MASS Medical SPEC

Mass spectrometer (MALDI-TOF), LEXI-MS®

manufactured by ASCEND Diagnostics Ltd., United Kingdom

MALDI-TOF mass spectrometer LEXI-MS® manufactured by Ascend Diagnostics Ltd. with complete accessories and software was designed to perform fast identification of pathogenic microorganisms from samples as clinical isolates and positive blood-cultures are.

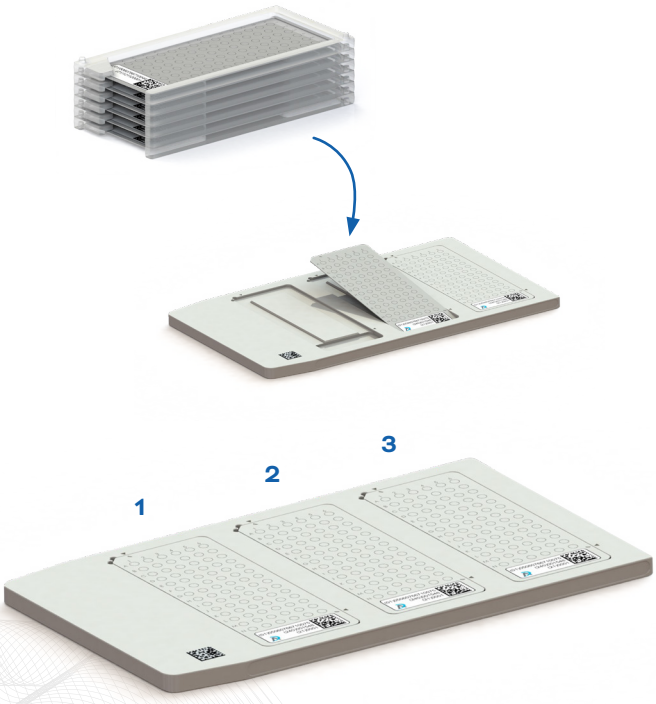
SYSTEM'S SPECIFICATION

LEXI-MS® MALDI-TOF is the system for fast automated identification of bacteria, yeast, fungi and mycobacteria. It is based on a principle of MALDI-TOF (Matrix Assisted Laser Desorption/Ionization – Time of Flight). It quickly detects pathogenic microorganisms directly from bacterial cultures on microbiological culture media or from positive bloodculture vial. It is used for early diagnosis in conjunction with other clinical and diagnostic procedures. The instrument is designed for laboratory use by fully trained professionals in a laboratory environment and in accordance with good laboratory practice.

This mass spectrometer with accessories is the smallest available system worldwide. It can be installed on a standard laboratory bench with a total load capacity of up to 100 kg, installation, commissioning and staff training takes 2 – 3 working days in total.

INSTRUMENT LEXI-MS®

LEXI PLATE



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TECHNICAL DATA

Height: 82,2 cm Depth: 67,8 cm Width: 48,8 cm Weight: 84 kg

TECHNICAL SPECIFICATION- LEXI-MS® SYTEM:

Ion source

New patented „Dynamic Focusing“ ion optics technology that is optimized to provide improved resolution over an extended m/z range (corresponding to the microbial mass range (2,000 m/z to 18,000 m/z)). Technology with the performance required for microbial identification in the smallest benchtop instrument on the market.

The source uses the latest discrete dynode ETP detector - when used in conjunction with „Dynamic focusing“ ion optics, which increases the ion momentum with high m/z, this means that this instrument does not need to be „tuned“ for detector gain to maintain sensitivity.

This new technology eliminates any need for service visits due to periodic cleaning outside of the recommended preventive maintenance frequency. MALDI ion source cleaning is performed automatically by GreenClean without the need for physical operator intervention or service support.

Dual output laser 355 and 532 nm

Nd:YAG laser with diode pumping (DPSS)
Wavelenght: 355 and 532 nm (UV)

The ability of the laser to emit the second 532 nm wavelength (green light) used for the patented automatic source cleaning function.

