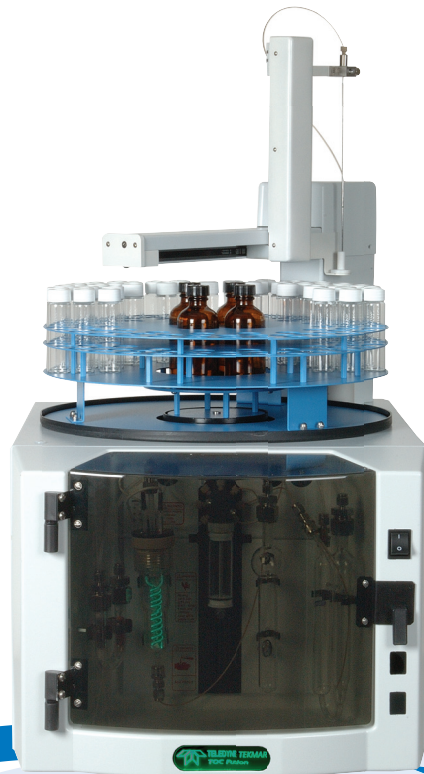


Doc # MKT-20002



Fusion UV/Persulfate TOC Analyzer Tools for 21 CFR 11 Compliance

Rev: A, April - 2020



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Teledyne Tekmar

4736 Socialville Foster Road
Mason, OH 45040 U.S.A
www.teledynetekmar.com

Toll Free: 800-543-4461

Sales/Support: 800-874-2004

Main: 513-229-7000

Fax: 513-229-7050

Fusion UV/Persulfate TOC Analyzer Tools for 21 CFR 11 Compliance

OVERVIEW OF FUSION TOC TEKLINK TOOLS FOR 21 CFR 11 COMPLIANCE

Fusion TOC TekLink software provides tools to aid in 21 CFR 11 compliance. This means that:

- User accounts and access privileges are secure.
- Methods, calibrations and schedules are all versioned, user-tracked and archived.
- Report data is secure, versioned, archived and retrieved with audit capability.
- Report data can have electronic signatures attached.
- System history and error logs can be viewed and printed.

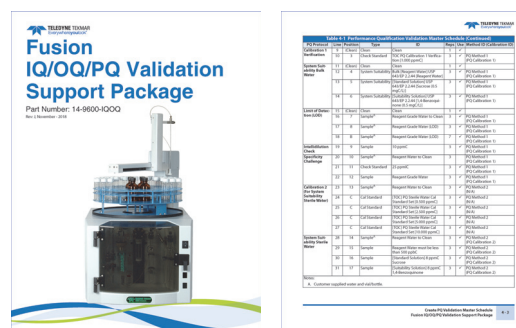
The Fusion TOC TekLink software can be used as a tool for 21 CFR 11 compliance, but it should be noted that maintaining the instrument by performing preventative maintenance and replacement of consumables, according to the *Fusion User Manual*, is also a necessary component of complying with 21 CFR 11.

FUSION INSTALLATION QUALIFICATION (IQ), OPERATIONAL QUALIFICATION (OQ) AND PERFORMANCE QUALIFICATION (PQ) VALIDATION SUPPORT

To support 21 CFR 11 compliance, Teledyne Tekmar offers a Fusion UV/Persulfate TOC analyzer IQ/OQ/PQ Validation Support Package (p/n 14-9600-IQOQPQ) performed by a factory certified service engineer. The Fusion IQ/OQ/PQ validates:

- The installation of the Fusion is in accordance with the manufacturer’s design or recommendation and intended use, as well as current good manufacturing practices (GMP) and principles.
- The Fusion meets the operational criteria as a Low-Level TOC Analyzer System for pharmaceutical or drinking water analysis.
- The Fusion meets the performance criteria validating that it is effective and reproducible as a TOC Analyzer System for pharmaceutical or drinking water analysis.

