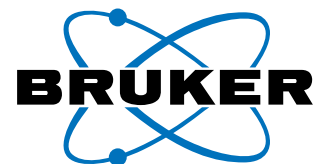


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Clinical Microbiology

MALDI Biotyper

- Fast & Accurate Identification of Microorganisms

Innovation with Integrity

MALDI-TOF



In Microbiology, Every Minute Counts



A Powerful Technology for Better Results

To help answer key challenges in Clinical Microbiology, Bruker has utilized its many years of experience to create the truly ground breaking **MALDI Biotyper** system. With its combination of performance and utility, the **MALDI Biotyper** has changed the way microbial identification is done in laboratories around the world.

Identifying Microorganisms by Their Molecular Fingerprint

The **MALDI Biotyper** identifies microorganisms using MALDI-TOF (Matrix Assisted Laser Desorption Ionization-Time of Flight) Mass Spectrometry to measure a unique molecular fingerprint of an organism. Specifically, the **MALDI Biotyper** measures highly abundant proteins that are found in all microorganisms.

The characteristic patterns of these highly abundant proteins are used to reliably and accurately identify a particular microorganism by matching the respective pattern with an extensive open database to determine the identity of the microorganism down to the species level.

The MALDI Biotyper System:

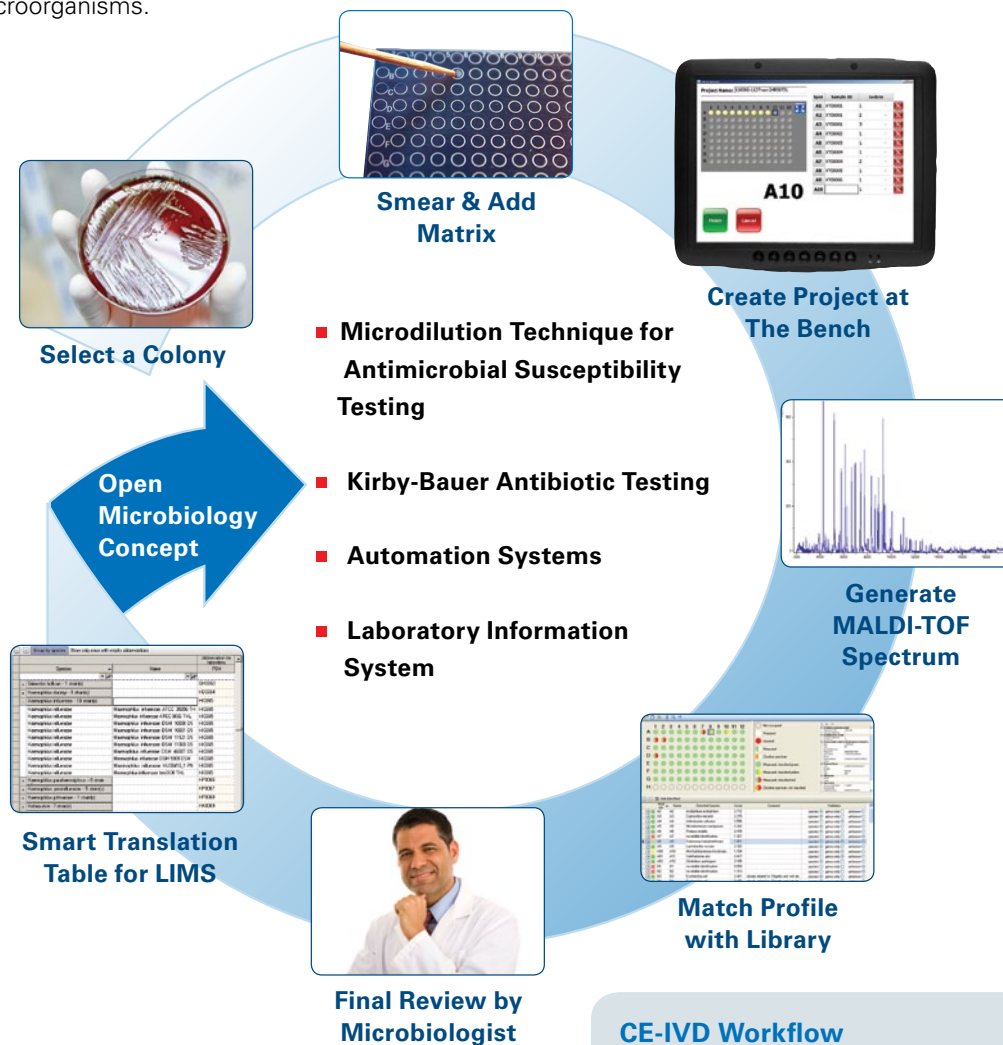
- **Highly Accurate**
- **Applicable to a Wide Range of Microorganisms**
- **Much Faster than Traditional Methods**
- **Cost Effective**
- **Robust and Easy to Use**

