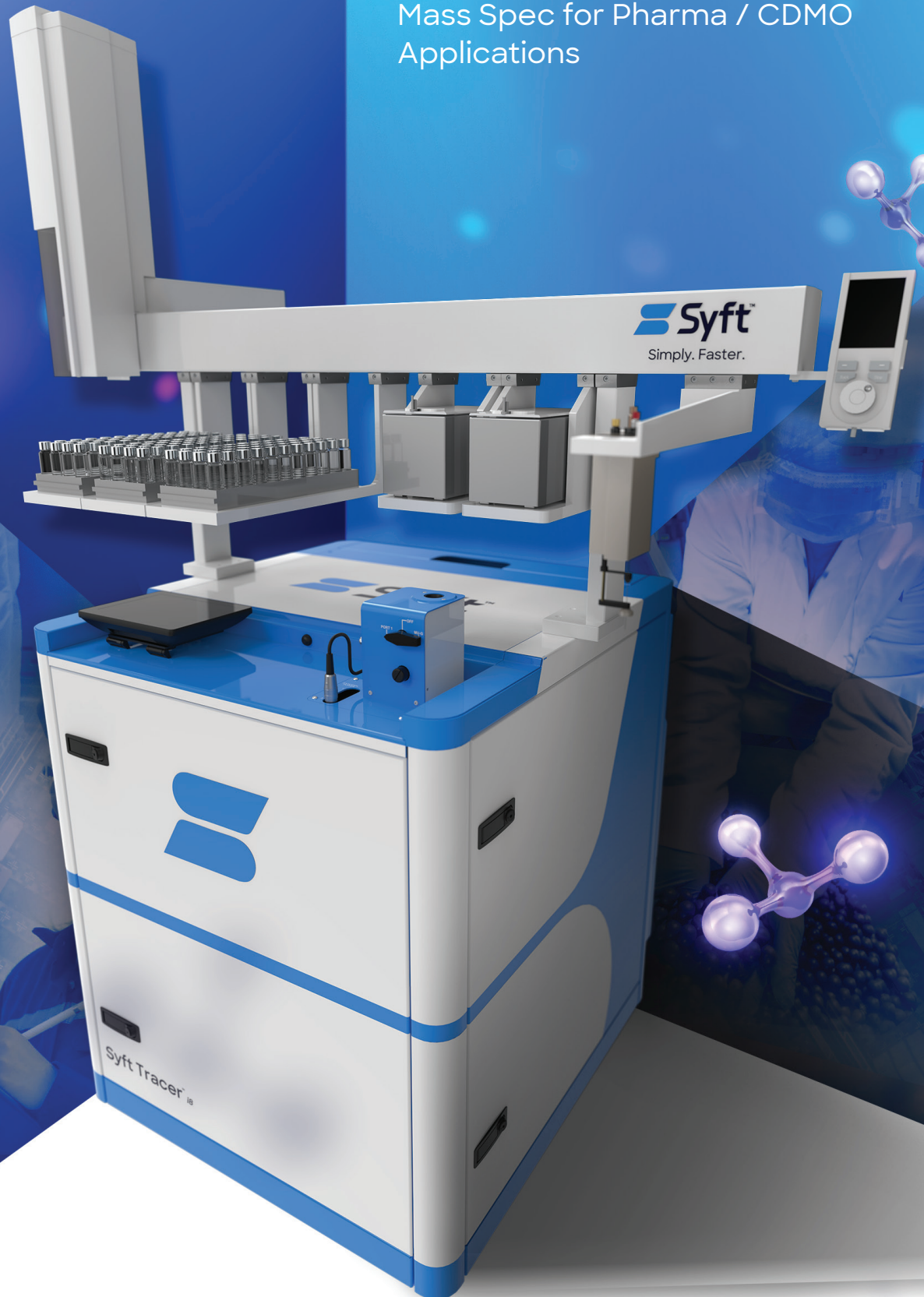


Syft Tracer Pharm11

The **Only** Compliant Real-Time
Mass Spec for Pharma / CDMO
Applications

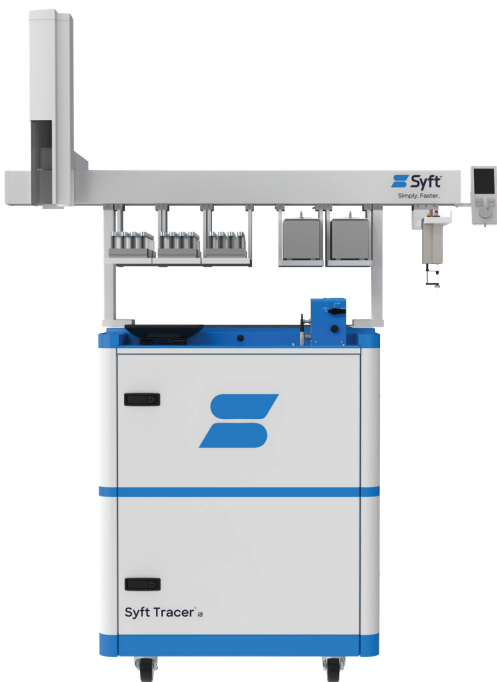


Syft Tracer[®] 11

A complete solution for high-throughput, 21 CFR Part 11 compliant, automated workflows

Syft Tracer Pharm11 is a bundle solution for high-throughput, 21 CFR Part 11 compliant, automated workflows in pharmaceutical and CDMO applications. It includes Syft Tracer, a CTC autosampler, a High Throughput (HTP) Inlet, and SyftAuditTracer 21 CFR Part 11 compliant software. Syft Tracer™ is the next generation of real-time, direct injection mass spectrometry (MS) that is built to solve the most difficult analytical challenges. It delivers trace-level detection sensitivity, unparalleled performance stability, and highly reproducible data.

Syft Tracer Pharm11 provides a single configuration for analyzing chemically diverse compounds with a single method or between multiple methods without the need for column changeover or other chromatographic delays. Perform headspace extraction, dissolution in aqueous solvents or non-polar alternatives, and direct sampling from powder or solid headspace back-to-back using the same instrument configuration. Syft Tracer Pharm11 enables the analysis of >200 samples daily with full user and data traceability. SyftAuditTracer software is fully compliant with 21 CFR Part 11 and includes a user-friendly interface for easy operation and data analysis.