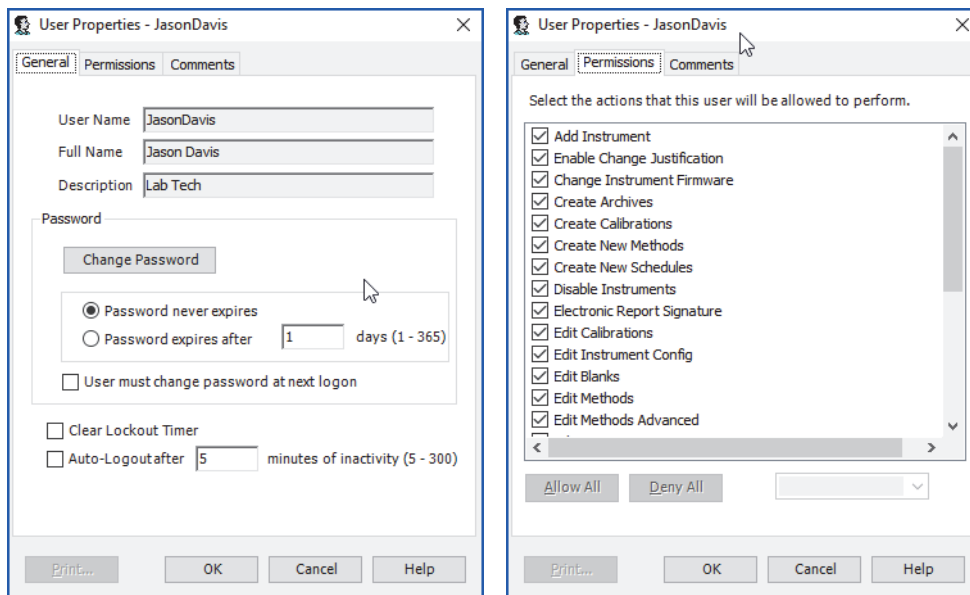
Figure 1 Fusion IQ/OQ/PQ Validation Support Package



FUSION TOC TEKLINK SOFTWARE TOOLS FOR 21 CFR 11 COMPLIANCE

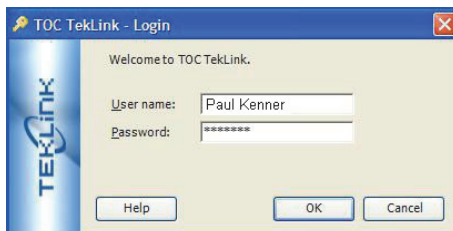
- Administrator Managed User Accounts with Permission Levels - The Administrator (typically an IT specialist) performs all account management functions including adding users and assigning user’s default or custom permissions within the Fusion TOC TekLink software. Default and custom user permissions restrict and allow specific software and instrument activities, as well as create an audit trail. As a check and balance, the administrator is not permitted to operate the Fusion.

Figure 2 Creating a User Account and Assigning Privileges



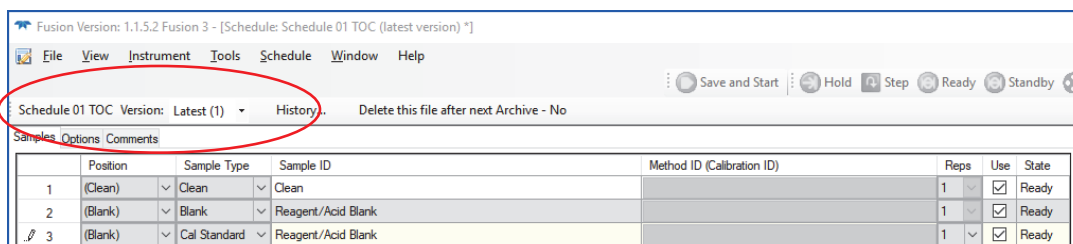
- User Identification Authentication - Anyone intending to use the Fusion TOC TekLink software or instrument must have a user account and password. Each user is then required to sign into the software to perform software functions and instrument actions. While logged in, software and instrument actions are associated with that user and recorded to create an audit trail.

