



Pharmaceutical Microbiology

MALDI Biotyper[®]

- Changing Microbiology

Fast, Accurate and Traceable Identification of Microorganisms



The MALDI Biotyper System:

- Robust and Easy to Use
- Compact Bench Top System
- Comprehensive Species Library
- Easy to Integrate
- Intuitive Software
- 21 CFR part 11 Support
 - Audit Trail
 - User Management
 - Data Security
 - Electronic Signature
- IQ/OQ/PV Support

Ensure Safety and Quality of Pharmaceutical Products

Pharmaceutical microbiologists are responsible for ensuring that the supply of life-saving drugs and vaccines are free from contamination of microorganisms.

MALDI Biotyper provides specific identification of microorganisms within minutes.

Its performance reaches far beyond traditional methods and its outcome is comparable to molecular sequencing techniques.

Implementing MALDI Biotyper in the microbial QC workflow can directly translate to significant cost savings by accelerated control of raw materials as well as quicker in-process production and end-product testing.



Straightforward to Result

There is nothing faster - and easier

The MALDI Biotyper identifies microorganisms using MALDI-TOF (Matrix Assisted Laser Desorption Ionization-Time of Flight) Mass Spectrometry to determine the unique proteomic fingerprint of an organism.

The characteristic spectrum pattern of this proteomic fingerprint is used to reliably and accurately identify a particular microorganism by matching thousands of reference spectra of microorganism strains.

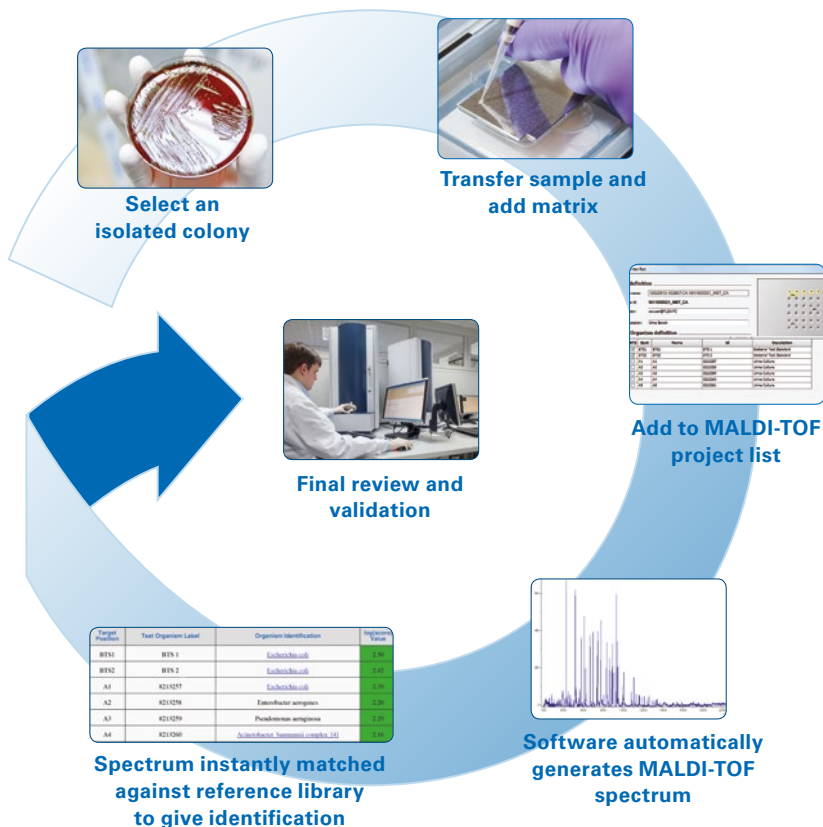
The MALDI Biotyper workflow has been designed to be as robust and easy to perform as possible.

Only a few simple steps are required to generate high quality and reliable microorganism identification.

The process of mass spectra acquisition and spectra-matching is standardized, resulting in highly accurate microorganism identifications in every run.

Typically, no more than an isolated colony from a culture plate or small aliquot from a broth is required. The entire procedure takes only a few minutes to complete. Fully traceable paperless workflows are possible through the use of barcoded MALDI target plates.

MALDI Biotyper Identification Workflow



Rigorous and Sophisticated Data Analysis Assures Accuracy

Meaning of score values

The acquired spectrum of the sample is transformed into a peak pattern, utilizing dedicated spectral analysis tools. This pattern is compared to reference peak lists of organisms in the reference library and a log(score) value between 0.00 and 3.00 is calculated.

The higher the log(score) value, the higher the degree of similarity to a given organism in the reference library. Values ≥ 2 (green) indicate high confidence identifications. Log (score) values between 1.70 and 1.99 (yellow) need to be confirmed by additional methods. Values below 1.70 (red) indicate that no organism identification was possible.

Score Values			
Range	Interpretation	Symbols	Color
2.000 - 3.000	High Confidence Identification	(+++)	green
1.700 - 1.999	Low Confidence Identification	(+)	yellow
0.000 - 1.699	No Organism Identification Possible	(-)	red

More Than a Comprehensive Library

Up-to-date and traceable

The integrated library of the MALDI Biotyper Software comprises spectra of thousands of strains including bacteria and fungi (yeast and mold). The library is continuously maintained and updated according to strict quality controlled procedures.

