GP

Pharmaceutical Microbiology

MALDI Biotyper®

Changing Microbiology

Not for use in clinical diagnostic procedures.

Innovation with Integrity

MALDI-TOF

In Microbiology, Speed and Accuracy Matter

The MALDI Biotyper® System

Identification of microorganisms by their molecular fingerprint

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

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

Features and benefits

- Accuracy comparable to Nucleic Acid Sequencing
- Faster than traditional methods and PCR
- Cost-effective
- Robust and easy to use
- A true benchtop system
- Intuitive software, supporting 21 CFR part 11 compliance
- Easy to implement
- Optional workflow improvement tools
- IQ - OQ/PV Support

Fast identification of microbial contaminants and biotechnological strains during quality and hygiene controls

With the MALDI Biotyper implemented in your workflow, specific identification of microorganisms is achieved within minutes. This can directly translate to significant cost savings by accelerated control of raw materials as well as quicker in-process QC, process environment and end-product testing.

Integrating the MALDI Biotyper into routine testing workflows results as well in a significant consolidation of resources, as it eliminates the burden of multiple steps and workstations required for DNA sequencing.

Additionally, the MALDI Biotyper can be conveniently used as a fast and easy pre-screening method, prior to extensive strain characterization by the Bruker IR Biotyper®, by sequencing or another DNA fingerprinting technique.

A Simple Procedure for a Sophisticated Platform

Bacteria, yeast or mold: one workflow for all

The MALDI Biotyper system workflow has been designed to be efficient and easy. No previous experience with mass spectrometry is required. As shown, the fully traceable workflow has been streamlined and requires only a few simple steps to generate high quality microorganism identifications.

No need to know the type of microorganism prior to analysis; bacteria, yeast or mold samples are all analyzed together, following the same workflow.

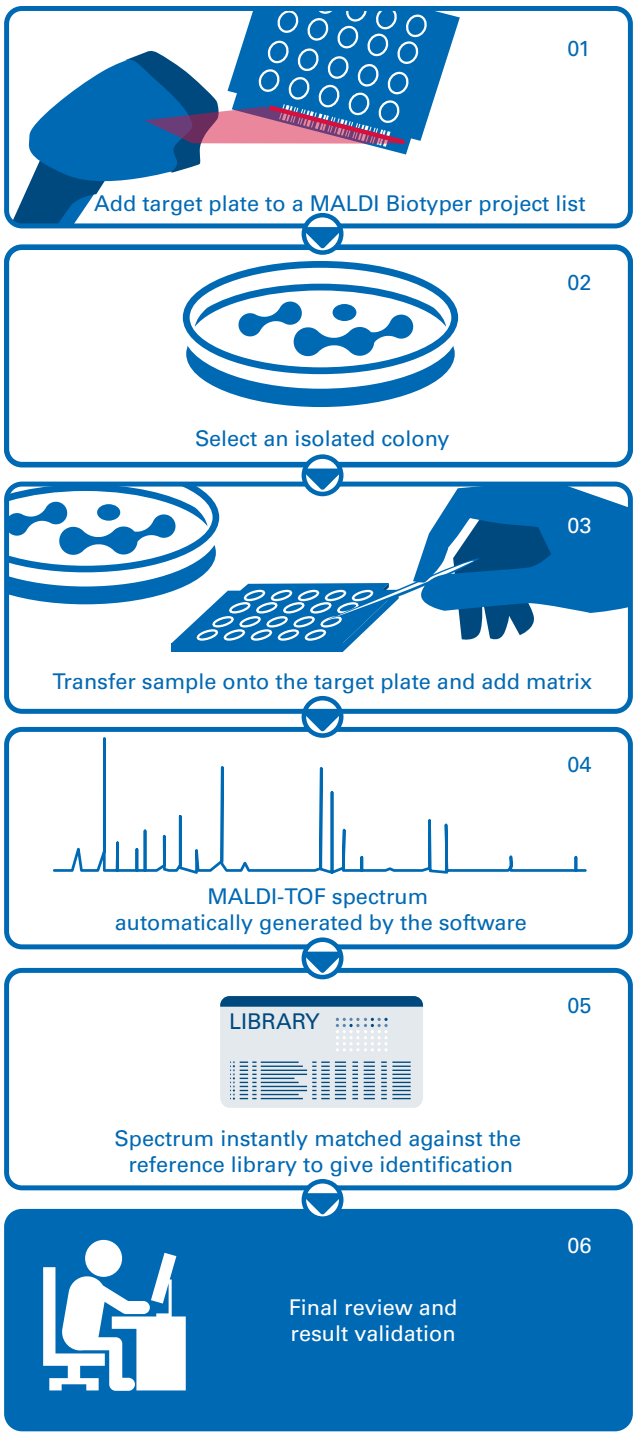
Typically, no more than an isolated single colony from a culture is required.

