### pharmaceuticals

## Productivity from all angles

Thermo Scientific TriPlus 500 Gas Chromatography Headspace Autosampler





## Superior repeatability. Easy method transfer. High data quality.

Powered by an innovative new design, the Thermo Scientific<sup>™</sup> TriPlus<sup>™</sup> 500 GC Headspace Autosampler delivers more of what you want, and less of what you don't. Helping you to maximize valuable time with smoother validation procedures and compliance to United States Pharmacopeial Convention (USP) qualification requirements, this modular platform is the ideal choice for pharmaceutical quality control laboratories seeking the next level of productivity.



TriPlus 500 Headspace Autosampler coupled to the Thermo Scientific<sup>™</sup> TRACE<sup>™</sup> 1300 Gas Chromatograph

## Drive reliability through innovation

For any testing laboratory conducting volatiles analysis, static headspace-gas chromatography, with its simplicity and broad applicability is one of the most reliable and robust techniques. When seeking highly accurate analytical results, the valve-and-loop sampling technique is a must-have. Packed with innovative features, the TriPlus 500 Headspace (HS) autosampler makes the most of daily workflows by addressing the biggest challenges facing today's laboratories doing routine volatiles determination.



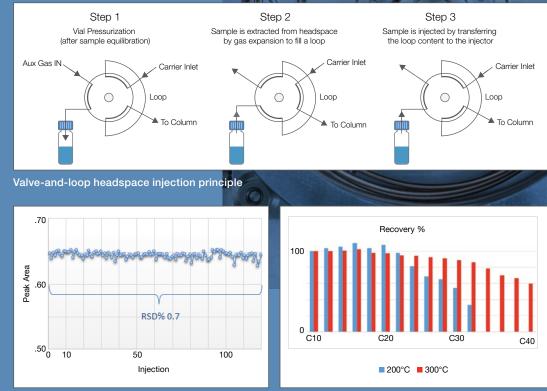
#### New pneumatic circuit design

A proprietary pneumatic circuit design and a highly precise heating control work together for an accurate sampling process, increasing the system reliability and robustness. The repeatability of the area counts is the highest in the market. This, coupled with the sample integrity maintained during the injection process, ensure the required data quality is easily achieved.

**High precision** – Innovative control of the pressure in the sampling loop during venting delivers excellent repeatability of the sample amount injected into the gas chromatograph.

**High robustness** – Efficient heating of the entire sample path greatly reduces the risk of high boiling solvents contamination, especially through the vent line, which guarantees an extended robustness of the system.

**Low carryover** – Effective purging over 5 levels of flow rates and short sample path assure minimal to no carryover. An empty blank vial analyzed after undiluted 2-butanol headspace injection shows a carryover <0.0003%.



Long Sequence Area Counts Repeatability. 120 consecutive headspace injections of a 50 ppm ethanol solution in water (5 ml in 10 ml crimp top vial). Overall RSD%=0.7. Recovery of a standard hydrocarbon mixture C10-C40 at high temperature operation, showing >60% recovery at 300°C

## Solve the toughest challenges with smart design

Optimize productivity, reliability and data quality with key features



#### **Direct GC column interface**

Instead of a long transfer line connecting the static headspace to the GC column, the TriPlus 500 HS autosampler features a direct connection from the valve manifold to the GC column, maintaining split flow control capability.

This creates a shorter sample path which eliminates possible cold or hot spots, assuring sample integrity during transfer into the column.



#### **Quick Spin Shaking (QSS)**

The new proprietary design for vial shaking during vial incubation provides a larger exchange surface area between liquid and gas phases, accelerating the sample equilibration with valuable time-saving benefits:

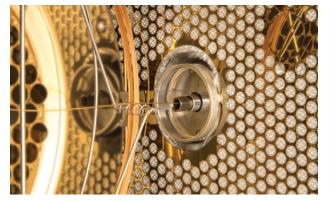
- Reduced overall cycle time: the spin shaking device offers three levels of agitation to speed sample equilibration and shorten the incubation time.
- High extraction efficiency: consistent equilibrium between liquid and gas phase enables highly repeatable extraction efficiency.



