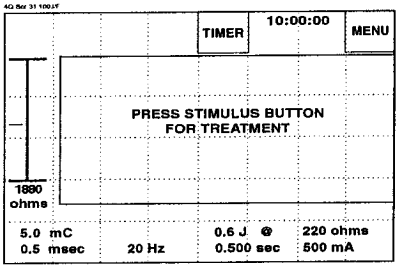
Touching the MENU button accesses the menu display system, where various system options may be set.

5000 models Trace selections will appear as set up in the LCD TRACES MENU.

The numbers at the bottom of the display are the stimulus parameter values. They are adjusted via the one (M model) or four (Q model) control knobs on the SPECTRUM front panel.

4000 models NOTE:

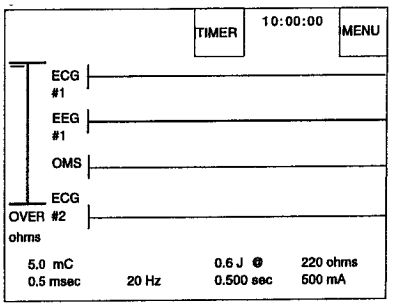
- 4000 models will show neither CHART RECORDER printouts, nor trace data, nor any of the following displays which show trace data.

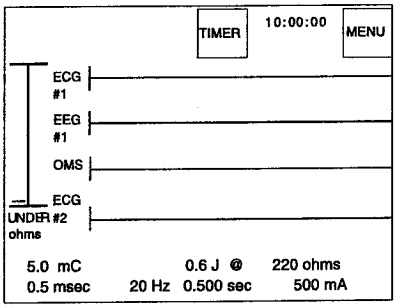


Treatment Ready display (4000 model)

If the static impedance is over 5,000 ohms, the measured value on the impedance display will indicate OVER. If it is below the nominal 100 ohm level, it will indicate UNDER. See the following TREATMENT READY displays:

5000 models

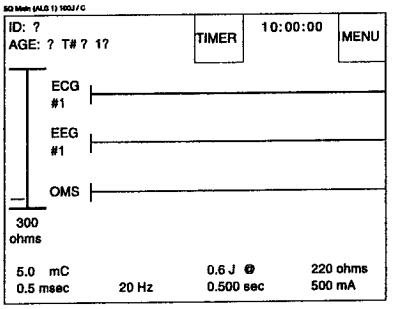


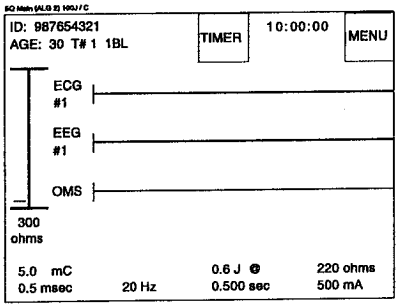


Displaying Patient Information on the TREATMENT READY display

If the optional EEG DATA feature is enabled in the EEG DATA MENU, the TREATMENT READY display will show patient and treatment session information (from the PATIENT DATA MENU).

5000 models





5000 models

If EEG DATA is set to ON, but no patient information has been entered, the TREATMENT READY display appears and displays "?" for all four values. In this case, the EEG DATA analyses will use default values.

NOTE:

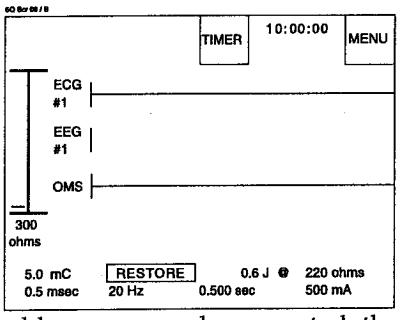
- Patient information entered in the PATIENT DATA MENU is erased on powering-down the SPECTRUM and must be re-entered for each new patient to prevent mis-identification. It will automatically be deleted 15 minutes after the SPECTRUM's last stimulus delivery.

CHART RECORDER checkout

Push the ON push button located on the CHART RECORDER if an immediate printout is desired. Push the Recorder's OFF push button to stop printing.

Leads Off Indication

If a monitoring channel is selected for display on the LCD/Touch Screen, or selected for printing on the CHART RECORDER, and the corresponding disposable electrode pad monitor lead or cable is not connected to the SPECTRUM, the corresponding trace will disappear from the LCD/Touch Screen, and a RESTORE button will appear. In the display example below, EEG#1 lead is disconnected.



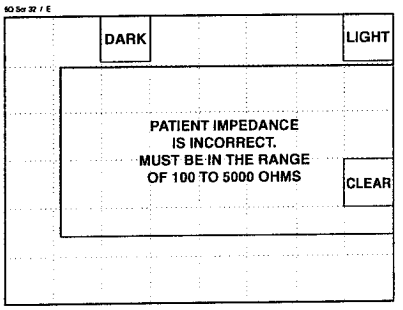
When all selected leads and cables are properly connected, the traces should all reappear, and the RESTORE button should disappear. If not, touch the RESTORE button. If the traces still do not reappear, there is still a problem with the lead or cable(it could be broken, for example).

TREATMENT DELIVERY

Impedance Self-Test Safety Feature

With the stimulus electrodes not connected to the patient, and the Patient Impedance display showing OVER, push the STIMULUS CONTROL push button as though attempting a treatment.

The following error message should appear. Touch the CLEAR or EXIT button to clear the error message, and return to the TREATMENT READY display. The SPECTRUM will only deliver a stimulus if the static impedance is greater than 100, and less than 5,000 ohms.



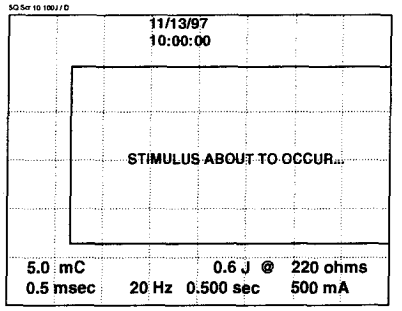
Stimulus Control Procedures

The stimulus delivered during treatment is a constant current bipolar pulse wave. The four stimulus parameters that specify the generated waveform include: PULSE WIDTH, FREQUENCY, DURATION, and the constant CURRENT. The actual voltage of the pulses will depend on the load impedance (patient impedance) during the stimulation.

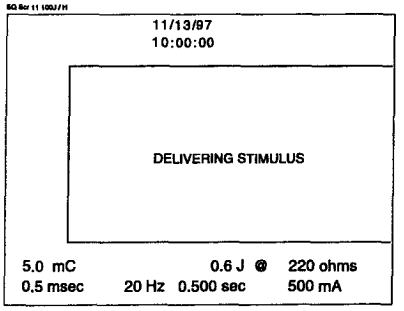
Q models All four parameters have adjustable settings. These knobs are located on the SPECTRUM's front panel just below the LCD Screen, and are labeled accordingly.

M models One STIMULUS INTENSITY knob varies the stimulus parameters. The corresponding values are then displayed on the LCD Screen.

To initiate a stimulus, set each of the stimulus parameter controls to the desired level. Push and HOLD the STIMULUS CONTROL push button during the three warning tones, and then for the duration of the stimulus, or the constant tone. The following messages will appear on the LCD Screen:



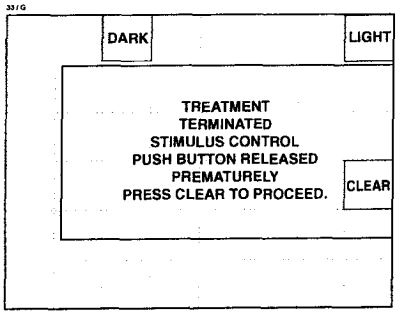
Stimulus Warning display



Delivering Stimulus display

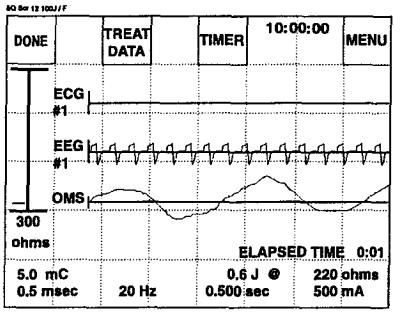
The CHART RECORDER will also start printing data (if enabled in the CHART OPTIONS MENU).

If the STIMULUS CONTROL push button is pushed and released before the stimulus is delivered or completed, a "Premature Release" message appears (as below). Touch the CLEAR or EXIT button to continue.



TREATMENTS REPORTS

When stimulus delivery is complete, the POST TREATMENT TRACE display will show the trace data.



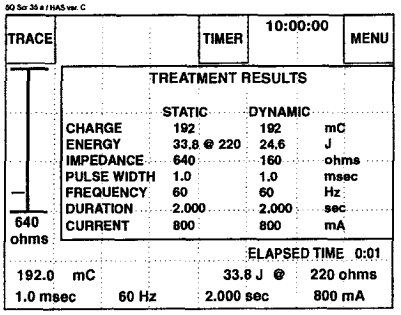
Post Treatment Trace display

The traces being monitored reflect user choices which are set in the LCD TRACE MENU.

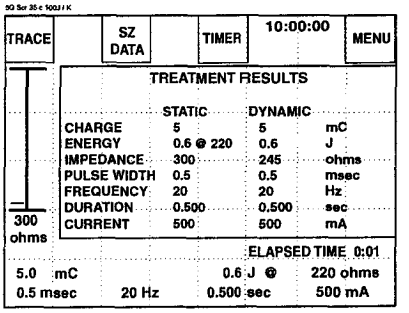
Patient physiological traces are displayed until the DONE button is touched. If the CHART RECORDER is set to ON, they will also be printed on chart paper. The STIMULUS CONTROL push button remains active, and the sPECTRUM is ready to deliver additional treatments, until the DONE button is touched. The DONE button initiates a new set of internal tests, stops the CHART RECORDER trace printout, and initiates the post-treatment printouts. Then the system returns to the TREATMENT READY display.

The time elapsed since completion of the most recent treatment is shown in the lower right corner of the display.

Touch the TREAT DATA button on the POST-TREATMENT TRACE display to access the TREATMENT RESULTS display, showing TREATMENT RESULTS for the last treatment.



Treatment Results display



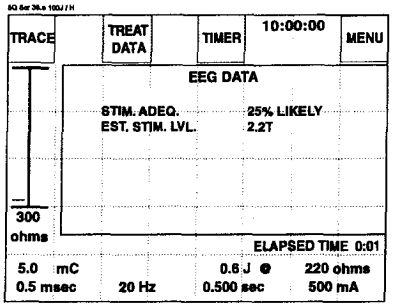
Treatment Results SZ display

The data headings on the TREATMENT RESULTS display are:

- STATIC, indicating what treatment setting levels were specified. This column gives the control settings used, and the energy that was expected to be delivered based on those settings and an assumed 220 ohm impedance.
- DYNAMIC, indicating the actual electrical parameters delivered in the last stimulation, including the actual dynamic impedance and the actual energy. In the event of a premature termination, this column shows the electrical parameters administered before the stimulus was aborted.
- ELAPSED TIME, indicating the number of seconds passed since the end of the last stimulus.

5000 models

If the optional EEG DATA feature is enabled, the TREATMENT RESULTS display will appear with the extra SZ DATA button present (as above right). Touching this button will bring up the EEG DATA display.



EEG Data display

Touch this display's TRACE button to return to the POST-TREATMENT TRACE display.

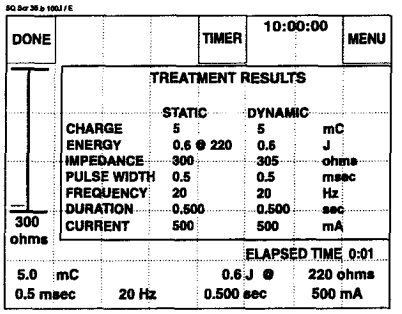
Then, touch either the DONE button on the POST-TREATMENT TRACE display, or the CHART RECORDER's OFF push button. In either case, the CHART RECORDER will stop printing trace data and will print the treatment results and EEG data.

NOTE:

- Many practitioners routinely choose to get treatment results and EEG Data from the CHART RECORDER printout, rather than from the LCD/Touch Screen display of this information, which must be manually transcribed.

4000 models

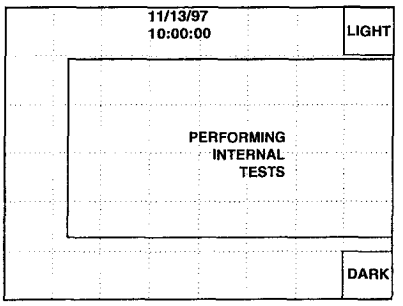
When stimulus delivery is complete using a 4000 model, it will display its TREATMENT RESULTS display.



The data headings on the TREATMENT RESULTS display are:

- STATIC, indicating what treatment setting levels were specified. This column gives the control settings used, and the energy that was expected to be delivered based on those settings and an assumed 220 ohm impedance.
- DYNAMIC, indicating the actual electrical parameters delivered in the last stimulation, including the actual dynamic impedance and the actual energy. In the event of a premature termination, this column shows the electrical parameters administered before the stimulus was aborted.
- ELAPSED TIME, indicating the number of seconds passed since the end of the last stimulus.

Touch the DONE or EXIT button on the TREATMENT RESULTS display and the INTERNAL TESTS display will appear.



After completing the internal test, the spECTrum will return to the TREATMENT READY display. At this point, the spECTrum is ready to begin a new treatment sequence. This cycle of treatment and monitoring may be repeated as often as necessary.

Menu System

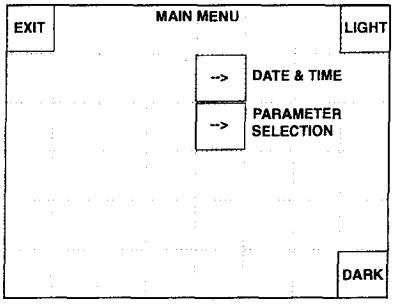
Menu System

The menu system allows customization of many SPECTRUM features. It may be accessed by touching the MENU button whenever it is present in the upper right corner of the LCD/Touch Screen.

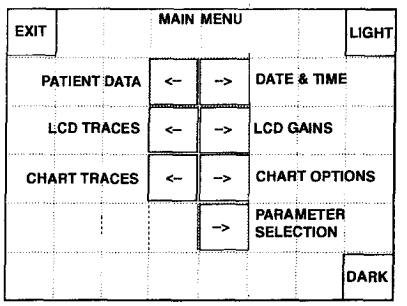
MAIN MENU

5000 and 4000 models with Touch Screen;
4000 models with Membrane Switch Front Panel, go to Parameter Selection Section

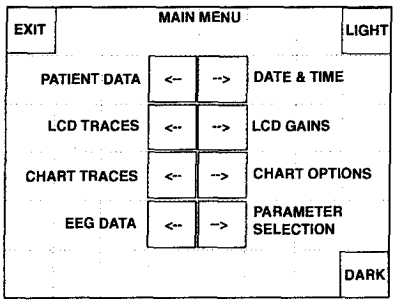
When entering the menu system, the MAIN MENU is the first to appear. The 5000 model MAIN MENU provides eight options for control of the display and processing of the physiological monitoring signals and the selection of the energy parameter set.



Main Menu (4000 Series)



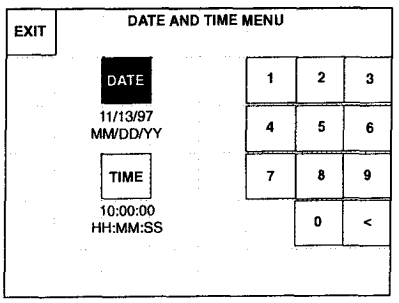
Main Menu (5000 Series)



Main Menu (with EEG DATA option)

DATE AND TIME MENU

Touching the DATE & TIME button on the MAIN MENU displays the DATE AND TIME MENU.



Initially, the DATE button is highlighted to indicate that touching any of the keypad buttons will

change the date. Enter the month, day, and year, each as a two digit number (enter a 0 first if needed). The "<" button erases the previously entered digit. The new date will appear under the DATE button as it is entered.

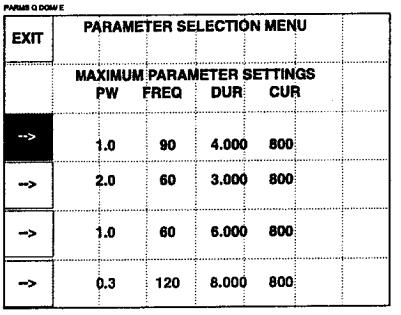
Touching the TIME button switches to time entry. The TIME button will be highlighted to indicate time entry. Enter the hours, minutes, and if desired, seconds, each as a two digit number (enter a 0 first if needed). The new time will appear under the TIME button as it is entered.

The SPECTRUM's clock is always on, even when the SPECTRUM's power is off and it is unplugged from the AC mains outlet. Hence, use of this MENU should be very rare. When done entering the date and time, touch the EXIT button to return to the MAIN MENU.

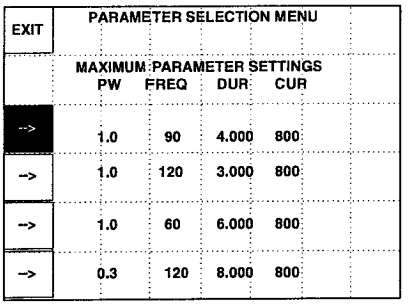
PARAMETER SELECTION MENU

(All models)

Touching the PARAMETER SELECTION button on the MAIN MENU displays the PARAMETER SELECTION MENU.



Q model menu



M model menu

This menu allows selection of the desired parameter ranges for the stimulus delivery. The parameters shown on this menu vary according to the SPECTRUM model in use. The highlighted arrow indicates the parameter set currently selected. Having selected a particular option, no treatment parameter will be allowed to exceed the value shown in the selected option. The SPECTRUM will retain the selected parameter set option until changed via this menu, even if its power is turned off and it is unplugged from the AC mains outlet.

Touch the EXIT button to return to the MAIN MENU.

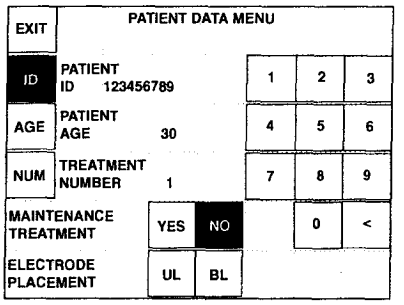
Membrane Switch 4000 models

Push the MENU button repeatedly to cycle through the available selections.
Touch EXIT to return to pretreat screen.

PATIENT DATA MENU

Touching the PATIENT DATA button on the MAIN MENU shows the PATIENT DATA MENU.

This menu provides for entry of a number of types of patient related information. This optional information may be printed by the CHART RECORDER (see CHART OPTIONS MENU for details), and is used by the EEG DATA option (see EEG DATA option section of this manual).



To enter the PATIENT ID, highlight the ID button by touching it (if not already highlighted). Then enter the PATIENT ID using the numeric keypad buttons on the right side of the display. Up to nine digits may be entered. The new entry will appear to the right of *ID* as it is entered.

To enter the PATIENT AGE, highlight the AGE button by touching it (if not already highlighted). Then enter the PATIENT AGE using the numeric keypad buttons on the right side of the display. The new entry will appear to the right of AGE as it is entered.

To enter the TREATMENT NUMBER, highlight the NUM button by touching it (if not already highlighted). Then enter the TREATMENT NUMBER using the numeric keypad buttons on the right side of the display. If this is the first treatment in a series, enter 1, etc. The new entry will appear to the right of NUMBER as it is entered. If this series of treatments is a maintenance series, touch the YES button in the MAINTENANCE TREATMENT section. If not, touch the NO button.