Our dedicated microbiology software automates the process of acquiring the mass spectrum and performing the match against the extensive reference library. The results, presented using a 'traffic light' color scheme, are effortless to interpret.

The hands-on time per isolate is only 20 seconds for 95% of the microorganisms. The short time-to-result allows preparation and analysis of a full 96-spot target plate within 30 minutes. The MALDI Biotyper simplifies microbial identification, and facilitates and harmonizes the workflow with only one system.

Sample preparation hands-on time:
- 1 isolate ~20 seconds
- 95 isolates < 20 min

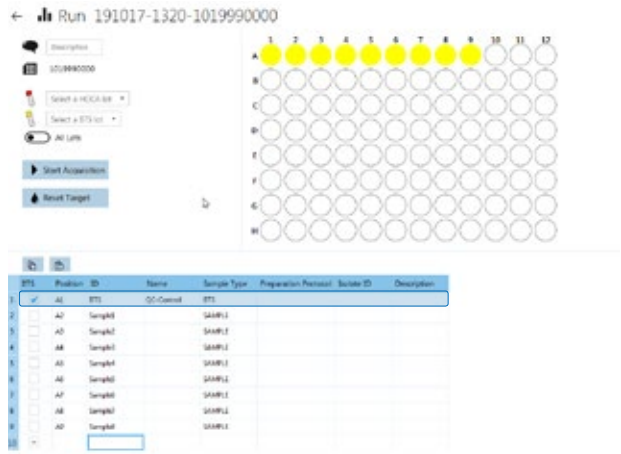
MALDI Biotyper sirius:
Time-to-Result including sample preparation:
- 95 isolates + 1 QC sample: ~30 min



Easy-to-Use Software

In just a few steps, the simple-to-use software guides users through the set-up of samples for analysis.

Automatic Calibration and Quality Control Check



A system suitability test (SST) with a Bruker Bacterial Test Standard (BTS), performed prior to every identification run, guarantees system performance, reproducibility and the fulfillment of local compliance criteria. Only after successful completion of the SST the system starts to acquire and process the sample data.

After the acquisition of the spectral data has been completed, a report is generated. The result for each sample is clearly listed under 'Organism (best match)' accompanied by the resulting score and an appropriate 'traffic light' color scheme.

Clear Identification Results Display at Species Level

Sample ID	Target Pos.	Organism (best match)	log(score) (Conf.)
BTS	A1	*Escherichia coli*	2,68
Sample1	A2	*Micrococcus luteus*	2,36
Sample2	A3	*Staphylococcus epidermidis*	2,21
Sample3	A4	*Ralstonia pickettii*	2,37
Sample4	A5	*Bacillus pseudofirmus*	2,14
Sample5	A6	*Corynebacterium diphtheriae*	2,44
Sample6	A7	*Micrococcus luteus*	2,28
Sample7	A8	*Streptococcus sanguinis*	2,18
Sample8	A9	*Streptococcus salivarius*	2,47