#### Compact footprint with modular design

Directly coupled to the capillary column, the TriPlus 500 HS autosampler offers a compact footprint that optimizes your valuable bench space. Its industrial design complements the Thermo Scientific<sup>™</sup> TRACE<sup>™</sup> 1300 Series Gas Chromatograph systems with about 30% less bench space than competitive systems.\* Its modular design enables easy system upgrades over time to accommodate increased sample throughput needs from 12 up to 240 vials capacity with no additional bench space required.

\*when compared to a similar configuration.



GC oven view with direct column connection to the TriPlus 500 HS autosampler



Screen capture of vial in quick spin shaking mode



TriPlus 500 Headspace Autosampler coupled to the TRACE 1310 Gas Chromatograph

## Labor-saving headspace injection capability

## Automated tools for enhanced analytical performance

The advanced functionalities of the TriPlus 500 HS autosampler help you to save time when higher sensitivity is required or when complex sample matrix strongly impacts volatiles quantitation. Automatic Leak Check confirms sample integrity at each injection while multiple headspace extraction (MHE) and multiple headspace injection (MHI) techniques offer higher analytical flexibility in a manner that is fully-automated and unattended.

#### Automatic leak check



To guarantee the expected sample integrity at every analysis, each vial is automatically checked for possible leaks just prior to the loop filling stage. If a vial leak is detected, the error is tracked in the log file. Moreover, the user has different choices on how to handle the error during the sample sequence — either continue with the injection, abort the injection and proceed with the next sample, or abort the whole sequence.

#### Multiple headspace extraction



MHE is an absolute quantitative method for volatiles in solid samples, or any time the matrix cannot be easily reproduced as external standard. Each vial is automatically analyzed several times to track decreasing analyte area counts and extrapolate its concentration in the sample.

#### Multiple headspace injection

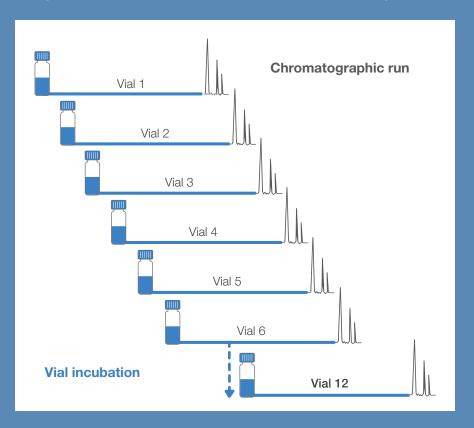


Ideal for testing low concentrated samples, this tool enables users to enrich the headspace by making multiple injections from the same vial before starting GC separation.

#### Save time with unattended sampling workflow

In busy pharmaceutical testing labs, efficiency is critical. The TriPlus 500 HS system offers the highest sample capacity for a valve-and-loop headspace autosampler, saving time and increasing productivity. With its 120-position tray (expandable to 240-position) and 12 positions for simultaneous incubation, the TriPlus 500 HS autosampler offers the highest overlapping capability for long unattended sequences with cycle time optimization.

Ideal for highly regulated workflows and routine environments, this flexible sample handling solution enables testing laboratories to maximize sample throughput and accelerate volatiles determinations while minimizing downtime.



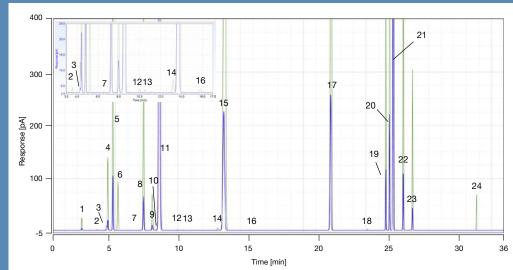


# Residual solvents according to USP method <467>

## Ensure excellent high-throughput performance

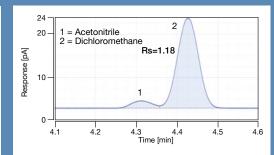
The TriPlus 500 HS autosampler coupled to the TRACE 1300 Series GC fully matches USP method <467> requirements, combining excellent performance with high-throughput operations.

