REGULATORY UPDATE TO THYMATRON® SYSTEM IV INSTRUCTION MANUAL

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

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

ECT may result in anterograde or retrograde amnesia. Such post-treatment amnesia typically dissipates over time; however, incomplete recovery is possible. In rare cases, patients may experience permanent memory loss or permanent brain damage.

ECT—and use of the Thymatron® System IV specifically—has been shown to be effective in treating major depressive episodes associated with major depressive disorder (MDD) or bipolar depressive disorder (BPD) in patients 18 years of age and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition. A few studies performed with the device are highlighted below, with additional references provided in the bibliography.

TECHNIQUE OF ECT

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

EFFICACY, SAFETY, AND SIDE-EFFECTS

EFFICACY

A randomized, double-blind, controlled trial of ECT in 230 patients with major depression treated with a Thymatron found 3 different electrode placements equally and significantly effective in reducing depression scale scores, with the greatest effect achieved with traditional bitemporal ECT (Kellner et al, 2010).

A randomized, controlled trial of ECT in 489 major depressive patients, with or without atypical features, treated with a Thymatron DGx. Both the atypical and the typical groups experienced significant improvement in depression (Husain et al, 2008).

A randomized, controlled trial of ECT in 253 unipolar depressed patients with and without psychosis treated with a Thymatron. An 87% overall remission rate was obtained that was greater and more complete in the psychotic depressives (Petrides et al, 2001).