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for In Vitro Diagnostic Use

Enhanced sensitivity with remarkable speed and robustness for laboratory developed tests

Benefits

- Powered by Thermo Scientific[™] TraceFinder[™] LDT Software, which provides a workflow-oriented approach to high-throughput quantitation
- Ultimate performance in human specimens at low levels of analyte through enhanced Thermo Scientific[™] Active Ion Management (AIM⁺) technology
- QR5 Segmented hyperbolicsurface quadrupoles deliver attogram sensitivity consistently and reproducibly
- Ultra-fast selected-reaction monitoring enables robust quantitation of more compounds faster
- Automated compound optimization and intuitive instrument interface increase productivity
- Optional bi-directional LIS connection

The Thermo Scientific[™] TSQ Altis[™] MD Series Mass Spectrometer offers enhanced sensitivity for demanding quantitative analyses together with remarkable speed and robustness. The TSQ Altis MD Series MS will be used by clinical diagnostic laboratories to address their more sensitive requirements for laboratory developed tests. With AIM+ technology, the TSQ Altis MD Series delivers ultimate performance in human specimens at low levels of analyte.





Hardware features

Active Ion Management

AIM+ technology maximizes ion transmission, from inception to detection, with novel hardware designs to precisely manage electrical fields and remove sources of noise to achieve unprecedented levels of quantitative performance.

Thermo Scientific[™] OptaMax[™] NG API source

- Automatic connection of all gases and voltages on installation simplifies operation and improves reliability
- Automatic source recognition simplifies use and data logging
- Sweep gas reduces chemical noise
- Enhanced exhaust port efficiently removes solvent vapor, improving uptime and reducing chemical noise
- Flexible X, Y, and Z positioning for all ionization probes maximizes performance
- Optimal 60 degree spray angle
- Integrated APCI functionality with interchangeable HESI and APCI ionization probes

High-capacity transfer tube

The optimized high-capacity transfer tube (HCTT) transfers more ions into the vacuum system for improved sensitivity while maintaining robustness and ease of use.

Ion optics

Electrodynamic ion funnel RF lens

The electrodynamic ion funnel (EDIF) efficiently captures ions as they leave the transfer tube. Its broad transmission curve reduces ion losses, increasing sensitivity. By design, the EDIF gently moves ions from atmosphere to vacuum, reducing in-source fragmentation.

Ion beam guide and neutral blocker

The ion beam guide, with its neutral blocker, stops neutrals and high-velocity clusters, keeping the ion path cleaner, reducing noise, increasing sensitivity and robustness.

QR5 Segmented hyperbolic-surface quadrupoles mass filters (Q1 and Q3)

Segmented hyperbolic-surface quadrupole mass filters with 5.25 mm field radius deliver industry leading ion transmission across the mass range at resolutions up to 0.2 Da FWHM for the ultimate in sensitivity at all masses and resolutions.

Active collision cell (Q2)

The 90 degree high-pressure argon-filled collision cell produces efficient fragmentation for high sensitivity while guiding ions away from neutral reaction products to reduce noise. The axial DC field speeds ion transits through the collision cell yielding up to 600 SRMs/sec with zero cross talk, providing excellent sensitivity and speed.

Detector

- Discrete-dynode detector with increased surface area greatly extends the detector lifetime
- Dual-mode function increases sensitivity by operating in pulse-counting mode when ion flux is low and analog mode when ion flux is high
- Six orders of dynamic range for enhanced sensitivity

Vacuum system

- Four-stage differentially pumped vacuum manifold
- Advanced triple-inlet turbomolecular pump integrated with the vacuum manifold
- Roots pump forepump, which does not require oil

Integrated divert valve and syringe pump

Fully automated data system control of the divert valve and syringe pump with plug-and-play support. Automated control of the divert valve enables switching the solvent front, gradient end point, or any portion of the HPLC run to waste.

Optional bi-directional LIS connection

B-Link[®] is a Universal LIS/LIMS CONNECTOR validated for TraceFinder LDT Software. The B-Link LIS/LIMS CONNECTOR is comprised of a downloadable software package of "middleware" capable of providing bidirectional communication between TraceFinder LDT Software and the Laboratory Information System (LIS).

The B-Link LIS/LIMS CONNECTOR is a turnkey middleware solution that facilitates sharing data between:

- The LIS/LIMS and B-Link (ASTM-1394-91 and ASTM 1381-95); and,
- B-Link and TraceFinder LDT Software (.csv)

The B-Link LIS/LIMS CONNECTOR software is installed on the TSQ Altis MD Series Data system—there is no need for any additional hardware.

