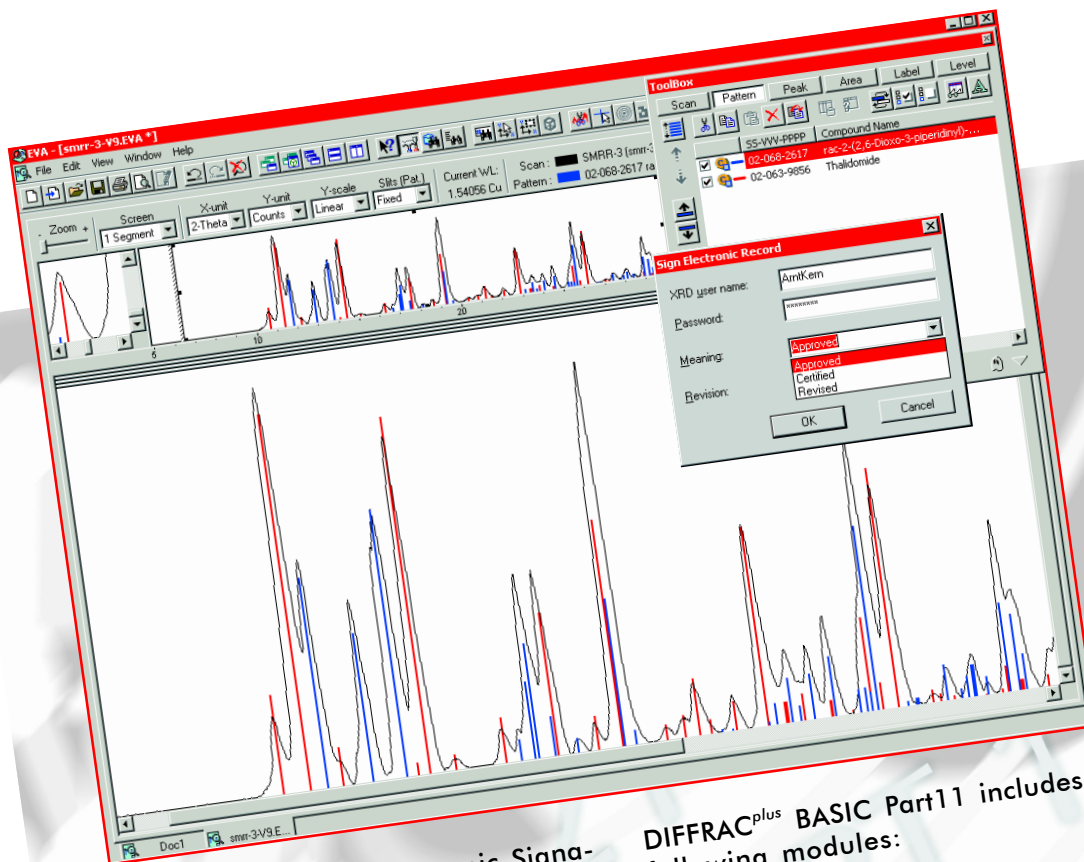


21 CFR PART 11

DIFFRAC^{plus} BASIC Part11 – THE SOLUTION FOR YOUR COMPLIANT LAB



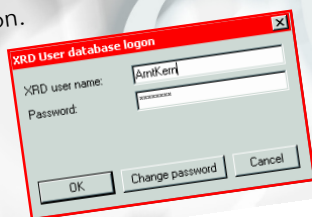
Electronic Records / Electronic Signatures - easy and safe

For nearly 10 years DIFFRAC^{plus} BASIC has been the leading software for XRD data acquisition, evaluation, and presentation. Recognizing the needs of regulated labs, the new DIFFRAC^{plus} BASIC Part11 is setting the standard for a new software generation by meeting the requirements of the US Food and Drug Administration's 21 CFR Part 11 regulation.

DIFFRAC^{plus} BASIC Part11 includes the following modules:

- User Manager
- Config
- XRD Commander
- XRD Wizard
- EVA
- SEARCH*

Are you already using DIFFRAC^{plus} BASIC? DIFFRAC^{plus} BASIC Part11 has the same functionality and user interface – you don't have to learn anything new!



*with its outstanding performance recently proven in the international SMRR 2002 round robin, <http://www.cristal.org/smr>

DIFFRAC^{plus} BASIC Part11

DIFFRAC^{plus} BASIC Part11 is being developed according to Bruker AXS's ISO9001:2000 certified product development procedures. Our formal design process incorporates written standards for coding, configuration management, programmer qualifications, software version control, maintenance, formal testing of software/hardware, incident reporting and tracking, and disaster recovery.

For the Integration into a 21 CFR Part 11 compliant laboratory, DIFFRAC^{plus} BASIC Part11 offers several tools to provide and guarantee authenticity, integrity and confidentiality of electronic records and electronic signatures, including

- Secure system log-ins
- Automatic audit trail generation
- Electronic signatures with reports and data
- Network security with Windows NT4/2000
- Tamper proof data files with the ability to discern invalid or altered records



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