Figure 3 User Login with Password



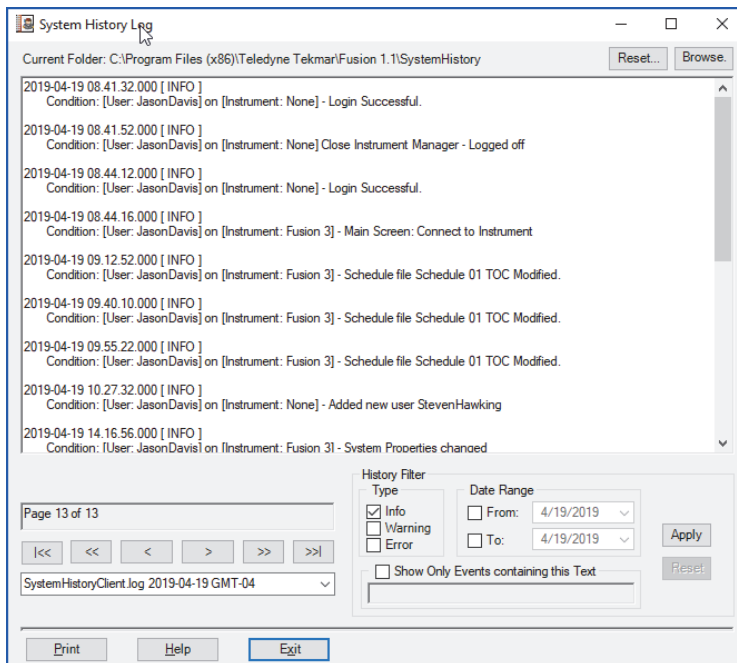
- Versioning and System History - Each method, calibration, schedule and report file has a version component built into the file. Anytime the file is changed or modified, a version is created. From the VERSION TOOL BAR, a drop-down menu shows the latest VERSION along with previous versions. Each time the version is changed, a HISTORY EVENT is created that records the VERSION NUMBER, CREATION DATE TIME STAMP, USER NAME and CHANGE JUSTIFICATION.

Figure 4 Schedule Showing Version Number



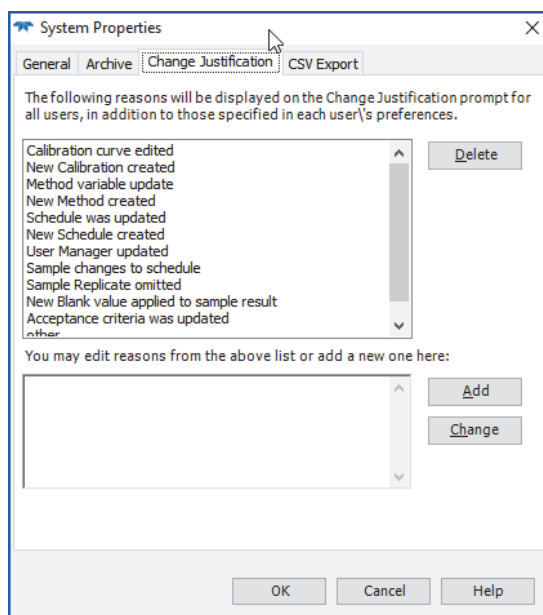
- Traceability/Audit Trail - A complete audit trail of software activity is created and SYSTEM HISTORY LOGS can be viewed and printed.

Figure 5 System History Log



- Change Justifications - User account permissions can be configured to require “Change Justifications” after a variety of software actions. Both default and custom change justifications can be configured.

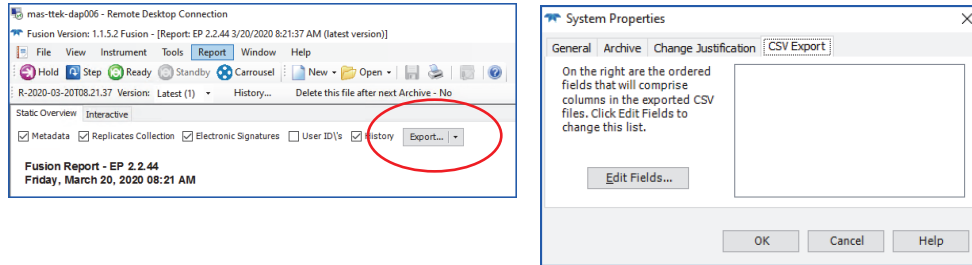
Figure 6 Default and Custom Change Justifications are Configurable in System Properties



FUSION TOC TEKLINK SOFTWARE DATA INTEGRITY

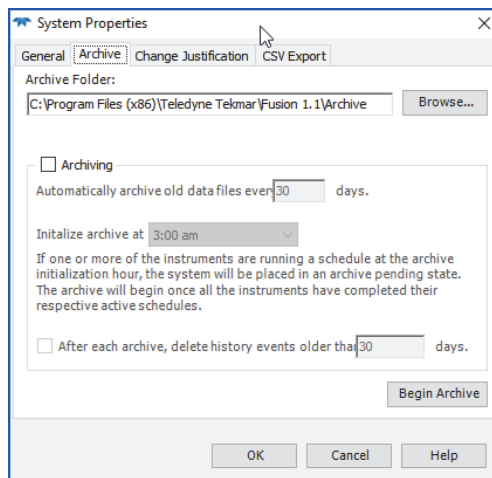
- Ability to automatically export a comma separated value (CSV) report file to a LIMS-based system.

