



Solutions for Radiopharmacy

www.lablogic.com

 **LabLogic**
EXPERIENCE & EXPERTISE

LIMS Software

QC Solution

QC Software

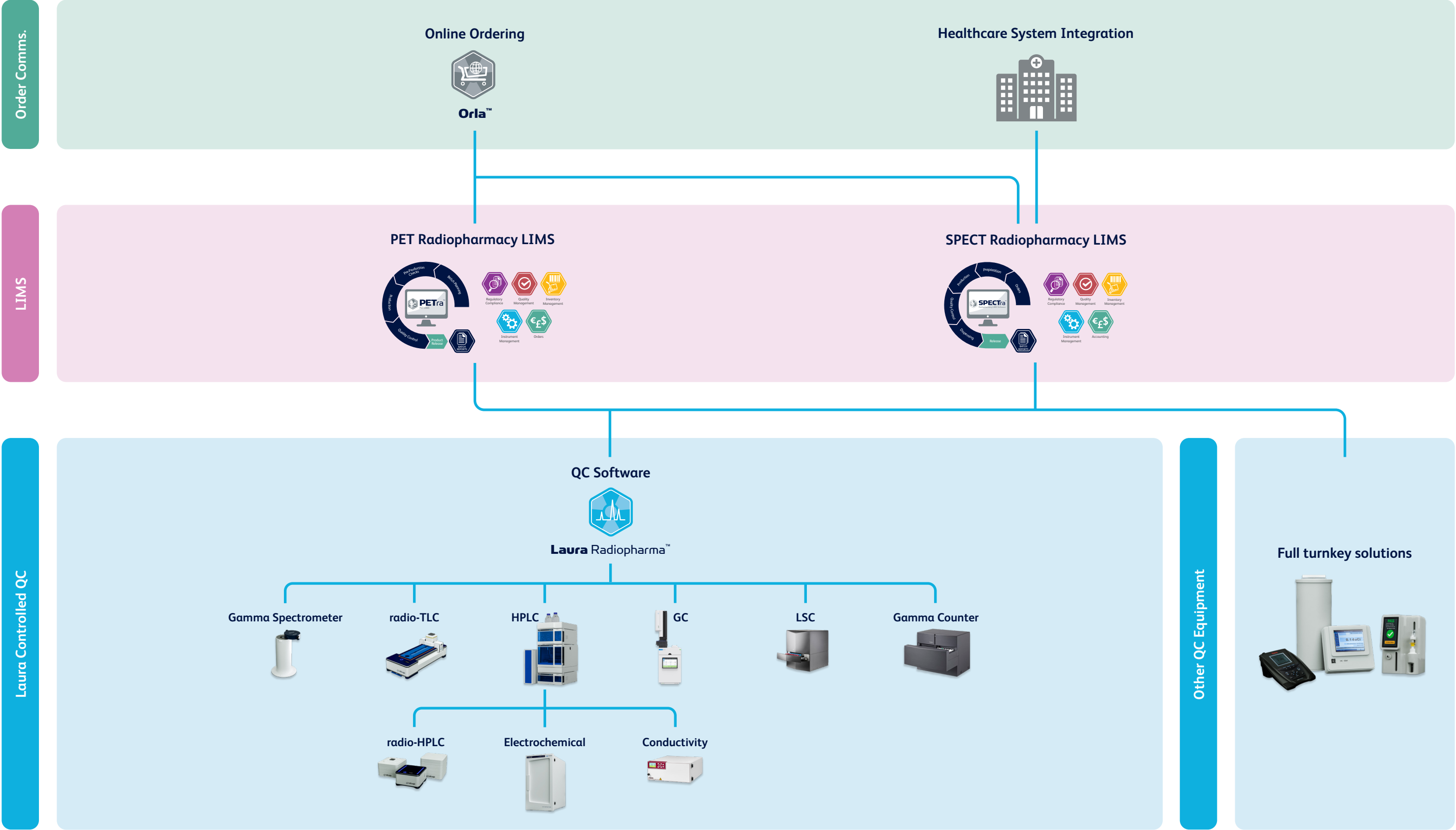
LabLogic QC Equipment

Complimentary QC Equipment

Qualification / Validation and Training

Service and Support

LabLogic products are unique in their seamless integration to one another. Data integrity is maintained from ordering through to production and quality control.



Orla™

Orla™ is designed for efficient online ordering of radiopharmaceuticals directly from customer to radiopharmacy supplier. It can be used as a standalone system or with a bi-directional integration to a LIMS solution.

For the customer ordering the radiopharmaceuticals, it provides a simple and effective way to order products, with full visibility and a full audit trail.

For the radiopharmaceutical supplier, it ensures all orders are received on time, with no missing information, and that no transcription errors are added on their part.

Integrated

- Can have an automated bi-directional integration with PETra™ and SPECTra™, via an on-premises integration service, providing near real-time order upload to the LIMS and status download from the LIMS.
- Integration to third-party software available via the system's REST API.

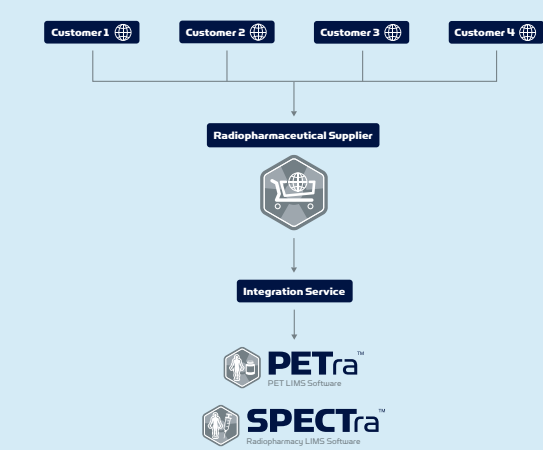
Standalone

- Can be implemented as a standalone solution for radiopharmaceutical suppliers and their customers.
- Order management and customised direct data export via the system's UI.

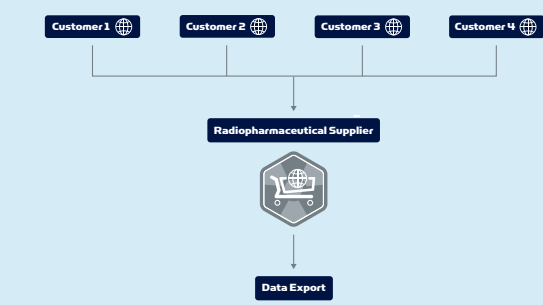
Multi-Site Supplier

- Ability to collect and direct customer orders to suppliers with multiple manufacturing locations.

