M-Trace^{TM} Electronic Test Record Software

Intended Use

The M-Trace^{TM} Electronic Test Record Software automizes and digitalizes all data recording steps during sterility testing and other quality control workflows.

Description

- The M-Trace^{TM} Electronic Test Record Software is 21 CFR part 11 and GAMP5 compliant.
- The software is validated and pre-installed on an M-Trace^{TM} All-in-One Computer. To fulfil individual laboratory integration requirements the software can be connected to other equipment, software or databases such as LIMS and can also be installed on other devices than an M-Trace^{TM} All-in-One Computer. Both requires customized integration projects.
- Prior to routine use, each workflow needs to be set up in the M-Trace^{TM} Electronic Test Record Software by creating Master Test Records (MTRs) in which all process steps and the data to generate can be defined according to individual user requirements.
- 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
  - Voice commands via the M-Trace^{TM} 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
- M-Trace^{TM} Mobile App, hosted on the M-Trace^{TM} Touch Mobile Computer, allows flexible data recording and scanning, independently of the testing location.
- 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 life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the US and Canada.

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	MTRATRAIN
M-Trace™ Integration Service	MTRAINTEG
M-Trace™ Master Test Record Creation	MTRAMTRC

Learn more at **SigmaAldrich.com/M-Trace**

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