To select for ELECTRODE PLACEMENT, touch either the UL (unilateral) or BL (bilateral) button. The selected button will highlight when touched, showing which option is active.

If the EEG DATA option has been purchased, and its button has been made active via the MAIN MENU, the system will display this patient data on the TREATMENT READY display, and on the CHART RECORDER printout.

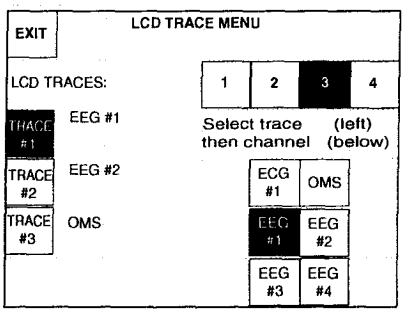
Information entered in this menu will not be saved when the SPECTRUM power is turned off. Further, it will automatically be erased under certain conditions to prevent accidental use of the same information with two different patients. Erasure will occur when in the TREATMENT READY display if a stimulus has been delivered (after the information was entered) and 15 minutes has elapsed since the last stimulus was completed.

When the patient data has been entered, touch the EXIT button to return to the MAIN MENU.

5000 models

LCD TRACE MENU

Touching the LCD TRACES button on the MAIN MENU displays the LCD TRACE MENU.



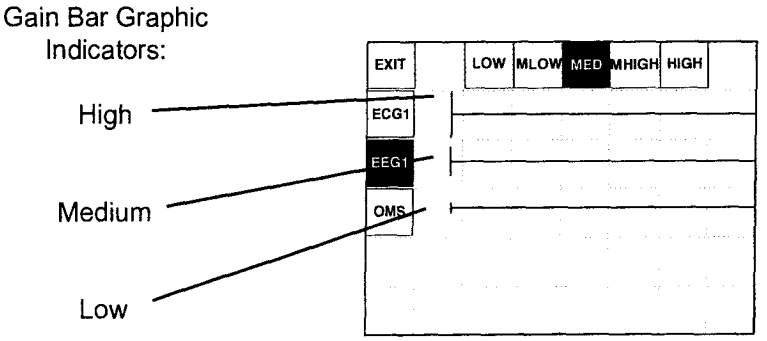
This menu controls the appearance of the LCD/Touch Screen trace displays. In particular, it is used to specify how many traces will be displayed, and which physiological monitoring channels will be displayed.

Touching one of the top row of numbered buttons specifies and highlights how many traces will be displayed.

On the left side of the display, a vertical row of numbered trace buttons and labels appears, one for each authorized trace. In the lower right section of the display is a list of the physiological monitoring channels available for display. Touching a numbered trace button on the left side selects that trace for assigning its monitoring channel. Touching any button in the list of available channel buttons assigns that channel to the selected trace. The currently selected channels are identified to the right of the numbered trace buttons. If desired, a monitoring channel may be displayed more than once. This could be done to display the same channel at two different gain settings. When done entering the trace specifications, touch the EXIT button to return to the MAIN MENU.

LCD GAINS MENU

Touching the LCD GAINS button on the MAIN MENU displays the LCD GAINS MENU.



This menu controls the amplification (gain) applied to each of the trace signals before it is displayed. The displayed traces are those previously specified in the LCD TRACE MENU. Touching one of the trace label buttons on the left side of the display highlights the button and selects that trace for gain adjustment. For each trace, five different gain settings are available as indicated by the row of gain buttons along the top of the display. Touching one of these buttons applies that gain to the signal. The displayed trace immediately shows the effects of the gain change. Addi-

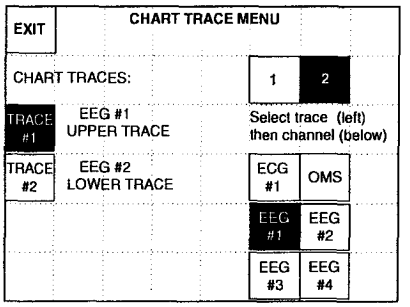
5000 models

tionally, the length of the vertical bar to the left of the trace changes to reflect the gain: shorter lengths for lower gains and longer lengths for higher gains. These vertical bars appear on all trace displays to indicate the current gain setting for that trace.

When finished specifying the gain specifications, touch EXIT to return to the MAIN MENU.

CHART TRACE MENU

Touching the CHART TRACES button on the MAIN MENU displays the CHART TRACE MENU.

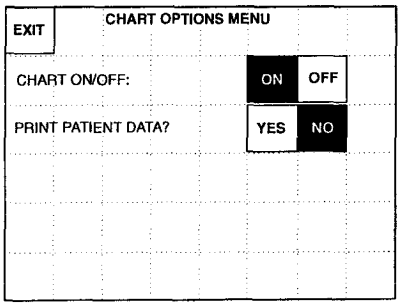


This menu controls the appearance of the CHART RECORDER trace printouts. In particular, it specifies whether one or two traces will be printed, and which physiological monitoring channel will be printed by each trace. Touching one of the top row of numbered buttons specifies and highlights how many traces will be printed.

On the left side of the display, a vertical row of numbered trace buttons and labels appears, one for each authorized trace. In the lower right section of the display is a list of the physiological monitoring channels available for display. Touching a numbered trace button on the left side selects that trace for assigning its monitoring channel. Touching any button in the list of available channels assigns that channel to the selected trace. The currently selected channels are identified to the right of the numbered trace buttons. When done entering the trace specifications, touch the EXIT button to return to the MAIN MENU.

CHART OPTIONS MENU

Touching the CHART OPTIONS button on the MAIN MENU displays the CHART OPTIONS MENU.



This menu controls the use of the CHART RECORDER.

The CHART ON/OFF option enables or disables future CHART RECORDER use. The button does not take effect immediately. Any current printing will continue to its normal completion. When OFF is selected, the ON and OFF buttons on the CHART RECORDER are disabled, as well as all future automatic printouts.

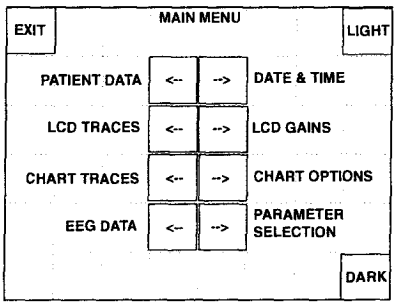
5000 models The PRINT PATIENT DATA option enables or disables the automatic printing of the patient data entered in the PATIENT DATA MENU. When enabled, this data prints after the treatment results when the LCD/Touch Screen DONE button is touched, or the CHART RECORDER OFF button is pushed. If the EEG DATA ANALYSIS option is in use, the patient data prints automatically (regardless of the setting of this option) after each treatment. (See the EEG DATA option section of this manual for details.)

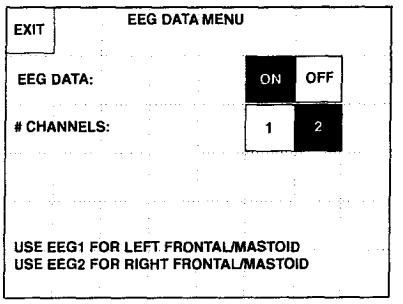
See the CHART RECORDER section of this manual for details of the CHART RECORDER printouts.

When done entering chart options, touch the EXIT button to return to the MAIN MENU.

EEG DATA MENU

When the EEG DATA option is present in the SPECTRUM, the MAIN MENU displays an EEG DATA button (below left). Touching the EEG DATA button displays the EEG DATA MENU (below right).





The ON/OFF buttons enable or disable the EEG DATA processing. A dark button with the light lettering indicates the current state.

The numbered buttons select the number of EEG monitoring channels being used: 1 for EEG1 only (left frontal/mastoid location), and 2 for EEG1 (left frontal/mastoid location) and EEG2 (right frontal/mastoid location).

When done entering the EEG DATA, touch the EXIT button to return to the MAIN MENU.

Error Messages

Error Messages

The SPECTRUM reports error conditions encountered during treatments, and directs the user to solutions. The displays stay visible until cleared by touching the CLEAR or EXIT button.

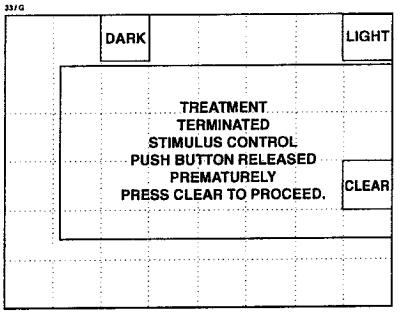
NOTE:

- The STIMULUS CONTROL push button, parameter knobs, and other functions are disabled until the CLEAR button is touched. For some types of errors, the STIMULUS CONTROL push button may remain disabled until the DONE button is touched.

CLINICAL ERRORS

This series of errors is related to the operation or clinical use of the machine, and can be corrected by the user. These errors will disable the STIMULUS CONTROL push button (the STIMULUS STATUS indicator will go out), until the CLEAR or EXIT button is touched.

Premature Release error message

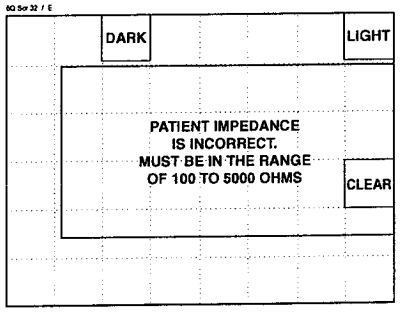


This error is generated by pressing the STIMULUS CONTROL push button, but releasing it before the stimulus delivery has completed. Thus, the stimulus is prematurely terminated.

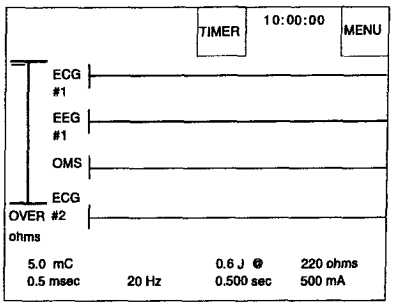
5000 models

The CHART RECORDER will finish printing the SELF TEST RESULTS. Then, if the button was released before the stimulus delivery began, it will stop printing. However, if the Stimulus Control is released prematurely during the passage of a stimulus, the same error message will appear, but the CHART RECORDER will start printing the monitoring traces. The TREATMENT RESULTS will accurately report the true duration of the delivered stimulus.

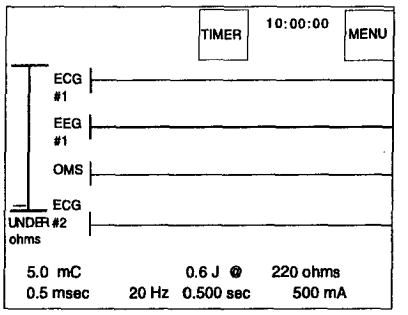
Patient Impedance error message



This message occurs when a stimulus is attempted while OVER or UNDER appears on the graphical impedance display. This error is usually due to improper or poor stimulus electrode connections to the patient (shorted or broken wires, too much or too little gel, etc.).

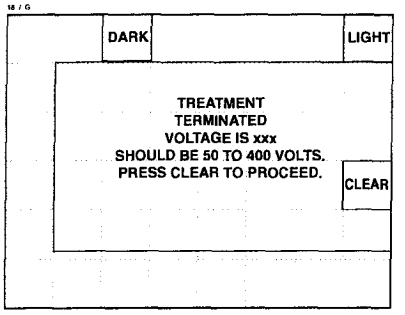


OVER condition



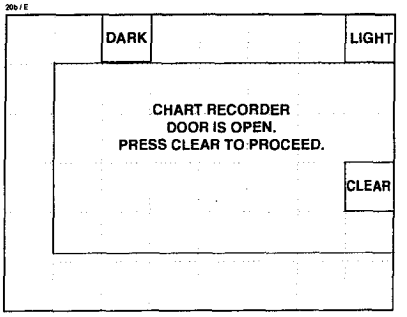
UNDER condition

Treatment Voltage error message



This error occurs because the voltage applied to the patient during treatment is out of the allowed range (> 400V). This ordinarily is caused by improper or poor electrode connection to the patient, including removing the hand-held electrodes prior to the end of the treatment duration. Again, if this high impedance condition occurs during the passage of the stimulus, the TREATMENT RESULTS will report the accurate values for the portion of the stimulus that was delivered.

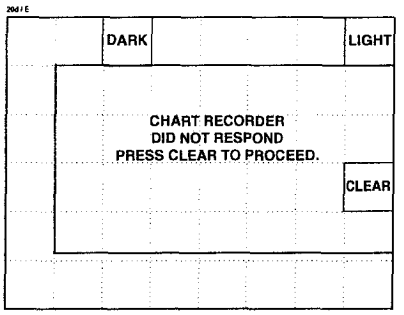
Recorder Door error message



This error occurs when the CHART RECORDER door is opened.

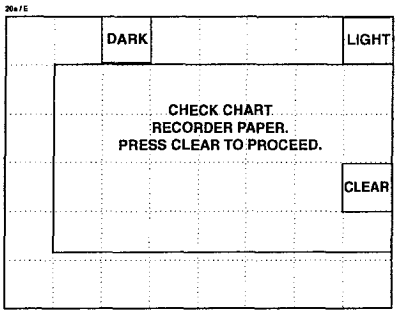
Press the paper compartment door to ensure it is properly reseated. Then touch CLEAR or EXIT button to resume work.

Recorder Not Responding error message



This message occurs when the system, on powering up, runs its internal tests and finds the CHART RECORDER out of service (door open, paper out, etc.). Adjust paper supply, printer door, etc., and touch CLEAR.

Recorder Paper error message



This error occurs when there is a problem with the paper in the CHART RECORDER. Push the CHART RECORDER door latch to access the paper roll mechanism, and replace or straighten the paper in the transport path, with a bit of paper exiting the door.

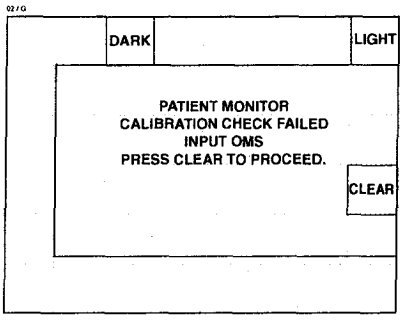
NOTES:

- Be sure the paper spools off the bottom of the roll when placed in the CHART RECORDER (when the door is open and the paper is loaded), and then is fed upward to the exit gate.
- When the paper spool is almost empty, a colored line appears in one of the strip's margins. This indictates that there is about 10 feet of paper (two minutes) left on that roll.

TECHNICAL ERRORS

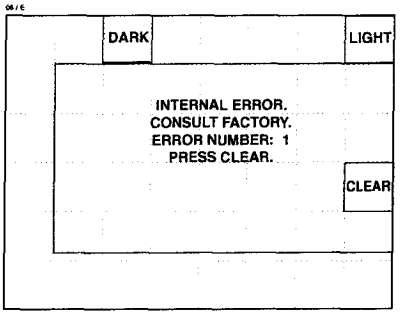
This series of errors is related to the operational or physical condition of the machine. Some of these can be corrected by the user; some will require factory involvement. If the error occurs repeatedly, the user should contact MECTA for assistance.

Patient Monitor Calibration Check display



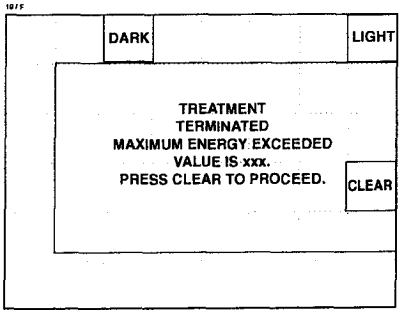
This screen reports on the status of the calibration check that the system performs on the patient monitoring module (5000 model only). It is an announcement only, and does not affect the stimulus delivery system.

Numbered Error display



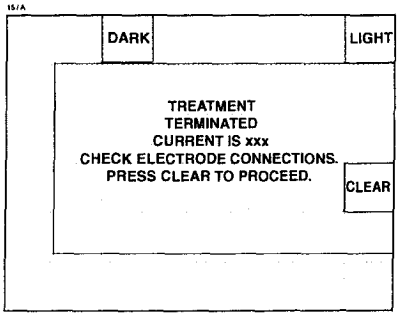
Numbered error messages similar to the above format may occur, but should be rare. If one occurs repeatedly, turn the SPECTRUM off, then on again. If it persists, contact MECTA or your local distributor for assistance.

Treatment Energy error message



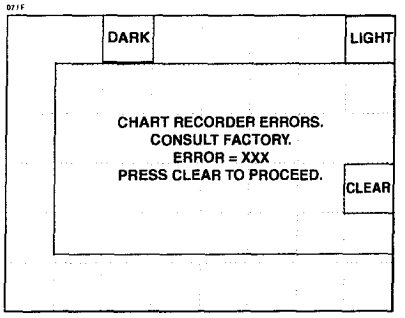
This error occurs because the energy delivered to the patient has exceeded the maximum allowed energy prior to completing the selected stimulus duration. This usually indicates a poor electrode connection to the patient.

Treatment Current error message



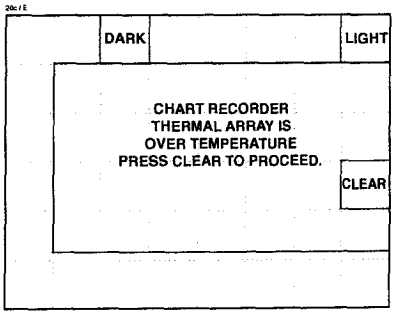
This error may occur if the STIMULUS CONTROL push button is released prematurely.

CHART RECORDER Errors



This error occurs when multiple simultaneous errors occur on the CHART RECORDER. It may be necessary to turn the SPECTRUM off and on before the CHART RECORDER will print data.

Internal error message



This message indicates the CHART RECORDER is out of service until it cools down.

Cleaning and Servicing

Cleaning and Servicing

CLEANING

Cleaning Recommendations

The SPECTRUM should be wiped with a nearly-dry cloth containing one of the mild cleaning solutions recommended below. Thoroughly wipe off any excess residual cleaning solution from the unit's case. Do not allow cleaning solution or water to run into crevices or connector openings. Use only recommended cleaning agents.

While cleaning the SPECTRUM, it should be checked for unusual wear or possible damage from an accident.

CAUTION:

- Do not autoclave the SPECTRUM or its accessories.

These cleaning agents are acceptable*:

--warm water	--Fantastik ®	--Hydrogen peroxide solution
--Windex ®	--Liquid soap	--Cidex ®
--Wex-cide (1)	--T.B.Q. ® (2)	--Formula 409 ®

* SPECTRUM units may be disinfected to comply with OSHA requirements for cleaning and decontaminating spills of blood and other body fluids. (Federal OSHA standard on bloodborne pathogens: 29 CFR 1910.1030, 12/6/91.)

(1) Wex-cide (Wexford Labs, Inc. Kirkwood, MO.)
and
(2) T.B.Q. (Calgon Vestal Labs, Calgon Corp, St. Louis, MO)
are disinfectants that meet the OSHA requirements, are EPA approved, and will not harm the outside of the SPECTRUM. The disinfectants should be wiped away with a water-dampened cloth after the manufacturer's recommended period of time. Do not immerse the SPECTRUM in water.

NOTE:

- If moisture gets into the SPECTRUM's connectors, they must be dried with warm air. Then do a functional checkout of the affected functions to verify proper operation.