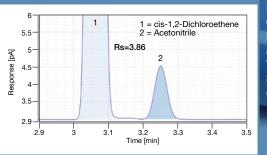
The highly efficient pneumatic control and the sample path inertness ensure outstanding repeatability and routine precision. Average peak area %RSD (n=18 consecutive injections) is consistently <1.2% for Class 1, Class 2A and Class 2B solvents in water/dimethyl sulfoxide (DMSO). Resolution between critical pairs is no challenge and always well above the USP requirements of Rs≥1.0. This is achievable due to the high performance of the Thermo Scientific<sup>™</sup> TraceGOLD<sup>™</sup> GC columns, delivering low bleed and superior inertness for both procedures A and B. In particular, enhanced resolution is achieved by using the TraceGOLD TG-624SiIMS capillary column, giving the opportunity to speed up the chromatographic separation, maintaining USP compliance.



1 = Methanol 2 = 1,1 - Dichloroethene 3 = Acetonitrile 4 = Dichloromethane 5 = trans-1,2-Dichloroethene 6 = Hexane 7 = Nitromethane 8 = cis-1,2-Dichloreethene 9 = Tetrahydrofuran 10 = Chloroform 11 = Cyclohexane/1,1,1-Tirchloroethane 12 = Benzene 13 = 1,2-Dichloroethane/1,2-Dimetoxyethane 14 = Tirchloroethene 15 = Methylcyclohexane 16 = 1,4-Dioxane 17 = Toluene/Pyridine 18 = 2-Hexanone 19 = Chlorobenzene 20 = Ethylbenzene 21 = m-Xylene/2-Xylene 22 = o-Xylene 24 = Cumene 24 = Tetralin

Comparison between peak profiles obtained for a spiked test solution (green) and Class 2A standard solution (blue). The standard USP <467> conditions have been applied.



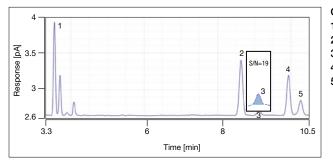


Procedure A: Chromatographic resolution between acetonitrile and dichloromethane by using TraceGOLD TG-624 30m, 0.32mm id, 1.8µm capillary column

Procedure B:

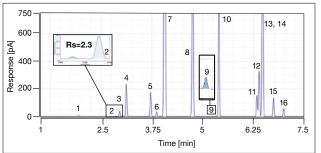
Chromatographic resolution between cis-1,2-dichloroethene and acetonitrile by using TraceGOLD TG-WaxMS 30m, 0.32mm id, 0.25µm capillary column The excellent resolution of critical pairs that exceed the USP requirements allows optimization of the standard USP <467> conditions, including more rapid analysis time for increased throughput, even when using nitrogen as carrier gas. The run time is reduced to less than 8 minutes for Class 2A and 2B, and to about 10 minutes for Class 1, with 7 times improvement in speed of analysis without compromising chromatographic resolution and method performance. In addition, efficient vial shaking permits a faster equilibrium of the sample, from 60 minutes to 20 minutes incubation, offering a significant reduction in overall cycle time.

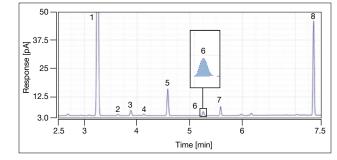
This newly available high-throughput and cost-effective HS-GC-FID method for residual solvents determination is key to enhancing the laboratory productivity.



