YOUR DIGITAL QC COMPANION FOR STERILITY TESTING

M-Trace® Software for Trusted and Efficient Data Traceability
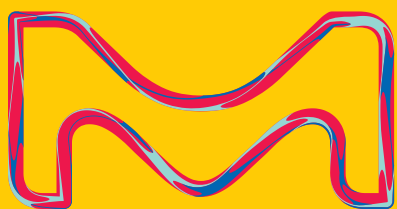
Millipore®

Preparation, Separation, Filtration & Monitoring Products

YOUR DIGITAL QC COMPANION

M-Trace® Electronic Test Record Software & Mobile App
Your 21 CFR Part 11 compliant Digital QC companion for Sterility Testing, for trusted and efficient data traceability!

- **NEW!** • Run the M-Trace® software from any computer using your centralized user management for Microsoft Windows

- **NEW!** • Benefit from enhanced 21 CFR part 11 compliance thanks to the audit trail function

- **NEW!** • Control all your Steritest® Symbio pumps with a single software

- **NEW!** • Make the system fit your SOP: take advantage of customizable functionalities and create digital clones of your internal protocols

- Use the voice control function to confirm completion of steps (optional)

- Ensure full traceability and regulatory compliance with contemporaneous, automatic, and complete management of data for each of your Sterility tests

- Increase process safety with guided QC workflows and deviation alerts

- Improve efficiency by eliminating paper-based documentation and digitizing management and review processes

- Facilitate automated control of your Steritest® Symbio pump and advanced connectivity of your testing data to your lab IT environment (e.g. LIMS)

- Centralize management of your Steritest® Symbio pumps and SOPs

Get full control of your entire testing workflow

By giving step-by-step guidance and recording data automatically in realtime, the M-Trace® system offers a convenient and reliable way to comply with regulatory requirements regarding traceability and data integrity. During each sterility test, the M-Trace® software gives step-by-step handling instructions, either on the pump's display or by voice, while capturing all relevant test data in realtime.

Track activities beyond the pump with our mobile device
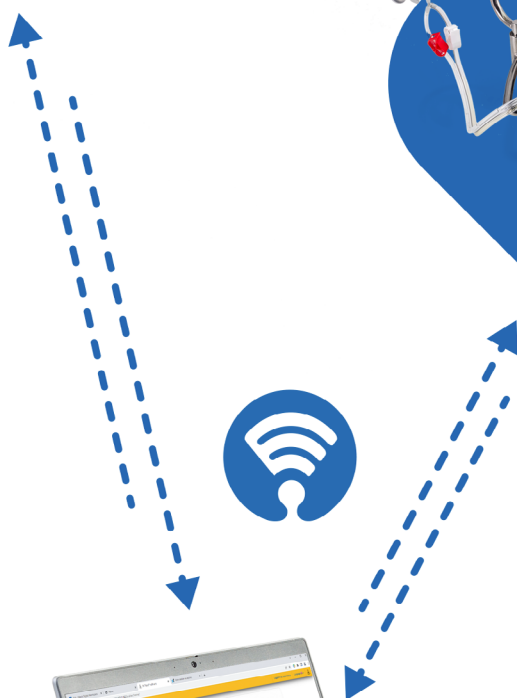
HOW DOES IT WORK?

This is how a fully traceable, reliable and efficient sterility test performed with the assistance of the M-Trace® software could look like at your site.

Get started

Transfer and digitalize your SOPs in the M-Trace® software, optionally connect the system with your QC-IT environment such as LIMS and finally connect the M-Trace® sotware with your Steritest® Symbio pump to be all set.

Workflow preparation

Scan LIMS label of sample with the M-Trace® mobile device to register sample information in the M-Trace® software.
Collect and register consumables or equipment needed for testing based on item list provided by the M-Trace® mobile device to make sure no item is forgotten.