These cleaning agents are NOT acceptable:
(Some may damage the SPECTRUM; others are toxic to users)

--Acetone	--Mild chlorine bleach solution	--Butyl alcohol
--Misty	--Denatured ethanol	--Staphene
--Enviroquat	--Glutaraldehyde	--Isopropyl alcohol
--Trichloroethane	--Trichloroethylane	

Cleaning Electrodes and Sensors

• ECT ELECTRODES: Stimulus electrodes should be cleaned after each use. Wipe paste and gel residue off with a soft cloth, then wash with a mild soap solution. Rinse the electrodes with water to remove soap residue. Allow to air dry. Be sure electrodes are clean and dry before preparing them for the next treatment.

• OMS SENSOR: OMS sensors should be cleaned after each use. Place the sensor into a pan containing Manuklenz™, or an equivalent mild soap solution, and clean the strap portion with a soft-bristle brush. Rinse the OMS sensor with water to remove soap residue, then dry with a soft, clean cloth. Clean the metal "sensor" area with a 70% isopropyl alcohol wipe.

Cleaning Cables and Accessories

Cables and accessories can be wiped with a damp cloth moistened in a mild detergent solution, or according to the manufacturer's instructions. All cables should be checked for fraying or cracking. All damage should be reported to the biomedical department or biomedical repair service person.

Cleaning Bite Blocks

• STEAM (AUTOCLAVING) METHOD:

Latex and Red Rubber products (e.g., Endotracheal tubes, urology catheters)
Sterilize at 121°C (250° F) for 15 minutes. Avoid contact with instruments or any metal objects. Allow to dry and recover for 48 hours.

• ETO GAS (ETHYLENE OXIDE) METHOD:

Latex, Black Rubber, Red Rubber and Silicone products
On face masks, plugs must be removed and luer caps on red rubber E.T. tubes left open. Even so, if the vacuum cycle is too rapid, damage may result. So care must be taken during the evacuation cycle.
In other respects, all re-useable products are suitable for ETO gas sterilization. The usual is an ethylene oxide mixture at 125° but the sterilizer manufacturer's recommendations must be followed.

• COLD METHOD

All products: (except Laryngoscopes)
Cidex and Sporidicin have been tested, and have been found to be compatible with the materials we use. Sterilants based on phenol compounds are not suitable.
Follow the sterilant manufacturer's guidelines carefully.

1. Immerse product fully in the solution, ensuring displacement of trapped air.
2. Soak for 10-15 minutes to disinfect.
   Soak for 10-15 hours to sterilize.
   (This is based on Arbrook's claims for Cidex)
3. Remove products and allow to drain.
4. Rinse in sterile water for at least five minutes.
   Traces of Cidex may be removed by rinsing in a solution of sodium bisulfate, 1 tablespoon per gallon of sterile water. Then rinse in running sterile water.
5. Blot dry on a sterile field.
6. Allow rubber and latex at least 48 hours to dry and recover elasticity.

RECOMMENDED SERVICING

MECTA Corp. recommends that the Functional Performance Verification, outlined in the SPECTRUM Service Manual be performed every six months or according to hospital protocols.

If the unit is dropped or suspected of damage or rough handling, do all safety leakage checks and all functional verifications. If there is a suspected malfunction with all or part of monitoring or ECT parameters, do functional verifications and calibration checks of all suspected parameters. If the unit does not pass the functional verification or calibration checks, see Service Manual's Calibration section. A Service Manual containing the safety checks is available from MECTA.

At least every two years, a factory-performed Quality Control Check should be performed which includes the following tests:

- Visual inspection
- Functional testing
- Operational testing
- Verification to specification
- Safety tests
- Required calibration
- Identification of components that are worn or in need of replacement
- Central and Safety Processor software will be upgraded to the current versions.

Rental units are available if required. Contact MECTA's Service Department to schedule.

DEVICE DISPOSAL

The SPECTRUM devices should be recycled at the end of their useful lifetime, according to the local/national legal regulations/laws. If there are no local recycling facilities available, units can be returned to MECTA for recycling.

Safety Cautions

All SPECTRUM users should read this summary. Specific warnings and cautions are found throughout the SPECTRUM documentation, where they apply.

CAUTIONS:

- Federal law restricts this device to sale by or on the order of a physician.
- Hospital-grade plug grounding integrity can only be maintained when equipment is connected to a receptacle marked "hospital-grade". A Potential Equalization has been provided to reduce leakage currents if required.

PATIENT SAFETY

- To ensure patient safety, use only accessories recommended or supplied by MECTA Corp. Accessories must be used according to your hospital's standards, and the manufacturer's recommendations. Always refer to the manufacturer's directions for use.
- Connect no more than one patient to the SPECTRUM patient monitoring inputs at any one time.
- Do not allow the conductive parts of any accessory, or any EEG/ECG electrodes applied to a patient to come into contact with other conductive parts, such as grounded objects.
- Locate the SPECTRUM where it cannot harm patients or personnel if it should fall.
- Use only parts and accessories supplied (or recommended) by MECTA, and use them only as directed in SPECTRUM's manuals and technical bulletins.
- The Electrocardiograph incorporated in the 5000 series units IS NOT SUITABLE FOR DIRECT CARDIAC APPLICATION.
- During stimulation, keep the discharge electrodes away from ECG or other electrodes, as well as other conductive parts which are in contact with a patient. Also, avoid contact with the OMS (Optical Motion Sensor).
- Never apply the ECT output in such a way that the patient's heart is close to the electrical pathway between the ECT electrodes. When applied in this manner, the ECT output may cause the patient's heart to go into fibrillation. Never use a SPECTRUM to attempt defibrillating a patient.
- Avoid delivering stimulus over or near a defect in the skull of the patient.
- The SPECTRUM produces no alarms or heart-rate indicators that are affected by pacemakers. The presence of a pacemaker will be detectable in the ECG channel, and some artifact may show up in the EEG channels. The attending physician should be aware of these facts, and take them into account when analyzing patient data. The MECTA device is safe for use with properly functioning internal cardiac pacemakers. Certain Demand Pacemakers should be converted temporarily to a fixed mode at the time of the treatment, using a magnet. Check with the appropriate medical specialist if there are any questions.

DEVICE/OPERATOR SAFETY

- Place the unit and accessories in locations where they cannot harm the patient or operator should they fall off their shelf or mount.
- Frequently inspect all power cords, electrode wires, and cables for fraying and/or other damage. Do not use an accessory which shows physical damage.
- Refer malfunctioning, dropped or damaged SPECTRUM devices/accessories only to qualified MECTA service technicians, especially while under warranty.
- Do not autoclave a SPECTRUM or its accessories except as directed. Autoclaving can cause severe damage.
- Do not allow Hand-Held (or other ECT) treatment electrodes to come in contact with any monitoring electrodes.

5000 models

- (5000 models only) If a patient must be defibrillated while the SPECTRUM patient monitoring is connected, keep the discharge paddles away from ECG electrodes, as well as from other conductive parts in contact with the patient. During defibrillation, avoid operator contact with any of the SPECTRUM's cables or accessories.
- EEG/ECG Patient Monitor cables must contain 1K series current-limiting resistors to protect the SPECTRUM unit from damage and possible patient burns during defibrillation. Use only MECTA monitoring cables.
- If a patient is defibrillated while monitoring electrodes and cables from the SPECTRUM are connected, allow 30 seconds for monitoring channels to return to normal functionality.
- Staff holding hand-held electrodes or the patient's head during stimulus should wear non-conductive gloves. Otherwise, staff should take care to keep well clear of stimulus electrodes during the passage of electricity to the patient.
- To ensure patient safety, use only accessories recommended or supplied by MECTA Corp. Accessories must be used according to your hospital's standards, and the manufacturer's recommendations. Always refer to the manufacturer's directions for use.
- A product that has been dropped or severely abused should be checked by qualified service personnel to verify proper operation and acceptable risk (leakage) current values.
- If the SPECTRUM detects an unrecoverable problem, an error message appears, containing an error number. If cycling the power OFF/ON does not clear the problem, report such messages to MECTA Corp.
- The SPECTRUM is a constant-current device. Therefore patient impedance affects the output voltage. Please refer to the output wave forms shown in the manual.
- ECG traces are removed from the LCD/Touch Screen and CHART RECORDER when the signal levels are invalid.
- While the device minimizes the risk of burns when used with specified cables and HF surgical equipment, it is strongly advised that electrodes not be placed near an electrocautery site.

NOTE:

- Within certain governmental jurisdictions, all interconnected accessory equipment must be labeled by an approved testing laboratory. After interconnection with accessory equipment, risk (leakage) current and grounding requirements must be maintained.

GENERAL SAFETY

- Do not operate the SPECTRUM in the presence of flammable chemicals/gases (including flammable anesthetics), or an explosion could result.
- Do not operate the SPECTRUM or any of its cables in an MRI location or in a hyperbaric chamber (or other oxygen-enriched atmosphere). The equipment may be damaged and the patient burned by the cables, or fire may result.
- While delivering treatments, do not touch the conductive (metal) portions of the stimulus electrodes. To ensure patient safety, the conductive parts of any EEG/ECG electrode (including their associated connectors and/or leads), the metal body of the OMS, or other patient-applied parts should not contact other conductive parts, including earth ground, at any time.
- While the SPECTRUM complies with the applicable electromagnetic compatibility standards, operation of cellular telephones or other two-way radios in near proximity to the SPECTRUM may cause measurment errors, interface problems, or equipment malfunctions.
- Stimulus electrodes should be cleaned after each use. Please see Cleaning section.
- The Electrocardiograph incorporated in the 5000 series units IS NOT SUITABLE FOR DIRECT CARDIAC APPLICATION.
- MECTA Corp. recommends that the functional performance tests (which include safety tests and functional verification) be performed on a bi-annual basis.

The warranty period of the SPECTRUM is one year. During that period, DO NOT attempt or allow repairs on the SPECTRUM. Call MECTA Technical Support to arrange factory service. It is recommended that only qualified personnel perform any repairs to the SPECTRUM when the warranty period has elapsed.

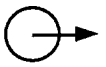
The MECTA units should be shipped in the original packaging only. WARRANTY WILL BE VOIDED IF THE SPECTRUM IS NOT RETURNED IN ITS ORIGINAL CONTAINER, WITH ITS ORIGINAL FOAM PACKAGING.

SYMBOLS

These internationally recognized symbols are defined by the International Electrotechnical Commission, IEC 878 and IEC 417A.
Symbols used on the front and rear SPECTRUM panels may be understood as follows:

On/Off push button

For continued fire protection, use only the specified fuse



Signal output

Type BF isolated defibrillation protected patient connection

Type BF isolated patient connection

Equipotential Post

See Operating Instructions

Graphical Recorder

Adjustable input

Alternating current

"On" (only for CHART RECORDER)

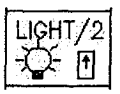
"Off" (only for CHART RECORDER)

ms	Pulse width in milliseconds
Hz	Frequency in Hertz
s	Duration in seconds
mA	Current in milliAmps
CH A	Chart Channel A's Gain setting dial.
CH B	Chart Channel B's Gain setting dial.
CE0197	TÜV Rheinland Annex II, Article 3 ISO 13485:1996 ISO 13485:2000 "Type tested" in Munich, Germany by TÜVPS.

4000 Membrane Switch Symbols

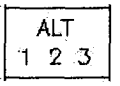
Enter the Menu system

TIMER Start/Stop or "1" if ALT button pressed at the same time



Increase brightness or "2" if ALT button pressed at the same time

Decrease brightness or "3" if ALT button pressed at the same time



Select ALT button definitions. Change TIMER to "1", LIGHT to "2" and DARK to "3".

Exit the Menu or DONE with treatment or CLEAR

Spectrum Specifications

spECTrum Specifications

All specifications are nominal and subject to change without notice.

ECT FEATURES

Pulse Configuration	Constant current, bi-directional, square pulses
Internal Tests	Treatment pulses into internal 300Ω load and checked for pulse width, frequency, duration and energy. Safety features are also self-tested.
Energy Measure	Delivered energy is measured, based on actual current and voltage delivered in each pulse, so as to be inherently correct for entire range of dynamic patient impedance.
Patient Impedance Range (to start)	100-5000 ohms nominally.
Allowed Voltage Range for proper ECT delivery	50-400 volts.
Protection	Protected against paddle-to-paddle or other short-circuit conditions, and open circuit conditions.
Visual Indicator	Three-color LED gives green for Stimulus Control enabled; yellow for Treating; red for Stimulus Delivery fault.
Audible Indicator	Tones provided for pre-treatment and treatment warnings.

LCD DISPLAY SPECIFICATIONS

Type	Blue and white FSTN with cold-cathode backlight
Dimensions	3.4 x 4.6" (5.7" diagonal)
Resolution	240 (v) x 320 (h) pixels
Contrast adjustment	via buttons LIGHT/DARK
Display sweep speed	25mm/second

POWER REQUIREMENTS

115 volts nominally, 50/60 Hz @ .25 A Typical (idle) to 2.7 A max (treat), or
230 volts nominally, 50/60 Hz @ .13 A Typical (idle) to 1.4 A max (treat)

4000 DIMENSIONS

Weight	26.5 pounds / 12.0 Kg
Height	6.9 inches / 17.5 cm
Width	11.8 inches / 30.0 cm
Depth	21.4 inches / 54.4 cm

5000 DIMENSIONS

Weight	37 pounds / 16.8 Kg
Height	6.9 inches / 17.5 cm
Width	20.4 inches / 57.8 cm
Depth	21.4 inches / 54.4 cm

ENVIRONMENTAL AND REGULATORY SPECIFICATIONS

All devices are Class I, continuous-operation devices. The Stimulus circuits are Type BF; the Patient Monitoring circuits are Type BF defibrillation-protected. The fuses are 5 X 20mm time lag (slo-blo) fuses. 4 amp (T4.0A) for 115VAC and 2 amp (T2.0A) for 230VAC. Users should choose cUL-approved fuses for United States and Canada, and IEC-rated fuses everywhere else.

OPERATING CONDITIONS

Temperature, operating	41 to 95° F / 5 to 35° C
Relative humidity, operating	30 to 70%, non-condensing

STORAGE AND TRANSPORTATION CONDITIONS

Temperature	-4 to 140° F / -20 to 60° C
Humidity	10 to 95%, non-condensing
Pressure	220 to 1052 HPa
CHART RECORDER paper roll	Removed

REGULATORY QUALIFICATIONS

The spECTrum 5000 series of products comply with the standards listed when connected to an external personal computer (as verified during EMC testing). If connected to other devices, it is the user's responsibility to confirm that the device still complies with the listed standards.

UL Classified

cUL Classified

Designed and tested to:

UL 2601-1, 2 Dec 1994

CE Certification

Designed and tested to:

IEC 601-1, Medical Electrical Equipment, general requirements for safety, 1988

IEC 601-1, Amendment 1, 1991

IEC 601-1, Amendment 2, 1995

IEC 601-2-14, Medical Electrical Equipment, Specifications for electroconvulsive therapy equipment, 1989

IEC 601-1-2, Medical Electrical Equipment. Electromagnetic compatibility, 1994

IEC 601-2-25, Medical Electrical Equipment. Particular Requirements for the Safety of Electrocardiographs, 1993

IEC 601-2-26, Medical Electrical Equipment. Particular Requirements for the Safety of Electroencephalographs, 1994

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (I.E. IEC 950 for data processing equipment, and IEC 601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 601-1-1. Everyone who connects additional equipment to the signal input or output ports configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard, IEC 601-1-1. If in doubt, contact the technical service department, or your local representative.

ECT PARAMETERS

Q models

Q Models Four Parameter Sets:	Set 1	Set 2	Set 3	New Ultrabrief Set 4
Stimulus Current in 100mA increments	500-800 mA	500-800 mA	500-800 mA	500-800 mA
Frequency in 10-Hz steps	20-90 Hz	20-60 Hz	20-60 Hz	20-120 Hz
Pulse Width in .10 msec steps	0.5-1.0 msec	0.5-2.0 msec	0.5-1.0 msec	0.3-0.37 msec
Stimulus Duration in .25-.5 steps	0.5-4.0 sec	0.5-3.0 sec	0.5-6.0 sec	0.5-8.0 sec
Charge	5.0-576 mC	5.0-576 mC	5.0-576 mC	3.0-568.3 mC
Energy @ 220 ohm patient impedance	0.6-101.4 joules	0.6-101.4 joules	0.6-101.4 joules	0.3-100.0 joules

M models

M Models Four Parameter Sets:	Set 1	Set 2	Set 3	New Ultrabrief Set 4
Stimulus Current	800 mA	800 mA	800 mA	800 mA
Frequency	20-90 Hz	20-120 Hz	20-60 Hz	20-120 Hz
Pulse Width	1.0 msec	1.0 msec	1.0 msec	0.3-0.38 msec
Stimulus Duration	0.18-4.0 sec	0.18-3.0 sec	0.18-6.0 sec	0.5-8.0 sec
Charge in 100 settings	5.8-576 mC	5.8-576 mC	5.8-576 mC	5.8-576 mC
Energy @ 220 ohm patient impedance	1.0-101.4 joules	1.0-101.4 joules	1.0-101.4 joules	1.0-101.4 joules

MONITORING SPECIFICATIONS

EEG/ECG/OMS PATIENT INPUTS (5000 models only)

Maximum Number of Channels	6
EEG Trace Restoration	Automatic rapid return to display
EEG Lead-Off Detection Current	≈ 30 nA DC
EEG Lead-Off Indication	Trace disappears, Restore button provided when any selected/displayed EEG channel is unhooked
EEG Channel Gain	5000 x from optional analog output (+/- 10%)
EEG Input Range, AC	2mV p-p max.
EEG Input Range, DC	+/- 200mV
EEG Frequency Response	1.4 to 48 Hz band pass (-3dB)
EEG Common Mode Rejection	For 10V RMS, 50/60 Hz input having 200 pF source capacitance, feeding unbalanced 51K/ .047 uF input network, resultant signal will be < 1 mV p-p R.T.I. with notch filter off, and < .1 mV p-p R.T.I. with notch filter on.
EEG Noise	≤ 15mV p-p R.T.I. with notch filter on.
EEG Display/CHART RECORDER Gain	(see chart on next page)
EEG Input Impedance	> 2.5 MΩ single-ended @ 10 Hz.
EEG Protection Against ECT Pulses	Provided (requires patient monitor cables w/ 1k series resistors)
ECG Trace Restoration	Automatic rapid return to display
ECG Lead-Off Detection Current	≈ 30 nA DC
ECG Lead-Off Indication	Trace disappears, Restore button provided when any selected/displayed ECG channel is unhooked
ECG Channel Gain	1000 x from optional analog output, +/- 10%
ECG Input Range, AC	10mV p-p max.
ECG Input Range, DC	+/- 300mV
ECG Frequency Response	0.5 to 48 Hz band pass (-3dB)
ECG Common Mode Rejection	For 10V RMS, 50/60 Hz input having 200 pF source capacitance, feeding unbalanced 51K/ .047 uF input network, resultant signal will be ≤ 1 mV p-p R.T.I. with notch filter off, and ≤ 0.1 mV p-p R.T.I. with notch filter on.
ECG Noise	≤ 30mV p-p R.T.I. with notch filter on.
ECG LCD/CHART RECORDER Gain	(see chart on next page)
ECG Input Impedance	>2.5 MΩ single-ended @ 10 Hz.
ECG Protection Against Defib and ECT Pulses	Provided (requires patient monitor cables w/ 1K series resistors)
OMS Technique	Photoplethysmography
OMS Frequency Response	0.5 to 6.0 Hz (-3 dB) typical
OMS Trace Restoration	Automatic rapid return to display
OMS No-sensor Detection	Trace disappears, Restore button provided when OMS is selected/displayed and disconnected

DUAL CHANNEL RECORDER SPECIFICATIONS (5000 models only)

Chart Speed	25 mm/sec
Waveform zone width	48 mm max
Overall paper width	50 mm
Resolution	8 dots/mm vertical x 32 dots/mm horizontal
Printing method	Thermal

EEG SCREEN GAIN SETTINGS (mV/mm)

Displayed Traces *

Tr.	LOW	MLOW	MED	MHIGH	HIGH
1.	.0357	.0178	.0071	.0036	.0014
2.	.0732	.0366	.0146	.0073	.0029
3.	.1113	.0557	.0223	.0111	.0045
4.	.1504	.0752	.0301	.0150	.0060

ECG SCREEN GAIN SETTINGS (mV/mm)

Displayed Traces *

Tr.	LOW	MLOW	MED	MHIGH	HIGH
1.	.1784	.0713	.0357	.0178	.0089
2.	.3661	.1465	.0732	.0366	.0183
3.	.5565	.2226	.1113	.0557	.0278
4.	.7521	.3008	.1504	.0752	.0376

* "Displayed traces" means the total number of traces on the LCD screen, including EEG, ECG and OMS.