Class 1

- 1 = 1,1-Dichloroethene
- 2 = 1,1,1-Trichloroethane
- 3 = Carbon Tetrachloride
- 4 = Benzene
- 5 = 1,2-Dichloroethane





Fast chromatographic separation for Class 1, 2A , 2B using a TG-624SiIMS 30m, 0.32mm id, 1.8µm capillary column and nitrogen as carrier gas

#### Class 2A

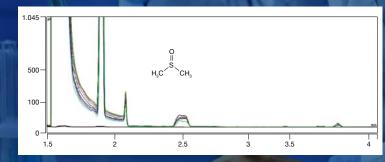
- 1 = Methanol 2 = Acetonitrile
- 3 = Dichloromethane
- 4 = trans-1,2-Dichloroethene
- 5 = cis-1,2-Dichloroethene
- 6 = Tetrahydrofuran 7 = Cyclohexane
- 8 = Methylcyclohexane 9 = 1,4-Dioxane
- 10 = Toluene 11 = Chlorobenzene
- 12 = Ethylbenzene 13 = m-Xylene
- 14 = p-Xylene 15 = o-Xylene 16 = Cumene

#### Class 2B

- 1 = Hexane 2 = Nitromethane
- 3 = Chloroform 4 = 1,2-Dimethoxyethane
- 5 = Trichloroethene
- 6 = Pyridine 7 = 2-Hexanone 8 = Tetralin

The TriPlus 500 HS autosampler is designed to minimize any carryover effect, especially with high boiling residual solvents. The direct column connection to the valve manifold eliminates the need for high temperature settings

manifold eliminates the need for high temperature setting: typically applied to the external transfer line. Additionally, the highly inert sample path and the effective purging of the loop and the needle contribute to deliver the best performance in terms of reduced carryover.



Carryover <0.0015% after 9 consecutive headspace injections of undiluted DMSO

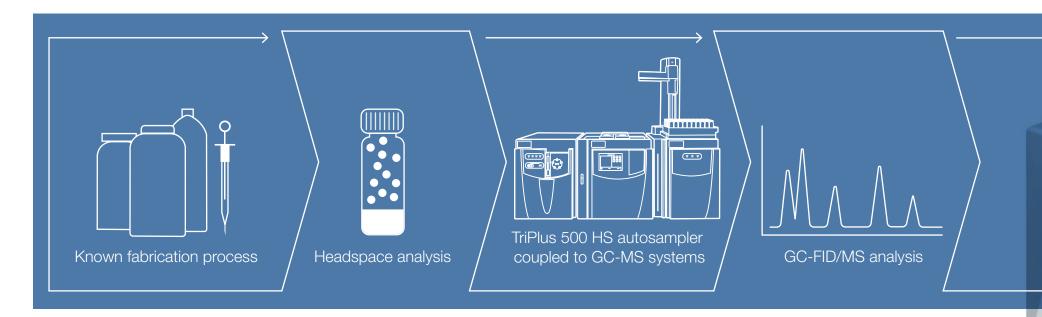
## Volatile extractable and leachable organic compounds Detect the unexpected

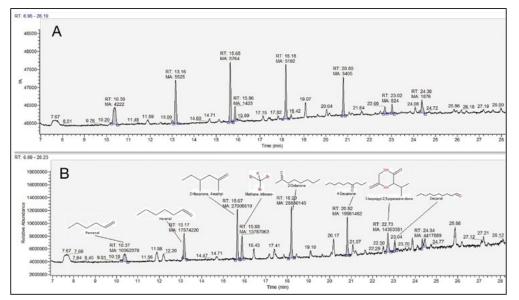
The TriPlus 500 HS autosampler is ideal for automating the determination of organic volatile impurities in products or contact materials. With the increasing use of novel single-use bioproduction components and innovative food and pharmaceutical packaging, the potential for unknown leachables entering testing workflows is also on the rise. Determining the identity of compounds not present in commercial libraries was once a complex challenge, requiring a significant amount of time and analytical detective work. However, advanced software solutions,

along with highly sensitive full-scan acquisition GC-MS, greatly facilitates this task, leveraging the highest amount of analytical information. From unit-mass resolution Thermo Scientific<sup>™</sup> ISQ<sup>™</sup> 7000 single quadrupole gas chromatography mass spectrometry (GC-MS) up to high-resolution accurate mass (HRAM) Orbitrap<sup>™</sup> GC-MS, unmatched results in unknown identification are easily achieved, helping testing laboratories to identify unexpected compounds more quickly and confidently than ever before.



