MECTA

Instruction Manual

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

November 4, 2015
Revision 11

OPTIMIZED 100 Joules Domestic

19799 SW 95th Avenue, Suite B, Building D
Tualatin, OR 97062
503-612-6780 / fax 503-612-6542
email: info@mectacorp.com

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

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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.

The intended use of MECTA SPECTRUM is to administer electroconvulsive therapy. It should only be used by a physician, and it should not be used for any other purpose.

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.

If this manual is damaged or portions become unusable, please contact MECTA Corporation for a replacement.

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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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 (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). 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 medical grade 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

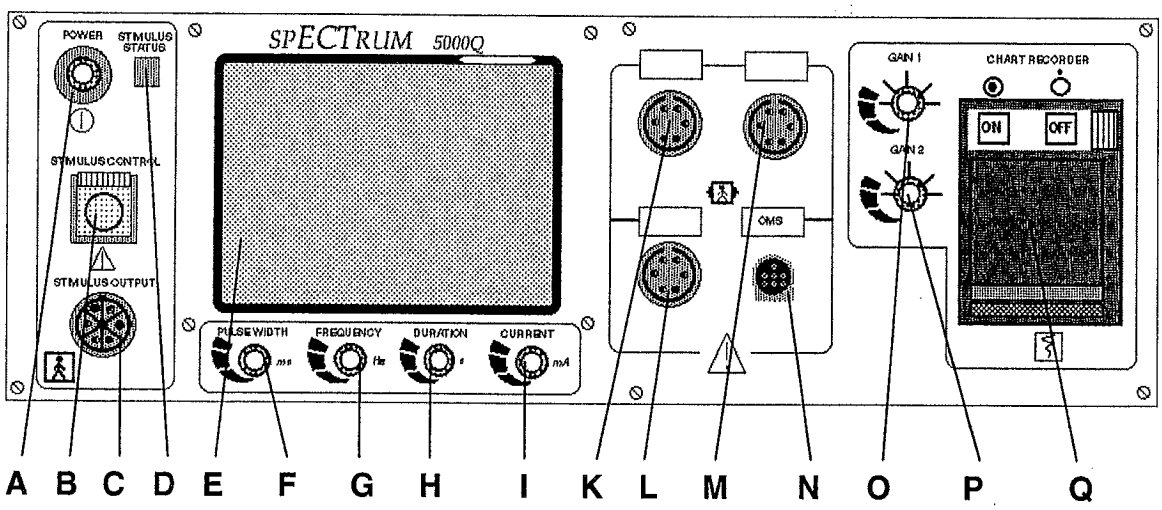
CHART RECORDER Tests

These tests confirm that the printer and printouts are operational.

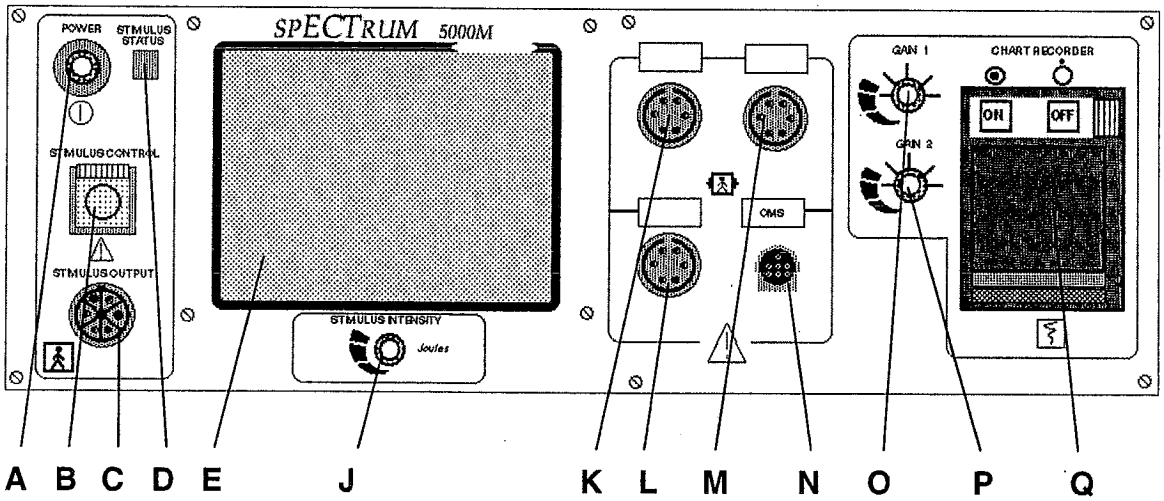
____ 1. Push the ON button located on the CHART RECORDER. Verify that the Chart Recorder prints timing marks, grid patterns, and channel information. (Because a patient is not yet connected, no actual traces will appear).

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

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

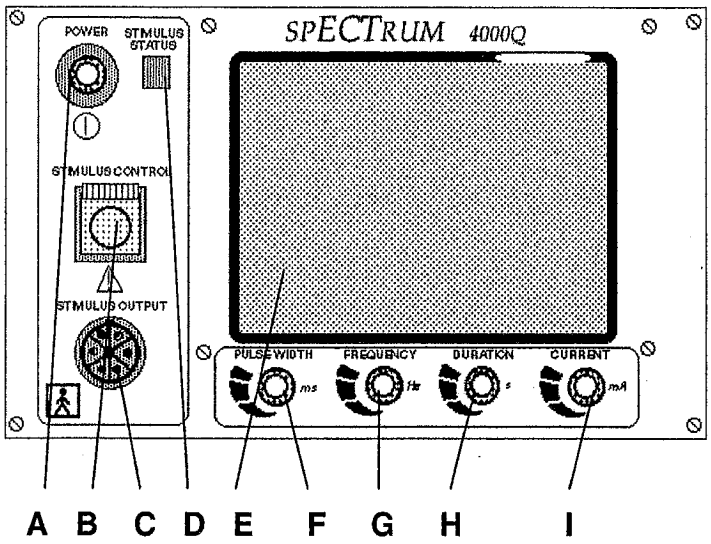
P GAIN 2 knob

Q CHART RECORDER

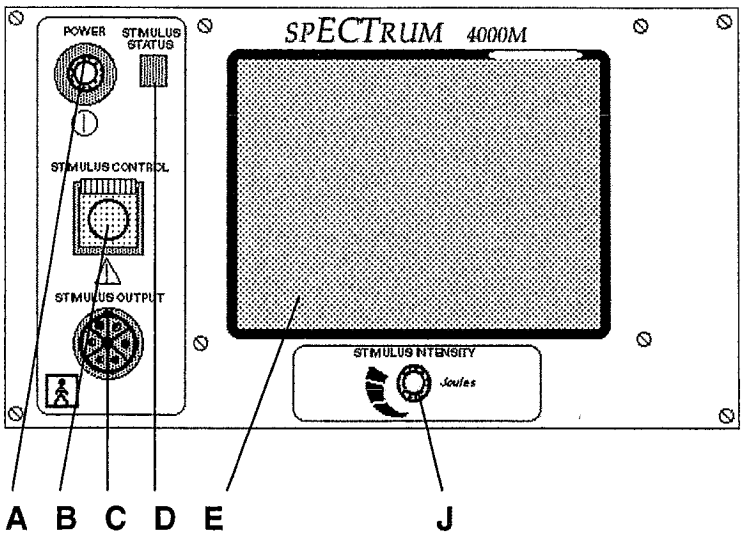
See pgs. 14-15 for descriptions

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)

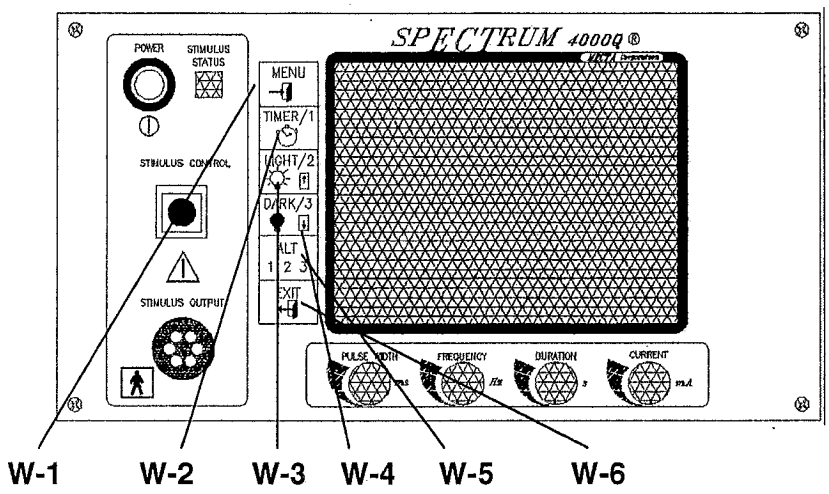
I CURRENT knob (milliAmps)

J STIMULUS INTENSITY knob (M models)

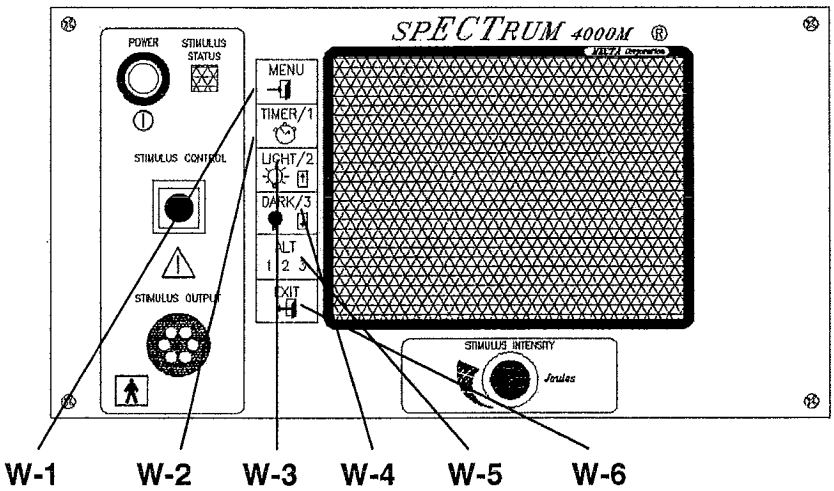
See pgs. 14-15 for descriptions

MEMBRANE SWITCH MODELS

4000Q MEMBRANE SWITCH FRONT PANEL DIAGRAM



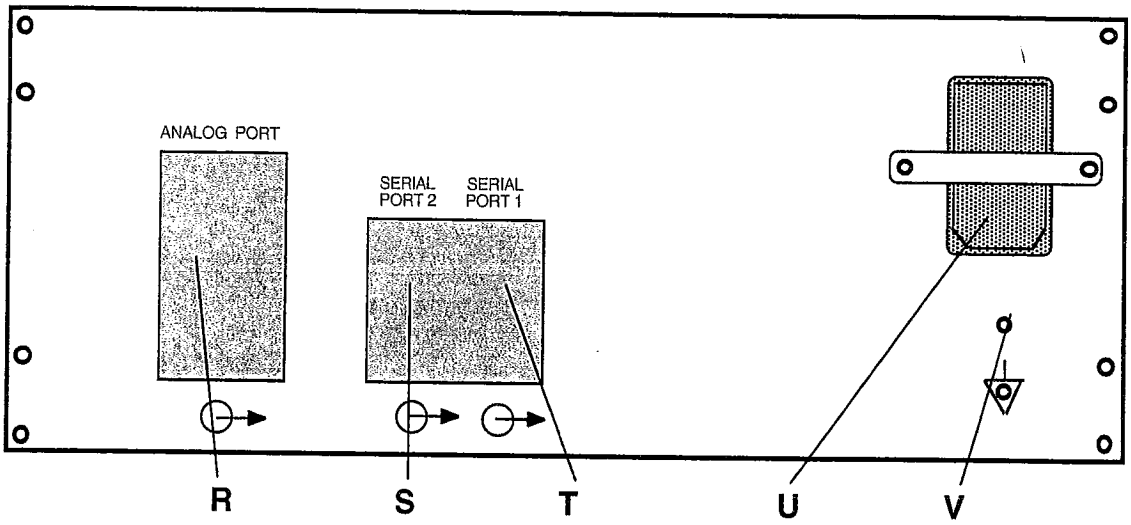
4000M MEMBRANE SWITCH FRONT PANEL DIAGRAM



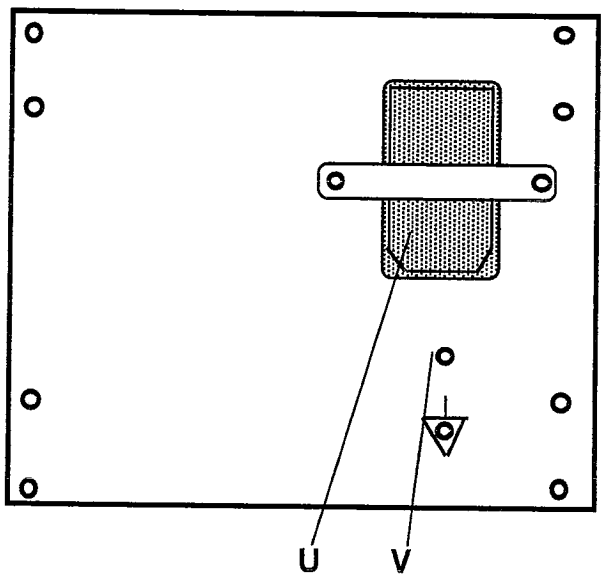
W-1	MENU	Enter the Menu system.
W-2	TIMER	TIMER Start/Stop or "1" if ALT button pressed at the same time.
W-3	LIGHT	Increase brightness or "2" if ALT button pressed at the same time.
W-4	DARK	Decrease brightness or "3" if ALT button pressed at the same time.
W-5	ALT	Select ALT button definitions. Changes 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 (100/115/230 VAC)
and fuse drawer (5 x 20mm)

V Equipotential Post

See pg. 15 for descriptions

PANEL CONTROL/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 has determined by the patient Self-Test that static impedance is in an acceptable range, pushing the STIMULUS CONTROL push-button and holding the button down during the delivery tone results in delivery of the pre-selected 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 (on Models with Touch Screens)

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 stimulus level by simultaneously varying pulse frequency and train duration.

5000 models

K-M. Patient Monitor Input connectors

Connects the patient to the internal instrumentation amplifiers. The Patient Safety Monitor Cable is 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 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

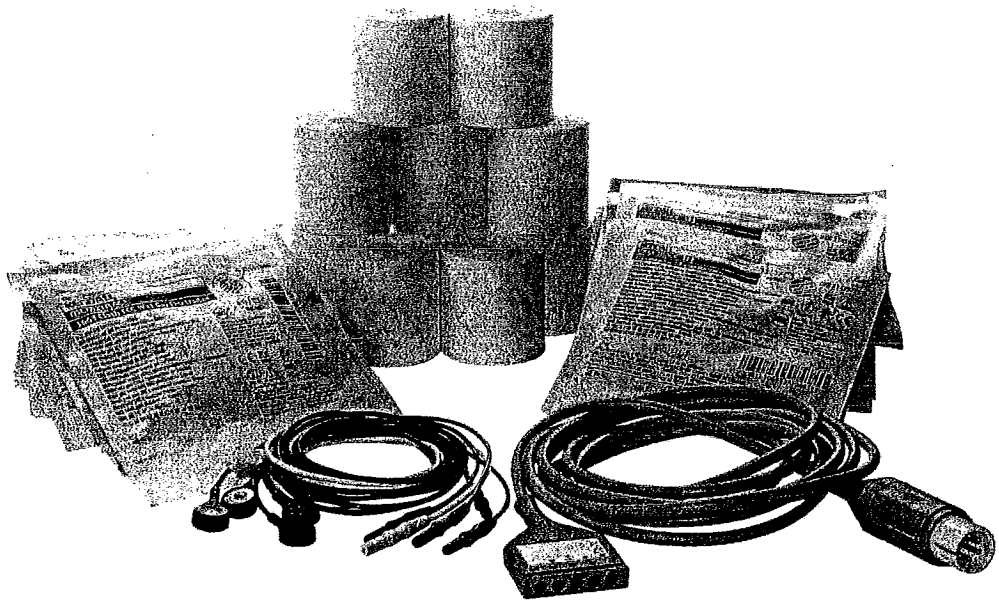
Membrane Switch Front Panel Diagram

W-1. to W-6. MEMBRANE SWITCHES

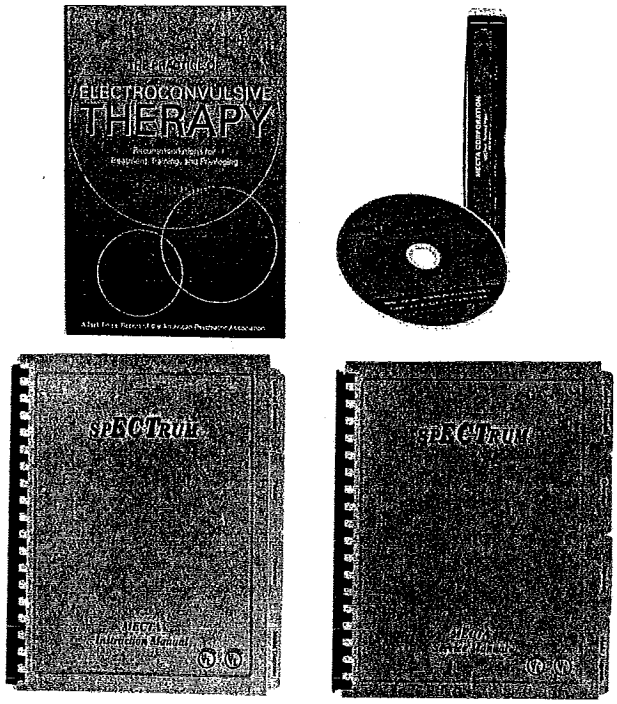
Switches used for menu navigation and system control.

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.

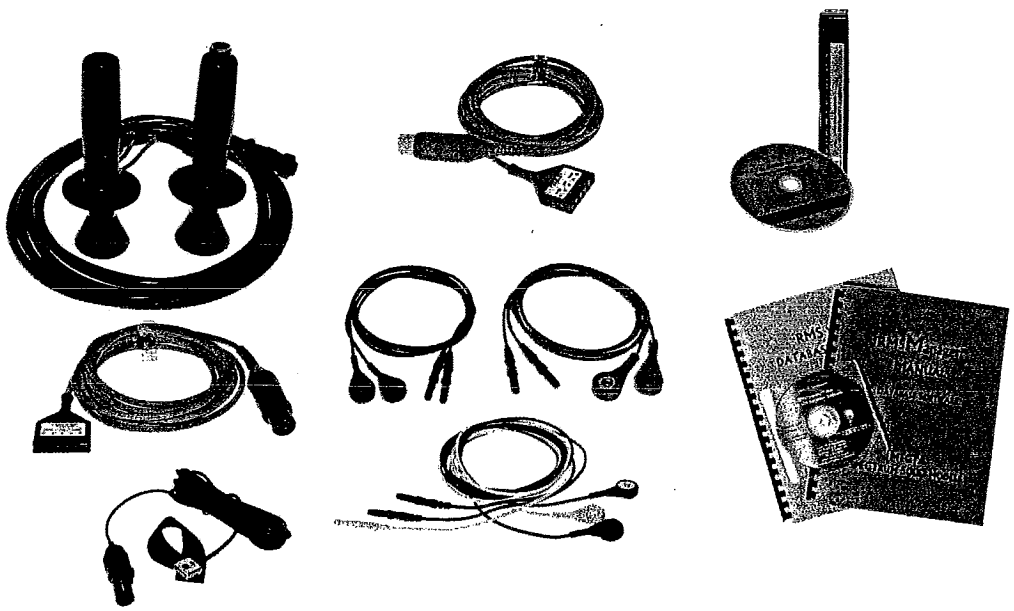
4000 AND 5000 DEVICES. One Patient Stimulus Cable, one set flat stimulus electrodes, one set concave stimulus electrodes, one headband, two each fuses—2 amp or 4 amp, one bite block Blachly, one tube electrode gel, one tube electrode paste.



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



EDUCATIONAL MATERIALS – Two each Instruction manuals, two each Service manuals, one MECTA videotape or DVD (technical), one 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 included the EEG Data Analysis feature, the RMS (Remote Monitor Software videotape or DVD and manual), the RMS MANAGER (database software), and one Windows-compatible PC).

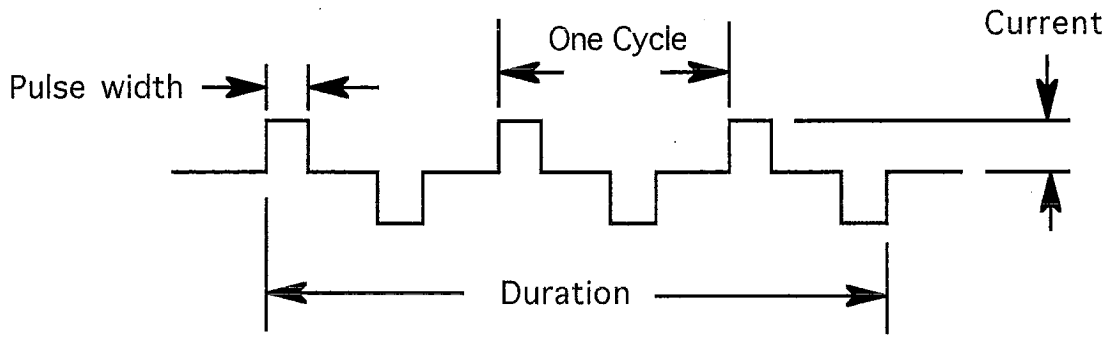
ECT Module

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 0.3, 0.5, or 1.0 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.

