GAIA & LUNA

PEPTIDE RADIO- LABELLING MODULE

Quick and easy synthesis control
for peptides and radiometals
(68Ga, 177Lu,225Ac ...)

- ✓ SUITES ANY GENERATOR (*)
- ✓ MINIMIZES DOSE COSTS
- ✓ EASY AND INTUITIVE HANDLING
- ✓ COMPACT DESIGN

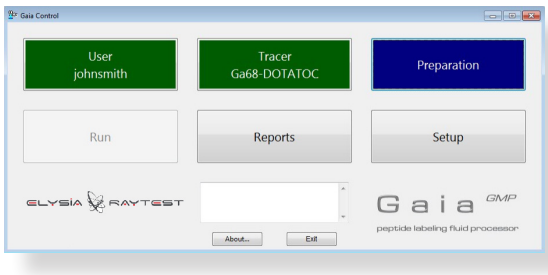
GAIA & LUNA are our synthesis solutions for the labeling of peptides such as DO TATOC or PSMA with radioactive metals (e.g. 68Ga, 177Lu). The size was reduced to a maximum, and optimized to provide a fast, simple and intuitive production of common radio tracers. The position of the connections reduces the need for space in the Hot Cell and facilitate accessibility for maintenance. A list of specific methods and synthesis kits is available, and new methods can easily be adapted.

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

• Reduce costs and increase efficiency

The GAIA v2 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 for gases
- High performance electrical heating & cooling 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 time and maintenance costs
- Functional units (pump, valve gears, reactor...) can be exchanged in just a few simple steps.



• Easy and intuitive Handling

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.

- 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.

ELYSIA RAYTEST

LUNA

LUNA is an optional extension to the Gaia unit for the labeling of peptides with radioactive metals (e.g. 177Lu) delivered in a capped vessel. The LUNA can simply be added at any time to the GAIA. Just plug in the control cable and it will automatically be recognized and incorporated into the GAIA control software.

