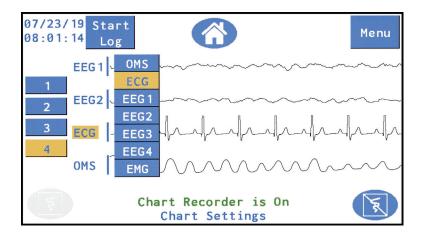
With a new and intuitive interface, nine menu screens greatly enhance the capabilities of the Sigma™



New pop-ups and selectable options provide visible and easy-to-use treatment capabilities without confusing, buried menus

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Home is the center of operations and provides the interface for administering the treatment. This screen displays treatment parameter settings, patient impedance, and up to seven physiological monitoring traces.



Options presents selectable choices for setting device defaults, customizing user interface controls, and printing reports.



Parameters affords ready access to the full set of parameter options and allows selection of four different parameter ranges (One or Four Knob Mode) to optimize treatment.

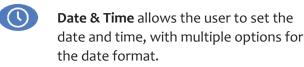


LCD selects and configures up to seven continuous physiological monitoring traces for display here and on the Home screen. Trace configurations include 2-6 EEG, 1 ECG, 1 EMG, and the Optical Motion Sensor (OMS*).

Chart configures up to four physiological monitoring traces for printing. This screen controls turning the Chart Recorder on or off.

Lead Impedance activates impedance testing of all monitoring leads, continuously updating the values on the screen. Used to ensure patient conductivity for each lead to avoid data loss.

> Replay Manager retains trace data and treatment results from the last successful or problematic stimulations so that data can be preserved and reprinted.



Info offers the user basic information about the Σ igma and how to contact SigmaStim.

MAR-2004 Ver. 1

SigmaStim *Zigma*[™]

The Sum of All ECT Neuromodulation **Innovations in One Device**





Unique Advantages of the *Sigma*

Sum of All ECT Modalities

Maximum Treatment Flexibility in One Device

The Σ igma^{**} provides a smooth transition from the spECTrum[®] 5000Q, 5000M, or other ECT models—all in one simple to use device. The practitioner can easily switch from One Knob Mode (automatically and optimally alters stimulus intensity) to Four Knob Mode (adjusts individual parameter values). The Σ igma has the widest range of stimulus parameters of any ECT device: pulse width from 0.15* to 1 ms; current from 500 to 900 mA; pulse frequency from 10* to 120 Hz; and train duration from 0.03 to 8 seconds.

Enhanced Performance and Superior Ease-of-Use

With simple pop-up menus, users easily choose options from the main Home screen – no buried menus.

- Select among seven physiological monitoring channels (6 EEG/1 ECG), including the new electromyography (EMG) and Optical Motion Sensor (OMS*)
- See all seven traces on the ultra-sharp 7" LCD screen, or select four channels to print on the new, high-resolution Chart Recorder
- Power on and internal tests are faster so you can begin treatments in half the time

Innovative Features and Capabilities

Practitioners and researchers will appreciate new features like:

- One and Four Knob Modes for stimulus parameter selection
- New Lead Impedance Test
- Added electromyography (EMG) channel for seven channels of monitoring
- New Event, Timer, and Elapsed Timer markers
- New Replay Manager replay, print and save the last treatment to review
- New Biomedical Report documenting most recent internal safety tests
- New four-channel, high
- resolution Chart Recorder



With continuous monitoring of static impedance and automatic shutdown, you never have to worry when it is safe to treat. And you won't lose valuable trace data again due to excessive artifact or lead malfunction, as monitoring lead conductivity is readily available in the Lead Impedance Test Screen. Printed reports like the new Biomedical Report and Error Logs Report help ensure the device operational status is optimal.

New Lightweight. **Portable Design**

The Σ igma is a new ECT device that meets the needs of hospitals concerned about portability and space. At 25.5 lbs. and measuring 8 X 17.5 X 19.5 inches, the sleek design of the Σ igma allows easy storage in a cupboard or on Σ igma's versatile, new hospital cart. Add a Σ igma Hand-Held Electrode Assembly and approved SigmaStim treatment accessories for an efficient ECT delivery system.

Digital Patient Data with SigmaStim EMR[®]

The SigmaStim EMR[©] is a powerful software program that greatly expands the capabilities of the Σ igma:

- Automatically record and database treatment data
- Replay, search, customize, and create reports of essential information
- Nine preconfigured forms and one customizable report
- Mirrors the Σigma EMR LCD screen on a larger monitor
- Compatible with EHR systems like EPIC



SigmaStim denotes SigmaStim Domestic LLC, for Sigma devices sold in the USA, and SigmaStim International LLC, for Sigma devices sold outside of the USA.

Designed, tested, and assembled in the U.S.A.

Mar-2004 (DOC-19) Ver. 1

Approved By:

(CO-25) SigmaStim Cotton Bite Blocks

Description

Cotton Bite Block From MECTA to SigmaStim

Justification

Manufacturer Change for our Cotton Bite Blocks from MECTA to SigmaStim results in Document Updates associated with that specific product.

Assigned To:	Initiated By:	Priority:	li	npact:	
Rebecca Weber	Rebecca Weber	Medium	Μ	Minor	
Version History:					
Author	Effective Dat	e	CO#	Ver.	Status
Rebecca Weber	September 6, 2	2023 8:41 AM PDT	<u>CO-25</u>	1	Published
Adrian Kettering	August 16, 202	23 7:00 AM PDT	<u>CO-1</u>	0	Superseded