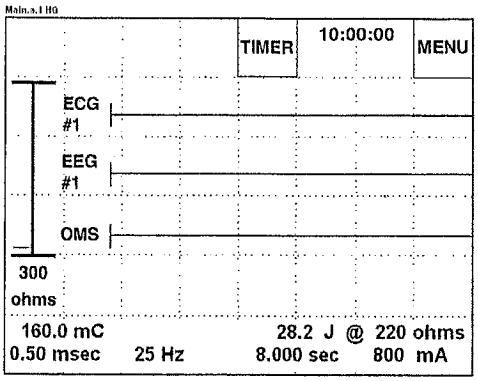
The SPECTRUM measures two types of patient impedance. One is assessed during the patient Self-Test and is displayed at all times, except during the passage of the stimulus. This type is often referred to as STATIC IMPEDANCE. The second type concerns the impedance encountered during the passage of the 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

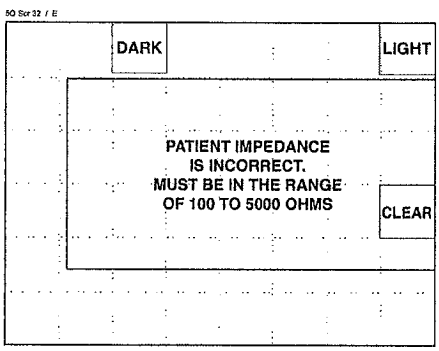
Prior to treatment, the Self-Test impedance measurement provides continuous monitoring of the stimulus electrode connection and display of the static impedance value. Static impedance is continuously assessed by passage of a high frequency, imperceptible low amplitude current through the entire circuit, including the device, Patient Stimulus cable, and patient. To help prevent poor stimulus delivery and ensure 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. Other conditions may cause the STIMULUS STATUS indicator to turn off as well. 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

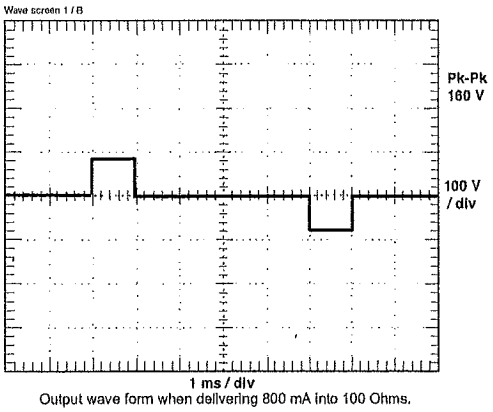
The SPECTRUM models use constant current principles. Independent of the dynamic impedance encountered during stimulation, the SPECTRUM device will maintain the peak current during each pulse at the user specified value for 5000Q and 4000Q models and at the fixed value of 800 mA for 5000M and 4000M models. 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).

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

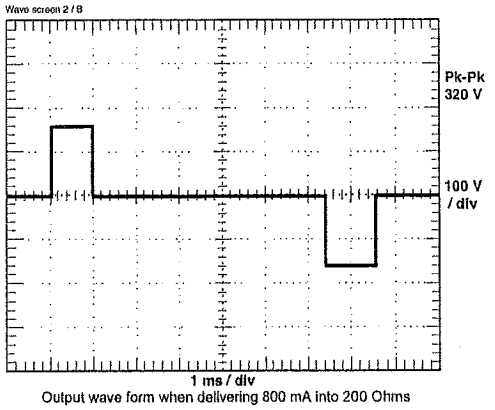
where

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

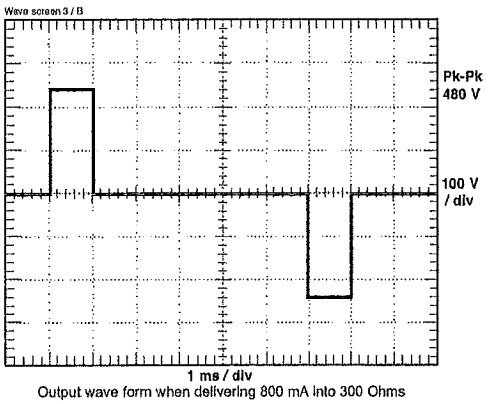
From Ohm's law, it is evident that as dynamic impedance increases, voltage must increase to keep current at a specified value. For example, when the electrical contact between the electrodes and the scalp is poor and dynamic impedance is high, the SPECTRUM must deliver a higher voltage to keep the current at the specified level. Excessively high energy delivery rates can result in burns



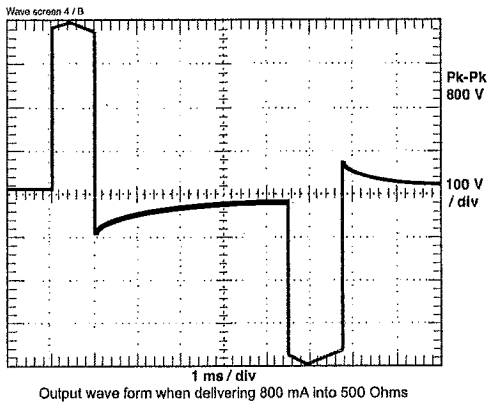
Output wave form when delivering 800 mA into 100 Ohms.



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

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. Also delivery will not be allowed if the rate of energy delivery is expected to exceed a safe level (applicable to the FULL SPECTRUM DOSING Parameter Set on the Q models only). 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. When using the FULL SPECTRUM DOSING Parameter Set on the Q models, delivery will not be allowed if the expected energy exceeds regulatory limits (101 Joules or 202 Joules) into 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:

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

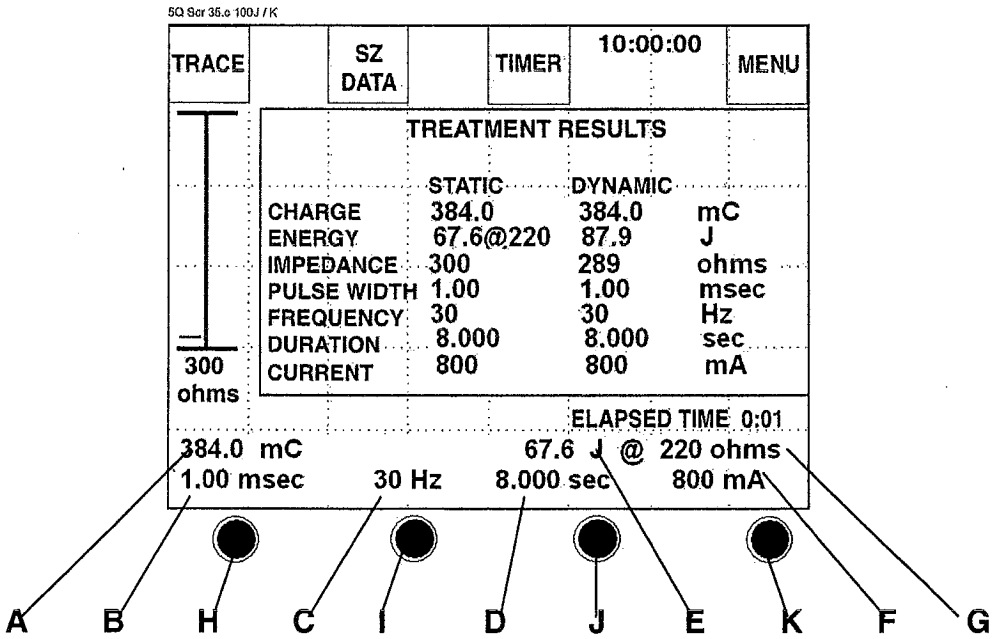
where

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 289, then the energy shown will be larger than the estimate (in the STATIC column) by a factor approximately equal to the DYNAMIC impedance divided by 220, i.e. 289/220 x 67.6 is approximately 88.8 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. 384.0 mC indicates the amount of charge to be delivered (in milliCoulombs) in the next stimulation.
B. 1.0 msec indicates the pulse width.
C. 30 Hz indicates the frequency of pairs of pulses being delivered per second.
D. 8.0 sec indicates the total duration of the pulse train.
E. 67.6 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. In the FULL SPECTRUM DOSING Parameter Set, a DOSAGE EXCEEDED message will appear in place of the Energy, E and G, if the settings exceed allowed safety and regulatory limits.

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 maximum charge / energy output of the device. The display's bottom line is similar to the following:

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;
- the DOSAGE EXCEEDED message appears in which case the parameter settings must be reduced to enable delivery.

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

Through the use of a setup menu system, all SPECTRUM models allow the practitioner to select from among three OPTIMIZED DOSING Parameter Sets. These parameter sets are mainly distinguished by the choice of pulse width (initial values of 0.3, 0.5, or 1.0 ms). All three OPTIMIZED DOSING Parameter Sets offer the capacity to deliver maximum device charge, and each has a maximum train duration of 8 seconds, and delivers a fixed 0.8 A current. In addition to pulse width, the parameter sets differ in maximum frequency.

Q models

The SPECTRUM 4000 or 5000 Q models offer a fourth parameter set, the FULL SPECTRUM DOSING Parameter Set. This parameter set allows full independent control of all four stimulus parameters (PULSE WIDTH, FREQUENCY, DURATION, and CURRENT).

Q models

Q Models - 4 parameter ranges

	Pulse Width	Frequency	Duration	Current	Energy (@ 220)	Charge
OPTIMIZED DOSING Parameter Sets	0.3-0.37 ms	20-120 Hz	0.5-8.0 sec.	800 mA	0.8-100.0 J	4.8-568 mC
	0.5 ms	20-90 Hz	0.5-8.0 sec.	800 mA	1.4-101.4 J	8.0-576 mC
	1.0 ms	20-45 Hz	0.5-8.0 sec.	800 mA	2.8-101.4 J	16.0-576 mC
FULL SPECTRUM DOSING Parameter Set	0.3-1.0 ms	20-120 Hz	0.5-8.0 sec.	500-900 mA	0.3-101.9 J	3.0-579 mC

M models

M Models - 100 settings in 1% steps

	Pulse Width	Frequency	Duration	Current	Energy (@ 220)	Charge
OPTIMIZED DOSING Parameter Sets	0.3-0.38 ms	20-120 Hz	0.60-8.0 sec.	800 mA	1.0-101.4 J	5.8-576.4 mC
	0.5 ms	20-90 Hz	0.36-8.0 sec.	800 mA	1.0-101.4 J	5.8-576 mC
	1.0 ms	20-45 Hz	0.18-8.0 sec.	800 mA	1.0-101.4 J	5.8-576 mC

Unilateral and Bilateral 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).

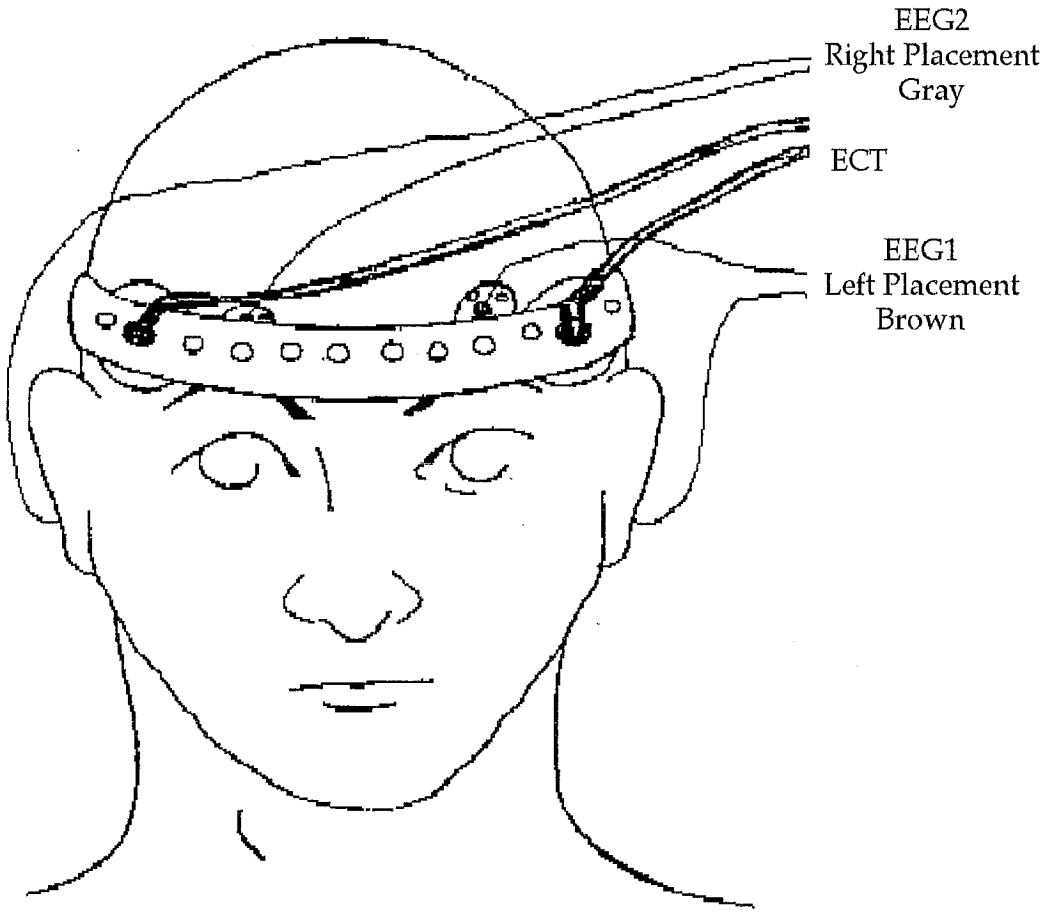


Figure 1

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

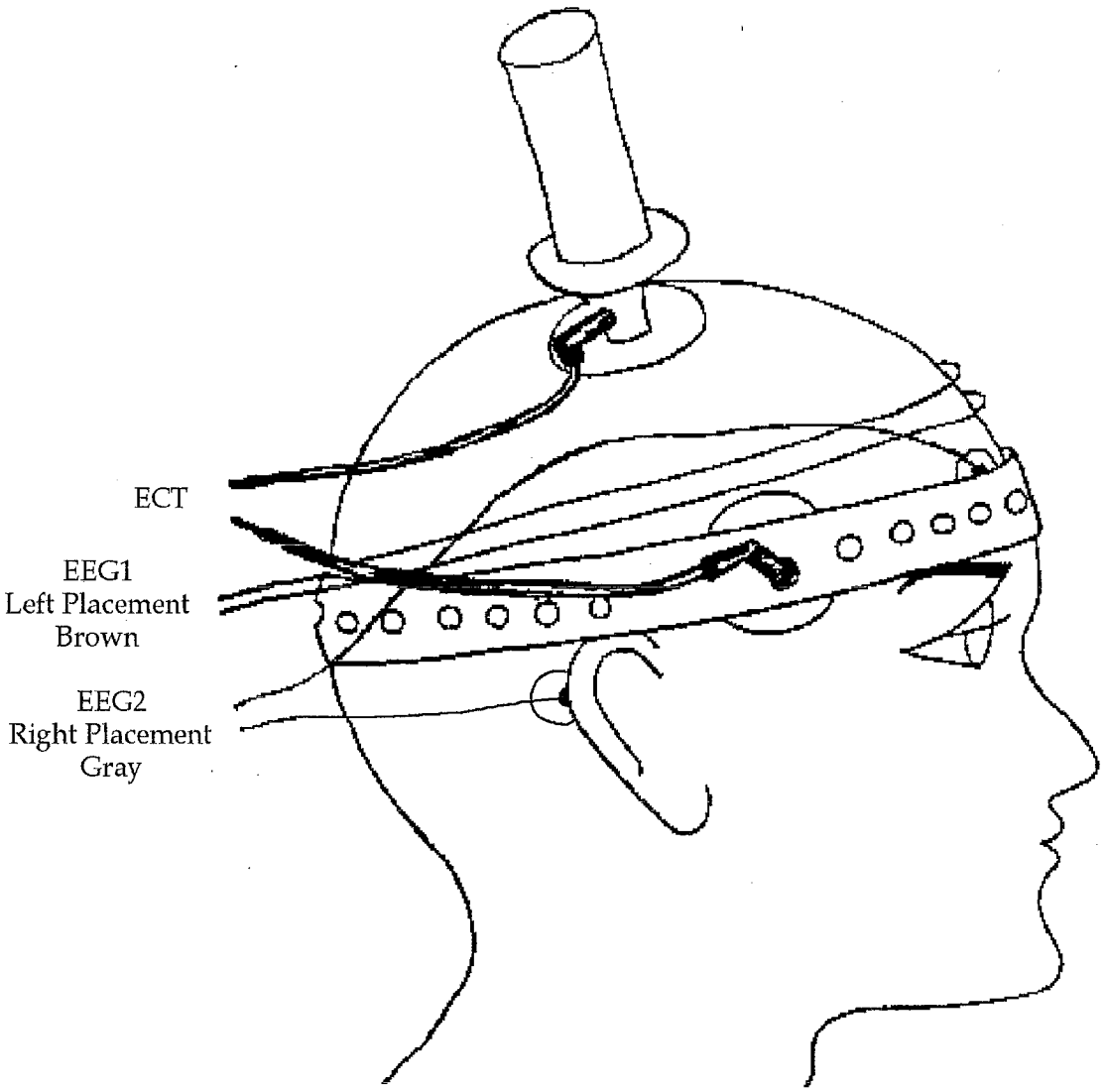


Figure 2

D'Elia unilateral non-dominant placement. The headband holds 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.

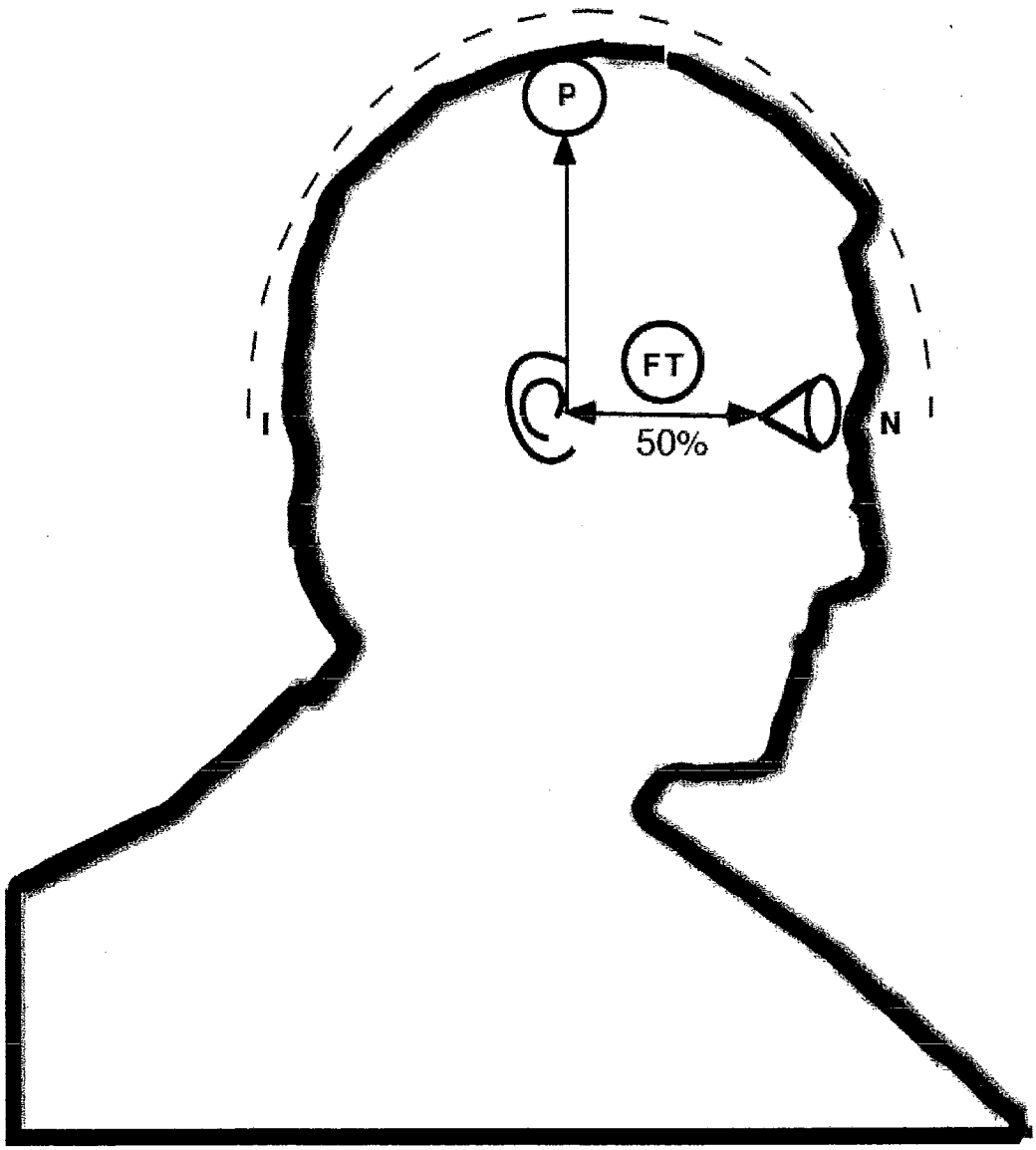


Figure 3

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.