A Simple Procedure for A Sophisticated Platform

Innovative Design Leads to Enhanced Performance and Productivity

The **MALDI Biotyper** workflow has been designed to be as robust and easy to perform as possible. No previous experience with Mass Spectrometry is required. The workflow has been streamlined and requires only a few simple steps to generate high quality species identifications, our dedicated microbiology software automates the process of acquiring the mass spectrum and performing the library matching providing a report showing the closest matches to the extensive library of microorganisms.

Typically no more than a single colony from a plate or a small aliquot from a broth is required, the entire procedure requires only a few minutes to complete. Additional workflows are also available for the processing of positive blood cultures as well as other traditionally difficult to analyze groups of organisms including fungi and mycobacterium.



CE-IVD Workflow

A fully validated workflow according to the European Union IVD Directive 98/79/EC is also available and utilizes most of the same strains contained within the combined database.



Easy System Setup

A Workflow that Empowers Microbiology Laboratories

Choosing the Right Sample Platform

Bruker offers a selection of bar-coded, disposable, or reusable 24, 48, or 96 position Sample Targets to best suit your individual requirements. All sample positions can be randomly accessed by the system, in any combination, for maximum assay flexibility.



Have an Urgent Sample?

No problem. Just pause the running project, exchange the sample target, and get results in a few minutes. The unique system design facilitates on-the-fly changes to handle urgent samples.

Matches Your Sample Project

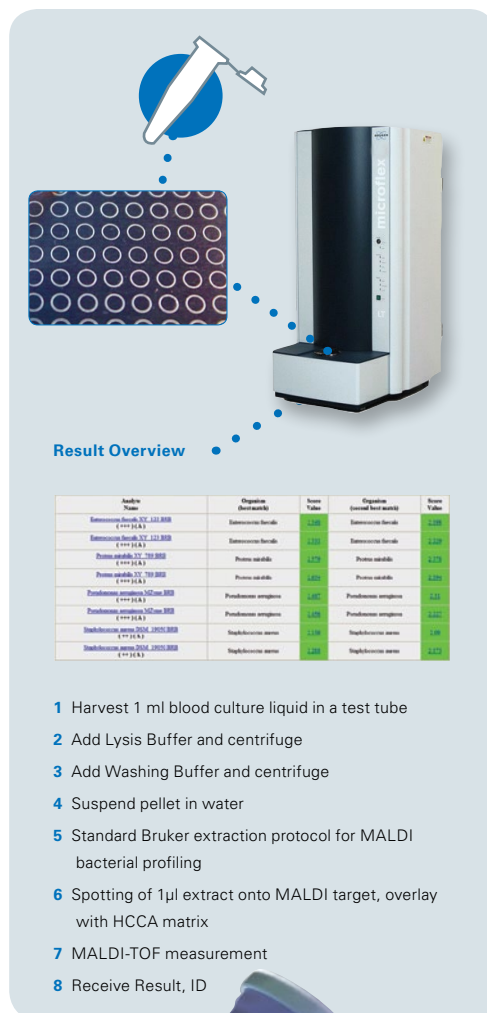
With on board barcode reading, the **MALDI Biotyper** matches your sample with its corresponding target, ensuring you never analyse the wrong samples.



