HIPER-FDG

HIGH PERFORMANCE RADIO HPLC FOR F18-FDG QUALITY CONTROL

OPTIMIZED FOR ROUTINE F18-FDG QUALITY CONTROL

- ✓ IMPROVE COMPLIANCY
- ✓ GAIN TIME & SITE RESILIENCE
- ✓ INCREASED RADIATION PROTECTION
- ✓ HIGH PERFORMANCE MEASUREMENT

The Hiper-FDG is a radio-HPLC specially designed for the complete HPLC analysis of F18-FDG. The Hiper has two built-in High Performance radioflow detectors optimized for PET tracers' analysis. The double flow detection, combined with an internal shielding, ensures a low background noise and, combined with Gina X, allows to determine the column output radioactivity recovery rate. The Limit of Detection is about two times better than with a classical 2x2' NaI setup. The system includes a column lead shielding, two injectors to increase radioprotection, and site resilience.

Radio HPLC is a crucial and powerful tool for the development and the quality control of radiopharmaceuticals. Our Hiper radio-HPLC represents the latest enhancements in flow detectors for Radio HPLC.

This setup does not require active cooling and is an optimal compromise of resolution vs. sensitivity which makes the systems the perfect choice for the measurement of radionuclidic impurities when the potential impurities profile is established.

Improve compliancy

The Hiper has been designed to be GMP / GLP / CFR part 11 compliant. It is optimal to perform the quality control of 18F-FDG and some other PET tracers according to the European pharmacopeia, the British Pharmacopeia (BP) and the (CMC) section from United States Food and Drug Administration (US FDA) PET draft guidance documents.

For full GMP compliance and complete documentation we thoroughly control the Hiper with our chromatography software (Gina X). This combination allows a fully digital signal transfer and a complete integrated solution facilitating GMP/GLP compliance.

Control and recording of active carbonation protection of the mobile phase. For 18F-FDG application, the NaOH mobile phase protection from carbonatation is achieved by applying an overpressure with an inert gas to avoid CO2 entry in the mobile phase bottle. The overpressure is regulated through a digitally controlled valve linked to a pressure meter. By this approach, the overpressure applied is controlled and recorded in the software, optimizing documentation, reducing gas consumption, increasing GMP documentation and detecting automatically a problem with the gas flow.