TriPlus 500 Headspace Autosampler coupled to TRACE 1310 GC and Thermo Scientific<sup>™</sup> Q Exactive<sup>™</sup> GC Orbitrap GC-MS/ MS systems

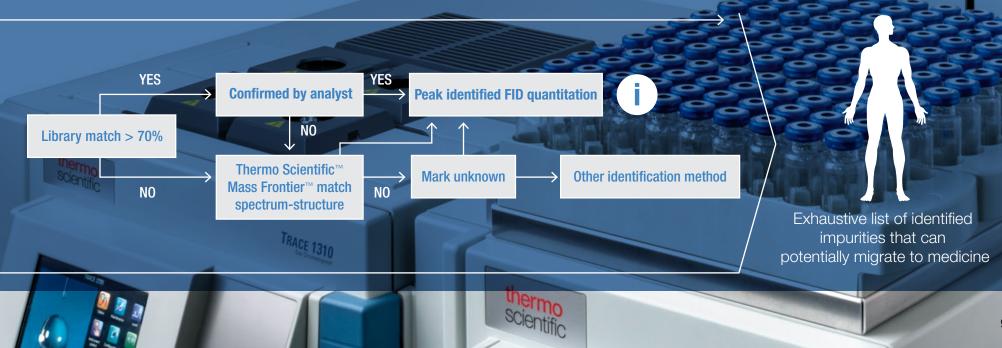




HS-GC-FID/HRMS analysis of water extract of pre-fill syringe plunger stoppers. A: FID chromatogram, B: HRMS chromatogram.

Pharmaceutical products may come into contact with a wide range of polymeric materials which contain a wide range of extractable and leachable additives and storage aids such as antioxidants, plasticisers, emulsifiers and colorants.

Powerful HS-GC-MS instrumentation and software solutions allow accurate identification and quantification of known and unknown volatile extractables in contact materials, which cuts through the complexity of extractables testing workflows.



## Centralized, single point of control Seamless integration with Chromeleon CDS

#### Simplify chromatography processes

By seamlessly integrating the Thermo Scientific<sup>™</sup> Chromeleon<sup>™</sup> Chromatography Data System (CDS) software with the TriPlus 500 HS autosampler, you gain the simplicity and convenience of having a single point of control for the entire analytical workflow and beyond.

With its rich and intelligent functionality, Chromeleon CDS does everything you need, and thanks to its Operational Simplicity, everything is fast and easy to use. It reduces data review and processing time with unique automation tools such as the Cobra detection algorithm, SmartPeaks<sup>™</sup> Integration Assistant, and SmartLink data review. Chromeleon software uses eWorkflow<sup>™</sup> procedures to accelerate chromatography analysis by reducing manual data entries and processing errors. They provide a solution to easily create complete, correct sequences with predefined associated files and a well-defined structure. They minimize the amount of training, effort and time required to get from sampling to reliable results. This increase in productivity is reinforced by 24/7 laboratory uptime and prevention of data loss through industry-leading network failure protection.

#### Ensure regulatory compliance

Chromeleon software is a critical partner in delivering technical controls that help ensure compliance. These will inevitably sit alongside both procedural and administrative controls, such as Standard Operating Procedures (SOPs), training and administration that must be put in place by the user.

Chromeleon CDS enables you to meet the full requirements of the Food and Drug Administration Title 21 Code of Federal Regulations Part 11 (FDA 21 CFR Part 11) Electronic Records and Electronic Signatures. The software provides features that allow users to implement controls in accordance with their interpretation, including comprehensive audit trails and security tools to ensure compliance and data integrity.

## Keep your instrument suitably qualified and application ready

### Easy compliance through automated procedures

#### USP <1058> Analytical Instrument Qualification (AIQ)

Compliance and adherence to data quality guidelines is a critical focus for any business that follows regulatory guidelines, such as the pharmaceutical industry. Both procedural and technical controls must be in place to ensure data integrity is not compromised, while system qualification must provide evidence that the instrument performs suitably for its intended purposes, matching the User Requirement Specification (URS), in compliance with USP <1058>.