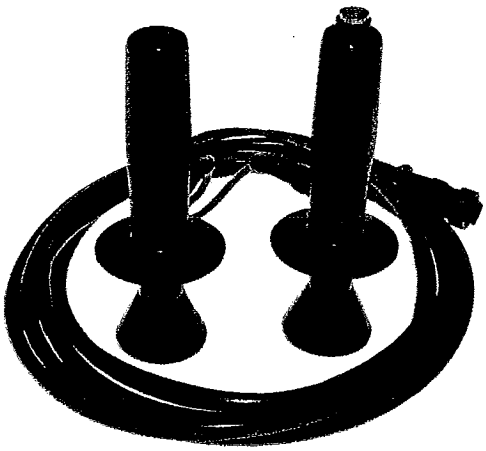
Hand-Held Electrodes

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.

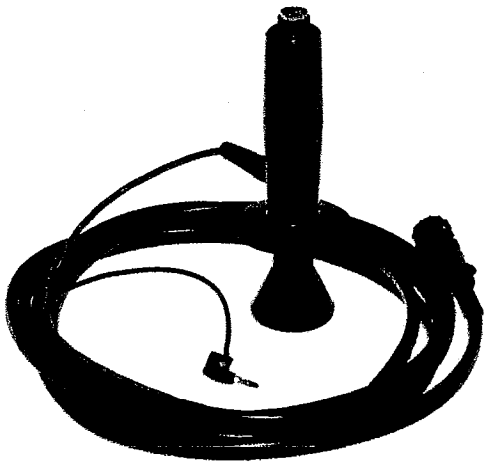
Stability of positioning or slippage may be a concern with the use of hand-held electrodes. This may be a particular problem with unilateral placements, since during the stimulation the patient's head should be projected upward and backward as a result of positive pressure applied under the chin until 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 time by releasing pressure on the remote treatment button.

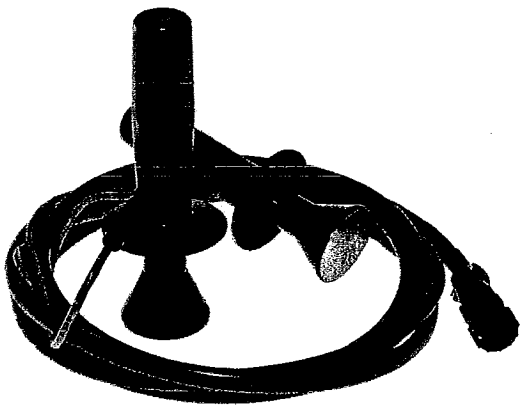
DUAL HAND-HELD WITH REMOTE TREAT SWITCH



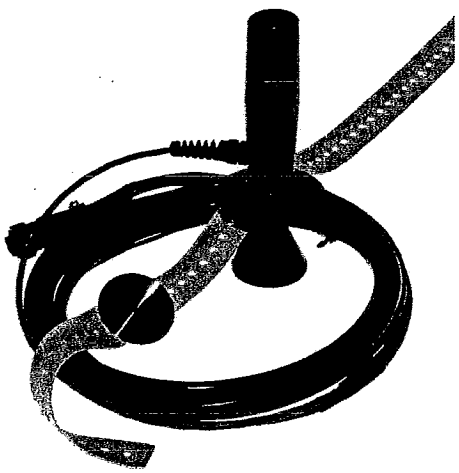
SINGLE HAND-HELD WITH REMOTE TREAT SWITCH



DUAL HAND-HELD W/OUT REMOTE TREAT SWITCH



SINGLE HAND-HELD W/OUT REMOTE TREAT SWITCH



MECTA SPECTRUM *third-generation* Hand-Held Electrodes are an efficient and economical accessory for initiating a treatment with the SPECTRUM 5000 or 4000 model ECT devices. Hand-Held Electrodes replace the need for expensive and often ineffective disposable electrode pads. The NEW, IMPROVED Hand-Helds are up to a ½ lb. lighter than second-generation models, and they are comprised of single molded handles and a flange that is waterproof and easy to clean. There are no extra insulators or O-rings. Remote treat switches are waterproof with two redundant contacts that ensure safety and detect malfunctions. The single molded handle provides an added safety barrier to prevent the clinician from coming in contact with the electrode gel or paste. The Hand-Helds have watertight cable strain reliefs that are more electrically and mechanically sound.

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 resulting in a low impedance failure, 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 pre-selected.

Under no circumstance will the device deliver a stimulus in excess of the device's specified maximal output or deliver the desired energy too quickly. When using the FULL SPECTRUM DOSING Parameter Set that is available with Q models, the practitioner is free to set parameters across the full range of device capabilities. Consequently, combinations of parameters may be selected that exceed maximal device output or rate of safe energy increase. Under these circumstances, the device will not arm for stimulus delivery and the DOSAGE EXCEEDED error message conveys that dosage is excessive, and one or more parameters should be reduced in value.

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 button on the LCD/Touch Screen 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 ensure that stimulus delivery will remain within safe limits even if the processors fail. The SPECTRUM represents the state of the art in safety.

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 principally 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 (0.8 A) and a parameter set is selected during setup that starts with at pulse width of either 0.3, 0.5, or 1.0 millisecond.

Through the use of a setup menu system, all SPECTRUM models allow the practitioner to select from among three OPTIMIZED DOSING Parameter Sets. These parameter sets are mainly distinguished by the choice of pulse width (initial values of 0.3, 0.5, or 1.0 ms). All three OPTIMIZED DOSING Parameter Sets offer the capacity to deliver maximum device charge, and each has a maximum train duration of 8 seconds, and delivers a fixed 0.8 A current. In addition to pulse width, the parameter sets differ in maximum frequency. The SPECTRUM 4000 or 5000 Q models offer a fourth parameter set, the FULL SPECTRUM DOSING Parameter Set. This parameter set allows full independent control of all four stimulus parameters (PULSE WIDTH, FREQUENCY, DURATION, and CURRENT).

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 total 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). The choice is unlimited in range with the FULL SPECTRUM DOSING Parameter Set and guided to preferred values when one of the three OPTIMIZED DOSING Parameter Sets is selected.

In selecting 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. There is also evidence 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), 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 (0.5 or 1.0 ms parameter sets), 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 (0.3 ms parameter set), 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 or bifrontal ECT and a traditional pulse width (0.5 or 1.0 ms parameter sets), 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 or bifrontal ECT with a wide pulse width (0.5 or 1.0 ms parameter sets). 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 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 (or bifrontal) 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 may result at times in excessive side effects and premature termination of the ECT course. The Pre-Selected Dosing method described below offers a guide to dosing that accounts for the effects of electrode placement, gender and age.

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., 0.5, 1.0 ms or more). For example, relative to a 1.5 ms pulse width, the charge (overall intensity) that reliably induced generalized seizures was found to be 3-4 times less when randomly compared to a 0.3 ms pulse width. 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.

Choice of Parameter Sets

Tables in this manual describe the parameter sets for the SPECTRUM 100 J Models (US and Canada). Note that the M and Q models have three OPTIMIZED DOSING Parameter Sets that differ principally in initial pulse width. The Q Models also have the FULL SPECTRUM DOSING Parameter Set.

The choice of pulse width is a fundamental consideration and the parameter with the greatest impact on the efficiency of stimulation. There is substantial evidence that the cognitive side effects of ultrabrief stimulation (0.3 ms pulse width) are markedly less than those of traditional brief pulse stimulation (1.0 ms or greater). Furthermore, it is also evident that a very substantial number of patients remit when treated with ultrabrief high dose (6.0 x ST) right unilateral ECT. For this reason, this form of ECT has become widely used across the world. However, there remain concerns that this form of treatment may be slower in its response. In any case, not all patients benefit from this treatment and other considerations may dictate the choice of a "near ultrabrief" (0.5 ms) pulse width or a traditional pulse width (1.0 ms).

For these reasons, all MECTA devices contain three OPTIMIZED DOSING Parameter Sets that differ principally in the initial value for pulse width (0.3, 0.5, 1.0). Furthermore, the Titration Tables and Pre-Selected Dosing Tables described below in this manual are specific to the choice of pulse width (0.3, 0.5 or 1.0 ms). In the past, MECTA offered the capability of delivering pulses up to 2 ms in width. Since the inefficiency of wider pulses is firmly established, the upper-limit for all SPECTRUM devices is now 1.0 ms.

There is some evidence that increasing the duration of the pulse train is more efficient than increasing pulse frequency. For example, it is believed that an increase of train duration from 1 to 2 seconds is more likely to result in seizure induction than a comparable increase of pulse frequency from 20 to 40 Hz. In addition, it has also been argued that the optimal frequency of pulses (pulse-pairs per second) may be relatively slow, around 20 Hz, although this has not been investigated in human ECT. Overall, the evidence suggests that increases in train duration may be the next most critical parameter in terms of impact on efficiency of seizure elicitation. For this reason, within an OPTIMIZED DOSING Parameter Set, the SPECTRUM M models increase train duration before changing any other parameter. In other words, on the single dial M models, increases in dose first involve an increase in train duration, until the maximum of 8 seconds is reached and before any other parameter is altered. For similar theoretical reasons, the recommended Titration Tables (see below) first increment train duration before altering any other parameter when increasing dose in a titration session or when increasing dose a fixed percentage relative to seizure threshold for dosing in subsequent treatments. On all MECTA models and in all parameter sets, the range of train duration is from 0.5 (or less) to 8 seconds. Thus, across all models, the maximum of 8 second train duration can be delivered within any parameter set.

To increase stimulus dose, increments in train duration may be insufficient. The parameter that is changed after train duration is stimulus frequency. It is firmly established that increases in stimulus frequency contribute to seizure induction since stimulus dose titration has often been conducted with stimulus frequency, the primary variable manipulated when incrementing dosing.

Given this relative status, on the single-dial M models, pulse frequency is incremented only after train duration has been maximized. The ranges of pulse frequency available within a parameter set vary. The maximum frequency in the ultrabrief (0.3 ms) parameter set is 120 Hz. At the longer pulse widths (0.5 and 1.0 ms), maximum device output (576 mC US and Canada devices) is achieved at lower pulse frequencies, resulting in a pulse frequency cutoff specific to each parameter set. Likewise, titration and dosing tables increment frequency only after train duration has been maximized.

The fourth parameter is current or pulse amplitude. There is little information on optimal pulse amplitude in ECT. The vast body of clinical research with MECTA devices has exclusively used the 800 mA setting, although there has been speculation that titration in the current domain may ultimately prove superior in refining stimulus properties. On M Models the current is fixed at 800 mA. Consequently, all Titration and Pre-Selected Dosing tables provided here assume a fixed 800 mA current. However, the current value is selectable on Q Models when using the FULL SPECTRUM DOSING Parameter Set, within a range of 500-900 mA, in 100 mA steps. This extended range in the current domain is unique to MECTA Q devices.

On the M models, change of the single dial automatically increments values within a parameter set in the manner described above, first maximizing values for duration, then frequency, and then pulse width, leaving current fixed.

On the Q models, the alteration of the four knobs on the device results in value changes restricted to the ranges specified in the OPTIMIZED DOSING Parameter Sets. For example, when the frequency knob is altered on the 100 J model (Table 3) using the 1.0 ms parameter set, the range of frequency is restricted to 20-45 Hz, but is 20-120 Hz with the 0.3 ms parameter set. There are three benefits to use of the OPTIMIZED DOSING Parameter Sets. They ensure that a pre-specified pulse width (ultrabrief, near ultrabrief, and traditional brief pulse) is consistently used. They limit parameter ranges to those optimized for the particular pulse width. Finally, for each parameter set, maximal device settings deliver the maximal charge.

The Q models also have the FULL SPECTRUM DOSING Parameter Set. Choice of this parameter set gives the clinician maximum freedom in selecting parameter values. Any combination of stimulus parameters across the total range of the device can be selected, as long the maximal device output (576 mC for 100 J Models) or maximal rate of energy increase are not exceeded. The FULL SPECTRUM DOSING Parameter Set also allows for adjustment of current in the new expanded range (500-900 mA). Care should be used when using this parameter set, as the greater freedom entails greater responsibility. The greater choice in parameter values means that settings can be selected with little scientific rationale (e.g. wide pulse width, high frequency, short duration stimulation). Were the clinician to attempt to maximize all parameter settings, the maximal device output would be greatly exceeded. Therefore, when the clinician selects a parameter configuration that would exceed the device maximum or deliver the energy too quickly, the device does not arm for delivery and a DOSAGE EXCEEDED message will appear, indicating that dosage was exceeded. The FULL SPECTRUM DOSING Parameter Set allows the clinician the widest choice in stimulus parameters, permits the use of historical stimulus configurations, and widens the parameters that can be varied to include current. In turn, this parameter set is intended for the experienced clinician and researcher and requires care in its use. The principal practical difference in use of this parameter set is that the knobs on the device may be set at values that in combination would exceed the device's maximal output limit. As indicated, the user is informed of this circumstance and the device will arm when one or more of the parameter values are reduced to acceptable levels.

Choice of Stimulus Parameters: Practical Considerations

Two general approaches have been recommended by the APA Task Force on ECT for determining ECT stimulus intensity. One approach involves empirically determining the threshold 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, gender and pulse width) and pre-select 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 Pre-Selected Dosing method.

The simplest formula-based or Pre-Selected Dosing 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 suggests that age and seizure threshold have little association. Therefore, when determining dosage on the basis of age alone 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 alone will intrinsically result in the oldest patients receiving the greatest excess of electrical stimulation. This approach also 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 pre-selected 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 Pre-Selected Dosing method when the medical condition of the patient dictates avoidance of subconvulsive stimulation. Others who have less experience with empirical titration may rely on the Pre-Selected Dosing Tables until they have more experience.

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 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 due to concerns over loss of efficacy.

The greater propensity for side effects with bilateral ECT necessitates a different dosing range. With a traditional pulse width (0.5 or 1.0 ms), the dosage of bilateral ECT generally should not exceed 2.5 times the initial seizure threshold. Of note, 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, if used at all, be given with an intensity 4-6 times seizure threshold.

There is controversy in the field as to whether the use of the bifrontal electrode placement has advantages over bilateral or right unilateral ECT. Some contend that this method has both superior cognitive side effects and strong efficacy. However, the studies suggesting this possibility are problematic and much 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. Many facilities limit the number of stimulations in a session to five and ensure that the final stimulation is at maximal device dosage.

HOW TO USE A 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 knob) models. Within each device type, separate tables are provided for devices that have an upper output limit of 100 J (576 mC). The limit on maximal stimulation pertains to the commercial devices in the US and Canada. Finally, and most critically, separate tables are given for ultrabrief (0.3 ms), near ultrabrief (0.5 ms) and traditional brief (1.0 ms) pulse 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 mC). Furthermore, all MECTA SPECTRUM devices are now capable of delivering traditional brief pulse, near ultrabrief, or ultrabrief stimuli. Since pulse width radically determines the efficiency of stimulation (defined as charge at seizure threshold), separate titration tables should be used when patients are treated with one of the three OPTIMIZED DOSING Parameter Sets (0.3, 0.5, or 1.0 ms pulse width). At any one facility it is likely that only one or two of the "extensive" titration tables will be applicable.

In each titration table, the left-hand column presents the stimulus settings for titration (identifying the seizure threshold). Note that up to 7 steps are provided in the tables for 100 J (576 mC US and Canada) 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 percentage increment above the initial ST for the selected dosing values.

For SPECTRUM Q models, all dosing values assume that an 800 mA current setting is used. (This is always the case with M models). If the practitioner wishes to use a lower or higher setting for current (with the FULL SPECTRUM DOSING Parameter Set), 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 are reflected preferentially in an increase in the duration of the stimulus train. The increases in dose at subsequent treatments also preferentially weight duration over pulse frequency (pulse width is set at 0.3, 0.5, 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 more efficient in seizure elicitation than incrementing pulse frequency. Thus, the titration tables are desighed to use the most efficient stimulus parameter sets available for seizure induction.

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 (0.3) 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) and whether you will use an ultrabrief stimulus, a near ultrabrief stimulus or a traditional pulse width.

This treatment strategy indicates that you will be using Table 1-the SPECTRUM Q 100 Joule Titration Table - Ultrabrief (0.3 ms). 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 directions 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 seconds 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 increase in train duration from 4.0 to 8.0 seconds (a two-fold increase) and an increment in pulse frequency from 20 to 60 Hz (a 3-fold change). This produces a total charge of 230.4 mC, which is 6 times the threshold value of 38.4 mC.

USING THE PRE-SELECTED DOSING TABLES

Under some circumstances the practitioner may prefer to give a pre-selected, suprathreshold dose at the first and all subsequent treatments, but at the same time take into account some of the factors that impact on seizure threshold. The Pre-Selected Dosing Tables make best-guess or probabilistic estimates of seizure threshold based on the electrode placement, gender, age, and the pulse width being administered. Separate Pre-Selected Dosing Tables are available for 4000/5000 M and 4000/5000 Q devices. Once the practitioner identifies the device being used, the Pre-Selected Dosing Tables presents values that vary with the choice of pulse width (0.3, 0.5, or 1.0 ms). In other words, the Pre-Selected Dosing Table selected should correspond to the device being used, and values chosen in the table should correspond to the OPTIMIZED and FULL SPECTRUM DOSING Parameter Sets selected.

The Pre-Selected Dosing Tables provide uniform weighting for the factors of electrode placement, gender, age, and pulse width. Seizure threshold is assumed to be 100% greater with bilateral or bifrontal ECT than right unilateral ECT; 50% greater in males compared to females; 50% greater in those 50 years of age relative to those less than 50. Finally, seizure threshold is assumed to be 25% higher with a 0.5 ms pulse width (near ultrabrief) relative to a 0.3 ms pulse width (ultrabrief). Similarly, a pulse width of 1.0 ms is assumed to result in a 100% increase in seizure threshold relative to the 0.3 ms pulse width. The assumed seizure threshold values are given in parenthesis in the first column of the Pre-Selected Dosing Tables.

For example, presume that one is to treat a male, younger than 50, with bilateral ECT and a 0.5 pulse width. Presume that you want to treat the patient with a dose 2.5 above the assumed seizure threshold and that you are using an M 100 J Model device. One first identified the Pre-Selected Dosing Table for the 100 J M Model (Table 8). In this table, one identifies the grouping corresponding to treatment of a male, < 50 years of age. Within this grouping one identifies patients treated with BL (or bifrontal) ECT and use of a 0.5 ms pulse width. Note that in this case the presumed threshold is 75 mC. To treat this patient at 2.5 times the seizure threshold we maintain the row and move the column to the extreme right (150% or 2.5 x ST). There we find that the recommended dosage is a STIMULUS INTENSITY setting of 33%. This Pre-Selected Dosing can be used at all treatments, as long as clinical progress is satisfactory and side effects are not severe.

Thus, the Pre-Selected Dosing method allows the practitioner to pre-select a dosage to use at all treatments without engaging in empirical titration. It is of particular value when ECT is used on an emergency basis or when practitioners require more experience with empirical titration.

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 Empirical Titration tables and Pre-Selected Dosing tables are likely to be conservative estimates of the stimulus intensity necessary to produce adequate seizures.