Supporting 21 CFR part 11 compliance

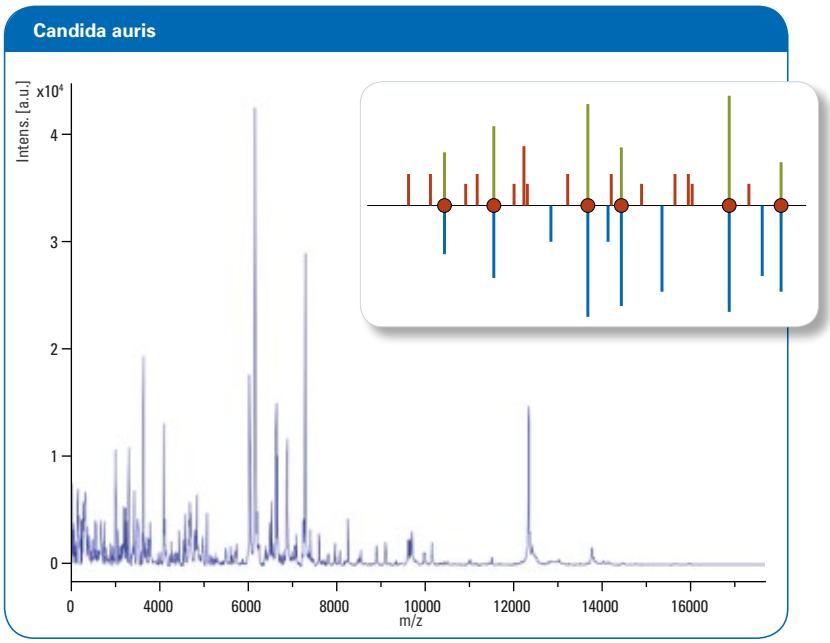
MBT Compass HT software has been designed to support compliance with the rules of regulated environments, addressing the following aspects:

- Authentication and user management
- User Rights management
- Data integrity and archiving
- Audit Trail including reason entry and timestamps
- Digital signatures

Open microbiology concept

The MALDI Biotyper allows for smooth integration with existing laboratory informatics. MALDI Biotyper results are converted into a format that can easily be exported to the LIMS.

More Than a Comprehensive Library



The Main Spectra Concept

Reference library entries in the MALDI Biotyper system are stored as Main Spectra (MSP). These MSPs are based on multiple measurements of a single defined strain to ensure that the true biological variability of an organism has been captured.

Unknowns are then compared to the MSP library using a superior pattern-matching approach. This includes peak positions, intensities and frequencies, ensuring the highest possible levels of accuracy and reproducibility across the complete range of microorganisms.

A continuously updated reference library

Bruker is fully committed to the continuous development of the reference library. An active program of reference spectra generation culminates in regular library updates for MALDI Biotyper users. These updates are focused on recommendations from our collaboration partners from the industrial, veterinary and clinical field including certified strain collections.

Taxonomy becomes easy

The metadata of the MALDI Biotyper Reference Library facilitate the access to taxonomical information, such as synonyms and taxonomical modifications.

Reduce the need for mycology expertise

The MALDI Biotyper is perceived as the most promising alternative for molds identification. A dedicated MBT Filamentous Fungi Library is available to facilitate the identification of this group of microorganisms.