EEG CHART GAIN SETTINGS (mV/mm)

Displayed Traces **

Tr.	LOW	MLOW	MED	MHIGH	HIGH
1.	.050	.025	.010	.005	.002
2.	.100	.050	.020	.010	.004

ECG CHART GAIN SETTINGS (mV/mm)

Displayed Traces **

Tr.	LOW	MLOW	MED	MHIGH	HIGH
1.	.250	.100	.050	.025	.010
2.	.500	.200	.100	.050	.020

** "Displayed traces" means the total number of traces on the Chart Recorder printout, including EEG, ECG and/or OMS.

Troubleshooting

Troubleshooting Chart

See also the section on Error Messages in this manual for additional input on identifying and clearing problems. Machines will need servicing mainly for errors that users cannot clear by themselves. These will appear as numbered errors, and the user will need to consult the factory for assistance.

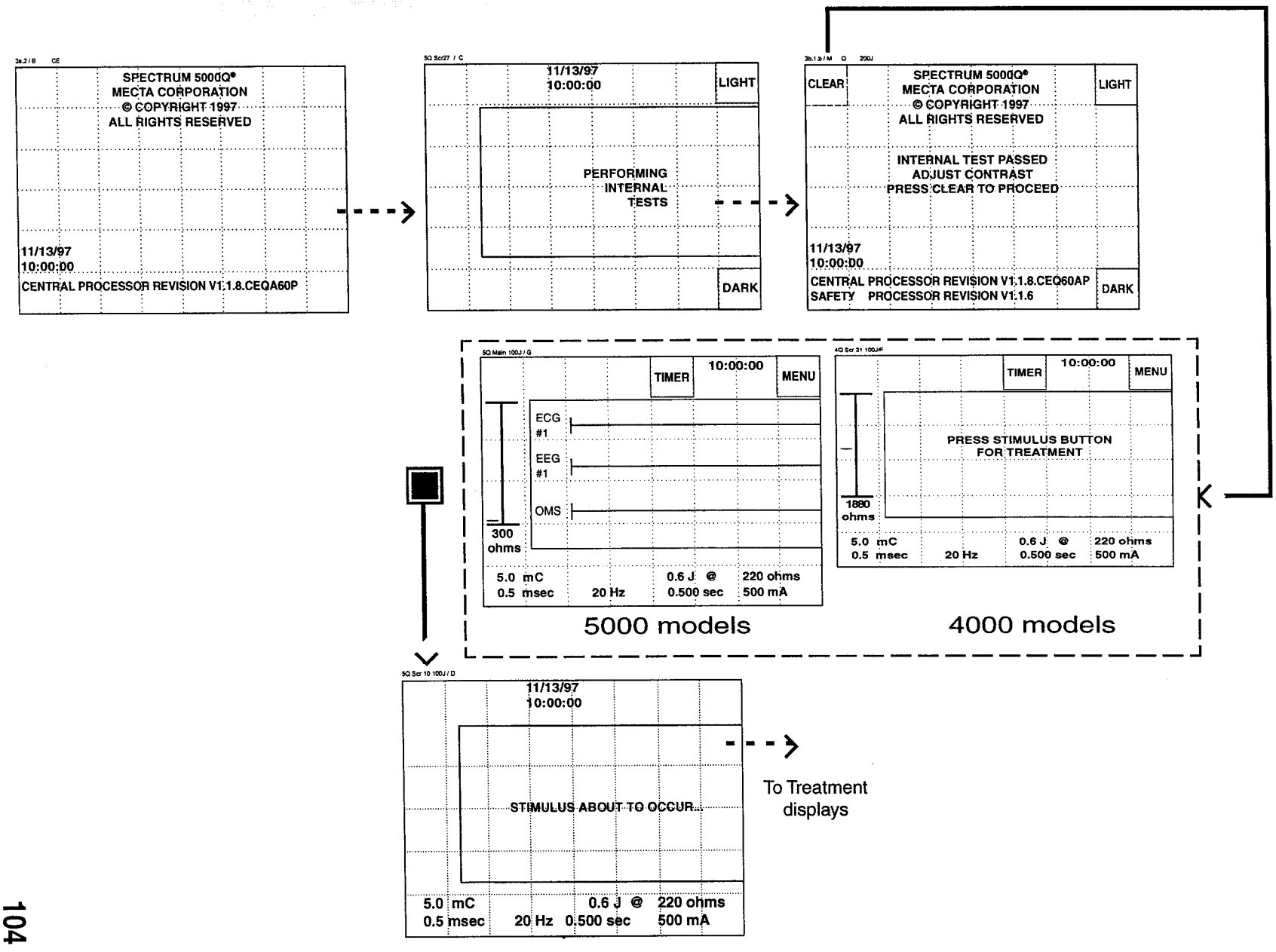
Problem Description	Possible Problem or Solution
sPECTrum does not operate.	No line voltage connected and/or fuse may be blown. Verify that: a. Fuses are OK, b. Power switch is ON, c. Unit is plugged into a proper outlet, and cord is fully seated in power entry module. d. Outlet works for other equipment. e. Power entry module is set for correct line voltage.
CHART RECORDER does not operate at all.	Make sure Chart Recorder is turned on in the CHART OPTIONS MENU, paper is properly loaded, recording module is fully seated, and its door is fully closed.
STIMULUS CONTROL does not work when the STIMULUS STATUS INDICATOR is Green.	STIMULUS CONTROL push button is disabled if hand-held electrodes are connected to the STIMULUS OUTPUT connector.
Static impedance indicates OVER, or gets PATIENT IMPEDANCE INCORRECT message.	Scalp electrodes have insufficient contact area, or insufficient electrode gel, or are not connected to the patient, or cable is broken.
RESTORE button appears.	a. Insure all selected leads are displaying traces. b. De-select disconnected leads in the LCD and CHART TRACE MENUS. c. Lead connections to cables are scrambled or defective. d. A non-sPECTrum type cable is used. e. Cable is plugged into wrong connector. f. A very old electrode is being used. g. OMS is unplugged, or defective.

Problem Description	Possible Problem or Solution
Paper prints from CHART RECORDER, but no printout is produced.	Check to see that paper roll is so inserted that paper feeds off underside of the roll, and is laid over the top of the recorder door. Thermal paper will print only on one side. Scraping thermal paper rapidly with a finger nail should leave a black mark.
LCD is too dark/too light.	Use the contrast control buttons on the COPY-RIGHT and MAIN MENU displays to lighten or darken the display.
LCD or CHART RECORDER trace data is not displaying.	Check the appropriate lead for good connections from the SPECTRUM to the patient.
Touch Screen buttons do not work.	If the unit has Membrane Switches to the left of the LCD, use those instead. (there is no touch screen).

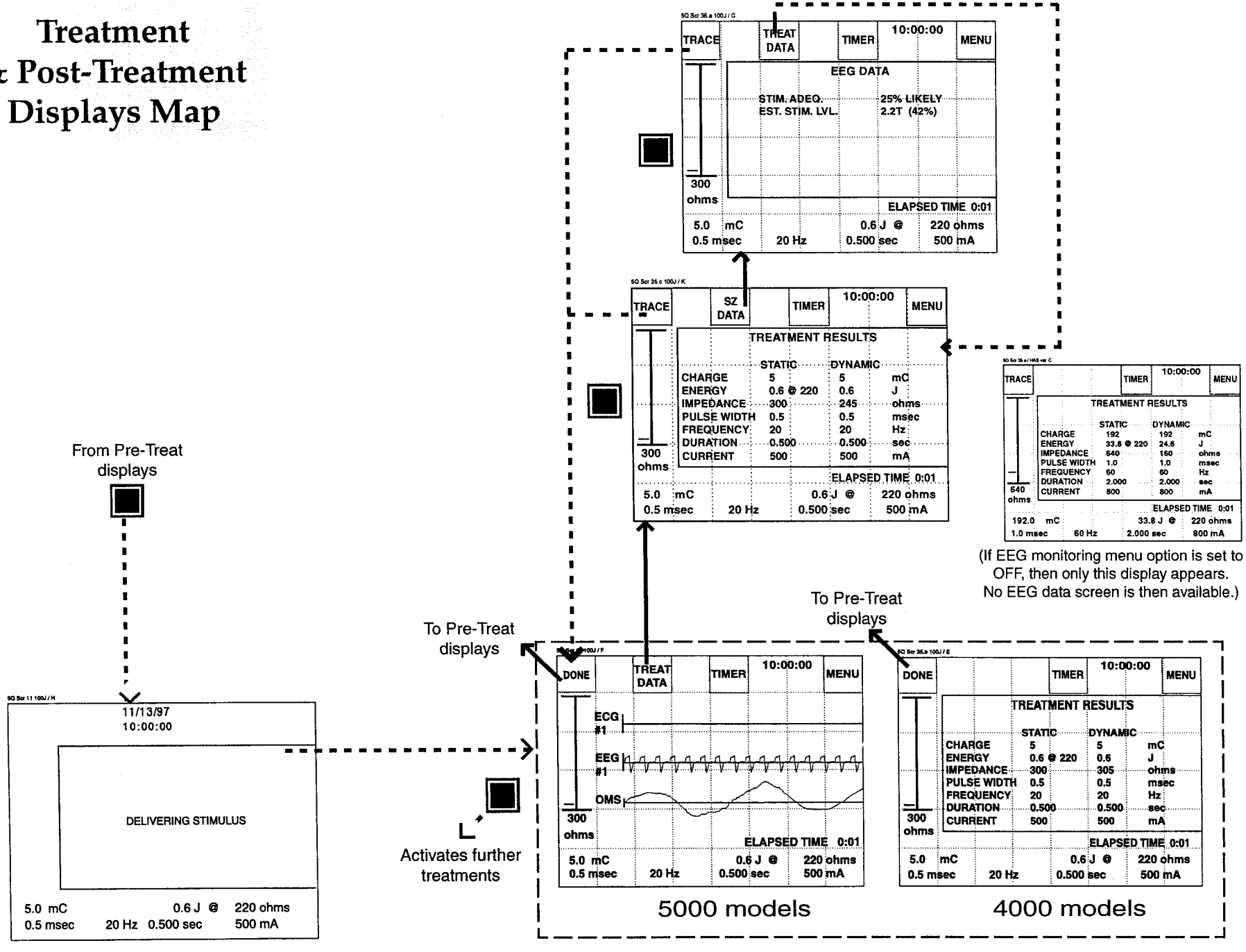
Display Maps

Pre-Treatment Displays Map

These maps depict the routine display sequences on the SPECTRUM Q-model.
M-model displays will show different parameter configurations.
Error message displays and most variations are not shown.



Treatment & Post-Treatment Displays Map

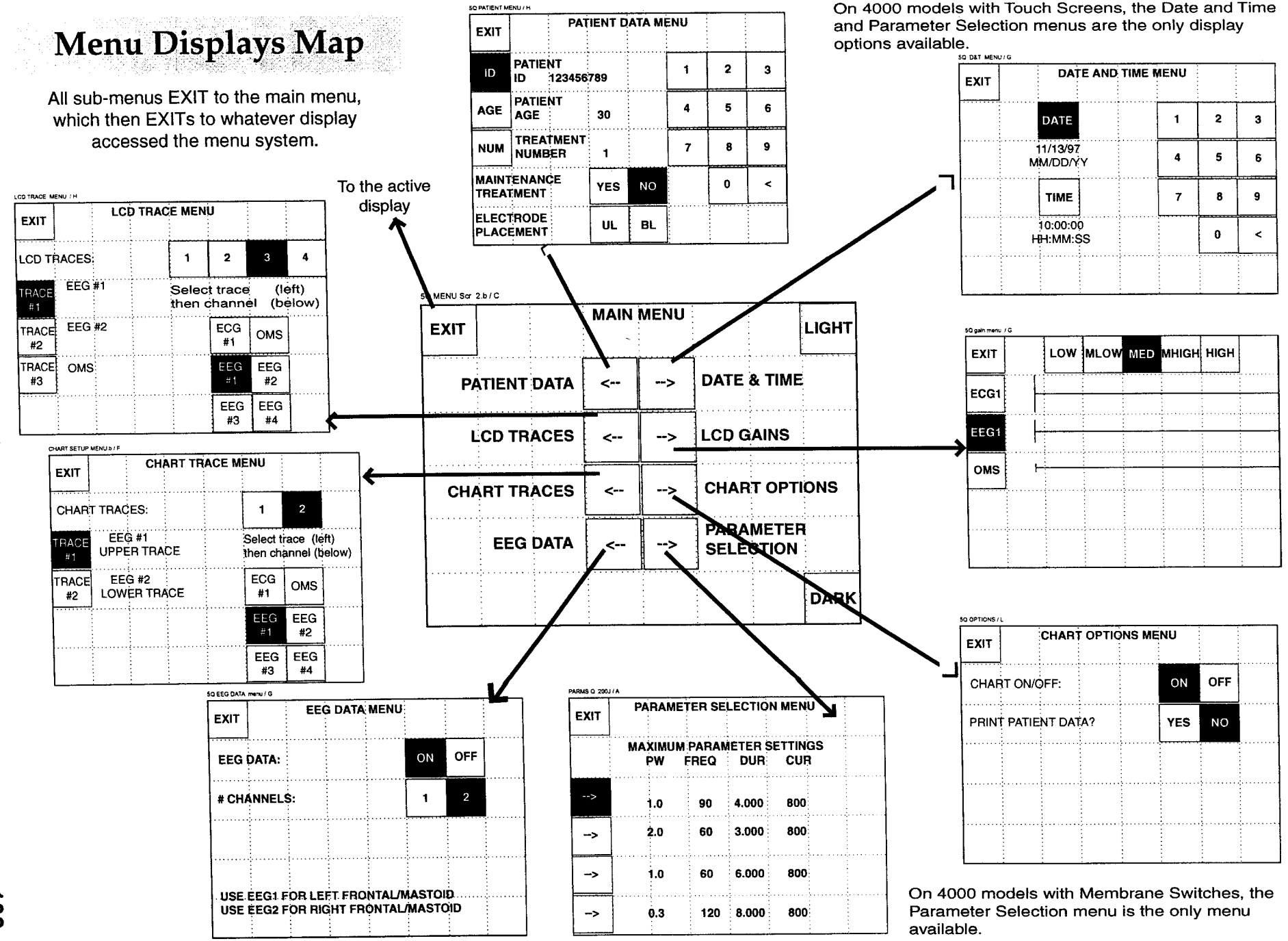


(If EEG monitoring menu option is set to OFF, then only this display appears. No EEG data screen is then available.)

Menu Displays Map

All sub-menus EXIT to the main menu, which then EXITs to whatever display accessed the menu system.

On 4000 models with Touch Screens, the Date and Time and Parameter Selection menus are the only display options available.



On 4000 models with Membrane Switches, the Parameter Selection menu is the only menu available.

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APPENDIX E

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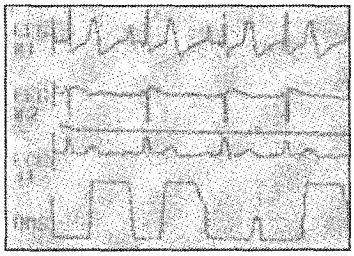
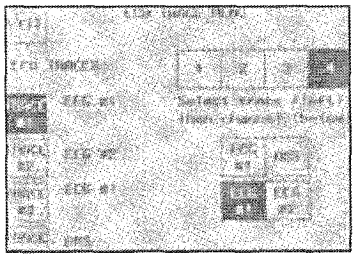
Additional Monitoring Channels



Each 5000 model spECTrum purchase includes the choice of two monitoring channels: EEG 1 and EEG 2, or EEG 1 and an ECG channel (electrocardiogram). However, for clinicians who wish redundancy or have specific research requirements, up to four additional monitoring channels may be added to an EEG/ECG base model. Three channels of EEG and one Optical Motion Sensor for monitoring motor activity complete the six channels of monitoring available on the spECTrum 5000 series, providing maximum monitoring capabilities for all ECT treatment requirements. An EEG/EEG/ECG option with or without Optical Motion Sensor is also available.

Click to enlarge



For those who wish to view or database the real-time trace data, add Remote Monitor Software© and MECTA RMS MANAGER©, or MECTA EMR©.

Click to enlarge

Features:	
	Real time, simultaneous monitoring of up to eight channels: 4 EEG, 1 ECG and 1 Optical Motion Sensor and duplicate EEG traces.
	Four user-selected channels of real-time monitoring on the LCD/Touch Screen.
	Two user-selected channels on the Chart Recorder.
	Enhanced waveform quality by digital signal processing (DSP), which filters unwanted interference for reduced artifact.

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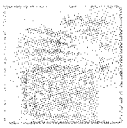
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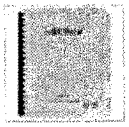
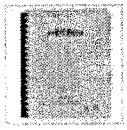
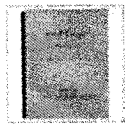

spECTrum Instruction Manual


spECTrum Service Manual


Remote Monitor Software Manual

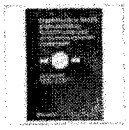

RMS MANAGER Software Manual

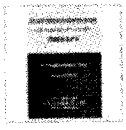

spECTrum Instruction Manual - International Version


spECTrum Service Manual - International Version

CLINICAL PUBLICATIONS


The Practice of Electroconvulsive Therapy-A Taskforce Report of the APA


La practica de la terapia electroconvulsive - APA Taskforce Report - Spanish


ECT: A Programmed Text

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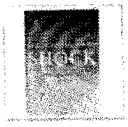
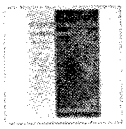

Shock - The Healing Power of Electroconvulsive Therapy by Kitty Dukakis and Larry Tye


Undercurrents - A Life Beneath the Surface by Martha Manning


Shock DVD - A documentary produced by AMS Production Group, Inc. 2007

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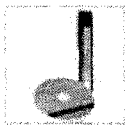

Remote Monitor Software Option DVD or Video

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MECTA – Supporting advances and research for the treatment of depressive disorders with the use of electroconvulsive therapy

In this section, clinicians can find resources, research, and helpful links and downloads for more information on meetings, the current standard of care, training and fellowships and MECTA educational materials.