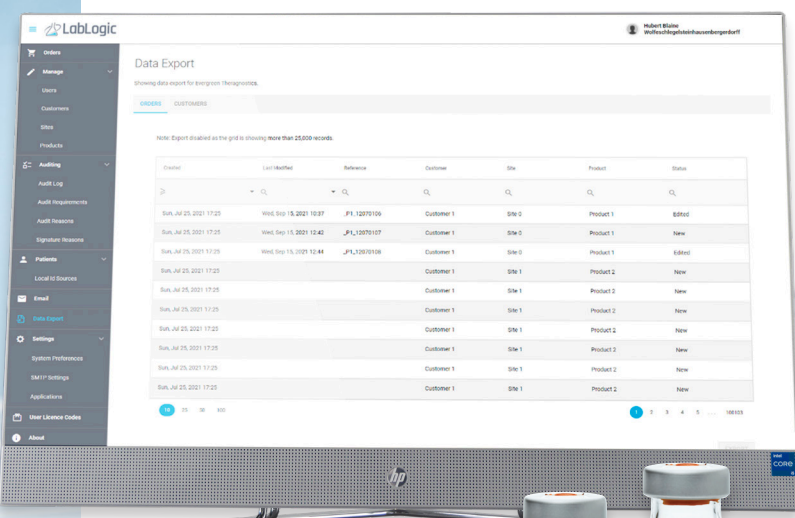
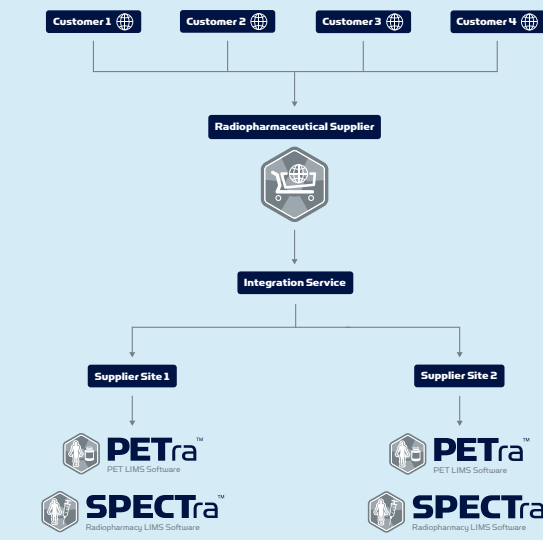
Integrated



Standalone



Multi-Site Supplier



PETra™

A true PET Laboratory Information Management System (LIMS), PETra™ is a batch-driven LIMS designed specifically for use within PET production facilities, in order to improve workflow and compliance.

Optimised workflow efficiency

PETra™ significantly improves operational efficiency by managing data electronically.

- Pre-production checks can be configured in preparation for batch production.
- Configurable design of batch Production, QC and Product Release processes (through Product Method Explorer) ensure logical organisation of batch or sub-batch manufacturing records.
- Multiple-user log-ins allow for batch tasks to be performed and recorded in parallel.
- Trending of batch parameters over time enables further process optimisation, by ensuring that key areas receive the required additional focus.

Materials and Instrument Compliance

- Barcode-driven inventory management (including live status of stock items) ensures use of only approved/released materials in your GMP process.
- Instrument Maintenance / Calibration schedules – ensure equipment is maintained in accordance with your SOPs and that only compliant instruments are used for capturing batch data.

Standardised Production

- PETra™ can be configured for multi-site facilities to ensure the same processes are being routinely carried out, removing inconsistencies.

Data Integrity

- PETra™ is designed to comply with ALCOA+ principles and following the latest ISPE / EMA Data Integrity guidance.
- PETra™ can securely capture data from all equipment and software involved in the manufacture and testing of a radiopharmaceutical product.
- As a result of direct data capture, PETra™ completely eliminates manual transcription, reducing the likelihood of data entry errors.
- Original data and/or true copies are permanently retained in the secure PETra™ database, where they can be accurately retrieved (at any future time).

User Access and Auditing Features

- User access is managed via a unique login ID and password for every user.
- User access to specific PETra™ modules and functionality can be directly linked to users' GMP training and certified functional skill set.
- Electronic signatures and audit trails are configurable, enabling compliance with both Eudralex Volume 4 GMP, Annex 11 and with US FDA 21 CFR part 11 requirements.
- Audit trails allow tracking of all GMP actions via a time/date/User ID stamp. Audit retrieval and review is a simple process, requiring the effort of just a few mouse clicks.



SPECTra™

A dedicated Laboratory Information Management System, flexible for different workflows seen in radiopharmacies worldwide who work with kit based and processing of finished radiopharmaceutical products.

SPECTra™ for Central Radiopharmacy

For central radiopharmacies who send either individual unit doses or multidose vials to their customers SPECTra™ provides an intuitive platform to manage all data throughout the production process. Using Orla customer orders can be automatically integrated from a web page directly into SPECTra™ to improve operational workflow.

SPECTra™ for In-house Radiopharmacy

SPECTra™ can be configured for use within in-house radiopharmacies who want to integrate patient data from their RIS, create unit doses and through to administration to the patient.

Modules

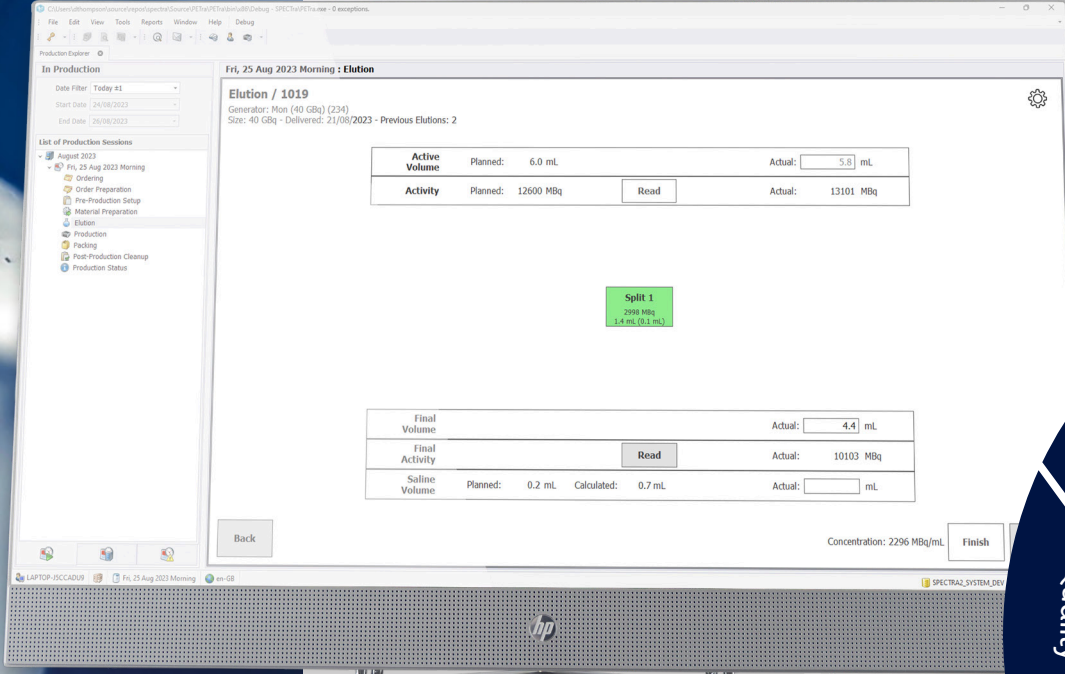
- SPECTra™ shares various modules with PETra™, including:
- Barcode Driven Inventory Management.
 - Pre/Post-Production Checks.
 - Quality Control.
 - Regulatory compliance with electronic signatures, audit trail, user management and training records.
 - Quality Management System with modules for SOP, CAPA, Document Management, OOS, Change Control, Deviations.
 - Trending.
 - Instrument Maintenance.
 - Performance checks.
 - Ordering via HL7.
 - Ordering via Orla.