Puls energy:	> 42 µJ @ 355 nm
	> 10 µJ @ 532 nm
Repetition rate (Hz):	Single shot to 1000 Hz
Puls width FWHM:	> 1,5 ns @ 355 nm
Polarization ratio:	> 100:1, vertical @ 355 nm
Power stability over 6 hours:	< ±5 @ 355 nm
Puls-To-Puls RMS:	< 2% @ 1 kHz, 355 nm
Beam diameter:	300 ± 100 @ 355 nm
Static alignment:	Output height 23,5 ± 1 mm Vertical pointing < ±5 mrad Horizontal pointing < ±10 mrad
Spatial mode:	TEM00 @ 355 nm
Sync Module Output Voltage:	positive, > 1,5 ... 3,5 V at 50 Ohm load
Sync Module Operating Voltage (V):	12 DC over SMB socket
Power consumption Mean / Max:	40/80 W
Communication interfaces:	RS232, ESB, TTL
Warm-up Time:	< 5 min
Dimension Laser Head:	184 x 54 x 39 cm including sync module
Weight of Laser Head:	0,7 kg
Laser Class:	3B/IIIb
Laser lifetime:	1,8 x 10^{10} pulse (5000 hours)
Linear TOF instrument with 50 cm long flight tube, technology different from other mass spectrometers.	
Detection of ions in both positive and negative mode.	
Resolution (FWHM):	3,000 in the microbial range (2,000 m/z to 18,000 m/z)
The stated resolution over the entire range of microbial masses due to the new dynamic focusing.	
Mass range in linear mode:	0 – 100,000 m/z

ACCESSORIES, CONSUMABLES, REAGENTS

1. LEXI Sample Plates
LEXI plates containing 84 spots in 6 x 14 format
Disposable plates.
The plate's identification via barcode
Application of control E. coli strain as a calibrant only to the first spot of the plate even with several series of measurements within one disposable plate. The calibration can be also run in duplicates or triplicates.
Capacity of the plate: calibration + up to 83 samples.

2. LEXI Sample Holder
Made of stainless steel in matt finish.
Barcoded.
Equipped with magnetic lock for locking the plate(s) into the holder.
Holds up to 3 plates at a time side by side.
The holder can hold 1 plate individually, 2 plates or all 3 plates at once.
The plates are inserted into the LEXI system with the holder
Total possible number of the samples that can be loaded into the instrument at once:
3 x up to 83 samples = 249 samples + 3 E.coli calibrators (one per each plate)
Time required to load 3 plates at once: < 2min
Complete sample traceability and result ID thanks to barcodes on the individual plates and on the holder.

Possibility of Remote diagnostics via the internet (Teamviewer connection)
Fast remote diagnostics of the device via network interface by a directly trained service engineers.

Technical specification of the system's LEXI-MS® accessories:
LEXI Control PC kit (INTEL NUC 9 EXTREME/ PRO)
LEXI Monitor kit
Healthcare scanner
Keyboard
PC mouse
Tablet supplied by MicroID lab application
Ethernet Router with WIFI
UPS unit

Electrical requirements:

Voltage	100–240 VAC (+/- 10%)
Frequency	50/60 Hz
Current	Max 5A
Outlets	Total capacity of 13A
Instrument fuse	5A, Time-Lag T, 250VAC, 5 × 20-mm
Connection plug	Acc. IEC 60320-1 C13
Position of outlets	Within 1 m from the proposed installation

Operating environment:

The Instrument is designed to be operated in an indoor controlled environment under the following conditions:

Operating temperature	15 °C – 32 °C
Performance temperature	18 °C – 28 °C
Relative humidity	10% – 90%
Atmospheric pressure	Minimum 70 kPa
Altitude	0 – 2000 m

The instrument has a pollution level II.
The device may only be installed in environments with non-conductive pollutants such as dust particles or wood chips.
Typical environments with pollution level II are laboratories and sales and commercial premises.

Softwares' specification®:

- **MICRO-IDLAB software, version DEP0056**

SW for icroorganisms' midentification by measuring MS spectra and comparison of their protein fingerprints with reference spectra in a database.
The SW works with spectra measured by the user and compares them with spectra from reference databases.
The software works with the obtained spectra and databases and performs on-line analysis and identification of microorganisms very efficiently and quickly - in tens of seconds, max. minutes.
Free upgrade of the software package as soon as a new software version is available.

- **CoreDB software, version 1.27.04**

IVD database for rapid and automated identification of microorganisms from clinical isolates and positive bloodculture samples.
The database contains 2555 bacterial and yeast species.
Free upgrade of the software package as soon as a new software version is available.

- **MoldDB software, version 1.22**

IVD database for rapid and automated identification of microorganisms from clinical isolates and positive hemoculture samples.
The database contains 132 species of filamentous fungi.
Free upgrade of the software package as soon as a new software version is available.

- **MycoDB software, version 2.0.01**

IVD database for rapid and automated identification of microorganisms from clinical isolates and positive hemoculture samples.
The database contains 100 species of mycobacteria.
Free upgrade of the software package as soon as a new software version is available.

Possibility to test Carbapenemase resistance a Colistin resistance using dedicated Reagent Kits.

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