Syft Tracer Pharm11 equips you to make critical decisions faster

- The first and only compliant solution for direct MS
- One configuration for multiple, diverse analyses
- Autosampler integration tailored to high-throughput SIFT-MS analysis, enabling the analysis of >200 samples / day
- Includes HTP Inlet designed for high-throughput applications
- Flexibility to append sequences to running batches
- Batch processing of quantitative run results
- Trace level multi-analyte detection sensitivity
- Highly selective and quantitative
- No chromatography or sample prep required
- Easy to operate and interpret data

SyftAuditTracer compliant software provides everything needed for user & data traceability

SyftAuditTracer delivers a complete software package for user and data traceability. This is the first and only real-time mass spectrometry software that is fully compliant with 21 CFR Part 11 guidelines. An audit trail is created in every step of the workflow including the login process, user logs and permissions, data acquisition, and data processing.

SyftAuditTracer

Login

Username

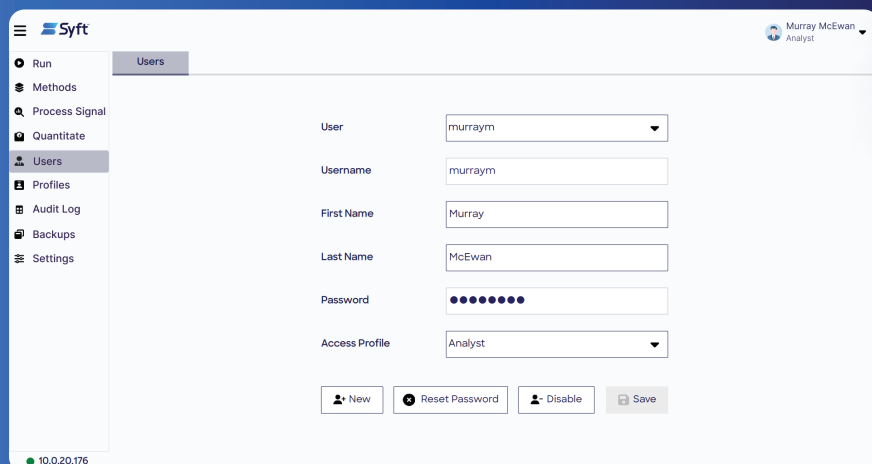
Password

Analyzer IP

Login process

SyftAuditTracer is a password protected system, requiring login to gain access to the interface. Only authorized users are permitted to engage the software. Security settings are included such as password expiry, password requirements, and automatic logout after inactivity.