Whilst having built in workflows for production of various radiopharmaceuticals as either multi-dose vials or individual patient syringes including:

- Tc-99m kit production.
- Other kit-based production (Ga-68 and Lu-177).
- Finished radiopharmaceutical products labelling.
- Blood labelling production.



Inventory Management



Instrument Management



Regulatory Compliance



Quality Management



Accounting



BATCH REPORTS

PET QC Lab Installation

LabLogic offers off-the-shelf and customised traditional QC solutions which address whatever requirements you may have. We ensure your lab is fit for purpose, with hassle-free implementation, using market leading solutions, that are backed by global warranty.

Full Project Management

Our team of experienced staff will fully project manage the whole process using tried and tested methods. Having installed QC labs in many of the world's leading facilities, you can trust us, we know what it takes deliver a successful deployment.

Cost and time efficiency

Having one company supply all the equipment within the QC laboratory offers many benefits, none more so than significant cost and time savings.

Optimise your workflow and compliance

At LabLogic we understand the need for efficient workflow processes and regulatory compliance. To help with this, we design lab layouts and utilise proven solutions to help you achieve these fundamental goals.

On the product front, the Laura Radiopharma™ radiochromatography package offers a single point of control software for all related instruments. Another example is our innovative Scan-RAM™; a system that is available in various configurations. One of these is radio-TLC and radio-HPLC in one system that saves you space and money.



Laura Radiopharma™

Laura Radiopharma™ is the industry standard single point control and data analysis software. It supports over 350 r-HPLC detectors, r-TLC scanners, MCA, GC and HPLC modules from leading manufacturers.

Whether you work within a regulated or academic environment, you will only need to learn one software system for the complete suite of QC instruments.

Compliant

Laura Radiopharma™ can be installed and configured to meet the most rigorous regulatory compliance requirements. Featuring a configurable audit trail, multi level security, e-signatures and data storage into a secure database environment.

Scalable

From a standalone installation to a full client server implementation, Laura Radiopharma™ offers a scalable solution to your data storage requirements. Application and data can be separated across local clients and central servers to match IT requirements.

Easy to use

Wizards guide users through configuring the software in a simple step-by-step approach.

For consistency of data capture and presentation users can lock the configuration of methods, reports, etc.

The **new quick start wizard** below makes completing a measurement as simple as two clicks.

Single point of control

Rather than having several software systems, Laura Radiopharma™ provides a single point of control, supporting over 1,000 instruments including radio-HPLC detectors, radio-TLC scanners, gamma spectrometers, GC and HPLC modules from leading manufacturers.

Signal to Noise Calculation

Whether you work to USP or EP, Laura Radiopharma™ has the option to calculate signal to noise in line with both requirements.

Half-Life Correction

Automatic pass-fail criteria

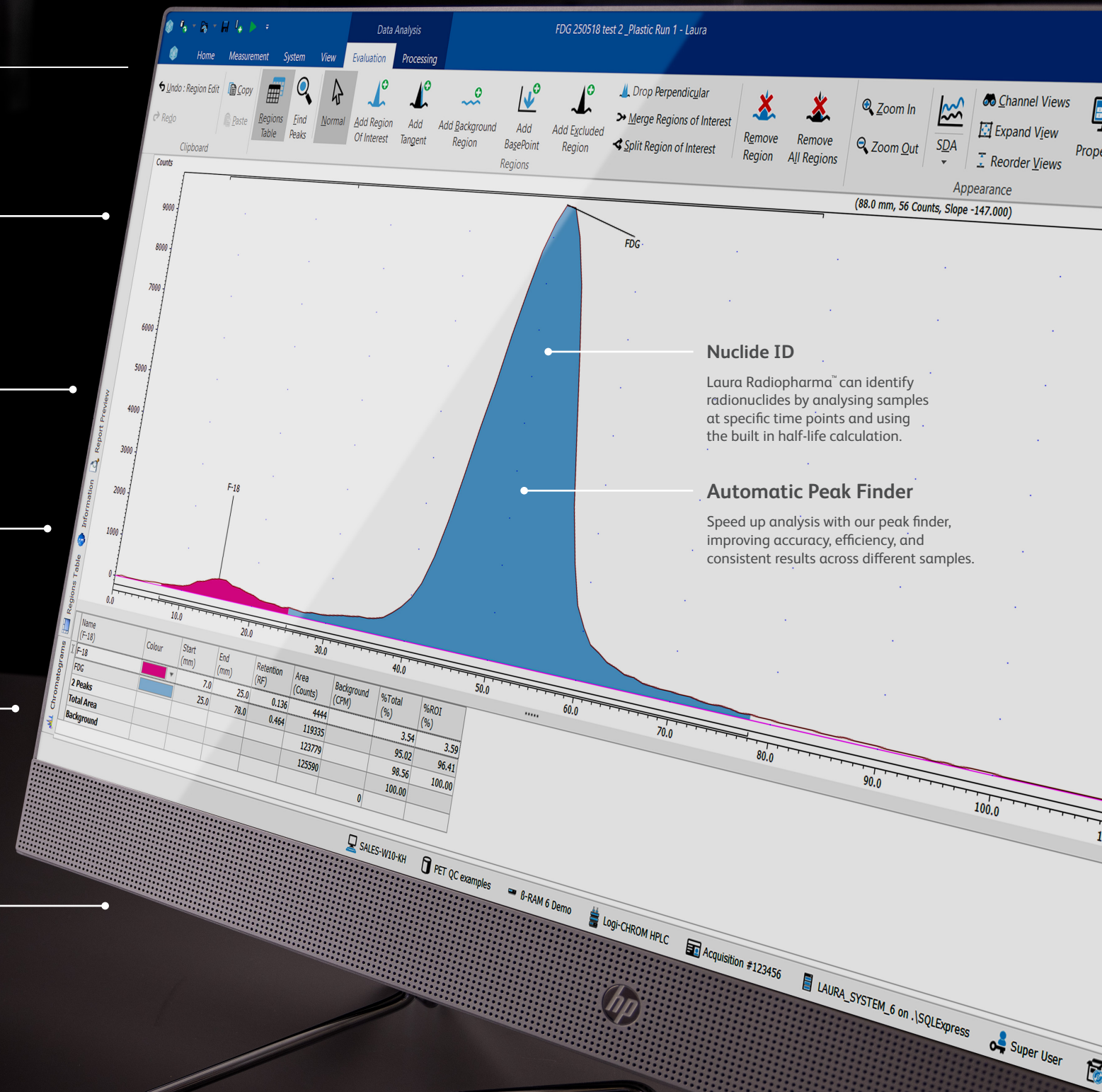
Eliminate subjectivity, save time, and trust in your results.