**The efficient
pathway
for fast,
reliable,
unambiguous
species
identification
from positive
blood culture
bottles**

Using the MALDI Sepsityper Kit in combination with the **MALDI Biotyper**, can result in a 70-90% identification rate in positive blood culture samples,

This high confidence result is available much earlier than with conventional technology. Use of the Sepsityper Kit can typically save at least one day in the time-to-result for the crucial identification step in analyzing blood borne infections.



Easy to Use Software That's Dedicated to Microbiology...

MALDI Biotyper Realtime Classification Wizard

Analyte Placement

Please specify the target positions for your analytes by drawing a rectangle, clicking on row/column names or directly on the appropriate spots. Analytes are inserted using the Insert key or with Add Analytes from the context menu. Available target spots are shown in hollow. Spots containing analytes of the current project are white (not yet measured) or green (already measured). Please fill in the ID column if it is empty.

Position	Chip	Creation Date	Name [opt]	ID	Description [optional]
A1	0	22/04/2011 16:39	A1	Bacterial Test Standard	Calibration
A2	0	22/04/2011 16:39	A2	8213257	Blood Culture
A3	0	22/04/2011 16:39	A3	8213258	Blood Culture
A4	0	22/04/2011 16:39	A4	8213259	Blood Culture
A5	0	22/04/2011 16:39	A5	8213260	Blood Culture
A6	0	22/04/2011 16:39	A6	8213261	Blood Culture
A7	0	22/04/2011 16:39	A7	8213262	Blood Culture
A8	0	22/04/2011 16:39	A8	8213263	Blood Culture
A9	0	22/04/2011 16:39	A9	8213264	Blood Culture
A10	0	22/04/2011 16:39	A10	8213265	Blood Culture
A11	0	22/04/2011 16:39	A11	8213266	Blood Culture
A12	0	22/04/2011 16:39	A12	8213267	Blood Culture

Validation Position: A1:0

Cancel << Back Next >> Finish Help

The Wizard

A simple to use Real Time Classification wizard guides you through setting up a sample for analysis in just a few easy steps. Import sample information from LIMS or Excel or even enter it manually using a barcode reader.

Automatic Calibration

Using the Bruker Bacterial Test Standard, you can select any position on your target, and the **MALDI Biotyper** will automatically calibrate the system.

Validate Your Results

The **MALDI Biotyper** expert system supports both the identification and validation of results. Make better, more informed decisions with the help of "matching hints" and view relevant sample data or information from your LIMS.

MALDI Biotyper Realtime Classification Wizard

Validation

Not occupied
Prepared
Aborted
Measured
Zero line spectrum
Measured, classified green
Measured, classified yellow
Measured, classified red
Zero line spectrum, not classified

Position	Name	Detected Species	Score	Comment	Validation
A2	A2	Acidiphilium acidophilum	2.712		species: genus-only: unknown
A3	A3	Cupriavidus necator	2.215		species: genus-only: unknown
A4	A4	Arthrobacter sulfureus	2.596		species: genus-only: unknown
A5	A5	Microbacterium maritimum	2.342		species: genus-only: unknown
A6	A6	Proteus mirabilis	2.415		species: genus-only: unknown
A7	A7	no reliable identification	1.261		species: genus-only: unknown
A8	A8	Halomonas halodenitrificans	1.861		species: genus-only: unknown
A9	A9	Lactobacillus rossiae	2.392		species: genus-only: unknown
A10	A10	Methylobacterium rhodesianum	1.784		species: genus-only: unknown
A11	A11	Xanthomonas pisi	2.417		species: genus-only: unknown
A12	A12	Clostridium perfringens	2.105		species: genus-only: unknown
B1	B1	no reliable identification	0.859		species: genus-only: unknown
B2	B2	no reliable identification	1.313		species: genus-only: unknown
B3	B3	Escherichia coli	2.441	closely related to Shigella and not de...	species: genus-only: unknown
B4	B4	Escherichia coli	2.479	closely related to Shigella and not de...	species: genus-only: unknown
B5	B5	Escherichia coli	2.470	closely related to Shigella and not de...	species: genus-only: unknown

Connecting to flexControl successful | Server: localhost Port: 8080

...With A Powerful & Flexible Data System Architecture

MBT Client Server Architecture



Direct Connection to LIMS

All LIMS integration is handled by the MBT Server. CSV and ASTM are supported as exchange formats and have established connections to many LIMS providers.