DESIGNED TO ENSURE COMPLIANCE

DIGITALIZED TO BOOST PRODUCTIVITY

GUIDANCE TO AVOID ERRORS

A PRE-VALIDATED SETUP
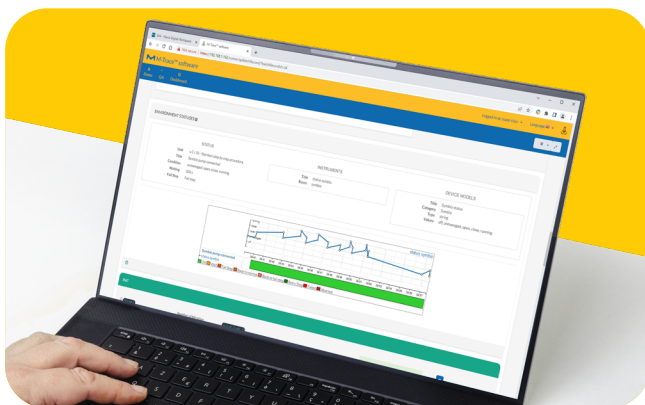
Report

A comprehensive digital test report is automatically generated for convenient test record review and approval, while mainting 21CFR 11 compliance.


Examination

Your personalized SOPs allow you to scan the test sample anywhere at your facility, so you can continuously document the results with the M-Trace® mobile app. This app also lets you organize your sample management and reference a sample ID to a specific incubator.


Testing

Scan consumables for your work steps and be alerted if an expired or invalid consumable was selected. Get work instructions either by voice control or on the Steritest® Symbio pump and confirm proper execution. In all this, the pump is controlled semi-automatically.
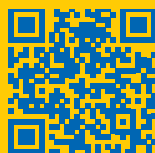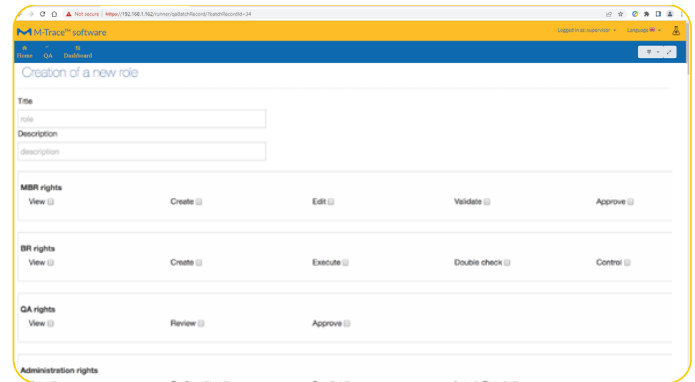

WATCH VIDEO
SigmaAldrich.com/video-mtrace

BOOST PRODUCTIVITY ENSURE COMPLIANCE

with the M-Trace® solution
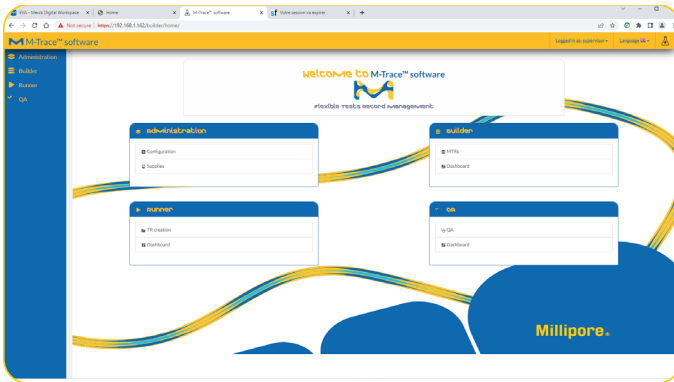
Organize your lab material and users in the Administration module. Create your Master Test Records in the Builder, execute them in the Runner and organize the test records in the QA module.


Define roles and user rights in the comprehensive and convenient 21 CFR part 11 compliant user management system.
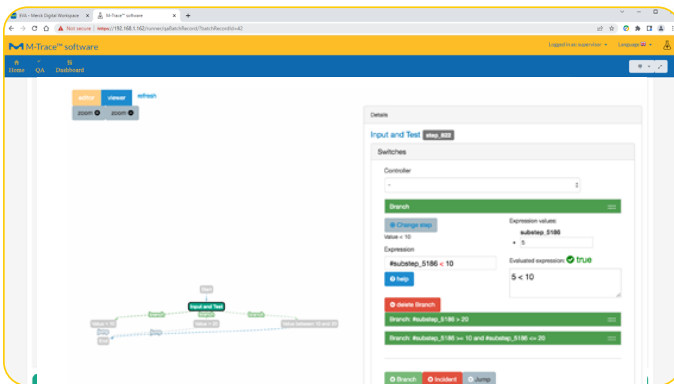