Digital Signal

Full dynamic range of the detector is processed avoiding limitations commonly seen with analogue signals.

Reporting

Fully configurable to meet needs of Radiochemists.

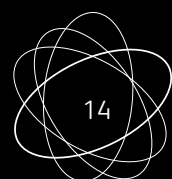
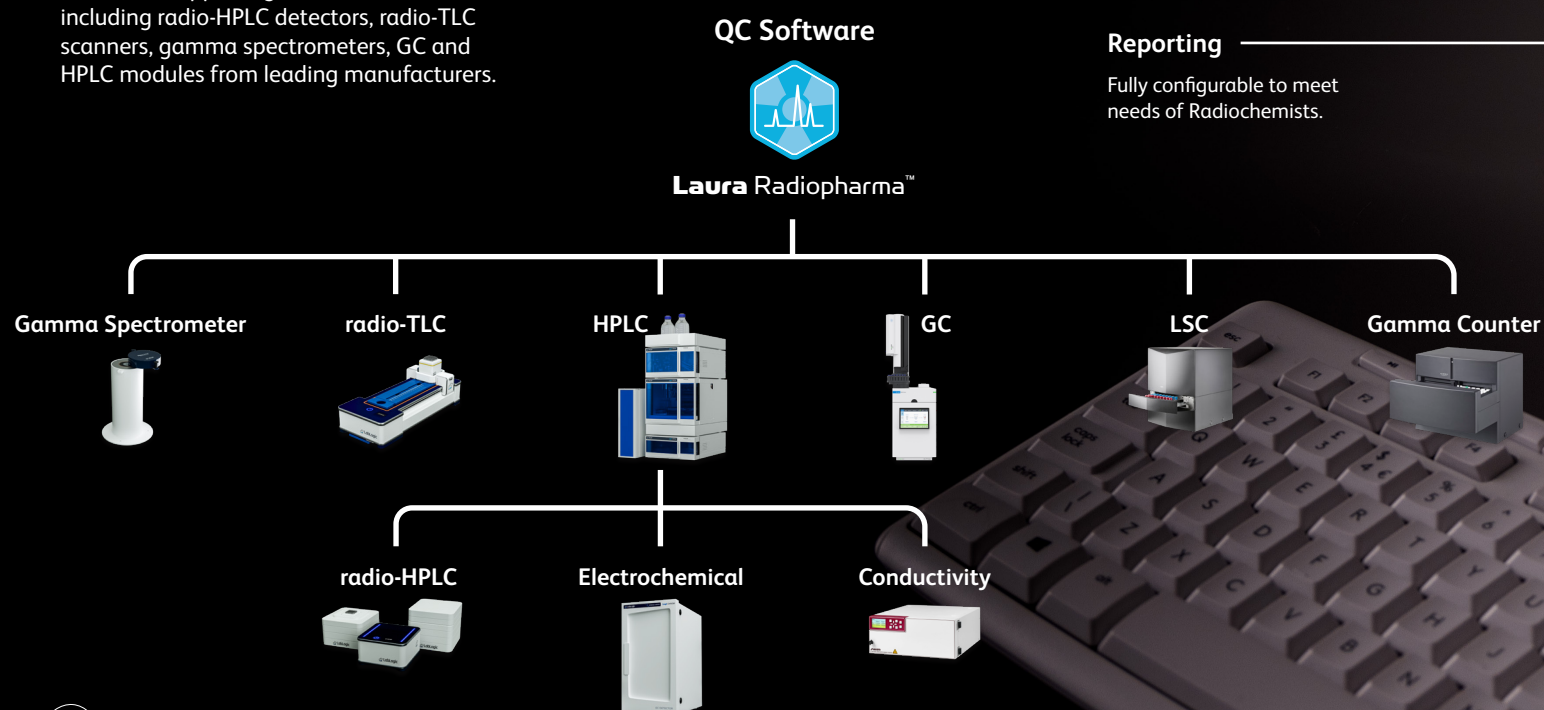


Nuclide ID

Laura Radiopharma™ can identify radionuclides by analysing samples at specific time points and using the built in half-life calculation.

Automatic Peak Finder

Speed up analysis with our peak finder, improving accuracy, efficiency, and consistent results across different samples.



LabLogic QC Equipment

Scan-RAM 2™

The Scan-RAM 2™ is LabLogic's advanced radio-TLC scanner for PET, SPECT, high-energy beta, and alpha radionuclides.

This next-generation model builds upon the reliability and success of its predecessor, offering enhanced counting efficiency and a range of innovative features. With complete control through the industry-standard radiochromatography software, Laura Radiopharma™, and available in six configurations, the Scan-RAM 2™ provides a flexible and compliant solution. It ensures precise and reproducible results for radiochemical purity measurements and beyond.



Scan-RAM 2™

Scan-RAM 2™ Duo

The Duo simultaneously uses a 1" NaI detector for SPECT radionuclides and a Plastic PMT detector for PET and high-energy beta radionuclides to provide the best possible performance.

Scan-RAM 2™ Dual

The Dual is a combined radio-TLC scanner and radio-HPLC detector that can work either simultaneously or independently. By combining two instruments into one it has a reduced footprint.

A single output option is also available.



Scan-RAM 2 Duo™

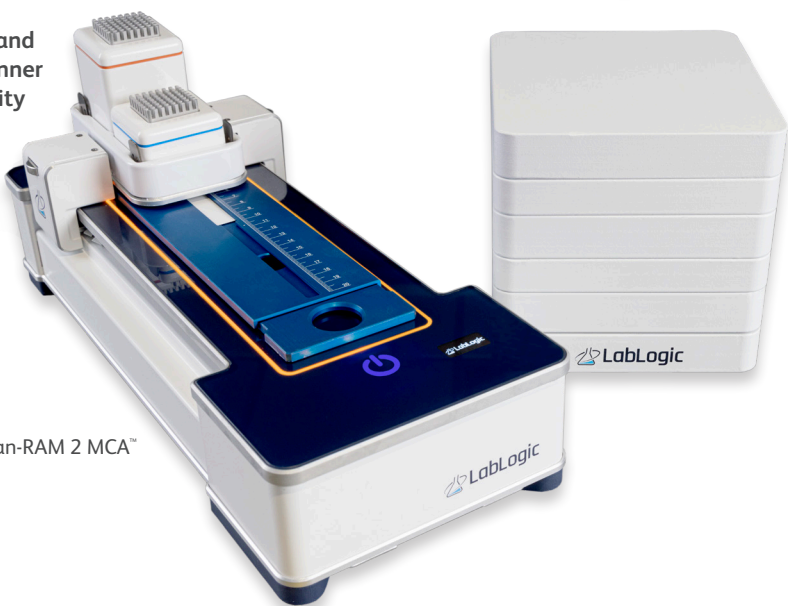
Scan-RAM 2™ All-in-One

The All-in-One combines a radio-HPLC detector and a Multi-channel Analyser with a radio-TLC scanner, allowing users to perform radionuclidic identity and radiochemical purity tests on all radionuclides with high and low energies.