Easy Integration with Laboratory Informatics

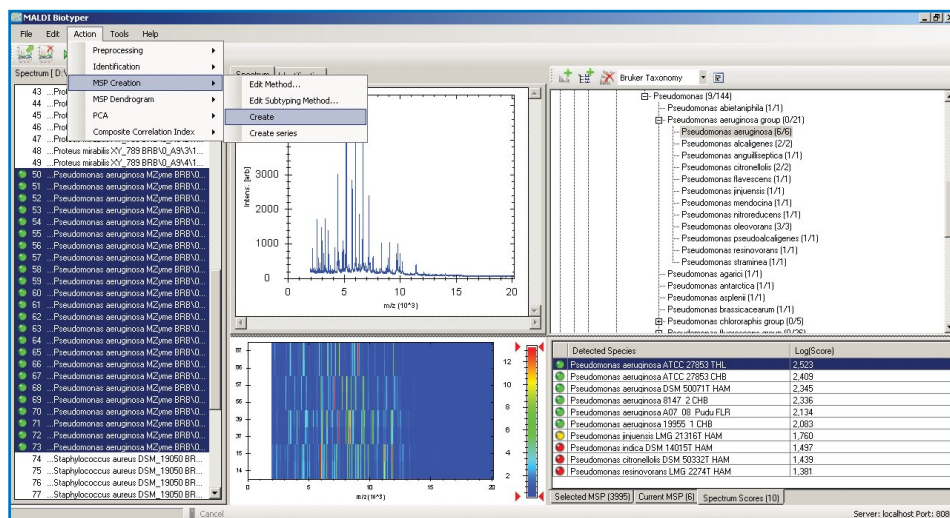
The central **MALDI Biotyper** Server manages all requests for information and stores all data. The Server also manage requests and processes data from several instruments or remote clients. Installation of remote clients on existing computers in the laboratory is supported. This enables system set up and operation directly from the lab bench, or allows for the validation of an already completed run.

Translate Your Results

Using the customizable smart translation tool, the thousands of species covered by the **MALDI Biotyper** are automatically converted into a format that a LIS, an expert system, or an AST System can understand.

Group by species Show only rows with empty abbreviations		
Species	Name	Abbreviation for laboratory
		FSM
+ Grimontia hollisae - 1 strain(s)		GH0363
+ Haemophilus ducreyi - 1 strain(s)		HD0364
- Haemophilus influenzae - 10 strain(s)		HI0365
Haemophilus influenzae	Haemophilus influenzae ATCC 35056 TH	HI0365
Haemophilus influenzae	Haemophilus influenzae ATCC 9006 THL	HI0365
Haemophilus influenzae	Haemophilus influenzae DSM 10000 DS	HI0365
Haemophilus influenzae	Haemophilus influenzae DSM 10001 DS	HI0365
Haemophilus influenzae	Haemophilus influenzae DSM 11121 DS	HI0365
Haemophilus influenzae	Haemophilus influenzae DSM 11969 DS	HI0365
Haemophilus influenzae	Haemophilus influenzae DSM 4690T DS	HI0365
Haemophilus influenzae	Haemophilus influenzae DSM 9999 DSM	HI0365
Haemophilus influenzae	Haemophilus influenzae HU30410_1 PN	HI0365
Haemophilus influenzae	Haemophilus influenzae besS130 THL	HI0365
+ Haemophilus parahaemolyticus - 6 strain		HP0366
+ Haemophilus parainfluenzae - 5 strain(s)		HP0367
+ Haemophilus pittmaniae - 1 strain(s)		HP0368
+ Hafnia alvei - 7 strain(s)		HA0369
+ Haloraccula vallismortis - 1 strain(s)		HV036A

An Open Microbiology Platform and Database



An Open and Comprehensive Database

MALDI Biotyper integrates a ready to use reference library of microorganisms comprising thousands of individual strains of microorganisms. The library is constantly maintained and updated with contributions from many collaborating partners from countries around the world.