Spectra are determined from isolates from collaborating partners, round robin strains and strains from isolates from strain collections developed under the ISO 9001:2008 quality management system.

Flexible

Laboratories that need to create their own spectra entries can make use of an optional software module to compile customized microorganism libraries. Users can create, export and share libraries.

Intuitive Software Tailored to the Needs of the QC Laboratory

In just a few easy steps, the simple-to-use software guides users through the set-up of an isolate or batch of isolates for analysis.

Convenient user interface for easy set-up of working lists

Project definition

Project name: 140506-1516-181000234
 Plate Id: 181000234
 Creator: Micro Lab Manager
 Description: QC Control and Monitoring

Analyte definition

Spot	Name	Id	Description
1	BTS1	QC Control	Performance Check
2	A1	QC 002 – 08561	Extraction
3	A2	QC 003 – 06734	Extraction
4	A3	QC 004 – 07144	direct transfer
5	A4	QC 005 – 04324	direct transfer
6	A5	QC 006 – 03563	direct transfer
7	A6	QC 007 – 03221	direct transfer
8	A7	QC 008 – 02751	direct transfer
9	A8	QC 009 – 08863	direct transfer

Before each identification run, the MALDI Biotyper system executes a performance check using the BTS-QC standard. This guarantees consistent system performance for every spectra acquisition.

Clear identification results display at species level

Analyte ID or Name	Organism (best match)	Score Value
QC 001 – BTS	Escherichia coli	2.446
QC 002 – 08561	Bacillus subtilis	2.266
QC 003 – 06734	Bacillus cereus	2.204
QC 004 – 07144	Pseudomonas aeruginosa	2.562
QC 005 – 04324	Candida albicans	2.354
QC 006 – 03563	Aspergillus brasiliensis	2.332
QC 007 – 03221	Staphylococcus aureus	2.446
QC 008 – 02751	Kocuria rhizophila	2.241

After the acquisition of the spectral data has been completed, a report is generated. The result for each sample shows the best match along with the respective matching score.

The Best Technology from the Experts in Mass Spectrometry

As the leader in MALDI-TOF technology it is of great importance to Bruker to design robust, compact, high performance platforms intended for extensive and routine usage in the microbiology laboratory.

The core of the MALDI Biotyper system is the cutting-edge microflex LT/SH MALDI-TOF mass spectrometer.

A space saving system

A true bench-top solution taking up less than 1 meter/ 3 feet of counter space to provide flexibility in meeting laboratory needs. Requires only a 110/220 V electrical supply and generates minimal thermal output.

Resolution meets sensitivity

Resolution and sensitivity of the spectrometer are tailored to the needs of microbiologists. Optimal results are achieved without the need for long and bulky instrument flight tubes.

Accelerated data acquisition

With Smart Spectra Acquisition, data generation is accelerated by minimizing the number of laser shots per sample needed to generate a signal.

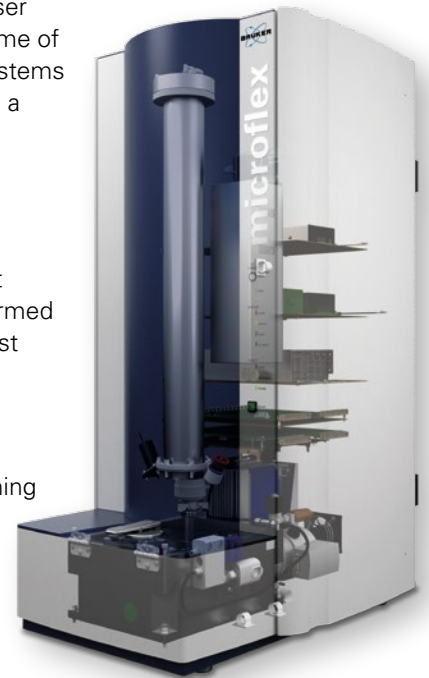
An additional benefit of this function is the optimal exploitation of the laser lifetime. Fastest target exchange time of all microbial mass spectrometry systems shrinks measurement cycle time to a minimum.

Highly reproducible results – run-to-run

The quick and simple Bacterial Test Standard (BTS) quality check performed before each run provides the highest standard of reproducibility.

Continuous operation

Routine maintenance such as cleaning is reduced to a minimum and can be easily performed by the user.