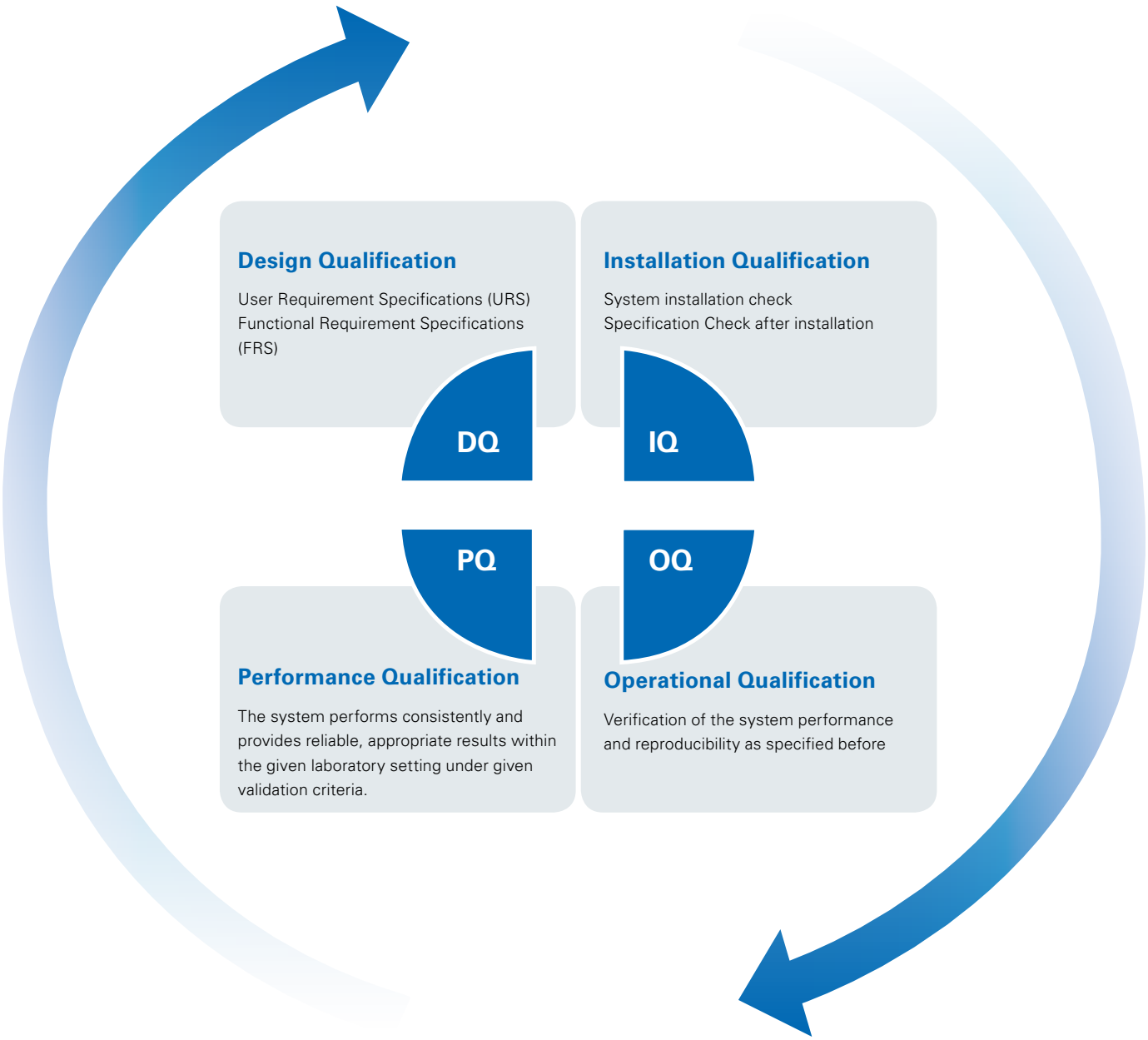
Create your own libraries

Laboratories that need to create their own libraries can make use of software tools to easily compile customized microorganism entries and to share and export libraries.