Audit logs and reporting

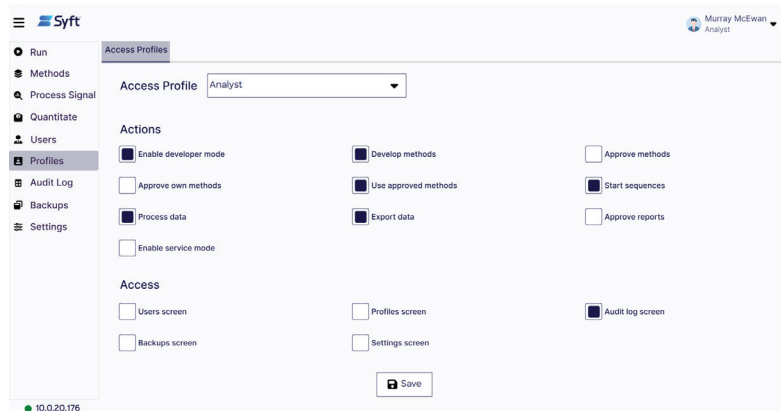


The screenshot shows the Syft user management interface. The 'Users' tab is active, displaying a form for user management. The form includes the following fields and values:

- User: murraym
- Username: murraym
- First Name: Murray
- Last Name: McEwan
- Password: [masked]
- Access Profile: Analyst

Buttons at the bottom include: New, Reset Password, Disable, and Save.

The audit logs of **SyftAuditTracer** record *which* actions were taken, by *whom*, and *when*, ensuring full traceability from before data acquisition, through analysis and completion of reporting. Important records (data, methods, audit log, reports, etc.) are retained in a non-editable format. The software enables users to periodically backup their systems (daily, overnight, etc.).



The screenshot shows the Syft 'Access Profiles' configuration interface. The 'Access Profile' dropdown is set to 'Analyst'. The 'Actions' section includes the following checkboxes:

- Enable developer mode:
- Approve own methods:
- Process data:
- Enable service mode:
- Develop methods:
- Use approved methods:
- Export data:
- Approve methods:
- Start sequences:
- Approve reports:

The 'Access' section includes the following checkboxes:

- Users screen:
- Profiles screen:
- Settings screen:
- Audit log screen:
- Backups screen:

A 'Save' button is located at the bottom right.

User profile permissions

The user roles and rights are configurable in **SyftAuditTracer** software. Different rights (create methods, run methods, sign off reports, user management, etc.) can be selected to match the responsibilities of defined roles (admin, analyst, lab manager, etc.). Syft can provide default rights for defined roles as needed.



Sample_Seq	Reports	Performance Tune Results
Sample_Seq	Report_001,Report_002,Report_00...	Syft Standard Validation-4409-23456
Sample_Seq1	Report_009,Report_008,Report_01...	Syft Standard Validation-4409-23456
Sample_Seq2	Report_011,Report_012,Report_01...	Syft Standard Validation-4759-25556

