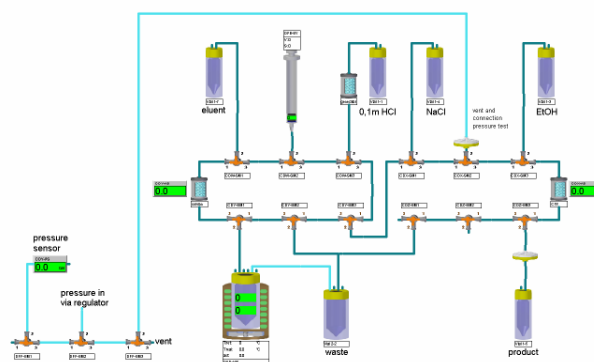
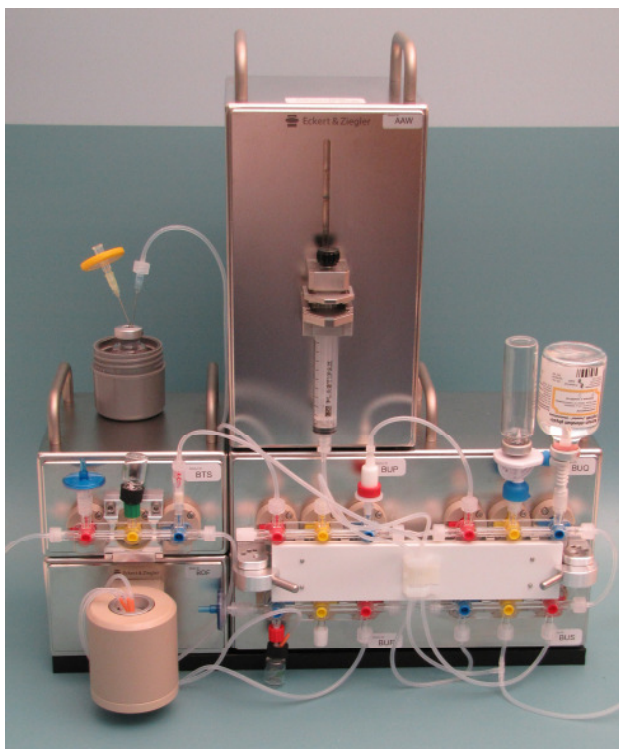


Modular-Lab PharmTracer

For production of ^{68}Ga -, ^{111}In -, ^{177}Lu - and ^{90}Y - DOTA conjugated peptides



Modular-Lab PharmTracer is the clinical production solution for labelling radiodiagnostics (^{68}Ga , ^{111}In) and radiotherapeutics (^{177}Lu , ^{90}Y) with the same setup.

■ Description

The laboratory equipment Modular-Lab PharmTracer has been specifically designed to allow versatile radiopharmaceutical routine production for different tracers without cross contamination issues. Modular-Lab PharmTracer setup for the labelling of ^{68}Ga , ^{111}In , ^{177}Lu and ^{90}Y -DOTA-peptides will be combined with a Heater Reactor Module (HRM), a Syringe Module (SYM) and, if necessary, with a Single Stopcock Module (SMM) when performing the pre-purification method for ^{68}Ga -labelling. Single-use sterile cassettes ensure easy handling by click'n'run

technology. An easy-to-program intuitive graphical interface is used to control the synthesis process.

■ Single-use sterile cassettes

Cassettes are assembled under GMP-compliant clean room conditions, sterilized with gamma-radiation and vacuum-packed. All consumables used are chemical resistant and have been tested for their suitability with the specific syntheses. A shelf life of 12 months can be guaranteed. All cartridges are included and preconditioned automatically if necessary. Due to the cassettes one-time use no cleaning, drying or sanitation routines are necessary.

■ Advantages

Modular-Lab PharmTracer is based on a unique, modular approach combining the speed and safety of a remote, fully-automated system with the option to configure syntheses for novel PET tracers. The GMP-

manufactured single-use sterile cassettes avoid intense cleaning and sanitation routines. Synthesis process is programmed by Eckert & Ziegler Eurotope making additional programming unnecessary. Modular-Lab PharmTracer's multifunctionality supports routine production of ^{68}Ga , ^{111}In , ^{177}Lu and ^{90}Y -DOTA peptides. The setup can also be combined with an analytical HPLC and TLC.

The intuitive user interface complies with GMP, cGMP, GLP and GAMP 5 requirements. Parameters such as temperature, activity detector readings, flow rates, or valve settings can be monitored easily in one window. Reports containing all relevant data and information are created automatically after each run.

Modular-Lab PharmTracer

■ Application results for:

⁶⁸ Ga-DOTA-peptides (fractionated method)	Yield: 79.7±2.0% d.c. Purity: > 95% Synthesis time: 15 min
⁶⁸ Ga-DOTA-peptides (pre-cleaning method)	Yield: 66.1±4.9% d.c. Purity: > 95% Synthesis time: 22 min
¹¹¹ In-DOTA-peptides	Yield: 95.5±2.9% d.c. Purity: > 98% Synthesis time: 25 min
¹⁷⁷ Lu-DOTA-peptides	Yield: 86.9±9.2% d.c. Purity: > 99% Synthesis time: 30 min
⁹⁰ Y-DOTA-peptides	Yield: > 90%* Purity: > 98% Synthesis time: 30 min

* of ⁹⁰Y transferred into system (some ⁹⁰Y may be left in vial, optimization ongoing)

■ Technical Data

Module Characteristics

4-fold Modular-Lab PharmTracer (SLM-4)	262 x 198 x 191 mm
Heator Reactor Module (HRM)	dimensions: 130 x 220 x 78 mm heating via heating foil from room temperature to 220°C
1-fold Modular-Lab PharmTracer (SLM-1)	dimensions: 130 x 130 x 78 mm only necessary for pressure test of cassette and elution run of the ⁶⁸ Ge/ ⁶⁸ Ga generator
Syringe Dispensing Module (SYM)	dimensions: 130 x 130 x 234 mm responsible for liquid transport
Pressure	max. 2 bar

Main Unit

Power supply (electrical cabinet)	115 V ~ 60 Hz or 230 V ~ 50 Hz
Power consumption (electrical cabinet)	standard 480W, 2 x bus 1050W, extension to 2100W possible
Environment temperature	+10°C – +40°C
Environment humidity	max. 70% rel.

Unit Control

Software	Modular-Lab Software (cGMP, GAMP 5, 21 CFR part 11 compliant)
Interfaces	Ethernet

Before delivery all components are being tested and validated in-house. If requested, a performance qualification of the complete system will be provided on-site. Extensive documentation will be generally provided with the delivery of the system.

USA & Canada:

Eckert & Ziegler Eurotope GmbH

Robert-Rössle-Strasse 10
13125 Berlin
Germany
www.eurotope.com

Phone: +49 (0) 30 94 10 84-197
Fax: +49 (0) 30 94 10 84-470
E-Mail: eurotope@ezag.de

Eckert & Ziegler Eurotope GmbH

63 South Street, Suite #140
Hopkinton, MA 01748
USA
www.eurotope.com

Phone: +1 508 497 0060
Fax: +1 508 497 0061
E-Mail: eurotope@ezag.com