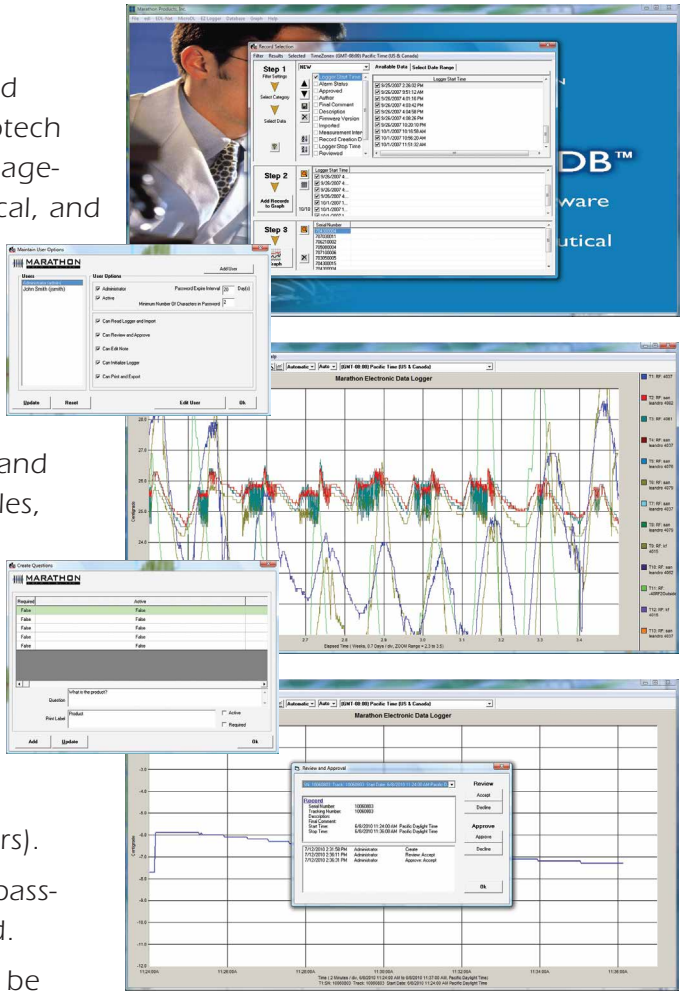
MARATHON PRODUCTS

21CFR DB™ Software for Regulatory Compliance

Marathon CRM Software



Meeting the FDA's requirements for electronic records and electronic signatures used in the pharmaceutical and biotech industries, our database and Customer Relationship Management Software has been designed for the biotech, medical, and pharmaceutical industries to comply with the Code of Federal Regulations Section 21 CFR Part 11 as required by the Food and Drug Administration.

Marathon 21 CFR DB validates data and works seamlessly with Marathon's intelligent data collection devices. The software provides sophisticated data encryption and storage, administrative and multi-level user security profiles, and tools for manipulating and retrieving data. In conjunction with Marathon's time and temperature data loggers, the software provides a complete analytical solution for quality assurance. Our industry focused approach benefits your operations even if your best practices do not require regulatory compliance.

CONTROLS FOR CLOSED AND OPEN SYSTEMS

- Password protection (up to 10 alpha-numeric characters).
- Unique user names, login names, and alpha-numeric passwords up to 10 characters. Users can never be deleted.
- Multiple levels of security privileges: system access can be customized for each user by the administrator.
- Encrypted Data means no risk of record alteration. Recorded files are encrypted to 128 bits or more in a RC4 variant. Recorded files are in binary, compressed and checksummed format proprietary to Marathon Products, Inc.
- Sort by dates, product codes, tracking numbers, shipper or any user-defined attribute to electronically manage your data.

§ 11.10	Controls for closed systems	Comply
§ 11.30	Controls for open systems	Comply
§ 11.50	Signature manifestations	Comply
§ 11.70	Signature/record linking	Comply
§ 11.100	General requirements	Comply
§ 11.200	Electronic signature components and controls	Comply

MARATHON PRODUCTS, INC.

Don't ship without us!®

- Microsoft Access Database: industry-standard format allows exporting to other databases. Complete and accurate electronic copies are available for reviewing the data, copying the raw data, exporting or printing into a "pdf " format.

ELECTRONIC AUDIT TRAILS FOR REGULATORY COMPLIANCE.

- Secure computer generated, time-stamped run-time audit trail of authorship, signatures, detailed configuration changes, imports and exports, administrator activities, etc.
- Audit trails are embedded in the history file guaranteeing retention alongside the records and available for review/copying.
- A separate Audit log monitoring individual logins, is kept outside the Marathon 21 CFR DB™ program and can be deleted according to your Standard Operating Procedures.

ELECTRONIC SIGNATURES MAKE PAPER RECORDS OBSOLETE.

- Signed records contain printed name, date, time and meaning. Meaning includes Reviewed and Declined Review, Approved and Declined Approved, Record Created and Record Imported. Signed authorization (authorship) and optional operator entered note. Name, time-stamp and meaning are all embedded in the binary format history file.

SYSTEMS REQUIREMENTS

Microsoft Windows Operating Systems 98, NT, 2000, XP, Vista, and Windows 7 & 8 for client workstations. We recommend that the database software be installed on a Windows 2000 or 2003 server by your IS or IT department. All Marathon's electronic temperature data loggers are backward compatible with the Marathon 21 CFR DB™ program.

SOFTWARE FEATURES

- Secure Database
- Electronic Signatures
- Levels of access permission, privileges, and authorization to customize user actions
- Audit Trails
- User Names, Login Names & Passwords
- Password Minimum Number of Characters and Expire Interval
- Record Statistics & Details
- Microsoft Access Database
- Intelligent Handling of Time Zones
- Export Data to other 21 CFR Databases
- Read Logger
- Mean Kinetic Temperature

21CFR DB ADDITIONAL FEATURES:

- Record Search Filter
- Customized Filter Attributes
- Record Summary
- Customized Data Entries & Queries
- Realtime Display
- Import Record

MARATHON 21CFR DB Full Database	**MARATHON 21CFR LE** Limited Edition	**VIEWER** Read Only
5 users plus administrator	2 users plus administrator	2 users plus administrator
Up to 120 traces in one graph	1 trace by graph only	1 trace by graph only
One document containing the set of testing procedures and the template to perform the in-house validation	Optional Validation Manual, $250	Optional Validation Manual, $250
A document reports how the 21CFR DB software addresses the 21 CFR Part 11 Requirements	A document reports how the 21CFR LE software addresses the 21 CFR Part 11 Requirements	A document reports how the 21CFR Viewer software addresses the 21 CFR Part 11 Requirements
RECOMMEND FOR: • Companies with multiple locations • Manage more than 100 records a year • Require more than 2 users • Require software validation documents in place for FDA inspections • Use multi-use & single use units. • Logger Initialization	RECOMMEND FOR: • Companies with only one location • Manage less than 100 records a year • Require no more than 2 users • Write their own validation manual • Use multi-use & single use units. • Logger Initialization	RECOMMEND FOR: • Locations that only receive units. • Read-only version. It cannot program loggers. • No Logger Initialization
2 years of customer support, service packs and version upgrades (including enhancements). 90 day warranted satisfaction or full refund	1 year of customer support, service packs and version upgrades (including enhancements) 90 day warranted satisfaction or full refund	1 year of customer support, service packs and version upgrades (including enhancements) 90 day warranted satisfaction or full refund

Please call 1-510-562-6450

for more information or for a live demonstration over the internet.

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