MSPs can be created and added to the database by users. This process is simple and highly automated within the software. MSP's can then be associated into their unique libraries with just a few additional mouse clicks.

The screenshot shows the MALDI Biotyper MSP Metadata Editor dialog box. It contains fields for Organism, Strain, Provided by, Determined by, Conserved, Extraction Method, Matrix, Growing Conditions, and Comment. The Organism field is set to *Pseudomonas aeruginosa* and the Strain field is set to ATCC 27853. The Extraction Method is set to EtOH-FA and the Matrix is set to HCCA. The Growing Conditions are set to 'according to http://www.jgcprochem-atcc'. The Comment field contains a matching hint: 'Is a member of the Pseudomonas aeruginosa group (aeruginosa / alcaligenes / anguilliseptica)'.

The Main Spectra Concept

Database entries in the MALDI Biotyper 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.

An unbiased sophisticated algorithm creates the MSP completely unsupervised by extracting information about peak position, intensity and frequency, while employing very effective de-noising and patented mass corrections to the peak data.

Unknowns are then compared to the MSP library using a superior pattern matching approach which is based on true statistical multi-variant analysis; and includes peak positions, intensities and frequencies ensuring the highest possible levels of accuracy and reproducibility across the complete range of microbes.

The screenshot shows the MALDI Biotyper Taxonomy Tree Editor dialog box. It displays a tree structure with 'Projects' and 'Filamentous_Fungi_Consortium' as the root. Below the tree, there are two tables: 'Unassigned MSPs (0)' and 'MSPs of Mycobacterium consortium library (227)'. The 'MSPs of Mycobacterium consortium library' table lists MSP names, creation dates, and peak list counts.

MSP Name	Creation ...	Peak List Count
Mycobacteri	10.06.20	21
Mycobacteri	10.06.20	14
Mycobacteri	10.06.20	20
Mycobacteri	10.06.20	24
Mycobacteri	10.06.20	6
Mycobacteri	10.06.20	21

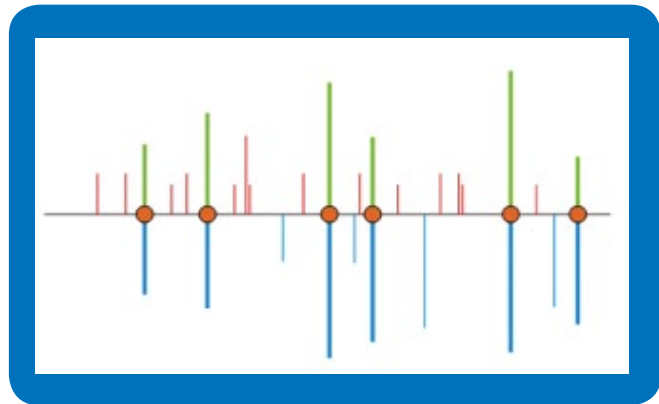
Continuous Database Expansion and Expert Support

Bruker is fully committed to the future development of the database. An active program of library generation culminates in regular database updates for **MALDI Biotyper** users. These updates are especially focused in areas of major clinical importance.

Rigorous and Sophisticated Data Analysis Assures Accuracy

Analyzing and Displaying Results

Sample data can be displayed against different reference strains. Sample data is displayed above the axis, while Reference data is displayed below in blue. Perfect matches between the sample data and the reference standard are indicated in green. Differences between the sample and reference are highlighted in red. Light blue indicates peaks found in the reference, but not the sample.