SPECTRUM 4000Q / 5000Q

TITRATION AND PRE-SELECTED DOSING TABLES FOR USE WITH OPTIMIZED AND FULL SPECTRUM DOSING PARAMETER SETS

TITRATION TABLES FOR USE WITH OPTIMIZED AND FULL SPECTRUM DOSING PARAMETER SETS

TABLE 1

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

Titration	50% above or 1.5 x ST (BL or BF)	100% above or 2 x ST (BL or BF)	150% above or 2.5 x ST (BL or BF)	500% above or 6 x ST (RUL)
Q	Q	Q	Q	Q
Stimulus 1 Charge	Charge %Inc	Charge %Inc	Charge %Inc	Charge %Inc
Freq 20 Hz	20 Hz	20 Hz	20 Hz	20 Hz
PW 0.3 ms	0.3 ms	0.3 ms	0.3 ms	0.3 ms
Dur 1.0 s 9.6 mC	1.5 s 14.4 mC 50%	2.0 s 19.2 mC 100%	2.5 s 24.0 mC 150%	6.0 s 57.6 mC 500%
Stimulus 2 Charge	Charge %Inc	Charge %Inc	Charge %Inc	Charge %Inc
Freq 20 Hz	20 Hz	20 Hz	20 Hz	30 Hz
PW 0.3 ms	0.3 ms	0.3 ms	0.3 ms	0.3 ms
Dur 2.0 s 19.2 mC	3.0 s 28.8 mC 50%	4.0 s 38.4 mC 100%	5.0 s 48.0 mC 150%	8.0 s 115.2 mC 500%
Stimulus 3 Charge	Charge %Inc	Charge %Inc	Charge %Inc	Charge %Inc
Freq 20 Hz	20 Hz	20 Hz	25 Hz	60 Hz
PW 0.3 ms	0.3 ms	0.3 ms	0.3 ms	0.3 ms
Dur 4.0 s 38.4 mC	6.0 s 57.6 mC 50%	8.0 s 76.8 mC 100%	8.0 s 96.0 mC 150%	8.0 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 270%
Stimulus 6 Charge	Charge %Inc	Charge %Inc		
Freq 80 Hz	120 Hz	120 Hz		
PW 0.3 ms	0.3 ms	0.37 ms		
Dur 8.0 s 307.2 mC	8.0 s 460.8 mC 50%	8.0 s 568.3 mC 85%		
Stimulus 7 Charge				
Freq 120 Hz				
PW 0.37 ms				
Dur 8.0 s 568.3 mC				

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

TITRATION TABLES FOR USE WITH OPTIMIZED AND FULL SPECTRUM DOSING PARAMETER SETS

TABLE 2

100 JOULE TITRATION TABLE - SPECTRUM Q (0.5 ms Pulsewidth)

Titration	50% above or 1.5 x ST (BL or BF)	100% above or 2 x ST (BL or BF)	150% above or 2.5 x ST (BL or BF)	500% above or 6 x ST (RUL)
Q	Q	Q	Q	Q
Stimulus 1 Charge	Charge %Inc	Charge %Inc	Charge %Inc	Charge %Inc
Freq 20 Hz	20 Hz	20 Hz	20 Hz	20 Hz
PW 0.5 ms	0.5 ms	0.5 ms	0.5 ms	0.5 ms
Dur 1.0 s 16.0 mC	1.5 s 24.0 mC 50%	2.0 s 32.0 mC 100%	2.5 s 40.0 mC 150%	6.0 s 96.0 mC 500%
Stimulus 2 Charge	Charge %Inc	Charge %Inc	Charge %Inc	Charge %Inc
Freq 20 Hz	20 Hz	20 Hz	20 Hz	30 Hz
PW 0.5 ms	0.5 ms	0.5 ms	0.5 ms	0.5 ms
Dur 2.0 s 32.0 mC	3.0 s 48.0 mC 50%	4.0 s 64.0 mC 100%	5.0 s 80.0 mC 150%	8.0 s 192.0 mC 500%
Stimulus 3 Charge	Charge %Inc	Charge %Inc	Charge %Inc	Charge %Inc
Freq 20 Hz	20 Hz	20 Hz	25 Hz	60 Hz
PW 0.5 ms	0.5 ms	0.5 ms	0.5 ms	0.5 ms
Dur 4.0 s 64.0 mC	6.0 s 96.0 mC 50%	8.0 s 128.0 mC 100%	8.0 s 160.0 mC 150%	8.0 s 384.0 mC 500%
Stimulus 4 Charge	Charge %Inc	Charge %Inc	Charge %Inc	Charge %Inc
Freq 20 Hz	30 Hz	40 Hz	50 Hz	90 Hz
PW 0.5 ms	0.5 ms	0.5 ms	0.5 ms	0.5 ms
Dur 8.0 s 128.0 mC	8.0 s 192.0 mC 50%	8.0 s 256.0 mC 100%	8.0 s 320.0 mC 150%	8.0 s 576.0 mC 350%
Stimulus 5 Charge	Charge %Inc	Charge %Inc	Charge %Inc	
Freq 40 Hz	60 Hz	80 Hz	90 Hz	
PW 0.5 ms	0.5 ms	0.5 ms	0.5 ms	
Dur 8.0 s 256.0 mC	8.0 s 384.0 mC 50%	8.0 s 512.0 mC 100%	8.0 s 576.0 mC 125%	
Stimulus 6 Charge	Charge %Inc			
Freq 80 Hz	90 Hz			
PW 0.5 ms	0.5 ms			
Dur 8.0 s 512.0 mC	8.0 s 576.0 mC 12.5%			

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

TITRATION TABLES FOR USE WITH OPTIMIZED AND FULL SPECTRUM DOSING PARAMETER SETS

TABLE 3

100 JOULE TITRATION TABLE - SPECTRUM Q (1.0 ms Pulsewidth)

Titration	50% above or 1.5 x ST (BL or BF)	100% above or 2 x ST (BL or BF)	150% above or 2.5 x ST (BL or BF)	500% above or 6 x ST (RUL)
Q	Q	Q	Q	Q
Stimulus 1 Charge	Charge %Inc	Charge %Inc	Charge %Inc	Charge %Inc
Freq 20 Hz	20 Hz	20 Hz	20 Hz	20 Hz
PW 1.0 ms	1.0 ms	1.0 ms	1.0 ms	1.0 ms
Dur 0.75 s 24.0 mC	1.25 s 40.0 mC 50%	1.5 s 48.0 mC 100%	2.0 s 64.0 mC 150%	4.5 s 144.0 mC 500%
Stimulus 2 Charge	Charge %Inc	Charge %Inc	Charge %Inc	Charge %Inc
Freq 20 Hz	20 Hz	20 Hz	25 Hz	25 Hz
PW 1.0 ms	1.0 ms	1.0 ms	1.0 ms	1.0 ms
Dur 1.5 s 48.0 mC	2.0 s 64.0 mC 50%	3.0 s 96.0 mC 100%	3.0 s 120.0 mC 150%	7.0 s 256.0 mC 500%
Stimulus 3 Charge	Charge %Inc	Charge %Inc	Charge %Inc	Charge %Inc
Freq 20 Hz	20 Hz	20 Hz	25 Hz	45 Hz
PW 1.0 ms	1.0 ms	1.0 ms	1.0 ms	1.0 ms
Dur 3.0 s 96.0 mC	4.5 s 144.0 mC 50%	6.0 s 192.0 mC 100%	6.0 s 240.0 mC 150%	8.0 s 576.0 mC 500%
Stimulus 4 Charge	Charge %Inc	Charge %Inc	Charge %Inc	Charge %Inc
Freq 20 Hz	25 Hz	30 Hz	40 Hz	45 Hz
PW 1.0 ms	1.0 ms	1.0 ms	1.0 ms	1.0 ms
Dur 6.0 s 192.0 mC	7.0 s 280.0 mC 50%	8.0 s 384.0 mC 100%	7.5 s 480.0 mC 150%	8.0 s 576.0 mC 200%
Stimulus 5 Charge	Charge %Inc			
Freq 30 Hz	45 Hz			
PW 1.0 ms	1.0 ms			
Dur 8.0 s 384.0 mC	8.0 s 576.0 mC 50%			
Stimulus 6 Charge				
Freq 45 Hz				
PW 1.0 ms				
Dur 8.0 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

PRE-SELECTED DOSING TABLES FOR USE WITH OPTIMIZED AND FULL SPECTRUM DOSING PARAMETER SETS

TABLE 4

PRE-SELECTED DOSING TABLES-100 / 200 JOULE SPECTRUM Q (Current is 800 mA)

(Numbers in parentheses are Average Stimulus Thresholds.)

Female, Under 50

	500% or 6 x ST	50% or 1.5 x ST	100% or 2 x ST	150% or 2.5 x ST
0.3 ms RUL (20 mC)	30 Hz, 8 s 115.2 mC			
0.5 ms RUL (25 mC)	25 Hz, 8 s 160.0 mC			
1.0 ms RUL (40 mC)	20 Hz, 7.5 s 240.0 mC			
0.3 ms BL or BF (40 mC)		20 Hz, 6.5 s 62.4 mC	20 Hz, 8 s 76.8 mC	25 Hz, 8 s 96.0 mC
0.5 ms BL or BF (50 mC)		20 Hz, 5 s 80.0 mC	20 Hz, 6.5 s 104.0 mC	20 Hz, 8 s 128.0 mC
1.0 ms BL or BF (80 mC)		20 Hz, 3.75 s 120.0 mC	20 Hz, 5 s 160.0 mC	20 Hz,6.5 s 208.0 mC

Female, 50 and Older, Male Under 50

	500% or 6 x ST	50% or 1.5 x ST	100% or 2 x ST	150% or 2.5 x ST
0.3 ms RUL (30 mC)	45 Hz, 8 s 172.8 mC			
0.5 ms RUL (38 mC)	35 Hz, 8 s 224.0 mC			
1.0 ms RUL (60 mC)	30 Hz, 8 s 384.0 mC			
0.3 ms BL or BF (60 mC)		25 Hz, 7.5 s 90.0 mC	30 Hz, 8 s 115.2 mC	40 Hz, 8 s 153.6 mC
0.5 ms BL or BF (75 mC)		20 Hz, 7 s 112.0 mC	25 Hz, 7.5 s 150.0 mC	30 Hz, 8 s 192.0 mC
1.0 ms BL or BF (120 mC)		20 Hz, 5.5 s 176.0 mC	20 Hz, 7.5 s 240.0 mC	25 Hz, 8 s 320.0 mC

Male, 50 and Older

	500% or 6 x ST	50% or 1.5 x ST	100% or 2 x ST	150% or 2.5 x ST
0.3 ms RUL (40 mC)	65 Hz, 8 s 249.6 mC			
0.5 ms RUL (50 mC)	45 Hz, 8 s 288.0 mC			
1.0 ms RUL (80 mC)	40 Hz, 7.5 s 480.0 mC			
0.3 ms BL or BF (80 mC)		30 Hz, 8 s 115.2 mC	40 Hz, 8 s 153.6 mC	50 Hz, 8 s 192.0 mC
0.5 ms BL or BF (100 mC)		25 Hz, 7.5 s 150.0 mC	30 Hz, 8 s 192.0 mC	40 Hz, 8 s 256.0 mC
1.0 ms BL or BF (160 mC)		20 Hz, 7.5 s 240.0 mC	25 Hz, 8 s 320.0 mC	30 Hz, 8 s 384.0 mC

SPECTRUM 4000M / 5000M

TITRATION AND PRE-SELECTED DOSING TABLES FOR USE WITH OPTIMIZED DOSING PARAMETER SETS ONLY

TITRATION TABLES FOR USE WITH OPTIMIZED SPECTRUM DOSING PARAMETER SETS ONLY

TABLE 5

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

Titration	50% above or 1.5 x ST (BL or BF)	100% above or 2 x ST (BL or BF)	150% above or 2.5 x ST (BL or BF)	500% above or 6 x ST (RUL)
M	M	M	M	M
Stimulus 1 Charge 2% 11.5 mC	3% 17.3 mC 50%	4% 23.0 mC 100%	5% 28.8 mC 150%	12% 69.1 mC 500%
Stimulus 2 Charge 4% 23.0 mC	6% 34.6 mC 50%	8% 46.1 mC 100%	10% 57.6 mC 150%	24% 138.4 mC 500%
Stimulus 3 Charge 8% 46.1 mC	12% 69.1 mC 50%	16% 92.2 mC 100%	20% 115.2 mC 150%	48% 276.5 mC 500%
Stimulus 4 Charge 16% 92.2 mC	24% 138.4 mC 50%	32% 184.4 mC 100%	40% 230.4 mC 150%	96% 553.4 mC 500%
Stimulus 5 Charge 32% 184.4 mC	48% 276.5 mC 50%	64% 368.8 mC 100%	80% 460.8 mC 150%	100% 576.4 mC 215%
Stimulus 6 Charge 64% 368.8 mC	96% 553.4 mC 50%	100% 576.4 mC 56%		
Stimulus 7 Charge 100% 576.4 mC				

STIMULUS PARAMETERS ARE AT 800 mA.

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TITRATION TABLE FOR USE WITH OPTIMIZED SPECTRUM DOSING PARAMETER SETS ONLY

TABLE 6

100 JOULE TITRATION TABLE - SPECTRUM M (0.5 ms Pulsewidth)

Titration		50% above or 1.5 x ST (BL or BF)			100% above or 2 x ST (BL or BF)			150% above or 2.5 x ST (BL or BF)			500% above or 6 x ST (RUL)		
M		M			M			M			M		
Stimulus 1	Charge		Charge	%Inc		Charge	%Inc		Charge	%Inc		Charge	%Inc
3%	17.3 mC	4%	23.0 mC	50%	6%	34.6 mC	100%	7%	40.3 mC	150%	18%	103.7 mC	500%
Stimulus 2	Charge												
6%	34.6 mC	9%	51.8 mC	50%	12%	69.1 mC	100%	15%	86.4 mC	150%	36%	207.5 mC	500%
Stimulus 3	Charge												
12%	69.1 mC	18%	103.7 mC	50%	24%	138.3 mC	100%	30%	172.9 mC	150%	72%	415.0 mC	500%
Stimulus 4	Charge												
24%	138.3 mC	36%	207.5 mC	50%	48%	276.7 mC	100%	60%	345.8 mC	150%	100%	576.0 mC	318%
Stimulus 5	Charge												
48%	276.7 mC	72%	415.0 mC	50%	96%	553.3 mC	100%	100%	576.0 mC	109%			
Stimulus 6	Charge												
96%	553.3 mC	100%	576.0 mC	50%									

STIMULUS PARAMETERS ARE AT 800 mA.

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TITRATION TABLE FOR USE WITH OPTIMIZED SPECTRUM DOSING PARAMETER SETS ONLY

TABLE 7

100 JOULE TITRATION TABLE - SPECTRUM M (1.0 ms Pulsewidth)

Titration	50% above or 1.5 x ST (BL or BF)	100% above or 2 x ST (BL or BF)	150% above or 2.5 x ST (BL or BF)	500% above or 6 x ST (RUL)
M	M	M	M	M
Stimulus 1 Charge 4% 23.0 mC	Charge %Inc 6% 34.6 mC 50%	Charge %Inc 8% 46.1 mC 100%	Charge %Inc 10% 57.6 mC 150%	Charge %Inc 24% 138.2 mC 500%
Stimulus 2 Charge 8% 46.1 mC	12% 69.1 mC 50%	16% 92.2 mC 100%	20% 115.2 mC 150%	48% 276.7 mC 500%
Stimulus 3 Charge 16% 92.2 mC	24% 138.2 mC 50%	32% 184.3 mC 100%	40% 230.4 mC 150%	96% 553.3 mC 500%
Stimulus 4 Charge 32% 184.3 mC	48% 276.7 mC 50%	64% 368.9 mC 100%	80% 461.2 mC 150%	100% 576.0 mC 324%
Stimulus 5 Charge 64% 368.9 mC	96% 553.3 mC 50%	100% 576.0 mC 57%		
Stimulus 6 Charge 100% 576.0 mC				

STIMULUS PARAMETERS ARE AT 800 mA.

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PRE-SELECTED DOSING TABLES
FOR USE WITH OPTIMIZED DOSING PARAMETER SETS ONLY

TABLE 8

PRE-SELECTED DOSING TABLES-100 JOULE SPECTRUM M (Current is 800 mA)

(Numbers in parentheses are Average Stimulus Thresholds.)

Female, Under 50

	500% or 6 x ST
0.3 ms RUL (20 mC)	21% 121.0 mC
0.5 ms RUL (25 mC)	26% 149.8 mC
1.0 ms RUL (40 mC)	42% 241.9 mC

	50% or 1.5 x ST	100% or 2 x ST	150% or 2.5 x ST
0.3 ms BL or BF (40 mC)	10% 57.6 mC	14% 80.7 mC	18% 103.8 mC
0.5 ms BL or BF (50 mC)	13% 74.9 mC	18% 103.7 mC	22% 126.7 mC
1.0 ms BL or BF (80 mC)	21% 121.0 mC	28% 161.3 mC	35% 201.6 mC

Female, 50 and Older, Male Under 50

	500% or 6 x ST
0.3 ms RUL (30 mC)	31% 178.7 mC
0.5 ms RUL (38 mC)	40% 230.6 mC
1.0 ms RUL (60 mC)	63% 362.8 mC

	50% or 1.5 x ST	100% or 2 x ST	150% or 2.5 x ST
0.3 ms BL or BF (50 mC)	13% 74.9 mC	18% 103.8 mC	22% 126.8 mC
0.5 ms BL or BF (75 mC)	20% 115.2 mC	26% 149.8 mC	33% 190.1 mC
1.0 ms BL or BF (120 mC)	31% 178.6 mC	42% 241.9 mC	52% 299.5 mC

Male, 50 and Older

	500% or 6 x ST
0.3 ms RUL (40 mC)	42% 242.1 mC
0.5 ms RUL (50 mC)	52% 299.7 mC
1.0 ms RUL (80 mC)	83% 478.5 mC

	50% or 1.5 x ST	100% or 2 x ST	150% or 2.5 x ST
0.3 ms BL or BF (80 mC)	21% 121.0 mC	28% 161.4 mC	35% 201.7 mC
0.5 ms BL or BF (100 mC)	26% 149.8 mC	35% 201.7 mC	44% 253.4 mC
1.0 ms BL or BF (160 mC)	42% 241.9 mC	56% 322.8 mC	70% 403.5 mC

spECTrum 4000Q / 5000Q

HISTORICAL TITRATION TABLES FOR USE WITH FULL spECTrum DOSING PARAMETER SETS ONLY

TABLE 9 - *100 JOULE TITRATION TABLE - spECTrum Q - ULTRABRIEF (0.3 ms Pulsewidth)*

TABLE 10 - *100 JOULE TITRATION TABLE - spECTrum Q (0.5 ms Pulsewidth)*

TABLE 11 - *100 JOULE TITRATION TABLE - spECTrum Q (1.0 ms Pulsewidth)*

HISTORICAL TITRATION TABLES FOR USE WITH FULL SPECTRUM DOSING PARAMETER SETS ONLY

TABLE 9

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

HISTORICAL TITRATION TABLES FOR USE WITH FULL SPECTRUM DOSING PARAMETER SETS ONLY

TABLE 10

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	16.0 mC
Stimulus 2		Charge
Freq	20 Hz	
PW	0.5 ms	
Dur	2.00 s	32.0 mC
Stimulus 3		Charge
Freq	20 Hz	
PW	0.5 ms	
Dur	4.00 s	64.0 mC
Stimulus 4		Charge
Freq	40 Hz	
PW	0.5 ms	
Dur	4.00 s	128.0 mC
Stimulus 5		Charge
Freq	50 Hz	
PW	0.5 ms	
Dur	6.00 s	240.0 mC
Stimulus 6		Charge
Freq	60 Hz	
PW	0.9 ms	
Dur	6.00 s	518.0 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	96.0 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

HISTORICAL TITRATION TABLES FOR USE WITH FULL SPECTRUM DOSING PARAMETER SETS ONLY

TABLE 11

100 JOULE TITRATION TABLE - SPECTRUM Q (1.0 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		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

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;
- 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. This optional analysis 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 eyebrow
	2	R frontopolar to R mastoid	
4	1	L frontopolar (1 cm 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 (1 cm 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 the analysis of the EEG signal(s). This analysis estimates the adequacy of the induced seizure.

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 in the following section titled "EEG Placements for Four Channels."

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 ensure 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 CHANNELS

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 the following graphics. 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.

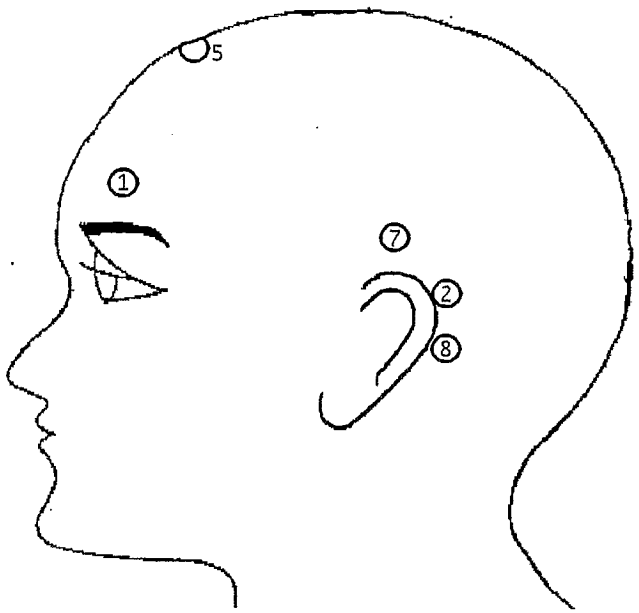
7. Make a short vertical mark through the horizontal frontopolar mark (from step 2) at a point directly over the nasion.

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.