#### **Operational Qualification** and Performance Qualification

Checks the analytical operation of your instrumen

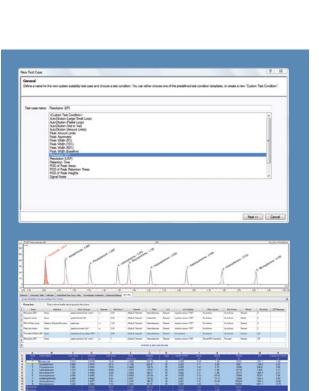
checks the analytical performance of your instrume

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Automated tools in Chromeleon CDS make it easy for you to set-up and run sequences that test the performance of all your chromatograph components. The tools automatically generate detailed reports that show actual performance and comparison against acceptability limits. Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) of the entire system are easily performed using the Chromeleon CDS gualification wizards, which automate the setup of sequences and generate reports for qualification tests.

Quality control check samples	Instrument Qualification Wizard Choose Qualification Type Select the type of instrument qualification to run
System suitability tests	Custification Type C Installation Custification Checks the general functionality of (Spessional Custification.) Checks the analysical operation of C Pedromace Custification.
Analytical method validation	Checks the analytical performance
Analytical instrument qualification	

Components of data quality



#### System Suitability Testing (SST)

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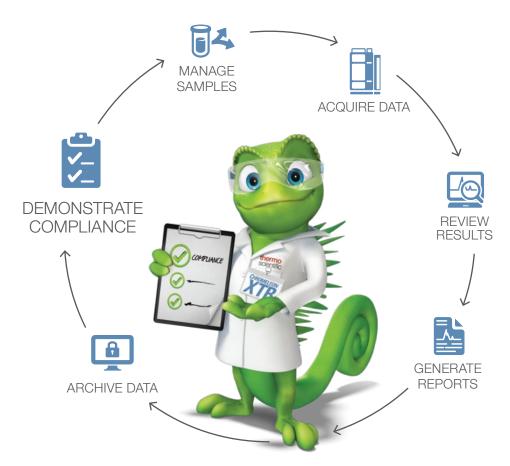
Consistency of system and method performance can be automatically monitored during sample analysis via System Suitability Tests.

Chromeleon CDS provides a flexible straightforward wizard driven route for SST creation, allowing users to incorporate performance checks that are integrated into their daily sequences. In addition to common tests for peak shape and reproducibility, you can include any number of customized tests based on Chromeleon software's extensive set of result variables.

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## Compliance, connectivity, and confidence

Do you have that with your enterprise software solution?



#### Scale up your expectations for your CDS

Expand the capabilities of your laboratory with an enterprise solution, ensuring data security with increased productivity. Utilize electronic records and eliminate paper-based, manual and error prone processes. Automate operations and integrate individual solutions to reduce paperwork, increase efficiency and throughput, reduce costs, foster collaboration and make faster, better informed business decisions.

#### Thermo Scientific<sup>™</sup> Chromeleon<sup>™</sup> XPS Open Access software

Provides a streamlined open access interface allowing any user to run samples with minimal training requirements, while utilizing the full power of Chromeleon CDS in the background.

#### Thermo Scientific<sup>™</sup> Chromeleon<sup>™</sup> CDS software

Offers compliant data acquisition, data processing and data management for your chromatography instruments, making use of superior networking capabilities and automated processes.

#### Thermo Scientific<sup>™</sup> Chromeleon<sup>™</sup> XTR Laboratory Management System software

In addition to your CDS this system delivers secure, compliant control of all analytical data across the lab regardless of instrument vendor or type.

## Thermo Scientific<sup>™</sup> Chromeleon CDS & Thermo Fisher<sup>™</sup> SampleManager<sup>™</sup> (LIMS/SDMS)

Integrate both platforms to provide a single solution that will control your lab processes and workflows, delivering complete laboratory management, data management, and process execution/procedural ELN capabilities.

Learn more about enterprise software solutions.

## Chromatography consumables

## The perfect partner for optimal analytical performance

Thermo Scientific<sup>™</sup> chromatography consumables are designed to complement our innovative range of GC and GC-MS systems together with our autosamplers. Get the most out of the TriPlus 500 HS autosampler by pairing it with advanced, high-performance Thermo Scientific products.