Figure 7 Report Export Button and CSV Export Configuration Screen



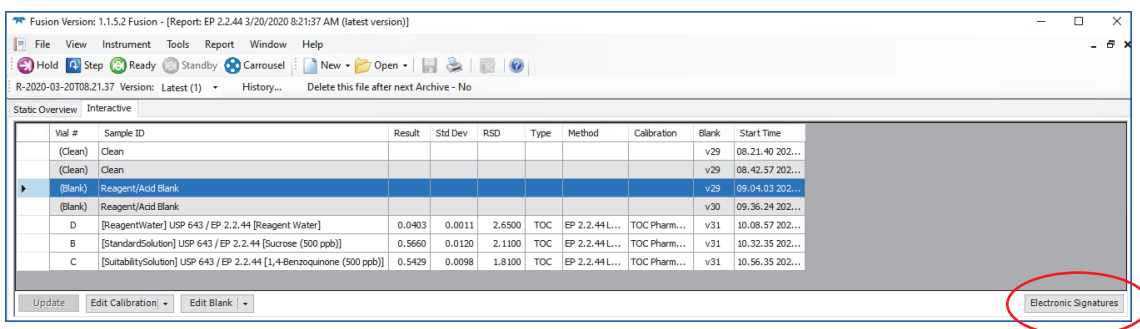
- Scheduled Automatic Archiving of Data Sets - When archiving is initiated, the file is copied into the ARCHIVE DIRECTORY designated in the SYSTEM PROPERTIES DIALOG. After archiving, the file is deleted from the current file directory, if the DELETE THIS FILE AFTER NEXT ARCHIVE CHECK BOX is selected.

Figure 8 System Properties Dialog - Scheduled Data Archive and Location



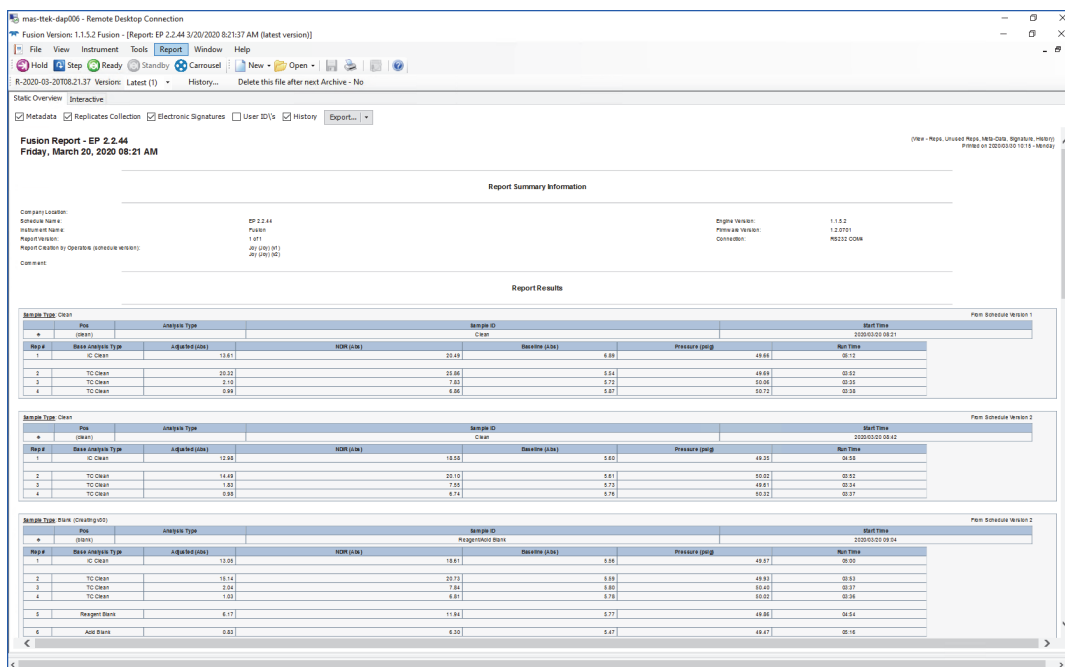
- Electronic Signing of Reports – Reports can be reviewed and approved by other users to add an additional level of quality assurance and accountability.

