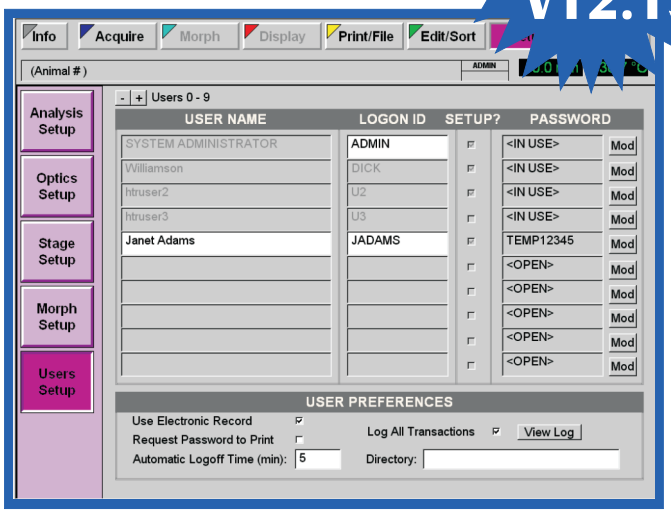
TOX-IVOS Version 12.1

Complies with 21 CFR 11

NEW for V12.1

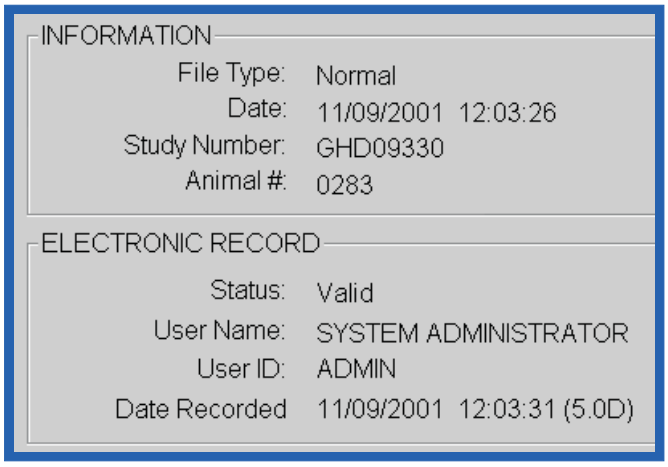
Enhanced Security Features

- System Administrator assigns User Name, Logon ID, Setup Access, and Temporary Password
- New user required to create personal password at first logon session
- Passwords must be 8 - 12 characters in length and contain a mix of letters and numbers
- User may change password at any time
- System Administrator may assign a new temporary password for any user at any time
- Automatic lock out of all users except System Administrator when an invalid Logon ID or password is entered 5 time consecutively



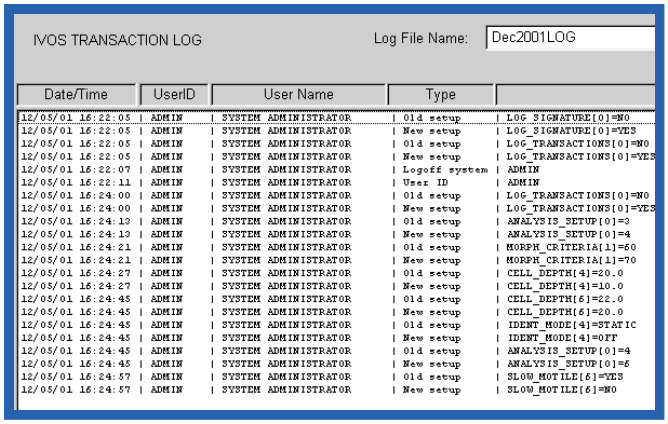
Electronic Records Keep Data Safe

- Digital image files stored along with setup files in a single record
- Previous setup parameters automatically inserted into new Setup 8 to ensure reanalysis with exact settings
- Any attempts to alter the Electronic Record are detected and reported as corruption when the record is retrieved
- Printout automatically includes footer containing User Name, User ID, TOX IVOS serial number and software version



Log File Tracks Exact Changes

- Lists User Name, User ID, Date/Time, and Actions performed
- "Old Setup" and "New Setup" values are shown
- Multiple attempts at ID or password penetration are logged
- Log file may be printed by System Administrator



See back of page for 21 CFR 11 Evaluation Results

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Compliance Status

On November 15th, 2001, the TOX IVOS Analyzer system version 12.1 was evaluated against FDA 21 Code of Federal Regulations Part 11 (21 CFR 11): Electronic Records and Electronic Signatures and found to meet all applicable requirements. The TOX IVOS Analyzer system version 12.1 is fully compliant with applicable sections of 21 CFR 11 sections as cited in the 15th November 2001 Assessment Observations cited below.

Summary

The TOX IVOS Analyzer system was reviewed for 21 CFR Part 11 classification. It was determined that the TOX IVOS Analyzer system is required to comply with Electronic Record sections 11.1, 11.2, 11.3, and 11.10. The Electronic Signature rulings of 21 CFR Part 11are not applicable based on the following observations: (1) Protocol for the TOX IVOS Analyzer system does not create or produce a dual record system i.e. a paper and electronic record, which would be considered keeping two sets of records with the paper record only bearing a signature for authentication; and (2) The TOX IVOS Analyzer system is exempt from 21 CFR Part 11 Sections 11.50, 11.70, 11.100(a), 11.200(b), 11.300(a), (b), (d) and 11.300(c), (e). Section 11.30 applies to controls for open systems and, therefore, not is not applicable to the TOX IVOS Analyzer system.

Assessment Observations* **(Applicable 21 CFR 11 Sections are designated)**

§11.1 (a) Electronic records were found to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper; (d) The TOX IVOS Analyzer (including hardware and software), controls, and attendant documentation were readily available for inspection.

§11.2 (a) Electronic records created and maintained in lieu of paper records.

§11.3 (b)(4) The TOX IVOS system is contained in an environment in which system access (user record) is controlled by persons who are responsible for the content of the electronic records that are on the system; and (b)(6) Electronic records are created, modified, maintained, archived, and retrieved by the computerized system.

§11.10 Controls for closed systems were found to be adequate and in compliance. Established procedures and controls ensure the authenticity and integrity of electronic records. Procedures and controls found adequate and in compliance include:

(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

(b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection.

(c) Protection of records to enable their accurate and ready retrieval.

(d) Limiting system access to authorized individuals.

(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Observed record changes were clear and complete.

(g) Use of authority checks to ensure that only authorized individuals use the system.

Please contact Hamilton Thorne Research for a copy of the original report.