Sequence ID	Analysis ID	Product ID	Type	Mean	RSD	Min-Max	Points	Window	Information
Sample_Seq	RSA V1-HS5-B005-...	C10H12+ [132] / NO+ ...	Blank	1.23	0.021	1.21-1.24	5	62-109	Blank sample...
Sample_Seq1	RSA V1-HS5-B005-...	C10H12+ [132] / NO+ ...	Blank	0.85	0.015	0.84-0.86	5	62-109	Info-2
Sample_Seq2	RSA V1-HS5-B005-...	C10H12+ [132] / NO+ ...	Blank	1.12	0.042	1.10-1.15	5	62-109	Info-2
Sample_Seq3	RSA V1-HS5-B005-...	C10H12+ [132] / NO+ ...	Blank	0.96	0.049	0.93-0.99	5	62-109	Blank sample...
Sample_Seq	RSA V1-HS5-B005-...	C10H12+ [132] / NO+ ...	Blank	0.92	0.020	0.91-0.94	5	62-109	Info-3
Sample_Seq	RSA V1-HS5-B005-...	C10H12+ [132] / NO+ ...	Blank	1.05	0.035	1.02-1.06	5	62-109	Info-3
Sample_Seq	RSA V1-HS5-B005-...	C10H12+ [132] / NO+ ...	Blank	1.02	0.041	0.99-1.04	5	62-109	Info-3
Sample_Seq	RSA V1-HS5-B005-...	C10H12+ [132] / NO+ ...	Blank	0.94	0.031	0.93-0.97	5	62-109	Info-2
Sample_Seq	RSA V1-HS5-B005-...	C10H12+ [132] / NO+ ...	Blank	0.92	0.053	0.90-0.96	5	62-109	Info-2

Data acquisition & processing

SyftAuditTracer allows you to build, import, and manage SIFT-MS and autosampler methods with an intuitive user interface. This walk-up solution allows users to choose from pre-validated methods, initiate and monitor running sequences, view system status and metrics, append running batches, and batch process data. Steps and results of the daily Performance Tune procedure are recorded automatically. SyftAuditTracer makes it easy to track steps in your entire workflow from login and permissions setting to sequence setup and data processing.

Chromatogram showing intensity (AU) vs time (ms) with peaks at 48334 and 75409.

Analysis Results	Points	Mean	RSD
SEQUENCE-3			
SAMPLE-1111			
CH(CI-35)(CI-37)(B5)O2+/chloro	6	5872.13	1.230
SAMPLE-1112			
CH(CI-35)(CI-37)(B5)O2+/chloro	6	4915.99	1.059
SAMPLE-1113			
CH(CI-35)(CI-37)(B5)O2+/chloro	6	5170.15	1.119
SAMPLE-1114			
CH(CI-35)(CI-37)(B5)O2+/chloro	6	5681.83	1.241
SAMPLE-1115			
CH(CI-35)(CI-37)(B5)O2+/chloro	6	4887.36	1.029

Standard data processing tools are included with SyftAuditTracer including data viewing, raw signal processing, blank subtraction, quantitation using calibration curves or single point calibration, and the ability to export data as CSV files for further processing in other programs.

Physical Specifications

Instrument Size (including autosampler rail)	<ul style="list-style-type: none"> ○ Width: 135 cm (max, rail option may decrease) ○ Height: 185 cm ○ Depth: 114 cm
Computers	<ul style="list-style-type: none"> ○ Integrated into the instrument: Debian Linux ○ Mini PC
Minimum Computer Specs	<ul style="list-style-type: none"> ○ OS: Windows 11 pro ○ CPU: Intel Core i5 ○ Processor: 4.2GHz 64-bit processor ○ Memory: 16 GB RAM ○ Storage: 500 GB ○ 1 built in Ethernet port ○ USB-C to Gigabit Ethernet adapter included ○ 3 USB 3.2 ports, 1 USB 2.0 port, 1 free USB 4 (type C) port ○ Wi-Fi 6
Power	110-240 VAC
Syft CTC Autosampler Options	Lite, High-throughput, High-throughput flex
Headspace Syringe Temperature (°C)	40 - 150
Injection Volume Range (mL)	1 - 5 (Headspace Autosampler Dependent)
Incubation Temperature (°C)	50 - 100 recommended, up to 200 °C
Typical Incubation Time (min)	20 - 45
Typical Injection Time (s)	50 - 100
Typical Injection Speed (µL/s)	10 - 100
Incubator Capacity (n samples)	6
Samples per Hour	Method dependent up to 12
Inlet Temperature (°C)	120
Samples on Autosampler Rail	Up to 180

Syft CTC Autosampler Specifications

Lite	85 cm RSI, 1 x agitator, 2 x sample tray with rack, 2.5 mL HS syringe (+ extra syringe)
High-throughput	120 cm RSI, 2 x agitator, 3 x sample tray with rack, 2.5 mL HS syringe (+ extra syringe)
High-throughput Flex	120 cm RTC, 2 x agitator, 3 x sample tray with rack, 2.5 mL HS syringe (+ extra syringe)

