

NOVA[®] *e* SERIES

HIGH-SPEED SURFACE AREA & PORE SIZE ANALYZERS

21 CFR PART 11 COMPLIANT SYSTEMS FOR THE
PHARMACEUTICAL INDUSTRY



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INSTRUMENTS

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NOVA_e SERIES FOR THE PHARMACEUTICAL INDUSTRY

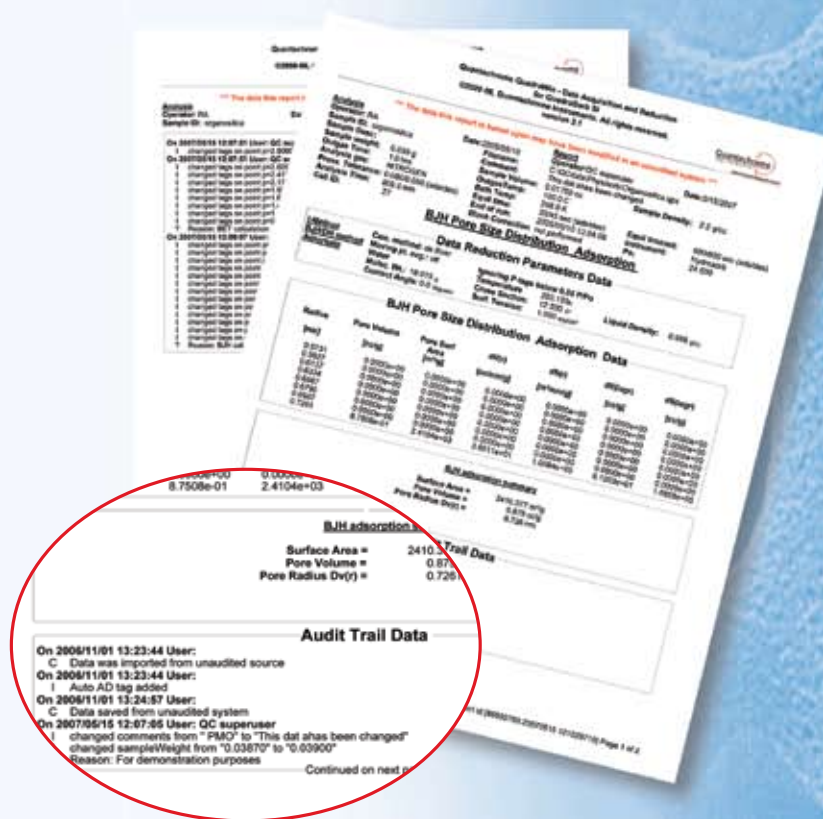
NOVAWin-CFR Software

Functions Relating to System Access, Electronic Signatures and Security

- Required login with unique user i.d./full name combination.
- Password aging and forced change.
- Automatic user account expiration and/or manual suspension.
- Selectable minimum i.d. and password length.
- Three user levels gives three privilege levels.
- Access level programmable by administrator level.
- Programmable session time-out (auto log-off through inactivity).
- Tamper resistant binary-encoded data files.
- Data security is established through the closed NOVA_e / NOVAWin system.
- Data reduction parameters (metadata) used to calculate final results are included as part of the data file.
- "Operator" user level does not have the access privileges to change metadata.
- Changes to metadata are reflected in the audit trail (see details below).
- Data files acquired by means other than directly from the NOVA_e instrument are flagged as such in the audit trail.

The NOVA_e series, when configured for security and used with its 21 CFR Part 11 compliant version of NOVAWin™ software, is designed to meet the regulatory requirements for electronic records within the pharmaceutical and allied industries as set forth by the US Food and Drug Administration (FDA). The FDA intends to enforce Part 11* compliance under FDA Regulations, the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act as outlined in its 2003 Guidance for Industry "Part 11, Electronic Records; Electronic Signatures — Scope and Application" prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER). The compliant version of the NOVA_e adopts both hardware and software design features to allow for easy integration into pharmaceutical and other GLP laboratories.

* Final Rule, Federal Register / Vol. 62, No. 54, pp13429-13466, 1997



Printed reports, electronic and hardcopy, include a complete copy of the audit trail and multiple page report sets are linked by a unique report I.D.

Audit Trail Functions & Reporting Features: The audit trail does not obscure previous entries - old and new values are both recorded and visible. The audit trail itself cannot be edited and is included as part of the securely encoded data file - it cannot become disconnected. Changes to metadata require that the user enter a reason, to be in accordance with the underlying predicate record rules, which is then retained as part of the audit trail. The audit trail is included in all human readable formats, screen display, print preview, PDF and hardcopy formats. Multiple-page report sets are linked by a unique report i.d. generated automatically by NOVAWin.



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Quantachrome Instruments' quality management system is certified to be in accordance with ISO9001:2008.

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