

# User Manual

## Thymatron® System IV



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## User's Manual for Thymatron® System IV



CAUTION

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

Electroconvulsive Therapy (ECT) is a complex medical procedure. Its proper and safe conduct requires a staff of licensed healthcare professionals who are trained and have experienced in-person supervision with the associated procedures, have received clinical privileges for ECT from the appropriate hospital committee, and have carefully read and are thoroughly familiar with the medical literature concerning the risks, benefits, complications, and methods of ECT. Specifically, practitioners intending to use the Thymatron System IV should be familiar with ECT-related concerns including medical conditions that affect risks, adverse effects, pre-ECT evaluation, medications used during ECT, ECT procedures and techniques, physiological phenomena, consent, ECT unit staffing, evaluation of outcome, and post-course ECT management. Practitioners should keep current with information about these concerns published in major textbooks, in major journals of psychiatry, and by professional psychiatric organizations. They should also be familiar with the FDA final order of December 26, 2018 (83 FR 66103-66124). Clinicians who administer ECT should participate in continuing education about ECT.

It is essential that doctors planning to use the Thymatron® System IV device read and follow the warnings and recommendations of the Task Force Report of the American Psychiatric Association as set forth in "The Practice of Electroconvulsive Therapy" (APA, 2001), which states, in part, that "A small minority of patients treated with ECT later report devastating cognitive consequences. Patients may indicate that they have dense amnesia extending far back into the past for events of personal significance or that broad aspects of cognitive function are so impaired that the patients are no longer able to engage in former occupations...in some patient self-reports of profound ECT-induced deficits may reflect objective loss of function...In rare cases, ECT may result in a dense and persistent retrograde amnesia extending to years..."

It is essential to read all of the information in the Safety Information section of this manual, pages 7 - 9.

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