Result Overview

Scoring the Results

The resultant report for each sample shows the top two matches along with their respective matching score. The top ten matches, along with precise information about the closest matching strain, can also be displayed.

Analyte Name	Organism (best match)	Score Value	Organism (second best match)	Score Value
Enterococcus faecalis XY 123 BRB (+++)(A)	Enterococcus faecalis	2.348	Enterococcus faecalis	2.198
Enterococcus faecalis XY 123 BRB (+++)(A)	Enterococcus faecalis	2.331	Enterococcus faecalis	2.229
Proteus mirabilis XY 789 BRB (+++)(A)	Proteus mirabilis	2.579	Proteus mirabilis	2.378
Proteus mirabilis XY 789 BRB (+++)(A)	Proteus mirabilis	2.634	Proteus mirabilis	2.394
Pseudomonas aeruginosa MZyme BRB (+++)(A)	Pseudomonas aeruginosa	2.407	Pseudomonas aeruginosa	2.31

Pseudomonas aeruginosa (+++)	Rank (Quality)	Matched Pattern	Score Value	NCBI Identifier
Staphylococcus aureus (++)	1 (+++)	Pseudomonas aeruginosa ATCC 27853 THL	2.407	287
Staphylococcus aureus (++)	2 (+++)	Pseudomonas aeruginosa 8147_2 CHB	2.31	287
	3 (++)	Pseudomonas aeruginosa DSM 50071T HAM	2.27	287
	4 (++)	Pseudomonas aeruginosa ATCC 27853 CHB	2.219	287
	5 (++)	Pseudomonas aeruginosa 19955_1 CHB	2.183	287
	6 (++)	Pseudomonas aeruginosa A07_08_Pudu FLR	2.017	287
	7 (+)	Pseudomonas jinjuensis LMG 21316T HAM	1.751	198616
	8 (-)	Pseudomonas citronellolis DSM 50332T HAM	1.622	53408
	9 (-)	Pseudomonas indica DSM 14015T HAM	1.382	137658
	10 (-)	Pseudomonas resinovorans LMG 2274T HAM	1.172	53412

Symbols	Color
(+++)	green
(++)	green
(+)	yellow
(-)	red

A - C)

Meaning of Score Values

Range	Description	Symbols	Color
2.300 ... 3.000	highly probable species identification	(+++)	green
2.000 ... 2.299	secure genus identification, probable species identification	(++)	green
1.700 ... 1.999	probable genus identification	(+)	yellow
0.000 ... 1.699	not reliable identification	(-)	red

Meaning of Consistency Categories (A - C)

Category	Description
A	Species Consistency: The best match was classified as 'green' (see above). Further 'green' matches are of the same species as the first one. Further 'yellow' matches are at least of the same genus as the first one.
B	Genus Consistency: The best match was classified as 'green' or 'yellow' (see above). Further 'green' or 'yellow' matches have at least the same genus as the first one. The conditions of species consistency are not fulfilled.
C	No Consistency: Neither species nor genus consistency (Please check for synonyms of names or microbial mixture).

Grading the Results

In addition to the score, the sample match result is also given a Consistency Category. This data parameter gives a indication of the degree of consistency. The categories are rated as Species Consistent, Genus Consistent, or No Consistency.



The Best Technology from The Market Leader in MALDI-TOF

Bruker's FLEX™ Series of MALDI-TOF Instruments

The **MALDI Biotyper** is based on the well proven, industry leading FLEX Series of MALDI-TOF MS instruments. These systems are designed as robust, compact, high performance platforms intended for extensive and routine usage.

Many features of these outstanding systems have been incorporated into the **MALDI Biotyper** to enhance performance, simplify operation, and extend system lifetime and utility.