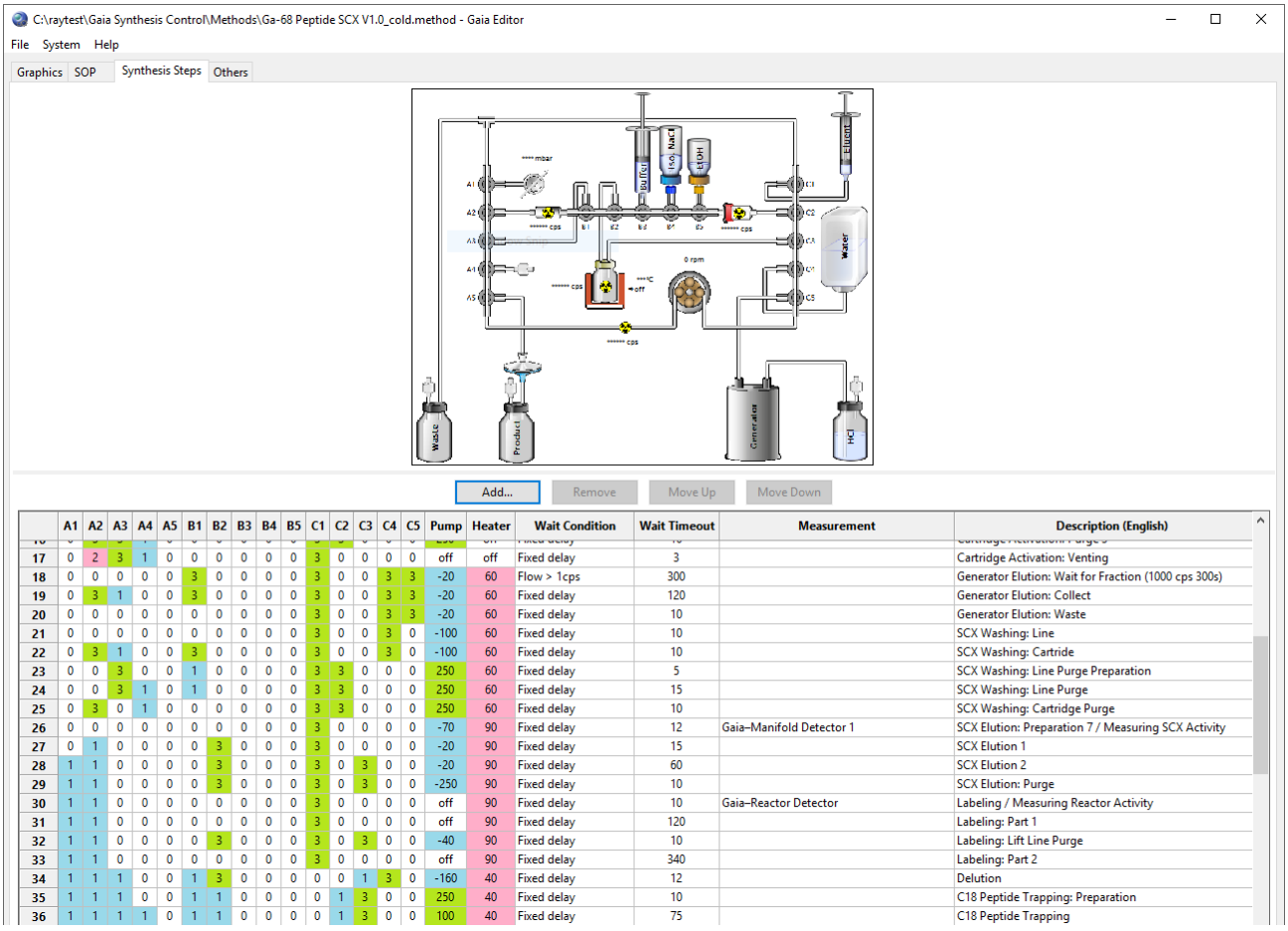
AUTOMATED HOLLOW NEEDLE SYSTEM
NO TRANSFER LOSS OF RADIOACTIVITY

The delivered vessel, including the dissolved radio activity, is placed inside the LUNA heating block. The addition of precursor and buffer system is performed by an automated hollow needle system which is also used for transferring the final product to the product vessel and the following saline-flushing of the reactor vessel. That leads to almost no tran fer losses of radioactivity and a big improvement in radiation safety corresponding to personal doses. Special single use Luna Kits ensure that all components, which get in contact with the reagents, are part of the kit, to avoid any possible cross-contamination.

• Pre-installed methods

With GAIA control 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 to separate other metals
- trapping and elution of 68Ga with efficient separation of other metals



	A1	A2	A3	A4	A5	B1	B2	B3	B4	B5	C1	C2	C3	C4	C5	Pump	Heater	Wait Condition	Wait Timeout	Measurement	Description (English)
17	0	2	3	1	0	0	0	0	0	0	3	0	0	0	0	off	off	Fixed delay	3		Cartridge Activation: Venting
18	0	0	0	0	0	3	0	0	0	0	3	0	0	3	3	-20	60	Flow > 1cps	300		Generator Elution: Wait for Fraction (1000 cps 300s)
19	0	3	1	0	0	3	0	0	0	0	3	0	0	3	3	-20	60	Fixed delay	120		Generator Elution: Collect
20	0	0	0	0	0	0	0	0	0	0	3	0	0	3	3	-20	60	Fixed delay	10		Generator Elution: Waste
21	0	0	0	0	0	0	0	0	0	0	3	0	0	3	0	-100	60	Fixed delay	10		SCX Washing: Line
22	0	3	1	0	0	3	0	0	0	0	3	0	0	3	0	-100	60	Fixed delay	10		SCX Washing: Cartride
23	0	0	3	0	0	1	0	0	0	0	3	3	0	0	0	250	60	Fixed delay	5		SCX Washing: Line Purge Preparation
24	0	0	3	1	0	1	0	0	0	0	3	3	0	0	0	250	60	Fixed delay	15		SCX Washing: Line Purge
25	0	3	0	1	0	0	0	0	0	0	3	3	0	0	0	250	60	Fixed delay	10		SCX Washing: Cartridge Purge
26	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	-70	90	Fixed delay	12	Gaia–Manifold Detector 1	SCX Elution: Preparation 7 / Measuring SCX Activity
27	0	1	0	0	0	0	3	0	0	0	3	0	0	0	0	-20	90	Fixed delay	15		SCX Elution 1
28	1	1	0	0	0	0	3	0	0	0	3	0	3	0	0	-20	90	Fixed delay	60		SCX Elution 2
29	1	1	0	0	0	0	3	0	0	0	3	0	3	0	0	-250	90	Fixed delay	10		SCX Elution: Purge
30	1	1	0	0	0	0	0	0	0	0	3	0	0	0	0	off	90	Fixed delay	10	Gaia–Reactor Detector	Labeling / Measuring Reactor Activity
31	1	1	0	0	0	0	0	0	0	0	3	0	0	0	0	off	90	Fixed delay	120		Labeling: Part 1
32	1	1	0	0	0	0	3	0	0	0	3	0	3	0	0	-40	90	Fixed delay	10		Labeling: Lift Line Purge
33	1	1	0	0	0	0	0	0	0	0	3	0	0	0	0	off	90	Fixed delay	340		Labeling: Part 2
34	1	1	1	0	0	1	3	0	0	0	0	0	1	3	0	-160	40	Fixed delay	12		Delution
35	1	1	1	0	0	1	1	0	0	0	0	1	3	0	0	250	40	Fixed delay	10		C18 Peptide Trapping: Preparation
36	1	1	1	1	0	1	1	0	0	0	0	1	3	0	0	100	40	Fixed delay	75		C18 Peptide Trapping