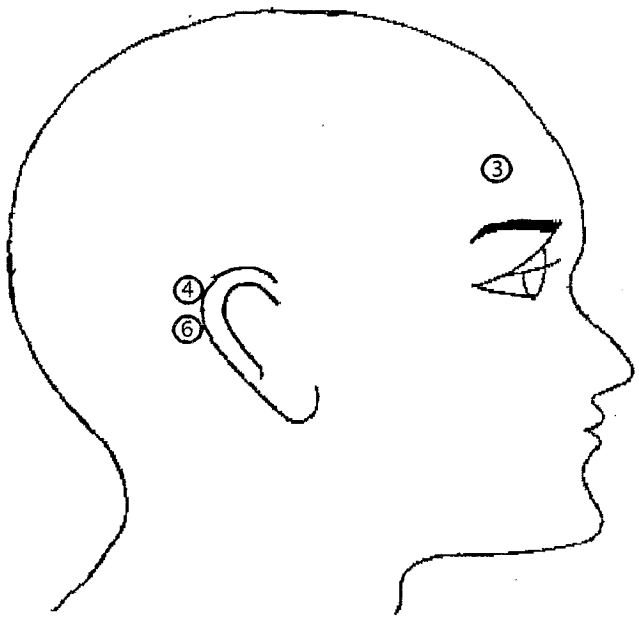
9. Measuring across the midfrontal (30%) horizontal mark from step 2, going from the left pre-auricular notch to the right pre-auricular notch; make a short vertical mark at the midpoint of this anterior transverse distance though the midfrontal horizontal mark; the intersection of these lines denotes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

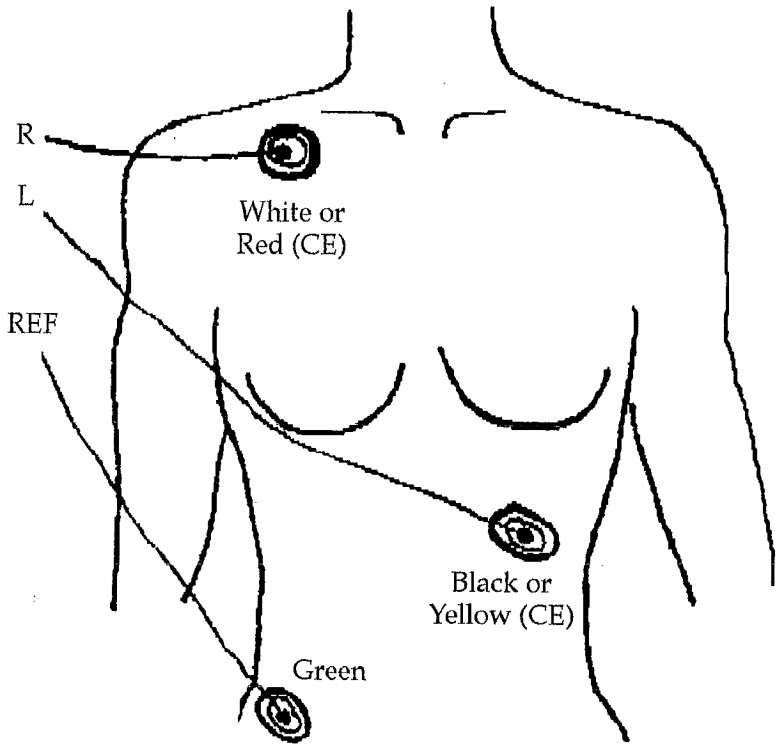
ECG

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 Black, 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 Placement 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.



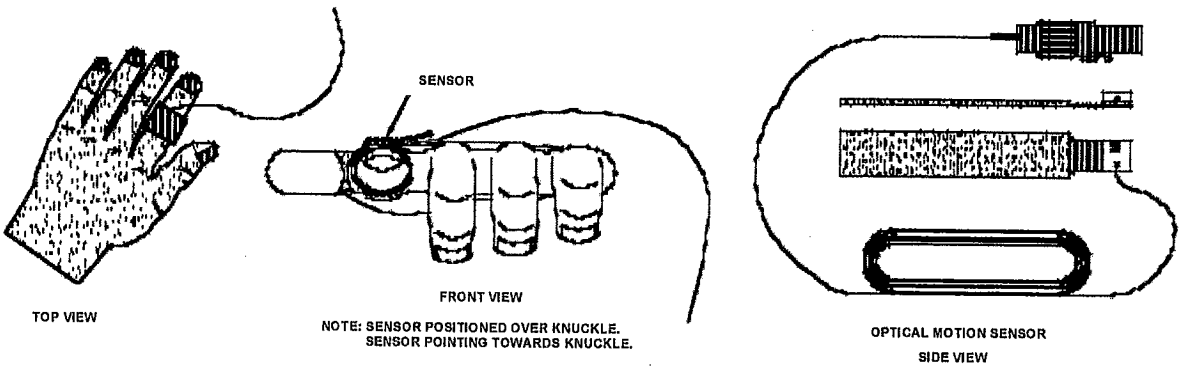
Placement of ECG electrodes

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 a 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

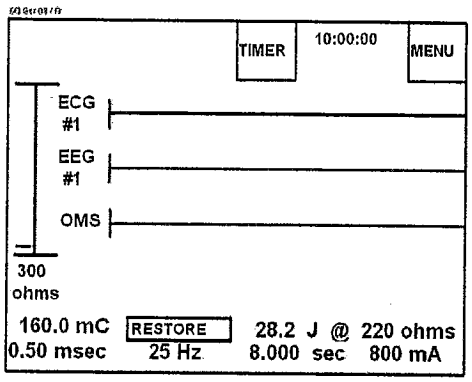
Leads-Off Indication

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 auto trace 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.

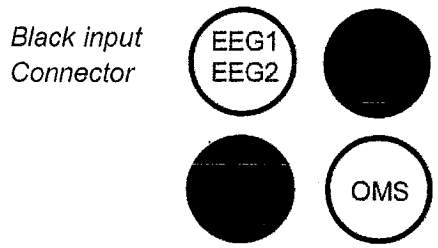
The top 2 configurations are the basic 2 channel configurations shown with an optional OMS channel. The OMS, if included, comes with its own cable and connector. The other active connector uses a 5 lead cable to connect the two monitoring channels to the patient. The green REF lead should be used in 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:

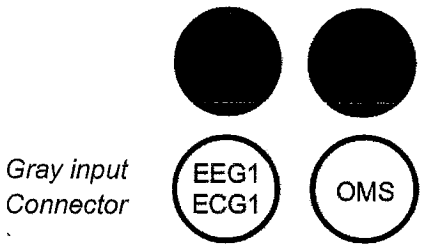
- In patient cables that combine an EEG and an ECG channel in the same cable, be careful to connect EEG and ECG leads correctly to the patient, and to the Patient Monitor cable.
- Confirm that the patient monitor cables are connected to the appropriate connectors (i.e., the cable connector color matches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

Front Panel Input Configuration Options

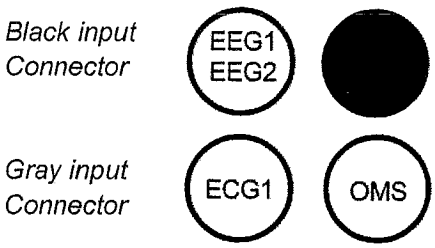
- 2 EEG channels:
  One cable - Black connector
  Optional OMS sensor



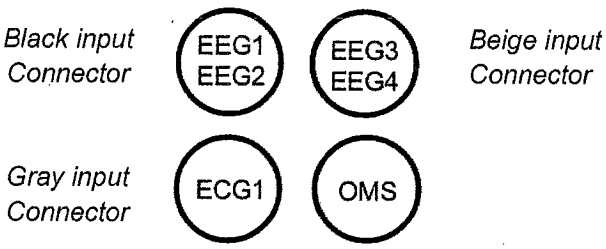
- 1 EEG and 1 ECG channels
  One cable - Gray connector
  Optional OMS sensor



- 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. 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.

If selected via the EEG DATA Menu with OPTIMIZED (1.0 ms) and historical FULL SPECTRUM DOSING Parameter Sets, this measure is displayed on the trace printout after the end of the seizure as "ADEQ XX%", for STIMULUS ADEQUACY. 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.

EEG DATA Analysis and OPTIMIZED DOSING (0.3 ms and 0.5 ms) Parameter Sets

The OPTIMIZED DOSING Parameter Sets (0.3 ms and 0.5 ms) cannot be used with the EEG DATA Analysis feature as the algorithm does not yet incorporate treatment data for these two treatment sets. The EEG DATA Analysis will be turned off automatically if you select the 0.3 ms and 0.5 ms parameter sets. It MUST BE turned back on again using the touch screen menus when the 1.0 ms or FULL SPECTRUM DOSING Parameter Sets are used. Future updates will incorporate the parameters sets into the 0.3 ms and 0.5 ms 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.

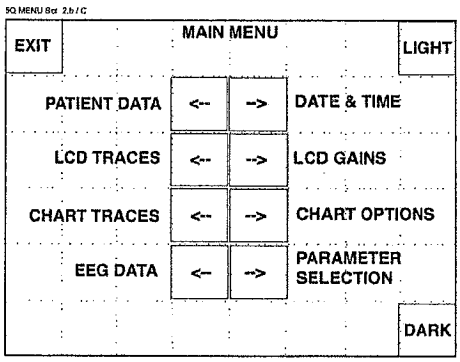
NOTES:

- 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.

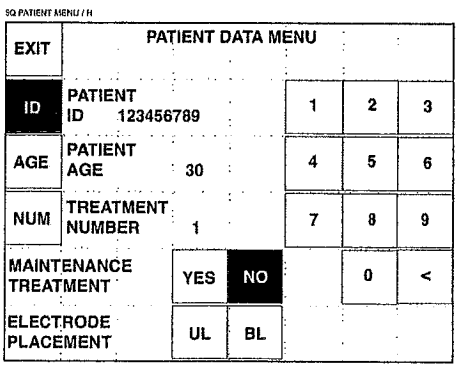
MAIN MENU

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:



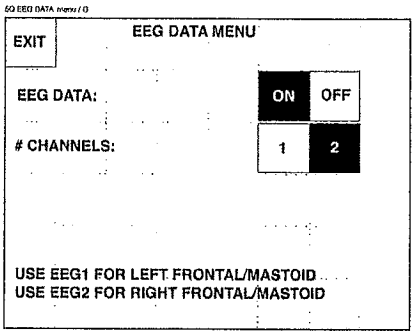
PATIENT DATA MENU

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.



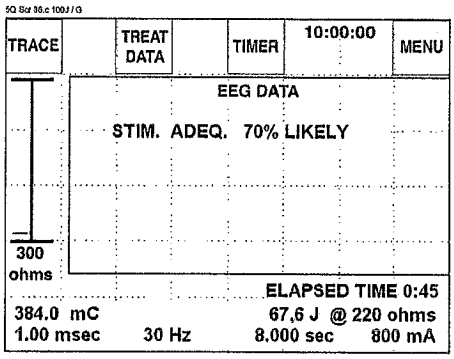
The ON/OFF buttons enable or disable the EEG DATA processing. A dark button with the light lettering indicates the current state.

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

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 occurred. 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 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). This estimate was developed through analysis of ictal EEG data on over 200 patients and has been tested on data from over 80 patients, confirming their validity. As such, this seizure adequacy feature allows the user the unique opportunity to compare the EEG recorded during the present treatment to ictal EEG data from a large database where the stimulus intensity compared to both seizure threshold and therapeutic efficacy was known.

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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.

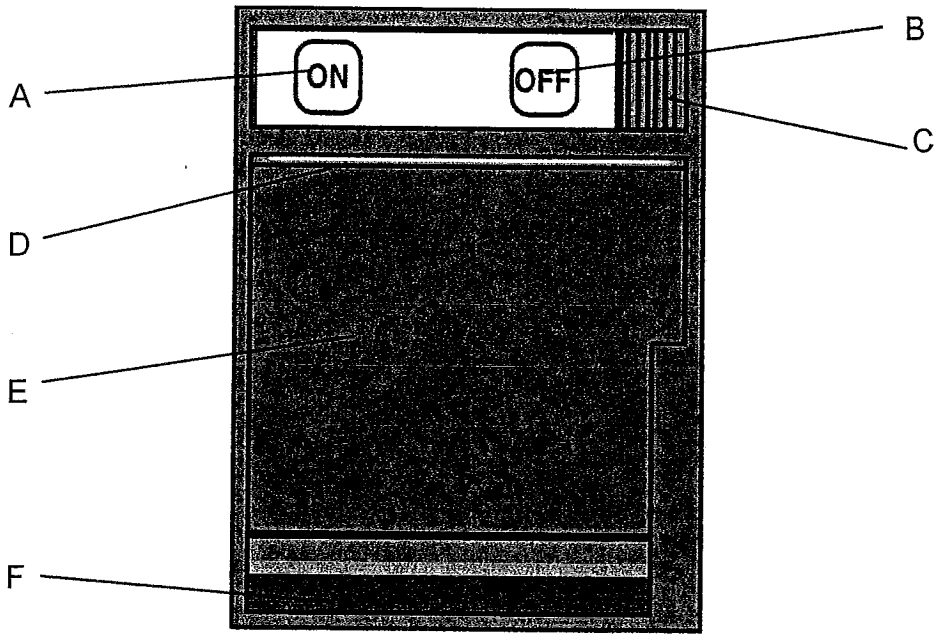
Sackeim HA, Devanand DP, Prudic J. "Stimulus intensity, seizure threshold and seizure duration: Impact on the efficacy and safety of electroconvulsive therapy." Psychiatr. Clin. North Am. 1991; 14:803-843.

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

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).

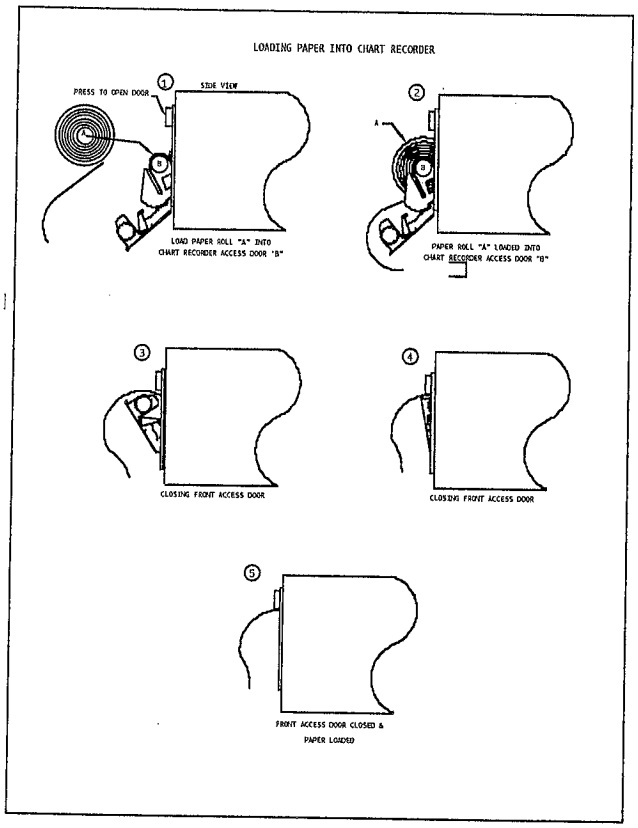
C - CHART RECORDER door latch.

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.

The SPECTRUM does not save the trace data, so if the chart paper runs out and the data is not being logged on a computer, the trace data will be permanently lost.

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.

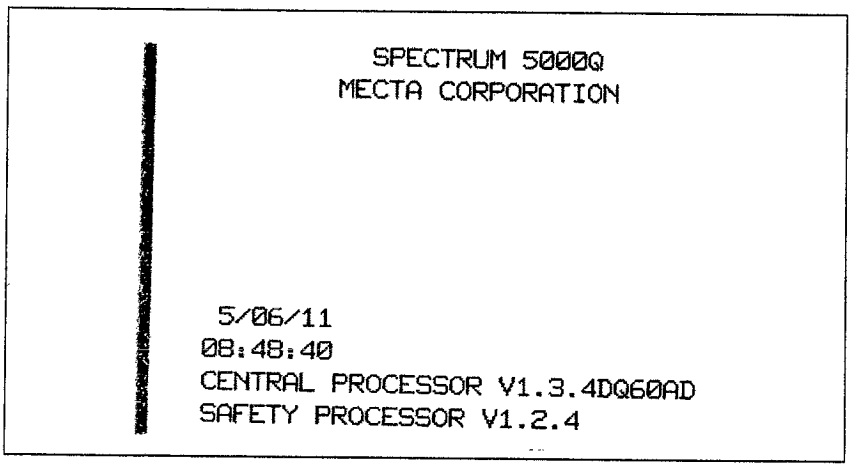
The typical sequence of automatically-initiated printouts is:

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

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.

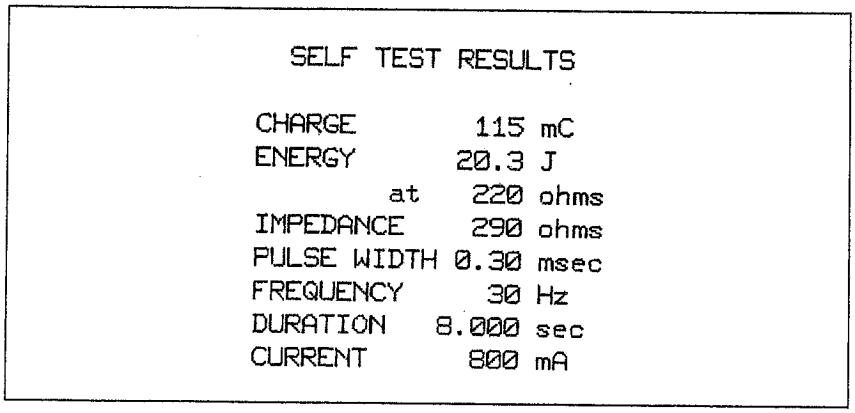
Initial Power-up printout

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:

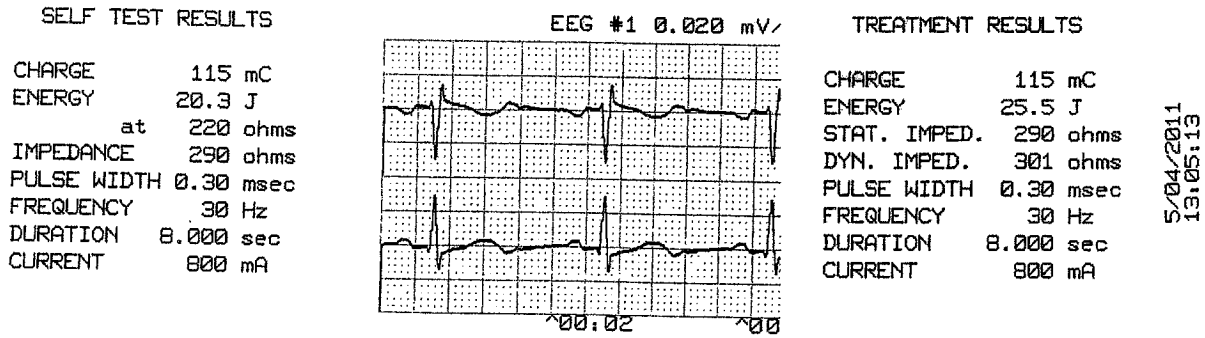
- Channel ID. The ECG and EEG inputs will show type, lead number (for multiple EEG channels), and millivolt/millimeter division. (The OMS sensor, having no voltage, will show only "OMS".)
- One or two traces will be printed, depending on the number of traces selected in the CHART TRACE MENU. The trace 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:

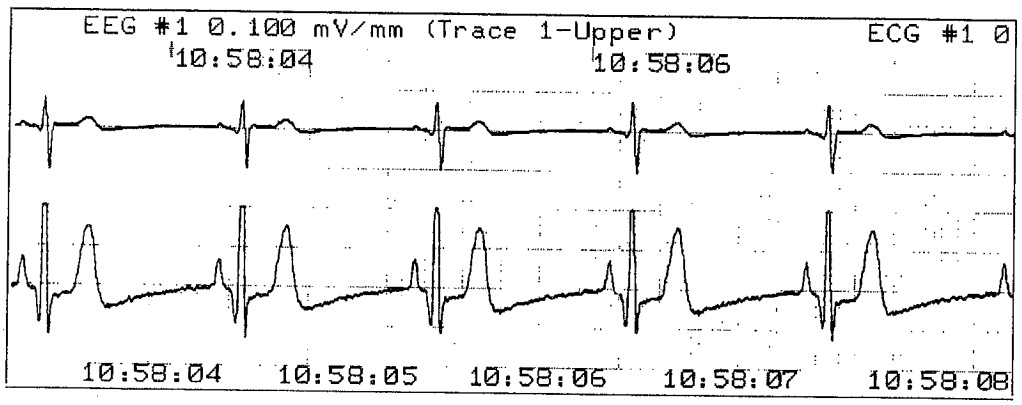
- The upper (or only) waveform trace is always GAIN 1.
- The size of printed traces is controlled only by the GAIN 1 and GAIN 2 gain adjustment settings. Printed trace size is not affected by the gain settings selected for the LCD/Touch Screen.



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.

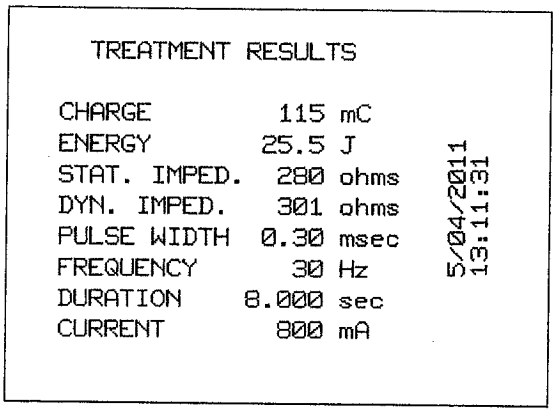
NOTE:

- 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.