High Quality Consumables Ensure Optimum Identification Performance

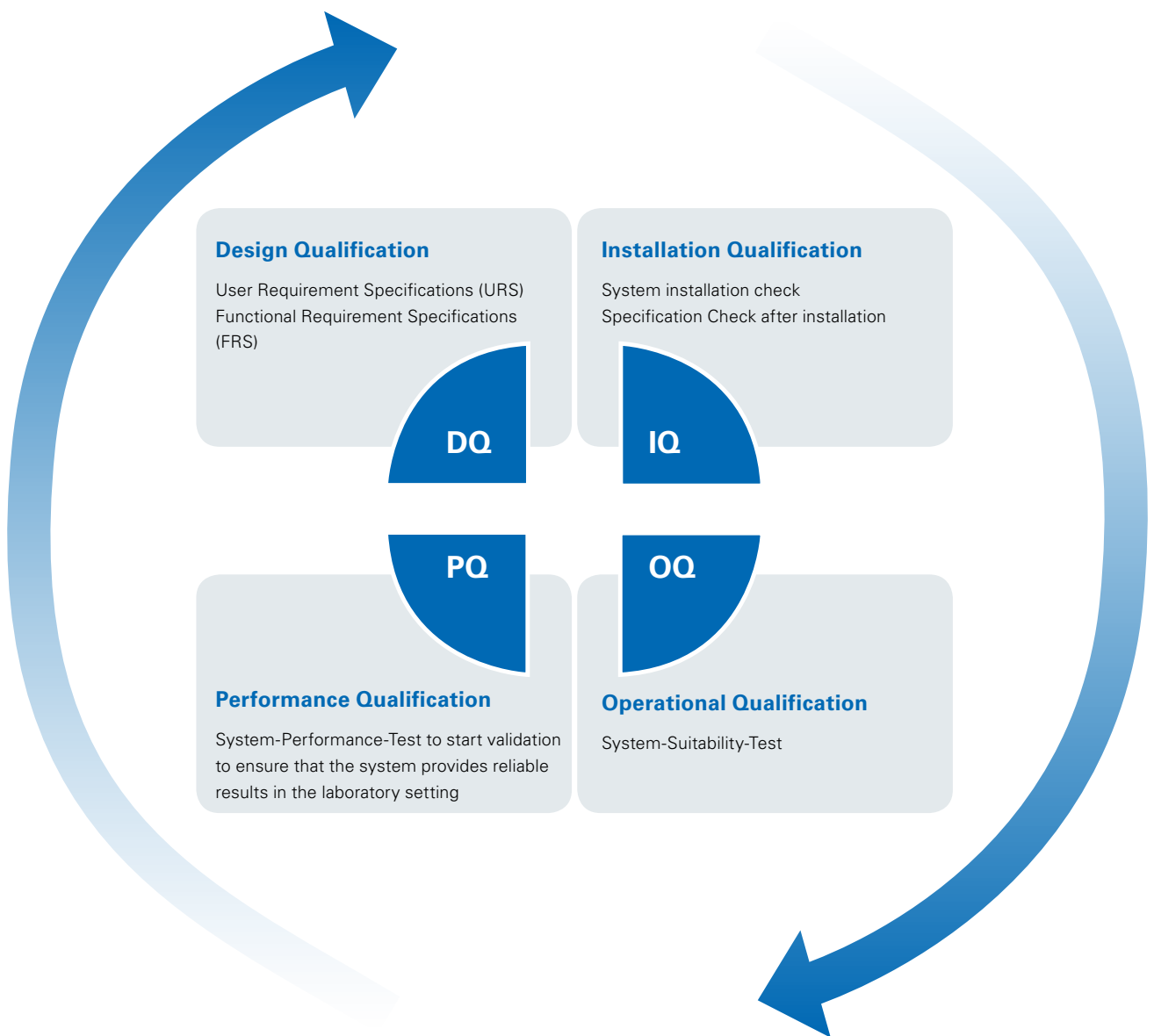
Over 20 years of experience in the manufacture of high quality consumables used in mass spectrometry, such as calibration standards and HCCA matrix, guarantees optimal system performance.



Continuous Process Control

Installation qualification (IQ) and operation qualification (OQ) for new technologies in the Quality Control laboratory must be efficiently performed and documented.

Dedicated documents for the MALDI Biotyper IQ and OQ-PV are provided which fully supports 21 CFR part 11 compliance.



MALDI Biotyper System Overview

Microbial Identification Applications

- Gram +/- Bacteria, Yeast, Filamentous Fungi, Mycobacteria

System Components

- Instrument: microflex LT/SH mass spectrometer (manufactured under QSR regulations)
- Computer: MALDI Biotyper datasystem running under Windows® 7
- MALDI Biotyper® System Software
- MALDI Biotyper Reference Library

Consumables and Ancillaries

- Matrix HCCA
- Bacterial Test Standard (BTS)
- Reusable polished stainless steel MALDI target plates: 48 & 96 position with barcode
- Disposable 48 position MALDI Biotarget with individual barcode
- MALDI Biotyper Pilot workstation for guided sample transfer
- MALDI Biotyper Galaxy – automated MALDI target preparation system

System Implementation and Qualification

- IQ and OQ-PV documentation
- 21 CFR part 11 support (option)

Dimensions & Operating Parameters

LxWxH:	510 x 680 x 1093mm [20.1" x 26.8" x 43"]
Weight:	84kg (185 lb) net weight
Noise:	<50 dB
Temp Range:	10-30 °C (50-86 °F)
Operating Humidity:	15-85% non-condensing @ 30 °C

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Not for use in diagnostic procedures.

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