

# MadgeTech 4 Secure Software

#### Features & Benefits

- » Install, validate and operate one software program universally
- » Compatible with most MadgeTech products
- Time and cost saving validation package, stands up to interrogation from auditors
- » Automatic data security and audit trail
- » Sophisticated user maintenance
- » Traceability with customizable electronic signatures and audit trails
- » Aids in compliance with FDA 21 CFR Part 11/820 and GxP guidelines

#### Applications

- » Pharmaceutical
- » Medical
- » Hospitals
- » FDA regulated organizations
- » Temperature Mapping

# Validated Software Aids in Compliance with FDA 21 CFR Part 11

The MadgeTech 4 Secure Software aids customers in compliance with 21 CFR Part 11 requirements. The software ensures standards in which electronic files are considered equivalent to paper records, saving time and effort. MadgeTech 4 Secure Software contains criteria such as electronic signatures, access codes, secure data files, and an audit trail which meet the requirements of 21 CFR Part 11 and help provide data integrity.

IQ/OQ/PQ protocols are included with the purchase of the MadgeTech 4 Secure Software to validate that the software has been installed and is operating correctly. On-site support is available for IQ/OQ/PQ implementation and software training.

The layout of the secure software is similar to the MadgeTech 4 Standard Software, allowing users to easily learn the additional features.



The Windows<sup>®</sup> based software package allows the user to effortlessly collect, display and analyze data. A variety of powerful tools provide the ability to examine, export, and print professional looking data with just a click of the mouse.

Get more information at www.madgetech.com



### Product Overview - Security Settings

Below is an overview of the important 21 CFR Part 11 compliance features found in the MadgeTech 4 Secure Software. Each feature is important in securing data and ensuring tampered data is recognized by the MadgeTech 4 Secure Software.



Users	Login attempts:	3			
Groups	Lockout duration:	0 hours, 30 minutes			
Login	Lock software after inactivity				
Audit Trail	Inactivity duration:	30 minutes			
	Minimum password length:	6			
	Password must include:				
	Uppercase letter				
	Special character				
	Enable password expiration	1			
	Expiration interval:	30 days			
	Warning interval:	3 days			

#### Login

Login attempts and lockout duration can be assigned within the Login tab. There are numerous password and account settings for the administrator to set such as the complexity of the password and status of each user account. The user management tab is only available to administrative users.

Users	Print		All users	•
Groups	Start time: 4/23/2013	4:45 PM 🔹	End time: 4/24/2013 1:44 PM	dates
Login	Timestamp	User	Description	
Audit Trail	4/23/2013 4:45:57 PM	Administrator	Logged in	
	4/23/2013 5:17:27 PM	Administrator	Logged out	
	4/24/2013 1:39:24 PM	Administrator	Logged in	
	4/24/2013 1:42:56 PM	Administrator	Saved report "Data" to the file database	
	4/24/2013 1:42:56 PM	Administrator	Logged out	
	4/24/2013 1:44:35 PM	Administrator	Logged in	

#### Audit Trail

An Audit Trail is kept automatically with information such as who has logged in and out, what files were downloaded, save, printed etc. Each record is date and time stamped and includes the user information.

115-	Electronic Signature
114	<ul> <li>Accept changes</li> <li>Reject changes</li> <li>Meaning of change:</li> </ul>
111-	-
109-4         3:06:40 PM         8:40:00 PM           6/26/2012         6/26/2012           -04:00         -04:00           rt User (Administrator) accepted report modifications on 4/30/2013 2:04:26 P           ning: Approved	Username: User M Password:

#### **Electronic Signature**

By clicking the Electronic Signature button, users and administrators can add electronic signatures. The electronic signature contains the printed name of the signer, date and time of the signing and the meaning of the signing.

## **Great New Features**

The new MadgeTech Data Logger Software 4 is a powerful, intuitive tool containing features that are designed to save on both time and headaches. Both management and users will find MadgeTech's new software exciting: users will love the familiar interface and numerous shortcuts, while management will appreciate the increased data security and time-saving elements. Some of the most highly-anticipated new features include:



**Logger Auto-Detection** Saves Time, Secures Data

MadgeTech software automatically detects loggers as soon as they are plugged into the computer. With minimal user involvement, drivers are then installed, data is downloaded, and a graph of the data is rendered on screen.



**Linked Data** Saves Time & Effort

Graphs and data grids can now be linked, allowing the user to quickly and easily modify multiple views of the same information. Make a change to the data grid and the information on the linked graph synchronizes immediately and automatically!



Multiple Data Sets Makes Mapping a Breeze

Mapping data has never been so easy or fast! Now data from multiple loggers can be easily combined in a single data grid by simply dragging and dropping data sets, creating a side by side comparison of data for each logger.

To determine the ideal solution for your application, contact MadgeTech today at **sales@madgetech.com** or **(603) 456-2011**.