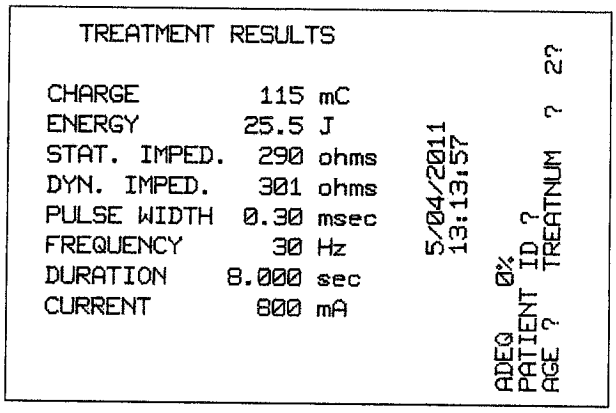
PATIENT DATA and EEG DATA are printed after each stimulus if the EEG DATA ANALYSIS option has been purchased and is set to ON in the EEG DATA MENU. Patient data follows after the last stimulus (when the DONE button on the LCD is touched, or the Recorder's OFF button is used) if PRINT PATIENT DATA is 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:

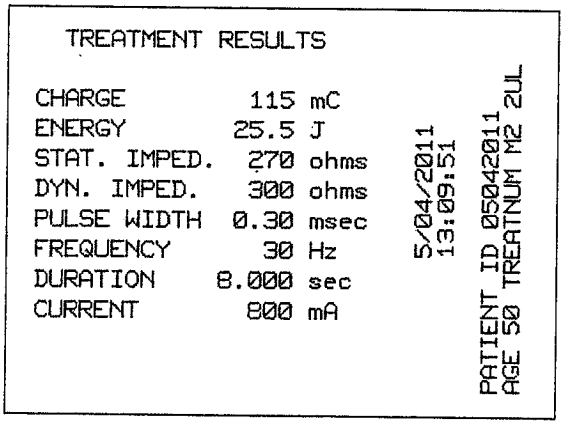
--setting of PRINT PATIENT DATA in the CHART OPTIONS menu;
--setting of EEG DATA ON in the EEG DATA menu;
--setting of ELECTRODE PLACEMENT in the PATIENT DATA menu.
--status of the EEG leads (ON or OFF) used in the EEG DATA analysis.



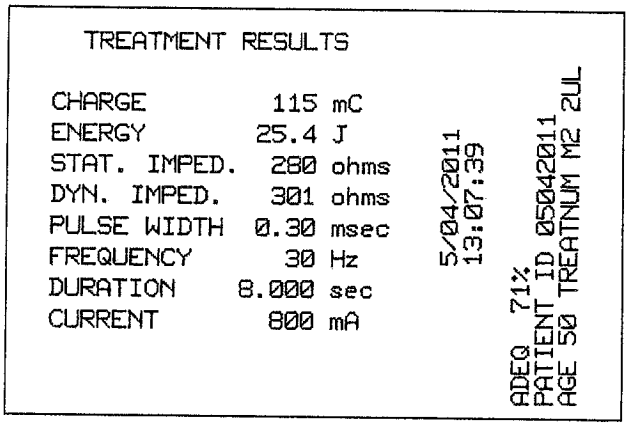
A. Date and time only appears. Both "Print Patient Data" and "EEG Data" are set to OFF. No EEG or patient data is printed.



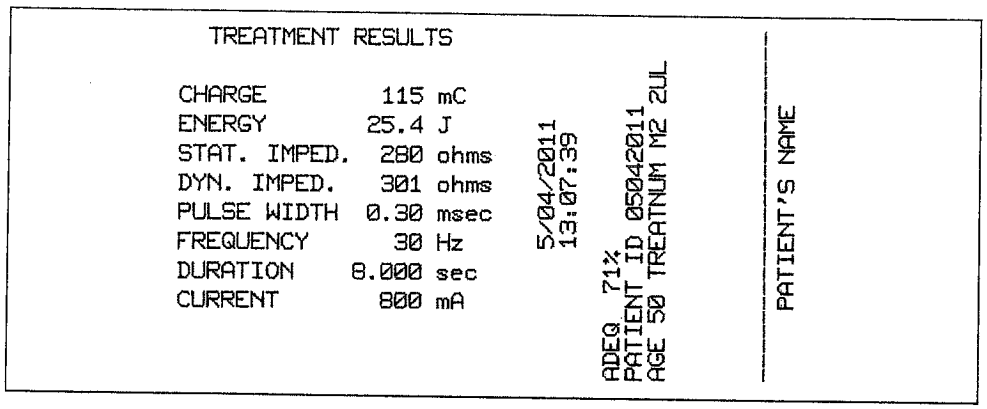
B. Both options are set to ON, but Patient Info displayed shows "?" because no information was entered in the PATIENT INFO menu.



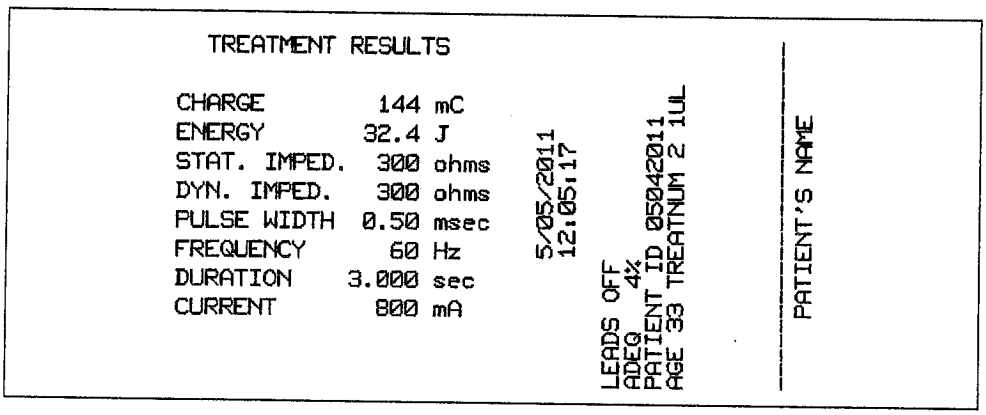
C. "Print Patient Data" is ON; "EEG Data" is set to OFF. Patient information appears. No EEG data is printed.



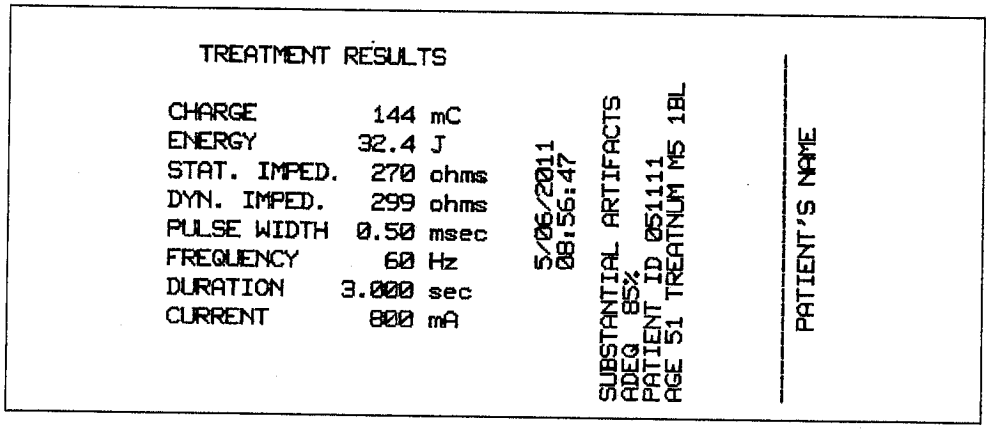
D. Both options are set to ON, and all info appears. "Adequacy" entry shows that BL was entered in the PATIENT INFO menu.



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



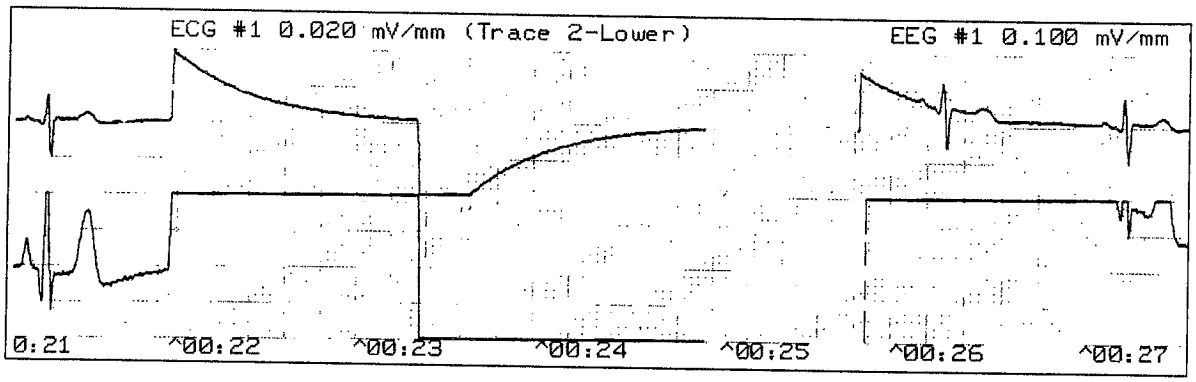
F. When EEG DATA is set to ON, if the EEG1/EEG2 connector is unplugged from its Front Panel connector, the message "LEADS OFF" appears on the EEG DATA display when the EEG DATA is updated (8.5 seconds after treatment ends). If the lead remains unplugged when DONE or OFF is touched, LEADS OFF prints on 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.



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.
- **All Models:**

  The patient should always be at least 1.5 meters from the SPECTRUM and all non medical equipment. The only parts of the SPECTRUM in the patient environment should be stimulus and monitoring cables and electrodes.

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.)

5000 models

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. Verify that the DOSAGE EXCEEDED message does not appear in place of the energy display.

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

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 and gel. See "ECT Module" Preparing the scalp for stimulus electrode placement in this manual for details.

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, 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:

5000 models

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

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 OFF. Go to the EEG DATA menu to verify and set or change the EEG DATA options.

5000 models

8. PARAMETER SELECTION MENU default option for the Q and the M models is the 0.3 millisecond OPTIMIZED DOSING Parameter Sets. 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.

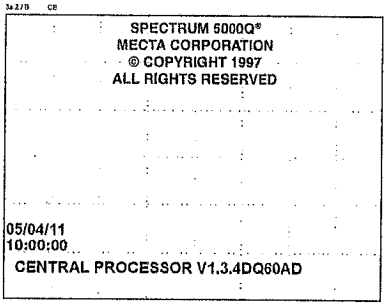
5000 models

2. Connect the Patient Safety Monitor cable(s) and EEG electrode leads 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.

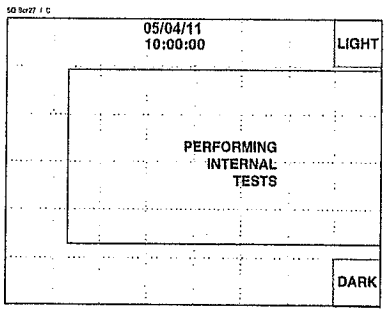
5000 models

(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.

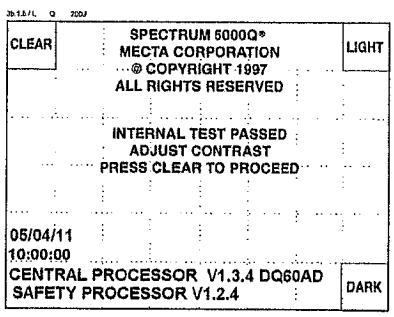
During the power-up steps, three tones will sound and the STIMULUS STATUS indicator on the front panel should flash yellow--green--red in quick succession, then go out. The LCD Screen will display messages stating that the internal tests have passed.



Copyright display



Internal Tests message



Copyright display

Contrast Adjustment

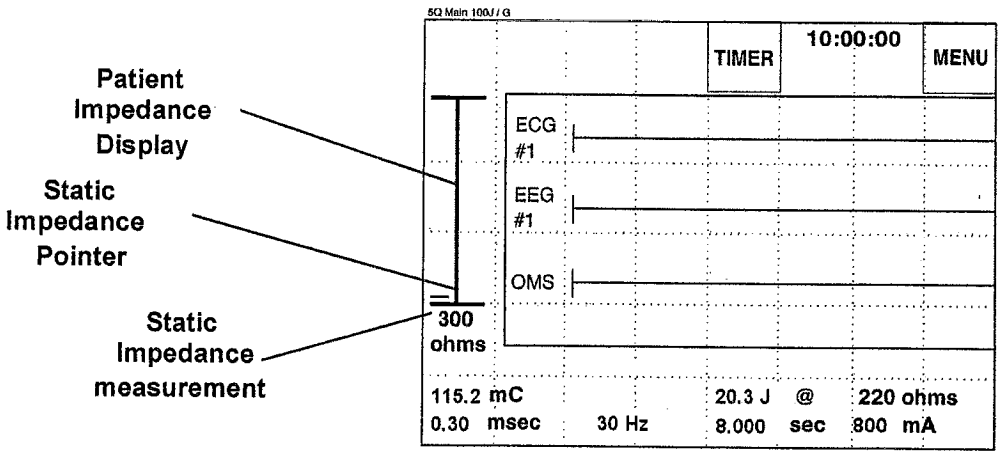
The LCD Screen may appear darker or lighter than necessary for comfortable use. The INTERNAL TEST display (pictured above) provides contrast control buttons (LIGHT and DARK) that allow 11 steps of contrast adjustment settings. Touch LIGHT to lighten the display, or touch DARK to darken it, until desired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

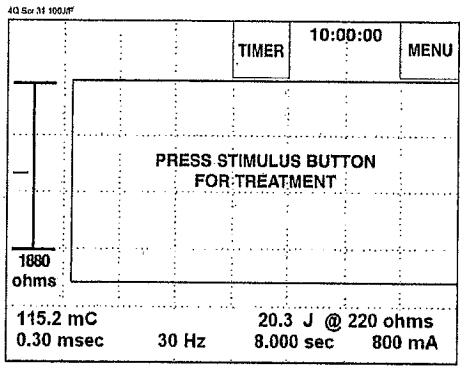
Trace selections will appear as set up in the LCD TRACES MENU.

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:

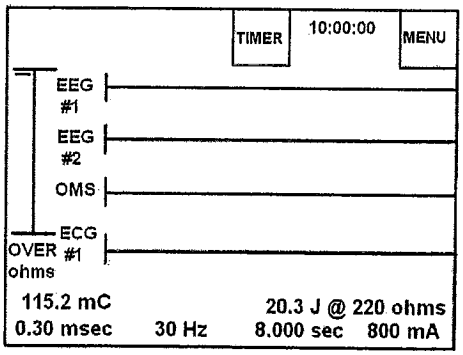
- 4000 models will show neither CHART RECORDER printouts, nor trace data, nor any of the following displays which show trace data.

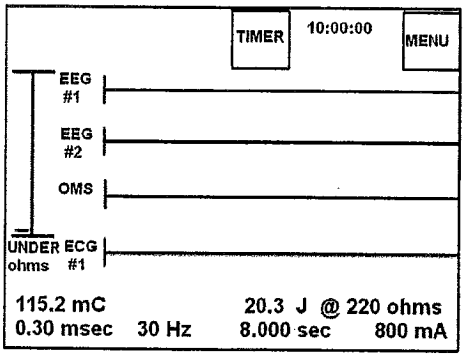


Treatment Ready display (4000 model)

5000 models

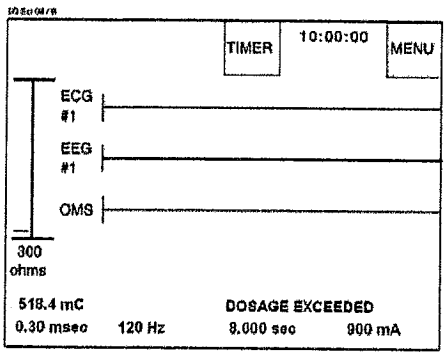
If the static impedance is over 5,000 ohms, the measured value on the impedance display will indicate OVER. If it is below the nominal 100 ohm level, it will indicate UNDER. See the following TREATMENT READY displays:





5000 models

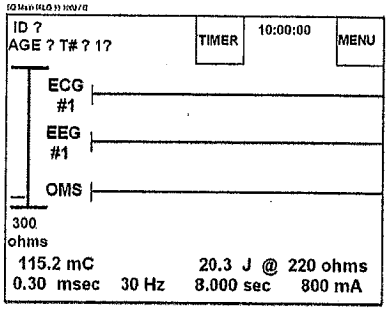
If the parameters are set to deliver too much energy, or deliver the energy too fast (FULL SPECTRUM Parameter Set on 5000Q model only), then the DOSAGE EXCEEDED message will appear as shown in the following display.

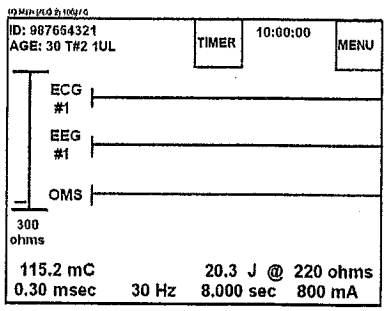


Displaying Patient Information on the TREATMENT READY display

5000 models

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).





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:

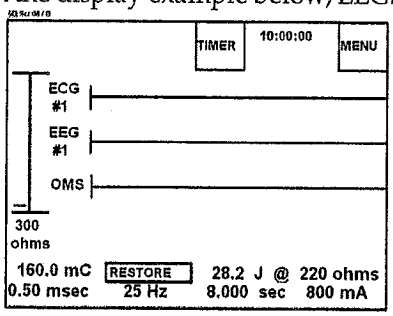
- Patient information entered in the PATIENT DATA MENU is erased on powering-down the SPECTRUM and must be re-entered for each new patient to prevent mis-identification. It will automatically be deleted 15 minutes after the SPECTRUM's last stimulus delivery.

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.



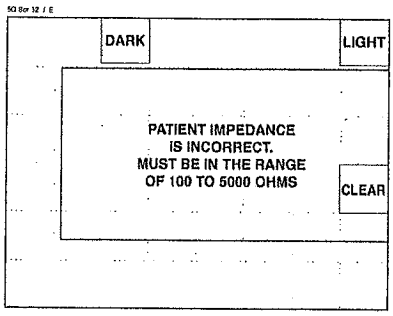
When all selected leads and cables are properly connected, the traces should all reappear, and the RESTORE button should disappear. If not, touch the RESTORE button. If the traces still do not reappear, there is still a problem with the lead or cable (it could be broken, for example).

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.



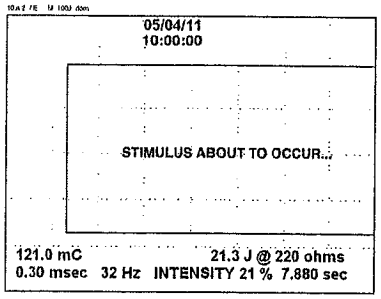
Stimulus Control Procedures

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.

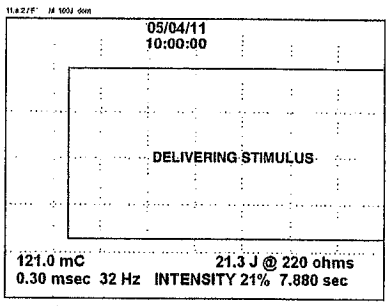
Q models All four parameters have adjustable settings. These knobs are located on the SPECTRUM's front panel just below the LCD Screen, and are labeled accordingly.

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:



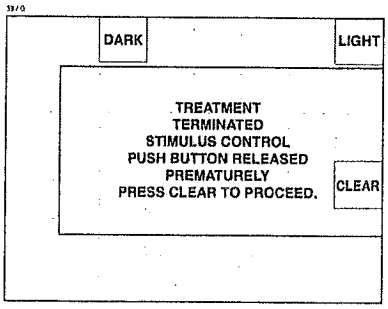
Stimulus Warning display



Delivering Stimulus display

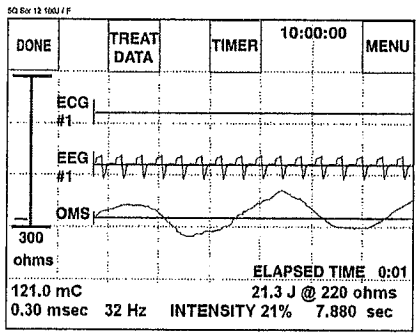
The CHART RECORDER will also start printing data (if enabled in the CHART OPTIONS MENU).

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.