Qualification of the MALDI Biotyper

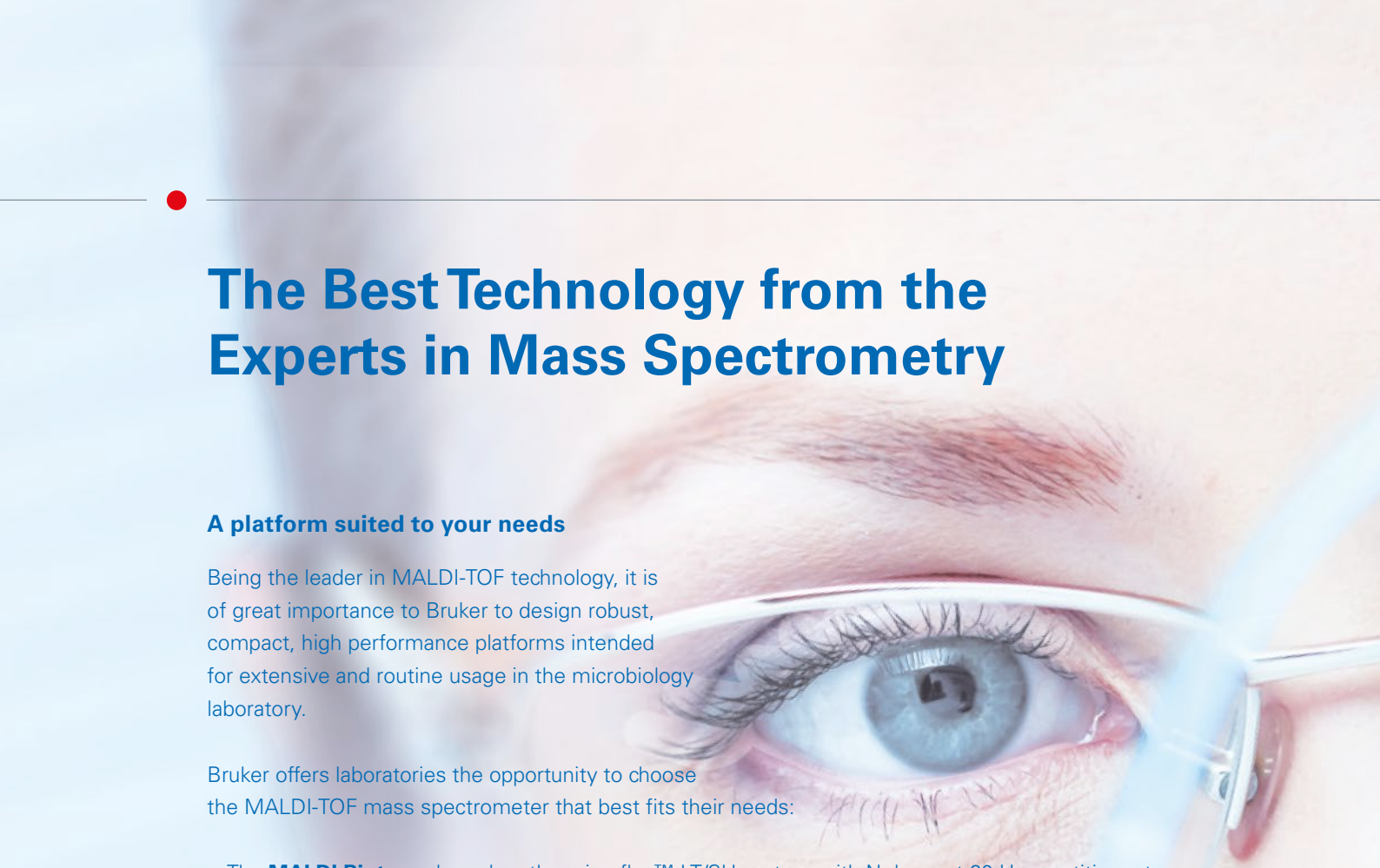
Installation qualification (IQ) and operational qualification (OQ) for new technologies in the Quality Control laboratory must be efficiently performed and documented.

Dedicated IQ and OQ/PV documents for the MALDI Biotyper are provided, supporting 21 CFR part 11 compliance.



MALDI Biotyper® sirius
BRUKER

The Best Technology from the Experts in Mass Spectrometry



A platform suited to your needs

Being 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.

Bruker offers laboratories the opportunity to choose the MALDI-TOF mass spectrometer that best fits their needs:

- The **MALDI Biotyper** based on the microflex™ LT/SH system with N_2 laser at 60 Hz repetition rate
- The **MALDI Biotyper smart** based on the microflex™ LT/SH smart system with Bruker's proprietary smartbeam™ solid state laser technology at 200 Hz repetition rate, the first MALDI-TOF system for microbial identification using a lifetime* laser. Measurement cycle time is reduced due to the high laser speed and fast target exchange time.
- The new **MALDI Biotyper sirius** with Bruker's 200 Hz smartbeam™ laser and latest developments in electronics allowing for positive and negative ion detection, and even faster target exchange times for accelerated time-to-result.