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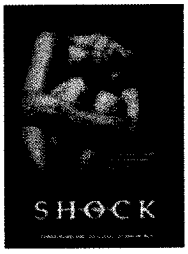

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A documentary film by Brad Osborne and based upon the book by Kitty Dukakis and Larry Tye. ©2006 AMS Production Group, Inc. All Rights Reserved.

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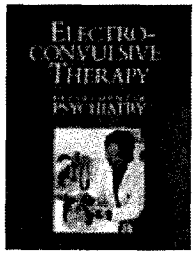

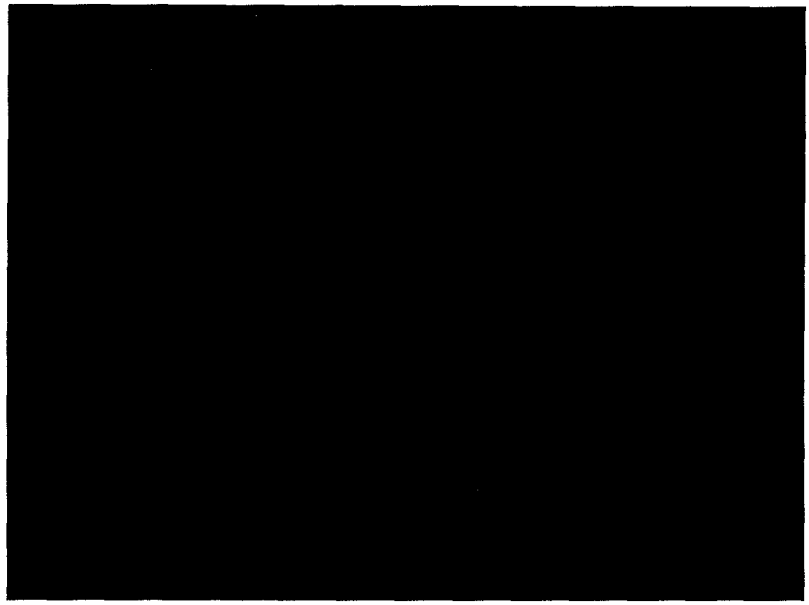

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Canadian Psychiatric Association's Annual Conference
English: http://www.cpa-apc.org/browse/documents/92&xwm=true
French: http://www.cpa-apc.org/i8n.php?location=/browse/documents/92&i8nID=2

American Association for Geriatric Psychiatry Annual Meeting
http://www.AAGPmeeting.org/

U.S. Psychiatric and Mental Health Congress
http://www.cmellc.com/psychcongress/

American Psychiatric Nurses Association Meetings
http://www.apna.org

International Meetings

Annual Meeting of the Royal College of Psychiatrists – Great Britain
http://www.rcpsych.ac.uk/

DGPPN Kongress - Germany
http://www.dgppn-congress.de/

Hong Kong College of Psychiatrists
http://www.hkcpsych.org.hk/

Korean NeuroPsychiatric Association Meetings
http://www.knpa.or.kr/

Malaysian Psychiatric Association Meetings
http://www.psychiatry-malaysia.org/listcat.php?cid=8&all=N&dc=cur

Nordic Association for Convulsive Therapy
http://www.nact.se

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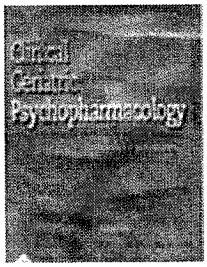

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Electroconvulsive Therapy in Late-Life Depression

Sackeim, H.A., Ph.D.

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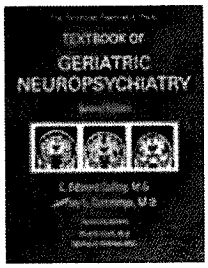

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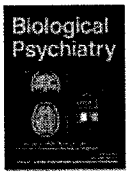

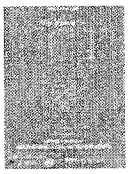

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OVER THIRTY-FIVE YEARS OF NEUROMODULATION INNOVATIONS

- Clinician
  - Meetings
  - Standard of Care
  - Training and Fellowships
  - Educational Materials

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Training and Fellowships

Below are helpful links for ECT training and education opportunities for physicians and nurses. Contact the registrars directly at each site for more information and schedules. MECTA is not affiliated with any of these institutions.

Electroconvulsive Therapy Training Course – Physicians and Nurses, 3-Day Mini-Fellowship
Wesley Woods Geriatric Hospital, Emory University, Atlanta-GA

Visiting ECT Fellowship Program – Physicians and Nurses
Physician Fellowship email: vaulx-smithpm@upmc.edu
Nurse Fellowship email: wiskemancl@upmc.edu
University of Pittsburgh School of Medicine, Pittsburgh-PA

Visiting Fellowship in ECT – Physicians and Nurses
Duke University, Durham-NC

Visiting Fellowship in ECT – Physicians and other mental health professionals
Email: BrainStimCME@columbia.edu
Division of Brain Stimulation and Therapeutic Modulation, New York State Psychiatric Institute
Columbia University College of Physicians and Surgeons, New York, NY

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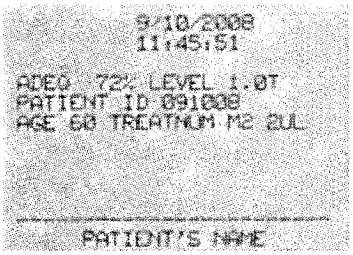
EEG Data Analysis



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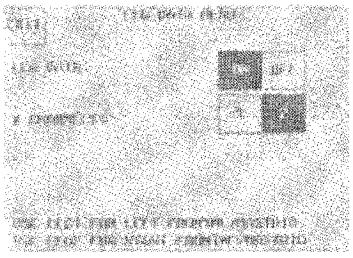
The assessment of a patient's baseline and post-stimulus electroencephalogram (EEG) provides the clinician with a visual indication of the nature, quality and duration of seizure activity. The EEG Data Analysis feature was developed by Duke University, patented, and exclusively licensed by MECTA for use in the spECTrum 5000 model ECT devices. This feature provides the capability to automatically analyze EEG signals using a patented algorithm developed over years of acquired treatment data to provide seizure adequacy information that has been demonstrated to be of clinical relevance.[1] The Seizure Adequacy* and Stimulus Level* measures are recorded on the chart strip and in MECTA RMS MANAGER© or MECTA EMR© software.



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[1] Krystal AD. The clinical utility of ictal EEG seizure adequacy models. Psychiatic Annals. 1998;28:30-35.
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*Duke U.K. Patent #2 304 196 B – U.S. Patent #5,626,627
(Under exclusive license from Duke University)

THE ONLY DUKE UNIVERSITY DEVELOPED AND PATENTED ANALYSIS FEATURES. MECTA IS THE ONLY COMPANY LICENSED TO INCLUDE THE DUKE UNIVERSITY EEG SEIZURE QUALITY MEASURES IN ITS PRODUCTS.

Features

- EEG Data Analysis is a valuable tool to assist the clinician with an empirically-based means to predict seizure adequacy and to regulate stimulus dosing.
- These are the only existing ECT indices developed with actual clinical stimulus dosing and treatment response data shown to have a significant relationship to outcome.
- EEG Data Analysis was developed by Duke University and based on ten years of research, with results detailed in double-blind, randomized, peer-reviewed scientific literature [2].

EEG Data Analysis data sheet DOM
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EEG Data Analysis is patented and licensed exclusively to MECTA. It is available as an option in the 5000Q® and 5000M™ spECTrum models.

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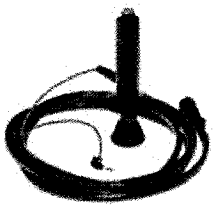
Hand-Held Electrodes

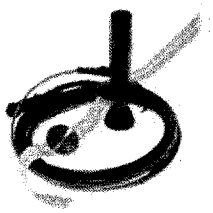
Hand-Held Electrodes are an efficient and economical accessory for initiating a stimulus during ECT treatments. These **third-generation** electrodes have been re-designed with a single molded handle and flange making them lighter-weight, waterproof and easier to clean.

Four styles are available for use with a spECTrum ECT device:

For Unilateral Treatments – Single handle with or without a Remote Button

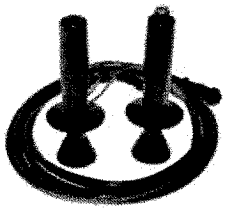


Single Hand-Held Electrode with Remote

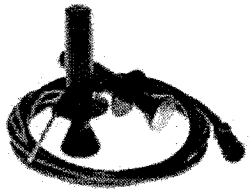


Single Hand-Held Electrode without Remote configured with a headband with electrode

For Unilateral and Bilateral Treatments – Dual handles with or without a Remote Button



Dual Hand-Held Electrodes with Remote



Dual Hand-Held Electrodes without Remote configured with electrode

Home

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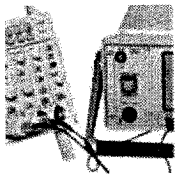
Redefining Electroconvulsive Therapy

MECTA Corporation has defined the highest standard of excellence in the field of ECT neuromodulation devices through evidence-based research since its inception. A breakthrough by Dr. Paul Blachley with MECTA ECT research in 1973 at Oregon Health Sciences University produced the *first and only, monitored (EEG/ECG), brief pulse* ECT devices – MECTA C and D. Subsequent research at Columbia University was implemented into the third generation MECTA SR and JR digital devices which were introduced in 1985, and they utilized the *first RUL ECT, multiple dosing schemes and titration.*[46]

In 1998 controlled research from Duke University and Columbia University was integrated into the current MECTA spECTrum 5000®* and 4000™* devices, *the first and only EEG Data Analysis** feature,*[38] *and the spECTrum ULTRABRIEF© 0.3 ECT*[49] which dramatically minimizes cognitive effects. These advances continue to lead the field.

MECTA ECT has advanced the highest standard of excellence for over thirty-five years. ECT continues to be the only neuromodulation modality providing up to an 80% response rate. [41] We are proud that MECTA's innovative device designs, which have been utilized worldwide in peer reviewed, randomized, double-blind studies, have resulted in optimized patient outcomes through four generations of ECT devices.



Design All MECTA devices include extensive redundant hardware and software testing to verify that they are operating correctly. The safety of these devices is unparalleled, and as such these devices are an advance that will impact the safety and effectiveness of the ECT treatment.
* U.S. Patent #5,755,744 – U.S. Patent #6,014,587 – U.K. Patent #GB 2 307 413 B
** Duke U.K. Patent #2 304 196 B – U.S. Patent #5,626,627

TÜV

Quality and Safety Standards MECTA's manufacturing and service operations are regulated under the international ISO 9001 Quality Standard so that MECTA customers can be assured of product safety and quality. MECTA has extensive regulatory agency approvals worldwide: U.S. (UL); Canada (CSA (cUL), Health Canada-8 Approvals, #1537, #62578, #62576); European Union, TUV (EN ISO 13485:2003+AC 2007; CMDCAS ISO 13485:2003, EC 93/42/EEC Annex II, Article 3); Korea (KFDA); Australia (TGA).

Environment MECTA has always recognized the need to be responsible stewards of the environment. Reduction of manufacturing waste and emissions, responsible operations resources management, and no-charge device recycling, are all integral parts of MECTA's environmental policy. We are voluntarily committed to achieving 100% RoHS (lead-free) compliance.

Quality Policy It is the policy of MECTA to design, fabricate, market, distribute, and service its ECT equipment with consistently high quality so that MECTA will continue in its position of leadership in the industry. All of our products will meet all

SCC Accredited CB-MS

applicable laws and regulations. MECTA's emphasis on quality involves all personnel. Our goal is satisfied customers. MECTA continually improves its Quality Management System to meet these objectives.

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OVER THIRTY-FIVE YEARS OF NEUROMODULATION INNOVATIONS

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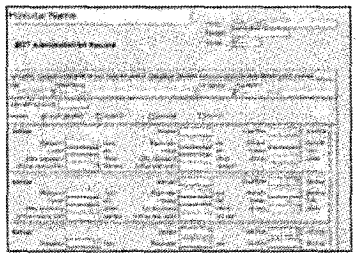

New health IT mandates require digitization of patient medical records. MECTA EMR©, an MS Access™ - based, networkable electronic medical record, will revolutionize the data acquisition of your ECT treatments. The spECTrum 5000 alphanumeric data, physiological monitoring and patient data inputted by psychiatrists, anesthesiologists and nurses are imported into six permanent ECT medical records that can be saved as pdfs on your PC laptop or desktop computer. Improve patient safety and privacy, contain costs and eliminate paperwork with MECTA EMR.

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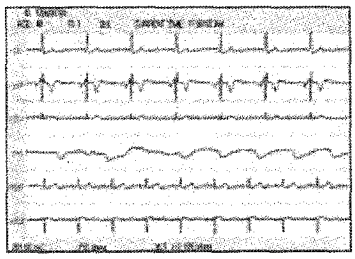

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Features:	
	Revolutionize your ECT team's management of patient data and prepare for paperless medicine!
	Electronic medical records have been shown to improve patient safety and reduce time and costs.
	The spECTrum physiological data imports directly into EMR. An auto-fill feature prevents needless inputting.
	Forms include: ECT Referral Form, Pre-Anesthesia Evaluation Form, Pre-ECT Nursing Checklist, ECT Administration Records, ECT Medication Log and Post-ECT Nursing Recovery Record.

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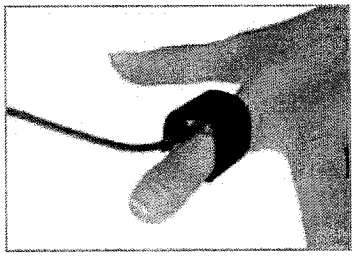
Optical Motion Sensor



Motor activity is commonly monitored during the course of the ECT treatment. The MECTA spECTrum 5000 series Optical Motion Sensor (OMS) with Velcro® attachment is faster and easier to use than EMG. The sensor is strapped to a finger or toe distal to the blood pressure cuff, where its infrared sensor captures the intra-muscular motor movement during the clonic phase. These slow wave movements are displayed on the spECTrum LCD monitor, chart recorder or PC monitor where they may be stored, viewed, analyzed or printed using Remote Monitor Software©, MECTA RMS MANAGER© Software, or MECTA EMR© Software.

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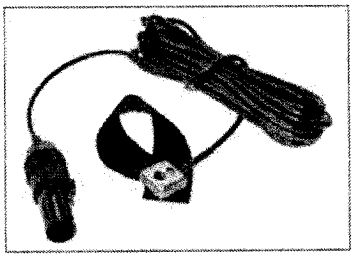

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Features:
Optical Motion Sensor is a tool used to detect intra-muscular motor movement following initiation of a stimulus.
It is faster and easier to use than electromyography (EMG).
There are no additional expensive electrode pads or messy gels to apply.
The Velcro strap promotes easy attachment of the sensor to the patient.
Display, print or record OMS traces using Remote Monitor Software©, MECTA RMS MANAGER© Software, or MECTA EMR© Software.

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MECTA spECTrum ECT Devices

The Newest Standard of Care Available Only From MECTA

The spECTrum 5000 and 4000 models are the fourth generation of MECTA's ECT devices. They continue to be the most advanced ECT devices technically, while continuing to offer even more safety and effectiveness clinically.

The 5000Q® and 5000M™ model devices offer up to five channels of ECG and EEG monitoring, and one Optical Motion Sensor. The 4000Q™ and 4000M™ devices are simply the 5000 devices without physiological monitoring capability.

The 5000Q® and 4000Q™ offer the user flexibility with four stimulus parameter knobs to control Energy and Charge. The 5000M™ and 4000M™ units offer simplicity, with one single Stimulus Intensity knob. This varies Frequency and Duration simultaneously, to control Energy and Charge. Each spECTrum device is custom manufactured to user specifications according to the Options selected and includes a complete Starter Kit.

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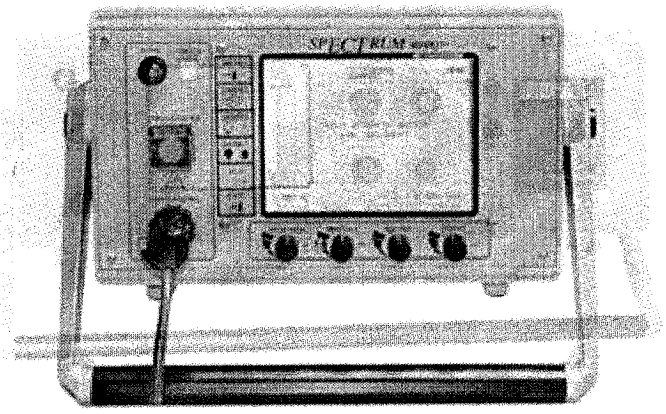

spECTrum 4000Q™

spECTrum ULTRABRIEF© ECT (0.3 ms)

Experience Optimized Patient Outcomes with the Newest Dosing Methodologies

No other ECT manufacturer provides a proven evidence based methodology as simple and effective to use as the spECTrum ULTRABRIEF© (0.3 ms) ECT feature. This feature was designed and tested at Columbia University in the late 1990s, results were reported[46,49] and it was introduced as a feature into MECTA spECTrum ECT devices in July of 2003.

Right unilateral (0.3 ms) ultrabrief six times seizure threshold ECT is equivalent in efficacy to a robust form of bilateral ECT with little sign of cognitive deficit and is simplified by the use of the MECTA spECTrum titration tables. Stimulus dose titration tables are included with each purchase.

No other ECT device implementation of an ultrabrief feature is based on peer reviewed, randomized, double-blind studies. Only spECTrum ULTRABRIEF (0.3ms) ECT is highly efficient at the lower range, with patients demonstrating seizure thresholds at 5 mC, and can treat the patient across the entire range.

Only MECTA offers hospitals a state of the art ECT device and ultrabrief option that provides the highest benefit by reducing side effects for patients.

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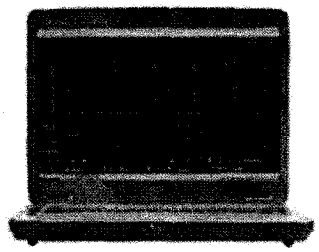

The Remote Monitor Software© (RMS) option allows the user to set up a remote monitoring display and data storage system for a spECTrum 5000 model, using a PC and monitor. This also facilitates using a remote overhead display, particularly useful when using hand-held stimulus electrodes. The monitor will display and log the physiological monitoring seen on the spECTrum's LCD screen. For six channel spECTrum systems, all traces will be displayed simultaneously and in real-time. RMS is a useful data capture tool for physicians, anesthesiologists and researchers.

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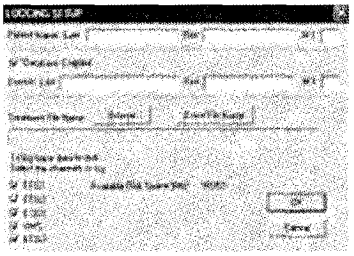

Combined with MECTA RMS MANAGER© database software, realize the superior benefits of a fully-featured ECT data capture and analysis system

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Features:	
	View up to eight traces of real-time monitoring on a PC monitor: 4 EEG, 1 ECG, 1 OMS and 2 duplicate EEG traces.
	Treatment parameters, patient data and the spECTrum impedance display also appear on the PC monitor to ensure patient safety.
	Physiological monitoring and treatment data may be stored for later analysis, dosing management or treatment assessment.
	Add MECTA RMS MANAGER© for automated importation of RMS data files into an extremely versatile and easy-to-use ECT database.

