

Technical Datasheet

M-Trace® Electronic Test Record Software

Intended Use

The M-Trace® Electronic Test Record Software automizes and digitalizes all data recording steps during sterility testing with your existing Steritest® Symbio pump.

Description

- The M-Trace® Electronic Test Record Software is 21 CFR part 11 and GAMP5 compliant.
- The software is validated and compatible with Microsoft Windows operating systems. It can be connected to one or several Steritest® Symbio pumps.
- It can be pre-installed on the M-Trace® all-in-one computer or deployed in the company IT infrastructure, allowing unlimited client workstations to access its services and resources.
- Prior to routine use, each SOP can be set up in the M-Trace® Electronic Test Record Software by creating Master Test Records (MTRs).
- During execution of the QC workflow the software leads the operator through the workflows, requests data as defined in the MTR and alerts the operator in case of invalid data entries or other process deviations.
- Data can be entered in the following ways:
 - Machine-to-machine interface for the Steritest® Symbio pump, to transfer instrument parameters such as pump speed or pressure measurement
 - Voice commands via the M-Trace® Headset for hand-free, contemporaneous documentation, e.g. when the operator's hands are carrying out tasks inside an isolator
 - Scanning of data matrix codes, e.g. to check the validity (expiry date) of consumables
- The operator can scan and record data in various locations of the lab, thanks to the M-Trace® Mobile App hosted on the M-Trace® Touch Mobile Device.
- All recorded data for each tested batch are stored in a Test Record (TR) in which incidents are clearly highlighted to facilitate the subsequent TR review and approval.
- Periodic system backups are automatically created at time intervals that can be individually defined by the user.
- In a dedicated user management module, the various user and access rights can be defined and managed.
- The software can utilize Microsoft Windows Active Directory to enhance software security and management by providing centralized user authentication, access control, and streamlined administration of user permissions across the organization.
- The audit trail function systematically records and tracks all user activities and changes within a system, providing a comprehensive log for security, compliance, and accountability purposes.

Ordering Information

Item Description	Cat. Number
M-Trace® Software - Annual License	MTRASOFTW
M-Trace® All-in-One Computer	MTRACEPC1
M-Trace® Touch Mobile Computer	MTRACEMC1
M-Trace® Charging Cradle	MTRACECR1
M-Trace® Headset	MTRACEHS1
M-Trace® Mobile Computer Mount	MTRACEMM1
M-Trace® Battery	MTRACEBT1
M-Trace® Backup Drive	MTRACEBD1
M-Trace® Mobile Computer USB Charger	MTRACECH1
M-Trace® On-Site Installation Service	MTRAINSTAL
M-Trace® On-Site IQ OQ Service	MTRAVAL11
M-Trace® IQ OQ e-Protocol	MTRAIQOQEP
M-Trace® On-Site Software User Training	MTRATRRAIN
M-Trace® Integration Service	MTRAINTEG
M-Trace® Master Test Record Creation	MTRAMTRC
M-Trace® Custom Test Report creation	MTRACTRPC

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