Scan-RAM 2™ MCA

The MCA combines a gamma spectrometer and Multi-channel Analyser with a radio-TLC scanner to allow users to perform radionuclidic identity and radiochemical purity tests in one combined run.

A single output option is also available.



Scan-RAM 2 MCA™



Scan-RAM 2™



Posi-RAM™

Posi-RAM™

Designed specifically for the detection and quantification of low-level PET metabolites in the presence of higher levels of a single substance, therapeutic agent, test compound, or substrate.

Posi-FLOW™

High sensitivity radio-HPLC detector for Beta+ without the need for heavy lead shielding. Utilising a proprietary flow cell, the Posi-FLOW™ is also suitable for detection of Alpha and high energy Beta radionuclides.



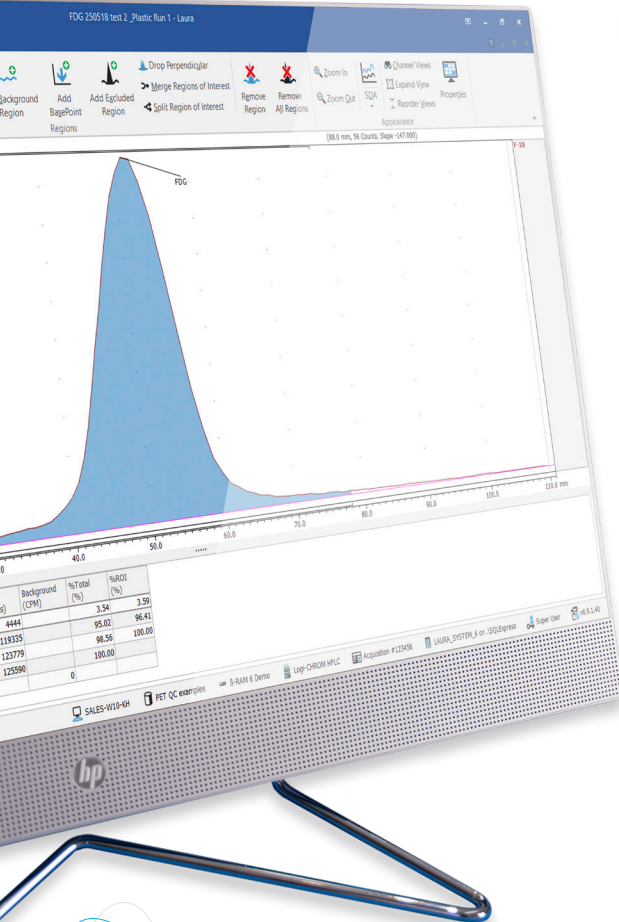
Posi-Flow™

Flow-RAM 2™

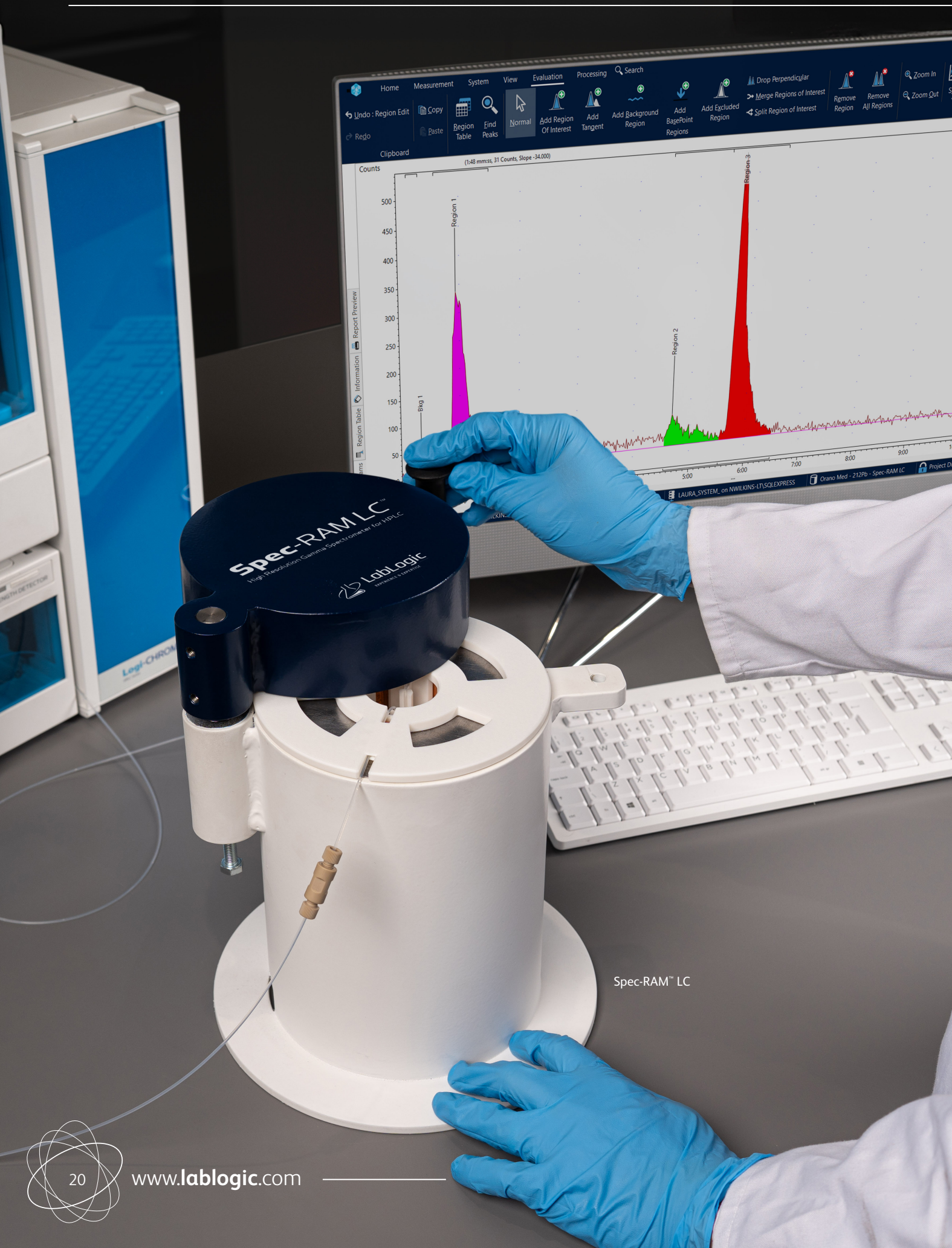
The Flow-RAM 2™ is available in a single or dual detector configuration. In the latter configuration, each of the detectors can be set up independently of each other and used for different applications, if required. With a wide range of detectors suitable for both low and high levels of radioactivity, the Flow-RAM 2™ is an ideal quality control and research instrument.



Flow-RAM 2™



Flow-RAM 2™



Spec-RAM[™] LC

Spec-RAM LC[™]

The Spec-RAM LC[™] uses high resolution gamma spectrometry to analyse the isotopic composition of HPLC eluants. It allows precise window setting and isolation of the signal from the parent isotope, when chromatographic peaks contain daughters. This allows online, instant measurement of radio-chemical purity with no waiting for decay of daughters, no fraction collecting and no manual data handling.