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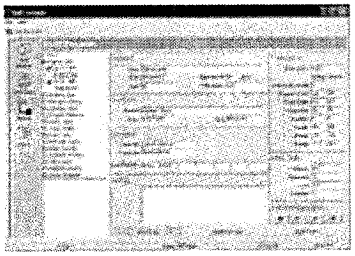

This groundbreaking software program combines seamlessly with Remote Monitor Software© (RMS) and either spECTrum 5000 model to automatically import ECT treatment data into an extremely versatile and easy-to-use database. With MECTA RMS MANAGER© collect up to 52 data fields, including 10 user-defined fields, sort, select, query, print, incorporate notes, backup, and export to Excel and other commonly used programs.

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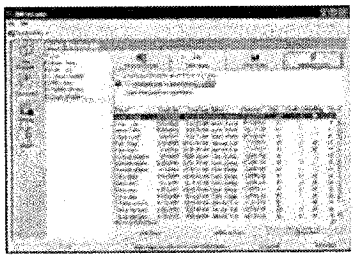

Used with a PC laptop or desktop computer, MECTA RMS MANAGER is the only ECT software program needed to organize and analyze the ECT treatment data.

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Features:	
	MECTA RMS MANAGER is a powerful database program to manage ECT treatment data.
	Patient data and monitoring are captured and automatically imported from the spECTrum 5000 device and Remote Monitor Software.
	Up to 52 columns of patient information is available, including 10 user-defined fields.
	Sort, Select, Query, Print, Incorporate Notes, Backup, and Export to Excel and other commonly used programs.
	Based on the Windows Access™ format, MECTA RMS MANAGER is extremely versatile and easy to use.

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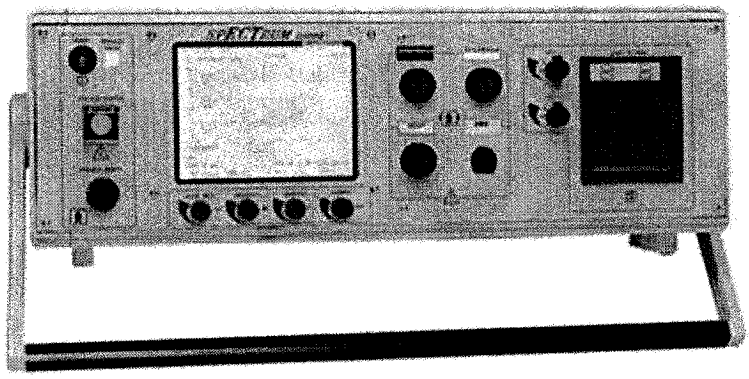
spECTrum 5000Q®



Click to Enlarge

The spECTrum 5000Q® is MECTA's top-selling device. It offers maximum flexibility to treat with four individual parameter sets of Pulse Width, Frequency, Duration and Current. The treatment dosage is set using the four knobs beneath the LCD touch screen so that the user can easily see and quickly choose the best treatment option to maximize efficacy and reduce side effects. The spECTrum ULTRABRIEF© (0.3 ms) pulse width settings and titration tables are included with all MECTA devices.

The base unit includes a choice of two channels of EEG or/and one EEG/ECG arrangement. Add up to four more channels of monitoring for four channels of EEG, one ECG and one Optical Motion Sensor (OMS). EEG Data Analysis, Remote Monitor Software©, MECTA RMS MANAGER© and MECTA EMR© software options may be added for a fully featured device.

Individualize patient treatments for safety and effectiveness with the 5000's nine menu options: Main, Patient Data, Date & Time, LCD Traces, LCD Gains, Chart Traces, Chart Options, EEG Data and the Parameter Selection menus. One menu display is available in the 4000 models. The LCD touch screen provides the user with an easy interface to set menu options.

The new 5000 models have been enhanced with lighter-weight RoHS (lead-free) cases that provide enhanced durability (3 lbs. lighter). The new robust handle ensures easy repositioning. Touch screen advanced technology offers increased sensitivity and clarity.

MECTA devices also include extensive redundant hardware and software testing to verify that they are operating correctly. The safety of these devices is unparalleled, and as such these devices are an advance that dramatically impact the safety and effectiveness of the ECT treatments.

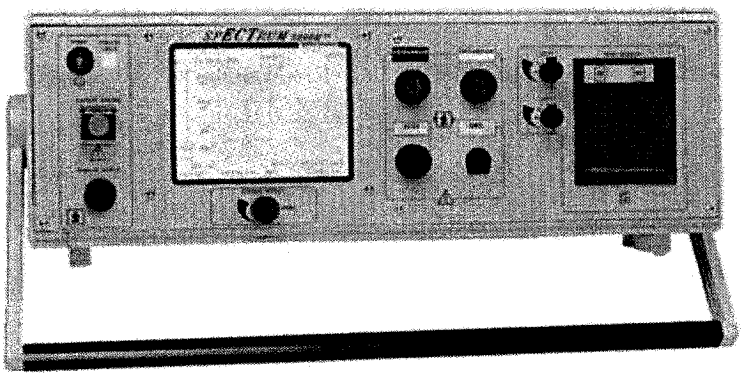
Best option:	For hospitals, clinicians and researchers who desire the optimal functionality and the features of the psychiatric field's top-selling ECT device
	Where maximum flexibility and the widest range of treatment parameters is desired for reduction of side-effects

	When up to six channels of real-time physiological monitoring and EEG Data Analysis are needed to provide the clinician with additional patient information
	When enhanced data capture is required either through physiological monitoring or recording treatment and/or medical information
Efficacious:	spECTrum ULTRABRIEF© (0.3 ms) option with up to sixteen therapeutic treatment parameters
Intuitive:	Nine visual, easy to use menus accessed by the LCD touch screen to individualize patient treatments. No hard to find menus
Portable:	New enhanced, lighter-weight RoHS (lead-free) case for a smaller footprint and more robust handle
Safe:	Extensive regulatory agency approvals worldwide U.S. (UL); Canada (CSA, Health Canada 8 Approvals, #1537, #62578, #62576); European Union, TUV (EN ISO 13485:2003+AC:2007; CMDCAS ISO 13485:2003; EC 93/42/EEC Annex 11, Article 3); Korea (KFDA); Australia (TGA)

MECTA

OVER THIRTY-FIVE YEARS OF NEUROMODULATION INNOVATIONS

spECTrum 5000M™



Click to Enlarge

The popular spECTrum 5000M™ offers dosing simplicity with one single Stimulus Intensity knob. This varies Frequency and Duration simultaneously, to control Energy and Charge. For those used to a single stimulus knob, the 5000M™ model is the best option in dosing flexibility, while retaining parameters that maximize efficacy and reduce side effects for the patient. The spECTrum ULTRABRIEF© (0.3 ms) pulse width settings and titration tables are included with all MECTA devices.

The base unit includes a choice of two channels of EEG or/and one EEG/ECG arrangement. Add up to four more channels of monitoring for four channels of EEG, one ECG and one Optical Motion Sensor (OMS). EEG Data Analysis, Remote Monitor Software©, MECTA RMS MANAGER© and MECTA EMR© software options may be added for a fully featured device.

Individualize patient treatments for safety and effectiveness with the 5000's nine menu options: Main, Patient Data, Date & Time, LCD Traces, LCD Gains, Chart Traces, Chart Options, EEG Data and the Parameter Selection menus. One menu display is available in the 4000 models. The LCD touch screen provides the user with an easy interface to set menu options.

The new 5000 models have been enhanced with lighter-weight RoHS (lead-free) cases that provide enhanced durability (3 lbs. lighter). The new robust handle ensures easy repositioning. Touch screen advanced technology offers increased sensitivity and clarity.

MECTA devices also include extensive redundant hardware and software testing to verify that they are operating correctly. The safety of these devices is unparalleled, and as such these devices are an advance that dramatically impact the safety and effectiveness of the ECT treatments.

Best option:	For hospitals, clinicians and researchers who desire optimal functionality and features with the most ease of use
	One treatment knob for simplicity in 1% steps. Vary Frequency and Duration simultaneously, to control Energy and Charge

	When up to six channels of real-time physiological monitoring and EEG Data Analysis are needed to provide the clinician with additional patient information
	When enhanced data capture is required either through physiological monitoring or recording treatment and/or medical information
Efficacious:	spECTrum ULTRABRIEF© (0.3 ms) option with up to sixteen therapeutic treatment parameters
Intuitive:	Nine visual, easy to use menus accessed by the LCD touch screen to individualize patient treatments. No hard to find menus
Portable:	New enhanced, lighter-weight RoHS (lead-free) case for a smaller footprint and more robust handle
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MECTA

OVER THIRTY-FIVE YEARS OF NEUROMODULATION INNOVATIONS

Products
- spECTrum Devices
  - spECTrum 5000Q®
  - spECTrum 5000M™
  - spECTrum 4000Q™
  - spECTrum 4000M™
  - Starter Kit
  - Options
- Clinical Accessories

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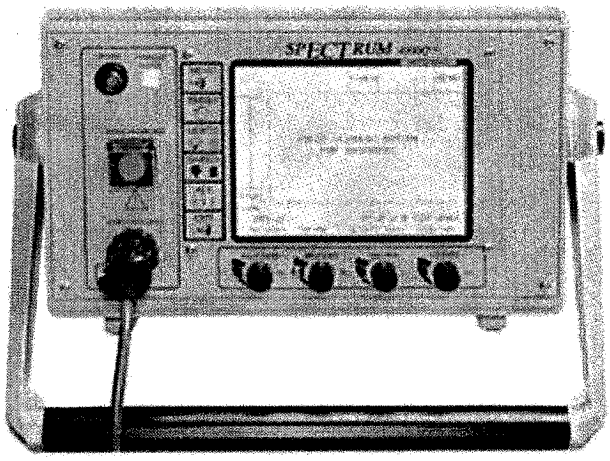
Request for Quotation

Request for Service Quote

- spECTrum Brochure
- 4000Q/4000M data sheet DOM
- 4000Q/4000M data sheet INT

spECTrum 4000Q™



Click to Enlarge

This re-designed spECTrum 4000Q™ is more economical, light-weight and portable than the 5000. The 4000Q™ model offers flexibility with four parameter sets of Pulse Width, Frequency, Duration and Current. The treatment dosage is set using the four knobs beneath the LCD touch screen so that the user can easily see and quickly choose the best treatment option to maximize efficacy and reduce side effects for the patient. The spECTrum ULTRABRIEF© (0.3 ms) pulse width settings and titration tables are included with all MECTA devices.

As the ECT section of the 5000 devices, it offers cost effectiveness without physiological monitoring, but still ensures that the clinician has all of the technology, safety and effectiveness of the 5000 spECTrum.

Best option:	Where maximum flexibility to select treatment parameters is desired
	Where alternative monitoring is available
	A high degree of portability is required
	When cost-effectiveness is a priority
Efficacious:	spECTrum ULTRABRIEF© (0.3 ms) with up to sixteen therapeutic treatment parameters
Intuitive:	Six tactile membrane switches with only one selection menu
Portable:	Robust handle, small footprint and lightweight case
Safe:	Extensive regulatory agency approvals worldwide U.S. (UL); Canada (CSA, Health Canada 8 Approvals, #1537, #62578, #62576); European Union, TUV (EN ISO 13485:2003+AC:2007; CMDCAS ISO 13485:2003; EC

93/42/EEC Annex 11, Article 3); Korea (KFDA); Australia (TGA)

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- spECTrum Brochure
- 4000Q/4000M data sheet DOM
- 4000Q/4000M data sheet INT

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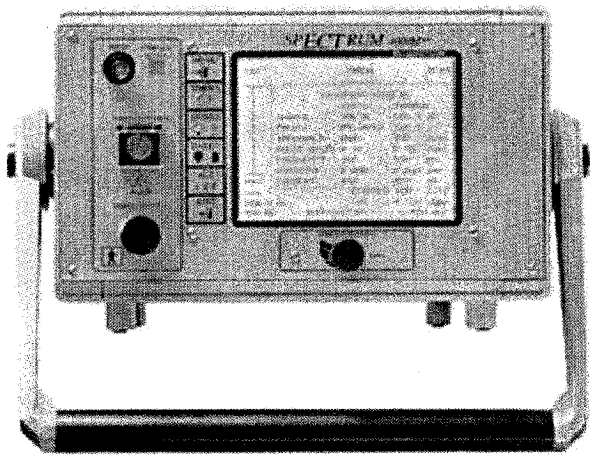
spECTrum 4000M™



Click to Enlarge

This re-designed, economical and light-weight spECTrum 4000M™ offers dosing simplicity with one single Stimulus Intensity knob. This varies Frequency and Duration simultaneously, to control Energy and Charge. For those used to a single stimulus knob, the 4000M model is the best option in dosing flexibility, while retaining parameters that maximize efficacy and reduce side effects for the patient. The spECTrum ULTRABRIEF© (0.3 ms) pulse width settings and titration tables are included with all MECTA devices.

As the ECT section of the 5000 devices, it offers cost effectiveness without physiological monitoring, but still ensures that the clinician has all of the technology, safety and effectiveness of the 5000 spECTrum.

Best option:	Where simplicity to treat is a functional requirement
	Where alternative monitoring is available
	A high degree of portability is required
	When cost-effectiveness is a priority
Efficacious:	spECTrum ULTRABRIEF© (0.3 ms) with up to sixteen therapeutic treatment parameters
Intuitive:	Six tactile membrane switches with only one selection menu
Portable:	Robust handle, small footprint and lightweight case
Safe:	Extensive regulatory agency approvals worldwide U.S. (UL); Canada (CSA, Health Canada 8 Approvals, #1537, #62578, #62576); European Union, TUV (EN ISO 13485:2003+AC:2007; CMDCAS ISO 13485:2003; EC 93/42/EEC Annex 11, Article 3); Korea (KFDA); Australia (TGA)

- Service
  - Upgrades
  - spECTrum Features Tutorial
  - spECTrum Diagnostics
    - Clinical Accessories Approvals
    - Clinical Symptoms and Solutions
    - Technical Symptoms and Solutions
    - Test Symptoms and Solutions
  - Repairs and Rentals
  - Clinical Fact Sheets

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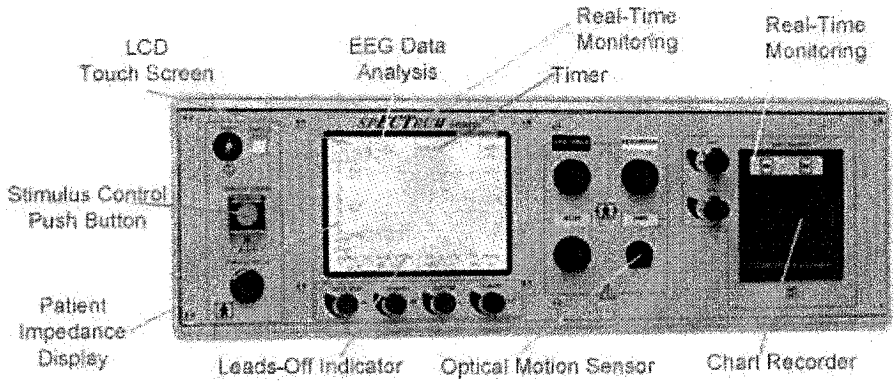
spECTrum Features Tutorial



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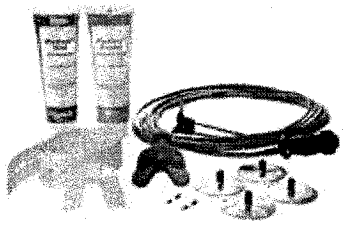
Starter Kit



Click to enlarge

An extensive starter kit is included at no charge with the purchase of any spECTrum 5000 or 4000 ECT device (kits may vary according to the model ordered). By supplying everything the clinician and biomed need to get started, MECTA ensures a turn-key startup. Manuals and visual aids, test equipment and clinical supplies assure hospital staff that treatments can begin promptly, efficiently and efficaciously. All starter kit items have been designed, tested and approved to comply with their respective regulatory standards. Therefore, these clinical accessories offered by MECTA for use with the spECTrum 5000 and 4000 series ECT devices are recommended. Purchase additional clinical accessories from MECTA for competitive pricing, quantity packaging, flexible delivery options and guaranteed quality for all starter kit consumable supplies.

Patient Stimulus Cable	Chart Recorder Paper
Patient Safety Monitor Cable	Bite Block
EEG and/or ECG Safety Leads	Oberto Mouth Prop
Adjustable Headband	Electrode Gel
Flat Stimulus Electrodes	Electrode Paste
Concave Stimulus Electrodes	ECG Disposable Electrode Pads
Fuse (2 or 4 Amp)	EEG Disposable Electrode Pads
Sensor Box	Dynamic Load Box

Stimulus Electrode Site Preparation

I. DEFINITIONS

Redux Paste
MECTA part #9800-0002
Manufacturer - Hewlett Packard
Conductive gel with abrasive material

Redux Gel -
MECTA part #9800-0001
Manufacturer - Hewlett Packard
Conductive gel

II. GENERAL INFORMATION

The ECT device provides an electrical current that is directed to the brain via a pair of metallic electrodes. The electrodes are electrically connected to the stimulus generator through the Stimulus Cable or Handheld Electrodes.

In order for the current to reach the brain, it must follow a path between the electrodes. Since the blood is conductive (hemoglobin), the capillaries, arteries and veins act as the conduction system to the brain. By maintaining adequate contact between the electrode and the skin, the energy path is maintained.

The skin is inherently a non-conductor, with increasing resistance (impedance) to current flow on the external skin layers. When the electrode site is properly prepared, low or high impedance is avoided, and treatment can be performed successfully.

The MECTA spECTrum provides a continuous display of patient impedance. Static impedance testing allows a small amount of current to pass through the electrodes to assess whether impedance is in range. Abnormal impedance readings may result from:

- Improper type of paste or gel as approved by FDA/CE for use with the spECTrum.
- Smearing of conductant between the electrodes.
- Buildup of hair conditioner, hair spray, gels or creams on the skin.

Proper and consistent use of Redux gel and paste ensure impedance is in range for effective and consistent stimulation.

III. WHEN TO USE PASTE AND/OR GEL

GEL – Use with each treatment. May be used alone when skin is ductile and compliant and on areas that are smooth.

PASTE – Used in addition to gel. It is helpful for use on older patients; in areas where skin is not protected by hair; when the skin surface is not smooth (wrinkled); and when SELF TEST has indicated that impedance is too high. It is also used on areas where there is a lot of hair (The paste allows more volume of conductant (gel) to be applied to a specific site. It does not run or drip). May be used to slightly abrade skin prior to treatment in order to remove dead skin cells.

IV. PROCEDURE (Using Both Paste and Gel)

Always start with clean, dry skin and clean electrodes. Using a gauze pad, swab the skin beneath the electrode site with acetone (gentler on the skin), or alcohol. Allow the site to air dry for a few seconds and then apply a small quantity of REDUX PASTE onto the skin under the ECT electrode site. Gently rub in, taking care not to overly abrade the skin. Remove excessive abrasive grains using a gauze pad or cloth. Do not use wipe with alcohol because discomfort may result.

Apply REDUX GEL to the ECT electrodes. The electrodes should be uniformly covered in gel. A tongue depressor may be useful to create an even spread. Care should be taken not to use too large a quantity of conductant to avoid spreading outside the electrode area when it is placed firmly against the scalp. A small quantity of gel should also be rubbed into the skin.

If skin is smooth and clean, the application of paste may be eliminated, although it is helpful in lowering impedance.

For use on the scalp, part the hair, rub the scalp with solvent, and apply paste. Gel should be applied onto the electrode as above.