Resolution meets sensitivity

Resolution and sensitivity are tailored to the needs of microbiologists. Due to Bruker's patented PAN™ resolution the MALDI Biotyper achieves optimal results from a compact benchtop instrument.

Highly reproducible results

The quick and simple Bacterial Test Standard quality check performed before each run ensures the highest standard of run-to-run reproducibility.

Accelerated data acquisition

With Smart Spectra Acquisition™, data generation is accelerated by minimizing the number of laser shots per sample needed to acquire a spectrum. An additional benefit of this function is the optimal utilization of the laser lifetime.

Continuous operation

The integrated ion source cleaning permits continuous high performance with minimized maintenance requirements. Cleaning the source using the separate IR-laser is performed easily under push-button operator control.

Compact Benchtop Systems – No Performance Compromise

True benchtop solutions

Low-noise operating systems with low weight and requiring less than 1 m / 4 feet of counter space offer flexibility in meeting laboratory needs for compact system solutions. All above mentioned systems need only a 220 V / 110 V electrical supply which results in very minimal heat output.

	MALDI Biotyper System (microflex™ LT/SH)	MALDI Biotyper smart System (microflex™ LT/SH smart)	MALDI Biotyper sirius System
Laser	Nitrogen Laser • 60 Hz repetition rate • ~300 samples/hr • 60 million laser shots	Bruker's proprietary lifetime* smartbeam laser • 200 Hz repetition rate • ~500 samples/hr • 500 million laser shots	Bruker's proprietary lifetime* smartbeam laser • 200 Hz repetition rate • ~600 samples/hr • 500 million laser shots
Polarity	Positive ion mode only		Positive and negative ion mode
Mass range	0-500.000 Da; with MALDI Biotyper applications focused to: • 0-1000 Da (resistance detection) • 2.000-20.000 Da (microorganism identification)		
Vacuum system	Classical vacuum system • fast target exchange	High capacity turbomolecular pump • three times greater pumping capacity • even faster target exchange • less down-time after maintenance	
L x W x H	530 x 680 x 1093 mm / 20.9" x 26.8" x 43"		500 x 710 x 1070 mm / 19.7" x 28.0" x 42.2"
Weight	84 kg / 185 lb	99 kg / 218 lb	75 kg / 165.4 lb
Common features	Perpetual Ion Source™ with IR-laser self-cleaning functionality Whispermode™ Oil-free membrane pre-vacuum pump and turbo pump <60 dB under normal operating conditions Patented PAN™ technology for high mass resolution over a wide mass range Voltage: 220 V / 110 V		
Additional features			LED strip to remotely observe system status

** Lifetime means: 500 million laser shots or seven years (whichever occurs first)*

MBT Consumables for Basic Identification

Bacterial Test Standard (BTS)

The BTS is an *E.coli* extract spiked with two high molecular weight proteins and has been developed for the quality control process of the MALDI Biotyper System. Its specific composition covers the entire mass range of proteins used for precise identification of microorganisms.

Content: One box consisting of 5 tubes providing 50 µL per tube / Part No 8255343

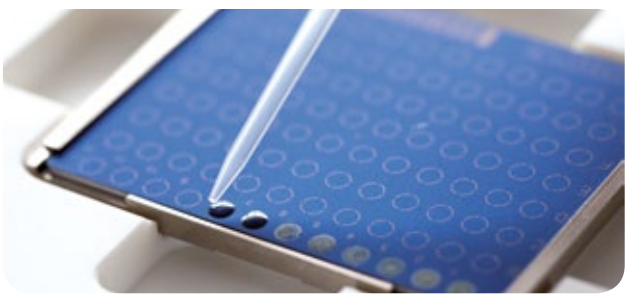
HCCA Matrix, portioned

The instant HCCA matrix enables easy and convenient preparation of HCCA matrix solutions. The matrix is soluble in standard organic solvent, easy to handle, and enables highly sensitive measurements.

