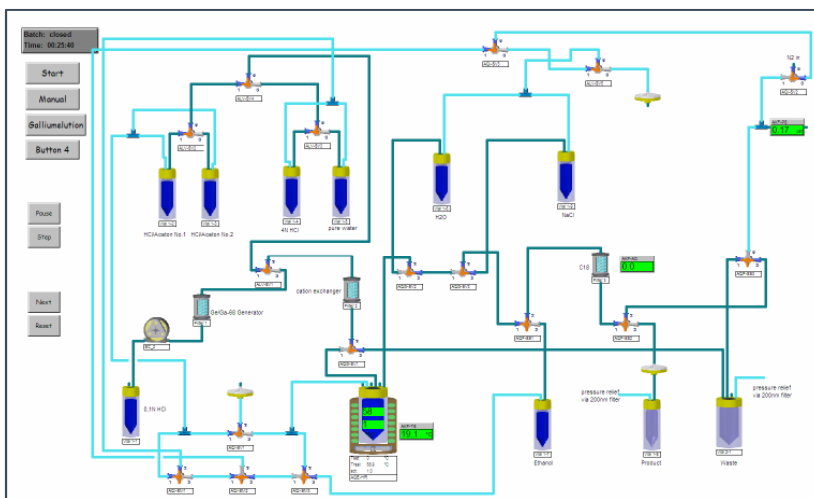
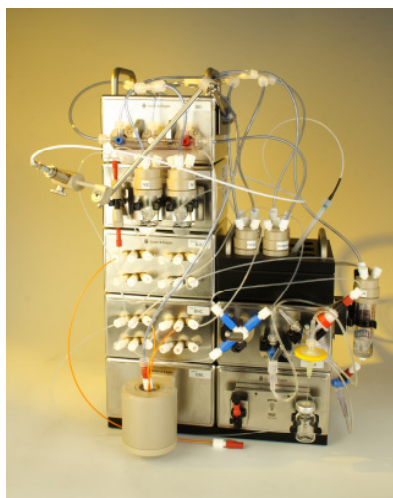


Modular-Lab

For ^{68}Ga -DOTA-conjugated peptides incl. pre-purification step



The Modular-Lab technology offers the synthesis of ^{68}Ga -DOTA-conjugated peptides with a pre-cleaning step to ensure removal of metal impurities and ^{68}Ge breakthrough as well as low acidic and low volume ^{68}Ga fractions for labelling.

■ Application

Radioisotope techniques play an important role in the imaging of tumors by positron emission tomography (PET). Based on the specific peptide-receptor mediated binding of radiolabelled somatostatin analogues, radiopharmaceuticals like ^{68}Ga -DOTA-conjugated peptides for example have become widely accepted for the PET-based diagnosis of neuroendocrine tumors.

■ Technology

The pre-validated and ready for synthesis setup of Modular-Lab* allows the fully automated production of ^{68}Ga -DOTA-conjugated peptide compounds including the patented pre-purification step. The ^{68}Ga -eluate is concentrated and purified by using a miniaturized column with a cation-exchange resin. The purified fraction is then transferred to the reaction vial for the labelling of nanomolar amounts of octreotide derivatives either in pure aqueous solution or in buffers. A final product purification (C18 cartridge) after the labelling process step guarantees for excellent chemical purity of the ^{68}Ga -labelled pep-

tides. The system has been validated for using a maximum of 0.1 M HCL when eluting the $^{68}\text{Ge}/^{68}\text{Ga}$ generator.

■ Standardized Regulatory Compliance

The Modular-Lab Software combines easy programming via a self-explanatory graphical user interface with the highest standards compliant to GMP, GAMP 4/5 and 21 CFR part 11 regulations. Access control with four defined security levels meets all demands for the security of the process data and the application-specific setup. The logging of all system and user operations runs fully automatically in Audit Trails.

■ Advantages

- Pre-cleaning step provides almost ^{68}Ge -free ^{68}Ga for labelling
- Lower metal impurities results in high specific activities
- No buffer needed for labelling
- Highest chemical purity of ^{68}Ga guarantees for high synthesis yields

*patent pending

■ Key Features

- Fully automated generator elution, eluate post-processing, synthesis and product purification process, no user intervention necessary
- Fully automated cleaning routine after each process to ensure a minimum of chemical or bacterial contamination of the system
- Integrated Bubble-Point-Test to verify the sterile filter integrity
- Pre-validated process for a standardized and reproducible synthesis
- Traceability of the complete process, including documentation of all process parameters and functions
- Upgradeable for further applications
- Uses off-the-shelf tubing, vials, reagents and other consumables
- Synthesis time: 10 minutes (further data upon request)
- Pre-purification time: 6 minutes
- Setup dimensions: 30 x 45 x 35 cm (W x H x D)
- Pre-purification time: 6 minutes

■ Modular-Lab Components

Solenoid Valve Module (SVM)	Dimensions: 130 x 130 x 78 mm With 4 valves (3-way or 2-way) for liquid transport. Standard UNF connectors at front. Easy to access for mounting of "finger tight" fittings. Optional one valve (barbed fitting) at back for gas transport. Bürkert 6604, max. 3 bar, dead volume 45 µl, body: PEEK, sealing: FFKM (Simriz)
Stopcock Manifold Module (SMM)	Dimensions: 130 x 130 x 78 mm Holder and adapter for quick mounting of stopcock manifold. Standard stopcock manifold with Luer connectors for medical application (one way, sterile) is used. Stopcocks are driven by servo motors.
Single Stopcock Module (SSM)	Dimensions: 130 x 130 x 78 mm Holders and adapters for quick mounting of 3 single stopcocks (driven by servo motors). Stopcocks of different material and size can be used on the same module.
Heater Reactor Module (HRM) or Peltier Reactor Module (PRM)	Dimensions: 130 x 230 x 156 mm; Weight: 2.5 kg Power supply and data transfer by bus cable. Heating and cooling with a heating-foil from room temperature to 220°C. Lead-shielding of activity detector and electronics is included. Additional external thermo sensor, stirrer and pressure sensor are available. Vials from 1 to 24 mL can be used with different adapter rings. Connection by needles via septum of vial or with standard UNF fittings via reaction vial head. (Upgrade with a Peltier Reactor Module is possible)
Vial Holder Module (VHM) List of further applications upon request	Holds up to 3 vials or cartridges of different sizes. The holders can be easily adjusted in their position and fit with the respective handles of all modules coming with the Modular-Lab.
Vial Holder Plate (VHP)	Holds up to 3 vials or cartridges of different sizes. The holders can be easily adjusted in their position and fit with the respective handles of all modules coming with the Modular-Lab.
Electrical Cabinet	Control Unit
Modular-Lab Software	Including template for 68Ga-DOTA-conjugated peptide synthesis with pre-cleaning step (GMP, GAMP 4/5 and 21 CFR part 11 compliant)
Further components:	Peristaltic pump, Flex Module, vial heads, holder for external activity detector

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