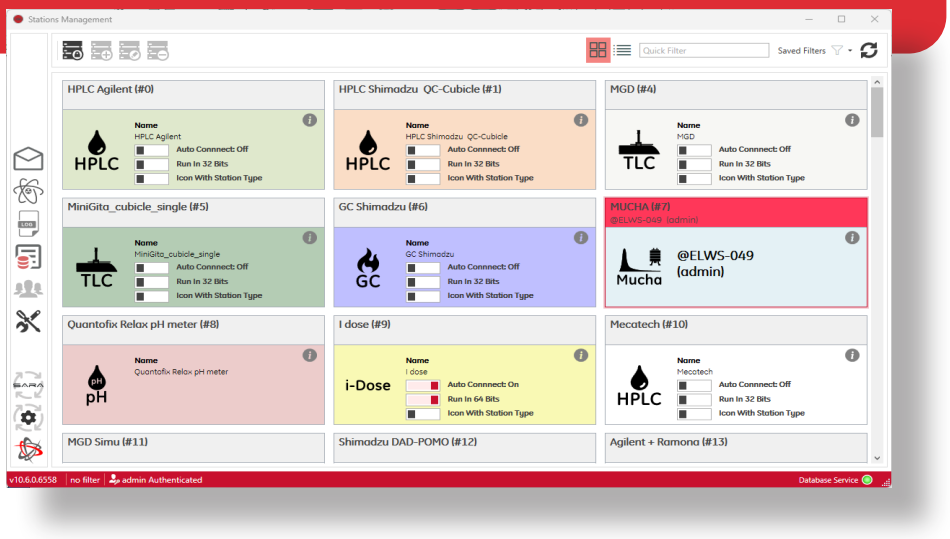
ELYSIA RAYTEST

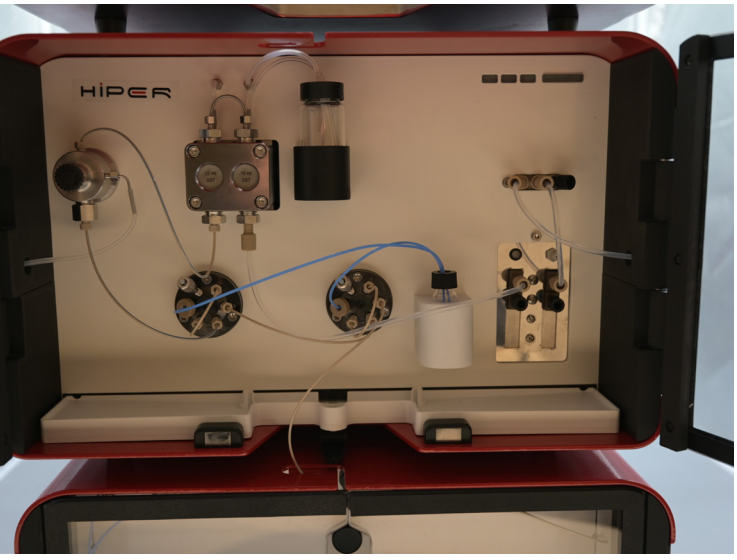
Gain time & site resilience

The Hiper has dedicated features allowing the user to save time. The typical Hiper runtime to assess the radio chemical purity of 18F-FDG is ~15 minutes (European pharmacopeia method). The Hiper has two electric injection valves allowing to preload a standard and a blank and schedule their injection and run before the radioactive QC sample availability, without the need of an operator in the QC room. The system suitability function in Gina X will ensure readiness of the system before proceeding to these injections.

The timing option in GINA X 11.0 allows to plan the injection of the different samples (blank and standard) and allows to inject automatically the samples, for instance overnight. The system will run the standard and the blank without the need of an intervention of the user. You could prepare the HPLC in the evening before you leave the lab and the next morning the blank and standard run would just have finished when you arrived, and the system would be ready for the injection of the QC sample. From our long experience with quality control of PET tracers, we know that one of the main reasons for HPLC system downtime are problems with injection valves. We equipped the Hiper with a second injection valve for redundancy and ensuring continuity of your operations.

The internal dual detectors, used to determine the column output radioactivity recovery rate, also offer a fallback position in case of problems with the post column detector, as the pre-column detector can be reconnected to take over post-column detection.





Increased radiation protection

To increase the radiation protection, we have added several shieldings into the system. The entire column compartment is shielded by 1 to 2 cm of lead, reducing significantly the dose rate received by the operator.

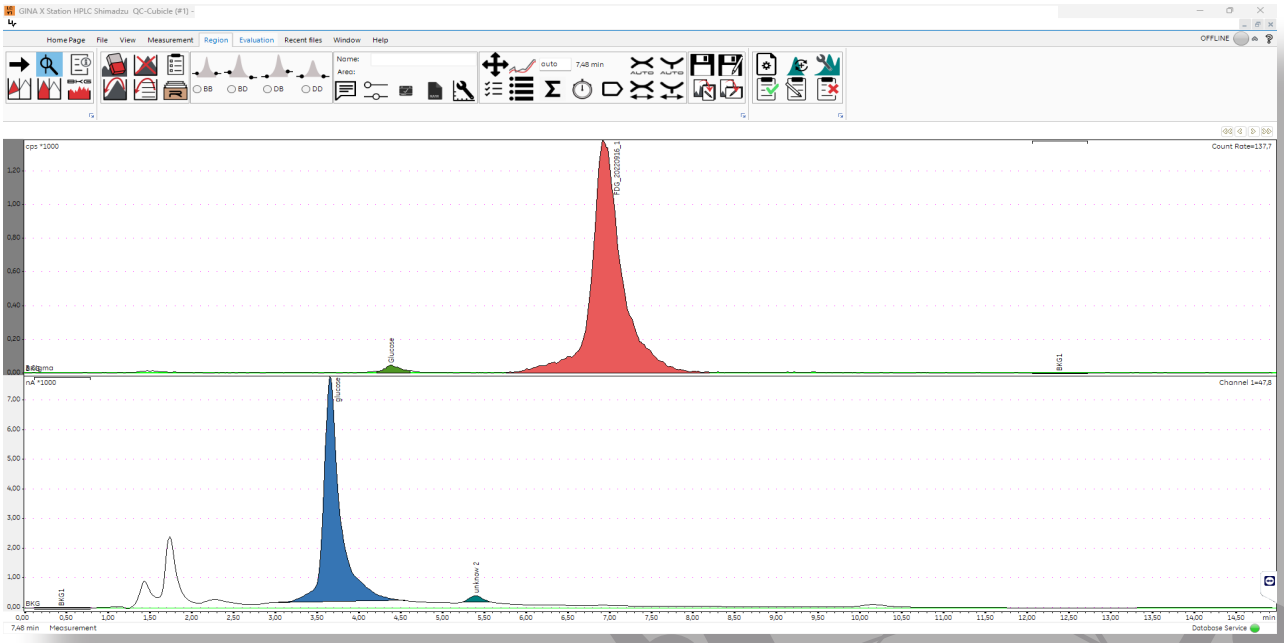
The overflow vial connected to the injectors, as well as the waste bottle (WABO option), is also shielded to reduce the operator exposition. Finally, the Ethernet control gives you the possibility to control the Hiper out of the laboratory or the office and to reduce the time spent in front of the HPLC.