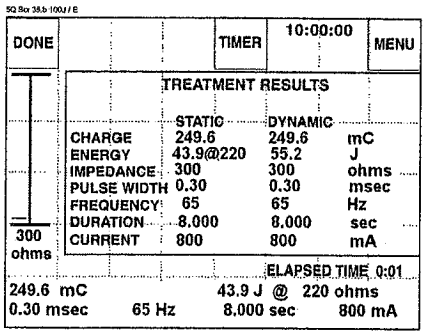
Post Treatment Trace display

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

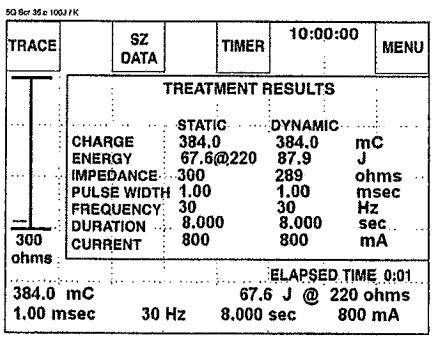
Patient physiological traces are displayed until the DONE button is touched. If the CHART RECORDER is set to ON, they will also be printed on chart paper. The STIMULUS CONTROL push button remains active, and the SPECTRUM is ready to deliver additional treatments, until the DONE button is touched. The 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



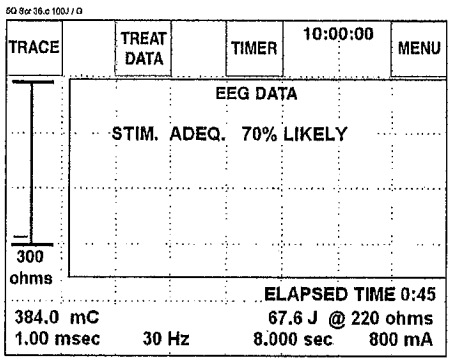
Treatment Results SZ display

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.

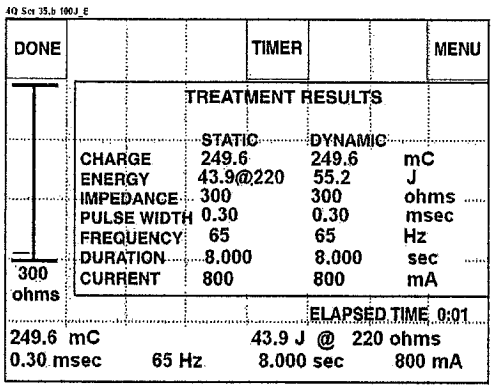
Then, touch either the DONE button on the POST-TREATMENT TRACE display, or the CHART RECORDER's OFF push button. In either case, the CHART RECORDER will stop printing trace data and will print the treatment results and EEG data.

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

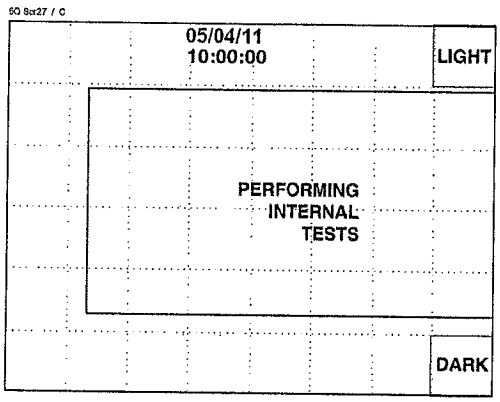
When stimulus delivery is complete using a 4000 model, it will display its TREATMENT RESULTS display.



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.

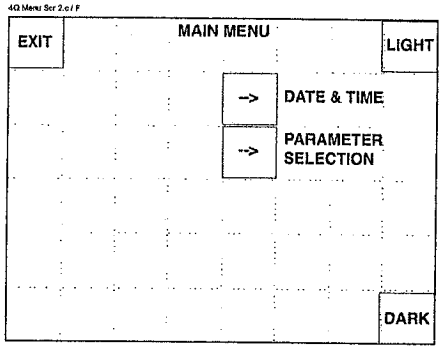
Menu System

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.

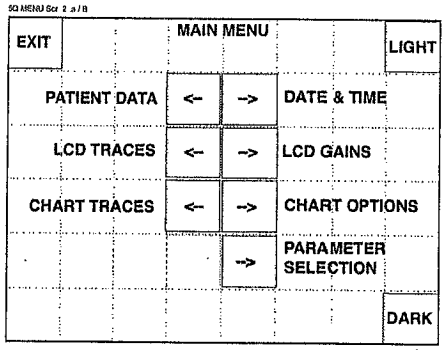
MAIN MENU

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

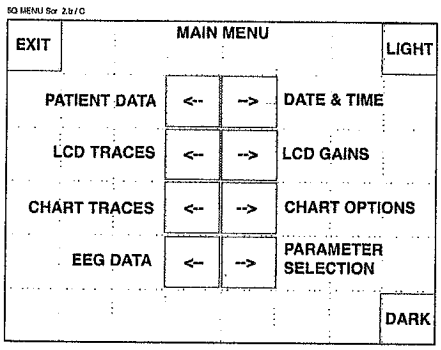
When entering the menu system, the MAIN MENU is the first to appear. The 5000 model MAIN MENU provides eight options for control of the display and processing of the physiological monitoring signals and the selection of the energy parameter set.



Main Menu (4000 model)



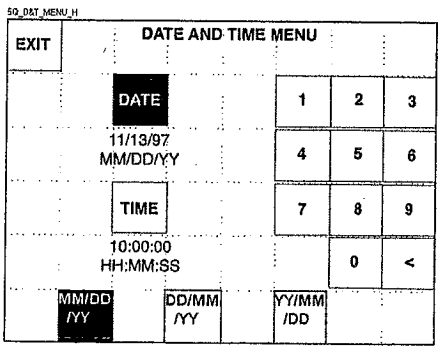
Main Menu (5000 model)



Main Menu (5000 model 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 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.

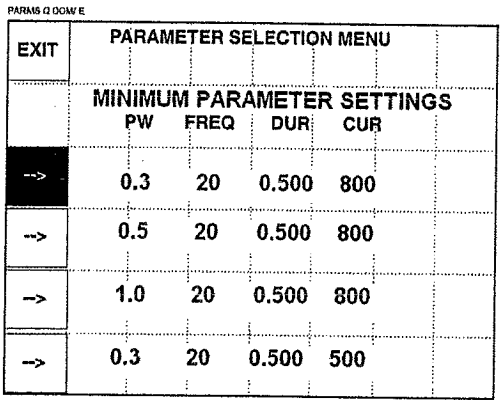
Touching the TIME button switches to time entry. The TIME button will be highlighted to indicate time entry. Enter the hours, minutes, and if desired, seconds, each as a two digit number (enter a 0 first if needed). The new time will appear under the TIME button as it is entered.

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.

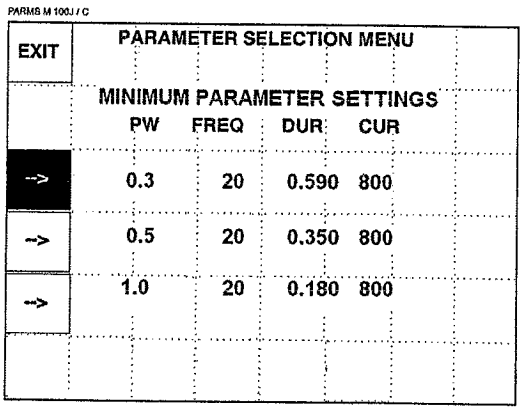
PARAMETER SELECTION MENU

(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.

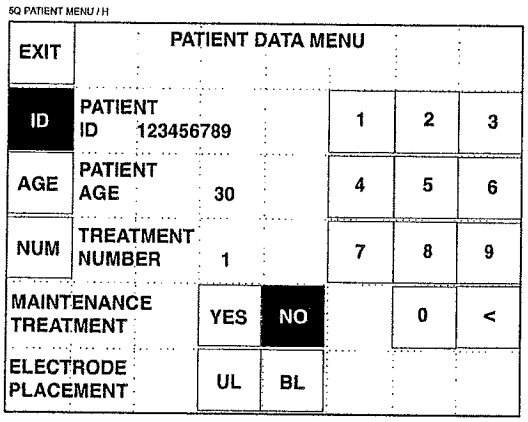
Membrane Switch 4000 models

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.

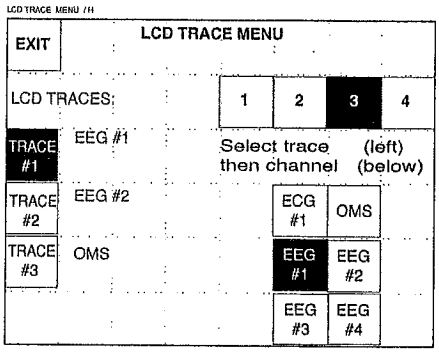
If the EEG DATA option has been purchased, and its button has been made active via the MAIN MENU, the system will display this patient data on the TREATMENT READY display, and on the CHART RECORDER printout.

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.

LCD TRACE MENU

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



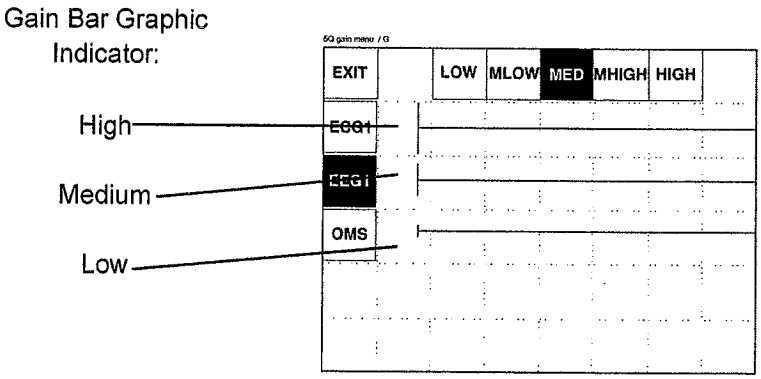
This menu controls the appearance of the LCD/Touch Screen trace displays. In particular, it is used to specify how many traces will be displayed, and which physiological monitoring channels will be displayed.

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.



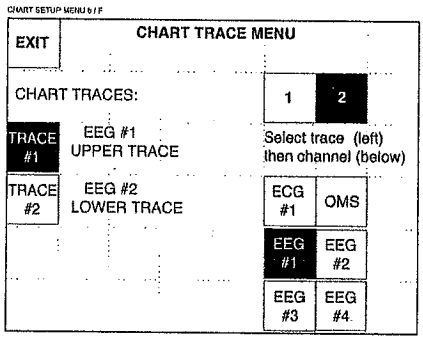
This menu controls the amplification (gain) applied to each of the trace signals before it is displayed. The displayed traces are those previously specified in the LCD TRACE MENU. Touching one of the trace label buttons on the left side of the display highlights the button and selects that trace for 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. Additionally, 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.

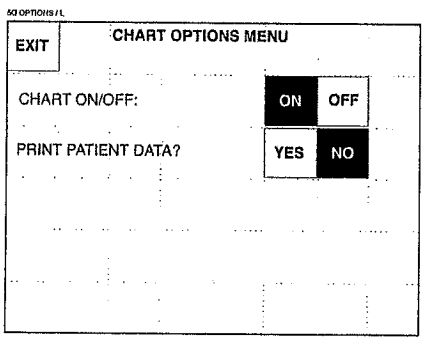


This menu controls the appearance of the CHART RECORDER trace printouts. In particular, it specifies whether one or two traces will be printed, and which physiological monitoring channel will be printed by each trace. Touching one of the top row of numbered buttons specifies and highlights how many traces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

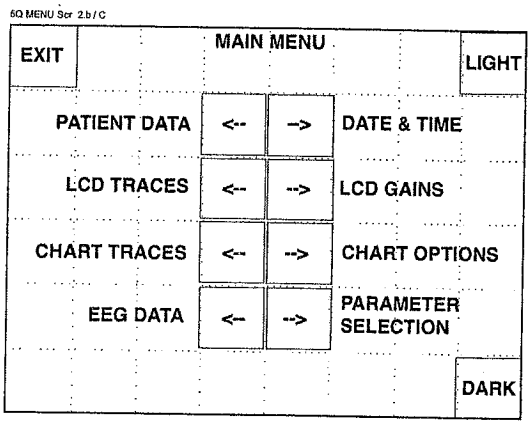
The PRINT PATIENT DATA option enables or disables the automatic printing of the patient data entered in the PATIENT DATA MENU. When enabled, this data prints after the treatment results when the LCD/Touch Screen DONE button is touched, or the CHART RECORDER OFF button is pushed. If the EEG DATA ANALYSIS 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.)

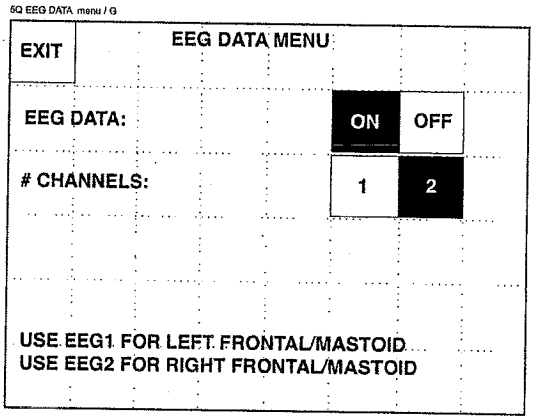
See the CHART RECORDER section of this manual for details of the CHART RECORDER printouts.

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

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.

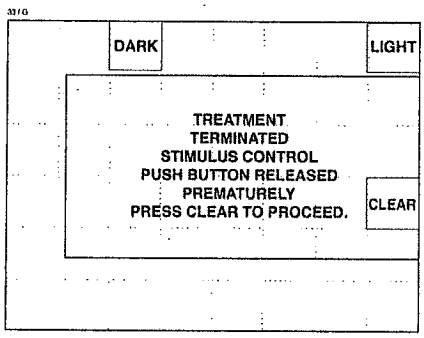
NOTE:

- 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

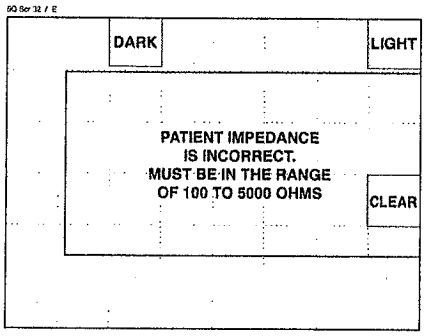


This error is generated by pressing the STIMULUS CONTROL push button, but releasing it before the stimulus delivery has completed. Thus, the stimulus is prematurely terminated.

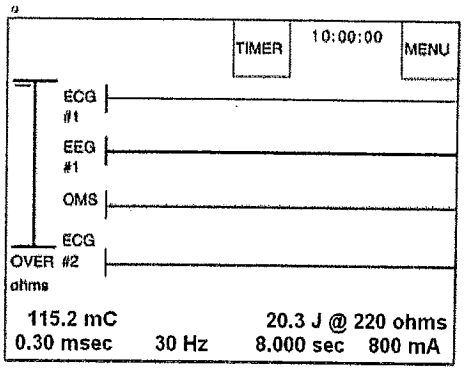
5000 models

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.

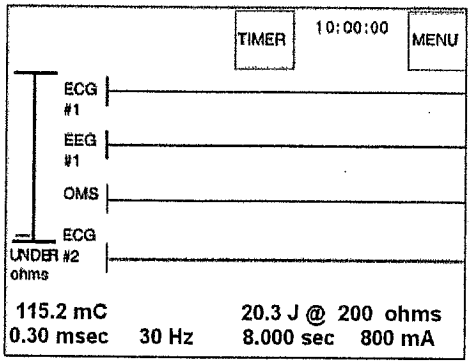
Patient Impedance error message



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.).

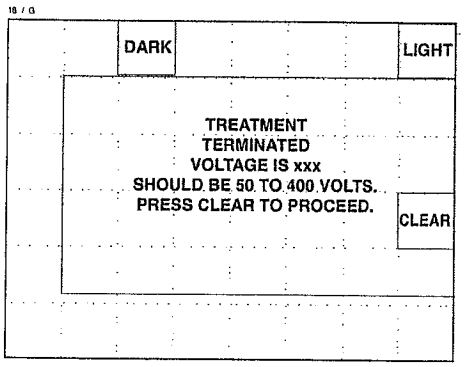


OVER condition



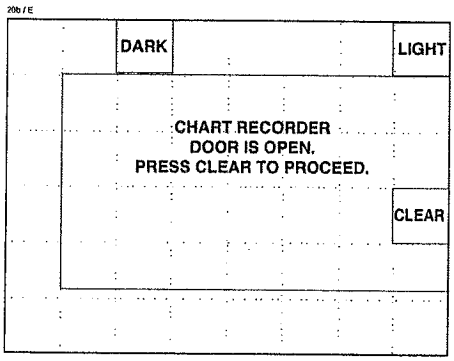
UNDER condition

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.

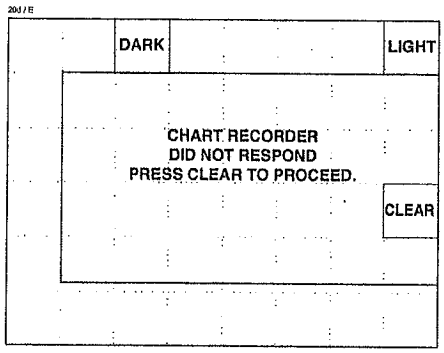
Recorder Door error message



This error occurs when the CHART RECORDER door is opened.

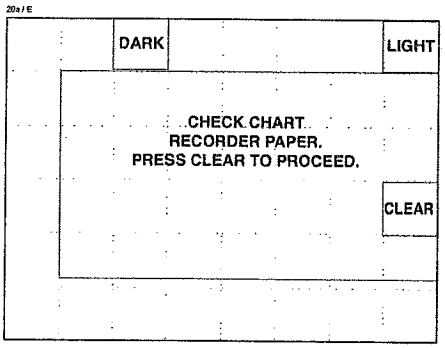
Press the paper compartment door to ensure it is properly reseated. Then touch CLEAR or EXIT button to resume work.

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.

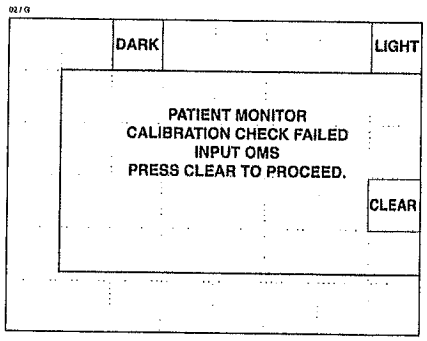
NOTES:

- 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 indicates that there is about 10 feet of paper (two minutes) left on that roll.

TECHNICAL ERRORS

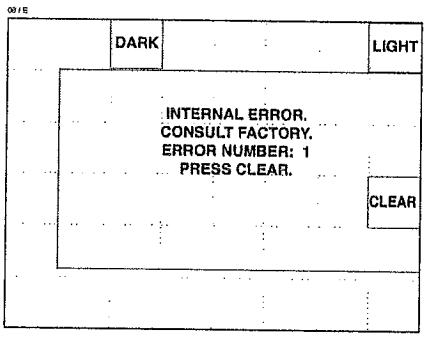
This series of errors is related to the operational or physical condition of the machine. Some of these can be corrected by the user; some will require factory involvement. If the error occurs repeatedly, the user should contact MECTA for assistance.

Patient Monitor Calibration Check display



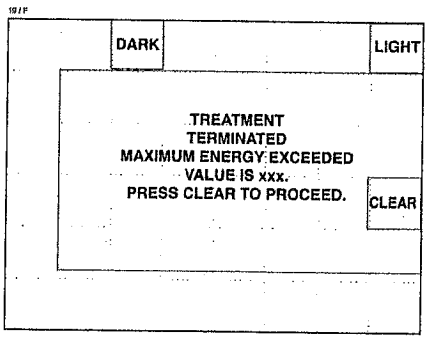
This screen reports on the status of the calibration check that the system performs on the patient monitoring module (5000 model only). It is an announcement only, and does not affect the stimulus delivery system.

Numbered Error display



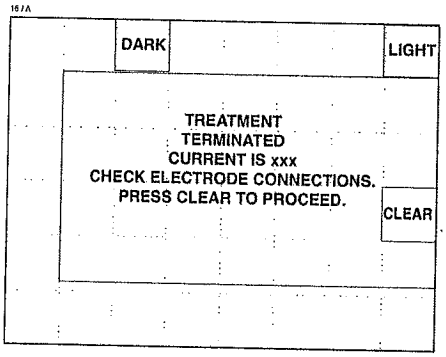
Numbered error messages similar to the above format may occur, but should be rare. If one occurs repeatedly, turn the SPECTRUM off, then on again. If it persists, contact MECTA or your local distributor for assistance.

Treatment Energy error message



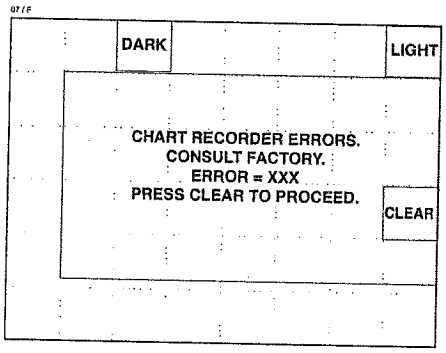
This error occurs because the energy delivered to the patient has exceeded the maximum allowed energy prior to completing the selected stimulus duration. This usually indicates a poor electrode connection to the patient.

Treatment Current error message



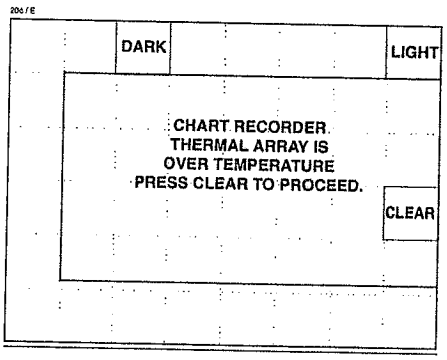
This error may occur if the STIMULUS CONTROL push button is released prematurely.