Transfer your sterility testing SOP into the M-Trace® software by creating fully customizable Master Test Records which will lead the operator through your workflow as defined. Thanks to the M-Trace® software's versatility the Master Test Records are not limited to sterility testing but could also be created for any other workflow.
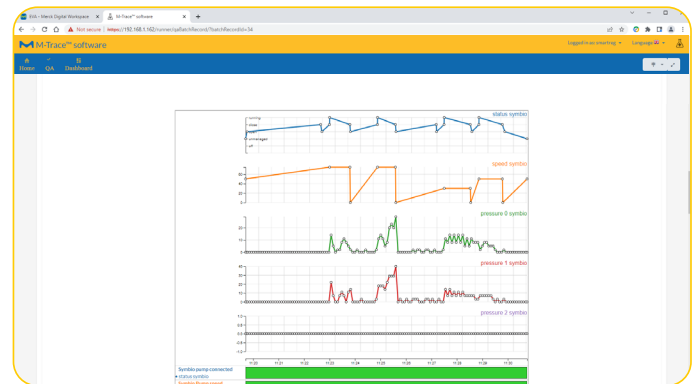
Obtain comprehensive meta data form the Steritest® Symbio pump, for example pump speed, pressure or a detailed pump activity profile. This profile can prove that no overpressure has occurred and the Steritest® cannisters were not incubated under pressure that could harm microorganisms and thus lead to false negative results.
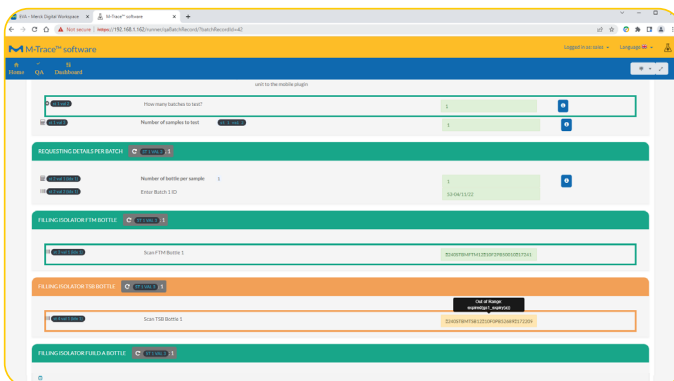
In the test record potential incidents that occurred during the testing are clearly highlighted.
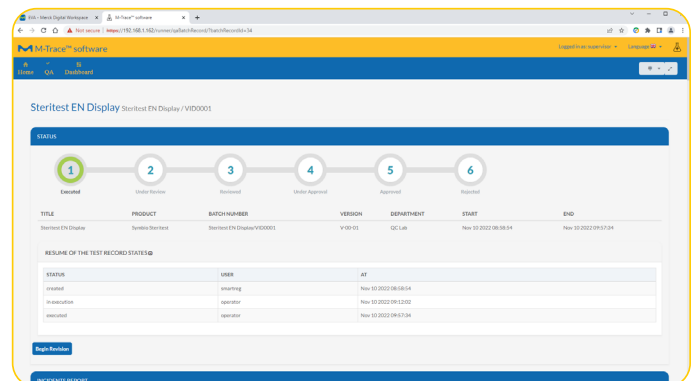
The dedicated QA module facilitates structured review and approval of the test records.

