

Thermo Scientific SOLAARsecurity Software

Meeting the requirements of Rule 21 CFR Part 11

Thermo Scientific SOLAARsecurity software assists laboratories in meeting the requirements of the Food and Drugs Administration Rule 21 CFR Part 11 when using a Thermo Scientific iCE 3000 Series Atomic Absorption Spectrometer



What is the 21 CFR Part 11 Rule?

Companies that market food, drugs and some other classified products in the USA, or supply any raw materials that are used in the manufacture of these products, are required by US law to satisfy the regulatory requirements of the US Food and Drugs Administration. Such companies are required to keep detailed records of the development, production and quality control of their products.

The 21 CFR Part 11 Rule provides detailed requirements for controls to ensure the authenticity, integrity and confidentiality of this data when it is stored in electronic format. The Rule also defines the conditions under which an organization must operate when using electronic records and signatures to meet its record keeping and record submission requirements. Where the requirements of the Rule are met in full, the FDA considers the electronic records and signatures to be the legally binding equivalent of paper records with hand written signatures, and other general signings.

Companies that are compliant with the 21 CFR Part 11 Rule can adopt paperless record systems and submit regulatory documents in the form of electronic records. These companies benefit from a more cost effective and shorter approval process, which can have a tremendous and positive impact on their revenue stream.

Thermo Scientific SOLAARsecurity software has been designed to assist such companies in meeting the requirements of the Rule, when a Thermo Scientific Atomic Absorption Spectrometer is being used to generate analytical results that will be incorporated into the records and submissions required by the FDA.



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Software tools for the regulated laboratory

User Authentication

A primary requirement of the Rule is User Authentication – to ensure that e-records are created by and traceable to responsible, named individuals. SOLAAR*security* software utilises the User Authentication features of the secure Windows® operating systems to set up a centrally managed database of authorised users, each with defined functions, responsibilities and permissions that control their access to and use of the AA system.

Electronic Signatures

Facilities are provided to permit authorised users to execute electronic signatures to e-records, and such signatures meet the requirements for electronic signatures set out in the Rule.

Audit Trails and Event Logs

The Rule requires that all relevant e-records are audit trailed, so that all manipulations of the data are recorded and traceable, and data validity can be checked and confirmed. SOLAAR*security* software provides facilities for audit trailing all Results, Methods and Validation e-records that meet the requirements of the Rule. Further, other events that can affect data validity (such as unauthorised attempts to use the instrument) can be recorded in the event logs provided by the Windows® operating system.

Compatibility

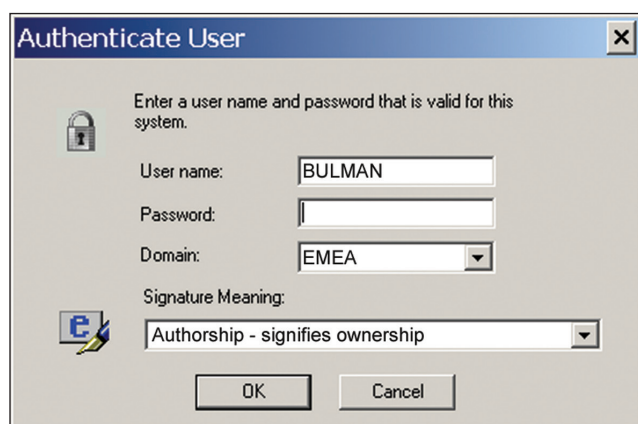
SOLAAR*security* software is compatible with the iCE 3000 Series Atomic Absorption Spectrometers.

Upgrades

Thermo Scientific AA systems can be upgraded with SOLAAR*security* software. Any existing e-records created by earlier versions of the SOLAAR software will remain available, but will be treated as Read Only. Facilities are provided for copying such e-records into new, secure databases where they can be signed and audit trailed.

Operating Systems

The Thermo Scientific SOLAAR*security* Administrator software runs under Windows® XP Professional, Windows® VISTA Ultimate or Windows® 7 Professional. It can be run on a local PC or a network server. The SOLAAR*security* Client software (that controls the spectrometer) runs on a local PC. If the Administrator software is running on a different PC on the network, the local PC can run the Client software under Windows® XP Professional, Windows® VISTA Ultimate or Windows® 7 Professional. If the Administrator and the Client software are running on the same PC, then they must run under Windows® XP Professional, Windows® VISTA Ultimate or Windows® 7 Professional.



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Africa-Other +27 11 570 1840
Australia +61 3 9757 4300
Austria +43 1 333 50 34 0
Belgium +32 53 73 42 41
Canada +1 800 530 8447
China +86 10 8419 3588
Denmark +45 70 23 62 60

Europe-Other +43 1 333 50 34 0
Finland/Norway/Sweden
 +46 8 556 468 00
France +33 1 60 92 48 00
Germany +49 6103 408 1014
India +91 22 6742 9434
Italy +39 02 950 591

Japan +81 45 453 9100
Latin America +1 561 688 8700
Middle East +43 1 333 50 34 0
Netherlands +31 76 579 55 55
New Zealand +64 9 980 6700
Russia/CIS +43 1 333 50 34 0
South Africa +27 11 570 1840

Spain +34 914 845 965
Switzerland +41 61 716 77 00
UK +44 1442 233555
USA +1 800 532 4752

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