■ A True Bench Top System

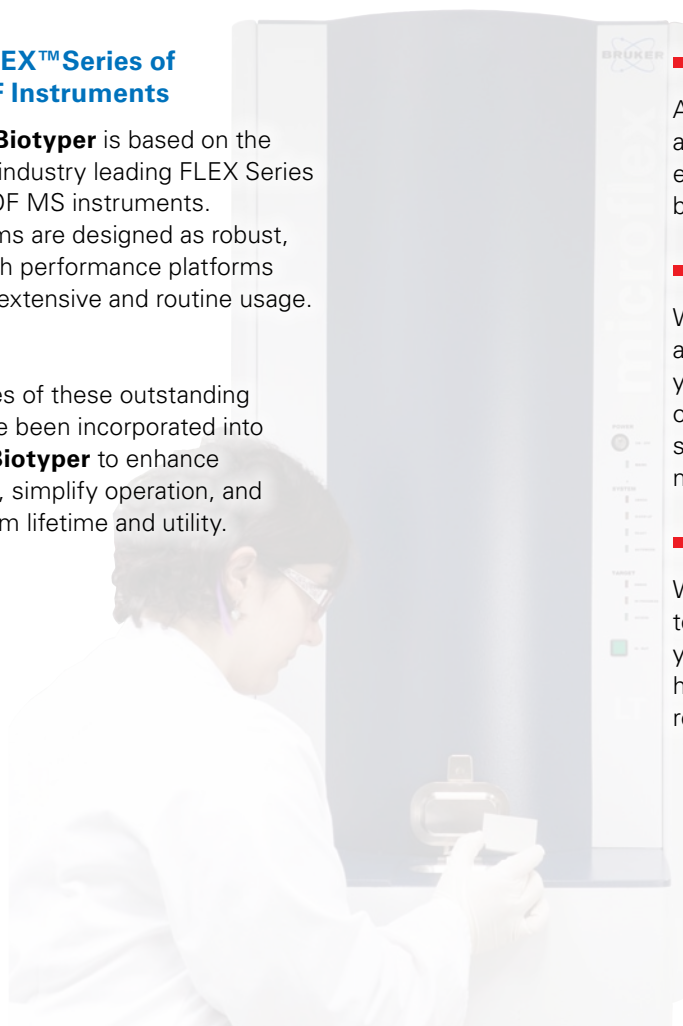
A smart compact design that packs a punch. Employs the same high end electronics and developments from its big brothers.

■ Silent and Pleasant Operation

With WhisperMode™ you really have a system that can sit on bench next to you almost silently. By eliminating noisy oil based vacuum pumps, the vacuum system is not only quiet, but virtually maintenance free.

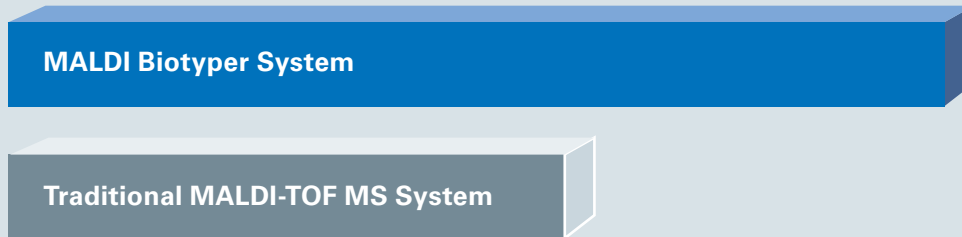
■ Greatly Enhanced Sensitivity

With the most sensitive detector technology available (FlashDetector™) you can benefit from having the same high performance technology as large research grade instruments.



Size Doesn't Equal Performance

Overall System and Technology Performance for Clinical Microbiology



Full Spectrum Resolution

Patented, intelligent pulsed Ion Extraction across a wide protein mass range. This unique technology enhances peak resolution and separation, and mitigates the need for unnecessarily long and bulky instrument flight tubes.

Maximize Laboratory Productivity and Return on Investment

Self Cleaning Source

The Perpetual™ Ion Source* is a unique, automated self cleaning instrument source. This technology enables routine maintenance of the system to insure peak performance in less than 15 minutes without the costly and time consuming need to break system vacuum.