V. WARNINGS & CAUTIONS

- OTHER gels are not recommended. Do NOT use gels that are designed to be used on ultrasound or Dopler devices. Multiple use gels are generally not suitable. Failure to use recommended gel may result in local skin burns or SELF TEST FAILURES.
- Smearing of conductant between electrodes will create an alternate path for the treatment current. More current will pass through this direct path between the electrodes, lowering impedance, making it difficult to elicit seizure. Failing to use gel or inadequate contact (pressure) will often result in a local focus (skin burn).
- To ensure the best connection between the electrode and the patient, the SELF TEST should be performed immediately prior to stimulus delivery.
- Both gel and paste are water based - the tube cap must be replaced. Use of insufficient, incorrect or expired gel (3 years) may result in less than optimum results.

If you have further questions, we would be happy to refer you to one of the clinicians who are currently using MECTA products.

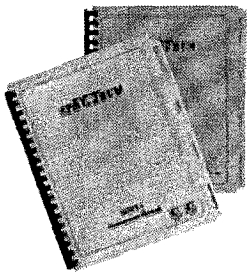
SPECTRUM ULTRABRIEF©

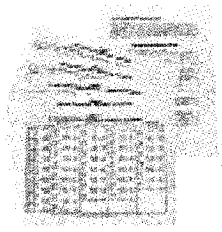
ULTRABRIEF ECT - ENSURING EFFICACY WHILE MARKEDLY REDUCING COGNITIVE SIDE EFFECTS

These landmark parameters were introduced in the Fall of 2003 by MECTA and already are having a major impact on the field.[1,3] Controlled research at Columbia University has shown that the 0.3 msec ultrabrief pulse width sharply reduces seizure threshold, allowing treatments to be given at much lower electrical dosage than had been previously possible. Most critically, when compared to standard brief pulse stimulation, use of ultrabrief parameters results in a profound reduction in cognitive side effects. In many domains, this advantage for ultrabrief stimulation is as large or larger than the difference between bilateral and right unilateral ECT in their cognitive effects. Definitive research published in 2008 confirms that right unilateral ECT given at 6 times initial seizure threshold with a 0.3 ms pulse width is equivalent in efficacy to the therapeutic effects using a robust form of bilateral ECT (1.5 ms pulse width and 2.5 times seizure threshold)[3] Right unilateral ultrabrief ECT is a clear advance for the field as patients show rapid improvement with little sign of cognitive deficit. The SPECTRUMS offer the only ultrabrief parameter set that allows for ultrabrief pulse stimulation across nearly the full output range of the device. All four SPECTRUM units can be upgraded to include this new form of stimulation as a menu selection.

1. Lisanby SH MD, Sackeim HA PhD:New developments in convulsive therapy. Epilepsy & Behavior 2001;2:S68-73.
2. Sackeim HA PhD:Convulsant and anticonvulsant properties of ECT:towards a focal form of brain stimulation.Clinical Neuroscience Research 2004;4:39-57).
3. Sackeim HA PhD et al:Effects of pulse width and electrode placement on the efficacy and cognitive effects of electroconvulsive therapy. Brain Stimulation 2008;2.

Contact MECTA for pricing and upgrade information and also to order Titration Tables and/or a new MECTA Instruction Manual containing the instructions for using these new stimulus dosing parameters.





ECT PARAMETERS / 100 JOULES SYSTEMS

Q Models Four Parameter Sets:	Set 1	Set 2	Set 3	*New!* SPECTRUM Ultrabrief Set 4
Stimulus Current in 100mA increments	500-800 mA	500-800 mA	500-800 mA	500-800 mA
Frequency in 10-Hz steps	20-90 Hz	20-60 Hz	20-60 Hz	20-120 Hz
Pulse Width in .10 msec steps	0.5-1.0 msec	0.5-2.0 msec	0.5-1.0 msec	0.3-0.37 msec
Stimulus Duration	0.5-4.0 sec	0.5-3.0 sec	0.5-6.0 sec	0.5-8.0 sec
Charge	5.0-576 mC	5.0-576 mC	5.0-576 mC	3.0-568.3 mC
Energy @ 220 ohm patient impedance	0.6-101.4 joules	0.6-101.4 joules	0.6-101.4 joules	0.3-100.0 joules

M Models Four Parameter Sets:	Set 1	Set 2	Set 3	*New!* SPECTRUM Ultrabrief Set 4
Stimulus Current	800 mA	800 mA	800 mA	800 mA
Frequency in 100 settings	20-90 Hz	20-120 Hz	20-60 Hz	20-120 Hz
Pulse Width	1.0 msec	1.0 msec	1.0 msec	0.3-0.38 msec
Stimulus Duration	0.18-4.0 sec	0.18-3.0 sec	0.18-6.0 sec	0.5-8.0 sec
Charge in 100 settings	5.8-576 mC	5.8-576 mC	5.8-576 mC	5.8-576 mC
Energy @ 220 ohm patient impedance	1.0-101.4 joules	1.0-101.4 joules	1.0-101.4 joules	1.0-101.4 joules

APPENDIX C

MECTA CORPORATION

19799 SW 95th Place
Suite B, Building D
Tualatin, Oregon 97062

February 15, 2001

To whom it may concern:

Subject: spECTrum Safety Information

The spECTrum ECT units have been designed and are tested to the highest standards applicable to non-invasive devices, and have FDA, ISO 9002, and CE mark approvals, as well as other electrical standard approvals such as UL and cUL. The documents accompanying this letter document the safety features of these devices.

The Essential Requirements/Standards Checklist lists in detail the Essential Requirements outlined in the Medical Device Directive of the CE community, as well as the tools and means used to ensure the design, manufacturing and usage of the units conforms to the requirements.

The Hazard Analysis addresses potential usage hazards. It lists each potential hazard and the approach used to address that hazard.

The Clinical Risk to Intended Benefit Analysis summarizes relevant research and expert opinions about ECT usage and practice. It specifically covers the various treatment parameters and energy related issues of MECTA spECTrum units, including the benefits of 200 Joule machines.

MECTA's manufacturing process includes extensive testing of every single unit shipped from the factory. In addition, spECTrum units run extensive self-tests every time the unit is turned on and every time a treatment session ends. Finally, the units continuously run many internal tests whenever the unit is on. The Overall Quality Plan document summarizes this testing plan.

SpECTrum units deliver a predetermined charge (in milli-coulombs) to the patient. This charge is fully determined by the current, pulsewidth, frequency and duration of the delivered pulse train. These parameters are directly controlled by the knobs on the front panel. The expected energy delivery (based upon a dynamic patient impedance of 220 ohms) is displayed as an aid in choosing the desired stimulus level, and is limited to 100 or 200 joules depending upon regulatory requirements in the destination country. During the delivery, both software and independent backup hardware monitor the current, pulsewidth, frequency and duration. Any deviations from the specified values cause termination of the energy delivery. In addition, the delivery terminates if the delivered voltage ever exceeds 400 volts. These safeguards, the most extensive in the industry, ensure correct energy delivery each and every time. The allowed tolerance on each of these parameters is 10% or less.

Sincerely,

John B. Shaw

John Shaw
Quality Manager
MECTA Corporation

7015 SW McEwan Road
Lake Oswego, Oregon 97035
503/624-8778 FAX 503/624-8729

MECTA Corporation

June 16, 1997

Dr. Med Beate Henrikus
TUV Product Service GMBH
Clinical Affairs
Ridlerstrabe 31
D-80339
Munich, Germany

Dear Dr. Henrikus:

I have enclosed the final report from Dr. Harold Sackeim for you to review. I would be sending you copies of the bibliography if they are required under separate cover with the ORIGINAL REPORT. THEY WILL COME BY FEDERAL EXPRESS TO ARRIVE ON FRIDAY OF THIS WEEK 6/20, 1997.

IT IS IMPERATIVE THAT YOU CONTACT DR. SACKEIM WITH ANY QUESTIONS THAT YOU MAY HAVE PRIOR TO 5;00 PM ON FRIDAY 6/.20/97 AS HE WILL BE OUT OF THE OFFICE FOR THREE WEEKS AND WILL NOT BE AVAILABLE AGAIN UNTIL 6/9/97. HIS PHONE AND HIS FAX ARE ON HIS LETTERHEAD AND HE WILL BE DELIGHTED TO TALK WITH YOU IN THE NEXT FOUR DAYS.

I will call you in the morning at 7:00 am our time to confirm that you received this fax and to be sure that your secretary has notified you of the time constraints that you have. I am very appreciative of your attention to this matter and look forward to talking with you in the morning!

Sincerely,

Robin H. Nicol
President

College of Physicians & Surgeons of Columbia University | *New York, N.Y. 10032*

Harold A. Sackeim, Ph.D.
Professor of Clinical Psychology in Psychiatry
Chief, Department of Biological Psychiatry
New York State Psychiatric Institute

722 West 168th Street, Unit 72
Telephone: (212) 960-5855
Facsimile: (212) 960-5854
email: has1@columbia.edu

June.12, 1997

Dr. med. Beate Henrikus
Clinical Affairs
TUV Product Service GMBH
Ridlerstraße 31
80339 München 2
Germany

Dear Dr. Henrikus:

I am writing to provide a clinical evaluation report of the MECTA SR1/2 and JR1/2 devices used in the delivery of electroconvulsive therapy (ECT), and produced by the MECTA Corporation (7015 S.W. McEwan Road, Lake Oswego, Oregon 97305, US). This report is intended to meet the requirements of EC Directive 93/42/EEC (MDD). I end the report with a description of my experience with the new MECTA spECTrum 5000 series and compare its features to the earlier MECTA SR1/2 and JR1/2.

Background

Enclosed is a copy of my curriculum vitae. I have been engaged in clinical provision and research on ECT since 1979. I am a member of the American Psychiatric Association Task Force on ECT. I hold a MERIT Award from the National Institute of Mental Health (USA) for my research on the affective and cognitive consequences of ECT. I supervise separate clinical services that provide ECT at the New York State Psychiatric Institute and the Presbyterian Hospital at the Columbia-Presbyterian Medical Center. I direct a large research program on ECT as Chief of the Department of Biological Psychiatry, New York State Psychiatric Institute and Professor of Clinical Psychology in Psychiatry and Radiology, College of Physicians and Surgeons of Columbia University. I have substantial experience with the use of these MECTA devices in routine clinical care and in carefully controlled research projects.

Device Description

The MECTA SR1/2 and JR1/2 devices are used in the administration of ECT. Each device delivers a constant current, bidirectional, brief pulse waveform. The SR1 and JR1 models allow the practitioner to independently vary pulse frequency, pulse width, train duration, and current (pulse amplitude). The SR2 and JR2 devices provide a single control that varies stimulus output from 5 to 100% by linearly

increasing pulse frequency and train duration. With the SR2 and JR2 devices pulse width is fixed at 1 ms and current is fixed at 800 mA. Other than this difference in control over stimulus characteristics, the four devices are identical with respect to ECT stimulus delivery features. Common features include the requirement to pass a "self-test" that assesses integrity of the electrical circuit prior to arming the device for stimulus delivery, calculation and display of the dynamic impedance encountered and the energy and voltage administered during delivery of the ECT stimulus, the capability to use remote hand-held electrodes for stimulus delivery, etc.

The SR1/2 models are distinguished from the JR1/2 models by the capacity to record up to two channels of physiology (EEG and/or ECG), and to display the physiology and computations of stimulus characteristics on a chart recorder. Specifically, the JR1/2 models lack these capabilities.

Other details about the particular devices can be found in the SR/JR Domestic Instruction Manual (pages 1-14,16-17) and the SR/JR British Instruction Manual (pages 1-13, 16-17). The book, *The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training, and Privileging*, by the American Psychiatric Association Task Force on ECT (APA, 1990) contains information comparing devices from various manufacturers (pages 165-166). Similar information is provided in the report by the Royal College of Psychiatrists' Special Committee on ECT, *The ECT Handbook* (pages 122-148) (RCP, 1995).

Intended use/indications/contraindications

ECT should be considered only for suitable patients with selected psychiatric disorders. A combination of factors determine if and when the use of ECT is considered. These include the patient's diagnosis, the nature and severity of symptomatology, treatment history, evaluation of the anticipated risks and benefits of alternative treatments, and patient preference.

By far, ECT is the most commonly administered in the treatment of patients with major depressive disorder. ECT is widely considered the most effective form of antidepressant treatment currently available (Sackeim et al., 1993, 1995). There is also substantial evidence regarding the efficacy of ECT in acute mania (Mukherjee et al., 1994) and schizophrenia (Krueger & Sackeim, 1995). Although ECT may be of clinical value in other selective conditions, such use is rare.

Regardless of diagnosis, most patients receive ECT after failing to respond to alternative pharmacological treatments. One of the factors leading to referral to ECT is a history of resistance to adequate pharmacological treatment. For instance, there is substantial evidence that a high percentage of patients who do not respond to adequate trials of antidepressant medications have a strong response to ECT (Prudic et al., 1996). ECT is also considered when patients manifest unacceptable side effects with alternative treatments or when such treatments are deemed to present excessive risk. Particularly with respect to some types of cardiovascular disease, the likelihood of significant medical morbidity or mortality will be less with ECT than

with some pharmacological alternatives (Zielinski et al., 1993). ECT is also considered when there is a particular need to ensure that a patient has rapid and definitive clinical improvement. Relative to pharmacological alternatives in the treatment of major depression, ECT often has a greater probability of resulting in a clinically significant response, as well as greater speed of improvement (Sackeim et al., 1995). For patients who present with psychiatric (suicidal) or medical (inanition) emergencies, these characteristics prompt consideration of ECT. Finally, history of previous response to ECT (and alternatives) and patient preference are additional factors that contribute to decision making.

There are no absolute contraindications to the use of ECT (APA, 1990). Undoubtedly, the medical risks of ECT are substantially heightened in specific circumstances. However, even in circumstances where the risks are substantial, use of ECT may be compelled by a determination that alternative treatments or no treatment likely have inferior risk-to-benefit ratios. The risks of ECT are substantially increased in conditions associated with elevated intracranial pressure (e.g., space-occupying cerebral lesions), in patients who can not tolerate brief peripheral or central hypertension (e.g., bleeding or otherwise unstable vascular aneurysm or malformation; patients with unstable cardiac conditions, such as after myocardial infarction), and in patients with other selected conditions (retinal detachment, pheochromocytoma, increased anesthetic risk).

The indications and relative contraindications for ECT are independent of the device used in ECT administration. Additional information on the indications for use of ECT may be found in the APA (1990) Task Force Report (pages 6-9, 49-57) and the RCP (1995) Special Committee Report (pages 3-23). Information on contraindications may be found in the APA (1990) Task Force Report (pages 9, 57-59) and the Royal College (1995) Special Committee Report (pages 26-29).

Therapeutic Effects of the Device

The purpose of administering the ECT electrical stimulus is to trigger a self-limiting generalized seizure. The application of the electrical stimulus and the elicitation of the seizure can have profound therapeutic effects in specific therapeutic conditions (Abrams, 1997).

Over the last 60 years, a wealth of data has accumulated with respect to the efficacy of ECT in specific psychiatric conditions. Furthermore, there is considerable clinical experience and a body of research reports explicitly using the MECTA SR1/SR2 and JR1/JR2 models.

With respect to major depression, a series of sham-controlled trials conducted in England in the 1970's and 1980's compared real ECT to the repeated administration of anesthesia alone (see Sackeim, 1989 for a review). This work controlled for much of the psychological factors surrounding use of ECT (e.g., high expectations for remission, repeated and stereotyped procedure, etc.) and established that the short-term antidepressant effects of ECT are greater than those of anesthesia alone. More recent

double-blind, randomized research (using the MECTA SR-1 and its predecessor the MECTA Model D) demonstrated that the antidepressant effects of ECT are contingent on the anatomic positioning of electrodes and the extent to which electrical stimulus intensity exceeds seizure threshold (Sackeim et al., 1987a; Sackeim et al., 1993). In other words, the current paths traversed by the ECT stimulus and the current density within these paths can profoundly influence antidepressant response. This work definitively established that technical factors in ECT administration are fundamental in determining the efficacy of the treatment. An older literature compared ECT and antidepressant medications in the treatment of major depression. While subject to a number of methodological qualifications, it is a fair statement that no study has ever shown a pharmacological or other form of somatic treatment to be superior to ECT in short-term antidepressant effects. The literature on the antidepressant efficacy of ECT is critically reviewed in Sackeim (1989) and Sackeim et al. (1995).

The most comprehensive review of the use of ECT in acute mania was published by Mukherjee et al. (1994). It appears that approximately 80% of patients with acute mania will experience marked improvement when treated with ECT. Randomized controlled studies indicate that the therapeutic effects of ECT in acute mania are equivalent or superior to those of some pharmacological alternatives (e.g., lithium combined with antipsychotic) and superior to those of sham treatment (Mukherjee et al., 1988; Small et al., 1988; Sikdar et al., 1994). In the case of patients in manic delirium where the risk of death is extraordinarily high, use of ECT may be life saving.

The therapeutic role of ECT in the treatment of schizophrenia has been extensively reviewed by Krueger and Sackeim (1995). In brief, relative to monotherapy with traditional antipsychotic medication, ECT alone appears to be less efficacious. However, there is a substantial literature that suggests that the combination of ECT and antipsychotic medications may be more efficacious than either treatment alone, particularly for patients with relatively short duration of illness or acute psychotic exacerbation. A substantial case series literature suggests that ECT may be of value when combined with antipsychotic medication when patients with schizophrenia have manifested medication resistance, including patients who have failed the new generation of atypical antipsychotics. Expert bodies have recommended that ECT be particularly considered for medication resistant patients with schizophrenia who have prominent affective symptoms or catatonia (APA, 1990).

Other than the possibility that the efficacy of ECT may be compromised by the use of ultra-brief pulse widths (i.e., < .1 ms) (Cronholm & Ottosson, 1963; Robin & de Tissera , 1982), there is no evidence that the efficacy of ECT for any condition is contingent on the ECT device that is used. Indeed, comparisons of an older generation of devices that output an inefficient constant voltage sine wave stimulus with constant current brief pulse stimulation failed to identify significant differences in therapeutic properties (Valentine et al., 1968; Robin & de Tissera , 1982; Weiner et al., 1986). A number of controlled trials and clinical series have been reported with the MECTA SR1 or SR2 in the treatment of major depression and acute mania (e.g., Mukherjee et al., 1988; Small et al., 1988; Sackeim et al., 1993; Beale et al., 1994; Lerer

et al., 1995). This work has been fundamental in certifying the efficacy of ECT in these conditions and to document the specific therapeutic effects of these devices.

Side Effects of the Device

ECT has the potential to result in a variety of medical complications, and in very rare cases (estimated to be 1 per 10,000 treatments) may result in death (Abrams, 1997). The most common form of medical morbidity and mortality reflects cardiovascular complications (Zielinski et al., 1993). The likelihood and nature of these complications are strongly predicted by the medical status of the patient prior to ECT. There is no evidence that the type of device used in ECT has impact on the incidence or severity of medical morbidity or mortality. This is expected since the medical complications associated with ECT almost all derive from physiological consequences of seizure induction (e.g., hypertension secondary to catecholamine release with a generalized seizure) and are independent of physical characteristics of the electrical stimulus.

The most common side effects of ECT are in the cognitive domain, and it is the potential for adverse cognitive effects that limits the use of ECT. The nature of the cognitive effects of ECT have been the subject of hundreds of investigations, and the most detailed and recent investigations in this area have used the MECTA SR1 (Sackeim et al., 1993; McElhiney et al., 1995; Sobin et al., 1995). The cognitive effects of ECT have been extensively reviewed (Sackeim, 1992).