It can also be used as a simple online gamma detector for a wide range of isotopes, or as a benchtop gamma spectrometer for radionuclide identity or purity measurements.

Full control and data analysis is provided by Laura Radiopharma[™] software, which ensures full regulatory compliance and data integrity.

Efficient and compliant

- Integrated 2048 channel MCA.
- Online high-resolution gamma spectrometry (2.5% FWHM at 662 keV).
- Low background <0.2 cps.
- Isolate the signal from parent isotope.
- All system components (including HPLC modules) can be controlled by Laura Radiopharma[™] software.
- Full GMP compliance and fully automated data analysis and reporting in Laura Radiopharma[™] software.
- Small footprint detector (24 cm diameter).
- Rapid and simple energy and efficiency calibration.
- Range of fixed volume flow cells from 50 μ L - 200 μ L. Additional flow cell volumes available on request.

Flexible and precise

- Allows analysis of isotopic composition of HPLC peaks.
- Ideal for isotopes such as Pb-212, where chromatographic peaks can contain parent and daughter isotopes.
- Allows isolation of signal from parent isotope, with no counts from daughters.
- Radiochemical purity measurement is possible immediately, with no fraction collecting and no waiting for decay of short-lived daughters.
- More precise measurement of radiochemical purity.
- High sensitivity – low background gives excellent signal/noise ratio, with detection of low-level peaks at sub kBq levels.
- Single point of control and data analysis if Laura Radiopharma[™] software is used to control your HPLC modules.
- Much less risk of error and improved GMP compliance.
- Intuitive calibration procedure allows rapid system suitability testing and ensures accuracy of results.
- Easily optimised for chromatographic resolution and sensitivity with a range of fixed-volume flow cells.
- Can also be used as an online gamma detector for other isotopes (Tc-99m, F-18, Ga-68, Lu-177 and more).

GMP compliant software for gamma spectrometry

Like all LabLogic instrumentation, the Spec-RAM LC[™] is controlled by Laura Radiopharma[™], our industry-standard software for instrument control that is compliant with global regulations such as FDA 21 CFR Part 11 and EU Annex 11. The introduction of compliant software to gamma spectrometry facilitates easier validation for sites while improving workflow efficiency.

Features include:

- Full audit trail.
- User defined access levels.
- Electronic signatures.
- Secure database.
- Multi-level security.

Maintaining data integrity

Laura Radiopharma[™] is seamlessly integrated into LabLogic's LIMS such as PETra[™] and SPECTra[™], allowing captured data to be instantly populated. This integration between the software packages preserves data integrity in accordance with ALCOA principles.

Spec-RAM™

An ideal solution for spectroscopic analysis of samples with low radionuclidic activity (ascertaining radionuclidic impurities in the sample), the Spec-RAM™ is a high-performance fully integrated detector and multi-channel analyser solution that contains everything needed to support scintillation spectrometry.

With its simple and intuitive operation, Spec-RAM™ is the perfect solution for radiopharmacies.

Spec-RAM CZT™

Designed for radionuclidic identity and radionuclidic purity measurements, the SPEC-RAM CZT™ is a benchtop gamma spectrometer with GMP compliant software.

The SPEC-RAM CZT™ offers a cost-effective alternative to High Purity Germanium (HPGe) detectors, making it the ideal solution for medical radioisotope producers, radiopharmacies, and research facilities when identifying any impurities or contaminants present in a sample.

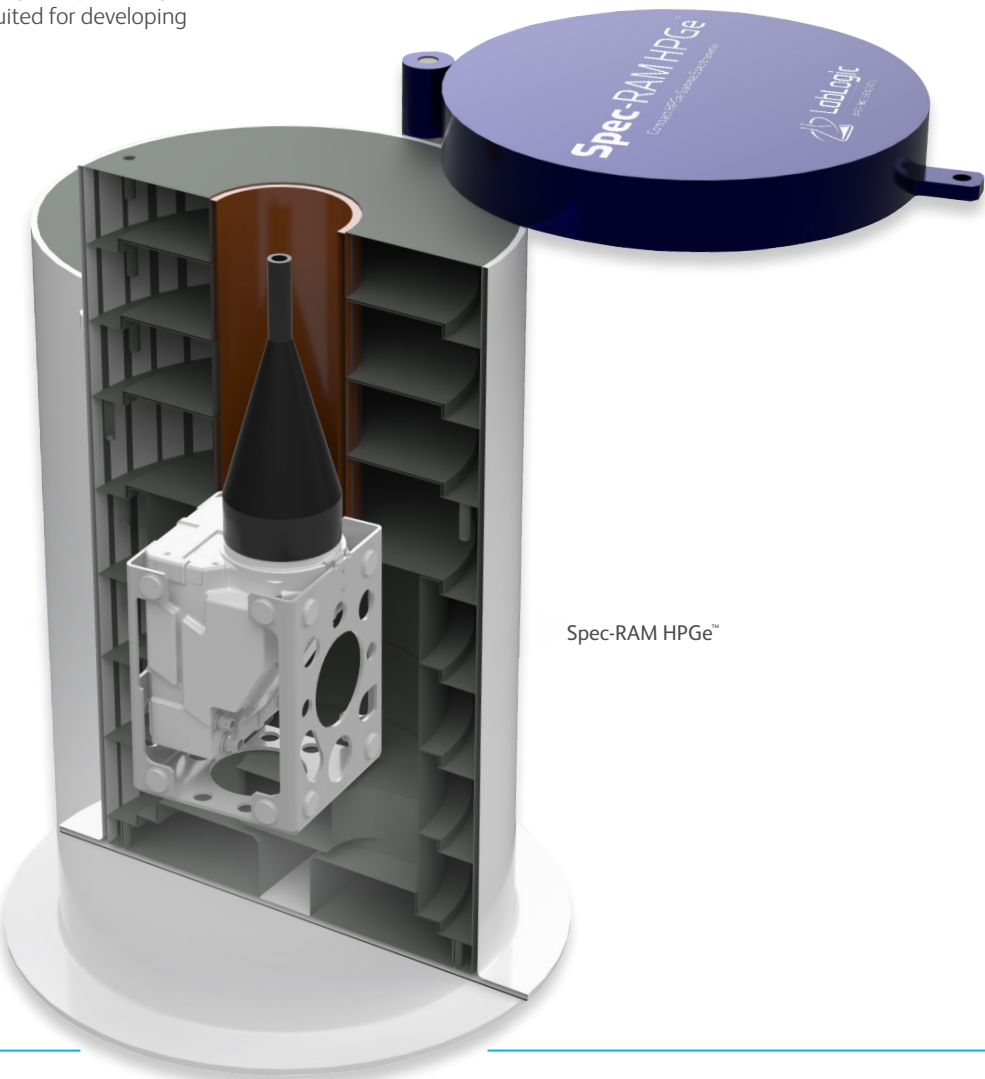
Spec-RAM HPGe™

HPGe is the gold standard of gamma spectrometry due to its exceptional resolution. However, traditional HPGe gamma spectrometers are mostly large, overcomplicated, and do not include GMP compliant software, and can be costly to run.

