

**FOR IMMEDIATE RELEASE**

**Electrochemistry**

Contact Information:

Laura Brockway  
(978)-232-6057  
laura.brockway@thermo.com  
www.thermo.com

Sarah Millerick  
(617) 275-6516  
smillerick@greenoughcom.com

**Thermo Electron Announces Compliance Enabling Tools**

*New Software and Documentation Tools Facilitate Compliance With  
Auditors and Regulatory Agencies*

BEVERLY, Mass., (March 13, 2006) — Thermo Electron Corporation, a world leader in electrochemistry technology, today announced the availability of the Orion Star Navigator 21™, 21 CFR Part 11 compliant data collection software and the Orion Star™ Series Meter Installation Qualification and Operational Qualification (IQOQ) documentation. Designed to enable compliance with auditors and regulatory agencies, these tools set the bar for industry best-practices in the pharmaceutical, food and beverage and environmental industries.

On August 20, 1997, the Food and Drug Administration (FDA) ruling on 21 CFR Part 11: Electronic Records; Electronic signatures was put into effect. Aimed at modernizing the regulation of pharmaceutical manufacturing and product quality, this policy enables FDA auditors to facilitate timely reviews and audits. Part 11 guidance addresses systems validation, security and audit trails, system operation, system documentation control or archiving and record retention and recovery.

“The launch of these compliance tools shows that Thermo is dedicated to fostering industry best-practices that will help protect and promote the safety of our customers and public health,” noted Stuart Georgitis, director of instrumentation development and product management, Water Analysis Instruments at Thermo Electron. “The Star Navigator 21 and the IQOQ will ensure the highest level of quality is maintained, especially in the manufacturing of human drugs. As regulations evolve worldwide we will be at the forefront of innovation to ensure our customers remain compliant.”

Thermo Electron’s Star Navigator 21™ data collection software allows users not only to uphold FDA guidelines and to effectively operate to varying specification requirements world-wide, but also allows for significant savings in time and productivity associated with data management. The Star Navigator 21 collection software includes the following:

- *User Management* - User accounts are defined by a unique user name and

password as provided by the Microsoft® Windows® Operating System. Individual access privileges such as 21 CFR permission and Method Edit permission vary depending on each user's profile.

- *System Access (Login/Logoff)* - Login is strictly regulated by entering a valid username and password. Security measures include account lockout after a predetermined number of unsuccessful login attempts and automatic password protected screensavers that initialize after a set period of inactivity to prevent unauthorized access as provided by the Microsoft Windows Operating System.
- *Password Rules and Management* - Complex password capabilities (i.e., a combination of uppercase and lowercase characters, digits, and/or non-alphanumeric characters) may be enforced as a means of extended security. The accounts may also include a password history and age limits that prevent old passwords from being reused and expire current passwords after a specified number of days in use as provided by the Microsoft Windows Operating System.
- *Audit Trail* – Records important events and includes in the audit trail function which lists user, date, time, event importance, application, description of event, and details of the event. The log file can be viewed and exported. All data is stored in a secure database and cannot be changed or altered.
- *Electronic Signatures* - All changes are recorded with a digital signature and the users must provide reasons for changes. The user name and password are verified against the Microsoft Windows Operating System user name and password.
- *Data Security* - All data is stored in a database and it is impossible to remove or alter data in an uncontrolled manner. The database can only be accessed with the proper tools and user rights. Data integrity is verified each time data is accessed.

Companies using Orion Star™ Series meters and the Star Navigator 21 software can adopt paperless record systems and submit regulatory documents in the form of electronic records. These companies benefit from a more cost effective, time efficient system driving shorter approval processes.

Designed to facilitate laboratory validation procedures, the Star Series IQOQ procedure provides the documentation that pharmaceutical companies need to comply with the requirements of their auditors and regulatory agencies. This documentation system includes easy-to-use forms that document the operation of a system and verify that the system operation conforms to design specifications.

Installation Qualification (IQ) demonstrates that the installation of the Orion Star™ Series Meter is verified by reviewing the instrument installed. The Operational Qualification (OQ) demonstrates that the Orion Star Series Meter operates appropriately throughout the normally intended operating ranges.

For more information about the Star Navigator 21 data collection software, IQOQ documentation or any of Thermo's water quality products, please visit [www.thermo.com/water](http://www.thermo.com/water).

### **About Electrochemistry**

The Orion and Russell Electrochemistry Products from Thermo Electron, Water Analysis Instruments are ISO 9001:2000-registered manufacturer of quality chemical measurement products. The products include meters, electrodes and solutions for the

measurement of pH, select ions, dissolved oxygen, conductivity and titration where accuracy, quality and consistency are absolutely critical. Thermo Electron also offers a complete line of colorimeters, syringe pumps, microbalances and Pure Water™ online process monitors.

### **About Thermo Electron Corporation**

Thermo Electron Corporation is the world leader in analytical instruments. Our instrument solutions enable our customers to make the world a healthier, cleaner and safer place. Thermo's Life and Laboratory Sciences segment provides analytical instruments, scientific equipment, services and software solutions for life science, drug discovery, clinical, environmental and industrial laboratories. Thermo's Measurement and Control segment is dedicated to providing analytical instruments used in a variety of manufacturing processes and in-the-field applications, including those associated with safety and homeland security. For more information, visit [www.thermo.com](http://www.thermo.com).

# # #