Briefly, the cognitive side effects of ECT display four key features. (1) Because there is rapid recovery of cognitive functioning following a treatment session, the magnitude and nature of adverse cognitive side effects are contingent on the time of examination. In general, cognitive side effects are most severe in the acute postictal period, particularly at the end of the treatment course. (2) Methods of treatment administration, including characteristics of the ECT stimulus, can have a profound effect on the magnitude of short-term or transient cognitive side effects. In particular, the use of sine wave relative to brief pulse stimulation (Weiner et al., 1986), high intensity relative to low intensity electrical dosage (Sackeim et al., 1993), bilateral relative to right unilateral electrode placement (Weiner et al., 1986; Sackeim et al., 1993), number and spacing of treatments (Lerer et al., 1995) and other factors strongly influence the magnitude and nature of cognitive side effects. (3) Independent of treatment technique, there are individual differences in the magnitude and persistence of adverse cognitive effects. It appears that patients with pre-existing cognitive impairment may be at greater risk for more extensive and persistent retrograde amnesia (Sobin et al., 1995). (4) The adverse cognitive effects of ECT are highly stereotyped. Cognitive functions impaired by the psychiatric condition, typically those dependent on the adequacy of attention and concentration, commonly show improvement within a few days of the ECT course, due to symptomatic improvement. For example, general intelligence measures (IQ) typically improve shortly following ECT (Sackeim et al., 1992). In contrast, ECT introduces deficits in the capacity to retain newly learned information (rapid forgetting, anterograde amnesia), and deficits in the capacity to remember events in the recent past (temporally-graded

retrograde amnesia). This pattern reflects a classic medial temporal lobe amnestic syndrome (Sackeim & Stern, 1997). The anterograde amnesia resolves quickly following termination of ECT, and after several weeks objective evidence of difficulties in learning and remembering new information is not available (Sackeim, 1992; Sackeim et al., 1993). Some patients may experience a permanent retrograde amnesia, with gaps in memory for events that occurred in the weeks to months surrounding the ECT course.

As indicated, the adverse cognitive side effects of ECT are partly contingent on the characteristics of the ECT stimulus. The constant current brief pulse stimulus used in the MECTA SR1/SR2 and JR1/JR2 models is associated with a superior cognitive side effect profile relative to the stimulus administered by sine wave devices (e.g., Weiner et al., 1986). Due to the capacity with these devices to carefully titrate electrical intensity to the needs of individual patients (Sackeim et al., 1993; Beale et al., 1994; Coffey et al., 1995), it has also been demonstrated that acute and short-term cognitive side effects can be markedly reduced (Sackeim et al., 1986, 1993).

Verification that the device achieves the performance intended by the manufacturer and that it is suitable for its functions as a medical device
The MECTA SR1/SR2 and JR1/JR2 output the type of ECT stimulus that has been strongly recommended by experts world-wide (APA, 1990; RCP, 1995). Theoretical analysis of the physical characteristics of the ECT stimulus suggests that constant current brief pulse stimulation is optimal for ECT (Sackeim et al., 1994). These theoretical analyses are fully congruent with empiricial evidence indicating that this form of stimulation is considerably more efficient in seizure-eliciting properties (Weiner,1980; Sackeim et al., 1991) and results in less severe cognitive side effects (Weiner et al., 1986) than sine wave stimulation.

I have had the opportunity to verify the accuracy of the MECTA SR1/SR2 stimulus output characteristics, and other features of the stimulus delivery system (e.g., measurement of static impedance, calculation of delivered energy, voltage, dynamic impedance, etc.). The methods used to independently test a series of MECTA SR1 and SR2 devices have been published (Sackeim et al., 1994). In brief, using custom equipment, we have independently sampled the ECT stimulus administered in over 2,000 treatments sessions of patients. To my knowledge, on no other occasion has the stimulus actually administered to patients during ECT been independently verified at this level of resolution. Sampling rate was 100,000 Hz for both current and voltage, and the complete stimulus train was captured for off-line analysis. This high resolution has allowed us to determine output accuracy within each pulse of the delivered stimulus.

In my experience, the MECTA devices perform according to the manufacturer's claims. In particular, they are highly accurate in pulse frequency, pulse width, and train duration. I have never observed departures from expected values greater than 2%. Current values (pulse amplitude) have shown greater variability across devices (constant within a device) and have never deviated more than 7% from nominal

values. This range of deviation is not meaningful in terms of clinical use of the device. The fact that each of the devices allows for small increments in stimulus intensity (e.g., 256 steps for the single dial SR2 and JR2) is critical in allowing adjustment of the delivered charge to the needs of patients.

The SR1/SR2 have the capacity for physiological monitoring, providing two channel, hard copy of EEG or EEG and ECG. On numerous occasions, I have verified the accuracy of amplifier output on these devices, using standard calibration techniques with known signals that vary in frequency and amplitude. Of note, a variety of studies have used the chart recorded representation of the EEG for manual ratings of ECT seizures (Nobler et al., 1993) or have digitized the analog output of the SR1/SR2 in quantitative studies of ECT seizure characteristics (Krystal et al. 1996). The fact that reliable ratings have been obtained and consistent findings regarding quantitative EEG features also supports the adequacy of device performance for physiological monitoring.

The design and construction of the MECTA SR1/SR2 and JR1/JR2 provide the necessary and appropriate features for use in an ECT medical suite. Extensive use of these devices here at Columbia University and by practitioners world-wide underscores their suitability for ECT practice.

Risk-benefit analysis

There are a variety of risks associated with administration of the electrical stimulus in ECT, the production of generalized seizures, and the adequacy of physiological monitoring during the treatment.

Electrical safety. The electrical safety risks of ECT include the possibility of electrical burns, improper grounding and passage of the ECT stimulus through the patient's heart, and excessive electrical stimulation of the brain.

Burns. Electrical burns result from conditions of high voltage. With a constant current ECT device, the impedance encountered during stimulus delivery determines the voltage administered. The MECTA SR1/SR2 and JR1/JR2 have two provisions that radically reduce the possibility of electrode burns. First, before the devices will arm, a self-test sequence must be passed (or deliberately by-passed). The self-test measures impedance in the circuit and will only pass if values are in the range of 200-10,000 ohms. By determining the integrity of the circuit before arming, the possibility of encountering high impedance is markedly reduced. A particular feature is the detection of low impedance failures. When a conductive medium bridges the two ECT electrodes (hair spray, electrode jell, etc.), impedance will be very low. This circumstance will result in virtually all the current being shunted between the electrodes through the scalp, without the intended seizure production, and can also result in burns. The automatic detection of both excessively low and high impedance is a safety feature of these devices. For these devices, a self-test over-ride is useful in that very exceptional patients may have extremely low impedance in the absence of improper electrode site preparation or other bridging

problems. Of note, in my use of these devices, I have never encountered an electrode burn, nor is there documentation of such a report in the literature. The manuals for the MECTA devices describe accepted procedures for site preparation and use of the self-test protection (Domestic Manual, page 22-33).

Ground faults. A requirement in ECT is that ECG be monitored, given that cardiovascular complications are the greatest source of morbidity and mortality. When an independent ECG device is used on a separate ground, and were a ground fault to develop in the ECT device, there is the theoretical possibility of the ECT electrical stimulus passing through the patient's heart. The intensity of the ECT stimulus approaches that used in cardiac defibrillation. In line with expert body recommendations (APA, 1990), the MECTA instruction manuals explicitly review electrical dangers and steps to minimize risk (e.g., Domestic Manual, page 12). The grounding of the MECTA device should never be defeated, the grounding of other electrical devices in contact with the patient should be verified, and all electrical devices in contact with the patient should share the same ground. Other precautions include ensuring that the ECT electrodes are only in contact with the patient and flammable anesthetics are not used. In testing many MECTA devices, I have never encountered a ground fault. I know of no instance world-wide where use of one of these devices has resulted in morbidity or mortality due to electrical injury to a patient.

Electrical dosage. The third form of electrical risk concerns the administration of excessive electrical dosage during ECT. Markedly exceeding the seizure threshold at intensity levels beyond that needed to achieve clinical response may augment adverse cognitive side effects (Sackeim, 1992). The use of a constant current brief pulse waveform by these devices introduces intrinsic safety features. First, the greater efficiency of the brief pulse waveform relative to sine wave stimulation is associated with a superior profile of cognitive side effects (Weiner et al. 1986). Second, the biological and behavioral effects of electrical brain stimulation is determined by current or charge density (Sackeim et al., 1994). The use of constant current brief pulses that reach a maximum of only 800 mA provides intrinsic protection. The maximum current density in neural tissue with these devices is at least an order of magnitude below the threshold for tissue damage (Devanand et al., 1994). Third, with each of these devices the practitioner has a flexible means of individualizing the delivered charge. Indeed, the instruction manuals for these devices describe two different methods for individualizing the electrical dose (Domestic Manual pages 34-39). While adverse cognitive side effects are an unavoidable consequence of ECT, these devices are designed to minimize such adverse effects. There is a substantial empirical literature that supports this claim (Sackeim et al., 1986, 1993).

A key issue in considering the clinical utility and safety of an ECT device is the maximal charge it can output and the gradations available to adjust the delivered charge to patient needs. The first generation of constant current brief pulse devices produced by MECTA (Models C and D) were under powered, with a maximal charge of 448 mC and maximal energy of approximately 78 J (delivered into 220 ohms). There is remarkable variability among psychiatric patients in seizure threshold, the

minimum charge needed to elicit an adequate generalized seizure. Work at Columbia, now widely replicated world-wide, indicates that this range (with brief pulse constant current stimulation) is in excess of 50-fold (Sackeim et al., 1987b, 1991, 1993). Many patients will have adequate seizures at approximately 20 mC, and using repeated empirical titration we have recently documented that some very exceptional patients have thresholds in excess of 1,000 mC. Consequently, the experience with the first generation of MECTA devices was that a substantial number of patients failed to have the intended generalized seizure when receiving maximal stimulation. This would expose patients to the risks of general anesthesia and subconvulsive electrical brain stimulation, without any possibility of therapeutic benefit. Thus, practitioners were often forced to use double stimulation, an intrinsically awkward technique, in which a second electrical stimulus is given at a variable interval following the first stimulus. This method was not always effective, due to the interval required for devices to re-arm, and was inherently imprecise in control over the administered electrical dose. A related problem arose with the discovery that the extent to which electrical dosage exceeds seizure threshold (in percentage terms) is a critical determinant of the efficacy of the treatment (particularly when using the right unilateral electrode placement) and speed of response (regardless of the positioning of electrodes) (Sackeim et al., 1987a, 1993). This discovery indicated that in patients with high seizure threshold one could elicit generalized seizures at the maximal device output that fully lacked therapeutic properties or that resulted in slow clinical response due to insufficient charge in excess of threshold (APA, 1990).

The initial versions of the MECTA SR1/SR2 and JR1/JR2 models attempted to correct this problem by increasing maximal output to 576 mC or 101.4 J (delivered into 220 ohms). However, the rapidly advancing information on the range in human seizure threshold and the need to exceed the threshold by a substantial amount (i.e., 150-450%) to ensure the efficacy of right unilateral ECT (which has a superior side effect profile), led the clinical community to call for modifications to these devices (Sackeim, 1991). Indeed, based on these considerations, the Royal College of Psychiatrists Special Committee called for 1,200 mC being the minimum maximal output of an ECT device (RCP, 1995). Modifications were then made to the SR1/SR2 and JR1/JR2 models which can now reach 1,200 mC.

In research supported by the National Institute of Mental Health, I have used MECTA SR1 devices with this extended range since 1986. We have documented that some patients could not be effectively treated without this higher output range (Sackeim, 1991, Sackeim et al., 1991, 1993; Lisanby et al., 1996). Like our experience, practitioners at other facilities in the U.S. and Europe report that a substantial proportion of patients require an ECT dose between 600-1,200 mC.

In determining the electrical dose to be administered in ECT, two points are key. First, with constant current brief pulse stimulation, the charge administered is of consequence and not the energy. It is now widely accepted in ECT that the charge administered (and consequently charge density in neural tissue) is responsible for neurobiological and behavioral effects (Sackeim et al., 1987c, 1994). Except for

limiting the possibility of burns, the voltage administered with the constant current stimulus (and consequently the energy) is largely irrelevant. Fortunately, with the constant current devices, variations in the stimulus parameters directly alter the delivered charge. The energy administered during the treatment cannot be known beforehand, as it will depend on patient impedance. This consideration is relevant to evaluating the size of the steps taken by the MECTA devices in altering dosage. When current (pulse amplitude) is increased, the size of steps will differ when computed in units of charge and units of energy. The steps will appear larger in units of energy due to the squaring of current values.

More critically, it is appropriate in ECT that the gradations of steps be larger at higher absolute doses. Expert bodies generally concur that ideally the electrical dosage administered in ECT should be a percentage multiple of the initial seizure threshold determined at the first treatment (APA, 1990; RCP, 1995). Furthermore, all published methods of empirical dose titration, the most sensitive procedure to quantify initial seizure threshold, use larger absolute size steps at the top of the range (for patients with high thresholds) relative to the low end of the range (Sackeim et al., 1987b; Beale et al., 1994; Coffey et al., 1995). This characteristic of ECT reflects individual differences in extent of shunting of current away from brain. Indeed, there is substantial evidence that dynamic impedance during passage of the ECT stimulus (an indirect measure of shunting) and the minimum charge necessary for seizure induction (an indirect measure of current density in brain) show a substantial, inverse relationship (Sackeim et al., 1987c, 1994). Finer gradations at low relative to high charge is theoretically and empirically justified and is reflected in the MECTA SR1/SR2 and JR1/JR2 models.

Medical risks. The medical risks of ECT were summarized earlier. The procedure is associated with a low rate of mortality. The rate of serious medical complications with ECT is believed to be lower than with some accepted forms of pharmacological treatment, and patients with complicated medical conditions are often preferentially referred for ECT (APA, 1990; Sackeim et al., 1995). There is no evidence that the rates or nature of medical morbidity or mortality vary among ECT devices.

Physiological monitoring. Physiological monitoring of the electrocardiogram (ECG) and the electroencephalogram (EEG) are strongly encouraged in order to prevent or detect complications. Post-ictal arrythmias are not uncommon in ECT and EEG monitoring is necessary to establish that seizures have terminated (i.e., risk of nonconvulsive status epilepticus). As indicated above, clinical experience and the research literature both indicate that the monitoring features of the SR1/SR2 devices are reliable and valid.

In summary, provision of ECT may have substantial benefit in terms of providing improvement in the symptoms of specific psychiatric conditions. The efficacy of ECT for specific conditions is well established, and in some instances, provision of this treatment may be life saving. Much of the modern evidence confirming the efficacy of ECT was obtained with MECTA SR1/SR2 or JR1/JR2 devices. Substantial

experience with these devices confirms their utility in clinical practice. With respect to the risks of ECT, some classes of risk are independent of the ECT device used as they are a consequence of seizure induction and not the methods used to induce the seizure or to monitor physiological function. In the areas of electrical safety, flexibility in determining electrical dosage, and physiological monitoring, the MECTA devices are state-of-the-art and provide several safety features not found in other devices. Consequently, the likely benefits of administering ECT with these devices outweigh the risks.

Experience with the MECTA spECTrum models.
I have had the opportunity to use a MECTA spECTrum 5000Q in the treatment of patients at the New York State Psychiatric Institute. I have also extensively tested the reliability and accuracy of the stimulus output characteristics and the physiological monitoring capabilities of the device. My view is that the spECTrum models retain the benefits of the previous generation MECTA SR1/SR2 and JR1/JR2 models, but go beyond these devices in being safer and clinically more useful.

No difficulties were encountered in using a MECTA spECTrum 5000Q in routine clinical care. Examination of the stimulus output characteristics indicated that accuracy either equaled or exceeded that of MECTA SR1/SR2 models. Similarly, use of known calibration signals verified the accuracy of spECTrum analog and digital output for physiological monitoring.

There are several key advantages of the MECTA spECTrum over previous models. The spECTrum provides continuous assessment of static impedance (integrity of the circuit). MECTA SR1/SR2 and JR1/JR2 models required a deliberate self-test to arm and the devices would stay armed for stimulus delivery until they were shut off. Practitioners could avoid use of this safety precaution by leaving the device powered up and not conducting the self-test procedure. The spECTrum provides accurate and continuous values for static impedance, with a more conservative range for arming (100-5,000 ohms) than in the MECTA SR1/SR2 and JR1/JR2 models (200-10,000 ohms). Under conditions where the static impedance has increased from 800 to 3,000 ohms prior to stimulus delivery the prudent practitioner will now be aware of this fact and can investigate the cause of this shift (most commonly poor contact at the electrode/skin interface).

The spECTrum does not permit override in low or high static impedance conditions and delivery of the stimulus is contingent on the static impedance reading once the stimulus delivery button is depressed. By decreasing the low pass range to 100 ohms, the rare patients with intrinsically low static impedance are accommodated. Impedance values below 100 ohms should reflect a conductive bridge needing correction. Similarly, I have never encountered a static impedance of 5,000 ohms or greater that did not reflect lack of integrity of the circuit or poor site preparation. To my knowledge, the spECTrum is unique in requiring correction and preventing stimulus delivery in these circumstances.

The spECTrum contains additional safety features that abort stimulus delivery when voltage or energy thresholds are exceeded. Clinically, this would most likely occur due to slippage of the electrodes during stimulus delivery. The optional hand held electrodes are of superior design to previous models, providing greater assurance that the operator cannot come in contact with the stimulating electrodes. The computation of the delivered stimulus dosage characteristics is inherently more accurate with the spECTrum than the previous SR1/SR2 and JR1/JR2 models. The spECTrum independently samples voltage and current and the computations reflect what was delivered to the patient. In the SR1/SR2 and JR1/JR2 models, the computations of voltage and energy were partly based on assessments of the delivered stimulus, but the report of pulse width, frequency, duration and current values only reflected the device settings, and not what was actually administered. For example, premature release of the stimulus delivery button with the older models could only be determined by noting the mismatch between the energy calculation and what would be calculated based on the stated values for stimulus parameters and voltage. The spECTrum provides accurate calculation, and furthermore, warns the practitioner about instances of premature release.

The spECTrum models have greater flexibility in choice of stimulus parameters, selectable through a menu system, while maintaining limits on the total charge and energy that may be administered. This flexibility is important as there is active investigation in the field of ECT regarding the relative efficiency of parameter combinations (Sackeim et al., 1994). There are substantial reasons to suspect that pulse widths of shorter duration (i.e., 0.5 ms) and trains of longer duration (i.e. > 2 s) may produce seizures at lower total charge than other combinations. In turn, it is likely that cognitive side effects may be reduced. By offering flexibility in choice of parameter set, these devices are less likely to become obsolete with advances in the field. Finally, the spECTrum 5000 models offer options for additional channels of physiological monitoring (EEG, ECG, and OMS), analysis of the EEG seizure characteristics, and the option of monitoring multiple channels of physiology on a remote computer screen and of saving in digital format the treatment parameters and the physiological data. These features can only enhance the practice of ECT.

As I have indicated, the MECTA SR1/SR2 and JR1/JR2 models represented an advance for the field of ECT and their benefits outweigh their risks. In my view, the spECTrum models represent a further advance that will further ensure safe and effective practice of ECT.

Please feel free to contact me if additional information would be helpful.

Sincerely yours,

Harold A. Sackeim

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