• 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

• Single Use Kits

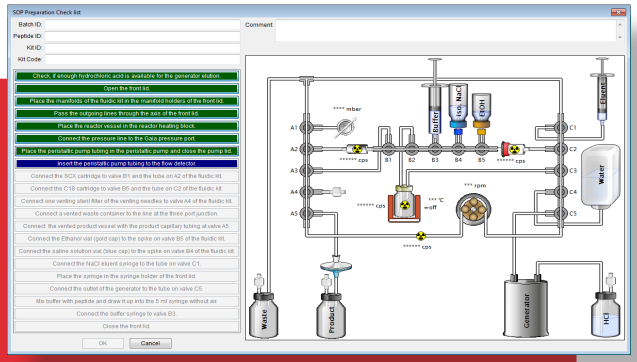
The operation of the GAIA v2 & LUNA was optimized to obtain fast and simple production of common tracers. All components in contact with reagents are part of single use kits to avoid cross or bacterial contamination and to fulfill GMP needs. Therefore, different tracers can be produced under GMP conditions 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	Illumination of the workplace
Pulsating blue	Method is running
Green	Method successfully terminated
Red	Operational error

• Designed for compliant GMP production

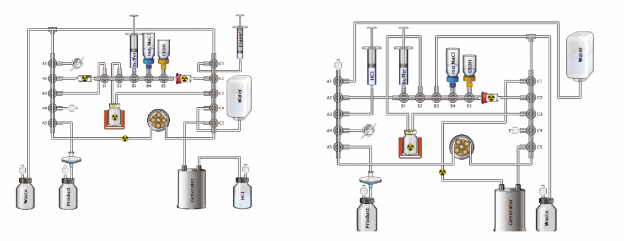
The GAIA v2 6 LUNA were developed for routine use in a GMP production facility. User access control, write protected data files, audit trail, pre-defined methods, bar code reader and color-coded connections are only some features of GAIA-GMP tools.



• 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.

All purification procedures can be combined 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).



• 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 methods for upcoming new ligands or radionuclides.

• Maintenance

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.

• Easy Access

The easily removable splash plate allows 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 to avoid mistakes with the choice of the correct labeling method and for digital transfer of the cassette batch number.

Specifications

Technical

Communication	USB or LAN	
Power requirement	230V	
Power consumption	230V / 100VA	
Operation conditions	Max.humidity 70% relative, temperature 10-40 °C	
Over-pressure stability	5 bar	
Components	**GAIA**	**LUNA**
Peristaltic pump	+/- 1 tot +/- 300 rpm, with rotation and lid sensor	N/A
Number of valves	3 x 5	N/A
Number of syringe holders	2	1
Number of reactors	1	1
Sensors	**GAIA**	**LUNA**
Radioactivity detectors	3 detectors for process control 1 detector for fractioning	1
Gas pressure sensor	1	
Pressure sensor accuracy	200 to 7000 mbar : +/- 10 mbar	
Electrical reactor cooling and heating	**GAIA**	**LUNA**
Dynamic range	10-150 °C	10-150 °C
Temperature accuracy	+/- 1.0 °C	+/- 1.0 °C
Heating speed	25 °C - 100 °C < 50s	25 °C - 100 °C < 50s
Cooling speed	100 °C - 30 °C < 75s	100 °C - 30 °C < 75s

Physical

Dimension Gaia	L377,6 x W206,2 x H305,7 mm (L14,86" x W8,12" x H12.04")
Dimension Gaia & Luna	Max. L555,12 x W233,4 mm (L21,86 x W9,19")
Weight max. Gaia	25 kg

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