GAIA V2

PEPTIDE LABELLING FLUIDIC PROCESSOR

QUICK AND EASY SYNTHESIS CONTROL FOR PEPTIDES AND RADIOMETALS (^{68}Ga, ^{90}Y, ^{177}Lu, ...)

- CAN BE CONNECTED TO ANY GENERATOR (*)
- MINIMIZES DOSE COSTS
- EASY AND INTUITIVE HANDLING
- COMPACT DESIGN

Gaia V2 is the second generation of our synthesis unit for the labeling of peptides such as DOTA-TOC or PSMA with radioactive metals (e.g. 68Ga). The design was reworked to reduce the size to a maximum and optimized to provide a fast, simple and intuitive production of common radio tracers. The position of the connections has been modified to reduce the need for space in the Hot Cell and to improve the accessibility for maintenance.
A large list of specific methods and synthesis kits is available and new methods can easily be adapted. The Gaia V2 is fully compatible with the labelling kits and methods of the Gaia 1.

(*) Gallileo, E&Z, ITG, ITB Ithemba generators can be used with GAIA, for other generators please contact our technical service.

ELYSIA RAYTEST

Reduce costs and increase efficiency

With its new compact design, optimized electrical connections reduced to a minimum and smooth surfaces, the device is easy to handle and to clean. Thanks to the economic application of single-use materials, running costs are minimized.

The entire module has been developed to reduce cost per dose. To reach the goal we have implemented:

- Short synthesis time, minimizing yield loss due to decay
- No need of gases
- High performance electrical heating module for faster and efficient labelling
- Multiple radio detectors to enhance labelling processes, allowing efficient product quality review (trend detection)
- Integrated filter integrity test to reduce QC time and cost
- Simple and robust mechanics to reduce down time and maintenance costs
- Functional units (pump, valve gears, reactor...) can be exchanged in just a few simple steps.

Easy and intuitive handling

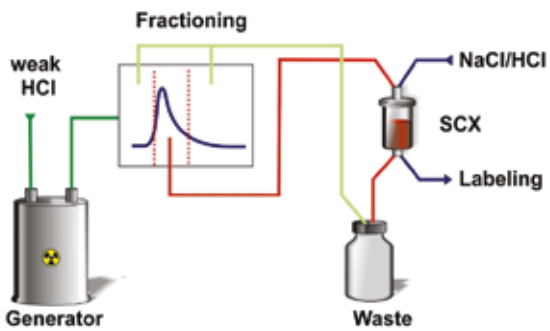
Both soft- and hardware have been designed for easy and intuitive handling, without the need for long training, enabling the user to use the system directly after installation.

- Touch controlled User Interface.
- Quick and easy synthesis control & evaluation
- Fully interactive method editor
- Graphical editor for process layout, timetable with graphical displays of flow paths, SPO editor, report generator and full user management.

Pre-installed methods

The main application of GAIA V2 is the labeling of peptides with ^{68}Ga. After the elution of the ^{68}Ga / ^{68}Ge generator, three different procedures can be implemented depending on the type of generator and on local regulations:

- labeling with the eluate without previous cleaning
- labeling with the eluate after fractionated elution in order to separate other metals
- trapping and elution of 68Ga with efficient separation of other metals

