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.

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

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

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

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)

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### Installation

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

### Other

<table>
<thead>
<tr>
<th><strong>Power consumption</strong></th>
<th>2.3 kW</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Heat production</strong></td>
<td>7000 BTU/h</td>
</tr>
<tr>
<td><strong>Noise production average</strong></td>
<td>&lt;75 dB including Cascadion Accessory Cabinet</td>
</tr>
</tbody>
</table>

### Dimensions

<table>
<thead>
<tr>
<th><strong>Size (width x depth x height)</strong></th>
<th>225 cm x 96 cm x 140 cm (88.6 in x 37.8 in x 55.1 in)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weight</strong></td>
<td>770 kg (1698 lb) Weight with supplies 810 kg (1786 lb)</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99990000</td>
<td>Cascadion SM Clinical Analyzer</td>
</tr>
<tr>
<td>990600</td>
<td>Cascadion SM Roughing Pump</td>
</tr>
<tr>
<td>990700</td>
<td>Cascadion SM Accessory Cabinet</td>
</tr>
<tr>
<td>995978</td>
<td>Cascadion SM Argon Cart</td>
</tr>
<tr>
<td>990400</td>
<td>Cascadion SM Earthquake Bracket</td>
</tr>
</tbody>
</table>

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Find out more at thermofisher.com/cascadion