Software features

Data system

- High-performance PC with Intel® microprocessor
- High-resolution LCD color monitor
- Microsoft® Windows® 10 operating system (64-bit)

Standard MD software

- TSQ Series II Altis MD and Thermo Scientific[™] TSQ Quantis[™] MD software for system calibration, diagnostics, compound optimization and method development
- TraceFinder LDT software provides a workfloworiented approach to high-throughput quantitation; Administrator console for user-based permissions, data repositories, and auditing configuration

Scan functions

- Highly sensitive full-scan MS
- Selected-ion monitoring (SIM)
- Selected-reaction monitoring (SRM) with up to 30,000 SRMs definable and up to 600 SRMs/sec and timed SRMs
- High-resolution (0.2 Da FWHM) selected-reaction monitoring (H-SRM)
- Product ion scan
- Precursor ion scan
- Neutral-loss scan
- Polarity switching capabilities
- Automated on-the-fly adjustment of retention time windows to accommodate chromatographic fluctuations

Usage

Intended use

The TSQ Altis MD Series mass spectrometer is intended to identify and quantify inorganic and organic compound in human specimens. For *in vitro* diagnostic use only by trained, qualified laboratory personnel.

Indications for use

The TSQ Altis MD Series mass spectrometer will be used by clinical diagnostic laboratories as a component of a laboratory developed test (LDT) method or workflow.

Contraindications of use

For *in vitro* diagnostic applications only. The TSQ Altis MD Series mass spectrometer is to be operated only with hardware or software labeled for in vitro diagnostic use.

Limitations of use

The TSQ Altis MD Series mass spectrometer is compatible with the following Thermo Fisher Scientific instruments:

- Thermo Scientific[™] Vanquish[™] MD Single Channel HPLC
- Thermo Scientific[™] Prelude MD[™] Dual Channel HPLC
- Thermo Scientific[™] Prelude LX-4 MD[™] Four Channel HPLC

As a component of an LDT method or workflow, validation of the LDT method or workflow is the responsibility of the clinical laboratory.

Performance specifications

Sensitivity

Positive electrospray (HESI)

A 5 μ L injection of a 200 fg/ μ L reserpine solution will produce a minimum signal-to-noise ratio of 500,000:1 for the transition of the protonated molecule at *m*/*z* 609.3 to the fragment ion at *m*/*z* 195.1 when operated in selectedreaction monitoring (SRM) mode with Q1 and Q3 resolution set to 0.2 and 0.7 Da FWHM respectively.

Atmospheric pressure chemical ionization (APCI)

A 5 μ L loop injection of a 200 fg/ μ L reserpine solution will produce a minimum signal-to-noise ratio of 100,000:1 for the transition of the protonated molecular ion at *m*/*z* 609.3 to the fragment ion at *m*/*z* 195.1 when operated in selected reaction monitoring (SRM) mode with Q1 and Q3 resolution both set to 0.7 Da FWHM.

Negative electrospray (nHESI)

A 5 μ L loop injection of a 200 fg/uL chloramphenicol solution will produce a minimum signal-to-noise ratio of 500,000:1 for the transition of the deprotonated molecular ion at *m/z* 321.0 to the fragment ion at *m/z* 152.0 when operated in selected reaction monitoring mode (SRM) with Q1 and Q3 resolution set to 0.7 Da FWHM.

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Mass range

m/z 5–2000

Resolution

Q1 and Q3 adjustable to 0.2 Da peak width (FWHM) across the entire mass range

Scan rate

- 15,000 amu/second at a resolution of 2 Da FWHM
- Up to 600 SRMs/sec (for resolutions from 0.2 through 2.0 FWHM)
- Polarity Switching: <20 msec electronic switching (25 msec total including signal stabilization time)

Mass stability

Mass assignment will be within ± 0.1 Da over a 24-hour period. The laboratory room temperature must be maintained between 18–27°C (65–81°F). The room temperature may not change by more than 5°C (9°F) during this period.

Installation requirements

Power

- Two 230 Vac ±10%, 50/60 Hz at 16 A minimum
- Four 120 Vac ±6–10%, 50/60 Hz at 20 A or four 230 Vac ±10%, 50/60 Hz at 13 A
- Earth ground hardwired to main panel
- Free from voltage variations above or below the recommended operating range

Gas

- Collision gas: 99.995% pure Argon (99.995% Nitrogen also supported)
- Collision gas supply pressure: 135 \pm 70 kPa (20 \pm 10 psig)
- Sheath/aux/sweep gas: 99% pure Nitrogen
- Sheath/aux/sweep gas supply pressure: 690 ± 140 kPa (100 ± 20 psig)
- Maximum gas consumption: ~20 L/min

Environment

- Functional temperature range: 15–27°C (59–81°F)
- Optimal temperature range: 18–21°C (65–70°F)
- Heat output: 1550 W (5400 Btu/h)
- Total system heat output: 4420 W (15,380 Btu/h)
- Particulate matter: <3,500,000 particles per cubic meter of air (<100,000 particles of >5 μm diameter per cubic foot of air)
- Relative humidity: 20% to 80%, without condensation
- Floors must be free of vibration

Dimensions

Size

- TSQ Altis MD Series MS: 70 × 66 × 84 cm (h, w, d – 28 × 26 × 33 in)
- Edwards[™] nXL110i forepump: 31 × 35 × 66 cm (h, w, d - 12 × 14 × 26 in)

Weight

- TSQ Altis MD Series MS: 125 kg (275 lb)
- Edwards[™] nXL110i forepump: 75 kg (165 lb)

Find out more at thermofisher.com/BeSure

IVD In Vitro Diagnostic Medical Device

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