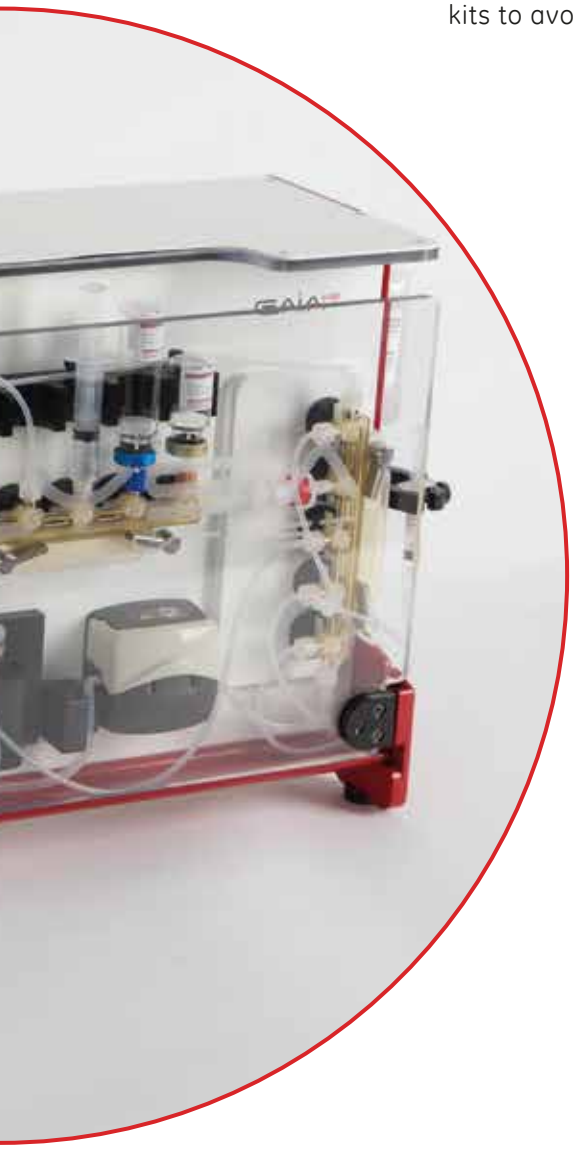


Self-testing

Once a kit is loaded, the system performs an automated self-test to detect possible material or manipulation errors. Tests cover functions such as interaction and position of the valve gears, reactor temperature, radio-detectors, pump driving speed, pump lid, door status or communication with the PC system.

Operation and software

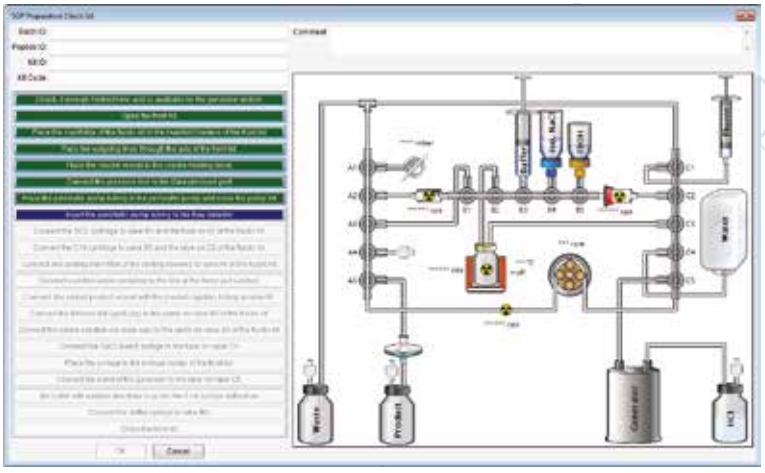
The operation of Gaia V2 was optimized in order to obtain the fast and simple production of common tracers. All components in contact with reagents are part of single use kits to avoid cross or bacterial contamination and to fulfill GMP needs.



After each synthesis run the kit is disposed; a cleaning procedure is not necessary. Therefore different tracers can be produced under GMP conditions on one single synthesis unit.

A color status light gives information about the working condition of the Gaia V2.

Condition	Operational state
Yellow	System operational, communication to the software established
Blue	Communication to the software established, no method running
White	Illumnation of the workplace with open front lid, system operational
Pulsating blue	Method is running
Green	Method succesfully terminated
Red	Operational error



Compliant for GMP production

The GAIA V2 was developed for routine use in a GMP production facility. User access control, write protected data files, audit trail, pre-defined methods, bar code reader and color coded connections are only some features of GAIA-GMP tools.

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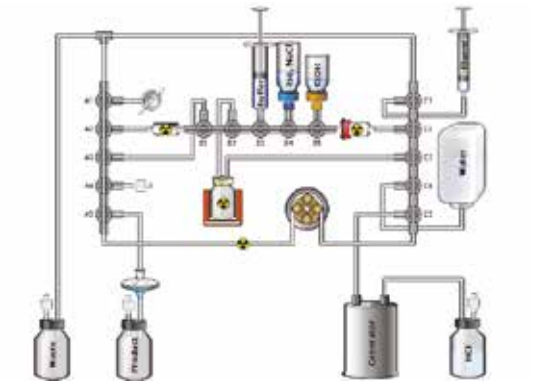
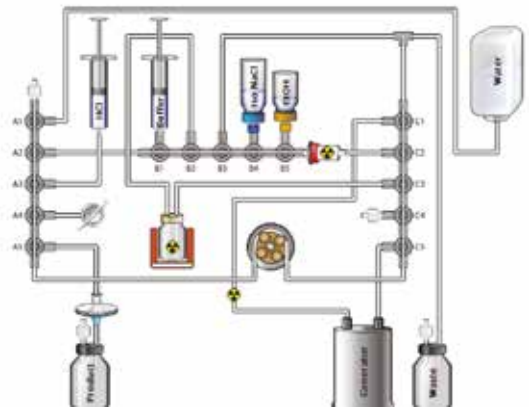
Yield and purification process

Depending on the purification process, yield will vary and synthesis time will be impacted. Typically, the obtained yield with the complete purification process (fractionation, trapping, elution) is 65-80% depending on the labelled ligands (without trapping / elution the obtained yield is 80-85%). Thanks to the efficient radio detectors installed in the unit, the process yield is automatically calculated by the GAIA software.