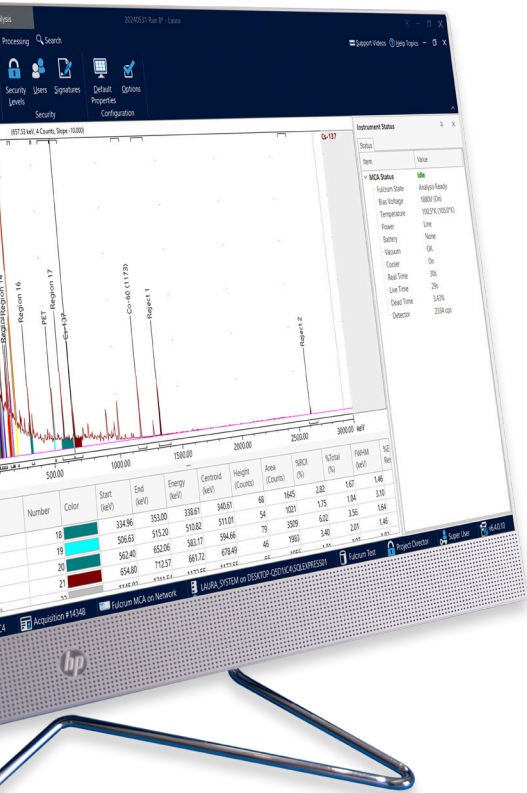
The Spec-RAM HPGe™, is a compact solution designed specifically for nuclear medicine applications and ideally suited for developing novel tracers and working with alpha-emitters.



Spec-RAM™



Spec-RAM HPGe™



Spec-RAM CZT™

EC-Detector

LabLogic's Logi-CHROM™ Electrochemical Detector has been developed to meet the demands of fast analysis, with excellent detection sensitivity, acquisition frequency and an integrated temperature-controlled compartment.

This detector is the ideal solution for all HPLC applications that routinely use electrochemical detection.

Logi-CHROM ONE™

Logi-CHROM ONE™ has been developed specifically for radiopharmaceutical quality control which requires a small footprint and simple to use solution for radiochemical purity testing.

We have used our experience and expertise in supplying radio-HPLC systems to nuclear medicine environments to develop a simple solution with a significantly reduced footprint.

We have combined the most common HPLC modules into one compact system including a Low Pressure Gradient Quaternary Pump, a UV Detector and a Flow-RAM radio detector.

Logi-CHROM™

Logi-CHROM™ HPLC modules, are a recent addition to LabLogic's radiochromatography range. Compact, cost effective and fully integrated within Laura™ software, Logi-CHROM™ is available as a standard HPLC or UHPLC.

These systems are flexible in many ways, offering a range of materials, flow rates and complexity levels. Logi-CHROM™ accomplishes your demanding analytical tasks with a selection of detectors, pumps, and columns.

EC Detector



Logi-CHROM™



Logi-CHROM ONE™





Capintec CRC-55tR

Complimentary QC Equipment

LabLogic also provide a range of products to complement our QC instruments and software. Sourced from leading manufacturers, these products enable us to offer a complete QC solution and can be controlled by our LIMS software packages.

Analytical Balances

Whether is determining the difference between initial or residual weights or calculating the density of solids and liquids, we supply a range of precision balances which are ideal for laboratory use.

Cooled Incubators

The cooled incubators which we would recommend are state-of-the-art in application and provide complete protection of samples.

Conductivity Detectors

Conductivity Detectors feature a multi-electrode flow cell that offers exceptional sensitivity and stability for single-column or suppressor-based ion chromatography.

Dose Calibrators

Designed to meet the demands of your department with accuracy and ease of operation, the dose calibrators that we can provide offer reduced chamber pressure and increased bias voltage, increasing the maximum activity range for high energy isotopes.

Filter Integrity Testers

The iPhase Filter Integrity Tester is a compact standalone bench-top unit capable of fully automating the process of bubble-point testing commonly used vented and non-vented sterilising filters used in radiopharmaceutical quality control.

Gas Chromatographs

Agilent GC's are an excellent choice for any laboratory where bench space, ease of use, and independent channel flexibility are important.

Gamma Counters

Our gamma counter recommendation would be the Hidex AMG. Specifically designed to meet the needs of modern laboratories, the Hidex AMG's touchscreen operated software and application-focused design delivers effortless workflow and provides results quickly and efficiently.

'Hybrid' Cryostats

'Hybrid' cryostats combine the advantages of electric cooling with the reliability of liquid nitrogen.

HPLC and UHPLC Systems

HPLC and UHPLC systems are suitable for a broad range of analytical, bio-analytical, purification and other specialised workflows.

Lab Ovens

A range of highly efficient, reliable, cost effective units to suit most drying, warming and general laboratory applications.

Laminar Flow Isolators

For applications where you are concerned about process generated particles we can provide a range of Laminar Flow Isolators to suit your needs.

L-Block Shields

Designed for receiving and preparing unit doses of high-energy radionuclides, these L-Blocks provide a 2" thick lead shielding in front with an integrated glass window, and 1" thick lead in the base.

pH Meters and pH Strip Readers

We can offer a range of reliable portable pH meters which ensure precise testing and analysis of samples.

We also supply pH Strip Readers which simplify testing procedures and the decision process by eliminating the subjectivity of visual readings and by providing higher accuracy.

Radiosynthesisers

The iPhase compact multi-synthesis Radiosynthesisers allows the user to standardise and simplify a labs radiochemistry requirements with one versatile synthesiser.

Refrigerators and Freezers

We can supply a range of pharmacy fridges and freezers, which offer a high degree of safety and security for cold chain pharmaceutical storage.

Spectrophotometers

We can provide a rapid, point-of-use handheld spectrophotometer that uses USP/BET-compliant disposable cartridges for accurate, convenient, and real-time endotoxin testing, glucan concentration determination, and Gram identification.

Water Baths

Water baths are used to incubate samples in H₂O maintained at a constant temperature. Our range of water baths are ideal for lab-based applications.

Water Purification Systems

Designed to meet or exceed Type 2 water quality (corresponding to analytical-grade water), these water systems use potable tap water as feed to produce consistent, high quality pure water for all your lab's needs.

Tailored solutions to meet your needs

Our specialists can guide you through the qualification and validation process to ensure your systems are set up and in service in a timely manner.

Qualification / Validation

Get your systems implemented quickly and with minimum effort using LabLogic's range of validation services.

As focused industry specialists, our validation specialists incorporate years of experience in GLP/GMP system validation, detailed knowledge of our systems, together with other industry standard systems to help you meet company and regulatory requirements.

Many highly regulated environments require software and instruments to be qualified with respect to installation (IQ), operational (OQ) and performance (PQ).

Installation / Operational Qualification

All installations performed by LabLogic, whether software or hardware, can include an IQ/OQ service. LabLogic has tried and tested qualification scripts for all products, saving our customers valuable time and effort.