Performance Parameters

Linearity	$R^2 > 0.99$
Mass Range	15 - 400 amu
Compound Coverage	1500+ compounds, expandable library of VOCs and inorganics

Example Working Concentration Ranges*

Ethylene Oxide ¹	100 - 5000 ng/g
Nitrosamines ²	2 - 160 ng/g
Class 2A & 2B Residual Solvents ³	9 - 90000 ng/mL (analyte dependent)
Benzene ³	0.1-600 ng/mL
Xylene (all isomers; ethylbenzene) ³	0.1-600 ng/mL

*Ranges can be much wider and vary from analyte to analyte; typical SIFT-MS LDR is >5 orders of magnitude

¹EtO measurement in polysorbate materials

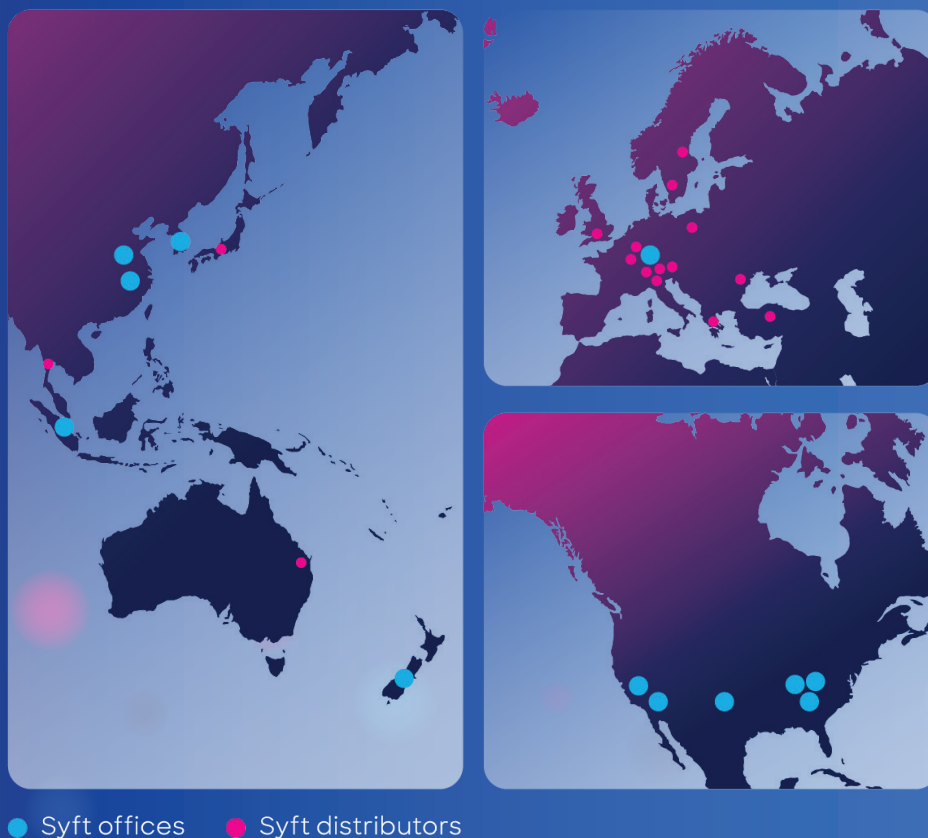
² NDMA measurement across full concentration range using NO+ m/z 74 quantitation ion.

³ Concentration in 10 mL aqueous solution contained in 20 mL headspace vial.

About Syft: the trusted partner for real-time volatile analysis solutions.

Syft was founded in 2002 and has over 150 professionals in 7 countries. Syft is considered the world leader in real-time, direct injection mass spectrometry with more than 20 years of SIFT-MS expertise. Syft instruments support a broad range of industries worldwide including semiconductor manufacturing, pharma and CDMO, environmental protection, automotive, food, flavor and fragrances, and many more.

Customer Support offices are located throughout the world offering 24/7 service and support including those in New Zealand, Korea, Taiwan, Singapore, Germany and the U.S. Factory trained field support engineers and field application scientists are staffed in each Customer Support office. Regional service and application development support is available to assist with expanding your analyte compound list of interest.



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