*Patent pending



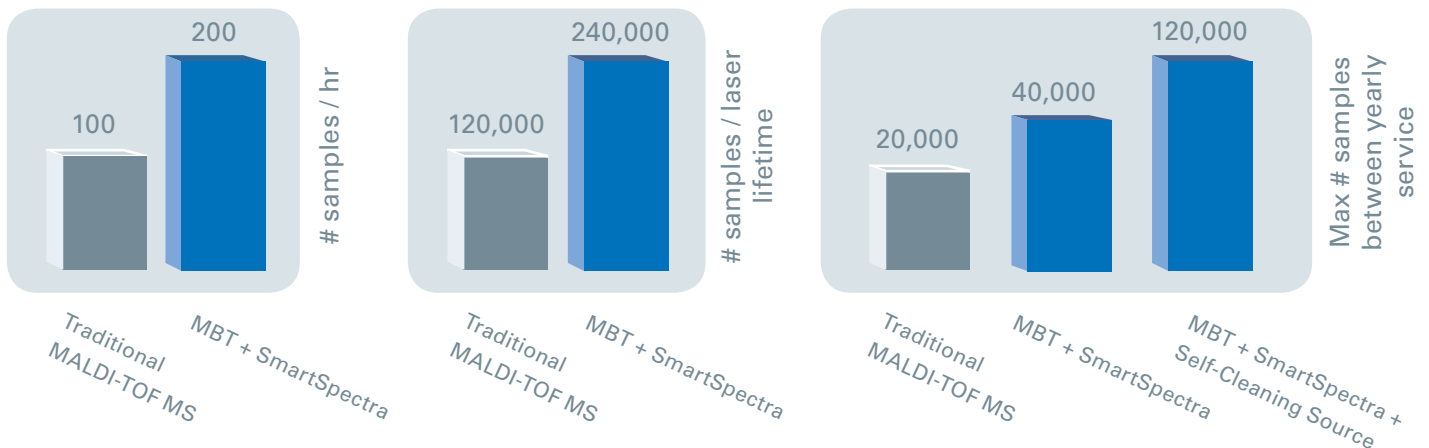
Before Cleaning



After Cleaning

SmartSpectra™ Acquisition

This capability accelerates data acquisition speed by minimizing the time and amount of sample needed to generate a signal. Typically, 96 samples can be fully analyzed in well under 30 minutes.



Technical Specifications

Dimensions & Operating Parameters

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

Instrument: Microflex LT

- Nitrogen Laser with 60Hz repetition rate
- Full Spectrum Resolution (FSR) with broadband focusing mode (PAN™)
- Smart Spectra Acquisition™
- Perpetual Ion Source™ with IR-laser self-cleaning functionality
- FlashDetector™
- Whispermode™
- Oil-free membrane pre-vacuum pump and turbo pump
- Manufactured under all cGMP and QSR regulations

Microbial Identification Applications:

- Gram +/- Bacteria, Yeast, Fungi, Filamentous Fungi, Mycobacteria, Direct from Blood Culture

Computer, Software & Database:

- Windows XP operating system with Quad-Core CPU 2.66 GHz, Laser printer and Remote Service Capability via 128-bit SSL
- **MALDI Biotyper** Database
- **MALDI Biotyper** Client Server

Optional System Upgrades and Accessories:

- IVD **MALDI Biotyper** Software according to the European Union IVD Directive 98/79/EC
- Sepsityper Kit for processing samples directly from Blood Cultures

Sample Targets:

- Reusable Polished Stainless Steel Targets: 48 & 96 position with and without barcode
- Disposable 48 position Biotargets with individual barcode
- 24 and 96 position BigAnchorChip™ Targets



Frank Laukien, President & CEO
Bruker Corporation

"Bruker is a pioneer and leader in providing mass spectrometry systems for the clinical laboratory. Bruker optimizes and enhances its systems to bring the analytical power and utility of sophisticated, high performance instruments to bear on improving the capabilities, time to result, and data quality in clinical laboratories."

Bruker systems are not just leading technology, they can be the pathway to delivering the answers needed to manage and treat serious health issues around the world."

For research use only. Not for use in diagnostic procedures.

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