Our team of engineers and specialists have many years experience in successfully performing qualifications in numerous facilities around the world. Use of these services has proven to be the quickest and easiest way for many customers to get their systems installed, qualified and in use.

Depending on the regulatory guidelines being worked to, regular requalification of systems may be required. LabLogic can provide this service, which is often available at a discounted rate as part of a service / support contract.

Performance Qualification

LabLogic can streamline the PQ process; we will work with you to understand your procedures and create suitable documentation for your systems.

Bespoke Services

LabLogic can provide expert guidance with bespoke qualification / validation services to meet the individual customer needs. We work as a partner with your Quality Manager, System Manager and users to provide a tailored validation plan suited to your needs.

Training

Our fully certified training courses are delivered by product specialists and are available as off-the-shelf or bespoke packages to suit your needs.

Training delivery can include a variety of methods and materials including:

- Interactive classroom presentations.
- One-on-one training.
- Laboratory hands-on demonstrations.
- Group exercises and practice.
- Proficiency tests.
- Training guides.
- Training videos.
- Webinars.
- Pre-configured training laptops.
- Off-site training options.

Introductory Training

Every installation that we perform is accompanied by a product familiarisation training session. This takes users through the basic functions of the system to ensure they are able to start using it quickly and effectively.

New User / Refresher Training

We recognise that as staff changes occur, system knowledge is often either lost, forgotten or diluted. This can result in inefficiencies, or the system not being used to its full potential. To avoid this, we recommend regular refresher training, both for existing users and also for new users who are unfamiliar with the system.

If customers' systems have been upgraded since the initial introductory training, refresher training can also incorporate details on new features and functionality.

System Manager Training

All systems require an on-site system owner or manager who is responsible for configuration and ongoing maintenance. We will provide assistance and training during initial setup of the system, including security setup, user management, library and settings configuration and regulatory compliance.

Regulatory Compliance

LabLogic has many years experience in implementing software and hardware solutions into regulated environments. We are experts in GLP and GMP and can provide guidance on how to use your products and systems in a compliant manner.



Minimise downtime and maximise reliability

At LabLogic, we understand the need for outstanding services to allow customers to use our products quickly and easily, minimising downtime and maximising reliability.

Our team of product specialists, engineers and software developers provide unrivalled experience and expertise in the delivery of a complete range of after sales services.

If you need expert advice or assistance, help is only an e-mail or phone call away.

Software

Support Contract

A support contract gives you the ultimate technical support capabilities, with immediate answers to any questions you may have. It future-proofs your investment by providing free and discounted upgrades, as well as priority implementation of new feature requests.

Software Development

Customers on a support contract can directly influence the development of the software. We are able to prioritise requests for change from customers with a support contract; we work with you to add new functionality and build the system around your needs.

Technical Support

Our team includes experienced help-desk professionals who can offer support by telephone and e-mail, as well as remote online assistance.

You will have unique access to the developers who write the software, our Quality Assurance personnel who can advise on validation requirements, as well as industry specialists, who are renowned for their knowledge of our products and their applications.

Free Upgrades

Customers on a support contract are entitled to free releases within a specified major version (e.g. Laura 5, Debra 6). Each release is accompanied with detailed software release note documentation, enabling customers to track changes and identify the benefits of implementation of the new release, as well as getting guidance on appropriate validation and testing of the change.

Future-proof your software; upgrades to new major versions are available at a significantly reduced cost to customers on a support contract.

Equipment

Service Contract

Our all-inclusive service contracts offer ultimate peace of mind. We pro-actively schedule preventative maintenance (PM) visits and will take care of all repairs at no additional cost.

As well as providing contracts for LabLogic equipment, we can also simplify your service needs by supplying cover for related third party equipment in your laboratory.

Preventative Maintenance / Qualification

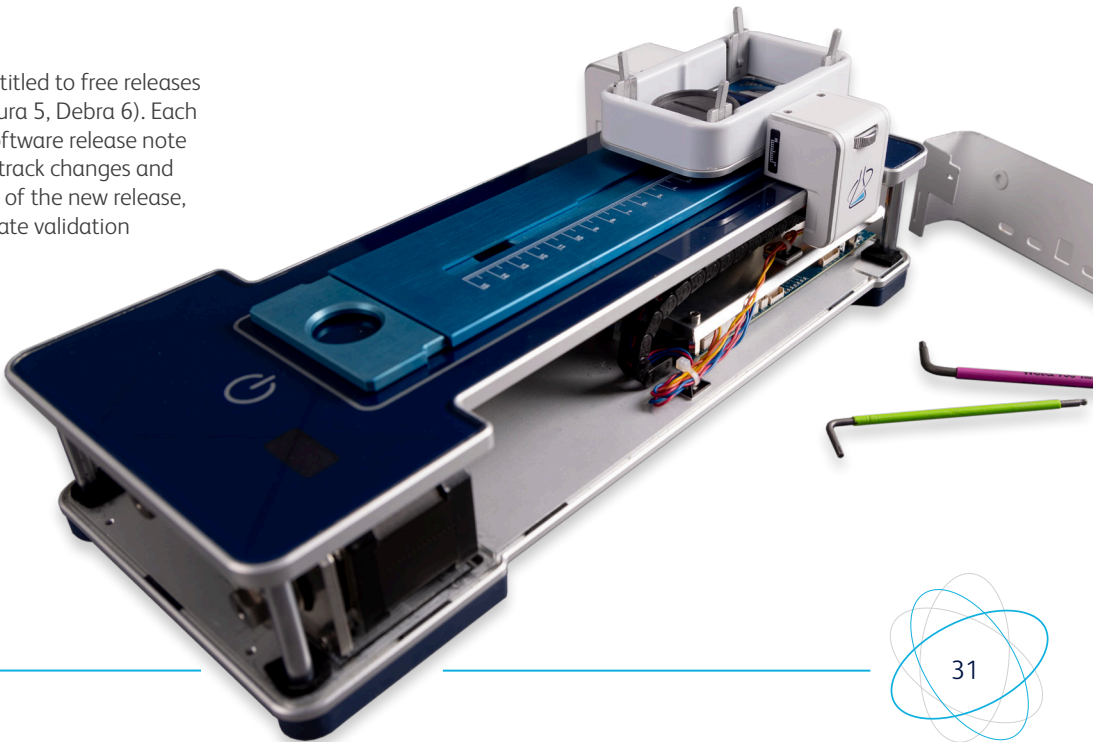
LabLogic can provide a maintenance service and qualification on all our equipment, and many third party systems that work in conjunction with LabLogic products.

Repairs

If you have a problem or fault with your instrument, our engineers will diagnose and repair the fault. We also have fully equipped service centres where instruments can be repaired, serviced and calibrated by our qualified personnel.

Third Party Service

LabLogic provide a full range of services and contracts on associated third party equipment.





Visit our website



Download the brochure



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LabLogic

EXPERIENCE & EXPERTISE



Certificate No. 1535
ISO 9001

INVESTORS IN PEOPLE
We invest in people Gold



Certificate No. 10526
ISO 9001