High performance measurement

The built-in double ultra-low background detector ensures the best measurement performance. Hiper uses two highly sensitive detectors, allowing a low gamma response, providing unique detection capabilities for PET isotope (F-18, C-11, Ga-68, N-13, Cu-64 ...) or high energy Beta emitters (Lu-177, Tb-161, Y-90, I-131...) and ensures, in combination with the internal flow cell shielding, a low background noise and the best limit of detection values.

The internal setup allows shorter distance from the column to the detector, increasing the radiation safety, and minimizes the dead volume, resulting in sharper peaks and better resolution. The GINA X software is tailored for radio-HPLC applications and has special features related to typical problems and challenges of radio-chromatography, such as half-life-time correction, specific radioactive background subtraction or a unique powerful suitability function that allows to check the quality of the different signals before injecting the sample (pressure value and stability), UV or RID detector noise and drift, radio-detector noise, ...

The double flow detection allows to measure the column output and to determine the column radioactivity recovery rate.



Specifications

Technical

The system is composed of

- Solvent bottle tray
- Inert gas pressure regulation and monitoring system to avoid 18F-FDG mobile phase carbonatation (NaOH 0.1N)r (1 line)
- Isocratic pump (a quaternary pump is optional)
- Refractive index detector
- Double Ultra-low background Radio-detectors
- For PET radioisotopes and high energy Beta emitters

Isocratic pump

- Pump pressure: up to 850 bar
- Flow rate: 0.001-10ml/min
- Degasser
- Automated seal wash
- Enhanced Biocompatibility
- 2 Automatized injectors
- 2 sample loops
- Injection volume 20µl (other loop size on request)

Refractive Index Detector

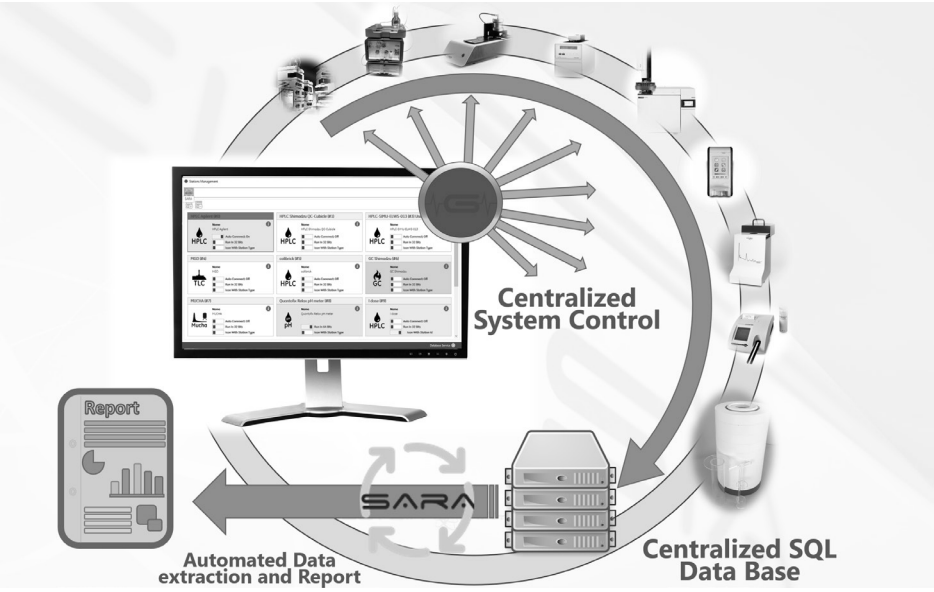
- 2 counting channels (one per detector)
- Linearity: 0 – 1.500.000 cps r2 >= 0.99
- Sensitive differential refractometer
- Optical unit with advanced temperature control
- Fast baseline stabilization
- Excellent reproducibility
- Wide linear dynamic range
- Low internal volume of <45 µl

Radio detector

- Typical background: <= 1 CPS
- Count rate: 0 – 2.500.000 cps
- Linearity: 0 – 1500.000 cps r2 >= 0.99
- Sensitivity: LOQ of 350 Bq (Ga-68 analysis)
- Data outputs: USB2.0, 10/100 Ethernet, 2 Relay outputs (potential free SSR)
- Radio-Flow cell volume: 5 µl

Physical

- Dimensions 515 mm W x 390Xmm D x 510mm H (without bottles)
- Weight 40kg



Headquarters : Elysia s.a.
Rue du Sart-Tilman 375
4031 Angleur - **Belgium**
Tel : +32 4 243 43 50
info@elysia-raytest.com

USA office: Elysia-raytest USA inc.
4302 SW 73rd Ave
Miami, FL 33155 **- USA**
Tel : +1 786 230 1067
info.usa@elysia-raytest.com

Production : Elysia-raytest GmbH
Benzstraße 4
75334 Straubenhardt - **Germany**
Tel : +49 7082 9255 0