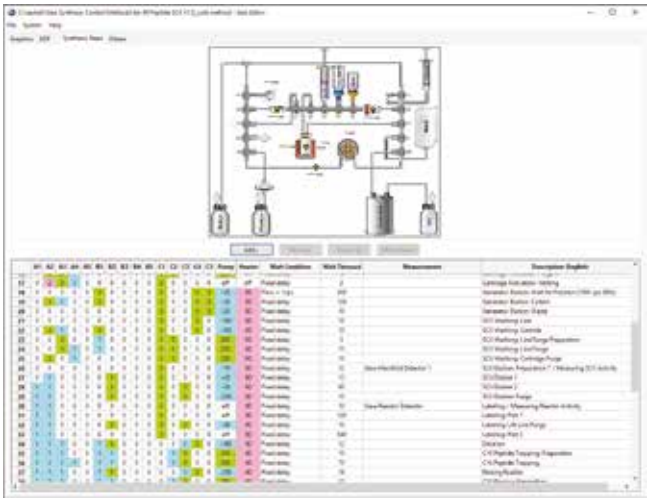
If no cartridge cleaning of the eluate is needed, the elution of the generator can be performed by pressure or vacuum depending on your generator.
You still have the possibility to elute either with or without fractioning.





R&D module

The optional R&D method editor allows you to adapt existing Elysia-Raytest methods or to develop your own methods. Simply optimize the labelling time, change the temperature, modify the SOPs, develop new kit graphic and adapt for upcoming new ligands or radionuclides.



Maintenance

In order to achieve a long, failure-free runtime, the number of moveable elements was reduced to a minimum. We propose various service and warranty contracts adapted to your personal needs.

Instrument validation (IQ/OQ)

We propose IQ/OQ services, performed by Elysia-Raytest service engineers, with certified measurement tools and standards. All relevant data, comprising all important functions, which are indispensable for correct operation, are registered electronically.

Interactive tutorial functions

SOP methods are supported by a video tutorial. With a simple click, every single step is explained in a short video. This makes the use very simple and gives you a high level of confidence.

Easy Access

The easily removable splash plate allows a direct access to the system even in the smallest workspaces. Simply lay down or remove the Splash plate for easy handling and cleaning.

GMP kits

We provide a complete set of validated GMP kits. The kits have color coded connections for easy handling. The kits are bar code labelled in order to avoid mistakes with the choice of the correct labeling method and for digital transfer of the cassette batch number.

All purification procedures can be combined in order to achieve the best possible purity of the eluate. With the trapping and elution process, the prior and final part of the fractioned elution is transferred to waste (green lines) while the main fraction is transferred over the SCX cartridge to trap the Gallium (red line). After the purging of the cartridge, Gallium is eluted to the reactor for the labelling step (blue line).

ELYSIA RAYTEST

Technical specifications

Communication	USB or LAN (computer Windows 7 or higher, 32 or 64 bits)
Power requirement	230V
Power consumption	230V / 100VA
Operation conditions	Max.humidity 70% relative, temperature 10-40 °C
Over-pressure stability	5 bar

Components

Peristaltic pump	+/- 1 tot +/- 300 rpm, with rotation and lid sensor
Number of valves	3 x 5
Number of syringe holders	2
Number of reactors	1

Sensors

Radioactivity detectors	3 detectors for process control
	1 detector for fractioning
Gas pressure sensor	1
Pressure sensor accuracy	200 to 7000 mbar : +/- 10 mbar

Electrical reactor cooling and heating

Dynamic range	10-150 °C
Temperature accuracy	+/- 1.0 °C
Heating speed	25 °C - 100 °C < 50s
Cooling speed	100 °C - 30 °C < 7s

Physical specifications

Dimensions	L379xW195xH307 mm (L14.92" x 7.67" x 12.08")
	L440mm (17.32") with inlet/outlet
Weight	max. 25 kg

Email: info@elysia-raytest.com
Website: www.elysia-raytest.com
Headquarters: Elysia s.a.
rue du Sart-Tilman 375
4031 Angleur - Belgium
Tel +32 (0)4 243 43 50
Production: Elysia-raytest GmbH
Benzstraße 4
75334 Straubenhardt - Germany
Tel. +49 (0)7082 92 55 0