

## ADDITIONAL GAIA GMP MODULE

### FOR THERAPEUTIC PEPTIDE RADIONUCLIDE LABELLING

- RADIO METAL LABELLING
- SINGLE-USE SYNTHESIS KITS
- AUTOMATED HOLLOW NEEDLE SYSTEM
- NO TRANSFER LOSS OF RADIOACTIVITY



LUNA is a synthesis unit for the labeling of peptides like DOTAToc with radioactive metals (e.g. <sup>177</sup>Lu) delivered in a capped vessel. Other labeling procedures can also be adapted as long as they don't include distillation steps and are not conducted under inert atmosphere.

Luna was developed according to the following guidelines:

- compact design
- smooth surfaces, that are easy to clean
- reduction of the required electrical connections to the absolute minimum
- complete abdication of compressed gases
- economized application of the single-use materials in order to minimize the running costs for the user
- fully automated addition of precursor and buffer-system
- radiation safety
- easy handling of both soft- and hardware

The materials in the synthesis kits are widely available, can be sterilized and set up as a modular system.

### Comprehensive software

Luna is controlled by the GAIA Control software. The new Gaia software was optimized for quick and easy synthesis control and evaluation. It offers a „touch“-controlled interface and full visualization of a running process. Due to the fact that the interface was designed to manual input on a touch-sensitive screen, the software is executed on a panel computer, which complies industrial standards. The method editor is full interactive and offers a graphical editor for the process layout, a timetable with graphical display of the actual flow paths and an SOP editor.

A report generator and full user management with an electronical signature system is also implemented.

### Luna Performance

The main application of Luna is the labeling of peptides with  $^{177}\text{Lu}$ . The delivered vessel, including the dissolved radio activity, is placed inside an additional 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 transfer losses of radioactivity and a big improvement in radiation safety corresponding to personal doses.

### Luna Operation

The operation of Luna was optimized with regard on a fast and automated production of common tracers with a multitude of available radio-metals.

The synthesis kit can be mounted in the Gaia main module on an integrated working surface without the use of cassettes. The mentioned working surface constitutes the front lid and is hinged down in order to equip the construction. By folding the lid up, the operational state is set up easily. After each synthesis run the kit is disposed; a cleaning procedure is not necessary. Due to the fact that all components, which get in contact with the reagents, are part of the single-use kit, no concerns regarding a possible cross-contamination by previous synthesis runs are raised. Therefore, different tracers can be produced under GMP conditions on one single synthesis unit.

Via a colour code, a light strip in the upper region of the construction gives information about the working condition of the synthesis unit. In addition, this light strip illuminates the working surface while the synthesis kit is mounted. At the start of each synthesis run the kit is tested for integrity.

The software is also optimized with regard on a fast and simple production. The required preparation steps are recorded and defined within the software. Prior to each production process the user needs to sign the synthesis run with a name and a batch number. These signed preparation steps are part of the all-over documentation of the production process and are mentioned in the production report. The latter collects and records additionally the QC data of the production.

## Technical specifications

### GAIA

Communication:	USB or LAN
Computer:	Windows 7 or higher, 32 or 64 bit
Power requirement:	230 V
Power consumption:	max. 230 V / 100 VA
Humidity max.:	70 % relative
Temperature:	10 – 40 °C
Over pressure stability:	5 bar
Installation requirements:	See document "Luna installation requirements"

### SENSOR

radioactivity detectors:	1 semiconductor detector for process control
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### COMPONENTS

Hollow needle system:	+/- 79 mm vertical distance
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### REACTOR COOLING AND HEATING

Suitable vessels:	capped vessels with $\varnothing < 24,1$ mm
Dynamic range:	10 – 150 °C
Temperature accuracy:	+/- 1.0 °C
Cooling & Heating:	electrical method
Heating speed:	25 °C – 100 °C < 50 s
Cooling speed:	100 °C – 30 °C < 75 s

## Physical specifications

Dimensions:	W300 x H170 x D90 mm
Weight:	5 kg



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