

Fully automated, random access analyzer for *in vitro* diagnostic use

Clinical analyzer incorporating sample preparation, liquid-chromatography and mass spectrometry

Thermo Scientific™ Cascadion™ SM Clinical Analyzer is a fully automated liquid-chromatography mass spectrometric random access analyzer for the *in vitro* determination of a variety of analytes that may be adaptable to the analyzer depending on the assays used.

The Cascadion SM Clinical Analyzer and the assays included in this system are for *in vitro* diagnostic use in clinical laboratories.

System Solution/ Functionality and Features

- Closed system: all components needed to produce test results available through Thermo Fisher Scientific
- Random Access: continuous, random loading of patient samples without analyzer operation interruption
- Walkaway Operation: seamless transfer between all operation steps without operator intervention, manual steps eliminated
- Multi-analyte Processing: multiple tests can be run from a single sample within an assay
- Intuitive Graphical User Interface: select local languages available
- Access Rights Assignment: operator specific log-in credentials and access rights designation
- On-board Help: help available all times with content routing

Together the Cascadion SM Clinical Analyzer and Cascadion SM Assays determine the concentration of selected analytes. Depending on the analyte, serum, plasma, or whole blood in different sample collection containers may be used. Uncapped primary tubes and cups can be loaded into racks in random order.

Bi-directional host-query LIS interface allows for automated order processing. The integrated keyboard and barcode scanner are available as backup. Ready-to-use reagents and controls are loaded into a refrigerated compartment and required wash solutions are stored within the analyzer.

Software algorithms ensure data quality and flag test specific parameters when values are not met. Results are displayed in the user interface and can be sent to LIS. Related reports can be printed or transferred to an external USB-device.

Analyzer

Sample preparation

Fully automated assay specific work flow

Chromatography or Separation

Liquid chromatographic separation with TurboFlow technology

Measurement

Triple quadrupole mass spectrometer in selected reaction monitoring acquisition mode

Quantitation

Matrix matched external calibration, isotopically labelled internal standard utilized, automatic peak detection and integration, and result calculation

Reporting

Multiple reporting and report options

Sample capabilities

Throughput

Up to 25 samples/hr (serum, plasma)

Up to 23 samples/hr (whole blood)

Onboard sample capacity

60 samples, six racks holding ten uncapped primary tubes or sample cups

Supported sample types*

Serum, plasma and whole blood

*Sample type depends on assay and assay availability in each country depends on local regulatory marketing authorization status.

Minimum sample dead volume

100 µl (excluding whole blood assays)

Supported sample containers*

Specified 0.5 mL, 2.0 mL cups and tubes (outer diameter 11.0-17.4 mm, length 63-100 mm)

*Limitations apply for whole blood assays

Supported barcode types

Code 128, Interleaved 2 of 5, Code 39 with check digit available as standard

On-board Consumables and Disposables

Reagents

60 reagent or control vials

ten racks holding six 10 mL or 35 mL vials in refrigerated compartment,

barcode identified unique ID's

Extraction vessels

150 (5 x 30) single use disposable extraction vessels

Mixing tip (for whole blood sample processing)

168 (4 x 42) single use disposable mixing tips with level sensing

Probe wash solutions

4 ready-made probe wash solutions in 2.5 L barcode identified glass bottles

Solvents

Three different ready-made solvents in 1L barcode-identified bottles

Quick connect cartridge

2 serial number identified quick connect cartridges

Waste

Disposable solid and liquid waste containers with fill level sensors with replacement interval above 24 hour workload

Connectivity

LIS

RS-232 or TCP/IP according to CLSI LIS01-A2 and CLSI LIS02-A2 standards

Remote Diagnostics

TCP/IP over the ethernet with 128-bit SSL encryption to secure data flow

- Enables automated monitoring and diagnostics through software to provide real-time monitoring and automatic notification of instrument performance and diagnostics for quick problem resolution, no sample data transmitted

Automated sample preparation

Sample dispensing volume

Range 20 - 300 µL, volume assay specific

Reagent dispensing volume

Range 150 - 400 µL, volume assay specific

Injection volume

Range 10 - 100 µL, volume assay specific

Features

- Priority sample functionality
- Foam, sample clot and probe crash detection
- Level and short sample detection with related alarm (or notifications)
- Probe alignment check for sample and injector probes

Liquid chromatography

Number of channels

Two separate chromatographic channels with multiplexing capability

Number of solvents

Five per channel (3 for use with TurboFlow column, 2 for use with analytical column)

Solvent consumption

<100 mL/h per solvent, volume assay specific

Gradient formation

High-pressure mixing

Operating flow rate

Range 0.010-2.000 mL/min in 0.001 mL increments

Pump type

Syringe, 100 MPa (1000 bar) maximum

Automated features

- Run pressure profile surveillance with automated error flagging and safety shut down
- Priming, temperature control, column equilibration, channel selection, column lifetime monitoring

Tandem mass spectrometry

Ionization

HESI in positive or negative mode

Acquisition mode

Selected reaction monitoring

SRM rate

300 SRM/s supported

Mass range

Operation range over 30-1500 Da

Resolution

Unit resolution of 0.7 Da FWHM or Unit, 0.7 Da peak width (FWHM)

Installation

Temperature	Range 18–27 °C (65–81 °F), rate of allowable temperature change < 1 °C/hr
Humidity	Range 20 % - 80 % (non-condensing, dew point <16 °C)
Power, nominal values	Voltage 230 V, frequency 50-60 Hz
Ventilation requirements	Ventilation exhaust for MS waste container
External vacuum source	Validated roughing pump
Argon gas	Purity 99.995 %, supply pressure 135±70 kPa (20±10 psi)
Nitrogen gas	Purity >99 %, supply pressure 690±140 kPa (100±20 psi) or validated nitrogen generator

Other

Power consumption	2.3 kW
Heat production	7000 BTU/h
Noise production average	<75 dB including Cascadion Accessory Cabinet

Dimensions

Size (width x depth x height)	225 cm x 96 cm x 140 cm (88.6 in x 37.8 in x 55.1 in) Floor based unit
Weight	770 kg (1698 lb) Weight with supplies 810 kg (1786 lb)

Regulatory compliance

Europe

Conformity with the IVD (in vitro diagnostic medical devices) directive 98/79/EC and RoHS directive

International

Conformity with the following international regulations

IEC 61010 series

Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use

CAN/CSA-C22.2 No. 61010 series

Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use

UL Std. No. 61010 series

Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use

IEC 61326 series

Electrical Equipment for Measurement, Control and Laboratory Use - EMC Requirements

FCC 47CFR Part 15, subpart B

Generic Emission Standard, Class A

FDA 21 CFR 820, Quality Systems Regulations, as applicable

Quality System Certification

ISO 9001:2015 Certified by BSI

ISO 13485:2016 Certified by BSI

ISO 14001:2015 Certified by BSI

Canadian MDSAP ISO 13485:2016 Certified by BSI

Ordering codes

99990000	Cascadion SM Clinical Analyzer
990600	Cascadion SM Roughing Pump
990700	Cascadion SM Accessory Cabinet
995978	Cascadion SM Argon Cart
990400	Cascadion SM Earthquake Bracket



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Find out more at thermofisher.com/cascadion

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