Content: One box consisting of 10 tubes providing 250 µL per tube / Part No 8255344

Disposable MBT Biotargets

The ready-to-use disposable MBT Biotargets offer 96 positions and a unique barcode for full traceability in paperless workflows. Disposable MBT Biotargets render the same level of performance as reusable MALDI target plates without the need for time-consuming cleaning.



MBT Biotarget 96

Set of 20 individually barcoded disposable 96 position MALDI target plates / Part No 1840375

MSP adapter for MBT Biotarget 96

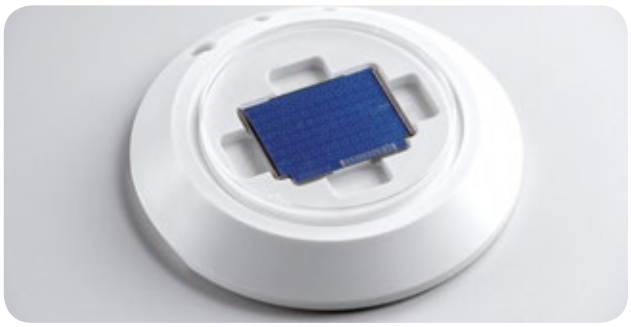
Adapter required to use MBT Biotargets with benchtop MALDI Biotyper systems / Part No 8267615

MBT Workflow Accessories

MBT Shuttle Target Holder

The MBT Shuttle target holder is used to securely hold MBT Biotargets during the sample preparation process. The secure grip, non-slip rubber feet and ergonomic form make sample preparation easier.

One target holder / Part No 1847032



MBT Pilot

The MBT Pilot facilitates correct sample positioning through patented microprojection technology by indicating the next free MALDI target plate position.

Part No 1822041

MBT Galaxy

The MBT Galaxy, for automated application of HCCA matrix and formic acid, frees laboratory personnel from cumbersome pipetting while ensuring the highest preparation quality under controlled conditions and complete traceability in a paperless workflow.

Part No 1821269

MALDI Biotyper System Overview

Microbial Identification Applications

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

System Components

- Based on one of the following instruments (manufactured under QSR regulations):
  - microflex LT/SH mass spectrometer with N_2 laser at 60 Hz
  - microflex LT/SH "smart" mass spectrometer with 200 Hz smartbeam™ solid-state laser
  - MALDI Biotyper sirius with 200 Hz smartbeam™ laser and latest developments in electronics allowing for positive and negative ion detection
- MALDI Biotyper data system running under Windows® 10 operating system
- MBT Compass HT Software including MBT HT Compliance Assistant Module
- MBT Compass Library

Optional Libraries

- MBT Mycobacteria Suite
- MBT Filamentous Fungi Suite

Consumables and Ancillaries

- Matrix HCCA, portioned
- Bacterial Test Standard (BTS)
- Disposable MBT Biotarget 96 with individual barcode and 96 positions

Accessories for workflow optimization

- MBT Shuttle ergonomic target holder
- MBT Pilot for optically guided sample transfer
- MBT Galaxy for automated application of HCCA matrix and formic acid

System Implementation and Qualification

- IQ and OQ/PV documentation
- MBT HT Compliance Assistant Module to support 21 CFR part 11 compliance

Dimensions & Operating Parameters

	MALDI Biotyper System (microflex™ LT/SH)	MALDI Biotyper smart System (microflex™ LT/SH smart)	MALDI Biotyper sirius System
L x W x H	530 x 680 x 1093 mm (20.9" x 26.8" x 43")		500 x 710 x 1070 mm (19.7" x 28.0" x 42.2")
Weight	84 kg (185 lb) net weight	99 kg (218 lb) net weight	75 kg (165.4 lb) net weight
Noise	<60 dB		
Temperature Range	16-33°C (61-91°F)		16-30°C (61-86°F)
Operating Humidity	20-75% non-condensing @ 33°C (91°F)		

MALDI Biotyper®, MBT Galaxy®, microflex® and MBT Pilot® are registered trademarks of Bruker Daltonik GmbH in the European Union and the USA.

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