The TriPlus 500 HS autosampler can use 10 mL, 20 mL and 22 mL vials with crimp or screw caps, and flat or rounded bottom, without using a vial adapter. Completing the consumables solution for headspace analysis are high temperature septa and closures. This flexibility ensures full compatibility with existing methods to meet any analytical requirement. Learn more about Thermo Scientific vials.

Thermo Scientific chromatography consumables offer a leap forward in capillary column performance delivering ultra-low bleed, superior inertness for excellent peak shape and sensitivity, and the highest levels of run-to-run and column-to-column reproducibility.

The wide range of vials, septa, capillary columns and accessories offers application-focused solutions that are ideal for pharmaceutical, forensics/ toxicology, environmental, food analysis, petrochemical and general analytical industries.

Learn more about Thermo Scientific chromatography consumables.





# Extend productivity with optional devices

## Improve sample traceability, management and quality

For laboratories in need of complete and continued sample traceability, the TriPlus 500 HS autosampler barcode capability offers a flawless solution, eliminating the need for laborious manual sample tracking. The vials are automatically scanned and the barcode is read before the sample is placed into the headspace oven for analysis, transferring all the relevant information to the data system.

#### Benefits of a multi-format barcode reader

- **Time-savings:** no need to manually log sample information
- **Increased efficiency:** eliminate errors when recording information or tracking samples
- Safer, smoother internal operations: improves sample traceability and management with state-of-the-art technology



Vials are compatible with 1D and 2D barcode formats for more flexibility



TriPlus 500 Headspace autosampler coupled to the TRACE 1310 Gas Chromatograph, highlighting the barcode reader

**HS-GC** integrated solution

The TriPlus 500 HS autosampler is fully integrated with the TRACE 1310 GC and controlled through its wide, color touchscreen user interface. Having direct access to the instrument through the local GC interface is ideal for rapid instrument control, method development and troubleshooting.



#### Reliability for today. Scalability for tomorrow.

Whether you need an entry-level solution with 12-vial capacity or a high-throughput system with up to 240-vial capacity, the modular and fully scalable TriPlus 500 HS platform delivers the throughput you need. The system's basic configuration is easily upgradable to accommodate sample growth over time, yet never compromises on analytical performance.

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- Entry-level solution: 12-vial capacity
- **High-throughput solution:** 120-vial capacity this can be further expanded to accommodate up to 240 vials by adding one vial tray

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TriPlus 500 Headspace Autosampler with 240-vial capability coupled to the TRACE 1310 Gas Chromatograph

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### Comprehensive GC and GC-MS solutions

#### Gas chromatographs

Tailor the Thermo Scientific<sup>™</sup> TRACE<sup>™</sup> 1300 Series Gas Chromatograph to your needs and eliminate maintenance downtime with the proprietary user-exchangeable Thermo Scientific<sup>™</sup> Instant Connect injector and detector modules. Swapping modules for continuous operation is easily done in a few minutes by the user without special tools.



TriPlus 500 HS Autosampler coupled to the TRACE 1310 GC and ISQ 7000 MS systems

#### Single quadrupole GC-MS and triple quadrupole GC-MS/MS systems

With unprecedented sensitivity, ease-of-use and uptime, the Thermo Scientific<sup>™</sup> ISQ<sup>™</sup> 7000 single quadrupole GC-MS and TSQ<sup>™</sup> 9000 triple quadrupole GC-MS/MS systems are truly scalable platforms that empower you to overcome increasingly challenging regulatory requirements and productivity pressure.

#### **Orbitrap GC-MS systems**

An unparalleled level of quantitative and qualitative GC-MS performance can be realized easily and routinely with Orbitrap GC-MS. Thermo Scientific<sup>™</sup> Exactive<sup>™</sup> GC Orbitrap<sup>™</sup> GC-MS and Q Exactive GC Orbitrap<sup>™</sup> GC-MS/MS systems cover all the GC-MS requirements in your research or routine laboratory — from targeted quantitation, and broad scope screening through to compound discovery workflows.

#### Find out more at thermofisher.com/TriPlus500

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