Figure 9 Interactive Report EP 2.2.44 with Electronic Signature Button



- Report Data Security - Report data files are completely self-contained, meaning all data required to produce the report is contained within the report file. The file contains an encrypted data content validation stamp to protect from corruption.

Figure 10 Static Report



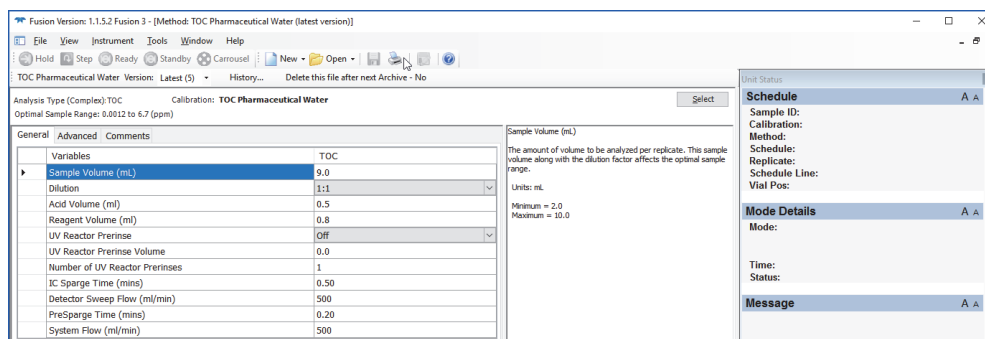
- For an additional level of data integrity, Teledyne Tekmar offers an optional accessory software (named “TT Run As...”) that works in conjunction with Fusion TOC TekLink. This software program runs the Fusion TOC TekLink software as a specific user within the Windows™ operating system and allows written privileges to TekLink files. Files that are locked by this user, cannot be accessed outside of the Fusion TOC TekLink software, preventing accidental or intentional corruption of software data.

FUSION TOC TEKLINK SOFTWARE FEATURES FOR EXPEDITED PHARMACEUTICAL WORK FLOW

In addition to 21 CFR 11 compliance tools, the Fusion TOC TekLink software was designed to provide intuitive features to simplify pharmaceutical analysis.

- Default pharmaceutical TOC instrument method that optimizes the instrument for pharmaceutical analysis.

Figure 11 TOC Pharmaceutical Method



- USP <643> and EP 2.2.44 Systems Suitability Checks - The suitability function automatically calculates if the system has passed the System Suitability Test mandated by USP or EP regulations.

Figure 12 Report Indicating Pass/Fail

Sample Type: System Suitability			From Schedule Version 2			
Pos	System Suitability Sample Type	Sample ID	Result	Std. Dev.	RSD	Start Time
◆ D	Reagent Water	[ReagentWater] USP 643 / EP 2.2.44 [Reagent Water]	0.0403 ppm (PASS)	0.0011 ppm	2.65%	2020/03/20 10:08
◆ B	Standard Solution	[StandardSolution] USP 643 / EP 2.2.44 [Sucrose (500 ppb)]	0.5660 ppm	0.0120 ppm	2.11%	2020/03/20 10:32
◆ C	Suitability Solution	[SuitabilitySolution] USP 643 / EP 2.2.44 [1,4-Benzoquinone (500 ppb)]	0.5429 ppm	0.0098 ppm	1.81%	2020/03/20 10:56

Response Efficiency: 95.61% (Acceptance Criteria 85% to 115%)

Limit Response (Ru): 525.7 ppb

ADDITIONAL INFORMATION

For **in-depth information** on using Fusion TOC TekLink 21 CFR 11 software tools, refer to the following webinar recording: [“Utilizing the Fusion as a Tool for 21 CFR 11 Compliance”](#).