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

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*:

--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. All service should be performed by qualified service personnel.

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

- This equipment should only be used in a hospital or equivalent medical environment.
- 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.
- Power up the SPECTRUM, wait for self test and press CLEAR before anesthetizing the patient.
- 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. Since it has no alarms, it is intended only for use during ECT treatments.
- 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.
- There should be no non medical equipment within 1.5 meters of the patient.
- There should be no device controls within 1.5 meters of the patient.
- If there are any other connections to the patient (from other equipment), they must be only approved type BF or CF, and it is the users' responsibility to confirm that the total patient leakage current is within safe limits as defined in IEC 60601-1 3rd or subsequent editions.
- In the unlikely event that a patient has a "prolonged seizure" (lasting longer than 3 minutes), hospitals should have a "prolonged seizure protocol" in place as described in the following textbooks: "Clinical Manual of Electroconvulsive Therapy" by Mankad, Beyer, Weiner and Krystal, 2010, pp 154-156, "The Practice of Electroconvulsive Therapy, 2nd Ed an APA Task Force Report", 2001, pp 171-172, 61-62, 75 or "Electroconvulsive Therapy: A Programmed Text", 2nd Ed, Beyer, Weiner, Glenn, 1998, pp 125-127, to terminate the seizure.
- NO part of the SPECTRUM shall be serviced or maintained while connected to a patient.

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.
- To minimize the possibility of patient burns from poor electrode contact, follow procedure in "ECT Module" Preparing the scalp for stimulus electrode placement in this manual.
- To avoid operator shock hazard, clean hand-held handles after each use. Make sure there is no gel path from electrodes up to operators' hand on handle.
- If the SPECTRUM unit has been subjected to harsh environments outside of the recommended operating conditions, it should be moved to a suitable environment for 48 hrs and then pass leakage current and functional tests before use. If uncertain of safe operation, it should be returned to the factory for a Quality Control Check.

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

WARNING: No modification of this equipment is allowed.

- Do not operate the SPECTRUM in the presence of flammable chemicals/gases (including flammable anesthetics), or an explosion could result.
- When using a computer connected to the SPECTRUM, do not place the computer, its peripherals, or any connecting cables within 1.5 meters of the patient.
- Connect the computer to the same outlet as the SPECTRUM, or verify that the impedance between the PC case and the SPECTRUM is less than 200 milliohms.
- Do not touch the patient and non-medical equipment (such as a computer) at the same time.
- Make sure cuffed distal extremity is restrained, so there is no hazard of harm to patient or operator during seizure motor activity.
- Be sure that the cable connecting the computer and the SPECTRUM is protected from physical damage.
- There should be no bystanders within 1.5 meters of the patient.
- 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 measurement errors, interface problems, or equipment malfunctions.
- Stimulus electrodes should be cleaned after each use. Please see Cleaning section.
- 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.

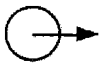
SYMBOLS

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)

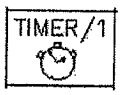

"Off" (only for CHART RECORDER)


Read Operator's Manual

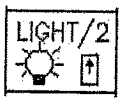
ms	Pulse width in milliseconds
Hz	Frequency in Hertz
s	Duration in seconds
mA	Current in milliAmps
Gain 1	Chart Channel 1's Gain setting dial.
Gain 2	Chart Channel 2's Gain setting dial.
CE0197	TÜV Rheinland Annex II, Article 3 ISO 13485:1996 ISO 13485:2000 "Type tested" in Munich, Germany by TÜVPS.

4000 Membrane Switch Symbols

Enter the Menu system.

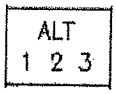


TIMER Start/Stop or "1" if ALT button pressed at the same time.



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. Changes TIMER to "1", LIGHT to "2", and DARK to "3".

Exit the Menu or DONE with treatment or CLEAR.

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 300 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 LED 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

100/115 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	27.5 pounds / 12.5 Kg
Height	6.25 inches / 16.0 cm
Width	10.7 inches / 27.2 cm
Depth	19.35 inches / 48.5 cm

5000 DIMENSIONS

Weight	33.0 pounds / 15.0 Kg
Height	6.25 inches / 16.0 cm
Width	20.75 inches / 52.3 cm
Depth	19.35 inches / 48.5 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.

At the time the SPECTRUM was manufactured, the device complied with all standards required by the EC as set forth in MECTA's Declaration of Conformity (available upon request).

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (I.E. IEC 60950 for data processing equipment, and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. 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 60601-1-1. If in doubt, contact the technical service department, or your local representative.

Declaration of Electromagnetic Immunity, MECTA SPECTRUM 4000 and 5000 series.
The SPECTRUM 4000 and 5000 series units are designed to be used in a hospital/clinical environment as defined below. Use of any cables other than those supplied by MECTA (including the power cord) or operating outside of the defined environment may invalidate this declaration.

Immunity Test	Test Level	Compliance Level	Environment Guidance
ESD IEC 61000-4-2	+/- 8KV – Air +/- 6KV – Contact	No Anomalies	Hospital
Radiated RF IEC 61000-4-3	3V/M, 80MHz to 2.5GHz	No Anomalies	Hospital
EFT/Burst IEC 61000-4-4	+/- 2KV – Mains +/- 1KV – I/O Cables	Pulse visible on OMS only, Self correcting	Typical Mains power
Surge IEC 61000-4-5	+/- 2KV Common +/- 1KV Differential	No Anomalies	Typical Mains power
Conducted RF IEC 61000-4-6	3VRMS, 150KHz to 80MHz	Single spike on monitoring channels Self correcting	Hospital
Dips/Interruptions IEC 61000-4-11	100%, ½ cycle 60%, 5 cycles 30%, 25 cycles 100%, 5 seconds	No Anomalies No Anomalies No Anomalies Re boot, press clear	Typical Mains power
Power Frequency Magnetic Field IEC 61000-4-8	3A/M	No Anomalies	Typical Environment

Cables used with the SPECTRUM

Power Cord – UL Listed SJT No. 18 AWG, 3 Conductor Shielded, 3M max

EEG/ECG Monitor Cables - 1W, 1K Resistors molded in Connector, AAMI EC-53 compliant, 3.04M nominal

OMS Monitor Cable - 3 wire Shielded, 3.65M nominal

Stimulus Cables, MECTA only - 3.65M nominal

ECT PARAMETERS

Q Models

	OPTIMIZED DOSING Parameter Sets			*FULL SPECTRUM Parameter Set*
Four Parameter Sets:	0.3	0.5	1.0**	Set 4**
Pulse Width	0.3-0.37 ms	0.5 ms	1.0 ms	0.3-1.0 ms
Stimulus Duration	0.5-8.0 sec	0.5-8.0 sec	0.5-8.0 sec	0.5-8.0 sec
Frequency	20-120 Hz	20-90 Hz	20-45 Hz	20-120 Hz
Stimulus Current	800 mA	800 mA	800 mA	500-900 mA
Charge	4.8-568 mC	8.0-576 mC	16.0-576 mC	3.0-579 mC
Energy @ 220 ohm patient impedance	0.8-100 joules	1.4-101.4 joules	2.8-101.4 joules	0.3-101.9 joules

M Models

	OPTIMIZED DOSING Parameter Sets		
Three Parameter Sets:	0.3	0.5	1.0**
Pulse Width	0.3-0.38 ms	0.5 ms	1.0 ms
Stimulus Duration	0.60-8.0 sec	0.36-8.0 sec	0.18-8.0 sec
Frequency	20-120 Hz	20-90 Hz	20-45 Hz
Stimulus Current	800 mA	800 mA	800 mA
Charge	5.8-576.4 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

*Patent Pending
**EEG Data Analysis enabled

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	.0416	.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 Chart

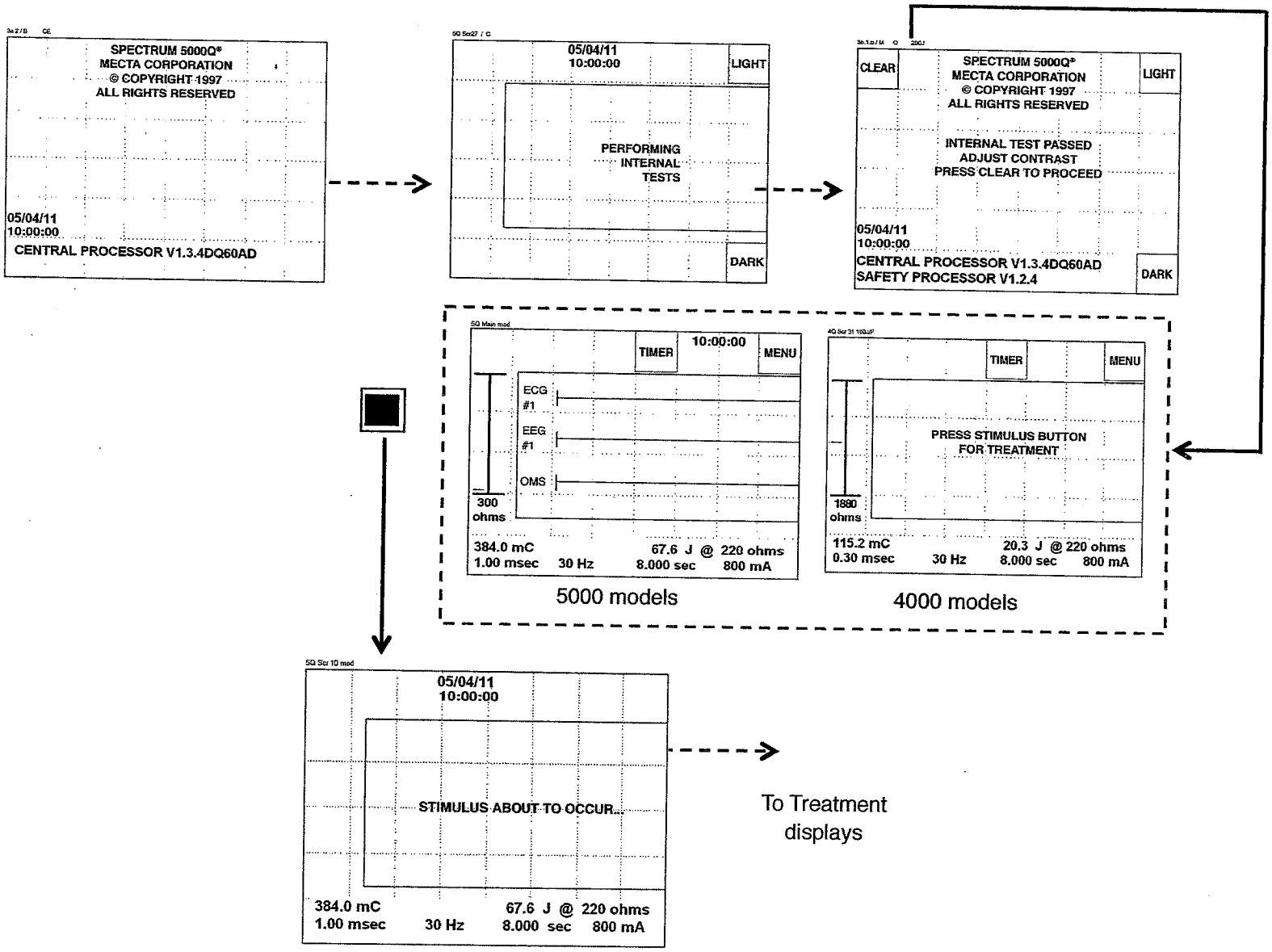
See also the section on Error Messages in the Instruction Manual for additional input on identifying and clearing problems. Machines will need servicing mainly for errors that users cannot clear by themselves. These will appear as numbered errors, and the user will need to consult the factory for assistance.

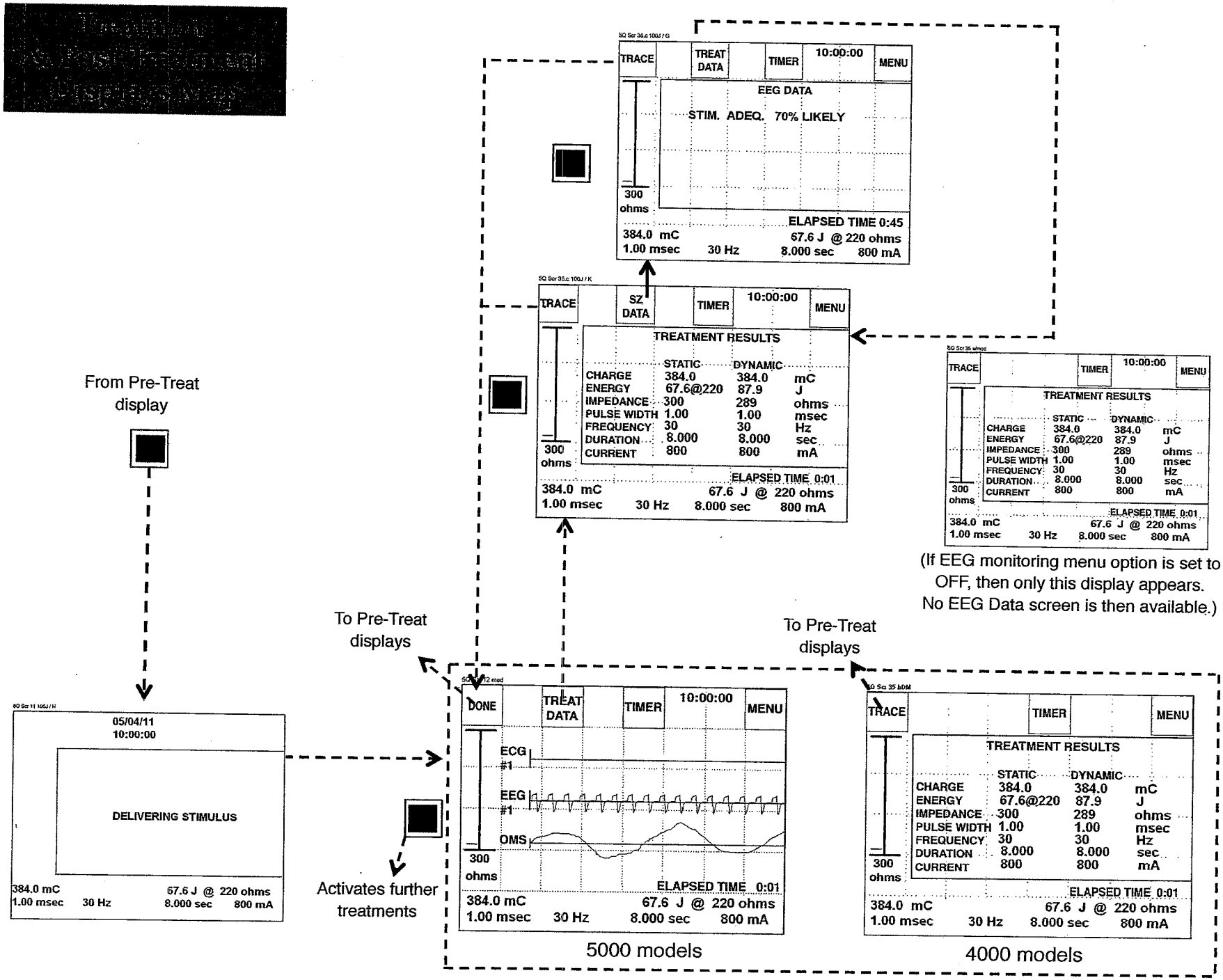
Problem Description	Possible Problem or Solution
SPECTRUM does not operate.	No line voltage connected and/or fuse may be blown. Verify that: a. Fuses are OK, b. Power switch is ON, c. Unit is plugged into a proper outlet, and cord is fully seated in power entry module. d. Outlet works for other equipment. 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. Ensure 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 COPYRIGHT 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).
DOSAGE EXCEEDED message appears.	Change the parameter settings until the message disappears. This occurs when the energy delivery requested is too high (decrease one or more parameters) or the rate of energy delivery requested is too high (decrease PULSE WIDTH, FREQUENCY, or CURENT).

Pre-Treatment Test Map

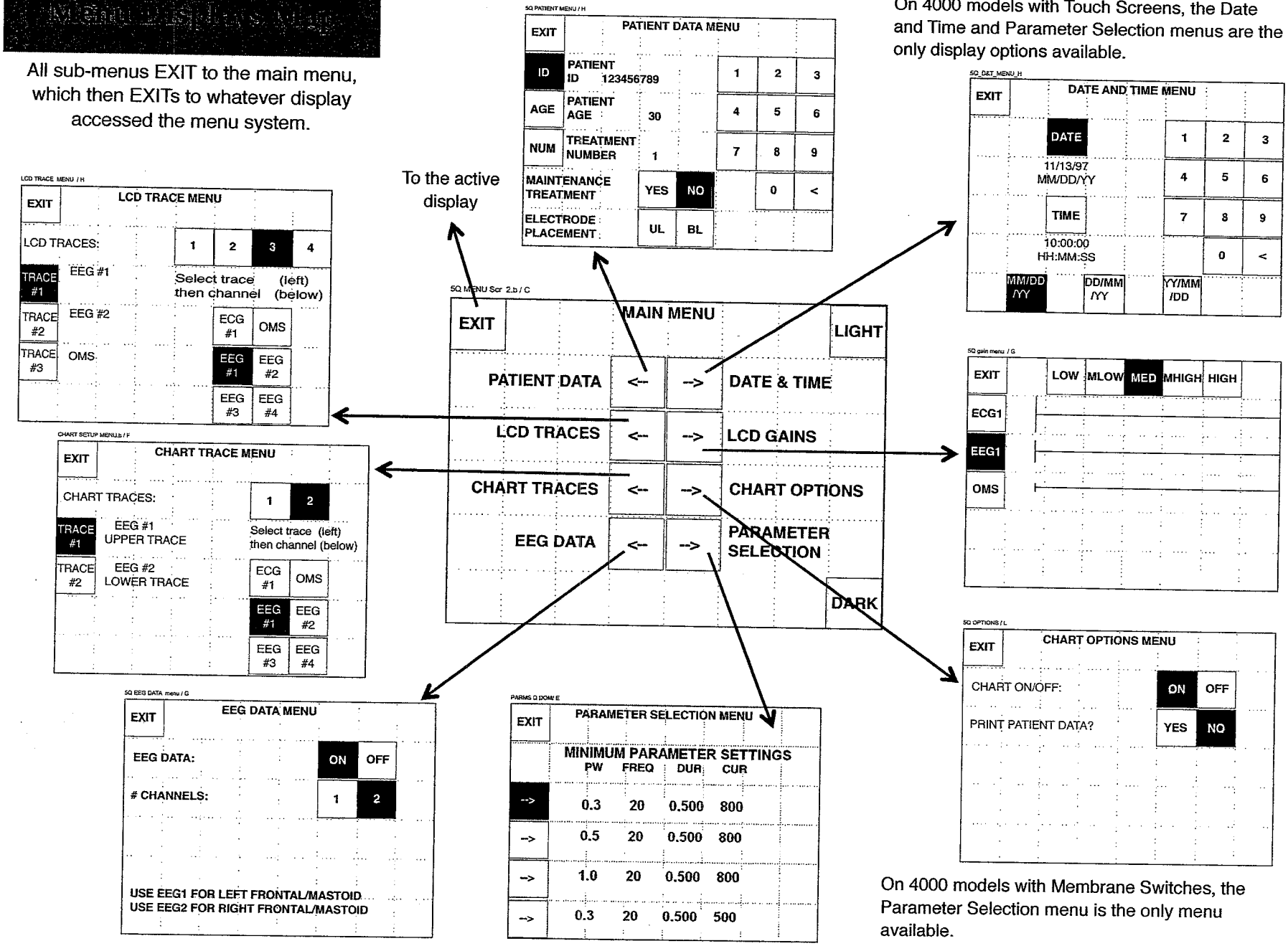
These maps depict the routine display sequences on the SPECTRUM Q-model.
M-model displays will show different parameter configurations.
Error message displays and most variations are not shown.




From Pre-Treat display
TRACE
TREAT DATA
TIMER
10:00:00
MENU
EEG DATA
STIM. ADEQ. 70% LIKELY
300 ohms
ELAPSED TIME 0:45
384.0 mC
67.6 J @ 220 ohms
1.00 msec
30 Hz
8.000 sec
800 mA
SZ DATA
TREATMENT RESULTS
STATIC
DYNAMIC
CHARGE 384.0 384.0 mC
ENERGY 67.6@220 87.9 J
IMPEDANCE 300 289 ohms
PULSE WIDTH 1.00 1.00 msec
FREQUENCY 30 30 Hz
DURATION 8.000 8.000 sec
CURRENT 800 800 mA
ELAPSED TIME 0:01
(If EEG monitoring menu option is set to OFF, then only this display appears. No EEG Data screen is then available.)
05/04/11
10:00:00
DELIVERING STIMULUS
To Pre-Treat displays
To Pre-Treat displays
DONE
ECG #1
EEG #1
OMS
Activates further treatments
5000 models
4000 models

Menu Display 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.

MECTA Corporation

19799 S.W. 95th Avenue, Suite B, Bldg. D, Tualatin, OR 97062