FULL TRACEABILITY
for your sterility testing data with the M-Trace® solution

Ordering information

| Product		Ordering No.
M-Trace® All-in-One Computer	All-in-One Computer for running the M-Trace® Electronic Test Record Software	**MTRACEPC1**
M-Trace® Touch Mobile Computer	Touch Mobile Computer for running the M-Trace® Mobile App	**MTRACEMC1**
M-Trace® Charging Cradle	Charging Cradle for M-Trace® Touch Mobile Computer	**MTRACECR1**
M-Trace® Headset	Headset for voice control of the M-Trace™ Electronic Test Record Software	**MTRACEHS1**
M-Trace® Mobile Computer Mount	Mount for the M-Trace® Mobile Computer	**MTRACEMM1**
M-Trace® Battery	Replacement battery of the M-Trace® Touch Mobile Computer	**MTRACEBT1**
M-Trace® Backup Drive	Drive to create backups out of the M-Trace® Electronic Test Record Software	**MTRACEBD1**
M-Trace® Software - Annual License Fee	Annual license to run the M-Trace® Electronic Test Record Software	**MTRASOFTW**
M-Trace® On-Site Installation Service	Service for on-site installation of the M-Trace® hardware and software	**MTRAINSTAL**
M-Trace® On-Site IQ OQ Service	Service for on-site IQ/OQ of the M-Trace® hardware and software	**MTRAVAL11**
M-Trace® IQ OQ e-Protocol	Electronic protocol for IQ/OQ of the M-Trace® hardware and software	**MTRAIQOQEP**
M-Trace® On-Site Software User Training	On-site end-user training of the M-Trace® Electronic Test Record Software	**MTRATRAIN**
M-Trace® Integration Service	Customized integration service of the M-Trace® hardware and software into end-users IT environment	**MTRAINTEG**
M-Trace® Master Test Record Creation	Service to create customized Master Test Records in the M-Trace® Electronic Test Record Software	**MTRAMTRC**
M-Trace® Custom Test Report Creation	Service to create customized Test Reports in the M-Trace® Electronic Test Record Software	**MTRACTRPC**
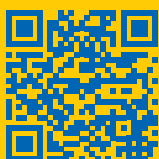
**REQUEST
INFORMATION**
SigmaAldrich.com/info-mtrace

SHAPE YOUR FUTURE

We help you bring robotics and automation together

Our mission is to transform microbiology quality control processes to accelerate the release of safe pharmaceutical products. We collaborate with the global scientific community to develop integrated automation and robotic solutions to improve QC testing reliability and data integrity.

Learn more:
SigmaAldrich.com/shapeyourfuture
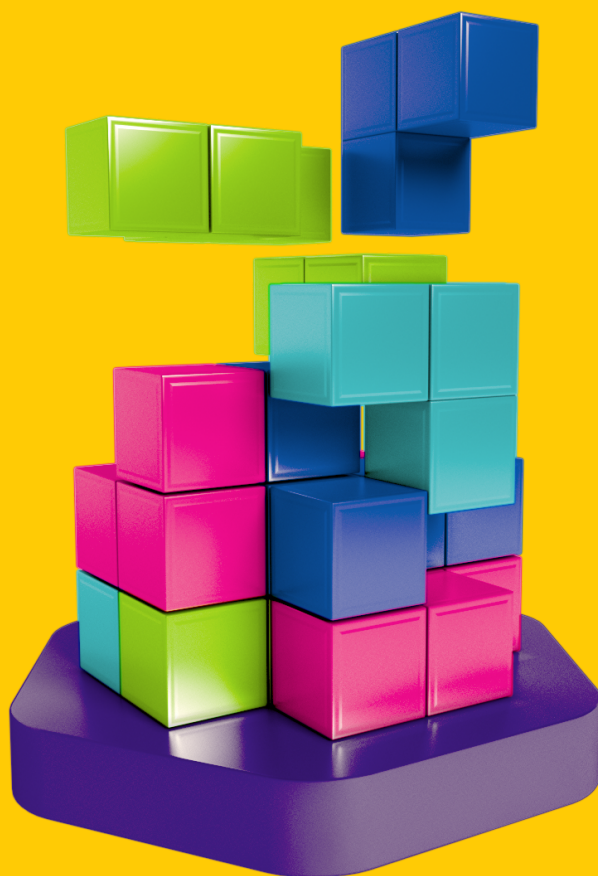
REQUEST INFORMATION
SigmaAldrich.com/info-mtrace

WATCH VIDEO
SigmaAldrich.com/video-mtrace

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

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

To Place an Order or Receive Technical Assistance

Order/Customer Service: **SigmaAldrich.com/order**

Technical Service: **SigmaAldrich.com/techservice**

MK_BR11751EN 60338
12/2024